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Management of Lower Urinary Tract Symptoms Attributed to Benign Prostatic Hyperplasia: AUA GUIDELINE PART II—Surgical Evaluation and Treatment

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Abbreviations and Acronyms

5-ARI = 5- Alpha Reductase Inhibitor
AUR = Acute Urinary Retention
AUA = American Urological Association
BPH = Benign Prostatic Hyperplasia
BOO = Bladder Outlet Obstruction
CT = Computed Tomography
EjD = Ejaculatory Dysfunction
ED = Erectile Dysfunction
EF = Erectile Function
HoLEP = Holmium Laser Enucleation of the Prostate
LUTS = Lower Urinary Tract Symptoms
LUTS/BPH = Male Lower Urinary Tract Symptoms Secondary/attributed to BPH
MRI = Magnetic Resonance Imaging
MIST = Minimally Invasive Surgical Therapies
PVP = Photoselective Vaporization of the Prostate
PVR = Post-Void Residual
PAE = Prostate Artery Embolization
PSA = Prostate Specific Antigen
PUL = Prostatic Urethral Lift
QoL = Quality of Life
RCT = Randomized Controlled Trials
RWT = Robotic Waterjet Treatment
ThuLEP = Thulium Laser Enucleation of the Prostate
TUIP = Transurethral Incision of the Prostate
TUNA = Transurethral Needle Ablation
TURP = Transurethral Resection of the Prostate
TUVP = Transurethral Vaporization of the Prostate
UTI = Urinary Tract Infection
WVTT = Water Vapor Thermal Therapy

Purpose: Surgical therapies for symptomatic bladder outlet obstruction (BOO) due to benign prostatic hyperplasia (BPH) are many, and vary from minimally invasive office based to high-cost operative approaches. This Guideline presents effective evidence-based surgical management of male lower urinary tract symptoms secondary/attributed to BPH (LUTS/BPH). See accompanying algorithm for a detailed summary of procedures (figure).

Materials/Methods: The Minnesota Evidence Review Team searched Ovid MEDLINE, Embase, Cochrane Library, and AHRQ databases to identify eligible studies published between January 2007 and September 2020, which includes the initial publication (2018) and amendments (2019, 2020). The Team also reviewed articles identified by Guideline Panel Members. 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, information is provided as Clinical Principles and Expert Opinions (table).

Results: Twenty-four guideline statements pertinent to pre-operative and surgical management were developed. Appropriate levels of evidence and supporting text were created to direct urologic providers towards suitable and safe operative interventions for individual patient characteristics. A re-treatment section was created to direct attention to longevity and outcomes with individual approaches to help guide patient counselling and therapeutic decisions.

Conclusion: Pre-operative and surgical management of BPH requires attention to individual patient characteristics and procedural risk. Clinicians should adhere to recommendations and familiarize themselves with criteria that yields the highest likelihood of surgical success when choosing a particular approach for a particular patient.

Key Words: Prostate surgery, LUTS, BPH, TURP, TUIP, TUVP, HoLEP, ThuLEP, PVP, aquablation, PUL, TUMT, MIST, water vapor thermal therapy, robotic assisted simple prostatectomy, open prostatectomy, simple prostatectomy

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TREATMENT INDICATIONS

The primary goal of treatment of symptomatic benign prostatic hyperplasia (BPH) has been to alleviate bothersome lower urinary tract symptoms (LUTS) that result from benign prostatic obstruction. More recently, treatment has also addressed prevention of disease progression and complications, such as acute urinary retention.[1] When lifestyle, pharmacologic or non-procedural approaches fail to improve symptoms or prevent progression, surgical therapies enter the discussion. Indications for surgery include a desire by the patient to avoid taking a daily medication, failure of medical therapy to sufficiently ameliorate bothersome LUTS, intolerable pharmaceutical side effects, and/or the following conditions resulting from BPH and for which medical therapy is insufficient: acute and/or chronic renal insufficiency, refractory urinary retention, recurrent urinary tract infections (UTIs), recurrent bladder stones, and recalcitrant gross hematuria.

Surgical treatment of symptomatic BPH has three general types: 1. Transurethral surgery; 2. Simple prostatectomy; and 3. Minimally invasive surgical therapies (MIST). Transurethral surgery involves removal of obstructing adenomatous tissue via an endoscopic transurethral route, classically with monopolar electroconductive transurethral resection of the prostate (TURP). A variety of alternatives to standard monopolar TURP have been developed, including bipolar TURP and various laser-based therapies, to achieve similar clinical efficacy while reducing the risks of perioperative bleeding and short- and long-term complications. In appropriate patients for whom the physical size of the prostate cannot be addressed due to the expertise of the surgeon via a safe or efficacious transurethral approach, simple prostatectomy (ie, adenoma enucleation) may be considered using an open, laparoscopic or robotic-assisted approach. Finally, in select patients, recent innovations in MIST allow for office-based treatments that obviate the need for regional/general anesthesia, hospital stay, or discontinuation of anticoagulation therapy.

To provide reference to the clinical efficacy and side effect profile of the procedures discussed, clinical Guideline statements are made in comparison to the generally accepted historical standard—TURP (monopolar and/or bipolar). The Panel evaluated commonly used and FDA approved surgical procedures and MISTs that treat LUTS/BPH. Data utilized to generate these statements are based on the results from acceptably performed randomized control trials (RCTs) and clinical control trials comparing each technique to TURP or SHAM. In order to generate equivalent reviews, a common comparator was necessary. Other studies may have relatively strong data and were not included in the Guideline Statements, however, many of these studies were included in supporting text and therefore, the Panel encourages readers to review the full Guidelines.

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

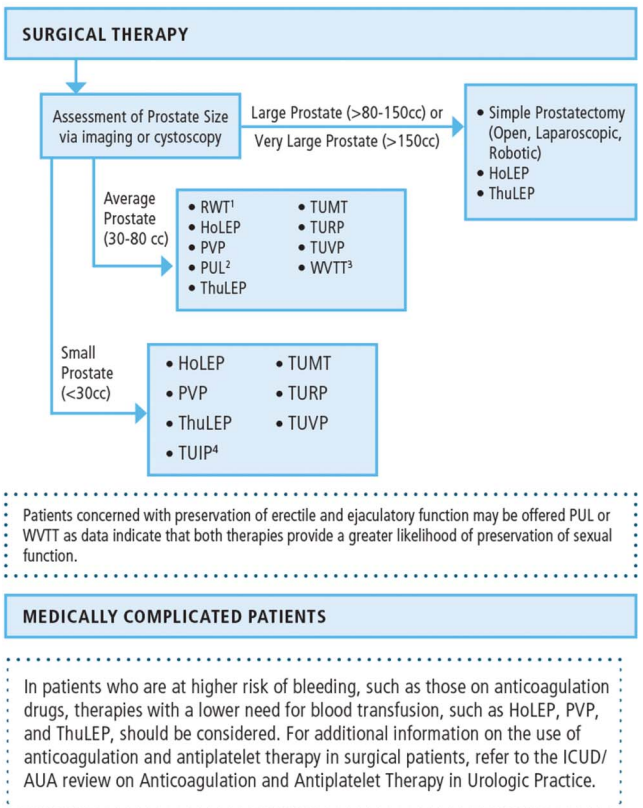

Figure. Surgical Management of Lower Urinary Tract Symptoms Attributed to Benign Prostatic Hyperplasia

Prostate Size and Choice of Surgical Procedure

The first LUTS Guidelines published by the Agency for Health Care Policy and Research in 1994 recommended against measuring prostate size to guide treatment. Knowledge gained over the past 25 years now allows surgeons to select treatments using a refined approach informed in large part by prostate size and morphology. The Panel recognizes and embraces these important developments and, where possible, provides specific size criteria in statements to inform treatment decisions based on higher-order evidence. Statements without size criteria are those modalities that the Panel concluded are efficacious

Table. *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 Expert Opinion	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 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		

and safe for a broad range of prostate sizes, or sizes have not been defined. In this sense, the Panel also recognizes that the availability of various surgical technologies will vary from one practice setting to another and sought to avoid overly restrictive size criteria.

The Panel also made the following observations with respect to prostate size:

1. **Since the specific gravity of the prostate is 1.05 g/mL, the units gram and milliliter and cc can be used interchangeably to denote size or volume.[2]**
2. **Given a lack of standardized prostate size categories in the literature, the Panel proposes consideration of the following categorical size descriptions when planning treatment: small (<30 g), average (30–80 g), large (>80 to 150 g), and very large (>150 g). These category suggestions assume surgical expertise with BPH and reflect Panel opinion, but do not necessarily imply lack of efficacy in prostates outside the recommended ranges. The Panel hopes that surgeons will choose the surgical technique with the best benefit-to-risk ratio for a specific size range and, in cases where that technique is not readily available or where no expertise exists, the patient is referred to another surgeon with such access and expertise.**
3. **Randomized trials for some devices enrolled men with prostates within specific size ranges. As such, statements for those treatments contain the size ranges most commonly referenced in the currently available and reviewed RCT's included in these Guidelines, and/or as used for FDA approval. However, the Panel recognizes that these devices do not necessarily lack efficacy in prostates below or above the size ranges stipulated in the Statements.**

Sexual Dysfunction and Surgical Therapy

Data on sexual side effects of BPH surgery can be difficult to ascertain as many studies are not primarily designed to answer this question. As a result, many studies evaluate reported adverse events only, rather than specifically assessing sexual function. In addition, 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.[3] 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 contribute to or worsen erectile dysfunction (ED). Interventions for LUTS/BPH have clear sexual side effects with significant rates of EjD. Libido, however, does not appear to be affected significantly by surgical therapy, and some studies have even shown an improvement in erectile function (EF) after surgical treatment (this improvement is controversial as other studies show a worsening of EF).[4] 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 option.

GUIDELINE STATEMENTS

This summary will review those statements pertinent to the surgical work up for and treatment of patients with symptomatic BPH, namely #5–9, and #25–43. The remaining statements are included Management of LUTS attributed to BPH: AUA Guideline Part I, Initial Work-up and Medical Management.

Preoperative Testing

5. Clinicians should consider assessment of prostate size and shape via transrectal or abdominal ultrasound, cystoscopy, or cross-sectional imaging (ie, magnetic resonance imaging [MRI]/ computed tomography [CT]) if such studies are available, prior to intervention for LUTS/BPH. (Clinical Principle)

6. Clinicians should perform a post void residual (PVR) assessment prior to intervention for LUTS/BPH. (Clinical Principle)

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

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

9. Clinicians should inform patients of the possibility of treatment failure and the need for additional or secondary treatments when considering surgical and minimally-invasive treatments for LUTS/BPH. (Clinical Principle)

Over time, the approach to the differential diagnosis and differentiated treatment of LUTS/BPH has become substantially more sophisticated with prostate size and morphology playing important roles in the decision-making process. For example, intravesical protrusion (e.g., intravesical lobe, ball-valving middle lobe) has been recognized to predict poor outcomes from watchful waiting and most medical therapies.[5] Some of the available MISTs are indicated for prostates between specific sizes (i.e. 30–80cc), and some very large prostates should be treated with transurethral laser, open, laparoscopic, or robotically-assisted laparoscopic enucleation. Since digital rectal exam is unreliable in estimating prostate size and cannot assess for a middle lobe, and serum Prostate Specific Antigen (PSA) is only a rough indicator, it's reasonable to obtain prostate imaging. This is particularly important prior to surgical interventions given that prostate size may direct the clinician as to which interventions to consider.[6] Assessment of prostate anatomy can be achieved by transrectal or abdominal ultrasonography, 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, or non-urologic conditions that include evaluation of pelvic anatomy; therefore, any such imaging obtained in the recent past preceding the planned surgical intervention may be utilized for size and shape assessment to verify suitability for the therapeutic alternatives under consideration. When existing imaging is "older," considering prostate growth rates of 1.6% per year on average can give a reasonably accurate estimate of current size.[7]

PVR and flow rate (Q_{max}) measurements are discussed in Part I of the Guidelines Summary, but when proceeding to surgery, these tests are valuable for post-operative management and determining success of surgical interventions. Baseline assessments with post-operative comparisons can provide objective outcome measurements, determine the impact of therapy on improving obstruction, and demonstrate to both surgeon and patient that the intervention led to improvement. Lack of change with continued symptoms can indicate another process that may warrant further investigation or treatment.

Pressure flow studies are the most complete means to determine the presence of BOO, but most patients can be managed and treated surgically without them.[8] A recent randomized trial comparing routine care to urodynamic testing for LUTS found a similar rate for progression to surgery (38% versus 36%, total n = 820).[9] However, certain circumstances dictate a more complex evaluation and proceeding directly to surgery without confirming BOO may not lead to meaningful improvement,[10] subject patients to unnecessary surgery, and carry increased risks for incontinence and exacerbated voiding symptoms post-operatively. Urodynamics can help differentiate urinary retention related to detrusor underactivity, detrusor sphincter dyssynergia, overactivity unrelated to obstruction, and categorize LUTS related to DO or low bladder compliance. 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 patients (e.g., those with bladder diverticulum) in whom studies inaccurately indicate a lack of detrusor contractility.

Surgical treatment failure was a focus of this Panel, as choosing a therapy based on expertise, resources available, direct to consumer marketing with patient preferred choices, industry influence, and financial gains represent factors at play when a urologist counsels a patient towards a particular intervention. With many options available, it is expected that these factors contribute to decision making, but without attention to appropriate selection and risk for treatment failure, or lack of longevity with a high risk for future interventions needed, the patient may not receive proper counselling and may choose an approach under a set of assumptions that are not accurate. Definitions of retreatment or treatment failure have varied considerably across trials. The FDA has not issued a standardized definition of retreatment, or requires reporting of retreatment in clinical trials. As a result, individual trial designs employ different definitions and this lack of consistency may potentially lead to misinterpretation of data, or bias, in assessing retreatment outcomes between different trials and therapies.[11] Several core concepts of treatment failure and retreatment were identified by the Panel and consideration of these issues when interpreting outcomes of trials comparing different therapeutic modalities, or of trials of a single modality with different lengths of follow-up, is important.

First, treatment failure and retreatment are influenced by the completeness of the procedure and success in addressing BOO; while *reported* rates of retreatment are influenced by both the duration and the completeness of follow-up. The defined durations of post-treatment follow-up as short- (<6 months), intermediate- (6 to 12 months), or longer-term (>12 months).

Second, the risks of objective (e.g., urinary retention, reduction of flowrate, increasing PVR, infection) and subjective failure (e.g., worsening of International Prostate Symptom Score and/or QoL) increase with longer duration of follow-up.

Third, retreatment may take the form of medical therapy, a minimally invasive intervention, or a surgical procedure.

Fourth, thresholds for and types of retreatments will vary substantially by provider, patient, category of failure (ie, objective, subjective, or both), and initial treatment modality.

Finally, in contrast to minimally-invasive and newer surgical therapies, older clinical trials do not consistently report retreatment with medical therapy as an outcome. The difficulty of accurately recording initiation and duration of medical therapy precludes routine assessment. This pattern may lead to underreporting of medical retreatment relative to minimally invasive and surgical retreatments, for which there are clearly definable timepoints at which retreatment takes place.

The re-treatment section for individual therapies is too long to include in this summary and unfortunately, the quality and availability of data varied considerably. This undertaking by the Panel revealed some significant shortcomings in BPH research and identified that the field would benefit from development of an evidence-based and universally employed classification system for retreatment. Until this can happen and urologists and patients have critical and transparent evidence of retreatment risk before determining the best clinical approach, urologists are strongly encouraged to view the Guidelines to familiarize themselves with what data could be found for those procedures included in the Guidelines.

Surgical Therapy

25. 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/BPH refractory to or unwilling to use other therapies. (Clinical Principle)

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

Despite the more prevalent use of medical therapy for men suffering from LUTS associated with BPH, there 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 it and LUTS/BPH is considered the culprit. Classically, these conditions include chronic renal insufficiency (defined as GFR <60 for at least 3 months), refractory urinary retention, recurrent UTIs, recurrent bladder stones or gross hematuria, and/or symptoms refractory to, or desire to avoid, other therapies.

As regards an elevated PVR, this should not be used as the only indication for bladder outlet surgery. The *American Urological Association (AUA) Non-Neurogenic Chronic Urinary Retention* White paper suggests that patients presenting with non-neurogenic chronic urinary retention should be evaluated for safety issues mentioned above (renal

insufficiency, chronic UTI) and then for symptoms which impact urinary QoL (obstructive urinary symptoms, urinary frequency). Following a trend is important, or proceeding on to testing to determine presence of BOO is best practice.[12]

Transurethral Resection of the Prostate (TURP).

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

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

Simple Prostatectomy.

29. Open, laparoscopic, or robotic assisted prostatectomy should be considered as treatment options by clinicians, depending on their expertise with these techniques, only in patients with large to very large prostates. (Moderate Recommendation; Evidence Level: Grade C)

Transurethral Incision of the Prostate (TUIP).

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

Transurethral Vaporization of the Prostate (TUVP).

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

Photoselective Vaporization of the Prostate (PVP).

32. PVP should be offered as an option using 120W or 180W platforms for the treatment of LUTS/BPH. (Moderate Recommendation; Evidence Level: Grade B)

Prostatic Urethral Lift (PUL).

33. PUL should be considered as a treatment option for patients with LUTS/BPH provided prostate volume 30–80cc and verified absence of an obstructive middle lobe. (Moderate Recommendation; Evidence Level: Grade C)

34. PUL may be offered as a treatment option to eligible patients who desire preservation of erectile and ejaculatory function. (Conditional Recommendation; Evidence Level: Grade C)

Transurethral Microwave Therapy (TUMT).

35. TUMT may be offered as a treatment option to patients with LUTS/BPH. (Conditional Recommendation; Evidence Level: Grade C)

Water Vapor Thermal Therapy (WVTT).

36. WVTT should be considered as a treatment option for patients with LUTS/BPH provided prostate volume 30–80cc. (Moderate Recommendation; Evidence Level: Grade C)

37. WVTT may be offered as a treatment option to eligible patients who desire preservation of erectile and ejaculatory function. (Conditional Recommendation; Evidence Level: Grade C)

Transurethral Needle Ablation (TUNA).

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

Laser Enucleation.

39. Holmium laser enucleation of the prostate (HoLEP) or thulium laser enucleation of the prostate (ThuLEP) should be considered as an option, depending on the clinician's expertise with these techniques, as prostate size-independent options for the treatment of LUTS/BPH. (Moderate Recommendation; Evidence Level: Grade B)

Robotic Waterjet Treatment (RWT).

40. Robotic waterjet treatment (RWT) may be offered as a treatment option to patients with LUTS/BPH provided prostate volume 30–80cc. (Conditional Recommendation; Evidence Level: Grade C)

Statements 27–40 are directed towards specific therapies, with all of these except one (TUNA) receiving some level of support for their use. By and large, the decisions on which to choose come down to several factors:

- Experience of the urologist
- Resources/type of equipment available to the urologist
- Bias of the urologist based on their anecdotal data and/or training
- Size of the prostate
- Morphology of the prostate (ie, presence of middle lobe)
- Health of the patient and ability to tolerate anesthesia
- Bias/preference of the patient based on their own information gathering
- Cost
- Location of care delivery and access (office, ambulatory surgical center, hospital)
- Risk threshold for various side effects (ie, retreatment, retrograde ejaculation, anesthesia, incontinence)
- Desires for fertility

With such a large number of approaches and devices available, it can be challenging for both patient and urologist, alike, to know which

technique is ideal. Most urologists who perform BPH surgery are not specialists in male voiding dysfunction and this could influence choices they make, sometimes inadvertently. What is essential is appropriate selection with patient outcomes at the forefront of decision making. Unfortunately, studies of comparative efficacy between all procedures is lacking and, for certain, there is no one single best choice for every patient. Rather, there are likely several good choices, each with a different risk profile, and potentially different long-term efficacy. Many procedures do not actually remove tissue, or aim to "debulk" the adenoma. Patients require appropriate counselling so they can make informed decisions, and urologists need to be transparent and guide patients towards appropriate options. Urologists must also be willing to consider referral if they are unable to perform the procedure that may be in the patient's best interest.

For specific outcomes by approach, see the full Guidelines.

Prostate Artery Embolization (PAE).

41. PAE for the routine treatment of LUTS/BPH is not supported by current data, and benefit over risk remains unclear; therefore, PAE is not recommended outside the context of clinical trials. (Expert Opinion)

Hematuria.

42. After exclusion of other causes of hematuria, 5-Alpha Reductase Inhibitors (5-ARIs) may be an appropriate and effective treatment alternative in men with refractory hematuria presumably due to prostatic bleeding. (Expert Opinion)

Medically Complicated Patients.

43. HoLEP, PVP, and ThuLEP should be considered as treatment options in patients who are at higher risk of bleeding. (Expert Opinion)

Refractory hematuria secondary to prostatic bleeding poses a challenging treatment dilemma for urologists and patients alike, particularly in the era of anticoagulation. Surgical interventions for symptomatic BPH are often used and have been described in the management approach.[13] However, surgical intervention may not be desired depending on the ability to hold anticoagulation and/or the frailty of the patient.

One of the early intraprostatic effects of finasteride is the suppression of vascular endothelial growth factor (VEGF).[14–16] Several studies report men with prostate-related bleeding (ie, all other causes of hematuria had been excluded) responded to finasteride therapy with a reduction or cessation of such bleeding and a reduced likelihood of recurrence.[17–20] The role of short term use of finasteride to decrease perioperative bleeding in men undergoing TURP is less defined and is not considered to be a routine method of care.[21]

While PAE as a primary treatment for BPH has, as of yet, not shown robust results or enough definitive benefit over risk to meet criteria to recommend its use for this indication, the potential role of PAE in the management of refractory hematuria is evolving and makes intuitive sense. While many of the studies include a small number of patients with various etiologies of hematuria, the ability to both decrease prostate volume and vascular inflow makes PAE a potential adjunct in management of BPH related refractory hematuria.[22]

For patients who take anticoagulants and must proceed to operative intervention without cessation of their medication, laser surgery leads as the preferred choice given the coagulative power of these energy sources, including reduced postoperative bleeding. If surgeons are not experienced with this technology, referral to an appropriate urologist is warranted.

FUTURE DIRECTIONS

Within the context of surgical management of BOO related to BPH, several areas of interest for future study merit discussion.

New Therapeutic Options

Many promising MISTs and surgical alternatives are in development. Given this, the Panel is compelled to consider the necessary attributes to qualify as a reasonable MIST therapy, as well as which patient characteristics will likely confer successful outcomes. Future MISTs should strive to attain outcomes similar to standard technologies with fewer side effects, as well as ability to perform them in an office setting under local anesthesia.

From the patient perspective, the hallmarks of a successful MIST might include: 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. From the urologist's perspective, successful attributes might include: 1. Capacity for performance in an ambulatory setting under reduced anesthesia, 2. A fast learning curve, 3. Generalizability from RCT, 4. Ease of performance and follow-up care, 5. Low risk, 6. Applicable to a wide variety of patients.

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 and Definition of Efficacy and Treatment Failure

Studies of comparative efficacy of medical therapies versus MISTs, and surgical treatments compared to each other, 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. Development of a calculator with patient characteristics, and side effect risk stratification as defined by the patient, to obtain a set of appropriate surgical options could streamline approaches and care.

In addition, MIST and surgical therapies for BPH require a different regulatory process where only patients who remain in follow-up are seen. Many who recover and no longer have symptoms do not return to the urologist or seek care. With medical therapy, patients remain in the care of their providers as therapy is ongoing and prescription renewals are necessary. This variance in patient interaction can lead to different definitions and criteria for treatment failure and in tracking of rates of retreatment.

More data are needed, and a proposed evidence-based classification system for guiding patient care, reimbursement practices, and research outcomes assessment that is applicable across a variety of surgical treatments is of critical importance.

Costs of Delivering Care for Symptomatic BPH

Costs of BPH devices and surgical approaches can be complex considerations. While expensive technology may be able to deliver the care needed, does it *need* to deliver the care? Are other technologies equal in efficacy and less resource heavy? These answers are likely future drivers of surgical approaches when hospitals, insurance companies, and surgeons consider the economics of surgical therapy for BPH.

DISCLAIMER

This document was written by the Benign Prostatic Hyperplasia Panel of the American Urological Association Education and Research, Inc., which was created in 2016. The Practice Guidelines Committee (PGC) of the AUA selected the committee chair. Panel members were selected by the chair. Membership of the Panel included specialists in urology and primary care with specific expertise on this disorder. The mission of the panel was to develop recommendations that are analysis based or consensus-based, depending on panel processes and available data, for optimal clinical practices in the treatment of early stage testicular cancer. 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, and the Panel Chair, with the support of AUA Guidelines staff and the PGC, reviews all disclosures and addresses any potential conflicts per AUA's Principles, Policies and Procedures for Managing Conflicts of Interest. While these guidelines do not necessarily establish the standard of care, AUA seeks to recommend and to encourage compliance by practitioners with current best practices related to the condition being treated. As medical knowledge expands and technology advances, the guidelines will change. Today these evidence-based guidelines statements represent not absolute mandates but provisional proposals for treatment under the specific conditions described in each document. For all these reasons, the guidelines do not pre-empt physician judgment in individual cases. Treating physicians must take into account variations in resources, and patient tolerances, needs, and preferences. Conformance with any clinical guideline does not guarantee a successful outcome. The guideline text may include information or recommendations about certain drug uses ('off label') that are not approved by the Food and Drug Administration (FDA), or about medications or substances not subject to the FDA approval process. AUA urges strict compliance with all government regulations and protocols for prescription and use of these substances. The physician is encouraged to carefully follow all available prescribing information about indications, contraindications, precautions and warnings. These guidelines and best practice statements are not intended to provide legal advice about use and misuse of these substances. Although guidelines are intended to encourage best practices and potentially encompass available technologies with sufficient data as of close of the literature review, they are necessarily time-limited. Guidelines cannot include evaluation of all data on emerging technologies or management, including those that are FDA-approved, which may immediately come to represent accepted clinical practices. For this reason, the AUA does not regard technologies or management which are too new to be addressed by this guideline as necessarily experimental or investigational.

DISCLOSURES

All panel members completed COI disclosures. Disclosures listed include both topic– and non-topic-related relationships. Consultant/Advisor: Michael J. Barry, MD: US Preventive Services Task Force; Anurag Kumar Das, MD: Teledoc; Tobias S. Kohler, MD: Coloplast, American Medical Systems; Kevin T. McVary, MD: Merck, Olympus; Claus G. Roehrborn, MD: Glaxo-Smith-Kline, Neotract, Procept Biorobotics, Boston Scientific, ZenFlow, Teleflex; Charles Welliver, MD: Medscape. Scientific Study or Trial: Michael J. Barry, MD: Healthwise; Steven A. Kaplan, MD: Urotronics; Kevin T. McVary, MD: NIDDK, NxThera, Olympus, MedeonBio, Urotronic, Francis Medical; John T. Stoffel, MD: Department of Defense. Leadership Position: Anurag Kumar Das, MD: Indian American Urological Association; Kevin T. McVary, MD: Uro-Next; John T. Stoffel, MD: The Journal of Urology®, Neurogenic Bladder Research Group. Health Publishing: Kevin T. McVary, MD: SRS Medical Systems; Claus G. Roehrborn, MD: NIDDK; Charles Welliver, MD: Oakstone Publishing. Other: Anurag Kumar Das, MD: Novartis, Sanofi-Aventis, Astellas, Johnson & Johnson, Novo Nordisk, SchwabCare; Charles Welliver, MD: ALX Oncology

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