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American Urological Association (AUA)

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

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Purpose

Benign prostatic hyperplasia (BPH) is a histologic diagnosis that refers to the proliferation of smooth muscle and epithelial cells within the prostatic transition zone. The prevalence and the severity of lower urinary tract symptoms (LUTS) in the aging male can be progressive and is an important diagnosis in the healthcare of patients and the welfare of society. In the management of bothersome LUTS, it is important that healthcare providers recognize the complex dynamics of the bladder, bladder neck, prostate, and urethra, in addition to the fact that symptoms may result from interactions of these organs as well as with the central nervous system or other systemic diseases (e.g., metabolic syndrome, congestive heart failure). Despite the more prevalent (and often first line) use of medical therapy for men suffering from LUTS attributed to BPH, there still remain clinical scenarios where surgery is indicated as the initial intervention for LUTS/BPH and should be recommended, providing other medical comorbidities do not preclude this approach. It is the hope that this revised guideline will provide a useful reference on the effective evidence-based surgical management of male LUTS secondary to BPH (LUTS/BPH). Please see the accompanying algorithm for a summary of the surgical procedures detailed in the guideline.

Methodology

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. Following initial publication in 2019, this Guideline underwent an amendment in 2019 that included literature published through January 2019. 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.

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 [MRI]/ computed tomography [CT]) prior to surgical intervention for LUTS attributed to BPH.

(Clinical Principle)

3. Clinicians should perform a PVR assessment prior to surgical intervention for LUTS attributed to BPH. (Clinical Principle)
4. Clinicians should consider uroflowmetry prior to surgical intervention for LUTS attributed to BPH. (Clinical Principle)
5. Clinicians should consider pressure flow studies prior to surgical intervention for LUTS attributed to BPH when diagnostic uncertainty exists. (Expert Opinion)

SURGICAL THERAPY

6. Surgery is recommended for patients who have renal insufficiency secondary to BPH, refractory urinary retention secondary to BPH, recurrent urinary tract infections (UTIs), recurrent bladder stones or gross hematuria due to BPH, and/or with LUTS attributed to 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)

TRANSURETHRAL RESECTION OF THE PROSTATE (TURP)

8. TURP should be offered as a treatment option for men with LUTS attributed to 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)

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)

TRANSURETHRAL INCISION OF THE PROSTATE (TUIP)

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

TRANSURETHRAL VAPORIZATION OF THE PROSTATE (TUVP)

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

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 attributed to BPH. (Moderate Recommendation; Evidence Level: Grade B)

PROSTATIC URETHRAL LIFT (PUL)

14. Clinicians should consider PUL as an option for patients with LUTS attributed to 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. Patients should be informed that evidence of efficacy and retreatment rates are poorly defined. (Moderate Recommendation; Evidence Level: Grade C)
15. PUL may be offered to eligible patients concerned with erectile and ejaculatory function for the treatment of with LUTS attributed to BPH. (Conditional Recommendation; Evidence Level: Grade C)

TRANSURETHRAL MICROWAVE THERAPY (TUMT)

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

WATER VAPOR THERMAL THERAPY

17. Water vapor thermal therapy may be offered to patients with LUTS attributed to BPH provided prostate volume <80g; however, patients should be counseled regarding efficacy and retreatment rates. (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)

TRANSURETHRAL NEEDLE ABLATION (TUNA)

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

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 attributed to BPH. (Moderate Recommendation; Evidence Level: Grade B)

AQUABLATION

21. Aquablation may be offered to patients with LUTS attributed to BPH provided prostate volume >30/<80g, however, patients should be informed that long term evidence of efficacy and retreatment rates, remains limited. (Conditional Recommendation; Evidence Level: Grade C)

PROSTATE ARTERY EMBOLIZATION (PAE)

22. PAE is not recommended for the treatment of LUTS attributed to BPH outside the context of a clinical trial. (Expert Opinion)

MEDICALLY COMPLICATED PATIENTS

23. 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)

INTRODUCTION

PURPOSE

Benign prostatic hyperplasia (BPH) is a histologic diagnosis that refers to the proliferation of smooth muscle and epithelial cells within the prostatic transition zone. The prevalence and the severity of lower urinary tract symptoms (LUTS) in the aging male can be progressive and is an important diagnosis in the healthcare of patients and the welfare of society. In the management of bothersome LUTS, it is important that healthcare providers recognize the complex dynamics of the bladder, bladder neck, prostate, and urethra, in addition to the fact that symptoms may result from interactions of these organs as well as with the central nervous system or other systemic diseases (e.g., metabolic syndrome, congestive heart failure). Despite the more prevalent (and often first line) use of medical therapy for men suffering from LUTS attributed to BPH, there still remain clinical scenarios where surgery is indicated as the initial intervention for LUTS/BPH and should be recommended, providing other medical comorbidities do not preclude this approach. It is the hope that this revised guideline will provide a useful reference on the effective evidence-based surgical management of male LUTS secondary to BPH (LUTS/ BPH). Please see the accompanying algorithm for a summary of the surgical procedures detailed in the guideline.

METHODOLOGY

The American Urological Association (AUA) Guideline: Management of Benign Prostatic Hyperplasia was last revised in 2010.[1] In preparation for an update of the guideline, the Panel provided the Minnesota Evidence-based Practice Center with key questions, interventions, comparators, and outcomes to be addressed. The review team worked closely with the Panel to refine the scope, key questions, and inclusion/exclusion criteria. The key questions were divided into three topics: 1. Preoperative parameters that are necessary before surgical intervention is instituted, 2. Surgical management of bladder outlet obstruction (BOO) secondary to BPH, and 3. Acute urinary retention.

Panel Formation. The LUTS/ BPH Panel was created in 2016 by the American Urological Association Education and Research, Inc. (AUAER). The Practice Guidelines Committee (PGC) of the AUA selected the Panel Chairs who in turn appointed the additional panel members with specific expertise in this area. The AUA conducted a thorough peer review

process. The draft guideline document was distributed to 130 peer reviewers. The panel reviewed and discussed all submitted comments and revised the draft as needed. Once finalized, the guideline was submitted for approval to the PGC and Science and Quality Council (SQC) and subsequently to the AUA Board of Directors for final approval. Funding of the panel was provided by the AUA; panel members received no remuneration for their work.

Searches and Article Selection. The evidence review team searched Ovid MEDLINE, the Cochrane Library, and the Agency for Healthcare Research and Quality (AHRQ) database to identify randomized controlled trials (RCTs), clinical controlled trials (CCTs), systematic reviews/meta-analyses, and observational studies published and indexed between January 2007 and September 2017. Following initial publication in 2019, this Guideline underwent an amendment in 2019 that included literature published through January 2019. Note, additional studies published outside of this date range may be included to inform background sections or provide historical context. A unique search strategy was used for each of the three topics. Systematic reviews and meta- analyses were searched to identify additional eligible studies. The review team also reviewed articles for inclusion identified by the Panel. Search terms included Medical Subject Headings (MeSH) and keywords for procedures, devices, and conditions related to LUTS or BPH. Limits were used to restrict the search to English language publications.

Abstract review was completed independently by two investigators to determine if citations were eligible for full text review. Two investigators independently reviewed full text articles to identify studies that met inclusion criteria. Conflicts between investigators on inclusion status were resolved through discussion or by a third investigator when necessary.

Risk of Bias (ROB) and Data Extraction. The review team used the Cochrane Collaboration's tool for assessing risk of bias (ROB).[2] A bias is a systematic error in results or inferences that can lead to underestimation or overestimation of the true intervention effect. Differences in ROB can help explain heterogeneity in the results of studies included in a systematic review. ROB domains include random sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessment, incomplete outcome data, and selective reporting. Reviewers assessed ROB for the following outcomes: change in International Prostate Symptom Score (I-PSS), percent responders based on I-PSS (e.g., percentage achieving a minimally detectable

difference [MDD] such as a 30-50% reduction in score from baseline or achieving an I-PSS score of ≤7 points following treatment), change from baseline in quality of life (I-PSS-QoL), perioperative adverse events, and other adverse events (e.g., symptom recurrence, need for reoperation). For blinding of outcome assessment and incomplete outcome data the review team assessed ROB for short-, intermediate-, and long-term follow-up. The overall ROB judgement for each outcome across domains was determined using an approach suggested in the Cochrane Handbook version 5.1.[3] ROB was assessed by a single reviewer and quality checked by a subject expert. Discrepancies were resolved by consensus.

Data Synthesis and Analysis. Reviewers assessed clinical and methodological heterogeneity to determine appropriateness of pooling data. Data were analyzed in RevMan[4] using DerSimonian-Laird random effects to calculate risk ratios (RR) with corresponding 95 percent confidence intervals (CI) for binary outcomes and weighted mean differences (WMD) with the corresponding 95 percent CIs for continuous outcomes. Statistical heterogeneity was assessed with the I^2 statistic. If substantial heterogeneity was present (i.e., I2 ≥70%), reviewers stratified the results to assess treatment effects based on patient or study characteristics and/or explored sensitivity analyses. For I-PSS and I-PSS- QoL, reviewers determined the statistical significance of the effect of interventions versus control but defined clinical efficacy based on whether the mean or median effect between intervention and control exceeded thresholds for clinical significance (i.e., the MDD). For I- PSS this is a difference of > 3 points. For QoL reviewers defined this as greater than 1 point.

Overall quality of evidence for the primary outcomes within each comparison was evaluated using GRADEpro[5] based on give assessed domains.[6,7] The quality of evidence levels range from high to very low. The five domains include 1. Study limitations (ROB), 2. Directness (single, direct link between intervention and outcome), 3. Consistency (similarity of effect direction and size among studies), 4. Precision (degree of certainty around an estimate assessed in relationship to MDD), and 5. Reporting bias.

Determination of Evidence Strength. The categorization of evidence strength is conceptually distinct from the quality of individual studies. Evidence strength refers to the body of evidence available for a particular question and includes not only individual study quality but consideration of study design, consistency of findings across studies, adequacy of sample sizes, and generalizability of samples, settings, and treatments for the purposes of the guideline. The AUA categorizes body of evidence strength as Grade A (well-conducted and highly-generalizable RCTs or exceptionally strong observational studies with consistent findings), Grade B (RCTs with some weaknesses of procedure or generalizability or moderately strong observational studies with consistent findings), or Grade C (RCTs with serious deficiencies of procedure or generalizability or extremely small sample sizes or observational studies that are inconsistent, have small sample sizes, or have other problems that potentially confound interpretation of data). By definition, Grade A evidence is evidence about which the Panel has a high level of certainty, Grade B evidence is evidence about which the Panel has a moderate level of certainty, and Grade C evidence is evidence about which the Panel has a low level of certainty.

AUA Nomenclature: Linking Statement Type to Evidence Strength. The AUA nomenclature system explicitly links statement type to body of evidence strength, level of certainty, magnitude of benefit or risk/burdens, and the Panel's judgment regarding the balance between benefits and risks/burdens (Table 1). ***Strong Recommendations*** are directive statements that an action should (benefits outweigh risks/burdens) or should not (risks/burdens outweigh benefits) be undertaken because net benefit or net harm is substantial. ***Moderate Recommendations*** are directive statements that an action should (benefits outweigh risks/burdens) or should not (risks/burdens outweigh benefits) be undertaken because net benefit or net harm is moderate. ***Conditional Recommendations*** are non-directive statements used when the evidence indicates that there is no apparent net benefit or harm or when the balance between benefits and risks/burden is unclear. All three statement types may be supported by any body of evidence strength grade. Body of evidence strength Grade A in support of a Strong or Moderate Recommendation indicates that the statement can be applied to most patients in most circumstances and that future research is *unlikely to change confidence*. Body of evidence strength Grade B in support of a Strong or Moderate Recommendation indicates that the statement can be applied to most patients in most circumstances but that better evidence *could change confidence*. Body of evidence strength Grade C in support of a Strong or Moderate Recommendation indicates that the statement can be applied to most patients in most circumstances but that

TABLE 1: AUA Nomenclature Linking Statement Type to Level of Certainty, Magnitude of Benefit or Risk/Burden, and Body of Evidence Strength

	Evidence Strength A (High Certainty)	**Evidence Strength B (Moderate Certainty)**	**Evidence Strength C (Low Certainty)**
Strong Recommendation (Net benefit or harm substantial)	Benefits > Risks/Burdens (or vice versa) Net benefit (or net harm) is substantial Applies to most patients in most circumstances and future research is unlikely to change confidence	Benefits > Risks/Burdens (or vice versa) Net benefit (or net harm) is substantial Applies to most patients in most circumstances but better evidence could change confidence	Benefits > Risks/Burdens (or vice versa) Net benefit (or net harm) appears substantial Applies to most patients in most circumstances but better evidence is likely to change confidence (rarely used to support a Strong Recommendation)
Moderate Recommendation (Net benefit or harm moderate)	Benefits > Risks/Burdens (or vice versa) Net benefit (or net harm) is moderate Applies to most patients in most circumstances and future research is unlikely to change confidence	Benefits > Risks/Burdens (or vice versa) Net benefit (or net harm) is moderate Applies to most patients in most circumstances but better evidence could change confidence	Benefits > Risks/Burdens (or vice versa) Net benefit (or net harm) appears moderate Applies to most patients in most circumstances but better evidence is likely to change confidence
Conditional Recommendation (No apparent net benefit or harm)	Benefits = Risks/Burdens Best action depends on individual patient circumstances Future research unlikely to change confidence	Benefits = Risks/Burdens Best action appears to depend on individual patient circumstances Better evidence could change confidence	Balance between Benefits & Risks/Burdens unclear Alternative strategies may be equally reasonable Better evidence likely to change confidence
Clinical Principle	A statement about a component of clinical care that is widely agreed upon by urologists or other clinicians for which there may or may not be evidence in the medical literature		
Expert Opinion	A statement, achieved by consensus of the Panel, that is based on members' clinical training, experience, knowledge, and judgment for which there is no evidence		

better evidence is *likely to change confidence*. Body of evidence strength Grade C is only rarely used in support of a Strong Recommendation. Conditional Recommendations can also be supported by any evidence strength. When body of evidence strength is Grade A, the statement indicates that benefits and risks/burdens appear balanced, the best action depends on patient circumstances, and future research is unlikely to change confidence. When body of evidence strength Grade B is used, benefits and risks/burdens appear balanced, the best action also depends on individual patient circumstances and better evidence *could change confidence*. When body of evidence strength Grade C is used, there is uncertainty regarding the balance between benefits and risks/burdens, alternative strategies may be equally reasonable, and better evidence is *likely to change confidence*.

Where gaps in the evidence existed, the Panel provides guidance in the form of ***Clinical Principles*** *or* ***Expert Opinion*** with consensus achieved using a modified Delphi technique if differences of opinion emerged.[4] A *Clinical Principle* is a statement about a component of clinical care that is widely agreed upon by urologists or other clinicians for which there may or may not be evidence in the medical literature. *Expert Opinion* refers to a statement, achieved by consensus of the Panel, that is based on members' clinical training, experience, knowledge, and judgment for which there is no evidence.

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, hence the term "stromo-glandular hyperplasia."[8,9] While several hypotheses exist, BPH is likely the result of a multifactorial process, the exact etiology of which is unknown. It is clear that male androgenic steroid hormones testosterone and dihydrotestosterone (DHT) play at least a permissive role as the absence of these hormones prior to puberty prevents the development of BPH. BPH is nearly ubiquitous in the aging male with worldwide autopsy proven histological prevalence increases starting at age 40-45 years to reach 60% at age 60 and 80% at age 80.[10]

BPH or histological hyperplasia in itself does not require treatment and is not the target of therapeutic intervention. BPH does, however, in many men lead to an enlargement of the prostate called benign prostatic enlargement (BPE). The onset of the enlargement is highly variable as is the growth rate, though a 5% increase in volume has been shown in longitudinal studies of placebo treated patients.[11] Clearly not all men with BPH will develop any evidence of BPE. The prostate gland may cause eventually obstruction at the level of the bladder neck, which in turned is termed benign prostatic obstruction (BPO), assuming a non-cancerous anatomy. It is important to realize that not all men with BPE will develop obstruction or BPO, just as not all men with BPH will have BPE. To complicate matters further, obstruction may also be caused by other conditions referred to as BOO. Thus, BPO is a subset of BOO.

Parallel to these anatomical and functional processes, LUTS increase in frequency and severity with age and are divided into those associated with storage of urine and with voiding or emptying. In addition, there are other symptoms following urination (e.g. post void dribbling).

Male LUTS may be caused by a variety of conditions, which include BPE and BPO. The enlarged gland has been proposed to contribute to the male LUTS complex via at least two routes: 1. Direct BOO/BPO from enlarged tissue (static component), and 2. From increased smooth muscle tone and resistance within the enlarged gland (dynamic component). This complex of storage symptoms is often referred to as overactive bladder (OAB). In men, OAB may be the result of primary detrusor overactivity/underactivity or develop secondary to the obstruction induced by BPE and BPO.[12]

It is important to recognize that LUTS are non-specific, occur in men and women with similar frequency, and may be caused by many conditions, including BPE and BPO. Histological BPH is common and may lead to BPE. BPE may cause BPO, but not all men with BPH will develop BPE, and not all BPE will cause BPO. Because BPH is nearly ubiquitous and because LUTS in men is commonly associated with and/or caused by BPE/BPO, a compromise terminology is often used referring to "LUTS most likely associated with BPE/BPO and BPH" or "LUTS secondary to BPH." In this guideline, the Panel refers to "LUTS attributed to BPH" to indicate LUTS among older men for whom an alternative cause is not apparent after a basic evaluation. The Panel acknowledges that with a more extensive evaluation, some of these men will be found to have other conditions causing or contributing to their symptoms. As treatments being considered specifically for BPO become more invasive and risky, the importance of a more definitive diagnosis increases.

Lower Urinary Tract Symptoms (LUTS)

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. In assessing the burden of disease, the Urologic Diseases in America BPH Project examined the prevalence of moderate-to-severe LUTS reported in U.S. population-based studies that used the definition of an AUA-SI score of ≥7.[13] Results from the Olmsted County Study showed a progressive increase in the prevalence of moderate-to-severe LUTS, rising to nearly 50% by the eighth decade of life. The presence of moderate-to-severe LUTS was also associated with the development of acute urinary retention as a symptom of BPH progression, increasing from a prevalence of 6.8 episodes per 1,000 patient years of follow-up in the overall population to a high of 34.7 episodes in men aged 70 and older with moderate-to-severe LUTS. Another study has estimated that 90% of men between 45 and 80 years of age suffer some type of LUTS.[14] Although LUTS/BPH is not often a life-threatening condition, the impact of LUTS/BPH on QoL can be significant and should not be underestimated.[13] When the effect of BPH-associated LUTS on QoL was studied in a number of community-based populations, for many, the most important motivations for seeking treatment were the severity and the degree of bother associated with the symptoms. These were also important considerations when assessing BPH and deciding when treatment is indicated.[15]

Treatment of LUTS attributed to BPH

The main focus of this guideline is on the treatment of LUTS attributed to BPH utilizing common surgical techniques and minimally invasive surgical therapies (MIST), although some additional statements are made regarding specific pre-operative tests and their utility in identifying appropriate surgical candidates. To provide some reference to the clinical efficacy and side effect profile of the procedures discussed in this guideline, clinical statements are made in comparison to what is generally accepted as the gold standard, that being a TURP (monopolar and/or bipolar).

Traditionally, the primary goal of treatment has been to alleviate bothersome LUTS that result from BPO. More recently, treatment has also been focused on the alteration of disease progression and prevention of complications that can be associated with BPH/LUTS, such as acute urinary retention.[16] A variety of pharmacologic classes of medications are employed to treat LUTS attributed to BPH, including alpha-adrenergic antagonists (alpha-blockers), beta adrenergic agonists, 5-alpha- reductase inhibitors (5-ARIs), anticholinergics, vasopressin analogs, PDE-5 inhibitors, and phytotherapeutics, which can be utilized alone or in combination to take advantage of their different mechanisms of action. Conversely, there exist clinical scenarios when either conservative management , including life style changes (e.g., fluid restriction, avoidance of substances with diuretic properties) or pharmacological management are either inadequate or inappropriate, warranting consideration of one of the many invasive procedures available for the treatment of LUTS attributed to BPH. Indications for the use of one of these modalities may include a desire by the patient to avoid taking a daily medication, failure of medical therapy to sufficiently ameliorate bothersome LUTS, and certain conditions that require more aggressive intervention where medical therapy is inappropriate. This latter category includes patients with acute and/or chronic renal insufficiency, refractory urinary retention, recurrent UTIs, and bladder stones or gross hematuria thought secondary to BPH.

Surgical treatment of symptomatic BPH has classically involved removal of the obstructing adenomatous tissue typically via the transurethral route (TURP) using monopolar electroconductivity. In instances where the physical size of the prostate precludes the ability to achieve this task safely utilizing TURP (i.e. risk of transurethral resection [TUR] syndrome resulting in dilutional hyponatremia/hypervolemia), open simple prostatectomy (OSP) (i.e. retropubic or suprapubic) has been the treatment of choice. These procedures generally require regional (spinal, epidural) or general anesthesia in addition to varying durations of hospital convalescence. Furthermore, as many patients who require surgery for BPH have concomitant medical conditions (e.g., history of coronary artery disease, cerebrovascular disease, deep vein thrombosis) that necessitate anticoagulation or antiplatelet therapy, use of TURP or OSP can present significant clinical challenges or in some cases may be contraindicated. In addition, known complications associated with TURP and open prostatectomy, such as intraoperative and perioperative bleeding requiring transfusion, urethral stricture, bladder neck contracture, stress urinary incontinence, erectile dysfunction (ED), and retrograde ejaculation (RE), can negatively impact QoL. For reasons including obviating the need for regional or general anesthesia, hospital stay, discontinuation of anticoagulation therapy, and open surgery, a variety of alternatives to the standard monopolar TURP have been developed and utilized to varying degrees in an attempt to achieve similar clinical efficacy and a reduction in short- and long-term complications. These

alternative surgical treatments and MISTs either use modifications to existing technology used in TURP or utilize altogether new technologies and concepts. In this guideline, a decision was made to evaluate the commonly used surgical procedures and MISTs to treat LUTS attributed to BPH when indicated based on evaluation by an appropriately trained clinician. These procedures include monopolar and bipolar TURP, robotic simple prostatectomy (retropubic, suprapubic, and laparoscopic), TUIP, bipolar TUVP, PVP, PUL, thermal ablation using TUMT, water vapor thermal therapy, TUNA of the prostate, enucleation using HoLEP or ThuLEP, and PAE. Data utilized to generate these statements are based on the results from what the Panel felt were acceptably performed RCTs and CCTs comparing each technique to TURP .

Index Patient

For this guideline, the Index Patient is a male aged 45 or older who is consulting a qualified 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 an enlarged prostate gland, BOO, or histological BPH.

Sexual Dysfunction and Surgical Therapy

Data on the sexual side effects of BPH surgery can be difficult to ascertain as many studies are not primarily designed to answer this question. As such, many studies evaluate sexual side effects by looking at reported adverse events only, rather than specifically assessing sexual function. In addition, in some studies, especially those evaluating surgical treatments, patients may not only be undergoing a surgical procedure but are also stopping the previous medical therapy, which can confound interpretation of postoperative sexual function.

Given the strong observed relationship between ED and LUTS/BPH, this group of men is at high risk for sexual dysfunction.[17] 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 (EjD) and may worsen ED. Interventions for LUTS/BPH have clear sexual side effects. These treatments have a significant rate of EjD. Libido does not appear to be affected significantly by surgical therapy, and some studies have shown an improvement in erectile function (EF) after surgical treatment, although this improvement is controversial as other studies show a worsening of EF.[18] Most importantly, sexual side effects from surgical treatments are more likely to be permanent than those from medical treatments, which can often be reversed by stopping medical treatment or switching to an alternative treatment.

Shared Decision Making

It is the hope that this clinical guideline will provide a useful reference on the effective evidence-based management of male LUTS attributed to BPH utilizing standard surgical techniques, MISTs using newer technologies, and treatments the Panel feels are investigative. This guideline also reviews a number of important aspects of the evaluation of LUTS, including available diagnostic tests to identify the underlying pathophysiology and to better assist in identifying appropriate candidates for invasive treatments. Certain treatment modalities recommended in the guideline may be unavailable to some clinicians, for example due to lack of access to the necessary equipment/ technology or a lack of expertise in the use of such modalities. In such instances, clinicians should discuss the key treatment classes with patients and engage in a shared decision making approach to reach a treatment choice, which may necessitate a referral to another clinician for the chosen treatment. In all instances, 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 treatment plans.

GUIDELINE STATEMENTS

EVALUATION AND PEROPERATIVE 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)**

A complete medical history should be taken to assess patient symptoms, prior procedures that could explain presence of symptoms, sexual history, use of medications, and overall fitness and health. The AUA-SI, a validated self-administered questionnaire, can provide clinicians with information regarding the symptom burden patients are experiencing. Additionally, while a urinalysis cannot diagnose BPH, it

can help clinicians to rule out other causes of LUTS not associated with BPH through the detection of bacteria, blood, white cells, or protein in the urine.

Optional studies that may be used to confirm the diagnosis or evaluate the severity of BPH include PVR, uroflowmetry, and pressure flow studies. A PVR can be useful in determining a baseline ability of the bladder to empty, detecting severe urinary retention that may not be amenable to medical therapy, and/or indicating detrusor dysfunction. There is no universally accepted definition of a clinically significant residual urine volume, and likely following a trend over time is the best way to use this tool.

Uroflowmetry is a simple and risk-free office-based procedure that can be an important adjunct in the evaluation of LUTS. Flow rates of <10 mL/s have shown a specificity of 70%, a positive predictive value of 70%, and a sensitivity of 47% for BOO.[19] If the patient's condition is not sufficiently suggestive of obstruction (e.g., peak urinary flow [Q_{max}] >10 mL/sec), pressure flow studies are optional as treatment failure rates are somewhat higher in the absence of obstruction. If interventional therapy is planned without clear evidence of the presence of obstruction, the patient needs to be informed of possible higher failure rates of the procedure.

Following initial evaluation, clinicians and patients should utilize a shared decision making approach to determine the need for and type of therapy. This decision will guide the need for further evaluation should the patient desire treatment.

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 [MRI]/ computed tomography [CT]) prior to surgical intervention for LUTS attributed to BPH. (Clinical Principle)

Since the publication of previous iterations of this guideline, the approach to the differential diagnosis and the differentiated treatment of male LUTS/BPH has become substantially more sophisticated with prostate size and morphology playing an important role in the decision making process. For example, the intravesical protrusion (e.g., intravesical lobe, ball-valving middle lobe) has been recognized to predict poor outcomes from watchful waiting and most medical therapies as well as the presence of urodynamic obstruction.[20]

Currently available MISTs, such as water vapor thermal therapy and PUL are only indicated for prostates between 30g and 80g, and some very large prostates should be treated with open, laparoscopic, or robotically assisted laparoscopic enucleation. The weight of the prostate gland in grams, without the seminal vesicles, can be used as an alternative for prostate volume. [21]

Since digital rectal examination is unreliable in estimating prostate size and serum prostate specific antigen (PSA) is only a rough indicator of prostate size, it appears reasonable to recommend prostate imaging, particularly prior to surgical interventions given that prostate size may direct the clinician as to which intervention to consider.[22]

Assessment of prostate size and morphology can be achieved by abdominal or transrectal ultrasonography or cystoscopy, or by cross-sectional imaging using CT or MRI. Many patients may have had such imaging as part of the workup for PSA elevation and/or prostate biopsy; therefore, any such imaging obtained in the 12 months preceding the planned surgical intervention may be utilized for size and shape assessment to verify suitability for the therapeutic alternatives under consideration since prostate growth rates are 1.6% per year on average.[23] Imaging should provide cross-sectional and sagittal imaging of sufficient resolution to calculate prostate volume and assess presence or absence of an intravesical lobe.[24]

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

While the evidence base is limited, multiple organizations and their guidelines generally include PVR measurement as part of the basic evaluation of LUTS. A rising PVR can indicate medication failure and the need for surgical intervention, or further workup may be warranted. A "large" PVR (>300 mL) is worth monitoring, at the very least. Patients with symptoms from an elevated PVR (i.e. overflow incontinence, bladder stones, UTI, upper tract deterioration), may need to proceed on to surgery or for further urodynamics testing. To fully determine the etiology of an elevated PVR, formal urodynamics testing with a pressure flow study would need to be performed. While a clinically useful test that may drive management choices, PVR does not seem to be a strong predictor of acute urinary retention.[25]

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

The generally accepted minimum threshold voided volume for adequate interpretation is 150 cc, and patients should be instructed not to Valsalva void. In addition to the flow rate, the shape of the curve and duration of voiding provide useful information as a screening tool for LUTS. These results can help to characterize the voiding dysfunction and are useful in counseling patients regarding surgical outcomes and expectations. 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.

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

Pressure flow studies are the most complete means to determine the presence of BOO.[26] Non-invasive tools provide useful information, but only pressure flow studies can determine bladder function or lack thereof. The likelihood of obstruction is greatly increased in patients with a Q_{max} <10mL/s. A large volume PVR may indicate poor detrusor contractility, but correlation with obstruction is weak.[27] Most patients can likely be managed and treated surgically without pressure flow studies; however, certain circumstances dictate more complex evaluation. OAB symptoms and incontinence can be sequelae of obstruction or secondary to non-obstructive etiologies. In addition, patients with catheter-dependent urinary retention may have compromised detrusor function. Surgery in these individuals may not lead to meaningful improvement,[28] subject patients to unnecessary surgery, and carry increased risks for incontinence and exacerbated voiding symptoms.

SURGICAL THERAPY

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

The overwhelming majority of patients with LUTS attributed to BPH who desire treatment will choose some form of medical therapy either with a single agent or a combination of agents with different mechanisms of action. Since the advent of medical therapy for BPH, this has resulted in a steady reduction in surgical therapies for this condition. In fact, between 1999 and 2005, there was a 5% per year decrease in TURP.[29] When this study was updated, there was a further 19.8% decrease from 2005 to 2008.[30] As a result, patients who now undergo surgery for BPH are generally older[31] and have more medical comorbidities.[32] In addition, "failure of medical therapy" as an indication for surgery rose from essentially 0% in 1988 to 87% in 2008.[33]

Despite the more prevalent (and often first line) use of medical therapy for men suffering from LUTS associated with BPH, there still remain clinical scenarios where surgery is indicated as the initial intervention for LUTS/BPH and should be recommended, providing other medical comorbidities do not preclude this approach. Classically, these conditions include renal insufficiency secondary to BPH, refractory urinary retention secondary to BPH, recurrent UTIs, recurrent bladder stones or gross hematuria due to BPH, and/or with LUTS attributed to BPH refractory to and/or unwilling to use other therapies. Such patients are at much higher risk of renal deterioration if inadequately treated on medication.

Long standing BOO from BPH can progress to incomplete bladder emptying, bilateral hydroureteronephrosis, and ultimately acute and/or chronic renal insufficiency. Although transient urethral catheterization with concomitant medical therapy using an alpha adrenergic antagonist can be considered, it is unlikely that the latter will adequately ameliorate the obstructive process to sufficiently prevent further upper urinary tract deterioration. In men with refractory urinary retention thought secondary to BPH, as opposed to that related to other etiologies (e.g., urethral stricture, neurogenic bladder), surgery should be the mainstay of therapy. Recurrent UTIs not due to other causes (e.g., bacterial prostatitis, renal calculi) and the presence of recurrent bladder calculi are generally thought to result from incomplete bladder emptying and a persistently elevated PVR. Surgical elimination of the obstruction when combined with the presence of adequate detrusor contractility should allow almost complete bladder emptying, thereby decreasing the risk

of future infections.

Cystolithalopaxy can be performed concomitantly with the surgical procedure used to remove the obstructing prostate tissue, and depending on the size and number of stones present, can influence the choice of surgical approach (e.g., transurethral, open, or laparoscopic). It has been well demonstrated that the use of a 5-alpha reductase inhibitor (i.e. finasteride, dutasteride) can be an effective treatment for gross hematuria secondary to BPH.[34] If, however, gross hematuria persists, surgical removal/ablation of the offending adenomatous tissue should be the next step unless precluded by other reasons. Finally, in patients with medically refractory LUTS associated with BPH or who choose not to pursue other minimally invasive therapies, surgery should be offered.

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)

Indications for surgical intervention include recurrent UTI, recurrent bladder stones, progressive bladder dysfunction (i.e. loss of low pressure bladder storage function due to poor compliance), and renal insufficiency secondary to progressive bladder dysfunction. 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 attributed to BPH. (Moderate Recommendation; Evidence Level: Grade B)

TURP remains the historical standard by which all other subsequent surgical approaches to treatment of BPH are compared and serves as the reference group for all other techniques in this guideline. Shared medical decision making determines at which time point surgical intervention is performed along the spectrum of LUTS severity secondary to BPH. Thus, in some patients, a trial of medical management of LUTS attributed to BPH is not necessary prior to surgery. TURP helps to reduce urinary symptoms associated with BPH, including frequent/urgent need to urinate, difficulty initiating urination, prolonged urination, nocturia, non-continuous urination, a feeling of incomplete bladder emptying, and UTIs. Successful TURP can relieve symptoms quickly with most men experiencing significantly stronger urine flow within days of the procedure. TURP remains the single best gold standard against which to measure the efficacy, effectiveness, and safety of any other invasive treatments for male LUTS/BPH.

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

A large body of literature has been published in recent years regarding certain modifications of the standard TURP using monopolar energy, most notably the use of bipolar energy transmission.

Contrary to monopolar TURP, the energy does not travel through the body to reach a skin pad in bipolar TURP systems. The energy is confined between an active (resection loop) and a passive pole situated on the resectoscope tip. While monopolar TURP requires the use of either iso-osmolar solutions of sorbitol, mannitol, or glycine, bipolar TURP may be performed in 0.9% NaCl solution. This reduces (if not eliminates) the risk for acute dilutional hyponatremia during prolonged resection, which may lead to the so-called TUR syndrome.

Regarding the comparative efficacy, effectiveness, and safety of monopolar versus bipolar TURP, there are five systematic reviews and meta-analyses published between 2009 and 2015 that compared bipolar TURP to monopolar TURP.[35-39] None of the authors found significant differences in terms of I-PSS improvement at 12 months or improvements in peak urinary flow rates, the main efficacy parameters of interest.

However, there were differences regarding safety parameters. Time to catheter removal or catheterization time was evaluated in four pooled analyses. All four favored bipolar TURP; however, the differences in the effect estimate were highly variable as was the degree of heterogeneity. Length of stay and dilution hyponatremia both favored bipolar TURP; however, there was close to 98% heterogeneity in each of the meta-analyses that evaluated these outcomes. Pooled data from Mamoulakis (2009), Burke (2010), Tang (2014), and Omar (2014) all supported that TUR syndrome occurred less frequently in the group that received bipolar TURP.[36-39]

Risk reduction for clot retention favored bipolar TURP in

general. Bleeding and drops in hemoglobin seem to favor bipolar TURP but with a relatively high degree of heterogeneity in both meta-analyses. Need for blood transfusion post-operatively seems to favor bipolar TURP, although two out of six meta-analyses revealed no statistical significance.

The findings of the meta-analyses and systematic reviews allow the following conclusions:

- Since there are no differences in efficacy, it is reasonable to compare surgical interventions in this guideline document with either monopolar or bipolar TURP series regarding efficacy measures.
- Since the main difference between monopolar and bipolar TURP is regarding TUR syndrome, which is unique to TURP and no other treatment, safety parameters other than TUR syndrome can also be compared between surgical interventions and monopolar and bipolar TURP.
- The reduced risk of hyponatremia and TUR syndrome allows for longer resection times; therefore, bipolar TURP may be used in larger glands compared to monopolar TURP.
- Since not all hospitals have bipolar TURP equipment available, it is left to the surgeon's discretion and level of experience as to which type of TURP energy she/he may use.

For the remainder of this document the reader should assume that all efficacy comparisons between surgical interventions and TURP make no difference as to what type of energy was used for the TURP comparator arm (s).

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)

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 generally be avoided with monopolar approaches. Bipolar TURP was subsequently introduced and extended the safe duration of TURP and thus the indication for larger glands. 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 OSP, either by suprapubic or retropubic approach. In recent years, alternative techniques have been developed that include laparoscopic (mostly transabdominal and transvesical) and robot-assisted laparoscopic approach.

Four RCTs (n=433) were identified that compared OSP techniques to TURP.[40-43] Three trials used an open standard transvesical approach. Two trials[41,42] reported significant differences in maximum urine flow at 12 months favoring OSP, while one trial found no difference between the groups.[40] Need for blood transfusions were similar between groups (RR: 1.2; CI: 0.4, 3.4).[40-42] Need for reoperation as reported in 2 trials was lower in the OSP group compared to TURP (RR: 0.1; CI: 0.01, 0.8).[41,42] Long-term results for mean change in I-PSS were not reported. The remaining study showed mean change in I-PSS through 36 months, blood transfusions, need for reoperation, and urinary incontinence was similar for laparoscopic simple prostatectomy compared with TURP.[43]

TRANSURETHRAL INCISION OF THE PROSTATE (TUIP)

11. TUIP should be offered as an option for patients with prostates ≤30g for the surgical treatment of LUTS attributed to 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 of the AUA and other guidelines, a large number of prospective cohort trials were analyzed, and adequate results were reported in terms of I-PSS and Q_{max} changes. A meta-analysis comparing TUIP with TURP after a minimum follow-up of 6 months identified a lower rate of RE (18.2% versus 65.4%) and need for blood transfusion (0.4% versus 8.6%) as the key advantages of TUIP versus TURP.[44]

For the search period of this guideline, 1 RCT (n=86, data reported for 80 completers) conducted in Egypt that compared TUIP to TURP in men with small prostates (≤30g) was identified.[45] Mean age of the

participants was 65 years, and baseline I-PSS was 19. Baseline prostate size was 28g. Follow-up was 48 months. In men with small prostates, long-term mean change from baseline in I-PSS was similar between the TUIP and TURP groups (WMD: 0.5; CI: -0.2, 1.2). Need for reoperation and blood transfusion was similar between the TUIP and TURP groups. In terms of sexual side effects, ED was reported for 8% of TUIP participants compared to 20% for TURP participations, though this difference was not significant (RR: 0.4; CI: 0.1, 1.3). There was, however, a significant difference in reports of RE with a total of 30 participants experiencing RE (9 in the TUIP arm and 21 in the TURP arm).

TRANSURETHRAL VAPORIZATION OF THE PROSTATE (TUVP)

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

Transurethral electrovaporization (TUVP) of the prostate is a technical electrosurgical modification of the standard transurethral resection of the prostate. TUVP can utilize a variety of energy delivery surfaces including amongst others: a spherical rolling electrode (rollerball), grooved roller electrode (vaportrode), or hemi-spherical mushroom electrode (button). TUVP typically uses saline and is powered with a bipolar energy source. Compared to traditional resection loops, the various TUVP designs hope to improve upon tissue visualization, blood loss, resection speed and patient morbidity.

Fourteen RCTs evaluating 1,828 participants compared bipolar TUVP with TURP.[40,46-64] Mean age among participants was 67 years (range 56 to 70). Mean baseline IPSS was 23 (range 18 to 27) and mean prostate volume was 51 mL (range 36 to 65 mL). Length of follow-up ranged from 3 months to 10.1 years. Overall, outcomes were similar in both groups for long-term response to treatment based on varying definitions using the International Prostate Symptom Score (IPSS); mean change in IPSS through 7 years; need for reoperation; and urinary incontinence. However, need for blood transfusion was lower for TUVP compared with TURP (<1% versus 4% (RR 0.20 [95% CI 0.08 to 0.52).

Six RCTs (n=601) compared effectiveness of TUVP and bipolar TURP.[65-70] Mean age was 66 years (range 60 to 69), baseline I-PSS was 21 (range 18 to 24), and mean prostate volume was 56mL (range 32 to 64). Data were insufficient to compare I-PSS changes. However, TUVP showed similar need for reoperation (RR: 1.5; CI: 0.6, 3.9) and incontinence rates (RR: 0.9; CI: 0.4, 2.1) as well as need for blood transfusion (RR: 0.6; CI: 0.3, 1.4).

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 attributed to BPH. (Moderate Recommendation; Evidence Level: Grade B)

PVP is a transurethral form of treatment that utilizes a 600-micron side firing laser fiber in a noncontact mode. The laser wavelength is 532nm, which is preferentially absorbed by hemoglobin resulting primarily in tissue ablation/vaporization with a thin layer of underlying coagulation that provides hemostasis. The procedure is generally performed with saline irrigation, eliminating the possibility of TUR syndrome that can occur with non-ionic irrigation. The goal of the procedure is to vaporize the prostate adenoma sequentially outwards until the surgical capsule is exposed and a defect is created within the prostate parenchyma through which the patient may now void.

A substantial collection of data has been published on PVP since the last publication of this guideline. As part of this review, RCTs of PVP versus TURP were identified and examined for the 80W,[71-80] 120W,[81-90] and 180W platforms.[91-93] However, given the lack of availability of the 80W platform and the superior outcomes as compared to the higher powered lasers, clinicians utilizing PVP should utilize either the 120W or 180W options.

Men considering PVP should be informed of the generally similar outcomes with regards to symptomatic, urinary improvement in LUTS/BPH and complication rates between TURP and PVP. Men should be counseled on the possible higher rates of retreatment for LUTS/BPH if an 80W platform is employed for surgery (RR: 2.0; CI: 1.01, 3.8). In the GOLIATH study,[91-93] an international multicenter RCT comparing the 180W PVP to TURP, the recently published 24-month data reported similar adverse events related to urinary incontinence (RR: 1.0; CI: 0.3, 3.28), need for blood transfusion (RR: 0.3; CI: 0.01, 7.9), and overall need for reoperation (RR: 1.4; CI: 0.6, 3.0) between the two modalities. Outcomes at study termination were also similar with regards to

PSA, transurethral ultrasound (TRUS)-based prostate volume, PVR, and EF. 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 (defined as a 3-point difference in the I-PSS). In a single center study comparing M-TURP, B-TURP and 120W PVP through 36 months supports the above insofar as there is similar change in IPSS and IPSS-QOL between PVP and the TURP cohorts. [89,90]

The Panel noted that PVP may be more efficacious for smaller volume prostates and that patient expectations should be aligned accordingly. The GOLIATH trial excluded men with prostate volumes > 80 cc,[73] and at least two cohort studies noted an increased probability of intraoperative conversion to TURP for prostate volumes > 60 cc to 80 cc.[94,95]

As detailed in Statement 23, the need for a blood transfusion was lower for PVP 120W compared to TURP.

While other laser technologies can be utilized for laser ablation/vaporization of the prostate, the Panel concluded that these were either still investigational or had results that were not considered sufficient or safe to recommend them for routine use. This includes Nd:YAG, which is preferentially absorbed by hemoglobin and has a depth of penetration of approximately 1 cm. This laser was used in the 1990's, but fell out of favor secondary to side effects and high reoperation rates. It has recently had a resurgence, but data are lacking to support its routine use. Other lasers, such as various diode wavelengths, are also available on the market. Diode lasers are absorbed by hemoglobin and water. Like Nd:YAG, the depth of penetration is deeper than PVP. Clinicians should be aware that use of lasers for prostate surgery can lead to significant delivery of energy to the irrigating fluid, thereby increasing the temperature of the irrigant. High -powered and/or continuous lasers are at higher risk for temperature increases. Surgeons are advised to use continuous irrigation, occasionally test the temperature of the efflux, and consider whether a fluid warmer should be avoided. Thermal injuries to the bladder from hot irrigant have been reported after laser prostate surgery.

PROSTATIC URETHRAL LIFT (PUL)

14. **Clinicians should consider PUL as an option for patients with LUTS attributed to 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. Patients should be informed that evidence of efficacy and retreatment rates are poorly defined. (Moderate Recommendation; Evidence Level: Grade C)**

PUL was developed in 2004 as a treatment option for LUTS/BPH that works by altering prostatic anatomy without ablating tissue. These permanent transprostatic implants take the forms of sutures that are delivered by a hand-held device through a cystoscope to mechanically open the prostatic urethra by compressing the prostate parenchyma. The sutures have "T-shaped" bars on the ends of the suture and are spring loaded and placed so that the bars are set with one outside the prostate capsule and the other within the prostatic urethral lumen. The T-shaped sutures are placed such that there is sufficient tension on them thus pulling the lumen of the prostatic urethra towards the capsule, compressing the tissue, and opening the prostatic urethral lumen. Roehrborn et al. (2013) [96] demonstrated with cystoscopy that the implant does not encrust, and epithelializes within 12 months. Histopathologic analysis of tissue obtained after PUL demonstrates a benign response to the implant. [97] Additionally, no changes were noted in PSA. [98]

A single study comparing PUL versus TURP (BPH6 Study) was found during evidence review. [99,100] The data indicate that a lower proportion of individuals in the PUL group responded to treatment at 12 months follow up compared to TURP 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 (CI: 2.2, 10.0) favoring TURP; however, changes in I-PSS-QoL were similar between groups at all follow up intervals. Additionally, Q_{max} was significantly lower in participants allocated to PUL at all follow up intervals, while changes in prostate volume were not reported.

The need for reoperation due to symptom recurrence did not differ between groups over the 2-year study (RR: 2.4; CI: 0.5, 11.1). Although the incidence of serious and non-serious harms related to treatment, need for reoperation, and incontinence was similar between the PUL and TURP groups, reported incidence for incontinence for TURP was reported at 17.1% compared to 1.7% for PUL (CI: 0.3 to 18.0). In reviewing this study, the Panel noted that "incontinence" was poorly defined as it relates to the unusually high incidence reported in the TURP arm. The reader should note that the quality of evidence for non-

serious harms related to the procedure was rated low, while that for incontinence, need for reoperation, and serious harms related to treatment was rated very low.

Regarding PUL compared with sham (L.I.F.T Study), [96,101-104] both mean change from baseline I-PSS (MD: -5.2; CI: -7.45, -2.95) and improvements in I-PSS-QoL (MD: 1.2; CI: 1.7, -0.7) favored PUL. Additionally, mean change in Q_{max} at 3 months was higher for those who underwent the PUL procedure (4.3mL/s) compared to the sham control (2.0mL/s), P=.005. Of the participants randomized to PUL, five year follow up data slight decreases in mean I-PSS and QoL scores; however, both remained significantly improved from baseline.

Only one treatment-related serious adverse event was reported during the double-blind phase of the study. In the short-term, there were significantly more treatment -related harms, serious and non-serious, in the PUL group compared to sham (RR: 2.7; CI: 1.8, 3.9), Events included dysuria, hematuria, pelvic pain/ discomfort, urgency, bladder spasm, UTI, and retention.

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 encrusted implants was required in 10 participants while 3 non-encrusted implants exposed to the bladder were removed prophylactically. Additionally, 15 participants were taking an alpha blocker or 5-alpha reductase inhibitor at five years. Given that approximately one third of the initial study population experienced unsatisfactory results necessitating further treatment, patients selecting PUL should be informed that this is a relatively new intervention for LUTS/BPH with uncertainties in long-term durability, though such uncontrolled data are available.

Given the limitation of PUL to prostates <80g without obstructive lobes in the evaluated studies, the Panel recommends that clinicians limit this procedure to such patients until further data are available to indicate safety in other patient populations. Due to these restrictions, clinicians should verify prostate morphology and volume as previously detailed in the Evaluation and Preoperative Testing section herein.

Additionally, there was a study of PUL that purposely treated men with obstruction including a middle lobe (a cystoscopic exclusion from previous RCT). We reviewed and excluded this study by Rukstalis et al. because it is not a randomized trial. The study is a "nonrandomized cohort" that used criteria identical to the LIFT trial except for some defined variables.[96,105] It is essentially a case series with pre-post outcomes. For this reason the statement above in which PUL must "verify absence of an obstructive middle lobe" remains unchanged in this update.

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

One of the purported advantages of PUL includes the higher likelihood of preservation of sexual function. McVary et al. (2014) [101] demonstrated that the sexual function of men with normal or moderate ED at baseline was unaffected, and those with severe ED reported modest improvement. There was no evidence of de novo EjD or ED over the course of the study. Ejaculatory bother improved by 40% at 1 year ($p<0.001$), while intensity of ejaculation and amount of ejaculate improved by 23% and 22%, respectively ($p<0.001$). This larger study verified the findings previously published in initial testing.[98]

In the BPH6 Study, no participants in the PUL group experienced adverse events related to sexual function. In comparison, ED and RE occurred in 9% and 20%, respectively, of the participants in the TURP group. While measures of EF using the Sexual Health Inventory for Men (SHIM) was similar between groups at all time points, ejaculatory function based on Male Sexual Health Questionnaire for Ejaculatory Dysfunction (MSHQ-EjD) scores was better in the PUL group with TURP participants experiencing declines from month one onward. MSHQ-EjD bother scores were similar throughout the 24-month follow up. The L.I.F.T. Study showed non-significant differences in sexual function between PUL and sham groups as measured via SHIM, IIEF-5, MSHQ-EjD function, and MSHQ-EjD bother. In men so concerned about new onset of ED and/or EjD, PUL likely does not pose additional risk.

TRANSURETHRAL MICROWAVE THERAPY (TUMT)

16. TUMT may be offered to patients with LUTS attributed to 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 (n=499) compared TUMT to TURP or control. [106-113] Mean baseline I-PSS was 21 (range 20 to 21), and mean prostate volume was 56mL (range 50 to 69). Follow-up periods ranged from six months to five years. Response to treatment, defined as an I-PSS ≤7 or >50% improvement from baseline, through 12 months was similar between the TUMT and TURP groups. 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%).

One trial (n=190) compared 40-minute TUMT with sham. Mean I-PSS at baseline was 22 in both groups. Mean changes in I-PSS from baseline through 3 months was greater with TUMT compared with sham (-10 and -5.8 points, respectively). [114] Another trial (n=44) compared 30- or 60-minute TUMT to a sham procedure. Although not statistically significant, the International Continence Society (ICS) score, AUA Bother Score and Q_{max} improved from baseline in all treatment groups when reassessed at 4 month follow-up (P>0.05, all). Over the 12-month study period, 7 participants in the sham group and 5 in the TUMT group required retreatment. [115]

WATER VAPOR THERMAL THERAPY

17. Water vapor thermal therapy may be offered to patients with LUTS attributed to BPH provided prostate volume <80g; however, patients should be counseled regarding efficacy and retreatment rates. (Conditional Recommendation; Evidence Level: Grade C)

One double-blind trial [116-118] (n=197) compared water vapor thermal therapy (also referred to as transurethral destruction of prostate tissue by radiofrequency generated water thermotherapy). Mean age of study participants was 63 years. Patients had a mean baseline I-PSS of 22 and a mean prostate volume of 45 cm^3. Given the study inclusion criteria of prostate volume <80g, applicability of this therapy to larger glands is unknown. Unlike other MISTs, this technology did not exclude those men with obstructing middle lobes or median bars.

Response to treatment through 3 months, based on an improvement in I-PSS of ≥30% or ≥8 points, was significantly greater in the water vapor thermal therapy group (74%) compared to the sham group (31%) (RR: 2.4; CI: 1.6, 3.5). Mean changes from baseline in I-PSS and I-PSS-QoL at 3 months were greater in the water vapor thermal therapy group compared to the sham group 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.

Three-year results showed sustained improvements for the IPSS IPSS-QoL, and Qmax, with scores remaining significantly improved from baseline;[119] Qmax improvement was > 50% from 3 to 24 months and 39% at 36 months.[13] At 36 months in the intent-to-treat population of the original 136 participants, mean change from baseline in IPSS was -11.0 points and the mean score was 10.4 points, representing a 50% improvement from baseline. Mean IPSS-QoL was improved from baseline by 49% at 3 years.

Rates of serious adverse events were low and similar between groups. The incidence of non-serious transient adverse events, including dysuria, hematuria, frequency and urgency, and UTI, was significantly higher in the water vapor thermal therapy group.

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)

In the RCT comparing water vapor thermal therapy to sham, the original 136 patients randomized to water vapor thermal therapy are expected to be followed for five years. [117] At 36 months, no de novo erectile dysfunction was reported but dysuria was reported by 1% of participants.[116-119] No significant changes in IIEF-EF scores were observed compared to baseline. Bother and function scores associated with ejaculation, assessed by the MSHQ-EjD, were significantly improved at 12 and 36 months following treatment, P=.006 and P=.003 respectively.

TRANSURETHRAL NEEDLE ABLATION (TUNA)

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

Initially after its release by the FDA, there was considerable literature generated evaluating the prostate morphology before and after TUNA using ultrasound, MRI, PSA, and endoscopy to evaluate this volume reduction issue. The conclusion now is that the prostatic volume is reduced less than initially anticipated. BPH histologic architecture is likely

replaced in part with scar, leaving modest at best volume reduction. Absent a consensus on mechanism of action, attempts to identify favorable candidates for TUNA, both in terms of short-term response and in terms of durability of improvement have been found to be difficult and inconsistent.

In 2010 the AUA BPH Clinical Guidelines Panel commented that since the development of the 2003 Guideline, little new information on effectiveness and safety had been published. [1,115] At that time, the Panel concluded that a degree of uncertainty remained regarding TUNA because of a paucity of high-quality studies. In the development of the current guideline, the Panel again searched for studies meeting the updated inclusion criteria, yet none were identified. 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 any 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 attributed to BPH. (Moderate Recommendation; Evidence Level: Grade B)

Due to the chromophore of water and minimal tissue depth penetration with both holmium and thulium (0.4mm for holmium, 0.2 mm for 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 thulium and holmium are reasonable for endoscopic enucleation. [121]

HoLEP and ThuLEP have similar outcomes when compared to TURP for the treatment of symptomatic BPH as measured by I-PSS and I-PSS-QoL outcomes. Based on 4 studies reporting long-term follow-up comparing HoLEP to TURP, ranging from 12 to 92 months, mean changes in I-PSS (approximately -19) between groups were statistically similar (WMD: -0.5; CI: -1.2, 0.3). [122-128] Only 2 studies reported I-PSS-QoL outcomes (mean change approximately -3.5) at follow up of greater than 12 months, and mean differences between groups were not statistically significant (0.10; CI: -0.05, 0.25). [127,128]

When comparing ThuLEP to TURP, 3 trials [129-132] reported long-term results in I-PSS reduction (mean change approximately -15), ranging from 18 to 60 months (WMD: 0.4 points; CI: -0.9, 1.6). Similarly, there was no significant difference in mean reduction in I-PSS-QoL outcomes (mean change approximately -2.0). At long-term follow-up, the mean difference was -0.3 (CI: -0.4, 0.9).

Qmax at last follow-up after HoLEP and ThuLEP compared to TURP is generally similar. Of the 11 studies reporting Qmax, 9 found the HoLEP and TURP groups to be similar. [123-137] Two studies, however, found significantly higher Qmax in the HoLEP groups. [122,138] The ThuLEP and TURP groups were similar at 3 months, [128,129,139-142] 12 months, [128,140,143,144] 18 months, [132] 48 months, [143] and 5-year follow-up.[131]

Recurrence of symptoms or need for reoperation were reported in five studies comparing HoLEP to TURP. One of these reported no events. [134] Pooled analysis with the 4 remaining studies resulted in no differences (RR: 0.42; CI: 0.07, 2.48]. [123-127] Other adverse events, including urethral stricture and bladder neck contracture, were similar for the HoLEP and TURP groups. Similarly, few patients required reoperation following ThuLEP and TURP, and pooled analysis from 3 studies found that the groups were similar (RR: 1.3; CI: 0.2, 11.3). [129, 139,140] Other post-surgical complications (e.g., urethral stricture, urge incontinence, stress incontinence, urinary retention, UTI) were similar between the groups.

In reviewing the need for blood transfusion, either peri- or post-operatively, likelihood was significantly lower compared to TURP for both HoLEP (RR 0.20; CI: 0.08, 0.47) and ThuLEP (RR: 0.4; CI: 0.1, 0.9).

AQUABLATION

21. Aquablation may be offered to patients with LUTS attributed to BPH provided prostate volume >30/<80g, however, patients should be informed that long term evidence of efficacy and retreatment rates remains limited. (Conditional Recommendation; Evidence Level: Grade C)

Aquablation surgery utilizes a robotic handpiece, console and conformal planning unit (CPU). The

technique is not in the minimally invasive surgical treatment (MIST) category as patients must undergo general anesthesia. The resection of the prostate is performed using a water jet from a transurethrally placed robotic handpiece. Pre-treatment transrectal ultrasound is used to map out the specific region of the prostate to be resected with a particular focus on limiting resection in the area of the vermontanum. It is also used to monitor tissue resection in real time during the procedure. After completion of the resection, electro-cautery via a standard cystoscope/resctoscope or traction from a 3 way catheter balloon are used to obtain hemostasis.

One low risk of bias RCT (n = 181) assessing Aquablation was evaluable by the panel.[145-147] The trial utilized standard inclusion/exclusion criteria limiting participants to prostate sizes between 30-80 grams. Treatment response through 12 months, defined as at least a 5-point improvement in International Prostate Symptom Score (IPSS), was similar for Aquablation and TURP (Quality of Evidence: Moderate).[145,146] Mean improvement in lower urinary tract symptoms (LUTS) based on the IPSS through 12 months was similar for Aquablation and TURP (Quality of Evidence: Moderate).[145,146] Mean improvement in quality of life based on the IPSS-QoL through 12 months was similar for Aquablation and TURP (Quality of Evidence: Moderate).145,146 Need for blood transfusion and reoperation were similar for Aquablation and TURP (Quality of Evidence: Very low) with blood transfusion reported for one Aquablation participant and none receiving TURP (RR 1.69 [95% CI 0.70 to 41.0]). At follow-up (12 months), maximum flow rates increased similarly in the Aquablation group compared to TURP, 10.3 vs 10.6 mL/s (P=.86), respectively.

At 3 months, Aquablation resulted in fewer harms classified as Clavien-Dindo grade ≥2 compared to TURP, 26% versus 42%, P=.015.[145,146] Additionally, rates of retrograde ejaculation were higher (P=.002) with TURP (23%) compared to Aquablation (6%). Other harms occurring at similar rates in both groups, and classified as Clavien-Dindo grades 1-4, included bladder spasms, bleeding, dysuria, pain, and urethral damage. No deaths were reported. Also at 3 months, reduction in prostate volume was significantly less with Aquablation (31%) compared to TURP (44%) (P=.007).[145,146]

Aquablation has a theoretical advantage in preservation of erectile function or ejaculation as conductive heat (and its potential damage of erectile nerves) is not used to remove prostate tissue. This theoretical advantage may be in part mitigated by use of electro-cautery to achieve hemostasis. In addition, there are unknowns as to the MOA for the decreased rates of ejaculatory dysfunction. It may be secondary to decreased tissue removal at the verumontanum or possibly treatments that avoid effecting the bladder neck. This requires further inquiry to address. Among a non-random subset of sexually active men, the proportion of subjects who reported worsening sexual function through 6 months on the IIEF-5 (6-point decrease) or the Male Sexual Health Questionnaire (MSHQ-EjD) (2-point decrease) was 33% in the Aquablation group compared with 56% in TURP group (P=.03).[145,146] No 12 -month follow-up data have been reported to date.

PROSTATE ARTERY EMBOLIZATION (PAE)

22. PAE is not recommended for the treatment of LUTS attributed to BPH outside the context of a clinical trial. (Expert Opinion)

PAE is a newer, largely unproven MIST for BPH. High level evidence remains sparse, and the overall quality of the studies is uniformly low. Some of the deficiencies of the included trials include 1. A lack of randomization, 2. High levels of susceptibility to selection, detection, attrition, and reporting biases, 3. The common inclusion of a preoperative status of urinary retention, and 4. The absence of standard inclusion/exclusion criteria for a LUTS/BPH RCT.

Three RCTs (n=247) were identified comparing PAE to TURP; however, there was substantial heterogeneity between the two trials (I2= 90%).[148-150] One trial reported outcomes up to 2 years[149], one up to 12 months[148], and the other only through 12 weeks.[150] There was substantial heterogeneity between trials and pooled results must therefore be interpreted with caution. Definitions of and outcomes for subjective symptom response varied substantially between trials. One trial reported the proportion of responders, defined as achieving an IPSS score ≤8 points and/or a QoL ≤3 points, was similar between the PAE and TURP groups (RR 0.9 [95%CI 0.7 to 1.1]; low quality of evidence).[148] Success through 12 months was reported for 87% of the PAE participants compared with 100% in the TURP group. Overall, results at intermediate term follow-up (>3 to ≤12 months) were similar between groups (WMD 4.8 points [95% CI -2.9 to 12.5]; very low quality of evidence).[148,149] The smallest trial (n=30) reported substantially greater improvement in symptoms with TURP compared with PAE (MD 9 points [95% CI 4.6 to 13.1]),[148] and the other (n=107)

reported no significant difference between the groups at 3 and 12 months.[149]

Results also differed between the trials regarding improvements in Qmax. Two trials reported lower flow rates with PAE compared with TURP[148,150] and one trial reported similar flow rates between groups.[149] Mean prostate volumes were significantly higher in the PAE group compared with the TURP group at all follow-up time points.[148,149] Two studies found mean prostate size decreased among participants in the TURP group at short,[150] intermediate, and long-term follow up.[149] Additionally, the 12-week trial reported PAE was not as effective in reducing bladder outlet obstruction, indicated by change in detrusor pressure at maximum flow rate, compared with TURP, -17.2 vs. -41.1 cmH2O (P=.002).[150] Postoperatively, 56% of PAE patients were considered less obstructed compared with 93% of TURP (P=.003).[150]

The need for reoperation was reported for 7 participants in the PAE group compared with 2 in the TURP group (RR 2.9; CI: 0.7, 11.9; very low quality of evidence). Two trials found incidences of sexual dysfunction to be higher with TURP compared with PAE. One trial reported all 15 TURP participants experienced retrograde ejaculation while no cases were reported among PAE participants.[148] The short-term trial found incidence of ejaculatory dysfunction was lower with PAE (56%) compared with TURP (84%) after 12 weeks (RR 0.67 [95%CI 0.45 to 0.98).[150] One trial reported a higher incidence of acute urinary retention requiring re-catheterization in the PAE group (26%) versus the TURP group 6%, P=.004).[149] This trial also found adverse events were half as frequent after PAE (n=36) compared to TURP (n=70), P=.003. Additionally, more cases of hematuria, urinary retention, UTI, and strictures were found after TURP,[148-150] Although postoperative incidences of clot retention and strictures were infrequent.[149,150] One incidence of TUR syndrome was reported.[149] No deaths were reported in any trial.

Given the heterogeneity in the literature—and concerns regarding radiation exposure, post-embolization syndrome, vascular access, technical feasibility, and quality control at lower volume centers—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 definitive clinical benefit. The Panel recommends trials involve multi-disciplinary teams of urologists and radiologists; and that, as with other MIST therapies, RCTs comparing PAE to sham be considered to account for significant placebo effects.[96,116]

MEDICALLY COMPLICATED PATIENTS

23. 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 a blood transfusion (either peri- or post-operatively) was significantly 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. [66,123,125,134-136,138,140,143,144,151-153] In addition, studies of holmium laser prostate surgery in patients maintained on anticoagulation therapy at time of surgery have supported a relatively low transfusion rate. In a 2013 retrospective review on a series of 125 patients treated with HoLEP (52 patients were on antithrombotic therapy at the time of surgery and 73 patients were not), only 4 men (7.7%) in the antithrombotic group required a blood transfusion compared to none in the control group. [154] A similar 2016 study compared 116 patients who required anticoagulation/antiplatelet therapy at the time of HoLEP to 1,558 patients who did not. Other than a slightly increased duration of bladder irrigation and hospital stay, the use of anticoagulation/ antiplatelet therapy did not adversely affect outcomes. [155] Lastly, a 2017 meta-analysis of patients on therapeutic anticoagulation/antiplatelet therapy when undergoing HoLEP supported that this approach can be performed safely on these patients, but stressed that there are limited data surrounding the class of direct oral anticoagulants and safety. [158]

While there are differences between wavelengths as well as the chromophore in which laser energy is absorbed (i.e. water, hemoglobin, pigment), in general, lasers have favorable hemostatic properties that treat bleeding more effectively than monopolar energy. Most lasers used in urology (532 nm, holmium, thulium) have superficial penetration and thermal diffusion depths that lead to the concentration of high-density energy in a superficial layer thereby "sealing" vessels and creating shallow coagulation zones. Holmium and thulium both have similar wavelengths (holmium 2,140nm, thulium 2,013nm) and are absorbed by water. The major difference is that holmium is a pulsed laser while thulium is continuous, which impacts how quickly the temperature rises in the tissue. The decreased penetration depth of holmium and thulium as compared to monopolar energy leads to a more

superficial area of ischemia and can reduce risk for delayed bleeding as eschar sloughs approximately 7-14 days post procedure. During this timeframe, any anticoagulant therapy that may have been discontinued will have resumed and be in effect, thereby making the reduction in eschar a significant benefit. [121,155-160]

The safety of thulium in anticoagulated patients has been reported in several publications. In one study of 56 patients (32 on aspirin, 8 on clopidogrel or clopidogrel plus aspirin, and 16 on phenprocoumon), 4 patients needed blood transfusions, and 4 patients required immediate reoperation. Given this high risk group and despite the reported issues, the patients did well overall. [161] Two other studies have described the feasibility of thulium laser for prostate surgery in anticoagulated patients and those bridged with low molecular weight heparin (LMWH). A 2013 study of 76 patients compared those on anticoagulant/antiplatelet therapy during surgery to those who were bridged with LMWH. There were no statistically significant variations in hemoglobin between the two groups. [159]

A similar more recent 2017 study of 103 patients revealed the drop in hemoglobin levels in the pre- and post-operative periods were significantly higher in the LMWH bridged group than those who remained on anticoagulant/antiplatelet therapy during surgery. Given that no cardiopulmonary adverse events occurred and bleeding was not problematic, the authors recommend abandoning LMWH bridging and continuing anticoagulant/antiplatelet therapy during thulmium laser surgery. [162]

PVP is performed using the LBO laser, which has a wavelength of 532 nm and a chromophore of hemoglobin. The depth of penetration with PVP is 0.8 mm. 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. [163-166] A 2017 study confirmed these findings in 59 of 373 patients undergoing PVP. Overall, Greenlight PVP with the 180W laser unit on patients therapeutic on heparin, warfarin, clopidogrel, dipyridamole, or new oral anticoagulant drugs revealed good safety outcomes. [167] As expected, anticoagulated patients were older, had a higher American Society of Anesthesiologists (ASA) score than the control group and, although no patient required blood transfusion, there was a higher incidence of high-grade Clavien–Dindo events. Similar to other studies, the therapeutically anticoagulated group had a significantly longer length of hospital stay and duration of catheterization as compared to the controls. In support of the concept of 120W PVP use in anticoagulated patients, recent publications report that the need for a blood transfusion was lower for photoselective vaporization prostatectomy 120W compared to TURP.[89,90]

For additional information on the use of anticoagulation and antiplatelet therapy in surgical patients, refer to the ICUD/AUA review on Anticoagulation and Antiplatelet Therapy in Urologic Practice. [168]

FUTURE DIRECTIONS

BPH and ensuing LUTS is a significant health issue affecting millions of men. There are enormous gaps in knowledge and, therefore, ensuing opportunities for discovery. These include but are not limited to many unanswered questions, such as 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.

Disease Etiology

Currently, there are few animal and human tissue models for BPH/LUTS. This limits the ability and efforts to understand both pathogenesis and progression. More specifically, computational biology and genomic factors should be aimed towards understanding drivers of BPH and prostate growth and therapeutic targets.

LUTS are differentially bothersome. Moreover, qualitative rather than quantitative changes have not been well described. For example, the most prevalent and bothersome of the LUTS is nocturia. The differential diagnosis of increased nighttime urination frequency/ volumes and the role of sleep apnea is an area of great importance given that nocturia is also associated with increases in overall mortality. Enhanced metrics including bother, pain, and incontinence will need to be incorporate and evaluated.

Management of Nocturia

Due to the considerable burden of nocturia on QoL and a lack of effective management options, more funded research is needed. Nocturia is often multifactorial in origin and symptomatic of other medical problems, further complicating effective management. Nocturia, whether global, reduced bladder capacity, or mixed, is

a unique symptom complex requiring special concern and judicious evaluation.

Urodynamic Evaluation and Imaging

The natural history and predictive ability of various urodynamic measures, such as flow rate and PVR, in regards to predicting patient reported outcomes (e.g., symptoms, QoL), and objective outcomes (e.g., peak flow, development of total retention, need for retreatment) is an area of great interest with substantial clinical and health care economic consequences.

The importance of prostate imaging and, specifically, the presence of an intravesical or obstructing lobe in determining natural history and treatment responses are of great clinical importance to make the best therapeutic decisions.

New Therapeutic Options

At the time of writing these guidelines there were many promising MISTs in development. It is the hope of this Panel that further data will be available in the peer reviewed literature on these therapies to allow incorporation into future iterations of this guideline. With so many MISTs being developed for LUTS/BPH, the Panel is compelled to consider the attributes to which successful MISTs should include characteristics for patients and urologists. Future MISTs should strive for novel therapies that approach standard technologies in outcomes, ideally providing effective therapy with fewer side effects.

From the patient standpoint, the hallmarks of a successful MIST might include the following: 1. Tolerability, 2. Rapid and durable relief of symptoms, 3. Short recovery time with rapid return to life activities, 4. Minimal adverse events, and 5. Affordability. In addition to addressing the patients' concerns, urologists strive for the following in looking to future therapies: 1. Capacity for performance in an ambulatory setting under reduced anesthesia, 2. A fast learning curve, 3. Generalizability from RCT, and 4. Ease of performance.

Traditionally, the primary goal of treatment has been to alleviate bothersome LUTS that result from BOO. While a MIST may not alleviate symptoms to the same degree or durability as more invasive surgical options, a more favorable risk profile and reduced anesthetic risk would make such a treatment attractive to many patients and providers. Since many men discontinue medical therapy, yet proportionately few seek surgery, there is a large clinical need for an effective treatment that is less invasive than surgery. With this treatment class, perhaps a significant portion of men with BOO who have stopped medical therapy can be treated prior to impending bladder dysfunction.

Treatment Failure

Surgical studies often underestimate treatment failure. In large part, these studies are reported as per protocol analyses versus intent to treat. Therefore, results focus on responders. Ensuing underassessment of surgical follow up (e.g., need for retreatment, re-medication) is an assessment gap that can result in an incomplete assessment of safety and efficacy of both office and surgical procedures.

Treatment Comparative Efficacy

Studies of comparative efficacy of behavioral and lifestyle intervention versus medical treatment and medical therapies versus MISTs for male LUTS and BPH are lacking and would be of great benefit for all levels of providers and patients and perhaps result in cost savings. Models could include population science, the development of registries and analysis of electronic medical records and insurance databases.

ABBREVIATIONS

American Urological Association	AUA
AUA-Symptom Index	AUA-SI
Benign Prostatic Enlargement	BPE
Benign Prostatic Hyperplasia	BPH
Benign Prostatic Obstruction	BPO
Bipolar Transurethral Enucleation	BTE
Bladder Outlet Obstruction	BOO
Clinical Controlled Trials	CCT
Computed Tomography	CT
Confidence Interval	CI
Dihydrotestosterone	DHT
Ejaculatory Dysfunction	EjD
Erectile Dysfunction	ED
Erectile Function	EF
Holmium Laser Enucleation of the Prostate	HoLEP
International Continence Society	ICS
International Prostate Symptom Score	I-PSS
Low Molecular Weight Heparin	LMWH
Lower Urinary Tract Symptoms	LUTS
Magnetic Resonance Imaging	MRI
Minimally Detectable Difference	MDD
Minimally Invasive Surgical Therapies	MIST
Open Simple Prostatectomy	OSP
Overactive Bladder	OAB
Photoselective Vaporization of the Prostate	PVP
Post Void Residual	PVR
Prostate Artery Embolization	PAE
Prostate Specific Antigen	PSA
Prostatic Urethral Lift	PUL
Quality of Life	QoL
Randomized Controlled Trials	RCT
Retrograde Ejaculation	RE
Risk of Bias	ROB
Risk Ratio	RR
Thulium Laser Enucleation of the Prostate	ThuLEP
Transurethral Bipolar Vaporization	TUVis
Transurethral Incision of the Prostate	TUIP
Transurethral Needle Ablation	TUNA
Transurethral Resection of the Prostate	TURP
Transurethral Ultrasound	TRUS
Transurethral Vaporization of the Prostate	TUVP
Urinary Tract Infections	UTI
Weighted Mean Difference	WMD

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CONFLICT OF INTEREST DISCLOSURES

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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. This amended Benign Prostatic Hyperplasia Guideline was drafted in 2019 by a subset of the original panel. This amendment updates the original guideline document to reflect literature released following original publication.

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.

Funding of the panel was provided by the AUA. Panel members received no remuneration for their work. Each member of the panel provides an ongoing conflict of interest disclosure to the AUA.

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 in-tended 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.