MT06 (6 months)

Urinary and sexual function after treatment with temporary implantable nitinol device (iTind) in men with LUTS: 6-month interim results of the MT06 study.

Cosimo De Nunzio, Francesco Cantiello, Cristian Fiori, Fabio Crocerossa, Piero Tognoni, Daniele Amparore, Valeria Baldassarri, Javier Reinoso Elbers, Fernando Gomez Sancha, and Francesco Porpiglia. 

Introduction and Objective

To evaluate functional and sexual outcomes after treatment with temporary implantable nitinol device (iTind; Medi-Tate Ltd, Israel); a novel minimally-invasive treatment for Lower Urinary Tract Symptoms (LUTS) due to Benign Prostatic Hyperplasia (BPH).

Methods

To report 6 month interim results of a single-arm, multicenter prospective study evaluating functional outcomes after treatment with a temporarily implantable nitinol device (iTind; Medi-Tate Ltd, Israel).

Inclusion Criteria:
- IPSS ≥ 10
- Qmax < 12 mL/s
- Prostate volume < 120 mL

Exclusion Criteria:
- Previous prostate surgery
- Prostate cancer
- Urethral stricture
- Bladder stones
- Urinary tract infection (UTI)
- Obstructing median lobe (considered >1.2 cm)
- Neurological conditions that may affect voiding function
The iTind was implanted within the bladder neck and prostatic urethra using a 22 Fr rigid cystoscope under intravenous sedation and removed 5-7 days later through a 22 Fr Foley catheter under local anesthesia. Patients were not washed-out of BPH medications or required to cease anti-coagulation or anti-platelet therapy prior to the procedure. Postoperative VAS and complications (Clavien Dindo-Grading System) were recorded. Preservation of urinary continence and sexual and ejaculatory function were assessed according to ISI, MSHQ-EjD and SHIM. Post-operative IPSS, QoL, Qmax and PVR were also assessed at 1, 3, and 6 months post-operatively.

Results

This interim report includes results out to 6 months on the first 70 patients enrolled in the study. The median age was 62.31yrs, with an average prostate volume of 37.68mL (15-80mL). Baseline and follow-up data are reported. No intraoperative complications were observed and the average postoperative VAS score was 3.24 ±2.56. On average, patients returned to daily life 4.3 days following the retrieval procedure, and mean quality of recovery visual analog scale (QoR VAS) was 0.77. Significant improvement ($p<0.0001$) from baseline was recorded in IPSS, QoL and Qmax in response to iTind treatment at 6 months. Sexual function and urinary continence were preserved in all subjects according to ISI, SHIM and MSHQ-EjD questionnaires.

<table>
<thead>
<tr>
<th>Results</th>
<th>Baseline</th>
<th>6 Month FU ($p$ value)</th>
</tr>
</thead>
<tbody>
<tr>
<td>IPSS</td>
<td>21.2</td>
<td>8.3 ($p&lt;0.01$)</td>
</tr>
<tr>
<td>QoL</td>
<td>4.1</td>
<td>2.0 ($p&lt;0.01$)</td>
</tr>
<tr>
<td>Qmax</td>
<td>7.3 mL/sec</td>
<td>12.0 mL/sec ($p&lt;0.01$)</td>
</tr>
<tr>
<td>PVR</td>
<td>69.3 mL</td>
<td>48.1 mL ($p=0.12$)</td>
</tr>
<tr>
<td>SHIM</td>
<td>16.1</td>
<td>18.2 ($p=0.06$)</td>
</tr>
<tr>
<td>ISI</td>
<td>1.1</td>
<td>0.8 ($p=0.14$)</td>
</tr>
<tr>
<td>MSHQ-EjD</td>
<td>9.2</td>
<td>11.2 ($p&lt;0.01$)</td>
</tr>
</tbody>
</table>

Conclusion

iTind is a well-tolerated minimally-invasive treatment for BPH-related LUTS. Interim results demonstrate iTind offers a rapid recovery and return to daily life, preservation of sexual function and urinary continence as well as a significant improvement in symptoms and urinary flow at 6 months follow-up.