Surgical Treatment of Female Stress Urinary Incontinence: AUA/SUFU Guideline


From the American Urological Association Education and Research Inc., Linthicum, Maryland and the Society of Urodynamics, Female Pelvic Medicine & Urogenital Reconstruction, Schaumburg, Illinois

Purpose: Stress urinary incontinence is a common problem experienced by many women that can have a significant negative impact on the quality of life of those who suffer from the condition and potentially those friends and family members whose lives and activities may also be limited.

Materials and Methods: A comprehensive search of the literature was performed by ECRI Institute. This search included articles published between January 2005 and December 2015 with an updated abstract search conducted through September 2016. 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.

Results: The AUA (American Urological Association) and SUFU (Society of Urodynamics, Female Pelvic Medicine & Urogenital Reconstruction) have formulated an evidence-based guideline focused on the surgical treatment of female stress urinary incontinence in both index and non-index patients.

Conclusions: The surgical options for the treatment of stress urinary incontinence continue to evolve; as such, this guideline and the associated algorithm aim to outline the currently available treatment techniques as well as the data associated with each treatment. Indeed, the Panel recognizes that this guideline will require continued literature review and updating as further knowledge regarding current and future options continues to grow.

Key Words: female; algorithms; urinary incontinence, stress

BACKGROUND
Stress urinary incontinence is the symptom of urinary leakage due to increased abdominal pressure. 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 quality of life and on that of her family and friends.1–3 While many women choose surgical management for their SUI, the specific options for surgical treatment have evolved over time.4 Urgency urinary incontinence 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 urinary incontinence refers to a combination of SUI and UUI.
Index Patient
The index patient for this guideline is an otherwise healthy female who is considering surgical therapy for the correction of pure SUI or stress-predominant MUI who has not undergone previous SUI surgery. Patients with low-grade pelvic organ prolapse were also considered to be index patients. However, while the stage of prolapse was often specified in more recent trials, it was not indicated in many of the earlier studies.

Non-index Patient
Non-index patients reviewed in this analysis include women with SUI and POP (stage 3 or 4), MUI (non-stress-predominant), incomplete emptying/elevated post-void residual and/or other voiding dysfunction, prior surgical interventions for SUI, recurrent or persistent SUI, mesh complications, high body mass index, neurogenic lower urinary tract dysfunction and advanced age (geriatric).

GUIDEINE STATEMENTS
The table provides the AUA nomenclature linking statement type to level of certainty, magnitude of benefit or risk/burden and body of evidence strength applied to these guideline statements. This document is designed to be used in conjunction with the associated treatment algorithm (see figure).

Table. AUA nomenclature linking statement type to level of certainty, magnitude of benefit or risk/burden and body of evidence strength

<table>
<thead>
<tr>
<th>Evidence Strength A (High Certainty)</th>
<th>Evidence Strength B (Moderate Certainty)</th>
<th>Evidence Strength C (Low Certainty)</th>
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<tr>
<td><strong>Strong Recommendation</strong> (Net benefit or harm substantial)</td>
<td>Benefits &gt; 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</td>
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<td><strong>Moderate Recommendation</strong> (Net benefit or harm moderate)</td>
<td>Benefits &gt; 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</td>
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<tr>
<td><strong>Conditional Recommendation</strong> (No apparent net benefit or harm)</td>
<td>Benefits = Risks/Burdens Best action depends on individual patient circumstances Future research unlikely to change confidence</td>
<td>Benefits = Risks/Burdens Best action depends on individual patient circumstances Better evidence could change confidence</td>
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Patient Evaluation
1. In the initial evaluation of patients with SUI 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 SUI with a comfortably full bladder (any method)
- Assessment of PVR 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 SUI
- Known or suspected neurogenic lower urinary tract dysfunction
- Abnormal urinalysis, such as unexplained hematuria or pyuria
- Urgency-predominant MUI
- Elevated PVR per clinician judgment
- High grade POP (POP-Q stage 3 or higher) if SUI not demonstrated by POP reduction
- Evidence of significant voiding dysfunction
## Female Stress Urinary Incontinence: AUA/SUFU Evaluation and Treatment Algorithm

### EVALUATION (INDICATIONS)

**Initial evaluation**
- The initial evaluation of patients desiring to undergo surgical intervention should include the following components:
  - History
  - Physical exam
  - Demonstration of SUI
  - PVR assessment
  - Urinalysis

**Additional evaluation**
- Additional evaluation should be performed in the following scenarios:
  - Lack of definitive diagnosis
  - Inability to demonstrate SUI
  - Known/suspected NLUTD
  - Abnormal urinalysis
  - Urgency-predominant MUI
  - Elevated PVR
  - High-grade POP (if SUI not demonstrated with POP reduction)
  - Evidence of significant voiding dysfunction
- Additional evaluation may be performed in the following scenarios:
  - Concomitant OAB symptoms
  - Failure of prior anti-incontinence surgery
  - Prior POP surgery

**Cystoscopy**
- Should not be performed unless there is a concern for lower urinary tract abnormalities

**Urodynamics**
- May be omitted when SUI is clearly demonstrated

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In patients who wish to undergo treatment, physicians should counsel regarding the availability of observation, pelvic floor muscle training, other non-surgical options, and surgical interventions. Physicians should counsel patients on potential complications specific to the treatment options.

### TREATMENT

**Non-Surgical**
- Contience pessary
- Vaginal inserts
- Pelvic floor muscle exercises

**Surgical**
- Bulking agents
- Mid urethral sling (synthetic)
- Autologous fascia pubovaginal sling
- Burch colposuspension

If a mid urethral sling surgery is selected, either the retropubic ortransoburator mid urethral sling may be offered. A single-incision sling may be offered to index patients if they are informed as to the immaturity of evidence regarding their efficacy and safety. Physicians must discuss the specific risks and benefits of mesh as well as alternatives to a mesh sling.

### SPECIAL CASES

1. **Fixed immobile urethra**
   - Pubovaginal sling
   - Retropubic midurethral sling
   - Urethral bulking agents

2. **Concomitant surgery for POP repair and SUI**
   - Any incontinence procedure

3. **Concomitant NLUTD**
   - Surgical treatment following appropriate evaluation and counseling

4. **Child-bearing, diabetes, obesity, geriatric**
   - Surgical treatment following appropriate evaluation and counseling

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*MUI= mixed urinary incontinence; NLUTD= neurogenic lower urinary tract dysfunction; OAB= overactive bladder; POP= pelvic organ prolapse; PVR= post-void residual; SUI= stress urinary incontinence*

**Figure.** Evaluation and treatment algorithm for female stress urinary incontinence
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 POP 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.

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.

Cystoscopy and Urodynamics Testing
4. Physicians should not perform cystoscopy in index patients for the evaluation of SUI unless there is a concern for urinary tract abnormalities. (Clinical Principle)

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

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

In a large multicenter randomized controlled trial, investigators in the VALUE trial 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. 5

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

Urodynamic testing may be performed at the clinician’s discretion in certain non-index patients, including but not limited to those patients with:

- History of prior anti-incontinence surgery
- History of prior POP surgery
- Mismatch between subjective and objective measures
- Significant voiding dysfunction
- Significant urgency, UUI, OAB
- MUI with significant urgency component
- Elevated PVR per clinician judgment
- Unconfirmed SUI
- Neurogenic lower urinary tract dysfunction

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

Since SUI is a condition that impacts quality of life, 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.

8. In patients with SUI or stress-predominant MUI 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

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. The primary categories of surgical options include bulking agents, colposuspension and slings.

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

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.

10. Prior to selecting synthetic MUS procedures for the surgical treatment of SUI 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 thoroughly regarding the use of synthetic mesh to treat SUI. The focus should be on the benefits, the potential risks and the FDA (U. S. Food and Drug Administration) 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.

Treatment

11. In patients with SUI or stress-predominant MUI, 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 SUI or stress-predominant MUI. 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.

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

- MUS (synthetic)
- Autologous fascia PVS
- Burch colposuspension
- Bulking agents

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.

Mid urethral synthetic sling. MUS may be characterized as retropubic (top-down or bottom-up), transobturator (inside-out or outside-in), single incision sling or adjustable sling types.

Retropubic mid urethral synthetic sling. 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 exceed 15 years of follow-up. Success rates are reported to be between 51 and 88%. The retropubic top-down versus bottom-up approach was also evaluated, but definitive superiority for one approach over the other has not been found.

Transobturator mid urethral synthetic sling. The TMUS was developed in an effort to simplify and even minimize the complication profile realized with the retropubic approach by avoiding the need to traverse the retropubic space. Single and multi-center prospective and retrospective studies have confirmed efficacy with success rates ranging between 43 and 92% in follow-up of up to 5 years. Short-term analyses demonstrated statistical equivalence between RMUS and TMUS; however, slight advantages toward the RMUS were seen with longer follow-up (five years).

Single incision synthetic sling. 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. 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 twofold difference in success rates in favor of RMUS. Comparison of SIS and TMUS have been performed in both 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 of lower level evidence.

Autologous fascia pubovaginal sling. 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 several decades. Using varying definitions, single center studies have confirmed between 85% and 92% success with 3-15 years of follow-up. The SISTEr trial compared the fascial sling to the Burch colposuspension, and data suggest effectiveness and need for re-treatment favoring the fascial sling over the Burch colposuspension (66% versus 49%).

Colposuspension. While largely supplanted by MUS, the suture-only based colposuspension still has a role in the management of SUI. 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. 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 re-treatment rates.

**Bulking agents.** The Panel believes that bulking agents are viable treatments for SUI; however, little long-term data exist for them. Re-treatment tends to be the norm for bulking agent therapy, and there are inadequate data to allow the recommendation of one injectable agent over another.

13. In index patients who select MUS surgery, physicians may offer either the RMUS or TMUS. (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.

A large systematic review including 55 trials with a total of 8,652 patients with SUI or stress-predominant MUI showed similar rates of subjective and objective cure between TMUS and RMUS in the short term (up to 1 year). 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 (Incontinence Impact Questionnaire Visual Analog Scale, International Consultation on Incontinence Questionnaire Short Form and Urinary Incontinence Severity Score) found no significant between-group differences.

RMUS has been associated with more major vascular or visceral injuries, bladder or urethral perforations, voiding dysfunction and suprapubic pain, 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.

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

Data from 10 RCTs of both index and non-index patients are consistent in finding equivalence between the two approaches. Subjective and objective cure at various follow-up times indicated equivalence between the procedures. 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.

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 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.

14. Physicians may offer SIS to index patients undergoing MUS 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. Nambiar et al 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.

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, for all other outcomes, meta-analyses were inconclusive.

15. Physicians should not place a mesh sling if the urethra is inadvertently injured at the time of planned MUS 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 are currently not enough data to support this treatment modality.

Special Cases
17. In patients with SUI and a fixed, immobile urethra (often referred to as “intrinsic sphincter deficiency”) who wish to undergo treatment, physicians should offer PVS, RMUS or urethral bulking agents. (Expert Opinion)

Some argue that a MUS should be avoided in a patient with an immobile urethra as 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, some data suggest that the RMUS is preferred over the TMUS.26

The Panel believes that in the case of a minimally mobile urethra, RMUS or PVS may be a preferred option, and in the case of the non-mobile urethra, PVS may be the preferred option.

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.

18. Physicians should not utilize a synthetic MUS in patients undergoing concomitant urethrovaginal fistula or urethral mesh excision and SUI 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. Mesh placed near or adjacent to a concurrent urethral incision can theoretically affect wound healing, potentially resulting in mesh perforation.

19. Physicians should strongly consider avoiding the use of mesh in patients undergoing SUI 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) may be at increased risk for complications following synthetic mesh placement.

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

SUI may coexist with POP in many patients. Physicians may choose to perform a concomitant incontinence procedure when repairing POP; however, they must balance the benefits with the potential for an unnecessary surgery and possible additional morbidity.26,27

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

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 or a synthetic sling. 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.

22. Physicians may offer synthetic MUS, 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

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

Diabetic women planning to undergo sling surgery should be counseled regarding their higher risk for mesh erosion and reduced effectiveness compared with their non-diabetic counterparts.26–33

There appears to be a slight correlation suggesting worse clinical effectiveness of slings in obese patients compared with those with lower body mass index.28,34–37
Geriatric patients should be counseled that they are at lower likelihood of successful clinical outcomes compared with younger patients.

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. 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.38

24. Patients should be seen and examined by their physicians or designees within six months postoperatively. 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 OAB 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 PVR should be obtained.
- A standardized questionnaire (e.g. PGI-I) may be considered.

FUTURE DIRECTIONS

All future 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.

DISCLAIMER

This document was written by the Stress Urinary Incontinence Guideline Panel of the American Urological Association Education and Research, Inc., which was created in 2015. 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 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.

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

While these guidelines do not necessarily establish the standard of care, AUA seeks to recommend and to encourage compliance by practitioners with current best practices related to the condition being treated. As medical knowledge expands and technology advances, the guidelines will change. Today these evidence-based guidelines statements represent not absolute mandates but provisional proposals for treatment under the specific conditions described in each document. For all these reasons, the guidelines do not preempt 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 U. S. Food and Drug Administration (FDA), or about medications or substances not subject to the FDA approval process. AUA urges strict compliance with all government regulations and protocols for prescription and use of these substances. The physician is encouraged to carefully follow all available prescribing information about indications, contraindications, precautions and warnings. These guidelines and best practice statements are not intended to provide legal advice about use and misuse of these substances.

Although guidelines are intended to encourage best practices and potentially encompass available technologies with sufficient data as of close of the literature review, they are necessarily time-limited. Guidelines cannot include evaluation of all data on emerging technologies or management, including those that are FDA approved, which may immediately come to represent accepted clinical practices. For this reason, the AUA does not regard technologies or management which are too new to be addressed by this guideline as necessarily experimental or investigational.
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