Outpatient Thermachoice Endometrial Balloon Ablation: Long-Term, Prognostic and Quality-of-Life Measures

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Key Words

Endometrial ablation • Menorrhagia • Thermachoice • Quality of life • Amenorrhoea • Satisfaction • Prognostic factors • Long-term outcomes • Anaesthesia, local

Abstract

Study Objective: To evaluate short- and long-term treatment outcomes of outpatient local anaesthetic thermal balloon endometrial ablation (LA-TBEA) and identify any prognostic factors. **Study Design:** Prospective observational study in a UK teaching hospital involving 102 menorrhagic women undergoing LA-TBEA between 2001 and 2005. Women underwent either Gynecare® Thermachoice I (n = 51) or Thermachoice III (n = 51) TBEA performed in the outpatient setting under local anaesthesia without conscious sedation. The main outcome measures were: treatment completion, pain and analgesia, duration of stay (from admission to discharge), duration of follow-up, primary treatment success and nature of any secondary treatment, menstrual symptoms and amenorrhoea, patient satisfaction, and quality of life. **Results:** TBEA was completed in 97% of women. Mean duration of stay was 8.0 h (95% CI 6.6–9.3). Mean follow-up was 30 months (95% CI 26–32). Secondary treatment with the levonorgestrel intrauterine system, repeat TBEA or hys-

terectomy occurred in 19/102 (19%). Overall, 50% of surgical re-interventions occurred by 19 months. There were high rates of amenorrhoea (29%) and treatment satisfaction (76%). Higher mean intrauterine ablation pressure was associated with increased treatment satisfaction. **Conclusion:** TBEA can be successfully performed in the outpatient setting. Higher endometrial ablation pressure may improve long-term treatment outcome.

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Introduction

There is wide variation in the preferred endometrial ablation device and whether treatment should be performed in the outpatient or daycase general anaesthesia setting. In relation to thermal balloon endometrial ablation (TBEA), there are particular prognostic factors associated with favourable outcome following ablation: anteverted compared to retroverted uterus, older age, shorter uterine length, lower (<10 ml) intrauterine balloon volumes and higher intrauterine pressures [1–5]. Our aim was to evaluate the efficacy of outpatient local anaesthetic (LA)-TBEA and identify any prognostic factors.

Table 1. Peri-procedure outcomes of endometrial ablation

	Thermachoice I	Thermachoice III	Thermachoice I+III	p value (Thermachoice I vs. III)
Mean volume of fluid, ml ^a (95% CI; SD)	24.1 (16.5–31.8; 13.3)	19.2 (15.8–22.7; 11.6)	20.4 (17.3–23.5; 12.1)	0.07
Average intrauterine pressure (95% CI; SD)	157 (147–166; 16)	169 (164–176; 19)	167 (162–172; 19)	0.004
Mean hospital stay, min (h) ^b	433 (7.2)	522 (8.7)	478 (8.0)	0.277
95% CI; SD, min	318–547; 382	405–639; 398	397–559; 391	
95% CI; SD, h	5.3–9.1; 6.4	6.8–10.7; 6.6	6.6–9.3; 6.5	
Mean visual analogue pain (95% CI; SD)	5.6 (4.7–6.6; 1.6)	5.9 (5.1–6.8; 2.9)	5.8 (5.2–6.5; 2.7)	0.541
Rescue analgesia ^c				
Paracetamol (frequency)	32	25	57	0.412
Diclofenac (frequency)	3	0	3	0.074
Mean morphine equivalent dose, mg (95% CI; SD)	4.8 (3.0–6.5; 6.2)	13.0 (10.7–15.3; 8.0)	8.9 (7.3–10.5; 8.3)	0.001
Overall strength of analgesia ^b				
No rescue analgesia	12	3	15	0.005
Mild	30	25	55	
Moderate	4	6	10	
Strong	5	17	22	

Comparisons in bold are those that are statistically significant with a p value <0.05.

^a The mean volumes recorded are higher than that reported by other groups. This is due to our inclusion of a 'top up volume' additional to the 'commencement volume' in order to maintain higher intrauterine ablation pressures (see Methods).

^b Excluding 13/102 cases that stayed overnight, the mean duration of hospital stay (min) with 95% CI are: 294 [257–330], 364 [326–402] and 329 [303–357; SD 120] for Thermachoice I, III and overall combined I and III, respectively.

^c Data not reported in all cases, calculation based on cases that were reported.

Methods

The study population was comprised of pre-menopausal women with subjectively defined heavy menstrual bleeding who failed to respond to at least 6 months of medical therapy and who opted for LA-TBEA between February 2001 and August 2005. Women were excluded from the study if they had intrauterine uterine fibroids sized >3 cm, uterine cavity length >10 cm, abnormally shaped uterine cavity or endometrial pathology. LA-TBEA was performed according to our previously described protocol [6] using Thermachoice I (Gynecare®, Menlo Park, Calif., USA) at study commencement (February 2001–July 2003) and upgraded to Thermachoice III (Gynecare®, Ethicon Inc., Somerville, N.J., USA) from August 2003 onwards. A postal questionnaire was sent to all subjects between August 2006 and September 2006 to determine the long-term effectiveness of therapy. Both menorrhagia disease-specific (Shaw) [7] and generic (EuroQol-5D) [8] quality-of-life measures were utilized [9, 10]. A formal ethics application was not required as the study was classified as clinical service evaluation. All statistical analyses were performed using SPSS 13.0 statistical software (release Sept. 1, 2004, ©SPSS Inc., USA).

Results

Of 105 consecutively recruited women who underwent planned LA-TBEA, the procedure was successfully completed in 102 (97%). Fully completed questionnaires were

returned by 88/102 participants (86%). All peri-procedure outcomes are depicted in table 1. The mean duration of hospital stay was 8.0 h (95% CI 6.6–9.3 h).

Mean treatment follow-up was 30 months (95% CI 26–32) (table 2). Secondary treatment with the levonorgestrel intrauterine system (LNG-IUS), repeat TBEA or hysterectomy occurred in 19/102 (19%). Of the 14 hysterectomies performed as secondary treatment, around two-thirds had adenomyosis or fibroids on uterine histopathology. Satisfied compared to dissatisfied women reported higher levels of quality of life and menstrual improvement. Overall, 50% of surgical re-interventions (n = 16, 14 hysterectomies, 2 repeat ablations) occurred by 19 months (range 10–46). Survival analysis showed no statistically significant difference in the likelihood of surgical re-intervention between Thermachoice I and Thermachoice III. Multivariate analysis, correcting for all baseline and peri-procedure characteristics, showed: (1) Thermachoice III compared to Thermachoice I increased the likelihood for amenorrhoea (p = 0.001), and (2) regardless of the type of Thermachoice device, higher mean intrauterine ablation pressure (p = 0.014) and/or higher morphine rescue analgesia (p = 0.030) correlated to better long-term patient satisfaction.

Table 2. Long-term outcomes of endometrial ablation

	Thermachoice I	Thermachoice III	Thermachoice I+III	p value (Thermachoice I vs. III)
Mean follow-up time, months (95% CI; SD)	41 (38–43)	18 (16–19)	30 (26–32)	0.001
Range	26–54	12–29	12–54	
SD	8	5	13	
Further treatment (repeat ablation, hysterectomy or LNG-IUS)				0.005
No	36 (70.6%)	47 (92.2%)	83 (81%)	
Yes	15 (29.4%)	4 (7.8%)	19 (19%)	
All types of further treatment				0.024
No further treatment (i.e. primary treatment success)	30	44	74 (73%)	
LNG-IUS	3	0	3	
Drugs (including HRT)	6	3	9	
Repeat endometrial ablation	1	1	2 ^a	
Hysterectomy (histology) ^b	11	3	14 (14%)	
Periods at review ^c				0.009
Amenorrhoea	11 (23%)	16 (35%)	27 (29%)	
Lighter	23 (49%)	28 (61%)	51 (55%)	
No change or worse	13 (28%)	2 (4%)	15 (16%)	
Dysmenorrhoea at review ^c				0.027
Less pain or no pain	27	37	64	
No change	6	5	11	
Worsening	14	4	18	
Satisfaction				0.062
Satisfied	35 (69%)	43 (84%)	78 (76%)	
Dissatisfied	16 (31%)	8 (16%)	24 (24%)	
Mean EuroQoL VAS score (95% CI; SD)	76 (69–84; 19)	80 (73–87; 19)	78 (73–83; 19)	0.420
Mean EuroQoL Index (95% CI; SD)	0.81 (0.74–0.88; 0.19)	0.87 (0.80–0.96; 0.21)	0.84 (0.79–0.90; 0.20)	0.022
Mean Shaw QoL (95% CI; SD)	83 (73–92; 25)	87 (78–96; 24)	84 (78–91; 25)	0.504

Comparisons in bold are those that are statistically significant with a p value <0.05.

^a Two cases underwent repeat TBEA and 3 cases underwent LNG-IUS insertion. However, it is suggested by some that repeat ablation or LNG-IUS insertion is contraindicated after ablation due to likely uterine cavity distortion and therefore constitutes a potentially increased risk of uterine perforation and thermal bowel injury.

^b Histology of the 14 hysterectomies reported adenomyosis, fibroids and normal uterus in 4, 5 and 5 cases, respectively.

^c Data not reported in all cases, calculation based on cases that were reported.

HRT = Hormone replacement therapy.

Discussion

LA-TBEA is an effective outpatient daycase procedure. Higher intrauterine ablation pressure may be associated with improved long-term treatment outcome. There appear to be improved rates of amenorrhoea when using Thermachoice III compared to Thermachoice I.

We believe this prospective study to be the largest cohort of outpatient LA-TBEA [3, 6, 11–14]. Apart from two other studies with a 4- to 6-year follow-up [14, 15], this study also represents the longest follow-up of outpatient TBEA. This TBEA study is the first to utilize the recommended menorrhagia-specific [7] and generic [8] quality-of-life tools for outcome evaluation [9, 10]. The long-term outcomes are derived from a high response rate (86%) which improves the accuracy of reported data. Our re-

ported rates of amenorrhoea are consistent with other groups [3, 13–15].

There may be limitations in this study which lessens the reliability of its conclusions. The study population may be heterogeneous in relation to different heavy menstrual bleeding patterns. The study did not collect baseline quality-of-life data and there are differences in lengths of follow-up between Thermachoice I and III cohorts.

Our mean duration of stay of around 8.0 h is longer than 1 h 40 min reported by an analogous outpatient TBEA study [11]. This discrepancy may be due to differences in nursing-led or physician-led discharge practices. It is not unexpected that Thermachoice III has higher amenorrhoea rates, given its unique impeller design and better temperature distribution across the balloon. Our observation of increased intrauterine pressure and im-

proved outcome has been noted by other groups [1, 2, 4, 5] and may be related to better surface contact of the balloon against the target endometrial surface and improved heat energy transfer.

In order to determine the optimum role for outpatient endometrial ablation, further trials are needed that com-

pare second-generation ablation techniques in different outpatient and daycase settings and against appropriate treatment alternatives (e.g. LNG-IUS, laparoscopic/abdominal hysterectomy), and incorporate long-term outcome analyses.

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