MT02 (12 months)
Second-generation of temporary implantable nitinol device for the relief of lower urinary tract symptoms due to benign prostatic hyperplasia: results of a prospective, multicenter study at 1 year of follow-up.


Objective
To report the clinical experience with a second-generation of temporary implantable nitinol device (iTind; Medi-Tate Ltd, Or-Akiva) for the treatment of lower urinary tract symptoms (LUTS) due to benign prostatic hyperplasia (BPH) after 1 year of follow-up.

Patients and Methods
This multicenter, single-arm, prospective study evaluated the feasibility and safety of the second-generation temporary implantable nitinol device (iTind) in 81 patients.

Inclusion Criteria:
· IPSS ≥ 10
· Qmax ≤ 12 mL/s
· Prostate volume < 75 mL

Exclusion Criteria:
· Haemostatic disorders
· PVR > 250 mL
· Obstructive median lobe
· Previous prostate surgery

The iTind was implanted within the bladder neck and the prostatic urethra under light sedation, using a rigid cystoscope. The device was removed 5-7 days later in an outpatient setting. Demographics, perioperative results, complications (according to the Clavien-Dindo system), functional results and quality of life (QoL) were evaluated. Follow-up assessments were conducted at 1, 3, 6 and 12 months postoperatively.
Results

The mean (SD) patient age was 65 (8.9) years and prostate volume was 40.5 (12.25) mL. At baseline, Qmax was 7.3 (2.6) mL/s, IPSS was 22.5 (5.6), and the median (interquartile range) IPSS QoL score was 4 (2–5). All the implantations were successful, with no intraoperative complications recorded; all patients were discharged on the same day of surgery. The devices were retrieved at a mean (SD) of 5.9 (1.1) days after implantation, typically under topical anesthesia. No Clavien–Dindo Grade >II complications were recorded. The mean (SD) Qmax at 1 month follow-up was 11.2 (5.7) mL/s and continued to improve thereafter, reaching 14.7 (8.1) mL/s at 12 month follow-up (+100%). The mean (SD) IPSS QoL score was 11.7 (8.0) after 1 month and further improved to 8.8 (6.4) at 12 month follow-up (60%). In parallel, the mean (SD) patient age was 65 (8.9) years and prostate volume was 40.5 (12.25) mL. At baseline, none of the 61 sexually active patients who completed the 12 month follow-up period reported sexual or ejaculatory dysfunction.

Adverse Events

<table>
<thead>
<tr>
<th>Complication</th>
<th>%</th>
<th>Treatment</th>
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</thead>
<tbody>
<tr>
<td>Hematuria</td>
<td>12.3%</td>
<td>Self-resolving</td>
</tr>
<tr>
<td>Urgency</td>
<td>11.1%</td>
<td>Self-resolving</td>
</tr>
<tr>
<td>Pain</td>
<td>9.9%</td>
<td>Oral analgesic</td>
</tr>
<tr>
<td>Dysuria</td>
<td>7.4%</td>
<td>Self-resolving</td>
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</tbody>
</table>
| Urinary retention (immediately post-procedure) | 9.9% | - Empty bladder with 12F catheter through device struts  
                                      |       | - Patient discharged without catheter                |

Conclusion

iTind implantation is feasible, safe and effective in providing relief of BPH-related symptoms for at least 1 year after treatment. Sexual and ejaculatory functions are fully preserved. Further studies with a longer follow-up period are needed to assess the durability of these results and to clearly define the indications for iTind implantation.