Pregnancy Outcomes After Myomectomy With Polytetrafluoroethylene Placement

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ABSTRACT

Background and Objectives: The aim of this study was to report preliminary data on pregnancy outcomes after myomectomy with placement of an expanded polytetrafluoroethylene adhesion barrier membrane.

Methods: In this retrospective case series, 68 women who underwent myomectomy with expanded polytetrafluoroethylene membrane placement between January 1, 2003, and December 31, 2009, were identified. Of these women, 15 subsequently had documented pregnancies and were included in the final dataset.

Results: Eighteen pregnancies were documented among 15 women. There were no reported cases of preterm labor, preterm premature rupture of membranes, or uter-ine rupture.

Conclusion: In this case series, there were no documented cases of preterm labor, preterm premature rupture of membranes, or uterine rupture after myomectomy with expanded polytetrafluoroethylene membrane placement.

Key Words: Adhesion barrier, Leiomyoma, Myomectomy, Pregnancy outcomes.

DOI: 10.4293/JSLS.2014.00013

INTRODUCTION

Peritoneal adhesions are a common sequela of abdominal and pelvic surgery, with an estimated prevalence of 60% to 95%.1-3 Potential consequences of adhesions include intestinal obstruction, chronic pelvic pain, and infertility.4-6 Given the high prevalence of postoperative adhesions and the severity of associated complications, adhesion barriers are commonly placed after major gynecologic surgery. Expanded polytetrafluoroethylene (ePTFE) (Gore Preclude; W. L. Gore & Associates, Flagstaff, Arizona) is a thin (0.1-mm) adhesion barrier membrane that may be permanently sutured to the uterus after myomectomy.7 Evidence suggests that the incidence of postmyomectomy adhesions is decreased after placement of ePTFE compared with no adhesion barrier.7 Furthermore, ePTFE has been shown to be more effective than oxidized regenerated cellulose (Interceed TC7; Johnson & Johnson Medical, Arlington, Texas) in the prevention of pelvic sidewall adhesions.8 The use of ePTFE, however, has been limited because of its permanence and theoretical need for removal.9 The necessity of membrane removal has been questioned in the literature, and there are currently no data to support this practice.^{10,11}

At our academic center, ePTFE is not routinely removed after placement at the time of myomectomy. Given its permanent nature, it is possible that the risk of obstetric complications might be increased among women who subsequently become pregnant. Therefore the objective of this study was to provide important preliminary data on obstetric complications after myomectomy with placement of an ePTFE membrane. Specifically, we aimed to determine the proportion of women who subsequently had preterm labor, preterm premature rupture of membranes (PPROM), or uterine rupture.

MATERIALS AND METHODS

The study was approved by the Northwestern University Institutional Review Board. All women who underwent myomectomy with ePTFE membrane placement between January 1, 2003, and December 31, 2009, at Prentice Women's Hospital were identified. Those with documented pregnancies after surgery were included in the final dataset.

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Preoperative uterine size was determined by pelvic examination. Total fibroid weight in grams was measured by the pathologist. Myomectomies were performed by laparotomy or were laparoscopically assisted. All procedures were performed with patients under general endotracheal anesthesia. Dilute vasopressin (5 U in 20 mL of normal saline solution) was infiltrated in the subserosal plane overlying each myoma. The pseudocapsule was scored transversely electrosurgically, and each myoma was enucleated with blunt and sharp dissection. In laparoscopically assisted cases, excision and morcellation were performed laparoscopically and the uterus was repaired by mini-laparotomy. If entered, the endometrium was reapproximated. The myometrium was closed with at least 2 but more commonly 4 layers of delayed absorbable suture, and the serosa was reapproximated with a baseball stitch. An ePTFE membrane was then cut to size, positioned over the serosal incisions, and fixed at the periphery with 4 to 8 interrupted stitches of No. 6-0 nylon (Ethilon; Ethicon Endo-Surgery, Somerville, New Jersey) or polypropylene (Prolene; Ethicon Endo-Surgery) suture. Second-look surgical procedures to remove the membrane were not performed.

Delivery records of patients with subsequent pregnancies were obtained and used to calculate the proportion of deliveries complicated by preterm labor, PPROM, or uterine rupture. Among women who underwent cesarean delivery, the presence or absence of adhesions and/or residual ePTFE membrane was determined from the operative reports.

RESULTS

Sixty-eight women underwent myomectomy with ePTFE membrane placement by 6 surgeons at our institution during the study period. Within this study population, 18 pregnancies were subsequently documented among 15 women. Patient demographic data and operative characteristics are displayed in **Table 1**. Of the myomectomies, 14 (93.3%) were performed abdominally and 1 (6.7%) was laparoscopically assisted. Two patients (13.3%) had undergone previous hysteroscopic myomectomy; none had a history of laparoscopic or abdominal myomectomy. One patient (6.7%) had a history of cesarean delivery.

On average, the age at delivery or spontaneous abortion was approximately 3 years higher than that at myomectomy (**Table 2**). Most deliveries were performed by cesarean section (**Table 2**). The patient with a history of cesarean delivery delivered vaginally. There were no documented cases of preterm labor, PPROM, or uterine rup-

| Table 1.Patient Demographic Data and Operative Characteristics | |
|--|-------------------|
| | Data |
| Age at surgery (y) | 33.9 ± 5.4 |
| Gravidity | 0.9 ± 1.5 |
| Parity | 0.1 ± 0.3 |
| Preoperative uterine size (cm) | 13.5 ± 4.2 |
| No. of fibroids removed | 3.7 ± 2.4 |
| Total fibroid weight (g) | 281.7 ± 192.9 |
| No. of subsequent pregnancies | 1.2 ± 0.4 |
| Values are presented as mean \pm SD. | |

| Table 2. | | |
|--------------------------|-------|--|
| Pregnancy Outcomes | | |
| | Data | |
| delivery (mean ± SD) (y) | 36.3 | |
| of spontaneous abortions | 4 (22 | |

| Age at derivery (mean ± 5D) (y) | 30.3 ± 3.1 |
|--------------------------------------|----------------|
| No. (%) of spontaneous abortions | 4 (22.2) |
| No. (%) of vaginal deliveries | 3 (16.7) |
| No. (%) of primary cesarean sections | 9 (50.0) |
| No. (%) of repeat cesarean sections | 2 (11.1) |
| | |

ture among any of the women who delivered. Adhesions were encountered in 6 of the 9 primary cesarean sections (66.7%). Two of the 6 women with adhesions subsequently underwent repeat cesarean section. One of the repeat cesarean sections was complicated by severe adhesions and intraoperative bleeding, necessitating emergency right salpingo-oophorectomy. Interestingly, the ePTFE membrane was noted to be in place during both of this patient's cesarean deliveries. Only 1 other patient had residual ePTFE membrane seen at the time of primary cesarean section; however, adhesions were also noted.

DISCUSSION

This retrospective case series showed no cases of preterm labor, PPROM, or uterine rupture after myomectomy with permanent ePTFE membrane placement. Two-thirds of patients had adhesions noted at the time of cesarean section, but the majority had no residual ePTFE membrane.

Few published studies have examined the influence of adhesion barrier placement on pregnancy outcomes.

Hurst¹¹ reported pregnancy outcomes in 32 women who underwent various gynecologic surgeries with ePTFE placement. As in our study, ePTFE membranes were not removed. Among these women, there were 3 spontaneous abortions, 12 vaginal deliveries, 10 cesarean sections, and 1 stillbirth, and the remainder had ongoing pregnancies at the time of publication. The stillbirth was attributed to a nuchal cord, and the ePTFE membrane had been placed in the posterior cul-de-sac. Therefore the stillbirth was not likely related to ePTFE placement. Among the 22 women who delivered live infants, 10 had uterine ePTFE implantation sites. Of these women, 2 delivered vaginally and 8 delivered by cesarean section. As in our study, there were no documented complications.

Sawada et al¹² examined pregnancy outcomes in 38 infertility patients who underwent myomectomy, ovarian cystectomy, tuboplasty, or ureteroplasty. Oxidized regenerated cellulose was placed in 23 cases, whereas no adhesion barrier was used in 15 cases. After surgery, 78.3% of women in the adhesion barrier group became pregnant compared with 46.7% of women in the non– adhesion barrier group. Obstetric outcomes, however, were not evaluated.

In our study two-thirds of women had adhesions noted at the time of primary cesarean delivery. One of these women subsequently underwent repeat cesarean section complicated by bleeding and right salpingo-oophorectomy; the bleeding was attributed to severe adhesions. The high prevalence of postmyomectomy adhesions in our study is comparable with published data on myomectomy without adhesion barrier placement.¹³ In contrast, a randomized controlled trial reported adhesion formation in only 44.4% of uterine incisions covered with ePTFE compared with 92.6% of incisions with no ePTFE.⁷ Other studies have reported an adhesion prevalence of only 30% to 40% after ePTFE placement; however, these studies included gynecologic surgeries with a lower risk of adhesion formation than myomectomy.^{11,12}

Interestingly, most patients in our study had no residual ePTFE membrane visible at the time of cesarean delivery. This finding has not been reported in the existing literature; however, in prior studies second-look laparoscopy was performed within 1 to 6 weeks after the initial surgery.^{7,8} This is in contrast to our study, in which a mean of 3 years elapsed between myomectomy and cesarean delivery. Our data suggest either that the membrane may migrate over time or that visceral peritoneum may grow over its surface, obscuring visualization of the membrane.

It is also possible that some delivering physicians failed to describe the ePTFE in their operative reports.

One potential barrier to the use of ePTFE is the need for suturing of the material to the uterus, which makes it impractical for use during laparoscopic or robotic myomectomy. At our institution, we have only used ePTFE for abdominal myomectomies or rare laparoscopically assisted procedures in which the hysterotomy is closed through a mini-laparotomy incision. Of the 15 patients in this study, the majority underwent abdominal myomectomy. Laparoscopically assisted myomectomy was performed in 1 patient, for whom a proper laparoscopic multilayer hysterotomy closure could not be performed because of the size and location of the fibroid. More typically, we laparoscopically reapproximate the hysterotomy with multiple layers of suture and apply a polyethylene glycol adhesion barrier (CoSeal; Baxter Healthcare, Deerfield, Illinois).

This case series provides important preliminary data regarding obstetric complications after myomectomy with ePTFE placement. To our knowledge, only 1 other study has examined this relationship.¹¹ The limitations of our study include its retrospective case-series design, by definition lacking a control group. As mentioned previously, it is possible that details were missing from the operative reports obtained retrospectively. Furthermore, our sample size was small and limited by our inability to access obstetric records of women who delivered at other institutions. Obtaining the external medical records of the other 53 women would certainly strengthen our findings. Unfortunately, because of the retrospective nature of the study and waiver of informed consent, it was not possible to obtain those records.

In summary, this retrospective case series showed no cases of preterm labor, PPROM, or uterine rupture after myomectomy with ePTFE membrane placement. Among women who subsequently delivered by cesarean section, the prevalence of adhesions was high despite the placement of an adhesion barrier.

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