



The AUA/SUFU Guideline on the Diagnosis and Treatment of Idiopathic Overactive Bladder

Anne Pelletier Cameron, Doreen E. Chung, Elodi J. Dielubanza, Ekene Enemchukwu, David A. Ginsberg, Brian T. Helfand, Penny Holland, Brian J. Linder, Leila Rahimi, W. Stuart Reynolds, Eric S. Rovner, Lesley Souter, Anne M. Suskind, Elizabeth Takacs, Blayne Welk, and Ariana L. Smith

Purpose: The purpose of this guideline is to provide evidence-based guidance to clinicians of all specialties on the evaluation, management, and treatment of idiopathic overactive bladder (OAB). The guideline informs the reader on valid diagnostic processes and provides an approach to selecting treatment options for patients with OAB through the shared decision-making process that will maximize symptom control and quality of life, while minimizing adverse events and burden of disease.

Methods: An electronic search employing OVID was used to systematically search the MEDLINE and EMBASE databases, as well as the Cochrane Library, for systematic reviews and primary studies evaluating diagnosis and treatment of OAB from January 2013 to November 2023. Criteria for inclusion and exclusion of studies were based on the Key Questions and the populations, interventions, comparators, outcomes, timing, types of studies and settings (PICOTS) of interest. Following the study selection process, 159 studies were included and were used to inform evidence-based recommendation statements.

Results: This guideline produced 33 statements that cover the evaluation and diagnosis of the patient with symptoms suggestive of OAB; the treatment options for patients with OAB, including non-invasive therapies, pharmacotherapy, minimally invasive therapies, invasive therapies, and indwelling catheters; and the management of patients with BPH and OAB.

Conclusion: Once the diagnosis of OAB is made, the clinician and the patient with OAB have a variety of treatment options to choose from and should, through shared decision-making, formulate a personalized treatment approach taking into account evidence-based recommendations as well as patient values and preferences.

Key Words: urinary bladder, overactive, urinary incontinence, incontinence, urination disorders, decision making, shared

Overactive bladder (OAB) has been defined as "urinary urgency, usually accompanied by frequency and nocturia, with or without urgency urinary incontinence (UUI), in the absence of urinary tract infection (UTI) or other obvious pathology." The impact on a patient's quality of life (QoL) is significant and many suffer with symptoms for an extended time before seeking medical advice.

Historically, treatment of OAB has followed a stepwise progression of interventions from least invasive to most invasive, based on responses to therapy. This guideline has eliminated the concept of "step therapy," and instead has emphasized the importance of shared decision-making to select the best therapy or therapies, regardless of invasiveness, based on the patient's needs. desires. and side effect

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tolerance. Treatment options have been grouped categorically (Table), rather than in a specific order. This new framework provides a menu of treatment options for patients to select from, including the option to select from multiple treatment categories simultaneously to best suit their individual wishes.

EVALUATION AND DIAGNOSIS

STATEMENT ONE: In the initial office evaluation of patients presenting with symptoms suggestive of OAB, clinicians should:

- a) Obtain a medical history with comprehensive assessment of bladder symptoms,
- b) Conduct a physical examination, and
- c) Perform a urinalysis to exclude microhematuria and infection.

(Clinical Principle)

STATEMENT TWO: Clinicians may offer telemedicine to initially evaluate patients with symptoms suggestive of OAB with the understanding that a physical exam will not be performed, and urinalysis should be obtained at a local laboratory (or recent lab results reviewed, if available). (Expert Opinion)

The clinician's initial assessment of patients with symptoms suggestive of OAB should include questions about symptoms and urinary storage impairments; evaluation of bladder emptying; review of current medications, particularly diuretics and diabetic medications that cause glucosuria; and a directed physical exam. Anatomic factors and/or concomitant conditions that may contribute to OAB symptoms should be assessed as well as an observation of patient's gait and transfers, which may identify mobility impairments that can impact

symptoms like UUI. Dipstick or microscopic urinalysis should be performed in all patients with symptoms suggestive of OAB and urine culture should be performed if urinalysis is suggestive of infection and/or hematuria.

Telemedicine is a viable option for patients with OAB; however, it will not allow for all elements of the initial in-office evaluation. Urinalysis can be obtained at a local laboratory or, if available, by review of recent lab results. For patients that do not respond to therapy after the initial telemedicine evaluation, an in-office visit with a physical examination, measurement of post-void residual (PVR), and urinalysis as indicated should be considered.

STATEMENT THREE: Clinicians may obtain a post-void residual in patients with symptoms suggestive of OAB to exclude incomplete emptying or urinary retention, especially in patients with concomitant voiding or emptying symptoms. (Clinical Principle)

PVR should be performed to exclude urinary retention in patients with concomitant emptying symptoms; a history of urinary retention, enlarged prostate, or neurologic disorders; prior incontinence or prostate surgery; or long-standing diabetes. If PVR is elevated, further evaluation with non-invasive uroflow, urodynamics (UDS), and/or cystoscopy may be indicated.

STATEMENT FOUR: Clinicians may obtain a symptom questionnaire and/or a voiding diary in patients with symptoms suggestive of OAB to assist in the diagnosis of OAB, exclude other disorders, ascertain the degree of bother, and/or evaluate treatment response. (Clinical Principle)

Validated symptom questionnaires provide a reliable and specific measure of bother related to urinary

Table.

Treatment category	Description	Examples
Incontinence management strategies	Products to better cope with or tolerate urinary incontinence. These do not treat or prevent incontinence, rather they reduce adverse sequalae of incontinence, such as urine dermatitis.	Diapering, pads, liners, absorbent underwear, barrier creams, external urine collection system, condom catheters
Behavioral therapies	Actions that patients with OAB can perform at home to directly address and improve their OAB symptoms. Can be supported by education or training but are driven by the patient.	Timed voiding, urgency suppression, fluid management, bladder irritant (caffeine, alcohol) avoidance
Optimization of comorbidities	Medical conditions known to affect the severity of OAB that can be treated or managed.	BPH, constipation, diuretic use, obesity, diabetes mellitus, genitourinary syndrome of menopause, pelvic organ prolapse, tobacco abuse
Non-invasive therapies	Treatments provided by a nurse or allied health professional that may involve practice or treatments at home.	Pelvic floor muscle training, biofeedback, transcutaneous tibial nerve stimulation, electromagnetic therapy
Pharmacologic therapies	Prescription medications that are taken to directly treat bladder symptoms.	Beta-3 agonists, antimuscarinic medications
Minimally invasive therapies	Treatments that are procedural or surgical but with low risk of complication or adverse events.	Botulinum toxin injection of bladder, sacral neuromodulation, percutaneous tibial nerve stimulation, acupuncture, implantable tibial nerve stimulation
Invasive therapies	Surgical treatments that have higher risks of complications or adverse events.	Urinary diversion, bladder augmentation cystoplasty
Indwelling catheters	Any urinary catheter left in the bladder as a method to treat incontinence.	Indwelling urethral or suprapubic catheters

symptoms and clinicians may utilize these to assess baseline bother and monitor treatment response. Many OAB-specific symptom measures are used, but a more comprehensive assessment of lower urinary tract symptoms (LUTS) can be measured with the Bristol Female Lower Urinary Tract Symptoms, which is validated for females only or LURN-SI-29 (or the LURN-SI-10 short form), which captures voiding symptoms, storage symptoms, incontinence and is validated for all genders. A 24- to 72-hour fluid intake and voiding diary that records the time and circumstances of each void and/or incontinence episode can also provide detail about toileting and fluid intake when recall is difficult.

STATEMENT FIVE: Clinicians should not routinely perform urodynamics, cystoscopy, or urinary tract imaging in the initial evaluation of patients with OAB. (Clinical Principle)

STATEMENT SIX: Clinicians may perform advanced testing, such as urodynamics, cystoscopy, or urinary tract imaging in the initial evaluation of patients with OAB when diagnostic uncertainty exists. (Clinical Principle)

UDS are not beneficial in the initial evaluation of patients with symptoms suggestive of OAB since there are no pathognomonic findings on UDS that confirm diagnosis.³ However, if the patient has mixed incontinence, obstructive voiding symptoms, elevated PVR, or possible neurogenic lower urinary tract dysfunction (NLUTD), or if diagnostic uncertainty remains after the initial evaluation, then UDS can be considered to clarify diagnosis and rule out other lower urinary tract pathology.

Likewise, there are no findings on cystoscopy to make the diagnosis of OAB; however, it is diagnostically helpful in those with hematuria at the time of evaluation, in patients with history of recurrent UTI, in those with obstructive voiding, or in women with symptoms of OAB and a history of a prior sling for stress urinary incontinence. Findings such as recurrent UTI, hematuria, or NLUTD may necessitate upper tract imaging; the indication for imaging in these clinical scenarios is well described in their respective guidelines.

STATEMENT SEVEN: Clinicians should assess for comorbid conditions in patients with OAB that may contribute to urinary frequency, urgency, and/or urgency urinary incontinence and should educate patients on the role that managing these conditions can have on bladder symptoms. (Expert Opinion)

A variety of medical conditions, such as obesity, constipation, pelvic organ prolapse, genitourinary syndrome of menopause, glucosuria, obstructive sleep apnea, anxiety, depression, and tobacco use may contribute to urinary frequency, urgency, and/or UUI. Addressing these underlying co-morbidities

may help to alleviate urinary symptoms that are resultant sequela to OAB or work synergistically with other primary OAB treatments.

STATEMENT EIGHT: Clinicians may use telemedicine for follow-up visits with patients with OAB. (Expert Opinion)

Telemedicine is effective and convenient for patients when evaluating response to therapy, adjusting or refilling medications, and/or considering a change in therapy. If patients are undergoing certain therapies such as intradetrusor botulinum toxin (BTX) injection, percutaneous tibial nerve stimulation (PTNS), or if more invasive evaluations are needed (eg, UDS, cystoscopy), then an in-office visit would be required.

SHARED DECISION-MAKING

STATEMENT NINE: Clinicians should engage in shared decision-making with patients with OAB taking into consideration the patient's expressed values, preferences, and treatment goals in order to help them make an informed decision regarding different treatment modalities or to explore the option of no treatment. (Clinical Principle)

Shared decision-making is an interactive patient-clinician dialogue in which decisions on the best care options are made taking into account evidence-based recommendations as well as patient values and preferences. This is particularly important in preference-centered health decisions, such as OAB, where multiple options exist for the same condition and the clinical outcomes are relatively equal. Once the correct diagnosis of OAB is obtained and other conditions are ruled out, it is appropriate for the clinician to educate the patient about the nature of OAB and to engage in shared decision-making regarding the patient's choice of treatments or the option of no treatment at all.

NON-INVASIVE THERAPIES

STATEMENT TEN: Clinicians should discuss incontinence management strategies (eg, pads, diapering, barrier creams) with all patients who have urgency urinary incontinence. (Expert Opinion)

Patients who present with UUI symptoms should be evaluated and counseled regarding potential strategies used to manage incontinence (eg, liners, pads, diapers, barrier creams, external catheters, and absorbent washable protective briefs or underwear) and to mitigate the impact of leaking on QoL. It is important to note that no randomized controlled trials (RCTs) have compared the clinical effectiveness of, or patient satisfaction with, these strategies; the clinician should present a description, as well as the risks and benefits, of each of the options to the patient in the context of shared decision-making.

STATEMENT ELEVEN: Clinicians should offer bladder training to all patients with OAB (Strong Recommendation; Evidence Level: Grade A)

STATEMENT TWELVE: Clinicians should offer behavioral therapies to all patients with OAB. (Clinical Principle)

Behavioral therapies for OAB, such as fluid management, caffeine reduction, physical activity/ exercise, dietary modifications, and mindfulness offer patients with OAB some efficacy, excellent safety, and few if any adverse effects. However, the success of these measures is highly dependent on patient acceptance, adherence, and compliance. While the research on the effectiveness of behavioral therapies is highly variable, bladder training has been extensively studied and is recommended based on strong evidence.⁴

STATEMENT THIRTEEN: Clinicians may offer select non-invasive therapies to all patients with OAB. (Clinical Principle)

Non-invasive therapies, such as pelvic floor muscle therapy (PFMT), transcutaneous tibial nerve stimulation, transvaginal electrical stimulation, and yoga are conservative therapies for OAB that are provided by a healthcare professional and require participation by the patient. While safety profiles are excellent across modalities, with few adverse effects and a high risk-benefit ratio, all non-invasive therapies do not have equivalent efficacy and the evidence base is highly variable. Most non-invasive therapies require long-term patient compliance to maintain a durable effect and patients should be counselled as such before embarking on a course of a potentially lifelong therapy.

STATEMENT FOURTEEN: In patients with OAB whose symptoms do not adequately respond to monotherapy, clinicians may combine one or more of the following: behavioral therapy, non-invasive therapy, pharmacotherapy, and/or minimally invasive therapies. (Expert Opinion)

Historically, treatment of OAB has followed a stepwise progression of therapies from least invasive to most invasive based on patient response. However, clinicians may use a layering or combination approach of two or more therapies simultaneously. Behavioral therapies have been added to other non-invasive,⁵ minimally invasive, and pharmacological therapy with potentially additive favorable effects. When combining therapies, the practitioner should carefully monitor improvement of OAB symptoms, and if no improvement is noted, then one or both therapies should be discontinued, and other treatments pursued. When combining greater than two therapies, the practitioner should proceed in a stepwise fashion, not instituting multiple additions simultaneously thereby allowing the practitioner to determine the individual impact of each therapy on symptoms.

STATEMENT FIFTEEN: Clinicians should counsel patients that there is currently insufficient evidence to support the use of nutraceuticals, vitamins, supplements, or herbal remedies in the treatment of patients with OAB. (Expert Opinion)

There are not adequately powered RCTs demonstrating efficacy for any of these agents and therefore are not recommended at this time.

PHARMACOTHERAPY

STATEMENT SIXTEEN: Clinicians should offer antimuscarinic medications or beta-3 agonists to OAB patients to improve urinary urgency, frequency, and/or urgency urinary incontinence. (Strong Recommendation; Evidence Level: Grade A).

The body of evidence supporting the use of antimuscarinic medications and beta-3 (β3) adrenergic agonist oral medications has demonstrated improvement in urgency urinary episodes, voiding episodes, and UUI⁸⁻¹⁷ as compared to placebo. Clinical studies have also demonstrated that OAB agents significantly improve other outcomes of interest, including overall and condition-specific QoL, ^{10,11,14}, ¹⁸⁻²⁰ satisfaction with treatment, ⁹ and work productivity ²¹; however, there is considerable variance in estimated magnitudes of effects,8-16 and given the lack of evidence indicating superiority for either class when evaluating OAB symptoms control, the Panel concluded that the efficacies of antimuscarinic medications and β3-agonists were similar. Furthermore, the Panel felt it was important to note that the observed placebo effect is very strong in some clinical studies.²

STATEMENT SEVENTEEN: Clinicians should counsel patients with OAB on the side effects of all oral medication options; treatment should be chosen based on side effect profiles and in the context of shared decision-making. (Clinical Principle)

While efficacy may be similar among OAB medications, side effect profiles differ among agents and between antimuscarinic medications and β 3-agonists specifically. Therefore, clinicians should choose a pharmacologic treatment option with the patient, in the context of shared decision-making, that incorporates patient preferences and values.

STATEMENT EIGHTEEN: Clinicians should discuss the potential risk for developing dementia and cognitive impairment with patients with OAB who are taking, or who are prescribed, antimuscarinic medications. (Clinical Principle)

There is evidence to suggest an association between antimuscarinic medications and the development of incident dementia, which may be cumulative and dose-dependent. ²³ A meta-analysis of 11 cohort studies and three case-control studies found that antimuscarinic medications were associated with increased risk of all-cause dementia and Alzheimer's disease. ²⁴ Clinicians should consider potential cognitive risks in all patient populations when prescribing these medications for chronic use. Additionally, a trial of a β 3-agonists is typically preferred before antimuscarinic medications. ²⁵

STATEMENT NINETEEN: Clinicians should use antimuscarinic medications with extreme caution in patients with OAB who have narrowangle glaucoma, impaired gastric emptying, or a history of urinary retention. (Clinical Principle)

Additional considerations in prescribing antimuscarinic medications should be given in patients with diabetes, prior abdominal surgery, narcotic use, scleroderma, hypothyroidism, Parkinson's disease, multiple sclerosis, and any other conditions that may impact gastric emptying. If a patient has a history of urinary retention, or is at risk for retention, a PVR should be obtained, and the risks and benefits should be considered and discussed with the patient regarding the potential for worsening of bladder emptying.

STATEMENT TWENTY: Clinicians should assess patients with OAB who have initiated pharmacotherapy for efficacy and for onset of treatment side effects. (Expert Opinion)

The Panel recommends that patients should be assessed within 4 to 8 weeks after initiating OAB pharmacotherapy for efficacy of the treatment as well as the onset of side effects. Most clinical studies included assessments of efficacy and/or side-effects at 4 weeks and most were able to demonstrate medication effects by that time. ^{10-13,16}

Assessment after initiating OAB therapy is important to avoid medical "purgatory," in which patients remain in a state of none to minimal improvement or significant side-effects. Those who do not achieve appropriate improvement should be offered change in therapy.

STATEMENT TWENTY-ONE: In patients with OAB who experience intolerable side effects or who do not achieve adequate improvement with an OAB medication, clinicians may offer a different medication in the same class or a different class of medication to obtain greater tolerability and/or efficacy. (Clinical Principle)

Overall, there are limited data that support substituting one agent for another, especially in the same class of medication. In one study that surveyed patients with OAB who were enrolled in a regional medical group,²⁶ those who switched to a different agent did not report improvement in their frequency of UUI episodes. β3-agonists appear to

have lower rates of common side-effects; therefore, switching to a $\beta 3$ agonist may be more tolerable for patients while maintaining efficacy.²⁷

STATEMENT TWENTY-TWO: In patients with OAB who do not achieve adequate improvement with a single OAB medication, clinicians may offer combination therapy with a medication from a different class. (Conditional Recommendation; Evidence Level: Grade B)

While patients are often started on a single OAB medication, many may not experience the benefit that they desire. The clinician may offer combination therapy with both an antimuscarinic medication and a $\beta 3$ agonist by adding a medication from a different drug class. While the two large RCTs evaluating combination therapy are limited to two drugs (the BESIDE²⁸ and SYNERGY²⁹ studies evaluating solifenacin and mirabegron, respectively), the Panel felt that the principle of combination therapy is likely generalizable to other medications within these classes of drugs.

MINIMIALLY INVASIVE THERAPIES

STATEMENT TWENTY-THREE: Clinicians may offer minimally invasive procedures to patients who are unable or unwilling to undergo behavioral, non-invasive, or pharmacologic therapies. (Clinical Principle)

STATEMENT TWENTY-FOUR: Clinicians may offer patients with OAB, in the context of shared decision making, minimally invasive therapies without requiring trials of behavioral, non-invasive, or pharmacologic management. (Expert Opinion)

STATEMENT TWENTY-FIVE: In patients with OAB who have an inadequate response to, or have experienced intolerable side effects from, pharmacotherapy or behavioral therapy, clinicians should offer sacral neuromodulation, percutaneous tibial nerve stimulation, and/or intradetrusor botulinum toxin injection. (Moderate Recommendation: Evidence Level: Grade A)

Behavioral therapy and pharmacotherapy historically have been the first two lines of treatment for patients with OAB based on risk/benefit relationships and degree of invasiveness; however, long-term compliance with these measures is poor resulting in high rates of failure³⁰ and patient frustration. As a result, many patients fail to move on to more invasive therapies which have the potential for therapeutic success.³¹ Minimally invasive treatment options for OAB (eg, PTNS, implantable tibial nerve stimulation, BTX, and sacral neuromodulation [SNM]) have been associated with high success rates, durable efficacy, and excellent patient satisfaction,³² and offer considerable therapeutic benefits for

treatment naïve patients who do not want to or cannot pursue behavioral or pharmacological treatment options.

The advantages and disadvantages of minimally invasive OAB therapies can have a wide range of implications for individual patients. Integrating patient preferences and values enables providers to craft personalized treatment plans aligned with patient goals, potentially enhancing the effectiveness of OAB management. In addition to clinical efficacy and side effects, the mode and frequency of administration varies among these therapy options, creating differing levels of treatment burden, and emphasizes the importance of individualized therapy approaches in patients with OAB.

SNM, PTNS, and transcutaneous tibial nerve stimulation have all shown effectiveness in patients in reducing voiding frequency, nocturia, the number of urgency episodes, the number of incontinence episodes, and QoL in patients who had an inadequate response to or cannot tolerate other therapies, ³³ or BTX. ^{34,35} One limitation of PTNS is the necessity for individuals to undergo repeated inoffice treatments. To address this, two implantable tibial nerve stimulators have been developed and approved by the FDA. ³⁶

There is strong evidence that 100U intradetrusor BTX injection improves OAB symptoms in patients who have had an inadequate response to, or have experienced intolerable side effects from, antimuscarinic medications $^{34,37-40}$ and/or $\beta3$ -agonist medications. It is reasonable to bypass antimuscarinics and move directly to BTX injections in those patients who cannot take, or do not wish to try, these agents.

STATEMENT TWENTY-SIX: Clinicians should measure post-void residual in patients with OAB prior to intradetrusor botulinum toxin therapy. (Clinical Principle)

Patients should have a PVR measured prior to BTX injection and counseled about the risk of incomplete bladder emptying, which may necessitate clean intermittent catheterization (CIC) following the procedure. RCTs included in the evidence based used a PVR > 100 to 200 mL as exclusion criteria, 34,37,40 leading the Panel to conclude that caution should be used when performing BTX injection in patients with a PVR > 100 to 200 mL.

STATEMENT TWENTY-SEVEN: Clinicians should obtain a post-void residual in patients with OAB whose symptoms have not adequately improved or worsened after intradetrusor botulinum toxin injection. (Clinical Principle)

Clinicians should evaluate patients approximately 2 weeks after the initial BTX injection to assess symptom improvement and to rule out potential urinary retention. If a patient does not have symptom improvement following BTX injection, a

PVR, urinalysis, and if positive, a urine culture should be obtained since UTI or incomplete emptying may be the reason for these symptoms.

STATEMENT TWENTY-EIGHT: Clinicians should discontinue oral medications in patients with OAB who have an appropriate response to a minimally invasive procedure but should restart pharmacotherapy if efficacy is not maintained. (Expert Opinion)

Limited evidence examined the effect of discontinuing oral medications following BTX injection, SNM, or PTNS; however, the Panel recommends that if a patient has a good treatment response to a treatment modality, there is likely no added benefit continuing OAB medications. If discontinuation results in symptom recurrence, then these agents should be restarted.

STATEMENT TWENTY-NINE: Clinicians may perform urodynamics in patients with OAB who do not adequately respond to pharmacotherapy or minimally invasive therapies or procedures to further evaluate bladder function and exclude other disorders. (Clinical Principle)

OAB is a clinical diagnosis predicated on the presence of urinary urgency; therefore, UDS are not required to make the diagnosis of OAB. However, in patients that present with atypical symptoms, or those with an inadequate response to treatment, UDS can be considered. Except for cases where OAB symptoms coexist with elevated PVR requiring further management, no urodynamic parameter is an absolute contraindication to an interventional therapy trial. 42,43

INVASIVE THERAPIES

STATEMENT THIRTY: The clinician may offer bladder augmentation cystoplasty or urinary diversion in severely impacted patients with OAB who have not responded to all other therapeutic options. (Expert Opinion)

There is a very small subset of patients with OAB who, despite trials of numerous medical and interventional therapies, experience persistent and substantial impairment in their QoL due to inadequately controlled OAB symptoms. In these patients, invasive surgical procedures may be considered by experienced physicians following a comprehensive discussion of the potential risks, benefits, and alternatives, including short and long-term surgical morbidity, the need for CIC, and the absence of data on QoL outcomes.⁴⁴

INDWELLING CATHETERS

STATEMENT THIRTY-ONE: Clinicians should only recommend chronic indwelling urethral

or suprapubic catheters to patients with OAB when OAB therapies are contraindicated, ineffective, or no longer desired by the patient and always in the context of shared decision-making due to risk of harm. (Expert Opinion)

When OAB therapies are contraindicated, ineffective, or no longer desired by the patient, providers may recommend, or patients may request, indwelling catheterization. Before deciding on this form of bladder management, it is essential to counsel the patient on the potential long-term risk, benefits, and alternatives. Chronic indwelling urethral catheters can cause urethral trauma, including erosion and, in severe cases, urethral loss, significant urinary incontinence, and the need for reconstructive surgery. Therefore, individuals opting for urethral catheterization should be counseled on the importance of regular follow-up to detect and address potential signs of urethral trauma. Suprapubic tubes (SPT) are the preferred chronic indwelling catheter option due to the reduced likelihood of urethral damage. They may also be preferred by individuals seeking to maintain their capacity for sexual activity or those experiencing urethral discomfort associated with the urethral catheter. While SPTs are less likely to cause urethral complications. SPT placement is associated with potential risks, such as bowel perforation or vascular injury. Some of this risk can be mitigated with routine use of ultrasound guided SPT placement. Other SPT associated complications include development of granulation tissue, bleeding, catheter site erosion, and loss of access during catheter changes.

BPH AND OAB

STATEMENT THIRTY-TWO: Clinicians may offer patients with BPH and bothersome OAB, in the context of shared decision-making, initial management with non-invasive therapies, pharmacotherapy, or minimally invasive therapies. (Expert Opinion)

Clinicians may offer bladder outlet reduction surgeries for patients who present with LUTS and

BPH. There are an increasing number of surgical therapies that have been utilized to treat BPH and range from minimally invasive to invasive therapies, with some procedural considerations specific to the size and shape of the prostate. Men with OAB predominant LUTS and BPH have showed significant improvements in Qmax, PVR, and the presence of detrusor overactivity after transurethral resection of the prostate, holmium laser enucleation of the prostate, or photovaporization of the prostate. 45 Patients also had significant improvement on International Prostate Symptom Scores, frequency, urgency, nocturia, and urinary incontinence. 45 For those opting for procedural interventions, clinicians should discuss that some patients may experience de novo or worsening OAB symptoms after BPH surgical interventions, among other potential adverse events.

STATEMENT THIRTY-THREE: Clinicians should offer patients with BPH and OAB monotherapy with antimuscarinic medications or beta-3 agonists, or combination therapy with an alpha blocker and an antimuscarinic medication or beta-3 agonist. (Conditional Recommendation; Evidence Level: Grade B)

Clinicians consider may pharmacologic terventions among patients with predominant OAB symptoms and who happen to have BPH, such as antimuscarinics, β3 agonists, alpha adrenergic antagalpha reductase inhibitors, 5 phosphodiesterase-5 inhibitors. Antimuscarinics and β3-agonists are effective in treating OAB in this population as monotherapy, and while antimuscarinic medications may increase PVR volumes slightly, they do not appear to be associated with a significant increased risk of urinary retention among groups of patients with co-existing bladder outlet obstruction secondary to BPH.46 A discussion of the risk of retention should occur when discussing these medications with those presenting with elevated PVR values. 47,48 Randomized studies of individual antimuscarinic medications and \(\beta \)-agonists demonstrate efficacy for each among men with predominant OAB symptoms. 47-49

REFERENCES

- Ackerman AL. Penny-wise but pound-foolish: the hidden costs of step therapy for overactive bladder. J Urol. 2023;209(6):1045-1047. doi. 10. 1097/JU.0000000000003430
- Cella D, Smith AR, Griffith JW, et al; LURN Study Group. A new outcome measure for LUTS: symptoms of lower urinary tract dysfunction research network symptom index-29 (LURN SI-29) questionnaire. Neurourol Urodyn. 2019;38(6):1751-1759. doi. 10.1002/nau.24067
- Hashim H, Abrams P. Is the bladder a reliable witness for predicting detrusor overactivity?. J Urol. 2006;175(1):191-195. doi. 10.1016/S0022-5347(05)00067-4
- Funada S, Yoshioka T, Luo Y, Sato A, Akamatsu S, Watanabe N. Bladder training for treating overactive bladder in adults. *Cochrane Database Syst Rev.* 2023;10:CD013571. doi. 10.1002/ 14651858.CD013571.pub2
- Firinci S, Yildiz N, Alkan H, Aybek Z. Which combination is most effective in women with
- idiopathic overactive bladder, including bladder training, biofeedback, and electrical stimulation? A prospective randomized controlled trial. *Neurourol Urodyn.* 2020;39(8):2498-2508. doi. 10. 1002/nau.24522
- Kasman A, Stave C, Elliott CS. Combination therapy in overactive bladder-untapped research opportunities: a systematic review of the literature. Neurourol Urodyn. 2019;38(8):2083-2092. doi. 10.1002/nau.24158

- Burgio KL, Kraus SR, Johnson TM, et al. Effectiveness of combined behavioral and drug therapy for overactive bladder symptoms in men: a randomized clinical trial. *JAMA Intern Med.* 2020;180(3):411-419. doi. 10.1001/iamainternmed.2019.6398
- Herschorn S, Barkin J, Castro-Diaz D, et al. A phase III, randomized, double-blind, parallel-group, placebo-controlled, multicentre study to assess the efficacy and safety of the β- adrenoceptor agonist, mirabegron, in patients with symptoms of overactive bladder. *Urology*. 2013;82(2):313-320. doi. 10.1016/j.urology.2013. 02.077
- Khullar V, Amarenco G, Angulo JC, et al. Efficacy and tolerability of mirabegron, a β3-adrenoceptor agonist, in patients with overactive bladder: results from a randomised European-Australian phase 3 trial. *Eur Urol.* 2013;63(2):283-295. doi. 10.1016/j.eururo.2012.10.016
- Newman DK, Thomas E, Greene H, Haag-Molkenteller C, Varano S. Efficacy and safety of vibegron for the treatment of overactive bladder in women: a subgroup analysis from the doubleblind, randomized, controlled EMPOWUR trial. *Urogynecology*. 2023;29(1):48-57. doi: 10.1097/ SPV.0000000000000001258
- Nitti VW, Auerbach S, Martin N, Calhoun A, Lee M, Herschorn S. Results of a randomized phase III trial of mirabegron in patients with overactive bladder. *J Urol.* 2013;189(4):1388-1395. doi. 10. 1016/j.juro.2012.10.017
- Staskin D, Frankel J, Varano S, et al. Vibegron for the treatment of patients with dry and wet overactive bladder: a subgroup analysis from the EMPOWUR trial. Int J Clin Pract. 2022;2022:6475014. doi. 10.1155/2022/6475014
- Staskin D, Frankel J, Varano S, Shortino D, Jankowich R, Mudd PN Jr. International phase III, randomized, double-blind, placebo and active controlled study to evaluate the safety and efficacy of vibegron in patients with symptoms of overactive bladder: empowur. J Urol. 2020;204(2):316-324. doi. 10.1097/JU.0000000000000007
- Stoniute A, Madhuvrata P, Still M, Barron-Millar E, Nabi G, Omar MI. Oral anticholinergic drugs versus placebo or no treatment for managing overactive bladder syndrome in adults. *Cochrane Database Syst Rev.* 2023;5:CD003781. doi. 10. 1002/14651858.CD003781.pub3
- Yamaguchi O, Marui E, Kakizaki H, et al. Phase III, randomised, double-blind, placebo-controlled study of the β3-adrenoceptor agonist mirabegron, 50 mg once daily, in Japanese patients with overactive bladder. *BJU Int.* 2014;113(6):951-960. doi. 10.1111/bju.12649
- 16. Yoshida M, Takeda M, Gotoh M, Nagai S, Kurose T. Vibegron, a novel potent and selective β3-adrenoreceptor agonist, for the treatment of patients with overactive bladder: a randomized, double-blind, placebo-controlled phase 3 study.

- *Eur Urol.* 2018;73(5):783-790. doi. 10.1016/j. eururo.2017.12.022
- 17. Yoshida M, Takeda M, Gotoh M, et al. Efficacy of novel β_3 -adrenoreceptor agonist vibegron on nocturia in patients with overactive bladder: a post-hoc analysis of a randomized, double-blind, placebo-controlled phase 3 study. *Int J Urol.* 2019;26:369-375. doi. 10.1111/iju.13877
- Chapple CR, Kaplan SA, Mitcheson D, et al. Randomized double-blind, active-controlled phase 3 study to assess 12-month safety and efficacy of mirabegron, a β3-adrenoceptor agonist, in overactive bladder. *Eur Urol.* 2013;63(2):296-305. doi. 10.1016/j.eururo.2012.10.048
- Frankel J, Varano S, Staskin D, Shortino D, Jankowich R, Mudd PN Jr. Vibegron improves quality-of-life measures in patients with overactive bladder: patient-reported outcomes from the EMPOWUR study. *Int J Clin Pract*. 2021;75(5):e13937. doi: 10.1111/ijcp.13937
- Robinson D, Kelleher C, Staskin D, et al. Patientreported outcomes from synergy, a randomized, double-blind, multicenter study evaluating combinations of mirabegron and solifenacin compared with monotherapy and placebo in OAB patients. Neurourol Urodyn. 2018;37(1):394-406. doi. 10. 1002/nau.23315
- Khullar V, Amarenco G, Angulo JC, et al. Patientreported outcomes with the β3-adrenoceptor agonist mirabegron in a phase iii trial in patients with overactive bladder. *Neurourol Urodyn*. 2016;35(8):987-994. doi. 10.1002/nau.22844
- Mostafaei H, Janisch F, Mori K, et al. Placebo response in patients with oral therapy for overactive bladder: a systematic review and metaanalysis. Eur Urol Focus. 2022;8(1):239-252. doi. 10.1016/j.euf.2021.02.005
- Gray SL, Anderson ML, Dublin S, et al. Cumulative use of strong anticholinergics and incident dementia: a prospective cohort study. *JAMA Intern Med.* 2015;175(3):401-407. doi. 10.1001/jamainternmed.2014.7663
- Zheng YB, Shi L, Zhu XM, et al. Anticholinergic drugs and the risk of dementia: a systematic review and meta-analysis. *Neurosci Biobehav Rev*. 2021;127:296-306. doi. 10.1016/j.neubiorev.2021. 04.031
- Zillioux J, Welk B, Suskind AM, Gormley EA, Goldman HB. SUFU white paper on overactive bladder anticholinergic medications and dementia risk. *Neurourol Urodyn.* 2022;41(8):1928-1933. doi. 10.1002/nau.25037
- Chancellor MB, Yehoshua A, Waweru C, et al. Limitations of anticholinergic cycling in patients with overactive bladder (OAB) with urinary incontinence (UI): results from the consequences of treatment refractory overactive bladder (CON-TROL) study. *Int Urol Nephrol.* 2016;48(7):1029-1036. doi. 10.1007/s11255-016-1277-0
- Liao CH, Kuo HC. High satisfaction with direct switching from antimuscarinics to mirabegron in

- patients receiving stable antimuscarinic treatment. *Medicine (Baltimore)*. 2016;95(45):e4962. doi. 10.1097/MD.0000000000004962
- MacDiarmid S, Al-Shukri S, Barkin J, et al; BE-SIDE Investigators. Mirabegron as add-on treatment to solifenacin in patients with incontinent overactive bladder and an inadequate response to solifenacin monotherapy: responder analyses and patient-reported outcomes from the BESIDE study [corrected]. *J Urol.* 2016;196(3):809-818. doi. 10. 1016/j.juro.2016.03.174
- Herschorn S, Chapple CR, Abrams P, et al. Efficacy and safety of combinations of mirabegron and solifenacin compared with monotherapy and placebo in patients with overactive bladder (SYNERGY study). BJU Int. 2017;120(4):562-575. doi: 10.1111/bju.13882
- Benner JS, Nichol MB, Rovner ES, et al. Patientreported reasons for discontinuing overactive bladder medication. *BJU Int.* 2010;105(9):1276-1282. doi. 10.1111/j.1464-410X.2009.09036.x
- Miller JM, Garcia CE, Hortsch SB, Guo Y, Schimpf MO. Does instruction to eliminate coffee, tea, alcohol, carbonated, and artificially sweetened beverages improve lower urinary tract symptoms?: a prospective trial. *J Wound Ostomy Continence Nurs.* 2016;43(1):69-79. doi. 10.1097/ WON.0000000000000000197
- 32. Lo CW, Wu MY, Yang SS, Jaw FS, Chang SJ. Comparing the efficacy of onabotulinumtoxinA, sacral neuromodulation, and peripheral tibial nerve stimulation as third line treatment for the management of overactive bladder symptoms in adults: systematic review and network meta-analysis. *Toxins* (*Basel*). 2020;12(2):128. doi. 10. 3390/toxins12020128
- Yang G, Xu Y, Qu G, Zhang Y. Refractory overactive bladder patients who chose sacral neuromodulation therapy after failed onabotulinumtoxinA treatment: a systematic review and meta-analysis. *PLoS ONE*. 2020;15(3):e0230355. doi. 10.1371/journal. pone.0230355
- Amundsen CL, Komesu YM, Chermansky C, et al; Pelvic Floor Disorders Network. Two-year outcomes of sacral neuromodulation versus onabotulinumtoxinA for refractory urgency urinary incontinence: a randomized trial. *Eur Urol.* 2018;74(1):66-73. doi. 10.1016/j.eururo.2018.02. 011
- Siegel S, Noblett K, Mangel J, et al. Results of a prospective, randomized, multicenter study evaluating sacral neuromodulation with interstim therapy compared to standard medical therapy at 6-months in subjects with mild symptoms of overactive bladder. *Neurourol Urodyn*. 2015;34(3):224-230. doi. 10.1002/nau.22544
- Vollstedt A, Gilleran J. Update on implantable PTNS devices. *Curr Urol Rep.* 2020;21(7):28. doi. 10.1007/s11934-020-00980-5
- 37. Chapple C, Sievert KD, Macdiarmid S, et al. OnabotulinumtoxinA 100 U significantly

- improves all idiopathic overactive bladder symptoms and quality of life in patients with overactive bladder and urinary incontinence: a randomised, double-blind, placebo-controlled trial. *Eur Urol.* 2013;64(2):249-256. doi. 10. 1016/j.eururo.2013.04.001
- Herschorn S, Kohan A, Aliotta P, et al. The efficacy and safety of onabotulinumtoxinA or solifenacin compared with placebo in solifenacin naive patients with refractory overactive bladder: results from a multicenter, randomized, double-blind phase 3b trial. *J Urol.* 2017;198(1):167-175. doi: 10.1016/j.juro.2017.01.069
- McCammon K, Gousse A, Kohan A, et al. Early and consistent improvements in urinary symptoms and quality of life with onabotulinumtoxinA in patients with overactive bladder and urinary incontinence: results from a randomized, placebocontrolled, phase IV clinical trial. Female Pelvic Med Reconstr Surg. 2020;27(7):450-456. doi. 10. 1097/SPV.00000000000000014
- Nitti VW, Dmochowski R, Herschorn S, et al; EMBARK Study Group. OnabotulinumtoxinA for the treatment of patients with overactive bladder and urinary incontinence: results of a phase 3, randomized, placebo controlled trial. *J Urol*. 2013;189(6):2186-2193. doi. 10.1016/j.juro.2012. 12.022

- 41. Yokoyama O, Honda M, Yamanishi T, et al. OnabotulinumtoxinA (botulinum toxin type A) for the treatment of Japanese patients with overactive bladder and urinary incontinence: results of single-dose treatment from a phase iii, randomized, double-blind, placebo-controlled trial (interim analysis). *Int J Urol.* 2020;27(3):227-234. doi. 10.1111/iju.14176
- Abrar M, Pindoria N, Malde S, Chancellor M, DeRidder D, Sahai A. Predictors of poor response and adverse events following botulinum toxin a for refractory idiopathic overactive bladder: a systematic review. *Eur Urol Focus* 2021;7(6):1448-1467. doi. 10.1016/j.euf.2020.06.013
- Jairam R, Drossaerts J, Marcelissen T, van Koeveringe G, Vrijens D, van Kerrebroeck P. Predictive factors in sacral neuromodulation: a systematic review. *Urol Int.* 2022;106(4):323-343. doi. 10.1159/000513937
- Reyblat P, Ginsberg DA. Augmentation enterocystoplasty in overactive bladder: is there still a role?. Curr Urol Rep. 2010;11(6):432-439. doi. 10. 1007/s11934-010-0135-3
- 45. Mostafa MM, Khallaf A, Khalil M, Elgammal MA, Mahdy A. Efficacy and safety of TURP, HoLEP, and PVP in the management of OAB symptoms complicating BPH in patients with moderately

- enlarged prostates: a comparative study. *Can Urol Assoc J.* 2023;17(1):E1–E7. doi. 10.5489/cuaj. 7905
- Andersson KE. The use of pharmacotherapy for male patients with urgency and stress incontinence. *Curr Opin Urol.* 2014;24(6):571-577. doi. 10.1097/MOU.0000000000000106
- 47. Shin DG, Kim HW, Yoon SJ, et al. Mirabegron as a treatment for overactive bladder symptoms in men (MIRACLE study): efficacy and safety results from a multicenter, randomized, double-blind, placebo-controlled, parallel comparison phase iv study. Neurourol Urodyn 2019;38(1):295-304. doi. 10.1002/nau.23852
- Ginsberg D, Schneider T, Kelleher C, et al. Efficacy of fesoterodine compared with extendedrelease tolterodine in men and women with overactive bladder. *BJU Int.* 2013;112(3):373-385. doi. 10.1111/bju.12174
- 49. Tubaro A, Batista JE, Nitti VW, et al. Efficacy and safety of daily mirabegron 50 mg in male patients with overactive bladder: a critical analysis of five phase III studies. *Ther Adv Urol.* 2017;9(6):137-154. doi. 10.1177/1756287217702797