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Original Article

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Magnetic resonance imaging-guided transurethral ultrasound ablation for benign prostatic hyperplasia: 12-month clinical outcomes of a phase I study

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Objectives

To investigate the safety and feasibility of magnetic resonance imaging (MRI)-guided transurethral ultrasound ablation (TULSA) for the treatment of benign prostatic obstruction (BPO).

Patients and methods

An investigator-initiated, prospective, registered (NCT03350529), phase I study enrolled men with lower urinary tract symptoms due to benign prostatic hyperplasia in need of surgical intervention. Patients were followed for 12 months after TULSA. Uroflowmetry, prostate-specific antigen (PSA) level, and a comprehensive set of functional questionnaires including the Expanded Prostate cancer Index Composite-26, International Prostate Symptom Score (IPSS) and five-item version of the International Index of Erectile Function were obtained at baseline and every 3 months afterwards. MRI was obtained at baseline, and at 3 and 12 months after TULSA. Medication use before and after TULSA were recorded. Adverse events (AEs) were reported using the Clavien–Dindo classification.

Results

A total of 10 men underwent TULSA with no severe AEs encountered. The baseline median (interquartile range [IQR]) age and prostate volume were 68 (63–72) years and 53 (45–66) mL, respectively. At baseline, six patients were moderately symptomatic and four patients severely symptomatic. Nine patients at baseline were on BPO medication. The median (IQR) improvement in the IPSS was 82%, from 17.5 (15.3–23.0) at baseline to 4.0 (2.3–6.3) at 12 months. Similarly, the median maximum urinary flow rate improved by 101%, from a median (IQR) of 12.4 (8.8–17.6) mL/s at baseline to 21.8 (17.6–26.5) mL/s at 12 months. Improvements were already seen at 3 months. The median prostate volume and PSA reduction at 12 months were 33% and 48%, respectively. There were no changes in continence, sexual, erectile or bowel functions. At 12 months, five out of six men with normal ejaculatory function before TULSA reported normal antegrade ejaculations. All patients taking BPO medication before TULSA discontinued medication after TULSA.

Conclusion

TULSA appears to be a safe and effective treatment for BPO, with promising 12-month follow-up outcomes. Further studies with larger cohorts are needed to confirm the observed results.

Keywords

benign prostatic hyperplasia, benign prostatic obstruction, LUTS, MRI-guided, transurethral ultrasound ablation, TULSA, #UroBPH

Introduction

Many men have LUTS due to benign prostate obstruction (BPO) caused by BPH [1]. When conservative treatment fails and surgical intervention is indicated, the current 'gold standard' is TURP or endoscopic enucleation of prostate [2].

TURP is currently the most common endoscopic procedure with proven effectiveness [2]. However, TURP carries a risk of adverse events (AEs), which increase with age [3] including UTI, clot retention, re-catheterisation, blood transfusion due to bleeding, urinary incontinence and sexual dysfunction, among others [4, 5].

Compared to TURP, holmium laser enucleation of the prostate (HoLEP) can treat larger prostates and provides a similar therapeutic effect with comparable safety profile but with reduced catheterisation and hospitalisation times, as well as lower re-intervention rates. Both TURP and HoLEP carry a high risk of retrograde ejaculation [4–7]. Other typical AEs for HoLEP include bladder injury, capsular perforation, dysuria and urinary urgency [6, 8]. HoLEP is preferred for patients already receiving anticoagulants. However, HoLEP is a demanding procedure with a rather long learning curve, and it is associated with longer operation time than TURP [4, 6, 7].

Other minimally invasive techniques have been used for BPO treatment including transurethral microwave thermotherapy [9, 10], prostatic urethral implants and nitinol butterfly-like stent (e.g. UroLift and iTIND [Temporarily Implanted Nitinol Device]), water vapour thermal therapy, Aquablation, and prostate artery embolisation [11]. These treatment methods are not as effective and durable as TURP [9–11] and most of them lack long-term follow-up data [11].

A novel treatment method is MRI-guided transurethral ultrasound ablation (TULSA), which combines real-time MRI guidance, transurethral-delivered high-intensity directional ultrasound and closed-loop temperature feedback control to provide customisable prostate ablation. Active cooling of the prostatic urethra and rectum spares these organs from thermal injury. TULSA has primarily been investigated for the ablation of localised prostate cancer (PCa) [12, 13], demonstrating good efficacy with low toxicity and an ability to treat large prostates up to 125 mL [13]. More recently, TULSA has been investigated for salvage treatment of radiorecurrent PCa [14] and palliative treatment of locally advanced PCa [15]. Results from a retrospective subgroup analysis of nine men with localised PCa and concurrent symptomatic BPO who underwent TULSA showed encouraging results, reporting an 89% improvement in IPSS and quality of life (QoL), and preservation of antegrade ejaculations in eight out of nine patients at 12 months after TULSA [16], although the few patients and retrospective study design makes it difficult to draw any firm conclusions.

For these reasons we designed the first prospective study to evaluate TULSA for the treatment of BPO.

Patients and Methods

Study Design

This was an investigator-initiated, prospective, non-randomised, single-arm and single-centre Phase I study (ClinicalTrials.gov identifier NCT03350529). A limited number of patients were therefore included and no comparative arm was used. The study was approved by the local Ethics Committee and was conducted in accordance with the principles of the Declaration of Helsinki. Written informed consent was obtained from all participants.

Patients

Men with symptomatic BPO due to BPH and previously scheduled for primary TURP were enrolled in the study. Study eligibility included men with predominantly enlarged transition zones who were screened using TRUS, cystoscopy, and prostate MRI. Exclusion criteria included evidence of PCa, presence of calcifications or prostate cysts of >1 cm in diameter, any contraindications for MRI (claustrophobia, pacemaker etc.), hip replacement surgery or other metal in the pelvic area.

Study Intervention

Patients were treated using the TULSA system (Profound Medical Inc., Mississauga, Ontario, Canada) [12]. A detailed description of the TULSA procedure is provided in Appendix S1. The ablation was planned to cover the adenomatous tissue in the transition zones, with as much extension into the bladder neck as possible. All treatments were conducted under general anaesthesia.

Follow-up and Assessment

Safety was assessed by recording the frequency and severity of AEs using the Clavien–Dindo Classification for Surgical Complications [17]. Treatment effect was assessed with uroflowmetry (maximum urinary flow rate [Q_{max}], average flow rate, post-void residual [PVR] measurement), PSA level, MRI-measured prostate volume, and a comprehensive set of functional status and QoL questionnaires at baseline and at 3, 6, 9, and 12 months after TULSA. The collected questionnaires included the IPSS and QoL, Danish Prostatic Symptom Score (DAN-PSS), Expanded Prostate cancer Index Composite-26 (EPIC-26), five-item version of the International Index of Erectile Function (IIEF-5), and International Consultation on Incontinence Questionnaire - Short Form (ICIQ-SF). Erectile function was further evaluated by isolating specifically IIEF-5 Question 2 (Q2), which measures quality of the erections

regardless of whether the patient is having intercourse or not. Additional qualitative information on ejaculatory function was collected at 12 months. Catheter removal and an initial voiding trial was planned 2 weeks after TULSA. Prostate MRI was performed at 3 and 12 months after TULSA. Medication use before and after TULSA was monitored. Cystoscopy was performed at 12 months.

Statistical Analysis

Statistical analyses were conducted in Excel for medians and interquartile ranges (IQRs), and in R (v.3.6.3; R: A language and environment for statistical computing. R Foundation for Statistical Computing, Vienna, Austria) for statistical significance. To evaluate statistical significance, we used a paired Wilcoxon signed-rank test between the baseline and 12-month follow-up data that was available for the eight participants completing the follow-up period. Continuity correction was used for the discrete variables (functional status and QoL questionnaire data), but not for the continuous variables (PSA level, prostate volume, uroflowmetry). As Wilcoxon is not suited for data that is limited by the extremes of possible data range at baseline, *P* values are not reported for the IIEF-5 and IIEF-5 Q2, although they are accounted for when calculating the multiple test correction.

A permutation/re-sampling-based algorithm was used to adjust *P* values for multiple comparisons. The algorithm was used to generate a null distribution of *P* values using all time-point-label permutations of baseline and 12-month follow-up time-points for each participant. The distribution of minima of *P* values for each round of permutation was used as a quantile function to define corrected *P* values.

The full R code for statistical analyses and a more detailed description on *P* value adjustments is available online [18].

Results

Patient Characteristics

The study flow chart is presented in Fig. 1. A total of 10 patients underwent TULSA treatment, and eight of them completed their 12-month follow-up. For two patients, follow-up was discontinued due to a PCa diagnosis.

Characteristics of the study population are presented in Table 1. The median (IQR) age at baseline was 68 (63–72) years, body mass index was 26 (24–30) kg/m^2 and Charlson Comorbidity Index 2 (2–3), with all patients having normal performance status. The median (IQR) PSA level and prostate volume at baseline were 3.4 (2.1–6.3) μg/L and 53 (45–66) mL, respectively.

Before TULSA nine patients were using medication to treat their urinary symptoms (Table 1). At baseline, the median (IQR) IPSS symptom score was 17.5 (15.3–23.0), IPSS QoL 4 (2.8–5.3), Q_{max} 12.4 (8.8–17.6) mL/s and PVR 79 (40–384) mL. Based on IPSS symptom score, even with the benefit of medication, four patients were severely (IPSS 20–25) and six moderately (IPSS 9–19) symptomatic. Two patients were taking ongoing antithrombotics (first patient: acetylsalicylic acid, second patient: acetylsalicylic acid/dipyridamole), which were not discontinued.

Baseline prostate MRI images for every study patient are presented in Fig. S1. One patient who harboured a single subcapsular peripheral zone Prostate Imaging-Reporting and Data System (PI-RADS) 4 lesion suspicious for PCa was included in the study after negative systematic and targeted biopsy findings. The TULSA ablation plan of this patient did not cover the PI-RADS 4 lesion.

Procedural Outcomes

The treatment planning and delivered ablation images for every study patient are presented in Fig. S2. The median (IQR) planned ablation volume and sonication time were 31 (26–35) mL and 53 (41–66) min, respectively (Table 1). Nine patients had a suprapubic catheter during the procedure, while one patient received a transurethral catheter afterwards. All patients were discharged on the first postoperative day, with a median (IQR) catheterisation time of 16 (14–17) days. At discharge, patients were prescribed paracetamol and/or NSAIDs for use as needed. None of the patients required additional analgesics or other medication.

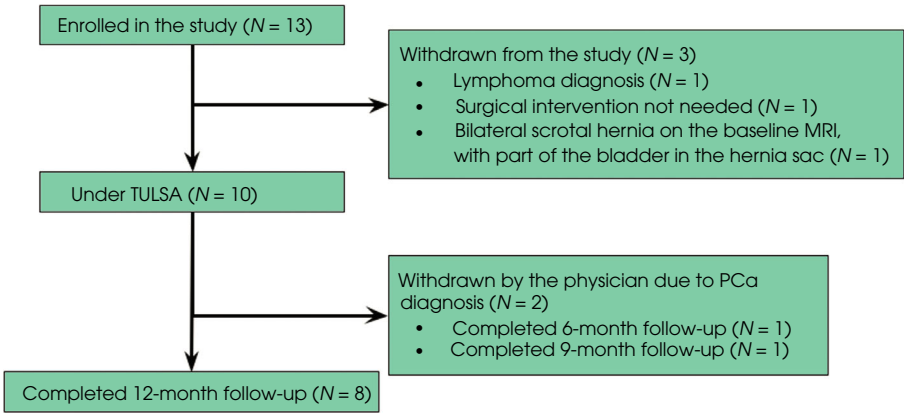
Safety Outcomes

There were four AEs in three patients, which all resolved by the first 3-month follow-up visit. In one patient, an abscess of the epididymis required drainage under general anaesthesia (Grade IIIb) 2 weeks after TULSA. Another patient had prolonged catheterisation (Grade I) and subsequent UTI resolving with oral antibiotics (Grade II). One patient developed urinary retention after removal of a suprapubic catheter treated with a short-term Foley catheterisation (Grade I). There were no bowel-related AEs of any grade. The 12-month cystoscopy revealed patency of the entire urethra in all patients with no strictures. During the 12-month follow-up, one patient received overactive bladder medication (mirabegron) for urinary urgency, which he had used for the same indication before participating in this study. Otherwise, no new medications affecting urinary or sexual function were needed.

Uroflowmetry Outcomes

A summary of uroflowmetry results is shown in Fig. 2. The median (IQR) Q_{max} improved from 12.4 (8.8–17.6) mL/s at baseline to a 3-month value of 24.9 (20.0–33.0) mL/s and was

Fig. 1 Study flowchart. Study patients were identified for this study by the Department of Urology at the Turku University Hospital. Out of 13 screened patients 10 received TULSA. For two patients, follow-up was discontinued due to a PCa diagnosis.



21.8 (17.6–26.5) mL/s at 12 months. This corresponded to a median Q_{max} increase of 101% at 12 months, despite discontinuation of BPO medication in all nine patients receiving BPO medication before TULSA. Compared to baseline, median increases in average flow rate and voided volume were 67% and 20% at 12 months, respectively. In all four patients with significant PVR (PVR >200 mL) at baseline, the PVR decreased substantially as early as 3 months after TULSA, remaining stable at the latest follow-up visit. In other patients, PVR remained stable throughout the follow-up.

QoL Outcomes

A summary of patient-reported functional status and QoL questionnaire responses at baseline, and 3 and 12 months after TULSA are presented in Table 2. The median (IQR) IPSS improved from 17.5 (15.3–23.0) at baseline to a 3-month value of 4.0 (2.8–8.5) and remained 4.0 (2.3–6.3) at 12 months, corresponding to a median reduction of 82% at 12 months. The median (IQR) IPSS QoL improved from 4.0 ('mostly dissatisfied') (2.8–5.3) at baseline to 1.0 ('pleased') (0.0–2.3) at 3-months and 0.5 ('delighted-pleased') (0.0–1.0) at 12 months. On a patient-specific level, all seven men who reported 'mostly dissatisfied' or worse at baseline improved to 'delighted' or 'pleased'. The three men who reported an IPSS QoL of either 'mixed' or 'mostly satisfied' at baseline also improved to 'delighted' or 'pleased'.

Other urinary function questionnaires (DAN-PSS and EPIC-26-Urinary domain) had similar trends. Improvements were already seen at 3 months and remained stable at 12 months. All patients had normal urinary continence (leak-free, pad-free) (EPIC26-Urinary incontinence and ICIQ-SF) throughout the 12-month follow-up. No changes were observed in sexual, erectile (EPIC-26-Sexual domain, IIEF-5, and IIEF-5 Q2) or bowel functions (EPIC-26-Bowel domain). Five out of six men with normal ejaculatory function before TULSA reported normal antegrade ejaculations at 12 months (Fig. 3).

Imaging and PSA Outcomes

There was a reduction in the PSA level and prostate volume during the follow-up in all patients (Fig. 2). The median (IQR) prostate volume decreased from 53 (45–66) mL at baseline to 3-month value of 37 (30–40) mL and 32.5 (31–40) mL at 12 months, corresponding to median reduction of 33% at 12 months.

The median (IQR) PSA level improved from 3.4 (2.1–6.3) μg/L at baseline to a 3-month value of 1.8 (1.2–2.4) μg/L and 1.8 (0.9–3.4) μg/L at 12 months, corresponding to median reduction of 48% at 12 months.

Two patients failed to complete their 12-month follow-up due to a PCa diagnosis during the follow-up. The follow-up was discontinued at 6 and 9 months after TULSA because they sought additional PCa therapy. In both cases the lesions were in the peripheral zone and fell outside of the planned BPO TULSA ablation volume.

Significance Analysis

Before multiple test correction, nine out of 18 outcome measures had a statistically significant improvement ($P < 0.05$) at 12 months. After performing multiple test correction, three of the outcomes reached statistical significance: prostate volume reduction ($P = 0.03$), DAN-PSS storage ($P = 0.039$) and DAN-PSS voiding ($P = 0.031$).

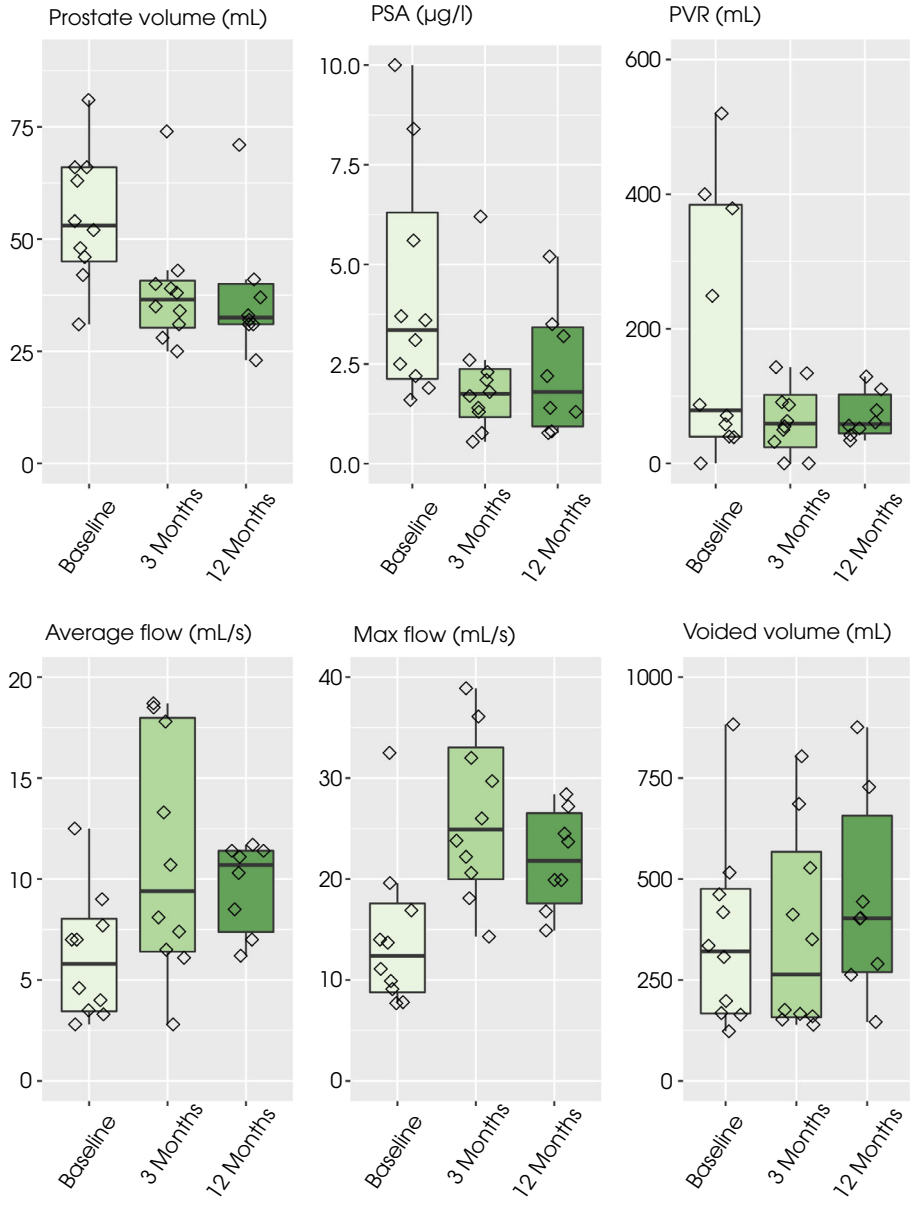
Discussion

Our present study is the first prospective study to evaluate TULSA as a primary treatment for BPO, and our results indicate TULSA is a safe and feasible therapy option for BPO

Table 1 Patient characteristics and procedural outcomes.

Patient number	Age, years	Prostate volume, mL	PSA, μg/L/% free PSA	Relevant medication	Sonication time, min	Planned ablation volume, mL	Duration of catheterisation, days	Hospitalisation, h	AEs (Clavien–Dindo), comments
1	72	46	2.5/35	Tamsulosin	25	31	20	24	Prolonged catheterisation (Grade I), UTI requiring hospitalisation (Grade II).
2	63	48	1.9/17	Dutasteride/tamsulosin	65	31	9	24	-
3	56	42	3.7/18	Dutasteride/tamsulosin	57	34	16	14	-
4	72	66	8.4/7	Dutasteride/tamsulosin	58	31	16	24	Abscess of the epididymis requiring drainage under general anaesthesia (Grade IIIb), PCa diagnosis at 9 months.
5	68	66	10.0/15%	None (finasteride discontinued due to side effects)	72	28	16	24	-
6	68	81	2.2/25%	Dutasteride/tamsulosin, acetylsalicylic acid	67	36	16	48	Patient had discontinued mirabegron for urinary urgency prior to enrolment.
7	65	31	1.6	Tamsulosin	36	15	9	24	Ejaculatory ducts excluded from the ablation area.
8	73	52	3.1/7	Dutasteride/tamsulosin, acetylsalicylic acid/dipyridamole	42	22	16	24	PCa diagnosis at 6 months.
9	69	63	3.6/15	dutasteride/tamsulosin	45	38	16	24	-
10	63	54	5.6/8	dutasteride/tamsulosin	48	29	65	24	Urinary retention (Grade I), Prolonged catheterisation due to urinary retention.

Fig. 2 Measurable outcomes at baseline, 3 and 12 months. Boxplot: median and IQR values. Whiskers: minimum and maximum values, except for outlier data points. Prostate volume and PSA level reduction are seen already at 3 months, together with clear improvement in uroflowmetry values. Nine of 10 patients used medication for their urinary symptoms at baseline, and none after the treatment.



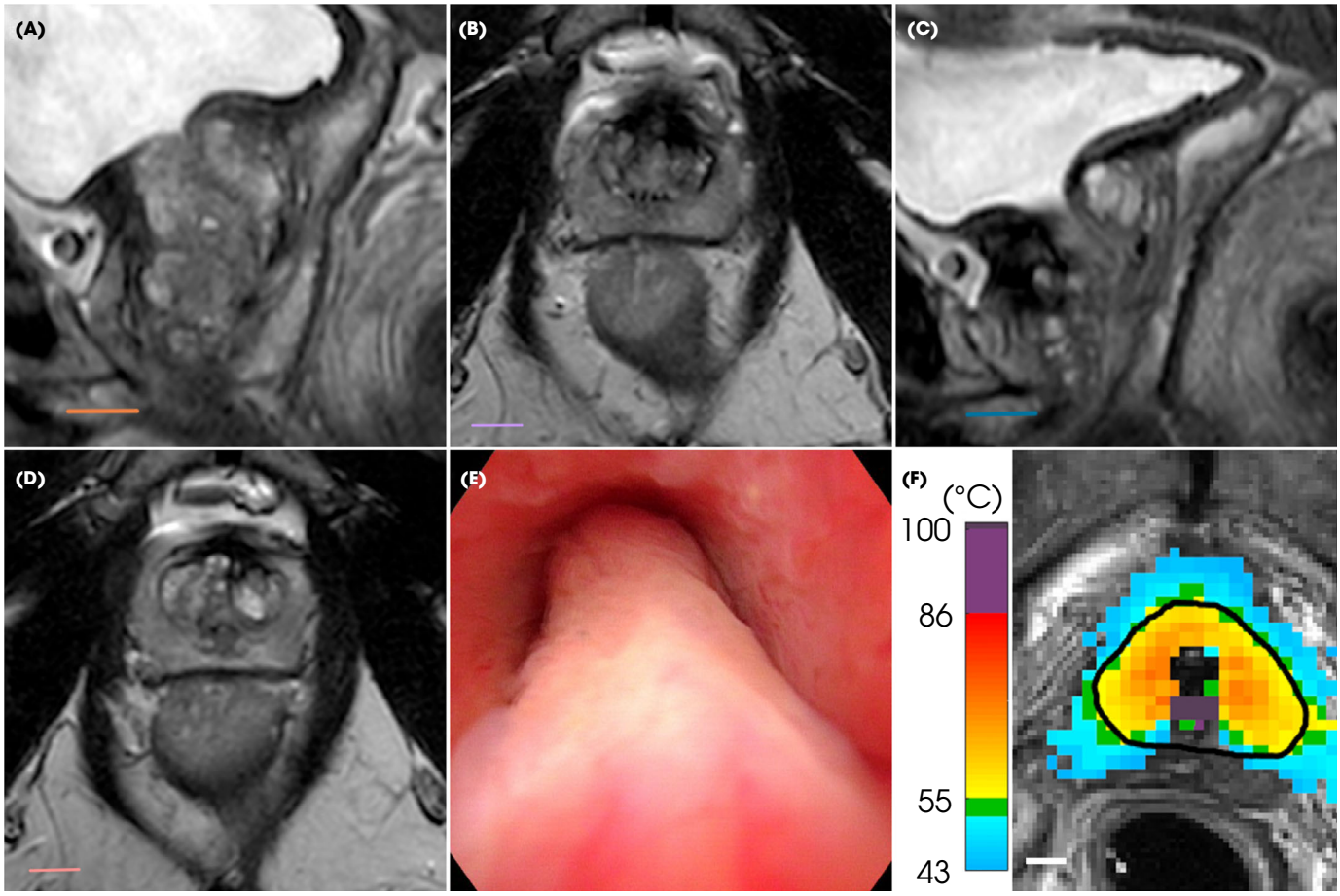
with promising clinical outcomes. Uroflowmetry and validated questionnaires scores improved substantially, with benefits observed already at 3 months and remaining durable to 12 months. Notable median improvements of 101%, 67% and 82% for Q_{max}, average flow rate and IPSS were observed, which compares favourably with TURP [2, 4].

All nine patients taking medication for urinary symptoms at baseline discontinued medication after TULSA, which carried through to the final follow-up visit. At the 12-month post-TULSA visit, one patient was prescribed overactive bladder medication for urinary urgency. Noteworthy is that this same patient had already been taking medication for similar symptoms before TULSA, suggesting he may have had overactive bladder syndrome in addition to BPO. On the other hand, urinary urgency can also be related to the TULSA treatment. It is known that patients commonly have urinary urgency after TURP or HoLEP procedures [4]. No other medication affecting urinary or sexual function was prescribed. Two patients did not discontinue antithrombotics before TULSA, a promising sign as many patients who have symptomatic BPO are older and have comorbidities.

Table 2 QoL outcomes.

	Median (IQR)				
Questionnaire	**Baseline**	**3 months**	**6 months**	**9 months**	**12 months**
IPSS symptoms	17.5 (15.3–23.0)	4.0 (2.8–8.5)	3.5 (1.0–5.3)	3.0 (2.0–5.0)	4.0 (2.3–6.3)
IPSS QoL	4.0 (2.8–5.3)	1.0 (0.0–2.3)	1.0 (0.0–1.0)	1.0 (0.0–2.0)	0.5 (0.0–1.0)
DAN-PSS voiding	12.5 (8.8–16.8)	2.0 (0.0–3.0)	2.0 (0.0–2.3)	1.0 (0.0–5.8)	0.5 (0.0–1.8)
DAN-PSS storage	9.0 (7.5–13.0)	3.5 (1.0–5.3)	2.5 (1.0–3.3)	1.0 (1.0–4.0)	1.0 (1.0–2.8)
ICIQ-SF	5.5 (0.0–9.3)	0.0 (0.0–6.0)	0.0 (0.0–1.5)	0.0 (0.0–0.5)	0.0 (0.0–2.0)
IIEF-5	24.0 (7.0–25.0)	24.0 (13.5–25.0)	22.0 (7.0–25.0)	25.0 (23.3–25.0)	22.5 (14.5–25.0)
IIEF-5 Q2	5.0 (2.5–5.0)	5.0 (4.0–5.0)	5.0 (3.0–5.0)	5.0 (4.3–5.0)	4.5 (4.0–5.0)
EPIC-26–Urinary incontinence	85.5 (69.9–91.8)	100.0 (82.4–100.0)	93.8 (92.2–100.0)	100.0 (92.8–100.0)	100.0 (82.9–100.0)
EPIC-26–Urinary irritative/obstructive	56.3 (56.3–78.1)	93.8 (84.4–100.0)	93.8 (87.5–95.3)	100.0 (90.6–100.0)	96.9 (93.8–100.0)
EPIC-26–Bowel	87.5 (77.1–95.8)	95.8 (93.8–100.0)	100.0 (91.7–100.0)	95.8 (93.8–100.0)	100.0 (91.7–100.0)
EPIC-26–Sexual	66.7 (79.2–79.2)	70.8 (84.4–84.4)	68.8 (80.2–80.2)	83.3 (87.5–87.5)	77.1 (87.5–87.5)
EPIC-26–Hormonal	95.0 (67.5–100.0)	92.5 (83.8–100.0)	97.5 (88.8–100.0)	100.0 (90.0–100.0)	100.0 (91.3–100.0)

Fig. 3 BPO case example. Case 7. Patient specifically requested during consultation that his ejaculatory ducts should be spared to avoid retrograde ejaculation. This request was incorporated into the treatment plan. After TULSA this patient retained antegrade ejaculations. (**A**) Pre-treatment T2 axial. (**B**) Pre-treatment T2 sagittal. (**C**) 12-month T2 axial. (**D**) 12-Month T2 sagittal. (**E**) 12-month cystoscopy of the prostatic urethra. (**F**) Treatment time axial thermal map showing the ejaculatory duct-sparing ablation pattern, with no heating in the posterior segment. Scale bars of 1 cm are shown in the corners.



Four expected AEs were reported across 10 patients, including UTI, epididymitis, urinary retention, and prolonged catheterisation. All completely resolved at the 3-month follow-up and were comparable in severity and frequency to those encountered after TURP or other minimally invasive techniques [4, 19–23]. An incision of the abscess in the

epididymis performed under general anaesthesia was the only Grade III AE reported. There was no perioperative bleeding or bleeding with urination throughout the 12-month follow-up. Furthermore, there were no late complications such as urethral or bladder neck strictures during 12-month follow-up. Although rare, these complications have been reported after TURP and other tissue removal surgical techniques [4, 22].

The role of MRI in the TULSA procedure, both for treatment planning and real-time monitoring of the ablation, gives it an inherent advantage over existing methods regarding safety and toxicity. Importantly, minimal toxicity of the TULSA procedure to genitourinary organs was demonstrated, with all patients remaining leak-free and pad-free at 12 months and no reported changes in erectile or bowel functions.

In addition to potential safety and toxicity benefits, the customisation of TULSA may also be leveraged to positively influence functional outcomes and incorporate patient wishes. One patient specifically requested during consultation that his ejaculatory ducts should be spared to avoid retrograde ejaculation (Fig. 3). This request was incorporated into the treatment plan and proved successful. However, it is difficult to ascertain the causal relationship, as only one patient received this treatment plan. Moreover, of the five other patients with antegrade ejaculation at baseline, four retained it despite having their ejaculatory ducts directly ablated. Another potential benefit of TULSA is that it can be used as a combined therapy for localised PCa and symptomatic BPO, where the dominant index lesion and the obstructive adenomatous tissue could be ablated in the same treatment session [16]. More investigation is warranted for these applications.

The relatively long 2-week catheterisation time and mandatory overnight stay after TULSA was established *a priori* and based on existing literature [12, 13]. However, we see room for improvement. In one patient, the suprapubic catheter was already successfully removed 1 week after TULSA, with no issues encountered thereafter. Furthermore, in our previous treat-and-resect trial where six patients underwent lesion-targeted TULSA for PCa, the transurethral catheter was successfully removed 2–3 days after TULSA in all patients [24]. Patients in the present study were hospitalised overnight to ensure close follow-up and monitoring; however, same-day discharge has been successfully demonstrated [12, 13, 24].

Study limitations include the low number of participants, lack of control group, and absence of randomisation. Nevertheless, there was a statistically significant improvement in several outcome measures, which is promising given the small sample size. Limitations of the TULSA procedure in the present study included prolonged MRI-suite occupation, need for patient transfer to and from the MRI-suite, requirement for general anaesthesia with MR-compatible anaesthesia equipment, and relative technical complexity of the device. These factors all affect the cost of the procedure.

To confirm the effectiveness of TULSA, we see the need for further studies with larger cohorts.

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Data Availability Statement

De-identified data will be available for anyone who wishes to access it for a period commencing with publication and ending 5 years later. Proposals for access to the data should be directed to sara.karnell@tyks.fi. Requesters will need to sign a data access agreement.

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University hospital of Turku urology and radiology departments have received an unrestricted educational grant from Profound Medical Inc., which enabled us to conduct this trial in accordance with our own predefined protocol. Our study was planned and implemented solely by the clinical authors.

Conflict of Interest

Peter J. Boström has received honorarium from Profound Medical Inc. Cameron Wright is employed by Profound Medical Corp. and a PhD student at the University of Turku. Other authors have no conflicts of interest to declare.

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Abbreviations: AE, adverse event; BPO, benign prostatic obstruction; DAN-PSS, Danish Prostatic Symptom Score; EPIC-26, Expanded Prostate cancer Index Composite-26; HoLEP, holmium laser enucleation of the prostate; ICIQ-SF, International Consultation on Incontinence Questionnaire - Short Form; IIEF-5, five-item version of the International Index of Erectile Function; IQR, interquartile range; PCa, prostate cancer; PVR, post-void residual; Q2, Question 2; Qmax, maximum urinary flow rate; QoL, quality of life; TULSA, transurethral ultrasound ablation.

Supporting Information

Additional Supporting Information may be found in the online version of this article:

Appendix S1. Description of the TULSA procedure.
Fig. S1. T2 prostate MRI for each patient before treatment and at 12 months after treatment.
Fig. S2. Treatment planning.