

Thermablate Thermal Balloon Endometrial Ablation System

Office Based Global Endometrial Ablation: Feasibility & Outcome for 3 modalities

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Objectives

To evaluate the safety, feasibility and efficacy of an office based global endometrial ablation technology under local anaesthesia.

Methods

Three office based global endometrial ablation techniques including Thermablate EAS were evaluated and compared prospectively since 1998 employing a local anaesthesia regimen. In this comparison a total of 259 patients have been treated for intractable menorrhagia. Pre-procedure evaluation included sonohysterography to ensure normal cavity geometry and an endometrial biopsy. Patients received a pre-op oral dose of oxycodone/acetaminophen combination and a paracervical block immediately before the ablation consisting of 50/50 mix of mercaine 0.25% and lidocaine 1%. Visual analog pain scales measured the patient pain tolerance during and post procedure. The clinical outcomes for the treatment modalities were measured by pictorial menstrual blood loss calendars.

Clinical Outcomes (at 12 months)

Thermablate EAS (42 patients)

Amenorrhoea – 35%; Hypomenorrhoea – 50%;
Eumenorrhoea – 12%; Failure – 3%

Novasure (122 patients)

Amenorrhoea – 37%; Hypomenorrhoea – 54%;
Eumenorrhoea – 7%; Failure – 2%

Gynelase (95 patients)

Amenorrhoea – 32%; Hypomenorrhoea – 61%;
Eumenorrhoea – 5%; Failure – 2%

Conclusions

Global ablation technologies evaluated are equally efficacious, safe and well tolerated in an office setting under local anaesthesia.

Patient pain tolerances were measured using VAS which showed lower pain levels both intra and post operatively for Thermablate EAS when compared with the Novasure system.

Earlier studies by Leberge, Sabbah, Fortin and Gallinat compared pain associated with the Novasure and Thermachoice systems, using VAS, reported that the Novasure system had significantly lower intra and post operative pain than the Thermachoice. It can then be determined that pain levels associated with treatment with Thermablate EAS offers a significant improvement over both other systems evaluated.

Description of the Thermablate EAS System

The Thermablate EAS system consists of a light weight (700g) hand-held automated treatment control unit (TCU) and disposable catheter-balloon cartridge. The single-use cartridge is pre-filled with a proprietary biocompatible liquid that can be safely heated to a temperature of 170°C. This high temperature consistently affects the tissue of the endometrial layer which allows the time of each treatment to be a constant 2 minutes and 8 seconds. An insulated 6mm diameter catheter connects the liquid reservoir to the soft, flexible tipped preformed silicone balloon which makes full contact with the endometrial cavity transferring the thermal energy to the endometrial lining and underlying myometrium.

Thermablate EAS is a simple to use device. During patient preparation the system is quickly assembled and turned on to heat the treatment fluid to the operating temperature of 173°C within 8 minutes. An easy to read LCD display on the handheld unit provides pertinent information and instruction to the user.

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Once ready the catheter is inserted transcervically into the uterine cavity to a depth predetermined by intra-operative sounding and the treatment is initiated with the depressing of a finger trigger switch. After performing a system check for balloon leak and device function the TCU commences treatment. A series of pressurisation and depressurisation cycles occurs which pump the heated fluid through the catheter and inflates the balloon to a pressure of 180mm Hg. The cycle is repeated every 10

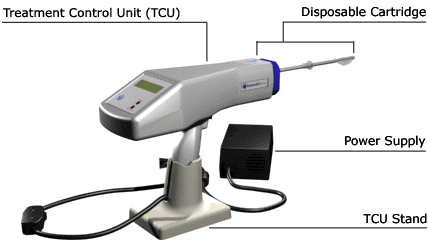
seconds which creates fluid temperature and treatment uniformity plus adjusts for any cavity volume change that may occur during treatment. At the conclusion of the treatment TCU automatically draws all the fluid from the balloon back through the catheter and into the reservoir.

Treatment with Thermablate ES can be performed under local anaesthetic with or without intravenous sedation. Post treatment care is typically under one hour with a patient returning to normal activities the next day.



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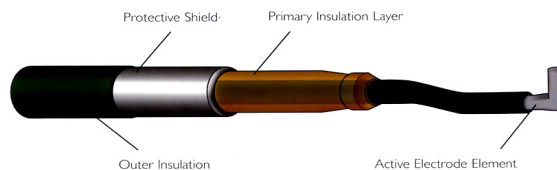
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