A randomized controlled trial of 2 techniques of salpingectomy during cesarean delivery

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BACKGROUND: Total salpingectomy during benign gynecologic surgery is recommended after completion of childbearing to reduce the risk of developing ovarian cancer.

OBJECTIVE: This study aimed to assess operating time and complication rates of "traditional" salpingectomy using the "Knot and Cut" technique, compared with bipolar salpingectomy for sterilization at the time of cesarean delivery.

STUDY DESIGN: This was a randomized controlled trial. Women undergoing planned cesarean delivery who desired sterilization were randomized to traditional salpingectomy or bipolar salpingectomy. The bipolar salpingectomy was performed using the LigaSure Precise. The primary outcome was the surgical time of the salpingectomy procedure. Secondary outcomes included total cesarean delivery time and associated bleeding parameters. We estimated that 42 patients would provide 80% power and a 2-sided alpha of 0.05 to identify a 10-minute difference in the primary outcome.

RESULTS: A total of 26 women were randomized to bipolar salpingectomy and 25 to traditional salpingectomy. Baseline demographic characteristics were similar between the groups. Six procedures were converted from traditional to bipolar salpingectomy, and 2 traditional salpingectomies failed. The surgical time (16.16±9.53 vs 5.19±3.57 minutes; $P<.001$), estimated blood loss (928.08±414.66 mL vs 677.15±380.42 mL; $P=.029$), and need for blood transfusion (20% vs 0%; $P=.016$) were significantly greater in the traditional salpingectomy than in the bipolar salpingectomy group. The cesarean delivery time was similar (88.92±17.87 vs 88.23±19.85 minutes; $P=.89$). Hospitalization time was significantly longer following traditional salpingectomy than bipolar salpingectomy (5.24±2.27 vs 3.92±2.01 days; $P=.034$).

CONCLUSION: "Traditional" salpingectomy is associated with longer surgical and hospitalization time, and greater blood loss and risk of blood transfusion compared with "bipolar" salpingectomy. In practices in which "bipolar" salpingectomy is available, it should be preferred over alternative methods of salpingectomy.

Key words: bipolar salpingectomy, cesarean delivery, surgical complications, traditional salpingectomy

Introduction

Ovarian cancer carries the highest mortality rate of all gynecologic malignancies, with an annual rate of approximately 22,000 incidences and roughly 14,000 deaths in the United States alone in 2020.[1] Evidence from studies performed during the last 2 decades suggests that ovarian cancer most often originates in the distal fallopian tubes.[2–6] Accordingly, both the American College of Obstetricians and Gynecologists and the Society of Gynecologic Oncology have recommended the performance of total salpingectomy during benign gynecologic surgeries after completion of childbearing, to reduce the risk of developing ovarian cancer.[7,8]

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EDITOR'S CHOICE

Data regarding the optimal surgical technique for total bilateral salpingectomy during cesarean delivery (CD) are limited. A randomized controlled trial (RCT) that compared salpingectomy using bipolar energy with tubal ligation during CD showed similar procedure time, completion rate, and complication rate.[9] Conversely, suture-ligation salpingectomy compared with tubal ligation demonstrated increased operating time and a lower completion rate, especially when adhesions presented.[10] Two studies reported that salpingectomy by bipolar electrocautery device reduced surgical time by 12 minutes when compared with suture-ligation salpingectomy.[9,11] A novel suture-ligation technique that was performed in 142 CDs showed increased total surgical time by 5 minutes, and no complications.[12] A meta-analysis that compared total salpingectomy with standard sterilization methods demonstrated increased total surgical time in cohort studies,[13] although only a trend was shown in the analysis of RCTs.

The feasibility of total salpingectomy is also debatable. The completion rate of suture-ligation salpingectomy was previously reported as 68%.[9,10] In contrast, a number of publications reported a 100% success rate following a proper implantation program.[14–17]

The heterogeneity of surgical techniques used in the forementioned studies makes the comparison between them difficult. Currently, the method of salpingectomy used during CD is determined by surgeon's preference. A direct comparison of surgical parameters between salpingectomy techniques during CD has not been published. The current study aimed to compare surgical timing and complications of 2 techniques of bilateral salpingectomy during CD.

Materials and Methods

Study design and population

We conducted a RCT at an academic, tertiary hospital between January 2019 and July 2020, which ended after the

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Why was this study conducted?

Ovarian cancer is the deadliest gynecologic malignancy. Total salpingectomy during benign gynecologic surgery is recommended after completing childbearing. Data are limited regarding the optimal surgical technique for bilateral salpingectomy during cesarean delivery.

Key findings

All 26 bipolar salpingectomies were completed successfully. Of the 25 traditional salpingectomies, 2 were not completed, and 6 were converted to bipolar salpingectomies. For bipolar compared with traditional salpingectomy, surgical and hospital time were shorter, and blood loss and need for blood transfusion were decreased.

What does this add to what is known?

This randomized controlled trial demonstrated better feasibility and safety of bipolar compared with traditional salpingectomy.

completion of study enrollment. The trial was approved by our institutional review board (0427-18-RMB) on December 31, 2018, and registered with ClinicalTrials.gov (NCT03788421). Written informed consent was obtained from all the trial participants. Women receiving obstetrical care who desired surgical sterilization at the time of their elective CD were eligible to participate. At our institution, consent for surgical sterilization is obtained the week before CD, after patient counseling regarding the risks, benefits, and alternatives of surgical sterilization, and after signing sterilization consent paperwork. The patient's desire for surgical sterilization is reconfirmed on the day of surgery. Study exclusion criteria included the inability to give informed consent, preterm delivery (<37 weeks' gestation), fetal death, prenatally diagnosed fetal anomalies or placental abnormalities, previous tubal surgery, use of anticoagulants, and associated immunosuppressive conditions. Patients were randomly assigned to undergo either "traditional" salpingectomy (TS) or "bipolar" salpingectomy (BS). A computer-generated randomization scheme with a block size of 50 was used by our data center. Only our research coordinator had access to the algorithm. The surgical team was notified regarding the randomized procedure before skin incision.

Study procedures, data collection, and outcomes. BS entailed complete bilateral salpingectomy using the LigaSure Precise (Covidien, Medtronic, Edgewater, MD). TS entailed classic complete bilateral salpingectomy (step-by-step clamping and suturing of the mesosalpinx until achievement of total salpingectomy). For this procedure, the fallopian tube was first grasped with a Babcock clamp, after which a window was created in the avascular portion of the mesosalpinx by either cautery or blunt dissection. A Kelly clamp was then placed laterally to medially across the mesosalpinx and through the avascular window, followed by division of the mesosalpinx (leaving enough clamped tissue for a substantial pedicle) and suture ligation or free tying. These steps were repeated until placement of the final clamp at the proximal end of the fallopian tube.

At our institution, CD is typically performed by a maternal–fetal medicine (MFM) attending physician and a resident. The salpingectomy procedures were performed entirely by MFM attending physicians. The practice at our center during the years of the study was BS, but all participating MFM physicians had extensive previous experience in performing traditional salpingectomies as well. Salpingectomy times were measured by the research coordinator. Any complications, additional procedures, adhesiolysis, and estimated blood loss during the tubal procedure alone were documented in the patients' surgical report. Start and end times of the complete operative procedures were also documented in the patients' surgical reports.

The primary outcome was total bilateral salpingectomy time. Secondary outcomes included clinically estimated blood loss (during salpingectomy alone and total blood loss), changes in hemoglobin levels (pre- and postoperatively), blood transfusion rate (transfusions are only given to patients with a postpartum hemoglobin level <7 g/dL or symptomatic patients with a hemoglobin level of 7–8 g/dL), the length of maternal postoperative stay (patients routinely remain in the hospital for 3 nights after elective CDs and may stay longer only if there is clinical justification for a longer stay based on on-call resident and department head decision given that the surgeons are not involved in postpartum care but are only notified regarding patient treatment and complications), mean postoperative visual analogue score (range, 0–10), the need for opioid analgesia (patients are given analgesics on request, starting with paracetamol, then nonsteroidal antiinflammatory drugs, and then opiates if pain still remains an issue), and wound complications (infectious or noninfectious).

Statistical analysis

We estimated that 42 patients (21 per group) would provide 80% power to identify a 10- minute difference in the primary outcome (total salpingectomy time) from a baseline operative time of 5 minutes (per institutional data review regarding BS), with a standard deviation of 2 minutes and a 2-sided alpha of 0.05. All the analyses of the primary outcome and the secondary surgical outcomes were performed according to the intent-to-treat principle. To evaluate factors associated with successful completion of salpingectomy, characteristics were compared between women who successfully completed bilateral salpingectomies and women who did not (but surgical sterilization was performed, ie, standard bilateral tubal ligation or partial salpingectomy). The chi-square for categorical variables and the Student *t*-test or Wilcoxon rank-sum test for

continuous variables were used for analysis. All analyses were performed using SPSS for Windows, version 26 (SPSS, Inc, Chicago, IL), and all outcomes were evaluated at a 0.05 level of significance.

Results

Of the 51 women enrolled, 26 were randomized to undergo BS and 25 to undergo TS (Figure). Baseline demographics and obstetrical information were similar between the groups (Table 1). Salpingectomy was completed in all women in the BS group, and could not be completed in 2 of 25 women in the TS group. The latter was a result of adhesions, although adhesion rate and severity did not differ substantially between the groups. Six procedures were converted from TS to BS because of excess blood loss and adhesion severity during the procedure. Surgical time was significantly longer for TS than for BS (16.16±9.53 vs 5.19±3.57 minutes; *P*<.001) (Table 2).

TABLE 1
Baseline patient characteristics

Characteristics	BS (n=26)	TS (n=25)	*P* value
Age, mean (SD)	37.6 (3.2)	37.3 (2.7)	.72
Parity, median (range)	4 (2–6)	4 (2–6)	.52
BMI, mean (SD)	32.4 (4.5)	33.1 (3.8)	.66
Gestational week at the time of CD, mean (SD)	38.1 (0.6)	38.2 (0.8)	.42
Number of previous CDs, median (range)	3 (2–5)	3 (2–5)	.74
Pre-operative hemoglobin level, mean (SD)	10.7 (1.1)	11.1 (1.4)	.28

CD, cesarean delivery; *BS*, bipolar salpingectomy; *SD*, standard deviation; *TS*, traditional salpingectomy.

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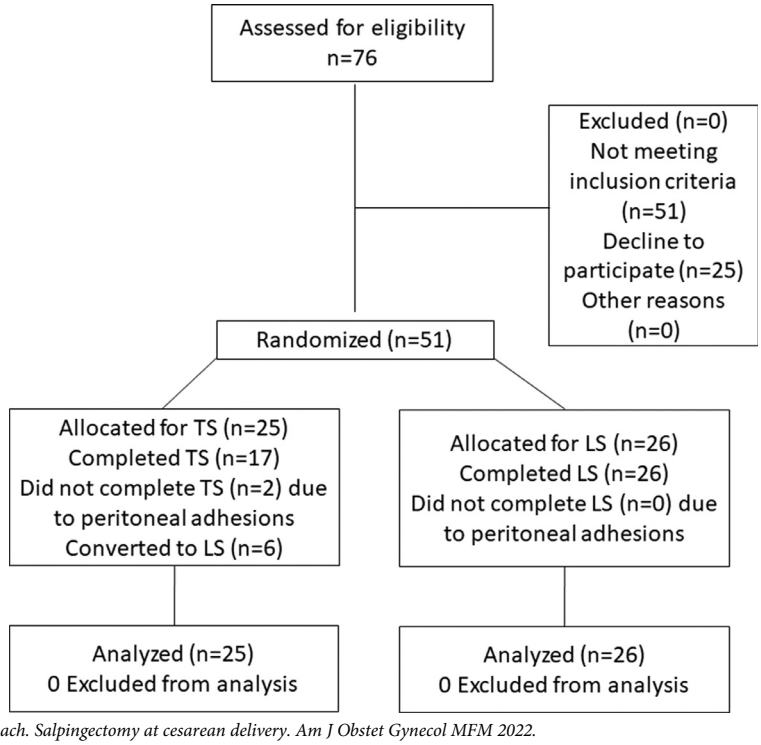
Estimated blood loss and the need for blood transfusion were significantly higher in the TS than in the BS group (928.08±414.66 vs 677.15±380.42 mL; *P*=.029 and 20% vs 0%; *P*=.016, respectively). Postoperative decreases in hemoglobin levels were similar (2.7±2.1 vs 2.1±2.2 g/dL; *P*=.31). The mean visual analogue scores and the need for opiates for analgetic treatment were significantly higher in the TS than in the BS group (6 [range, 4–9] vs 2 [range, 0–3]; *P*=.003 and 24% vs 0%; *P*=.011, respectively). Hospitalization time was significantly longer in the TS than in the BS group (5.24±2.27 vs 3.92±2.01 days; *P*=.034).

FIGURE
Study enrollment flow chart



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Discussion

Principal findings

This RCT demonstrated the superiority of BS compared with TS in surgical procedure duration and feasibility, blood loss, need for blood transfusion, postoperative hospitalization length, pain scoring, and need for opiate treatment.

Results

The mean surgical time was significantly shorter by 11 minutes for BS compared with TS: 16 vs 5 minutes. Similar procedure times were observed in previous studies that compared salpingectomy techniques retrospectively. For example, procedure times of approximately 6 minutes using a bipolar source of energy[11] and of 12 minutes using a suture-ligation salpingectomy were demonstrated.[9] A surgical time of 15 minutes was reported for suture-ligation salpingectomy during CD.[12] A recently published meta-analysis of retrospective cohort studies demonstrated a 6-minute increase in total operative time for salpingectomy compared with standard tubal interruption performed during CD.[13] The same publication reported a trend of increased operative times in an analysis of RCTs. A novel

TABLE 2
Comparison of surgical outcomes

Outcome	BS (n=26)	TS (n=25)	*P*-value
Salpingectomy time in min, mean (SD)	5.19 (3.57)	16.16 (9.53)	<.0001[a]
Total CD time in min, mean (SD)	88.23 (19.85)	88.92 (17.87)	.89
Postoperative hemoglobin level, mean (SD)	8.02 (4.10)	8.98 (2.24)	.31
Estimated blood loss in mL, mean (SD)	677.15 (380.42)	928.08 (414.66)	.029[a]
Blood transfusion rate, n (%)	0 (0%)	5 (20%)	.016[a]
Days of hospitalization, mean (SD)	3.92 (2.01)	5.24 (2.27)	.034[a]
Visual analogue score, median (range)	2 (0–3)	6 (4–9)	.003[a]
Need for opiates for pain management, n (%)	0 (0%)	6 (24%)	.011[a]

CD, cesarean delivery; *BS*, bipolar salpingectomy; *SD*, standard deviation; *TS*, traditional salpingectomy.

[a] p <0.05, statistically significant.

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technique of bilateral suture ligation in 141 women undergoing CD demonstrated a mean surgical time of 15 minutes when performed by inexperienced surgeons, and only 5 minutes when performed by experienced surgeons.[14] The difference in surgical time between the 2 methods demonstrated in our study may be explained by the use of the bipolar device as a vessel sealant and the operating surgeons' familiarity with this application.

The feasibility of achieving bilateral salpingectomy using BS was 100% vs 68% using TS. This is similar to the rate of suture-ligation salpingectomy reported in a previous RCT.[12] In contrast, other studies reported a similar success rate for TS and BS following a proper implantation program.[15–17] In the current study, failed TS was because of adhesions and excessive blood loss, similarly to what was observed in a previous report.[18] In addition, all unsuccessful TS were converted to BS and were completed successfully using this method. The 100% feasibility using the LigaSure device and the success after conversion to BS from TS might be explained by surgeons' experience with the device as a vessel sealant and by the low level of expertise required to use the device.

Previous studies demonstrated the overall safety of salpingectomy during CD, with a low complication rate.[14] In the current RCT, the estimated blood loss was significantly higher with use of TS than of BS; 20% vs 0% of the women required a blood transfusion, respectively. Previous studies reported no differences between TS and tubal ligation in the average hematocrit and total estimated blood loss, or in the need for blood transfusion.[16,18] Nevertheless, the average accepted blood loss during CD is 1000 mL, which correlates with the estimated blood loss reported in the current study using both salpingectomy procedures.

Notably, hospitalization time was significantly longer following TS than BS. This contrasts with studies that reported no difference in this parameter between TS and tubal ligation groups.[11–18] Our finding may be explained by differences in need for blood transfusion, pain scores, need for opiate use for postoperative analgesia, and possibly the small sample size.

Clinical implications

The 68% feasibility rate reported here for TS is unacceptable in a clinical setting that offers the opportunity to prevent ovarian and tubal malignancies. In comparison, the BS seemed as a highly feasible surgical technique with a low adverse event rate. This may enable physicians with even lower levels of surgical expertise to complete the surgery.

Research implications

Further studies are required to evaluate the benefits of BS in clinical settings that use this procedure. In addition, to improve comparisons, a standard regarding procedure timing is required. Moreover, comparing superior techniques of nonenergy-based salpingectomy with BS may be more appropriate.

Strengths and limitations

The study's major strength stems from the RCT design. This study compared 2 surgical methods of bilateral salpingectomy during CD, in contrast to previous studies that compared TS with tubal ligation. All surgeries were performed by well-trained and experienced attending surgeons using the same surgical technique. A limitation of the current study is the small sample size, which makes it difficult to sufficiently assess differences between groups in infrequent outcomes, including wound infection, readmission, and reoperation, and may also explain the differences in transfusion rates and hospitalization length. In addition, the surgeries were performed by skilled surgeons, and the results may not reflect success rates and adverse events in surgeries performed by less experienced surgeons or residents.

Conclusion

TS is associated with longer surgical times, increased blood loss, need for blood transfusion, need for conversion between surgical techniques, longer hospitalization time, greater postoperative pain, and need for analgesia compared with BS. BS should be preferred and implemented as the primary method for salpingectomy over alternative methods in centers where it is available. In practices where BS is not available, TS is an acceptable option provided that it is performed by experienced surgeons. ■

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