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 18 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.

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

6 months after the procedure all patients reported reduced blood loss and the amenorrhea rate was 56% (10/18). (table 3) The mean Menstrual Pictogram score was reduced from 268 at baseline to 11,7 at month 6. (figure 1)

All patients reported reduced bleeding and the amenorrhea rate was 56%

Table 3. Impact on menstrual bleeding

	1 Month n=18	3 Months n=18	6 Months n=18
Patients with reduced bleeding (%)	100% (18)	100% (18)	100% (18)
Patients with amenorrhea (%)	72% (13)	56% (10)	56% (10)

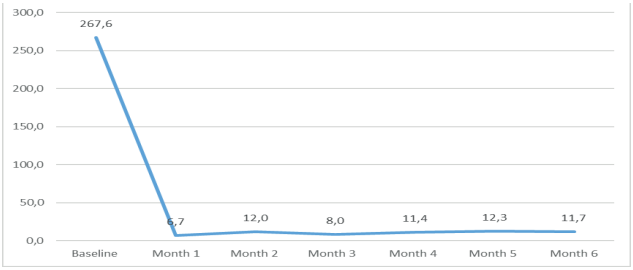

Figure 1. Average Baseline and Follow Up Menstrual Pictogram Score

6 months after the procedure all patients reported that their symptoms of dysmenorrhea had improved. (figure 2) Premenstrual symptoms were improved in 47% of the patients (8/17).

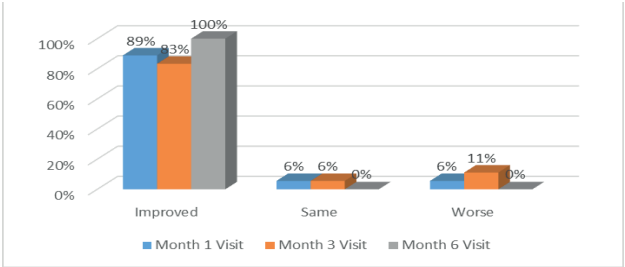

Figure 2. Dysmenorrhea – patient self-assessment

All patient were very satisfied (11/18), satisfied (4/18) or fairly satisfied (3/18) with the procedure at 6 months.

Table 4. Patient satisfaction

Responses	1 Month (n=18)	3 Months (n=18)	6 Months (n=18)
Very satisfied	72% (13)	72% (13)	61% (11)
Satisfied	6% (1)	22% (4)	22% (4)
Fairly satisfied	6% (1)	0%	17% (3)
Not sure	6% (1)	6% (1)	0%
Dissatisfied	11% (2)	0%	0%

Mean total MMAS scores were improved from 39,7 at baseline to 89,5 at month 6. Improvements were observed in all MMAS domains (practical difficulties, social life, family life, work and daily routine, psychological well-being and physical health). (table 5)

Improvement in quality of life

Table 5. Quality of life assessment

Domain	Mean	
	Baseline	6 Months
Practical difficulties	2.5	12.3
Social life	5.6	8.9
Psychological health	8.1	12.3
Physical health and wellbeing	6.0	18.8
Work/daily routine	7.2	15.9
Family life/relationships	10.5	21.3
Average Total MMAS score (all domains included)[2]	39.7	89.5

No patient required further treatment. There were no adverse patient consequences due to the procedures.

Conclusions: The Librata endometrial ablation device is an effective 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