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3-Year follow-up of temporary implantable nitinol device implantation for the treatment of benign prostatic obstruction

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Objectives

To report 3-year follow-up results of the first implantations with a temporary implantable nitinol device (TIND®; Medi-Tate Ltd., Or Akiva, Israel) for the treatment of lower urinary tract symptoms (LUTS) secondary to benign prostatic hyperplasia (BPH).

Patients and Methods

In all, 32 patients with LUTS were enrolled in this prospective study. The study was approved by the local Ethics Committee. Inclusion criteria were: age >50 years, International Prostate Symptom Score (IPSS) ≥10, peak urinary flow (Q_{max}) <12 mL/s, and prostate volume <60 mL. The TIND was implanted within the bladder neck and the prostatic urethra under light sedation, and removed 5 days later in an outpatient setting. Demographics, perioperative results, complications (according to Clavien–Dindo classification), functional results, and quality of life (QoL) were evaluated. Follow-up assessments were made at 3 and 6 weeks, and 3, 6, 12, 24 and 36 months after the implantation. The Student's *t*-test, one-way analysis of variance and Kruskal–Wallis tests were used for statistical analyses.

Results

At baseline, the mean (standard deviation, SD) patient age was 69.4 (8.2) years, prostate volume was 29.5 (7.4) mL, and Q_{max} was 7.6 (2.2) mL/s. The median (interquartile range, IQR) IPSS was 19 (14–23) and the QoL score was 3 (3–4). All the implantations were successful, with a mean total operative time of 5.8 min. No intraoperative complications were recorded. The change from baseline in IPSS, QoL score and Q_{max} was significant at every follow-up time point. After 36 months of follow-up, a 41% rise in Q_{max} was achieved (mean 10.1 mL/s), the median (IQR) IPSS was 12 (6–24) and the IPSS QoL was 2 (1–4). Four early complications (12.5%) were recorded, including one case of urinary retention (3.1%), one case of transient incontinence due to device displacement (3.1%), and two cases of infection (6.2%). No further complications were recorded during the 36-month follow-up.

Conclusions

The extended follow-up period corroborated our previous findings and suggests that TIND implantation is safe, effective and well-tolerated, for at least 36 months after treatment.

Keywords

BPH, LUTS, minimally invasive techniques, nitinol, urethral implantable device, TIND, #UroBPH

Introduction

LUTS associated with BPH affect ~30% of men aged >50 years, including >30 million men in Europe and the USA [1]. Whilst medical therapy is the first-line treatment, in more than a quarter of cases it fails or induces significant side-effects, leading many patients to opt for surgical intervention [1,2]. TURP remains the 'gold standard' surgical treatment for BPH, but perioperative morbidity and long-term complications, such as postoperative bleeding, urinary retention, incontinence, urethral strictures, and sexual dysfunction, are not negligible [3–6]. Alternative laser-based methods have only partially overcome these drawbacks [7–10]. In light of this, many men seek more significant symptomatic improvement than those provided by drugs, yet are not willing to face the risks associated with surgery.

In the past, various techniques, including transurethral needle ablation, transurethral microwave thermotherapy, and transurethral ethanol ablation of the prostate, have been

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proposed to fill this gap, but they have not substantially impacted on clinical practice, their use being limited today [11–13]. The recently developed prostatic urethral lift (PUL) [14,15] transurethrally delivers permanent implants aimed to separate the prostate lobes and relieve urethral obstruction without cutting, burning, or destroying the tissues. Recent studies have shown that PUL can offer encouraging results 24 months after surgery [16–18].

The temporary implantable nitinol device (TIND®; Medi-Tate Ltd., Or Akiva, Israel) was designed to create prostate incisions, thereby relieving BPH-related LUTS in a minimally invasive fashion [19]. 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.

In our first experience with this device [20], TIND implantation in 32 patients presenting with BPH-related LUTS, was safe and elicited functional improvements and enhanced patient quality of life (QoL) at 12 months after surgery. The aim of the present paper was to report on the 3-year outcomes of the same 32 patients.

Patients and Methods

After approval from the Institutional Ethics Committee, 32 patients were included in this single-arm, prospective study. The study was conducted at the Division of Urology of San Luigi Gonzaga Hospital – University of Turin, Orbassano (Turin), Italy. Patients were enrolled between May 2010 and July 2013.

Inclusion criteria included: age >50 years, IPSS ≥10, peak urinary flow (Q_{max}) ≤12 mL/s, and prostate volume (as assessed by TRUS) <60 mL.

Patients were excluded if they had history of prostate surgery, prostate cancer, urethral stricture, bladder stones, obstructive median lobe, and history of significant medical co-morbidities, haemostatic disorders or suspected neurological conditions that could underlie impaired voiding function.

All eligible patients were informed about the procedure and signed a detailed consent form.

TIND Device

The TIND is comprised of elongated nitinol struts and a nitinol anchoring leaflet. The total length of the device is 50 mm and its outer diameter is 33 mm. When in its expanded configuration, the struts of the TIND exert radial force outwardly on the bladder neck and the prostatic urethra, leading to the incision of the bladder neck and the prostatic urethra. These incisions are thought to 'reshape' the prostatic urethra and the bladder neck, and reduce the urinary flow obstruction caused by the enlarged prostatic tissue.

Surgical Procedure

The procedure for TIND implantation has been previously described [20]. The patient is placed in lithotomy, under light i.v. sedation. Briefly, monitored anaesthesia care is employed with this type of sedation and analgesia during spontaneous breathing. Specifically, midazolam 0.02 mg/kg, fentanyl 1 λ/kg and propofol 0.7 mg/kg are administered i.v. with the patient spontaneously breathing.

Urethrocystoscopy is performed with a standard 22-F cystoscope. 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 manipulated under direct vision, until the anchoring leaflet slid into position at 6 o'clock distal to the bladder neck, and is securely positioned within the bladder neck and the prostatic urethra. Finally, the bladder is emptied and the cystoscope is removed. No catheterisation is required.

At 5 days after placement, rigid urethroscopy is performed in an outpatient setting; the TIND is identified and retracted into the cystoscope sheath, under vision, and then removed.

Follow-Up Visits

Patients visited in an outpatient setting at 5 days (removal day), 3 and 6 weeks, and 3, 6, 12, 24 and 36 months after the implantation, for assessment of uroflowmetry, IPSS, and IPSS QoL score. Sexual dysfunction (i.e., retrograde ejaculation) in sexually active patients was investigated at 12, 24 and 36 months after the surgery by asking the patient: 'after the intervention, did you record any changes in terms of ejaculation?'.

In addition, patient satisfaction with the surgical intervention was assessed by posing Question 32 of the Expanded Prostate Cancer Index Composite (EPIC) questionnaire [21] to the patients during the follow-up visits: 'Overall, how satisfied are you with treatment you received for your prostate disease intervention?', with a choice of five possible responses; (i) extremely dissatisfied; (ii) dissatisfied; (iii) uncertain; (iv) satisfied; (v) extremely satisfied.

During the follow-up visits, any need for medical therapy or surgical intervention due to recurrent/persistent LUTS, was recorded. Complications were recorded during the entire follow-up period. Early complications (<30 days) were classified according to the Clavien–Dindo classification [22]. Treatment failure during follow-up was defined as the need for any surgical treatment for LUTS related to BPH.

Statistical Analyses

Continuous variables are presented as means and standard deviations (SDs); categorical variables are presented as frequencies and proportions or medians and interquartile ranges (IQRs). The means of continuous variables were compared 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 of categorical variables amongst different subgroups were performed using the Kruskal–Wallis test.

Simple and multiple linear regression models were built aimed at identifying independent factors of the need for BPH-related medical therapy after intervention, for improvement of Q_{max} and any decrease in IPSS at 36 months after surgery. Clinical characteristics including age, American Society of Anesthesiologists (ASA) score, body mass index (BMI), prostate size, Q_{max} and IPSS at baseline were used in the regression models. A subgroup analysis of patients with an IPSS QoL of ≥3 at 36 months after surgery was performed.

A $P < 0.05$ was considered statistically significant. StatSoft (Tulsa, OK, USA) version 8.0 for Windows was used for statistical analyses.

Results

The TIND implantation was performed in 32 men, with a mean (SD) age of 69.4 (8.2) years, prostate volume of 29.5 (7.4) mL, and Q_{max} of 7.6 (2.2) mL/s. All patients were on α-blocker therapy at the time of the procedure, with 46% regularly using 5α-reductase inhibitors (5-ARIs). Patient demographics and baseline characteristics are summarised in Table 1. All the procedures were performed under light sedation. No intraoperative complications were recorded. The mean (SD) total operative time was 5.8 (2.5) min. The median (IQR) visual analogue pain scale (VAS) score 6 h after the procedure was 2 (2–4). After discharge, no patients required re-admission before device removal. Table 2 summarises various perioperative parameters. All but one of the devices was removed 5 days after implantation, in an outpatient setting, with no complications.

Functional Results

Overall, there was a statistically significant increase in Q_{max} values over the first 12 months after treatment, peaking at a mean 72% increase by 6 weeks after treatment and remaining steady over the ensuing 12 months ($P < 0.001$; Fig. 1). Q_{max} values slightly declined between 24 and 36 months after treatment, but the changes from the 12-month follow-up visit were insignificant ($P = 0.374$ and $P = 0.157$, respectively). At the end of the 36-month monitoring period, the mean Q_{max} volume was 41% (+3 mL/s) higher than the mean baseline recordings (Fig. 2). Similarly, there was a statistically significant difference between baseline values and the postoperative IPSS and QoL scores (Fig. 3; $P < 0.001$). A significant decline in IPSS was noted within 3 weeks of treatment, followed by further reductions. At the end of follow-up the IPSS was 19% (−4 IPSS score points) lower that the mean baseline recordings (Fig. 2).

Table 1 Baseline characteristics of the patients.

Variable	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)
Median (IQR)	
ASA score	2 (2–3)
ECOG score	0 (0–1)
Preoperative IPSS	19 (14–23)
Preoperative IPSS QoL score	3 (3–4)
Charlson Comorbidity Index	1 (0–2)
N (%)	
α-Blocker therapy	32 (100)
α-Blockers + 5-ARI therapy	15 (46)
Patients with sexual activity	19 (59)

All patients were able to discontinue LUTS-related medical therapy 3 months after the implantation, but three patients (9%) required the therapy again within 12 or 24 months of treatment (Table 3). The multiple regression analysis failed to identify any independent prognostic factors predictive of the need for BPH-related medical therapy after the TIND implantation, increase of Q_{max} or decrease of IPSS.

A comparative analysis of the outcomes of patients presenting with an IPSS QoL score >3 vs ≤3 at the end of the study period was performed (Table 4). Whilst no statistically significant differences were found between the baseline measures and demographics of the two subgroups, a multivariable analysis identified an IPSS of >8 at 6 weeks after TIND implantation as independent predictor of an IPSS QoL score of ≥3 at 36 months after treatment.

Overall, no patients required any surgical therapy for BPH during the follow-up. Three men recommenced medical therapy. None of the 19 patients reporting preoperative sexual activity reported any ejaculatory dysfunction during the follow-up period.

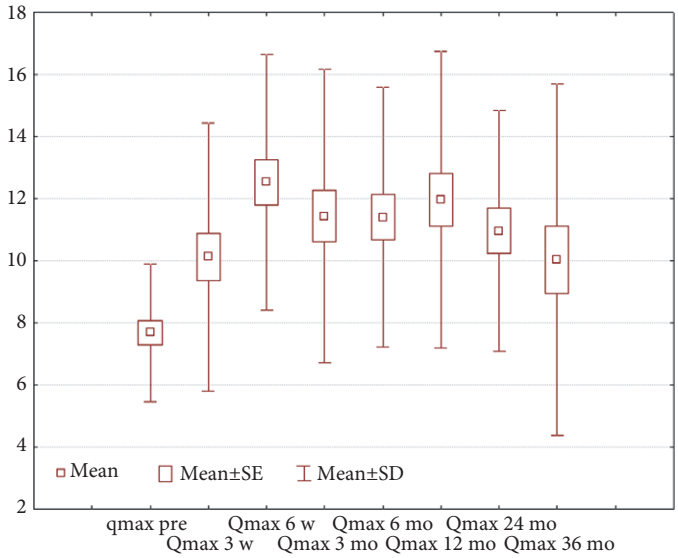
Patient Satisfaction with the Surgical Intervention

Differences in terms of EPIC score at different time points were not significant ($P = 0.180$; Fig. 3).

Table 2 Perioperative data.

Variable	Value
Number of patients	32
Mean (SD)	
Operative time (from introduction of the TIND system until withdrawal of the delivery system), min	5.8 (2.5)
Operative time for TIND removal, min	2 (1)
N (%)	
Patients treated by using light sedation	32 (100)
Intraoperative complications	0
Readmitted before device removal	0
Median (IQR)	
VAS pain score, 6 h after the procedure	2 (2-4)
Paracetamol use (1 000 mg vials)	1 (1–1)
Hospital stay, days	1 (1–2)

Fig. 1 Q_{max} evaluated pre- and postoperatively. The differences between the pre- and postoperative values at every time point were statistically significant (36-month follow-up analysis was based on 31 patients). p.o., postoperatively.



Complications

Overall, four patients (12.5%) had complications (Table 5). One patient (3.1%) reported urinary incontinence due to device displacement. After its removal (day 1), the patient reported no urine leakage. One patient (3.1%) had urinary retention on the same day as the implantation. The bladder was voided via a catheter that was immediately removed; no further complications were recorded in this patient. Finally, two patients (6.2%) developed genito-urinary infections, which resolved after antibiotic therapy. Aside from these early stage complications, no further complications were recorded during the follow-up period. One patient died 26 months after the TIND implantation, due to causes that were unrelated to the surgical treatment.

Fig. 2 Mean changes (SD) in IPSS and Q_{max} at the different time points with respect to baseline values (36-month follow-up analysis was based on 31 patients). w., weeks; mo., months.

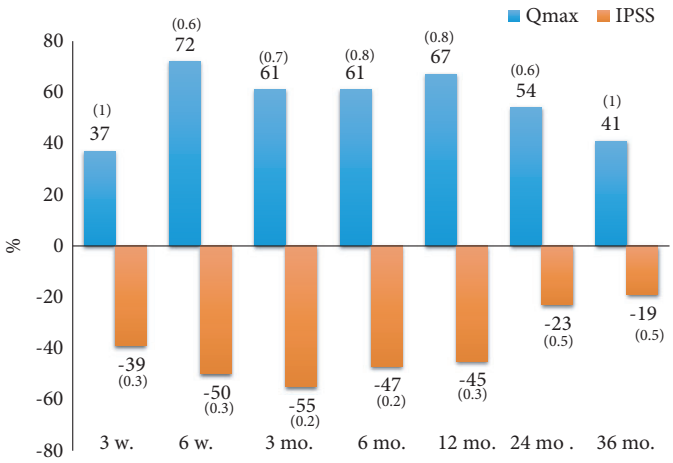
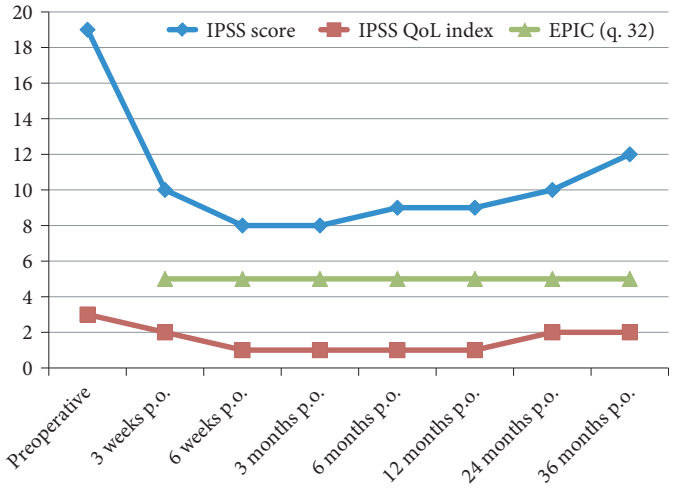


Fig. 3 Median IPSS, QoL and EPIC score evaluated pre- and postoperatively. The differences between the pre- and postoperative values (IPSS and QoL) at every time point were statistically significant for all the considered variables (36-month follow-up analysis was based on 31 patients). p.o., postoperatively.



Discussion

LUTS are some of the most common medical complaints filed by the ageing man [23,24]. Surgical intervention is typically the treatment of choice following failed medical therapy, but prostate surgery for BPH still presents significant morbidity including incontinence (3%), urethral stricture (7%), erectile (10%) and ejaculatory dysfunction (65%) [25,26]. The TIND was developed as a means of minimally invasively treating the symptoms of urinary outflow obstruction secondary to BPH. Our early experience with the device in 32 patients, established an acceptable

Table 3 Patients who required drug therapy for LUTS after TIND implantation.

Variable	Patient identification number		
	ITA 0113	ITA 0124	ITA 0126
Age, years	68	80	66
BMI, kg/m^2	22	21	29
Charlson Comorbidity Index	2	0	0
ASA score	2	3	2
Prostate volume, mL	21	31.5	32
Q_{max}, mL/s	7	5	10
IPSS	25	17	20
QoL score	3	3	3
Months after TIND implantation	24	24	12
Medical therapy	Silodosin	Tamsulosin	Tamsulosin

Table 4 QoL at the end of the follow-up period. Patients were divided into two groups based on QoL results. Data from 31 patients were available for the analysis as one patient died during follow-up.

Variable	QoL score ≤3 (36 months after surgery)	QoL score >3 (36 months after surgery)	*P*
Number of patients	22	9	
Mean (SD)			
Age, years	68.40 (9.5)	70.38 (7.2)	0.309
BMI, kg/m^2	26.29 (4.4)	27.32 (3.8)	0.277
Prostate volume, mL	29.45 (7.7)	31.19	0.364
Q_{max}, mL/s	8.1 (2.2)	7.69	0.900
Median (IQR)			
Charlson Comorbidity Index	1 (0–2)	1 (1–2)	0.74
ASA score	2 (2–3)	2 (2–3)	0.611
IPSS	18 (14–23)	22 (16–23.5)	0.758
QoL score	3 (2–4)	4 (2–4)	0.240

Table 5 Early (<30 days) complications after first-generation TIND implantation. No patients had sequelae after treatment of complications.

Patient identification number and demographic data	Complication/ grade*	Management
ITA 0101 Age 69 years BMI 18.7 kg/m^2 Charlson Comorbidity Index score 3 ASA score 3 Prostate volume 25 mL	Prostatic abscess (sepsis, AF, uncontrolled glycaemia)/II	Readmission: Antibiotics (i.v.), amiodarone, insulin Postoperative stay of readmission: 10 days
ITA 0109 Age 78 years BMI 21.9 kg/m^2 Charlson Comorbidity Index score 0 ASA score 3 Prostate volume 27 mL	Urinary retention (same day of implantation)/II	Catheter positioning (immediately removed)
ITA 0119 Age 71 years BMI 27.6 kg/m^2 Charlson Comorbidity Index score 0 ASA score 2 Prostate volume 34 mL	Transient incontinence due to device displacement/III	Early (postoperative day 1) removal of device
ITA 0123 Age 71 years BMI 30.1 kg/m^2 Charlson Comorbidity Index score 4 ASA score 3 Prostate volume 39 mL	UTI/II	Antibiotics (given orally)

*AF, atrial fibrillation. *According to Clavien–Dindo classification.*

safety profile and treatment efficacy up to 1 year after treatment [20]. The procedure was simple, quick, whilst the patient was under light i.v. sedation. The implantation did not require any special equipment. During the postoperative period, no patients required adjunctive analgesic drugs, suggesting that the procedure was well tolerated. After the first cases, which were performed with extra surveillance, all the patients were discharged on the same day of the implantation and neither unplanned visits nor re-admissions were required before TIND removal (at day 5). Device removal was uneventful in all the cases and no procedure-related complications were reported. The 1-year functional results were encouraging, with a significant improvement in Q_{max}, IPSS and IPSS QoL score and discontinued medical therapy for BPH by all patients. The present report, summarising the 3-year outcomes of the same patient cohort, demonstrated continued maintained LUTS relief and safety of the TIND. More specifically, change from baseline in Q_{max} and IPSS at 24 and 36 months after treatment, were statistically significant. Whilst Q_{max} began to decline at 24 and 36 months after treatment, the changes from the 12-month time point were not significant. At 36 months after treatment, the Q_{max} values were 41% above baseline, a considerable improvement, at least comparable with other minimally invasive novel approaches, such as PUL [17]. Similarly, whilst the IPSS began to increase 24 months after surgery, the reduction from baseline was still significant and remained so until the end of the 36-month follow-up period. Moreover, none of the patients required more invasive surgeries to treat BPH symptoms in the study period, further demonstrating the effectiveness of the procedure even after 36 months.

Whilst all patients discontinued their BPH-related medical therapy after the implantation, three patients (9%) resumed therapy within 12 or 24 months of treatment. Yet, statistical analyses failed to identify any risk factor predictive of medical therapy after the TIND implantation. This could be related to the small number of events recorded in the analysed cohort. Similarly, multivariable regression analysis failed to identify any independent prognostic factor of increased Q_{max} or decreased IPSS.

A median QoL score of 2 was recorded at 24 and 36 months after treatment, suggesting that TIND implantation positively affected the QoL of the patients, a key factor when assessing a new surgical strategy for BPH treatment. No preoperative

independent prognostic factor discriminating patients with low (<3) vs high (>3) QoL scores at the close of the study, was identified. However, a dedicated multivariable model identified an IPSS of >8 at 6 weeks after the implantation as a predictor of higher QoL.

None of the 19 patients who were sexually active at enrolment reported ejaculatory dysfunction. Even though we assessed this specific point in a very simple, not standardised way, these findings are of significance, as many men consider ejaculation a basic part of their sexual activity. Thus, we believe these results are noteworthy, especially when compared with the results of other surgical approaches for BPH [27], such as TURP or laser-based interventions: these interventions lead to a 65% rate of ejaculatory dysfunction. Aside from the early complications, represented by infections (two cases) and urinary retention (one case), none of the patients reported procedure-related complications during the entire follow-up. Again, we think that this is an important point in favour of TIND implantation.

With respect to patients' satisfaction, the results of the EPIC Question 32 remained stable over the follow-up, thus suggesting that the patients were satisfied with the TIND implantation, further confirming that the procedure was well accepted by the patients.

The present study was not devoid of limitations: first, the sample size was very limited, but the study was based on the follow-up of a previously published cohort. Moreover, the reported cohort represents the first one of patients treated in the entire urological community and, to date, the data series with the highest number of enrolled patients. Secondly, the mean prostate volume was small and the effectiveness of the treatment in larger prostates remains to be determined. Thirdly, the duration of follow-up was still limited. Moreover, the observed trend toward a worsening of functional results after 24 and 36 months, with respect to previous time points, may be a sign of the need for re-intervention after a certain period of time. For this reason, patients are still being followed-up. Fourthly, no specific questionnaire to evaluate ejaculatory dysfunction was used. Finally, whilst the present study applied the first-generation TIND, a second-generation device has since become available and remains to be assessed. Nevertheless, clinical results from the first-generation device should be transferable to the second one, being that the second-generation device is of the same size, with a few minor structural differences [19]. Ongoing, multicentric studies will help us to overcome these limitations.

Conclusions

This extended follow-up of the first cohort of patients undergoing TIND therapy, corroborated our previous findings, which showed that TIND implantation is safe, effective and well tolerated for at least 36 months. Further studies are required to assess the durability of TIND results over a longer follow-up, to better define the indications of this approach, and to demonstrate the advantages of the second-generation device over the first.

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None.

Conflict of Interest

None of the authors has anything to disclose.

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Abbreviations: 5-ARI, 5α-reductase inhibitor; ASA, American Society of Anesthesiologists; BMI, body mass index; EPIC, Expanded Prostate Cancer Index Composite; IQR, interquartile range; PUL, prostatic urethral lift; Q_{max}, maximum urinary flow rate; QoL, quality of life; TIND, temporary implantable nitinol device; VAS, visual analogue pain scale.