iTIND - A New Alternative for Benign Prostatic Hyperplasia: Surgical Technique and Literature Review

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ABSTRACT

Introduction and Objectives. Benign prostatic hyperplasia (BPH) is one of the main causes of low urinary tract symptoms (LUTS) and the surgical standard of treatment for of symptomatic BPH up to 80 mL is the trans-urethral resection (TUR-P). One of the non-ablative techniques is the second-generation Temporary Implantable Nitinol Device (iTIND), a safe technology with promising results that does not seem to affect the patient's sexual or ejaculatory functions and treats effectively the BPH-related LUTS in the short and medium terms, further studies being required to confirm the results. The aim of this work is to describe its characteristics, the surgical technique and to provide a systematic review of the available literature.

Materials and Methods. The PubMed, SCOPUS and Google Scholar databases were utilized for a comprehensive literature research of original English-language articles on the subject, focusing on the functional results and perioperative morbidity.

Results. The few prospective available studies from the published literature reveal promising short-term results at 6 and 12 months, regarding symptom control, maximum urinary flow, sexual and ejaculatory function and complication rates.

Conclusions. The iTIND procedure seems to be a safe, minimally invasive alternative to the usual techniques proposed for the surgical treatment of the clinical BPH but it is still under evaluation. Further randomized controlled studies are required to assess the selection criteria and the utility of this procedure over a longer period of time also compared to the available techniques.

Key-words: alternative therapies, benign prostatic hyperplasia, BPH, iTIND, LUTS, minimally invasive

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INTRODUCTION AND OBJECTIVES

Pathological evidence of BPH is found in approximately 50% of men > 50 years of age [1] and clinical BPH is one of the most common diseases in ageing men with a prevalence that increases with age (8-60% at the age of 90 years). Moreover, lower urinary tract symptoms' (LUTS) incidence in men is directly correlated with the presence of clinical BPH.[2]

The increase of life expectancy in most countries associated with the natural evolution of BPH leads to an increase in the number of patients that need to have this condition treated, medically and/or surgically. Oral medication is often the first choice of treatment for the patient with BPH-related LUTS, but it can be insufficient and associated with numerous side-effects in particular regarding the sexual and ejaculatory functions. The alternative treatment in the case of intolerance or ineffective medical treatment is the surgical approach.[3]

Over the years, multiple surgical techniques have been described for the treatment of symptomatic BPH, either by trans-urethral or abdominal approaches, and in the last decades, new technologies (Rezum®, Urolift®, HoLEP) have been developed with the goal of offering an improvement in terms of morbidity and recovery compared to the classical surgical approaches, particularly to the transurethral resection of the prostate (TUR-P) – a technique that has proven its efficiency but also its limits in regard to complications such as perioperative bleeding and retrograde ejaculation.[4,5]

One of the latest surgical alternatives in the market is the second-generation Temporary Implantable Nitinol Device (iTIND).

MATERIALS AND METHODS

Based on the available experience, the contraindications of the device are prostates larger than 75 mL or with a median lobe, active urinary tract infection, post-void residual volume (PVR) > 250 mL, impaired renal function, neurogenic bladder and/or sphincter abnormalities. The device was not tested in patients with previous prostate cancer, urethral stricture, concomitant bladder stones, or previous prostate surgery.[6]
The iTIND consists of three struts of nitinol wire (Figure 1.) that release force on the prostatic urethra for a limited period of time, determining local ischemia and necrosis and creating three incisions at this level. (Figure 4.)



Figure 1. iTIND containing three struts of nitinol wire, one anchoring leaflet and the tail that covers the wire used for removing the device – courtesy of Olympus

The implantation technique is performed usually in an ambulatory setting. A cystoscope is used (Figure 2.) that, with the help of a plastic sheath, releases the device into the full bladder.



Figure 2. Insertion of the device through the cystoscope sheath

After that, the scope is reinserted and the anchoring leaflet is placed between the bladder neck and the verumontanum at the 6 o'clock position, with the three struts at the 5, 7 and 12 o'clock position (Figure 3.) and a wire is attached at the end of the device that is cut near the urinary meatus. At the end of the procedure the bladder is voided. No urinary drainage by catheter is required.



Figure 3. The placement of the device with the anchoring leaflet at the 6 o'clock position, between the bladder neck and the verumontanum

The procedure seems to be feasible in a urology office, without the need for general or locoregional anesthesia. [7]
The removal is done 5 to 7 days later, under topical anesthesia, by using a urinary catheter inserted along the device's wire into the urethra and concomitantly pulling the wire, followed by removing the catheter with the device into its lumen. A similar technique is described by using a rigid cystoscope instead of a catheter.



Figure 4. The effect of the iTind over the prostatic urethra - courtesy of Olympus

The PubMed, SCOPUS and Google Scholar databases were utilized for a comprehensive literature research of original English-language articles on the subject, focusing on the functional results and perioperative morbidity.

Only few prospective studies including one randomized controlled trial were available at the time of the review and this paper tries to sum up their findings.

Table 1. List of included studies

Chughtai et all [8]	Multicenter, randomized controlled trial of 175 patients (118 iTind vs 57 sham) Follow-up at 12 months
MT-06 [9]	Prospective study of 81 patients Follow-up at 6 months (70 patients)
MT-02 [10]	Follow-up of the MT-06 study at 12 months (67 patients) and at 24 months (51 patients)
Amparore et all [11]	Follow-up of the MT-02 study at 36 months (50 patients)
Porpiglia et all [12]	Prospective study of 81 patients Follow-up at 12 months (67 patients)
Elteman et all [13]	Prospective, randomized, single-blinded study of 185 patients (2:1 iTind vs sham) Follow-up at 12 months

RESULTS

The only multicenter, randomized, controlled trial available is a study of 175 men conducted by B. Chughtai et all. The iTIND was compared to a sham procedure and an assessment was made at the 1.5, 3 and 12 months postoperatively. The iTIND procedure has shown a reduction of at least 3 points in IPSS in 78.6% cases at 3 months. At 12 months the results of the iTIND arm showed a 9.25 decrease in IPSS and a 3.25 mL/sec increase in peak urinary flow rate without de novo ejaculatory or erectile dysfunction. [8]

The interim results of the prospective MT-06 study showed promising results at 6 months [9] that were confirmed by the MT-02 study which followed 67 men at 1 year and 51 men at 2 years. The IPSS improved from 20.51 (±4.58) to 8.51 (±5.51) after 24 months and the peak urinary flow rate increased from 7.62 mL/sec (±2.25) to 16.00 mL/sec (±7.43). [10] A follow-up at 3 years of 50 patients showed a stabilization of the Qmax, IPSS and post-void residual (PVR) in the third year. [11] In this three-year follow-up, only one patient (1.4%) presented a Dindo Clavien grade III complication – an episode of gross hematuria after the iTIND removal. In the failure group (14,8%) 7 out of 12 had median lobes. Only 5 patients (9.8%) required another type of surgery for BPH in the first 2 years and four of them had median lobes. The sexual function was preserved in all subjects at 6 months post-operatively according to the ISI, SHIM and MSHQ-EjD questionnaires. [9,10,11]

Another prospective, multicenter study conducted

by Porpiglia et all that included 81 men, with a 1-year follow-up after surgery, showed an increase in the Qmax from 7.61 mL/sec (±2.25) before the surgery to 14.91 mL/sec (±8.06) and a decrease by nearly 60% in the IPSS from 21.7 (±5.56) to 8.78 (±6.41). In this study all complications were graded as I or II according Dindo Clavien System. [12]

The prospective, randomized single-blinded study conducted by Elteman et all that studied 185 men over the course of 12 months and their sexual and ejaculatory functions, found no changes at a 12 months follow-up. [13]

DISCUSSIONS

The clinical evidence regarding the use of the second-generation nitinol device (iTIND) is still limited and new prospective, randomized controlled studies need to be conducted to verify the efficiency of this procedure, especially comparing it to other non-ablative techniques and the TUR-P that remains the up-to-date standard of care for many of the patients having BPH-related LUTS.
The efficiency of the procedure seems to be correlated with a good selection of the patients (prostate under 60-80 mL, absence of an obstructive median lobe, good detrusor function, PVR < 250 mL, desire of preservation of the sexual and ejaculatory functions).

The available studies are reporting only the short-term and mid-term results. The results of this procedure need to be evaluated on the long-term.

CONCLUSIONS

The iTIND procedure seems to be a safe, minimally invasive alternative to the usual techniques proposed for the surgical treatment of BPH, but it is still being evaluated. A major advantage of the iTIND seems to be the minimal morbidity of the surgical technique, with good results regarding the ejaculatory and sexual functions, associated with what seems to be an improvement of the BPH-related LUTS. Further randomized controlled trials are required to assess the selection criteria and the utility of this procedure over a longer period of time compared to the available techniques.

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