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Surgical Management of Stress Incontinence

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Abstract: The aim was to describe contemporary surgical procedures for the treatment of stress urinary incontinence (SUI) in women. The 4 most commonly performed surgical procedures for the treatment of SUI were reviewed using standardized terminology. We addressed the history and evolution of the procedures as well as the mechanisms of action by which they work. Efficacy and safety data were also presented. Midurethral Sling, Pubovaginal Sling, Retropubic Colposuspension, and Urethral Bulking are safe and effective procedures. Midurethral Sling, Pubovaginal Sling, Retropubic Colposuspension, and Urethral Bulking are contemporary procedures for the treatment of SUI in women.

Key words: midurethral sling, retropubic colposuspension, pubovaginal sling, urethral bulking, stress incontinence, surgical management

Introduction

Of all approaches available to treat stress urinary incontinence (SUI), the "involuntary loss of urine on effort or physical exertion, or on sneezing or coughing,"[1] definitive cure is most likely after surgery. The last several decades have seen an evolution of the procedures most commonly offered to women for the treatment of SUI. They vary by surgical approach (abdominal vs. vaginal), anatomic space (retropubic vs. transobturator), and materials used [grafts, urethral bulking agents (UBAs) including particulate and nonparticulate materials, sutures or native tissue].

In early 2020, a joint report from the American Urogynecologic Society (AUGS) and the International Urogynecological Association (IUGA) on the terminology for surgical procedures to treat SUI in women[2] was published. It offers a comprehensive, evidence-based resource for surgeons, researchers, and trainees and describes the steps and mechanisms of action of the current operations that treat SUI, including midurethral sling, retropubic colposuspension, pubovaginal sling, urethral bulking, and artificial urinary sphincter. Moreover, it establishes clear terms that avoid variable proper names and brand identities, which may change over time and create confusion. This article will use these terms and will review the primary contemporary surgical procedures widely offered nationally and internationally. We will focus attention on historical perspective, terminology updates, procedure descriptions, and clinical data for midurethral sling, retropubic colposuspension, pubovaginal sling, and urethral bulking procedures.

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The author declares that there is nothing to disclose.

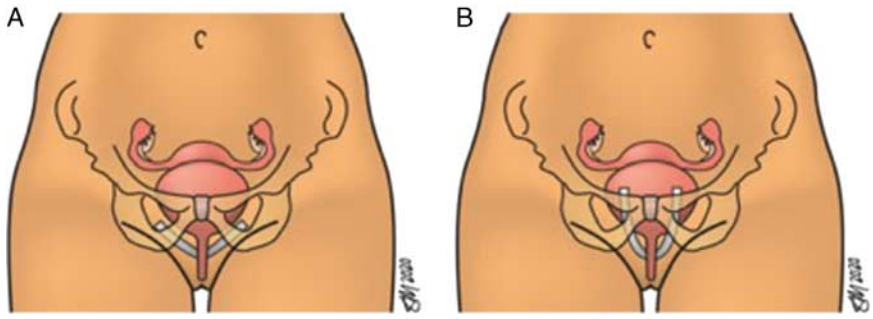

FIGURE 1. Midurethral sling. A, Transobturator midurethral sling. B, Retropubic midurethral sling. full color online

MIDURETHRAL SLING

The midurethral sling is a vaginal surgery involving tension-free placement of a type 1 polypropylene mesh strip, or tape, between the vagina and the urethra near its midpoint.[2] See Figure 1. It was initially named "intravaginal slingplasty" and was first introduced in a 1990 publication[3] by 2 urogynecologists, Australian Peter EP Petros and Scandinavian Ulf Ulmsten. The proposed mechanism of action of the procedure represented a departure from contemporary thinking and focused on the anatomic role of the vagina as the structural and functional support of the urethra and bladder neck. The original operation was described as a 2-staged office procedure under local anesthesia involving passage of a woven polyethylene terephthalate tape beneath the midurethra using retropubic trocars, or "tunnelers." The tape was removed in a second procedure 4 to 8 weeks later, and a "vaginal tuck" operation, in which 2 oblong, 1-cm-long areas of vaginal epithelium were excised from either side of the urethra to "tighten" the suburethral vagina.

From the original prototype of the retropubic midurethral sling (RMUS) to the permanent, implantable mesh material used today, the grafts used have varied and evolved with the science around their properties. Early midurethral slings used a woven polyethylene terephthalate and had a relatively high rate of symptomatic exposure of 8%.[4] Other materials[5] have been used with varying success, and now, monofilament, macroporous Amid type 1[6] polypropylene mesh is used ubiquitously in midurethral slings. Exposure rates have decreased significantly.[7] The first commercially available midurethral sling, the Tension-free Vaginal Tape (TVT, Gynecare; Ethicon, Somerville, NJ) was released in 1995. The procedure soon became widely used in Europe and in the United States, and after a well-designed, multicentered, randomized controlled trial[8] revealed comparable safety and efficacy to retropubic colposuspension, midurethral sling became a the most commonly performed procedure for the treatment of SUI in women.

While the original RMUS was designed with trocars that traveled from the periurethral vaginal incisions to the suprapubic skin, in a "bottom-up" direction, a variation in which the trocars are passed from the suprapubic skin incisions down into the periurethral dissections also is available. The mesh is then drawn back through the path of the trocar on either side of the urethra. This "top-down" approach is slightly less effective and more morbid (with higher rates of intraoperative bladder perforation, postoperative voiding dysfunction, and

vaginal mesh exposure) than the "bottom-up" approach.[5]

Another variation in the path of the mesh, through the bilateral obturator foramina instead of the retropubic space, was described first in 2001 and offered the purported advantage of avoiding blind passage of trocars into the retropubic space. The original transobturator midurethral sling (TO-MUS) was performed in an "out-to-in" direction,[9] in which the trocars pass from the skin laterally to the vaginal dissections medially. Soon after, an "in-to-out" transobturator procedure[10] was described in which the trocars pass the mesh tape laterally from the vaginal periurethral dissections to the skin. One multicentered, randomized trial of transobturator versus RMUSs, which included close to 600 women, revealed that 1 year after surgery, success rates (defined by composite objective and subjective criteria) for TO-MUS and RMUS are equivalent.[11] At 2 and 5 years, however, the criteria for equivalence were no longer met, and outcomes with RMUS are slightly more favorable. Because confidence intervals included 0, however, success rates were still considered to be similar between TO-MUS and RMUS.[12] A more recent Cochrane review revealed similar findings with short-term and long-term objective and subjective cure rates for SUI hovering around 85% for both RMUS and TO-MUS.[5]

Another variation on the midurethral sling includes single-incision slings (SI-MUS). These shorter slings are inserted using permanent anchors into the retropubic ("U configuration") or obturator ("H-" or "Hammock configuration")[13] tissues but do not pass all the way to the patient's skin. These slings were designed to offer the advantages of a decreased mesh burden and faster operating time. The first single-incision sling, the TVT Secur, however, proved to be disappointingly ineffective. In fact, a meta-analysis of the results of trials comparing TVT Secur to RMUS and to TO-MUS revealed that TVT-Secure was more than twice as likely as both full length slings to fail.[14] Ultimately, this device was pulled from the marked in 2013. Several other SI-MUS devices have been developed since then, and results from clinical efficacy trials suggest that they offer cure rates more similar to RMUS and TO-MUS devices. A 2013 meta-analysis comparing the subjective and objective cure rates of SI-MUS devices other than TVT Secur to retropubic and transobturator full length midurethral slings with follow up at 12 to 36 months revealed no significant differences.[15] A 2017 meta-analysis of longer term (36 to 60 mo) subjective and objective cure rates of SI-MUS devices compared with RMUS and TO-MUS devices also was performed excluding studies reporting on TVT-Secure. With an average follow-up period of 40 months, subjective cure rates were not significantly different between SI-MUS and full length TO-MUS and RMUS, objective cure rates were lower in SI-MUS (odds ratio: 0.68, 95% confidence interval: 0.47-0.99; $P = 0.04$). Adverse events including intraoperative blood loss, immediate postoperative pain, and voiding dysfunction, however, occurred less frequently in SI-MUS.[16] Additional studies, including a recently published prospective, multicentered, parallel cohort study of a specific SI-MUS compared with a TO-MUS manufactured by the same company, show promising results. The composite objective and subjective success rate of the SI-MUS at 36 months was similar to the that of the TO-MUS (90.4% vs. 88.9%, $P = 0.93$), and other outcomes including operative and adverse outcomes also were similar.[17]

Regardless of the specific design of the device, patient counseling before midurethral sling procedures should address risks associated with any surgical procedure for SUI as well as those risks associated with the use of permanent mesh. The former

risks include failure,[18] voiding dysfunction, urinary retention, worsening or de novo urgency, urinary tract infection, and pain related to vaginal scarring. The latter includes mesh exposure through the vagina and into the lower urinary tract.[19,20] Overall, patients should be reassured that midurethral sling surgery is safe and effective.[21–23]

PUBOVAGINAL SLING

A pubovaginal sling is an abdominovaginal surgery that uses a length of fascia, tissue, or graft to support the urethra with an abdominal wall fixation site.[2] First described in the early 20th century, this procedure typically uses autologous sling material and has been referred to as a "fascial" sling; specifically, fascia from the rectus sheath or fascia lata has been used, but other materials (including allogenic, xenogenic, or synthetic grafts) have been described with varying success rates and complications.

In 1907, Giordano described the use of the gracilis muscle to support the urethra, and over the next 10 years, the Goebell-Frangheim-Stoekel procedure evolved and used the pyramidalis, rectus fascia, or rectus muscle placed below the urethrovesical junction.[24] In 1933, Price used a strip of fascia lata below the urethra through a suprapubic approach with the free ends passed through and fixed to the rectus muscles.[24] The Aldridge sling was described in 1942 and involved dissection of 2 strips of rectus sheath, leaving the medial 2 cm of each side intact. The ends were passed down on either side of the urethra and sutured in an overlapping manner below it.[25] A modification of this technique used a strip of rectus sheath placed under the proximal urethra, hinged on 1 side ~2 cm from the midline.[26] Technical innovation led to the use of a fascial stripper to harvest fascia lata for the sling.[27]

Materials other than autologous fascial tissue have been used for pubovaginal sling procedures. Allogenic grafts of fascia lata, usually harvested from cadavers, and Lyodura (homologous lyophilized dura mater) have been used, but concerns regarding antigenicity and transmission of infection, such as HIV and slow viruses including Creutzfeld-Jacob disease, have been raised.[24] Xenogenic grafts include porcine dermis and small bowel porcine submucosa (SIS) also have been used as alternative grafts with lower success rates.[28] Synthetic slings were developed to avoid wound morbidity but had the risk of vaginal or urethral foreign body complications. Examples include Silastic strips reinforced with Dacron, Mers ilene (Ethicon), polyethylene, Polypropylene Marlex, and Gore-Tex (expanded polytetrafluoroethylene[24]).

The most commonly practiced current technique for pubovaginal sling placement initially was described in the 1990s by Blaivas and Jacobs[29] and Cross et al.[30] The procedure involves the use of a detached rectus sheath sling with free ends affixed to suture, the so-called "sling-on-a-string." Nonabsorbable (as Blavais described) or heavy absorbable suture (as McGuire described) was utilized.

Pubovaginal sling procedures have been performed for over 100 years, and there are several publications reporting on safety and efficacy of the procedure. A multicentered, randomized trial of over 600 women showed that at 2 years, success for SUI (no self-reported SUI symptoms, a negative cough stress test, and no retreatment for SUI) were higher after pubovaginal sling than retropubic colposuspension (66% vs. 49%, $P < 0.001$).[31] This study provided robust outcome data by including a large number of women who underwent procedures by experienced PFMRS surgeons who agreed to standardize surgical technique. Systematic reviews have confirmed these finding and suggest that, in the medium term (1 to 5 years after surgery), pubovaginal sling is more likely to be successful than

retropubic colposuspension and less likely to require repeat surgery for SUI.[32] Success in the medium term is likely comparable after pubovaginal sling and MUS, but MUS is likely to be a less morbid procedure with fewer perioperative compl ications.[32] De novo urinary urgency (8.6%) and return to the operating room for urinary retention (3%) is more common after pubovaginal sling than after retropubic olposuspension or MUS.[7]

RETROPUBIC COLPOSUSPENSION

Retropubic colposuspension is an abdominal or laparoscopic surgery involving dissection of the retropubic space in which the proximal urethra is elevated toward the retropubic periosteal fascia[2] (Fig. 2). It can be performed laparoscopically, with or without robotic assistance, or through a laparotomy.[33] The proposed mechanism of action involves the elevation and stabilization of the proximal urethra and/or bladder neck. As originally described, the procedure involved affixing the periurethral connective tissue of the anterior vaginal wall to the periosteum of the pubic symphysis using a technique called the Marshall, Marchetti, and Krantz procedure after the authors who published the original description.[34] Rare cases of osteitis pubis of the posterior symphysial periosteum occurred, however, and other points of fixation were sought. Innovation led to usage of the pectineal ligament (previously termed Cooper's ligament) as a fixation site in a procedure initially termed a Burch Colposuspension.[35]

Traditional descriptions of retropubic colposuspension use suture, but modifications using mesh strips also have been described.[32] Another group of modifications, needle suspensions, were performed by passing needles through a suprapubic skin incision, then through the rectus fascia at its attachment to the pubic symphysis, and then down through the retropubic space. The suture then was attached to the periurethral portion of the endopelvic fascia of the anterior vaginal wall. Eventually, the retropubic dissection was considered unnecessary, and the procedures were performed primarily through a vaginal approach.[36] The needle suspension procedures demonstrated poor long-term success rates and have largely been abandoned.[37,38]

While literature comparing retropubic colposuspension to pubovaginal sling

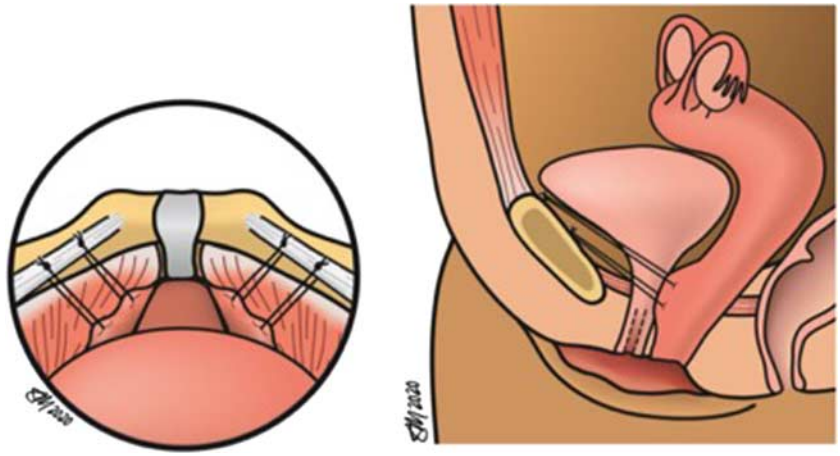

FIGURE 2. Retropubic colposuspension demonstrated from an abdominal view of the retropubic space, left, and in the sagittal view, right. full color online

surgery and MUS suggest lower success rates than the sling procedures, there is strong evidence that retropubic colposuspension provides long-term cure of SUI in most women.[39] Compared with open retropubic colposuspension, laparaoscopic colposuspension is more expensive. It appears to provide comparable subjective and objective short-term success rates and likely fewer perioperative complications.[40]

URETHRAL BULKING

Urethral bulking refers to a transvaginal or transurethral surgery in which a substance is injected into the urethral submucosa at the bladder neck to facilitate coaptation[2] (Fig. 3). The aim is to achieve coaptation of the urethra during the storage phase of the micturition cycle and during phases of increased abdominal pressure to prevent SUI. In a continent urethra, coaptation is achieved in part by the vascular and smooth muscle cushions, which are an integral component of the continence mechanism supporting the bladder base and urethra.[41] When this mechanism fails, artificial cushioning can be created by injecting bulking agents into the area around the urethra. This increases the urethral resistance at rest while allowing it to remain patent during voiding.

Types of UBAs

Urethral injections first were described in 1938, and many substances have been utilized as UBAs, including autologous fat,[42] bovine collagen,[43] and several different synthetic polymers and suspensions. Currently available UBAs include particulate substances, which are composed of particles suspended in a biodegradable carrier gel, and nonparticulate ones, which are homogenous gels. The particulate UBAs include Macroplastique,[44] a silicone polymer, Durasphere,[45] made of a suspension carbon coated zirconium beads, and Coaptite,[46] which is composed of calcium hydroxylapatite particles in an aqueous gel carrier. The nonparticulate UBAs include Bulkamid,[47] a hydrophilic gel consisting of polyacrylamide hydrogel and water.

There is very limited data to guide counseling about the success of urethral bulking procedures, though efficacy is likely much poorer than expected from

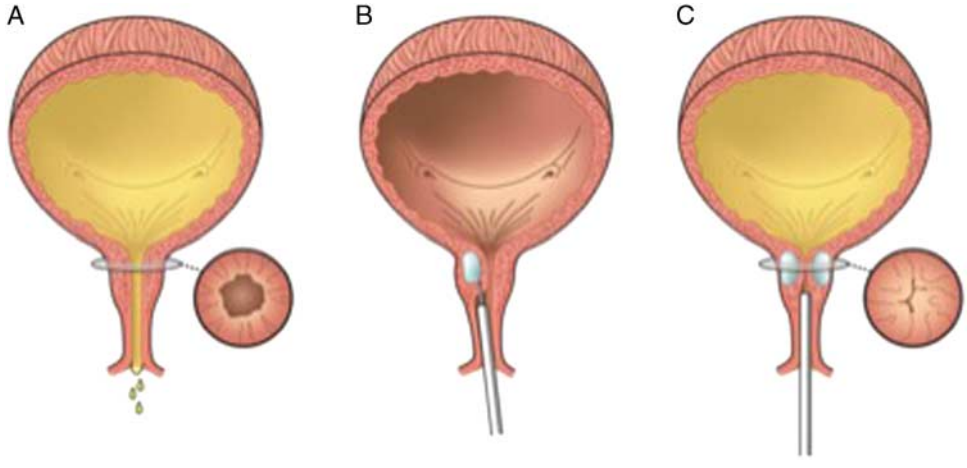

FIGURE 3. Urethral bulking procedure. A, The urethra before bulking, in the coronal view and in cross-section. B, Placement of bulking material. C, The urethra after bulking, in the coronal view and in cross-section. full color online

MUS, pubovaginal sling, and retropubic colposuspension. This decrease in efficacy is balanced by a decrease in overall procedure and postprocedural risk.[48] Robust studies on the short-term and long-term efficacy of urethral bulking is needed. With growing media focus on complications associated with the use of mesh materials, midurethral slings are performed less frequently in some parts of the world. In these settings, UBAs have gained popularity,[49] and research is ongoing to find injectable agents that improve efficacy and minimize risk.

Summary

The surgical treatment of SUI has evolved and improved over the past 50 to 100 years. Innovation has led to new procedures and to the refinement of older ones. Today, women can receive excellent symptom control with less surgical and postoperative morbidity than ever before. Fortunately, robust research has kept up with surgical innovation, and there is excellent safety and efficacy data to support the use of many surgical options. Additional comparative studies with long-term efficacy data on the midurethral sling, pubovaginal sling, and retropubic colposuspension is needed. In the meantime, providers and legislators worldwide can advocate for women by providing access to all safe and effective surgical procedures for the treatment of SUI.

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