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iTind Clinical Summaries

Reshaping BPH Treatment

The iTind Temporarily Implanted Nitinol Device for the Treatment of Lower Urinary Tract Symptoms Secondary to Benign Prostatic Hyperplasia: A Multicenter, Randomized, Controlled Trial (MT03)

Urology. 2020;S0090-4295(20)31520-X. doi:10.1016/j.urology.2020.12.022

Bilal Chughtai, Dean Elterman, Neal Shore, Marc Gittleman, Jay Motola, Sheldon Pike, Craig Hermann, William Terrens, Alfred Kohan, Ricardo R. Gonzalez, Aaron Katz, Jeffery Schiff, Evan Goldfischer, Ivan Grunberger, Le Mai Tu, Mark N. Alshak, and Jed Kaminetzky

Objective and Indication

To compare results of treatment with iTind vs. sham treatment in lower urinary tract symptoms (LUTS) due to benign prostatic hyperplasia (BPH)

Design

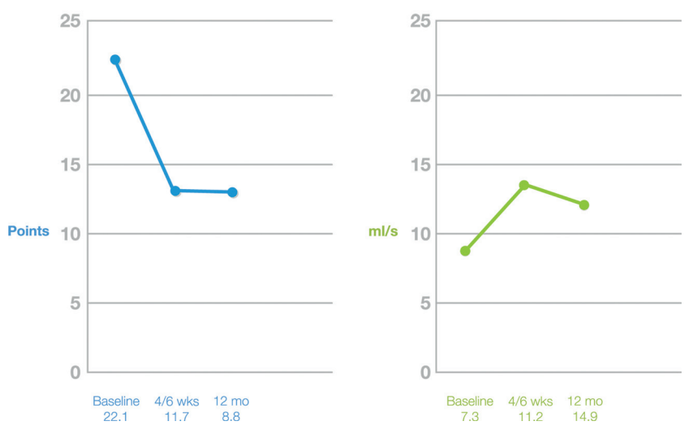
Multicenter, randomized, controlled trial (RCT): iTind vs. sham treatment (randomized 2:1)
Assessment at baseline, 1.5, 3, and 12 months postoperatively: IPSS, PFR (Qmax), residual urine, QoL, and IIEF

Subjects

175 men 50 years or older (mean age 61.1 years); (118 iTind vs. 57 sham)

Results

- At 3 months, 78.6% of iTind patients had a reduction of ≥3 points in IPSS, vs. 60% in the sham group
- At 12 months, iTind patients showed a significant decrease in IPSS (-9.25 points), a significant increase in PFR (+3.52ml/s) and a significant reduction in QoL (-1.9 points)
- No patient experienced de novo ejaculatory or erectile dysfunction. AEs, which were typically mild and transient, occurred in 38.1% of iTind patients and 17.5% of sham patients (most were Clavien-Dindo grade I or II).



Key Findings

- Second-generation iTind proved to provide a significant, rapid and durable improvement in LUTS.
- iTind is effective and safe, especially in terms of preservation of sexual function.

Conclusion

iTind provides significant, rapid and durable improvement in LUTS due to BPH and preserves sexual function over a follow-up period of 12 months.

Urinary and sexual function after treatment with temporary implantable nitinol device (iTind) in men with LUTS: 6-month interim results of the MT-06-study

World J Urol. 2021;39(6):2037-2042. doi:10.1007/s00345-020-03418-2

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

Objective and Indication

Evaluation of functional outcome and preservation of urinary continence and sexual function in men treated with iTind for LUTS due to BPH.

Design

Prospective, single arm, multicenter, international clinical study. Interim report: Assessment of post-operative VAS, complications (Clavien Dindo-Grading System), preservation of urinary continence and erectile and ejaculatory function (according to ISI, MSHQ-EjD and SHIM), and post-operative IPSS, QoL, Qmax and PVR at 1, 3, and 6 months follow up.

Subjects

- 70 men with symptomatic benign prostatic obstruction (BPO) and IPSS ≥10, Qmax <12ml/s, prostate volume <120ml.
- Patients did not wash out BPH medication before iTind treatment

Results

- 70 patients with a median age of 62.31 years and a mean prostate volume of 37.68 ml (15–80 ml) were enrolled
- No intraoperative complications were observed, average post-operative VAS score was 3.24 ± 2.56
- Return to daily life after an average of 4.3 days post iTind retrieval
- All patients showed preserved sexual function and urinary continence according to ISI, SHIM and MSHQ-EjD
- IPSS, QoL and Qmax improved significantly ($p < 0.0001$) vs. baseline levels

Key Findings

- iTind treatment preserves sexual function and urinary continence, offers a rapid return to daily life, and provides a significant improvement of symptoms and urinary flow up until 6-months post-surgery.

Conclusion

Minimal invasive treatment with iTind is well-tolerated, preserves sexual function and urinary continence, offers rapid recovery/return to daily life and provides significant improvements in LUTS and urinary flow at 6-month follow-up.

Temporary implantable nitinol device for benign prostatic hyperplasia-related lower urinary tract symptoms: over 48-month results (MT02)

Minerva Urol Nephrol. 2023;10.23736/S2724-6051.23.05322-3. doi:10.23736/S2724-6051.23.05322-3.

Amparore D, De Cillis S, Schulman C, Kadner G, Fiori C, Porpiglia F

Objective and Indication

To follow up on the >48-month (50-79 months) results of patients treated with iTind for lower urinary tract symptoms (LUTS) due to benign prostatic hyperplasia (BPH).

Design

Prospective, single arm, multicenter, international clinical study
Assessment at baseline, 1, 3, 6 months, 12, 24, 36 and >48 months postoperatively. OR-time, pain, postoperative complications, functional results (IPSS, Qmax, PVR, QoL), sexual and ejaculatory function (two yes/no questions) were assessed up to 36 months. >48-month outcomes are assessed via IPSS, IPSS-QoL, change in medication, need for surgical re-treatment and adverse events.

Subjects

81 men with symptomatic benign prostatic obstruction (BPO) and IPSS ≥10, Qmax <12ml/s, prostate volume <75ml were originally enrolled. Fifty out of these 81 (62%) patients at 3/9 sites (Italy, Switzerland, and Belgium) continued the follow-up beyond 36 months. Due to the COVID-19 pandemic, the over 48-month follow-up was amended: Each patient was assessed once during 50-79 months postoperatively telephonically.

Results

- >48 months results were available for 41 patients: 5 subjects were lost to follow-up and 2 died (unrelated to iTind device placement). Two subjects required surgical re-treatment (1 TURP; 1 ThuLEP)
- iTind device treatment showed significant improvement in symptoms: IPSS was reduced by 45.3% (P<0.0001) and IPSS-QoL improved by 45.1% (P<0.0001) from baseline to 79 months post-procedure; with a mean±SD of 11.26±7.67 and 2.10±1.41 points, respectively
- No complications occurred from 36 up to 79 months and no patient required additional medication

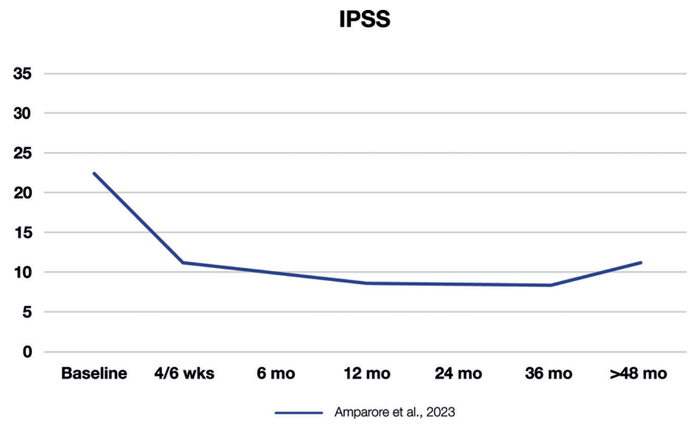


Figure 1: Improvement of IPSS over time. ITT analysis set.

*Graph created by Olympus, based on the data in the given publication

Conclusion

iTind device provided significant and durable symptom reduction and improved IPSS-QoL for >48 months post treatment. No late postoperative complications were reported beyond 36 months of follow-up. Surgical re-treatment rate for >36 months was 4%.

The Mechanism of Action of TIND for Minimally Invasive Ischemic Incision of the Prostate: In Vivo Study

Urology, May 28, 2021; S0090-4295(21)00446-5. DOI: 10.1016/j.urology.2021.05.031.

Tylor Garman, Ahra Cho, Micholina D Stoddard, Ido Kllomnik, Vanossa Malka, Dean Elterman, Bllal Chughtal

Objective and Indication:

To demonstrate the histologic effect of iTIND on prostate tissue.
(Note: Used in the study was TIND, a modified version of ITIND, which has been adapted to the canine model.)

Design:

Observational proof-of-principle in vivo animal study, in three live male canines.

Subjects:

CTIND was externally implanted in the prostate and left for up to 14 days.
Device placement and the biologic effects on the prostatic tissue were studied.

Results:

· CTIND remained in position until animal sacrifice on day 14.
· Prostate tissue showed abrupt transition from normal, viable glandular tissue to an area of necrosis and fibrosis.

Key Findings:

· In this canine model, TIND successfully induced incisions in the periurethral prostate through focal areas of ischemic necrosis.
· There was minimal inflammation, no evidence of edema and only minimal injury to prostatic tissue.

Conclusion:

Implantation of TIND resulted in focal areas of ischemic necrosis in the affected periurethal prostate tissue.
There was no evidence of edera, and inflammation was minimal.

Notes

Place to Write Down Notes

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