

Multicentre Outpatient Thermal Balloon Endometrial Ablation (Thermablate™) with & without Concomitant Hysteroscopic Fallopian Tube Microinserts (Essure™)

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Objective

To determine feasibility, safety and efficacy of the 2 minute Thermablate balloon to treat menorrhagia, with and without concomitant hysteroscopic fallopian tube microinserts (Essure).

Design

Prospective multicentre cohort trial (Canadian Task Force Classification II-2), including 120 women with menorrhagia.

Methods

Procedures were performed under general anesthesia (n=36) or conscious sedation, with or without paracervical block (n=84). Pre-operative patient assessment included Papanicolaou smear, endometrial biopsy and transvaginal sonography, with or without intrauterine saline or gel infusion, and/or hysteroscopy. Intra-operative assessment included pelvic exam and uterine sounding to confirm uterine position and cavity length, followed by

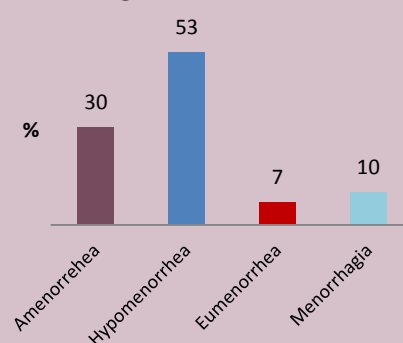
cervical dilatation to 6-7 mm, and hysteroscopy prior to Thermablate balloon insertion. The new Thermablate controller/balloon system delivered preheated (~170°C) glycerin solution and sustained intra-balloon pressures at ~220 mmHg for 30, 30 and 60 sec treatment cycles.

Post-treatment hysteroscopy was performed in all patients and micro-inserts (Essure) were inserted in 15 women. In 10 women the micro-inserts were placed prior to, and in 5 women after Thermablate balloon ablation.

Results

There were no intra, nor post-operative adverse events. At 3 to 12 months (median 9), patients reported amenorrhea-30%, spotting/hypomenorrhea-53%, eumenorrhea-7%, menorrhagia-10%, and overall satisfaction rate of 85%. All micro-inserts were placed successfully, and at 3-6 months, all tubes were obstructed.

Bleeding Pattern at 9 Months



Conclusions

1. Following Thermablate balloon endometrial ablation, patient satisfaction was 85% with amenorrhea rate of 30%.
2. Micro-inserts (Essure) were successfully inserted both before and after thermal balloon ablation.

