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Factors affecting the outcome of endometrial ablation using Cavaterm™ *plus*

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Abstract

Objective: To study treatment outcome using the modified technique: *Cavaterm™ plus*.
Study design: Retrospective postal questionnaire, in a large teaching hospital. One hundred and twenty-eight women with menorrhagia were treated between February 2001 and April 2003. Data were collected prospectively for the duration of the procedure and alternatives offered. Follow up questionnaire was distributed during November 2003 to assess menstrual status. Multiple binary logistic regression was performed to assess factors influencing success.
Results: The mean follow up was 72 weeks, 103 patients (80.5%) completed the questionnaire. In 26 (25.2%) cases, there were one or more important deviations from recommended procedure. Twenty (19.4%) women had procedure-related amenorrhoea, 6 (5.8%) had spotting, 35 (34%) had light, and 26 (25.2%) had moderate bleeding. Eleven (10.7%) had a hysterectomy. The risk of failure was inversely related to age (OR 0.778, 95% CI 0.669–0.905), was higher in women who prior to surgery had longer duration of bleeding (OR 1.29, 95% CI 1.1–1.52), and when recommended selection or operative procedures were not followed (OR 5.056, 95% CI 1.097–23.3).
Conclusion: Cavaterm™ *plus* is associated with high patient satisfaction. The technique remains a good choice for women wishing to avoid hysterectomy, but there is a need to observe determinants of poor outcome.

Keywords: Cavaterm balloon ablation; Menorrhagia

1. Introduction

Endometrial ablation techniques are well-established alternatives to hysterectomy for women with menorrhagia [1,2]. Early indications were that the introduction of ablative techniques lowered the threshold for surgical intervention, thus increasing surgical rates overall [3]. More recent evidence suggests that the annual number of hysterectomies and overall surgical rates in England has fallen, whilst the number of endoscopic procedures continues to rise [4]. This trend is consistent with accumulating evidence of efficacy [1,2,5].

Cavaterm™ (Wallsten Medical SA, Lausanne) thermal balloon ablation is a second-generation minimally invasive technique for the treatment of heavy menstrual bleeding. Like other second-generation techniques it is, by and large, less operator-dependent compared to earlier methods. Published studies demonstrate favourable outcomes, including high amenorrhoea rates and patient satisfaction. However, although such data could inform policy decisions, there is little evidence to address the extent to which such outcomes can be duplicated in a clinical setting, or the factors that affect outcome.

Whilst patient satisfaction is consistently high, there is a wide variation in reported amenorrhoea rates (12–68%) using the previous version (Cavaterm™) [6–15]. There is no published data addressing the success rate of Cavaterm™ *plus*. This differs from the older version in several ways; it requires less cervical dilatation, utilizes higher balloon pressure (230–240 mmHg), the silicon balloon is filled with 5% glucose and heated to 65–75 °C, and runs for a shorter

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treatment cycle of 10 min. The parent device was filled with 1.5% glycine till a stable pressure of 180–220 mmHg was obtained, the fluid was then heated to 75–80 °C. Initially, treatment was for 30 min but this was reduced to 15 min [6,7,16]. It is recommended that the procedure be offered to women as an alternative to hysterectomy if medical treatments have failed, or if it is considered appropriate by the woman and her doctor [5]. Balloon ablation is suitable for women with a structurally normal uterine cavity measuring 4–10 cm, with normal endometrium. Pre-operative pharmacological endometrial preparation is not essential but is replaced by pre-ablation curettage [6].

We set out to examine the factors predictive of successful outcome for women undergoing the procedure in a large teaching hospital with reference to case selection, operative procedure, complications and patient satisfaction.

2. Method

Women who underwent endometrial balloon ablation between February 2001 and April 2003 were followed up for a minimum of 6 months. The indication of the procedure was a complaint of heavy menstrual bleeding where surgery was indicated (failed or declined medical treatment) provided normal endometrium, no intracavitary lesions on hysteroscopy, and no desire for future pregnancy. With ethical approval, all patients were sent a postal questionnaire in October 2003, followed by two reminder letters to non-responders at 2- and 4-week intervals. The questionnaire explored their menstrual pattern and any subsequent treatments. Women were asked to compare their periods before and after the procedure using a 10 cm visual analogue scale (VAS) with a ''0, much worse'' and ''10, much better'' at opposite ends, and the mid point representing no change. Dysmenorrhoea was also assessed using a similar VAS. Patients were asked to report their level of satisfaction with the procedure using a 10 cm scale with ''very satisfied'' and ''very dissatisfied'' on the opposite ends. Women reporting the onset of amenorrhoea beyond 6 months following balloon ablation were asked to rate their periods prior to cessation. Patient characteristics, menstrual pattern and treatment history prior to surgery, haemoglobin concentration at presentation, pre-operative investigations and operative data were obtained from case-notes.

A successful procedure was defined by: (i) the onset of amenorrhoea, not due to hysterectomy, within 6 months after balloon ablation, or (ii) menstrual loss described as spotting or light, or (iii) menstrual loss described as moderate bleeding, provided comparative VAS for bleeding was >5, and no further treatment was required. Failure was defined by: (i) the need for further medical or surgical treatment following balloon ablation till time of reporting, or (ii) menstrual loss described as heavy, or (iii) cases with moderate bleeding if the comparative VAS for bleeding was ≤ 5.

3. Data analysis

The returned questionnaire were entered into a Microsoft Access Database. Results were analysed using frequency tables, Student's *t*-test and chi-squared test. To determine which factors were linked to a satisfactory outcome, the following demographic and procedural variables were analysed using multi-variable binary regression analysis: age, number of days of bleeding, pre-operative haemoglobin, compliance with recommended case selection and operative procedure, enlarged uterus (sound length >10 cm, and/or fluid distension >30 ml), pre-operative endometrial thinning (using curettage or pharmacologic agents), presence or absence of pre-operative dysmenorrhoea, cycle regularity, and whether patients had tried medical treatment before proceeding to surgery. We produced a multi-variable model using backward deletion of variables until all remaining were significant at the 5% level. All analyses were undertaken in SPSS Version 11.5. Statistical significance was defined at the 5% level throughout.

4. Results

During the study period, 128 women underwent balloon ablation; their mean age was 43.6 years (median 44.5, range 28.2–56.8). The procedure was performed under a general anaesthetic in all but two cases; one of whom was considered a high surgical risk because of gross obesity and cardio-respiratory compromise, and the second patient requested a local anaesthetic.

One hundred and three women returned a completed questionnaire, giving a response rate of (80.5%). The mean follow up period was 72 weeks (range 29–121); 61 (47.7%) women from the whole cohort had regular cycles (defined as a regular bleeding pattern occurring between 21 and 35 days), and 83 (64.8%) had dysmenorrhoea. One patient was post-menopausal with persistent unscheduled bleeding on HRT; all other patients had heavy menstrual cycles (Table 1). Most women had undergone a trial of medical treatment before balloon ablation, but none had undergone previous ablation; 48 (37.5%) patients had tried one medical treatment previously and 57 (44.5%) patients had tried two or more treatments. Balloon ablation was the primary treatment in 19 (14.8%) cases, information on previous treatments was unavailable in 4 (3%) patients.

There were no statistically significant differences between responders and non-responders with regards to age, parity, or indication of the procedure (Table 1). Among those who returned completed questionnaire, 93/103 (90.3%) balloon ablations were performed on a day-case basis. An overnight stay was necessary for the rest ($n = 10$), either because of co-existing illness or for pain control. The mean duration of the procedure including anaesthetic time was 39 min (S.D. = 12, range 20–107 min). The reason for the case requiring 107 min was an anaesthetic complication.

Table 1
Characteristics of the whole cohort, responders and non-responders

	Responders, $n = 103$ (80.5%)	Non-responders, $n = 25$ (19.5%)	P-value
Mean age at time of procedure (S.D.)	44.1 (5.6)	41.7 (10.7)	0.116
Parity, median (range)	2 (0–6)	2 (1–4)	
Indication			
Heavy bleeding	102 (99%)	25 (100%)	
Bleeding on HRT[a]	1 (1.0%)	0 (0%)	
Dysmenorrhoea			0.924
Yes	67 (65%)	16 (64%)	
No	32 (31.1%)	8 (32%)	
Unknown/not recorded	4 (2.9%)	1 (4%)	
Cycle regularity[b]			0.681
Regular	50 (48.5%)	11 (44%)	
Irregular	49 (47.6%)	13 (52%)	
Unknown/not recorded	4 (3.9%)	1 (4%)	
Duration of bleeding (days)			0.516
Mean (range)	9.3 (4.4)	8.6 (3.8)	
Unknown (women)	10	4	
Haemoglobin (g/dl)			0.584
Mean (S.D.)	12.2 (1.7)	12.4 (1.4)	
Unknown (women)	11	2	
Medical treatments attempted (no.)			0.755
0	16	3	
1	38	10	
2	35	7	
3 or more	11	4	
Missing/unknown	3	1	

[a] Persistent bleeding despite several changes to preparation, no pathology identified.
[b] Cycle defined as regular if within 21–35 days, and irregular if outside 21–35 days, irregular pattern or IMB.

The alternative for balloon ablation that was considered pre-operatively was laser ablation in 14 (13.6%) cases and a hysterectomy in 89 (86.4%) cases.

Of the 103 women, who returned the questionnaire, 81 (78.6%) indicated overall satisfaction (VAS > 5). The mean VAS for patient satisfaction was 7.55 (scale 0–10). At the time of the study, 4 women still had heavy periods, 13 had a hysterectomy (11 because of heavy periods, one was diagnosed with endometrial cancer at the time of pre-operative curettage, and one developed a haematometra and was later diagnosed with an ectopic pregnancy), 20 (19.4%) women had procedure-related amenorrhoea, 6 (5.8%) had spotting only, 35 (34%) had light, and 26 (25.2%) had moderate bleeding (Table 2).

The patient later diagnosed with ectopic pregnancy was 47 years old at the time of balloon ablation. She reported post-operative bleeding for a few days but subsequently became amenorrheic. A transvaginal ultrasound scan performed 40 weeks post-operatively because of pelvic pain, demonstrated an echo-filled endometrial cavity measuring $3.5\,\text{cm} \times 4.1\,\text{cm} \times 3.1\,\text{cm}$ indicative of an haematometra. She opted for a hysterectomy. At operation, the uterus was found to be distended to 10–12 weeks size with a tense haematometra and histological examination confirmed a right-sided missed tubal ectopic pregnancy and ovarian deciduosis. The patient who had hysterectomy for

Table 2
The outcome of Cavaterm™ *plus* in women with heavy periods

Outcome measure	No. (%)
Comparative VAS for overall satisfaction[a]	
>5	81 (78.6)
≤ 5	21 (20.4)
Missing	1 (1)
Bleeding pattern at time of study	
No bleeding[b]	32 (31.1)
Procedure-related amenorrhoea	19 (18.4)
Spotting	6 (6)
Light	35 (34)
Moderate	25 (24.3)
Heavy	4 (4)
Cycle regularity at time of study	
Regular	46 (65.7)
Irregular	24 (34.3)
Missing	1 (1)
Comparative VAS for post-operative dysmenorrhoea[c]	
<5	16 (28.6)
≥ 5	40 (71.4)

Values in parentheses are in percentages.
[a] Compared to before treatment; scale 0: much worse; 5, no difference; 10, much better.
[b] Includes 13 women who had a hysterectomy, 11 hysterectomies were due to heavy periods.
[c] Amongst women with pre-operative dysmenorrhoea still experiencing periods ($n = 56$); scale: 0, much worse; 5, no difference; 10, much better.

endometrial cancer was 42 years old. She reported heavy regular bleeding and had a hysteroscopy and biopsy 5 months prior to ablation. Histology reported inactive endometrium, with short tubular glands often lined by syncitial metaplastic epithelium, the stroma was compact and haemorrhagic consistent with recent shedding, with some basal type endometrium. Well-differentiated endometrial cancer was diagnosed from curettings obtained immediately prior to endometrial ablation.

Amongst the group, which returned the questionnaire, and excluding the case with endometrial cancer, the procedure was judged as a success in 85/102 (83.3%) cases, but failed in 17 (16.6%) women (11 required a hysterectomy, 4 had persistent heavy bleeding, 2 had moderate bleeding and a VAS ≤ 5). Overall, we ascertained that 20 women (responders and non-responders) had undergone or were awaiting hysterectomy at the time of the study. The indication for hysterectomy in 18 cases was heavy periods.

Recommended operative or selection procedure was not followed in a number of cases. The following non-exclusive deviations from recommended procedure were noted: 6 women had a uterine length of $\geq$10 cm, 7 needed $>$ 30 ml of distension medium, 4 had endometrial polyps, 9 had submucous fibroids; 35 women did not undergo curettage immediately prior to endometrial ablation, 19 of whom had medical endometrial thinning using either danazol ($n = 6$) or a GnRH analogue ($n = 13$). Taken together, in 26/103 cases, there was one or more important deviation from recommended operative or selection procedure, of these, 12 cases had no medical pre-treatment and no curettage, a large uterus and/or intracavitary lesion was noted in 10 cases and both factors were present in 4 cases. Of the 18 women who had or were scheduled to have a hysterectomy because of persistent menorrhagia, 9 (50%) had a large uterus, and 8 (44%) did not undergo curettage prior to balloon ablation, compared to 10% and 23% respectively of the rest of the group.

Using multiple binary logistic regression, the risk of failure was inversely related to patients' age (calculated per year of age, OR 0.778, 95% CI 0.669, 0.905). The risk of failure was higher in women who had longer duration of bleeding (calculated per day of bleeding, OR 1.29, 95% CI 1.1, 1.52) and in those whose management did not follow recommended operative or selection procedure (OR 5.056, 95% CI 1.097, 23.3). The risk of failure was not associated with the number of treatments received prior to balloon ablation, the presence of dysmenorrhoea, parity, or cycle regularity. Younger age (OR 0.88, 95% CI 0.794, 0.975), and longer menses in terms of days of bleeding per cycle prior to balloon ablation (OR 1.135, 95% CI 1.01, 1.273) were also associated with reduced patient satisfaction.

Sixty-seven women reported pre-operative dysmenorrhoea. The mean VAS for pain amongst all women with pre-operative dysmenorrhoea was 6.9 (0, much worse; 10, much better). Nine of these women underwent hysterectomy, 9 did not have dysmenorrhoea following balloon ablation, another 33 women reported improvement, and in 16 women the pain was reported as worse post-operatively (VAS < 5). The VAS for pain in women still experiencing pain post-operatively compared to the pain pre-operatively was 6.74 (0, much worse; 10, much better). There were seven new cases of dysmenorrhoea following balloon ablation.

There were no cases of uterine perforation or bleeding intra- or post-operatively. Thirteen women received post-operative antibiotics for suspected endometritis. There were two cases of haematometra at 8 and 10 months post-operatively. One of these drained spontaneously, the other underwent hysterectomy and was later diagnosed with an ectopic pregnancy.

5. Discussion

In August 2003, the National Institute for Clinical Excellence (NICE) published its guidance for the use of thermal endometrial ablation (including Cavaterm™ and Gynecare™) and concluded that evidence on safety and efficacy of balloon ablation appears to support the use of the procedure [5]. The conclusion by NICE, although based on studies using an older device which has been superseded, is supported by this study which is the first to report on the use

Table 3
The amenorrhoea and hysterectomy rates for the use of Cavaterm™ endometrial thermal balloon ablation in published studies

Study	Study population using cavaterm (*n*)	Number followed up (*n*)	Follow up interval (months)	Number (%) with amenorrhoea	Number undergoing hysterectomy for bleeding
Friberg et al. [15]	36	32	18–28	10 (31)	4
Gerber et al. [14]	67	55	6–24	17 (31)	3
Hawe et al. [7]	50	50	6–24	34 (68)	1
Friberg and Ahlgren [6]	117	102	10–49	23 (23)	10
Mettler [11]	70	65	48	38 (58)	3
Pellicano et al. [19]	40	35	48	Not stated	5.6[a]
Hawe et al. [8]	37	34	12	10 (29)	3
Vihko et al. [13]	16	15	6	2 (13)	0
Abbott et al. [9]	18	17	12	2 (12)	0
Alaily et al. [10]	77	61	24	28 (46)	3

[a] Re-operation rate (%).

of the modified device: Cavaterm™ *plus*. The older device was set for a higher temperature, lower balloon pressure and longer treatment time [6,13,15]. The results presented here suggest a modest procedure-related amenorrhoea rate (19.4%), but an additional 5.8% of patients had cyclical spotting and 33% described their periods as light. There was high patient satisfaction. On the other hand, we found a higher subsequent hysterectomy rate than previously reported (Table 3).

Although the amenorrhoea and hysterectomy rates previously reported with the use of Cavaterm™ varied (Table 3), the procedure was associated with a consistently high patient satisfaction rate (90–96%) [7,8,10]. A previous study demonstrated comparable effects on patients' quality of life with the use of techniques that produced different amenorrhea rates, and the authors argued against amenorrhoea as a measure of success [17]. But although this may render direct comparison between techniques more difficult, amenorrhoea is not the only desired clinical end-point of treatment. Comparison is also complicated by the fact that published studies have had different inclusion criteria, and because of differences between typical and ideal users of the devices.

The Cavaterm™ *plus* procedure is largely standardised because of the inbuilt safety features of the device, such as temperature, pressure and time control. But operator-dependent variables, such as patient selection and pre-balloon endometrial thinning by curettage, persist and appear to explain some, but not all, causes of failure. Previous studies used different inclusion criteria. The cut-off point for uterine size is variably taken as a uterine cavity length of 4–10 cm [6,13] or as uterine length of $<$12 cm [9,10]. However, most authors excluded or recommended the exclusion of patients with polyps or submucous fibroids. We took 10 cm uterine length as a conservative cut-off point for the purpose of the analysis. Pre-operative endometrial thinning was used in a substantial proportion of patients. This obviates the need for pre-ablation curettage, but at increased cost. The finding of endometrial carcinoma in the immediate pre-operative curettage in one patient is another consideration.

Overall, endometrial balloon ablation avoided a hysterectomy in the majority of cases and resulted in considerable reduction in the use of hospital beds. The ablation time (10 min) is only a fraction of the overall procedure time (mean 39 min), which is largely taken by the time needed for administering the anaesthetic, patient transfer and positioning. Thus, shorter procedures are likely to have a small effect on overall theatre utilisation.

The majority of patients underwent balloon ablation following unsuccessful attempts at medical treatment, although a significant minority (14.8%) underwent balloon ablation with no prior attempt at medical treatment. This may reflect clinical practice where doctors' and patients' preferences play a larger role in the choice of procedure, and is consistent with the recent NICE guidance [5]. This is also reflected by the number of patients who did not fulfil the recommended criteria for the use of the device, as rigid criteria are impractical in a clinical setting. Thus, the outcomes reported here may reflect the 'typical' rather than the 'ideal' use of the device, a notion that is important in the context of service provision and planning. However, the study emphasises the need to adhere to selection criteria and operative procedure.

Another main determinant of patient satisfaction using multi-variate regression analysis was patients' age. This is consistent with our findings in relation to endometrial laser ablation [18] and with the findings from studies using other ablation devices [20,21] and suggests the need for careful consideration of the optimal surgical intervention in younger women.

Symptoms disappeared in a proportion of women with pre-operative dysmenorrhoea, but there were a number of new cases. However, comparative VAS for pain suggested an overall improvement. Our results are consistent with the study by Friberg and Ahlgren who reported that out of the 53 women who had pre-operative dysmenorrhoea and who continued to experience periods, 16 had no dysmenorrhoea, 13 reported reduced severity, whilst 12 reported increased severity. In their study group of 116 patients, there were 8 new cases with dysmenorrhoea [6]. Another study reported a significant (72%) reduction in both dysmenorrhoea and premenstrual symptoms [10]. It is difficult to ascertain the relative importance of dysmenorrhoea to overall patient satisfaction, but it is possible that pain becomes relatively more significant as bleeding improves. Careful counselling is advisable in women complaining of significant dysmenorrhoea. This remains an area for future research. It is important to note that patients' subjective evaluation of outcome compared to their symptom before treatment may have been influenced by recall bias, but the effect of such bias remains uncertain.

6. Conclusion

The use of Cavaterm™ *plus* in a clinical setting, where optimal selection and operative criteria were not always met, resulted in modest amenorrhoea rates. The findings emphasis the need to adhere to recommended inclusion and exclusion criteria, and operative procedure. There is a need for long-term follow up and further research into determinants of success and on the impact of dysmenorrhoea on patient satisfaction.

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