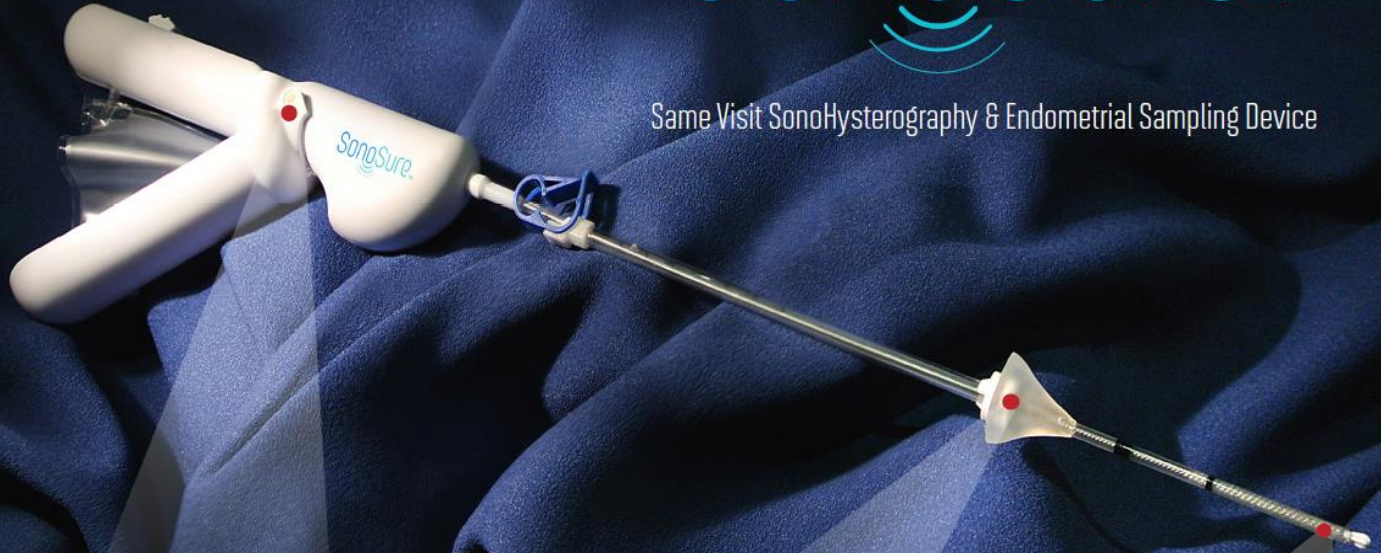




SonoSure™

Same Visit SonoHysteroGRAPHY & Endometrial Sampling Device



SonoSure™ Features:

Single Handed Controls:

Maintains cervical seal

Infusion up to 40cc without refilling

Cervical seal release

Endometrial sample brush extension & rotation

Shapeable Catheter with External Cervical Seal:

Bendable catheter tip for antiflex &

Provides uterine distention upon infusion

Release for evacuation without forceps

Echogenic Brush and Tip

Observe catheter tip under ultrasound retroflex placement

Observe sampling brush under ultrasound

Blunt tip to avoid perforation

ABSTRACT: 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

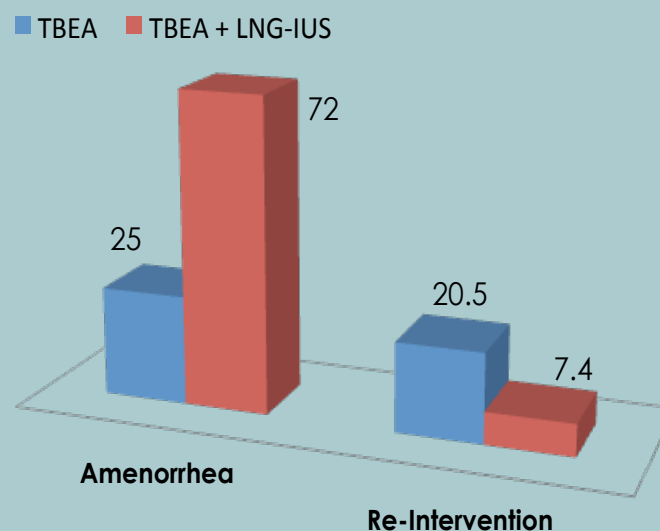
Authors: Angelos G. Vilos MD, George A. Vilos MD, Jennifer L. Marks, Ayman Oraif, MD1, Hanin Abduljabar, MD, Basim Abu-Rafea. Institution: The Fertility Clinic, London Health Sciences Centre Department of Obstetrics and Gynecology, Western University, London, Ontario, Canada.

Objectives: To determine clinical outcomes of the two minute thermal balloon endometrial ablation (TBEA, Thermablate) system with and without concomitant use of the Levonorgestrel Intra-uterine System (LNG-IUS) in women with heavy menstrual bleeding (HMB)

Study Methods: After REB approval and informed consent, 89 women with HMB, normal office endometrial biopsy and sonographically normal uterine cavity participated in this pilot study (TBEA, n=44 & TBEA+LNG-IUS, n=45). Inclusion of LNG-IUS to TBEA was patient driven and not randomized. 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.

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.

12 Month Follow Up



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.