Endometrial Thermal Ablation

A Two-Minute Balloon Treatment

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Study Objective

To evaluate the safety and efficacy of the Thermablate EAS balloon system as an alternative to hysterectomy in women with menorrhagia.

Design/Setting

Prospective evaluation of 60 women treated in a university affiliated hospital.

Patients

From March through December 2003, 60 women with menorrhagia were treated with Thermablate EAS. The cervix was dilated to 7mm and a pre and post treatment hysteroscopy was performed. All 60 of the women were evaluated at 6 months,17 of which were also evaluated at 12 months. The average patient age was 41.2 years (range 16-53) and the average gravidity was 2.2 (range 0-5). The average BMI in 30 of the women was 34.5 kg/m^2 with an average range of 27-47 kg/m^2.

Other risk factors (# of cases)

- cardiopulmonary disease 7
- ileostomy 3
- multiple sclerosis 3
- thromboembolism 2
- renal transplant 1

Pre-op evaluation

- Pap smear
- endometrial biopsy
- sonography (TVS,SIS)

Anesthesia/Analgesia

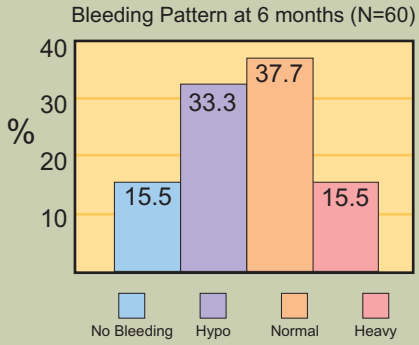
- general 12 (20%)
- conscious sedation & paracervical block 48 (80%)

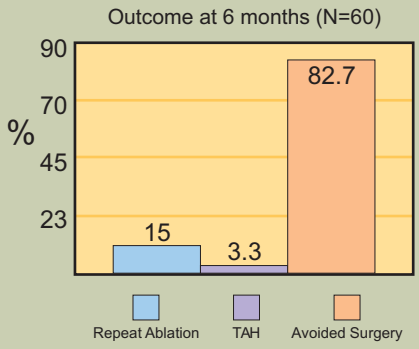
Thermablate EAS [1,2]

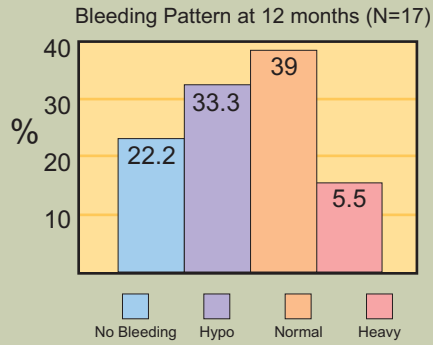
Thermablate EAS is a hot liquid balloon endometrial ablation system that consists of a hand-held treatment control unit (TCU) and a single-use disposable cartridge. The TCU weighs approximately 830g, preheats 28ml of glycerine solution contained within the cartridge and automatically controls the treatment settings of time, pressure and temperature. Before treatment the liquid is heated within the TCU to 173^{0}C in about 8 minutes. The unit remains in the treatment-ready mode for 35 minutes and automatically turns itself off if treatment has not been initiated. The unit can be restarted again if required.

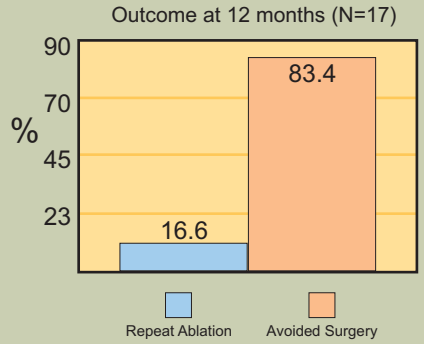
After cervix dilation the 6mm diameter catheter with a pre-shaped silicone balloon is inserted into the uterus to the sounded depth. Once treatment is initiated by a finger trigger action on the TCU a 15-second balloon leak check is automatically performed to confirm a secured system. Then the hot liquid is forced into the balloon by the device pump to a pressure of 180-200mm Hg. The hot liquid is pumped in and out of the balloon in a series of 14 pressurization and depressurizations over a period of 128 seconds. Optimally designed endomyometrial necrosis of 4-5 mm occurs in the uterine cavity and fundus regions while a depth of 2-3 mm is achieved in the internal os and cornual regions.

Results









Conclusions

- The Thermablate EAS was safe and effective in all women including 30 at high risk for other therapies.
- The 6mm diameter catheter and the 2-minute duration allowed treatment under minimal analgesia in 80% of women.
- At least 80% of women with menorrhagia avoided hysterectomy or other surgical intervention at 6 and 12

References

1. Mangeshikar PS, Kapur A, Yackel D. Endometrial Ablation with a New Thermal Balloon System. J Am Assoc Gynecol Laparasc 2003; 10: 27-32.
2. Yackel D, Vilos GA. Thermablate EAS: A New Endometrial Ablation System. Gynecological Surgery 2004; 1(2): 129-132.

Thermablate™ EAS
THERMAL BALLOON ENDOMETRIAL ABLATION SYSTEM

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