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Bariatric Surgery in Women of Reproductive Age: Special Concerns for Pregnancy

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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 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 written comments on this evidence report. They may be sent to: Director, Center for Outcomes and Evidence, Agency for Healthcare Research and Quality, 540 Gaither Road, Rockville, MD 20850, or by email to epc@ahrq.gov .

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Structured Abstract

Context: The use of bariatric surgery for treating severe obesity has increased dramatically over the past 10 years; about half of patients who undergo these procedures are women of reproductive age. This report was commissioned to measure the incidence of bariatric surgery in this population and review the evidence on the impact of bariatric surgery on fertility and subsequent pregnancy.

Objectives: To measure the incidence of contemporary bariatric surgery procedures in women age 18-45 and to assess its impact on fertility, contraception, prepregnancy risk factors, and pregnancy outcomes, including those of neonates.

Data Sources and Study Selection: We used the Nationwide Inpatient Sample (NIS), a national sample of over 1,000 hospitals, to measure the trend in the number of women of reproductive age who underwent bariatric procedures from 1998-2005. We searched numerous electronic databases, including Medline and Embase, for potentially relevant studies involving bariatric surgery (gastric bypass, laparoscopic adjustable gastric band, vertical-banded gastroplasty, biliopancreatic diversion), and consequent fertility, contraception, pregnancy, weight management, maternal outcomes, neonatal outcomes, and nutritional deficiencies. We scanned reference lists for additional relevant articles and contacted experts in the fields of bariatric surgery and obstetrics/gynecology (OB/GYN).

Of 223 screened articles, we accepted 57 that reported on fertility following surgery (19 articles), contraception use/recommendations (11), maternal weight or nutrition management (28), maternal outcomes including morbidity and mortality (48), cesarean-section rates (16), and neonatal outcomes (44). These articles included reports on gastric bypass, both open and laparoscopic (27 articles), laparoscopic adjustable band (15), biliopancreatic diversion (16), and vertical-banded gastroplasty (6). Studies could contribute to one or more analyses.

We found one case-control study and the observational data accepted included 12 cohort studies, 21 case series, and 23 individual case reports.

Data Extraction: We abstracted information about study design, fertility history, fertility outcomes, prepregnancy weight loss, nutritional management, outcomes following pregnancy, and adverse events (during pregnancy) related to surgery.

Data Synthesis: Nationally representative data showed a six-fold increase in bariatric surgery inpatient procedures from 1998 to 2005. Women age 18-45 accounted for about half of the patients undergoing bariatric surgery; over 50,000 have these procedures as inpatients annually. An unknown number have outpatient bariatric procedures.

We identified one case-control study that directly addressed some of the key questions, but no randomized controlled trials or prospective cohort studies, which would be the strongest study designs to answer questions about effectiveness, risk and prognosis. Consequently, all of our conclusions are limited by the available data, and are cautious.

The evidence suggests that bariatric surgery results in improved fertility; the strongest evidence is in women with the polycystic ovarian syndrome, where biochemical studies showing normalization of hormones after surgery support case series data. Observational studies (retrospective cohorts and case series) suggest that fertility improves following bariatric

procedures and weight loss; similar to that seen when obese women lose weight through nonsurgical means. There is almost no evidence on post-surgical contraceptive efficacy or use. Research is needed to determine whether differences in absorption, particularly for oral contraceptives, affect contraceptive efficacy.

Nutrient deficiencies were reported in infants born to women who underwent procedures that resulted in malabsorption, as well as women who did not take prenatal vitamins or had difficulty with their own nutrition (i.e., from chronic vomiting). Literature suggests that gastric bypass and laparoscopic adjustable band procedures confer only minimal, if any, increased risk of nutritional or congenital problems if supplemental vitamins are taken and maternal nutrition is otherwise adequate. Biliopancreatic diversion has an appreciable risk for nutritional problems in some patients.

Women who have undergone bariatric surgery may have less risk than obese women for certain pregnancy complications such as gestational diabetes, preeclampsia, and pregnancy-induced hypertension. There is no evidence that cesarean section rates and delivery complications are higher in the post-surgery group, but data are limited.

Conclusions: Weight loss procedures are being performed more frequently to treat morbid obesity, with a six-fold increase over a recent 7-year time span; almost half of all patients are women of reproductive age. The level of evidence on fertility, contraception, and pregnancy outcomes is limited to observational studies. Data suggest that fertility improves after bariatric surgical procedures, nutritional deficiencies for mother and child are minimal, and maternal and neonatal outcomes are acceptable with laparoscopic adjustable band and gastric bypass as long as adequate maternal nutrition and vitamin supplementation are maintained. There is no evidence that delivery complications are higher in post-surgery pregnancies.

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Evidence Tables and other Appendixes are provided electronically at
http://www.ahrq.gov/downloads/pub/evidence/pdf/bariatricrep/barirep.pdf

Executive Summary

Introduction

Obesity has reached epidemic proportions in the United States. Along with this increase, weight loss surgeries, known as bariatric procedures, have become increasingly common. This report assesses the incidence of these operations in women of reproductive age and reviews the evidence on the impact of such surgery on fertility, contraception, prepregnancy risk factors, and pregnancy outcomes, including those for neonates.

Methods

The American College of Obstetricians and Gynecologists (ACOG) nominated the topic of this report and provided the following initial list of questions:

1. What is the incidence of bariatric surgery in women of reproductive age? What are the trends in incidence of bariatric surgery in women of reproductive age?

2. What is the evidence that bariatric surgery affects (directly or indirectly) future fertility?

3. What is the evidence that bariatric surgery affects (directly/indirectly) choice of contraception?

4. In patients who have had bariatric surgery, what is the evidence for prenatal risk factors (e.g., of reduced nutrient absorption, unusual weight gain) that may result in poor pregnancy outcomes?

5. What is the evidence that certain management strategies for addressing nutrient absorption and weight gain reduce the risks of poor pregnancy outcomes?

6. For women who have had bariatric surgery, what is the evidence for morbidity and mortality risks for: a) mother and b) neonate?

7. What is the evidence that cesarean section for women who have had bariatric surgery affects the risks of morbidity and mortality for: a) mother and b) neonate?

To answer key question one, we used the Nationwide Inpatient Sample (NIS), a national sample of over 1,000 hospitals, to measure the trend in the number of women of reproductive age undergoing bariatric procedures from 1998-2005. For key questions two through seven, we searched numerous electronic databases, including Medline and Embase, for potentially relevant studies involving bariatric surgery (gastric bypass, laparoscopic adjustable gastric band, vertical-banded gastroplasty, biliopancreatic diversion), and consequent fertility, contraception, pregnancy, weight management, maternal outcomes, neonatal outcomes, and nutritional

deficiencies. We scanned reference lists for additional relevant articles and contacted experts in the fields of bariatric surgery and obstetrics/gynecology (OB/GYN).

We abstracted information about study design, fertility history, fertility outcomes, prepregnancy weight loss, nutritional management, outcomes following pregnancy, and adverse events (during pregnancy) related to surgery. Data are narratively summarized.

Results

We screened 223 articles. Of those, we accepted 57 studies that reported on the following: fertility following surgery (19 articles), contraception use/recommendations (11), maternal weight or nutrition management (28), maternal outcomes including morbidity and mortality (48), cesarean-section rates (16), and neonatal outcomes (44). (Studies could contribute to more than one analysis.) These reports included gastric bypass, both open and laparoscopic (27 articles), laparoscopic adjustable band (15), biliopancreatic diversion (16), and vertical-banded gastroplasty (six). Only one study was a randomized controlled trial, but it did not have a nonsurgical treatment group, and only one of the three surgical procedures studies is still performed frequently (gastric bypass). Consequently, we treated this study as a case series of gastric bypass. In total, the studies accepted included 12 cohort studies, 21 case series, 23 individual case reports, and one case-control study. Hence, all of the data come from studies with less rigorous designs and therefore the findings are more prone to bias, and, as such, our conclusions are cautious.

Key Question 1. What is the incidence of bariatric surgery in women of reproductive age? What are the trends in incidence of bariatric surgery in women of reproductive age?

At least 50,000 women between the ages of 18 and 45 undergo bariatric procedures each year in an inpatient setting. The rate of performance of these procedures is increasing rapidly—more than six fold in the past 7 years. Many more women in this age group are also likely undergoing bariatric procedures in the outpatient setting; however these procedures are not reflected in this statistic.

Key Question 2. What is the evidence that bariatric surgery affects (directly or indirectly) future fertility?

It is likely that fertility improves following bariatric surgery and subsequent weight loss, but this finding is based only on observational data. Fertility did appear to improve for individuals with polycystic ovarian syndrome. These findings are consistent with improvements in fertility seen when obese women lose weight with nonsurgical methods.

Key Question 3. What is the evidence that bariatric surgery affects (directly/indirectly) choice of contraception?

There is almost no evidence on this topic. We found only a single study that reported data on the effectiveness of contraceptive methods following surgery. A small case series of 40 patients who had undergone biliopancreatic diversion (BPD) and who were advised to avoid pregnancy for at least 2 years reported two failures for oral contraceptives (OCP), one at 9 months

postoperatively and the other at 24 months. Based on this, these authors advised the use of something other than OCP, and called for a large RCT to determine the best method of contraception. It is not clear whether the failure rate of OCPs in this case series is significantly worse than expected in average use.

Key Question 4. In patients who have had bariatric surgery, what is the evidence for prenatal risk factors (e.g., of reduced nutrient absorption, unusual weight gain) that may result in poor pregnancy outcomes?

We did not identify any *prospective* cohort studies, which would be the strongest study design to assess this question of risk. Consequently, our conclusions are tempered by the limited available evidence. Based on these data, gastric bypass and laparoscopic adjustable band seem to confer minimal if any risk for nutrient problems, as long as maternal nutrition is maintained. However, BPD has an appreciable risk for nutritional problems: In one large case series, 20 percent of pregnant women required parenteral nutrition and case reports of pregnancy following BPD show nutritional adverse events, even with good compliance with supplementation.

Key Question 5. What is the evidence that certain management strategies for addressing nutrient absorption and weight gain reduce the risks of poor pregnancy outcomes?

It is common practice to recommend nutritional supplementation, such as multi-vitamins and iron, following bariatric surgery for all patients. However, evidence is scarce regarding specific recommendations for pregnant women. We did not identify any randomized studies assessing this question of efficacy of management strategies. Studies evaluating pregnancy following laparoscopic adjustable gastric banding or gastric bypass have shown minimal nutritional adverse events; however, most of these studies monitored and ensured that the women complied with vitamin supplementation. Some case reports/case series stated that the patients who had nutritional deficiencies did not take the recommended supplements. Regarding laparoscopic adjustable gastric band, some reports indicated that the band needed adjustment in order to allow for proper oral nutrition intake.

A number of reports in the literature describe the need for supplementation and parenteral nutrition in pregnancy following BPD. Case series and cohort studies have shown that the rate of parenteral nutrition use in pregnancy after BPD is approximately 20 percent.

Key Question 6. For women who have had bariatric surgery, what is the evidence for morbidity and mortality risks for: a) mother and b) neonate?

We identified no *prospective* cohort studies, which would be the strongest study design for this question regarding risk and prognosis, Consequently, our conclusions are tempered by the limited available evidence. Women who have had bariatric surgery may have a lesser risk than obese women for certain pregnancy complications. The one case-control study reported a lower rate of large-for-gestational-age neonates, lower mean birth weights, and less pregnancy-associated hypertension in the postsurgery pregnancies. The observational data, in general, showed lower rates of gestational diabetes, preeclampsia, and pregnancy-induced hypertension in postsurgery pregnancies. In addition, observational studies support that mean birth weight, rates

of low birth weight, and rates of premature delivery are similar among babies born to women following bariatric surgery to those in the general population.

There are case reports of surgical complications in women who became pregnant following bariatric surgery, including maternal deaths and fetal death—however there are similar reports in nonpregnant bariatric patients. These complications are uncommon and appeared to be due to internal hernias. Delays in diagnosis were a common factor in many case reports, and use of CT scan, even though the patients were pregnant, was helpful in reaching a diagnosis. Women who elect to have bariatric surgery will have an increased risk of certain complications that would not have occurred had they not had bariatric surgery, but the impact of how pregnancy affects the risk is unknown.

Key Question 7. What is the evidence that cesarean section for women who have had bariatric surgery affects the risks of morbidity and mortality for: a) mother and b) neonate?

One case control study assessed the effects of cesarean section among women who have had bariatric surgery or their offspring. Comparing 57 women postbariatric surgery and 57 presurgery pregnancies matched for presurgical body mass index, they found no difference in primary or secondary cesarean section rates. In addition, they found no difference in rates of transfusions, peripartum need for antibiotics, or thromboembolic events. The overall rates of cesarean section vary greatly from in the cohort and case series studies. It appears that the obstetric complications are consistent with reports from the nonobese population.

Discussion

This review has a number of limitations, the most important being the quality of the original studies. The clinical questions of interest are best answered by studies using a *prospective* cohort design (for studies of risk and prognosis, such as key questions 2 and 4) or randomized clinical trials (for questions of management, such as key questions 3 and 5). We found no such studies, and therefore were compelled to use data from studies with designs of lesser theoretical strength. The inherent limitations in these study designs preclude us from drawing strong conclusions regarding the answers to most questions.

Future Research

More research is needed to answer almost every key question in this report.

Regarding rates of use, methods are needed to capture the rise in outpatient delivery of bariatric procedures, mainly the laparoscopic adjustable-band. Without this information, estimates of use based on the Nationwide Inpatient Sample will underestimate the total number of cases.

For all issues related to risk and prognosis, such as the effects on fertility, timing of pregnancy, development of complications of pregnancy, outcomes of pregnancy, and cesarean section rates, prospective cohorts are required to provide better estimates.

For the issues related to management, such as choice of contraceptive and nutritional management, randomized controlled trials are needed.

Conclusions

Weight loss procedures are being performed more frequently to treat morbid obesity, with a six-fold increase over a recent 7-year time span; almost half of patients are women of reproductive age. The level of evidence on fertility, contraception, and pregnancy outcomes is limited primarily to case series and case reports. The evidence suggests that fertility improves after bariatric surgical procedures; however, data are too sparse to reach definite conclusions about the degree of improvement in fertility that is achieved. Evidence also suggests that nutritional deficiencies for mother and child are minimal, and maternal and neonatal outcomes are acceptable with laparoscopic adjustable band and gastric bypass as long as adequate maternal nutrition and vitamin supplementation are maintained.

Evidence Report

Chapter 1. Introduction

Obesity has reached epidemic proportions in the United States. Current estimates suggest that more than 30 percent of the U.S. population is obese, and obesity is now one of the leading causes of health-related disorders.[1-12] Obesity is defined as body mass index (BMI) of 30 kg/m^2 or greater, with severe obesity defined as a BMI of 35-39.9 kg/m,^{2} and morbid obesity defined as BMI $\geq$ 40 kg/m.^{2} In general, most morbidly obese individuals are more than 100 lbs over their ideal body weight. From 2000 to 2005, the prevalence of morbid obesity increased by 50 percent in the United States.[13] Obesity is linked strongly to many chronic diseases, such as type II diabetes, heart disease, hypertension, and hyperlipidemia.[14-16] Weight loss is associated with substantial improvements in these obesity-related disorders.[17] As such, treatments for obesity, both medical and surgical, have become increasingly common.

Surgery Produces Substantial Weight Loss

For patients who are severely obese, most nonsurgical treatments—such as diet, exercise, and medications—are not very effective at producing significant weight loss and, more importantly, maintaining weight loss. A recent meta-analysis by Li found that medications, along with diet and other exercise interventions, produce only modest weight loss (5 kg lost at one year).[18] Similarly, controlled studies of diets have shown mostly minimal weight loss.[19] In contrast, observational reports have concluded that surgical treatments for severe obesity result in substantial weight loss that patients are able to maintain over the long term.[17] A recent meta-analysis by Maggard et al reported that bariatric procedures generate, on average, 20-30 kg of weight loss and that the weight loss can be maintained for at least 10 years.[20]

Bariatric Surgical Procedures

A variety of surgical procedures have been used to induce weight loss for obese patients. These procedures result in weight loss via different mechanisms, and some employ a combination of mechanisms. In general, bariatric surgery employs three mechanisms to induce weight loss: (1) restricting the size of the stomach limits the quantity of food a patient can consume at a single meal, (2) malabsorptive procedures decrease the proportion of nutrients that are absorbed from a meal, and (3) a combination of hormonal changes are induced by creating a small gastric pouch (and outlet) along with a proximal bypass. Details of selected bariatric procedures (those performed frequently now) are provided below.

Adjustable Gastric Banding. Gastric banding achieves weight loss by creating gastric restriction. The uppermost portion of the stomach is encircled by a band to create a gastric pouch with a capacity of approximately 15 to 30 cubic centimeters (cc). The band consists of an inflatable doughnut-shaped balloon whose diameter can be adjusted in the clinic by adding or removing saline via a reservoir port positioned beneath the skin. The bands are adjustable to allow the size of the gastric outlet to be modified as needed, depending on the rate of a patient's weight loss. Weight loss is achieved mainly by restricting caloric intake. Currently, almost all of the banding procedures are performed laparoscopically. While this procedure is technically reversible (e.g., removal of the band for failed weight loss), doing so exposes the patient to potential risks associated with a second operation and, of course, will necessitate identifying an alternative method for weight loss.

Vertical Banded Gastroplasty (VBG) and other gastroplasty procedures. VBG uses the strategy of mechanical restriction to cause weight loss. The upper part of the stomach is stapled to create a narrow gastric inlet or pouch that remains connected with the remainder of the stomach. In addition, a nonadjustable band is placed around this new inlet in an attempt to prevent future enlargement of the stoma. As a result, patients experience a sense of fullness after eating small meals. Weight loss from this procedure results entirely from eating less: There is no component of malabsorption. VBG was one of the more common surgical procedures for weight loss in the late 1980s and early 1990s but has been superseded since 1995 by adjustable band procedures and procedures that combine mechanical restriction with bypass (see below).

Biliopancreatic diversion (BPD). BPD involves removing 70 percent of the stomach along with bypassing a significant proportion of small intestine. By reducing the size of the stomach, less acid is produced, but the remaining capacity is generous compared to that achieved with gastric bypass. As such, patients eat relatively normal-sized meals and do not need to restrict intake severely. Malabsorption is caused by (1) the diversion of food downstream, decreasing the opportunity for nutrient absorption and (2) reduction in the quantities of enzymes and bile in the bypassed segment, which decreases absorption. Patients develop steatorrhea from the decrease in fat absorption.

Although this procedure is not as commonly performed as either banding procedures or gastric bypass, the approach is strongly favored by some bariatric surgery specialists. The partial biliopancreatic diversion with duodenal switch is a variant of the BPD procedure that, until recently, was performed mostly in Italy and only rarely performed in the United States. Recently, a number of centers in the United States and Canada have begun to perform this procedure, which involves resection of the greater curvature of the stomach, preservation of the pyloric sphincter, and transection of the duodenum above the ampulla of Vater with a duodeno-ileal anastomosis and a lower ileo-ileal anastomosis.

Gastric Bypass. Roux en Y gastric bypass (RYGB), which we will refer to as "gastric bypass" throughout the report, achieves weight loss through a complex mechanism. The surgery involves creating a small gastric pouch (and outlet) along with a proximal intestinal bypass. This small pouch (30 cc) is connected to a segment of the jejunum (which is downstream), thus bypassing the duodenum and very proximal small intestine. Although the procedure generates minimal malabsorption, significant changes in hormones (e.g., ghrelin, PYY) and neural signals to the gastrointestinal tract lead to hunger control and satiety. In addition, following ingestion of high-density carbohydrates, many patients will experience the resultant "dumping" syndrome, whose unpleasant symptoms include flushing, palpitations, abdominal pain, cramping, and diarrhea. As a result, patients develop an aversion to high-carbohydrate foods. The overall result is that patients make major changes in their diet and eating habits. Gastric bypass for weight loss has been performed regularly since the early 1980s. It was first performed laparoscopically in the early 1990s and is now one of the most common types of weight loss procedures.

Rates of Surgery are on the Rise

The effectiveness of bariatric surgery at generating weight loss has been well publicized by word of mouth through patients, celebrity success stories, and the media. As a result, more obese patients have been increasingly turning to the procedures. The American Society of Bariatric and Metabolic Surgery has estimated that 140,000 gastric bypass cases were completed in 2005, and an estimated 200,000 bariatric surgery cases will be performed in 2007.[21, 22]

Majority of Cases Are Performed in Women

More than 80 percent of patients who have bariatric surgery are women.[23] The average age of women undergoing these procedures is around 42. Thus, many tens of thousands of women of childbearing age have had bariatric surgery. Because nutrition is a vital component of pregnancy and producing a healthy baby, it is imperative to understand the effects of bariatric surgery, both positive and negative, on fertility and pregnancy outcomes. The American College of Obstetrics and Gynecology therefore proposed to the Agency for Healthcare Research and Quality this review of the evidence regarding the use of bariatric surgery in women of reproductive age and the impact of surgery on subsequent fertility and pregnancy outcomes.

Chapter 2. Methods

Original Proposed Key Questions

The American College of Obstetricians and Gynecologists (ACOG) nominated the topic of this report and provided the following initial list of questions:

1. What is the incidence of bariatric surgery in women of reproductive age? What are the trends in incidence of bariatric surgery in women of reproductive age?

2. What is the evidence that bariatric surgery affects (directly or indirectly) future fertility?

3. What is the evidence that bariatric surgery affects (directly/indirectly) choice of contraception?

4. In patients who have had bariatric surgery, what is the evidence for prenatal risk factors (e.g., of reduced nutrient absorption, unusual weight gain) that may result in poor pregnancy outcomes?

5. What is the evidence that certain management strategies for addressing nutrient absorption and weight gain reduce the risks of poor pregnancy outcomes?

6. For women who have had bariatric surgery, what is the evidence for morbidity and mortality risks for: a) mother and b) neonate?

7. What is the evidence that cesarean section for women who have had bariatric surgery affects the risks of morbidity and mortality for: a) mother and b) neonate?

Technical Expert Panel

Each AHRQ evidence report is guided by a Technical Expert Panel (TEP). We invited a distinguished group of scientists and clinicians, including individuals with expertise in obesity, obstetrics, surgery, pediatrics, and fertility, to participate in the TEP for this report. A list of members is included in Appendix A*. TEP conference calls were held on March 7, 2007, and June 14, 2007. On the first call, staff presented the literature search results and asked experts to suggest additional studies. On the second call, staff presented the study findings and obtained feedback.

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

Literature Search

Our search for studies began in November 2006 with an electronic search of PubMed® and Embase for reports on pregnancy after bariatric surgery. We also searched the Cochrane Controlled Clinical Trials Register Database and the Cochrane Database of Reviews of Effectiveness (DARE). (The Cochrane Collaboration is an international organization that helps people make well-informed decisions about health care by preparing, maintaining, and promoting the accessibility of systematic reviews on the effects of heath care interventions.) Search updates were conducted monthly through May 2007.

Appendix B shows our specific search terms. Per our TEP, we included articles on adjustable gastric banding, vertical-banded gastroplasty, Roux-en-Y gastric bypass (RYGB), and biliopancreatic diversion (BPD). Jejunoileal bypass, one of the earliest procedures performed for weight loss, was not included, as this procedure was abandoned about 25 years ago due to a high rate of complications. We used various search terms for each type of procedure. For example, for Roux-en-Y gastric bypass, we also used: gastric bypass, RYGB, laparoscopic gastric bypass, and open gastric bypass. We ordered all articles on pregnancy after bariatric surgery, regardless of study design, language, or publication date.

Article Review

Study Inclusion

Our literature search was unrestricted by study design. The studies included in the review are of one of the following types of designs.

- *Review articles* identified by the search were classified as either *systematic* (including meta-analyses) or *nonsystematic*. Systematic reviews were identified by reading the methods section of the article to determine whether an acceptable method was employed to identify evidence (such as a description of the name of the computerized database searched and the full set of search terms used, as well as details about the method for accepting and rejecting identified articles).
- *Randomized controlled trials (RCTs)* are studies where the participants are definitely assigned prospectively to one of two (or more) alternative forms of intervention, using a process of random allocation (e.g., random number generation, coin flips).
- *Controlled clinical trials (CCTs)* are studies where participants (or other units) are either
    - definitely assigned prospectively to one of two (or more) alternative forms of health care using a quasi-random allocation method (e.g., alternation, date of birth, patient identifier)
      OR
    - possibly assigned prospectively to one of two (or more) alternative forms of health care using a process of random or quasi-random allocation.
- *Observational studies (such as cohort and cases series)* are those where the investigators do not control who gets the interventions. Almost all of the data included in this report comes from observational studies.
- *Individual case reports* are reports of complications / adverse events submitted to medical journals by physicians.

To be included, studies had to report on one of the surgical procedures described in the introduction, and had to report on pregnancy outcomes.

Screening

Using a single-page "screening form" (included in Appendix C*), we reviewed the studies retrieved from the various sources against our exclusion criteria. Items included specific surgical procedure, study design, sample size, and type of outcome reported (i.e., fertility, morbidity, mortality). Two reviewers, each trained in the critical analysis of scientific literature, independently reviewed each study and resolved disagreements by consensus. The lead investigator resolved any disagreements that remained after discussions between the reviewers.

Data Abstraction & Synthesis of Results

Results from one case-control study, cohort studies, cases series, and individual case reports were abstracted by physicians into separate data tables. Because of study heterogeneity, pooling was not possible; thus, we summarize the data qualitatively. Data abstracted included surgical adverse events, nutritional deficiencies, and adverse outcomes such as gestational diabetes, hypertension, preeclampsia and macrosomia. Data on miscarriages, premature delivery, and other neonatal outcomes was abstracted where applicable, as was any information on fertility and contraception use/effectiveness.

Analysis of Trends in Surgery Utilization

We used the Nationwide Inpatient Sample (NIS)[24] to produce national estimates of trends in bariatric surgical procedures for the years 1998-2005. The NIS is a database of hospital inpatient stays from states participating in the Healthcare Cost and Utilization Project (HCUP). The NIS is the only national hospital inpatient database with charge information on all patients, regardless of payer, including Medicare, Medicaid, private insurance, as well as the uninsured. As the largest such publicly available database it includes data from five to eight million hospital stays from roughly 1,000 hospitals sampled to estimate a 20-percent stratified sample of U.S. community hospitals (all non-Federal, short-term, general, and other specialty hospitals, excluding hospital units of institutions). Because the NIS is available from 1988 to 2005, it allows for a robust analysis of trends over time.

The NIS includes all inpatient discharges within the sampled hospitals. Discharge weights developed by HCUP to account for the sampling scheme were used to produce national estimates. Weights were constructed consistently across the years of data used in our analysis. Hospitals were stratified by region, location/teaching status, bed size category, and ownership. Clustering was accounted for at the hospital level. All analyses were conducted using SAS/STAT® software.[25]

Table 1 displays the International Classification of Diseases 9th Edition (ICD-9) procedure codes for bariatric procedures included in this report. For the seven year time span included in our study, the International Classification of Diseases did not have specific codes for all the

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

bariatric procedures. Previous studies using HCUP data were consulted, they used the Centers for Medicare & Medicaid Services' billing guidelines to compile a comprehensive list of ICD-9 procedure codes that would capture the bariatric operations.[23] In addition, we accounted for changes in the coding system that occurred. For example, as laparoscopic gastric bypass became more common, a separate code was created for this method. Prior to 2004, gastric bypass, open or laparoscopic, could be coded under a variety of ICD-9 procedure code options, like 44.39 (other gastroenterostomy) or 44.31 (high gastric bypass). In 2004, code 44.38 was created to represent laparoscopic gastric bypass.

Procedure codes for corresponding gastric procedures were also restricted by ICD-9 codes for obesity (278.0-278.8) or diagnosis-related group code (DRG) for obesity surgery (288). Furthermore, we used several exclusion criteria to decrease the possibility that we were capturing operations not performed for weight loss purposes. Only discharges that had a DRG code for obesity (278 or 288) were included. Emergency admission types were excluded as were cancer (150-159.9) and noninfectious enteritis and colitis (555-558) diagnoses.

Overall estimates of bariatric surgery procedures were calculated for each year of data. Because we were interested in how bariatric surgery affects women of child bearing age, we estimated the number of procedures within the 18-45 age range, overall and by gender. We also performed a subanalysis looking at women between 18-35 and 36-45. The percent change from 1998 was calculated for each of the proceeding years.

Table 1. Bariatric surgical procedures by ICD-9 code

Procedure		ICD-9 Code
Gastric bypass		
	High gastric bypass	44.31
	Gastroenterostomy other (1998-2005)	44.39
	Gastroenterostomy - laparoscopic (2004-2005)	44.38
Gastroplasty		
	Gastroplasty - not otherwise specified (1998-2005)	44.69
	Gastroplasty - laparoscopic (2004-2005) [including vertical banded gastroplasty and those combined with gastroenterostomy]	44.68
Adjustable Band		
	Laparoscopic Adjustable Band (2004-2005) [prior to 2004 coded as 44.69]	44.95
	Laparoscopic Band revision (2004-2005) [prior to 2004 coded as 44.69]	44.96
	Laparoscopic band removal (2004-2005) [prior to 2004 coded as 44.99]	44.97
Malabsorptive		
	Sleeve gastrectomy	43.89
	Partial gastrectomy with jejunal anastomosis	43.7
	Gastrectomy, distal	43.6
	Gastrectomy, proximal	43.5
	Small bowel to small bowel anastomosis	45.50
	Small bowel segment isolation	45.51
	Partial resection jejunum	45.62
	Intestine to intestine anastomosis, not specified	45.90
	Intestinal isolation, not specified	45.91
Other	Gastric operation, not specified elsewhere	44.99

Peer Review

A draft of this report was prepared in July 2007 and sent to the TEP members and national and international experts for review. Peer reviewer comments were considered by the EPC in preparation of the final report. Synthesis of the scientific literature presented here does not necessarily represent the views of individual reviewers, and service as a peer reviewer or member of the TEP cannot be construed as endorsement of the report's findings.

Chapter 3. Results

Description of the Studies

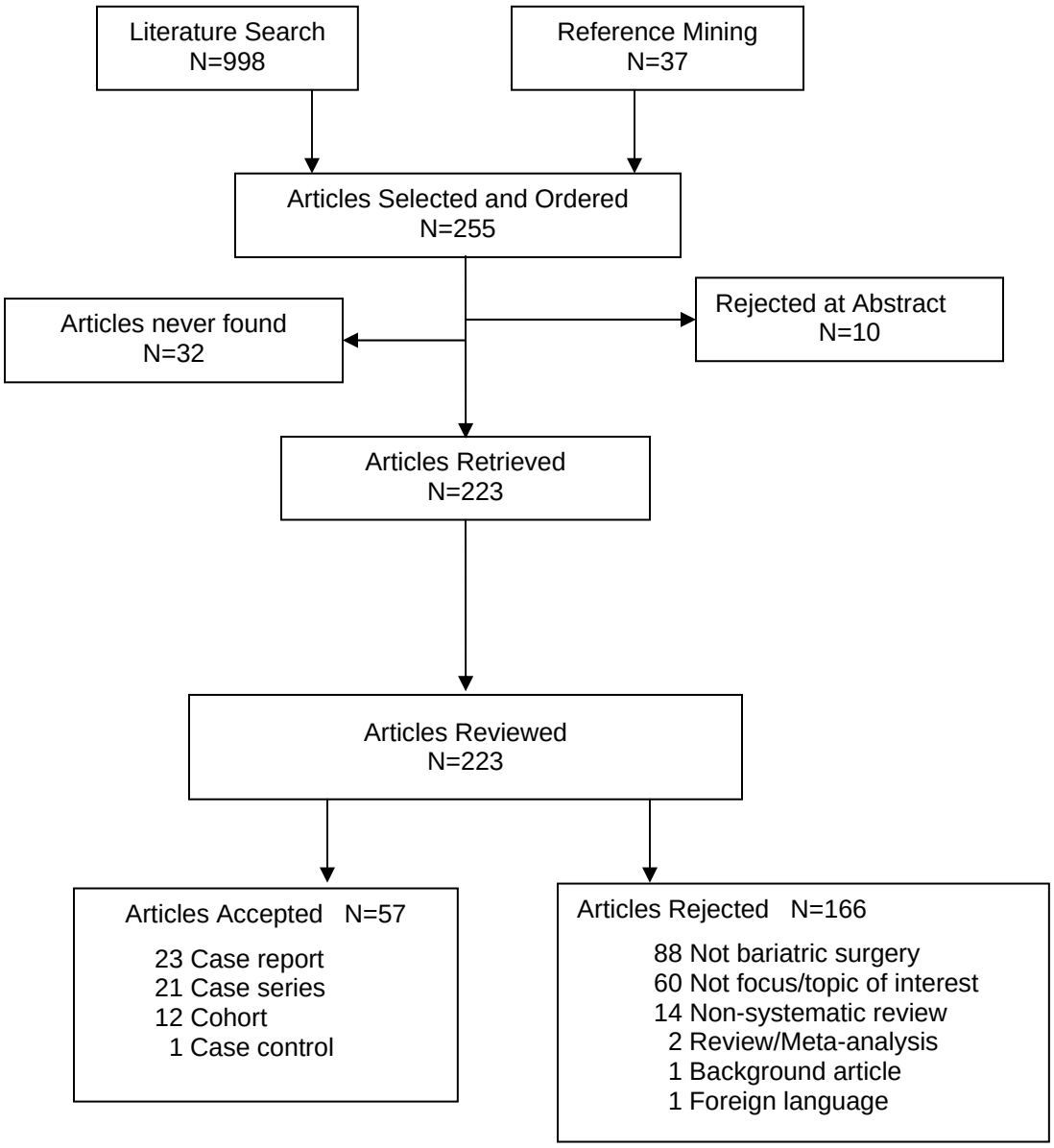
Our literature search resulted in 998 titles. Reference mining of obtained articles resulted in 37 additional titles. Of these 1,035 titles, 231 titles appeared potentially relevant to our scope and were ordered. We were unable to obtain eight articles before our deadline. Thus, a total of 223 articles were screened using the one-page form described in the Methods section. Figure 1 displays the article flow for the project.

Of the 223 articles screened, 57 were accepted for our report, including 23 case reports, 21 case series, 12 cohort studies, and one case-control study. Details of all accepted articles are presented in the Evidence Tables (Appendix D*). A total of 166 articles were rejected: 88 were not actually on bariatric surgery despite the article title, 60 were not on a procedure of interest or did not include pregnant women, 14 were nonsystematic reviews, two were systematic reviews, one was a background article, and one was in a foreign language where an interpreter was not available.

We identified one case-control study that directly addressed some of the key questions, but no randomized controlled trials or prospective cohort studies. Our findings are based on observational studies, which have a potential for greater bias. Furthermore, many of the studies lacked the necessary design to allow for definite conclusions (i.e., patient selection not defined, no presurgery pregnancy information). Our overall findings are therefore tempered by the limitations in the available data, and are cautious.

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

Figure 1. Literature Flow Diagram



Key Question 1. What is the incidence of bariatric surgery in women of reproductive age? What are the trends in incidence of bariatric surgery in women of reproductive age?

For this question, a search for published data on this topic did not find articles reporting data on use of surgery in women of reproductive age. The closest article we found reported use rates overall and by sex, but did not report separately use rates for our target population, women aged 18-45.[23] Therefore, with the agreement of AHRQ and our TEP, we performed our own analyses to answer this question. We analyzed data from AHRQ's Healthcare Cost and Utilization Project (HCUP) Nationwide Inpatient Sample for the years 1998-2005 (the last year for which data are present). ICD-9 procedure codes and inclusion criteria of diagnosis of obesity were used to select the cases. Additionally, ICD recodes of bariatric surgery during this time period were also accounted for where appropriate. Table 2 and Figure 2 report our findings. We present estimates of the number of bariatric procedures done, per year, by sex and certain age ranges. These estimates are based on the actual number of procedures in the Nationwide Inpatient Sample database multiplied by the weights used to estimate the total U.S. population. Note that this database will not capture procedures done as an outpatient. As the delivery of outpatient laparoscopic adjustable band procedures increases, this database will increasingly underestimate the use of bariatric procedures. In addition, some gastric bypass procedures have been done as outpatient operations. All estimates are subject to some degree of error due to coding issues.

For both men and women, and across all age ranges, we found a dramatic increase in the number of procedures performed each year—about 600-800 percent. This observation mirrors recent findings by other researchers.[26] An interesting finding of this analysis is that the growth in use of bariatric procedures delivered in the inpatient setting has been even more pronounced in persons over the age of 45. Also of note, there was actually a leveling off of incidence rates in 2003 and a drop in the incidence rate between years 2004 and 2005. One potential explanation for this plateau in the later years, and the lesser rate of increase in younger patients as compared to older patients, is the likely increase in the number of laparoscopic adjustable band procedures being delivered on an outpatient basis and that proportionately more of these procedures are being performed in the older population. Alternatively, the observation could represent a true drop off in the number of cases, perhaps related to changes in insurance coverage.

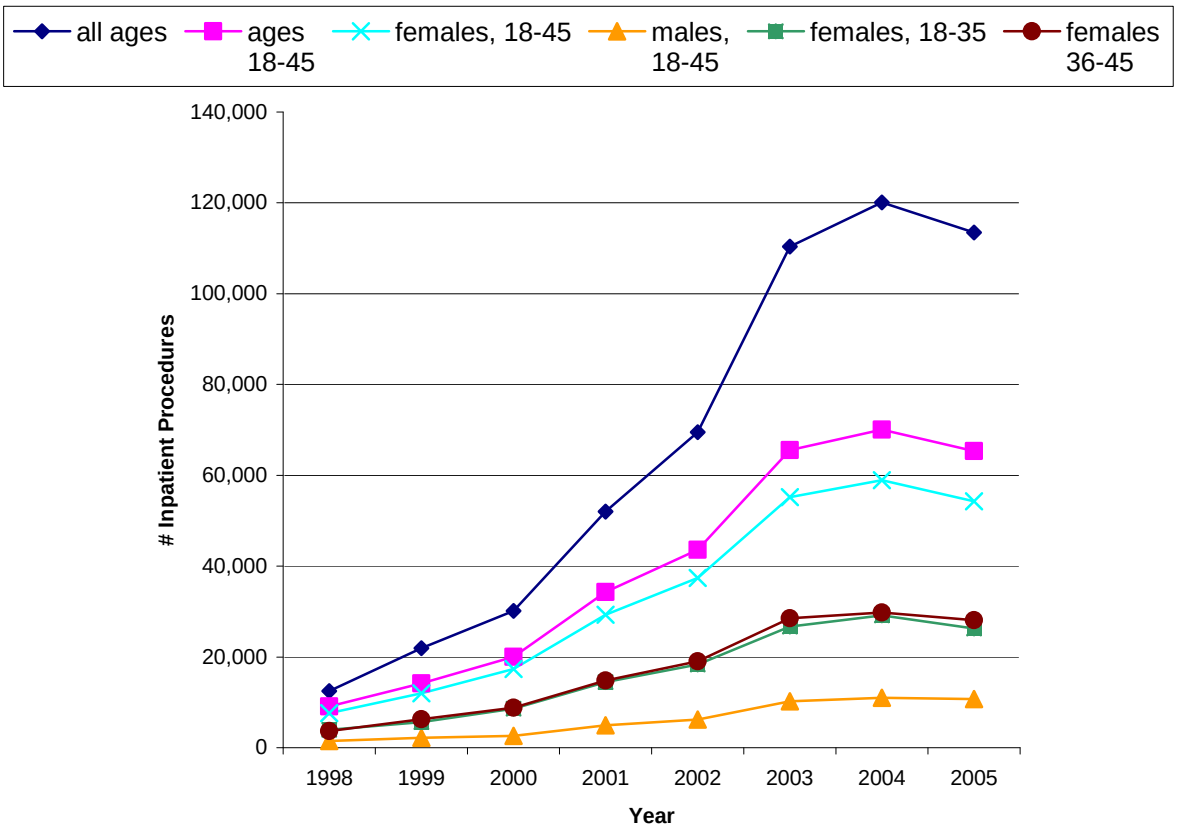
In summary, in the past 3 years, more than 50,000 women of reproductive age underwent bariatric surgery inpatient procedures annually. Many more women in this age group are also likely undergoing bariatric procedures in the outpatient setting that are not captured in this inpatient dataset. The proportion of these women who subsequently get pregnant is not known.

Table 2. Number of inpatient bariatric procedures*

# Bariatric Procedures (standard error)											
year	all ages	%change from 1998	ages 18-45	% change from 1998	males, 18-45	% change from 1998	females, 18-45	% change from 1998	females, 18-35	% change from 1998	females 36-45	% change from 1998
1998	12,480 (1,895)	-	9,075 (1,400)	-	1,480 (240)	-	7,595 (1,194)	-	3,957 (654)	-	3,638 (562)	-
1999	21,963 (4,273)	76.0%	14,173 (2,682)	56.2%	2,200 (416)	48.6%	11,968 (2,278)	57.6%	5,668 (1,090)	43.2%	6,300 (1,206)	73.2%
2000	30,116 (4,587)	141.3%	20,020 (3,010)	120.6%	2,639 (395)	78.3%	17,381 (2,657)	128.8%	8,583 (1,353)	116.9%	8,789 (1,339)	141.6%
2001	51,989 (6,811)	316.6%	34,261 (4,486)	277.5%	4,950 (666)	234.5%	29,311 (3,856)	285.9%	14,463 (1,904)	265.5%	14,848 (1,992)	308.1%
2002	69,476 (8,298)	456.7%	43,624 (5,344)	380.7%	6,210 (894)	319.6%	37,414 (4,497)	392.6%	18,330 (2,224)	363.2%	19,084 (2,310)	424.6%
2003	110,332 (9,851)	784.1%	65,581 (5,882)	622.7%	10,221 (946)	590.6%	55,183 (4,979)	626.6%	26,660 (2,433)	573.7%	28,523 (2,599)	684.0%
2004	120,119 (10,917)	862.5%	70,080 (6,499)	672.2%	11,020 (1,067)	644.6%	58,896 (5,477)	675.5%	29,128 (2,796)	636.1%	29,767 (2,731)	718.2%
2005	113,500 (11,045)	809.5%	65,373 (6,342)	620.4%	10,700 (1,205)	623.0%	54,292 (5,174)	614.8%	26,237 (2,539)	563.1%	28,055 (2,673)	671.2%

***From Nationwide Inpatient Sample, Healthcare Cost and Utilization Project (HCUP), U.S Agency for Healthcare Research and Quality. Accessed July 2007.**

Figure 2. Trend in bariatric inpatient procedures, 1998-2005 *



*** From Nationwide Inpatient Sample, Healthcare Cost and Utilization Project (HCUP), U.S. Agency for Healthcare Research and Quality. Accessed July 2007.**

Key Question 2. What is the evidence that bariatric surgery affects (directly or indirectly) future fertility?

We identified few studies focused specifically on the question of fertility in postbariatric surgery patients. Most studies recruited patients because they were already pregnant; thus they failed to include those patients who remained infertile following the procedure. Additionally, although many studies provided the number of patients who were previously infertile or had undergone fertility treatments in the past, it was usually not clear how many women, out of the total number of women of reproductive potential, desired a pregnancy; therefore, these data should be interpreted with some caution.

Most studies that reported on fertility following bariatric surgery compared patients before and after surgery. These studies are displayed in Table 3. One study compared pre and postoperative reproductive histories of female patients who underwent bariatric surgery and had lost more than 50 percent of excess weight (unclear if consecutive patients). Twenty five percent (29/115) of the women had suffered from infertility prior to bariatric surgery. There were data available on nine women who conceived after surgery, eight were in the group that had had infertility problems preoperatively. Unfortunately, the follow-up time is not stated and it is unknown how many other patients in the postsurgery cohort had tried to conceive.[27] This difficulty in determining how many patients, either preoperatively or postoperatively, actually desired pregnancy is common to almost all studies in this group. Another retrospective cohort study compared nine women before and after vertical banded gastroplasty with respect to fertility; two of these patients had not attempted pregnancy prior to surgery. Whereas five out of seven women underwent fertility treatments prior to surgery, only one woman underwent ovulation induction after the surgery. All nine women became pregnant within 5 years after surgery; they represent all female bariatric surgery patients at the site.[28] In another retrospective cohort study comparing pregnancies of the same women before and after BPD, of 32 women who had unsuccessfully attempted conception prior to surgery, 15, or 47 percent were able to become pregnant following BPD.[29]

Other studies compared a group of patients who had bariatric surgery to those who did not and were not obese. One study compared patients who had undergone bariatric surgery to the general population in Negev, Israel; patients who had undergone bariatric surgery were more likely to have received fertility treatments (6.7 percent vs. 2.3 percent).[30] In a study evaluating patients with gestational diabetes who either had bariatric surgery or did not, the bariatric surgery group had higher rates of fertility treatments, which persisted after controlling for obesity.[31] However, in both of these studies, it is not entirely clear whether the fertility treatments were "after surgery" or "lifetime." Similarly, one randomized controlled trial comparing three bariatric procedures (gastric bypass and two kinds of gastroplasty) found that about 10 percent of postsurgical women (<40 y/o) got pregnant in 3 years (21/214), but the number attempting pregnancy was unknown.[32]

In general, most of the data on need for fertility treatments following bariatric surgery lack information on the number of postoperative patients attempting to get pregnant and number ultimately successful. In general, sample sizes are too small to have statistical power. In addition, most of these data represent convenience samples of women able to get pregnant along with their presurgery fertility histories. The larger studies compare the postsurgery cohorts (although they lost weight still have a higher rate of obesity) to nonobese population, a comparison which is limited since obesity is associated with higher infertility rates. This may explain why some

studies report improvements in fertility comparing women before and after bariatric surgery, while other studies report elevated fertility problems in women following bariatric surgery compared to the nonobese general population.

Table 3. Cohort studies reporting on fertility

Author/Year	Bariatric procedure	How was the cohort assembled?	Dropout rate or other measure of loss to follow up.	# Women	# Pregnant Women	# Pregnancies	# Neonates	Fertility Treatments	# Previously Infertile	# Infertile after Surgery
SHEINER;2006[31]	Gastric bypass, Adjustable banding	Consecutive patients	None							
1. Postsurgery, gestational diabetes				28	28	28	28	21.4%	21.4% fert tx	N/A
2. No bariatric surgery, gestational diabetes				7986	7986	7986	7986	5.5%	5.5% fert tx	N/A
SHEINER;2004[30]	Gastric bypass, Adjustable banding, BPD, VBG	Consecutive patients	None							
1. Postsurgery				298	298	298	NR	6.7%	NR	NR
2. No surgery (controls)				158,912	158,912	158,912	NR	2.3%	NR	NR
MARCEAU;2004[29]	BPD	Consecutive patients	85% response rate							
1. Presurgery				783	594	1577	1257	32 (# infert)	N/A	N/A
2. Postsurgery				783	132	251	166	17 (# infert)	32	17
BILENKA;1995[28]	VBG	Not stated	None							
1. Presurgery data				9	6	18 in 6 women	18	5/7 (71%)	NR	N/A
2. Postsurgery data				9	9	14 in 9 women	14	1/9(11%)	NR	0
DEITEL;1988[27]	BPD, VBG	Not stated	None							
1. Presurgery				115	86	274	205	NR	29/115 (25.2%)	N/A
2. Postsurgery				115	9	9	9	NR	8/9 (88.9%)	0/9

Several case series mentioned prior infertility rates in patients who were able to become pregnant following bariatric surgery. In patients who were able to conceive after bariatric surgery, infertility rates prior to surgery ranged from 15 to 44 percent.[33-36] In another case series that included 49 postsurgery pregnancies, it was mentioned that no fertility drugs were used.[37]

In addition to this limited evidence of improved fertility by increased pregnancy rates, there is also evidence of normalization of hormones and menstrual cycles as well as improvement of polycystic ovarian syndrome (PCOS). A prospective case series evaluating hormone levels in women of reproductive age both pre and post BPD demonstrated a normalization of hormones, specifically, a rise in sex hormone binding globulin and decreasing levels of serum testosterone and dehydroepiandrosterone sulfate (DHEA-S).[38] In addition to the direct laboratory evidence of hormone normalization, there is also indirect evidence of normalization through the return of normal menstrual cycles in women who had had irregular menses. Of the 40 percent of women of reproductive age who were having irregular menses preoperatively in a cohort study, 89 percent of these patients resumed regular menses following bariatric surgery.[27] Lastly, the resolution of PCOS was seen following gastric bypass; in a retrospective cohort study that included 24 women with PCOS, all women resumed normal menstrual cycles in a mean of 3.4 months, and five women were able to conceive without the use of clomiphene. Additionally, of the 23 women with hirsutism, 52 percent had complete resolution of symptoms.[39]

Key Question 3. What is the evidence that bariatric surgery affects (directly/indirectly) choice of contraception?

There is almost no evidence on this topic. We found only a single study that reported data on the effectiveness of contraceptive methods following surgery. A small case series of 40 patients who had undergone BPD and who were advised to avoid pregnancy for at least 2 years reported two failures for oral contraceptive (OCP) birth control, one at 9 months postoperatively and the other at 24 months. Based on this 5.0 percent failure rate, these authors advised the use of something other than OCP, and called for a large RCT to determine the best method of contraception.[38] Given that the failure rate of oral contraceptives in the first year of typical use has been reported at 3 percent for American women,[40] the failure rate after BPD may not be higher; clearly more data are needed before conclusions can be drawn.

Key Question 4. In patients who have had bariatric surgery, what is the evidence for prenatal risk factors (e.g., of reduced nutrient absorption, unusual weight gain) that may result in poor pregnancy outcomes?

Key Question 5. What is the evidence that certain management strategies for addressing nutrient absorption and weight gain reduce the risks of poor pregnancy outcomes?

Nutritional Supplementation

It is common practice to recommend nutritional supplementation such as multi-vitamins and iron following bariatric surgery for all patients.[41, 42] However, evidence is scarce regarding specific recommendations for pregnancy after bariatric surgery.

Studies evaluating pregnancy following gastric banding or gastric bypass have shown minimal nutritional adverse events; however, most of these studies monitored and ensured that the women complied with vitamin supplementation. In a study where 84 percent of 79 pregnant women reported compliance with multivitamin supplementation following gastric banding, no nutritional problems were reported during pregnancy.[43] Three studies describing pregnancy after gastric bypass also describe low rates of anemia requiring either oral or parenteral supplementation (ranging from 0 percent to 4 percent); however these studies did not describe the vitamin supplementation regimen that these women followed.[37, 44, 45]

There are reports in the literature describing the need for supplementation and parenteral nutrition in pregnancy following BPD. Three reports (one in abstract form) from the same investigators and institution describe nutritional problems in patients following BPD.[35, 46, 47] In the largest of these three reports, 1136 women who received BPD surgery between 1976 and 1994 at a single institution had 245 pregnancies occurring two to 17.3 months following the surgery. There were 73 abortions, two for nutritional causes (no additional data provided). In 21 percent of patients, parenteral nutritional support was required (criteria unstated), with about a third of these requiring hospitalization. For all other patients "the usual supplements were given."[47] In a small case series evaluating the efficacy of contraception following BPD, four pregnancies occurred; one woman suffered from anemia, while another suffered from an unspecified vitamin deficiency. While one of these pregnant women was taking nutritional supplementation, the other was not.[38] In another small case series that included nine pregnancies following BPD, all four patients who were tested suffered from nutritional deficiencies, requiring blood transfusions, parenteral nutrition, or parenteral iron supplementation.[48] Lastly, there have been case reports of adverse events in pregnancy following BPD. In one case, dehydration and malnutrition as a result of vomiting and diarrhea led to an emergent caesarian section despite vitamin supplementation and multiple hospitalizations to administer intravenous fluids.[49] Another case report demonstrated vitamin A deficiency in pregnancy following BPD; late in the pregnancy, the patient was hospitalized 5 days weekly for parenteral nutrition. The baby was still found to have symptoms of vitamin A deficiency, such as micropthalmia, at birth.[50] As the risk of nutritional adverse events in pregnancy following BPD is appreciable, even with good compliance with supplementation, it is logical that there are reports of adverse events following noncompliance with supplementation. For example, there is a case report demonstrating neonatal

vitamin A deficiency with maternal night blindness during the third trimester associated with refusal of nutritional treatment during pregnancy following BPD.[51]

Studies on pregnancy following bariatric surgery rarely describe the specific supplementation regimens employed; however, some case reports document adverse maternal or neonatal nutritional outcomes following poor compliance with supplementation. Two studies report neural tube defects in patients who underwent gastric bypass prior to pregnancy. Each of these studies, one in Maine, and the other in Iowa, found three neonates affected by neural tube defects; none of the six pregnant women were compliant in taking nutritional supplements.[52, 53] Unfortunately, the amount of folic acid included in the nutritional supplements was rarely mentioned in the reports of studies of bariatric surgery. Also, among two gastric bypass case reports, one report documented failure to thrive in a neonate, which was thought to be caused by low fat content in the maternal breast milk, and a second case report documented neonatal vitamin B_{12} deficiency. Neither of the women in these cases was compliant with their recommended supplementation.[54, 55] There are also case reports of maternal and neonatal nutritional deficiencies during pregnancy in patients following gastric bypass despite compliance with supplementation. One case study reported on neonatal B_{12} deficiency despite the use of prenatal vitamins during pregnancy and lactation.[56] Another case report documented iron and vitamin B_{12} deficiencies starting at six weeks gestation; the patient required parenteral B_{12} and blood transfusion due to the anemia being refractory to parenteral iron.[57]

We conclude that published reports of adverse nutritional outcomes in pregnant patients who underwent gastric banding or gastric bypass and subsequently received standard nutritional supplementation are rare. There are more reports of severe malabsorption and nutritional deficiencies following BPD, occasionally requiring parenteral nutrition in pregnant patients. Although some maternal and neonatal adverse events occurred among women who had undergone bariatric surgery even with maternal vitamin supplementation, many of these adverse outcomes were attributed to maternal noncompliance with vitamin supplementation. An important caveat is that, in general, vitamin, mineral, and trace element levels were not monitored in mother or baby, and if clinical manifestations of these deficiencies are subtle and thus difficult to detect, they may be higher than reported.

Adjustable Gastric Band Management

There is no consensus on band management in pregnancy following gastric band placement; in fact, while there were studies that either deflated the band or did not, no studies compared different methods of band management. Studies that systematically deflated the bands early in the pregnancy did so in order to allow for optimal nutrition during fetal development and to decrease vomiting in the first trimester.[33, 58, 59] Other studies, which did not deflate the band routinely, did so only if there were symptoms of nausea and vomiting, or by request of the patient. We identified three case series of pregnant women who had received adjustable gastric banding. Among 67 potentially fertile women who had the procedure performed at a single institution, 21 women had 25 pregnancies, of which 18 of these went to term. Deflation of the band was required in two women (11 percent) for nausea and vomiting.[36] In another single-institution study, 49 pregnancies in 44 women were identified from a database of all women who received adjustable band surgery. Eight women (18 percent) required band deflating.[60] Finally, among 359 women who enrolled in two clinical trials of adjustable gastric banding, 256 were fertile, and in this group, there were 20 women with 23 pregnancies. Among the 18 deliveries,

six (33 percent) had adjustments to the band; three patients required it for nausea and vomiting, one patient had band deflation "to prevent vomiting," and two patients had band adjustment or removal at their own request.[34, 61] Across all three studies, with 84 deliveries, 16 patients (19 percent) had adjustment or removal of their band.[34, 36, 61] In a large case series, two women presented in the second trimester with severe vomiting, dehydration, and electrolyte abnormalities and were found to have band slippage; the band was removed in both patients, without any further complications.[62] We judge the evidence is insufficient to reach conclusions regarding band management in pregnant patients.

How Long To Delay Pregnancy After Surgery

Expert opinion is that patients should not attempt pregnancy within the period of rapid weight loss (first year) following bariatric surgery. We identified little published evidence that assessed the evidence on this issue. One letter to the editor reported on 18 women who had 21 babies after gastric bypass surgery; ten of these women conceived within the first year after surgery.[63] The authors state that there were no statistical differences between babies conceived within the first year and those conceived later on with respect to rates of cesarean section, other delivery complications, neonatal jaundice, low birth weight, or congenital abnormalities. However, the small sample size limited the study's power to detect anything other than very large differences between the two groups. Furthermore, the results of statistical tests were not reported in the letter. Another study compared 21 pregnancies beginning within the first year following gastric bypass to 13 that began later.[45] Again, no statistically significant differences were found between groups, and again, the small sample sizes limits the conclusions that can be drawn. In a study comparing birth outcomes in women before and after laparoscopic adjustable gastric banding, the authors report on the 20 pregnancies (out of a total of 79 that were included) where conception occurred within the first year after the procedure.[43] While maternal weight gain during pregnancy was lower in these 20 pregnancies than in pregnancies occurring later, the birth weight of babies did not differ, and there were no statistically significant differences in complications of pregnancy or preterm deliveries. Another study investigated the characteristics of pregnancies that occurred within 18 months of BPD compared to pregnancies after 18 months postoperatively; a higher rate of spontaneous abortion was seen in the early group (31 percent vs. 18 percent). However, birth weights showed no difference.[64] One study investigating pregnancies within the first 2 years after gastric bypass found a high rate of premature births (18 percent), but, unfortunately, this study had no comparison group.[44] When extending the period of time to 2 years following adjustable gastric banding, a study found an increased spontaneous abortion rate of 29 percent as well as two band-related complications, including slippage and balloon leakage. As there was no comparison group in this study, nothing was concluded regarding relative birth weights or complications.[58] Lastly, a case report documented a pregnancy that was determined to have begun one day prior to gastric stapling surgery. Although the woman experienced minor dehiscence of the gastric wound by endoscopy and minor liver enzyme elevation, the remainder of the pregnancy and birth were uneventful.[65] We conclude there is scant evidence of pregnancy outcomes upon which to make recommendations about how long to delay pregnancy following surgery.

Key question 6. For women who have had bariatric surgery, what is the evidence for morbidity and mortality risks for: a) mother and b) neonate?

Laparoscopic Adjustable Gastric Band

We identified two cohort studies and five case series that reported on morbidity and mortality outcomes following laparoscopic adjustable gastric banding. These studies are summarized in Tables 4 and 5. In the two cohort studies, samples sizes of pregnancies were small (22 and 79). Both studies compare pregnancy outcomes in the same women before and after laparoscopic adjustable band placement, and also to community outcomes or to the outcomes of obese patients who did not undergo bariatric surgery. Before surgery, patients had rates of pregnancy complications such as gestational diabetes, preeclampsia, and hypertension that were similar to other obese pregnant women. After laparoscopic adjustable gastric band placement, the rates of these pregnancy complications were similar to rates seen in the community. However, due to small sample sizes, it is not possible to determine whether the rates of these complications may still be elevated following bariatric surgery. For example, in the study by Dixon,[43] the rate of gestational diabetes in postsurgery pregnancies was 6.3 percent (as compared to 15 percent in presurgery pregnancies), while in the community it is 5.5 percent. The difference in these two rates is – 0.8 percent, but the 95-percent confidence interval of the difference is – 6.8 percent to 5.2 percent. This means that the rate of gestational diabetes in past surgery pregnancies could conceivably still be twice as high as community rates. Therefore, it is premature to conclude that bariatric surgery reduces the rates of these complications to those of the average woman. One stillbirth and one case of duodenal atresia occurred in pregnancies following bariatric surgery; sample sizes were too small to draw conclusions. The five case series articles included 141 pregnancies in total. Rates of pregnancy complications were low. These data support the cohort data that rates of pregnancy complications following laparoscopic adjustable gastric band placement are low. Data are insufficient to comment on rare outcomes.

Of note, we identified one case report following open nonadjustable gastric band where the woman developed severe vomiting secondary to pouch outlet obstruction.[66] Subsequent weight loss led to significant fetal growth retardation, and enteral nutrition via feeding tube was required to normalize the weight gain for the fetus. Following delivery, the women's outlet obstruction resolved.

Table 4. Cohort studies reporting morbidity and mortality with laparoscopic adjustable band

Author/Year	How was the cohort assembled?	Dropout rate or other measure of loss to follow up.	# Pregnant Women / # Pregnancies	Gestational Diabetes / Preeclampsia / Pregnancy Induced by HTN	Birth weight	Low Birth weight (<2500g) / Perinatal Mortality	Delivery <36wks	Macro-somia	Congenital Malformations	Surgical AE
DIXON;2005[43]	Consecutive patients	2%								
1. Postsurgery pregnancies			79 / 79	6.3% / 5% / 10%	3397	6.3% / 1 (stillbirth)	6.30%	11.40%	1 duodenal atresia	0
2. Presurgery pregnancies			40 / 40	15% / 28% / 45%	3350	NR / 0	NR	NR	0	N/A
3. Matched obese preg (no surgery)			79 / 79	19% / 25% / 38%	3297	8.9% / 0	12.70%	17.70%	0	N/A
4. Community outcomes			61,000 / NR	5.5% / NR / 10-13%	3356	6.9% / NR	7.80%	11.80%	NR	N/A
DIXON;2001[33]	Not stated	Not stated								
1. Presurgery			10 / 15	9.4% / NR / 37%	3415 +/- 520g	NR / NR	NR	NR	NR	N/A
2. Postsurgery			20 / 22	5% / NR / 5%	3485+/- 485g	5 <3000g / 0	0	4.50%	0	1 (gall stones)
3. Community rates			NR / NR	5.5% / NR / 20%	NR	NR / NR	NR	NR	NR	NR

Table 5. Case series reporting morbidity and mortality with laparoscopic adjustable band

Author/Year	Women of repro age s/p Bariatric surgery	# Pregnant Women / # Pregnancies	# Live Births	Gestational Diabetes / Preeclampsia and/or Eclampsia / Pregnancy Induced HTN	Birth weight	Low Birth weight (<2500g) / SGA	Macro-somia	Congenital Malformations	Surgical AE
BAR-ZOHAR;2006[62]	873	74 / 81	81	13 / NR / 6	3.09+/-0.5 kg (2.12-4.18)	NR / NR	NR	Neonatal Jaundice: 2	Band slippage x 2
WEINER;2003[36]	678	21 / 25	19	0 / 0 / 0	mean 3680 2385-3989g	NR / NR	0	NR	Fluid removal from band x 2
WEISS;2001[58]	215	7 / 7	5	0 / 0 / 0	2110-3860 g	1 / 0	0	NR	Band leak x1 Band migration x 1
MARTIN;2000[34]	265	20 / 23	18	0 / 0 / 0	mean: 3676g (2381-3912)	NR / NR	NR	Neural Tube Defects: 0	NR
MARTIN;1997[61]	72	5 / 5	3 (2 still pregnant)	NR / NR / NR	NR	NR / NR	NR	NR	NR

Gastric Bypass and Vertical Banded Gastroplasty

We identified one case-control study, six cohort studies and six case series that reported on morbidity and mortality outcomes following gastric bypass or vertical banded gastroplasty. Some studies reported combined outcomes for patients who had received gastric bypass or some other bariatric procedure; those studies are included here.

The case-control study included women who had received bariatric surgery and surveyed them on their pregnancy histories and outcomes.[67] Authors compared postoperative pregnancies (n=57) to presurgery pregnancies (n=57) that were matched for presurgery weight, age, parity at index pregnancy, and delivery year. They reported no difference in gestational diabetes (3 cases in postsurgery pregnancies compared to 6 in presurgery control group, p=NS), less hypertension, which included chronic and pregnancy-induced (9 percent v 46 percent, $p<0.001$). The average neonatal birth weight was lower in the postsurgery group (3,205 versus 3,604 grams, $p<0.001$) and there were less large-for-gestational-age neonates (16 percent versus 36 percent, $p<0.02$). They found no statistical difference in small for gestation age neonates (4 vs 2, p=NS), premature deliveries at <37 weeks (7 vs 4, p=NS), or perinatal deaths (4 vs 4, p=NS).

The cohort studies are summarized in Tables 6 and 7. Like the data for the laparoscopic adjustable gastric band, the findings of these cohort studies suggest that rates of gestational diabetes, preeclampsia, and hypertension are decreased following bariatric surgery. As with the laparoscopic adjustable band data, the number of cases studied is relatively small—across all studies, data are reported on a total of 188 pregnancies following surgery. There were no differences seen in average birth weight, proportion with low birth weight, or premature delivery between babies born before or after bariatric surgery. In the only article to report data, the proportion of babies with congenital malformations was 7.1 percent in patients with gestational diabetes after bariatric surgery, compared to 4 percent in pregnant women with gestational diabetes who did not receive bariatric surgery. The sample sizes were too small to draw conclusions.

The six case series studies reported on about 300 pregnancies in total. The most notable finding was that two case series reported more babies with neural tube defects than expected. One report was about three women who had four pregnancies, all of which had neural tube defects,[53] and the other report was a case series of 110 pregnancies in 87 women who had received gastric bypass; three babies had neural tube defects.

Table 6. Cohort studies reporting morbidity and mortality with gastroplasty and gastric bypass

Author/Year	Bariatric Procedure	How was the cohort assembled?	Dropout rate or other measure of loss to follow up	# Pregnant Women / # Pregnancies	Gestational diabetes / Preeclampsia and/or Eclampsia / Pregnancy Induced HTN	# Miscarr/ Abortions/ Ectopic	Other Delivery Complications	Birth weight	Low birth weight (<2500g) / Macrosomia	Delivery <36wks / Perinatal Mortality	Congenital Malformations	Surgical AE
SHEINER;2006[31]	Gastric bypass, Adjustable banding	Consecutive patients	None				Labor Induction /Polyhydram/ Oligohydram /Abruption /Placenta Previa					
1. Post-surgery, gestation diabetes				28 / 28	100% / NR / 17.9%	14.3%	35.7%/17.9%/3.6%/-/-	3195+/-701.7 g	NR / NR	NR / 0	7.10%	1
2. No bariatric surgery, gestational diabetes				7986 / 7986	100% / NR / 12.3%	8.4%	30.7%/11.6%/2.0%/.7%/.6%	3188.7+/-577 g	NR / NR	NR / 11/1000	4.00%	NA
SKULL; 2004[60]	Lap adjustable banding	Not stated	None									
1. Pre-surgery historical controls				44 / 31	8 (27%) / 2(6.4%), 1(3.2%) / 7 (22.5%)	NR		3.53 (2.4-4.6)	NR / NR	NR / NR	NR	NR
2. Post-surgery				44 / 49	4 (8%) / 0/1 (2%) / 4 (8.1%)	NR	1 patient pregnant at surgery	3.31 kg (1.1-4.6)	NR / NR	NR / NR	NR	2 (4.1%)
WITTGROVE ;1998[37]	Gastric bypass	Convenience sample	Not stated									
1. Total Postsurgery (n=36)				36 / 49	1 / NR / 0	7 spontaneous 1 therapeutic		NR	NR / 2/36(5.5%)	NR / 0	NR	NR
2. Pre-surgery (n=17)				17 / 17	4 / NR / 7	NR		NR	NR / 7/23(30.4%)	NR / 0	NR	NR
3. Post-surgery, longitudinal (n=17)				17 / 17	0 / NR / 0	NR		NR	NR / 1/18(5.5%)	NR / 0	NR	NR
BILENKA; 1995[28]	VBG	Not stated	None									
1. Pre-surgery data				6 / 18	3/1/1	6 spon/1 term*		NR	NR / NR	NR / NR	NR	NR
2. Post-surgery data				9 / 13	0 / 1 / 3	1 spon		NR	NR / NR	NR / NR	NR	NR

*The 6 miscarriages occurred in two women.

Table 6. Cohort studies reporting morbidity and mortality with gastroplasty and gastric bypass (continued)

Author/Year	Bariatric Procedure	How was the cohort assembled?	Dropout rate or other measure of loss to follow up	# Pregnant Women / # Pregnancies	Gestational diabetes / Preeclampsia and/or Eclampsia / Pregnancy Induced HTN	# Miscarr/ Abortions/ Ectopic	Other Delivery Complications	Birth weight	Low birth weight (<2500g) / Macrosomia	Delivery <36wks / Perinatal Mortality	Congenital Malformations	Surgical AE
DEITEL; 1988[27]	VBG	Not stated	None									
1. Pre-surgery				86 / 274	6/86 (7%) / 11/86 (12.8%) / 23/86 (26.7%)	69 (25.2%)	NR	3801 +/- 772g	NR / NR	NR / 0	NR	NR
2. Post-surgery				9 / 15	0/7 (0%) / 0/7 (0%) / 0/9 (0%)	6 (40.0%)*	NR	3398 +/- 354g	NR / NR	NR / 0	NR	NR
DAO;2006[45]	Gastric bypass	Consecutive patients	Not stated									
1. Early Group postsurgery (pregnant in one year)				21 / 21	NR / 0/13 (0%) / 1/21 (4.8%)	5/1 ectopic	1 PTL, 1 bed rest,	2868 g (1786 - 3940)	2 / NR	2 / 0	0	NR
2. Late Group postsurgery (pregnant after one year)				13 / 13	NR / 1/13 (7.8%) / 0/21 (0%)	0	2 PTL, 1 abruption, 1 bed rest	2727 g (1616 - 1899)	4 / NR	4 / 0	0	NR

Table 7. Case Series reporting morbidity and mortality with gastroplasty and gastric bypass

Author/Year	Bariatric Procedure	Women of Repro Age s/p Bariatric Surgery	# Pregnant Women / # Pregnancies	# Live Births	Gestational diabetes / Preeclampsia and/or Eclampsia / Pregnancy Induced HTN	Birth-weight	Low Birth weight (<2500g) / SGA	Macro-somia	Congenital Malformations	Surgical AE
RAND;1989[63]	Gastric bypass	18	18 / 21	21	NR / NR / NR	Statistically comparable	5 / NR	NR	Neonatal Jaundice: 2 Trisomy 21: 1	NR
HADDOW;1986[53]	Gastric bypass	133	3 / 4	1	NR / NR / NR	NR	NR / NR	NR	Neural Tube Defects:4	NR
MARTIN;1988[52]	Gastric bypass	NR	87 / 110	NR	NR / NR / NR	NR	NR / NR	NR	Neural Tube Defects: 3	NR
PRINTEN;1982[44]	Gastric bypass	NR	45 / 54	38	NR / NR / NR	1078-4820 g	7 / NR	NR	Microcephaly: 1	NR
JESTER;1997[68]	Gastric bypass, other surgery	NR	NR / >100	NR	0 / NR / NR	NR	NR / NR	NR	NR	NR
STRAUSS;2001[69]	Gastric bypass	7	3 / 6	6	NR / NR / NR	NR	0 / 0	NR	0	SBO 10 yrs after surgery (not during preg)

Biliopancreatic Diversion

We identified two cohort studies and four case series that reported on morbidity and mortality following biliopancreatic diversion. The BPD cohorts were larger than either the laparoscopic adjustable gastric band or gastric bypass cohorts - a total of 490 pregnancies were reported. In the first cohort, out of 1,136 women who had received BPD over the past 18 years, 129 women had 239 pregnancies, of which 152 were brought to term.[47] The authors report that 32 patients (21 percent of pregnancies) required parenteral nutritional support, including 10 patients who needed to be hospitalized. One woman developed pregnancy-induced hypertension. Before BPD surgery, among these 129 women, there were seven cases of preeclampsia, three cases of gestational diabetes, and two cases of pregnancy-induced hypertension. In pregnancies after BPD, 40 newborns (26 percent) were small for gestational age, although all had good Apgar scores. Four babies died at or shortly after birth, two for unknown reasons and one each after surgery to try to correct diaphragmatic eventration and meconium obstruction. In the other cohort study, a mailed survey to 916 women who had received BPD surgery yielded 783 responses. There were 251 pregnancies in 132 women, resulting in 166 infants born to 109 mothers. Compared to pregnancies prior to surgery, the number of miscarriages remained about the same (21.6 percent prior to surgery compared to 26.0 percent after). There was no significant difference in the incidence of stillbirths or malformation.[29]

The four case series were small, reporting on a total of 108 pregnancies. The most notable was a report of nine adverse neonatal outcomes all associated with severe nutritional deficiencies.[48] Another reported that out of 84 pregnancies after BPD, 21 were voluntarily aborted and another ended in miscarriage.[35] They report that parenteral nutrition is safe and could be of benefit for mother and infant.[46]

The number of reports of severe nutritional problems during pregnancy is higher for BPD than for the other types of bariatric surgery. Since data for all procedures come from a limited number of providers and patients, extrapolation of the results from such limited samples to the larger population may not be justified. Still, the increased number of reports of severe nutritional deficiencies in pregnant women is consistent with the greater degree of malabsorption caused by BPD relative to the other bariatric procedures.

We identified two studies that reported on growth and development of children born to mothers who had undergone BPD. The first study was reported[68] only in abstract form and consisted of a large case series from a single practice. This study, which included data on 100 pregnancies (from among 2,500 patients having had bariatric surgery), found that some of the children were now over 10 years of age, and found no statistical differences in development. No additional details were reported. The second report compared 172 children, aged 2 to 18 years, who were born to 113 obese mothers who had undergone BPD surgery to 45 same-age siblings born to these mothers prior to surgery, and also compared the outcomes to current population standards. On average, the mothers had a presurgery BMI of 48 and a postsurgery BMI of 31. All patients underwent surgery at the same center. The authors found that the proportion of children who were overweight or obese was much higher for those born to the mother prior to bariatric surgery (60 percent versus 35 percent). The proportion of children who were underweight did not differ statistically between those born before or after maternal bariatric surgery (4.4 percent vs. 7.5 percent, $p=0.742$).[70]

Table 8. Cohort Studies reporting morbidity and mortality for biliopancreatic diversion

Author/Year	How was the cohort assembled?	Dropout rate or other measure of loss to follow up	# Pregnant Women / # Pregnancies	Gestational Diabetes / Preeclampsia and/or Eclampsia/ Pregnancy Induced HTN	# Miscarr/ Abortions/ Ectopic	Birth-weight	Low birth weight (<2500g) / Macrosomia	Delivery <36wks / Perinatal Mortality	Congenital Malformations	Surgical AE
FRIEDMAN;1995[47]	Consecutive patients	Not stated								
1. Presurgery			129 / 124 /77 (term)	3 / 7 / 2	24 vol/ 21 spon/ 2 other	2500-6500g	NR / NR	NR / 2	Downs Syndrome: 1 (abort)	N/A
2. Postsurgery			129 / 152 (term)	NR / NR / NR	41 vol /28 spon/4 other	1200-4600g	NR / NR	26 / 4	NR	NR
MARCEAU;2004[29]	Consecutive patients	85%								
1. PreSurgery			594 / 1577	NR / NR / NR	341 spon/NR vol (21.6% miscarriage)	Mean: 3.5 +/- 0.7 kg	NR / 222	141 / 12	33	N/A
2. Postsurgery			132 / 251	NR / NR / NR	57 spon/32 vol (26.0% miscarriage)*	Mean: 3.0 +/- 0.5 kg	NR / 12	22 / 1	7	NR

*calculated as miscarriage divided by pregnancies not terminated voluntarily

Table 9. Case Series reporting morbidity and mortality for biliopancreatic diversion

Author/Year	Women of repro age s/p Bariatric surgery	# Pregnant Women / # Pregnancies	# Live Births	Gestational Diabetes / Preeclampsia and/or Eclampsia / Pregnancy Induced HTN	# Miscarr / Abortions	Birth - weight	Low Birth weight (<2500g) / Perinatal Mortality	SGA / Macrosomia	Delivery <36wks	Congenital Malformations	Surgical AE
COOLS;2006[48]	NR	7 / 9	8	NR / NR / NR	0	1050-3030g	5 / 2	NR / 0	5	5	NR
GERRITS;2003[38]	40	4 / 4	4	NR / NR / NR	0	NR	NR / NR	NR / NR	1	NR	NR
FRIEDMAN;1992[46]	747	11 / 11	11	NR / NR / NR	NR	1600-3500g	NR / 0	5 / NR	1	0	0
FRIEDMAN;1989[35]	649	NR / 84	48 (8 still pregnant)	NR / NR / NR	21 vol/ 7 spon (12.7% miscarriage)*	FT:1760 -4200 g	NR / 1	6 / NR	10	Diaphragmatic hernia: 1 Rectal Atresia: 1	0

*calculated as miscarriage divided by pregnancies not terminated voluntarily

Maternal and neonatal surgical adverse events following bariatric surgery

While there are many potential benefits of bariatric surgery for women considering future pregnancy, there are also risks. We identified over a dozen reports of complications requiring surgical intervention during pregnancy following bariatric surgery, many with deleterious effects for the neonate and mother. There were 13 case reports that described 14 complications requiring surgical intervention (one report discussed two patients): eight small bowel obstructions due to internal hernia, two mid-gut volvulus (one from adhesions), one perforated gastric ulcer, two band complications (including erosion and bleeding), and one staple line stricture.[71-83] Eight of these bariatric procedures were performed laparoscopically and six were performed in an open fashion. Time from surgery to pregnancy ranged from 1.5 to 108 months (median=24 months).

Most women presented with nonspecific abdominal pain, nausea, and/or vomiting; in fact, two patients were treated for pancreatitis days prior to the correct diagnosis. Given the vague, rather common symptoms, there were often delays of up to several days prior to surgical intervention. Eight patients ultimately underwent Computed Tomography (CT), which often prompted surgery immediately upon receipt of the results. Several patients were in florid septic shock at the time of the intervention.

At the time of the adverse event, gestational age ranged from 25 to 36 weeks (median = 29.5 weeks). Most required urgent surgical intervention. Examples of findings at exploration included pulling-through of sutures placed to close a mesenteric defect, internal hernia through Peterson's Space, and band erosion. An emergent cesarean section or premature rupture of membranes occurred in six of 13 cases (46 percent). Overall five of 13 (38.5 percent) neonates died (one natal outcome was not reported). Five were delivered at full-term. There were three maternal deaths (21.4 percent).

It is not known if pregnancy increases risk for surgical complications, as these types of reports are also found for nonpregnant patients and there are relatively uncommon. However, the maternal and fetal mortality and morbidity rates associated with these types of complications are high. Early diagnosis and surgical intervention are key to addressing bowel obstructions, band erosions, and gastrointestinal hemorrhage. Although the data are retrospective and self-reported, CT scan was helpful in diagnosing many of the patients with internal hernias. These data suggest that these types of complications should be considered early in the work-up of pregnant women who present with signs and symptoms of intestinal obstruction, perforation, or hemorrhage.

Key question 7. What is the evidence that cesarean section for women who have had bariatric surgery affects the risks of morbidity and mortality for: a) mother and b) neonate?

One case-control study assessed effects of cesarean section on women who have had bariatric surgery.[67] Postoperative pregnancies (n=57) were compared to presurgery pregnancies (n=57) matched for presurgery weight, age, parity at index pregnancy, and delivery year. They reported no difference in rate of primary cesarean section (7 patients vs 8 patients, p=NS) or rate of repeat cesarean section (7 vs 1, p=0.07). For the observational studies, the rates of cesarean section vary

greatly from study to study and the difference between postsurgery deliveries and presurgery also varied with some showing higher rates, others lower, and other no difference. In one study, bariatric surgery was found to be an independent risk factor for cesarean delivery.[30] However, the author indicated there is no known physiologic reason for performing more cesarean deliveries among patients who have had bariatric surgery, and it is difficult to ascribe the increased use of cesarean delivery in patients with previous bariatric surgery to anything but caregiver bias. In general, most of the observational studies reporting on cesarean section rates did not have details on number of previous cesarean sections, breech position of fetus, or maternal choice in delivery method, thus making comparisons with the population difficult.

The case-control study reported on specific delivery complications.[67] They found no differences in need for transfusions (5 patients versus 1 patient, p=NS), peripartum need for intravenous antibiotics (4 versus 4, p=NS), or peripartum thromboembolic events requiring heparin (1 versus 1, p=NS). Blood transfusions were associated with cesarean section in 3/5 cases in the postsurgery group and 1/1 for the control group. Receipt of antibiotics was associated with cesarean section in 2/4 cases for postoperative group and 3/4 for the control.

We did not find any data specifically looking at possible operative injury complications following cesarean section.

Chapter 4. Discussion

Limitations

Publication Bias

Our literature search procedures were extensive and included canvassing experts regarding studies we may have missed. However, it is possible that we may have missed studies, and even more possible that some data relevant to these questions exist but have not been published.

Study Quality

The most important limitation to this review is the quality of the original studies. The clinical questions of interest are best answered by studies using a prospective cohort design (for studies of risk and prognosis, such as key questions 2 and 4) or randomized clinical trials (for questions of management, such as key questions 3 and 5). We found no such study, and therefore were compelled to use data from study designs of lesser theoretical strength—even case series and case reports. Most studies were not designed to address issues of fertility and pregnancy outcomes following bariatric surgery. Many publications reporting the results of cohort studies and case series for bariatric surgery fail to clearly report the method of assembly, fail to report the dropout rates clearly, or report high dropout rates. The inherent limitations in these study designs preclude us from drawing strong conclusions to most questions.

Conclusions

Overall, relevant evidence is scant. Only one case control study and 12 cohort studies were found. All of the other data were from case series or case reports. Given this major limitation in data, these are the preliminary findings:

1) What is the incidence of bariatric surgery in women of reproductive age? What are the trends in incidence of bariatric surgery in women of reproductive age?

    - More than 50,000 women between the ages of 18 and 45 undergo bariatric procedures each year in an inpatient setting. The rate of use is increasingly rapidly—more than six-fold in the past 7 years. It is possible that even more women in the 18-45 age group are undergoing outpatient bariatric surgery procedures, like laparoscopic adjustable gastric band, that were not reported in our dataset.

2) What is the evidence that bariatric surgery affects (directly or indirectly) future fertility?

    - It is likely that fertility in the context of the polycystic ovarian syndrome improves following bariatric surgery. This finding is consistent with improvements in fertility seen when obese women lose weight with nonsurgical methods.[84, 85] Data are too sparse to reach definitive conclusions about other effects of bariatric surgery on fertility.

3) What is the evidence that bariatric surgery affects (directly/indirectly) choice of contraception?

- There is almost no evidence on this topic. A small case series of 40 patients who had undergone BPD and who were advised to avoid pregnancy for at least 2 years reported 2 failures for oral birth control, one at 9 months postoperatively and the other at 24 months. However, the reported failure rate of OCPs in typical use is 3 percent, so this result may not be atypical.

4) In patients who have had bariatric surgery, what is the evidence for prenatal risk factors (e.g., reduced nutrient absorption, unusual weight gain) that may result in poor pregnancy outcomes?

- Gastric bypass and laparoscopic adjustable band seem to confer minimal if any risk for nutrient problems, as long as maternal nutrition is maintained.
- One large case series reported that 21 percent of pregnant women who had received BPD required parenteral nutrition support.

5) What is the evidence that certain management strategies for addressing nutrient absorption and weight gain reduce the risks of poor pregnancy outcomes?

- Some case reports/case series stated that the patients who had nutritional deficiencies did not take the recommended multivitamin and iron.
- In some reports, the gastric band needed adjustment to allow sufficient oral nutrition intake.

6) For women who have had bariatric surgery, what is the evidence for morbidity and mortality risks for a) mother and b) neonate?

- Obese women who had bariatric surgery may have a lesser risk than obese women for certain pregnancy complications, such as gestational diabetes, preeclampsia, and pregnancy-induced hypertension.
- Reports of mean birth weight, rates of low birth weight, and rates of premature delivery are no different in babies born to women following bariatric surgery than babies in the general population, although firm conclusions cannot be drawn due to small sample sizes.
- There are case reports of surgical adverse events following bariatric surgery in women who then became pregnant, including maternal deaths and fetal death—but there are similar reports in nonpregnant patients who had bariatric surgery. These events are uncommon and the majority appeared to be due to internal hernias. Delays in diagnosis were a common factor in many case reports, and use of the CT scan, even though the patients were pregnant, was helpful in reaching a diagnosis. Therefore, women who elect to have bariatric surgery will have an increased risk of certain complications that would not have occurred had they not had bariatric surgery, but it is unknown if pregnancy affects the risk. Although the net benefit-to-risk for pregnancy following bariatric surgery is still likely to be favorable, these additional risks must be acknowledged.

7) What is the evidence that cesarean section for women who have had bariatric surgery affects the risks of morbidity and mortality for a) mother and b) neonate?

- One case-control study attempted to answer this specific question, and found no significant difference in rates of cesarean section postsurgery The rates of cesarean section vary greatly from among the observational studies. The case-control study found no difference in delivery complications such as transfusions, need for antibiotics, or thromboembolic events. No study specifically assessed possible operative injury following cesarean section.

Future Research

Much more research is needed to answer almost every key question in this report.

Regarding rates of use, methods are needed to capture the rise in outpatient delivery of bariatric procedures, mainly the laparoscopic adjustable gastric band. Without this data, estimates of use based on the Nationwide Inpatient Sample will underestimate the total number of cases.

For all issues related to risk and prognosis, such as the effects on fertility, timing of pregnancy, development of complications of pregnancy, outcomes of pregnancy, and cesarean section rates, prospective cohorts are required to provide better estimates. For example, to address the issue of impact of surgery on fertility a large, prospective cohort study comparing a consecutive group of women who underwent bariatric surgery and desire pregnancy, for ability to get pregnant compared to a matched obese group who is also attempting pregnancy. Groups will need to be matched on presurgery parity, age, and type of procedure.

For the issues related to management, such as choice of contraceptive and nutritional management, randomized controlled trials are needed. With regards to understanding the effectiveness of contraception methods following surgery, we will first need clinical studies assessing changes in absorption of oral contraceptive pill (OCP). Then RCTs or matched cohort study comparing barrier methods, OCP, and other methods for contraception in women not desiring pregnancy and follow them for one year looking at pregnancy as an outcome. Because pregnancy rates will be low, a large sample size will be required in each arm to adequately power the study [n=750 in each arm to detect 50 percent absolute difference (3 percent to 6 percent)].

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Appendix A. Technical Expert Panel Members and Peer Reviewers

Technical Expert Panel Members

Name	Affiliation
Edward Livingston, MD	University of Texas, Southwestern Medical Center at Dallas
Carol Major, MD	University of California at Irvine Medical Center
John Morton, MD	Stanford University Medical Center
Nanette Santoro, MD	Albert Einstein College of Medicine

Peer Reviewers

Name	Affiliation
Alison Avenell, MD	University of Aberdeen, Health Services Research Unit
Susan Meikle, MD	National Institute of Child Health and Human Development
Claudia Steiner, MD	Agency for Healthcare Research and Quality

Appendix B. Search Strategies

BARIATRIC SURGERY & PREGNANCY – SEARCH METHODOLOGIES

SEARCH #1 (Performed 11/3/2006):

DATABASES SEARCHED & TIME PERIOD COVERED:
PubMed – 1985-2006 (November)

SEARCH STRATEGY:
bariatric surgery OR bariatric*[tiab] OR gastric bypass OR gastric band OR gastric bands OR laparoscopic adjustable band OR laparoscopic adjustable bands OR lap band OR lap bands OR lap-band OR lap-bands OR sleeve gastrectom* OR intragastric balloon* OR intra-gastric balloon* OR gastric stimulat* OR biliopancreat* diversion* OR duodenal switch* OR scopinaro switch* OR gastroplast* OR gastric restrictive surgery OR jejunal ileal bypass* OR jejunal-ileal bypass* OR jejunoileal bypass* OR obesity surgery OR weight loss surgery OR weight reduction surgery OR weight reduction operation* OR (intestinal bypass* OR surgical management OR surgical treatment OR gastric surgery) and (obesity OR obese) OR gastric banding OR vertical banded gastroplasty
AND
fertility OR contraception OR pregnan* OR prenatal OR cesarean OR mother OR neonate* OR obstetric*

TOTAL NUMBER OF ITEMS RETRIEVED – 804

SEARCH #2 (Performed 11/6/2006):

DATABASES SEARCHED:
PubMed

SEARCH STRATEGY:
“Related Articles” search on the following article:
O'Brien PE, Dixon JB, Laurie C, Skinner S, Proietto J, McNeil J, Strauss B, Marks S, Schachter L, Chapman L, et al. Treatment of mild to moderate obesity with laparoscopic adjustable gastric banding or an intensive medical program: a randomized trial. Ann Intern Med 2006 May 2;144(9):625-33.

TOTAL NUMBER OF ITEMS RETRIEVED – 131

SEARCH #3 (Performed 11/9/2006):

DATABASES SEARCHED:

Appendix B. Search Strategies

Cochrane Database of Systematic Reviews – 1985-2006
Cochrane Database of Abstracts of Reviews of Effects – All years

SEARCH STRATEGY:
(bariatric surgery or bariatric$ OR gastric bypass OR gastric band OR gastric bands OR laparoscopic adjustable band OR laparoscopic adjustable bands OR lap band OR lap bands OR lap-band OR lap-bands OR sleeve gastrectom$ OR intragastric balloon$ OR intra-gastric balloon$ OR gastric stimulat$ OR biliopancreat$ diversion$ OR duodenal switch$ OR scopinaro switch$ OR gastroplast$ OR gastric restrictive surgery OR jejunal ileal bypass$ OR jejunal-ileal bypass$ OR jejunoileal bypass$ OR obesity surgery OR weight loss surgery OR weight reduction surgery OR weight reduction operation OR ((intestinal bypass$ OR surgical management OR surgical treatment OR gastric surgery) AND (obesity OR obese)) OR gastric banding OR vertical banded gastroplasty).mp. [mp=ti, ot, ab, sh, hw, kw, tx, ct]
AND
fertility OR contraception OR pregnan$ OR prenatal OR cesarean OR mother OR neonat$e OR pregnancy complications OR pregnancy outcome OR obstetric$.mp.

TOTAL NUMBER OF ITEMS RETRIEVED – 37

SEARCH #4 (Performed 11/16/2006):

DATABASES SEARCHED:
Embase - 1985-2006

SEARCH STRATEGY:
bariatric surgery! OR gastric banding OR gastric bypass OR stomach bypass OR gastric(2n)bypass? OR (laparoscopic surgery AND band?) OR lap?(2w)band? OR gastrectom?(2n)sleeve? OR intragastric(2n)balloon? OR intra(1w)gastric(2n)balloon? OR gastric(2n)stimulat? OR biliopancreatic()bypass OR duoden?(2n)switch? OR scopinaro(2n)switch? OR biliopancreatic(2n)diver? OR gastroplasty OR gastric(2w)restrict? OR jejunal(2w)ileal(f)bypass? OR (obesity/ti,de AND (surgery/de,ti OR operation)) OR (weight reduction AND (surgery/ti,de OR operation)) OR ((intestin?(2n)bypass? OR surgical management OR surgical approach OR surgical(2n)risk? OR surgery(2n)risk? OR stomach surgery) AND obes?) OR (surgery/ti,de AND obes?)
AND
fertility! OR pregnancy! OR pregnancy complication! OR pregnan?/ti OR contracept? OR prenatal development! OR prenatal disorder! OR prenatal mortality OR prenatal/ti OR neonatal OR newborn OR cesarean section? OR perinatal development OR perinatal mortality OR perinatal morbidity OR perinatal/ti

TOTAL NUMBER OF ITEMS RETRIEVED – 495

Appendix C. Data Collection Form

EPC PROJECT: BARIATRIC SURGERY IN WOMEN OF REPRODUCTIVE AGE SCREENER FORM FINAL 12-18-06

1. Reviewer: _____

2. Last name, first author: _____

3. Year of publication: _____

4. Does article study bariatric surgery?

(**Check all that apply)**

Gastric bypass ..... ☐
Adjustable banding ..... ☐
Biliopancreatic diversion ..... ☐
Vertical banded gastroplasty ..... ☐

Other bariatric surgeries ..... ☐ **(STOP)**
Not bariatric surgery ..... ☐ **(STOP)**

If only "Other bariatric surgeries" or "Not bariatric surgery" is checked then STOP form. If interested in flagging article for background or want to order a reference, go to Q7/Q8.

5. Does the study focus on any of the following issues?
(**Check all that apply)**

Fertility after surgery ..... ☐
Contraception recommendations ..... ☐
Contraception effectiveness ..... ☐

Recommendations for time following surgery to delay pregnancy ..... ☐

Nutrition and/or weight management during pregnancy ..... ☐

Pregnancy morbidity or mortality risks .. ☐
C-Section after surgery ..... ☐
Neonatal outcomes ..... ☐
Other maternal outcomes ..... ☐

None of the above ..... ☐ **(STOP)**

6. Study design: (**Circle one)**

Background (historical, editorial etc.) ..... 1 **(STOP)**
Non-systematic review ..... 2 **(STOP)**
Systematic review / Meta-analysis ..... 3 **(STOP)**

Case report (N=1) 4
Case series/Cohort 5
Controlled trial 6

Case control 7
Other 8

7. Total sample size of <u>women</u> entering study. If entering sample not reported then total completing sample size: (**Enter # or 9999 if no sample reported)**

___ ___ ___ ___

8. Language of article: **(Circle one)**

English 1
Other 2

Language (specify): _____

9. Do you think that this article might be a duplicate or include the same data as another study? **(Circle one)**

Yes 1
No 2
If YES, which one(s) :

_____
(Enter study ID #, author or 9999 if don't know.)

10. Is there a reference that needs to be checked?
(Circle one)

Yes 1
No 2
If YES, which one(s) :

_____
(Enter reference # and/or author or 9999 if don't know.)

11. Should article be flagged as background for report writing?

Yes 1
No 2

Notes:

Appendix D. Bariatric Surgery for Women of Reproductive Age Overall Evidence Table.

First Author Year	Type of Surgery	Study Design	Sample Size	Years Surgery Performed	Selection Criteria
AHMED 2006[70]	Gastric bypass	Case report	1	NR	Not applicable (not cohort study)
BAKER 2005[72]	Gastric bypass	Case report	1	NR	Not applicable (not cohort study)
BAR-ZOHAR 2006[58]	Adjustable gastric banding	Case series	74	1996-2003	Selected sample
BELLANGER 2006[71]	Gastric bypass	Case report	1	NR	Not applicable (not cohort study)
BILENKA 1995[26]	Vertical banded gastroplasty	Cohort	9	1985-1990	Assembly method not reported
BIRON 1999[60]	Biliopancreatic diversion	Case series	544	Pre 1995	Consecutive patients
CAMPBELL 2005[50]	Gastric bypass	Case report	1	NR	Not applicable (not cohort study)
CHAPMAN 1991[61]	Vertical banded gastroplasty	Case report	1	NR	Not applicable (not cohort study)
COOLS 2006[44]	Biliopancreatic diversion	Case series	9	NR	Assembly method not reported
DAO 2006[41]	Gastric bypass	Cohort	2423	2001-2004	Selected sample
DEITEL 1988[25]	Biliopancreatic diversion, Vertical banded gastroplasty	Cohort	138	1977-1984	Selected sample
DIXON 2001[30]	Adjustable gastric banding	Cohort	650	NR	Assembly method not reported
DIXON 2005[39]	Adjustable gastric banding	Cohort	79	1995-2003	Selected sample
DOMINGO 2005[65]	Gastric bypass	Case report	1	NR	Not applicable (not cohort study)
EID 2005[36]	Gastric bypass	Cohort	24	1997-2001	Selected sample
EREZ 2004[77]	Adjustable gastric banding	Case report	1	NR	Not applicable (not cohort study)
FLESER 2003[73]	Gastric bypass	Case report	1	NR	Not applicable (not cohort study)
FRIEDMAN 1989[32]	Biliopancreatic diversion	Case series	649	NR	Consecutive patients
FRIEDMAN 1992[42]	Biliopancreatic diversion	Case series	747	1976-1990	Assembly method not reported
FRIEDMAN 1992[78]	Biliopancreatic diversion	Case series	747	1976-1990	Assembly method not reported
FRIEDMAN 1995[43]	Biliopancreatic diversion	Cohort	1136	1976-1994	Consecutive patients
FRIEDMAN 1996[79]	Gastric bypass, Biliopancreatic diversion	Case series	152	Pre 1995	Other (literature review)
GANDRY 2006[80]	Adjustable gastric banding	Case report	1	2004	Not applicable (not cohort study)
GAUDRY 2004[55]	Adjustable gastric banding	Case report	1	NR	Not applicable (not cohort study)
GEORGE 2005[45]	Biliopancreatic diversion	Case report	1	NR	Not applicable (not cohort study)
GERRITS 2003[35]	Biliopancreatic diversion	Case series	40	1997-1998	Consecutive patients
GRANGE 1994[52]	Gastric bypass	Case report	1	NR	Not applicable (not cohort study)
GRANSTROM 1990[81]	Adjustable gastric banding	Case report	1	NR	Not applicable (not cohort study)
GRAUBARD 1988[69]	Biliopancreatic diversion	Case report	1	NR	Not applicable (not cohort study)
GUREWITSCH 1996[53]	Gastric gastric bypass	Case report	1	NR	Not applicable (not cohort study)
HADDOW 1986[49]	Gastric gastric	Case series	3	1980-1984	Assembly method not reported

First Author Year	Type of Surgery	Study Design	Sample Size	Years Surgery Performed	Selection Criteria
	bypass				
HALL 1990[82]	Gastric bypass, Vertical banded gastroplasty	Controlled trial	310	NR-1984	Clinical trial
HODA 2002[83]	Adjustable gastric banding	Case series	2		Not applicable (not cohort study)
HUERTA 2002[47]	Biliopancreatic diversion	Case report	1		Not applicable (not cohort study)
JESTER 1997[62]	Gastric bypass, other surgery	Case series	100	NR	Convenience sample
KAKARLA 2005[66]	Gastric bypass	Case series	2	NR	Not applicable (not cohort study)
KRAL 2006[64]	Biliopancreatic diversion	Cohort	113	1982-2001	Assembly method not reported
LOAR 2005[68]	Gastric bypass	Case report	1	NR	Not applicable (not cohort study)
MARCEAU 2004[27]	Biliopancreatic diversion	Cohort	783	1984-2000	Consecutive patients
MARTENS 1990[51]	Gastric bypass	Case report	1	NR	Not applicable (not cohort study)
MARTIN 1988[48]	Gastric bypass	Case series	87	NR	Selected sample
MARTIN 1997[57]	Adjustable gastric banding	Case series	98	NR	Consecutive patients
MARTIN 2000[31]	Adjustable gastric banding	Case series	265	1990-1998	Clinical trial
MOOR 2004[67]	Gastric bypass	Case report	1	NR	Not applicable (not cohort study)
PRINTEN 1982[40]	Gastric bypass	Case series	45	NR	Assembly method not reported
RAMIREZ 1995[84]	Vertical banded gastroplasy	Case report	1	NR	Not applicable (not cohort study)
RAND 1989[59]	Gastric bypass	Case series	18	NR	Assembly method not reported
RICHARDS 1987[85]	Gastric bypass	Case control	243	1979-1983	Selected sample
SHEINER 2004[28]	Gastric bypass, Adjustable gastric banding, Biliopancreatic diversion, Vertical banded gastroplasty	Cohort	159210	1988-2002	Selected sample
SHEINER 2006[29]	Gastric bypass, Adjustable gastric banding	Cohort	8014	1988-2002	Selected sample
SKULL 2004[56]	Adjustable gastric banding	Cohort	44	1996-NR	Consecutive patients
SMETS 2006[46]	Biliopancreatic diversion	Case report	1	NR	Not applicable (not cohort study)
STRAUSS 2001[63]	Gastric bypass	Case series	7	1983-1999	Selected sample
TSENOV 1994[86]	Biliopancreatic diversion	Case report	1	MISSING	Not applicable (not cohort study)
WEINER 2003[33]	Adjustable gastric banding	Case series	678	1994-2002	Consecutive patients
WEISS 2001[54]	Adjustable gastric banding	Case series	215	1996-2000	Consecutive patients
WEISSMAN 1995[87]	Gastric bypass	Case report	1	NR	Not applicable (not cohort study)
WITTGROVE 1998[34]	Gastric bypass	Cohort	41	early 1980's-1998	Volunteers, response to media

Appendix E. Rejected Titles

Rejected: At Abstract

1. American College of Obstetricians and Gynecologiests. Guidelines for perinatal care. Washington DC. 2002.

2. Bowne WB, Julliard K, Castro AE, et al. Laparoscopic gastric bypass is superior to adjustable gastric band in super morbidly obese patients: A prospective, comparative analysis. Arch Surg 2006;141(7):683-9.

3. Deitel M. Pregnancy after bariatric surgery. Obes Surg 1998;8:465-6.

4. Deitel M, Ternamian A.M. Gynecologic-obstetric features of morbid obesity and the effect of weight loss. In: Deitel M. (Editor) Update: Surgery for the Morbidly Obese Patient. Toronto: FD-Communications Inc.; 2000. p. 481-5.

5. Higa KD, Tienchin H, Boone KB. Internal hernia after laparoscopic Roux-en-Y gastric bypass: incidence, treatment and prevention. Obes Surg 2003;13:350-4.

6. Houston BD, Turner T. Severe electrolyte abnormalities in a pregnant patient with a jejunoileal bypass. Arch Intern Med 1978;138(11):1712-3.

7. Hrgovic Z, Alnor PC. [Pregnancy after treatment of obesity using jejuno-ileal anastomosis]. Jugosl Ginekol Perinatol 1985;25(1-2):39-41.

8. Pugnale N, Giusti V, Suter M, et al. Bone metabolism and risk of secondary hyperparathyroidism 12 months after gastric banding in obese pre-menopausal women. Int J Obes Relat Metab Disord 2003;27 (1):110-6.

9. Schein M. Collar material erosion after vertical-banded gastroplasty--an underestimated problem? A case report. S Afr J Surg 1990;28(2):73-4.

10. Smets RM, Waeben M. Unusual combination of night blindness and optic neuropathy after biliopancreatic bypass. Bull Soc Belge Ophtalmol 1999;271:93-6.

Rejected: Not Bariatric Surgery

1. ACOG Committee Opinion. Number 299, September 2004 (replaces No. 158, September 1995). Guidelines for diagnostic imaging during pregnancy. Obstet Gynecol 2004;104(3):647-51.

2. Safety considerations and avoiding complications in the massive weight loss patient. Plast Reconstr Surg 2006;117(1 Suppl):74S-81S; discussion 82S-83S.

3. Abrams B, Parker JD. Maternal weight gain in women with good pregnancy outcome. Obstet Gynecol 1990;76(1):1-7.

4. Akira S, Abe T, Igarashi K, et al. Gasless laparoscopic surgery using a new intra-abdominal fan retractor system: an experience of 500 cases. J Nippon Med Sch 2005;72(4):213-6.

5. Andreasen KR, Andersen ML, Schantz AL. Obesity and pregnancy. Acta Obstet Gynecol Scand 2004;83(11):1022-9.

6. Baeten JM, Bukusi EA, Lambe M. Pregnancy complications and outcomes among overweight and obese nulliparous women. Am J Public Health 2001;91(3):436-40.

7. Beck WW Jr. Intestinal obstruction in pregnancy. Obstet Gynecol 1974;43(3):374-8.

8. Belsey EM, d'Arcangues C, Carlson N. Determinants of menstrual bleeding patterns among women using natural and hormonal methods of contraception. II. The influence of individual characteristics. Contraception 1988;38(2):243-57.

9. Bowers D, Cohen WR. Obesity and related pregnancy complications in an inner-city clinic. J Perinatol 1999;19(3):216-9.

10. Calandra C, Abell DA, Beischer NA. Maternal obesity in pregnancy. Obstet Gynecol 1981;57(1):8-12.

11. Cedergren MI. Maternal morbid obesity and the risk of adverse pregnancy outcome. Obstet Gynecol 2004;103(2):219-24.

12. Cnattingius R, Cnattingius S, Notzon FC. Obstacles to reducing cesarean rates in a low-cesarean setting: the effect of maternal age, height, and weight. Obstet Gynecol 1998;92(4 Pt 1):501-6.

13. Cnattingius R, Hoglund B, Kieler H. Emergency cesarean delivery in induction of labor: an evaluation of risk factors. Acta Obstet Gynecol Scand 2005;84(5):456-62.

14. Cnattingius S, Bergstrom R, Lipworth L, et al. Prepregnancy weight and the risk of adverse pregnancy outcomes. N Engl J Med 1998;338(3):147-52.

15. Crane SS, Wojtowycz MA, Dye TD, et al. Association between pre-pregnancy obesity and the risk of cesarean delivery. Obstet Gynecol 1997;89(2):213-6.

16. Crerand CE, Wadden TA, Sarwer DB, et al. A comparison of weight histories in women with class III vs. class I-II obesity. Surg Obes Relat Dis 2006;2(2):165-70.

17. Crerand CE, Wadden TA, Sarwer DB, et al. A comparison of weight histories in women with class III vs. class I-II obesity. Obesity (Silver Spring) 2006;14 Suppl 2:63S-69S.

18. Crosignani PG, Vegetti W, Colombo M, et al. Resumption of fertility with diet in overweight women. Reprod Biomed Online 2002;5(1):60-4.

19. Curet MJ. Special problems in laparoscopic surgery. Previous abdominal surgery, obesity, and pregnancy. Surg Clin North Am 2000;80(4):1093-110.

20. Davis MR, Bohon CJ. Intestinal obstruction in pregnancy. Clin Obstet Gynecol 1983;26(4):832-42.

21. De Sutter P. Rational diagnosis and treatment in infertility. Best Pract Res Clin Obstet Gynaecol 2006;20(5):647-64.

22. Dempsey JC, Ashiny Z, Qiu CF, et al. Maternal pre-pregnancy overweight status and obesity as risk factors for cesarean delivery. J Matern Fetal Neonatal Med 2005;17(3):179-85.

23. Durnwald CP, Ehrenberg HM, Mercer BM. The impact of maternal obesity and weight gain on vaginal birth after cesarean section success. Am J Obstet Gynecol 2004;191(3):954-7.

24. Ehrenberg HM, Durnwald CP, Catalano P, et al. The influence of obesity and diabetes on the risk of cesarean delivery. Am J Obstet Gynecol 2004;191(3):969-74.

25. Ekblad U, Grenman S. Maternal weight, weight gain during pregnancy and pregnancy outcome. Int J Gynaecol Obstet 1992;39(4):277-83.

26. Ferreira MF, Sobrinho LG, Pires JS, et al. Endocrine and psychological evaluation of women with recent weight gain. Psychoneuroendocrinology 1995;20(1):53-63.

27. Finlay M, Huang LL. A new variant of serum leucine aminopeptidase in the mouse: its development and possible regulation. Biochem Genet 1985;23(1-2):169-80.

28. Galtier-Dereure F, Boulot P. [Obstetrical complications of maternal overweight]. Contracept Fertil Sex 1994;22 (2):113-6.

29. Galtier-Dereure F, Montpeyroux F, Boulot P, et al. Weight excess before pregnancy: complications and cost. Int J Obes Relat Metab Disord 1995;19(7):443-8.

30. Goldman M, Kitzmiller JL, Abrams B, et al. Obstetric complications with GDM. Effects of maternal weight. Diabetes 1991;40 Suppl 2:79-82.

31. Goodall PT, Ahn JT, Chapa JB, et al. Obesity as a risk factor for failed trial of labor in patients with previous cesarean delivery. Am J Obstet Gynecol 2005;192(5):1423-6.

32. Gray DS, Cabaniss ML. Home total parenteral nutrition in a pregnant diabetic after jejunoileal bypass for obesity. JPEN J Parenter Enteral Nutr 1989;13(2):214-7.

33. Grimes DA, Shields WC. Family planning for obese women: challenges and opportunities. Contraception 2005;72(1):1-4.

34. Grossetti E, Beucher G, Regeasse A, et al. [Obstetrical complications of morbid obesity]. J Gynecol Obstet Biol Reprod (Paris) 2004;33(8):739-44.

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