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Original Article

Reproductive Outcomes following Use of Barbed Suture during Laparoscopic Myomectomy

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ABSTRACT **Study Objective:** To review pregnancy outcomes after laparoscopic myomectomy with the use of barbed suture.
Design: Retrospective cohort study and follow-up survey.
Setting: Single, large academic medical center.
Patients: Patients who underwent laparoscopic myomectomy with the use of barbed suture for myometrial closure between 2008 and 2016.
Intervention: Laparoscopic myomectomy and a follow-up survey regarding pregnancy outcome.
Measurements and Main Results: A total of 486 patients met inclusion criteria and underwent a laparoscopic myomectomy between 2008 and 2016. Of the 428 with viable contact information, 240 agreed to participate (56%). Of those who responded to the survey, 101 (42%) attempted to get pregnant, and there were 4 unplanned pregnancies. There were 110 pregnancies among 76 survey respondents. In total, of the women attempting a postoperative pregnancy, 71% had at least 1 pregnancy. Comparing the women who did and did not conceive postoperatively, the group who got pregnant was on average younger, 33.8 ± 4.5 years vs 37.5 ± 6.5 years (p = .001); had fewer myomas removed, median = 2 (range 1-9) vs median = 2 (range 1-16) myomas (p = .038); and had a longer follow-up period, 30 months (vs 30 (11-93 months) ± 20 (p <.001). The mean time to first postoperative pregnancy was 18.0 months (range 2−72 months). Of the 110 reported postoperative pregnancies, there were 60 live births (55%), 90% by means of cesarean section. The mean gestational age at birth was 37.8 weeks. In the cohort, there were 8 preterm births, 3 cases of abnormal placentation, 2 cases of fetal growth restriction, 3 cases of hypertensive disorders of pregnancy, and 2 cases of myoma degeneration requiring hospitalization for pain control. There were no uterine ruptures reported.
Conclusion: According to our findings, pregnancy outcomes after laparoscopic myomectomy with barbed suture are comparable with available literature on pregnancy outcomes with conventional smooth suture. Journal of Minimally Invasive Gynecology (2020) 27, 1566−1572. © 2020 AAGL. All rights reserved.

Keywords: Fertility; Pregnancy rate; Uterine cavity; Uterine rupture

Since its use in gynecologic surgery was first reported in 2008, barbed suture has become an important tool for surgeons performing minimally invasive surgery, particularly in cases requiring extensive suturing [1−3]. Incorporation of tiny barbs cut into the length of traditional suture material in a helical array, the suture self-anchors every 1 mm thereby eliminating the need for knot tying [1,3]. Barbed suture has been consistently shown to significantly decrease the time required to repair a uterine wall defect, total operative time, and intraoperative blood loss at the time of minimally invasive myomectomy [1,4,5]. Complications related to barbed suture have been limited to case reports, and it is

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widely considered a safe and time-saving alternative to intracorporeal or extracorporeal knot tying [6−8].

A common motivation for women to pursue a myomectomy for management of leiomyomas is the prospect of future fertility [9]. Thus, central to any evaluation of the success of a fertility preserving surgery is an evaluation of the postoperative pregnancy outcomes. Proper suturing with multilayer closure of the uterine defect has been reported to reduce adverse obstetric outcomes in subsequent pregnancies, particularly incidences of uterine rupture and placental complications [10,11]. Pregnancy outcomes of laparoscopic myomectomy with smooth suture are comparable with abdominal myomectomy; however, little published data exists that examines pregnancy outcomes after laparoscopic myomectomy employing barbed suture [11,12].

It has been reported that incisions closed with barbed suture have less suture migration and more resistance to suture line failure than traditional suture [13−15]. This is likely due to the more evenly distributed tension in incisions closed with barbed suture, which avoids areas of high tension susceptible to necrosis and disrupted wound healing [13,16,17]. There may be improved hysterotomy healing with the use of barbed suture at the time of myomectomy, but the impact on fertility is unknown. As with the introduction of any new material, its outcomes should be studied to ensure no new risks are introduced, in this case, with regard to fertility and pregnancy [18].

The interpretation of fertility and pregnancy outcomes after myomectomy can be complex. Although women with myomas in any location have lower pregnancy and live birth rates, the role of removing myomas without a direct submucosal component to improve fertility and pregnancy outcomes remains controversial [19,20]. The primary outcome of this work is to report on the pregnancy outcomes of women who underwent a laparoscopic myomectomy using barbed suture. Knowledge of pregnancy outcomes after myomectomy is central to helping women choose the correct myoma management strategy for them.

Materials and Methods

Population

In this retrospective cohort survey study, all women who underwent a laparoscopic myomectomy (with or without robotic assistance) in which barbed suture was used to close the uterine defect between April 2008 and December 2016 at Brigham and Women's Hospital and Brigham and Women's Faulkner Hospital were identified using an internal hospital database, the Research Patient Data Registry [21]. Women younger than 18 years were excluded from the study to avoid the need for parental consent because of the confidential subject matter of the study. Women with a history of permanent sterilization were also excluded. Patients with additional procedures conducted at the time of myomectomy, such as excision of endometriosis or hysteroscopic myomectomy, were included in the sample. Operative reports were individually reviewed to confirm the use of barbed suture. Adhesion barriers and size 0 polydioxanone barbed suture were used routinely in this population. Consistently, all possible myomas were removed, not just symptomatic myomas. Approval was obtained by the hospital's institutional review board (protocol numbers 2011P000719 and 2018P000265).

Data were collected retrospectively on demographics, operative data, and perioperative outcomes for all women meeting the inclusion criteria. In addition, the women were sent a mail survey asking questions about fertility plans and pregnancy outcomes after myomectomy. Women were contacted in 2 rounds, the fall of 2011 and winter of 2018. The second round of surveys was necessary to allow for longer follow-up time and an increase in the sample size of patients who had barbed suture used at the time of their surgery. Patients who did not respond to the survey were contacted by phone within 2 months of the initial mailing and asked to complete the survey via phone. Informed consent for participation in the study was implied with completion of the survey. All survey recipients were given the option to decline study participation at each point of contact.

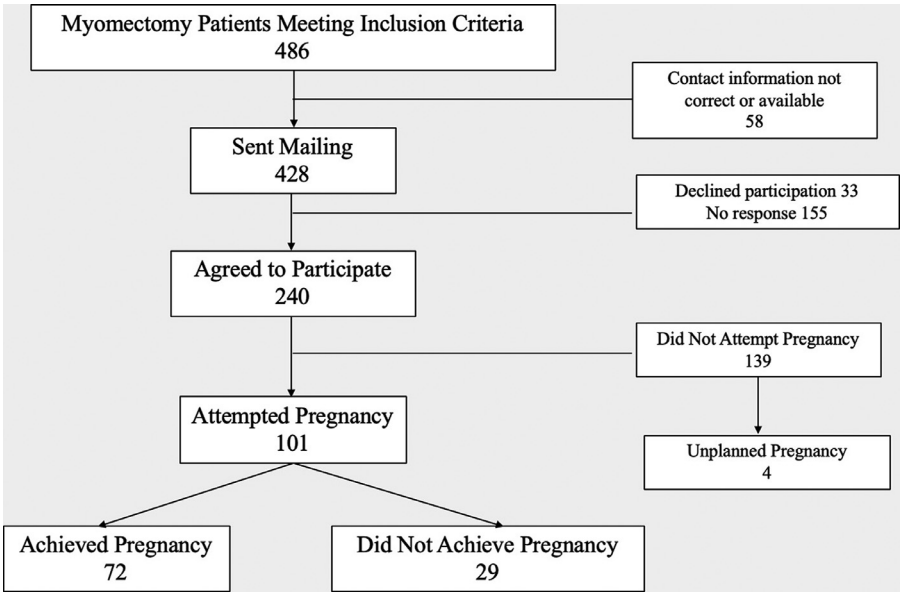
The survey consisted of 11 questions, with 2 questions for all participants and the remaining questions just for participants who experienced a postoperative pregnancy. Participants were asked if they attempted pregnancy after myomectomy and if they ever became pregnant after myomectomy. Follow-up questions inquired about the timing of pregnancy, use of fertility assistance, outcome of the pregnancy, delivery mode, and complications of pregnancy. Patients were also asked for consent to be contacted for clarification of reported data, if needed. When possible, pregnancy and delivery information reported in the survey were confirmed via institutional chart review.

The demographic data collected included age, body mass index, pregnancy history, race, insurance type, and indication for myomectomy. The intraoperative data reported included estimated blood loss (mL), number of myomas removed, operative time (minutes), layers of uterine wall closure, intraoperative complication occurrence (defined as blood loss greater than 1 L, organ injury, conversion to hysterectomy or open procedure, aborted procedure), transfusion requirement, location of myomas, size of largest myoma removed (cm), adhesion barrier use, and report of breach of the uterine cavity. Postoperatively patient charts were reviewed for instances of postoperative complications (Clavien-Dindo classification 2 or greater), need for transfusion, total length of stay, and weight of myomas removed (g).

The primary outcomes of interest were pregnancy outcomes. Additional outcomes included pregnancy achievement, interest in fertility, and delivery mode after myomectomy. In addition, perioperative characteristics were compared between those who did and did not achieve pregnancy after surgery.

Fig. 1

Flow diagram for patient inclusion.



All data were analyzed in Stata v.15.0 (StataCorp LLC, College Station, TX). Continuous variables were compared with *t* tests or Wilcoxon rank sum tests. Categoric variables were compared using chi-square or Fisher exact tests. Logistic regression was used to evaluate the impact of demographic and surgical factors on pregnancy achievement.

Results

A total of 486 women met inclusion criteria for the study, having undergone laparoscopic myomectomy using barbed suture during the study period. Of those, 58 subjects had no functional address or phone number. Thus, the survey was successfully sent to 428 women. Of the women who were

Table 1

Demographic and operative characteristics of survey respondents and nonrespondents

Characteristic	Respondents (n = 239)	Nonrespondents (n = 240)	p-Value
Age, yrs	37 ± 6	38 ± 5	.166
BMI, kg/m^2	26.6 ± 5.9	27.2 ± 5.6	.270
Race			<.001
White	143 (62)	91 (40)	
Black	42 (18)	80 (34)	
Other	46 (20)	61 (26)	
Parity	0.6 ± 1.1	0.6 ± 1.0	.951
Insurance type			.022
Public	29 (12)	46 (20)	
Private	206 (86)	182 (80)	
Indication for surgery			
Pain or pressure	151 (64)	167 (71)	.133
Abnormal uterine bleeding	145 (61)	155 (65)	.312
Infertility	34 (14)	26 (11)	.269
Intraoperative complication	6 (3)	5 (2)	.771
Postoperative complication	40 (18)	40 (17)	.898
Number of myomas removed	3.5 ± 3.4	4.4 ± 5.0	.015
Weight of myomas removed, g	322 ± 320	327 ± 376	.867

BMI = body mass index.
Values are given in mean ± standard deviation or numbers (%).

sent the survey, 240 agreed to participate (56%), 33 declined to participate (8%), and 155 participants did not reply (36%) (Fig. 1). Among survey respondents, 101 attempted to get pregnant, and 139 did not attempt pregnancy. Of the 101 women who wanted to get pregnant, 72 (71%) achieved pregnancy. In addition, there were 4 unplanned pregnancies.

Demographic and surgical data were comparable between women who did and did not respond to the survey, apart from race, insurance type, and number of myomas removed (Table 1). White women accounted for 62% of respondents vs 40% of nonresponders, and black women accounted for 18% of respondents vs 34% of nonresponders ($p < .001$). Black women had more myomas removed at the time of surgery, median 4 (1-27) myomas than white women, median 2 (1-20) myomas ($p < .001$). Survey respondents had fewer myomas removed at the time of surgery than nonrespondents, median 2 (1-22) myomas vs median 2 (1-27) myomas ($p = .015$). When adjusting for race differences, there was no difference in the number of myomas between respondents and nonrespondents. A greater percentage of respondents had private insurance compared with nonrespondents, 89% vs 80% ($p = .022$). With the exception of 3 international patients who did not use insurance, all other patients had public or private insurance. In terms of surgical data, there were no differences in indication for surgery, complication occurrence, or weight of the myoma pathology specimen between respondents and nonrespondents.

Comparing women who were and were not able to conceive after myomectomy, there were few differences between the groups (Table 2). Women who successfully conceived were younger, 33.8 ± 4.5 years vs 37.5 ± 6.5 years, $p = .001$. Women who conceived also had fewer myomas removed, median 2 (range 1-9) vs. median 2 (range 1-16) myomas ($p = .038$). Women who reported at least 1 pregnancy had a longer period of follow-up after surgery than those who did not report pregnancy, median 59 months (range 12-94) vs. 30 months (range 11-93) ($p < .001$). Those who did and did not conceive did not vary significantly with regard to body mass index, gravidity, parity, race, insurance type, indication for surgery, blood loss at time of surgery, complication rate, uterine cavity entry, operative time, weight of myomas removed, location of myomas, layers of closure, or presence of endometriosis. When adjusting for age, the number of myomas removed was not a significant predictor of postoperative pregnancy.

Table 2

Demographic and operative characteristics of patients who did and did not conceive

Characteristic	Conceived (n = 76)	Did not conceive (n = 29)	p-Value
Age, yrs	33.8 ± 4.5	37.5 ± 6.5	.001
BMI, kg/m^2	27.6 ± 5.8	28.1 ± 7.9	.758
Gravida	0.9 ± 0.9	0.6 ± 0.7	.157
Parity	0.5 ± 0.6	0.3 ± 0.6	.388
Insurance type			.344
Public	12 (16)	2 (8)	
Private	61 (84)	24 (92)	
Race			.305
White	49 (66)	15 (58)	
Black	10 (14)	7 (27)	
Other	15 (20)	4 (15)	
Follow-up time, mo	54 ± 24	34 ± 20	<.001
Estimated blood loss, mL	131 ± 232	170 ± 230	.446
Operative time, min	107 ± 43	127 ± 78	.120
Intraoperative complication	2 (3)	1 (3)	.822
Number of myomas removed	2.6 ± 1.9	3.7 ± 3.5	.038
Cavity entered	15 (22)	7 (27)	.599
Number of layers of closure	2.8 ± 0.1	2.8 ± 0.8	.963
Myoma location			
Submucosal	9 (13)	4 (14)	1.00
Intramural	49 (68)	18 (62)	.643
Subserosal	31 (43)	17 (59)	.198
Weight of pathology specimen, g	264 ± 321	327 ± 410	.410
Postoperative complication	13 (18)	4 (15)	1.00
Indication for surgery			
Pain or pressure	35 (47)	18 (67)	.074
Abnormal uterine bleeding	39 (52)	18 (64)	.373
Infertility	18 (24)	10 (37)	.215
Endometriosis present	8 (11)	3 (11)	1.00

BMI = body mass index.
Values are given in mean ± standard deviation or numbers (%).

Table 3

Pregnancy outcomes among survey respondents

Pregnancy outcomes	n (%)
Conception type	
Spontaneous	85 (78)
ART	24 (22)
Pregnancy outcome	
Live birth	60 (55)
Spontaneous abortion	34 (30)
Pregnancy termination	4 (4)
Ectopic pregnancy	4 (4)
Ongoing pregnancy or unknown outcome	8 (7)
Delivery mode	
Vaginal	6 (10)
Cesarean	54 (90)
Gestational age of live birth, wk, mean ± SD	37.8 ± 1.7
Complications	
Preterm delivery	8 (13)
Abnormal placentation	3 (5)
Fetal growth restriction	2 (3)
Hypertensive disorder of pregnancy	3 (5)
Myoma degeneration requiring hospitalization	2 (3)
Postpartum hemorrhage	2 (3)

ART = assisted reproductive technology; SD = standard deviation.

There were 110 total pregnancies in the cohort among 76 women. Most women had just 1 postoperative pregnancy, but 24 women had 2 postoperative pregnancies, 2 women had 3 postoperative pregnancies, and 2 women had a fourth postoperative pregnancy. Twenty-two percent of pregnancies were conceived with reproductive assistance. The mean time to the first postoperative pregnancy was 18.0 months (range 2−72 months).

Of the 110 reported postoperative pregnancies, there were 60 live births (55%) (Table 3). The mean gestational age at birth was 37.8 weeks, with 8 births occurring before 37 weeks. Seven of the 8 preterm births occurred in the late preterm period (between 34 + 0 and 36 + 6 weeks), and 4 were scheduled preterm deliveries to avoid uterine rupture. There were 3 cases of abnormal placentation, all placenta previas. There were 2 cases of fetal growth restriction, 3 of hypertensive disorders of pregnancy, and 2 of myoma degeneration requiring hospitalization for pain control. There were 6 vaginal deliveries, and the remainder of deliveries were by cesarean section. Previous uterine surgery was universally reported as the indication for cesarean. Only 3 delivery complications were reported, 2 postpartum hemorrhages (defined as blood loss >1000 cc at the time of cesarean section) and 1 postoperative pulmonary embolism. There were no uterine ruptures reported.

A total of 34 (30%) pregnancies ended in a spontaneous abortion. All but 1 of these spontaneous abortions occurred in the first trimester, with a mean gestational age of 8.4 weeks. The second trimester spontaneous abortion was in a patient who had a concurrent abdominal cerclage placed at the time of her laparoscopic myomectomy, for a history of cervical insufficiency. There were 4 pregnancy terminations and 4 ectopic pregnancies in the cohort. Seven patients were pregnant at the time they returned the survey, and 1 respondent did not share the outcome of her pregnancy.

Discussion

In this study, we found overall favorable pregnancy outcomes among women with a history of laparoscopic myomectomy in which the uterine defect was closed with barbed suture. Among women hoping to conceive postoperatively, 71% were able to get pregnant. Of the 110 pregnancies among 76 women, 78% were conceived spontaneously, and 55% resulted in live births. Nearly all deliveries were by cesarean section with no cases of uterine rupture and relatively low rates of pregnancy and delivery complications. This is compared with studies after myomectomy with smooth suture, which report conception rates between 50% and 80% and live birth rates between 73% and 85% [22,23]. Our live birth rate is lower than previous reports because of the inclusion of women in our study with ongoing pregnancies and those with unintended pregnancies ending in pregnancy termination.

The results of this study lend further support to the use of barbed suture for closure of uterine defects at the time of laparoscopic myomectomy. Most studies of barbed suture use during laparoscopic myomectomy to date have focused on short-term outcomes at the time of surgery including blood loss, operative time, and length of stay [4,18,24]. However, very few studies have examined the safety of barbed suture in future pregnancies, an impactful consideration for patients undergoing this uterine-sparing procedure.

The popularity of barbed suture has grown swiftly in recent years, owing to the increased efficiency of wound closure, more evenly distributed suture tension, and less suture migration [13]. This is potentially impactful for hysterotomy closure, of which the goal is to have a securely closed wound without increased adhesion formation, as had been reported with barbed suture [18]. With absorption time of 120 to 180 days, if patients are appropriately counselled, their sutures should be almost fully absorbed by the time a pregnancy starts stretching the myometrium [25]. However, there concerns have been raised about unanticipated deleterious adverse effects of barbed suture use, including pregnancy complications (especially if the barbed suture was used to close the endometrial cavity) and bowel obstruction [6−8].

In our study, there were few pregnancy complications. Fetal growth restriction, estimated to occur in 3% to 7% of all pregnancies, occurred in 4% of the pregnancies we observed after myomectomy [26]. Of the live births in our cohort, 13% were preterm births, which is above the national average of 10% [27]. This likely reflects intentional early delivery because of concern for uterine rupture, though this practice may be changing in more recent years [28,29]. In our cohort, there were just 2 cases of postpartum hemorrhage (3%), with incidence of postpartum hemorrhage reported to

be 3% to 5% of all deliveries [30]. This may be due to the fact that most women with a history of laparoscopic myomectomy deliver by scheduled cesarean and are subject to a lower risk of uterine atony that can complicate prolonged or augmented labor. There were no cases of uterine rupture in our cohort, though given the rarity of this event, it is not possible to estimate a true risk for this adverse outcome [31].

The rate of spontaneous abortion in our cohort (30%) is higher than what is normally reported in the literature, at a rate of approximately 20% of pregnancies. This could be due to the high use of assisted reproduction technology (20%), the older age of our cohort compared with that in population-wide studies of spontaneous abortion, or the self-reported nature of outcomes in our study [32,33]. The cavity was not breached at a higher rate at the time of surgery in those who had a spontaneous abortion compared with those with a live birth. The rate of spontaneous abortion in this cohort is similar to what has been previously reported for patients after laparoscopy with smooth suture [23]

Despite being the largest report on pregnancy outcomes after myomectomy using barbed suture with 48 months of mean follow-up, there were several limitations to our study. The retrospective nature of the study made it vulnerable to recall bias. It is possible that patients with a poor pregnancy outcome remembered issues affecting their pregnancy in greater detail. These biases are inherent to the design of the study and difficult to avoid as a lag time is needed after myomectomy to allow patients to recover and attempt pregnancy. To minimize this bias, pregnancy data were corroborated with medical record review for patients who received obstetric care at our institution.

In addition, though most demographic data were similar, it is possible that the population that responded to the survey differed from the population that did not respond. Patients who responded to the survey had fewer myomas than those who did not, a reflection of the racial differences between respondents. When controlling for race, the number of myomas removed did not differ between respondents and nonrespondents. It is possible, given these differences, that the results of this study are not generalizable to all patients who have undergone myomectomy. A prospective study design would help eliminate some unmeasured bias and standardize follow-up time. This would be a natural next step, as our study found women reporting pregnancy had a longer follow-up period than those who did conceive.

Another limitation of the study was that women with previous pregnancy complications and concurrent procedures at the time of myomectomy were not excluded; however, this makes our sample more generalizable to other patients who have undergone myomectomy. In addition, though this is the largest report of pregnancy outcomes in this population, it is still a relatively small number of pregnancies and would be improved if repeated using multiple clinical sites. Additional studies could also elucidate why more than half of women electing a uterine-preserving procedure never attempted to get pregnant afterward.

In conclusion, the findings of our study can be used to counsel patients that hysterotomy closure with barbed suture is safe, not only with regard to immediate operative measures but also for future pregnancies.

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