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 > 1 cm and intramural fibroids > 3 cm 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

<table>
<thead>
<tr>
<th>Variable</th>
<th>Mean ± SD (n=18)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>42 ± 5.2</td>
</tr>
<tr>
<td>BMI (kg/m²)</td>
<td>28 ± 6.2</td>
</tr>
<tr>
<td>Parity</td>
<td>2 ± 2</td>
</tr>
<tr>
<td>Severity of menstrual bleeding</td>
<td></td>
</tr>
<tr>
<td>Menstrual Pictogram score¹</td>
<td>267.6 ± 211.9</td>
</tr>
<tr>
<td>Quality of life MMAS score²</td>
<td>19.7 ± 20.8</td>
</tr>
</tbody>
</table>

The procedure was completed without complications in all patients. The overall performance of all devices was rated as excellent. Patients received cervical dilation 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.

Table 2. Procedural data – uterine measurements

<table>
<thead>
<tr>
<th>Variable</th>
<th>Mean ± SD (n=18)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cervical dilation (mm)</td>
<td>6.5 ± 0.5</td>
</tr>
<tr>
<td>Fundus to external cervical</td>
<td>9.0 ± 1.0</td>
</tr>
<tr>
<td>(Sound, in cm)</td>
<td></td>
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</tbody>
</table>

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

Table 4. Patient satisfaction

<table>
<thead>
<tr>
<th>Responses</th>
<th>1 Month (n=18)</th>
<th>3 Months (n=18)</th>
<th>6 Months (n=18)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Very satisfied</td>
<td>72% (13)</td>
<td>72% (13)</td>
<td>61% (11)</td>
</tr>
<tr>
<td>Satisfied</td>
<td>6% (1)</td>
<td>22% (4)</td>
<td>22% (4)</td>
</tr>
<tr>
<td>Fairly satisfied</td>
<td>6% (1)</td>
<td>0%</td>
<td>17% (3)</td>
</tr>
<tr>
<td>Not sure</td>
<td>6% (1)</td>
<td>6% (1)</td>
<td>0%</td>
</tr>
<tr>
<td>Dissatisfied</td>
<td>11% (2)</td>
<td>0%</td>
<td>0%</td>
</tr>
</tbody>
</table>

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)

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.