

# The Concomitant Use of the Two Minute Thermal Balloon Endometrial Ablation (Thermablate EAS™) System and the Levonorgestrel Intra-uterine System (LNG-IUS) Significantly Improves Clinical Outcomes in Women with Heavy Menstrual Bleeding

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**STUDY OBJECTIVES:** The LNG-IUS is an effective treatment of heavy menstrual bleeding (HMB) in up to 70% of women. The Thermablate balloon endometrial ablation (TBEA) system is comparable to all other nonhysteroscopic devices in treating HMB in up to 70% of women. In the present study, we hypothesized that combining the TBEA and LNG-IUS will increase clinical outcomes in over 70% of women.

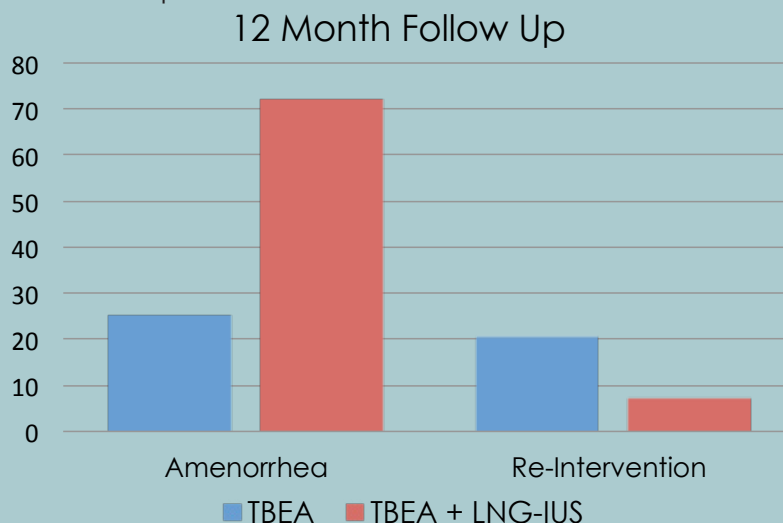
**DESIGN:** An REB approved prospective comparison of two cohorts of women with HMB. Inclusion of LNG-IUS to TBEA was patient driven and not randomized.

**SETTING:** University affiliated hospital.

**PATIENTS:** 71 women with HMB, normal office endometrial biopsy and sonographically normal uterine cavity volunteered for the study after informed consent, (TBEA, n=44 & TBEA+LNG-IUS, n=27).

**INTERVENTIONS:** TBEA and LNG-IUS placement took place in an operating room under general anaesthesia. Hysteroscopy was performed pre and post TBEA and the LNG-IUS was placed immediately thereafter. Patients were assessed at 3, 6, and 12 months. Clinical outcomes included menstrual reduction (amenorrhea/hypomenorrhea), patient satisfaction and re-intervention. We used Chi-squared analysis and Fisher's exact test.

**MEASUREMENTS & MAIN RESULTS:** Age, BMI, parity and uterine sounding were equal in both groups. At 12 months, amenorrhea and re-intervention rates were 25% (9/36) vs. 72% (18/25) and 20.5% (9/44) vs. 7.4% (2/27) in the TBEA and TBEA+LNG-IUS groups, respectively ( $p < .001$ ) while satisfaction rates were 68% (30/44) vs. 81.4%, respectively. There were 2 hysterectomies in the TBEA group. Adenomyosis was found in both and fibroids in one. One patient in the TBEA group required OCP. Repeat resectoscopic resection was performed in all others of the TBEA failures and adenomyosis was found in 3 specimens.



**CONCLUSION:** The concomitant use of LNG-IUS immediately after TBEA significantly increases amenorrhea and patient satisfaction rates and decreases requirement for re-intervention compared with each treatment alone.