Surgical Management of Lower Urinary Tract Symptoms Attributed to Benign Prostatic Hyperplasia: AUA Guideline

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Abbreviations and Acronyms

AUA = American Urological Association

AUA-SI = AUA-Symptom Index

BOO = bladder outlet obstruction

BPE = benign prostatic enlargement

BPH = benign prostatic hyperplasia

BPO = benign prostatic obstruction

ED = erectile dysfunction

HoLEP = holmium laser enucleation of the prostate

LUTS = lower urinary tract symptoms

LUTS/BPH = lower urinary tract symptoms attributed to benign prostatic hyperplasia

PAE = prostate artery embolization

PUL = prostatic urethral lift

PVP = photoselective vaporization of the prostate

QoL = quality of life

ThuLEP = thulium laser enucleation of the prostate

TUIP = transurethral incision of the prostate

TUNA = transurethral needle ablation

TURP = transurethral resection of the prostate

TUVP = transurethral vaporization of the prostate

Purpose: Male lower urinary tract symptoms (LUTS) secondary to benign prostatic hyperplasia (BPH) is common in men and can have negative effects on quality of life (QoL). It is the hope that this Guideline becomes a reference on the effective evidence-based surgical management of LUTS/BPH.

Materials and Methods: The evidence team searched Ovid MEDLINE, the Cochrane Library, and the Agency for Healthcare Research and Quality (AHRQ) database to identify studies indexed between January 2007 and September 2017. When sufficient evidence existed, the body of evidence was assigned a strength rating of A (high), B (moderate), or C (low) for support of Strong, Moderate, or Conditional Recommendations. In the absence of sufficient evidence, additional information is provided as Clinical Principles and Expert Opinions (table 1 in supplementary unabridged guideline, http://jurology.com/).

Results: This Guideline provides updated, evidence-based recommendations regarding management of LUTS/BPH utilizing surgery and minimally invasive surgical therapies; additional statements are made regarding diagnostic and preoperative tests. Clinical statements are made in comparison to what is generally accepted as the gold standard (i.e. transurethral resection of the prostate [TURP]—monopolar and/or bipolar). This guideline is designed to be used in conjunction with the associated treatment algorithm.

Conclusions: The prevalence and the severity of LUTS increases as men age and is an important diagnosis in the healthcare of patients and the welfare of society. This document will undergo additional literature reviews and updating as the knowledge regarding current treatments and future surgical options continues to expand.

Key Words: transurethral resection of the prostate, laser therapy, lower urinary tract symptoms, prostate

BACKGROUND

BPH is a histologic diagnosis that refers to the proliferation of glandular epithelial tissue, smooth muscle, and connection tissue within the prostatic transition zone. BPH is ubiquitous in the aging male with prevalence increasing with age.

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BPH does not require treatment and is not the target of interventions; however, BPH can lead to an enlargement of the prostate (benign prostatic enlargement [BPE]). The prostate may cause obstruction at the level of the bladder neck (benign prostatic obstruction [BPO]). Obstruction may also be caused by other conditions referred to as bladder outlet obstruction (BOO).

Parallel to these anatomical and functional processes, LUTS increase in frequency and severity with age. LUTS may be caused by a variety of conditions, including BPE and BPO. In this Guideline, the Panel refers to "LUTS attributed to BPH" (LUTS/BPH) to indicate LUTS among men for whom an alternative cause is not apparent.

Lower Urinary Tract Symptoms (LUTS)

In assessing the burden of disease, studies reveal a progressive increase in the prevalence of moderate-to-severe LUTS, rising to nearly 50% by the eighth decade of life.[1] Others estimate that 90% of men between 45 and 80 years suffer some type of LUTS.[1] Although LUTS/BPH is not often life-threatening, the impact of LUTS/BPH on QoL can be significant and should not be underestimated.

Index Patient

The Index Patient is a male $\geq$45 who is consulting a clinician for his LUTS. He does not have a history suggesting non-BPH causes of LUTS, and his LUTS may or may not be associated with BPE, BOO, or BPH.

Sexual Dysfunction and Surgical Therapy

Given the strong observed relationship between erectile dysfunction (ED) and LUTS/BPH, this group of men is at high risk for sexual dysfunction.[2] Patients should be counselled about the sexual side effects of any surgical intervention and should be made aware that surgical treatment can cause ejaculatory dysfunction and may worsen ED.

Shared Decision Making

Patients should be provided with the risk/benefit profile for all treatment options in light of their circumstances to allow them to make informed decisions regarding their treatments.

GUIDELINE STATEMENTS

Evaluation and Preoperative Testing

1. **Clinicians should take a medical history and utilize the AUA-Symptom Index (AUA-SI) and urinalysis in the initial evaluation of patients presenting with bothersome LUTS possibly attributed to BPH; select patients may also require post-void residual (PVR), uroflowmetry, or pressure flow studies. (Clinical Principle)**

2. **Clinicians should consider assessment of prostate size and shape via abdominal or transrectal ultrasound, or cystoscopy, or by preexisting cross-sectional imaging (i.e. magnetic resonance imaging/ computed tomography) prior to surgical intervention for LUTS/BPH. (Clinical Principle)**

3. **Clinicians should perform a PVR assessment prior to surgical intervention for LUTS/BPH. (Clinical Principle)**

4. **Clinicians should consider uroflowmetry prior to surgical intervention for LUTS/BPH. (Clinical Principle)**

5. **Clinicians should consider pressure flow studies prior to surgical intervention for LUTS/BPH when diagnostic uncertainty exists. (Expert Opinion)**

A complete medical history should be taken to assess symptoms, prior procedures that could explain symptoms, sexual history, medication use, and overall health. The AUA-SI can provide clinicians with information regarding symptoms. Additionally, while a urinalysis cannot diagnose BPH, it can help clinicians to rule out other causes of LUTS not associated with BPH.

While the evidence base is limited, multiple guidelines include PVR measurement as part of the basic evaluation of LUTS. A rising PVR can indicate the need for surgical intervention, or further workup may be warranted. Patients with symptoms attributed to an elevated PVR may need to proceed on to surgery or further urodynamic testing.

Preoperative uroflowmetry can inform the urologist with reasonable certitude that BPO is causal for LUTS. In patients with catheter-dependent urinary retention who may have underactive detrusor function, a pressure flow study is advised; however, clinicians should be aware that there are such patients (e.g., those with bladder diverticulum) in whom studies inaccurately indicate a lack of detrusor contractility.

Pressure flow studies are the best means to determine the presence of BOO.[3] Non-invasive tools provide useful information, but only pressure flow studies can determine bladder function or lack thereof.

Finally, prostate volume/morphology is a critical attribute for surgical selection. Preoperative assessment may be achieved by abdominal or transrectal ultrasonography, cystoscopy, or by cross-sectional imaging using magnetic resonance imaging or computed tomography. Many patients may have had prior imaging; therefore, any such imaging obtained in the 12 months preceding the planned surgical intervention may be utilized.

Imaging should provide cross-sectional and sagittal imaging of sufficient resolution to calculate prostate volume and assess presence or absence of an intravesical lobe.[4]

Surgical Therapy (see figure)

6. **Surgery is recommended for patients who have renal insufficiency secondary to BPH, refractory urinary retention secondary to BPH, recurrent urinary tract infections, recurrent bladder stones or gross hematuria due to BPH, and/or with LUTS/BPH refractory to and/or unwilling to use other therapies. (Clinical Principle)**

7. **Clinicians should not perform surgery solely for the presence of an asymptomatic bladder diverticulum; however, evaluation for the presence of BOO should be considered. (Clinical Principle)**

Despite the more prevalent use of medical therapy for LUTS/BPH, there are clinical scenarios where surgery is indicated as the initial intervention and should be recommended, providing a lack of precluding medical comorbidities. Prior to surgery for bladder diverticulum, clinicians should perform assessment for BOO and treat as clinically indicated.

Transurethral Resection of the Prostate (TURP)

8. **TURP should be offered as a treatment option for men with LUTS/BPH. (Moderate Recommendation; Evidence Level: Grade B)**

9. **Clinicians may use a monopolar or bipolar approach to TURP, depending on their expertise with these techniques. (Expert Opinion)**

TURP remains the single best standard against which to measure the efficacy, effectiveness, and safety of other interventions for LUTS/BPH.

Interventions discussed in this Guideline may be reasonably compared to either monopolar or bipolar TURP regarding efficacy measures given the lack of differences between monopolar and bipolar TURP in this regard. The main difference between monopolar and bipolar TURP is TUR syndrome, which is unique to TURP. As such, safety parameters other than TUR syndrome can also be reliably compared between interventions and either form of TURP.

Previous guidelines have emphasized the fact that complications increase with increasing resection time and increasing resected tissue volume following monopolar TURP. While no clear guidelines have been established, prolonged resection times should be avoided with monopolar approaches. Bipolar TURP has a reduced risk of hyponatremia and TUR syndrome, which allows for longer resection times and surgery on larger glands.

Simple Prostatectomy

10. **Clinicians should consider open, laparoscopic or robotic assisted prostatectomy, depending on their expertise with these techniques, for patients with large prostates. (Moderate Recommendation; Evidence Level: Grade C)**

The Panel recognizes that "large" is a relative term as some providers have excellent results utilizing transurethral approaches (e.g., bipolar TURP, HoLEP) in prostates >60g. However, not all providers have access to or are using bipolar TURP or HoLEP technology, and may not wish to approach large glands transurethrally.

Alternatively, larger prostates have been treated with open simple prostatectomy. In recent years, alternative techniques have been developed that include laparoscopic and robot-assisted laparoscopic approaches.

Transurethral Incision of the Prostate (TUIP)

11. **TUIP should be offered as an option for patients with prostates ≤30g for the treatment of LUTS/BPH. (Moderate Recommendation; Evidence Level: Grade B)**

TUIP has been used to treat small prostates, usually defined as ≤30g, for many decades. In past updates, a large number of prospective cohort trials were analyzed, and adequate results were reported in terms of AUA-SI and Q_{max} changes. A meta-analysis comparing TUIP with TURP after a minimum follow-up of 6 months identified a lower rate of retrograde ejaculation (18.2% versus 65.4%) and need for blood transfusion (0.4% versus 8.6%) as advantages of TUIP versus TURP.[5]

Transurethral Vaporization of the Prostate (TUVP)

12. **Bipolar TUVP may be offered to patients for the treatment of LUTS/BPH. (Conditional Recommendation; Evidence Level: Grade B)**

TUVP is an electrosurgical modification of the standard TURP. TUVP can utilize a variety of energy delivery surfaces with saline and bipolar energy. Compared to traditional loops, the various TUVP designs hope to improve upon visualization, blood loss, resection speed, and patient morbidity.

Photoselective Vaporization of the Prostate (PVP)

13. **Clinicians should consider PVP as an option using 120W or 180W platforms for patients for the treatment of LUTS/BPH. (Moderate Recommendation; Evidence Level: Grade B)**

Men considering PVP should be informed of the similar outcomes with regards to symptomatic improvement in LUTS/BPH and complications versus TURP. In a multicenter randomized controlled trial comparing the 180W PVP to TURP,

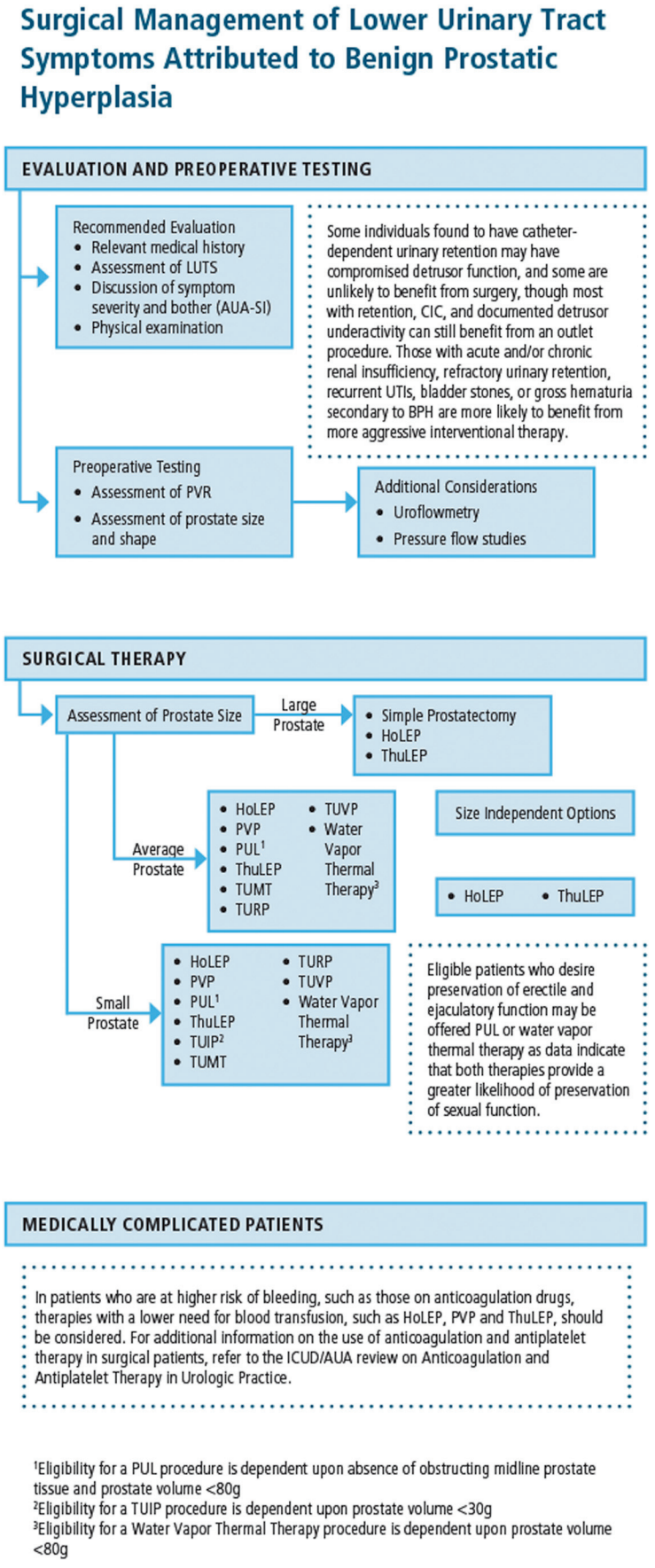

Figure. Surgical management of lower urinary tract symptoms attributed to benign prostatic hyperplasia algorithm

24-month data reported similar adverse events related to urinary incontinence, need for blood transfusion, and overall need for reoperation between the two modalities.[6–8] While the I-PSS at 24 months was 5.9 for TURP (compared to 6.9 for PVP), this difference did not meet the non-inferiority criteria in the study.

Prostatic Urethral Lift (PUL)

14. **Clinicians should consider PUL as an option for patients with LUTS/BPH provided prostate volume < 80g and verified absence of an obstructive middle lobe; however, patients should be informed that symptom reduction and flow rate improvement is less significant compared to TURP. (Moderate Recommendation; Evidence Level: Grade C)**

15. **PUL may be offered to eligible patients concerned with erectile and ejaculatory function for the treatment of LUTS/BPH. (Conditional Recommendation; Evidence Level: Grade C)**

In comparing PUL with TURP in the BPH6 study, a lower proportion of individuals in the PUL group responded to treatment at 12 months as measured by the I-PSS reduction goal of ≥30% (73% versus 91%; P=.05). At 24-months follow-up, the mean difference between PUL and TURP was 6.1 points favoring TURP. Additionally, Q_{max} was significantly lower with PUL at all follow-up intervals.[9,10] Measures of erectile function were similar between groups at all time points, but ejaculatory function based on Male Sexual Health Questionnaire for Ejaculatory Dysfunction scores favored PUL. Similarly, McVary et al.[11] demonstrated that there was no evidence of de novo ejaculatory dysfunction or ED seen with PUL procedures, and ejaculatory bother improved by 40% at 1 year (p<0.001). Intensity of ejaculation and amount of ejaculate improved by 23% and 22%, respectively (p<0.001).

Regarding PUL compared with sham (L.I.F.T. Study),[12–15] mean change from baseline I-PSS (MD: -5.2; CI: -7.45, -2.95) favored PUL. Mean change in Q_{max} at 3 months was higher for those who underwent the PUL (4.3mL/s) compared to sham (2.0mL/s), P=.005. Of the participants randomized to PUL, five-year follow-up data showed slight decreases in mean I-PSS improvement and stable QoL scores; however, both remained significantly improved from baseline. Data showed non-significant differences in sexual function between PUL and sham groups. Reoperation due to symptom recurrence at 5 years was reported for 19 of 140 participants with 6 receiving additional PUL implants and 13 undergoing TURP or laser procedures. Removal of implants was required in 13 participants while 15 participants were taking LUTS medications.

Given the study limitation of PUL to prostates <80g without obstructive lobes, the Panel recommends that clinicians limit this procedure to such patients until further data are available to indicate safety in other patient populations.

Transurethral Microwave Therapy (TUMT)

16. **TUMT may be offered to patients with LUTS/BPH; however, patients should be informed that surgical retreatment rates are higher compared to TURP. (Conditional Recommendation; Evidence Level: Grade C)**

Evidence regarding efficacy, symptom improvement, adverse events, and urinary flow rates are inconsistent. Four trials compared TUMT to TURP or control.[16–23] Response to treatment was similar between the TUMT and TURP groups, while reoperation was significantly higher with TUMT (9.9%) compared to TURP (2.3%). Incontinence through long-term follow-up was significantly lower with TUMT (0.7%) compared to TURP (3.9%). ED was similar for TUMT (6.3%) compared to TURP (11.5%).

Water Vapor Thermal Therapy

17. **Water vapor thermal therapy may be offered to patients with LUTS/BPH provided prostate volume < 80g; however, patients should be informed that evidence of efficacy, including longer-term retreatment rates, remains limited. (Conditional Recommendation; Evidence Level: Grade C)**

18. **Water vapor thermal therapy may be offered to eligible patients who desire preservation of erectile and ejaculatory function. (Conditional Recommendation; Evidence Level: Grade C)**

One double-blind trial[24–26] compared water vapor thermal therapy to sham in men with prostate volume <80g. Response to treatment through 3 months was significantly greater in the water vapor thermal therapy group (74%) compared to sham (31%). Mean changes from baseline in I-PSS and I-PSS-QoL at 3 months were greater in the treatment group compared to sham with a MDD of >3 points (MD: -6.9; CI: -9.1, -4.8). Two-year results showed sustained improvements for the I-PSS, I-PSS-QoL, and Q_{max}, with scores remaining significantly improved from baseline. The incidence of non-serious transient adverse events was significantly higher in the water vapor thermal therapy group. No de novo ED was reported long term, and no significant changes in IIEF-EF scores or ejaculatory functions scores were observed compared to baseline.[26]

Transurethral Needle Ablation (TUNA)

19. **TUNA is not recommended for the treatment of LUTS/BPH. (Expert Opinion)**

The lack of peer-reviewed publication in the literature review timeframe meeting the inclusion criteria and the decreasing clinical relevance resulted in a lack of enthusiasm by the Panel to recommend TUNA for the treatment of LUTS attributed to BPH.

Laser Enucleation

20. **Clinicians should consider holmium laser enucleation of the prostate (HoLEP) or thulium laser enucleation of the prostate (ThuLEP), depending on their expertise with either technique, as prostate size-independent suitable options for the treatment of LUTS/BPH. (Moderate Recommendation; Evidence Level: Grade B)**

Due to the chromophore of water and minimal tissue depth penetration with both holmium and thulium, these two lasers achieve rapid vaporization and coagulation of tissue without the disadvantage of deep tissue penetration. They have better coagulative properties in tissue than either monopolar or bipolar TURP, and combined with their superficial penetration, both are reasonable for endoscopic enucleation.[27]

Prostate Artery Embolization (PAE)

21. **PAE is not recommended for the treatment of LUTS/BPH outside the context of a clinical trial. (Expert Opinion)**

Given the heterogeneity in the sparsely available literature in addition to safety concerns regarding radiation exposure, post-embolization syndrome, vascular access, technical feasibility, and adverse events, it is the opinion of the Panel that PAE should only be performed in the context of a clinical trial until sufficient evidence from rigorously performed studies is available to indicate benefit over other more well established therapies.

Medically Complicated Patients

22. **HoLEP, PVP, and ThuLEP should be considered in patients who are at higher risk of bleeding, such as those on anti-coagulation drugs. (Expert Opinion)**

Multiple studies have shown the need for blood transfusion (peri- or post-operatively) was less likely with HoLEP and ThuLEP as compared to TURP (RR: 0.20; CI: 0.08, 0.47) and (RR 0.4; CI: 0.1, 0.9), respectively.[28–40] Additionally, anticoagulation/antiplatelet therapy has not been shown to adversely affect outcomes of HoLEP procedures, other than a slightly increased duration of bladder irrigation and hospital stay.[41]

Multiple studies have found that PVP is safe and effective for patients who continue their anticoagulant/antiplatelet therapy, with negligible transfusion rates. However, surgeons should be aware that longer catheterization and irrigation with an increased rate of complications has been reported, and delayed bleeding is more pronounced in these patients.[42–45]

FUTURE DIRECTIONS

There are enormous gaps in knowledge and, therefore, ensuing opportunities for discovery. These include but are not limited to many unanswered questions related to the role of inflammation, metabolic dysfunction, obesity, and environmental factors in etiology, as well as the role of behavior modification, self-management, and evolving therapeutic algorithms in both the prevention and progression of disease.

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DISCLAIMER

This document was written by the Benign Prostatic Hyperplasia Guideline Panel of the American Urological Association Education and Research, Inc., which was created in 2016. The Practice Guidelines Committee (PGC) of the AUA selected the committee chair. Panel members were selected by the chair. Membership of the Panel included specialists in urology and primary care with specific expertise on this disorder. The mission of the panel was to develop recommendations that are analysis-based or consensus-based, depending on panel processes and available data, for optimal clinical practices in the surgical treatment of benign prostatic hyperplasia.

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While these guidelines do not necessarily establish the standard of care, AUA seeks to recommend and to encourage compliance by practitioners with current best practices related to the condition being treated. As medical knowledge expands and technology advances, the guidelines will change. Today these evidence-based guidelines statements represent not absolute mandates but provisional proposals for treatment under the specific conditions described in each document. For all these reasons, the guidelines do not pre-empt physician judgment in individual cases.

Treating physicians must take into account variations in resources, and patient tolerances, needs, and preferences. Conformance with any clinical guideline does not guarantee a successful outcome. The guideline text may include information or recommendations about certain drug uses ('off label') that are not approved by the Food and Drug Administration (FDA), or about medications or substances not subject to the FDA approval process. AUA urges strict compliance with all government regulations and protocols for prescription and use of these substances. The physician is encouraged to carefully follow all available prescribing information about indications, contraindications, precautions and warnings. These guidelines and best practice statements are not intended to provide legal advice about use and misuse of these substances.

Although guidelines are intended to encourage best practices and potentially encompass available technologies with sufficient data as of close of the literature review, they are necessarily time-limited. Guidelines cannot include evaluation of all data on emerging technologies or management, including those that are FDA-approved, which may immediately come to represent accepted clinical practices.

For this reason, the AUA does not regard technologies or management which are too new to be addressed by this guideline as necessarily experimental or investigational.

CONFLICT OF INTEREST DISCLOSURES

All panel members completed COI disclosures. Disclosures listed include both topic- and non-topic-related relationships.

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