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Original Article

Postpartum Permanent Sterilization: Could Bilateral Salpingectomy Replace Bilateral Tubal Ligation?

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ABSTRACT **Study Objective:** There has recently been an expansion in the use of bilateral salpingectomy at the time of sterilization to theoretically decrease ovarian cancer risk. We sought to determine if postpartum salpingectomy is equivalent to postpartum bilateral tubal ligation (BTL) in terms of duration, estimated blood loss (EBL), and complication rate.

Design: A retrospective case series (Canadian Task Force Classification II-2).

Setting: An academic inner-city hospital.

Patients: All patients admitted for delivery of full-term intrauterine pregnancy desiring permanent sterilization between March 2014 and March 2015 were included. Excluded patients included those who had sterilization at the time of the cesarean section or other surgical procedure. Two cohorts were identified, those who had a planned postpartum tubal ligation and those having a postpartum salpingectomy.

Interventions: Postpartum sterilization.

Measurements and Main Results: Researchers of this study recorded demographics, medical histories, and abdominal surgical histories for all patients who met the inclusion criteria. Surgical times, EBL, and complication rates were reviewed. Unpaired *t* test calculations were used to identify differences between age, body mass index, parity, and surgical time between the 2 cohorts. Chi-square tests were used to determine the statistical significance between complication rates, history of abdominal surgery, and past medical history of tubal disease between the 2 cohorts. Eighty women were identified, 64 in the BTL group and 16 in the salpingectomy cohort. The demographics of each cohort were equivocal. The average surgical time was 59.13 and 71.44 minutes in the BTL and salpingectomy cohorts, respectively. Of the 80 patients, only 1 had an EBL greater than 50 mL; this patient was in the BTL group. Four complications were noted in the BTL cohort, but none were evident in the salpingectomy group. There were no documented sterilization failures in the follow-up period (median = 9 months).

Conclusion: Postpartum salpingectomy is slightly longer in duration but with similar blood loss and complication rates. Salpingectomy could be considered in particularly high-risk patients at risk for ovarian cancer when consenting for a postpartum sterilization procedure. Journal of Minimally Invasive Gynecology (2016) 23, 928–932 Published by Elsevier Inc. on behalf of AAGL.

Keywords: Postpartum tubal ligation; Salpingectomy; Sterilization

High-grade cancers of the fallopian tubes, ovaries, and peritoneum have been shown to have similar molecular profiles, thereby representing the same disease. Recent studies in women who are inherently at high risk for ovarian cancer show that approximately 80% of malignancies originate from the fallopian tube. Similarly, mutations of fallopian tubal epithelial cells have been identified in sporadic ovarian cancer. Both inherited ovarian cancer and sporadic cases have similar p53 mutations similar to those of fallopian carcinoma [1]. The American Congress of Obstetricians and Gynecologists recommends potentially counseling women on bilateral salpingectomy as an alternative method for laparoscopic sterilization [2]. The Society of Gynecologic Oncology supports the hypothesis that by removing these cells before malignancy has the opportunity to develop, the overall incidence of ovarian cancer and death rates from ovarian cancer may decrease [1].

Walker et al [1] have explained how ovarian cancer can be subdivided into 2 categories, types 1 and 2. Type 1 ovarian

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cancers are less common and tend to present at a lower stage. Type 2 ovarian cancers are associated with an advanced stage, account for the majority of ovarian cancer deaths, and are believed to develop from the neoplastic progression of epithelial cells of the fallopian tube. These neoplastic epithelial cells of the fallopian tube possess p53 mutations similar to those noted in type 2 ovarian cancers [1].

Postpartum sterilization is a popular and effective method of contraception in the United States. As of 2012, postpartum sterilization is performed after 10% of all hospital deliveries. Sterilization can be conveniently performed at the time of cesarean delivery or in the immediate postpartum period after a vaginal delivery [3]. Advantages of the postpartum approach include the technical ease; the 1-time use of anesthesia in the case of a patient receiving an epidural during labor; the use of a current hospitalization; and increased compliance, especially in low-income patients [4].

Available methods of postpartum bilateral tubal ligation (BTL) include the modified Pomeroy, Parkland, Irving, and Uchida procedures. The modified Pomeroy technique is the most common postpartum sterilization method performed in the United States, with a 10-year failure rate of $<1\%$ [5,6].

Based on the current understanding of the etiology of ovarian cancer, postpartum bilateral salpingectomy could be offered in place of tubal ligation for women desiring sterilization in the postpartum period [7]. The primary objective of this study was to see if postpartum bilateral salpingectomy was equivalent to postpartum BTL in terms of estimated blood loss (EBL), surgical time, and complication rate. If these factors are equivalent, bilateral salpingectomy could potentially replace BTL. Salpingectomy could provide the added benefit of ovarian cancer risk reduction while providing permanent sterilization.

Methods

This study received institutional review board approval from the Department of Clinical Research Operations, Drexel University College of Medicine at Hahnemann University Hospital, Philadelphia, PA (protocol #1509003895). This was a retrospective case series at an academic inner-city hospital. Inclusion criteria included all vaginal postpartum permanent sterilization cases spanning from March 1, 2014, to March 1, 2015, performed by the Department of Obstetrics and Gynecology of Drexel University College of Medicine at Hahnemann University Hospital. Exclusion criteria included sterilizations performed at the time of cesarean section or if combined with other surgical procedures.

All postpartum sterilization procedures were performed within 24 hours of delivery. A single attending physician had exclusively advised performing a bilateral salpingectomy for sterilization, whereas all other attending physicians traditionally supervised the types of BTLs. All cases were managed by a senior resident. Every senior resident had an equal distribution of salpingectomies and BTLs. The types of BTLs performed included the modified Pomeroy and Parkland methods. It was up to the discretion of the surgical team whether they decided to perform a modified Pomeroy or a Parkland approach for the BTL. Both types of BTLs were performed as previously described in the literature [8]. The control group for this study was sterilization by BTL. Salpingectomy cases represented the investigational group.

Postpartum bilateral salpingectomy was initiated with a 2- to 3-cm vertical skin incision at the level of the umbilicus, which was sharply carried down to the fascia. The fascia was then grasped with 2 Allis or Kelly clamps and entered with Mayo scissors. The peritoneum was entered bluntly or sharply with Metzenbaum scissors. An Alexis retractor (Applied Medical, Rancho Santa Margarita, CA) or Army-Navy retractors were then inserted to clear the surgical field of extraneous tissue. Of note, 4 operative reports did not document how retraction was obtained. Surgeons externally manipulated the patient's abdomen to bring the adnexa into view. Once a fallopian tube was identified, the surgeon grasped the tube with a Babcock clamp. To ensure proper identification, the tube was tracked laterally toward the fimbriae. Once this was completed, 1 Babcock was placed at the isthmic portion of the fallopian tube and another along the ampulla. With the fallopian tube elevated out of the abdominal cavity, the surgeons used monopolar electrosurgery to incise 2 or 3 windows in the mesosalpinx depending on the length of the fallopian tube. A Kelly clamp then grasped a portion of the mesosalpinx parallel to the fallopian tube. This was performed in approximately 3 separate areas of the mesosalpinx, from the fimbriae to the uterotubal junction. The surgeon used a polyglactin 910 (Vicryl; Ethicon, Somerville, NJ) suture to ligate the mesosalpinx. The fallopian tubes were then excised and removed.

Data on sterilization procedures were obtained by reviewing inpatient electronic medical records and were placed in an encrypted Excel (Microsoft, Redmond, WA) spreadsheet for analysis. Data collection included patient demographics, duration of the sterilization procedure, EBL, complication rates, history of abdominal surgery, and history of tubal disease.

Duration of surgery was calculated by reviewing anesthesia records for incisional time and time out of the operating room. EBL was obtained by reviewing operative reports. The prevalence of immediate postoperative complications was obtained by reviewing electronic medical records within 30 days of the sterilization procedure. A history of abdominal surgery and tubal disease was identified by reviewing medical records. A past medical history of tubal disease included a history of pelvic inflammatory disease, hydrosalpinx, or tubo-ovarian abscess. To confirm adequate sterilization, each pathology report needed to verify a complete cross section of each fallopian tube. Sterilization failure was determined by reviewing obstetric records up to the time of data collection. If a patient had a

documented intrauterine pregnancy after the sterilization procedure, the sterilization was determined to be a failure.

Statistical analysis consisted of calculating the mean and standard deviation of surgical time for each cohort. Unpaired *t* test analysis was performed to compare the difference between the means regarding age, parity, body mass index on admission, and surgical time. A p value $< .05$ was determined to be statistically significant. Postoperative complications of surgery included a prolonged hospital stay secondary to pain control, bleeding from the mesosalpinx, and/or pelvic infection postoperatively. A chi-square test was used to evaluate the clinical significance of complication rates, history of abdominal surgery, and tubal disease between the 2 groups. Unfortunately, EBL was documented as a qualitative amount (e.g., "minimal" or "<50 mL"), thereby limiting statistical analysis.

Results

Eighty women were identified during the study period who underwent permanent sterilization, sixty-four (80.0%) in the BTL group and 16 (20.0%) in the salpingectomy cohort. The groups were not statistically different in regard to demographics (Table 1). Most subjects were between the ages of 26 and 35 (Fig. 1). Most subjects had a body mass index of less than 30 on the day of admission (Fig. 2).

Of the 80 patients, only 1 had an EBL greater than 50 mL; this patient was in the BTL group. The average surgical time was 59.13 minutes (±16.00 minutes) in the BTL cohort and 71.44 minutes (±5.81 minutes) in the salpingectomy cases. The difference between these surgical times was statistically significant ($p = .003$).

Four complications were noted in the BTL cohort. Two patients experienced postoperative ileus. One patient's surgery was complicated by excessive bleeding from the mesosalpinx, and another case was complicated by an incisional site hematoma. No complications were noted in the salpingectomy group. The difference in complication rates was not statistically significant between the 2 cohorts ($p = .71$). There was no evidence of sterilization failures for the median 9-month follow-up period. (The follow-up period ranged from 2 to 14 months.)

Table 1

Demographics of bilateral tubal ligation (BTL) versus salpingectomy cohorts

	BTL (n = 64)	Salpingectomy (n = 16)	p Value
Age (years)	31.11 (±4.45)	29.44 (±4.38)	.182
Parity	3.60 (±1.16)	4.19 (±2.46)	.172
BMI on day of admission	32.83 (±5.61)	33.86 (±6.92)	.533
Weight on day of admission (kg)	86.57 (±17.2)	86.24 (±19.29)	.870
History of abdominal surgery	14/64 (21.88%)	3/16 (18.75%)	.411
History of tubal disease	2/64 (3.13%)	0/16 (0%)	.255

BMI = body mass index.

Discussion

In the present study, we attempted to show how bilateral salpingectomy was similar to BTL for postpartum permanent sterilization in regard to EBL, duration of surgery, and complications. Physicians may have avoided salpingectomy because of the concern for increased blood loss, surgical time, and complication rate [2]. Kwon et al [9] indicated in their cost-effective analysis that the magnitude of ovarian cancer risk reduction by performing a salpingectomy may seem negligible because of the relatively low absolute risk of developing ovarian cancer in North America. They calculated that in order to prevent 1 case of ovarian cancer, 366 salpingectomies would need to be performed in place of tubal ligation for permanent sterilization. However, there are no alternatives for ovarian cancer risk reduction, which is why the American Congress of Obstetricians and Gynecologists suggests that clinicians may counsel women on bilateral salpingectomy as an effective method of sterilization [2,9].

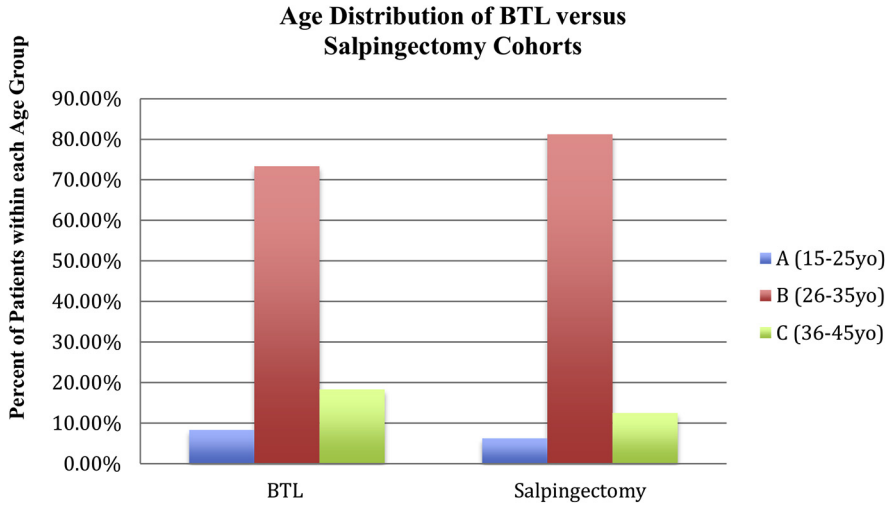
Salpingectomy would also protect the patient against epithelial, endometrioid, and clear cell carcinomas of the ovary [1]. Furthermore, incorporating salpingectomy at the time of tubal sterilization does not appear to increase complications such as readmission or the need for blood transfusion [2].

Previous studies have focused on replacing laparoscopic tubal ligation with salpingectomy or performing salpingectomy at the time of hysterectomy for ovarian cancer risk reduction. This study uniquely focused on using the immediate postpartum period while comparing BTL with salpingectomy. Although this is a pilot case series limited by case number and the study time period, our study did not show significant differences between the BTL and the salpingectomy cohorts regarding a majority of these factors. Other than surgical time, EBL and the complication rates between the 2 cohorts were statistically insignificant.

The salpingectomy cohort did not have any cases of more than minimal EBL or cases with postoperative complications; yet, the average salpingectomy case lasted approximately 12 minutes longer than the average BTL case. McAlpine et al [10] performed a retrospective cohort study from 2008 to 2011 comparing the operative time of BTL versus bilateral salpingectomy outside of the postpartum period. The average operative time for the salpingectomy cohort (1569 cases over the 3-year period) was 10.2 minutes longer than the BTL group (13 317 cases), but this difference was not statistically significant ($p < .001$). Their study also researched the length of hospital stay as a potential

Fig. 1

Along the x-axis, the blue-shaded column, labeled as A on the right hand side of the table, represents the age range of 15 to 25 years old. The red-shaded column, labeled B, represents the age range of 26 to 35 years old. The green-shaded column, labeled C, represents the age range 36 to 45 years old. In the BTL group, 8.33% of patients were 15 to 25 years old, 73.33% were 26 to 35 years old, and 18.33% were 36 to 45 years old. In the salpingectomy group, 6.25% of patients were 15 to 25 years old, 81.25% were 26 to 35 years old, and 12.50% were 36 to 45 years old. The y-axis represents the percent of subjects of each age range within each cohort.

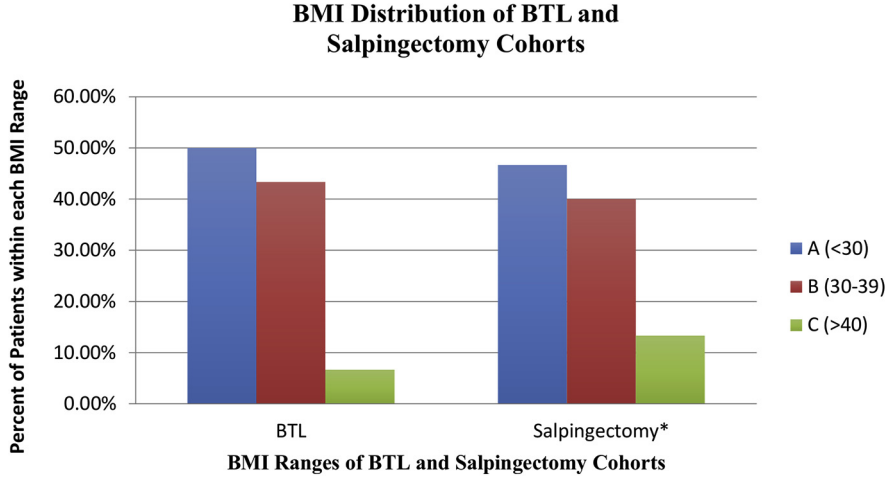


discriminating factor between the 2 groups; yet, there was no statistically significant difference found [10]. It appears that salpingectomies are not inferior to BTL when comparing EBL or complication rate. Additionally, despite our smaller-sized study showing a significant difference between the surgical times of the BTL and salpingectomy groups, it seems that a longer surgical time for salpingectomy may not always be significant.

An advantage of this study was the inherent lack of selection bias. The decision to perform BTL versus salpingectomy was left to the discretion of the attending physician's preference; yet, senior resident physicians rotating on the

Fig. 2

Along the x-axis, the blue-shaded column, labeled as A on the right hand side of the table, represents a BMI of less than 30. The red-shaded column, labeled B, represents the BMI range 30 to 39. The green-shaded column, labeled C, represents a BMI greater than 40. In the BTL group, 50.00% of patients had a BMI on admission less than 30, 43.33% of patients had a BMI between 30 and 39, and 6.67% of patients had a BMI greater than 40. In the salpingectomy group, 46.67% of patients had a BMI less than 30, 40.00% of patients had a BMI between 30 and 39, and 13.33% of patients had a BMI greater than 40. The y-axis represents the percent of subjects of each BMI category within each cohort. *The BMI for 1 subject could not be calculated secondary to the absence of prepregnancy weight in the patient's medical record. Percentages of each BMI range for the salpingectomy cohort were calculated out of 15 rather than 16 subjects because of incomplete data.



labor and delivery service performed all types of sterilization procedures. None of the attending physicians varied their method of sterilization. Although only 1 physician performed salpingectomy, he did so exclusively. This eliminated the possibility of choosing a patient based on body habitus or previous surgical history. The fact that all senior residents rotated working with every attending physician when performing postpartum sterilization procedures eliminated bias toward having particular residents perform 1 method of sterilization over the other based on skill level.

A significant weakness of this study was sample size. Because of this being limited by the length of the study period and the number of cases, generalized conclusions for larger populations of patients cannot be made. The complication rate for the salpingectomy cohort was 0 of 16. Although the difference in complication rates was not statistically significant, it was reassuring to see no complications in the salpingectomy cohort. The average surgical time was the only variable in this study that showed statistical significance. This is in contrast to the retrospective study by McAlpine et al [10]. It is possible that with a larger sample size, the surgical times between the BTL and salpingectomy cohorts would be statistically insignificant.

A key explanation for the small sample size of the salpingectomy cohort was the fact that 1 particular attending physician began instructing his residents around the time of the start of the study's data collection to perform a postpartum bilateral salpingectomy in place of a tubal ligation. Around the start of 2014, this 1 physician started to modify his sterilization technique in support of ovarian cancer risk reduction, which limited the time span for this study's data collection. Additionally, having only 1 surgeon strongly advocating for postpartum salpingectomy in place of traditional BTL limited the possible number of salpingectomy cases performed within the study period.

Another weakness of this study was documentation. One of our objectives was to compare EBL between the 2 cohorts. Unless otherwise indicated, EBL was frequently documented as "minimal" in the operative records. Estimations of small amounts of blood loss in large surgical canisters can be imprecise. The hospital operative reports did not define the definition of "minimal" EBL. "Minimal" could have been any volume less than 50 mL or less than 10 mL. Therefore, we could not safely assume that the amount of "minimal" EBL was the same amount in every case.

An additional factor hindering our documentation was calculating the operative time. Using the difference between the incision time to the time out of the operating room overestimates the length of the case. Closure time was not documented in the anesthesia or physicians' records. If this had been the case, the operative time would have been more accurate.

In the present study, sterilization failure was not noted in the medical records. However, we did not know if a patient had received management of an unintended intrauterine pregnancy at an outside institution. Similarly, we did not know if patients with postoperative complications went to other facilities, thereby potentially underestimating the postoperative complication rates of each cohort. Our findings on sterilization failure are limited to only our institution.

Conclusion

Early diagnosis of ovarian cancer is a challenge. It may be more beneficial to focus on prevention strategies rather than early diagnostic tools. Current evidence suggests that fallopian tubal cells represent at least a partial role in the development of serous epithelial, clear cell, and endometrioid ovarian cancers; we need to pay more attention to possible risk-reducing procedures [1]. Performing a salpingectomy in the immediate postpartum period on a patient who desires permanent sterilization may be a safe procedure and an opportune time to remove sources for the development of ovarian cancer.

Furthermore, bilateral salpingectomy would be protective against the distorted anatomy and/or imbalanced weight on the remaining fallopian tube status after BTL. This would ultimately lower and/or eliminate the risk of ovarian torsion, hydrosalpinx, and/or ectopic pregnancy [11]. A larger cohort should be studied to address the incidence of complications postoperatively with postpartum salpingectomy versus postpartum BTL.

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