

participants who had selected their surgical procedure. Despite the lack of masking, only 40% of 116 women who completed the treatment knowledge form reported knowing their assignment.

Our results can be used to encourage other surgical trialists to consider the use of placebo-controlled designs with sham

incisions when planning randomized surgical trials.

#### CLINICAL IMPLICATIONS

■ Our study confirms the feasibility of sham incisions in randomized surgical trials.

■ Only a small number of treated participants in either the tension-free vaginal tape (13%) or sham (11%) groups were unmasked by 12 months.

■ Surgical trialists should consider the use of placebo-controlled designs with sham incisions when planning randomized surgical trials. ■

## Preoperative uterine bleeding pattern and risk of endometrial ablation failure

Katelyn R. Smithling, MD; Gina Savella; Christina A. Raker, ScD;  
Kristen A. Matteson, MD, MPH

**OBJECTIVE:** The objectives of the study were to compare among women who had an endometrial ablation the risks of treatment failure and subsequent gynecological procedures between women with regular and irregular heavy uterine bleeding and to determine other characteristics associated with the risk of treatment failure.

**STUDY DESIGN:** This study was a retrospective cohort of 968 women who underwent endometrial ablation between January 2007 and July 2009. Preoperative bleeding pattern was categorized as regular or irregular. Treatment failure was defined as reablation or hysterectomy. Subsequent gynecological procedures included endometrial biopsy, dilation and curettage, hysteroscopy, reablation, or hysterectomy. We calculated the odds of treatment failure and gynecological procedures using multiple logistic regression.

**RESULTS:** Bleeding pattern prior to ablation was heavy and regular in 30% ( $n = 293$ ), heavy and irregular in 36% ( $n = 352$ ), and unspecified in 30% ( $n = 286$ ). We found no differences in treatment

failure (13% vs 12%,  $P = .9$ ) or subsequent procedures (16% vs 18%,  $P = .7$ ) between women with regular and irregular bleeding. Compared with the women with regular bleeding, the women with irregular bleeding were not at increased odds of treatment failure or subsequent procedures (odds ratio [OR], 1.07; 95% confidence interval [CI], 0.65–1.74 and OR, 1.17; 95% CI, 0.76–1.80, respectively). Factors associated with an increased odds of treatment failure and subsequent procedures included tubal ligation (OR, 1.94; 95% CI, 1.30–2.91 and OR, 1.71; 95% CI, 1.20–2.43, respectively); dysmenorrhea (OR, 2.42; 95% CI, 1.44–4.06 and OR, 1.93; 95% CI, 1.20–3.13, respectively); and obesity (OR, 1.82; 95% CI, 1.21–2.73 and OR, 1.75; 95% CI, 1.22–2.50, respectively).

**CONCLUSION:** Preoperative bleeding pattern did not appear to affect failure rates or the need for gynecological procedures after endometrial ablation. Other risk factors for ablation failure identified included preoperative dysmenorrhea, prior tubal ligation, and obesity.

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### BACKGROUND AND OBJECTIVE

Abnormal uterine bleeding (AUB) is one of the most common gynecological symptoms for which women seek medical care. In women with AUB whose medical therapy fails or are not suitable candidates for medical therapy, surgical

management is limited to endometrial ablation and hysterectomy. Endometrial ablation studies have generally excluded women with irregular bleeding patterns suggestive of ovulatory dysfunction (AUB-O); its effectiveness in this population is not established.

The objective of this study was to determine whether preoperative bleeding pattern and other preoperative characteristics were associated with risks of treatment failure and subsequent gynecological procedures after endometrial ablation.

### MATERIALS AND METHODS

This retrospective cohort study included all patients who had their first endometrial ablation from January 2007 through June 2009 at Women and Infants Hospital. We excluded women who had had a prior endometrial ablation.

From the Department of Obstetrics and Gynecology, Women and Infants Hospital, Warren Alpert Medical School of Brown University, Providence, RI.

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TABLE

**Preoperative characteristics and odds of subsequent gynecological procedures,<sup>a</sup> including treatment failure<sup>b</sup> (n = 963)**

Characteristic	Subsequent gynecological procedures ORs (95% CI)		Treatment failure ORs (95% CI)	
	Unadjusted	Adjusted <sup>c</sup>	Unadjusted	Adjusted
Bleeding pattern				
Heavy and regular	—	—	—	—
Heavy and irregular	1.14 (0.75–1.74)	1.17 (0.76–1.80)	1.03 (0.63–1.66)	1.07 (0.65–1.74)
Heavy NOS	0.87 (0.55–1.38)	0.96 (0.60–1.54)	0.87 (0.51–1.46)	0.99 (0.58–1.69)
Previous tubal ligation	1.65 (1.17–2.33)	1.71 (1.20–2.43)	1.84 (1.24–2.74)	1.94 (1.30–2.91)
Dysmenorrhea or pelvic pain	1.96 (1.22–3.14)	1.93 (1.20–3.13)	2.40 (1.45–3.98)	2.42 (1.44–4.06)
Obesity	1.79 (1.26–2.54)	1.75 (1.22–2.50)	1.86 (1.25–2.76)	1.82 (1.21–2.73)

CI, confidence interval; NOS, not otherwise specified; OR, odds ratio.

<sup>a</sup> Gynecological procedures (endometrial biopsy, dilation and curettage, hysteroscopy, repeat ablation, or hysterectomy) were performed in the 36 months following endometrial ablation; <sup>b</sup> Treatment failure was defined as repeat ablation or hysterectomy in the 36 months following endometrial ablation; <sup>c</sup> OR was adjusted for bleeding pattern, previous tubal ligation, dysmenorrhea or pelvic pain, and obesity.

Smithling. Uterine bleeding patterns and ablation failure. *Am J Obstet Gynecol* 2014.

The main independent variable, preoperative bleeding pattern (heavy and irregular or heavy and irregular), was determined by a review of the hospital medical record and history and physical examinations for the operating room. The main dependent variable, treatment failure, was defined as hysterectomy or repeat ablation within 36 months after the endometrial ablation. We defined our secondary dependent variable, subsequent gynecological procedures, as endometrial biopsy, dilation and curettage, hysteroscopy, repeat ablation, or hysterectomy within 36 months after the endometrial ablation.

## RESULTS

We found 968 records of women who had undergone endometrial ablation during the study period and were eligible for this review. Of these procedures, 961 (99.3%) were radiofrequency bipolar endometrial ablations. Records showed that 293 women (30.3%) had heavy, regular uterine bleeding and 352 (36.4%) had heavy, irregular uterine bleeding.

During the 36 months following endometrial ablation, 16.3% of women (n = 158) had a gynecological procedure, 1.2% had a repeat ablation (n = 12), and 10.7% had a hysterectomy

(n = 104). We found no difference in the proportion of women who had a subsequent gynecological procedure or experienced treatment failure between women with heavy and regular vs heavy and irregular uterine bleeding (16.4% vs 17.6%,  $P = .7$ , and 12.6% vs 12.2%,  $P = .9$ , respectively). Women with a history of tubal ligation were more likely to experience treatment failure after endometrial ablation than those without a history of tubal ligation (16.4% vs 9.0%,  $P = .0008$ ). Women with dysmenorrhea or pelvic pain and women who were obese were more likely to experience treatment failure after ablation (21.8% vs 10.7%,  $P = .002$ , and 16.7% vs 9.8%,  $P = .003$ , respectively).

The odds of treatment failure for women with heavy and irregular uterine bleeding was not significantly increased compared with women with heavy and regular uterine bleeding (adjusted odds ratio [aOR], 1.07; 95% confidence interval [CI], 0.65–1.74). Compared with women without a previous tubal ligation, women with a tubal ligation were at an increased odds of both treatment failure and subsequent gynecological procedures (aOR, 1.94; 95% CI, 1.30–2.91, and aOR, 1.71; 95% CI, 1.20–2.43, respectively). Women with preoperative pelvic pain or obesity were also at increased odds of

treatment failure and gynecological procedures (aOR, 2.42; 95% CI, 1.44–4.06, and aOR, 1.93; 95% CI, 1.20–3.13 for pain; aOR, 1.82; 95% CI, 1.21–2.73, and aOR, 1.75; 95% CI, 1.22–2.50 for obesity, respectively) (Table).

## COMMENT

In our retrospective study comparing women with heavy irregular bleeding to women with heavy regular bleeding who underwent endometrial ablation, we did not find a difference in the incidence of treatment failure or gynecological procedures in the 3 years after endometrial ablation was performed. In addition, we found that a history of tubal ligation, pelvic pain or dysmenorrhea, and obesity were risk factors for treatment failure and additional gynecological procedures.

Tubal ligation is a well-established risk factor for hysterectomy after endometrial ablation secondary to post-ablation tubal sterilization syndrome. Preoperative pain caused by endometriosis, leiomyoma, or sources outside the reproductive tract would not be addressed by ablation, and previous studies have identified preoperative pelvic pain as a risk factor for hysterectomy after endometrial ablation. We chose to consider any hysterectomy for benign

indications after the performance of endometrial ablation to represent a failure of ablation. We still consider these cases as treatment failures because endometrial ablation failed to allow the patient to avoid hysterectomy and was not the final definitive procedure. This suggests that for patients with AUB and pelvic pain or dysmenorrhea, proceeding with hysterectomy as the initial surgical intervention may prove to be a better use of health care resources.

The main strengths of this study are our large sample size and investigation of a commonly encountered clinical situation that has been not been adequately studied. A limitation of this study is that with its retrospective cohort design we were limited to documentation by clinicians within the medical record.

Concern has been expressed that performing endometrial ablation on women

with AUB-O not only may yield unsatisfactory results but also could make it difficult to evaluate development of endometrial hyperplasia and cancer post-ablation. The results of this study do not suggest that endometrial ablation is a good option for all patients with AUB-O but rather that it may represent a reasonable option for a well-selected and counseled population of women with AUB-O.

In conclusion, we found similar rates of treatment failure after endometrial ablation in women with heavy and regular uterine bleeding and those with heavy and irregular bleeding. Women with a history of tubal ligation, pelvic pain, and obesity had an increased odds of treatment failure. Our results support that endometrial ablation may be appropriate for women with heavy and irregular bleeding (AUB-O) whose medical treatment have failed or do not

accept medical treatment and want to avoid the increased morbidity of a hysterectomy.

#### CLINICAL IMPLICATIONS

- Women with heavy and irregular bleeding did not have increased incidence of treatment failure compared with women with heavy and regular bleeding; therefore, carefully selected women may be appropriate candidates for endometrial ablation.
- Women with pelvic pain or dysmenorrhea, previous tubal ligation, and obesity had increased incidence of treatment failure; counseling such patients carefully about treatment options, including medical options and hysterectomy, might enhance the use of health care resources. ■

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