MT03 (12 months)

The iTind Temporarily Implanted Nitinol Device for the Treatment of Lower Urinary Tract Symptoms Secondary to Benign Prostatic Hyperplasia: A Multicenter, Randomized, Controlled Trial

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https://pubmed.ncbi.nlm.nih.gov/33373708/

Objective

To report the results of a multicenter, randomized, controlled trial with a temporarily implanted nitinol device (iTind; Medi-Tate Ltd, Hadera, Israel) compared to sham for the treatment of lower urinary tract symptoms secondary to benign prostatic hyperplasia.

Materials and Methods

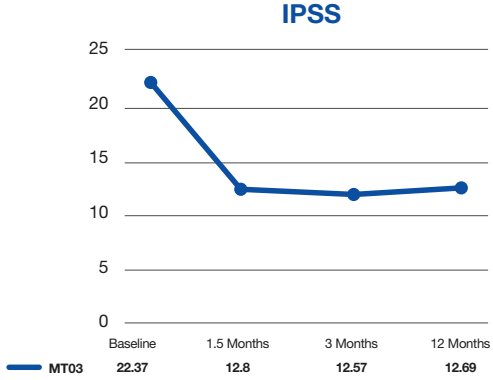
Men 50 years or older were randomized 2:1 between iTind and sham procedure arms. A self-expanding, temporary nitinol device was placed for 5 to 7 days and an 18F Foley catheter was inserted and removed for the iTind and sham group, respectively. Patients were assessed at baseline, 1.5, 3, and 12 months post-operatively using the IPSS, peak urinary flow rate (PFR), residual urine, quality of life (QoL), and the International Index of Erectile Function (IIEF). Unblinding occurred at 3 months.

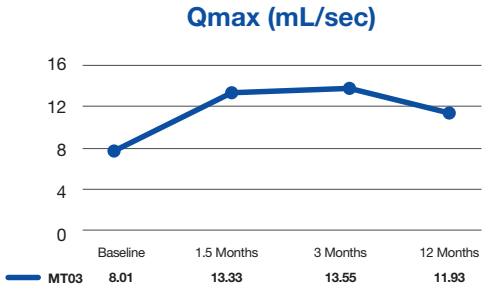
Results

A total of 175 men (mean age 61.1±6.5) participated (118 iTind vs 57 sham). 78.6% of patients in the iTind arm showed a reduction of ≥3 points in IPSS, versus 60% of patients in the control arm at 3 months. At 12 months, the iTind group reported a 9.25 decrease in IPSS ($p<0.0001$), a 3.52ml/s increase in PFR ($p<0.0001$) and a 1.9-point reduction in QoL ($p<0.0001$). Adverse events were typically mild and transient, most Clavien-Dindo grade I or II, in 38.1% of patients in the iTind arm and 17.5% in the control arm. No de novo ejaculatory or erectile dysfunction occurred.

Conclusion

Treatment with the second-generation iTind provided rapid and sustained improvement in lower urinary tract symptoms for the study period while preserving sexual function.





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