Current Urology Reports (2019) 20: 47
https://doi.org/10.1007/s11934-019-0912-6

BENIGN PROSTATIC HYPERPLASIA (K MCVARY, SECTION EDITOR)

First- and Second-Generation Temporary Implantable Nitinol Devices As Minimally Invasive Treatments for BPH-Related LUTS: Systematic Review of the Literature

Daniele Amparore[1] · Sabrina De Cillis[1] · Gabriele Volpi[1] · Enrico Checcucci[1] · Matteo Manfredi[1] · Ivano Morra[1] · Michele Di Dio[1] · Cristian Fiori[1] · Francesco Porpiglia[1] · on behalf of ESUT Group

Published online: 5 July 2019

Abstract

Introduction In the last decade, there has been a growing interest in minimally invasive treatment for benign prostatic hyperplasia (BPH) associated with lower urinary tract symptoms (LUTS). In this field, one of the options currently available is the temporary implantable nitinol device (iTIND) (Medi-Tate®; Medi-Tate Ltd., Or Akiva, Israel).

Purpose of the Work To review the recent data available in the literature regarding the role of the first-generation (TIND) and second-generation (iTIND) devices for the management of BPH with LUTS, especially focusing on follow-up of functional outcomes.

Evidence Acquisition PubMed, Embase, and the Cochrane Central Register of Controlled Trials were screened for clinical trials on this topic.

Evidence Synthesis Literature evidences regarding implantation of TIND and iTIND for PBH with LUTS are limited. There are only three studies available, one with a medium-term follow-up. The results of these studies suggested that both the TIND and iTIND implantations are safe, effective, and well-tolerated procedures, allowing spare ejaculation in sexually active patients.

Conclusions Current evidences emphasize that the temporary implantable nitinol devices are promising alternatives to the standard minimally invasive surgical options for BPH-related LUTS. Further studies are needed to confirm the effectiveness over a long-term follow-up.

Keywords BPH · LUTS · iTIND · Minimally invasive techniques · Nitinol · Urethral implantable device

Introduction

Benign prostatic hyperplasia (BPH) associated with lower urinary tract symptoms (LUTS) is a common clinical syndrome that affects aging men most often [1]. Since the quality of life in these patients can be significantly impaired by the daily symptoms, several treatments have been proposed, such as lifestyle changes, pharmacological therapy, and surgical approaches. Among these, the change in lifestyle is by far the most conservative option, avoiding side effects for the patients, but is also generally limited to the management of low or mild LUTS with a good quality of life. Non-surgical therapy is usually the first treatment choice for patient with LUTS, leading both to symptom relief (α-blockers) and disease progression interruption (5α-reductase inhibitors). However, the incidence of side effects (e.g., sexual dysfunction, postural hypotension) along with insufficient symptom control often leads to early pharmacological discontinuation and switching towards more operative approaches [2, 3••, 4]. Most of these patients can benefit from an endoscopic surgical approach, such as the transurethral resection of the prostate (TURP), still recognized as the gold standard surgical treatment for BPH. TURP has demonstrated long-term effects on

This article is part of the Topical Collection on *Benign Prostatic Hyperplasia*

✉ Francesco Porpiglia
porpiglia@libero.it

[1] Division of Urology, Department Of Oncology, School of Medicine, University of Turin, San Luigi Hospital, Regione Gonzole 10, Orbassano, 10043 Turin, Italy

decreasing IPSS and increasing maximum urinary flow rate (Qmax) up to 70% and 149% respectively, but risks perioperative and long-term complications (e.g., bleeding, urinary retention, and retrograde ejaculation) [5–9]. Other surgical alternatives for the treatment of BPH have been proposed, such as enucleation based on laser energies or photo-vaporization of the prostate. However, these techniques reported similar rates of complications as TURP [10–12]. In this setting, several minimally invasive techniques have been introduced to offer better symptom relief than pharmacological therapy, avoiding or minimizing at the same time surgery-related risks. Among these techniques, some examples are transurethral needle ablation (TUNA), transurethral microwave thermotherapy (TUMT), and steam injection (REZUM), although their role in the management of BPH remains controversial [6, 11, 13]. Despite the large amount of approaches for the management of BPH, there still exists a vast pool of patients that desire a treatment with fewer side effects while providing the same effectiveness as standard procedures [14]. Recently, the implantation of prostatic urethral lift (PUL) has been proposed. With the help of either general or local anesthesia, a small permanent suture-based implant, delivered under cystoscopic guidance, allows the prostatic urethra to open due to the retraction of the prostatic lateral lobes. This technique has demonstrated quick and durable improvement of LUTS and minimal impact on sexual function [15]. In the field of minimally invasive surgical options for BPH, the temporary implantable nitinol device offers an alternative technique. Despite the fact that both the first- (TIND) and second-generation devices (iTIND) (Medi-Tate®; Medi- Tate Ltd., Or Akiva, Israel) are left in place at the level of the prostatic urethra only for a limited time — differently from all the other devices available — they have been developed to be used alongside a real surgical procedure, with permanent incisions made through the mucosa.

The aim of this review is to present the most recent literature evidences of short- and long-term results after TIND and iTIND implantation.

Evidence Acquisition

Different search engines (PubMed, Embase, Cochrane Central Register of Controlled Trials) were used to perform a systematic review of the literature available up to March 2019 on the implant of TIND for BPH with LUTS. The research was performed using the keywords “BPH” and “TIND,” and only original studies were included. Identification and selection of the studies were conducted according to Preferred Reporting Items for Systematic Reviews and Meta-Analysis criteria (http://www.prisma-statement.org) (Fig.1). The PI(C)O model was as follows: the population consisted of patients with LUTS related to BPH (P) who underwent TIND (I). Outcomes of interest were perioperative outcomes and durability at follow-up (O). Only English-language articles have been selected. Two of the authors (D.A and S.D.) performed the article selection. Title and abstracts were first reviewed to ascertain whether they would potentially follow the inclusion criteria. For those passing the first screening, a full-text analysis was performed to confirm inclusion. Studies without primary data (letters to the editor or authors, case reports, and commentaries) as well as conference abstracts were not considered. References of collected studies were manually reviewed to find additional studies of interest.

Evidence Synthesis

1416 articles were identified from the search engines. Six additional items were identified through other sources. Of these, 1124 remained after duplicate removal, and were critically reviewed for evidence synthesis according to the PRISMA protocols (Fig. 1). Finally, three studies reporting on the outcomes of temporary implantable nitinol devices in the clinical setting were considered. Given the mostly non-comparative design of the studies identified, the evidence synthesis was performed in a descriptive and narrative manner.

According to the available evidence in the literature, there are two different temporary implantable nitinol devices that have similar structure and the same indications. The first one (TIND) is currently off the market because of the introduction of a second-generation device, the iTIND. Three prospective single-arm studies concerning these devices have been published, two of them about TIND, and one about iTIND.

In order to give the reader a proper understanding of the clinical implications and results of these observational prospective studies, it is necessary to precisely describe the first- and second-generation devices, as well as explain implantation and retrieval techniques.

TIND

The TIND is a CE Mark-approved first-generation device, composed of four elongated struts and an anchoring leaflet all made of nitinol. The tip of the device is covered by a soft plastic material made to avoid any bladder injury. The tail of the device is composed of a nylon wire for retrieval (Fig. 2). The total length and outer diameter of the device are 50 and 33 mm, respectively, to cover the entire length of the prostatic urethra, from the bladder neck to the external urinary sphincter. The struts are designed to exert a circumferential force that produces local ischemic necrosis of the urethral mucosa, creating prostatic incisions at the 12, 5, and 7 o’clock positions. The struts’ elongation effect is progressive: after 5 days, the device reaches its complete expansion, allowing for a decrease in bladder neck tension.

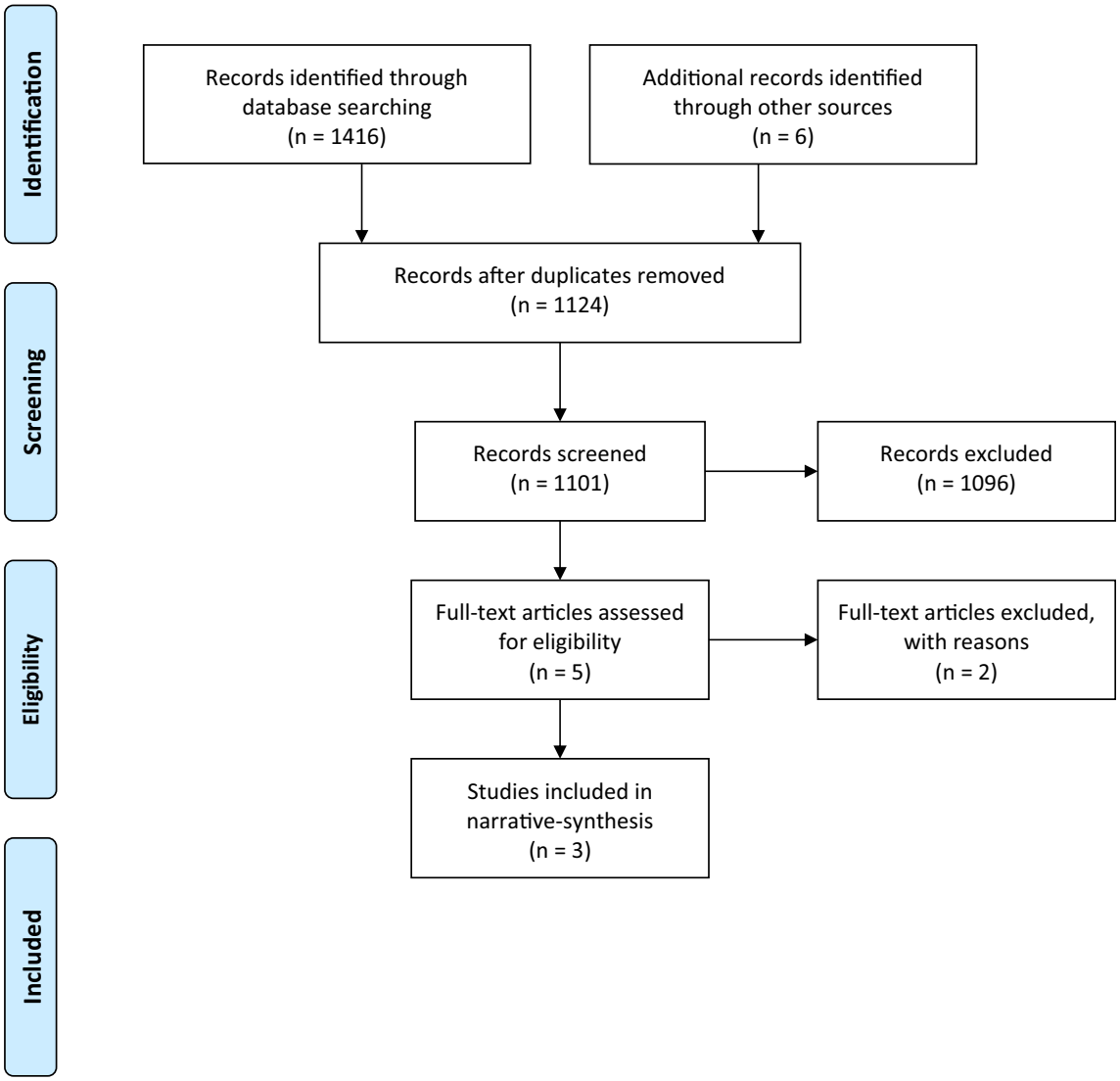

Fig. 1 Records identified through the following search string: PubMed: TIND[tw] OR iTIND[tw] OR i-TIND[tw] OR nitinol-device*[tw] OR ("nitinol"[Supplementary Concept] OR nitinol*[tw] AND prostat*[tw]) OR (implant*[tw] AND ("Prostatic Hyperplasia"[Mesh] OR BPH[tw] OR (prostat*[tw] AND (hyperpl*[tw] OR hypertr*[tw])))); EMBASE: TIND:ti,ab,kw,de OR iTIND:ti,ab,kw,de OR I TIND:ti,ab,kw,de OR nitinol-device*:ti,ab,kw,de OR ('nitinol'/exp. OR nitinol*:ti,ab,kw,de AND prostat*:ti,ab,kw,de) OR (implant*:ti,ab,kw,de AND ('prostate hypertrophy'/exp OR BPH:ti,ab,kw,de OR (prostat*:ti,ab,kw,de AND (hyperpl*:ti,ab,kw,de OR hypertr*:ti,ab,kw,de)))); Cochrane Central Register of Controlled Trials: #1 (TIND OR iTIND OR i-TIND OR nitinol-device*):ti,ab,kw; #2 (nitinol* AND prostat*):ti,ab,kw; #3 (implant*):ti,ab,kw; #4 MeSH descriptor: [Prostatic Hyperplasia] explode all trees; #5 (BPH):ti,ab,kw; #6 (prostat*):ti,ab,kw AND (hyperpl* OR hypertr*):ti,ab,kw; #7: #4 OR #5 OR #6; #8: #3 AND #7; #9:#1 OR #2 OR #8

iTIND

The iTIND is a CE Mark-approved second-generation device. It is currently the only such device available on the market. iTIND is the same size as the first-generation device, but it only has three struts, with double intertwined nitinol wires configured in a tulip shape. The struts are located at the 12, 5, and 7 o'clock positions. The iTIND also differs from the TIND in its cranial portion: the three intertwined wires are linked together, supporting the action of the struts on the urethral mucosa when expanded, and avoiding potential injuries of the bladder mucosa, the top of the device not being pointy (compared to the TIND, which needs a soft plastic cover). As in the first-generation device, the iTIND also has an anchoring leaflet as well as a distal nylon wire for removal (Fig.3).

Device Implantation

Whether first- or second-generation, device implantation follows the same surgical steps. Positioning is performed by transurethral approach using a rigid cystoscope. The device is preloaded into a 14 Fr delivery system, pushing it into the urethra through the cystoscope sheath. When the device is delivered into the filled bladder, the surgeon perceives the

Fig. 2 First-generation TIND device in expanded configuration

Fig. 3 Second-generation iTIND device in expanded configuration

friction being reduced against the internal surface of the sheath. The plastic sheath around the nylon wire is then removed, and the knot at the end of the wire is cut. The cystoscope is then reinserted, and the device placed at the bladder neck, under visualization. The device leaflet should be placed at a 6 o'clock position, under the bladder neck, but cranially to the veru montanum. To complete the implantation, the bladder should be checked by cystoscopy and voided at the end of the procedure. Figure 4 shows the correct placement of the device at the level of the bladder neck and its action on the prostatic urethral walls.

Device Retrieval

Five days after implantation, the device should be removed. Two different methods can be used: (1) by a rigid cystoscope under anesthesia. With the aid of a semi-rigid double wire (SNARE device), the nylon wire anchored to the device that comes out of the urethral meatus is inserted into the cystoscope sheath. The cystoscope is then inserted into the urethra and the device is closed into the sheath under direct visualization. The second (2) removal technique requires only topical anesthesia and can be performed in an ambulatory setting. The nylon wire is pulled into a 20–22-Fr open-ended catheter using the SNARE. The catheter is then pushed into the urethra, and the wire simultaneously pulled. When the catheter reaches the lower part of the device, the surgeon pulls the wire allowing its retrieval into the catheter lumen, as shown in Fig. 5. The catheter is then removed.

Current Clinical Evidences

Focusing on the clinical data inferable from the literature results, both of the two generation devices are nowadays available. In fact, of the three studies found during our systematic review of the literature, two of them take in consideration the first-generation TIND device, while one (recently published) examines the second-generation iTIND device outcomes.

The first clinical experience in the implantation of the TIND device is a prospective single-arm study (MT01 study), published in 2015 by Porpiglia et al. with the aim to assess the feasibility and safety of the procedure [16••]. In this prospective series, all the 32 procedures included were successfully performed under light sedation. The inclusion criteria were age > 50 years, IPSS ≥ 10, Qmax ≤ 12 mL/s, and a prostate volume assessed by TRUS as < 60 mL. Patients were excluded from the study in cases of previous prostate surgery, prostate cancer, urethral stricture, bladder stones, obstructing median lobe, history of significant medical comorbidity, hemostatic disorder, or suspected neurological conditions potentially affecting the voiding function.

The mean operative time was 5.8 min, no intraoperative complications were recorded, and all the patients were discharged within 24 h. All but one of the devices was removed 5 days after implantation, in an outpatient setting. Four postoperative complications were recorded: one prostatic abscess, one urinary retention, one UTI, and one transient incontinence. Concerning the functional outcomes, a reduction of IPSS from the baseline value of 19 to the one-year value of 9 was recorded, while showing an increase in Qmax from 7.6 to 11.9 mL/s (p values > 0.05) at the same time points. Notably, no retrograde ejaculation was recorded among the preoperatively sexually active patients. Median IPSS QoL improved from three preoperatively, to 12 months after surgery, and no patients required further medical or surgical treatment. These data resulted to be comparable to those of other minimally invasive procedures [17••,18]. This evidence was confirmed by the answers to EPIC question 32 ("Overall, how satisfied are you with treatment you received for your prostate disease intervention? '1: extremely dissatisfied; 2: dissatisfied; 3: uncertain; 4; satisfied; 5: extremely satisfied'") [19]. In fact, 1 year after surgery, 82% (28) of the patients were "satisfied" or "extremely satisfied" with the procedure.

In order to strengthen the results of this first study, the same group published a 36-month follow-up data of the same cohort of patients [20]. In this second study, the researchers

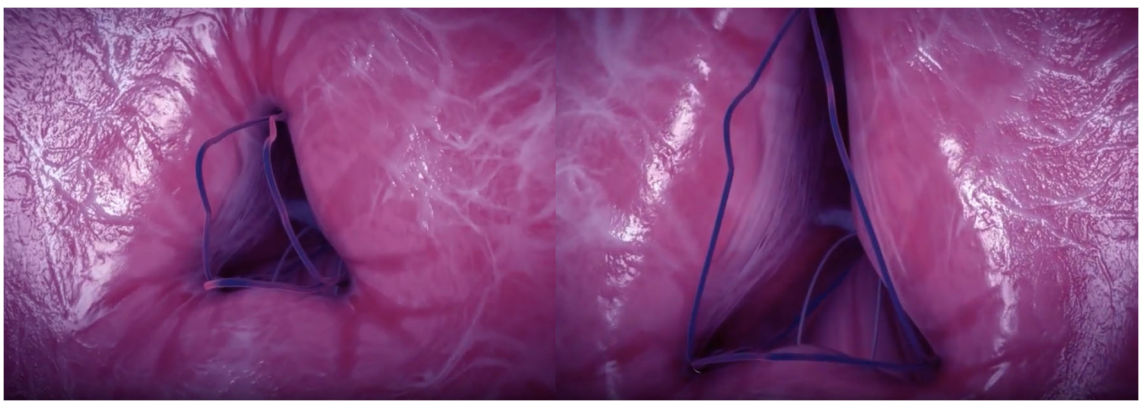

Fig. 4 Correct placement of the iTIND device at the level of the bladder neck, with the tongue above the veru montanum and its struts at 12, 5, and 7 o'clock position

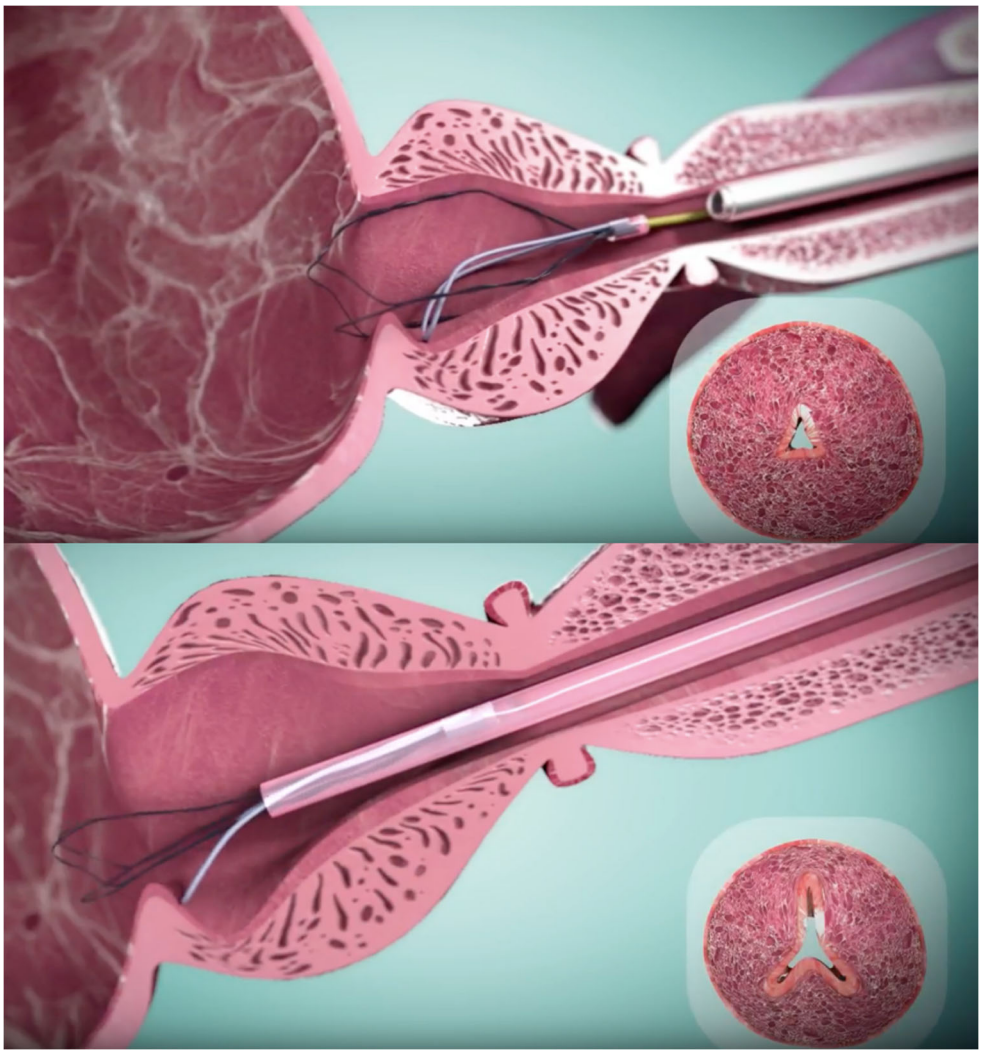

Fig. 5 Device retrieval trough a 20/22 ch open-ended silicon catheter. The device, pulled from the nylon wire, is withdrawn into the catheter lumen and removed

confirmed that the change in Qmax, IPSS, and QoL score was significant at every time point. Namely, after a 36-month follow-up, a rise in 41% of Qmax (mean 10.1 mL/s) was recorded, median IPSS was 12 (6–24), and median IPSS QoL was 2 (1–4). Overall, no patients required additional surgical treatment after the implantation of TIND, while 9% (3 patients) needed medical therapy for LUTS in the period between 12 and 24 months postoperatively. Regarding the EPIC score, no statistical difference was found between the time points, suggesting that patient satisfaction after treatment persists after 3 years. Moreover, aside from the early stage complications described in the first study, no further complications were recorded during the 36-month period. The authors concluded that the findings of this 36-month follow-up evaluation corroborated the previous data, confirming the safety, efficacy, and tolerability of TIND implantation.

At the end of 2018, the first clinical results of the second-generation device implantation were published (MT02 study). Together with other European and non-European urological sites, Porpiglia et al. performed a single-arm, multicenter study, with the aim to assess the feasibility, safety, and efficacy of iTIND implantation, with a 12-month follow-up [21••]. This study is more relevant than the others, because the second-generation device is currently the only one available on the market.

Between December 2014 and December 2016, 81 patients were enrolled in nine different centers. For inclusion in the study, a symptomatic BPH with an IPSS ≥ 10, Qmax ≤ 12 mL/s, and prostate volume < 75 mL, was needed. Contrarily, patients with hemostatic disorders, neurogenic bladder or sphincter abnormalities, impaired renal function, history of urethral strictures, post-void residual urine volume (PVR) > 250 mL, urinary bladder stones, bladder cancer, obstructive median lobe, active UTI, and previous prostate surgery were excluded from the study. In contrast to the first-generation device study, age (> 50 years old) was not considered a necessary criterion for treatment with the device implantation, and younger patients with Marion's disease were also treated. Moreover, all patients discontinued pharmacological therapy for BPH before undergoing the surgical procedure (alpha-blockers or 5-ARIs, or both).

Technically, the procedure for implantation of iTIND was the same as described for the first-generation device.

All the implantations were successful with no intraoperative complications. The mean postoperative VAS was 4 (0–10) and all the patients were discharged the same day of the procedure. The retrieval of the device was performed at a mean of 5.9 days after the implantation in an ambulatory setting, with a mean VAS pain score recorded as 2 (0–10).

In terms of postoperative complications, the following were recorded: hematuria (12.3%), micturition urgency (11.1%), pain (9.9%), and dysuria (7.4%). All of them were self-limiting and occurred mostly in the short-term period (54.7% ≤7 days; 30.2% 8–20 days; 15.1% 20–30 days). Eight patients (9.9%) experienced urinary retention, five of them with the device in situ. These patients were treated by emptying the bladder through the temporary placement of a 10–12 Fr Tiemann catheter. In the cases when retention occurred after device removal, a Foley catheter was placed for few days and then removed.

Concerning treatment failures (cases of pharmacological or surgical treatment needed), two patients required TURP. One patient experienced a significant increase in voiding symptoms, and required combined therapy with α–blockers and a 5α-reductase inhibitor.

Focusing on the functional results, the authors emphasized an improvement in IPSS and Qmax from baseline starting from 1 month and then maintained at every time point. The mean (SD) Qmax at the 1 month follow-up visit was 11.2 (5.7) mL/s, with an increase of 3.9 (5.2) mL/s from baseline, and continued to improve thereafter, reaching maximum values at the 12-month follow-up, with a mean (SD) of 14.7 (8.1) mL/s. IPSS urinary symptom scores dropped from a mean (SD) of 22.5 (5.6) at baseline to 11.7 (8.0) within 1 month of the procedure, and further improved until reaching 8.8 (6.4) at the 12-month follow-up, a total improvement of 12.9 (6.9).

QoL scores followed the same trend as the IPSS, with patients reporting significant improvements at follow-up. No sexual or ejaculatory disfunction was reported by the patients who were sexually active before the procedure.

In summary, the authors concluded that the implantation of iTIND was feasible and safe, permitting a prompt and stable improvement of functional results and QoL up to 1 year after surgery, without injuring sexual and ejaculatory function.

Figure 6 shows a comparison in terms of functional outcomes (Qmax at flowmetry and IPSS Urinary Symptoms) between first- (TIND) and second-generation (i-TIND) devices. Looking at the functional results at every time point, the values demonstrated functional improvements for both the devices until 12 months after surgery.

Ongoing Studies and Future Perspectives

In addition to the MT02 study (of which the follow-up is still ongoing after 12 months), there are three other clinical studies that are being carried out on the iTIND device. The first is a prospective, multi-center, randomized controlled trial where iTIND is compared 2:1 to a sham procedure. This trial was carried out in the USA and Canada (MT03; IDE study for US FDA approval). One hundred and seventy-two patients were recruited and followed for 12 months. A prospective, multi-center, single-arm study is also being carried out in the UK using the iTIND to treat patients with acute urinary retention (MT04). This study includes 50 patients. Finally, a prospective, multi-center, single-arm study including 200 patients is being carried out by sites in Italy, Spain, Germany, France, and Australia (MT06). Endpoints of all additional studies include IPSS as a primary endpoint and QoL, Qmax, PVR, SHIM, and IIEF questionnaires as secondary endpoints.

The results of these ongoing studies are being awaited, in order to confirm the available data already published in the literature, and to understand if device implantation can be purposed in other patient settings, such as those with acute urinary retention.

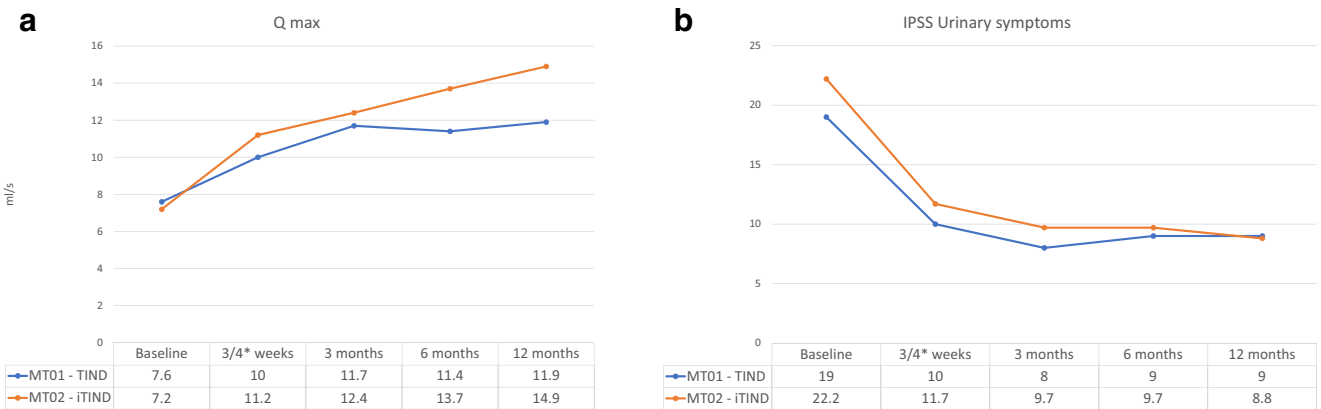

Fig. 6 In Graph A, the Qmax at flowmetry for TIND (blue line) and iTIND (orange line) is reported at every time point from baseline to 12 months follow-up. Graph B shows the same comparisons considering the IPSS Urinary Symptoms score

Conclusions

As shown in this systematic review, the available data about temporary implantable nitinol devices are still limited to a few studies. As concerns the currently available second-generation device (iTIND), the only published multi-centric study shows good results in terms of safety, tolerability, and efficacy, until 1 year follow-up. On the basis of this evidence, the temporary implantable nitinol device might be able to be included in the current list of new minimally invasive options to treat the proportion of men with LUTS due to BPH who seek more significant symptomatic improvement than is offered by non-surgical therapy, but who are not willing to address the risks associated with surgery. Further studies and a longer follow-up are needed in order to confirm these promising evidences.

Compliance with Ethical Standards

Conflict of Interest Daniele Amparore, Sabrina De Cillis, Gabriele Volpi, Enrico Checcucci, Matteo Manfredi, Ivano Morra, Michele Di Dio, Cristian Fiori, and Francesco Porpiglia each declares no potential conflicts of interest.

Human and Animal Rights and Informed Consent This article does not contain any studies with human or animal subjects performed by any of the authors.

References

Papers of particular interest, published recently, have been highlighted as:
•• Of major importance

1. Vuichoud C, Loughlin KR. Benign prostatic hyperplasia: epidemiology, economics and evaluation. Can J Urol. 2015;22(Suppl 1):1–6.
2. Verhamme KM, Dieleman JP, Bleumink GS, Bosch JL, Stricker BH, Sturkenboom MC. Treatment strategies, patterns of drug use and treatment discontinuation in men with LUTS suggestive of benign prostatic hyperplasia: the Triumph Project. Eur Urol. 2003;44:539–45.
3.•• Dahm P, Brasure M, MacDonald R, Olson CM, Nelson VA, Fink HA, et al. Comparative effectiveness of newer medications for lower urinary tract symptoms attributed to benign prostatic hyperplasia: a systematic review and meta-analysis. Eur Urol. 2017;71(4):570–81. **A complete resign of the available medical treatment of BPH.**
4. Presicce F, De Nunzio C, Gacci M, et al. The influence of the medical treatment of LUTS on benign prostatic hyperplasia surgery: do we operate too late. Minerva Urol Nefrol. 2017;69:242–52.
5. Marszalek M, Ponholzer A, Pusman M, Berger I, Madersbacher S. Transurethral resection of the prostate. Eur Urol Suppl. 2009;8:504–12.
6. Oelke M, Bachmann A, Descazeaud A, Emberton M, Gravas S, Michel MC, et al. EAU guidelines on the treatment and follow-up of non-neurogenic male lower urinary tract symptoms including benign prostatic obstruction. Eur Urol. 2013;64:118–40.
7. DE Nunzio C, Lombardo R, Nacchia A, Deroma M, Alkhatatbeh H, Brassetti A, et al. Young academic urologist benign prostatic obstruction nomogram predicts clinical outcome in patients treated with transurethral resection of prostate: an Italian cohort study. Minerva Urol Nefrol. 2017. https://doi.org/10.23736/S0393-2249.17.03008-9.
8. Geavlete P. Is classical transurethral resection of the prostate, the gold standard endoscopic treatment for benign prostate hyperplasia, in real danger of being replaced? Eur Urol. 2010;58:356–9.
9. Rieken M, Presicce F, Autorino R, DE Nunzio C. Clinical significance of intravesical prostatic protrusion in the management of benign prostatic enlargement: a systematic review and critical analysis of current evidence. Minerva Urol Nefrol. 2017;69(6):548–55.
10. Brassetti A, De Nunzio C, Delongchamps NB, Fiori C, Porpiglia F, Tubaro A. Green light vaporization of the prostate: is it an adult technique? Minerva Urol Nefrol. 2017;69:109–18.
11. Gravas S, Bachmann A, Reich O, Roehrborn CG, Gilling PJ, De La Rosette J. Critical review of lasers in benign prostatic hyperplasia (BPH). BJU Int. 2011;107:1030–43.
12. Naspro R, Gomez Sancha F, Manica M, Meneghini A, Ahyai S, Aho T, et al. From "gold standard" resection to reproducible "future standard" endoscopic enucleation of the prostate: what we know about anatomical enucleation. Minerva Urol Nefrol. 2017;69(5):446–58.
13. Helo S, Holland B, McVary KT. Convective radiofrequency water vapor thermal therapy with Rezūm system. Curr Urol Rep. 2017;18(10):78.
14. Gratzke C, Bachmann A, Descazeaud A, Drake MJ, Madersbacher S, Mamoulakis C, et al. EAU guidelines on the assessment of non-neurogenic male lower urinary tract symptoms including benign prostatic obstruction. Eur Urol. 2015;67(6):1099–109.
15. Gratzke C, Barber N, Speakman MJ, Berges R, Wetterauer U, Greene D, et al. Prostatic urethral lift vs transurethral resection of the prostate: 2-year results of the BPH6 prospective, multicentre, randomized study. BJU Int. 2017;119:767–75.
16.•• Porpiglia F, Fiori C, Bertolo R, Garrou D, Cattaneo G, Amparore D. Temporary implantable nitinol device (TIND): a novel, minimally invasive treatment for relief of lower urinary tract symptoms (LUTS) related to benign prostatic hyperplasia (BPH): feasibility, safety and functional results at 1 year of follow-up. BJU Int. 2015;116(2):278–87. **Literature showing clinical results of the temporary implantable nitinol device.**
17.•• Porpiglia F, Fiori C, Amparore D, Kadner G, Manit A, Valerio M, et al. Second-generation of temporary implantable nitinol device for the relief of lower urinary tract symptoms due to benign prostatic hyperplasia: results of a prospective, multicentre study at 1 year of follow-up. BJU Int. 2018;123:1061–9. https://doi.org/10.1111/bju.14608. **Literature showing clinical results of the temporary implantable nitinol device.**
18. Ahyai SA, Gilling P, Kaplan SA, Kuntz RM, Madersbacher S, Montorsi F, et al. Meta-analysis of functional outcomes and complications following transurethral procedures for lower urinary tract symptoms resulting from benign prostatic enlargement. Eur Urol. 2010;58(3):384–97.
19. Magistro G, Chapple CR, Elhilali M, Gilling P, McVary KT, Roehrborn CG, et al. Emerging minimally invasive treatment options for male lower urinary tract symptoms. Eur Urol. 2017;72(6):986–97.
20. Wei JT, Dunn RL, Litwin MS, Sandler HM, Sanda MG. Development and validation of the expanded prostate cancer index composite (EPIC) for comprehensive assessment of health-related

quality of life in men with prostate cancer. Urology. 2000;56:899–905.

21.•• Porpiglia F, Fiori C, Bertolo R, Giordano A, Checcucci E, Garrou D, et al. Three-year follow-up of temporary implantable nitinol device (TIND®) implantation for the treatment of benign prostatic obstruction. BJU Int. 2018;122:106–12. https://doi.org/10.1111/bju.14141. **Literature showing clinical results of the temporary implantable nitinol device.**