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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

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Objectives

To report the first clinical experience with a temporary implantable nitinol device (TIND; Medi-Tate®) for the treatment of lower urinary tract symptoms (LUTS) due to benign prostatic hyperplasia (BPH).

Patients and Methods

In all, 32 patients with LUTS were enrolled in this prospective study, which was approved by our Institutional Ethics Committee. Inclusion criteria were: age >50 years, International Prostate Symptom Score (IPSS) of ≥10, maximum urinary flow rate (Q_{max}) of ≤12 mL/s, and prostate volume of <60 mL. The TIND was implanted within the bladder neck and the prostatic urethra under light sedation, using a rigid cystoscope. The device was removed 5 days later in an outpatient setting. Demographics, perioperative results, complications (according to the Clavien system), functional results and quality of life (QoL) were evaluated. Follow-up assessments were made at 3 and 6 weeks, and 3, 6 and 12 months postoperatively. The Student's *t*-test, analysis of variance (ANOVA), Kruskall–Wallis test, and simple and multiple linear regression models were used in the statistical analyses.

Results

The mean patient age was 69.4 years, the mean (standard deviation, SD) prostate volume was 29.5 (7.4) mL and the Q_{max} was 7.6 (2.2) mL/s. The median (interquartile range, IQR) IPSS was 19 (14–23) and QoL score was 3 (3–4). All the implantations were successful, with no intraoperative complications recorded. The mean operative time (SD) was 5.8 (2.5) min and the median (IQR) postoperative stay was 1 (1–2) day. All but one of the devices (96%) was removed 5 days at after implantation in an outpatient setting. Four complications (12.5%) were recorded, including urinary retention (one, 3.1%), transient incontinence due to device displacement (one, 3.1%), prostatic abscess (one, 3.1%), and urinary tract infection (one, 3.1%). Multiple regression analysis failed to identify any independent prognostic factor for complications. There were statistically significant differences in the IPSS, QoL score and Q_{max} when comparing pre- and postoperative results at every time point. After 12 months, the median (IQR) IPSS and QoL score were 9 (7–13) and 1 (1–2), respectively, and the mean (SD) Q_{max} was 12 (4.7) mL/s. The mean variations with respect to baseline conditions at the same time points were −45% for the IPSS and +67% for Q_{max}. At 12 months after surgery (last follow-up visit), no patients required medical therapy or surgical procedures for BPH.

Conclusion

TIND implantation is a feasible and safe minimally invasive option for the treatment of BPH-related LUTS. The functional results are encouraging and the treatment significantly improved patient QoL. Further studies are required to assess durability of TIND results and to optimise the indications of such a procedure.

Keywords

BPH, LUTS, minimally-invasive techniques, nitinol, urethral implantable device, TIND

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Introduction

Moderate-to-severe LUTS resulting from BPH affect ≈30% of men aged >50 years, including 26 million men in Europe and 8 million in the USA [1]. Medical therapy (α-blockers and 5α-reductase inhibitors) is often the first therapeutic option for these patients, even if it provides only modest symptomatic relief, as assessed by improvements in the IPSS [1,2]. Due to the incidence of side-effects, together with inadequate symptoms relief, >25% of patients on drug therapy discontinue treatment; some of these patients opt for surgical intervention [1,2].

TURP remains the 'gold standard' in the surgical treatment of BPH, and has documented decreased IPSS and increased maximum urinary flow rate (Q_{max}) by up to 70% and 149%, respectively [3–6]. The main disadvantages of TURP include perioperative morbidity and long-term complications, such as postoperative bleeding, urinary retention, incontinence, urethral strictures and sexual dysfunction (up to 65% of patients if retrograde ejaculation is considered) [6]. The newer, extremely attractive laser-based methods of treatment such as holmium laser enucleation of the prostate, thulium laser enucleation of the prostate, and photovaporisation of the prostate, are still associated with complication rates comparable with those of TURP [7,8].

Considering these findings, there is still a considerable proportion of men who seek more significant symptomatic improvement than is offered by medicinal therapy but who are not willing to subject themselves to the risks associated with surgery. Thus, different minimally invasive procedures have been introduced with the aim of reducing the morbidity of TURP, such as transurethral needle ablation (TUNA), transurethral microwave thermotherapy (TUMT), and transurethral ethanol ablation of prostate (TEAP). However, their position in the management of BPH is still controversial [5,7]. More recently, a step in this direction was made: some reports presented data about a new procedure called prostate urethral lift (PUL) [9,10].

In the present study, we report the first clinical experience with a temporary implantable nitinol device (TIND; Medi-Tate®; Medi-Tate Ltd., Or Akiva, Israel), a new device developed to provide a minimally invasive means of increasing prostatic urethral patency to relieve the symptoms of urinary outflow obstruction secondary to BPH. The TIND is crimped and delivered through a cystoscope sheath, and then, when placed in the urethra, it is released from the cystoscope sheath to assume its expanded configuration, thereby reshaping the urethra and the bladder neck. The purpose of the present study was to determine the feasibility and safety of the TIND procedure in patients with LUTS due to BPH.

Patients and Methods

Study Design

In this single-arm, prospective study, we evaluated the feasibility and the safety of TIND implantation in patients presenting with LUTS secondary to BPH. After the approval of the Local Institutional Ethic Committee, the study was conducted at the Division of Urology, San Luigi Gonzaga Hospital, University of Turin, Orbassano (Turin), Italy and the enrolment phase lasted from May 2010 to July 2013. All patients were accurately informed about the procedure and signed a detailed consent form.

Inclusion Criteria

Age >50 years, IPSS of ≥10, Q_{max} of ≤12 mL/s, prostate volume assessed by TRUS of <60 mL.

Exclusion Criteria

Previous prostate surgery, prostate cancer, urethral stricture, bladder stones, obstructing median lobe. Patients were also excluded if they had a history of significant medical co-morbidity, haemostatic disorder or suspected neurological conditions that could potentially affect voiding function.

TIND and Surgical Equipment

The TIND is comprised of elongated struts and an anchoring leaflet all made of nitinol, a biocompatible super elastic shape-memory alloy widely used in the manufacture of medical devices (Fig. 1). The total length of the device is 50 mm and its outer diameter is 33 mm, designed to cover the entire length of the prostatic urethra, from the bladder neck to a point proximal to the external urinary sphincter.

When in its expanded configuration, the struts of the TIND exert radial force outwardly on the bladder neck and the prostatic urethra, to push obstructive tissue away from the urinary path. The TIND is left in position for 5 days. The device is subsequently removed using a cystoscope sheath under visualisation. The device is delivered and removed through a standard 22 F cystoscope (Storz, Tuttlingen, Germany) with a 5-mm 30° optic.

Mechanism of Action

The radial force exerted by the struts cause ischaemic necrosis of the tissue, leading to bladder neck and prostatic urethra incision. The hypothesis is that these incisions 'reshape' the prostatic urethra and the bladder neck and reduce the urinary flow obstruction caused by the prostatic tissue.

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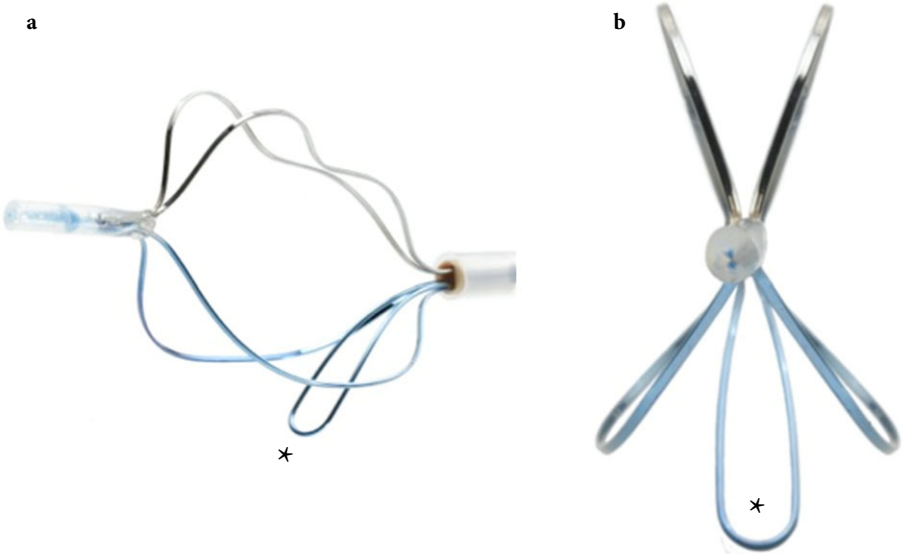

Fig. 1 The Medi-tate TIND in its expanded configuration. (**a**) Longitudinal view. Note the nitinol struts and the anchoring leaflet (*). The total length of the device is 50 mm. The tip of the device is covered (soft plastic material) to avoid any bladder injury. (**b**) Front view. The width of the device is 33 mm, the struts are designed to create prostate incisions anteriorly, at the 5 and 7 o'clock positions. The anchoring leaflet is marked with*.

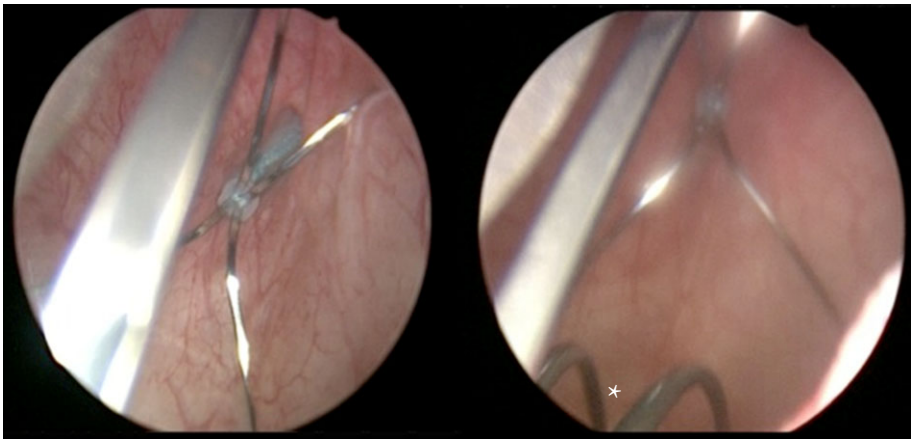

Fig. 2 (**a**) The device, preloaded on a dedicated delivery system, is advanced into the bladder through the cystoscope sheath, and deployed inside the bladder. (**b**) The device rotated by using the delivery system until the anchoring leaflet (*) reaches the 6 o'clock position. To facilitate this step, the bladder is filled with saline solution.

Surgical Procedure

1 TIND implantation. The procedure is performed under light i.v. sedation. In addition, as antibiotic prophylaxis, a single i.v. dose (500 mg) of levofloxacin is administered. The patient is placed in a lithotomy position. The cystoscope is gently inserted in to the urethral meatus, and a standard urethro-cystoscopy is performed. The TIND, preloaded on a dedicated delivery system, is advanced into the bladder through the cystoscope sheath, and deployed inside the bladder. The device is then further manipulated under direct visualisation, until the anchoring leaflet slides to its position at 6 o'clock distal to the bladder neck and the device is securely positioned within the bladder neck and the prostatic urethra (Figs 2 and 3). Finally, the bladder is emptied and the cystoscope is removed. No catheterisation is required.
2 TIND removal. At 5 days after placement, the TIND is retrieved in an outpatient setting. The patient is placed in a lithotomy position and 20 mL lidocaine gel is applied to the urethral meatus. Urethroscopy is performed with a standard 22-F cystoscope, and the TIND is identified (Fig. 4), retracted into the cystoscope sheath under visualisation, and then removed.

Post-Implantation Care

Patients were monitored after surgery as per protocols for a standard endoscopic procedure. Paracetamol (1 000 mg) was administered i.v. after surgery per local protocol, and then if required by the patients. Subjective pain levels were scored using a visual analogue scale (VAS).

Follow Up Visits

Patients were visited at 5 days (removal day), 3 and 6 weeks, and 3, 6, and 12 months after the implantation. Follow-up visits included uroflowmetry, IPSS and IPSS quality-of-life (QoL) assessments.

To assess patient satisfaction with the surgical intervention, question 32 of the Expanded Prostate Cancer Index

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Fig. 3 Once the device is correctly oriented, it is gently retracted into the prostatic urethra, until the anchoring leaflet (*) slides to its position, between the bladder neck and the verumontanum. This step of the procedure is performed under direct vision and the surgeon has the tactile feedback of the correct positioning of the device. By this way the device is secured within the bladder neck and prostatic urethra. —, bladder neck.

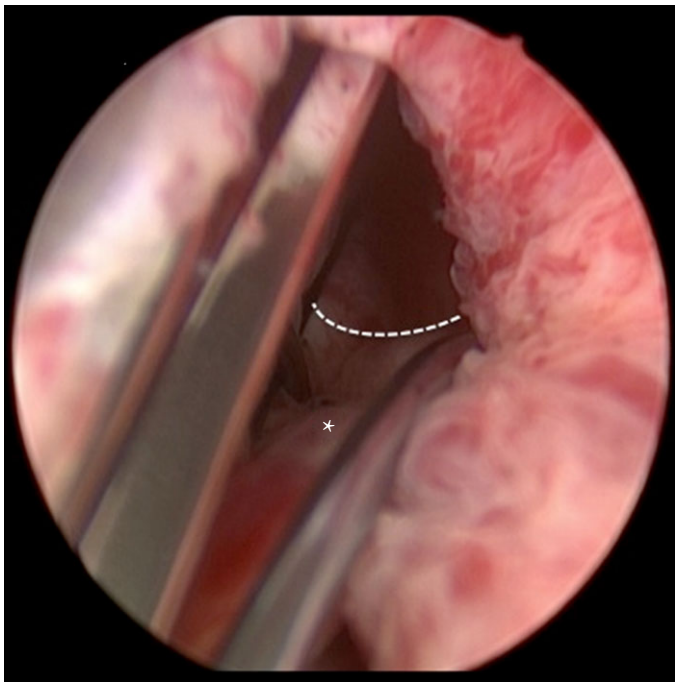
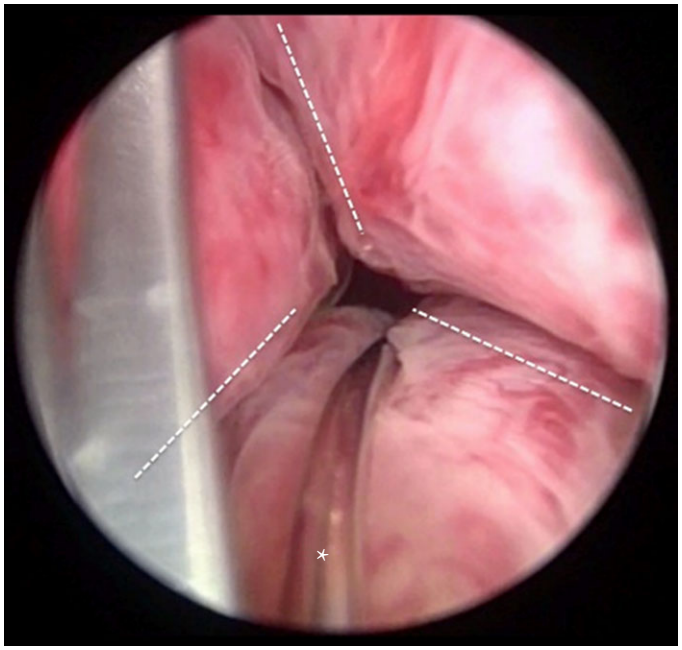


Fig. 4 Endoscopic vision just before TIND removal. Note that anchoring leaflet (*) in its correct position, and the incision done by the device anteriorly, at 5 and 7 o'clock positions (—).



Composite (EPIC) questionnaire [11,12] was posed during the follow-up visits: '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).

Adverse events during the follow-up period were recorded. For the purpose of this study, complications were defined as 'early' when they occurred ≤30 days of surgery and 'late' if they occurred >30 days after surgery. Early complications were classified according to the Clavien system [12].

Study Endpoints

The primary endpoint of the study was to evaluate the feasibility and safety of the procedure; the secondary endpoint was to evaluate the functional results of the procedure based on the IPSS and uroflowmetry.

Statistical Analysis

Data were expressed as means and standard deviations (SDs) for continuous variables, and as frequencies and proportion or median and interquartile ranges (IQRs) for categorical variables. The means of continuous variables were compared by using the Student's *t*-test after verifying that the variables to be analysed were approximately normally distributed. ANOVA was used to compare the means of more than two groups, whilst statistical comparisons among different subgroups were performed by using the Kruskall–Wallis test for categorical variables.

Simple and multiple linear regression models were built to identify any independent factors for overall complications, improvement of Q_{max} and decrease in the IPSS at 12 months after surgery. Clinical characteristics including age, American Society of Anesthesiologists (ASA) score, body mass index (BMI), prostate size, Q_{max} and the IPSS at baseline, and surgeon were used in the regression models. A $P < 0.05$ was considered to indicate statistical significance. Statsoft (Tulsa, OK, USA) Version 8.0 for Windows was used for statistical analysis.

Results

Patient Demographics

In all, 32 patients underwent TIND implantation; their demographic and baseline characteristics are summarised in Table 1.

Perioperative Results

All patients were treated with light sedation, and all the implantations were successful. No intraoperative complications were recorded. The mean (SD) operative time,

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Table 1 Baseline characteristics of the patients.

Characteristic	Value
Number of patients	32
Mean (SD)	
Age, years	69.4 (8.2)
BMI, kg/m^2	26.1 (4.2)
PSA level, ng/mL	1.3 (1.2)
Prostate volume, mL	29.5 (7.4)
Q_{max}, mL/s	7.6 (2.2)
Preoperative haemoglobin levels, g/dL	14.0 (1.2)
Median (IQR)	
ASA score	2 (2–3)
ECOG score	0 (0–1)
Preoperative IPSS	19 (14–23)
Preoperative IPSS QoL index	3 (3–4)
Charlson comorbidity index	1 (0–2)
N (%)	
Patients with bladder catheter before the intervention	0
α-blocker therapy	32 (100)
α-blocker + 5-ARI therapy (%)	15 (46)

ECOG, Eastern Cooperative Oncology Group (performance status); 5-ARI, 5α-reductase inhibitor.

from introduction of the TIND system until withdrawal of the delivery system, was 5.8 (2.5) min.

The median (IQR) VAS score at 6 h after the procedure was 2 (2–4), while the median paracetamol use during this period was one 1 000 mg vial per patient. The median (IQR) duration of the postoperative stay was 1 (1–2) days. From the 20th procedure, patients were discharged on the same day as the surgery. None of the patients was readmitted before device removal. All but one of the devices was removed 5 days after implantation, in an outpatient setting. The mean (SD) operative time was 2 (1) min, and all procedures were uneventful.

Complications

Overall, four patients (12.5%) presented complications that are summarised in Table 2. One patient (3.1%) reported urinary incontinence 1 day after surgery, so the device was immediately removed. During the cystoscopy, the distal portion of the wires was identified distal to the sphincter, suggesting displacement of the device. After TIND removal, the patient reported no urine leakage. One patient (3.1%) had urinary retention the same day of the implantation. In this case, the bladder was voided by using a small (10 F) Tieman catheter, which was immediately removed. Thereafter, the patient was able to urinate spontaneously. Two patients (6.2%) developed infections. In the first case, a UTI was diagnosed 2 weeks after the implantation and was successfully treated by antibiotic therapy. The second patient (affected with type II diabetes) presented fever (38 °C) with urinary symptoms, atrial fibrillation and uncontrolled glucose levels (>400 mg/dL) 4 weeks after implantation. He was readmitted, blood tests and TRUS were performed with a diagnosis of a 2-cm prostatic abscess. The patient was successfully treated with medical therapy, with no sequelae after discharge (Table 2). No late complications were recorded. Furthermore, no patients required adjunctive surgical treatments during the follow-up period. When comparing the subgroup of patients who had postoperative complications (four patients) with the subgroup of patients who did not (28), there were no differences in age, BMI, preoperative PSA levels, IPSS, co-morbidities, ASA score, prostate volume or operative time. Multiple regression analysis failed to identify any independent prognostic factors for complications.

Functional Results

Q_{max} values, the IPSS and IPSS QoL index results measured at the baseline and at scheduled time points during the follow-up period are reported in Figs 5 and 6. Figures 7 and 8 show the percentage changes in Q_{max} and the IPSS at the different time points with respect to baseline. There were no differences in the IPSS and IPSS QoL index among the different time points during the follow-up, on the contrary, there were statistically significant variations in Q_{max} during the follow-up (Table 3). All patients discontinued medical therapy at 3 months after surgery. Multiple regression analysis did not identify any independent prognostic factor predictive of higher improvement of the IPSS and Q_{max}. At 12 months after surgery (last follow-up visit), no patients required medical therapy or surgical procedures for BPH. For the EPIC score (Fig. 6 and Table 3) at 12 months after surgery, 26 patients (82%) were 'satisfied' or 'extremely satisfied' with the intervention, five (15%) patients were uncertain about their satisfaction and only one (3%) patient was 'dissatisfied'.

Discussion

Many men with LUTS due to BPH are dissatisfied with current medical treatment options but do not accept TURP or more recent laser-based therapies as an option, mainly due to subsequent sexual dysfunction, perioperative urinary urgency/frequency symptoms or risks of complications. In addition, some Authors have reported that LUTS have a lower impact on QoL than sexual dysfunction or incontinence [1,13–15]. To reduce the invasiveness of TURP, many minimally invasive surgical options have been proposed during recent decades (Table 4) [16–24].

The 'prostatic' stent was primarily designed as an alternative to an indwelling catheter in patients unfit for surgery but it has also been indicated as a primary treatment option in patients without significant co-morbidities [16,25]. Because of the side-effects and the high migration rate, prostatic stents have a limited role in BPH treatment [5]. Heating therapies with microwaves and radiofrequencies (TUMT and TUNA) may have fewer complications than TURP [17,18]. However,

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Table 2 Complications after TIND implantation.

Patient ID	Demographic data	Complication	Grade*	Early/late	Management	Sequelae
ITA 0101	Age 69 years BMI 18.7 kg/m^2 Charlson score 3 ASA score 3 PSA level 0.5 ng/mL Prostate size 25 mL	Prostatic abscess (sepsis, AF, uncontrolled glycaemia)	II	Early	Readmission 1 Ertapenem (1 g/day i.v.) for 9 days, amikacin for 7 days 2 Amiodarone (300 mg, i.v.) for 1 day 3 Insulin (s.c) for 10 days, then usual oral therapy Postoperative stay of readmission: 10 days	None
ITA0109	Age 78 years BMI 21.9 kg/m^2 Charlson score 0 ASA score 3 PSA level 0.47 ng/mL Prostate size 27 mL	Urinary retention (same day of implantation)	II	Early	Catheter positioning (immediately removed)	None
ITA0119	Age 71 years BMI 27.6 kg/m^2 Charlson score 0 ASA score 2 PSA level 0.4 ng/mL Prostate size 34 mL	Transient incontinence due to device displacement	III	Early	Early (postoperative day 1) removal of device	None
ITA0123	Age 71 years BMI 30.1 kg/m^2 Charlson score 4 ASA score 3 PSA level 1.2 ng/mL Prostate size 39 mL	UTI	II	Early	Levofloxacin 500 mg/day orally for 14 days	None

*AF, atrial fibrillation; *According to Clavien system.*

Fig. 5 Q_{max} evaluated pre- and postoperatively. The differences between the pre- and postoperative values at every time point were statistical significant. pre., preoperative; w., weeks; mo., months.

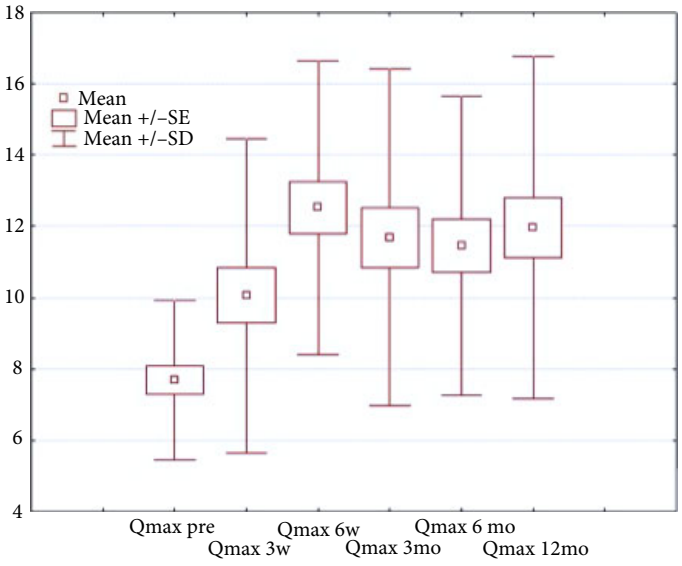
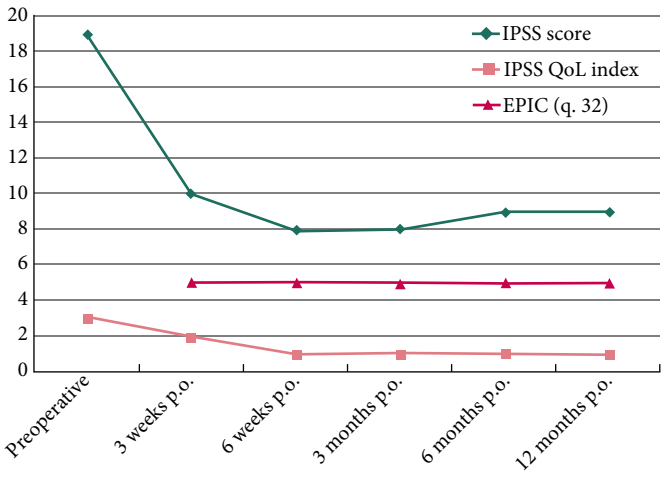


Fig. 6 The IPSS, IPSS QoL score and EPIC score evaluated pre- and postoperatively. The differences between the pre- and postoperative values at every time point were statistical significant for all the considered variables. p.o., postoperatively.



it is known they might have unpredictable results and require up to 2 months of worsened symptoms before a significant improvement of Q_{max} and the IPSS [5,26].

The minimally invasive TEAP option is scarcely covered in the Literature and its mechanism of action has not been well investigated. In addition, the technique has not been standardised and finally, severe adverse events have been reported [19]. For these reasons, TEAP is still considered experimental and should be used only in trials [5,20]. More recently, the PUL procedure has been proposed as a novel, minimally invasive technique to improve LUTS due to BPH [9,10]. In the PUL procedure, the lateral lobes of the prostate

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Fig. 7 Changes in Q_{max} at the different time points with respect to baseline values. IQmax, increase in Q_{max}; w., weeks; mo., months.

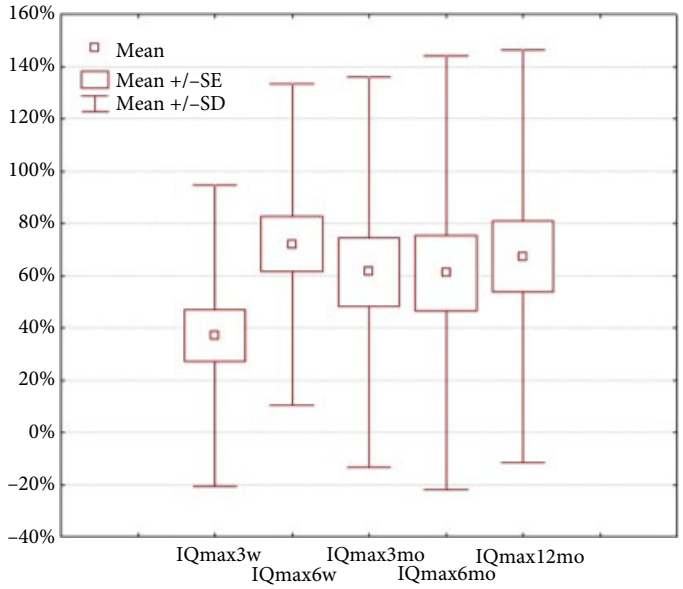

Fig. 8 Changes in the IPSS at the different time points with respect to baseline values. DIPSS, decrease in IPSS; w., weeks; mo., months.

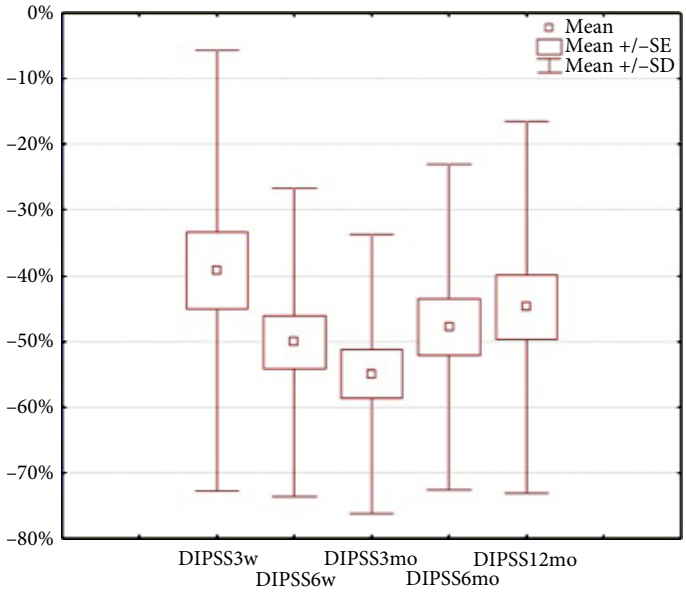

Table 3 Functional results and overall satisfaction of patients with TIND procedures evaluated during the follow-up.

	3 weeks	6 weeks	3 months	6 months	12 months	*P*
Mean (SD) Q_{max}, mL/s	10.0 (4.4)	12.5 (4.1)	11.7 (4.7)	11.4 (4.2)	11.9 (4.7)	<0.01
Median (IQR)						
IPSS	10 (8–11)	8 (7–10)	8 (6–10)	9 (7–12)	9 (7–13)	0.18
IPSS QoL index	2 (1–2)	1 (1–2)	1 (1–2)	1 (1–2)	1 (1–2)	0.45
EPIC index question 32*	5 (4–5)	5 (4–5)	5 (4–5)	5 (4–5)	5 (4–5)	1

*'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).

are displaced by small suture-based implants towards the capsule with the aim of expanding the urethral lumen [9,10,27]. In the first clinical experience with 19 patients, at 1 year after PUL the mean IPSS decreased by 39% compared with the baseline value [9]. However, non-significant increases in Q_{max} at the different time points were reported. In a recent multinational experience, the IPSS, IPSS QoL score and Q_{max} significantly improved 1 year after the procedure, yet 6.5% of the patients progressed to TURP within 1 year [10].

TIND was developed in an effort to create an efficient and minimally invasive technique for treating the symptoms of urinary outflow obstruction secondary to BPH. In the present study, we report the first clinical experience with TIND and show that the implantation of this device is feasible and safe in the treatment of BPH-related symptoms. All the procedures were successfully completed, performed under light sedation, and required only a few minutes to perform. Neither intraoperative complications nor technical difficulties were recorded. From a technical point of view, the procedure was simple and did not require any special equipment. The key point is the correct placement of the device; after filling of the bladder with saline solution, the device must be delivered into the bladder and rotated until the anchoring leaflet is placed at the 6 o'clock position at the bladder neck. Once this orientation is correct, the device is gently retracted until the anchoring leaflet slides distal to the bladder neck. Unlike other minimally invasive procedures, the surgeon has direct visualisation of the device throughout the procedure. Moreover, at his discretion, the surgeon can easily relocate and even withdraw the device even after it has been deployed. During the postoperative period, paracetamol (1 000 mg, i.v.) was administered to all patients, per local protocol, and no patients required adjunctive analgesic drugs, suggesting that overall the procedure was well tolerated. All but one patient was able to void the same day of surgery, with no need of

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Table 4 Results of minimally invasive techniques for the treatment of LUTS due to BPH.

References	Procedure	Follow-up, weeks	Patients, *n*	Estimated change in IPSS, %	Estimated change in Q_{max}, %	Main complications
Hoffman et al. [18]	TUMT	52	322	−65	70	NA
Trock et al. [21]	TUMT	208	541	−42.7	35	NA
Guazzoni et al. [16]	Urolume	18	91	−66.6	83.8	Long-term complications 38%
Gesenberg and Sintermann [22]	Memotherm	104	123	−74.5	125.6	*Early postoperative* Haematuria 51.2%; dislocation 8.9% *3–12 months postoperative* UTI 45.5%; urothelial hyperplasia 27.6%, dislocation 1.6%, explantation 4.1%, ureteric stricture 10.6%, stone formation 3.2%
Perry et al. [23]	Memokath	336	211	−59.6	NA	Migration 13%; urinary retention 10%, incontinence 6%; UTI 6%, stone formation 2%
Grise et al. [19]	TEAP	52	115	−50	35	Urinary retention 17%, haematuria 16%, UTI 8%, incontinence 4%, erectile dysfunction 3%, ejaculatory dysfunction 1%
Plante et al. [20]	TEAP	24	79	−47 to −55*	37–94*	Irritative voiding symptoms 40.3%, urinary retention 22.1%, UTI 10.1%; erectile dysfunction 3.7%, ejaculatory dysfunction 3.7%
Hill et al. [17]	TUNA	52	56	−51.2	NA	Erectile dysfunction 3%, urinary incontinence 2%; re-intervention 13.8%
Zlotta et al. [24]	TUNA	52	131	−58.3	40.6	NA

*Three study arms comparing transurethral, transrectal and transperineal injections; NA, not available.

postoperative catheterisation. This is one of the most positive aspects of the procedure. The duration of hospital stay was longer for the first patients, who were more strictly monitored during the postoperative period, as it is standard when implementing new techniques. However, after the initial encouraging results, all patients were discharged on the same day of the surgery.

Theoretically, one of the major concerns of this procedure was the tolerability of the device once implanted. After the discharge and before the TIND removal (at day 5), we recorded neither unplanned visits nor readmissions, suggesting that the device was well tolerated by all the patients.

Removal of the device was performed without any complications in all cases. All patients were able to void immediately after device removal, confirming the feasibility of this manoeuvre in an ambulatory setting.

Overall, there were four 'early' complications (Table 2). Of note, one patient reported urinary incontinence due to device displacement, but after removal, the patient was completely continent. In one patient, prostatic abscess complicated by sepsis, atrial fibrillation and uncontrolled glycaemia was recorded 4 weeks after implantation. The patient was readmitted and pharmacologically treated with no sequelae after discharge. Regression models failed to identify any independent prognostic factors for complications, despite the fact that both infections were recorded in patients with ASA 3 and a Charlson comorbidity index higher than the median value. After implantation, no complications occurred in the studied population during the first 30 days, demonstrating the safety of the procedure. For functional results, significant improvements in the postoperative IPSS and Q_{max} compared with baseline were recorded. Notably, this improvement was recorded early, within 3 weeks of the procedure, presenting an important positive aspect of this procedure, as the vast majority of other minimally invasive techniques can require several weeks before improvement [5,19]. Moreover, the IPSS remained stable during the entire follow-up period. Slight but statistically significant changes were observed in Q_{max} measured at the different time points during the follow-up (Table 3), even if probably not clinically relevant. After 1 year, the mean improvement of the IPSS and Q_{max} was 45% and 67%, respectively. Notably, all patients discontinued medical therapy 3 months after surgery. These results are at least comparable, if not superior, to those of other minimally invasive procedures, even the most novel ones [7,28]. The QoL scores followed the same trend as the IPSS, with patients reporting a significant improvement in QoL, which remained stable at the different follow-up time points throughout the study (Table 3). These data suggested that TIND implantation positively affected the QoL of the patients, a key factor when assessing a new surgical strategy for BPH treatment. The results of EPIC question 32 further confirmed that the procedure was well accepted by the patients. Finally, no patients required more invasive treatments (i.e., TURP) during the follow-up period, further demonstrating the efficacy (at least measured in a short follow-up period) of the

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procedure. We consider this result noteworthy when compared with other techniques [10,29,30].

The present study was not devoid of limitations. Firstly, the sample size was small. Secondly, the duration of follow-up was somewhat short. Nevertheless, one must note that the main endpoint of our present study was to demonstrate the feasibility and safety of the procedure, and we think that the presented data are sufficient in demonstrating these points. Thirdly, prostate size was small and treatment results for larger prostates are lacking.

Notwithstanding the abovementioned limitations, we can conclude that TIND implantation is a feasible and safe minimally invasive option for the treatment of BPH-related LUTS, as evidenced by the excellent perioperative results and the low complication rate. The procedure is simple, fast (a few minutes) and does not require any special equipment. The functional results are encouraging and the treatment significantly improved the patient's QoL. Further studies are required to assess the long-term durability of TIND results and to better define the indications of such a procedure.

Conflict of Interest

The authors declare that they have no conflicts of interest.

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Abbreviations: ASA American Society of Anesthesiologists; BMI body mass index; EPIC Expanded Prostate Cancer Index Composite (questionnaire); IQR interquartile range; PUL prostate urethral lift; Q_{max} maximum urinary flow rate; QoL quality of life; TEAP transurethral ethanol ablation of prostate; TIND temporary implantable nitinol device; TUMT transurethral microwave thermotherapy; TUNA transurethral needle ablation; VAS visual analogue scale.

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