Initial Clinical Evaluation of the Librata Endometrial Ablation Device

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Introduction:

The Librata endometrial ablation device is a novel handheld, battery operated ablation device using heated glycine within a silicone balloon.

Figure 1: Librata endometrial ablation device

Glycine is preheated to 150C in a reservoir within the hand piece and is delivered to the balloon during the treatment phase via a motorized pump to create pressure of up to 187mmHg within the balloon. The treatment cycle lasts for 132 seconds at which point the pump automatically deflates the balloon and withdraws the glycine back into the reservoir. Intra-uterine pressure is constantly measured by the device and excess pressure or loss of pressure, which could indicate a fault will automatically terminate the procedure and withdraw the glycine. The surgeon also has a manual override to allow termination of the procedure at any stage.

Proof of concept data performed on extirpated uteri has shown that the device provides cavity coverage and depth of destruction that is equivocal to other devices. Figure 2 *(Coad A, Blend B, Rubenstein J, Cook C, Castillo-Saenz L, Garza-Leal J. Librata – A fully handheld endometrial ablation device. Proof of concept using extirpated human uteri. AAGL presentation 2015)*.

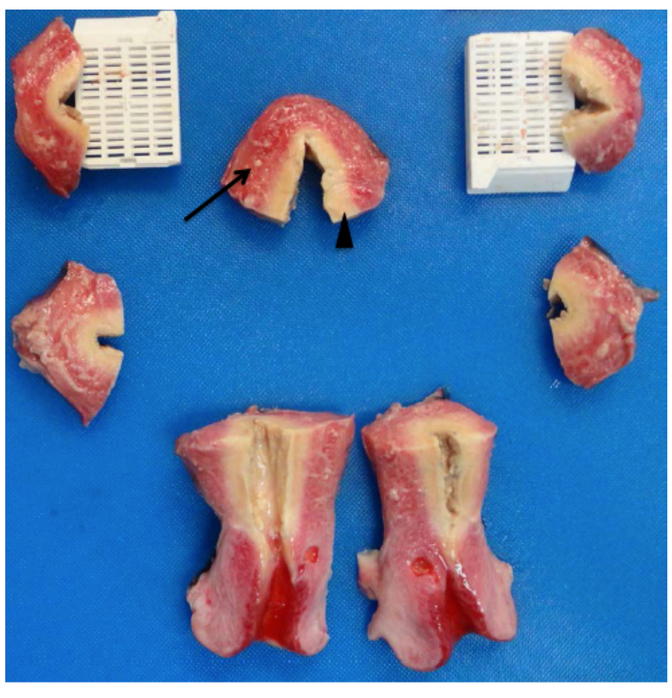

Figure 2: Uterine cavity coverage and depth of destruction

Initial clinical use has also demonstrated good cavity coverage with the ablation.

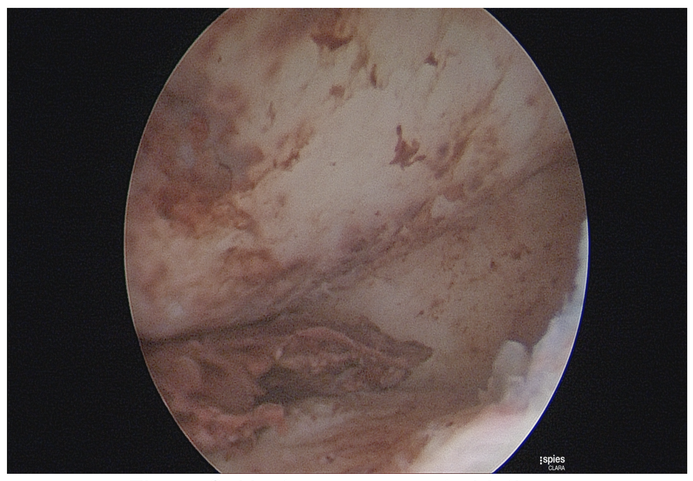

Figure 3: Hysteroscopy post ablation

Methods:

Patients seen through gynaecology clinics who were deemed suitable for an endometrial ablation were appropriately counselled about the procedure and information specific to the balloon endometrial ablation was provided prior to consent. Patients were mainly scheduled for an outpatient procedure and a small number were performed under general anaesthesia in the day surgical unit. All patients had a prior hysteroscopy and endometrial biopsy and those who had caesarean sections were assessed with ultrasound to ensure the myometrial thickness at the scar was no less than 10mm. For those having the procedure in the outpatient setting, a pre procedure regime of diclofenac 100mg, co-codamol 30/500x2 and diazepam 5mg was given 30 minutes pre-operatively. A cervical block with 30mls chirocaine (5mg/ml) was performed 10 minutes prior to the ablation. Inhalational nitrous oxide was available during the procedure with tramadol and buscopan available as rescue analgesia post operatively.

Our aims were to assess the device reliability and acceptability in an outpatient setting. We have also managed to collect some preliminary follow up data to assess effectiveness.

To date, 29 patients have had the procedure in our unit, 7 under general anaesthesia and 22 with local anaesthesia. Table 1 shows the demographic data for the patients in the study. In 3 cases the procedure was automatically aborted due to excess pressure noted by the device. In all cases this was associated with a smaller uterine cavity where the total uterine sound measurement was 7cm or less.

	Median	Range
Age	45	30-53
BMI	29	17-41
Parity	2	0-5
	Number	Percentage
Previous LSCS	7	24%
Uterine fibroids <3 cm	7	24%

Table 1: Patient demographics

Table 2 shows the intra-operative data collected. Pain scores were obtained during the immediately after completion of the ablation using a 10 point visual analogue scale. The need for cervical dilation is recorded as the tip of the device is designed to minimize the need for this and reduce the risk of uterine perforation. Of note, all patients in the outpatient group appeared to tolerate the procedure with none being abandoned due to discomfort.

Total No. of procedures	29	
Procedures completed	26	
Procedures abandoned (Device)	3	
Procedure abandoned (surgeon)	0	
Cervical dilatation	10	345
Rescue medication	10	34%
Ward admission	0	
Maximum pain score	Median 6	Range 3-9

Table 2: Intra operative data

Table 3 shows follow up data on the first 19 patients who are at least 8 months post procedure.

Reduced menstrual loss	9	47%
No periods	7	37%
Satisfied with outcome	16	84%
Required further treatment	3	16%

Table 3: Follow up data

Conclusion:

Following the proof of concept studies, this small clinical study has shown that the Librata endometrial ablation device is both reliable and acceptable to use. With an appropriate outpatient setup and analgesic strategy, patients are able to tolerate the procedure awake. The reduced need for cervical dilation minimizes the risk of inadvertent uterine perforation with dilators and the continuous pressure monitoring during ablation makes the device safe to use. Whilst numbers are small, to date no complications have arisen as a result of the procedure.

Follow up has been performed on a small number of patients and the evidence to date indicates good clinical effectiveness.

More studies with greater patient numbers will be required to confirm initial suspicions and provide some comparison with currently available devices.