

## Review – Benign Prostatic Hyperplasia

# A Systematic Review and Meta-analysis of Prostatic Urethral Lift for Male Lower Urinary Tract Symptoms Secondary to Benign Prostatic Hyperplasia

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### Abstract

**Context:** Recently, prostatic urethral lift (PUL) is being used to treat lower urinary tract symptoms (LUTS) secondary to benign prostatic hyperplasia (BPH). Although preliminary clinical studies on PUL are increasing, the long-term efficacy and safety of this procedure are still not well evaluated.

**Objective:** The objective of our study is to synthesize the existing literature evidence, and make a comprehensive and long-term systematic review for the PUL procedure.

**Evidence acquisition:** A systematic search was performed from the electronic databases including PubMed, Embase, and OVID. The search period was up to January 1, 2020. Comprehensive retrospective and prospective studies on PUL were collected in accordance with specific inclusion and exclusion criteria. Pooled prostatic symptom scores, sexual health scores, and functional outcomes were calculated by using a fixed or random-effect model.

**Evidence synthesis:** Nineteen articles meet our determined inclusion and exclusion criteria, and 11 independent patient series were included in the final analysis. Meta-analysis results indicated improvement after the PUL procedure, including International Prostate Symptom Score improvement of 9.73–12.16 points, BPH Impact Index improvement of 3.74–4.50 points, maximum flow rate improvement of 3.44–4.26 ml/s, and quality of life improvement of 2.20–2.55 points. Postvoid residual volume at most of the intervals was not significantly variable. Data regarding sexual function remained stable or improved slightly during the 24-mo follow-up period. Pooled estimates were largely heterogeneous except for sexual function.

**Conclusions:** PUL can continue to relieve prostatic symptoms for 24 mo without causing serious complications. The extremely important advantage of the PUL procedure is that it can preserve or slightly improve sexual function. Longer-term and more comprehensive clinical trials are still needed to further clarify the functional outcomes and cost effectiveness of PUL.

**Patient summary:** Prostatic urethral lift is an attractive option for selected patients who seek rapid and durable relief of lower urinary tract symptoms with complete preservation of sexual function.

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## 1. Introduction

Lower urinary tract symptoms (LUTS) secondary to benign prostatic hyperplasia (BPH) are common in elderly men over 50 yr. Treatment options for bothersome LUTS/BPH comprises conservative approaches, watchful waiting, pharmacotherapy, and surgical intervention [1,2]. It has been reported that different pharmacotherapies, including alpha-adrenergic antagonists, 5-alpha-reductase inhibitors, anticholinergics, and phosphodiesterase inhibitors, can improve the International Prostate Symptom Score (IPSS) by 30–40% and increased urine flow by 20–25%, especially for smaller prostate (<40 ml) [1–4]. These classic drugs are often considered the first-line treatments for LUTS/BPH. However, in general practice, studies have indicated that as the duration of drug treatment is extended to 1 yr, about one-third of men will stop taking drugs because of lower adherence rates, insufficient response, or side effects [4–6].

The indications for surgical intervention in patients with LUTS/BPH included moderate to severe LUTS, poor effects of drug treatment, recurrent urinary retention, renal failure, bladder stones, and repeated urinary tract infections. Transurethral resection of the prostate (TURP) is the gold standard for treating LUTS/BPH, and it has been proved by numerous studies that it can improve subjective symptom scores and functional outcomes significantly. However, there are various accompanied complications and morbidity at the same time, including ejaculatory dysfunction (65%), erectile dysfunction (10%), urethral strictures (7%), urinary tract infection (4%), blood transfusion (2%), urinary incontinence (2%), and a retreatment rate of 6% [1,2,7,8]. New laser-based modes including photoselective vaporization (PVP) can reduce bleeding and avoid TUR syndrome, but similar to TURP, it has higher morbidity rates [1,9,10]. Minimally invasive surgical treatments including transurethral microwave therapy (TUMT) and transurethral needle ablation (TUNA) reduce the possibility of serious complications at the cost of improving IPSS [1,11]. For the treatment of LUTS/BPH, except for surgical interventions mentioned above, many new technologies have emerged to reduce existing side effects.

Prostatic urethral lift (PUL), an emerging technology for the treatment of LUTS/BPH, can be operated under local anesthesia [12–14]. PUL has undergone numerous clinical studies and was finally allowed in Europe in 2009, Australia in 2010, and the USA in 2013 [15]. The protocol of PUL procedure contained two steps. First, move the lateral lobes in the prostate to the capsule to dilate the prostatic urethra, and then place small suture-based implants to hold the lobes and keep the prostatic urethra expanded [14]. This procedure is a mechanical dilatation of the urethra without removing the prostate tissue. Previous meta-analysis results on PUL suggest that urinary symptoms and functions improved while maintaining sexual function during the follow-up of 12 mo [16]. However, the long-term efficacy and safety of this procedure are still not well evaluated. In recent years, with the increase of original research and long-term data of this technology, the latest summary needs to be performed.

The aim of this study was to synthesize the existing literature evidence and develop a comprehensive and long-term systematic review of the PUL procedure.

## 2. Evidence acquisition

A systematic review was performed based on the recommendations defined in the Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) statement.

### 2.1. Search strategy

A systematic search of PubMed, Ovid Medline, and EMBASE electronic databases was performed using several keywords including benign prostatic hyperplasia, prostate, Urolift, and urethral lift. The search period was up to January 1, 2020 (Supplementary Table 1). Two independent reviewers selected the articles, and when discrepancies occurred over the results, they discussed with a third author to reach consensus.

### 2.2. Inclusion and exclusion criteria

The analysis included prospective and retrospective studies that reported Urolift treatment for BPH, evaluating prostate symptoms, function, and sexual outcomes. Searches were restricted to publications in English (non-English articles were excluded). We also excluded studies that lacked standard deviations. In the event of duplication of data, more recent studies or those with comprehensive papers were preferentially considered. We did not include conference documents because of inappropriate methodology and incomplete data.

### 2.3. Quality assessment

A quality-assessment tool was based on the method of published in the studies of Perera et al. [16], Ramsay et al. [17], and Hoffman et al. [18] (Supplementary Table 2). Two reviewers scored each paper independently (Supplementary Table 3) [19]. Meanwhile, as for methodological quality assessment, the Newcastle-Ottawa Scale was also chosen for nonrandomized controlled trials (non-RCTs) in our analysis (Supplementary Table 4) and the Jadad scale was also used for RCTs (Supplementary Table 5). We evaluated the level of evidence of included studies according to the criteria recommended by the Oxford Centre for Evidence-based Medicine (2011; Supplementary Table 6).

### 2.4. Data extraction and analysis

Data extracted from included researches involved baseline characteristics (eg, patient age, number, prostate volume, and IPSS), operative details and complications (eg, local anesthetic, number of implants, operative time, and perioperative complications), and postoperative outcomes. The main outcomes comprised prostate symptom scores (IPSS and BPH Impact Index [BPHII]), sexual health scores

(Sexual Health Inventory for Men [SHIM], Male Sexual Health Questionnaire for ejaculatory function [MSHQ-EjD], and bother [MSHQ-Bother]), and functional outcomes such as postvoid residual volume (PVR) and maximum flow rate (Qmax). For postoperative complication, we used only descriptive analysis because different definitions and terms restricted statistical comparisons.

### 2.5. Statistical analysis

Statistical analysis was performed by RevMan version 5.3 software (The Cochrane Collaboration, Copenhagen, Denmark). Dichotomous variables were analyzed by odds ratios and continuous variables were analyzed by weighted mean differences. The statistical significance for the combined estimate of absolute change from baseline was determined by calculated  $p$  values. The  $Z$  test and  $p < 0.05$  were regarded as a statistical difference. The Cochrane  $\chi^2$  test and  $I^2$  were used to analyze the heterogeneity between the trials. A  $p$ -value of  $<0.10$  or  $I^2 > 50\%$  showed that the heterogeneity was unacceptable, such that a random-effect model was employed; otherwise, a fix-effect model was employed. All tests and graphics in this study were performed using RevMan 5.3 (The Cochrane Collaboration) and GraphPad Prism 8 (GraphPad Software Inc., San Diego, CA, USA) software. To facilitate drawing with GraphPad Prism 8 software

(GraphPad Software Inc.), we considered 1–1.5 and 3–4 mo as 1 and 3 mo, respectively.

## 3. Evidence synthesis

We have retrieved a total of 803 documents about PUL. Nineteen articles were in accordance with our determined inclusion and exclusion criteria, and 11 independent patient series were identified for the analysis (see Fig. 1 [13,14,20–36]). These independent patient series have been published from 2011 to 2019, including five prospective cohort studies, three retrospective studies, two randomized controlled trials, and one crossover trial (see Table 1). The summary of comprehensive baseline data for included studies is shown in Table 2.

### 3.1. Baseline characteristics

In the included study groups, the inclusion and exclusion criteria were maintained comparatively constant, such as patients aged  $>50$  yr, IPSS  $>10$ , Qmax  $<15$  ml/s, and washed out or naive to medical therapy. The exclusion criteria usually included patients with obstructive middle lobes, but the study reported PUL treatment for BPH with obstructive middle lobes [25]. The demographic data of 11 patient series were comparable, with an average age range of 63–70.5 yr and an average operation time range of 8.5–66 min. The PUL

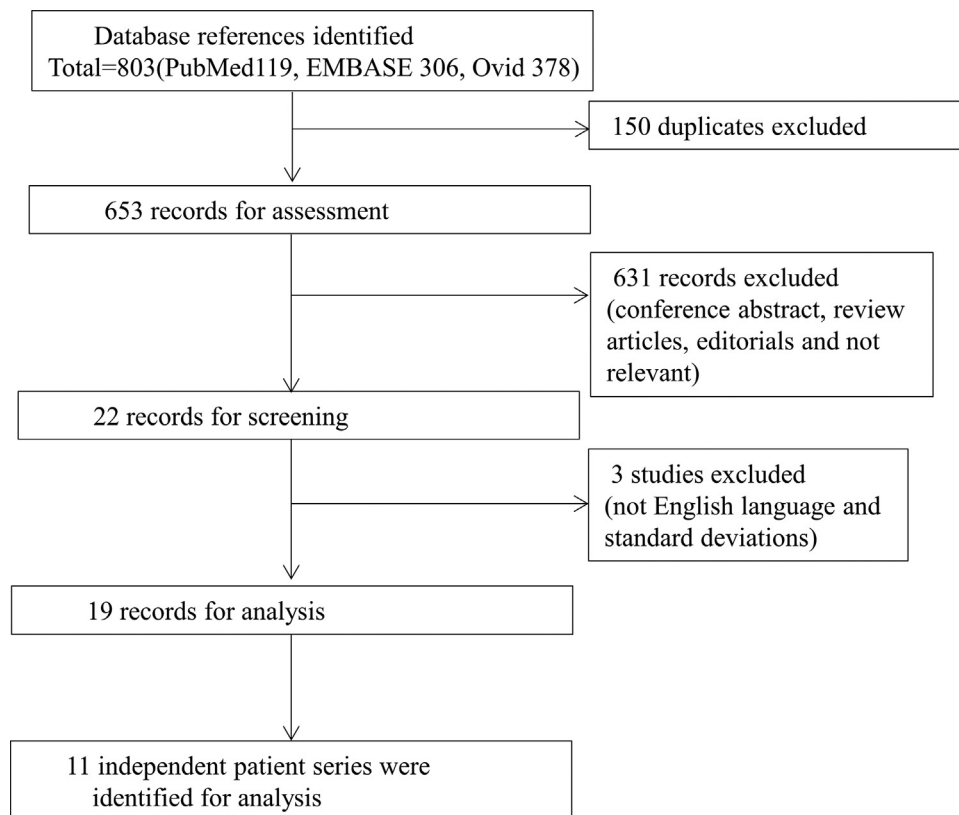


Fig. 1 – Flow diagram of the study.

**Table 1 – Characteristics of included studies.**

Publication	Study type	Inclusion criteria	Exclusion criteria	Follow-up (mo)	Outcome measures
Roehrborn (2013) [20]	Blinded RCT	Aged $\geq 50$ yr, no prior BPH treatment, washed out or naive to medical therapy, IPSS $>12$ , Qmax $\leq 12$ ml/s, PV 30–80 ml	Obstructive median lobe, retention, PVR $>250$ ml, infection, PSA $>10$ ng/ml (unless negative biopsy), cystolithiasis, bacterial prostatitis	12	IPSS, QoI, BPHII, Qmax, PVR
Roehrborn (2015) [21]				24	IPSS, QoI, BPHII, Qmax
Roehrborn (2015) [22]				36	IPSS, SHIM, MSHQ-EjD, MSHQ-Bother, Qmax, QoI, BPHII, PVR
Roehrborn (2017) [23]				60	IPSS, SHIM, MSHQ-EjD, MSHQ-Bother, Qmax, QoI, BPHII,
McVary (2014) [24]				12	IPSS, SHIM, MSHQ-EjD, MSHQ-Bother, Qmax
Rukstalis (2016) [26]	Crossover study	Aged $\geq 50$ yr, no prior BPH treatment, washed out or naive to medical therapy, IPSS $>12$ , Qmax $\leq 12$ ml/s, PV 30–80 ml	Obstructive median lobe, PVR $>250$ ml, infection, PSA $>10$ ng/ml (unless negative biopsy), cystolithiasis, bacterial prostatitis	24	IPSS, SHIM, MSHQ-EjD, MSHQ-Bother, Qmax, QoI, BPHII, PVR
Cantwell (2014) [27]				12	IPSS, QoI, BPHII, SHIM, MSHQ-EjD, MSHQ-Bother
Rukstalis (2019) [25]	Prospective cohort	Age $\geq 50$ yr, IPSS $>12$ , Qmax $\leq 12$ ml/s, PV 30–80 ml, washed out or naive to medical therapy, obstructive median lobe	Prior surgical intervention for BPH, retention, active urinary tract infection, and other potentially confounding conditions	12	IPSS, QoI, BPHII, SHIM, Qmax, MSHQ-EjD, MSHQ-Bother
Shore (2014) [28]	Prospective cohort	Aged $\geq 50$ yr, no prior BPH treatment, washed out or naive to medical therapy, IPSS $>12$ , Qmax $\leq 12$ ml/s, PV 30–80 ml	Obstructive median lobe, PVR $>250$ ml, retention, infection, gross hematuria, cystolithiasis, bacterial prostatitis	1	IPSS, BPHII, SHIM, MSHQ-EjD, MSHQ-Bother, Qmax, QoI
McNicholas (2013) [13]	Prospective cohort	PV $<60$ ml, IPSS $>12$ , Qmax $<15$ ml/s, PVR $<350$ ml	High bladder neck or obstructive middle lobe, PV $>100$ ml	12	IPSS, QoI, BPHII, Qmax, PVR
Woo (2012) [29]	Prospective cohort	Aged $\geq 55$ yr, IPSS $>13$ , Qmax 5–12 ml/s, PVR $<250$ ml, washed out to medical therapy	Obstructive median lobe, infection, retention, PSA $>10$ ng/ml, compromised renal function, previous surgery	12	IPSS, SHIM, MSHQ-EjD, MSHQ-Bother
Chin (2012) [14]				24	IPSS, QoI, BPHII, SHIM, MSHQ-EjD, Qmax, PVR, MSHQ-Bother
Woo (2011) [30]				12	IPSS, QoI, Qmax, PVR
Bardoli (2017) [31]	Retrospective study	Age $>50$ yr, IPSS $\geq 10$ , Qmax $\leq 14$ ml/s	Obstructive median lobe, PV $>80$ ml, retention, medical comorbidities, neurological conditions affect voiding	4	IPSS, QoI, Qmax, PVR
Kim (2019) [32]	Retrospective study	Age $\geq 50$ yr, IPSS $>12$ , and PV 30–80 ml	NA	12	IPSS, QoI, Qmax, SHIM
Sievert (2019) [33]	Prospectively study	Moderate-to-severe LUTS were unresponsive to oral therapy	Obstructive median lobe	24	IPSS, QoI, Qmax, PVR
Sonksen (2015) [34]	Nonblinded RCT	Age $\geq 50$ yr, IPSS $>12$ , positive response to MSHQ-EjD, Qmax $\leq 15$ ml/s, PVR $<350$ ml, PV $\leq 60$ ml, SHIM $>6$	Infection, bacterial prostatitis, cystolithiasis, obstructive median lobe, retention, previous TURP or laser procedure, pelvic surgery or irradiation, PSA $\geq 10$ ng/ml, prostate or bladder cancer, severe comorbidities	12	IPSS, BPHII, SHIM, MSHQ-EjD, MSHQ-Bother, Qmax, QoI, PVR
Gratzke (2017) [35]				24	
Bozkurt (2016) [36]	Retrospective study	LUTS secondary to BPH were unresponsive to oral therapy	PV $>100$ ml, IPSS $<12$ , PVR $>350$ ml, Qmax $>15$ ml/s, PSA $>4$ ng/ml, obstructive median lobe, neurogenic bladder, prostatic surgery, infection, bladder diseases	12	IPSS, SHIM, MSHQ-EjD, Qmax, QoI, PVR

BPH = benign prostatic hyperplasia; BPHII = Benign Prostatic Hyperplasia Impact Index; EjD = ejaculatory dysfunction; IPSS = International Prostate Symptom Score; LUTS = lower urinary tract symptoms; MSHQ = Male Sexual Health Questionnaire; NA = not available; PSA = prostate-specific antigen; PV = prostate volume; PVR = postvoid residual volume; Qmax = maximum flow rate; QoI = quality of life; RCT = randomized controlled trial; SHIM = Sexual Health Inventory for Men; TURP = transurethral resection of the prostate.

**Table 2 – Patient baseline characteristics of clinical studies included in this meta-analysis.**

Publication	Number	Age (yr), mean (SD)	PV (ml), mean (SD)	IPSS, mean (SD)	Qol, mean (SD)	BPHII, mean (SD)	Qmax (ml/s), mean (SD)	PVR (ml), mean (SD)	SHIM, mean (SD)	MSHQ-EjD, mean (SD)	MSHQ-Bother, mean (SD)
Roehrborn (2013) [20]	140	67 (8.6)	44.5 (12.4)	22.2 (5.4)	4.6 (1.1)	6.9 (2.8)	8.9 (2.2)	85.5 (69.2)	13.0 (8.4)	8.7 (3.2)	2.4 (1.7)
Roehrborn (2015) [21]											
Roehrborn (2015) [22]											
Roehrborn (2017) [23]											
McVary (2014) [24]											
Rukstalis (2016) [26]	53	64 (8.0)	40.3 (9.9)	23.3 (5.5)	4.5 (1.2)	6.3 (3.0)	8.8 (4.2)	67.8 (66.4)	12.8 (8.3)	9.5 (10.0)	2.7 (1.7)
Cantwell (2014) [27]											
Rukstalis (2019) [25]	45	64 (7.0)	44.2 (11.2)	24.2 (4.9)	4.9 (0.8)	7.7 (2.8)	7.2 (2.9)	107.3 (79.9)	15.1 (9.0)	9.4 (3.1)	1.6 (1.8)
Shore (2014) [28]	51	66 (7.6)	41.3 (11.6)	21.5 (5.4)	4.6 (1.0)	6.7 (3.1)	8.2 (2.2)	77.1 (74.9)	16.5 (7.3)	10.0 (2.6)	1.8 (1.4)
McNicholas (2013) [13]	102	68 (10.0)	48 (21)	23.2 (6.1)	4.7 (1.0)	NA	8.7 (4.0)	NA	NA	NA	NA
Woo (2012) [29]	64	67 (7.3)	51 (23)	22.6 (5.4)	4.9 (0.9)	7.2 (2.9)	8.3 (2.2)	89 (86)	18.2 (4.9)	10.6 (2.1)	1.5 (1.4)
Chin (2012) [14]											
Woo (2011) [30]											
Bardoli (2017) [31]	11	70.5 (10.2)	45.5 (15.1)	25.6 (5.3)	5.0 (0.6)	NA	7.0 (2.8)	306.3 (120.6)	NA	NA	NA
Kim (2019) [32]	32	67 (7)	50 (7)	19.3 (2.4)	4.4 (0.6)	NA	12.1 (2.4)	NA	18.8 (4.7)	NA	NA
Sievert (2019) [33]	86	66.2 (11.5)	43 (18.8)	20.82 (6.5)	4.1 (1.2)	NA	11.2 (3.2)	149.5 (251.5)	NA	NA	NA
Sonksen (2015) [34]	44	63 (6.8)	38 (12)	22 (5.7)	4.6 (1.1)	7.3 (2.5)	9.2 (3.5)	86 (72)	20 (4.9)	11 (2.7)	1.7 (1.8)
Gratzke (2017) [35]											
Bozkurt (2016) [36]	17	67 (10.8)	44.1 (14.3)	22.8 (4.4)	3.2 (0.9)	NA	7.6 (2.9)	50.3 (31.2)	15.5 (6.3)	9.7 (2.8)	NA

BPHII = Benign Prostatic Hyperplasia Impact Index; EjD = ejaculatory dysfunction; IPSS = International Prostate Symptom Score; MSHQ = Male Sexual Health Questionnaire; NA = not available; PV = prostate volume; PVR = postvoid residual volume; Qmax = maximum flow rate; Qol = quality of life; SD = standard deviation; SHIM = Sexual Health Inventory for Men.

technique can be achieved using local, general, or spinal anesthesia.

### 3.2. Safety, effectiveness, and durability

#### 3.2.1. IPSS and BPHII

Overall, the pooled estimates for IPSS incorporated 304–605 patients without repetitive data among 2 yr. We also showed individual study data reported from 3 to 5 yr

[22,23]. Figure 2A and Table 3 show the pooled IPSS improvement at 1–1.5, 3–4, 6, 12, and 24 mo after the PUL operation. IPSS at 1–1.5 mo ( $-10.97$  [ $-12.44$ ,  $-9.51$ ],  $p < 0.00001$ ), 3–4 mo ( $-12.16$  [ $-13.64$ ,  $-10.68$ ],  $p < 0.00001$ ), 6 mo ( $-11.09$  [ $-12.51$ ,  $-9.68$ ],  $p < 0.00001$ ), 12 mo ( $-10.45$  [ $-11.70$ ,  $-9.20$ ],  $p < 0.00001$ ), and 24 mo ( $-9.73$  [ $-10.77$ ,  $-8.69$ ],  $p < 0.00001$ ) improved significantly after PUL treatment. During the follow-up period of 24 mo, the mean improvement for IPSS ranged from 9.73 to 12.16 points,

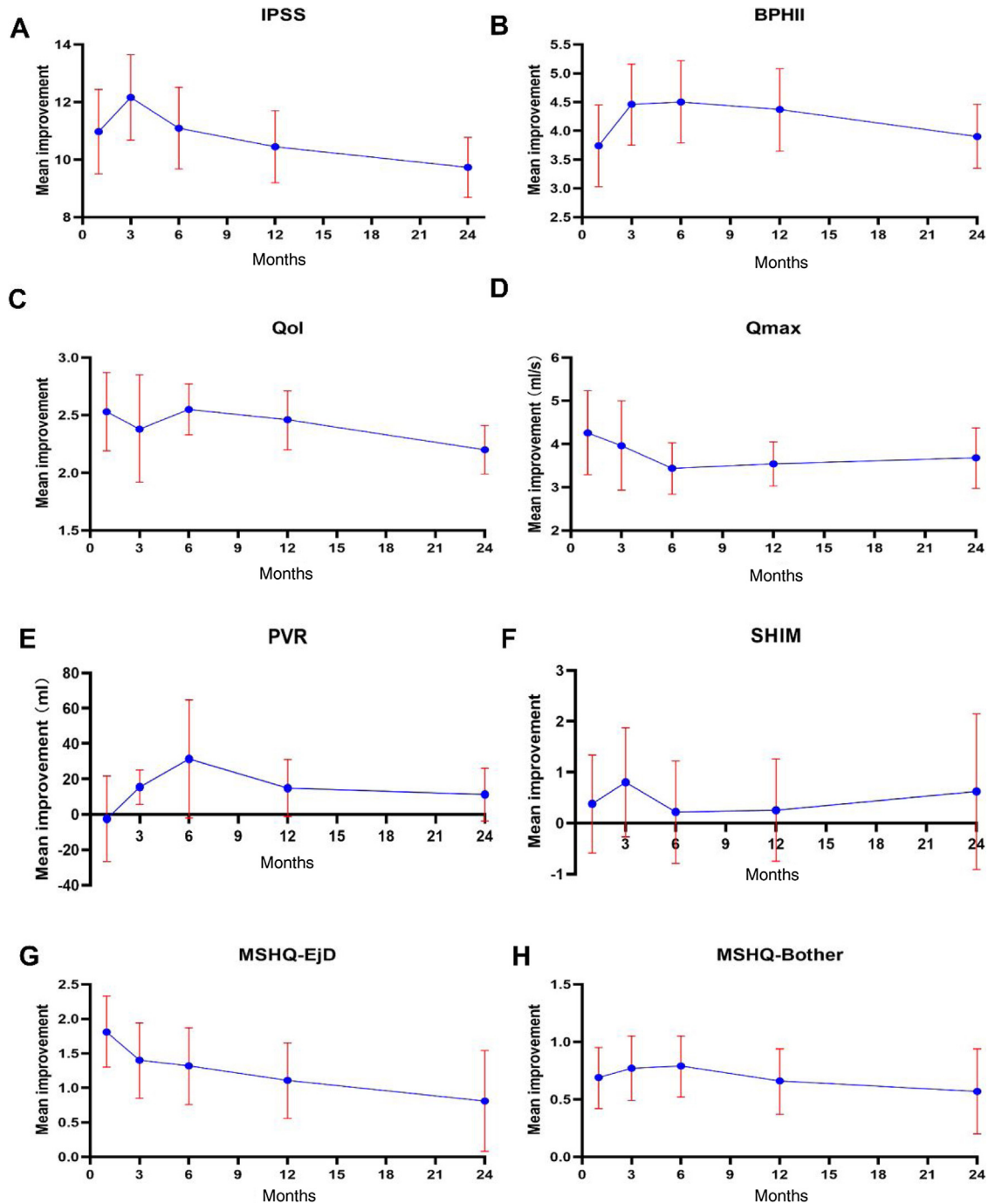


Fig. 2 – Pooled estimates with 95% confidence intervals at follow-up periods (1, 3, 6, 12, and 24 mo): (A) IPSS outcomes (pooled benefit estimates as mean improvement), (B) BPHII outcomes, (C) QoI outcomes, (D) Qmax outcome (ml/s), (E) PVR outcome (ml), (F) SHIM outcome, (G) MSHQ-EJD outcome, and (H) MSHQ-Bother outcome.

BPHII = Benign Prostatic Hyperplasia Impact Index; EJD = ejaculatory dysfunction; IPSS = International Prostate Symptom Score; MSHQ = Male Sexual Health Questionnaire; PVR = postvoid residual volume; Qmax = maximum flow rate; QoI = quality of life; SHIM = Sexual Health Inventory for Men.

**Table 3 – Pool estimates of outcomes including IPSS, QoL, BPHII, Qmax, PVR, SHIM, MSHQ-EjD, and MSHQ-Bother after PUL.**

Outcomes	1–1.5 mo	3–4 mo	6 mo	12 mo	24 mo
<b>IPSS</b>					
No. of data sources, patients ( <i>n</i> )	9 (605)	8 (448)	8 (526)	9 (497)	5 (304)
Effect size (95% CI)	–10.97 (–12.44 to –9.51)	–12.16 (–13.64 to –10.68)	–11.09 (–12.51 to –9.68)	–10.45 (–11.70 to –9.20)	–9.73 (–10.77 to –8.69)
Heterogeneity ( $I^2/p$ )	81% <0.00001	70% 0.002	77% <0.0001	70% 0.0007	0 0.83
<b>BPHII</b>					
No. of data sources, patients ( <i>n</i> )	7 (450)	6 (394)	6 (388)	6 (348)	4 (211)
Effect size (95% CI)	–3.74 (–4.45 to –3.03)	–4.46 (–5.16 to –3.75)	–4.50 (–5.22 to –3.79)	–4.37 (–5.08 to –3.65)	–3.90 (–4.46 to –3.35)
Heterogeneity ( $I^2/p$ )	72% 0.001	69% 0.006	71% 0.004	65% 0.01	0 0.95
<b>QoL</b>					
No. of data sources, patients ( <i>n</i> )	9 (583)	8 (431)	8 (510)	8 (471)	5 (304)
Effect size (95% CI)	–2.53 (–2.87 to –2.19)	–2.38 (–2.85 to –1.92)	–2.55 (–2.77 to –2.33)	–2.46 (–2.71 to –2.20)	–2.20 (–2.41 to –1.99)
Heterogeneity ( $I^2/p$ )	83% <0.00001	86% <0.00001	54% 0.03	59% 0.02	0 0.84
<b>Qmax</b>					
No. of data sources, patients ( <i>n</i> )	6 (315)	8 (390)	6 (290)	9 (424)	5 (256)
Effect size (95% CI)	4.26 (3.29–5.23)	3.96 (2.93–5.00)	3.44 (2.84–4.03)	3.54 (3.03–4.05)	3.68 (2.97–4.38)
Heterogeneity ( $I^2/p$ )	57% 0.04	64% 0.007	42% 0.13	19% 0.28	0 0.42
<b>PVR</b>					
No. of data sources, patients ( <i>n</i> )	3 (194)	7 (355)	4 (224)	7 (396)	5 (296)
Effect size (95% CI)	2.53 (–21.62 to 26.68)	–15.41 (–25.16 to –5.66)	–31.33 (–64.17 to 2.06)	–14.84 (–31.08 to 1.40)	–11.22 (–26.16 to 3.72)
Heterogeneity ( $I^2/p$ )	24% 0.27	10% 0.36	66% 0.03	49% 0.07	74% 0.004
<b>SHIM</b>					
No. of data sources, patients ( <i>n</i> )	7 (278)	6 (244)	6 (258)	7 (251)	4 (145)
Effect size (95% CI)	0.38 (–0.59 to 1.34)	0.80 (–0.27 to 1.87)	0.22 (–0.79 to 1.22)	0.25 (–0.75 to 1.26)	0.62 (–0.91 to 2.15)
Heterogeneity ( $I^2/p$ )	0 0.71	0 0.63	0 0.61	0 0.84	0 0.93
<b>MSHQ-EjD</b>					
No. of data sources, patients ( <i>n</i> )	6 (242)	6 (238)	5 (223)	6 (217)	4 (142)
Effect size (95% CI)	1.81 (1.30–2.33)	1.40 (0.85–1.94)	1.32 (0.76–1.87)	1.11 (0.56–1.65)	0.81 (0.08–1.54)
Heterogeneity ( $I^2/p$ )	0 0.96	34% 0.18	0 0.56	0 0.51	39% 0.18
<b>MSHQ-Bother</b>					
No. of data sources, patients ( <i>n</i> )	6 (242)	5 (219)	5 (223)	5 (200)	4 (142)
Effect size (95% CI)	–0.69 (–0.95 to –0.42)	–0.77 (–1.05 to –0.49)	–0.79 (–1.05 to –0.52)	–0.66 (–0.94 to –0.37)	–0.57 (–0.94 to –0.20)
Heterogeneity ( $I^2/p$ )	0 0.98	0 0.63	31% 0.22	0 0.91	0 0.46

CI = confidence interval; BPHII = Benign Prostatic Hyperplasia Impact Index; EjD = ejaculatory dysfunction; IPSS = International Prostate Symptom Score; MSHQ = Male Sexual Health Questionnaire; PVR = postvoid residual volume; Qmax = maximum flow rate; QoL = quality of life; SHIM = Sexual Health Inventory for Men; PUL = prostatic urethral lift.

indicating a marked decrease in symptoms score. A study by Roehrborn et al. [23] suggested that IPSS was reduced by 8.83 points (−10.84, −6.82) at 3 yr, 8.80 points (−10.99, −6.61) at 4 yr, and 7.55 points (−9.94, −5.16) at 5 yr after PUL.

The pooled BPHII data were obtained from between 211 and 450 patients. The mean gain in BPHII ranged between 3.74 and 4.50 points. The changes in BPHII scores were −3.74 points (−4.45, −3.03) at 1–1.5 mo, −4.46 points (−5.16, −3.75) at 3–4 mo, −4.50 points (−5.22, −3.97) at 6 mo, −4.37 points (−5.08, −3.65) at 12 mo, and −3.90 points (−4.46, −3.35) at 24 mo of follow-up (Fig. 2B and Table 3). Only a few pooled estimates in the analysis were homogeneous (IPSS and BPHII at 24 mo,  $I^2/p = 0/0.83$  and  $I^2/p = 0/0.95$ , respectively), and most of them were heterogeneous.

### 3.2.2. Quality of life

The mean improvement score of quality of life (QoI) ranged from 2.20 (−2.41, −1.99) to 2.55 points (−2.77, −2.33) according to the responses from 304 to 583 patients (Fig. 2C and Table 3). A homogeneous pooled estimate at the follow-up of 24 mo was observed ( $I^2/p = 0/0.84$ ), and the remaining were heterogeneous.

### 3.2.3. Qmax and PVR

Evaluation of functional outcomes (Qmax and PVR) was comparatively objective because of the results from the instrument. Advantageous pooled outcomes were noticed for Qmax, with an enhancement from 3.44 (2.84, 4.03) to 4.26 (3.29, 5.23) ml/s (Table 3). The Qmax data at 6, 12, and 24 mo were homogeneous ( $I^2/p = 42%/0.13$ ,  $19%/0.28$ , and  $0/0.42$ , respectively). Figure 2D also proves that after the PUL procedure, improved effects were observed early and were continuous during the 24-mo follow-up. Overall, pooled outcomes for PVR revealed that PVR at 1–1.5mo (2.53 ml [−21.62, 26.68]), 6 mo (−31.33 ml [−64.71, 2.06]), 12 mo (−14.84 ml [−31.08, 1.40]), and 24 mo (−11.22 ml [−26.16, 3.72]) were not significantly variable (Fig. 2E and Table 3). However, a significantly small improvement was noted in PVR at 3–4 mo (−15.41 ml [−25.16, −5.66]). Pooled estimates for PVR at 1–1.5 and 3–4 mo were homogeneous ( $I^2/p = 24%/0.27$  and  $I^2/p = 10%/0.36$ , respectively).

### 3.2.4. Complications

Postoperative complications were usually early, mild, and transient without any special treatment. During the follow-up period of 3 mo, the complications reported most frequently comprised dysuria (9.09–52.9%), hematuria (2.64–74.5%), pelvic pain (0–52.3%), urinary tract infection (0.98–10.9%), and incontinence (0–7.81%). The use of different definitions and terms for complications restricts statistical comprehensive comparisons.

No article reported deaths related to the PUL procedure throughout the follow-up period of 24 mo. Meanwhile, no patient required a blood transfusion. It is worth noting that none of the studies showed recurrence or deterioration of sexual function. At 12-mo follow-up, 0–6.82% of patients with insufficient improvements in IPSS or Qmax progressed to TURP. At 24 mo, 3.57–18.8% of patients progressed to TURP (see Table 4).

## 3.3. Preservation of sexual function

### 3.3.1. Sexual Health Inventory for Men

The scores of SHIM, which reflects erection function, ranged between 0.22 (−0.79, 1.22) and 0.80 (−0.27, 1.87) throughout the 24-mo follow-up (Fig. 2F and Table 3). Pooled data revealed acceptable heterogeneity ( $I^2 = 0$  in all groups), and there is no significant difference between all the selected intervals.

### 3.3.2. MSHQ-EjD and MSHQ-Bother

Pooled data analysis for MSHQ-EjD has indicated a significant improvement at all the selected follow-up points. Pooled estimates for MSHQ-EjD range between 0.81 (0.08, 1.54) and 1.81 (1.30, 2.33; Fig. 2G and Table 3), and pooled estimates for MSHQ-Bother range between −0.57 (−0.94, −0.20) and −0.79 (−1.05, −0.52; Fig. 2H and Table 3). There was no significant heterogeneity among studies when pooling the data on the MSHQ-EjD and MSHQ-Bother scores ( $I^2/p$  range: 0–39%/0.18–0.98).

For a forest plot of all meta-analysis results, please see Supplementary Figure 1.

## 4. Discussion

This systematic review and meta-analysis presents the latest summary of available clinical studies for the PUL procedure during a 24-mo follow-up period.

The PUL procedure improves LUTS largely according to the pooled analysis of IPSS and BPHII scores. The average improvement of IPSS was 10.45 (−11.70, −9.20) and 9.73 (−10.77, −8.69) points at 12- and 24-mo follow-ups, respectively. PUL has a similar effect on symptom relief to other minimally invasive treatments (TUNA and TUMT) [1,16,37,38] and is superior to medical therapies and placebo [37]. In addition, the relatively stable improvement of IPSS by PUL can last throughout 24 mo of follow-up. QoI of patients who received PUL recovered rapidly within a short period of time and continued to be maintained for the entire period of 24 mo. This also leads to indirect cost savings as patients return to work earlier than those undergoing other surgical interventions [37].

Although the data on PUL have obviously shown improvement in subjective results (eg, IPSS and QoI), merely a small improvement was observed in more objective outcomes (eg, Qmax and PVR). Functional improvements after PUL operation were fewer than those after TURP, PVP, and holmium laser enucleation of the prostate (HoLEP), which are related to an obviously beneficial Qmax (10–13 ml/s) [39–41]. Furthermore, although there is no statistically significant difference in PVR values at 12 and 24 mo, the PVR worsened at 12 mo in three studies [13,14,34] and at 24 mo in one study [14]. According to the present evidence, PUL surgery needs to be changed to improve functional parameters, in order to achieve an effect comparable with surgical procedures.

The maintenance of sexual function after the PUL procedure is likely because prostatic tissue, bladder neck, and urethral tissues are all preserved. According to the



**Table 4 – Operative details and complications.**

Publication	Local anesthetic	Operative time (min), mean (SD)	Implants, mean (range)	Postoperative catheter	Early postoperative complications (0–3 mo)					Total complications in patients during 3 mo	Progression to TURP at 24 mo	Progression to TURP at 12 mo
					Dysuria	Hematuria	Pelvic pain	UTI	Incontinence			
Roehrborn (2013) [20]	Most patients	66 (24)	4.9 (2–11)	72/140 (51.4)	48/140 (34.3)	34/140 (24.3)	25/140 (17.9)	4/140 (2.86)	5/140 (3.57)	100/140 (87.1)	5/140 (3.57)	2/140 (1.43)
Roehrborn (2015) [21]												
Roehrborn (2015) [22]												
Roehrborn (2017) [23]												
McVary (2014) [24]												
Rukstalis (2016) [26]	46/53 (86.8)	53 (15)	4.4 (2–8)	26/53 (49.1)	19/53 (3.58)	14/53 (2.64)	11/53 (2.08)	1/53 (1.89)	1/53 (1.89)	41/53 (77.4)	4/53 (7.55)	1/53 (1.89)
Cantwell (2014) [27]												
Rukstalis (2019) [25]	6/45 (13.3)	NA	6.3 (SD 1.6)	36/45 (80)	Most frequent	Most frequent	NA	NA	NA	NA	NA	NA
Shore (2014) [28]	51/51 (100)	52 (22)	3.7 (2–6)	10/51 (19.6)	27/51 (52.9)	38/51 (74.5)	8/51 (15.7)	NA	2/51 (3.92)	47/51 (92)	NA	NA
McNicholas (2013) [13]	17/102 (16.7)	58 (16)	4.5 (2–9)	54/102 (52.9)	25/102 (24.5)	16/102 (15.7)	NA	1/102 (0.98)	NA	NA	NA	4/102 (3.92)
Woo (2012) [29]	26/64 (40.6)	NA	4 (2–9)	34/64 (53.1)	NA	NA	NA	7/64 (10.9)	5/64 (7.81)	NA	12/64 (18.8)	4/64 (6.25)
Chin (2012) [14]												
Woo (2011) [30]												
Bardoli (2017) [31]	2/11 (18.2)	8.5 (1.7)	4 (2–6)	NA	NA	NA	NA	NA	NA	NA	NA	NA
Kim (2019) [32]	32/32 (100)	NA	2.2 (NA)	NA	NA	Most frequent	0/32 (0)	NA	0/32 (0)	NA	NA	0/32 (0)
Sievert (2019) [33]	24/86 (27.9)	57 (12)	3.8 (2–7)	86/86 (100)	12/86 (14.0) <sup>a</sup>	3/86 (3.49)	NA	NA	NA	NA	9/86 (10.5) <sup>a</sup>	
Sonksen (2015) [34]	1/44 (2.27)	55 (17)	4.7 (2–6)	44/44 (100)	4/44 (9.09)	17/44 (38.6)	23/44 (52.3)	3/44 (6.82)	1/44 (2.27)	37/44 (84.1)	6/44 (13.6)	3/44 (6.82)
Gratzke (2017) [35]												
Bozkurt (2016) [36]	5/17 (29.4)	29.1 (11.6)	3.71 (2–7)	0/17 (0)	NA	NA	NA	NA	NA	NA	NA	0/17 (0)

NA = not available; SD = standard deviation; TURP = transurethral resection of the prostate; UTI = urinary tract infection.  
Data are shown as frequency (%) unless indicated otherwise.  
<sup>a</sup> Sum of two numbers.

pooled data of the SHIM score, erectile function remained steady during the 24 mo of follow-up. MSHQ-EjD, which assessed ejaculatory function, improved slightly (scores 0.81–1.81) during each follow-up period. Likewise, during the entire follow-up period, the score of MSHQ-Bother improved significantly (scores 0.57–0.79). Postoperative sexual function was preserved, and no new episodes of persistent erectile or ejaculatory dysfunction were reported following the PUL procedure. The effects of drug therapy ( $\alpha$ 1-blockers and 5 $\alpha$ -reductase inhibitors) on sexual function have been reported discrepantly, but they are commonly believed to be caused by loss of libido, and erectile and ejaculatory dysfunction [42,43]. Minimally invasive treatments including TUMT and TUNA increase the risk of retrograde ejaculation (9.2–22.2%) and erectile dysfunction (0–18.2%) [18,44]. After TURP or PVP surgery, the incidences of erectile and ejaculatory dysfunction were 14–26% and 15–63%, respectively [16,38,43]. Therefore, preserved sexual function is a main advantage of the PUL procedure among numerous minimally invasive operations for BPH.

In our study, durability has been proved to reach 2 yr, in which the average IPSS improved by 10.45 at 1 yr and by 9.73 at 2 yr. Following PUL, the TURP rates due to postoperative disease progression still remained low, with about 3.57–18.8% of patients requiring it at 2 yr. Moreover, conventional TURP surgery after PUL will not cause implant-related complications [14,20]. Last but not least, a single study has reported that PUL can quickly improve symptoms, QoL, and Qmax, and the improvement can last for 5 yr [23]. These improvements were associated with a reduction in the use of catheters, a swift return to normal activity, and conservation of sexual functions.

The majority of PUL studies used similar inclusion and exclusion criteria for BPH patients. PUL is usually used in patients with hyperplasia of the lateral lobe and prostate size <80 g [37,45–47]. However, MedLift study in 2018 sought to assess efficacy and safety of the PUL procedure in the treatment of BPH with obstructive middle lobe [25]. This study demonstrated promising results with significant improvements of IPSS, BPHII, QoL, and Qmax throughout 1 yr of follow-up. Long-term and RCT studies are needed to determine whether PUL is an option for obstructive middle lobe in BPH. Therefore, in the latest American Urological Association guideline, the statement that PUL surgery must “verify absence of an obstructive middle lobe” stays unaltered [47]. Recently, using a large unconstrained multicenter data set, Eure et al. [48] have indicated that the PUL procedure for real-world BPH patients (eg, prostate volume <30 ml, prostate volume >80 ml, IPSS <13) can be managed effectively and safely. This study was not conducted in the context of clinical trials, and the real-world BPH included a wide range of patient baseline values. Shah et al. [49] evaluated whether the PUL procedure was also effective for larger prostates (prostate size >80 g) and considered that men with larger prostates appear to benefit from PUL. PUL durability in patients with prostate sizes >80 g requires longer follow-up data for assessment and validation. Local anesthesia protocols for

the PUL procedure has been described in detail in the study by Barkin et al. [12]. Patients who underwent the PUL procedure under local anesthesia have good tolerance and most of them did not require catheterization postoperatively. With these advantages, selected BPH patients can complete PUL by day-case surgery, thereby reducing hospital-related costs [37,50,51].

No cost-effectiveness analysis was conducted for all the included PUL clinical studies. According to the UK healthcare market, Ray et al. [52] have reported that compared with monopolar and bipolar TURP, Urolift saves £286 and £159 per patient, respectively, and compared with HoLEP, it costs an additional £90 per patient. Recently, another literature result indicates that the total cost associated with Urolift is about US\$6400 over 2 yr. On average, Urolift costs US\$1205 more than the total cost of TURP surgery (US\$5181) over 2 yr. PUL was more expensive and less effective than TURP in this study [53]. The primary cost for PUL depends on the number of implants used per treatment. The average number of implants needed is four per procedure, but this can vary depending on the configuration and size of the prostate. In the future, it is necessary to conduct further comparative research on benefits and costs to guide clinicians in using the technology in their daily work.

At the same time, there are other emerging technologies for treating LUTS secondary to BPH. Aquablation therapy is a surgeon-planned, image-guided, and robotically executed technique to resect prostate tissue using a high-velocity waterjet. Aquablation under spinal or general anesthesia delivers effective relief (IPSS improvement of 15 points at 1 yr), but is associated with unwanted problems including 1.8–2.9 g/dl hemoglobin drop, 7.8–26.7% rate of ejaculatory dysfunction, 10–11% rate of urinary tract infection, and nearly 100% postoperative catheterization [54–57]. A limited study demonstrated that i-TIND implantation resulted in a reduction of IPSS from the baseline value of 22.5 to the 1-yr value of 8.8, while 9.9% of patients experienced urinary retention and 6.2% of them experienced urinary tract infections. Long-term RCTs are needed to confirm the available data already published in the literature and to understand whether device implantation can be proposed in other patient settings, such as those with acute urinary retention [58,59]. Intraprostatic steam injection (Rezum) uses steam to ablate prostate tissue, which improves IPSS by 11 points at 1 yr and maintains it for about 4 yr. However, it is associated with unwanted complications such as a 3–6% rate of ejaculatory dysfunction and 7–17% rate of urinary tract infection. Meanwhile, most patients require an average of 4 d of catheterization or 19 d of insertion of a temporary Spanner prostate stent after treatment [60–62].

Recently, Tanneru et al. [63] systematically evaluated the different outcomes of PUL at the follow-up of 24 mo. In comparison, our paper has several key advantages. Overall, we have included a large number of studies on the PUL procedure in our paper. We searched the literature regarding the PUL procedure with different follow-up periods, systematically evaluated the short- and long-term outcomes caused by PUL, and intuitively expressed these

comprehensive outcome data in the form of a line chart. Moreover, we comprehensively evaluated more outcomes, including prostate symptom scores (IPSS and BPHII), sexual health scores (SHIM, MSHQ-EjD, and MSHQ-Bother), functional outcomes (PVR and Qmax), and QoL score. We systematically assessed each outcome during different follow-up periods to understand their trend after PUL.

Our review has some limitations. First of all, all the studies that we have included are of different quality. Therefore, if the pooled results have significant heterogeneity, we use a random-effect model for analysis. Moreover, benefits secondary to placebo may confound results. Most of the included studies did not set blank or standard controls (TURP). Future clinical studies of the PUL procedure are needed to set up these controls to eliminate interference factors in order to further determine its therapeutic effect for BPH. Furthermore, the current research is not registered, and there may be small deviation, but we still strictly followed the steps of a systematic review. Last but not least, when comparing the merits and demerits of approaches with similar results, cost is one of the variables that has to be considered. Therefore, when we compare the safety and efficacy of several surgical procedures, we need to add cost-effectiveness analysis at the same time.

## 5. Conclusions

The meta-analysis results show that the PUL procedure can continue to relieve symptoms for 24 mo without causing serious complications. Among the various treatments of BPH, the extremely important advantage of the PUL procedure is that it can preserve or slightly improve sexual function. However, longer-term and more comprehensive clinical trials are still needed to clarify the functional outcomes and cost effectiveness of PUL, so as to guide clinicians in treatment selection.

**Author contributions:** Hao Ping had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

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## Appendix A. Supplementary data

Supplementary data associated with this article can be found, in the online version, at [doi:10.1016/j.euros.2020.05.001](https://doi.org/10.1016/j.euros.2020.05.001).

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