Guideline for the Surgical Management of Female Stress Urinary Incontinence: 2009 Update

Female Stress Urinary Incontinence Guideline Update Panel:
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Definitions

- **Stress urinary incontinence** is a symptom that refers to leakage of urine during events that result in increased abdominal pressure such as sneezing, coughing, physical exercise, lifting, bending and even changing positions.
Stress Urinary Incontinence

- There are two principle causes of this symptom
  - SUI and
  - the rarer stress-induced detrusor overactivity (involuntary detrusor contractions that are caused by sudden increases in abdominal pressure).
Stress Urinary Incontinence

• The distinction between these two can be determined by (in order of increasing specificity) patient history, physical examination (e.g., urinary loss after a stress event) and urodynamic studies.

• For the purposes of this guideline, it is assumed that patients in the extracted studies had **surgical management of SUI**.
Definitions

• **Urgency** refers to a sudden, compelling desire to pass urine which is difficult to defer or a strong need to pass urine for fear of leakage.

• **Urge urinary incontinence** is defined as involuntary leakage accompanied by or immediately preceded by urgency.
Definitions

• Mixed incontinence refers to SUI that occurs in combination with urge urinary incontinence.
Index patient

- otherwise healthy female patient who has elected surgical therapy for the correction of SUI as in the previous guideline.
Index patient

• An additional index patient defined by the panel is an otherwise healthy female patient with SUI and pelvic organ prolapse who elects to have treatment of her SUI along with surgical correction of pelvic organ prolapse.
Index patient

- Either index patient may be untreated or previously surgically-treated and may have urethral hypermobility and/or intrinsic sphincter deficiency.
- Urethral hypermobility was defined by the author; no uniform definition was used.
Methodology

• The Panel did not review needle suspensions or anterior colporrhaphy in developing this guideline update.
• The Panel believes that they are largely of historical interest only and no longer considers these procedures contemporary treatments for SUI.
Surgical efficacy was defined in 3 parts

• 1) the resolution and lack of recurrence of SUI and urgency
• 2) the resolution of prolapse and the lack of recurrence or new onset of prolapse
• 3) the incidence and severity of adverse events of these treatments.
Treatments Included in the Analysis

- Retropubic Suspensions
- Slings
- Injection Therapy
- Artificial Sphincters
Problem Definition

• Anterior repairs for prolapse reduction in conjunction with other surgical treatments for incontinence were included as prolapse surgeries.

• Procedures used to correct prolapse included hysterectomy in conjunction with or as a component of surgical treatment of SUI and site-specific repairs.
Patient Groups

• one in which no patient received concomitant surgical treatment for prolapse (comparable to the previous guideline)

• another in which some or all patients received concomitant treatment for prolapse.
Efficacy Analysis

• Levels of continence analyzed:
  o cured/dry
  o cured/dry/improved

• For analysis of postoperative urgency
  o without pre-existing urgency
  o with pre-existing urgency
  o unknown or uncertain pre-existing urgency
Efficacy Analysis

• Postoperative urgency categories
  o urge incontinence
  o urge symptoms
  o unspecified
Standard:

A guideline statement is a standard if

1. the health outcomes of the alternative interventions are sufficiently well known to permit meaningful decisions, and
2. there is virtual unanimity about which intervention is preferred.
Recommendation:

• A guideline statement is a recommendation if
  o (1) the health outcomes of the alternative interventions are sufficiently well known to permit meaningful decisions, and
  o (2) an appreciable, but not unanimous majority agrees on which intervention is preferred.
Option:

- A guideline statement is an option if
  - (1) the health outcomes of the interventions are not sufficiently well known to permit meaningful decisions, or
  - (2) preferences are unknown or equivocal.
New Nomenclature for AUA Clinical Practice Guideline Statements

• Recommendations
  o “Strong,”
  o “Moderate,”
  o “Conditional”
• Will replace the older nomenclature:
  o “Standard”
  o “Recommendation”
  o “Option”
• All new AUA guidelines will use the new nomenclature system beginning with Peyronie’s Disease: AUA Guideline, which was release at the 2015 Annual Meeting in New Orleans, LA.
Diagnostic Guidelines for the Index Patient

- **Standard**: The evaluation of the index patient should include the following components:
  - *Focused* history
  - *Focused* physical examination
  - Objective demonstration of SUI
  - Assessment of postvoid residual urine volume
  - Urinalysis, and culture if indicated
Recommendation: Elements of the history should include the following:

- Characterization of incontinence (stress, urge, etc.)
- Frequency, bother and severity of incontinence episodes
- Impact of symptoms on lifestyle
- Patient’s expectations of treatment
Diagnostic Guidelines for the Index Patient

- **Recommendation:** Additional diagnostic studies can be performed to assess the integrity and function of the lower urinary tract.
  - Pad testing and/or voiding diary
  - Urodynamics
  - Cystoscopy
  - Imaging
Diagnostic Guidelines for the Index Patient

• **Recommendation:** Indications for further testing include the following:
  - An inability to make a definitive diagnosis based on symptoms and the initial evaluation
  - Concomitant overactive bladder symptoms
  - Prior lower urinary tract surgery, including failed anti-incontinence procedures
  - Known or suspected neurogenic bladder
Diagnostic Guidelines for the Index Patient

• **Recommendation:** Indications for further testing include the following:
  
  - Negative stress test
  - Abnormal urinalysis such as unexplained hematuria or pyuria
  - Excessive residual urine volume
  - Grade III or greater pelvic organ prolapse
  - Any evidence for dysfunctional voiding
Therapeutic Options

• Nonsurgical Treatment
  o Management of SUI includes the option of nonsurgical therapies. The Panel did not review nonsurgical therapies because they are outside the scope of this report.

• Surgical Treatment
  o The outcomes analyzed fell into two general categories: efficacy outcomes and complications.
Outcomes Analysis: Efficacy

- The primary efficacy outcome was the resolution of stress incontinence as measured two ways
  - patients who were completely dry (cured/dry)
  - patients who showed improvement (cured/dry/improved)

- Secondary efficacy outcomes dealt with changes in urgency
Outcomes Analysis: Complications

- Gastrointestinal
- Vascular
- Neurological
- Infectious
- General medical
- Death
- Urinary retention
- Perioperative genitourinary
- Delayed genitourinary
Complications

- Subjective complications (pain, sexual dysfunction, and voiding dysfunction) were also included as a separate category
Retropubic Suspensions

1) open suspensions regardless of type (including Burch suspensions)
2) open Burch suspensions alone
3) laparoscopic suspensions.
Retropubic Suspensions

- cured/dry rates at 12 to 23 months
  - for open suspensions with no concomitant prolapse treatment to be **82%** (1,085 patients; CI: 74%-87%)
  - for laparoscopic suspensions were **69%** (368 patients; CI: 52%-84%)
Open Retropubic Suspensions

- cured/dry rates at 24 to 47 months were similar among all procedures, ranging from 74% to 76%.
- cured/dry rates at 48 months or longer, for all open procedures were 73%. No data were available for laparoscopic procedures.
Open Retropubic Suspensions

- postoperative urge incontinence was 14% (CI: 6%-25%) in patients with pre-existing urge incontinence
- novo urge incontinence and “unspecified” urge incontinence was estimated in 8% (713 patients; CI: 5%-12%) and 41% of patients (305 patients; CI: 30%-54%), respectively
Laparoscopic Retropubic Suspensions

- novo urge incontinence 5\% (CI: 1\%-14\%)
- “unspecified” urge incontinence 6\% (CI: 1\%-14\%)
- lower overall risk of febrile complications (0\% reported) and urinary tract infection (2\%)
- Ureteral injury was estimated to occur in 4-11\%
Retropubic Suspensions

- retention could occur in 3% to 4%
- febrile complications (8%)
- urinary tract infection (13%)
- bladder injury (4%)
- voiding dysfunction (9%)
- Ureteral injury 1%
Open Retropubic Suspensions

• with concomitant prolapse treatment cured/dry rates at 12 to 23 months
  88% for all
• at 24 to 47 months
  open retropubic suspensions 88%
  Burch suspensions 83%
  laparoscopic suspensions 85%
• at 48 months or longer
  67% (1,072 patients; CI: 56%-76%) for all open retropubic suspensions
  No data on lap
Open Retropubic Suspensions

- **open** retropubic suspensions with **concurrent** prolapse repair
  - postoperative urge incontinence rate for **22%** (CI: 4%-56%)
  - De novo urge incontinence **14%**
  - “unspecified” urge incontinence **13%**

- **laparoscopic** suspensions
  - De novo urge incontinence **11%** (CI: 6%-17%)
  - Retention **1% to 2%**
Slings: Autologous Fascial Slings

- autologous slings without bone anchors without concurrent prolapse.
  - For patients without concurrent prolapse treatment, the estimated cured/dry rates ranged between 90% at 12 to 23 months and 82% at 48 months or longer.

- autologous slings with bone anchors and a concurrent prolapse treatment.
  - Cured/dry rates ranged from 85% to 92%.
Cadaveric Slings: cured/dry rate

• without bone anchors and no concomitant prolapse treatment was 74% at 12 to 23 months and 80% at 24 to 47 months

• with bone anchors with concomitant prolapse treatment, 82% (234 patients CI: 77%-86%) at 12 to 23 months

• without bone anchors with concomitant prolapse treatment, 58% (133 patients, CI: 36%-78%)
Synthetic Slings at the Bladder Neck: cured/dry rate

- Without bone anchors, without prolapse 73% (CI: 64%-80%) at 24 to 47 months
- With concurrent prolapse 73% to 75% at 24 months and longer
- Data suggest an increased probability of urinary tract erosion following synthetic slings placed at the bladder neck.
Synthetic Slings at the Midurethra

- These procedures are performed using one of two techniques—transvaginal/retropubic or transobturator.
- At the time of this analysis, data on the transobturator technique was limited, with insufficient numbers of patients having long-term follow-up to reach any conclusions regarding efficacy.
Synthetic Slings at the Midurethra

- Transvaginal/retropubic technique cured/dry rates in patients without prolapse treatment 81% to 84% at all time points.
- De novo urge incontinence was projected in 6%.
- Retention estimates were 3% of patients.
- Complications: bladder injury (6%), urinary tract infection (11%) and extrusions (7% for vaginal extrusions and 1% for unknown).
Mesh in pelvic floor surgery**

- FDA Manufacturer and User Facility Device Experience Database (MAUDE) database
  - 1) In this meta-analysis, the midurethral slings had an efficacy comparable to autologous slings in the surgical treatment of SUI.
  - 2) Several “versions” of the midurethral sling procedures do not have similar long-term efficacy data.

**The FDA issued an updated warning in July 2011 regarding the use of vaginal mesh. Please read the alert on the cover of this guideline. ([http://www.fda.gov/cdrh/safety/102008-surgicalmesh.html](http://www.fda.gov/cdrh/safety/102008-surgicalmesh.html))**
Mesh in pelvic floor surgery**

- FDA Manufacturer and User Facility Device Experience Database (MAUDE) database
  - There are complications that may occur that are unique to specific mesh materials; however, these complications appear to be rare. Intraoperative use of cystoscopy can be performed to minimize the risk of urinary tract injury or erosion.

**The FDA issued an updated warning in July 2011 regarding the use of vaginal mesh. Please read the alert on the cover of this guideline. ([http://www.fda.gov/cdrh/safety/102008-surgicalmesh.html](http://www.fda.gov/cdrh/safety/102008-surgicalmesh.html))
Mesh in pelvic floor surgery**

- FDA Manufacturer and User Facility Device Experience Database (MAUDE) database
  - 4) **The midurethral sling is an alternative in the management of SUI.** The incidence and implications of these complications along with the more rapid recovery and more efficient return to normal voiding after surgery should be discussed with patients before surgery.

**The FDA issued an updated warning in July 2011 regarding the use of vaginal mesh. Please read the alert on the cover of this guideline.**
(http://www.fda.gov/cdrh/safety/102008-surgicalmesh.html)
Injectable Agents: efficacy

- Injectable agents may provide immediate relief for some patients and are an option for patients who do not wish to undergo more invasive surgery and who understand that both efficacy and duration are inferior to surgery.

- For this analysis, injectable agents were subdivided into collagen (bovine gluteraldehyde cross-linked) and other nondegradable synthetic agents.
Injectable Agents: efficacy

- with collagen without concomitant prolapse
  - declined over time, from 48% at 12 to 23 months to 32% at 24 to 47 months

- Very limited information is available for the other injectable agents
Artificial Urinary Sphincters

- Data on use of the AUS in the index patient are limited.
- Erosion/extrusion rate was computed to be **28%**
- With respect to the index patient, the AUS might be useful in the Valsalva-voiding woman who must abdominally strain to empty the bladder.
- The Panel feels that the role of the AUS is limited.
Treatment Guidelines for the Index Patient

- **Standard:** The patient should be counseled regarding the surgical and nonsurgical options including both benefits and risks. Choice of the procedure should be made as a collaborative effort between the surgeon and patient and should consider both patient preferences and the surgeon’s experience and judgment.
Treatment Guidelines for the Index Patient

• **Standard:** Patients with urge incontinence without stress incontinence should not be offered a surgical procedure for stress incontinence.
Treatment Guidelines for the Index Patient

- **Recommendation:** Synthetic sling surgery is contraindicated in stress incontinent patients with a concurrent urethrovaginal fistula, urethral erosion, intraoperative urethral injury and/or urethral diverticulum.
Treatment Guidelines for the Index Patient

- **Standard:** Intraoperative cystourethroscopy should be performed in all patients undergoing sling surgery.
Treatment Guidelines for the Index Patient

• Option: The five major types of procedures (injectables, laparoscopic suspensions, midurethral slings, pubovaginal slings and retropubic suspensions), although not equivalent, may be considered for the index patient.
Treatment Guidelines for the Index Patient

- Option: The artificial urinary sphincter may be indicated in certain circumstances.
- Option: Stress incontinence procedures may be considered for patients with mixed incontinence with a significant stress incontinence component.
Treatment Guidelines for the Index Patient

- **Recommendation:** Surgical procedures for SUI and prolapse may be safely performed concomitantly in appropriately selected women. Tensioning of any sling should not be performed until prolapse surgery is completed.
Transobturator Tape Procedures

• modifications to the pubovaginal sling since the 1997 guideline include development of two minimally invasive procedures for the surgical treatment of SUI: the tension-free vaginal tape procedure introduced in 1996 and the transobturator technique, introduced in 2001.

• In the development of this guideline, the Panel established June 2005 as a cut-off date for literature review. At that time, the transobturator was a novel procedure with limited information available in the published literature, precluding inclusion of the procedure in the data analyses.
Transobturator Tape Procedures

- Since that **deadline**, numerous **articles** have been published in the peer-reviewed literature regarding the **transobturator** procedure. The Panel is very aware of the importance of the transobturator procedure in the current practice of urology and urogynecology.

**FIGURE 3** TOT: The insert shows the transobturator location with reference to the bony landmarks.
"El futuro de la cirugía mínimamente invasiva”
Dr. Rene Sotelo

jueves 28 de mayo a las 7pm
Hotel Miramar Intercontinental
AUA POSITION STATEMENT
ON THE USE OF VAGINAL MESH FOR THE SURGICAL TREATMENT OF STRESS URINARY INCONTINENCE
Stress urinary incontinence (SUI)

- Extensive data exist to support the use of synthetic polypropylene mesh suburethral slings for the treatment of female SUI, with minimal morbidity compared with alternative surgeries.
- Advantages include shorter operative time/anesthetic need, reduced surgical pain, reduced hospitalization, and reduced voiding dysfunction.
Stress urinary incontinence (SUI)

• Mesh-related complications can occur following polypropylene sling placement, but the rate of these complications is acceptably low.

• It is important to recognize that many sling-related complications are not unique to mesh surgeries and are known to occur with non-mesh sling procedures as well.
Stress urinary incontinence (SUI)

- It is the AUA's opinion that **any restriction** of the **use of synthetic polypropylene mesh suburethral slings** would be a **disservice** to women who choose surgical correction of SUI.

*AUA Board of Directors, November 2011 Board of Directors, October 2013 (Revised)*
Stress urinary incontinence (SUI)

- both the Society of Urodynamics, Female Pelvic Medicine and Urogenital Reconstruction (SUFU) and the AUA support the use of multi-incision monofilament midurethral slings for the treatment of SUI in properly selected patients who are appropriately counseled regarding this surgical procedure by surgeons who are trained in the placement of such devices, as well as the recognition and management of potential complications associated with their use.
Stress urinary incontinence (SUI)

• Multiple case series and randomized controlled trials attest to the efficacy of synthetic polypropylene mesh slings at 5-10 years.
• This efficacy is equivalent or superior to other surgical techniques.
• There is no significant increase in adverse events observed over this period of follow-up.

AUA Board of Directors, November 2011 Board of Directors, October 2013 (Revised)
Stress Urinary Incontinence

• Based on these data, the AUA Guideline for the Surgical Management of Stress Urinary Incontinence (2009) concluded that synthetic slings are an appropriate treatment choice for women with stress incontinence, with similar efficacy but less morbidity than conventional non-mesh sling techniques.

AUA Board of Directors, November 2011 Board of Directors, October 2013 (Revised)
Stress Urinary Incontinence

• The AUA Guideline also indicates that intra-operative cystoscopy should be performed during all synthetic sling procedures to identify urinary tract injury.
Stress Urinary Incontinence

• The AUA strongly agrees with the FDA that a thorough informed consent should be conducted prior to synthetic sling surgery.

• The AUA also agrees that surgeons who wish to perform synthetic sling surgery should:
  o Undergo rigorous training in the principles of pelvic anatomy and pelvic surgery.
  o Be properly trained in specific sling techniques.
  o Be able to recognize and manage complications associated with synthetic mesh sling placement.

AUA Board of Directors, November 2011 Board of Directors, October 2013 (Revised)
"El futuro de la cirugía mínimamente invasiva"
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jueves 28 de mayo a las 7pm Hotel Miramar Intercontinental.