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Review Articles

Surgical Management of Stress Urinary Incontinence

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ABSTRACT

Introduction: This review evaluates the most recent knowledge regarding surgical management of stress urinary incontinence.

Materials and Methods: A comprehensive MEDLINE search was performed, limited to those articles published from 1995 to 2005. In total, 470 articles were reviewed—the most relevant of which were considered, and additional ones were selected by reviewing these studies' bibliographies. Overall, 53 articles were selected and used in this study.

Results: Few randomized controlled trials have been performed. The best results of retropubic procedures are seen when the intrinsic urethral sphincter is competent and its effectiveness is sustained in the long term. A laparoscopic approach, although less popular and with a lower short-term cure rate, is an alternative. Sling surgeries can be the first-line treatment for all types of stress urinary incontinence. Autologous grafts are still considered the gold standard, but synthetic materials such as tension-free tape have comparable results with standard open retropubic procedures. Still, long-term cure and complication rates have not yet been elucidated. Using urethral bulking agents is the least invasive approach, applicable in both intrinsic sphincter deficiency and urethral hypermobility. However, it has a poor long-term outcome and necessitates repeat injections.

Conclusion: Long-term data suggest that Burch colposuspension and sling procedures produce similar objective cure rates. New synthetic suburethral slings such as tension-free vaginal tape have gained popularity in recent years. Complications of traditional and newer suburethral slings are declining but still occur and often are associated with serious morbidity. New therapies must be studied in randomized clinical trials.

KEY WORDS: stress urinary incontinence, pubovaginal sling, retropubic procedure, tension-free vaginal tape

Introduction

Stress urinary incontinence (SUI) is the most common type of incontinence in women, with 86% of incontinent women presenting with symptoms of SUI in either pure (50%) or mixed (36%) forms.[1] Stress urinary incontinence, the complaint of involuntary leakage during exertion, occurs at least weekly in one third of adult women. Although SUI is not life-threatening, it may have considerable impact on a woman's quality of life. However, no considerable research on the prevention of urinary incontinence has been done. Initial treatment includes nonsurgical

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management,[2] and although surgical procedures are more likely to cure SUI, they are associated with more adverse events. Nearly, 300 procedures have been proposed for SUI, but only a few have survived with enough supportive evidence to be recommended. Currently, less-invasive modifications of these procedures are being done, and studies on their efficacy are ongoing.

Pathophysiological concepts and theories on the clinical staging of SUI have changed in recent years. For decades, the physiological concepts of urinary incontinence were a summation of factors and forces. The *urethral closure mechanism* is composed of the urethral mucosal seal, the submucosal vascular plexus, and competence of the bladder neck, as well as intrinsic and extrinsic sphincters. This closure mechanism is supported by the pelvic floor muscles and their fascial coverings, which function as a hammock.[3] The normal position of the bladder base and urethra provides pressure transmission, so that pressure from the intra-abdominal cavity is exerted equally on the bladder dome and the proximal urethra.[4] The logical extension of these ideas is that SUI is caused by a loss of pressure transmission and hammock-like support due to urethral hypermobility and prolapse and impaired intrinsic sphincter function.[3,5] The foregoing is known as *integral theory*.

First introduced by Petros and Ulmsten,[6,7] this theory initiated crucial changes in the way clinicians view the management of SUI. Integral theory emphasizes the importance of fixation of the midurethra to the pubic bone by pubourethral ligaments and suggests that opening and closing of the urethra and bladder neck are regulated by a "battery of surrounding structures."[7] This theory has led to a novel anti-incontinence support therapy known as *tension-free vaginal tape* (TVT).[8] Tension-free vaginal tape is placed in the midportion of the urethra instead of at the level of the bladder neck, and it should be loose enough to ensure that the urethra is compressed as little as possible at rest.

Surgical treatment of SUI can be divided into 3 basic types: colposuspension, suburethral sling procedures, and injection of urethral bulking agents. It is recommended that women who plan for future pregnancies postpone colposuspension and sling procedures until they have completed their family. Although not documented, it has been suggested that postmenopausal women with urogenital atrophy receive vaginal estrogen prior to surgery.[9] The question that confronts the clinician is which procedure to use for which patient—TVT, or one of its modifications, colposuspension, or conventional slings.

Few studies compare these procedures. And unfortunately, many postoperative patients experience continued incontinence, despite improvement of SUI. Although surgical procedures have been adopted based on "expert" opinion, the fact remains that untested techniques and materials frequently have been introduced without careful human subject testing. When choosing surgical management then, the surgeon must weigh the chance of cure against the chance of severe complications. Less common, but still serious complications, such as vascular and bowel injuries, require further studies with large samples of patients that compare the different surgical approaches.

Diagnostic and Treatment Managements

To diagnose SUI, clinical and urodynamic (simple or complex) examinations must be performed to evaluate the bladder filling and emptying phases. Loss of urine through the urethra with a simultaneous increase in intra-abdominal pressure can be seen visually. The role of radiology such as cystography, sonography, and magnetic resonance imaging is controversial. Thirty percent of stress incontinent patients may show some forms of detrusor overactivity during urodynamic study, which may be associated with a decrease in the cure rate after surgery. Nonetheless, there have been no randomized trials on the influence of a comprehensive preoperative evaluation (including urodynamic study) compared with a basic preoperative clinical evaluation on the treatment outcome in women with SUI symptoms. In a cohort study of 442 women, Black and coworkers[10] reported improvement of the severity of SUI in 87% of patients and cure (continence) in only 28% after surgical operation. These improvements persisted for at least 12 months. The likelihood ratio of improvement was similar regardless of whether urodynamic studies had been conducted before operation or not.

Generally, conservative therapy should be attempted initially in women with SUI. Conservative treatments include pelvic muscle exercises, bladder retraining, pharmacologic

therapy, functional electrical or magnetic stimulation, and the use of mechanical devices such as pessaries. Although not documented, it is suggested that postmenopausal women with urogenital atrophy receive topical estrogen.

In the past decade, surgeons have put their efforts into differentiating *intrinsic sphincter deficiency* from *hypermobility*, choosing a pubovaginal sling or bulking agents for the former and colposuspension for the latter. This was based initially on a preliminary report in which women younger than 50 years with urethral closure pressure less than 20 cm H2O had a higher failure rate after a Burch colposuspension than did women with a closure pressure greater than 20 cm H2O.[11] Recently, however, this dichotomy has been called into question, substituted by the idea that all women with SUI have some degree of sphincter weakness. To date, it is not clear from which surgeries women with hypermobility and degrees of sphincter weakness benefit. As SUI is considered a degenerative tissue disorder, the outcomes of different surgical procedures are relatively similar at short-term follow-up; however, the cure rate dramatically declines at long-term follow-up for the majority of procedures.

Retropubic Procedures

These procedures are indicated for women with the diagnosis of urodynamic SUI and hypermobility of the proximal urethra and bladder neck. The best results are seen when the urethral sphincter (intrinsic sphincter or bladder neck) is competent. Marshall and colleagues,[12] in 1949, first described retropubic urethrovesical suspension for the treatment of SUI. In 1961, Burch introduced his technique.[13]

Although numerous terms and variations of retropubic repair have been described, the goal is the same: to stabilize the urethra by lifting tissues near the bladder neck and proximal urethra in the area of the pelvis behind the pubic symphysis to prevent their descent, and to allow urethral compression against a stable suburethral layer. The approach may be either abdominal (open or laparoscopic) or vaginal. The 3 most popular retropubic procedures are the Burch colposuspension, the Marshall-Marchetti-Krantz vesicourethropexy, and the paravaginal defect repair. Of these 3, the Burch colposuspension has been studied most extensively. The surgical technique in most studies on the Burch colposuspension is a modification described by Tanagho in 1976.[14] Two to 3 permanent or delayed absorbable sutures are passed through the endopelvic fascia lateral to the midurethra and bladder neck and then through the ipsilateral Cooper's ligament and tied with gentle tension. Many studies have reported their results with the Burch technique, mostly with methodologic limitations. A few randomized trials have been or are being conducted. A short-term cure rate (defined as the percentage with complete continence) of 73% to 92%, and a success rate (defined as the percentage with cure or improvement) of 81% to 96% have been reported.[15] This technique's effectiveness continues for the long term; after 5 to 10 years, approximately 70% of patients are still continent.[15,16]

Several studies have assessed the long-term outcome of the Burch procedure. Alcaly and coworkers have studied 109 women with the Burch colposuspension for a mean follow-up of 13.8 years.[17] The cure rate in this population is 69%. This rate has been significantly lower in women who had had pervious bladder neck surgery. Results from a Cochrane review indicate that open colposuspension is the most effective treatment for SUI, especially for long-term outcomes. Patient satisfaction has been reported high (82% in 146 patients with colposuspension).[18]

Voiding dysfunction (in 2% to 27% of patients) and de novo detrusor overactivity (in 8% to 27% of patients) are the most frequently reported complications of the Burch method.[18-20] It has been reported that 5% to 13.6% of women with a history of Burch colposuspension may develop an enterocele,[13,17,21] although all do not require surgical correction. In an evaluation of pelvic organ prolapse following isolated Burch colposuspension, Kwon and colleagues[22] concluded that the majority of patients undergoing an isolated Tanagho modification of the Burch procedure without preoperative prolapse did not appear to be at increased risk for subsequent operative intervention.

A recent systematic review[23] evaluating the effectiveness of laparoscopic colposuspension compared 5 trials of laparoscopic with open colposuspension. The objective cure rate (assessed as leakage on clinical stress and urodynamically) was lower for laparoscopic than

for open colposuspension. However, the subjective cure rate was comparable between the 2 groups at 6-month to 18-month follow-up. Trends were shown toward higher complication rates, less postoperative pain, shorter hospital stays, and less time to return to normal function for laparoscopic compared with open colposuspension.

Ankardal and colleagues have reported a higher cure rate (subjective and objective) at 1-year follow-up for open colposuspension (120 patients) compared with the laparoscopic (120 patients) approach.[24] Further well-designed and adequately powered randomized trials are required to definitively compare these 2 approaches.

Suburethral Slings

Aldridge[25] introduced the fascial suburethral sling in 1942. A suburethral sling procedure is used mainly as a treatment of intrinsic sphincter deficiency (ISD) or failed previous SUI surgery. However, few studies have been performed that evaluate the suburethral sling as a first-line procedure.[26] The materials used as a sling can be categorized as autologous, cadaveric, xenograft, and synthetic. These categories can be further subdivided into rectus fascia, fascia lata, and vaginal wall for autologous materials; freeze-dried irradiated cadaveric fascia lata, solvent-dehydrated cadaveric fascia lata, fresh-frozen cadaveric fascia lata, and cadaveric dermis for cadaveric materials; and porcine dermis, porcine subintestinal mucosa, and porcine pericardium for xenograft; and polypropylene, polyester, Silastic, and expanded polytetrafluoroethylene for synthetic materials.

The advantages of using allografts or synthetic slings include a reduction in the morbidity of harvesting from a second surgical site, decreased operative time, early postoperative recovery, and an unlimited supply of artificial material. Nonetheless, autologous rectus fascia and fascia lata are the most common materials used. Additionally, they are considered the gold standard for slings to which the outcomes of all other materials are compared.[27] It has been said that failure of sling procedures—especially those of autografts and allografts—become apparent in the first 6 months after surgery. This is related to degeneration of the fascia or breakdown of anchoring sutures; however, after this phase, surgical results remain stable. Allografts carry a theoretical risk of unwanted transmission of infections. Experimental studies have shown no difference in mechanical strength between autografts and cadaveric allografts.[28,29] However, the long-term durability of allograft fascia continues to be studied.

Morgan and associates,[30] in 247 women, reported an 88% overall cure rate (91% for type-2 and 84% for type-3 SUI) using autologous rectus fascia at a mean follow-up of 51 months. Chaikin[31] has reported a 92% objective cure rate in 25 patients followed for an average of more than 1 year. The overall reported cure rates (defined as the percentage with complete continence) vary between 73% and 95%, and success rates (defined as the percentage with cure or improvement) vary between 64% and 100%.[19,32] Outcomes might be better in primary as opposed to repeat surgery.

Synthetic materials have the disadvantage of potentially generating an inflammatory reaction to a foreign body. This may result in a higher risk of erosion and fistula formation compared with autologous materials, although this has not been proved in a comparative trial. In the short term, objective cure rates using polyester and polypropylene mesh are reported as being 73% to 93%.[27] Many conventional synthetic materials—including polytetrafluoroethylene or Teflon,[33-37] expanded polytetrafluoroethylene (Gore-Tex; WL Gore & Associates, Inc, Newark, Del, USA), silicone, and polyester (ProteGen; Boston Scientific, Natick, Mass, USA)—have been withdrawn owing to erosion and infection. The most frequently reported complications of sling procedures are postoperative voiding dysfunction in an average of 12.8% of patients (range, 2% to 37%),[26] urinary retention and self-catheterization in 2% to 7.8%,[26,27,31] de novo urge incontinence in 6% to 14% of patients,[19,38,39] and erosion of the sling in the bladder, urethra, and vagina, mostly after synthetic slings, in up to 5% of patients.[19,38,39] Misplacement of the suburethral sling to the distal urethra or proximal to the bladder neck also can be a problem. In general, synthetic materials seem to be associated with lower cure rates and higher complication rates than autologous materials.[27]

Tension-Free Vaginal Tape

Tension-free vaginal tape procedure is based on a theory of SUI pathophysiology by Petros and Ulmsten.[6] The concept behind the TVT is that SUI is the result of inadequate urethral support

due to weak pubourethral ligaments in the midurethra. Tension-free vaginal tape aims at reinforcing the functional pubourethral ligaments and secure proper fixation of the midurethra to the pubic bone to maintain continence. Under local or regional anesthesia, a strip of polypropylene tape is inserted via a small incision. The patient is asked to cough frequently to adjust the position of the tape and to lie in a resting position to exert sufficient pressure on the urethra only during stress, not at rest.[6,7,39] Cure rates (complete dryness) of 66% to 91% have been reported.[18,40,41,42] The long-term objective results of the TVT procedure have been demonstrated by Nilsson and colleagues,[43] who found an 85% cure, 10.6% improvement, and a 4.7% failure rate at a median follow-up of 56 months.

The operative time of TVT is relatively short and is performed mainly under local or regional anesthesia, with a short hospitalization (ie, outpatient or overnight). The success of TVT has encouraged the introduction of similar products with modified methods of midurethral sling placement (ie, retropublic top-down, prepubic, and transobturator approaches). Ward and colleagues have reported the 2-year follow-up of 344 women with SUI in a multicenter, randomized, controlled trial comparing TVT and open Burch colposuspension. The objective cure rate (defined as the percentage of patients with a negative 1-hour pad test) ranged from 63% to 85% for the TVT procedure and 51% to 87% for open colposuspension.[18] However, with regard to subjective assessment, only 43% of the women in the TVT group and 37% in the open colposuspension group reported having a cure. Women undergoing TVT are more likely to have a cystocele after surgery; whereas, those undergoing Burch colposuspension are more likely to have apical prolapse.

Since its description, it is estimated that more than 800 000 TVT procedures have been performed worldwide, and there has been increasing interest in the transobturator tape (TOT) approach. Tension-free vaginal tape mainly suits patients with urethral hypermobility and mild degrees of intrinsic sphincter deficiency (known as "good urethra"), and we should rely on the old concepts of urethral compression to treat SUI with a "bad (scarred, open) urethra."[10]

Complications. Adverse events are related to entry into the retropubic space and include bleeding, retropubic hematoma, and injury to adjacent structures such as the bladder, urethra, and vagina. Bladder perforation is the most frequent intraoperative complication, occurring in between 0% to 25% of patients.[44-46] There is a higher risk in patients who have previously undergone surgery for incontinence. Voiding difficulties occur in 3% to 5%,[17,47] and de novo urgency is reported in 6% to 15% of patients.[44,48,49] Urinary tract infection occurs in 6% to 22% of patients, and retropubic hematoma in 0% to 5%.[50] Other complications such as bowel injury, erosion to the vagina or urethra, and injury to the greater and lesser vessels (epigastric arteries) and obturator nerve are rare, but may occur.[50] For the first time, Johnson and associates have reported necroticizing fascitis as a very rare complication after TVT, resulting in exploration and wide debridement of the anterior rectus fascia.[51] According to the unpublished data, there have been 7 deaths reported after TVT, 6 associated with bowel perforation, and 1 of vascular injury.[52] No such data are available for other techniques.

Within the last 2 years, numerous other surgical devices for stress incontinence have been introduced worldwide. One example is TOT, which was designed in 1998. Theoretically, this procedure avoids the risk of bladder, bowel, or vascular injury, because the procedure passes the polypropylene midurethral sling through the obturator membrane along its ischiorectal fossa path, bypassing the pelvic cavity altogether. However, the surgical effectiveness and complication rates of this procedure remain to be established.

Urethral Bulking Agents

Several bulking agents have been used to treat SUI in women. The rationale for their use arises from the need for a *washer effect* on the tissues at the proximal urethra and the bladder neck.[53,54]

This approach is the least invasive surgical procedure, originally described for patients with SUI caused by intrinsic sphincter deficiency, although it might be effective in patients with urethral hypermobility. It can be done under local anesthesia on an outpatient basis. Various bulking agents are available including autologous fat, glutaraldehyde cross-linked bovine dermal (GAX) collagen, silicone microparticles, carbon-coated zirconium beads, and dextranomer/

hyaluronic acid copolymer.[53,54] The challenges of these bulking agents (eg, carbon-coated zirconium beads, calcium hydroxylapatite and dextranomer/hyaluronic acid [Dx/HA] copolymer, silicone, polytetrafluoroethylene and bovine collagenase) are their durability, cost-effectiveness, safety (concerns regarding migration, foreign-body reaction, and immunologic reaction), and long-term results. Organic substances may be reabsorbed, while synthetic and biocompatible products seem to have a better stability.[54]

The agent is injected transurethrally or transvaginally into the periurethral tissue around the bladder neck, proximal to midurethra, to increase outlet resistance. Many reports have studied GAX collagen as a bulking agent. Dmochowski and colleagues[55] have summarized the literature on GAX collagen for SUIs caused by intrinsic sphincter deficiency. They also found that most patients had a history of failed anti-incontinence surgeries with a fixed bladder neck or "bad urethra." The cure rate was 7% to 83% in 17 studies. Only 8 studies had defined intrinsic sphincter deficiency (either as Valsalva leak point pressure lower than 60 cm H2O or stress videourodynamic to assess bladder neck opening). In general, short-term cure rates of GAX collagen (defined as complete dryness) are 30% to 78%. Success rates (defined as leakage of less than 1 pad per day) are 40% to 86%.[53,54] Long-term results (up to 2 years) suggest a continuous decline in cure and success rates.[19] In a randomized controlled trial, GAX collagen and Durasphere (Advanced Uroscience, St Paul, Minn, USA) have had similar results for SUIs due to intrinsic sphincter deficiency.[56] The disadvantages of bulking agents include the need for repeat injections, their costs, and the occurrence of adverse effects (eg, migration, introduction of a foreign body, and generalized immunologic reaction) of using nonautologous materials. In addition, the surgeon is unable to precisely determine the quantity of materials needed for an individual patient.[57] Complications such as urgency, urinary retention, and urinary tract infections are rare; thus, this therapy might be more suitable for women who wish to avoid complications associated with more invasive surgery.[58] Several new bulking agents and techniques are in various stages of development, including microballoons, human collagen, autologous cartilage, bioglass, cross-linked hyaluronic acid, calcium hydroxylapatite, hyaluronic acid, dextranomer microspheres, silicone, and ethylene vinyl alcohol polymers.[55]

At present, use of bulking agents is not widely accepted, since data are limited.[58] The recommended indications for injection are previous surgical failure, high risk of surgical operation, and patient preference.

Conclusion

Stress urinary incontinence is common in women and may impact their activity and quality of life. After a basic evaluation, most women can receive treatment. Conservative management should precede surgery. However, surgical management is the most effective treatment, albeit it has more adverse events. Long-term data suggest that Burch colposuspension and sling procedures produce similar objective cure rates. These results are supported by several randomized trials as well as a large number of case series. It has been shown that laparoscopic Burch technique has a lower cure rate; however, better-designed studies are ongoing. New synthetic suburethral slings such as TVT have gained popularity in recent years. Short-term results of TVT demonstrate success rates similar to those of Burch colposuspension. Long-term complications after Burch colposuspension, pubovaginal slings, and TVT are mostly related to voiding dysfunction and urgency. The complications of traditional and newer suburethral slings are declining but still occur and often are associated with serious morbidities. Despite the advantages of synthetic materials, the lack of an ideal material and treatment for incontinence persists. Bulking agents have poor long-term results, necessitating repeat injections. Further research is needed to study the factors that impact treatment success and durability of various techniques. New therapies must be studied in randomized clinical trials preceding general clinical use, determining the efficacy as well as the safety of new surgical techniques.

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