Tubal interruption and subsequent surgery for pain after endometrial ablation: A retrospective cohort study.

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Running title: Tubal interruption and post-ablation surgery

MeSH Keywords: tubal ligation, endometrial ablation, pelvic pain, surgical outcome

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Abstract

Background: Endometrial ablation (EA) is an alternative to hysterectomy for abnormal uterine bleeding (AUB), with reduced recovery time and lesser operative risks. However, post-ablation pain may be associated with subsequent surgery, including hysterectomy. It is uncertain what factors affect surgery rates for post-ablation pain, particularly with respect to timing and technique of tubal interruption.

Aim: To evaluate the relationship between tubal interruption and post-ablation pain and subsequent surgery.

Materials and Methods: We conducted a retrospective cohort study involving 324 patients at a Melbourne tertiary hospital from 2009-2020. The primary outcome was subsequent pelvic surgery for pain following EA.

Results: Pain following EA was reported by 29.7% of patients, with 10.5% of patients undergoing subsequent surgery for pain. Patients with tubal interruption were more likely to undergo subsequent surgery for pain than those with no tubal interruption (OR: 3.49, 95%CI: 1.59, 7.66; p=0.002). Tubal ligation was strongly associated with subsequent surgery for pain (OR: 3.12, 95%CI: 1.48, 6.57; p=0.003). In contrast, those with salpingectomy did not have an increased risk of subsequent surgery for pain, compared to those with no tubal interruption (OR: 1.5; 95% CI 0.32, 7.13). Pre-ablation pain (adjusted OR: 2.98, 95%CI: 1.37, 6.48; p=0.006) and previous caesarean section (OR: 2.66; 95%CI: 1.13, 6.25; p=0.025) were also associated with subsequent surgery for pain.

Conclusion: Our results suggest that tubal interruption, pre-ablation pain and previous caesarean section are associated with subsequent surgery for pain. These results can better inform preoperative counselling regarding the risk of subsequent surgery after EA.

Introduction

Endometrial ablation (EA) is an effective procedure for the treatment of abnormal uterine bleeding (AUB). It is a minimally invasive alternative to hysterectomy, with reduced recovery time and fewer operative risks[1]. Most patients experience reduced bleeding[2, 3] and improved quality of life after ablation[1-3]. However, 10-30% of patients require further surgery including hysterectomy[4, 5]. Indications for hysterectomy include persistent AUB and new or increased pelvic pain[5].

Reliable contraception is recommended with EA due to the risks of pregnancy to mother and fetus[6]. Tubal ligation and salpingectomy are effective, permanent options. However, previous studies suggest tubal ligation is associated with post-ablation pelvic pain [7-9].

Post-ablation tubal sterilisation syndrome (PATSS) describes pelvic pain in patients with tubal ligation post EA [9, 10]. Following ablation, persistent endometrial tissue in the cornual and tubal areas can bleed. For patients with tubal ligation, bleeding into the proximal tubal segment causes distension. Resulting haematometra may present as severe, cyclic pain. The definitive treatment for PATSS is hysterectomy [10, 11]. It remains unclear whether tubal ligation increases the risk of subsequent surgery for post-ablation pain. Salpingectomy is thought to be effective in relieving PATSS symptoms [10]. However, it is unknown whether salpingectomy could reduce the risk of post-ablation pain.

This study aimed to assess the risk of subsequent surgery for pain after EA, dependent on tubal interruption status. Furthermore, the impact of the technique and timing of tubal interruption on subsequent surgery rate was examined.

Materials and Methods

Data Collection

Patients who underwent an endometrial ablation at a tertiary women's hospital in Victoria were identified using MBS codes. Files for all participants were reviewed and pathology results accessed using the electronic pathology database, Clinical Patient Folder (InfoMedix, Melbourne). Baseline characteristics including maternal age, gravidity, parity, history of pelvic pain, previous EA and previous tubal interruption were recorded. The operation

report was used to record indication, generation of EA and whether concurrent tubal interruption was performed. First-generation ablation included hysteroscopic methods (rollerball ablation or endometrial resection) and second-generation ablation included non-hysteroscopic methods (electrosurgical radiofrequency ablation (NovaSure®, Hologic, Marlborough MA).

Outcomes

Our primary outcome was subsequent pelvic surgery for pain following EA. We evaluated tubal interruption status (salpingectomy or tubal ligation; prior or concurrent tubal interruption) to determine its association with subsequent surgery for pain.

Secondary outcomes were pre-ablation factors (age, parity, history of pelvic pain or dysmenorrhoea, previous EA) associated with subsequent surgery and features of EA (indication for procedure, generation of ablation, completeness of procedure and follow-up time).

Statistical Analysis

Statistical analyses were conducted in Stata/IC v16.1. A p-value of 0.05 was considered the threshold for statistical significance in all analyses. Descriptive statistics were generated for participant characteristic and explanatory and outcome variables, with comparisons between non-randomised surgery groups compared using Wilcoxon rank-sum tests for skewed continuous variables, and Pearson's chi-squared tests for categorical variables. For primary analyses, a logistic regression was conducted to determine whether subsequent surgery was associated with tubal interruption prior to, or concurrent with, EA. Results from analyses are reported as odds ratios with 95% confidence intervals and corresponding p-values from both unadjusted analyses, and as analyses adjusted for the potential confounders EA type (1^{st} generation vs. 2^{nd} generation), age, any prior tubal surgeries, completeness of EA (complete, incomplete, or unknown), any pre-EA pain, and indication for EA (AUB vs AUB with comorbid pain). Secondary analyses utilising chi-square tests and logistic regression were conducted to examine the distribution of the type of post-EA surgery, the experience of pain post-EA (controlling for pre-EA pain), and an exploration of

factors associated with specific combinations of post-EA surgery types and indications (e.g., hysterectomy for pain).

Ethics

Ethics approval was obtained prior to commencing this study through the Mercy Hospital for Women research ethics committee (approval project number 2020-030). As this was a retrospective cohort study, individual patient consent was not required.

Results

A total of 372 patients had an endometrial ablation at the study institution between 1st January 2010 and 1st January 2020. Patients were excluded if they were lost to follow-up or had insufficient information, leaving 324 cases. We had 203 (62.65%) patients with no tubal interruption and 121 (37.34%) with prior or concurrent tubal interruption, of whom 96 (79.33%) had tubal ligation and 25 (20.66%) had salpingectomy (Figure 1).

Patient characteristics and details of the surgery performed are provided in Table 1. Patient characteristics did not differ by tubal interruption status; however, those who had prior or concurrent tubal interruption were followed-up over a slightly longer period.

Subsequent surgery for any indication

The overall rate of pelvic surgery subsequent to EA was 19.8% (64/324). Overall, 17.6% (57/234) of patients underwent a hysterectomy after ablation, accounting for the majority of post-ablation surgeries (57/64; 89%); with 2.2% (7/324) undergoing laparoscopy and/or hysteroscopy (11% of post-EA surgeries) (Table 3.). There was no statistical evidence that type of surgery differed by tubal interruption status ($\chi^2(2)=1.55$, p=0.46). We found no association between tubal interruption and further surgery overall (adjusted OR: 0.85, 95%CI: 0.35, 2.10; p=0.73).

Clinical factors associated with subsequent surgery

A history of pre-ablation pain was associated with an increased risk of subsequent pelvic surgery (adjusted OR: 1.99, 95%CI: 1.06, 3.72; p=0.032). Age (adjusted OR 1.02, 95%CI 0.96, 1.08; p=0.58), type of EA (adjusted OR 2.24, 95%CI 0.62, 8.00; p=0.22) and indication for

ablation (adjusted OR 1.21, 95%CI 0.52, 2.82; p=0.65) were not associated with subsequent pelvic surgery.

Post-ablation pain

Almost a third of patients experienced new or worsening pelvic pain after EA (29.7%). Sixty-one (18.9%) experienced cyclical pain, whilst 6.2% (20/324) experienced non-cyclical pain and 4.6% (15/324) experienced both. Patients with tubal interruption had a 2.01-fold increased odds of post-ablation pain compared to patients without tubal interruption after controlling for pre-ablation pelvic pain (OR: 2.01, 95%CI: 1.22, 3.34, p=0.007).

Subsequent surgery for pain

Subsequent pelvic surgery for pain was performed in 10.5% (34/324) of cases and 11.7% of patients (38/324) had subsequent surgery for bleeding complaints. The rate of hysterectomy after EA was 8.6% (28/324) for pain and 10.8% (35/324) for abnormal uterine bleeding (AUB). In patients who underwent hysterectomy for pain, histopathology found 42.9% (12/28) had adenomyosis, 46.4% (13/28) had fibroids, 7.1% (2/28) had endometriosis and 7.1% (2/28) had haematometra. Of the six patients who underwent laparoscopy +/- hysteroscopy for pain, 16.6% (1/6) had haematometra, 16.6% (1/6) had another cause of pain and the remaining 66.66% had no cause of pain identified (4/6).

Patients with prior tubal interruption had a 3.49-fold increased risk of post-ablation surgery for pain than those with no tubal interruption (OR: 3.49, 95%CI: 1.59, 7.66; p=0.002). This remained true after controlling for ablation type, completeness of ablation, age, and pre-ablation pain (OR: 3.55, 95%CI: 1.57, 8.02; p=0.002). There was no evidence (p=0.22) of a difference in timing to reintervention (months) by tubal interruption status; the median timing to reintervention for those with no tubal interruption (n=36) was 14.5 months (IQR: 6.5, 21.5 months) compared to 10 months (IQR: 4, 22 months) for those with any tubal interruption (n=27). There was no statistical difference between prior and concurrent tubal interruption for subsequent surgery for pain (OR: 1.97, 95%CI: 0.66, 5.86; p=0.23).

We found an association between history of caesarean section (OR: 2.66; 95%CI: 1.13, 6.25; p=0.025) and pre-existing pelvic pain (OR: 3.03, 95%CI 1.29, 7.10; p=0.011) and the risk of

post-ablation hysterectomy for pain (Table 2). Furthermore, there was an association between the type of tubal interruption and the risk of post-ablation hysterectomy for pain (p=0.03) (Table 3). Patients who had tubal ligation were more likely to have post-ablation surgery for pain (OR: 3.13, 95%CI: 1.34, 7.33; p=0.009) than those with no tubal interruption. This remained true when controlling for EA type, completeness, age, pre-EA pain, history of caesarean section, abnormal pre-ablation ultrasound, such as features of adenomyosis or fibroids (OR: 3.29, 95%CI: 1.35, 8.04; p=0.009).

Patients who had tubal ligation were more likely to have any post-ablation surgery for pain (OR: 3.12, 95%CI: 1.48, 6.57; p=0.003) than those with no tubal interruption. In contrast, those with salpingectomy did not have increased odds of subsequent surgery for pain, compared to those with no tubal interruption (OR: 1.5; 95% CI 0.32, 7.13). However, when we compared both groups, there was no statistical difference in subsequent surgery for pain between tubal ligation and salpingectomy (OR: 2.08, 95%CI: 0.44, 9.77; p=0.36).

Discussion

Our study found a positive association between tubal interruption and new or worsening post-ablation pain. Other retrospective studies have reported similar findings, accounted for by post-ablation tubal sterilization syndrome (PATSS) [8, 9]. After EA, residual cornual endometrium continues to bleed. A haematometra develop against occluded fallopian tubes, leading to severe, cyclic pain. PATSS has been pathologically confirmed in 6-8% of patients with tubal ligation after ablation [9, 12]. Similarly, we found 7.1% (2/34) of patients had haematometra requiring subsequent surgery for pain. However, the majority (20/34) of patients who underwent subsequent surgery for pain had non-tubal interruption related pathology. This could be accounted for by difficulties in confirming tubal interruption related pathology with histopathology. Haematometra are not routinely commented on at our institution unless specifically requested by the surgeon and haematometra may be disrupted by formalin prior to pathology analysis. Due to these limitations, we specifically looked at subsequent surgery for pain as a clinical maker of PATSS. We hoped to identify patients at risk of treatment failure due to pain and guide optimal counselling regarding reliable contraception.

Patients with prior or concurrent tubal interruption were significantly more likely to undergo subsequent surgery for pain compared to patients with patent fallopian tubes. This contrasts previous studies that found although tubal ligation increases post-ablation pain, it does not increase hysterectomy rate [13-15]. These studies grouped together AUB and pain as indications of subsequent surgery. We similarly found tubal ligation does not increase the overall hysterectomy rate (p=0.37). The incidence of patients requiring subsequent surgery for any indication is 12-16.5% [8, 9, 13, 14]. Other causes of pelvic pain requiring subsequent surgery may include adenomyosis which was confirmed in 42.9% of our patients and is similar to other retrospective studies [13, 15].

The association between tubal ligation and subsequent surgery for pain remained true when controlling for pre-existing pain. We found pre-existing pain was also significantly associated with subsequent surgery for pain (p=0.006). This is similar to a recent retrospective study which showed pre-ablation pain was an independent risk factor for ablation failure [16]. EA decreases menstrual bleeding and the associated dysmenorrhoea from heavy menses. However, pain not associated with bleeding may not be treated by ablation. Other causes of dysmenorrhoea include adenomyosis and endometriosis which were pathologically confirmed in 12 (42.9%) and 2 (7.1%) of patients who underwent hysterectomy for pain respectively. Nine (64.2%) of these patients reported pre-ablation pain. These disorders can be difficult to recognise on ultrasound, likely explaining why we did not find an association between abnormal pre-ablation ultrasound and subsequent hysterectomy for pain. Patients with pre-existing pelvic pain should be aware of the possibility of ongoing pain after ablation, which may require further surgery.

We found a history of caesarean section was associated with subsequent hysterectomy for pain (p=0.025). Previous studies found an association between caesarean section and subsequent hysterectomy for any indication[14, 15]. This may be explained by an increased incidence of anomalies occurring along the distorted lower uterine segment[14]. Our results suggest age, abnormal ultrasound findings, pre-existing adenomyosis or fibroids, the generation of ablation and the completeness of ablation are not associated with subsequent surgery due to pain. In contrast, a recent systematic review by Beelen et al that found

younger age was prognostic of ablation failure [11]. This difference might be explained by EA 'failures' being attributable to ongoing AUB, and differences in the median ages of the cohorts. Our median age of 45 (IQR 42.0, 48.5) is older than previous studies which showed increased post-ablation hysterectomy rates for patients under age 40 [5, 17]. Older patients have a larger decrease in bleeding and higher rate of amenorrhoea post ablation [3, 11, 18].

Limitations of this study include those inherent in its retrospective study design. Data abstraction relied on interpretation of operation and clinic notes, which can be subject to bias and inaccuracies. Almost 20% of patients in our study underwent further pelvic surgery, which is similar to previous studies that reported 10-30% hysterectomy rates post-ablation [8, 19]. However, we may have underestimated the hysterectomy rate since some patients were lost to follow-up, whilst others may have sought subsequent surgery at other institutions. Previous studies show most women undergo hysterectomy within three years post ablation [13, 14]. Future studies could employ questionaries to general practitioners to account for external follow-up and re-referrals for women seeking hysterectomy after discharge. Furthermore, due to sample size we were unable to demonstrate a significant difference in the rate of subsequent surgery between tubal ligation and salpingectomy. Our preliminary results suggest salpingectomy is not associated with post-ablation failure due to pain. These results would benefit from prospective research.

Pain is a subjective outcome to measure. It is open to bias from patient recall and clinician interpretation. As this was a retrospective study, we used pain requiring subsequent surgery as our primary outcome. This could be objectively measured and was a clinically relevant indicator of ablation failure. Ideally prospective studies would employ validated tools including numeric pain scales and visual analog scales to better qualify new and worsening pain post ablation.[20]

Strengths of this study include a high number of cases obtained over a ten-year period. Our diverse demographic should demonstrate external validity when applied to a general Australian population. Furthermore, data was collected from one health service, which may reduce bias caused by different clinical practice.

This research is significant as it extends upon previous understanding of tubal interruption and ablation failure in several ways. Firstly, previous studies have been underpowered to evaluate whether the timing of tubal ligation effects ablation failure [9]. We found no difference in post-ablation pain or subsequent surgery between concurrent or prior tubal-interruption. We expect patients with or considering tubal interruption to have similar post-ablation outcomes. Secondly, we investigated whether there was a difference between types of tubal interruption. Salpingectomy is used to treat PATSS in patients with prior tubal ligation. However, no previous studies have evaluated whether salpingectomy reduces the development of PATSS. We found that whilst tubal ligation is associated with post-ablation pain and surgery, salpingectomy is not a risk factor. Patients may benefit from salpingectomy rather than tubal ligation if contraception is required at the time of ablation, however due to our small sample size further research is needed to evaluate this possible association.

Our results are important when discussing possible EA in patients with or considering permanent contraception. Most patients avoid hysterectomy after EA. However, patients with tubal ligation or pre-existing pelvic pain should be counselled on the risk of post-ablation pain, which may require further management including hysterectomy. Future studies should assess these associations prospectively, and compare outcomes between tubal ligation and salpingectomy.

Table 1. Sample characteristics for patients who underwent EA

Characteristic	Overall (N=324)	Tubal Interruption Status		p-value
		No Tubal Interruption (n=203)	Tubal Interruption (n=121)	
Age, years, median (IQR)	45.0 (42.0, 48.5)	46.0 (42.0, 49.0)	45.0 (42.0, 48.0)	0.28
Parity, median (IQR)	2.0 (2.0, 3.0)	2.0 (1.0, 3.0)	2.0 (2.0, 3.0)	0.090
Prior multiple births, n (%)	7 (2.2%)	3 (1.5%)	4 (3.3%)	0.27

History of caesarean section	81 (25.0%)	50 (24.6%)	31 (25.6%)	0.84
Abnormal pre-ablation ultrasound	91 (8.1%)	59 (29.1%)	32 (26.4%)	0.61
Ultrasound evidence of fibroids	64 (19.8%)	40 (19.7%)	24 (19.8%)	0.98
Ultrasound evidence of adenomyosis	24 (7.4%)	17 (8.4%)	7 (5.8%)	0.39
Tubal surgery details				
No prior or concurrent tubal surgery	203 (62.7%)	203 (100%)	-	
Concurrent bilateral tubal ligation	27 (8.3%)	-	27 (22.3%)	
Concurrent bilateral salpingectomy	16 (4.9%)	-	16 (13.2%)	
Prior tubal ligation	69 (57.0%)	-	69 (57.0%)	
Prior bilateral salpingectomy	4 (3.3%)	-	4 (3.3%)	
Prior unilateral salpingectomy with concurrent unilateral salpingectomy	5 (4.1%)	-	5 (4.1%)	
Indication for EA				
AUB	280 (86.4%)	176 (86.7%)	104 (86.0%)	0.43
Pain + AUB	43 (13.3%)	27 (13.3%)	16 (13.2%)	
Other	1 (0.3%)	0 (0.0%)	1 (0.8%)	
Type of EA				
1st Generation	24 (7.4%)	14 (6.9%)	10 (8.3%)	0.65
2nd Generation	300 (92.6%)	189 (93.1%)	111 (91.7%)	
Surgical completeness				
Complete	298 (92.0%)	185 (91.1%)	113 (93.4%)	0.25
Incomplete	17 (5.2%)	10 (4.9%)	7 (5.8%)	
Unknown	9 (2.8%)	8 (3.9%)	1 (0.8%)	
Time (months) from EA to outpatient discharge, median (IQR)	3.0 (2.0, 8.0)	3.0 (2.0, 7.0)	4.0 (3.0, 8.0)	0.033
Post-EA surgery performed	64 (19.8%)	37 (18.2%)	27 (22.3%)	0.37
Post-EA surgery type				

Hysterectomy	57 (17.6%)	34 (16.7%)	23 (19.0%)	0.46
Laparoscopy and/or hysteroscopy	7 (2.2%)	3 (1.5%)	4 (3.3%)	

EA, endometrial ablation; AUB, abnormal uterine bleeding; IQR, inter-quartile range

Table 2. Unadjusted and adjusted odds ratios from logistic regression of having hysterectomy for pain subsequent to endometrial ablation

	Unadjusted OR (95%CI)	p-value	Adjusted OR (95%CI)	p-value
Intervention		.031		0.031
EA Only	1.00 (ref)		1.00 (ref)	
EA plus concurrent tubal interruption	1.63 (0.50, 5.33)		1.42 (0.40, 4.98)	
EA plus prior tubal interruption	3.13 (1.34, 7.33)		3.29 (1.35, 8.04)	
Potential confounders				
EA Type				0.30
1st generation			1.00 (ref)	
2nd generation			3.05 (0.37, 25.10)	
Age (/year)			0.98 (0.90, 1.07)	0.69
Complete EA				0.68
Complete			1.00 (ref)	
Incomplete			1.75 (0.34, 9.02)	
Unknown			2.00 (0.20, 19.50)	
Pre-EA pain				0.011
No			1.00 (ref)	
Yes (any)			3.03 (1.29, 7.10)	
History of caesarean section				0.025
No			1.00 (ref)	
Yes			2.66 (1.13, 6.25)	
Abnormal pre-ablation ultrasound				0.60
Normal			1.00 (ref)	
Abnormal			0.53 (0.05, 5.77)	
Ultrasound evidence of fibroids				0.36
No			1.00 (ref)	

Yes			3.07 (0.28, 33.35)	
Ultrasound evidence of adenomyosis				0.72
No			1.00 (ref)	
Yes			0.61 (0.04, 9.20)	

EA, endometrial ablation; AUB, abnormal uterine bleeding; TS, tubal surgery; OR, odds ratio

Table 3: Post-ablation surgery for pelvic pain if tubal ligation or salpingectomy

	Unadjusted OR (95%CI)	**p-value**	**Adjusted OR (95%CI)**	**p-value**
Intervention		.011		0.015
EA Only	1.00 (ref)			
Tubal ligation	3.12 (1.48, 6.57)		2.94 (1.36, 6.33)	
Salpingectomy	1.50 (0.32, 7.13)		0.86 (0.17, 4.36)	
Potential confounders				
EA Type				0.29
1st generation			1.00 (ref)	
2nd generation			3.04 (0.38, 24.2)	
Age (years)			0.96 (0.90, 1.04)	.032
Complete EA				0.95
Complete			1.00 (ref)	
Incomplete			1.12 (0.22, 5.60)	
Unknown			1.37 (0.15, 12.7)	
Pre-EA pain				0.007
No			1.00 (ref)	
Yes (any)			2.90 (1.34, 6.27)	

EA, endometrial ablation; OR, odds ratio

Figure 1: Flowchart of recruitment

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Figure 1: flowchart of recruitment