

**Endometrial ablation with Thermablate: a new 2 minute hot liquid balloon endometrial
ablation system. Results after 2 years of use.**

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Abstract

Objectives: To evaluate the feasibility, safety and clinical outcomes of Thermablate: a new 2 minute hot liquid balloon endometrial ablation system.

Design: Prospective observational study of 72 women with menorrhagia (Canadian Task Force Classification II-2).

Setting: University affiliated teaching hospital, Alexandroupolis, Greece.

Patients: 72 pre-menopausal women with menorrhagia.

Intervention: All patients were treated from February 2005 through February 2008 under general anaesthesia. Thinning of the endometrium was achieved by sharp curettage immediately prior to the procedure. Pre-treatment evaluation of menstrual blood flow, cycle length 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 3 months (n = 72), 6 months (n = 62), 12 months (n = 47) and 24 months (n = 17) showed an increased 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 3 months and decreased to 23.5% at 24 months (**p < 0.05**) ?.

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.

Keywords: Menorrhagia, endometrial ablation, Thermablate, dysfunctional uterine bleeding.

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⁾.

The Thermablate system consists of a disposable, pre-filled 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 - 7mm to allow introduction of the catheter. The liquid treatment temperature is much higher than other units at 173°C, pressure is similar at 200mmHg, 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 2 years following treatment.

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 & 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 cellular atypia, active genital tract 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 prescribed to all patients.

Pre-treatment evaluation of blood flow, duration of menses and frequency of menstruation were determined on all patients (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 3, 6, 12 and 24 months.

Results

Seventy-two patients were treated and experienced no intra operative nor post operative adverse events. Post operative pain was experienced by 46 of 72 (63.9%), however only 11 of 72 (15.3%) requested analgesics.

Results at 3 months (n = 72), 6 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 after 2 years. The combined amenorrhea and hypomenorrhea rates increased from 39% at 3 months to 73%, 77% and 70% at 6, 12 and 24 months respectively. Figure 2 shows the satisfaction rate with a slight increase from 86% at 3 months to 93.5% at 6 and 12 months. A slight decrease of satisfaction to 82.4% noticed at 24 months follow up (**NS?**) Figure 3 shows that dysmenorrhea increased from 37.5% before surgery to 57% at 3 months and decreased to 23.5% at 24 months follow up. The significance of this remains elusive.

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 2 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 post-operative infection or hematometra, 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 pre-malignant 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 2 minutes along with the small diameter catheter (6 mm), allow the device to be used with ease and minimal anesthesia.

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 amenorrhea, hypomenorrhea and patient satisfaction make this device a very attractive option for the treatment of menorrhagia.

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Table 1. Patient Demographics, Median and Range

Age (years)	41	35-51
Parity	2	1-5
BMI (kg/m²)	27	19-39
Comorbidities (hypertension, diabetes, cardiovascular disease etc)	38/72	52.8%

Table 2. Pre-treatment bleeding pattern of patients

Description of Flow	
Heavy	47
Very heavy with clots	11
Duration of Menses (days)	
Median	9.2
Range	5-16
Frequency of Menses	
Median	25.3
Range	17-32

NOTE 1: TABLE 2 DESCRIPTION OF FLOW MISSING 14 PATIENTS – INSERT

NOT RECORDED IN 14 WOMEN

NOTE 2: TABLES 3 & 4 REDUNDANT – DELETE

Table 3. Follow-up results – Blood flow and Satisfaction

		3 months		6 months		12 months		24 months	
Flow	Amenorrhea	3	4.2%	11	17.7%	20	42.6%	8	47.1%
	Hypomenorrhea	25	34.7%	34	54.8%	16	34.0%	4	23.5%
	Eumenorrhea	34	47.2%	13	21.0%	8	17.0%	3	17.6%
	No change	10	13.9%	4	6.5%	3	6.4%	2	11.8%
	Total	72	100%	62	100%	47	100%	17	100%
Patient satisfaction	Very satisfied	9	12.5%	46	74.2%	33	70.2%	11	64.7%
	Satisfied	53	73.6%	12	19.3%	11	23.4%	4	23.5%
	Unsatisfied	10	13.9%	4	6.5%	3	6.4%	2	11.8%
	Total	72	100%	62	100%	47	100%	17	100%

Table 4. Follow-up results – Dysmenorrhoea

Dysmenorrhoea	Pre-treatment		3 months		6 months		12 months		24 months	
No	45	62.5%	31	43.1%	39	62.9%	31	66.0%	13	76.5%
Mild	18	25.0%	26	36.1%	17	27.4%	14	29.8%	3	17.6%
Moderate	6	8.3%	10	13.9%	4	6.5%	2	4.2%	1	5.9%
Severe	3	4.2%	5	6.9%	2	3.2%	0	0.0%	0	0.0%
Total	72	100%	72	100%	62	100%	47	100%	17	100%

Figure 1. Clinical Outcomes – Menstrual Blood Flow

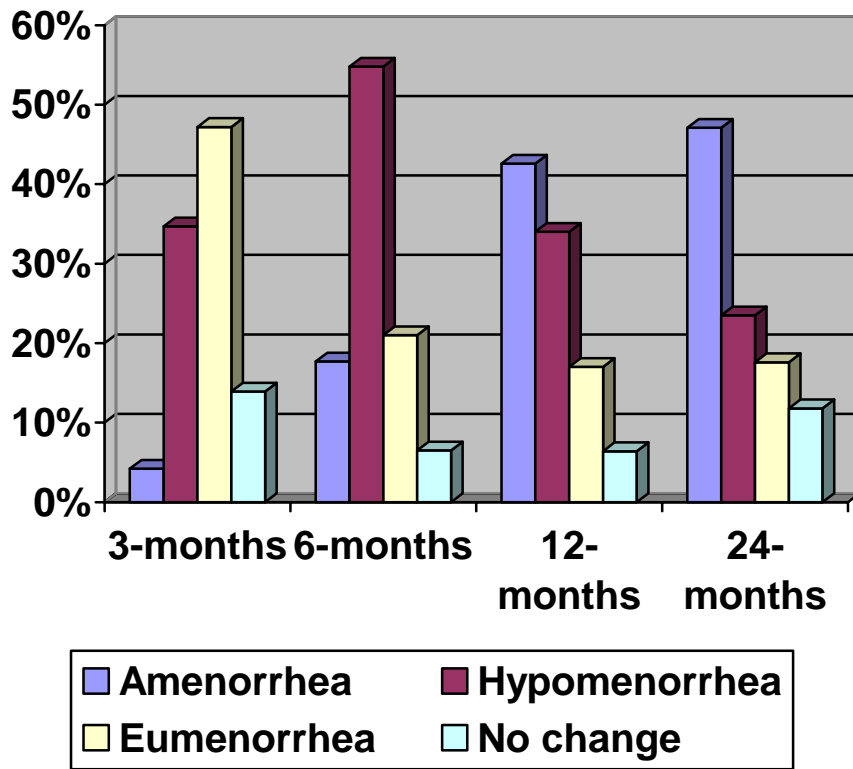


Figure 2. Clinical Outcomes – Dysmenorrhea

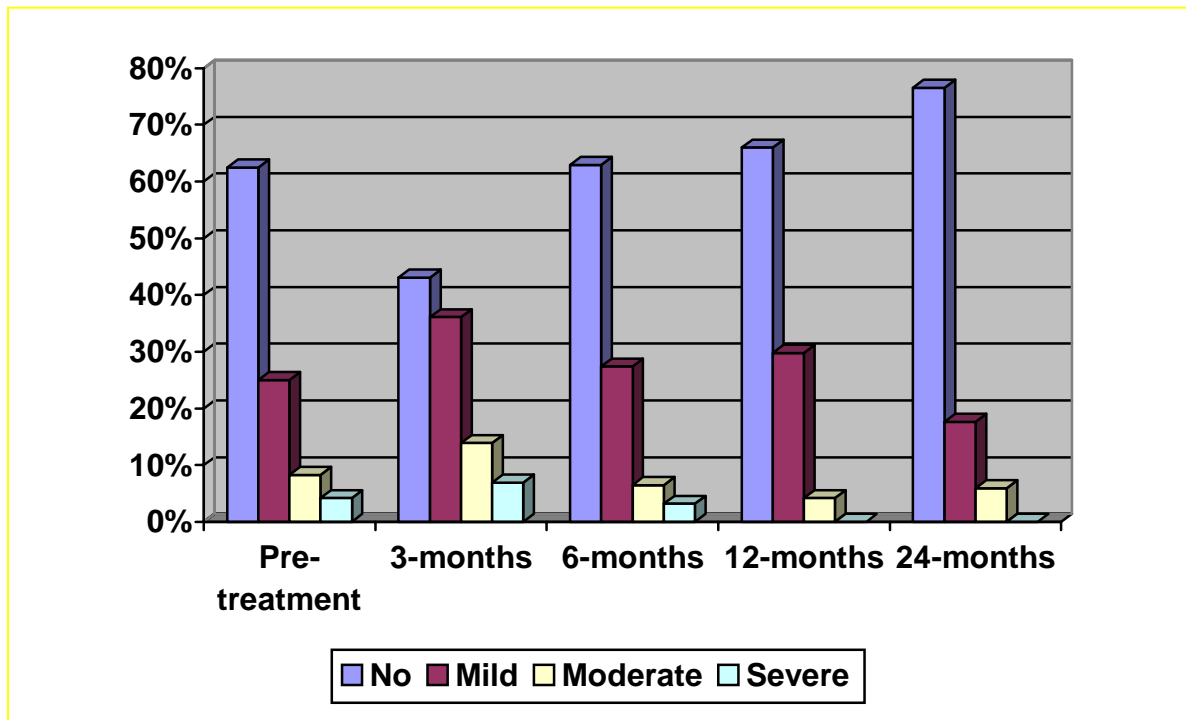


Figure 3. Post-treatment Patient Satisfaction

