Severe Mesh Complications Following Intravaginal Slingplasty

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OBJECTIVE: Synthetic meshes are increasingly used in the management of stress urinary incontinence and pelvic organ prolapse. This report describes severe complications following anterior and/or posterior intravaginal slingplasties employing a multifilament polypropylene mesh.

METHODS: We describe the symptoms, findings, subsequent management, and outcome of 19 consecutive women who have been referred with complications following anterior (n = 11) and/or posterior intravaginal slingplasty (n = 13) employing the multifilament polypropylene tape.

RESULTS: The main indications for removal of the 11 anterior intravaginal slings were intractable mesh infection in 6 women, retropubic abscess with cutaneous sinus in one, and vesico-vaginal fistula in one, intravesical mesh and pain syndrome in one, and voiding difficulties and pain syndrome in two. The main indications for removal of the 13 posterior intravaginal slings were intractable mesh infection in three and pain syndrome and dyspareunia in 10 women. Removal of the slings was performed after a median time of 24 months post-slingplasty. At follow-up between 6 weeks and 6 months, in all women genital pain, chronic vaginal discharge and bleeding, voiding, and defecation difficulties had been markedly alleviated (5) or they had ceased (14). Twelve of 17 sexually active women (71%) resumed sexual intercourse without difficulties. Ten women required subsequent surgery for stress incontinence and pelvic organ prolapse.

CONCLUSION: Surgeons should be aware of the potential complications of synthetic meshes. Until data on the safety and efficacy of the intravaginal slingplasties are available, these procedures cannot be recommended.
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Synthetic meshes are increasingly used in the surgical management of urinary incontinence and pelvic organ prolapse. Although mesh erosion and defective healing after the tension-free vaginal tape (TVT) procedure for stress urinary incontinence using monofilament mesh is rare,[1] vaginal mesh erosions after abdominal sacrocolpopexies with multifilament mesh have been reported in up to 12%.[2] They usually require local excision and re-epithelialization,[2,3] but cases necessitating multiple excisions and removal of the mesh have also been described.[3]

The original nylon mesh used for the anterior and posterior intravaginal slingplasty (IVS Tunneller; Tyco Healthcare, Norwalk, CT) for stress incontinence and pelvic organ prolapse was associated with tape rejection in 10%.[4] A multifilament polypropylene tape was introduced to reduce the incidence of complications with the nylon tape. No cases of rejections or infections have subsequently been reported although the literature on the efficacy and safety of the intravaginal slingplasty and the posterior intravaginal slingplasty in particular is scarce, representing the experiences of 2 surgeons.[4,5]

This report describes cases of serious complications following anterior and/or posterior intravaginal slingplasty procedures using multifilament polypropylene tape.

MATERIALS AND METHODS

We describe the symptoms, findings, subsequent management, and outcome of 19 women who have been referred to 4 centers from April 2001 to April

2004 for complications following anterior and/or posterior intravaginal slingplasty using multifilament polypropylene tape. These procedures have been described elsewhere.[5,6] The authors of this report do not perform intravaginal sling operations. All but 3 patients were referred by general practitioners or gynecologists who were not involved in the surgery. The Human Research Ethics Committee of the Royal Brisbane and Women's Hospital gave approval for this study.

To determine the significance of the presented complications, we performed a MEDLINE literature search from 1966 to September 2004 with the terms "intravaginal sling," "intravaginal slingplasty," "intravaginal slingplasty and infracoccygeal sacropexy." No language limitations were employed. We also handsearched the conference proceedings of the International Continence Society for 2002, 2003, and 2004.

RESULTS

The median age was 51 years (range 35–71, mean 53). Six women had an anterior intravaginal sling inserted, 8 women had a posterior, and 5 women had both anterior and posterior intravaginal slings. Five patients had an additional graft overlay, 3 of them Pelvicol (Bard, Covington, GA) and 2 Prolene (Ethicon, Somerville, NJ). Three patients underwent concomitant posterior bridge repair. One woman had a second posterior intravaginal sling inserted for recurrent prolapse.

Table 1 summarizes the symptoms and findings separately for the 11 anterior and 13 posterior intravaginal slings in the 19 women. All women complained of severe pain in the bladder, vagina, or rectum or dyspareunia if sexually active. All women with a posterior intravaginal sling reported buttock/rectal pain aggravated by sitting, defecation, or sexual intercourse. This pain could be reproduced during vaginal and rectal palpation. One woman presented with a urethro-vaginal fistula. Two women had persistent retropubic abscess. In one of these women, the abscess developed into a cutaneous sinus, and in the other, into a vesico-cutaneous fistula draining pus and urine. Nine women presented with intractable mesh erosions and infection: vaginal mesh erosions not responding to antibiotics and oversewing (performed elsewhere up to 4 times), purulent vaginal discharge and bleeding, recurrent urinary tract infections, and severe pain. One of these women had previously had an infected anterior nylon mesh removed, and the new polypropylene intravaginal sling was inserted during the same procedure, which subsequently led to recurrent symptoms consistent with mesh infection. One woman had previously had the posterior intravaginal sling trimmed for a perineal erosion and presented with persistent vaginal/rectal pain and clinical signs of mesh infection.

The median time to commencement of symptoms after the initial intravaginal sling procedure was 1 month (range up to 12 months). Surgery to remove the mesh was performed after a median time of 24 months (range 10 weeks–36 months). Preoperative

Table 1. Symptoms and Findings in 19 Patients With Complications After Intravaginal Slingplasty, Evaluated Separately for 11 Anterior and 13 Posterior Intravaginal Slings*

	Anterior IVS (n = 11)	Posterior IVS (n = 13)
Predominant pain		
Vagina	6	1
Rectum/buttocks	0	12
Bladder	4	0
Dyspareunia/sexually active patients	10/10	12/12
Vaginal erosion and vaginal bleeding	6	5
Purulent/offensive vaginal discharge	6	3
Retropubic abscess and cutaneous sinus	1	0
Retropubic abscess and vesico-cutaneous fistula	1	0
Intravesical mesh/permanent sutures	2	0
Voiding difficulties	4	4
Fecal urgency	0	2
Difficult and painful defecation/buttock pain sitting	0	13
Pelvic organ prolapse stage 2 or more		
Anterior	1	3
Vault	0	3
Posterior	0	7

IVS, intravaginal slingplasty.
* Five patients had both anterior and intravaginal sling.

investigations included urodynamics, barium enema, pelvic and abdominal ultrasound examination, intravenous pyelograms, and colonoscopy, as appropriate. All women were given prophylactic antibiotics during the sling removal. The main indications for removal of the 11 anterior intravaginal slings were intractable mesh infection in 6 women, retropubic abscess with cutaneous sinus in 1 woman, vesico-vaginal fistula in 1 woman, intravesical mesh and pain syndrome in 1 woman, and voiding difficulties and pain syndrome in 2 women. The main indications for removal of the 13 posterior intravaginal slings were intractable mesh infection in 3 women and pain syndrome and dyspareunia in 10 women.

The anterior intravaginal slings were removed vaginally in 4 women, combined vaginally-laparoscopically in 4 women and combined vaginally-open-abdominally in 3 women. All posterior intravaginal slings were partially or completely removed vaginally. In 2 women the Prolene mesh had also eroded into the vagina and was removed concomitantly. The Pelvicol mesh was not clearly distinguishable as a structure and was probably partly removed within substantial scar tissue. No complications occurred during the removal of the mesh. The median operating time was 60 minutes (range 20–125). The removed mesh and adjacent tissue was sent for histopathology in 8 women and revealed acute and chronic inflammation (large amount of neutrophils present as well as foreign body giant cells).

At follow-up between 6 weeks and 6 months, in all women, genital pain, chronic discharge and bleeding, voiding and defecation difficulties had been markedly alleviated (n = 5) or had ceased (n = 14). Twelve of 17 sexually active women (71%) resumed sexual intercourse without difficulties. Ten women required subsequent surgery for stress incontinence and pelvic organ prolapse, including Burch colposuspension in 3 women, tension-free vaginal tape in 1 woman, transobturator tape in 1 woman, anterior and/or posterior repairs in 7 women, sacrospinous colpopexy in 1 woman, and sacrocolpopexy in 2 women. One woman had a significantly shortened and narrowed vagina and underwent a vaginoplasty to restore adequate vaginal capacity.

DISCUSSION

We report a series of mesh infections and pain syndromes following anterior and posterior intravaginal slingplasty with the new multifilament polypropylene mesh. All necessitated surgical interventions because of symptoms debilitating to the patient's quality of life. The exact incidence of these complications remains unclear because of the unknown denominator.

There is a paucity of published data on the efficacy and safety of both the employed mesh and the surgical technique, particularly for the posterior intravaginal sling. The MEDLINE search revealed 8 clinical trials; 5 of them were personal case series of one surgeon.[5–9] Six articles assessed the anterior intravaginal slingplasty (n = 240),[6–11] including one randomized controlled trial comparing the anterior intravaginal slingplasty and the tension-free vaginal tape (TVT) procedure, with similar results.[10] Two trials reported on the efficacy of the posterior intravaginal slingplasty (n = 168) without formal quality-of-life assessment.[4,5] Petros described one mesh rejection and mesh erosions in 4 of 71 patients requiring surgical intervention.[5] There was also one case report on a suburethral vaginal erosion and pyogenic granuloma formation after anterior intravaginal slingplasty.[12] We were unable to find any independent (third party) prospective follow-up studies or randomized controlled trials of the posterior intravaginal slingplasty. There were 2 abstracts on the intravaginal slingplasty published in the conference proceedings of the International Continence Society 2004 (Pifarotti P, Meschia M, Gattei U, Bernasconi F, Magatti F, Viganò R. Multicenter randomized trial of tension-free vaginal tape (TVT) and intravaginal slingplasty (IVS) for the treatment of stress urinary incontinence in women. Neurourol Urodynam 2004;23:494; and Krause H, Goh J, Khoo SK, Williams R, Galloway S. Biocompatible properties of surgical mesh using an animal model. Neurourol Urodynam 2004;23:425). A randomized trial of the TVT procedure and anterior intravaginal slingplasty, while demonstrating similar success rates for stress urinary incontinence, reported a 9% intravaginal slingplasty-mesh erosion rate; all but one subject required removal of the intravaginal slingplasty (Pifarotti et al, 2004). The other study described more fibrosis and foreign body giant cells around the intravaginal slingplasty tape as compared with the TVT (Krause et al, 2004).

According to Amid's classification for mesh used in abdominal hernia repairs, the intravaginal sling tape consists of a type III polypropylene mesh, which is a macroporous mesh with multifilamentous components. Because the small interstices of the mesh (less than 10 microns), bacteria might infiltrate but cannot be eliminated by macrophages, which are too large to enter the pores and interstices, therefore contributing to infection.[13] This might explain the cases of persistent infection of the intravaginal sling mesh. In comparison, the tension-free vaginal tape is a type I

macroporous and monofilament polypropylene mesh, which allows also macrophages to infiltrate. An infection is unlikely, and if present, it can be treated with antibiotics. Complications of the tension-free vaginal tape are well described, and infections or rejections are rare.[14]

Apart from the multifilament mesh used in intravaginal sling procedures, the route of mesh insertion has also to be considered, particularly for the posterior intravaginal sling. It is known, that vaginal suture and mesh placement in sacrocolpopexies result in a significantly higher erosion rate (20% versus 4% if inserted abdominally).[3] Another possible confounder is the lack of a plastic sheath protecting the mesh during insertion until placed in the correct position. Rates of potential risk factors like age, parity, smoking, body mass index, chronic bronchitis/asthma, diabetes mellitus, and previous and concomitant operations were similar to those of cohorts of urogynecology patients in tertiary referral centers (data not presented).[15] No woman had a known autoimmune disease.

The main indication for removal of the posterior intravaginal slings was severe pain, especially during defecation and sexual intercourse. The exact origin of this pain syndrome is not clear, but the lack of plastic deformation or high stiffness[16] of the intravaginal sling and the marked fibrosis surrounding the mesh (Krause et al, 2004) might contribute. However, in women who received additional Pelvicol or Prolene mesh, it can be difficult to distinguish the origin of the pathologies.

As the insertion of synthetic meshes in gynecologic surgery is gaining in popularity, surgeons should be aware of these potential complications that are probably associated with vaginal-perineal mesh placement and the use of multifilament mesh. Until further data on the safety and efficacy of the intravaginal sling techniques and the type of mesh used is available, these procedures cannot be recommended and should be used in controlled clinical trials only.

REFERENCES

1. Karram MM, Segal JL, Vassallo BJ, Kleeman SD. Complications and untoward effects of the tension-free vaginal tape procedure. Obstet Gynecol 2003;101:929–32.
2. Kohli N, Walsh PM, Roat TW, Karram MM. Mesh erosion after abdominal sacrocolpopexy. Obstet Gynecol 1998;92: 999–1004.
3. Visco AG, Weidner AC, Barber MD, Myers ER, Cundiff GW, Bump RC, et al. Vaginal mesh erosion after abdominal sacral colpopexy. Am J Obstet Gynecol 2001;184:297–302.
4. Farnsworth BN. Posterior intravaginal slingplasty (infracoccygeal sacropexy) for severe posthysterectomy vaginal vault prolapse–a preliminary report on efficacy and safety. Int Urogynecol J Pelvic Floor Dysfunct 2002;13:4–8.
5. Petros PE. Vault prolapse II: Restoration of dynamic vaginal supports by infracoccygeal sacropexy, an axial day-case vaginal procedure. Int Urogynecol J Pelvic Floor Dysfunct 2001; 12:296–303.
6. Petros PP. The intravaginal slingplasty operation, a minimally invasive technique for cure of urinary incontinence in the female. Aust N Z J Obstet Gynaecol 1996;36:453–61.
7. Petros PP. Medium-term follow-up of the intravaginal slingplasty operation indicates minimal deterioration of urinary continence with time. Aust N Z J Obstet Gynaecol 1999;39: 354–6.
8. Petros PE. New ambulatory surgical methods using an anatomical classification of urinary dysfunction improve stress, urge and abnormal emptying. Int Urogynecol J Pelvic Floor Dysfunct 1997;8:270–7.
9. Papa Petros PE. Cure of urinary and fecal incontinence by pelvic ligament reconstruction suggests a connective tissue etiology for both. Int Urogynecol J Pelvic Floor Dysfunct 1999;10:356–60.
10. Rechberger T, Rzezniczuk K, Skorupski P, Adamiak A, Tomaszewski J, Baranowski W, et al. A randomized comparison between monofilament and multifilament tapes for stress incontinence surgery. Int Urogynecol J Pelvic Floor Dysfunct 2003;14:432–6.
11. Plachta Z, Adamiak A, Jankiewicz K, Skorupski P, Rechberger T. Quality of life after mid-urethra polypropylene tape sling surgery (IVS, TVT) in female stress urinary incontinence [in Polish]. Ginekol Pol 2003;74:986–91.
12. Lim YN, Rane A. Suburethral vaginal erosion and pyogenic granuloma formation: an unusual complication of intravaginal slingplasty (IVS). Int Urogynecol J Pelvic Floor Dysfunct 2004;15:56–8.
13. Amid PK. Classification of biomaterials and their related complications in abdominal wall hernia surgery. Hernia 1997; 1:15–21.
14. Boublil V, Ciofu C, Traxer O, Sebe P, Haab F. Complications of urethral sling procedures. Curr Opin Obstet Gynecol 2002; 14:515–20.
15. Meschia M, Buonaguidi A, Pifarotti P, Somigliana E, Spennacchio M, Amicarelli F. Prevalence of anal incontinence in women with symptoms of urinary incontinence and genital prolapse. Obstet Gynecol 2002;100:719–23.
16. Dietz HP, Vancaillie P, Svehla M, Walsh W, Steensma AB, Vancaillie TG. Mechanical properties of urogynecologic implant materials. Int Urogynecol J Pelvic Floor Dysfunct 2003;14:239–243.