FEMALE UROLOGY

Invited Review

Pubovaginal sling materials and their outcomes

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ABSTRACT

Stress urinary incontinence (SUI) is the most common type of urinary incontinence, and approximately 200 different methods have been described for its surgical management. A better understanding of the pathophysiology of SUI has led to the development of surgical therapies focused on creating a strong suburethral supportive layer and urethral resistance. The most important advantage of the pubovaginal sling (PVS) procedure is that it restores urethral resistance during stress maneuvers to prevent incontinence, while improving urethral coaptation at rest and allowing for spontaneous micturition. Various autologous, allograft, xenograft and synthetic materials have been used for the PVS. The autologous PVS procedure for the treatment of SUI offers the highest success rate and is the most commonly used PVS surgical method. Unlike xenograft and allograft materials, the autologous procedure does not result in a tissue reaction and is associated with a low rate of material-related complications.

Key words: Outcome; pubovaginal sling; sling materials; urinary incontinence.

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Introduction

The International Continence Society (ICS) defines urinary incontinence as the involuntary loss of urine with social and hygienic consequences. Stress urinary incontinence (SUI) affects 4.5% to 53% of females, as determined by population-based studies.[1] SUI is the most common type of urinary incontinence, and approximately 200 different methods have been described for its surgical management.[2] Most of these surgical methods involve supporting the midurethra or bladder neck. A better understanding of the physiopathology of SUI has led to the development of surgical therapies focused on creating a strong suburethral supportive layer and an increased urethral resistance or kinking during times of stress.[3]

Sling procedures involving the use of autologous materials for the treatment of urinary incontinence in women have been around for over 100 hundred years. The German surgeon Goebell first described this method in 1910. In his surgery, Goebell[4] utilized the pyramidalis muscle to create a muscular sling below the urethra. In 1942, Aldridge[5] described a pioneering approach to the pubovaginal sling (PVS) procedure. In this surgery, strips of rectus fascia are looped below the bladder neck and attached to the abdominal wall. In 1978, this PVS procedure was modified and re-described by McGuire and Lytton.[6] Particularly in patients with intrinsic sphincter insufficiency, these authors reported high success rates. Early studies of this new autologous PVS technique reported success rates ranging from 92% to 95%; however, a more recent meta-analysis evaluating the long-term outcomes of PVS procedures reported a slightly lower success rate of up to 83% after 48 months.[7,8] The most important advantage of the PVS procedure is that it restores urethral resistance during stress maneuvers while improving urethral coaptation at rest and allowing for spontaneous micturition.[9]

Indications

Currently, PVS procedures are used primarily to treat patients with intrinsic sphincter dysfunction from a variety of difference causes.[10-12] However, recent studies support the notion that the PVS can be used as the primary surgical method in all of the cases of SUI.[13-15] PVS procedures can be successfully performed in patients with mixed urinary incontinence, neuropathic disorders that result in the loss of the closing function of the proximal urethra, acquired conditions such as a urethral diverticulum that may result in tissue loss when repaired, urethral erosions caused by a

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synthetic material or an artificial sphincter, and in patients who previously underwent unsuccessful incontinence surgery.[13-19]

Pubovaginal sling materials

1) Pubovaginal sling autologous graft materials

Rectus muscle fascia obtained through a suprapubic incision is the most commonly used sling material, offering the advantage of maximum bio-compatibility.[20] In a study by Fitzgerald et al.[21] evaluating biopsy samples obtained from the rectus fascia sling after the PVS procedure, the sling exhibited excellent incorporation into the host tissue with evidence of abundant fibroblasts and connective tissue ingrowth microscopically. The authors of another study looking at surgically removed slings and compared the histological appearance of different types of extracted PVS materials (autologous, synthetic, allograft and xenograft). This study also reported an extensive fibroblast infiltration and neovascularization and a minimal inflammatory reaction in the autologous slings.[22] In general, the rejection of autologous rectus fascia and urethral erosion are extremely rare complications. However, increased operation time, relatively increased postoperative suprapubic pain, fluid collections in the suprapubic wound, and incisional hernias are disadvantages of using this material.[20]

Fascia lata obtained from the lateral thigh is another autologous tissue that can be used for the PVS. It offers bio-compatibility and tissue effects similar to that of the rectus fascia PVS.[23] However, it has the advantages of a shorter recovery time, less wound site complications and no associated risk of abdominal herniation. However, this method has the disadvantages of prolonged operative time and the fact that most urologists have limited experience in this body area.[24] One study from 1997 noted that 67% of the patients reported pain walking in the first postoperative week after undergoing a fascia lata harvest for ophthalmologic surgery.[25]

Another technique using autologous tissue is the vaginal wall sling.[26-28] Raz et al.[29] first described this procedure in 1989. This method utilizes midline vaginal mucosa and the underlying periurethral support structures to create a sling. Importantly, the long-term outcomes of this technique depend significantly on the durability of the supporting structures. In addition, there are risks of cyst formation and shortening of the vaginal length.[29-32]

Outcomes

In 2001, Groutz et al.[33] employed the PVS procedure in 67 patients with genuine SUI. The mean follow up was 33.0 (range: 12-60) months. The patients were considered cured if there was no urinary incontinence in a 24-hour voiding diary and a negative pad test. Overall, 67% achieved a cure and 33% achieved improvement. None of the patients developed perioperative or postoperative complications, and the authors highlighted that the PVS procedure was an effective and safe method for the treatment of simple sphincteric incontinence. In a longer follow-up study by Morgan et al.[34], 247 patients who underwent the PVS procedure were followed for a mean duration of 51 months. Of these patients, 85% were free of complaints at the end of five years, and 5.7% required a second surgical operation, such as a periurethral bulking agent, PVS or urethrolysis.

In 2007, Albo et al.[35] compared the effectiveness of the Burch colposuspension and the autologous rectus fascia PVS for the treatment of SUI. This multicenter, randomized, clinical trial evaluated the success of surgery based on a negative pad test, the absence of urine leakage in a 3-day diary, a negative cough stress test, and the absence of incontinence symptoms. In the scope of the study, 326 of the 655 patients underwent the PVS procedure, and 329 patients underwent the Burch procedure (79% of which had adequate follow up). After two years of follow up, although the patients in the PVS group achieved higher success rates, they also exhibited higher rates of morbidities including difficulty voiding and de novo urge urinary incontinence (UUI).

In a study comparing tension-free vaginal tape (TVT) and PVS procedures, Wadie et al.[36] reported a 92% success rate in 25 patients who underwent the autologous PVS procedure and a 92.9% success rate in 28 patients who underwent the TVT procedure. They performed prolonged urinary catheterization for one more week in seven patients in the PVS group and in three patients in the TVT group. Six months after the treatment, they reported de novo UUI in one patient in each group. Although the authors reported similar short-term outcomes in terms of SUI, the PVS procedure was considerably less expensive than the TVT procedure.

In a retrospective study by Asthanasopoulos et al.[37] from 2011, the authors reported the outcomes of 264 patients who were treated with PVS surgery using rectus fascia with three years of follow up. At the end of the follow-up period, 200 patients (75.8%) remained dry and 24 patients (9.1%) had improvement in their symptoms. The overall rate of complications was 29.2%, and de novo urgency was the most common micturition problem. Interestingly, 29.9% of the patients in this study had a history of prior midurethral sling surgery, and all had the implanted mesh material partially removed during the PVS procedure. The authors placed particular emphasis on the fact that their outcomes were not affected by the previously implanted sling material. In a more recent study by Lee et al.[38] with a median follow up of 89 months, the authors compared the outcomes of patients undergoing a primary or secondary (history of previous major incontinence surgery) PVS procedure. They reported a 76% success rate after a primary PVS procedure and a 69% success rate after a secondary PVS procedure. In addi-

tion, nine patients in the secondary PVS group and only three patients in the primary PVS group required additional interventions. Overall, the authors reported that the cure rates were not significantly different between the two groups of patients.

2) Pubovaginal sling allograft materials

Allograft materials harvested from cadavers have been used in orthopedic, ophthalmologic, and neurosurgical procedures for over 20 years; however, these materials were only recently introduced into the surgical management of SUI.[39,40] Some SUI surgery studies have reported success rates with cadaveric fascia lata and rectus fascia comparable to that with autograft materials, while other studies have reported lower success rates.[41,42] Particularly in reconstructive urology, dermal allografts are commonly utilized for the treatment of hypospadias, congenital chordee, Peyronie's disease, bladder augmentation, and cystocele repair.[43]

Solvent dehydration and lyophilization (freeze-drying) are the primary methods used for allograft tissue preparation. Currently, cadaveric fascia lata and allograft sling materials prepared from acellular cadaveric dermis are lyophilized and then subjected to secondary sterilization by gamma radiation. These procedures decrease the risk of transmission of infectious agents to the recipient.[44]

The only difference between autograft and allograft sling materials during surgery is the use of a smaller midline suprapubic incision in the later. In both surgeries, the sling sutures are placed above the rectus muscle and tied at the midline. Despite the advantages of a smaller incision, shorter operative time, and reduced postoperative discomfort, surgeons must consider the increased cost and the risk of infections associated with the use of allograft materials.[26,45] Allograft tissues are transferred from a human donor to a human recipient and therefore bring the potential risk of transferring DNA and protein material. Theoretically, infections caused by prions are possible with the use of such tissues, and allograft-associated transmission of human immunodeficiency virus may occur in one in eight million cases.[44,46]

Outcomes

Allogenic grafts were first used in the treatment of SUI in 1996.[47] The outcomes achieved with such tissues were initially promising, and early studies reported a success rate ranging from 76% to 98%.[48,49] In 2004, Onur et al.[50] investigated the efficacy of solvent-dehydrated cadaveric dermis tissue as an alternative tissue source. In this study with a mean follow up of 9 months, 21 patients underwent the surgery. The authors reported a SUI cure rate of 86%. Of the patients with recurrent symptoms, 9 had high post-void residual urine volumes (>100 mL) and had to undergo clean intermittent catheterization for a mean duration of 19 days (4-30). Two patients (10%) with preoperative genuine SUI developed postoperative de novo UUI. The authors highlighted that cadaveric dermis tissue offered an effective and safe alternative allograft material for the PVS procedure. On the other hand, in their series of 12 patients with recurrent SUI after allograft PVS surgery who required revision, Fitzgerald et al.[27] suggested that such tissues were not effective in sling surgery because of disorganized remodeling and graft degradation in the removed specimens. In a similar study of cadaveric rectus fascia, the same primary author reported recurrent SUI in the early postoperative period in 8 out of 35 patients who underwent surgery using cadaveric rectus fascia. This high failure rate was attributed to the freeze-drying processing technique and the unsuitability of the proximal urethra as an implantation site for graft remodeling.[42]

In another study by Brown and Govier[48], the outcomes of 121 patients treated with the PVS using cadaveric fascia lata were compared with 46 patients treated using autologous fascia lata. The study reported 90% and 83% success rates with allograft and autologous tissues, respectively. The authors concluded that cadaveric fascia lata offered a good alternative to autologous tissue. In 2008, Onur et al.[51] compared the outcomes of solvent-dehydrated cadaveric dermis tissue (n=24) with the outcomes of autologous rectus fascia (n=25). The surgical outcomes were assessed by the urogenital distress inventory (UDI-6) and the incontinence impact questionnaire (IIQ-7) forms. This questionnaire-based analysis revealed no significant difference between the success rates in the two groups (79% versus 84%, p>0.05).

In another study, Owens and Winters[52] used Duraderm™ allograft (C.R. BARD, Inc.) PVS material in 25 patients. The authors reported that after a mean follow up of 14.8 months, 32% of the patients remained dry, 36% of the patients achieved improvement, and 32% of the patients showed no improvement. Overall, 76% were satisfied with the surgery, 68% reported that they would undergo this operation again, and 68% reported that they would recommend this surgery to others.

3) Pubovaginal sling xenograft materials

Xenografts are another material used in PVS operations, and similar to allografts, xenografts are subjected to some preparation procedures to suppress the immune response and decrease the risk of infection. For xenografts, the diisocyanate processing method is used to remove the genetic material. Xenografts prepared from bovine pericardium, porcine bowel, and porcine dermis are the most commonly used for PVS surgery.[45]

Histopathological analyses by Wiedemann and Otto[53] indicated that growth factors contained in the small intestinal submucosa (SIS) most likely result in the significant reduction in donor-recipient immunogenic reaction and scar tissue formation seen

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with this type of PVS. Thiel et al.[54] analyzed the fibrotic and inflammatory reaction caused by four different sling materials in 70 Wistar rats. The authors found that the amount of inflammation and collagen fibers was higher in SIS compared to polycaprolactone, polylactic acid copolymers, and monofilament polypropylene mesh. In 2001, Kubricht et al.[55] compared SIS and cadaveric fascia lata in terms of tensile strength. Although SIS had lower tensile strength compared to cadaveric fascia, both were described as effective sling materials for PVS surgery.

Wiedemann and Otto[53] reported the very first histopathological results of SIS in human subjects after the PVS procedure. The biopsy specimens obtained from the vaginal mucosa just below the implanted SIS sling demonstrated no foreign body reaction or evidence of immunological reaction, and the findings were most suggestive of chronic inflammation. On the other hand, John et al.[56] found a more intense inflammatory reaction after the PVS procedure using SIS. In their study, 5 out of 16 patients (31.3%) had suprapubic pain, one patient had induration of the mons pubis requiring surgical drainage, and one patient had vaginal inflammation requiring the extraction of the sling material. In addition, the authors reported inflammation of the rectus fascia that was diagnosed by computerized tomography and treated with conservative therapy. Because of these outcomes, the authors stated that they ceased using SIS in sling procedures. Overall, the use of xenograft materials appears to be decreasing due to concerns about their efficacy and high cost.

Outcomes

Rutner et al.[57] first described the use of porcine SIS in PVS surgery in 2003. In this series 152 patients were followed for four years and 142 patients (93.4%) reported improvement or resolution of their SUI, and seven patients (4.6%) reported dissatisfaction with the surgery. In addition, after the surgery, one patient required self-catheterization for three days, and one patient required urethral catheterization for five days. The authors did not report postoperative sling infection, exposure, or perforation in any of the patients, and concluded that porcine SIS was a strong, biocompatible, and durable material.

In another study by Arunkalaivanan and Barrington[58], the porcine dermal sling (Pelvicol implant) was compared with TVT sling. A total of 142 patients were randomized, and 74 underwent the porcine dermal sling procedure and 68 underwent the TVT procedure; the patients were followed for a median of 12 months. They reported a success rate of 89% in the PVS group and 85% in the TVT group. Importantly, six months after the procedure, 6% of the patients in the PVS group and 9% of the patients in the TVT group developed de novo urgency. In a more recent prospective and randomized study by Abdel-Fattah et al.[59], the long-term outcomes at three years were compared between patients who underwent Pelvicol (n=74) or TVT (n=68) procedures. There was no difference between the groups in terms of success rate (77.8% versus 79.1%, p>0.05), and the authors reported that Pelvicol was as safe as TVT and offered high patient satisfaction.

In a non-randomized, consecutive study by Giri et al.[60], postoperative efficacy at three years was compared between porcine dermis (n=51) and autologous rectus fascia (n=50). A questionnaire was sent to the postal address of each patient, and a blinded assessor contacted all patients over the phone. The authors reported an 80.4% success rate in the rectus fascia group and a 54% success rate in the porcine dermis group. All of the patients with unsuccessful outcomes underwent postoperative urodynamic evaluations. According to the results of the urodynamic studies, SUI was detected in 6.5% of the patients in the rectus fascia group and 90% of the patients in the porcine dermis group. Based on their results, the authors concluded that acellular cross-linked porcine dermis could be used as an alternative to rectus fascia.

4) Pubovaginal sling synthetic prosthetic materials

Synthetic sling materials are sterile, biocompatible, and non-carcinogenic, and many have been studied in the literature over the past decade.[45] These materials offer the availability of high-quality materials with various sizes and shapes and shorter operative time.[22,61,62] Although there is no risk of infectious agent transmission, these materials are more likely to cause erosion and local infections.[61-63] In 2008, Woodruff et al.[22] compared the histological structure of different extracted PVS materials (synthetic, autologous, allograft, xenograft). In the synthetic material specimens, the authors did not find any graft degradation. Additionally, fibroblast and host tissue infiltration along the graft were the highest of all the materials.

The commonly utilized synthetic materials include monofilament polypropylene loosely woven mesh, multifilament polyester (polyethylene and polyethylene terephthalate) mesh (Marlex; CR Bard, Cranston, RI and Mersilene; Ethicon Endo-Surgery Inc., Somerville, NJ, USA), polytetrafluoroethylene (Gore-Tex; W.I. Gore & Associates, Inc., Flagstaff, Arizona, USA), silicone elastomer (Silastic, Dow Corning Corporation, Midland, Michigan, USA) and collagen injected polyester tissue (ProteGen, Boston Scientific, Natick, Massachusetts, USA).[45] Currently, loosely woven polypropylene mesh is the most commonly used material because it allows for the best ingrowth of the host tissue and macrophage transition.[64]

Outcomes

In a prospective and randomized study from 2000, Sand et al.[65] compared the outcomes of the PVS procedure utilizing polytetrafluoroethylene (PTFE) mesh (n=17) to the Burch retropubic urethropexy (n=19). The authors observed no difference in the outcomes between the two methods after three months of follow up. In an earlier study, Weinberger and Ostergard[66] reported a

Table 1. Pubovaginal sling materials and their advantages and disadvantages

	Used Materials	Advantages	Disadvantages
Autologous Graft Materials	Rectus muscle Fascia lata Vaginal wall	* Maximum bio-compatibility * Negligible tissue reaction * Negligible urethral perforation * Highest success rates * Lower rates of complications	* Increased operation time * Increased suprapubic pain * Increased hospital stay * Risk of suprapubic seroma * Risk of suprapubic incisional hernia
Allograft Materials	Cadaveric rectus fascia Cadaveric fascia lata Cadaveric dermis tissue	* Easy to use * Available in a variety of sizes * Smaller suprapubic incision * Reduced operative time * Reduced hospital stay * Decreased postoperative pain	* Risk of transmitting illnesses such as CJD, hepatitis, HIV * Less tensile strength * Increased costs
Xenograft Materials	Bovine pericardium Porcine bowel Porcine dermis	* Smaller suprapubic incision * Decreased postoperative pain * Reduced operative time * Reduced hospital stay	* Less tensile strength * Tendency of encapsulation * Foreign body reaction * Increased costs

HIV: human immunodeficiency virus; CJD: Creutzfeldt-Jacob prion disease

61% success rate at a minimum of one year after the suburethral sling procedure using PTFE. Overall, 40% developed a wound site infection and 22% required sling material extraction. The authors concluded that patients should be informed of the high complication rates related to synthetic suburethral sling materials and that extraction of the materials may be required under some conditions.

In 2001, Young et al.[67] presented short- and long-term outcomes in patients who underwent the PVS procedure using Mersilene (n=176). The objective cure rate using a stress test was 93% after 30-months of follow up and 94% after longer-term follow up. The subjective cure rates in the short- and long-term periods were 95.3% and 90.4%, respectively. In addition, the authors reported a 3.5% rate of persistent urinary retention, an 8.8% rate of de novo urgency and a 4% rate of vaginal and inguinal sling exposure. Seven years later, Wohlrab et al.[68] performed the PVS sling procedure using Mersilene in 772 patients. In this study, 62 (8%) patients developed mesh exposure. The most common symptoms in these patients were vaginal discharge in 37% of the patients, followed by vaginal bleeding (31%), dyspareunia (13%), and voiding dysfunction (21%). The PVS materials and their advantages-disadvantages are shown on Table 1.

In conclusion, PVS procedures were introduced for surgical treatment of SUI in the early 1900s, and since then, numerous studies have attempted to find the "ideal" sling material. In these studies, various autologous, allograft, xenograft, and synthetic materials have been employed. These materials yield variable rates of success, infection and exposure. An ideal implant material for the PVS procedure should demonstrate maximum efficacy, demonstrate minimum complications, be chemically inert, should not be modified by host factors, should not induce inflammation, should not result in hyper-reactivity and should be resistant to mechanical stress.

In general, the autologous pubovaginal sling procedure for the treatment of stress urinary incontinence offers the highest success rate and is the most commonly used PVS surgical method. The procedure does not result in excess tissue reaction and is associated with a low rate of complications. Other allograft and sling materials have been used in an attempt to reduce operative time and length of hospital stay; however, all of these materials have failed to achieve the desired efficacy, safety and tensile strength. Furthermore, allografts, albeit very uncommon, bring the risk of transmitting infections, and xenografts are associated with significant encapsulation. Lastly, synthetic materials are not commonly used for PVS surgery due to their high risk of infection, perforation and exposure.

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