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Management of Uterine Fibroids: An Update of the Evidence

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The information in this report is intended to help clinicians, employers, policymakers, and others make informed decisions about the provision of health care services. This report is intended as a reference and not as a substitute for clinical judgment.

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Preface

The Agency for Healthcare Research and Quality (AHRQ), through its Evidence-based Practice Centers (EPCs), sponsors the development of evidence reports and technology assessments to assist public- and private-sector organizations in their efforts to improve the quality of health care in the United States. The reports and assessments provide organizations with comprehensive, science-based information on common, costly medical conditions and new health care technologies. The EPCs systematically review the relevant scientific literature on topics assigned to them by AHRQ and conduct additional analyses when appropriate prior to developing their reports and assessments.

To bring the broadest range of experts into the development of evidence reports and health technology assessments, AHRQ encourages the EPCs to form partnerships and enter into collaborations with other medical and research organizations. The EPCs work with these partner organizations to ensure that the evidence reports and technology assessments they produce will become building blocks for health care quality improvement projects throughout the Nation. The reports undergo peer review prior to their release.

AHRQ expects that the EPC evidence reports and technology assessments will inform individual health plans, providers, and purchasers as well as the health care system as a whole by providing important information to help improve health care quality.

We welcome comments on this evidence report. They may be sent by mail to the Task Order Officer named below at: Agency for Healthcare Research and Quality, 540 Gaither Road, Rockville, MD 20850, or by e-mail to **epc@ahrq.gov.**

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Structured Abstract

Objectives: The RTI International–University of North Carolina at Chapel Hill Evidence-based Practice Center (RTI–UNC EPC) systematically updated evidence on the management of uterine fibroids, specifically incidence and prevalence of fibroids, treatment outcomes, comparisons of treatment, modifiers of outcomes, and costs.

Data Sources: We searched MEDLINE®, Cochrane Collaboration resources, and Embase.

Review Methods: We included studies published in English from February 2000 through August 2006. We excluded studies with low sample size (based on study design, cases series < 100 and cohorts < 40) or lack of relevance to uterine fibroids. Of 107 included studies, 3 were good quality, 56 fair, and 48 poor.

Results: The cumulative incidence by age 50 is 70 percent to 80 percent; black women are more likely to get fibroids at younger ages. Appearance of new fibroids and growth of existing fibroids after treatment are poorly studied. Trials of preoperative medical management indicate that treatment reduces fibroid volume but do not provide sufficient evidence of improvement in important operative outcomes. When women are treated for reasons other than symptom relief, such as when pregnancy is desired, weak evidence supports treating submucous fibroids via hysteroscopy.

No well-conducted trials in U.S. populations directly compared treatment options, including the option of expectant management, or followed women to determine whether the intervention met their treatment objectives. Common procedures such as hysterectomy and myomectomy, including choice among types of myomectomy, still cannot be meaningfully compared. Studies comparing uterine artery embolization (UAE) with other procedures reported procedure time and length of stay favoring UAE, but inconsistency of the direction of effect for complications and absence of key information on longer-term outcomes suggest that this evidence base is inadequate to comment on the relative risks and benefits of UAE versus hysterectomy or myomectomy.

Costs of fibroid treatment, despite shorter average lengths of stay, are rising.

Conclusions: The dearth of high-quality evidence supporting the effectiveness of most interventions for uterine fibroids is remarkable, given how common this problem is. The current state of the literature does not permit definitive conclusions about benefit, harm, or relative costs to help guide women's choices. Significant research gaps include well-conducted trials in U.S. populations that directly compare interventions on short- and, especially, long-term outcomes, studies on therapeutics for medical management, and information on treatment decisions for women who desire a pregnancy.

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Appendixes and Evidence Tables for this report are provided electronically at http://www.ahrq.gov/downloads/pub/evidence/pdf/uterupdate/uterup.pdf

Executive Summary

Introduction

Fibroids are the most common female pelvic tumor; developing a fibroid or multiple fibroids by the time of menopause is the rule rather than the exception. The RTI International–University of North Carolina at Chapel Hill Evidence-based Practice Center (RTI–UNC EPC) conducted a systematic review of the literature to update the evidence on the management of uterine fibroids. We systematically assessed the evidence on seven key questions (KQs): (1) incidence and prevalence of uterine fibroids, (2) outcomes of treatment for symptoms, (3) outcomes of treatment for reasons other than symptoms, (4) costs, (5) modifiers of treatment outcomes, (6) comparisons of treatments, and (7) geographic variation in treatment.

Methods

We searched MEDLINE®, Cochrane Collaboration resources, and Embase. We dually reviewed each study against a priori inclusion/exclusion criteria. For included articles, a primary reviewer abstracted data directly into evidence tables; a second senior reviewer confirmed accuracy. We included 107 studies in English, published from February 2000 through August 2006, from developed countries. We excluded studies with low sample size (based on study design, cases series < 100 and cohorts < 40) or lack of relevance to uterine fibroids.

Results

The first Agency for Healthcare Research and Quality (AHRQ) systematic review on the management of uterine fibroids was published in January 2001. It found that the overall quality of the literature on the management of fibroids was poor, with almost no evidence to support the effectiveness of commonly recommended treatments. The review found consistent evidence from randomized trials that preoperative use of gonadotropin-releasing hormone (GnRH) agonist therapy reduced estimated blood loss and may facilitate the surgical approach by reducing uterine size. It also reported that the outcomes of hysterectomy up to 2 years after surgery are favorable for most symptomatic women, although up to 12 percent of women develop new symptoms after surgery. The review did not attempt to deduce the clinical significance of these outcomes compared with outcomes of other treatments, because of significant differences in the severity of preintervention disease. The prior review found almost no data to allow estimation of the overall costs of fibroids to the economy. The remainder of this summary reflects our update of the literature and synthesis of evidence.

KQ 1: Incidence and Prevalence of Uterine Fibroids

Two studies provided weak evidence (limited number of studies) on the incidence and prevalence of uterine fibroids. One study used randomly selected participants from a prepaid

urban health plan with 50 percent black membership to report ultrasound-confirmed incidence for premenopausal women and medical records and self-report for postmenopausal women for a cumulative incidence rates by age 50 of nearly 70 percent among white women and more than 80 percent among black women. Another study reported an incidence rate of 2.97 for every 100 person-years from a black nationwide U.S. sample. The literature provides no guidance on the overall burden of disease posed by uterine fibroids.

KQ 2: Outcomes of Treatment of Uterine Fibroids for Symptoms

Studies provided information on effectiveness more commonly than on adverse outcomes. We summarize data on adverse outcomes when available below**.**

Expectant Management. We identified no literature to document the natural history of uterine fibroid incidence, growth, symptomatology, use of clinical care, or outcomes when women choose watchful waiting over intervention.

Pharmaceutical Management. *GnRH agonists.* Of the 19 studies that we reviewed for pharmaceutical management of fibroids, 13 (7 RCTs) addressed the effect of GnRH agonists. Eight of these studies provided moderate evidence (consistent effects and strong design but small sample sizes) that GnRH agonists were effective in decreasing overall uterine size when used either as preoperative treatment or as an alternative to surgery. Another subset (six studies) on hemoglobin levels provided weak evidence of increases in hemoglobin levels by 0.9 g/dL to 5.2 g/dL after treatment and before surgery.

Three studies provided weak evidence (limited number of studies, inconsistent effects) on the effect of GnRH agonists on symptom relief. A small nonrandomized study reported relief from hot flashes among women receiving tibolone and a GnRH agonist. The other two studies found that raloxifene was not effective in reducing fibroid symptoms compared with placebo.

Progestins. A small randomized controlled trial (RCT) presented weak evidence of reduction in fibroid size among women receiving lynestrenol compared with women receiving leuprolide acetate.

Mifepristone. One study (weak evidence) comparing two doses of mifepristone reported significant reductions in uterine size and menstrual blood loss from baseline values in both groups but no differences between the dose groups, suggesting that the lower dose is sufficient.

Estrogen Receptor Modulators and Antagonists. Three trials provided weak evidence (limited number of studies, inconsistent effects) comparing raloxifene with placebo; two reported a significant reduction in uterine and fibroid size compared with baseline values for postmenopausal women on raloxifene and an increase in uterine and fibroid size for premenopausal women on raloxifene. A fourth study was a five-arm trial of poor quality comparing three different doses of the estrogen receptor antagonist fulvestrant with goserelin and a placebo. Goserelin significantly reduced fibroid growth and endometrial thickness compared with placebo and fulvestrant, but fulvestrant did not significantly alter fibroid volume or endometrial thickness compared with placebo.

Uterine Artery Embolization (UAE). Twenty-three studies examined short- and long-term outcomes following UAE. Of these, six studies (one RCT) compared UAE with either hysterectomy or myomectomy. They yielded evidence of moderate strength (consistent effects but weak design) suggesting shorter procedure (operative) times and shorter lengths of hospital stay for UAE than for hysterectomy or myomectomy. However, they provided only weak

evidence (either no significant differences or inconsistent direction of effect) about the impact of UAE on complications and symptom relief.

The remaining studies were case series or cohort studies, of poor or fair quality, with sample sizes ranging from 46 to 3,140. They do not provide consistent definitions or time points for measuring key outcomes such as complications. The largest case series on UAE reported an in-hospital complication rate of 2.7 percent, (0.6 percent rate of major events), and a postdischarge complication rate of 26.1 percent (4.1 percent rate of major events).

Only one study examined rates of subsequent interventions for UAE and another procedure. It reported statistically significant higher rates of subsequent interventions with UAE than with myomectomy (29 percent versus 3 percent) in followup ranging from 3 to 5 years. Another study reported a subsequent intervention rate of 20 percent at 5 years. The value of this information is limited by the lack of comparable data for other types of treatment.

Endometrial Ablation. We found only three studies, all of poor quality, about endometrial ablation, which is used to treat bleeding symptoms. Of these, two combined ablation with hysteroscopic resection (retrospective case series) and one evaluated ablation only (prospective case series). These publications poorly document operative and longer-term outcomes; they lack enough common data elements to permit any substantive summary of findings.

Magnetic Resonance Imaging (MRI) Guided Focused Ultrasound. The strength of evidence about MRI-guided ultrasound ablation of fibroids is weak, although we identified one carefully conducted prospective case series. Overall, the study suggested reasonable tolerance (16 percent of women reported severe pain at some point during the treatment and 8 percent reported severe to moderate pain after the procedure), improvement in quality of life (71 percent improved), and modest change in fibroid size (13 percent decrease). During more than a year of followup, 11 percent of women experienced worsened symptoms; 28 percent elected further treatment including myomectomy and hysterectomy.

Myomectomy. The strength of evidence overall is weak because of the predominance of weak study designs, the restricted scope of outcomes studied, and the limited quality of measurements in the few studies of stronger design.

Abdominal Myomectomy. The abdominal myomectomy literature comprised 13 studies of small to modest size. Transfusion risk in the eight studies that reported it varied widely, from 5 percent to 21 percent, with higher risk in studies in less specialized surgical settings. Among women for whom myomectomy had been the original plan, 3 percent to 4 percent required intraoperative conversion to hysterectomy. Wound healing complications affected 2 percent to 4 percent of women receiving abdominal myomectomy.

In four studies that assessed symptoms, most women reported improvements in symptoms such as bleeding, pressure, and pain, for which they sought care, although the degree of improvement varied by symptom. Recurrence of fibroids likely affected more than 18 percent of women and may have been as high as 62 percent within 3 to 4 years after surgery.

Laparoscopic Myomectomy. Transfusion ranged from <1 percent to 8 percent in 11 of 16 studies that reported. A single study provided direct comparison between abdominal and laparoscopic myomectomy, reporting statistically significant lower risk among those having laparoscopic procedures. Conversion to open procedures occurred in approximately 9 percent of women; a small proportion had an immediate hysterectomy. Length of stay in the hospital is shorter after laparoscopy than after abdominal procedures, and wound healing complications are rare. Recurrence of fibroids ranged from 13 percent to 27 percent, and 7 percent to 12 percent of

women had additional surgery over the first few years after myomectomy, Although these operative risks appear similar to those for abdominal myomectomy, we found no direct comparisons with power adequate to compare long-term outcomes between laparoscopic and abdominal myomectomy.

Hysteroscopic Myomectomy. Across five studies with 2,061 participants, we found little detail about operative complexity and complications. The risk of perforations of the uterus (two studies) was consistent with the often clinically cited rate of 1 in 100. Repeat procedures and subsequent surgery affect 2 percent to 20 percent of women in the years immediately after hysteroscopic myomectomy. In these studies > 80 percent of women reported good outcomes as defined by self-report of "control of bleeding."

Hysterectomy. Seventeen studies (eight RCTs) of poor and fair quality provided weak evidence on outcomes of hysterectomy, comparisons of types of hysterectomy, and modifiers of hysterectomy.

Outcomes. The hysterectomy literature is limited largely to short-term outcomes such as operative time, length of stay, and complications. Most studies reporting on comparative studies of hysterectomy either did not have sufficient sample sizes to derive estimates of risks of individual operative or postoperative complications or were not of generalizable practice settings.

Long-term outcomes are similarly limited to small studies of comparisons between treatments. These studies did not have sufficient sample sizes to derive estimates of long-term outcomes.

Comparisons of Types of Hysterectomy. In three studies comparing vaginal to abdominal hysterectomy, the most consistent finding was shorter average hospital stay (by 1 to 2 days) for patients undergoing vaginal procedures. Rates of transfusion and intraoperative complications were generally comparable; in one cohort study the combined rate of postoperative complications was significantly higher in women undergoing abdominal hysterectomy.

The two studies reporting on laparoscopically assisted vaginal hysterectomy (LAVH) and abdominal hysterectomy demonstrated improved outcomes for LAVH on a limited set of perioperative outcomes, namely hospital stay, convalescence, and use of analgesia.

The only study comparing outcomes of LAVH and vaginal hysterectomy reported significantly longer hospital stay and higher rates of total perioperative complications among women undergoing LAVH.

Complementary and Alternative Medicine. A single study of poor quality provided weak evidence favoring traditional Chinese medicine over standard medical management. Differences in degree of motivation between treatment arms may have potentially biased the results.

KQ 3: Outcomes of Treatment of Uterine Fibroids for Other Reasons

The sole clinical trial comparing surgical intervention with no intervention to improve fertility (in the absence of assisted reproductive technology) supported benefit from removing fibroids that have a submucosal component. This benefit was substantial (>15 percent absolute increase in the proportion of women becoming pregnant); the trial was limited, however, by small study size, to reporting only ability to conceive and not other pregnancy outcomes. The 10 studies we identified provided weak evidence that was insufficient to assess risk of pregnancy

complications related to myomectomy. Uterine rupture was rare (1 in 314 births); all studies combined are underpowered to estimate risk accurately.

We found no evidence on the effects of treatment to prevent further fibroid growth among asymptomatic women. However, concerns about further growth during the postmenopausal period limit the use of hormone replacement therapy to treat postmenopausal symptoms. Moderate evidence from three studies indicated that menopausal hormone therapy had no effect on fibroid size; one reported a higher rate of uterine growth with the percutaneous-oral schedule of hormone replacement therapy than with a single oral combination of oestradiol valerate and cyproterone acetate.

KQ 4: Costs of Fibroid Treatment

Three studies report on UAE, either on its own or in comparison with other interventions. They do not suggest cost savings for UAE; rather, they demonstrate comparable or higher costs of UAE, despite shorter length of stay.

Our analysis of Healthcare Cost and Utilization Project data showed that the average costs of uterine fibroid treatment increased by almost 30 percent between 1997 and 2004. In 1997 the average inpatient costs were $11,978 (adjusted to 2004 dollars); by 2004 the average costs had increased to $15,405. During the same period, the average length of stay dropped from 2.9 days to 2.6 days.

The source of increase in costs is unclear; possible explanations include higher professional costs with procedures such as UAE and overall increase in health care costs. We found no information comparing average costs of procedural interventions with pharmaceutical treatments.

KQ 5: Modifiers of Outcomes

In eight studies, larger and more numerous fibroids often predict worse outcomes for several uterine fibroid procedures other than UAE (seven studies), for which the evidence is unclear. Eight studies addressed patient health characteristics or provider characteristics as modifiers of outcomes; they suggested that greater provider experience predicts fewer adverse events. For UAE, three studies demonstrated that a history of previous procedures predicts a higher risk of failure and adverse events.

KQ 6: Comparisons of Treatments

The majority of comparative studies (8 of 10) compared UAE with hysterectomy or myomectomy. They reported procedure time and length of stay favoring UAE. However, the inconsistency of the direction of effect for complications and the absence of information on longer-term outcomes suggested that this evidence base is inadequate to comment on the relative risks and benefits of UAE versus hysterectomy or myomectomy. Only one study addressed the need for further invasive therapy; it reported a much higher risk of hysterectomy, myomectomy, or repeat UAE in the UAE group than in the myomectomy group.

One study comparing abdominal hysterectomy with abdominal myomectomy reported no difference in the only outcome considered (febrile morbidity). Another study, comparing

Chinese traditional medicine with conventional therapy, as discussed earlier in this summary, provides weak evidence (weak design, potential bias) favoring traditional Chinese medicine.

KQ 7: Geographic Variation in Treatment

We found no study on geographic variation in treatment within the United States. Studies in our systematic review were generally conducted in academic medical centers, and we could not assess the generalizability of their patterns of care with the broader population from which they were drawn.

Discussion

As with the prior review, we find a remarkable lack of high-quality evidence supporting the effectiveness of most interventions for symptomatic fibroids. Specifically notable is the lack of well-conducted trials in U.S. populations that directly compared treatment options, including the option of expectant management, and that followed women to determine whether their objectives for treatment were met by the intervention received.

Appearance of new fibroids and growth of existing fibroids after treatment are poorly studied. Trials of preoperative medical management indicate that treatment reduces fibroid volume but do not provide sufficient evidence of improvement in important operative outcomes. When women are treated for reasons other than symptom relief, such as when pregnancy is desired, weak evidence supports treating submucous fibroids via hysteroscopy.

We limited our search to articles published in English, primarily for reasons of time and resources; our review of complementary and alternative medicine is likely to be significantly limited by this constraint. We also excluded case reports and case series with fewer than 100 women; this may have resulted in underreports of rare complications of fibroid treatment.

Selection bias is an important weakness in trying to compare outcomes across different interventions in nonrandomized studies. Underlying features of the fibroids and patient risk factors likely influence clinicians in their choice of treatments and operative approaches. Few studies reported these details adequately to allow either adjustment for these potential confounders or pooling across studies.

Across management options, lack of evidence is not equivalent to evidence of no benefit or of harm. Some interventions may be effective in at least some patients. Research to assess how patient characteristics influence outcomes is meager. The current state of the literature does not permit definitive conclusions about benefit, harm, or relative costs to help guide women's choices. Significant research gaps include well-conducted trials in U.S. populations that directly compare interventions on short- and, especially, long-term outcomes, studies on therapeutics for medical management, and information on treatment decisions for women who desire a pregnancy.

Given how common and concerning fibroids can be to women and their health care providers, a redoubled emphasis on promoting high-quality fibroid research in the United States is imperative. Women deserve better information to guide their choices.

Evidence Report

Chapter 1. Introduction

Uterine leiomyomata, or fibroids, are benign growths of smooth muscle and connective tissue anchored in the muscular wall of the uterus. Fibroids are the most common female pelvic tumor; their etiology is unknown. They develop from microscopic nests of uterine muscle cells and have been documented to be composed of numerous copies of the same or very few cells, which is termed monoclonal expansion. Clinically they may initially be detected as small nodules identified only by imaging studies; they can potentially progress through a spectrum of growth from grape size to large masses that can be palpated through the abdominal wall. Research is limited for the purposes of describing the typical fibroid because most data are derived from intervention studies in which the participants had sought treatment and further determined by the inclusion and exclusion criteria of the studies. With that caveat, fibroids documented in treatment studies are often in the size range of 2 to 7.5 centimeters or the dimensions of a large marble to modestly smaller than a baseball.

Clinical convention holds that symptoms and need for treatment are in large part related to a combination of type of fibroid, position within the uterus, and fibroid size. Fibroids are most often grouped as one of four types: submucous (beneath the mucosa, or uterine lining) are immediately adjacent to or jut into the uterine cavity; intramural are entirely within the wall of the uterus; subserous (beneath the serosa) distort the contour of the outer surface of the uterus; and pedunculated are attached to the uterus by a stalk. Some larger fibroids may have characteristics of each type, for instance distorting the interior of the uterus, occupying a component of the uterine wall, and distorting the external contour. Thus, in examining articles for systematic review, noting how authors have operationalized these categories for analysis is important.

Submucous fibroids are clinically described as having the greatest influence on irregular bleeding and reproductive outcomes because the fibroid may act as a physical irritant, much like a foreign body in the uterus, that interferes with the stability of the uterine lining, called endometrium, or with successful implantation of an embryo. Architectural explanations, such as overall enlargement of the uterus by the size and number of fibroids, are often used to describe why fibroids cause common symptoms like heavy menstrual bleeding. Position and size with respect to other structures such as the bladder, bowel, vaginal vault, and nerve bundles in the pelvis are most often used to explain bulk symptoms (i.e., pressure, urinary frequency, constipation or pain with bowel movements, pressure or pain with intercourse, and more generalized pain symptoms). Nonetheless, many fibroids across a large range of sizes do not cause symptoms. The factors that determine which women develop symptoms are unknown.

Fibroids have not been identified before onset of menses. Prevalence increases with age until the hormonal changes of menopause, after which new fibroids are rare.[1-4] Developing a fibroid or multiple fibroids by the time of menopause is the rule rather than the exception; the cumulative incidence by age 49 is nearly 70 percent among white women and more than 80 percent among black women.[2] Thus, across the reproductive years, most women whether with or without symptoms are developing fibroids from initial microscopic nests of monoclonal uterine muscle cells. Prevalence estimates, from clinical populations, range from 20 percent to 77 percent.[1,5,6] The highest of these estimates is from a study that evaluated all hysterectomy specimens from a single institution by using 2 millimeter sections to detect even very small fibroids.[6] The central challenge in understanding the onset of fibroids and their growth is the need for uniform

documentation using imaging techniques in women, across a wide age spectrum and variety of reproductive histories.

Risk Factors for Uterine Fibroids

Valid population-based estimates of fibroid prevalence in younger reproductive years, teens through 30s among U.S. women, are not yet available. Incidence is also poorly documented. However, cross-sectional studies, clinical databases, and case-control studies are investigating epidemiologic markers of risk of fibroids. Because fibroids arise after menarche and become largely quiescent after menopause, they clearly are subject to hormonal stimuli. Age at onset of menstrual cycles, a surrogate for cumulative exposure to menstrual cycle hormonal changes, is inconsistently associated with risk. In studies that find a relationship, younger age at menarche is associated with increased probability of having a diagnosis of fibroids.[7,8] Parity has been consistently associated with a 20 percent to 40 percent reduction in risk of having fibroids, with risk declining as number of births increases.[7-17] In addition, a birth after myomectomy (surgical removal of fibroids), compared with no further births, has been associated with reduced recurrence.[18] The few studies that report on miscarriage or induced abortion[8,9,13,16] show little or no evidence of a protective effect of these early pregnancy losses. One exception reported that induced abortion showed a protective association, but the study had no adjustment for parity.[9] Protective associations with pregnancy do not appear to result from infertility among women with fibroids.[19] Age at first birth categorized as ≥ 35 years has suggested a protective association with relative risk reductions of 40 percent to 50 percent.[7,10,13] Shorter interval since last birth is also related to lower risk.[15,16,19] Because age at first birth, age at last birth, and time since last birth are correlated, these factors would be expected to interact to determine risk. The direction of these associations suggests that the process of uterine renovation that occurs after term pregnancy may mitigate or resolve fibroids, but this has not been proven.

Links between contraceptive history and fibroids are inconsistent; most have focused on oral contraceptives because they expose women to pharmacologic levels of estrogen and progesterone. Taking into account interaction with use of gynecologic care (which increased likelihood of detection), Samadi and colleagues[12] found that women who self-reported a diagnosis of fibroids were 4.3- to 5.0-fold more likely to have used oral contraceptives for 3 months or longer, adjusting for many other factors, including menopausal status and age at menarche but not for parity or other measures of reproductive history. Others have reported less pronounced associations of a 1.4-1.5-fold increase in fibroids for ever-use of these agents.[9,11] In the Nurses Health Study cohort, risk was unrelated to current use and modestly associated with past use.[1] Other reports have found no relationship[7,20] or reduced risk.[8,10,21] Because women with abnormal bleeding patterns or heavy menstrual bleeding may be treated with hormonal contraceptives, confounding by indication may also be at work when an association is seen.

Use of the intrauterine device (IUD) has been investigated based on an inflammatory, rather than a strictly hormonal, model of promotion of fibroid growth. A clinical case-control study found that women with fibroids had 5.3-fold greater odds (95% confidence interval [CI]: 1.8-16.3) of having had IUD use complicated by infection.[21] Likewise, this study showed that a history of pelvic inflammatory disease and chlamydia were also associated with fibroids; however, models were not adjusted for parity or history of infertility.

African-American women have consistently been found to have a 2-fold or higher risk of fibroids than white women.[1,6,17,22-24] However, as discussed below, such estimates may be

confounded by other characteristics such as body weight and diabetes status. Baird and colleagues, using ultrasound assessment and pathology reports from a cohort of women ages 35 to 49 years randomly selected from registrants in a health maintenance organization, found that black women developed fibroids at younger ages and were more likely to have a clinical diagnosis and a hysterectomy.[22] Overall, the odds of developing fibroids by age 50 were 2.9 times higher among blacks than whites. Less is known about the prevalence of fibroids among other minority women in the United States, although Asian and Hispanic women have been reported to have rates similar to those for whites.[1]

Body mass index (BMI) is associated with increased risk of fibroids,[9,10,25] in a dose-response relationship, in most studies.[14,17] Those that adjust for age and race or ethnicity found, at the extremes of their weight categories, that BMI $\geq$ 25.4 compared with $\leq$ 20.3, and $\geq$ 30.0 compared with < 20.0 were associated with 1.5- and 2.3-fold increase in odds, respectively.[17] Other findings in large prospective cohorts suggest a more complex relationship.[14,26] African-American women had lower risk at the extremes of BMI and had the highest adjusted incidence of fibroids for BMIs between 25 and 30; the influence was more pronounced among women who have had births.[26] The effect of BMI was relatively modest: from 23 percent to 47 percent greater in the higher risk categories.[14,26]

The effect of race has been reported to be diminished when BMI enters multivariable models and vice versa,[12] although others have found little influence of race. The risk estimate for incidence among African-American women from Baird and colleagues falls from 2.9 to 2.7, when adjusting for parity and BMI.[2] A potential explanation for the influence of BMI is that both increased production of estrogens in peripheral body fat and increased risk of anovulatory cycles are associated with increasing body weight. Both mechanisms would increase cumulative estrogen exposure over time, in the latter case simultaneously decreasing exposure to progesterone because of an absence of the luteal phase (the second half of an ovulatory menstrual cycle in which progesterone levels peak).

Physical activity is also intimately related to body habitus, energy metabolism, sex steroid levels, and ovulatory function. Based on self-report of physical activity levels for recreation and household chores, the highest levels of activity compared with the lowest may be protective, reducing risk of having fibroids by 40 percent. The general trend for both African-American and white women is that increasing levels of activity were associated with lower risk.[27] Hypertension and correlates of atherosclerosis and heart disease risk have also been related to likelihood of developing fibroids;[21,28,29] such findings suggest either a common smooth muscle abnormality that promotes proliferation of uterine or vascular smooth muscle cells or direct damage to myometrium or vascular structures in the uterus from elevated blood pressure. In the Nurses Health Study prospective cohort, elevated blood pressure was linked to higher risk of clinical diagnosis of fibroids even after taking into account use of medical care and treatment with blood pressure medications.[28]

Smoking is associated with impaired production and reduced levels of endogenous circulating estrogens. This is a potential dual effect of direct inhibition by nicotine and of trends toward lower body weight among smokers. Smoking status has been variably reported to relate to fibroid risk in a fashion that fits this model; heavier smoking or longer histories of smoking (or both) have been linked to decreased risk of fibroids. The reductions in relative risk (adjusting for BMI, age, education, oral contraceptive use, and parity) range from 30 percent for ever smoked to approximately 50 percent for current smokers.[9,11] Consistent with body weight as an

important predictor, others have reported that the influence of smoking is not significant when BMI and reproductive factors are included in multivariable models.[17,19,28]

Each of these characteristics may influence risk of fibroids. Many others, which are biologically plausible and largely uninvestigated (e.g., genetic, environmental, and dietary factors), also have potential to modify the course and consequences of fibroids. We would expect that they would also influence treatment outcomes and risk of recurrence.

Management of Uterine Fibroids

Conservatively estimated, 35 million women in the United States have uterine fibroids (www.census.gov/popest/national).[30] Fewer than half are likely to have a diagnosis of fibroids made by a clinical care provider,[31] in part because many women with fibroids have no symptoms.[2,31] When symptomatic, fibroids can be linked to at least three major problems: (1) bleeding complaints including heavy menstrual cycles, irregular bleeding, and anemia; (2) mass effects related to the size and location of fibroids, including pelvic pressure or pain, urinary frequency, constipation or painful bowel movements, and discomfort or pain with intercourse; and (3) pregnancy complications that may include difficulty conceiving, increased miscarriage risk, and later complications such as preterm birth. These symptoms and consequences have been shown to diminish quality of life.[32]

Up to one in three women who receive a new diagnosis of fibroids have related surgery within the year.[33] Indeed, fibroids are currently the leading indication for hysterectomy in the United States.[34] Myomectomy—surgical removal of fibroids—is the second most common fibroid surgery.[34]

The proportions of women with fibroids likely to be receiving medical therapy to address symptoms are higher than those receiving surgery. In a large U.S. claims database, 34 percent of women with a new diagnosis of uterine fibroids filled prescriptions for hormone-based therapies (including oral contraceptives and other hormonal treatments) and 28 percent were given nonsteroidal anti-inflammatory agents (NSAIDS). Much smaller proportions (< 2 percent) were treated with hormone antagonists, such as gonadotropin-releasing hormone (GnRH) agonists, or with aggressive treatments for anemia such as erythropoietin injections, both most often used in preparation for surgery.[33]

Large-scale observational research has not yet identified target risk factors suitable for intervention to prevent, resolve, or reduce symptoms associated with uterine fibroids. Nonetheless, fibroids are common and often concerning for women and their health care providers, as well as costly to the individual and the health care system. Thus, this evidence review focuses on summarizing the evidence about currently available clinical management options and updating evidence about burden of disease, geographic variation in choice of treatment, and cost of care.

Key Questions and Analytic Framework

Key Questions

The first Agency for Healthcare Research and Quality (AHRQ) systematic review on the management of uterine fibroids was published in January 2001.[30] That review found that the

overall quality of the literature on the management of fibroids was poor, with almost no evidence to support the effectiveness of commonly recommended medical treatments. The review found consistent evidence from randomized trials that preoperative use of GnRH agonist therapy reduced estimated blood loss and may facilitate the surgical approach by reducing uterine size. The review also found that the outcomes of hysterectomy up to 2 years after surgery are favorable for most symptomatic women, although up to 12 percent of women develop new symptoms after surgery. The review did not attempt to deduce the clinical significance of these outcomes compared with outcomes of myomectomy, medical therapy, or no intervention, because of significant differences in the severity of preintervention disease. The prior review found almost no data to allow estimation of the overall costs of fibroids to the economy.

Since then, new treatment approaches, such as uterine artery embolization and ablation of fibroids via ultrasound guided by magnetic resonance imaging (MRI), have become available for management of uterine fibroids. More recent publications have also expanded the evidence base and may better reflect the variety of currently available medical management resources and the range of surgical interventions in use. New direct comparisons of different types of management approaches, as well as new research with longer lengths of followup of participants, have also become available.

The American College of Obstetricians and Gynecologists (ACOG) (the partner for this evidence report) proposed an update to the 2001 systematic review. ACOG developed the initial scope of this review; AHRQ forwarded it to the RTI International–University of North Carolina Evidence-based Practice Center (RTI–UNC EPC). The original work assignment proposed eight provisional questions for review; they recapitulate those of the original review.

The RTI–UNC EPC revised the proposed questions after discussions with internal technical staff, AHRQ staff, ACOG, and our Technical Expert Panel (TEP, see below). We aimed to allow a cross-walk between the 2001 report and this update while expanding the modalities considered and regrouping questions to result in chapters that better conform to the clinical care concerns confronting women and their care providers. The final seven key questions (KQs) are listed below.

KQ 1. What is the incidence and prevalence of uterine fibroids, as estimated in representative U.S. populations through use of diagnostic imaging or histology to document uniformly the presence or absence of fibroids? Among women with symptomatic fibroids, what are the incidence, type, and severity of symptoms?

KQ 2. Among women with symptomatic fibroids (e.g., anemia, problem bleeding patterns, bulk symptoms, pain, dyspareunia), what are the short- and long-term outcomes of the following treatment approaches or combinations of treatment approaches:

1. expectant management without intervention?
2. medical (pharmaceutical) management (including oral contraceptives, menopausal hormone therapy, GnRH agonist therapy, antiprogestins, progesterone-containing IUDs, and nonsteroidal anti-inflammatory drugs)?
3. uterine artery embolization?
4. endometrial ablation (with or without myomectomy)?
5. in situ destructive techniques (MRI-guided focused ultrasound and cryotherapy)?
6. myomectomy (abdominal, laparoscopic, and hysteroscopic)?

7. hysterectomy (abdominal, laparoscopic, vaginal)?
8. complementary and alternative therapies including acupuncture?

KQ 3. Among women with fibroids (symptomatic or asymptomatic), what are the short- and long-term outcomes of these treatment approaches when used with the objective of:
   a. enhancing fertility?
   b. reducing adverse pregnancy outcomes?
   c. preventing further growth?
   d. ruling out uterine malignancy?

KQ 4. What are the costs associated with fibroids care?

KQ 5. Are the short- and long-term outcomes of these treatment approaches (including risk of fibroid recurrence) modified by age, race or ethnicity, parity, breastfeeding, contraceptive choices, body habitus, insulin resistance, concurrent medical conditions such as diabetes, hormone replacement status, or other factors?

KQ 6. Where direct comparisons have been made between or among the treatment modalities of interest, which modalities achieve superior outcomes with respect to benefits, short- and long-term risks, quality of life, and costs?

KQ 7. Do rates of use of these treatments for fibroids vary geographically in the United States?

Analytic Framework for the Management of Uterine Fibroids

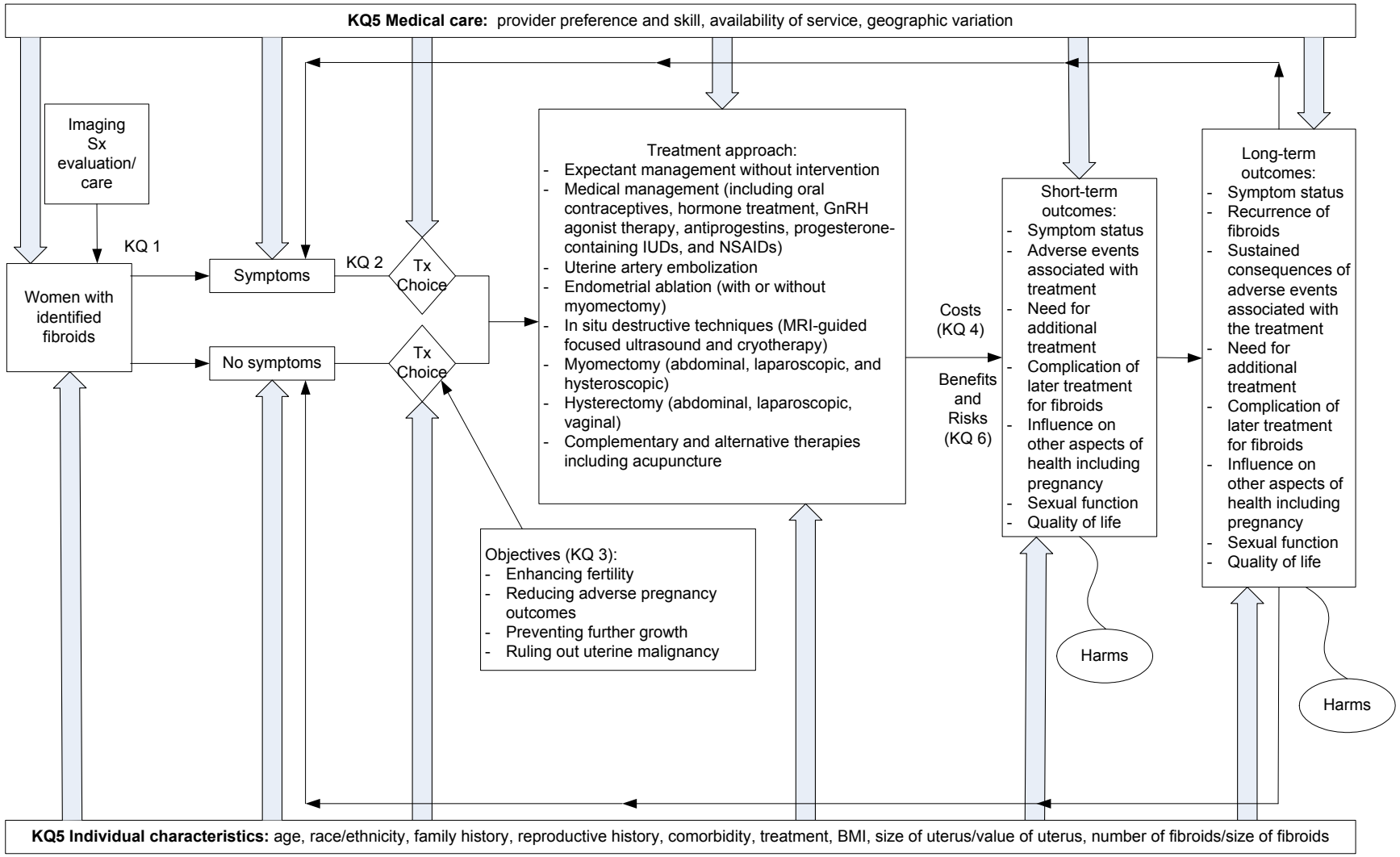
The analytic framework in Figure 1 (i.e., the conceptual model developed to guide this systematic review) summarizes the critical topics addressed by this report and their links to the key questions. The KQs are noted on the boxes on arrows as appropriate; KQ 7, which is essentially derivative of KQ 1, is not shown. The starting population of interest is women with identified fibroids, with and without symptoms (KQs 1 and 2). Treatment choices have several objectives (KQ 3) and vary markedly (KQ 6), producing both benefits and harms (noted in the short and long run [far right boxes]); they also are associated with variable costs (KQ 4). We recognize that outcomes of fibroid therapy are modified by a host of medical and individual characteristics; we address a subset of these in KQ 5.

Production of This Evidence Report

Organization of This Evidence Report

Chapter 2 describes our methods, including our search strategies and inclusion/exclusion criteria; we also document our approach to grading the quality of articles and rating the strength of evidence. In Chapter 3, we present the results of our literature search and synthesis of retained articles by key question. Specifically, we address KQs 1, 2, 3, and 4, as they directly draw upon evidence. Chapter 4 further discusses the findings and addresses KQs 5, 6, and 7, as they are further analyses of the evidence presented in Chapter 3. Chapter 4 also presents our conclusions, and offers recommendations for future research.

Figure 1. Analytic framework for management of uterine fibroids



BMI, body mass index; GnRH, gonadotropin-releasing hormone; IUD, intrauterine device; KQ, key question; MRI, magnetic resonance imaging; NSAIDs, non-steroidal anti-inflammatory drugs; Sx, symptom; Tx, treatment.

Our references and included studies follow Chapter 4. Appendices include a detailed description of our search strings (Appendix A*), data collection forms (Appendix B*), detailed evidence tables (Appendix C*), excluded studies (Appendix D*), and acknowledgments (Appendix E*). Appendixes and evidence tables cited in this report are provided electronically at http://www.ahrq.gov.

Technical Expert Panel (TEP)

We identified technical experts in the field of fibroid evaluation and treatment to provide assistance throughout the project. The TEP (see Appendix E*) was expected to contribute to AHRQ's broader goals of (1) creating and maintaining science partnerships as well as public-private partnerships and (2) meeting the needs of an array of potential customers and users of its products. Thus, the TEP was both an additional resource and a sounding board during the project. The TEP included seven members serving as technical or clinical experts, including an ACOG representative. To ensure robust, scientifically relevant work, we called on the TEP to provide reactions to work in progress and advice on substantive issues or possibly overlooked areas of research. TEP members participated in conference calls and discussions through e-mail to:

- Refine the analytic framework and key questions at the beginning of the project;
- Discuss the preliminary assessment of the literature, including inclusion/exclusion criteria; and
- Provide input on the information and categories included in evidence tables.

Because of their extensive knowledge of the literature, including numerous articles authored by TEP members themselves, and their active involvement in professional societies and as practitioners in the field, we also asked TEP members to participate in the external peer review of the draft report.

Uses of This Report

This evidence report addresses the key questions outlined above using methods described in Chapter 2 to conduct a systematic review of published literature. We anticipate that the report will be of value to all women's health care providers, including ACOG (the original partner), the American Academy of Family Physicians, American Academy of Nurse Practitioners, and other clinical groups who care for women from menarche through the remainder of their lives, such as the American Society of Reproductive Medicine. In addition, this review will be of use to the National Institutes of Health, Centers for Disease Control and Prevention, Centers for Medicare & Medicaid Services, and the Health Resources and Services Administration – all of which have offices or bureaus devoted to women's health issues. This report can bring practitioners up to date about the current state of evidence, and it provides an assessment of the quality of studies that aim to determine the outcomes of therapeutic options for the management of uterine fibroids. It will be of interest to individual women and the general public because of the high

* Appendixes cited in this report are provided electronically at http://ahrq.gov/clinic/tp/uteruptp.htm

prevalence of fibroids and the recurring need for women and their health care providers to make the best possible decisions among numerous options. We also anticipate it will be of use to private sector organizations concerned with women's health, such as Our Bodies Ourselves, the National Women's Health Network, and the National Black Women's Health Imperative.

Researchers can obtain a concise analysis of the current state of knowledge in this field. They will be poised to pursue further investigations that are needed to understand the causes of fibroids, clarify risk factors, develop prevention strategies, develop new treatment options, and optimize the effectiveness and safety of clinical care.

Chapter 2. Methods

In this chapter, we document the procedures that the RTI International–University of North Carolina Evidence-based Practice Center (RTI–UNC EPC) used to develop this comprehensive evidence report on management of uterine fibroids. We first describe our strategy for identifying articles relevant to our seven key questions, our inclusion and exclusion criteria, and the process we used to abstract relevant information from the eligible articles and generate our evidence tables. We also discuss our criteria for grading the quality of individual articles and for rating the strength of the evidence as a whole. Finally, we explain the peer-review process.

Literature Review Methods

Inclusion and Exclusion Criteria

Our inclusion and exclusion criteria are documented in Table 1. As noted in Chapter 1, this is an update of a systematic review originally published by the Agency for Healthcare Research and Quality (AHRQ) in 2001. Largely for that reason, we limited our searches to articles published in or after February 2000 through August 2006. We also restricted our searches to developed countries so that we could have data generally comparable to the standard of care in the United States.

Table 1. Inclusion/exclusion criteria for management of uterine fibroids

Category	Criteria
Study population	Women (all ages)
Study settings and geography	Developed nations: United States, Canada, United Kingdom, Western Europe, Scandinavia, Japan, Australia, New Zealand, Israel
Time period	February 2000 through August 2006
Publication languages	English only

Admissible evidence (study design and other criteria)	Admissible study designs
	Controlled trials, prospective trials with historical controls, prospective or retrospective cohort studies, and medium-to-large case series (n > 100)
	
	Other criteria
	• Original research studies must provide sufficient detail regarding methods and results to enable use and adjustment of the data and results.
	• Patient populations must include women with uterine fibroids.
	• Studies must address one or more of the following for uterine fibroids:
	  o Treatment modality
	  o Symptom management approach
	  o Short- and long-term outcomes and quality of life.
	• Relevant outcomes must be able to be abstracted from data presented in the papers.
	• Sample sizes must be appropriate for the study question addressed in the paper; single case reports or small case series (fewer than 100 subjects) are excluded.

We excluded studies that (1) were published in languages other than English (given the available time and resources); (2) did not report information pertinent to the key clinical questions; (3) had fewer than 40 subjects for randomized controlled trials (RCTs) or nonrandomized cohorts with comparisons or fewer than 100 subjects for case series; and (4) were not original studies.

For most of our key questions, the relevant population consists of women with fibroids. For KQ 3a and 3b, however, the relevant population is a subset of women with treatment for fibroids. For KQ 3a, on outcomes of treatment for enhancing fertility, and KQ 3b, on outcomes of treatment to reduce adverse pregnancy outcomes, the relevant subpopulation is women with treatment for fibroids who are attempting to get pregnant. For these two subquestions, we applied our sample size criterion to the relevant subpopulation of interest. To illustrate this strategy: assume that a publication about a cohort of 80 women with and without prior myomectomy reported treatment outcomes and 30 pregnancies but that it did not report the number of women trying to conceive. We would exclude this publication from KQ 3a and 3b (the section on enhancing fertility) but include it in KQ 2 (the section on treatment outcomes).

We included studies that did not provide a denominator (number attempting conception) but had sufficient pregnancies to infer that the denominator exceeded our size cutoff. To illustrate, we included case series examining the effect of assisted reproductive technologies on pregnancies that did not report the number attempting conception, if number of pregnancies was 100 or higher.

Our definitions of study design appear in Appendix B[*].

Literature Search and Retrieval Process

Databases. We used multifaceted search strategies to include current and valid research on the KQs, which we applied to three standard electronic databases—MEDLINE®, Cochrane Collaboration resources, and Embase. We also hand-searched the reference lists of relevant articles to make sure that we did not miss any relevant studies. We consulted with our Technical Expert Panel (TEP) about any studies or trials that are currently under way or that may not be published yet.

Search Terms. Based on the inclusion/exclusion criteria above, we generated a list of Medical Subject Heading (MeSH) search terms (Table 2 and Appendix A[*]). Our TEP also reviewed these terms to ensure that we were not missing any critical areas, and this list represents our collective decisions as to the MeSH terms used for all searches.

Our searches on EMBASE and Cochrane used the search term "Leiomyoma OR Fibroid*" and retrieved 3 and 52 citations, respectively, that had also been identified by our MEDLINE® searches. Peer reviewers suggested an additional eight citations.

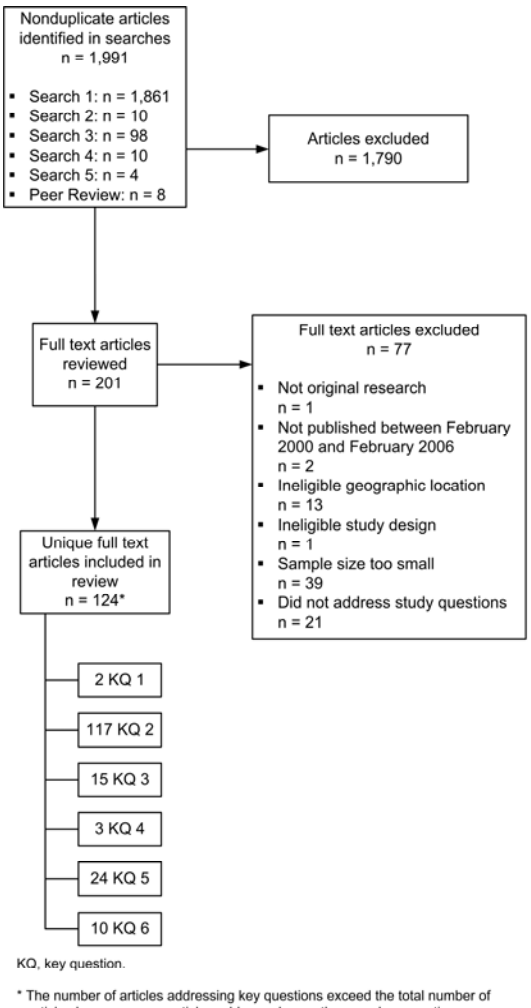
[*] Appendixes cited in this report are provided electronically at http://ahrq.gov/clinic/tp/uteruptp.htm

Table 2. MEDLINE® search strategy and unduplicated results

Search Terms	Search Results
#7 Search "Leiomyoma"[MeSH]OR fibroid* OR leiomyomata	13,887
#8 Search "Leiomyoma"[MeSH]OR fibroid* OR leiomyomata Field: All Fields, Limits: Publication Date from 2000, English, Humans	2,584
#19 Search Editorial OR Letter OR Practice Guideline OR Review Limits: Publication Date from 2000, English, Humans	547
#20 Search #8 NOT #19 Limits: Publication Date from 2000, English, Humans	1,983

Figure 2 presents the yield and results from our searches, which we conducted from March through August 2006. Beginning with a yield of 1,991 articles, we retained 124 articles covering 107 studies that we determined were relevant to address our KQs and met our inclusion/exclusion criteria (Table 1). We reviewed titles and abstracts of the articles against the basic inclusion criteria above; we retained relevant articles, all published after our search cutoff date of February 2000, and used them as appropriate in the discussion in Chapter 4.

Figure 2. Disposition of articles for management of uterine fibroids



KQ, key question.

* The number of articles addressing key questions exceed the total number of articles because some articles addressed more than one key question.

Article Selection Process. Once we had identified articles through the electronic database searches, review articles, and bibliographies, we examined abstracts of articles to determine whether studies met our criteria. Two reviewers separately evaluated the abstracts for inclusion or exclusion, using an Abstract Review Form (Appendix B*). If one abstractor concluded that the article should be included in the review, we retained it. The group included three physicians (Katherine Hartmann, MD, PhD, Scientific Director, Gretchen Stuart, MD, and Nicole Rankins, MD), one senior health services researcher (Meera Viswanathan, PhD, Study Director), and two junior health services researchers (Nikki McKoy, BS, and Patricia Thieda, MS).

Of this entire group of 1,991 articles, 201 required full review because of missing or uninformative abstracts. For the full article review, one reviewer read each article and decided whether it met our inclusion criteria, using a Full Text Inclusion/Exclusion Form (Appendix B*). Reasons for article exclusion are listed in Appendix D*.

Literature Synthesis

Development of Evidence Tables and Data Abstraction Process

The staff members who conducted this systematic review jointly developed the evidence tables. We designed the tables to provide sufficient information to enable readers to understand the studies and to determine their quality; we gave particular emphasis to essential information related to our KQs. We based the format of our evidence tables on successful designs that we have used for prior systematic reviews; we incorporated some elements of the tables in the prior review on uterine fibroids.[30]

We trained abstractors by having them abstract several articles into evidence tables and then reconvening as a group to discuss the utility of the table design. The abstractors repeated this process through several iterations until they decided that the tables included the appropriate categories for gathering the information contained in the articles.

All team members shared the task of initially entering information into the evidence tables. Another member of the team also reviewed the articles and edited all initial table entries for accuracy, completeness, and consistency. The two abstractors reconciled all disagreements concerning the information reported in the evidence tables. The full research team met regularly during the article abstraction period and discussed global issues related to the data abstraction process.

The final evidence tables are presented in their entirety in Appendix C*. Studies are presented in the evidence tables alphabetically by the last name of the first author. A list of abbreviations and acronyms used in the tables appears at the beginning of that appendix.

Quality Rating of Individual Studies

Rating the Quality of Individual Articles. We developed our approach to assessing the quality of individual articles based on the prior review on management of uterine fibroids conducted by the Duke EPC;[30] the rationale is that we wished to preserve as much consistency as appropriate between that review and this update. The original review assessed each study on a range of factors affecting internal and external validity and generally assigned "+" scores when

* Appendixes cited in this report are provided electronically at http://ahrq.gov/clinic/tp/uteruptp.htm

studies met criteria, and "-" scores when studies did not, but it did not aggregate those factors into a single score. We made minor modifications to that earlier quality assessment list to allow us to construct an aggregate score; our final set of criteria is described below. Our final assessment of quality is based largely on the prior review, presented below in double-indented text, with our modifications, presented in regular text. We included citations from the prior review in the text below but recoded them to follow in numerical sequence in our own text and reference list.

Internal Validity. The criteria for assessing internal validity were as follows:

Randomized Allocation to Treatment. We modified the approach to this variable by combining randomization and method of randomization into a single criterion with a three-point scale. We employed the same rationale to evaluate this criterion, as follows (Matchar et al., 2001, pp.36-37):[30]

- Rationale: By randomly assigning groups to the intervention of interest, other factors that may confound the results are equally distributed between groups (assuming a large enough sample size). This equal distribution minimizes the chances of over- or underestimation of treatment effect based on unequal distribution of confounding factors.

If randomized, we evaluated the study for randomization methods, using the rationale described in Matcher et al., 2001, p.37:[30]

- Rationale: "Pseudo-randomization" methods may be susceptible to bias, as demonstrated by evidence of unequal distribution of subject characteristics[35] and larger effect sizes compared with studies using more rigorous methods.[36] In addition, methods of allocation concealment are also important in preventing bias (e.g., use of prepared sealed envelopes).

We combined these elements into a single operational definition, as described below:

- Operational definition: Criterion met if randomization methods were not susceptible to bias, such as computer-generated numbers in sealed envelopes (+). Criterion not met by studies that either used methods more prone to bias, such as alternate medical record numbers, or did not describe randomization methods or methods of allocation concealment (-). Criterion not applicable if treatment was not randomly allocated (NA).

We added a criterion to measure blinding.

Blinding.

- Rationale: Blinding, also known as masking, refers to the concealment of treatment allocation from the care provider, the assessor, and the patient. In certain trials, particularly surgical trials, masking the patient or the surgeon from the treatment allocation can be challenging or impossible. Similarly, masking the assessor assigned to record immediate postprocedural outcomes such as wound healing can also be difficult. Nevertheless, when possible, masking prevents expectations from influencing findings.

- Operational definition: Criterion met if at least assessors were blinded (+). Criterion not met if care provider, assessor, or patient were not blinded (-). Criterion not applicable if treatment was not randomly allocated or blinding was not possible (NA).

For adequate description of patients and controls, we relied on the scoring used by the prior review (Matcher et al., 2001, p.37).[30] Unless otherwise specified, we followed the prior review's practice of assigning a '+' for studies that met the criterion or '–' for studies that did not meet the criterion:

Adequate Description of Patients and Controls.

- Rationale: Patient characteristics that might affect outcomes (such as obesity, prior surgery, or medical comorbidities) are likely to differ between two interventions. If these differences are not characterized, then erroneous conclusions may be drawn. For example, comparison of outcomes from a series of laparoscopic appendectomies with those from concurrent open appendectomies found better outcomes with the laparoscopic procedure.[37] These differences were not seen when the same group performed a randomized trial, a finding attributable to differential patient selection criteria in the nonrandomized study.[38]

- Operational definition: Criterion met if (a) inclusion and exclusion criteria for participation in the study were described or (b) for nonrandomized studies, description of the rationale for selecting a particular intervention was given. Criterion not met if (a) inclusion/exclusion criteria were not described or (b) description of the rationale for selection of the interventions was not given (e.g., a nonrandomized comparison of concurrent laparoscopic and abdominal myomectomies that did not describe why patients received one or the other procedure).

We modified our reporting of the item on description of patient and control to account separately for missing versus inadequate inclusion and exclusion criteria. We assigned a '-' score (negative) to studies with no description of inclusion and exclusion, a '+' score to studies unable to control or account for confounding factors, and a '++' score to studies able to control and account for confounding factors in patient selection through clear inclusion and exclusion criteria.

We did not include the prior review's item on description of loss to followup as an additional internal validity criterion, because we accounted for loss to followup in internal validity and appropriateness of length of followup in evaluating external validity. We retained other aspects of the prior review's internal validity assessment as follows:[30(p38)]

Description of Loss to Followup.

- Rationale: Failing to account for patients lost to followup may lead to erroneous conclusions, especially if the loss to followup is related to either the underlying disease or the intervention (e.g., patients seeking care elsewhere because of continuing symptoms or unacceptable side effects of treatment).

- Operational definition: Criterion met if (a) loss to followup was explicitly reported, (b) number of subjects for whom data were presented was equal to number of subjects receiving intervention at start of study, or (c) for studies reporting only hospital-based outcomes,

number of missing charts or records was reported. Criterion not met if loss to followup was not reported and number of subjects at beginning and end of study was not equal.

Description of Dropout Rates.

- Rationale: Dropout rates may reflect differences in clinically important variables, such as side effects or treatment response. Failure to account for dropouts may result in erroneous conclusions similar to those seen with failure to account for loss to followup.

- Operational definition: Criterion met if (a) patients dropping out of the study prior to completion were reported or (b) number of subjects at beginning and end of study were equal. Criterion not met if patients dropping out were not reported and numbers of subjects at beginning and end of study were not equal. Criterion not applicable for studies reporting only hospital-based outcomes.

We made minor modifications to the assessment above by distinguishing among three loss-to-followup rates: <10 percent (++), 10 percent to 20 percent (+), and >20 percent (-). We also distinguished among dropout rates of <5 percent (++), 5 percent to 10 percent (+), and >10 percent (-).

Recognition and Description of Statistical Issues.

- Rationale: Use of inappropriate tests may lead to misleading conclusions. For example, variables such as blood loss, length of stay, or costs are often not normally distributed; use of means instead of medians when data may be affected by outlying observations can be misleading. Many studies, especially case series, may lack sufficient power to detect clinically important differences in outcomes or patient characteristics.

- Operational definition: Criterion met if (a) appropriate statistical tests were used (e.g., nonparametric methods for variables with nonnormal distributions, or survival analysis techniques to account for loss to followup and dropouts) and (b) potential study limitations regarding design and analysis, especially sample size and power issues, were discussed. Criterion not met if (a) inappropriate statistical tests were used or (b) study limitations were not discussed.

We modified this aspect of quality by crediting studies that accounted for crossover and loss to followup in intention-to-treat analysis.

External Validity. We also modeled our assessment of external validity on the earlier review. The criteria for assessing external validity were as follows:[30(pp39-42)]

Description of Age of Study Population.

- Rationale: The outcomes of many interventions are affected by patient age. Age is especially important in studies of reproductive disorders in women, since childbearing potential and ovarian hormone production, both key components in decisionmaking regarding management of fibroids, are directly related to age.

- Operational definition: Criterion met if summary statistics of subject age were given. Criterion not met if summary statistics were not given.

Description of Racial/Ethnic Distribution of Population.

- Rationale: The epidemiology, and possibly the biology, of fibroids clearly varies between white and black women. Additionally, there is widespread racial variation in the United States in utilization and outcomes of a wide variety of interventions.[39]

- Operational definition: Criterion met if (a) racial/ethnic distribution was described or (b) the geographical setting of the study strongly implied the racial/ethnic background of the entire population (e.g., studies of hysterectomy outcomes in Japan or Nigeria). Criterion not met if (a) racial/ethnic distribution was not described and (b) geographic setting was likely to include subjects of diverse racial/ethnic background.

Description of Pregnancy History of Population.

- Rationale: Pregnancy history may affect the natural history or biology of fibroids.[9] For surgical interventions, pregnancy history may affect the technical difficulty of a procedure; for example, prior vaginal delivery may facilitate vaginal hysterectomy, while prior cesarean section, by increasing the risk of adhesions, may make either abdominal or vaginal hysterectomy more difficult.

- Operational definition: Criterion met if (a) summary statistics on gravidity or parity were given or (b) percentage of women with prior pregnancy was given. Criterion not met if (a) no summary statistics were given and (b) no distribution data on prior pregnancies were given.

Description of Prior Surgery.

- Rationale: A history of prior surgery for fibroids might reflect differences in the natural history or biology between patients. Additionally, previous abdominal surgery might increase the risk of complications by increasing the likelihood of intraperitoneal adhesions.

- Operational definition: Criterion met if (a) any description of history of intra-abdominal surgery was given or (b) proportion of women with prior surgery for fibroids was given. Criterion not met if no description of prior surgery was given.

We modified this criterion for studies of pharmaceutical management and complementary alternative medicine. For these studies, we assigned the category as ‘not applicable’ since surgical history was unlikely to influence the likelihood of complications.

Adequate Characterization of Fibroid and/or Uterine Size.

- Rationale: Individual fibroid size, or aggregate uterine size, may affect the nature or severity of symptoms, the response to various treatments, and the risk of complications of surgical treatments.

- Operational definition: Criterion met if data given on (a) uterine size in weeks of gestational age; (b) uterine volume, area, or length as estimated by radiologic techniques; (c) uterine weight in grams (for hysterectomy specimens); (d) fibroid diameter or volume as estimated by radiologic techniques; or (e) fibroid dimensions or weight based on pathological examinations. Criterion not met if none of the above were provided.

Adequate Characterization of Fibroid Number.

- Rationale: The number of fibroids may affect the nature or severity of symptoms, the response to various treatments, and the risk of complications of surgical treatments.

- Operational definition: Criterion met if summary statistics or distribution of number of fibroids was provided. Criterion not met if no data were provided on number of fibroids.

Adequate Characterization of Fibroid Location.

- Rationale: The location of fibroids may affect the nature or severity of symptoms, the response to various treatments, and the risk of complications of surgical treatments.

- Operational definition: Criterion met if (a) distribution of fibroids by location (subserosal, intramural, submucosal, or pedunculated) was given or (b) other anatomical descriptions were given (e.g., anterior, posterior, fundal, or within the broad ligament). Criterion not met if no anatomical description was given.

Adequate Characterization of Baseline Symptoms.

- Rationale: Because fibroids may present with a variety of symptoms, assessing the effectiveness of therapy requires an adequate description of the nature and severity of symptoms prior to institution of therapy.

- Operational definition: Criterion met if distribution of specific symptoms or symptom classes associated with fibroids were provided. Criterion not met if specific symptoms were not described (e.g., if the only description of inclusion criteria was “symptomatic fibroids”).

Adequate Description of Timing of Outcome Measurement.

- Rationale: Outcome measures may vary depending on when they are obtained. Description of when outcomes were measured facilitates comparison between studies.

- Operational definition: Criterion met if (a) time after initiation of therapy at which outcomes were measured was reported or (b) study was limited to hospital-based outcomes. Criterion not met if (a) time was not reported and (b) study was not strictly hospital-based.

We expanded the measure on adequacy of description of the timing of outcome measures to include appropriateness of the timing of outcome measures. Specifically, we assigned a ‘-’ score to studies that were missing descriptions of the length of followup, a ‘+’ score to studies that had

insufficient followup to comment meaningfully on relevant outcomes, and a '++' score to studies that had adequate length of followup.

Adequate Description of Methods Used for Outcome Measurement.

- Rationale: Comparison between studies requires common methods of measurement, which in turn requires adequate description of the methods used to assess comparability.

- Operational definition: Criterion met if (a) methods used to measure outcomes were adequately described or referenced (e.g., pain or bleeding scales), (b) definitions were given (e.g., description of outcomes classified as "complications"), or (c) outcomes were unambiguous (e.g., pregnancy, need for hysterectomy). Criterion not met if (a), (b), or (c) was not present.

Adequate Description of Validity and Reliability of Outcome Measurement.

- Rationale: Measurements of outcomes are only useful if changes in the outcome being measured are reflected in changes in the measurement (validity) and if these changes are reasonably consistent between the same observer measuring at different times or between different observers (reliability). For example, changes in a scale to assess menstrual blood flow should correlate with some other physiological measure of menstrual blood loss, and this correlation should be consistent when different women apply the same scale.

- Operational definition: Criterion met if (a) a description of the methods used to assess validity and reliability of at least one outcome measure was provided, (b) a reference to another article documenting validity and reliability was provided, or (c) only unambiguous outcomes such as pregnancy were included. Criterion not met if (a), (b), or (c) was not present.

Adequate Description of Clinical Care Provided to Subjects.

- Rationale: The ability to replicate study results is dependent on adequate description of methods. Additionally, readers should be aware of aspects of clinical care that might influence outcomes.

- Operational definition: Criterion met if (a) a detailed description of the therapy (dose, dosing schedule, and route of administration for medications and/or techniques for invasive therapies) was provided; (b) a reference to another publication describing the procedure was provided; or (c) statistical adjustment was made for likely sources of variation in clinical care (e.g., site where care was given, type of specialist providing care, individual provider). Criterion not met if (a), (b), or (c) was not provided.

Use of Previously Validated and Standardized Measures.

- Rationale: Use of measures used by other researchers enhances the ability to compare results across studies. Use of measures used with other medical conditions enhances the ability to

compare the impact of uterine fibroids to that of other common conditions, which may be important when setting research and resource allocation priorities.

- Operational definition: Criterion met if at least one measure previously used by another group was used. Criterion not met if all measures were internally developed.

We then combined these scores into an aggregate measure of quality for internal and external validity (Table 3). To receive a rating of good overall, the study had receive good scores for both internal and external validity (that is, no negative scores and the lowest level of loss to followup or dropout). To receive a rating of fair overall, the study could receive a fair rating for both internal and external validity, or a mixed rating (good and fair, or good and poor) for internal and external validity. We assigned studies with one negative score for internal validity or intermediate loss to followup (10 percent to 20 percent), or intermediate dropout rate (5 percent to 10 percent) a rating of fair for internal validity. We assigned studies with one to three negative scores for external validity a rating of fair for external validity.

Table 3. Scoring algorithm for internal validity, external validity, and overall quality rating for individual studies

Definition and Scoring Algorithm*	Rating
Score Algorithm for Internal Validity Quality Rating	
• No negative scores, lowest level of loss-to-followup score, and lowest dropout rate	Good internal validity
• One negative score, or intermediate loss-to-followup, or intermediate dropout rate	Fair internal validity
• Poor randomization, high loss-to-followup score, or high dropout rate ***OR*** • Two negative scores ***OR*** • One negative score and one intermediate loss-to-followup score or dropout rate	Poor internal validity
Score Algorithm for External Validity Quality Rating	
• No negative scores	Good external validity
• One to three negatives scores	Fair external validity
• Four negatives scores	Poor external validity
Score Algorithm for Overall Quality Rating	
• Good internal validity and good external validity	Good overall
• Fair internal validity and fair external validity ***OR*** • Good internal validity and fair external validity ***OR*** • Good internal validity and poor external validity ***OR*** • Fair internal validity and good external validity ***OR*** • Poor internal validity and good external validity	Fair overall
• Poor internal validity and poor external validity ***OR*** • Fair internal validity and poor external validity ***OR*** • Poor internal validity and fair external validity	Poor overall

*Negative scores are those scored '-.'

To receive a rating of poor overall, the study could receive a poor rating for both internal and external validity, or a mixed rating of fair and poor for internal and external validity. We considered poor randomization, high loss to followup (> 20 percent), or high dropout rates (> 10 percent) to be in the nature of fatal flaws, and we assigned these studies poor ratings for internal

validity. Studies without these flaws that nevertheless received two or more negative scores for internal validity were also rated poor for internal validity. Studies with four or more negative scores for external validity were assigned a poor rating for external validity.

Strength of Available Evidence

Our scheme follows the criteria applied in an earlier RTI–UNC EPC systematic review of systems for rating the strength of a body of evidence.[40] That system included three domains: quality of the research, quantity of studies (including number of studies and adequacy of the sample size), and consistency of findings. Two senior staff members assigned grades by consensus.

We graded the body of literature for each KQ and present those ratings as part of the discussion in Chapter 4. The possible grades in our scheme are as follows:

I. Strong: The evidence is from studies of strong design; results are both clinically important and consistent with minor exceptions at most; results are free from serious doubts about generalizability, bias, or flaws in research design. Studies with negative results have sufficiently large samples to have adequate statistical power.

II. Moderate: The evidence is from studies of strong design, but some uncertainty remains because of inconsistencies or concern about generalizability, bias, research design flaws, or adequate sample size. Alternatively, the evidence is consistent but derives from studies of weaker design.

II. Weak: The evidence is from a limited number of studies of weaker design. Studies with strong design either have not been done or are inconclusive.

IV. No evidence: No published literature.

External Peer Review

As is customary for all evidence reports and systematic reviews done for AHRQ, the RTI–UNC EPC requested review of this report from a wide array of individual outside experts in the field, including our TEP, and from relevant professional societies and public organizations. AHRQ also requested review from its own staff. We sent 15 invitations for peer review: 7 TEP members, 3 relevant organizations, and 5 individual experts. Reviewers included clinicians (e.g., obstetrics and gynecology, reproductive endocrinology, family practice), representatives of federal agencies, advocacy groups, and potential users of the report.

We charged peer reviewers with commenting on the content, structure, and format of the evidence report, providing additional relevant citations, and pointing out issues related to how we had conceptualized and defined the topic and KQs. We also asked them to complete a peer review checklist. We received 9 responses in addition to comments from AHRQ staff. The individuals listed in Appendix E* gave us permission to acknowledge their review of the draft. We compiled all comments and addressed each one individually, revising the text as appropriate.

* Appendixes cited in this report are provided electronically at http://ahrq.gov/clinic/tp/uteruptp.htm

Chapter 3. Results

This chapter presents the results of our evidence review for the first four key questions (KQs): KQ 1, incidence and prevalence of uterine fibroids; KQ 2, outcomes of interventions intended to relieve symptoms of uterine fibroids; KQ 3, outcomes of interventions for uterine fibroids for reasons other than symptom relief (enhancing fertility, reducing further growth, or other reasons); and KQ 4, costs. As explained in Chapter 2, this review is an update of an earlier systematic review with a publications cutoff date of 2000. For our searches, therefore, we did not include any citations published before February 2000.

KQ 5, on modifiers of outcomes, KQ 6, on comparisons of interventions, and KQ 7, on the geographic variation in treatment in the United States, are derivative of these first four questions. We did not do systematic literature searches for them but instead relied on the systematic searches for the primary questions. For that reason, we discuss KQs 5, 6, and 7 in Chapter 4 of this report.

Appendix C* provides the detailed evidence tables for KQs 1, 2, 3, and 4. Our summary tables below feature groups of studies addressing each treatment; they are organized alphabetically by author, unless otherwise stated.

KQ 1: Incidence and Prevalence of Uterine Fibroids

KQ 1 refers to the incidence and prevalence of uterine fibroids, as estimated in representative U.S. populations through use of diagnostic imaging or histology to document uniformly the presence or absence of fibroids. The prior systematic review estimated that the cumulative risk of diagnosis for fibroids between the ages of 25 and 44 was approximately 30 percent.[30]

The evidence concerning prevalence of uterine fibroids in women since 2001 is limited to two articles that meet our inclusion criteria, both of fair quality (Table 4 and Evidence Table 1).[2,41] One study used a combination of medical records and self-report for the 16 percent of its sample that was postmenopausal and ultrasound for the 84 percent of the sample that was premenopausal.[2] The other study relied on self-reports of ultrasound- or hysterectomy-confirmed diagnosis of fibroids of premenopausal women without a prior diagnosis of uterine fibroids among U.S. black women.[41]

A prospective cohort study conducted in the Washington, DC, metropolitan area randomly selected 1,364 subjects between the ages of 35 to 49 years from a prepaid health plan for ultrasound examination to detect uterine fibroids.[2] Of this sample, 38 percent of the women were white and 62 percent were black. The two groups were similar in age but, compared with the white women, the black women were less educated, had more children, and had a higher body mass index (BMI). Black women were more likely to have been previously diagnosed with uterine fibroids (45 percent) than white women (21 percent) and, in those not previously diagnosed, to show ultrasound evidence of uterine fibroids (59 percent vs. 43 percent, respectively). Overall, black women were significantly more likely to have uterine fibroids with an odds ratio (OR) of 2.9 (95% confidence interval [CI], 2.5-3.4; $P < 0.001$). The authors reported that the importance of race changed little after adjusting for BMI and parity (OR, 2.7;

* Appendixes cited in this report are provided electronically at http://ahrq.gov/clinic/tp/uteruptp.htm

95% CI, 2.3-3.2; $P < 0.001$). In both groups, prevalence increased with age. Estimated cumulative incidence of fibroids by age 50 was more than 80 percent for black women and nearly 70 percent for white women.

Table 4. Prevalence and incidence of uterine fibroids

Author, Year	N	Population	Prevalence	Incidence
Baird et al., 2003[2]	1,364	Washington, DC, randomly selected participants from a prepaid urban health plan with 50% black membership and broad socioeconomic base	Previously diagnosed cases in sample among premenopausal women (based on self-report): 35% overall Black 45% White 21% Clinically relevant fibroid tumors among premenopausal women ages 35 to 39: Black 30% to 40% White 10% to 15% Clinically relevant fibroid tumors among women in late 40s: Black 50% White 35%	New diagnosis in sample among premenopausal women without previous self-report of fibroids (based on ultrasound exam): 51% overall Black 59% White 43% Estimated cumulative incidence of tumors by age 50 (based on ultrasound records, surgical pathology records, and self-report): Black > 80% White nearly 70%
Wise et al., 2004[41]	76,711	Black nationwide U.S. sample	Not applicable; sample limited to women without previously diagnosed uterine fibroids	Incidence: 2.97 for every 100 person-years

A second study examined the incidence of uterine fibroids and factors that affect them in black women.[41] The study is a prospective, ongoing cohort study of U.S. black women with data reported from 1997 to 2001. The sample for this study was limited to premenopausal women with intact uteri and no reported diagnosis of fibroids before 1997. The study found uterine fibroids in 2,279 women in 76,711 documented person-years (2.97 percent). Factors that affected the prevalence of uterine fibroids included age at first birth, years since last birth, and younger age at menarche. Women who were parous had an incidence risk ratio of 0.7 (95% CI, 0.6-0.8) relative to nulliparous women. Women who had a child less than 5 years of age were less likely to have uterine fibroids than those who had had a child 5 to 9 years previously (multivariate incidence rate ratio [IRR], 2.0; 95% CI, 1.6-2.5). Finally, women who were older at menarche were less likely to have uterine fibroids than women who experienced onset of menses at 12 to 13 years (IRR, 0.8; 95% CI, 0.7-0.9). The current use of progestin-only injectables as birth control was associated with a 40 percent reduction in risk (95% CI, 0.4-0.9).

KQ 1 also asks about the incidence, type, and severity of symptoms. We found no direct evidence based on prospective observational studies of representative U.S. populations.

KQ 2: Outcomes of Interventions for Relief of Symptoms Related to Uterine Fibroids

We document here our findings about outcomes of interventions for women with symptomatic fibroids. Symptoms can include anemia, problematic bleeding patterns, bulk symptoms (low back pain, urinary frequency, and constipation), pain, and dyspareunia (pain

during or after sexual intercourse). We initially considered the following treatment approaches or combinations of treatment approaches:

1. Expectant management without intervention;

2. Medical management (including oral contraceptives, menopausal hormone therapy, GnRH [gonadotropin-releasing hormone] agonist therapy, antiprogestins, progesterone-containing intrauterine devices [IUDs], and nonsteroidal anti-inflammatory drugs [NSAIDs]), referred to henceforth as pharmaceutical management;

3. Uterine artery embolization (UAE);

4. Endometrial ablation with or without myomectomy;

5. In situ destructive techniques, specifically by focused ultrasound guided by magnetic resonance imaging (MRI) and cryotherapy;

6. Myomectomy by abdominal, laparoscopic, or hysteroscopic techniques;

7. Hysterectomy by abdominal, laparoscopic, or vaginal techniques; and

8. Complementary and alternative therapies including acupuncture.

KQ 2 distinguishes between short- and long-term outcomes. Most studies in this literature, however, limit themselves to the postoperative period. We do not report short- and long-term outcomes separately for each intervention, but we do call attention to longer-term outcomes whenever reported.

Expectant Management: Overview and Nomenclature

We did not identify any studies that specifically focused on documenting the natural history of uterine fibroids, course of fibroid symptoms, or clinical care received for fibroids over time in a cohort of women with known baseline fibroid status. No studies focused on either outcomes, such as anemia, bleeding patterns, pain, and health-related quality of life, or modifiers of outcomes of expectant management *per se* as the primary topic of their research. However, RCTs that include a no-treatment comparison group may provide a glimpse of anticipated outcomes in the absence of intervention. With caveats about the limitations of such data, we summarize in this section information about the outcomes of women in trial groups that received no treatment, placebo treatment, or minimal intervention such as multivitamin use (Appendix C[*], Evidence Table 2).

Thirteen studies included groups that received no treatment or only minimal intervention.[42-57] Five studies did not include symptoms or fibroid size; instead, they used the comparison group to assess characteristics of specimens of surgical tissue as they related to the anticipated effects of the treatment drug on the fibroids[42,43,45] or to examine other aspects of treatment response such as

[*] Appendixes cited in this report are provided electronically at http://ahrq.gov/clinic/tp/uteruptp.htm

changes in bone marrow density[49] or hemoglobin[47] in response to medical treatment. Information on these trials can be found in Appendix C*, Evidence Table 2.

Eight studies with nine publications provided information about uterine size, fibroid size, or participants' symptoms for the no-treatment comparison groups at baseline and at the end of followup.[44,46,48,50,51,55,56,58] All but one[48] were conducted in Italy by two inter-related groups of investigators whose work on medical management and preoperative management of fibroids was featured in detail in the section on outcomes of pharmaceutical management. In the seven Italian study groups, women were followed for a range of 2 months to 12 months without treatment, with the median duration being 6 months across the studies. The majority of studies used no treatment or placebo; some used a calcium, iron, or multivitamin tablet as the placebo. We do not discuss hemoglobin changes for the studies in which women received iron or multivitamins.

Expectant Management: Results

Shorter treatment spans, of 2 and 3 months, were associated with preoperative studies done most often in premenopausal participants. For those reasons they may be the least informative—all women had symptoms enough to warrant surgery and the followup is extremely brief. In no case was a significant change in uterine size documented. Most studies documented almost identical fibroid volume;[46,55,59] one study, which did not note masking of the individuals conducting the ultrasounds, reported an increase in fibroid volume of 11 percent over 3 months. The longest followup for symptoms was in a group of women using a multivitamin placebo for 6 months. Compared to baseline values, their severity of bleeding, length of bleeding with menses, and hemoglobin levels were unchanged; 72 percent had no change in fibroid size; 24 percent had increases in fibroid size; and 3 percent had a decrease;[51] the increase was not statistically significant.[44] One other study reported a nonsignificant increase in menorrhagia, pelvic pain, and pressure among women receiving iron tablets only for 2 months.[59]

Longer studies were generally done among postmenopausal women to determine whether a specific medication influenced fibroid size or symptoms. Overall, these untreated comparison groups were the most likely to have less severe presentations and perhaps be more representative. However, they can shed light only on postmenopausal management. In these groups, observed for 12 months, the investigators saw no trend for fibroid growth; they did not, however, document any significant decrease in fibroid or uterine size. Fibroids were consistently reported to be unchanged;[50,56,58] one study noted that 2 of 35 women had a "mild reduction in uterine and fibroid size,"[56(p40)] suggesting that fibroid involution (regression in size) may not be marked during menopause.

The last study group was a medical record control group matched to participants in a study of complementary and alternative medicine treatments. The study was conducted in a U.S. academic center. Symptoms at clinical encounters and available radiologic studies were provided for 6 months of followup. Within a group of 37 women (who may have received other clinical care), none had documented worsening of symptoms, three had reduced size or reduced growth of fibroids documented, 20 had no change in fibroid size, and four had documented growth of more than 1 centimeter (cm) per month in diameter of a fibroid.[48]

The size of the comparison groups from these trials is small, from 22 to 60 women, and the time frames are very brief. They offer an initial impression that fibroids may not have a continuous, slow-growth pattern before menopause and that, after menopause, decreases in size may not be as profound as clinical wisdom suggests. However, the total picture provided is

insufficient to project what the course of watchful waiting might be for an individual woman with fibroids. Because these studies were not designed for this purpose, the overall quality of the research is too poor to inform the choice of expectant management over other intervention options.

Pharmaceutical Management: Overview and Nomenclature

The etiology of uterine fibroids is not well understood. Pharmaceutical management of fibroids is most commonly done as an adjunctive treatment before surgery. Few medications serve as permanent alternatives to surgery. KQ 2b asks about outcomes from GnRH agonist therapy, menopausal hormone therapy, antiprogestins, oral contraceptives, progesterone-containing IUDs, and NSAIDs among possible medical treatments for uterine fibroids. We did not find any new studies since February 2000 on oral contraceptives, progesterone-containing IUDs, or NSAIDS. The majority of our included studies examined the effect of GnRH agonists on uterine fibroids (Appendix C*, Evidence Table 3). Some studies also reported on progestin, estrogen receptor antagonists and modulators, and antiprogestin. We also report on studies that examined the effects of tibolone as adjuvant therapy to GnRH on uterine fibroid growth. For convenience and consistency, we briefly list and define medications evaluated in the studies reviewed below.

GnRH Agonists and Other Adjuvant Therapies. GnRH agonists are often used as preoperative adjunctive therapy to surgery. They cause down-regulation of estrogen receptors, which decreases fibroid growth. GnRH agonist therapy also helps to optimize hematocrit levels that may have declined secondary to menorrhagia from fibroids. Low hematocrit levels can pose a risk for surgical complications. Studies in this review examined leuprolide acetate, triptorelin, and goserelin. One study also reviewed the effect of ipriflavone as adjuvant therapy to prevent osteoporotic side effects of GnRH agonists.[60]

Leuprolide or Leuprolide Acetate. Leuprolide is a potent inhibitor of gonadotropin secretion. Trade names for use with uterine fibroids include Eligard®, Lupron Depot-Ped®, Lupron Depot®, Lupron®, and Viadur®. Leuprolide is often used as an alternative to surgery for fibroids or for preoperative adjunctive therapy. Its potent effect on reducing estrogen activity in the uterus can decrease fibroid size and symptoms including menorrhagia. The majority of studies (13, in 15 articles) evaluated a GnRH agonist treatment of uterine fibroids; of these, 10 evaluated leuprolide as the primary intervention.[42-45,49,51-55,59-62]

Triptorelin. Triptorelin (trade names Decapeptyl® and Gonapeptyl®) is generally used in the United States to treat men for advanced prostate carcinoma. Its activity on fibroids and use for fibroid management is similar to that for leuprolide. Two studies from Italy examined the effect of triptorelin on fibroids.[63,64]

Goserelin. Goserelin (Zoladex®) is also a potent inhibitor of gonadotropin secretion. In one study, goserelin was used in one treatment arm of a five-arm study to evaluate fulvestrant (a drug that blocks estrogen in the treatment of breast cancer [see below]).[46]

Ipriflavone. Ipriflavone is a synthetic isoflavone in the herb category of natural products with a structure similar to that for estrogen. It has gained acceptance as an alternative medication for treatment of osteoporosis. One study uses ipriflavone as adjuvant therapy to prevent osteoporotic side effects of GnRH agonists.[60]

* Appendixes cited in this report are provided electronically at http://ahrq.gov/clinic/tp/uteruptp.htm

Tibolone. Tibolone is an estrogen and progestin combination therapy used for several purposes: to prevent postmenopausal osteoporosis, to treat symptoms such as hot flashes and associated sweating resulting from menopause (surgical or natural), and to improve bone mineral density (BMD) in patients with established postmenopausal osteoporosis. It is used in these studies as adjunctive therapy to GnRH agonists to prevent negative side effects of GnRH agonists or to study whether the addition of tibolone as add-back therapy alters the effect of GnRH on fibroids. Currently this drug is not available in the United States. International brand names include Climatix®, Livial®, Tibial®, and Tibofem®.

Progestin. *Lynestrenol,* a progestin, known by international brand names including Endometril®, Exluton®, Linestrenol®, and Orgametril®, is used to treat endometriosis, prevent pregnancy, and treat symptomatic fibroids in countries other than the United States, where it is not currently available. One study compared lynestrenol to leuprolide in an assessment of preoperative treatment of fibroids.[62]

Antiprogestin. *Mifepristone (Mifeprex®;* also known as RU-486) is a synthetic steroid that competitively binds to the intracellular progesterone receptor, thereby blocking the effects of progesterone and causing significant shrinkage in fibroids. One study (two articles) evaluated mifepristone as an alternative medical treatment for fibroids.[65,66]

Estrogen Receptor Antagonists and Modulators. *Raloxifene hydrochloride (Evista®)* is a selective estrogen receptor modulator (SERM) that has been reported to cause a significant reduction in fibroid size. One study (three articles) evaluated raloxifene.[50,56,67]

Fulvestrant (Faslodex®) is an estrogen receptor antagonist used to prevent fibroid growth; it is also used for treatment of postmenopausal breast cancer. One study evaluated fulvestrant.[46]

Pharmaceutical Management: Results

The prior review on uterine fibroids attempted to identify the most appropriate candidates for GnRH agonists, to document the incidence of need for additional treatment following GnRH agonist therapy, and to estimate risks and benefits of pharmaceutical management.[30] The review found some evidence that GnRH agonist therapy may be more effective in perimenopausal women than in premenopausal women, but it cautioned that additional studies were necessary. The review did not find sufficient evidence to draw conclusions on the proportion of women likely to experience recurrence of symptoms, the level of severity of symptoms, and the probability of success of alternative treatments after GnRH agonist therapy. The review found "good evidence based on randomized trials that use of GnRH agonists prior to myomectomy or hysterectomy reduces estimated blood loss and may facilitate certain surgical approaches (use of laparoscopic or vaginal approaches and use of transverse abdominal incisions as opposed to vertical incisions)."[30(p8)] The review noted, however, that there are no long-term data on the clinical significance of these effects and that some studies suggest that fibroids are more difficult to separate from the uterus after GnRH agonist treatment because "pretreatment with GnRH agonists obliterates the cleavage plane between myometrium and fibroid."[30(p92)] The review found that hormone therapy and progestins were ineffective in alleviating fibroid symptoms or fibroid growth, but progestins, when used concurrently with GnRH agonists, were effective in eliminating hot flashes associated with GnRH agonist therapy.

Studies, Designs, and Populations. We identified 19 studies reported in 24 publications[42-46,49-56,59-69] on outcomes of fibroids after medical interventions. The studies were predominantly of fair quality, unless otherwise stated. Some study populations are represented

more than once in the total number of publications because the authors focused on individual outcomes in separate publications. A study on mifepristone[65] reported on a 12-month extension of the study in a subsequent publication.[66] Another set of authors reported the outcomes of their study in two publications.[55,59] In addition to their first publication on one study group,[52] Palomba and colleagues focused on individual outcomes in three additional publications.[51,53,54] In summary, the 24 publications reviewed in this section represent 19 studies of 19 distinct populations.

Thirteen studies were conducted as randomized controlled trials (RCTs).[46,49-56,59-67] The majority (eight trials) had two arms, but four studies randomized participants into three arms;[49,55,59,61,67] in addition, one study randomized subjects into five evaluable groups.[46]

We identified five prospective cohort studies with comparisons[42-45,61] and two retrospective cohort studies.[68,69]

The majority of the studies were undertaken in Italy at academic medical centers.[42-45,49-56,59,61,63,64,67-69] One study was done in the United States,[65,66] one in Japan,[60] and one in France.[62] One was a multinational study.[46]

Fifteen studies evaluated a patient population in their premenopausal years.[42-46,51-55,59-62,64-69] Two studies specifically evaluated women in the perimenopausal years,[49] and two evaluated women who were postmenopausal.[50,56] One study did not specifically state which group of women it was targeting.[63]

Most studies included information on changes in fibroids or uterus size. The six studies that also examined the effects of medical treatment on hemoglobin are discussed separately below.[42,55,59,61-64] Five studies reported on changes in symptoms.[56,58,61,63,65] Measurement of symptoms varied from study to study; inconsistencies across the literature make comparisons of symptom relief challenging. Intraoperative outcomes generally included length of time of surgery or intraoperative blood loss.[63,64] Two studies evaluated the effects that medical management of fibroids has on metabolic measurement such as lipid profiles.[51-54,60]

Outcomes of GnRH Agonists. Thirteen studies in 17 articles reported on outcomes after administration of GnRH agonists.[42-45,49,51-55,59-64,69] Seven studies were RCTS;[49,51-55,59,60,62-64] five were prospective cohorts with comparisons;[42-45,61] and one was a retrospective cohort with a comparison group.[69] Four studies were of poor quality and the remainder were of fair quality.[60-63]

Outcomes. Six studies compared leuprolide alone to leuprolide with additional treatment to evaluate differences in effects of leuprolide on outcomes such as BMD, metabolic changes, symptoms, and overall tolerance.[49,51-55,59-62] One study compared leuprolide alone to leuprolide plus raloxifene and evaluated BMD, uterine size, and metabolic differences.[52]

Two studies evaluated the effects of pharmaceutical management on BMD. A side effect of hypoestrogenism, from GnRH agonist administration, is bone loss, which may or may not be recoverable; generally, the recommended length of treatment with GnRH agonists is limited to 6 months to avoid bone loss. Two studies evaluated the protective impact that therapy additional to GnRH may have on bone loss. One study of GnRH and raloxifene[51-54] studied the effect that adding raloxifene may have on BMD.[51] The authors reported that BMD was significantly higher in the group that received raloxifene. The second study addressing this question reported on a three-arm RCT comparing (1) leuprolide plus tibolone for medical management of fibroids as an alternative to surgery, (2) hysterectomy and bilateral oophorectomy for surgical management of symptomatic fibroids, and (3) natural menopause.[49] The authors reported that the two groups that underwent treatment of fibroids had comparable bone loss; both treated groups had greater bone loss than the natural menopause group. The rate of bone loss in the two groups treated for

fibroids was 5.7 percent and 6.4 percent; comparisons between baseline and followup were statistically significant for both treated groups. The study provides little information on the effectiveness of the addition of tibolone to GnRH agonist treatment.

Two studies (five articles) that compared leuprolide plus supplemental therapy to leuprolide alone reported metabolic parameters as their outcomes.[51-54,60] One study evaluated leuprolide at a dose of 1.88 mg per month with supplemental ipriflavone for 6 months to the same dose of leuprolide for 6 months.[60] The group treated with leuprolide plus ipriflavone had an 8.4 percent increase in low-density lipoprotein (LDL) levels when compared with baseline levels ($P < 0.01$). The group treated with leuprolide alone had a 22.4 percent increase in LDL levels ($P < 0.01$) when compared to baseline. After the full 6 months of treatment the increase in LDL was significantly less ($P < 0.01$) in the group that received supplemental treatment with ipriflavone.

The second study compared the effect of leuprolide (3.75 mg per month) administered with supplemental raloxifene with leuprolide plus placebo on serum levels of lipoproteins.[51-54] After six cycles of treatment, total cholesterol, high-density lipoprotein (HDL), LDL, and total triglyceride levels were significantly increased ($P < 0.05$) in the placebo group when compared with baseline levels. The group that received raloxifene was reported to have minimal increase in LDL levels; this increase in LDL levels was significantly lower than in the leuprolide plus placebo group ($P < 0.05$). Similarly, levels of total cholesterol were also higher in both groups compared with baseline levels, but the increase in total cholesterol in the group that received supplemental raloxifene was significantly less than in the leuprolide plus placebo group.

One study measured a surrogate marker for estrogen activity in the uterus as a "quick score." The authors found that the group treated with leuprolide had decreased estrogen receptors after 3 months of treatment compared with no treatment.[43]

Three studies compared triptorelin with no treatment.[63,64,68] Two studies reported improvements in fibroid size, hemoglobin changes, and intraoperative outcomes for the triptorelin group;[63,64] the third study found significantly shorter operative times for the triptorelin group but no difference in hemorrhage, uterine perforation, length of stay, recurrence of fibroids, or abnormal uterine bleeding.[68]

Pharmaceutical treatment is generally intended to reduce fibroid size and stabilize hemoglobin levels before surgery. The following discussion presents the effects of pharmaceutical treatment on fibroid size and hemoglobin first, followed by studies on symptom control and other outcomes.

Fibroid and Uterine Size Outcomes. GnRH agonists were effective in decreasing overall uterine size when used as preoperative treatment or as an alternative to surgery in all eight studies that reported on uterine and fibroid size changes in response to GnRH agonists (see Table 5).[42-45,55,61,63,64] Three studies reported GnRH agonist effects on fibroid size alone.[60,62,69] Study groups receiving GnRH agonists alone had an average decrease in uterine size of 209.8 cm^3 from an average starting size of 637 cm^3. Mean decrease in fibroid size was 66 cm^3 decreased from a mean starting size of 247 cm^3. The addition of add-back therapy to GnRH agonists did not affect the extent of uterine or fibroid size decrease. In these groups, the mean decrease in uterine size was 111.6 cm^3 and the mean decrease in fibroid size was 49 cm^3.

Three studies reported fibroid or uterine size changes over time in women who received no treatment[44,63] or placebo treatment with iron only.[59] All three studies reported an increase in uterine size ranging from 2 cm^3 to 60.7 cm^3 with an average increase of 23.6 cm^3. The increase in size of individual fibroids was reported in only one study and that increase was very small at 1 cm^3.[59]

Trials with comparative groups produced good evidence that administration of GnRH agonists with or without add-back therapy significantly decreases the overall size of the uterus and fibroids by as little as 22 percent to as much as 53 percent. The greatest decrease in uterine size was reported by Di Lieto and colleagues,[61] who treated their study group with 4 months of leuprolide 3.75 mg subcutaneously. They reported an average baseline uterine size of 977.1 cm^3 and an average decrease in size of 42 percent.

Table 5. Gonadrotropin-releasing hormone (GnRH) agonist therapy and change in uterine and fibroid size

Author, Year	Drug (dose)	N	Treatment (months)	Uterine Size Baseline; Followup (cm^3)	Change (cm^3)	Fibroid Size Baseline; Followup (cm^3)	Change (cm^3)
Study Groups with GnRH Agonist Administration Only ± Iron or Multivitamin							
Di Lieto, De Falco, Mansueto, et al., 2005[61]	Leuprorelin acetate 3.75 mg subcutaneously every month	23	4	977.1 ± 104.7 569.6 ± 84.8	↓407.5 *P* NR	NR	NR
Di Lieto, De Falco, Pollio, et al., 2005[42]	Leuprorelin acetate 3.75 mg subcutaneously every month	31	3	725.6 ± 193.5 492.7 ± 134.2	↓232.9 *P* NR	NR	NR
Di Lieto, De Falco, Staibano, et al., 2003[43]	Leuprorelin acetate 3.75 mg subcutaneously every month for 3 months	25	3	774.5 ± 203.1 484.9 ± 144.5	↓289.6 *P* < 0.05	NR	NR
Di Lieto, De Rosa, De Falco, et al., 2002[44]	Leuprorelin acetate 3.75 mg subcutaneously every month	39	3	571.3 ± 266.7 413.4 ± 217.0	↓157.9 *P* NR	NR	NR
Di Lieto, Iannotti, De Falco, et al., 2003[45]	Leuprorelin acetate 3.75 mg subcutaneously every month	48	3	675.8 ± 176.0 466.6 ± 113.3	↓209.2 *P* NR	NR	NR
Palomba, Pellicano, Affinitio, et al., 2001[55]	Leuprorelin acetate 3.75 mg IM every month	22	2	504 ± 92 337 ± 50	↓167 *P* < 0.05	167 ± 41 113 ± 23	↓54 *P* < 0.05
Seracchioli, et al., 2003[63]	Triptorelin 11.25 mg IM, once, 3 months before surgery	31	One injection 3 months before surgery	528 ± 275 388 ± 193	↓140 *P* < 0.005	NR	NR
Litta et al., 2005[69]	GnRH analog, details NR	30	3	NR	NR	494.4 ± 488.7 369.2 ± 358.9	↓ 125 ± 160 *P* < 0.001
Somekawa, et al., 2001[60]	Leuprorelin acetate 1.88 mg IM every month	51	6	NR	NR	NR	↓ 48.9% *P* NR
Vercellini, et al., 2003[64]	Triptorelin 3.75 mg IM once, 3 months before surgery	50	2	343 ± 130 269 ± 119	↓74 *P* NR	NR	NR
Verspyck, et al., 2000[62]	Leuprorelin acetate 3.75 mg subcutaneously every month	33	4	NR	NR	78.7 ± 5.0 NR	↓20.1 *P* NR
			Total (mean of groups)	637.4 427.6	↓209.8	246.7 241.1	↓66.4

cm, centimeters; GnRH, gonadotropin-releasing hormone; IM, intramuscular; mg, milligram; NR, not reported; po, per oral (by mouth).

Table 5. GNRH agonist therapy and change in uterine and fibroid size (continued)

Author, Year	Drug (dose)	N	Treatment (months)	Uterine Size Baseline; Followup (cm^3)	Change (cm^3)	Fibroid Size Baseline; Followup (cm^3)	Change (cm^3)
Study Groups with GnRH and Add-back Therapy							
DiLieto, deFlaco, Mansueto et al., 2005[61]	Leuprolide 3.75 mg subcutaneously every month with tibolone 2.5 mg po every day	22	4	992.7 ± 115.9 584.0 ± 87.3	↓408.7 *P* NR	NR	NR
Palomba, Morelli, Di Carlo, et al., 2002[49]	Leuprolide 3.75 mg IM every month with tibolone 2.5 mg po every day	60	12	831 ± 192.6 390 ± 147.8	↓441 *P* < 0.05	261.9 ± 73.8 137.4 ± 59.7	↓124 *P* < 0.05
Palombo, Orio, Russo, Falbo, Cascella, et al., 2004[53]	Leuprolide 3.75 mg every month with raloxifene 60 mg po every day	50	18	473 ± 112 NR	↓75% *P* < 0.05	197 ± 61 NR	↓80% *P* < 0.05
Palomba, Pellicano, Affinitio, et al., 2001[55]	Leuprolide 3.75 mg subcutaneously every month with tibolone 2.5 mg po every day	22	2	528 ± 83 373 ± 51	↓155 *P* < 0.05	179 ± 48 130 ± 23	↓49 *P* < 0.05
Somekawa, et al., 2001[60]	Leuprorelin acetate 1.88 mg IM every month with ipriflavone 600 mg po every day	51	6	NR	NR	NR	↓52.9% *P* NS
			Total (mean of groups)	706 449	↓111.6	212.6 133.7	↓49
Study Groups That Were Untreated Comparison or Placebo Groups ± Iron or Multivitamin							
Di Lieto, De Rosa, et al., 2002[44]	None	31	3	540.4 ± 250.8 601.1 ± 241.3	↑60.7 *P* NR	NR	NR
Palomba, Morelli, Noia, et al., 2002[59]	Iron tablets 2 per day	22	3	496 ± 99 498 ± 97	↑2 *P* NR	163 ± 38 164 ± 39	↑1 *P* NR
Seracchioli et al., 2003[63]	None	31	3	579 ± 337 587 ± 341	↑8 *P* NR	NR	NR
			Total (mean of groups)	538.5 562.0	↑23.6	163 ± 38 164 ± 39	↑1

Hemoglobin Outcomes. Six studies (three of fair quality,[42,55,59,64] and three of poor quality[61-63]) in seven articles reported hemoglobin changes after GnRH agonist therapy, to assess if its use

would improve anemia in women with fibroids (Table 6). The outcome reported in five studies was hemoglobin (grams/deciliter [g/dL]) measured before surgery (preoperatively).[42,55,59,61-63] All five studies reported an increase in hemoglobin when measured preoperatively, after the completion of GnRH agonist treatment ranging from 2 to 4 months. The reported increase in hemoglobin ranged from 0.9 g/dL to 5.2 g/dL. None of these five studies was designed to determine if GnRH agonist administration can improve anemia in women with symptomatic fibroids before surgery, so they provide only weak evidence to answer that question. Additionally, the results were statistically significant in only two of these studies.[55,59,63] One study reported hemoglobin measurement only after surgery, and hence the result was a decrease in hemoglobin.[64]

Symptom Outcomes. Three studies on GnRH agonist therapy examined symptom outcomes.[51-54,56,61] One study comparing leuprolide, leuprolide plus tibolone, and placebo reported significant differences in menorrhagia and pelvic pain at baseline, but no differences after treatment between the leuprolide-only group and the leuprolide plus tibolone group.[61] The authors also reported a significant difference in the leuprolide and leuprolide plus tibolone groups, with the former group reporting increases in hot flash episodes, and the latter group reporting constant numbers of hot flashes. Another study of raloxifene versus placebo did not demonstrate any differences in amenorrhea or abnormal uterine bleeding at 3, 6, 9, or 12 months of treatment.[56] A third study, comparing leuprolide plus raloxifene versus leuprolide plus placebo found no differences in menorrhagia, pelvic pain, pelvic pressure, urinary frequency, or constipation after treatment.[51-54]

One study provides evidence from a single small nonrandomized study of relief from hot flashes from tibolone.[61] The two studies together provide no evidence of effectiveness of raloxifene.[51-54,56]

Outcomes of Progestins. A single RCT of poor quality compared outcomes from 33 women receiving lynestrenol with 23 women receiving leuprolide acetate.[62] Patients receiving leuprolide reported a significantly greater reduction in fibroid size than the group receiving lynestrenol, but the study found no differences in hemoglobin after 16 weeks of therapy and before surgery.

Outcomes of Antiprogestins. One fair-quality study compared the outcomes of 5 mg per day to 10 mg per day of mifepristone.[65] The authors reported significant reductions in uterine volume compared with baseline values at 2, 4, and 6 months. They also reported significant reductions in menstrual blood loss from baseline values in both groups, but the differences between groups were not significant other than at a single time, 1 month after therapy. The authors noted that although all women reported menstrual activity on registration in the study, 61 percent and 65 percent, respectively, had amenorrhea by the end of the trial. A followup to the original study evaluated the development of endometrial hyperplasia after 18 months of treatment with mifepristone in 21 of the original 40 women in the study.[66] The authors reported no hyperplasia at both 6 months and 12 months at the 5 mg dose, and a 25 percent rate at 6 months and 7.7 percent rate at 12 months at the 10 mg dose.[66]

Outcomes of Estrogen Receptor Modulators and Antagonists. Three studies (all of fair quality) evaluating the outcomes of the SERM raloxifene in comparison with a placebo were conducted in Italy by Palomba and colleagues.[50,56,67] Two studies evaluated women who had undergone menopause within the previous 2 years.[50,56] Both reported that uterine size and fibroid size significantly decreased after treatment compared with baseline values. These significant

Table 6. Outcomes of treatment: change in hemoglobin

Author, Year	N	Treatment Groups	Length of Treatment and Time of Measurement	Change in Hemoglobin (g/dL)
Di Lieto, De Falco, Mansueto, 2005[61]	G1: 22 G2: 23 G3: 28	G1: Leuprolide + tibolone G2: Leuprolide G3: Control (no treatment)	4 months Preoperative	G1: 3.3+ G2: 0.4- G3: NR *P* > 0.05 for comparisons between groups *P* = NR for comparison to baseline
Di Lieto, De Falco, Pollio, et al., 2005[42]	G1: 31 G2: 55	G1: Leuprolide G2: Control (no treatment)	3 months Preoperative	G1: 5.2+ G2: NR *P* = NR
Palomba, Pellicano, Affinito, et al., 2001[55] Palomba, Morelli, Noia, et al., 2002[59]	G1: 22 G2: 22 G3: 22	G1: Leuprolide + iron 2 tablets daily + tibolone po 2.5 mg/d G2: Leuprolide + iron 2 tablets daily G3: Iron 2 tablets daily	2 months Preoperative (1 week before surgery)	G1: 1.4+ G2: 1.6+ G3: 0.3- *P* < 0.05 for G3 compared with G1 and G2
Seracchioli, et al., 2003[63]	G1: 31 G2: 31	G1: Triptorelin 11.25 mg G2: No therapy	3 months Preoperative	G1: 1.1+ G2: 0.2- *P* < 0.02
Vercellini et al., 2003[64]	G1: 50 G2: 50	G1: Triptorelin 3.75 mg IM every 28 days G2: Immediate myomectomy no treatment	2 months 24 hours after surgery	G1: 1.3- G2: 1.3- *P* = NR
Verspyck, 2000[62]	G1: 33 G2: 23	G1: Leuprolide G2: Lynestrenol 10 mg po per day on days 5-25 of each menstrual cycle	4 months Preoperative	G1: 0.9+ G2: 1.2+ *P* = NR

G1, G2, G3, group number; g/dL, grams per deciliter; IM, intramuscular; mg, milligram; mg/d, milligrams per day; NR, not reported; po, per oral (by mouth).

differences did not extend to amenorrhea and abnormal uterine bleeding in the one study that also reported these outcomes.[56] The study that evaluated premenopausal women reported that uterine and fibroid size increased after 3 months of treatment compared with baseline levels.[67]

A five-arm trial of poor quality compared three different doses of the estrogen receptor antagonist fulvestrant with goserelin and a placebo.[46] Goserelin significantly reduced fibroid growth and endometrial thickness compared with placebo and fulvestrant, but fulvestrant did not significantly alter fibroid volume or endometrial thickness compared with placebo.

Uterine Artery Embolization: Overview and Nomenclature

This section presents the results of our literature searches and findings about outcomes of fibroids treated with uterine artery embolization (UAE), also known as uterine fibroid embolization. UAE blocks the blood vessels supplying the fibroids by injections of small particles into the arteries feeding the uterus. Because the procedure is minimally invasive, it is an option available to women who wish to avoid surgery, are poor surgical candidates, or wish to retain their uterus. The literature discussed in this section includes studies focusing on UAE only, with the exception of UAE compared with laparoscopic occlusion of the uterine arteries. Studies comparing UAE with myomectomy or hysterectomy are discussed in those respective sections below. For convenience and consistency, we have used uniform terminology and abbreviations to describe the different techniques used to treat uterine fibroids.

Laparoscopic Occlusion of the Uterine Arteries involves a laparoscopic procedure in which the clinician places clips over the uterine arteries at the level of the internal iliac artery. The collateral arteries between the uterus and the ovaries are also coagulated with bipolar forceps. *UAE* is a technique in which the clinician introduces tiny particles or microspheres into the arteries feeding the uterus. The procedure is based on the theory that occluding blood flow to the muscular portion of the uterus will produce infarction of the fibroids and control symptoms.

Given the relatively new nature of this procedure, very little information was available at the time of the prior review on uterine fibroids; the authors concluded that they could not make estimations of recurrence, persistence, or need for subsequent therapy.[30]

Studies and Designs. Thirty-one articles report on outcomes of UAE, comparisons of UAE with other procedures, modifiers of UAE outcomes, and related issues (Appendix C*, Evidence Table 4).[70-100] The 31 publications represent 24 studies and 22 distinct study populations.

The UAE literature consists primarily of studies done at academic centers; at least two-thirds of the studies took place in this setting. One study was done in a community setting, and three combined data from both academic and community hospitals. The majority (13) of the studies was done in the United States; the remaining countries accounted for fewer studies: Canada, 3; United Kingdom, Netherlands, and Japan, 2 each; and Norway, 1. Finally, one study compiled data from studies done in both the United States and abroad.

Study Populations and Outcomes Measured. Twelve of the publications listed here represent five studies and three distinct populations. In the summary tables below, we elected to group articles primarily by study groups and secondarily in alphabetical order by author, owing to the multiplicity of papers from single studies, overlapping samples, and distinct differences in quality of studies across these study groups. We report on multiple studies from a common population source in Table 7 and on single studies from varied populations in Table 8.

One set of five publications, all by Pron and colleagues, on the Canadian Ontario Uterine Fibroid Embolization Trial focused on individual outcomes from the same sample in separate publications; we count all five as a single study, of fair quality.[83-87]

* Appendixes cited in this report are provided electronically at http://ahrq.gov/clinic/tp/uteruptp.htm

Table 7. Outcomes of uterine artery embolization: multiple studies from single source or population

Source or Population and Author, Year	Study Focus and Followup	N	Symptom Improvement/ Satisfaction with Procedure	Mean Uterine Volume Reduction	Subsequent Interventions	Mean Recovery Time (days)	Complications
Ontario Uterine Fibroid Embolization Trial							
Pron, Bennett, Common, Sniderman, et al., 2003[83] Pron, Bennett, Common, Wall, et al., 2003[84] Pron, Couchie, Soucie, et al., 2003[85] Pron, Mocarski, Bennett et al., 2003[86] Pron, Mocarski, Cohen, et al., 2003[87]	Short-term outcomes, symptoms, satisfaction; median followup 8 months	555	91% satisfied	27% at 3 months	8 hysterectomies	13.1	Postprocedural complications: 8% (N = 44)
Precursor Studies to the FIBROID Registry Studies							
Spies, Ascher et al., 2001[92] Spies, Roth, et al., 2002,[96] Spies, Bruno, et al., 2005[93]	Complications and outcomes through 5 years	200	93% improved at 3 months 92% improved at 1 year 73% improved at 5 years	27% at 3 months 38% at 12 months	At 3 months: 9 hysterectomies (7 related to fibroids) 1 abdominal myomectomy 2 repeat UAEs 4 hysteroscopic resections 5 D&Cs At 5 years: 19 hysteroscopies or D&C 25 hysterectomies 6 myomectomies 3 repeat UAE	8	Major perioperative complications: 0.5% (N = 1) Minor perioperative complications: 6.5% (N = 13)
Spies, Spector, Roth, et al., 2002[97]	Complications through 1 year	400 *	NR	NR	Unintended procedures: 2.5% (10)	NR	Major perioperative complications: 1.25% (N = 5) Minor perioperative complications: 7.25% (N = 29) Total complications: 10.5% (N = 42)

D&C, dilatation and curettage; N, number; NR, not reported; UAE, uterine artery embolization.
* First 200 reported in the row above.

Table 7. Outcomes of uterine artery embolization: multiple studies from single source or population (continued)

Source or Population and Author, Year	Study Focus and Followup	N	Symptom Improvement / Satisfaction with Procedure	Mean Uterine Volume Reduction	Subsequent Interventions	Mean Recovery Time (days)	Complications
FIBROID Registry Studies							
Spies, Myers, Worthington-Kirsch et al., 2005[95]	Symptoms and quality of life (FIBROID registry); 12 months	2,112	94% improved at 1 year	NR	At least 1 gynecological procedure by 6 months: 3.6% (N = 64) At least one gynecological procedure by 12 months (cumulative): 9.5% (N = 141) 49 hysterectomies 25 myomectomies 17 hysteroscopies 21 repeat UAE 33 D&Cs 4 endometrial ablations	NR	NR
Worthington-Kirsch et al., 2005[100] Myers et al., 2005[82]	Short-term outcomes (FIBROID registry); 30 days	3,041	NR	NR	Additional surgical intervention: 1% (N = 31) 3 hysterectomies 3 myomectomies 9 D&Cs 1 repeat UAE	13.9	Major in-hospital complications: 0.6% (N = 18) Minor in-hospital complications: 2.1% (N = 71) Major postdischarge complications: 4.1% (N = 111) Minor postdischarge complications: 22% (N = 610)

Table 8. Outcomes of uterine artery embolization: single studies

Author, Year	Study Focus and Followup	N	Satisfaction with Procedure	Mean Uterine Volume Reduction	Subsequent Interventions	Mean Recovery Time (days)	Complications
Huang et al., 2006[77]	Factors associated with failure; Mean, 13 months	22 in failure group 211 in non-failure group	NR	28% at 6 months	16 hysterectomies 6 myomectomies	NR	NR
Lohle et al., 2006[79]	Outcomes following UAE; 1 year	158 at baseline, 142 at followup	Satisfaction score at 1 year: Very satisfied: 81 (57%) Satisfied: 51 (36%) Not satisfied: 10 (7%)	47% ± 34% at 12 months *P* < 0.0001	9 repeat UAE 3 hysterectomies	NR	No deaths Permanent amenorrhea: 17 (11%) Transient amenorrhea: 20 (13%) Fibroid expulsion: 16 (10%)
Katsumori et al., 2003[78]	Risks of large fibroids; Mean, 17.5 months	Fibroids ≥ 10 cm: 47 Fibroids < 10 cm: 105	Satisfaction score at 1 year (2 = markedly satisfied 1 = slightly satisfied): Fibroids ≥ 10 cm: 1.79 Fibroids < 10 cm: 1.90 *P* = 0.247	Fibroids ≥ 10 cm: 50% Fibroids < 10 cm: 54% at 12 months *P* = 0.29	3 hysterectomies (1 for fibroid symptoms) 3 transvaginal fibroid resections	Fibroids ≥ 10 cm: 13.6 Fibroids < 10 cm: 11.7 *P* = 0.391	Fibroids ≥ 10 cm: major, 3; minor, 9 Fibroids < 10 cm: major, 2; minor, 16
McLucas et al., 2001[80]	Outcomes; Longest, 12 months	167	87% at 6 months would recommend the procedure to others	52% (mean, 6 months)	6 hysterectomies	NR	NR
Rajan et al., 2004[88]	Risks of uterine infection	410 overall, 5 with infection	NR	NR	1 hysterectomy	NR	Total complication rate: 6.1% Major compliation rate: 2.7% Intrauterine infection rate: 1.2%
Walker and Pelage, 2002[98]	Outcomes; Mean, 16.7 months	400	97% satisfied	55% (mean, 9 months	12 hysterectomies 4 myomectomies 3 repeat UAE 2 hysteroscopies 1 endometrial ablation	13.6	3 infective complications requiring hysterectomy (1%)

NR, not reported; UAE, uterine artery embolization.

Table 8. Outcomes of uterine artery embolization: single studies (continued)

Author, Year	Study Focus and Followup	N	Satisfaction with Procedure	Mean Uterine Volume Reduction	Subsequent Interventions	Mean Recovery Time (days)	Complications
Watson and Walker, 2002[99]	Reduction in size and success of treatment; Median, 12 months	114	89% with large fibroids were satisfied	58% (median, 6 months)	1 hysterectomy 1 myomectomy 2 hysteroscopic resections	NR	Major, none Minor, NR

A second population served as the precursor to the FIBROID registry (specifically, the Uterine Artery Embolization Fibroid Registry for Outcomes Data [FIBROID], a U.S. multicenter prospective voluntary registry of patients undergoing uterine embolization for fibroids [www.fibroidregistry.org]). Spies and colleagues published short-term outcomes,[92] a subanalysis,[96] and long-term outcomes[93] from a case series of 200 women. They subsequently closed enrollment of patients in that protocol, began a new protocol to coincide with participation with the FIBROID registry, and published one study presenting results from both populations.[97] The studies published from this group are of fair to good quality.

The third, and largest, study population is from the FIBROID registry. Two publications reported on different samples based on eligibility for the outcome considered in the publication (N = 3,041[82,100] and N = 2,112[95]), although the articles do not specify whether these two samples overlap completely. We consider the two FIBROID registry papers as two separate studies but, for purposes of tabulating information from the same or similar sources, kept them in Table 7. We rated these studies to be of fair quality.

The other 19 publications that address UAE represent 19 distinct study populations. Of these, the majority (11 studies) are of poor quality.[70-72,77-80,89-91,98,99]

Outcomes and Modifiers. Among the 24 distinct UAE studies, 17 reported on outcomes or modifiers of UAE. Of these, three were retrospective case series, focusing on outcomes associated with failure or success of UAE.[77,78,88] Twelve studies are prospective case series. Of these, nine reported on short- and/or long-term outcomes;[79,80,82-87,92,93,95-100] two reported on imaging modalities associated with UAE;[71,81] and one reported on use of a percutaneous closure device during UAE.[72]

Two cohort studies addressed pain in relation to the UAE procedure. One investigated a prospective sample to compare pain medications,[89] and the other examined data for a retrospective sample comparing the use of embospheres and polyvinyl alcohol particles.[91]

Comparative Studies. Seven studies compared more than one type of procedure. Two were retrospective cohorts, comparing UAE and myomectomy.[70,90] Four prospective cohorts were identified; one compared UAE with myomectomy,[73] two compared UAE with hysterectomy,[75,94] and one compared UAE and laparoscopic occlusion of the uterine arteries.[74] The only RCT compared UAE with hysterectomy.[76]

UAE Outcomes. This literature comprises nine prospective case series studies (in 15 articles, one of good quality,[80,92,93] four of fair quality,[82-87,95,97,100] and four of poor quality[79,80,98,99]) and three retrospective case series (two of poor quality[77,78] and one of fair quality[88]) that described either short- or long-term outcomes (or both) (see Table 7 and Table 8).

Satisfaction. All studies reported high levels of satisfaction on the part of the women assessed, measured at various points in time and along varied scales. They reported a range from 87 percent to 97 percent satisfaction with outcomes.

Symptom Improvement. Studies reported high levels of symptom improvement, however longer-term studies appeared to indicate some decline in improvement in symptoms over time. One study found that, at 3 months, the great majority (93 percent) of women had improved symptoms; by 5 years, the proportion reporting improvement in symptoms had declined to 73 percent (of 143 women still in the sample).[92,93] Studies also reported some variability in which symptoms were improved: one study found that women reported statistically significant improvement in menorrhagia (83 percent), dysmenorrhea (77 percent), bulk symptoms (84 percent), and urinary symptoms (86 percent) at 3 months.[86] Improvement in menorrhagia was not related to preprocedure uterine volume or amount of volume reduction. Overall life impact scores (representing the interference of symptoms with everyday or usual activities) were markedly improved after UAE. Before UAE, 72 percent reported impact scores of 7 to 10 (high interference with daily activities); after UAE, this figure dropped to 11 percent.

Pain. In one study, 70 percent of patients reported no pain and 4 percent reported ineffective pain management during the procedure; with respect to postoperative pain, 92 percent reported at least some pain (tolerable pain through unbearable pain) and 10 percent reported ineffective pain management after the procedure.[83-87]

Uterine Volume Reduction. Studies varied in their period of reporting for uterine volume reduction. Studies reported the following percentages of mean uterine volume reduction: at 3 months, 27 percent;[83-87,92,93,96] at 6 months, 52 percent[80] and 58 percent;[99] and at 12 months, 38 percent[92,93,96] and 47 percent.[79]

Mean Recovery Time. Three studies, set in Canada, the United Kingdom, and the United States, were consistent in reporting a 13- to 14-day period for recovery.[83-87,98,100] One U.S. study reported an 8-day period for recovery.[92,93,96]

Complications. Variations in the methods and timing of reporting make the summary evaluation of complication rates across all studies extremely challenging. The largest of these studies, the FIBROID registry, reported a major in-hospital complication rate (e.g., hospitalization, major therapy, unplanned increase in care, or permanent adverse sequelae) of 0.6 percent of the sample; the postdischarge major complication rate was 4.1 percent.[100] The rates of minor complications (nominal or no therapy, no consequences) was 2.1 percent during the admission and 22 percent within 30 days of discharge.

Rate of Subsequent Interventions. As with complication rates, studies vary in the method and timing of reporting rates of subsequent interventions. The FIBROID registry reported that 141 women (9.5 percent of their sample) had experienced at least one gynecological procedure by 12 months; procedures included 49 hysterectomies, 25 myomectomies, and 21 repeat UAEs. The study with the longest period of measurement reported a 25 percent failure (no improvement in symptoms—menstrual bleeding, pain, pressure—or major intervention) by 60 months.[92,93,96]

Modifiers of UAE Outcomes. *Demographic Variables and Uterine Characteristics.* Nine studies examined modifiers of UAE outcomes,[77-80,83-88,95,96,100] including two from the FIBROID registry trial.[95,100] These studies examined a variety of demographic characteristics including age, race, parity, menopausal status; uterine characteristics, including size and location of the dominant fibroid; health characteristics such as prior surgery and smoking; and UAE characteristics such as UAE particle type and load. Outcomes examined included volume reduction, treatment failure, treatment success, satisfaction, and complications.

Studies that examined age found no association between age and UAE failure[80] or satisfaction with outcomes.[96] One of two studies[96,100] examining race found it to be a significant predictor of outcomes; the study found that African-American women have a higher risk of adverse events following UAE.[100] Parity and menopausal status were not significant predictors of UAE failure.[80]

Regarding uterine characteristics, four studies that examined baseline uterine characteristics found no relationship between size or volume and UAE failure,[77,80] satisfaction with outcomes,[96] or development of intrauterine infection.[88] Two of four studies examining fibroid size found no effect on outcomes (failure[77] or complications[78]). Other studies on volume reduction reported conflicting results: one study reported that larger fibroid size predicted greater decrease in volume,[83-87] whereas two others reported that size of the dominant fibroid at baseline predicted less volume reduction at both 3[95,96] and 12[96] months after therapy. Studies also found that adjusted for fibroid volume, submucosal dominant fibroids predicted greater volume reduction[96] and improvement in symptoms[95] than subserosal fibroids. The location of the fibroid did not predict intrauterine infections.[88]

Regarding health characteristics, one study found that the occurrence of earlier fibroid or pelvic surgery was related to failure[77,80] and the risk of adverse events.[100]

UAE characteristics such as size of particles used, particle load, and post-UAE complication events did not predict treatment failure at 6 months[80] or intrauterine infection[88] in two studies; in a third study, the use of EmboGold® particles versus Embosphere® particles resulted in significantly higher risk of skin rash and slower return to usual activities with EmboGold®, but no difference in volume reduction, fibroid expulsion, or satisfaction.[79]

Modifiers of Pain Associated With UAE. Two studies addressed pain in relation to the UAE procedure.[89,91] A prospective case series evaluated the effectiveness of superior hypogastric nerve block (SHNB) in addition to conventional conscious sedation for pain control in 139 patients.[89] The investigators contacted patients on the third and fifth day after their procedures to elicit pain scores (numeric rating scale from 0 to 10). The first 100 patients had received the standard pre- and postprocedural analgesia. However, after review with the institutional pain management clinic, clinicians had identified a potential for enhanced postprocedural pain and antiemetic treatment, and the last 39 patients received the different regimen, involving SHNB (see Evidence Table 4, Appendix C[*]), which added 8 minutes to 10 minutes to the procedure. All patients could be discharged home by 6 hours after the procedure and had mild pain or no pain at the time of discharge. Readmission rates did not differ significantly between the two regimens (6 percent for conventional vs. 2.6 percent for enhanced intervention). The mean peak pain score did differ significantly between groups; women receiving the enhanced SHNB protocol reported lower pain scores (5.7 ± 2.2 vs. 2.7 ± 2.5; $P < 0.01$).

Based on animal models, Ryu and colleagues had hypothesized that Embosphere® would be associated with less pain after UAE than polyvinyl alcohol particles. They compared 29 patients in an Embosphere group with 26 patients in a polyvinyl alcohol particles group in a retrospective analysis.[91] They reported no difference between the groups either in the dosages administered through a patient-controlled analgesia pump that delivered morphine sulfate or in the mean subjective pain scores.

Use of Imaging Techniques in UAE. Two studies evaluated the role of imaging modalities in UAE, such as magnetic resonance imaging (MRI).[71,81] One study prospectively followed 111 patients to assess them for the presence of persistent contrast enhancement of fibroids on a

[*] Appendixes cited in this report are provided electronically at http://ahrq.gov/clinic/tp/uteruptp.htm

routine 6-month follow-up MRI; the investigators specifically tested whether continued gadolinium enhancement (contrast material–enhanced MRI) of the fibroid after failed primary UAE would predict a subsequently successful repeated UAE.[71] Clinical failure was reported in 11 patients (10 percent). Of these 11 patients, eight (73 percent) showed persistent gadolinium enhancement of their dominant treated fibroids on MRI. All eight women were offered a repeat UAE; six accepted. All six had complete resolution of clinical symptoms at 12 months' followup. Additionally, in all six patients, no contrast material enhancement was identified on follow-up MRI at 6 months. The three patients who did not show persistent enhancement demonstrated complete tumor necrosis and were not offered a repeat procedure. Of note, of the 100 clinically successful cases, four had some persistent enhancement of their dominant fibroid with complete necrosis of the remainder.

The second study sought to determine whether Doppler flow measurements are useful in predicting variables associated with UAE, including shrinkage of the uterus and fibroids, adenomyosis, and procedure failure.[81] The investigators evaluated 188 women with Doppler sonography before and 6 months after the procedure. The specific factor analyzed in this study was peak systolic velocity (PSV), an indicator of blood flow. Pre-embolization PSV values were positively correlated with total uterine volume and the diameter of the largest fibroid; that is, stronger blood flow was positively correlated with larger uterine and fibroid volume. In addition, the authors noted a positive correlation between the particle load required to block the vessel and the pre-embolization PSV values ($P = 0.009$). Higher pre-embolization PSV was associated with greater reduction of the largest uterine fibroid ($P = 0.0174$) and reduction in uterine volume ($P = 0.0440$); however, pre-embolization PSV was a significant predictor of failure ($P = 0.02$). Finally, the authors did not report any association between baseline uterine size or factors related to the procedure and failure of embolization.

Effects of Operator Experience on UAE. One Canadian study examined the effects of the experience of interventional radiologists on procedure and fluoroscopy time through a multicenter prospective design.[83] UAE was successful bilaterally (in both uterine arteries) in 97 percent of patients; 94 percent of the procedures were completed on the first attempt. The overall procedural complication rate was 5.3 percent (30 of 570 procedures). Of these 30 procedures with complications, the most common complications were related to angiography; three women required extra care or an extended hospital stay. The article does not provide information on whether complications were influenced by operator experience. The study also found that procedure time and fluoroscopy time differed significantly for early experience (the first 20 consecutive procedures) versus later experience (the next 20 consecutive procedures) ($P < 0.001$).

Evaluation of Devices Used in UAE. Previous studies have suggested that the use of suture-mediated closure devices (SMCDs) may be associated with a higher rate of complications in patients who are undergoing UAE than in patients who have peripheral vascular disease and/or are undergoing anticoagulation.[101] One study assessed the safety and efficacy of SMCDs in UAE through a prospective case series involving attempts to use SMCDs in 328 of 342 consecutive patients.[72] Device failure occurred in eight patients (2.4 percent; 99% CI, 0.2-4.5 percent). No long-term major complications occurred; however, the rate of minor complications, including thigh pain related to the puncture site and minor hematomas, was 22 percent (72 of 328 women; 99% CI, 16-28 percent).

Comparative Studies. Three studies compared UAE with myomectomy.[70,73,90] Three studies compared UAE with hysterectomy.[75,76,94] The results of these studies are reported in detail in the myomectomy and hysterectomy sections, respectively, later in this chapter.

A single study compared two different methods of UAE: 24 women undergoing UAE and 22 women undergoing laparoscopic occlusion of the uterine arteries; the project was done in a nonrandomized prospective cohort of women with symptomatic fibroids in Norway.[74] The investigators assigned women to laparoscopic occlusion when the size of the uterus did not exceed the umbilical level and to embolization regardless of fibroid size. They reported no differences between the groups in bulk symptoms or initial pictorial blood loss assessment score. Both groups had a statistically significant decrease in the volume of the dominant fibroid and the uterus from baseline following the procedure, but the groups did not differ significantly from each other. Postoperative pain medication consumption was significantly greater in the UAE group. By the final followup at 6 months, 15 UAE and 14 laparoscopy patients reported a satisfactory reduction in their bleeding. Four hysteroscopies, one dilatation and curettage, and two hysterectomies were performed during the follow-up period.

Endometrial Ablation (With or Without Myomectomy)

The prior evidence review did not identify publications about use of endometrial ablation specifically for the management of uterine fibroids.[30] A single study appearing since 2001 reported results on endometrial ablation in comparison with myomectomy.[102] The results are reported in the section on myomectomy (Appendix C*, Evidence Table 5).

In Situ Destructive Techniques (MRI-Guided Focused Ultrasound): Overview and Nomenclature

One part of KQ 2 assesses outcomes of interventions to treat fibroids that use techniques to destroy them in situ. Methods previously explored in the research literature include cryoablation (which is freezing the fibroid tissue) and laser ablation (which burns the tissue to destroy the fibroid) via laparoscopy. Neither of these methods is currently available in clinical practice outside research settings. We did not identify any publications on these methods in the timeframe for this review. MRI-guided focused ultrasound, a new technique, is the only in situ destructive technique currently being used outside academic and specialty clinics. This method did not have eligible publications to include in the prior evidence review on management of fibroids. Our search identified two publications of fair quality from a single cohort.[103,104]

In MRI-guided focused ultrasound, the clinician uses the MRI to guide the ultrasound energy (i.e., sound waves from the ultrasound) directly to the fibroid. The highly focused ultrasound beam (very different from ultrasound used for imaging studies) causes the temperature in the target tissue to rise. The clinician can monitor the thermal destruction of the fibroid during the procedure with the MRI and avoid damage to nearby tissue or structures. We describe both the conduct of the procedure and the findings of these studies in some detail because the technique is so new.

The treatment is conducted in an MRI suite using an imaging system that integrates real-time MRI and thermometry with an ultrasound unit specially designed to focus the ultrasound waves

* Appendixes cited in this report are provided electronically at http://ahrq.gov/clinic/tp/uteruptp.htm

to create heat; a process like this, which is intended to disrupt biologic materials by use of sound wave energy, is also termed sonication. The woman receives light sedation and is positioned face down on a gantry over a contact pad required for the ultrasound. The gantry, which is a treatment table on a track, is moved to help position her correctly within the MRI machine. The MRI is used to image the fibroids, to finalize positioning of the patient, to help avoid exposing other organs such as the bladder and bowel to the ultrasound, and to define tightly the area of each fibroid for treatment. The clinician uses a "test dose" of ultrasound so that the MRI thermal measurements can confirm that the correct area will receive treatment and then begins the focused ultrasound heating of the target fibroid tissue. Thermal destruction is monitored in real time using MRI estimates of the tissue temperatures achieved. Each fibroid is treated separately, and total treatment times are generally longer than an hour for most women, with a 3-hour total treatment time limit.[103-106] The U.S. Food and Drug Administration approved the treatment system in 2004.[107]

We identified two publications that present data from the same study population (Appendix C[*], Evidence Table 6).[103,104] This work was undertaken to assess the safety and efficacy of this technique, within a collaborative network of sites including three U.S. centers, two European centers, and one Israeli center, all at academic institutions.

The research collaborative focused on documenting adverse events and identifying the proportion of women who had meaningful improvement in their symptoms as defined by use of the standardized and validated, disease-specific Uterine Fibroid Symptoms Quality-of-Life (UFS-QOL) scale[32] in addition to the Medical Outcomes Trust Short Form-36 (SF-36).[103,104] The UFS-QOL questionnaire has eight symptom questions and 29 health-related quality-of-life questions (with six subscales), scored on a 100-point scale with higher numbers indicating more severe impairment.

The study population comprised 109 women who were premenopausal and who reported that they had completed childbearing. Eleven percent of the women were African American, African, or Afro-Caribbean. All participants scored above the mean for women with fibroids on the UFS-QOL, reflecting good representation of highly symptomatic women. Each woman was clinically considered a candidate for hysterectomy or myomectomy based on disease severity.

Fifty-five percent had one fibroid treated; the remainder had two or more treated. Overall, 22 percent of fibroids were submucosal, 57 percent intramural, and 21 percent subserosal. The average duration of time within the MRI scanner was 202 minutes (range, 90 to 370 minutes); a portion of this was ascribed to the time required to position the patient correctly. At some point during the procedure, 16 percent of women reported severe pain; 1 percent and 7 percent reported severe or moderate pain, respectively, immediately following the procedure. The majority of women reported mild (33 percent) or moderate (33 percent) pain during the treatment portion of the procedure and no (75 percent) or mild (18 percent) pain immediately afterwards. The single serious complication deemed related to the procedure was a sciatic nerve palsy that fully resolved by 12 months. The injury resulted in a change to pretreatment planning during the balance of the study. One woman had an abdominal skin burn that caused ulceration prior to healing and was traced to incomplete shaving of the abdomen. (Complete shaving in the path of the ultrasound beam is critical because it prevents air pockets that can result in local skin heating.) Six percent of women had febrile morbidity and all six received antibiotics as a precaution. Overall, participants returned to work an average of 1 day after the procedure.

[*] Appendixes cited in this report are provided electronically at http://ahrq.gov/clinic/tp/uteruptp.htm

At 6 months after treatment, 77 participants (70.6 percent) reported a 10-point or greater improvement on the UFS-QOL questionnaire. The mean decrease in the score of the women treated was 23.8 points; symptom relief was similar for "bulk symptoms" related to the size and position of fibroids, and for bleeding symptoms. This similarity in levels of improvement for both pressure and bleeding symptoms is notable in the context of a 13.5 percent decrease in the average total volume of fibroids treated; specifically, it suggests possible placebo effects at work because actual volume reduction was quite modest. By 12 months, 51 percent (42 of 82 women who could be evaluated) had sustained improvement of 10 points or more on the UFS-QOL. Scores on the SF-36, which was also administered, indicated improvements at 1, 3, and 6 months compared with baseline scores.

Failure, defined as worsening of symptoms by 6 months, was 11 percent (12 of 109 women); 10 women were classified as unchanged. By 1 year, 23 of 82 evaluable women (28 percent) had sought additional treatment including myomectomy, hysterectomy, or UAE.

The authors noted that the safety protocol requirements of this initial research were highly conservative and required that only a small proportion of the fibroid volume be treated. Clinical practice now successfully targets substantially larger proportions of the total fibroid volume. Future research may yield greater improvements in outcome, but these data do demonstrate the safety and preliminary efficacy of the procedure for improving symptoms.[103,104] The need for comparative trials and longer-term followup for this and all fibroid treatment modalities is highlighted in the discussion in Chapter 4.

Myomectomy: Overview and Nomenclature

This section presents the results of our literature search and findings about outcomes of surgical removal of fibroids, termed myomectomy. Myomectomy removes the fibroid(s) that can be surgically removed, repairs the defect in the uterine wall, and does not remove the uterus. For this reason, myomectomy is the surgical option available to women who wish to have future pregnancies or who wish to retain their uterus.

As we briefly describe below, the content of the literature spans the range of surgical approaches currently available in routine clinical practice. We found no publication that described outcomes of robotic surgery, which is becoming available at a limited number of highly specialized sites. Detailed information on all studies relating to myomectomy can be found in Evidence Table 7 in Appendix C[*].

For convenience and consistency we have used uniform terminology to describe and discuss the different surgical techniques used to remove or destroy uterine fibroids. The groupings that follow—abdominal, laparoscopic, and hysteroscopic—are approximately in the order of "invasiveness" as reflected by the size of the surgical incision to be healed, the degree of disruption of nearby tissue, and, therefore, the amount of healing required after the procedure.

Abdominal Myomectomy and its Variants. Abdominal myomectomy *per se* is the removal of fibroids through an incision in the skin of the abdomen; this is also called a laparotomy incision. This includes midline incisions made along the line between the umbilicus and the pubic symphysis or "pelvic bone," as well as incisions made lower on the abdomen at a right angle to that line. The surgeon operates with his or her hands and instruments in direct contact with the abdominal and pelvic organs.

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Minilaparotomy is the removal of fibroids through an incision in the skin of the lower abdomen that is smaller than conventional abdominal myomectomy; it is intentionally made to be as small as possible while still allowing the surgery to be performed. Surgeons use several techniques to accomplish this, including raising the uterus through a small incision to operate on the uterus "exteriorized," meaning elevated out of the pelvis through the skin incision, or raising each fibroid individually up to, or out of, the incision. In our classification of surgical methods, we use this term to refer to myomectomies done by minilaparotomy and accomplished with the surgeon's hands and conventional instruments in direct contact with the abdominal and pelvic organs.

Laparoscopically assisted myomectomy is the removal of fibroids assisted by use of a laparoscope and other instruments inserted through small incisions in the abdominal wall; generally, each incision is less than 1.0 to 1.5 centimeters in size. The laparoscope is attached to a video camera and the surgeon(s) conduct a portion of the procedure while watching the surgery progress on a display screen. In the majority of the cases described in this literature as laparoscopically assisted, the laparoscope was used to augment minilaparotomy to ensure that the skin incision size could be kept small and still allow surgeons to view and operate in areas of the uterus that were more difficult or not possible to reach through the minilaparotomy incision alone; this situation might occur, for instance, low on the posterior aspect of the uterus. Some publications also describe laparoscopic removal of the fibroid followed by closing the defect in the uterus after the fibroid is removed by working through a minilaparotomy incision, in which the surgeon raises the uterine defect up to the incision to close the incision in the uterus using traditional open surgical techniques.

Laparoscopic Myomectomy. Laparoscopic myomectomy is the removal of fibroids using a laparoscope and instruments inserted through "ports" in the abdominal and pelvic wall to accomplish the entire surgery. The surgeon's hands are not directly in contact with the fibroid(s) or pelvic organs during the surgery. The fibroid is removed and the uterine defect is repaired entirely through the laparoscope. During laparoscopic myomectomy, fibroids are generally morcellated (i.e., cut into smaller pieces) to remove them from the abdomen through small openings. This can be accomplished with laparoscopic instruments like scissors or various forms of scalpels or with a specialized device called a morcellator. For this review we have included in this category any myomectomy done via colpotomy, which involves a vaginal incision to remove the fibroid(s) intact or in large pieces from the pelvis.

Hysteroscopic Myomectomy. Hysteroscopic myomectomy is the removal of fibroids using a hysteroscope. This instrument is inserted via the vagina through the cervix, which is dilated to allow the hysteroscope to pass into the uterus. Most often, a camera is attached to the hysteroscope and used to view the procedure on a display screen, although the surgeon may also view the procedure directly through the hysteroscope. Instruments are passed through a single tube that houses the lens for the camera, allows fluid to flow into the uterus to distend it, and provides access for operative instruments, one at a time. The instruments are used to cut, burn, or "shave down" fibroids that can be seen and reached through this interior view of the uterus. As needed, pieces of fibroid are flushed out with the fluid or grasped and removed from the uterus using instruments.

Endometrial ablation, which is the permanent surgical scarring or removal of the lining of the uterus (i.e., the endometrium), is reported in this literature as a concurrent hysteroscopic procedure; in one publication, it is considered as a primary treatment for fibroids associated with abnormal bleeding. To accomplish it, the surgeon inserts the hysteroscope as for hysteroscopic

myomectomy and then uses an instrument to resect or cauterize and destroy the endometrium so that it is scarred and unable to support growth of an endometrial lining. When all or a sufficient proportion of the interior of the uterus is ablated, future bleeding decreases or stops altogether. In the literature in this review, all procedures were done with roller-ball or loop ablation techniques. No publications that reported on thermal balloon or wire mesh systems, which are designed to treat the interior surface in a single round of heating, met inclusion criteria.

Myomectomy: Results

The prior evidence review identified 43 studies about myomectomy outcomes, overwhelmingly case series. All studies that included symptom outcomes reported improvements, although measures and follow-up timing were poorly described. Transfusion was the most common short-term complication reported (1.2 percent to 16 percent); uterine perforations and fluid and electrolyte disturbances after hysteroscopy were inconsistently noted.

In summary, our review yielded the following findings. Data were limited on the effect of myomectomy for long-term symptomatic relief. No data supported use of prophylactic myomectomy in women with asymptomatic fibroids. Clear data from multiple studies indicated that myomectomies do have a risk of complications, which appears to increase with increasing number of fibroids removed. Data were insufficient to allow estimation of the cumulative incidence of recurrent symptoms after conservative management of fibroids. Reported recurrence rates ranged up to 50 percent by 5 years after myomectomy, with up to 8 percent of patients undergoing hysterectomy. Data for direct comparison of the risks and benefits of myomectomy and hysterectomy were lacking. The report noted two modifiers of myomectomy outcomes: (1) risk of recurrence of symptoms and fibroids may be lower when only one fibroid is present and removed, and (2) myomectomy may be more effective in perimenopausal women than in premenopausal women. Overall, we judged the quality of the literature about myomectomy to be weak.[30]

Studies, Designs, and Populations. For this update, we identified 39 unique studies (with 44 publications) that reported on outcomes of myomectomy of any type, including comparisons of myomectomy with other treatments or procedures.[70,73,90,102,108-148] Some publications dealt with use of GnRH agonist medications to reduce the size of fibroids prior to surgery, either hysterectomy or myomectomy; we summarized these findings above (in pharmaceutical interventions) and do not review them in detail here.

The overall quality of this literature was poor (21 publications) to fair (22 publications); with a single small RCT receiving a quality rating of good.[146] Statistical weaknesses were most common. Six studies either provided an *a priori* calculation of statistical power and required study size or calculated power achieved. They also included multivariate analysis to adjust for potential confounders or to identify and assess effect modifiers as needed. Nine had either a power calculation or multivariable analysis; the remainder provided neither. Likewise, documentation of inclusion and exclusion criteria was weak, as was documentation of participant characteristics including key information about fibroids such as baseline number and size.

Some study populations are represented more than once in the total number of publications because the authors focused on individual outcomes in separate publications,[108-110] published subanalyses,[128,129] followed up participants at a later time in order to report on later outcomes such as satisfaction with surgery or pregnancies,[125,126] or expanded on a case series by including the original participants in a larger series in a subsequent publication.[119,149]

This literature base included 24 case series studies, which we have operationally defined as descriptive analyses of a sequence of participants having the same type of procedure without a comparison with another type of surgery or treatment. Eighteen of these studies are retrospective case series of a particular type of myomectomy: five report on abdominal myomectomy,[90,123,133,136,144] one on minilaparotomy,[122] six on laparoscopic myomectomy,[116-119,134,147,149] four on hysteroscopic myomectomy,[102,111,124,132] and one on myomectomy at the time of cesarean.[114] Six studies are prospective case series: four of laparoscopic myomectomy[115,125,127,150] and two of hysteroscopic myomectomy (one with multiple reports).[108-110,130]

Eight studies are cohort studies that compare outcomes across two or more types of myomectomy procedures. Of these studies, five involve retrospective cohorts: three of fair quality compared abdominal and laparoscopic myomectomy outcomes;[128,138,139] one of poor quality compared abdominal myomectomy with UAE;[70] and one of fair quality compared myomectomy to expectant management to examine the outcomes of assisted reproductive technology (ART) treatment.[141] We identified three prospective cohort studies: one of fair quality compared abdominal and laparoscopic myomectomy;[121] one of fair quality compared abdominal myomectomy and UAE;[73] and one of poor quality compared laparoscopic myomectomy and expectant management before in vitro ART treatment.[112]

Eight studies were RCTs: one of good quality examined "chemically assisted dissection" with sodium-2-mercaptoethanesulfonate (mesna) to define tissue planes and facilitate fibroid resection during myomectomy;[146] two trials, one poor and one fair, examined interventions to reduce blood loss at the time of myomectomy;[145,148] two trials, one fair and one poor, examined products applied at the time of myomectomy to reduce adhesion formation,[142,143] two fair-quality studies randomly allocated participants to abdominal or laparoscopic myomectomy;[135,137] and one, of fair quality, randomly allocated participants to three arms—abdominal myomectomy, minilaparotomy, and laparoscopically assisted minilaparotomy.[113]

The myomectomy literature is dominated by case series from large academic, tertiary care centers and internationally recognized fibroid surgery centers. Studies conducted in Europe outnumber those conducted in the United States or Canada by more than two to one. Among European studies, the majority were conducted in Italy or France. All but one of 11 North American studies were conducted in the United States, including one study that had a study site in Taiwan.

Regardless of country, the majority of studies were conducted in academic centers or specialty fibroid care facilities. Ten studies reflected care in community hospitals or clinics. Two studies relied on large databases, one in a national health care database in Norway and the other in a large private insurer database in the United States.

Outcomes Measured. For each type of surgical procedure, we combed the publications for the outcomes and complications summarized in the analytic framework presented in Chapter 1 (Figure 1). The majority of studies included perioperative outcomes. The clinical outcomes fairly uniformly included the number or size (or both) of fibroids removed, estimated blood loss or change in blood count (e.g., hemoglobin levels), transfusions (number needed or percentage of women receiving at least one), febrile morbidity, and complications. Virtually all studies used conventional clinical measures for these outcomes; some specified operational definitions or specifically timed measurements. Two measures assessed clinical processes including the length of the procedure and length of the entire hospital stay.

Retrospective studies, by definition, rely entirely on existing clinical or administrative data. Such use of clinical data means that measures such as intraoperative blood loss will be biased by documented phenomena such as digit and rounding preferences and by the a priori impressions of the surgical team about how the type of procedure relates to anticipated blood loss. Likewise, clinical practice routines play a large part in determining outcomes such as pain medication strategies or timing of discharge after the procedure. Of note, given the peculiarity of surgical studies, even RCTs are not insulated from these effects of practice patterns and assumptions about likely outcomes. Unless intraoperative details, such as blood volume in the suction canisters and on sponges, were recorded by an observer for whom the group allocation was unknown, and unless postoperative care was coordinated by an individual unaware of type of surgery, the influence of practice patterns on outcomes cannot be avoided. In this literature, such a high level of masking of assessors and care providers is understandably not achieved.

Fourteen studies included some level of detail about the degree to which myomectomy improved symptoms related to recurrence of fibroids or was followed by other surgical interventions after the index myomectomy. None of the identified studies of myomectomy outcomes made use of standardized and validated measures of menstrual bleeding, participant satisfaction, or health-related quality of life.

Eighteen studies provided data about pregnancy outcomes after myomectomy; a large proportion of these focused exclusively on ART outcomes.[112,115-117,119,123,125-128,130,133,134,137,139,141,147,150-152] However, several of these did not meet inclusion criteria for our later discussion of pregnancy outcomes in KQ 3 because they did not track or report the proportion of the women in the original study group who attempted to conceive or because they did not provide denominator data among those who did conceive to allow calculation of the probability of conception, pregnancy loss, or live birth among participants.

Limitations of Study Quality for Reproductive Outcomes. The overall quality of these studies was poor to fair. Because so many of these studies appear low on most study design hierarchies and because quite a few do not meet reasonable quality criteria, we have included in this review even articles and studies that we graded as poor. Quality grading procedures, drawing largely on the original review,[30] are explained in Chapter 2. Except for studies in which the myomectomy was done concurrent with evaluation and treatment for infertility, most of the case series and cohorts do not report an approach to data collection that would provide an accurate measure of the proportion of women in the studies who desired a future pregnancy and who attempted conception. Without this information, and without clearly specified lengths of followup, reports of pregnancy, miscarriage, and birth rates are flawed because rates require both an accurate denominator and unit of time over which the outcome was assessed. Likewise, simple proportions of women achieving pregnancy after myomectomy require at minimum an accurate denominator of women attempting to conceive.

Reports of the outcomes of pregnancies achieved can nonetheless be accurately summarized as descriptive data about the proportion of known pregnancies resulting in miscarriage, preterm birth, or cesarean birth and about the proportion associated with complications such as uterine rupture. Miscarriage data will underrepresent true reproductive inefficiency because some pregnancies will be lost before conventional pregnancy testing identifies the pregnancy. No studies of reproductive outcomes after myomectomy used daily urine or serum human chorionic gonadotropin testing to identify pregnancies close to the time of implantation and none, other than those among women receiving care for infertility, tested for pregnancy on a predetermined schedule. If women with one type of treatment for fibroids or without fibroids are differentially

likely to conduct pregnancy testing earlier rather than later, the potential for bias caused by differences in very early loss rate is not negligible but cannot be assessed using outcomes reported in these studies.

Abdominal Myomectomy: Perioperative Outcomes. Thirteen publications (eight of poor quality, four of fair, and one of good) provided information about perioperative outcomes of abdominal myomectomy (Table 9).[90,113,121,122,128,133,136-138,140,144,146,148] This category includes studies of abdominal surgery and those involving minilaparotomy or laparoscopically assisted myomectomies, as all involve some form of abdominal incision. Four studies presented RCT results.[113,137,146,148] One study was a prospective cohort;[121] two were retrospective cohorts;[128,138] and six were retrospective case series.[90,122,133,136,140,144]

One RCT evaluated use of mesna as a "chemical aid to dissection" of the myoma at the time of abdominal myomectomy.[146] One RCT evaluated techniques for reducing blood loss at the time of myomectomy.[148] In a total study population of 94 women, 31 had vaginal myomectomy. The authors did not provide data separately by myomectomy approach. We present surgical and trial outcomes here (with respect to results for abdominal myomectomy) because this was the only study in the review that included any women who had vaginal myomectomy, which is not a common technique in the United States.

One other trial compared abdominal myomectomy, minilaparotomy, and laparoscopically assisted myomectomy.[113] Data from each arm of this trial and the results of comparisons across arms appear here because each participant had at least a minilaparotomy incision. One RCT compared abdominal with laparoscopic myomectomy;[137] outcomes for the abdominal group are presented here, and more detailed consideration of direct comparisons are discussed in the next section on laparoscopic myomectomy.

One case series,[122] one group within a cohort,[121] and one arm of a clinical trial[113] focused exclusively on outcomes of minilaparotomy. Finally, the largest study (N = 1,959), conducted using data in a large private insurance database in the United States, includes some outcomes data, which are presented here.[140] As this work was focused predominantly on costs, and we review those results as part of KQ 4.

Excluding the large insurance database study, the remainder of the publications that include operative outcomes reported on study populations of small to modest size. Populations range from 41 in a clinical trial to 225 in a retrospective cohort formed by hospital record review.

Abdominal myomectomy is a major surgical procedure, as reflected in the data on perioperative outcomes and complications presented in Table 9. We summarize the clinical and utilization measures below.

Fibroids Removed. Seven studies reported some form of data on this outcome. With respect to the number of fibroids removed, the range over five studies was 1.2 to 9, and with respect to weight, the range (three studies) was 170 grams to 286 grams.

Blood Loss and Transfusions. Average operative blood loss, for six studies, ranged from 200 ml to more than a half liter of blood loss (508 ml). Two studies reported decreases in hemoglobin ranging from 1.8 g/dl to 3.1 g/dl. The study that evaluated mesna to assist resection reported the lowest blood loss in the mesna arm (0.9 g/dl) and a more conventional decrease, 1.7 g/dl, in the placebo control group. Finally, one study reported that 31 percent of patients had a blood loss greater than 500 ml. Most of these studies reported mean estimated blood loss without commenting on the handling of extremes of minimal or excessive blood loss. Few authors commented on other measures of centrality such as the median or any skew in the data.

Table 9. Perioperative outcomes and complications of abdominal myomectomy

Author, Year	N	Perioperative Outcomes						Complications
		Fibroids Removed (mean)	Blood Loss (ml ± SD)	Trans-fusions	Febrile Morbidity	Operative Time (mins)	Length of Stay	
Agostini, 2005[148]	Oxytocin 47	NR	508	15%	NR	90	NR	NR
	Placebo 47	NR	451	4%	NR	86	NR	NR
Benassi et al., 2000[146]	Mesna 29	9	Hgb↓ 0.9	NR	3%	70	2 days	None
	Saline 29	6	Hgb↓ 1.7	NR	3%	90	3 days	None
Cagnacci et al., 2003[113]	AM 17	1.6	Hgb↓ 3.1 ± 0.3	NR	23.5%	91	5.9 days	NR
	"mini"17	1.9	Hgb↓ 2.4 ± 0.4	NR	23.5%	86	5.0 days	NR
	LAM 17	1.2	Hgb↓ 1.8 ± 0.2	NR	23.5%	93	3.4 days	NR
Fanfani et al., 2005[121]	120	2.9	315	NR	3.3%	62	2.8 days	None out to 30 days
Glasser 2005[122]	139	Wt: 286 gm	330	0.7%	NR	110	13.6 hours (0.6 days)	1 emergency hysterectomy, 1 wound infection, 3 seromas
Marret et al., 2004[128]	176	2.9	504	5.2%	15.9%	89	6.9 days	2.3% operative complications: 1 endometritis, 1 wound infection, 10 wound hematomas
Olufowobi et al., 2004[133]	109	5	31% >500 ml	21%	38%	NR	4.8 days	5% wound infection, 4% emergency hysterectomy, 1% bowel injury
Razavi et al., 2003[90]	44	NR	376	7%	NR	NR	2.9 days	16% complications: 3 transfusions, 2 wound infections, 1 readmission for ileus
Roth et al., 2003[136]	225	NR	NR	20%	2.9%	NR	NR	6.1% complications: 2.4% ileus, 0.7% urinary retention or bladder injury, 3% infection or wound breakdown, 1% respiratory complications

AM, abdominal myomectomy; cc, cubic centimeters; EBL, estimated blood loss; gm, gram; Hgb, hemoglobin; LAM, laparosopically assisted myomectomy; ml, milliliter; NR, not reported; wt, weight.

Table 9. Perioperative outcomes and complications of abdominal myomectomy (continued)

Author, Year	N	Perioperative Outcomes						Complications
		Fibroids Removed (mean)	Blood Loss (ml ± SD)	Trans-fusions	Febrile Morbidity	Operative Time (mins)	Length of Stay	
Seracchioli et al., 2000[137]	65	NR	Hgb↓ 2.2 ± 1.6	5%	26.2%	89	6.0 days	No intraoperative complications: 26.2% antibiotic treatment
Silva et al., 2000[138]	51	Wt: 170 gm	200	18%	26%	180	Median, 4 days	1 >1,200 cc EBL, 1 cystotomy
Subramanian et al., 2001[140]	1,959	NR	NR	NR	NR	NR	2.9 days	3.7% conversion to hysterectomy
Vavilis et al., 2005[144]	102	NR	NR	NR	17%	NR	NR	NR

Transfusion risk was reported in eight studies. The percentage of women requiring transfusions ranged from < 1 percent to 21 percent. In four studies, the numbers of transfusions ranged from 1 to 7. Use of intravenous oxytocin (compared with placebo) for reducing blood loss did not provide evidence of advantage when comparing mean blood loss; the study was underpowered to evaluate influence of risk of transfusion.[148] The publications that reported on minilaparotomy and laparoscopically assisted minilaparotomy provided too little detail to determine if these approaches were associated with reports of higher or lower blood loss.

Emergency hysterectomy at the time of abdominal myomectomy is most often a response to excessive bleeding. The two studies that best reflect general practice (including a large number of surgeons at community sites) are one in the United Kingdom and a U.S. insurance database. These studies reported that 4 percent and 3.7 percent (respectively) of women presenting for abdominal myomectomy had their procedure converted to a hysterectomy.[133,140]

Fever. Clinicians believe that febrile morbidity is a common occurrence after myomectomy. Definitions of febrile morbidity in this literature ranged from a single temperature recorded at 38° degrees Centigrade (C) or higher, to requiring repeated measures of fever over a number of hours. The three studies that reported low febrile morbidity (2.9 percent,[136] 3.3 percent,[121]) and 12 percent (aggregate of two small study arms with 3 and 20 percent per arm)[146] based their information on undefined "fever" from chart review[136,146] or a requirement for temperature of 38° C on two occasions at least 6 hours apart, excluding the first day after surgery.[121] The remainder of studies reporting on febrile morbidity all reported that temperature elevation occurred in 15 percent or more of the study population (15.9, 17, 23.5, 26, 26.2, and 38 percent).

The clinical relevance of a high proportion of postoperative patients having fevers is related to the degree to which clinical examinations and diagnostic testing are done to evaluate the patient and rule out other sources of infection including urinary tract infection, pelvic operative site, and wound infection. Regardless of cost and effort required to evaluate the febrile patient, the occurrence of fever also influences length of stay; virtually all authors reported that a common clinical criterion for discharge is that the patient be afebrile.

Other Complications. Frank infectious complications and wound healing abnormalities are known outcomes of all surgical procedures. Women having myomectomies are generally young and healthy and rates of such complications are low. Endometritis and wound infections were reported at rates below 1 in 100 women. Wound healing complications, which can be difficult to

distinguish from wound infection, were more common, affecting between 2 percent and 6 percent of participants in studies of abdominal procedures. Only one minilaparotomy study reported on wound healing complications, which occurred in 2 percent of their participants.[122] Because wound healing complications such as seromas and hematomas generally require opening the incision and either allowing it to heal by secondary intention with daily wound care and dressing changes or reclosing the incisions with suture or staples after debridement, they present significant morbidity for the patient.

Other complications (data not shown in Table 9) such as intraoperative bowel and bladder injuries were rare. Readmissions were rare as were postoperative bowel and bladder complications such as ileus and urinary retention. No perioperative deaths were reported in these studies.

Utilization Measures. Table 9 also contains information for abdominal myomectomy or its variants on operative times and length of stay. Operative times among the seven studies reporting them all exceeded 1 hour (range from 62 minutes to 180 minutes). Length of stay varied from 13.6 hours to 6.9 days in ten studies.

Abdominal Myomectomy: Longer-Term Outcomes. Nine studies, six of poor quality and three of fair quality, followed up participants months to years after abdominal myomectomy (Table 10).[70,90,122,123,128,133,135,137,140]

The longest followup included women who were contacted an average of 49 months from the initial abdominal myomectomy; shortest follow-up periods were generally 24 months (except for one study that had a range including some women followed for as short a time as 2 months).

Improved Symptoms. After abdominal myomectomy, more than half of women studied had improvements in the symptoms for which they sought care. Outcomes evaluated, most often by survey or telephone interview, included the following: "improved symptoms," 68 percent; no recurrence of heavy bleeding over 5 years, 50 percent; and "completely" or "significantly" improved menorrhagia in 64 percent of women, pain in 54 percent, and mass effects in 91 percent. One study with 30 participants who had abdominal myomectomies specifically addressed satisfaction with treatment outcomes. At an average follow-up time of 49 months, 10 percent of women had had no improvement or worsening of symptoms and 21 percent were very dissatisfied with the therapy, indicating that 69 percent had satisfactory results.[70] The investigators for the studies reported here did not carry out formal health-related quality of life, functional status, or detailed satisfaction surveys.

Subsequent Interventions. Incidence of fibroids rises through the late reproductive years. For that reason, recurrence of fibroids after myomectomy is expected, either through growth of small fibroids that could not be identified or removed at the time of first surgery or through appearance of new fibroids.[30] In some proportion of such cases, further surgery or other interventions may be advised and carried out.

Two studies of fair quality assessed all participants for recurrence through uniform use of imaging at regular intervals (both were RCTs comparing abdominal myomectomy with other surgeries); they reported that 18 percent of women at 32 months[137] and 23 percent of women at 40 months[135] had newly identified fibroids. Hanafi, using data linked to clinical records of ultrasounds done after the index surgery, found that 62 percent of women (followed for an average of 38 months) had fibroids on subsequent ultrasound.[123]

Table 10. Long-term outcomes of abdominal myomectomy

Study, Year	N	Mean Length of Followup (months)	Symptom Relief and Recurrence	Subsequent Intervention
Broder et al., 2002[70]	30	49	No improvement or worsening of symptoms: 10% Somewhat or very dissatisfied with therapy: 21%	Subsequent surgery: 3%; 1 hysterectomy
Glasser, 2005[122]	139	NR	Fibroid recurrence: 2 of 139 procedures	Subsequent surgery: 1.4%; 2 hysterectomies (follow-up approach unclear)
Hanafi, 2005[123]	132	38	By 5 years: Recurrence of menometrorrhagia: 50% Dysmenorrhea: 24% Fibroid(s): 62%	Subsequent surgery by 5 years: 17%; 9% "major" surgery; 52% of women with proven fibroid recurrence had surgery
Marret et al., 2004[128]	176	24	Fibroid recurrence: 3.6%	NR
Olufowobi et al., 2004[133]	109	2 to 24	Improved symptoms (majority had mass symptoms): 68%	NR
Razavi et al., 2003[90]	44	15	"Completely" or "significantly" improved by indication: Menorrhagia: 64% Pain: 54% Mass effect: 91%	Subsequent surgery: 10%
Rossetti et al., 2001[135]	40	40	Recurrence, most between 10 and 30 months (ultrasound assessment every 6 months): 23%	NR
Seraccholi et al., 2000[137]	65	32	Fibroid recurrence: 18%	Subsequent surgery: 6%; 3 myomectomies; 1 hysterectomy
Subramanian et al., 2001[140]	1,959	24	NR	Subsequent surgery (myomectomy and hysterectomy): 7.3%

NR, not reported.

In studies of longer-term operative outcomes, recurrence is presumed to be the underlying cause for subsequent surgeries; this association, however, is generally not proven by documenting recurrence to the reports of the proportions who have subsequent procedures. In the six studies that sought self-report, medical record evidence, or prospective follow-up data about subsequent intervention, between 1.4 percent and 17 percent of women had another surgery, but we found only limited information to describe what proportion of these procedures were hysterectomy compared to myomectomy.

This literature is limited by the dominance of retrospective case series and cohorts that do not have sufficient opportunity to operationalize outcome definitions and unify measurement for research purposes. As throughout this review, we emphasize that (with the exception of two community-based sources of data) these outcomes reflect the experience of women receiving care in academic centers and specialty clinics with an explicit interest in fibroid care. The community studies suggest higher rates of complications than those observed in academic centers. Outcomes cannot be predictably generalized to all abdominal myomectomies performed in all care settings.

With this concern noted, we can summarize that transfusion and febrile morbidity are expected to be common. Consent for abdominal myomectomy should specifically address the real possibility of transfusion. Exploring autologous blood banking and use of cell-saver and other technologies may be advisable to reduce risks from heterologous transfusion. However, autologous and cell-saver technologies are not without risk themselves. Thus, in general, strategies for minimizing blood loss are preferable to increased use of tools to accommodate high blood loss.

Laparoscopic Myomectomy: Overview. In all, 16 studies (17 articles) dealt with laparoscopic myomectomy alone. Thirteen studies, nine of fair quality and four of poor quality, (14 publications) provided information about perioperative outcomes of laparoscopic myomectomy (Table 11).[115-117,119,121,125,127,128,134,137-140,145] Five publications provided some information about longer-term outcomes that include resolution of symptoms and subsequent surgeries—four already noted[128,135,137,140] and one additional study.[118] Three of the longer-term outcome publications were retrospective analyses; two were RCTs comparing abdominal with laparoscopic myomectomy.[135,137] One study reported short-term operative outcomes stratified by whether the participant subsequently achieved a pregnancy; the means and ranges are not provided in aggregate for all participants. The data by pregnancy status are not presented here because the analysis was conducted to examine what characteristics at the time of surgery predicted improved reproductive outcomes. This study is addressed in more detail in KQ 3.[147]

In short, the overlap in this literature is small. This lack of continuity is important because it means that the findings of follow-up studies do not reflect the outcomes of the populations studied in the perioperative studies. Overwhelmingly, data were not prospectively gathered to capture details about how surgical events influence long-term outcomes.

Table 11. Laparoscopic myomectomy: perioperative outcomes

		Perioperative Outcomes						
Author, Year	N	**Fibroids Removed (mean)**	**Blood Loss (ml)**	**Trans-fusion**	**Febrile Morbidity**	**Operative Time (mins)**	**Length of Stay (days)**	**Complications**
Damiani et al., 2003[115]	279	3.1	102	None	1.1%	73	2.6	No conversions; no infections, no vascular injuries
Dessolle et al., 2001[116]	Laparo-scopy 88	1.7 ± 0.6	NR	None	NR	150	3.0	Conversions: 17%; 5 complications: 1 subcutaneous emphysema; 1 DVT, 1 bowel injury, 1 wound infection (AM), 1 fever
Soriano et al., 2003[139]	Laparo-conversion 18	1.6 ± 0.6	NR	NR	NR	148	5.5	
Di Gregorio et al., 2002[117]	635	1.7	NR	None	None	30-140	NR	Conversions: <1% Urinary retention: 3%
Dubuisson et al., 2001[119]	426	2.2 ± 1.8	Postop Hgb = 11.5	0.7%	NR	129	2.6	Conversions: 11% to AM or LAM ("minilap"); 11 for hemorrhage, 1 for hypercapnia; remainder not specified

Table 11. Laparoscopic myomectomy: perioperative outcomes (continued)

Author, Year	N	Perioperative Outcomes						Complications
		Fibroids Removed (mean)	Blood Loss (ml)	Trans-fusion	Febrile Morbidity	Operative Time (mins)	Length of Stay (days)	
Fanfani et al., 2005[121]	93	1.4 (1-3)	270	NR	4.3%	62	2.3	No conversions; No complications out to 30 days
Landi et al., 2001[125]	368	2.1 (1-10)	Hct↓ 4.8 ± 2.9	3%	3.3%	101	2.9	Conversions: 2.2%, Complications: 3.3% epigastric vessel injury, uterine perforation, needle break during fascial repair, bowel injury, subcutaneous emphysema
Malzoni et al., 2003[127]	144	1.6	NR	0.7%	NR	95	2.6	Conversions: 1.4% Operative complications: 2.1%
Marret et al., 2004[128]	126	1.5 ± 1.7	226	None	1.1%	89	3.6	Conversions: 29% Operative complications: 2.2%, including 1 wound hematoma
Ou et al., 2002[134]	Colpotomy 143	5.8	243	NR	13.9%	144	NR	Conversions: <1%, 2 hysterectomies; 4 EBL > 500 ml
	Morcel-lation 22	4.2	378			168		
Seracchioli et al., 2000[137]	65	NR	Hgb↓ 1.3 ± 1.2	None	12.1%	100	3.1	Conversions: 4.3% Complications: 1 case of infiltration of laparoscopy gas beneath the skin
Silva et al., 2000[138]	25	Wt: 151 gm	300	8%	16%	223	Median = 2	Conversions: 12%; No major complications
Subramania n et al., 2001[140]	398	NR	NR	NR	NR	NR	2.3	Conversions: 13.3% to open myomectomy; 2.8% to hysterectomy
Zullo et al., 2004[145]	B+E 28	1.3	144	None	3.6%	79	2	No conversions, no complications
	Saline 28	1.2	213	None	7.1%	109	2	No conversions, no complications

AM, abdominal myomectomy; DVT, deep vein thrombosis; EBL, estimated blood loss; Gm, gram; Hbg, hemoglobin; Hct, hematocrit; LAM, laparoscopically assisted myomectomy; NR, not reported; wt, weight; B+E, bupivacaine plus epinephrine.

Laparoscopic Myomectomy: Perioperative Outcomes. The 13 studies with perioperative outcomes (Table 11) covered essentially the same outcomes as reported for abdominal myomectomy. Complications, however, are different insofar as they can include conversion of this particular operative procedure to one or another form of abdominal myomectomy. These studies involved study populations of small to moderate size with a total of 2,887 participants and an average of 222 participants per study. The range of size was 18 participants to 635 in a European specialty clinic case series.

Fibroids Removed. All but two studies provided some information about fibroids removed. In seven studies, the number of fibroids removed was, on average, fewer than 2; in four others, the number ranged from just over 2 to almost 6; and in one study, the fibroid weight removed was 151 grams.

Blood Loss or Transfusions. Nine studies reported data on average operative blood loss or on postoperative change in hematocrit or hemoglobin. Among those studies that reported estimated blood loss, the mean reported was 235 ml, with a range from 102 ml to 378 ml (in one arm of a trial). When direct comparisons are made within a single study population, laparoscopic myomectomy is statistically associated with lower operative blood loss (data not shown) and decreased length of stay,[113,128,137,138] though not in each case statistically significant.[121]

Transfusion was rare—less than 1 percent across studies. Seven studies reported no transfusions; of the remainder, the number ranged from one to ten.

Fever. Febrile morbidity was variably defined by authors; typically, they did not document operational criteria (such as interval of temperature measurement and duration of elevation). Ten studies had data on febrile morbidity. In terms of numbers of subjects with any fever, the values ranged from 1 (of 28) to 12 (of 368); using percentages as the metric, the values for any febrile morbidity ranged from 1.1 percent to 16 percent.

Complications. The primary adverse outcome was conversion from laparoscopic procedure to abdominal myomectomy, attributed commonly to difficulty with controlling bleeding, accommodating challenging anatomy laparoscopically, or closing the defect in the uterine wall.

Three Italian studies, each with highly specialized laparoscopic surgeons, reported no conversions among a total of 400 participants.[115,121,145] Another large Italian series, also with highly specialized surgeons, reported a conversion rate below 1 percent among 635 procedures.[117] Including these studies, the risk of conversion to an open incision, averaged across studies, was 6.1 percent. Excluding these reports, approximately 9 percent of women had conversion to abdominal myomectomy with a range from less than 1 percent to 29 percent.

Conversion in the study based on a large insurance database was 13.3 percent (to abdominal procedures), with an additional 2.8 percent conversion to hysterectomy.[140] In a U.S. retrospective cohort, conversion was 12 percent;[138] and in a group of 11 Italian university and community hospitals, it was 29 percent.[128] This spectrum from highly specialized to more generalized practice suggests that, in conventional clinical practice, women and their care providers should anticipate a conversion rate of 10 percent or higher when discussing likely outcomes of laparoscopic myomectomy and planning for postoperative recovery.

Utilization Measures. In the 12 studies reporting on average operative times, all studies reported average times longer than 1 hour (range 62 minutes to 223 minutes) except for one study reporting its own range of 30 minutes to 140 minutes.

Across 11 studies, the length of postoperative admission (i.e., length of stay) generally averaged fewer than 3 days. One study reported a median of 2 days. Most studies apparently discharged their laparoscopic myomectomy patients by the middle of the second postoperative

day. European studies tended to report somewhat longer lengths of stay than those done in the United States. This is the case across types of surgery and likely reflects underlying differences in practice styles rather than real differences in the trajectory of postoperative recovery.

Laparoscopic Myomectory: Longer-Term Outcomes. Resolution of symptoms and satisfaction with surgical outcomes were not investigated in the studies that we identified for this review. Five studies did report on recurrence (Table 12). Of these, three of fair quality used regularly repeated ultrasounds for all participants during followup over (on average) 31 months to 47 months;[118,135,137] they documented recurrence rates of 12.7 percent at 1 year (or 16.7 percent by 5 years) to 22 percent or 27 percent (between 10 and 30 months). Contrasted with the estimated 2.5 percent recurrence of fibroids in a poor-quality study based on retrospective documentation of clinical findings and symptoms,[128] these higher rates document the value of prospective surveillance for presence of uterine fibroids as a research tool.

Table 12. Long-term outcomes of laparoscopic myomectomy

Author, Year	N	Mean Length of Followup (months)	Symptom Relief and Recurrence	Subsequent Intervention
Doridot et al., 2001[118]	173	47	Fibroid recurrence: 12.7% (1 year); 16.7% (5 years)	Subsequent surgery: 4.6%; 3 laparoscopic myomectomy, 1 abdominal myomectomy, 1 abdominal hysterectomy
Marret et al., 2004[128]	126	24	Fibroid recurrence (clinically defined by symptoms): 2.5%	NR
Rossetti et al., 2001[135]	41	40	Fibroid recurrence: 22% to 27% (most between 10 and 30 months)	NR
Seracchioli et al., 2000[137]	66	31	Fibroid recurrence: 18%	None during followup
Subramanian et al., 2001[140]	398	24	NR	Subsequent myomectomy or hysterectomy: 12.3%

NR, not reported.

Three studies, two of fair and one of poor quality, with a total of 637 participants followed for, on average, 24 months to 47 months, sought to document subsequent surgeries.[118,137,140] One Italian group reported that no subsequent procedures were performed over a mean of 31 months; a French study reported that 4.6 percent of women had further surgery (predominantly myomectomies) over an average of 47 months; and the U.S. insurance database study showed that 12.3 percent of women had a subsequent myomectomy or hysterectomy within 2 years.

Hysteroscopic Surgery: Overview. Eight studies, with 10 publications, provided information about perioperative outcomes of hysteroscopic myomectomy. Seven of these also provided some information about longer-term outcomes including subsequent surgeries (Table 13).[108-111,124,130,132,140,153,154]

Studies ranged in size from a small comparison of endometrial ablation techniques with 42 participants to a case series of 948 participants. Two studies reported on combining hysteroscopic myomectomy with endometrial ablation during the same hysteroscopic procedure;[111,154] a single study reported primarily on use of endometrial ablation as a method of controlling bleeding for women with uterine enlargement from fibroids.[153]

Hysteroscopic Myomectomy: Perioperative Outcomes. The five studies of hysteroscopic resection (myomectomy) without associated endometrial ablation included 2,061 women (top

panel of Table 13).[102,108-110,130,132,140] Generally, the authors provided relatively little information about operative complexity and perioperative complications.

Fibroids Removed, Blood Loss, and Transfusion. Few authors documented the number of fibroids removed at the time of hysteroscopy. Authors often reported the number of fibroids present on ultrasound (details are recorded on Evidence Table 7 in Appendix C[*]), but the identification of fibroids does not necessarily equate to the number that were able to be resected at the time of surgery. Authors did not routinely report blood loss or transfusion risk; the latter appears to be low but is poorly documented.

Table 13. Perioperative outcomes of hysteroscopic myomectomy with and without endometrial resection or ablation

Author, Year	N	Perioperative Outcomes						Complications
		Fibroids Removed (mean)	Blood Loss	Trans-fusion	Fluid Absorption (mean, ml)	Perforation (n, %)	Operative Time (min)	
Hysteroscopic Resection of Fibroid(s)								
Agostini, 2002[108-110]	782	NR	NR	None	NR	9 1.2%	NR	Endometritis: 0.5% Hemorrhage: 0.4% No emergency hysterectomy
Loffer et al., 2005[154]	104	1.5 ± 1.1	NR	NR	1,053 ± 1,176	NR	NR	NR
Marziani, et al., 2005[130]	107	NR	NR	NR	No over-load	None	20 to 50	Postoperative hemorrhage: 3, medically managed 13.1% of incomplete HMs led to a second HM
Munoz et al., 2003[132]	120	NR	NR	NR	281	1 0.8%	NR	22 incomplete HMs 1 fluid overload 1 hemorrhage 1 infection
Subramanian et al., 2001[140]	948	NR	NR	NR	NR	NR	NR	Conversions: to AM, 7.4% to hysterectomy, 1.5%
Hysteroscopic Resection of Fibroid(s) and Endometrium								
Boe Engelsen, et al., 2006[111]	149	NR	↓ Hgb: 1.4 ± 1.1	NR	292 ± 518	16 10%	43 ± 21	NR for only women with fibroids
Loffer et al., 2005[154]	73	1.5 ± 1.1	NR	NR	1,031 ± 1,145	NR	NR	NR
Endometrial Ablation								
Eskandar et al., 2000[153]	42	NR	NR	NR	645 ± 175	NR	29 ± 25	Hospitalized for observation: 5%

AM, abdominal myomectomy; Hgb, hemoglobin; HM, hysteroscopic myomectomy; NR, not reported.

Fluid Absorption. Three of five groups reporting on hysteroscopic resection with no other procedure described fluid absorption. This is an important measure because volume imbalances

[*] Appendixes cited in this report are provided electronically at http://ahrq.gov/clinic/tp/uteruptp.htm

can lead to volume overload and/or hyponatremia, which can be life-threatening. Fluid absorption happens when the fluid used to distend the uterine cavity enters the blood stream via the rich network of blood vessels that serve the endometrium (lining) of the uterus and that can be exposed during hysteroscopic resection. The reported range of fluid absorption is wide, from a mean of 281 ml to a mean of more than 1 liter; one group reported only that they observed no cases of volume overload. Good overall operative technique and low average fluid volumes do not prevent adverse events; for example, the publication reporting a mean of 281 ml fluid absorption also reported one case of volume overload.

Perforations. Perforations of the uterus at the time of the procedure occurred in approximately 1 percent of women who had hysteroscopic myomectomy (10 of 1,009 women for whom data were available in the Agostini and colleagues study and the Munoz et al., study).

Utilization Measures. Length of surgery was not routinely reported by authors.

Other Complications. Seven women (0.7 percent) experienced hemorrhage. Infection was rare, affecting 0.55 percent of women in the two studies that tracked infection risk (data not shown). Incomplete procedures and conversion to other types of procedures were the most common undesired outcomes. In one study, 7.4 percent of cases were converted to abdominal myomectomy and 1.5 percent to hysterectomy. Other studies reported 13.1 percent to 18.3 percent incomplete resections.

This variation in conversion and incomplete procedures likely reflects practice patterns and routines for obtaining preoperative consent of patients. Surgeons who prefer to conduct a second procedure to attempt to complete the hysteroscopic myomectomy are less likely to obtain consent for same-day conversion to abdominal or laparoscopic myomectomy or hysterectomy (unless it is an emergency procedure). In the study that reported conversions, the proportion of these that followed from advanced contingency plans to continue to more definitive surgery in order to have a high level of certainty that symptoms would be resolved is not clear; some may have been responses to operative complications such as hemorrhage or perforations.

In summary, general details are poorly reported in these studies. Serious complications are inconsistently reported for hysteroscopic myomectomy, but they likely occur in fewer than 1 percent of procedures. However, incomplete procedures or immediate conversion to another surgery may occur at rates higher than 5 in 100 women.

Hysteroscopic Myomectomy With Other Procedures: Perioperative Outcomes. Two publications reported on hysteroscopic myomectomy with concurrent endometrial ablation (middle panel of Table 13).[102,111] They were both relatively small studies (73 and 149 participants). One reported an average operative time of 43 minutes. Fluid absorption averages were again wide, from 292 to 1,031 ml, with the same study that reported higher fluid absorption for hysteroscopic myomectomy reporting averages over a liter for the combined procedure as well. One study reported a 10 percent perforation rate.[111]

Endometrial Ablation: Perioperative Outcomes. A single small study that included 42 women with uterine size greater than 12 weeks compared two methods of endometrial destruction: using a roller ball versus a resection approach.[153] It reported mean fluid absorption of 645 ml and an operative time of 29 minutes. Five percent of participants were hospitalized for observation but the reasons were not clearly specified. Fibroids removed, blood loss, perforation, hemorrhage, and other serious complications were not reported.

Hysteroscopic Myomectomy: Long-Term Outcomes. Seven research groups followed up participants at time periods of a year or longer;[102,111,124,130,132,140,153] the average length of

followup was around 2 years, and the longest followup included women who were tracked for 10 years after the initial procedure (with the minimum followup in that cohort being 4 years).

Women who had hysteroscopic myomectomy alone were followed up for satisfaction and symptom control at a minimum of 12 months in one study and at 36 months in another.[102,111,124,130,132,140,153] Outcomes were poorly operationalized in these studies; the authors gave no definition of how they collected these data. One study reported that 80.8 percent of women achieved "control of bleeding"; the other reported that 81 percent reported "good control" of bleeding with 6 percent reporting return of frank menorrhagia after one or two procedures. In this cohort, 13.1 percent had a second hysteroscopic resection of fibroids.

Across the four studies of hysteroscopic myomectomy reporting such information, between 11 percent and 22 percent of women elected to have subsequent surgical intervention related to fibroids and fibroid symptoms. With the exception of the study in which repeat procedures were common (13.1 percent), myomectomy and hysterectomy were the most common procedures, with hysterectomy being selected by 2 percent to 22 percent of women as definitive management.

Results for women with both hysteroscopic myomectomy and endometrial ablation suggest potential for better control of symptoms. The smaller study group (73 women) was followed up at a minimum of 12 months after their procedure; 95.9 percent reported "control of bleeding." This study included a comparison group of participants (n = 104) who had hysteroscopic resection only, with 81 percent achieving "control of bleeding." This difference as well as the rates of hysterectomy by group (22 versus 18 percent) within this cohort favor performance of endometrial ablation at the time of hysteroscopic myomectomy.[102] Istre and Langebrekke studied the largest group (N = 188) and reported that 5 percent of women experienced recurrent fibroids, 4 percent had recurrent bleeding, and 6 percent had recurrent pain (not mutually exclusive) within a minimum follow-up period of 4 years. Eighteen percent of their participants had repeat hysteroscopic resection of the endometrium. Of those who had repeat procedures 36 percent eventually had hysterectomies.

In the single study of endometrial ablation alone, Eskander and colleagues collected more detailed outcomes than other authors reporting on resection and ablation at the time of hysteroscopic myomectomy but had only 42 patients. They reported 67 to 77 percent of women achieved complete absence of menses, 13 percent to 15 percent had light bleeding, and 93 percent to 96 percent were "very satisfied" with their treatment outcomes during 2 years of followup.[153]

Across studies of hysteroscopy with ablation, the rate of eventual selection of hysterectomy for fibroid management is similar to the rate in hysteroscopy alone: 2 percent to 18 percent. None of the studies can clearly delineate whether subsequent surgeries were indicated by the appearance of new fibroids. Several of these studies used survival analysis techniques or other approaches to define the trajectory of time to subsequent procedure. The majority of women who failed treatment in these studies with an average of more than 3 years of followup, did so early, seeking subsequent surgical intervention within 1 to 2 years of the initial procedures. This may reflect the fact that treatment failure is fairly immediately apparent and women choose to act quickly. An additional consideration is that, as women age, some proportion exit the window of chaotic bleeding patterns that can occur in the perimenopause and become frankly menopausal, markedly reducing the need for further fibroid-related treatment.

This literature is limited by a general lack of direct comparisons of intervention methods and by lack of comparison of hysteroscopic approaches to other surgical and medical management

methods for outcomes, costs, and risks of harms. With that caveat, the identified case series and cohorts do document that serious complications are rare in the context of hysteroscopic intervention. Expertise and the number of procedures done by a surgeon have been shown to be related to decreased complications. Physicians and clinical care settings that have sufficient participant volume to publish results of case series and cohorts are likely to be more experienced and specialized than some community care settings. They also are likely to accumulate patients, and therefore study participants, who are referred with different expectations for symptom resolution and persistence of intervention to address symptoms than may be the case in general practice. The degree and direction of bias from lack of comparability of surgical skills and patient populations cannot be quantified.

Nonetheless, although repeat procedures and subsequent surgery are not uncommon, more than 80 percent of women followed across hysteroscopy studies for an average of more than 3 years do not have subsequent surgical interventions. Because hysteroscopic interventions are generally outpatient procedures and associated with rapid return to usual activities, these data suggest that the majority of women who have fibroids amenable to hysteroscopic intervention (which is not the case for all) can achieve good outcomes without resorting to more complex and costly procedures that also have a longer recovery time.

Hysterectomy: Overview and Nomenclature

This section presents the results of our literature search and findings about outcomes of hysterectomy, which is surgical removal of the uterus. Hysterectomy does not require removal of the ovaries, which is termed oophorectomy, however both procedures are often done concurrently. Surgery that removes the entire uterus and cervix as well as the ovaries is properly called total hysterectomy with bilateral salpingo-oophorectomy. Surgery that leaves the uterine cervix is called “supracervical” or “subtotal” rather than “total” hysterectomy. Hysterectomy is not a surgical option for women who wish to have future pregnancies or who wish to retain their uterus.

The content of the literature spans the range of surgical approaches currently available in routine clinical practice. These surgical approaches are described below. We did not identify any publication that met inclusion criteria and described outcomes of robotic surgery, which is becoming available at a limited number of highly specialized sites.

For convenience and consistency we have used uniform terminology and abbreviations to describe and discuss hysterectomy. The list that follows is approximately in the order of “invasiveness” as reflected by size and location of the surgical incision to be healed and the degree of disruption of nearby tissue and, therefore, the amount of healing required after the procedure.

Abdominal Hysterectomy. Abdominal hysterectomy consists of removal of uterus (with or without the associated surgery of removing ovaries and fallopian tubes) through an incision in the skin of the abdomen; this is also called a laparotomy incision. This includes midline incisions made along the imaginary line between the umbilicus and the pubic symphysis or “pelvic bone,” as well as incisions made lower on the abdomen at a right angle to that line. The surgeon operates with his or her hands and instruments in direct contact with the abdominal and pelvic organs.

Laparoscopically Assisted Hysterectomy. Laparoscopically assisted hysterectomy is the removal of the uterus assisted by use of a laparoscope and other instruments inserted through

small incisions in the abdominal wall. Generally each incision is less than 1.0 to 1.5 centimeters size. The laparoscope is attached to a video camera and the surgeons conduct a portion of the procedure while watching the surgery progress on a display screen. In the majority of the cases described in this literature as laparoscopically assisted, the laparoscope was used to complete the portion of the surgery required to identify and transect the major blood supply to the uterus (and ovaries if they are to be removed), and the procedure, including closing the vaginal incision, was completed through a vaginal approach using conventional vaginal surgical techniques.

Laparoscopic Hysterectomy. Laparoscopic hysterectomy is the removal of the uterus (with or without the ovaries and fallopian tubes) using a laparoscope and instruments inserted through "ports" in the abdominal and pelvic wall to accomplish the entire surgery. The surgeon's hands are not directly in contact with the uterus or pelvic organs during the surgery. The surgery is accomplished and the vaginal incision is closed entirely through the laparoscope. During laparoscopic hysterectomy, the uterus and fibroids may be morcellated (i.e., cut into smaller pieces), to remove them from the abdomen through small openings. This can be accomplished with laparoscopic instruments like scissors or various forms of scalpels or with a specialized device termed a "morcellator." For the purposes of this review we have indicated when laparoscopic hysterectomy was supracervical or total.

Vaginal Hysterectomy. Vaginal hysterectomy is the removal of the uterus (with or without the ovaries and fallopian tubes) via an exclusively vaginal approach. The operative incisions are made through the upper vagina to allow access to the uterus and pelvis, and the uterus is removed by operating through the vagina.

The approach to hysterectomy is in some part determined by a match between the size of the uterus, the patient's anatomy, the plan to perform or not perform oophorectomy, concerns about potential adhesions (which is scarring) from prior surgery like cesarean, and the surgeon's skill sets via the available approach. Vaginal hysterectomy is more challenging as the size and number of fibroids increases; the very large uterus is generally not compatible with vaginal removal, even when the surgeon uses techniques to divide the uterus or morcellate the segments. Abdominal approaches have traditionally been clinically taught to be appropriate for very large fibroids, i.e., those at and above the umbilicus. However, surgeons continue to compare open and laparoscopic approaches and to examine what size of uterus and fibroids can be safely removed. The influence of pretreatments with medical (pharmaceutical) interventions such as GnRH agonists, to diminish the size of fibroids prior to surgery, was discussed earlier.

The prior review on the management of uterine fibroids found that in prospective studies, hysterectomy resulted in improvement in symptoms and quality of life up to 2 years after the procedure in most women with sufficiently severe symptoms. Type of hysterectomy or short-term outcomes such as complications did not appear to influence longer-term outcomes.[30]

Studies, Designs, Populations, and Outcomes Measured. Eighteen articles from 17 distinct study populations address hysterectomy (Appendix C[*], Evidence Table 8).[47,75,76,94,144,155-167] Five of these studies are retrospective case series or cohorts;[144,159,161,166,167] the remainder are either RCTs[47,76,155-158,160,163,165] or nonrandomized prospective cohorts.[75,94,162,164]

Five studies were conducted in Italy,[155,158,160,164,165] four in the United States,[94,161,166,167] and the remainder in the United Kingdom,[162,163] France,[156,157] Sweden,[159] Netherlands,[76] Greece,[47,144] and Canada.[75] Three were multicenter trials.[76,94,162] One study was based on an inpatient registry,[159] and the others were hospital-based studies.[75,144,156,157,160,161,163-167]

[*] Appendixes cited in this report are provided electronically at http://ahrq.gov/clinic/tp/uteruptp.htm

With the exception of three studies,[75,94,159] no study examined outcomes beyond the immediate perioperative window. Most studies reported on the length of the procedure, intraoperative and postoperative complications, and length of hospital stay.

Two studies reported outcomes of hysterectomy from large case-series data.[159,162] Three studies compared UAE with hysterectomy.[75,76,94] One study compared abdominal myomectomy with abdominal hysterectomy.[144] All other studies compared different types of hysterectomy or modifiers of hysterectomy outcome. Six studies compared different types of hysterectomy: three studies compared vaginal hysterectomy with abdominal hysterectomy,[94,155,161] two studies compared laparoscopically assisted vaginal hysterectomy (LAVH) with abdominal hysterectomy,[160,165] and one study compared LAVH with vaginal hysterectomy.[156,157] Eight studies addressed modifiers of hysterectomy outcomes.[47,76,94,158,160,163,164,167]

Hysterectomy: Outcomes

Our findings are presented in Appendix C*, Evidence Table 8 and summary tables below. Two studies reported outcomes of hysterectomy from large case-series data (Table 14).[159,162] Of these, one poor-quality study drew upon data from the National Health Service and private hospitals from England, Wales, and Northern Ireland to report a severe operative complication rate of 4.4 percent and a severe postoperative complication rate of 1.2 percent in the 6-week period following surgery from 1994 and 1995.[162] The other study, of fair quality, reported myocardial infarction rates from a national registry of patients from Sweden over an average of 8.9 years of followup.[159] The relative risk of myocardial infarction for women with only fibroids rather than other indications for hysterectomy was not statistically significant (relative risk [RR], 1.1; 95% CI, 0.7-1.7). However, the relative risk of myocardial infarction for naturally menopausal women with fibroids compared with that for all other women was statistically significant but imprecise (RR, 6.2; 95% CI, 1.9-20).

Table 14. Outcomes of hysterectomy

Author, Year	Intervention	N	Length of Followup	Outcomes
Falkeborn et al., 2000[159]	All hysterectomies	75% of 16,455, actual N NR	8.9 years on average	Relative risk of myocardial infarction for women with only fibroids compared to other indications: 1.1 (95% CI, 0.7-1.7)
				Relative risk of myocardial infarction for naturally menopausal women with fibroids compared with all other women: 6.2 (95% CI, 1.9-2.0)
McPherson et al., 2004[162]	All hysterectomies	6,604	6 weeks	Number of severe* operative complications: 291 (4.4%)
				Number of severe* postoperative complications: 82 (1.2%)

CI, confidence interval; NR, not reported.
* Severe complications defined as death, deep venous thrombosis, pulmonary embolism, myocardial infarction, renal failure.

* Appendixes cited in this report are provided electronically at http://ahrq.gov/clinic/tp/uteruptp.htm

Comparative Studies. *Uterine Artery Embolization (UAE) Versus Hysterectomy.* Three fair-quality studies compared the outcomes of UAE and hysterectomy (Table 15).[75,76,94] Two were multicenter studies of UAE versus a mixed group of hysterectomies (abdominal, laparoscopic vaginal, LAVH) and focused on symptoms and clinical outcomes.[76,94]
These studies consistently demonstrated shorter procedure and hospital times for the UAE group than for the hysterectomy group, but they were not consistent in the rate or direction of complications.[76,94] Hehenkamp and colleagues reported a significantly higher rate of minor complications at 6 weeks postprocedure in the UAE group than in the hysterectomy group;[76] the Spies et al., study reported a significantly lower rate of minor complications and overall morbidity in the UAE group than in the hysterectomy group.[94] Hehenkamp documented a higher rate of readmissions among UAE patients[76] whereas Spies et al., did not find any significant differences in rates of readmission.[94] Spies et al., reported significant differences in days before return to work favoring UAE (UAE: 10.7 days, hysterectomy: 32.5 days; $P < 0.001$), and significant differences in the proportion reporting improved pelvic pain at 12 months (UAE: 84 percent, hysterectomy: 98 percent; $P = 0.021$), favoring hysterectomy. They found no differences in other symptoms, quality of life, satisfaction, or overall health assessment.[94]

The third, hospital-based study compared UAE with laparoscopic hysterectomy to assess the risk of damage to ovarian function. The authors reported no differences between the groups in ovarian function between baseline and 6 months following the procedure.[75]

Abdominal Myomectomy Versus Abdominal Hysterectomy. One poor-quality study compared abdominal myomectomy with abdominal hysterectomy, seeking to provide evidence on whether abdominal myomectomy was associated with febrile morbidity.[144] The study's retrospective analysis of 204 patients suggested no difference in the incidence or length of febrile morbidity. The study presented no other outcomes.

Vaginal Versus Abdominal Hysterectomy. Three studies compared vaginal hysterectomy with abdominal hysterectomy (Table 16); two were of fair quality[155,161] and one of poor quality.[166] Two of the three were retrospective cohorts[161,166] and one was an RCT.[155] All three studies focused on perioperative outcomes.

All three studies reported higher operative times for abdominal hysterectomy, although the difference was statistically significant in only one study.[155] They reported no difference in blood transfusion or intraoperative complications. With regard to postoperative decrease in hemoglobin, the studies yielded inconsistent effects: one study reported no differences in hemoglobin,[155] another reported a higher but nonsignificant decrease in postoperative hemoglobin,[166] and a third reported a significantly lower postoperative decrease in hemoglobin with abdominal hysterectomy than with vaginal hysterectomy.[161] All three studies reported higher but nonsignificant rates of blood transfusion among abdominal hysterectomy patients. All three studies reported either no differences in postoperative complication rates or higher rates of postoperative complications among the abdominal hysterectomy patients. These differences are significant for the risk of ileus in one study[161] and for postoperative complications in another study.[166] All three studies are consistent in reporting significantly longer hospital stays among abdominal hysterectomy patients.

Table 15. Outcomes of UAE versus hysterectomy

Author, Year	Groups	N at Enrollment	Length of Procedure (min±SD)	Perioperative Complications (at surgery or within 30 days)		Longer-term Complications (measured at 30 days or 6 weeks)		Overall Morbidity (n, %)‡	Hospital Stay (mean days±SD)	Re-admissions (n, %)	FSH at 6 Months (IU/L±SEM)
				Minor Operative Complications: No. of Complications/No. of Patients (%)*	Major Operative Complications: No. of Complications/No. of Patients (%)†	Minor Complications at 6 Weeks: No. of Complications/No. of Patients (%)*	Major Complications at 6 Weeks: No. of Complications/No. of Patients (%)†				
Healey et al., 2004[75]	UAE	48									9.9 ±1.0
	Laparoscopic hysterectomy	13									7.8 ±1.8
											P NS
Hehenkamp et al., 2003[76]	UAE	81	79	23/18	1/1	68/47	3/3		2.0±2.1	9 (11.1)	
	Hysterectomy (abdominal, vaginal, LAVH, laparoscopic)	75	95.4	26/23	1/1	34/30	1/1		5.1±1.3	0	
			P = 0.007	*P* = 0.23	*P* = 0.99	*P* = 0.024	*P* = 0.62		*P* < 0.001	*P* = 0.0032	
Spies et al., 2004[94]	UAE	102	57.9	N NR (17.6)		N NR (12.7)		15 (14.7)	0.83 (SD NR)	3 (2.9)	
	Hysterectomy (abdominal, LAVH, laparoscopic)	50	93.6	N NR (28)		N NR (32)		17 (34.0)	2.3 (SD NR)	4 (8.0)	
			P < 0.001	*P* = 0.15		*P* = 0.01		*P* = 0.01	*P* < 0.001	*P* = 0.22	

FSH, follicle-stimulating hormone; IU/L, international units per liter; LAVH, laparoscopically assisted vaginal hysterectomy; NR, not reported; NS, not significant; SD, standard deviation; SEM, standard error of mean; UAE, uterine artery embolization.

* Minor complications: Vaginal discharge, pain requiring readmission, pain/fever requiring readmission, fibroid expulsion not requiring reintervention, hematoma, wound abscess, woundbleeding, wound dehiscence, urinary tract infection, urinary retention, urinary incontinence, endometritis, hot flashes, anemia requiring transfusion, hypertension, hypotension, other.

† Major complications: Pneumonia, ileus, thrombosis, vesicovaginal fistula, pulmonary embolism, intra-abdominal infection, sepsis, fibroid expulsion requiring re-intervention, death.

‡ More than one of the following: febrile morbidity, readmission, unintended surgery, hemorrhage, or life-threatening complications such as cardiopulmonary arrest, resuscitation, unplanned admission to special (intensive) care unit, or death.

Table 16. Vaginal versus abdominal hysterectomy

Author, Year	Groups	N	Operative Time (min ± SD)	Decrease in Hemoglobin/ Hematocrit	Blood Transfusions n (%)	Perioperative Complications n (%)*		Hospital Stay (mean days ± SD)
						Intraoperative Complications n (%)[† ‡]	Postoperative Complications n (%)[**, ††]	
Benassi et al., 2002[155]	Vaginal hysterectomy	60	86 ± 25.32	No difference in hemoglobin levels at postoperative day 1 (P = 0.897), or in the difference between pre- and postoperative levels (P = 0.848)	2 (3.3)	0	2 (3.3)	3.4 ± 0.7
	Abdominal hysterectomy	59	102 ± 31.02		4 (6.8)	0	6 (10.1)	4.3 ± 1.5
			P < 0.001		P NR	NA	P = 0.136	P < 0.001
Harmanli et al., 2004[161]	Vaginal hysterectomy	88	114.3 ± 46.3	1.9 ± 1.2 (decrease in Hgb)	8 (9.2)	Only risk of ileus (OR, 2.42; 95% CI, 1.08-5.43) was significantly higher for women who underwent abdominal hysterectomy compared to vaginal hysterectomy		1.9 ± 0.9
	Abdominal hysterectomy	200	137.4 ± 69.8	1.6 ± 1.4 (decrease in Hgb)	23 (11.5)			3.7 ± 1.3
			P NS	P = 0.03	P NS			P = 0.0001
Taylor et al., 2003[166]	Vaginal hysterectomy	139	172 ± 70.0	7.5 ± 4.6 (decrease in hematocrit)	Intraoperative and postoperative transfusion reported separately, no significant differences between groups	8 (5.8)	10 (7.2)	2.6 ± 1.5
	Abdominal hysterectomy	208	173 ± 66.6	8.3 ± 5.9 (decrease in hematocrit)		16 (7.7)	48 (23.1)	3.9 ± 2.6
			P = 0.88	P = 0.18		P = 0.53; OR, 1.4 (0.6, 3.3)	P < 0.001; OR, 3.9 (1.9, 7.9)	P < 0.001

CI, confidence interval; Hgb, hemoglobin; min, minutes; NA, not applicable; NR, not reported; n, number; NS, not significant; OR, odds ratio; SD, standard deviation.

* Postoperative febrile morbidity, bleeding requiring transfusion, ureteral injury, bladder injury, venous thromboembolism, ileus, hematoma, urinary tract infection, readmission.

† Major vessel injury, ureteral injury, bladder injury, bowel injury.

‡ Intraoperative transfusion, conversion to total abdominal hysterectomy, cystotomy, ureteral obstruction, bowel laceration.

** Vaginal cuff hematoma, pelvic hematoma, wound infection, wound dehiscence.

†† Postoperative transfusion, pelvic hematoma, reoperation, febrile morbidity, other.

Laparoscopically Assisted Vaginal Hysterectomy (LAVH) Versus Abdominal Hysterectomy. Two RCTS conducted in Italy reported on comparisons of LAVH and abdominal hysterectomy, one of fair quality[165] and one of poor quality[160] (Table 17). Both trials demonstrated significantly longer hospital stays for the abdominal route. Additionally, one study reported significantly shorter convalescence for the LAVH group (LAVH, 22.0 ± 11.3 days; abdominal hysterectomy, 36.0 ± 12.1 days; $P < 0.001$),[165] and the other reported significantly reduced use of analgesia for the LAVH group (LAVH, 3 percent of 7 patients; abdominal hysterectomy, 77 percent of 24 patients; $P < 0.001$).[160] Neither reported significant differences in the rates of blood transfusion or postoperative decrease in hemoglobin.

Table 17. Laparoscopically assisted vaginal hysterectomy versus abdominal hysterectomy

Author, Year	Groups	N	Operative Time in Mean Min ± SD or Median (range)	Conversion to Laparotomy (n)	Decrease in Hemoglobin	Blood Transfusions n (%)	Hospital Stay in Mean Days ± SD or Median (range)
Ferrari et al., 2000[160]	LAVH	60	135 (115-173)	3	1.1 (0.8-1.9)	0	3.8 (3.4-4.0)
	Abdominal hysterectomy	62	120 (98-123) *P* = 0.001	NA	1.8 (0.7-2.5)	1 (3)	5.8 (5.3-6.3)
			P = 0.001		*P* NS	*P* NS	*P* < 0.001
Seracchioli et al., 2002[165]	LAVH	31	95.2 ± 32.4	1	1.8 ± 1.1	0	3.2 ± 0.5
	Abdominal hysterectomy	31	88.6 ± 29.3	NA	2.3 ± 1.8	1	2.0 ± 0.7
			P NS		*P* NS	*P* NS	*P* < 0.001

LAVH, laparoscopically assisted vaginal hysterectomy; n, number; NA, not applicable; NS, not significant; SD, standard deviation.

LAVH Versus Vaginal Hysterectomy. A single fair-quality study (two publications) compared outcomes following LAVH or vaginal hysterectomy (Table 18).[156,157] This RCT reported significantly longer operating times, higher rates of total perioperative complications, and longer hospital stays in the LAVH group. The study did not find significant differences in the rates for individual complications, use of paracetamol, use of nonsteroidal anti-inflammatory drugs, use of opioid drugs during hospitalization, or time of passing gas and stool.

Table 18. Laparoscopically assisted vaginal hysterectomy versus vaginal hysterectomy

Author, Year	Groups	N	Operative Time (min ± SD)	Decrease in Hemoglobin ± SD	Blood Transfusions n (%)	Perioperative Complications n (%)*	Hospital Stay (mean days ± SD)
Darai et al., 2001[156] Soriano et al., 2001[157]	LAVH	40	160 ± 50	2.1 ± 1.4	1 (2.5)	16 (40.0†)	5.7 ± 3.0
	Vaginal hysterectomy	40	108 ± 35	2.0 ± 1.2	1 (2.5)	6 (15.0)	5.3 ± 2.1
			P < 0.001	*P* NR	*P* NR	*P* < 0.05	*P* < 0.001

LAVH, laparoscopically assisted vaginal hysterectomy; NR, not reported.

* Excessive hemorrhage, blood transfusion, major vessel injury, conversion to laparotomy, bladder laceration, emphysema, abdominal wall hematoma, vaginal cuff hematoma, pyrexia, vaginal cuff infection, abdominal wall infection.

† Reported as 37.5 percent in the article, calculated as 40.0 percent by reviewers.

Modifiers of Hysterectomy Outcomes. Eight studies reported on a variety of modifiers of outcomes of hysterectomy (Table 19): five of fair quality[47,76,94,164,167] and three of poor quality.[158,160,163]

Few studies examined the variety of modifiers identified for KQ 5, such as age, race, or ethnicity, parity, breastfeeding, contraceptive choices, body habitus, insulin resistance, concurrent medical conditions such diabetes, or hormone replacement status. Two studies that compared UAE with hysterectomy found that factors such as uterine volume, previous therapies, age, and race[94] or radiologists' experience, hospital experience, and type of hysterectomy[76] did not predict perioperative complication rates.

Another study based on a prospective case series of vaginal hysterectomy found that generally considered contraindications to vaginal hysterectomy, such as large uterus, adnexal pathology, nulliparity, previous pelvic surgery, or more than one contraindication, were not significant predictors of complications.[164]

Two studies examined uterine weight as a modifier of outcomes of an RCT of LAVH and total abdominal hysterectomy[160] or retrospective study of abdominal hysterectomy.[167] One study found that uterine weight was a significant predictor of at least one complication (estimated blood loss > 500 mL, perioperative blood transfusion, major organ injury, postoperative antibiotic therapy, readmission);[167] the other study reported that uterine weight was a significant predictor of conversion to laparotomy among LAVH patients.[160]

Three RCTs addressed clinical modifiers designed to reduce blood loss; these included use of bipolar electrocautery scissors vs. conventional scissors,[158] vasopressin vs. placebo,[163] and recombinant human erythropoietin (rHuEPO) plus iron supplementation vs. iron supplementation alone.[47] Dessole et al., demonstrated lower operating time and number of ligations for the electrocautery group than for the conventional scissors group; they did not find differences in hemoglobin or hematocrit until day 5 following the procedure, when the electrocautery group did better than the conventional scissors group.[158] Okin et al., reported lower estimated blood losses for the vasopressin group than for the placebo group, but they did not demonstrate significant differences in postoperative hemoglobin, change in hemoglobin, intraoperative transfusion, total operating room time, hysterectomy time, or hospital stays of 4 or more days.[163] Doussias et al., reported improved hemoglobin levels at days 3, 7, and 14 postoperatively in the rHuEPO plus iron group than in the iron-only group. The study also found significantly higher rates of blood transfusion in the iron-only group but not differences in blood loss or length of hospital stay.[47]

Table 19. Modifiers of hysterectomy outcomes

Author, Year	Design, Intervention, Modifiers	N	Results
Dessole et al., 2000[158]	RCT of abdominal hysterectomy with CT vs. abdominal hysterectomy with BES Modifiers: use of CT vs. BES	CT: 25 BES: 25	Operating time (min, mean ± SD) CT: 121 ± 32 BES: 90 ± 15 *P* < 0.01 Ligations (mean ± SD) CT: 14 ± 4 BES: 6 ± 2 *P* < 0.01 Hgb concentration not significantly different preoperatively, day 1 postoperative, day 2 postoperative Hgb concentration day 5 postoperative (g/dL, mean ± SD): CT: 10.0 ± 1.4 BES: 10.4 ± 1.1 *P* < 0.001 Hct not significantly different preoperatively, day 1 postoperative, day 2 postoperative Hct day 5 postoperative (%, mean ± SD): CT: 32.5 ± 3.3 BES: 34.0 ± 3.1 *P* < 0.001
Ferrari et al., 2000[160]	RCT of LAVH vs. TAH Modifiers: uterine size (≤ 500 g and > 500 g)	LAVH: 31 TAH: 31	Uterine weight significant predictor of conversion to laparotomy LAVH (uterine size ≤ 500 g): 0/20 LAVH (uterine size > 500 g): 3/11 *P* = 0.04
Okin et al., 2001[163]	RCT of abdominal hysterectomy with vasopressin vs. placebo Modifiers: use of vasopressin vs. placebo	Vasopressin: 30 Placebo: 27	Total estimated blood loss (mL ± SD) Vasopressin: 445.41 ± 239.99 Placebo: 748.42 ± 296.97 *P* = 0.001 Hysterectomy-related estimated blood loss (mL ± SD) Vasopressin: 410.63 ± 227.76 Placebo: 690.21 ± 294.76 *P* =0.001 Vasopressin vs. placebo not significant predictor of postoperative hemoglobin, change in hemoglobin, intraoperative transfusion, total operating room time, hysterectomy time, stay ≥ 4 days

AOR, adjusted odds ratio; BES, bipolar electrocautery scissors; CT, conventional technique; EBL, estimated blood loss; g, gram; g/dL, grams per deciliter; Hgb, hemoglobin; LAVH, laparoscopically assisted vaginal hysterectomy; mL, milliliter; RCT, randomized controlled trial; rHuEPO, recombinant human erythropoietin; SD, standard deviation; TAH, total abdominal hysterectomy; UAE, uterine artery embolization; U/ml, units per milliliter; vs., versus.

Table 19. Modifiers of hysterectomy outcomes (continued)

Author, Year	Design, Intervention, Modifiers	Sample size	Results
Unger et al., 2002[167]	Retrospective case series of abdominal hysterectomy Modifiers: Uterus < 500 g Uterus 500-999 g Uterus ≥ 1,000 g	Uterus < 500 g: 208 Uterus 500-999 g: 63 Uterus ≥ 1,000 g: 47	At least one complication (EBL > 500 mL, perioperative blood transfusion, major organ injury, postoperative antibiotic therapy, readmission) (n,%) Uterus < 500 g: 68 (32.7) Uterus 500-999 g: 26 (41.3) Uterus ≥ 1,000 g: 29 (61.7) *P* = 0.006 AOR for G3 vs. G1: 3.42 (1.63, 7.25) AOR for G3 vs. G2: 2.64 (1.14, 6.13)
Dousias et al., 2003[47]	RCT of preoperative therapy before total abdominal hysterectomy of rHuEPO 600 U/ml SC plus iron supplementation once weekly for 3 weeks vs. only iron supplementation Modifiers: rHuEPO plus iron supplementation vs. iron alone	rHuEPO plus iron: 23 Iron alone: 27	No difference in Hgb levels at day -7, 0. Higher Hgb levels at days 3, 7, and 14 postoperatively in the rHuEPO plus iron group No difference in blood loss or length of hospital stay Blood transfusion (n,%) rHuEPO plus iron: 0 iron alone: 5 (21.7) *P* < 0.05
Spies et al., 2004[94]	Nonrandomized prospective cohort of UAE vs. hysterectomy (abdominal, LAVH, laparoscopic) Modifiers: uterine volume, previous therapies, age, and race	UAE: 102 Hysterectomy: 50	Uterine volume, previous therapies, age, and race were not significant predictors of perioperative complications
Paparella et al., 2004[164]	Prospective case series of vaginal hysterectomy in generally considered contraindications to vaginal surgery Modifiers: large uterus, adnexal pathology, nulliparity, previous pelvic surgery, more than one contraindication	204	Large uterus, adnexal pathology, nulliparity, previous pelvic surgery, more than one contraindication are not significant predictors of complications

Table 19. Modifiers of hysterectomy outcomes (continued)

Author, Year	Design, Intervention, Modifiers	Sample size	Results
Hehenkamp et al., 2005[76]	RCT of UAE vs. hysterectomy (abdominal, vaginal, LAVH, laparoscopic) Modifiers: radiologists' experience, hospital experience, type of hysterectomy	UAE: 88 Hysterectomy: 89	Radiologists' experience with UAE not associated with the technical failure rate Less-experienced hospitals not associated with higher complication or readmission rates Overall major and minor complication rates do not differ significantly in subset of abdominal hysterectomies (P = 0.28 and P = 0.70)

Complementary and Alternative Medicine

The prior review on the management of uterine fibroids found a single study on Chinese herbal medicine.[30] Similarly, we found a single poor-quality study that met our inclusion criteria for complementary and alternative medicine involving traditional Chinese medicine (Appendix C[*], Evidence Table 9);[48] it is also discussed in the section on expectant management. This nonrandomized cohort study compared a group of women who received weekly acupuncture, Chinese herbs, and nutritional therapy (N = 37) to a comparison group (N = 37); patients in the traditional Chinese medicine group also received pelvic bodywork, guided imagery, and meditation. Study investigators selected herbs and nutritional therapies for each patient but standardized them in accordance with traditional Chinese medicine tenets. Patients in the comparison group received progestational agents to stop excessive uterine bleeding, oral contraceptives to control menstrual bleeding, and NSAIDs for pain. Patients in the treatment group had significantly smaller fibroids after 6 month of treatment than in the comparison group (-0.8 cm vs. +1.9 cm; $P < 0.01$). A greater proportion were improved (that is, cured, reduced in size, stopped growth, or reduced rate of growth) than in the comparison group (22 [60 percent] versus 3 [8 percent]; $P < 0.001$). The traditional Chinese medicine treatment group was also more likely to be very satisfied with their treatment than the comparison group (14 [38 percent] versus 8 [22 percent]; $P < 0.05$). The author noted potential biases from the differences in degree of motivation between the two groups: the treatment group was selected from the author's practice or by word-of-mouth referral from current patients; the comparison group, although selected to match the treatment group in age, fibroid size, presenting symptoms, and health insurance status, was entirely drawn from a sample of women who used the emergency room.

KQ 3: Treatment for Goals Other than Symptom Relief

KQ 3 asks about treatment for goals other than symptom relief; specifically, the focus is on enhancing fertility, reducing adverse pregnancy outcomes, preventing further growth, or ruling out uterine malignancy. We found 10 studies relating to reproductive outcomes. We did not find publications about preventing growth of existing fibroids that compared treatment with either no treatment or alternative treatments. Information about fibroid recurrence after myomectomy was presented above for KQ 2. We did, however, find five studies examining uterine fibroid

[*] Appendixes cited in this report are provided electronically at http://ahrq.gov/clinic/tp/uteruptp.htm

outcomes in postmenopausal women undergoing hormone replacement therapy for postmenopausal symptoms. No studies, in the time frame reviewed, reported on the probability of identifying a uterine malignancy when surgery or biopsy was done for treating or evaluating presumed uterine fibroids. These questions are new to our review, and had not been directly addressed by the prior review on the management of uterine fibroids.[30]

Pregnancy Outcomes: Overview

We identified 10 studies (10 articles) providing information about objectives for fibroid management other than symptom relief or treating the health consequences of the fibroids (e.g., anemia) (Appendix C*, Evidence Table 10). All concerned reproductive outcomes among women after treatment for their fibroids. All studies that contained fertility and pregnancy data and that met the review inclusion criteria of more than 40 women in a trial or cohort or more than 100 women in a case series who desired or achieved a pregnancy were related to outcomes after myomectomy.

Studies, Designs, and Populations. Table 20 provides information on these 10 studies in four blocks with information about specific subgroups; for that reason some studies appear more than once. For example, when authors reported data for both laparoscopic and hysteroscopic myomectomy, these cohort data will be recorded for each intervention group separately; we did not duplicate any study data in this table.

Seven publications focused on laparoscopic myomectomy; two were of poor quality[112,151] and five were of fair quality.[116,117,127,139,147] Three publications of fair quality included more than one type of myomectomy;[137,141,152] of these, one included a cohort of women who had either laparoscopic or hysteroscopic myomectomy and combined the outcome data;[152] one assessed use of hysteroscopic or abdominal myomectomy as indicated by fibroid type before ART and presented outcomes separately;[141] and the third was a randomized trial that examined conception and pregnancy outcomes after laparoscopic or abdominal myomectomy.[137]

This literature is exclusively from large academic, tertiary care centers and internationally recognized fibroid surgery centers. Except for one study conducted in the United States[141] and one in Japan,[147] the remainder were performed in Europe, mostly in Italy or France.

* Appendixes cited in this report are provided electronically at http://ahrq.gov/clinic/tp/uteruptp.htm

Table 20. Pregnancy outcomes following myomectomy of various types

Author, Year	Intervention and Length of Followup	Number Attempting Pregnancy	Number Achieving Pregnancy (%)	Number with Miscarriage Among Pregnancies (%)	Number of Births Among Pregnancies (%)	Births to Women Attempting Pregnancy (%)	Number of Cesarean Births Among Births (%)
		Pregnancy Outcomes					
Study Groups with All or Predominantly Spontaneous Conceptions (> 93%)							
Casini et al., 2006[152]	Laparoscopic/ hysteroscopic myomectomy 12-60 months	92	40 (43%)	15 (37%)	NR	NR	NR
Di Gregorio et al., 2002[117]	Laparoscopic myomectomy 12 months	148	61 (41%)	7 (11%)	54 (88%)	36%	45 (83%)
Malzoni et al., 2003[127]	Laparoscopic myomectomy NR	104	26 (25%)	4 (15%)	21 (80%)	20%	12 (57%)
Totals		344	127 (37%)	26 (20%)	75 (86%)	30%	57 (76%)
Study Groups with Mix of Spontaneous Conceptions and Infertility Treatment (≤ 20%)							
Dessolle et al., 2001[116]	Laparoscopic myomectomy > 12 months	103	42 (41%)	6 (14%)	34 (82%)	39%	10 (29%)
Kumakiri et al., 2005[147]	Laparoscopic myomectomy Minimum 6 months; mean 17 months	108	40 (37%)	11/47 (total) (23%)	32/47 (68%)	30%	13 (41%)
Soriano et al., 2003[139]	Laparoscopic myomectomy ≥ 12 months	88	44 (50%)	6 (14%)	34 (77%)	39%	8 (24%)
Soriano et al., 2003[139]	Conversion to abdominal myomectomy ≥ 12 months	18	10 (56%)	3 (30%)	4 (40%)	22%	2 (50%)
Totals		317	136 (43%)	26 (18%)	104 (73%)	33%	33 (32%)
Study Groups with Unknown Mix of Spontaneous Conceptions and Infertility Treatment							
Dubuisson et al., 2000[151]	Laparoscopic myomectomy Annual survey	NR	145	38 (26%)	100 (69%)	NR	42 (42%)
Seracchioli et al., 2000[137]	Abdominal myomectomy ≥ 12 months	59	33 (56%)	4 (12%)	27 (82%)	46%	21 (78%)

NR, not reported.

Table 20. Pregnancy outcomes following myomectomy of various types (continued)

Author, Year	Intervention and Length of Followup	Number Attempting Pregnancy	Number Achieving Pregnancy (%)	Number with Miscarriage Among Pregnancies (%)	Number of Births Among Pregnancies (%)	Births to Women Attempting Pregnancy (%)	Number of Cesarean Births Among Births (%)
		Pregnancy Outcomes					
Seracchioli et al., 2000[137]	Laparoscopic myomectomy ≥ 12 months	56	30 (54%)	6 (20%)	20 (67%)	36%	13 (65%)
Totals		115	63 (55%)	10 (16%)	47 (75%)	41%	34 (72%)
Study Groups with All Receiving Assisted Reproductive Technology Care							
Bulletti et al., 2004[112]	Laparoscopic myomectomy 1 - 3 cycles	84	28 (33%)	8 (29%)	21 (75%)	25%	NR
Surrey et al., 2005[141]	Hysteroscopic myomectomy NR	31	24% cycles	39%	NR	NR	NR
Surrey et al., 2005[141]	Laparoscopic myomectomy NR	29	26% cycles	48%	NR	NR	NR
Totals		144	27.66%	38.66%	75%	25%	NR

Fertility Status. The fertility status of the populations varied widely. One prospective cohort compared women with existing fibroids with those who had had myomectomy before in vitro fertilization and embryo transfer.[112] One retrospective cohort made similar comparisons among six groups of women: those who had hysteroscopic myomectomy with and without donor oocytes, those who had laparoscopic myomectomy with or without donor oocytes, and a comparison group of women without fibroids with and without donor oocytes.[141] The other retrospective cohort included only women with infertility as an indication for surgery; it compared laparoscopic myomectomy outcomes to those of the small group of women whose procedure was converted to an abdominal myomectomy. This study reported modest subsequent use of ART, which indicated potentially less severe fertility impairment.[139] One trial compared myomectomy for unexplained infertility with expectant management among women who did not have ART;[152] another randomized trial investigated different myomectomy methods among women with infertility and did not report use of ART;[137] the remaining four are case series with varied rates of use of ART in their study populations.

Outcomes Measured. The majority of this literature relies on clinical followup, at times with individual contact when records were insufficient. One group conducted annual questionnaires,[151] and several specified prospective followup but did not report how this was accomplished. Overall, loss to followup is minimal (< 5 percent) to modest (5 percent to 10 percent), although completeness of data and details about timing of attempted conception is limited by the nature of clinical records.

Ideally, data about ability to conceive would be reported as cycle- or even day-specific probability of conception, or fecundability, and the investigators would do analyses based on comparison of time-to-event across groups or by characteristics. By definition, rates, such as

pregnancy rates, require documentation of a time period in which the event occurred among a known population. Overall, the poor quality of outcome assessment is a central challenge of interpreting this literature. Other than the ART studies, which reported outcomes for a group average of embryo transfer cycles, no authors reported per-cycle fecundability. Only one conducted a time-to-event analysis, estimating that 60 percent of women would conceive within 2 years.[147]

Several publications reported average time-to-pregnancy as a descriptor and not a focus of the data analysis. These data, however, cannot be equated to fecundability data because we cannot know whether all the elapsed time between the surgical intervention and the pregnancy was associated with cycles in which the women could have conceived or attempted to conceive. Two studies that calculated proportions of women who achieved a pregnancy did not note duration of followup; several reported broad ranges, such as from 12 months to 60 months; and yet others indicated that all participants had a minimum of some fixed time of followup such as 1 year. None adjusted for time attempting conception during or before followup.

Pregnancy Outcomes: Results

Among the three studies, all of fair quality, that included participants or identified a subgroup within the study with predominantly (> 93 percent) spontaneous conceptions (Table 20, first panel), two reported outcomes of laparoscopic myomectomy and one included some proportion of hysteroscopic procedures. In those three studies, the proportions of women attempting to conceive who had a subsequent pregnancy averaged 37 percent (range, 25 percent to 43 percent).[117,127,152] Among spontaneous conceptions, the risk of spontaneous abortion (i.e., miscarriage) was 11 percent, 15 percent, and 37 percent of recognized pregnancies. The proportions of women who achieved a pregnancy and had a live birth in this group of predominantly spontaneous conceptions were 80 percent and 88 percent (not reported in one study). Overall, in this group of studies predominantly reflecting spontaneous conceptions, 20 percent to 36 percent of all women who desired a pregnancy had a live birth.

One study in this group had randomized women with intramural and/or submucous fibroids to receive myomectomy or forego surgery.[152] The investigators reported an increase of more than 15 percent in the proportion of women who achieved a pregnancy among those who had surgery for fibroids with any submucosal component, which is a meaningful, statistically significant improvement. The trend also favored higher numbers of women achieving a pregnancy for intramural fibroids; however, the number of participants was small and the comparison across groups was not significant. This was also the case for comparing miscarriage rates; in each case the miscarriage risk was higher among women without surgery, but the authors did not comment on statistical significance, which was likely not reached given the limited power of this trial.

Among the three studies of fair quality of women who had and who had not had infertility treatment (Table 20, second panel), the proportion of women who achieved pregnancies was 37 percent to 56 percent.[116,139,147] In this subset of studies with a small proportion of women receiving infertility treatment, 40 percent to 82 percent of women who achieved a pregnancy gave birth. Overall, 22 percent to 39 percent of women who desired to conceive after myomectomy were able to conceive and have a live birth. Outcomes were similar to these in the studies that did not specify the proportion of participants who had infertility treatment (Table 20, second and third panels).

Among these studies of fair quality, two compared outcomes by type of myomectomy. Soriano and colleagues compared women who had laparoscopic myomectomy (n = 88) with those who had complications at the time of laparoscopic myomectomy and whose procedure was converted to abdominal myomectomy (n = 18). Noting the small number of conversions, they did not find a statistically significant difference in the proportion of women who became pregnant (50 percent and 56 percent), although time to becoming pregnant was longer by approximately 7 months among those who had a conversion to open procedure ($P < 0.001$).[139]

Seracchiolli and colleagues randomly assigned participants to either abdominal (n = 65) or laparoscopic (n = 66) myomectomy. They reported similar numbers of pregnancy, miscarriage, preterm births, and cesarean birth across study arms; this finding suggests that the choice of method of myomectomy may exert little influence on outcomes.[137]

In the two studies that included exclusively ART patients, one of poor quality[112] and one of fair quality[141] (Table 20, bottom panel), the proportions who achieved a clinical pregnancy were 24 percent to 33 percent, with an overall higher miscarriage risk (29 percent, 39 percent, and 48 percent) than other studies had reported. This finding may relate to the very close surveillance of these embryo transfer pregnancies.

Surrey and colleagues retrospectively compared hysteroscopic and laparoscopic myomectomy in a population of women receiving ART.[141] The method of myomectomy did not have a statistically meaningful influence on outcomes. Moreover, women who had myomectomy had neither better nor worse outcomes than a comparison group of women with no history of fibroids undergoing similar ART procedures.

Maternal age is a strong predictor of reproductive performance, especially in ART research. In this case, the authors did in effect adjust for some components of maternal age and oocyte quality by comparing groups with similar treatments who did and did not have oocyte donation, which would be from young, healthy donors. The findings were comparable for both those using donor eggs and their own.[141] Births are not well reported in these studies, which are oriented toward immediate infertility care outcomes.

Across the other studies with data about route of birth, seven reported on cesarean births; among the women who had had myomectomy, 24 percent of births to 83 percent of births were accomplished by cesarean delivery.[116,117,127,137,139,147,151]The data are insufficient to understand what proportion of these births were planned as cesarean deliveries or resulted from difficulties during labor. Among the 314 births were three documented cases of uterine rupture; two were at the site of a prior cesarean scar and not in the location of the myomectomy scar. Thus, one rupture is properly attributed as related to the myomectomy.

In summary, the literature about pregnancy outcomes after care for fibroids is quite restricted in scope and of overall fair quality; we did not identify any good-quality studies. The majority of research is descriptive, conducted in clinical settings outside the United States, and is especially limited with respect to representativeness of the population, study size, and statistical analysis. The sole clinical trial with evidence comparing surgical intervention to none, without additional ART care, supports a benefit from removing fibroids that have a submucosal component (i.e., those in which the fibroid is immediately adjacent to or distorts the uterine cavity). The benefit reported in that study is substantial (> 15 percent absolute increase in proportion of women becoming pregnant) but limited, by small study size, to reflecting on only ability to conceive.[152] Other outcomes were promising but not significant. Given how common and concerning fibroids are to women and their care providers, this literature will require expansion beyond infertility care with careful attention to design of large-scale prospective cohorts and intervention trials that

shed light on the risks and benefits of intervening with fibroids only for the sake of modifying reproductive outcomes.

Preventing Further Growth: Overview

Despite the widespread use and effectiveness of hormone replacement therapy to reduce symptoms of menopause, clinicians are often hesitant to prescribe hormone therapy to postmenopausal women with fibroids because of the risk of fibroid growth.[58]

Studies, Designs, and Populations. We found five studies (one of good quality,[168] two of fair quality[58,169] and two of poor quality[170,171]) that evaluated the outcomes associated with menopausal hormone therapy (Table 21).[58,169-171]

One of the five studies was an RCT,[170] three were prospective cohorts,[58,168,169] and one was a retrospective case control design.[171]

Three of the five studies were conducted in Italy,[58,169,170] one in Greece,[168] and one in the United States.[171]

Preventing Further Growth: Results

Our findings are reported in Appendix C[*], Evidence Table 11. Four of five studies included only postmenopausal women.[58,168-170] One study evaluated the risk of a first diagnosis of fibroids in peri- and postmenopausal women associated with prior use of estrogen and progestogen therapy.[171] This study reported no statistically significant effects for all women; a subanalysis of women stratified by BMI status, however, demonstrated an increased risk of development of fibroids with prior combined estrogen-progestin therapy among women with a BMI less than 24 (ever-use: OR, 2.3; 95% CI, 1.2-4.3) and hormone therapy use for 5 or more years (OR, 4.0; 95% CI, 1.6-10.3). The remaining four studies reported on size changes.[58,168-170] One study compared an oral cyclic association of oestradiol valerate and cyproterone acetate with a sequential combination of transdermal E2 and orally administered medroxyprogesterone acetate on 240 postmenopausal women with and without uterine myomas. The study demonstrated a higher risk of uterine growth with the percutaneous-oral schedule of hormone replacement therapy than a single oral combination of oestradiol valerate and cyproterone acetate.[170] The three remaining studies did not report significant increases in uterine volume with hormone therapy.

[*] Appendixes cited in this report are provided electronically at http://ahrq.gov/clinic/tp/uteruptp.htm

Table 21. Outcomes of menopausal hormone replacement therapy on uterine or fibroid size

Study, Year	Groups	Length of Treatment	Uterus/Fibroid Size	Additional Measurements
Colacurci et al., 2000[169]	Transdermal oestradiol 0.05 mg/day plus progestogen with reduced androgenic activity (nomegestrol acetate 5 mg) sequentially in all groups G1: Single asymptomatic myoma < 3 cm/14 cm³ G2: Single asymptomatic myoma > 3 cm/14 cm³ G3: Control group, no myomas	1 year	"On the whole the volume of uterine leiomyomas was unchanged or not significantly increased (28.8 ± 30 cm³) during 1-year hormonal treatment without significant differences between groups 1 and 2" (pp. 169-170)	Baseline fibroid size (G1 & G2): 24.14 ± 20.02 cm³
Gregorio et al., 2001[168]	Tibolone 2.5 mg/day Asymptomatic, intramural, or subserous fibroid with diameter ≤ 2 cm G2: Asymptomatic, intramural or subserous fibroid with diameter >2 cm to ≤ 5 cm G3: Women without any detectable fibroids	3 years	No change in fibroid volume, N (%): G1: 21 (91.3) G2: 20 (86.9) Increase in fibroid volume, N (%): G1: 2 (8.7) G2: 3 (13.1) Percent increase in fibroid volume, 12 months: G1: 5.2% G2: 9.2% Percent increase in fibroid volume, 24 months: G1: 6.1% G2: 10.3% *P* not significant, specific values not reported	NR
Palomba, Sena et al., 2001[58]	G1: Transdermal E2 and MPA 2.5 mg/day for 12 cycles of 28 days each for postmenopausal women without fibroids G2: Calcium carbonate for 12 cycles of 28 days each for postmenopausal women with fibroids G3: Transdermal E2 and MPA 2.5 mg/day for 12 cycles of 28 days each for postmenopausal women without fibroids	12 cycles	Uterine size (cm³) after 12 months of treatment: G1: 324.6 ± 104.3 G2: 338.1 ± 96.4 *P* not significant, specific values not reported	Baseline uterine size (cm³): G1: 313.1 ± 83.9 G2: 327.7 ± 89.9 G3: NR

Cm, centimeter; E2, estradiol; G1, G2, G3, group number; MPA, medroxyprogesterone acetate; NA, not applicable; NR, not reported; µg, microgram.

Table 21. Outcomes of menopausal hormone replacement therapy on uterine or fibroid size (continued)

Study, Year	Groups	Length of Treatment	Uterus/Fibroid Size	Additional Measurements
Polatti et al., 2000[170]	G1: Cyclic estradiol/progestin combination for women without fibroids G2: Sequential cyclic E2 50 µg transdermally for 21 days and MPA 10 mg/day orally from day 10-21, followed by a 7-day therapy break for women without fibroids G3: Cyclic estradiol/progestin combination for women with fibroids G4: Sequential cyclic E2 50 µg transdermally for 21 days and MPA 10 mg/day orally from day 10-21, followed by a 7-day therapy break for women with fibroids	24 months	Fibroid volume (cm^3): G1: No new uterine formation G2: 5% of cases after 24 months of treatment G3: Fibroid volumes increased by 3.2% after 12 months of treatment and remained virtually unchanged after 24 months (4.8%) (*P* not significant for difference between baseline and followup [12 or 24 months]) G4: Mean increase in fibroid size of 23.3% and 25.3% after 12 and 24 months of treatment, respectively. *P* < 0.01	Baseline fibroid size (cm^3): G1: N/A G2: N/A G3: 18.6 ± 1.4 G4: 19.3 ± 1.3
Reed et al., 2004[171]	Peri- and postmenopausal combined estrogen-progestin therapy G1: Single asymptomatic myoma < 3 cm/14 cm^3 G2: Single asymptomatic myoma > 3 cm/14 cm^3 G3: Control group, no myomas	NA, retrospective case control	NA, main outcome is first fibroid diagnosis	No significant association found between length of hormone use and onset of first fibroid diagnosis for all women Ever-use and use of hormone therapy for 5 years or more significant only for women with low BMI

KQ 4: Costs of Fibroid Treatment

The prior review used multiple sources (2000 "Red Book" of wholesale drug prices, published literature on hospital costs for surgical management of uterine fibroids, primary data from the Nationwide Inpatient Sample, and primary data from Duke University Medical Center) but nevertheless concluded that "most administrative data sources do not provide sufficient clinical detail to allow comparison between procedures."[30(p98)] We, too, found only very limited evidence on the cost of treating uterine fibroids. We identified three studies on this topic (Table 22), all of poor quality; two examined costs from a hospital perspective[172,173] and one used an insurance claims database evaluation.[140] Detailed information for these studies appears in Evidence Table 12 in Appendix C[*].

[*] Appendixes cited in this report are provided electronically at http://ahrq.gov/clinic/tp/uteruptp.htm

Table 22. Costs of treatment for uterine fibroids

Study	Treatment	N	Type of Cost	Cost and Cost Denomination	Setting
Beinfeld et al., 2004[173]	UAE Hysterectomy	58 306	Hospital costs and physician fees	$8,223 $6,406 U.S.$ (1999)	Massachusetts General Hospital
Baker et al., 2002[172]	UAE Myomectomy	23 17	Hospital costs plus professional costs plus average imaging costs	$6,708 $7,630 U.S.$ (2000)	Georgetown University Hospital
Subramanian et al., 2001[140]	Hysteroscopic myomectomy	Inpatient: 49 Outpatient: 764	Facility plus professional costs	Inpatient: $7,704 Outpatient: $4,291 U.S.$ (1997)	Marketscan database: inpatient and outpatient insurance claims
	Laparoscopic myomectomy	Inpatient: 24 Outpatient: 323		Inpatient: $8,018 Outpatient: $7,357	
	Abdominal myomectomy	Inpatient: 1,400 Outpatient: NA		Inpatient: $8,860 Outpatient: NA	

NA, not applicable; UAE, uterine artery embolization; U.S., United States

One study compared 23 UAE patients with 17 myomectomy patients from Georgetown University Hospital.[172] The UAE sample was significantly older on average (42.65 years) than the myomectomy sample (35.5 years) ($P < 0.001$). On average, the hospital, professional, and imaging costs were $6,708 for UAE and $7,630 for myomectomy. The authors attributed differences in costs to higher hospital care and operating room costs for myomectomy even though UAE had much higher professional costs, $2,220 for UAE and $1,611 for myomectomy ($P = 0.002$). Overall, the authors found a trend for UAE to be the least expensive option, but the difference was not significant ($P = 0.086$).

The second hospital-based study was a retrospective comparison of UAE with hysterectomy.[173] Women who were treated with UAE were significantly younger (43.1 vs. 47.0 years; $P < 0.001$) and less likely to be white (69.6 percent vs. 77.0 percent; $P = 0.01$), had bigger fibroids (8.0 cm vs. 6.3 cm in diameter; $P = 0.001$), and had more fibroids (2.8 vs. 2.0; $P < 0.001$). The mean total hospital costs were significantly different for the two modalities—$8,223 for UAE and $6,406 for hysterectomy ($P < 0.0001$)—even though UAE had a significantly shorter length of stay than hysterectomy (0.95 days vs. 2.6 days; $P < 0.0001$).

The third study performed a retrospective database analysis of the costs involved in different types of myomectomies.[140] The study measured facility and professional costs of inpatient and outpatient procedures. The authors found that outpatient hysteroscopic myomectomy ($4,291) was less than half the cost of inpatient abdominal myomectomy ($8,860). They also found that, because of repeated procedures (at the rate of about 16.5 percent over 2 years), the mean overall cost rose from $6,737 for the initial procedure to a mean of $8,001 at 2 years for the repeat procedure.

Chapter 4 discusses the findings for each of the KQs presented in Chapter 3. We also provide a further analysis of these findings responding to KQ 5 on modifiers, KQ 6 on comparisons, and KQ 7 on variations in treatment.

Chapter 4. Discussion

This chapter first discusses our findings for four key questions (KQs) relating to incidence and prevalence of uterine fibroids, outcomes of treatment for symptoms, outcomes of treatment for other reasons, and costs of treatment of uterine fibroids. We then address KQ 5, summarizing the effect of modifiers on outcomes, KQ 6, on comparisons between treatments, and KQ 7, on variation in treatment.

We note in this discussion both the quality of individual studies (good, fair, or poor, as explained in Chapter 2) and the strength of the evidence for each question or subquestion (also described in Chapter 2). To reiterate the strength grades, the levels of strength of evidence are as follows:

I. Strong: The evidence is from studies of strong design; results are both clinically important and consistent with minor exceptions at most; results are free from serious doubts about generalizability, bias, or flaws in research design. Studies with negative results have sufficiently large samples to have adequate statistical power.

II. Moderate: The evidence is from studies of strong design, but some uncertainty remains because of inconsistencies or concern about generalizability, bias, research design flaws, or adequate sample size. Alternatively, the evidence is consistent but derives from studies of weaker design.

III. Weak: The evidence is from a limited number of studies of weaker design. Studies with strong design either have not been done or are inconclusive.

IV. No evidence: No published literature.

We conclude with a discussion of the limitations of this review and the evidence base, and we present our recommendations for future research.

Principal Findings

KQ 1: Incidence and Prevalence of Uterine Fibroids

Two studies, both of fair quality, provided weak evidence (Level III) on the incidence of uterine fibroids. One reported on incidence among black women alone and relied primarily on self-report of ultrasound- or hysterectomy-confirmed diagnosis of uterine fibroids.[41] Although self-reports are likely to be accurate, this study very probably underestimates, perhaps to a considerable degree, the incidence of uterine fibroids because it was not based on ultrasound evidence for all women (diagnosed or undiagnosed). The second study relied primarily on ultrasound-confirmed diagnosis of a random sample of women.[2] The results suggested cumulative incidence rates by age 50 of nearly 70 percent among white women and more than 80 percent among black women. Black women had earlier onset, and more and larger fibroids, than white women. Black women were more likely to have fibroids than white women, even after controlling for body mass index (BMI) and parity.[2] Additionally, women who were young at

menarche, had no children, or had not had a child within the previous 5 years were more likely to have uterine fibroids.[41]

The estimate of cumulative incidence of 70 percent to 80 percent suggests that the vast majority of women will experience uterine fibroids during their lifetimes. Given such high levels of cumulative incidence, the absence of evidence on the proportion of women with uterine fibroids is striking. Currently, the literature provides no guidance on the overall burden of disease posed by uterine fibroids.

KQ 2: Outcomes of Treatment of Uterine Fibroids for Symptoms

Expectant Management. Evidence is lacking (Level IV) to address the subquestion about likely outcomes of expectant management. We identified no literature to document the natural history of uterine fibroid incidence, growth, symptomatology, use of clinical care, or outcomes when women choose watchful waiting over intervention.

Solely as a weak surrogate, we summarized the limited information about outcomes among women who received no intervention, or vitamin supplementation only, in 12 clinical trials and one retrospective clinical comparison group. None had been designed to assess expectant management. The quality of the identified literature for informing this question was poor, and all but one study reflected European populations recruited at specialized fibroid care centers.

Three sets of investigators used imaging to measure fibroids in three small samples (N = 22, 31, and 60) of premenopausal women.[44,46,55] They followed up these women at 2 months to 3 months and documented no clinically meaningful or statistically significant changes in fibroid size as assessed by ultrasound in untreated women. Given that these studies were conducted among women awaiting surgery, this finding suggests an absence of rapid growth even among women in a highly symptomatic population. Another study reported that bleeding severity, pelvic pain, and pressure did not appreciably change in 2 months. The longest followup that addressed symptoms was 6 months, during which severity of bleeding, length of bleeding with menses, and hemoglobin levels remained unchanged.

These results have quite limited implications for clinical care; they provide minimal evidence that, at least among premenopausal women with symptoms, their condition and fibroid characteristics are not likely to change rapidly. This information, with the caveats noted, could be interpreted to mean that decisions about fibroid management do not need to be made with great urgency. Such findings also suggest that some number of months are available in which both women and their clinicians can consider options, continue watchful waiting, and treat discrete symptoms such as pain, with low risk of exacerbation of the condition.

The remaining studies, in postmenopausal women, were done to assess the influence of pharmaceutical agents on fibroids, with the goal of assessing whether use of these medications for menopausal symptoms or to treat other conditions (e.g., bone mineral density) would exacerbate fibroids. The untreated groups were followed for up to a year. The notable finding in the area of expectant management is that these women had little change in fibroid size.

Clinical wisdom reflects a general belief that fibroids undergo involution, or shrinking, after menopause. These findings raise the question about whether and in what circumstances that is the case. The data are poor for asserting the absence of involution for two reasons: (1) the studies had not been designed to assess the natural history of fibroids after menopause and (2) they represented only a cross-sectional sample of women at varied times after menopause and with a broad range of baseline fibroid characteristics that may influence the results observed.

These studies offer two preliminary impressions: (1) fibroids do not have a continuous slow growth pattern before menopause, and (2) after menopause, a decrease in size may not be as profound as believed. Nonetheless, we emphasize that these studies do not provide appropriate information about the growth trajectory or biological behavior of fibroids across the lifespan. The study populations are small, even for the purposes of preliminary descriptive data, and the research was not intended to assess changes in fibroids or related symptoms. In summary, we identified no evidence of sufficient quality to inform the decision to pursue expectant management of uterine fibroids.

Pharmaceutical Management. Although several new randomized controlled trials (RCTs) have been published since the prior review in 2001,[30] together they provide moderate to weak evidence about the use of pharmaceutical management on fibroid growth and symptom relief.

Gonadotropin-Releasing Hormone (GnRH) Agonists. Of the 19 studies that we reviewed for pharmaceutical management of fibroids,[42-46,49-56,59-69] 13 addressed the effect of GnRH agonists.[42-45,49,51-55,59-64,69] Of these, eight reported on uterine and fibroid size changes in response to GnRH agonists.[42-45,55,61,63,64] These studies together provided moderate evidence (Level II) that GnRH agonists were effective in decreasing overall uterine size when used either as preoperative treatment or as an alternative to surgery. A subset of these GnRH agonist studies (six studies) on hemoglobin levels provided weak evidence of increases in hemoglobin levels by 0.9 g/dL to 5.2 g/dL after treatment and before surgery.[42,55,59,61-63] The results were statistically significant in two of these studies.[55,59,63]

Three studies provided weak evidence (Level III) on the effect of GnRH agonists on symptom relief. One study reported evidence from a single small nonrandomized study of relief from hot flashes from tibolone.[61] The other two studies together provided no evidence of the effectiveness of raloxifene for dealing with symptomatology alone.[51-54,56]

One study found weak evidence (Level III) that adding raloxifene to leuprolide therapy improves bone mineral density.[51] Two studies compared the effects of leuprolide plus supplemental therapy (ipriflavone or raloxifene) to leuprolide alone on low-density lipoprotein cholesterol (LDL).[51-54,60] The studies found weak evidence (Level III) that levels of LDL increased after therapy for both groups, but leuprolide-only groups had significantly higher levels of LDL than did groups receiving leuprolide plus supplemental therapy.

Progestins. A single small RCT presented weak evidence (Level III) of reduction in fibroid size among women receiving lynestrenol compared with women receiving leuprolide acetate.[62]

Mifepristone. The literature provided weak evidence (Level III) comparing two different doses of mifepristone. The single study reported significant reductions in uterine volume and menstrual blood loss from baseline values in both groups but no differences between the groups.[65]

Estrogen Receptor Modulators and Antagonists. Three studies[50,56,67] provided weak evidence (Level III) from trials comparing raloxifene with placebo: two reported a significant reduction in uterine and fibroid size compared with baseline values for postmenopausal women on raloxifene and an increase in uterine and fibroid size for premenopausal women on raloxifene.[50,56]

Uterine Artery Embolization (UAE). Twenty-four studies examined short- and long-term outcomes following UAE.[70-100] Of these, six studies provided evidence on comparisons between UAE and either hysterectomy or myomectomy.[70,73,75,76,90,94]

The comparative studies yielded evidence of moderate strength (Level II) suggesting shorter procedure (operative) times and shorter lengths of hospital stay for UAE than for hysterectomy or myomectomy. However, we found only weak evidence (Level III), either no significant

differences or inconsistent direction of effect, concerning the impact of UAE on complications and symptom relief.

Studies of UAE alone were generally case series or cohort studies, of poor or fair quality, ranging from a sample size of 46 to 3,140. They do not provide consistent definitions or time points for measuring key outcomes such as complications. Outcomes included all complications, major and minor complications, perioperative complications, or at least one adverse event; these outcomes are reported from points varying from within the hospital to a 2-year followup window.

The largest of these studies reported an in-hospital complication rate of 2.7 percent, of which 0.6 percent was for major events, and a postdischarge complication rate of 26.1 percent, of which 4.1 percent was for major events.[100]

Very few studies reported the rate of subsequent interventions in the long term; of these, only one compared the rate of subsequent interventions between UAE and another procedure. This study reported statistically significant higher rates of subsequent interventions for UAE than for myomectomy (29 percent versus 3 percent, in a follow-up period ranging from 3 to 5 years).[70] Another study reported a subsequent intervention rate of 20 percent at 5 years.[93] The lack of comparable data for other types of treatment limits the value of this information.

Since the formal compilation of this review, the REST trial of Embolization versus Surgical Management was published comparing outcomes for 106 women randomly assigned to UAE compared to surgery (43 hysterectomies and 8 myomectomies). This trial of good quality was designed to evaluate health-related quality of life at 1 year using the Medical Outcomes Study 36-item Short Form General Health Survey. The investigators found no differences between groups in health-related quality of life. UAE patients had shorter hospital stays (1 day compared to 5) and returned to work sooner. At 1 year, symptom scores were superior in the surgical intervention group although the majority of UAE (88 percent) and surgical (93 percent) patients would recommend the treatment they received to a friend. Fifteen and 20 percent of the groups, respectively, had major complications. Twenty percent of women who had UAE subsequently had additional procedures, the majority hysterectomies. Among adverse outcomes were two women who had a hysterectomy immediately due to technical failure of the UAE and one conversion in the operative group, of a myomectomy to an emergency hysterectomy.[174]

REST reinforces the general impression of the data in the review: Uterine artery embolization offers documented symptom improvement and a more rapid recovery trajectory. For the majority of women the procedure provides sufficient relief of symptoms that they do not pursue additional intervention. However, more than one in five women who have UAE are likely to seek additional management of their fibroids in the years immediately after UAE. This is important for women and their care providers to understand as is the small but consistently documented risk that women who choose uterus-conserving therapy may have hysterectomy as a complication of either UAE or myomectomy.

Endometrial Ablation. The strength of evidence on endometrial ablation, which is used to treat bleeding symptoms, is weak (Levels III). We found only three studies, all of poor quality. Of these, two combined ablation with hysteroscopic resection (retrospective case series) and one (prospective case series) evaluated ablation only. Operative and longer-term outcomes are poorly documented in each of these publications, such that across the studies they lack enough common data elements to permit any substantive summary of findings. In this and other areas lacking sufficient evidence, it is important to note that absence of evidence is equated not with absence of benefit but rather with lack of data to properly estimate benefit (if any) and potential risks. In

these areas women and their health care providers lack meaningful information to guide treatment decisions.

Magnetic Resonance Imaging (MRI) Guided Focused Ultrasound. The strength of evidence about MRI-guided ultrasound ablation of fibroids is weak (Level III). The literature included one carefully conducted prospective case series (N = 109), but it nonetheless ranks as poor for informing clinical decisionmaking. This work had been conducted to support an application for approval from the U.S. Food and Drug Administration (FDA, given in 2004) of the system designed to conduct MRI-guided ultrasound.

Overall, women tolerated the procedure well. Sixteen percent of women reported severe pain at some point during the treatment, but few reported residual pain immediately after it was completed. Patient-reported outcomes were gathered using validated measures; 71 percent of women reported a 10-point or greater improvement on a quality-of-life measure. The investigators also documented improvements in bleeding and pressure. However, the change in fibroid size was modest (13 percent decrease), and 11 percent of women met criteria for treatment failure defined by worsening of symptoms, with 28 percent electing further treatment by other modalities including myomectomy and hysterectomy.

Clinicians need to consider carefully the reality that, now that the systems are in use, care providers are using this new modality to treat fibroids more aggressively than had been allowed during the strict study protocol. The major change in how the systems are now being used is that a greater proportion of the total volume of the fibroid is treated. Therefore, no information exists at present that reflects *current* practice in terms of procedure-related risks and anticipated outcomes.

Myomectomy. The quality of the evidence to guide decisions about myomectomy for management of uterine fibroids is poor to fair, with limited strength (Level III) because of the dominance of weak study designs, the restricted scope of outcomes studied, and the limited quality of measurements even in the few studies of stronger design. We identified 44 publications that represent 39 distinct study populations;[70,73,90,102,108-148] these included 24 case series studies, of which six were prospective; eight cohort studies that compared outcomes across two or more types of myomectomy, of which three were prospective; and five RCTs, of which two compared interventions to reduce blood loss, not broader outcomes of myomectomy.

Short-term outcomes were most robust for immediate measures of operative outcomes (blood loss, length of surgery) and for longer-term outcomes reflecting subsequent care received and fibroid recurrence. Few studies addressed resolution of symptoms, quality of life, sexual function, or satisfaction with treatment outcomes; those that do report such measures did not describe use of validated measures. We summarize here the main findings by type of myomectomy (abdominal, laparoscopic, laparoscopically assisted, and hysteroscopic).

Abdominal Myomectomy. The abdominal myomectomy literature consisted of studies of small to modest size, meaning that they generally lacked precision about risk.[90,113,121,122,128,133,136-138,140,144,146,148] For instance, transfusion risk varied widely, from < 1 percent to 21 percent, with higher risk in studies in less specialized surgical settings. A single small trial of good quality reported promising results for using a "chemical aid for dissection" in reducing blood loss and operative time.[146] Across studies 3 percent to 4 percent of women required intraoperative conversion to hysterectomy although myomectomy had originally been intended. Wound healing complications affected 2 percent to 4 percent of women having this form of myomectomy.

When the investigators studied improvement in symptoms, women did report improvements in symptoms for which they sought care, although improvements were not universal: 68 percent

reported “improved symptoms”; 64 percent reported “completely” or “significantly” improved menorrhagia; 54 percent reported improved pain; and 91 percent reported resolution of mass effects.

Only one study with 30 participants provided any data about satisfaction, with 69 percent finding their results satisfactory.[70] Recurrence of fibroids, when defined by identification of new fibroids through imaging, likely affected more than 18 percent of women and may be as high as 62 percent within 3 to 4 years after surgery. Between 1.4 percent and 17 percent of women have additional surgery after myomectomy, but we found only limited information to describe what proportion of these procedures were hysterectomy or another myomectomy.

The nature and strength of this evidence mean that it cannot be used to compare expected outcomes of abdominal myomectomy with those of other types of myomectomy. However, this literature does provide some cautionary data. Women and their surgeons should explicitly discuss risk of transfusion, conversion to hysterectomy, and wound healing complications; although the estimates that might be taken from this body of evidence are imprecise, they indicate that the risks are not negligible. Likewise, when symptoms are attributed to fibroids, a common belief among those seeking treatment is that their removal is a virtual guarantee of resolution of symptoms. Although the majority of women have improvements (poorly measured), that proportion is not likely to be as high as the 8 or 9 of 10 women undergoing this surgery. In the absence of higher quality research, women may still wish to weigh the information that likelihood of complete resolution of symptoms or complete satisfaction is meaningfully less than universal. Clinicians should also share information that emphasizes that myomectomy does not preclude continued appearance of new fibroids and that it is likely that more than 15 percent of women will have recurrence, some of whom will choose additional surgery in the years after myomectomy.

Laparoscopic Myomectomy. With respect to risks, and with the same caveats about study size, design, and generalizability that apply to the entire body of myomectomy literature, summaries of risks from 16 studies offer context for clinical decisionmaking.[115-117,119,121,125,127,128,134,137-140,145] Transfusion ranged from < 1 percent to 8 percent; a single study provided direct comparison between abdominal and laparoscopic myomectomy, reporting statistically significant lower risk among those having laparoscopic procedures. Conversion to open procedures occurred in approximately 9 percent of women, with a range from < 1 percent to 29 percent, among which a small proportion goes to immediate hysterectomy. The less specialized the surgical setting, the more likely conversion appears. Women and their care providers should anticipate a conversion rate of 10 percent or higher when discussing likely outcomes of laparoscopic myomectomy and planning for postoperative recovery. When investigators did make direct comparisons, length of stay in the hospital was shorter after laparoscopy than abdominal procedures, and wound healing complications were rare.

Satisfaction with outcomes and resolution of specific symptoms was poorly studied after laparoscopic procedures. Most of the research emphasized technical and process outcomes, not providing data about how well surgery addressed the key indications for which women elected to have these procedures in the first place. Recurrence of fibroids ranged from 13 percent to 27 percent, and 7 percent to 12 percent of women had additional surgery during the first few years after myomectomy. Although these postoperative risks appear similar to those for abdominal myomectomy, and biologically would be expected to be similar, we found no direct comparisons with power adequate to declare them comparable. The same observations apply about the sole

use of these data being cautionary information to provide rough estimates for counseling about probable risks.

Hysteroscopic Myomectomy. Across five studies with 2,061 participants, we found little detail about operative complexity and complications such as transfusions.[108-110,130,132,140,154] The risk of perforations of the uterus, reported in two studies, was consistent with the often clinically cited rate of 1 in 100. Some proportion of resections will be incomplete (13 percent to 18 percent); conversions to abdominal myomectomy (7 percent) and hysterectomy (1 percent) do happen. Repeat procedures and subsequent surgery affect approximately 2 percent to 20 percent of women who are followed for the years immediately after hysteroscopic myomectomy. Because hysteroscopic interventions are generally outpatient procedures and associated with rapid return to usual activities, the limited data available suggest that the majority of women who have fibroids amenable to hysteroscopic intervention (> 80 percent) may achieve good outcomes without resorting to more complex and costly procedures that also have a longer recovery time.

Hysterectomy. A limited number of studies of poor and fair quality provided weak evidence (Level III) on outcomes of hysterectomy, comparisons of types of hysterectomy, and modifiers of hysterectomy.

Outcomes. The literature on hysterectomy is limited largely to short-term outcomes. Most of the studies reporting on comparative studies of hysterectomy did not have sufficient sample sizes to derive estimates of risks of individual operative or postoperative complications. A single study based on large case-series data reported severe operative and postoperative complications up to 6 weeks following surgery,[162] but the time frame (1994-1995) and location of the study (United Kingdom) make generalizations to current U.S.-based practice uncertain.

Long-term outcomes are similarly limited to small studies of comparisons between treatments. These studies together did not have sufficient sample size to derive reliable estimates of long-term outcomes. The few studies that reported long-term outcomes examined a mix of variables, including comparisons of ovarian function 6 months following UAE and hysterectomy;[75] comparisons of symptoms, quality of life, satisfaction, pain, and overall health 12 months following UAE and hysterectomy;[94] and rates of myocardial infarction several years following hysterectomy.[159] These studies did not yield sufficiently consistent or statistically significant variables to comment on long-term outcomes following hysterectomy within the first 12 months following the procedure. We found no evidence on quality of life or health outcomes beyond the first 12 months following hysterectomy.

Comparisons of Types of Hysterectomy. Studies comparing hysterectomy with UAE or myomectomy or comparing different types of hysterectomy all reported primarily on short-term outcomes. They were not powered to estimate rates of individual perioperative complications. From a small set of underpowered studies, the direction of effect suggested better outcomes on a limited range of perioperative measures (of which length of hospital stay has the most consistent direction and significance of effect) for vaginal hysterectomy and laparoscopically assisted vaginal hysterectomy (LAVH) compared with abdominal hysterectomy and for vaginal hysterectomy compared with LAVH.

All three studies that reported on vaginal versus abdominal hysterectomy focused on perioperative outcomes.[155,161,166] They consistently reported significantly longer hospital stays with abdominal hysterectomy. Other perioperative outcomes occurred with higher frequency among the abdominal hysterectomy group, with significantly higher risk of ileus reported in one study,[161] and significantly higher rates of postoperative outcomes (postoperative transfusion, pelvic hematoma, reoperation, febrile morbidity, and other complications) in another study.[166]

The interpretation of these results remains unclear. The studies were not powered to test differences in the occurrence of rare perioperative outcomes. Two of the three studies were not randomized trials; because they did not account for potential differences in baseline fibroid size, selection bias could have potentially influenced outcomes for these two groups.

The two studies reporting on LAVH and abdominal hysterectomy[160,165]demonstrated improved outcomes for LAVH on a limited set of perioperative outcomes, namely hospital stay, convalescence, and use of analgesia. These studies were not powered to test differences in perioperative complications: one of the studies noted that the absence of statistically significant differences for wound infection could be attributed to insufficient sample size.[165]

The only study reporting outcomes on the comparison between LAVH and vaginal hysterectomy reported significantly worse outcomes for LAVH for hospital stay and total perioperative complications.[156,157] Again, the evidence is limited to perioperative outcomes, and the sample size is underpowered to test for differences in individual perioperative complications.

Modifiers of Hysterectomy. We also reviewed the literature for modifiers of hysterectomy outcomes; we sought information on age, race or ethnicity, parity, breastfeeding, contraceptive choices, body habitus, insulin resistance, concurrent medical conditions such diabetes, and hormone replacement status. We found no evidence at all for these variables. We found some evidence of effect of uterine weight and certain procedures on hysterectomy outcomes, described below.

Two studies found worse outcomes with larger uterine weight.[160,167] Three studies comparing interventions to reduce postoperative blood loss and improve postoperative hemoglobin found some evidence of effectiveness on an inconsistent group of outcomes such as operating time and number of ligations for bipolar electrocautery scissors compared with conventional scissors,[158] estimated blood losses for vasopressin compared with placebo,[163] and hemoglobin levels and rates of blood transfusion for preoperative therapy of recombinant human erythropoietin plus iron compared with iron alone.[47]

Complementary and Alternative Medicine. A single study of poor quality compared traditional Chinese medicine with standard medical management (progestational agents, oral contraceptives, or nonsteroidal anti-inflammatory drugs).[48] The investigator reported significantly smaller fibroid size, greater proportion of women improved, and greater satisfaction with their treatment among women in the traditional Chinese arm. As noted in Chapter 3, the author reported potential biases from the differences in degree of motivation between the two groups. Therefore, we consider the available evidence to be weak (Level III).

KQ 3: Outcomes of Treatment of Uterine Fibroids for Other Reasons

In clinical care, women are often advised to consider surgical intervention for fibroids to achieve the goals delineated in this KQ: (a) to improve fertility; (b) to reduce adverse pregnancy outcomes; (c) to prevent further growth; or (d) to rule out uterine malignancy. For the last two of these indications, there is no recent evidence. Prior reviews have suggested that surgery is not required for ruling out malignancy.[30] However, as emphasized in KQ 1, little evidence is available about the incidence and prevalence of uterine fibroids and even less about the natural history of how fibroids change over time. Our evidence review team is not aware of any publications that would allow projection of risk that a particular fibroid will grow.

Pregnancy Outcomes. The strength of the evidence is weak (Level III) about interventions intended to improve ability to conceive and have a successful pregnancy. The 16 studies we

identified studied pregnancy after myomectomy and were of fair to poor quality with the exception of a single clinical trial of good quality. This body of literature comprised predominantly case series and retrospective analyses. The majority of research is descriptive with no additional statistical analysis, conducted in clinical settings outside the United States, and focused on women with known infertility who conceived after specialized fertility care. The sole clinical trial with evidence comparing surgical intervention to none, without additional assisted reproductive technology care, supports benefit from removing fibroids that have a submucosal component (i.e., those in which the fibroid is immediately adjacent to or distorts the uterine cavity). The benefit reported was substantial (> 15 percent absolute increase in proportion of women becoming pregnant); however, the work is limited, by small study size, to reflecting only on ability to conceive and not other pregnancy outcomes. The group of studies identified was insufficient to assess risk of complications at the time of birth that could be related to myomectomy; uterine rupture was rare in these studies. The designs, populations, and documentation of methods (as well as failure to document) for these studies were so divergent that pooled analyses of the observational studies is inappropriate. However, even if all studies could be combined, they would be underpowered to estimate risk accurately. Virtually all studies that summarized cesarean rates documented rates above the national average in the United States (which is rising); however, these study populations received care in European settings and Japan, and this information cannot be meaningfully interpreted.

In summary, women with fibroids who hope to have a pregnancy soon or in the future are faced with difficult decisions about whether, and in what circumstances, to seek care for fibroids. When an exposure is common, such as fibroids, and distressing events are also common, such as difficulty conceiving or miscarriage, there is substantial risk of assuming a direct causal association that may be unwarranted; such assumptions call for careful investigation. Current research is meager for assisting women who do not have known fertility impairment in assessing the risks and benefits of intervention. Additional research in representative U.S. populations is essential.

Preventing Further Growth. We found no evidence on the effects of treatment to prevent further fibroid growth. However, concerns about further growth of fibroids after menopause limit the use of hormone replacement therapy to treat postmenopausal symptoms. We found five studies that provide moderate evidence (Level III) on the effects of menopausal hormone therapy on uterine fibroids. One study reports higher risks of first diagnosis of fibroids in peri- and postmenopausal women with a body mass index (BMI) less than 24 and 5 years or more of estrogen and progestogen therapy. Three of four studies reported no effect on fibroid size; one reported a higher rate of uterine growth with the percutaneous-oral schedule of hormone replacement therapy than with a single oral combination of oestradiol valerate and cyproterone acetate.

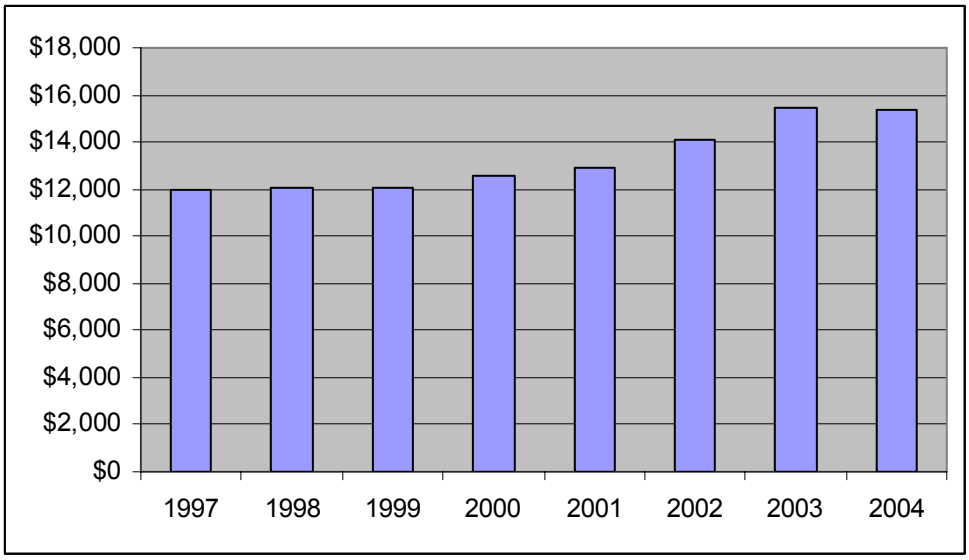
KQ 4: Costs of Fibroid Treatment

The literature is limited in its evaluation of costs of the treatment of uterine fibroids. Included studies are retrospective in design and may not record all costs, inputs are heterogeneous, and sample sizes are very small. Studies from a single institution are necessarily limited in their generalizability, and insurance claims data are limited in their completeness. Two studies report on UAE costs and costs of other interventions. One compared the hospital, professional, and imaging costs for 23 UAE patients ($6,708 on average) with the same costs for 17 myomectomy

patients ($7,630 on average);[172] the other compared total hospital costs for 58 UAE patients ($8,223 per patient) and 306 hysterectomy patients ($6,406 per patient).[173] A third study reported on facility and professional costs of inpatient and outpatient abdominal myomectomy.[140] The investigators reported that outpatient hysteroscopic myomectomy per patient ($4,291) was less than half the cost of inpatient abdominal myomectomy per patient ($8,860). They also found that, because of repeated procedures (at the rate of about 16.5 percent over 2 years), the mean overall cost rose from $6,737 for the initial procedure to a mean of $8,001 at 2 years for the repeat procedure.

In an attempt to estimate changes in the costs of treating uterine fibroids, we analyzed Healthcare Cost and Utilization Project (HCUP) data. As part of the HCUP's family of databases, the National Inpatient Sample (NIS) presents detailed information on individual inpatient visits, including diagnoses and procedures utilized. Figure 3 illustrates the rising costs of treating women with uterine fibroids, specifically those admitted with uterine fibroids as a primary diagnosis; we adjusted the figures to 2004 dollars. The average cost of uterine fibroid treatment increased by almost 30 percent between 1997 and 2004. In 1997, the average inpatient costs were $11,978; by 2004 the average costs had risen to $15,405. During the same period, the average length of stay dropped from 2.9 days to 2.6 days.

Figure 3. Average inpatient costs for treatment of uterine fibroids, by year



The source of increase in costs is unclear. Possible explanations include higher professional costs with procedures such as UAE and overall increase in health care costs relative to other costs. We found no information comparing average costs of procedural interventions with pharmaceutical treatments.

KQ 5: Modifiers of Outcomes

KQ 5 asks about the short- and long-term outcomes of these treatment approaches (including risk of fibroid recurrence), modified by age, race or ethnicity, parity, breastfeeding, contraceptive choices, body habitus, insulin resistance, concurrent medical conditions such as diabetes, hormone replacement status, or other factors. Despite the relatively large number of studies

reporting on modifiers of outcomes of treatment for fibroids (Table 23 to Table 26 below and Evidence Table 13 in Appendix C[*]), the wide range of modifiers and outcomes and the limited number of studies make the summative assessment of each modifier extremely challenging. In Chapter 3, we addressed each intervention and reported on modifiers of each intervention. In this section, we report all included evidence for each modifier. We note the specific relationship between modifier, intervention, and outcome within the table, and discuss overall issues of modifiers below.

In Chapter 1, we presented a summary of risk factors for uterine fibroids. Few of the studies evaluated in this review address the modifying effects of these risk factors on the treatment of uterine fibroids. Many studies focus on patient demographics and fibroid characteristics as modifiers of fibroid treatment. Comparatively fewer studies address patient health characteristics or provider characteristics as modifiers of outcomes.

Table 23. Patient demographics as modifiers of outcomes of fibroid treatment

Modifier	Author, Year	Intervention	Outcome	Direction of Effect
Age	McLucas et al., 2001[80]	UAE	UAE failure	No association between age and UAE failure
	Kumakiri et al., 2005[147]	Laparoscopic myomectomy	Pregnancy success	Pregnancy success is negatively correlated with age at myomectomy
	Spies, Ascher et al., 2001[92] Spies, Roth et al., 2002,[96] Spies, Bruno et al., 2005[93]	UAE	Satisfaction with outcomes	No association between age and satisfaction
Race/ethnicity	Spies, Ascher et al., 2001[92] Spies, Roth et al., 2002,[96] Spies, Bruno et al., 2005[93]	UAE	Satisfaction with outcomes	No association between race and satisfaction
	Worthington-Kirsch et al., 2005[100]	UAE	Risk of adverse events by 30 days following procedure	Black women are more likely than other women to have an adverse event
Parity	Doridot et al., 2001[118]	Laparoscopic myomectomy	Fibroid recurrence	Nulliparity is significantly associated with a higher risk of recurrence
	Hanafi et al., 2005[123]	Myomectomy	Fibroid recurrence	Subsequent parity is significantly associated with reduced recurrence
	McLucas et al., 2001[80]	UAE	UAE failure	No association between parity and UAE failure

UAE, uterine artery embolization.

[*] Appendixes cited in this report are provided electronically at http://ahrq.gov/clinic/tp/uteruptp.htm

Table 24. Health status characteristics as modifiers of outcomes of fibroid treatment

Modifier	Author, Year	Intervention	Outcome	Direction of Effect
Menopausal status	McLucas et al., 2001[80]	UAE	UAE failure	No association between menopausal status and UAE failure
BMI	Roth et al., 2003[136]	Abdominal myomectomy	Complications and transfusions	No association between BMI and complications and transfusions
Prior surgery/ surgical pathology	Huang et al., 2006[77]	UAE	UAE failure	Prior myomectomy significantly increases the risk of UAE failure
	McLucas et al., 2001[80]	UAE	UAE failure	Earlier pelvic surgery significantly associated with likelihood of UAE failure
	Roth et al., 2003[136]	Abdominal myomectomy	Complications and transfusions	No association between prior abdominal surgery or adhesion and complications and transfusions
	Worthington-Kirsch et al., 2005[100]	UAE	Risk of adverse events by 30 days following procedure	Prior procedures significantly predict the risk of an adverse event
Smoking status	Worthington-Kirsch et al., 2005[100]	UAE	Risk of adverse events by 30 days following procedure	Smoking status significantly predicts the risk of an adverse event
Medical conditions	Roth et al., 2003[136]	Abdominal myomectomy	Complications and transfusions	Comorbidities significantly predict complications and transfusions

BMI, body mass index; UAE, uterine artery embolization.

Table 25. Uterine and fibroid characteristics as modifiers of outcomes of fibroid treatment

Modifier	Author, Year	Intervention	Outcome	Direction of Effect
Uterine characteristics	Ferrari et al., 2000[160]	Laparoscopically assisted vaginal hysterectomy	Laparotomy	Uterine size > 500 grams significantly predicts conversion to laparotomy
	Huang et al., 2006[77]	UAE	UAE failure	No association between baseline uterine size and UAE failure
	Spies, Ascher et al., 2001[92] Spies, Roth et al., 2002,[96] Spies, Bruno et al., 2005[93]	UAE	Satisfaction with outcomes	No association between baseline uterine volume and satisfaction
	McLucas et al., 2001[80]	UAE	UAE failure	No association between uterine characteristics and UAE failure
Fibroid number	Doridot et al., 2001[118]	Laparoscopic myomectomy	Fibroid recurrence	> 1 fibroid is significantly associated with a higher risk of recurrence
	Hanafi et al., 2005[123]	Myomectomy by exploratory laparotomy	Fibroid recurrence	> 1 fibroid is significantly associated with fibroid recurrence compared with 1 fibroid

Table 25. Uterine and fibroid characteristics as modifiers of outcomes of fibroid treatment (continued)

Modifier	Author, Year	Intervention	Outcome	Direction of Effect
	Kumakiri et al., 2005[147]	Laparoscopic myomectomy	Pregnancy	Positively correlated with number of removed fibroids
	Marziani et al., 2005[130]	Hysteroscopic myomectomy	Control of menorrhagia	Higher numbers of fibroids are significantly associated with poorer control of menorrhagia postprocedure
	Roth et al., 2003[136]	Abdominal myomectomy	Complications and transfusions	Higher numbers of fibroids significantly predict complications and transfusions
Fibroid size	Hanafi et al., 2005[123]	Myomectomy by exploratory laparotomy	Fibroid recurrence	Fibroid size > 10 weeks is significantly associated with fibroid recurrence compared with fibroid size ≤ 10 weeks
	Huang et al., 2006[77]	UAE	UAE failure	No association between baseline fibroid size and UAE failure
	Katsumori et al., 2005[175]	UAE	Complications and menorrhagia	No effect of fibroid size on complications Significantly greater improvement of menorrhagia likely with smaller fibroids
	Kumakiri et al., 2005[147]	Laparoscopic myomectomy	Pregnancy	Size of fibroid removed positively predictive of conception
	Litta et al., 2005[69]	GnRH versus no treatment prior to myomectomy	Blood loss and operating time	Increasing fibroid volume and weight associated with blood loss and operating time across groups
	Marret et al., 2006[129]	Myomectomy	Laparotomy	Greater fibroid size significantly predicts more laparoconversions
	McLucas et al., 2001[80]	UAE	UAE failure	Size of largest fibroid does not predict failure
	Munoz et al., 2003[132]	Hysteroscopic myomectomy	Operative time	Fibroid size > 3 cm is significantly associated with longer procedure times
	Rajan et al., 2004[88]	UAE	Intrauterine infection	No association between size of dominant fibroid and development of intrauterine infection
	Roth et al., 2003[136]	Abdominal myomectomy	Complications and transfusions	Greater fibroid size significantly predicts complications and transfusions

Table 25. Uterine and fibroid characteristics as modifiers of outcomes of fibroid treatment (continued)

Modifier	Author, Year	Intervention	Outcome	Direction of Effect
	Pron, Bennett, Common, Sniderman et al., 2003[83] Pron, Bennett, Common, Wall et al., 2003[84] Pron, Couchie, Soucie et al., 2003[85] Pron, Mocarski, Bennett et al., 2003[86] Pron, Mocarski, Cohen et al., 2003[87]	UAE	Decrease in fibroid volume	Larger fibroids more likely to have volume decrease
	Spies, Myers et al., 2005[95]	UAE	Decrease in fibroid volume	Size of the dominant fibroid at baseline volume predicted less volume reduction at both 3 and 12 months after therapy
	Spies, Ascher et al., 2001[92] Spies, Roth et al., 2002,[96] Spies, Bruno et al., 2005[93]	UAE	Satisfaction with outcomes	No association between baseline fibroid volume and satisfaction
			Decrease in fibroid volume	Size of the dominant fibroid at baseline volume predicted less volume reduction at 3 months after therapy
Fibroid type	Marret et al., 2006[129]	Myomectomy	Laparotomy	Intramural fibroid significantly predicts fewer laparoconversions
	Rajan et al., 2004[88]	UAE	Intrauterine infection	Submucosal fibroids are more likely to be associated with intrauterine infections than nonsubmucosal fibroids; the relationship is not statistically significant in multivariate analysis
	Spies, Myers et al., 2005[95]	UAE	Improvement in symptoms	Submucosal dominant fibroids predict significantly greater improvement in symptoms than subserosal fibroids
	Spies, Ascher et al., 2001[92] Spies, Roth et al., 2002,[96] Spies, Bruno et al., 2005[93]	UAE	Volume reduction	Submucosal dominant fibroids predict significantly greater volume reduction than subserosal fibroids at 3 months, but not at 12 months

GnRH, gonadotropin-releasing hormone; UAE, uterine artery embolization.

Table 26. Provider and intervention characteristics as modifiers of outcomes of fibroid treatment

Modifier	Author, Year	Intervention	Outcome	Direction of Effect
Surgical skills	Marret et al., 2006[129]	Myomectomy	Laparotomy	Greater experience significantly predicts fewer laparoconversions
	Lohle et al., 2006[79]	EmboGold® vs. Embospheres® for UAE	Skin rash, return to usual activities, volume reduction, satisfaction, and fibroid expulsion	Similar volume reduction, satisfaction, and fibroid expulsion for both agents Significantly greater risk of skin rash and slower return to usual activities with EmboGold®
Procedure characteristics	McLucas et al., 2001[80]	UAE	UAE failure	No association between procedure characteristics (size of particles and particle load in UAE) and UAE failure
	Worthington-Kirsch et al., 2005[100]	UAE	Risk of adverse events by 30 days following procedure	Greater length of procedure significantly predicts the risk of an adverse event
	Rajan et al., 2004[88]	UAE	Intrauterine infection	No association between pre-procedure antibiotics, type of particles used, or vials of particles used and development of intrauterine infection
Post-procedure complications	McLucas et al., 2001[80]	UAE	UAE failure	No association between complications and UAE failure
Subsequent interventions	Spies, Ascher et al., 2001[92] Spies, Roth et al., 2002[96] Spies, Bruno et al., 2005[93]	UAE	Satisfaction with outcomes	No association between subsequent interventions and satisfaction

UAE, uterine artery embolization.

KQ 6: Comparisons of Treatments

Several studies in our review compared different modalities of the same treatment—for example, different drug regimens for pharmaceutical management or different types of hysterectomy. From the point of view of clinical management, these studies do not address the larger issue of how to weigh outcomes across treatments; they weigh outcomes following the decision to choose a primary clinical pathway.

We previously discussed comparisons of modalities of a single treatment within each relevant section; this section singles out comparisons *across* treatments (Table 27 and Evidence Table 14 in Appendix C[*]). Ten studies compared different types of treatment. Of these, eight compared UAE with other treatments,[70,73,75,76,90,94,172,173] one compared myomectomy with hysterectomy,[144] and one compared traditional Chinese medicine with standard medical therapy.[48] Two of the 10 studies report on cost.[70,173]

[*] Appendixes cited in this report are provided electronically at http://ahrq.gov/clinic/tp/uteruptp.htm

Table 27. Papers with direct comparisons of treatments

Author, Year	Direction of Effect
Comparisons of UAE and Myomectomy	
Broder et al., 2002[70]	Significantly higher risk of further invasive therapy (hysterectomy, myomectomy, or repeat UAE) in 3-5 years with UAE; no significant difference in worsening of symptoms; higher proportion dissatisfied with myomectomy, differences are not statistically significant at $P < 0.05$
Goodwin et al., 2006[73]	Significantly fewer adverse events; shorter length of hospital stay, fewer days missed from work, and shorter time to resume normal activities with UAE; no difference in dominant fibroid volume, quality of life assessments, or menstrual bleeding scores
Razavi et al., 2003[90]	Significantly fewer days of pain medication use, shorter length of stay, fewer complications, and fewer days to resume normal activities with UAE; significantly greater menorrhagia relief with UAE; no significant differences in bulk symptoms and proportion experiencing pain
Baker et al., 2002[172] (Cost)	Higher overall costs with myomectomy; differences are not statistically significant at $P < 0.05$
Comparisons of UAE and Hysterectomy	
Healey et al., 2004[75]	No significant difference in ovarian function at 6 months following procedure
Hehenkamp et al., 2005[76]	Significantly shorter procedure time and length of stay with UAE; no difference in operative complications; significantly more minor complications and readmissions with UAE
Spies et al., 2004[94]	Significantly shorter procedure time and length of stay with UAE
Beinfeld, Bosch, Gazelle, 2002[173] (Cost)	Significantly shorter length of stay with UAE; significantly higher costs with UAE
Comparison of Abdominal Myomectomy and Abdominal Hysterectomy	
Vavilis, Togaridoce, Agorastos, 2005[144]	No significant differences in febrile morbidity (other outcomes not reported)
Comparison of Chinese Traditional Medicine and Standard Medical Therapy	
Mehl-Madrona, 2002[48]	Significantly smaller fibroids, significantly greater proportion improved, and significantly higher proportion likely to be satisfied with Chinese traditional medicine

UAE, uterine artery embolization.

Four studies compared UAE with myomectomy.[70,73,90,172] Of the three studies that addressed clinical outcomes,[70,73,90]only one study reported on the need for further invasive therapy; the study reported a much higher risk (adjusted odds ratio, 12.5; 95% confidence interval [CI], 1.4-110.1) of hysterectomy, myomectomy, or repeat UAE in the UAE group than in the myomectomy group.[70] Two other studies in this group were consistent in reporting shorter procedure times and length of stay and fewer adverse events; the studies were also consistent in not finding statistically significant differences in symptoms.[73,90] A single study reported a trend toward higher overall costs with myomectomy, although the differences were not statistically significant.[172]

Four studies compared UAE with hysterectomy. None of the studies that compared UAE outcomes and hysterectomy outcomes reported on the proportion of women in the UAE arm who had had to undergo additional treatment.[75,76,94] Studies reporting procedure time and length of stay favored UAE, but the inconsistency of the direction of effect for complications and the absence of information on longer-term outcomes suggested that this evidence base is inadequate to comment on the relative risks and benefits of UAE versus hysterectomy. A study comparing

costs of UAE with those of hysterectomy found that UAE, despite significantly shorter length of hospital stay, had significantly higher costs.[173]

As noted earlier, the only study in our review on complementary and alternative medicine (Chinese traditional medicine versus conventional therapy) favored Chinese traditional medicine, but it has distinctly different comparisons with an unknown degree of bias that would favor Chinese traditional medicine.[48] We also note that our limitation to English-language studies limits our ability to summarize the evidence on Chinese traditional medicine.

KQ 7: Geographic Variation in Treatment

We did not find any studies that reported on geographic variation in treatment within the United States (Level IV). We did not attempt to derive an estimate of variation in treatment from the studies that we included in our systematic review. These studies were generally conducted in academic medical centers; we could not assess the generalizability of their patterns of care for the broader population from which they were drawn.

Limitations of the Evidence Base and This Review

Limitations of the Evidence Base

The original systematic review on this topic highlighted several limitations of the literature.[30] Specifically, those authors pointed out the paucity of data from randomized trials, the lack of comparability of women in nonrandomized trials, the lack of comparability of outcome measures, and the limited duration of followup. Six years after that report appeared, our update, which covers only "new" publications appearing in the intervening period, finds that most of these limitations continue. As documented above, most of the key questions posed for this update had Level III strength of evidence (weak); none had Level I (strong) evidence, only two had Level II (moderate) evidence (limited to intermediate outcomes of uterine size, procedure time, and length of hospital stay), and a dismaying number had no evidence (Level IV).

The lack of robust epidemiologic information over time on rates of incidence or prevalence of uterine fibroids among U.S. women is striking. What is available suggests that between 70 percent and 80 percent of women will experience fibroids (either symptomatic or asymptomatic) in their lifetimes, and the evidence that fibroids might shrink after menopause is not as solid as clinical opinion might have it. Moreover, little information is available, except for race (black women being more likely than white women to have fibroids), to clarify how the risk of fibroids might differ by sociodemographic or health characteristics.

The treatment literature is larger than the epidemiologic literature, but it is not of much better quality. Of the 102 studies we examined across all treatment modalities, only 35 were randomized trials, and only 20 were prospective cohorts. The prospective cohort studies in this review often did test for comparability of subjects. The remaining studies were either prospective case series or retrospective studies.

Studies continued to report on a wide variety of outcomes, often using unvalidated instruments. Most postprocedural studies focused on perioperative outcomes, although a small minority recorded long-term outcomes, with one study reporting on 5-year outcomes.[93]

The literature is further restricted in its ability to answer questions of immediate relevance to the management of uterine fibroids because only a small number of studies compared different

types of fibroid management. Although several studies compared different types of hysterectomy, myomectomy, or pharmaceutical management, only 10 studies compared two different treatments. Of the remainder, a single RCT compared hysterectomy with myomectomy.

Finally, the cost data were quite meager; our analyses of HCUP data document a steady escalation in costs of procedural interventions. Because of the aggregate nature of these data, we cannot pinpoint the causes of these increases or whether they are associated with patient characteristics, particular types of treatments, or even secular increases in the cost of medical care in general.

Limitations of the Review

As with the earlier review,[30] we limited our search to articles published in English, primarily for reasons of time and resources. We acknowledge that our review of complementary and alternative medicine is likely to be significantly limited by this constraint. We also excluded case reports and case series with fewer than 100 women; as with the original review, our exclusion may have resulted in underreports of rare complications of fibroid treatment.

For similar time and resource reasons, we did not conduct dual independent, blinded review of articles for inclusion or abstraction of information into evidence tables. Instead, one reviewer performed the initial review, and a second reviewer examined that input and recommended changes or corrections when needed. These two reviewers reconciled any differences by consensus discussion. These procedures are generally in accord with the usual procedures for the RTI–UNC EPC. To enable us to address any systematic bias in our work that the above approach may have introduced, however, we did apply dual independent review for assessing the quality of individual articles and grading the strength of evidence.

The paucity of "similar" articles (populations, settings, patient characteristics, and outcomes measured) precluded any efforts to pool findings statistically.

Future Research Directions

Key components of study design, analysis, and reporting are the leading weaknesses of the literature for every topic addressed in this systematic review. Overall, the literature identified is limited by the following gaps and problems.

Ability To Assess Internal and External Validity

Key characteristics of populations studied (e.g., race/ethnicity, reproductive history) are not reported consistently. Many studies mix groups of women with varied indications for treatment without separately reporting outcomes or adjusting for differences among participants that may be confounders (e.g., age, smoking status, menopausal status). Furthermore, the dominance of European literature means that we cannot assume that processes of care and outcomes will be similar to those in the United States. Moreover, practice variation and outcomes have been shown in other areas of research such as cardiac care to have substantial variability within the United States and even within individual states and facilities. We see no reason to believe that such variation is not also at work in the care of fibroids; more and better information from U.S. studies is required to advance our understanding about this important women's health issue.

Study Populations of Adequate Size for Assessing Key Outcomes

The majority of the studies reviewed were observational; they were not well suited to hypothesis testing or causal inference. Moreover, the small size of observational studies and clinical trials generally precluded both meaningful descriptive analysis of modifiers of outcomes and appropriate adjustment in multivariable models. Although most trials and many study designs, other than case series, reported power calculations, those calculations were most often linked to intermediate outcomes such as blood loss at surgery, length of hospital stay, or bleeding pattern at 3 months of medical therapy; generally, even with power calculations, the sizes of the samples precluded having adequate numbers of participants for the types of answers that are needed to inform women and their care providers about the critical questions raised for this report. Future research would be better able to provide such answers if funding agencies supported studies of adequate size to answer questions about resolution of symptoms, satisfaction with outcomes, recurrence or growth of fibroids, and further care needs at time horizons of a year and longer.

Standard Nomenclature and Validated Measures

To advance knowledge, investigators need to adopt common classifications across the whole spectrum of operational definitions required for research. Several deficiencies introduce bias and handicap our ability to compare interventions and populations or aggregate data to estimate effect size and outcome probabilities. Three shortcomings are especially problematic: (1) failure to define operationally details such as inclusion and exclusion parameters and fibroid type or position in the uterus; (2) reliance on clinical measures such as estimated blood loss from operative reports or febrile morbidity from nursing notes; and (3) use of ad hoc measures of outcome that lack validity and reliability data (e.g., intuitively derived approaches to collecting data about success in controlling bleeding or altering bleeding patterns).

Analysis Methods Matched to the Outcomes of Interest

Follow-up data that investigate topics such as time to return to work, maintenance of symptom control, recurrence of fibroids, subsequent surgery, and fertility and pregnancy outcomes should be addressed with analysis methods that explicitly incorporate time to event. Few studies used life table or hazard model approaches to reporting outcomes; even fewer used such advanced models either to assess for confounding of the relationship between the management received and outcomes or to investigate modifiers of outcomes.

Direct Comparisons of Treatment Options

Randomized trials with common endpoints that reflect the treatment goals of women with fibroids must become a priority. New medical therapeutics are needed. Studies that are currently under way on antiprogestin and progestin treatments, if promising, should be rapidly followed by larger effectiveness and comparison studies. If such pharmacotherapies are introduced into the market, then population-level surveillance efforts will be required to examine safety across methods.

Although changing entrenched treatment patterns is often difficult, especially for surgical procedures that have been clinically available in varied forms for decades, trials must be done. Researchers would do well to incorporate into such trials comparisons of older methods with newer techniques such as UAE and MRI-guided ultrasound ablation, and endometrial ablation, because these therapies are currently unsupported by adequate data from controlled comparisons. When possible, such as for women without or with mild symptoms, trials should include a delayed treatment arm or expectant management group in order to better understand the natural history of fibroids and to examine the degree to which symptoms may wax and wane.

Content Priorities

With the goal of achieving care tailored to the individual woman's fibroid status and characteristics, we need sophisticated information about a considerable array of issues. These include the burden of disease for both her and, possibly, her family; along with societal costs from loss of ability to function well in the usual family or occupational roles. Transitions associated with appearance of uterine fibroids, growth patterns, and influences on growth (e.g., concurrent medical conditions like diabetes, use of medications like hormonal contraception, influence of lactation and duration) are also high-priority topics, as are predictors of symptom development and resolution. Care-seeking behaviors and health and quality-of-life outcomes with and without treatment are yet other matters that investigators should attempt to address. Such data will also be required to examine the disparities between white and black women in the age at appearance of fibroids and in the number and size of fibroids, and we note as well the critical need for documenting fibroid status in other racial and ethnic groups. Variations in incidence, prevalence, and the natural course of fibroid development have potential to generate new hypotheses about etiology and such comparative studies must be pursued.

Current practice suggests that women without symptoms may forego intervention because of the general belief that care should be aimed at improving symptoms or addressing a specific clinical concern such as difficulty conceiving or recurrent pregnancy loss. Although foregoing intervention can be wise in the absence of data that the intervention will prevent future difficulties, nonetheless we emphasize that no data yet support expectant management as a "safe" choice; neither do any data indicate whether use of therapeutics short of surgery might forestall or prevent future changes in fibroids or appearance of symptoms.

The concept of preventive strategies is appealing. However, as long as the etiology of fibroids remains unclear and medical treatment choices are few, the prospect for dietary management, exercise, hormonal management, or other prevention trials is slim. The clinical research agenda will likely depend on new translational research and large-scale epidemiology studies that are yet to be done.

Much remains to be learned that will require large-scale prospective observational studies of sufficient size and rigor to support time-to-event analysis of outcomes. We emphasize in particular both the appearance of symptoms and the modifiers of risk of growth and symptoms. We must also invest in basic and translational research to understand the pathogenesis and pathophysiology of uterine fibroids. Such research is required to best guide selection of pathways for exploration of genetic determinants of the timing and severity of disease, gene-environment interactions that may influence onset and symptoms, proteomic and treatment targeting research, as well as to discover potential prevention strategies. Research effort must be focused on documenting first the course and consequences of uterine fibroids using optimal imaging

strategies, then the modifiers of that course, so that we can offer women an accurate account of the likely outcome of expectant management based on their individual status.

Conclusions

In accord with the prior systematic evidence review on management of uterine fibroids, we find a remarkable lack of high-quality evidence supporting the effectiveness of most interventions for symptomatic fibroids. Specifically notable is the lack of well-conducted trials in U.S. populations that provided direct comparisons among treatment options, including the option of expectant management, and that follow women to determine whether their objectives for treatment were met by the intervention received. Trials of preoperative medical management do support decrease in fibroid volume with treatment, but they do not provide sufficient evidence of improvement in important operative outcomes. The lack of available therapeutics for medical management without surgery is striking. Tremendously common procedures like hysterectomy and myomectomy, including the choice among types of myomectomy, still cannot be meaningfully compared. Appearance of new fibroids and growth of existing fibroids is poorly studied among the management options that leave the uterus in situ. Data to help women with fibroids who desire a pregnancy make treatment decisions are problematic because they originate in populations dominated by participants with known fertility impairments and adverse pregnancy outcomes. With these caveats, some evidence supports intervention for submucous fibroids via hysteroscopy when pregnancy is desired.

Across management options, we must note that lack of evidence is not equivalent to evidence of no benefit or of harm. Some of these interventions may well be effective in at least some patients. Research to assess how patient characteristics influence outcomes is also meager. Uncontrolled studies are notably biased for overestimating the degree of benefit subsequently reported in randomized trials. Indeed, not uncommonly, trials negate the findings of what in this case is largely retrospective and case series research. The current state of the literature does not permit definitive conclusions about benefit, harm, or relative costs to achieve similar results. Given how common and concerning fibroids can be to women and their care providers, a redoubled emphasis on promoting high-quality fibroid research in the United States is imperative. Women deserve better information to guide their choices.

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APPENDIXES:

to

“Management of Uterine Fibroids: An Update of the Evidence”

Prepared by the RTI International-University of North Carolina Evidence-based Practice Center
(Contract #290-02-0016)

Appendix A. Exact Search Strings

Search Strategy

Medline Focused Search 1: January 2006

#7	Search "Leiomyoma"[MeSH]OR fibroid* OR leiomyomata	13470
#8	Search "Leiomyoma"[MeSH]OR fibroid* OR leiomyomata Field: All Fields, Limits: Publication Date from 2000, English, Humans	2362
#15	Search "Leiomyoma"[MeSH]OR fibroid* OR leiomyomata Field: All Fields, Limits: Publication Date from 2000, English, Editorial, Humans	12
#16	Search "Leiomyoma"[MeSH]OR fibroid* OR leiomyomata Field: All Fields, Limits: Publication Date from 2000, English, Letter, Humans	127
#17	Search "Leiomyoma"[MeSH]OR fibroid* OR leiomyomata Field: All Fields, Limits: Publication Date from 2000, English, Practice Guideline, Humans	11
#18	Search "Leiomyoma"[MeSH]OR fibroid* OR leiomyomata Field: All Fields, Limits: Publication Date from 2000, English, Review, Humans	356
#19	Search #15 OR #16 OR #17 OR #18 Limits: Publication Date from 2000, English, Humans	500
#20	Search #8 NOT #19 Limits: Publication Date from 2000, English, Humans	1861

Medline Focused Search 2: February 2006

#4	Search "Leiomyoma"[MeSH] OR fibroid* OR leiomyomata	13539
#5	Search "Leiomyoma"[MeSH] OR fibroid* OR leiomyomata Field: All Fields, Limits: 60 Days, English, Humans	10*

Unduplicated in previous searches

Medline Focused Search 3: May 2006

#2	Search "Leiomyoma"[MeSH] OR fibroid* OR leiomyomata	13690
#3	Search "Leiomyoma"[MeSH] OR fibroid* OR leiomyomata Limits: added to PubMed in the last 1 year, English, Humans	304
#4	Search "Leiomyoma"[MeSH] OR fibroid* OR leiomyomata Limits: added to PubMed in the last 1 year, English, Editorial, Letter, Practice Guideline, Review, Humans	63
#5	Search #3 NOT #4	98*

*Unduplicated from previous searches

Medline Focused Search 4: August 2006

#1	Search "Leiomyoma"[MeSH]OR fibroid* OR leiomyomata	13811
#2	Search "Leiomyoma"[MeSH]OR fibroid* OR leiomyomata Limits: added to PubMed in the last 1 year, English, Publication Date from 2000/02 to 2006/02, Humans	222
#3	Search "Leiomyoma"[MeSH]OR fibroid* OR leiomyomata Limits: added to PubMed in the last 1 year, English, Publication Date from 2000/02 to 2006/02, Editorial, Letter, Practice Guideline, Review, Humans	47
#4	Search #2 NOT #3	175
#5	Search #2 NOT #3 Limits: added to PubMed in the last 180 days	10*

*Unduplicated in previous searches

Medline Focused Search 5: September 2006

#1	Search "Leiomyoma"[MeSH] OR fibroid* OR leiomyomata	13887
#2	Search "Leiomyoma"[MeSH] OR fibroid* OR leiomyomata Limits: added to PubMed in the last 90 days, English, Publication Date from 2000/02 to 2006/02, Humans	4*

Cochrane

Leiomyoma OR Fibroid* = 3

*Unduplicated in previous searches

EMBASE

Leiomyoma OR Fibroid* = 52

*Unduplicated in previous searches

Appendix B. Sample Data Abstraction Forms

Systematic Review of the Management of Uterine Fibroids

Abstract Review Form

First Author, Year: _____ Journal: _____

Endnote #_____ Abstractor Initials: ___ ___ ___

Primary Inclusion/Exclusion Criteria			
1. Original research (Exclude editorials, commentaries, letters to editor, reviews, etc.)	Yes	No	Cannot Determine
2. Study published between February 2000 and February 2006	Yes	No	Cannot Determine
3. Study published in English	Yes	No	Cannot Determine
4. Is this study located in a developed nation? (US, Canada, UK, Western Europe, Japan, Australia, New Zealand, Israel, Scandinavia)	Yes	No	Cannot Determine
5. Eligible Study type (Include all RCTs and cohorts with comparison) a. ___RCT b. ___Cohorts with comparison c. ___Case-control d. ___Case series (N =_____) e. ___Incidence/prevalence in US populations f. ___Cost of treatment in US populations	Yes	No	Cannot Determine
6. Applies to research topic (if not select one of the following reasons): a. ___Basic science b. ___Imaging/diagnostic study c. ___Not "uterine" fibroids	Yes	No	Cannot Determine

Retain for:

_____BACKGROUND/DISCUSSION

_____REVIEW OF REFERENCES

_____Other

COMMENTS:

Systematic Review of the Management of Uterine Fibroids

Full-text Review Form

First Author, Year: _____ Journal: _____

Endnote #_____ Abstractor Initials: ___ ___ ___

Primary Inclusion/Exclusion Criteria			
1. Original research (Exclude editorials, commentaries, letters to editor, reviews, etc.)	Yes	No	Cannot Determine
2. Study published between February 2000 and February 2006	Yes	No	Cannot Determine
3. Study published in English	Yes	No	Cannot Determine
4. Is this study located in a developed nation? (US, Canada, UK, Western Europe, Japan, Australia, New Zealand, Israel, Scandinavia)	Yes	No	Cannot Determine
5. Eligible Study type (Include all RCTs and cohorts with comparison) g. ___RCT h. ___Cohorts with comparison i. ___Case-control j. ___Case series ___N ≥ 100 k. ___Incidence/prevalence in US populations l. ___Cost of treatment in US populations	Yes	No	Cannot Determine
6. Addresses one or more topics in the content inventory?	Yes	No	

Content Inventory
1. _____Treatment of women with fibroids with symptoms a. ___Expectant management without intervention b. ___Medical management c. ___Uterine artery embolization d. ___Endometrial ablation (with or without myomectomy e. ___In situ destructive techniques f. ___Myomectomy (abd, lap, and hysteroscopic) g. ___Hysterectomy (abd, lap, vag) h. ___Complementary and alternative therapies i. ___Other Methods_____

2. _____Treatment of women with fibroids without symptoms for:

   a. ___Enhancing fertility
   b. ___Reducing adverse pregnancy outcomes
   c. ___Preventing further growth/recurrence
   d. ___Ruling out uterine malignancy
   e. ___Other _____

3. _____Modification of short term outcomes by:

   1. ___Age
   2. ___Race/ethnicity
   3. ___Parity
   4. ___Breastfeeding
   5. ___Contraceptive choices
   6. ___Body habitus
   7. ___Insulin resistance
   8. ___Concurrent medical conditions
   9. ___Fibroids size/number
   10. ___Uterine volume
   11. ___Other factors_____

4. _____Modification of long term outcomes by:
   1. ___Age
   2. ___Race/ethnicity
   3. ___Parity
   4. ___Breastfeeding
   5. ___Contraceptive choices
   6. ___Body habitus
   7. ___Insulin resistance
   8. ___Concurrent medical conditions
   9. ___Fibroids size/number
   10. ___Uterine volume
   11. ___Other factors_____

Retain for:

_____BACKGROUND/DISCUSSION

_____REVIEW OF REFERENCES

_____Other

COMMENTS:

- **IF ANY ITEMS IN GRAY BOX, THE ARTICLE IS EXCLUDED.**

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria Other details	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author: Country and setting: Enrollment period: Funding:	Design: Intervention: Groups: N at enrollment: N at followup: Age: Race/Ethnicity: Parity: Baseline Hgb/Hct:	Inclusion criteria: Exclusion criteria: Indications: Pre-operative therapy: Associated procedure(s):	Baseline uterine size: Number of fibroids: Baseline fibroid size: Type of fibroid:	Outcomes: Modifiers:	Direct comparison: Quality: INTERNAL VALIDITY A. Random: B. Methods and blinding: C. Pt selection criteria: D. Length of follow-up: E. Loss to follow-up: F. Drop-out rates: G. Statistical issues: EXTERNAL VALIDITY H. Age: I. Race: J. Route of previous delivery/Pregnancy history: K. Surgical history: L. Fibroid/uterine size: M. Number of fibroids: N. Location of fibroids: O. Baseline characteristics: P. Measurement timing: Q. Measurement methods: R. Measurement reliability: S. Clinical care: T. Standardized measures:

Notes:

SOME POINTERS ABOUT STUDY DESIGN CLASSIFICATION

Case series, prospective – subjects (ideally consecutive patients) having **the same type of procedure or treatment for fibroids are identified prior** to surgery/treatment and consented to participate. Pre-and post-treatment evaluation methods tend to be specified more uniformly and in greater detail that retrospective series. At times, carefully timed and implemented evaluation plans are in place, such as every six month ultrasounds to identify fibroid recurrence, and uniform measurements such as blood draws to assess improvement of anemia are used. The components of the study and outcome follow-up are designed before the participants are enrolled. Data analysis is descriptive including the full range of potential outcome measures such as length of stay, satisfaction with care, quality of life, etc. Analysis may include construction of predictive models that seek to examine influences on the risk of outcomes, such as wound breakdown or "treatment failure", among a group of women who have all had abdominal myomectomy or uterine artery embolization.

Case series, retrospective – investigators obtain permission to review existing clinical records in order to summarize the outcomes from a sequence (ideally consecutive patients) having the **same procedure or treatment**. Most often post-hoc consenting of individual participants is not required by internal review boards (unless follow-up contact is planned) and data is limited by the availability, quality, and uniformity of record keeping methods used. Some measure such as operative time or transfusion are likely to be of good quality, others such as peri-operative complications or recurrence of fibroids based on office records of follow-up visits are likely to be of lower quality. Follow-up of the members of a case series identified from medical records or databases using methods such as surveys should still be counted as **"retrospective"** if the **design of the study and future data collection were not established prior to the time of the treatment or surgery** under study. Such follow-up can achieve very high quality but the case series is still classified as retrospective for classification. As for retrospective case series, analysis is descriptive.

Cohort, prospective – subjects having **more than one type of procedure or treatment** are identified prior to the surgery/treatment and consented to participate for the purpose of making comparisons of the outcomes of treatment. The prior evidence review inconsistently called such studies "prospective cohorts" or "cohorts with comparisons". For the purpose of this review, we will term studies with more than one "exposure" group prospective cohorts to distinguish them from case series as described above. Analysis is focused on estimating the risk or odds of the outcome(s) based on the participants' exposure (treatment group status).

Randomized clinical trials – are special instances of prospective cohorts in which the "exposure" or treatment group is assigned by chance through use of an allocation method.

Cohort, retrospective – subjects having **more than one type of procedure or treatment** (i.e. more than one "exposure") are identified after having had surgery or intervention. Most often consenting of individual participants is not required by internal review boards (unless follow-up contact is planned) and data is limited by the availability, quality, and uniformity of record keeping methods used. Data limitations are similar to those described above for retrospective case series. Likewise even studies that have some component of follow-up should be classified as retrospective if the intent to follow-up the cohort in the fashion done for the research being reviewed was not designed and future data collection planned prior to the time of the treatment or surgery under study. Analysis estimates the risk or odds of the outcome(s) based on the participants' exposure (treatment group status).

Case-control studies – cases are identified based on the outcome under study, for instance women who required transfusion for fibroid related bleeding, or who had a miscarriage. A control, comparison population is identified that is intended to be a representative sample of similar women. In order to assure similar characteristics overall with respect to covariates not being studied, matching is often used, such as matching on age or race to assure a similar distribution of these potential confounders. Analysis is technically estimating the odds of having had a particular exposure or characteristic given known presence or absence of the outcome.

Appendix C. Evidence Tables

Glossary

AOR	adjusted odds ratio
AUB	abnormal uterine bleeding
bFGF	basic fibroblast growth factor
BMD	body mineral density
BMI	body mass index
CA	cyproterone acetate
cc	cubic centimeter
CI	confidence interval
cm	centimeter
cm/s	centimeters per second
cm^2	centimeters squared
cm^3	cubic centimeters
COPD	chronic obstructive pulmonary disease
CPT-4	Current Procedural Terminology, Fourth Edition
C-section	cesarean section
d	day
E_2	estradiol
EBL	estimated blood loss
ER	emergency room
ET	embryo transfer
EV	estradiol valerate
EZ	estradiol
FSH	follicle-stimulating hormone
g	gram
g/dl	grams per deciliter
GIFT	gamete intrafallopian transfer
gm	grams
GnRH	Gonadotropin releasing hormone
GnRHa/GnRH-a	Gonadotropin releasing hormone agonist/analogue
gyn	gynecologic
HDL-C	high-density lipoprotein cholesterol
Hct	hematocrit
Hgb	Hemoglobin
hrs	hours
ICD-9-CM	International Classification of Diseases, Ninth Revision, Clinical Modification
im	intramuscular
IM	intramuscular
IQR	interquartile range
IU	international units
IU/L	international units per liter
IUI	intrauterine insemination
IVF	invitro fertilization
kg	kilograms
LA	leuprorelin
LA-MLT	laparoscopically assisted minilaparotomy
LAVH	laparoscopically assisted vaginal hysterectomy
lb	pound
LDL-C	low-density lipoprotein cholesterol
LH	luteinizing hormone
LM	laprascopic myomectomy
LT	laparotomy
mg	milligram
mg/d	milligrams per day
mg/dL	milligram per deciliter
min	minute(s)
ml	millileter
MLT	minilaparotomy
mlU/mL	milli-international units per million
mm	millimeter
mmol/L	millimoles per liter
mos	months

MPA	Medroxyprogesterone Acetate
MR	magnetic resonance
MRgFUS	magnetic resonance guided focused ultrasound
MRI	magnetic resonance imaging
N	number
NA	not applicable
ng/ml	nanogram/milliliter
nmol/l	nanomoles per liter
NR	not reported
NRS	numeric rating scale
NS	not significant
NSAIDs	non-steroidal anti-inflammatory drugs
OCP	oral contraceptive pill
OR	odds ratio
PID	Pelvic Inflammatory Disease
pmol/L	picomoles per liter
po	per oral (by mouth)
PROM	premature rupture of membranes
q28d	every 28 days
RCT	randomized controlled trial
rHuEPO	recombinant human erythropoietin
RR	relative risk
sc	subcutaneous
SC	subcutaneous
SD	standard deviation
SEM	standard error of mean
SLL	second-look laparoscopy
SSS	symptom severity scale
TAH	total abdominal hysterectomy
TC	total cholesterol
TCR	transcervical resection
TCRE	transcervical resection of endometrium
TCRM	transcervical resection of submucous fibroids
TG	triglycerides
u/s	ultrasound
UAE	Uterine artery embolization
UFE	uterine fibroid embolization
UFS-QOL	uterine fibroid symptoms – quality-of-life
UK	United Kingdom
US	United States
VAS	visual analog scale
vs.	versus
WHR	waist-to-hip ratio
wk(s)	week(s)
wt	weight
yr(s)	year(s)
ZIFT	zygote intrafallopian transfer

Evidence Table 1. KQ 1

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria and Other Details	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author: Baird et al., 2003 **Country and setting:** US, Community **Enrollment period:** NR **Funding:** NIEHS	**Design:** Prospective cohort **Intervention:** NA **Groups:** **G1:** Black women **G2:** White women **N at enrollment:** **G1:** 840 **G2:** 524 **N at follow-up:** NA **Age, %:** 35 to 39 yr: **G1:** 33 **G2:** 31 40 to 44 yr: **G1:** 34 **G2:** 32 ≥ 45 yr: **G1:** 33 **G2:** 38 **Race/ethnicity:** See groups **Parity, at age 35, (%):** 0: **G1:** 186 (23) **G2:** 332 (66) 1: **G1:** 194 (24) **G2:** 87 (17) 2: **G1:** 251 (31) **G2:** 68 (13) ≥ 3: **G1:** 187 (23) **G2:** 17 (3) **Baseline Hgb/Hct:** NR	**Inclusion criteria:** • Age 35 to 49 yr **Exclusion criteria:** • Not a member of health plan at Washington, DC site • No telephone • Non-English speaking **Indications:** NA **Preoperative therapy:** NA **Additional procedures:** NA	**Baseline uterine size:** NR **Number of fibroids:** NR **Baseline fibroid size:** NR **Type of fibroid:** NR	**Cumulative incidence by race:** OR = 2.9; 95% CI, 2.5-3.4 *P* < 0.001 **Age at fibroid diagnosis (mean):** **G1:** 33 **G2:** 36 *P* < 0.001 **Multiple fibroids, %:** **G1:** 73 **G2:** 45 **Hysterectomy with previous fibroid diagnosis, %:** **G1:** 12 **G2:** 5 **Premenopausal women previously diagnosed, %:** **G1:** 45 **G2:** 21 **Fibroids detected by ultrasound in women previously diagnosed, %:** **G1:** 87 **G2:** 78 **Fibroids detected by ultrasound in premenopausal women not previously diagnosed, %:** **G1:** 59 **G2:** 43 **Modifiers:** NR	**Quality:** Overall quality score: fair **INTERNAL VALIDITY: fair** Random: + Methods and blinding: NA Pt selection criteria: ++ Loss to follow-up: 10-20% Drop-out rates: NA Statistical issues: ++ **EXTERNAL VALIDITY: good** Age: +, reported Race: +, reported Pregnancy history: -, NR Surgical history: -, NR Fibroid/uterine size: NA Number of fibroids: NA Location of fibroids: NA Baseline characteristics: +, reported Length of follow-up: ++ Measurement methods: + Measurement reliability: + Clinical care: NA

Evidence Table 1. KQ 1 (continued)

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author: Wise et al., 2004 **Country and setting:** US, National survey **Enrollment period:** 03/1997 to 03/2001 **Funding:** Grant from National Cancer Institute	**Design:** Prospective cohort **Intervention:** NA **Groups:** Ultrasound confirmed fibroids: 2,006 Hysterectomy confirmed fibroids: 273 **N at enrollment:** 22,895 **N at follow-up:** NR **Age:** Median 34 **Race/ethnicity, %:** African-American: 100 **Parity, parous, %:** 57 (average of 2 births) **Baseline Hgb/Hct:** NR	**Inclusion criteria:** • Premenopausal women with intact uteri • Age: 21 to 69 yrs • Subscribers of *Essence* magazine, member of Black professional organizations, and friends and relatives of respondents **Exclusion criteria:** • Natural or medical menopause • Hysterectomy • Bilateral oophorectomy • Unknown menopausal status • Diagnosis of leiomyomata before 1997 • Did not complete 1999 and 2001 follow-up questionnaires • No information about year of diagnosis or confirmation type • Women with incomplete exposure or covariate information **Indications:** NR **Preoperative therapy:** NR **Associated procedure(s):** NR	**Baseline uterine size:** NR **Number of fibroids:** NR **Baseline fibroid size:** NR **Type of fibroid:** NR	**New cases of UF:** 2,279 **Age at menarche, IRR (95% CI):** < 11: 1.0 11: 0.9 (0.8-1.1) 12 to 13: 0.8 (0.7-0.9) 14: 0.8 (0.6-0.9) > 14: 0.6 (0.5-0.8) *P* < 0.001 **Nulliparous, IRR:** 1.0 **Parity, IRR (95% CI):** 0.7 (0.6-0.7) **Age at first birth, IRR (95% CI):** <20: 1.0 20-24: 0.9 (0.8-1.1) 25-29: 0.7 (0.6-0.9) >29: 0.5 (0.4-0.9) *P* = 0.002 **Current use of hormonal contraceptive, IRR (95% CI):** Progestin-only injectables: 0.5 (0.4-0.9) Progestin-only implants: 0.4 (0.2-1.5) Progestin-only OCP: 0.8 (0.4-3.0) Combined OCP: 1.0 (0.9-1.1) **Years since last birth, IRR (95% CI):** < 5: 1.0 (referent) 5-9: 2.2 (1.6-2.5) 10 to 14: 3.5 (2.2-3.7) 15 to 19: 3.5 (1.9-3.5) > 19: 3.4 (1.4-3.2) *P* < 0.001	**Quality:** Overall quality score: fair **INTERNAL VALIDITY: good** Random: NA Methods and blinding: NA Pt selection criteria: ++ Loss to follow-up: <10% Drop-out rates: NA Statistical issues: ++ **EXTERNAL VALIDITY: fair (1)** Age: +, reported Race: +, reported Pregnancy history: NA Surgical history: NA Fibroid/uterine size: NA Number of fibroids: NA Location of fibroids: NA Baseline characteristics: +, reported Length of follow-up: ++ Measurement methods: + Measurement reliability: - Clinical care: NA

Evidence Table 2. KQ2 Expectant management

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria Other details	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author: Di Lieto, De Falco, Pollio et al., 2005 **Country and setting:** Italy, Academic medical center **Enrollment period:** NR **Funding:** Italian Ministry of University and Scientific Research	**Design:** Prospective cohort **Intervention:** Medical management followed by uterine surgery **Groups:** **G1:** Leuprolide acetate depot injections for 3 months **G2:** No pre-treatment **N at enrollment:** **G1:** 31 **G2:** 55 **N at follow-up:** NR **Age, yrs ± SD:** **G1:** 37.5 ± 3.9 **G2:** 38.1 ± 3.5 **Race/ethnicity:** NR **Parity, mean ± SD:** **G1:** 2.2 ± 1.4 **G2:** 2.1 ± 1.6 **Baseline Hgb, g/dL ± SD:** **G1:** 7.6 ± 0.3 **G2:** 7.8 ± 0.5	**Inclusion criteria:** • Pre-menopausal • Symptomatic fibroids **Exclusion criteria:** • Malignant neoplasm In last 12 months: • Received hormonal therapy • Delivered • Underwent uterine surgery **Indications:** NR **Preoperative therapy:** See Groups **Additional procedures:** NR	**Baseline uterine size, cm³ ± SD:** **G1:** 725.6 ± 193.5 **G2:** 762.7 ± 201.2 **Number of fibroids:** NR **Baseline fibroid size:** NR **Type of fibroid:** NR	**Hgb, after therapy, g/dL ± SD:** **G1:** 12.8 ± 0.3 **G2:** NA **Hgb, after surgery, g/dL ± SD:** **G1:** 11.3 ± 0.5 **G2:** 6.5 ± 0.8 **Uterine volume, cm³ ± SD:** **G1:** 492.7±134.2 **G2:** N/A **Modifiers:** NR	**Quality:** Overall quality score: fair **INTERNAL VALIDITY: good** Random: NA Methods and blinding: NA Pt selection criteria: + Loss to follow-up: <10% Drop-out rates: <5% Statistical issues: + **EXTERNAL VALIDITY: fair (3)** Age: +, reported Race: NA, not US study Pregnancy history: +, reported Surgical history: +, reported Fibroid/uterine size: + Number of fibroids: - Location of fibroids: - Baseline characteristics: +, reported Length of follow-up: + Measurement methods: + Measurement reliability: + Clinical care: -

Evidence Table 2. KQ2 Expectant management (continued)

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria Other Details	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author: Di Lieto, De Falco, Staibano et al., 2003 **Country and setting:** Italy, Academic medical center **Enrollment period:** NR **Funding:** NR	**Design:** Prospective cohort **Intervention:** Monthly subcutaneous leuprorelin acetate depot 3.75 mg for 3 cycles prior to myomectomy or hysterectomy **Groups:** **G1:** Leuprorelin acetate depot 3.75 mg **G2:** No medical intervention women **N at enrollment:** **G1:** 25 **G2:** 46 **N at follow-up:** **G1:** 25 **G2:** 46 **Age, yrs ± SD:** **G1:** 38.4 ± 4.3 **G2:** 37.9 ± 3.5 **Race/ethnicity:** NR **Parity, mean ± SD:** **G1:** 2.3 ± 1.4 **G2:** 1.9 ± 1.5 **Baseline Hgb/Hct:** NR	**Inclusion criteria:** • Pre-menopausal • Fibroids present **Exclusion criteria:** • Malignant neoplasm In last 12 mos: • Received hormonal therapy • Delivered • Underwent uterine surgery **Indications:** NR **Preoperative therapy:** See Groups **Additional procedures:** NR	**Baseline uterine size, cm³ ± SD:** **G1:** 774.5 ± 203.1 **G2:** 804.7 ± 233.7 **Number of fibroids:** NR **Baseline fibroid size:** NR **Type of fibroid:** NR	**Uterine size:** **G1:** 484.9 ± 144.5 **G2:** N/A *P* < 0.05 **"Quickscore"* for bFGF:** **G1:** 7.96 ± 2.22 **G2:** 9.61 ± 2.54 *P* < 0.05 **Modifiers:** NR	**Quality:** Overall quality score: fair **INTERNAL VALIDITY: good** Random: NA Methods and blinding: NA Pt selection criteria: + Loss to follow-up: <10% Drop-out rates: <5% Statistical issues: + **EXTERNAL VALIDITY: fair (3)** Age: +, reported Race: NA, not US study Pregnancy history: +, reported Surgical history: +, reported Fibroid/uterine size: + Number of fibroids: - Location of fibroids: - Baseline characteristics: +, reported Length of follow-up: + Measurement methods: + Measurement reliability: + Clinical care: -

Evidence Table 2. KQ2 Expectant management (continued)

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria Other details	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author: Di Lieto, De Rosa et al., 2002 **Country and setting:** Italy, Academic medical center **Enrollment period:** NR **Funding:** NR	**Design:** Prospective cohort **Intervention:** Monthly subcutaneous leuprorelin acetate depot 3.75 mg for 3 cycles prior to myomectomy **Groups:** **G1:** Leuprorelin acetate depot 3.75 mg **G2:** No medical intervention **N at enrollment:** **G1:** 39 **G2:** 31 **N at follow-up:** **G1:** 39 **G2:** 31 **Age, mean yrs ± SD:** **G1:** 36.1 ± 3.2 **G2:** 37.3 ± 3.7 **Race/ethnicity:** NR **Parity, mean ± SD:** **G1:** 2.2 ± 1.8 **G2:** 1.9 ± 1.8 **Baseline Hgb/Hct:** NR	**Inclusion criteria:** • Pre-menopausal • Symptomatic fibroids **Exclusion criteria:** • Malignant neoplasm In last 12 months: • Received hormonal therapy • Delivered • Underwent uterine surgery **Indications:** NR **Preoperative therapy:** See Groups **Additional procedures:** NR	**Baseline uterine size, cm³ ± SD:** **G1:** 571.3 ± 266.7 **G2:** 540.4 ± 250.8 **Number of fibroids:** NR **Baseline fibroid size:** NR **Type of fibroid:** NR	**Uterine Size, cm³ ± SD:** **G1:** 413.4 ± 217 **G2:** 601.1 ± 241.3 **Modifiers:** NR	**Quality:** Overall quality score: fair **INTERNAL VALIDITY: good** Random: NA Methods and blinding: NA Pt selection criteria: + Loss to follow-up: <10% Drop-out rates: <5% Statistical issues: + **EXTERNAL VALIDITY: poor (4)** Age: +, reported Race: NA, not US study Pregnancy history: +, reported Surgical history: NA Fibroid/uterine size: + Number of fibroids: - Location of fibroids: - Baseline characteristics: -, NR Length of follow-up: + Measurement methods: + Measurement reliability: + Clinical care: -

Evidence Table 2. KQ2 Expectant management (continued)

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria Other details	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author: Di Lieto, Iannotti et al., 2003 **Country and setting:** Italy, Academic medical center **Enrollment period:** NR **Funding:** NR	**Design:** Prospective cohort **Intervention:** Monthly subcutaneous leuprorelin acetate depot 3.75 mg for 3 cycles prior to myomectomy **Groups:** **G1:** Leuprorelin acetate depot 3.75 mg **G2:** No medical intervention **N at enrollment:** **G1:** 48 **G2:** 41 **N at follow-up:** **G1:** 48 **G2:** 41 **Age, yrs ± SD:** **G1:** 38 ± 4 **G2:** 38.8 ± 3.7 **Race/Ethnicity:** NR **Parity, mean ± SD:** **G1:** 2.2 ± 1.8 **G2:** 1.5 ± 1.3 **Baseline Hgb/Hct:** NR	**Inclusion criteria:** • Pre-menopausal • Symptomatic fibroids **Exclusion criteria:** • Malignant neoplasm In last 12 months: • Received hormonal therapy • Delivered • Underwent uterine surgery **Indications:** NR **Preoperative therapy:** See Groups **Additional procedures:** NR	**Baseline uterine size, cm³ ± SD:** **G1:** 675.8 ± 176 **G2:** 646.9 ± 191.4 **Number of fibroids:** NR **Baseline fibroid size:** NR **Type of fibroid:** NR	**Uterine volume, cm³ ± SD:** **G1:** 466.6 ± 113.3 **G2:** NR *P* < 0.05 **Modifiers:** NR	**Quality:** Overall quality score: fair **INTERNAL VALIDITY: good** Random: NA Methods and blinding: NA Pt selection criteria: + Loss to follow-up: NR Drop-out rates: NR Statistical issues: + **EXTERNAL VALIDITY: fair (3)** Age: +, reported Race: NA, not US study Pregnancy history: +, reported Surgical history: +, reported Fibroid/uterine size: + Number of fibroids: - Location of fibroids: - Baseline characteristics: +, reported Length of follow-up: + Measurement methods: + Measurement reliability: + Clinical care: -

Evidence Table 2. KQ2 Expectant management (continued)

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria Other Details	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author: Donnez et al., 2003 **Country and setting:** Multi-national, Academic medical centers **Enrollment period:** NR **Funding:** AstraZeneca Pharma-ceuticals	**Design:** RCT **Intervention:** Medical management with anti-estrogen and GnRH-a followed by hysterectomy **Groups:** **G1:** Fulvestrant 50 mg IM injection monthly x 3 **G2:** Fulvestrant 125 mg IM monthly x 3 **G3:** Fulvestrant 250 mg IM monthly x 3 **G4:** Goserelin 3.6 mg SC x 3 **G5:** No treatment **N at enrollment:** **G1:** 59 **G2:** 66 **G3:** 62 **G4:** 66 **G5:** 60 **N at follow-up:** **G1:** 55 **G2:** 63 **G3:** 61 **G4:** 62 **G5:** 60 **Age, yrs ± SD:** **G1:** 44.0 ± 4.0 **G2:** 44.0 ± 4.4 **G3:** 44.0 ± 4.5 **G4:** 44.0 ± 4.0 **G5:** 44.0 ± 5.1 **Race/ethnicity:** NR **Parity:** NR **Baseline Hgb/Hct:** NR	**Inclusion criteria:** • Pre-menopausal • Uterine fibroids requiring hysterectomy • Willing to use barrier contraception for 4 weeks before and during presurgical stage of trial • Not involved in night-shift work **Exclusion criteria:** • Previously received >3mos GnRHa • Completed GnRHa treatment within 3 mos of study • Received sex-hormone therapy, used OCP, or danazol within 4 weeks of study • History of disease affecting bone or steroid metabolism • Change in menstrual frequency or changes related to onset of menopause **Indications:** NR **Preoperative therapy:** NR **Associated procedure(s):** NR	**Baseline uterine size cm^3 ± SD:** Numerical values not reported **Number of fibroids:** NR **Baseline fibroid size:** NR **Type of fibroid:** NR	**Fibroid volume:** G1 vs. G5: *P* = 0.833 G2 vs. G5: *P* = 0.938 G3 vs. G5: *P* = 0.506 G1 vs. G4: *P* = 0.001 G2 vs. G4: *P* = 0.0002 G3 vs. G4: *P* = 0.023 **Endometrial thickness:** G1 vs. G5: *P* = 0.468 G2 vs. G5: *P* = 0.868 G3 vs. G5: *P* = 0.755 G1 vs. G4: *P* = 0.025 G2 vs. G4: *P* = 0.002 G3 vs. G4: *P* = 0.009 **Uterine Volume:** Numerical values not reported G3/G4 superior, G4 > G3 **Modifiers:** NR	**Quality:** Overall quality score: poor **INTERNAL VALIDITY: poor** Random: - Methods and blinding: - Pt selection criteria: + Loss to follow-up: <10% Drop-out rates: 5-10% Statistical issues: + **EXTERNAL VALIDITY: poor (5)** Age: +, reported Race: NA, not US study Pregnancy history: -, NR Surgical history: NA Fibroid/uterine size: + Number of fibroids: - Location of fibroids: - Baseline characteristics: -, NR Length of follow-up: + Measurement methods: + Measurement reliability: + Clinical care: -

Evidence Table 2. KQ2 Expectant management (continued)

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria Other Details	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author: Dousias et al., 2003 **Country and setting:** Greece, Academic medical center **Enrollment period:** NR **Funding:** NR	**Design:** RCT **Intervention:** Preoperative recombinant human erythropoietin (rHuEPO) **Groups:** **G1:** Iron 200 mg/day and rHuEPO 600 U/ml SC once weekly for 3 weeks **G2:** Iron 200 mg/d **N at enrollment:** **G1:** 23 **G2:** 27 **N at follow-up:** **G1:** 23 **G2:** 27 **Age, yrs ± SD:** **G1:** 48.2 ± 4.1 **G2:** 49.2 ± 4.7 **Race:** NR **Parity:** NR **Baseline Hgb/Hct, g/dL ± SD:** **G1:**10.3 ± 4.1 **G2:**10.4 ± 4.6	**Inclusion criteria:** • No major medical illness • Age: 30 to 60 yrs • Hgb: ≥ 9 and < 12 g/dl • Weight: 50 to 80 kg • Ferritin > 50 ng/ml • Uterine fibroids by ultrasound **Exclusion criteria:** NR **Indications:** NR **Preoperative therapy:** None **Additional procedures:** NR	**Baseline uterine size:** NR **Number of fibroids:** NR **Baseline fibroid size:** NR **Type of fibroid:** NR	**Estimated blood loss, ml ± SD:** **G1:** 645 ± 116 **G2:** 593 ± 130 **Length of stay, days ± SD:** **G1:** 7.6 ± 0.5 **G2:** 7.8 ± 0.9 **Mean Hgb on Day 7, g/dL ± SD:** **G1:** 11.2 ± 0.7 **G2:** 10.5 ± 0.6 95% CI, 0.3-1.1 **Mean Hgb on Day 0, g/dL ± SD:** **G1:** 11.9 ± 0.7 **G2:** 10.7 ± 0.7 95% CI, 0.8-1.6 **Mean Hgb on Day +3, g/dL ± SD:** **G1:** 10.3 ± 0.8 **G2:** 8.8 ± 0.7 95% CI, 1.9-2.0 **Mean Hgb on Day +7, g/dL ± SD:** **G1:** 10.7 ± 0.8 **G2:** 8.8 ± 0.7 95% CI, 1.4-2.3 **Mean Hgb on Day +14, g/dL ± SD:** **G1:** 10.8 ± 0.2 **G2:** 9.1 ± 0.7 95% CI, 1.3-2.1 **Modifiers:** NR	**Quality:** Overall quality score: fair **INTERNAL VALIDITY: good** Random: + Methods and blinding: + Pt selection criteria: + Loss to follow-up: NR Drop-out rates: NR Statistical issues: + **EXTERNAL VALIDITY: poor (5)** Age: +, reported Race: NA, not US study Pregnancy history: -, NR Surgical history: NA Fibroid/uterine size: - Number of fibroids: - Location of fibroids: - Baseline characteristics: -, NR Length of follow-up: + Measurement methods: + Measurement reliability: + Clinical care: +

Evidence Table 2. KQ2 Expectant management (continued)

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria Other Details	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author: Mehl-Madrona, 2002 **Country and setting:** US, Academic medical center **Enrollment period:** NR **Funding:** NR	**Design:** Prospective cohort **Intervention:** Traditional Chinese medical approach **Groups:** **G1:** Traditional Chinese Medicine with combination of weekly acupuncture, Chinese herbs, and nutritional therapy **G2:** Matched controls medically managed with any medical treatment **N at enrollment:** **G1:** 37 **G2:** 37 **N at follow-up:** **G1:** 37 **G2:** 37 **Age:** Mode: 36 (24 to 45) **Race/ethnicity:** NR **Parity:** NR **Baseline Hgb/Hct:** NR	**Inclusion criteria:** • Pre-menopausal • Intact uterus of ≥ 6 to 8 week size with palpable fibroids • Fibroids 2 to 3 cm in diameter **Exclusion criteria:** • Fibroids growing > 6 cm/year • Hgb < 8g/dL • Hydronephrosis • Taking hormonal contraceptives **Indications:** • Palpable fibroids • Fibroids 2 to 3 cm in diameter **Pre-operative therapy:** NA **Associated procedure(s):** NA	**Baseline uterine size:** NR **Number of fibroids:** NR **Baseline fibroid size:** NR **Type of fibroid:** NR	**Mean size change, cm:** **G1:** -0.8 **G2:** +1.9 **Size and/or rate of growth of fibroids, 6 mos, mean change in size (cm):** Cured (gone) **G1:** 3 **G2:** 0 Reduced size (>2cm) **G1:** 11 **G2:** 1 Stopped growing (± 1cm) **G1:** 8 **G2:** 2) Decreased rate of growth (change >1cm) **G1:** 10 (+1.1) **G2:** 9 (+0.9) Total improved*: **G1:** 32 **G2:** 13 *P* < 0.001 No change **G1:** 3 (+0.9) **G2:** 20 (+1.9) Increased rate of growth (change >1cm) **G1:** 2 (+9.2) **G2:** 4 (+7.0) Total unimproved: **G1:** 5 **G2:** 24 *P* < 0.001 **Symptom change, N:** Heavy menstrual bleeding, before treatment: **G1:** 20 **G2:** 20	**Quality:** Overall quality score: poor **INTERNAL VALIDITY: fair** Random: NA Methods and blinding: NA Pt selection criteria: + Loss to follow-up: <10% Drop-out rates: <5% Statistical issues: - **EXTERNAL VALIDITY: poor (5)** Age: +, reported Race: -, NR Pregnancy history: -, NR Surgical history: NA Fibroid/uterine size: + Number of fibroids: - Location of fibroids: - Baseline characteristics: -, NR Length of follow-up: + Measurement methods: + Measurement reliability: + Clinical care: +

Evidence Table 2. KQ2 Expectant management (continued)

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria Other Details	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author: Mehl-Madrona, 2002 (continued)				Heavy menstrual bleeding, 6 mos: **G1:** 9 **G2:** 11 Prolonged menstrual bleeding, before treatment: **G1:** 9 **G2:** 9 Prolonged menstrual bleeding, 6 mos: **G1:** 5 **G2:** 5 Dysmenorrhea before treatment, N: **G1:** 9 **G2:** 9 Dysmenorrhea, 6 mos: **G1:** 5 **G2:** 7 Decreased exercise/activity tolerance, before treatment: **G1:** 2 **G2:** 2 Decreased exercise/activity tolerance, before treatment: **G1:** 2 **G2:** 2 Decreased exercise/activity tolerance, 6 mos: **G1:** 1 **G2:** 1 **Modifiers:** NR	

Evidence Table 2. KQ2 Expectant management (continued)

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria Other Details	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author: Palomba, Morelli, Di Carlo et al., 2002 **Country and setting:** Italy, Academic medical center **Enrollment period:** NR **Funding:** NR	**Design:** RCT **Intervention:** Leuprolide acetate plus tibolone for 12 mos vs. hysterectomy with bilateral oophorectomy **Groups:** **G1:** Symptomatic fibroids treated with leuprolide acetate plus tibolone **G2:** Symptomatic fibroids treated with laparoscopic or laparotomic hysterectomy with bilateral oophorectomy **G3:** Non randomized comparison group of naturally postmenopausal women **N at enrollment:** **G1:** 60 **G2:** 60 **N at followup:** **G1:** 56 **G2:** 54 **Age, yrs ± SD:** **G1:** 53.9 ± 1.6 **G2:** 53.1 ± 1.5 **G3:** 54.2 ± 1.8 **Race/Ethnicity:** NR **Parity (mean ± SD):** **G1:** 2.1 ± 1.6 **G2:** 1.9 ± 1.9 **G3:** 2.0 ± 1.7 **Baseline Hgb/Hct:** NR	**Inclusion criteria:** • Age >52 years • No hormone therapy after menopause **Exclusion criteria:** • BMD <1.0 SD • Medical illnesses with impact calcium metabolism • Treatment with drugs for or interfering with bone metabolism • BMI<18 or >30 • Cigarette use >20/day • Alcohol > 3 drinks/day **Indications:** NR **Preoperative therapy:** See groups **Associated procedure(s):** NR	**Baseline uterine size:** NR **Number of fibroids:** NR **Baseline fibroid size:** NR **Type of fibroid:** NR	**Change in BMD, %:** **G1:** 5.7[a] **G2:** 6.4[a] **G3:** 3.4[a,b] **Change in Bone Alkaline Phosphatase, %:** **G1:** 33.5[a] **G2:** 36.7[a] **G3:** 21.2[a,b] [a] *P* < 0.05 vs baseline [b] *P* < 0.05 vs. G1&2 No significant difference in BMD or in bone turnover markers was detected between G1 and G2. The decrease in BMD and in bone turnover markers was statistically significant (*P* < .05) when G1 & G2 were compared to G3. **Modifier:** NR	**Quality:** Overall quality score: fair **INTERNAL VALIDITY: fair** Random: + Methods and blinding: - Pt selection criteria: ++ Loss to follow-up: <10% Drop-out rates: <5% Statistical issues: ++ **EXTERNAL VALIDITY: fair (2)** Age: +, reported Race: NA, not US study Pregnancy history: +, reported Surgical history: -, NR Fibroid/uterine size: + Number of fibroids: NA Location of fibroids: NA Baseline characteristics: -, NR Length of follow-up: ++ Measurement methods: + Measurement reliability: + Clinical care: +

[a] *P* < 0.005 vs. baseline
[b] *P* <0.05 versus Group 2

Evidence Table 2. KQ2 Expectant management (continued)

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria Other Details	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author: Palomba, Orio, Russo, et al., 2005 **Country and setting:** Italy, Academic medical center **Enrollment period:** NR **Funding:** NR	**Design:** RCT **Intervention:** Raloxifene vs. placebo **Groups:** **G1:** 180 mg/day orally for 3 cycles of 28 days **G2:** 3 placebo tablets/day for 3 cycles of 28 days **N at enrollment:** **G1:** 20 **G2:** 20 **N at follow-up:** NR **Age, yrs ± SD:** **G1:** 53.4 ± 4.1 **G2:** 52.2 ± 4.0 **Race/ethnicity:** NR **Parity, mean ± SD:** **G1:** 2.2 ± 1.3 **G2:** 2.1 ± 1.2 **Baseline Hgb/Hct:** NR	**Inclusion criteria:** • Natural menopause for 1 to 2 yrs • 1 to 2 fibroids with at least 1 > 2 cm **Exclusion criteria:** • Neoplastic, metabolic, or infectious diseases • Vascular thrombosis or coagulation abnormality • BMI >30 • Use of hormone therapy in previous 6 mos • Moderate or severe vasomotor symptoms **Indications, N (%):** Uterine prolapse: **G1:** 16 (80) **G2:** 17 (85.9) Complex endometrial hyperplasia: **G1:** 2 (10) **G2:** 2 (10) High-grade intrasquamous lesion: **G1:** 2 (10) **G2:** 1 (5) **Preoperative therapy:** NR **Associated procedure(s):** NR	**Baseline uterine size, cm³ ± SD:** **G1:** 313.1 ± 87.9 **G2:** 327.7 ± 89.8 **Number of fibroids:** NR **Baseline fibroid size, cm³ ± SD:** **G1:** 141.7 ± 37.8 **G2:** 150.3 ± 58.7 **Type of fibroid:** All intramural	**Uterine size at 3 mos, cm³ ± SD:** **G1:** 274.9 ± 71.9 **G2:** 327.5 ± 90.7 G1 vs baseline: *P* < 0.001 G2 vs baseline: *P* = 0.824 G1 vs G2: *P* = 0.048 **Fibroid size at 3 mos, cm³ ± SD:** **G1:** 116.3±27.4 **G2:** 150.4±58.0 G1 vs baseline: *P* < 0.001 G2 vs baseline: *P* = 0.993 G1 vs **G2:** *P* = 0.022 **Modifiers:** NR	**Quality:** Overall quality score: fair **INTERNAL VALIDITY: good** Random: + Methods and blinding: + Pt selection criteria: ++ Loss to follow-up: <10% Drop-out rates: <5% Statistical issues: ++ **EXTERNAL VALIDITY: poor (4)** Age: +, reported Race: NA, not US study Pregnancy history: +, reported Surgical history: -, NR Fibroid/uterine size: + Number of fibroids: - Location of fibroids: - Baseline characteristics: +, reported Length of follow-up: ++ Measurement methods: + Measurement reliability: + Clinical care: -

Evidence Table 2. KQ2 Expectant management (continued)

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author: Palomba, Orio et al., 2002 Palomba, Russo, Orio, Tauchmanova et al., 2002 Palomba, Orio, Russo, Falbo et al., 2004 Palomba, Russo et al., 2004 **Country and setting:** Italy, Academic medical center **Enrollment period:** 06/2000 to 01/2001 **Funding:** NR	**Design:** RCT **Intervention:** Leuprolide acetate depot and raloxifene hydrochloride vs. placebo **Groups:** **G1:** Leuprolide acetate depot 3.75 mg every 28 days and raloxifene hydrochloride 60 mg/d **G2:** Leuprolide acetate depot 3.75 mg every 28 days and placebo each day **N at enrollment:** **G1:** 50 **G2:** 50 **N at follow-up:** NR Age, yrs ± SD: **G1:** 49.1 ± 4.2 **G2:** 48.6 ± 3.9 **Race/ethnicity:** NR **Parity (mean ± SD):** **G1:** 1.8 ± 1.4 **G2:** 1.7 ± 1.3 **Baseline Hgb/Hct:** NR	**Inclusion criteria:** • Premenopausal women • Symptomatic fibroids **Exclusion criteria:** • Serious medical illness • Vascular thrombosis • BMD < 1 SD from mean peak value • BMI <18 or >30 • Smoking >20 cigarettes/day • Alcohol>3 drinks/day • WHR > 0.8 • Hyper androgenemia • Serum folate > 12.5 nmol/l • Hyperhomo-cystenaemia **Indications, N:** • Menorrhagia: 50 • Pelvic pressure: 44 • Pelvic pain: 36 • Urinary frequency: 31 • Constipation: 11 **Preoperative therapy:** NA **Associated procedure(s):** NR	**Baseline uterine size, cm^3 ± SD:** **G1:** 473 ± 113 **G2:** 446 ± 105 **Number of fibroids:** NR **Baseline fibroid size , cm^3 ± SD:** **G1:** 197 ± 61 **G2:** 189 ± 154 **Type of fibroid:** NR	**Uterine volume*:** G1 vs. baseline: *P* < 0.05 G2 vs. baseline: *P* < 0.05 **Fibroid volume*:** G1 vs. baseline: *P* < 0.05 G2 vs. baseline: *P* < 0.05 **Menorrhagia, N %:** **G1:** 0(0)[a] **G2:** 0(0)[a] **Pelvic pressure, N %:** **G1:** 3 (6.7)[a] **G2:** 3 (6.5)[a] **Pelvic pain, N %:** **G1:** 2 (4.4)[a] **G2:** 3 (6.5)[a] **Urinary frequency, N %:** **G1:** 3 (6.7)[a] **G2:** 2 (4.3)[a] **Constipation:** **G1:** 0 (0)[a] **G2:** 0 (0)[a] **Change in BMD, Lumbar spine*:** G2 vs. baseline/G1: *P* < 0.05 **Change in BMD, Trochanter*:** G2 vs. baseline/G1: *P* < 0.05 **Change in BMD, Femoral Neck*:** G2 vs. baseline/G1: *P* < 0.05 **Change in TC (mmol/l)*:** G1: 0.26[a,b] G2: 0.47[a]	**Quality:** Overall quality score: fair **INTERNAL VALIDITY: good** Random: + Methods and blinding: + Pt selection criteria: ++ Loss to follow-up: <10% Drop-out rates: <5% Statistical issues: ++ **EXTERNAL VALIDITY: poor (4)** Age: +, reported Race: NA, not US study Pregnancy history: +, reported Surgical history: -, NR Fibroid/uterine size: + Number of fibroids: - Location of fibroids: - Baseline characteristics: -, NR Length of follow-up: ++ Measurement methods: + Measurement reliability: + Clinical care: +

[a] *P* < 0.005 vs. baseline
[b] *P* <0.05 versus Group 2
*Tabular data only

Evidence Table 2. KQ2 Expectant management (continued)

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria Other Details	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author: Palomba, Pellicano et al., 2001 Palomba, Morelli, Noia, et al., 2002 **Country and setting:** Italy, Academic medical center **Enrollment period:** NR **Funding:** NR	**Design:** RCT **Intervention:** Leuprolide acetate, tibolone and iron vs. leuprolide acetate and iron vs. placebo prior to myomectomy **Groups:** **G1:** IM leuprolide acetate 3.75 mg q28d; iron 2 tablets daily; tibolone oral 2.5mg/d **G2:** IM leuprolide acetate 3.75 mg q28d; iron 2 tablets daily; **G3:** Iron tablets, 2 orally daily **N at enrollment:** **G1:** 22 **G2:** 22 **G3:** 22 **N at follow-up:** **G1:** 20 **G2:** 20 **G3:** 21 **Age, yrs ± SD:** **G1:** 24.9 ± 3.9 **G2:** 27.0 ± 3.3 **G3:** 26.6 ± 4.1 **Race/ethnicity:** NR **Parity:** NR **Baseline Hgb, g/dL ± SD:** **G1:** 12.2 ± 1.6 **G2:** 11.9 ± 1.5 **G3:** 12.4 ± 1.7	**Inclusion criteria:** • Infertility >3 years • Recurrent miscarriage • Increased vaginal bleeding • Pelvic pressure and pain • Urinary frequency • Constipation • Largest Intramural fibroid 400 to 500 cm³ • ≤ 3 fibroids **Exclusion criteria:** • Serious medical illnesses • Submucosal fibroids • Abnormal endometrial biopsy • Abnormal pap smear • Pregnant • Calcification or hyperechoic fibroids **Indications:** NR **Preoperative therapy:** See groups **Associated procedure(s):** NR	**Baseline uterine size, cm^3 ± SD:** **G1:** 528 ± 83 **G2:** 504 ± 92 **G3:** 496 ± 99 **Number of fibroids, mean ± SD:** **G1:** 1.90 ± 0.9 **G2:** 2.0 ± 0.9 **G3:** 1.9 ± 0.9 **Baseline fibroid size, cm^3 ± SD:** **G1:** 179 ± 48 **G2:** 167 ± 41 **G3:** 163 ± 38 **Type of fibroid:** All intramural	**Operative time, min ± SD:** **G1:** 99.8 ± 22.7 **G2:** 91.5 ± 17.6 **G3:** 117.6 ± 16.1 G1/G2 vs. G3: $P < 0.05$ G1 vs. G2: P = NS **Estimated blood loss, ml ± SD:** **G1:** 186.8 ± 62.2 **G2:** 171.2 ± 64.3 **G3:** 245.8 ± 53.0 G1/G2 vs. G3: $P < 0.05$ G1 vs. G2: P = NS **Hgb, Visit 2, g/dL ± SD:** **G1:** 13.6 ± 0.9[a] **G2:** 13.5 ± 0.9[a] **G3:** 12.1 ± 1.5[c] **Hgb, Visit 3, g/dL ± SD:** **G1:** 12.0 ± 0.8[b] **G2:** 12.2 ± 0.8[b] **G3:** 10.7 ± 1.1[b,c] **Uterine volume, Visit 2, cm^3 ± SD:** **G1:** 373 ± 51[a] **G2:** 337 ± 50[a] **G3:** 498 ± 97[c] **Uterine volume, Visit 3, cm^3 ± SD:** **G1:** 198 ± 27[a,b] **G2:** 193 ± 18[a,b] **G3:** 201 ± 19[a,b] **Fibroid Volume, Visit 2, cm^3 ± SD:** **G1:** 130 ± 31[a] **G2:**113 ± 23[a] **G3:**164 ± 39[c] [a] $P < 0.05$ vs. Visit 1 [b] $P < 0.05$ vs. Visit 2 [c] $P < 0.05$ vs. G1 & **Modifiers:** NR	**Quality:** Overall quality score: fair **INTERNAL VALIDITY: good** Random: + Methods and blinding: + Pt selection criteria: ++ Loss to follow-up: <10% Drop-out rates: <5% Statistical issues: ++ **EXTERNAL VALIDITY: fair (2)** Age: +, reported Race: NA, not US study Pregnancy history: +, reported Surgical history: -, NR Fibroid/uterine size: + Number of fibroids: + Location of fibroids: - Baseline characteristics: +, reported Length of follow-up: ++ Measurement methods: + Measurement reliability: + Clinical care: +

[a] $P < 0.005$ vs. baseline
[b] $P < 0.05$ versus Group 2

Evidence Table 2. KQ2 Expectant management (continued)

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria Other Details	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author: Palomba, Sammartino et al., 2001 **Country and setting:** Italy, Academic medical center **Enrollment period:** NR **Funding:** NR	**Design:** RCT **Intervention:** Raloxifene vs. placebo **Groups:** **G1:** 60 mg/day x 12 cycles **G2:** 60 mg/day placebo x 12 cycles **N at enrollment:** **G1:** 35 **G2:** 35 **N at follow-up:** **G1:** 31 **G2:** 31 **Age, yrs ± SD:** **G1:** 54.2±4.9 **G2:** 51.2±3.9 **Race/ethnicity:** NR **Parity, mean ± SD:** **G1:** 2.0 ± 1.5 **G2:** 2.1 ± 1.7 **Baseline Hgb/Hct:** NR	**Inclusion criteria:** • Natural menopause for 1 to 2 yrs • 1 to 2 fibroids with at least 1 > 2 cm **Exclusion criteria:** • Neoplastic, metabolic or infectious disease • Vascular thrombosis or coagulation abnormality • BMI >30 • Hormone therapy in prior 6 mons • Moderate or severe vasomotor symptoms **Indications:** NR **Preoperative therapy:** NR **Associated procedure(s):** NR	**Baseline uterine size, cm³ ± SD:** **G1:** 295.6 ± 81.0 **G2:** 316.6 ± 113.7 **Number of fibroids:** NR **Baseline fibroid size, cm³ ± SD:** **G1:** 127.1 ± 38.2 **G2:** 138.5 ± 55.7 **Type of fibroid:** NR	**Uterine and fibroid size:** After 6, 9, and 12 cycles of treatment a reduction in mean uterine and fibroid size was observed in comparison to baseline and between groups ($P < 0.05$)* **Amenorrhea** 3 mo, %: **G1:** 83.9 **G2:** 82.8 P = NS 6 mo, %: **G1:** 84.9 **G2:** 84.9 P = NS 9 mo, %: **G1:** 82.8 **G2:** 83.9 P = NS 12 mo, %: **G1:** 88.1 **G2:** 86.0 P = NS **AUB episodes, mean ± SD:** At 3 mos **G1:** 1.40 ± 0.63 **G2:** 1.40 ± 0.63 P =NS At 6 mos **G1:** 1.29 ± 0.47 **G2:** 1.38 ± 0.62 P =NS At 9 mos **G1:** 1.13 ± 0.34 **G2:** 1.20 ± 0.41 P =NS	**Quality:** Overall quality score: fair **INTERNAL VALIDITY: good** Random: + Methods and blinding: + Pt selection criteria: ++ Loss to follow-up: <10% Drop-out rates: 5-10% Statistical issues: ++ **EXTERNAL VALIDITY: fair (3)** Age: +, reported Race: NA, not US study Pregnancy history: +, reported Surgical history: -, NR Fibroid/uterine size: + Number of fibroids: - Location of fibroids: - Baseline characteristics: +, reported Length of follow-up: ++ Measurement methods: + Measurement reliability: + Clinical care: +

*Graphs, not quantitative data provided

Evidence Table 2. KQ2 Expectant management (continued)

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria Other Details	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author: Palomba, Sammartino, et al., 2001 (continued)				**AUB episodes, mean ± SD:** At 12 months **G1:** 1.18 ± 0.41 **G2:** 1.15 ± 0.38 *P* =NS **Modifiers:** NR	

Evidence Table 2. KQ2 Expectant management (continued)

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria, Other Details	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author: Palomba, Sena, et al., 2001 **Country and setting:** Italy, Academic medical center **Enrollment period:** NR **Funding:** NR	**Design:** Prospective cohort **Intervention:** Transdermal estradiol (E_2) and Medroxyprogest-erone Acetate (MPA) **Groups:** **G1:** women with fibroids, 50 µg/day transdermal E_2 + 2.5 mg/day MPA X 12 cycles **G2:** women with fibroids, 1 tablet calcium carbonate per day X 12 cycles **G3:** women without fibroids, 50 µg/day transdermal E_2 + 2.5 mg/day MPA X 12 cycles **N at enrollment:** **G1:** 35 **G2:** 35 **G3:** 35 **N at follow-up:** **G1:** 31 **G2:** 31 **G3:** 30 **Age, yrs ± SD:** **G1:** 53.8 ± 3.8 **G2:** 52.4 ± 3.7 **G3:** 54 ± 3.8 **Race/ethnicity:** NR **Parity. mean ± SD:** **G1:** 2.1 ± 1.7 **G2:** 2.2 ± 1.6 **G3:** 2.1 ± 1.7 **Baseline Hgb/Hct:** NR	**Inclusion criteria:** • Natural menopause for 1 to 2 yrs • 1 to 2 intramural or subserosal uterine fibroids, with at least one >2 cm **Exclusion criteria:** • Neoplastic, metabolic or infectious diseases • Vascular thrombosis • BMI > 30 • Hormonal therapy in prior 6 mos • Endometrial abnormalities by ultrasound • Endometrial thickness > 5 mm • Hypoechoic or calcified fibroids **Indications:** NR **Preoperative therapy:** NR **Associated procedure(s):** NR	**Baseline uterine size, cm³ ± SD:** **G1:** 313.1 ± 83.9 **G2:** 327.7 ± 89.9 **G3:** NA **Number of fibroids:** NR **Baseline fibroid size, cm³ ± SD:** **G1:** 141.7 ± 37.8 **G2:** 150.3 ± 58.7 **G3:** NA **Type of fibroid:** NR	**Fibroid size** 3rd cycle, cm³ ± SD: **G1:** 143.9±38.8 **G2:** 153.1±62.1 *P* = NS 6th cycle, cm³ ± SD: **G1:** 146.6±45.5 **G2:** 155.3±64.7 *P* = NS 9th cycle, cm³ ± SD: **G1:** 147.1±49.1 **G2:** 155.4±68.6 *P* = NS 12th cycle, cm³ ± SD: **G1:** 147.5±53.3 **G2:** 156.0±72.5 *P* = NS No significant difference in bleeding patterns between G1 and G2 Amenorrhea, at cycle 3, G1 and G3 less prevalent that G2 ($P < 0.05$) Abnormal uterine bleeding episodes at cycle 3, G1 and G3 more severe than G2 ($P < 0.05$) By 6th, 9th, and 12th treatment cycles bleeding pattern was not significantly different between 3 groups **Modifiers:** NR	**Quality:** Overall quality score: fair **INTERNAL VALIDITY: fair** Random: NA Methods and blinding: NA Pt selection criteria: ++ Loss to follow-up: <10% Drop-out rates: 5-10% Statistical issues: + **EXTERNAL VALIDITY: fair (3)** Age: +, reported Race: NA, not US study Pregnancy history: +, reported Surgical history: -, NR Fibroid/uterine size: + Number of fibroids: - Location of fibroids: - Baseline characteristics: +, reported Length of follow-up: ++ Measurement methods: + Measurement reliability: + Clinical care: +

Evidence Table 3. KQ 2 Pharmaceutical management

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria Other details	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author: Campo et al., 2005 **Country and setting:** Italy, Academic medical center **Enrollment period:** NR **Funding:** NR	**Design:** Retrospective cohort **Intervention:** Two month pretreatment with triptorelin, Decapeptyl 3.75 mg followed by resectoscopic myomectomy **Groups:** **G1:** Triptorelin 3.75 mg **G2:** No pretreatment **N at enrollment:** **G1:** 38 **G2:** 42 **N at follow-up:** **G1:** 38 **G2:** 42 **Age, yrs ± SD:** **G1:** 38.97 ± 7.46 **G2:** 38.8 ± 5.39 **Race/Ethnicity:** NR **Parity, parous, N (%):** **G1:** 26 (68.4) **G2:** 28 (66) **Baseline Hgb/Hct:** NR	**Inclusion criteria:** • Premenopausal • Undergoing myomectomy • Diagnosis by transvaginal ultrasound and confirmed by diagnostic hysteroscopy **Exclusion criteria:** NR **Indications:** Abnormal uterine bleeding: **G1:** 30 (79) **G2:** 33 (79) **Pre-operative therapy:** See groups **Associated procedure(s):** NR	**Baseline uterine size, mm ± SD:** NR **Number of fibroids removed, mean ± SD:** **G1:** 1.09 ± 0.29 **G2:** 1.1 ± 0.53 **Baseline fibroid size:** **G1:** 29.73 ± 14.47 **G2:** 28.72 ± 11.57 **Type of fibroid, N:** Completely intracavitary: **G1:** 15 **G2:** 16 Intramural extension < 50%: **G1:** 20 **G2:** 23 Intramural extension ≥ 50%: **G1:** 7 **G2:** 9	**Operative time, min ± SD:** **G1:** 57.65 ± 29.61 **G2:** 40 ± 18.06 *P* = 0.002 **Hemorrhage, N:** **G1:** 0 **G2:** 0 **Uterine perforation, N:** **G1:** 0 **G2:** 1 *P* = NS **Length of stay, days ± SD:** **G1:** 1.15 ± 0.44 **G2:** 1.05 ± 0.22 *P* = NS **Fibroid recurrence in 24 mos, N (%):** **G1:** 2 (5.26) **G2:** 3 (7.1) *P* = 0.908 **Recurrence of abnormal uterine bleeding, N (%):** **G1:** 8/30 (26.6) **G2:** 12/33 (36.3) *P* = 0.57 **Repeat hysteroscopy, N:** **G1/G2:** 2 **Modifiers:** NR	**Quality:** **Overall quality score: fair** **INTERNAL VALIDITY: fair** Random: NA Methods and blinding: NA Pt selection criteria: + Loss to follow-up: <10% Drop-out rates: NA Statistical issues: - **EXTERNAL VALIDITY: fair (1)** Age: +, reported Race: NA, not US study Pregnancy history: +, reported Surgical history: -, NR Fibroid/uterine size: + Number of fibroids: + Location of fibroids: + Baseline characteristics: +, reported Length of follow-up: ++ Measurement methods: + Measurement reliability: + Clinical care: +

Evidence Table 3. KQ 2 Pharmaceutical management (continued)

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria Other Details	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author: Di Lieto, De Falco, Mansueto et al., 2005 **Country and setting:** Italy, Academic medical center **Enrollment period:** NR **Funding:** NR	**Design:** RCT **Intervention:** Medical management with GnRH-a (Leuprorelin acetate 3.75 mg subcutaneously every month) **Groups:** **G1:** GnRH-a plus tibolone **G2:** GnRH-a **G3:** Control **N at enrollment:** **G1:** 22 **G2:** 23 **G3:** 28 **N at follow-up:** 70 **Age:** G1: 36.8 ± 4.1 G2: 37.2 ± 3.9 G3: NR **Race/ethnicity:** NR **Parity:** NR **Baseline Hgb, g/dL ± SD:** **G1:** 9.1 ± 1.2 **G2:** 9.5 ± 0.9 **G3:** NR	**Inclusion criteria:** • Pre-menopausal women • Symptomatic fibroids **Exclusion criteria:** • Hormonal therapy • Delivery • Uterine surgery within 12 mos prior to study **Indications:** NR **Pre-operative therapy:** See groups **Associated procedure(s):** Myomectomy, hysterectomy or hysteroscopic resection	**Baseline uterine size, cm³ ± SD:** **G1:** 992.7 ± 115.9 **G2:** 977.1 ± 104.7 **G3:** NR **Number of fibroids:** NR **Baseline fibroid size:** NR **Type of fibroid:** NR	**Uterine Size, cm³ ± SD:** **G1:** 584 ± 87.3 **G2:** 569 ± 84.8 **G3:** NR **G1**vs **G2:** *P* > 0.05 **Hgb, g/dL ± SD:** **G1:** 12.4 ± 1.6 **G2:** 9.1 ± 1.2 **G3:** NR G1 vs. G2**:** *P* > 0.05 **Menorrhagia, using VAS at baseline:** **G1:** 6.9 ± 1.1 **G2:** 7.2 ± 1.3 *P* > 0.05 No menorrhagic at followup **Pelvic pain, using VAS at baseline:** **G1:** 3.9 ± 1.2 **G2:** 4.1 ± 1.5 *P* > 0.05 No pelvic pain at followup **Hot flashes (data presented graphically)** **G1:** No change **G2:** Increase over time *P* significant value NR **Modifiers:** NR	**Quality:** Overall quality score: poor **INTERNAL VALIDITY: poor** Random: - Methods and blinding: + Pt selection criteria: + Loss to follow-up: <10% Drop-out rates: <5% Statistical issues: + **EXTERNAL VALIDITY: poor (5)** Age: +, reported Race: NA, not US study Pregnancy history: -, NR Surgical history: +, reported Fibroid/uterine size: + Number of fibroids: - Location of fibroids: - Baseline characteristics: -, NR Length of follow-up: + Measurement methods: + Measurement reliability: + Clinical care: -

Evidence Table 3. KQ 2 Pharmaceutical management (continued)

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria Other Details	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author: Di Lieto, De Falco, Pollio et al., 2005 **Country and setting:** Italy, Academic medical center **Enrollment period:** NR **Funding:** Italian Ministry of University and Scientific Research	**Design:** Prospective cohort **Intervention:** Medical management followed by uterine surgery **Groups:** **G1:** Leuprolide acetate depot injections for 3 mos **G2:** No pre-treatment **N at enrollment:** **G1:** 31 **G2:** 55 **N at follow-up:** NR **Age, yrs ± SD:** **G1:** 37.5 ± 3.9 **G2:** 38.1 ± 3.5 **Race/ethnicity:** NR **Parity, mean ± SD:** **G1:** 2.2 ± 1.4 **G2:** 2.1 ± 1.6 **Baseline Hgb, g/dL ± SD:** **G1:** 7.6 ± 0.3 **G2:** 7.8 ± 0.5	**Inclusion criteria:** • Pre-menopausal • Symptomatic fibroids **Exclusion criteria:** • Malignant neoplasm In last 12 mos: • Received hormonal therapy • Delivered • Underwent uterine surgery **Indications:** NR **Preoperative therapy:** See Groups **Additional procedures:** NR	**Baseline uterine size, cm³ ± SD:** **G1:** 725.6 ± 193.5 **G2:** 762.7 ± 201.2 **Number of fibroids:** NR **Baseline fibroid size:** NR **Type of fibroid:** NR	**Hgb, after therapy, g/dL ± SD:** **G1:** 12.8 ± 0.3 **G2:** NA **Hgb, after surgery, g/dL ± SD:** **G1:** 11.3 ± 0.5 **G2:** 6.5 ± 0.8 **Uterine volume, cm³ ± SD:** **G1:** 492.7±134.2 **G2:** N/A **Modifiers:** NR	**Quality:** Overall quality score: fair **INTERNAL VALIDITY: good** Random: NA Methods and blinding: NA Pt selection criteria: + Loss to follow-up: <10% Drop-out rates: <5% Statistical issues: + **EXTERNAL VALIDITY: fair (3)** Age: +, reported Race: NA, not US study Pregnancy history: +, reported Surgical history: +, reported Fibroid/uterine size: + Number of fibroids: - Location of fibroids: - Baseline characteristics: +, reported Length of follow-up: + Measurement methods: + Measurement reliability: + Clinical care: -

Evidence Table 3. KQ 2 Pharmaceutical management (continued)

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria Other Details	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author: Di Lieto, De Falco, Staibano et al., 2003 **Country and setting:** Italy, Academic medical center **Enrollment period:** NR **Funding:** NR	**Design:** Prospective cohort **Intervention:** Monthly subcutaneous leuprorelin acetate depot 3.75 mg for 3 cycles prior to myomectomy or hysterectomy **Groups:** **G1:** Leuprorelin acetate depot 3.75 mg **G2:** No medical intervention women **N at enrollment:** **G1:** 25 **G2:** 46 **N at follow-up:** **G1:** 25 **G2:** 46 **Age, yrs ± SD:** **G1:** 38.4 ± 4.3 **G2:** 37.9 ± 3.5 **Race/ethnicity:** NR **Parity, mean ± SD:** **G1:** 2.3 ± 1.4 **G2:** 1.9 ± 1.5 **Baseline Hgb/Hct:** NR	**Inclusion criteria:** • Pre-menopausal • Fibroids present **Exclusion criteria:** • Malignant neoplasm In last 12 mos: • Received hormonal therapy • Delivered • Underwent uterine surgery **Indications:** NR **Preoperative therapy:** See Groups **Additional procedures:** NR	**Baseline uterine size, cm³ ± SD:** **G1:** 774.5 ± 203.1 **G2:** 804.7 ± 233.7 **Number of fibroids:** NR **Baseline fibroid size:** NR **Type of fibroid:** NR	**Uterine size:** **G1:** 484.9 ± 144.5 **G2:** N/A *P* < 0.05 **"Quickscore"* for bFGF:** **G1:** 7.96 ± 2.22 **G2:** 9.61 ± 2.54 *P* < 0.05 **Modifiers:** NR	**Quality:** Overall quality score: fair **INTERNAL VALIDITY: good** Random: NA Methods and blinding: NA Pt selection criteria: + Loss to follow-up: <10% Drop-out rates: <5% Statistical issues: + **EXTERNAL VALIDITY: fair (3)** Age: +, reported Race: NA, not US study Pregnancy history: +, reported Surgical history: +, reported Fibroid/uterine size: + Number of fibroids: - Location of fibroids: - Baseline characteristics: +, reported Length of follow-up: + Measurement methods: + Measurement reliability: + Clinical care: -

Evidence Table 3. KQ 2 Pharmaceutical management (continued)

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria Other Details	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author: Di Lieto, De Rosa et al., 2002 **Country and setting:** Italy, Academic medical center **Enrollment period:** NR **Funding:** NR	**Design:** Prospective cohort **Intervention:** Monthly subcutaneous leuprorelin acetate depot 3.75 mg for 3 cycles prior to myomectomy **Groups:** **G1:** Leuprorelin acetate depot 3.75 mg **G2:** No medical intervention **N at enrollment:** **G1:** 39 **G2:** 31 **N at follow-up:** **G1:** 39 **G2:** 31 **Age, yrs ± SD:** **G1:** 36.1 ± 3.2 **G2:** 37.3 ± 3.7 **Race/ethnicity:** NR **Parity, mean ± SD:** **G1:** 2.2 ± 1.8 **G2:** 1.9 ± 1.8 **Baseline Hgb/Hct:** NR	**Inclusion criteria:** • Pre-menopausal • Symptomatic fibroids **Exclusion criteria:** • Malignant neoplasm In last 12 mos: • Received hormonal therapy • Delivered • Underwent uterine surgery **Indications:** NR **Preoperative therapy:** See Groups **Additional procedures:** NR	**Baseline uterine size, cm³ ± SD:** **G1:** 571.3 ± 266.7 **G2:** 540.4 ± 250.8 **Number of fibroids:** NR **Baseline fibroid size:** NR **Type of fibroid:** NR	**Uterine Size, cm³ ± SD:** **G1:** 413.4 ± 217 **G2:** 601.1 ± 241.3 **Modifiers:** NR	**Quality:** Overall quality score: fair **INTERNAL VALIDITY: good** Random: NA Methods and blinding: NA Pt selection criteria: + Loss to follow-up: <10% Drop-out rates: <5% Statistical issues: + **EXTERNAL VALIDITY: poor (4)** Age: +, reported Race: NA, not US study Pregnancy history: +, reported Surgical history: NA Fibroid/uterine size: + Number of fibroids: - Location of fibroids: - Baseline characteristics: -, NR Length of follow-up: + Measurement methods: + Measurement reliability: + Clinical care: -

Evidence Table 3. KQ 2 Pharmaceutical management (continued)

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria Other Details	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author: Di Lieto, Iannotti et al., 2003 **Country and setting:** Italy, Academic medical center **Enrollment period:** NR **Funding:** NR	**Design:** Prospective cohort **Intervention:** Monthly subcutaneous leuprorelin acetate depot 3.75 mg for 3 cycles prior to myomectomy **Groups:** **G1:** Leuprorelin acetate depot 3.75 mg **G2:** No medical intervention **N at enrollment:** **G1:** 48 **G2:** 41 **N at follow-up:** **G1:** 48 **G2:** 41 **Age, yrs ± SD:** **G1:** 38 ± 4 **G2:** 38.8 ± 3.7 **Race/ethnicity:** NR **Parity, mean ± SD:** **G1:** 2.2 ± 1.8 **G2:** 1.5 ± 1.3 **Baseline Hgb/Hct:** NR	**Inclusion criteria:** • Pre-menopausal • Symptomatic fibroids **Exclusion criteria:** • Malignant neoplasm In last 12 mos: • Received hormonal therapy • Delivered • Underwent uterine surgery **Indications:** NR **Preoperative therapy:** See Groups **Additional procedures:** NR	**Baseline uterine size, cm³ ± SD:** **G1:** 675.8 ± 176 **G2:** 646.9 ± 191.4 **Number of fibroids:** NR **Baseline fibroid size:** NR **Type of fibroid:** NR	**Uterine volume, cm³ ± SD:** **G1:** 466.6 ± 113.3 **G2:** NR *P* < 0.05 **Modifiers:** NR	**Quality:** Overall quality score: fair **INTERNAL VALIDITY: good** Random: NA Methods and blinding: NA Pt selection criteria: + Loss to follow-up: NR Drop-out rates: NR Statistical issues: + **EXTERNAL VALIDITY: fair (3)** Age: +, reported Race: NA, not US study Pregnancy history: +, reported Surgical history: +, reported Fibroid/uterine size: + Number of fibroids: - Location of fibroids: - Baseline characteristics: +, reported Length of follow-up: + Measurement methods: + Measurement reliability: + Clinical care: -

Evidence Table 3. KQ 2 Pharmaceutical management (continued)

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria Other Details	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author: Donnez et al., 2003 **Country and setting:** Multi-national, Academic medical centers **Enrollment period:** NR **Funding:** AstraZeneca Pharma-ceuticals	**Design:** RCT **Intervention:** Medical management with anti-estrogen and GnRH-a followed by hysterectomy **Groups:** **G1:** Fulvestrant 50 mg IM injection monthly x 3 **G2:** Fulvestrant 125 mg IM monthly x 3 **G3:** Fulvestrant 250 mg IM monthly x 3 **G4:** Goserelin 3.6 mg SC x 3 **G5:** No treatment **N at enrollment:** **G1:** 59 **G2:** 66 **G3:** 62 **G4:** 66 **G5:** 60 **N at follow-up:** **G1:** 55 **G2:** 63 **G3:** 61 **G4:** 62 **G5:** 60 **Age, yrs ± SD:** **G1:** 44.0 ± 4.0 **G2:** 44.0 ± 4.4 **G3:** 44.0 ± 4.5 **G4:** 44.0 ± 4.0 **G5:** 44.0 ± 5.1 **Race/ethnicity:** NR **Parity:** NR **Baseline Hgb/Hct:** NR	**Inclusion criteria:** • Pre-menopausal • Uterine fibroids requiring hysterectomy • Willing to use barrier contraception for 4 weeks before and during presurgical stage of trial • Not involved in night-shift work **Exclusion criteria:** • Previously received >3mos GnRHa • Completed GnRHa treatment within 3 mos of study • Received sex-hormone therapy, used OCP, or danazol within 4 weeks of study • History of disease affecting bone or steroid metabolism • Change in menstrual frequency or changes related to onset of menopause **Indications:** NR **Preoperative therapy:** NR **Associated procedure(s):** NR	**Baseline uterine size, cm^3 ± SD:** Numerical values not reported **Number of fibroids:** NR **Baseline fibroid size:** NR **Type of fibroid:** NR	**Fibroid volume:** G1 vs. G5: *P* = 0.833 G2 vs. G5: *P* = 0.938 G3 vs. G5: *P* = 0.506 G1 vs. G4: *P* = 0.001 G2 vs. G4: *P* = 0.0002 G3 vs. G4: *P* = 0.023 **Endometrial thickness:** G1 vs. G5: *P* = 0.468 G2 vs. G5: *P* = 0.868 G3 vs. G5: *P* = 0.755 G1 vs. G4: *P* = 0.025 G2 vs. G4: *P* = 0.002 G3 vs. G4: *P* = 0.009 **Uterine Volume:** Numerical values not reported G3/G4 superior, G4 > G3 **Modifiers:** NR	**Quality:** Overall quality score: poor **INTERNAL VALIDITY: poor** Random: - Methods and blinding: - Pt selection criteria: + Loss to follow-up: <10% Drop-out rates: 5-10% Statistical issues: + **EXTERNAL VALIDITY: poor (5)** Age: +, reported Race: NA, not US study Pregnancy history: -, NR Surgical history: NA Fibroid/uterine size: + Number of fibroids: - Location of fibroids: - Baseline characteristics: -, NR Length of follow-up: + Measurement methods: + Measurement reliability: + Clinical care: -

Evidence Table 3. KQ 2 Pharmaceutical management (continued)

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria Other Details	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author: Eisinger et al., 2003 Eisinger et al., 2005 **Country and setting:** US, Community **Enrollment period:** 10/2000 to 04/2001 **Funding:** David and Lucille Packard Foundation and the Abortion Rights Mobilization	**Design:** RCT **Intervention:** Oral mifepristone daily **Groups:** **G1:** 5 mg/day po mifepristone **G2:** 10 mg/day po mifepristone **N at enrollment:** **G1:** 20 **G2:** 20 **N at follow-up:** 6 mos: **G1:** 18 **G2:** 20 12 mos: **G1:** 8 **G2:** 10 **Age, yrs ± SD:** **G1:** 43.9 ± 5.1 **G2:** 41.1 ± 5.3 **Race/ethnicity, N (%):** White: **G1:** 13 (65) **G2:** 12 (60) Black: **G1:** 5 (25) **G2:** 8 (40) Hispanic: **G1:** 1 (5) **G2:** 0 Asian: **G1:** 1 (5) **G2:** 0 **Parity, mean ± SD:** **G1:** 0.4 ± 0.8 **G2:** 0.4 ± 0.7 **Baseline Hgb, g/dL:** **G1:** 12 ± 2.3 **G2:** 12.2 ± 2.1	**Inclusion criteria:** • Premenopausal • Symptomatic fibroid(s) • Uterine volume ≥ 300 cc by U/S • Use non-hormonal contraception • Indications for hysterectomy **Exclusion criteria:** • Pregnancy or attempting pregnancy • FSH > 11.6 mIU/mL • Breast-feeding • Adnexal masses • Abnormal vaginal bleeding • Suspected/ diagnosed gynecologic cancer • Contraindica-tions to mifepristone • Anticoagulants • Herbals or botanicals with hormonal effects • Oral contraception, hormone replacement therapy, GnRH analogues, or depo-medroxypro-gesterone in prior 6 mos **Indications:** NR **Preoperative therapy:** NR **Associated procedure(s):** NR	**Baseline uterine size, cc ± SD:** **G1:** 832 ± 443 **G2:** 850 ± 380 **Number of fibroids:** NR **Baseline fibroid size:** NR **Type of fibroid:** NR	**Outcomes at 2 mos:** **Uterine volume, cc:** **G1:** 660 **G2:** 640 *P* comparison to baseline: **G1:** 0.003 **G2:** <0.001 **Outcomes at 4 mos:** **Uterine volume, cc:** **G1:** 498 **G2:** 539 *P* comparison to baseline: **G1:**<0.001 **G2:**<0.001 **Outcomes at 6 mos:** **Uterine volume, mean cc:** **G1:** 435 **G2:** 438 **Decrease in volume, mean cc:** **G1:** -400 **G2:** -416 *P* comparison to baseline: **G1:** < 0.001 **G2:** < 0.001 **Amenorrhea:** **G1:** 61% **G2:** 65% **Menstrual blood loss index score, mean:** **G1:** 10.9 (95% CI, 5.8-15.9) **G2:** 5.9 (95% CI, 1.0-10.7) *P* NS, value NR **Simple hyperplasia on biopsy:** **G1:** 0 **G2:** 5	**Quality:** Overall quality score: fair **INTERNAL VALIDITY: fair** Random: + Methods and blinding: - Pt selection criteria: ++ Loss to follow-up: <10% Drop-out rates: <5% Statistical issues: ++ **EXTERNAL VALIDITY: fair (3)** Age: +, reported Race: +, reported Pregnancy history: +, reported Surgical history: -, NR Fibroid/uterine size: + Number of fibroids: - Location of fibroids: - Baseline characteristics: +, reported Length of follow-up: + Measurement methods: + Measurement reliability: + Clinical care: +

Evidence Table 3. KQ 2 Pharmaceutical management (continued)

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria Other Details	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author: Eisinger et al., 2003 Eisinger et al., 2005 (continued)				**Outcomes at 12 mos:** **Change in uterine volume, cc:** All: -439 (95% CI, -563 - -316) **Amenorrhea,%:** **G1:** 40% **G2:** 70% **Simple hyperplasia on biopsy, N:** **G1:** 0 **G2:** 1 (No atypia in any biopsies) **Modifiers:** NR	

Evidence Table 3. KQ 2 Pharmaceutical management (continued)

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria Other details	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author: Litta et al., 2005 **Country and setting:** Italy, Academic medical center **Enrollment period:** 01/2000 to 9/2003 **Funding:** NR	**Design:** Retrospective cohort **Intervention:** Treatment with GnRH analog for 3 months prior to laparoscopic myomectomy **Groups:** **G1:** GnRH analog for 3 months **G2:** No treatment prior to myomectomy **N at enrollment:** **G1:** 30 **G2:** 30 **N at follow-up:** **G1:** 30 **G2:** 30 **Age, yrs ± SD:** **G1:** 39.2 ± 6.1 **G2:** 38.9 ± 5.4 **Race/Ethnicity:** NR **Parity:** NR **Baseline Hgb/Hct:** NR	**Inclusion criteria:** • Reproductive age • Single fibroid ≤ 4cm • Undergoing laparoscopic myomectomy **Exclusion criteria:** • Intrauterine lesions **Indications:** NR **Pre-operative therapy:** See groups **Associated procedure(s):** NR	**Baseline uterine size:** NR **Number of fibroids removed, N:** **G1:** 30 **G2:** 30 **Baseline fibroid size, ml ± SD:** **G1:** 494.4 ± 488.7 **G2:** NR **Type of fibroid:** NR	**Operative time, min ± SD:** **G1:** 96.0 ± 38.5 **G2:** 103.9 ± 33.8 *P* = NS **Mean estimated blood loss, ml ± SD:** **G1:** 201.7 ± 209.4 **G2:** 203.8 ± 193.9 *P* = NS **Conversion to laparotomy, N (%):** **G1:** 1 (3.3) **G2:** 0 **Length of stay, days ± SD:** **G1:** 1.6 ±1.3 **G2:** 1.7 ± 1.6 *P* = NS **Fever > 38°C, N (%):** **G1:** 2 (6.6) **G2:** 1 (3.3) **Fibroid volume vs. baseline, ml ± SD:** **G1:** 369.2 ± 358.9 **G2:** 397.7 ± 409.2 *P* < 0.001 **Decrease in fibroid volume, ml ± SD:** **G1:** 125.2 ± 159.8 **G2:** NR **Modifiers:** Increasing fibroid volume and weight associated with blood loss, and operating time within and across groups (*P* < 0.0001).	**Quality:** **Overall quality score: poor** **INTERNAL VALIDITY: fair** Random: NA Methods and blinding: NA Pt selection criteria: + Loss to follow-up: NA Drop-out rates: NA Statistical issues: - **EXTERNAL VALIDITY: poor (6)** Age: +, reported Race: NA, not US study Pregnancy history: -, NR Surgical history: -, NR Fibroid/uterine size: + Number of fibroids: - Location of fibroids: - Baseline characteristics: -, NR Length of follow-up: NA Measurement methods: + Measurement reliability: + Clinical care: -

Evidence Table 3. KQ 2 Pharmaceutical management (continued)

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria Other Details	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author: Palomba, Morelli, Di Carlo et al., 2002 **Country and setting:** Italy, Academic medical center **Enrollment period:** NR **Funding:** NR	**Design:** RCT **Intervention:** Leuprolide acetate plus tibolone for 12 mos vs. hysterectomy with bilateral oophorectomy **Groups:** **G1:** Symptomatic fibroids treated with leuprolide acetate plus tibolone **G2:** Symptomatic fibroids treated with laparoscopic or laparotomic hysterectomy with bilateral oophorectomy **G3:** Non randomized comparison group of naturally postmenopausal women **N at enrollment:** **G1:** 60 **G2:** 60 **N at followup:** **G1:** 56 **G2:** 54 **Age, yrs ± SD:** **G1:** 53.9 ± 1.6 **G2:** 53.1 ± 1.5 **G3:** 54.2 ± 1.8 **Race/ethnicity:** NR **Parity, mean ± SD:** **G1:** 2.1 ± 1.6 **G2:** 1.9 ± 1.9 **G3:** 2.0 ± 1.7 **Baseline Hgb/Hct:** NR	**Inclusion criteria:** • Age > 52 yr • No hormone therapy after menopause **Exclusion criteria:** • BMD <1.0 SD • Medical illnesses with impact calcium metabolism • Treatment with drugs for or interfering with bone metabolism • BMI < 18 or >30 • Cigarette use >20/day • Alcohol > 3 drinks/day **Indications:** NR **Preoperative therapy:** See groups **Associated procedure(s):** NR	**Baseline uterine size:** NR **Number of fibroids:** NR **Baseline fibroid size:** NR **Type of fibroid:** NR	**Change in BMD, %:** **G1:** 5.7[a] **G2:** 6.4[a] **G3:** 3.4[a,b] **Change in Bone Alkaline Phosphatase, %:** **G1:** 33.5[a] **G2:** 36.7[a] **G3:** 21.2[a,b] [a] *P* < 0.05 vs. baseline [b] *P* < 0.05 vs. G1&2 **Modifiers:** No significant difference in BMD or in bone turnover markers was detected between G1 and G2 The decrease in BMD and in bone turnover markers was statistically significant (*P* < .05) when G1 & G2 were compared to G3	**Quality:** Overall quality score: fair **INTERNAL VALIDITY: fair** Random: + Methods and blinding: - Pt selection criteria: ++ Loss to follow-up: <10% Drop-out rates: <5% Statistical issues: ++ **EXTERNAL VALIDITY: fair (2)** Age: +, reported Race: NA, not US study Pregnancy history: +, reported Surgical history: -, NR Fibroid/uterine size: + Number of fibroids: NA Location of fibroids: NA Baseline characteristics: -, NR Length of follow-up: ++ Measurement methods: + Measurement reliability: + Clinical care: +

[a] *P* < 0.005 vs. baseline
[b] *P* <0.05 versus Group 2

Evidence Table 3. KQ 2 Pharmaceutical management (continued)

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria Other Details	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author: Palomba, Pellicano et al., 2001 Palomba, Morelli, Noia, et al., 2002 **Country and setting:** Italy, Academic medical center **Enrollment period:** NR **Funding:** NR	**Design:** RCT **Intervention:** Leuprolide acetate, tibolone and iron vs. leuprolide acetate and iron vs. placebo prior to myomectomy **Groups:** **G1:** IM leuprolide acetate 3.75 mg q28d; iron 2 tablets daily; tibolone oral 2.5mg/d **G2:** IM leuprolide acetate 3.75 mg q28d; iron 2 tablets daily; **G3:** Iron tablets, 2 orally daily **N at enrollment:** **G1:** 22 **G2:** 22 **G3:** 22 **N at follow-up:** **G1:** 20 **G2:** 20 **G3:** 21 **Age, yrs ± SD:** **G1:** 24.9 ± 3.9 **G2:** 27.0 ± 3.3 **G3:** 26.6 ± 4.1 **Race/ethnicity:** NR **Parity:** NR **Baseline Hgb, g/dL ± SD:** **G1:** 12.2 ± 1.6 **G2:** 11.9 ± 1.5 **G3:** 12.4 ± 1.7	**Inclusion criteria:** • Infertility >3 years • Recurrent miscarriage • Increased vaginal bleeding • Pelvic pressure and pain • Urinary frequency • Constipation • Largest Intramural fibroid 400 to 500 cm³ • ≤ 3 fibroids **Exclusion criteria:** • Serious medical illnesses • Submucosal fibroids • Abnormal endometrial biopsy • Abnormal pap smear • Pregnant • Calcification or hyperechoic fibroids **Indications:** NR **Preoperative therapy:** See groups **Associated procedure(s):** NR	**Baseline uterine size, cm^3 ± SD:** **G1:** 528 ± 83 **G2:** 504 ± 92 **G3:** 496 ± 99 **Number of fibroids, mean ± SD:** **G1:** 1.90 ± 0.9 **G2:** 2.0 ± 0.9 **G3:** 1.9 ± 0.9 **Baseline fibroid size, cm^3 ± SD:** **G1:** 179 ± 48 **G2:** 167 ± 41 **G3:** 163 ± 38 **Type of fibroid:** All intramural	**Operative time, min ± SD:** **G1:** 99.8 ± 22.7 **G2:** 91.5 ± 17.6 **G3:** 117.6 ± 16.1 G1/G2 vs. G3: $P < 0.05$ G1 vs. G2: P = NS **Estimated blood loss, ml ± SD:** **G1:** 186.8 ± 62.2 **G2:** 171.2 ± 64.3 **G3:** 245.8 ± 53.0 G1/G2 vs. G3: $P < 0.05$ G1 vs. G2: P = NS **Hgb, Visit 2, g/dL ± SD:** **G1:** 13.6 ± 0.9[a] **G2:** 13.5 ± 0.9[a] **G3:** 12.1 ± 1.5[c] **Hgb, Visit 3, g/dL ± SD:** **G1:** 12.0 ± 0.8[b] **G2:** 12.2 ± 0.8[b] **G3:** 10.7 ± 1.1[b,c] **Uterine volume, Visit 2, cm^3 ± SD:** **G1:** 373 ± 51[a] **G2:** 337 ± 50[a] **G3:** 498 ± 97[c] **Uterine volume, Visit 3, cm^3 ± SD:** **G1:** 198 ± 27[a,b] **G2:** 193 ± 18[a,b] **G3:** 201 ± 19[a,b] **Fibroid Volume, Visit 2, cm^3 ± SD:** **G1:** 130 ± 31[a] **G2:**113 ± 23[a] **G3:**164 ± 39[c] [a] $P < 0.05$ vs. Visit 1 [b] $P < 0.05$ vs. Visit 2 [c] $P < 0.05$ vs. G1 & G2 **Modifiers:** NR	**Quality:** Overall quality score: fair **INTERNAL VALIDITY: good** Random: + Methods and blinding: + Pt selection criteria: ++ Loss to follow-up: <10% Drop-out rates: <5% Statistical issues: ++ **EXTERNAL VALIDITY: fair (2)** Age: +, reported Race: NA, not US study Pregnancy history: +, reported Surgical history: -, NR Fibroid/uterine size: + Number of fibroids: + Location of fibroids: - Baseline characteristics: +, reported Length of follow-up: ++ Measurement methods: + Measurement reliability: + Clinical care: +

Evidence Table 3. KQ 2 Pharmaceutical management (continued)

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author: Palomba, Orio et al., 2002 Palomba, Russo, Orio, Tauchmanova et al., 2002 Palomba, Orio, Russo, Falbo et al., 2004 Palomba, Russo et al., 2004 **Country and setting:** Italy, Academic medical center **Enrollment period:** 06/2000 to 01/2001 **Funding:** NR	**Design:** RCT **Intervention:** Leuprolide acetate depot and raloxifene hydrochloride vs. placebo **Groups:** **G1:** Leuprolide acetate depot 3.75 mg every 28 days and raloxifene hydrochloride 60 mg/d **G2:** Leuprolide acetate depot 3.75 mg every 28 days and placebo each day **N at enrollment:** **G1:** 50 **G2:** 50 **N at follow-up:** NR **Age, yrs ± SD:** **G1:** 49.1 ± 4.2 **G2:** 48.6 ± 3.9 **Race/ethnicity:** NR **Parity, mean ± SD:** **G1:** 1.8 ± 1.4 **G2:** 1.7 ± 1.3 **Baseline Hgb/Hct:** NR	**Inclusion criteria:** • Premenopausal women • Symptomatic fibroids **Exclusion criteria:** • Serious medical illness • Vascular thrombosis • BMD < 1 SD from mean peak value • BMI <18 or >30 • Smoking >20 cigarettes/day • Alcohol>3 drinks/day • WHR > 0.8 • Hyper androgenemia • Serum folate > 12.5 nmol/l • Hyperhomo-cystenaemia **Indications, N:** • Menorrhagia: 50 • Pelvic pressure: 44 • Pelvic pain: 36 • Urinary frequency: 31 • Constipation: 11 **Preoperative therapy:** NA **Associated procedure(s):** NR	**Baseline uterine size, cm^3 ± SD:** **G1:** 473 ± 113 **G2:** 446 ± 105 **Number of fibroids:** NR **Baseline fibroid size , cm^3 ± SD:** **G1:** 197 ± 61 **G2:** 189 ± 154 **Type of fibroid:** NR	**Uterine volume*:** G1 vs. baseline: $P < 0.05$ G2 vs. baseline: $P < 0.05$ **Fibroid volume*:** G1 vs. baseline: $P < 0.05$ G2 vs. baseline: $P < 0.05$ **Menorrhagia, N %:** **G1:** 0(0)[a] **G2:** 0(0)[a] **Pelvic pressure, N %:** **G1:** 3 (6.7)[a] **G2:** 3 (6.5)[a] **Pelvic pain, N %:** **G1:** 2 (4.4)[a] **G2:** 3 (6.5)[a] **Urinary frequency, N %:** **G1:** 3 (6.7)[a] **G2:** 2 (4.3)[a] **Constipation:** **G1:** 0 (0)[a] **G2:** 0 (0)[a] **Change in BMD, Lumbar spine*:** G2 vs. baseline/G1: $P < 0.05$ **Change in BMD, Trochanter*:** G2 vs. baseline/G1: $P < 0.05$ **Change in BMD, Femoral Neck*:** G2 vs. baseline/G1: $P < 0.05$ **Change in TC, mmol/l*:** G1: 0.26[a,b] G2: 0.47[a]	**Quality:** Overall quality score: fair **INTERNAL VALIDITY: good** Random: + Methods and blinding: + Pt selection criteria: ++ Loss to follow-up: <10% Drop-out rates: <5% Statistical issues: ++ **EXTERNAL VALIDITY: poor (4)** Age: +, reported Race: NA, not US study Pregnancy history: +, reported Surgical history: -, NR Fibroid/uterine size: + Number of fibroids: - Location of fibroids: - Baseline characteristics: -, NR Length of follow-up: ++ Measurement methods: + Measurement reliability: + Clinical care: +

[a] $P < 0.005$ vs. baseline
[b] $P < 0.05$ versus Group 2
*Tabular data only

Evidence Table 3. KQ 2 Pharmaceutical management (continued)

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author: Palomba, Orio et al., 2002 Palomba, Russo, Orio, Tauchmanova et al., 2002 Palomba, Orio, Russo, Falbo et al., 2004 Palomba, Russo et al., 2004 (continued)				**Change in HDL-C, mmol/l*:** G1: 0.09[a] **G2: 0.10[a] Change in LDL-C, mmol/l*:** G1: 0.02 [b] G2: 0.23 [a] **Change in TG, mmol/l*:** G1: 0.10 [a] G2: 0.13 [a] **Modifiers:** NR	

[a] $P < 0.005$ vs. baseline
*Tabular data only

Evidence Table 3. KQ 2 Pharmaceutical management (continued)

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria Other Details	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author: Palomba, Orio, Morelli, Russo et al., 2002 **Country and setting:** Italy Academic medical center **Enrollment period:** NR **Funding:** NR	**Design:** RCT **Intervention:** Raloxifene vs. placebo **Groups:** **G1:** Raloxifene 60 mg/d plus polyvitamins for 6x28d cycles **G2:** Raloxifene 180 mg/d plus polyvitamins for 6x28d cycles **G3:** Polyvitamins **N at enrollment:** **G1:** 30 **G2:** 30 **G3:** 30 **N at follow-up:** **G1:** 29 **G2:** 30 **G3:** 29 **Age, yrs ± SD:** **G1:** 36.3 ± 5.4 **G2:** 35.9 ± 6.1 **G3:** 37.2 ± 5.8 **Race/ethnicity:** NR **Parity, mean ± SD:** **G1:** 1.1 ± 1.0 **G2:** 1.2 ± 1.1 **G3:** 1.2 ± 1.1 **Baseline Hgb/Hct:** NR	**Inclusion criteria:** • Healthy pre-menopausal women • Ovulatory cycles from 26-30d • ≤ 2 asymptomatic fibroids < 20mm **Exclusion criteria:** • Neoplastic disease • Serious medical illnesses • Vascular thrombosis/coagulation disorder • BMI >30 • Hormone therapy in prior 6 mos • Moderate to severe vasomotor symptoms **Indications:** NR **Preoperative therapy:** NR **Associated procedure(s):** NR	**Baseline uterine size, cm^3 ± SD:** **G1:** 203.9 ± 58.4 **G2:** 206.7 ± 61.0 **G3:** 195.9 ± 56.5 **Number of fibroids:** NR **Baseline fibroid size, cm^3 ± SD:** **G1:** 51.7±18.9 **G2:** 47.4±16.3 **G3:** 49.0±14.9 **Type of fibroid:** NR	**Uterine size, 3rd cycle, cm^3 ± SD:** **G1:** 205.5 ± 58.3 **G2:** 207.5 ± 62.3 **G3:** 197.3 ± 54.1 *P = NS* **Uterine size, 6th cycle, cm^3 ± SD:** **G1:** 209.5 ± 59.3 **G2:** 207.5 ± 64.4 **G3:** 202.0 ± 52.6 G1/G3 vs. baseline: *P* < 0.05 **Fibroid size, 3rd cycle, cm^3 ± SD:** **G1:** 53.3 ± 19.7 **G2:** 47.6 ± 18.1 **G3:** 50.6 ± 14.9 *P* < 0.05 vs. baseline *P = NS* **Fibroid size, 6th cycle, cm^3 ± SD:** **G1:** 57.4±23.7 **G2:** 47.7±21.8 **G3:** 55.3±17.9 G1/G3 vs. baseline: *P* < 0.05 **Modifiers:** NR	**Quality:** Overall quality score: fair **INTERNAL VALIDITY: good** Random: + Methods and blinding: + Pt selection criteria: ++ Loss to follow-up: <10% Drop-out rates: <5% Statistical issues: ++ **EXTERNAL VALIDITY: fair (3)** Age: +, reported Race: NA, not US study Pregnancy history: +, reported Surgical history: -, NR Fibroid/uterine size: + Number of fibroids: - Location of fibroids: - Baseline characteristics: +, reported Length of follow-up: + Measurement methods: + Measurement reliability: + Clinical care: +

Evidence Table 3. KQ 2 Pharmaceutical management (continued)

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria Other Details	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author: Palomba, Orio, Russo et al., 2005 **Country and setting:** Italy, Academic medical center **Enrollment period:** NR **Funding:** NR	**Design:** RCT **Intervention:** Raloxifene vs. placebo **Groups:** **G1:** 180 mg/day orally for 3 cycles of 28 days **G2:** 3 placebo tablets/day for 3 cycles of 28 days **N at enrollment:** **G1:** 20 **G2:** 20 **N at follow-up:** NR **Age, yrs ± SD:** **G1:** 53.4 ± 4.1 **G2:** 52.2 ± 4.0 **Race/ethnicity:** NR **Parity, mean ± SD:** **G1:** 2.2 ± 1.3 **G2:** 2.1 ± 1.2 **Baseline Hgb/Hct:** NR	**Inclusion criteria:** • Natural menopause for 1 to 2 yrs • 1 to 2 fibroids with at least 1 > 2 cm **Exclusion criteria:** • Neoplastic, metabolic, or infectious diseases • Vascular thrombosis or coagulation abnormality • BMI >30 • Use of hormone therapy in previous 6 mos • Moderate or severe vasomotor symptoms **Indications, N (%):** Uterine prolapse: **G1:** 16 (80) **G2:** 17 (85.9) Complex endometrial hyperplasia: **G1:** 2 (10) **G2:** 2 (10) High-grade intrasquamous lesion: **G1:** 2 (10) **G2:** 1 (5) **Preoperative therapy:** NR **Associated procedure(s):** NR	**Baseline uterine size, cm³ ± SD:** **G1:** 313.1 ± 87.9 **G2:** 327.7 ± 89.8 **Number of fibroids:** NR **Baseline fibroid size, cm³ ± SD:** **G1:** 141.7 ± 37.8 **G2:** 150.3 ± 58.7 **Type of fibroid:** All intramural	**Uterine size at 3 mos, cm³ ± SD:** **G1:** 274.9 ± 71.9 **G2:** 327.5 ± 90.7 G1 vs. baseline: *P* < 0.001 G2 vs. baseline: *P* = 0.824 G1 vs. G2**:** *P* = 0.048 **Fibroid size at 3 mos, cm³ ± SD:** **G1:** 116.3±27.4 **G2:** 150.4±58.0 G1 vs. baseline: *P* < 0.001 G2 vs. baseline: *P* = 0.993 G1 vs. G2**:** *P* = 0.022 **Modifiers:** NR	**Quality:** Overall quality score: fair **INTERNAL VALIDITY: good** Random: + Methods and blinding: + Pt selection criteria: ++ Loss to follow-up: <10% Drop-out rates: <5% Statistical issues: ++ **EXTERNAL VALIDITY: poor (4)** Age: +, reported Race: NA, not US study Pregnancy history: +, reported Surgical history: -, NR Fibroid/uterine size: + Number of fibroids: - Location of fibroids: - Baseline characteristics: +, reported Length of follow-up: ++ Measurement methods: + Measurement reliability: + Clinical care: -

Evidence Table 3. KQ 2 Pharmaceutical management (continued)

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria Other Details	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author: Palomba, Sammartino et al., 2001 **Country and setting:** Italy, Academic medical center **Enrollment period:** NR **Funding:** NR	**Design:** RCT **Intervention:** Raloxifene vs. placebo **Groups:** **G1:** 60 mg/day x 12 cycles **G2:** 60 mg/day placebo x 12 cycles **N at enrollment:** **G1:** 35 **G2:** 35 **N at follow-up:** **G1:** 31 **G2:** 31 **Age, yrs ± SD:** **G1:** 54.2±4.9 **G2:** 51.2±3.9 **Race/ethnicity:** NR **Parity, mean ± SD:** **G1:** 2.0 ± 1.5 **G2:** 2.1 ± 1.7 **Baseline Hgb/Hct:** NR	**Inclusion criteria:** • Natural menopause for 1 to 2 yrs • 1 to 2 fibroids with at least 1 > 2 cm **Exclusion criteria:** • Neoplastic, metabolic or infectious disease • Vascular thrombosis or coagulation abnormality • BMI >30 • Hormone therapy in prior 6 mos • Moderate or severe vasomotor symptoms **Indications:** NR **Preoperative therapy:** NR **Associated procedure(s):** NR	**Baseline uterine size, cm³ ± SD:** **G1:** 295.6 ± 81.0 **G2:** 316.6 ± 113.7 **Number of fibroids:** NR **Baseline fibroid size, cm³ ± SD:** **G1:** 127.1 ± 38.2 **G2:** 138.5 ± 55.7 **Type of fibroid:** NR	**Uterine and fibroid size:** After 6, 9, and 12 cycles of treatment a reduction in mean uterine and fibroid size was observed in comparison to baseline and between groups ($P < 0.05$)* **Amenorrhea** 3 mo, %: **G1:** 83.9 **G2:** 82.8 *P* = NS 6 mo, %: **G1:** 84.9 **G2:** 84.9 *P* = NS 9 mo, %: **G1:** 82.8 **G2:** 83.9 *P* = NS 12 mo, %: **G1:** 88.1 **G2:** 86.0 *P* = NS **AUB episodes** 3 mo (mean ± SD): **G1:** 1.40 ± 0.63 **G2:** 1.40 ± 0.63 *P* =NS 6 mo (mean ± SD): **G1:** 1.29 ± 0.47 **G2:** 1.38 ± 0.62 *P* =NS 9 mo (mean ± SD): **G1:** 1.13 ± 0.34 **G2:** 1.20 ± 0.41 *P* =NS	**Quality:** Overall quality score: fair **INTERNAL VALIDITY: good** Random: + Methods and blinding: + Pt selection criteria: ++ Loss to follow-up: <10% Drop-out rates: 5-10% Statistical issues: ++ **EXTERNAL VALIDITY: fair (3)** Age: +, reported Race: NA, not US study Pregnancy history: +, reported Surgical history: -, NR Fibroid/uterine size: + Number of fibroids: - Location of fibroids: - Baseline characteristics: +, reported Length of follow-up: ++ Measurement methods: + Measurement reliability: + Clinical care: +

*Graphs, not quantitative data provided

Evidence Table 3. KQ 2 Pharmaceutical management (continued)

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria Other Details	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author: Palomba, Sammartino, et al., 2001 (continued)				**AUB episodes, mean ± SD:** At 12 months **G1:** 1.18 ± 0.41 **G2:** 1.15 ± 0.38 *P* =NS **Modifiers:** NR	

Evidence Table 3. KQ 2 Pharmaceutical management (continued)

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria Other Details	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author: Seracchioli et al., 2003 **Country and setting:** Italy, Academic medical center **Enrollment period:** NR **Funding:** NR	**Design:** RCT **Intervention:** Triptorelin depot IM injection 11.25 mg 3 mos prior to laparoscopic hysterectomy **Groups:** **G1:** Triptorelin depot injection 11.25 mg 3 mos prior to surgery starting in midluteal phase **G2:** No therapy **N at enrollment:** **G1:** 31 **G2:** 31 **N at follow-up:** NR **Age, yrs ± SD:** **G1:** 47.6 ± 3.5 **G2:** 48.4 ± 4.6 **Race/ethnicity:** NR **Parity:** NR **Baseline Hgb, g/dl ± SD:** **G1:**11.2 ± 1.3 **G2:**11.6 ± 1.4 **Preoperative Hgb, g/dl ± SD:** **G1:** 12.3 ± 1.4 **G2:** 11.4 ± 1.4 *P* < 0.02	**Inclusion criteria:** • Uterine volume 16-20 wks • Absence of pelvic pathology • No prior therapy with GnRHa, progestational agents, or danazol in past 6 mos • Mobile uterus with mean volume 380-680 ml • Regular vaginal accessibility **Exclusion criteria:** • Diseases requiring hospital monitoring • Prior longitudinal laparotomy • Contra-indications to laparoscopy **Indications, N (%):** • Uterine bleeding: 54 (87) • Pelvic pain/pressure: 35 (56) • Recurrent urinary disorder: 23 (37) **Pre-operative therapy:** see Groups **Associated procedure(s):** Bilateral salpino-oophorectomy: **G1:** 7 (22.6) **G2:** 8 (25.8)	**Baseline uterine volume (ml ± SD):** **G1:** 528 ± 275 **G2:** 579 ± 337 **Preoperative uterine volume (ml ± SD):** **G1:** 388 ± 193 **G2:** 587 ± 341 *P* < 0.005 **Number of fibroids:** NR **Baseline fibroid size:** NR **Type of fibroid:** NR	**Operative time, min ± SD:** **G1:** 85.3 ± 29.1 **G2:** 115.3 ± 38.2 *P* < 0.001 **Conversion to laparotomy, N:** **G1:** 0 **G2:** 3 **Decrease in Hgb, g/dl ± SD:** **G1:** 1.2 ± 0.8 **G2:** 1.9 ± 1.0 *P* < 0.005 **Transfusion, N:** **G1:** 0 **G2:** 3 **Length of stay, hrs ± SD:** **G1:** 76.3 ± 24.4 **G2:** 80.4 ± 26.5 **Modifiers:** NR	**Quality:** Overall quality score: poor **INTERNAL VALIDITY: poor** Random: - Methods and blinding: - Pt selection criteria: ++ Loss to follow-up: NR Drop-out rates: NR Statistical issues: + **EXTERNAL VALIDITY: fair (3)** Age: +, reported Race: NA, not US study Pregnancy history: -, NR Surgical history: NA Fibroid/uterine size: + Number of fibroids: - Location of fibroids: - Baseline characteristics: +, reported Length of follow-up: + Measurement methods: + Measurement reliability: + Clinical care: +

Evidence Table 3. KQ 2 Pharmaceutical management (continued)

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria Other Details	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author: Somekawa et al., 2001 **Country and setting:** Japan, Academic medical center **Enrollment period:** NR **Funding:** NR	**Design:** RCT **Intervention:** GnRH analog **Groups:** **G1:** Leuprolide acetate 1.88 mg IM monthly plus Ipriflavone 600 mg/day po for 6 mos **G2:** Leuprolide acetate 1.88 mg IM monthly for 6 mos **N at enrollment:** **G1:** 51 **G2:** 51 **N at follow-up:** NR **Age, yrs ± SD:** **G1:** 45 ± 1 **G2:** 46 ± 1 **Race/ethnicity:** NR **Parity, mean ± SD:** **G1:** 1.7 ± 0.1 **G2:** 1.7 ± 0.1 **Baseline Hgb/Hct:** NR	**Inclusion criteria:** • Appropriate for leuprolide treatment • Normal cyclic menses **Exclusion criteria:** • Performing excessive exercise • Heavy smokers • Alcoholics • Clinically diagnosed with serious medical illnesses • History of carcinoma **Indications:** NR **Pre-operative therapy:** See groups **Associated procedure(s):** NR	**Baseline uterine size:** NR **Number of fibroids:** NR **Baseline fibroid size:** NR **Type of fibroid:** NR	**Change in fibroid volume, %:** **G1:** 52.9 **G2:** 49.8 *P* = NS **Change in LDL-C , 6 mos, %:** G1: 8.4 G2: 22.6 *P*<0.01 **Modifiers:** NR	**Quality:** Overall quality score: poor **INTERNAL VALIDITY: poor** Random: - Methods and blinding: - Pt selection criteria: - Loss to follow-up: NR Drop-out rates: NR Statistical issues: + **EXTERNAL VALIDITY: poor (5)** Age: +, reported Race: NA, not US study Pregnancy history: +, reported Surgical history: NA Fibroid/uterine size: - Number of fibroids: - Location of fibroids: - Baseline characteristics: -, NR Length of follow-up: + Measurement methods: + Measurement reliability: + Clinical care: -

Evidence Table 3. KQ 2 Pharmaceutical management (continued)

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria Other Details	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author: Vercellini et al., 2003 **Country and setting:** Italy, Academic medical center **Enrollment period:** NR **Funding:** NR	**Design:** RCT **Intervention:** GnRH analog treatment prior to myomectomy **Groups:** **G1:** Triptorelin 3.75 mg IM q28days x 2 prior to myomectomy surgery **G2:** Immediate myomectomy **N at enrollment:** **G1:** 50 **G2:** 50 **N at followup:** 97 **Age, yrs ± SD:** **G1:** 34 ± 4 **G2:** 33 ± 4 **Race/ethnicity:** NR **Parity, parous, %:** **G1:** 15 (31) **G2:** 18 (37) **Baseline Hgb, g/dL ± SD:** **G1:** 12.7 ± 1.2 **G2:** 12.3 ± 1.1 **Baseline Hct (% ± SD):** **G1:** 38.4 ± 3.4 **G2:** 37.6 ± 3.3	**Inclusion criteria:** • Pre-menopausal • Age: 18 to 40 yrs • FSH < 30 mIU/mL **Exclusion criteria:** • Predominantly intracavitary fibroids • Previous pelvic surgery for gyn pathology • GnRHa use in last 6 mos • Ultrasono-graphic signs of uterine calcifications • Coagulation disorders • Unstable general conditions • Hgb <10 g/dL **Indications:** • Menorrhagia • Pelvic compression • Infertility **Pre-operative therapy:** Triptorelin as per intervention **Associated procedure(s):** None	**Baseline uterine size, ml ± SD:** **G1:** 343 ± 130 **G2:** 338 ± 148 **Baseline uterine size, wks gestation ± SD:** **G1:** 12 ± 2 **G2:** 12 ± 2 **Number of fibroids removed, mean ± SD:** **G1:** 3 ± 3 **G2:** 3 ± 3 **Baseline largest fibroid size, mm ± SD:** **G1:** 69 ± 25 **G2:** 66 ± 23 **Type of fibroid:** NR	**Operative time, min ± SD :** **G1:** 93 ± 32 **G2:** 90 ± 32 **Mean estimated blood loss, ml ± SD:** **G1:** 265 ± 181 **G2:** 296 ± 204 **Hgb, 6 hrs after surgery, g/dL ± SD:** **G1:** 12.1 ± 1.2 **G2:** 11.8 ± 1.2 **Hct, 6 hrs after surgery, % ± SD:** **G1:** 35.2 ±3.1 **G2:** 34.5 ± 3.3 **Hgb, 24 hrs after surgery, g/dL ± SD:** **G1:** 11.4 ± 1.0 **G2:** 11.0 ± 1.4 **Hct, 24 hrs after surgery, % ± SD:** **G1:** 34.1 ± 2.9 **G2:** 33.1 ± 3.9 *P* = NR **Modifiers:** NR	**Quality:** Overall quality score: fair **INTERNAL VALIDITY: fair** Random: + Methods and blinding: - Pt selection criteria: ++ Loss to follow-up: <10% Drop-out rates: <5% Statistical issues: ++ **EXTERNAL VALIDITY: fair (2)** Age: +, reported Race: NA, not US study Pregnancy history: +, reported Surgical history: +, reported Fibroid/uterine size: + Number of fibroids: - Location of fibroids: - Baseline characteristics: +, reported Length of follow-up: NA Measurement methods: + Measurement reliability: + Clinical care: +

Evidence Table 3. KQ 2 Pharmaceutical management (continued)

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria Other Details	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author: Verspyck et al., 2000 **Country and setting:** France, Multi-site, NR **Enrollment period:** 3 yr **Funding:** NR	**Design:** RCT **Intervention:** Leuprorelin vs. lynestrenol prior to surgery **Groups:** **G1:** SC injections of LA 3.75 mg every 28 days for 16 weeks prior to surgery **G2:** Lynestrenol 10 mg po per day days 5 to 25 of each menstrual cycle for 16 weeks prior to surgery **N at enrollment:** **G1:** 33 **G2:** 23 **N at follow-up:** **G1:** 28 **G2:** 18 **Age, yrs ± SD:** **G1:** 42.24 ± 1.27 **G2:** 40.17 ± 1.69 **Race/ethnicity:** Caucasian: 91% **Parity (reported as gravidity):** **G1:** 1.97 ± 0.29 **G2:** 2.35 ± 0.42 **Baseline Hgb, g/dL ± SD:** **G1:** 12.54 ± 0.31 **G2:** 12.43 ± 0.33	**Inclusion criteria:** • Symptomatic uterine fibroids • ≥ 1 fibroids ≥ 5 cm by ultrasound • Any size submucous fibroid **Exclusion criteria:** • Amenorrhea • Calcified fibroids • GnRHa therapy in last 6 mos **Indications, N (%),** Infertility: **G1:** 1 (3) **G2:** 2 (8.7) **Pre-operative therapy:** See groups **Associated procedure(s):** Myomectomy and hysterectomy	**Baseline uterine size:** NR **Number of fibroids (mean ± SD):** **G1:** 2.59 ± 0.31 **G2:** 2.04 ± 0.42 **Baseline fibroid size (mm ± SD):** **G1:** 78.69 ± 4.99 **G2:** 65.55 ± 4.72 **Type of fibroid:** ≥ 5 cm as determined by ultrasound OR any size submucous fibroid	**Decrease in fibroid size (mm ± SD):** **G1:** 20.93 ± 4.17 **G2:** 5 ± 3.01 *P* = 0.01 **Hgb, at 16 wks, g/dL ± SD:** **G1:** 13.38 ± 0.21 **G2:** 13.56 ±0.32 *P* = NR **Modifiers:** NR	**Quality:** Overall quality score: poor **INTERNAL VALIDITY: poor** Random: + Methods and blinding: NA Pt selection criteria: + Loss to follow-up: <10% Drop-out rates: >10% Statistical issues: + **EXTERNAL VALIDITY: fair (3)** Age: +, reported Race: NA, not US study Pregnancy history: +, reported Surgical history: NA Fibroid/uterine size: + Number of fibroids: - Location of fibroids: - Baseline characteristics: +, reported Length of follow-up: + Measurement methods: + Measurement reliability: + Clinical care: -

Evidence Table 4. KQ 2 UAE

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria Other Details	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author: Broder et al., 2002 **Country and setting:** US, Academic medical center **Enrollment period:** 02/1996 to 08/1997 **Funding:** Partial support form NIH (NICHD) BIRCWH Grant	**Design:** Retrospective cohort (survey) **Intervention:** Uterine artery embolization or abdominal myomectomy **Groups:** **G1:** Uterine artery embolization **G2:** Abdominal myomectomy **N at procedure:** **G1:** 59 **G2:** 38 **N contacted:** **G1:** 53 **G2:** 32 **N respondents:** **G1:** 51 of 59 **G2:** 30 of 38 **Age, mean yrs:** **G1:** 43.5 (27 to 66) **G2:** 37.6 (28 to 45) *P* = 0.03 **Race/ethnicity, N (%):** **G1:** White: 23 (45) Black: 17 (33) Hispanic: 3 (6) Asian: 1 (2) Other: 7 (14) **G2:** White: 14 (47) Black: 7 (23) Hispanic: 2 (7) Asian: 3 (10) Other: 4 (13) **Parity:** NR **Baseline uterine size:** NR **Baseline Hgb/Hct:** NR	**Inclusion criteria:** Patients having bilateral uterine artery embolization or abdominal myomectomy at a single institution **Exclusion criteria:** NA **Elapsed time from procedure to survey (mean mos, range):** **G1:** 46 (41 to 59) **G2:** 49 (37 to 59) **Indications:** NR **Preoperative therapy:** NR **Additional procedures:** NR	**Number of fibroids:** NR **Baseline fibroid size:** NR **Type of fibroid:** NR	**Further invasive therapy (hysterectomy, myomectomy, or UAE), N (%):** **G1:** 51 (29) **G2:** 1 (3) *P* = 0.004 (AOR: 12.5; 95%CI: 1.4, 110.1) **No improvement/worsening of symptoms, N (%):** **G1:** 3 (8) **G2:** 3 (10) *P* = 0.78 **Somewhat/very dissatisfied, N (%):** **G1:** 2 (6) **G2:** 6 (21) *P* = 0.06 **Clinical failure (a priori definition as combination of three above outcomes), N (%):** **G1:** 20 (39) **G2:** 9 (30) *P* = 0.40 **Modifiers:** NR (in multivariate models, months elapsed total and between procedure and survey did not predict failure)	**Quality:** Overall quality score: poor **INTERNAL VALIDITY: poor** Random: NA Methods and blinding: NA Pt selection criteria: - Loss to follow-up: 10-20% Drop-out rates: NA Statistical issues: + **EXTERNAL VALIDITY: poor (5)** Age: +, reported Race: +, reported Pregnancy history: -, NR Surgical history: +, reported Fibroid/uterine size: - Number of fibroids: - Location of fibroids: - Baseline characteristics: +, reported Length of follow-up: ++ Measurement methods: + Measurement reliability: - Clinical care: +

Evidence Table 4. KQ 2 UAE (continued)

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria Other Details	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author: Chrisman, West et al., 2005 **Country and setting:** US, Academic medical center **Enrollment period:** 11/2000 to 09/2001 **Funding:** NR	**Design:** Prospective case series **Intervention:** UAE **Groups:** Patients who underwent primary UAE **N at enrollment:** 111 **N at follow-up:** 111 **Age:** NR **Race/ethnicity:** NR **Parity:** NR **Baseline Hgb/Hct:** NR	**Inclusion criteria:** Patients who underwent technically successful UAE **Exclusion criteria:** • Not interested in treatment option • History of severe reaction to iodinated contrast agent • Other pathologic process (adenomyosis, infarcted leiomyomas, or other nonuterine disease) **Indications:** • Significant uterine bleeding • Bulk-related symptoms • Pain **Pre-operative therapy:** No **Associated procedure(s):** NR	**Baseline uterine size:** NR **Number of fibroids:** NR **Baseline fibroid size:** NR **Type of fibroid:** NR	**Clinical failure, N (%):** 11 (10%) **Continued symptoms, N (%):** Menorrhagia: 5 (45) Bulk symptoms: 3 (27) Both: 3 (27) Persistent contrast enhancement: 8 (73) Complete tumor necrosis: 3 (27) Offered repeat UAE: 8 (73) 2 refused and sought alternate care **Modifiers:** NR	**Quality:** Overall quality score: poor **INTERNAL VALIDITY: poor** Random: NA Methods and blinding: NA Pt selection criteria: - Loss to follow-up: <10% Drop-out rates: <5% Statistical issues: - **EXTERNAL VALIDITY: poor (7)** Age: +, reported Race: -, NR Pregnancy history: -, NR Surgical history: -, NR Fibroid/uterine size: - Number of fibroids: - Location of fibroids: - Baseline characteristics: +, reported Length of follow-up: + Measurement methods: - Measurement reliability: - Clinical care: +

Evidence Table 4. KQ 2 UAE (continued)

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author: Chrisman, Liu et al., 2005 **Country and setting:** US, Academic medical center **Enrollment period:** 01/2001 to 09/2003 **Funding:** NR	**Design:** Prospective case series **Intervention:** UAE and percutaneous closure device **Groups:** NA **N at enrollment:** 342 **N at follow-up:** 328 **Age, mean range:** Overall: 45 (32 to 54) **Race/ethnicity:** NR **Parity:** NR **Baseline Hgb/Hct:** NR	**Inclusion criteria:** • Patients undergoing UAE for symptomatic fibroids **Exclusion criteria:** NR **Indications:** NR **Preoperative therapy:** NR **Associated procedure(s):** NR	**Baseline uterine size:** NR **Number of fibroids:** NR **Baseline fibroid size:** NR **Type of fibroid:** NR	**Primary hemostasis, N (%):** 320 (97) **Device failure, N (%):** 8 (2.4) (99% CI; 0.2%, 4.6%) **Minor complications, N (%):** 72 (22) (99% CI; 16-28) **Major complications, N:** 0 **Modifiers:** NR	**Quality:** Overall quality score: poor **INTERNAL VALIDITY: fair** Random: NA Methods and blinding: NA Pt selection criteria: ++ Loss to follow-up: <10% Drop-out rates: <5% Statistical issues: - **EXTERNAL VALIDITY: poor (8)** Age: -, NR Race: -, NR Pregnancy history: -, NR Surgical history: -, NR Fibroid/uterine size: - Number of fibroids: - Location of fibroids: - Baseline characteristics: -, NR Length of follow-up: ++ Measurement methods: + Measurement reliability: + Clinical care: +

Evidence Table 4. KQ 2 UAE (continued)

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria and Other Details	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author: Goodwin et al., 2006 **Country and setting:** US, Academic medical centers **Enrollment period:** NR **Funding:** Boston Scientific Corporation	**Design:** Prospective cohort **Intervention:** UAE vs. myomectomy **Groups:** **G1:** UAE **G2:** Myomectomy **N at enrollment:** **G1:** 149 **G2:** 60 **N at follow-up:** **G1:** 121 **G2:** 45 **Age, mean yrs:** **G1:** 43.9 **G2:** 38.2 *P* < 0.0001 **Race:** NR **Parity, parous,%:** **G1:** 75.2 **G2:** 48.3 *P* < 0.0001 **Baseline Hgb/Hct:** NR	**Inclusion criteria:** • Symptomatic fibroids confirmed on MRI • ≥ 30 yr old • Regular menses • Normal Pap smear • Able to complete follow-up requirements **Exclusion criteria:** • Hysteroscopically resectable fibroids • Pelvic infection • Gynecologic malignancy • Undiagnosed pelvic mass outside of uterus • Unexplained abnormal menstrual bleeding • Infection • Coagulopathy • History of pelvic irradiation • ASA score ≥ 4 • FSH level > 40 IU/L • Participation in any other investigational device or drug study • Desire to become pregnant • Abnormal serum creatinine level • Uterine arteriovenous fistula	**Baseline uterine size, cm^3:** **G1:** 658.4 **G2:** 590.6 *P* > 0.05 **Number of fibroids N (%):** 0 **G1:** 2 (1.3) **G2:** 1 (1.7) 1 **G1:** 9 (6.0) **G2:** 5 (8.3) 2 **G1:** 10 (6.7) **G2:** 4 (6.7) 3 **G1:** 10 (6.7) **G2:** 8 (13.3) 4 **G1:** 10 (6.7) **G2:** 7 (11.7) 5 **G1:** 6 (4.0) **G2:** 2 (3.3) 6–10 **G1:** 27 (18.1) **G2:** 14 (23.3) >10 **G1:** 75 (50.3) **G2:** 13 (21.7) *P* = 0.0001 **Baseline dominant fibroid size, cm^3:** **G1:** 182.12 **G2:** 226.92 *P* = 0.081 **Type of fibroid, N (%):** Intramural **G1:** 88 (59.1) **G2:** 26 (43.3) Submucosal **G1:** 1 (0.007) **G2:** 3 (5.0)	**At least 1 adverse event, N (%):** **G1:** 33 (22.1) **G2:** 24 (40) *P* < 0.01 **Major adverse event, N:** **G1:** 6 **G2:** 1 *P* > 0.05 **Length of stay, mean hrs:** **G1:** 23.8 **G2:** 61.6 *P* < 0.0001 **Dominant fibroid volume, 3 mos or 6 mos:** *P* = NS **Quality-of-life assessments, 6 mos:** *P* = NS **Menstrual bleeding score, 3 mos or 6 mos:** *P* = NS **Return to normal activities, mean days:** **G1:** 14.6 **G2:** 44.4 *P* < 0.05 **Missed workdays:** **G1:** 9.9 **G2:** 37.0 *P* < 0.001 **Modifiers:** NR	**Quality:** Overall quality score: fair **INTERNAL VALIDITY: good** Random: NA Methods and blinding: NA Pt selection criteria: ++ Loss to follow-up: 10-20% Drop-out rates: <5% Statistical issues: ++ **EXTERNAL VALIDITY: fair (3)** Age: +, reported Race: -, NR Pregnancy history: +, reported Surgical history: -, NR Fibroid/uterine size: + Number of fibroids: + Location of fibroids: + Baseline characteristics: +, reported Length of follow-up: ++ Measurement methods: + Measurement reliability: + Clinical care: -

Evidence Table 4. KQ 2 UAE (continued)

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria and Other Details	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author: Goodwin et al., 2006 (continued)		• Severe contrast allergy • Pedunculated subserosal fibroid **Indications, N (%):** Abnormal bleeding **G1:** 77 (51.7) **G2:** 20 (33.3) *P* = 0.02 Bulk/pressure **G1:** 38 (25.5) **G2:** 16 (26.7) Pelvic pain **G1:** 29 (19.5) **G2:** 18 (30.0) Infertility **G1:** 0 (0.0) **G2:** 2 (3.3) Other **G1:** 5 (3.4) **G2:** 4 (6.7) **Preoperative therapy:** NR **Additional procedures:** NR	Submucosal pedunculated **G1:** 17 (11.4) **G2:** 2 (3.3) Sebserosal **G1:** 8 (5.4) **G2:** 8 (13.3) Subserosal pedunculated **G1:** 31 (20.8) **G2:** 13 (21.7) Other **G1:** 0 (0.0) **G2:** 1 (1.7) Cannot determine **G1:** 2 (1.3) **G2:** 0 (0.0) Missing **G1:** 2 (1.3) **G2:** 7 (11.7)		

Evidence Table 4. KQ 2 UAE (continued)

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria Other Details	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author: Hald et al; 2004 **Country and setting:** Norway, Academic medical center **Enrollment period:** NR **Funding:** NR	**Design:** Prospective cohort **Intervention:** Laparoscopic occlusion of uterine vessels vs. embolization of uterine arteries **Groups:** **G1:** Radiologic embolization **G2:** Laparoscopic closure of uterine arteries **N at enrollment:** **G1:** 24 **G2:** 22 **N at follow-up:** 32 **Age, mean, yrs:** **G1:** 41 **G2:** 44 *P* = 0.08 **Race/ethnicity, N:** White: 41 African: 2 Arabic: 1 Indian: 2 **Parity, parous, %:** Nulliparous **G1:** 79 **G2:** 45 **Baseline Hgb/Hct:** NR	**Inclusion criteria:** • Pre-menopausal **Exclusion criteria:** • Currently pregnant • Breastfeeding • Current or recent PID • Abnormal Pap • Endometriosis • Breast cancer • Previous history of DVT, thrombo-embolism or liver disease • Hormone therapy in 3 mos prior to study **Indications, N (%):** • Bulk symptoms: 6 (13) • Bulk symptoms and menorrhagia: 29 (63) • Menorrhagia only: 11 (24) **Pre-operative therapy:** NR **Associated procedure(s):** NR	**Baseline uterine volume (ml ± SD):** **G1:** 833 ± 469 **G2:** 665 ± 376 **Number of fibroids:** NR **Baseline dominant fibroid size by ultrasound, ml ± SD:** **G1:** 263 ± 196 **G2:** 187 ± 141 **Baseline dominant fibroid size by MRI, ml ± SD:** **G1:** 293 ± 245 **G2:** 232 ± 157 **Type of fibroid:** NR	**Decrease in size of dominant fibroid, N (%):** Measured by U/S: **G1:** 28 (54) **G2:** 27 (45) *P* = NS Measured fibroid by MRI: **G1:** 27 (45) **G2:** 30 (36) *P* = NS Decreased in uterine volume, measured by MRI: **G1:** 19 (40) **G2:** 17 (36) *P* = NS Pictorial blood loss assessment score: **G1:** 28 (66) **G2:** 33 (50) Postoperative pain, cm (SD): 43 patients **G1:** 1.9 (1.8) **G2:** 1.4 (1.4) *P* = 0.40 Pain relief (ketobemidon), mg (SD): **G1:** 38 (19.6) **G2:** 16 (13.0) *P* = 0.00 **Modifiers:** NR	**Quality:** Overall quality score: fair **INTERNAL VALIDITY: fair** Random: NA Methods and blinding: NA Pt selection criteria: ++ Loss to follow-up: 10-20% Drop-out rates: <5% Statistical issues: ++ **EXTERNAL VALIDITY: fair (2)** Age: +, reported Race: +, reported Pregnancy history: +, reported Surgical history: +, reported Fibroid/uterine size: + Number of fibroids: - Location of fibroids: - Baseline characteristics: +, reported Length of follow-up: + Measurement methods: + Measurement reliability: + Clinical care: +

Evidence Table 4. KQ 2 UAE (continued)

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria Other Details	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author: Healey et al., 2004 **Country and setting:** Canada, Academic medical center **Enrollment period:** 08/2000 to 04/2003 **Funding:** NR	**Design:** Prospective cohort **Intervention:** UAE vs. hysterectomy **Groups:** **G1:** UAE **G2:** Hysterectomy **N at enrollment:** **G1:** 68 **G2:** 16 **N at follow-up:** **G1:** 48 **G2:** 13 **Age, yrs ± SD:** **G1:** 44.9 ± 3.8 **G2:** 43.7 ± 3.6 **Race/ethnicity:** NR **Parity, parous (%):** Nulliparous: **G1:** 11 (22.0) **G2:** 0 **Baseline Hgb/Hct:** NR	**Inclusion criteria:** • Healthy premenopausal women • Age: 39 to 50 • Symptomatic uterine fibroids • Regular menstrual cycles • Day 3 serum FSH levels < 40 IU/L **Exclusion criteria:** See inclusion criteria **Indications, N (%):** Bleeding: **G1:** 42 (61.8) **G2:** 16 (100) Pain/pressure: **G1:** 5 (7.4) **G2:** 0 Urinary symptoms: **G1:** 3 (4.4) **G2:** 0 Multiple symptoms: **G1:** 14 (20.1) **G2:** 0 **Preoperative therapy:** NR **Associated procedure(s):** NR	**Baseline uterine size, ml ± SD:** **G1:** 538 ± 50 **Number of fibroids (%):** 1: **G1:** 11 (16.3) **G2:** NA ≥ 2: 57 (83.8) **G2:** NA **Baseline (dominant) fibroid size, ml ± SD:** **G1:** 154 ± 19.9 **G2:** NA **Type of fibroid, N (%):** Submucosal: **G1:** 10 (14.7) **G2:** NA Intramural or subserosal: **G1:** 58 (85.3) **G2:** NA	**Fibroid volume, 3 mos, ml ± SD:** **G1:** 434.1 ± 51.5 **G2:** NA *P* < 0.05 (95% CI, 6-201) **Fibroid volume, 6 mos, ml ± SD:** **G1:** 361.0 ± 38.4 **G2:** NA *P* < 0.01 (95% CI, 44-241) **Hormone measures at 6 mos** FSH (IU/L ± SEM): **G1:** 9.9 ± 1.0 95% CI, -1.7-1.2 **G2:** 7.8 ± 1.8 95% CI, -0.2-4.0 LH (IU/L ± SEM): **G1:** 7.0 ± 1.1 95% CI, -1.2-0.8 **G2:** 11.2 ± 5 95% CI, -1.91-3.3 E2 (pmol/L ± SEM): **G1:** 214 ± 34.9 95% CI, -52-36 **G2:** 326 ± 79.2 95% CI, -39.8-212.6 **Modifiers:** NR	**Quality:** Overall quality score: fair **INTERNAL VALIDITY: poor** Random: NA Methods and blinding: NA Pt selection criteria: ++ Loss to follow-up: >20% Drop-out rates: <5% Statistical issues: + **EXTERNAL VALIDITY: good** Age: +, reported Race: +, reported Pregnancy history: +, reported Surgical history: +, reported Fibroid/uterine size: + Number of fibroids: + Location of fibroids: + Baseline characteristics: +, reported Length of follow-up: + Measurement methods: + Measurement reliability: + Clinical care: +

Evidence Table 4. KQ 2 UAE (continued)

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria and Other Details	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author: Hehenkamp et al., 2005 **Country and setting:** The Netherlands, Hospitals **Enrollment period:** 03/2002 to 02/2004 **Funding:** Netherlands Organisation for Health Research and Development and Boston Scientific Corporation	**Design:** RCT **Intervention:** UAE versus hysterectomy **Groups:** **G1:** UAE **G2:** Hysterectomy (abdominal, vaginal, laparoscopically assisted vaginal, and laparoscopic) **N at enrollment:** **G1:** 88 **G2:** 89 **N at follow-up:** **G1:** 81 **G2:** 75 **Age, yrs ± SD:** **G1:** 44.6 ± 4.8 **G2:** 45.4 ± 4.2 **Race/ethnicity, N (%):** Black: **G1:** 24 (27.3) **G2:** 20 (22.5) White: **G1:** 54 (61.4) **G2:** 57 (64.0) Other: **G1:** 10 (11.4) **G2:** 12 (13.5) **Parity, N (%):** 0: **G1:** 30 (34.1) **G2:** 20 (22.5) ≥1: **G1:** 58 (65.9) **G2:** 69 (77.5) **Baseline Hgb/Hct:** NR	**Inclusion criteria:** • Ultrasound confirmation uterine fibroids • Menorrhagia • Premenopausal scheduled for hysterectomy **Exclusion criteria:** • Other treatment options available • Future pregnancy desired • Renal failure • Active pelvic infection or clotting disorders • Allergic to contrast material • Uterine malignancy suspected • Submucosal fibroids with 50% of diameter within uterine cavity or dominant pedunculated serosal fibroids **Indications, N (%):** Dysmenorrhea: **G1:** 47 (53.4) **G2:** 50 (56.2) Pressure/Pain: **G1:** 38 (43.1) **G2:** 39 (43.8) Bladder/Bowel symptoms: **G1:** 18 (20.5) **G2:** 25 (28.1) Anemia: **G1:** 43 (48.9) **G2:** 42 (47.2) Other symptoms: **G1:** 6 (6.8) **G2:** 11 (12.4)	**Baseline uterine volume, median cm^3 (range):** **G1:** 321 (31 to 3,005) **G2:** 313 (58 to 3,617) **Number of fibroids (%):** 1 fibroid: **G1:** 35 (39.8) **G2:** 25 (28.1) 2 fibroids: **G1:** 13 (14.8) **G2:** 16 (18.0) 3 fibroids: **G1:** 17 (19.3) **G2:** 25 (25.8) >3 fibroids: **G1:** 18 (20.5) **G2:** 14 (15.7) **Baseline dominant fibroid volume, median cm^3 (range):** **G1:** 59 (1-673) **G2:** 87 (4-1641) **Type of fibroid:** NR	**Procedure time, min:** **G1:** 79.0 **G2:** 95.4 *P* = 0.007 **Mean estimated blood loss, ml ± SD:** **G1:** 30.9 ± 23.8 **G2:** 436.1 ± 474.5 *P* < 0.001 **Length of stay, days ± SD:** **G1:** 2.0 ± 2.1 **G2:** 5.1 ± SD1.3 *P* < 0.001 **Readmissions, N:** **G1:** 9 **G2:** 0 *P* = 0.0032 **Minor complications at surgery, complications/ patients:** **G1:** 23/18 **G2:** 26/23 (RR = 0.72; 95% CI, 0.43-1.23) *P* = 0.23 **Minor complications at 6 weeks, complications/ patients:** **G1:** 68/47 **G2:** 34/30 (RR = 1.45; 95% CI, 1.04-2.02) *P* = 0.024 **Major complications at surgery, complications/ patients:** **G1:**1/1 **G2:** 1/1 (RR = 0.93; 95% CI, 0.06-14.54) *P* = 0.99	**Quality:** Overall quality score: fair **INTERNAL VALIDITY: good** Random: + Methods and blinding: NA Pt selection criteria: ++ Loss to follow-up: <10% Drop-out rates: <5% Statistical issues: ++ **EXTERNAL VALIDITY: fair (1)** Age: +, reported Race: +, reported Pregnancy history: +, reported Surgical history: +, reported Fibroid/uterine size: + Number of fibroids: + Location of fibroids: - Baseline characteristics: +, reported Length of follow-up: + Measurement methods: + Measurement reliability: + Clinical care: +

Evidence Table 4. KQ 2 UAE (continued)

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria and Other Details	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author: Hehenkamp et al., 2005 (continued)		**Preoperative therapy:** NR **Additional procedures, N:** Hysterectomy: **G1:** 4 **G2:** NA Removal of hydrosalpinx: **G1:** 0 **G2:** 1 Adhesiolysis: **G1:** 1 **G2:** 0 Unilateral salpingo-oophorectomy: **G1:** 1 **G2:** 2 Bilateral salpingo-oophorectomy: **G1:** 0 **G2:** 1		**Major complications at 6 weeks, complications/ patients:** **G1:** 3/3 pts **G2:** 1/1 pts (RR = 2.78; 95% CI, 0.30-26.13) *P* = 0.62 **Unscheduled doctor visits, surgery to 6 wks, visits/pts:** **G1:** 45/24 **G2:** 30/19 (RR = 1.45; 95% CI, 0.90-2.37) *P* = 0.12) **Modifiers:** NR	

Evidence Table 4. KQ 2 UAE (continued)

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria Other Details	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author: Huang et al. 2006 **Country and setting:** Canada, Academic medical center **Enrollment period:** 11/1997 to 02/2004 **Funding:** NR	**Design:** Retrospective case series **Intervention:** UAE **N at enrollment:** 233 **N at follow-up:** 233 **Age:** NR **Race/ethnicity:** NR **Parity:** NR **Baseline Hgb/Hct:** NR	**Inclusion criteria:** • Consecutive UAE patients **Exclusion criteria:** NR **Indications, N:** • Menorrhagia: 125 • Abdominal distension: 59 • Abdominal/pelvic pain: 38 **Preoperative therapy:** NR **Associated procedure(s):** NR	**Baseline uterine size, cm^3:** 531.5 **Number of fibroids:** NR **Baseline dominant fibroid size, cm^3:** 201.4 **Type of fibroid:** NR	**UAE Failure** (persistent or recurrent bleeding, pain, or bulk systems with repeat UAE, myomectomy, and/or hysterectomy)**, N (%):** Total: 22 (9.4) Hysterectomy: 16 (6.9) Myomectomy: 6 (2.6) **Modifiers:** Baseline fibroid size (cm^3): Failed: 355.2 Succeeded: 183.8 *P* = NS Baseline uterine size, cm^3: Failed: 590.2 Succeeded: 525.3 *P* = NS Prior myomectomy Failed: 13% vs. Succeeded: 2.4%, *P* < 0.05 Fibroid volume reduction at 6 mos, % Failed: 54.4 Succeeded: 36.0 *P* < 0.05	**Quality:** Overall quality score: poor **INTERNAL VALIDITY: poor** Random: NA Methods and blinding: NA Pt selection criteria: - Loss to follow-up: NA Drop-out rates: NA Statistical issues: - **EXTERNAL VALIDITY: poor (5)** Age: +, reported Race: -, NR Pregnancy history: -, NR Surgical history: +, reported Fibroid/uterine size: + Number of fibroids: - Location of fibroids: - Baseline characteristics: +, reported Length of follow-up: + Measurement methods: + Measurement reliability: - Clinical care: +

Evidence Table 4. KQ 2 UAE (continued)

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria Other Details	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author: Katsumori et al., 2003 **Country and setting:** Japan, Community **Enrollment period:** 2002 **Funding:** NR	**Design:** Retrospective case series **Intervention:** UAE **Groups:** **G1:** Fibroid ≥ 10 cm **G2:** Fibroid < 10 cm **N at enrollment:** **G1:** 47 **G2:** 105 **N at follow-up:** 30 days: 152 > 4 mos: 134 > 12 mos: 96 > 24 mos: 49 **Age:** 42.5 (31 to 52) **Race/ethnicity:** NR **Parity:** NR **Baseline Hgb/Hct:** NR	**Inclusion criteria:** • Pre-menopausal • At least 1 clinical symptom uncontrolled by medication **Exclusion criteria:** • Desire future pregnancy • Refused major surgery **Indications:** Symptomatic fibroids **Pre-operative therapy:** NR **Associated procedure(s):** NR	**Baseline uterine size, ml ± SD:** **G1:** 1,380 ± 500 **G2:** 684 ± 337 *P* < 0.001 **Number of fibroids:** NR **Baseline fibroid size, diameter of largest, cm ± SD:** **G1:** 12.4 ± 2.2 **G2:** 6.8 ± 2.0 *P* < 0.001 **Largest fibroid volume (ml ± SD):** **G1:** 701 ± 336 **G2:** 154 ± 107 *P* < 0.001 **Type of fibroid:** NR	**Procedure time, min ± SD:** **G1:** 55.3 ± 15.8 **G2:** 46.6 ± 14.3 **Length of stay, days ± SD:** **G1:** 4.0 ± 1.6 **G2:** 3.8 ± 0.8 **Minor complications, N (%):** **G1:** 9 (19.1) **G2:** 16 (15.2) *P* = 0.637 **Major complications, N (%):** **G1:** 3 (6.4) **G2:** 2 (1.9) *P* = 0.172 **Increased care, prolonged hospitalization, N (%):** **G1:** 2 (4.3) **G2:** 2 (1.9) **Symptom control, mean score ± SD:** Menorrhagia at 4 mos: **G1:** 3.36 ± 0.99 **G2:** 3.79 ± 0.55 *P* = 0.003 Menorrhagia at 1 yr: **G1:** 3.58 ± 0.50 **G2:** 3.79 ± 0.56 *P* = 0.022 Patient satisfaction at 4 mos: **G1:** 1.80 ± 0.46 **G2:** 1.97 ± 0.18 *P* = 0.004 Complete devascularization at 1 week, N (%): **G1:** 34 (72) **G2:** 94 (90) *P* = 0.007 **Modifiers:** NR	**Quality:** Overall quality score: poor **INTERNAL VALIDITY: fair** Random: NA Methods and blinding: NA Pt selection criteria: ++ Loss to follow-up: NA Drop-out rates: <5% Statistical issues: - **EXTERNAL VALIDITY: poor (4)** Age: +, reported Race: NA, not US study Pregnancy history: -, NR Surgical history: -, NR Fibroid/uterine size: + Number of fibroids: - Location of fibroids: - Baseline characteristics: +, reported Length of follow-up: ++ Measurement methods: + Measurement reliability: + Clinical care: +

Evidence Table 4. KQ 2 UAE (continued)

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria Other details	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author: Lohle et al., 2006 **Country and setting:** Netherlands, Academic medical center **Enrollment period:** 02/2001 to 02/2004 **Funding:** NR	**Design:** Prospective case series **Intervention:** UAE **Groups:** NA **N at enrollment:** 158 **N at follow-up, 12 months:** 126 (MRI) 142 (survey) **Age, mean yrs (range):** 42.3 (23-53 **Race/Ethnicity, N:** White: 142 Afro-Caribbean: 11 Asian: 5 **Parity:** NR **Baseline Hgb/Hct:** NR	**Inclusion criteria:** • Presence of uterine fibroid • Symptoms including: heavy menstrual bleeding, pain, and/or bulk-related symptoms unresolved by previous treatment **Exclusion criteria:** • Postmenopausal • Malignancy • Pedunculated fibroids • Pregnancy **Indications:** See inclusion criteria **Pre-operative therapy:** NR **Associated procedure(s):** NR	**Baseline uterine size, ml ± SD:** 532 ± 375 **Number of fibroids:** NR **Baseline dominant fibroid size, cm^3 ± SD:** 201 ± 249 **Type of fibroid:** NR	**UAE, N (%):** Bilateral: 152 (96) Unilateral: 6 (4) **Amenorrhea, N (%):** Permanent: 17 (11) Transient: 20 (13) **Fibroid expulsion, N (%):** 16 (10) **Additional procedures, N:** Second UAE: 9 Hysterectomy: 3 **Dominant fibroid size, 12 mos, cm^3 ± SD:** 78 ± 100 **Dominant fibroid volume reduction, % ± SD:** 60 ± 40 *P*<0.0001 **Uterine volume reduction, % ± SD:** 47 ± 34 *P*<0.0001 **Symptom resolution, N (%):** Heavy bleeding: 113/126 (91) Pain: 80/91 (92) Bulk symptoms: 70/81 (92) **Satisfaction, N (%):** Very satisfied: 81 (57) Satisfied: 51 (36) Not satisfied: 10 (7) **Modifiers:** **Embosphere vs Embogold:** Embogold: similar volume reduction, satisfaction, and fibroid expulsion *P*=NS Embogold : greater risk of skin rash (*P* = 0.031); slower return to usual activities (*P* = 0.004)	**Quality:** Overall quality score: poor **INTERNAL VALIDITY: poor** Random: NA Methods and blinding: NA Pt selection criteria: - Loss to follow-up: <10% Drop-out rates: NA Statistical issues: - **EXTERNAL VALIDITY: poor (4)** Age: +, reported Race: +, reported Pregnancy history: -, NR Surgical history: -, NR Fibroid/uterine size: + Number of fibroids: - Location of fibroids: - Baseline characteristics: +, reported Length of follow-up: + Measurement methods: + Measurement reliability: + Clinical care: +

Evidence Table 4. KQ 2 UAE (continued)

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria Other Details	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author: McLucas et al., 2001 **Country and setting:** US, Academic center **Enrollment period:** 04/1997 to 08/1999 **Funding:** NR	**Design:** Prospective cohort **Intervention:** UAE **Groups:** NA **N at enrollment:** 167 **N at follow-up (12 mos):** 46 **Age (range):** 43 (29 to 63) **Race/ethnicity:** NR **Parity*:** 0.7 **Baseline uterine size:** Without lupron: 155 (1,389 mL) With lupron: 12 (1,404 mL) **Baseline Hgb/Hct:** NR	**Inclusion criteria:** • Menorrhagia or postmenopausal bleeding secondary to uterine myomata **Exclusion criteria:** • Contraindications to angiography and embolization, such as coagulopathy, pelvic inflammatory disease, diabetes mellitus, or vasculitis **Indications:** NR **Preoperative therapy:** NR **Associated procedure(s):** NR	**Number of fibroids:** NR **Baseline fibroid size: (cm) (range):** 7.8 (1.5 to 16.3) **Type of fibroid:** NR	**Improvement or stabilization of symptoms 6 mos after UFE:** 88% **Total uterine volume decreased:** 52% (N = 46) **Treatment failures, N (%):** 21/167 (13) **Post UFE complications, %:** • Fever: 7 • Nausea/vomiting: 1 • Passage of submucosus myoma: 5 • Premature menopause: 2.4 • Hysterectomy: 3.5 **Other modifiers:** Lupron use Earlier pelvic surgery – more likely to fail UFE: *P* = 0.012 Age, parity, menopausal status, uterine characterics, procedure characteristics (partial size and partial load), and post-procedure complications unrelated to UAE falure	**Quality:** Overall quality score: poor **INTERNAL VALIDITY: poor** Random: NA Methods and blinding: NA Pt selection criteria: ++ Loss to follow-up: >20% Drop-out rates: <5% Statistical issues: + **EXTERNAL VALIDITY: fair (3)** Age: +, reported Race: -, NR Pregnancy history: +, reported Surgical history: +, reported Fibroid/uterine size: + Number of fibroids: - Location of fibroids: - Baseline characteristics: +, reported Length of follow-up: ++ Measurement methods: + Measurement reliability: + Clinical care: +

*Included in models but not reported

Evidence Table 4. KQ 2 UAE (continued)

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria Other Details	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author: McLucas, et al., 2002 **Country and setting:** US, Academic medical center **Enrollment period:** 04/1996 to 05/1999 **Funding:** NR	**Design:** Prospective case series **Intervention:** UAE **Groups:** NA **N at enrollment:** 227 **N at follow-up (6 mos):** 188 **Age*:** NR **Race/ethnicity:** NR **Parity*:** NR **Baseline Hgb/Hct:** NR	**Inclusion criteria:** NR **Exclusion criteria:** NR **Indications:** NR **Preoperative therapy:** NR **Associated procedure(s):** NR	**Baseline uterine size*:** NR **Number of fibroids:** NR **Baseline fibroid size:** NR **Type of fibroid:** NR	Peak systolic velocity positively correlated with volume of embolization particles *P* = 0.05 Higher baseline peak systolic velocity correlated with decrease in myoma and uterine volume *P* = 0.001 High peak systolic velocity (> 64 cm/s) significant predictor of failure *P* = 0.02 **Other modifiers:** NR	**Quality:** Overall quality score: poor **INTERNAL VALIDITY: poor** Random: NA Methods and blinding: NA Pt selection criteria: - Loss to follow-up: 10-20% Drop-out rates: NA Statistical issues: + **EXTERNAL VALIDITY: poor (9)** Age: -, NR Race: -, NR Pregnancy history: -, NR Surgical history: -, NR Fibroid/uterine size: - Number of fibroids: - Location of fibroids: - Baseline characteristics: -, NR Length of follow-up: + Measurement methods: + Measurement reliability: + Clinical care: -

*Included in models but not reported

Evidence Table 4. KQ 2 UAE (continued)

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria Other Details	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author: Pron, Bennett, Common, Sniderman et al., 2003 Pron, Bennett, Common, Wall et al., 2003 Pron, Cohen, Soucie et al., 2003 Pron, Mocarski, Bennett et al., 2003 Pron, Mocarski, Cohen, et al., 2003 **Country and setting:** Canada, Academic medical centers **Enrollment period:** 11/98 to 11/00 **Funding:** NR	**Design:** Prospective case series **Intervention:** UAE **Groups:** NA **N at enrollment:** 555 **N at follow-up:** 548 (98%) at 2 wks 464 (83.6%) at 3 mos ultrasound **Age, mean (yrs):** 43 (18 to 59) **Race/ethnicity:** White: 66% Black: 23% Other: 11% **Parity, parous, %:** Nulliparous: 50 **Baseline Hgb/Hct:** NR	**Inclusion criteria:** • Symptomatic, ultrasound documented fibroids **Exclusion criteria:** • Active PID • Renal insufficiency • Endometrial carcinoma • Undiagnosed pelvic mass • Pregnancy **Indications, %:** • Menorrhagia: 17 • Menorrhagia/ dysmenorrhea: 63 • Pelvic pain: 13 • Bulk effects: 8 **Pre-operative therapy:** NR **Associated procedure(s):** NR	**Baseline uterine size, cm^3 , N (%):** 0 to 250: 106 (22) 251 to 500: 131 (37) 501 to 1,000: 149 (31) ≥1,001: 102 (21) **Number of fibroids, N (%):** 1: 150 (30) 2 to 4: 220 (44) ≥ 5: 125 (26) **Baseline fibroid size mean cm^3:** 293 (95% CI, 259-327) **Type of fibroid, N (%):** • Intramural: 285 (60) • Intramural and subserosal/ submucosal: 63 (13) • Subserosal: 92 (19) • Submucosal: 33 (7)	**Procedure time, min (median):** 61 (55) (95% CI, 58-63) **Fluoroscopy time, mean min:** 18.9 (95% CI, 18.0-19.8) **Complications, N (%):** 30 (5.3) (95% CI, 3.6%-7.4%) **Major complications, N:** 3 **Intra-procedural pain, N (%):** None: 386 (70) Minor/tolerable: 162 (30) Uncomfortable: 54 (10) Very uncomfortable: 50 (9) Unbearable: 23 (4) NRS (1 to 10)- mean (median): 6.3 (6.0) Ineffective analgesia: 24 (4%) **Postprocedural pain, N (%):** None: 44 (8) Minor/tolerable: 86 (18) Uncomfortable: 103 (19) Very uncomfortable: 188 (35) Unbearable: 116 (22) NRS (1 to 10)- mean (median): 7.0 (7.5) Ineffective pain management: 57 (10%)	**Quality:** Overall quality score: fair **INTERNAL VALIDITY: fair** Random: NA Methods and blinding: NA Pt selection criteria: ++ Loss to follow-up: <10% Drop-out rates: <5% Statistical issues: - **EXTERNAL VALIDITY: good** Age: +, reported Race: +, reported Pregnancy history: +, reported Surgical history: +, reported Fibroid/uterine size: + Number of fibroids: + Location of fibroids: + Baseline characteristics: +, reported Length of follow-up: + Measurement methods: + Measurement reliability: + Clinical care: +

Evidence Table 4. KQ 2 UAE (continued)

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria Other Details	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author Pron, Bennett, Common, Sniderman et al., 2003 Pron, Bennett, Common, Wall et al., 2003 Pron, Cohen, Soucie et al., 2003 Pron, Mocarski, Bennett et al., 2003 Pron, Mocarski, Cohen, et al., 2003 (continued)				**Prescription pain medication use , days(median):** 6.8 (6.0) **Fever, N (%);** 157 (29) **Length of stay, nights (range):** 1.3 (0 to 11) **Infection rate, %:** 2.4 (95% CI, 1.3-4.0) **Fibroid expulsion, N (%):** 19 (3) **Readmission, N (%):** 16 (3) **Mean change in dominant fibroid volume:** 33% (95% CI, 28-38) **Mean change in uterine volume:** 27% (95% CI, 23-32) **Improvement in menorrhagia, N (%):** 358/429 (83) (95% CI, 80-87) **Improvement in dysmenorrhea, N (%):** 249/322 (77) (95% CI, 72-82) **Improvement in bulk related symptoms, N (%):** 388/464 (84) (95% CI, 80-87) **Improvement in urinary urgency/ frequency, N (%):** 263/306 (86) (95% CI, 82-90)	

Evidence Table 4. KQ 2 UAE (continued)

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria Other Details	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author Pron, Bennett, Common, Sniderman et al., 2003 Pron, Bennett, Common, Wall et al., 2003 Pron, Cohen, Soucie et al., 2003 Pron, Mocarski, Bennett et al., 2003 Pron, Mocarski, Cohen, et al., 2003 (continued)				**Duration of menstrual flow, mean days:** Pre UAE: 7.6 Post UAE: 5.4 *P* < 0.001 **Pad count for day heaviest flow, median:** Pre UAE: 9 Post UAE: 4 *P* < 0.0001 **Satisfactory intra-procedural care, %:** 97 **Satisfactory post-procedural ward care, %:** 87 **Median life-impact score (higher = greater impact):** Pre UAE: 8 Post UAE: 3 *P* < 0.001 **Overall satisfaction, (%:** 91 (95% CI, 89-94) **Strong dissatisfaction, N (%):** 32/487 (7) **Would repeat UAE, N (%):** 414/487 (85) **Time until recovery, days, (median):** 13.1 (10.0) **Subsequent hysterectomy, N (%):** 8 (1.5) **Modifiers:** Larger fibroids were more likely to have significant volume decrease	

Evidence Table 4. KQ 2 UAE (continued)

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria Other Details	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author: Rajan et al., 2004 **Country and setting:** Canada, Community **Enrollment period:** 01/2000 to 07/2003 **Funding:** NR	**Design:** Retrospective case series **Intervention:** UAE **Groups:** NA **N at enrollment:** 410 **N at follow-up:** NA **Age, yrs ± SD:** 42.8 ± 5.8 **Race/ethnicity:** White: 66% Asian: 11% Afro-Caribbean: 23% **Parity:** NR **Baseline Hgb/Hct:** NR	**Inclusion criteria:** • UAE for symptomatic fibroids **Exclusion criteria:** • Pregnancy • Gynecologic malignancy or pre-malignancy • Adenomyosis with no fibroids • Severe renal insufficiency • Acute vasculitis • Any acute or chronic infection • Active pelvic infection or history of pelvic inflammatory disease • Uncorrectable coagulopathy **Indications:** NR **Preoperative therapy:** NR **Additional procedures:** NR	**Baseline uterine size:** NR **Number of fibroids:** NR **Baseline fibroid size (cm ± SD):** 7.7 ± 3.2 **Type of fibroid, N (%):** Submucosal: 148 (36.1) Non-submucosal: 262 (63.9)	**All complications, N (%):** 25 (6.1) **Minor complications, N (%):** 14 (3.4) **Major complications, N(%):** 11 (2.7) **Intrauterine infection** (requiring intravenous antibiotic therapy and/or surgery), N (%)**:** 5 (1.2%) **Modifiers:** Intrauterine infection more common in submucosal than nonsubmucosal In univariate analysis $P = 0.006$; logistic regression not significant ($P = 0.079$)	**Quality:** Overall quality score: fair **INTERNAL VALIDITY: good** Random: NA Methods and blinding: NA Pt selection criteria: + Loss to follow-up: NA Drop-out rates: <5% Statistical issues: + **EXTERNAL VALIDITY: poor (4)** Age: +, reported Race: +, reported Pregnancy history: -, NR Surgical history: -, NR Fibroid/uterine size: + Number of fibroids: - Location of fibroids: + Baseline characteristics: +, reported Length of follow-up: + Measurement methods: + Measurement reliability: - Clinical care: +

Evidence Table 4. KQ 2 UAE (continued)

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria Other Details	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author: Rasuli et al., 2004 **Country and setting:** Canada, Academic medical center **Enrollment period:** 04/1998 to 01/2004 **Funding:** NR	**Design:** Prospective cohort **Intervention:** UAE with superior hypogastric nerve block **Groups:** **G1:** Short-acting morphine tablets and indomethacin suppositories **G2:** Long-acting morphine tablets with short-acting morphine tablets for breakthrough pain, and naproxen suppositories **N at enrollment:** **G1:** 100 **G2:** 39 **N at follow-up:** Post-op: **G1:** 100 **G2:** 39 6 mos: Total: 125 **Age, mean yrs (range):** 43.3 (28 to 53) **Race/ethnicity:** NR **Parity:** NR **Baseline Hgb/Hct:** NR	**Inclusion criteria:** • UAE • Premenopausal **Exclusion criteria:** • Pregnancy • Desire for future pregnancy • PID • Endometriosis • Adenomyosis • Uterine malignancy • Fibroid volume > 780 cm^3 **Indications, N (%):** • Menorrhagia: 16 (11.5) • Pressure: 8 (5.8) • Dysmenorrhea: 1 (0.7) • Menorrhagia/pressure: 20 (14.4) • Menorrhagia/dysmenorrhea: 9 (6.5) • Dysmenorrhea/pressure: 1 (0.7) • Three symptoms: 84 (60.4) **Preoperative therapy:** NR **Associated procedure(s):** NR	**Baseline uterine size:** NR **Number of fibroids:** NR **Baseline fibroid size:** NR **Type of fibroid:** NR	**Length of stay:** All discharged within 6 hours of UAE **Return for pain management, N (%):** **G1:** 6 (6.0) **G2:** 1 (2.6) *P* = NS **Mean peak pain score, 5 days post-UAE (SD):** **G1:** 5.7 ± 2.2 **G2:** 2.7 ± 2.5 *P* < 0 .01 **No pain, N (%):** **G1:** 5 (5.0) **G2:** 12 (30.8) *P* < 0.001 **Nausea and Vomiting, N (%):** **G1:** 20 (20.0) **G2:** 1 (2.6) *P* < 0.01 **Satisfaction with UAE, at 6 mos, N (%):** • Completely satisfied: 118/125 (94.4) • Partially satisfied: 3/125 (2.4) • Unsatisfied: 4/125 (3.2%) **Modifiers:** NR	**Quality:** Overall quality score: poor **INTERNAL VALIDITY: poor** Random: + Methods and blinding: NA Pt selection criteria: + Loss to follow-up: 10-20% Drop-out rates: NA Statistical issues: - **EXTERNAL VALIDITY: poor (6)** Age: +, reported Race: -, NR Pregnancy history: -, NR Surgical history: -, NR Fibroid/uterine size: - Number of fibroids: - Location of fibroids: - Baseline characteristics: +, reported Length of follow-up: ++ Measurement methods: + Measurement reliability: + Clinical care: -

Evidence Table 4. KQ 2 UAE (continued)

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria Other Details	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author: Razavi et al., 2003 **Country and setting:** US, Academic medical center **Enrollment period:** 07/1998 to 12/2000 **Funding:** NR	**Design:** Retrospective cohort **Intervention:** Myomectomy and UFE **Groups:** **G1:** UFE **G2:** Abdominal myomectomy **N at enrollment:** **G1:** 62 **G2:** 40 **N at follow-up:** NA **Age, mean yrs (range):** **G1:** 37.7 (28 to 48) **G2:** 44.2 (31 to 56) **Race/ethnicity:** NR **Parity:** NR **Baseline uterine size:** NR **Baseline Hct, %:** **G1:** 35.5 **G2:** 36	**Inclusion criteria:** • Abdominal myomectomy • Uterine fibroid embolization **Exclusion criteria:** • Planned laparoscopic myomectomy within 3 mos of UFE • Primary reason for surgery was the treatment of infertility without other symptoms **Indications:** NR **Preoperative therapy:** NR **Associated procedure(s):** NR	**Baseline uterine size:** NR **Number of fibroids:** NR **Baseline fibroid size:** NR **Type of fibroid:** NR	**Pain medication use (days):** **G1:** 5.1 **G2:** 8.7 *P* < 0.05 **Length of stay, days:** **G1:** 0 **G2:** 2.9 *P* < 0.05 **Complications, N (%):** **G1:** 7 (11) **G2:** 10 (25) *P* < 0.05 **Menorrhagia relief, N (%):** **G1:** 48 (92) **G2:**14 (64) *P* < 0.05 **Pain relief, N (%):** **G1:** 25 (74) **G2:** 14 (54) *P* = NS **Mass effect, N (%):** **G1:** 28 (76) **G2:** 21 (91) *P* < 0.05 **Time to resume normal activities (days):** **G1:** 8 **G2:** 36 *P* < 0.05 **Modifiers:** NR	**Quality:** Overall quality score: poor **INTERNAL VALIDITY: fair** Random: NA Methods and blinding: NA Pt selection criteria: + Loss to follow-up: NA Drop-out rates: NA Statistical issues: - **EXTERNAL VALIDITY: poor (9)** Age: +, reported Race: -, NR Pregnancy history: -, NR Surgical history: -, NR Fibroid/uterine size: - Number of fibroids: - Location of fibroids: - Baseline characteristics: -, NR Length of follow-up: NA Measurement methods: + Measurement reliability: - Clinical care: -

Evidence Table 4. KQ 2 UAE (continued)

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria Other Details	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author: Ryu et al., 2003 **Country and setting:** US, Academic medical centers **Enrollment period:** 03/1997 to 12/1999 **Funding:** NR	**Design:** Retrospective cohort **Intervention:** UAE **Groups:** **G1:** Tri-acryl gelatin microspheres **G2:** Polyvinyl alcohol particles **N at enrollment:** **G1:** 36 **G2:** 36 **N at follow-up:** **G1:** 29 **G2:** 26 **Age, mean yrs:** **G1:** 44 (29 to 59) **G2:** 44 (35 to 51) **Race/ethnicity, N (%):** African American: **G1:** 11/29 (38) **G2:** 9/26 (35) **Parity:** NR **Baseline Hgb/Hct:** NR	**Inclusion criteria:** Consecutive UAE patients **Exclusion criteria:** NR **Indications, N (%):** Menorrhagia: **G1:** 14 (48) **G2:** 6 (23) Bulk symptoms: **G1:** 2 (7) **G2:** 2 (8) Both: **G1:** 13 (45) **G2:** 16 (620 **Preoperative therapy:** NR **Associated procedure(s):** NR	**Baseline fibroid size:** NR **Number of fibroids:** NR **Baseline fibroid size:** NR **Type of fibroid:** NR	**Embolic volume, cc ± SD:** **G1:** 4.86 ± 3.01 **G2:** 3.52 ± 1.63 *P* = 0.05 **Morphine dose, 5 mg, N ± SD:** **G1:** 37.2 ± 23.5 **G2:** 47.1± 26.8 *P* > 0.15 **Subjective pain score, (mean ± SD:** **G1:** 5.07 ± 2.99 **G2:** 5.58 ± 2.77 *P* > 0.5 **Technical success** (successful superselective bilateral UAE)**, N (%):** **G1:** 29/29 (100) **G2:** 26/26 (100) **Clinical success** (complete/ significant improvement of symptoms)**, N (%):** **G1:** 28/29 (96) **G2:** 25/26 (96) **Modifiers:** NR	**Quality:** Overall quality score: poor **INTERNAL VALIDITY: poor** Random: NA Methods and blinding: NA Pt selection criteria: - Loss to follow-up: >20% Drop-out rates: <5% Statistical issues: + **EXTERNAL VALIDITY: poor (4)** Age: +, reported Race: +, reported Pregnancy history: -, NR Surgical history: -, NR Fibroid/uterine size: - Number of fibroids: - Location of fibroids: - Baseline characteristics: +, reported Length of follow-up: + Measurement methods: + Measurement reliability: + Clinical care: +

Evidence Table 4. KQ 2 UAE (continued)

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria Other Details	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author: Spies, Ascher et al., 2001 Spies, Roth, et al., 2002 Spies, Bruno, et al., 2005 **Country and setting:** US, Academic medical center **Enrollment period:** 07/1997 to 12/1999 **Funding:** NR	**Design:** Prospective case series **Intervention:** Bilateral uterine artery embolization **Groups:** NA **N at enrollment:** 200 **N at follow-up:** 3 mo: 193 12 mo: 190 24 mo: 161 36 mo: 183 48 mo: 180 60 mo: 182 **Age, mean yrs:** 43.1 (95% CI, 42.4-43.7) **Race/ethnicity, %:** Black: 50% White: 45% Asian: 2.5% Hispanic: 1.5% Other: 1.0% **Parity:** NR **Baseline Hgb/Hct:** NR	**Inclusion criteria:** At least 1 of the following: • Heavy menstrual bleeding ± anemia • Pelvic pain or pressure; back, flank, or leg pain • Urinary frequency or other bladder symptoms • Hydronephrosis • Failed, refused, or not suitable for medical therapy Patients 1 to 50: • Age: <35 yrs or wished to maintain fertility required to exhaust all therapies Patients 51 to 200: • Age: <35 yrs if failed medical therapy and only remaining option extensive myomectomy, repeat myomectomy, or hysterectomy **Exclusion criteria:** • Pregnancy • Suspicion of uterine, ovarian, or cervical cancer • Pedunculated fibroids • Hystero-scopically resectable fibroids • Uterus >24 wks	**Baseline uterine size, mean ml:** 717.0 (95% CI, 648.8-785.2) **Number of fibroids,N (%):** 1: 28 (14.8) 2 to 5: 138 (73.0) >5: 23 (12.2) Missing: 11 **Baseline dominant fibroid size (mean ml):** 240.0 (95% CI, 200.8-279.3) **Type of fibroid, N (%):** • Intramural: 108 (54) • Submucosal: 35 (17.5) • Subserosal: 39 (19.5) • Missing: 18	**Outcomes at 3 mos:** **Subsequent intervention, N (%):** Hyst/D&C: 6 (3) (95% CI, 1-6) Hysterectomy: 1 (1) (95% CI, 0-3) Repeat UAE: 0 Myomectomy: 0 **Improved symptoms, N (%):** At 3 mos Yes: 180 (93) (95% CI, 89-96) No: 9 (5) (95% CI, 2-9) At 5 yrs 143 (73) **Bleeding, N (%):** Amenorrhea: 14, (8) (95% CI, 4-12) Mean change in bleeding score: 3.33 (95% CI, 3.04-3.61) **Pain:** Mean change pain score: 3.47 (95% CI, 3.17-3.78) **Outcomes at 60 mos:** **Improved symptoms, N (%):** Yes: 133 (73) (95% CI, 66-79) No:10 (5) (95% CI, 3-10) **Bleeding, N (%):** Amenorrhea: 42 (29) (95% CI, 21-37) Mean change in bleeding score: 3.98 (95% CI, 3.67-4.28) **Pain:** Mean change in pain score: 3.72 (95% CI, 3.34-4.10)	**Quality:** Overall quality score: good **INTERNAL VALIDITY: good** Random: NA Methods and blinding: NA Pt selection criteria: ++ Loss to follow-up: <10% Drop-out rates: <5% Statistical issues: ++ **EXTERNAL VALIDITY: good** Age: +, reported Race: +, reported Pregnancy history: +, reported Surgical history: +, reported Fibroid/uterine size: + Number of fibroids: + Location of fibroids: + Baseline characteristics: +, reported Length of follow-up: ++ Measurement methods: + Measurement reliability: + Clinical care: +

Evidence Table 4. KQ 2 UAE (continued)

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria Other Details	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author: Spies, Ascher et al., 2001 Spies, Roth, et al., 2002 Spies, Bruno, et al., 2005 (continued)		**Indications:** NR **Preoperative therapy:** NR **Associated procedure(s):** NR		**Subsequent interventions, (Years1 to 5), (%):** • Hysteroscopy/ D&C: 19 • Hysterectomy: 25 • Myomectomy: 6 • Repeat UAE: 3 • Failed or recurred: 46 (25) • Continued relief: 133 (73) **Modifiers:** Baseline imaging variables not associated with failure at 12 mos Age, race, baseline leiomyoma volume, baseline uterine volume, and subsequent interventions were not associated with satisfaction	

Evidence Table 4. KQ 2 UAE (continued)

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria and Other Details	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author: Spies, Cooper, Worthington-Kirsch et al., 2004 **Country and setting:** US, Community and academic medical centers **Enrollment period:** NR **Funding:** Biosphere Medical Inc.	**Design:** Prospective cohort **Intervention:** UAE and hysterectomy **Groups:** **G1:** UAE **G2:** Hysterectomy **N at enrollment:** **G1:** 102 **G2:** 50 (40 TAH, 2 LAVH, and 8 LH) **N at follow-up, 12 months:** **G1:** 76 **G2:** 30 **Age, yrs ± SD:** **G1:** 42.6 ± 4.0 **G2:** 41.6 ± 5.3 *P* = 0.264 **Race/ethnicity, N (%):** Asian/Pacific Island: **G1:**1 (1) **G2:** 2 (4) Black: **G1:** 61 (60) **G2:** 9 (18) Hispanic: **G1:** 7 (7) **G2:** 8 (16) White: **G1:** 31 (30) **G2:** 31 (62) Other: **G1:** 2 (2) **G2:** 0 (0) *P* < 0.001	**Inclusion criteria:** • Age: 30 to 50 yrs • Symptomatic fibroids **Exclusion criteria:** • Submucosal fibroids with > 50% diameter within uterine cavity • Dominant pedunculated serosal fibroid **Indications:** NR **Preoperative therapy:** NR **Additional procedures:** NR	**Baseline uterine size, ml ± SD:** **G1:** 689.4 ± 466.1 **G2:** 389.2 ± 521.2 *P* < 0.001 **Number of fibroids N (%):** 1 fibroid: **G1:** 27 (26) **G2:** 20 (40) 2 fibroids: **G1:** 33 (32) **G2:** 19 (38) ≥3 fibroids: **G1:** 42 (41) **G2:** 10 (20) *P* = 0.021 **Baseline dominant fibroid size (ml ± SD):** **G1:** 146.8 ± 158.5 **G2:** 90.6 ± 354.8 *P* = 0.330 **Type of fibroid, N (%):** Intramural: **G1:** 61 (60) **G2:** 32 (64) *P* = 0.724 Subserosal: **G1:** 19 (19) **G2:** 8 (16) *P* = 0.823 Submucosal: **G1:** 17 (17) **G2:** 13 (26) *P* = 0.197 Transmural: **G1:** 11 (11) **G2:** 1 (2) *P* = 0.108 Pedunculated: **G1:** 2 (2) **G2:** 4 (8) *P*=0.072	**Procedure time, min:** **G1:** 57.9 **G2:** 93.6 *P* < 0.001 **At least 1 complication, N (%):** **G1:** 28 (27.5%; 95% CI, 19.1-37.2) **G2:** 25 (50%; 95% CI, 35.5-64.5) *P* = 0.01 **Complications within 30 days, %:** **G1:** 17.6 **G2:** 28 *P* = 0.15 **Complications after 30 days, %:** **G1:** 12.7 **G2:** 32 *P*=0.01 **Major complications, N (%):** **G1:** 4 (3.9) **G2:** 6 (12) *P* = 0.08 **Life threatening Complications, %:** **G1:** 0 **G2:** 0 **Overall morbidity N (%):** **G1:** 15 (14.7) **G2:** 17 (34.0) *P* = 0.01 **Hemorrhage, N (%):** **G1:** 0 (0) **G2:** 4 (8) *P* = 0.01	**Quality:** Overall quality score: fair **INTERNAL VALIDITY: poor** Random: NA Methods and blinding: NA Pt selection criteria: + Loss to follow-up: >20% Drop-out rates: NR Statistical issues: + **EXTERNAL VALIDITY: good** Age: +, reported Race: +, reported Pregnancy history: +, reported Surgical history: +, reported Fibroid/uterine size: + Number of fibroids: + Location of fibroids: + Baseline characteristics: +, reported Length of follow-up: ++ Measurement methods: + Measurement reliability: + Clinical care: +

Evidence Table 4. KQ 2 UAE (continued)

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria and Other Details	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author: Spies, Cooper, Worthington-Kirsch et al., 2004 (continued)	**Parity, N (%):** Nulliparous: **G1:** 44 (43) **G2:** 11 (22) Para 1: **G1:** 20 (20) **G2:** 10 (20) Multiparous: **G1:** 38 (37) **G2:** 29 (58) *P* = 0.025 **Baseline Hgb, (%):** <12 g/dL: **G1:** 59 (58) **G2:** 19 (38) ≥12 g/dL: **G1:** 43 (42) **G2:** 31 (63) *P* = 0.025			**Febrile morbidity, N (%):** **G1:** 13 (12.7) **G2:** 12 (24.0) *P* = 0.10 **Length of stay, days:** **G1:** 0.83 **G2:** 2.3 *P* < 0.001 **Readmission, N (%):** **G1:** 3 (2.9) 4 (8) *P* = 0.22 **Satisfaction with symptom outcome:** *P* = NS **Mean time to return to work, days:** **G1:** 10.7 **G2:** 32.5 *P* < 0.001 **Unintended surgery, N (%):** **G1:** 2 (2) **G2:** 4 (8) *P* = 0.09 **Modifiers:** NR	

Evidence Table 4. KQ 2 UAE (continued)

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria Other Details	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author: Spies, Myers, Worthington-Kirsch et al., 2005 [See evidence table for Spies, Spector, Roth, et al., 2002] **Country and setting:** US, Academic medical centers **Enrollment period:** 12/2000 to 12/2002 **Funding:** Society for Interventional Radiology Foundation	**Design:** Prospective case series **Intervention:** UAE **Groups:** NA **N at enrollment:** 2,112 **N at follow-up:** 6 mos: 1,797 1 year: 1,701 **Age:** NR **Race/ethnicity, %:** White: 47.2% **Parity:** NR **Baseline Hgb/Hct:** NR	**Inclusion criteria:** • Undergoing UAE for fibroid treatment • Entered into Fibroid Registry for Outcomes Data **Exclusion criteria:** NR **Indications:** • Heavy bleeding • Bulk related symptoms • Pain **Pre-operative therapy:** NR **Associated procedure(s):** NR	**Baseline uterine size:** NR **Number of fibroids:** NR **Baseline fibroid size:** NR **Type of fibroid:** NR	**Subsequent care, 12 mos, N (%):** • Medical treatment: 121 (7) • Gyn interventions: 77 (6) • Hysterectomy: 27 (1.6) • Unplanned ER care: 52 (3) **Symptom Score change, 12 mos:** -38.94 ± 24.79 *P* < 0.001 **HRQOL score change, 12 mos:** 39.67 ± 25.28 *P* < 0.001 **Modifiers:** NR	**Quality:** Overall quality score: fair **INTERNAL VALIDITY: fair** Random: NA Methods and blinding: NA Pt selection criteria: ++ Loss to follow-up: 10-20% Drop-out rates: <5% Statistical issues: ++ **EXTERNAL VALIDITY: good** Age: +, reported Race: +, reported Pregnancy history: +, reported Surgical history: +, reported Fibroid/uterine size: + Number of fibroids: + Location of fibroids: + Baseline characteristics: +, reported Length of follow-up: ++ Measurement methods: + Measurement reliability: + Clinical care: +

Evidence Table 4. KQ 2 UAE (continued)

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author: Spies, Spector, Roth, et al., 2002 [See evidence tables for Spies, Ascher, Roth, et al., 2001; Spies, Roth, Jha, et al., 2002; and Spies, Bruno, et al., 2005] **Country and setting:** US, Academic medical center **Enrollment period:** 07/1997 to 04/2001 **Funding:** NR	**Design:** Prospective case series **Intervention:** UAE **Groups:** NA **N at enrollment:** 400 **N at follow-up:** 391 **Age, mean yrs (range):** 43 (27 to 57) **Race/ethnicity:** Black: 53% White: 43% Hispanic: 1.8% Other: 1.5% **Parity:** NR **Baseline Hgb/Hct:** NR	**Inclusion criteria:** • Symptomatic fibroids **Exclusion criteria:** • Pregnant • Infertility due to fibroids • Desire for pregnancy with fibroids that could be removed by myomectomy • Pedunculated submucosal fibroids that are hystero-scopically respectable • Uterus > 24 wks **Indications:** Reported in {481} **Preoperative therapy:** NR **Associated procedure(s):** NR	**Baseline uterine size:** NR **Number of fibroids:** NR **Baseline fibroid size:** NR **Type of fibroid:** NR	**All complications, N (%):** 42 (10.5) (95% CI, 7.7-13.9) **Perioperative complications, %:** 8.5% (95% CI, 6.0-11.7). **Hemorrhage, N (%):** 3 (0.75) (95% CI, 0.2-2.2) **Fever, N (%):** 8 (2) (95% CI, 0.9-3.9) **Readmission, N (%):** 14 (3.5) (95% CI, 1.9-5.8) **Unintended procedure, N (%):** 10 (2.5) (95% CI, 1.2-4.5) **Life threatening events, N (%):** 2 (0.5) (95% CI, 0.1-1.8) **Overall morbidity, N (%):** 20 (5) (95% CI, 3.1-7.7) **Modifiers:** NR	**Quality:** Overall quality score: fair **INTERNAL VALIDITY: good** Random: NA Methods and blinding: NA Pt selection criteria: ++ Loss to follow-up: <10% Drop-out rates: <5% Statistical issues: + **EXTERNAL VALIDITY: fair (4)** Age: +, reported Race: +, reported Pregnancy history: -, NR Surgical history: -, NR Fibroid/uterine size: - Number of fibroids: - Location of fibroids: - Baseline characteristics: +, reported Length of follow-up: ++ Measurement methods: + Measurement reliability: + Clinical care: +

Evidence Table 4. KQ 2 UAE (continued)

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria Other Details	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author: Walker and Pelage, 2002 **Country and setting:** UK, Community **Enrollment period:** 12/1996 to 10/2001 **Funding:** NR	**Design:** Prospective case series **Intervention:** UAE **Groups:** NA **N at enrollment:** 400 **N at follow-up:** Questionnaire: 383 6 week questionnaire: 262 > 1 yr: 252 > 2 yrs: 131 **Age, yrs ± SD:** 43.2 ± 6.6 **Race/ethnicity, %:** Caucasian: 81% Afro-Caribbean: 12% Indian: 1% Chinese: 1% Other: 5% **Parity:** NR **Baseline Hgb/Hct:** NR	**Inclusion criteria:** • Women receiving UAE for symptomatic fibroids **Exclusion criteria:** NR **Indications:** NR **Preoperative therapy:** NR **Associated procedure(s):** NR	**Baseline uterine size, cc ± SD:** 787 ± 648 **Number of fibroids:** NR **Baseline fibroid size (cc ± SD):** 248 ± 354 **Type of fibroid:** NR	**Pregnancy, N (%):** 10/24 attempting (41.7) and 3 unexpected **Miscarriage, N (%):** 2/13 (15.4) **Live births, N (%):** 9/13 (69.2) **Median uterine and dominant fibroid volumes:** 255 and 19 cc *P* = 0.0001 compared to baseline **Time until no pain, days ± SD:** 17.2 ± 14.0 **Improved menstrual bleeding, %:** 84 **Improved menstrual pain, N (%):** 383 (79) **Satisfaction, %:** 97 **Time to resume normal activity, days ± SD:** 13.6 ± 9.8 **Time to back at work, days ± SD:** 16.6 ± 10.8 **Clinical failure or recurrence, N (%):** 23 (6) **Modifiers:** NR	**Quality:** Overall quality score: poor **INTERNAL VALIDITY: poor** Random: NA Methods and blinding: NA Pt selection criteria: - Loss to follow-up: >20% Drop-out rates: <5% Statistical issues: - **EXTERNAL VALIDITY: fair (3)** Age: +, reported Race: +, reported Pregnancy history: -, NR Surgical history: -, NR Fibroid/uterine size: + Number of fibroids: - Location of fibroids: + Baseline characteristics: +, reported Length of follow-up: + Measurement methods: + Measurement reliability: + Clinical care: +

Evidence Table 4. KQ 2 UAE (continued)

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria Other Details	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author: Watson and Walker, 2002 **Country and setting:** UK, Community **Enrollment period:** NR **Funding:** NR	**Design:** Prospective case series **Intervention:** UAE **Groups:** NA **N at enrollment:** 114 **N at follow-up:** 6mos: 105 **Age, mean yrs:** 42 **Race/ethnicity:** NR **Parity:** NR **Baseline Hgb/Hct:** NR	**Inclusion criteria:** • Patients receiving UAE and had magnetic resonance scans at 6 mos **Exclusion criteria:** NR **Indications:** NR **Preoperative therapy:** NR **Associated procedure(s):** NR	**Baseline uterine size:** NR **Number of fibroids, %:** 1 to 3: 64% 4 to 10: 12% > 10: 24% **Baseline largest size in cm, %:** < 8.5 cm: 89% ≥ 8.5 cm: 56% **Type of fibroid, %:** • Complex fibroid mass: 45 • Interstitial: 33 • Submucosal: 29 • Subserousal: 26 • Pedunculated subserousal: 6 • Peduncalated submucosal: 5	**Median fibroid reduction:** 58% **Symptom relief, %:** • No symptoms: 38 • Improved symptoms: 53 • No symptom change: 8 • Worse symptoms: 2 **Modifiers:** NR	**Quality:** Overall quality score: poor **INTERNAL VALIDITY: poor** Random: NA Methods and blinding: NA Pt selection criteria: - Loss to follow-up: <10% Drop-out rates: NA Statistical issues: - **EXTERNAL VALIDITY: fair (3)** Age: +, reported Race: -, NR Pregnancy history: -, NR Surgical history: +, reported Fibroid/uterine size: + Number of fibroids: + Location of fibroids: + Baseline characteristics: -, NR Length of follow-up: + Measurement methods: + Measurement reliability: + Clinical care: +

Evidence Table 4. KQ 2 UAE (continued)

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author: Worthington-Kirsch et al., 2005 Myers et al., 2005 **Country and setting:** US, Varied sites (72) **Enrollment period:** 12/2000 to 12/2002 **Funding:** Society of Interventional Radiology Foundation through unrestricted grants from Biosphere Medical, Boston Scientific Corporation, COOK, Inc., and Cordis Endovascular	**Design:** Prospective case series **Intervention:** UAE **Groups:** NA **N at enrollment:*** 3,041 (30-day follow-up eligible) 2,112 (1-year follow-up eligible) **N at follow-up:** 2,729 (30 days) 1,797 (1 year) **Age, yrs ± SD:** 43.5 ± 5.6 **Race/ethnicity, %:** African American: 48 White: 44.4 Hispanic: 3.6 Asian/Pacific Islander: 2.8 Other: 1.3 **Parity, %:** Nulliparous: 44.1 **Baseline Hgb/Hct:** NR	**Inclusion criteria:** • Women undergoing uterine embolization for fibroids at 1 of 72 sites of FIBROID Registry **Exclusion criteria:** NR **Indications (predominant symptom), N (%):** • Heavy menstrual bleeding: 1,932 (64.7)) • Pelvic pain: 314 (10.5) • Bulk symptoms: 694 (23.3) • Other symptoms: 45 (1.5) **Preoperative therapy, N (%):** GnRH agonist: 133 (4.4) **Additional procedures:** NR	**Baseline uterine size, ml ± SD:** 677.7 ± 520.4 **Number of fibroids, N (%):** 1 to 2: 1249 (43.4) 3 to 4: 690 (24.1) ≥ 5: 936 (32.6) **Baseline fibroid size:** NR **Type of fibroid, N (%):** • Intramural: 1231 (42.8) • Transmural: 585 (20.3) • Subserosal: 410 (14.3) • Submucosal: 376 (13.1) • Pedunculated: subserosal: 64 (2.2) • Pedunculated: submucosal: 9 (0.3)	**Length of stay, days:** 1.68 (95% CI, 1.21-2.15) **AE, during hospitalization, N (%):** 94 in 90 (3) **AE between discharge and 30 days, N (%):** 710 (26) **Major events, N (%):** 111 (4) **Recurrent pain, N (%):** 65 (2.1) **Possible infection, N (%):** 19 (0.62) **Minor events, N (%):** 610 (22) **Hot flushes, N (%):** 156 (5.7) **Pain, N (%):** 264 (9.6) **Mean lost work days:** 9.63 (95% CI, 9.38-9.88) **Modifiers:** **Increased risk of AEs in hospital: Univariate:** Length of procedure: OR = 1.012; 95% CI, 1.005-1.019 Core site status: OR = 0.334; 95% CI, 0.15-0.76 Size of fibroid: OR = 1.073; 95% CI, 1.013-1.138	**Quality:** Overall quality score: fair **INTERNAL VALIDITY: fair** Random: NA Methods and blinding: NA Pt selection criteria: ++ Loss to follow-up: 10-20% Drop-out rates: <5% Statistical issues: ++ **EXTERNAL VALIDITY: good** Age: +, reported Race: +, reported Pregnancy history: +, reported Surgical history: +, reported Fibroid/uterine size: + Number of fibroids: + Location of fibroids: + Baseline characteristics: +, reported Length of follow-up: ++ Measurement methods: + Measurement reliability: + Clinical care: +

*Registry without complete overlap

Evidence Table 4. KQ 2 UAE (continued)

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author: Worthington-Kirsch et al., 2005 Myers et al., 2005 (continued)				**Multivariate:** Length of procedure: OR = 1.10; 95% CI, 1.005-1.01 Size of fibroid: OR = 1.11; 95% CI, 1.028-1.20 Uterine volume: OR 0.999; 95% CI, 0.998-0.999 **Increased risk of AE at 30 days:** **Univariate:** Prior procedures or medical therapy: OR = 1.242; 95% CI, 1.113-1.38) *P* < 0.001 African American: OR = 1.158; 95% CI, 1.048-1.28 *P* = 0.004 Smoking status: OR = 1.139; 95% CI, 1.009-1.286 *P* = 0.035 **Multivariate:** Smoking status: OR = 1.141; 95% CI, 1.007-1.293 *P* = 0.039 African American: OR = 1.129; 95% CI, 1.019-1.251 *P* = 0.021 Prior procedures: OR = 1.235; 95% CI, 1.103-1.383 *P* < 0.001 Duration of procedure: OR = 1.004; 95% CI, 1.001-1.006 *P* = 0.009 DVT prophylaxis: OR = 0.757; 95% CI, 0.622-0.919	

Evidence Table 5. KQ 2 Endometrial ablation

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria Other Details	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author: Loffer, 2005 **Country and setting:** US, Academic medical center **Enrollment period:** 08/1984 to 08/2003 **Funding:** NR	**Design:** Retrospective cohort **Intervention:** Endometrial ablation at time of hysteroscopic myomectomy for submucosal fibroids **Groups:** **G1:** Endometrial ablation **G2:** Without endometrial ablation **N at enrollment:** **G1:** 73 **G2:** 104 **N at follow-up (12 mos):** **G1:** 72 **G2:** 103 **Age, yrs ± SD:** **G1:** 44.0 ± 4.7 **G2:** 37.6 ± 6.0 *P* < 0.001 **Race/ethnicity:** NR **Parity:** NR (15 infertile, no ablations in this group) **Baseline Hgb/Hct:** NR	**Inclusion criteria:** • All hysteroscopic myomectomies by a single surgeon for premenopausal women with menorrhagia/ menometrorr-hagia **Exclusion criteria:** • Procedures done by author outside US or for which follow-up information was unavailable **Indications:** • Menorrahagia and/or metrorrhagia **Pre-operative therapy, N (%):** Endometrial suppression: **G1:** 58 (79.5) **G2:** 22 (27.5) **Associated Procedure(s):** NR	**Baseline uterine size:** NR **Number of fibroids, mean ± SD:** **G1:** 1.5 ± 1.1 **G2:** 1.5 ± 1.1 *P* = 0.96 **Baseline fibroid size, cm ± SD:** **G1:** 3.0 ± 1.1 **G2:** 3.4 ± 1.5 *P* = 0.06 **Type of fibroid, %:** Type 0: **G1:** 30.1 **G2:** 33.7 Type I: **G1:** 49.3 **G2:** 36.5 Type II: **G1:** 20.5 **G2:** 29.8	**Bleeding controlled, N (%):** **G1:** 70 (95.9) **G2:** 84 (80.8) *P* = 0.003 (OR = 0.18; 95%CI, 0.05-0.63) **Success (no recurrence of bleeding problems or hysterectomy):** Log Rank = 5.3; *P* = 0.02 (Kaplan-Meier survival analysis) **Modifiers:** Complete vs. incomplete removal of fibroids **Success (defined above), N (%):** G1 with complete removal: 58 of 60 (96.7) G1 with incomplete removal: 12 of 13 (92.3) G2 with complete removal: 65 of 77 (84.4) G2 with incomplete removal: 19 of 27 (70.4) **Hysterectomy, N (%):** G1 with complete removal: 11 (18.3) G1 with incomplete removal: 2 (15.4) G2 with complete removal: 13 (16.9) G2 with incomplete removal: 10 (37)	**Quality:** Overall quality score: poor **INTERNAL VALIDITY: fair** Random: NA Methods and blinding: NA Pt selection criteria: + Loss to follow-up: <10% Drop-out rates: NA Statistical issues: - **EXTERNAL VALIDITY: poor (4)** Age: +, reported Race: -, NR Pregnancy history: -, NR Surgical history: -, NR Fibroid/uterine size: + Number of fibroids: + Location of fibroids: + Baseline characteristics: -, NR Length of follow-up: ++ Measurement methods: + Measurement reliability: + Clinical care: +

Evidence Table 6. KQ2 in situ destructive techniques (MRI-guided focused ultrasound and cryotherapy)

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria and Other Details	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author: Hindley, et. al., 2004 Stewart et al., 2006 **Country and setting:** US, Israel, UK, Germany, Academic medical centers **Enrollment period:** NR **Funding:** Insightec, Ltd., manufacturer of MR guided focused ultrasound system	**Design:** Prospective case series **Intervention:** MRI guided focused ultrasound surgery **Groups:** NA **N at enrollment:** 176 **N at follow-up:** 6 mos: 109 12 mos: 82 **Age, yrs ± SD:** 44.8 ± 4.9 **Race/ethnicity, %:** Caucasian: 81 Black :11 American Indian/ Alaskan Native: 0 Asian: 3 Hispanic: 0 Other: 5 **Parity:** NR **Baseline Hgb/Hct:** NR	**Inclusion criteria:** • ≥ 18 yr old • No desire future childbearing • Clinically significant uterine fibroids **Exclusion criteria:** • Pelvic or uncontrolled systemic disease • Postmenopausal • Weight > 250 lb (113 kg) • Unable to communicate during treatment • Unsuitable for MRI • Change of OCP's or NSAID's 1 to 3 mos pretreatment • Extensive or treatment blocking abdominal scars • Fibroids > 10 cm • Uterus > 24 wks **Indications:** Symptomatic fibroids normally treated by conventional surgical therapy **Preoperative therapy:** NR **Additional procedures:** NR	**Baseline uterine size, cm^3 ± SD:** 595 ± 362 **Number of fibroids, mean ± SD:** 2.3 ± 2.0 **Baseline fibroid size, dominant fibroid, cm^3 ± SD:** 372 ± 235 **Type of fibroid, %:** • Submucosal: 22% • Intramural: 57% • Subserosal: 21%	**Pain, N (%):** None: 79 (75) Mild: 19 (18) Moderate: 7 (7) Severe: 1 (1) **Fibroid volume, 6 mos, mean ± SD:** -13.5% ± 32 **Transfusion, 6 mos:** 3% **Rehospitalization, 6 mos:** 7% **Skin burns after MRgFUS, %:** 5% **Skin ulceration, N:** 1 **Sciatic nerve palsy, N:** 1 **Improvement rated by decrease of ≥ 10 points of questionnaire, N (%):** 82 (79.3) *P* < 0.0001 **Symptom severity score, mean (range):** - 27.3 points (18.75 to 81.25) *P* < 0.0001 **Improvement 1 to 3 mos:** -24.1 points **Mass effect:** -32.7 points **Bleeding symptoms:** -34.8 points	**Quality:** Overall quality score: fair **INTERNAL VALIDITY: short term: fair long term: poor** Random: NA Methods and blinding: NA Pt selection criteria: ++ Loss to follow-up: <10%/>20% Drop-out rates: <5% Statistical issues: ++ **EXTERNAL VALIDITY: good** Age: +, reported Race: +, reported Pregnancy history: -, NR Surgical history: +, reported Fibroid/uterine size: + Number of fibroids: + Location of fibroids: + Baseline characteristics: +, reported Length of follow-up: ++ Measurement methods: + Measurement reliability: + Clinical care: +

Evidence Table 6. KQ2 in situ destructive techniques (MRI-guided focused ultrasound and cryotherapy) (continued)

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria and Other Details	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author: Hindley, et. al., 2004 Stewart et al., 2006 (continued)				**Heavy menses requiring blood transfusion, N (%):** 5 (5) **10-point improvement in transformed symptom severity scale (SSS) of Uterine Fibroid Symptoms Quality-of-Life questionnaire (UFS-QOL) at 6 mos, (%):** 77/109 (70.6) *P* < 0.0001 **After 12 mos:** 42/82 (51.2) **Modifiers:** NR	

Evidence Table 7. KQ 2 Myomectomy

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria Other Details	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author: Agostini, Cravello, Bretelle, et al., 2002 Agostini, Cravello, Desbriere, et al., 2002 Agostini, Cravello, Shojai, et al., 2002 **Country and setting:** France, Community **Enrollment period:** 01/1990 to 01/2000 **Funding:** NR	**Design:** Prospective case series **Intervention:** Hysteroscopy **Groups:** NA **N at enrollment:** 782 (There were 2,116 surgical hysteroscopies performed and reported on 1,952 women; 782 were for fibroid resection) **N at follow-up:** NA **Age, yrs ± SD:** 46.2 ± 4.2 **Race/ethnicity:** NR **Parity:** NR **Baseline Hgb/Hct:** NR	**Inclusion criteria:** NR **Exclusion criteria:** NR **Indications:** NR **Preoperative therapy:** NR **Additional procedure(s):** NR	**Baseline uterine size:** NR **Number of fibroids:** NR **Baseline fibroid size:** NR **Type of fibroid:** NR	**Hemorrhage, N:** 3 *P* = 0.01 (RR for fibroid resection vs. synechiolysis = 6.55; 95% CI, 1.58-27.17) **Uterine perforation, N:** 9 *P* < 0.0001 (RR for fibroid resection vs. synechiolysis = 7; 95% CI, 2.83-17.62) **Early-onset endometritis, N:** 4 *P* = 0.0066 (RR for fibroid resection vs. synechiolysis = 5.89; 95% CI, 1.68-20.69) **Modifiers:** NR	**Quality:** Overall quality score: poor **INTERNAL VALIDITY: poor** Random: NA Methods and blinding: NA Pt selection criteria: - Loss to follow-up: NR Drop-out rates: NR Statistical issues: - **EXTERNAL VALIDITY: poor (9)** Age: -, NR Race: NA, not US study Pregnancy history: -, NR Surgical history: -, NR Fibroid/uterine size: - Number of fibroids: - Location of fibroids: - Baseline characteristics: -, NR Length of follow-up: - Measurement methods: + Measurement reliability: - Clinical care: +

Evidence Table 7. KQ 2 Myomectomy (continued)

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author: Agostini et al., 2005 **Country and setting:** France, Academic medical center **Enrollment period:** 10/1998 to 05/2002 **Funding:** NR	**Design:** RCT **Intervention:** Intravenous oxytocin during abdominal or vaginal myomectomy **Groups:** **G1:** 15 IU oxytocin in "physiologic serum" over 30 min at uterine incision **G2:** 125 cc of "physiologic serum" over 30 min at uterine incision **N at enrollment:** **G1:** 47 **G2:** 47 **N at follow-up:** **G1:** 47 **G2:** 47 **Age, yrs ± SD:** **G1:** 40 ± 5.2 **G2:** 39 ± 4.3 **Race/ethnicity:** NR **Parity:** NR **Baseline Hgb, g/dl ± SD:** **G1:** 12 ± 1.3 **G2:** 11.95 ± 1.82	**Inclusion criteria:** • Need myomectomy **Exclusion criteria:** • Preoperative embolization • Preoperative administration of GnRH agonists **Indications:** Bleeding, N (%): **G1:** 24 (51) **G2:** 21 (44.7) Pelvic pain, N (%): **G1:** 27 (36.2) **G2:** 20 (42.5) Fertility, N (%): **G1:** 6 (12.8) **G2:** 6 (12.8) **Preoperative therapy:** NR **Additional procedures:** **Surgical route, N (%):** Laparotomy: **G1:** 32 (68.1) **G2:** 31 (66) Vaginal: **G1:** 15 (31.9) **G2:** 16 (34)	**Baseline uterine size:** NR **Number of fibroids:** NR **Baseline fibroid size (gm ± SD):** **G1:** 286 ± 206 **G2:** 268 ± 253 *P* = 0.71 **Type of fibroid:** NR	**Operative time, min ± SD:** **G1:** 90 ± 12 **G2:** 86 ± 15 *P* = 0.16 **Mean estimated blood loss, ml ± S):** **G1:** 508 ± 558 **G2:** 451 ± 336 *P* = 0.55 **Decrease in Hgb, g/dl ± SD:** **G1:** 1.89 ± 1.26 **G2:** 1.93 ± 1.20 *P* = 0.87 **Autotransfusion, N (%):** **G1:** 19 (40.4) **G2:** 16 (34.0) *P* = 0.5 **Blood transfusion, N (%):** **G1:** 7 (14.9) **G2:** 2 (4.2) *P* = 0.09 **Modifiers:** NR	**Quality:** Overall quality score: poor **INTERNAL VALIDITY: poor** Random: - Methods and blinding: + Pt selection criteria: + Loss to follow-up: <10% Drop-out rates: NA Statistical issues: ++ **EXTERNAL VALIDITY: fair (3)** Age: +, reported Race: NA, not US study Pregnancy history: -, NR Surgical history: -, NR Fibroid/uterine size: + Number of fibroids: - Location of fibroids: - Baseline characteristics: +, reported Length of follow-up: NA Measurement methods: + Measurement reliability: + Clinical care: +

Evidence Table 7. KQ 2 Myomectomy (continued)

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria Other details	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author: Benassi, et al., 2000 **Country and setting:** Italy, Academic medical center **Enrollment period:** 02/1997 to 10/1998 **Funding:** NR	**Design:** RCT **Intervention:** Myomectomy Groups: **G1:** Myomectomy using sodium-2-mercaptoethane sulfonate (mesna) **G2:** Myomectomy using saline solution **N at enrollment:** **G1:** 29 **G2:** 29 **N at follow-up:** **G1:** 29 **G2:** 29 **Age, median yrs (IQR):** **G1:** 34 (25 to 43) **G2:** 35 (25 to 45) **Race/Ethnicity:** NR **Parity, parous, N (%):** **G1:** 6 (20.7) **G2:** 8 (27.6) **Baseline Hgb, median g/dL (IQR):** **G1:** 11.1 (10-11.9) **G2:** 11.4 (10-12.7) **Baseline Hct, median% (IQR):** **G1:** 34.3 (31.5-36.3) **G2:** 35.7 (33-37.5)	**Inclusion criteria:** • Symptomatic fibroids, including menorrhagia, pelvic pain, and compression **Exclusion criteria:** • Use of hormone in past 6 months • Previous uterine surgery • PID **Indications:** NR **Pre-operative therapy:** None **Associated procedure(s):** NR	**Baseline uterine size:** NR **Number of fibroids, median (IQR):** **G1:** 9 (2-17) **G2:** 6 (2-11) **Baseline largest fibroid size, median (IQR) mL:** **G1:** 67.96 (7.98-334.72) **G2:** 45.88 (2.78-234.3) **Type of fibroid:** NR	**Operative time, median min (IQR):** **G1:** 70 (40-100) **G2:** 90 (40-120) *P* < 0.05 **Complications, N:** **G1:** 1 **G2:** 6 **Length of stay, days (range):** **G1:** 2 (2-3) **G2:** 3 (3-4) **Decrease in Hgb, 24hr, g/dL:** **G1:** 0.9 (-0.1-2.1) **G2:** 1.7 (0.1-2.9) *P* < 0.006 **Decrease in Hct 24hr, %:** **G1:** -0.4 (-5.3 to 3.8) **G2:** 3.0 (-1.9 to 6.8) *P* < 0.01 **Modifiers:** NR	**Quality:** Overall quality score: good **INTERNAL VALIDITY: good** Random: + Methods and blinding: NA Pt selection criteria: ++ Loss to follow-up: NA Drop-out rates: NA Statistical issues: + **EXTERNAL VALIDITY: good** Age: +, reported Race: NA, not US study Pregnancy history: +, reported Surgical history: +, reported Fibroid/uterine size: + Number of fibroids: + Location of fibroids: + Baseline characteristics: +, reported Length of follow-up: NA Measurement methods: + Measurement reliability: + Clinical care: +

Evidence Table 7. KQ 2 Myomectomy (continued)

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria Other Details	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author: Boe Engelsen et al., 2006 **Country and setting:** Norway, Academic medical center **Enrollment period:** 01/1992 to 12/1998 **Funding:** NR	**Design:** Retrospective cohort **Intervention:** TCRE or TCRM **Groups:** **G1:** TCRM and TCRE or TCRM only **G2:** TCRE only **N at enrollment:** **G1:** 149 **G2:** 241 **N at follow-up:** • 320 underwent examinations at 3 mos • 327 completed questionnaire 4-10 yr after 1st procedure **Age, mean yrs (range):** 44.4 (23 to 68) **Race/ethnicity:** NR **Parity, parous (range):** 2.5 (0 to 6) **Baseline Hgb/Hct:** NR	**Inclusion criteria:** • All TCR procedures • Uterus size < 12 wks on bimanual examination • Uterine cavity depth less than 12 cm • Submucous fibroids < 5 cm on vaginal ultrasound **Exclusion criteria:** NR **Indications, N (%):** • Menorrhagia: 380/ 386 (98.4) • Dysmenorrhea: 95/380 (25)* • Postmenopausal bleeding: 6/386 (1.6) **Pre-operative therapy, %:** • Gestagens: 54.1 • GnRHa: 4.9 • No pretreatment: 41 **Associated procedure(s):** NR	**Baseline uterine size:** NR **Number of fibroids:** NR **Baseline fibroid size:** NR **Type of fibroid, N:** Submucous: 149	**Operative time, min ± SD:** **G1:** 42.8 ± 20.6 **G2:** 31.4 ± 13.7 *P* < 0.001 **Fluid absorption, ml ± SD:** **G1:** 292 ± 518 **G2:** 186 ± 385 *P* < 0.05 **Uterine perforation, N (%):** **G1:** 16 (10.7) **G2:** 15 (6.2)* **Tissue resected, gm ± SD:** **G1:** 21.5 ± 14.2 **G2:** 9.5 ± 4.7 *P* < 0.001 **Decrease in Hgb, g/dl ± SD:** **G1:** 1.4 ± 1.1 **G2:** 1.1 ± 0.9 *P* < 0.01 **Modifiers:** NR	**Quality:** Overall quality score: poor **INTERNAL VALIDITY: poor** Random: NA Methods and blinding: NA Pt selection criteria: ++ Loss to follow-up: 10-20% Drop-out rates: NA Statistical issues: - **EXTERNAL VALIDITY: poor (4)** Age: +, reported Race: NA, not US study Pregnancy history: +, reported Surgical history: -, NR Fibroid/uterine size: - Number of fibroids: - Location of fibroids: - Baseline characteristics: +, reported Length of follow-up: ++ Measurement methods: + Measurement reliability: + Clinical care: +

*Numbers and percentages in text do not agree

Evidence Table 7. KQ 2 Myomectomy (continued)

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria Other Details	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author: Bulletti et al., 2004 **Country and setting:** Italy, Academic medical center **Enrollment period:** 1997 to 2003 **Funding:** NR	**Design:** Prospective cohort **Intervention:** Myomectomy before IVF **Groups:** **G1:** Myomectomy before IVF **G2:** No myomectomy before IVF **N at enrollment:** **G1:** 84 **G2:** 84 **N at follow-up:** • 193 enrolled • 143 completed the study • 25 replaced to reach 168 • Followup interval: NR **Age, yrs ± SD:** **All:** 33.04 ± 4.76 **G1:** 32.83 ± 4.12 **G2:** NR **Race/ethnicity:** NR **Parity, parous, %:** **G1:** 0 **G2:** 0 **Baseline Hgb/Hct:** NR	**Inclusion criteria:** • Nulliparity • Age 25 to 39 • ≥ 1 fibroid > 5 cm with tubal occlusion **Exclusion criteria:** • Male factor infertility • Bilateral tubal occlusion • Submucous fibroid(s) • Diagnosis with increased abortion risk other than fibroid(s) **Indications:** • Infertility: 100% **Pre-operative therapy:** NR **Associated procedure(s):** NR	**Baseline uterine size:** NR **Number of fibroids:** NR **Baseline fibroid size:** NR **Type of fibroid:** NR	**Cumulative pregnancy rate, N (%):** **G1:** 28 (33) **G2:** 13 (15) *P* < 0.05 **Miscarriage rate, N (%):** **G1:** 8 (7) **G2:** 3 (4) *P* = NS **Delivery rate, N (%):** **G1:** 21 (25) **G2:** 10 (12) *P* < 0.05 **Modifiers:** NR	**Quality:** Overall quality score: poor **INTERNAL VALIDITY: poor** Random: NA Methods and blinding: NA Pt selection criteria: ++ Loss to follow-up: 10-20% Drop-out rates: >10% Statistical issues: - **EXTERNAL VALIDITY: poor (6)** Age: +, reported Race: NA, not US study Pregnancy history: -, NR Surgical history: -, NR Fibroid/uterine size: - Number of fibroids: - Location of fibroids: - Baseline characteristics: -, NR Length of follow-up: + Measurement methods: + Measurement reliability: + Clinical care: +

Evidence Table 7. KQ 2 Myomectomy (continued)

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria Other Details	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author: Cagnacci et al., 2003 **Country and setting:** Italy, Specialty treatment center **Enrollment period:** 01/2001 to 07/2002 **Funding:** NR	**Design:** RCT **Intervention:** Laparotomy, minilaparotomy, and laparoscopically-assisted minilaparotomy for myomectomy **Groups:** **G1:** Laparo-scopically-assisted minilaparotomy for myomectomy **G2:** Minilaparo-tomy **G3:** Laparotomy **N at enrollment:** **G1:** 17 **G2:** 17 **G3:** 17 **N at follow-up:** **G1:** 17 **G2:** 17 **G3:** 17 **Age, yrs ± SEM:** **G1:** 37.6 ± 1.9 **G2:** 39.4 ± 1.6 **G3:** 37.7 ± 0.9 **Race/ethnicity:** NR **Parity:** NR **Baseline Hgb/Hct:** NR	**Inclusion criteria:** • Symptomatic fibroids or fibroids with associated infertility • < 5 total intramural or subserous fibroids • Diameter between 5 and 15 cm **Exclusion criteria:** • Pedunculated fibroids **Indications:** NR **Pre-operative therapy:** NR **Associated procedure(s):** NR	**Baseline uterine size:** NR **Number of fibroids, mean ± SD:** **G1:** 1.18 ± 0.4 **G2:** 1.87 ± 0.3 **G3:** 1.58 ± 0.7 **Baseline fibroid size, max cm diameter):** **G1:** 7.1 ± 0.7 **G2:** 6.8 ± 0.7 **G3:** 5.8 ± 0.4 **Type of fibroid:** NR	**Operative time, min ± SEM:** **G1:** 92.6 ± 4.4 **G2:** 85.9 ± 7.2 **G3:** 91.3 ± 7.2 G1 vs. G2 vs. G3: *P* < 0.01 vs. G3 **Decrease in Hgb, mg/dl ± SEM:** **G1:** 1.8 ± 0.15 **G2:** 2.4 ± 0.4 **G3:** 3.07 ± 0.3 G1 vs. G2 vs. G3: *P* < 0.025 **Fever >38C, N (%):** **G1:** 4 (23.5) **G2:** 4 (23.5) **G3:** 4 (23.5) **Length of stay, hrs ± SEM:** **G1:** 81.5 ± 8.2 **G2:** 119.3 ± 9.6 **G3:** 141.6 ± 5.2 G1 vs. G2 vs. G3: *P* < 0.01 G3 vs. G2**:** *P* < 0.05 **Ileus, hrs ± SEM:** **G1:** 33.4 ± 3.4** **G2:** 41.8 ± 3.9* **G3:** 55.0 ± 4.5 * *P* < 0.05 ** *P* < 0.01 vs. G3 **Pain scores by 10 cm VAS** Abdominal pain at 7 days: **G1:** 0.9 ± 0.4* **G2:** 0.5 ± 0.2* **G3:** 3.0 ± 0.6 **P* < 0.05 vs. G3 **Modifiers:** NR	**Quality:** Overall quality score: fair **INTERNAL VALIDITY: good** Random: + Methods and blinding: + Pt selection criteria: ++ Loss to follow-up: NA Drop-out rates: NA Statistical issues: ++ **EXTERNAL VALIDITY: fair (3)** Age: +, reported Race: NA, not US study Pregnancy history: -, NR Surgical history: -, NR Fibroid/uterine size: + Number of fibroids: + Location of fibroids: - Baseline characteristics: +, reported Length of follow-up: NA Measurement methods: + Measurement reliability: + Clinical care: +

Evidence Table 7. KQ 2 Myomectomy (continued)

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria Other Details	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author: Cobellis et al., 2002 **Country and setting:** Italy, Academic medical center **Enrollment period:** NR **Funding:** NR	**Design:** Retrospective case series **Intervention:** Myomectomy during cesarean section **Groups:** NA **N at enrollment:** 322 **N at follow-up:** NA **Age (mean):** 33.5 **Race/ethnicity:** NR **Parity, parous, %:** Nulliparous: 65 **Baseline Hgb/Hct:** NR	**Inclusion criteria:** • Women submitted to myomectomy during cesarean **Exclusion criteria:** NR **Indications: Cesarean, %:** • Anomalous presentation: 33 • Previous C-section: 26 • Prolonged labor/ cardiotoco-graphy anomalies: 15 • Hypertensive disorders: 12 • Fetopelvic disproportion: 11 • Other: 3 **Pre-operative therapy:** NR **Associated procedure(s):** NR	**Baseline uterine size:** NR **Number of fibroids, %:** One: 63% **Baseline fibroid size:** Subserosal ≤ 4 cm: 71% **Type of fibroid, %:** • Subserosal: 71 • Subserosal/ intramural: 17 • Intramural: 8 • Intraligamen-tous associated/ another location: 4	**Transfusion, N (%):** 34 (11%) **Length of stay, %:** 4 to 5 days: 100 **Modifiers:** NR	**Quality:** Overall quality score: poor **INTERNAL VALIDITY: fair** Random: NA Methods and blinding: NA Pt selection criteria: - Loss to follow-up: <10% Drop-out rates: NA Statistical issues: - **EXTERNAL VALIDITY: poor (5)** Age: -, NR Race: NA, not US study Pregnancy history: -, NR Surgical history: -, NR Fibroid/uterine size: - Number of fibroids: - Location of fibroids: + Baseline characteristics: +, reported Length of follow-up: NA Measurement methods: + Measurement reliability: + Clinical care: +

Evidence Table 7. KQ 2 Myomectomy (continued)

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria Other Details	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author: Damiani et al., 2003 **Country and setting:** Italy; Academic medical center **Enrollment period:** 04/1997 to 10/2001 **Funding:** NR	**Design:** Prospective case series **Intervention:** Gasless laparoscopic myomectomy **Groups:** NA **N at enrollment:** 279 **N at follow-up:** NA **Age, yrs (range):** 35.2 (22 to 48) **Race/ethnicity:** NR **Parity:** NR **Baseline Hgb/Hct:** NR	**Inclusion criteria:** • ≥ 1 symptomatic subserosal or intramural fibroid • Fibroid > 30 mm **Exclusion criteria:** NR **Indications:** NR **Preoperative therapy, N (%):** GnRHa: 48 (16.8) **Additional procedures:** NR	**Baseline uterine size:** NR **Number of fibroids, (range):** 3.1 (1 to 8) 21.1% had multiple fibroids **Baseline fibroid size, cm (range):** 5.9 cm (3-12 cm) **Type of fibroid, N (%):** • Intramural: 118 (42.3) • Subserosal: 161 (57.7) • Anterior: 71 • Fundal: 106 • Posterior: 102	**Operative time, min (range):** 73 (35 to 145) **Mean estimated blood loss, ml (range):** 102 (40 to 320) **Fever >° 38C, N:** 3 **Length of stay, days (range):** 2.6 (2 to 5) **Modifiers:** NR	**Quality:** Overall quality score: fair **INTERNAL VALIDITY: fair** Random: NA Methods and blinding: NA Pt selection criteria: + Loss to follow-up: NA Drop-out rates: NA Statistical issues: - **EXTERNAL VALIDITY: fair (3)** Age: +, reported Race: NA, not US study Pregnancy history: -, NR Surgical history: -, NR Fibroid/uterine size: + Number of fibroids: + Location of fibroids: + Baseline characteristics: -, NR Length of follow-up: NA Measurement methods: + Measurement reliability: + Clinical care: +

Evidence Table 7. KQ 2 Myomectomy (continued)

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria Other Details	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author: Dessolle et al., 2001 Soriano et al., 2003 **Country and setting:** France, Community **Enrollment period:** 01/1990 to 10/1988 **Funding:** NR	**Design:** Prospective case series **Intervention:** Laparoscopic myomectomy **Groups:** **G1:** Laparoscopic myomectomy **G2:** Laparo-conversion for myomectomy **N at enrollment:** **G1:** 88 **G2:** 18 **N at follow-up:** NR **Age, yrs ± SD:** **G1:** 36.1 ± 2.1 **G2:** 34.7 ± 2.4 **Race/ethnicity:** NR **Parity:** NR **Baseline Hgb/Hct:** NR	**Inclusion criteria:** • Age 18 to 43 yrs • Infertility ≥ 24 mos • Intramural or subserous fibroids > 3 cm in diameter • < 4 myomas, and largest myoma < 10 cm **Exclusion criteria:** • Anesthetic contra-indications • Only submucous fibroids **Indications, N (%):** Primary infertility: **G1:** 28 (31.8) **G2:** 6 (33.4) **Pre-operative therapy:** None **Associated procedure(s):** NR	**Baseline uterine size:** NR **Number of fibroids (mean ± SD):** **G1:** 1.7 ± 0.6 **G2:** 1.6 ± 0.6 *P* = NS **Baseline size of largest fibroid (cm ± SD):** **G1:** 6.2 ± 1.8 **G2:** 8.1 ± 1.4 *P* < 0.001 **Type of fibroid, N (%):** Subserosal: **G1:** 31 (35) **G2:** 0 Intramural: **G1:** 57 (65) **G2:** 18 (100)	**Operative time, min ± SD:** **G1:** 150 ± 60 **G2:** 148 ± 47 **Complications, N:** **G1:** 4* **G2:** 2 **Length of stay, days ± SD:** **G1:** 3.0 ± 1 **G2:** 5.5 ± 1 *P* < 0.001 **Pregnancy rate, N (%):** **G1:** 42 (48) **G2:** 10 (56) *P* = NS **Pregnancies, N:** **G1:** 44 **G2:** 10 *P* = NS **Spontaneous pregnancy, N (%):** **G1:** 36/44 (82) **G2:** 8/10 (80) *P* = NS **Ovulation induction + IUI, N (%):** **G1:** 2 (5) **G2:** 1 (10) **IVF + ET, N (%):** **G1:** 6 (13) **G2:** 1 (10) **First-trimester miscarriage, N:** **G1:** 6 **G2:** 3 **Abortion, N:** **G1:** 2 **G2:** 2 **Dehiscence of uterine scar, N:** **G1:** 0 **G2:** 0	**Quality:** Overall quality score: fair **INTERNAL VALIDITY: fair** Random: NA Methods and blinding: NA Pt selection criteria: ++ Loss to follow-up: NA Drop-out rates: NA Statistical issues: - **EXTERNAL VALIDITY: fair (3)** Age: +, reported Race: NA, not US study Pregnancy history: -, NR Surgical history: -, NR Fibroid/uterine size: + Number of fibroids: + Location of fibroids: + Baseline characteristics: +, reported Length of follow-up: ++ Measurement methods: + Measurement reliability: - Clinical care: +

*Calculated by reviewer.

Evidence Table 7. KQ 2 Myomectomy (continued)

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria Other Details	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author: Dessolle et al., 2001 Soriano et al., 2003 (continued)				**Vaginal delivery, N (%):** **G1:**26/34 (77) **G2:** 2/4 (50) **Cesarean delivery, N (%):** **G1:** 8/34 (24) **G2:** 2/4 (50) **Ectopic pregnancy, N:** **G1:** 1 **G2:** 0 **Live newborn, N (%):** **G1:** 36/44 (41) **G2:** 4/10 (40) **Premature delivery, N:** **G1:** 0 **G2:** 1 **Time to conception , mos ± SD:** **G1:** 7.5 ± 2.6 **G2:** 15.1 ± 2.4 *P* < 0.001 **Patients with unexplained infertility, N (%):** **G1:** 32/42 (76) **G2:** 8/9 (89) *P* = NS **Patients with minor infertility factors, N (%):** **G1:** 10/42 (24) **G2:** 2/9 (22) *P* = NS **Patients with primary infertility, N (%):** **G1:** 14/28 (50) **G2:** 2/6 (33) *P* = NS	

*Calculated by reviewer.

Evidence Table 7. KQ 2 Myomectomy (continued)

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria Other Details	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author: Dessolle et al., 2001 Soriano et al., 2003 (continued)				**Patients with secondary infertility, N (%):** **G1:** 28/60 (47) **G2:** 8/12 (66) *P* = NS **Adhesions, N (%):** **G1:** 12/16 (75) **G2:** 4/4 (100) **Recurrence N (%):** **G1:** 6/66 (9)* **G2:** 2/12 (17) **Re-operation (%):** **G1:** 0 **G2:** 2 **Modifiers:** NR	

*Calculated by reviewer.

Evidence Table 7. KQ 2 Myomectomy (continued)

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria Other Details	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author: Di Gregorio et al., 2001 **Country and setting:** Italy, Specialty fibroid treatment center **Enrollment period:** 03/1988 to 04/2001 **Funding:** NR	**Design:** Retrospective case series **Intervention:** Laparoscopic myomectomy **Groups:** NA **N at enrollment:** 635 patients (1,170 fibroids) **N at follow-up:** 121 second look surgeries **Age, mean yrs (range):** 34.5 (24 to 51) **Race/ethnicity:** NR **Parity, parous, N (%):** Overall: 278 (43.8) **Baseline Hgb/Hct:** NR	**Inclusion criteria:** • Women who received myomectomy for symptomatic fibroids, infertility, or "size and/or number of fibroids required surgical treatment" • Fibroid size ≥ 10 mm **Exclusion criteria:** NR **Indications, N:** • Infertility: 445 **Preoperative therapy:** NR **Additional procedures, N:** • Adhesiolysis: 118 • Ovarian cystectomy: 89 • Coagulation of endometriotic lesions: 157 • Salpingectomy for ectopic pregnancy: 5 • Appendectomy: 5	**Baseline uterine size:** NR **Number of fibroids N (range):** 1 to 9 **Baseline fibroid size (mm):** < 20: 633 (54%) 21 to 39: 357 (30.5%) 40 to 59: 123 (10.5%) > 60: 57 (4.9%) **Type of fibroid, N (%):** • Subserous: 630 (53.8) • Intramural: 412 (35.2) • Pedunculated: 128 (10.9)	**Operative time range in min:** 30 to 140 **Conversion to laparotomy, N:** 2/635 **Adhesions at second look, N (%):** 2/121 (1.6) **Modifiers:** NR	**Quality:** Overall quality score: fair **INTERNAL VALIDITY: fair** Random: NA Methods and blinding: NA Pt selection criteria: + Loss to follow-up: NA Drop-out rates: NA Statistical issues: - **EXTERNAL VALIDITY: fair (3)** Age: -, NR Race: NA, not US study Pregnancy history: +, reported Surgical history: -, NR Fibroid/uterine size: + Number of fibroids: + Location of fibroids: + Baseline characteristics: -, NR Length of follow-up: NA Measurement methods: + Measurement reliability: + Clinical care: +

Evidence Table 7. KQ 2 Myomectomy (continued)

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria Other Details	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author: Doridot et al., 2001 **Country and setting:** France, Academic medical center **Enrollment period:** 03/1989 to 12/1996 **Funding:** NR	**Design:** Retrospective case series **Intervention:** Laparoscopic myomectomy **Groups:** NA **N at enrollment:** 196 **N at follow-up:** 173 **Age, yrs ± SD (range):** 36.6 ± 6.6 (18 to 54) **Race/ethnicity:** NR **Parity, N (%):** 0: 143 (72.9) 1: 40 (20.4) 2: 10 (5.1) 3: 3 (1.5) **Baseline Hgb/Hct:** NR	**Inclusion criteria:** • Women undergoing laparoscopic myomectomy **Exclusion criteria:** NR **Indications, N (%):** • Pain: 51 (26) • Menometrorrhagia: 45 (23) • Infertility: 63 (32.1) • Size: 32 (16.3) • Pressure: 3 (1.5) • Recurrent miscarriage: 2 (1) **Pre-operative therapy:** • GnRH agonist, (%): • No: 122 (70.5) • Yes: 51 (29.5) **Associated procedure(s):** NR	**Baseline uterine size:** NR **Number of fibroids, N (%):** 1: 114 (58.1) 2: 36 (18.4) ≥ 3: 46 (23.5) **Baseline fibroid size (mm), (%):** < 50: 86 (43.9) 50 to 70: 67 (34.2) ≥ 70: 43 (21.9) **Type of fibroid, N (%):** • Intramural: 74 (37.8) • Subserous: 97 (49.5) • Pedunculated: 25 (12.8)	**Recurrence rate, N (%):** 45 (22.9%) **Mean recurrence time, mos ± SD:** 42 ± 22 (4-95) **Recurrence requiring surgery, N (%):** 8 (4.6) **Second operative procedures, N:** LM: 3 Myomectomy by laparotomy: 1 Hysterectomy by laparotomy: 4 **Cumulative risk of recurrence:** At 2 yr: 12.7% At 5 yr: 16.7% **Modifiers:** Nulliparity, %: At 2 yr: 12.8% At 5 yr: 47.6% *P* = 0.0025 Multivariate analysis of recurrence risk: • Nulliparity: *P* = 0.004; 95% CI, 1.4-8.7 • > 1 fibroid: *P* = 0.05; 95% CI, 0.27-0.98	**Quality:** Overall quality score: fair **INTERNAL VALIDITY: fair** Random: NA Methods and blinding: NA Pt selection criteria: + Loss to follow-up: 10-20% Drop-out rates: NA Statistical issues: + **EXTERNAL VALIDITY: good** Age: +, reported Race: NA, not US study Pregnancy history: +, reported Surgical history: -, NR Fibroid/uterine size: + Number of fibroids: + Location of fibroids: + Baseline characteristics: +, reported Length of follow-up: ++ Measurement methods: + Measurement reliability: + Clinical care: +

Evidence Table 7. KQ 2 Myomectomy (continued)

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria Other Details	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author: Dubuisson et al., 2001 **Country and setting:** France, Academic medical center **Enrollment period:** 03/1989 to 10/1999 **Funding:** NR	**Design:** Retrospective case series **Intervention:** Laparoscopic myomectomy **Groups:** **N at enrollment:** 426 **N at follow-up:** 265 (with adequate preoperative ultrasound) **Age, yrs ± SD:** 37.8 ± 7.3 **Race/ethnicity:** NR **Parity:** NR **Baseline Hgb/Hct:** NR	**Inclusion criteria:** • Underwent LM at institution • Subserous or intramural fibroid >20 mm in diameter • Adequate ultrasound examination **Exclusion criteria:** NR **Indications, N (%):** Meno-metrorrhagia: 123 (28.9) Infertility/recurrent spontaneous abortion: 132 (32) Pain: 146 (34.3) Pressure: 52 (12.2) Size/rapid growth: 53 (12.4) **Pre-operative therapy** No: **Associated procedure(s), N:** 3 (procedure not reported)	**Baseline uterine size:** NR **Number of fibroids (mean ± SD):** 2.2 ± 1.8 **Baseline fibroid size (mm ± SD):** 56 ± 22 **Type of largest fibroid, N (%)*:** Intramural: 147 (55.5) Subserous: 92 (34.7) Pedunculated: 26 (9.8)	**Operative time, min ± SD:** 129 ± 57 **Successful laparoscopic myomectomy:** 378/426 (88.7) **Conversion to laparoscopic-assisted myomectomy:** 33/426 (7.8) **Conversion to laparotomy:** 15/426 (3.5) **Modifiers:** NR	**Quality:** Overall quality score: fair **INTERNAL VALIDITY: good** Random: NA Methods and blinding: NA Pt selection criteria: + Loss to follow-up: <10% Drop-out rates: NA Statistical issues: ++ **EXTERNAL VALIDITY: fair (1)** Age: +, reported Race: NA, not US study Pregnancy history: -, NR Surgical history: +, reported Fibroid/uterine size: + Number of fibroids: + Location of fibroids: + Baseline characteristics: +, reported Length of follow-up: ++ Measurement methods: + Measurement reliability: + Clinical care: +

*Calculated by reviewer

Evidence Table 7. KQ 2 Myomectomy (continued)

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria Other Details	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author: Elliot et al., 2005 **Country and setting:** UK, Academic medical center **Enrollment period:** NR **Funding:** NR	**Design:** Retrospective cohort **Intervention:** Intra-operative uterine tourniquet during multiple myomectomy **Groups:** **G1:** Tourniquet used **G2:** No tourniquet used **N at enrollment:** **G1:** 20 **G2:** 37 **N at follow-up:** NA **Age (mean):** **G1:** 35.9 **G2:** 35.8 **Race/ethnicity, N (%):** Afro-Caribbean: 44 (77.2) **Parity:** NR **Baseline Hgb/Hct:** NR	**Inclusion criteria:** • Open myomectomy cases logged in operating room logbooks **Exclusion criteria:** NR **Indications:** NR **Pre-operative therapy:** NR **Associated procedure(s):** NR	**Baseline uterine size, weeks gestation:** **G1:** 17 **G2:** 18 *P* = 0.55 **Number of fibroids:** NR **Baseline fibroid size, cm^3:** **G1:** 603 **G2:** 395 *P* = 0.7 **Type of fibroid:** NR	**Mean EBL, ml:** **G1:** 705 G3: 795 *P* = 0.10 **Mean EBL/fibroid volume, ml/cm^3:** **G1:** 4.6 **G2:** 4.7 *P* = 0.83 **Mean EBL/uterine size (units not given):** **G1:** 38.1 **G2:** 40.6 *P* = 0.84 **Mean fall in Hgb, g/dL:** **G1:** 2.80 **G2:** 2.33 *P* = 0.16 **Mean fall in Hgb/fibroid volume, g/dL/cm^3:** **G1:** 0.02 **G2:** 0.02 *P* = 0.65 **Intra-operative transfusion, N (range of units):** **G1:** 4 (1-3) **G2:** 1 (2) *P* > 0.1 **Post-operative transfusion, N (range of units):** **G1:** 8 (1-3) **G2:** 5 (1-7) *P* > 0.1 **Modifiers:** NR	**Quality:** Overall quality score: poor **INTERNAL VALIDITY: poor** Random: NA Methods and blinding: NA Pt selection criteria: - Loss to follow-up: NA Drop-out rates: NA Statistical issues: - **EXTERNAL VALIDITY: poor (6)** Age: +, reported Race: +, reported Pregnancy history: -, NR Surgical history: -, NR Fibroid/uterine size: + Number of fibroids: - Location of fibroids: - Baseline characteristics: -, NR Length of follow-up: NA Measurement methods: + Measurement reliability: + Clinical care: -

Evidence Table 7. KQ 2 Myomectomy (continued)

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria Other Details	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author: Fanfani et al., 2005 **Country and setting:** Italy, Academic medical center **Enrollment period:** 01/2003 to 12/2004 **Funding:** NR	**Design:** Prospective cohort **Intervention:** Laparoscopy and minilaparotomy myomectomy **Groups:** **G1:** Laparoscopy **G2:** Mini-laparotomy **N at enrollment:** **G1:** 93 **G2:** 120 **N at follow-up:** **G1:** 93 **G2:** 120 **Age, mean yrs:** **G1:** 34.4 (26 to 40) **G2:** 33.6 (24 to 39) **Race/ethnicity:** NR **Parity:** NR **Baseline Hgb/Hct:** NR	**Inclusion criteria:** • Symptomatic or infertility-associated fibroids • < 5 intramural or subserosal fibroids with ≤10 cm diameter • Age < 45 yrs **Exclusion criteria:** • Submucosal and/or pedunculated fibroids • Prior suprapubic longitudinal laparotomy **Indications:** Infertility, N (%): **G1:** 19 (20.5) **G2:** 34 (28.4) AUB, N (%): **G1:** 30 (32.2) **G2:** 43 (35.8) Pelvic pain, N (%): **G1:** 24 (25.8) **G2:** 28 (23.3) **Pre-operative therapy:** NR **Associated procedure(s):** NR	**Baseline uterine size:** NR **Number of fibroids removed:** **G1:** 1.4 (1 to 3) **G2:** 2.9 (1 to 5) *P* < 0.05 **Baseline fibroid size, by largest fibroid removed (cm):** **G1:** 5.6 (4 to 9) **G2:** 5.4 (4 to 9) **Type of fibroid, N (%):** Intramural: **G1:** 79 (60.7) **G2:** 224 (64.3) Subserosal: **G1:** 51 (39.3) **G2:** 124 (35.7)	**Operative time, min:** **G1:** 61.6 (40 to 90) **G2:** 62.3 (45 to 80) *P* = NS **Median estimated blood loss, ml:** **G1:** 270 (100 to 420) **G2:** 315 (150 to 400) *P* = NS **Intra-operative complications, N (%):** **G1:** 0 (0) **G2:** 0 (0) *P* = NS **Postoperative anemia, N (%):** **G1:** 0 (0) **G2:** 2 (1.7) *P* = NS **Fever > 38°C, N (%):** **G1:** 4 (4.3) **G2:** 4 (3.3) *P* = NS **Length of stay, days (range):** **G1:** 2.3 (2 to 3) **G2:** 2.8 (2 to 3) *P* = NS **Ileus, days:** **G1:** 1.4 (1 to 2) **G2:** 1.3 (1 to 2) *P* = NS **Modifiers:** NR	**Quality:** Overall quality score: fair **INTERNAL VALIDITY: good** Random: NA Methods and blinding: NA Pt selection criteria: ++ Loss to follow-up: <10% Drop-out rates: <5% Statistical issues: + **EXTERNAL VALIDITY: fair (1)** Age: +, reported Race: NA, not US study Pregnancy history: -, NR Surgical history: +, reported Fibroid/uterine size: + Number of fibroids: + Location of fibroids: + Baseline characteristics: +, reported Length of follow-up: + Measurement methods: + Measurement reliability: + Clinical care: +

Evidence Table 7. KQ 2 Myomectomy (continued)

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author: Glasser, 2005 **Country and setting:** US, Community **Enrollment period:** 01/1995 to 12/2003 **Funding:** NR	**Design:** Retrospective case series **Intervention:** Minilaparotomy myomectomy **Groups:** NA **N at enrollment:** 139 **N at follow-up:** NA **Age, mean yrs:** 38.9 (23 to 56) **Race:** NR **Parity:** NR **Baseline Hgb/Hct:** NR	**Inclusion criteria:** • Myomectomy **Exclusion criteria:** • Laparoscopic myomectomy alone • Abdominal incision > 6 cm **Indications:** NR **Preoperative therapy:** GnRHa: 70/139 **Additional procedures:** NR	**Baseline uterine size:** NR **Number of fibroids:** NR **Baseline fibroid size, mean gm (range):** 285.6 (30 to 925) **Type of fibroid:** NR	**Operative time, mean min (range):** 110 (55 to 260)* **Mean estimated blood loss (range):** 330 (50 to 2,000) **Length of stay, hrs (range):** 13.6 (4 to 48) **Modifiers:** None	**Quality:** Overall quality score: poor **INTERNAL VALIDITY: fair** Random: NA Methods and blinding: NA Pt selection criteria: ++ Loss to follow-up: NA Drop-out rates: NA Statistical issues: - **EXTERNAL VALIDITY: poor (7)** Age: +, reported Race: -, NR Pregnancy history: -, NR Surgical history: -, NR Fibroid/uterine size: + Number of fibroids: - Location of fibroids: - Baseline characteristics: +, reported Length of follow-up: + Measurement methods: - Measurement reliability: - Clinical care: +

*Discrepancy in paper

Evidence Table 7. KQ 2 Myomectomy (continued)

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria and Other Details	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author: Goodwin et al., 2006 **Country and setting:** US, Academic medical centers **Enrollment period:** NR **Funding:** Boston Scientific Corporation	**Design:** Prospective cohort **Intervention:** UAE vs. myomectomy **Groups:** **G1:** UAE **G2:** Myomectomy **N at enrollment:** **G1:** 149 **G2:** 60 **N at follow-up:** **G1:** 12o (1 yr) **G2:** 54 (6 mos) **Age, mean yrs:** **G1:** 43.9 **G2:** 38.2 *P* < 0.0001 **Race:** NR **Parity, parous (%):** **G1:** 75.2 **G2:** 48.3 *P* < 0.0001 **Baseline Hgb/Hct:** NR	**Inclusion criteria:** • Symptomatic fibroids confirmed on MRI • ≥ 30 yr old • Regular menses • Normal Pap smear • Able to complete follow-up requirements **Exclusion criteria:** • Hysteroscopically resectable fibroids • Pelvic infection • Gynecologic malignancy • Undiagnosed pelvic mass outside of uterus • Unexplained abnormal menstrual bleeding • Infection • Coagulopathy • History of pelvic irradiation • ASA score ≥ 4 • FSH level > 40 IU/L • Participation in any other investigational device or drug study • Desire to become pregnant • Abnormal serum creatinine level • Uterine arteriovenous fistula	**Baseline uterine size, cm^3:** **G1:** 658.4 **G2:** 590.6 *P* > 0.05 **Number of fibroids N (%):** 0 **G1:** 2 (1.3) **G2:** 1 (1.7) 1 **G1:** 9 (6.0) **G2:** 5 (8.3) 2 **G1:** 10 (6.7) **G2:** 4 (6.7) 3 **G1:** 10 (6.7) **G2:** 8 (13.3) 4 **G1:** 10 (6.7) **G2:** 7 (11.7) 5 **G1:** 6 (4.0) **G2:** 2 (3.3) 6–10 **G1:** 27 (18.1) **G2:** 14 (23.3) >10 **G1:** 75 (50.3) **G2:** 13 (21.7) *P* = 0.0001 **Baseline dominant fibroid size, cm^3:** **G1:** 182.12 **G2:** 226.92 *P* = 0.081 **Type of fibroid, N (%):** Intramural **G1:** 88 (59.1) **G2:** 26 (43.3) Submucosal **G1:** 1 (0.007) **G2:** 3 (5.0)	**At least 1 adverse event, N (%):** **G1:** 33 (22.1) **G2:** 24 (40) *P* < 0.01 **Major adverse event, N:** **G1:** 6. **G2:** 1 *P* < 0.05 **Length of stay, mean hrs:** **G1:** 23.8 **G2:** 61.6 *P* < 0.0001 **Dominant fibroid volume, 3 mos or 6 mos:** *P* = NS **Quality-of-life assessments, 6 mos:** *P* = NS **Menstrual bleeding score, 3 mos or 6 mos:** *P* = NS **Return to normal activities, mean days:** **G1:** 14.6 **G2:** 44.4 *P* < 0.05 **Missed workdays:** **G1:** 9.9 **G2:** 37.0 *P* < 0.001 **Modifiers:** NR	**Quality:** Overall quality score: fair **INTERNAL VALIDITY: good** Random: NA Methods and blinding: NA Pt selection criteria: ++ Loss to follow-up: 10-20% Drop-out rates: <5% Statistical issues: ++ **EXTERNAL VALIDITY: fair (3)** Age: +, reported Race: -, NR Pregnancy history: +, reported Surgical history: -, NR Fibroid/uterine size: + Number of fibroids: + Location of fibroids: + Baseline characteristics: +, reported Length of follow-up: ++ Measurement methods: + Measurement reliability: + Clinical care: -

Evidence Table 7. KQ 2 Myomectomy (continued)

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria and Other Details	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author: Goodwin et al., 2006 (continued)		• Severe contrast allergy • Pedunculated subserosal fibroid **Indications, N (%):** Abnormal bleeding **G1:** 77 (51.7) **G2:** 20 (33.3) *P* = 0.02 Bulk/pressure **G1:** 38 (25.5) **G2:** 16 (26.7) Pelvic pain **G1:** 29 (19.5) **G2:** 18 (30.0) Infertility **G1:** 0 (0.0) **G2:** 2 (3.3) Other **G1:** 5 (3.4) **G2:** 4 (6.7) **Preoperative therapy:** NR **Additional procedures:** NR	Submucosal pedunculated **G1:** 17 (11.4) **G2:** 2 (3.3) Sebserosal **G1:** 8 (5.4) **G2:** 8 (13.3) Subserosal pedunculated **G1:** 31 (20.8) **G2:** 13 (21.7) Other **G1:** 0 (0.0) **G2:** 1 (1.7) Cannot determine **G1:** 2 (1.3) **G2:** 0 (0.0) Missing **G1:** 2 (1.3) **G2:** 7 (11.7)		

Evidence Table 7. KQ 2 Myomectomy (continued)

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria and Other Details	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author: Hanafi, 2005 **Country and setting:** US, Community **Enrollment period:** 01/1992 to 10/2002 **Funding:** NR	**Design:** Retrospective case series **Intervention:** Myomectomy by exploratory laporotomy **Groups:** NA **N at enrollment:** 154 **N at follow-up:** 132 **Age, median yr:** 36 (24 to 49) **Race/ethnicity:** NR **Parity, median:** 1 (0 to 6), 89% had not completed families **Baseline Hgb/Hct:** NR	**Inclusion criteria:** NR **Exclusion criteria:** NR **Indications, %:** • Menometrorrhagia: 91 • Dysmenorrhea: 82 • Dyspareunia: 41 • Noncyclic pelvic pain: 22 • Anemia: 3 • Infertility: 30 • No symptoms: 3 **Preoperative therapy:** None **Associated procedure(s):** NR	**Baseline uterine size, median:** 10 gestational weeks **Number of fibroids, N (%):** 1: 37 (26) > 1: 108 (74) **Baseline fibroid size, median gm (range):** 103 (8-590) (N=28) **Type of fibroid, N (%):** • Subserous: 34 (23) • Intramural or intramural/ subserous: 98 (68) • Submucous or intramural/ submucosal: 6 (4) • All locations: 7 (5)	**5 year cumulative probability:** Fibroid recurrence: 62% Any surgery for recurrence: 17% Major surgery for recurrence: 9% **Modifiers of fibroid recurrence:** Number of fibroids: 1 fibroid: 11% > 1 fibroid: 74% *P* = 0.011 Uterine size: ≤ 10 weeks: 46% > 10 weeks: 82% *P* = 0.03 Subsequent parity: 26% Without subsequent parity: 76% *P* = 0.010	**Quality:** Overall quality score: fair **INTERNAL VALIDITY: fair** Random: NA Methods and blinding: NA Pt selection criteria: - Loss to follow-up: <10% Drop-out rates: <5% Statistical issues: + **EXTERNAL VALIDITY: fair (3)** Age: +, reported Race: +, reported Pregnancy history: +, reported Surgical history: -, NR Fibroid/uterine size: + Number of fibroids: + Location of fibroids: - Baseline characteristics: +, reported Length of follow-up: ++ Measurement methods: + Measurement reliability: + Clinical care: -

Evidence Table 7. KQ 2 Myomectomy (continued)

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria and Other Details	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author: Istre and Langebrekke, 2003 **Country and setting:** Norway, National registry and hospital database **Enrollment period:** 1989 to 1996 **Funding:** NR	**Design:** Retrospective cohort **Intervention:** Follow-up women who failed conservative medical treatment for fibroids **Groups:** Patients with fibroid resection **N at enrollment:** 188 **N at follow-up ("at least 4 yr"):** 188 **Age:** NR **Race/ethnicity:** NR **Parity:** NR **Baseline Hgb/Hct:** NR	**Inclusion criteria:** • Failed conservative medical treatment, including hormone therapy **Exclusion criteria:** NR **Indications:** NR **Preoperative therapy:** NA **Additional procedures:** NR	**Baseline uterine size:** NR **Number of fibroids:** NR **Baseline fibroid size:** NR **Type of fibroid:** NR	**Repeat resection among women with fibroids, N (%):** 33/188 (17) **Hysterectomy after repeat resection, N (%):** 12/33 (36) **Modifiers:** NR	**Quality:** Overall quality score: poor **INTERNAL VALIDITY: poor** Random: NA Methods and blinding: NA Pt selection criteria: + Loss to follow-up: 10-20% Drop-out rates: <5% Statistical issues: - **EXTERNAL VALIDITY: poor (5)** Age: -, NR Race: NA, not US study Pregnancy history: -, NR Surgical history: +, reported Fibroid/uterine size: - Number of fibroids: - Location of fibroids: - Baseline characteristics:+, reported Length of follow-up: ++ Measurement methods: + Measurement reliability: + Clinical care: +

Evidence Table 7. KQ 2 Myomectomy (continued)

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria Other details	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author: Kumakiri et al., 2005 **Country and setting:** Japan, Academic medical center **Enrollment period:** 01/1998 to 12/2002 **Funding:** NR	**Design:** Retrospective case series **Intervention:** Laparoscopic myomectomy **Groups:** NA **N at enrollment:** 108 **N at follow-up:** NA **Age, yrs ± SD:** 35.5 ± 3.5 **Race/Ethnicity:** NA **Parity, parous (N):** Multiparous: 10 **Baseline Hgb/Hct:** NR	**Inclusion criteria:** • Menorrhagia and abdominal fullness • Infertility • Fibroids ≥ 5 cm • Wishing to have children • Largest fibroid ≤ 12 cm • Uterus size ≤ 14 weeks gestation **Exclusion criteria:** See inclusion criteria **Indications, N:** Infertility: 59 Menorrhagia: 20 Dysmenorrhea: 17 Lower abdominal pain: 6 Other: 6 **Pre-operative therapy, N (%):** GnRH: 86 (79.6) **Associated procedure(s):** NR	**Baseline uterine size:** NR **Number of fibroids enucleated, mean ± SD:** Pregnancy: 3.2 ± 2.7 No pregnancy: 3.7 ± 3.6 *P* = 0.04 **Baseline largest fibroid size mm ± SD:** Pregnancy: 67.5 ± 16.9 No pregnancy: 62.3 ± 16.3 *P* = 0.004 **Type of fibroid:** NR	**Operative time, min ± SD:** Pregnancy: 105.3 ± 45.3 No pregnancy: 106.0 ± 51.5 *P* =0.75 **Mean estimated blood loss, ml ± SD:** Pregnancy: 85.2 ± 105.8 No pregnancy: 120.3 ± 174.5 *P* =0.53 **Pregnancy success rate, N (%):** 40/108 (37) **Spontaneous pregnancies, N (%):** 40/47 (85.1) **ART pregnancies, N (%);** 7/47 (14.9) **Miscarriages, N (%):** 11/47 (23.4) **Ectopic, N:** 1/47 (2.1) **Live births, N (%):** 32/47 (68.1) **Elective Cesarean delivery, N (%):** 9/32 (28.1) **VBALM failure, N (%):** 4/23 (17.4) **Modifiers:** Pregnancy rate correlated positively with diameter of largest fibroid: OR =1.06; 95% CI, 1.02-1.10 *P* = 0.004	**Quality:** Overall quality score: fair **INTERNAL VALIDITY: fair** Random: NA Metods and blinding: NA Pt selection criteria: + Loss to follow-up: <10% Drop-out rates: NA Statistical issues: - **EXTERNAL VALIDIT: fair (2)** Age: +, reported Race: NA, not US study Pregnancy history: -, NR Surgical history: -, NR Fibroid/uterine size: + Number of fibroids: + Location of fibroids: + Baseline characteristics: +, reported Length of follow-up: + Measurement methods: + Measurement reliability: + Clinical care: +

Evidence Table 7. KQ 2 Myomectomy (continued)

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria Other details	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author: Kumakiri et al., 2005 (continued)				**Modifiers:** Pregnancy rate correlated negatively with age at myomectomy: OR = 0.88; 95% CI, 0.80-0.98 *P* = 0.02 Pregnancy rate correlated negatively with number of enucleated fibroids: OR =1.17; 95% CI, 1.01-1.37 *P* = 0.04	

Evidence Table 7. KQ 2 Myomectomy (continued)

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author: Landi et al., 2001 **Country and setting:** Italy, Academic medical center **Enrollment period:** 05/1997 to 09/1999 **Funding:** NR	**Design:** Prospective case series **Intervention:** Laparoscopic myomectomy **Groups:** NA **N at enrollment:** 368 **N at follow-up, 1 mo:** 282 **Age, yr ± SD:** 37.1 ± 6.9 **Race/ethnicity:** NR **Parity:** NR **Baseline Hgb/Hct:** NR	**Inclusion criteria:** • Healthy • Non-pregnant • Undergoing laparoscopic myomectomy **Exclusion criteria:** • Pre-operative medical therapy with GnRH agonists **Indications, %:** • Pelvic mass: 170 (46.2) • AUB: 82 (22.3) • Pelvic pain: 69 (18.8) • Primary infertility: 16 (4.3) **Preoperative therapy:** None **Additional procedures, N, (%):** • Endometrial biopsy: 151 (41) • Adhesiolysis: 108 (29.3) • Chromoperturba-tion: 55 (14.9) • Coagulation of endometriosis: 50 (13.5) • Ovarian cystectomy: 44 (11.9)	**Baseline uterine size:** NR **Number of fibroids, %:** One: 52.3 Two: 18.9 Three: 11.6 Four: 6.6 ≥ Five: 10.0 (totals to 99.4%) **Baseline diameter of largest fibroid, (mm ± SD):** 56.9 ± 27.6 **Type of fibroids, %:** Subserous: 37.2 Intramural: 41.4 Pedunculated: 16.5 Intraligamentous: 4.8 (N = 768)	**Operative time, min ± SD:** 100.7 ± 43.8 **Mean estimated blood loss, ml ± SD:** 381.4 ± 324.8 **Estimated blood loss < 100 ml, N:** 63 **Conversion to laparotomy, N %:** 8 (2.1) **Any operative complications** (major vessel, ureteral, bladder, bowel injury, needle breaks, uterine manipulator and sound injuries)**, N %:** 12 (3.3) **Decrease in Hgb, g/100 ml ± SD:** 1.38 ± 0.93 **Transfusion, N:** 4 **Fever > 38°C, N %:** 12 (3.3) **Intermittent pelvic pain, N:** 5 **Length of stay, days ± SD:** 2.89 ± 1.30 **Any cuff hematoma, pelvic hematoma, wound infection, antibiotic treatment, wound dehiscence, N:** 18 **Time to subjective well-being, days ± SD:** 10.58 ± 6.68 **Modifiers:** NR	**Quality:** Overall quality score: poor **INTERNAL VALIDITY: poor** Random: NA Methods and blinding: NA Pt selection criteria: + Loss to follow-up: >20% Drop-out rates: NA Statistical issues: - **EXTERNAL VALIDITY: fair (2)** Age: +, reported Race: NA, not US study Pregnancy history: -, NR Surgical history: -, NR Fibroid/uterine size: + Number of fibroids: + Location of fibroids: + Baseline characteristics: +, reported Length of follow-up: + Measurement methods: + Measurement reliability: + Clinical care: +

Evidence Table 7. KQ 2 Myomectomy (continued)

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria Other Details	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author: Loffer, 2005 **Country and setting:** US, Academic medical center **Enrollment period:** 08/1984 to 08/2003 **Funding:** NR	**Design:** Retrospective cohort **Intervention:** Endometrial ablation at time of hysteroscopic myomectomy for submucosal fibroids **Groups:** **G1:** Endometrial ablation **G2:** Without endometrial ablation **N at enrollment:** **G1:** 73 **G2:** 104 **N at follow-up (12 mos):** **G1:** 72 **G2:** 103 **Age, yrs ± SD:** **G1:** 44.0 ± 4.7 **G2:** 37.6 ± 6.0 *P* < 0.001 **Race/ethnicity:** NR **Parity:** NR (15 infertile, no ablations in this group) **Baseline Hgb/Hct:** NR	**Inclusion criteria:** • All hysteroscopic myomectomies by a single surgeon for premenopausal women with menorrhagia/ menometrorr-hagia **Exclusion criteria:** • Procedures done by author outside US or for which follow-up information was unavailable **Indications:** • Menorrahagia and/or metrorrhagia **Pre-operative therapy, N (%):** Endometrial suppression: **G1:** 58 (79.5) **G2:** 22 (27.5) **Associated Procedure(s):** NR	**Baseline uterine size:** NR **Number of fibroids, mean ± SD:** **G1:** 1.5 ± 1.1 **G2:** 1.5 ± 1.1 *P* = 0.96 **Baseline fibroid size, cm ± SD:** **G1:** 3.0 ± 1.1 **G2:** 3.4 ± 1.5 *P* = 0.06 **Type of fibroid, %:** Type 0: **G1:** 30.1 **G2:** 33.7 Type I: **G1:** 49.3 **G2:** 36.5 Type II: **G1:** 20.5 **G2:** 29.8	**Bleeding controlled, N (%):** **G1:** 70 (95.9) **G2:** 84 (80.8) *P* = 0.003 (OR = 0.18; 95%CI, 0.05-0.63) **Success (no recurrence of bleeding problems or hysterectomy):** Log Rank = 5.3; *P* = 0.02 (Kaplan-Meier survival analysis) **Modifiers:** Complete vs. incomplete removal of fibroids **Success (defined above), N (%):** G1 with complete removal: 58 of 60 (96.7) G1 with incomplete removal: 12 of 13 (92.3) G2 with complete removal: 65 of 77 (84.4) G2 with incomplete removal: 19 of 27 (70.4) **Hysterectomy, N (%):** G1 with complete removal: 11 (18.3) G1 with incomplete removal: 2 (15.4) G2 with complete removal: 13 (16.9) G2 with incomplete removal: 10 (37)	**Quality:** Overall quality score: poor **INTERNAL VALIDITY: fair** Random: NA Methods and blinding: NA Pt selection criteria: + Loss to follow-up: <10% Drop-out rates: NA Statistical issues: - **EXTERNAL VALIDITY: poor (4)** Age: +, reported Race: -, NR Pregnancy history: -, NR Surgical history: -, NR Fibroid/uterine size: + Number of fibroids: + Location of fibroids: + Baseline characteristics: -, NR Length of follow-up: ++ Measurement methods: + Measurement reliability: + Clinical care: +

Evidence Table 7. KQ 2 Myomectomy (continued)

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria Other Details	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author: Malzoni et al., 2003 **Country and setting:** Italy, Community **Enrollment period:** 01/1997 to 07/1999 **Funding:** NR	**Design:** Retrospective case series **Intervention:** Laparoscopic myomectomy for fibroids ≥ 5cm **Groups:** NA **N at enrollment:** 144 **N at follow-up:** NR **Age, mean yrs:** 33.7 (22 to 41) **Race/ethnicity:** NR **Parity, parous, N (%):** Nulligravida: 98 (60.5) **Baseline Hgb/Hct:** NR	**Inclusion criteria:** • Undergoing laparoscopic myomectomy **Exclusion criteria:** NR **Indications, N (%):** • Infertility: 102 (70.8) • Abnormal bleeding: 98 (68) • Pain: 64 (44.4) • More than 1 symptom: 81 (56.2) **Pre-operative therapy:** None **Associated procedure(s), N (%):** • Lysis: 24 (16.6) • Tubal plasty: 6 (4.16) • Appendectomy: 5 (3.47) • Ovarian cystectomy: 4 (2.77) • Coagulation of endometriosis: 3 (2.08)	**Baseline uterine size:** NR **Fibroids removed, N (%):** 1: 84 (58.33) 2: 35 (24.3) 3: 17 (11.8) 4: 6 (4.17) **Baseline dominant fibroid size, mean cm (range):** 7.8 (5 to 18) **Type of fibroid, N (%):** • Interstitial submucous: 108 (75) • Subserous sessile: 15 (10.4) • Pedunculated: 7 (4.86) • Intraligamentous: 14 (9.7)	**Operative time, mean min (range):** 85 (58 to 180) **Conversion to laparotomy, N (%):** 2 (1.39) **Transfusion, N (%):** 1 (0.69) **Length of stay, days (range):** 2.6 (2 to 5) **Intramural hematoma, N (%):** 1 day post-op: 108 (75) 2 day post-op: 14 (9.7) **Pregnancy rate N (%)*:** 26 in 21 patients (25%) Spontaneous: 20 After IVF: 1 **Live birth, N:** 21 **Cesarean delivery, N:** 12/21 **Vaginal delivery, N:** 9/21 **Uterine rupture, N:** 0 **Miscarriage, N:** 4/26 **Ectopic pregnancy, N:** 1/26 **Pregnancy rate, 1997, N (%):** 6-mon: 13/38 (34.21) 12-mon: 21/38 (55.26) **Adhesions at 2nd-look, N (%):** 6/18 (33) **Severity of adhesions, N (%):** Type 1: 4 (22.2) Type 2: 2 (11.1) Type 3: 0 **Modifiers:** NR	**Quality:** Overall quality score: fair **INTERNAL VALIDITY: fair** Random: NA Methods and blinding: NA Pt selection criteria: + Loss to follow-up: NA Drop-out rates: NA Statistical issues: - **EXTERNAL VALIDITY: fair (1)** Age: +, reported Race: NA, not US study Pregnancy history: +, reported Surgical history: -, NR Fibroid/uterine size: + Number of fibroids: + Location of fibroids: + Baseline characteristics: +, reported Length of follow-up: + Measurement methods: + Measurement reliability: + Clinical care: +

* Pregnancy rate was only calculated for patients who had LM in 1997

Evidence Table 7. KQ 2 Myomectomy (continued)

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria Other Details	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author: Marret et al., 2006 **Country and setting:** France, Academic medical center and Community **Enrollment period:** 01/1996 to 12/2000 **Funding:** NR	**Design:** Retrospective case series **Intervention:** Myomectomy **Groups:** **G1:** Conversion to laparotomy **G2:** Laparoscopy **N at enrollment:** **G1:** 33 **G2:** 83 **N at follow-up:** NA **Age:** NR **Race/ethnicity:** NR **Parity:** NR **Baseline Hgb/Hct:** NR	**Inclusion criteria:** • Planned laparoscopic myomectomy **Exclusion criteria:** • Missing medical record data **Indications:** • Pelvic pain: 41% • Infertility: 38% • Bleeding: 14% **Pre-operative therapy:** GnRHa: **G1:** 1 (3.0) **G2:** 2 (2.4) *P* = NS **Associated procedure(s):** NR	**Baseline uterine size:** NR **Number of fibroids, mean ± SD:** **G1:** 2.4 ± 2.5 **G2:** 1.7 ± 1.8 **Baseline largest fibroid size, mm ± SD:** **G1:** 67.9 ± 18.2 **G2:** 47.8 ± 18.6 **Type of fibroid, N (%):** Subserous: **G1:** 19 (57.6) **G2:** 61 (73.5) Intramural: **G1:** 15 (45.5) **G2:** 21 (25.3)	**Risk of laparo-conversion, multivariate:** Increase in largest fibroid size of 1 mm: OR = 1.06 (95% CI, 1.03-1.09) *P* < 0.001 Dominant fibroid intramural: OR = 3.24 (95% CI, 1.11-10.21) *P* = 0.036 Surgeon's experience (senior vs. junior): OR = 0.15 (95% CI, 0.04-0.46) *P* = 0.001	**Quality:** Overall quality score: fair **INTERNAL VALIDITY: good** Random: NA Methods and blinding: NA Pt selection criteria: + Loss to follow-up: NA Drop-out rates: NA Statistical issues: + **EXTERNAL VALIDITY: poor (5)** Age: -, NR Race: -, NR Pregnancy history: -, NR Surgical history: -, NR Fibroid/uterine size: + Number of fibroids: + Location of fibroids: + Baseline characteristics: +, reported Length of follow-up: NA Measurement methods: + Measurement reliability: + Clinical care: -

Evidence Table 7. KQ 2 Myomectomy (continued)

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria Other Details	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author: Marret et al., 2004 **Country and setting:** France, Community and Academic medical centers **Enrollment period:** 01/1996 to 01/2000 **Funding:** French Society of Gynaecology and Obstetrics West Group	**Design:** Retrospective cohort **Intervention:** Myomectomy (abdominal vs. laporoscopic) **Groups:** **G1:** Abdominal myomectomy **G2:** Laparoscopic myomectomy **G2a:** Laparoscopy **G2b:** Laparoconversion **N at enrollment:** **G1:** 176 **G2:** 126 **G2a:** 89 **G2b:** 37 **N at follow-up, 2 yr:** **G1:** 176 **G2:** 126 **G2a:** 89 **G2b:** 37 **Age:** NR **Race/ethnicity:** NR **Parity:** NR **Baseline Hgb/Hct:** NR	**Inclusion criteria:** NR **Exclusion criteria:** NR **Indications, %:** Pain: **G1:** 35 **G2:** 41 Infertility: **G1:** 35 **G2:** 38 Bleeding: **G1:** 30 **G2:** 14 **Preoperative therapy, %:** GnRH agonists **G1:** 16 **G2:** 3 **Additional procedures:** NR	**Baseline uterine size:** NR **Number of fibroids, median (range):** **G1:** 1 (1 to 18) **G2:** 1 (1 to 15) *P* = 0.010 **Baseline largest fibroid size, mm ± SD:** **G1:** 81.4±39.7 **G2:** 53.7±20.4 *P* < 0.001 **Type of fibroid N (%):** Subserous: **G1:** 83 (47.4) **G2:** 85 (69.7) *P* < 0.001 Intramural: **G1:** 89 (51.1) **G2:** 36 (29.5) *P* < 0.001	**Operative time, min ± SD:** **G1:** 89 ± 33 **G2a:** 89 ± 45 **G2b:** 98 ± 30 G1 vs. G2a: *P* = 0.963 G2a vs. G2b: *P* = 0.248 **Mean estimated blood loss, ml ± SD:** **G1:** 504 ± 542 **G2a:** 226 ± 320 **G2b:** 643 ± 999 G1 vs. G2a: *P* = 0.039 G2a vs. G2b: *P* = 0.114 **Decrease in Hgb, g/dL ± SD:** **G1:** 2.6 ± 1.6 **G2a:** 1.6 ± 1.4 **G2b:** 2.6 ± 1.4 G1 vs. G2a: *P* < 0.001 G2a vs. G2b: *P* = 0.005 **Transfusions, N (%):** **G1:** 9/173 (5.2) **G2a:** 0/88 (0.0) **G2b:** 2/35 (5.7) G1 vs. G2a: *P* = 0.031 G2a vs. G2b: *P* = 0.079 **Fever, N (%):** **G1:** 28 (15.9) **G2a:** 1/88 (1.1) **G2b:** 2/35 (5.7) G1 vs. G2a: *P* < 0.001 G2a vs. G2b: *P* = 0.195	**Quality:** Overall quality score: poor **INTERNAL VALIDITY: poor** Random: NA Methods and blinding: NA Pt selection criteria: - Loss to follow-up: <10% Drop-out rates: NA Statistical issues: - **EXTERNAL VALIDITY: poor (6)** Age: -, NR Race: -, NR Pregnancy history: -, NR Surgical history: -, NR Fibroid/uterine size: + Number of fibroids: + Location of fibroids: + Baseline characteristics: +, reported Length of follow-up: + Measurement methods: + Measurement reliability: - Clinical care: -

Evidence Table 7. KQ 2 Myomectomy (continued)

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria Other Details	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author: Marret et al., 2004 (continued)				**Length of stay, days ± SD:** **G1:** 6.9 ± 2.0 **G2a:** 3.6 ± 1.3 **G2b:** 6.5 ± 1.8 G1 vs. G2a: *P* < 0.001 G2a vs. G2b: *P* < 0.001 **Uterine cavity opening, N (%):** **G1:** 58/173 (33.5) **G2a:** 7 (7.9) **G2b:** 7/36 (19.4) G1 vs. G2a: *P* < 0.001 G2a vs. G2b: *P* = 0.113 **Complications or injuries, N (%):** **G1:** 4/176 (2.3) **G2a:** 2/89 (2.2) **G2b:** 2/35 (5.7) G1 vs. G2a: *P* = 1.000 G2a vs. G2b: *P* = 0.316 **Wound hematoma, N (%):** **G1:** 10 (5.7) **G2a:** 1 (1.1) **G2b:** 3/35 (8.6) G1 vs. G2a: *P* = 0.106 G2a vs. G2b: *P* = 0.068 **Wound infection, N (%):** **G1:** 1 (0.6) **G2a:** 0 (0.0) **G2b:** 0 (0.0) G1 vs. G2a: *P* = 1.000 **Endometritis, N (%):** **G1:** 1 (0.6) **G2a:** 0 (0.0) **G2b:** 0 (0.0) G1 vs. G2a: *P* = 1.000	

Evidence Table 7. KQ 2 Myomectomy (continued)

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria Other Details	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author: Marret et al., 2004 (continued)				**Deep vein thrombosis, N (%):** **G1:** 0 (0.0) **G2a:** 0 (0.0) **G2b:** 0 (0.0) G1 vs. G2a: *P* = 1.000 **Urinary tract infection, N (%):** **G1:** 7 (4.0) **G2a:** 0 (0.0) **G2b:** 0 (0.0) G1 vs. G2a: *P* = 1.000 **Surgeon's experience (consultant/ fellow), N (%):** **G2a:** 69/82 (84.1) **G2b:** 18/32 (56.2) G2a vs. G2b: *P* < 0.001 **Modifiers:** NR	

Evidence Table 7. KQ 2 Myomectomy (continued)

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria Other Details	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author: Marziani et al., 2005 **Country and setting:** Italy, Academic medical center **Enrollment period:** 01/1997 to 12/2001 **Funding:** NR	**Design:** Prospective case series **Intervention:** Hysteroscopic myomectomy **Groups:** **G1:** Women with submucous uterine fibroids **N at enrollment:** 107 **N at follow-up, 36 mos:** **G1:** 104 **Age, mean yrs:** **G1:** 35 (30 to 46) **Race/ethnicity:** NR **Parity:** NR **Baseline Hgb/Hct:** **G1:** 10.33 g/dL	**Inclusion criteria:** • Excessive uterine bleeding defined by history with Hgb < 10 g/dl and Hct < 37 • Infertility • Fibroids defined by transvaginal ultrasound and diagnostic hysteroscopy **Exclusion criteria:** • Myoma size ≥ 3 cm • Intramural fibroid with < 5 mm of myometrium between fibroid and serosa • Adnexal pathology • Abnormal endometrial biopsy **Indications, N (%)** • Abnormal uterine bleeding: 84 (78.5) • Infertility: 23 (21.5) **Pre-operative therapy:** GnRH to reduce size of fibroid if ≥ 3 cm or desired by surgeon **Associated procedure(s):** NR	**Baseline uterine size:** NR **Number of fibroids, mean (range):** 1.5 (1 to 3) **Baseline fibroid size, cm^3 ± SD:** Type 0: 22 ± 9 Type 1: 25 ± 9 Type 2: 23 ± 10 **Type of fibroid, N (%):** Type 0: 51 (47.7) Type 1: 43 (40.2) Type 2: 13 (12.1)	**Conversion to open myomectomy, N:** 3 **Conversion to hysterectomy, N:** 2 **Uterine perforation, N:** 0 **Post-operative hemorrhage, N:** 3 **Number of procedures, N (%):** One: 91 (85) Two: 16 (15) **Control of menorrhagia, N (%):** • One procedure: 68 (81.0) • Two procedures: 11 (13.1) • Not controlled: 5 (4.7) **Modifiers:** Number of fibroids and control of menorrhagia after one procedure: • 1 fibroid: 46 of 46 (100%) • 2 fibroids: 21 of 24 (87.5%) • 3 fibroids: 12 of 14 (85.7%) *P* < 0.05	**Quality:** Overall quality score: fair **INTERNAL VALIDITY: fair** Random: NA Methods and blinding: NA Pt selection criteria: ++ Loss to follow-up: <10% Drop-out rates: NA Statistical issues: - **EXTERNAL VALIDITY: fair (3)** Age: +, reported Race: NA, not US study Pregnancy history: -, NR Surgical history: -, NR Fibroid/uterine size: + Number of fibroids: + Location of fibroids: + Baseline characteristics: +, reported Length of follow-up: - Measurement methods: + Measurement reliability: + Clinical care: +

Evidence Table 7. KQ 2 Myomectomy (continued)

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria Other Details	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author: Mettler et al., 2004 **Country and setting:** Germany and France, Academic medical center and specialty fibroid treatment center **Enrollment period:** NR **Funding:** Confluent Surgical (Phase III Trial)	**Design:** RCT **Intervention:** Sprayable adhesion barrier after myomectomy (SprayGel; Confluent Surgical, Waltham, MA) **Groups:** **G1:** Myomectomy plus adhesion barrier **G2:** Myomectomy alone **N at enrollment:** **G1:** 34 **G2:** 30 **N at follow-up:** **G1:** 34 **G2:** 30 **N at second look, N (%):** **G1:** 22 (64.7) **G2:** 18 (60.0) **Age, yrs ± SD:** **G1:** 34.9 ± 5.2 **G2:** 35.0 ± 5.9 **Race/ethnicity:** NR **Parity:** NR **Baseline Hgb/Hct:** NR	**Inclusion criteria:** • Age ≥ 18 • Candidates for myomectomy via laparoscope or laparotomy; "thought to benefit from second-look laparoscopy within 16 weeks of surgery" **Exclusion criteria:** NR **Indications, N (%):** Infertility: **G1:** 11 (32.4) **G2:** 9 (30) Pain: **G1:** 16 (47.1) **G2:** 16 (53.3) Other: **G1:** 7 (20.6) **Other:** 5 (16.7) **Pre-operative therapy:** NR **Associated procedure(s):** Myomectomy by laparotomy: **G1:** 6 **G2:** 7	**Baseline uterine size:** NR **Baseline fibroid size:** NR **Number of fibroids removed, mean ± SD:** **G1:** 2.6 ± 3.2 **G2:** 2.6 ± 3.2 **Weight of fibroids removed, gm ± SD:** **G1:** 115.0 ± 121 **G2:** 101.0 ± 104 **Type of fibroid, N (%)** Intramural: **G1:** 29 (84.4) **G2:** 27 (89.7) **Number of uterine incisions, mean ± SD:** **G1:** 1.9 ± 1.5 **G2:** 1.5 ± 1.2 **Length of uterine incisions, mean cm ± SD:** **G1:** 7.4 ± 4.9 **G2:** 7.0 ± 4.6	**No adhesions on 2nd look, N (%):** **G1:** 7 of 22 (31.8) **G2:** 2 of 18 (11.1) *P* = NS **Severity of adhesions (tenacity score: 0 = none; 1 = filmy, avascular; 2 = vascular, dense; 3 = cohesive):** **G1:** 1.0 **G2:** 1.9 *P* = 0.002 **Extent of adhesions, median area of uterus involved in cm^2:** **G1:** 7.4 **G2:** 7.8 *P* = NS **Increased incidence of adhesions:** **G1:** 0.64 **G2:** 1.22 *P* = 0.035 **Increased adhesion area from baseline, median increase in area of uterus involved cm^2:** **G1:** 4.5 **G2:** 7.2 *P* = NS **Modifiers:** NR	**Quality:** Overall quality score: poor **INTERNAL VALIDITY: poor** Random: - Methods and blinding: + Pt selection criteria: ++ Loss to follow-up: >20% Drop-out rates: 5-10% Statistical issues: - **EXTERNAL VALIDITY: poor (5)** Age: +, reported Race: NA, not US study Pregnancy history: -, NR Surgical history: -, NR Fibroid/uterine size: - Number of fibroids: - Location of fibroids: + Baseline characteristics: +, reported Length of follow-up: - Measurement methods: + Measurement reliability: + Clinical care: +

Evidence Table 7. KQ 2 Myomectomy (continued)

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria Other Details	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author: Munoz et al., 2003 **Country and setting:** Spain, Academic medical center **Enrollment period:** 01/1992 to 12/1999 **Funding:** NR	**Design:** Retrospective case series **Intervention:** Hysteroscopic myomectomy **Groups:** NA **N at enrollment:** 120 **N at follow-up:** 120 **Age (median yrs):** 44.8 (23 to 74) **Race/ethnicity:** NR **Parity (range):** 1.6 (0 to 6) Nulliparous: 25.8% **Baseline Hgb/Hct:** NR	**Inclusion criteria:** • Symptomatic fibroid or infertility • Desire for uterine preservation • Fibroid <6cm • Less than 50% of endometrial surface affected **Exclusion criteria:** • Labastida's Type V fibroid • Pathology that contraindicates procedure **Indications, N (%):** • AUB: 101 (84.1) • Infertility: 14 (11.6) • Pain: 7 (5.8%) **Pre-operative therapy, N (%)** • None: 39 (32.5) • Danazol: 9 (7.5) • GnRHa: 72 (60) **Associated procedure(s), N (%):** 37 (30.8)	**Baseline uterine size:** NR **Number of fibroids:** NR **Baseline fibroid size, cm (%):** 1: 5 (4.1) 2: 31 (25.8) 3: 63 (52.5) 4: 19 (15.9) 5: 2 (1.7) **Type of fibroid, N (%):** Type 0: 52 (43.3) Type I: 51 (42.5) Type II: 17 (14.1)	**Operative time (median mins):** 32.5 (10-105) **Uterine perforation:** N = 1 **Hemorrhage:** N = 1 **Unable to complete procedure:** N = 22 **Length of stay, N (%):** 12 hrs: 15 (47.5) 24 hrs: 33 (27.5) 36 hrs: 5 (4.3) 48 hrs: 17 (14.1) 72 hrs: 7 (5.8) > 72 hrs: 1 (0.8) **Infection, N:** N = 1 **Excess glycine, N:** N = 1 **Later interventions, N (%):** • 107 (89.1) • Hysterectomy: 3 • Myomectomy: 9 **Glycine retention, median:** 281 ml **Modifiers:** **Operative time modified by size, median mins (range):** < 3cm: 26.5 (10 to 45) > 3cm: 36.3 (10 to 105) **Glycine retention by modified by complexity, median:** Simple procedure: 270 ml Combined procedures: 302 ml	**Quality:** Overall quality score: fair **INTERNAL VALIDITY: fair** Random: NA Methods and blinding: NA Pt selection criteria: + Loss to follow-up: <10% Drop-out rates: NA Statistical issues: - **EXTERNAL VALIDITY: fair (3)** Age: +, reported Race: NA, not US study Pregnancy history: +, reported Surgical history: -, NR Fibroid/uterine size: + Number of fibroids: - Location of fibroids: + Baseline characteristics: +, reported Length of follow-up: - Measurement methods: + Measurement reliability: + Clinical care: +

Evidence Table 7. KQ 2 Myomectomy (continued)

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria Other Details	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author: Olufowobi et al., 2004 **Country and setting:** UK, Community **Enrollment period:** 1996 to 2001 **Funding:** NR	**Design:** Retrospective case series **Intervention:** Myomectomy **Groups:** NR **N at enrollment:** 109 **N at follow-up:** NA **Age, yrs ± SD:** 36 ± 4.7 **Race/ethnicity:** NR **Parity:** NR **Baseline Hgb/Hct:** NR	**Inclusion criteria:** • Reproductive age • Myomectomy during study period **Exclusion criteria:** NR **Indications, N (%):** • Menstrual disorder only: 20 (18) • Menstrual disorder and pain: 23 (21) • Menstrual disorder and infertility: 26 (24) • Menstrual disorder and mass: 7 (6) • Abdominal/pelvic pain only: 3 (3) • Abdominal/pelvic pain and infertility: 14 (13) • Abdominal/pelvic pain and mass: 10 (9) • Abdominal mass only: 4 (4) • Abdominal mass and infertility: 11 (10) • Infertility alone: 16 (15) **Preoperative therapy:** Medical management (NSAIDS or GnRHa): 48% **Associated procedure(s):** NR	**Baseline uterine size:** NR **Number of fibroids removed, mean (range):** 5 (1-27) **Baseline removed fibroid size, mean cm:** 8.2 (2-30) **Type of fibroid:** NR	**Estimated blood loss >500ml, N (%):** 34 (31) **Conversion to laparotomy, %:** 32 **Conversion to hysterectomy, N (%):** 4 (4) **Length of stay, days ± SD:** 4.8 ± 1.8 **Fever, %:** 38% **Transfusion, N (%):** 23 (21) **Wound infection, N, (%):** 5 (5) **Improved symptoms (excluding infertility), N (%):** 34/50 (68) **Improved symptoms with infertility, N (%):** 21/59 (36) **IVF conception, N (%):** 2/17 (14) **Natural conception, N (%):** 13/28 (46) **Modifier:** NA	**Quality:** Overall quality score: poor **INTERNAL VALIDITY: fair** Random: NA Methods and blinding: NA Pt selection criteria: + Loss to follow-up: NA Drop-out rates: NA Statistical issues: - **EXTERNAL VALIDITY: poor (5)** Age: +, reported Race: NA, not US study Pregnancy history: -, NR Surgical history: -, NR Fibroid/uterine size: - Number of fibroids: - Location of fibroids: - Baseline characteristics: +, reported Length of follow-up: + Measurement methods: + Measurement reliability: + Clinical care: -

Evidence Table 7. KQ 2 Myomectomy (continued)

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria Other Details	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author: Ou et al., 2002 **Country and setting:** US and Taiwan, Community **Enrollment period:** 01/1992 to 01/2002 **Funding:** NR	**Design:** Retrospective cohort study **Intervention:** Colpotomy and harmonic scalpel **Groups:** **G1:** Colpotomy **G2:** Morcellation **N at enrollment:** **G1:** 143 **G2:** 22 **N at follow-up:** NA **Age, mean yrs:** 31.6 (18-44) **Race/ethnicity:** NR **Parity:** NR **Baseline Hgb/Hct:** NR	**Inclusion criteria:** • Women undergoing myomectomy for UF **Exclusion criteria:** NA **Indications, N (%):** • Primary infertility: 62 (37) • Secondary infertility: 28 (17) • Menometrorrhagia: 52 (32) • Dysmenorrhea: 25 (15) • Mass on ultrasound: 121 (72) **Preoperative therapy:** NA **Associated procedure(s), N (%):** Tuboplasty or adhesion lysis: 17 (10.3) Myolysis: 11 (6.7)	**Baseline uterine size:** NR **Number of fibroids (median removed):** **G1:** 7 **G2:** 4 Overall mean: 5.6 **Baseline fibroid size (gm):** **G1:** 103.4 **G2:** 92.4 **Type of fibroid:** NR	**Operative time, min:** **G1:** 144 (110-260) **G2:** 168 (140-244) *P* < 0.05 **Mean estimated blood loss (ml):** Harmonic scalpel: 243 (150-350) Unipolar cautery: 378 (203-800) *P* < 0.01 **Modifier:** NA	**Quality:** Overall quality score: poor **INTERNAL VALIDITY: fair** Random: NA Methods and blinding: NA Pt selection criteria: + Loss to follow-up: NA Drop-out rates: NA Statistical issues: - **EXTERNAL VALIDITY: poor (5)** Age: +, reported Race: -, NR Pregnancy history: -, NR Surgical history: -, NR Fibroid/uterine size: - Number of fibroids: - Location of fibroids: - Baseline characteristics: +, reported Length of follow-up: NA Measurement methods: + Measurement reliability: + Clinical care: +

Evidence Table 7. KQ 2 Myomectomy (continued)

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria Other Details	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author: Razavi et al., 2003 **Country and setting:** US, Academic medical center **Enrollment period:** 07/1998 to 12/2000 **Funding:** NR	**Design:** Retrospective cohort **Intervention:** Myomectomy and UFE **Groups:** **G1:** UFE **G2:** Abdominal myomectomy **N at enrollment:** **G1:** 62 **G2:** 40 **N at follow-up:** NA **Age, mean yrs (range):** **G1:** 37.7 (28 to 48) **G2:** 44.2 (31 to 56) **Race/ethnicity:** NR **Parity:** NR **Baseline uterine size:** NR **Baseline Hct, %:** **G1:** 35.5 **G2:** 36	**Inclusion criteria:** • Abdominal myomectomy • Uterine fibroid embolization **Exclusion criteria:** • Planned laparoscopic myomectomy within 3 mos of UFE • Primary reason for surgery was the treatment of infertility without other symptoms **Indications:** NR **Preoperative therapy:** NR **Associated procedure(s):** NR	**Baseline uterine size:** NR **Number of fibroids:** NR **Baseline fibroid size:** NR **Type of fibroid:** NR	**Pain medication use, days:** **G1:** 5.1 **G2:** 8.7 *P* < 0.05 **Length of stay, days:** **G1:** 0 **G2:** 2.9 *P* < 0.05 **Complications, N (%):** **G1:** 7 (11) **G2:** 10 (25) *P* < 0.05 **Menorrhagia relief, N (%):** **G1:** 48 (92) **G2:**14 (64) *P* < 0.05 **Pain relief, N (%):** **G1:** 25 (74) **G2:** 14 (54) *P* = NS **Mass effect, N (%):** **G1:** 28 (76) **G2:** 21 (91) *P* < 0.05 **Time to resume normal activities, days:** **G1:** 8 **G2:** 36 *P* < 0.05 **Modifiers:** NR	**Quality:** Overall quality score: poor **INTERNAL VALIDITY: fair** Random: NA Methods and blinding: NA Pt selection criteria: + Loss to follow-up: NA Drop-out rates: NA Statistical issues: - **EXTERNAL VALIDITY: poor (9)** Age: +, reported Race: -, NR Pregnancy history: -, NR Surgical history: -, NR Fibroid/uterine size: - Number of fibroids: - Location of fibroids: - Baseline characteristics: -, NR Length of follow-up: NA Measurement methods: + Measurement reliability: - Clinical care: -

Evidence Table 7. KQ 2 Myomectomy (continued)

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria Other Details	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author: Rossetti et al., 2001 **Country and setting:** Italy, Academic medical center **Enrollment period:** 01/1991 to 06/1998 **Funding:** NR	**Design:** RCT **Intervention:** Myomectomy method **Groups:** **G1:** Laparoscopic **G2:** Abdominal **G3:** Laparoscopic (non-randomized comparison) **N at enrollment:** **G1:** 41 **G2:** 40 **G3:** 84 **N at follow-up:** **G1:** 41 **G2:** 40 **G3:** 78 **Age (yrs ± SD):** **G1:** 35 ± 5 **G2:** 35 ± 3 **G3** (median): 36 (25 to 42) **Race/ethnicity:** NR **Parity:** NR **Baseline Hgb/Hct:** NR	**Inclusion criteria:** • Age < 42 • At least one symptomatic fibroid > 3 cm • ≤ 7 fibroids • No submucous fibroids that could be removed by hysteroscope **Exclusion criteria:** NR **Indications, (%):** **G1:** Pelvic Pain: 29% **G1:** 29 **G2:** 30 Infertility: **G1:** 34 **G2:** 35 Menorrhagia: **G1:** 31 **G2:** 29 Pelvic Mass: **G1:** 6 **G2:** 6 **Pre-operative therapy:** **G3:** 30.7% received 3 mos course of GnRH agonist **Associated procedure(s):** NR	**Baseline uterine size:** NR **Number of fibroids N (range):** **G1:** 2.2 (1 to 7) **G2:** 2.3 (1 to 7) **Baseline fibroid volume (cm^3 ± SD):** **G1:** 92.5 ± 108.5 **G2:** 152 ± 137.0 **Type of fibroid:** NR (submucous excluded)	**Operative time, mins:** **G1/G2:** 40 to 240 **Conversion to laparotomy, N:** **G1:** 2 **G2:** NA **G3:** NR **Decrease in Hgb, mg/dL ± SD:** **G1/G2:** 1.3 ± 0.9 **Transfusion:** 0 **Major or late complications:** 0 **Fibroid recurrence, 40 mos N (%):** **G1:** 11 (27) **G2:** 9 (23) *P* = NS **G3:** 17 (22) **Fibroid recurrence in cohort:** Age, pre- and post-operative gravidity, parity, size, number, depth of fibroids *P* = NS Pre-operative GnRH agonist use (independent of number of fibroids): Without: 8 of 54 (14.8%) *P* < 0.02 Recurrence with GnRHa: 9 of 24 treated (37.5%) **Modifier:** NR	**Quality:** Overall quality score: fair **INTERNAL VALIDITY: good** Random: + Methods and blinding: NA Pt selection criteria: ++ Loss to follow-up: <10% Drop-out rates: NA Statistical issues: + **EXTERNAL VALIDITY: fair (3)** Age: +, reported Race: -, NR Pregnancy history: +, reported Surgical history: -, NR Fibroid/uterine size: + Number of fibroids: + Location of fibroids: - Baseline characteristics: +, reported Length of follow-up: ++ Measurement methods: + Measurement reliability: + Clinical care: +

Evidence Table 7. KQ 2 Myomectomy (continued)

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria Other Details	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author: Roth et al., 2003 **Country and setting:** US, Academic medical center **Enrollment period:** 07/1992 to 06/1998 **Funding:** AHRQ	**Design:** Retrospective case series **Intervention:** Abdominal myomectomy **Groups:** **G1:** White **G2:** Black **N at enrollment:** **G1:** 107 **G2:** 118 **N at follow-up:** **G1:** 107 **G2:** 118 **Age, yrs ± SD:** **G1:** 35.6 ± 6.9 **G2:** 34.8 ± 5.0 *P* = 0.021 **Race/ethnicity:** NA – see groups **Parity:** NR **Baseline Hct (mean ± SD) :** **G1:** 37.3 ± 4.0 **G2:** 36.4 ± 3.8 *P* = 0.232	**Inclusion criteria:** • Abdominal myomectomy • Black or white race **Exclusion criteria:** NR **Indications:** NR **Preoperative therapy:** NR **Associated procedure(s):** NR	**Baseline uterine size:** NR **Number of fibroids removed, %:** 1 fibroid: **G1:** 36.5 **G2:** 10 2 to 3 fibroids: **G1:** 23.5 **G2:** 25 ≥ 4 fibroids: **G1:** 40 **G2:** 65 *P* = 0.001 **Baseline fibroid size (wk gestation), %:** <12 wks: **G1:** 28.8 **G2:** 13.8 12 to 16 wks: **G1:** 27.3 **G2:** 37.9 16 to 20 wks: **G1:** 19.7 **G2:** 29.9 >20 wks: **G1:** 9.1 **G2:** 12.6 *P* = 0.12 **Type of fibroid:** NR	**Complications, %:** 29% G2 vs. G1 OR = 1.36; 95%CI, 0.56-3.15 **Urinary retention or bladder injury, %:** 0.7 **Transfusion, %:** 20 G2 vs. G1 OR = 0.9; 95%CI, 0.27, 2.76 **Fever, %:** 2.9 **Ileus, %:** 2.4 **Disruption of wound, %:** 1.0 **Infection, %:** 2.0 **Respiratory complications, %:** 1.0 **Modifiers:** Uterine size (OR = 6.3; 95%CI, 3.18-12.4) and number of fibroids (OR = 2.6; 95% CI, 1.25-5.44) predicted transfusion Uterine size (OR = 1.86; 95%CI: 1.3-2.67), number of fibroids (OR = 1.83; 95% CI, 1.1-3.14), and co-morbidities (OR = 2.77; 95% CI, 1.1-7.69) predicted complications Prior abdominal surgery, BMI, adhesions, and pre-op diagnoses not associated with complications or transfusion	**Quality:** Overall quality score: poor **INTERNAL VALIDITY: fair** Random: NA Methods and blinding: NA Pt selection criteria: - Loss to follow-up: NA Drop-out rates: NA Statistical issues: + **EXTERNAL VALIDITY: poor (6)** Age: +, reported Race: +, reported Pregnancy history: -, NR Surgical history: -, NR Fibroid/uterine size: + Number of fibroids: - Location of fibroids: - Baseline characteristics: -, NR Length of follow-up: + Measurement methods: + Measurement reliability: + Clinical care: -

Evidence Table 7. KQ 2 Myomectomy (continued)

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria Other Details	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author: Seracchioli et al., 2000 **Country and setting:** Italy, Academic medical center **Enrollment period:** 01/1993 to 01/1998 **Funding:** NR	**Design:** RCT **Intervention:** Myomectomy **Groups:** **G1:** Abdominal myomectomy **G2:** Laparoscopic myomectomy **N at enrollment:** **G1:** 65 **G2:** 66 **N at follow-up:** **G1:** 59 **G2:** 56 **Age, yrs ± SD:** **G1:** 33.97 ± 4.79 **G2:** 34.00 ± 4.11 **Race/ethnicity:** NR **Parity:** See fertility status **Baseline Hgb/Hct:** NR	**Inclusion criteria:** • Fibroid(s) ≥ 5 cm • Infertility **Exclusion criteria:** • Pedunculated fibroids • Uterine size above umbilicus • > 3 fibroids of > 5 cm size • Other causes of infertility **Indications for LM, N (%):** • Primary infertility: 87 (66.4) • Secondary infertility: 44 (33.6) **Preoperative therapy:** None **Associated procedure(s):** NR	**Baseline uterine size:** NR **Number of fibroids, mean ± SD:** **G1:** 2.75 ± 1.98 **G2:** 2.94 ± 1.53 **Baseline size of largest fibroid (cm ± SD):** **G1:** 7.47 ± 2.60 **G2:** 7.07 ± 2.54 **Type of fibroid, N (%):** Subserosal: **G1:** 19 (44.2) **G2:** 24 (55.8) Intramural: **G1:** 54 (52.9) **G2:** 48 (47.1) "Reaching Cavity": **G1:** 5 (9.2) **G2:** 2 (4.1)	**Operative time, min ± SD:** **G1:** 88.85 ± 26.91 **G2:** 100.23 ± 38.34 **Conversion to laparotomy, N (%):** **G1:** NA **G2:** 3 (4.3) **Intra-operative complications:** None **Decrease in Hgb:** **G1:** 2.17 ± 1.57 **G2:** 1.33 ± 1.23 *P* < 0.001 **Transfusion, N:** **G1:** 3 **G2:** 0 **Fever > 38° C, N (%):** **G1:** 17 (26.2) **G2:** 8 (12.1) **Length of stay, hrs ± SD:** **G1:** 142.80 ± 34.60 **G2:** 75.61 ± 37.09 **Antibiotic Rx, N (%):** **G1:** 17 (26.2) **G2:** 8 (12.1) **Pregnancy rate, N (%):** **G1:** 33/59 (55.9) **G2:** 30/56 (53.6) **Miscarriage, N (%):** **G1:** 4 (12.1) **G2:** 6 (20.0) **Ectopic:** **G1:** 0 **G2:** 1 **Births:** **G1:** 27/59 **G2:** 20/56	**Quality:** Overall quality score: fair **INTERNAL VALIDITY: fair** Random: + Methods and blinding: NA Pt selection criteria: ++ Loss to follow-up: 10-20% Drop-out rates: NA Statistical issues: + **EXTERNAL VALIDITY: fair (1)** Age: +, reported Race: NA, not US study Pregnancy history: +, reported Surgical history: -, NR Fibroid/uterine size: + Number of fibroids: + Location of fibroids: + Baseline characteristics: +, reported Length of follow-up: + Measurement methods: + Measurement reliability: + Clinical care: +

Evidence Table 7. KQ 2 Myomectomy (continued)

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria Other Details	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author: Seracchioli et al., 2000 (continued)				**Preterm births, N (%):** **G1:** 2 (7.4) **G2:** 1 (5.0) **Cesarean rate, N (%):** **G1:** 21 (77.8) **G2:** 13 (65.0) **Uterine Rupture:** 0 **Fibroid recurrence, by US every 6 mos, N (%):** **G1:** 12 (20.3) **G2:** 12 (21.4) **Subsequent treatment, N:** **G1:** Myomectomy: 3 Hysterectomy: 1 **G2:** 0 **Modifiers:** NR	

Evidence Table 7. KQ 2 Myomectomy (continued)

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria Other Details	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author: Silva et al., 2000 **Country and setting:** US, Academic medical center **Enrollment period:** Prospective: 10/96-10/97 Historical comparison group: 1/90-10/97 (14 prospective; 37 historical) **Funding:** Cleveland Clinic Foundation	**Design:** Prospective case series with historical comparison group **Intervention:** Myomectomy **Groups:** **G1:** Laparoscopic (complete and assisted) **G2:** Abdominal **N at enrollment:** **G1:** 25 **G2:** 51 **N at follow-up:** **G1:** 25 **G2:** 51 **Age (median yrs):** **G1:** 37 **G2:** 37 **Race/ethnicity:** NR **Parity (median):** **G1:** 0 **G2:** 0 **Baseline Hgb/Hct:** NR	**Inclusion criteria:** • Eligible to consent • Age ≥ 18 yr • Uterus ≥ 14 wk size **Exclusion criteria:** • Prior myomectomy • Concurrent hysteroscopic myomectomy • History of bleeding diathesis • Fibroid > 8cm diameter; > 4 intramural fibroids > 3cm diameter by ultrasound • Malignant/pre-malignant condition • Pregnancy • Lactation **Historic controls: Inclusion criteria*:** • Abdominal myomectomy in correct time frame • Frequency matched within 100 gm of fibroid weight **Indications:** NR **Preoperative therapy:** NR **Additional procedures, (%):** **G1:** 16 (64) **G2:** 33 (65)	**Baseline uterine size, median cm^3:** **G1:** 526 **G2:** 828 **Number of fibroids:** **G1:** NR **G2:** NR **Baseline fibroid size (median gm; 25%, 75%):** **G1:** 151 (31, 262) **G2:** 170 (81, 285 **Type of fibroid:** NR (submucosal excluded)	**Operative time, median min (25%, 75%)** **G1:** 222.5 (192.5, 270) **G2:** 180(160, 220) **EBL (median ml, 25%, 75%)** **G1:** 300 (100, 550) **G2:** 200 (150, 375) **EBL > 1200ml:** **G1:** 0 **G2:** 1 **Hemorrhage:** **G1:** 0 **G2:** 3 **Bladder injury:** **G1:** 0 **G2:** 1 **Fever ≥ 38.0, N (%):** **G1:** 4 (16) **G2:** 13 (26) **Length of stay, median hours (1st Quartile, 3rd Quartile)** **G1:** 30.5 (25, 52.5) **G2:** 65 (45, 76) **Ileus, N (%):** **G1:** 1 (4) **G2:** 1 (2) **Urinary tract infection, N (%):** **G1:** 1 (4) **G2:** 1 (2) **Anemia (Hct < 28%):** **G1:** 2 (8) **G2:** 10 (20) **Anemia requiring transfusion, N (%):** **G1:** 2 (8) **G2:** 6 (12) **Modifiers:** NR	**Quality:** Overall quality score: fair **INTERNAL VALIDITY: good** Random: NA Methods and blinding: NA Pt selection criteria: ++ Loss to follow-up: <10% Drop-out rates: <5% Statistical issues: ++ **EXTERNAL VALIDITY: poor (5)** Age: +, reported Race: -, NR Pregnancy history: +, reported Surgical history: -, NR Fibroid/uterine size: + Number of fibroids: - Location of fibroids: - Baseline characteristics: -, NR Length of follow-up: + Measurement methods: + Measurement reliability: + Clinical care: +

*Additional detail not provided

Evidence Table 7. KQ 2 Myomectomy (continued)

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria Other Details	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author: Surrey et al., 2005 **Country and setting:** US, Fertility treatment center **Enrollment period:** 2 yr **Funding:** NR	**Design:** Retrospective cohort **Intervention:** • Precycle hysteroscopic or abdominal myomectomy and fresh IVF-ET or oocyte donation **Groups:** **G1:** Submucosal fibroids, hystero-scopic resection, fresh IVF-ET **G2:** Submucosal fibroids, hystero-scopic resection, donor IVF-ET **G3:** Myomectomy and fresh IVF-ET **G4:** Myomectomy and donor IVF-ET **G5:** No fibroids, fresh IVF-ET **G6:** No fibroids, donor IVF-ET **N at enrollment:** **G1:** 31 **G2:** 15 **G3:** 29 **G4:** 26 **G5:** 896 **G6:** 552 **N at follow-up:** NA **Age, yrs ± SD:** **G1:** 38.8 ± 0.9 **G2:** 40.3 ± 1.2 **G3:** 37.5 ± 0.5 **G4:** 42.2 ± 0.8 **G5:** 38 ± 0.1 **G6:** 40.0 ± 0.2 G4 vs. G6: *P* < 0.05 **Race/ethnicity:** NR **Parity:** NR **Baseline Hgb/Hct:** NR	**Inclusion criteria:** • Early follicular phase serum FSH level of < 12 mIU/mL • At least six resting antral follicles 2 to 10 mm **Exclusion criteria:** NR **Indications:** • Submucosal or intramural leiomyomata that distorted or abutted endometrial cavity with < 2 mm of intervening normal myometrium **Pre-operative therapy:** NR **Associated procedure(s):** None	**Baseline uterine size:** NR **Number of fibroids, mean ± SD:** **G1:** 1.3 ± 0.2 **G2:** 1.2 ± 0.2 **G3:** 2.3 ± 0.3 **G4:** 3.5 ± 0.6 G1 vs. G3: *P* < 0.01 G2 vs. G4: *P* < 0.01 **Baseline fibroid size (cm ± SD):** **G1:** 1.7 ± 0.3 **G2:** 1.4 ± 0.2 **G3:** 6.1 ± 0.8 **G4:** 6.8 ± 0.8 G1 vs. G3: *P* < 0.01 G2 vs. G4: *P* < 0.01 **Type of fibroid, %:** Submucosal only: **G1:** 67.7% **G2:** 73.3% **G3:** 0.0% **G4:** 0.0% Intramural only: **G1:** 25.8% **G2:** 28.0% **G3:** 93.1% **G4:** 92.3[b]% Intramural and submucosal: **G2:** 6.7% **G4:** 7.7[b]% **G1:** 6.5% **G3:** 6.9[c]% G1 vs. G3: *P* < 0.01 G2 vs. G4: *P* < 0.01	**Ongoing pregnancy rate, %:** **G1:** 61 **G2:** 86.7 **G3:** 52 **G4:** 84.6 **G5:** 53 **G6:** 77 **Biochemical pregnancy rate, %:** **G1:** 16 **G2:** 13.3 **G3:** 20 **G4:** 8.3 **G5:** 14 **G6:** 13.1 **Implantation rate, %:** **G1:** 24 **G2:** 57.8 **G3:** 26 **G4:** 55.2 **G5:** 23 **G6:** 49.1 No statistical differences were noted in ongoing pregnancy, biochemical pregnancy, or implantation rates among the groups undergoing each procedure **Modifier:** NR	**Quality:** Overall quality score: fair **INTERNAL VALIDITY: fair** Random: NA Methods and blinding: NA Pt selection criteria: + Loss to follow-up: <10% Drop-out rates: NA Statistical issues: - **EXTERNAL VALIDITY: fair** Age: +, reported Race: -, NR Pregnancy history: -, NR Surgical history: -, NR Fibroid/uterine size: + Number of fibroids: + Location of fibroids: + Baseline characteristics: +, reported Length of follow-up: + Measurement methods: + Measurement reliability: + Clinical care:+

Evidence Table 7. KQ 2 Myomectomy (continued)

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria and Other Details	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author: Takeuchi et al., 2005 **Country and setting:** Japan, Academic medical center **Enrollment period:** 01/2001 to 06/2002 **Funding:** NR	**Design:** RCT **Intervention:** Laparoscopic myomectomy with anti-adhesion therapy **Groups:** **G1:** Fibrin gel **G2:** Fibrin sheet **G3:** Control **N at enrollment:** **G1:** 68 **G2:** 68 **G3:** 69 **N at follow-up:** **G1:** 29 **G2:** 30 **G3:** 32 **Age, yrs ± SD:** **G1:** 35.3 ± 4.7 **G2:** 35.7 ± 3.8 **G3:** 35.0 ± 4.1 **Race/ethnicity:** NR **Parity:** NR **Baseline Hgb/Hct:** NR	**Inclusion criteria:** At enrollment: • Symptomatic uterine fibroids At follow-up: • Underwent SLL because desired children and were not pregnant **Exclusion criteria:** • Diameter of largest fibroid < 5 cm • Largest fibroid pedunculated • Additional procedures (cystectomy, adnexal adhesiolysis, cul-de-sac opening) **Indications:** Infertility: **G1:** 10 (34.5) **G2:** 11 (36.7) **G3:** 11 (34.4) **Preoperative therapy:** GnRH agonist: **G1:** 25 (86.2) **G2:** 25 (83.3) **G3:** 28 (87.5) **Additional procedures:** None	**Baseline uterine size:** NR **Number of fibroids, mean ± SD:** **G1:** 3.6 ± 4.0 **G2:** 4.7 ± 4.0 **G3:** 4.5 ± 4.4 **Baseline fibroid size** (wt extracted fibroid)**, gm ± SD:** **G1:** 188 ± 93.7 **G2:** 212 ± 118 **G3:** 201 ± 114 **Type of fibroid, %:** Submucosal: **G1:** 2 (2.9) **G2:** 3 (2.1) **G3:** 3 (2.1) Intramural: **G1:** 57 (54.8) **G2:** 59 (42.2) **G3:** 60 (41.7) Subserosal: **G1:** 44 (42.3) **G2:** 78 (55.7) **G3:** 81 (56.2)	**Adhesion formation per patient, %:** **G1:** 10 (34.5) **G2:** 20 (67.7) **G3:** 20 (62.5) G1/G3: $P < 0.05$ **Modifiers:** NR	**Quality:** Overall quality score: fair **INTERNAL VALIDITY: good** Random: + Methods and blinding: + Pt selection criteria: ++ Loss to follow-up: NA Drop-out rates: NA Statistical issues: + **EXTERNAL VALIDITY: poor (5)** Age: +, reported Race: NA, not US study Pregnancy history: -, NR Surgical history: -, NR Fibroid/uterine size: + Number of fibroids: + Location of fibroids: + Baseline characteristics: -, NR Length of follow-up: - Measurement methods: + Measurement reliability: + Clinical care: +

Evidence Table 7. KQ 2 Myomectomy (continued)

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria and Other Details	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author: Tsuji et al., 2005 **Country and setting:** Japan, Academic medical center **Enrollment period:** 12/1999 to 12/2003 **Funding:** NR	**Design:** Prospective cohort **Intervention:** Anti-adhesion treatment during myomectomy **Groups:** **G1:** Hyaluronic acid carboxy-methylcellulose film implants (Seprafilm® Genzyme Corp.) **G2:** Irrigation with 250 ml of Dextran 40 (10% Dextran 40 Low Injection®, Nichi-iko Pharmaceutical Corp.) **G3:** Factor 13 with fibrinogen (Beriplast®, Aventis Behring Corp.) **G4:** No treatment **N at enrollment:** **G1:** 21 **G2:** 17 **G3:** 12 **G4:** 13 **N at follow-up, 7 days:** **G1:** 21 **G2:** 17 **G3:** 12 **G4:** 13 **Age, yrs ± SD:** **G1:** 33.0 ± 4.4 **G2:** 34.7 ± 3.8 **G3:** 34.8 ± 3.6 **G4:** 33.0 ± 4.7 **Race:** NR **Parity:** NR **Baseline Hgb/Hct:** NR	**Inclusion criteria:** Diagnosed with uterine fibroids alone **Exclusion criteria:** Additional procedures **Indications:** NR **Preoperative therapy:** NR **Additional procedures:** None	**Baseline uterine size:** NR **Number of fibroids, mean ± SD:** **G1:** 4.5 ± 3.7 **G2:** 2.8 ± 2.6 **G3:** 2.7 ± 2.5 **G4:** 2.2 ± 1.0 **Baseline dominant size (cm ± SD):** **G1:** 7.7 ± 3.6 **G2:** 6.4 ± 2.9 **G3:** 6.1 ± 1.6 **G4:** 7.5 ± 2.7 **Type of fibroid:** NR	**Operative time, min ± SD:** **G1:** 103 ± 25 **G2:** 94 ± 23 **G3:** 99 ± 41 **G4:** 105 ± 36 **Mean estimated blood loss (ml ± SD):** **G1:** 123 ± 97 **G2:** 136 ± 56 **G3:** 125 ± 82 **G4:** 134 ± 89 **Uterine adhesion, %:** **G1:** 3 (14.3) **G2:** 12 (70.6) **G3:** 9 (75.0) **G4:** 10 (76.9) G1/**G2:** *P* = 0.0004 G1/G3: *P* = 0.0005 G1/G4: *P* = 0.0003 G2/G3: *P* = 0.7928 G2/G4: *P* = 0.6974 G3/G4: *P* = 0.9105 **Adnexal adhesion, %:** **G1:** 3 (14.3) **G2:** 9 (52.9) **G3:** 2 (16.7) **G4:** 12 (92.3) G1/**G2:** *P* = 0.0098 G1/G3: *P* = 0.855 G1/G4: *P* < 0.0001 G2/G3: *P* = 0.041 G2/G4: *P* = 0.0136 G3/G4: *P* < 0.0001 **Peritoneal adhesion, %:** **G1:** 3 (14.3) **G2:** 5 (29.4) **G3:** 5 (41.6) **G4:** 9 (69.2) G1/**G2:** *P* = 0.2557 G1/G3: *P* = 0.0818 G1/G4: *P* = 0.001 G2/G3: *P* = 0.4953 G2/G4: *P* = 0.0283 G3/G4: *P* < 0.1654 **Modifiers:** NR	**Quality:** Overall quality score: poor **INTERNAL VALIDITY: fair** Random: NA Methods and blinding: NA Pt selection criteria: ++ Loss to follow-up: <10% Drop-out rates: <5% Statistical issues: - **EXTERNAL VALIDITY: poor (4)** Age: +, reported Race: NA, not US study Pregnancy history: -, NR Surgical history: -, NR Fibroid/uterine size: + Number of fibroids: + Location of fibroids: + Baseline characteristics: -, NR Length of follow-up: - Measurement methods: + Measurement reliability: + Clinical care: +

Evidence Table 7. KQ 2 Myomectomy (continued)

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria Other Details	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author: Vavilis et al., 2005 **Country and setting:** Greece, Academic medical center **Enrollment period:** 01/2000 to 01/2003 **Funding:** NR	**Design:** Retrospective cohort **Intervention:** Abdominal myomectomy vs. abdominal hysterectomy **Groups:** **G1:** Abdominal myomectomy **G2:** Abdominal hysterectomy **N at enrollment:** **G1:** 102 **G2:** 102 **N at follow-up:** NA **Age, yrs ± SD:** **G1:** 35 ± 5.8 **G2:** 45 ± 3.4 **Race/ethnicity:** NR **Parity:** NR **Baseline Hgb/Hct:** NR	**Inclusion criteria:** • Undergoing abdominal myomectomy or hysterectomy **Exclusion criteria:** NR **Indications:** NR **Pre-operative therapy:** NR **Associated procedure(s):** NR	**Baseline uterine size:** NR **Number of fibroids:** NR **Baseline fibroid size:** NR **Type of fibroid:** NR	**Fever >38° C, N (%):** **G1:** 17 (16.63) **G2:** 14 (13.72) *P* = NS **Fever lasting > 24 hrs, N (%):** **G1:** 4 (3.92) **G2:** 5 (4.9) *P* = NS **Modifiers:** NR	**Quality:** Overall quality score: poor **INTERNAL VALIDITY: fair** Random: NA Methods and blinding: NA Pt selection criteria: - Loss to follow-up: NA Drop-out rates: NA Statistical issues: + **EXTERNAL VALIDITY: poor (6)** Age: +, reported Race: NA, not US study Pregnancy history: -, NR Surgical history: -, NR Fibroid/uterine size: - Number of fibroids: - Location of fibroids: - Baseline characteristics: -, NR Length of follow-up: NA Measurement methods: + Measurement reliability: + Clinical care: +

Evidence Table 7. KQ 2 Myomectomy (continued)

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria Other Details	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author: Zullo et al., 2004 **Country and setting:** Italy, Academic medical center **Enrollment period:** 03/2002 to 12/002 **Funding:** NR	**Design:** RCT **Intervention:** Intraoperative injection of bupivacaine plus epinephrine vs. saline solution during laparoscopic myomectomy **Groups:** **G1:** Bupivacaine **G2:** Saline **N at enrollment:** **G1:** 30 **G2:** 30 **N at follow-up:** 56 **Age, yrs ± SD:** **G1:** 28.2 ± 3.1 **G2:** 27.1 ± 2.9 **Race/ethnicity:** NR **Parity, mean ± SD:** **G1:** 1.1 ± 0.8 **G2:** 1.0 ± 0.7 **Baseline Hgb/Hct:** NR	**Inclusion criteria:** • Infertility > 3 yr • Recurrent first trimester miscarriages • Increased vaginal bleeding • Pelvic pressure and pain • Urinary frequency • Constipation **Exclusion criteria:** • Serious medical illnesses or malignancy • Largest intramural fibroid on ultrasound < 3 cm or > 5 cm • >2 fibroids • Calcified fibroids • Submucosal fibroids • Pregnancy • Abnormal pap smear or endometrial biopsy • Anemia • Treatment with GnRHa within 2 mos of surgery **Indications:** See inclusion criteria **Pre-operative therapy:** None **Associated procedure(s):** None	**Baseline uterine size, cm³ ± SD:** **G1:** 272.9 ± 36.3 **G2:** 265.4 ± 29.9 *P* < 0.001 **Number of fibroids, mean ± SD:** **G1:** 1.3 ± 0.4 **G2:** 1.2 ± 0.3 **Baseline largest fibroid size, cm³ ± SD:** **G1:** 80.5 ± 24.1 **G2:** 73.5 ± 19.7 **Type of fibroid:** None submucosal	**Operative time, min ± SD:** **G1:** 78.7 ± 13.1 **G2:** 109.2 ± 15.2 *P* < 0.001 **Mean estimated blood loss, ml ± SD:** **G1:** 143.9 ± 48.1 **G2:** 212.5 ± 51.0 *P* < 0.001 **Decrease in Hgb:** *P* < 0.05 Value of VAS significantly lower in group A than in group B was observed 24 hours after surgery, but not at any other time point measured **Pain medication use, number of vials:** **G1:** 4.0 ± 0.9 **G2:** 7.6 ± 1.3 *P* < 0.001 **Modifiers:** NR	**Quality:** Overall quality score: fair **INTERNAL VALIDITY: good** Random: + Methods and blinding: + Pt selection criteria: ++ Loss to follow-up: <10% Drop-out rates: <5% Statistical issues: ++ **EXTERNAL VALIDITY: fair (2)** Age: +, reported Race: NA, not US study Pregnancy history: +, reported Surgical history: -, NR Fibroid/uterine size: + Number of fibroids: + Location of fibroids: - Baseline characteristics: +, reported Length of follow-up: NA Measurement methods: + Measurement reliability: + Clinical care: +

Evidence Table 8. KQ 2 Hysterectomy

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author: Benassi et al., 2002 **Country and setting:** Italy, Academic medical center **Enrollment period:** 01/1997 to 12/2000 **Funding:** NR	**Design:** RCT **Intervention:** Vaginal or abdominal hysterectomy **Groups:** **G1:** Vaginal hysterectomy **G2:** Abdominal hysterectomy **N at enrollment:** **G1:** 60 **G2:** 59 **N at follow-up, 1 month:** **G1:** 60 **G2:** 59 **Age, yrs ± SD:** **G1:** 48 ± 5.3 **G2:** 47 ± 5.1 *P* = 0.403 **Race/ethnicity, %:** White: 100% **Parity, mean ± SD:** **G1:** 1.38 ± 0.58 **G2:** 1.42 ± 0.69 *P* = 0.966 **Baseline Hgb, g/dL ± SD:** **G1:** 12.7 ± 1.6 **G2:** 12.5 ± 2.02 *P* = 0.840	**Inclusion criteria:** • Women with large symptomatic uteri necessitating hysterectomy **Exclusion criteria:** • Prolapse • Uterine/adnexial neoplasm • Pelvic inflammation • Vaginal stenosis • Previous pelvic/ vaginal procedures • Hormone treatment 6 mos before surgery **Indications:** NR **Preoperative therapy:** Antithrombotic and antibiotic prophylaxis **Additional procedures:** Adnexectomy, N (%): **G1:** 38 (63) **G2:** 41 (69.4)	**Baseline uterine size, gm ± SD:** **G1:** 380 ± 165 **G2:** 436 ± 171 *P* = 0.072 **Number of fibroids:** NR **Baseline fibroid size:** NR **Type of fibroid:** NR	**Operative time, min ± SD:** **G1:** 86 ± 25.32 **G2:** 102 ± 31.02 *P* < 0.001 **Transfusions, N (%):** **G1:** 2 (3.3) **G2:** 4 (6.7) **Fever > 38°C, N (%):** **G1:** 10 (16.6) **G2:** 18 (30.5) *P* < 0.05 **Postoperative complications, N (%):** **G1:** 2 (3.3) **G2:** 6 (10.1) *P* = 0.136 **Pain medication use, N (%):** **G1:** 40 (66.6) **G2:** 51 (86.4) *P* < 0.05 **Length of stay, days ± SD:** **G1:** 3.4 ± 0.7 **G2:** 4.3 ± 1.5 *P* < 0.001 **Treatment satisfaction, N (%):** Good/very good,: **G1:** 50 (83.4) **G2:** 19 (32.1) Normal: **G1:** 8 (13.3) **G2:** 35 (59.3) Bad/very bad: **G1:** 2 (3.3) **G2:** 5 (7.3) **Modifiers:** NR	**Quality:** Overall quality score: fair **INTERNAL VALIDITY: fair** Random: + Methods and blinding: NA Pt selection criteria: ++ Loss to follow-up: <10% Drop-out rates: NA Statistical issues: + **EXTERNAL VALIDITY: fair (3)** Age: +, reported Race: +, reported Pregnancy history: +, reported Surgical history: -, NR Fibroid/uterine size: + Number of fibroids: - Location of fibroids: - Baseline characteristics: +, reported Length of follow-up: NA Measurement methods: + Measurement reliability: + Clinical care: +

Evidence Table 8. KQ 2 Hysterectomy

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria and Other Details	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author: Darai et al., 2001 Soriano et al., 2001 **Country and setting:** France, Community **Enrollment period:** 01/1999 to 12/1999 **Funding:** NR	**Design:** RCT **Intervention:** Hysterectomy (laparoscopic vaginal, vaginal [laparoscopic vaginal, vaginal hysterectomy [LAVH]) **Groups:** **G1:** Vaginal hysterectomy **G2:** LAVH **N at enrollment:** **G1:** 40 **G2:** 40 **N at follow-up, 6 to 8 wks:** **G1:** 40 **G2:** 40 **N at follow-up, pain assessment:** **G1:** 40 **G2:** 37 (3 laparotomy patients excluded) **Age, mean yrs ± SD:** **G1:** 49.1 ± 4.7 **G2:** 50.2 ± 6.8 **Race/ethnicity:** NR **Parity, mean ± SD:** **G1:** 2.7 ± 2.6 **G2:** 1.6 ± 1.1 **Baseline Hgb/Hct:** NR	**Inclusion criteria:** • Uterine size >280 gm • Previous pelvic surgery • History of pelvic inflammatory disease • Moderate or severe endometriosis • Adnexal masses • Adnexectomy **Exclusion criteria:** • Anesthetic contraindications • Suspicious adnexal mass • Vagina < than two fingers wide • Immobile uterus without descent and lateral mobilization **Indications:** Menorrhagia, N (%): **G1:** 16 (40) **G2:** 14 (35) Fibroids, N (%): **G1:** 40 (100) **G2:** 40 (100) Dysmenorrhea, N (%): **G1:** 16 (40) **G2:** 15 (37.5) **Preoperative therapy:** None **Additional procedures:** NR	**Baseline uterine size, gm ± SD:** **G1:** 424 ± 211 **G2:** 513 ± 360 **Number of fibroids:** NR **Baseline fibroid size:** NR **Type of fibroid:** NR	**Operative time, min ± SD:** **G1:** 108 ± 35 **G2:** 160 ± 50 *P* <0.001 **Conversion to laparotomy, N (%):** **G1:** 0 **G2:** 3 (7.5) *P* < 0.05 **Hemorrhage, N (%):** **G1:** 1 (2.5) **G2:** 1 (2.5) **Bladder injury, N (%):** **G1:** 0 **G2:** 1 (2.5) **Decrease in Hgb, g/dl ± SD:** **G1:** 2.0 ±1.2 **G2:** 2.1 ± 1.4 **Post-operative transfusion, N (%):** **G1:** 1 (2.5) **G2:** 1 (2.5) **Fever > 38°C, N (%):** **G1:** 2 (5.0) **G2:** 3 (7.5) **Length of stay, days ± SD:** **G1:** 5.3 ± 2.1 **G2:** 5.7 ± 3.0 **Abdominal wall hematoma, N (%):** **G1:** 0 **G2:** 2 (5.0) **Vaginal cuff hematoma, N (%):** **G1:** 2 (5.0) **G2:** 1 (2.5) **Vaginal cuff infection, N (%):** **G1:** 1 (2.5) **G2:** 2 (5.0) **Abdominal wall infection, N (%):** **G1:** 0 **G2:** 1 (2.5) **Modifiers:** NR	**Quality:** Overall quality score: fair **INTERNAL VALIDITY: good** Random: + Methods and blinding: + Pt selection criteria: ++ Loss to follow-up: <10% Drop-out rates: NA Statistical issues: ++ **EXTERNAL VALIDITY: fair (3)** Age: +, reported Race: +, reported Pregnancy history: +, reported Surgical history: -, NR Fibroid/uterine size: + Number of fibroids: - Location of fibroids: - Baseline characteristics: +, reported Length of follow-up: NA Measurement methods: + Measurement reliability: + Clinical care: +

Evidence Table 8. KQ 2 Hysterectomy (continued)

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria and Other Details	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author: Dessole et al., 2000 **Country and setting:** Italy, Academic medical center **Enrollment period:** NR **Funding:** Ethicon	**Design:** RCT **Intervention:** Bipolar electrocautery scissors **Groups:** **G1:** Abdominal hysterectomy with conventional technique **G2:** Abdominal hysterectomy with bipolar electrocautery scissors **N at enrollment:** **G1:** 25 **G2:** 25 **N at follow-up, 5 days:** **G1:** 25 **G2:** 25 **Age, mean yrs ± SD:** **G1:** 51.2 ± 10 **G2:** 48.5 ± 5.6 *P* = NS **Race/ethnicity:** NR **Parity:** NR **Baseline Hgb, g/dL ± SD:** **G1:** 12.4 ± 1.9 **G2:** 11.6 ± 1.7 *P* = NS **Baseline Hct, mean ± SD:** **G1:** 39.5 ± 4.6 **G2:** 37.5 ± 4.8 *P* = NS	**Inclusion criteria:** Uterine fibroids **Exclusion criteria:** NR **Indications:** NR **Preoperative therapy:** NR **Additional procedures:** NR	**Baseline uterine size, gm ± SD:** **G1:** 305 ± 91 **G2:** 330 ± 85 **Number of fibroids:** NR **Baseline fibroid size:** NR **Type of fibroid:** NR	**Operative time, min ± SD:** **G1:** 121 ± 32 **G2:** 90 ± 15 *P* < 0.01 **Ligations, mean ± SD:** **G1:** 14 ± 4 **G2:** 6 ± 2 *P* < 0.01 **Hgb, Day 5 post-op, g/dL ± SD:** **G1:** 10.0 ± 1.4 **G2:** 10.4 ± 1.1 *P* < 0.001 **Hct, Day 5 post-op, mean ± SD:** **G1:** 32.5 ± 3.3 **G2:** 34.0 ± 3.1 *P* < 0.001 **Modifiers:** NR	**Quality:** Overall quality score: poor **INTERNAL VALIDITY: fair** Random: + Methods and blinding: + Pt selection criteria: - Loss to follow-up: NA Drop-out rates: NR Statistical issues: ++ **EXTERNAL VALIDITY: poor (5)** Age: +, reported Race: NA, not US study Pregnancy history: -, NR Surgical history: -, NR Fibroid/uterine size: + Number of fibroids: - Location of fibroids: - Baseline characteristics: -, NR Length of follow-up: NA Measurement methods: + Measurement reliability: + Clinical care: -

Evidence Table 8. KQ 2 Hysterectomy (continued)

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria Other Details	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author: Dousias et al., 2003 **Country and setting:** Greece, Academic medical center **Enrollment period:** NR **Funding:** NR	**Design:** RCT **Intervention:** Preoperative recombinant human erythropoietin (rHuEPO) **Groups:** **G1:** Iron 200 mg/day and rHuEPO 600 U/ml SC once weekly for 3 weeks **G2:** Iron 200 mg/d **N at enrollment:** **G1:** 23 **G2:** 27 **N at follow-up:** **G1:** 23 **G2:** 27 **Age, yrs ± SD:** **G1:** 48.2 ± 4.1 **G2:** 49.2 ± 4.7 **Race:** NR **Parity:** NR **Baseline Hgb/Hct, g/dL ± SD:** **G1:**10.3 ± 4.1 **G2:**10.4 ± 4.6	**Inclusion criteria:** • No major medical illness • Age: 30 to 60 yrs • Hgb: ≥ 9 and < 12 g/dl • Weight: 50 to 80 kg • Ferritin > 50 ng/ml • Uterine fibroids by ultrasound **Exclusion criteria:** NR **Indications:** NR **Preoperative therapy:** None **Additional procedures:** NR	**Baseline uterine size:** NR **Number of fibroids:** NR **Baseline fibroid size:** NR **Type of fibroid:** NR	**Estimated blood loss, ml ± SD:** **G1:** 645 ± 116 **G2:** 593 ± 130 **Length of stay, days ± SD:** **G1:** 7.6 ± 0.5 **G2:** 7.8 ± 0.9 **Mean Hgb on Day 7, g/dL ± SD:** **G1:** 11.2 ± 0.7 **G2:** 10.5 ± 0.6 95% CI, 0.3-1.1 **Mean Hgb on Day 0, g/dL ± SD:** **G1:** 11.9 ± 0.7 **G2:** 10.7 ± 0.7 95% CI, 0.8-1.6 **Mean Hgb on Day +3, g/dL ± SD:** **G1:** 10.3 ± 0.8 **G2:** 8.8 ± 0.7 95% CI, 1.9-2.0 **Mean Hgb on Day +7, g/dL ± SD:** **G1:** 10.7 ± 0.8 **G2:** 8.8 ± 0.7 95% CI, 1.4-2.3 **Mean Hgb on Day +14, g/dL ± SD:** **G1:** 10.8 ± 0.2 **G2:** 9.1 ± 0.7 95% CI, 1.3-2.1 **Modifiers:** NR	**Quality:** Overall quality score: fair **INTERNAL VALIDITY: good** Random: + Methods and blinding: + Pt selection criteria: + Loss to follow-up: NR Drop-out rates: NR Statistical issues: + **EXTERNAL VALIDITY: poor (5)** Age: +, reported Race: NA, not US study Pregnancy history: -, NR Surgical history: NA Fibroid/uterine size: - Number of fibroids: - Location of fibroids: - Baseline characteristics: -, NR Length of follow-up: + Measurement methods: + Measurement reliability: + Clinical care: +

Evidence Table 8. KQ 2 Hysterectomy (continued)

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria Other Details	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author: Falkeborn et al., 2000 **Country and setting:** Sweden, Inpatient Registry **Enrollment period:** 1965 to 1983 **Funding:** The Faculty of Medicine, University of Uppsala, the Swedish Society of Medicine and the Swedish Medical Research Council	**Design:** Retrospective case-control (controls chosen randomly) **Intervention:** Hysterectomy and/or oophorectomy **Groups:** NA **N at enrollment:** 75% of 16,455 cases with hysterectomy for all causes had fibroids, actual N NR **Age, mean yrs:** 45.9 **Race/ethnicity:** NR **Parity:** NR **Baseline Hgb/Hct:** NR	**Inclusion criteria:** • Lived in Uppsala Health Care Region • Underwent hysterectomy and/or oophorectomy 1965-1983 **Exclusion criteria:** • Cancer other than cervical cancer in situ (n = 4,456); • Malignancy diagnosed ≤ 90 days of surgery (n = 232) • Emigrated (n = 43) • Had more than 1 of any procedures (n = 238) • Myocardial infarction before surgery (n = 26) **Indications:** NR **Preoperative therapy:** NR **Additional procedures:** NR	**Baseline uterine size:** NR **Number of fibroids:** NR **Baseline fibroid size:** NR **Type of fibroid:** NR	**Myocardial infarction:** Relative risk of myocardial infarction NS for women with only fibroids compared to other indications: RR = 1.1; 95% CI, 0.7-1.7 Relative risk of myocardial infarction significant for naturally menopausal women with fibroids compared with all other women: RR = 6.2; 95% CI, 1.9-20 **Modifiers:** NR	**Quality:** Overall quality score: fair **INTERNAL VALIDITY: good** Random: NA Methods and blinding: NA Pt selection criteria:c+ Loss to follow-up: NA Drop-out rates: NA Statistical issues:c+ **EXTERNAL VALIDITY: poor (7)** Age: +, reported Race: NA, not US study Pregnancy history: -, NR Surgical history: -, NR Fibroid/uterine size: - Number of fibroids: - Location of fibroids: - Baseline characteristics: -, NR Length of follow-up: ++ Measurement methods: + Measurement reliability: + Clinical care: -

Evidence Table 8. KQ 2 Hysterectomy (continued)

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria and Other Details	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author: Ferrari et al., 2000 **Country and setting:** Italy, Academic medical center **Enrollment period:** NR **Funding:** NR	**Design:** RCT **Intervention:** Hysterectomy **Groups:** **G1:** Laparoscopically assisted vaginal hysterectomy **G1a:** Uterus ≤ 500 g **G1b:** Uterus > 500 g **G2:** Total abdominal hysterectomy **G2a:** Uterus ≤ 500 g **G2b:** Uterus > 500 g **N at enrollment:** **G1:** 31 **G2:** 31 **N at follow-up:** **G1:** 31 **G1a:** 20 **G1b:** 11 **G2:** 31 **G2a:** 21 **G2b:** 10 **Age (mean, range):** **G1:** 48 (46 to 49) **G2:** 46 (43 to 50) **Race Ethnicity:** NR **Parity, parous, N (%):** Nulliparous: **G1:** 5 (16) **G2:** 7 (23) **Baseline Hgb/Hct:** NR	**Inclusion criteria:** NR **Exclusion criteria:** NR **Indications:** NR **Preoperative therapy:** NR **Additional procedures:** Bilateral salpingo-oophorectomy, N (%) **G1:** 19 (61) **G2:** 21 (68)	**Baseline uterine size, mean ml (range):** **G1:** 388 (257 to 520) **G2:** 370 (243 to 463) **Number of fibroids:** NR **Baseline fibroid size:** NR **Type of fibroid:** NR	**Operative time, mean min (range):** **G1:** 135 (115-173) **G2:** 120 (98-123) *P* = 0.001 **Conversion to laparotomy, N:** **G1:** 3 **G2:** NA **Decrease in Hgb, mean g/dL:** **G1:** 1.1 (0.8-1.9) **G2:** 1.8 (0.7-2.5) *P* = NS **Transfusions, N (%):** **G1:** 0 **G2:** 1 (3) *P* = NS **Febrile morbidity (not defined), N (%):** **G1:** 1 (3) **G2:** 5 (16) *P* = NS **Pain medication use, N (%):** **G1:** 7 (23) **G2:** 24 (77) *P* < 0.001 **Length of stay, mean days (range):** **G1:** 3.8 (34 to 4.0) **G2:** 5.8 (5.3 to 6.3) *P* < 0.001 **Uterine weight, mean gm (range):** **G1:** 400 (263 to 590) **G2:** 400 (255 to 556) *P* = NS **Operating time, mean min, (range):** **G1b:** 150 (125 to 173) **G2b:** 108 (83 to 120) *P* = 0.002	**Quality:** Overall quality score: poor **INTERNAL VALIDITY: poor** Random: + Methods and blinding: - Pt selection criteria: - Loss to follow-up: NA Drop-out rates: <5% Statistical issues: + **EXTERNAL VALIDITY: fair (3)** Age: +, reported Race: NA, not US study Pregnancy history: +, reported Surgical history: +, reported Fibroid/uterine size: + Number of fibroids: - Location of fibroids: - Baseline characteristics: -, NR Length of follow-up: NA Measurement methods: + Measurement reliability: + Clinical care: +

Evidence Table 8. KQ 2 Hysterectomy (continued)

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria and Other Details	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author: Ferrari et al., 2000 (continued)				**Pain medication use, N (%):** **G1a:** 1 (5) **G2a:** 16 (76) *P* = 0.0001 **Length of stay, days (range):** **G1a:** 3.4 (3.2 to 4.0) **G2a:** 5.8 (5.0 to 6.4) *P* = 0.0001 **Length of stay, days (range):** **G1b:** 4.0 (3.9 to 5.8) **G2b:** 6.0 (5.8 to 6.0) *P* = 0.03 **Modifier:** **Conversion to laparotomy:** **G1a:** 0/20 **G1b:** 3/11 *P* = 0.04	

Evidence Table 8. KQ 2 Hysterectomy (continued)

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria and Other Details	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author: Harmanli et al., 2004 **Country and setting:** US, Academic medical center **Enrollment period:** 03/1990 to 09/2000 **Funding:** NR	**Design:** Retrospective cohort **Intervention:** Hysterectomy (vaginal vs. abdominal) **Groups:** **G1:** Vaginal hysterectomy **G2:** Abdominal hysterectomy **N at enrollment:** **G1:** 88 **G2:** 200 **N at follow-up:** NA **Age, yrs ± SD:** **G1:** 44.0 ± 4.7 **G2:** 44.1 ± 6.2 *P* = NS **Race/ethnicity:** NR **Parity, parous, mean ± SD:** **G1:** 2.4 ± 1.3 **G2:** 2.3 ± 1.5 *P* = NS **Baseline Hgb/Hct:** NR	**Inclusion criteria:** • Uterus ≥ 250g • Surgical indication for hysterectomy **Exclusion criteria:** • Pelvic malignancies • Hysterectomy with any other major pelvic or abdominal surgery **Indications, N (%):** Uterine fibroids **G1:** 84 (95.5) **G2:**188 (94.0) *P* = NS Menometrorrhagia **G1:** 3 (3.4) **G2:** 6 (3.0) *P* = NS Pelvic pain, endometriosis, or adenomyosis **G1:** 1 (1.1) **G2:** 5 (2.5) *P* = NS Other **G1:** 0 **G2:** 1 (0.5) *P* = NS **Preoperative therapy:** None **Additional procedures:** None	**Baseline uterine size, gm ± SD:** **G1:** 500.9 ± 277.4 **G2:** 737.4 ± 637.8 *P* = 0.0006 **Number of fibroids:** NR **Baseline fibroid size:** NR **Type of fibroid:** NR	**Operative time, min ± SD:** **G1:** 114.3 ± 46.3 **G2:** 137.4 ± 69.8 *P* = NS **Hemorrhage, N (%):** **G1:** 8 (9.2) **G2:** 23 (11.5) *P* = NS **Bladder injury, N (%):** **G1:** 1 (1.1) **G2:** 3 (1.5) *P* = NS **Ureteral injury, N (%):** **G1:** 1 (1.1) **G2:** 1 (0.5) *P* = NS **Change in Hgb, g/dL ± SD:** **G1:** 1.9±1.2 **G2:** 1.6±1.4 *P* = 0.03 **Febrile morbidity N (%):** **G1:** 18 (20.5) **G2:** 28 (14) *P* = NS **Length of stay, days ± SD:** **G1:** 1.9±0.9 **G2:** 3.7±1.3 *P* < 0.0001 **Ileus, N (%):** **G1:** 1 (1.1) **G2:** 21 (10.5) *P* = 0.006 **Hematoma, N (%):** **G1:** 2 (2.3) **G2:** 5 (2.5) *P* = NS **Venous thromboembolism:** **G1:** 0 **G2:** 0 *P* = NS	**Quality:** Overall quality score: fair **INTERNAL VALIDITY: good** Random: NA Methods and blinding: NA Pt selection criteria: + Loss to follow-up: NR Drop-out rates: NR Statistical issues: + **EXTERNAL VALIDITY: poor (5)** Age: +, reported Race: -, NR Pregnancy history: +, reported Surgical history: -, NR Fibroid/uterine size: + Number of fibroids: - Location of fibroids: - Baseline characteristics: +, reported Length of follow-up: NA Measurement methods: + Measurement reliability: - Clinical care: +

Evidence Table 8. KQ 2 Hysterectomy (continued)

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria and Other Details	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author: Harmanli et al., 2004 (continued)				**Urinary tract infection, N (%):** **G1:** 5 (5.4) **G2:** 13 (6.5) *P* = NS **Readmission, N (%):** **G1:** 3 (3.4) **G2:** 6 (3.0) *P* = NS **Modifiers:** NR	

Evidence Table 8. KQ 2 Hysterectomy (continued)

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria Other Details	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author: Healey et al., 2004 **Country and setting:** Canada, Academic medical center **Enrollment period:** 08/2000 to 04/2003 **Funding:** NR	**Design:** Prospective cohort **Intervention:** UAE vs. hysterectomy **Groups:** **G1:** UAE **G2:** Hysterectomy **N at enrollment:** **G1:** 68 **G2:** 16 **N at follow-up:** **G1:** 48 **G2:** 13 **Age, yrs ± SD:** **G1:** 44.9 ± 3.8 **G2:** 43.7 ± 3.6 **Race/ethnicity:** NR **Parity, parous (%):** Nulliparous: **G1:** 11 (22.0) **G2:** 0 **Baseline Hgb/Hct:** NR	**Inclusion criteria:** • Healthy premenopausal women • Age: 39 to 50 • Symptomatic uterine fibroids • Regular menstrual cycles • Day 3 serum FSH levels < 40 IU/L **Exclusion criteria:** See inclusion criteria **Indications, N (%):** Bleeding: **G1:** 42 (61.8) **G2:** 16 (100) Pain/pressure: **G1:** 5 (7.4) **G2:** 0 Urinary symptoms: **G1:** 3 (4.4) **G2:** 0 Multiple symptoms: **G1:** 14 (20.1) **G2:** 0 **Preoperative therapy:** NR **Associated procedure(s):** NR	**Baseline uterine size, ml ± SD:** **G1:** 538 ± 50 **Number of fibroids, N (%):** 1: **G1:** 11 (16.3) **G2:** NA ≥ 2: **G1:** 57 (83.8) **G2:** NA **Baseline (dominant) fibroid size, ml ± SD:** **G1:** 154 ± 19.9 **G2:** NA **Type of fibroid, N (%):** Submucosal: **G1:** 10 (14.7) **G2:** NA Intramural or subserosal: **G1:** 58 (85.3) **G2:** NA	**Fibroid volume, 3 mos, ml ± SD:** **G1:** 434.1 ± 51.5 **G2:** NA *P* < 0.05 (95% CI, 6-201) **Fibroid volume, 6 mos, ml ± SD:** **G1:** 361.0 ± 38.4 **G2:** NA *P* < 0.01 (95% CI, 44-241) **Hormone measures at 6 mos** FSH (IU/L ± SEM): **G1:** 9.9 ± 1.0 95% CI, -1.7-1.2 **G2:** 7.8 ± 1.8 95% CI, -0.2-4.0 LH (IU/L ± SEM): **G1:** 7.0 ± 1.1 95% CI, -1.2-0.8 **G2:** 11.2 ± 5 95% CI, -1.91-3.3 E2 (pmol/L ± SEM): **G1:** 214 ± 34.9 95% CI, -52-36 **G2:** 326 ± 79.2 95% CI, -39.8-212.6 **Modifiers:** NR	**Quality:** Overall quality score: fair **INTERNAL VALIDITY: poor** Random: NA Methods and blinding: NA Pt selection criteria: ++ Loss to follow-up: >20% Drop-out rates: <5% Statistical issues: + **EXTERNAL VALIDITY: good** Age: +, reported Race: +, reported Pregnancy history: +, reported Surgical history: +, reported Fibroid/uterine size: + Number of fibroids: + Location of fibroids: + Baseline characteristics: +, reported Length of follow-up: + Measurement methods: + Measurement reliability: + Clinical care: +

Evidence Table 8. KQ 2 Hysterectomy (continued)

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria and Other Details	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author: Hehenkamp et al., 2005 **Country and setting:** The Netherlands, Hospitals **Enrollment period:** 03/2002 to 02/2004 **Funding:** Netherlands Organisation for Health Research and Development and Boston Scientific Corporation	**Design:** RCT **Intervention:** UAE versus hysterectomy **Groups:** **G1:** UAE **G2:** Hysterectomy (abdominal, vaginal, laparoscopically assisted vaginal, and laparoscopic) **N at enrollment:** **G1:** 88 **G2:** 89 **N at follow-up:** **G1:** 81 **G2:** 75 **Age, yrs ± SD:** **G1:** 44.6 ± 4.8 **G2:** 45.4 ± 4.2 **Race/ethnicity, N (%):** Black: **G1:** 24 (27.3) **G2:** 20 (22.5) White: **G1:** 54 (61.4) **G2:** 57 (64.0) Other: **G1:** 10 (11.4) **G2:** 12 (13.5) **Parity, N (%):** 0: **G1:** 30 (34.1) **G2:** 20 (22.5) ≥1: **G1:** 58 (65.9) **G2:** 69 (77.5) **Baseline Hgb/Hct:** NR	**Inclusion criteria:** • Ultrasound confirmation uterine fibroids • Menorrhagia • Premenopausal scheduled for hysterectomy **Exclusion criteria:** • Other treatment options available • Future pregnancy desired • Renal failure • Active pelvic infection or clotting disorders • Allergic to contrast material • Uterine malignancy suspected • Submucosal fibroids with 50% of diameter within uterine cavity or dominant pedunculated serosal fibroids **Indications, N (%):** Dysmenorrhea: **G1:** 47 (53.4) **G2:** 50 (56.2) Pressure/Pain: **G1:** 38 (43.1) **G2:** 39 (43.8) Bladder/Bowel symptoms: **G1:** 18 (20.5) **G2:** 25 (28.1) Anemia: **G1:** 43 (48.9) **G2:** 42 (47.2) Other symptoms: **G1:** 6 (6.8) **G2:** 11 (12.4)	**Baseline uterine volume, median cm^3 (range):** **G1:** 321 (31 to 3,005) **G2:** 313 (58 to 3,617) **Number of fibroids, N (%):** 1 fibroid: **G1:** 35 (39.8) **G2:** 25 (28.1) 2 fibroids: **G1:** 13 (14.8) **G2:** 16 (18.0) 3 fibroids: **G1:** 17 (19.3) **G2:** 25 (25.8) >3 fibroids: **G1:** 18 (20.5) **G2:** 14 (15.7) **Baseline dominant fibroid volume, median cm^3 (range):** **G1:** 59 (1-673) **G2:** 87 (4-1641) **Type of fibroid:** NR	**Procedure time, min:** **G1:** 79.0 **G2:** 95.4 *P* = 0.007 **Mean estimated blood loss, ml ± SD:** **G1:** 30.9 ± 23.8 **G2:** 436.1 ± 474.5 *P* < 0.001 **Length of stay, days ± SD:** **G1:** 2.0 ± 2.1 **G2:** 5.1 ± SD1.3 *P* < 0.001 **Readmissions, N:** **G1:** 9 **G2:** 0 *P* = 0.0032 **Minor complications at surgery, complications/ patients:** **G1:** 23/18 **G2:** 26/23 (RR = 0.72; 95% CI, 0.43-1.23) *P* = 0.23 **Minor complications at 6 weeks, complications/ patients:** **G1:** 68/47 **G2:** 34/30 (RR = 1.45; 95% CI, 1.04-2.02) *P* = 0.024 **Major complications at surgery, complications/ patients:** **G1:**1/1 **G2:** 1/1 (RR = 0.93; 95% CI, 0.06-14.54) *P* = 0.99	**Quality:** Overall quality score: fair **INTERNAL VALIDITY: good** Random: + Methods and blinding: NA Pt selection criteria: ++ Loss to follow-up: <10% Drop-out rates: <5% Statistical issues: ++ **EXTERNAL VALIDITY: fair (1)** Age: +, reported Race: +, reported Pregnancy history: +, reported Surgical history: +, reported Fibroid/uterine size: + Number of fibroids: + Location of fibroids: - Baseline characteristics: +, reported Length of follow-up: + Measurement methods: + Measurement reliability: + Clinical care: +

Evidence Table 8. KQ 2 Hysterectomy (continued)

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria and Other Details	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author: Hehenkamp et al., 2005 (continued)		**Preoperative therapy:** NR **Additional procedures, N:** Hysterectomy: **G1:** 4 **G2:** NA Removal of hydrosalpinx: **G1:** 0 **G2:** 1 Adhesiolysis: **G1:** 1 **G2:** 0 Unilateral salpingo-oophorectomy: **G1:** 1 **G2:** 2 Bilateral salpingo-oophorectomy: **G1:** 0 **G2:** 1		**Major complications at 6 weeks, complications/ patients:** **G1:** 3/3 pts **G2:** 1/1 pts (RR = 2.78; 95% CI, 0.30-26.13) *P* = 0.62 **Unscheduled doctor visits, surgery to 6 wks, visits/pts:** **G1:** 45/24 **G2:** 30/19 (RR = 1.45; 95% CI, 0.90-2.37) *P* = 0.12) **Modifiers:** NR	

Evidence Table 8. KQ 2 Hysterectomy (continued)

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria Other Details	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author: McPherson et al., 2004 **Country and setting:** UK, Community **Enrollment period:** 10/1994 to 09/1995 **Funding:** Department of Health, BUPA Foundation	**Design:** Prospective case series **Intervention:** Hysterectomy (abdominal, vaginal, laparoscopic) **Groups:** NA **N at enrollment:** 37,295 **N at follow-up, 6 wks:** **G1:** 26,973 **Age, median:** 45 (12 to 95) **Race/ethnicity:** NR **Parity:** NR **Baseline Hgb/Hct:** NR	**Inclusion criteria:** • Hysterectomy **Exclusion criteria:** • Cancer • Postpartum hysterectomies **Indications:** NR **Preoperative therapy:** NR **Additional procedures:** NR	**Baseline uterine size:** NR **Number of fibroids:** NR **Baseline fibroid size:** NR **Type of fibroid:** NR	**Overall severe operative complications:** 3% **Severe complications in women with fibroids, N (%):** 291 (4.4) **Severe postoperative complications in women with fibroids, N (%):** 82 (1.2) **Modifiers:** NR	**Quality:** Overall quality score: poor **INTERNAL VALIDITY: poor** Random: NA Methods and blinding: NA Pt selection criteria: - Loss to follow-up: NR Drop-out rates: NR Statistical issues: - **EXTERNAL VALIDITY: poor (10)** Age: -, NR Race: -, NR Pregnancy history: -, NR Surgical history: -, NR Fibroid/uterine size: - Number of fibroids: - Location of fibroids: - Baseline characteristics: -, NR Length of follow-up: + Measurement methods: - Measurement reliability: + Clinical care: -

Evidence Table 8. KQ 2 Hysterectomy (continued)

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria and Other Details	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author: Okin et al., 2001 **Country and setting:** US, Community **Enrollment period:** 04/1999 to 05/2000 **Funding:** Department of Obstetrics, Gynecology, and Reproductive Sciences	**Design:** RCT **Intervention:** Abdominal hysterectomy **Groups:** **G1:** Abdominal hysterectomy with vasopressin **G2:** Abdominal hysterectomy with placebo **N at randomization:** **G1:** 30 **G2:** 27 **N at follow-up:** **G1:** 27 **G2:** 24 **Age, yrs ± SD:** **G1:** 44.22 ± 4.92 **G2:** 44.71 ± 5.36 *P*=0.74 **Race/ethnicity, N:** White: **G1:** 26 **G2:** 15 Black **G1:** 0 **G2:** 9 Asian **G1:** 1 **G2:** 0 **Parity:** NR **Baseline Hgb, g/dL ± SD:** **G1:** 12.9 ± 1.9 **G2:** 12.7 ± 1.5 *P*=0.71	**Inclusion criteria:** • Age ≥ 18 yr • Diagnosed with fibroids • Scheduled for TAH with or without bilateral salpingo-oophorectomy **Exclusion criteria:** • Angina • Myocardial infarction • Cardiomyopathy • Congestive heart failure • Uncontrolled hypertension • Migraine • Asthma • Severe COPD • Known or suspected malignancy of pelvic organ • Major concomitant surgical repair except bilateral salpingo-oophorectomy **Indications, N:** Menorrhagia/ metrorrhagia: **G1:** 16 **G2:** 14 **Preoperative therapy, N:** GnRH agonist: **G1:** 5 **G2:** 4 *P* = 1.0	**Baseline uterine size, wks ± SD:** **G1:** 13.8 ± 4.5 **G2:** 13.45 ± 3.15 *P* = 0.74 **Number of fibroids:** NR **Baseline fibroid size:** NR **Type of fibroid:** NR	**Operative time, min ± SD:** **G1:** 54 ± 24 **G2:** 59 ± 19 *P* = 0.35 **Mean estimated blood loss, ml ± SD:** **G1:** 445.41 ± 239.99 **G2:** 748.42 ± 296.97 *P* = 0.001 **Hysterectomy-related estimated blood loss, ml ± SD:** **G1:** 410.63 ± 227.76 **G2:** 690.21 ± 294.76 *P* = 0.001 **Intra-operative transfusion, N:** **G1:** 1 **G2:** 1 *P* = 01.0 **Decrease in Hgb, g/dL ± SD:** **G1:** 2.1±1.1 **G2:** 2.0±1.4 *P* = 0.95 **Postoperative hemoglobin, g/dL ± SD:** **G1:** 10.9±1.4 **G2:** 10.7±1.1 *P* = 0.65 **Length of stay ≥ 4 days, N:** **G1:** 0 **G2:** 3 *P* = 0.10 **Modifiers:** **NR**	**Quality:** Overall quality score: poor **INTERNAL VALIDITY: poor** Random: + Methods and blinding: + Pt selection criteria: ++ Loss to follow-up: 10-20% Drop-out rates: >10% Statistical issues: ++ **EXTERNAL VALIDITY: poor (4)** Age: +, reported Race: +, reported Pregnancy history: -, NR Surgical history: -, NR Fibroid/uterine size: + Number of fibroids: - Location of fibroids: - Baseline characteristics: +, reported Length of follow-up: NA Measurement methods: + Measurement reliability: + Clinical care: +

Evidence Table 8. KQ 2 Hysterectomy (continued)

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria and Other Details	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author: Okin et al., 2001 (continued)		**Additional procedures, N:** Bilateral salpingo-oopherectomy: **G1:** 13 **G2:** 13 *P* = 0.78 Left or right salpingo-oopherectomy **G1:** 2 **G2:** 2 *P* = 1.0 Lysis of adhesions **G1:** 4 **G2:** 4 *P* = 1.0 Other procedures: **G1:** 5 **G2:** 5 *P* = 1.0			

Evidence Table 8. KQ 2 Hysterectomy (continued)

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria Other Details	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author: Paparella et al., 2004 **Country and setting:** Italy, Community **Enrollment period:** 11/1999 to 12/2001 **Funding:** NR	**Design:** Prospective case series **Intervention:** Vaginal hysterectomy **Groups:** **G1:** Vaginal hysterectomy in generally considered contraindications to vaginal surgery **G1a:** Large uterus **G1b:** Adnexal pathology **G1c:** Nulliparity **G1d:** Previous pelvic surgery **G1e:** More than 1 contraindication **N at enrollment:** **G1:** 204 **G1a:** 128 **G1b:** 28 **G1c:** 16 **G1d:** 16 **G1e:** 18 **N at follow-up:** NR **Age, yrs ± SD:** 46.96 ± 4.8 **Race/ethnicity:** NR **Parity, parous, N (%):** Mean: 1.94±0 Nulliparous: 34 (16.7) Multiparous: 174 (83.3) **Baseline Hgb/Hct:** NR	**Inclusion criteria:** • Enlarged uterus 280 to 2,000 gm • One or more contraindications to vaginal surgery **Exclusion criteria:** • Pelvic prolapse or relaxation or uteri < 280 gm **Indications, (%):** Fibroids: 112 (54.9) Fibroids and AUB or menorrhagia: 64 (31.4) Fibroids and adnexal pathology: 28 (13.7) **Preoperative therapy:** None **Additional procedures:** NR	**Baseline uterine size, gm ± SD:** 427.74 ± 254.75 **Number of fibroids:** NR **Baseline fibroid size:** NR **Type of fibroid:** NR	**Operative time, mean min:** **G1:** 61.59 **G1a:** 68.00 **G1b:** 55.62 **G1c:** 52.50 **G1d:** 62.52 **G1e:** 71.00 *P* = NS **Conversion to laparotomy, N (%):** **G1:** 10 (4.9) **G1a:** 0 **G1b:** 0 **G1c:** 2 (11.1) **G1d:** 8 (6.45) **G1e:** 0 **Change in Hgb, g/dL:** **G1:** 1.36 **G1a:** 1.02 **G1b:** 0.73 **G1c:** 1.2 **G1d:** 1.45 **G1e:** 1.87 *P* = NS **Pain medication use (mean days):** **G1:** 0.74 **G1a:** 0.57 **G1b:** 0.6 **G1c:** 0.9 **G1d:** 0.7 **G1e:** 0.66 *P* = NS **Length of stay, mean days:** **G1:** 2.94 **G1a:** 3.36 **G1b:** 3.13 **G1c:** 2.67 **G1d:** 2.90 **G1e:** 2.67 *P* NS	**Quality:** Overall quality score: fair **INTERNAL VALIDITY: good** Random: NA Methods and blinding: NA Pt selection criteria: + Loss to follow-up: NR Drop-out rates: NR Statistical issues: + **EXTERNAL VALIDITY: fair (3)** Age: +, reported Race: NA, not US study Pregnancy history: +, reported Surgical history: +, reported Fibroid/uterine size: + Number of fibroids: - Location of fibroids: - Baseline characteristics: +, reported Length of follow-up: NA Measurement methods: + Measurement reliability: + Clinical care: -

Evidence Table 8. KQ 2 Hysterectomy (continued)

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria Other Details	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author: Paparella et al., 2004 (continued)				**Complications, N (%):** **G1:** 20 (9.8) **G1a:** 2 (7.1) **G1b:** 2 (12.5) **G1c:** 0 **G1d:** 14 (11.3) **G1e:** 2 (11.1) *P* = NS **Postoperative complications, N (%):** **G1:** 18 (8.8) **G1a:** 2 (7.1) **G1b:** 2 (12.5) **G1c:** 0 **G1d:** 14 (11.3) **G1e:** 0 *P* = NS **Modifiers:** NR	

Evidence Table 8. KQ 2 Hysterectomy (continued)

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria and Other Details	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author: Seracchioli et al., 2002 **Country and setting:** Italy, Academic medical center **Enrollment period:** 01/1997 to 01/2001 **Funding:** NR	**Design:** RCT **Intervention:** Hysterectomy method **Groups:** **G1:** Total laparoscopic hysterectomy **G2:** Total abdominal hysterectomy **N at enrollment:** **G1:** 60 **G2:** 62 **N at follow-up:** **G1:** 60 **G2:** 62 **Age, yrs ± SD:** **G1:** 46.3 ± 3.5 **G2:** 47.4 ± 4.9 **Race/ethnicity:** NA **Parity, (parous, %):** **G1:** 86.7 **G2:** 78.1 **Baseline Hgb/Hct:** NR	**Inclusion criteria:** • Uterus >14 wks caused by fibroids • Uterine weight ≥ 300 gm **Exclusion criteria:** • Endometrial malignancy • Medical conditions requiring hospital monitoring • Previous abdominal surgery with longitudinal laparotomy • Contraindications to laporotomy **Indications:** NR **Preoperative therapy:** NR **Additional procedures:** NR	**Baseline uterine size, gm ± SD:** **G1:** 411.8 ± 175 **G2:** 429.6 ± 125 *P* NS **Number of fibroids, mean ± SD:** **G1:** 3.3 ± 3.2 **G2:** 2.9 ± 2.6 *P* NS **Baseline fibroid size (cm ± SD):** **G1:** 4.2 ± 3.1 **G2:** 4.9 ± 2.8 *P* NS **Type of fibroid:** NR	**Operative time, min ± SD:** **G1:** 95.2 ± 32.4 **G2:** 88.6 ± 29.3 *P* NS **Mean estimated blood loss (ml ± SD):** **G1:** 311.6 ± 182 **G2:** 376.9 ± 225 *P* NS **Conversion to laparotomy, N:** **G1:** 1 **G2:** 0 *P* NS **Decrease in Hgb, g/100ml ± SD:** **G1:** 1.8 ± 1.1 **G2:** 2.3 ± 1.8 *P* NS **Transfusion, N:** **G1:** 0 **G2:** 1 *P* < NS **Fever >38°C, N (%):** **G1:** 8 (13.3) **G2:** 18 (29) *P* < 0.05 **Length of stay, hrs ± SD:** **G1:** 76.4 ± 30.4 **G2:** 121.8 ± 41.8 *P* < 0.001 **Wound infection, N:** **G1:** 0 **G2:** 6 *P* NS **Convalescence, days ± SD:** **G1:** 22.0 ± 11.3 **G2:** 36.0 ± 12.1 *P* < 0.001 **Modifiers:** NR	**Quality:** Overall quality score: fair **INTERNAL VALIDITY: fair** Random: + Methods and blinding: - Pt selection criteria: + Loss to follow-up: NA Drop-out rates: <5% Statistical issues: + **EXTERNAL VALIDITY: fair (1)** Age: +, reported Race: NA, not US study Pregnancy history: +, reported Surgical history: +, reported Fibroid/uterine size: + Number of fibroids: + Location of fibroids: - Baseline characteristics: +, reported Length of follow-up: + Measurement methods: + Measurement reliability: + Clinical care: +

Evidence Table 8. KQ 2 Hysterectomy (continued)

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria and Other Details	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author: Spies, Cooper , Worthington-Kirsch et al., 2004 **Country and setting:** US, Community and academic medical centers **Enrollment period:** NR **Funding:** Biosphere Medical Inc.	**Design:** Prospective cohort **Intervention:** UAE and hysterectomy **Groups:** **G1:** UAE **G2:** Hysterectomy **N at enrollment:** **G1:** 102 **G2:** 50 (40 TAH, 2 LAVH, and 8 LH) **N at follow-up, 12 months:** **G1:** 76 **G2:** 30 **Age, yrs ± SD:** **G1:** 42.6 ± 4.0 **G2:** 41.6 ± 5.3 *P* = 0.264 **Race/ethnicity, N (%):** Asian/Pacific Island: **G1:**1 (1) **G2:** 2 (4) Black: **G1:** 61 (60) **G2:** 9 (18) Hispanic: **G1:** 7 (7) **G2:** 8 (16) White: **G1:** 31 (30) **G2:** 31 (62) Other: **G1:** 2 (2) **G2:** 0 (0) *P* < 0.001	**Inclusion criteria:** • Age: 30 to 50 yrs • Symptomatic fibroids **Exclusion criteria:** • Submucosal fibroids with > 50% diameter within uterine cavity • Dominant pedunculated serosal fibroid **Indications:** NR **Preoperative therapy:** NR **Additional procedures:** NR	**Baseline uterine size, ml ± SD:** **G1:** 689.4 ± 466.1 **G2:** 389.2 ± 521.2 *P* < 0.001 **Number of fibroids, N (%):** 1 fibroid: **G1:** 27 (26) **G2:** 20 (40) 2 fibroids: **G1:** 33 (32) **G2:** 19 (38) ≥3 fibroids: **G1:** 42 (41) **G2:** 10 (20) *P* = 0.021 **Baseline dominant fibroid size (ml ± SD):** **G1:** 146.8 ± 158.5 **G2:** 90.6 ± 354.8 *P* = 0.330 **Type of fibroid, N (%):** Intramural: **G1:** 61 (60) **G2:** 32 (64) *P* = 0.724 Subserosal: **G1:** 19 (19) **G2:** 8 (16) *P* = 0.823 Submucosal: **G1:** 17 (17) **G2:** 13 (26) *P* = 0.197 Transmural: **G1:** 11 (11) **G2:** 1 (2) *P* = 0.108 Pedunculated: **G1:** 2 (2) **G2:** 4 (8) *P*=0.072	**Procedure time, min):** **G1:** 57.9 **G2:** 93.6 *P* < 0.001 **At least 1 complication, N (%):** **G1:** 28 (27.5%; 95% CI, 19.1-37.2) **G2:** 25 (50%; 95% CI, 35.5-64.5) *P* = 0.01 **Complications within 30 days, %:** **G1:** 17.6 **G2:** 28 *P* = 0.15 **Complications after 30 days, %:** **G1:** 12.7 **G2:** 32 *P*=0.01 **Major complications, N (%):** **G1:** 4 (3.9) **G2:** 6 (12) *P* = 0.08 **Life threatening Complications, N:** **G1:** 0 **G2:** 0 **Overall morbidity N (%):** **G1:** 15 (14.7) **G2:** 17 (34.0) *P* = 0.01 **Hemorrhage, N (%):** **G1:** 0 (0) **G2:** 4 (8) *P* = 0.01	**Quality:** Overall quality score: fair **INTERNAL VALIDITY: poor** Random: NA Methods and blinding: NA Pt selection criteria: + Loss to follow-up: >20% Drop-out rates: NR Statistical issues: + **EXTERNAL VALIDITY: good** Age: +, reported Race: +, reported Pregnancy history: +, reported Surgical history: +, reported Fibroid/uterine size: + Number of fibroids: + Location of fibroids: + Baseline characteristics: +, reported Length of follow-up: ++ Measurement methods: + Measurement reliability: + Clinical care: +

Evidence Table 8. KQ 2 Hysterectomy (continued)

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria and Other Details	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author: Spies, Cooper, Worthington-Kirsch et al., 2004 (continued)	**Parity, N (%):** Nulliparous: **G1:** 44 (43) **G2:** 11 (22) Para 1: **G1:** 20 (20) **G2:** 10 (20) Multiparous: **G1:** 38 (37) **G2:** 29 (58) *P* = 0.025 **Baseline Hgb, (%):** <12 g/dL: **G1:** 59 (58) **G2:** 19 (38) ≥12 g/dL: **G1:** 43 (42) **G2:** 31 (63) *P* = 0.025			**Febrile morbidity, N (%):** **G1:** 13 (12.7) **G2:** 12 (24.0) *P* = 0.10 **Length of stay, days:** **G1:** 0.83 **G2:** 2.3 *P* < 0.001 **Readmission, N (%):** **G1:** 3 (2.9) 4 (8) *P* = 0.22 **Satisfaction with symptom outcome:** *P* = NS **Mean time to return to work, days:** **G1:** 10.7 **G2:** 32.5 *P* < 0.001 **Unintended surgery, N (%):** **G1:** 2 (2) **G2:** 4 (8) *P* = 0.09 **Modifiers:** NR	

Evidence Table 8. KQ 2 Hysterectomy (continued)

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria and Other Details	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author: Taylor et al., 2003 **Country and setting:** US, Academic medical center **Enrollment period:** 08/1990 to 07/2001 **Funding:** NR	**Design:** Retrospective cohort **Intervention:** Hysterectomy **Groups:** **G1:** Vaginal hysterectomy with morcellation **G2:** Abdominal hysterectomy **N at enrollment:** **G1:** 139 **G2:** 208 **N at follow-up:** NA **Age, yrs ± SD:** **G1:** 43.4 ± 7.6 **G2:** 42.2 ± 6.3 *P* = 0.11 **Race/ethnicity, N:** White: **G1:** 51 **G2:** 72 Hispanic: **G1:** 63 **G2:** 88 American Indian: **G1:** 16 **G2:** 16 Other: **G1:** 6 **G2:** 20 *P* = 0.2 **Parity, mean ± SD:** **G1:** 2.6 ± 1.5 **G2:** 2.3 ± 1.9 *P* = 0.1 **Baseline Hgb/Hct:** NR	**Inclusion criteria:** • Vaginal or abdominal hysterectomy for uterine fibroids • No known malignancy **Exclusion criteria:** Uterine weight >982 g **Indications:** • Symptomatic fibroids • Dysfunctional bleeding • Pelvic relaxation **Pre-operative therapy:** NR **Additional procedures, (%):** Oophorectomy: **G1:** 31 **G2:** 53 *P* < 0.001 Anterior repair: **G1:** 30 (21.6) Posterior repair: **G1:** 23 (16.5) Vaginal urethropexy: **G1:** 16 (11.5) Retropubic urethropexy: **G2:** 18 (8.7) Concurrent surgeries in G1 vs. G2: *P* > .05	**Baseline uterine size, gm ± SD:** **G1:** 211 ± 114 ***G2:*** *431 ± 236* *P* < 0.001 **Number of fibroids:** NR **Baseline fibroid size:** NR **Type of fibroid:** NR	**Operative time, min ± SD:** **G1:** 172 ± 70.0 **G2:** 173 ± 66.6 *P* = 0.88 **Intraoperative transfusion, N:** **G1:** 4 **G2:** 6 *P* = 1.00 (OR = 1.0; 95% CI, 0.3-3.6) **Conversion to laparotomy, N:** **G1:** 2 **G2:** 0 *P* = 1.00 **Intraoperative complications, N:** **G1:** 8 **G2:** 16 *P* = 0.53 (OR = 1.4; 95% CI, 0.6-3.3) **Bowel injury, N:** **G1:** 1 **G2:** 3 *P* = 0.65 (OR = 2.0; 95% CI, 0.2-19.6) **Bladder injury, N:** **G1:** 3 **G2:** 7 *P* = 0.75 (OR = 1.6; 95% CI, 0.4-6.2) **Ureteral injury, N:** **G1:** 1 **G2:** 4 *P* = 0.65 (OR = 2.7; 95% CI 0.3-24.5) **Decrease in Hct, mean ± SD:** **G1:** 7.5 ± 4.6 **G2:** 8.3 ± 5.9 *P* = 0.18	**Quality:** Overall quality score: poor **INTERNAL VALIDITY: fair** Random: NA Methods and blinding: NA Pt selection criteria: + Loss to follow-up: NA Drop-out rates: NA Statistical issues: - **EXTERNAL VALIDITY: poor (5)** Age: +, reported Race: +, reported Pregnancy history: -, NR Surgical history: -, NR Fibroid/uterine size: + Number of fibroids: - Location of fibroids: - Baseline characteristics: +, reported Length of follow-up: NA Measurement methods: + Measurement reliability: - Clinical care: +

Evidence Table 8. KQ 2 Hysterectomy (continued)

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria and Other Details	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author: Taylor et al., 2003 (continued)				**Postoperative transfusion, N:** **G1:** 4 **G2:** 9 *P* = 0.57 (OR = 1.5; 95% CI, 0.5-5.1) **Fever > 38°C, N:** **G1:** 4 **G2:** 34 *P* < 0.001 (OR = 6.6; 95% CI, 2.2-19.0) **Length of stay, days ± SD:** **G1:** 2.6 ± 1.5 **G2:** 3.9 ± 2.6 *P* < 0.001 **Postoperative complications, N:** **G1:** 10 **G2:** 48 *P* < 0.001 (OR = 3.9; 95% CI, 1.9-7.9) **Pelvic hematoma, N:** **G1:** 2 **G2:** 5 *P* = 0.71 (OR = 1.7; 95% CI, 0.3_8.8) **Reoperation, N:** **G1:** 0 **G2:** 5 *P* = 0.09 **Other complications, N:** **G1:** 1 **G2:** 7 *P* = 0.15 (OR = 4.8; 95% CI, 0.6-39.5) **Modifiers:** NR	

Evidence Table 8. KQ 2 Hysterectomy (continued)

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria and Other Details	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author: Unger et al., 2002 **Country and setting:** US, Academic medical center **Enrollment period:** 1997 to 2000 **Funding:** NR	**Design:** Retrospective case series **Intervention:** Abdominal hysterectomy **Groups:** **G1:** Uterus <500gm **G2:** Uterus 500-999gm **G3:** Uterus ≥1000gm **N at enrollment:** **G1:** 208 **G2:** 63 **G3:** 47 **N at follow-up:** NA **Age, yrs ± SD:** **G1:** 41.0 ± 8.7 **G2:** 42.8 ± 6.0 **G3:** 45.1 ± 5.5 *P* = 0.034 **Race/ethnicity, N (%):** Black: **G1:** 131(63.0) **G2:** 59 (93.6) **G2:** 44 (93.6) *P* < 0.001 **Parity, mean ± SD:** **G1:** 2.5 ± 1.6 **G2:** 2.6 ± 1.8 **G3:** 2.2 ± 1.6 **Baseline Hgb/Hct:** NR	**Inclusion criteria:** • Abdominal hysterectomy for benign disease **Exclusion criteria:** Concurrent anterior-posterior colporraphy or retropubic urethropexy **Indications:** **G1:** 100% "gynecological problems" (bleeding and pain) **G2:** 3.7% asymptomatic **G3:** 17.5% asymptomatic **Preoperative therapy:** NR **Additional procedures:** NR	**Baseline uterine size, gm ± SD:** **G1:** 227.7± 129.6 **G2:** 729.3 ± 120.3 **G3:** 1658.8 ± 793.5 *P* < 0.001 **Number of fibroids:** NR **Baseline fibroid size:** NR **Type of fibroid:** NR	**Operative time, min ± SD:** **G1:** 122.6 ± 41.7 **G2:** 129.5 ± 40.7 **G3:** 124.0 ± 30.6 *P* = 0.49 **Mean estimated blood loss, ml ± SD:** **G1:** 387.6 ± 281.4 **G2:** 464.3 ± 285.2 **G3:** 555.9 ± 386.5 *P* = 0.032 **Estimated blood loss > 500 ml, N (%):** **G1:** 53 (25.5) **G2:** 26 (41.3) **G3:** 26 (55.3) *P* = 0.004 (AOR for G3 vs. G1 = 3.42; 95% CI, 1.63-7.19) (AOR for G3 vs. G2 = 1.96; 95% CI 0.85-4.5) **Transfusion, N (%):** **G1:** 6 (2.9) **G2:** 4 (6.4) **G3:** 4 (8.5) *P* = 0.14 **At least one complication, N (%):** **G1:** 68 (32.7) **G2:** 26 (41.3) **G3:** 29 (61.7) *P* = 0.006 (AOR for G3 vs. G1 = 3.42; 95% CI, 1.63-7.25) (AOR for G3 vs. G2 = 2.64; 95% CI 1.14-6.13) **Length of stay, days ± SD:** **G1:** 2.9 ± 0.9 **G2:** 2.8 ± 1.0 **G3:** 2.9 ± 0.8 *P* = 0.72 **Modifiers:** NR	**Quality:** Overall quality score: fair **INTERNAL VALIDITY: fair** Random: NA Methods and blinding: NA Pt selection criteria: - Loss to follow-up: NA Drop-out rates: NA Statistical issues: + **EXTERNAL VALIDITY: fair (3)** Age: +, reported Race: +, reported Pregnancy history: +, reported Surgical history: NA Fibroid/uterine size: + Number of fibroids: - Location of fibroids: - Baseline characteristics: +, reported Length of follow-up: + Measurement methods: + Measurement reliability: + Clinical care: -

Evidence Table 8. KQ 2 Hysterectomy (continued)

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria Other Details	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author: Vavilis et al., 2005 **Country and setting:** Greece, Academic medical center **Enrollment period:** 01/2000 to 01/2003 **Funding:** NR	**Design:** Retrospective cohort **Intervention:** Abdominal myomectomy vs. abdominal hysterectomy **Groups:** **G1:** Abdominal myomectomy **G2:** Abdominal hysterectomy **N at enrollment:** **G1:** 102 **G2:** 102 **N at follow-up:** NA **Age, yrs ± SD:** **G1:** 35 ± 5.8 **G2:** 45 ± 3.4 **Race/ethnicity:** NR **Parity:** NR **Baseline Hgb/Hct:** NR	**Inclusion criteria:** • Undergoing abdominal myomectomy or hysterectomy **Exclusion criteria:** NR **Indications:** NR **Pre-operative therapy:** NR **Associated procedure(s):** NR	**Baseline uterine size:** NR **Number of fibroids:** NR **Baseline fibroid size:** NR **Type of fibroid:** NR	**Fever >38° C, N (%):** **G1:** 17 (16.63) **G2:** 14 (13.72) *P* = NS **Fever lasting > 24 hrs, N (%):** **G1:** 4 (3.92) **G2:** 5 (4.9) *P* = NS **Modifiers:** NR	**Quality:** Overall quality score: poor **INTERNAL VALIDITY: fair** Random: NA Methods and blinding: NA Pt selection criteria: - Loss to follow-up: NA Drop-out rates: NA Statistical issues: + **EXTERNAL VALIDITY: poor (6)** Age: +, reported Race: NA, not US study Pregnancy history: -, NR Surgical history: -, NR Fibroid/uterine size: - Number of fibroids: - Location of fibroids: - Baseline characteristics: -, NR Length of follow-up: NA Measurement methods: + Measurement reliability: + Clinical care: +

Evidence Table 9. KQ2 Complementary and alternative medicine

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria Other Details	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author: Mehl-Madrona, 2002 **Country and setting:** US, Academic medical center **Enrollment period:** NR **Funding:** NR	**Design:** Prospective cohort **Intervention:** Traditional Chinese medical approach **Groups:** **G1:** Traditional Chinese Medicine with combination of weekly acupuncture, Chinese herbs, and nutritional therapy **G2:** Progestational agents to stop excessive uterine bleeding, or 4 contraceptive agents to control menstrual bleeding, and NSAIDS for pain **N at enrollment:** **G1:** 37 **G2:** 37 **N at follow-up:** **G1:** 37 **G2:** 37 **Age:** Mode: 36 (24 to 45) **Race/ethnicity:** NR **Parity:** NR **Baseline Hgb/Hct:** NR	**Inclusion criteria:** • Pre-menopausal • Intact uterus of ≥ 6 to 8 week size with palpable fibroids • Fibroids 2 to 3 cm in diameter **Exclusion criteria:** • Fibroids growing > 6 cm/year • Hgb < 8g/dL • Hydronephrosis • Taking hormonal contraceptives **Indications:** • Palpable fibroids • Fibroids 2 to 3 cm in diameter **Pre-operative therapy:** NA **Associated procedure(s):** NA	**Baseline uterine size:** NR **Number of fibroids:** NR **Baseline fibroid size:** NR **Type of fibroid:** NR	**Mean size change, cm:** **G1:** -0.8 **G2:** +1.9 *P* < 0.001 **Size and/or rate of growth of fibroids, 6 mos, mean change in size, cm:** Cured (gone) **G1:** 3 **G2:** 0 Reduced size (>2cm) **G1:** 11 **G2:** 1 Stopped growing (± 1cm) **G1:** 8 **G2:** 2) Decreased rate of growth (change >1cm) **G1:** 10 (+1.1) **G2:** 9 (+0.9) Total improved*: **G1:** 32 **G2:** 13 *P* < 0.001 No change **G1:** 3 (+0.9) **G2:** 20 (+1.9) Increased rate of growth (change >1cm) **G1:** 2 (+9.2) **G2:** 4 (+7.0) Total unimproved: **G1:** 5 **G2:** 24 *P* < 0.001 **Symptom change, N:** Heavy menstrual bleeding, before treatment: **G1:** 20 **G2:** 20	**Quality:** Overall quality score: poor **INTERNAL VALIDITY: fair** Random: NA Methods and blinding: NA Pt selection criteria: + Loss to follow-up: <10% Drop-out rates: <5% Statistical issues: - **EXTERNAL VALIDITY: poor (5)** Age: +, reported Race: -, NR Pregnancy history: -, NR Surgical history: NA Fibroid/uterine size: + Number of fibroids: - Location of fibroids: - Baseline characteristics: -, NR Length of follow-up: + Measurement methods: + Measurement reliability: + Clinical care: +

Evidence Table 9. KQ2 Complementary and alternative medicine (continued)

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria Other Details	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author: Mehl-Madrona, 2002 (continued)				Heavy menstrual bleeding, 6 mos: **G1:** 9 **G2:** 11 Prolonged menstrual bleeding, before treatment: **G1:** 9 **G2:** 9 Prolonged menstrual bleeding, 6 mos: **G1:** 5 **G2:** 5 Dysmenorrhea before treatment, N: **G1:** 9 **G2:** 9 Dysmenorrhea, 6 mos: **G1:** 5 **G2:** 7 Decreased exercise/activity tolerance, before treatment: **G1:** 2 **G2:** 2 Decreased exercise/activity tolerance, before treatment: **G1:** 2 **G2:** 2 Decreased exercise/activity tolerance, 6 mos: **G1:** 1 **G2:** 1 **Modifiers:** NR	

Evidence Table 10. KQ 3 Reproductive outcomes

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria Other Details	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author: Bulletti et al., 2004 **Country and setting:** Italy, Academic medical center **Enrollment period:** 1997 to 2003 **Funding:** NR	**Design:** Prospective cohort **Intervention:** Myomectomy before IVF **Groups:** **G1:** Myomectomy before IVF **G2:** No myomectomy before IVF **N at enrollment:** **G1:** 84 **G2:** 84 **N at follow-up:** 193 enrolled 143 completed the study 25 replaced to reach 168 Followup interval: NR **Age, yrs ± SD:** **All:** 33.04 ± 4.76 **G1:** 32.83 ± 4.12 **G2:** NR **Race/ethnicity:** NR **Parity, parous, N:** **G1:** 0 **G2:** 0 **Baseline Hgb/Hct:** NR	**Inclusion criteria:** • Nulliparity • Age 25 to 39 • ≥1 fibroid > 5 cm with tubal occlusion **Exclusion criteria:** • Male factor infertility • Bilateral tubal occlusion • Submucous fibroid(s) • Diagnosis with increased abortion risk other than fibroid(s) **Indications:** • Infertility: 100% **Pre-operative therapy:** NR **Associated procedure(s):** NR	**Baseline uterine size:** NR **Number of fibroids:** NR **Baseline fibroid size:** NR **Type of fibroid:** NR	**Cumulative pregnancy rate, N (%):** **G1:** 28 (33) **G2:** 13 (15) *P* < 0.05 **Miscarriage rate, N (%):** **G1:** 8 (7) **G2:** 3 (4) *P* = NS **Delivery rate, N (%):** **G1:** 21 (25) **G2:** 10 (12) *P* < 0.05 **Modifiers:** NR	**Quality:** Overall quality score: poor **INTERNAL VALIDITY: poor** Random: NA Methods and blinding: NA Pt selection criteria: ++ Loss to follow-up: 10-20% Drop-out rates: >10% Statistical issues: - **EXTERNAL VALIDITY: poor (6)** Age: +, reported Race: NA, not US study Pregnancy history: -, NR Surgical history: -, NR Fibroid/uterine size: - Number of fibroids: - Location of fibroids: - Baseline characteristics: -, NR Length of follow-up: + Measurement methods: + Measurement reliability: + Clinical care: +

Evidence Table 10. KQ 3 Reproductive outcomes (continued)

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria Other Details	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author: Casini et al., 2006 **Country and setting:** Italy, Academic medical center **Enrollment period:** 01/1998 to 04/2005 **Funding:** NR	**Design:** RCT **Intervention:** Myomectomy for unexplained infertility **Groups:** **G1:** Hysteroscopic or laparoscopic surgery **G2:** No surgery **N at enrollment:** **G1:** Submucosal: 30 Intramural: 23 Subserosal: no surgeries Intramural-subserosal: 17 Submucosal-intramural: 22 **G2:** Submucosal: 22 Intramural: 22 Subserosal: 11 Intramural-subserosal: 14 Submucosal-intramural: 20 **N at follow-up:** NR **Age, yrs ± SD:** NR by group; by fibroid type: Submucosal: 31.4 ± 2.5 Intramural: 32.2 ± 1.9 Subserosal: 32.4 ± 2.1 Intramural-subserosal: 29.9 ± 1.6 Submucosal-intramural: 32.2 ± 2.5 **Race/ethnicity:** NR **Parity:** NR **Baseline Hgb/Hct:** NR	**Inclusion criteria:** • Infertility ≥ 1yr • No other explanation for infertility • Age < 35 • One fibroid • ≤ 40mm diameter **Exclusion criteria:** • ≥ 2 fibroids • Size ≥ 40 mm • Body wt. > 20% above normal • Use of hormones within 8 wks **Indications:** Unexplained infertility **Pre-operative therapy:** None **Associated procedure(s):** NR	**Baseline uterine volume:** NR **Number of fibroids:** One **Baseline fibroid size:** NR **Type of fibroid:** As per groups	**Pregnancy rate, %:** **G1:** Submucosal: 43.3* Intramural: 56.5 Subserosal: no surgeries Intramural-subserosal: 35.3 Submucosal-intramural: 36.4* **G2:** Submucosal: 27.2* Intramural: 40.9 Subserosal: 63.6 Intramural-subserosal: 21.4 Submucosal-intramural: 15.0* *P < 0.05 **Miscarriage rate, % ,** **G1:** Submucosal: 38.5 Intramural: 30.8 Subserosal: no surgeries Intramural-subserosal: 33.3 Submucosal-intramural: 50.0 **G2:** Submucosal: 50.0 Intramural: 33.3 Subserosal: 0 Intramural-subserosal: 66.6 Submucosal-intramural: 66.6 P = NR **Modifiers:** NR	**Quality:** Overall quality score: fair **INTERNAL VALIDITY: good** Random: NA Methods and blinding: NA Pt selection criteria: + Loss to follow-up: NR Drop-out rates: NR Statistical issues: + **EXTERNAL VALIDITY: poor (4)** Age: +, reported Race: NA, not US study Pregnancy history: +, reported Surgical history: -, NR Fibroid/uterine size: - Number of fibroids: - Location of fibroids: + Baseline characteristics: +, reported Length of follow-up: - Measurement methods: + Measurement reliability: + Clinical care: +

Evidence Table 10. KQ 3 Reproductive outcomes (continued)

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria Other Details	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author: Dessolle et al., 2001 Soriano et al., 2003 **Country and setting:** France, Community **Enrollment period:** 01/1990 to 10/1988 **Funding:** NR	**Design:** Prospective case series **Intervention:** Laparoscopic myomectomy **Groups:** **G1:** Laparoscopic myomectomy **G2:** Laparo-conversion for myomectomy **N at enrollment:** **G1:** 88 **G2:** 18 **N at follow-up:** NR **Age, yrs ± SD:** **G1:** 36.1 ± 2.1 **G2:** 34.7 ± 2.4 **Race/ethnicity:** NR **Parity:** NR **Baseline Hgb/Hct:** NR	**Inclusion criteria:** • Age 18 to 43 yrs • Infertility ≥ 24 mos • Intramural or subserous fibroids > 3 cm in diameter • < 4 myomas, and largest myoma < 10 cm **Exclusion criteria:** • Anesthetic contra-indications • Only submucous fibroids **Indications, N (%):** Primary infertility: **G1:** 28 (31.8) **G2:** 6 (33.4) **Pre-operative therapy:** None **Associated procedure(s):** NR	**Baseline uterine size:** NR **Number of fibroids, mean ± SD:** **G1:** 1.7 ± 0.6 **G2:** 1.6 ± 0.6 *P* = NS **Baseline size of largest fibroid (cm ± SD):** **G1:** 6.2 ± 1.8 **G2:** 8.1 ± 1.4 *P* < 0.001 **Type of fibroid, N (%):** Subserosal: **G1:** 31 (35) **G2:** 0 Intramural: **G1:** 57 (65) **G2:** 18 (100)	**Operative time, min ± SD:** **G1:** 150 ± 60 **G2:** 148 ± 47 **Complications, N:** **G1:** 4* **G2:** 2 **Length of stay, days ± SD:** **G1:** 3.0 ± 1 **G2:** 5.5 ± 1 *P* < 0.001 **Pregnancy rate, N (%):** **G1:** 42 (48) **G2:** 10 (56) *P* = NS **Pregnancies, N:** **G1:** 44 **G2:** 10 *P* = NS **Spontaneous pregnancy, N (%):** **G1:** 36/44 (82) **G2:** 8/10 (80) *P* = NS **Ovulation induction + IUI, N (%):** **G1:** 2 (5) **G2:** 1 (10) **IVF + ET, N (%):** **G1:** 6 (13) **G2:** 1 (10) **First-trimester miscarriage, N:** **G1:** 6 **G2:** 3 **Abortion, N:** **G1:** 2 **G2:** 2 **Dehiscence of uterine scar, N:** **G1:** 0 **G2:** 0	**Quality:** Overall quality score: fair **INTERNAL VALIDITY: fair** Random: NA Methods and blinding: NA Pt selection criteria: ++ Loss to follow-up: NA Drop-out rates: NA Statistical issues: - **EXTERNAL VALIDITY: fair (3)** Age: +, reported Race: NA, not US study Pregnancy history: -, NR Surgical history: -, NR Fibroid/uterine size: + Number of fibroids: + Location of fibroids: + Baseline characteristics: +, reported Length of follow-up: ++ Measurement methods: + Measurement reliability: - Clinical care: +

*Calculated by reviewer.

Evidence Table 10. KQ 3 Reproductive outcomes (continued)

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria Other Details	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author: Dessolle et al., 2001 Soriano et al., 2003 (continued)				**Vaginal delivery, N (%):** **G1:**26/34 (77) **G2:** 2/4 (50) **Cesarean delivery, N (%):** **G1:** 8/34 (24) **G2:** 2/4 (50) **Ectopic pregnancy, N:** **G1:** 1 **G2:** 0 **Live newborn, N (%):** **G1:** 36/44 (41) **G2:** 4/10 (40) **Premature delivery, N:** **G1:** 0 **G2:** 1 **Time to conception, mos ± SD:** **G1:** 7.5 ± 2.6 **G2:** 15.1 ± 2.4 *P* < 0.001 **Patients with unexplained infertility, N (%):** **G1:** 32/42 (76) **G2:** 8/9 (89) *P* = NS **Patients with minor infertility factors, N (%):** **G1:** 10/42 (24) **G2:** 2/9 (22) *P* = NS **Patients with primary infertility, N (%):** **G1:** 14/28 (50) **G2:** 2/6 (33) *P* = NS	

*Calculated by reviewer.

Evidence Table 10. KQ 3 Reproductive outcomes (continued)

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria Other Details	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author: Dessolle et al., 2001 Soriano et al., 2003 (continued)				**Patients with secondary infertility, N (%):** **G1:** 28/60 (47) **G2:** 8/12 (66) *P* = NS **Adhesions, N (%):** **G1:** 12/16 (75) **G2:** 4/4 (100) **Recurrence N (%):** **G1:** 6/66 (9)* **G2:** 2/12 (17) **Re-operation (%):** **G1:** 0 **G2:** 2 **Modifiers:** NR	

*Calculated by reviewer.

Evidence Table 10. KQ 3 Reproductive outcomes (continued)

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria Other Details	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author: Di Gregorio et al., 2001 **Country and setting:** Italy, Specialty fibroid treatment center **Enrollment period:** 03/1988 to 04/2001 **Funding:** NR	**Design:** Retrospective case series **Intervention:** Laparoscopic myomectomy **Groups:** NA **N at enrollment:** 635 patients (1,170 fibroids) **N at follow-up:** 121 second look surgeries **Age, mean yrs (range):** 34.5 (24 to 51) **Race/ethnicity:** NR **Parity, parous (%):** Overall: 278 (43.8) **Baseline Hgb/Hct:** NR	**Inclusion criteria:** • Women who received myomectomy for symptomatic fibroids, infertility, or "size and/or number of fibroids required surgical treatment" • Fibroid size ≥ 10 mm **Exclusion criteria:** NR **Indications, N:** • Infertility: 445 **Preoperative therapy:** NR **Additional procedures, N:** • Adhesiolysis: 118 • Ovarian cystectomy: 89 • Coagulation of endometriotic lesions: 157 • Salpingectomy for ectopic pregnancy: 5 • Appendectomy: 5	**Baseline uterine size:** NR **Number of fibroids, range:** 1 to 9 **Baseline fibroid size (mm):** < 20: 633 (54%) 21 to 39: 357 (30.5%) 40 to 59: 123 (10.5%) > 60: 57 (4.9%) **Type of fibroid, N (%):** • Subserous: 630 (53.8) • Intramural: 412 (35.2) • Pedunculated: 128 (10.9)	**Operative time range in min:** 30 to 140 **Conversion to laparotomy, N:** 2/635 **Adhesions at second look, N (%):** 2/121 (1.6) **Modifiers:** NR	**Quality:** Overall quality score: fair **INTERNAL VALIDITY: fair** Random: NA Methods and blinding: NA Pt selection criteria: + Loss to follow-up: NA Drop-out rates: NA Statistical issues: - **EXTERNAL VALIDITY: fair (3)** Age: -, NR Race: NA, not US study Pregnancy history: +, reported Surgical history: -, NR Fibroid/uterine size: + Number of fibroids: + Location of fibroids: + Baseline characteristics: -, NR Length of follow-up: NA Measurement methods: + Measurement reliability: + Clinical care: +

Evidence Table 10. KQ 3 Reproductive outcomes (continued)

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria Other details	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author: Dubuisson et al., 2000 **Country and setting:** France, Academic medical center **Enrollment period:** 03/1989 to 12/1996 **Funding:** NR	**Design:** Retrospective case series **Intervention:** Laparoscopic myomectomy **Groups:** NA **N at enrollment:** 263 **Number of women at follow-up, N (%):** 98 (37.2) 145 pregnancies/ 100 delivered viable neonates; Data presented here is on 100 neonates No pregnancy during follow-up after LM: 128 (48.7) Lost to follow-up 37 (14.1) **Age, yrs ± SD:** 33.2 ± 4.0 **Race/Ethnicity:** NR **Parity, parous, N (%):** Nullipara: 78 (79) Primipara: 9 (9) Multipara: 11 (12) **Baseline Hgb/Hct:** NR	**Inclusion criteria:** • Age < 45 years • Underwent LM • ≥1 subserous or intramural myoma >20 mm in diameter **Exclusion criteria:** NR **Indications, N (%):** • Infertility/recurrent spontaneous abortion: 53 (54) • Pain/pressure: 29 (29.6) • Abnormal bleeding: 16 (16.3) • Rapidly growing myoma: 14 (14.3) **Pre-operative therapy:** NR **Associated procedure(s):** NR	**Baseline uterine size:** NR **Number of fibroids, (%):** 1: 60 (61) 2: 18 (18) ≥3: 20 (21) **Baseline largest fibroid size, mm ± SD :** 47.8 ± 20.6 **Type of largest fibroid, (%):** Intramural: 32 (32.6) Subserous: 41 (41.8) Pedunculated: 25 (25.6)	**Neonates, N (%):** 100 of 145 (69%) delivered viable neonates **Mode of delivery, N (%):** Spontaneous vaginal delivery: 36 (36) Forceps delivery: 22 (22) C-section during labor: 14 (14) C-section before labor: 28 (28) **Gestational age, weeks ± SD:** 36.5 ± 2.7 **Birth weight, kg ± SD:** 3.2 ± .06 **1-min Apgar score, SD:** 8.9 ±2.0 **Premature delivery, N (%):** 14 (14) **Indications for C-section after LM, N (%):** Elective C-section of uterine scar: 16/42 (38.1) Failed trial of labor,: 14 (33.3) Maternal/fetal pathology: 6 (14.3) Breech presentation: 3 (7.1) Suspected uterine rupture: 3 (7.1) **Uterine rupture on LM scar, N (%):** 1 (2.4)	**Quality:** Overall quality score: poor **INTERNAL VALIDITY: poor** Random: NA Methods and blinding: NA Pt selection criteria: + Loss to follow-up: 10-20% Drop-out rates: NA Statistical issues: - **EXTERNAL VALIDITY: poor (4)** Age: +, reported Race: NA, not US study Pregnancy history: +, reported Surgical history: -, NR Fibroid/uterine size: - Number of fibroids: - Location of fibroids: - Baseline characteristics: +, reported Length of follow-up: ++ Measurement methods: + Measurement reliability: + Clinical care: +

Evidence Table 10. KQ 3 Reproductive outcomes (continued)

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria Other details	Fibroids Characteristics	Outcomes	Notes/Quality Rating
				Uterine rupture away form LM scar, N (%): 2 (4.8) **Obstetric complications, N (%):** Uterine rupture: 3 (3) Uterine rupture related to LM: 1 (1) Postpartum hemorrhage: 3 (3) Rate of uterine rupture: 1.0% (95% CI 0.0-5.5) **Modifiers:** NR	

Evidence Table 10. KQ 3 Reproductive outcomes (continued)

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria Other details	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author: Kumakiri et al., 2005 **Country and setting:** Japan, Academic medical center **Enrollment period:** 01/1998 to 12/2002 **Funding:** NR	**Design:** Retrospective case series **Intervention:** Laparoscopic myomectomy **Groups:** NA **N at enrollment:** 108 **N at follow-up:** NA **Age, yrs ± SD:** 35.5 ± 3.5 **Race/Ethnicity:** NA **Parity, parous (N):** Multiparous: 10 **Baseline Hgb/Hct:** NR	**Inclusion criteria:** • Menorrhagia and abdominal fullness • Infertility • Fibroids ≥ 5 cm • Wishing to have children • Largest fibroid ≤ 12 cm • Uterus size ≤ 14 weeks gestation **Exclusion criteria:** See inclusion criteria **Indications, N:** Infertility: 59 Menorrhagia: 20 Dysmenorrhea: 17 Lower abdominal pain: 6 Other: 6 **Pre-operative therapy (%):** GnRH: 86 (79.6) **Associated procedure(s):** NR	**Baseline uterine size:** NR **Number of fibroids enucleated, mean ± SD:** Pregnancy: 3.2 ± 2.7 No pregnancy: 3.7 ± 3.6 *P* = 0.04 **Baseline largest fibroid size mm ± SD:** Pregnancy: 67.5 ± 16.9 No pregnancy: 62.3 ± 16.3 *P* = 0.004 **Type of fibroid:** NR	**Operative time, min ± SD:** Pregnancy: 105.3 ± 45.3 No pregnancy: 106.0 ± 51.5 *P* =0.75 **Mean estimated blood loss, ml ± SD:** Pregnancy: 85.2 ± 105.8 No pregnancy: 120.3 ± 174.5 *P* =0.53 **Pregnancy success rate, N (%):** 40/108 (37%) **Spontaneous pregnancies, N (%):** 40/47 (85.1) **ART pregnancies, N (%);** 7/47 (14.9) **Miscarriages, N (%):** 11/47 (23.4) **Ectopic, N:** 1/47 (2.1) **Live births, N (%):** 32/47 (68.1) **Elective Cesarean delivery, N (%):** 9/32 (28.1) **VBALM failure, N (%):** 4/23 (17.4) **Modifiers:** Pregnancy rate correlated positively with diameter of largest fibroid: OR =1.06; 95% CI, 1.02-1.10 *P* = 0.004	**Quality:** Overall quality score: fair **INTERNAL VALIDITY: fair** Random: NA Metods and blinding: NA Pt selection criteria: + Loss to follow-up: <10% Drop-out rates: NA Statistical issues: - **EXTERNAL VALIDIT: fair (2)** Age: +, reported Race: NA, not US study Pregnancy history: -, NR Surgical history: -, NR Fibroid/uterine size: + Number of fibroids: + Location of fibroids: + Baseline characteristics: +, reported Length of follow-up: + Measurement methods: + Measurement reliability: + Clinical care: +

Evidence Table 10. KQ 3 Reproductive outcomes (continued)

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria Other details	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author: Kumakiri et al., 2005 (continued)				**Modifiers:** Pregnancy rate correlated negatively with age at myomectomy: OR = 0.88; 95% CI, 0.80-0.98 *P* = 0.02 Pregnancy rate correlated negatively with number of enucleated fibroids: OR =1.17; 95% CI, 1.01-1.37 *P* = 0.04	

Evidence Table 10. KQ 3 Reproductive outcomes (continued)

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria Other Details	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author: Malzoni et al., 2003 **Country and setting:** Italy, Community **Enrollment period:** 01/1997 to 07/1999 **Funding:** NR	**Design:** Retrospective case series **Intervention:** Laparoscopic myomectomy for fibroids ≥ 5cm **Groups:** NA **N at enrollment:** 144 **N at follow-up:** NR **Age, mean yrs:** 33.7 (22 to 41) **Race/ethnicity:** NR **Parity, parous, N (%):** Nulligravida: 98 (60.5) **Baseline Hgb/Hct:** NR	**Inclusion criteria:** • Undergoing laparoscopic myomectomy **Exclusion criteria:** NR **Indications, N (%):** • Infertility: 102 (70.8) • Abnormal bleeding: 98 (68) • Pain: 64 (44.4) • More than 1 symptom: 81 (56.2) **Pre-operative therapy:** None **Associated procedure(s), N (%):** • Lysis: 24 (16.6) • Tubal plasty: 6 (4.16) • Appendectomy: 5 (3.47) • Ovarian cystectomy: 4 (2.77) • Coagulation of endometriosis: 3 (2.08)	**Baseline uterine size:** NR **Fibroids removed, N (%):** 1: 84 (58.33) 2: 35 (24.3) 3: 17 (11.8) 4: 6 (4.17) **Baseline dominant fibroid size, mean cm (range):** 7.8 (5 to 18) **Type of fibroid, N (%):** • Interstitial submucous: 108 (75) • Subserous sessile: 15 (10.4) • Pedunculated: 7 (4.86) • Intraligamentous: 14 (9.7)	**Operative time, mean min (range):** 85 (58 to 180) **Conversion to laparotomy, N (%):** 2 (1.39) **Transfusion, N (%):** 1 (0.69) **Length of stay, days (range):** 2.6 (2 to 5) **Intramural hematoma, N (%):** 1 day post-op: 108 (75) 2 day post-op: 14 (9.7) **Pregnancy rate N (%)*:** 26 in 21 patients (25%) Spontaneous: 20 After IVF: 1 **Live birth, N:** 21 **Cesarean delivery, N:** 12/21 **Vaginal delivery, N:** 9/21 **Uterine rupture, N:** 0 **Miscarriage, N:** 4/26 **Ectopic pregnancy, N:** 1/26 **Pregnancy rate, 1997, N (%):** 6-mon: 13/38 (34.21) 12-mon: 21/38 (55.26) **Adhesions at 2nd-look, N (%):** 6/18 (33) **Severity of adhesions, N (%):** Type 1: 4 (22.2) Type 2: 2 (11.1) Type 3: 0 **Modifiers:** NR	**Quality:** Overall quality score: fair **INTERNAL VALIDITY: fair** Random: NA Methods and blinding: NA Pt selection criteria: + Loss to follow-up: NA Drop-out rates: NA Statistical issues: - **EXTERNAL VALIDITY: fair (1)** Age: +, reported Race: NA, not US study Pregnancy history: +, reported Surgical history: -, NR Fibroid/uterine size: + Number of fibroids: + Location of fibroids: + Baseline characteristics: +, reported Length of follow-up: + Measurement methods: + Measurement reliability: + Clinical care: +

Evidence Table 10. KQ 3 Reproductive outcomes (continued)

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria Other Details	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author: Seracchioli et al., 2000 **Country and setting:** Italy, Academic medical center **Enrollment period:** 01/1993 to 01/1998 **Funding:** NR	**Design:** RCT **Intervention:** Myomectomy **Groups:** **G1:** Abdominal myomectomy **G2:** Laparoscopic myomectomy **N at enrollment:** **G1:** 65 **G2:** 66 **N at follow-up:** **G1:** 59 **G2:** 56 **Age, yrs ± SD:** **G1:** 33.97 ± 4.79 **G2:** 34.00 ± 4.11 **Race/ethnicity:** NR **Parity:** See fertility status **Baseline Hgb/Hct:** NR	**Inclusion criteria:** • Fibroid(s) ≥ 5 cm • Infertility **Exclusion criteria:** • Pedunculated fibroids • Uterine size above umbilicus • > 3 fibroids of > 5 cm size • Other causes of infertility **Indications for LM, N (%):** • Primary infertility: 87 (66.4) • Secondary infertility: 44 (33.6) **Preoperative therapy:** None **Associated procedure(s):** NR	**Baseline uterine size:** NR **Number of fibroids, mean ± SD:** **G1:** 2.75 ± 1.98 **G2:** 2.94 ± 1.53 **Baseline size of largest fibroid (cm ± SD):** **G1:** 7.47 ± 2.60 **G2:** 7.07 ± 2.54 **Type of fibroid, N (%):** Subserosal: **G1:** 19 (44.2) **G2:** 24 (55.8) Intramural: **G1:** 54 (52.9) **G2:** 48 (47.1) "Reaching Cavity": **G1:** 5 (9.2) **G2:** 2 (4.1)	**Operative time, min ± SD:** **G1:** 88.85 ± 26.91 **G2:** 100.23 ± 38.34 **Conversion to laparotomy, N (%):** **G1:** NA **G2:** 3 (4.3) **Intra-operative complications:** None **Decrease in Hgb:** **G1:** 2.17 ± 1.57 **G2:** 1.33 ± 1.23 *P* < 0.001 **Transfusion, N:** **G1:** 3 **G2:** 0 **Fever > 38° C, N (%):** **G1:** 17 (26.2) **G2:** 8 (12.1) **Length of stay, hrs ± SD:** **G1:** 142.80 ± 34.60 **G2:** 75.61 ± 37.09 **Antibiotic Rx, N (%):** **G1:** 17 (26.2) **G2:** 8 (12.1) **Pregnancy rate, N (%):** **G1:** 33/59 (55.9) **G2:** 30/56 (53.6) **Miscarriage, N (%):** **G1:** 4 (12.1) **G2:** 6 (20.0) **Ectopic:** **G1:** 0 **G2:** 1 **Births:** **G1:** 27/59 **G2:** 20/56	**Quality:** Overall quality score: fair **INTERNAL VALIDITY: fair** Random: + Methods and blinding: NA Pt selection criteria: ++ Loss to follow-up: 10-20% Drop-out rates: NA Statistical issues: + **EXTERNAL VALIDITY: fair (1)** Age: +, reported Race: NA, not US study Pregnancy history: +, reported Surgical history: -, NR Fibroid/uterine size: + Number of fibroids: + Location of fibroids: + Baseline characteristics: +, reported Length of follow-up: + Measurement methods: + Measurement reliability: + Clinical care: +

Evidence Table 10. KQ 3 Reproductive outcomes (continued)

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria Other Details	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author: Seracchioli et al., 2000 (continued)				**Preterm births, N (%):** **G1:** 2 (7.4) **G2:** 1 (5.0) **Cesarean rate, N (%):** **G1:** 21 (77.8) **G2:** 13 (65.0) **Uterine Rupture:** 0 **Fibroid recurrence, by US every 6 mos, N (%):** **G1:** 12 (20.3) **G2:** 12 (21.4) **Subsequent treatment, N:** **G1:** Myomectomy: 3 Hysterectomy: 1 **G2:** 0 **Modifiers:** NR	

Evidence Table 11. KQ3 Preventing further growth

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria Other Details	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author: Colacurci et al., 2000 **Country and setting:** Italy, Academic medical center **Enrollment period:** 01/1995 to 01/1998 **Funding:** NR	**Design:** Prospective cohort **Intervention:** Hormone therapy **Groups:** **G1:** Single asymptomatic fibroid < 3 cm/14 cm³ **G2:** Single asymptomatic fibroid > 3 cm/14 cm³ **G3:** No uterine fibroids **N at enrollment:** **G1:** 20 **G2:** 20 **G3:** 20 **N at follow-up:** **G1:** 15 **G2:** 18 **G3:** 20 **Age, yrs ± SD:** **G1:** 51.4 ± 2.87 **G2:** 51.3 ± 2.59 **G3:** 51.2 ± 2.26 **Race/ethnicity:** NR **Parity:** NR **Baseline Hgb/Hct:** NR	**Inclusion criteria:** • <57 yr • Amenorrheic 12-36 mos • Subserosal or intramural fibroid • Menopausal status confirmed by FSH > 30 IU/l and estradiol < 30 pg/ml • No previous HRT **Exclusion criteria:** • Submucosal fibroid • Liver disease • Heart disease • Hypercholes-terolemia • Severe hypertension • Estrogen dependent/ breast cancer • High alcohol intake • Cigarette smoking > 20/day • BMI >28 **Indications:** NR **Preoperative therapy:** NR **Associated procedure(s):** NR	**Baseline uterine size:** NR **Number of fibroids:** See Groups **Baseline fibroid size (cm³ ± SD):** **G1/G2:** 24.14 ± 20.02 **G3:** NA **Type of fibroid, N:** Subserosal: 26 Intramural: 14	**Fibroid size at 1 year, cm^3 ± SD:** **G1/G2:** 28.81 ± 30.02 **Modifiers:** NR	**Quality:** Overall quality score: fair **INTERNAL VALIDITY: fair** Random: NA Methods and blinding: NA Pt selection criteria: ++ Loss to follow-up: 10-20% Drop-out rates: NR Statistical issues: + **EXTERNAL VALIDITY: fair (2)** Age: +, reported Race: NA, not US study Pregnancy history: -, NR Surgical history: NA Fibroid/uterine size: + Number of fibroids: + Location of fibroids: + Baseline characteristics: -, NR Length of follow-up: ++ Measurement methods: + Measurement reliability: + Clinical care: +

Evidence Table 11. KQ3 Preventing further growth (continued)

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria Other Details	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author: Gregoriou et al., 2001 **Country and setting:** Greece, Academic medical center **Enrollment period:** 04/1996 to 04/1997 **Funding:** NR	**Design:** Prospective cohort **Intervention:** Administration of Tibolone in postmenopausal women **Groups:** **G1:** Asymptomatic, intramural or subserous fibroid with diameter ≤ 2cm **G2:** Asymptomatic, intramural or subserous fibroid with diameter >2cm to ≤ 5cm **G3:** Women without any detectable fibroids **N at enrollment:** **G1:** 23 **G2:** 23 **G3:** 20 **N at follow-up:** **G1:** 23 **G2:** 23 **G3:** 20 **Age, yrs ± SD:** **G1:** 51.1 ± 2.84 **G2:** 50.2 ± 2.32 **G3:** 50.5 ± 2.61 **Race/ethnicity:** NR **Parity, parous, %:** **G1:** 84.3% **G2:** 85% **G3:** 85% **Baseline Hgb/Hct:** NR	**Inclusion criteria:** • Age ≤ 54 yrs • No menses ≥ 18 mos • No contra-indication for HRT • Endometrial thickness ≤ 4 cm • No other medication for at least 6 mos prior to recruitment • Alcohol intake < 5 units/week • Non-smoker • BMI < 28 **Exclusion criteria:** NR **Indications:** NR **Pre-operative therapy:** NA **Associated procedure(s):** NR	**Baseline uterine size:** NR **Number of fibroids:** NR **Baseline fibroid size, mean volume ± SD:** **G1:** 15.8 ± 1.4 **G2:** 28.2 ± 1.6 **Type of fibroid:** NR	**No change in fibroid volume, N (%):** **G1:** 21 (91.3) **G2:** 20 (86.9) **Increase in fibroid volume, N (%):** **G1:** 2 (8.7) **G2:** 3 (13.1) **Percent increase in fibroid volume, 12 mos:** **G1:** 5.2% **G2:** 9.2% **Percent increase in fibroid volume, 24 mos:** **G1:** 6.1% **G2:** 10.3% **Modifiers:** NR	**Quality:** Overall quality score: good **INTERNAL VALIDITY: good** Random: NA Methods and blinding: NA Pt selection criteria: ++ Loss to follow-up: <10% Drop-out rates: <5% Statistical issues: + **EXTERNAL VALIDITY: good** Age: +, reported Race: NA, not US study Pregnancy history: +, reported Surgical history: NA Fibroid/uterine size: + Number of fibroids: + Location of fibroids: + Baseline characteristics: +, reported Length of follow-up: ++ Measurement methods: + Measurement reliability: + Clinical care: +

Evidence Table 11. KQ3 Preventing further growth (continued)

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria, Other Details	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author: Palomba, Sena, et al., 2001 **Country and setting:** Italy, Academic medical center **Enrollment period:** NR **Funding:** NR	**Design:** Prospective cohort **Intervention:** Transdermal estradiol (E_2) and Medroxyprogest-erone Acetate (MPA) **Groups:** **G1:** women with fibroids, 50 µg/day transdermal E_2 + 2.5 mg/day MPA X 12 cycles **G2:** women with fibroids, 1 tablet calcium carbonate per day X 12 cycles **G3:** women without fibroids, 50 µg/day transdermal E_2 + 2.5 mg/day MPA X 12 cycles **N at enrollment:** **G1:** 35 **G2:** 35 **G3:** 35 **N at follow-up:** **G1:** 31 **G2:** 31 **G3:** 30 **Age, yrs ± SD:** **G1:** 53.8 ± 3.8 **G2:** 52.4 ± 3.7 **G3:** 54 ± 3.8 **Race/ethnicity:** NR **Parity. mean ± SD:** **G1:** 2.1 ± 1.7 **G2:** 2.2 ± 1.6 **G3:** 2.1 ± 1.7 **Baseline Hgb/Hct:** NR	**Inclusion criteria:** • Natural menopause for 1 to 2 yrs • 1 to 2 intramural or subserosal uterine fibroids, with at least one >2 cm **Exclusion criteria:** • Neoplastic, metabolic or infectious diseases • Vascular thrombosis • BMI > 30 • Hormonal therapy in prior 6 mos • Endometrial abnormalities by ultrasound • Endometrial thickness > 5 mm • Hypoechoic or calcified fibroids **Indications:** NR **Preoperative therapy:** NR **Associated procedure(s):** NR	**Baseline uterine size, cm³ ± SD:** **G1:** 313.1 ± 83.9 **G2:** 327.7 ± 89.9 **G3:** NA **Number of fibroids:** NR **Baseline fibroid size, cm³ ± SD:** **G1:** 141.7 ± 37.8 **G2:** 150.3 ± 58.7 **G3:** NA **Type of fibroid:** NR	**Fibroid size** 3rd cycle, cm³ ± SD: **G1:** 143.9±38.8 **G2:** 153.1±62.1 *P* = NS 6th cycle, cm³ ± SD: **G1:** 146.6±45.5 **G2:** 155.3±64.7 *P* = NS 9th cycle, cm³ ± SD: **G1:** 147.1±49.1 **G2:** 155.4±68.6 *P* = NS 12th cycle, cm³ ± SD: **G1:** 147.5±53.3 **G2:** 156.0±72.5 *P* = NS No significant difference in bleeding patterns between G1 and G2 Amenorrhea, at cycle 3, G1 and G3 less prevalent that G2 ($P < 0.05$) Abnormal uterine bleeding episodes at cycle 3, G1 and G3 more severe than G2 ($P < 0.05$) By 6th, 9th, and 12th treatment cycles bleeding pattern was not significantly different between 3 groups **Modifiers:** NR	**Quality:** Overall quality score: fair **INTERNAL VALIDITY: fair** Random: NA Methods and blinding: NA Pt selection criteria: ++ Loss to follow-up: <10% Drop-out rates: 5-10% Statistical issues: + **EXTERNAL VALIDITY: fair (3)** Age: +, reported Race: NA, not US study Pregnancy history: +, reported Surgical history: -, NR Fibroid/uterine size: + Number of fibroids: - Location of fibroids: - Baseline characteristics: +, reported Length of follow-up: ++ Measurement methods: + Measurement reliability: + Clinical care: +

Evidence Table 11. KQ3 Preventing further growth (continued)

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author: Polatti et al., 2000 **Country and setting:** Italy, Academic medical center **Enrollment period:** 01/1996 to 01/1997 **Funding:** NR	**Design:** RCT **Intervention:** Hormonal therapy in postmenopausal women **Groups:** **G1:** No fibroids - oral combination of EV 2 mg and CA 1 mg 21 days **G2:** No fibroids - transdermal E_2 50µg 21 days and oral MPA 10 mg/day days 10-21 **G3:** With fibroids - oral combination of EV 2 mg and CA 1 mg 21 days **G4:** With fibroids - transdermal E_2 50µg 21 days and oral MPA 10 mg/day days 10-21 **N at enrollment:** **G1:** 80 **G2:** 80 **G3:** 40 **G4:** 40 **N at follow-up:** **G1:** 76 **G2:** 74 **G3:** 38 **G4:** 36 **Age, yrs ± SD:** **G1:** 51 ± 1.8 **G2:** 52 ± 1.4 **G3:** 51 ± 1.6 **G4:** 52 ± 1.5 **Race/ethnicity:** NR **Parity:** NR **Baseline Hgb/Hct:** NR	**Inclusion criteria:** • Menopause > 12 mos • 49 to 54 yrs of age • No prior hormonal therapy in 12 mos • No contra-indications to HRT • Endometrial thickness ≤ 4mm **Exclusion criteria:** NR **Indications:** NR **Pre-operative therapy:** NA **Associated procedure(s):** NA	**Baseline uterine size, cm^3 ± SD:** **G1:** 60 ± 10 **G2:** 64 ± 9 **G3:** 64 ± 10 **G4:** 62 ± 9 **Number of fibroids:** NR **Baseline fibroid size(cm^3 ± SD):** **G1:** NA **G2:** NA **G3:** 18.6 ± 1.4 **G4:** 19.3 ± 1.3 **Type of fibroid:** NR	**Uterine volume at 12 mos, cm^3 ± SD:** **G1:** 66 ± 8 **G2:** 70 ± 9 **G3:** 68 ± 9 **G4:** 69 ± 7 **Uterine volume at 24 mos, cm^3 ± SD:** **G1:** 66 ± 7 **G2:** 71 ± 8 **G3:** 69 ± 7 **G4:** 70 ± 8 **Fibroid Volume at 12 mos, cm^3 ± SD:** **G1:** NA **G2:** 25.4 ± 1.2* **G3:** 19.2±1.1 **G4:** 23.8±0.9, *P* < 0.01 **Fibroid Volume at 24 mos, cm^3 ± SD:** **G1:** NA **G2:** 26.2 ± 1.1* **G3:**19.5±1.1 **G4:**24.2±0.8, *P* < 0.01 *Four women in G2 developed fibroids **Modifiers:** NR	**Quality:** Overall quality score: poor **INTERNAL VALIDITY: poor** Random: + Methods and blinding: - Pt selection criteria: + Loss to follow-up: <10% Drop-out rates: >10% Statistical issues: + **EXTERNAL VALIDITY: poor (4)** Age: +, reported Race: NA, not US study Pregnancy history: -, NR Surgical history: NA Fibroid/uterine size: + Number of fibroids: - Location of fibroids: - Baseline characteristics: -, NR Length of follow-up: ++ Measurement methods: + Measurement reliability: + Clinical care: +

Evidence Table 11. KQ3 Preventing further growth (continued)

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria Other Details	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author: Reed et al., 2004 **Country and setting:** US, Community **Enrollment period:** 03/1994 to 06/1998 **Funding:** NR	**Design:** Retrospective case control **Intervention:** NA **Groups:** **G1:** Fibroids **G2:** No fibroids **N at enrollment:** **G1:** 256 **G2:** 276 **N at follow-up:** NA **Age, N (%):** **G1:** 40 to 44: 43 (16.8) 45 to 49: 98 (38.3) 50 to 54: 75 (29.3) 55 to 59: 40 (15.6) **G2:** 40 to 44: 39 (14.1) 45 to 49: 107 (38.8) 50 to 54: 92 (33.3) 55 to 59: 38 (13.8) **Race/ethnicity, N (%):** **G1:** White: 210 (82) Black: 15 (5.9) Hispanic: 14 (5.5) Asian: 13 (5.1) Other: 4 (1.5) **G2:** White: 233 (84.4) Black: 7 (2.5) Hispanic: 9 (3.3) Asian: 25 (8.3) Other: 4 (1.5) **Parity, N (%):** **G1:** 0: 54 (21.1) 1: 48 (18.8) 2: 91 (35.6) 3+: 63 (24.5) **G2:** 0: 55 (19) 1: 49 (17.9) 2: 106 (38.4) 3+: 66 (23.8)	**Inclusion criteria:** • No history of uterine fibroids • Myomectomy • Hysterectomy • Age: 40 to 59 yrs **Exclusion criteria:** • Having menstrual periods • Using unopposed postmenopausal estrogen therapy for at least 3 mos in the preceding 5 yr • Unopposed progestin use for at least 3 mos in past 5 yr **Indications:** NA **Pre-operative therapy:** None **Associated procedure(s):** N/A	**Baseline uterine size:** NR **Number of fibroids:** NR **Baseline fibroid size:** NR **Type of fibroid:** NR	Estrogen and progestogen therapy use > 5 yr was associated with a 1.7-fold increased risk of leiomyomas (95% CI; 0.9-3.3). Statistically significant associations with estrogen and progestogen therapy use were only present among women with a body mass index less than 24 kg/m^2; OR (ever-use), 2.3 (95% CI, 1.2-4.3); and OR (≥ 5 yr use), 4.0 (95% CI, 1.6-10.3) **Other Modifiers:** NR	**Quality:** Overall quality score: poor **INTERNAL VALIDITY: poor** Random: NA Methods and blinding: NA Pt selection criteria: + Loss to follow-up: >20% Drop-out rates: >10% Statistical issues: + **EXTERNAL VALIDITY: poor (6)** Age: +, reported Race: +, reported Pregnancy history: +, reported Surgical history: NA Fibroid/uterine size: + Number of fibroids: - Location of fibroids: - Baseline characteristics: -, NR Length of follow-up: NA Measurement methods: - Measurement reliability: - Clinical care: -

Evidence Table 11. KQ3 Preventing further growth (continued)

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria Other Details	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author: Reed et al., 2004 (continued)	**Baseline Hgb/Hct:** NR				

Evidence Table 12. KQ 4 Costs

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria and Other Details	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author: Baker et al., 2002 **Country and setting:** US, Academic medical center **Enrollment period:** 2001 **Funding:** NR	**Design:** Retrospective cohort **Intervention:** UAE and abdominal myomectomy **Groups:** **G1:** UAE **G2:** Abdominal myomectomy **N at enrollment:** **G1:** 23 **G2:** 17 **N at follow-up:** NA **Age, yrs ± SD:** **G1:** 42.6 ± 4.4 **G2:** 35.5 ± 4.6 *P* < 0.001 **Race/ethnicity:** NR **Parity:** NR **Baseline Hgb/Hct:** NR	**Inclusion criteria:** • Women > age 21 yr • Had UAE or myomectomy in 2001 for symptomatic fibroids **Exclusion criteria:** NR **Indications:** NA **Preoperative therapy:** NA **Additional procedures:** NA	**Baseline uterine size:** NR **Number of fibroids:** NR **Baseline fibroid size:** NR **Type of fibroid:** NR	**Total professional costs, (N):** **G1:** $2,220 (19) **G2:** $1,611 (9) *P* < 0.002 **Total hospital costs, (N):** **G1:** $3,193 (16) **G2:** $5,598 (16) *P* < 0.0001 **Total costs without imaging, (N):** **G1:** $5,371 (12) **G2:** $7,401 (8) *P* < 0.0001 **Total costs with imaging, (N):** **G1:** $6,708 (12) **G2:** $7,630 (8) *P* = 0.086 **Modifiers:** NR	**Quality:** Overall quality score: poor **INTERNAL VALIDITY: poor** Random: NA Methods and blinding: NA Pt selection criteria: - Loss to follow-up: NA Drop-out rates: NA Statistical issues: - **EXTERNAL VALIDITY: poor (8)** Age: +, reported Race: -, NR Pregnancy history: -, NR Surgical history: -, NR Fibroid/uterine size: - Number of fibroids: - Location of fibroids: - Baseline characteristics: -, NR Length of follow-up: NA Measurement methods: + Measurement reliability: + Clinical care: -

Evidence Table 12. KQ 4 Costs (continued)

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author: Beinfeld et al., 2002 **Country and setting:** US, Academic medical center **Enrollment period:** 10/1998 to 03/2001 **Funding:** NR	**Design:** Retrospective cohort **Intervention:** UAE vs. hysterectomy **Groups:** **G1:** UAE **G2:** Hysterectomy **N at enrollment:** **G1:** 57 **G2:** 300 **N at follow-up:** NA **Age, yrs ± SD:** **G1:** 43.1 ± 4.9 **G2:** 47.0 ± 6.8 *P* < 0.0001 **Race/ethnicity, %:** White **G1:** 69.6 **G2:** 77.0 Black **G1:** 28.6 **G2:** 14.2 Hispanic **G1:** 0 **G2:** 7.0 Asian **G1:** 1.8 **G2:** 1.7 *P* = 0.01 **Parity:** NR **Baseline Hgb/Hct:** NR	**Inclusion criteria:** • Patients with principal diagnosis of uterine fibroids • Principle procedure of hysterectomy based on ICD-9 codes **Exclusion criteria:** • Patients whose costs were > 3 SD above mean hospital costs **Indications:** NR **Preoperative therapy:** NR **Additional procedures:** NR	**Baseline uterine size:** NR **Number of fibroids, N ± SD:** **G1:** 2.8 ± 1.4 **G2:** 2.0 ± 1.1 *P* < 0.0001 **Baseline largest fibroid size, cm ± SD:** **G1:** 8.0 ± 3.0 **G2:** 6.3 ± 3.2 *P* = 0.001 **Type of largest fibroid, N (%):** Intramural: **G1:** 32 (72.3) **G2:** 171 (62.0) Submucosal: **G1:** 9 (19.2) **G2:** 52 (18.9) Subserosal: **G1:** 4 (8.5) **G2:** 53 (19.2) *P* = 0.18	**Complications, N (%):** **G1:** 2 (3.9) **G2:** 12 (4.8) *P* = 1.0 **Length of stay, days ± SD:** **G1:** 0.95 ± 0.4 **G2:** 2.6 ± 1.0 *P* < 0.0001 **Cost, $ ± SD:** **G1:** $8,223 ± 1,834 **G2:** $6,046 ± 1,589 *P* < 0.0001 **Modifiers:** NR	**Quality:** Overall quality score: poor **INTERNAL VALIDITY: poor** Random: NA Methods and blinding: NA Pt selection criteria: - Loss to follow-up: NA Drop-out rates: NA Statistical issues: - **EXTERNAL VALIDITY:poor (5)** Age: +, reported Race: +, reported Pregnancy history: -, NR Surgical history: -, NR Fibroid/uterine size: + Number of fibroids: + Location of fibroids: + Baseline characteristics: -, NR Length of follow-up: NA Measurement methods: + Measurement reliability: + Clinical care: -

Evidence Table 12. KQ 4 Costs (continued)

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria Other Details	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author: Subramanian et al., 2001 **Country and setting:** US, Database **Enrollment period:** 1995 to 1997 **Funding:** NR	**Design:** Retrospective cohort **Intervention:** Myomectomy **Groups:** **G1:** Hysteroscopy **G2:** Laparoscopy **G3:** Abdominal **N at enrollment:** 4394 **N at follow-up:** 1 year: 820 2 yr: 236 **Age, mean yrs:** 42 **In/Outpatient:** **G1:** 42.8/43.6 **G2:** 39.5/36.9 **G3:** 37.0/N/A **Race:** NR **Parity:** NR **Baseline Hgb/Hct:** NR	**Inclusion criteria:** • Inpatient and outpatient claims containing Current Procedural Terminology, 4th edition (CPT-4) codes for hysteroscopic (56354, 58145), laparoscopic (56309), or abdominal (58140) myomectomies or the International Classification of Diseases, 9th Revision, Clinical Modification (ICD-9-CM) procedure code for all types of myomectomies (68.29) **Exclusion criteria:** • Hysterectomy conversion **Indications:** NR **Preoperative therapy:** NR **Type of fibroid:** NR	**Baseline uterine size:** NR **Number of fibroids:** NR **Baseline fibroid size:** NR **Type of fibroid:** NR	**Conversion to open myomectomy, %:** **G1:** 7.4 **G2:** 13.3 **G3:** NA **Conversion to hysterectomy, %:** **G1:** 1.5 **G2:** 2.8 **G3:** 3.7 **Length of stay, mean days:** **G1:** 2.20 **G2:** 2.25 **G3:** 2.91 **Reoperation, 1 year, %:** **G1:** 14.4 **G2:** 12.3 **G3:** 7.2 **Cost ($)** **In/Outpatient:** **G1:** 7,704/4,291 **G2:** 8,018/7,357 **G3:** 8,860/N/A **Modifiers:** NR	**Quality:** Overall quality score: poor **INTERNAL VALIDITY: poor** Random: NA Methods and blinding: NA Pt selection criteria: - Loss to follow-up: NA Drop-out rates: >10% Statistical issues: - **EXTERNAL VALIDITY: poor (8)** Age: +, reported Race: -, NR Pregnancy history: -, NR Surgical history: -, NR Fibroid/uterine size: - Number of fibroids: - Location of fibroids: - Baseline characteristics: -, NR Length of follow-up: NA Measurement methods: + Measurement reliability: - Clinical care: -

Evidence Table 13. KQ 5 Modifiers of outcomes

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria Other Details	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author: Doridot et al., 2001 **Country and setting:** France, Academic medical center **Enrollment period:** 03/1989 to 12/1996 **Funding:** NR	**Design:** Retrospective case series **Intervention:** Laparoscopic myomectomy **Groups:** NA **N at enrollment:** 196 **N at follow-up:** 173 **Age, yrs ± SD (range):** 36.6 ± 6.6 (18 to 54) **Race/ethnicity:** NR **Parity, N (%):** 0: 143 (72.9) 1: 40 (20.4) 2: 10 (5.1) 3: 3 (1.5) **Baseline Hgb/Hct:** NR	**Inclusion criteria:** • Women undergoing laparoscopic myomectomy **Exclusion criteria:** NR **Indications, N (%):** • Pain: 51 (26) • Menometrorrhagia: 45 (23) • Infertility: 63 (32.1) • Size: 32 (16.3) • Pressure: 3 (1.5) • Recurrent miscarriage: 2 (1) **Pre-operative therapy:** GnRH agonist, N (%): • No: 122 (70.5) • Yes: 51 (29.5) **Associated procedure(s):** NR	**Baseline uterine size:** NR **Number of fibroids, N (%):** 1: 114 (58.1) 2: 36 (18.4) ≥ 3: 46 (23.5) **Baseline fibroid size (mm), N (%):** < 50: 86 (43.9) 50 to 70: 67 (34.2) ≥ 70: 43 (21.9) **Type of fibroid, N (%):** • Intramural: 74 (37.8) • Subserous: 97 (49.5) • Pedunculated: 25 (12.8)	**Recurrence rate, N (%):** 45 (22.9%) **Mean recurrence time, mos ± SD:** 42 ± 22 (4-95) **Recurrence requiring surgery, N (%):** 8 (4.6) **Second operative procedures, N:** LM: 3 Myomectomy by laparotomy: 1 Hysterectomy by laparotomy: 4 **Cumulative risk of recurrence:** At 2 yr: 12.7% At 5 yr: 16.7% **Modifiers:** Nulliparity, %: At 2 yr: 12.8% At 5 yr: 47.6% *P* = 0.0025 Multivariate analysis of recurrence risk: • Nulliparity: *P* = 0.004; 95% CI, 1.4-8.7 • > 1 fibroid: *P* = 0.05; 95% CI, 0.27-0.98	**Quality:** Overall quality score: fair **INTERNAL VALIDITY: fair** Random: NA Methods and blinding: NA Pt selection criteria: + Loss to follow-up: 10-20% Drop-out rates: NA Statistical issues: + **EXTERNAL VALIDITY: good** Age: +, reported Race: NA, not US study Pregnancy history: +, reported Surgical history: -, NR Fibroid/uterine size: + Number of fibroids: + Location of fibroids: + Baseline characteristics: +, reported Length of follow-up: ++ Measurement methods: + Measurement reliability: + Clinical care: +

Evidence Table 13. KQ 5 Modifiers of outcomes (continued)

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria and Other Details	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author: Ferrari et al., 2000 **Country and setting:** Italy, Academic medical center **Enrollment period:** NR **Funding:** NR	**Design:** RCT **Intervention:** Hysterectomy **Groups:** **G1:** Laparoscopically assisted vaginal hysterectomy **G1a:** Uterus ≤ 500 g **G1b:** Uterus > 500 g **G2:** Total abdominal hysterectomy **G2a:** Uterus ≤ 500 g **G2b:** Uterus > 500 g **N at enrollment:** **G1:** 31 **G2:** 31 **N at follow-up:** **G1:** 31 **G1a:** 20 **G1b:** 11 **G2:** 31 **G2a:** 21 **G2b:** 10 **Age (mean, range):** **G1:** 48 (46 to 49) **G2:** 46 (43 to 50) **Race Ethnicity:** NR **Parity, parous, N (%):** Nulliparous: **G1:** 5 (16) **G2:** 7 (23) **Baseline Hgb/Hct:** NR	**Inclusion criteria:** NR **Exclusion criteria:** NR **Indications:** NR **Preoperative therapy:** NR **Additional procedures:** Bilateral salpingo-oophorectomy, N (%) **G1:** 19 (61) **G2:** 21 (68)	**Baseline uterine size, mean ml (range):** **G1:** 388 (257 to 520) **G2:** 370 (243 to 463) **Number of fibroids:** NR **Baseline fibroid size:** NR **Type of fibroid:** NR	**Operative time, mean min:** **G1:** 135 (115-173) **G2:** 120 (98-123) *P* = 0.001 **Conversion to laparotomy, N:** **G1:** 3 **G2:** NA **Decrease in Hgb, mean g/dL:** **G1:** 1.1 (0.8-1.9) **G2:** 1.8 (0.7-2.5) *P* = NS **Transfusions, N (%):** **G1:** 0 **G2:** 1 (3) *P* = NS **Febrile morbidity (not defined), N (%):** **G1:** 1 (3) **G2:** 5 (16) *P* = NS **Pain medication use, N (%):** **G1:** 7 (23) **G2:** 24 (77) *P* < 0.001 **Length of stay, mean days (range):** **G1:** 3.8 (34 to 4.0) **G2:** 5.8 (5.3 to 6.3) *P* < 0.001 **Uterine weight, mean gm (range):** **G1:** 400 (263 to 590) **G2:** 400 (255 to 556) *P* = NS **Operating (mean min, range):** **G1b:** 150 (125 to 173) **G2b:** 108 (83 to 120) *P* = 0.002	**Quality:** Overall quality score: poor **INTERNAL VALIDITY: poor** Random: + Methods and blinding: - Pt selection criteria: - Loss to follow-up: NA Drop-out rates: <5% Statistical issues: + **EXTERNAL VALIDITY: fair (3)** Age: +, reported Race: NA, not US study Pregnancy history: +, reported Surgical history: +, reported Fibroid/uterine size: + Number of fibroids: - Location of fibroids: - Baseline characteristics: -, NR Length of follow-up: NA Measurement methods: + Measurement reliability: + Clinical care: +

Evidence Table 13. KQ 5 Modifiers of outcomes (continued)

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria and Other Details	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author: Hanafi, 2005 **Country and setting:** US, Community **Enrollment period:** 01/1992 to 10/2002 **Funding:** NR	**Design:** Retrospective case series **Intervention:** Myomectomy by exploratory laporotomy **Groups:** NA **N at enrollment:** 154 **N at follow-up:** 132 **Age, median yr:** 36 (24 to 49) **Race/ethnicity:** NR **Parity, median:** 1 (0 to 6), 89% had not completed families **Baseline Hgb/Hct:** NR	**Inclusion criteria:** NR **Exclusion criteria:** NR **Indications, %:** • Menometrorrhagia: 91 • Dysmenorrhea: 82 • Dyspareunia: 41 • Noncyclic pelvic pain: 22 • Anemia: 3 • Infertility: 30 • No symptoms: 3 **Preoperative therapy:** None **Associated procedure(s):** NR	**Baseline uterine size, median:** 10 gestational weeks **Number of fibroids, N (%):** 1: 37 (26) > 1: 108 (74) **Baseline fibroid size, median gm (range):** 103 (8-590) (N=28) **Type of fibroid, N (%):** • Subserous: 34 (23) • Intramural or intramural/ subserous: 98 (68) • Submucous or intramural/ submucosal: 6 (4) • All locations: 7 (5)	**5 year cumulative probability:** Fibroid recurrence: 62% Any surgery for recurrence: 17% Major surgery for recurrence: 9% **Modifiers of fibroid recurrence:** Number of fibroids, %: 1 fibroid: 11 > 1 fibroid: 74 *P* = 0.011 Uterine size, %: ≤ 10 weeks: 46 > 10 weeks: 82 *P* = 0.03 Subsequent parity, %: 26 Without subsequent parity, %: 76 *P* = 0.010	**Quality:** Overall quality score: fair **INTERNAL VALIDITY: fair** Random: NA Methods and blinding: NA Pt selection criteria: - Loss to follow-up: <10% Drop-out rates: <5% Statistical issues: + **EXTERNAL VALIDITY: fair (3)** Age: +, reported Race: +, reported Pregnancy history: +, reported Surgical history: -, NR Fibroid/uterine size: + Number of fibroids: + Location of fibroids: - Baseline characteristics: +, reported Length of follow-up: ++ Measurement methods: + Measurement reliability: + Clinical care: -

Evidence Table 13. KQ 5 Modifiers of outcomes (continued)

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria Other Details	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author: Huang et al. 2006 **Country and setting:** Canada, Academic medical center **Enrollment period:** 11/1997 to 02/2004 **Funding:** NR	**Design:** Retrospective case series **Intervention:** UAE **N at enrollment:** 233 **N at follow-up:** 233 **Age:** NR **Race/ethnicity:** NR **Parity:** NR **Baseline Hgb/Hct:** NR	**Inclusion criteria:** • Consecutive UAE patients **Exclusion criteria:** NR **Indications, N:** • Menorrhagia: 125 • Abdominal distension: 59 • Abdominal/pelvic pain: 38 **Preoperative therapy:** NR **Associated procedure(s):** NR	**Baseline uterine size, cm^3:** 531.5 **Number of fibroids:** NR **Baseline dominant fibroid size, cm^3:** 201.4 **Type of fibroid:** NR	**UAE Failure** (persistent or recurrent bleeding, pain, or bulk systems with repeat UAE, myomectomy, and/or hysterectomy)**, N (%):** Total: 22 (9.4) Hysterectomy: 16 (6.9) Myomectomy: 6 (2.6) **Modifiers:** Baseline fibroid size (cm^3): Failed: 355.2 Succeeded: 183.8 *P* = NS Baseline uterine size, cm^3: Failed: 590.2 Succeeded: 525.3 *P* = NS Prior myomectomy Failed: 13% vs. Succeeded: 2.4%, *P* < 0.05 Fibroid volume reduction at 6 mos, %: Failed: 54.4 Succeeded: 36.0 *P* < 0.05	**Quality:** Overall quality score: poor **INTERNAL VALIDITY: poor** Random: NA Methods and blinding: NA Pt selection criteria: - Loss to follow-up: NA Drop-out rates: NA Statistical issues: - **EXTERNAL VALIDITY: poor (5)** Age: +, reported Race: -, NR Pregnancy history: -, NR Surgical history: +, reported Fibroid/uterine size: + Number of fibroids: - Location of fibroids: - Baseline characteristics: +, reported Length of follow-up: + Measurement methods: + Measurement reliability: - Clinical care: +

Evidence Table 13. KQ 5 Modifiers of outcomes (continued)

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria Other Details	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author: Katsumori et al., 2003 **Country and setting:** Japan, Community **Enrollment period:** 2002 **Funding:** NR	**Design:** Retrospective case series **Intervention:** UAE **Groups:** **G1:** Fibroid ≥ 10 cm **G2:** Fibroid < 10 cm **N at enrollment:** **G1:** 47 **G2:** 105 **N at follow-up:** 30 days: 152 > 4 mos: 134 > 12 mos: 96 > 24 mos: 49 **Age:** 42.5 (31 to 52) **Race/ethnicity:** NR **Parity:** NR **Baseline Hgb/Hct:** NR	**Inclusion criteria:** • Pre-menopausal • At least 1 clinical symptom uncontrolled by medication **Exclusion criteria:** • Desire future pregnancy • Refused major surgery **Indications:** Symptomatic fibroids **Pre-operative therapy:** NR **Associated procedure(s):** NR	**Baseline uterine size, ml ± SD:** **G1:** 1,380 ± 500 **G2:** 684 ± 337 *P* < 0.001 **Number of fibroids:** NR **Baseline fibroid size, diameter of largest, cm ± SD:** **G1:** 12.4 ± 2.2 **G2:** 6.8 ± 2.0 *P* < 0.001 **Largest fibroid volume (ml ± SD):** **G1:** 701 ± 336 **G2:** 154 ± 107 *P* < 0.001 **Type of fibroid:** NR	**Procedure time, min ± SD:** **G1:** 55.3 ± 15.8 **G2:** 46.6 ± 14.3 **Length of stay, days ± SD:** **G1:** 4.0 ± 1.6 **G2:** 3.8 ± 0.8 **Minor complications N (%):** **G1:** 9 (19.1) **G2:** 16 (15.2) *P* = 0.637 **Major complications N (%):** **G1:** 3 (6.4) **G2:** 2 (1.9) *P* = 0.172 **Increased care, prolonged hospitalization, N (%):** **G1:** 2 (4.3) **G2:** 2 (1.9) **Symptom control, mean score ± SD:** Menorrhagia at 4 mos: **G1:** 3.36 ± 0.99 **G2:** 3.79 ± 0.55 *P* = 0.003 Menorrhagia at 1 yr: **G1:** 3.58 ± 0.50 **G2:** 3.79 ± 0.56 *P* = 0.022 Patient satisfaction at 4 mos: **G1:** 1.80 ± 0.46 **G2:** 1.97 ± 0.18 *P* = 0.004 Complete devascularization at 1 week, N (%): **G1:** 34 (72) **G2:** 94 (90) *P* = 0.007 **Modifiers:** NR	**Quality:** Overall quality score: poor **INTERNAL VALIDITY: fair** Random: NA Methods and blinding: NA Pt selection criteria: ++ Loss to follow-up: NA Drop-out rates: <5% Statistical issues: - **EXTERNAL VALIDITY: poor (4)** Age: +, reported Race: NA, not US study Pregnancy history: -, NR Surgical history: -, NR Fibroid/uterine size: + Number of fibroids: - Location of fibroids: - Baseline characteristics: +, reported Length of follow-up: ++ Measurement methods: + Measurement reliability: + Clinical care: +

Evidence Table 13. KQ 5 Modifiers of outcomes (continued)

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria Other details	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author: Kumakiri et al., 2005 **Country and setting:** Japan, Academic medical center **Enrollment period:** 01/1998 to 12/2002 **Funding:** NR	**Design:** Retrospective case series **Intervention:** Laparoscopic myomectomy **Groups:** NA **N at enrollment:** 108 **N at follow-up:** NA **Age, yrs ± SD:** 35.5 ± 3.5 **Race/Ethnicity:** NA **Parity, parous (N):** Multiparous: 10 **Baseline Hgb/Hct:** NR	**Inclusion criteria:** • Menorrhagia and abdominal fullness • Infertility • Fibroids ≥ 5 cm • Wishing to have children • Largest fibroid ≤ 12 cm • Uterus size ≤ 14 weeks gestation **Exclusion criteria:** See inclusion criteria **Indications, N:** Infertility: 59 Menorrhagia: 20 Dysmenorrhea: 17 Lower abdominal pain: 6 Other: 6 **Pre-operative therapy, N (%):** GnRH: 86 (79.6) **Associated procedure(s):** NR	**Baseline uterine size:** NR **Number of fibroids enucleated, mean ± SD:** Pregnancy: 3.2 ± 2.7 No pregnancy: 3.7 ± 3.6 *P* = 0.04 **Baseline largest fibroid size mm ± SD:** Pregnancy: 67.5 ± 16.9 No pregnancy: 62.3 ± 16.3 *P* = 0.004 **Type of fibroid:** NR	**Operative time, min ± SD:** Pregnancy: 105.3 ± 45.3 No pregnancy: 106.0 ± 51.5 *P* =0.75 **Mean estimated blood loss, ml ± SD:** Pregnancy: 85.2 ± 105.8 No pregnancy: 120.3 ± 174.5 *P* =0.53 **Pregnancy success rate, N (%):** 40/108 (37) **Spontaneous pregnancies, N (%):** 40/47 (85.1) **ART pregnancies, N (%);** 7/47 (14.9) **Miscarriages, N (%):** 11/47 (23.4) **Ectopic, N:** 1/47 (2.1) **Live births, N (%):** 32/47 (68.1) **Elective Cesarean delivery, N (%):** 9/32 (28.1) **VBALM failure, N (%):** 4/23 (17.4) **Modifiers:** Pregnancy rate correlated positively with diameter of largest fibroid: OR =1.06; 95% CI, 1.02-1.10 *P* = 0.004	**Quality:** Overall quality score: fair **INTERNAL VALIDITY: fair** Random: NA Metods and blinding: NA Pt selection criteria: + Loss to follow-up: <10% Drop-out rates: NA Statistical issues: - **EXTERNAL VALIDIT: fair (2)** Age: +, reported Race: NA, not US study Pregnancy history: -, NR Surgical history: -, NR Fibroid/uterine size: + Number of fibroids: + Location of fibroids: + Baseline characteristics: +, reported Length of follow-up: + Measurement methods: + Measurement reliability: + Clinical care: +

Evidence Table 13. KQ 5 Modifiers of outcomes (continued)

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria Other details	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author: Kumakiri et al., 2005 (continued)				**Modifiers:** Pregnancy rate correlated negatively with age at myomectomy: OR = 0.88; 95% CI, 0.80-0.98 *P* = 0.02 Pregnancy rate correlated negatively with number of enucleated fibroids: OR =1.17; 95% CI, 1.01-1.37 *P* = 0.04	

Evidence Table 13. KQ 5 Modifiers of outcomes (continued)

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria Other details	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author: Litta et al., 2005 **Country and setting:** Italy, Academic medical center **Enrollment period:** 01/2000 to 9/2003 **Funding:** NR	**Design:** Retrospective cohort **Intervention:** Treatment with GnRH analog for 3 months prior to laparoscopic myomectomy **Groups:** **G1:** GnRH analog for 3 months **G2:** No treatment prior to myomectomy **N at enrollment:** **G1:** 30 **G2:** 30 **N at follow-up:** **G1:** 30 **G2:** 30 **Age, yrs ± SD:** **G1:** 39.2 ± 6.1 **G2:** 38.9 ± 5.4 **Race/Ethnicity:** NR **Parity:** NR **Baseline Hgb/Hct:** NR	**Inclusion criteria:** • Reproductive age • Single fibroid ≤ 4cm • Undergoing laparoscopic myomectomy **Exclusion criteria:** • Intrauterine lesions **Indications:** NR **Pre-operative therapy:** See groups **Associated procedure(s):** NR	**Baseline uterine size:** NR **Number of fibroids removed, N:** **G1:** 30 **G2:** 30 **Baseline fibroid size, ml ± SD:** **G1:** 494.4 ± 488.7 **G2:** NR **Type of fibroid:** NR	**Operative time, min ± SD:** **G1:** 96.0 ± 38.5 **G2:** 103.9 ± 33.8 *P* = NS **Mean estimated blood loss, ml ± SD:** **G1:** 201.7 ± 209.4 **G2:** 203.8 ± 193.9 *P* = NS **Conversion to laparotomy, N (%):** **G1:** 1 (3.3) **G2:** 0 **Length of stay, days ± SD:** **G1:** 1.6 ±1.3 **G2:** 1.7 ± 1.6 *P* = NS **Fever > 38°C, N (%):** **G1:** 2 (6.6) **G2:** 1 (3.3) **Fibroid volume vs. baseline, ml ± SD:** **G1:** 369.2 ± 358.9 **G2:** 397.7 ± 409.2 *P* < 0.001 **Decrease in fibroid volume, ml ± SD:** **G1:** 125.2 ± 159.8 **G2:** NR **Modifiers:** Increasing fibroid volume and weight associated with blood loss, and operating time within and across groups (*P* < 0.0001).	**Quality:** **Overall quality score: poor** **INTERNAL VALIDITY: fair** Random: NA Methods and blinding: NA Pt selection criteria: + Loss to follow-up: NA Drop-out rates: NA Statistical issues: - **EXTERNAL VALIDITY: poor (6)** Age: +, reported Race: NA, not US study Pregnancy history: -, NR Surgical history: -, NR Fibroid/uterine size: + Number of fibroids: - Location of fibroids: - Baseline characteristics: -, NR Length of follow-up: NA Measurement methods: + Measurement reliability: + Clinical care: -

Evidence Table 13. KQ 5 Modifiers of outcomes (continued)

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria Other details	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author: Lohle et al., 2006 **Country and setting:** Netherlands, Academic medical center **Enrollment period:** 02/2001 to 02/2004 **Funding:** NR	**Design:** Prospective case series **Intervention:** UAE **Groups:** NA **N at enrollment:** 158 **N at follow-up, 12 months:** 126 (MRI) 142 (survey) **Age, mean yrs (range):** 42.3 (23-53 **Race/Ethnicity, N:** White: 142 Afro-Caribbean: 11 Asian: 5 **Parity:** NR **Baseline Hgb/Hct:** NR	**Inclusion criteria:** • Presence of uterine fibroid • Symptoms including: heavy menstrual bleeding, pain, and/or bulk-related symptoms unresolved by previous treatment **Exclusion criteria:** • Postmenopausal • Malignancy • Pedunculated fibroids • Pregnancy **Indications:** See inclusion criteria **Pre-operative therapy:** NR **Associated procedure(s):** NR	**Baseline uterine size, ml ± SD:** 532 ± 375 **Number of fibroids:** NR **Baseline dominant fibroid size, cm^3 ± SD:** 201 ± 249 **Type of fibroid:** NR	**UAE, N (%):** Bilateral: 152 (96) Unilateral: 6 (4) **Amenorrhea, N (%):** Permanent: 17 (11) Transient: 20 (13) **Fibroid expulsion, N (%):** 16 (10) **Additional procedures, N:** Second UAE: 9 Hysterectomy: 3 **Dominant fibroid size, 12 mos, cm^3 ± SD:** 78 ± 100 **Dominant fibroid volume reduction, % ± SD:** 60 ± 40 *P*<0.0001 **Uterine volume reduction, % ± SD:** 47 ± 34 *P*<0.0001 **Symptom resolution, N (%):** Heavy bleeding: 113/126 (91) Pain: 80/91 (92) Bulk symptoms: 70/81 (92) **Satisfaction, N (%):** Very satisfied: 81 (57) Satisfied: 51 (36) Not satisfied: 10 (7) **Modifiers:** **Embosphere vs Embogold:** Embogold: similar volume reduction, satisfaction, and fibroid expulsion *P*=NS Embogold : greater risk of skin rash (*P* = 0.031); slower return to usual activities (*P* = 0.004)	**Quality:** Overall quality score: poor **INTERNAL VALIDITY: poor** Random: NA Methods and blinding: NA Pt selection criteria: - Loss to follow-up: <10% Drop-out rates: NA Statistical issues: - **EXTERNAL VALIDITY: poor (4)** Age: +, reported Race: +, reported Pregnancy history: -, NR Surgical history: -, NR Fibroid/uterine size: + Number of fibroids: - Location of fibroids: - Baseline characteristics: +, reported Length of follow-up: + Measurement methods: + Measurement reliability: + Clinical care: +

Evidence Table 13. KQ 5 Modifiers of outcomes (continued)

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria Other Details	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author: Marret et al., 2006 **Country and setting:** France, Academic medical center and Community **Enrollment period:** 01/1996 to 12/2000 **Funding:** NR	**Design:** Retrospective case series **Intervention:** Myomectomy **Groups:** **G1:** Conversion to laparotomy **G2:** Laparoscopy **N at enrollment:** **G1:** 33 **G2:** 83 **N at follow-up:** NA **Age:** NR **Race/ethnicity:** NR **Parity:** NR **Baseline Hgb/Hct:** NR	**Inclusion criteria:** • Planned laparoscopic myomectomy **Exclusion criteria:** • Missing medical record data **Indications:** • Pelvic pain: 41% • Infertility: 38% • Bleeding: 14% **Pre-operative therapy:** GnRHa: **G1:** 1 (3.0) **G2:** 2 (2.4) *P* = NS **Associated procedure(s):** NR	**Baseline uterine size:** NR **Number of fibroids, mean ± SD:** **G1:** 2.4 ± 2.5 **G2:** 1.7 ± 1.8 **Baseline largest fibroid size, mm ± SD:** **G1:** 67.9 ± 18.2 **G2:** 47.8 ± 18.6 **Type of fibroid, N (%):** Subserous: **G1:** 19 (57.6) **G2:** 61 (73.5) Intramural: **G1:** 15 (45.5) **G2:** 21 (25.3)	**Risk of laparo-conversion, multivariate:** Increase in largest fibroid size of 1 mm: OR = 1.06 (95% CI, 1.03-1.09) *P* < 0.001 Dominant fibroid intramural: OR = 3.24 (95% CI, 1.11-10.21) *P* = 0.036 Surgeon's experience (senior vs. junior): OR = 0.15 (95% CI, 0.04-0.46) *P* = 0.001	**Quality:** Overall quality score: fair **INTERNAL VALIDITY: good** Random: NA Methods and blinding: NA Pt selection criteria: + Loss to follow-up: NA Drop-out rates: NA Statistical issues: + **EXTERNAL VALIDITY: poor (5)** Age: -, NR Race: -, NR Pregnancy history: -, NR Surgical history: -, NR Fibroid/uterine size: + Number of fibroids: + Location of fibroids: + Baseline characteristics: +, reported Length of follow-up: NA Measurement methods: + Measurement reliability: + Clinical care: -

Evidence Table 13. KQ 5 Modifiers of outcomes (continued)

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria Other Details	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author: Marziani et al., 2005 **Country and setting:** Italy, Academic medical center **Enrollment period:** 01/1997 to 12/2001 **Funding:** NR	**Design:** Prospective case series **Intervention:** Hysteroscopic myomectomy **Groups:** **G1:** Women with submucous uterine fibroids **N at enrollment:** 107 **N at follow-up, 36 mos:** **G1:** 104 **Age, mean yrs:** **G1:** 35 (30 to 46) **Race/ethnicity:** NR **Parity:** NR **Baseline Hgb/Hct:** **G1:** 10.33 g/dL	**Inclusion criteria:** • Excessive uterine bleeding defined by history with Hgb < 10 g/dl and Hct < 37 • Infertility • Fibroids defined by transvaginal ultrasound and diagnostic hysteroscopy **Exclusion criteria:** • Myoma size ≥ 3 cm • Intramural fibroid with < 5 mm of myometrium between fibroid and serosa • Adnexal pathology • Abnormal endometrial biopsy **Indications, N (%)** • Abnormal uterine bleeding: 84 (78.5) • Infertility: 23 (21.5) **Pre-operative therapy:** GnRH to reduce size of fibroid if ≥ 3 cm or desired by surgeon **Associated procedure(s):** NR	**Baseline uterine size:** NR **Number of fibroids, mean:** 1.5 (1 to 3) **Baseline fibroid size, cm^3 ± SD:** Type 0: 22 ± 9 Type 1: 25 ± 9 Type 2: 23 ± 10 **Type of fibroid, N (%):** Type 0: 51 (47.7) Type 1: 43 (40.2) Type 2: 13 (12.1)	**Conversion to open myomectomy, N:** 3 **Conversion to hysterectomy, N:** 2 **Uterine perforation, N:** 0 **Post-operative hemorrhage, N:** 3 **Number of procedures, N (%):** One: 91 (85) Two: 16 (15) **Control of menorrhagia, N (%):** • One procedure: 68 (81.0) • Two procedures: 11 (13.1) • Not controlled: 5 (4.7) **Modifiers:** Number of fibroids and control of menorrhagia after one procedure: • 1 fibroid: 46 of 46 (100%) • 2 fibroids: 21 of 24 (87.5%) • 3 fibroids: 12 of 14 (85.7%) *P* < 0.05	**Quality:** Overall quality score: fair **INTERNAL VALIDITY: fair** Random: NA Methods and blinding: NA Pt selection criteria: ++ Loss to follow-up: <10% Drop-out rates: NA Statistical issues: - **EXTERNAL VALIDITY: fair (3)** Age: +, reported Race: NA, not US study Pregnancy history: -, NR Surgical history: -, NR Fibroid/uterine size: + Number of fibroids: + Location of fibroids: + Baseline characteristics: +, reported Length of follow-up: - Measurement methods: + Measurement reliability: + Clinical care: +

Evidence Table 13. KQ 5 Modifiers of outcomes (continued)

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria Other Details	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author: McLucas et al., 2001 **Country and setting:** US, Academic center **Enrollment period:** 04/1997 to 08/1999 **Funding:** NR	**Design:** Prospective cohort **Intervention:** UAE **Medical Groups:** NA **N at enrollment:** 167 **N at follow-up (12 mos):** 46 **Age (range):** 43 (29 to 63) **Race/ethnicity:** NR **Parity*:** 0.7 **Baseline uterine size:** Without lupron: 155 (1,389 mL) With lupron: 12 (1,404 mL) **Baseline Hgb/Hct:** NR	**Inclusion criteria:** • Menorrhagia or postmenopausal bleeding secondary to uterine myomata **Exclusion criteria:** • Contraindications to angiography and embolization, such as coagulopathy, pelvic inflammatory disease, diabetes mellitus, or vasculitis **Indications:** NR **Preoperative therapy:** NR **Associated procedure(s):** NR	**Number of fibroids:** NR **Baseline fibroid size: (cm) (range):** 7.8 (1.5 to 16.3) **Type of fibroid:** NR	**Improvement or stabilization of symptoms 6 mos after UFE, %:** 88 **Total uterine volume decreased, N (%):** 46 (52) **Treatment failures, N (%):** 21/167 (13) **Post UFE complications, %:** • Fever: 7 • Nausea/vomiting: 1 • Passage of submucosus myoma: 5 • Premature menopause: 2.4 • Hysterectomy: 3.5 **Other modifiers:** Lupron use Earlier pelvic surgery – more likely to fail UFE: *P* = 0.012 Age, parity, menopausal status, uterine characterics, procedure characteristics (partial size and partial load), and post-procedure complications unrelated to UAE falure	**Quality:** Overall quality score: poor **INTERNAL VALIDITY: poor** Random: NA Methods and blinding: NA Pt selection criteria: ++ Loss to follow-up: >20% Drop-out rates: <5% Statistical issues: + **EXTERNAL VALIDITY: fair (3)** Age: +, reported Race: -, NR Pregnancy history: +, reported Surgical history: +, reported Fibroid/uterine size: + Number of fibroids: - Location of fibroids: - Baseline characteristics: +, reported Length of follow-up: ++ Measurement methods: + Measurement reliability: + Clinical care: +

Evidence Table 13. KQ 5 Modifiers of outcomes (continued)

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria Other Details	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author: Munoz et al., 2003 **Country and setting:** Spain, Academic medical center **Enrollment period:** 01/1992 to 12/1999 **Funding:** NR	**Design:** Retrospective case series **Intervention:** Hysteroscopic myomectomy **Groups:** NA **N at enrollment:** 120 **N at follow-up:** 120 **Age (median yrs):** 44.8 (23 to 74) **Race/ethnicity:** NR **Parity (range):** 1.6 (0 to 6) Nulliparous: 25.8% **Baseline Hgb/Hct:** NR	**Inclusion criteria:** • Symptomatic fibroid or infertility • Desire for uterine preservation • Fibroid <6cm • Less than 50% of endometrial surface affected **Exclusion criteria:** • Labastida's Type V fibroid • Pathology that contraindicates procedure **Indications, N (%):** • AUB: 101 (84.1) • Infertility: 14 (11.6) • Pain: 7 (5.8%) **Pre-operative therapy, N (%)** • None: 39 (32.5) • Danazol: 9 (7.5) • GnRHa: 72 (60) **Associated procedure(s), N (%):** 37 (30.8)	**Baseline uterine size:** NR **Number of fibroids:** NR **Baseline fibroid size, cm (%):** 1: 5 (4.1) 2: 31 (25.8) 3: 63 (52.5) 4: 19 (15.9) 5: 2 (1.7) **Type of fibroid, N (%):** Type 0: 52 (43.3) Type I: 51 (42.5) Type II: 17 (14.1)	**Operative time, median mins, (range):** 32.5 (10-105) **Uterine perforation:** N = 1 **Hemorrhage:** N = 1 **Unable to complete procedure:** N = 22 **Length of stay, N (%):** 12 hrs: 15 (47.5) 24 hrs: 33 (27.5) 36 hrs: 5 (4.3) 48 hrs: 17 (14.1) 72 hrs: 7 (5.8) > 72 hrs: 1 (0.8) **Infection, N:** N = 1 **Excess glycine, N:** 1 **Later interventions, N (%):** • 107 (89.1) • Hysterectomy: 3 • Myomectomy: 9 **Glycine retention, median:** 281 ml **Modifiers:** **Operative time modified by size, median mins (range):** < 3cm: 26.5 (10 to 45) > 3cm: 36.3 (10 to 105) **Glycine retention by modified by complexity, median:** Simple procedure: 270 ml Combined procedures: 302 ml	**Quality:** Overall quality score: fair **INTERNAL VALIDITY: fair** Random: NA Methods and blinding: NA Pt selection criteria: + Loss to follow-up: <10% Drop-out rates: NA Statistical issues: - **EXTERNAL VALIDITY: fair (3)** Age: +, reported Race: NA, not US study Pregnancy history: +, reported Surgical history: -, NR Fibroid/uterine size: + Number of fibroids: - Location of fibroids: + Baseline characteristics: +, reported Length of follow-up: - Measurement methods: + Measurement reliability: + Clinical care: +

Evidence Table 13. KQ 5 Modifiers of outcomes (continued)

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria Other Details	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author: Pron, Bennett, Common, Sniderman et al., 2003 Pron, Bennett, Common, Wall et al., 2003 Pron, Cohen, Soucie et al., 2003 Pron, Mocarski, Bennett et al., 2003 Pron, Mocarski, Cohen, et al., 2003 **Country and setting:** Canada, Academic medical centers **Enrollment period:** 11/98 to 11/00 **Funding:** NR	**Design:** Prospective case series **Intervention:** UAE **Groups:** NA **N at enrollment:** 555 **N at follow-up:** 548 (98%) at 2 wks 464 (83.6%) at 3 mos ultrasound **Age, mean (yrs):** 43 (18 to 59) **Race/ethnicity:** White: 66% Black: 23% Other: 11% **Parity, parous (%):** Nulliparous: 50 **Baseline Hgb/Hct:** NR	**Inclusion criteria:** • Symptomatic, ultrasound documented fibroids **Exclusion criteria:** • Active PID • Renal insufficiency • Endometrial carcinoma • Undiagnosed pelvic mass • Pregnancy **Indications, %:** • Menorrhagia: 17 • Menorrhagia/ dysmenorrhea: 63 • Pelvic pain: 13 • Bulk effects: 8 **Pre-operative therapy:** NR **Associated procedure(s):** NR	**Baseline uterine size, cm^3 (%):** 0 to 250: 106 (22) 251 to 500: 131 (37) 501 to 1,000: 149 (31) ≥1,001: 102 (21) **Number of fibroids, N (%):** 1: 150 (30) 2 to 4: 220 (44) ≥ 5: 125 (26) **Baseline fibroid size mean cm^3:** 293 (95% CI, 259-327) **Type of fibroid, N (%):** • Intramural: 285 (60) • Intramural and subserosal/ submucosal: 63 (13) • Subserosal: 92 (19) • Submucosal: 33 (7)	**Procedure time, min (median):** 61 (55) (95% CI, 58-63) **Fluoroscopy time, mean min:** 18.9 (95% CI, 18.0-19.8) **Complications, N (%):** 30 (5.3) (95% CI, 3.6%-7.4%) **Major complications, N:** 3 **Intra-procedural pain, N (%):** None: 386 (70) Minor/tolerable: 162 (30) Uncomfortable: 54 (10) Very uncomfortable: 50 (9) Unbearable: 23 (4) NRS (1 to 10)- mean (median): 6.3 (6.0) Ineffective analgesia: 24 (4%) **Postprocedural pain, N (%):** None: 44 (8) Minor/tolerable: 86 (18) Uncomfortable: 103 (19) Very uncomfortable: 188 (35) Unbearable: 116 (22) NRS (1 to 10)- mean (median): 7.0 (7.5) Ineffective pain management: 57 (10%)	**Quality:** Overall quality score: fair **INTERNAL VALIDITY: fair** Random: NA Methods and blinding: NA Pt selection criteria: ++ Loss to follow-up: <10% Drop-out rates: <5% Statistical issues: - **EXTERNAL VALIDITY: good** Age: +, reported Race: +, reported Pregnancy history: +, reported Surgical history: +, reported Fibroid/uterine size: + Number of fibroids: + Location of fibroids: + Baseline characteristics: +, reported Length of follow-up: + Measurement methods: + Measurement reliability: + Clinical care: +

Evidence Table 13. KQ 5 Modifiers of outcomes (continued)

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria Other Details	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author Pron, Bennett, Common, Sniderman et al., 2003 Pron, Bennett, Common, Wall et al., 2003 Pron, Cohen, Soucie et al., 2003 Pron, Mocarski, Bennett et al., 2003 Pron, Mocarski, Cohen, et al., 2003 (continued)				**Prescription pain medication use , days(median):** 6.8 (6.0) **Fever, N (%);** 157 (29) **Length of stay, nights (range):** 1.3 (0 to 11) **Infection rate, %:** 2.4 (95% CI, 1.3-4.0) **Fibroid expulsion, N (%):** 19 (3) **Readmission, N (%):** 16 (3) **Mean change in dominant fibroid volume, %:** 33 (95% CI, 28-38) **Mean change in uterine volume, %:** 27 (95% CI, 23-32) **Improvement in menorrhagia, N (%):** 358/429 (83) (95% CI, 80-87) **Improvement in dysmenorrhea, N (%):** 249/322 (77) (95% CI, 72-82) **Improvement in bulk related symptoms, N (%):** 388/464 (84) (95% CI, 80-87) **Improvement in urinary urgency/ frequency, N (%):** 263/306 (86) (95% CI, 82-90)	

Evidence Table 13. KQ 5 Modifiers of outcomes (continued)

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria Other Details	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author Pron, Bennett, Common, Sniderman et al., 2003 Pron, Bennett, Common, Wall et al., 2003 Pron, Cohen, Soucie et al., 2003 Pron, Mocarski, Bennett et al., 2003 Pron, Mocarski, Cohen, et al., 2003 (continued)				**Duration of menstrual flow (mean days):** Pre UAE: 7.6 Post UAE: 5.4 *P* < 0.001 **Pad count for day heaviest flow (median):** Pre UAE: 9 Post UAE: 4 *P* < 0.0001 **Satisfactory intra-procedural care:** 97% **Satisfactory post-procedural ward care:** 87% **Median life-impact score (higher = greater impact):** Pre UAE: 8 Post UAE: 3 *P* < 0.001 **Overall satisfaction, %:** 91 (95% CI, 89-94) **Strong dissatisfaction, N (%):** 32/487 (7) **Would repeat UAE, N (%):** 414/487 (85) **Time until recovery, days, (median):** 13.1 (10.0) **Subsequent hysterectomy, N (%):** 8 (1.5) **Modifiers:** Larger fibroids were more likely to have significant volume decrease	

Evidence Table 13. KQ 5 Modifiers of outcomes (continued)

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria Other Details	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author: Rajan et al., 2004 **Country and setting:** Canada, Community **Enrollment period:** 01/2000 to 07/2003 **Funding:** NR	**Design:** Retrospective case series **Intervention:** UAE **Groups:** NA **N at enrollment:** 410 **N at follow-up:** NA **Age, yrs ± SD:** 42.8 ± 5.8 **Race/ethnicity:** White: 66% Asian: 11% Afro-Caribbean: 23% **Parity:** NR **Baseline Hgb/Hct:** NR	**Inclusion criteria:** • UAE for symptomatic fibroids **Exclusion criteria:** • Pregnancy • Gynecologic malignancy or pre-malignancy • Adenomyosis with no fibroids • Severe renal insufficiency • Acute vasculitis • Any acute or chronic infection • Active pelvic infection or history of pelvic inflammatory disease • Uncorrectable coagulopathy **Indications:** NR **Preoperative therapy:** NR **Additional procedures:** NR	**Baseline uterine size:** NR **Number of fibroids:** NR **Baseline fibroid size (cm ± SD):** 7.7 ± 3.2 **Type of fibroid, N (%):** Submucosal: 148 (36.1) Non-submucosal: 262 (63.9)	**All complications, N (%):** 25 (6.1) **Minor complications, N (%):** 14 (3.4) **Major complications, N (%):** 11 (2.7) **Intrauterine infection** (requiring intravenous antibiotic therapy and/or surgery)**:** 5 (1.2%) **Modifiers:** Intrauterine infection more common in submucosal than nonsubmucosal In univariate analysis *P* = 0.006; logistic regression not significant (*P* = 0.079)	**Quality:** Overall quality score: fair **INTERNAL VALIDITY: good** Random: NA Methods and blinding: NA Pt selection criteria: + Loss to follow-up: NA Drop-out rates: <5% Statistical issues: + **EXTERNAL VALIDITY: poor (4)** Age: +, reported Race: +, reported Pregnancy history: -, NR Surgical history: -, NR Fibroid/uterine size: + Number of fibroids: - Location of fibroids: + Baseline characteristics: +, reported Length of follow-up: + Measurement methods: + Measurement reliability: - Clinical care: +

Evidence Table 13. KQ 5 Modifiers of outcomes (continued)

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria Other Details	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author: Roth et al., 2003 **Country and setting:** US, Academic medical center **Enrollment period:** 07/1992 to 06/1998 **Funding:** AHRQ	**Design:** Retrospective case series **Intervention:** Abdominal myomectomy **Groups:** **G1:** White **G2:** Black **N at enrollment:** **G1:** 107 **G2:** 118 **N at follow-up:** **G1:** 107 **G2:** 118 **Age, yrs ± SD:** **G1:** 35.6 ± 6.9 **G2:** 34.8 ± 5.0 *P* = 0.021 **Race/ethnicity:** NA – see groups **Parity:** NR **Baseline Hct (mean ± SD) :** **G1:** 37.3 ± 4.0 **G2:** 36.4 ± 3.8 *P* = 0.232	**Inclusion criteria:** • Abdominal myomectomy • Black or white race **Exclusion criteria:** NR **Indications:** NR **Preoperative therapy:** NR **Associated procedure(s):** NR	**Baseline uterine size:** NR **Number of fibroids removed, %:** 1 fibroid: **G1:** 36.5 **G2:** 10 2 to 3 fibroids: **G1:** 23.5 **G2:** 25 ≥ 4 fibroids: **G1:** 40 **G2:** 65 *P* = 0.001 **Baseline fibroid size (wk gestation), %:** <12 wks: **G1:** 28.8 **G2:** 13.8 12 to 16 wks: **G1:** 27.3 **G2:** 37.9 16 to 20 wks: **G1:** 19.7 **G2:** 29.9 >20 wks: **G1:** 9.1 **G2:** 12.6 *P* = 0.12 **Type of fibroid:** NR	**Complications, %:** 29 G2 vs. G1 OR = 1.36; 95%CI, 0.56-3.15 **Urinary retention or bladder injury, %:** 0.7 **Transfusion, %:** 20 G2 vs. G1 OR = 0.9; 95%CI, 0.27, 2.76 **Fever, %:** 2.9 **Ileus, %:** 2.4 **Disruption of wound, %:** 1.0 **Infection, %:** 2.0 **Respiratory complications, %:** 1.0 **Modifiers:** Uterine size (OR = 6.3; 95%CI, 3.18-12.4) and number of fibroids (OR = 2.6; 95% CI, 1.25-5.44) predicted transfusion Uterine size (OR = 1.86; 95%CI: 1.3-2.67), number of fibroids (OR = 1.83; 95% CI, 1.1-3.14), and co-morbidities (OR = 2.77; 95% CI, 1.1-7.69) predicted complications Prior abdominal surgery, BMI, adhesions, and pre-op diagnoses not associated with complications or transfusion	**Quality:** Overall quality score: poor **INTERNAL VALIDITY: fair** Random: NA Methods and blinding: NA Pt selection criteria: - Loss to follow-up: NA Drop-out rates: NA Statistical issues: + **EXTERNAL VALIDITY: poor (6)** Age: +, reported Race: +, reported Pregnancy history: -, NR Surgical history: -, NR Fibroid/uterine size: + Number of fibroids: - Location of fibroids: - Baseline characteristics: -, NR Length of follow-up: + Measurement methods: + Measurement reliability: + Clinical care: -

Evidence Table 13. KQ 5 Modifiers of outcomes (continued)

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria Other Details	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author: Spies, Myers, Worthington-Kirsch et al., 2005 [See evidence table for Spies, Spector, Roth, et al., 2002] **Country and setting:** US, Academic medical centers **Enrollment period:** 12/2000 to 12/2002 **Funding:** Society for Interventional Radiology Foundation	**Design:** Prospective case series **Intervention:** UAE **Groups:** NA **N at enrollment:** 2,112 **N at follow-up:** 6 mos: 1,797 1 year: 1,701 **Age:** NR **Race/ethnicity, %:** White: 47.2% **Parity:** NR **Baseline Hgb/Hct:** NR	**Inclusion criteria:** • Undergoing UAE for fibroid treatment • Entered into Fibroid Registry for Outcomes Data **Exclusion criteria:** NR **Indications:** • Heavy bleeding • Bulk related symptoms • Pain **Pre-operative therapy:** NR **Associated procedure(s):** NR	**Baseline uterine size:** NR **Number of fibroids:** NR **Baseline fibroid size:** NR **Type of fibroid:** NR	**Subsequent care, 12 mos, N (%):** • Medical treatment: 121 (7) • Gyn interventions: 77 (6) • Hysterectomy: 27 (1.6) • Unplanned ER care: 52 (3) **Symptom Score change, 12 mos:** -38.94 ± 24.79 *P* < 0.001 **HRQOL score change, 12 mos:** 39.67 ± 25.28 *P* < 0.001 **Modifiers:** NR	**Quality:** Overall quality score: fair **INTERNAL VALIDITY: fair** Random: NA Methods and blinding: NA Pt selection criteria: ++ Loss to follow-up: 10-20% Drop-out rates: <5% Statistical issues: ++ **EXTERNAL VALIDITY: good** Age: +, reported Race: +, reported Pregnancy history: +, reported Surgical history: +, reported Fibroid/uterine size: + Number of fibroids: + Location of fibroids: + Baseline characteristics: +, reported Length of follow-up: ++ Measurement methods: + Measurement reliability: + Clinical care: +

Evidence Table 13. KQ 5 Modifiers of outcomes (continued)

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria Other Details	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author: Spies, Ascher et al., 2001 Spies, Roth, et al., 2002 Spies, Bruno, et al., 2005 **Country and setting:** US, Academic medical center **Enrollment period:** 07/1997 to 12/1999 **Funding:** NR	**Design:** Prospective case series **Intervention:** Bilateral uterine artery embolization **Groups:** NA **N at enrollment:** 200 **N at follow-up:** 3 mo: 193 12 mo: 190 24 mo: 161 36 mo: 183 48 mo: 180 60 mo: 182 **Age, mean yrs:** 43.1 (95% CI, 42.4-43.7) **Race/ethnicity, %:** Black: 50% White: 45% Asian: 2.5% Hispanic: 1.5% Other: 1.0% **Parity:** NR **Baseline Hgb/Hct:** NR	**Inclusion criteria:** At least 1 of the following: • Heavy menstrual bleeding ± anemia • Pelvic pain or pressure; back, flank, or leg pain • Urinary frequency or other bladder symptoms • Hydronephrosis • Failed, refused, or not suitable for medical therapy Patients 1 to 50: • Age: <35 yrs or wished to maintain fertility required to exhaust all therapies Patients 51 to 200: • Age: <35 yrs if failed medical therapy and only remaining option extensive myomectomy, repeat myomectomy, or hysterectomy **Exclusion criteria:** • Pregnancy • Suspicion of uterine, ovarian, or cervical cancer • Pedunculated fibroids • Hystero-scopically resectable fibroids • Uterus >24 wks	**Baseline uterine size, mean ml:** 717.0 (95% CI, 648.8-785.2) **Number of fibroids, N (%):** 1: 28 (14.8) 2 to 5: 138 (73.0) >5: 23 (12.2) Missing: 11 **Baseline dominant fibroid size (mean ml):** 240.0 (95% CI, 200.8-279.3) **Type of fibroid, N (%):** • Intramural: 108 (54) • Submucosal: 35 (17.5) • Subserosal: 39 (19.5) • Missing: 18	**Subsequent intervention, at 3 mos, N (%):** Hyst/D&C: 6 (3) (95% CI, 1-6) Hysterectomy: 1 (1) (95% CI, 0-3) Repeat UAE: 0 Myomectomy: 0 **Improved symptoms, at 3 mos, N (%):** Yes: 180 (93) (95% CI, 89-96) No: 9 (5) (95% CI, 2-9) **Bleeding at 3 mos:** Amenorrhea, N: 14, 8 (95% CI, 4-12) Mean change in bleeding score: 3.33 (95% CI, 3.04-3.61) **Pain at 3 mos: :** Mean change pain score: 3.47 (95% CI, 3.17-3.78) **Improved symptoms, at 60 mos,N (%):** Yes: 133 (73) (95% CI, 66-79) No:10 (5) (95% CI, 3-10) **Bleeding, at 60 mos, N (%):** Amenorrhea: 42 (29) (95% CI, 21-37) Mean change in bleeding score: 3.98 (95% CI, 3.67-4.28) **Pain, at 60 mos:** Mean change in pain score: 3.72 (95% CI, 3.34-4.10)	**Quality:** Overall quality score: good **INTERNAL VALIDITY: good** Random: NA Methods and blinding: NA Pt selection criteria: ++ Loss to follow-up: <10% Drop-out rates: <5% Statistical issues: ++ **EXTERNAL VALIDITY: good** Age: +, reported Race: +, reported Pregnancy history: +, reported Surgical history: +, reported Fibroid/uterine size: + Number of fibroids: + Location of fibroids: + Baseline characteristics: +, reported Length of follow-up: ++ Measurement methods: + Measurement reliability: + Clinical care: +

Evidence Table 13. KQ 5 Modifiers of outcomes (continued)

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria Other Details	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author: Spies, Ascher et al., 2001 Spies, Roth, et al., 2002 Spies, Bruno, et al., 2005 (continued)		**Indications:** NR **Preoperative therapy:** NR **Associated procedure(s):** NR		**Subsequent interventions, (Years1 to 5), N (%):** • Hysteroscopy/ D&C: 19 • Hysterectomy: 25 • Myomectomy: 6 • Repeat UAE: 3 • Failed or recurred: 46 (25) • Continued relief: 133 (73) **Modifiers:** Baseline imaging variables not associated with failure at 12 mos Age, race, baseline leiomyoma volume, baseline uterine volume, and subsequent interventions were not associated with satisfaction	

Evidence Table 13. KQ 5 Modifiers of outcomes (continued)

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author: Worthington-Kirsch et al., 2005 Myers et al., 2005 **Country and setting:** US, Varied sites (72) **Enrollment period:** 12/2000 to 12/2002 **Funding:** Society of Interventional Radiology Foundation through unrestricted grants from Biosphere Medical, Boston Scientific Corporation, COOK, Inc., and Cordis Endovascular	**Design:** Prospective case series **Intervention:** UAE **Groups:** NA **N at enrollment:*** 3,041 (30-day follow-up eligible) 2,112 (1-year follow-up eligible) **N at follow-up:** 2,729 (30 days) 1,797 (1 year) **Age, yrs ± SD:** 43.5 ± 5.6 **Race/ethnicity, %:** African American: 48 White: 44.4 Hispanic: 3.6 Asian/Pacific Islander: 2.8 Other: 1.3 **Parity, %:** Nulliparous: 44.1 **Baseline Hgb/Hct:** NR	**Inclusion criteria:** • Women undergoing uterine embolization for fibroids at 1 of 72 sites of FIBROID Registry **Exclusion criteria:** NR **Indications (predominant symptom), N (%):** • Heavy menstrual bleeding: 1,932 (64.7)) • Pelvic pain: 314 (10.5) • Bulk symptoms: 694 (23.3) • Other symptoms: 45 (1.5) **Preoperative therapy, N (%):** GnRH agonist: 133 (4.4) **Additional procedures:** NR	**Baseline uterine size, ml ± SD:** 677.7 ± 520.4 **Number of fibroids, N (%):** 1 to 2: 1249 (43.4) 3 to 4: 690 (24.1) ≥ 5: 936 (32.6) **Baseline fibroid size:** NR **Type of fibroid, N (%):** • Intramural: 1231 (42.8) • Transmural: 585 (20.3) • Subserosal: 410 (14.3) • Submucosal: 376 (13.1) • Pedunculated: subserosal: 64 (2.2) • Pedunculated: submucosal: 9 (0.3)	**Length of stay, days:** 1.68 (95% CI, 1.21-2.15) **Number of AEs, during number of hospitalizations, (% of total pts):** 94 in 90 (3) **AE between discharge and 30 days, N (%):** 710 (26) **Major events, N (%):** 111 (4) **Recurrent pain, N (%):** 65 (2.1) **Possible infection, N (%):** 19 (0.62) **Minor events, N (%):** 610 (22) **Hot flushes, N (%):** 156 (5.7) **Pain, N (%):** 264 (9.6) **Mean lost work days:** 9.63 (95% CI, 9.38-9.88) **Modifiers:** **Increased risk of AEs in hospital: Univariate:** Length of procedure: OR = 1.012; 95% CI, 1.005-1.019 Core site status: OR = 0.334; 95% CI, 0.15-0.76) Size of fibroid: OR = 1.073; 95% CI, 1.013-1.138	**Quality:** Overall quality score: fair **INTERNAL VALIDITY: fair** Random: NA Methods and blinding: NA Pt selection criteria: ++ Loss to follow-up: 10-20% Drop-out rates: <5% Statistical issues: ++ **EXTERNAL VALIDITY: good** Age: +, reported Race: +, reported Pregnancy history: +, reported Surgical history: +, reported Fibroid/uterine size: + Number of fibroids: + Location of fibroids: + Baseline characteristics: +, reported Length of follow-up: ++ Measurement methods: + Measurement reliability: + Clinical care: +

*Registry without complete overlap

Evidence Table 13. KQ 5 Modifiers of outcomes (continued)

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author: Worthington-Kirsch et al., 2005 Myers et al., 2005 (continued)				**Multivariate:** Length of procedure: OR = 1.10; 95% CI, 1.005-1.01 Size of fibroid: OR = 1.11; 95% CI, 1.028-1.20 Uterine volume: OR 0.999; 95% CI, 0.998-0.999 **Increased risk of AE at 30 days:** **Univariate:** Prior procedures or medical therapy: OR = 1.242; 95% CI, 1.113-1.38) *P* < 0.001 African American: OR = 1.158; 95% CI, 1.048-1.28 *P* = 0.004 Smoking status: OR = 1.139; 95% CI, 1.009-1.286 *P* = 0.035 **Multivariate:** Smoking status: OR = 1.141; 95% CI, 1.007-1.293 *P* = 0.039 African American: OR = 1.129; 95% CI, 1.019-1.251 *P* = 0.021 Prior procedures: OR = 1.235; 95% CI, 1.103-1.383 *P* < 0.001 Duration of procedure: OR = 1.004; 95% CI, 1.001-1.006 *P* = 0.009 DVT prophylaxis: OR = 0.757; 95% CI, 0.622-0.919	

Evidence Table 14. KQ 6 Comparisons of Treatments

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria and Other Details	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author: Baker et al., 2002 **Country and setting:** US, Academic medical center **Enrollment period:** 2001 **Funding:** NR	**Design:** Retrospective cohort **Intervention:** UAE and abdominal myomectomy **Groups:** **G1:** UAE **G2:** Abdominal myomectomy **N at enrollment:** **G1:** 23 **G2:** 17 **N at follow-up:** NA **Age, yrs ± SD:** **G1:** 42.6 ± 4.4 **G2:** 35.5 ± 4.6 *P* < 0.001 **Race/ethnicity:** NR **Parity:** NR **Baseline Hgb/Hct:** NR	**Inclusion criteria:** • Women > age 21 yr • Had UAE or myomectomy in 2001 for symptomatic fibroids **Exclusion criteria:** NR **Indications:** NA **Preoperative therapy:** NA **Additional procedures:** NA	**Baseline uterine size:** NR **Number of fibroids:** NR **Baseline fibroid size:** NR **Type of fibroid:** NR	**Total professional costs, (N):** **G1:** $2,220 (19) **G2:** $1,611 (9) *P* < 0.002 **Total hospital costs, (N):** **G1:** $3,193 (16) **G2:** $5,598 (16) *P* < 0.0001 **Total costs without imaging, (N):** **G1:** $5,371 (12) **G2:** $7,401 (8) *P* < 0.0001 **Total costs with imaging, (N):** **G1:** $6,708 (12) **G2:** $7,630 (8) *P* = 0.086 **Modifiers:** NR	**Quality:** Overall quality score: poor **INTERNAL VALIDITY: poor** Random: NA Methods and blinding: NA Pt selection criteria: - Loss to follow-up: NA Drop-out rates: NA Statistical issues: - **EXTERNAL VALIDITY: poor (8)** Age: +, reported Race: -, NR Pregnancy history: -, NR Surgical history: -, NR Fibroid/uterine size: - Number of fibroids: - Location of fibroids: - Baseline characteristics: -, NR Length of follow-up: NA Measurement methods: + Measurement reliability: + Clinical care: -

Evidence Table 14. KQ 6 Comparisons of Treatments (continued)

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author: Beinfeld et al., 2002 **Country and setting:** US, Academic medical center **Enrollment period:** 10/1998 to 03/2001 **Funding:** NR	**Design:** Retrospective cohort **Intervention:** UAE vs. hysterectomy **Groups:** **G1:** UAE **G2:** Hysterectomy **N at enrollment:** **G1:** 57 **G2:** 300 **N at follow-up:** NA **Age, yrs ± SD:** **G1:** 43.1 ± 4.9 **G2:** 47.0 ± 6.8 *P* < 0.0001 **Race/ethnicity, %:** White **G1:** 69.6 **G2:** 77.0 Black **G1:** 28.6 **G2:** 14.2 Hispanic **G1:** 0 **G2:** 7.0 Asian **G1:** 1.8 **G2:** 1.7 *P* = 0.01 **Parity:** NR **Baseline Hgb/Hct:** NR	**Inclusion criteria:** • Patients with principal diagnosis of uterine fibroids • Principle procedure of hysterectomy based on ICD-9 codes **Exclusion criteria:** • Patients whose costs were > 3 SD above mean hospital costs **Indications:** NR **Preoperative therapy:** NR **Additional procedures:** NR	**Baseline uterine size:** NR **Number of fibroids, N ± SD:** **G1:** 2.8 ± 1.4 **G2:** 2.0 ± 1.1 *P* < 0.0001 **Baseline largest fibroid size, cm ± SD:** **G1:** 8.0 ± 3.0 **G2:** 6.3 ± 3.2 *P* = 0.001 **Type of largest fibroid, N (%):** Intramural: **G1:** 32 (72.3) **G2:** 171 (62.0) Submucosal: **G1:** 9 (19.2) **G2:** 52 (18.9) Subserosal: **G1:** 4 (8.5) **G2:** 53 (19.2) *P* = 0.18	**Complications, N (%):** **G1:** 2 (3.9) **G2:** 12 (4.8) *P* = 1.0 **Length of stay, days ± SD:** **G1:** 0.95 ± 0.4 **G2:** 2.6 ± 1.0 *P* < 0.0001 **Cost, $ ± SD:** **G1:** $8,223 ± 1,834 **G2:** $6,046 ± 1,589 *P* < 0.0001	**Quality:** Overall quality score: poor **INTERNAL VALIDITY: poor** Random: NA Methods and blinding: NA Pt selection criteria: - Loss to follow-up: NA Drop-out rates: NA Statistical issues: - **EXTERNAL VALIDITY:poor (5)** Age: +, reported Race: +, reported Pregnancy history: -, NR Surgical history: -, NR Fibroid/uterine size: + Number of fibroids: + Location of fibroids: + Baseline characteristics: -, NR Length of follow-up: NA Measurement methods: + Measurement reliability: + Clinical care: -

Evidence Table 14. KQ 6 Comparisons of Treatments (continued)

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria Other Details	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author: Broder et al., 2002 **Country and setting:** US, Academic medical center **Enrollment period:** 02/1996 to 08/1997 **Funding:** Partial support form NIH (NICHD) BIRCWH Grant	**Design:** Retrospective cohort (survey) **Intervention:** Uterine artery embolization or abdominal myomectomy **Groups:** **G1:** Uterine artery embolization **G2:** Abdominal myomectomy **N at procedure:** **G1:** 59 **G2:** 38 **N contacted:** **G1:** 53 **G2:** 32 **N respondents:** **G1:** 51 of 59 **G2:** 30 of 38 **Age, mean yrs:** **G1:** 43.5 (27 to 66) **G2:** 37.6 (28 to 45) *P* = 0.03 **Race/ethnicity, N (%):** **G1:** White: 23 (45) Black: 17 (33) Hispanic: 3 (6) Asian: 1 (2) Other: 7 (14) **G2:** White: 14 (47) Black: 7 (23) Hispanic: 2 (7) Asian: 3 (10) Other: 4 (13) **Parity:** NR **Baseline uterine size:** NR **Baseline Hgb/Hct:** NR	**Inclusion criteria:** Patients having bilateral uterine artery embolization or abdominal myomectomy at a single institution **Exclusion criteria:** NA **Elapsed time from procedure to survey (mean mos, range):** **G1:** 46 (41 to 59) **G2:** 49 (37 to 59) **Indications:** NR **Preoperative therapy:** NR **Additional procedures:** NR	**Number of fibroids:** NR **Baseline fibroid size:** NR **Type of fibroid:** NR	**Further invasive therapy (hysterectomy, myomectomy, or UAE), N (%):** **G1:** 51 (29) **G2:** 1 (3) *P* = 0.004 (AOR: 12.5; 95%CI: 1.4, 110.1) **No improvement/worsening of symptoms, N (%):** **G1:** 3 (8) **G2:** 3 (10) *P* = 0.78 **Somewhat/very dissatisfied, N (%):** **G1:** 2 (6) **G2:** 6 (21) *P* = 0.06 **Clinical failure (a priori definition as combination of three above outcomes), N (%):** **G1:** 20 (39) **G2:** 9 (30) *P* = 0.40 **Modifiers:** NR (in multivariate models, months elapsed total and between procedure and survey did not predict failure)	**Quality:** Overall quality score: poor **INTERNAL VALIDITY: poor** Random: NA Methods and blinding: NA Pt selection criteria: - Loss to follow-up: 10-20% Drop-out rates: NA Statistical issues: + **EXTERNAL VALIDITY: poor (5)** Age: +, reported Race: +, reported Pregnancy history: -, NR Surgical history: +, reported Fibroid/uterine size: - Number of fibroids: - Location of fibroids: - Baseline characteristics: +, reported Length of follow-up: ++ Measurement methods: + Measurement reliability: - Clinical care: +

Evidence Table 14. KQ 6 Comparisons of Treatments (continued)

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria and Other Details	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author: Goodwin et al., 2006 **Country and setting:** US, Academic medical centers **Enrollment period:** NR **Funding:** Boston Scientific Corporation	**Design:** Prospective cohort **Intervention:** UAE vs. myomectomy **Groups:** **G1:** UAE **G2:** Myomectomy **N at enrollment:** **G1:** 149 **G2:** 60 **N at follow-up:** **G1:** 121 **G2:** 45 **Age, mean yrs:** **G1:** 43.9 **G2:** 38.2 *P* < 0.0001 **Race:** NR **Parity, parous (%):** **G1:** 75.2 **G2:** 48.3 *P* < 0.0001 **Baseline Hgb/Hct:** NR	**Inclusion criteria:** • Symptomatic fibroids confirmed on MRI • ≥ 30 yr old • Regular menses • Normal Pap smear • Able to complete follow-up requirements **Exclusion criteria:** • Hysteroscopically resectable fibroids • Pelvic infection • Gynecologic malignancy • Undiagnosed pelvic mass outside of uterus • Unexplained abnormal menstrual bleeding • Infection • Coagulopathy • History of pelvic irradiation • ASA score ≥ 4 • FSH level > 40 IU/L • Participation in any other investigational device or drug study • Desire to become pregnant • Abnormal serum creatinine level • Uterine arteriovenous fistula **Indications:** NR **Preoperative therapy:** NR **Additional procedures:** NR	**Baseline uterine size, cm^3:** **G1:** 658.4 **G2:** 590.6 *P* > 0.05 **Number of fibroids, N (%):** 0 **G1:** 2 (1.3) **G2:** 1 (1.7) 1 **G1:** 9 (6.0) **G2:** 5 (8.3) 2 **G1:** 10 (6.7) **G2:** 4 (6.7) 3 **G1:** 10 (6.7) **G2:** 8 (13.3) 4 **G1:** 10 (6.7) **G2:** 7 (11.7) 5 **G1:** 6 (4.0) **G2:** 2 (3.3) 6–10 **G1:** 27 (18.1) **G2:** 14 (23.3) >10 **G1:** 75 (50.3) **G2:** 13 (21.7) *P* = 0.0001 **Baseline dominant fibroid size, cm^3:** **G1:** 182.12 **G2:** 226.92 *P* = 0.081 **Type of fibroid N (%):** Intramural **G1:** 88 (59.1) **G2:** 26 (43.3) Submucosal **G1:** 1 (0.007) **G2:** 3 (5.0)	**At least 1 adverse event N (%):** **G1:** 33 (22.1) **G2:** 24 (40) *P* < 0.01 **Major adverse event, N:** **G1:** 6 **G2:** 1 *P* > 0.05 **Length of stay, mean hrs:** **G1:** 23.8 **G2:** 61.6 *P* < 0.0001 **Dominant fibroid volume, 3 mos or 6 mos:** *P* = NS **Quality-of-life assessments, 6 mos:** *P* = NS **Menstrual bleeding score, 3 mos or 6 mos:** *P* = NS **Return to normal activities, mean days:** **G1:** 14.6 **G2:** 44.4 *P* < 0.05 **Missed workdays:** **G1:** 9.9 **G2:** 37.0 *P* < 0.001 **Modifiers:** NR	**Quality:** Overall quality score: fair **INTERNAL VALIDITY: good** Random: NA Methods and blinding: NA Pt selection criteria: ++ Loss to follow-up: 10-20% Drop-out rates: <5% Statistical issues: ++ **EXTERNAL VALIDITY: fair (3)** Age: +, reported Race: -, NR Pregnancy history: +, reported Surgical history: -, NR Fibroid/uterine size: + Number of fibroids: + Location of fibroids: + Baseline characteristics: +, reported Length of follow-up: ++ Measurement methods: + Measurement reliability: + Clinical care: -

Evidence Table 14. KQ 6 Comparisons of Treatments (continued)

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria Other Details	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author: Healey et al., 2004 **Country and setting:** Canada, Academic medical center **Enrollment period:** 08/2000 to 04/2003 **Funding:** NR	**Design:** Prospective cohort **Intervention:** UAE vs. hysterectomy **Groups:** **G1:** UAE **G2:** Hysterectomy **N at enrollment:** **G1:** 68 **G2:** 16 **N at follow-up:** **G1:** 48 **G2:** 13 **Age, yrs ± SD:** **G1:** 44.9 ± 3.8 **G2:** 43.7 ± 3.6 **Race/ethnicity:** NR **Parity, parous, N (%):** Nulliparous: **G1:** 11 (22.0) **G2:** 0 **Baseline Hgb/Hct:** NR	**Inclusion criteria:** • Healthy premenopausal women • Age: 39 to 50 • Symptomatic uterine fibroids • Regular menstrual cycles • Day 3 serum FSH levels < 40 IU/L **Exclusion criteria:** See inclusion criteria **Indications, N (%):** Bleeding: **G1:** 42 (61.8) **G2:** 16 (100) Pain/pressure: **G1:** 5 (7.4) **G2:** 0 Urinary symptoms: **G1:** 3 (4.4) **G2:** 0 Multiple symptoms: **G1:** 14 (20.1) **G2:** 0 **Preoperative therapy:** NR **Associated procedure(s):** NR	**Baseline uterine size, ml ± SD:** **G1:** 538 ± 50 **Number of fibroids, N (%):** 1: **G1:** 11 (16.3) **G2:** NA ≥ 2: 57 (83.8) **G2:** NA **Baseline (dominant) fibroid size, ml ± SD:** **G1:** 154 ± 19.9 **G2:** NA **Type of fibroid, N (%):** Submucosal: **G1:** 10 (14.7) **G2:** NA Intramural or subserosal: **G1:** 58 (85.3) **G2:** NA	**Fibroid volume, 3 mos, ml ± SD:** **G1:** 434.1 ± 51.5 **G2:** NA *P* < 0.05 (95% CI, 6-201) **Fibroid volume, 6 mos, ml ± SD:** **G1:** 361.0 ± 38.4 **G2:** NA *P* < 0.01 (95% CI, 44-241) **Hormone measures at 6 mos** FSH (IU/L ± SEM): **G1:** 9.9 ± 1.0 95% CI, -1.7-1.2 **G2:** 7.8 ± 1.8 95% CI, -0.2-4.0 LH (IU/L ± SEM): **G1:** 7.0 ± 1.1 95% CI, -1.2-0.8 **G2:** 11.2 ± 5 95% CI, -1.91-3.3 E2 (pmol/L ± SEM): **G1:** 214 ± 34.9 95% CI, -52-36 **G2:** 326 ± 79.2 95% CI, -39.8-212.6 **Modifiers:** NR	**Quality:** Overall quality score: fair **INTERNAL VALIDITY: poor** Random: NA Methods and blinding: NA Pt selection criteria: ++ Loss to follow-up: >20% Drop-out rates: <5% Statistical issues: + **EXTERNAL VALIDITY: good** Age: +, reported Race: +, reported Pregnancy history: +, reported Surgical history: +, reported Fibroid/uterine size: + Number of fibroids: + Location of fibroids: + Baseline characteristics: +, reported Length of follow-up: + Measurement methods: + Measurement reliability: + Clinical care: +

Evidence Table 14. KQ 6 Comparisons of Treatments (continued)

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria and Other Details	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author: Hehenkamp et al., 2005 **Country and setting:** The Netherlands, Hospitals **Enrollment period:** 03/2002 to 02/2004 **Funding:** Netherlands Organisation for Health Research and Development and Boston Scientific Corporation	**Design:** RCT **Intervention:** UAE versus hysterectomy **Groups:** **G1:** UAE **G2:** Hysterectomy (abdominal, vaginal, laparoscopically assisted vaginal, and laparoscopic) **N at enrollment:** **G1:** 88 **G2:** 89 **N at follow-up:** **G1:** 81 **G2:** 75 **Age, yrs ± SD:** **G1:** 44.6 ± 4.8 **G2:** 45.4 ± 4.2 **Race/ethnicity N (%):** Black: **G1:** 24 (27.3) **G2:** 20 (22.5) White: **G1:** 54 (61.4) **G2:** 57 (64.0) Other: **G1:** 10 (11.4) **G2:** 12 (13.5) **Parity, N (%):** 0: **G1:** 30 (34.1) **G2:** 20 (22.5) ≥1: **G1:** 58 (65.9) **G2:** 69 (77.5) **Baseline Hgb/Hct:** NR	**Inclusion criteria:** • Ultrasound confirmation uterine fibroids • Menorrhagia • Premenopausal scheduled for hysterectomy **Exclusion criteria:** • Other treatment options available • Future pregnancy desired • Renal failure • Active pelvic infection or clotting disorders • Allergic to contrast material • Uterine malignancy suspected • Submucosal fibroids with 50% of diameter within uterine cavity or dominant pedunculated serosal fibroids **Indications, N (%):** Dysmenorrhea: **G1:** 47 (53.4) **G2:** 50 (56.2) Pressure/Pain: **G1:** 38 (43.1) **G2:** 39 (43.8) Bladder/Bowel symptoms: **G1:** 18 (20.5) **G2:** 25 (28.1) Anemia: **G1:** 43 (48.9) **G2:** 42 (47.2) Other symptoms: **G1:** 6 (6.8) **G2:** 11 (12.4)	**Baseline uterine volume, median cm^3 (range):** **G1:** 321 (31 to 3,005) **G2:** 313 (58 to 3,617) **Number of fibroids, N (%):** 1 fibroid: **G1:** 35 (39.8) **G2:** 25 (28.1) 2 fibroids: **G1:** 13 (14.8) **G2:** 16 (18.0) 3 fibroids: **G1:** 17 (19.3) **G2:** 25 (25.8) >3 fibroids: **G1:** 18 (20.5) **G2:** 14 (15.7) **Baseline dominant fibroid volume, median cm^3 (range):** **G1:** 59 (1-673) **G2:** 87 (4-1641) **Type of fibroid:** NR	**Procedure time, min:** **G1:** 79.0 **G2:** 95.4 *P* = 0.007 **Mean estimated blood loss, ml ± SD:** **G1:** 30.9 ± 23.8 **G2:** 436.1 ± 474.5 *P* < 0.001 **Length of stay, days ± SD:** **G1:** 2.0 ± 2.1 **G2:** 5.1 ± SD1.3 *P* < 0.001 **Readmissions, N:** **G1:** 9 **G2:** 0 *P* = 0.0032 **Minor complications at surgery, complications/ patients:** **G1:** 23/18 **G2:** 26/23 (RR = 0.72; 95% CI, 0.43-1.23) *P* = 0.23 **Minor complications at 6 weeks, complications/ patients:** **G1:** 68/47 **G2:** 34/30 (RR = 1.45; 95% CI, 1.04-2.02) *P* = 0.024 **Major complications at surgery, complications/ patients:** **G1:**1/1 **G2:** 1/1 (RR = 0.93; 95% CI, 0.06-14.54) *P* = 0.99	**Quality:** Overall quality score: fair **INTERNAL VALIDITY: good** Random: + Methods and blinding: NA Pt selection criteria: ++ Loss to follow-up: <10% Drop-out rates: <5% Statistical issues: ++ **EXTERNAL VALIDITY: fair (1)** Age: +, reported Race: +, reported Pregnancy history: +, reported Surgical history: +, reported Fibroid/uterine size: + Number of fibroids: + Location of fibroids: - Baseline characteristics: +, reported Length of follow-up: + Measurement methods: + Measurement reliability: + Clinical care: +

Evidence Table 14. KQ 6 Comparisons of Treatments (continued)

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria Other Details	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author: Mehl-Madrona, 2002 **Country and setting:** US, Academic medical center **Enrollment period:** NR **Funding:** NR	**Design:** Prospective cohort **Intervention:** Traditional Chinese medical approach **Groups:** **G1:** Traditional Chinese Medicine with combination of weekly acupuncture, Chinese herbs, and nutritional therapy **G2:** Matched controls medically managed with any medical treatment **N at enrollment:** **G1:** 37 **G2:** 37 **N at follow-up:** **G1:** 37 **G2:** 37 **Age:** Mode: 36 (24 to 45) **Race/ethnicity:** NR **Parity:** NR **Baseline Hgb/Hct:** NR	**Inclusion criteria:** • Pre-menopausal • Intact uterus of ≥ 6 to 8 week size with palpable fibroids • Fibroids 2 to 3 cm in diameter **Exclusion criteria:** • Fibroids growing > 6 cm/year • Hgb < 8g/dL • Hydronephrosis • Taking hormonal contraceptives **Indications:** • Palpable fibroids • Fibroids 2 to 3 cm in diameter **Pre-operative therapy:** NA **Associated procedure(s):** NA	**Baseline uterine size:** NR **Number of fibroids:** NR **Baseline fibroid size:** NR **Type of fibroid:** NR	**Mean size change, cm:** **G1:** -0.8 **G2:** +1.9 **Size and/or rate of growth of fibroids, 6 mos, mean change in size (cm):** Cured (gone) **G1:** 3 **G2:** 0 Reduced size (>2cm) **G1:** 11 **G2:** 1 Stopped growing (± 1cm) **G1:** 8 **G2:** 2) Decreased rate of growth (change >1cm) **G1:** 10 (+1.1) **G2:** 9 (+0.9) Total improved*: **G1:** 32 **G2:** 13 *P* < 0.001 No change **G1:** 3 (+0.9) **G2:** 20 (+1.9) Increased rate of growth (change >1cm) **G1:** 2 (+9.2) **G2:** 4 (+7.0) Total unimproved: **G1:** 5 **G2:** 24 *P* < 0.001 **Symptom change, N:** Heavy menstrual bleeding, before treatment: **G1:** 20 **G2:** 20	**Quality:** Overall quality score: poor **INTERNAL VALIDITY: fair** Random: NA Methods and blinding: NA Pt selection criteria: + Loss to follow-up: <10% Drop-out rates: <5% Statistical issues: - **EXTERNAL VALIDITY: poor (5)** Age: +, reported Race: -, NR Pregnancy history: -, NR Surgical history: NA Fibroid/uterine size: + Number of fibroids: - Location of fibroids: - Baseline characteristics: -, NR Length of follow-up: + Measurement methods: + Measurement reliability: + Clinical care: +

Evidence Table 14. KQ 6 Comparisons of Treatments (continued)

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria Other Details	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author: Mehl-Madrona, 2002 (continued)				Heavy menstrual bleeding, 6 mos: **G1:** 9 **G2:** 11 Prolonged menstrual bleeding, before treatment: **G1:** 9 **G2:** 9 Prolonged menstrual bleeding, 6 mos: **G1:** 5 **G2:** 5 Dysmenorrhea before treatment, N: **G1:** 9 **G2:** 9 Dysmenorrhea, 6 mos: **G1:** 5 **G2:** 7 Decreased exercise/activity tolerance, before treatment: **G1:** 2 **G2:** 2 Decreased exercise/activity tolerance, before treatment: **G1:** 2 **G2:** 2 Decreased exercise/activity tolerance, 6 mos: **G1:** 1 **G2:** 1 **Modifiers:** NR	

Evidence Table 14. KQ 6 Comparisons of Treatments (continued)

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria Other Details	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author: Razavi et al., 2003 **Country and setting:** US, Academic medical center **Enrollment period:** 07/1998 to 12/2000 **Funding:** NR	**Design:** Retrospective cohort **Intervention:** Myomectomy and UFE **Groups:** **G1:** UFE **G2:** Abdominal myomectomy **N at enrollment:** **G1:** 62 **G2:** 40 **N at follow-up:** NA **Age, mean yrs (range):** **G1:** 37.7 (28 to 48) **G2:** 44.2 (31 to 56) **Race/ethnicity:** NR **Parity:** NR **Baseline uterine size:** NR **Baseline Hct, %:** **G1:** 35.5 **G2:** 36	**Inclusion criteria:** • Abdominal myomectomy • Uterine fibroid embolization **Exclusion criteria:** • Planned laparoscopic myomectomy within 3 mos of UFE • Primary reason for surgery was the treatment of infertility without other symptoms **Indications:** NR **Preoperative therapy:** NR **Associated procedure(s):** NR	**Baseline uterine size:** NR **Number of fibroids:** NR **Baseline fibroid size:** NR **Type of fibroid:** NR	**Pain medication use (days):** **G1:** 5.1 **G2:** 8.7 *P* < 0.05 **Length of stay, days:** **G1:** 0 **G2:** 2.9 *P* < 0.05 **Complications, N (%):** **G1:** 7 (11) **G2:** 10 (25) *P* < 0.05 **Menorrhagia relief, N (%):** **G1:** 48 (92) **G2:**14 (64) *P* < 0.05 **Pain relief, N (%):** **G1:** 25 (74) **G2:** 14 (54) *P* = NS **Mass effect, N (%):** **G1:** 28 (76) **G2:** 21 (91) *P* < 0.05 **Time to resume normal activities (days):** **G1:** 8 **G2:** 36 *P* < 0.05 **Modifiers:** NR	**Quality:** Overall quality score: poor **INTERNAL VALIDITY: fair** Random: NA Methods and blinding: NA Pt selection criteria: + Loss to follow-up: NA Drop-out rates: NA Statistical issues: - **EXTERNAL VALIDITY: poor (9)** Age: +, reported Race: -, NR Pregnancy history: -, NR Surgical history: -, NR Fibroid/uterine size: - Number of fibroids: - Location of fibroids: - Baseline characteristics: -, NR Length of follow-up: NA Measurement methods: + Measurement reliability: - Clinical care: -

Evidence Table 14. KQ 6 Comparisons of Treatments (continued)

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria and Other Details	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author: Spies, Cooper, Worthington-Kirsch et al., 2004 **Country and setting:** US, Community and academic medical centers **Enrollment period:** NR **Funding:** Biosphere Medical Inc.	**Design:** Prospective cohort **Intervention:** UAE and hysterectomy **Groups:** **G1:** UAE **G2:** Hysterectomy **N at enrollment:** **G1:** 102 **G2:** 50 (40 TAH, 2 LAVH, and 8 LH) **N at follow-up, 12 months:** **G1:** 76 **G2:** 30 **Age, yrs ± SD:** **G1:** 42.6 ± 4.0 **G2:** 41.6 ± 5.3 *P* = 0.264 **Race/ethnicity, N (%):** Asian/Pacific Island: **G1:** 1 (1) **G2:** 2 (4) Black: **G1:** 61 (60) **G2:** 9 (18) Hispanic: **G1:** 7 (7) **G2:** 8 (16) White: **G1:** 31 (30) **G2:** 31 (62) Other: **G1:** 2 (2) **G2:** 0 (0) *P* < 0.001	**Inclusion criteria:** • Age: 30 to 50 yrs • Symptomatic fibroids **Exclusion criteria:** • Submucosal fibroids with > 50% diameter within uterine cavity • Dominant pedunculated serosal fibroid **Indications:** NR **Preoperative therapy:** NR **Additional procedures:** NR	**Baseline uterine size, ml ± SD:** **G1:** 689.4 ± 466.1 **G2:** 389.2 ± 521.2 *P* < 0.001 **Number of fibroids, N (%):** 1 fibroid: **G1:** 27 (26) **G2:** 20 (40) 2 fibroids: **G1:** 33 (32) **G2:** 19 (38) ≥3 fibroids: **G1:** 42 (41) **G2:** 10 (20) *P* = 0.021 **Baseline dominant fibroid size (ml ± SD):** **G1:** 146.8 ± 158.5 **G2:** 90.6 ± 354.8 *P* = 0.330 **Type of fibroid, N (%):** Intramural: **G1:** 61 (60) **G2:** 32 (64) *P* = 0.724 Subserosal: **G1:** 19 (19) **G2:** 8 (16) *P* = 0.823 Submucosal: **G1:** 17 (17) **G2:** 13 (26) *P* = 0.197 Transmural: **G1:** 11 (11) **G2:** 1 (2) *P* = 0.108 Pedunculated: **G1:** 2 (2) **G2:** 4 (8) *P*=0.072	**Procedure time, min:** **G1:** 57.9 **G2:** 93.6 *P* < 0.001 **At least 1 complication, N (%):** **G1:** 28 (27.5%; 95% CI, 19.1-37.2) **G2:** 25 (50%; 95% CI, 35.5-64.5) *P* = 0.01 **Complications within 30 days, %:** **G1:** 17.6 **G2:** 28 *P* = 0.15 **Complications after 30 days, %:** **G1:** 12.7 **G2:** 32 *P*=0.01 **Major complications, N (%):** **G1:** 4 (3.9) **G2:** 6 (12) *P* = 0.08 **Life threatening Complications, N:** **G1:** 0 **G2:** 0 **Overall morbidity N (%):** **G1:** 15 (14.7) **G2:** 17 (34.0) *P* = 0.01 **Hemorrhage, N (%):** **G1:** 0 (0) **G2:** 4 (8) *P* = 0.01	**Quality:** Overall quality score: fair **INTERNAL VALIDITY: poor** Random: NA Methods and blinding: NA Pt selection criteria: + Loss to follow-up: >20% Drop-out rates: NR Statistical issues: + **EXTERNAL VALIDITY: good** Age: +, reported Race: +, reported Pregnancy history: +, reported Surgical history: +, reported Fibroid/uterine size: + Number of fibroids: + Location of fibroids: + Baseline characteristics: +, reported Length of follow-up: ++ Measurement methods: + Measurement reliability: + Clinical care: +

Evidence Table 14. KQ 6 Comparisons of Treatments (continued)

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria and Other Details	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author: Spies, Cooper, Worthington-Kirsch et al., 2004 (continued)	**Parity, N (%):** Nulliparous: **G1:** 44 (43) **G2:** 11 (22) Para 1: **G1:** 20 (20) **G2:** 10 (20) Multiparous: **G1:** 38 (37) **G2:** 29 (58) *P* = 0.025 **Baseline Hgb, (%):** <12 g/dL: **G1:** 59 (58) **G2:** 19 (38) ≥12 g/dL: **G1:** 43 (42) **G2:** 31 (63) *P* = 0.025			**Febrile morbidity, N (%):** **G1:** 13 (12.7) **G2:** 12 (24.0) *P* = 0.10 **Length of stay, days:** **G1:** 0.83 **G2:** 2.3 *P* < 0.001 **Readmission, N (%):** **G1:** 3 (2.9) 4 (8) *P* = 0.22 **Satisfaction with symptom outcome:** *P* = NS **Mean time to return to work (days):** **G1:** 10.7 **G2:** 32.5 *P* < 0.001 **Unintended surgery, N (%):** **G1:** 2 (2) **G2:** 4 (8) *P* = 0.09 **Modifiers:** NR	

Evidence Table 14. KQ 6 Comparisons of Treatments (continued)

Study Description	Study Design, Interventions, and Patient Population	Inclusion/ Exclusion Criteria Other Details	Fibroids Characteristics	Outcomes	Notes/Quality Rating
Author: Vavilis et al., 2005 **Country and setting:** Greece, Academic medical center **Enrollment period:** 01/2000 to 01/2003 **Funding:** NR	**Design:** Retrospective cohort **Intervention:** Abdominal myomectomy vs. abdominal hysterectomy **Groups:** **G1:** Abdominal myomectomy **G2:** Abdominal hysterectomy **N at enrollment:** **G1:** 102 **G2:** 102 **N at follow-up:** NA **Age, yrs ± SD:** **G1:** 35 ± 5.8 **G2:** 45 ± 3.4 **Race/ethnicity:** NR **Parity:** NR **Baseline Hgb/Hct:** NR	**Inclusion criteria:** • Undergoing abdominal myomectomy or hysterectomy **Exclusion criteria:** NR **Indications:** NR **Pre-operative therapy:** NR **Associated procedure(s):** NR	**Baseline uterine size:** NR **Number of fibroids:** NR **Baseline fibroid size:** NR **Type of fibroid:** NR	**Fever >38° C, N (%):** **G1:** 17 (16.63) **G2:** 14 (13.72) *P* = NS **Fever lasting > 24 hrs, N (%):** **G1:** 4 (3.92) **G2:** 5 (4.9) *P* = NS **Modifiers:** NR	**Quality:** Overall quality score: poor **INTERNAL VALIDITY: fair** Random: NA Methods and blinding: NA Pt selection criteria: - Loss to follow-up: NA Drop-out rates: NA Statistical issues: + **EXTERNAL VALIDITY: poor (6)** Age: +, reported Race: NA, not US study Pregnancy history: -, NR Surgical history: -, NR Fibroid/uterine size: - Number of fibroids: - Location of fibroids: - Baseline characteristics: -, NR Length of follow-up: NA Measurement methods: + Measurement reliability: + Clinical care: +

Appendix D. List of Excluded Studies

Excluded Articles

Full Text Article Exclusion Criteria Codes for Database

X-1: Not original research
X-2: Not published from February 2000-February 2006
X-3: Not published in English
X-4: Study not conducted in appropriate geographic location
X-5: Ineligible study design
X-6: Study does not answer study question
CASE REPORT: Case report

List of Excluded Studies

1. Women's Health and the Environment: The Next Century--Advances in Uterine Leiomyoma Research. Conference proceedings. 7-8 October 1999, Research Triangle Park, North Carolina, USA. Environ Health Perspect. 2000 Oct;108 Suppl 5:767-853.
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2. Procedure minimizes need for hysterectomies. Rep Med Guidel Outcomes Res. 2000 Aug 3;11(16):8-10.
X-1

3. The future of women's health. Harv Womens Health Watch. 2000 Jan;7(5):4-6.
X-1

4. Uterine artery embolization for leiomyomata. Clin Privil White Pap. 2001 Jul 19(63):1-7.
X-1

5. Leuprorelin and triptorelin: new indication. Preoperative treatment of uterine leiomyoma: no proven value. Prescrire Int. 2001 Jun;10(53):73-7.
X-1

6. Gastrointestinal: gastric inflammatory fibroid polyp. J Gastroenterol Hepatol. 2001 Sep;16(9):1069.
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7. Alternatives to hysterectomy. Harv Womens Health Watch. 2001 Apr;8(8):5-7.
X-1

8. Uterine artery embolization for treatment of symptomatic uterine fibroids. TEC Bull (Online). 2002 Jul 8;19(2):37-9.
X-1

9. Stopping heavy periods. For some women, endometrial ablation is a viable alternative to hysterectomy. Health News. 2002 Aug;8(8):4.
X-1

10. HRT patches: ok for women with fibroids? Health News. 2002 Feb;8(2):9.
X-1

11. Patient page. Uterine fibroid embolization. Radiol Technol. 2003 Nov-Dec;75(2):176.
X-1

12. Ultrasound treatment zaps fibroids. Health News. 2004 Aug;10(8):2.
X-1

13. Medical image. Pseudocyesis. N Z Med J. 2004 Mar 12;117(1190):2 p following U801.
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14. Uterine artery embolization for fibroids. Med Lett Drugs Ther. 2005 Apr 11;47(1206):31-2.
X-1

15. Noninvasive treatment for uterine fibroids. FDA Consum. 2005 Jan-Feb;39(1):4.
X-1

16. Molecule of the month: asoprisnil. Drug News Perspect. 2005 Jul-Aug;18(6):404.
X-1

17. Magnetic resonance-guided focused ultrasound therapy for symptomatic uterine fibroids. Technol Eval Cent Asses Program Exec Summ. 2005 Oct;20(10):1-3.
X-1

18. Health highlights. Good news that greeted women in 2005. Mayo Clin Womens Healthsource. 2005 Dec;9(12):1-2.
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19. Can you tell me about the new device the FDA has approved for treating uterine fibroids? Mayo Clin Womens Healthsource. 2005 Apr;9(4):8.

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20. M. A. Abbas, M. Al-Kandari and F. M. Dashti. Laparoscopic-assisted resection of bleeding jejunal leiomyoma. Surg Endosc. 2001 Nov;15(11):1359.
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21. I. Abdulkader, J. Cameselle-Teijeiro, F. Gude, M. Fraga, J. Varela-Duran, F. Barreiro, et al. Predictors of malignant behaviour in gastrointestinal stromal tumours: a clinicopathological study of 34 cases. Eur J Surg. 2002;168(5):288-96.
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22. A. P. Aboyeji and M. A. Ijaiya. Uterine fibroids: a ten-year clinical review in Ilorin, Nigeria. Niger J Med. 2002 Jan-Mar;11(1):16-9.
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23. S. Abramson, R. C. Gilkeson, J. D. Goldstein, P. K. Woodard, R. Eisenberg and N. Abramson. Benign metastasizing leiomyoma: clinical, imaging, and pathologic correlation. AJR Am J Roentgenol. 2001 Jun;176(6):1409-13.
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24. O. Abulafia, K. Kleinhaus, G. Levi, Y. C. Lee and D. M. Sherer. Effect of gonadotropin-releasing hormone agonist treatment upon angiogenesis in uterine leiomyoma. Gynecol Obstet Invest. 2001;52(2):108-13.
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25. G. L. Adani, D. Marcello, A. Sanna, J. Mazzetti, G. Anania and A. Donini. Gastrointestinal stromal tumours: evaluation of biological and clinical current opinions. Chir Ital. 2002 Mar-Apr;54(2):127-31.
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26. K. A. Adelusola and S. O. Ogunniyi. Hysterectomies in Nigerians: histopathological analysis of cases seen in Ile-Ife. Niger Postgrad Med J. 2001 Mar;8(1):37-40.
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27. P. I. Adolfsson, I. Haug, G. Berg and S. P. Svensson. Changes in beta(2)-adrenoceptor expression and in adenylyl cyclase and phosphodiesterase activity in human uterine leiomyomas. Mol Hum Reprod. 2000 Sep;6(9):835-42.
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28. A. P. Advincula, J. C. Hernandez and R. Lieberman. Images in reproductive medicine. Disseminated leiomyomatosis peritonei. Fertil Steril. 2005 Nov;84(5):1505-7.
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29. A. P. Advincula, A. Song, W. Burke and R. K. Reynolds. Preliminary experience with robot-assisted laparoscopic myomectomy. J Am Assoc Gynecol Laparosc. 2004 Nov;11(4):511-8.
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30. A. K. Agarwal, R. Bansal and D. Singhal. Sinonasal leiomyoma: report of 2 cases. Ear Nose Throat J. 2005 Apr;84(4):224, 226-30.
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31. S. N. Agoff, V. S. Grieco, R. Garcia and A. M. Gown. Immunohistochemical distinction of endometrial stromal sarcoma and cellular leiomyoma. Appl Immunohistochem Mol Morphol. 2001 Jun;9(2):164-9.
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32. S. N. Agoff, J. E. Mendelin, V. S. Grieco and R. L. Garcia. Unexpected gynecologic neoplasms in patients with proven or suspected BRCA-1 or -2 mutations: implications for gross examination, cytology, and clinical follow-up. Am J Surg Pathol. 2002 Feb;26(2):171-8.
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33. T. Agorastos, K. Dinas and K. Patsiaoura. Cystic degenerated angioleiomyoma mimicking ovarian pathology. Acta Obstet Gynecol Scand. 2001 Sep;80(9):863-5.
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34. A. Agostini, J. Banet, F. Bretelle, L. Cravello and B. Blanc. Leiomyoma remaining after vaginal hysterectomy for symptomatic leiomyomas. A case report. J Reprod Med. 2003 Feb;48(2):119-20.
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35. A. Agostini, M. Beerli, F. Franchi, F. Bretelle and B. Blanc. Garnerella vaginalis bacteremia after vaginal myomectomy. Eur J Obstet Gynecol Reprod Biol. 2003 Jun 10;108(2):229.
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36. A. Agostini, N. Vejux, M. Capelle, I. Ronda and B. Blanc. Laparoscopic removal of a remaining myoma after vaginal hysterectomy: a case report. J Minim Invasive Gynecol. 2005 Jul-Aug;12(4):372-3.
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37. K. S. Ahamed and G. S. Raymond. Answer to case of the month #103. Large subserosal uterine leiomyoma with cystic degeneration presenting as an abdominal mass. Can Assoc Radiol J. 2005 Oct;56(4):245-7.
CASE REPORT

38. A. Ahmad, L. Qadan, N. Hassan and K. Najarian. Uterine artery embolization treatment of uterine fibroids: effect on ovarian function in younger women. J Vasc Interv Radiol. 2002 Oct;13(10):1017-20.
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39. I. Ahmad, C. E. Ray, Jr. and C. Conyers. Transvaginal sonographic appearance of thrombosed uterine arteries after uterine artery embolization: the "white snake" sign. J Clin Ultrasound. 2003 Oct;31(8):401-6.
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40. A. H. Ahmed, D. Martin and T. S. Onon. Secondary abdominal pregnancy associated with uterine fibroid. J Obstet Gynaecol. 2005 Feb;25(2):206-8.
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41. M. Ahmed, S. Zangos, W. O. Bechstein and T. J. Vogl. Intravenous leiomyomatosis. Eur Radiol. 2004 Jul;14(7):1316-7.
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42. W. S. Ahn, K. W. Kim, S. M. Bae, J. H. Yoon, J. M. Lee, S. E. Namkoong, et al. Targeted cellular process profiling approach for uterine leiomyoma using cDNA microarray, proteomics and gene ontology analysis. Int J Exp Pathol. 2003 Dec;84(6):267-79.
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43. S. Ahsan, S. Naeem and A. Ahsan. A case notes analysis of hysterectomy performed for non-neoplastic indications at Liaquat National Hospital, Karachi. J Pak Med Assoc. 2001 Oct;51(10):346-9.
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44. I. Ak, S. Ozalp, O. T. Yalcin, E. Zor and E. Vardareli. Uptake of 2-[18F]fluoro-2-deoxy-D-glucose in uterine leiomyoma: imaging of four patients by coincidence positron emission tomography. Nucl Med Commun. 2004 Sep;25(9):941-5.
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45. T. Akaeda, K. Isaka, T. Nakaji, D. Kakizaki and K. Abe. Clinical application of virtual hysteroscopy by CO(2)-multidetector-row computed tomography to submucosal myomas. J Minim Invasive Gynecol. 2005 May-Jun;12(3):261-6.
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46. T. Akase, S. Onodera, T. Jobo, R. Matsushita, M. Kaneko and S. Tashiro. A comparative study of the usefulness of toki-shakuyaku-san and an oral iron preparation in the treatment of hypochromic anemia in cases of uterine myoma. Yakugaku Zasshi. 2003 Sep;123(9):817-24.
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47. O. I. Akinola, A. O. Fabamwo, A. T. Ottun and O. A. Akinniyi. Uterine artery ligation for management of uterine fibroids. Int J Gynaecol Obstet. 2005 Nov;91(2):137-40.
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48. T. Akisue, K. Matsumoto, N. Tsumura, I. Fujita, T. Yamamoto and S. Yoshiya. Bone marrow edema syndrome associated with uterine myoma: a case report. Clin Orthop Relat Res. 2003 Apr(409):151-7.
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49. F. Aksu, A. Gezer and E. Oral. Seventeen-year review of hysterectomy procedures in a university clinic in Istanbul (1985-2001). Arch Gynecol Obstet. 2004 Dec;270(4):217-22.
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50. M. Al Azzam, J. M. Orrell and D. P. Vasey. Vulval leiomyoma with a myxoid hyaline stroma. J Obstet Gynaecol. 2004 Nov;24(8):936.
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51. M. Alam, A. D. Rabinowitz and D. E. Engler. Gabapentin treatment of multiple piloleiomyoma-related pain. J Am Acad Dermatol. 2002 Feb;46(2 Suppl Case Reports):S27-9.
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52. N. A. Alam, E. Barclay, A. J. Rowan, J. P. Tyrer, E. Calonje, S. Manek, et al. Clinical features of multiple cutaneous and uterine leiomyomatosis: an underdiagnosed tumor syndrome. Arch Dermatol. 2005 Feb;141(2):199-206.
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55. N. A. Alam, S. Olpin, A. Rowan, D. Kelsell, I. M. Leigh, I. P. Tomlinson, et al. Missense mutations in fumarate hydratase in multiple cutaneous and uterine leiomyomatosis and renal cell cancer. J Mol Diagn. 2005 Oct;7(4):437-43.
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56. N. A. Alam, A. J. Rowan, N. C. Wortham, P. J. Pollard, M. Mitchell, J. P. Tyrer, et al. Genetic and functional analyses of FH mutations in multiple cutaneous and uterine leiomyomatosis, hereditary leiomyomatosis and renal cancer, and fumarate hydratase deficiency. Hum Mol Genet. 2003 Jun 1;12(11):1241-52.
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57. A. Al-Badr and W. Faught. Uterine artery embolization in an undiagnosed uterine sarcoma. Obstet Gynecol. 2001 May;97(5 Pt 2):836-7.
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58. C. Alenda, F. I. Aranda, A. Paya and C. Cordoba. Mesectodermal leiomyoma of ciliary body. Int J Surg Pathol. 2002 Oct;10(4):309-12.

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59. G. Alessi, M. Lemmerling, L. Vereecken and L. De Waele. Benign metastasizing leiomyoma to skull base and spine: a report of two cases. Clin Neurol Neurosurg. 2003 Jul;105(3):170-4.
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60. H. Al-Fozan, J. Dufort, M. Kaplow, D. Valenti and T. Tulandi. Cost analysis of myomectomy, hysterectomy, and uterine artery embolization. Am J Obstet Gynecol. 2002 Nov;187(5):1401-4.
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61. A. Al-Hendy, E. J. Lee, H. Q. Wang and J. A. Copland. Gene therapy of uterine leiomyomas: adenovirus-mediated expression of dominant negative estrogen receptor inhibits tumor growth in nude mice. Am J Obstet Gynecol. 2004 Nov;191(5):1621-31.
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62. B. Ali-El-Dein, M. Abdel-Latif, A. Mosbah, I. Eraky, A. A. Shaaban, N. M. Taha, et al. Secondary malignant involvement of gynecologic organs in radical cystectomy specimens in women: is it mandatory to remove these organs routinely? J Urol. 2004 Sep;172(3):885-7.
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63. H. M. Al-Kadri, H. A. Al-Turki and A. M. Saleh. Short and long term complications of abdominal and vaginal hysterectomy for benign disease. Saudi Med J. 2002 Jul;23(7):806-10.
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64. E. C. Almeida, A. A. Nogueira, F. J. Candido dos Reis and J. C. Rosa e Silva. Cesarean section as a cause of chronic pelvic pain. Int J Gynaecol Obstet. 2002 Nov;79(2):101-4.
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65. M. Alper, A. Aydin, I. Ozdemir, M. Suna, H. Ciralik and K. A. Aksoy. Blue nevus with an unusual presentation: two patients with endocervical location. Ceska Gynekol. 2004 Sep;69(5):411-3.
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66. M. Alper, A. H. Parlak, A. Kavak and K. A. Aksoy. Bilateral multiple piloleiomyomas on the breast. Breast. 2004 Apr;13(2):146-8.
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67. S. Al-Shanafey, Y. Cartier, G. E. Stiles and A. G. Casson. Circumferential giant leiomyoma of the esophagus. J Am Coll Surg. 2001 Oct;193(4):453.
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70. I. Alvarado-Cabrero, F. Candanedo-Gonzalez and A. Sosa-Romero. Leiomyoma of the urethra in a Mexican woman: a rare neoplasm associated with the expression of estrogen receptors by immunohistochemistry. Arch Med Res. 2001 Jan-Feb;32(1):88-90.
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71. K. Amagasaki, N. Takeuchi, T. Kakizawa and T. Shimizu. Bilateral cortical blindness associated with cerebral angiitis. Acta Neurochir (Wien). 2002 Jul;144(7):749.
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72. F. Amant, M. Debiec-Rychter, E. F. Schoenmakers, A. Hagemeijer-Hausman and I. Vergote. Cumulative dosage effect of a RAD51L1/HMGA2 fusion and RAD51L1 loss in a case of pseudo-Meigs' syndrome. Genes Chromosomes Cancer. 2001 Dec;32(4):324-9.
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75. F. Amant, E. Huys, A. Geurts-Moespot, B. G. Lindeque, I. Vergote, F. Sweep, et al. Ethnic variations in uterine leiomyoma biology are not caused by differences in myometrial estrogen receptor alpha levels. J Soc Gynecol Investig. 2003 Feb;10(2):105-9.
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77. P. Amato and A. C. Roberts. Transient ovarian failure: a complication of uterine artery embolization. Fertil Steril. 2001 Feb;75(2):438-9.
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85. J. Andre, A. Theunis, B. Richert and N. de Saint-Aubain. Superficial acral fibromyxoma: clinical and pathological features. Am J Dermatopathol. 2004 Dec;26(6):472-4.
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87. R. T. Andrews, P. J. Bromley and M. E. Pfister. Successful embolization of collaterals from the ovarian artery during uterine artery embolization for fibroids: a case report. J Vasc Interv Radiol. 2000 May;11(5):607-10.
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88. C. Anichini, G. Calamai, E. Pedemonte, M. Moroni, S. Tozzini and G. Nesi. Intravenous leiomyoma with cardiac involvement. Int Angiol. 2001 Dec;20(4):345-7.

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89. K. Ankem. Influence of information sources on the adoption of uterine fibroid embolization by interventional radiologists. J Med Libr Assoc. 2003 Oct;91(4):450-9.
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91. K. Appiah-Sakyi, L. Byrd and R. J. Slade. Thermal balloon ablation--a rare case of fibroid necrosis. J Obstet Gynaecol. 2004 Jun;24(4):467.
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92. D. Aranovich, O. Kaminsky and A. Schindel. Retroareolar leiomyoma of the male breast. Isr Med Assoc J. 2005 Feb;7(2):121-2.
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93. S. Argibay Vazquez, C. Lancha Hernandez and A. Martinez Muniz. Metastases in the sphenoidal sinus in a patient with papillary thyroid cancer. Clin Transl Oncol. 2005 Aug;7(7):324-7.
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94. A. Arici and I. Sozen. Transforming growth factor-beta3 is expressed at high levels in leiomyoma where it stimulates fibronectin expression and cell proliferation. Fertil Steril. 2000 May;73(5):1006-11.
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97. P. J. Armstrong and D. P. Franklin. Pararenal vena cava leiomyosarcoma versus leiomyomatosis: difficult diagnosis. J Vasc Surg. 2002 Dec;36(6):1256-9.
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Appendix E. List of Peer Reviewers

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Technical Expert Panel

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Peer Reviewers

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