

# Opportunistic Salpingectomy Versus Traditional Partial Salpingectomy at the Time of Cesarean Delivery: A Randomized Controlled Trial

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## Research Article

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# Abstract

**BACKGROUND:** It is estimated that one third of women in the United States opt for permanent tubal sterilization at the time of cesarean delivery. Evidence suggests that ovarian cancer begins in the fallopian tubes. Ovarian cancer has the highest mortality of all gynecologic malignancies. There is no proven effective screening for ovarian cancer. In view of this, the Royal College of Obstetricians & Gynecologists and the American College of Obstetricians and Gynecologists recommend considering counseling patients about prophylactic salpingectomy as an effective method of sterilization. There are limited well designed clinical trials that compare the safety and feasibility of total salpingectomy to that of traditional partial salpingectomy for tubal sterilization at the time of cesarean delivery.

**METHODS:** We conducted a non-inferiority randomized controlled trial at the Mayo Clinic, Rochester, Minnesota. Women age 21 years and older who were undergoing cesarean delivery and desired concomitant sterilization were enrolled between May 17, 2017 and July 16, 2018. Stratified randomization was performed based on number of previous cesarean deliveries and their Basal Metabolic Index, into a bilateral total salpingectomy group and bilateral partial salpingectomy group. All salpingectomies were performed using clamps and suture. The primary outcome was to compare the mean peri-operative hemoglobin change for both groups. Secondary objectives included sterilization completion time, postoperative length of stay, estimated blood loss, postoperative pain and adverse events.

**RESULTS:** Of the 111 women screened, 40 were enrolled and randomized. Of these, 38 underwent the assigned procedure (18 BTS, 20 BPS). There were no demographic differences between groups. No difference in Mean  $\pm$ SD hemoglobin drop between groups ( $1.4\pm 0.7$  g/dl for the BTS group and  $1.8\pm 1.0$  g/dl for the BPS group,  $p=0.08$ ). Mean time to completion of sterilization procedure was significantly longer in the BTS group ( $16.3\pm 5.6$  minutes for the BTS group vs  $5.1\pm 1.6$  minutes for the BPS group,  $p < .01$ ). No significant differences for other outcome measures.

**CONCLUSIONS:** Bilateral total salpingectomy at the time of cesarean delivery does not increase the risk for blood loss and has similar peri-operative outcomes, with a small increase in operative time when compared to traditional bilateral partial salpingectomy.

**TRIAL REGISTRATION:** ClinicalTrials.gov, NCT03135431, 27/04/2017

## Background

Ovarian cancer has the highest mortality of all gynecologic malignancies and is the fifth leading cause of cancer death for women in the developed world (1). Evidence suggests the origin of extrauterine pelvic serous carcinomas begins in the fallopian tubes, is often high grade, and is associated with poor prognosis (2). There are no proven effective screening methods for such cancers in low risk women and symptoms are often vague and non-specific which contributes to a higher stage and grade at the time of diagnosis. In view of this, the Royal College of Obstetricians & Gynecologists and the American College of

Obstetricians and Gynecologists (ACOG) recommend considering counseling patients interested in permanent tubal sterilization about prophylactic salpingectomy as an effective method that may also prevent ovarian carcinogenesis.(2–4)

The United Nations Report 'Trends in Contraceptive Use Worldwide 2015' notes that 19% of women worldwide relied on tubal sterilization as a method of contraception (5). The United States National Health Statistics Report of 2015 stated that 9.4 million (approximately 15%) of women between ages 15–44 years are currently using tubal sterilization as a method of birth control, making it the second most common contraceptive method used in the United States, following contraceptive pills (6). There are two types of sterilization: the postpartum sterilization (performed within the first six days after delivery), and laparoscopic (or interval) sterilization. In the United States, over 50% of all sterilization procedures are performed in the postpartum period (7).

Prophylactic salpingectomy at the time of cesarean delivery is an ideal opportunity for primary prevention of ovarian cancer. With the recent ACOG committee opinion endorsing offering prophylactic salpingectomy at the time of sterilization counseling in the United States, numerous physicians have begun performing bilateral total salpingectomy (BTS) during interval sterilization.

There are limited well designed randomized controlled trials looking at prophylactic salpingectomy at the time of cesarean delivery. Roeckner et al. (2020) in a systemic review and metanalysis of 3 randomized controlled trials and 8 retrospective studies, showed that salpingectomy at the time of cesarean delivery was associated with an increase in operative time without any increase in complications (8). Out of the three randomized controlled trials included in Roeckner et al.'s (2020) systemic review and metanalysis, Ganer-Herman et al. (2017) did not performed a power calculation; Garcia et al. (2018) was powered to assess the difference in operative times but used a bipolar vessel sealing device to perform the salpingectomies, and Subramaniam et al. (2018) was under-powered (they needed 40 in each group but only had 27 bilateral salpingectomies and 38 bilateral tubal ligations) and the surgical providers performing the surgeries did not have any formalized training in performing total bilateral salpingectomies at the time of cesarean delivery (8–11). Our study attempts to address these limitations noted above in the existing randomized controlled trials.

In order to assess the risk of hemorrhage and in turn the safety profile of the BTS procedure at the time of cesarean delivery, we designed a non-inferiority randomized controlled trial powered to look at the peri-operative change in hemoglobin in women undergoing concomitant sterilization at the time of cesarean delivery using the routinely available surgical clamps and sutures (12). Our hypothesis was that patients desiring permanent contraception who undergo BTS would have equivalent surgical blood loss to those undergoing traditional bilateral partial salpingectomy (BPS) during cesarean delivery as measured by peri-operative change in hemoglobin (g/dL).

## Materials And Methods

This was a single center, non-inferiority, two–arm randomized controlled trial. The trial was conducted between May 17, 2017 and July 16, 2018 at the Mayo Clinic in Rochester, Minnesota and was approved by the Mayo Clinic institutional review board (17–000898). The study was registered on ClinicalTrials.gov, NCT03135431, on 27/04/2017.

Women were stratified by number of prior cesarean deliveries and Body Mass Index (BMI). Mean difference (post- vs. pre-procedure) in hemoglobin of participants undergoing cesarean non-emergent delivery with BPS via Pomeroy or Parkland method was compared to those undergoing cesarean delivery with BTS. Inclusion criteria included women 21 years of age and older who desired permanent contraception and had an obstetric indication for a cesarean delivery. Women were excluded if they needed an emergent or immediate cesarean delivery, their BMI was greater than or equal to 50 kg/m<sup>2</sup>, and or if they had a single ovary/fallopian tube.

The study coordinator approached women at their scheduled obstetric clinic visit to inform them about the trial. In addition, women who were admitted to the hospital for inpatient care, and whose cesarean delivery was not deemed an emergency, were informed of the trial by the study coordinator or one of the investigators. The informed consent was written in English; however, women who did not speak English were consented with the aid of an interpreter. After informed consent for the study was obtained, the participants were randomly assigned to either BTS or BPS using a computer based electronic dynamic allocation platform based on the Pocock-Simon algorithm according to the number of prior cesarean deliveries (first vs. repeat) and BMI (< 35 vs. ≥35 kg/m<sup>2</sup>). Women who were enrolled and randomized prior to delivery underwent their assigned sterilization method regardless of the urgency of their cesarean delivery. The participants were blinded to the operative intervention at the time of the randomization, and this was later disclosed to them after their cesarean delivery.

Following enrollment, a pre-operative complete blood count (CBC) was collected from participants at the time of their preoperative labs or upon hospital admission, but not to exceed 72 hours before delivery. On admission, women were asked if they wanted to proceed with permanent contraception and consent was obtained for cesarean delivery and the assigned procedure. In the operating room, the delivering team proceeded with the cesarean delivery as indicated. Once completed, the feasibility of the participants' assigned contraceptive procedure was assessed. The start and stop time of the permanent contraceptive procedure was recorded by the nurse in the room and collected by the study coordinator. Participants assigned to BPS did so via Pomeroy or Parkland method based on the surgeon's preference. BTS was standardized using the technique described by Hall, et al. (ACOG May 2017 Film Festival, A Novel, Safe, Low Cost Approach to Bilateral Salpingectomy at Cesarean Section) using clamps and suture (13). This method involves using cautery to skeletonize the mesosalpinx, leaving only perforating vessels which were then suture ligated. Surgeons to be performing the bilateral total salpingectomies were first demonstrated this surgical technique via a training module and they then had to perform one proctored bilateral total salpingectomy and be checked off as competent by another competent surgeon prior to performing the bilateral total salpingectomies on their own on participants. Estimated blood loss (EBL) was calculated for the combined cesarean and sterilization procedure using visual estimation and

recorded per standard practice. A post-operative CBC was collected 24 to 48 hours after the procedure. Following the participants' six week post-partum visits, their charts were reviewed for data collection including pre and post-operative hemoglobin, EBL, post-operative pain scores, postoperative length of stay, and adverse events (significant postoperative pain, anemia, need for blood product transfusion, cesarean hysterectomy, loss of one or both adnexa, and return to the operating room and or death). Pain scores were based on a Numeric Pain intensity Score of 0–10. Post-operative length of stay was calculated using date of discharge minus date of surgery. All abstraction was performed by a single study coordinator who used a hard copy of the electronic data capture system (REDCap) data instrument to record information from charts and then input them into REDCap electronically. She then performed quality checks intermittently by cross-checking REDCap entries every 2–3 data points in the hardcopy abstraction tool. In addition, post-operative complications and adverse events were abstracted from the chart.

Due to the lack on pre-existing studies at the time this trial was started, sample size was initially calculated based on previous studies that reported a mean (SD) drop in hemoglobin of 1.32 g/dl (0.94) following a repeat cesarean delivery and 1.40 g/dl (1.2) following a first cesarean delivery.<sup>7</sup> Based on a review of indications of cesarean deliveries performed at the study site in 2015, we anticipated that over 75% of the cases would be repeat cesarean deliveries. As a non-inferiority study, we chose a threshold of a difference of .5 g/dl, approximately one-half a unit of packed cells, as a clinically important difference between BPS and BTS. Assuming that a difference of 0.5 g/dl in the drop in hemoglobin between study arms would be considered as equivalent, and assuming a common standard deviation of 1.1 based on previous studies of cesarean deliveries, the study would have 80% power to test for non-inferiority with 60 participants in each arm (120 total). Although .5 g/dl clinically is often negligible a conservative approach was used to ensure finding a difference if there was one. This calculation was based on a two-group 1-sided t-test with a type I error of 0.05. Approximately 1 year after our study commenced, data from a separate, retrospective study on salpingectomy at the time of cesarean delivery within the study site's larger health system revealed the mean decrease in hemoglobin among women who underwent salpingectomy (n = 30) was 1.6 g/dl (SD 0.7) and 1.8 g/dl (SD 0.9) for women who underwent BPS (n = 43)(12). Based on this information, we conducted a post-hoc power analysis using a common standard deviation of 0.7 instead of 1.1 and the number of accrued participants at the one-year mark of study recruitment. Based on this calculation, our study was well powered (84%) to assess our primary aim with 38 participants (18 BTS, 20 BPS); therefore, we discontinued recruitment and completed the study with the accrued subjects.

The data monitoring safety plan (DSMP) included a review of charts after the first 10 patients and then quarterly for the duration of the trial. The clinical trial was to be placed on hold if an increase in adverse events were noted. Stopping rules included greater than 20 cases of mild (increased pain scores, mild anemia) or moderate (severe anemia not requiring transfusion) adverse events; greater than 3 cases of severe adverse events (severe anemia requiring transfusion, loss of one or both ovaries); and or any life threatening adverse event (cesarean hysterectomy, return to the operating room) or death. If the above

criteria for discontinuation are met, the trial was to be put on clinical hold. A Data Monitoring and Safety committee will be convened to assess the causal linkage between the adverse events and the procedure. If causal linkage is established, the study would have been permanently stopped. Participants would still have been followed, with their permission, even if the study was discontinued. If no causal linkage was established the study would have been taken off hold.

No interim analysis was performed. The data were descriptively summarized using means and standard deviations or medians and interquartile ranges for the continuous variables, and frequencies and percentages for the categorical variables. The primary endpoint, change (post- minus pre-procedure) in hemoglobin was calculated using a one-sided two sample T-test for non-inferiority. Secondary endpoints were analyzed using the two-sample T-test, Wilcoxon Rank Sum, Fishers exact test, and chi-square test, as appropriate. Statistical analyses were performed using SAS software version 9.4 (SAS Institute Inc., Cary, NC) and R 3.1.1 (R Foundation for Statistical Computing, Vienna, Austria).

## Results

A total of 111 participants were screened and 80 eligible participants were approached, of which 40 participants were enrolled for this study between May 17, 2017 and July 16, 2018. The participants that declined to enter study did so due to either reported lack of interest, concern for cost, concern for the risk of the BTS procedure, and or a desire to proceed with BPS without randomization. Of the 40 participants enrolled, 38 participants were able to undergo their assigned method of sterilization, which included 18 who underwent BTS and 20 who underwent BPS (Figure 1). Of two participants that were initially randomized to the BTS, one did not receive it as the delivering staff had not yet received formalized surgical training in the standardized surgical technique and the other participant decided to opt out of sterilization prior to their cesarean delivery. The trial ended once we achieved the desired sample size. All the participants undergoing surgery as part of this trial were followed up until their 6-week postpartum visit.

At the time of randomization, there were no statistically significant demographic differences between participants randomized to BPS versus BTS. The average age of participants in the BPS group was 34.4 years compared to 32.7 years in the BTS ( $p = 0.18$ ). The median parity was two for those undergoing BPS and one and a half for those assigned BTS ( $p = 0.15$ ). Most participants were white, with some college education, and undergoing a repeat cesarean delivery (Table 1). The primary outcome, change in hemoglobin pre- versus post- procedure, was not statistically higher for participants who underwent BTS versus BPS (mean difference (upper 95%):  $-0.41\text{g/dl}$  ( $0.07$ );  $P = 0.08$ ). The average decrease in hemoglobin was  $1.8\text{ g/dl}$  ( $SD 1.0$ ) for participants with a BTS, while those who received a BPS had an average decrease of  $1.4\text{ g/dl}$  ( $0.7$ ), which was below the threshold of  $0.5\text{ g/dl}$  that was defined a priori as a clinically important difference between the groups. When considering secondary endpoints, a significant difference was found in operation time for the sterilization, with BPS taking an average of  $5.1$  minutes ( $SD 1.6$ ) to complete and BTS taking  $16.3$  minutes ( $SD 5.6$ ) ( $P < 0.01$ , Table 2). There was no statistical difference in postoperative length of hospital stay, or pain scores in the sample (Table 2).

There were no differences in the number of adverse events between the participants who underwent BPS versus those who underwent BTS. One participant in the BTS group required transfusion of 1 unit of blood for symptomatic anemia two days post-delivery. The participant's operative report did not mention any source of hemorrhage and an appropriate rise in her hemoglobin was appreciated post transfusion. She was discharged home on post-operative day three. One participant in the BPS group experienced an increased pain score above goal. This participant had a significant personal history of substance abuse, and it was undetermined if her increased post-operative pain was related to her BPS.

## Discussion

Our study shows that there was no difference in the perioperative hemoglobin change in participants who underwent BTS versus those who underwent BPS at the time of cesarean delivery indicating that BTS at the time of cesarean delivery poses no risk of increased blood loss as compared to BPS. With regards to the time to completion of the sterilization procedure, our study shows that BTS took an average 16.3 minutes to complete (SD 5.6) S in comparison to BPS which took 5.1 minutes (SD 1.6). There was no difference in adverse events, postoperative length of stay and postoperative pain between the two groups.

Pregnancy is associated with significant venous engorgement (14) and this is evident at the time of a cesarean delivery. These venous vessels can be closely associated with the fallopian tubes and accidental injury to which can lead to significant hemorrhage. This risk of injury is often a concern when performing sterilization at the time of cesarean delivery and may theoretically be increased with BTS when compared to BPS at the time of a cesarean delivery due to the complete removal of the fallopian tubes with the BTS procedure. Our study is in agreement with the existing studies. Roeckner et al. (2020) in a recent systematic review and metaanalysis of salpingectomy at the time of cesarean delivery showed that bilateral salpingectomy at the time of cesarean delivery was not associated with an increased rate of surgical complications (8). Most of the other existing literature on BTS at the time of cesarean delivery are retrospective studies. Ferrari et al (2019), in a retrospective study of 528 pregnant women undergoing BTS ( $n = 245$ ), BPS ( $n = 239$ ) and other permanent sterilization methods ( $n = 48$ ) at the time of cesarean delivery showed no difference in EBL and postoperative complications (5.3% in the BTS group vs. 2.5% in the BPS group;  $p = 0.11$ ) between the groups (15). Powell et al (2017), in a retrospective study of 206 salpingectomies performed at the time of cesarean delivery, showed a similar median blood loss between BTS and BPS at cesarean delivery (16). Shinar et al (2017) in another retrospective study comparing BTS ( $n = 50$ ) to BPS ( $n = 99$ ) at the time of cesarean delivery, found no difference in estimated blood loss and other complications within 1-month postpartum (17). At our institution, Parikh et al (2019), in a retrospective study in the larger Mayo Clinic Health System comparing BTS ( $n = 41$ ) and BPS ( $n = 48$ ) at the time of cesarean delivery and showed no evidence of inferiority with a mean difference in pre and postop hemoglobin of 0.18 mg/dL (95% lower bound of 0.46,  $P = 0.99$ ) with less reduction in hemoglobin in the BTS group (12). There are three randomized controlled trial in literature comparing BTS and BPS at the time of cesarean delivery, however they are limited by their study designs. Ganer-Herman et al. (2017) looked at the effect BTS on ovarian reserve (22 women underwent BTS and 24 underwent BPS). They did

not find any difference in ovarian reserve and complications between both groups, however they did not performed a power calculation to be able to determine if their findings were statistically significant. Garcia et al. (2018) in another randomized controlled trial looked at the difference in operative times in 19 women undergoing BTS and 18 undergoing BPS at the time of cesarean delivery. They found no difference in operative times between both the groups, however they used a bipolar vessel sealing device to perform the salpingectomies which could have impacted their findings. Subramaniam et al. (2018) also looked at the difference in operative times between the BTS group and BPS group at the time of cesarean delivery, however they were under-powered, as they required 40 in each group but they only had 27 participants in the BTS group and 38 participants in the BPS group. Also, the surgical providers performing the surgeries did not have any formalized training before doing the procedures. There is some conflicting evidence with regards to the feasibility of BTS at the time of cesarean delivery. Subramaniam et al (2018) showed that BTS could only be completed successfully in 68% cases (27 if the 40 women enrolled) (11), however, Garcia et al (2018) showed that BTS could be completed in 95% (19 out of 20 patients enrolled for BTS) (10). In our study, all patients (n = 18) for which BTS were attempted were able to have a BTS without any failures of the procedure.

There are many strengths to our study. Firstly, our study is unique in that it attempts to address the limitations of the existing randomized controlled trials in literature that compare BTS and BPS at the times of cesarean delivery. Our study is adequately powered to assess the difference in mean drop in hemoglobin between the two procedures, and we provided formalized surgical training to the surgeons in the standardized surgical technique used to perform the salpingectomy. We used instruments and suture that are generally available in all operative rooms without using costly disposable vessel sealing devices. However, our use of suture and clamps may have contributed to the increase in operative time with the BTS group when compared to the BPS group. We were able to quantitatively assess the risk of bleeding with BTS at the time of cesarean delivery in a randomized controlled trial. Our study was powered to find a difference in the change in hemoglobin between the two groups if the difference was greater than a threshold of .5 g/dl, and we confirmed no difference which may not appear clinically relevant when taking into account the relatively larger blood loss of a cesarean delivery. However using a conservative threshold bolsters the argument even further that there are no differences in the two modalities. We understand that a large population study is likely a better study design to assess the safety and perioperative complications associated with BTS at the time of cesarean delivery, however we feel that our study is a well-designed randomized controlled trial that contributes to the existing literature.

One limitation of our study is the small sample size; however, we are adequately powered. Another limitation was the exclusion of women with a BMI greater than 50 kg/m<sup>2</sup>. Ten percent of the women screened were unable to participate in the study due to their pre-pregnancy BMI. As obese women with BMI greater than 50 kg/m<sup>2</sup> represent an increasing proportion of our obstetric population, the findings of this study may not apply to this group. Performing BTS in women with a BMI greater than or equal to 50 kg/m<sup>2</sup> may be more difficult and decreased access to the entire fallopian tube may increase the risks. Special attention should be paid in further studies with this specific group.

## Conclusion

In conclusion, BTS at the time of cesarean delivery appears to be safe and feasible. It is associated with a small increase in operative time, however a cesarean delivery presents a significant opportunity to potentially intervene and decrease ovarian cancer incidence for these women at an earlier time in their lives. With the increasing evidence of its safety, providers can feel safe to offer it as an option for permanent contraception. Future research should focus on the reasons for lack of widespread adoption of BTS by obstetricians at the time of cesarean delivery as well as evaluating the risk of BTS in women with a BMI of  $\geq 50$ .

## Declarations

- **Ethics Approval and Consent to Participate:** This clinical trial study protocol was approved by the Mayo Clinic Institutional Review Board (17-000898) and is in accordance with the guidelines laid by the Declaration of Helsinki. A written informed consent was obtained from all participants prior to their enrollment in this trial.
- **Consent for Publication:** The written informed consent collected from the participants included consent for us to report the results of this trial to the public in a de-identified manner.
- **Availability of Data and Materials:** All datasets generated and/or analyzed during this current study are available from the corresponding author on reasonable request.
- **Competing Interests:** The authors report no relevant financial, personal, political, intellectual or religious interests.
- **Funding:** The Department of Obstetrics and Gynecology at Mayo Clinic, Rochester Minnesota, provided funding to complete this study
- **Authors' Contributions**

RR: Study protocol development, recruitment, final manuscript writing and review

ERC: Study protocol development, recruitment, final manuscript writing and review

AT: Study protocol development, recruitment, final manuscript writing and review

MD: Study protocol development, recruitment, final manuscript review

KT: Recruitment, final manuscript review

LLE: Recruitment, final manuscript review

MMW: Recruitment, data collection, final manuscript review

MAH: Data analysis, and final manuscript review

VET: Study protocol development, recruitment, final manuscript writing and review

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## Tables

**Table 1:** Participant Characteristics comparing women who underwent tubal ligation and those who underwent salpingectomy

	<b>Bilateral Partial Salpingectomy Group</b> (N=20)	<b>Bilateral Total Salpingectomy Group</b> (N=18)	<b>p-Value</b>
<b>Demographics</b>			
Age at Cesarean, Mean (SD)	34.4 (4.1)	32.7 (4.8)	0.18 <sup>1</sup>
Race, Count (%)			0.47 <sup>2</sup>
Hispanic and/or Latino	0 (0.0)	1 (5.6)	
White	20 (100.0)	17 (94.4)	
Baseline BMI, Mean (SD)	31.0 (7.7)	30.0 (7.1)	0.74 <sup>1</sup>
Married, Count (%)	15 (75.0)	11 (61.1)	0.36 <sup>3</sup>
Education, Count (%)			0.07 <sup>2</sup>
At least some College	2 (10.5)	2 (11.1)	
Some College, 2 year degree	5 (26.3)	11 (61.1)	
4 Year or professional degree	12 (63.2)	5 (27.8)	
Gravidity, Median (IQR)	4 (3 – 5)	3 (2 – 5)	0.17 <sup>4</sup>
Parity, Median (IQR)	2 (1.5 – 3)	1.5 (1-2)	0.15 <sup>4</sup>
Smoking Status, Count (%)			0.11 <sup>2</sup>
Current	3 (15.0)	5 (27.8)	
Former	7 (35.0)	1 (5.6)	
Never	10 (50.0)	12 (66.7)	
<b>Cesarean Summaries</b>			
Repeat Cesarean, Count (%)	17 (85.0)	16 (88.9)	0.72 <sup>3</sup>
Prior Vaginal Delivery,	10 (50.0)	5 (28.0)	

Count (%)			0.16 <sup>3</sup>
Gestational age, Mean (SD)	37.6 (2.6)	38.0 (2.4)	0.54 <sup>1</sup>

<sup>1</sup>Two sample t-test

<sup>2</sup>Fishers exact test

<sup>3</sup>Chi-square test

<sup>4</sup>Wilcoxon Two-Sample test

**Table 2:** Summaries of Primary and Secondary Outcomes

	<b>Bilateral Partial Salpingectomy Group</b> (N=20)	<b>Bilateral Total Salpingectomy Group</b> (N=18)	<b>p-Value</b>
Pre Cesarean, Mean (SD)	11.5 (1.0)	11.3 (1.1)	0.52 <sup>1</sup>
Post Cesarean, Mean (SD)	10.0 (0.8)	9.3 (1.5)*	0.06 <sup>1</sup>
Reduction (Pre-Post), Mean (SD)	1.4 (0.7)	1.8 (1.0)*	0.08 <sup>2</sup>
<b>Secondary Endpoints</b>			
Operation Time (mins), Mean (SD)	5.1 (1.6)	16.3 (5.6)	<0.01 <sup>1</sup>
Estimated Blood loss (mL), Mean (SD)	833 (105.5)	842 (84.5)	0.77 <sup>1</sup>
EBL By Group, Count (%)			0.79 <sup>3</sup>
< 800 mL	11 (55)	11 (61)	
800 mL	3 (15)	1 (5.6)	
> 800 mL	6 (30)	6 (33.3)	
AEs, Mean (SD)	0.10 (0.31)	0.22 (0.43)	0.31 <sup>1</sup>
Post-Operative Length of Stay, Median IQR	3 (3, 4)	3 (3, 4)	0.91 <sup>4</sup>
Highest Pain Score, Mean (SD)			
First 12 Hours	5.2 (2.5)	5.1 (1.9)	0.89 <sup>1</sup>
First 12 to 24 hours	5.8 (2.3)	5.7 (2.2)	0.93 <sup>1</sup>
First 24 to 48 hours	6.9 (1.6)	6.8 (1.5)	0.90 <sup>1</sup>

\*Summaries reflect 17 of the 18 patients. One patient was missing the post cesarean hemoglobin.

<sup>1</sup>Two sample t-test

<sup>2</sup>One sided T-test for non-inferiority.

<sup>3</sup>Fishers exact test

<sup>4</sup>Wilcoxon Two-Sample test

# Figures

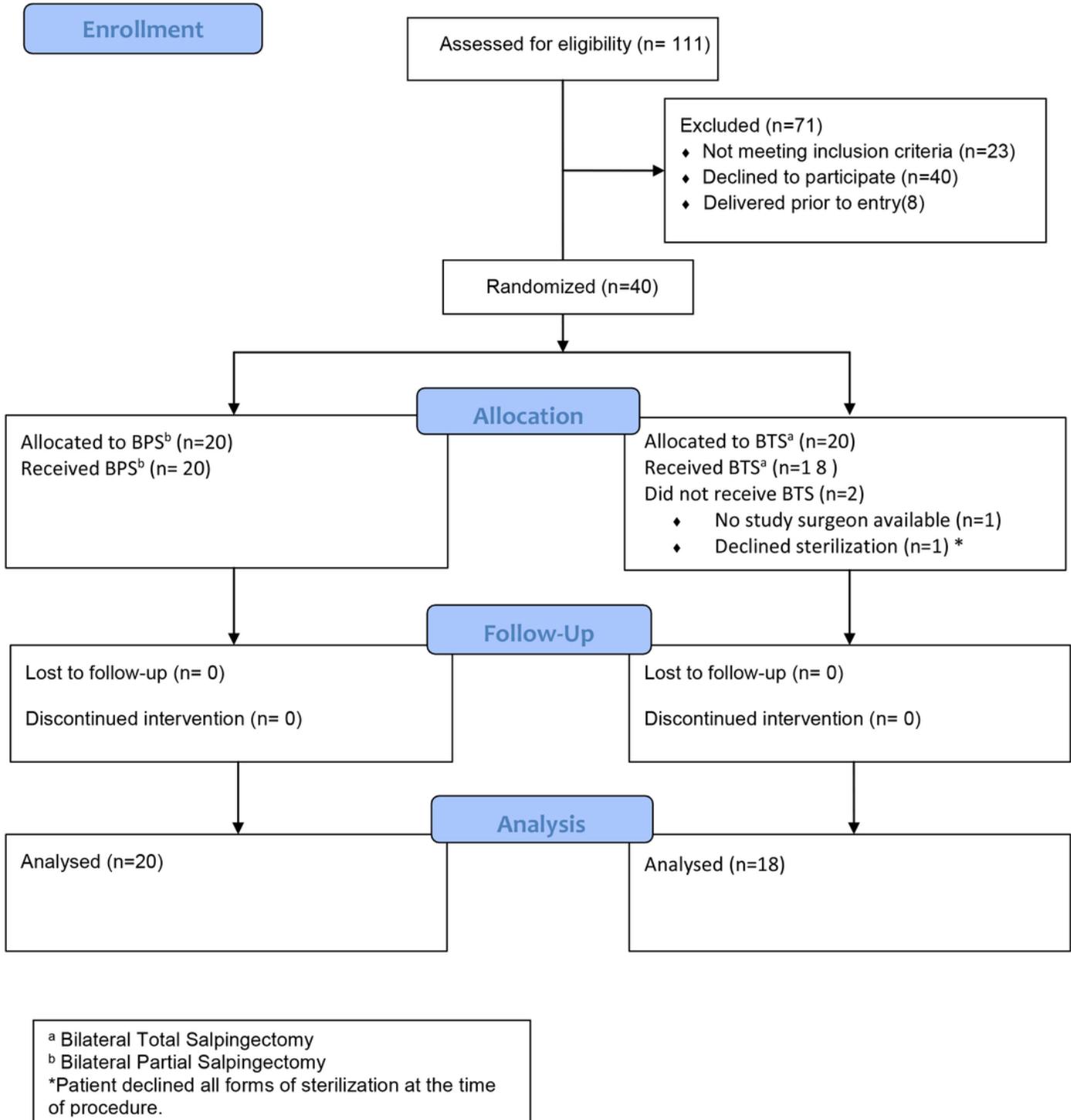


Figure 1

Flow diagram of cases randomized to Bilateral Partial Salpingectomy (BPS) and Bilateral Total Salpingectomy (BTS).