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Original Article

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Opportunistic Salpingectomy Techniques at the Time of Cesarean Delivery: A Retrospective Cohort Study

Nancy T. Nguyen[a], Amy Alabaster[b], Sarah Simmons[c], Miranda L. Ritterman Weintraub[d], C. Bethan Powell[b, e, f]

Abstract

Background: Recent studies have addressed uptake and safety of opportunistic salpingectomy at the time of cesarean delivery. However, there are limited data on outcomes of the surgical techniques used for salpingectomy at cesarean delivery, thus addressing this topic may influence uptake of opportunistic salpingectomy. This study aimed to compare perioperative outcomes of opportunistic salpingectomy techniques used at the time of cesarean delivery.

Methods: This was a retrospective cohort study of women undergoing opportunistic salpingectomy for elective sterilization at cesarean delivery between 2011 and 2016 within Kaiser Permanente Northern California. We compared outcomes of salpingectomy performed with a bipolar electrocautery device (LigaSure, Metronic, MD, USA) versus suture ligation. Primary outcomes were surgical and operative room times. Secondary outcomes included estimated blood loss, intraoperative complications, blood transfusions, number of surgeons, length of hospital stay, readmissions and emergency room visits after discharge. We used bivariate and multivariable analyses to identify factors associated with salpingectomy technique.

Results: We identified 194 patients with salpingectomies at time of cesarean delivery, of whom 97 (50%) had salpingectomies by bipolar electrocautery and 97 (50%) by suture ligation. In bivariate analysis, salpingectomy by bipolar electrocautery was associated with less estimated blood loss (600 vs. 760 mL, 95%, P = 0.04), shorter operating room times (96 vs. 104 min, P = 0.046) and more surgeons involved (P < 0.001), while the difference in surgery time was not significant (59 vs. 65 min, P = 0.06). Adjusting for statistically significant covariates in multivariable analysis, body mass index and prior abdominal surgery, salpingectomies using bipolar electrocautery were shorter in surgery time than using suture ligation (-10.74 min, confidence interval: -21, -0.49). There were no statistical differences in length of stay, readmission, emergency room visits after discharge, or number of surgeons involved. Two intraoperative complications occurred during salpingectomy and there were two blood transfusions.

Conclusions: Salpingectomy was associated with shorter surgery time of 11 min with bipolar electrocautery instead of suture ligation, with no observed differences in postoperative complications.

Keywords: Opportunistic salpingectomy; Ovarian cancer; Sterilization

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[a]Kaiser Permanente Oakland Obstetrics and Gynecology Residency Program, Oakland, CA, USA
[b]Kaiser Permanente Northern California Division of Research, Oakland, CA, USA
[c]Kaiser Permanente San Francisco Obstetrics and Gynecology Residency Program, San Francisco, CA, USA
[d]Department of Graduate Medical Education, Kaiser Permanente Oakland, CA, USA
[e]Kaiser Permanente Northern California Gynecologic Cancer Program, San Francisco, CA, USA
[f]Corresponding Author: C. Bethan Powell, Kaiser Permanente Northern California Gynecologic Cancer Program, 2238 Geary Boulevard, San Francisco, CA 94115, USA. Email: Bethan.powell@kp.org

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Introduction

Ovarian cancer is the leading cause of mortality among gynecologic malignancies in the United States [1]. Recent evidence over the past decade showing the fallopian tubes to be a primary source of serous ovarian cancer has led to recommendations by both the Society of Gynecology Oncology and American College of Obstetrics and Gynecology to perform opportunistic salpingectomies for potential ovarian cancer risk reduction [2-6]. Studies have described uptake and safety of salpingectomy at the time of hysterectomy [7], at the time of interval sterilization [8] and at the time of elective sterilization at cesarean delivery with risk profiles similar to tubal ligation [9-17].

Two recent randomized controlled studies compared tubal ligation to salpingectomy at the time of cesarean delivery: one study assessing salpingectomies performed using an electrocautery device and the other study assessing using suture ligation. When reviewed side by side, the studies serve as an indirect comparison of the two types of surgical technique used for salpingectomy at cesarean delivery [16, 17]. The study by Garcia et al [16] that assessed salpingectomies performed using an electrocautery device showed non-inferior surgical time to tubal ligation. While the other study by Subramaniam et al [17] used suture ligation, and found longer surgical time for salpingectomies compared to tubal ligation. This current study

compared perioperative outcomes among women who underwent an elective sterilization by salpingectomy at time of cesarean delivery according to surgical technique: bipolar electrocautery device versus suture ligation. The primary objective was to directly compare surgical and operative room times for salpingectomy performed with a bipolar cautery device versus suture ligation at the time of cesarean delivery.

Materials and Methods

This was a retrospective cohort study of women who underwent salpingectomy for elective sterilization at the time of cesarean delivery between June 1, 2011 and May 31, 2016 within Kaiser Permanente Northern California (KPNC), an integrated health care system made up of six sub-regional service areas providing local access for the nearly four million members in the Northern California region. Broad guidelines, policies, operating room training and procedures as well as staffing and equipment procurement are standardized, and performance metrics are continuously analyzed, reported and compared throughout the Northern California region. The study compared surgical time, operative room time and additional perioperative outcomes according to salpingectomy surgical technique: bipolar electrocautery device (LigaSure, Metronic, MD, USA) and suture ligation (technique using clamps, suture and ligation). We used electronic medical records to identify surgery time, operative room times and additional perioperative outcomes including estimated blood loss (EBL), intraoperative complications, blood transfusions, length of hospital stay, and postoperative readmission rates and emergency department visits.

The Kaiser Foundation Research Institute's Institutional Review Board approved this study with waiver of patient consent for retrospective chart review. We performed an initial search of the electronic medical record to identify all women aged 18 and older undergoing sterilization by salpingectomy at the time of cesarean delivery between June 2011 and May 2016. We identified the study cohort by an electronic medical record procedure code search for tubal ligation, salpingectomy, sterilization and cesarean delivery. Bilateral salpingectomy procedures were confirmed by chart review and defined as the removal of most of the fallopian tubes bilaterally. We excluded women if they had a procedure that involved oophorectomy, had a diagnosis of ectopic pregnancy, personal history of ovarian cancer, were a *BRCA1*, *BRCA2* or Lynch mutation carrier, or had concurrent surgery at the time of salpingectomy. Concurrent surgery was defined as sterilization performed with any other surgical procedure such as ovarian cystectomy, excluding cesarean delivery.

We performed electronic data extraction to obtain information on patient age, race, parity, neighborhood poverty level which was based on patient's address mapped to the most recent national census block level data, body mass index (BMI), medical center, surgery time, operative room time, postoperative length of stay and EBL. Operative room time was defined as time of patient entry to departure from the operating room; surgical time was from the time of skin incision to closure and postoperative length of stay was hours from surgery end time to time of hospital discharge. Postoperative readmission and emergency room visits, indicators of postoperative complications, were identified as readmission to the hospital within 30 days from surgery or an emergency department visit within 7 days from surgery, respectively. A physician investigator performed medical record chart review to validate that bilateral salpingectomies were performed and identify the surgical technique used for each salpingectomy, indications for cesarean delivery, number of surgeons involved, patient medical and surgical history, intraoperative surgical complications and postpartum blood transfusions.

In 2013, KPNC adopted a regional guideline recommending opportunistic salpingectomy be performed. This was implemented by widespread dissemination of policy guidelines and education of providers. Rates of salpingectomy completed for sterilization at time of cesarean delivery were evaluated, pre- and post-guideline publication from June 2011 to May 2016. Rates of salpingectomies were calculated for 1-year intervals from June to May in the study period, given the guideline publications occurred in the month of May 2013.

We performed bivariate analyses to describe and assess demographic, clinical and surgical factors associated with salpingectomy technique. Continuous variables were described with means or medians and compared with the *t*-test or Kruskal-Wallis test. Chi-square and Fisher's exact tests were used for categorical variables. All tests were two-tailed, with a $P < 0.05$ considered statistically significant. We performed multivariable regression analyses to assess perioperative outcome variations, adjusting for BMI and history of abdominal surgery. Parsimonious models were built using clinically relevant covariates, based on literature and authors' judgment. Categorical outcomes (number of surgeons) were assessed using ordinal logistic regression, whereas continuous outcomes (length of stay, operating room time, surgery time and EBL) were assessed using linear regression. Each outcome was modeled twice, first using a simple adjusted model, and secondly using a hierarchical mixed model, which accounted for correlation within each of six medical service areas using a random intercept. We performed all analyses using SAS 9.3 (SAS Institute, Cary, NC).

Results

An initial cohort of 206 salpingectomies performed at the time of cesarean delivery was identified. Of the 206 salpingectomies, 100 (48.5%) were performed with a bipolar electrocautery device and 98 (47.6%) were performed by suture ligation. The technique was insufficiently described in eight cases. Three patients in the bipolar electrocautery group and one patient in the suture ligation group were excluded from analysis due to concurrent surgery. A final analysis cohort of 194 was identified, 97 (50%) in the bipolar electrocautery group and 97 (50%) in the suture ligation group.

The clinical and demographic characteristics of the study cohort stratified by surgical technique are shown in Table 1. There were no significant differences in demographic (mean age, parity, race/ethnicity, socioeconomic status) or clinical characteristics (obesity status, prior abdominal or fallopian

Table 1. Clinical and Demographic Characteristics of Women Who Underwent Salpingectomies at Cesarean Delivery by Surgical Technique

	Bipolar electrocautery (n = 97)	Suture ligation (n = 97)	P-value[a]
Demographic characteristics			
Age (years), mean (SD)	34.59 (4.6)	35.30 (4.2)	0.26
Parity, n (%)			0.56
0	0 (0)	1 (1.03)	
1 - 2	42 (43.30)	46 (47.42)	
≥ 3	55 (56.70)	50 (51.55)	
Race/ethnicity, n (%)			0.40
Asian	20 (20.62)	28 (28.87)	
Black	8 (8.25)	5 (5.15)	
Hispanic	27 (27.84)	27 (27.84)	
White	36 (37.11)	35 (36.08)	
Other/unknown	6 (6.19)	2 (2.06)	
Households below poverty level, n (%)			0.88
Greater than 10%	34 (35.05)	33 (34.02)	
Less than 10%	63 (64.95)	64 (65.98)	
Clinical characteristics			
Body mass index (kg/m^2), n (%)			0.71
< 30	29 (29.90)	28 (29.17)	
30 - 39.9	51 (52.58)	55 (57.29)	
≥ 40	17 (17.53)	13 (13.54)	
History of abdominal surgery, n (%)	87 (89.69)	88 (90.72)	0.81
History of fallopian tube surgery, n (%)	1 (1.03)	3 (3.09)	0.62
History of endometriosis, n (%)	4 (4.12)	2 (2.06)	0.68
Cesarean indication, n (%)			0.79
Non-reassuring fetal heart rate tracing	1 (1.03)	2 (2.06)	
Arrest of labor	3 (3.09)	1 (1.03)	
Elective repeat cesarean	86 (88.66)	86 (88.66)	
Other	7 (7.22)	8 (8.25)	
Service area, n (%)			< 0.001
A	8 (8.25)	38 (39.18)	
B	0 (0)	1 (1.03)	
C	0 (0)	5 (5.15)	
D	63 (64.95)	1 (1.03)	
E	0 (0)	35 (36.08)	
F	26 (26.80)	17 (17.53)	
Study year, n (%)			< 0.001
June 2011 - May 2012	0	1 (1.03)	
June 2012 - May 2013	0	2 (2.06)	
June 2013 - May 2014	3 (3.09)	14 (14.43)	
June 2014 - May 2015	25 (25.77)	34 (35.05)	
June 2015 - May 2016	69 (71.13)	46 (47.42)	

[a]Statistical tests used: *t*-test for continuous variable and Chi-square tests or Fisher's exact tests (when expected cell size < 5) for categorical variables.

Table 2. Perioperative Outcomes of Salpingectomies at Cesarean Delivery by Surgical Technique

	Bipolar electrocautery (n = 97)	Suture ligation (n = 97)	P-value[a]
Intraoperative characteristics			
Surgery time (min), median (IQR)	59 (46 - 71)	65 (52 - 80)	0.06
Operating room time (min), median (IQR)	96 (83 - 112)	104 (89 - 120)	0.046
Number of surgeons			< 0.001
1	8 (8.25)	30 (30.93)	
2	84 (86.60)	61 (62.89)	
3	5 (5.15)	6 (6.19)	
Intraoperative complications	4 (4.12)	4 (4.12)	1.0
Estimated blood loss (mL), median (IQR)	600 (445 - 800)	760 (500 - 864)	0.04
Postoperative characteristics			
Blood transfusions, n (%)	1(1.03)	1 (1.03)	1.0
Length of stay (h), median (IQR)	53 (49 - 72)	52 (48 - 71)	0.28
Readmission within 30 days, n (%)	10 (10.4)	10 (10.4)	0.96
Emergency room visit within 7 days, n (%)	0	0	n/a

[a]Statistical tests used: non-parametric Kruskal-Wallis for continuous variables and Chi-square tests or Fisher's exact tests (when expected cell size < 5) for categorical variables. IQR: interquartile range.

surgery, history of endometriosis) between the two cohorts. The most common indication for cesarean delivery was for elective repeat cesarean delivery. Surgical technique for salpingectomy did not differ based on the four categories of cesarean delivery indication. Surgical techniques varied by service area within northern California (P < 0.001), and service area B had the lowest frequency of salpingectomies performed during the study period (n = 1). Three of the five service regions performed salpingectomies by suture ligation only. Service area D was more likely to perform salpingectomies at time of cesarean delivery compared to the other regions, with more than 98% of the salpingectomies completed by bipolar electrocautery. There was no distinguishable pattern based on geography, including proximity to a major city, number of cesarean deliveries performed or having a residency program to account for service area variation.

Prior to the release of the KPNC opportunistic salpingectomy guidelines in May 2013, salpingectomy was uncommon with only three salpingectomies performed within KPNC between 2011 and 2013, all via suture ligation (Table 1). After the 2013 systemwide recommendation to perform salpingectomy instead of tubal ligation, salpingectomies at time of cesarean delivery significantly increased each year. The use of bipolar electrocautery salpingectomies also increased each year compared to suture ligation, and by the last study year (2015 - 2016), there were 115 salpingectomies performed within KPNC with higher rates of bipolar electrocautery utilized (71.13% vs. 47.42%, overall P < 0.001 for time period comparison).

In the bivariate analysis, salpingectomies performed by bipolar electrocautery compared to suture ligation were associated with lower median EBL (600 vs. 760 mL, P = 0.04); however, there was no difference in rate of postpartum blood transfusions, with a total of two transfusions (Table 2). Although surgical time was 6 min shorter, this difference was not significant (59 min vs. 65 min, P = 0.06). Operative room time was 8 min shorter for bipolar electrocautery than suture ligation (96 vs. 104 min, P = 0.046). The median length of stay postoperatively did not differ (53 vs. 52 h, P = 0.28). Overall there was no difference in complication rates between the two cohorts. There were eight intraoperative complications, two of which were specifically related to the salpingectomy portion of the surgery. Both intraoperative complications occurred during suture ligation salpingectomies and involved bleeding of the uterine cornua in one case and bleeding in the mesosalpinx in the other case, which contributed to postpartum hemorrhage, defined as EBL > 1000 mL. Neither of the two cases required blood transfusions. There were no emergency room visits within 7 days of discharge in either group and no observed difference in 30-day readmission rates (Table 2). When comparing number of surgeons (primary and assistant surgeons), suture ligation was more often used in single surgeon cases, whereas bipolar electrocautery was more likely used in cases with two or more surgeons (P < 0.001).

In the hierarchical multivariable analysis (Table 3), adjusting for BMI and history of abdominal surgery, and accounting for correlation among service areas, bipolar electrocautery was associated with shorter surgery time (adjusted difference in minutes: -10.74; 95% confidence interval (95% CI): -21.00, -0.49) compared to suture ligation. In the adjusted model, no differences in operative times, EBL or number of surgeons were noted between bipolar electrocautery and suture ligation groups.

Discussion

Our study directly compares surgical outcomes in women with opportunistic salpingectomies at the time of cesarean delivery

Table 3. Multivariable Comparison of Bipolar Electrocautery Vs. Suture Ligation (Reference) for Select Perioperative Outcomes

Perioperative outcome	Adjusted model[a]	Adjusted hierarchical model
	OR (95% CI)	OR (95% CI)
Number of surgeons	3.09 (1.53, 6.23)	2.72 (0.39, 18.79)
	Difference β (95% CI)	**Difference β (95% CI)**
Length of stay (h)	4.14 (-0.96, 9.24)	3.85 (-6.30, 14.01)
Operating room time (min)	-6.90 (-14.17, 0.36)	-10.67 (-22.06, 0.71)
Surgery time (min)	-5.33 (-11.68, 1.03)	-10.74 (-21.00, -0.49)
Estimated blood loss (mL)	-53.3 (-148.6, 41.9)	-81.7 (-232.0, 68.7)

[a]Each row represents a separate model run for each perioperative outcome, adjusting for body mass index and history of abdominal surgery. The hierarchical models take into account correlation within each of the six medical service areas using a random intercept. Number of surgeons is an ordinal logistic regression. All other variables use linear regression. OR: odds ratio; CI: confidence interval.

based on surgical technique: bipolar electrocautery compared to suture ligation. On bivariate analysis, bipolar electrocautery technique was associated with significantly lower EBL and operating room time. When controlling for BMI, history of abdominal surgery and taking into account correlation within the six medical service areas, surgical time was significantly shorter by 11 min with bipolar electrocautery compared to suture ligation, whereas EBL, operating room time and number of surgeons were not significantly different.

Our study corroborates prior evidence that salpingectomy at the time of cesarean delivery is feasible and safe [8-17] even when considering high risk patients with higher BMI, or prior abdominal or fallopian tube surgery. Two recent randomized controlled studies comparing standard tubal ligation occlusion and salpingectomies (one study used electrocautery and the other used suture ligation for salpingectomies) at time of cesarean delivery also concluded no difference in surgical complications [16, 17]. However, the study by Subramaniam et al [17] using suture ligation for salpingectomy reported an extra 15 min to total operative time compared to tubal ligation and salpingectomy success rate of only 68%, while Garcia et al [16] showed no difference in operative time and salpingectomy success rate of 95% using the bipolar device. Additionally, 29% of surgeons reported dissatisfaction with performing salpingectomy using suture ligation and 54% reported they would not perform the procedure again [17]. Surgeons may be concerned about potential bleeding from engorged uterine vasculature with suture ligature, contributing to the decision on whether to perform a salpingectomy. The two intraoperative complications in our study associated with salpingectomy, both postpartum hemorrhages, occurred in the suture ligation group. One case described bleeding at the cornual stump after salpingectomy requiring additional suture ligation, while the other case described a mesosalpinx hematoma. Given both cases occurred in the suture ligation cohort, suture knot integrity or tying technique are possibly linked to these outcomes.

Cost-effective modeling of opportunistic salpingectomy has been favorable [18-20], with salpingectomy for interval sterilization reported to be cost-effective when costs were less than approximately $1,000 compared to tubal ligation [19]. Venkatesh et al [20] recently showed salpingectomy at the time of cesarean delivery to be more cost-effective compared to tubal ligation when estimates of salpingectomy perioperative complication risk was less than 2%. Additionally, costs of electrocautery device and differences in operative time were not included in the cost-effective analysis. While our study did not investigate costs of surgical techniques for salpingectomies at the time of cesarean delivery, the decreased operative room times associated with bipolar electrosurgery may suggest potential cost savings. The cost of the bipolar device is approximately $400, thus operating room costs would need to be in the order of $50 per minute to be cost neutral. Operating room costs per minute vary by hospital but $50 per minute is consistent with KPNC operating room costs and in the range of many institutions [9, 21, 22].

Strengths of our study include comprehensive access to electronic data and follow-up in our integrated healthcare system. Additionally, our study is the largest cohort investigating perioperative outcomes for salpingectomies at time of cesarean delivery. Limitations include the inherent limitations of a retrospective cohort study design. We are not able to determine if outcomes associated with the bipolar device are related to the device itself or the surgeons who were more likely to use or have access to the bipolar device. Residency involvement varied within service areas, some with solely teaching hospitals and others involve rotating residents, likely reflecting the various numbers of surgeons observed and possibly affecting surgical outcomes when compared to non-resident participating surgeries. KPNC has regional standardization of operating room equipment, policy and procedures; however, sub-regional service area variations may impact the operative room time, surgical time and potential complications. For instance, some labor and delivery units do not stock bipolar devices and some providers may prefer not to perform salpingectomies. Making the bipolar device readily available may offer providers reassurance and improve uptake of salpingectomy. Findings in our system may not be representative of other health care systems, limiting the generalizability of our results. Given the low complication and readmission rates, this study is underpowered to show significant differences between techniques. Larger studies will be needed to determine differences in complication rates or EBL according to salpingectomy technique. The extent of benefit rendered by salpingectomy on ovarian cancer

incidence also remains to be determined.

The decision to perform salpingectomies for elective sterilization at the time of cesarean delivery should be supported and surgeon's concern for potential bleeding complications or increased surgical time may be alleviated by availability of bipolar devices on labor and delivery services.

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Conflict of Interest

All authors declare no conflict of interest.

Informed Consent

Kaiser Foundation Research Institute's Institutional Review Board approved this study with waiver of patient consent for retrospective chart review.

Author Contributions

NTN: project development, data collection, data analysis, manuscript writing/editing. AA: project development, data management, data analysis, manuscript writing/editing. SS: data collection, manuscript writing/editing. MLRW: manuscript writing/editing. CBP: project development, data management, data analysis, manuscript writing/editing.

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