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A randomised controlled trial comparing the Cavaterm endometrial ablation system with the Nd:YAG laser for the treatment of dysfunctional uterine bleeding

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Objective To compare the effectiveness of the Cavaterm thermal balloon endometrial ablation system with the Nd:YAG laser for the treatment of dysfunctional uterine bleeding.

Design Randomised controlled trial.

Setting Minimal access gynaecological surgery unit in a district general hospital.

Population Seventy-two women with dysfunctional uterine bleeding requesting conservative surgical management of their condition.

Methods Women with a normal endometrial biopsy and normal uterine cavity were randomly allocated to endometrial ablation by Cavaterm or Nd:YAG laser. Patients completed pre-operative and 6- and 12-month post-operative questionnaires assessing menstrual symptoms, quality of life, sexual activity and procedural satisfaction and acceptability. All patients received a single dose of gonadotropin-releasing hormone analogue one month pre-operatively and kept blinded to the procedure performed until after the 6-month assessment.

Main outcome measures The primary outcome measure was amenorrhoea rate. Secondary outcomes were effect on blood loss, quality of life, sexual activity, patient satisfaction and procedure acceptability.

Results Seventy-two women were randomised. Amenorrhoea rates at 12 months in the Cavaterm and endometrial laser ablation groups were 29% *vs* 39% ($P = 0.286$), with combined amenorrhoea and hypomenorrhoea rates of 73% *vs* 69%, respectively. At 12 months, repeat surgery rates were higher in the endometrial laser ablation group (15% *vs* 12%, $P = 0.395$). Cavaterm was an acceptable procedure and 93% of patients satisfied or very satisfied at 12 months (95% endometrial laser ablation). Both treatments were associated with an increase from baseline in the SF-12 physical score (Cavaterm mean difference −3.9, 95% CI −7.9, 0.2, ns; endometrial laser ablation mean difference −5.1, 95% CI −9.5, −0.7, $P = 0.003$) and mental health score (Cavaterm mean difference −5.6, 95% CI −9.9, −1.3, $P = 0.001$; endometrial laser ablation mean difference −5.9, 95% CI −11.7, −0.2, $P = 0.04$). Patient's own assessment of health (EQ-5D VAS) improved from baseline in both groups (Cavaterm mean difference −7.6, 95% CI −13.9, −1.3, $P = 0.02$; endometrial laser ablation mean difference −5.4, 95% CI −14.9, 4.2, ns). EQ-5D index scores also improved (Cavaterm mean difference −0.06, 95% CI −0.2, 0.005, ns; endometrial laser ablation mean difference −0.17, 95% CI −0.3, −0.02, $P = 0.02$). There were no major complications in either group.

Conclusions The results with the Cavaterm thermal balloon endometrial ablation system are as good as those obtained with the Nd:YAG laser when used for the treatment of dysfunctional uterine bleeding in the short term. It results in a significant reduction in menstrual blood loss, patient satisfaction and improvement in patient quality of life. Larger studies with longer follow up are required to determine its place in the modern treatment of dysfunctional uterine bleeding.

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INTRODUCTION

First generation techniques, such as transcervical resection of the endometrium, rollerball and endometrial laser ablation have been shown to be effective and safe for the treatment of menorrhagia[1–7]. These techniques are technically difficult with a long learning curve and for this reason are not offered by all gynaecologists to women with symptomatic dysfunctional uterine bleeding. Second generation endometrial ablation techniques have been introduced to make endometrial ablation simpler, safer and at least as effective as first generation techniques to improve women's access to endometrial ablation.

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The Cavaterm thermal balloon ablation system (Wallsten Medical, Morges, Switzerland) is one such device, which was introduced clinically in May 1993 for the treatment of dysfunctional uterine bleeding. The first 60 women were treated for 30 minutes, but since 1995, the treatment time has been 15 minutes. Published studies have shown it to be an effective technique achieving amenorrhoea rates of 22–68%, combined amenorrhoea and hypomenorrhoea rates of 56–82% and overall 'success' rates of 92–98%[8–10].

The aim of this study was to compare the effectiveness and acceptability of the Cavaterm thermal balloon ablation system with the Nd:YAG laser that has been our technique of choice for the management of menorrhagia since 1989.

METHODS

The study was a 'blinded' randomised controlled trial. Subjects, nursing staff and the subjects' GP were blinded as to the treatment arm. Outcomes were assessed at six months in the Out Patient Department by a nurse, unaware of the original treatment allocation, using a questionnaire. Once this assessment was completed, the patient was 'unblinded' as to which treatment she had received.

Approval for the study was obtained from the local ethics committee. Women with symptoms that indicated an endometrial ablation were eligible to participate if they had Higham blood loss score[11] >100, measured premenopausal gonadotrophin levels, uterine length of <12 cm, no intrauterine pathology (determined by in patient or out patient hysteroscopy or ultrasound scan), normal endometrial biopsy, normal cervical cytology, completed her family and were using a reliable form of contraception. History of previous caesarean section(s) or clotting abnormalities was not considered a contraindication. Exclusion criteria included endometrial hyperplasia and malignancy, active pelvic infection and intrauterine pathology. Seventy-two patients referred to the Gynaecology Out Patient Department of South Cleveland Hospital, Middlesbrough, were recruited between August 1997 and April 2000.

Randomisation was achieved using random permuted blocks predetermined by computer-generated random-number tables in balanced blocks of four. Treatment allocation was obtained after the woman had given informed consent by opening sequentially numbered envelopes from one of two groups (<45 or ≥ 45 years) showing the treatment code.

The primary outcome measure was amenorrhoea rate. Secondary measures were comparisons of effect on menstrual status (other than amenorrhoea), patient satisfaction and acceptability, health-related quality of life, sexual activity, and operative details and morbidity.

Patients completed pre-operative questionnaire and follow up questionnaires at 6 and 12 months post-operatively along with a pictorial blood loss assessment chart pre-operatively and at 6 months post-operatively if still menstruating. The questionnaires used both closed- and open-ended questions and include validated health questionnaires in the form of EQ-5D[12,13], Short Form-12 (SF-12)[14,15], and a sexual activity questionnaire (SAQ)[16]. The pre-operative questionnaires also obtained the subjects' demographics and subjective assessment of symptoms using visual analogue scale scores of menstrual loss, dysmenorrhoea, dyspareunia and premenstrual syndrome. Data were also collected on the number of days bleeding and cycle length, past obstetric history, contraception, previous failed therapies and body mass index. The follow up questionnaire was completed at six months after treatment (before disclosing the treatment arm allocation) and at 12 months by post. It re-assessed the symptoms using the same format and included questions on the development of new pain post-operatively, satisfaction, subsequent medical and surgical treatments and a retrospective preference for hysterectomy.

Patient acceptability was assessed four hours post-operatively using a validated semantic differential technique[17]. This technique uses pairs of opposite adjectives to find out how the patient felt about the procedure. A score of -3 represents the *best score* and $+3$ the *worst*. Included in the

Table 1. Patient baseline characteristics. Values are given as mean [SD] and range.

Variable	Cavaterm		Endometrial laser ablation	
	Mean [SD]	Range	Mean [SD]	Range
Age (years)	41.4 [5.5]	31–51	41.1 [5.0]	29–49
Parity	2.3 [1.1]	0–5	2.6 [1.1]	0–5
Body mass index	27.3 [6.4]	17.1–44.9	27.9 [6.9]	17.1–46.0
Menstrual blood loss chart	354.5 [130.5]	180–704	424.3 [297.7]	140–1820
Period visual analogue scale score (0–100)	82.2 [13.1]	43–100	85.1 [10.1]	64–100
Days bleeding	7.2 [1.9]	4–13	7.9 [2.8]	3–18
Cycle length	24.2 [4.2]	14–31	25.0 [4.6]	14–31
Dysmenorrhoea visual analogue scale score (0–100)	61.5 [25.5]	5–96	70.3 [21.2]	12–95
Premenstrual syndrome visual analogue scale score (0–100)	55.0 [22.8]	6–100	64.9 [25.3]	5–100
Cavity length* (cm)	7.5* [1.1]	6–10	8.0* [0.7]	6.5–9.0

* $P = 0.02$.

Table 2. Menstrual outcomes at 6 and 12 months (a). Values are given as *n* (%).

Outcome	Cavaterm		Endometrial laser ablation	
	6 months ($n = 37$)	12 months ($n = 34$)	6 months ($n = 33$)	12 months ($n = 33$)
Amenorrhoea	15 (40.5)	10 (29)	12 (37)	13 (39)
Hypomenorrhoea	15 (40.5)	15 (44)	10 (30)	10 (30)
Eumenorrhoea	4 (11)	4 (12)	8 (24)	4 (42)
Menorrhagia	3 (8)	1 (3)	2 (6)	1 (3)
Repeat surgery	0	4 (12)	1 (3)	5 (15)

acceptability questionnaire was a further 11-point visual analogue scale (0–100) designed to assess pain at rest, four hours post-operatively.

Although the Cavaterm system does not require hormonal pretreatment, all women were given a single injection of a 3.6 mg goserelin (Zoladex, Zeneca Pharma, Cheshire, UK) 4–5 weeks prior to surgery to ensure blinding and because pretreatment is preferable prior to endometrial laser ablation. Women either underwent a Cavaterm endometrial ablation as previously described by Hawe *et al.*[8] or an endometrial laser ablation using the Nd:YAG laser as described by Garry *et al.*[18]. Patients in the Cavaterm group had a pre- and post-operative hysteroscopy. This was part of the trial protocol in order to exclude false passage and assess treatment, but is not recommended by the manufacturers. Data were collected for cavity length, operative laser-on time, fluid absorption and intra-operative complications. All cases were performed under general anaesthesia (to maintain blinding) and patients received a paracervical block of 10 mL of 0.5% bupivicaine hydrochloride (Astra, Kings Langley, Herts) and a single bolus of 1.2 g of intravenous Augmentin (Beecham Research, Herts, UK), unless they were allergic to penicillin, when a third generation cephalosporin was used as an alternative. The operative details were recorded on a separate operating note, which could be opened in the event of an emergency or after the 6-month visit. A standardised operating note was otherwise recorded in the notes for both techniques describing operative findings and outcome, but not technique. Women were discharged the same day and reviewed in the research clinic in six months or earlier if medically indicated.

Unpublished data on endometrial laser ablations performed in the Middlesbrough unit show that the amenorrhoea rate at 12 months is 32%. Data from the pilot study using Cavaterm system reported an amenorrhoea rate of 68% for a mean follow up of 14 months[8]. To detect a similar difference (68% *vs* 32% at 12 months), a sample size of 34 patients in each trial arm was required for 80% power and a two-sided type 1 error rate of 5% (Epi Info 6 produced by Epidemiology Programme Office, Centers for Disease Prevention and Control). Continuous data were analysed by means of a *t* test. The Fisher's Exact Test was used to analyse fourfold tables. There was no correction for multiple testing.

RESULTS

Seventy-two women were randomised between August 1997 and June 2000. There was an imbalance in randomisation (37 Cavaterm to 35 endometrial laser ablation). One woman in the endometrial laser ablation arm was excluded due to the finding of submucous fibroids at the time of surgery. At the final analysis, 37 women were recruited to Cavaterm and 34 to endometrial laser ablation. All patients underwent the procedure to which they were randomised. Three women in the Cavaterm and one woman in the endometrial laser ablation group underwent a concurrent laparoscopic sterilisation procedure. Questionnaires were completed at 6 and 12 months by 100% and 91% of the Cavaterm group and 97% and 96% of the endometrial laser ablation group.

There was no significant difference in patient characteristics (Table 1). Thirty-five (95%) and 29 (87.9%) complained of dysmenorrhoea in the Cavaterm and endometrial laser ablation groups, respectively, and their visual analogue scale scores are shown in Table 1. There was no significant difference with the reporting of dyspareunia and premenstrual

Table 3. Menstrual outcomes at 6 and 12 months (b). Values are given as mean [SD].

Variable	Cavaterm			Endometrial laser ablation		
	Baseline	6/12	12/12	Baseline	6/12	12/12
Menstrual blood loss chart	354.5 [130.5]	28.8 [59.6]		424.3 [297.7]	27.4 [57.6]	
Menstrual loss visual analogue scale score	82.2 [13.1]	16.4 [24.7]	16.2 [21.9]	85.1 [10.1]	17.2 [23.8]	13.6 [23.5]
Days	7.2 [1.9]	3.6 [2.2]	3.4 [1.9]	7.9 [2.8]	3.6 [1.7]	4.5 [3.1]
Cycle	24.2 [4.2]	26.1 [6.5]	29.7 [5.3]	25.0 [4.6]	27.1 [5.0]	29.9 [18.8]
Dysmenorrhoea visual analogue scale score	61.5 [25.5]	24.0 [30.9]	25.2 [31.5]	70.3 [21.2]	23.0 [33.9]	16.5 [22.3]
Premenstrual syndrome visual analogue scale score	55.0 [22.8]	24.6 [33.0]	21.9 [26.9]	64.9 [25.3]	34.8 [36.0]	30.5 [34.7]

Table 4. Patient satisfaction. Values are given as *n* (%).

Satisfaction	Cavaterm		Endometrial laser ablation	
	6 months ($n = 37$)	12 months ($n = 30$)	6 months ($n = 32$)	12 months ($n = 27$)
Very satisfied	24 (64.9)	21 (70)	24 (75)	19 (70.4)
Satisfied	11 (29.7)	7 (23.4)	5 (15.6)	7 (25.9)
Dissatisfied	1 (2.7)	1 (3.3)	3 (9.2)	1 (3.7)
Very dissatisfied	1 (2.7)	1 (3.3)	0	0

syndrome between the two groups (dyspareunia 21.6% *vs* 39.3%, premenstrual syndrome 72% *vs* 85%; Cavaterm *vs* endometrial laser ablation, respectively). Only cavity length (cm) was significantly different between the two groups (Cavaterm 7.45 [1.03] *vs* endometrial laser ablation 7.96 [0.67], $P = 0.02$), but this difference is not clinically significant.

Both techniques were equally effective in reducing menstrual blood (Tables 2 and 3). Amenorrhoea rates for the Cavaterm and endometrial laser ablation groups at 6 and 12 months, respectively, were 40.5% *vs* 37% ($P = 0.673$) and 29% *vs* 39% ($P = 0.395$). Visual analogue scale scores of menstrual loss reduced at 12 months from baseline by 80.5% (mean difference 66.5, 95% CI 56.7, 76.2, $P \leq 0.0001$) and 83.5% (mean difference 71, 95% CI 61.4, 80.6, $P \leq 0.0001$) in the Cavaterm and endometrial laser ablation group, respectively. Pictorial blood loss assessment chart scores were similarly reduced at six months by 92% (mean difference 330.5, 95% CI 282, 379, $P \leq 0.0001$) and 94% (mean difference 336.8, 95% CI 268, 406, $P \leq 0.0001$) in the Cavaterm and endometrial laser ablation groups, respectively. There was no statistically significant difference for any of the recorded outcome measures between the two groups.

In those who continued to menstruate at 12 months, treatment with Cavaterm was associated with a significant reduction in the number of days bleeding from 7.2 to 3.4 ($P \leq 0.0001$), increased cycle length from 24 to 30 ($P = 0.02$), a 60% reduction in dysmenorrhoea score from 62 to 25 ($P \leq 0.0001$) and a 60% reduction in premenstrual syndrome score from 55 to 22 ($P = 0.04$). Similar findings were seen in the endometrial laser ablation group with no significant difference between the groups (Table 3).

There was no difference in patient satisfaction at 6 and 12 months between the two groups (Table 4). At 6 and 12 months, 95% (35) *vs* 91% (29) and 93% (28) *vs* 96% (26) were either satisfied or very satisfied in the Cavaterm and endometrial laser ablation groups, respectively. There was no statistically significant difference for patient satisfaction between the two groups at 6 and 12 months.

Both procedures were acceptable to patients. Outcomes that reached statistical significance were that patients felt more positive about endometrial laser ablation (mean difference 1.27, 95% CI 0.43, 2.1, $P = 0.004$), felt endometrial laser ablation was safer (mean difference 0.87, 95% CI 0.12, 1.63, $P = 0.03$) and endometrial laser ablation was more agreeable (mean difference 1.08, 95% CI 0.29, 1.87, $P = 0.08$) than Cavaterm.

Patients completed a visual analogue scale (0–100) for pain at rest four hours post-operatively. There was no adjustment made for analgesia. Endometrial laser ablation was found to be significantly less painful than Cavaterm 63.6 [17.6] *vs* 30.9 [20.4] (mean difference 32.7, 95% CI 14.0, 51.4, $P = 0.002$). This difference was also seen with the semantic differential technique, but this did not reach statistical significance (Cavaterm 1.17 [1.8] *vs* endometrial laser ablation 0.55 [1.92], mean difference 0.63, 95% CI −0.43, 1.68, $P = 0.23$).

There were no major intra-operative complications in either group. All patients were treated as day cases apart from one patient in the Cavaterm group who required overnight admission for right-sided abdominal pain.

Table 5. SF-12 scores. Values are given as mean [SD] and mean difference (95% CI), *P*.

	Physical component score	Mental component score
Mean [SD]		
Cavaterm		
Baseline	46.0 [8.4]	45.4 [10.4]
6/12	52.1 [6.8]	52.2 [7.7]
12/12	49.9 [8.3]	51.0 [7.1]
Endometrial laser ablation		
Baseline	45.1 [9.5]	43.0 [11.8]
6/12	50.4 [9.4]	48.8 [8.5]
12/12	50.1 [7.1]	48.9 [9.9]
Mean difference (95% CI), *P*		
Cavaterm		
0 *vs* 6/12	−6.1 (−9.7, −2.4), $P = 0.001$	−6.8 (−11.2, −2.4), $P = 0.03$
0 *vs* 12/12	−3.9 (−7.9, 0.2), ns	−5.6 (−9.9, −1.3), $P = 0.01$
Endometrial laser ablation		
0 *vs* 6/12	−5.3 (−10.1, −0.5), $P = 0.03$	−5.7 (−11.7, −0.2), $P = 0.03$
0 *vs* 12/12	−5.1 (−9.5, −0.7), $P = 0.03$	−5.9 (−11.7, −0.2), $P = 0.04$

Table 6. EuroQol scores. Values are given as mean [SD] and mean difference (95% CI), *P*.

	EQ-5D index	EQ-5D VAS
Mean [SD]		
Cavaterm		
Baseline	0.78 [0.26]	77.3 [14.2]
6/12	0.81 [0.26]	82.1 [14.2]
12/12	0.81 [0.23]	84.9 [11.5]
Endometrial laser ablation		
Baseline	0.65 [0.31]	69.4 [18.0]
6/12	0.80 [0.24]	80.9 [16.1]
12/12	0.82 [0.25]	74.8 [19.4]
Mean difference (95% CI), *P*		
Cavaterm		
0 *vs* 6/12	−0.01 (−0.1, 0.1), ns	−4.7 (−11.5, 1.9), ns
0 *vs* 12/12	−0.06 (−0.2, 0.005), ns	−7.6 (−13.9, −1.3), $P = 0.02$
Endometrial laser ablation		
0 *vs* 6/12	−0.15 (−0.3, −0.007), $P = 0.04$	−11.5 (−20.2, −2.9), $P = 0.01$
0 *vs* 12/12	−0.17 (−0.3, −0.02), $P = 0.02$	−5.4 (−14.9, 4.2), ns

Investigations, including ultrasound scan, were normal and she was discharged the next day.

There was a balloon failure in two cases and a further catheter had to be used in both cases. A leak was detected prior to the start of treatment and the catheters were replaced. In the endometrial laser ablation group, three patients had excessive fluid absorption (>1500 mL), which was treated by intravenous frusemide 20 mg and catheterisation. In one of these patients, blood loss was excessive and was managed using an intrauterine 30 mL balloon Foley catheter, which was left *in situ* for four hours to tampon blood loss. Post-operatively, four (11%) and two (6%) patients in the Cavaterm and endometrial laser ablation groups, respectively, had oral antibiotics for suspected endometritis.

At 12 months, four (11%) patients in the Cavaterm group had had repeat surgery. Three (9%) had undergone a hysterectomy and one patient had a repeat ablation procedure (endometrial laser ablation). Histology showed an intramural fibroid in one case, adenomyosis in another and no abnormality was found in the third. In the patient who underwent a repeat ablation procedure, there was marked active endometrium in the cornual areas and fundus suggesting that the balloon had not been inserted to the full cavity length in the original treatment. In contrast, five (14.7%) of patients in the endometrial laser ablation group had undergone hysterectomy, one before 6 months (stage 4 endometriosis) and four between 6 and 12 months. A further two patients were listed for surgery (one hysterectomy, one repeat endometrial laser ablation) between 6 and 12 months post-operatively, but were still on the waiting list at 12-month data collection.

Table 5 shows the results for the physical and mental component scores for the SF-12. Both techniques showed a significant improvement in the physical and mental component scores at 6 months compared with baseline and in the endometrial laser ablation group at 12 months to

Table 7. SAQ data. Values are given as mean [SD] and mean difference (95% CI), *P*.

	Pleasure	Habit	Discomfort
Mean [SD]			
Cavaterm			
Baseline	12.2 [4.4]	0.72 [0.5]	1.04 [1.3]
6/12	13.9 [4.0]	1.04 [0.7]	0.96 [1.8]
12/12	13.8 [4.3]	0.81 [0.5]	1.2 [1.8]
Endometrial laser ablation			
Baseline	11.3 [3.9]	0.7 [0.6]	1.4 [1.7]
6/12	13.4 [3.7]	1.2 [0.4]	1.1 [1.8]
12/12	14.4 [4.4]	0.9 [0.2]	1.1 [1.4]
Mean difference (95% CI), *P*			
Cavaterm			
0 *vs* 6/12	−1.6 (−3.3, 0.07), ns	−0.3 (−0.7, 0.05), ns	0.08 (−0.5, 0.6), ns
0 *vs* 12/12	−1.6 (−3.9, 0.8), ns	−0.1 (−0.4, 0.15), ns	−0.09 (−0.7, 0.5), ns
Endometrial laser ablation			
0 *vs* 6/12	−2.0 (−3.5, −0.5), $P = 0.01$	−0.5 (−0.8, −0.2), $P = 0.05$	0.3 (−0.8, 1.4), ns
0 *vs* 12/12	−2.8 (−4.6, −1.0), $P = 0.05$	−0.3 (−0.5, −0.05), $P = 0.02$	0.5 (−0.5, 1.6), ns

baseline. There was no difference in the improvement of the SF-12 scores seen between the two groups.

Quality of life was also assessed by the EQ-5D health measure. The results in Table 6 show that the endometrial laser ablation group had a lower quality of life at baseline compared with the Cavaterm group. This difference was not seen in the SF-12 data. There was an improvement in the EQ-5D index and EQ-5D VAS scores compared with baseline at 6 and 12 months in the Cavaterm group reaching statistical significance at 12 months in the thermometer score (Table 6). In the endometrial laser ablation group, there was a statistically significant improvement in the EQ-5D index scores at 6 and 12 months compared with the baseline. The EQ-5D VAS score was statistically improved at 6 months compared with baseline, but by 12th month, this was not seen (Table 6).

The percentage of patients who were sexually active during the trial was 68%, 73% and 76.5% in the Cavaterm group and 82%, 75% and 75% in the endometrial laser ablation group at baseline, 6 and 12 months, respectively. The main indication for no sexual activity was lack of partner. In both groups, there was an increase in the pleasure and habit scores and no change was seen in discomfort score compared with baseline at 6 and 12 months. In the endometrial laser ablation group, these changes reached statistical significance (Table 7). When the results were compared between the Cavaterm and endometrial laser ablation groups, no statistically significant difference was seen.

DISCUSSION

When any new surgical technique is introduced, it is essential to define its place in routine practice. To date, there have only been three published papers in the English language assessing the use of the Cavaterm ablation system[8–10]. The traditional methods of endometrial resection and ablation have been carefully evaluated[1–7], and their role in current gynaecological practice is well understood[1]. It is important that any new technique is not introduced without proper assessment against the established techniques, which have been carefully evaluated.

The primary outcome measure for this study was amenorrhoea rate. This was chosen as it is an easily identifiable outcome measure compared with more subjective measures such as pictorial blood loss assessment chart scores and satisfaction rates, the validity of which have been questioned[19]. This study is weakened by our choice in outcome measure. The choice of amenorrhoea rate has led to a small sample size, which makes meaningful comments concerning outcome measures more difficult to interpret and subject to chance. The main goal in ablative treatments is not amenorrhoea rates, but menstrual reduction, patient satisfaction and improvement in quality of life. Choosing the latter outcome measures would have led to larger sample sizes that may have led to more meaningful differences in outcome.

Previous published work has reported amenorrhoea rates between 22% and 68%[8–10,20] with the Cavaterm system. This study showed amenorrhoea rates at 6 and 12 months of 40.5% and 29% for Cavaterm and 37% and 39% for endometrial laser ablation, respectively. The rate for Cavaterm is less than we saw for the pilot study of 50 patients (68%)[8] but similar to rates reported by Friberg *et al.*[9] and Friberg and Ahlgren[10] (31% and 29.4%). The amenorrhoea rate in the Cavaterm group fell from 40.5% to 29% between 6 and 12 months. When the data are analysed, three patients who were amenorrhoeic at 6 months reported spotting at 12 months and a further patient developed a 'normal' loss. One patient who was amenorrhoeic was lost to follow up. This reduction was not statistically significant and was not seen in a previous study with longer term follow up were the amenorrhoea rate did not significantly change[10] and may be a chance finding due to the small numbers. The amenorrhoea rate in the endometrial laser ablation arm was similar to that seen in the study by Phillips *et al.*[3] and higher than that reported in a previous randomised controlled trial where the amenorrhoea rate at 12 months was only 21%[21].

The amenorrhoea rate compares favourably with other second generation ablation systems assessed by randomised controlled trials. The ThermaChoice balloon system[22], VestaDUB[23] and HydroThermAblator[24] reported amenorrhoea rates of 15%, 31% and 40% at 12 months, respectively. Reduction of blood loss to normal levels or less at 12 months is very similar with the three treatments (Cavaterm 85%, ThermaChoice 81%, VestaDUB 87%, HydroThermAblator 77%). Reductions in pictorial blood loss assessment chart scores were also comparable (Cavaterm 92%, ThermaChoice 85.5%). The microwave endometrial ablation system was associated with the highest amenorrhoea rate (40%), but the patient population was different, with 11% of the microwave endometrial ablation patients having intrauterine pathology[25], which was an exclusion criterion in Cavaterm and other evaluated balloon systems. Along with a reduction in menstrual loss, patients also reported a reduction in dysmenorrhoea and premenstrual syndrome in both arms of the study (Table 3). The results are comparable to those previously reported with the Nd:YAG laser[3], and other first[2] and second generation techniques assessed in randomised controlled trials[22–25].

Satisfaction rates were high in both groups and similar to those reported in previous trials of both traditional techniques of endometrial ablation[2,3,5,6,21] and second generation techniques[8–10,21–25]. Patient satisfaction results at 12 months are more biased than those seen at 6 months due to a reduction in responses from women who had had repeat surgery.

In addition to reduction in blood loss and patient satisfaction rates, treatment effect can be assessed by quality of life improvements. Heavy menstrual loss has been shown to

cause significant deterioration in general health and quality of life[25–27]. Similar findings were found in this study, with both groups experiencing reduced quality of life scores at baseline measurements compared with normal population (endometrial laser ablation > Cavaterm). Both groups had improvements in all quality of life scores. Endometrial laser ablation was associated with greater improvement, due to scores being lower at baseline, but there was no difference seen in scores at 6 and 12 months between the two groups. The observed difference in baseline measures may be caused by the small number of subjects. The improvements in quality of life seen with endometrial laser ablation and Cavaterm are similar to those reported by other randomised controlled trials assessing microwave endometrial ablation and transcervical resection of the endometrium using a similar validated health questionnaire SF-36[25,26]. Meyer *et al.*[22] also report an improvement in quality of life associated with treatment of menorrhagia with both rollerball and ThermaChoice, but this study used formal questions rather than a validated quality of life instrument and therefore the data are not comparable.

At 12 months, four (12%) patients in the Cavaterm group had undergone repeat surgery (hysterectomy 9%, repeat ablation 3%) compared with five (15%) in the endometrial laser ablation group. For the Cavaterm group, this figure is higher than that reported by Hawe *et al.*[8] (4%) with a mean follow up of 14 months, with survival curve analysis demonstrating a repeat surgery rate of 7% at 24 months. Friberg and Ahlgren[10] reported that the risk of undergoing repeat surgery at 49 months in their cohort was 15%. Similarly, the repeat surgery rate in the endometrial laser ablation group is higher than that previously reported, 6.8% with a mean follow up of 18 months[28], 15% with a mean follow up of 38 months, with survival curve analysis demonstrating a 21% risk of hysterectomy at 6.5 years[3]. Compared with ThermaChoice (2%[22]), the hysterectomy rate at 12 months was higher for Cavaterm (9%).

There were no major complications reported in either group. Due to the small sample size however, no comment can be made regarding safety. All the published randomised controlled trials[22–25] evaluating second generation techniques are insufficiently powered to examine complication rates. The Mistletoe study reporting on 10,686 cases provided meaningful data on complication rates for transcervical resection of the endometrium, endometrial laser ablation and rollerball[7]. It is unlikely that this study will be repeated to examine for complication rates in the second generation devices.

CONCLUSION

This study suggests that the results with the Cavaterm system are as good as those obtained with the Nd:YAG laser endometrial ablation for patients with dysfunctional uterine bleeding in the short term. We make no claims from this study that either technique provides superior results, but it seems that the second generation device is easier to use and it is worth reporting that it achieves similar results to those obtained with a more skill-dependent device. Long term follow up is required to determine if these promising early results are maintained and larger randomised studies are required to determine its effective value in the management of dysfunctional uterine bleeding.

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