Long term results after complication of "prophylactic" suburethral tape placement

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Introduction: *To report the long term result following complications that arose after "prophylactic" placement of midurethral sling (MUS) during prolapse repair.*
Materials and methods: *After institutional review board approval, the records of patients who presented with complications of prophylactic MUS and had a minimum 1 year follow up after repair of their complication were reviewed. Data collected included age, body mass index, operative note documenting primary procedure and type of prophylactic MUS, indication for prophylactic MUS, presenting complaint, duration and severity of symptoms since MUS placement, operative events if any, and outcomes after repair of the complication.*
Results: *Between 2007 and 2009, ten patients presented with complications of prophylactic MUS and underwent transvaginal suburethral tape excision. At a median 35 (mean 36) month follow up post-MUS excision, a secondary midurethral stricture, an infected paravesical retropubic tape, and symptomatic incontinence and/or secondary anterior compartment prolapse requiring additional repair in five patients, occurred. Three patients experienced residual lower urinary tract symptoms (LUTS). Pain resolved in all four patients.*
Conclusion: *"Prophylactic" placement of a MUS can be fraught with complications requiring MUS removal, followed by additional corrective surgery in some, and persistent LUTS managed by continuous pharmacological therapy in others, thus requiring careful consideration and full patient agreement.*

Key Words: long term results, prophylactic surgery, suburethral tape, female stress urinary incontinence, surgical complications

Introduction

Notwithstanding the 2008 FDA public warning about the risks of synthetic materials for surgical repair of vaginal prolapse and incontinence,[1] a trend has emerged in the "prophylactic" placement of synthetic midurethral sling (MUS) during a variety of pelvic reconstructive procedures. Advocates of a prophylactic MUS procedure at the time of pelvic organ prolapse (POP) repair argue that the procedure is brief, minimally invasive, overall well tolerated, and will spare the patient the need for another procedure in the future. Such an approach is also supported by the fact that there are no perfect tests to predict who might suffer from stress urinary incontinence (SUI) after a POP repair. Similarly, only urodynamics (UDS) could unmask SUI preoperatively but is not always performed prior to POP repair, especially if the patient does not complain of SUI. Furthermore, there is recognition that postoperative incontinence in a patient dry preoperatively may result in major patient dissatisfaction. No matter how logical these arguments may be, when an immediate or long term complication occurs after a "prophylactic" MUS placement, this line of reasoning can be easily turned around. The definition of prophylactic is to "maintain health and prevent spread of disease".[2] In this study the term "prophylactic" MUS referred to a surgical decision made in the absence of demonstrable SUI. If indeed the corrective procedure is technically simple and so successful, why not reserve it for the few who will need it secondarily rather than imposing it systematically to all those who might need it?

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As the literature suggests, there is no such procedure yet that works on everyone perfectly and has no attached complications. In fact, the best data available suggests a ceiling effect at 80% success for most synthetic sling procedures, with variable rates and types of complications but always with some.[3,4] We report a series of complications which arose after "prophylactic" placement of MUS at the time of prolapse repair.

Materials and methods

After institutional review board approval, the records of patients who presented with complications of "prophylactic" MUS and were followed after repair for a minimum of 1 year follow up were reviewed. Data collected included age, body mass index, operative note documenting primary procedure and type of "prophylactic" MUS, indication for "prophylactic" MUS (when available), presenting complaint, and duration of symptoms since MUS placement. Initial evaluation included questionnaires when relevant (Urogenital Distress Inventory Short Form (UDI-6), International Incontinence Questionnaire (IIQ-7), and one question on quality of life based on a visual analogue scale from 0 (perfect) to 10 (terrible)), urinalysis, non-invasive uroflow with post-void residual measurement by bladder scan, physical examination, and urethro-cystoscopy and/or imaging studies depending on the nature of the complication. Urethro-cystoscopy was performed to evaluate the urethra and bladder for the presence of exposed MUS. Voiding cystourethrogram with lateral views during voiding was performed to assess for possible urethral distortion[5] and/or to exclude a urethro-vaginal fistula in patients complaining of de novo incontinence. Specific issues were raised during surgical consenting related to the possibility of residual pain (when present preoperatively), persistent or recurrent incontinence (stress, urge, or mixed), and/or dyspareunia after MUS removal, and risk of urethral injury during tape excision.

During MUS removal procedure, a urethro-cystoscopy was first performed with a 17.5 Fr female scope to try to locate the course of the tape which typically provokes a flattening of the urethral floor. An inverted U-shape vaginal incision was then made to permit access to the lateral extensions of the tape and to facilitate repair of a urethral injury if it occurred during MUS excision by allowing the insertion of a Martius fat pad graft and/or a fascial patch as covering layers over the urethral repair. This anterior vaginal flap can at times be difficult to take down beneath the tape because of the prior midline incision used to place the tape. Hydrodissection may be useful in some instances. During suburethral MUS excision, some tapes can be difficult to identify when they are not blue colored. This is especially true when a MUS was placed a long time ago resulting in tissue in-growth, or has traveled deep into the urethral wall and is not visible or palpable on the outer surface of the urethra. To minimize the risk of urethral injury, we prefer to locate the tape on the side of the urethra (3 or 9 o'clock position), Figure 1a, and divide it there. Identification of the tape at either of these locations appeared to minimize the risk of urethral injury. Loops may be beneficial in identification and dissection of the tape during its removal. Once divided on one side of the urethra, the tape was carefully peeled off the under surface of the urethra from one side to the opposite side, Figure 1b. The lateral extensions of the mesh past the inferior edge of the pubic ramus towards the obturator fossa for a TOT or the tails of the tape extending towards the retropubic space for a TVT were left intact, Figure 1c. Urethro-cystoscopy was repeated

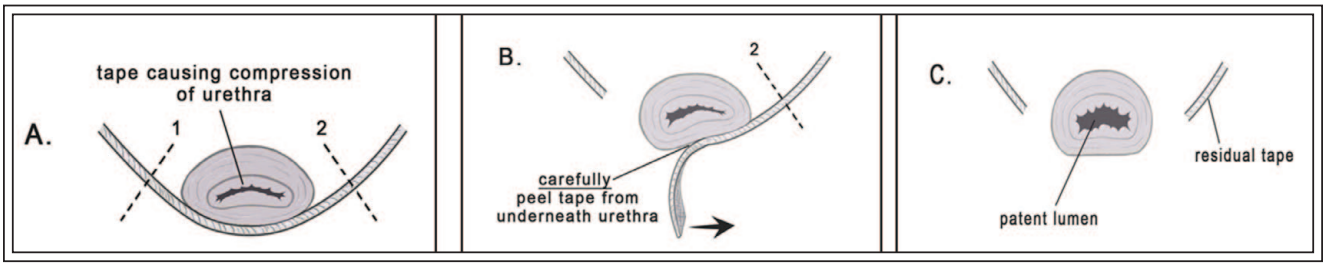

Figure 1. a) Midurethral sling placed underneath the urethra should be tension free. 1 and 2 indicate locations where the tape can be incised safely away from the urethral floor, thus potentially decreasing the risk of urethral injury. **b)** It is preferable to locate the tape on the side of the urethra (3 or 9 o'clock) to minimize the risk of urethral injury. **c)** After suburethral tape excision, it is important to perform a urethroscopy to exclude a urethral injury and document restoration of a normal urethral lumen.

after suburethral tape removal to ensure no urethral injury and a return to normal of the urethral lumen. Postoperatively, patients were re-evaluated with the same validated questionnaires, physical examination, non-invasive uroflow, and measurement of post-void residual volume at 6 weeks, 6 months and yearly thereafter. For questionnaires, the scores at the last visit were chosen for final reporting. All charts were reviewed by a third party investigator not involved in patient care and using an electronic record (EPIC) for the most part.

Results

Between February 2007 and October 2009, ten patients (mean age 54, range 36-75) who presented with complications of "prophylactic" MUS underwent vaginal suburethral tape excision. Table 1 provides demographic information on original procedure performed, type of suburethral tape placed, and presenting complaints. According to patient's statement, none complained of SUI, had demonstrable SUI on exam or had tests unmasking SUI preoperatively, affirming our understanding that MUS was performed "prophylactically". The original surgeon's note, recovered in 8/10 patients, was not always clearly explicit as to the indication for MUS placement.

Median duration of follow up was 35 months (range 24-58). Prior to MUS removal, six patients were incontinent, two with predominant stress urinary incontinence (SUI), two with urge incontinence (UUI), one with mixed urinary incontinence (MUI) and one with a fistula, Figure 2, while eight patients reported urgency. Seven patients had severe trabeculations on cystoscopy and one patient presented with complaints of recurrent urinary tract infections. Four patients reported pain (pelvic pain (3), urethral pain (1)) and all four had dyspareunia. VCUG was obtained in nine patients: seven had a midurethral kinking with proximal urethral and bladder neck ballooning, Figure 3, and two were unable to void during the study. The patient with exposed urethral mesh was diagnosed on cystoscopy and did not undergo VCUG.

TABLE 1. **Demographic characteristics of patients with prophylactic suburethral tape**

	Age at tape surgery	Body mass index	Parity	Surgery at time of tape placement	Type of tape	Time presentation (weeks)	Presenting complaints
1	71	23.38	2	Cystocele repair	TOT	16	U/WS/DV/F/N
2	37	22.24	3	Hysterectomy and cystocele/rectocele repair	TVT	16	U/UUI/H/F/P/Dy
3	58	28.89	3	Hysterectomy and uterosacral suspension	TOT	40	WS/H/DV/F/N
4	35	23.41	3	Hysterectomy	TVT-O	56	SUI/U/UUI/Dy
5	47	23.49	0	Cystocele repair	TVT-O	20	U/F/P/Dy
6	63	27.52	3	Rectocele and cystocele repair	TVT	14	SUI/U/UUI/F/
7	66	23.63	.	Vaginal prolapse repair	Sparc	32	U/WS/F
8	53	32.11	2	Hysterectomy	TVT	12	Urethral erosion
9	75	21.79	0	Laparoscopic sacrocolpopexy	TVT	4	SUI
10	32	42.4	3	Laparoscopic hysterectomy and anterior-posterior repair	TVT-O	44	U/UUI/P/Dy

TVT = tension free vaginal tape; TVT-O = tension free vaginal tape obturator; TOT = transobturator tape sling; Sparc = top-down retropubic midurethral sling; SUI = stress urinary incontinence; U = urgency; UUI = urge urinary incontinence; H = hesitancy; WS = weak stream; DV = double voiding; F = frequency; P = pain; Dy = dyspareunia; N = nocturia > 1

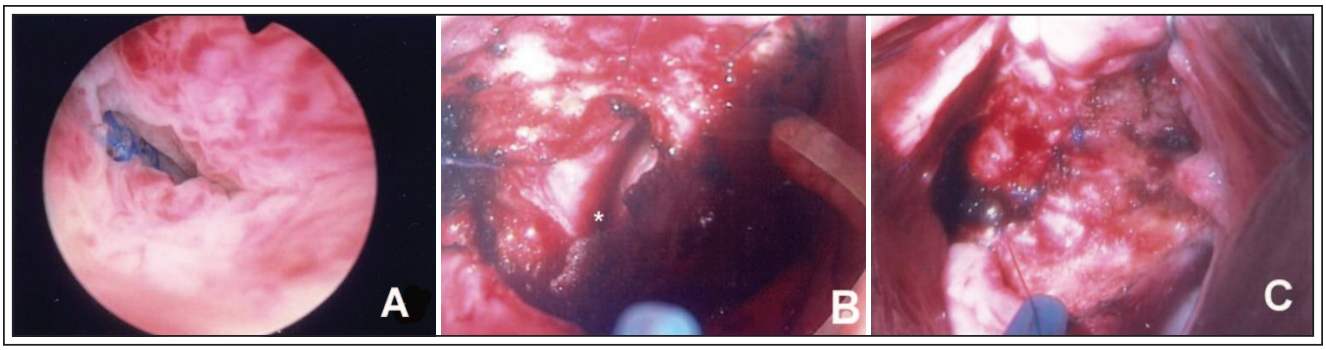

Figure 2. Eroded tape in the urethral lumen was removed **(a)**, followed by urethral reconstruction (*)**(b)**. Then, an autologous fascial sling patch was placed over the repair to prevent a secondary urethrovaginal fistula **(c)**.

After MUS removal, three patients reported persistent urinary urgency (2 requiring long term anti-cholinergic therapy). Pain and dyspareunia resolved in all four patients. SUI was managed with collagen injection (1) and rectus fascial sling (1) with complete SUI resolution and no further treatment. During follow up, five patients underwent secondary procedures: midurethral stricture requiring urethral dilations under general anesthesia (1), infected paravesical retropubic tape requiring removal (1), and symptomatic anterior compartment prolapse (3) requiring vaginal repair with an anterior vaginal wall suspension.[6] Mean postoperative QoL scores available for 8/10 patients was 3, with two patients reporting a score of 0, three a score of 2, two a score of 5 and one a score of 7. Mean postoperative UDI-6 score was 32 (16.5-44), while mean IIQ-7 was 14 (0-42). Overall, following re-operation for MUS takedown, an additional surgical repair in 70% of patients and persistent LUTS requiring continuous pharmacological therapy were needed.

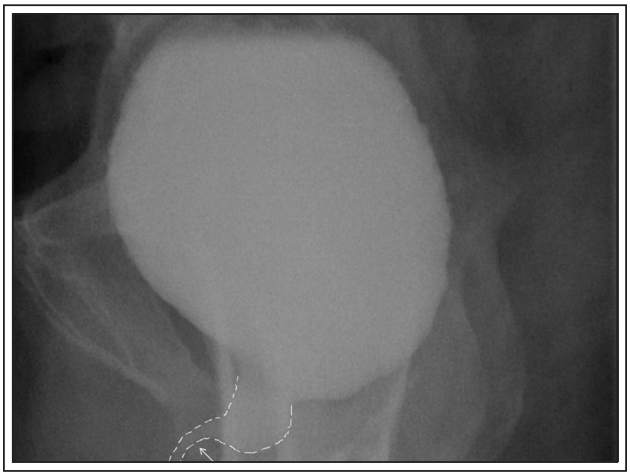

Figure 3. During a laparoscopically assisted vaginal hysterectomy, a prophylactic retropubic midurethral sling was placed. Lateral voiding views revealed a distorted kinked midurethra with proximal ballooning of the proximal urethra and bladder neck area (arrow) while urodynamic testing confirmed bladder outlet obstruction.

Discussion

This report highlights a series of complications that occurred after "prophylactic" placement of a MUS at the time of POP repair and the long term follow up that ensued after sling removal. New onset bothersome incontinence, urinary fistula, dyspareunia, groin pain, urgency and frequency, recurrent urinary tract infections, presented alone or in combination in very frustrated patients who were not expecting much problem for that portion of their corrective surgery. Since the first description of the TVT by Ulmsten in 1996, many reports of complications including serious ones[1] with even death in rare cases have emerged.[7] The transobturator tape (TOT), introduced by Delorme in 2001, was intended to avoid the risk of bladder injury and reduce the risk of voiding dysfunction. As recently established by a meta-analysis[3] as well as one multicentric study from the UITN, the TOT also carries its own set of risks, including groin pain, vaginal erosion and risk of voiding dysfunction.[4,8]

In 2001, an original report by Gordan et al in 30 women diagnosed with occult SUI who received a prophylactic TVT at time of surgery for "severe genitourinary prolapse" launched the concept of prophylactic anti-incontinence procedure. Although none of these women demonstrated clinical SUI at a mean follow up of 14 months, 10% had urodynamic SUI, and 66% of patients with preoperative detrusor overactivity (DO) had postoperative DO. De novo DO was noted in 13% of patients.[9] In 2004, the same group updated their series by reporting their findings in 100 consecutive patients

with occult SUI undergoing prolapse repair who had a concomitant prophylactic TVT. At a mean follow up of 27 months, de novo urge incontinence developed in 8% of patients, while 2% developed urinary retention and another 2% recurrent SUI. Three patients with erosion of the vaginal tape required subsequent removal of the tape.[10]

In 2006 the Pelvic Floor Disorders Networks (PFDN) published the results of the Colpopexy and Urinary Reduction Efforts (CARE) trial. This study set out to determine if a prophylactic Burch colposuspension at the time of abdominal sacrocolpopexy (ASC) would decrease symptoms of SUI in women without preoperative symptoms of SUI. The study concluded that Burch colposuspension at the time of ASC "… cannot be generalized to women undergoing prolapse surgery other than abdominal sacrocolpopexy (i.e., by the vaginal approach) or continence procedures other than Burch colposuspension (e.g., a sling, a procedure that works by a different mechanism, assisting sphincteric closure)".[11] In conjunction with reports indicating that postoperative stress urinary incontinence (POSUI) occurs in 11%-22% of patients after anterior compartment repair, the debate over the role of prophylactic anti-incontinence procedure intensified.[12-14]

Togami et al recently published a review on the controversy of prophylactic midurethral slings, and proposed a management strategy toward patients undergoing surgical repair for high grade prolapse.[14] In their review, the authors echoed the improper extension of the CARE trial findings using MUS in replacement for a Burch procedure. They proposed that in patients without evidence of clinical SUI, placement of a MUS should not be performed unless patients "accept the risk of second-step management." Lastly, they concluded that patients should be actively involved in the decision process if an anti-incontinence procedure is to be performed.

In 2011, the International Consultation on Incontinence-Research Society (ICI-RS) proposed the development of an algorithm on whether to perform an anti-incontinence procedure at the time of prolapse repair. Goldman published the discussion that ensued and the conclusions that were reached in the form of an algorithm. Ultimately there was no consensus by the ICI-RS. All participants agreed that appropriate patient counseling is of utmost importance before performing surgery.[15]

Recently, the PFDN reported on the Outcomes following vaginal prolapse repair and midurethral sling (OPUS) trial.[16] This trial studied women with symptomatic POP without SUI who, at the time of prolapse surgery, were randomized to receive a TVT or a sham incision. At 12 months, those who underwent the TVT had a lesser rate of SUI than those in the sham group. However, of the 40% patients in the sham group who developed secondary SUI, only 10% underwent subsequent SUI surgery. In the TVT arm, there was a significant rate of complications, including bladder perforations, UTI, bleeding complications and incomplete bladder emptying.[17] Regardless of the findings of the OPUS trial, this case series emphasizes the reality that severe complications can occur with a prophylactic MUS in everyday practice.

There is increasing evidence to suggest that a MUS is not a benign procedure and can be fraught with complications, both in the short and long terms. Complications of MUS can be divided into two classes: surgically-related and post-placement (pain, dyspareunia, erosion, extrusion, voiding dysfunction, recurrent UTI). There have been numerous studies reporting on the surgical complications of MUS. Among them, Deng et al compared the number of complications reported in the literature to the Manufacturer and User Facility Device Experience (MAUDE) database. The incidence of reported complications in the literature was < 1% (both major and minor complications). Although an actual complication rate cannot be determined from the MAUDE database, as there is no denominator, the breakdown of major complications/total complications between the MAUDE database and published literature was very different, with four times as many major complications being reported in the MAUDE database.[18] Daneshgari et al reported that the incidence of complications from TVTs ranged from 4.3% to 75.1% while those from TOT were from 10.5% to 31.3%.[19] The types of complications were wide ranging and some very severe. Complications for both the retropubic and obturator approaches included hemorrhage, bladder and urethral perforations, and groin and thigh pain. Bowel perforation was also a reported complication of the TVT, with reports of death as a consequence.

One might argue that the voiding dysfunction complications can be more troublesome than the surgical complications, as MUS may result in non-reversible damage to the bladder wall and or the urethra. The exact incidence of postoperative voiding dysfunction remains unknown. Nevertheless, many studies have shown that de novo urgency and urinary retention are the two most common complications following MUS.[20,21] In our series, two patients developed SUI after prophylactic MUS, which is counterintuitive. Although we cannot definitely say why this occurred, we hypothesize that the sling may have migrated from

its midurethral position to a more proximal position thereby pulling open the sphincteric mechanism and resulting in SUI.[22,23] Similarly, we suspect that our patients with UUI and double voiding had bladder outlet obstruction from the MUS. Pain following MUS can be secondary to the sling being too tight, or muscle and/or nerve damage during trocar passage.[19,24] After MUS excision, incontinence and urgency were still present in some of our patients. In those with persistent SUI after tape excision, a peri-urethral injection or an autologous fascial sling was recommended since none desired a secondary synthetic sling placement.

Patients in our series presented with a myriad of complaints. Although 70% of our patients required multiple procedures, at a mean follow up of 36 months, most had a marked improvement in their QoL scores. Dyspareunia resolved in 4/4 patients after MUS excision. In both patients with de-novo SUI, corrective procedures resolved their incontinence without any further sequelae. Somewhat disappointing, however, was the incomplete resolution of LUTS in three patients, two of whom remain on long term anti-cholinergic treatment.

Based on this select series with long term follow up, and following the recent FDA notification, proceeding with a prophylactic MUS should be undertaken only after a thorough discussion on its benefits and risks with each patient, and with appropriate documentation. There is no anti-incontinence procedure that works perfectly well, has no complications, and is forever durable. The long term data for both procedures is still rather limited. Few reports on TVT have now reached 7 to 11 years while ONLY ONE has extended to 5 years yet for the TOT. Recently, the first TVT versus TOT report at 5 years was published. At 60 months, 72% of patients were cured (72.9% TVT-O and 71.4% TVT). However, only 61% were satisfied long term. Sexual dysfunction was the main cause for patient dissatisfaction, specifically dyspareunia or incontinence during intercourse. There was 17% complication rate, with de novo urgency developing in 5%, dyspareunia in 5% and incontinence during intercourse in 10%.[25] Furthermore, a recent series on TVT at ten years raised concerns on a high incidence of UUI.[26] One of the limitations of this study is that our series, like others, lacks a denominator on how many women receive "prophylactic" MUS for unmasked SUI. The OPUS trial will appropriately address the question without this bias. Furthermore, preoperative UDS searching for the presence of occult SUI was not obtained in the majority of our referred patients. Arguably, if one is recommending placement of a "prophylactic" MUS (ie. MUS placement in the absence of demonstrable SUI), consideration for preoperative UDS or office provocative stress test with prolapse reduction should be entertained to provide a more objective justification. Lastly, although patient recollection and operative notes contributed to our understanding that MUS was done in a "prophylactic" manner, it is acknowledged that patient recall might be influenced by a disappointing outcome.

Conclusion

This report describes a series of patients who developed complications following "prophylactic" synthetic suburethral tape at time of prolapse surgery, with follow up at a median of 35 months after suburethral tape excision in all of them. Additional surgical repair and pharmacological therapy was needed in the majority, ultimately yielding a globally favorable outcome. Adherence to the recently issued FDA notification is critical. □

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