Innovation in Gynecology

Clinical evaluation of the **Librata** endometrial ablation device in an outpatient setting

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Objective: To evaluate the acceptability and effectiveness of the endometrial ablation device LiNA Librata™ in an outpatient setting.

Methods: Prospective cohort study including 53 patients with Librata endometrial ablation. All patients suffered from menorrhagia for benign reasons and were unresponsive to medical therapy. 46 patients were treated in an outpatient setting and 7 procedures were performed under general anaesthesia in the day surgical unit. Prior to the procedure hysteroscopy and endometrial biopsy were performed. Patients with caesarean sections were assessed with ultrasound to ensure the myometrial thickness at the scar was no less than 10 mm. Endometrial thinning was not performed. In the outpatient setting a pre-procedure regime of diclofenac 100mg, co-codamol 30/500x2 and diazepam 5mg was given 30 minutes preoperatively. 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 as rescue analgesia post operatively. Pain scores were obtained immediately after the procedure using a 10-point visual analogue scale. The patients were followed up for 6 - 9 months post-ablation.

Results: The median age of the study group was 45, the median BMI was 27 and the median number of parity was 2 with lower segment caesarean sections in 26% of the patients (14/53). The median uterine sound measurement was 8 cm (range 5-14 cm) and 15 patients (28%) had intramural uterine fibroids sized < 3 cm. (table 1)

Table 1. Baseline characteristics

	Median	**Range**
Age	45	30-53
BMI	27	17-42
Median uterine sound length (cm)	8	5-14
Parity	2	0-5
	Number	**Percentage**
Previous caesarean sections	14	26%
Intramural fibroids < 3 cm	15	28%

All patients in the outpatient group appeared to tolerate the procedure with none being abandoned due to discomfort. Cervical dilation was conducted in 43% of the patients (23/52). The mean (SD) pain score was 5,4 (2,2) and 13 patients (25%) received rescue medication. There were no adverse patient consequences due to the procedures. (table 2)

➔ **All patients in the outpatient group tolerated the procedure with none being abandoned due to discomfort.**
➔ **Cervical dilation was performed in 43% of the patients.**

Table 2. Procedural data

Total number of procedures	53
Procedures completed	49
Procedures aborted by device	4
Adverse events	0
Cervical dilation	23 (43%)
Rescue medication	13 (25%)
Pain score (mean)	5,4

Follow up data are available for 52 patients. 87% reported reduced menstrual blood loss (45/52) including 33% with amenorrhea (n=17/52). 81% were satisfied with the procedure (42/52). 19% required further treatment (10/52), including 5 patients with hysterectomy. Two of the patients with hysterectomy had adenomyosis, one patient had fibroids. (table 3)

➔ **87% reported reduced menstrual bleeding**
➔ **33% had amenorrhea**

Table 3. Follow up data

	Percentage	**n**
Patients with reduced bleeding	87%	45/52
Patients with amenorrhea	33%	17/52
Further treatment required*	19%	10/52
Satisfied with procedure	81%	42/52

*Hysterectomy (n=5, including 1 patient with fibroids and 2 patients with adenomyosis), Esmya (n=3), Progestogen (n=1), Rollerball ablation (n=1)

Conclusions:
The Librata endometrial ablation device is an effective treatment for abnormal uterine bleeding and well tolerated in an outpatient setting.

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