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Image-guided, urethra-sparing transperineal radiofrequency ablation for benign prostatic hyperplasia: a prospective bicenter outpatient study

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PURPOSE

To evaluate the feasibility, reproducibility, and clinical outcomes of an image-guided, urethra-sparing transperineal radiofrequency ablation (TPTA) strategy for benign prostatic hyperplasia (BPH) in an outpatient interventional radiology setting.

METHODS

This was a prospective, bicenter, non-randomized study of consecutive men with moderate-to-severe lower urinary tract symptoms (LUTS) refractory or intolerant to medication treated with ultrasound-guided, urethra-sparing TPTA. Outcomes included the International Prostate Symptom Score (IPSS), quality of life, maximum urinary flow rate (Qmax), post-void residual volume (PVR), prostate volume, prostate-specific antigen (PSA), and ejaculatory function [assessed using the Male Sexual Health Questionnaire–Ejaculatory Dysfunction Short Form (MSHQ-EjD-SF)]; complications were graded using the Clavien–Dindo classification. The primary endpoint was a 12-month change in ejaculatory function; secondary endpoints included composite clinical response (≥ 30% IPSS reduction without retreatment) and urinary and structural changes.

RESULTS

At 12 months, clinically meaningful improvements were observed across patient-reported symptoms and concordant objective functional and anatomical parameters in a carefully selected outpatient cohort. The median IPSS decreased from 19.5 at baseline to 5.0 at 6 months and 4.0 at 12 months ($P < 0.001$), accompanied by sustained increases in the Qmax and reductions in PVR, prostate volume, and PSA (all $P < 0.001$). Among sexually active men, MSHQ-EjD-SF function scores remained stable during the follow-up period, and antegrade ejaculation was preserved in 90% of patients. The composite clinical response rate (≥ 30% IPSS reduction without retreatment) was 97.1% at both 6 and 12 months, with no device-related Clavien–Dindo ≥ III complications observed.

CONCLUSION

These findings suggest that image-guided, urethra-sparing TPTA is a reproducible outpatient interventional radiology procedure capable of achieving clinically meaningful symptom relief while preserving ejaculatory function, supporting further comparative and multicenter evaluation.

CLINICAL SIGNIFICANCE

Urethra-sparing TPTA has proven to be a safe, feasible, and effective treatment for LUTS and may represent a minimally invasive and effective alternative for BPH.

KEYWORDS

Benign prostatic hyperplasia, minimally invasive surgical therapy, transperineal radiofrequency ablation, urethra-sparing technique, ejaculatory function preservation, outpatient procedure

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Benign prostatic hyperplasia (BPH) is a leading cause of lower urinary tract symptoms (LUTS) in aging men, substantially impairing quality of life (QoL) and generating substantial healthcare costs.[1] Although transurethral resection of the prostate remains the gold standard, minimally invasive surgical therapies have been developed to reduce morbidity.[2]

Transurethral options such as prostatic urethral lift and water-vapor thermal therapy (Rezūm) provide symptom relief but require urethral instrumentation, which may contribute to discomfort and ejaculatory dysfunction (EjD).[3] By contrast, urethra-sparing approaches aim to preserve periurethral structures and potentially maintain sexual function while ensuring durable outcomes.[4]

However, systematic evaluation of ejaculatory function following urethra-sparing procedures in Western populations is limited, and few studies have incorporated validated tools such as the Male Sexual Health Questionnaire–EjD Short Form (MSHQ-EjD-SF).[5,6] We therefore report the 12-month clinical, functional, and safety outcomes of ultrasound-guided transperineal radiofrequency ablation (TPTA) performed in an outpatient bicenter cohort.

From an interventional radiology perspective, minimally invasive treatments for BPH have progressively shifted toward image-guided, tissue-selective approaches that prioritize procedural safety, anatomical precision, and functional preservation. In this context, transperineal access under real-time ultrasound guidance enables direct targeting of adenomatous tissue while avoiding urethral instrumentation, potentially reducing periurethral injury and preserving ejaculatory pathways. However, prospective data evaluating the reproducibility and functional profile of urethra-sparing, image-guided TPTA in routine outpatient practice remain limited.

Main points

- Urethra-sparing transperineal radiofrequency ablation preserves urological and sexual function.
- This strategy represents a treatment option for benign prostatic hyperplasia.
- This treatment option provides an alternative for patients otherwise ineligible for standard treatments.

Methods

Study design and rationale

This study was conceived as a pragmatic, prospective, bicenter cohort evaluating the feasibility, safety, and functional outcomes of a urethra-sparing, ultrasound-guided TPTA strategy in routine outpatient practice. Given the early clinical adoption phase of this technique, a non-comparative design was intentionally selected to prioritize procedural safety, technical reproducibility, and patient-reported functional outcomes before formal comparative evaluation against established surgical or minimally invasive therapies. All procedures complied with institutional and national standards and the 1964 Declaration of Helsinki, and written informed consent was obtained from all participants. This study was approved by Institutional Review Board of Paulista School of Medicine – Federal University of São Paulo (UNIFESP) (protocol number: CAAE: 74939723.1.0000.5505, date: 20.02.2024)

Participants

Consecutive men aged ≥ 50 years with moderate-to-severe LUTS [International Prostate Symptom Score (IPSS) ≥ 8] who were refractory or intolerant to medication or dissatisfied with α-blockers or 5α-reductase inhibitors (5-ARIs) were included. Additional requirements were a prostate volume of 30–200 mL on transrectal ultrasound or multiparametric magnetic resonance imaging (mpMRI) and a maximum urinary flow rate (Qmax) < 15 mL/s or catheter dependence despite medication. Prostate-specific antigen (PSA) levels were generally < 4 ng/mL, with higher values permitted when prostate cancer was excluded (mpMRI/biopsy). Exclusion criteria included known or suspected prostate cancer, neurogenic bladder, urethral stricture, bladder stones, or uncontrolled systemic disease. Baseline assessment comprised the IPSS, QoL, PSA, uroflowmetry, post-void residual volume (PVR), and prostate imaging. Demographics, American Society of Anesthesiologists class, comorbidities, medication use, and intravesical prostatic protrusion (IPP), when present, were recorded (Figure 1). At baseline, two patients (5.9%) had an indwelling urinary catheter. Given this very small number, no stratified subgroup analysis was prespecified or performed.

Preliminary 3-month outcomes from an earlier phase of this prospective cohort have been reported previously. The present manuscript reports the planned extended follow-up of the same cohort up to 12 months and includes additional longitudinal analyses and outcomes not available in the prior report.

Procedure

After sedation, the patient was placed in the lithotomy position (Figure 2a), and the perineum was prepared and draped under sterile conditions. The Aplio A ultrasound system (Canon Medical Systems Co., Ltd., Otawara, Tochigi, Japan) with a high-frequency biplanar end-fire probe was used in all procedures. With the patient under sedation, the probe was gently inserted into the anal canal for continuous prostate visualization, and the gland was assessed for morphology, echogenicity, capsule integrity, prostate volume, and its relationship with the bladder wall. After ultrasound documentation, a 20G × 20 cm needle was advanced under transperineal ultrasound guidance to perform bilateral perineal nerve block with 5 mL of 1% lidocaine per side, followed by an additional 5 mL per side for periprostatic nerve block. A 17G radiofrequency ablation (RFA) probe with a 10-mm active tip (Amica, HS Hospital Service S.p.A., Italy) was then positioned in the anterosuperior transition zone unilaterally (Figure 2b). For safety, ablation was always performed at a distance of at least 5 mm from the urethra and bladder floor to reduce the risk of stenosis, retrograde ejaculation, and cystitis. The RFA probe was powered at 40 W, and the needle was slowly pulled caudally, allowing real-time visualization of tissue vaporization. After completing ablation on one side of the transition zone, the procedure was repeated contralaterally. The device parameters, periprocedural medications, and discharge criteria are summarized in Table 1.

Postprocedure and follow-up

Routine catheterization was avoided. Acute urinary retention (AUR) was defined as the inability to void within 2 h with discomfort or PVR > 300 mL and was managed with temporary catheterization. Patients were discharged the same day per standard ambulatory criteria. Follow-up at 1, 3, 6, and 12 months included the IPSS, QoL, Qmax, PVR, PSA, prostate volume, ejaculatory function, adverse events, and medication changes. Complications were graded using the modified Clavien–Dindo classification.

Postprocedural contrast-enhanced ultrasound (CEUS) was performed to assess early ablation-related perfusion changes. CEUS

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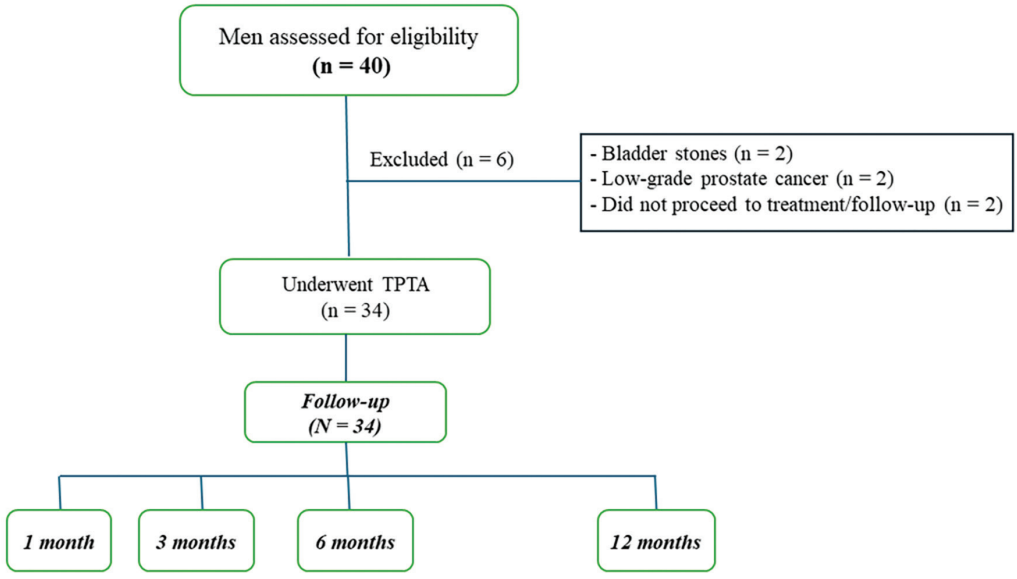


Figure 1. Flowchart of study population selection. TPTA, transperineal radiofrequency ablation.

Table 1. Periprocedural devices, medications, and parameters by center

Item	Center 1	Center 2	Notes
TRUS platform/probe	Aplio A-series, biplanar end-fire	Aplio A-series, biplanar end-fire	Equivalent resolution and needle-tracking workflow
Access needle	17G transperineal introducer	17G transperineal introducer	
RF generator	Commercial unit (HS Hospital Service Amica RF)	Commercial unit (STARmed)	Both temperature-controlled
RF electrode	Internally cooled monopolar, 10-mm active tip	Internally cooled monopolar, 10-mm active tip	Same geometry across centers
Irrigation/pump	Peristaltic pump (continuous saline)	Peristaltic pump (continuous saline)	Maintains tip temperature < 60 °C
Typical power range	70–150 W	35–70 W	Tailored to gland size and tissue response
Urethral safety margin	≥ 5 mm from urethra/bladder neck	≥ 5 mm from urethra/bladder neck	Mandatory criterion for adequacy
Sedation	Midazolam 1–3 mg IV + fentanyl 25–100 µg IV	Same	Titrated to moderate sedation
Local anesthesia	1% lidocaine 10–20 mL/side periprostatic	Same	Field block
Antimicrobial prophylaxis (cohort)	Levofloxacin 750 mg PO q24h from −48 h to +7 d	Same	Legacy regimen used in this series
Current prophylaxis (policy)	Cefazolin 1–2 g IV single dose (± ≤ 48 h extension per risk)	Same	Preferred for future cases; culture-guided
Ancillary meds (cohort)	Tamsulosin 0.4 mg qd + prednisone 20 mg qd × 7 d	Same	Started 48 h pre-procedure
CEUS availability	Yes (routine when feasible)	Yes (selective)	SonoVue® 2.4 mL + 5 mL saline
Trial-of-void	Attempt within 2 h	Same	AUR: PVR > 300 mL or discomfort → Foley 16F 48–72 h
Discharge criteria	Aldrete ≥ 9, PVR < 100 mL, stable vitals, oral analgesia	Same	Same-day discharge intended

AUR, acute urinary retention; CEUS, contrast-enhanced ultrasound; MCID, minimal clinically important difference; PVR, post-void residual; QoL, quality of life; RF, radiofrequency; TRUS, transrectal ultrasound.

enabled real-time visualization of non-perfused ablation zones and facilitated identification of any residual enhancing tissue suggestive of incomplete treatment, thereby providing an early functional assessment of ablation adequacy beyond morphological imaging alone.

Outcomes

The prespecified primary endpoint was a 12-month change in ejaculatory function using the validated MSHQ-EjD-SF (3 items on function, 1 item on bother). Preservation of antegrade ejaculation was captured by a structured patient-reported item and considered alongside the MSHQ domains. Secondary endpoints were the 12-month composite responder rate (≥ 30% IPSS reduction without BPH retreatment) and absolute and percentage changes in the IPSS, Qmax, PVR, prostate volume, and PSA. Minimal clinically important differences (MCIDs) were IPSS ≥ 3 points, QoL ≥ 1 point, and Qmax ≥ 3 mL/s; proportions were reported with exact 95% confidence intervals (CIs).

Follow-up visits were scheduled at 1, 3, 6, and 12 months after the procedure. The 1- and 3-month visits were primarily intended to assess early safety and recovery parameters, including adverse events, voiding status, catheter dependence, and medication discontinuation. The 6- and 12-month visits were prespecified as the main timepoints for evaluation of sustained efficacy outcomes, including symptom scores, functional parameters, prostate volume changes, and patient-reported sexual and ejaculatory outcomes.

Database lock and handling of missing data

All treated participants completed the scheduled 12-month clinical follow-up. Therefore, no attrition-related sensitivity analyses were required. For outcomes not measurable at baseline in catheter-dependent patients (e.g., uroflowmetry or PVR), analyses were conducted on an observed-case basis with explicit denominators reported for each endpoint.

Statistical analysis

Continuous variables are summarized as the median [interquartile range (IQR)] and categorical variables as a number (percentage). Paired comparisons were performed using the Wilcoxon signed-rank test, as appropriate. Between-group comparisons were assessed using the Mann–Whitney U test. Proportions are presented with exact 95% CIs. A two-sided P value < 0.05 was considered statistically significant.

Responder analyses were additionally reported using MCID thresholds commonly applied in BPH/LUTS research. For the IPSS, an improvement of ≥ 3 points was used as a clinically meaningful change. For the Qmax, a ≥ 2 mL/s increase was used as a pragmatic clinically relevant threshold. Because a formally established MCID for the MSHQ-EjD-SF has not been clearly defined, changes in ejaculatory scores were interpreted cautiously and complemented by reporting the clinically intuitive endpoint of antegrade ejaculation preservation.

Results

Patient flow and baseline

Of the 40 men screened, 6 were excluded (bladder stones, n = 2; low-grade prostate cancer, n = 2; did not proceed to treatment or follow-up, n = 2), leaving 34 treated patients, who comprised the analysis cohort. Follow-up was completed at 6 and 12 months for 34/34 patients (100%) (Table 2).

Primary endpoint

Of the 34 men included, 30 were sexually active. On the MSHQ-EjD function domain (higher scores indicate better function), mean scores were 9.66 ± 1.59 at baseline (n = 29), 9.59 ± 2.34 at 6 months, and 9.48 ± 2.26 at 12 months. Paired two-sided tests showed no evidence of change from baseline to 6 months [Δ(6m–BL): −0.07; 95% CI: −0.86 to 0.72; $P = 0.860$] or to 12 months [Δ(12m–BL): −0.17; 95% CI: −1.09 to 0.75; $P = 0.704$]. For the MSHQ-EjD bother domain (lower scores indicate less bother), the baseline mean was 2.63 ± 0.71 (n = 32), increasing to 2.78 ± 0.75 at 6 months [Δ(BL–6m): −0.16; 95% CI: −0.49 to 0.18; $P = 0.344$] and to 2.86 ± 0.64 at 12 months among participants with available data [n = 22; Δ(BL–12m): −0.32; 95% CI: −0.78 to 0.14; $P = 0.167$]. Ejaculatory outcomes were assessed using the validated MSHQ-EjD-SF. Although antegrade ejaculation was preserved in 27/30 (90%) sexually active patients at 12 months, we observed a small reduction in the mean MSHQ-EjD-SF score from baseline to 12 months. This change was numerically modest and occurred in the context of concurrent improvements in urinary symptom burden and functional parameters.

Secondary endpoints

The composite responder rate (≥ 30% IPSS reduction without BPH retreatment) was 33/34 (97.1%; 95% CI: 84.7–99.9) at both 6 and 12 months. The median IPSS decreased from 19.5 (IQR: 14.0–30.3) at baseline to 5.0 (5.0–6.0) at 6 months and 4.0 (4.0–5.0) at 12 months (n = 34) ($P < 0.001$). The median Qmax increased from 9.6 (7.6–10.9) to 18.0 (17.0–20.5) mL/s at 6 months and 20.0 (18.0–21.3) mL/s at 12 months ($P < 0.001$). Two patients (5.9%) were catheter dependent at baseline.

Table 2. Baseline demographic and clinical characteristics of the study population (n = 34). Values are presented as mean ± standard deviation or number (percentage), as appropriate

Characteristic	n = 34
Age (years), mean ± SD	69.7 ± 5.8
BMI (kg/m^2), mean ± SD	27.5 ± 2.5
ASA score ≤ 2, n (%)	19 (55.9)
Comorbidities, n (%)	
Hypertension	22 (64.7)
Diabetes mellitus	13 (38.2)
Cardiovascular disease	5 (14.7)

ASA, American Society of Anesthesiologists; BMI, body mass index; SD, standard deviation.

PVR volume decreased from 34.5 (25.3–52.0) mL at baseline to 10.0 (5.0–12.0) mL at 6 months and 9.0 (7.0–11.0) mL at 12 months ($P < 0.001$). Prostate volume was reduced from 70.0 (52.5–101.0) to 43.5 (27.8–62.8) mL at 6 months and 40.0 (24.8–61.0) mL at 12 months ($P < 0.001$). Median PSA declined from 3.8 (2.0–7.4) ng/mL at baseline to 1.5 (0.8–2.5) ng/mL at both 6 and 12 months ($P < 0.001$) (Table 3).

Importantly, symptom improvement was accompanied by concordant objective changes, including increased urinary flow (Qmax), reduced PVR, and sustained reductions in prostate volume and PSA, supporting a physiological treatment effect beyond symptom perception alone.

In stratified analyses according to baseline prostate volume (< 80 vs. ≥ 80 mL), significant within-group improvements were observed at 6 months across all functional and anatomical outcomes, whereas no statistically significant between-group differences were identified, indicating comparable early efficacy across gland size categories (Table 4).

At baseline, 19/34 (55.9%) patients were receiving alpha-blockers and 7/34 (20.6%) were receiving 5-ARIs, including 6/34 (17.6%) on combination therapy; 2/34 (5.9%) were not receiving prostate-related medications. Per protocol, prostate-related medications were discontinued at 1 month whenever clinically feasible. By 12 months, 32/34 (94.1%) patients had discontinued prostate-related medications completely; 2/34 (5.9%) remained on a single medication despite marked symptom improvement (both had received dual therapy preprocedure).

Adverse events and reinterventions

No Clavien–Dindo ≥ III events occurred. Within 30 days, transient urinary morbidity (AUR/urinary tract infection/dysuria) was common, along with less frequent gross hematuria, perineal pain, and hematoma; all events were non-device-related and managed conservatively. Emergency department visits and readmissions were infrequent. Between 31 and 365 days, reinterventions and retreatments were uncommon (Table 5).

Sensitivity to missing data

Because all treated participants completed the 12-month clinical follow-up assessment, sensitivity analyses for follow-up attrition were not required. For endpoints with baseline measurements unavailable in catheter-dependent patients, analyses were conducted using observed-case denominators, with explicit denominators (n) reported per endpoint.

Percentages are shown with exact 95% CIs (Clopper–Pearson) for proportions. Continuous outcomes are summarized as the median (IQR); *P* values and effect-size estimates are provided in Tables 3 and 4.

Table 3. Comparison of functional and anatomical outcomes before treatment and at the 6 month and 1-year follow-up after transperineal radiofrequency ablation

Outcomes	Baseline	6 months	1 year	% change 6 months	% change 1 year	*P*
IPSS	19.5 (14.0–30.3)†	5.0 (5.0–6.0)	4.0 (4.0–5.0)	72.1 (66.1–80.6)	74.2 (69.1–83.9)	< 0.001
PVR (mL)	34.5 (25.3–52.0)	10.0 (5.0–12.0)	9.0 (7.0–11.0)	77.0 (61.8–84.6)	78.6 (60.4–84.1)	< 0.001
Qmax (mL/s)	9.6 (7.6–10.9)	18.0 (17.0–20.5)	20.0 (18.0–21.3)	94.0 (68.2–167.4)	111.0 (70.1–168.8)	< 0.001
QoL	5.0 (4.0–5.0)	1.0 (1.0–1.0)	1.0 (1.0–1.0)	80.0 (66.7–80.0)	80.0 (75.0–80.0)	< 0.001
Prostate volume (mL)	70.0 (52.5–101.0)	43.5 (27.8–62.8)	40.0 (24.8–61.0)	42.5 (33.3–51.1)	47.7 (38.5–54.1)	< 0.001
PSA (ng/mL)	3.8 (2.0–7.4)	1.5 (0.8–2.5)	1.5 (0.9–2.5)	63.9 (49.9–70.5)	61.5 (50.2–71.8)	< 0.001

†Baseline IPSS available for 32 patients; follow-up IPSS available for 34 patients. IPSS, International Prostate Symptom Score; PVR, post-void residual volume; Qmax, maximum urinary flow rate; QoL, quality of life; PSA, prostate-specific antigen.

Table 4. Comparison of functional and anatomical outcomes before treatment and at 6 month follow-up after transperineal radiofrequency ablation according to baseline prostate volume. Values are presented as median (interquartile range)

Outcome	Prostate volume < 80 mL (n = 20)			Prostate volume ≥ 80 mL (n = 14)			*P*†
	Baseline	6 months	% change	Baseline	6 months	% change	
IPSS	22.0 (16.0–30.0)	2.0 (1.0–2.3)	90.9 (86.2–93.6)	17.0 (14.0–30.0)	2.0 (2.0–2.0)	89.5 (85.7–92.9)	0.759
PVR (mL)	35.0 (30.0–52.0)	10.0 (5.0–10.8)	77.8 (66.7–85.7)	32.0 (25.0–54.0)	10.0 (7.3–15.0)	68.0 (53.1–84.3)	0.343
Qmax (mL/s)	10.0 (7.9–12.9)	18.0 (17.0–22.0)	80.0 (63.6–120.8)	8.5 (6.8–10.2)	18.0 (16.8–19.3)	110.5 (76.5–181.3)	0.099
QoL	5.0 (5.0–5.0)	1.0 (1.0–1.0)	80.0 (75.0–80.0)	4.0 (3.0–5.0)	1.0 (1.0–1.0)	75.0 (66.7–80.0)	0.217
Prostate volume (mL)	55.0 (42.8–63.5)	29.0 (22.0–39.8)	44.1 (30.4–53.7)	111.5 (89.3–167.8)	70.0 (52.5–101.0)	41.6 (33.3–50.7)	0.769
PSA (ng/mL)	2.7 (1.3–4.0)	1.1 (0.5–1.7)	55.2 (45.2–69.6)	7.6 (6.1–9.4)	2.4 (1.6–3.3)	66.1 (62.3–78.0)	0.071

†*P* value for between-group comparison of percentage change at 6 months (Mann–Whitney U test). IPSS, International Prostate Symptom Score; PVR, post-void residual volume; Q_{max}, maximum urinary flow rate; QoL, quality of life; PSA, prostate-specific antigen.

Table 5. Adverse events, healthcare utilization, and reinterventions up to 12 months after urethra-sparing, ultrasound-guided transperineal radiofrequency ablation

Event	Definition	0–30 d n/N (%)	Management	Clavien–Dindo
Acute urinary retention	Inability to void for ≤ 2 h with discomfort or PVR > 300 mL; managed with temporary catheterization.	5/34 (14.7%)	Temporary catheterization (typically 48–72 h)	1
Urinary tract infection	New urinary symptoms accompanied by a positive urine culture requiring antibiotic therapy; culture obtained when available.	4/34 (11.7%)	Oral antibiotics (10–14 days), guided by urine culture when available; no hospitalizations (length of stay 0 days)	1
Dysuria (clinically significant)	New/worse dysuria lasting ≥ 7 d or requiring unplanned contact/analgesic escalation.	12/34 (35%)	Oral analgesics/anti-inflammatories	1
Gross hematuria	Visible blood in urine; assess for clot retention and Hb drop.	3/34 (8%)	Hydration/observation; bladder irrigation if needed	1
Perineal pain (significant)	Pain NRS ≥ 5 beyond 48 h or requiring opioid prescription.	3/34 (8%)	Oral analgesics ± short opioid course	1
Skin/perineal hematoma	Clinically evident subcutaneous hematoma; intervention if expanding or symptomatic.	3/34 (8%)	Observation/ice	1

Discussion

In this bicenter outpatient cohort, urethra-sparing, ultrasound-guided TPTA was associated with clinically meaningful improvements in LUTS and objective functional parameters through 12 months of follow-up. This report extends our previously published 3-month findings[5] by providing a planned 12-month follow-up with additional longitudinal outcome assessments; the prior publication is cited to ensure full transparency regarding the cohort.

Rather than establishing comparative efficacy against existing surgical or minimally invasive therapies, the present study was designed to assess the reproducibility, safety, and functional profile of an image-guided, urethra-sparing TPTA strategy when performed in a real-world interventional radiology setting (Figure 3).

Real-time ultrasound guidance, combined with predefined safety margins from the urethra and bladder neck, allowed consistent anatomical targeting across centers. When available, immediate CEUS served as a quality-assurance step to confirm treatment coverage and exclude early complications, reinforcing procedural reproducibility without compromising periurethral perfusion (Figure 4). The addition of postoperative CEUS provided clinically meaningful functional information by allowing early assessment of ablation perfusion patterns. Unlike grayscale ultrasound, CEUS enabled confirmation of devascularized tissue and identification of residual perfused areas that may not be apparent on conventional imaging. This early functional evaluation supports procedural adequacy, enhances safety surveillance, and may help explain interindividual variability in subsequent symptom improvement and volume reduction. Although CEUS findings were not used to mandate immediate retreatment in this study, their use may inform future protocols incorporating early response assessment and tailored follow-up strategies.

Within this framework, improvements were internally consistent across both patient-reported outcomes and objective measures, including the Qmax, PVR, prostate volume, and PSA.

When positioned within the contemporary minimally invasive surgical therapy landscape, the present outcomes appear directionally consistent with reports of other urethra-sparing and non-transurethral approaches. However, differences in study design, patient selection, and outcome definitions preclude direct comparisons or claims of superiority. Accordingly, the present findings should be viewed as complementary, contributing prospective evidence on functional and ejaculatory outcomes in a real-world outpatient setting.[4,6]

Mean scores on the MSHQ-EjD-SF function domain remained statistically stable during the follow-up period, with no significant changes observed at either 6 or 12 months. Although a slight numerical decline was noted at the latter timepoint, this finding should be interpreted in the context of two consistent signals: the bother domain did not worsen significantly, and 90% of sexually active men reported preservation of antegrade ejaculation. Taken together, these results suggest that symptom relief was achieved without a proportional increase in patient-perceived ejaculatory burden, indicating that ejaculatory function was largely maintained following ultrasound-guided, urethra-sparing TPTA.[5]

In our cohort, only one patient did not achieve an adequate clinical response, with only a 20% reduction in IPSS and a continued need for prior BPH medications. Multiparametric MRI demonstrated a marked increase in IPP, suggesting a possible valvular mechanism. Post-contrast sequences showed enhancement of the periurethral tissue and IPP. A second TPTA session was performed, specifically targeting the IPP region. Thirty days later, the patient reported marked improvement, with a decrease in IPSS from 14 to 2 and discontinuation of all BPH medications. Follow-up endocavitary ultrasound also confirmed a reduction in IPP from 14 to 2 mm. No other patients required retreatment or medication adjustments during follow-up (Figure 5).

Although the absolute magnitude of IPSS reduction was substantial, these findings should be interpreted in the context of a non-randomized study conducted in a carefully selected population with moderate-to-severe baseline symptoms. The ob-

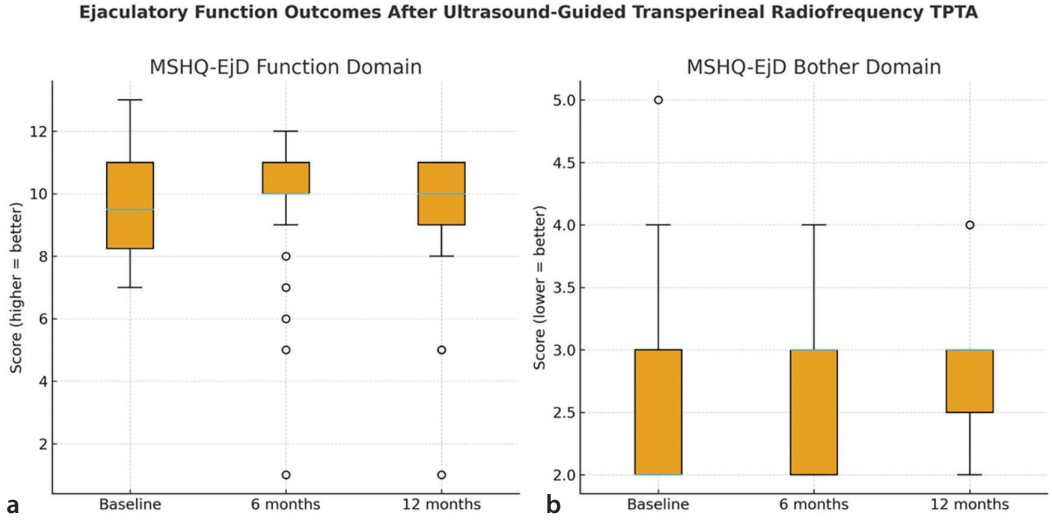


Figure 2. Boxplot comparison of Male Sexual Health Questionnaire–Ejaculatory Dysfunction scores (MSHQ-EjD). **(a)** Ejaculatory function domain. **(b)** Ejaculatory bother domain. Values are shown at baseline, 6 months, and 12 months after ultrasound-guided transperineal radiofrequency ablation for benign prostatic hyperplasia. Horizontal lines within the boxes represent the median, boxes represent interquartile ranges, and whiskers indicate the minimum and maximum values. TPTA, transperineal radiofrequency ablation.

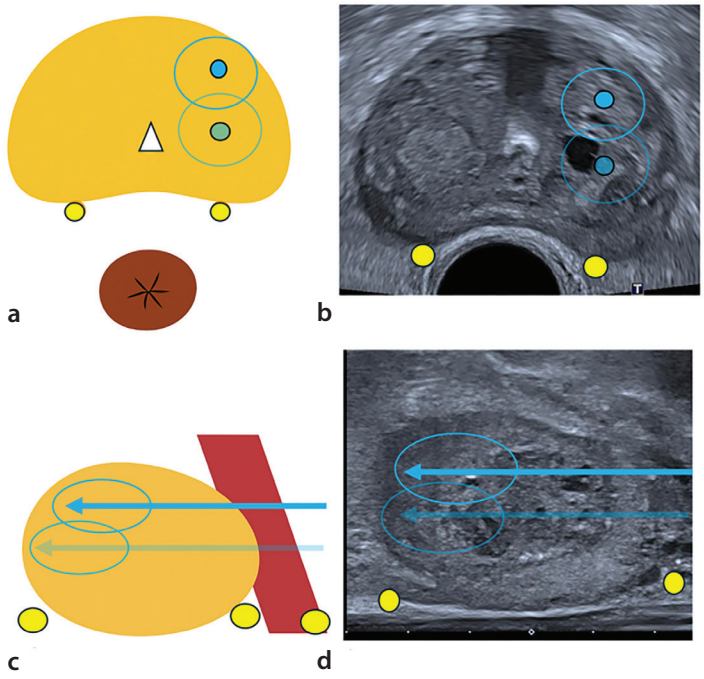


Figure 3. Figure self-designed by authors; no copyright restrictions. Schematic and ultrasound views of the prostate (orange), rectum (brown), and levator ani muscle (red) in axial (**a, b**) and paramedian sagittal (**c, d**) acquisitions. The two yellow dots (**a-d**) indicate the periurethral and periprostatic sites for regional nerve block. The positions of the radiofrequency probes (blue circles and arrows) are shown in both planes, with ablation initiated anteriorly and subsequently performed posteriorly, maintaining a minimum 5-mm distance from the urethra and distal to the verumontanum. Hollow blue circles represent the expected ablation zones surrounding each probe (blue arrows).

served symptom improvement exceeded established MCIDs and was paralleled by concordant objective changes, which argues against symptom fluctuation alone.

Several non-procedural factors may account for the subtle downward drift in function scores over time. Aging across the study interval, the burden of comorbidities such as diabetes or cardiovascular disease, and concomitant use of medications known to affect emission or expulsion (including alpha-blockers, 5-ARIs, selective serotonin reuptake inhibitors, or antihypertensives) may all plausibly contribute.[7-11] Additionally, regression to the mean and survivorship bias among men who remained sufficiently sexually active to complete questionnaires may have influenced the observed trends. These considerations argue against overinterpreting small changes within a single patient-reported outcome domain, particularly when convergent measures such as bother and self-reported antegrade preservation remain favorable.

From a clinical perspective, the consistent preservation of antegrade ejaculation observed in our cohort has practical implications for shared decision-making.[12] Many men with BPH place a high value on maintaining sexual function when selecting among treatment options. By providing validated evidence that a urethra-sparing, non-transurethral approach can achieve robust LUTS relief while minimizing sexual compromise, our findings may help physicians engage patients in more informed discussions and align therapeutic choices with individual priorities.

The overall pattern—meaningful IPSS/Qmax improvements with high rates of antegrade ejaculation—appears directionally consistent with reports from urethra-sparing approaches, but differences in the inclusion criteria and outcome definitions preclude claims of superiority or non-inferiority.[13-17] Where possible, we provide effect sizes and CIs to facilitate evidence synthesis by future systematic reviews rather than making indirect comparative assertions.

Immediate CEUS after ablation served as a real-time quality-assurance step to confirm coverage and exclude periprocedural complications, potentially improving reproducibility without jeopardizing urethral perfusion. Future studies should test whether systematic CEUS integration standardizes outcomes.[18-20]

Although we observed a modest decline in MSHQ-EjD-SF scores, the clinical relevance of this numerical change is uncertain and should be interpreted cautiously. First, antegrade ejaculation was preserved in the vast majority of sexually active men, suggesting that urethra-sparing treatment planning may mitigate clinically overt ejaculatory dysfunction. Second, patient-reported ejaculatory scores can fluctuate over time due to factors not directly attributable to the procedure, including variability in sexual activity, aging, comorbidities, relationship factors, and medication adjustments.[21,22] Third, an established MCID for the MSHQ-EjD-SF in this specific context is not well defined; therefore, small between-timepoint differences may not translate into clinically meaningful impairment. Future comparative studies with larger samples, standardized assessment of sexual activity, medication changes, and broader sexual-function instruments are warranted to better characterize the trajectory and clinical significance of ejaculatory outcomes after transperineal urethra-sparing ablation.[23] Recent studies evaluating contemporary minimally invasive BPH therapies have emphasized the importance of preserving sexual and ejaculatory function alongside symptom relief, reinforcing the clinical relevance of patient-centered outcome measures used in the present study.[24-26]

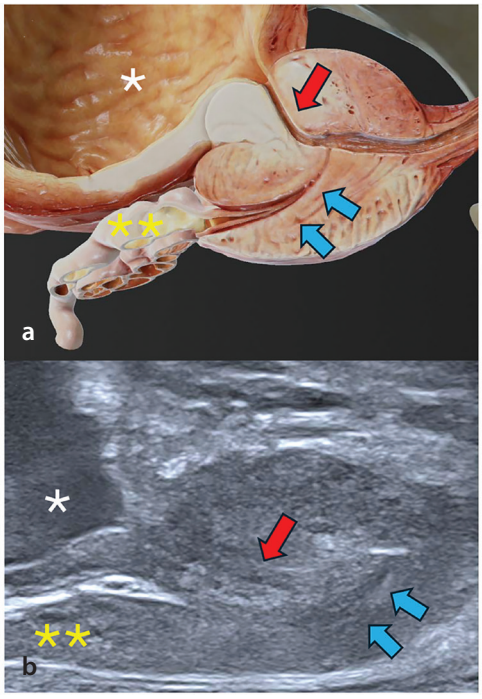


Figure 4. Schematic correlation of the ejaculatory duct pathway between an anatomical illustration **(a)** and transrectal ultrasound imaging obtained with a high-frequency transperineal linear transducer **(b)**. This view is critical as it demonstrates the relationship between the seminal vesicle (double asterisk), bladder (single asterisk), prostatic urethra (red arrow), and ejaculatory duct entering the urethra at the level of the verumontanum (blue arrows). Inadvertent ablation of this region may result in ejaculatory dysfunction.

Several limitations should be acknowledged. Although the sample size (n = 34) is appropriate for a prospective feasibility and safety evaluation, the single-arm design and modest cohort limit causal inference and preclude definitive comparisons with other minimally invasive BPH therapies; thus, these findings should be considered exploratory and hypothesis-generating. Ejaculatory outcomes were assessed using a validated

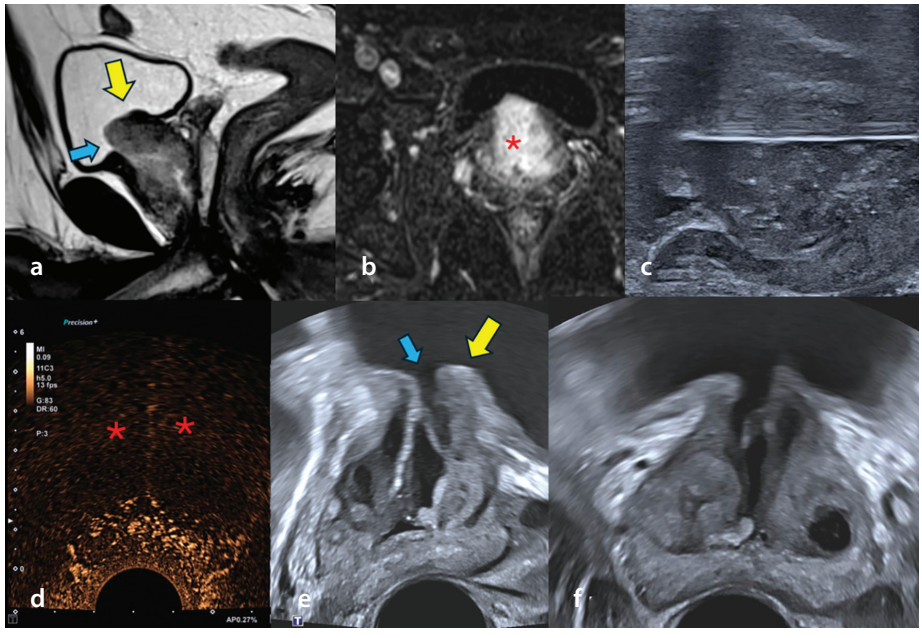


Figure 5. Patient with inadequate initial response requiring retreatment. **(a, b)** Multiparametric prostate magnetic resonance imaging at 6 months post-ablation, sagittal **(a)** and axial post-contrast **(b)**, demonstrates an intravesical prostatic protrusion [intravesical prostatic protrusion (IPP), yellow arrow] measuring 12 mm, consistent with a possible valvular mechanism compressing the proximal urethral lumen (blue arrow). Hyperenhancement of the periurethral tissue and IPP is also noted (red asterisk). **(c)** Repeat transperineal radiofrequency ablation was performed with direct probe placement into the IPP and periurethral zone. **(d)** Immediate contrast-enhanced ultrasound confirmed devascularization of the transition zone and IPP. **(e, f)** Follow-up transrectal ultrasound at 30 days demonstrated marked IPP reduction, opening of the urethral channel, and likely resolution of the valvular mechanism. Clinically, International Prostate Symptom Score improved from 18 pre-retreatment to 2 at 30 days, with complete discontinuation of benign prostatic hyperplasia medications.

instrument (MSHQ-EjD-SF) and antegrade ejaculation preservation, but the study was not powered to define clinically meaningful change thresholds, and an established MCID for the MSHQ-EjD-SF in this setting is lacking; therefore, responder analyses and longitudinal score changes should be interpreted cautiously. In addition, medication discontinuation beyond the planned 1-month withdrawal attempt was not fully protocolized and may have influenced sexual outcomes, and erectile function was not prospectively assessed with the International Index of Erectile Function questionnaire (IIEF-5). Larger, adequately powered multicenter comparative studies with longer follow-up and standardized patient-centered sexual and ejaculatory endpoints are warranted to confirm durability and better define the role of this technique in contemporary BPH care.

Prospective multicenter registries or randomized pragmatic trials are needed to confirm durability and generalizability, ideally using standardized urethra-sparing protocols, independent outcome adjudication, and a core set for sexual function. Given the outpatient setting, a formal health economic analysis (cost-utility, return to usual activities, resource use) is also warranted and may guide adoption by healthcare systems.[18-23] Future prospective studies should incorporate a broader sexual-function battery, including the IIEF-5, to better characterize erectile outcomes alongside ejaculatory preservation after urethra-sparing TPTA. Regarding clinical implications, in the stratified analysis, urethra-sparing TPTA achieved similar symptom relief in men with prostates < 80 and ≥ 80 mL, with consistent improvements across urinary and structural outcomes, supporting its feasibility even in larger glands that are often more challenging to treat.

In summary, a carefully selected outpatient population, urethra-sparing TPTA was associated with clinically meaningful improvements in LUTS and urinary flow at 12 months, with preservation of antegrade ejaculation in the majority of sexually active patients.

Footnotes

Conflict of interest disclosure

The authors declared no conflicts of interest.

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