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Urethral necrosis and proximal urethro-vaginal fistula resulting from tension-free vaginal tape

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Abstract Urethral erosion is an uncommon complication after sub-urethral sling placement using the TVT procedure. Strangulation necrosis of the entire distal urethra with a fistulous connection between proximal urethra and vagina is a devastating complication that has not been previously reported, resulting in significant morbidity and the necessity for challenging management. This is a report of a 64-year-old woman with stress urinary incontinence who underwent a TVT resulting in a large fistula between the proximal urethra and the vagina, and the necrosis of the entire urethra distal to the fistula. This problem necessitated a staged reconstruction involving three separate procedures. Initially, she underwent debridement and removal of the TVT fragments, a secondary vaginal flap urethroplasty with a labial fibro-fatty graft to restore urethral length, and a tertiary coaptive occlusive sling to restore continence.

Keywords Stress urinary incontinence · TVT · Urethral erosion · Urethral necrosis · Fistula

Abbreviations TVT: Tension-free vaginal tape · SUI: Stress urinary incontinence

Introduction

Stress urinary incontinence (SUI) has emerged as a highly prevalent medical condition and has engendered a large and competitive marketplace for “new age” commercially available slings. Synthetic slings have dramatically increased in popularity in the management of SUI and have been rapidly adopted by the uro-gynecological community. Petros and Ulmsten [1] are primarily responsible for a

major paradigm shift including the use of synthetic tape for placement at the level of the mid-urethra, tension-free support, fixation by friction, and the use of local anesthesia. The tension-free vaginal tape (TVT) is a minimally invasive sling commonly utilized for the management of SUI. Major complications after TVT are uncommon. Tape-associated adverse events include bladder perforation at the time of TVT placement, postoperative voiding dysfunction, denovo bladder overactivity and the rare occurrences of vaginal extrusion of the tape, erosion of the tape into the urethra, and vascular, nerve or bowel injury. One of the key premises of the TVT is placement of the tape without tension on the urethra. This case demonstrates the potential pitfalls and devastating complications that may arise when a TVT is presumptively placed with excessive tension.

Case report

A 64-year-old woman with a medical history of diabetes mellitus, hypercholesterolemia, and gastro-esophageal reflux went to her gynecologist with a complaint of urinary incontinence with coughing, sneezing, and lifting. She was evaluated by cystoscopy and urodynamics by a urologist consultant and was diagnosed with stress urinary incontinence due to urethral hypermobility. The gynecologist performed a pubo-vaginal sling procedure under general anesthesia using the Gynecare TVT system. A cystoscopy was done at the time of the TVT and there was no bladder perforation reported, however, there was no mention of urethroscopy. Within the first postoperative week, she was found to have vaginal voiding and significant incontinence and a fistula was found between her anterior vaginal wall and the urinary tract. Three weeks after the TVT was initially placed, the gynecologist performed a vesico-vaginal fistula repair.

This patient was first contacted 2 months after TVT. At that time, she said she had gravitational incontinence, incontinence with sneezing and coughing, while sleeping, and incontinence without awareness requiring four diapers per day, which became saturated. There was minimal

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spontaneous voiding, most of the urine output being via incontinence. A pelvic exam revealed a fistulous opening in the anterior vaginal wall into the proximal urethra-bladder neck region that could admit one finger with complete absence of the urethra. Cystoscopy demonstrated intact urethral orifices and normal urothelium. An excretory urogram revealed normal upper urinary tracts.

She was made to take topical vaginal estrogens with the plan of performing a one-stage reconstruction. However, 8 weeks after the procedure, it was evident that she had residual fragments of the tape that necessitated extraction and debridement, precluding a one-stage reconstruction (Figs. 1 and 2).

Several months later, after allowing sufficient time for healing, she underwent an *in situ* urethral reconstruction [2] with a labial fibro-fatty graft to help buttress the repair. A U-shaped incision was made in the anterior vaginal wall with the apex extending 5 mm proximal to the fistula and the limbs extending to the level of the designated neomeatus, chosen to be at the location of the original urethral meatus. Metzenbaum scissor dissection was carried out medial to the incision, undermining the vaginal wall and dorsal urethral epithelium to create an island of vaginal wall, with the central attachments left intact. A #16 French Foley catheter was placed within the bladder and aligned over the vaginal wall island. Urethral reconstruction was performed by rolling the medial edges of the island over the catheter using fine, interrupted 4-0 absorbable sutures, starting proximally and proceeding distally. By approximating the lateral edges of the vaginal wall island in the midline, the neo-urethra was tubularized and the fistula was closed. Approximately 3 cm of urethral length was thus achieved. A fibro-fatty labial graft was then mobilized to provide a well-vascularized cover for the entire neo-urethra. It was clear that sling placement would not be prudent at the time of this procedure to allow the reconstructed neo-urethra to fully heal. An anterior vaginal wall flap was then developed proximal to the initial U incision. When advanced and sutured to the edges of the U-shaped incision, it provided adequate cover for the neo-urethra and fibro-fatty graft. The reconstruction was performed on an outpatient basis, and she was discharged on antibiotics, anticholinergics, and a small-caliber catheter. The catheter was removed 4 weeks later, and 6 weeks later, the pelvic exam and



Fig. 1 Vaginal view of exposed tape seen just distal to bladder neck and absence of a urethra

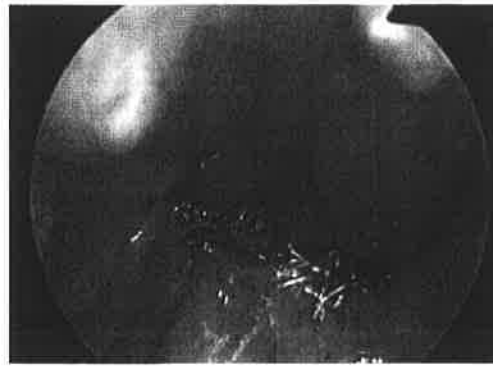


Fig. 2 Zoomed-in view of exposed tape seen just distal to bladder neck and absence of a urethra. Fistula is just proximal to tape and cannot be seen without retraction

urethroscopy revealed a nicely healed neo-urethra with restored length and an open, nonfunctional bladder neck.

Approximately 3 months after the urethral reconstruction, she underwent an outpatient pubo-vaginal sling using donor fascia with the intent of providing sufficient tension to support and coapt the urethra to provide a continence mechanism for the intrinsic sphincteric deficiency. The urethra was approached via an inverted U anterior vaginal wall incision, and the flap was developed to expose the urethra. The retropubic space was accessed via blunt and sharp dissection and a 2×12 cm piece of cadaveric fascia (Mentor Tutoplast) was folded lengthwise to create a double pleated 1×12 cm sling. Polypropylene transfixion sutures were placed at each end, and a double-pronged Cook ligature transferring device was passed from the suprapubic area to the vagina under digital guidance and then used to transfer the sutures from the vagina to the suprapubic area. The sling was tensioned moderately with the goal of creating coaptation without obstruction and then tied over the rectus fascia and then the vaginal flap was advanced to provide adequate cover for the sling. She was discharged on antibiotics, anticholinergics, and a small-caliber catheter that was removed 2 weeks later.

Subsequently, her stress and gravitational incontinence were improved, although she still requires the use of pads. She voids with no difficulty whatsoever, with no further element of vaginal voiding. She has been maintained on anticholinergic medication for persistent irritative lower urinary tract symptoms and urgency incontinence. Follow up video-urodynamics has demonstrated intrinsic sphincteric deficiency.

Discussion

Synthetic slings have become increasingly popular in the past decade. Advantages include elimination of harvest-site morbidity, shortened operative and recovery time and an unlimited supply of synthetic material [3]. Despite many potential advantages, synthetic slings are clearly associated with higher rates of vaginal and urethral erosion [4, 5]. Since its introduction in 1996, the TVT has been rapidly

adopted as a reference standard minimally invasive procedure for the treatment of SUI. Major complications are few and far between, although reports of bleeding, urinary retention, *denovo* urgency, vaginal mesh extrusion, urethral erosion, vascular injury, nerve injury, bowel injury and even death have been reported. Karram et al. [6] in a study of 350 patients who underwent the TVT concluded that it is a safe procedure with an acceptable complication rate when performed by surgeons who have experience with retropubic and transvaginal anti-incontinence procedures.

Erosion of synthetic mesh in the urethral lumen is fortunately a rare occurrence with patients typically having hematuria, irritative symptoms, and periurethral discomfort [7]. However, it is one of the most potentially devastating complications of the use of synthetic material. It often will take up to 9 months to establish a diagnosis of urethral erosion [8]. Urethral erosion may be on the basis of local, technical and iatrogenic factors [9]. Local factors include scarring, urogenital atrophy, estrogen deficiency, and radiation changes. Technical factors include improper tensioning, dissecting in a plane too close to the urethra, or urethral perforation. Iatrogenic causes include post-op traumatic catheterization or urethral dilatation. A common theme in case reports of urethral erosion is postoperative urinary retention [6, 10–12], particularly when it is managed by repeated urethral dilation [6, 10]. Clifford [7] emphasized the importance of a mandatory comprehensive urethroscopy to check for urethral injury in addition to the cystoscopy that is done to check for bladder injury. However, Haferkamp [13] reported a case of delayed transmural migration of tape not present at the time of the intraoperative urethroscopy or the initial postoperative urethroscopy, thus urethroscopy is not an infallible method. All of the case reports reviewed involved urethral erosion and not fistula formation with urethral necrosis. The case reports of urethral erosion were similar to this case in terms of excessive tensioning likely being a causative factor of the problem, but different in terms of the magnitude of the problem.

In this case, the occurrence of urethral necrosis and a large proximal urethral fistula is a very unusual and unfortunate complication after the TVT procedure. A Medline search was unable to find a previously reported case of fistula and strangulation necrosis of the urethra associated with the use of a TVT. As opposed to urethral erosion in which the mesh erodes through the ventral wall of the urethra into the lumen, this case represents the mesh eroding both through the ventral and dorsal walls, creating a fistula proximal to the erosion and vascular necrosis of the urethra distal to the erosion. It is certainly possible that a major contributing cause to the large fistula could be the attempted fistula repair, although it is impossible to quantify the relative roles of the initial TVT procedure vs. the fistula repair in engendering the ultimate complication.

The presumptive explanation for this complication is that the sling was placed with excessive tension causing urethra constriction. It is impossible to say retrospectively if the urethra was perforated at the time of the TVT or if the dissection was in the wrong plane. Cystoscopy was done

but there was no mention of urethroscopy in the operative report; if not performed, this should be considered a breach of proper technique. Other potential factors may be urogenital atrophy, estrogen deficiency, and the fact that the patient was a diabetic. The excessive tensioning most likely compromised of the urethral vascular supply resulted in the dual problems of strangulation necrosis of the urethra and a fistulous connection proximal to where the sling eroded into the urethra. Additionally, as per the initial operative report, the sling was placed very proximally—at the urethrovesical junction—not at the mid-urethra as described classically. Thus, the surgical technique was at odds with three of the tenets of the Petros-Ulmstein paradigm: anesthesia type, location of the sling, and presumptively, tensioning. Notably, general anesthesia is not uncommonly used for TVT, particularly when the surgeon needs to address other pelvic floor defects, but the fact that the procedure was not performed under local anesthesia is simply a point and not necessarily a relevant issue. This injury resulted in significant morbidity to the patient who, prior to the TVT, had moderate SUI but after her TVT experienced virtually total urinary incontinence with minimal spontaneous voiding.

As a result of this complication and the unsuccessful primary fistula repair, the patient underwent three additional surgical procedures that were all technically challenging. The first procedure involved debridement and removal of the exposed mesh, the second, reconstruction of the urethra to provide tubularization and length, and the third, placement of an coaptive allograft sling to provide continence.

To quote Dr. Roger Dmochowski's editorial comment: "It is important to remember that synthetic sling use is prosthetic surgery and should be approached with the solicitude involved with that branch of science" [14]. The very name of the TVT—an acronym for *tension-free* vaginal tape—expresses the most fundamentally important premise of the Petros-Ulmstein paradigm that if breached, as was presumed in this case, can have onerous consequences.

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