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Adverse Events over Two Years after Retropubic or Transobturator Midurethral Sling Surgery: Findings from the Trial of Midurethral Sling (TOMUS) Study

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Abstract

Objectives—To describe surgical complications in 597 women over a 24 month period following randomization to retropubic or transobturator midurethral slings.

Study Designs—During the Trial of Midurethral Sling (TOMUS) study, the DSMB regularly reviewed summary reports of all adverse events (AE) using the Dindo Surgical Complication Scale. Logistic regression models were created to explore associations between clinico-demographic factors and surgical complications.

Results—A total of 383 AEs were observed among 253 of the 597 women (42%). Seventy-eight AEs (20%) were classified as serious (SAE); occurring in 72 women. Intra-operative bladder perforation (15 events) occurred exclusively in the retropubic group. Neurologic adverse events were more common in the transobturator group than in retropubic (31 events versus 18 events, respectively). Twenty-three (4%) women experienced mesh complications, including delayed presentations, in both groups.

Conclusions—Adverse events vary by procedure, but are common after midurethral sling. Most events resolve without significant sequelae.

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Reprints will not be available.

Keywords

Surgical Complications; Midurethral Slings; Adverse Events

Introduction

Retropubic and transobturator midurethral synthetic slings are now considered gold standard procedures for primary surgical treatment of stress urinary incontinence in women[1]. The less invasive nature of the MUS has significantly reduced many forms of surgical morbidity; however, long-term follow-up had not been available to addressed clinical concerns about delayed complications including mesh-related complications over time. While mesh-associated complications are common to all mesh midurethral slings, AEs specific to the retropubic midurethral sling include bladder perforation, post-operative voiding dysfunction, *de novo* urgency and urge incontinence, and rare complications such as bowel perforation, vascular injury and neurological injuries[1, 2]. Although the transobturator midurethral sling was designed to minimize bladder and bowel perforation, complications such as thigh pain and neurological pain known to occur [3].

The investigators of the Urinary Incontinence Treatment Network (UITN) recently reported one year outcomes of a randomized equivalence design trial (the Trial of Mid-Urethral Sling (TOMUS) study) comparing these two approaches [4, 5]. The 12-month objective success rates for the retropubic and transobturator procedures were relatively high at 80.8% and 77.7%, and met the prespecified criteria for equivalence[5]. In that report, we also briefly summarized adverse events during the first post-op year. These included bladder perforation and voiding dysfunction, which were uncommon and occurred only in the retropubic group; women in this group were also more likely than women in the transobturator group to have postoperative urinary tract infections. In contrast, the frequency of neurologic symptoms was higher in the transobturator-sling group.

This report details the two year adverse event experience of women enrolled in the TOMUS Study. The relationship between clinical and demographic factors measured at baseline with the occurrence was also examined.

MATERIALS AND METHODS

To ensure standardization across the participating sites, uniform definitions of adverse events (AEs) and serious AEs (SAEs) were established prior to trial initiation. Adverse events were collected at each study visit or between visits when known to the research team. Adverse events were classified with a modified version of the Dindo classification system as described previously [6]. A complications work group, comprised of 5 principal investigators, reviewed all adverse event reports for quality control purposes and accuracy. The Complications Work Group members were masked to site, surgeon and randomization assignment, although for some of the complications, narrative descriptions may have revealed treatment assignment. The group met regularly to review each adverse event report. Prior to each meeting, 2 work group members independently reviewed each adverse event report, graded the event using the modified Dindo classification and assigned the body system which was affected. During the group meetings, if there was consensus of the two primary reviewers and no concerns expressed by other members, the adverse event coding was entered into the data system. In case of disagreement, the work group members discussed the case until consensus was reached. For internal consistency, an on-going record of prior consensus decisions was maintained to facilitate recollection of previous decision. Participants were asked to identify specific locations of pain, using anatomical pictures, and

rate the intensity of the pain associated with the study surgery. Patient self-reports were collected daily for the first two weeks after surgery, then at each subsequent study visit. Patients who reported surgical pain at the 2-week follow-up visit were asked to complete a daily pain diary for an additional 2 weeks.

Neurologic symptoms were defined as new paresthesias or alterations in motor function that developed within the first six weeks after surgery. Participants were considered to have a neurological complication related to TOMUS surgery if the patient responded affirmatively to either of the following questions; “do you have any *numbness* in your legs or pelvic area that has developed since surgery?” and “do you have any *weakness* in your legs or pelvic area that has developed since surgery?” Patients who responded affirmatively were asked to specify the location and magnitude of the symptoms. They were also asked about bother with response categories of “not at all, slightly, moderately or greatly bothersome”.

Reporting of urinary tract infections (UTIs) was based on the time from study surgery. Within the first 6 weeks postoperatively, bother from presumed (not culture-proven) and/or culture-proven UTIs was reported. In the interval between 6 weeks and one year post-op, only recurrent UTIs were considered as AEs and were defined as ≥3 episodes of symptoms characteristic UTI symptoms that resulted in antibiotic treatment, regardless of urine culture results.

Mesh-related adverse events included erosion (defined as occurring after primary healing, into an organ or surrounding tissue) or exposure (defined as mesh visualized through a prior incision area with or without an inflammatory reaction. There was no time limit for reporting mesh-related adverse events.

Descriptive statistics were generated for the following clinical and demographic factors: age, BMI, self-reported pelvic surgical history, concomitant surgery, operative time, blood loss, prolapse stage, self-reported history of UTI, smoking, menopausal status/HRT use and diabetes. Bivariate associations between these factors and presence/absence of any AE were explored; odds ratios were calculated from logistic regression models. We compared intra-operative vs. post-operative complications by event type between treatment groups. P-values were calculated using Fisher’s Exact test. Logistic regression models were created to explore associations between clinical-demographic factors and surgical complications.

RESULTS

Baseline clinical and demographic characteristics and primary results of the TOMUS Study have been previously described [5]. Five hundred thirty two of the original 597 randomized participants completed the 24-month assessments or failed treatment at or before that visit [261 (89.7%) retropubic and 271 (92.8%) transobturator]. Over a period of 24 months forty-two percent (253/597) of all study participants experienced at least one adverse event (AE) including 12% (72/597) that experienced at least one SAE. These 253 patients experienced a total of 383 adverse events (AEs); 78 AEs (20%) were classified as serious adverse events (SAEs) (Table 1). Most (77%) of the adverse events had an onset date on or before 6 week post-op visit. Participants were more likely to experience at least one AE (table 2) if they reported a prior UTI (OR=2.37, 1.24–4.52; p=0.01, prior continence surgery (OR=1.99, 1.23–3.22; p=0.01), experienced longer surgical times or increased blood loss. Adverse events had no effect on subjective or objective surgical success.

Of 597 women randomized in the TOMUS trial (298 retropubic, 299 transobturator), one-quarter (25%) had concomitant procedures, most often vaginal surgery to repair pelvic organ prolapse. Table 3 lists adverse events stratified by study surgery and concomitant surgery. Mesh-related complications (exposures and erosions) affected 3–5% of participants

(retropubic 4.7% vs. transobturator 3.0%). During months 12–24, there were 5 new mesh-related adverse events.

The distribution of adverse events differed by sling type. Intra-operative bladder perforation occurred only in the retropubic group. Intra-operative blood loss (more than 100 mL) was the second most common intra-operative complication in both study surgery groups and occurred twice as frequently in the retropubic group.

Over a period of 24 months after surgery, 53 adverse events from neurologic symptoms were reported, including 3 SAEs. In women without concomitant surgery, postoperative neurological symptoms were the most common AE. Neurologic adverse events were more common in the transobturator group, regardless of concomitant surgery (retropubic 16 (5.4%), vs. transobturator 29 (9.7%) p=0.06 from Fisher Exact test). Most neurologic symptoms were mild in nature and had resolved by six weeks postoperatively; however at 24 months 4 remain unresolved. Neurologic symptoms sometimes occurred in groin areas when a retropubic approach was used, and occurred in suprapubic areas when a transobturator approach was used. Of the 53 neurological symptom adverse events, 49 were resolved with a mean resolution time of 105 days.

While concomitant surgery did not increase the overall occurrence of an SAE, it appears to influence the frequency of AEs. For example, in women who underwent concomitant surgery, a postoperative UTI was the most common AE, occurring more frequently in this group compared to women who underwent MUS only (19.2% vs. 12.3%, p<.05).

The most common SAEs were intra-operative vaginal epithelial perforation, (n=19) and intra-operative bladder perforation (n=15). Perforations of the vaginal epithelium and the bladder were defined *a priori* by the Dindo classification system as SAEs (because they required procedures to resolve the problem during the index surgery), but these events were managed during surgery with no short or long-term consequences.

Urinary tract infection was common. When combining all *a priori* defined UTI categories (culture-proven, empiric, recurrent) accounted for 25.8% of AEs (16.7%, retropubic; 9.1%, transobturator) (Table 4).

Conclusions

In the first two years after midurethral sling surgery, 42% of women undergoing TOMUS midurethral sling procedures experienced at least one AE. Most of these complications occurred during surgery or within the first 6 weeks after surgery. Complication patterns differed by surgical approach, with bladder perforation, voiding dysfunction requiring surgical treatment and UTI occurring more commonly in the retropubic group and neurological symptoms occurring more commonly in the transobturator group. Since surgical efficacy is similar for these two procedures, the differences in type and frequency of adverse events may influence the decision on which type of surgery is to be performed. Post-operative mesh complications occurred in both groups with new problems occurring in the second post-operative year in a minority of women. Longer term follow-up of such sequelae will be important to further inform pre-operative counseling.

Recent systemic reviews and meta-analyses of midurethral slings similarly reported higher rates of bladder perforation and voiding dysfunction with retropubic procedures compared to the transobturator procedures. Urinary tract infection and neurologic symptoms are poorly reported in most series [1,2,6,7,8, 9].

Urinary tract infection was the most common adverse event in both surgical groups. Most events occurred within the first 6 weeks after surgery. The higher incidence of UTIs in the retropubic group may be related to the higher rate of voiding dysfunction. Data from both the SISTEr and TOMUS trials demonstrate a high incidence of urinary tract infection following surgery for stress incontinence. While it has been difficult to reach a consensus on an exact definition of a UTI there is no question that a large number of women receive antibiotic therapy for UTI symptoms following surgery for stress incontinence. Given the morbidity of both UTI and the antibiotic therapy to treat them, there should be further efforts to understand the etiology and to develop methods of prevention.

The number of mesh complications was similar to what has been reported elsewhere. Most are vaginal exposures that did not require surgical treatment. Mesh-related complications continued to occur up to two years after surgery, however events were infrequent.

Demographic variables associated with a higher likelihood of adverse events included, history of previous incontinence or pelvic prolapse surgery and a prior history of urinary tract infection. Clinical variables associated with a higher complication rate included retropubic approach, intraoperative blood loss and operative time. Post-operative mesh complications and urinary tract infections occurred in both groups with new events continuing into the second post-operative year in a minority of women. Concomitant surgery did not appear to increase the risk of adverse events for either treatment group.

Previous studies found difference in adverse events in women who had concomitant surgery. However, in the SISTEr trial comparing Burch and pubovaginal sling, concomitant surgery was associated with significantly higher rates of both AEs and SAEs [10]. The SISTEr trial allowed both vaginal and abdominal pelvic prolapse repair whereas concomitant surgery was limited to the vaginal approach in the TOMUS trial. The TOMUS concomitant surgery group demonstrated a number of statistical differences in adverse event patterns; however it is not clear that these differences are clinically significant given the small number of events.

This data is unique in that the TOMUS SAE and AE data were collected prospectively and robustly as part of a large, randomized surgical trial. Quality controls included a predefined list of AEs to monitor. Cross-checks of related variables on study forms were performed at every visit and patients were also queried about office visits outside of their follow-up time points. Furthermore, a complications work group reviewed, categorized and graded all complications in blinded fashion using a validated surgical complication instrument.

Assessment of clinically important adverse events in surgical trials remains a challenge. Adverse event definitions and reporting vary between investigators making it difficult to compare data from one study to the next. Standardization of event classification with a surgical complication scale (such as Dindo) is a good first start; however the instrument was not developed for assessment of the complications profile typical for midurethral slings. Moreover, these scales do not take into account the patient perception of complications which may differ from the physician perspective. We found that while the Dindo scale allowed us to reliably define and capture events across multiple investigators and clinical sites, at times the events were allocated to categories that were not compatible with the patient's clinical course; for example, a perforation of the bladder during retropubic sling requires a simple replacement of the sling needles, but is categorized as an SAE because in the Dindo classification, any additional procedures, however small, are categorized as "severe". Although bladder or vaginal perforations are undesirable events, we did not detect clinically relevant consequences in a two year follow-up.

Two years post-operatively, the retropubic procedures demonstrate higher rates of voiding dysfunction and UTI, while the transobturator procedures were associated with higher rates

of transient neurologic symptoms. Mesh related problems are not common but continue to occur throughout the 2 year period. The frequency and distribution of adverse events after midurethral slings found in this study may be used by surgeons when counseling patients about known risks of midurethral sling procedures with their patients who are candidates for these procedures.

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TABLE 1

Complications by treatment group at 24 months

	No. of events/No. Pts (%-complication rate)		
	Retropubic	**Transobturator**	**P-value***
Total # of pts	298	299	
SAEs			
Bladder Perforation	15/15 (5.0%)	0/0	<0.0001
Urethral Perforation	1/1 (0.3%)	0/0	0.50
Pulmonary Embolus	0/0	1/1 (0.3%)	1.00
Postoperative Bleeding	1/1 (0.3%)	0/0	0.50
Mesh Complication: Erosion	1/1 (0.3%)	1/1 (0.3%)	1.00
Mesh Complication: Exposure	10/9 (3.0%)	6/6 (2.0%)	0.45
Surg Site Inf: Deep Incisional	0/0	1/1 (0.3%)	1.00
Surg Site Inf: Organ/Space	0/0	2/2 (0.7%)	0.50
Recurrent UTI	3/3 (1.0%)	0/0	0.12
Neurologic Symptoms	3/3 (1.0%)	1/1 (0.3%)	0.37
Granulation Tissue	0/0	1/1 (0.3%)	1.00
Vaginal Epithelium Perforation	6/6 (2.0%)	13/13 (4.4%)	0.16
Voiding dysfunction requiring surgery (and/or catheter use)	9/9 (3.0%)	0/0	0.002
Other	0/0	3/3 (1.0%)	0.25
Total SAEs	49/46 (15.4%)	29/26 (8.7%)	0.01
AEs			
Intraoperative Bleeding	14/14 (4.7%)	7/7 (2.3%)	0.13
Postoperative Bleeding	6/6 (2.0%)	0/0	0.02
Mesh Complication: Exposure	4/4 (1.3%)	2/2 (0.7%)	0.45
Surg Site Inf: Superficial Incisional	2/2 (0.7%)	0/0	0.25
UTI Culture proven	27/25 (8.4%)	16/14 (4.7%)	0.07
Empiric	16/15 (5.0%)	9/9 (3.0%)	0.22
Recurrent	18/16 (5.4%)	10/10 (3.4%)	0.24
Neurologic Symptoms	18/13 (4.4%)	31/28 (9.4%)	0.02

	No. of events/No. Pts (%-complication rate)		
	Retropubic	**Transobturator**	**P-value***
Voiding dysfunction	10/10 (3.4%)	6/6 (2.0%)	0.33
Pain per patient self-report ≥6 weeks	7/7 (2.3%)	7/6 (2.0%)	0.79
De novo urge incontinence	0/0	1/1 (0.3%)	1.00
Persistent urge incontinence	42/42 (14.1%)	38/38 (12.8%)	0.63
Other	8/7 (2.3%)	6/6 (2.0%)	0.79
Total AEs	172/120 (40.3%)	133/97 (32.4%)	0.051

* P-values were from Fisher Exact test comparing the rate

Table 2

Bivariate Analysis of Clinico-demographic Factors Associated with S/AE within 24 months

Factors	OR (95% CI)*	p-value*	P-value**
Treatment group		**0.003**	
Retropubic vs. Transobturator	1.63 (1.18--2.26)		
Age (per 10 year interval)	1.01 (0.87, 1.17)	0.88	0.83
BMI (per 5 units)	1.12 (0.99, 1.26)	0.08	0.10
Diabetes		0.87	0.73
Yes vs. No (ref)	1.05 (0.55--2.03)		
Prior UI surgery		**0.005**	**0.004**
Yes vs. No (ref)	1.99 (1.23--3.22)		
Prior POP surgery		0.051	**0.04**
Yes vs. No (ref)	0.37 (0.13--1.01)		
Previous Hysterectomy Surgery		0.07	0.052
Yes vs. No (ref)	0.71 (0.49--1.03)		
Concomitant surgery		0.25	0.23
Yes vs. No (ref)	1.24 (0.86--1.80)		
Operative time (per 30 min interval)	1.23 (1.09, 1.37)	**<0.001**	**<0.001**
Blood loss - Entire case (per 50 cc)	1.24 (1.11, 1.39)	**<0.001**	**<0.001**
- Mid-urethral sling (per 50 cc)	1.82 (1.40, 2.37)	**<0.0001**	**<0.0001**
POP-Q stage		0.87	0.87
Stage 0/1 vs. Stage 3/4	0.87 (0.47--1.61)		
Stage 2 vs. Stage 3/4	0.85 (0.46--1.57)		
History of UTI		**0.009**	**0.005**
Yes vs. No (ref)	2.37 (1.24--4.52)		
Smoking		0.97	0.93
Never Smoker vs. Current smoker (ref)	1.05 (0.64--1.72)		
Former smoker vs. Current smoker (ref)	1.07 (0.63--1.81)		
Menopausal status/HRT		0.56	0.57
No vs. Pre-Menopausal (ref)	1.21 (0.82--1.79)		
Yes vs. Pre-Menopausal (ref)	1.23 (0.80--1.88)		

* Unadjusted

** Adjusted for treatment

Table 3

Complications stratified by continence surgery alone vs. continence surgery with concomitant surgery and by treatment group at 24 month

	No. of events/No. Pts (% - complication rate)					
	Continence Only			Continence + Concomitant		
	Retropubic	Transob.	P-value*	Retropubic	Transob.	P-value*
Total # of pts	225	221		73	78	
SAEs						
Bladder Perforation	10/10 (4.4%)	0/0	0.002	5/5 (6.8%)	0/0	0.02
Urethral Perforation	1/1 (0.4%)	0/0	1.00	0/0	0/0	-
Pulmonary Embolus	0/0	0/0	-	0/0	1/1 (1.3%)	1.00
Postoperative Bleeding	0/0	0/0	-	1/1 (1.4%)	0/0	0.48
Mesh Complication: Erosion	1/1 (0.4%)	1/1 (0.5%)	1.00	0/0	0/0	-
Mesh Complication: Exposure	10/9 (4.0%)	5/5 (2.3%)	0.42	0/0	1/1 (1.3%)	1.00
Surg Site Inf: Deep Incisional	0/0	1/1 (0.5%)	0.50	0/0	0/0	-
Surg Site Inf: Organ/Space	0/0	0/0	-	0/0	2/2 (2.6%)	0.50
Recurrent UTI	2/2 (0.9%)	0/0	0.50	1/1 (1.4%)	0/0	0.48
Neurologic Symptoms	2/2 (0.9%)	1/1 (0.5%)	1.00	1/1 (1.4%)	0/0	0.48
Granulation Tissue	0/0	0/0	-	0/0	1/1 (1.3%)	1.00
Vaginal Epithelium Perforation	6/6 (2.7%)	9/9 (4.1%)	0.44	0/0	4/4 (5.1%)	0.12
Voiding dysfunction requiring surgery (and/or catheter use)	6/6 (2.7%)	0/0	0.03	3/3 (4.1%)	0/0	0.11
Other	0/0	1/1 (0.5%)	0.50	0/0	2/2 (2.6%)	0.50
Total SAEs	38/36 (16.0%)	18/17 (7.7%)	0.008	11/10 (13.7%)	11/9 (11.5%)	0.81
AEs						
Intraoperative Bleeding	10/10 (4.4%)	6/6 (2.7%)	0.45	4/4 (5.5%)	1/1 (1.3%)	0.20
Postoperative Bleeding	4/4 (1.8%)	0/0	0.12	2/2 (2.7%)	0/0	0.23
Mesh Complication: Exposure	3/3 (1.3%)	1/1 (0.5%)	0.62	1/1 (1.4%)	1/1 (1.3%)	1.00
Surg Site Inf: Superficial Incisional	2/2 (0.9%)	0/0	0.50	0/0	0/0	-
UTI Culture proven	15/14 (6.2%)	10/9 (4.1%)	0.39	12/11 (15.1%)	6/5 (6.4%)	0.11
Empiric	11/11 (4.9%)	7/7 (3.2%)	0.47	5/4 (5.5%)	2/2 (2.6%)	0.43
Recurrent	13/12 (5.3%)	7/7 (3.2%)	0.35	5/4 (5.5%)	3/3 (3.8%)	0.71

	No. of events/No. Pts (% - complication rate)					
	Continence Only			Continence + Concomitant		
	Retropubic	Transob.	P-value*	Retropubic	Transob.	P-value*
Neurologic Symptoms	14/11 (4.9%)	20/17 (7.7%)	0.25	4/2 (2.7%)	11/11 (14.1%)	0.02
Voiding dysfunction	4/4 (1.8%)	6/6 (2.7%)	0.54	6/6 (8.2%)	0/0	0.01
Pain per patient self-report ≥6 weeks	5/5 (2.2%)	3/3 (1.4%)	0.72	2/2 (2.7%)	4/3 (3.8%)	1.00
De novo urge incontinence	0/0	1/1 (0.5%)	0.50	0/0	0/0	-
Persistent urge incontinence	34/34 (15.0%)	33/33 (14.9%)	1.00	8/8 (11.0%)	5/5 (6.4%)	0.39
Other	3/2 (0.9%)	2/2 (0.9%)	1.00	5/5 (6.8%)	4/4 (5.1%)	0.74
Total AEs	118/84 (37.3%)	96/70 (31.7%)	0.23	54/36 (49.3%)	37/27 (34.6%)	0.07

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Table 4

UTI events and number of women (percent of total randomized) who reported any UTI by interval treatment group

	No. Events/No. Pts (% transobturatoral)		
Post-operative period [2]	**Retropubic (n=293)**	**Transobturator (n=297)**	**P-value** [1]
Any UTI in first 6 weeks	47/39 (13)	26/23 (8)	**0.03**
Recurrent UTI (>=3) from 6 week to 24 mo.	25/17 (7)	12/10 (4)	0.17
Total [3]	64/52 (21)	35/32 (13)	**0.02**

[1] p-value based on Fisher Exact test testing incidence rate (% women).

[2] Overall # of patients are those who had data on either time interval.

[3] If a patient had UTI during any time interval, the patient was considered having had UTI, if a patient did not have UTI in one time interval but unknown at the other, then the status was set to missing