

# Preoperative uterine bleeding pattern and risk of endometrial ablation failure

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**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.

**Key words:** abnormal uterine bleeding, endometrial ablation, heavy and irregular uterine bleeding, heavy menstrual bleeding

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**A**bnormal uterine bleeding (AUB) is one of the most common gynecological symptoms for which women seek medical care.<sup>1,2</sup> The prevalence of heavy and irregular uterine bleeding has been increasing, largely because of an

increase in the prevalence of obesity and polycystic ovarian syndrome and their associated ovulatory dysfunction.<sup>3</sup> In women with AUB whose medical therapy has failed or are not suitable candidates for medical therapy, surgical management is limited to endometrial ablation and hysterectomy.<sup>4-6</sup>

Endometrial ablation has been shown to be an effective treatment for AUB-E, which is bleeding presumed secondary to endometrial hemostatic dysfunction. However, endometrial ablation studies have generally excluded women with irregular bleeding patterns suggestive of ovulatory dysfunction (AUB-O), and its effectiveness in this specific population is not established.<sup>5,7,8</sup> Women with AUB-O may be at higher risk for treatment failure than women with AUB-E because although the bleeding may become lighter, the continual endometrial proliferation and subsequent erratic bleeding patterns may continue because ablation does not result in

complete endometrial destruction. Endometrial ablation is not recommended as a first-line therapy for AUB-O,<sup>6</sup> but it is used in this population with proper counseling about its risks and benefits.

With the continued rise in the prevalence of obesity, data on clinical outcomes after endometrial ablation for women with AUB-O could better inform treatment decisions for a substantial population.

The objectives of this study were to determine whether preoperative bleeding pattern and other preoperative characteristics were associated with risk of treatment failure and subsequent gynecological procedures after endometrial ablation. We hypothesized that women with heavy and irregular uterine bleeding suggestive of AUB-O would have higher rates of both treatment failure and subsequent gynecological procedures after endometrial ablation compared with women with

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heavy and regular bleeding suggestive of AUB-E.

## 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. This study was approved by the Institutional Review Board of Women and Infants Hospital (no. 12-0051).

We collected demographic information, medical history, preoperative bleeding pattern, and surgical information from hospital and office records. The main independent variable, preoperative bleeding pattern (heavy and irregular or heavy and regular), was determined by a review of documentation in the hospital medical record and in history and physical examinations for the operating room. Office charts were reviewed when the bleeding pattern could not be sufficiently classified with the information available in the hospital medical record.

Because of confusion and misuse of terms such as menorrhagia, menometrorrhagia, and dysfunctional uterine bleeding, we did not rely on these terms to determine the regularity of the bleeding. Examples of terms that designated the bleeding such as regular included regular, monthly, predictable, cyclic, or a statement that bleeding occurred every X to Y days. Examples of terms that designated the bleeding such as irregular included irregular, unpredictable, erratic, ovulatory dysfunction, or anovulation. The main dependent variable, treatment failure, was defined as hysterectomy for any benign indication or repeat ablation within 36 months after the endometrial ablation. Our secondary dependent variable, subsequent gynecological procedures, was defined as endometrial biopsy, dilation and curettage, hysteroscopy, repeat ablation, or hysterectomy within 36 months after the endometrial ablation.

For our sample size calculations, we assumed an  $\alpha = 0.05$  and  $\beta = 0.2$ . We estimated sample size needed for a 1:1 to 3:1 ratio of women with heavy and

regular to women with heavy and irregular bleeding. We estimated a treatment failure rate of 15% at 3 years after endometrial ablation in women with heavy and regular bleeding based on previous studies.<sup>7,8</sup> We set the minimal detectable difference in treatment failure between groups at 10%. Based on these assumptions, we needed a minimum of 560 patients with analyzable data. To account for the missing data in this retrospective chart review, we planned to review at least 960 medical records.

Categorical variables were compared by  $\chi^2$  or Fisher exact test. Continuous variables were compared between groups by Student *t* test or Wilcoxon rank-sum test. Multiple logistic regression was used to estimate the adjusted odds ratios (ORs) and 95% confidence intervals (CIs) for the association of several variables with the outcome, treatment failure. All *P* values presented are 2 tailed, with *P* < .05 considered statistically significant.

## RESULTS

There were 968 records of women with endometrial ablations performed during the study period who were eligible for this review. Nine hundred sixty-one of the records (99.3%) were radiofrequency bipolar endometrial ablations. Two hundred ninety-three women (30.3%) were classified as having heavy and regular uterine bleeding and 352 (36.4%) as having heavy and irregular uterine bleeding. The bleeding pattern of 286 women (29.5%) could not be classified more specifically and was called heavy not otherwise specified. There were no significant differences in demographic or clinical characteristics between women with the different bleeding patterns (Table 1).

During the 36 months following endometrial ablation, 16.3% of the 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 uterine bleeding and women with heavy and

irregular uterine bleeding (16.4% vs 17.6%, *P* = .7 and 12.6% vs 12.2% *P* = .9, respectively) (Tables 2 and 3).

Women with a history of tubal ligation were more likely to experience treatment failure after endometrial ablation compared with women without a history of tubal ligation (16.4% vs 9.0%, *P* = .0008) (Table 3). Similarly, compared with their counterparts who did not have preoperative dysmenorrhea or pelvic pain or obesity, 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 incidence of having a gynecological procedure in the 36 months following endometrial ablation was also greater in patients with prior tubal ligation, preoperative pelvic pain, and obesity (Table 3).

Multiple logistic regression was performed to estimate odds of treatment failure and subsequent gynecological procedures. We adjusted for preoperative uterine bleeding pattern and factors found to be associated with our dependent variables in the univariate analyses (previous tubal ligation, dysmenorrhea or pelvic pain, and obesity). 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 OR [aOR], 1.07; 95% CI, 0.65–1.74). However, consistent with our univariate analysis, we did identify several other factors that were associated with treatment failure.

Compared with women without a previous tubal ligation, women with a tubal ligation were at increased odds of both treatment failure and subsequent gynecological procedures (aOR, 1.94; 95% CI, 1.30–2.91, 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 4).

## COMMENT

Endometrial ablation has been extensively studied in women with heavy and regular menstrual bleeding; however, most studies have excluded women with irregular bleeding patterns suggestive of AUB-O. In our retrospective study comparing women with heavy irregular bleeding with 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 year period after endometrial ablation was performed. Additionally, we found that a history of tubal ligation, pelvic pain or dysmenorrhea, and obesity were risk factors for treatment failure and additional gynecological procedures.

The goal of endometrial ablation procedures is to destroy the endometrium to the basalis layer. Endometrial ablation does not address the pathology underlying AUB-O, namely ovulatory dysfunction that leads to uninterrupted endometrial proliferation, which in turn causes the irregular bleeding pattern. Because of this, it would make sense that patients with heavy and irregular uterine bleeding may be less satisfied and thus more likely to seek additional treatment. However, we did not find a difference in treatment failure between women with irregular and women with regular bleeding patterns.

There are several possible explanations for why we did not find a difference between women with heavy and regular and women with heavy and irregular bleeding. The first explanation is that no difference exists, that the lighter bleeding after ablation, even if irregular in terms of predictability and timing, represents a satisfactory result for women who experienced heavy and irregular bleeding prior to their ablation.

An alternative explanation for this failure to find a difference is that the women with irregular bleeding in this retrospective cohort study may have been carefully selected as candidates for ablation by their physician based on the physician's clinical judgment that the patient would be likely to have a successful

**TABLE 1**  
**Characteristics of women who had an endometrial ablation during the study period (n = 968)**

Characteristic	Total <sup>a</sup>
Age, mean in years (SD)	42.7 (5.6)
Parity, median (range)	2.0 (0.0–6.0)
Obesity (BMI $\geq$ 30 kg/m <sup>2</sup> )	312 (33.3)
Race/ethnicity	
White	832 (87.9)
Black	35 (3.7)
Hispanic	49 (5.2)
Other	30 (3.2)
Insurance	
Private	785 (81.6)
Public	146 (15.2)
None	31 (3.2)
Tobacco use	197 (21.1)
Preoperative bleeding pattern	
Heavy/regular	293 (30.3)
Heavy/irregular	352 (36.4)
Heavy NOS <sup>b</sup>	286 (29.5)
Other	37 (3.8)
Polyps on preoperative ultrasound	221 (23.5)
Fibroids on preoperative ultrasound	187 (19.9)
Previous tubal ligation	391 (40.4)
Preoperative dysmenorrhea or pelvic pain	110 (11.4)
Subsequent gynecological procedures <sup>c</sup>	
Any intervention	158 (16.3)
Hysterectomy	104 (10.7)
Repeat ablation	12 (1.2)
Endometrial biopsy	25 (2.6)
Dilation and curettage	21 (2.2)
Hysteroscopy	18 (1.9)

BMI, body mass index; NOS, not otherwise specified.

<sup>a</sup> Data are n (column percentage) unless otherwise noted; <sup>b</sup> Heavy uterine bleeding, regularity/predictability not otherwise specified; <sup>c</sup> Gynecological procedures performed in the 36 months following endometrial ablation.

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procedure. It is possible that women with irregular bleeding, who in the opinion of their physician were deemed to be at high risk of failure, may have been counseled about this risk and chose not to have an endometrial ablation. Our 12% failure rate at 3 years is a bit lower than the

16–40% failure rate after 3–5 years<sup>4,7,8</sup> found in previous studies.

Similar to previous studies, we found that a history of tubal ligation and pelvic pain or dysmenorrhea were risk factors for treatment failure and additional gynecological procedures.<sup>7</sup> Tubal ligation

TABLE 2

**Characteristics of women with preoperative uterine bleeding symptoms that were classified as heavy and regular or heavy and irregular (n = 645)**

Characteristic	Heavy and regular (n = 293) <sup>a</sup>	Heavy and irregular (n = 352)	P value
Age, mean in years (SD)	42.6 (5.2)	43.2 (5.7)	.1
Parity, median (range)	2.0 (0.0–6.0)	2.0 (0.0–5.0)	.6
<b>BMI</b>			
Nonobese (<30 kg/m <sup>2</sup> )	189 (68.0)	218 (63.4)	.2
Obese (≥30 kg/m <sup>2</sup> )	89 (32.0)	126 (36.6)	
<b>Race/ethnicity</b>			
White	252 (88.4)	302 (87.3)	.3
Black	13 (4.6)	11 (3.2)	
Hispanic	10 (3.5)	23 (6.6)	
Other	10 (3.5)	10 (2.9)	
<b>Insurance</b>			
Private	237 (81.4)	286 (81.7)	.5
Public	42 (14.4)	55 (15.7)	
None	12 (4.1)	9 (2.6)	
Tobacco use	51 (18.1)	80 (23.4)	.1
Polyps on preoperative ultrasound	76 (26.3)	83 (24.1)	.6
Fibroids on preoperative ultrasound	69 (23.9)	65 (18.9)	.1
Previous tubal ligation	133 (45.4)	134 (38.1)	.07
Preoperative dysmenorrhea or pelvic pain	43 (14.7)	42 (11.9)	.3
<b>Subsequent gynecological procedures<sup>b</sup></b>			
Any intervention	48 (16.4)	62 (17.6)	.7
Hysterectomy	35 (11.9)	39 (11.1)	.8
Repeat ablation	2 (0.7)	4 (1.1)	.7
Endometrial biopsy	7 (2.4)	11 (3.1)	.6
Dilation and curettage	7 (2.4)	8 (2.3)	1.00
Hysteroscopy	5 (1.7)	8 (2.3)	.8

BMI, body mass index.

<sup>a</sup> Data are n (column percentage) unless otherwise noted; <sup>b</sup> Gynecological procedures performed in the 36 months following endometrial ablation.

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is a well-established risk factor for hysterectomy after endometrial ablation secondary to postablation tubal sterilization syndrome.<sup>9</sup> This syndrome is thought to result from retrograde menstruation into an obstructed fallopian tube.

Also, 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.<sup>7</sup> We chose to

consider any hysterectomy for benign indications after the performance of endometrial ablation to be a failure of ablation.

Our definition of treatment failure is not synonymous with dissatisfaction with uterine bleeding or persisting abnormal uterine bleeding. In this study, patients with preexisting pelvic pain or tubal ligation who underwent hysterectomy may have been completely satisfied with their bleeding yet were dissatisfied with pelvic pain after their 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 in this population may prove a better utilization of health care resources.

In contrast to other studies, we found that obesity was significantly associated with treatment failure. A retrospective cohort study of 666 women, including 263 obese women, did not find a difference in treatment failure between obese and nonobese women.<sup>10</sup> A smaller retrospective study of 66 women found a nonsignificant trend toward treatment failure in women with a body mass index greater than 34 kg/m<sup>2</sup>.<sup>11</sup> Our larger study population may have permitted the detection of this difference in treatment failure between obese and nonobese women. Although a previous study<sup>7</sup> identified age at ablation and parity as risk factors for failure, these factors were not associated with treatment failure in our study.

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. We were able to look at treatment failure and subsequent gynecological procedures within a retrospective cohort at our institution because our clinical population is extremely stable: census data have shown that more than 85% of Rhode Island residents stay in the same household from year to year.<sup>12</sup>

A limitation of this study is that with its retrospective cohort design, we

TABLE 3

Preoperative characteristics and subsequent gynecological procedures,<sup>a</sup> including treatment failure<sup>b</sup> (n = 968)

Preoperative characteristic	Any subsequent gynecological procedure <sup>c</sup>			Treatment failure		
	Yes	No	P value	Yes	No	P value
Preoperative bleeding pattern <sup>d</sup>						
Heavy and regular	48 (16.4)	245 (83.6)	.7	37 (12.6)	256 (87.4)	.9
Heavy and irregular	62 (17.6)	290 (82.4)		43 (12.2)	309 (87.8)	
Previous tubal ligation						
Yes	82 (21.0)	309 (79.0)	.001	64 (16.4)	327 (83.6)	.0008
No	76 (13.2)	501 (86.8)		52 (9.0)	525 (91.0)	
Dysmenorrhea or pelvic pain						
Yes	28 (25.5)	82 (74.5)	.009	24 (21.8)	86 (78.2)	.002
No	130 (15.2)	728 (84.8)		92 (10.7)	766 (89.3)	
BMI						
Nonobese (<30 kg/m <sup>2</sup> )	86 (13.8)	539 (86.2)	.001	61 (9.8)	564 (90.2)	.003
Obese (≥30 kg/m <sup>2</sup> )	69 (22.1)	243 (77.9)		52 (16.7)	260 (83.3)	
Polyps on ultrasound						
Yes	36 (16.3)	185 (83.7)	1.00	24 (10.9)	197 (89.1)	.6
No	116 (16.1)	604 (83.9)		88 (12.2)	632 (87.8)	
Fibroids on ultrasound						
Yes	37 (19.8)	150 (80.2)	.1	28 (15.0)	159 (85.0)	.2
No	115 (15.2)	640 (84.8)		84 (11.1)	671 (88.9)	

BMI, body mass index.

<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> Data are n (row percentage); <sup>d</sup> The preoperative bleeding pattern was n = 645.

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were limited to documentation by clinicians within the medical record. To avoid misclassification bias, which could lead to the spurious finding of no association between groups, we established stringent standardized criteria for the classification of bleeding pattern, and the bleeding pattern was determined by only the principal investigators. Selection bias was avoided by collecting data on all endometrial ablations performed at our institution during the time period, and we avoided ascertainment bias by either determining bleeding pattern before collecting data on subsequent gynecological interventions or having a separate reviewer classify the independent and dependent variables.

We were unable to assess patient satisfaction and quality of life after ablation

with this study design. The medical records lacked sufficient detail to classify the bleeding pattern for a large number of patients (33%); however, given that we reviewed a large number of medical records, we had adequate power to compare women with heavy and regular and heavy and irregular bleeding patterns.

We also did not collect data about the subsequent use of medical therapies (ie, oral hormonal agents or the levonorgestrel intrauterine device) for the treatment of bleeding or pain, which may also indicate a failure of the ablation. Finally, because 99.3% of our ablations were performed using radiofrequency bipolar endometrial ablations, our findings may not be generalizable to other types of endometrial ablations.

Concern has been expressed that performing endometrial ablations on women with AUB-O not only may yield unsatisfactory results but also could make it difficult to evaluate the development of endometrial hyperplasia and cancer for these women after the ablation. Long-term unopposed estrogen exposure, which can occur in the setting of obesity, polycystic ovarian syndrome, and chronic AUB-O may place patients at risk for future endometrial hyperplasia and cancer. One large study by Dood et al<sup>13</sup> addressing this specific clinical issue failed to show a difference in the incidence of endometrial cancer and interval from treatment to cancer diagnosis between women with AUB treated with ablation and treated with medical therapies.

TABLE 4

**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.

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Nevertheless, challenges in evaluating continued AUB after ablation and risk of hyperplasia remain a concern for women with AUB-O.

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. The American College of Obstetricians and Gynecologists states that “women with anovulatory uterine bleeding are candidates for endometrial ablation if they have failed medical therapy and have completed their childbearing.”<sup>6</sup> As we mentioned previously it is quite likely, especially given our low treatment failure rate, that patients in our cohort with AUB-O and multiple risk factors for endometrial hyperplasia were directed toward treatment options other than ablation.

In conclusion, we found similar rates of treatment failure after endometrial ablation in women with heavy and regular uterine bleeding and women 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 an appropriate treatment for women with heavy

and irregular bleeding (AUB-O) who have failed or do not accept medical treatment and want to avoid the increased morbidity of a hysterectomy. Better understanding factors associated with treatment failure and need for subsequent gynecological procedures after endometrial ablation will better inform the counseling of this prevalent population of women seeking treatment for AUB. ■

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