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Research Article

Tubal Sterilization Preceding Endometrial Ablation is an Independent Risk Factor for Hysterectomy

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- Endometrial ablation; Tubal sterilization; Hysterectomy; Failure

Abstract

Objective: We sought to determine if tubal sterilization is an independent risk factor for hysterectomy following endometrial ablation.

Methods: We performed a retrospective cohort study in a single academic-affiliated community hospital. Study patients included pre-menopausal English speaking women undergoing a second-generation endometrial ablation from 2004 through 2015. We defined procedure failure as undergoing a hysterectomy at any time following the index ablation.

Results: 373 women were identified as having undergone an endometrial ablation within the study period. Of the 373 endometrial ablations, 74 (19.8%) women required hysterectomy following their ablation. Baseline demographics were similar between groups, except women requiring hysterectomy were more likely to be younger (p<.01) and undergo their endometrial ablation for menorrhagia (p=.01) compared to women not requiring hysterectomy. Tubal sterilization was an independent risk factor for hysterectomy even after adjusting for confounders (aOR 1.9; 95% CI 1.1-3.6). Tubal sterilization at the time of endometrial ablation was not associated with an increased risk for hysterectomy. However, endometrial ablation at any time point after tubal sterilization is associated with an increased risk for hysterectomy (OR 1.9; 95% CI 1.2-3.3). Of women requiring hysterectomy following endometrial ablation pain was more likely to be an indication for hysterectomy in women with tubal sterilization compared to those without (71.1% vs. 34.5%; p<.01).

Conclusion: Tubal sterilization is an independent risk factor for hysterectomy in women undergoing endometrial ablation. In those women who have a hysterectomy after an endometrial ablation, those with a history of tubal sterilization are more likely to have pain as an indication for their hysterectomy than women without tubal sterilization.

INTRODUCTION

Endometrial ablation is a minor surgical procedure for the treatment of abnormal uterine bleeding in premenopausal women who have completed childbearing [1]. Active or recent pregnancies, as well as the desire to maintain fertility, are reasons to avoid endometrial ablation for the management of bothersome bleeding. Reliable contraception for patients undergoing an ablation is highly encouraged as unique high-risk complications can affect subsequent pregnancies. There is a greater risk for miscarriage, ectopic pregnancy, intrauterine scarring, preterm birth, postpartum hemorrhage, and abnormal placentation in pregnancies following an ablation [2]. Tubal sterilization is the most common contraceptive method used by childbearing-aged women with more than 600 000 sterilizations performed annually [3]. Often tubal sterilization is the contraceptive method of choice in women undergoing endometrial ablation.

Careful patient selection to optimize treatment success, thus minimizing the need for further intervention is essential before performing an ablation. The need for any additional procedure for continued bothersome bleeding following an ablation is often considered treatment failure in the literature [2,4,5]. Published rates of surgical re-intervention following an ablation have reached as high as 21% [5]. Known risk factors for treatment failure following an ablation include: young age, history of cesarean delivery, and abnormal uterine findings on radiologic assessment [4-7]. Despite multiple established risk factors for failure, there are opposing data regarding whether tubal sterilization is a risk factor for ablation failure [5,8]. These opposing data often make patient counseling challenging when discussing how tubal sterilization will impact the success following ablation. The aim of this study is to evaluate whether tubal sterilization is a risk factor for hysterectomy following endometrial ablation.

METHODS

After obtaining approval by the Institutional Review Board, we performed a retrospective cohort study of women who had undergone an endometrial ablation between January 2004 and February 2015. Patients were identified using the health systems contemporaneous electronic database. Patient data was obtained using relevant International Classification of Disease – Ninth

and Tenth revisions (ICD-9 and ICD-10) codes as well as Current Procedural Terminology (CPT) codes. Women were included if they were between the ages of 18 and 55, were admitted under the employed hospital faculty staff, and underwent an endometrial ablation for benign indications at a single academic-affiliated community hospital. The technique and device used for all endometrial ablations were at the discretion of the physician. Studied devices included the uterine balloon ablation ThermaChoice® (UBA) (Gynecare, Somerville, New Jersey), the HydroThermAblator® hydrothermal ablation (HTA) (Boston Scientific, Marlborough, Massachusetts), and the NovaSure® radiofrequency ablation (RFA) (HologicInc, Marlborough, Massachusetts). Women were excluded if they had a diagnosis related to any gynecologic malignancy, if their ablation was performed for post-menopausal bleeding, or if their operative reports revealed contradictory information to their electronic coding.

The initial cohort of women identified was then re-analyzed using relevant ICD and CPT codes, as well as individual chart review to identify any patient who underwent a tubal sterilization procedure at any time point before, during, or after their ablation. The initial cohort was also analyzed to identify women who underwent a hysterectomy at any time after their endometrial ablation through February 2018. This allowed a minimum of three years for every analyzed patient to undergo a hysterectomy following their ablation. The operative reports for every patient identified were then reviewed to ensure each patient had undergone their stated procedure.

The primary outcome evaluated was the incidence of failed endometrial ablation, defined as hysterectomy at any point after the ablation, as it related to tubal sterilization. Exposures examined included the influence of age, body mass index (BMI), race, and ablation device type, tubal sterilization at any point, method for tubal sterilization, indication for endometrial ablation, and indication for hysterectomy following endometrial ablation. All pertinent patient data were either extracted from the electronic health record or identified by review of operative reports.

Analysis was completed using Stata Statistical Software (version 13.1; Stata Corp, College Station, TX) and a p-value < 0.05 was considered significant. Continuous variables were compared with t-test and categorical variables were compared with chi-square. Univariable logistic regression was used to determine the association between history of tubal sterilization, timing of tubal sterilization, type of tubal sterilization and endometrial ablation failure. A multivariable logistic regression model was used to determine the association between history of tubal sterilization and endometrial ablation failure with adjustment for age and indication for endometrial ablation.

RESULTS

Between January 2004 and February 2015 we identified 433 women who underwent an endometrial ablation at a single academic-affiliated community hospital, performed by the hospital-employed staff. After excluding 60 women, due to failure to undergo their endometrial ablation found only after operative report review, 373 women were available for analysis. Of the 373 included women 74 (19.8%) underwent hysterectomy following their endometrial ablation. Compared to women who did not fail, failed ablation patients were younger (40.1 ± 7.1 vs. 42.4 ± 5.7; p<.01) and were more likely to have their ablation for menorrhagia (87.8% vs. 67.9%; P=.01). Differences between failures and non-failures regarding race, BMI, and the device used for second-generation endometrial ablation were not statistically significant (Table 1).

Of the 373 women included 158 (42.4%) had an exposure to tubal sterilization at a time point before, during, or after their ablation. Tubal sterilization was a statistically significant risk factor for failed endometrial ablation (Table (2), aOR 2.0; 95%CI 1.1-3.6). Tubal sterilization before the endometrial ablation procedure was associated with ablation failure, compared to tubal sterilization either during or after the ablation (OR 2.0; 95%CI 1.2-3.4). Differences between method for tubal sterilization and the association with failed ablation were not statistically significant (Table 2).

Differences in age at ablation and indication for hysterectomy were statistically significant between failed ablations with a tubal sterilization compared to failed ablations with no tubal sterilization (Table (3), p<.01). Compared to failed ablations without a tubal sterilization, those failed ablations with a tubal sterilization were more likely to have a diagnosis related to pain as their indication for hysterectomy (71.1% vs. 34.5%; p<.01).

DISCUSSION

This study found tubal sterilization to be an independent risk factor for failed endometrial ablation. The overall incidence of failed endometrial ablation in this study (19.8%) is consistent with previous data [6,9]. Our findings contribute to the limited data available on the association between tubal sterilization and endometrial ablation failure. In previous studies tubal sterilization has been shown to confer an increased risk for failed endometrial ablation [5,10-12]. However, there is data to suggest that tubal sterilization does not confer any increased risk for failed endometrial ablation [8]. Many women with a history of tubal sterilization undergo ablation, and many women undergo tubal sterilization as a concomitant procedure during their ablation. To our knowledge our study is the first of its kind to analyze tubal sterilization with regard to timing in relation to endometrial ablation as well as the modality of sterilization. We found that only tubal sterilization preceding an endometrial ablation conferred a higher likelihood of failure, although the numbers of patients having a tubal sterilization either at the time of their ablation, or following their ablation, were low. Additionally, the type of sterilization procedure did not appear to impact the likelihood of failure following an ablation.

Our study suggests that postablation tubal sterilization syndrome may be the primary underlying etiology driving the need for hysterectomy following endometrial ablation. We found that women with a tubal ligation undergoing endometrial ablation were more likely to fail for reasons related to pain compared to women without a tubal ligation, regardless of the original indication for ablation. While in the original study describing post-ablation-tubal sterilization syndrome, salpingectomy appeared to relieve the associated symptoms our results suggest

Table 1: Demographic Data for the Cohort.

	Failed Ablation n=74(%)	No Failure n=299(%)	p-value
Age	40.1 (+7.1)	42.4(+5.7)	<0.01
Primary Indication for Ablation Menorrhagia AUB Dysmenorrhea Fibroid/Polyp Other	 65 (87.8%) 5 (6.8%) 1 (1.4%) 1 (1.4%) 2 (2.7%)	 203 (67.9%) 67 (22.4%) 6 (2.0%) 15 (5.0%) 8 (2.7%)	0.01
BMI	30.8 (+8.0)	31.2 (+7.8)	0.67
Race African American White Other	 33 (44.6%) 38 (51.4%) 3 (4.1%)	 112 (37.5%) 177 (59.2%) 10 (3.3%)	0.47
Ablation Modality HTA RFA UBA	 47 (63.5%) 27 (36.5%) 0 (0%)	 178 (59.5%) 118 (39.5%) 3 (1.0%)	0.60

Abbreviations: AUB: Abnormal Uterine Bleeding; BMI: Body Mass Index; HTA: Hydrothermalablation; RFA: Radiofrequency Ablation; UBA: Uterine Balloon Ablation

Table 2: Primary and Secondary Outcomes by Group.

	Failed Ablation N=74(%)	No Failure N=299 (%)	OR	95% CI	aOR	95% CI
History of TL	45 (60.8%)	113 (37.8%)	2.55	1.5-4.3	**1.97**	**1.1-3.6**
Timing of TL At EA Pre-EA Post-EA	 10 (13.5%) 33 (44.6%) 2 (2.7%)	 22 (7.4%) 87 (29.1%) 4 (1.3%)	 1.97 1.96 -	 0.89-4.36 1.16-3.36 -		
Type of TL Bipolar PP BTL Salpingectomy Essure Band Unknown	 16 (35.6%) 15 (33.3%) 1 (2.2%) 2 (4.4%) 6 (13.3%) 5 (11.1%)	 39 (34.5%) 41 (36.3%) 5 (4.4%) 2 (1.8%) 16 (14.2%) 10 (8.9%)	 1.0 0.89 0.49 2.44 0.91 1.22	 0.38-2.04 0.06-4.51 0.32-18.8 0.30-2.76 0.36-4.13		

TL: Tubal Ligation; EA: Endometrial Ablation; PP BTL: Postpartum Bilateral Tubal Ligation

salpingectomy was not protective against hysterectomy following endometrial ablation. The low overall number of salpingectomies performed does present a limitation to our results. Pain as an indication for ablation is known to be an associated risk factor for failure [14]. In this study the overall number of patients having pain related to their indication for ablation was low (7/373).

Consistent with the majority of prior data, younger age at the time of ablation conferred a higher likelihood of failure in this study [5-7,9,14]. We also found that the indication for endometrial ablation was related to an increased likelihood of failure. This is in contrast to previously published data, which did not find that preoperative bleeding pattern impacts failure rate [15]. However, because our study relied on ICD coding it is possible that certain patients with intrauterine pathology (leiomyoma), which can confer a higher likelihood of failure, were grouped inappropriately and thus not accounted for.

Our study has several limitations. It is limited by its retrospective design as well as the dependence on accurate ICD and CPT coding which is known to have inherent bias. Even though all endometrial ablations took place at a single center, we cannot account for any patients that were lost to follow-up, or who had a subsequent procedure at a different institution. The strengths of our study lie primarily in the accuracy of the data collection and follow-up. The patient population was limited to only those patients cared for by faculty physicians to ensure that all medical records would be accessible through the electronic database. Every patient analyzed underwent individual chart review to ensure accuracy wherever possible. We also allowed for a minimum of 3 years follow-up for each patient as this is the time when the majority of failures will occur [6]. This follow-up was chosen to minimize the chances that any failures would be missed. This is the first study to analyze both the timing of tubal sterilization as well as the modality by which the sterilization was performed and how this relates to failure rates.

This study should help gynecologists counsel their patients when discussing rates and risk factors for failed ablation. It also may influence surgeons performing concomitant tubal sterilization procedures at the time of endometrial ablations in an effort to minimize anesthesia exposure for their patients. These data warrant further studies, prospective in nature, to strengthen

Table 3: Outcomes of Women Requiring Hysterectomy With and Without Exposure to Tubal Ligation.

	With TL n=45(%)	No TL n=29(%)	p-value
Age at EA	36.8 (+6.7)	45.1 (+3.8)	<0.01
Race African American White Other	 19 (42.2%) 25 (55.6%) 1 (2.2%)	 14 (48.3%) 13 (44.8%) 2 (6.9%)	0.48
BMI	30.3 (+8.1)	31.5 (+8.0)	0.56
Ablation Modality HTA RFA	 28 (62.2%) 17 (37.8%)	 19 (65.5%) 10 (34.5%)	0.77
Indication for RI Menorrhagia AUB Dysmenorrhea Fibroid/Polyp PMB Other Menorrhagia/Pain	 13 (28.9%) 4 (8.9%) 7 (15.6%) 3 (6.7%) 0 (0%) 0 (0%) 18 (40.0%)	 14 (50.0%) 0 (0%) 3 (10.7%) 1 (3.6%) 1 (3.6%) 3 (10.7%) 6 (21.4%)	0.04
Pain	32 (71.1%)	10 (34.5%)	<0.01
Interval for RI	31.6 (+27.2)	26.8 (+25.2)	0.45
Age at RI	39.1 (+7.0)	47.1 (+4.0)	<0.01

Abbreviations: TL: Tubal Ligation; EA: Endometrial Ablation; BMI: Body Mass Index; HTA: Hydrothermablation; RFA: Radiofrequency Ablation; RI: Re-intervention; AUB: Abnormal Uterine Bleeding; PMB: Postmenopausal Bleeding

the conclusion that tubal sterilization is an independent risk factor for hysterectomy following endometrial ablation. As bilateral salpingectomy becomes more commonplace as the preferred method of tubal sterilization it will be interesting to see how this impacts the incidence of post ablation tubal sterilization syndrome.

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