Interventional procedure overview of image-guided transperineal laser ablation (TPLA) for treating lower urinary tract symptoms caused by benign prostatic hyperplasia

Contents

Table 1 Abbreviations

Abbreviation	Definition
ASA	American Society of Anesthesiology
BPO	Benign prostatic obstruction
BPE	Benign prostate enlargement
BPH	Benign prostatic hyperplasia
EJ-MSHQ	Male Sexual Health Questionnaire – Ejaculatory function domain
EPIC	Expanded Prostate Cancer Index Composite questionnaire
HGS	Haematuria Grading Scale
IPSS	International Prostate Symptom Score
IIEF-15	Fifteen item International Index of Erectile Function
LUTS	Lower urinary tract symptoms
MSHQ-EjD	Male Sexual Health Questionnaire – Ejaculation Dysfunction domain
PV	Prostate volume
PAE	Prostate artery embolisation
PVR	Post-voidal residual
PROMs	Patient-reported outcome measures
QoL	Quality of life
Qave	Average urinary flow rate
Qmax	Maximum urinary flow rate
SD	Standard deviation
TPLA	Transperineal interstitial laser ablation of the prostate
TURP	Transurethral resection of the prostate
TRUS	Transrectal ultrasound
VAS	Visual Analogue Scale

The condition, current treatments, unmet need and procedure

Information about the condition, current treatments, unmet need and procedure is available in section 2 of NICE's interventional procedures guidance for transperineal laser ablation for treating lower urinary tract symptoms of benign prostatic hyperplasia.

Outcome measures

The main outcomes included ejaculatory function (assessed by the MSHQ-EjD), erectile function (assessed by IIEF-5), symptom relief (assessed by IPSS), maximum urinary flow rate (Qmax), PVR urine volume, PV, QOL and complications. Some of the measures used are detailed in the following paragraphs.

MSHQ-EjD

The MSHQ is a 25-item self-administered questionnaire that includes questions on erection, ejaculation, desire and satisfaction. It is particularly useful to investigate ejaculatory disorders. The ejaculation dysfunction domain includes 7 questions scored from 0 to 5, with higher scores representing better function. A total MSHQ-EjD score in the range of 28 to 35 represents good ejaculatory function, scores of 22 to 27 represent average ejaculatory function, and a score less than 22 is used to diagnose ejaculatory dysfunction. The MSHQ-EjD short form is an abridged version that was developed and validated for assessing ejaculatory dysfunction. This includes 2 domains: ejaculatory function (3 items - completeness of ejaculation, strength of ejaculation and volume of semen on ejaculation) and bother or satisfaction (1 item). Each question is scored 0 to 5, with higher scores indicating better ejaculatory function.

IIEF-15

The IIEF is a 15-item PROM questionnaire used to assess sexual function in 5 domains: erectile function, orgasmic function, sexual desire, intercourse satisfaction, and overall satisfaction. Each domain has its own score range and lower scores represent greater dysfunction:

- erectile function score: range 0 to 30 (scores of 24 or less represent increasing dysfunction)
- orgasmic function score: range 0 to 10 (scores of 8 or less represent increasing dysfunction)
- sexual desire score: range 0 to 10 (scores of 8 or less represent increasing dysfunction)
- intercourse satisfaction score: range 0 to 15 (scores of 12 or less represent increasing dysfunction)
- overall satisfaction score: range 0 to 10 (scores of 8 or less represent increasing dysfunction).

IPSS

The IPSS is a validated questionnaire often used to assess symptoms of BPH (it is also referred to as the American Urological Association BPH Symptom Score Index). It includes questions on incomplete bladder emptying, frequency, intermittency and urgency of urination, weak urine stream, straining to urinate and nocturia. Higher scores represent worse symptoms. In general, an IPSS symptom score of 0 to 7 indicates mild symptoms, 8 to 19 indicates moderate symptoms and 20 to 35 indicates severe symptoms. An additional question asks the person how they feel about their BPH symptoms, and the response yields a score for quality of life (ranging from 0 to 6, with 0 representing ‘delighted’ and 6 representing ‘terrible’).

Qmax

In uroflowmetry, Q refers to the volume of fluid expelled by the urethra per unit time (flow rate). Qmax is the maximum measured value of the flow rate after correction for artefacts. It decreases with age and voided volume. A low Qmax value is commonly a sign of obstruction.

Evidence summary

Population and studies description

This interventional procedures overview is based on 800 people from 2 RCTs, 2 systematic reviews (1 of which also includes one RCT), and 7 prospective case series. Of these 660 people, 730 people had TPLA, 50 had TURP and 20 had PAE. This is a rapid review of the literature, and a flow chart of the complete selection process is shown in figure 1. This overview presents 11 studies as the key evidence in table 2 and table 3, and lists 15 other relevant studies in appendix B, table 5. There is an overlap of 6 primary studies across systematic reviews (Tafuri 2023 and Tzelves 2023). The RCT by Bertolo (2023) is also included in 1 systematic review (Tzelves 2023).

One RCT evaluated ejaculatory function in people with BPH after TPLA or TURP on a 1 to 1 ratio, but the sample size was small and was based on ejaculatory function outcomes. People were not blinded to interventions and 4 people in the TURP group refused treatment. A high proportion of people (88%) had medical therapy before the interventions and had no wash-out before surgery, so the baseline ejaculatory function scores could have been modified (Bertolo 2023). The study by Canat (2023) was described as a prospective, randomised controlled single-centre study, comparing TPLA with TURP. Randomisation was done by dividing people 1 to 1 according to order of admission. The study included people who were candidates for TURP.

A systematic review and meta-analysis included 6 small studies of low or intermediate quality (according to the Ottawa-Newcastle scoring system). Risk of bias was assessed using Cochrane tools for non-randomised studies. A pooled analysis was done, and high heterogeneity between studies was noted (Tafuri 2023).

Another systematic review included 11 studies of low or intermediate quality (except for 1 single centre RCT [Bertolo 2023]). Risk of bias was also assessed using Cochrane tools for randomised and non-randomised studies. No meta-analysis was done because of the lack of comparative studies using the same groups (Tzelves, 2023).

Seven prospective studies assessed the efficacy and safety of TPLA (van Kollenburg R 2024, Destefanis 2023, Polverino 2024, Bianco 2024, Minafra 2023, Lo Re 2024, Patelli 2024). One small pilot study (Kollenburg 2024) assessed the feasibility of TPLA in healthy people for whom standard surgery was suitable. Three single-centre studies assessed TPLA use in high surgical risk people for whom standard surgery was not an option (Polverino 2023, Destefanis 2023, Lo Re 2024).

Long term follow-up ranging from 2 to 4 years was assessed in 3 small studies (Minafra 2023, Bianco 2024, Patelli 2024).

Table 2 presents study details.

Figure 1 Flow chart of study selection

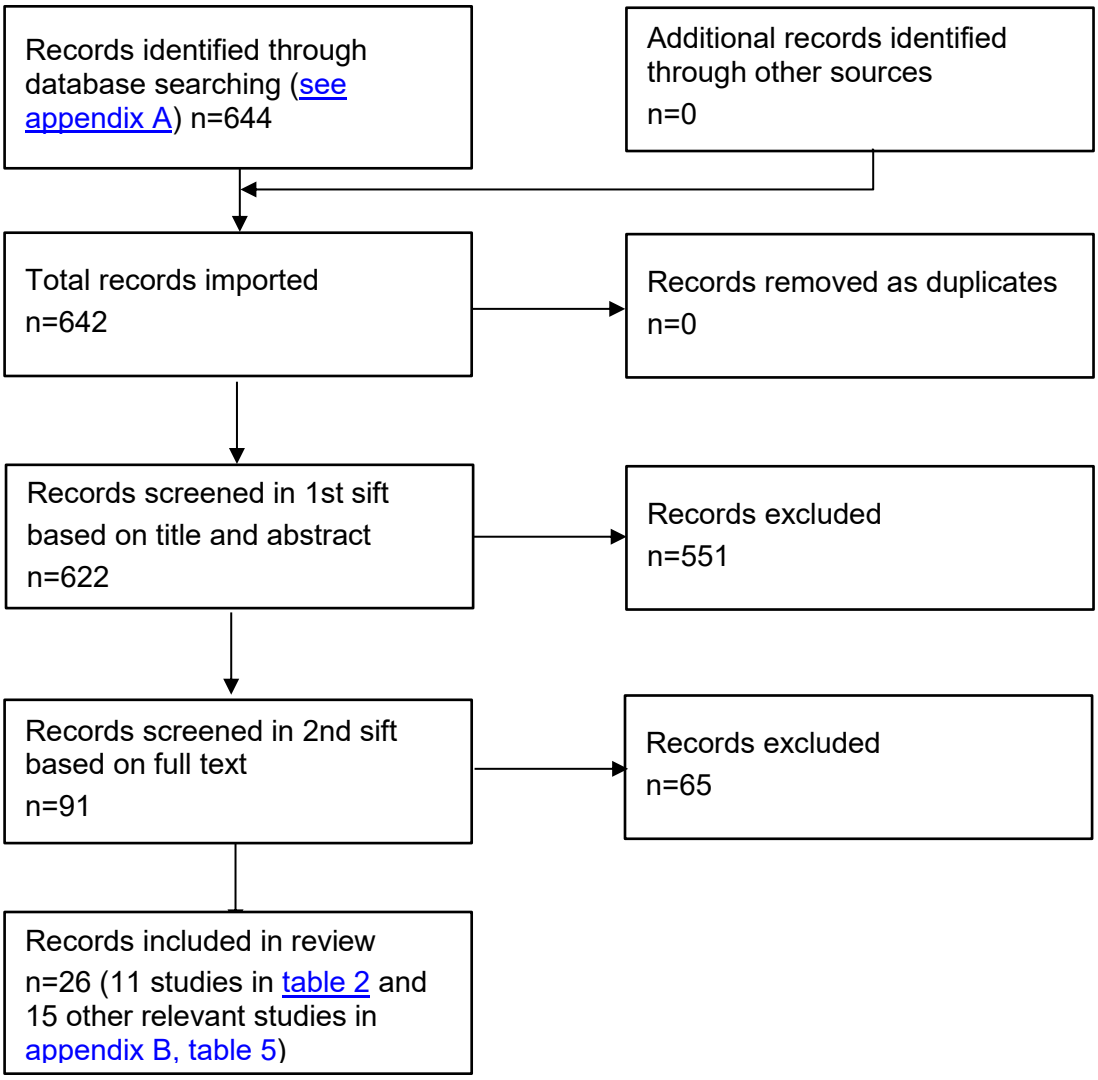

Table 2 Study details

Study no.	First author, date country	Characteristics of people in the study (as reported by the study)	Study design	Inclusion criteria	Intervention	Follow up
1	Bertolo 2023 Italy	51 people with BPH (26 TPLA versus 25 TURP) Mean age: TPLA 63.0; TURP 68.5 years.	RCT (single centre) (NCT04781049)	People with BPH between 18 and 75 years, with normal ejaculatory function (assessed by EJ-MSHQ), presence of antegrade ejaculation before surgery (or before medical therapy, or both), IPSS more than10; Qmax less than 15 ml/s, PV more than 100 ml, and normal urine analysis.	TPLA (using the EchoLaser) versus TURP (standard treatment using a bipolar energy resectoscope), both groups had spinal anaesthesia.	6 months
2	Canat 2023 Turkey	50 people (TPLA, 25; TURP, 25) Mean age (SD): TPLA 65.58 (6.59); TURP 64.20 (6.21)	RCT (single centre) Randomisation was done by dividing people into 1:1 groups according to the order of admission	People with IPSS above 12, maximum urine flow rate (Qmax) 15 ml/s or less, and age 50 or above	TPLA and TURP TPLA was done under local anaesthesia with sedation, TURP was done under spinal anaesthesia	12 months
3	Tafuri 2023 Italy	297 people with BPH Mean (years): Pacella 2019: 69.8	Systematic review and meta-analysis	English articles published between 2000 and 2022 focused on TPLA for BPH, with more than 20 people,	TPLA using EchoLaserTM (SoracteLiteTM)	Varied across studies, up to

Study no.	First author, date country	Characteristics of people in the study (as reported by the study)	Study design	Inclusion criteria	Intervention	Follow up
		Cai 2021: 73.9 Manenti 2021: 72.1 Median (years): De Rienzo 2021: 62 Frego 2021: 61.9 Sessa 2022: 72	6 studies (2 retrospective and 4 prospective studies).	and reporting outcomes of interest. In all studies, severity of LUTS and QoL assessed using the IPSS (cut off score of 12 in 4 studies and 8 in 1 study). People with prostate volume of more than 30 ml, Qmax 15 ml/s or less and a PVR between 50 and 400 ml were included; those unresponsive to previous medical therapy in 2 studies, with PSA value less than 4 ng/ml/negative biopsy/negative DRE in 1 study were included.		12 months.
4	Tzelves 2023 Europe	477 (432 had TPLA, 20 had PAE and 25 had TURP) Age: ranged between 61.9 and 73.9 years.	Systematic review (11 studies) 1 RCT, 9 observational studies and 1 animal study. (2 of these comparative –	Studies published from 2000 to 2023, observational studies (prospective or retrospective), single arm or comparative, and RCTs, reporting clinical outcomes were included. inclusion criteria of studies included: people over 18 years old and PV between 30 and 100ml (based on	TPLA (from the 11 studies 2 were comparative,1 with prostatic artery embolisation and 1 with TURP)	12 months

Study no.	First author, date country	Characteristics of people in the study (as reported by the study)	Study design	Inclusion criteria	Intervention	Follow up
			TPLA versus TURP TPLA versus PAE)	TRUS or MRI measurements) as well as LUTS with IPSS 12 or more, Qmax 15ml/s or less, or PVR 50 to 400ml.		
5	Minafra 2023 Italy	20 people affected by BPH related symptoms. Median age 63 years.	Prospective case series (single centre)	People with symptomatic benign prostatic obstruction: IPSS 12 points or higher, Qmax 15 ml per second or less, and transrectal ultrasound prostate volume between 30 ml and 100 ml.	TPLA using the SoracteLite™ EchoLaser X4 system Local anaesthesia with sedation	3 years
6	Destefanis 2023 Italy	40 people Median age (IQR): 80 (72.5 to 84)	Prospective case series	High-risk (high haemorrhagic risk, due to ongoing pharmacological therapy and preexisting diseases), adult, Caucasian people, seeking surgical treatment for BPH or LUTS with ASA score more than 3 affected by a moderate to severe or complicated BPH condition	TPLA (with SoracteLite™ Echolaser® X4 system) Local anaesthesia with or without light sedation	6 months
7	van Kollenburg R 2024 The Netherlands	20 people Mean age 70.3 years	Prospective case series (multicentre pilot study; NCT03653117)	People 40 years or older, had urodynamically proven bladder outlet obstruction, a Qmax of 5 to 15 ml/s, a prostate volume of 30 to 120 cc, spontaneous voiding,	TPLA (with SoracteLite™ Echolaser® X4 system) using local anaesthesia and optional sedation.	12 months

Study no.	First author, date country	Characteristics of people in the study (as reported by the study)	Study design	Inclusion criteria	Intervention	Follow up
				and were fit for standard transurethral surgery.	(16 in an outpatient setting, 4 in the operating room, of these 2 under general anaesthesia).	
8	Polverino 2023 Italy	23 people Median age (IQR): 77 (68 to 84)	Prospective case series	People with moderate to severe LUTS for whom standard surgery was not an option, prostate volume ranging from 30 to 100 ml, and an ASA Score 3 or above	TPLA using EchoLaser™ (Elesta SpA, Calenzano, Florence, Italy) multisource diode laser generator Local anaesthesia with or without sedation	Median follow-up: 12 months
9	Bianco 2024	20 people Mean age: 66 years	Prospective case series	People with benign prostatic hyperplasia with LUTS measured by an IPSS above 9, serum creatinine levels below 1.5 ng/dl and glomerular filtration rate above 55.	TPLA using EchoLaser X4 system (Elesta SpA, Calenzano, Italy) Local anaesthesia	24 months
10	Lo Re, 2024, Italy	100 people Mean age; 66 years	Prospective, descriptive single-centre study	People aged ≥45 years; having moderate to severe LUTS due to BPO with an International Prostate Symptom Score, (IPSS) score≥8; prostate volume 30	TPLA (EchoLaser™ multisource diode laser generator for the ablation), with local anaesthesia.	18 months

Study no.	First author, date country	Characteristics of people in the study (as reported by the study)	Study design	Inclusion criteria	Intervention	Follow up
				ml and ≤100 ml measured via transabdominal Ultrasound or MRI; ineffectiveness of medical therapies due to lack of efficacy, intolerance, poor compliance or strong desire to preserve antegrade ejaculation or very high risk for standard surgery due to comorbidities.		
11	Patelli, 2024, Italy	40 people Mean age: 65.1, SD 8.3	Prospective, observational, descriptive study	Eligible people had LUTS and at least 1 of the following criteria: male aged 50 years with symptomatic BPH, International Prostate Symptom Score (IPSS) of >13, prostate volume of >30 ml on transrectal US images, peak urinary flow rate (Qmax) of ≥5 to ≤15 ml/s, and postvoid residual (PVR) of >50 ml.	TPLA (EchoLaser SoracteLite), after insertion of a 3-way 18-F Foley catheter for continuous saline infusion, TPLA was performed with a 1,064-nm continuous-wave diode laser (EchoLaser XVG system), used in conjunction with a 2-plane transrectal US probe (TRT 33; Esaote,). Local anaesthesia with sedation.	36-76 months Median follow up: 57 months

Table 3 Study outcomes

First author, date	Efficacy outcomes	Safety outcomes
Bertolo 2023	**Ejaculatory function status (assessed by the EJ-MSHQ), median [IQR]** TPLA group: baseline 29 [25 to 30], 1 month 29 [25 to 30], p=0.2 TURP group: baseline 29 [25 to 30], 1 month 20 [10 to 25], p=0.01 p value between groups at 1 month, p=0.004. **Preserved antegrade ejaculation at 1 month, % (n)** TPLA 96.2 % (25/26) versus TURP 28% (7/25), p<0.001. **Changes in sexual function (assessed by IIEF-5 score):** TPLA: baseline 17 (15 to 21), 1 month 18 (14 to 23), p=0.5 TURP: baseline 20 (16 to 20.5), 1 month 19 (18 to 23), p=0.3 p value between groups at 1 month, p=0.3. **EPIC, question 32 response: satisfied with treatment at 1 month** TPLA 50% (13/26) versus TURP 80% (20/25), p=0.02. **Qmax, ml/s, median (IQR)** TPLA: baseline 10.2 (8.7 to 12.0); 6 months 15.2 (13.5 to 18.3), p<0.001 TURP: baseline 10.0 (6.5 to 11.6); 6 months 26.0 (22.0 to 48.0), p=0.006	Intra-operative complications 0 Procedure-related complications 0 Peri-operative pain (VAS scores), median [IQR] TPLA= 0 [0 to 2] versus TURP= 1 [0 to 1], p=0.9. Acute urinary retention after catheter removal TPLA 19% [5/26] versus TURP 0% [0]; p=0.02. Readmissions 0.

First author, date	Efficacy outcomes	Safety outcomes
	p value between groups at 6 months, p<0.001 **PVR, ml, median (IQR)** TPLA: baseline 70 (20 to 100), 6 months 0 (0 to 5) TURP: baseline 30 (20 to 70), 6 months 0 (0 to 20), p value between groups at 6 months, p=0.6. **IPSS** TPLA: baseline 24.0 (16.0 to 29.0), 6 months 11 (8 to 15), p=0.01, TURP: baseline 20 (18.5 to 24.0), 6 months 8 (3 to 9), p <0.001, p value between groups at 6 months, p=0.1 **QoL score** TPLA: baseline 5 (3 to 5), 6 months 2 (2 to 4), p=0.002, TURP: baseline 4 (3 to 5), 6 months 2 (1 to 2), p=0.001, p value between groups at 6 months, p=0.1. **Operating time, median minutes** TPLA group 35 [IQR 30 to 55] versus TURP 68 [IQR 60 to 95]; p<0.001. **Hospital stay, median days** TPLA 2 [IQR 2 to 3] versus TURP 3 [IQR 2 to 4]; p= 0.008. **Catheterisation time, median days** TPLA 4 [IQR 2 to 7] versus TURP 3 [IQR 3 to 4]; p=0.7.	

First author, date	Efficacy outcomes	Safety outcomes
Canat 2023	**IPSS, mean (SD)** TPLA: baseline 20.14 (6.02); 1 year 10.14 (3.21); p<0.01 TURP: baseline 21.17 (4.33), 1 year 10.95 (4.33), p<0.01 p=0.50 between groups at 1 year. **IPSS QoL, mean (SD)** TPLA: baseline 4.75 (0.75); 1 year 1.50 (0.90); p<0.01 TURP: baseline 4.69 (0.75); 1 year 1.31 (0.75); p<0.01 p=0.57 between groups at 1 year. **Qmax, mean (SD)** Baseline: TPLA: baseline 8.73 (3.77); 1 year 14.26 (3.73); p<0.01 TURP: baseline 8.32 (3,54); 21.37 (6.04) p<0.01 p<0.01 between groups at 1 year. **PVR, mean (SD)** TPLA: baseline 125 (68.50); 1 year 46.88 (32.40); p<0.01 TURP: baseline 139.4 (58.73); 1 year 49.13 (31.54); p<0.01 p=0.85 between groups at 1 year. **IIEF-5, mean (SD)** TPLA: baseline 14.84 (3.93); 1 year 14.68 (3.92); p=0.83 TURP: baseline 14.17 (4.09); 1 year 13.44 (4.53) p= 0.12	None reported

First author, date	Efficacy outcomes	Safety outcomes
	p= 0.38 between groups at 1 year. **MSHQ 1,2,3; mean (SD)** TPLA: baseline 10.75 (2.42); 1 year 10.33 (2.31); 0.54 TURP: baseline 11.07 (1.87); 5.93 (4.01) p<0.01 p=0.002 between groups at 1 year. **MSHQ 4, mean (SD)** TPLA: baseline 2.92 (0.90); 1 year 2.83 (1.03); p=0.34 TURP: baseline 3.33 (0.72); 1 year 1.80 (0.94); p<0.01 p=0.012 between groups at 1 year. **PV** In the TPLA group, the PV decreased from 66.77 mm at baseline to 47.32 ml at 1 year (p<0.01).	
Tafuri 2023	**Pooled analysis (mean values for random effects model)** **Micturition outcomes** **Qmax** Baseline 8.69 ml/s (95% CI 8.05; 9.33), p<0.01, I^2=81% (6 studies, n=297) 3 months 13.17 ml/s (11.59; 14.74), p<0.01, I^2=91% (3 studies, n=73) 6 months 14.55 ml/s (14; 15.09), p=0.55, I^2=0% (4 studies, n=223) 12 months 17.12 ml/s (13.93, 20.31), p<0.01, I^2=91% (3 studies, n=137)	**Complications** **Pacella 2019 (n=160)** Transient haematuria, n=3 Acute urinary retention, n=3 Orchitis, n=1 Prostatic abscess, n=1 Dysuria spontaneously resolved, n=6. **(De Rienzo 2021 (n=21)**

First author, date	Efficacy outcomes	Safety outcomes
	IPSS Baseline 20.96 (19.43 to 22.49), p<0.01, I^2=86% (6 studies, n=297) 3 months 9.80 (6.58 to 13.02) p<0.01; I^2=99% (3 studies, n=73) 6 months 6.92 (5.19 to 8.66), p<0.01, I^2=95% (4 studies, n=223) 12 months 6.40 (5.72 to 7.08), p=0.03; I^2=71% (3 studies, n=137) **PVR, ml** Baseline: 91.94 (95% CI 69.73 to 114.15), p<0.01, I^2=96% (6 studies, n=297) 3-months: 36.06 (95% CI 18.16 to 53.97), p<0.01, I^2=93% (3 studies, n=73) 6-months: 27.57 (95% CI 16.01 to 39.13), p<0.01, I^2=96% (4 studies, n=223) 12-months: 22.27 (95% CI 14.60 to 29.94), p=0.01, I^2=78% (3 studies, n=137) **QOL score** Baseline: 4.52 (95% CI 3.96 to 5.09), p<0.01, I^2=95% (6 studies, n=297) 3-months: 1.47 (95% CI 0.88 to 2.07), p<0.01, I^2=99% (3 studies, n=73) 6-months: 1.66 (95% CI 1.15 to 2.18), p<0.01, I^2=93% (4 studies, n=223)	Prostatic abscess, n=1 **Manenti 2021(n=44)** Prolonged haematuria, n=1 orchitis, n=1 Prostatic abscess, n=1. **Cai 2021 (n=20)** Intraoperative urethral burn, n=1 **Frego 2021 (n=22)** Acute urinary retention, 13.6% (3/22) Urinary tract infection 9.1% (2/22) Dysuria 36.3% (8/22).

First author, date	Efficacy outcomes	Safety outcomes
	12-months: 1.55 (95% CI 0.93 to 2.17), p<0.01, I^2=96% (3 studies, n=137) **Sexual outcomes** **IIEF-5 (3 studies)** Baseline: 18.35 (95% CI 15.28 to 21.43), p<0.01, I^2=93% (3 studies, n=95) 1-month: 17.98 (95% CI 17.20 to 18.75), p=0.84, I^2=0% (2 studies, n=51) 3-months: 20.54 (95% CI, 15.36 to 25.72) p<0.01, I^2=92% (2 studies, n=51) **MSHQ-EjD** Baseline MSHQ-EjD: 5.08 (95% CI 4.21 to 5.95) p=0.78, I^2=0% (3 studies, n=95) 1-months MSHQ-EjD: 7.34 (95% CI 6.63 to 8.06) p=0.42, I^2=0% (2 studies, n=51) 3-months MSHQ-EjD: 7.95 (95% CI 5.90 to 9.99) p=0.02, I^2=83% (2 studies, n=51). **Procedure outcomes** Procedure time ranged from 28.2 to 60.9 minutes, median length of hospital stay ranged from 6.4 hours to 1.8 days and catheterisation time ranged from 7 to 16.5 days.	
Tzelves 2023	**Urodynamic parameters** **QMax, ml/s** Baseline, median range 7.6 to 9.2 ml/s	Complications (Clavien Dindo classification) Bertolo 2023:

First author, date	Efficacy outcomes	Safety outcomes
	3 months, median range 11 to 13.3 ml/s 6-12 months, median range 11.5 to 20.5 ml/s **PVR, ml** Baseline, range 60 to 199.9 ml 3 months, range 45.6 to 54.8 ml 6-12 months, range 41.5 to 60.3 ml **Symptom relief (assessed by IPSS)** Baseline, median range 18.3 to 22.7 3 months, median range 8 to 13.1 6-12 months, median range 5 to 7 **QOL component of IPSS** Baseline, median range 5 to 5.8 3 months, median range 1 to 2.1 6-12 months, median range 1 to 2.3 **Sexual function (erectile function and ejaculation)** Pacella 2019 1.2% loss of ejaculation De Rienzo 2021 no change in IIEF, ejaculation returned to baseline after 3 to 6 months Frego 2021 ejaculation preserved in 95.6%, no IIEF change was noticed at 12 months of follow up (only 45.5% completed questionnaire at this timepoint)	TPLA, grade II 19% (5/26) TURP, no complications. <u>Pacella 2019 (n=160):</u> Transient hematuria [grade 1], 2% (3/160) Acute urinary retention 2% (3/160) Orchitis, 4.3% (7/160) Prostatic abscess [grade 3], 1% (1/160) Transient dysuria [grade 1], 3.7% (6/160). <u>De Rienzo 2021:</u> Prostatic abscess [grade 3], 4.8% (1/121) <u>Frego 2021:</u> Dysuria [grade 1], 36.3% (8/22) Urinary retention [grade 2], 13.6% (3/22) Urinary tract infection [grade 2], 9.1% (2/22) <u>Manenti 2021</u> Prolonged hematuria [grade 1], 2.3% (1/44) Orchitis [grade 2], 2.3% (1/44)

First author, date	Efficacy outcomes	Safety outcomes
	Manenti 2021 everyone retained erectile function and ejaculation Sessa 2022 preserved ejaculation in everyone (improvement in 15 to 29%), erections were stable with some improvement (+2 to 4%) Bertolo 2023 ejaculation preserved in 96%. **Comparative studies (2 studies)** Bertolo 2023 (RCT: 26 TPLA versus 25 TURP) Outcomes reported in study 1 above Cai 2022 (TPLA, n= 20 versus PAE, n= 20) QMax Baseline: TPLA, 8.2; PAE, 8.2, p=0.752 3 months TPLA, 11.8; PAE, 12.2, p=0.776 6 months TPLA, 15.2; PAE, 16.3, p=0.420 PVR Baseline: TPLA, 82.8; PAE, 83.9, p=0.779 3 months TPLA, 44.3; PAE, 40.5, p=0.745 6 months TPLA, 30.3; PAE, 25.3, p=0.607 IPSS Baseline: TPLA, 22.7; PAE, 24.4, p=0.276 3 months TPLA, 13.1; PAE, 11.9, p=0.235 6 months TPLA, 9.1; PAE, 7.8, p=0.151	Bilateral prostatic abscess [grade 3], 2.3% (1/44). Cai 2022: TPLA group Hematuria, dysuria [grade 1], 15% (3/20) PAE group: Pelvic pain [grade 1], 10% (2/20) Lagana 2022 Orchitis [grade 2], 1.6% (1/63) Prostatic abscess [grade 3], 3.2% (2/63).

First author, date	Efficacy outcomes	Safety outcomes
	<u>QoL</u> Baseline: TPLA, 5; PAE, 5.1, p=0.838 3 months TPLA, 3.5; PAE, 3.2, p=0.527 6 months TPLA, 2.3; PAE, 2.0, p=0.294 <u>PV</u> baseline TPLA 70.7; PAE 72.5, p=0.835 3 months TPLA 60.4, PAE 56.1, p=0.527 6 months TPLA 54.7, PAE 51.0, p=0.573 The IPSS, QoL, Qmax, PVR, and PV at 3 and 6 months after TPLA and PAE improved compared with baseline (p<0.001 for all outcomes). **Procedure outcomes** Procedure time ranged between 28 and 61 minutes, with the actual ablation time being between 13 and 42.6 minutes. Length of hospital stay ranged from 1 to 2 days. Catheterisation time ranged between 4 and 17.3 days, and most people needed a catheter for 7 to 8 days.	
Minafra P 2023 Italy (n=20)	**<u>IPSS, median (IQR)</u>** Baseline 18 (16 to 21) 6 months 6 (3 to 12) 3 years 12 (10 to 15)	TPLA related adverse events 0 Late-onset complications 0 Resumed medical treatment for BPH or underwent a second intervention- 0

First author, date	Efficacy outcomes	Safety outcomes
	change from baseline 6 points (IQR -9 to -5); p<0.01. decreased by 37.2% **QOL, median (IQR)** Baseline 4 (4 to 5) 6 months 2 (1 to 3) 3 years 2 (1 to 2) change from baseline -3 (-1 to -1), p<0.01 decreased by 60%, (IQR -76.3 to 45.8, p<0.01). **Qmax (ml/s), median (IQR)** Baseline 8.8 (7.8 to 10.8) 6 months 13.9 (5.0 to 32.0) 3 years 11.0 (9.0 to 12.8), p<0.01 change from baseline 3.2 ml/s (IQR 1.5 to 4.3 ml/s). increased by 45.8% **PVR (ml), median (IQR)** Baseline 70 (33-120) 6 months 14 (0-50) 3 years 15 (0-25) change from baseline -55 (IQR -33 to -95), p<0.01 decreased by 85.7%	

First author, date	Efficacy outcomes	Safety outcomes
	MHSQ-EjD, median (IQR) Baseline 4 (3 to 8) 6 months 9 (5 to 13) 3 years 11 (7 to 12), p<0.01 **IIEF-5, median (IQR)** Baseline 17 (15 to 21) 6 months 18 (3 to 25) 3 years 17 (15 to 20), p=not significant **PV, median (IQR)** Baseline 41.5 (40 to 54.3) 6 months NA 3 years 35 (32 to 38); reduced by 20.4% (p<0.01).	
Destefanis 2023	**Median (IQR) scores** **IPSS (evaluated in people not carrying chronic urinary catheters)** Baseline, n=40: 25 (19 to 30) 3-months, n=40: 10.5 (7.5 to 13), p<0.001 6-months, n=38: 8 (6 to 11.5), p=0.001 (compared with baseline) and p=0.037 (compared with 3 months) **IPSS QoL**	**Complications n (%)** Catheter displacement/malfunction, n=3 (7.5) Urinary Tract Infection, n= 5 (12.5) Haematuria n= 1 (2.5) Acute urinary retention, n= 13 (32.5) Blood transfusion, n= 1 (2.5) Heart failure, n= 3 (7.5)

First author, date	Efficacy outcomes	Safety outcomes
	Baseline, n=40: 6 (5 to 6) 3-months, n=40: 3 (0 to 4), p<0.001 6-months, n=38: 2 (0 to 4), p<0.001 (compared with baseline) and p=0.028 (compared with 3 months) **SF36** Baseline, n=40: 46.5 (30.5 to 64) 3-months, n=40: 50 (40 to 74), p=0.139 6-months, n=38: 55 (35 to 76), p=0.053 (compared with baseline) and p=0.153 (compared with 3 months) **Qmax (ml/sec) (evaluated in people not carrying chronic urinary catheters)** Baseline, n=40: 8 (5.5 to 10) 3-months, n=40: 12.5 (9.5 to 14), p=0.056 6-months, n=38: 12 (10 to 13), p=0.044 (compared with baseline) and p=0.161 (compared with 3 months) **PVR (cc) (evaluated in people not carrying chronic urinary catheters)** Baseline, n=40: 50 (15 to 180) 3-months, n=40: 30 (0 to 60), p=0.090 6-months, n=38: 30 (0 to 60), p=0.092 (compared with baseline) and p=0.547 (compared with 3 months) **Prostate volume (cc)** Baseline, n=40: 38 (30.5 to 73) 3-months, n=40: 35 (26 to 49), p<0.001	Death, n= 2 (5) Multiple complications, n= 5 (12.5) **Clavien-Dindo grade n (%)** 0, n= 19 (47.5) 1, n= 13 (32.5) 2, n= 5 (12.5) 3, n= 1 (2.5) 4, n= 0 (0) 5, n= 2 (5)

First author, date	Efficacy outcomes	Safety outcomes
	6-months, n=38: 34 (28 to 49), p<0.001 (compared with baseline) and p=0.040 (compared with 3 months). **PSA (ng/ml)** Baseline, n=40: 2.2 (0.8 to 3.8) 3-months, n=40: 2.3 (1.7 to 2.7), *p*=0.888 6-months, n=38: 1.8 (0.9 to 8), *p*=0.500 (compared with baseline) and p=0.317 (compared with 3 months)	
van Kollenburg 2024	**Qmax (ml/s), mean (SD)** Baseline 9.7 (3.5) 3 months 12.8 (6.1) 6 months 12.1 (6.1) 12 months 14.9 (6.0) change baseline to 12 months 5.2 (7.4), p=0.015 **Voiding, IPSS** Baseline 21.3 (5.2) 3 months 12.8 (6.0) 6 months 11.7 (5.2) 12 months 10.9 (5.5) change baseline to 12 months -9.7 (6.8), p<0.0001. **QoL** Baseline 4.9 (0.9) 3 months 2.6 (1.7) 6 months 1.8 (1.0)	Device related events: 0 Grade 3 and above events: 0 Grade 2 events Urinary retention (treated by catheter) 50% (10/20) Urinary tract infection (due to catheter, treated with antibiotics) 35% (7/20) Grade 1 events (all resolved with conservative treatment) Dysuria 25% (5/20) Urgency 20% (4/20) Haematuria 15% (4/20) Pain 10% (2/10) Frequency 5% (1/20)

First author, date	Efficacy outcomes	Safety outcomes
	12 months 1.9 (1.1) change baseline to 12 months -2.9 (1.5), p<0.0001. **Erectile function, IIEF-15** Baseline 35.4 (23.4) 3 months 36.9 (24.8) 6 months 40.5 (23.3) 12 months 31.1 (24.4) change baseline to 12 months -2.8 (13.5), p=0.570. **PVR (ml)** Baseline 61.8 (58.3) 3 months 64.8 (70.4) 6 months 74.2 (87.4) 12 months 4.2 (55.8) change baseline to 12 months -10.8 (66.8), p=0.755. **PV (ml)** Baseline 65.5 (23.0) 12 months 63.2 (20.6) change baseline to 12 months -4.7 (18.1), p=0.251. **Pain, VAS** Baseline 0.9 (2.23)	

First author, date	Efficacy outcomes	Safety outcomes
	3 months 0.5 (1.0) 6 months 0.3 (0.7) 12 months 0.1 (0.3) change baseline to 12 months -0.8 (2.4), p=0.313. **Haematuria, HGS** baseline 0 3 months 0.1 (0.4) 6 months 0.1 (0.4) 12 months 0.2 (0.5) change baseline to 12 months 0.2 (0.5), p=0.50. **Urological medication** stopped in 17/20 people at 12 months. **Sexual function preservation** at 12 months 85% (11/13) preserved antegrade ejaculation. 15% (2/13) had retrograde ejaculation. The other people had either no ejaculatory function at inclusion, or missing follow-up data. One person reported erectile dysfunction following the TPLA procedure, but IIEF-15 score returned to baseline at 12 months.	
Polverino 2023	**Clinical Outcomes (at median 12 months)** Reintroduction of medical therapy: 7/23 (30%)	No Clavien-Dindo Grade ≥2 postoperative complications were recorded.

First author, date	Efficacy outcomes	Safety outcomes
	Treatment failure: 8.5% (2/23) **IPSS** Improvement in IPSS symptoms: 57% (12/21) symptom class Severe to moderate 8/12 Moderate to mild 3/12 Severe to mild 1/12 Worsening of symptom status: n=1 **QOL score, median (IQR)** Pre-operative: 4 (IQR: 3-5) Post-operative: 2 (IQR: 1-3)	
Bianco 2024	**Qmax, ml/s (n=19), mean (SD)** Baseline 9.5 (2.2) 6 months 16.9 (5.6), p<0.001 12 months 20.7 (4.6), p<0.001 24 months 22.3 (4.2), p<0.001 **Qave, ml/s (n=19), mean (SD)** Baseline 5.0 (1.3) 6 months 9.7 (3.7), p<0.001 12 months 11.6 (3.4), p<0.001 24 months 12.0 (3.6), p <0.001 **PVR rate, % (n=19), mean (SD)**	Mean overall pain score (VAS) for treatment, n (%) 1= 3 (15%) 2= 8 (40%) 3= 6 (30%) 4= 3 (15%) Catheter-free at discharge = 12 (60%) Catheter-free at 30 days = 19 (95%) Urgent hospital admission at 30 days = 0 Surgical reintervention at 24 mo,= 1 (5%)

First author, date	Efficacy outcomes	Safety outcomes
	Baseline 24.6 (14.9) 6 months 9.7 (9.34), p=0.001 12 months 7.9 (5.3), p<0.001 24 months 7.4 (4.6), p<0.001 **IPSS (n=19), median (IQR)** Baseline 14 (12 to 17) 6 months 6 (3 to 8), p<0.001 12 months 3 (5 to 2), p<0.001 24 months 3 (5 to 2), p<0.001 **IPSS-QoL (n=19), median (IQR)** Baseline 5 (4 to 6) 6 months 2 (2 to 3), p=0.005 12 months 2 (1 to 3), p<0.001 24 months 1 (1 to 3), p<0.001 **Sexual Health in Men score (n=20), median (IQR)** Baseline 23 (18.5 to 24) 6 months 21.5 (18.5 to 24) 12 months 22 (18.2 to 23) 24 months 22 (19 to 22.7) **Anterograde ejaculation % (n=19)** Baseline 19 100% (19) 6 months 84.2% (16), p=0.001 12 months 89.5% (17), p<0.001	

First author, date	Efficacy outcomes	Safety outcomes
	24 months 89.5% (17), p<0.001 Procedures successfully completed= 20 (100%)	
Lo Re, 2024, Italy	**Qmax (Maximum Flow Rate) Improvement:** Baseline: 9.1 ml/s (IQR 6.9–12) 3 months: 11 ml/s (IQR 8.8–14.8) 6 months: 11 ml/s (IQR 8.5–16.0) 12 months: 13 ml/s (IQR 8.5–16.9) **IPSS (International Prostate Symptom Score) Improvement:** Baseline: 18 (IQR 15–23) 3 months: 10 (IQR 6–13) 6 months: 10 (IQR 5.7–14) 12 months: 10 (IQR 5–16.5) **QoL (Quality of Life) Improvement:** Baseline: 4 (IQR 3–4) 3 months: 2 (IQR 1–3) 6 months: 2 (IQR 1–3) 12 months: 2 (IQR 1–3) **MSHQ (Male Sexual Health Questionnaire) 3-item Improvement:** Baseline: 6 (IQR 2–11) 3 months: 10 (IQR 5–13)	• No intraoperative complications. • 2% experienced urinary tract infections (Clavien-Dindo 2) within 3 months. • No Clavien-Dindo grade 3–5 complications. • Median catheterization time was 7 days. • Of 14 people with pre-existing catheters, 5 (35.7%) required permanent catheterization; 3 later had their catheters removed after further surgery. • 99 people were discharged the same day; one required overnight hospitalization for pelvic pain. • Treatment failure rate was 9%, with 7 needing further endoscopic surgery.

First author, date	Efficacy outcomes	Safety outcomes
	6 months: 11 (IQR 5–14) 12 months: 9 (IQR 5–13) **PVR (Post-Void Residual) Improvement:** Baseline: 90 ml (IQR 50–150) 3 months: 45 ml (IQR 20–77.5) 6 months: 50 ml (IQR 20–90) 12 months: 45 ml (IQR 12–87.5**)** **All these improvements were statistically significant (p<0.001).**	
Patelli, 2024, Italy	**International Prostate Symptom Score (IPSS):** • Median reduction at 12 months: 74% (IQR, 60%–81%) (p<0.001) • Median reduction at last follow-up: 60% (IQR, 43%–75%) (p<0.001) **Quality of Life (QoL) Score:** • Median improvement at 12 months: from 5 (IQR, 4–5) to 1 (IQR, 0–1) (p<0.001) • Median improvement at last follow-up: from 5 (IQR, 4–5) to 1 (IQR, 0–2) (p<0.001) **Postvoid Residual (PVR):**	**Intraprocedural Adverse Events:** • None reported. **Periprocedural Adverse Events:** • 1 case of prostatitis (Society of Interventional Radiology [SIR] Grade I) • 1 case of urinary tract infection (SIR Grade I) • Both adverse events were mild and successfully treated with antibiotics. **Long-term Adverse Events:**

First author, date	Efficacy outcomes	Safety outcomes
	• Median reduction at 12 months: from 108 ml (IQR, 38–178 ml) to 13.5 ml (IQR, 0–40.5 ml) (p<0.001), a median reduction of 88% (IQR, 61%–100%) • Median reduction at last follow-up: from 108 ml (IQR, 38–178 ml) to 28.5 ml (IQR, 15–50 ml) (p=0.031), a median reduction of 63% **Prostate Volume:** • Median reduction at 12 months: from 66 ml (IQR, 48.5–86.5 ml) to 46 ml (IQR, 36–65 ml) (p<0.001), a median reduction of 32% (IQR, 21%–45%) • Median reduction at last follow-up: from 66 ml (IQR, 48.5–86.5 ml) to 61 ml (IQR, 37–89 ml) (p<0.001), a median reduction of 15% (IQR, 1%–34%) These outcomes indicate that TPLA significantly improved IPSS, QoL, PVR, and prostate volume, with benefits persisting at long-term follow-up.	• No cases of incontinence or erectile dysfunction. • 30 of 34 evaluable people (88.2%) had preserved antegrade ejaculation at long-term follow-up. These outcomes indicate that TPLA was well tolerated with a low incidence of adverse events, preserving key functions such as ejaculation and avoiding severe complications.

Procedure technique

All studies detailed the procedure technique and device used. TPLA was done using the SoracteLite EchoLaser, Elesta laser ablation system. A dedicated device (Echolaser Smart Interface) was used to support needle/fibre positioning in the prostate in a safe manner. The device assists in needle placement by safety margins projection on the ultrasound image. The procedure was done as a day-case procedure, mostly under local anaesthesia with or without sedation in a few small pilot studies. People could be discharged 6 hours after the procedure. Additional needles were used depending on the size of the prostrate. Ultrasound guidance was used mainly across studies, but one study used post procedural MRI. Low power laser light energy between 3 to 5 watts was used across studies.

Efficacy

Preservation of sexual function

Ejaculatory function (assessed by the MSHQ-EjD)

Six included studies reported this outcome.

A RCT of 51 people comparing TPLA (n=26) with TURP (n=25) reported that the distribution of ejaculatory function (assessed by the MSHQ-EjD) at 1 month remained unchanged from baseline in the TPLA group (29 to 29, p=0.2), but decreased significantly from baseline in the TURP group (29 to 20, p=0.01). The A statistically significant difference was found between the treatment groups at 1 month favouring TPLA. (p= 0.004; Bertolo 2023).

A RCT of 50 people, 25 of whom had TPLA showed that there was no change in first year of the MSHQ 1, 2, 3, and MSHQ 4 scores compared with the baseline values in the TPLA group (p=0.54 for MSHQ 1,2,3 and p=0.34 for MSHQ 4; Canat 2023).

In a systematic review and meta-analysis of 297 people assessing TPLA in people with BPH, ejaculatory function reported in 3 studies (n=95) improved from baseline at 1 and 3 months follow up. The overall pooled mean for MSHQ-EjD score improved from baseline score of 5.08 (based on 3 studies, n=95), to 7.34 at 1 month and 7.95 at 3 months (based on 2 studies, n=51; Tafuri, 2023).

In the systematic review of 477 people assessing TPLA, more than 95% of people retained their ejaculation function (Tzelves 2023).

The prospective case series of 21 people who had TPLA showed that there was a statistically significant improvement in median ejaculatory function, as assessed by the MSHQ-EjD questionnaire, from 4 at baseline to 11 at 3 years follow up (improved by 60%, p<0.01; Minafra 2023).

The prospective single centre study of 100 people having TPLA procedure reported a statistically significant improvement in ejaculatory function. The median MSHQ 3-item scores increased from a baseline of 6 (IQR 2–11) to 10 (5–13) at 3 months, 11 (5–14) at 6 months, and 9 (5–13) at 12 months (all p<0.001, Lo Re 2024).

Preserved antegrade ejaculation

Five studies reported this outcome.

In the RCT of 51 people comparing TPLA with TURP, presence of antegrade ejaculation (defined as ‘emission of semen after orgasm’) was statistically significantly higher in people in the TPLA group (96%, 25/26) compared with those in the TURP group (28%, 7/25) at 1 month follow up (p<0.001; Bertolo 2023).

In a prospective case series of 20 people who had TPLA, there was no significant change in the number of people reporting antegrade ejaculation at 6, 12 and

24 months (84%; 90%, 90% [17/19]) compared with baseline (p=0.1 at 24 months; Bianco 2024).

The small pilot study of 20 people who had TPLA in an outpatient setting under local anaesthesia reported that IIEF-15 total score remained stable, and 85% (11/13) of people preserved antegrade ejaculation and 15% (2/13) had retrograde ejaculation (van Kollenburg 2024).

In the prospective single centre descriptive study of 100 people who had TPLA, it was found that, in all sexually active people, antegrade ejaculation was fully preserved following the procedure (Lo Re, 2024).

In the prospective study of 40 people who had TPLA, at the long-term follow-up, 88.2% of the evaluable people (30 out of 34) retained antegrade ejaculation (Patelli, 2024).

Erectile function (assessed by IIEF-5)

Five studies reported this outcome.

The RCT of 51 people with BPH comparing TPLA (n=26) with TURP (n=25) reported no statistically significant difference in median IIEF-5 scores at 1 month follow up compared with baseline (TPLA group: from 17 at baseline to 18 at 1 month, p=0.5; TURP group: from 20 at baseline to 19 at 1 month, p=0.3). No statistically significant differences were found between the groups (p=0.3) at 1 month follow up (Bertolo 2023).

The RCT of 50 people showed similar IIEF-5 scores between TPLA and TURP groups (p=0.83 and p=0.12, respectively) at 1-year follow up (Canat 2023).

In the systematic review and meta-analysis of 297 people with BPH assessing TPLA, the overall pooled mean value for IIEF-5 score (based on 3 studies, n=95)

at baseline was 18.35 and remained unchanged at 1 month (17.98) and at 3 months (20.54; Tafuri, 2023).

In the systematic review of 477 people assessing TPLA, sexual function was evaluated after surgery. Most studies reported erectile function was maintained or improved (Tzelves 2023).

A prospective case series of 21 people who had TPLA showed no statistically significant change in median IIEF-5 score from baseline (17) to 3 years (17, $p>0.05$; Minafra 2023).

Symptom relief (assessed by IPSS)

All 11 studies reported this outcome.

The RCT of 51 people with BPH comparing TPLA (n=26) with TURP (n=25) reported statistically significant improvement in median IPSS scores for both treatments at 6 months follow up compared with baseline (TPLA group: from 24 at baseline to 11 at 6 months, $p=0.01$; TURP group: from 20 at baseline to 8 at 6 months, $p<0.001$). No statistically significant differences in IPSS score were found between the groups ($p=0.1$) at 6 months (Bertolo 2023).

The RCT of 50 people showed statistically significant improvement in IPSS score compared with baseline values in both TPLA and TURP groups at 1 year ($p<0.01$; Canat 2023).

In the systematic review and meta-analysis of 297 people with BPH assessing TPLA, the overall pooled mean for IPSS (based on 6 studies, n=297) improved statistically significantly from baseline (20.96) to 3 months (9.80), and then remained stable at 6 months (6.92), and 12 months (6.40) follow up ($p<0.01$ for 3 and 6 months, $p=0.03$ at 12 months; Tafuri, 2023).

In the systematic review of 477 people assessing TPLA, the baseline median IPSS score (range 18.3 to 22.7) reduced at 3 months (range 8 to 13.1) and 6 to 12 months (range 5 to 7) follow up. The QOL component of IPSS was also improved from baseline (Tzelves 2023).

A prospective case series of 21 people who had TPLA showed a statistically significant improvement in IPSS at 3 years follow up. Median IPSS values changed from 18 at baseline to 12 at 3 years, with a median score reduction of 6 points (score decreased by 37%, $p<0.01$; Minafra 2023).

A pilot study of 20 people who had TPLA in an outpatient setting under local anaesthesia reported statistically significant improvement in IPSS from 21.3 at baseline to 10.9 at 12 months follow up ($p<0.0001$; van Kollenburg 2024).

A prospective case series of 40 people who had TPLA showed statistically significant improvement in IPSS at 6 months after surgery compared with baseline median values (8 [6 to 11.5], −17 points, −68%, $p=0.001$). There was also a statistically significant improvement between the 3-month and the 6-month assessments ($p=0.037$; Destefanis 2023).

In a preliminary single-centre experience study of 21 people who had TPLA for BPH, 57% (12/21) people reported an improvement in IPSS symptom class, 38% (8/21) had significant improvement in IPSS scores but symptom class remained stable, and one person experienced worsening of symptom status at median 12 months follow up. (Polverino 2023).

The prospective case series of 20 people who had TPLA, reported statistically significant reduction in the median IPSS score from baseline 14 (IQR 12 to 17) to 6 (IQR 3 to 8) at 6 months; 3 (IQR 5 to 2) at 12 months, and 3 (IQR 2 to 4) at 24 months ($p<0.001$ at all timepoints; Bianco 2024).

The prospective single centre study on 100 people having TPLA procedure reported, there was a statistically significant improvement in urinary symptoms, with the median IPSS scores dropping from 18 (IQR 15–23) at baseline to 10 (6–13) at 3 months, 10 (5.7–14) at 6 months, and 10 (5–16.5) at 12 months (all p<0.001) (Lo Re, 2024).

In the prospective study of 40 people who had TPLA, IPSS score showed a statistically significant and sustained improvement over time. At 12 months, people experienced a median reduction of 74% (IQR 60-81%, p<0.001) in IPSS compared to baseline, with scores dropping from a median of 23 (IQR 19–26) to 5 (IQR 4–9). At the last follow-up, which had a median duration of 57 months, people still showed a 60% reduction in their symptom scores, with a median IPSS of 8.5 (IQR 4–12) (Patelli, 2024).

Urodynamic parameters

Maximum urinary flow rate (Qmax)

Ten studies reported this outcome.

The RCT of 51 people with BPH comparing TPLA (n=26) with TURP (n=25) reported that both treatments had a statistically significant mean improvement in Qmax at 6 months follow up compared with baseline (TPLA group: from baseline median value 10.2 to 15.2 at 6 months, p<0.001; TURP group: from baseline 10.0 to 26.0, p=0.006). A statistically significant difference was found between the treatment groups at 6 months favouring TPLA. (TPLA compared with TURP: 15.2 ml/s compared with 26.0 ml/s; p<0.001; Bertolo 2023).

The RCT of 50 people, 25 of whom had TPLA, showed a statistically significant improvement in Qmax compared with baseline values in both TPLA and TURP groups at 1 year (p<0.01). In the first year the Qmax values of the groups were

statistically significantly higher in the TURP group than in the TPLA group (p<0.01; Canat 2023).

In the systematic review and meta-analysis of 297 people assessing TPLA in people with BPH, the overall pooled mean for Qmax (based on 6 studies, n=297) statistically significantly improved from baseline 8.69 ml/s to 13.17 ml/s at 3 months (p<0.01), 14.55 ml/s at 6 months (p=0.55), and 17.12 ml/s at 12 months (p<0.01; Tafuri, 2023).

In the systematic review of 477 people assessing TPLA, the median Qmax at baseline ranged from 7.6 ml/s to 9.2 ml/s and increased to 11 ml/s to 13.3 ml/s at 3 months and 11.5 ml/s to 20.5 ml/s at 6 to 12 months. In 1 study comparing TPLA with PAE there was no significant difference in Qmax values at 3 and 6 months follow up between the groups (p=0.776; p=0.420; Tzelves 2023).

The small prospective case series of 21 people who had TPLA showed a statistically significant improvement in Qmax at 3 years follow up. Median Qmax values changed from baseline 8.8 to 11.0 at 3 years with a median score improvement of 3.2 ml/s (46% increase, p<0.01; (Minafra 2023).

The small pilot study of 20 people who had TPLA in an outpatient setting under local anaesthesia reported statistically significant improvement in Qmax from baseline 9.7 to 14.9 at 12 months follow up (p=0.015; van Kollenburg 2024).

A small prospective case series of 40 people who had TPLA showed significant improvement in Qmax score at 6 months after surgery compared with baseline median values (8 [IQR 5.5 to 10] to 12 [IQR 10 to 13], p=0.044) (Destefanis 2023).

The prospective case series of 20 people who had TPLA, showed a statistically significant improvement in the mean Qmax score from 9.5 at baseline to 16.9 at

6 months, 20.7 at 12 months and 22.3 at 24 months (p<0.001 at all timepoints; Bianco 2024).

The prospective study of 100 people had TPLA procedure, showed a statistically significant improvement in urinary flow rates. The median Qmax increased from 9.1 ml/s (IQR 6.9–12) at baseline to 11 (8.8–14.8) at 3 months, 11 (8.5–16.0) at 6 months, and 13 (8.5–16.9) at 12 months (all p<0.001) (Lo Re, 2024).

In the prospective study of 40 people who had TPLA, improvements were observed in Qmax scores in people who did not have an indwelling catheter before the procedure (n=24). The mean baseline Qmax score was 9.8 ml/s and improved to 12.8 ml/s at 12 months, and remained the same by the last follow-up (12.0 ml/s). Among people who were catheter-dependent before the procedure (n=16), a similar trend was reported (improved from 11.8 ml/s at 1 year to around 11.4 ml/s at the last follow-up), (p values not reported) (Patelli 2024).

PVR urine volume

Ten studies reported this outcome.

In the RCT of 51 people comparing TPLA with TURP, PVR decreased from baseline in both the groups at 6 months (TPLA from 70 at baseline to 0 at 6 months; TURP from baseline 30 to 0). No statistically significant differences were found between the groups for PVR urine volume (p=0.6) at a 6 month follow up (Bertolo 2023).

The RCT of 50 people, 25 of whom had TPLA, showed statistically significant improvement in PVR compared with baseline values in both TPLA and TURP groups at 1 year (p<0.01; Canat 2023).

In the systematic review and meta-analysis of 297 people assessing TPLA in people with BPH, the overall pooled mean value for PVR (based on 6 studies,

n=297) statistically significantly improved from 91.94 ml at baseline to 36.06 ml at 3 months, 27.57 ml at 6 months, and 22.27 ml at 12 months ($p<0.01$ for all timepoints; Tafuri, 2023).

In the systematic review of 477 people assessing TPLA, the median PVR ranged between 60.0 and 199.9 ml among studies at baseline with median postoperative values ranging between 45.6 ml and 54.8 ml at 3 months and 41.5 ml and 60.3 ml at 6 to 12 months of follow up. In 1 study comparing TPLA and PAE there was no statistically significant difference in PVR urine volume at 3 and 6 months follow up between the groups ($p=0.745$ and $p=0.607$, respectively; Tzelves 2023).

The small prospective case series of 21 people who had TPLA showed that the median PVR reduced from 70 ml at baseline to 15 ml at 3 years follow up (decreased by 86%, $p<0.01$; Minafra 2023).

The small pilot study of 20 people who had TPLA in an outpatient setting under local anaesthesia reported no statistically significant difference in PVR volume (from 61.8 ml at baseline to 44.2 ml, $p=0.755$ at 12 months) (van Kollenburg 2024).

A small prospective case series of 40 people who had TPLA showed no statistically significant difference in PVR volume from baseline to 6 months follow up (median 50 ml to 30 ml, $p=0.092$). There was no change in PVR between 3 and 6 months ($p=0.547$; Destefanis 2023).

In the prospective case series of 20 people who had TPLA, the mean PVR volume ratio significantly reduced from baseline 24.6 to 9.7 at 6 months ($p=0.001$), 7.9 at 12 months ($p<0.001$) and 7.4 at 24 months ($p<0.001$; Bianco 2024).

There was a statistically significant reduction over time in post-void residual urine volume in the prospective study of 100 people who had TPLA. The median PVR decreased from 90 ml (IQR 50–150) at baseline to 45 (20–77.5) at 3 months, 50 (20–90) at 6 months, and 45 (12–87.5) at 12 months (all p<0.001) (Lo Re, 2024).

In the prospective study of 40 people who had TPLA, people without an indwelling catheter before the procedure (n=24) reported a statistically significant reduction in median PVR at 12 months compared with baseline (from 108 ml to 13.5 ml; p<0.001); representing a median reduction of 88%. However, this improvement was not maintained and at the last follow-up, the median PVR had slightly increased to 28.5 ml (Patelli 2024).

PV

Five studies reported this outcome.

In the systematic review of 11 studies, 1 study comparing TPLA and PAE reported that there was no statistically significant difference in PV at 3 and 6 months follow up between the groups (p=0.527 and p=0.573, respectively; Tzelves 2023).

The small prospective case series of 21 people who had TPLA showed a statistically significant reduction in median TRUS PV by 20.4% (IQR -25.3; -16.0 ml) from 41.5 ml at baseline to 35.0 ml (IQR 32.0 to 38.8) at 3 years follow up (p<0.01; Minafra 2023).

The small pilot study of 20 people who had TPLA in an outpatient setting under local anaesthesia reported no statistically significant change in PV, from baseline 65.5 ml to 63.2 ml (p=0.251) at 12 months (van Kollenburg 2024).

A small prospective case series of 40 people who had TPLA reported a statistically significant reduction in median PV from baseline 38 [IQR 30.5 to 73]

to 35 [IQR 26 to 49], (p<0.001). There was no change in PV between 3 and 6 months (p=0.040; Destefanis 2023).

In the prospective study of 40 people who had TPLA, at baseline, the median prostate volume was 66 ml (IQR 48.5–86.5). By the 12-month follow-up, this had decreased by 32%, down to 46 ml (IQR 36–65). Even at the last follow-up, the prostate volume remained significantly reduced, with a median of 61 ml (IQR 37–89), indicating a 15% overall reduction from baseline (Patelli 2024).

Quality of life

Eleven studies reported this outcome.

The RCT of 51 people comparing TPLA with TURP reported that QoL scores statistically significantly improved for both groups at 6 months from baseline (the median score in the TPLA group from 5 to 2 [p=0.002] and in the TURP group from 4 to 2 (p=0.001). No statistically significant differences were found between the groups at 6 months follow up (p=0.1; Bertolo 2023).

The RCT of 50 people, showed statistically significant improvement in IPSS QoL scores at 1 year compared with the baseline values in both TPLA and TURP groups (TPLA, from 4.75 to 1.70, p<0.01; TURP from 4.69 to 1.31, p<0.01; Canat 2023).

In the systematic review and meta-analysis of 297 people with BPH assessing TPLA, the overall pooled mean value for QoL score (based on 6 studies, n=297) statistically significantly improved from 4.52 at baseline to 1.47 at 3 months, 1.66 at 6 months, and 1.55 at 12 months (p<0.01 for all timepoints; Tafuri, 2023).

In the systematic review of 477 people assessing TPLA, the median QoL ranged between 5 and 5.8 (based on the IPSS QoL-related question) among studies at baseline with median postoperative values ranging between 1 and 2.1 at

3 months and 1 and 2.3 at 6 to 12 months of follow up. In 1 study comparing TPLA and PAE there was no statistically significant difference in QoL at 3 and 6 months follow up between the groups (p=0.527 and p=0.294, respectively; Tzelves 2023).

The small prospective case series of 21 people who had TPLA showed that the median QoL score statistically significantly decreased from 4 at baseline to 2 at 3 years follow up (decreased by 60%, p<0.01; Minafra 2023).

The small pilot study of 20 people who had TPLA in an outpatient setting under local anaesthesia reported that QoL improved statistically significantly from 4.9 at baseline to 1.9 (p<0.0001) at 12 months (van Kollenburg 2024).

A small prospective case series of 40 people who had TPLA showed statistically significant improvement in IPSS QoL score at 6 months after surgery compared with baseline median values (2 [0 to 4.9], −4 points, −66.6%, p<0.001). There was also a statistically significant improvement between the 3-month and the 6-month assessments (p=0.028; Destefanis 2023).

In the preliminary single-centre experience study of 21 people who had TPLA for BPH, the median QoL score improved from a pre-operative score of 4 (IQR 3 to 5) to a postoperative score of 2 (IQR 1 to 3) at median 12 months follow up (p value not reported) (Polverino 2023).

In the prospective case series of 20 people who had TPLA, the median IPSS-QoL score statistically significantly reduced from baseline 5 (IQR 4 to 6) to 2 (IQR 2 to 3) at 6 months (p=0.005), 2 (IQR 1 to 3) at 12 months (p<0.001) and 1 (IQR 1 to 3) at 24 months (p<0.001; Bianco 2024).

The prospective study of 100 people who had the TPLA procedure reported that the QoL scores improved statistically significantly from 4 (IQR 3–4) at baseline to 2 (1–3) at 3, 6, and 12 months (all p<0.001; Lo Re, 2024).

In the prospective study of 40 people who had TPLA procedure, statistically significant improvements in median QOL score was reported at 12 months (from baseline 5 [IQR, 4–5] to 1 [IQR, 0–2] and even at last follow-up (1 [IQR 0-2], p<0.001) (Patelli, 2024).

Satisfaction with the treatment (EPIC, response to question 32)

In the RCT of 51 people, based on EPIC question 32, a statistically significantly smaller proportion of people were satisfied with treatment in the TPLA group compared with the TURP group at 1 month follow-up (50% [13/26] compared with 80% [20/25], p=0.02; Bertolo 2023).

Procedure outcomes

In the RCT of 51 people, the median procedure time was statistically significantly shorter in the TPLA group compared with TURP group (35 minutes compared with 68 minutes; p<0.001). The median hospital stay was longer in those who had TURP compared with TPLA (3 days compared with 2 days; p=0.008). The median catheterisation time was not statistically different between the groups (4 days for TPLA compared with 3 days for TURP, p=0.7; Bertolo 2023).

In the systematic review and meta-analysis of 6 studies on TPLA, procedure time ranged from 28.2 minutes to 60.9 minutes. Median length of hospital stay ranged from 6.4 hours to 1.8 days, and catheterisation time ranged from 7 days to 16.5 days (Tafuri 2023).

In the systematic review of 11 studies, procedure time ranged between 28 minutes and 61 minutes. Length of hospital stay ranged from 1 day to 2 days, and catheterisation time ranged between 4 days and 17.3 days (Tzelves 2023).

Safety

Pain

In the RCT of 51 people, there were no differences in the perception of pain (assessed by VAS perioperatively) between the TPLA and TURP groups (median score 0 compared with 1, p=0.9; Bertolo 2023).

The small pilot study of 20 people who had TPLA in an outpatient setting under local anaesthesia reported that pain score (assessed on VAS) improved after TPLA but was not significantly different between baseline and 12 months follow up (0.9 to 0.1; p=0.313; van Kollenburg 2024).

In the prospective case series of 20 people who had TPLA, post procedure, 15% (3/20) people had a mean pain score (VAS) of 1, 40% (8/20) people had a pain score of 2, 30% (6/20) people had a pain score of 3 and 15% (3/20) had a pain score of 4 (Bianco 2024).

In the prospective study of 100 people who had TPLA procedure, 1 patient required overnight hospitalisation for pelvic pain and was discharged on postoperative day 1 (Lo Re, 2024).

Haematuria

In the systematic review and meta-analysis of 297 people with BPH assessing TPLA, 1 study (Pacella 2019) reported that 3 people experienced transient haematuria and another study (Manenti 2021) reported that 1 person experienced prolonged haematuria. All were managed by keeping the bladder catheter in place for a few days (Tafuri, 2023).

The small pilot study of 20 people who had TPLA in an outpatient setting under local anaesthesia reported that HGS score improved after TPLA from baseline 0

to 0.2 at 12 months follow-up but this was not statistically significantly different (p=0.50; van Kollenburg 2024).

The small prospective case series of 40 people who had TPLA reported haematuria in 1 person (Destefanis 2023).

Urinary retention

In the RCT of 51 people, those who had TPLA had a higher rate of acute urinary retention after catheter removal compared with those who had TURP (19% [5/26] versus 0% [0/25]; p=0.02; Bertolo 2023).

In the systematic review and meta-analysis of 297 people assessing TPLA in people with BPH, acute urinary retention needing major antibiotic treatment was reported in 14% (3/22) of people in one study (Frego 2021) and 2% (3/160) of people in another study (Pacella 2019, Tafuri, 2023).

The small prospective case series of 40 people who had TPLA reported urinary retention in 33% (13/40) of people (Destefanis 2023).

The small pilot study of 20 people who had TPLA in an outpatient setting under local anaesthesia reported urinary retention in 50% (10/20) of people (van Kollenburg 2024).

Urinary tract infection

In the systematic review and meta-analysis of 297 people with BPH assessing TPLA, the authors reported that in 1 study (Frego 2021) 9% (2/22) of people had urinary tract infection needing major antibiotic treatment (Tafuri 2023).

From the prospective study on 100 people who had TPLA, 2% of people experienced urinary tract infections treated with oral antibiotics in the first 3 months after the procedure (Clavien-Dindo 2) (Lo Re, 2024).

In the prospective study of 40 people who had TPLA, 1 case reported urinary tract infection (SIR Grade I), which was successfully treated with antibiotics (Patelli, 2024).

Orchitis

In the systematic review and meta-analysis of 297 people assessing TPLA in people with BPH, 2 studies (Pacella 2019 and Manenti 2021) reported orchitis in 1 person in each study and both had antibiotic treatment (Tafuri, 2023).

In the systematic review of 477 people assessing TPLA, 1 study (Lagana 2022, n=63) reported orchitis in 1 person (1.6%; Tzelves 2023).

Prostatic abscess

In the systematic review and meta-analysis of 297 people with BPH assessing TPLA, 3 studies (Pacella 2019, De Rienzo 2021 and Manenti 2021) reported prostatic abscess in 1 person in each study. All cases had treatment with percutaneous drainage and antibiotic therapy (Tafuri, 2023).

In the systematic review of 477 people assessing TPLA, 4 studies (Pacella 2019, De Rienzo 2021, Manenti 2021, Lagana 2022) reported prostatic abscess in 5 people (1% to 5% of each study population; Tzelves 2023).

Intraoperative urethral burn

In the systematic review and meta-analysis of 297 people with BPH assessing TPLA, 1 study (Cai 2021, n=20) reported an intraoperative complication consisting of urethral burn. This was treated by keeping the bladder catheter for 25 days (Tafuri, 2023).

Dysuria

In the systematic review and meta-analysis of 297 people with BPH assessing TPLA, 1 study (Frego 2021) reported dysuria that resolved spontaneously in 36%

(8/22) of people and another study (Pacella 2019) reported transient dysuria in 4% (6/160) of people (Tafuri 2023).

The small pilot study of 20 people who had TPLA in an outpatient setting under local anaesthesia reported dysuria in 25% (5/20) of people (van Kollenburg 2024).

Prostatitis

In the prospective study of 40 people who had TPLA, 1 person had prostatitis (SIR Grade I), which was successfully treated with antibiotics (Patelli, 2024).

Anecdotal and theoretical adverse events

Expert advice was sought from consultants who have been nominated or ratified by their professional society or royal college. They were asked if they knew of any other adverse events for this procedure that they had heard about (anecdotal), which were not reported in the literature. They were also asked if they thought there were other adverse events that might possibly occur, even if they had never happened (theoretical).

They listed the following anecdotal adverse events:

- urethral irritation needing temporary catheterisation
- stress incontinence.

They listed the following theoretical adverse events:

- perforation or injury of surrounding structures such as rectum external sphincter, urethra, neurovascular bundles
- recto urethral fistula
- failure to void after catheter removal
- staff risks if the laser protocol not followed appropriately.

20 professional expert questionnaires for this procedure were submitted. Find full details of what the professional experts said about the procedure in the specialist advice questionnaires for this procedure.

Validity and generalisability

- There are 2 small RCTs comparing TPLA with TURP with outcomes reported at 12 months follow up.
- The study by Canat (2023) described simple 1:1 randomisation to TPLA or TURP according to order of admission, so there was no allocation concealment. Although most of the characteristics were similar between the groups at baseline, those assigned to the TPLA group had a statistically significantly higher American Society of Anesthesiologists score (p=0.03).
- Evidence is mainly from small observational studies with short-term follow up and most of the studies were done in Italy.
- There is a lack of medium- and long-term follow up.
- No significant modifications of the device or surgical technique were reported.

Registry

Professional experts stated that data on these procedures are added to the existing European data registry for TPLA BPH treatment.

Any ongoing trials

NCT03776006: Registry of transperineal laser ablation for treatment of LUTS with use of the Echolaser device. A multicentre, international registry to evaluate the treatment of lower urinary tract symptoms in terms of long-term efficacy, functional outcomes and safety. The long-term efficacy of TPLA for LUTS will be measured by the time until surgical retreatment. Follow-up 5 years; Study completion date 2029. Sponsor: Amsterdam University Medical Centers, University of Amsterdam.

NCT06564415: European registry for transperineal laser ablation of prostate (TPLA) for lower urinary tract symptoms due to BPO, prospective cohort study, n=2500 people, follow-up 5 years, study completion date January 2034; location Italy.

Related NICE guidance

Interventional procedures

Transurethral water-jet ablation for lower urinary tract symptoms caused by benign prostatic hyperplasia (2023). NICE Interventional procedures guidance 770 (Recommendation: standard arrangements).

Prostatic urethral temporary implant insertion for lower urinary tract symptoms caused by benign prostatic hyperplasia (2022). NICE Interventional procedures guidance 737 (Recommendation: special arrangements).

Insertion of prostatic urethral lift implants to treat lower urinary tract symptoms secondary to benign prostatic hyperplasia (2014). NICE interventional procedure guidance 475 (Recommendation: normal [standard] arrangements).

Prostate artery embolisation for benign prostatic hyperplasia (2018). NICE interventional procedures guidance 611 (Recommendation: standard arrangements).

Laparoscopic prostatectomy for benign prostatic obstruction. (2008) NICE interventional procedures guidance 275 (Recommendation: special arrangements).

Holmium laser prostatectomy. (2003) NICE interventional procedure guidance 17 (Recommendation: normal [standard] arrangements).

Transurethral electrovaporisation of the prostate. (2003) NICE interventional procedure guidance 14 (Recommendation: normal [standard] arrangements).

Medical technologies

Rezum for treating lower urinary tract symptoms secondary to benign prostatic hyperplasia (2020). NICE medical technologies guidance 49.

GreenLight XPS for treating benign prostatic hyperplasia (2022). NICE medical technologies guidance 74.

The PLASMA system for transurethral resection and haemostasis of the prostate. (2021) NICE medical technologies guidance 74.

UroLift for treating lower urinary tract symptoms of benign prostatic hyperplasia. (2021) NICE medical technologies guidance 58.

NICE guidelines

Lower urinary tract symptoms in men: management (2010, last updated: June 2015). NICE clinical guideline 97.

Professional societies

- British Association of Urological Surgeons
- British Society of Interventional Radiologists.

Company engagement

NICE asked companies who manufacture a device potentially relevant to this procedure for information on it. NICE received one completed submission. This was considered by the interventional procedures technical team and any relevant points have been taken into consideration when preparing this overview.

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Confirmatory Trial. JU Open Plus 2(2):e00007, February 2024. | DOI: 10.1097/JU9.0000000000000105

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11. Lo Re M, Polverino P, Rivetti A et al. (2024) Transperineal laser ablation (TPLA) of the prostate for benign prostatic obstruction: the first 100 patients cohort of a prospective, single-center study. World J Urol. 10; 42 (1):402.

Appendix A: Methods and literature search strategy

Methods and literature search strategy

NICE has identified studies and reviews relevant to transperineal laser ablation (TPLA) for treating lower urinary tract symptoms of benign prostatic hyperplasia using an ultra-micro invasive approach from the medical literature. Relevant published studies identified during consultation or resolution that are published after this date may also be considered for inclusion.

Search strategy design and peer review

This search report is informed by the Preferred Reporting Items for Systematic reviews and Meta-Analyses literature search extension (PRISMA-S).
A NICE information specialist ran the literature searches on 20/08/2024. See the search strategy history for the full search strategy for each database.
The principal search strategy was developed in MEDLINE ALL (Ovid interface). It was adapted for use in each of the databases listed in table 4, taking into account the database's size, search functionality and subject coverage. The MEDLINE ALL strategy was quality assured by a NICE senior information specialist. All translated search strategies were peer reviewed to ensure their accuracy. The quality assurance and peer review procedures were adapted from the Peer Review of Electronic Search Strategies (PRESS) 2015 evidence-based checklist.

Review management

The search results were managed in EPPI Reviewer version 5 (EPPIR5). Duplicates were removed in EPPIR5 using a 2step process. First, automated deduplication was done using a high-value algorithm. Second, manual deduplication was used to assess low-probability matches. All decisions about inclusion, exclusion and deduplication were recorded and stored.

Limits and restrictions

The CENTRAL database search removed trial registry records and conference material. The Embase search excluded conference material.
The limit to remove animal studies in the searches is standard NICE practice, which has been adapted from Dickersin K, Scherer R, Lefebvre C (1994) Systematic Reviews: Identifying relevant studies for systematic reviews. BMJ 309(6964): 1286.

Main search

Table 4 Main search results

Search strategy history

Databases	Date searched	Version/files
MEDLINE ALL (Ovid)	20/08/2024	1946 to August 19, 2024
EMBASE (Ovid)	20/08/2024	1974 to 2024 August 19
EMBASE Conference (Ovid)	20/08/2024	1974 to 2024 August 19
Cochrane Database of Systematic Reviews – CDSR (Cochrane Library)	20/04/2024	Issue 8 of 12, July 2024
Cochrane Central Database of Controlled Trials – CENTRAL (Cochrane Library)	20/04/2024	Issue 7 of 12, July 2024
International HTA database (INAHTA)	20/04/2024	-

MEDLINE ALL search strategy

Prostatic Hyperplasia/
Lower Urinary Tract Symptoms/
Urinary Bladder Neck Obstruction/
Prostatism/
(Prostat* adj4 (hyperplas* or hypertroph* or adenoma* or urethra* or enlarg* or disease*)).tw.
((bladder* or urinat* or urinar* or urethra*) adj4 (neck* or outflow* or outlet*) adj4 (obstruct* or block* or narrow*)).tw.
(LUTS or (low* adj4 urinar* adj4 tract* adj4 symptom*)).tw.
(BPO or BPH or BPE or BOO or prostatism*).tw.
or/1-8
Laser Therapy/
(laser* adj4 (therap* or ablat*)).tw.
10 or 11
minimally invasive surgical procedures/
((minimall* or non) adj4 invasive adj4 (surg* or treatment* or technolog* or procedure* or technique*)).tw.
(MIST or UMIST).tw.
or/13-15
9 and 12 and 16
SoracteLite.tw.
Echolaser.tw.
TPLA.tw.

18 or 19 or 20
(transperin* or trans-perin*).tw.
12 and 22
21 or 23
17 or 24
Animals/ not Humans/
25 not 26
limit 27 to ed=20240124-20240831

Inclusion criteria

The following inclusion criteria were applied to the abstracts identified by the literature search.

- Publication type: clinical studies were included with emphasis on identifying good quality studies. Abstracts were excluded if they did not report clinical outcomes. Reviews, editorials, and laboratory or animal studies, were also excluded and so were conference abstracts, because of the difficulty of appraising study methodology, unless they reported specific adverse events not available in the published literature.
- People with BPH.
- Intervention or test: TPLA.
- Outcome: articles were retrieved if the abstract contained information relevant to the safety, efficacy, or both.

If selection criteria could not be determined from the abstracts the full paper was retrieved.
Find out more about how NICE selects the evidence for the committee.

Appendix B: Other relevant studies

Other potentially relevant studies that were not included in the main evidence summary (tables 2 and 3) are listed in table 5 below.

Table 5 additional studies identified

Study	Number of people and follow up	Direction of conclusions	Reason study was not included in main evidence summary
Busetto GM, Checchia A, Recchia M et al. (2023)	Review	MISTs are a new promise, and clinical trials with longer follow-up are	Review

Minimally invasive surgical therapies (MISTs) for lower urinary tract symptoms (LUTS): promise or panacea? Asian J Androl.26(2):135–43.		lacking. Most of them are under investigation and, only a few options have been given as a recommendation for use. They cannot be considered as standard of care and are not suitable for all people.	
Cai HJ, Fang JH, Kong FL, et al. Ultrasound-guided transperineal laser ablation for percutaneous treatment of benign prostatic hyperplasia: a new minimally invasive interventional therapy. Acta Radiol 2022; 63: 553–558	Retrospective case series (single centre study) n=20 people with BPH who had US-TPLA. Follow-up 6 months	After 6 months, average IPSS improved from 22.7 to 9.1 (P < 0.001), the QoL improved from 4.9 to 2.3 (P < 0.001), the Qmax improved from 8.5 to 15.2 ml/s (P < 0.001), the PVR increased from 78.7 to 30.3 (P < 0.05), and the mean prostate volume ranged from 70.8 to 54.7 ml (P < 0.05).	Study included in systematic review added to the summary of evidence.
Cai H, Zhu C and Fang J. Ultrasound-guided perineal laser ablation versus prostatic arterial embolization for benign prostatic hyperplasia: two similar short-term efficacies. Acta Radiol 2022: 64: 2841851221140214.	Retrospective comparative study n=40 people with benign prostatic hyperplasia (BPH). n=20 had ultrasound-guided transperineal laser ablation (US-TPLA) and 20 had prostatic artery embolization (PAE). Follow-up 6 months.	US-TPLA and PAE seem to have a similar short-term efficacy for BPH treatment. The efficacy of the two procedures is comparable, and neither is associated with serious complications.	Study included in systematic review added to the summary of evidence.
de Rienzo G, Lorusso A, Minafra P, et al.	Prospective case series	TPLA is a micro-invasive treatment for BPH showing good functional,	Study included in systematic review added

Transperineal interstitial laser ablation of the prostate, a novel option for minimally invasive treatment of benign prostatic obstruction. Eur Urol 2021; 80: 95–103	n=21 people with LUTS due to BPH, in people with prostate volume<100ml had TPLA. Follow-up 6 months (at 12 months phone calls)	preservation of the ejaculation, and safety outcomes. The only complication was a prostatic abscess, treated with transperineal drainage and antibiotic.	to the summary of evidence.
Frego N, Saita A, Casale P, et al. Feasibility, safety, and efficacy of ultrasound-guided transperineal laser ablation for the treatment of benign prostatic hyperplasia: a single institutional experience. World J Urol 2021; 39: 3867–3873.	Prospective study N=22 people with BPH had US guided TPLA. Follow-up 12 months	14% (3/22) of people had acute urinary retention and 9% (2/22) had UTI. At 3, 6, and 12 months, median prostate volume significantly decreased by q 21%, 29%, and 41%, respectively. Median IPSS was 8 (−64%), 5 (−74%), and 6 (−75%), while median QoL score was 1 in all the timepoints of follow-up. The median postoperative Qmax at 3, 6, and 12 months improved by 58%, 98%, and 116%, respectively. Ejaculatory function was preserved in 21 out of 22 people (96%).	Study included in systematic review added to the summary of evidence.
Laganà A, Di Lascio G, Di Blasi A, et al. Ultrasound-guided SoracteLite™ transperineal laser ablation (TPLA) of the prostate for the treatment of symptomatic benign prostatic hyperplasia (BPH): a prospective single-center experience. World J Urol 2023; 41: 1157–1162.	Prospective study n=63 people with symptomatic BPH had TPLA. Follow-up 12 months	At 12 months, IPSS improved from 20.8 to 8.4 (p<0.001), QoL from 4.7 to 1.2 (p<0.001), and Qmax from 8.6 ml/s to 16.2 ml/s (p=0.014). PVR decreased from 124.8 ml to 40.6 ml (p=0.003), and prostate volume decreased from 63.6 ml to 42.8 ml (p=0.071). Two people had prostatic abscess and 1 patient had orchitis. TPLA for symptomatic BPH provides clinical	Study included in systematic review added to the summary of evidence.

		benefits at 3 and 12 months, and the treatment is well tolerated.	
Lorenzoni V, Palla I, Manenti G et al. (2023) Standard approach and future perspective for the management of benign prostatic hyperplasia from a health-economics point of view: the role of transperineal laser ablation. Front. Urol. 3:1100386. doi: 10.3389/fruro.2023.1100386	literature review on economic implications.	Economic literature on minimally invasive techniques and surgical approaches for the treatment of BPH is still lacking. Multicentre and long-term economic studies are needed to assess the estimated disease burden. However, direct and indirect costs associated with TPLA are minimized versus TURP and laser vaporization/enucleation.	Review
Manenti G, Perretta T, Calcagni A, et al. 3-T MRI and clinical validation of ultrasound-guided transperineal laser ablation of benign prostatic hyperplasia. Eur Radiol Exp 2021; 5: 41. NCT04044573	Prospective study N=44 people with BPH underwent US-guided TPLA. Follow-up 1 year.	53% mean reduction of adenoma volume and 71% of the ablated area, associated with clinical and functional improvement and resolution of LUTS in all cases. 11% (5/44) had urinary blockage due to clots and required re-catheterisation for 2 weeks. The overall adverse event rate was 7%.	Study included in systematic review added to the summary of evidence.
Nguyen DD, Li T, Ferreira R et al. (2024) Ablative minimally invasive surgical therapies for benign prostatic hyperplasia: A review of Aquablation, Rezum, and transperineal laser prostate ablation. Prostate Cancer Prostatic	Review of three ablative minimally invasive surgeries: Aquablation therapy, convective water vapor therapy (Rezum), and TPLA (diode laser source).	Ablative minimally invasive surgical therapies have demonstrated excellent safety and efficacy profiles while preserving sexual function. These modalities should be discussed with people to ensure informed and shared decision-making. These may be interesting to people who value the preservation of their sexual function.	Review

Dis. 2024 Mar;27(1):22-28.			
Pacella CM, Patelli G, Iapicca G, et al. Transperineal laser ablation for percutaneous treatment of benign prostatic hyperplasia: a feasibility study. Results at 6 and 12 months from a retrospective multi-centric study. Prostate Cancer Prostatic Dis 2020; 23: 356–363.	Retrospective multi-centre study n=160 people with urinary symptoms secondary to BPH underwent TPLA. Follow-up 6 (n=160) and 12 months (n=83).	SoracteLite™ TPLA allows significant improvement of IPSS, Qol, Qmax, PVR, and reduction of prostatic volume at 6 and 12 months. 7 (4%) grade 1 and 1 grade 3 complications occurred.	Study included in systematic review added to the summary of evidence.
Patelli G, Ranieri A, Paganelli A, et al. Transperineal laser ablation for percutaneous treatment of benign prostatic hyperplasia: a feasibility study. Cardiovasc Intervent Radiol 2017; 40: 1440–1446.	Prospective single centre pilot trial N=18 people with urinary symptoms secondary to BPH underwent TPLA. Follow-up 3 months.	All procedures were technically successful. No complications occurred. TPLA is feasible and safe in the treatment of BPH, providing significant clinical results at 3 months.	Study included in systematic review added to the summary of evidence.
Porto JG, Titus R, Camargo F et al. (2024) Minimally invasive techniques in quest of Holy Grail of surgical management of enlarged prostates: a narrative review. World J Urol. 42(1):35.	Review	This review provides valuable insights for urologists and researchers seeking to navigate the dynamic landscape of MISTs (including TPLA) in the quest for effective and minimally invasive solutions for enlarged prostates.	Review
Sessa F, Polverino P, Bisegna C, et al. Transperineal laser ablation of the prostate with	Prospective study	Our experience provides additional evidence supporting the feasibility and safety of TPLA for the treatment of carefully	Study by the same group (with 3 months follow-up) was included in

EchoLaser™ system: perioperative and short term functional and sexual outcomes. Front Urol 2022; 2.	N=38 people underwent TPLA for BPH. Follow-up 12 months.	selected people with LUTS due to BPH.	systematic review added to the summary of evidence.
Sessa F, Polverino P, Siena G et al. (2023) Transperineal Laser Ablation of the Prostate (TPLA) for Lower Urinary Tract Symptoms Due to Benign Prostatic Obstruction. J Clin Med. 19;12(3):793. doi: 10.3390/jcm12030793. PMID: 36769454; PMCID: PMC9918261.	Review of TPLA for LUTS due to BPH. n=7 studies (case series)	A good safety profile has been reported by all studies. Although promising results have been reported by different groups, selection criteria for TPLA and procedure technique were found to be heterogeneous across the studies.	Review
Cocci A, Pezzoli M, Bianco F et al. (2024) Transperineal laser ablation of the prostate as a treatment for benign prostatic hyperplasia and prostate cancer: The results of a Delphi consensus project. Asian J Urol.11(2):271-279.	Italian and international experts (32) on BPH and prostate cancer participated in a collaborative consensus project.	Agreement was achieved on recommending Echolaser TPLA as a treatment of BPH in people with ample range of prostate volume, from 80 ml (80%), comorbidities (100%), antiplatelet or anticoagulant treatment (96%), indwelling catheter (77%), and strong will of preserving ejaculatory function (100%). Majority of respondents (97%) agreed that Echolaser. Almost all participants agreed that the transperineal approach of this organ-sparing technique is safer than transrectal and transurethral approaches typical of other techniques.	Consensus report.