

HHS Public Access

Author manuscript *Obstet Gynecol.* Author manuscript; available in PMC 2018 November 01.

Published in final edited form as:

Obstet Gynecol. 2017 November ; 130(5): 979–987. doi:10.1097/AOG.0000000002323.

Contraception and Conception After Bariatric Surgery

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Abstract

Objective—To examine contraceptive practices and conception rates after bariatric surgery.

Methods—The Longitudinal Assessment of Bariatric Surgery-2 is a multicenter, prospective cohort study of adults undergoing first-time bariatric surgery as part of routine clinical care at 10 U.S. hospitals. Recruitment occurred between 2005 and 2009. Participants completed preoperative and annual post-surgical assessments for up to seven years until January 2015. This report was restricted to women 18–44 years old with no history of menopause, hysterectomy, or estrogen and progesterone therapy. Primary outcomes were self-reported contraceptive practices, overall conception rate and early (<18 months) post-surgical conception. Contraceptive practice (no

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Financial Disclosure: A. Courcoulas has received research grants from Covidien, Ethicon, Nutrisystem and PCORI, and consultant fees from Apollo Endosurgery. D. Flum has had an advisor role with Pacira Pharmaceuticals, has provided expert testimony for Surgical Consulting LLC, and has received travel expenses from Patient Centered outcomes research institute. W. Pories has received research grants from J & J, Janssen Pharmaceuticals. B. Wolfe has received consultant fees from Enteromedics. A. Pomp is a consultant and speaker for Medtronic and Ethicon and WL Gore and Associates. The other authors did not report any potential conflicts of interest.

Each author has indicated that he or she has met the journal's requirements for authorship.

Presented at the 33rd Annual Meeting of the American Society for Metabolic and Bariatric Surgery at Obesity Week, October 31 – November 4, 2016, New Orleans, LA.

intercourse, protected, unprotected, or tried to conceive) was classified based on the preceding year. Conception rates were determined from self-reported pregnancies.

Results—Of 740 eligible women, 710 (95.9%) completed follow-up assessment(s). Median (IQR) preoperative age was 34 (30–39) years. In the first postsurgical year, 12.7% (95%CI, 9.4–16.0) of women had no intercourse, 40.5% (95%CI, 35.6–45.4) had protected intercourse only, 41.5% (95%CI, 36.4–46.6) had unprotected intercourse while not trying to conceive, and 4.3% (95%CI, 2.4–6.3) tried to conceive. The prevalence of the first three groups did not significantly differ across the 7 years of follow-up (*P* for all >.05); however, more women tried to conceive in the second year (13.1%, 95%CI, 9.3–17.0; *P*<0.001). The conception rate was 53.8 (95%CI, 40.0–71.1) per 1,000 woman-years across follow-up (median [IQR]: 6.5 [5.9, 7.0] years); 42.3 (95%CI, 30.2–57.6)/1,000 woman-years in the 18 months after surgery. Age (ARR 0.41, [95% CI, 2.02–11.21], *P*<0.001), and rating future pregnancy as important preoperatively (ARR 8.50, [95% CI, 2.92–24.75], *P*<0.001) were associated with early conception.

Conclusion—Post-surgical contraceptive use and conception rates do not reflect recommendations for an 18-month delay in conception after bariatric surgery.

Clinical Trial Registration—ClinicalTrials.gov, NCT00465829.

INTRODUCTION

In the United States, reproductive-aged women represent 40 percent of patients undergoing bariatric surgery (i.e., at least 50,000 inpatient cases annually)^{1–3}. Clinical practice guidelines cosponsored by the American Association of Clinical Endocrinologists, the Obesity Society, and the American Society for Metabolic & Bariatric Surgery in 2013 recommend that women avoid conception for 12–18 months after bariatric surgery ⁴. The delay is intended to optimize the likelihood of maternal weight stability during fetal growth. This recommendation precedes recent evidence suggesting conception within two years of bariatric surgery increases the risk for prematurity, small for gestational age (SGA) infants, and neonatal intensive care unit (NICU) admissions⁵.

We previously reported that future pregnancy was important to 30 percent of reproductiveaged women at the time of bariatric surgery⁶. One-third of these women reported an intention to conceive within two years of surgery⁶. Despite the magnitude of this public health concern, little is known regarding the post-operative reproductive behavior of these patients.

The Longitudinal Assessment of Bariatric Surgery-2 (LABS-2) study is a multicenter, prospective cohort study that has previously reported the preoperative reproductive health status⁶, as well as the safety and efficacy of bariatric surgery procedures⁷ in adults undergoing bariatric surgery. The aim of this study is to report post-surgical contraceptive practices and conception rates among reproductive-aged women who undergo bariatric surgery, and determine factors related to 1) post-surgical unprotected intercourse while not trying to conceive, 2) early (<18 months) post-surgical conception, and 3) delayed (18–42 months) post-surgical conception.

MATERIALS AND METHODS

Participants were recruited into LABS-2, a multicenter prospective cohort study, at 10 hospitals within six clinical centers throughout the United States between 2005 and 2009. Patients were at least 18 years old undergoing a first bariatric surgical procedure by participating surgeons as part of routine clinical care. Recruitment methodology and study design have previously been described^{6–10.} Prior to data collection, the institutional review boards at each center approved the protocol and all participants gave written informed consent to participate. Research assessments were conducted by LABS-trained and certified personnel independent of surgical care within 30 days prior to scheduled surgery dates and annually post-operatively until January 2015 for up to seven years. Details of the LABS-2 cohort have previously been published^{6,9}.

This report was restricted to women who were 18–44 years old and reported no history of surgical or natural menopause, hysterectomy, or estrogen and progestin therapy (indicated as "hormone replacement therapy" on the data collection form) prior to their preoperative or first follow-up reproductive health assessment. Data collected after any of these criteria were met were excluded. Of 1,931 female participants, 740 women met eligibility requirements, 710 (95.9%) of whom reported post-surgical contraceptive practices or conception (Figure 1).

The preoperative Reproductive Health Questionnaire has been described (Appendix 1, **available online at** http://links.lww.com/xxx).⁶ A post-surgical version was self-administered annually to obtain outcomes in the year prior to assessment (Appendix 2, **available online at** http://links.lww.com/xxx).¹⁰ Primary outcomes were frequency of contraceptive need and use (as defined below), and conception rates. Secondary outcomes included identification of risk factors for post-surgical unprotected intercourse while not trying to conceive, early post-surgical conception and delayed post-surgical conception.

Items assessing frequency of contraceptive use during sexual intercourse with a male partner and attempts to conceive were used to categorize women as having 1) no sexual intercourse with a male partner, 2) protected intercourse only (i.e., used contraception during intercourse with a male partner 'all of the time'), 3) unprotected intercourse with a male partner, or 4) tried to conceive in the past year. This classification scheme reflects the fact that the proportion of women reporting contraceptive use "most of the time" or "about half of the time" was small, and that such practices increase risk of pregnancy. Thus these categories were grouped with "rarely" and "never" as "unprotected intercourse." ^{6,11} Women could only be positive for one of these four dichotomous (yes or no) variables; trying to conceive overrode the other options. Items assessing contraception for any reason, by method, were used to determine past-year use of any contraception, more than one method of contraception, oral contraception alone, and specific methods of contraception alone or in combination.

In addition to the annual post-surgical Reproductive Health Questionnaire, an annual Short Form (administered starting March 2010) and an Event and Complications Form (completed at the four or five year post-surgical assessment) assessed pregnancies "since surgery" to

The number of pregnancies and follow-up time were used to calculate conception rates. In order to account for variation in follow-up time, woman-years of follow-up were calculated using the time from date of surgery to the last date pregnancy status was known through the 7-year assessment window (90 months post-operatively). Rates are reported per 1000 woman-years, which is representative of the percentage of participants who would conceive over 10 years if each woman conceived no more than once. Post-surgical rates stratified by 1) the early post-surgical period during which pregnancy is not recommended (0–<18 months, i.e., "early"), 2) the following 2 years, during which pregnancy is no longer contraindicated (18–<42 months, i.e., "delayed"), and 3) the remaining follow-up period (42–90 months), as well as early and delayed post-surgical conception (i.e., yes or no variables) were also determined.

The Pregnancy Questionnaire allowed the outcome to be reported as: live birth, still birth (baby lost after 20 weeks or 5 months), ectopic or tubal pregnancy, miscarriage (fetus lost before 20 weeks or 5 months), or abortion.

At the preoperative assessment only, women rated the importance of being able to become pregnant in the future (on a scale from 0–10), and anticipated the timeframe in which they would first try to become pregnant after surgery. Based on their responses, post-surgical pregnancy was categorized as 1) important (rating of 8–10)⁶, 2) importance unclear (rating of 3–7), or 3) unimportant (rating of 0–2) or not planned (i.e., 'never'). History of polycystic ovary syndrome (PCOS) was determined by self-reported past diagnosis by a healthcare professional. Menstrual regularity was defined as a history of 10–12 menstrual periods lasting between 1–7 days on average, a usual cycle length of 21–35 days, and no spotting or bleeding at times other than menstrual period within the last 12 months.

Age, sex, race, ethnicity, education, medical insurance, and marital status were assessed using self-administered questionnaires. Race was considered missing for participants who did not report their race as at least 1 of the following: white or Caucasian, black or African American, Asian, American Indian or Alaska Native, or Native Hawaiian or Other Pacific Islander. When more than one type of insurance was reported, insurance type was coded according to the following hierarchy: government, private, other or unknown. Medical history was determined using a combination of laboratory values, physical examination measures, participant-reported medication use, and comorbid diagnoses from healthcare providers and medical records review^{9,12}. Medical contraceptive risk was defined as any level 3 or 4 risk for contraceptive use as reported by the United States Medical Eligibility Criteria for Contraceptive Use (e.g., ischemic heart disease); type of bariatric surgery was not included in this variable. ¹³

Analyses were conducted using SAS versions 9.4 (SAS Institute, Cary, NC, USA). All reported *P*-values were two-sided; *P*-values less than or equal to 0.05 were considered statistically significant. Longitudinal analyses were performed with mixed models with a person-level random intercept, with control for site, preoperative education and preoperative BMI, which were associated with missing follow-up contraception data, as fixed effects. Sensitivity analysis, performed to examine the robustness of results with respect to the missing at random assumption, is reported in Appendix 5, **available online at** http://links.lww.com/xxx.

Poisson mixed models with robust error variance were used to estimate and test for change in prevalence of contraception outcomes. If the *P*-value for variables regarding contraceptive need and use during intercourse (assessed post-operatively only) demonstrated a significant overall difference between follow-up time points, pairwise comparisons between years 1 and 2, and years 1 and 7, were made to assess changes after the first post-surgical year, when a delay in conception is recommended.⁴ Linear trend tests between years 2 and 7 examined the presence of changes after the first post-surgical year. For variables regarding contraceptive use for any reason (assessed pre- and post-operatively), a significant *P*-value for an overall difference between time points was followed by a comparison between preoperative and year 1 (to assess pre- to post-operative change) and a linear trend test between years 1 and 7 (to assess change across follow-up). This analysis was repeated for the two most common surgical procedures in the cohort, Roux-en-Y gastric bypass and laparoscopic adjustable gastric band. Modeled frequencies, 95% confidence intervals (CI), and *P*-values adjusted to control for overall type I error are reported. ¹⁴

Poisson mixed models with robust error variance were used to examine associations between participant characteristics and risk of post-surgical unprotected intercourse while not trying to conceive. Post-surgical assessments were excluded from this analysis if participants reported no intercourse, trying to conceive, or pregnancy in the past 12 months. The following independent variables were included: preoperative age¹⁵, race¹⁶, ethnicity¹⁶, education¹⁵, BMI, contraceptive use, history of PCOS¹⁷; surgical procedure; and post-surgical marital status¹⁶, medical insurance¹⁶, menstrual regularity¹⁸, and non-surgical contraception risk¹³. An interaction with time and each covariate was considered and retained if significant. Adjusted relative risks, 95%CI and *P*-values are reported.

Conception rates, with 95% confidence intervals constructed using the Poisson distribution, are reported. The mid-P exact test was used to determine whether conception rates differed by post-operative timeframe (early, delayed, and the remaining follow-up period).

Poisson mixed models with robust error variance were used to examine associations between participant preoperative characteristics with 1) early conception and 2) delayed conception. The following independent variables were included in each model: age¹⁹, race²⁰, ethnicity²¹, education²², marital status, BMI²³, current or recent smoker²⁴, menstrual regularity, contraceptive use, history of PCOS²⁵, primary infertility, importance of post-surgical pregnancy, and surgical procedure.

Descriptive statistics were used to report pregnancy outcomes.

RESULTS

This report includes 710 (95.9%) women who provided conception data, 670 (90.5%) of whom also provided contraception data at one or more follow-up assessments. (Figure 1). Excluding women who were ineligible for analysis at the time of follow-up or were due for an assessment after study data collection ended, contraception data attainment was 70% (516/740), 60% (417/691), 60% (382/638), 57% (340/599), 59% (326/556), and 60% (197/326) in years 1, 2, 3, 4, 5 and 7, respectively, among those eligible for follow-up (N=740). 10,26

Preoperative characteristics are shown in Table 1. The median (IQR) age was 34.0 (30.0–39.0) years and BMI was 46.3 (42.4–51.4) kg/m². The majority of participants underwent Roux-en-Y gastric bypass (72.7%) followed by laparoscopic adjustable gastric banding (23.3%). Slightly under one-third of women (30.0%) indicated that post-surgical pregnancy was important; the importance was unclear to an additional 15.2%.

Modeled prevalence of contraceptive need and use during intercourse by post-surgical time point is shown in Figure 2; supporting data are reported in supplemental materials (Appendix 6, **available online at** http://links.lww.com/xxx). In the first year, 12.7% (95%CI, 9.4–16.0) of women had no intercourse, 40.5% (95%CI, 35.6–45.4) protected intercourse only, and 41.5% (95%CI, 36.4–46.6) unprotected intercourse while not trying to conceive. The prevalence of these three groups did not significantly differ throughout the remainder of follow-up (*P* for all>.05). At each annual assessment, over 75% of women who reported unprotected intercourse used contraception never or rarely.

In the first post-surgical year, 4.3% (95%CI, 2.4–6.3) of women tried to conceive. More women tried to conceive by year two (13.1% [95%CI, 9.3–17.0], P<0.001). The prevalence decreased over time thereafter (years 2–7 linear trend P=0.02) although still remained higher than year one (10.6% [95% CI, 6.0–15.3] at year 7, P<.01).

Observed and modeled prevalence and confidence intervals by time point as well as results of linear trend analysis are reported (Appendix 7 and 8, **available online at** http://links.lww.com/xxx). Among all women, the prevalence of using any method of contraception increased from 52.3% (95%CI, 47.9–56.6) preoperative assessment to 60.3% (95%CI, 55.5–65.1) in the first post-operative year, (*P* for linear trend < 0.001). In particular, the prevalence of intrauterine device (IUD) use (6.4%, [95%CI, 4.5–8.4] to 8.8%, [95%CI, 6.2–11.4]) and sterilization (13.6%, [95%CI, 10.5–16.6] to 17.6%, [95%CI, 14.0–21.1]) significantly increased from preoperative assessment to year 1 and continued to increase from years 1 to 7 (*P* for linear trend for both <.001). No change was observed in use of nonoral hormonal contraceptives (overall *P*=0.57). Among women who reported contraceptive use in the year prior to and after surgery (47%; 223/470), 93.3% (208/223) used at least one of the same methods at both time points During the first year after Roux-en-Y gastric bypass, 21.1% (95%CI, 16.6–25.7) of women used oral contraceptives, a category 3 risk under US Medical Eligibility Criterial for Contraceptive Use for women who undergo this procedure¹³. For half of these women (10.6% [95%CI, 6.9–14.2] of all women who

underwent Roux-en-Y gastric bypass), it was their only form of contraception (Appendix 8, available online at http://links.lww.com/xxx).

Unadjusted and adjusted relative risks for unprotected intercourse while not trying to conceive by pre- and post-operative factors are shown in (Appendix 9, **available online at** http://links.lww.com/xxx). Non-white race (ARR=1.33 [95% CI, 1.08–1.62]), no contraception in the year prior to surgery (ARR=2.12 [95% CI, 1.74–2.58]) and having a post-operative non-surgical contraceptive risk (ARR=1.20 [95% CI, 1.02–1.40]) were associated with a higher risk of unprotected intercourse post-operatively. Interactions with time were not significant (data not shown) indicating associations did not differ by time point. Risk was not significantly different by surgical procedure.

Among 710 women, 237 pregnancies were reported by 154 women over a median (IQR) of 6.5 (5.9, 7.0) years of follow-up, translating to a conception rate of 53.8 (95% CI, 40.0–71.1) per 1,000 woman-years. Conception rates were not significantly different in the early post-surgical period during which pregnancy is not recommended (0–<18 months), the following 2 years, during which pregnancy is no longer contraindicated (18–<42 months), and the remaining follow-up period (42–90 months), 42.3 (95%CI, 30.2–57.6), 60.9 (95%CI, 46.9–79.2) and 46.5 (95%CI, 34.5–61.4) per 1,000 woman-years, respectively (Appendix 10, **available online at** http://links.lww.com/xxx)

Older age was independently associated with a lower risk of early conception (ARR 0.41 [95% CI, 0.19–0.89] per 10 years). Reported status of married or living as married was independently associated with a higher risk (ARR 4.76 [95% CI, 20.2–11.21]). Preoperative importance of a post-operative pregnancy was also independently associated with a higher risk of early conception (ARR 8.50 [95% CI, 2.92–24.75]) for important, and ARR 5.78 [95% CI, 1.74–19.21]) for importance unclear, vs. unimportant or not planned). Age and preoperative importance of a post-operative pregnancy were also significantly associated with risk of delayed conception (Appendix 11, **available online at** http://links.lww.com/xxx). Other preoperative variables and type of surgical procedure were not independently associated with risk of conception during either time frame (Appendix 11, http://links.lww.com/xxx).

As an exploratory analysis we examined whether percent weight loss was associated with post-operative conception. Percent weight loss from preoperative assessment to 6 months was not significantly associated with early conception (ARR 1.40 [95% CI, 0.96–2.06] for 5% weight loss; *P*=0.08). Likewise, percent weight loss from preoperative measurement to 12 months was not significantly related to delayed conception (ARR 1.05 [95% CI, 0.87–1.29] for 5% weight loss; *P*=0.57). Weight loss by time point is provided in the supplemental material (Appendix 12, **available online at** http://links.lww.com/xxx).

Outcomes for 183 out of 237 pregnancies (77.2%) were reported by 154 women over a median (IQR) of 6.5 (5.9, 7.0) years. Among pregnancies with reported outcomes, 68.9% (126/183) were reported as live births and 21.9% (40/183) were reported as miscarriages. The frequency of all reported pregnancies outcomes and the range of potential values

accounting for missing data (missing N = 54), are provided in the supplemental material (Appendix 13, **available online at** http://links.lww.com/xxx).

DISCUSSION

This large-scale, multi-center report provides post-surgical contraceptive practices and conception rates through a prospective cohort study of reproductive-aged female bariatric surgery patients. During the first post-surgical year, a delay in conception is recommended due to concerns for fetal health;⁴ however, 4% tried to conceive and an additional 42% of women reported unprotected intercourse. Unprotected intercourse while not trying to conceive, non-white race, no contraception use in the year prior to surgery and medical contraceptive risk were associated with greater risk of post-surgical unprotected intercourse while not trying to conceive. Younger age, being married or living like married, and rating post-surgical pregnancy as important prior to surgery were associated with early (<18 months) post-surgical conception.

Despite concerns regarding absorption of oral contraceptives in patients undergoing malabsorptive procedures,²⁸ risk of early or delayed conception was not associated with type of surgical procedure. However, among women who underwent Roux-en-Y gastric bypass just over one-tenth reported using only oral contraception in the first post-surgical year, despite the category 3 risk under the US Medical Eligibility Criteria for Contraceptive Use for women who have undergone malabsorptive procedures.¹³ A study by Chor, et al, suggests that approximately two-thirds of bariatric surgeons refer patients to an obstetrician gynecologist or primary care physician to obtain contraception; only 5 percent were comfortable or very comfortable prescribing contraception²⁸. However, this same study noted that approximately 40 percent of bariatric surgeons do not require early post-operative contraception²⁸.

A major strength of this study lies in the standardized and detailed assessment of a large, multi-center cohort of geographically diverse participants over seven years with relatively high retention.²⁶ Although missing data is a concern, our analyses of contraceptive use controlled for preoperative factors related to missing follow-up data. With imputed data not assumed missing at random, sensitivity analysis yielded similar estimates of unprotected intercourse over time. Although, we had limited statistical power to provide precise estimates of conception rates (i.e., confidence intervals were wide) and thus detect differences in these rates by postoperative timeframe, our initial sample size and retention rate ensured sufficient statistical power to evaluate contraceptive need and use over time and to identify several factors associated with unprotected intercourse while not trying to conceive and early conception.

A major limitation of this study is incomplete reporting regarding pregnancy outcomes among women who conceived. Other notable limitations include lack of assessment of preoperative contraceptive counseling practices, as well as post-operative contraceptive failure among those who conceived. Although a large cohort, given the number of variables under investigation this analysis had limited power to ensure that statistical adjustment

adequately corrected for baseline differences among participants, which might have influenced associations. Finally, because the study did not have a parallel control group, findings cannot be attributed to the surgery itself.

In conclusion, data from reproductive-age women in the LABS-2 cohort allows us to quantify contraceptive utilization during the at-risk post-surgical interval (currently defined as up to 18 months)⁴, as well as choice of contraceptive method by surgical procedure, e.g. combined oral contraceptive use in Roux-en-Y gastric bypass patients. The early conception rate reported in our study of 42.3/1,000 woman-years in the 18 month post-surgical window is especially concerning given recent findings that bariatric surgery increases the risk of SGA infants, preterm deliveries and NICU admissions in the first two years after surgery.^{5,29} Our findings highlight a public health concern that merits additional scrutiny regarding contraceptive counseling and provision of services for all reproductive age women undergoing bariatric surgery. Guidelines recommending inclusion of referral for counseling for post-operative contraceptive use as part of the preoperative evaluation would be prudent. Lack of patient awareness of current guidelines and potential post-operative reversal of preoperative conditions that affect fertility may also impact patient adherence to recommendations for contraception. Our findings also suggest that many of the risk factors for unprotected intercourse while not trying to conceive and early post-surgical conception can be identified prior to surgery and represent opportunities for targeted preoperative counseling.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

Acknowledgments

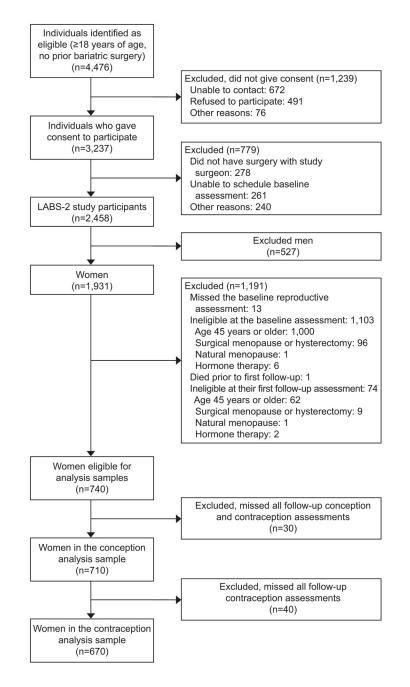
The Longitudinal Assessment of Bariatric Surgery-2 was funded by a cooperative agreement by the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK). Grant numbers: Data Coordinating Center -U01 DK066557; Columbia-Presbyterian - U01-DK66667 (in collaboration with Cornell University Medical Center CTSC, Grant UL1-RR024996); University of Washington - U01-DK66568 (in collaboration with CTRC, Grant M01RR-00037); Neuropsychiatric Research Institute - U01-DK66471; East Carolina University – U01-DK66526; University of Pittsburgh Medical Center – U01-DK66585 (in collaboration with CTRC, Grant UL1-RR024153); Oregon Health & Science University – U01-DK66555. M. Menke was funded under NIH K12 HD 063087.

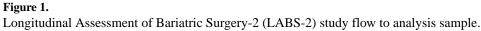
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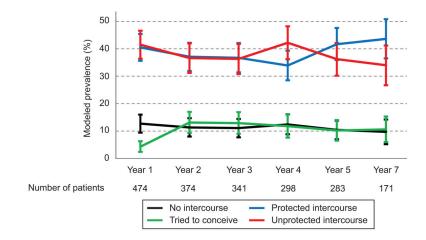


Figure 2.

Contraceptive need and frequency of use after bariatric surgery among women aged 18–44 years (n=584)*. The prevalence of trying to conceive increased between years 1 and 2 (P<. 001) and then decreased between years 2 and 7 (linear trend P=.02). However, the prevalence of trying to conceive remained higher in year 7 compared with year 1 (P<.01). The prevalence of no intercourse (P=.59), protected intercourse (P=.09), and unprotected intercourse (P=.10), did not significantly change over time. *Adjusted for factors related to missing follow-up (site, education level, and baseline body mass index). Observed and modeled data reported in Appendix 6 (see [insert URL]). Error bars indicate 95% CIs.

Table 1

Demographic and Clinical Characteristics of Women Aged 18-44 Years prior to Bariatric Surgery (N=710)*

Characteristic	u	% ∂†
Age, years, median (25 th , 75 th percentile)	34	(30, 39)
White race $\ddagger (No,\%)$ (missing, n=8)	585	83.3
Hispanic ethnicity	52	7.3
Education (missing, n=53)		
High school or less	115	17.5
Some college/post high school education	291	44.3
College degree or higher	251	38.1
Marital status (missing, n=54)		
Married	326	49.7
Living as married	48	7.3
Divorced/separated	79	12.1
Widowed	ю	0.5
Never married/ lived as married	200	30.5
Medical insurance		
Government	91	12.8
Private	480	67.6
Other/unknown	129	18.2
None	10	1.4
Current or recent smoker (No.,%), (missing, n=1)	138	19.5
Body mass index S , median (25 th , 75 th percentile)	46.3	(42.4, 51.4)
Menstrual regularity (No.,%) (missing, n=215)	253	51.1
History of PCOS (No.,%) (missing, n=66)	136	20.8
Gravidity (No.,%) (missing, n=66)		
None	209	32.5
1	116	18.0
2	122	18.9
3	76	15.1
4	50	7.8

19.9 24.3 ‰† 39.5 4.2 3.6 252 127 155 27 23 E History of live and still births (No.,%) (missing, n=74) Characteristic None 9 1 0

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З	77	12.1
4	27	4.2
Importance/plan for post-surgical pregnancy (missing, n=64)	ing, n=64)	
Unimportant or not planned	354	54.8
Importance unclear	98	15.2
Important	194	30.0
Surgical procedure//		
Roux-en-Y gastric bypass	516	72.7
Laparoscopic adjustable gastric band	166	23.3
Other//	28	3.9
Abbreviations: PCOS, polycystic ovary syndrome.		

Denominators shift between variables due to missing data.

 $\dot{\tau}^{\rm t}$ Data are reported as No. (%) unless otherwise indicated.

²Combined due to small numbers: Asian (n=0), American Indian/Alaska Native (n=4), black/African American (n=98), Native Hawaiian/other Pacific Islander (n=0), multiple races (n=15).

 $\overset{\mathcal{S}}{\mathcal{S}}$ calculated as weight in kilograms divided by height in meters squared.

Nsleeve gastrectomy (n=13), banded Roux-en-Y gastric bypass (n=7) and biliopancreatic diversion with duodenal switch (n=8) were combined due to the low frequency of each.