

Abstracts of publications from the Collaborative Review of Sterilization (CREST)

Dicker RC, Greenspan JR, Strauss LT, Cowart MR, Scally MJ, Peterson HB, DeStefano F, Rubin GL, Ory HW. Complications of abdominal and vaginal hysterectomy among women of reproductive age in the United States. The Collaborative Review of Sterilization. *Am J Obstet Gynecol.* 1982;144:841-8. PubMed PMID: 7148906.

Although hysterectomy was the most frequently performed major surgical procedure among women of reproductive age during the past decade, few recent studies have been conducted to determine the risk of complications. We examined data from the Collaborative Review of Sterilization, a prospective, multicenter, observational study coordinated by the Centers for Disease Control, to assess the comparative risks of complications among women undergoing hysterectomy by the abdominal and vaginal approaches. Between September 1978, and August 1981, 1,851 women from nine institutions were included in the study. Women who underwent vaginal hysterectomy experienced significantly fewer complications than women who had undergone abdominal hysterectomy. The difference was probably attributable to the prevalence and efficacy of prophylactic antibiotic use among the former group. Vaginal hysterectomy was associated with more unintended major surgical procedures but less febrile morbidity, bleeding requiring transfusion, hospitalization, and convalescence than abdominal hysterectomy. Vaginal hysterectomy with prophylactic antibiotics should be strongly considered for those women of reproductive age for whom either surgical approach is clinically appropriate.

Layde PM, Peterson HB, Dicker RC, DeStefano F, Rubin GL, Ory HW. Risk factors for complications of interval tubal sterilization by laparotomy. *Obstet Gynecol.* 1983;62:180-4. PubMed PMID: 6866361.

The complication rate among 282 women undergoing interval tubal sterilization by laparotomy was studied as part of the prospective multicenter Collaborative Review of Sterilization. Using a standard definition of major complications, the overall complication rate was 5.7 per 100 procedures. Women experiencing complications had a significantly lengthened postoperative recovery period before the resumption of normal activities. Important risk factors for complications included diabetes, cigarette smoking, previous abdominal or pelvic surgery, and a history of pelvic inflammatory disease. Women with an initial abdominal incision of 7 cm or longer had three times the complication rate of women with shorter incisions. These results provide objective evidence that, for tubal sterilizations, minilaparotomy (laparotomy with a small abdominal incision) is associated with lower morbidity than is conventional laparotomy.

Franks AL. Prior abdominal, pelvic surgery is factor in unintended laparotomy. *Contracept Technol Update.* 1984;5:104-5. PubMed PMID: 12266311.

Data from the Collaborative Review of Sterilization indicate that women with a history of abdominal or pelvic surgery are 10 times more likely than women without such a history to experience unintended laparotomy associated with laparoscopic tubal sterilization. The data

analysis included 5068 women ages 15–41 years who were scheduled for laparoscopic sterilizations at 11 institutions in 1978–82. Of these, 52 (1%) underwent unintended laparotomy. 40 of these procedures were performed to complete a sterilization procedure and 12 were performed to manage complications. Unintended laparotomy occurred most frequently among women who were more than 20% over their ideal body weight, who were black, who underwent general anesthesia, and for whom electrocoagulation was used for tubal occlusion. 21% of the women had histories of previous pelvic or abdominal surgery, 35% had histories of IUD use, and 10% had histories of pelvic inflammatory disease. The last 2 risk factors were not statistically significant, however. These statistics suggest that about 1200 US women with histories of pelvic or abdominal surgery will undergo unintended laparotomy each year. The procedure is considered undesirable because it involves anesthesia, thereby increasing the risk of morbidity. It is recommended that physicians discuss these risk factors with patients during counseling.

Lee NC, Dicker RC, Rubin GL, Ory HW. Confirmation of the preoperative diagnoses for hysterectomy. *Am J Obstet Gynecol.* 1984;150:283-7. PubMed PMID: 6486193.

Few previous studies have examined the relationship between the preoperative and pathologic diagnoses for hysterectomy. To determine the percentage of preoperative diagnoses that were confirmed by pathologic examination, we analyzed data from the Collaborative Review of Sterilization, a multicenter study of hysterectomies and tubal sterilizations in women aged 15 to 44 years. Data were collected from patient interviews and chart reviews. Of the 1851 women included in this study, 1283 (69%) had abdominal hysterectomies and 568 (31%) had vaginal hysterectomies. Overall, 52% of the hysterectomies were performed for a preoperative diagnosis that could potentially be confirmed by pathologic examination. Pathologic examination actually confirmed the preoperative diagnosis of endometrial hyperplasia in 95% of the cases, cervical intraepithelial neoplasia in 89%, leiomyomas in 84%, pelvic inflammatory disease in 75%, adenomyosis in 48%, and endometriosis in 47%. Among all of the potentially confirmable diagnoses, 80% were confirmed. The remaining 48% of the women who had hysterectomies had preoperative diagnoses that were not amenable to confirmation by pathology. Most of these were for one of three diagnoses: menstrual bleeding disorders, pelvic pain, or pelvic relaxation. In 47% of these cases, pathologic examination showed leiomyoma or adenomyosis; no abnormalities were found in 38% of these cases.

Grubb GS, Rubin GL, Layde PM. Contraceptive use before tubal sterilization. *J Reprod Med.* 1985;30:345-50. PubMed PMID: 4009552.

A woman's decision to undergo tubal sterilization may be affected by her experience with temporary contraception. To examine this issue we analyzed data from the Collaborative Review of Sterilization, a multicenter, prospective study of the health effects of sterilization operations on women aged 15–44 years. Data on contraceptive use by a comparison group of non-sterilized women were drawn from a random, population-based sample of women aged 20–44 years who were controls in a large study of cancer and steroid hormone use. Sterilized women reported ever using a higher average number of contraceptive methods

than did nonsterilized women. As compared with nonsterilized women, a higher percentage of sterilized women reported ever using contraceptives (99% versus 91%), especially two types, barrier and rhythm or withdrawal. Prior to selecting sterilization as a permanent contraceptive method, the sterilized women had more extensive experience with temporary contraceptives, particularly the less effective ones, than did the comparable nonsterilized women.

Akhter HH, Flock ML, Rubin GL. Safety of abortion and tubal sterilization performed separately versus concurrently. *Am J Obstet Gynecol.* 1985;152(6 Pt 1):619-23. PubMed PMID: 3895936.

Concurrent abortion and sterilization are preferred by many women to avoid a second hospitalization, operation, and, in some instances, general anesthesia. Several authors have shown concern, however, that the two procedures carry a higher risk of morbidity when performed concurrently versus separately. To determine whether the concurrent performance of sterilization and induced abortion is as safe as the two procedures performed separately, we selected women undergoing these procedures from two separate multicenter, prospective, national United States studies: the Joint Program for the Study of Abortion and the Collaborative Review of Sterilization. Using standard definitions of major morbidity, we calculated the crude rate of one or more major complications to be 0.9% for the abortion-only group, 1.7% for the group concurrent abortion and tubal sterilization. Thus our data suggest that performing concurrent abortion and sterilization is as safe as performing those procedures separately.

Grubb GS, Peterson HB, Layde PM, Rubin GL. Regret after decision to have a tubal sterilization. *Fertil Steril.* 1985;44:248-53. PubMed PMID: 4018280.

To determine characteristics associated with regretting sterilization that can be determined preoperatively, we analyzed data from the Collaborative Review of Sterilization (CREST), a multicenter, prospective, observational study. Of 5022 women, 2.0% regretted having had a tubal sterilization at 1 year after the procedure and 2.7% did so after 2 years. Using a multivariate analysis to identify risk factors for regret, we found that almost all characteristics were more closely associated with regret at 1 year than at 2 years post-operatively. Of the characteristics we examined that could be objectively determined preoperatively, we considered only age less than 30 years and (for whites) a concurrent cesarean section to be risk factors for regret at 2 years after sterilization. However, in absolute terms, less than 10% of women with both those risk factors regretted having the procedure.

Kendrick JS, Rubin GL, Lee NC, Schulz KF, Peterson HB, Nolan TF. Hysterectomy performed within 1 year after tubal sterilization. *Fertil Steril.* 1985;44:606-10. PubMed PMID: 4054340.

In the United States, approximately 650,000 women of reproductive age undergo tubal sterilization each year and some of these women later have hysterectomies. Little is known

about risk factors for having hysterectomy after tubal sterilization. For examination of this issue, we analyzed data from the Collaborative Review of Sterilization, an ongoing multicenter prospective study designed to assess the safety and efficacy of female sterilization operations. In 1979 and 1980, 4002 women 15 to 44 years of age had interval tubal sterilization; of these women, 64 had hysterectomies within 15 months, which yielded a cumulative incidence of 1.6%. Women with a history of menstrual complaints, leiomyomata, ovarian cysts, or endometriosis before their tubal sterilization had an increased risk of hysterectomy, compared with women without such a history. However, 98% of women with a history of these conditions did not have a hysterectomy within 15 months after tubal sterilization. Further follow-up of these women should help to better delineate their long-term risks.

Grubb GS, Peterson HB. Luteal phase pregnancy and tubal sterilization. *Obstet Gynecol.* 1985;66:784-8. PubMed PMID: 4069479.

The effectiveness of several measures that may reduce the risk of luteal phase pregnancies after interval tubal sterilization was analyzed. Using data from the Collaborative Review of Sterilization on 5495 women, 18 luteal phase pregnancies were identified. Women who underwent sterilization after their estimated date of ovulation had a low risk of having a luteal phase pregnancy if they used oral contraceptives or an intrauterine device in the month before sterilization. Of the 18 luteal phase pregnancies, 14 (78%) occurred among the 16.8% of the women who were sterilized after their estimated date of ovulation and who had used barrier, rhythm, or withdrawal methods of contraception in the month before sterilization. The use of concurrent dilatation and curettage in these women at increased risk of luteal phase pregnancy did not lower their risk to that of women who were sterilized before their estimated date of ovulation.

Franks AL, Kendrick JS, Peterson HB. Unintended laparotomy associated with laparoscopic tubal sterilization. *Am J Obstet Gynecol.* 1987;157:1102-5. PubMed PMID: 2961262.

Although the complication rate for laparoscopic tubal sterilization is generally low, laparotomy is sometimes necessary to complete the sterilization or manage complications. To better characterize factors that predispose women to unintended laparotomy, we analyzed data from the Collaborative Review of Sterilization. Of the 5027 women undergoing laparoscopic tubal sterilization, 12 had unintended laparotomies to manage complications, whereas 39 women had unintended laparotomies because of technical inability to complete the laparoscopic procedure. Women with prior abdominal or pelvic surgery had an increased risk of unintended laparotomy (relative risk = 10.2, 95% confidence interval = 5.3 to 19.7). Women with a history of intrauterine device use or pelvic inflammatory disease had elevated risks that were not statistically significant (relative risk = 2.2 and 1.5, respectively). Comparative studies of alternative surgical approaches for tubal sterilization are needed to formulate recommendations for women who may be at increased risk of unintended laparotomy associated with the laparoscopic approach.

Wilcox LS, Chu SY, Peterson HB. Characteristics of women who considered or obtained tubal reanastomosis: results from a prospective study of tubal sterilization. *Obstet Gynecol.* 1990;75:661-5. PubMed PMID: 2179781.

The Collaborative Review of Sterilization is a prospective study of women undergoing tubal sterilization at selected medical centers in the United States. This analysis examined 5817 study participants who were asked whether they had sought information on tubal reanastomosis after their sterilizations and whether they had actually obtained reanastomosis surgery. Characteristics that predicted the likelihood of seeking reanastomosis information were examined in multivariate, logistic regression models that included age, race, number of living children, history of abortion, education, timing of sterilization in relation to pregnancy, initial marital status, and change in marital status. Among the women studied, 6.2% reported that they had sought information on reanastomosis. Women who were younger than 30 years old at the time of sterilization were twice as likely to seek such information as women aged 30–34, and women who had experienced changes in marital status after sterilization were 2.8 times as likely to seek information as women with unchanged marital status. Thirteen women had actually obtained reanastomosis. Compared with the overall study population, these women were more likely to be white, to have lower gravidity, to be younger, and to have experienced changes in marital status.

Wilcox LS, Chu SY, Eaker ED, Zeger SL, Peterson HB. Risk factors for regret after tubal sterilization: 5 years of follow-up in a prospective study. *Fertil Steril.* 1991;55:927-33. PubMed PMID: 2022271.

The Collaborative Review of Sterilization is a prospective, multicenter study that interviewed 7,590 women before they underwent tubal sterilization and then conducted yearly follow-up interviews that included questions on sterilization regret. These women contributed 26,641 observations (for up to 5 years after the procedure, 1978 to 1988) to an analysis of the presterilization characteristics most consistently associated with poststerilization regret. Young age at the time of sterilization was the strongest predictor of regret, regardless of parity or marital status; among women 20 to 24 years of age at sterilization, an average of 4.3% reported regret over the follow-up period. The rate of regret was significantly lower for women 30 to 34 years of age (2.4%).

Wilcox LS, Martinez-Schnell B, Peterson HB, Ware JH, Hughes JM. Menstrual function after tubal sterilization. *Am J Epidemiol.* 1992;135:1368-81. PubMed PMID: 1510083.

More than 10 million women in the United States have undergone tubal sterilization. There has been concern that this procedure may increase the risk of later menstrual dysfunction. The Collaborative Review of Sterilization (CREST) is a large, multicenter, prospective study of tubal sterilization in the United States. This report describes CREST participants who were interviewed immediately before sterilization and again in annual poststerilization interviews for up to 5 years between 1978 and 1988. The authors analyzed reported changes in six

menstrual cycle characteristics for 5,070 women undergoing interval sterilizations. Longitudinal, multivariate regression was used to adjust for baseline menstrual function and other potential confounders. Five years after sterilization, 35% of the CREST participants reported high levels of menstrual pain, 49% reported heavy or very heavy menstrual flow, and 10% reported spotting between periods. In contrast to the fifth year, the first year of follow-up was similar to presterilization menstrual function; in the first year, 27% of participants reported high menstrual pain, 41% reported heavy menstrual flow, and 7% reported spotting. These findings may be affected by aging of the cohort and other study limitations, but they suggest that if tubal sterilization leads to changes in menstrual function, such changes may take some time to develop.

Martinez-Schnell B, Wilcox LS, Peterson HB, Jamison PM, Hughes JM. Evaluating the effects of tubal sterilization on menstrual function: selected issues in data analysis. *Stat Med*. 1993;12:355-63. PubMed PMID: 8456217.

We examined selected issues in data analysis in the Collaborative Review of Sterilization (CREST). CREST is a multicentre, prospective, observational study of women undergoing tubal sterilization. We analysed menstrual function after sterilization in over 5000 women who were enrolled in the period 1978–1983 and followed for 5 years with yearly follow-up interviews. To take into account the dependency among repeated responses from the same individuals, we used the generalized estimating equations (GEE) approach to longitudinal data analysis. Marginal modelling resulted in a statistically significant increase in the odds of menstrual dysfunction at 5 years after tubal sterilization. Transitional modelling produced rates of menstrual dysfunction given a woman's menstrual function at baseline, after adjusting for other baseline characteristics such as method of contraception before sterilization. To examine the direction of the bias that could result from non-random missing data, we refitted our models using imputed values. The models with imputed values showed the same trends as the original models.

Peterson HB, Xia Z, Hughes JM, Wilcox LS, Tylor LR, Trussell J. The risk of pregnancy after tubal sterilization: findings from the U.S. Collaborative Review of Sterilization. *Am J Obstet Gynecol*. 1996;174:1161-8; discussion 1168-70. PubMed PMID: 8623843.

Our purpose was to determine the risk of pregnancy after tubal sterilization for common methods of tubal occlusion. A multicenter, prospective cohort study was conducted in U.S. medical centers. A total of 10,685 women who underwent tubal sterilization were followed up for 8 to 14 years. The risk of pregnancy was assessed by cumulative life-table probabilities and proportional hazards models. A total of 143 sterilization failures were identified among 10,685 women following tubal sterilization. Cumulative 10-year probabilities of pregnancy were highest after clip sterilization (36.5/1000 procedures) and lowest after unipolar coagulation (7.5/1000) and postpartum partial salpingectomy (7.5/1000). The cumulative risk of pregnancy was highest among women sterilized at a young age with bipolar coagulation (54.3/1000) and clip application (52.1/1000). Although tubal sterilization is highly effective, the risk of sterilization failure is higher than generally

reported. The risk persists for years after the procedure and varies by method of tubal occlusion and age.

Peterson HB, Xia Z, Hughes JM, Wilcox LS, Tylor LR, Trussell J. The risk of ectopic pregnancy after tubal sterilization. U.S. Collaborative Review of Sterilization Working Group. *N Engl J Med.* 1997;336:762-7. PubMed PMID: 9052654.

Tubal sterilization is an increasingly common method of contraception in the United States. Although pregnancy after sterilization is uncommon, it can occur and may be ectopic. We used data from the U.S. Collaborative Review of Sterilization to estimate the risk of ectopic pregnancy in women who had undergone the common types of tubal sterilization. A total of 10,685 women undergoing tubal sterilization were followed in a multicenter, prospective cohort study. We intended to follow all the women for 5 years by means of annual telephone interviews; for women enrolled early in the study, we attempted an additional follow-up telephone interview 8 to 14 years after sterilization. To assess the risk of ectopic pregnancy in these women, we used cumulative life-table probabilities and proportional-hazards analysis. There were 47 ectopic pregnancies in the 10,685 women; the 10-year cumulative probability of ectopic pregnancy for all methods of tubal sterilization combined was 7.3 per 1000 procedures. The cumulative probability varied substantially according to the method of sterilization and the woman's age at the time of sterilization. Women sterilized by bipolar tubal coagulation before the age of 30 years had a probability of ectopic pregnancy that was 27 times as high as that among women of similar age who underwent postpartum partial salpingectomy (31.9 vs. 1.2 ectopic pregnancies per 1000 procedures). The annual rate of ectopic pregnancy for all methods combined in the 4th through 10th years after sterilization was no lower than that in the first 3 years. A history of tubal sterilization does not rule out the possibility of ectopic pregnancy, even many years after the procedure.

Hillis SD, Marchbanks PA, Tylor LR, Peterson HB. Tubal sterilization and long-term risk of hysterectomy: findings from the United States collaborative review of sterilization. The U.S. Collaborative Review of Sterilization Working Group. *Obstet Gynecol.* 1997;89:609-14. PubMed PMID: 9083322.

The objective of this study was to estimate the long-term probability of hysterectomy after sterilization according to demographic and clinical characteristics before the procedure. We used a prospective, multi-center cohort study of 10,698 women undergoing tubal sterilization to examine the cumulative probability of hysterectomy up to 14 years after sterilization. Independent risk factors for subsequent hysterectomy were examined using the life-table approach and the Cox proportional hazards model. The cumulative probability of undergoing hysterectomy 14 years after sterilization was 17%. The highest long-term cumulative probabilities of hysterectomy occurred among women who, at the time of sterilization, reported a history of endometriosis (35%) or were older than 30 years and reported prolonged bleeding during menses (46%). Multivariate modeling demonstrated an independently increased risk of hysterectomy among women who, at the time of tubal sterilization, reported a history of heavy menstrual flow (relative risk [RR] 1.4; 95%

confidence interval [CI] 1.1, 1.7), severe menstrual pain (RR 1.3; 95% CI 1.1, 1.6), bleeding of more than 7 days during menstrual cycles (RR 1.8; 95% CI 1.1, 2.8), pelvic inflammatory disease (RR 1.3; 95% CI 1.04, 1.7), ovarian cysts (RR 1.6; 95% CI 1.2, 2.0), endometriosis (RR 2.5; 95% CI 1.7, 3.9), or uterine leiomyomata (RR 2.7; 95% CI 2.0, 3.7). Although women with gynecologic disorders before tubal sterilization were at greater risk of hysterectomy during the 14 years after sterilization than were women without these disorders, the majority of sterilized women in both categories did not undergo subsequent hysterectomy.

Hillis SD, Marchbanks PA, Tylor LR, Peterson HB. Higher hysterectomy risk for sterilized than nonsterilized women: findings from the U.S. Collaborative Review of Sterilization. The U.S. Collaborative Review of Sterilization Working Group. *Obstet Gynecol.* 1998;91:241-6. PubMed PMID: 9469283.

The objective of this study was to compare the risk of hysterectomy among previously sterilized women and women whose husbands had undergone vasectomy, and to evaluate whether this risk differed by age at surgical procedure or by method of tubal occlusion. Our study population comprised 7718 women enrolled in a prospective, multicenter cohort study between 1978 and 1986. After stratifying by the woman's age at surgical procedure, we used the life-table approach and adjusted hazards ratios to examine whether the relative risk of hysterectomy during the 5 years after enrollment differed between the 7174 women who had been sterilized and the 544 women whose husbands had undergone vasectomy. The 5-year cumulative probability of hysterectomy was 8% among the 7,174 previously sterilized women and 2% among the 544 women whose husbands had undergone vasectomy. Among women 34 years of age and younger at enrollment, sterilized women were 4.4 times as likely to have a hysterectomy as women whose husbands had undergone vasectomy (95% confidence interval [CI] 1.9, 10.0). Findings were similar for women 35 years of age and older (rate ratio = 4.6; 95% CI 1.4, 14.5). Each of the six most commonly used methods of tubal occlusion was associated with an increased risk of hysterectomy. Women undergoing tubal sterilization were more likely than women whose husbands underwent vasectomy to undergo hysterectomy within 5 years after sterilization, regardless of age at sterilization. An increased risk of hysterectomy was observed for each method of tubal occlusion.

Hillis SD, Marchbanks PA, Tylor LR, Peterson HB. Poststerilization regret: findings from the United States Collaborative Review of Sterilization. *Obstet Gynecol.* 1999;93:889-95. PubMed PMID: 10362150.

The objective of this study was to evaluate the cumulative probability of regret after tubal sterilization, and to identify risk factors for regret that are identifiable before sterilization. We used a prospective, multicenter cohort study to evaluate the cumulative probability of regret within 14 years after tubal sterilization. Participants included 11,232 women aged 18-44 years who had tubal sterilizations between 1978 and 1987. Actuarial life tables and Cox proportional hazards models were used to identify those groups at greatest risk of experiencing regret. The cumulative probability of expressing regret during a follow-up interview within 14 years after tubal sterilization was 20.3% for women aged 30 or younger

at the time of sterilization and 5.9% for women over age 30 at sterilization (adjusted relative risk [RR] 1.9; 95% confidence interval [CI] 1.6, 2.3). For the former group, the cumulative probability of regret was similar for women sterilized during the postpartum period (after cesarean, 20.3%, 95% CI 14.5, 26.0; after vaginal delivery, 23.7%, 95% CI 17.6, 29.8) and for women sterilized within 1 year after the birth of their youngest child (22.3%, 95% CI 16.4, 28.2). For women aged 30 or younger at sterilization, the cumulative probability of regret decreased as time since the birth of the youngest child increased (2–3 years, 16.2%, 95% CI 11.4, 21.0; 4–7 years, 11.3%, 95% CI 7.8, 14.8; 8 or more years, 8.3%, 95% CI 5.1, 11.4) and was lowest among women who had no previous births (6.3%, 95% CI 3.1, 9.4). Although most women expressed no regret after tubal sterilization, women 30 years of age and younger at the time of sterilization had an increased probability of expressing regret during follow-up interviews within 14 years after the procedure.

Peterson HB, Xia Z, Wilcox LS, Tylor LR, Trussell J. Pregnancy after tubal sterilization with bipolar electrocoagulation. U.S. Collaborative Review of Sterilization Working Group. *Obstet Gynecol.* 1999;94:163-7. PubMed PMID: 10432120.

The objective of this study was to determine risk factors for pregnancy after tubal sterilization with bipolar electrocoagulation. A total of 2267 women who had bipolar electrocoagulation were followed for up to 8 to 14 years as part of a multicenter, prospective, cohort study conducted in medical centers in nine United States cities. We used proportional hazards analysis and cumulative life-table probabilities to assess pregnancy risk in these women. The 5-year cumulative probability of pregnancy for 2,267 women sterilized in 1978–1982 was 19.5 per 1000 procedures (95% confidence interval [CI], 12.2, 26.9); the comparable probability for women sterilized in 1985–1987 was significantly lower, 6.3 per 1000 procedures (95% CI, 0.0, 13.5) (one-tailed $P=.01$). Women enrolled in 1985–1987 who had fewer than three sites of coagulation had a probability of failure of 12.9 per 1000 procedures (95% CI, 0.0, 38.0); by contrast, women who had three or more sites coagulated had a probability of failure of 3.2 per 1000 procedures (95% CI, 0.0, 9.6) (one-tailed $P=.01$). The long-term probability of pregnancy after tubal sterilization with bipolar coagulation was very low when three or more sites of the fallopian tube were coagulated. Bipolar coagulating systems can be highly effective for sterilization when the fallopian tube is coagulated adequately.

Peterson HB, Jeng G, Folger SG, Hillis SA, Marchbanks PA, Wilcox LS; U.S. Collaborative Review of Sterilization Working Group. The risk of menstrual abnormalities after tubal sterilization. U.S. Collaborative Review of Sterilization Working Group. *N Engl J Med.* 2000;343:1681-7. PubMed PMID: 11106717.

The existence of a post-tubal-ligation syndrome of menstrual abnormalities has been debated for decades. We used data from the U.S. Collaborative Review of Sterilization to determine whether the likelihood of persistent menstrual abnormalities was greater among women who had undergone tubal sterilization than among women who had not. A total of 9514 women who underwent tubal sterilization and 573 women whose partners underwent vasectomy were followed in a multicenter, prospective cohort study for up to five years by

means of annual telephone interviews. All women were asked the same questions about six characteristics of their menstrual cycles in the presterilization and follow-up interviews. Multiple logistic-regression analysis was used to assess the risk of persistent menstrual changes. The women who had undergone sterilization were no more likely than those who had not undergone the procedure to report persistent changes in intermenstrual bleeding or the length of the menstrual cycle. They were more likely to have decreases in the number of days of bleeding (odds ratio, 2.4; 95 percent confidence interval, 1.1 to 5.2), the amount of bleeding (odds ratio, 1.5; 95 percent confidence interval, 1.1 to 2.0), and menstrual pain (odds ratio, 1.3; 95 percent confidence interval, 1.0 to 1.8) and to have an increase in cycle irregularity (odds ratio, 1.6; 95 percent confidence interval, 1.1 to 2.3). Among women who had had very heavy bleeding at base line, women who had undergone sterilization were more likely than women who had not undergone the procedure to report decreased bleeding (45 percent vs. 33 percent, $P=0.03$). Women who have undergone tubal sterilization are no more likely than other women to have menstrual abnormalities.

Jamieson DJ, Hillis SD, Duerr A, Marchbanks PA, Costello C, Peterson HB. Complications of interval laparoscopic tubal sterilization: findings from the United States Collaborative Review of Sterilization. *Obstet Gynecol.* 2000;96:997-1002. PubMed PMID: 11084192.

The objective of this study was to estimate the risk of intraoperative or postoperative complications for interval laparoscopic tubal sterilizations. We used a prospective, multicenter cohort study of 9475 women who had interval laparoscopic tubal sterilization to calculate the rates of intraoperative or postoperative complications. The relative safety of various methods was assessed by calculating overall complication rates for each major method of tubal occlusion. Method-related complication rates also were calculated and included only complications attributable to a method of occlusion. We used logistic regression to identify independent predictors of one or more complications. When we used a more restrictive definition of unintended major surgery, the overall rate of complications went from 1.6 to 0.9 per 100 procedures. There was one life-threatening event and there were no deaths. Complications rates for each of the four major methods of tubal occlusion ranged from 1.17 to 1.95, with no significant differences between them. When complication rates were calculated, the spring clip method had the lowest method-related complication rate (0.47 per 100 procedures), although it was not significantly different from the others. In adjusted analysis, diabetes mellitus (adjusted odds ratio [OR] 4.5; 95% confidence interval [CI] 2.3, 8.8), general anesthesia (OR 3.2; CI 1.6, 6.6), previous abdominal or pelvic surgery (OR 2.0; CI 1.4, 2.9), and obesity (OR 1.7; CI 1.2, 2.6) were independent predictors of one or more complications. Interval laparoscopic sterilization generally is a safe procedure; serious morbidity is rare.

Schmidt JE, Hillis SD, Marchbanks PA, Jeng G, Peterson HB. Requesting information about and obtaining reversal after tubal sterilization: findings from the U.S. Collaborative Review of Sterilization. *Fertil Steril.* 2000;74:892-8. PubMed PMID: 11056229.

Objective: To determine the cumulative probabilities over 14 y of requesting information on sterilization reversal and of obtaining a reversal and to identify risk factors observable at

sterilization for both measures of regret. Design: The U.S. Collaborative Review of Sterilization, a prospective cohort study. Setting: Fifteen medical centers in 9 cities. Patients: 11,232 women. Main outcome measures: Cumulative probabilities of requesting information on reversal and undergoing reversal. Results: The 14-y cumulative probability of requesting reversal information was 14.3% (95% confidence interval [CI], 12.4%-16.3%). Among women aged 18 to 24 y at sterilization, the cumulative probability was 40.4% (95% CI, 31.6%-49.2%). Women aged 18 to 24 y were almost 4 times as likely to request reversal information as were women \geq 30 years of age (adjusted rate ratio [RR], 3.5; 95% CI, 2.8-4.4). Number of living children was not associated with requesting reversal information. The overall cumulative probability of obtaining reversal was 1.1% (95% CI, 0.5-1.6). Younger women (18 to 30 y) were more likely to obtain reversal (RR, 7.6; 95% CI, 3.2-18.3). Women who were sterilized at a young age had a high chance of later requesting information about reversal, regardless of their number of living children.

Peterson HB, Xia Z, Wilcox LS, Tylor LR, Trussell J; US Collaborative Review of Sterilization Working Group. Pregnancy after tubal sterilization with silicone rubber band and spring clip application. *Obstet Gynecol.* 2001;97:205-10. PubMed PMID: 11165583.

The objective of this study was to determine risk factors for pregnancy after tubal sterilization with silicone rubber bands or spring clips. A total of 3329 women sterilized using silicone rubber bands and 1595 women sterilized using spring clips were followed for up to 14 years as part of a prospective cohort study conducted in medical centers in nine US cities. We assessed the risk of pregnancy by cumulative life-table probabilities and proportional hazards analysis. The risk of pregnancy for women who had silicone rubber band application differed by location of band application and study site. The 10-year cumulative probabilities of pregnancy varied from a low of 0.0 per 1000 procedures at one study site to a high of 42.5 per 1000 procedures in the four combined sites in which fewer than 100 procedures per site were performed. The risk of pregnancy for women who had spring clip application varied by location of clip application, study site, race or ethnicity, tubal disease, and history of abdominal or pelvic surgery. The probabilities across study sites ranged from 7.1 per 1000 procedures at 10 years to 78.0 per 1000 procedures at 5 years (follow-up was limited to 5 years at that site). The 10-year cumulative probability of pregnancy after silicone rubber band and spring clip application is low but varies substantially by both clinical and demographic characteristics.

Jamieson DJ, Kaufman SC, Costello C, Hillis SD, Marchbanks PA, Peterson HB; US Collaborative Review of Sterilization Working Group. A comparison of women's regret after vasectomy versus tubal sterilization. *Obstet Gynecol.* 2002;99:1073-9. PubMed PMID: 12052602.

The objective of this study was to compare the 5-year cumulative probability of regret and risk factors for regret among women whose husbands underwent vasectomy with women after tubal sterilization. A total of 525 women whose husbands underwent vasectomy were compared with 3672 women who underwent tubal sterilization in a prospective, multicenter, cohort study. The cumulative probability of a woman expressing regret within 5

years after her husband's vasectomy was 6.1% (95% confidence interval [CI] 3.6, 8.6), which was similar to the 5-year cumulative probability of regret among women after tubal sterilization (7.0%, 95% CI 5.8, 8.1). Women who reported substantial conflict with their husbands before vasectomy were more than 25 times more likely to request that their husband have a reversal than women who did not report such conflict (rate ratio 25.3, 95% CI 2.9, 217.2). Similarly, women who reported substantial conflict with their husbands or partners before tubal sterilization were more than three times as likely to regret their decision and more than five times as likely to request a reversal than women who did not report such conflict (rate ratio 3.1, 95% CI 1.4, 7.0, and rate ratio 5.4, 95% CI 1.6, 17.6, respectively). Most women did not express regret after their husband's vasectomy and the probability of regret was similar to sterilized women. However, when there was substantial conflict between a woman and her husband before vasectomy or tubal sterilization, the probability of subsequent request for reversal was increased.

Costello C, Hillis SD, Marchbanks PA, Jamieson DJ, Peterson HB; US Collaborative Review of Sterilization Working Group. The effect of interval tubal sterilization on sexual interest and pleasure. *Obstet Gynecol.* 2002;100:511-7. PubMed PMID: 12220771.

The objective of this study is to determine if interval tubal sterilization leads to a change in female sexual interest or pleasure and to identify predictors of a positive or negative effect. Our study population comprised 4576 women enrolled in a prospective, multicenter cohort study between 1978 and 1983. Potential demographic, clinical, and surgical predictors of sexual outcome were tested for significant variation from the overall pattern of unchanged, increased, and decreased sexual interest and pleasure. Over 80% of the 4,576 study women reported no consistent change in either sexual interest (80.0%) or pleasure (81.7%) after interval tubal sterilization. Among women with consistent change, positive effects were reported ten and 15 times more often than negative effects for sexual interest and pleasure, respectively. All subgroups of women, except for those with poststerilization regret, were significantly ($P < .05$) more likely to experience increased rather than decreased interest or pleasure. Women with poststerilization regret were the subgroup most likely to have a negative effect; in multivariate analyses, poststerilization regret was the only factor to be a predictor for decreased interest (odds ratio 4.0) and decreased pleasure (odds ratio 5.1). Similarly, women reporting regret were significantly less likely to report increased interest or pleasure. Whether the regret or the decreased sexual interest or pleasure occurred first is unclear. Interval tubal ligation is unlikely to result in changed sexual interest or pleasure. Among those with change, the majority experienced positive sexual effects.

Jamieson DJ, Costello C, Trussell J, Hillis SD, Marchbanks PA, Peterson HB; US Collaborative Review of Sterilization Working Group. The risk of pregnancy after vasectomy. *Obstet Gynecol.* 2004;103(5 Pt 1):848-50. PubMed PMID: 15121555.

The objective of this study was to describe the pregnancy rates among women whose husbands underwent vasectomy. Between 1985 and 1987, 573 women aged 18–44 years whose husbands underwent vasectomy in medical centers in 5 U.S. cities were enrolled in the U.S. Collaborative Review of Sterilization, a prospective cohort study of male and female

sterilization. Women were interviewed by telephone at 1, 2, 3, and 5 years after their husbands underwent vasectomy. Among the 540 eligible women at risk for pregnancy, there were 6 pregnancies occurring from 6 to 72 weeks after vasectomy. The cumulative probability of failure per 1,000 procedures (95% confidence interval) was 7.4 (0.2, 14.6) 1 year after vasectomy and 11.3 (2.3, 20.3) at years 2, 3, and 5. Couples considering vasectomy should be counseled about the small, but real, risk of pregnancy following the procedure and that men are not sterile immediately after vasectomy.