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# I-Tind for the treatment of lower urinary tract symptoms secondary to benign prostatic hyperplasia: Mid-term outcomes from a multicenter cohort

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## Abstract

Benign prostatic hyperplasia (BPH) is a common cause of lower urinary tract symptoms (LUTS) in aging men, significantly impacting quality of life. Although pharmacological therapies, especially alpha-blockers, are the standard first-line treatment, their long-term adherence is limited by side effects and insufficient symptom control. Transurethral resection of the prostate (TURP) remains the surgical gold standard but is associated with notable morbidity, prompting interest in minimally invasive alternatives. The temporary implantable nitinol device (I-Tind) offers a tissue-sparing approach designed to remodel the prostatic urethra and relieve LUTS without compromising sexual function. This multicenter prospective study evaluated the safety, efficacy, and functional outcomes of I-Tind in 120 patients with symptomatic BPH unresponsive to alpha-blockers, treated between 2019 and 2023. Follow-up assessments were done at 3, 6, and 12 months. The study showed significant improvements in urinary flow and symptom scores. Mean Qmax improved from 7.6 to 15.7 mL/s, and mean IPSS decreased from 21.5 to 9.7 at 12 month-follow-up ($p < 0.001$). Quality of life measures also improved, and sexual and ejaculatory functions were fully preserved. The procedure was well-tolerated, with all implants successfully retrieved after a mean of 6 days and a low complication rate. I-Tind appears to be a safe and effective minimally invasive option for selected BPH patients, combining symptom relief with preservation of quality of life. Further randomized trials are needed to confirm these findings and better define its role in the BPH treatment algorithm.

## Keywords

BPO, LUTS, iTind, urethral implantable device, minimal invasive techniques, MIST, IPSS

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## Introduction

Benign prostatic hyperplasia (BPH) is a common condition affecting over 50% of the adult male population prior to the sixth decade of life, with its incidence exhibiting a linear increase up to the age of 80.[1] Several studies on the management of newly diagnosed lower urinary tract symptoms associated (LUTS) with BPH in the general population found that more than 8% of patients undergo prostate surgery, while 45% receive pharmacological treatment within the first year following diagnosis.[1,2] Alfa-blockers are the most commonly prescribed first-line therapy. However, treatment is often non-continuous, with an average adherence rate of 70%.[3] Additionally, one-quarter of patients discontinue treatment prematurely, and pharmacological therapy is only utilized for approximately one-third of the follow-up period from treatment initiation.[4,5] For decades, transurethral resection of the prostate (TURP) has been the standard surgical approach, primarily indicated for severe cases or those unresponsive to pharmacological therapy.[6] Although it provides sustained urodynamic improvement, it is associated with both short- and long-term complications, including perioperative and postoperative morbidity, ejaculatory dysfunction, erectile dysfunction, and urethral strictures.[7]

Notably, the European Association of Urology (EAU) has acknowledged several minimally invasive surgical therapies (MIST), including water vapor therapy (Rezūm), prostatic artery embolization (PAE), and prostatic urethral lift (PUL). Interestingly, the LEST technique using laser energy has been proposed.[8,9] This technique consists in a debulking laser technique with the aim of preserving the "genital sphincter," an anatomical structure that include the para-urethral musculature, distinguished in proximal and distal portion, and in part the musculature of the bladder neck.[9] However, in a landscape of different solutions proposed for LUTS due to urinary flow obstruction it is necessary to find the right indication for a tailored therapy. In this context, the temporary implantable nitinol device (I-Tind, Medi-Tate Ltd®) has emerged as an alternative, promising minimal invasiveness while providing relief from BPH-related LUTS.[10] The second-generation i-Tind device demonstrated safety and effectiveness, evidenced by two recent multicenter prospective studies.[11,12] In our study, we aimed to report functional and quality of life outcomes, at 12 months follow-up, in patients with symptomatic BPH across a multicenter cohort.

## Materials and methods

### Study population

This multicentric prospective study includes a total of 120 consecutive patients treated with I-Tind from September 2019 to December 2023. Procedures were performed by two experienced surgeons (RL and MD). Baseline data, including medical history, age, prostate volume, patients' ejaculatory function was collected for all patients. Uroflowmetry, IPSS, PVR, and quality-of-life questionnaires, were collected within 40 days prior to the procedure. All patients referred an anterograde ejaculation before surgery. Lastly, before undergoing I-Tind implantation, all patients underwent digital rectal examination, renal and bladder ultrasonography and flexible cystoscopy. A wash-out period was implemented for BPH-related medications: 1 month for alpha-blockers and 6 months for 5-ARIs. This study was conducted in the accordance with good clinical practice guidelines and the ethical principles of the Declaration of Helsinki.

Inclusion criteria were the following: patients experiencing LUTS with IPSS $\geqslant$10 (Qmax $\leqslant$ 12 mL/s), non-responsive to alpha-blockers and prostate volume $<$50 cc. Exclusion criteria were patients with post-void residual (PVR) volume $>$80 mL, history of prostate cancer, a prominent median lobe, urethral strictures, neurogenic bladder, concomitant bladder stones, or previous prostate surgery.

### Device, mechanism of action, and surgical technique

The I-Tind is a temporary implantable device with three nitinol branches positioned at 12, 5, and 7 o'clock and a stabilizing flap at 6 o'clock to prevent migration into the bladder during expansion. It measures 50 mm in length and 33 mm in diameter, designed to cover the full length of the prostatic urethra from the bladder neck to the verumontanum. The device was implanted under mild sedation using a rigid 22 Fr cystoscope with 30-degree optics for direct visualization. It remained in situ for 7 days, during which it gradually remodeled the prostatic tissue at the bladder neck and anterior prostatic fossa through three ischemic incisions. Removal of the iTind device was performed using an open-ended 22 Fr. Foley catheter.

To prevent over-distension of the bladder, nursing staff and anesthesiologists were instructed to avoid administering high volumes of IV fluids, and patients were advised against excessive fluid intake immediately post-procedure. Following surgery, patients received a perioperative dose of intravenous antibiotics and nonsteroidal anti-inflammatory drugs (NSAIDs).

### Statistical analysis

Efficacy, safety and functional results were evaluated up to 12 months. Retreatment was defined as the requirement for any other surgical procedure for recurrent/persistent LUTS during follow-up. Data were expressed as means and standard deviation for continuous variables, and as frequencies for categorical variables. The comparison between baseline and follow-up clinical variables was

**Table 1.** Baseline characteristics of the patients.

| Variable | Value |
|---|---|
| Age, years, mean (SD) | 52.9 (±7.9) |
| BMI, median (IQR) | 26.1 (18.5–35.1) |
| Cardiac disease in medical history, *N* (%) | 14 (17.3) |
| Vascular disease in medical history, *N* (%) | 32 (39.5) |
| Endocrine disease in medical history, *N* (%) | 18 (22.2) |
| Prostate volume, mL (SD) | 40.5 (±12.25) |
| PSA level < 4 ng/mL, *N* (%) | 74 (93.7) |
| Peak uroflow, mL/s, mean (SD) | 7.6 (±2.6) |
| Post-void residual, mL, mean (SD) | 72.3 (±35.2) |
| Preoperative IPSS, mean (SD) | 21.5 (±5.1) |
| Preoperative IPSS QoL index, median (SD) | 6.0 (±2.5) |
| Time from diagnosis of BPO, years, mean (SD) | 5.2 (±5.9) |

performed using Wilcoxon rank test. All statistical tests were performed using R software v.3.5.3. Significance level was set at $p < 0.05$.

## Results

Overall, 120 patients presenting LUTS secondary to BPH underwent I-Tind implantation. The demographic characteristics of the patients are summarized in Table 1. At enrollment, patients mean age was of 52.9 ± 7.9 and mean prostate volume was of 40.3 cc ± 11.25. Mean Qmax and PVR was of 7.6 ± 2.6 mL/sec and 72.3 ± 35.2 mL, respectively. The reported mean QoL IPSS was 6 ± 2.5 and a mean urinary symptom IPSS of 21.5 ± 5.1. In terms of functional results at 6 months follow-up, the mean Qmax and PVR was of 11.1 ± 5.7 mL/s and 68.7 ± 20.8 mL ($p < 0.001$), respectively. These values continued to improve at the 12 months follow-up visit with a Qmax of 15.7 ± 7.1 mL/s and a PVR of 62.5 ± 15.9 mL ($p < 0.001$; Table 2). Moreover, statistically significant improvements in IPSS score and IPSS QoL were recorded at 3, 6, and 12 months follow up ($p < 0.001$; Table 2). Implants were retrieved 6.1 ± 0.9 days after deployment. All I-Tind implantation proceeded successfully, and all patients were discharged on the same day of surgery. Functional results of follow-up parameters are shown in Table 2. Overall, 2 patients with prostate of 60 gr. were submitted to a vaporization of the prostate, and one because the residual of urine was greater than 100 mL. Incomplete closure of the I-Tind during the removal was recorded in three cases. In one of these, a small hard fibrous adenoma of the prostate, 7 mm × 4 mm., was found responsible of the incomplete closure of the Stent (Figures 1 and 2). Lastly, none of the patients revealed sexual or ejaculatory dysfunction at last follow-up.

## Discussion

Regardless of the significant advancements in the management of lower urinary tract symptoms (LUTS), many men discontinue pharmacological treatment due to insufficient symptom relief and/or adverse effects.[13] Additionally, although transurethral resection of the prostate (TURP) remains the surgical gold standard for the treatment of LUTS secondary to benign prostatic hyperplasia (BPH), a non-negligible proportion of patients choose to avoid invasive resection or ablative procedures due to concerns about potential risks.[14,15]

Despite the effectiveness of medical and phyto-therapeutic treatment, current data on LUTS in the aging male population suggest that up to 36% of patients complaining with symptoms will require a surgical treatment.[16] Several well-established surgical techniques are available for treating non-neurogenic male LUTS, such as TURP, laser endoscopic enucleation and vaporization as well as robot-assisted procedures.[17] However, the evolution of treatment modalities has been marked by a significant shift toward minimally invasive surgical treatments (MISTs).[18–20] This shift is driven by the pursuit of therapeutic options that not only effectively alleviate symptoms but also minimize the risk of complications and preserve patients' quality of life.[21,22] Among the available MISTs, the I-Tind device—a nitinol implant designed to reshape the prostatic urethra without excising prostatic tissue—has emerged as a promising therapeutic option. Despite its innovative mechanism and potential advantages, including the preservation of sexual function and a shortened recovery period, the European Association of Urology (EAU) has endorsed the

**Table 2.** Summary of functional results during 12 month-follow-up.

| End-point | | Baseline | Months 3 | Months 6 | Months 12 |
|---|---|---|---|---|---|
| IPSS | | 21.5 ± 5.1 | 11.4 ± 5.7 | 11.1 ± 5.4 | 9.7 ± 5.5 |
| | *p*-value | — | <0.001 | <0.001 | <0.001 |
| QoL | | 6.0 ± 2.5 | 3.9 ± 0.8 | 3.9 ± 0.8 | 3.9 ± 0.8 |
| | *p*-value | — | <0.001 | <0.001 | <0.001 |
| PVR (mL) | | 72.3 ± 35.2 | 66.96 ± 22.8 | 68.7 ± 20.8 | 62.5 ± 15.9 |
| | *p*-value | — | 0.0001 | <0.0001 | <0.0001 |
| Qmax (mL/s) | | 7.6 ± 2.6 | 10.4 ± 2.4 | 11.1 ± 5.7 | 15.7 ± 7.1 |
| | *p*-value | — | <0.001 | <0.001 | <0.001 |

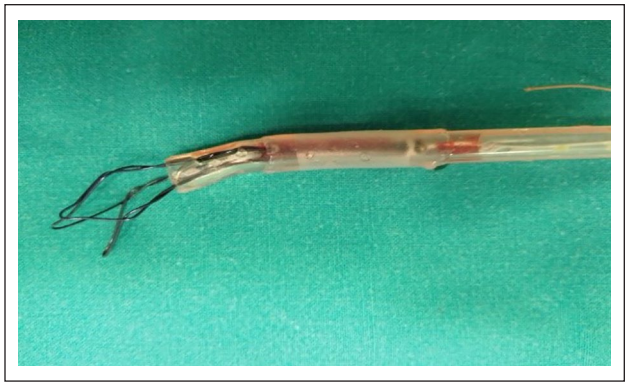

**Figure 1.** Incomplete closure of the I-Tind.

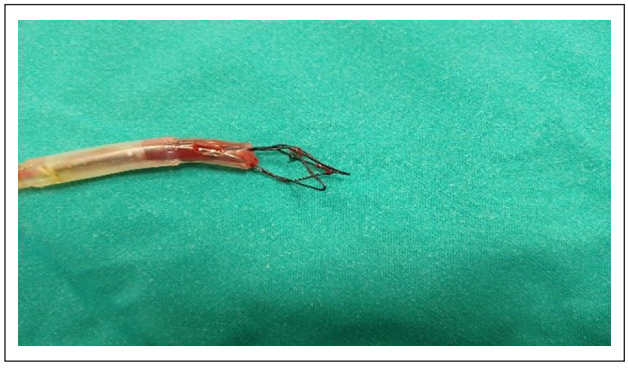

**Figure 2.** The small adenoma trapped inside the tip.

I-Tind with caution, largely due to its limited indications and the current lack of robust long-term clinical data.

This study aimed to contribute to the body of evidence by evaluating the safety, efficacy, and patient outcomes following the I-Tind procedure performed by a single surgeon in 120 consecutive patients. Notably, the significant improvements observed in our cohort—including reductions in IPSS scores, enhancements in quality of life (QoL) measures, and increases in Qmax values—underscore the potential utility of the I-Tind device as an effective treatment option for LUTS secondary to BPH. These findings are particularly relevant given the growing demand for MISTs that strive to balance therapeutic efficacy with the preservation of sexual function. Furthermore, this study confirms the procedural simplicity of I-Tind implantation, as evidenced by the successful completion of all procedures, the use of light sedation as the preferred anesthetic approach, and the absence of intraoperative complications.

Moreover, the low incidence of adverse events and the preservation of ejaculatory function observed in our study further support the favorable safety profile of the I-Tind device, aligning with the expected outcomes of minimally invasive treatment strategies.

To the best of our knowledge, this study provides data one of the largest series of patients treated with I-Tind. However, our study is not devoid of limitations.

First, despite the comprehensiveness of our data source, the retrospective design of our analysis introduces potential biases, including selection bias and the inability to control for all confounding variables, which could influence the observed outcomes. Second, the lack of a comparator group further limits the strength of our conclusions, preventing a direct comparison of the I-Tind device's efficacy and safety with those of other established treatments for LUTS/BPH. Additionally, although the procedures were performed by two experienced surgeons, this limited operator pool may not fully represent the broader surgical community's experiences and outcomes. Another important limitation is the role of adequate training, as variability in surgical expertise and the learning curve associated with the procedure could significantly impact clinical outcomes.[23–25] Recognizing these limitations, our study underscores the pressing need for well-designed, prospective, randomized controlled trials (RCTs) to generate high-quality evidence regarding the efficacy and safety of the I-Tind device. Such studies should aim to include diverse patient populations, standardized outcome measures, and long-term follow-up to comprehensively evaluate the I-Tind device's role in the treatment landscape for LUTS/BPH. Additionally, future research should focus on validating clear patient selection criteria, which will be crucial for optimizing treatment outcomes and identifying patients who are most likely to benefit from the iTind device.

## Conclusions

Our cohort confirms that temporary implantation of I-Tind is feasible and safe in providing relief of BPH symptoms at 12 months follow up. Moreover, sexual and ejaculatory functions were 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 of the iTind implantation.

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