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

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Abbreviation and Acronyms

AUA = American Urological Association

AUS = artificial urinary sphincter

FDA = Food and Drug Administration

SUI = stress urinary incontinence

UTI = urinary tract infection

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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-

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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