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

Kathleen C. Kobashi, MD, FACS, FPMRS; Michael E. Albo, MD; Roger R. Dmochowski, MD; David A. Ginsberg, MD; Howard B. Goldman, MD; Alexander Gomelsky, MD; Stephen R. Kraus, MD, FACS; Jaspreet S. Sandhu, MD; Tracy Shepler; Jonathan R. Treadwell, PhD; Sandip Vasavada, MD; Gary E. Lemack, MD

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. 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.

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. 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 that 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. When sufficient evidence existed, the body of evidence for a particular treatment was assigned a strength rating of A (high), B (moderate) or C (low) for support of Strong, Moderate, or Conditional Recommendations. In the absence of sufficient evidence, additional information is provided as Clinical Principles and Expert Opinions.

GUIDELINE STATEMENTS

PATIENT EVALUATION

1. In the initial evaluation of patients with stress urinary incontinence desiring to undergo surgical intervention, physicians should include the following components: (Clinical Principle)

   - History, including assessment of bother
   - Physical examination, including a pelvic examination
   - Objective demonstration of stress urinary incontinence with a comfortably full bladder (any method)
   - Assessment of post-void residual urine (any method)
   - Urinalysis

2. Physicians should perform additional evaluations in patients being considered

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for surgical intervention who have the following conditions: (Expert Opinion)

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

3. Physicians 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. Physicians should not perform cystoscopy in index patients for the evaluation of stress urinary incontinence unless there is a concern for urinary tract abnormalities. (Clinical Principle)

5. Physicians may omit urodynamic testing for the index patient desiring treatment when stress urinary incontinence is clearly demonstrated. (Conditional Recommendation; Evidence Level: Grade B)

6. Physicians may perform urodynamic testing in non-index patients. (Expert Opinion)

PATIENT COUNSELING

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

8. In patients with stress urinary incontinence or stress-predominant mixed urinary incontinence who wish to undergo treatment, physicians 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

9. Physicians 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 stress urinary incontinence in women, physicians 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 stress urinary incontinence or stress-predominant mixed urinary incontinence, physicians may offer the following non-surgical treatment options: (Expert Opinion)

- Continence pessary
- Vaginal inserts
- Pelvic floor muscle exercises

12. In index patients considering surgery for stress urinary incontinence, physicians may offer the following options: (Strong Recommendation; Evidence Level: Grade A)

- Midurethral sling (synthetic)

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- Autologous fascia pubovaginal sling
- Burch colposuspension
- Bulking agents

13. In index patients who select midurethral sling surgery, physicians may offer either the retropubic or transobturator midurethral sling. (Moderate Recommendation; Evidence Level: Grade A)

14. Physicians may offer single-incision slings to index patients undergoing midurethral sling surgery with the patient informed as to the immaturity of evidence regarding their efficacy and safety. (Conditional Recommendation; Evidence Level: Grade B)

15. Physicians should not place a mesh sling if the urethra is inadvertently injured at the time of planned midurethral sling procedure. (Clinical Principle)

16. Physicians should not offer stem cell therapy for stress incontinent patients outside of investigative protocols. (Expert Opinion)

SPECIAL CASES

17. In patients with stress urinary incontinence and a fixed, immobile urethra (often referred to as 'intrinsic sphincter deficiency') who wish to undergo treatment, physicians should offer pubovaginal slings, retropubic midurethral slings, or urethral bulking agents. (Expert Opinion)

18. Physicians 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)

19. Physicians 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)

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

21. Physicians may offer patients with stress urinary incontinence and concomitant neurologic disease affecting lower urinary tract function (neurogenic bladder) surgical treatment of stress urinary incontinence after appropriate evaluation and counseling have been performed. (Expert Opinion)

22. Physicians 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

23. Physicians 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 physicians 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, 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

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healing, tenderness, mesh extrusion (in the case of synthetic slings), and any other potential abnormalities.
- A post-void residual should be obtained.

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INTRODUCTION

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. 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.

METHODOLOGY

Systematic Review. A comprehensive search of the literature was performed by ECRI Institute. This search 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 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 that 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, TVT, ALIGN, Supris, Advantage, Lynx, Desara, I-STOP, TFS], transobturator [TVT-O, Monarc, ALIGN TO, Obtryx, Aris], Prepubic, Adjustable [Remeex]); pubovaginal slings (PVS) (autologous, allograft, xenograft); artificial urinary sphincter; 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.

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Data Extraction and Data Management. 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.

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

- For systematic reviews, analysts rated quality based on the review authors' ratings of the quality of their included studies (if review authors did not rate quality, analysts extrapolated a rating based on their description of study limitations). For diagnostic cohort studies, analysts used the QUADAS-2 instrument.[1]

- 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 systematic reviews and RCTs) and non-comparative data (comprising 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.[2]

- For patient factors predicting outcomes, analysts used the Quality in Prognostic Studies (QUIPS) tool.[3]

- In reviewing outcomes 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.[4]

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

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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.[5] 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.

Process. The Surgical Management of Female Stress Urinary Incontinence Panel was created in 2014 by the American Urological Association Education and Research, Inc. (AUA). 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. The AUA conducted a thorough peer review process. 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 (S&Q). It was then submitted to the AUA and SUFU Boards of Directors for final approval. Panel members received no remuneration for their work.

BACKGROUND

SUI is a common problem experienced by women. 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.[6-8] While many women choose surgical management for their SUI, the specific options for surgical treatment have evolved over time.[9] The first AUA Female SUI Guidelines Panel reviewed available literature up to 1994 while the literature search for the SUI Guidelines Panel that directly preceded the present iteration concluded in June 2005.[10] 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 iterations of the SUI guidelines, is an otherwise healthy female who is considering surgical therapy for the correction of pure stress and/or stress-predominant mixed urinary incontinence (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 of SUI do not meet the definition of the index patient. In fact, most of the studies in the literature do not enroll patients based on this definition

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TABLE 1: AUA Nomenclature Linking Statement Type to Level of Certainty, Magnitude of Benefit or Risk/Burden, and Body of Evidence Strength			
	Evidence Strength A (High Certainty)	Evidence Strength B (Moderate Certainty)	Evidence Strength C (Low Certainty)
Strong Recommendation (Net benefit or harm substantial)	Benefits > Risks/Burdens (or vice versa) Net benefit (or net harm) is substantial Applies to most patients in most circumstances and future research is unlikely to change confidence	Benefits > Risks/Burdens (or vice versa) Net benefit (or net harm) is substantial Applies to most patients in most circumstances but better evidence could change confidence	Benefits > Risks/Burdens (or vice versa) Net benefit (or net harm) appears substantial Applies to most patients in most circumstances but better evidence is likely to change confidence (rarely used to support a Strong Recommendation)
Moderate Recommendation (Net benefit or harm moderate)	Benefits > Risks/Burdens (or vice versa) Net benefit (or net harm) is moderate Applies to most patients in most circumstances and future research is unlikely to change confidence	Benefits > Risks/Burdens (or vice versa) Net benefit (or net harm) is moderate Applies to most patients in most circumstances but better evidence could change confidence	Benefits > Risks/Burdens (or vice versa) Net benefit (or net harm) appears moderate Applies to most patients in most circumstances but better evidence is likely to change confidence
Conditional Recommendation (No apparent net benefit or harm)	Benefits = Risks/Burdens Best action depends on individual patient circumstances Future research unlikely to change confidence	Benefits = Risks/Burdens Best action appears to depend on individual patient circumstances Better evidence could change confidence	Balance between Benefits & Risks/Burdens unclear Alternative strategies may be equally reasonable Better evidence likely to change confidence
Clinical Principle	A statement about a component of clinical care that is widely agreed upon by urologists or other clinicians for which there may or may not be evidence in the medical literature		
Expert Opinion	A statement, achieved by consensus of the Panel, that is based on members' clinical training, experience, knowledge, and judgment for which there is no evidence		

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of the 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 the 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_2O or a maximal urethral closure pressure of less than 20 cm H_2O, 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.

GUIDELINE STATEMENTS

PATIENT EVALUATION

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

   - **Focused history, including assessment of bother**

   - **Focused physical examination, including a pelvic examination**

   - **Objective demonstration of stress urinary incontinence with a comfortably full bladder(any method)**

   - **Assessment of post-void residual urine (any method)**

   - **Urinalysis**

2. **Physicians 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 stress urinary incontinence**

   - **Known or suspected neurogenic lower urinary tract dysfunction**

   - **Abnormal urinalysis, such as unexplained hematuria or pyuria**

   - **Urgency-predominant mixed urinary incontinence**

   - **Elevated post-void residual per clinician judgment**

   - **High grade pelvic organ prolapse (POP-Q stage 3 or higher) if stress urinary incontinence not demonstrated by pelvic organ prolapse reduction**

   - **Evidence of significant voiding dysfunction**

3. **Physicians 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 the diagnostic evaluation in the incontinent woman 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 the diagnostic evaluation is to confirm the diagnosis of SUI and optimally characterize the incontinence. The literature search regarding the optimal evaluation for the index

patient yielded two systematic reviews[11,12] and four individual studies that addressed this issue.[13-16] 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.[11] 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.[12] 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 the two systematic reviews for their ability to diagnose SUI.[11,12] 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 to the decision to operate in the 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.[17] 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.[13]

Q-tip test. Holroyd-Leduc et al. included two studies with a total of 253 patients that evaluated the Q-tip test, with one study using a cutoff angle of 20° and the other 35°.[11] 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 one study with 105 patients (Versi et al.)[18] 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.[12] One of these was the Versi study, while the study by Jorgensen et al.[19] 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 is low, and importantly, though a pad test may confirm the presence of incontinence, it does not distinguish the specific type of incontinence.

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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 the 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 occurs 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 physicians should obtain the following details from the history, bladder diary, questionnaires, and/or pad testing.

- Characterization of incontinence (stress, urgency, mixed, continuous, without sensory awareness)

- Chronicity of symptoms

- Frequency, bother, and severity of incontinence episodes

- Patient's expectations of treatment (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 the 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 physician 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

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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, a 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 physician's degree of certainty and comfort regarding the accuracy of the diagnosis, the degree of bother 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. **Physicians should not perform cystoscopy in index patients for the evaluation of stress urinary incontinence 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. **Physicians may omit urodynamic testing for the index patient desiring treatment when stress urinary incontinence 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.[15] 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 Urinary 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.[16] 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_2O.

6. Physicians 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 stress urinary incontinence, 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 stress urinary incontinence or stress-predominant mixed urinary incontinence who wish to undergo treatment, physicians 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.

Physicians 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. Physicians 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, physicians 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, and urethral injury, as well as inherent risks of anesthesia, and of 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 (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 urethrolysis. 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 urethrolysis 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 (i.e. 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 stress urinary incontinence in women, physicians 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 options 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.[20] 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 with regard to efficacy.

All surgical interventions (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 (https://www.fda.gov/medicaldevices/safety/alertsandnotices/ucm262435.htm) 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. There does appear to be a greater risk of mesh erosion associated with diabetes and a history of smoking;[21-23] 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.[24] However, a review of the literature did not find an association between obesity, parity,

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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 (http://sufuorg.com/docs/news/augs-sufu-mus-position -statement.aspx).

TREATMENT

11. **In patients with stress urinary incontinence or stress-predominant mixed urinary incontinence, physicians may offer the following non-surgical treatment options: (Expert Opinion)**

- **Continence pessary**

- **Vaginal inserts**

- **Pelvic floor muscle exercises**

Patients may opt for the use of conservative measures to treat stress or stress-predominant urinary incontinence. There are no comparative or direct observational data concerning the use of urethral plugs, continence pessaries, or vaginal inserts in the management of these patients. The Panel believes these are low-risk options to consider in the treatment of patients. Some basic maintenance should be followed with these devices, including regular visits to monitor time of use and tissue quality to minimize complications. The optimal patient for any of these treatment options is not currently established.

12. **In index patients considering surgery for stress urinary incontinence, physicians may offer the following options: (Strong Recommendation; Evidence Level: Grade A)**

- **Midurethral sling (synthetic)**

- **Autologous fascia pubovaginal sling**

- **Burch colposuspension**

- **Bulking agents**

Several surgical options exist for SUI. Choice of intervention should be individualized based upon the patient's symptoms, the degree of bother the symptoms cause the patient, patient goals and expectations, and the risks and benefits for a given patient. Although most of these procedures have been available for some time, very little comparative data between these broad treatment categories exists to assist the physician in choosing a therapy.

Midurethral synthetic sling. MUS may be characterized as retropubic (top-down or bottom-up), transobturator (inside-out or outside-in), single incision sling (SIS) or adjustable sling types. Long-term data exists for several of the slings 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.

Retropubic midurethral synthetic sling (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.[20,25] Success rates are reported to be between 51 and 87%. The TVTä 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[20] and one additional study.[26] Ford et al. (2015) included five trials with a total of 631 women with SUI or stress-predominant MUI symptoms that compared these two procedures.[20] 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.

Transobturator midurethral synthetic sling (TMUS). The TMUS was developed in an effort to simplify and even minimize the complication profile realized with the retropubic approach. Single and multicenter prospective and retrospective studies have confirmed efficacy with success rates ranging between 43 and 92% in follow up of up to 5 years.[20] With the possibility that TMUS would have an improved safety profile over RMUS, it was natural to do comparative efficacy analyses between the sling types. Overall, in aggregate, most short-term analyses that compared RMUS and TMUS found them to be equivalent. However, long-term comparisons are relatively lacking. The Trial of Mid-urethral Slings (TOMUS) compared the short (one and two year) and long (five year) outcomes of RMUS and TMUS. Short-term analyses demonstrated statistical equivalence between the two procedures; however, slight

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advantages towards the RMUS were seen with longer follow up (five years).[27]

The transobturator approaches have both outside-in and inside-out techniques. Evidence suggests that these approaches have similar effectiveness.

Single incision synthetic sling (SIS). In another development toward simplification of the synthetic sling, the SIS was introduced as a less invasive, lower morbidity surgery with the potential to maintain efficacy of the synthetic sling. It should be emphasized that no long-term data is available with the SIS, but more recent comparative analyses have become available. The SIS was compared with bottom-up RMUS. Overall evidence on effectiveness favors RMUS over SIS, but most of the SIS trials involved TVT-Secur, which is a device that has since been withdrawn from the market for poor results. The average study quality was moderate, and a five-study meta-analysis indicated a two-fold difference in success rates in favor of RMUS.[28] Comparison of SIS and TMUS have been studied with index and non-index patients. Taken in aggregate, the overall results show equivalence with the available SIS and TMUS with regard to effectiveness and sexual function, although the trials are primarily lower level evidence. Furthermore, there is a lack of long-term RCT data on SIS compared with other sling types. Accordingly, there is insufficient comparative data to favor a SIS over either RMUS or TMUS.

Autologous fascia pubovaginal sling (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 3-15 year follow up.[29-31] 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.[32]

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™ showed essentially equivalent outcomes with the TVT™ 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 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 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; however, little long-term data exists for them. Retreatment tends to be the norm for bulking agent therapy, and determination of absolute outcomes accordingly becomes challenging. There is 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 or 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.

13. **In index patients who select midurethral sling surgery, physicians may offer either the retropubic or transobturator midurethral**

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sling. (Moderate Recommendation; Evidence Level: Grade A)

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.

Five systematic reviews[20,33-36] and 11 publications citing RCT trials were reviewed by the panel. Of the 11 RCTs, 4 enrolled only index patients,[37-40] and 7 enrolled patients with MUI or did not clearly define enrollment.[41-47]

The largest systematic review included 55 trials with a total of 8,652 patients with SUI or stress-predominant MUI.[20] The rates of subjective and objective cure were similar between TMUS and RMUS in the short-term (up to 1 year). There were fewer and less robust studies with medium term (1-5 years) and long-term (>5 years) follow-up with subjective cure rates ranging from 43-92% for TMUS and 51-88% for RMUS. The review by Sun et al.[33] used more stringent inclusion criteria than that performed by Ford et al.[20] 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 (7 trials; index patients) and studies that evaluated patients with either isolated SUI or MUI (9 trials; mixed index and non-index patients). The review was inconclusive with regard to efficacy.

Eleven RCTs investigated comparative efficacy between the TMUS and RMUS, and the balance of data suggests similar effectiveness. Four of the 11 RCTs looked specifically at index-patients: one indicated equivalence,[37] and three[38-40] were inconclusive. Of the remaining seven trials, two found equivalence,[41,44] four were inconclusive,[43,45-47] and one[42] indicated an advantage of RMUS. The latter trial, Schierlitz et al.,[42] reported that the risk of failure was 15 times greater (95% CI: 2 to 113) in women who underwent a TMUS procedure compared to women who underwent an RMUS procedure. 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.[20] also demonstrated a significantly higher rate of repeat incontinence surgery within five years in the TMUS group.

Overall, however, some early short-term data suggested equivalence in incontinence rates after surgery when comparing TMUS to RMUS in both index and non-index patients. That being said, robust long-term data are lacking, and the data from increasing follow up appear to be demonstrating a lack of durability of TMUS versus RMUS.

Validated QOL and incontinence severity measures were assessed by Fan et al.[35] in seven RCTs that compared RMUS (TVT) and TMUS (TVT-O). A meta-analysis of six 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.[36] found no significant difference in patient satisfaction between TMUS or RMUS.

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 patient's only.

Ford et al.[20] 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.[33] 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 events outcomes were inconclusive due to wide confidence intervals, *de novo* urgency or UUI were equivalent between the two procedures.

In summary, the balance of evidence suggests equivalence in efficacy, QOL improvement, and satisfaction between the TMUS and RMUS, particularly within the first few years after surgery. Longer-term data are less clear, with some studies showing lower likelihood of the need for repeat treatment after RMUS. Adverse events differed with the TMUS having 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.

a. When performing TMUS in women with stress-predominant urinary incontinence surgeons

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may perform either the in-to-out or out-to-in TMUS technique.

Data from 10 RCTs of both index and non-index patients are consistent in finding equivalence between the two approaches. Ford et al.[20] 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. One trial 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.[39,48-51]

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.[20] detected a statistically significant difference in the subjective cure rates favoring the bottom-up approach; however, the relative risks 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.[26] 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 intrinsic sphincter deficiency 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 the 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), one 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.[34] 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[42] confirmed the conclusion of Ford et al. (2015)[20] that the rate of repeat sling surgery within one to five years is lower (better) after RMUS than after TMUS.

14. **Physicians may offer single-incision slings to index patients undergoing midurethral sling surgery with the patient informed as to the immaturity of evidence regarding their efficacy and safety. (Conditional Recommendation; Evidence Level: Grade B)**

SIS products were introduced into the market since the last review and have continued to evolve over time leading to inconsistent evidence regarding their efficacy and safety. Some evidence has suggested that SIS are associated with low rates of postoperative groin pain, but higher rates of vaginal mesh exposure and mesh perforation into the bladder or urethra. However, these higher rates appeared predominantly in meta-analyses/ studies that included TVT-Secur, which has been

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withdrawn from the market.

Three systematic reviews and 13 additional publications addressed the comparison of the transobturator midurethral sling with the single-incision sling. Most of the trials were of short duration, and a variety of SIS were used in the trials. Of the 13 individual RCTs that were reviewed, 4 utilized a non TVT-Secur SIS, and all showed similar effectiveness between the SIS and the TMUS. After removing the trials that included TVT-Secur, the remaining trials consistently suggest similar efficacy between the TMUS and a variety of currently marketed SIS.

Nambiar et al.[28] 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.[52] used more specific selection criteria, including five RCTs that compared the SIMS-AJUSTsling to TVT-O or TOT slings. They demonstrated equivalence in both objective and subjective cure rates.

Fan et al. (2015)[35] 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 five 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.

The literature regarding adverse events following SIS is inconsistent. In one study, data regarding four specific adverse events favored TMUS over SIS: less vaginal mesh exposure, less mesh perforation into the bladder or urethra, greater need for repeat SUI surgery, and greater need for any other additional or new surgical procedure. In contrast, meta-analyses of these same outcomes comparing TMUS and SIS were inconclusive. While both postoperative and long-term pain and discomfort favored SIS when compared to TMUS, all other outcomes, meta-analyses were inconclusive.

A meta-analysis of postoperative groin pain found a significant reduction favoring the SIMS-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.[53] found inconclusive results except that pain was less after Contasure Needless (C-NDL) when compared to TMUS. Foote[54] and Schellart et al.[55] also found less pain with the MiniArc SIS versus the TMUS and inconclusive results for other adverse events. Mostafa et al.[56] and Schweitzer et al.[57] compared TVT-O to SIMS-AJUST and found comparative adverse event rates to be inconclusive.

The Panel felt that longer-term data were necessary before being able to make a stronger statement regarding the SIS. The current data, while demonstrating similar efficacy to TMUS, are generally limited to short-term (12 months) trials involving substantially fewer patients than trials involving full length RMUS or TMUS.

15. **Physicians 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.

16. **Physicians should not offer stem cell therapy for stress incontinent patients outside of investigative protocols. (Expert Opinion)**

The Panel recognizes that stem cell therapy may be a future option for women with SUI; however, there is currently not enough data to support this treatment modality. Future studies are necessary to identify the best cell type and technique as well as patient characteristics to guide treatment decisions.

SPECIAL CASES

17. **In patients with stress urinary incontinence and a fixed, immobile urethra (often referred to as 'intrinsic sphincter deficiency') who wish to undergo treatment, physicians should offer pubovaginal slings, retropubic midurethral slings, or urethral bulking agents. (Expert Opinion)**

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There are multiple deficiencies in the literature with regard to ISD, including the definition of ISD, the coexisting morbidities, the variable outcomes measures and the variability in the procedures that have been performed and evaluated in the literature.

While there are a number of trials that have compared one procedure to another in patients with ISD, they are usually subanalyses of larger trials. Some argue that a 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.[58]

The Panel believes that in the case of a minimally mobile urethra, RMUS or PVS may a preferred option, and 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 artificial urinary sphincter.[59,60]

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.

18. **Physicians 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.

19. **Physicians 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. Physicians 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.

20. **In patients undergoing concomitant surgery for pelvic prolapse repair and stress urinary incontinence, physicians may perform any of the incontinence procedures (e.g., midurethral sling, pubovaginal sling, 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 stress leakage following reduction of the prolapse. Physicians

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may choose to perform a concomitant 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 incontinence procedure in all women undergoing prolapse surgery, (2) perform an 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.[61]

When specifically considering patients without 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.[62] 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 2 or greater anterior vaginal wall prolapse, without symptoms of SUI, to either undergo a concomitant RMUS or sham incision (i.e., no surgery for SUI).[63] 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 one case of incontinence was 6.3. Thus, one could argue that 5 of 6 patients who had a sling placed had an unnecessary procedure with the additional (small but real) risk of increased morbidity.

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

21. **Physicians may offer patients with stress urinary incontinence and concomitant neurologic disease affecting lower urinary tract function (neurogenic bladder) surgical treatment of stress urinary incontinence 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 the 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 followed 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.

22. **Physicians 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

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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.[21,22,64-67]

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.[21,24,43,68,69]

Geriatric patients (defined as 65 years old or older in most studies) undergoing incontinence surgery should be counseled that they are at lower likelihood of successful clinical outcomes compared with 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

23. **Physicians 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, such as 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 assessment are not performed. Though clearly this communication can be in person, there is no evidence that a phone discussion cannot provide the same information.[70] Recent evidence would suggest that verbal communication potentially supplemented by live internet-based communication (tele-medicine) of wounds can suffice for follow up evaluation in uncomplicated post-operative scenarios and can identify surgical complications expeditiously when present.[71] 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 physician 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 physicians 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, 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.[72-77] For physicians 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

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. Expanded use of tests of functional health literacy in adults (TOFHLA) may expedite literacy assessments in unique individuals.

Improving and honing a physician'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.[78] 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.

The use of telemedicine in surgery is expanding rapidly and across multiple specialties within surgical disciplines. Telesurgery has been performed for the last several decades, but the use of telemedicine, from a standpoint of mentoring and consultation, has recently become more popular. Although not completely explored, some pelvic floor disorders would appear to be uniquely suited to teleconsultation and telefollow-up for purposes of managing chronic conditions, which these disorders represent.[79]

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

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ten years.[80-83] Different stem cell populations have been evaluated for this indication. The six cell types include embryonic, muscle-derived (satellite cells), bone marrow-derived,[84] mesenchymal, adipose, urinary, and human umbilical cord blood types. Human amniotic fluid stem cells (hAFSCs) have also been proposed.[85,86]

Autologous muscle-derived cells (AMDSC) have been evaluated for intrasphincteric injection for SUI.[87] 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 three-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 outcomes 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, and improved understanding of wound healing evolves, 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 outcomes groups will provide continued improvement in interventions for SUI.

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Incontinence

Stress Urinary Incontinence Panel, Consultants and Staff

Kathleen C. Kobashi, MD (Chair)
Virginia Mason
Seattle, WA

Gary E. Lemack, MD (Vice Chair)
UT Southwestern
Dallas, TX

Michael E. Albo, MD
University of California, San Diego
San Diego, CA

Roger R. Dmochowski, MD, MMHC
Vanderbilt University
Nashville, TN

David A. Ginsberg, MD
Keck Medicine of USC
Los Angeles, CA

Howard B. Goldman, MD
Cleveland Clinic
Cleveland, OH

Alexander Gomelsky, MD
LSU Health
Shreveport, LA

Stephen R. Kraus, MD
University of Texas
San Antonio, TX

Jaspreet S. Sandhu, MD
Memorial Sloan Kettering Cancer Center
New York, NY

Tracy Shepler (Patient Advocate)
Bow, WA

Sandip P. Vasavada, MD
Cleveland Clinic
Cleveland, OH

Consultants

Jonathan R, Treadwell, PhD

Staff

Heddy Hubbard, PhD, MPH, RN, FAAN
Abid Khan, MHS, MPP
Erin Kirkby, MS
Shalini Selvarajah, MD
Nenellia K. Bronson, MA
Leila Rahimi
Brooke Bixler, MPH

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Consultant/Advisor: Kathleen C. Kobashi, Allergan, Medtronic; **Gary E. Lemack,** Allergan, Medtronic; **Michael E. Albo,** Astora; **Roger R. Dmochowski,** Allergan, Medtronic, Serenity; **David A. Ginsberg,** Allergan; **Howard B. Goldman,** Medtronic, Pfizer, Axonics; **Stephen R. Kraus,** Allergan, Astellas; **Jaspreet Sandhu,** American Medical Systems; **Sandip Vasavada,** Allergan, Axonics
Meeting Participant or Lecturer: Kathleen C. Kobashi, Astellas, Allergan; **Gary E. Lemack,** Astellas, Allergan; **David A. Ginsberg,** Allergan; **Howard B. Goldman,** Allergan, Astellas, Medtronic, Pfizer; **Stephen R. Kraus,** Medtronic; **Jaspreet Sandhu,** American Medical Systems; **Sandip Vasavada,** Allergan;
Scientific Study or Trial: Kathleen C. Kobashi, Medtronic; **Roger R. Dmochowski,** Myopowers; **David A. Ginsberg,** Allergan, Medtronic, NovaBay; **Howard B. Goldman,** Cook, Medtronic; **Stephen R. Kraus,** NIDDK; **Sandip Vasavada,** Allergan;
Investment Interest: Sandip Vasavada, NDI Medical LLC;
Other: Stephen R. Kraus, Laborie

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Peer Reviewers

We are grateful to the persons listed below who contributed to the Guideline by providing comments during the peer review process. Their reviews do not necessarily imply endorsement of the Guideline.

Nitya Abraham, MD
Peter C. Albertsen, MD
Humphrey Atiemo, MD
Timothy D. Averch, MD
Diane Bieri Esq.
Timothy Boone, MD
Marissa Clifton, MD
Craig Comiter, MD
Jordan Dimitrakoff, MD
James A. Eastham, MD
Elizabeth Ferry, MD
Farzeen Firoozi, MD
Ghoniem Gamal, MD
Angelo Gousse, MD
Melissa R. Kaufman, MD
Michael Kennelly, MD
Stephanie Kielb, MD
Ryan Krlin, MD
Una Lee, MD
Deborah J. Lightner, MD
Alvaro Lucioni, MD
Sarah McAchran, MD
Alana Murphy, MD
Charles Nager, MD
Victor Nitti,MD
Karen Noblett, MD
Glenn M. Preminger, MD
Leslie Rickey, MD
Eric Rovner, MD
Kamran Sajadi, MD
Roger E. Schultz, MD
Eila Curlee Skinner, MD
Ariana Smith, MD
Thomas F. Stringer, MD
Suzette Sutherland, MD
Chris Tenggardjaja, MD
J. Brantley Thrasher, MD
Christian Twiss, MD
Tracey Wilson, MD
J. Stuart Wolf, Jr., MD
Guo-Bing Xiong, MD

specific expertise on this disorder. The mission of the Panel was to develop recommendations that are analysis-based or consensus-based, depending on Panel processes and available data, for optimal clinical practices in the treatment of stress urinary incontinence.

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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 in-tended to provide legal advice about use and misuse of these substances.

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

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

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This document was written by the Stress Urinary Incontinence Guideline Panel of the American Urological Association Education and Research, Inc., which was created in 2014. The Practice Guidelines Committee (PGC) of the AUA selected the committee chair. Panel members were selected by the chair. Membership of the Panel included specialists in urology with