Journal of Obstetrics and Gynaecology (2003) Vol. 23, No. 1, 51–54

Taylor & Francis
healthsciences

GYNAECOLOGY

Endometrial ablation with the Cavaterm™ thermal balloon

A. B. ALAILY, B. J. AULD and Y. DIAB
Department of Obstetrics and Gynaecology, Conquest Hospital, St Leonards-on-Sea, UK

Summary
This prospective observational study evaluates the efficacy and safety of thermal Balloon endometrial ablation using the Cavaterm™ system for the treatment of dysfunctional uterine bleeding. Seventy-seven women with a mean age of 43 years who met the inclusion and exclusion criteria were treated under general anaesthesia. A 9-mm diameter catheter with a silicone balloon at its tip was inserted transcervically into the uterus and was inflated with sterile 1.5% glycine and connected to a control unit that maintained the temperature of the circulating heated fluid at 75°C, monitored the pressure and terminated the treatment after 15 minutes. There were no intra-operative complications and patients tolerated the treatment well. Satisfaction rates were 90% at both 12 and 24 months. At 24 months 10% of patients had heavy periods, 5% normal periods, 39% light periods and 46% amenorrhoea. Cavaterm balloon ablation seems a safe and effective option for women with menorrhagia. The procedure does not require additional training and expertise in operative hysteroscopy and compares favourably with established techniques.

Introduction

Heavy menstrual bleeding or menorrhagia is a significant cause of ill health in women. It has been clinically defined as greater than or equal to 80 ml blood loss per menstrual cycle (Cole *et al.*, 1971; Hallberg *et al.*, 1966).

A large proportion of women presenting for treatment of excessive menstruation have monthly blood loss within the normal range, but still request help. It is known that women complaining of heavy menstrual loss suffer a significant reduction in quality of life (Coulter *et al.*, 1994; Garratt *et al.*, 1994).

The woman's perception of her own menstrual loss is the key determinant in her referral and subsequent treatment. One in 12 women in the United Kingdom aged 30–49 years consults their general practitioner (GP) each year with heavy menstrual bleeding (Vessey *et al.*, 1992) and the condition affects about 22% of otherwise healthy premenopausal women aged more than 35 years (Gath *et al.*, 1987).

Surgical treatment of heavy menstrual bleeding often follows failed or ineffective medical therapy although it is also used as a first-line therapy. Hysterectomy has been regarded as the definitive surgical treatment for intractable heavy menstrual bleeding but in spite of a 100% success rate (complete cessation of menstruation) and high levels of satisfaction, it is a major surgical procedure with significant physical and emotional complications and a social and economic cost. Many women prefer a less invasive surgical treatment even when they are made aware that the success of the treatment is not always assured (Nagele *et al.*, 1998).

Several minimally invasive surgical techniques have been developed as alternatives to hysterectomy for the treatment of heavy menstrual bleeding. Goldrath introduced laser ablation of the endometrium in the 1981 (Goldrath *et al.*, 1981), and De Cherney and Polan used electrosurgical resection of the endometrium in 1983 (De Cherney and Polan, 1983). These techniques have become increasingly popular over the late 1980s and 1990s because of their apparent successful treatment of heavy menstrual bleeding without the need for hysterectomy.

Recently, a number of 'blind' endometrial ablative procedures utilising various energy sources have been developed that do not require skillful hysteroscopic surgery. These include the uterine thermal balloon such as Thermachoice™, Easy™ (Amso *et al.*, 1998; Meyer *et al.*, 1998) and the Cavaterm™ balloon system (Friberg *et al.*, 1996), cryoablation (Pittrof *et al.*, 1994), microwave ablation (Sharp *et al.*, 1995) and photodynamic therapy (Gannon, 1994).

The advantages of such techniques over traditional hysterectomy include shorter hospital stay, more rapid recovery allowing return to normal daily activity and reduced perioperative morbidity, with associated health and economic benefits.

Patients and methods

Patients

Patients with a mean age of 43 and suffering from heavy menstrual bleeding who would otherwise have required hysterectomy (and who had failed medical treatment) were included in this prospective observational study. They were treated with Cavaterm system in the Department of Obstetrics and Gynaecology at the Conquest Hospital in East Sussex in the period from 1997 to 2001.

Menorrhagia was evaluated using pictorial chart assessment of menstrual loss (Higham *et al.*, 1990). Dysmenorrhea and premenstrual symptoms were also assessed during history-taking; however, the patient's perception of her own menstrual loss and her request for help was a key determinant in her subsequent treatment. All had failed medical therapy or were unwilling or unable to carry on with it.

Correspondence to: Mr A. Alaily PhD, FRCOG, Conquest Hospital, The Ridge, St Leonards-on-Sea, E. Sussex TN37 7RD, UK.
Tel: +44(0) 1424 755255; Fax: +44(0) 1424 758086.

ISSN 0144-3615 print/ISSN 1364-6893 online/03/010051-04 © Taylor & Francis Limited, 2003
DOI: 10.1080/0144361021000043254

All patients were suitable for either hysterectomy or endometrial ablation and were given the option of endometrial ablation using the Cavaterm™ thermal balloon as an alternative to hysterectomy. During counselling, patients were informed that the aim of the procedure is either of stopping their periods, 'amenorrhoea', or reducing the amount of blood loss either back to normal or light periods as it has been shown that an expectation of amenorrhoea leads to higher re-operation rates despite lighter periods being achieved (Cooper *et al.*, 1997).

Inclusion criteria included a normal uterine cavity on hysteroscopic examination and normal endometrial histology and cervical cytology. These patients had no desire to maintain fertility and were counselled regarding the need to use a reliable form of contraception. Exclusion criteria included undiagnosed uterine bleeding, gross uterine abnormality, pregnancy or the desire to become pregnant, uterine cavity length greater than 12 cm or less than 4 cm. Suspicion of uterine wall weakness was considered as a constraindication, therefore patients with previous caesarean section were excluded, although there are no firm data to either support or refute this.

There was no preoperative endometrial preparation. Instead we used intraoperative curettage to thin the endometrium and obtain a final sample for histological diagnosis.

Methods

All procedures in our series were carried out under general anaesthesia. The cervix was dilated to 9 mm with Hegar's dilators. The total length of the uterine cavity was measured with a uterine sound and then reduced by the length of the cervical canal, which had been evaluated using the Hegar dilators. A curettage was performed before insertion of the catheter to reduce endometrial thickness and to obtain a last specimen confirming histopathological assessment. The internal uterine cavity length (total length minus cervical canal length) was used to adjust the balloon length of the catheter. After purging the air from the catheter system, the catheter end was inserted until the fundus was reached. The balloon was then inflated with glycine 1.5% (15 mg/ml) until a pressure of around 200 (± 20) mmHg was achieved. This pressure must be maintained during the entire procedure. The circulation and then heating were started. Once a temperature of 65°C was achieved the countdown started. The temperature usually stabilised at 75°C with a high of 81°C. The treatment lasted 15 minutes.

Once the set time has elapsed heating automatically stops, circulation stops and the volume of glycine retrieved and the catheter removed.

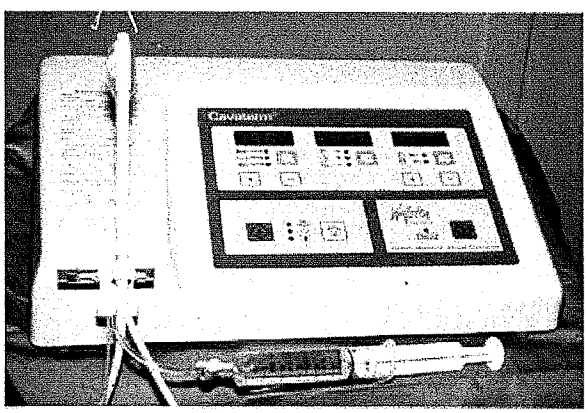

Figure 1. Cavaterm™ machine and balloon.

Technical aspects

The Cavaterm system (Figure 1) was designed to overcome the potential risks and complications of hysteroscopic ablative techniques. The highly flexible, strong, inflatable silicone balloon diminishes risks of rupture and conforms to the uterine cavity. The hypoallergenic property of silicone is an added advantage. The balloon length is adjustable to fit the cavity, thus adapting to individual uterine cavity sizes, in order to ensure the ideal balloon/cavity surface contact and to protect the cervical canal and vagina from heat damage. Also, the catheter is insulated below the balloon in order to protect the cervical canal and the vagina. The Soft Heat™ elements consist of thin lamellae of a special superconductive ceramic material with inherent self-regulating properties. The working temperature set at time of manufacturing (80°C) always maintains the liquid at around 75°C. This is obtained by using a large surface area element and an efficient circulation of the fluid. This unique self-regulating feature eliminates the need for external regulating techniques and for high temperature protection and allows for a relatively low working temperature due to the large surface eliminating the risk of overheating and pressure build-up. A device in the central unit generates pulses through the liquid in the catheter that promotes vigorous circulation in the balloon to ensure a uniform heat treatment. The system is equipped with an electronic security system and a mechanical pressure valve. The electronic security system will indicate high pressure in the system and the mechanical valve will open to release liquid to maintain a safe working pressure. The system is battery-operated and equipped with a back-up battery. This eliminates the risks related to mains connected equipment. The battery keeps the parameters on screen.

Follow-up

Outcome measures included operative details, pictorial menstrual charts and assessment of satisfaction and premenstrual symptoms.

At follow-up at 3, 6, 12 and 24 months postoperatively menstrual charts were examined, or alternatively the patients were asked about their bleeding pattern including whether or not there was bleeding, the number of days of bleeding, the interval between menses, the date of last menstruation and the subjective assessment of each day's maximal bleeding as the majority of patients did not continue using the charts.

A recognised quality of life questionnaire was not utilised. The patients' subjective assessment of satisfaction with the operation was assessed as excellent, good, moderate or no improvement.

Results

A total of 77 patients completed a 12-month follow-up; of these 62 completed 24 months of follow-up.

There were no immediate intra-operative complications. The treatment was performed as a day-case procedure in 65 patients and 12 returned home on the following day. These 12 patients stayed overnight for different reasons: postoperative pain, their home was far away, intercurrent disease, or it was late in the evening before they felt well.

Analgesia

The first few patients in the series experienced moderate to severe postoperative pain which required narcotic analgesics (pethidine 50–100 mg/morphine 5–10 mg) intramuscularly followed by Diclofenac sodium 50 mg t.d.s orally or in a combination with codeine phosphate 30 mg and paracetamol 500 mg (Tylex™) orally for 3 days. The rest of the patients were routinely given pethidine/morphine IV during the procedure and diclofenac 75 mg was administered rectally at the end of the procedure if there was no contraindication. The patients were prescribed postoperative oral analgesia routinely for 3 days as above. This regimen of pain control was adequate.

Postoperative morbidity was minimal. One patient presented as an emergency 9 months after the procedure because of a sudden onset of acute lower abdominal pain. Transvaginal ultrasound revealed haematometra, which was treated by cervical dilatation and drainage under general anesthesia. After drainage she was amenorrhoeic. Three other hysterectomies were performed abdominally for persistent heavy menstrual bleeding which was considered as treatment failure. Histopathological examination was normal and there was no evidence of thermal destruction of endometrium.

Four other patients were treated subsequently by the insertion of levonorgestrel-releasing intrauterine system (Mirena™) with improvement.

Table I shows that 27 of 77 (35%) patients were amenorrhoeic after 1 year, and 28 of 61 (46%) patients were amenorrhoeic in their second year of follow-up. Treatment was considered successful if there was subjective perception of reduction of menstrual blood loss whether to a normal pattern or light periods or when there was amenorrhoea. Assessment of dysmenorrhoea and premenstrual symptoms revealed a 72% reduction of both, which is a recognised and consistent finding following endometrial destructive procedures.

Discussion

Thermal balloon endometrial ablation using the Cavaterm™ system is safe and effective in treating menorrhagia. Our results compare favourably to the results from hysteroscopic 'first-generation' methods for endometrial ablation including endometrial resection, rollerball and Nd-YAG laser ablation, with the advantages of a significantly shorter learning period compared to first generation techniques which take longer to be mastered safely (Magos *et al.*, 1991; Garry *et al.*, 1995; Goldrath, 1995; Valle, 1995; Friberg *et al.*, 1996; O'Connor and Magos, 1996).

Other potentially serious complications such as fluid extravasation and its sequelae and haemorrhage are additional risks of the hysteroscopic procedures which were not reported with the Cavaterm™ (Magos *et al.*, 1991; Garry *et al.*, 1995; Goldrath, 1995; Valle, 1995; O'Connor and Magos, 1996).

Table I. Cavaterm balloon ablation 1997 to 2001

	12 Months (77 patients)	*2 Years (61 patients)*
Heavy	8 (10%)	6 (10%)
Normal	7 (9%)	3 (5%)
Light	35 (46%)	24 (39%)
Amenorrhoea	27 (35%)	28 (46%)

Table II. Patient satisfaction

Follow-up	*Satisfied*	*Not satisfied*
12 Months	69 (90%)	8 (10%)
24 Months	55 (90%)	6 (10%)

Compared to other thermal balloon systems such as Thermachoice™ and Easy™, although results are similar (Amso *et al.*, 1998; Meyer *et al.*, 1998; Friberg and Ahlgren, 2000), the Cavaterm™ differs in three important respects. First, the balloon is made of silicone rather than latex, which renders it highly flexible and more robust. It will therefore withstand higher pressures within the balloon diminishing the risk of rupture. Silicone is hypo-allergenic. Secondly, the fluid within the balloon is caused to circulate vigorously which ensures an even temperature distribution. Thirdly, the balloon length is adjustable to fit the cavity, thus adapting to individual uterine cavity sizes, in order to ensure the ideal balloon/cavity surface contact and protecting the cervical canal and vagina from heat damage. A relative disadvantage is the 9-mm diameter of the catheter, which necessitates cervical dilatation.

The Cavaterm can also be used under local anaesthesia (Friberg and Ahlgren, 2000), although this was not preferred by our patients.

The procedures were performed irrespective of the menstrual cycle with no pharmacological pretreatment to the endometrium. A thorough endometrial curettage was performed immediately before the procedure.

The procedure has been found particularly useful in obese patients and in high-risk surgical candidates, which is an additional advantage (Aletebi *et al.*, 1999). An additional benefit is the reduction of dysmenorrhoea and premenstrual symptoms (by 72% in our study), which is a finding consistent with other endometrial destructive techniques (Dwyer *et al.*, 1993; Abramovich *et al.*, 1994; Cooper *et al.*, 1997).

This study adds to other data regarding the efficacy of second generation devices and provides a simple and effective alternative to earlier techniques of endometrial ablation. This procedure can be learned quickly even by juniors in training and has a low complication rate. Longer-term results are still awaited and further research using randomised controlled trials is recommended.

Conclusion

Thermal balloon endometrial ablation using the Cavaterm™ system seems a safe and effective option in the treatment of women with idiopathic menorrhagia with high patient satisfaction (Table II). The procedure is simple and does not require additional training or expertise in operative hysteroscopy and compares favourably with other ablative techniques with minimal morbidity and complications. Our study showed favourable results without using endometrial preparation.

References

Abramovich D.R., Naji A., Alexander D.A., Russell I.T. and Kitchener H.C. (1994) Randomised trial of hysterectomy, endometrial laser ablation and transcervical endometrial

resection for dysfunctional uterine bleeding. *British Medical Journal*, **309**, 979–983.

Aletebi F.A., Vilos G.A. and Eskander M.A. (1999) Thermal balloon endometrial ablation to treat menorrhagia in high risk surgical candidates. *Journal of American Gynecological Laparoscopy*, **6**, 435–439.

Amso N.A., Stabinsky S.A., McFaul P., Blanc B., Pendley L. and Neuwirth R. (1998) Uterine thermal balloon therapy for the treatment of menorrhagia: the first 300 patients from a multicentre study. *British Journal of Obstetrics and Gynaecology*, **105**, 517–523.

Cole S., Billewicz W. and Thomson A. (1971) Sources of variation in menstrual blood loss. *Journal of Obstetrics and Gynaecology of the British Commonwealth*, **78**, 933–939.

Cooper K.G., Grant A.M. and Garratt A.M. (1997) The impact of using a partially randomised patient preference design when evaluating alternative managements for heavy menstrual bleeding. *British Journal of Obstetrics and Gynaecology*, **104**, 1367–1373.

Cooper K.G., Parkin D.E., Garratt A.M. and Grant A.M. (1977) A randomised comparison of medical and hysteroscopic management in women consulting a gynaecologist for treatment of heavy menstrual loss. *British Journal of Obstetrics and Gynaecology*, **104**, 1360–1366.

Coulter A., *et al.* (1994) Quality of life and patient satisfaction following treatment for menorrhagia. *Family Practice*, **11**, 394–401.

De Cherney A.H. and Polan M.L. (1983) Hysteroscopic management of intrauterine lesions and intractable uterine bleeding. *Obstetrics and Gynecology*, **61**, 392–397.

Dwyer N., Hutton J. and Strirrat G.M. (1993) Randomised controlled trial comparing endometrial resection with abdominal hysterectomy for the surgical treatment of menorrhagia. *British Journal of Obstetrics and Gynaecology*, **100**, 237–243.

Friberg B. and Ahlgren M. (2000) Thermal balloon endometrial destruction: the outcome of treatment of 117 women followed up for a maximum period of 4 years. *Gynaecological Endoscopy*, **9**, 389–395.

Friberg B., Persson B.R.R., Willen R. and Ahlgren M. (1996) Endometrial destruction by hyperthermia—a possible treatment for menorrhagia. An experimental study. *Acta Obstetricia Gynecologica Scandinavica*, **75**, 330–335.

Gannon M.J. (1994) Photodynamic therapy for menorrhagia. *Trends in Urological and Gynaecological Sexual Health*, **October**, 16–20.

Garratt A.M., Ruta D.A., Abdalla M.I. *et al.* (1994) The SF-36 health survey questionnaire 11. Responsiveness to changes in health status for patients with four common conditions. *Quality Health Care*, **3**, 186–192.

Garry R., Shelly-Jones D., Mooney P. and Phillips G. (1995) Six hundred endometrial laser ablations. *Obstetrics and Gynecology*, **85**, 24–29.

Gath D., Osborn M., Bungay G., Iles S., Day A., Bond A. and Passingham C. (1987) Psychiatric disorders and gynaecological sympotoms in middle aged women: a community survey. *British Medical Journal*, **294**, 213–218.

Goldrath M.H., Fuller T.A. and Segal S. (1981) Laser photovaporization of endometrium for the treatment of menorrhagia. *American Journal of Obstetrics and Gynecology*, **140**, 14–19.

Goldrath M.H. (1995) Hysteroscopic endometrial ablation. *Obstetric and Gynecology Clinics of North America*, **22**, 559–572.

Hallberg L., Hogdahl A.M., Nilsson L. and Rybo G. (1966) Menstrual blood loss—a population study. *Acta Obstetricia and Gynecologica Scandinavica*, **45**, 320–351.

Higham J.M., O'Brian P.M.S. and Shaw R.W. (1990) Assessment of menstrual blood loss using a pictorial chart. *British Journal of Obstetrics and Gynaecology*, **97**, 734–739.

Magos A.L., Baumann R., Lockwood G.M. and Turnbull A.C. (1991) Experience with the first 250 endometrial resections for menorrhagia. *Lancet*, **337**, 1074–1078.

Meyer W., Walsh B., Grainger D., Peacock L.M. and Loffer F.D. (1998) Thermal balloon and rollerball ablation to treat menorrhagia: a multicentre comparison. *Obstetrics and Gynecology*, **92**, 98–103.

Nagele F., Rubinger T. and Magos A. (1998) Why do women chose endometrial ablation rather than hysterectomy? *Fertility and Sterility*, **69**, 1063–1066.

O'Connor H. and Magos A.L. (1996) Endometrial resection for menorrhagia: evaluation of result at 5 years. *New England Journal of Medicine*, **335**, 151–156.

Pittrof R., Majid S. and Murray, A. (1994) Transcervical endometrial cryoablation (ECA) for menorrhagia. *International Journal of Gynaecology and Obstetrics*, **47**, 135–140.

Sharp N.C., Cronin N., Feldberg I., Evans M., Hodgson D. and Ellis S. (1995) Microwaves for menorrhagia; a new fast technique for endometrial ablation. *Lancet*, **346**, 1003–1004.

Valle R.F. (1995) Rollerball endometrial ablation. *Ballières Clinical Obstetrics and Gynaecology*, **9**, 299–316.

Vessey M., Villard-Mackintosh L., McPherson K., Coulter A. and Yeates D. (1992) The epidemiology of hysterectomy: findings in a large cohort study. *British Journal of Obstetrics and Gynaecology*, **99**, 402–407.