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# SURGICAL TREATMENT OF FEMALE STRESS URINARY INCONTINENCE: AUA/SUFU GUIDELINE

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## SUMMARY

### Purpose

Stress urinary incontinence (SUI) is a common problem experienced by many women. SUI can have a significant negative impact on the quality of life (QOL) of not only those who suffer from the condition, but also potentially on those friends and family members whose lives and activities may also be limited.

### Methodology

A comprehensive search of the literature was performed by ECRI Institute. This search included articles published between January 1, 2005 and December 31, 2015. In 2023, the SUI guideline was updated through the American Urological Association (AUA) amendment process in which newly published literature is reviewed and integrated into previously published guidelines in an effort to maintain currency. The amendment allowed for the incorporation of additional literature released since the initial publication of this guideline in 2017. For this update, the methodology team searched for studies published between January 1, 2016, and February 28, 2022.

## GUIDELINE STATEMENTS

### PATIENT EVALUATION

1. In the initial evaluation of patients with SUI desiring to undergo surgical intervention, clinicians should include the following components: (*Clinical Principle*)
  - History, including assessment of bother
  - Physical examination, including a pelvic examination
  - Objective demonstration of SUI with a comfortably full bladder (any method)
  - Assessment of post-void residual urine (any method)
  - Urinalysis

2. Clinicians should perform additional evaluations in patients being considered for surgical intervention who have the following conditions: (*Expert Opinion*)
  - Inability to make definitive diagnosis based on symptoms and initial evaluation
  - Inability to demonstrate SUI
  - Known or suspected neurogenic lower urinary tract dysfunction
  - Abnormal urinalysis, such as unexplained hematuria or pyuria
  - Urgency-predominant mixed urinary incontinence (MUI)
  - Elevated post-void residual per clinician judgment
  - High-grade pelvic organ prolapse (POP-Q stage 3 or higher) if SUI is not demonstrated with pelvic organ prolapse reduction
  - Evidence of significant voiding dysfunction
3. Clinicians may perform additional evaluations in patients with the following conditions: (*Expert Opinion*)
  - Concomitant overactive bladder symptoms
  - Failure of prior anti-incontinence surgery
  - Prior pelvic prolapse surgery

## CYSTOSCOPY AND URODYNAMICS TESTING

4. Clinicians should not perform cystoscopy in index patients for the evaluation of SUI unless there is a concern for urinary tract abnormalities. (*Clinical Principle*)
5. Clinicians may omit urodynamic testing for the index patient desiring treatment when SUI is clearly demonstrated. (*Conditional Recommendation; Evidence Level: Grade B*)
6. Clinicians may perform urodynamic testing in non-index patients. (*Expert Opinion*)

## PATIENT COUNSELING

7. In patients wishing to undergo treatment for SUI, the degree of bother that their symptoms are causing them should be considered in their decision for therapy. (*Expert Opinion*)
8. In patients with SUI or stress-predominant MUI who wish to undergo treatment, clinicians should counsel regarding the availability of the following treatment options: (*Clinical Principle*)
  - Observation
  - Pelvic floor muscle training ( $\pm$  biofeedback)
  - Other non-surgical options (e.g., continence pessary)
  - Surgical intervention
9. Clinicians should counsel patients on potential complications specific to the treatment options. (*Clinical Principle*)
10. Prior to selecting midurethral synthetic sling procedures for the surgical treatment of SUI in women, clinicians must discuss the specific risks and benefits of mesh as well as the alternatives to a mesh sling. (*Clinical Principle*)

## TREATMENT

11. In patients with SUI or stress-predominant MUI, clinicians may offer the following non-surgical treatment options: (*Expert Opinion*)
  - Continence pessary
  - Vaginal inserts

- Pelvic floor muscle exercises (PFME) ± biofeedback
12. Clinicians should counsel index patients considering surgery for SUI regarding the efficacy and safety of each of their options, which may include the following: (*Strong Recommendation; Evidence Level: Grade A*)
    - Midurethral sling (retropubic, transobturator, or single-incision sling)
    - Autologous fascia pubovaginal sling
    - Burch colposuspension
    - Bulking agents
  13. In index patients who select midurethral sling surgery, clinicians may offer a retropubic, transobturator, or single-incision sling. (*Conditional Recommendation; Evidence Level: Grade A [retropubic/transobturator midurethral sling]/Grade B [single-incision sling]*)
  14. Clinicians should not place a mesh sling if the urethra is inadvertently injured at the time of planned midurethral sling procedure. (*Clinical Principle*)
  15. Clinicians should not offer stem cell therapy (SCT) for stress incontinent patients outside of investigative protocols. (*Expert Opinion*)

### SPECIAL CASES

16. In patients with SUI and a fixed, immobile urethra who wish to undergo treatment, clinicians may offer pubovaginal slings, retropubic midurethral slings, urethral bulking agents, or adjustable retropubic midurethral slings. (*Expert Opinion*)
17. Clinicians should not utilize a synthetic midurethral sling in patients undergoing concomitant urethral diverticulectomy, repair of urethrovaginal fistula, or urethral mesh excision and stress incontinence surgery. (*Clinical Principle*)
18. Clinicians should strongly consider avoiding the use of mesh in patients undergoing stress incontinence surgery who are at risk for poor wound healing (e.g., following radiation therapy, presence of significant scarring, poor tissue quality). (*Expert Opinion*)
19. In patients undergoing concomitant surgery for pelvic prolapse repair and SUI, clinicians may perform any of the incontinence procedures (e.g., midurethral sling, pubovaginal sling, Burch colposuspension). (*Conditional Recommendation; Evidence Level: Grade C*)
20. Clinicians may offer patients with SUI and concomitant neurologic disease affecting lower urinary tract function (neurogenic bladder) surgical treatment of SUI after appropriate evaluation and counseling have been performed. (*Expert Opinion*)
21. Clinicians may offer synthetic midurethral slings, in addition to other sling types, to the following patient populations after appropriate evaluation and counseling have been performed: (*Expert Opinion*)
  - Patients planning to bear children
  - Diabetes
  - Obesity
  - Geriatric

### OUTCOMES ASSESSMENT

22. In women with severe outlet dysfunction or recurrent or persistent SUI after surgical intervention (e.g., surgical failure), clinicians may offer placement of an obstructing pubovaginal sling (PVS) or bladder neck closure with urinary drainage after counseling regarding the risks, benefits, and alternatives. (*Expert Opinion*)
23. Clinicians or their designees should communicate with patients within the early postoperative period to assess if patients are having any significant voiding problems, pain, or other unanticipated events. If patients are experiencing any of these outcomes, they should be seen and examined. (*Expert Opinion*)
24. Patients should be seen and examined by their clinicians or designees within six months post-operatively. Patients with unfavorable outcomes may require additional follow-up. (*Expert Opinion*)
  - The subjective outcome of surgery as perceived by the patient should be assessed and documented.
  - Patients should be asked about residual incontinence, ease of voiding/force of stream, recent urinary tract infection (UTI), pain, sexual function and new onset or worsened overactive bladder symptoms.
  - A physical exam, including an examination of all surgical incision sites, should be performed to evaluate healing, tenderness, mesh extrusion (in the case of synthetic slings), and any other potential abnormalities.
  - A post-void residual should be obtained.

# INTRODUCTION

## PURPOSE

As stated before, SUI is a common problem experienced by many women. The surgical options for the treatment of SUI continue to evolve; as such, this guideline and the associated algorithm aims to outline the currently available treatment techniques as well as the data associated with each treatment. It should be noted that some of the data included in the analysis involved techniques that are no longer commercially available for reasons not necessarily related to outcomes. Indeed, the Panel recognizes that this guideline will require continued literature review and updating as further knowledge regarding current and future options continues to develop.

## Terminology and Definitions

The prevalence of SUI has been reported to be as high as 49%, depending on population and definition, and it can have a significant negative impact on an individual's QOL and on that of her family and friends.<sup>1-3</sup> While many women choose surgical management for their SUI, the specific options for surgical treatment have evolved over time.<sup>4</sup> The first AUA Female SUI Guideline Panel reviewed available literature up to 1994 while the literature search for the SUI Guideline Panel that directly preceded the present iteration concluded in June 2005.<sup>5</sup> Indeed, the Panel recognized that given the rapidly changing landscape, this guideline would require ongoing literature review and continual updates to keep up with further developments in the management of SUI.

### *INDEX PATIENT*

The index patient for this guideline, as in the previous SUI guideline iterations, is an otherwise healthy female who is considering surgical therapy for the correction of pure stress and/or stress-predominant MUI who has not undergone previous SUI surgery. Patients with low-grade pelvic organ prolapse were also considered to be index patients. However, while the stage of prolapse was often specified in more recent trials, it was not indicated in many of the earlier studies. Where evidence was available, the data is presented separately for index patients and non-index patients. The Panel recognizes that many women who seek surgical correction for SUI do not meet this definition of an index patient. In fact, most of the studies

in the literature do not enroll patients based on this definition of an index patient. Therefore, the Panel felt it was also important to review the literature regarding patients undergoing surgery for SUI that did not meet this definition of an index patient.

### *NON-INDEX PATIENT*

Non-index patients reviewed in this analysis include women with SUI and pelvic prolapse (stage 3 or 4), MUI (non-stress-predominant), incomplete emptying/elevated post-void residual (PVR) and/or other voiding dysfunction, prior surgical interventions for SUI, recurrent or persistent SUI, mesh complications, high body mass index (BMI), neurogenic lower urinary tract dysfunction, and advanced age (geriatric). Finally, the Panel felt it was important to more fully understand the literature regarding the safety of mesh products used in the surgical treatment of SUI and, therefore, included studies of women who had undergone mesh procedures regardless of whether they were index or non-index patients. The Panel also acknowledges that persistent or recurrent SUI following any SUI treatment is not uncommon; however, there is a lack of robust data to substantiate any recommendation from the Panel regarding the management of these patients.

### *DEFINITIONS*

SUI is the symptom of urinary leakage due to increased abdominal pressure, which can be caused by activities such as sneezing, coughing, exercise, lifting, and position change. Though the utility of urethral function assessment remains controversial, some clinicians utilize leak point pressure and others utilize urethral closure pressure. Intrinsic sphincter deficiency (ISD) is often defined as a leak point pressure of less than 60 cm H<sub>2</sub>O or a maximal urethral closure pressure of less than 20 cm H<sub>2</sub>O, often in the face of minimal urethral mobility. Urgency urinary incontinence (UUI) is the symptom of urinary leakage that occurs in conjunction with the feeling of urgency and a sudden desire to urinate that cannot be deferred. Mixed incontinence refers to a combination of SUI and UUI.

## METHODOLOGY

The systematic review utilized to inform this guideline was conducted by a methodology team at ECRI Institute. Determination of the guideline scope and review of the

final systematic review to inform guideline statements was conducted in conjunction with the SUI Panel.

### Panel Formation

The Surgical Treatment of Female Stress Urinary Incontinence Panel was created in 2014 by the American Urological Association Education and Research, Inc. (AUAER). The Practice Guidelines Committee (PGC) of the AUA selected the Panel Chair who in turn appointed the Vice Chair. In a collaborative process, additional panel members, including additional members of the Society of Urodynamics, Female Pelvic Medicine & Urogenital Reconstruction (SUFU) with specific expertise in this area, were then nominated and approved by the PGC. Panel members received no remuneration for their work.

The Surgical Treatment of Female Stress Urinary Incontinence Amendment Panel was created in 2022, by the AUA, to review new literature and update this guideline with up-to-date information. Panel members received no remuneration for their work.

### Searches and Article Selection

A comprehensive search of the literature was performed by the ECRI Institute which included articles published between January 1, 2005 and December 31, 2015. Study designs included systematic reviews, randomized controlled trials (RCTs), controlled clinical trials (CCTs), and observational studies (diagnostic accuracy studies, cohort with and without comparison group, case-control, case series). Three methodologic research analysts reviewed the abstracts identified in the literature search; each article was screened by at least two of the three analysts. Articles that potentially fulfilled the outlined inclusion criteria and potentially answered one or more of the Key Questions specified by the Panel were retrieved in full text for review by the team. For all excluded studies, analysts recorded the reason for exclusion as well as whether the exclusion was based on abstract review or full-text review. To focus the analysis on the most relevant evidence, analysts only considered articles published in full after January 1, 2005 in the English language and reported SUI data for one or more of the Key Questions. An update abstract search was conducted through September 2016, which pulled in an additional 66 abstracts related to the Key Questions of interest.

*Included interventions:* Included interventions were limited to those that were FDA-approved with adequate robust data. Injectable bulking agents (Macroplastique, Coaptite, Contigen [collagen], silicone, Durasphere [carbon coated zirconium beads]); retropubic bladder neck suspensions (Burch colposuspension); midurethral slings (MUS) (retropubic [SPARC, tension-free vaginal tape (TVT), ALIGN, Supris, Advantage, Lynx, Desara, I-STOP, TFS], transobturator [tension-free vaginal tape-obturator (TVT-O), Monarc, ALIGN TO, Obtryx, Aris], Prepubic, Adjustable [Remeex]); pubovaginal slings (PVS) (autologous, allograft, xenograft); artificial urinary sphincter (AUS); single incision (Altis, MiniArc, Ajust, Solyx, SIMS, TVT-Secure)

*Excluded interventions:* Laparoscopic colposuspension\*, Obtape, ProteGen, Gore-Tex, bone-anchor, multifilament, In-Fast, anterior vaginal wall sling, Renessa, stem cell/tissue engineering, adjustable continence therapy, Bulkamid, MMK (Marshall-Marchetti-Krantz), needle suspensions (Stamey, Pereyra, Raz, Gittes), anterior colporrhaphy, Kelly plication.

\*While the Panel acknowledges that a minimally invasive Burch colposuspension may be utilized by some individuals, neither laparoscopic nor robotic Burch colposuspension, specifically, were included due to the lack of sufficient data regarding these approaches in the literature.

*Included comparisons:* Any comparisons of two or more of the included interventions was incorporated, though not all comparisons within a given category (e.g., comparisons of two bulking agents, or comparisons of two retropubic midurethral slings [RMUS]) were included. Additionally, analysts compared bottom-up versus top-down RMUS, as well as outside-in versus inside-out transobturator midurethral slings (TMUS).

The following outcomes are included in this review: QOL questionnaires (symptom, QOL, sexual function, satisfaction, expectation, bother), voiding diaries, stress test, pad test, urodynamics, surgical complications/adverse events, need for retreatment, UITN-based criteria, and complications (e.g., erosion, extrusion, retention, voiding dysfunction, perforation, dyspareunia, obstruction, exposure, de novo urgency, recurrent urinary tract infection [UTI], bleeding, pain, neuropathy, neurovascular or visceral injury, hematoma, infection, hernia, seroma, slow stream). Many studies

reported rates of “success” or “failure,” which was defined differently by different studies. Generally, outcomes were based on a set of variables such as stress tests, patient reports, and the need for retreatment.

Of the 450 publications retrieved for full review, 256 were excluded. The most common reasons for exclusion were RCTs that were a part of already included systematic reviews to avoid duplication.

### Data Abstraction

Information from each included article was extracted by one of three analysts using standard extraction forms. The team lead developed the forms and trained the extractors. The lead reviewed the work of the other extractors and searched for inconsistencies and missing information in the extracted data.

### Risk of Bias Assessment

Because different Key Questions involved different types of evidence, analysts tailored the quality assessments as follows:

- For systematic reviews, analysts rated the quality based on the review authors’ ratings of the quality of their included studies (if review authors did not rate the quality, analysts extrapolated a rating based on their description of study limitations). For diagnostic cohort studies, analysts used the QUADAS-2 instrument.<sup>6</sup>
- In reviewing effectiveness, analysts judged the quality of systematic reviews and RCTs using the same processes as previously discussed.
- For complications, analysts divided the evidence into comparative data (comprising of systematic reviews and RCTs) and non-comparative data (comprising of individual groups from RCTs and non-randomized studies).
- For comparative data, analysts used the same processes as previously discussed. For non-comparative data, analysts considered three items: prospective design, consecutive enrollment, and objective measurement of outcome. If all three were clearly true, the study was high quality; if just one was false or unclear, the study was moderate quality. If two or three were false or unclear, the study was low quality.

- In reviewing contraindications for MUS and indications for injectables, analysts did not assess quality because those questions involve patient enrollment criteria.
- In reviewing preoperative cystoscopy, analysts identified no studies on the effect of preoperative cystoscopy, so no quality assessment was necessary.
- For urodynamics, analysts judged the quality of randomized trials using the Cochrane risk-of-bias instrument.<sup>7</sup>
- For patient factors predicting outcomes, analysts used the Quality in Prognostic Studies (QUIPS) tool.<sup>8</sup>
- In reviewing outcome instruments, analysts did not assess quality since it is not clear what would constitute a high-quality study of instruments utilized to assess such outcomes.
- In reviewing length of follow-up, analysts judged quality solely on the basis of the percentage of enrolled patients who provided data during follow-up. Studies for which all follow-up time points had 85%+ completion were deemed high quality; studies for which any follow-up time point had 60% or less completion were deemed low quality; all others were deemed moderate quality.

### 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.<sup>9</sup>

### 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 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 also can 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.<sup>10</sup> A **Clinical Principle** is a statement for which there may or may not be evidence in the medical literature and that is widely agreed upon by urologists or other clinicians. **Expert Opinion** refers to a statement for which there is no evidence and that is achieved by consensus of the Panel.



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

Evidence Grade	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 (Net benefit or harm comparable to other options)	-Benefits=Risks/Burdens -Best action depends on individual patient circumstances -Future Research is 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 -Net benefit (or net harm) comparable to other options -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 may or may not be evidence in the medical literature		

### Peer Review and Document Approval

The AUA conducted a thorough peer review process in October of 2016. The draft guidelines document was distributed to 93 peer reviewers, 41 of which submitted comments. 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). It was then submitted to the AUA and SUFU Boards of Directors (BODs) for final approval.

In 2023, as a part of the amendment process, the AUA conducted a thorough peer review process. A call for peer reviewers was posted on November 2022 and the draft guideline document was distributed to 70 peer reviewers, 21 of which submitted comments. The Amendment 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 SQC. It was then submitted to AUA BODs for final approval. Panel members received no remuneration for their work.

## Guideline Statements

### PATIENT EVALUATION

**1. In the initial evaluation of patients with SUI desiring to undergo surgical intervention, clinicians should include the following components: (*Clinical Principle*)**

- **Focused history, including assessment of bother**
- **Focused physical examination, including a pelvic examination**
- **Objective demonstration of SUI with a comfortably full bladder (any method)**
- **Assessment of post-void residual urine (any method)**
- **Urinalysis**

**2. Clinicians should perform additional evaluations in patients being considered for surgical intervention who have the following conditions: (*Expert Opinion*)**

- **Inability to make definitive diagnosis based on symptoms and initial evaluation**
- **Inability to demonstrate SUI**
- **Known or suspected neurogenic lower urinary tract dysfunction**
- **Abnormal urinalysis, such as unexplained hematuria or pyuria**
- **Urgency-predominant MUI**
- **Elevated post-void residual per clinician judgment**
- **High-grade pelvic organ prolapse (POP-Q stage 3 or higher) if SUI is not demonstrated by pelvic organ prolapse reduction**
- **Evidence of significant voiding dysfunction**

**3. Clinicians may perform additional evaluations in patients with the following conditions: (*Expert Opinion*)**

- **Concomitant overactive bladder symptoms**
- **Failure of prior anti-incontinence surgery**
- **Prior pelvic prolapse surgery**

The purpose of diagnostic evaluation in incontinent women is to document, confirm, and characterize SUI; to assess the differential diagnosis and comorbidities; and to prognosticate and aid in the selection of treatment. The first goal of diagnostic evaluation is to confirm the diagnosis of SUI and optimally characterize the incontinence. The literature search regarding the optimal evaluation of an index patient yielded two systematic reviews<sup>11,12</sup> and four individual studies that addressed this issue.<sup>13-16</sup> The role of six variables was assessed: history, questionnaires/scales, stress test, Q-tip test, pad test, and urodynamics. Additional tests, including urinalysis, pelvic examination, prolapse assessment, cystoscopy, PVR volume, and voiding diary, yielded no additional meaningful evidence.

**History.** Holroyd-Leduc et al. performed a moderate-quality systematic review of various methods for diagnosing urinary incontinence during office assessment.<sup>11</sup> A meta-analysis of 10 cohort studies with

2,657 patients found that the presence of coughing, sneezing, lifting, walking, or running as initiators of incontinence increased the likelihood of SUI as the cause of urinary leakage, while their absence decreased the likelihood of SUI. Thus, a woman with a positive clinical history had a 74% chance of having SUI, whereas a woman with a negative clinical history had a 34% chance of having SUI. Likewise, in a systematic review by Martin et al. that combined data from 15 cohort studies with 3,545 patients, a woman with a positive clinical history had a 73% chance of having SUI, whereas a woman with a negative clinical history had a 16% chance of having SUI.<sup>12</sup> Thus, the evidence from two moderate-quality meta-analyses suggests that clinical history provides some diagnostic value for patients with signs/symptoms potentially caused by SUI; however, history alone, while helpful, does not definitively diagnose SUI in women.

**Questionnaires.** Eight questionnaires were assessed in two systematic reviews for their ability to diagnose SUI.<sup>11,12</sup> While most questionnaires showed small positive and negative likelihood ratios (LRs) for diagnosing or ruling out SUI, the limited number of studies for each questionnaire resulted in an overall strength of evidence of low. It is important to note that an assessment of bother, regardless of method or questionnaire, is paramount in the decision to operate on an index patient. Since SUI is a condition that impacts QOL (rather than quantity of life), the treatment decisions should be closely linked to the ability to improve bother caused by the symptoms. If bother is minimal, then strong consideration should be given to non-surgical management.

**Stress test.** Two moderate-quality systematic reviews and one additional study evaluated stress tests for diagnosis of SUI using urodynamic evaluations as the reference standard. While stress tests were performed under different protocols (e.g., retrograde filling with 200 mL saline; 20 minutes after catheterization for PVR volume), a positive stress test had a high sensitivity and specificity for detecting SUI on urodynamics. Similar results were obtained in a single study that combined the supine and standing stress test.<sup>17</sup> However, since this combined test was evaluated in only one study, the strength of evidence supporting it is low. Additionally, in a secondary analysis of an RCT by Albo et al., the sensitivity and specificity of the supine empty bladder stress test to predict ISD were 49% and 60%, respectively, suggesting that the supine stress test did not identify ISD.<sup>13</sup>

**Q-tip test.** Holroyd-Leduc et al. included 2 studies with a total of 253 patients that evaluated the Q-tip test, with 1 study using a cutoff angle of 20° and the other 35°.<sup>11</sup> Both studies used urodynamic tests as the reference standard and the pooled positive LR was very small, suggesting that a positive test is unlikely to aid in the diagnosis of SUI. Intuitively, this makes sense, since SUI may exist without urethral hypermobility and vice versa. Thus, moderate strength evidence suggests that a positive Q-tip test has little value for diagnosis of SUI, and this test cannot be recommended by the Panel to diagnose SUI. However, it can provide some potentially useful information regarding the degree of urethral mobility.

**Pad test.** The review by Holroyd-Leduc et al. included a study with 105 patients (Versi et al.)<sup>18</sup> that compared the 48-hour pad test to a reference standard of urodynamic findings. Women with a positive pad test had an 81% chance of having SUI, whereas women with a negative pad test had a 13% chance of having SUI. In this study, however, all patients had either SUI or no incontinence. Thus, the authors concluded that the pad test confirms an incontinence problem, but its role in distinguishing the type of incontinence cannot be commented on.

Martin et al. included two studies in their analysis.<sup>12</sup> One of these was the Versi study, while the study by Jorgensen et al.<sup>19</sup> compared the one-hour pad test to a reference standard of urodynamic findings. The latter study showed a high sensitivity (94%) but low specificity (44%) for diagnosing SUI. These results correspond to women with a positive pad test having a 69% chance of having SUI, and women with a negative pad test having a 15% chance of having SUI. Since each test was evaluated by only one small study, the strength of evidence for both tests are low, and importantly, though a pad test may confirm the presence of incontinence, it does not distinguish the specific type of incontinence.

After performing a history and physical examination, including a pelvic examination with a comfortably full bladder, the diagnosis of SUI may be fairly straightforward in an index patient. The sine-qua-non for a definitive diagnosis is a positive stress test or witnessing of involuntary urine loss from the urethral meatus coincident with increased abdominal pressure, such as with coughing and Valsalva maneuver. If leakage is not witnessed in the supine position, the test may be repeated in the standing position to facilitate the diagnosis. Once the increase in abdominal pressure has subsided, flow

through the urethra should subside as well. Rarely, one may witness urine loss after an increase in intra-abdominal pressure has subsided. In this scenario, the incontinence may be, at least in part, due to an involuntary detrusor contraction (stress-induced detrusor overactivity).

The Panel felt that clinicians should obtain the following details from the history, bladder diary, questionnaires, and/or pad testing:

- Characterization of incontinence (e.g., stress, urgency, mixed, continuous, without sensory awareness)
- Chronicity of symptoms
- Frequency, bother, and severity of incontinence episodes
- Patient's expectations of treatment (e.g., patient-centered goals)
- Pad or protection use
- Concomitant urinary tract symptoms (e.g., urgency, frequency, nocturia, dysuria, hematuria, slow flow, hesitancy, incomplete emptying)
- Concomitant pelvic symptoms (e.g., pelvic pain, pressure, bulging, dyspareunia)
- Concomitant gastrointestinal symptoms (e.g., constipation, diarrhea, splinting to defecate)
- Obstetric history (e.g., gravity, parity, method of delivery)
- Previous treatments for incontinence (e.g., behavioral therapy, Kegel exercises/pelvic floor muscle training, pharmacotherapy, surgery)
- Previous pelvic surgeries
- Past medical history (e.g., hypertension, diabetes, history of pelvic radiation)
- Current and past medications
- Fluid, alcohol, and caffeine intake
- Menopausal status

Additionally, the physical examination of an index or non-index patient should include the following components:

- Focused abdominal examination
- Evaluation of urethral mobility (any method)
- Supine and/or standing stress test with comfortably full bladder
- Assessment of pelvic prolapse (any method)
- Assessment of vaginal atrophy/estrogenization status

- Focused neurologic examination

Diagnostic evaluations that should be performed in the index or non-index patient include the following:

- Urinalysis
- PVR

The presence of microscopic hematuria may warrant additional evaluation with upper tract imaging and cystoscopy. The assessment of PVR may alert the clinician to the potential for incomplete bladder emptying. Several points deserve mention. First, the reliability of a single elevated PVR value for predicting emptying dysfunction remains in question, just as a single low PVR value does not rule out the presence of incomplete emptying. Second, the threshold value of a significant PVR is similarly undefined. Finally, a persistently elevated PVR does not characterize the cause of impaired emptying, but rather indicates the need for further evaluation. Additionally, an elevated PVR in the presence of SUI may impact patient counseling regarding surgical interventions and patient expectations. Elevated PVR may be an indication of hypocontractility of the bladder and may put a patient at risk for retention after treatment for SUI. Consideration of the relationship between incomplete bladder emptying and UTI should be considered, and a urinalysis with culture as indicated should be obtained in patients with elevated PVR in the face of symptoms of a UTI.

The second goal of a diagnostic evaluation in a woman with SUI is to assess the differential diagnosis of incontinence and evaluate the impact of coexisting conditions. The differential diagnosis of SUI includes other causes of urethral incontinence, such as overflow incontinence (a clinical diagnosis) and detrusor overactivity incontinence, low bladder compliance, and stress-induced detrusor overactivity (urodynamic diagnoses). Other anatomic findings such as pelvic organ prolapse and number and location of ureteral orifices can be diagnosed by physical examination and cystoscopy, respectively. Similarly, additional functional conditions, such as urethral obstruction and impaired or absent contractility, can be identified via urodynamics testing, including cystometry, non-invasive uroflow, pressure-flow study, and PVR assessment. Urinary incontinence may also occur due to a urethral diverticulum, urinary fistula, or an ectopic ureter. These entities are often suspected on the basis of history and examination, but generally

require cystoscopy and other urinary tract imaging for confirmation.

Certain coexistent conditions may influence surgical technique, impact the outcomes of treatment, and influence the nuances of patient counseling. For example, a patient with MUI who has a large PVR volume and detrusor underactivity might be counseled that her urgency symptoms may persist and that there is a potential for urinary retention following surgical treatment of SUI. Furthermore, surgical technique might be tailored based on some anatomic features and the presence of concomitant urinary urgency and UUI.

The third goal of the diagnostic evaluation is to aid in prognosis and selection of treatment. There are few facts and many opinions about predicting the outcome of surgery based on the conditions described above. However, few clinicians would disagree that operations for SUI should be confined to those who have demonstrable SUI, including occult SUI demonstrable only after reduction of pelvic organ prolapse. Nevertheless, an understanding of the specific concomitant conditions facilitates individualized treatment planning and informed consent. It also provides the surgeon information with which to formulate a sense regarding potential outcome and possible complications such as incomplete bladder emptying, persistent, worsened, or de novo urgency/UUI, and recurrent sphincteric incontinence. Urodynamic evaluation may be of assistance in elucidating complex presentations of incontinence.

Additional evaluation should also be performed in women with suspected neurogenic etiology for their incontinence or in women with evidence of dysfunctional voiding. Women who present with persistent or recurrent SUI after previous definitive surgical intervention may also benefit from additional evaluation. Likewise, in select patients with symptomatic SUI in whom SUI cannot be demonstrated, additional evaluation may be beneficial. It must be mentioned that the need for further evaluation of any given patient depends upon a number of additional factors, including the clinician's degree of certainty and comfort regarding the accuracy of the diagnosis, the degree of both the symptoms are causing the patient, the impact that further studies will have on diagnosis, and treatment risks, options, and likely outcomes. The desire and willingness of the patient to undergo further studies should also be taken into consideration.

## CYSTOSCOPY AND URODYNAMICS TESTING

### 4. Clinicians should not perform cystoscopy in index patients for the evaluation of SUI unless there is a concern for urinary tract abnormalities. *(Clinical Principle)*

The consensus of the Panel is that there is no role for cystoscopy in the evaluation of patients considering surgical therapy for SUI who are otherwise healthy and have a normal urinalysis. However, if these patients elect surgical therapy, intraoperative cystoscopy should be performed with certain surgical procedures (e.g., midurethral or pubovaginal fascial slings) to confirm the integrity of the lower urinary tract and the absence of foreign body within the bladder or urethra.

Cystoscopy should be performed as indicated in patients in whom bladder pathology is suspected based on history or concerning findings on physical exam or urinalysis. In particular, cystoscopy should be performed in patients found to have microhematuria on urinalysis with microscopy. A cystoscopy should also be performed in patients in whom there is a concern for structural lower urinary tract abnormalities.

The consensus of Panel members is that cystoscopy should be performed in patients who have a history of prior anti-incontinence surgery or pelvic floor reconstruction, particularly if mesh or suture perforation is suspected. This suspicion may be based upon new onset of lower urinary tract symptoms, hematuria, or recurrent UTI.

### 5. Clinicians may omit urodynamic testing for the index patient desiring treatment when SUI is clearly demonstrated. *(Conditional Recommendation; Evidence Level: Grade B)*

Urodynamics testing is not necessary in otherwise healthy patients during initial patient evaluation or to determine outcomes after surgery. The role of urodynamics in patients with uncomplicated SUI (pure SUI or stress-predominant MUI) undergoing surgery was evaluated in the Value of Urodynamic Evaluation (VALUE) trial.<sup>15</sup> The investigators in this large multicenter RCT compared office evaluation alone to urodynamics in addition to office evaluation in 630 patients and showed no difference in outcomes as measured by clinical reduction in complaints

measured by the Urogenital Distress Inventory and the Patient Global Impression of Improvement (PGI-I).

Another RCT did show that urodynamics in addition to office evaluation lead to better outcomes than office evaluation alone.<sup>16</sup> However, the conclusions of this study were weakened by the low enrollment of only 72 patients, 12 of whom were excluded from the urodynamics arm because of “unfavorable parameters” for surgery, including detrusor overactivity, and valsalva leak point pressure (VLPP) less than 60 cm H<sub>2</sub>O.

### **6. Clinicians may perform urodynamic testing in non-index patients. (*Expert Opinion*)**

In certain patients, urodynamic testing should be considered. Urodynamic testing may be performed at the urologist’s discretion in certain non-index patients, including but not limited to those patients listed below to facilitate diagnosis, treatment planning, and counseling:

- History of prior anti-incontinence surgery
- History of prior pelvic organ prolapse surgery
- Mismatch between subjective and objective measures
- Significant voiding dysfunction
- Significant urgency, UUI, overactive bladder (OAB)
- Elevated PVR per clinician judgment
- Unconfirmed SUI
- Neurogenic lower urinary tract dysfunction

## **PATIENT COUNSELING**

### **7. In patients wishing to undergo treatment for SUI, the degree of bother that their symptoms are causing them should be considered in their decision for therapy. (*Expert Opinion*)**

Since SUI is a condition that impacts QOL, treatment decisions should be closely linked to the ability of any intervention to improve the bother caused to the patient by her symptoms. If the patient expresses minimal subjective bother due to the SUI, then strong consideration should be given to conservative, non-surgical therapy. To this point, patients should be counseled on the risks, benefits, and alternatives to any intervention they may choose in addition to the concept that the primary goal of treatment is to improve QOL.

### **8. In patients with SUI or stress-predominant MUI who wish to undergo treatment, clinicians should counsel regarding the availability of the following treatment options: (*Clinical Principle*)**

- **Observation**
- **Pelvic floor muscle training (± biofeedback)**
- **Other non-surgical options (e.g., continence pessary)**
- **Surgical intervention**

The Panel believes that patients should be offered all of the above-mentioned options before a treatment decision is made. There are a variety of factors that impact the patient’s final decision with regard to treatment. Observation is appropriate for patients who are not bothered enough to pursue further therapy, not interested in further therapy, or who are not candidates for other forms of therapy. Pelvic floor muscle training and incontinence pessaries are appropriate for patients interested in pursuing therapy that is less invasive than surgical intervention. Pelvic floor physical therapy can be augmented with biofeedback in the appropriate patient. The patient must be willing and able to commit to regularly and consistently performing pelvic floor training for this to be successful.

Clinicians should educate the patient regarding appropriate surgical options before treatment decisions are made. The primary categories of surgical options include bulking agents, colposuspension, and slings. Patients should be made aware that slings can be performed with or without the use of synthetic mesh.

Discussing these various treatment options and their potential risks and benefits allows the patient to combine this information with her own goals for treatment in order to make an informed decision.

### **9. Clinicians should counsel patients on potential complications specific to the treatment options. (*Clinical Principle*)**

The potential complications related to a given intervention can play a significant role in the decision-making process for patients considering treatment for SUI. Accordingly, clinicians need to educate and counsel patients regarding possible complications, some of which are non-specific and others that are unique to the various types of SUI surgery. Patients should be aware that with any intervention there is a risk of continued symptoms of SUI immediately after the procedure or recurrent SUI at a later

time that may require further intervention.

Patients should be made aware of possible intra-operative risks that can occur with surgery to correct SUI. These risks include but are not limited to bleeding, bladder injury, urethral injury, inherent risks of anesthesia, and the procedure itself.

Voiding dysfunction can be seen after any type of intervention for SUI and may involve both storage and emptying symptoms. There is a risk of *de novo* storage symptoms (e.g., urgency, frequency and/or UUI) or worsening of baseline OAB symptoms for patients with MUI or SUI with urinary urgency. Depending on the symptoms, this may require one of the many options available to treat OAB or, if the symptoms are thought to be related to post-operative obstruction, may require sling incision, sling loosening, or urethrolisis. Obstruction resulting in urinary retention is also a potential complication and would require intermittent catheterization, indwelling Foley catheter drainage, and possible sling incision, sling loosening, or urethrolisis if this does not resolve spontaneously.

Complaints of abdominal, pelvic, vaginal, groin, and thigh pain can be seen after sling placement. In addition to generalized pain, patients should be counseled about the risk of pain associated with sexual activity. Symptoms of dyspareunia can occur following pelvic floor reconstructive surgery.

In patients who are considering a synthetic mesh sling, counseling regarding the risk of transvaginal mesh placement is imperative. Risks include mesh exposure into the vagina and/or perforation into the lower urinary tract, either of which could require additional procedures for surgical removal of the involved mesh and, if necessary, repair of the lower urinary tract.

UTI can occur following any intervention for SUI, and the incidence appears to be highest in the immediate postoperative period (within three months). Patients undergoing autologous fascial sling have the additional risk of possible wound infection, seroma formation, or ventral incisional or leg hernia depending on the fascial harvest site (e.g., rectus fascia versus fascia lata, respectively), and pain at the harvesting site.

### **10. Prior to selecting midurethral synthetic sling procedures for the surgical treatment of SUI in women, clinicians must discuss the specific risks and benefits of mesh as well as the alternatives to a mesh sling. (*Clinical Principle*)**

The Panel believes that patients considering surgical intervention should be counseled regarding the risks and benefits of the use of synthetic mesh to treat SUI. This detailed discussion should make clear to the patient the possible risks, benefits, and alternatives of MUS. The focus of the discussion should not be on the superiority of one technique over another; indeed, the literature does not definitively suggest that MUS is more or less effective to alternative interventions, such as PVS or colposuspension.

The focus should be on the benefits, the potential risks, and the FDA safety communication regarding MUS, thereby allowing the patient to make a goal-oriented, informed decision as to how she would like to approach her SUI treatment. MUS is the most studied surgical treatment for female SUI. Other than bulking agents, MUS is also the least invasive surgical option to treat SUI. Effectiveness is well documented in the short- and medium-term with increasing evidence supporting its effectiveness in the long-term as well.<sup>20</sup> This volume of literature and length of follow-up is not available for PVS or colposuspension; however, as mentioned above, there is no conclusive evidence that any one of the available sling procedures is superior or inferior to the others regarding efficacy.

All surgical interventions (e.g., MUS, PVS, colposuspension) to treat SUI have potential adverse outcomes, such as continued incontinence, voiding dysfunction, urinary retention, pain, and dyspareunia. Clinical outcomes appear to be worse for patients who have had prior surgery for SUI, irrespective of the approach. Patients considering MUS should be made aware of the prior FDA public health notifications regarding the use of transvaginal mesh to treat SUI or pelvic organ prolapse and be advised of possible mesh-related risks, such as vaginal exposure (which can also be associated with dyspareunia) and perforation into the lower urinary tract, or other neurovascular or visceral symptoms. Pre-operative counseling regarding MUS mesh complications results in significantly reduced levels of patient concern, greater willingness to proceed, and higher rates of satisfaction.<sup>21,22</sup> There does appear to be

a greater risk of mesh erosion associated with diabetes and a history of smoking;<sup>23-25</sup> Other factors that have been suggested to portend an increased risk of mesh erosion on multivariate analysis include older age, >2 cm vaginal incision length, and previous vaginal surgery.<sup>26</sup> However, a review of the literature did not find an association between obesity, parity, menopausal status, or use of hormone replacement and mesh-related adverse events.

An additional important resource for patients and clinicians is the joint SUFU/American Urogynecologic Society (AUGS) position statement regarding mesh (<https://sufuorg.com/resources/mus.aspx>).

### TREATMENT

#### 11. In patients with SUI or stress-predominant MUI, clinicians may offer the following non-surgical treatment options: (*Expert Opinion*)

- **Continence pessary**
- **Vaginal inserts**
- **Pelvic floor muscle exercises (PFME) ± biofeedback**

Patients may opt for the use of conservative measures to treat stress or stress-predominant urinary incontinence. These may include use of urethral plugs, continence pessaries or vaginal inserts. In addition, there are exercises that may aid patients with stress incontinence or stress-predominant mixed incontinence. These may include pelvic floor muscle exercises (PFME) with or without biofeedback. The Panel believes these are low-risk options to consider in the treatment of patients. The literature supports the use of this modality as conservative therapy for women with SUI and UUI. The addition of dynamic lumbopelvic stabilization (DLS) in short pelvic floor muscle and lumbar muscle resistance training has been shown to add to the efficacy of PFME alone in a recent small RCT.<sup>27</sup> In this study, at longer follow-up (90 days), patients in the PFME and DLS group had improved day and night urine loss and lower severity of urine loss as well as improved QOL than the group with just PFME alone ( $p < 0.05$ ). This difference was not seen at the immediate completion of training, but effect size increased with time.

#### 12. Clinicians should counsel index patients considering surgery for SUI regarding the efficacy and safety of each of their options, which may include the following: (*Strong Recommendation; Evidence Level: Grade A*)

- **Midurethral sling (retropubic, transobturator, or single-incision sling)**
- **Autologous fascia pubovaginal sling**
- **Burch colposuspension**
- **Bulking agents**

#### 13. In index patients who select midurethral sling surgery, clinicians may offer a retropubic, transobturator, or single-incision sling. (*Conditional Recommendation; Evidence Level: Grade A [retropubic/transobturator midurethral sling]/Grade B [single-incision sling]*)

Several surgical options exist for the treatment of SUI. The choice of intervention should be individualized based upon the patient's symptoms, the degree of symptom bother, patient goals and expectations, and the risks and benefits for a given patient. Although most of these procedures have been available for years, limited comparative data between these broad treatment categories exist to assist the clinician in recommending a therapy. Nevertheless, patients should be offered all viable options for treatment of their stress incontinence, with a discussion that includes detailed counseling regarding the risks, benefits, alternatives to each approach, and the safety and efficacy profiles of the various choices.

#### MUS

MUS may be characterized as retropubic slings (RMUS; top-down or bottom-up), transobturator slings (TMUS; inside-out or outside-in), single incision slings (SIS), or adjustable slings. Long-term data exist for several of these approaches but vary in their duration of follow up in both comparative and non-comparative analyses. Furthermore, it remains important to assess the manner in which success was defined in each of these studies as definitions vary between series.



### RMUS

Initially introduced as a bottom-up retropubic approach in the late 1990s, the TVT™ is arguably the most widely studied anti-incontinence procedure, with data that exceeds 15 years follow-up.<sup>20, 28</sup> Success rates are reported to be between 51% and 87%. The TVT™ has also been the subject of numerous comparative studies. The retropubic top-down versus bottom-up approach was evaluated in two publications, one systematic review<sup>20</sup> and one additional study.<sup>29</sup> Ford et al. included 5 trials with a total of 631 women with SUI or stress-predominant MUI symptoms that compared these 2 procedures.<sup>20</sup> The average study quality was moderate. Definitive superiority for one approach over the other has not been found; however, results favored the bottom-up approach in some meta-analyses. In these studies, a significant reduction in bladder or urethral perforation, voiding dysfunction, and vaginal tape erosion was noted with the bottom-up approach. Meta-analyses regarding other adverse events (perioperative complications, *de novo* urgency or urgency incontinence, and detrusor overactivity) were inconclusive due to wide confidence intervals. Accordingly, the Panel does not support one retropubic method over another.

### TMUS

The TMUS was developed in an effort to simplify and decrease the complication profile noted with the retropubic approach and can be placed using either outside-in or inside-out techniques. Evidence suggests that effectiveness is similar between these approaches. Single and multicenter prospective and retrospective studies have reported success rates ranging from 43% to 92% with follow-up of up to 5 years.<sup>20</sup>

### RMUS versus TMUS

With the prospect that the TMUS would have an improved safety profile over the RMUS, comparative efficacy and safety analyses between the sling types were performed. Overall, in aggregate, most short-term analyses that compared RMUS and TMUS found them to be equivalent. However, several long-term comparisons have borne out a favorable therapeutic advantage of RMUS over TMUS. The Trial of Mid-urethral Slings (TOMUS) compared the short (one- and two-year) and long (five-year) outcomes of RMUS and TMUS.<sup>30,41</sup> Short-term analyses demonstrated statistical equivalence for objective treatment success between the two procedures; however,

slight advantages toward the RMUS were seen with longer follow-up (five years).<sup>30</sup>

### Efficacy

Regarding therapeutic outcomes specifically, 5 systematic reviews<sup>20,31-34</sup> and 11 RCTs were reviewed by the original Panel. Of the 11 RCTs, 4 enrolled only index patients,<sup>35-38</sup> and 7 enrolled patients with MUI or did not clearly define enrollment.<sup>39-45</sup>

Of the four that were specifically limited to index-patients, one indicated equivalence,<sup>35</sup> and three<sup>36,37,38</sup> were inconclusive. In the remaining seven trials, two found equivalence,<sup>39,42</sup> four were inconclusive,<sup>41,43,44,45</sup> and one<sup>40</sup> reported a greater risk of failure with TMUS versus RMUS.<sup>40</sup> However, it should be noted that all patients in this trial had ISD based on either VLPP or maximum urethral closure pressure, which may limit its applicability. The meta-analysis by Ford et al.<sup>20</sup> also demonstrated a significantly higher rate of repeat incontinence surgery within five years in the TMUS group.

The largest systematic review included 55 trials with a total of 8,652 patients with SUI or stress-predominant MUI.<sup>20</sup> The rates of subjective and objective cure were similar between TMUS and RMUS in the short-term (up to one year). There were fewer and less robust studies with medium-term (1 to 5 years) and long-term (>5 years) follow-up with subjective cure rates ranging from 43% to 92% for TMUS and 51% to 88% for RMUS. The review by Sun et al.<sup>31</sup> used more stringent inclusion criteria than that performed by Ford et al.<sup>20</sup> and included 16 RCTs with a total of 2,646 women with SUI or MUI. The RCTs in that review included at least 40 patients, no more than 15% loss to follow-up, and objective cure as an outcome. They performed separate meta-analyses of studies that evaluated only patients with isolated SUI (seven trials; index patients) and studies that evaluated patients with either isolated SUI or MUI (nine trials; mixed index and non-index patients). The review was inconclusive with regard to efficacy.

Validated QOL and incontinence severity measures were assessed by Fan et al.<sup>33</sup> in seven RCTs that compared RMUS (TVT) and TMUS (TVT-O). A meta-analysis of 6 trials measuring Urogenital Distress Inventory scores found a statistically significant weighted mean difference favoring TMUS slings (2.28, 95% CI: 1.77 to 2.80). Meta-analyses of other instrument scores (IIQ, VAS, ICIQ-SF, and UISS) found no significant between-group

differences, but the 95% confidence intervals were all too wide to rule out the possibility of a difference between treatments. Schimpf et al.<sup>34</sup> found no significant difference in patient satisfaction between TMUS or RMUS.

In the past 5 years, 16 studies (9 systematic reviews<sup>46-52,59,78</sup> and 7 RCTs<sup>53-58,60</sup>) have examined the comparative effectiveness of RMUS or TMUS for women with SUI. Of these studies, 12 compared RMUS to TMUS or TVT to transobturator tape (TOT) or other anti-incontinence surgeries against either RMUS or TMUS in index patients.

Four studies<sup>46,51,53,60</sup> directly compared a RMUS to TMUS. Specifically, regarding therapeutic outcomes, the systematic review by Juliato et al.<sup>46</sup> saw no difference between groups with regard to patient satisfaction, QOL, and variable objective and subjective cure definitions, both overall and with intent to treat analysis. Similarly, a follow-up report on a previously reported RCT by Ross et al.<sup>60</sup> showed no statistically significant differences between the groups regarding problematic SUI in the prior 7 days or changes in urinary distress inventory, short form (UDI-6), incontinence impact questionnaire, short form (IIQ-7), and the pelvic organ prolapse/urinary incontinence sexual questionnaire (PISQ-12) scores from baseline. The only parameter that approached significance was problematic urgency incontinence in the prior 7 days, and this favored TOT over TVT (4.9% and 13.5%, respectively,  $p=0.05$ ). The RCT by Palos et al.<sup>53</sup> reported non-inferiority of the 2 approaches for all outcomes evaluated with the exception of a higher retention rate with the retropubic group, though generalizability was limited by the study's moderate sample size of 92.

Two systematic reviews<sup>48,78</sup> contained comparisons of other anti-incontinence procedures against patients receiving RMUS procedures. Saraswat et al.,<sup>48</sup> found comparable cure rates for traditional and RMUSs, and these interventions were favored over all other included comparisons. Imamura et al.<sup>78</sup> performed a network meta-analysis to assess all available surgical treatments to provide information on which may be best overall. The authors found greater improvements in cure rate and incontinence for RMUS over TMUS; however, all other comparisons (traditional sling and open colposuspension) saw no difference.

Several studies have specifically compared TVT to TOT or TVT-O. An RCT by Tammaa et al.<sup>57</sup> enrolled 569 total patients and found no difference for all outcomes of

interest at 5-year follow-up. A systematic review by Huang et al.<sup>52</sup> favored TOT over TVT for hospital stay and operating time, while all other outcomes displayed no difference. A long-term follow-up to a previously published RCT by Zhang et al.<sup>58</sup> demonstrated no difference for all outcomes.

Overall, while some data have suggested a lack of durability of TMUS versus RMUS, others have shown stable and similar subjective and objective outcomes between the TVT and TVT-O at long-term follow-up. Zhang et al.<sup>58</sup> reported follow-up on a previously published RCT of 120/140 (85.7%) patients at a mean of 95 months. The objective cure rates for TVT and TVT-O remained comparable at 79.3% and 69.4%, respectively, with no difference in the PISQ-12 scores and persistent improvement in the pelvic floor impact questionnaire (PFIQ-7) scores ( $p<0.001$ ).

### Adverse Events

Significant differences in adverse events were identified in both the systematic review and in individual RCTs. While the systematic reviews did not provide enough information on patient characteristics to separate index from non-index patients, seven of the individual RCTs reviewed reported data on index patients only.

Ford et al.<sup>20</sup> found more major vascular or visceral injuries, bladder or urethral perforations, voiding dysfunction, and suprapubic pain with the RMUS; while groin pain, repeat incontinence surgery between one and five years, and repeat incontinence surgery after more than five years were more likely to occur with the TMUS. Sun et al.<sup>31</sup> noted higher rates of bladder perforation, hematoma, and voiding dysfunction with the RMUS and higher rates of thigh/groin pain with the TMUS. While most other adverse event outcomes were inconclusive due to wide confidence intervals, *de novo* urgency or UUI were equivalent between the two procedures.

In the Juliato study,<sup>46</sup> with the exception of a 3-fold higher mesh extrusion rate in the TMUS over the RMUS, rates of *de novo* pain, *de novo* urinary urgency, post-void residual >100cc, and UTIs did not differ between the 2 approaches. A systematic review by Lian et al.<sup>59</sup> evaluating 9,223 cases from 33 trials reported a higher incidence of intraoperative vaginal perforation with the TMUS versus the RMUS at 2.1% and 0.89%, respectively, perhaps providing an explanation for the tape exposure findings. Ross et al.<sup>60</sup> similarly favored

retropubic TVT over transobturator tape regarding vaginally palpable tape in a follow-up on a previously reported RCT. Still, the composite outcomes including mesh exposure, urinary retention, repeat anti-incontinence surgery, and moderate to severe pelvic pain revealed no difference between the groups at five-year follow-up.

### **Summary**

In summary, the selection of RMUS versus TMUS should be determined by the surgeon based on comfort or preference, and degree of urethral mobility after discussion with the patient regarding the difference in risks of adverse events between each procedure. The TMUS bears a lower risk of intraoperative injury and voiding dysfunction, while the RMUS has lower rates of short-term groin pain and need for repeat stress incontinence surgery. As experience with the MUS has increased, the literature has borne out no clear frontrunner. Although, the general gestalt has seen movement toward favoring the relative durability of the RMUS over the TMUS.<sup>30</sup> Nevertheless, while some randomized studies conclude in favor of the retropubic approach,<sup>50</sup> others support the transobturator approach,<sup>52</sup> and still others determine that the two approaches are essentially equivalent.<sup>36</sup> The universal conclusion remains that well-conducted long-term RCTs are needed.

*a. When performing TMUS in women with stress-predominant urinary incontinence surgeons may perform either the in-to-out or out-to-in TMUS technique.*

Data from ten RCTs of both index and non-index patients are consistent in finding equivalence between the two approaches. Ford et al.<sup>20</sup> performed a meta-analysis that included 10 trials with a total of 1,463 women with SUI or MUI with stress-predominant symptoms that compared the outside-in and inside-out TMUS. Subjective and objective cure at various follow-up times indicated equivalence between the procedures. There was 1 trial that demonstrated a significant mean difference of 16.54 (95% CI: 4.84 to 28.24) in IIQ-7 scores favoring the inside-out procedure. Adverse events were different with vaginal perforation occurring more frequently with the outside-in approach and voiding dysfunction occurring more frequently with the inside-out approach. Four additional RCTs of moderate and high quality were consistent with the conclusion of equivalence between the two approaches.<sup>37,61-64</sup>

*b. When performing RMUS in women with stress-predominant urinary incontinence surgeons may perform either the bottom-up or the top-down approach.*

Most studies comparing the top-down to the bottom-up technique demonstrated equivalence or were inconclusive. The systematic review by Ford et al.<sup>20</sup> detected a statistically significant difference in the subjective cure rates favoring the bottom-up approach; however, the relative risks (RRs) for both the subjective and objective cure rates fell within the equivalence range. The top-down approach had higher rates of bladder and urethral perforation, voiding dysfunction, and vaginal tape erosion while an analysis of other adverse events such as perioperative complications, *de novo* urgency or urgency incontinence, and detrusor overactivity was inconclusive due to wide confidence intervals. Lord et al.<sup>29</sup> identified higher rates of urinary retention with the top-down approach (6.5%) versus the bottom-up approach (0%). Panelists felt that the limited evidence from one review demonstrating a small increase in adverse events with the top-down approach was insufficient to make a recommendation favoring the bottom-up approach over the top-down approach.

*c. A MUS may be considered in the non-index patient or in the patient with ISD after appropriate evaluation and counseling.*

Very few of the meta-analyses or individual studies restricted the enrollment to index patients. Studies that restricted to index patients had similar comparative outcomes to those studies that included some non-index patients. Therefore, while there are no evidence-based recommendations that the Panel can make regarding placement of a MUS in patients who do not fall into the definition of an index patient, the Panel feels that it is important to consider several factors when deciding whether or not to proceed with a MUS. Considerations may include prior pelvic floor reconstruction and technique, temporal relationship to any prior surgery, presence or absence of pelvic prolapse, degree of urethral mobility, concomitant and urinary urgency, or urgency incontinence symptoms.

Regarding patients with ISD (typically defined as VLPP <60 cm water and/or minimal urethral hypermobility), 1 review evaluated the comparative efficacy of RMUS and TMUS in 8 RCTs with a total of 399 patients with ISD-associated SUI or MUI. A meta-analysis of subjective cure

rate at up to 5-years follow-up found a statistically significant difference favoring RMUS, although the effect size was quite small and the 95% confidence interval fell within the range of equivalence (RR: 0.88; 95% CI: 0.80 to 0.96). A meta-analysis of objective cure rate at up to 5 years found no statistically significant between-group difference, but the effect size and 95% confidence interval was similar to that for subjective cure (RR: 0.90; 95% CI: 0.79 to 1.03). They also meta-analyzed 2 RCTs with 183 patients with ISD-associated SUI or MUI that performed QOL assessment.<sup>32</sup> In general, this review found equivalent effectiveness between the two treatments. However, they found that repeat incontinence surgery within five years was significantly lower in the RMUS group. One RCT<sup>40</sup> confirmed the conclusion of Ford et al.<sup>20</sup> that the rate of repeat sling surgery within one to five years is lower (better) after RMUS than after TMUS.

Lastly, a systematic review by Kim et al.<sup>51</sup> saw favorable outcomes for both subjective and objective outcomes for retropubic TVT over TOT in non-index patients, specifically in patients in the subpopulations including obesity, ISD, persistent SUI after MUS, and prolapse.

### SIS

In another effort to simplify MUS, the SIS was introduced as a less invasive, lower morbidity surgery with the potential to maintain the efficacy of the existing MUS techniques. SIS products were introduced into the market in 2006 and have continued to evolve over time. Initial studies comparing SIS to MUS showed significantly better outcomes with MUS but utilized a SIS product (TVT-Secur) that was removed from the market due to poor outcomes. Long-term data is now emerging, and several groups have demonstrated non-inferiority of the SIS to the TMUS.

Updated evidence comprises of an observational study evaluating the subjective outcomes of needle-less SIS, and 11 controlled trials (4 non-inferiority: 3 randomized and 1 non-randomized) comparing the efficacy and safety of SIS when compared with either the transobturator (TOT) or the standard MUS (SMUS: TVT, TVT-O, TOT).

Three studies<sup>65-67</sup> directly compared patients receiving SIS to standard MUS. An updated systematic review and meta-analysis of randomized controlled trials comparing SIS, except TVT-Secur, with TVT or TOT MUS with follow-up duration up to 60 months, identified similar subjective cure rates between groups. However, objective

cure rates were inferior with SIS compared to SMUS. In terms of operative parameters, Kim et al.<sup>66</sup> reported reduced intraoperative blood loss, operative time, immediate postoperative pain, and voiding dysfunction with the use of SIS versus MUS. Two RCTs compared outcomes between AJUST® (SIS) versus MUS on two different follow-up periods from the same RCT. They identified equivalent objective cure rates at 12 months and equivalent subjective cure rates at 12 and 36 months follow-up.<sup>65,67</sup> None of the studies reported on RMUS specifically.

There were 10 controlled trials (9 randomized and 1 non-randomized),<sup>67-75,81</sup> addressed the comparison of the TMUS with the SIS with follow-up ranging from 12 to 36 months. While definitions of objective and subjective cure were variable, and a variety of SIS were utilized, SIS appear to be comparable to TOT in terms of treatment success and adverse events.

Nambiar et al.<sup>76</sup> included 20 trials that compared adverse events between SIS, and either inside-out or outside-in TMUS. After removing the 8 trials that utilized TVT-Secur as the SIS, the remaining 12 trials were inconclusive with regard to efficacy. While they did not show any differences in subjective or objective cure rates, the confidence intervals were too large to rule out a significant difference.

Zhang et al.<sup>77</sup> used more specific selection criteria, including five RCTs that compared the SIS-AJUST sling to TVT-O or TOT slings. They demonstrated equivalence in both objective and subjective cure rates.

Fan et al.<sup>33</sup> assessed the impact on validated incontinence impact instruments using eight RCTs that compared SIS (two used TVT-Secur) to TVT-O slings. A meta-analysis of 5 trials using the PISQ-12 found significantly higher sexual function scores in the SIS group. One trial using the KHQ found significantly greater improvement in the total KHQ score in the TMUS group, while the other instruments yielded inconclusive results as they did not find a significant difference between treatments.

A systematic review comparing multiple surgical interventions for women with SUI<sup>78</sup> showed favorable outcomes for SIS over TMUS for tape and mesh exposure. The authors also noted favorable pain outcomes for SIS over RMUS.

A pragmatic, noninferiority, RCT comparing SIS versus a standard MUS with a follow-up of 36 months confirmed noninferiority of SIS for subjective cure rates. Patients also had similar rates of groin/thigh pain. However, mesh exposure, dyspareunia, and repeat surgery were higher in the SIS group.<sup>79</sup> In another prospective, non-randomized, parallel cohort study with 36 months of follow-up comparing the Solyx SIS to TOT (Obtryx II) MUS, composite objective and subjective success, mesh-related complications, and adverse events were similar between groups.<sup>70</sup> In an observational study (retrospective, single arm), at a mean follow-up of 54 months from SIS procedure, subjective improvement and subjective cure was observed in 75% and 60.8% of the patients (n=190), respectively.<sup>80</sup> Complications including recurrent UTI (5.3%), UTI (4.8%), urinary retention (4.3%), pain (3.5%), sling exposure (2.5%), de novo urgency (2.5%), and de novo UUI (2.0%) were reported. Sling failure was observed in 10% of the patients (76% of those failures occurring in the first 2 years post-surgery).<sup>80</sup>

Most studies found no significant differences between SIS and TOT. However, one RCT<sup>81</sup> and Kim et al.<sup>51</sup> found less immediate postoperative pain with SIS compared to TOT and MUS, respectively.

A meta-analysis of postoperative groin pain found a significant reduction favoring the SIS-AJUST sling. Meta-analyses for other adverse events (including postoperative pain, lower urinary tract injuries, postoperative voiding difficulties, de novo urgency and/or worsening of preexisting surgery, vaginal tape erosion, and repeat continence surgery) were inconclusive.

Five additional publications compared SIS other than TVT-Secur with the TMUS. Franco et al.<sup>82</sup> found inconclusive results except that pain was less after Contasure-Needleless (C-NDL) when compared to TMUS. Foote<sup>83</sup> and Schellart et al.<sup>84</sup> also found less pain with the MiniArc SIS versus the TMUS and inconclusive results for other adverse events. Mostafa et al.<sup>85</sup> and Schweitzer et al.<sup>86</sup> compared TVT-O to SIS-AJUST and found comparative adverse event rates to be inconclusive.

The Panel feels that with updated medium-long term data, SIS demonstrates similar efficacy to TMUS; however, there is limited comparative data to RMUS.

### **Autologous fascia PVS**

The autologous fascia PVS, which involves the placement of autologous fascia lata or rectus fascia beneath the urethra to provide support has been performed for many years. Using varying definitions, single center studies have confirmed between 87% and 92% success with 3- to 15-year follow-up.<sup>87-89</sup> Still, comparative analyses of this time-tested technique have been lacking until the last decade. Well-controlled and appropriately blinded comparisons of fascia sling versus other anti-incontinence procedures is difficult due to the inherent differences in morbidity of the techniques. The SISTEr trial compared the fascial sling to the Burch colposuspension in a well-conducted RCT. Data suggested effectiveness and need for retreatment favoring the fascial sling over the Burch colposuspension (66% versus 49%). This trial used strict composite outcome criteria of no self-reported SUI on questionnaire, no need for retreatment, and a negative stress test. The Panel believes that the autologous fascia PVS is a viable option for the management of SUI. The added morbidity of the fascial harvest should be considered in the preoperative discussion when considering sling type (see complications section). Efforts to use other materials, such as porcine dermis and cadaveric fascia, as substitution for the autologous fascia have shown inferior results.<sup>90</sup>

### **Colposuspension**

While largely supplanted by MUS, the suture-only based colposuspension still has a role in the management of SUI, although many would consider this primarily for patients concerned with the use of mesh or who are undergoing concomitant open or minimally invasive (laparoscopic or robotic) abdominal-pelvic surgery, such as hysterectomy. Comparative studies of the Burch colposuspension with the TVT<sup>TM</sup> showed essentially equivalent outcomes with the TVT<sup>TM</sup> in several RCTs. Despite the large number of trials, results were too sparse to indicate whether there is a difference between these two treatments. The SISTEr trial compared the Burch colposuspension with the autologous fascial PVS. This comparison had outcome data to five years and favored the autologous fascia PVS over the Burch colposuspension due to the lower retreatment rates (4% versus 13%). While no definitive selection criteria exist for this procedure over the others, the Panel believes colposuspension is a viable approach for women with SUI

who wish to avoid the morbidity of fascial harvest and also wish to avoid mesh, particularly if undergoing a simultaneous abdominal procedure such as an open or minimally invasive hysterectomy. One should realize that the colposuspension does carry some morbidity with its incision as shown in the SISTEr trial with over 20% of patients having wound-related issues. The data also suggest that the colposuspension is likely inferior to fascial sling in most efficacy related outcomes.

### **Bulking agents**

The Panel believes that bulking agents are viable treatments for SUI. Retreatment tends to be common for bulking agent therapy, and determination of absolute outcomes becomes challenging. There are inadequate data to allow the recommendation of one injectable agent over another. Still, the role for bulking agents may best be considered in patients who wish to avoid more invasive surgical management, who are concerned with the lengthier recovery time after surgery, or who experience insufficient improvement following a previous anti-incontinence procedure. Patients should be counseled on the expected need for repeat injections.

While no true comparative studies have demonstrated one currently available bulking agent to show superiority over another, an important facet is limited long term data on bulking agents. Calcium hydroxyapatite, polydimethylsiloxane, and polyacrylamide hydrogel (PAHG) have longer term data that show persistence of effect at 73.2, 83 and 96 months, respectively.<sup>91</sup> In an index SUI patient group studied in a recent RCT, PAHG demonstrated a lower satisfaction rate compared to TVT; however, the majority of women treated with PAHG were considered cured or improved at three-year follow-up.<sup>92,93</sup> Some interpret this finding to suggest that even if a lower success rate is attained with a bulking agent, patients may choose this method of therapy as it is less invasive than sling surgery. Reinjection may be required with all bulking agents, but complications of erosions were not present in PAHG patients versus other bulking agents in multiple studies.<sup>91</sup>

### **14. Clinicians should not place a mesh sling if the urethra is inadvertently injured at the time of planned midurethral sling procedure. (Clinical Principle)**

Given the risks of mesh erosion, the Panel felt that in cases where the urethra has been entered

unintentionally, mesh procedures for SUI should be avoided. If the surgeon feels it is appropriate to proceed with sling placement in the face of an inadvertent entry into the urethra, then a non-synthetic sling should be utilized.

### **15. Clinicians should not offer SCT for stress incontinent patients outside of investigative protocols. (Expert Opinion)**

The Panel recognizes that SCT may be a future option for women with SUI. Though there are increasing studies evaluating SCT, there are currently not enough data to support this treatment modality.

Klapper-Goldstein et al.<sup>94</sup> performed a systematic review of 773 patients in 19 studies that included randomized prospective interventional studies, prospective interventional case series, and prospective cohort studies. A second large meta-analysis<sup>95</sup> of 23 studies on “human clinical research” with a total of 890 patients included both men and women, with results for women analyzed separately.

Neither study reported comparators, outcomes, or outcome data in the abstract, rendering their direct relevance to support this statement unclear. Nevertheless, Klapper-Goldstein et al.<sup>94</sup> concluded that SCT is a safe and effective treatment for SUI, and Huang et al.<sup>95</sup> reported a 26% pooled complication rate for females with no serious complications reported.

Future comparative studies with clear outcomes assessment are necessary to identify the best cell type and technique, as well as patient characteristics to guide treatment decisions.

## **SPECIAL CASES**

### **16. In patients with SUI and a fixed, immobile urethra who wish to undergo treatment, clinicians may offer pubovaginal slings, retropubic midurethral slings, urethral bulking agents, or adjustable retropubic midurethral slings. (Expert Opinion)**

While there are a number of trials that have compared one procedure to another in patients with a fixed and immobile urethra, they are usually sub-analyses of larger trials. Some argue that an MUS should be avoided in a patient with an immobile urethra because the mechanism of action by which the MUS corrects incontinence is by compressing the urethral lumen as it moves into the sling

with increased intraabdominal pressure. The immobile urethra may require additional tension on the sling, which should be avoided when using mesh slings. Nevertheless, in situations in which a MUS is being considered, there is some data suggesting that the RMUS is preferred over the TMUS.<sup>96</sup>

The Panel believes that in the case of a minimally mobile urethra, RMUS or PVS may be a preferred option. In the case of the non-mobile urethra, PVS may be the preferred option. Other techniques that have been used effectively in this scenario include the spiral (circumferential) sling using autologous fascia, and the AUS.<sup>97,98</sup>

In addition, the adjustable RMUS offers an opportunity for a sling to be continually adjusted over time for a patient's SUI condition and level of urethral mobility. While studies have been performed in a wide variety of both index and non-index patients, the adjustable sling may be a suitable option for surgical management of the refractory or recurrent SUI patient.<sup>99</sup> Several studies have shown good success with recurrent SUI patients albeit with lower success rates than those without prior incontinence surgery.<sup>100</sup> Several of the studies performed with this device have small sample sizes and varying definitions of cure rates.<sup>99-101</sup> Furthermore, since this device offers the advantage of adjustability over time, it is difficult to obtain absolute success rates with this therapy since one can improve success later with further tightening should SUI recur.

Bulking injections have been shown to be effective in this setting as well; however, the risk of SUI recurrence, and the likely need for future injections should be discussed with the patient.

Overall, the consensus of the Panel was that while RMUS and bulking agents may be considered in these settings, the autologous PVS is a preferred approach based on the lack of robust evidence for RMUS in these patients, the suboptimal outcomes with bulking injections, and the long track record of PVS.

**17. Clinicians should not utilize a synthetic midurethral sling in patients undergoing concomitant urethral diverticulectomy, repair of urethrovaginal fistula, or urethral mesh excision and stress incontinence surgery. (Clinical Principle)**

It is a well-accepted principal that synthetic mesh should not electively be placed in close proximity to a fresh

opening into the genitourinary tract. High level evidence supporting or refuting this is noticeably lacking given the extant case reports suggesting urethral erosion associated with mesh slings. Mesh placed in close proximity to a concurrent urethral incision can theoretically affect wound healing, potentially resulting in mesh perforation. Thus, a synthetic sling should not be placed concurrently with any procedure in which the urethra is opened in proximity to the sling position. Specifically, if a concurrent anti-incontinence procedure is necessary when performing a urethral diverticulectomy, urethrovaginal fistula repair or removal of mesh from within the urethra, a synthetic sling should not be utilized. Instead, an anti-incontinence procedure that does not involve placement of synthetic material suburethrally or use of a biologic material, preferably autologous fascia, should be considered.

**18. Clinicians should strongly consider avoiding the use of mesh in patients undergoing stress incontinence surgery who are at risk for poor wound healing (e.g., following radiation therapy, presence of significant scarring, poor tissue quality). (Expert Opinion)**

Proper healing of the vaginal epithelium is critical in the prevention of mesh exposures. Compromised tissue may heal poorly, thereby increasing the risk for complications when mesh is placed. Patients with poor tissue characteristics (e.g., following radiation therapy, significant fibrosis from prior vaginal surgery, severe atrophy) are at increased risk for complications following synthetic mesh placement. Other chronic states that lead to impaired wound healing, such as long-term steroid use; impaired collagen associated with systemic autoimmune disorders, such as visceral Sjogren's disease or systemic lupus erythematosus; and immune suppression may also increase the risk of a mesh exposure. Clinicians should consider the presence of other comorbid conditions and treatments that may affect wound healing (e.g., radiation therapy, presence of significant scarring, poor tissue quality) when selecting sling type in patients undergoing stress incontinence surgery. In such cases, alternatives to synthetic mesh should be considered, although there is no direct evidence that patients are at increased risk of urethral perforation in these circumstances.

**19. In patients undergoing concomitant surgery for pelvic prolapse repair and SUI, clinicians may perform any of the incontinence procedures (e.g., midurethral sling, pubovaginal sling, or Burch colposuspension). (Conditional Recommendation; Evidence Level: Grade C)**

SUI may coexist with pelvic organ prolapse in a significant number of patients. Women with preexisting SUI may have worsening of urinary incontinence, and some without any symptoms of SUI may develop de novo stress leakage following reduction of the prolapse. Clinicians may choose to perform a concomitant anti-incontinence procedure when repairing pelvic organ prolapse; however, they must balance the benefits with the potential for an unnecessary surgery and possible additional morbidity. Several caveats are important in the consideration of this clinical scenario. Three general approaches can be considered: (1) perform a concomitant anti-incontinence procedure in all women undergoing prolapse surgery, (2) perform an anti-incontinence procedure in none, and (3) selectively perform an anti-incontinence procedure based on the presence of preexisting SUI and/or the finding of occult SUI (SUI that only becomes apparent when the prolapse is reduced). Informed patient decision-making is critical in this situation. A nomogram has been developed that can help estimate the risk of developing SUI after vaginal prolapse surgery and can aid in the decision regarding whether or not to perform a concomitant anti-incontinence procedure.<sup>102</sup>

When specifically considering patients with prolapse and no SUI symptoms preoperatively, two important studies provide guidance. The CARE trial showed that women undergoing an abdominal sacrocolpopexy, without preoperative complaints of SUI who had a concomitant Burch colposuspension, had a lower rate of postoperative SUI than those who did not have a Burch colposuspension.<sup>103</sup> Even when occult SUI was not demonstrated preoperatively, those who had the Burch colposuspension had a lower chance of developing SUI postoperatively. The OPUS trial randomized patients undergoing a vaginal repair of stage two or greater anterior vaginal wall prolapse, without symptoms of SUI, to either undergo a concomitant RMUS or sham incision (e.g., no surgery for SUI).<sup>104</sup> At 12 month follow-up, those who had a concomitant sling had a lower rate of SUI than those who did not. However, it is important to recognize that the difference was not marked (27.3% SUI in those

that had a sling and 43.0% in those that did not). Critically, the number of patients needed to treat with a sling to prevent 1 case of incontinence was 6.3. Thus, one could argue that five of six patients who had a sling placed had an unnecessary procedure with the additional (small but real) risk of increased morbidity.

Contemporary literature continues to support the notion that consideration of a concomitant anti-incontinence procedure at the time of prolapse repair is suitable. An RCT by Van der Ploeg et al.<sup>105</sup> compared pelvic organ prolapse (POP) surgery with or without an MUS and demonstrated an improvement in postoperative SUI when POP surgery was combined with MUS. Similarly, a systematic review of 1,361 prolapse patients with SUI demonstrated a statistically significantly higher post-operative continence rate and a favorable complication rate in the patients who underwent a concomitant TVT or SIS-TVT with their prolapse repair over those who underwent an unspecified “different surgical treatment.”<sup>106</sup>

Adverse events associated with combined vaginal pelvic organ prolapse surgery and SUI surgery showed decreased urgency incontinence after combination surgery compared to prolapse surgery alone (28% versus 42%; RR: 0.7). However, adverse events related to surgery occurred more commonly in the combination group (28% versus 15%; RR: 1.8), as did serious adverse events requiring an invasive procedure or reoperation, or resulting in failure of one or more organ systems or death (14% versus 8%; RR 1.7). Thus, it seems as if the combined surgery patients had lower rates of postoperative SUI, but voiding symptoms and complications were higher.<sup>107</sup>

Ultimately, the decision on whether or not to perform a concomitant anti-incontinence procedure at the time of prolapse surgery should be a product of a shared decision-making process between the clinician and patient after a review of the risks and benefits of this additional procedure.

**20. Clinicians may offer patients with SUI and concomitant neurologic disease affecting lower urinary tract function (neurogenic bladder) surgical treatment of SUI after appropriate evaluation and counseling have been performed. (Expert Opinion)**

Patients with neurogenic lower urinary tract dysfunction may have straightforward SUI or SUI related to their



neurologic process. In either event, patients with neurogenic lower urinary tract dysfunction do not fall into the category of an index patient, and a detailed evaluation should be performed. Other issues, such as incomplete emptying, detrusor overactivity, and impaired compliance should be identified and in many cases treated prior to surgical intervention for SUI. In a patient who requires intermittent catheterization, one must be cognizant of possible complications with the use of a bulking agent (bulking effect may be attenuated by frequent catheter passage) or a synthetic sling (potential catheter trauma in the area of the sling could place the patient at risk for mesh erosion into the urethra). These concerns must be discussed relative to the overall risks and benefits of the procedure. Should the sling need to be placed under tension with the goal of planned permanent surgical retention, clinical judgement would suggest that the procedural choice should be a non-mesh sling. Lastly, patients with neurogenic lower urinary tract dysfunction, who undergo sling procedures in particular, should be monitored long-term for changes in lower urinary tract function that could be either induced over time by the neurologic condition itself or potentially by the sling procedure.

**21. Clinicians may offer synthetic midurethral slings, in addition to other sling types, to the following patient populations after appropriate evaluation and counseling have been performed: (*Expert Opinion*)**

- Patients planning to bear children
- Diabetes
- Obesity
- Geriatric

The Panel believes that in most instances, placement of a sling should be postponed until child-bearing is complete. Overall, there does appear to be a relatively high rate of SUI recurrence following delivery, independent of mode of delivery, among women with a history of MUS. In light of the elective nature of the surgery, the Panel suggests that in most instances, surgical treatment of SUI should be deferred until after child-bearing is complete.

Diabetic women planning to undergo sling surgery should be counseled regarding their higher risk for mesh erosion and reduced effectiveness compared with their non-diabetic counterparts. There is some overlap with obesity in this category; however, after controlling for obesity,

diabetes was found to have a negative impact on outcomes.<sup>23,24,108-111</sup>

Obesity (defined as a BMI of > 30) has been well studied in several trials, and there appears to be a slight correlation suggesting worse clinical effectiveness of slings in obese patients compared with those with lower BMI. Increased risk of voiding dysfunction and mesh erosion were not found to be associated with obesity.<sup>23, 26,41,112,113</sup>

Geriatric patients (defined as 65 years of age or older in most studies) undergoing incontinence surgery should be counseled that they are at lower likelihood of successful clinical outcomes compared to younger patients. No clear association is noted between age and mesh erosion, or voiding difficulty in patients undergoing MUS surgery.

Due to the lack of robust data regarding various patient populations, there are no evidence-based recommendations that the Panel can make regarding the use of MUS in non-index populations, such as those with high-grade prolapse, high BMI, advanced age, or recurrent or persistent SUI. However, the Panel does feel that there are a number of factors that should be considered when making the decision to proceed with a MUS in these patients. These may include the type of previous surgery, length of time since previous surgery, presence or absence of hypermobility, degree of urgency or urgency incontinence symptoms, and other potential contributing factors.

## OUTCOMES ASSESSMENT

**22. In women with severe outlet dysfunction or recurrent or persistent SUI after surgical intervention (e.g., surgical failure), clinicians may offer placement of an obstructing pubovaginal sling or bladder neck closure with urinary drainage after counseling regarding the risks, benefits, and alternatives. (*Expert Opinion*)**

Patients who have an exceedingly compromised bladder outlet due to functional or anatomic issues such as neurogenic bladder, failed surgery for treatment of stress incontinence, or severe ISD may require more drastic measures to achieve relief from their SUI. Bladder neck occlusion to the extent necessary in these challenging situations may require a degree of tension that should preclude the use of synthetic slings. A traditional autologous pubovaginal sling is an option. However, in

more severe cases one may need to consider an obstructing autologous sling or formal bladder neck closure with a catheterizable stoma, an AUS, or total urinary diversion via ileal conduit or continent diversion.

Three recent meta-analyses specifically evaluating non-neurogenic SUI provided insight into the role of the AUS in the treatment of non-index SUI patients. Barakat et al.<sup>114</sup> performed a systematic review of 15 studies (n=964) in women with persistent SUI following unspecified anti-incontinence treatments. Success rates and complications associated with AUS implantation were analyzed and supported AUS as an effective treatment in women with severe urinary incontinence after failure of first-line therapy. Mean complete continence rate in the meta-analysis at mean follow-up of 22 months (range 6 to 204) was 80% (95% CI: 72% to 87%). However, the authors did note that the currently available study population is too small to render firm conclusions. Complications requiring revision or explantation both occurred at rates of 0% to 44% (mean: 15% and 13%, respectively). Mechanical complications (mean: 13%;, range 0% to 47%), vaginal erosion (mean: 9%; range 0% to 27%), and infection (mean: 7%; range 0% to 46%) were reported.

In another meta-analysis, Reus et al.<sup>115</sup> reviewed 12 non-randomized, non-prospective studies with short- and long-term follow-up of women with non-neurogenic SUI (n=886), implied to be ISD. The studies reported a zero-pad rate of 42% to 86% post-AUS, mechanical failure in 2% to 41%, and revision and explantation rates of 6% to 44% and 2% to 27%, respectively.

Finally, Peyronnet et al.<sup>116</sup> performed a systematic review of 17 retrospective or prospective non-comparative case series that reported various approaches to AUS implantation (e.g., vaginal, open, laparoscopic, robot-assisted) for treatment of ISD, most of whom had undergone a previous anti-incontinence procedure. The study reported on complete continence rates of 61% to 100% at mean follow-up of 5 to 204 months, and the authors concluded that AMS-800 AUS can provide excellent functional outcomes in female patients with SUI resulting from ISD but at the cost of a relatively high morbidity. Explantation and mechanical failure rates in this analysis were similar to that reported by Barakat et al.,<sup>114</sup> and urethral erosion rate varied from 0% to 22.2%. This series specifically noted intraoperative bladder neck

and vaginal injury rates of 0% to 43.8% and 0% to 25%, respectively.

The lack of clarity around the study types and statistical data of the studies described herein demonstrates the paucity of strong evidence upon which to draw indisputable conclusions. However, options such as the AUS are viable considerations in the challenging non-index patient with proper thorough counseling.

**23. Clinicians or their designees should communicate with patients within the early postoperative period to assess if patients are having any significant voiding problems, pain, or other unanticipated events. If patients are experiencing any of these outcomes, they should be seen and examined. (Expert Opinion)**

Early intervention may ameliorate potential complications in patients who have had SUI surgery. Specifically, if there is evidence a patient has symptoms of obstruction, early intervention may be necessary to reduce patient bother and to prevent development of bladder dysfunction in the long-term. Other postoperative complications (e.g., dyspareunia, persistent pain, frequent UTI, and mesh-specific complications such as vaginal extrusion and lower urinary tract erosion) might also be more expeditiously and effectively treated with early communication. Because patients may not recognize some of the potential adverse events that can occur, they may suffer unnecessarily if the appropriate questions and assessments are not performed. Though clearly this communication can be in person, there is no evidence that a phone discussion or telemedicine cannot provide the same information.<sup>117, 118</sup> Recent evidence would suggest that verbal communication potentially supplemented by live internet-based communication (telemedicine) of wounds can suffice for follow-up evaluation in uncomplicated post-operative scenarios, and can identify surgical complications expeditiously when present.<sup>119</sup> A recent prospective, RCT comparing three-week postoperative telemedicine versus office-based follow-up after MUS surgery identified no difference in satisfaction, unplanned events, or complications in the first three to five months postoperatively.<sup>118</sup> Similarly, Pan et al., compared in-person outpatient follow-up to telehealth follow-up using WeChat for women who recently underwent an MUS operation.<sup>120</sup> They identified favorable retention and

patient satisfaction for patients assigned to a WeChat follow-up group. No difference was seen for international consultation on incontinence questionnaire-urinary incontinence short form (ICIQ-UI SF) scores, global patient scores, or postoperative complications between groups.

If patients are having voiding dysfunction, a decrease in the force of their urinary stream, unexpected pain, recurrent UTI, new onset dyspareunia, or other unanticipated symptoms, they should be evaluated in person by the clinician or his/her designee. If appropriate, depending on the index surgery, the patient can be taught clean intermittent catheterization (CIC), a catheter can be placed, or surgical intervention may be necessary. Additionally, in circumstances of preoperative concern related to postoperative voiding dysfunction (e.g., poor quality bladder contraction identified on urodynamic evaluation), CIC instruction should be considered as a component of preoperative teaching.

#### **24. Patients should be seen and examined by their clinicians or designees within six months post-operatively. Patients with unfavorable outcomes may require additional follow-up. (Expert Opinion)**

- **The subjective outcome of surgery as perceived by the patient should be assessed and documented.**
- **Patients should be asked about residual incontinence, ease of voiding/force of stream, recent UTI, pain, sexual function and new onset or worsened overactive bladder symptoms.**
- **A physical exam, including an examination of all surgical incision sites, should be performed to evaluate healing, tenderness, mesh extrusion (in the case of synthetic slings), and any other potential abnormalities.**
- **A post-void residual should be obtained.**
- **A standardized questionnaire (e.g., PGI-I) may be considered.**

At some point between six weeks and six months after surgery, the patient should be assessed and examined in person by the surgeon or his/her designee to evaluate the outcomes of surgery and to assess for any potential complications.

At the time of follow-up, the subjective outcome of surgery as perceived by the patient should be assessed and documented. Information related to resolution of SUI, need for pads and number used, presence or absence of OAB symptoms, ease of voiding/force of the urinary stream, as well as other pertinent lower urinary tract symptoms should be elicited. New onset surgical site or pelvic pain and dyspareunia should also be explicitly queried.

Completion of a standardized questionnaire by the patient at this visit to assess her satisfaction may be considered. The PGI-I is an easy to use and responsive form that correlates well with other outcomes questionnaires and can be used to facilitate comparisons between centers. It is recommended, though several objective, validated incontinence questionnaires are also available for this purpose and can be utilized.<sup>121-126</sup> For clinicians who utilize a validated lower urinary tract questionnaire in the initial evaluation of their patients with SUI, repeating the same questionnaire postoperatively is recommended.

Sexual function, including whether the patient or their partner is experiencing any pain during intercourse, should be assessed. Patients should also be asked about any UTIs since surgery.

A physical exam should be performed and a PVR should be measured.

A pelvic exam as well as an abdominal/thigh exam, depending on the surgery performed, should be performed to assess for wound healing at the surgical sites. Tenderness at any trocar sites (prepubic/thigh) or incisions should be evaluated to rule out infection, hematoma or extruded mesh, and to document a baseline for longitudinal comparison. A vaginal exam should be performed to assess for any delay in healing, tenderness, potential wound disruption, and in the case of synthetic slings, mesh exposure. While exposure can be identified visually during a half-speculum exam, palpation of the anterior vaginal wall may also identify mesh exposure that is not easily visible. If the index of suspicion is high, in spite of inability to definitively identify extruded mesh, an examination under anesthesia can be considered. Wound complications specifically associated with autologous harvest sites (seroma, hernia) should also be assessed.

### Future Directions

#### Educational Opportunities

Continued emphasis on outcomes reporting has placed more focus on the importance of patient literacy in the informed consent process and the perioperative preparation schema. It is generally accepted that appropriate informed consent relies on adequate patient information and instruction. It is also clear that the complexity of functional urologic conditions such as female SUI provide unique and significant hurdles to patient understanding and appropriate determination of risk/benefit related to interventions for these conditions. Increased reliance on non-paper-based informational resources has evolved given the understanding that adult education requires repetitive delivery of information in discreet and discernable informatics groupings. Audiovisual content shows improvement in patient education, recall, and informed consent that may be appropriate for women with SUI.<sup>127, 128</sup> The use of validated questions such as “How confident are you filling out forms by yourself?”<sup>129</sup> or expanded use of tests of functional health literacy in adults (TOFHLA) may expedite literacy assessments in unique individuals.

Improving and honing a clinician’s ability to provide valuable and comprehensible education for patients regarding their condition and therapeutic options are of clear importance in accomplishing successful treatment. Patients who understand their condition and the rationale behind their treatment are more satisfied with their outcomes.<sup>130</sup> Accordingly, the development of ancillary tools that can supplement and move toward more effective and successful communication between patients and their surgeons would be of significant worth. Similarly, overcoming obstacles that result in disparities in healthcare, such as socioeconomic, language, and access barriers would provide great value to many.

#### Therapeutic Opportunities

In considering new treatments, stem cell injection for the indication of SUI represents possibly one of the most compelling emerging therapies. Stem cell use for the treatment of SUI has been proposed for more than ten years.<sup>131-134</sup> Different stem cell populations have been evaluated for this indication. The six cell types include embryonic, muscle-derived (satellite cells), bone marrow-derived,<sup>135</sup> mesenchymal, adipose, urinary, and human

umbilical cord blood types. Human amniotic fluid stem cells (hAFSCs) have also been proposed.<sup>136,137</sup>

Autologous muscle-derived cells (AMDSC) have been evaluated for intrasphincteric injection for SUI.<sup>138</sup> The primary outcome was the incidence and severity of adverse events. Treatment related complications included minor events such as pain/bruising at the biopsy and injection sites. A higher percentage of patients receiving high doses (in terms of cell numbers) experienced a 50% or greater reduction in pad weight, had a 50% or greater reduction in diary-reported stress leaks, and had zero to one leak during a 3-day period at final follow-up.

Stem cell use for the indication of SUI continues to evolve. Current evidence is limited by a lack of active comparator arms and outcome limitations. Additionally, the optimal cell type, injection method, and final administration characteristics for cell transfer (inclusive of volume of viable cells) remain areas for improvement and study.

It is anticipated that as materials science advances, the use of nanoparticulate technology expands, improved understanding of wound healing evolves, and other therapies will arise for SUI. These therapies will need to be carefully vetted and assessed for safety and efficacy, and it is hoped that enhanced collaboration between regulatory, academic, and patient outcome groups will provide continued improvement in interventions for SUI.

Laser and magnetic/electrical stimulation therapy are emerging therapies for the treatment of SUI. However, evidence to date is inconsistent and of poor quality. The Panel acknowledges that these therapies exist and may offer some benefit in index SUI patients seeking non-surgical treatment. However, given the limitations in rigorous evidence-based data supporting their use and FDA advisory warning against the use of energy-based devices for “vaginal rejuvenation”, patients should be extensively counseled on the immaturity of the data. (<https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-efforts-safeguard-womens-health-deceptive-health-claims>)

Two systematic reviews and one comparative study<sup>139-141</sup> evaluated the safety and efficacy of Er:YAG and CO2 lasers on women with SUI. Studies included in the systematic reviews were limited by unclear or observational study design, lack of a control/comparator

arms, short-term follow-up, poor methodological quality, and inconsistent results thus limiting the applicability of the results.

Three meta-analyses comparing magnetic stimulation to sham or placebo<sup>142-144</sup> were reviewed. The analysis of Hou et al.<sup>143</sup> suffered from significant heterogeneity and serious risk of bias in many of the studies included. Sun et al.<sup>142</sup> found improvements in QOL and success rates; however, confidence intervals were wide and there was a lack of consistency in stimulation protocols. Despite these limitations, all meta-analyses concluded that magnetic stimulation appears to be safe and may be effective in reducing SUI.

A Cochrane review<sup>145</sup> on electrical stimulation (ES) provided the most robust evidence on ES. This most recent review included 51 studies (n=3781) that compared non-implanted ES to various other interventions (e.g., PFME, vaginal cones, sham) or no intervention. The current evidence base indicated that ES is probably more effective than no active or sham treatment, but it is not possible to say whether ES is similar to PFME or other active treatments in effectiveness or not. Overall, the quality of the evidence was too low to provide reliable results. A meta-analysis of 9 RCTs (n=982) comparing ES to sham ES or no intervention<sup>146</sup> also identified improvements in QOL, possibly attributed to an additional favorable outcome with urinary frequency but only short-term (<3 months) improvement in urinary leakage.

The Panel concludes that while laser or magnetic/ES therapy may provide some benefit compared to placebo it remains vital to counsel patients on the immaturity of the data. It appears current data does not suggest superiority of these new emerging technologies in comparison to established non-invasive therapies such as PFME.

### Standardization of Outcomes

While technology continues to evolve and new innovative techniques emerge, accurate assessment of outcomes following medical intervention is paramount to optimizing one's ability to offer the best treatments for the patients. The lack of standardization around outcomes evaluation, assessment tools, and the very definition of success in pelvic floor medicine has been a long-standing barrier to

advancement of the field. Treatment of SUI is no exception to this predicament, and the state of the current literature unequivocally illustrates that little has changed over the years. Many individuals have acknowledged this quandary over the past several decades,<sup>147,148</sup> and just as many individuals have attempted to unite researchers in the field to establish minimum standards regarding the instruments utilized to measure the results of our interventions, and to determine how a favorable outcome should be defined.<sup>149,150</sup> Only when this consensus is reached will it be possible to accomplish meaningful comparison of outcomes from one center to another, foster collaborative learning from one another, and truly advance the field.

## Abbreviations

AMDSC	Autologous muscle-derived cells
AUA	American Urological Association
AUAER	American Urological Association Education and Research, Inc.
AUGS	American Urogynecologic Society
AUS	Artificial urinary sphincter
BOD	Board of Directors
BMI	Body mass index
CCT	Controlled clinical trials
CIC	Clean intermittent catheterization
C-NDL	Contasure needleless
DLS	Dynamic lumbopelvic stabilization
ES	Electrical stimulation
hAFSCs	Human amniotic fluid stem cells
ICIQ-UI SF	Incontinence questionnaire-urinary incontinence short form
ISD	Intrinsic urinary sphincter
MUI	Mixed urinary incontinence
MUS	Mid-urethral sling
OAB	Overactive bladder
PAHG	Polyacrylamide hydrogel
PFME	Pelvic floor muscle exercises
PGC	Practice Guidelines Committee
PGI-I	Patient global impression of improvement
POP	Pelvic organ prolapse
PVR	Post-void residual
PVS	Pubovaginal sling
QOL	Quality of life
RCT	Randomized controlled trial
RMUS	Retropubic mid-urethral sling
RR	Relative risk
SQC	Science & Quality Council
SIS	Single incision sling
SMUS	Synthetic mid-urethral sling
SUFU	Society of Urodynamics, Female Pelvic Medicine & Urogenital Reconstruction
SUI	Stress urinary incontinence
TMUS	Transobturator mid-urethral sling
TOFHLA	Tests of functional health literacy in adults
TOT	Transobturator tape
TVT	Tension-free vaginal tape
ULR	Update literature review
UTI	Urinary tract infection
UII	Urgency urinary incontinence
VLPP	Valsalva leak point pressure

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### DISCLAIMER

This document was written by the SUI Guideline Panel of the AUAER, which was created in 2017. The PGC of the AUA selected the Panel Chair. Panel members were selected by the Panel Chair in coordination with SUFU. Membership of the panel included specialists 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 diagnosis and treatment of SUI.

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

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

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

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

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