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Performance and effectiveness of the **Librata** endometrial ablation system

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

Methods: Prospective evaluation of 20 patients undergoing endometrial ablation with LiNA Librata™ in an outpatient setting. All patients had refractory heavy menstrual bleeding with no definable organic cause. Preprocedural hysteroscopy, endometrial biopsy or pelvic ultrasound showed no endometrial or uterine cavity abnormalities. Patients with intracavitary polyps > 2 cm, submucosal fibroids > 1cm and intramural fibroids > 3cm were excluded from the trial. Endometrial thinning was performed. The anaesthesia regimen included oral analgesia, cervical or spinal block and iv. sedation. Procedural pain scores were obtained using a 10-point visual analogue scale. A device performance form was completed after each procedure. Menstrual loss was measured by menstrual pictogram at 1, 3 and 6 months. Patient satisfaction and health related quality of life (Menorrhagia Multi-attribute Assessment Scale, MMAS) were assessed at 6 months. Treatment side effects and treatment failures were recorded. 24-36 month after the procedure the patients were followed up to assess their satisfaction with the treatment, menstrual status and requirement for reinterventions.

Results: The mean age of the study group was 42, the mean BMI was 28 and the median number of parity was 2. All patients suffered from dysmenorrhea, 83% (15/18) reported premenstrual symptoms and 22% (4/18) were anaemic. (table 1)

Table 1. Baseline characteristics

	Mean	SD
Age	42	4,2
BMI	28	6,2
Parity	2	1
Severity of menstrual bleeding: Menstrual Pictogram score[1]	267,6	211,9
Quality of life: MMAS score[2]	39,7	20,8
	Number	**Percentage**
Patients with anemia	4	22%
Patients with dysmenorrhea	20	100%
Premenstrual symptoms	15	83%

The procedure was completed without complications in all patients. The overall performance of all devices was rated as excellent. Patients received cervical dilatation to an average (SD) of 6,5 (0,17) mm. (table 2) The standardised thermal treatment time with the device is 126 seconds, the mean (SD) procedure duration was 165 (21) seconds. The mean (SD) pain score was 2,9 (2,5). All patients tolerated the procedure with none being abandoned due to discomfort. Average time spent in the recovery room was 1h 13 min and all patients were discharged the day of the procedure.

Patients received cervical dilatation to an average of 6.5 mm

Table 2. Procedural data – uterine measurements

Variable	Mean	Median	Minimum	Maximum
Cervical dilation (in mm)	6.5	6.5	6.0	7.0
Fundus to external cervical (Sound, in cm)	9.0	9.0	7.5	10.0

24-36 months after the procedure all patients reported reduced blood loss. (table 3)

All patients reported reduced bleeding

Table 3. Impact on menstrual bleeding

	12-24 months (n=20)
Patients with reduced bleeding (%)	100%
Patients with spotting and amenorrhea (%)	30%

24-36 months after the procedure all patients were very satisfied or satisfied with the procedure. (table 4)

All patients were very satisfied (11/20) or satisfied (9/20) with the procedure.

Table 4. Patient satisfaction

Responses	24-36 Months (n=20)
Very satisfied	55% (11 of 20)
Satisfied	45% (9 of 20)

The patients reported an improvement in Health Related Quality of Life. The mean total MMAS scores were improved from 39,7 at baseline to 89,5 at month 6. Improvements were observed in all MMAS Quality of Life domains (practical difficulties, social life, family life, work and daily routine, psychological wellbeing and physical health).

Two patients required further treatment, both undergoing hysterectomies, one due to fibroids and one due premalignant lesions.

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

[1] Menstrual Pictogram (MP): Score of ≥150 indicates heavy menstrual bleeding
[2] Menorrhagia Multi-attribute Scale (MMAS): Scoring from 0-100, 0 means worst affected and 100 unaffected

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