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% Cl, 1.30-2.91 and OR, 1.71; 95% Cl, 1.20-2.43, respectively); dysmenorrhea (OR, 2.42; 95% Cl, 1.44-4.06 and OR, 1.93; 95% Cl, 1.20—3.13, respectively); and obesity (OR, 1.82; 95% Cl, 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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bnormal uterine bleeding (AUB) is one of the most common gynecological symptoms for which women seek medical care.^{1,2} The prevalence of heavy and irregular uterine bleeding has been increasing, largely because of an

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© 2014 Elsevier Inc. All rights reserved. http://dx.doi.org/10.1016/j.ajog.2014.07.005 increase in the prevalence of obesity and polycystic ovarian syndrome and their associated ovulatory dysfunction.³ 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. 4-6

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. 5,7,8 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,6 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 irregular), 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.^{7,8} 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 χ^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% vs9.8%, 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).

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