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ORIGINAL ARTICLE

Prognostic factors that predict success in office endometrial ablation: a retrospective study

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Abstract The objective of the cohort study was to identify clinical factors that influence the rate of further surgical intervention in women who had endometrial ablation. Electronic databases and patient records were scrutinised to obtain examination, investigative and procedural data considered to be potentially predictive of the need for further surgical intervention after endometrial ablation in the office setting. A total of 391 consecutive women were identified who received endometrial ablation in the office setting between July 2005 and December 2012, with an average follow-up of 4.3 years. Univariable and multivariable logistic regressions were used to estimate the influence of these variables on prognosis. Factors predictive of further surgical treatment were dysmenorrhea (odds ratio [OR] 4.01; 95 % CI 1.63 to 9.91) and a uterine cavity length >9 cm (OR 2.65; 95 % CI 1.33 to 5.27). In conclusion, dysmenorrhoea before treatment or a uterine cavity length >9 cm was associated with the need for further surgical interventions after office endometrial ablation. These findings should help inform clinician and patient upon decision-making when considering treatment options for heavy menstrual bleeding.

Keywords Endometrial ablation · Office endometrial ablation · Predictive factors · Prognosis

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Introduction

Heavy menstrual bleeding is a common gynaecological condition that has a significant impact on the morbidity of premenopausal women [1, 2]. In the majority of cases, no organic cause is found, and this is termed dysfunctional uterine bleeding. The first-line therapy for dysfunctional uterine bleeding is pharmacological treatment [3]. If this fails, it is appropriate to perform an endometrial ablation [3]. The uterine sparing ablative procedure has the advantage that it can be performed in the office setting and does not have the costs, morbidity and mortality associated with major surgery [4]. However, in contrast to hysterectomy, endometrial ablation cannot guarantee amenorrhea and the need for further surgical intervention, usually in the form of a hysterectomy which is well recognised [5]. A randomised controlled trial (RCT) comparing the two most commonly used second generation ablative devices, bipolar radiofrequency ablation and thermal balloon ablation, showed satisfaction rates of 90 % and 79 % respectively at 1-year follow-up [6]. However, after five years, there were eight women in the bipolar radiofrequency group (9.8 %) and five in the thermal balloon ablation group (12.9 %) who had undergone a hysterectomy [6].

If it were possible to predict the chance of such treatment failure following endometrial ablation, then alternative, potentially more effective, treatment interventions could be considered. Two earlier studies evaluating treatment outcomes after second generation endometrial ablation as an inpatient under general anaesthesia have provided evidence that prognostic variables may be identified from information gleaned from the patient history, examination and uterine imaging [7, 8]. Both studies identified dysmenorrhea and enlarged uterine cavity size as predictive of treatment failure, although the results for age, parity and tubal sterilisation were conflicting [7, 8]. While a meta-analysis of second generation

endometrial ablation found that only uterine cavity length of >8 cm had an adverse impact on patient satisfaction [9].

In light of these inconsistent findings and the increasing adoption of the office setting to conduct endometrial ablation [10, 11], we studied our cohort of office endometrial ablations. Our objective was to identify pre-treatment clinical factors that predict the need for further intervention in women who have had endometrial ablation in the office setting.

Methods

We performed an observational analysis of 391 patients. The analysis included the following data parameters for each patient: age, body mass index (BMI), caesarean section, ablation type, duration of symptoms, uterine size, regularity of cycle, dysmenorrhea, premenstrual syndrome, antiplatelet medication, failed medical therapy, cycle phase, uterine axis, fibroids on imaging or examination, hysteroscopy findings and further surgical intervention. Data for 81 patients were collected prospectively as part of the comparison of office ablation techniques trial [10, 12], while data for the remaining 310 patients were collected retrospectively by scrutinising medical records.

All women who underwent endometrial ablation in the office setting at the Birmingham Women's Hospital, between July 2005 and December 2012 were included in the analysis. Women who had undergone office endometrial ablation for heavy menstrual bleeding were identified through the surgical logbooks. Endometrial ablations were done using either thermal balloon ablation (Thermachoice™; Gynecare™; Ethicon™ Inc., New Jersey, USA) or bipolar radiofrequency ablation (NovaSure™; Hologic™, Bedford, MA, USA).

The office endometrial ablative procedure has been previously described [10, 12]. In short, women were pre-medicated one hour before the procedure with either 100 mg diclofenac rectal suppository (or 100 mg oral tramadol hydrochloride if contraindicated) or two oral tablets of Co-dydramol 10 mg/500 mg and 50 mg of oral cyclizine. A direct intracervical block was administered by infiltrating 2.2 ml of 3 % mepivicaine into the 12 and 6 o'clock positions before infiltrating 1.1 ml into the 3 and 9 o'clock positions, using a 35 mm, 27 gauge dental syringe; the majority of the solution was infiltrated at the level of the internal os with the rest evenly distributed along the length of the cervix on withdrawal of the needle. A preliminary diagnostic hysteroscopy was performed to exclude pathology that would distort the intrauterine cavity and to ascertain likely compliance to the procedure, and the uterine length was sounded. This was followed by endometrial ablation with bipolar radiofrequency ablation or thermal balloon ablation, performed according to the recommended manufacturer's instructions for use.

Data were analysed using the SPSS statistical software version 21 (IBM, Armonk, NY, USA). Univariable logistic regression analysis was used to determine the influence of individual prognostic factors on the odds of requiring further surgery that was considered to be consistent with treatment failure. The relative importance of the above covariates was determined with multivariate regression analysis using the stepwise backward likelihood ratio method.

Results

Baseline characteristics

The average follow-up for the 391 women undergoing office endometrial ablation during the study period was 4.3 years (range 0.2 to 8.9 years). Table 1 shows the baseline demographics and clinical characteristics of the women. Of the 360/391 (92 %) who had been unsuccessfully treated with medical therapy, 216/360 (60 %) had a hormonal therapy, 95/360 (26 %) had a non-hormonal therapy and in 49/360 it was not stated which medical treatment they had received. Of the 64 women who had abnormalities on hysteroscopy before treatment, 18/64 (53 %) had fibroid changes (either small submucous fibroids or slight distortions by intramural fibroids), 8/64 (23 %) had endometrial polyps, 8/64 (14 %) had congenital abnormalities (mildly arcuate) and 6/64 (9 %) had synechiae.

Further surgery

Further surgical intervention after the office ablation was subsequently reported in 51 women: 48 (12 %) underwent hysterectomy, 2 (1 %) had a uterine artery embolization and 1 (<1 %) woman had a myomectomy. The majority of interventions were performed within 24 months of endometrial ablation; 41 % of interventions were performed by 1 year of follow-up and 75 % were performed by 2 years. Of those women that had a hysterectomy, pain was the most common indication (19/48; 40 %), followed by bleeding (17/48; 35 %), then bleeding and pain (7/48; 15 %), 2/48 (4 %) had an ovarian mass, 1/48 (2 %) with a persistent watery discharge, 1/48 (2 %) diagnosed with complex endometrial hyperplasia and 1/48 (2 %) who had a uterine prolapse.

Abnormal findings were found in 33/48 (69 %) of the hysterectomy specimens, while 15/48 (31 %) were normal (except for endometrial scarring secondary to the endometrial ablation). The most common abnormality found was adenomyosis alone (14/48; 29 %). The remainder comprised of fibroids and adenomyosis (6/48; 13 %), fibroids alone (5/48; 10 %), fallopian tube endometriosis (4/48; 8 %), endometrial polyps (2/48; 4 %), a benign ovarian mass (1/48; 2 %) and malignant ovarian mass (1/48; 2 %).

Table 1 Factors assessed for prediction of further uterine surgical intervention after office endometrial ablation

Characteristic		No intervention (n=340)	Further intervention (n=51)	Univariable analysis		Multivariable analysis	
				Odds ratio (95 % CI)	P^*	Odds ratio (95 % CI)	P^*
Age	>45	110 (33)	17 (35)	Reference			
	40 to 45	135 (40)	12 (25)	0.59 (0.27 to 1.27)	0.2		
	<40	96 (28)	20 (41)	1.36 (0.67 to 2.75)	0.5		
BMI	<18.5	1 (0)	0 (0)	Not recordable			
	18.5 to 25.0	95 (28)	7 (14)	Reference			
	25.1 to 30.0	103 (30)	18 (37)	2.37 (0.95 to 5.93)	0.07		
	>30.0	143 (42)	24 (49)	2.28 (0.94 to 4.570)	0.07		
Previous caesarean		82 (24)	14 (29)	1.27 (0.65 to 2.47)	0.5		
Endometrial ablation technique (bipolar radiofrequency vs thermal balloon)		189 (55)	29 (59)	1.17 (0.64 to 2.16)	0.6		
Failed medical treatment		364 (92)	44 (90)	0.72 (0.26 to 1.98)	0.8		
Phase of cycle	Secretory	110 (32)	17 (35)	Reference			
	Proliferative	120 (35)	12 (25)	0.65 (0.30 to 1.42)	0.3		
	Menses	33 (10)	6 (12)	1.18 (0.43 to 3.23)	0.8		
	Progesterone effect	79 (23)	14 (29)	1.15 (0.53 to 2.46)	0.7		
Uterine axis	Anteverted vs other	50 (15)	8 (16)	1.14 (0.51 to 2.57)	0.8		
Abnormal hysteroscopy findings[a]		57 (17)	7 (14)	0.83 (0.36 to 1.95)	0.7		
Presence of fibroids[b]		276 (81)	38 (78)	0.83 (0.40 to 1.70)	0.6		
Duration of symptoms (months)		40.0 (43.4)[c, d]	32.9 (32.0)[c, e]	1.00 (0.99 to 1.00)	0.3		
Uterine size >9 cm[f]		65 (20)[g]	18 (37)	2.28 (1.20 to 4.33)	0.01	3.13 (1.52 to 6.43)	0.002
Menstrual cycle irregular		137 (41)[h]	17 (37)[j]	0.84 (0.45 to 1.59)	0.6		
Dysmenorrhea		208 (61)	41 (84)	3.30 (1.50 to 7.26)	0.003	4.82 (1.81 to 12.82)	0.002
Premenstrual syndrome		90 (26)	15 (31)	1.24 (0.64 to 2.37)	0.5		
Antiplatelet drugs or anticoagulants		8 (2)	2 (4)	1.78 (0.37 to 8.62)	0.5		

Data are n (%) unless otherwise specified

* P=1 significant figure

[a] Of the 64 women who had abnormalities on hysteroscopy, 53 % had fibroid changes (either small submucous fibroids or slight distortions by intramural fibroids), 23 % had endometrial polyps, 14 % had congenital abnormalities (mildly arcuate) and 9 % had synechiae

[b] Fibroids of any location found on imaging, hysteroscopy or clinical examination

[c] Data are mean average (standard deviation)

[d] Data missing for 24 cases

[e] Data missing for 5 cases

[f] Measured on a uterine sound

[g] Data missing in 22 cases

[h] Data missing in 8 cases

[i] Data missing in 3 cases

Pre-operative predictors of the need for further surgery

Table 1 shows the results of univariable analysis. Both uterine cavity length (OR 2.74, 95 % CI 1.35 to 5.56; p=0.02) and dysmenorrhea before treatment (OR 3.00, 95 % CI 1.41 to 6.36; p=0.004) demonstrated evidence for an association with the need for further surgical intervention. These findings remained independently predictive of further surgical intervention after multivariable analysis: dysmenorrhea (OR 4.01, 95 % CI 1.63 to 9.91) and uterine size >9 cm (OR 2.65, 95 % CI 1.33 to 5.27).

Discussion

The most important risk factor for further intervention identified within this study was dysmenorrhea before treatment. This is consistent with previous studies that have shown similar

findings [7, 8]. Higher rates of further intervention among those women with pre-existing dysmenorrhea could be caused by coexisting conditions such as adenomyosis. This contention could be supported by the finding of adenomyosis in 42 % of all failed treatment hysterectomy specimens. However, 40 % of all women undergoing subsequent hysterectomy did so because of menstrual pain so that it is possible that the ablative procedure could have induced or exacerbated this symptom because of (i) iatrogenic adenomyosis (as it has been reported following first generation hysteroscopic ablation procedures [13] or (ii) formation of intrauterine adhesions obstructing menstrual outflow, i.e. hematometra. The second most important risk factor for further surgery after ablation was a uterine cavity depth >9 cm. In a larger cavity, there is a more endometrium to destruct, and the ablation devices may not be optimised for treatment of more capacious uterine cavities.

There were no significant differences in hysterectomy rates based on age. This is consistent with one previous case-controlled study [6] but contrasts with other research that identified age under 40 as significantly associated with increased hysterectomy rate [14, 15]. Having a previous caesarean section, taking anticoagulants/antithrombotics, irregular menstrual bleeding, uterine axis, duration of symptoms and BMI were not associated with an increased hysterectomy rate consistent with previous work [7]. The phase of menstrual cycle has not been previously assessed but was not associated with subsequent hysterectomy.

Previous work has identified submucous fibroids as being associated treatment failure and higher hysterectomy rates [8, 15, 16] following ablation which is thought to reflect suboptimal endometrial coverage because of cavity distortion. However, a recent meta-analysis of second generation techniques did not find the presence of submucous fibroids and intrauterine polyps predictive of satisfaction [9]. This study found no association between fibroids and further intervention, but these were not specifically submucous. The prevalence of submucous fibroids was low in this study, and where they did exist; they were <1 cm. While many second generation ablative devices only consider submucous fibroids of >3 cm as contraindications, in our unit, most women will have had a pre-treatment transvaginal ultrasound or office hysteroscopy, and this thorough diagnostic work up may have selected out women with any degree of cavity distortion thought to impact upon the feasibility of endometrial ablation.

This study showed no difference between the need for surgical intervention according to the type of ablative procedure, bipolar radiofrequency ablation or thermal balloon ablation, at a mean follow-up of 4 years. This finding is consistent with two RCTs that have reported similar rates of hysterectomy and of satisfaction health-related quality of life at five years of follow-up [6, 10].

This cohort study is the first to look specifically at ablations done in the office setting. Other strengths of the study include the exploration of a wide range of possible prognostic factors for subsequent surgical intervention within in a large population of women undergoing office endometrial ablation. Although the generalizability of the findings may be limited because data were derived from a single treatment centre, the findings are likely to be representative because standardised procedures were used in a large, diverse population of women with heavy menstrual bleeding.

A limitation of this study is that it does not show if women who did not have further intervention were completely satisfied after treatment. There will have been women who were not satisfied with treatment but were not willing, or considered not suitable, for a further surgical procedure. Also, all women with a hysterectomy were considered to have failed treatment. This not only included women who continued to have bleeding problems, but also women with pain, discharge and those with malignant and premalignant genital tract conditions. These patients were included because pain can be caused by endometrial ablation, and surveillance of premalignant conditions can be hampered by ablation due to Asherman's syndrome.

The majority of the data were collected retrospectively, so results in this paper depended on the quality of the data obtained from clinical records. However, the clinical information required was recorded as standard in the medical notes, and so most of the data were complete; the variable with the most missing data was duration of symptoms, and this was only missing in 7 % of cases. Conclusions about prognostic factors could be further improved by using a bigger dataset.

Conclusions

This study showed that one in eight women had further uterine surgery after office endometrial ablation and that dysmenorrhea before treatment and a uterine cavity length >9 cm were predictive of this need for subsequent surgery. These findings, derived from endometrial ablation performed in an innovative and increasingly utilised office, local anaesthetic setting, corroborate earlier studies performed with a variety of second generation ablative systems under general anaesthesia in hospital [7, 8, 15]. Women with pre-existing dysmenorrhoea or enlarged uteri should be counselled about their increased chance of requiring additional uterine surgery after endometrial ablation. This knowledge should help women and their clinicians formulate more informed decisions regarding treatment for heavy menstrual bleeding refractory to previous medical therapy.

Contribution to authorship PS collected data, performed the analyses and drafted the article. SK collected data and revised the article. TJC produced the original idea, contributed to interpretation and revised the article for important intellectual content.

Compliance with ethical standards Data collection and storage satisfied local and national regulations. Ethical approval was not required.

Conflict of interest T. Justin Clark has received research monies from Cytyc (now Hologic) for the administration costs of the thermal balloon compared to bipolar radiofrequency ablation trial. In addition to this, he has received honoraria from Hologic and Gynecare to run training workshops in office hysteroscopy techniques. The other authors did not report any potential conflicts of interest.

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