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MULTICENTER EXPERIENCE WITH A TEMPORARY IMPLANTABLE NITINOL DEVICE FOR THE MANAGEMENT OF LOWER URINARY TRACT SYMPTOMS: SHORT TERM RESULTS ON FUNCTIONAL SCORES

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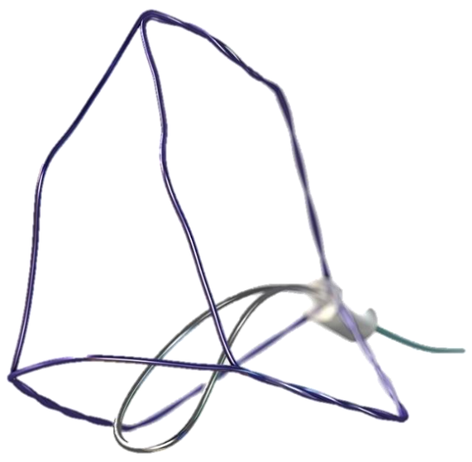
Hypothesis / aims of study

Lower urinary tract symptoms (LUTS) secondary to benign prostatic obstruction (BPO) are one of the most common conditions that negatively impact on the quality of life of men during their lifetime. Its prevalence starts at age 40-45 years, reaches 60% by age 60, and can be 80-100% by age 80
Among the options for reducing LUTS secondary to BPO physicians often offer watchful waiting and implementation of lifestyle changes, and then progresse to pharmaceutical therapy. Despite pharmaceutical therapy have been considered as a potential first line of therapy, many patients are unhappy with the level of symptomatic relief perceived , or are bothered by drug-related side effects. These are possible reasons for treatment low compliance (with only 29-30% of patients adhering to prescribed treatment during the first 12 months).
Considering that BPO is a mechanical problem, a mechanical solutions is desirable and this is the reasons why the gold standard surgical treatment for BPH has been considered for a century trans-urethral resection of the prostate (TURP). Unfortunately, this mechanical solution is associated with a 20% morbidity rate, including urinary incontinence (3%), bleeding requiring blood transfusion (2.9%), urethral stricture (7%), TUR syndrome (1.4%), erectile dysfunction (10%) and retrograde ejaculation (65%). All laser-based alternatives, while also effective in providing relief of BPH-related symptoms and obstruction, still present complications similar to those seen with TURP.
Among the different Minimally Invasive Surgical Therapies (MIST), the temporary implantable nitinol device (iTIND) has been developed to offer an effective alternative for treating LUTS due to BPO through the use of a temporarily implanted device, with a maximal preservation of ejaculatory function. The iTIND is left in place for only 5-7 days and after this period is removed. During its permanence it is able to reshape the prostatic urethra and bladder neck through ischemic pressure, improving micturition parameters and preserving sexual functions. Preservation of sexual function following iTIND offers a significant advantage to both traditional surgical treatments, such as TURP, or even pharmaceutical treatment. As a result we are assisting to an increasing number of men requesting MIST and among these iTIND of course. However, as a relatively new procedure , without a wide experience over the typical criteria of randomized studies, there is a need to better understand its durability and refine the surgical technique. Moreover, the pivotal iTIND studies found a very low surgical retreatment rate of 4% at 3 yr , with a total cumulative re-treatment rate from baseline up to 79 months of 11.1%.
In our study we report early real-world outcomes after iTIND implant.

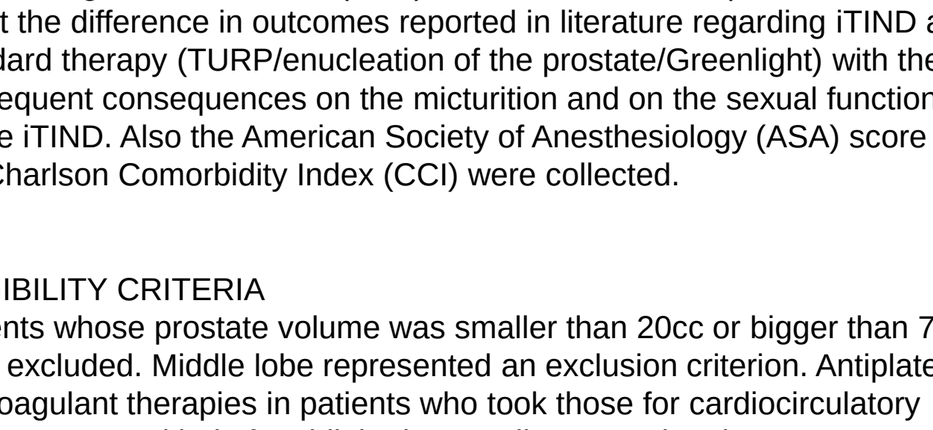


Study design, materials and methods

A comprehensive recording of medical history, digital rectal examination (DRE) and a prostate specific antigen (PSA) was conducted. In case of suspect prostate cancer, patients underwent a multiparametric magnetic resonance imaging and/or a prostatic biopsy in order to rule it out. To quantify LUTS and to assess continence and erectile function, patients were evaluated with the international prostatic symptom score (IPSS), and the International index of erectile function (IIEF5). All patients underwent also an ultrasonographic assessment of the prostate volume, and a uroflowmetry with post voiding residual volume (PVR) measurement. Each patient was informed about the difference in outcomes reported in literature regarding iTIND and standard therapy (TURP/enucleation of the prostate/Greenlight) with their subsequent consequences on the micturition and on the sexual function and chose iTIND. Also the American Society of Anesthesiology (ASA) score and the Charlson Comorbidity Index (CCI) were collected.

ELIGIBILITY CRITERIA
Patients whose prostate volume was smaller than 20cc or bigger than 70cc were excluded. Middle lobe represented an exclusion criterion. Antiplatelet or anticoagulant therapies in patients who took those for cardiocirculatory reasons, as any kind of antidiabetic or antihypertensive drug, were not interrupted and considered no exclusion criterion. Signed informed consent, age>18 years and a full data set were mandatory for inclusion in this study.

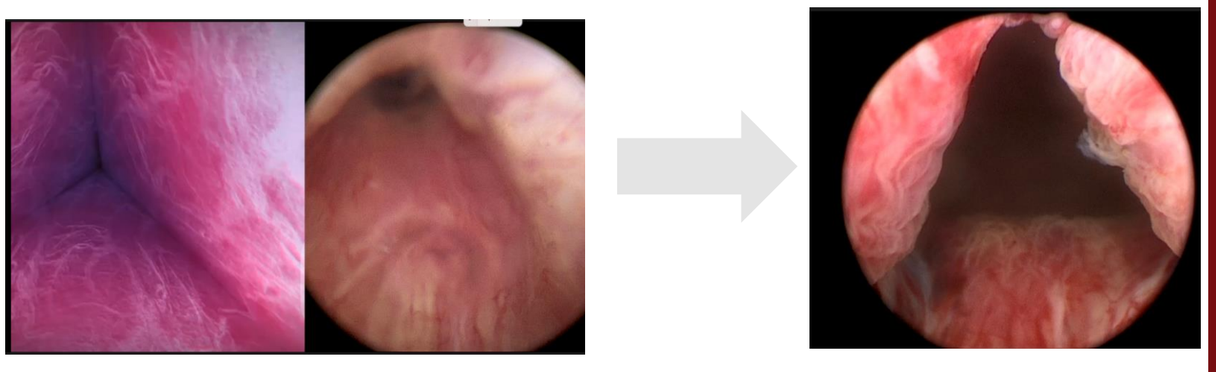
Surgical Technique
A preoperative negative urine culture needed to be achieved before treatment. After positioning the patient on a lithotomic position a 22Ch rigid or flexible cystoscopy is performed and the device released and 7 days later the device is removed, as previously described. Alpha blockers were prescribed or continued for the first month after the procedure. We assessed all data regarding the surgical procedure, including operative time, length of stay (hours), bladder catheter in site (days). The post-operative complications were recorded and classified according to the Clavien-Dindo classification.



Results and interpretation

A total of 48 subjects were enrolled and treated; median follow-up was 9 months. Mean age and prostate volume were 49y and 30ml respectively . IPSS and QoL changed from a mean of 20 and 4 points at baseline to 3 and 1.5 points respectively at the last follow-up. We recorded an improvement in Qmax and PVR from 9 ml/sec and 75 ml at baseline to 13 ml/sec and 0 ml at the last follow-up. Total median operative time was 10 min, the median time of i-TIND application was 7 days and median device remove time was 5min. There was no impact on sexual functions (no changes in IIEF5 scores and antegrade ejaculation rate).
We did not have intra operative complications, wherever not serious postoperative complications occurred in 6 patients (2 urinary retention, 2 mild hematuria, 2 cases with urinary infection) . Finally, 4 patients underwent reoperation during follow-up. In all patients the procedure was carried out in a day hospital setting. Five patients required pain management with opioids in the first postoperative week.

	PRE	POST
IPSS	20	3
QOL	4	1,5
Qmax (ml/sec)	9	13
PVR (ml)	75	0
IIEF5	25	25
Ant Ej Rate (%)	100	100



Conclusions

Benign prostatic hyperplasia (BPH) is a common problem among men and can have a significant impact on their quality of life. The side effects associated with drugs, and potential risks inherent in invasive surgery are of a great concern to many patients and may deter them from adhering to, or pursuing treatment for BPH. The results of this multi-center study confirms that the treatment with the iTIND is effective in terms of improving urinary symptoms and the patient's quality of life, in line with literature data and pivotal studies. The amelioration in terms of urinary and sexual symptom scores supported us to offer i-TIND as a valid option in the management of men with LUTS/BPH. Longer follow-up are required in order to better define the durability of this minimally invasive procedure.

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