Probability of Hysterectomy After Endometrial Ablation

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OBJECTIVE: To investigate risk factors for hysterectomy after endometrial ablation.

METHODS: This was a retrospective cohort analysis of data from Kaiser Permanente Northern California members, aged 25–60 years undergoing endometrial ablation from 1999 to 2004 and collected through 2007. Risk factors assessed included age, presence of leiomyomas, setting of procedure (inpatient or outpatient), and type of endometrial ablation procedure (first generation, radio frequency, hydrothermal, or thermal balloon). Univariable and survival analyses were performed to identify risk factors and estimate probability of hysterectomy.

RESULTS: From 1999 to 2004, 3,681 women underwent endometrial ablation at 30 Kaiser Permanente Northern California facilities. Hysterectomy was subsequently performed in 774 women (21%), whereas 143 women (3.9%) had uterine-conserving procedures. Age was a significant predictor of hysterectomy ($P<.001$). Cox regression analysis found that compared with women aged older than 45 years, women aged 45 years or younger were 2.1 times more likely to have hysterectomy (95% confidence interval 1.8–2.4). Hysterectomy risk increased with each decreasing stratum of age and exceeded 40% in women aged 40 years or younger. Overall, type of endometrial ablation procedure, setting of endometrial ablation procedure, and presence of leiomyomas were not predictors of hysterectomy. In analysis of individual procedure types, concomitant myomectomy was associated with a decreased risk of hysterectomy for patients receiving first-generation endometrial ablation ($P=.002$), and outpatient location for hydrothermal endometrial ablation increased hysterectomy risk ($P<.001$).

CONCLUSION: Age is more important than type of procedure or presence of leiomyomas in predicting subsequent hysterectomy after endometrial ablation. Women undergoing endometrial ablation at younger than 40 years of age are at elevated risk of hysterectomy, and rather than plateauing within several years of endometrial ablation, hysterectomy risk continues to increase through 8 years of follow-up.

(Obstet Gynecol 2008;112:1214–20)

LEVEL OF EVIDENCE: II

Menorrhagia is a major health problem confronting premenopausal women and is the most common reason for gynecologic visits in the United States.[1] Historically, when medical therapy for menorrhagia failed, hysterectomy was the primary surgical option. Destruction of the endometrium by endometrial ablation has emerged as a minimally invasive alternative to hysterectomy. Several randomized controlled studies have found that first-generation endometrial ablation techniques offer promising short-term results and are reasonable alternatives to hysterectomy for menorrhagia.[2–4] First-generation transcervical hysteroscopic methods include resection and ablation procedures (laser, loop resection, rollerball cautery). Newer nonhysteroscopic techniques involving heated fluid, thermal balloon, radio frequency, microwave energy, or cryotherapy have been developed as technically easier alternatives than hysteroscopy-based methods. A recent Cochrane review concluded that success rates and complication profiles of newer techniques compared favorably with first-generation methods, although they included limited data on hysterectomy rates beyond 2 years.[5] Without long-term follow-up it is difficult to accurately counsel patients on whether endometrial ablation techniques are more likely to replace, or merely delay, hysterectomy.

Few studies provide long-term comparative data. Published reports focus primarily on first-generation

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Supported by Kaiser Permanente Northern California.

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Financial Disclosure
The authors have no potential conflicts of interest to disclose.

ISSN: 0029-7844/08

methods and describe a wide range of hysterectomy rates ranging from 8–29% beyond 5 years.[6–13] Most follow-up data come from practices and centers focused on minimally invasive surgery and may not reflect the actual effectiveness of endometrial ablation procedures in a more representative sample of practicing gynecologists. To improve our knowledge of how best to counsel patients considering endometrial ablation, we conducted a large retrospective cohort analysis in a large managed care organization. Our goal was to estimate the relative importance of age, type endometrial ablation, procedure setting, and presence of leiomyomas in predicting endometrial ablation failure as defined by subsequent hysterectomy.

MATERIALS AND METHODS

Study data were collected from the Kaiser Permanente Northern California program. Kaiser Permanente Northern California is a prepaid group-model managed care organization that provides comprehensive medical services to approximately 30% of the Northern California population and is demographically representative of that population.[14] Recent Kaiser Member survey data note that for female members older than age 20 years, 62% are Caucasian, 7% are African American, 12% are Hispanic, 16% are Asian; 4% have less than 12 years education, 15% are high school graduates, 41% have some college, 40% are college graduates, 42% have annual household income less than $50,000, and 71% are married or living as part of a couple. Kaiser Permanente Northern California members are cared for exclusively by physicians and allied health professionals in The Permanente Medical Group, a multispecialty medical partnership of more than 5,500 physicians, including approximately 500 gynecologists.

The study used data from three comprehensive computerized clinical databases maintained by Kaiser Permanente Northern California. The Admissions, Discharge and Transfer hospitalization database contains records of discharge diagnoses and procedures coded using International Classification of Diseases, 9th Revision (ICD-9) codes. This database captures procedures performed in Kaiser Permanente Northern California ambulatory surgical centers. Outpatient visits are coded in the Outpatient Summary Clinical Record database, which includes provider-coded reasons for visits as well as the Physicians' Current Procedural Terminology Coding System codes for outpatient procedures. Late in 2004, Kaiser Permanente Northern California implemented the Kaiser Permanente HealthConnect system. Kaiser Permanente HealthConnect is a highly sophisticated information management and care delivery system that replaced the Admissions, Discharge and Transfer and Outpatient Summary Clinical Record systems. A separate database is maintained for descriptive pathology reports.

All endometrial ablations performed from January 1999 to December 2004 were identified. Study eligibility was limited to women aged 25.0 to 60.0 years at the time of endometrial ablation. Inpatient endometrial ablations were identified from the Admissions, Discharge and Transfer database using ICD-9 code 68.23 listed as the primary procedure. Outpatient endometrial ablation was identified from the Outpatient Summary Clinical Record database using appropriate Physicians' Current Procedural Terminology Coding System codes. For inpatient endometrial ablation, leiomyoma was diagnosed if the discharge diagnosis included an appropriate ICD-9 code (218.x) in any position for leiomyoma in the Admissions, Discharge and Transfer database. For outpatient endometrial ablation, leiomyoma was diagnosed if similar codes for leiomyoma were found in any position in Outpatient Summary Clinical Record database at the time of endometrial ablation.

During the study period there were no Kaiser Permanente Northern California policies or guidelines regarding management of menorrhagia, preoperative evaluation for endometrial ablation, or favoring a particular type of endometrial ablation. Each facility independently decided whether they would offer or encourage development of local expertise for any particular type of endometrial ablation. These decisions were local and depended on budgetary and discretionary decisions of local leadership. We surveyed departmental leadership at all Kaiser Permanente Northern California facilities that performed endometrial ablation to determine which technique(s) were available during the study period for the inpatient and outpatient settings. In Kaiser Permanente Northern California, the first thermal balloon endometrial ablation procedures started in 1999, hydrothermal endometrial ablation started in 2001, and radio-frequency endometrial ablation started in 2002.

Resection and ablation first-generation endometrial ablation procedures were grouped together in the database. Laser endometrial ablation was not performed at any facility. Nonhysteroscopic second-generation endometrial ablation procedures included thermal balloon endometrial ablation (Thermachoice, Ethicon Inc., Menlo Park, CA), hydrothermal endometrial ablation (HydroThermAblator, Boston Scientific, Natick, MA); and radio-frequency endometrial ablation (NovaSure, Cytyc Surgical Products, Palo Alto, CA). Eight cryoablation endometrial ablations

were performed at a single facility, and these were excluded from analysis. First-generation and thermal balloon endometrial ablation were only performed as inpatient procedures. Hydrothermal and radio-frequency endometrial ablation were performed as both inpatient and outpatient procedures. We reviewed computerized electronic records for individual patients to verify whether the endometrial ablation procedure was actually performed and to classify the type of procedure used. Coding during this time did not allow differentiation of endometrial ablation type, therefore we identified procedure type using electronically accessible pathology reports, outpatient clinic visits, radiology reports, and operative reports. For facilities that offered more than one type of endometrial ablation procedure, if the type of endometrial ablation could be verified in at least 95% of cases, then those identified were classified by specific procedure type. However, if verification of the specific type of endometrial ablation was less than 95%, then all cases were assigned to the unclassified group. We required a high level of accuracy for procedure classification to limit detection bias from hysterectomy operative reports.

All women undergoing hysterectomy after the initial endometrial ablation were identified by searching the Admissions, Discharge and Transfer and Kaiser Permanente HealthConnect databases through December 2007 using the appropriate ICD-9 codes. Women who had repeat endometrial ablation, uterine artery embolization, or myomectomy after the initial endometrial ablation were also identified through December 2007. Repeat endometrial ablations were identified for both inpatient and outpatient procedures as outlined. Uterine artery embolizations were identified as previously described.[15] Myomectomy procedures were identified by searching the Admissions, Discharge and Transfer and Kaiser Permanente HealthConnect databases for ICD-9 code 68.29. Univariable analysis was used to compare risk factors for hysterectomy in the study cohort. Analysis included Student t tests for continuous variables and χ^2 or Fisher exact tests for categorical variables. We also compared the hysterectomy rates among the six types of endometrial ablation in pairs using Fisher exact test adjusted for multiple comparisons by the permutation resampling method. All tests were two-tailed; $P<.05$ was considered to indicate statistical significance. Estimates of risk (hazard ratios) were computed using Cox proportional hazards models. The probability of hysterectomy after an initial endometrial ablation was estimated using the life-table method. Log rank tests were used to test for differences in survival curves by age group, presence of leiomyoma, setting of procedure, and endometrial ablation type. For life-table analysis, women were censored at the time of hysterectomy, death, termination of Kaiser Permanente Northern California membership, or if none of these occurred, then at end of study period (December 31, 2007). Statistical software (SAS 9.1, SAS Institute, Cary, NC) was used for analyses. The Kaiser Permanente Northern California Institutional Review Board approved this study on October 17, 2006.

RESULTS

We identified 4,046 women who underwent endometrial ablation between January 1999 and December 2004, of whom 365 were excluded after electronic chart review indicated than an endometrial ablation procedure was not performed (most were miscoded endometriosis ablations). The remaining 3,681 cases analyzed were performed at 30 Kaiser Permanente Northern California facilities (Table 1). Procedures were performed by 344 physicians (mean 10.7, median 6.0). The mean age (±standard deviation) of participants was 44.3±6.2 years. Presence of leiomyomas was noted in 742 (20.2%). There were 2,735 (74.3%) inpatient procedures, and the first outpatient procedure identified was in January 2002. All first-generation procedures were done as inpatients and included both resection and ablation techniques. For hydrothermal endometrial ablation procedures, 92 (14.8%) were done as inpatients, and for radio-fre-

Table 1. Univariable Analysis of Potential Risk Factors for Hysterectomy After Endometrial Ablation

Characteristic	No Hysterectomy	Hysterectomy	*P*
Total patients	2,907 (79)	774 (21)	
Age (y)			
Mean	44.8	42.5	<.001
Younger than 40	594 (71.5)	237 (28.5)	<.001
40–44.9	850 (74.4)	294 (25.6)	
45–49.9	919 (83.8)	178 (16.2)	
50 or older	544 (80.3)	65 (10.7)	
Endometrial ablation technique			.17
First generation	507 (77.5)	147 (22.2)	
Hydrothermal	505 (81.5)	115 (18.5)	
Radio frequency	319 (79.9)	80 (20.1)	
Thermal balloon	68 (86.1)	11 (13.9)	
Unclassified	1507 (78.2)	421 (21.8)	
Endometrial ablation technique			.19
Leiomyoma	573 (77.2)	169 (22.8)	
No leiomyoma	2334 (79.4)	605 (20.6)	
Surgical setting			.99
Inpatient	2160 (79)	575 (21)	
Outpatient	747 (79)	199 (21)	

Data are n (%) unless otherwise specified.

quency endometrial ablation procedures, 381 (95.5%) were inpatient. All thermal balloon endometrial ablation procedures were done as inpatients. For endometrial ablation procedures that could not be classified, 1,528 (79.3%) were inpatient, and 721 (37.4%) were before 2002.

Seven hundred seventy-four women (21%) had hysterectomy after endometrial ablation. One hundred forty-three (3.9%) had a repeat uterine conserving procedure: 106 (2.9%) repeat endometrial ablation, 23 (0.6%) uterine artery embolization, 14 (0.4%) myomectomy. Women aged younger than 40 years were not more likely than older women to have a repeat uterine conserving procedure, (3.73% compared with 3.72%, $P=.99$). Table 1 shows the results of univariable analysis to assess potential risk factors for subsequent hysterectomy. Only age was a significant risk factor when analyzed as either continuous or categorical variable ($P<.001$). Type of endometrial ablation was not a risk factor ($P=.17$). We also compared hysterectomy rates among the six types of endometrial ablation in pairs using Fisher exact tests adjusted for multiple comparisons and no statistically significant differences were found (P values ranged from .36–.99). Univariable analyses to assess potential risk factors for subsequent hysterectomy were repeated for each type of endometrial ablation. The results were similar with one exception, for hydrothermal endometrial ablation procedures 4.3% of inpatient procedures had hysterectomy compared with 21% of outpatient procedures ($P<.001$).

Among the 2,183 inpatient endometrial ablation procedures, 264 (21%) were concomitantly coded for myomectomy. There were 113 (22.4%) myomectomies among the first-generation endometrial ablation cases and 135 (22.1%) among the unclassified endometrial ablation group. There were too few myomectomies among the inpatient hydrothermal, radio-frequency and thermal balloon endometrial ablation groups (n=16 for all) to analyze. The hysterectomy rate was significantly lower for women who had first-generation endometrial ablation and myomectomy compared with women who did not have myomectomy (14.2% compared with 24.2%, $P=.02$). The hysterectomy rate was also lower for the unclassified group who had myomectomy, but the difference was not statistically significant (17.8% compared with 22.5%, $P=.21$).

Indication for hysterectomy was identified in 754 (97.4%) of the cases. The most common indications were vaginal bleeding in 389 (51.6%), pain in 166 (22%), and vaginal bleeding with pain in 153 (20.3%). Other additional indications included suspicion of cancer/precancer in 19 (2.5%), prolapse/incontinence in 37 (2.5%), infection in two (0.3%), and suspicion of adnexal pathology in 19 (2.5%). Pathology reports were available for 728 (94.1%) of the hysterectomy cases. The most common findings included leiomyomas in 243 (33.4%); adenomyosis in 172 (23.6%); leiomyomas and adenomyosis in 163 (22.4%); and no significant pathology was noted in 123 (16.9%). Additional findings included endometriosis in 51 (7%) and cancer/precancer in 12 (1.6%). Polyps were noted in 15 (2.1%) specimens, but was the sole diagnosis in only four.

Survival analysis using the life-table method was performed to assess probability of hysterectomy after endometrial ablation. Figure 1 shows cumulative and endometrial ablation type-specific survival analysis. Probabilities of hysterectomy at 1, 2, 5, and 8 years were 9.3%, 14.4%, 22.2%, and 26.2%, respectively. There was no statistically significant difference between endometrial ablation types ($P=.63$). Survival analysis showed no statistically significant differences by presence of leiomyomas ($P=.24$) or location of procedure ($P=.19$). Figure 2 shows survival analysis for age, which was a significant risk factor ($P<.001$). Probability of hysterectomy 8 years after endometrial ablation was 12% for women aged older than 50 years at time of endometrial ablation, 19.8% for women aged 45–49.9 years, 31% for women aged 40–44.9 years, and 40.6% for women aged younger than 40 years.

Survival analysis was performed for each type of endometrial ablation individually. Age was a statistically significant risk factor for first-generation endometrial ablation ($P<.001$), hydrothermal endometrial ablation ($P<.001$), and unclassified endometrial ablation ($P<.001$), but not for thermal balloon endometrial ablation ($P=.73$) and radio-frequency endometrial ablation ($P=.11$). Presence of leiomyomas was

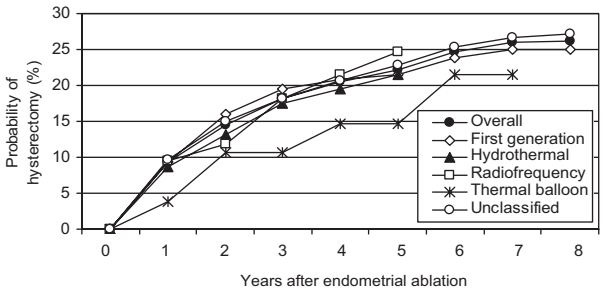

Fig. 1. Probability of hysterectomy by endometrial ablation technique: life-table method. Log rank test, $P=.63$.

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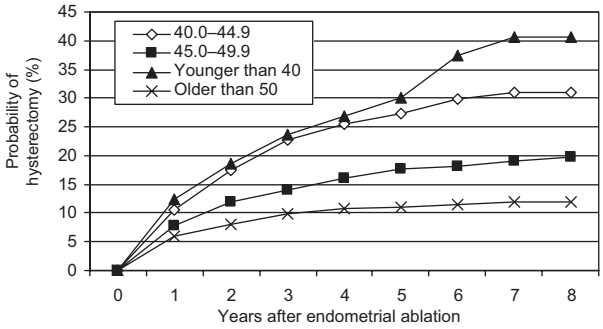

Fig. 2. Probability of hysterectomy by age group: life-table method. Log-rank test, $P<.001$.

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not statistically significant for any individual type of endometrial ablation. Only radio-frequency endometrial ablation and hydrothermal endometrial ablation were performed in both the inpatient and outpatient settings. Survival analysis found no statistically significant difference by location for radio-frequency endometrial ablation ($P=.81$). However, for hydrothermal endometrial ablation there was a statistically significant difference between settings ($P<.001$), with the probability of hysterectomy at 4 years 5.9% for inpatient procedures and 21.9% for outpatient procedures.

Cox proportional hazards regression analysis was completed to evaluate whether age or endometrial ablation type was predictive for hysterectomy. None of the individual endometrial ablation types were a statistically significant risk factor for hysterectomy (data not shown). Cox regression analysis with age dichotomized found that women aged 45 years or younger were significantly more likely to have hysterectomy (hazard ratio 2.1, 95% confidence interval 1.8–2.4). Hysterectomy risk varied across finer age classifications (younger than 40 years, 40–44 years, 45–59 years, 50 years or older), the highest being in women aged younger than 40 years (hazard ratio 3.2, 95% confidence interval 2.4–4.2) when compared with women aged 50 years or older.

DISCUSSION

Of the 3,681 women in our cohort, the probability of hysterectomy at 8 years was 26%; however, the majority were done within 3 years of endometrial ablation. This is similar to studies by Fürst et al[8] and Comino et al,[11] who reported on women from 6 to 10 years after endometrial ablation and noted most hysterectomies were done within 2 years of endometrial ablation. The most important risk factor we identified for hysterectomy following endometrial ablation was age at time of procedure, with increasing age having a lower probability of subsequent hysterectomy. This finding is consistent with findings from previous studies showing that after first-generation endometrial ablation women aged younger than 35 years were more likely to undergo hysterectomy than women aged older than 45 years and that endometrial ablation symptom relief was better with increasing age.[9,16–19] Importantly, for the youngest women in our cohort (aged younger than 40 years), the risk of hysterectomy did not plateau after 5 years; it continued to increase through all 8 years of follow-up.

Interestingly, we found that the probability of hysterectomy after hydrothermal endometrial ablation was much greater if performed in the outpatient setting compared with the inpatient setting, with hysterectomy rates at 4 years of 21.9% and 5.9%, respectively. A randomized control trial comparing hydrothermal endometrial ablation in the outpatient setting with "rescue analgesia" to day case procedures with general anesthesia found that outpatient procedures could be completed in 87%.[20] Radio-frequency endometrial ablation was the only other procedure performed in both settings, with probability of hysterectomy after 3 years being 17.9% for inpatient procedures and 22.2% for outpatient procedures. The explanation for this difference is not clear, although it is possible that less thorough procedures are performed in the outpatient setting for hydrothermal procedures due to issues related to pain control.

More than 20% of our cohort had a history of leiomyomas, although their presence was not found to be a risk factor for subsequent hysterectomy. It is difficult to compare and assess leiomyomas as a risk factor because of the variable exclusion criteria used for size and/or location of leiomyomas in our centers. Product labeling for the second-generation techniques used note that safety and effectiveness has not been fully evaluated for patients with submucous leiomyomas. The American College of Obstetricians and Gynecologists (ACOG) Practice Bulletin[21] referred to a single randomized controlled trial supporting the use of thermal balloon endometrial ablation with submucosal leiomyomas up to 3 cm, and several small reports suggest the presence of submucosal leiomyomas less than 3–4 cm may not be an absolute contraindication.[22–24] Comino et al[11] followed 89 women who underwent first-generation endometrial ablation for at least 6 years and found the presence of leiomyomas was a risk factor for hysterectomy. The lower hysterectomy rate for first-generation endometrial ablation with concomitant myomectomy was a surprising finding. It is possible that the symptoms

prompting endometrial ablation were primarily due to submucous leiomyomas that might have responded to resective myomectomy alone.

Our results revealed no differences in long-term hysterectomy rates among endometrial ablation modalities. This is consistent with results from randomized controlled trials comparing radio-frequency and thermal balloon endometrial ablation, radio-frequency and first-generation endometrial ablation, hydrothermal and first-generation endometrial ablation, and thermal balloon and first-generation endometrial ablation that found similar success using quality of life and bleeding diary scores.[6,25–27] Additionally, a recent Cochrane review[5] of endometrial ablation techniques concluded that existing evidence suggests that the newer second-generation techniques compare favorably with the criterion standard first-generation techniques.

Our study has several limitations related to coding accuracy. Our electronic database review identified and excluded 365 (9%) who were miscoded as having an endometrial ablation procedure when instead most had ablation of endometriosis. During the study period, unique codes for each different endometrial ablation technique did not exist, and review of electronic medical records only allowed us to determine the specific endometrial ablation technique in just one half of the cases, which could have affected results of our analyses for individual endometrial ablation techniques. It is reassuring that life-table analysis of hysterectomy rates in the unclassified group was similar to other techniques. We did not differentiate between resection and ablative first-generation endometrial ablation techniques. Identification of leiomyomas relied on accurate coding, and we could not assess size or location of leiomyomas, although it did not seem that presence of leiomyomas was a risk factor for hysterectomy. However, the lower hysterectomy rate for first-generation endometrial ablation procedures performed with concomitant myomectomy warrants further investigation. We could not compare preoperative preparation, treatment protocols, complication rates, or experience of providers at the different facilities. Some studies have suggested higher success with less pretreatment menorrhagia or smaller uterine cavity, neither of which we could assess.[16] Two studies suggested previous tubal ligation was a risk factor for hysterectomy, which we could not assess.[9,19]

In our study we defined endometrial ablation failure as the need for subsequent hysterectomy. However, this definition is likely to underestimate the true rate of dissatisfaction. A more robust definition would include all subsequent procedures for menorrhagia and the rate of dissatisfaction in endometrial ablation patients subsequently requiring medication. We did not assess any quality-of-life measures.

The strengths of our study derive from the size and diversity of our population of patients and clinicians. Our cohort of more than 1,500 classified procedures comprises significantly more patients than most other studies, including 655 first-generation endometrial ablations, 620 hydrothermal endometrial ablations, 399 radio-frequency endometrial ablations, and 79 thermal balloon endometrial ablation procedures. The Kaiser Permanente Northern California membership is relatively stable, allowing long-term outcomes to be determined. The databases used for our analysis are robust and complete, and we supplemented verification with electronic medical records when available. Our long-term outcomes representing the experience of a large geographic region in a diverse group of practicing gynecologists will permit more accurate counseling of women than data from centers and providers focused on performing a single endometrial ablation method.

We conclude that endometrial ablation for menorrhagia permits uterine conservation in more than 80% of women over age 45 years when followed up to 8 years. For women aged younger than 40 years, probability of hysterectomy is 40%, and rather than plateauing, it continues to increase throughout all 8 years of follow-up. Age at the time of endometrial ablation is more important than type of procedure or presence of leiomyomas in predicting subsequent hysterectomy. Additional studies with longer follow-up are necessary to determine whether endometrial ablation is more likely to replace, or merely delay, hysterectomy in women aged younger than 40 years at the time of the procedure.

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