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Hysterectomy Subsequent to Endometrial Ablation

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ABSTRACT **Study Objective:** To estimate the incidence of and factors associated with hysterectomy subsequent to endometrial ablation.
Design: Retrospective cohort study (Canadian Task Force classification II-2).
Setting: Gynecology practice.
Patients: Women who underwent endometrial ablation from January 2003 to June 2010, with a minimum follow-up of 9 months.
Interventions: Endometrial ablation and hysterectomy.
Measurements and Main Results: Of 1169 women, 157 (13.4%) underwent hysterectomy subsequent to endometrial ablation. Women who underwent subsequent hysterectomy were significantly younger at ablation (mean [SD; 95% CI] 39.0 [6.8; 38.0–40.1] years vs 41.4 [7.0; 41.0–41.9] years; $p < .001$) and were more likely to have previously delivered via cesarean section (26.3 vs 18.1%; $p = .02$). The rate of hysterectomy was significantly associated with the type of ablation performed: 33.0% for rollerball vs 16.5% for thermal balloon ($p = .003$), 11.0% for radiofrequency ($p < .001$), and 9.8% for cryoablation ($p < .001$). Time to hysterectomy also differed significantly based on the type of ablation performed ($p = .006$). Adenomyosis was present in 44.4% of hysterectomy specimens.
Conclusion: With a mean follow-up of 39 months, 13.4% of women underwent hysterectomy subsequent to ablation. Women who were younger at ablation had an increased likelihood of hysterectomy. Rate and time to hysterectomy were associated with the type of ablation performed. Journal of Minimally Invasive Gynecology (2012) 19, 459–464 © 2012 AAGL. All rights reserved.

Keywords: Adenomyosis; Cryoablation; Endometrial ablation; Hysterectomy; Radiofrequency; Rollerball; Thermal balloon

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Endometrial ablation has become an attractive minimally invasive alternative to hysterectomy in women with menorrhagia unresponsive to medical management. First-generation ablation techniques are hysteroscopy-dependent and include the use of lasers, loop resection, and rollerball coagulation. The newer second-generation devices do not rely on the hysteroscopic skill of the surgeon. The first device of this group, which consisted of heated fluid in a latex balloon, was approved by the US Food and Drug Administration (FDA) in 1997 [1]. Subsequent to its approval, other methods of performing endometrial ablation such as radiofrequency ablation, cryoablation, hydrothermal ablation, and microwave ablation have been introduced.

Although the rates of amenorrhea subsequent to endometrial ablation vary considerably in the literature, patient satisfaction due to decreased menstrual blood flow has been reported to be greater than 80% for most endometrial ablation devices, based on 12-month follow-up data from FDA clinical trials [2]. Nevertheless, a large number of women

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who undergo endometrial ablation require subsequent surgical intervention including hysterectomy. If factors predictive of hysterectomy could be identified, women could be counseled on a more individualized basis about the likelihood of subsequent hysterectomy. The objective of the present study was to collect data from a large cohort of women who underwent endometrial ablation to estimate the incidence, timing, and factors associated with hysterectomy subsequent to endometrial ablation.

Materials and Methods

This was a retrospective cohort study approved by the Institutional Review Board of Baylor Research Institute (Fort Worth, TX) that included premenopausal women who underwent endometrial ablation because of menorrhagia from January 2003 to June 2010. Endometrial ablation was performed according to FDA-approved indications in women who were not pregnant, who did not desire to become pregnant, who had not previously delivered via classic cesarean section or underwent transmural myomectomy, and who had a preablation endometrial biopsy that confirmed benign endometrium.

First-generation (rollerball endometrial ablation) and second-generation endometrial ablation procedures were performed during the study period. Second-generation endometrial ablation procedures consisted of radiofrequency endometrial ablation (NovaSure; Hologic (Cytyc) Corp., Marlborough, MA), thermal balloon endometrial ablation (Gynecare ThermaChoice II and III; Ethicon, Inc., Sommerville, NJ), cryoablation (Her Option; American Medical Systems, Inc., Minnetonka, MN), and hydrothermal endometrial ablation (HydroThermAblator, Boston Scientific Corp., San Diego, CA). The type of endometrial ablation was determined by the treating physician. Endometrial ablations were performed by 25 physicians with a minimum of 10 years of private practice experience. No residents or fellows were involved in patient care. Endometrial ablation was performed as an outpatient procedure in a hospital, surgical center, or office setting.

Patients were identified for inclusion on the basis of Current Procedural Terminology codes for endometrial ablation. Medical records were reviewed systematically to extract demographic and clinical characteristics for each patient, including age at endometrial ablation, gravidity, parity, race/ethnicity, history of cesarean section delivery or tubal ligation, and endometrial disease present before ablation. In addition, pelvic ultrasound findings including endometrial thickness and uterine length, and the presence, number, size, and location of uterine myomas were recorded. Procedural data collected consisted of the type of endometrial ablation performed, location of the procedure, uterine depth measured during the procedure, and the surgeon who performed the procedure.

Patients who underwent hysterectomy subsequent to endometrial ablation were identified by searching both office and hospital medical records. For those who underwent subsequent hysterectomy, the indication(s) for hysterectomy, type of hysterectomy performed, presence of adenomyosis, uterine weight, and interval in months between hysterectomy and endometrial ablation were recorded. Time between data collection and endometrial ablation was tabulated for each patient, and only those with a minimum of 9 months of follow-up were included in the analysis.

Data were entered into a database (SPSS version 19.0 for Windows; SPSS, Inc., Chicago, IL), and were analyzed using the Pearson χ^2 test and the Fisher exact test for categorical variables, and the *t* test for continuous variables. Normality was assessed using the Shapiro-Wilks test, and the Mann-Whitney U test was used for nonnormally distributed measures. Post hoc pairwise comparisons were performed using the Holm-Bonferoni method. Forward stepwise logistic regression was used to account for the effect of specific categorical variables on the probability of hysterectomy after ablation. Median values were used as cut-points, when applicable. Kaplan-Meier survival analysis and life table analysis comparing ablation with hysterectomy interval by ablation type were conducted to account for the potential for longer follow-up for ablation techniques that were available earlier. Cox proportional hazard regression was used to model the effect of type of ablation on time to hysterectomy. Data are given as mean (SD) and hazard ratio (HR), with 95% confidence interval (CI), except when otherwise noted. Statistical significance was considered at $p < .05$.

Results

From January 2003 through June 2010, 1169 women who underwent endometrial ablation were identified for inclusion in the present study. Time from endometrial ablation to data extraction ranged from 9 to 84 months (mean [SD], 39.3 [19.8] months; median, 39 months). Age of the women who underwent endometrial ablation was 41.1 [7.0] years (median, 41 years), with median gravidity of 2 (range, 0–9) and parity of 2 (range, 0–8). Most patients (90.9%) were white, 19.1% had previously delivered via cesarean section, and 57.7% had previously undergone tubal ligation.

Pathologic results from endometrial biopsy samples obtained before endometrial ablation were available for 90.2% of patients. Benign pathologic findings were identified in 96.4% of patients, polyps in 1.9%, and hyperplasia in 1.7%. At pelvic ultrasound, mean (SD; 95% CI) endometrial thickness was 10.3 (5.5; 9.93–10.63) mm, uterine length was 7.9 (1.9; 7.76–8.03) cm, and myomas were identified in 39.6% of women.

First-generation rollerball endometrial ablation was performed in 94 of 1162 patients (8.1%). Of second-generation endometrial ablations performed, 74.9% were radiofrequency endometrial ablations (NovaSure), 16.5% were thermal balloon endometrial ablations (ThermaChoice), 7.7% were cryoablations (Her Option), and 0.9% were hydrothermal endometrial ablations (HydroThermAblator).