Endometrial Ablation with a New Thermal Balloon System

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Abstract

Study Objective. *To assess the efficacy of Thermablate EAS, a new, simple, hand-held, portable endometrial ablation instrument, in the treatment of menorrhagia.*
Design. *Retrospective observational study (Canadian Task Force classification II-1).*
Setting. *Urban hospital and private clinic facilities in Bombay, India.*
Patients. *Sixteen women with menorrhagia.*
Intervention. *Endometrial ablation with the Thermablate EAS.*
Measurements and Main Results. *Follow-up at 6 months showed eight patients (50%) to have amenorrhea and six (38%) hypomenorrhea. The only failure was in a patient with cystic hyperplasia. No complications occurred.*
Conclusion. *Thermablate EAS is a promising instrument for endometrial ablation.*

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Menorrhagia affects up to 20% of all premenopausal women and is the leading cause of iron-deficiency anemia.[1] Thus it is a significant health problem to millions of women worldwide. Conventional medical therapy is often not well tolerated or is ineffective, especially over the long term. Surgical treatment such as dilatation and curettage (D&C) provides temporary respite at best. Hysterectomy often follows, with many structurally normal uteri removed for dysfunctional bleeding.[2]

In the 1980s hysteroscopic endometrial ablation was introduced as a minimally invasive alternative to hysterectomy. However, these procedures, involving transcervical resection of endometrium, laser vaporization, or rollerball electrocoagulation, have not received widespread acceptance for a number of reasons, including a significant learning curve, technical difficulties, and complications. During the past decade a second generation of endometrial ablation devices emerged primarily involving nonhysteroscopic methods whereby the entire endometrial surface is treated by thermal balloon or direct contact with electrosurgical, microwave, or other energy source.[3]

Product Development and Preclinical Studies

Thermablate EAS (MDMI Technologies, Inc., Richmond, B.C., Canada) is a new instrument for treating menorrhagia caused by dysfunctional uterine bleeding (Figure 1). It consists of a light-weight (~700 g), reusable, hand-held treatment control unit (TCU) and a disposable catheter-balloon cartridge (Figure 2). At the start of treatment the TCU automatically heats the liquid contained in a diaphragm in the cartridge to a specified temperature. Once the procedure is begun the hot liquid is forced through the catheter into the balloon by compressing the diaphragm with air pumped into the TCU heating chamber until a controlled set point air pressure has been reached. During treatment, the TCU performs a series

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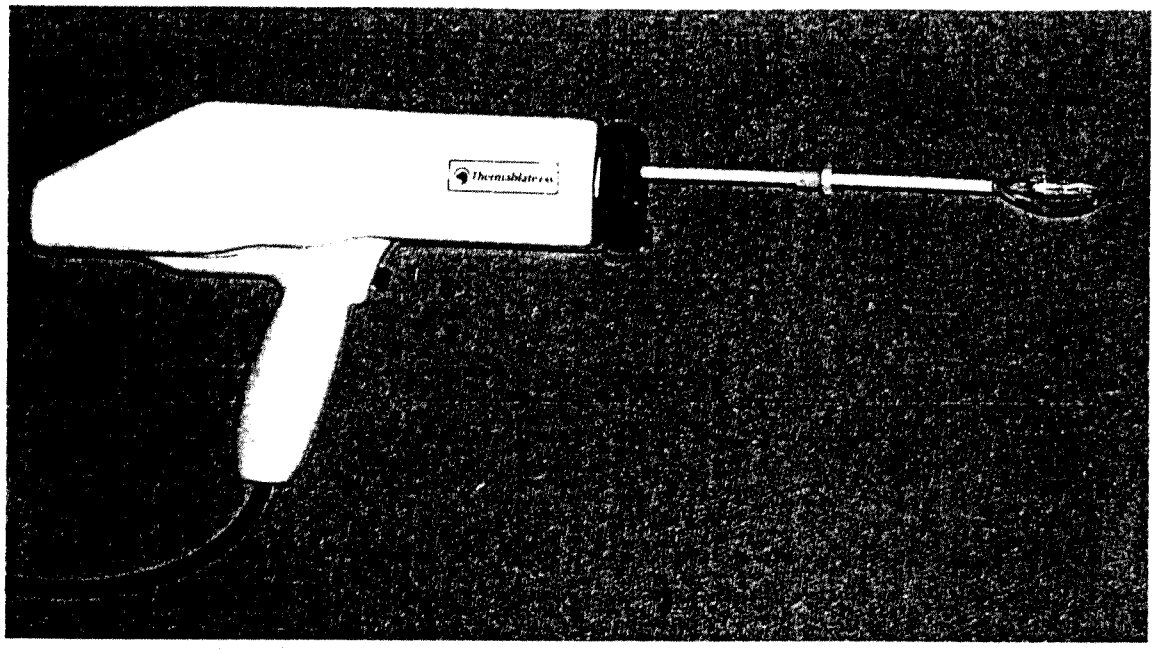

FIGURE 1. Thermablate EAS shown complete with the treatment control unit and a connected disposable catheter-balloon cartridge.

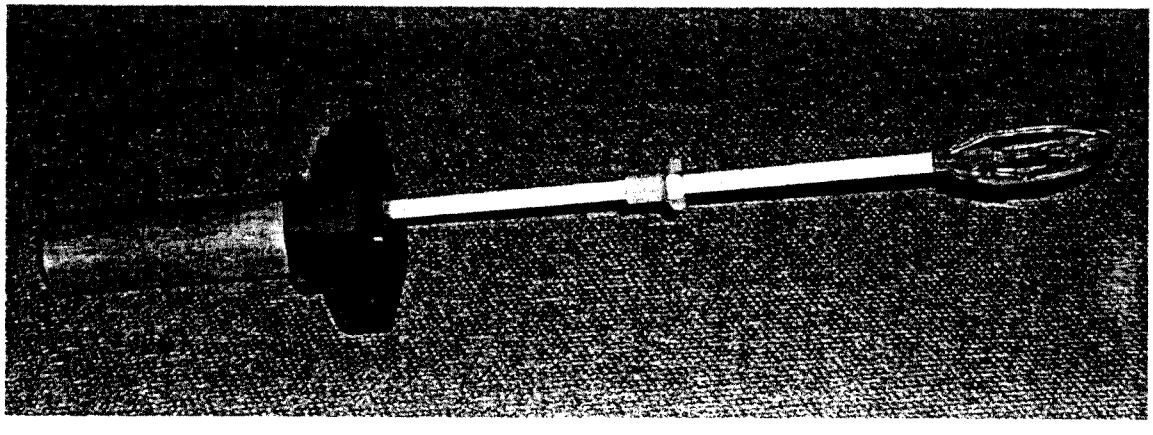

FIGURE 2. Disposable catheter-balloon cartridge.

of pressurization and depressurization cycles to homogenize the temperature of the liquid in the balloon, ensuring uniformity of treatment at the balloon surface. Treatment time, pressure, and temperature are automatically controlled by a microprocessor that operates the electromechanical heating and pumping-draining systems. A liquid crystal display (LCD) provides pertinent information to the user. Warm-up phase, system leak check, treatment phase, and completion of treatment are all clearly indicated (Figure 3). The TCU is reusable and has a projected lifespan of more than 600 cycles.

The disposable unit is a single-use cartridge with a prefilled, proprietary, biocompatible fluid approved by the Food and Drug Administration (FDA) that can be heated to a temperature in excess of 150° C. The disposable cartridge has a bayonet connector that forms an airtight seal to the hand-held unit. An insulated 6-mm catheter connects the liquid reservoir to a preformed silicone balloon that makes full contact

FIGURE 3. Assembled Thermablate EAS with view of LCD screen.

with the endometrial cavity, transferring thermal energy to the endometrial lining and underlying myometrium.

During research and development of the system, laboratory testing was carried out on a uterine test frame with 64 implanted thermocouples linked to a computer display. Additional testing was done on meat models. Preliminary design inputs to achieve adequate treatment settings for the Thermablate EAS involved time, pressure, and temperature variables. Mathematical modeling of heat transfer in thermal balloon ablation was developed to support selection of optimum treatment settings.

In a phase I safety trial to establish temperature and time, seven patients were treated with the Thermablate EAS before hysterectomy. Histologic examination of extirpated uteri indicated that the most satisfactory results were obtained with a starting liquid temperature of 173° C, pressure of 180 mm Hg, and treatment time of 128 seconds (2 min, 8 sec). Tissue necrosis to a uniform depth of 4 to 5 mm into myometrium, confirmed with vital staining using nitroblue tetrazolium, was obtained using these parameters. The higher temperature employed in the Thermablate EAS results in significantly shorter treatment time than is necessary with existing balloon technologies.

Clinical Study

A pilot study to determine the efficacy of the Thermablate EAS was carried out in Bombay, India. Sixteen women (mean age 41 yrs, range 34–48 yrs) with documented menorrhagia were recruited according to an FDA phase II protocol. This included informed consent and a history of dysfunctional uterine bleeding with a uterine sounding of 7 to 12 cm. Although no quantitative estimation of blood loss such as a pictorial diary was kept, all patients had a convincing history of menorrhagia (Table 1). Two women were nulliparous and two had had two cesarean deliveries. Three patients had been treated unsuccessfully with medroxyprogesterone acetate and another was taking mefanemic acid with little relief. Two had been treated with oral contraceptives with no appreciable benefit. Uterine soundings ranged from 7.0 to 9.5 cm and recorded fluid volumes ranged from 3 to 17 ml (average 7.5 ml).

TABLE 1. Patient Characteristics before and 6 Months after Endometrial Ablation

Before Ablation								6 Months		
Age (yrs)	Parity/ Living	Cycle (days)	Length (days)	Flow/ Clots	Dysmenorrhea	Uterine Sound (cm)	Uterine Volume (ml)	Flow (days)	Dysmenorrhea	Satisfaction
48	3/2	28–30	8	H/++	+++	8.0	8	0	0	V
42	2/2	25	10–12	H	+	7.5	3	0	0	V
46	3/2	20	10	H	+	8.5	7	Hyp 1–2	0	V
38	2/2	20	7	H/++	+++	9.5	17	Hyp 1–2	0	V
38	3/3	26	8–10	H	+	8.0	8	0	0	S
34	2/2[a]	28–30	9–10	VH/+++	+++	8.5	7	Eu 3–4/30	0	V
41	3/3	22–25	7–8	H/++	++	8.5	6	Hyp 3–4/26	0	V
37	2/2	30	6–8	H	+	7.0	5	0	0	V
43	2/2	24	6–8	H	+	9.0	6	Hyp 1–2	0	V
36	3/3	28	7–9	H/++	+++	8.0	5	0	0	V
48	0	28	15–18	H	+	8.0	7	0	0	V
38	3/3	28	10	H/++	+++	8.0	7	Hyp 1–2/28	0	S
44	4/4	26	10–12	H	+	9.0	9	Hyp 10–12/26	+	U
41	2/2[a]	30–32	8–9	H	+	8.0	8	0	0	S
37	1/1	28	8–9	H/++	++	8.0	5	Hyp 1–2/27	0	V
39	0	28–30	7–8	H	+++	8.5	9	0	0	S

[a]Cesarean section.
H = heavy; VH = very heavy; + = mild; ++ = moderate; +++ = severe; E = eumenorrhea; Hyp = hypomenorrhea; 0 = absent; V = very satisfied; S = satisfied; U = unsatisfied.

Exclusion criteria were active pelvic inflammatory disease, clotting defects or bleeding disorders, and history of malignant or premalignant disease such as cervical dysplasia or adenomatous endometrial hyperplasia. Submucous myomas, congenital uterine defects, previous ablation, and desire to preserve fertility also precluded this therapy.

Preprocedure evaluation consisted of pelvic examination, Papanicolaou smear, hemoglobin or hematocrit, endometrial biopsy, and pelvic ultrasound examination. Three patients had previous office hysteroscopy by referring physicians. No gonadotropin-releasing hormone analogs were administered, nor were treatments timed to the menstrual cycle.

Results

Treatment was carried out in a hospital or private clinic operating room. A diclofenac 100-mg suppository was administered 1 hour before treatment. Ablation was performed according to the manufacturer's instructions. Light general anesthesia was administered to six women and intravenous propofol sedation to six. A paracervical block with 2% lidocaine combined with intravenous sedation was used 4 times. All patients had a D&C for endometrial thinning immediately before ablation and 13 had a concurrent hysteroscopy. No complications occurred. Patients were discharged within a few hours after ablation. They required minimal to no postoperative analgesia.

Follow-up consisted of office visits or telephone interviews at 2 weeks and 3 and 6 months. At 6 months 8 women (50%) were amenorrheic and 6 (38%) had spotting or hypomenorrhea. Dysmenorrhea was noticeably absent in all but one patient. All but one patient (94%) were satisfied or very satisfied with the results of ablation. The treatment failure was a 44-year-old, para 4 woman with cystic endometrial hyperplasia who had been taking cyclic medroxyprogesterone acetate for 2 years. Hyperplasia was documented by endometrial biopsy 2 weeks before ablation and was noted at hysteroscopy at the time of treatment.

Discussion

In the United States it is estimated that approximately 200,000 structurally normal uteri are removed

each year because of failure of excessive uterine bleeding to respond to other therapies.[2] Extrapolating this figure and applying it to a worldwide estimated 1.5 million hysterectomies annually suggests that at least a half million women are having invasive procedures that might be treated with a minimally invasive alternative. Although hysterectomy is curative, it has associated morbidity as well as high cost and extended recovery time.

Hysteroscopic ablation has resulted in success rates ranging from 75% to 100% (mean 85%).[4–9] However, these methods are skill dependent and require intensive training and experience. Like any other surgical procedure, they are not free of complications, including mechanical or thermal necrotic perforation, hemorrhage, visceral injury, and fluid overload.

Thermal balloon ablation is simple to perform and does not require special training. Available systems including ThermaChoice (Ethicon Inc., Somerville, NJ) and CavaTerm (Walsten Medical, S.A., Morges, Switzerland) have treatment times of 8 and 15 minutes, respectively. No pretreatment of endometrium is required and therapy can be carried out at any time of the menstrual cycle. An accumulated series of thermal balloon procedures reported a low rate (2–4%) of minor problems (postoperative infection, hematometra formation).[10,11]

Correct patient selection is necessary to ensure good results.[12] The indication for ablation is heavy menstrual loss in the absence of organic disease. Large uterus (>12 cm), active pelvic infection, desire to maintain fertility, and evidence of malignancy or premalignancy changes are absolute contraindications. The presence of myomas, especially submucous, and suspicion of adenomyosis are both likely to reduce success.[13]

Success rates with thermal balloon therapy have paralleled other ablation techniques with 80% to 90% patient satisfaction expected.[10,13–16] Amenorrhea rates have long been the standard for evaluating success in hysteroscopic methods and generally they are higher than with balloon devices.[17]

In the present study, simplicity of use and portability of the Thermablate EAS were outstanding advantages compared with other second-generation methods. These features were even more dramatic when compared with nonballoon technologies such as microwave endometrial ablation, hydrothermablater, and cryotherapy. These three methods require large pieces of equipment that are nonportable and expensive.

Conclusion

The high rate of amenorrhea and hypomenorrhea achieved in this small series was not unexpected. Laboratory testing in the research and development phase indicated that high thermal transfer of energy for a short period of time combined with a preformed silicone balloon would give more uniform tissue necrosis. In turn, this would result in a predictably high amenorrhea rate. Clinically, it appears that the anticipated result of ablation with the Thermablate EAS has been achieved. A larger sample and longer follow-up are required, but initial results are extremely encouraging.

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