Two-year results of a new two-minute hot liquid balloon endometrial ablation system (Thermablate): a pilot study

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Summary

Purpose: To evaluate the feasibility, safety and clinical outcomes of a new 2-minute hot liquid balloon endometrial ablation system (Thermablate). *Material and Method:* This prospective observational study included 72 premenopausal women with menorrhagia. All patients were treated from February 2005 through February 2008 under general anaesthesia in the Department of Obstetrics and Gynaecology at the University Hospital of Alexandroupolis, Greece. Thinning of the endometrium was achieved by sharp curettage immediately prior to the procedure. Pretreatment evaluation of menstrual blood flow, duration of menses and frequency of menses were recorded on all patients. Patient records were screened for adverse events, post procedure pain and required medication, dysmenorrhea, satisfaction and menstrual bleeding patterns. *Results:* Follow-up at three months (n = 72), 6 months (n = 62), 12 months (n = 47) and 24 months (n = 17) showed a trend towards reduced monthly blood flow. Combined amenorrhea and hypomenorrhea rates at 3, 6, 12 and 24 months were 39%, 73%, 77% and 70%, respectively. The corresponding satisfaction rates were 86%, 93.5%, 93.5% and 82.4%, respectively. Dysmenorrhea rates increased from 37.5% prior to surgery, to 57% at three months and decreased to 23.5% at 24 months ($p < 0.0001$). *Conclusion:* Endometrial ablation with the Thermablate system is a safe and effective therapy for dysfunctional uterine bleeding when other therapies are contraindicated or have been tried and failed.

Key words: Menorrhagia; Dysfunctional uterine bleeding; Endometrial ablation; Thermablate.

Introduction

Abnormal uterine bleeding is a common presenting symptom in clinical practice. It affects as many as 20% of otherwise healthy, premenopausal women over age 35, and causes approximately 5% of women aged 30 to 49 years to seek medical care each year [1]. As a rule, in women of childbearing age, a detailed history, complete physical and pelvic examination, as well as appropriate laboratory tests enable the physician to rule out other causes of bleeding such as pregnancy and pregnancy-related disorders, iatrogenic causes, systemic conditions and obvious genital tract pathology. Dysfunctional uterine bleeding (anovulatory or ovulatory) is diagnosed by exclusion of these other causes [2, 3].

In premenopausal women with certain risk factors for endometrial neoplasia, initial evaluation should include endometrial biopsy, saline-infusion sonohysterography and/or diagnostic hysteroscopy in accordance with clinical practice guidelines. Women of childbearing age at low risk for endometrial neoplasia may be assessed initially by transvaginal ultrasonography [4].

Medical management of anovulatory dysfunctional uterine bleeding may include oral contraceptive pills or cyclic progestins [5]. Menorrhagia may also be managed effectively with nonsteroidal anti-inflammatory drugs (NSAIDs) or levonorgestrel intrauterine systems (LNG-IUS). When such therapy is ineffective, not tolerated or refused by patients for reason of personal choice, many women seek surgical treatments, especially if fertility is not an issue [6]. Initially, hysterectomy was the only choice for patient and surgeon but in the 1980s targeted destruction or excision of the endometrium under hysteroscopic guidance was introduced. However, hysteroscopic endometrial ablation requires additional training and a significant degree of surgical skill. This requirement led to the introduction of a number of automated, usually non-hysteroscopic controlled devices, aimed at achieving endometrial destruction in a predictable fashion. These devices use different energy sources such as hot liquid systems, microwave, bipolar radiofrequency, laser or cryotherapy [7].

Device description

The Thermablate system consists of a disposable, prefilled catheter-balloon cartridge and a reusable hand-held treatment control unit (TCU) that runs on direct current and is responsible for heating the liquid in the cartridge. Hot liquid is forced through the catheter into the uterine balloon by a pneumatic pump. Treatment time, pressure, and temperature, as well as safety checks are microprocessor controlled by the TCU. The cervix is dilated to 6-7 mm to allow introduction of the catheter. The liquid treatment temperature is much higher than other units at 173ºC, pressure is similar at 200 mmHg, and treatment time is reduced to 128 seconds. Balloon ablation devices were designed for women with structurally normal endometrial cavities devoid of intracavitary pathology. For Thermablate, the range for the sounded uterine length should be between 7.5 and 12 cm.

In our department, we have used thermal balloon endometrial ablation for the treatment of dysfunctional uterine bleeding since 2001. In the present study, we evaluated the feasibility, safety and clinical outcomes of the Thermablate system for two years following treatment.

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Fig. 1

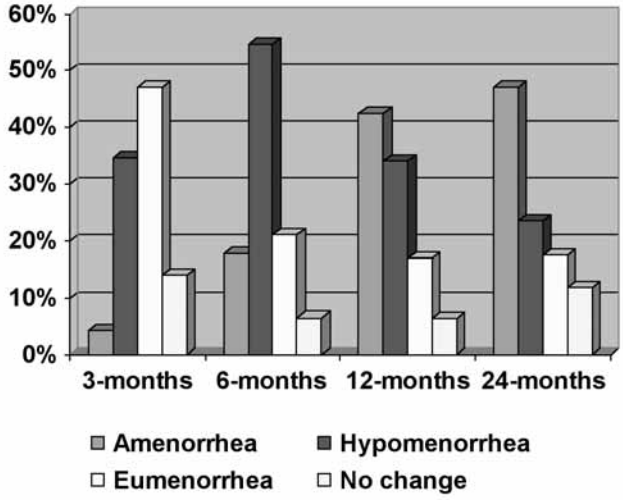


Fig. 2

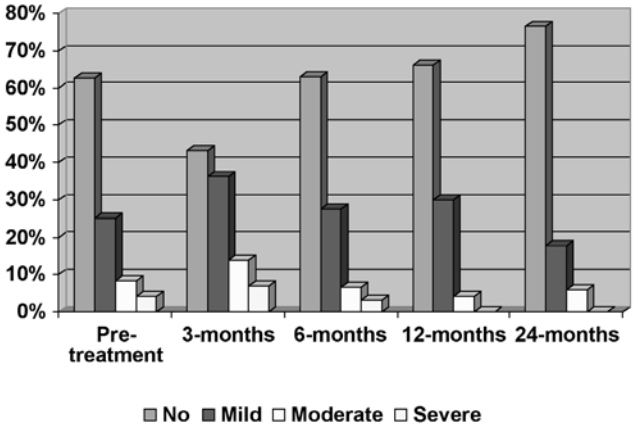
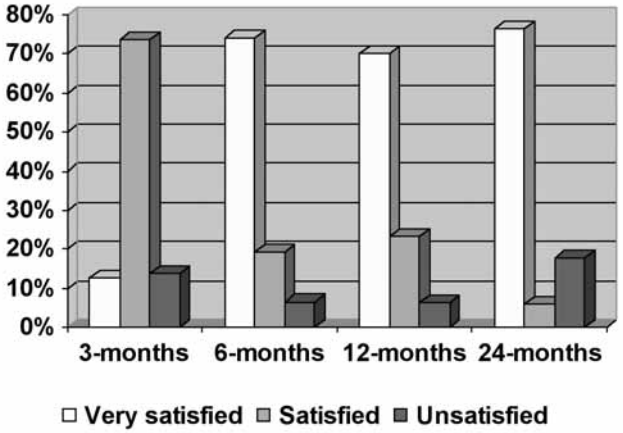


Figure 1. — Clinical outcomes - menstrual blood flow.

Figure 2. — Clinical outcomes - dysmenorrhea.

Figure 3. — Post-treatment patient satisfaction.

Fig. 3



Material and Methods

A total of 72 patients were treated from February 2005 through February 2008 at the Obstetric and Gynaecological Department of University General Hospital of Alexandroupolis, Greece. All patients were premenopausal with a history of at least two heavy menstrual bleedings requiring dilation and curettage within the last year. The age ranged from 35 to 51 years, with a median of 41. Table 1 shows the patient demographics. Candidates for balloon ablation were those women with structurally normal endometrial cavities, sounding between 7.5 cm and 12 cm, and no desire for fertility. Women with intrauterine lesions (myomas or polyps), intramural leiomyomas, endometrial hyperplasia with cellural atypia, active genital track or urinary infection, and those with a history of classical caesarean section or transmural myomectomy were excluded. The procedure was performed under general anaesthesia. Thinning of the endometrium was achieved by sharp curettage immediately prior to the procedure. Curettage, in addition to the thinning of the endometrium, provided additional endometrial tissue for histologic examination. Antibiotics (second generation cephalosporin or doxycycline) were administered to all patients.

Table 1. — *Patient demographics, median and range*.

Age (years)	41	35-51
Parity	2	1-5
BMI (kg/m^2)	27	19-39
Comorbidities (hypertension, diabetes, cardiovascular disease, etc.)	38/72	52.8%

Pretreatment evaluation of blood flow, duration of menses and frequency of menstruation were determined for all patients, except 14 women (Table 2). Patient records were reviewed for adverse events, post-procedure pain and required medication, satisfaction and dysmenorrhea and bleeding status. Patients were followed at three, six, 12 and 24 months.

Table 2. — *Pretreatment bleeding pattern of patients*.

Description of flow	No.
Heavy	47
Very heavy with clots	11
Not recorded	14
Duration of menses (days)	**No.**
Median	9.2
Range	5-16
Frequency of menses (days)	**No.**
Median	25.3
Range	17-32

Results

None of the 72 patients experienced intraoperative or postoperative adverse events. Postoperative pain was experienced by 46 of 72 (63.9%), however only 11 of 72 (15.3%) requested analgesics.

Results at three months (n = 72), six months (n = 62), 12 months (n = 47) and 24 months (n = 17) are shown in Figure 1. Thirteen patients were lost to follow-up. Figure 1 shows an increasing trend towards reduced monthly flow at two years. The combined amenorrhea and hypomenorrhea rates increased from 39% at three months to 73%, 77% and 70% at six, 12 and 24 months, respectively ($p < 0.0001$).

Figure 2 shows that dysmenorrhea increased from 37.5% before surgery to 57% at three months and decreased to 23.5% at 24 months follow-up. The significance of this remains elusive.

Figure 3 shows the satisfaction rate with a slight increase from 86% at three months to 93.5% at six and 12 months ($p < 0.00001$). A slight decrease of satisfaction to 82.4% was noticed at 24 months of follow-up ($p < 0.0001$).

Discussion

Hysteroscopic endometrial ablation has resulted in short-term success rates of 75-100% [8]. These methods are skill-dependent, require intensive training and expertise and are not free of complications such as perforation, haemorrhage, visceral injury and excessive fluid absorption. It is apparent that optimal outcomes require a level of skill and experience that may not be achieved by the average surgeon [9]. During the last two decades, however, there has been clear progress in the search for a less invasive yet still effective treatment with lower risk of complications. Recently, a number of devices have been developed to treat menorrhagia by non-hysteroscopic ablative methods. The advantage of these is that they require far less physician skill to perform successfully, and typically have reduced risk of complications. Today, there is an emerging trend toward simpler, quicker, safer and yet effective procedures that can take place in an outpatient or office setting under minimal analgesia. Indeed, two pilot studies have shown that Thermablate is feasible and safe in a clinic setting [10, 11].

Thermal balloon ablation requires minimal training and is easy to perform. Rates of 2-4% of minor adverse events such as postoperative infection or haematometra have been reported. Recently, serious complications such as bowel and other thermal injuries have been reported during the use of second generation endometrial ablation systems [12].

Appropriate patient selection is of utmost importance to ensure good clinical outcomes. A large uterus (> 12 cm cavity length), active pelvic infection, evidence of malignant or premalignant endometrial changes, the desire to maintain fertility and patient's expectation of amenorrhea, are absolute contraindications. The presence of myomas or suspected adenomyosis, are likely to reduce success.

Rates of success with the Thermablate endometrial ablation system have paralleled other ablation techniques with 70-100% patient satisfaction [11-15]. This device is the smallest, simplest and fastest of the ones presently available. A short treatment time of two minutes along with the small diameter catheter (6 mm), allow the device to be used with ease and minimal anaesthesia.

Conclusion

The Thermablate endometrial ablation system is safe and effective in treating dysfunctional uterine bleeding when other therapies are contraindicated or ineffective. High rates of menstrual reduction and patient satisfaction make this device a very attractive option for the treatment of menorrhagia.

References

[1] Gath D., Osborn M., Bungay G., Iles S., Day A., Bond A. *et al*.: "Psychiatric disorder and gynaecological symptoms in middle aged women: A community survey". *Br. Med. J*., 1987, *294,* 212.
[2] Brenner P.F.: "Differential diagnosis of abnormal uterine bleeding". *Am. J. Obstet. Gynecol*., 1996, *175* (3 Pt 2), 766.
[3] Livingstone M., Fraser I.S.: "Mechanisms of abnormal uterine bleeding". *Hum. Reprod Update,* 2002, *8,* 60.
[4] Krampl E., Bourne T., Hurlen-Solbakken H., Istre O.: "Transvaginal ultrasonography, sonohysterography and operative hysteroscopy for the evaluation of abnormal uterine bleeding". *Acta Obstet. Gynecol. Scand.,* 2001, *80*, 616.
[5] ACOG Committee on Practice Bulletins, American College of Obstetricians and Gynecologists. ACOG practice bulletin: management of anovulatory bleeding. *Int. J. Gynaecol. Obstet*., 2001, *72*, 263.
[6] Bayer S.R., DeCherney A.H.: "Clinical manifestations and treatment of dysfunctional uterine bleeding". *JAMA,* 1993, *269,* 1823.
[7] Vilos G.A.: "Global endometrial ablation". *J. Obstet. Gynaecol. Can*, 2000, *22,* 668.
[8] Erian J.: "Endometrial ablation in the treatment of menorrhagia". *Br. J. Obstet. Gynaecol*., 1994, *101* (suppl. 11), 19.
[9] Vilos G.A., Vilos E.C., King J.H.: "Experience with 800 hysteroscopic endometrial ablations". *J. Am. Assoc. Gynecol. Laparosc.,* 1996, *4,* 33.
[10] Prasad P., Powell M.: "Prospective observational study of thermablate endometrial ablation system as an outpatient procedure". *J. Min. Invas. Gynecol*., 2008, *15*, 476.
[11] Vilos G.A., DiCecco R., Power S. *et al*.: "Two minute thermal balloon endometrial ablation (Thermablate) under paracervical block in a hospital clinic: a pilot study". *J. Obstet. Gynecol. Canada*, 2008, *39*, S22.
[12] Della Badia C., Nyirjesy P., Atogho A.: "Endometrial ablation devices: review of a manufacturer and user facility device experience database". *J. Min. Invas. Gynecol.,* 2007, *14,* 436.
[13] Mangeshikar P.S., Kapur A., Yackel D.B.: "Endometrial ablation with a new thermal balloon system". *J. Am. Assoc. Gynecol. Laparosc*., 2003, *10*, 27.
[14] Roy K.H., Mattox J.H.: "Advances in endometrial ablation. CME Review Article". *Obstet. Gynecol. Surv*., 2002, *57,* 789.
[15] Vilos G.A., Edris F.: "Second-generation endometrial ablation technologies: the hot liquid balloons". *Best Prac. Res. Clin. Obstet. Gynecol*., 2007, *21*, 947.

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