THE JOURNAL of UROLOGY®
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Updates to Surgical Treatment of Female Stress Urinary Incontinence (SUI): AUA/SUFU Guideline (2023)

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Purpose: The purpose of this guideline is to provide a clinical structure with which to approach the diagnosis, counseling, and treatment of female patients with stress urinary incontinence (SUI).

Materials/Methods: The primary source of evidence for the 2017 version of the SUI guideline was the systematic literature review conducted by the ECRI Institute. The initial search spanned literature from January 2005 to December 2015, with an additional updated abstract search through September 2016. The current amendment represents the first update to the 2017 iteration and includes updated literature published through February 2022.

Results: This guideline has been amended to reflect changes in and additions to the literature since 2017. The Panel maintained that the differentiation between index and non-index patients remained important. The index patient is a healthy female with minimal or no prolapse who desires surgical therapy for treatment of pure SUI or stress-predominant mixed urinary incontinence. Non-index patients have factors that may affect their treatment options and outcomes, such as high grade prolapse (grade 3 or 4), urgency-predominant mixed incontinence, neurogenic lower urinary tract dysfunction, incomplete bladder emptying, dysfunctional voiding, SUI following anti-incontinence treatment, mesh complications, high body mass index, or advanced age.

Conclusion: While gains have been made in the field to support new methods for the diagnosis, treatment, and follow-up of patients with SUI, the field continues to expand. As such, future reviews of this guideline will take place to stay in keeping with the highest levels of patient care.

Key Words: stress urinary incontinence, counseling, diagnosis, education, complications, surgery, therapy, female

SUI is a prevalent condition characterized by loss of urine in the setting of increased abdominal pressure. The various treatment alternatives range from non-surgical to surgical, and the modalities have continued to evolve. As length of patient follow-up has increased and new therapeutic options have emerged, counseling of patients should inevitably progress as well. This

Submitted March 14, 2023; accepted March 15, 2023; published April 25, 2023.
The complete unabridged version of the guideline is available at https://www.jurology.com.
This document is being printed as submitted, independent of standard editorial or peer review by the editors of *The Journal of Urology*®.
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https://doi.org/10.1097/JU.0000000000003435
Vol. 209, 1091-1098, June 2023
Printed in U.S.A.

update reflects maturing outcomes of previously reported techniques and recent additions to the treatment armamentarium.

The original guideline included 24 statements that were divided into subsections that included Patient Evaluation, Cystoscopy and Urodynamics Testing, Patient Counseling, Treatment, Special Cases, and Outcomes Assessment. No changes were made to the 3 statements in either the Patient Evaluation or the Cystoscopy and Urodynamics sections. See Figure 1 for full summary recommendations. The unabridged guideline is available on the AUA website.

PATIENT COUNSELING

While no changes were made to any of the statements in this section, a short addendum was made to the supporting text to indicate that pre-operative counseling regarding midurethral sling (MUS) mesh complications results in reduced patient concern, greater willingness to proceed, and higher satisfaction.[1,2]

TREATMENT

Conservative Measures

Given the increase in available literature and follow-up, several updates were made to the treatment statement. More attention was paid to conservative measures with discussion around the use of pelvic floor muscle exercises with or without biofeedback and a small randomized controlled trial (RCT) that supports the addition of dynamic lumbopelvic stabilization (DLS) in short pelvic floor muscle and lumbar muscle resistance training. DLS has been shown to add to the efficacy of pelvic floor muscle exercises (PFME) alone.[3] In this study, patients in the PFME and DLS group had improved day and night urine loss, lower severity of urine loss, and improved quality of life (QOL) compared to the PFME-only group ($P < .05$) at 90 days follow-up. The effect size increased with time following training.

The statements regarding options that should be presented to patients were modified to reflect the increase in follow-up as well as several direct comparisons of techniques at longer term. The Panel maintains that it is essential to present all viable surgical options to patients, stressing the importance of counseling on the safety and efficacy of each approach. With maturity of the data for single incision slings (SIS) and adjustable slings now starting to be realized, the consideration of MUSs has been combined to address multi-incision and single-incision retropubic and transobturator slings in a merged conditional recommendation statement, while still acknowledging the difference in level of evidence. (Evidence Level A for retropubic midurethral sling (RMUS) and transobturator midurethral sling (TMUS); Evidence Level B for SIS).

TMUS versus RMUS

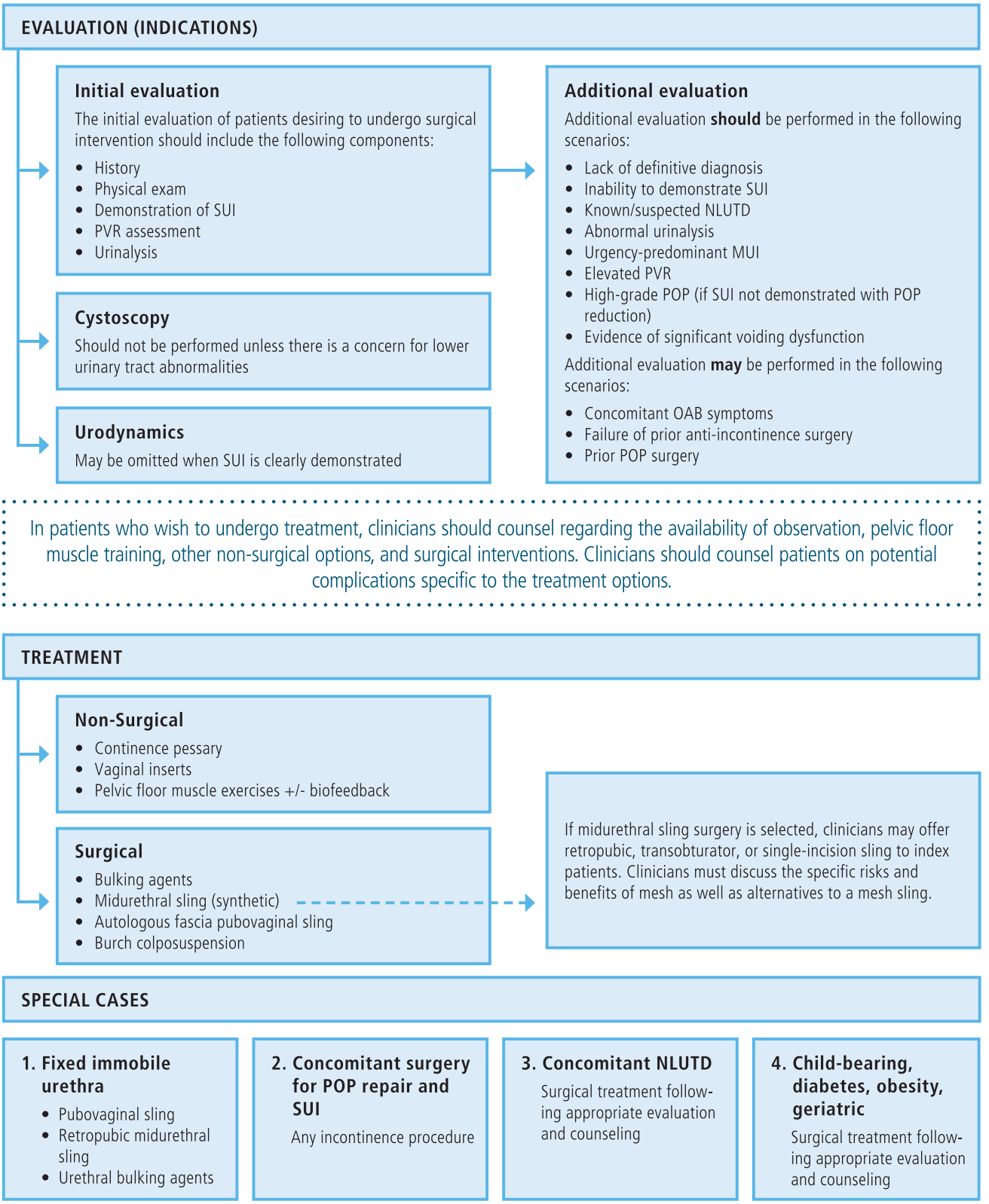
Given that the TMUS was introduced as a potentially safer option over the RMUS, comparative efficacy and safety analyses between the sling types were performed. In aggregate, most short-term analyses found RMUSs and TMUSs to be equivalent. However, several long-term comparisons showed a therapeutic advantage of the RMUS over the TMUS.[4] One- and 2-year analysis in the Trial of Mid-Urethral Slings (TOMUS) demonstrated statistical equivalence for objective success between the 2 procedures; however, slight advantages toward the RMUS were seen with longer follow-up (5 years).[4,5]

Still, updated systematic reviews as a whole have continued to be inconclusive with some studies showing no difference between groups with regard to patient satisfaction, QOL, and objective and subjective cure[6] and others showing greater improvements in cure rate and incontinence for the RMUS over the TMUS.[7] Similarly, a follow-up report on a previously reported RCT by Ross et al. (2016)[8] showed no statistically significant differences between the groups regarding problematic SUI in the prior 7 days or changes in UDI-6, IIQ-7, and PISQ-12 scores from baseline. The only parameter that approached significance was problematic urgency urinary incontinence (UUI) in the prior 7 days, which favored transobturator tape (TOT) over tension-free vaginal tape (TVT) (4.9% and 13.5%, respectively, $P = .05$). The RCT by Palos et al. (2018) reported noninferiority of the 2 approaches for all outcomes evaluated with the exception of a higher retention rate with the RMUS.[9]

Overall, while some data have suggested a lack of durability of TMUS versus RMUS, others have shown similar subjective and objective outcomes between the TVT and TVT-O long-term. At a mean of 95 months, Zhang et al. reported an RCT of 120/140 (85.7%) patients with comparable objective curates for TVT and TVT-O at 79.3% and 69.4%, respectively, no difference in PISQ-12, and persistent improvement in PFIQ-7 scores ($P < .001$).[10]

Regarding adverse events, with the exception of a 3-fold higher mesh extrusion rate with TMUS over RMUS, Juliato et al. reported no difference in rates of de novo pain, de novo urgency, post-void residual >100 cc, and urinary tract infections.[6] One systematic review by Lian et al.[11] evaluating 9,223 cases from 33 trials reported a higher incidence of intraoperative vaginal perforation with the TMUS versus RMUS (2.1% and 0.89%, respectively). Ross et al.[8] similarly favored TVT over TOT regarding vaginally palpable tape. Still, the composite outcomes, including mesh exposure, urinary retention, repeat anti-incontinence surgery, and moderate to severe pelvic pain revealed no difference between the groups at 5-year follow-up.

Female Stress Urinary Incontinence: AUA/SUFU Evaluation and Treatment Algorithm



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 1. Female Stress Urinary Incontinence: AUA/SUFU Evaluation and Treatment Algorithm.

For the non-index patient, 1 systematic review reported favorable outcomes for subjective and objective outcomes for TVT over TOT, specifically in patients with obesity, intrinsic sphincter deficiency (ISD), persistent SUI after MUS, and prolapse.[12]

SIS

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

Updated evidence includes 1 observational study evaluating the subjective outcomes of SIS and 11 controlled trials comparing the efficacy and safety of SIS with the transobturator or the standard MUS (TVT, TVT-O, TOT).

SIS versus Standard MUS

Three studies directly compared patients receiving SIS to standard MUS.[13-15] An updated systematic review and meta-analysis of RCTs comparing SIS with TVT or TOT-MUS with up to a 60-month follow-up identified similar subjective cure rates between groups. However, objective cure rates were inferior with SIS compared to standard MUS. Regarding operative parameters, Kim et al. reported reduced intraoperative blood loss, operative time, immediate postoperative pain, and voiding dysfunction with SIS versus MUS.[14] Two RCTs comparing outcomes between SIS and MUS identify the equivalent objective cure rate at 12 months and equivalent subjective cure rates at 12 and 36 months.

A pragmatic, non-inferiority RCT comparing SIS and standard MUS at 36 months confirmed non-inferiority of SIS for subjective cure rate with similar rates of groin/thigh pain. However, mesh exposure, dyspareunia, and repeat surgery were higher in the SIS group.[16]

SIS versus TMUS

Ten controlled trials compared TMUS with SIS with 12 to 36 month follow-up. While definitions of objective and subjective cure varied and a variety of SISs were utilized, SIS appears comparable to TOT regarding success and adverse events. A systematic review comparing multiple surgical interventions for women with SUI showed favorable outcomes for SIS over TMUS for tape exposure and for SIS over RMUS regarding pain.[17]

In another prospective, randomized, parallel cohort study with 36-month follow-up comparing SIS and TMUS, composite objective and subjective success, mesh related complications, and adverse events were similar.[17]

Long-term SIS Data

In a retrospective, single-arm observational study of SIS with minimum follow-up of 54 months, subjective improvement and cure was observed in 75% and 60.8%, respectively.[18] Complications included recurrent urinary tract infection (rUTI) (5.3%), urinary tract infection (UTI) (4.8%), urinary retention (4.3%), pain (3.5%), sling exposure (2.5%), de novo urgency (2.5%), and de novo UUI (2.0%). Sling failure was observed in 10% of patients, of which 76% occurred within 2 years post-surgery.[18]

Bulking Agents

Because re-treatment is common for urethral bulking injection, outcomes assessment is challenging. Inadequate data exist to support recommendation of 1 injectable agent over another. Still, bulking agents may have a role in patients who wish to avoid more invasive surgical management, lengthier recovery time after surgery, or who experience insufficient improvement following an anti-incontinence procedure. Patients should be counseled on the expected need for repeat injections.

There are limited long-term data on bulking agents. Calcium hydroxyapatite, polydimethylsiloxane, and polyacrylamide hydrogel (PAHG) have longer-term data that show persistence of effect at 73.2, 83, and 96 months, respectively.[19] In an index SUI patient group studied in a recent RCT, PAHG demonstrated a lower satisfaction rate compared with TVT; however, the majority of women treated with PAHG were considered cured or improved at 3-year follow-up.[20,21] Some interpret this finding to suggest that patients may choose the less invasive urethral bulking injection over sling surgery despite lower success. While re-injection may be required with all bulking agents, erosions were not noted in PAHG patients as with other bulking agents in multiple studies.[19]

Stem Cell Therapy

Stem cell therapy (SCT) may be a future option for women with SUI, but while there are increasing studies evaluating SCT, there are currently not enough data to support this treatment modality. Klapper-Goldstein et al. performed a systematic review of 773 patients in 19 studies with various study designs.[22] A second large meta-analysis of 23 studies with a total of 890 male and female patients reported results for women separately.[23] Neither study reported comparators, outcomes, or outcome data in the abstract, rendering the ability to draw meaningful support for SCT unclear. However, Klapper-Goldstein concluded that SCT is a safe and effective treatment for SUI,[22] and Huang reported a

26% pooled complication rate for females with no serious complications.[23]

SPECIAL CASES

Fixed Immobile Urethra

The Panel maintains the consensus from the 2017 guideline that the autologous pubovaginal sling (PVS) is a preferred approach over RMUS and bulking agents for treatment of SUI in the patient with a fixed immobile urethra. This position is based upon the lack of robust evidence for RMUS in these patients, the suboptimal outcomes with bulking injections, and the long track record of PVS.

An additional consideration, which is introduced in this current iteration of the guideline, is the adjustable RMUS that offers an opportunity for continued adjustability of the sling tension over time. While studies have been performed in a wide variety of both index and non-index patients, the adjustable sling may be a suitable option for surgical management of the refractory or recurrent SUI patient.[24] Several studies have shown good success with recurrent SUI patients albeit with lower success rates than those without prior incontinence surgery;[25] other studies have variable success with small sample sizes. However, because this device offers adjustability over time to address recurrent SUI, absolute success rates are difficult to determine.

Concomitant Sling at the Time of Prolapse Repair

As with the CARE[26] and OPUS[27] trials, contemporary literature continues to support consideration of a concomitant anti-incontinence procedure at the time of prolapse repair. An RCT by Van der Ploeg et al.[28] compared pelvic organ prolapse (POP) surgery with or without MUS and demonstrated an improvement in postoperative SUI when POP surgery was combined with MUS. Similarly, a systematic review of 1,361 prolapse patients with SUI demonstrated a statistically significantly higher post-operative continence rate and a favorable complication rate in the patients who underwent a concomitant TVT or SIS-TVT with their prolapse repair over those who underwent an unspecified "different surgical treatment."[29]

A decreased urgency incontinence rate following combination surgery as compared to prolapse surgery alone (28% versus 42%, RR: 0.7) has been demonstrated. Additionally, adverse events such as bladder perforation, urethral injuries, and tape exposure (14% versus 8%, RR: 1.7) occurred more commonly in the combination group (28% versus 15%, RR: 1.8). Consequently, though patients who undergo combined surgery had lower rates of postoperative SUI, they appear to have higher rates of voiding symptoms and complications.[30]

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

Severe Outlet Dysfunction, Recurrent or Persistent Postoperative SUI After Anti-incontinence Surgery

This represents a new statement to the guideline and suggests consideration of an obstructing PVS or bladder neck closure with urinary drainage in patients with a severely compromised bladder outlet. Functional or anatomic issues (eg, failed surgery for treatment of SUI, severe ISD, neurogenic bladder [covered in a separate guideline]) may require more drastic measures for successful treatment of SUI. Bladder neck occlusion to the extent necessary in these challenging situations could require a degree of tension that should preclude the use of synthetic slings. A traditional autologous PVS is an option, but in more severe cases, one may need to consider an obstructing autologous sling or formal bladder neck closure with a catheterizable stoma, an artificial urinary sphincter (AUS), or total urinary diversion via ileal conduit or continent diversion.

Three recent meta-analyses specifically evaluating non-neurogenic SUI provided insight into the role of the AUS in the treatment of non-index SUI patients. Barakat et al.[31] performed a systematic review of 15 studies (n=964) in women with persistent SUI following unspecified anti-incontinence treatments. Success rates and complications supported AUS as an effective treatment in women with severe UI after failure of first-line therapy. Mean complete continence rate in the meta-analysis at a 22-month mean follow-up (range 6 to 204) was 80% (95% CI: 72% to 87%). However, the authors acknowledged that the currently available study population is too small to render firm conclusions. Complications requiring revision or explantation both occurred at rates of 0% to 44% (mean 15% and 13%, respectively). Mechanical complications (mean 13%; range 0% to 47%), vaginal erosion (mean 9%; range 0% to 27%), and infection (mean 7%; range 0% to 46%) were reported.

In another meta-analysis, Reus et al.[32] reviewed 12 non-randomized, non-prospective studies with short- and long-term follow-up of women with non-neurogenic SUI (n=886), implied to be ISD. The studies reported a zero-pad rate of 42% to 86% post-AUS, mechanical failure in 2% to 41%, and revision and explantation rates of 6% to 44% and 2% to 27%, respectively.

Peyronnet et al.[33] performed a systematic review of 17 retrospective or prospective non-comparative case series reporting on various approaches to

AUS implantation (vaginal, open, laparoscopic, robot-assisted) for treatment of ISD, most of whom had undergone a previous anti-incontinence procedure. The study reported complete continence rates of 61% to 100% at mean follow-up of 5 to 204 months, and the authors concluded that AMS-800 AUS can provide excellent functional outcomes in female patients with SUI resulting from ISD but at the cost of a relatively high morbidity. Explantation and mechanical failure rates in this analysis were similar to that reported by Barakat et al.,[31] and urethral erosion rate varied from 0% to 22%. This series specifically noted intraoperative bladder neck and vaginal injury rates of 0% to 44% and 0% to 25%, respectively.

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

Outcomes Assessment

Early intervention may ameliorate potential problems that patients may not recognize as concerns. Accordingly, the Panel upholds the recommendation for early follow-up either in-person, by phone, or via telemedicine. Since the 2017 guideline, the COVID-19 pandemic accelerated the use and study of virtual medicine. A recent prospective, RCT comparing 3-week postoperative telemedicine versus office-based follow-up after MUS surgery identified no difference in satisfaction, unplanned events, or complications in the first 3 to 5 months postoperatively.[34] Similarly, Pan et al. compared in-person outpatient follow-up to telehealth follow-up using WeChat for women who had recently undergone an MUS.[35] They identified favorable retention and patient satisfaction for patients assigned to WeChat follow-up group. No difference was seen for International Consultation on Incontinence Questionnaire–Urinary Incontinence Short Form (ICIQ-UI SF) scores, global patient scores, or postoperative complications between groups.

FUTURE DIRECTIONS

Educational Opportunities

While patient education and the impact of health literacy was introduced in the 2017 guideline, a minor addendum was made pertaining to methods by which to approach and counsel patients. Assessment of health literacy with validated questions such as "How confident are you filling out forms by yourself?"[36] or expanded use of tests of functional health literacy in adults (TOFHLA) may provide valuable information to facilitate optimal communication. Additionally, use of audiovisual content has been shown to improve patient education, recall, and informed consent and may be appropriate for women with SUI.[37,38]

Therapeutic Opportunities

The Panel acknowledges that laser and magnetic/electrical stimulation therapy are emerging therapies for the treatment of SUI whose current data remain inconsistent and of poor quality. While these options may offer some benefit in index SUI patients seeking non-surgical treatment, patients must be extensively counseled on the immaturity of the data, particularly in the setting of the FDA advisory warning against the use of energy-based devices for "vaginal rejuvenation." (https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-efforts-safeguard-womens-health-deceptive-health-claims).

Studies included in systematic reviews evaluating the safety and efficacy of Er:YAG and CO^2 lasers on women with SUI were limited by unclear or observational study design, lack of a control/comparator arms, short-term follow-up, poor methodological quality, and inconsistent results, thus limiting the applicability of the results.[39,40] Similarly, despite limitations to the data that include significant heterogeneity in the data and stimulation protocols, all meta-analyses comparing magnetic stimulation to sham or placebo concluded that magnetic stimulation appears to be safe and may be effective in reducing SUI.[41-43]

A Cochrane review[44] of 3,781 patients in 51 studies comparing non-implanted electrical stimulation (ES) to various other interventions (PFME, vaginal cones, sham) or no intervention provided the most robust evidence on ES. While the review indicated that ES is more effective than sham or no active treatment, it was not possible to say whether or not ES has similar efficacy to PFME or other active treatments. Overall, the quality of the evidence was too low to provide reliable results. A meta-analysis of 9 RCTs (n = 982) comparing ES to sham ES or no intervention[45] also identified improvements in QOL, possibly attributed to an additional favorable outcome pertaining to urinary frequency but only short-term (<3 months) improvement in urinary leakage.

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

Standardization of Outcomes

The lack of standardization around outcomes evaluation, assessment tools, and the very definition of

success in female pelvic medicine and reconstructive surgery (FPMRS) has been a long-standing barrier to advancement of the field. Treatment of SUI is no exception to this predicament, and the state of the current literature unequivocally illustrates that little has changed over the years. Many have acknowledged this quandary over recent decades,[46,47] and there have been numerous attempts to unite researchers in the field to establish minimum standards regarding the instruments utilized to measure the results of our interventions and to determine how a favorable outcome should be defined.[48,49]

While technology continues to evolve and new innovative techniques emerge, accurate assessment of outcomes following medical intervention is paramount to optimizing one's ability to offer the best treatments for our patients. Only when a consensus around outcomes assessment is reached will it be possible to accomplish meaningful comparison of outcomes from 1 center to another, foster collaborative learning from 1 another, and truly advance the field.

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