Update of AUA Guideline on the Surgical Management of Female Stress Urinary Incontinence

Roger R. Dmochowski,* Jerry M. Blaivas, E. Ann Gormley, Saad Juma, Mickey M. Karram, Deborah J. Lightner, Karl M. Luber, Eric S. Rovner, David R. Staskin, J. Christian Winters and Rodney A. Appell†

From the American Urological Association Education and Research, Inc., Linthicum, Maryland

Abbreviation and Acronyms

AUA = American Urological Association

AUS = artificial urinary sphincter

FDA = Food and Drug Administration

SUI = stress urinary incontinence

UTI = urinary tract infection

Requests for reprints: Guidelines Department, American Urological Association, 1000 Corporate Blvd., Linthicum, Maryland 21090.

* Correspondence: Department of Urologic Surgery, Vanderbilt University, Room A 1302, Medical Center North, Nashville, Tennessee 37232 (telephone: 615- 335-2106; FAX: 615-322-8990; email: roger.dmochowski@vanderbilt.edu).

† Deceased.

Purpose: We updated the 1997 American Urological Association guideline on female stress incontinence.

Materials and Methods: MEDLINE® searches of English language publications from 1994 and new searches of the literature published between December 2002 and June 2005 were performed using identified MeSH terms. Articles were selected for the index patient defined as the otherwise healthy woman who elected to undergo surgery to correct stress urinary incontinence or the otherwise healthy woman with incontinence and prolapse who elected to undergo treatment for both conditions.

Results: A total of 436 articles were identified as suitable for inclusion in the meta-analysis, and an additional 155 articles were suitable for complications data only due to insufficient followup of efficacy outcomes in the latter reports. Surgical efficacy was defined using outcomes pre-specified in the primary evidence articles. Urgency (resolution and de novo) was included as an efficacy outcome due to its significant impact on quality of life. The primary efficacy outcome was resolution of stress incontinence measured as completely dry (cured/dry) or improved (cured/improved). Complications were analyzed similarly to the efficacy outcomes. Subjective complications (pain, sexual dysfunction and voiding dysfunction) were also included as a separate category.

Conclusions: The surgical management of stress urinary incontinence with or without combined prolapse treatment continues to evolve. New technologies have emerged which have impacted surgical treatment algorithms. Cystoscopy has been added as a standard component of the procedure during surgical implantation of slings.

Key Words: urinary retention; urinary incontinence, stress; urinary incontinence, urge; urologic surgical procedures

STRESS urinary incontinence has a major impact on the quality of life for many women, although estimates of prevalence vary widely.[1] A large meta-analysis reported a prevalence estimate of 30% for urinary incontinence in women 30 to 60 years old, with approximately half attributed to SUI,[2] while another study reported the prevalence of SUI to range from 5% to 30%.[3] In 1997 the American Urological Association published a guideline on female stress incontinence which focused on the patient with SUI without significant pelvic organ prolapse.[4] It has since become apparent that many women with SUI also have pelvic organ prolapse, and that surgical procedures for SUI and prolapse may be performed concurrently. For this rea-

0022-5347/10/1835-1906/0
THE JOURNAL OF UROLOGY®

Vol. 183, 1906-1914, May 2010
Printed in U.S.A.
DOI:10.1016/j.juro.2010.02.2369

son, the AUA elected to produce this guideline update.

The index patient is defined as 1) an otherwise healthy woman who has elected surgical therapy for the correction of SUI or 2) an otherwise healthy woman with SUI and prolapse who elects to undergo treatment for both conditions. Stress urinary incontinence is a symptom of leakage of urine during events that result in increased abdominal pressure such as sneezing, coughing, physical exercise, lifting, bending or even changing positions. The 2 underlying entities that contribute to this symptom are SUI and the rarer stress-induced detrusor overactivity (involuntary detrusor contractions caused by sudden increases in abdominal pressure). Urgency refers to a sudden, compelling desire to pass urine which is difficult to defer[5] or a strong need to pass urine for fear of leakage.[6] Urge urinary incontinence is defined as involuntary leakage accompanied by or immediately preceded by urgency,[5] and mixed incontinence refers to SUI that occurs in combination with urge urinary incontinence.

METHODOLOGY

MEDLINE® searches of English language publications from 1990 or later (from the previous guideline) and searches of the literature published from December 2002 through June 2005 were performed using the MeSH terms "female" and "urinary incontinence, stress," "stress incontinence" or "urinary incontinence." A total of 436 articles were identified as suitable for inclusion in the meta-analysis. An additional 155 articles were suitable for complications data only due to insufficient follow-up of efficacy outcomes in these reports (for a detailed methodology and meta-analytic findings see the complete Guideline at: http://www.auanet.org/content/guidelines-and-quality-care/clinical-guidelines.cfm). Data were extracted from the articles and meta-analyzed according to the several definitions.

Surgical efficacy was defined using outcomes prespecified in the primary evidence articles, which included 1) resolution and lack of recurrence of SUI and urgency; 2) resolution of prolapse and lack of recurrence or new onset of prolapse; and 3) incidence and severity of adverse events of these treatments. Urgency (resolution and de novo) was included as an efficacy outcome due to its significant impact on quality of life. For the analysis of postoperative urgency, cases were divided into the 3 categories of without preexisting urgency, with preexisting urgency and unknown or uncertain pre-existing urgency. Postoperative urgency categories included urge incontinence, urge symptoms and unspecified. The primary efficacy outcome was resolution of stress incontinence measured as completely dry (cured/dry) or improved (cured/dry/improved). The data are reported as percentages and credible intervals (Bayesian confident intervals).

Outcomes were analyzed separately based on whether the continence evaluation was subjective or objective, and only results that were clearly based on subjective or objective criteria were included in their respective analyses. An additional category was created, defined as "any" method of evaluation, to include all studies irrespective of the method of assessment. For studies reporting subjective and objective results, the subjective results of the study were included in the "any" category. Outcomes also were analyzed separately according to the postoperative interval of the final assessment of continence, with a minimum period of followup of 12 months. The 3 intervals analyzed were 12 to 23 months, 24 to 47 months and greater than 48 months. If a study reported data at multiple times during one of these intervals, the time point closest to 18 months, 36 months and 60 months was used for the 3 time ranges.

Complications were analyzed similarly to the efficacy outcomes (see the complete guideline for additional information and outcomes data. To facilitate the analysis of complications for the various SUI surgical procedures and because of the lack of standardized nomenclature in the literature, the Panel grouped the reported complications into urinary retention, perioperative genitourinary, delayed genitourinary, gastrointestinal, vascular, neurological, infectious, general medical and death. Subjective complications (pain, sexual dysfunction and voiding dysfunction) were also included as a separate category.

The treatments included in the analysis were retropubic suspensions, slings, injectable therapy and artificial sphincters, and procedures not generally available in the United States were excluded from analysis. 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.

Based on the outcomes of the analysis, guideline statements were developed by the Panel. These statements were graded with respect to the degree of flexibility in application. As a treatment policy, a "standard" has the least flexibility, a "recommendation" has significantly more flexibility, and an "option" is even more flexible. 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. A guideline statement is a recommendation if 1) the health outcomes of the alternative interventions are sufficiently well-known to permit meaningful decisions and 2) an appreciable but not unanimous majority agrees on which intervention is preferred. 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.

DIAGNOSTIC EVALUATION OF THE INDEX PATIENT

Although the meta-analysis did not encompass diagnostic evaluation of the index patient, the Panel developed guideline statements based on consensus. They defined the purpose of diagnostic evaluation as 1) to provide documentation and characterization of SUI, 2) to assess the differential diagnosis and comorbidities, and 3) to aid in the choice of treatment and in determining the prognosis. The definitive

diagnosis of SUI is based on involuntary urine loss from the urethral meatus coincident with increased abdominal pressure (positive stress test) such as that occurring during coughing and straining in a patient who complains of stress incontinence.

Standard: The evaluation of the index patient should include

- **Focused history**
- **Focused physical examination**
- **Objective demonstration of SUI**
- **Assessment of post-void residual urine volume**
- **Urinalysis and culture if indicated**

(Based on Panel consensus)

Recommendation: Elements of the history should include

- **Characterization of incontinence (stress, urge etc)**
- **Frequency, bother and severity of incontinence episodes**
- **Impact of symptoms on lifestyle**
- **Patient expectations of treatment**

(Based on Panel consensus)

Recommendation: Additional diagnostic studies that can be performed to assess the integrity and function of the lower urinary tract include

- **Pad testing and/or voiding diary**
- **Urodynamics**
- **Cystoscopy**
- **Imaging**

(Based on Panel consensus)

Recommendation: Indications for further testing include

- **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**
- **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**

(Based on Panel consensus)

OUTCOMES ANALYSIS: RETROPUBIC SUSPENSIONS AND SLINGS

See the complete guideline for a description of all of the results http://www.auanet.org/content/guidelines-and-quality-care/clinical-guidelines.cfm.

Cured/Dry Rates

For an estimation of resolution rates, cured/dry and cured/dry/improved outcomes were analyzed but only cured/dry outcomes are presented (for cured/dry/improved rates, see the complete guideline). Data from retropubic open suspensions regardless of type (including Burch suspensions), open Burch suspensions alone and laparoscopic suspensions were analyzed. The estimated cured/dry rates at 12 to 23 months were 82% (95% CI 74 to 87) for open suspensions without concomitant prolapse treatment and 69% for laparoscopic suspensions (95% CI 52 to 84) (table 1). Due to the

Table 1. *Cured/dry analysis of no concurrent prolapse treatment by any evaluation method including subjective and objective*

	12–23 Mos		24–47 Mos		48 Mos or Greater	
	No. Groups/ No. Pts.	% Median (95% CI 2.5–97.5)	No. Groups/ No. Pts	% Median (95% CI 2.5–97.5)	No. Groups/ No. Pts	% Median (95% CI 2.5–97.5)
Suspensions:						
All open retropubic	15/1,085	82 (74–87)	13/803	76 (68–82)	17/1,259	73 (64–77)
Burch	14/1,070	81 (73–87)	12/775	76 (68–83)	13/1,065	73 (65–80)
Laparoscopic	9/368	69 (52–84)	4/172	74 (61–85)		
Slings:						
Autologous fascial						
Without bone anchors	4/342	90 (76–98)	6/232	81 (72–88)	4/368	82 (67–93)
Vaginal wall slings with/without bone anchors	1/39	79 (65–90)			1/29	96 (85–100)
Vaginal wall slings with bone anchors			1/58	79 (68–88)		
Cadaveric without bone anchors	1/104	74 (65–82)	2/71	80 (43–98)		
Synthetic at bladder neck						
With bone anchors	2/34	88 (71–97)			1/27	92 (78–98)
Without bone anchors			9/349	73 (64–80)		
Synthetic at midurethra	14/1,215	84 (78–89)	7/483	81 (72–88)	3/199	84 (77–89)
Injectable agents: collagen	7/340	48 (41–55)	4/210	32 (24–42)	1/40	30 (18–45)

overlap in these CIs, the results are not considered significantly different. At 24 months and beyond the cured/dry rates were similar among all procedures, ranging from 73% to 76%. Data were comparable for studies in which any patient received concomitant prolapse treatment (table 2).

Efficacy data were available for a variety of types of autologous fascial slings, including autologous slings without bone anchors and autologous vaginal wall slings with or without bone anchors. Most of the studies described patients treated with autologous slings without bone anchors. The estimated cured/dry rates with no prolapse treatment ranged between 90% at 12 to 23 months and 82% at 48 months or longer (table 1). Again, efficacy was similar for studies in which any patient received concurrent prolapse treatment (table 2).

Cadaveric slings came into wide use following a report by Handa et al.[7] However, the long-term durability of these procedures has been questioned[8–15] and, due to the decline in the use of cadaveric slings, limited data were available for analysis. The estimated cured/dry rates for patients undergoing cadaveric sling procedures without bone anchors and no concomitant prolapse treatment were 74% at 12 to 23 months and 80% at 24 to 47 months (table 1). There were no longer term (48 months or greater) efficacy data available. For the studies in which any patient received concomitant prolapse treatment, the estimated cured/dry rates at 12 to 23 months were 82% (95% CI 77 to 86%) with bone anchors and 58% (95% CI 36 to 78) without bone anchors (table 2). Despite the fact that these confidence intervals had little overlap suggesting the difference may be significant, the Panel considered this a statistical aberration due to the small number of patients rather than a true difference.

For synthetic slings, efficacy data were available for slings placed at the bladder neck and slings placed at the midurethra. For slings at the bladder neck, most of the data were on slings without bone anchors and the estimated cured/dry rate without prolapse treatment was 73% at 24 to 47 months (table 1). Longer term data were not available. For slings at the bladder neck with concurrent prolapse treatment, the estimated cured/dry rates were similar (table 2). For slings at the midurethra without prolapse treatment (transvaginal/retropubic technique), the estimated cured/dry rates ranged from 81% to 84% (table 1). Results were comparable for studies in which any patient received concurrent prolapse treatment (table 2).

Urgency

The estimates of urge incontinence outcomes (whether de novo or those with preexisting urgency) at 12 to 23 months are shown in table 3. The "unspecified" category included studies in which the preoperative urgency status of patients with postoperative urgency was not reported, and those in which patients with and without preoperative urgency were combined. There were few data for long-term outcomes. For all open retropubic and Burch suspensions, the estimate of de novo urge incontinence was 8%, and the postoperative urge incontinence estimates for those with preexisting urge incontinence were 14%

Table 2. *Cured/dry analysis of any patient in the group/arm receiving concurrent prolapse treatment by any evaluation including subjective and objective*

	12–23 Mos		24–47 Mos		48 Mos or Greater	
	No. Groups/ No. Pts	% Median (95% CI 2.5–97.5)	No. Groups/ No. Pts	% Median (95% CI 2.5–97.5)	No. Groups/ No. Pts	% Median (95% CI 2.5%–97.5%)
Suspensions:						
All open retropubic	9/517	88 (83–92)	9/403	83 (75–90)	13/1,072	67 (56–76)
Burch	9/517	88 (83–92)	7/333	85 (75–93)	12/954	65 (53–74)
Laparoscopic	12/564	88 (85–91)	7/359	83 (73–91)	1/34	88 (74–96)
Slings:						
Autologous fascial						
Without bone anchors	3/78	92 (82–97)	1/80	85 (76–92)		
Vaginal wall slings with/without bone anchors	1/20	70 (48–86)	2/60	89 (64–99)	1/82	95 (89–98)
Vaginal wall slings with bone anchors, suprapubic	1/19	99 (88–100)	1/9	87 (59–99)		
Cadaveric						
With bone anchors, transvaginal	1/234	82 (77–86)				
Without bone anchors	3/133	58 (36–78)	2/92	64 (21–95)	1/13	31 (11–58)
Homologous dermis without bone anchors			1/19	89 (70–98)		
Synthetic at bladder neck						
With bone anchors, suprapubic					1/49	85 (74–93)
With bone anchors, transvaginal			1/32	81 (65–92)		
Without bone anchors	1/20	94 (79–99)	3/184	75 (56–90)	3/182	73 (62–82)
Synthetic at midurethra	14/1,089	85 (80–89)	11/881	87 (81–91)	2/101	76 (64–85)
Other sling	1/126	92 (86–96)				

Table 3. *Urge incontinence outcomes at 12 to 23 months*

	De Novo		Preexisting		Unspecified	
	No. Groups/ No. Pts	% Median (95% CI 2.5–97.5)	No. Groups/ No. Pts	% Median (95% CI 2.5–97.5)	No. Groups/ No. Pts	% Median (95% CI 2.5–97.5)
Studies in which no pt received concurrent prolapse treatment						
Suspensions:						
All open retropubic	10/713	8 (5–12)	5/186	14 (6–25)	4/305	41 (30–54)
Burch	9/695	8 (5–11)	3/108	17 (4–40)	4/305	41 (30–54)
Laparoscopic	2/112	5 (1–14)			2/100	6 (1–14)
Slings:						
Autologous fascial						
Without bone anchors	4/329	9 (6–13)	4/358	33 (28–40)		
Vaginal wall slings with/without bone anchors			1/13	9 (1–31)		
Vaginal wall slings with bone anchors						
Cadaveric without bone anchors	1/25	28 (13–47)	1/38	21 (10–36)		
Synthetic at bladder neck with bone anchors			1/6	96 (67–100)		
Synthetic at bladder neck without bone anchors	4/132	12 (6–20)	1/24	17 (6–35)		
Synthetic at midurethra	7/323	6 (3–10)	1/25	44 (26–63)	2/532	22 (3–58)
Other sling						
Injectable agents: collagen	1/337	13 (10–17)			1/50	8 (3–18)
Studies in which any pt received concurrent prolapse treatment						
Suspensions:						
All open retropubic	10/457	14 (8–21)	2/143	22 (4–56)	2/256	13 (7–22)
Burch	9/417	14 (8–22)	1/25	48 (30–67)	2/256	13 (7–22)
Laparoscopic	5/344	11 (6–17)			1/32	4 (0–14)
Slings:						
Autologous fascial						
Without bone anchors	2/97	10 (4–19)				
Vaginal wall slings with/without bone anchors	3/65	13 (2–36)	2/15	47 (21–75)		
Vaginal wall slings with bone anchors suprapubic	1/9	13 (1–41)				
Cadaveric with bone anchors, transvaginal	1/238	6 (3–9)				
Homologous tissue (dermis) without bone anchors	1/5	22 (2–63)				
Synthetic at bladder neck without bone anchors	4/150	15 (5–31)	3/119	29 (16–46)		
Synthetic at midurethra	11/805	11 (7–16)	5/107	52 (38–66)	2/174	9% (1–38)

and 17%, respectively. The unspecified urge incontinence estimate was 41% for both procedures (table 3). Of the small number of patients undergoing laparoscopic retropubic suspensions the estimate was 5% for de novo urge incontinence and 6% for unspecified urge incontinence. There were no data for patients with preexisting urge incontinence. The postoperative urge incontinence estimate for patients with preexisting urge incontinence treated with open retropubic suspensions with concurrent prolapse repair was approximately 22%. The estimates for de novo urge incontinence and unspecified urge incontinence were 14% and 13%, respectively (table 3).

For autologous fascial slings without bone anchors, the estimated rate of de novo urge incontinence was 9% and the rate of postoperative urge incontinence in patients with preexisting urge incontinence urge was 33% (table 3). For synthetic slings at the midurethra, the estimate was 6% for de novo urge incontinence and 22% for unspecified urgency. For studies in which any patient had concurrent prolapse treatment, the de novo urgency rate was 11%.

Retention

Retention, defined as that lasting longer than 1 month or requiring intervention, estimates were generally low (table 4). However, the estimated rate of retention for autologous fascial slings without bone anchors was 8% for patients not receiving concurrent prolapse treatment and 5% for patients receiving concurrent prolapse treatment. The retention rate for synthetic slings at the bladder neck was estimated at 9% for those without concurrent prolapse repair and 10% for those receiving concurrent prolapse treatment, while the retention rate for synthetic slings at the midurethra was 3% for both groups. The difference in retention rates between synthetic slings placed at the midurethra and those placed at the bladder neck was considered by the Panel to be an important finding.

Complications

For a description and summary of the complications data, see the complete guideline document (http://www.auanet.org/content/guidelines-and-quality-care/clinical-guidelines.cfm).

Table 4. *Retention for more than 1 month or requiring intervention*

	No Prolapse Treatment		Prolapse Treatment	
	No. Groups/No. Pts	% Median (95% CI 2.5–97.5)	No. Groups/No. Pts	% Median (95% CI 2.5–97.5)
Suspensions:				
All open retropubic	8/619	4 (1–8)	13/851	1 (1–3)
Burch	5/347	3 (1–7)	10/710	1 (1–3)
Laparoscopic	5/188	4 (1–8)	11/482	2 (1–4)
Slings:				
Autologous fascial				
Without bone anchors	8/480	8 (4–15)	3/301	5 (2–11)
Vaginal wall slings with/without bone anchors	2/68	2 (0–8)	3/142	5 (1–17)
Suprapubic			1/25	1 (0–9)
Cadaveric without bone anchors			1/26	1 (0–10)
Synthetic at bladder neck				
With bone anchors, suprapubic			1/49	4 (1–12)
With bone anchors, transvaginal			2/99	1 (0–6)
Without bone anchors	4/360	9 (5–15)	7/422	10 (5–18)
Synthetic at midurethra	17/2,119	3 (2–4)	11/1,107	3 (2–5)
Injectable agents: collagen	2/104	1 (0–5)		

Common complications and estimated rates of occurrence for open retropubic suspensions were fever (8%), urinary tract infection (13%), bladder injury (4%) and voiding dysfunction (9%). Common complications for Burch suspension were fever (11%), UTI (15%), bladder injury (6%) and voiding dysfunction (10%). Laparoscopic suspensions appeared to have a lower overall risk of febrile complications (0%) and UTI (2%), although these estimates were based on limited data. Ureteral injury rates were 11% of laparoscopic retropubic suspensions compared to only 1% of open suspensions. Again, these estimates were based on a small number of patients. Complication estimates for autologous fascial slings without bone anchors were generally infrequent and included UTI (11%), bladder injury (4%) and wound complications (8%). For cadaveric slings, vaginal extrusion was reported in 1 study[16] but erosion of cadaveric materials into the urinary tract was not identified in this meta-analysis. When these materials were used with concomitant prolapse repair, complications such as infection and graft extrusion were reported.[17]

Complications occurring with synthetic slings at the bladder neck without bone anchors included UTI (10%) and erosion/extrusion (5% urethral/bladder, 8% vaginal and 17% unknown). While these data may overestimate the risk of complications, they do suggest increased rates of urinary tract erosion following synthetic slings placed at the bladder neck. Complication rates for synthetic slings placed at the midurethra included bladder injury (6%), UTI (11%) and extrusions (7% vaginal and 1% unknown). Overall reported complication rates were generally higher than recently reported data. Wound complications were also reported in the literature. Recently, the United States FDA released a warning position statement concerning the use of mesh materials in stress incontinence surgery and pelvic organ prolapse surgery, noting more than 1,000 reported complications of vaginal and urinary erosion as well as bowel and vascular injuries (http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/PublicHealthNotifications/ucm061976.htm).

OUTCOMES ANALYSIS: TRANSOBTURATOR TAPE PROCEDURES

Modifications to the pubovaginal sling for the surgical treatment of SUI include the tension-free vaginal tape procedure introduced in 1996 [18] and the transobturator technique introduced in 2001.[19–21] Since the cutoff date for the literature review for this guideline was June 2005, limited data were available in the peer-reviewed literature to analyze these procedures, although subsequently numerous studies have been published. The Panel is aware of the importance of the transobturator technique in the treatment of SUI.

OUTCOMES ANALYSIS: INJECTABLE AGENTS

Injectable agents are an option for patients who do not wish to undergo more invasive surgery, and who understand that efficacy and duration are inferior to surgery. Other possible indications include elderly patients, those at high anesthetic risk and those willing to accept improvement in the incontinence without necessarily achieving dryness.

For this analysis, injectable agents were subdivided into collagen (bovine gluteraldehyde cross-linked) and other nondegradable synthetic agents. Sufficient data were available only for an analysis of collagen. The cured/dry estimates for patients treated with collagen without concomitant prolapse decreased

from 48% at 12 to 23 months to 32% at 24 to 47 months (table 1). The postoperative rates of urge incontinence as well as the rates of complications were low. Limited information was available for the other injectable agents, except for data from the multicenter trials that led to FDA approval for carbon-coated zirconium beads in beta-glucan gel[22] and calcium hydroxylapatite.[23] Overall, there were limited data with which to assess the long-term safety and efficacy of injectable agents.

OUTCOMES ANALYSIS: ARTIFICIAL URINARY SPHINCTERS

Data on the use of the artificial urinary sphincter in the index patient were limited, precluding analysis. The AUS is occasionally used in the patient with severe intrinsic sphincteric deficiency after other surgical procedures have failed or in those with diabetes or back injury and significant SUI and poor bladder contractility. Erosion, infection and device malfunction are potential complications. Based on the only recent study of complications the erosion/extrusion rate was 28%.[24] With respect to the index patient the AUS might be useful in the woman using the Valsalva maneuver to void who must abdominally strain to empty the bladder. When the cuff is opened for voiding, the AUS is not likely to be obstructive to the bladder in contrast to slings when straining may cause obstruction to the urinary flow. The Panel believes the role of the AUS in the treatment of SUI is limited.

TREATMENT GUIDELINE STATEMENTS FOR THE INDEX PATIENT

Standard: The patient should be counseled regarding the surgical and nonsurgical options including benefits and risks. Choice of the procedure should be made as a collaborative effort between the surgeon and patient, and should consider patient preferences as well as surgeon experience and judgment.

(Based on Panel consensus)

Standard: Patients with urge incontinence without stress incontinence should not be offered a surgical procedure for stress incontinence.

(Based on Panel consensus)

The index patient has genuine stress urinary incontinence with or without prolapse. The use of a prophylactic anti-incontinence procedure in the patient with occult incontinence with high grade prolapse is not the guideline index patient, and the Panel does not have an opinion about prophylactic incontinence surgery.

Recommendation: Synthetic sling surgery is contraindicated in stress incontinent patients with a concurrent urethrovaginal fistula, urethral erosion, intraoperative urethral injury and/or urethral diverticulum.

(Based on Panel consensus)

Although there is no peer-reviewed literature that specifically evaluates these uncommon conditions, the Panel believes that using synthetic material may place the patient at higher risk for subsequent urethral erosion, vaginal extrusion, urethrovaginal fistula and foreign body granuloma formation. In such patients the Panel believes that autologous fascial and alternative biological slings are options in the treatment of concomitant stress incontinence. The decision to use these materials should be based on the judgment of the surgeon and made in the best interests of the patient.

Standard: Intraoperative cystourethroscopy should be performed in all patients undergoing sling surgery.

(Based on Panel consensus)

For optimum detection of potential intraoperative complications, the urethra should be inspected with either a short beak rigid cystoscope or a flexible cystoscope.

Option: The 5 major types of procedures (injectables, laparoscopic suspensions, midurethral slings, pubovaginal slings and retropubic suspensions), although not equivalent, may be considered for the index patient.

(Based on Panel consensus)

Newer techniques and materials for the surgical treatment of stress incontinence have or are being developed. For the index patient, the Panel believes that these techniques, materials, and accompanying physician expertise and experience offer a number of advantages that include shorter operative time, shorter recovery time and less short-term morbidity. However, urethral erosion and vaginal extrusion of the synthetic material may occur, which can be difficult to treat. In addition, perforation of bowel and blood vessels, which pose a life threatening risk, may result from this procedure. Longer followup is needed before any definitive statements regarding the long-term efficacy and life long risk of erosion with these procedures can be made.

Option: The artificial urinary sphincter may be indicated in certain circumstances.

(Based on evidence and Panel opinion)

The Panel considers the use of the AUS in the index patient as an option, with a limited role for those not amenable to treatment with other procedures.

Option: Stress incontinence procedures may be considered for patients with mixed incontinence and a significant stress incontinence component.

(Based on review of the data and Panel consensus)

Ample support exists for the role of surgery in mixed incontinence.[25] The meta-analysis estimate of postoperative urge incontinence was 14% from data on 186 patients (95% CI 6 to 25) with pre-existing urge incontinence when treated with open retropubic suspensions while others have reported disparate outcomes.[26]

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.

(Based on Panel consensus)

RECOMMENDATIONS FOR FUTURE RESEARCH AND REPORTING

Although more than a decade has passed since the recommendations for improving the quality of data from clinical trials and studies were proposed in the 1997 AUA Panel report,[4] little progress has been made by editors and reviewers in instituting these recommendations.[27] Furthermore, the FDA has not altered the approval process. Thus, again, the Panel members were disappointed in data available for meta-analysis. In addition to the specific recommended outcome measures in the original Panel report,[4] editors and their reviewers should require the following:

- Defined outcome measures obtained preoperatively and followed postoperatively:
  - Validated questionnaires
  - Bladder diary
  - Pad test
  - Exam with full bladder
- For reporting of efficacy data, a minimum followup of all surgically treated patients for at least 12 months
- An assessment of prolapse (anterior, posterior, apical) as determined by preoperative pelvic examination recorded for all patients

For adverse event data, complications should be categorized as those occurring intraoperatively or postoperatively. It is essential to report the following adverse event data:

- Overactive bladder symptoms, which should include persistent overactivity (already present preoperatively) or de novo overactivity (occurring as a complication of the surgery)
- Other lower urinary tract symptoms (persistent or de novo)
- Urinary retention for longer than 1 month and/or requiring intervention
- Infection (reported as wound infection, vaginal infection, recurrent urinary tract infection, pelvic abscess etc)
- Fever (sepsis)
- Postoperative pain, bleeding, thromboembolus formation (lower extremity, pulmonary or other)
- Lower urinary tract or vaginal injury or erosion
- Refractory pain
- Other serious complications, including vascular or bowel injury, and death

The profession at large and the individual physician should ensure the safety and efficacy of any new device or sling. If safety and efficacy have not been shown with reasonable certainty, the new treatment should only be performed as part of clinical research studies and/or with informed consent recognizing that safety and/or efficacy has not been demonstrated.

ACKNOWLEDGMENTS AND DISCLAIMERS

This document was written by the Female Stress Urinary Incontinence Update Panel of the American Urological Association Education and Research, Inc., which was created in 2002. The Practice Guidelines Committee of the AUA selected the committee chair and panel members were selected by the chair. Membership of the committee included urologists and gynecologists with specific expertise on this disorder. The mission of the committee was to develop recommendations that are analysis based or consensus based, depending on Panel processes and available data, for optimal clinical practices in the diagnosis and surgical treatment of female SUI. This document was submitted for peer review to 76 urologists and other health care professionals. After the final revisions were made based upon the peer review process, the document was submitted to and approved by the Practice Guidelines Committee and the AUA Board of Directors. Funding of the committee was provided by the AUA. Committee members received no remuneration for their work. Each member of the committee provided a conflict of interest disclosure to the AUA.

This report is intended to provide medical practitioners with a consensus of principles and strategies for the surgical treatment of female stress urinary incontinence. The report is based on current professional literature, clinical experience and expert opinion. It does not establish a fixed set of rules or define the legal

standard of care, and it does not preempt physician judgment in individual cases.

Statistical analysis was provided by Hanan S. Bell, PhD, data compilation by Patrick M. Florer and editorial support by Linda Whetter, DVM, PhD of Zola Associates.

All Panel members completed conflict of interest disclosures. (C) indicates compensation was received and (U) indicates no compensation was received. Consultant or Advisor: Rodney Appell, Boston Scientific (C), Allergan (C), Astellas (C), Bayer, Schering-Plough (C), Pfizer (C), American Medical Systems (C); Roger R. Dmochowski, Novartis (C), Pfizer (C), Astellas (C), Watson Pharmaceuticals (C), Lilly (C); Mickey M. Karram, Astellas (C), Cooper Surgical (C), EWH&U (C); Karl M. Luber, Watson Pharmaceuticals (C), Indevus (C), Pfizer (C), Astella (C); David R. Staskin, Pfizer (C), GlaxoSmithKline (C), Astellas (C), Watson (C), Allergan (C), American Medical Systems (C); Saad Juma, Coloplast corporation (C), Contura (C); J. Christian Winters, Astellas (C); Jerry G. Blaivas, Navasys Medical (C), Bayer (C), Pfizer (C), Endogun (C); Eric Scott Rovner, Pfizer (C), Allergan (C), Astellas (C), Tengion (C). Investigator: Rodney Appell, Solace, Inc. (C), Novasys Medical, Inc. (C); Roger R. Dmochowski, Allergan (C); Saad Juma, Solace Therapeutics (C), Contura (C), Bioform (C); Eric Scott Rovner, Pfizer (C). Scientific Study or Trial: Eric Scott Rovner, Pfizer, (C), Solace, (C), Contura (C); J. Christian Winters, Solace Thera (U). Meeting Participant or Lecturer: Eric Scott Rovner, Allergan (C); Other: Rodney Appell, American Medical Systems (C), Boston Scientific Corporation (C); Jerry G. Blaivas, HDH (U); Mickey M. Karram, E-Medsco (C), Ethicon Women's Health & Urology(C), Cooper Surgical (C), Astellas (C); Linda E. Whetter, Zola Associates (C).

REFERENCES

1. Luber KM: The definition, prevalence, and risk factors for stress urinary incontinence. Rev Urol 2004; **6:** S3.
2. Hampel C, Wienhold D, Benken N et al: Definition of overactive bladder and epidemiology of urinary incontinence. Urology 1997; **50:** 4.
3. Hampel C, Artibani W, Espuña Pons M et al: Understanding the burden of stress urinary incontinence in Europe: a qualitative review of the literature. Eur Urol 2004; **46:** 15.
4. Leach GE, Dmochowski RR, Appell RA et al: Female Stress Urinary Incontinence Clinical Guidelines Panel summary report on surgical management of female stress urinary incontinence. The American Urological Association. J Urol 1997; **158:** 875.
5. Abrams P, Cardozo L, Fall M et al: The standardisation of terminology of lower urinary tract function: report from the Standardisation Subcommittee of the International Continence Society. Neurourol Urodyn 2002; **21:** 167.
6. Weber AM, Abrams P, Brubaker L et al: The Standardization of Terminology for Researchers in Female Pelvic Floor Disorders. Int Urogynecol J Pelvic Floor Dysfunct 2001; **12:** 178.
7. Handa VL, Jensen JK, Germain MM et al: Banked human fascia lata for the suburethral sling procedure: a preliminary report. Obstet Gynecol 1996; **88:** 1045.
8. Elliott DS and Boone TB: Is fascia lata allograft material trustworthy for pubovaginal sling repair? Urology 2000; **56:** 772.
9. Flynn BJ and Yap WT: Pubovaginal sling using allograft fascia lata versus autograft fascia for all types of stress urinary incontinence: 2-year minimum followup. J Urol 2002; **167:** 608.
10. Fitzgerald MP, Mollenhauer J, Bitterman P et al: Functional failure of fascia lata allografts. Am J Obstet Gynecol 1999; **181:** 1339.
11. Huang Y, Lin A, Chen K et al: High failure rate using allograft fascia lata in pubovaginal sling surgery for female stress urinary incontinence. Urology 2001; **58:** 943.
12. Carbone JM, Kavaler E, Hu JC et al: Pubovaginal sling using cadaveric fascia and bone anchors: disappointing early results. J Urol 2001; **165:** 1605.
13. Fitzgerald MP, Mollenhauer J and Brubaker L: Failure of allograft suburethral slings. BJU Int 1999; **84:** 785.
14. Owens DC and Winters JC: Pubovaginal sling using Duraderm graft: intermediate follow-up and patient satisfaction. Neurourol Urodyn 2004; **23:** 115.
15. O'Reilly KJ and Govier FE: Intermediate term failure of pubovaginal slings using cadaveric fascia lata: a case series. J Urol 2002; **167:** 1356.
16. Clemens JQ, DeLancey JO, Faerber GJ et al: Urinary tract erosions after synthetic pubovaginal slings: diagnosis and management strategy. Urology 2000; **56:** 589.
17. Chung SV, Franks M, Smith CP et al: Technique of combined pubovaginal sling and cystocele repair using a single piece of cadaveric dermal graft. Urology 2002; **59:** 538.
18. Ulmsten U, Henriksson L, Johnson P et al: An ambulatory surgical procedure under local anesthesia for treatment of female urinary incontinence. Int Urogynecol J Pelvic Floor Dysfunct 1996; **7:** 81.
19. Delorme E: Transobturator urethral suspension: mini-invasive procedure in the treatment of stress urinary incontinence in women. Prog Urol 2001; **11:** 1306.
20. Delorme E, Droupy S, de Tayrac R et al: Transobturator tape (Uratape). A new minimally invasive method in the treatment of urinary incontinence in women. Prog Urol 2003; **13:** 656.
21. Delorme E, Droupy S, de Tayrac R et al: Transobturator tape (Uratape): a new minimally-invasive procedure to treat female urinary incontinence. Eur Urol 2003; **45:** 203.
22. Lightner D, Calvosa C, Andersen R et al: A new injectable bulking agent for treatment of stress urinary incontinence: results of a multicenter, randomized, controlled, double-blind study of Durasphere. Urology 2001; **58:** 12.
23. Mayer RD, Dmochowski RR, Appell RA et al: Multicenter prospective randomized 52-week trial of calcium hydroxyl apatite versus bovine dermal collagen for treatment of stress urinary incontinence. J Urol 2007; **69:** 876.
24. Costa P, Motett N, Rabut B et al: The use of an artificial urinary sphincter in women with type III incontinence and a negative Marshall test. J Urol 2001; **165:** 1172.
25. Chou EC, Flisser AJ, Panappoulos G et al: Effective treatment for mixed urinary incontinence with a pubovaginal sling. J Urol 2003; **170:** 494.
26. Anger JT and Rodriguez LV: Mixed incontinence: stressing about urge. Curr Urol Rep 2004; **5:** 427.
27. Rovner ES, Wright CJ and Messer H: Adherence to the 1997 AUA Guidelines for the surgical treatment of stress urinary incontinence. Urology 2008; **71:** 239.