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Outcome of the first 220 cases of endometrial balloon ablation using Cavaterm™*plus*

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Summary
The objective of this prospective study was to evaluate the effectiveness of day-case Cavaterm™*plus* thermal balloon endometrial ablation in the treatment of therapy-resistant menorrhagia. The study included 220 patients with a mean age of 41 years, mean parity of 2.1 and mean duration of menorrhagia of 3.2 years. A 6-mm diameter Cavaterm™*plus* catheter with a silicone balloon at its tip was used. The ablation time was 10 minutes at a temperature of 78°C. No procedure-related operative or immediate postoperative complications were encountered. The mean follow-up period was 19 months (range 6–24 months). The amenorrhoea–hypomenorrhoea rates at the various follow-up periods ranged between 74% and 83%. At the end of follow-up, 83% of patients were satisfied with the procedure. We conclude that Cavaterm™*plus* is a safe and effective treatment for menorrhagia and has good patient acceptability.

Introduction

Menorrhagia is one of the most common problems encountered in clinical practice and can have a detrimental impact on the quality of life of its sufferers (Garratt *et al.*, 1994; Cooper *et al.*, 1997b). More than 20% of otherwise healthy premenopausal women above the age of 35 years consult their general practitioners with this problem (Gath *et al.*, 1987; Vessey *et al.*, 1992) and it accounts for one-third of gynaecological referrals (Coulter *et al.*, 1989). In over 50% of cases no cause is found and the diagnosis of dysfunctional uterine bleeding is made, for which medical therapy is usually the first line of treatment (Turner *et al.*, 2000). When it fails, surgery often follows with up to 60% of women complaining of menorrhagia undergoing a hysterectomy within 5 years of their referral to a gynaecologist (Coulter *et al.*, 1991).

Over the last 20 years, minimally invasive endometrial ablation techniques have gained increasing popularity as an alternative to hysterectomy for treatment of menorrhagia. Established techniques of ablation include laser and roller-ball endometrial ablation and loop electrosurgical resection (Goldrath *et al.*, 1981; Garry *et al.*, 1991; Dwyer *et al.*, 1993; Pinion *et al.*, 1994; O'Connor and Magos, 1996; Phillips *et al.*, 1998). The advantages of such techniques over hysterectomy are reduced perioperative morbidity, shorter hospital stay and more rapid recovery, allowing earlier return to normal daily activity with associated health and economic benefits. These techniques, however, require considerable hysteroscopic experience and carry the potential for some serious complications, such as uterine perforation and fluid overload. In recent years, a second generation of endometrial ablation techniques that are safer and require only basic hysteroscopic skills have been introduced with comparable efficacy to first-generation ablation techniques (Overton *et al.*, 1997; Amso *et al.*, 1998; Meyer *et al.*, 1998; Cooper *et al.*, 1999; Hawe *et al.*, 1999; Corson, 2001; Hefni *et al.*, 2002; Abbott *et al.*, 2003).

The aim of the present study was to evaluate the effectiveness of a new thermal balloon endometrial ablation system: Cavaterm™*plus* (Wallsten Medical SA, Morges, Switzerland), used in the department of gynaecology at the Princess Royal University Hospital and Farnborough Hospital in Kent over a 2-year period.

Patients and methods

Women suffering from heavy menstrual bleeding and referred to the gynaecology outpatient clinic were invited to participate in the study between April 2001 and March 2003. Menorrhagia was diagnosed on the basis of history including frequent change of pads or tampons and the presence of blood clots in menstrual flow. All patients were given verbal and written information about the procedure as well as alternative treatment options, and signed an informed consent form.

Eligibility criteria

Patients were included in the study if they were suffering from menorrhagia resistant to medical therapy, had completed their families and had no desire for future childbearing, had a normal cervical cytology, uterine cavity on hysteroscopic examination and endometrial histology and if they had no adnexal masses on transvaginal ultrasound scanning. Women who wished further childbearing or had significant intrauterine pathology such as polyps or submucous fibroids, a uterine cavity length of > 12 cm or evidence of endometrial hyperplasia or atypia, were excluded from the study. However, previous uterine surgery was not considered a contraindication. All patients were counselled regarding suitable contraception after surgery.

Procedure

All procedures were carried out on random menstrual cycle days and as day cases under general anaesthesia without any

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preoperative endometrial preparation. The cervix was dilated to 6 mm using Hegar dilators when necessary. The total uterine length was measured with a uterine sound and then reduced by the length of the cervical canal to obtain the uterine cavity length. Endometrial curettage was then performed to reduce endometrial thickness and obtain a second specimen for histological assessment. The Cavaterm™*plus* ablation system consists of a disposal silicone balloon mounted on a 6-mm-wide catheter and a battery-operated central processing unit. The length of the silicone balloon was adjusted according to the uterine cavity measurement. After purging the air from the Cavaterm™*plus* system, the catheter end was inserted to the fundus and the balloon inflated with glucose 5% until a pressure of 230 (± 10) mmHg was achieved. This pressure was maintained throughout the entire procedure. Fluid circulation and then heating were started. Once a temperature of 75°C was achieved ablation time started. Treatment lasted for 10 minutes with the temperature stabilised at 78°C. A device in the central unit generates pulses though the liquid in the catheter to promote vigorous circulation in the balloon in order to ensure a uniform heat distribution. The Cavaterm™*plus* system is equipped with an electronic security system and a mechanical pressure valve to maintain a safe working pressure throughout the ablation phase. Also, the ablation catheter is insulated below the balloon to protect the cervical canal and vagina from heat damage. After the 10 minutes had elapsed, heating was automatically stopped, the fluid retrieved and the catheter removed.

Analgesia

Patients were given morphine (5–10 mg) intramuscularly (i.m.) during the procedure and diclofenac 100 mg rectally at the end of the procedure (if there was no contra-indication). After surgery, patients were prescribed post-operative oral analgesia in the form of diclofenac sodium 50 mg or a combination of codeine phosphate 30 mg and paracetamol 500 mg orally twice daily for 2 days.

Outcome measures and follow-up schedule

Outcome measures included Perioperative morbidity, amenorrhoea and hypomenorrhoea rates, changes in premenstrual symptoms and patient satisfaction. Patients were seen at 6, 12 and 24 months after surgery. At each visit, patients were asked about their menstrual bleeding pattern, duration of menstrual flow and interval between menses (if still menstruating) and their subjective assessment of satisfaction with the operation outcome. Amenorrhoea was defined as absence of menstrual bleeding (after exclusion of pregnancy) and hypomenorrhoea as regular spotting at the time of menstruation.

Results

A total of 220 women who had menorrhagia resistant to medical therapy were eligible for the study. Their mean age was 41 years and mean parity was 2.1 (Table I). In addition to medical therapy, 23 patients (10%) had tried the levonorgestrel-releasing intrauterine (Mirena™) system. One-fourth of patients had had previous uterine surgery (Table II). All patients underwent Cavaterm™*plus* endometrial ablation as day cases. There were no cases of balloon failure as there were no operative or immediate postoperative complications.

All patients completed 6 months' follow-up and the mean follow-up period was 19 months (range 6–24). During follow-up, between 74% and 83% of patients reported either amenorrhoea or hypomenorrhoea in the form of menstrual spotting only. Table III shows the amenorrhoea/hypomenorrhoea rates at the various follow-up periods during the study. In addition, assessment of premenstrual symptoms revealed that 72% of patients reported reduction in dysmenorrhoea at 12 months after surgery.

At the end of follow-up, 74% of patients reported either amenorrhoea or hypomenorrhoea, 9% reported normal periods and both groups (83%) were satisfied with the procedure and would recommend it to a friend. Thirty-seven patients (17%) were not satisfied with the procedure, including 34 patients (15%) who either underwent (26/34) or are currently booked (8/34) for hysterectomy. Histopathological examination of the 26 uteri removed so far

Table I. Patient characteristics. Values are given as mean (SD) or as specified

Variable	*Value*
Age, years	41 (28–54)
Parity	2.1 (0–5)
Weight, kg	75.4 (65–156)
Duration of menorrhagia, years	3.2 (2–6)
Previous uterine surgery, no. (%)	55 (25)
Female sterilisation, no. (%)	114 (47)
Male sterilisation, no. (%)	43 (19.5)

Table II. Type of previous uterine surgery

Operation	*No. (%)*
One caesarean section	31 (14.1)
Two caesarean sections	14 (6.3)
Three caesarean sections	3 (1.4)
Hysteroscopic myomectomy	4 (1.8)
Abdominal myomectomy	3 (1.4)
Total	55 (25)

Table III. Amenorrhoea and hypomenorrhoea rates at the different follow-up periods

Follow-up	*No. of patients*	*Amenorrhoea rate*	*Hypomenorrhoea rate*	*Combined rate*
6 months	220	61%	22%	83%
12 months	210	48%	27%	75%
18 months	153	42%	31%	73%
24 months	108	39%	35%	74%

revealed the presence of adenomyosis in 10 (38%), uterine fibroids in seven (27%), a combination of the two in two (8%) and normal histology in seven patients (27%).

Discussion

The main aim of endometrial ablation is to achieve significant reduction of menstrual loss and patient satisfaction (Garry, 2002). We chose the combined amenorrhoea and hypomenorrhoea rates as the main outcome for this study as it represents the preferred treatment outcome, is a less subjective outcome measure compared to other measures such as pictorial menstrual charts (Reid *et al.*, 2000) and is identified easily by both patients and clinicians (Abbott *et al.*, 2003). We also included patient satisfaction as an outcome measure as patients' response to treatment outcome remains of great importance (Coulter *et al.*, 1994).

The original Cavaterm™ ablation system has been evaluated in prospective and randomised studies with encouraging results. It has been shown to achieve an 8 mm depth of destruction, enough to ablate the endometrium and the superficial 2–3 mm of the myometrium (Friberg *et al.*, 1996). In addition, using the system requires only basic hysteroscopic skills and has the advantage of an adjustable ablation balloon length, thus adapting to individual uterine cavity sizes in order to ensure a good balloon/cavity surface contact. However, the majority of published studies in the English literature assessing the outcome of the Cavaterm™ ablation system had each included a relatively small number of patients. To our knowledge, this is the first prospective study in a large number of patients to evaluate the outcome of endometrial ablation using the new Cavaterm™*plus* system, allowing reliable interpretation of treatment effectiveness and safety.

Cavaterm™*plus* differs from the older version in four main respects. First, the diameter of the device's catheter is smaller (6 mm) compared to 9 mm in the older version, thus obviating the need for cervical dilatation in most cases and allowing the procedure to be performed under local anaesthesia (Friberg and Ahlgren, 2000), although this was not preferred by our patients. Secondly, the balloon length is more adjustable to the cavity, thus adapting to a wider variety of cavity configurations. Thirdly, ablation time is 5 minutes shorter in the new system, thereby potentially increasing patient acceptability, enhancing the chances of the procedure being performed without a general anaesthetic and reducing overall costs (Garry, 2002). Finally, the heating pulsations and fluid circulation in the balloon have been improved for optimal treatment.

The combined amenorrhoea and hypomenorrhoea rates seen in the current study compare favourably to those seen in published studies utilising the old Cavaterm™ system (56–82%), despite a 33% reduction in ablation time from 15 to 10 minutes and longer follow-up (Hawe *et al.*, 1999; Abbott *et al.*, 2003; Alaily *et al.*, 2003; Vihko *et al.*, 2003). Similarly, the overall patient satisfaction with the new system is comparable to that reported in the earlier studies.

For a new procedure to be incorporated into routine clinical practice, it has to be at least as effective, safe and acceptable to patients as established techniques. Results of the present study compare favourably with those reported after both hysteroscopic first-generation methods for endometrial ablation such as endometrial resection, rollerball and Nd-YAG laser ablation (Magos *et al.*, 1991; Garry *et al.*, 1995; Goldrath, 1995; Valle, 1995; Friberg *et al.*, 1996; O'Connor and Magos, 1996) and second-generation ablation methods such as Thermachoice™, NovaSure™ and hydrothermal ablation (Amso *et al.*, 1998; Meyer *et al.*, 1998; Friberg and Ahlgren, 2000; Corson, 2001; Hefni *et al.*, 2002; Abbott *et al.*, 2003). Also, the low failure rate observed in the present study was comparable to those reported previously with the use of either first- or second-generation techniques of endometrial ablation (Pinion *et al.*, 1994; O'Connor and Magos, 1996, Phillips *et al.*, 1998; Hefni *et al.*, 2002). Such good results were achieved despite the procedure being performed with no pharmacological pretreatment to the endometrium. An additional benefit is the considerable reduction in dysmenorrhoea and premenstrual symptoms (by 72% in our study), a finding consistent with other endometrial destructive techniques (Dwyer *et al.*, 1993; Cooper *et al.*, 1997a; Hawe *et al.*, 2003).

Finally, endometrial ablation is associated with an overall complications rate of 1–4% (Overton *et al.*, 1997). In this study, no procedure-related major complications were encountered providing further reassurance regarding the safety of the technique even in those who had previous uterine surgery.

In conclusion, thermal balloon endometrial ablation using the Cavaterm™*plus* system offers a safe and effective option in the treatment of women complaining of menorrhagia with high patient satisfaction. The procedure is simple, does not require additional training in operative hysteroscopy and compares favourably with other ablative techniques. These good results, however, need to be confirmed in a randomised controlled trial in order to define the role of Cavaterm™*plus* in the contemporary management of menorrhagia.

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