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Prospective Observational Study of Thermablate Endometrial Ablation System as an Outpatient Procedure

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ABSTRACT This single-arm prospective observational study was designed to evaluate patient acceptability and feasibility of the Thermablate endometrial ablation (EA) system (TEAS), a new-generation endometrial thermal balloon ablation system, as an office procedure. It was set up in a one-stop menstrual disorder clinic with a facility for outpatient hysteroscopy in the Queen's Medical Center, Nottingham University Hospitals, Nottingham, United Kingdom. Seventy premenopausal women mainly, with menorrhagia, without earlier endometrial preparation were included in the study. The exclusion criteria were women requesting general anesthesia, presence of submucous myoma, suggestion of malignant lesions, and a desire to preserve fertility. The intervention involved the use of global thermal EA with TEAS. This is an endometrial balloon ablation system that combines a ''thermablation'' time of 128 seconds with automatic controls of the treatment parameters of temperature and pressure, without any earlier endometrial preparation. Patients were given diclofenac sodium (100 mg orally) 2 hours before the procedure, with intracervical 4% prilocaine and intracavitary lidocaine gel for analgesia. Main results involved measurement of overall satisfaction with TEAS as an outpatient (office) procedure, intraoperative and postoperative pain scores, need for additional analgesia, nausea and vomiting rate, total time in clinic and the need for any admission, speed of recovery, and time away from home. In conclusion, the TEAS appears to be a well-accepted and safe outpatient procedure for treating menorrhagia. Journal of Minimally Invasive Gynecology (2008) 15, 476–479 © 2008 AAGL. All rights reserved.

Keywords: Thermablate endometrial ablation system; Menorrhagia; Outpatient procedure; Pain; Patient satisfaction

Although the first-generation hysteroscopic endometrial ablation (EA) techniques such as roller ball and loop resection are reasonably safe and effective alternatives to hysterectomy, their use requires a high degree of skill. During the last decade, however, clear progress occurred in the search for a less operator-dependent but still effective treatment with lower risk of complications. Dr. Robert Neuwirth was responsible for the development of the EA device, which was a thermal ablation balloon [1].

Thermal balloon (Thermachoice; Gynecare, Somerville, NJ) was the first, second-generation global EA technique commercially available and was thoroughly evaluated [2]. It is accepted by the National Institute of Clinical Excellence, United Kingdom, as a safe and effective ''thermablation'' procedure for the management of menorrhagia of benign origin. It requires less surgical skill and has reduced the risk of complications associated with earlier thermablation techniques. In an outpatient setting, Thermachoice III (Gynecare) was associated with significantly less nausea and vomiting and less time spent in the hospital than the alternative as a routine outpatient procedure [3]. The desire, however, is toward finding an even simpler, quicker, and low-risk procedure that can be performed in an outpatient clinic.

The Thermablate EA system (TEAS) is one such new EA device to treat excessive uterine bleeding. It combines a short treatment time of 2 minutes and 8 seconds with automatic control of treatment parameters of high temperature (173°C) and pressure (180 mm Hg). A 6.5 mm–diameter catheter along with its portability and simplicity makes it ideal for outpatient use. It was shown to be effective and safe in a small group of patients where other therapies were contraindicated or difficult to perform [4,5].

The aim of this study was to estimate the acceptability of TEAS as an outpatient procedure in our population.

The authors have no commercial, proprietary, or financial interest in the products or companies described in this article. Thermablate is a product of MDMI Technologies Inc., Richmond, BC, Canada.

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Methods

Study Design

This was a prospective observational study conducted in a teaching hospital menstrual disorder clinic, with an outpatient hysteroscopic facility. All women at the clinic with menorrhagia from March 2005 through September 2006 (18 months) who had not responded to conservative medical management or levonorgestrel IUD were given the option of this procedure of thermablation with TEAS as an outpatient.

Seventy eligible women for whom further fertility was not a concern, who were premenopausal, who had intractable menorrhagia, and who had a normal uterine cavity were recruited. Exclusion criteria included submucous myomas, malignant lesions, and desire for general anesthesia. The ablation was carried out without pretreatment and at all stages of the menstrual cycle.

All were advised to take oral diclofenac sodium (100 mg) 2 hours before their thermablation. In addition, all were given perioperative intracervical block with 4% prilocaine and an intracavitary 6 mL of 2% lidocaine.

A questionnaire was formulated using a standard pain measurement score (analog scale) to assess intraoperative and postoperative pain, nausea, vomiting, and acceptability of the procedure. As pain and nausea are subjective sensations and are difficult to evaluate quantitatively, a scheme of none/mild/moderate/severe that equated to a scoring system from 1 to 10 on the numeric rating scale was used (none = 0, 1–4 = mild, 5–7 = moderate, ≥ 8 = severe). This was assessed and questionnaires were completed by a nurse practitioner in the clinic. The following day another telephone call was made to the patients at home for further evaluation of their postoperative symptoms.

Device Description

The TEAS consists of a lightweight (approximately 700 g) reusable handheld treatment control unit with a single-use disposable silicon catheter-balloon-cartridge system (Figs. 1 and 2).

The cartridge is filled with glycerin, which is heated to 173°C in the reservoir before the treatment begins. The temperature of the fluid in the balloon is approximately 155°C when it first enters the uterus, and decreases to approximately 115°C by the end of the 128-second treatment period. The higher temperature used in the TEAS results in significantly shorter treatment time than is required with other existing balloon technologies. Automatic adjustment of the pressure to 180 mm Hg is done every 10 seconds with the total treatment time being 128 seconds (2 minutes, 8 seconds). During treatment the pressure is pulsed periodically to help mix the fluid within the balloon. This ensures a uniform temperature distribution in the balloon and promotes a uniform treatment of the endometrium. The temperature of the endometrium increases significantly during treatment, causing tissue necrosis, whereas the temperature of the myometrium is only mildly elevated and is, therefore, left unharmed. Tissue necrosis to a uniform depth of 4 to 5 mm into the myometrium was seen in prehysterectomy studies. Balloon design provides lesser penetration of approximately 2-mm depth in both the cornual and internal cervical os areas. At the conclusion of treatment, the liquid is automatically withdrawn from the balloon into the canister, which is then removed from the endometrial cavity and disposed.

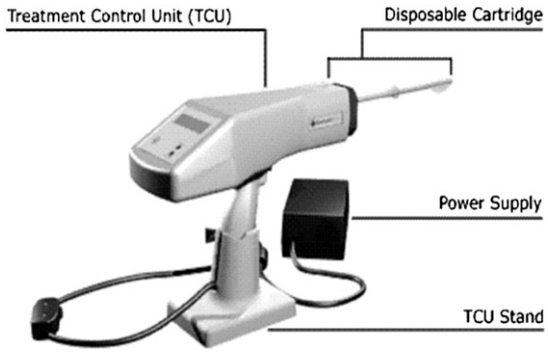

Fig. 1. Assembled Thermablate.

Results

The TEAS was successfully used as an outpatient procedure for global EA in this group of 70 patients. No procedure was abandoned because of technical difficulties or patient intolerance.

Of the 70 patients, only a fifth (21%) gave history of mild preoperative pain. During the thermablation, both at 1 minute and 2 minutes after starting the procedure, less than half (42%) the patients had mild to moderate pain and only 3 said the pain was severe. Postoperatively at 1 minute and 30 minutes these figures were 33% and 57%, respectively; in most the pain was said to be mild to moderate and only 2 had severe pain at 30 minutes after surgery (Table 1). None of the patients requested that the procedure stop or asked for additional analgesia. In spite of nearly half of them forgetting to take the prescribed preoperative oral diclofenac sodium, most (81%; 57 of 70) were happy with the

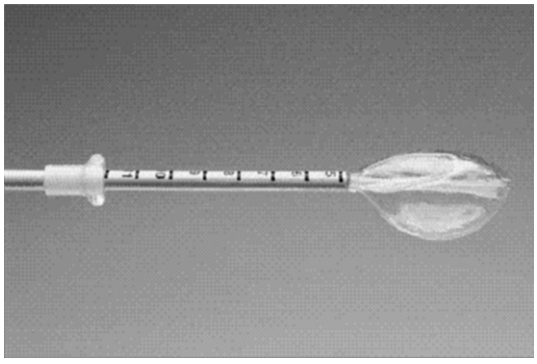

Fig. 2. Thin 6-mm Thermablate catheter with preshaped silicon balloon.

Table 1
Patient questionnaire on pain, nausea, and vomiting

		No pain (score 0)	Mild pain (score 1–4)	Moderate pain (score 5–7)	Severe pain (score 8–10)
Preoperative pain, abdominal or pelvic		55 (78%)	13	2	0
Perioperative pain	1 min	37	18	12	3
	2 min	41	11	15	3
Postoperative pain	1 min	47	15	7	1
	30 min	30	30	8	2
Nausea	1 min	58	9		3
	30 min	60	8		1 vomited
					2
					1 vomited

intraoperative analgesia (Table 2). Thirteen patients thought at the end that they needed additional pain relief during the procedure. Nausea occurred in 12 (17%) patients during and after the procedure. When asked about their general satisfaction with the procedure as an outpatient treatment 88% (62 of 70) scored it as high, either very satisfied or satisfied with the procedure; 3 (4%) were neither satisfied nor dissatisfied with the procedure; and another 5 (7%) were dissatisfied or very dissatisfied with the procedure. In all, 65 (93%) patients said they would have the same procedure again as an outpatient procedure if it was offered and a nearly similar number said they would recommend it to a friend or family member. Only 5 of them said they would neither have it again nor recommend it. Only 2 were unsure about recommending but would agree to having it themselves again. The total time the patients were in the clinic ranged between 50 and 120 minutes with an average of 90 minutes. All returned to normal activity within 2 days and, in fact, 55 (78%) of them returned to work the following day. A quarter had mild-moderate pain or discomfort for 1 or 2 days that responded to minor analgesics (paracetamol or ibuprofen). None of the patients needed admission to the ward, nor did any have to see their general practitioner for pain relief or possible infection in the next few days.

Table 2
Patient satisfaction of the procedure as an outpatient procedure

Preoperative analgesia*	Yes	No
	37 (53%)	33 (47%)
Needing additional pain relief during procedure	13 (18.5%)	57 (81.5%)
Patient satisfaction	62 (88%)†	5 (7%)‡
With procedure/pain relief	3 (4%)§	
Would they have this procedure again?	65 (93%)	5 (7%)
Would they recommend the procedure to a friend?	62 (88%)	5 (7%)
	3 (4%)//	

* Patients did/did not take oral analgesia prescribed.
† Scoring 8–10 = very satisfied to satisfied.
‡ Scoring 1–4 = very unsatisfied to unsatisfied.
§ Scoring 5–7 = neither satisfied nor dissatisfied (i.e., equivocal with response).
// Not sure whether to recommend or not.

Discussion

Uterine thermal balloon EA is accepted as an effective, safe, and simple alternative surgical management for treating menorrhagia [6,7]. It is known that when compared with hysterectomy, both thermal balloon EA and microwave endometrial ablation are less costly and result in slightly fewer quality-adjusted life years. The incremental cost-effectiveness ratio for hysterectomy compared with second-generation techniques is within acceptable limits for the National Health Service [8].

The emerging trend today, however, is toward simpler and quicker procedures that take place in an outpatient setting. This is most likely appropriate for selected women who are willing to accept a reduction in menstrual flow rather than amenorrhea as a treatment outcome. The main disadvantage of balloon ablation is the cost of the disposable balloons and the need for a dedicated electrosurgical unit.

This study showed overall high satisfaction with TEAS as an outpatient procedure. Thirteen patients wished that they had additional analgesia, but none asked for the procedure to be stopped. In all, 93% were happy to have the procedure again if required, as an office procedure, and a nearly similar number (88%) were happy to suggest it to friends. More than half (57%) of the women had pain 30 minutes after the procedure that was a result of thermal effect but this neither necessitated admission to hospital for further pain management nor was it severe enough to need any additional stronger analgesia.

As a result, the recovery was quick and patients were away from home only a few hours. More than three quarters of this group returned to work the next day and all of them returned to their normal activities by 2 days. This is an obvious advantage both to the patient and her employer, as it makes economic sense.

Conclusion

The TEAS system has high patient acceptability when used in an outpatient setting. The device is simpler to use than its counterparts making it far more attractive for a wider application. However, its success with improving

menorrhagia and cost effectiveness needs to be assessed before it is recommended as the primary surgical procedure in the control of menorrhagia.

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