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Findings of universal cystoscopy at incontinence surgery and their sequelae

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Abstract

OBJECTIVE—The purpose of this study was to report the frequency of abnormal cystoscopy at incontinence surgery and to identify risk factors and sequelae of injury.

STUDY DESIGN—Findings of cystoscopy were collected prospectively in 3 multicenter surgical trials. Clinical, demographic, and procedure characteristics and surgeon experience were analyzed for association with iatrogenic injury and noninjury abnormalities. Impact of abnormalities on continence outcomes and adverse events during 12 months after the procedure were assessed.

RESULTS—Abnormal findings in the bladder or urethra were identified in 95 of 1830 women (5.2%). Most injuries (75.8%) were iatrogenic. Lower urinary tract (LUT) injury was most common at retropubic urethropexy and retropubic midurethral sling procedures (MUS; 6.4% each), followed by autologous pubovaginal sling procedures (1.7%) and transobturator MUS (0.4%). Increasing age (56.9 vs 51.9 years; $P = .04$), vaginal deliveries (3.2 vs 2.6; $P = .04$), and blood loss (393 vs 218 mL; $P = .01$) were associated with LUT injury during retropubic urethropexy; however, only age (62.9 vs 51.4 years; $P = .02$) and smoking history ($P = .04$) were associated for pubovaginal sling procedures. No factors correlated with increased risk of injury at retropubic and transobturator MUS. Notably, previous incontinence surgery, concomitant

procedures, anesthesia type, and trainee participation did not increase LUT injury frequency. Although discharge with an indwelling catheter was more common after trocar perforation compared with the noninjury group (55.6% vs 18.5%; $P < .001$), they did not differ in overall success, voiding dysfunction, recurrent urinary tract infections, or urge urinary incontinence.

CONCLUSION—Universal cystoscopy at incontinence surgery detects abnormalities in 1 in 20 women. Urinary trocar perforations that are addressed intraoperatively have no long-term adverse sequelae.

Keywords

cystoscopy; iatrogenic bladder injury; incontinence surgery

Cystoscopy is often performed at the time of incontinence surgery to identify lower urinary tract (LUT) injury. Confirmatory cystoscopy that assures patient safety is easy to perform, low risk, and very effective in diagnosing these injuries. The reported rates of LUT injury during incontinence procedures range from 0–7%, depending on the procedure.^{1–6} Previously published rates are calculated predominantly from systematic reviews, review of the literature, and retrospective chart review. These calculations may underestimate the risk. One large prospective trial of 1136 women who underwent midurethral sling showed a bladder trocar injury rate of 3%.⁷ In this study, the rates of incidentally identified bladder disease or other LUT injuries were not reported. Incidental findings of bladder cancer or foreign bodies during cystoscopy at the time of midurethral sling have been described elsewhere.^{8,9}

The Stress Incontinence Surgical Treatment Efficacy Trial (SISTER), •••• (TOMUS), and •••• (ValUE) randomized clinical trials of surgical treatment for stress urinary incontinence (SUI)^{10–12} cumulatively provide a database of intraoperative findings and postoperative functional outcomes from >1800 women, all of whom had intraoperative cystoscopy routinely performed at their incontinence and concurrent gynecologic procedures. The goal of this secondary analysis was to report the frequency of LUT injury and other nontrauma-related disease of the urethra and bladder that have been recognized in women who undergo SUI surgery. Additionally, we sought to identify patient, procedure, and surgeon characteristics that are associated with these abnormalities. Last, using the available 12- and 24-month postoperative outcome and adverse event data, we sought to estimate the false-negative rate of intraoperative cystoscopy and the sequelae of urinary trocar injuries during midurethral sling procedures.

Methods

This is a secondary analysis of several surgical trials that have been conducted by the Urinary Incontinence Treatment Network. The methods, demographic details of the study population, and outcomes of these trials have been published separately.^{10–12} In the SISTER, TOMUS, and ValUE trials, all subjects underwent cystoscopy at the time of their index SUI surgery according to standardized protocols. The objective of cystoscopy was to survey the bladder and urethra for injury or foreign body and the ureters for patency. All subjects were women with bothersome and objectively demonstrable SUI. Although SUI was

demonstrated clinically, the women were not required to have urodynamic stress incontinence to be included in the trials. Other exclusion criteria in the 3 protocols included current urinary tract infection, a history of pelvic irradiation, urethral diverticulum, and a history of LUT cancer or neurologic conditions that impact bladder function. Subjects with hematuria (gross or microscopic) were not excluded, although they were required to have clinical evaluation before inclusion in the trials. The components of the hematuria work-up were driven clinically and not specified by protocol.

At the time of incontinence surgery, details about 2 kinds of cystoscopic findings were collected prospectively: LUT injury and bladder/urethral anatomy and disease. More specifically, we collected details about cystotomy (incidental or intentional); bladder perforation with needles, sutures or trocars; intravesical or intraurethral suture or mesh placement, and ureteral obstruction. In the SISTEr and ValUE trials, noninjury abnormalities were described as an open-ended response by the investigator surgeons. In the TOMUS trial, surgeons were asked to specify the location of the bladder trocar perforation as lateral, at the dome, or trigone and whether the perforations required additional management beyond trocar removal and replacement.

We collected information about patient and procedure-related factors, which included trainee involvement and concurrent procedures, that were associated with cystoscopically recognized LUT injury. Each protocol specified what level of trainee could participate in the continence procedure. In SISTEr, a resident, fellow or co-surgeon could participate; in TOMUS and ValUE, trainee participation was restricted to fellows. The study surgery and cystoscopy were performed or directly supervised by surgeon investigators who were urogynecologists or urologists. Management of LUT injury inclusive of the duration of indwelling Foley catheter use was not standardized across studies or clinical sites. Our secondary analysis reports on women and their clinical outcomes over the first year after their index SUI surgery.

Descriptive statistics were reported as the number and percent or the mean and standard deviation. Continuous variables were analyzed with Wilcoxon 2-sample tests. Categorical variables were analyzed by χ^2 test or Fisher exact test. Clinical and demographic factors considered were age, body mass index, parity, number of vaginal deliveries, hormone therapy/menopausal status, smoking status, stage of prolapse, urge index of the Medical, Epidemiological, and Social aspects of Aging questionnaire, any previous urinary incontinence surgeries, number of previous incontinence surgeries, previous Burch procedure, previous sling, previous cesarean delivery, type of anesthesia, estimated blood loss, concomitant surgery, and surgeon experience. All analyses were performed with SAS statistical software (version 9.3; SAS Institute, Cary, NC). Probability values $< .05$ were considered statistically significant. Each participating site of the Urinary Incontinence Treatment Network obtained institutional review board approval for the implementation of the SISTEr, TOMUS and ValUE clinical trials; all enrolled subjects provided written consent.

Results

Cystoscopy was performed in 1830 SISTER, TOMUS, and ValUE participants. Of these, 95 women (5.2%) had abnormal findings in the bladder or urethra. Iatrogenic injury accounted for most of the abnormalities (72; 75.8%), although noninjury findings were noted in the remaining 23 women (Table 1). When women from all 3 trials were grouped by the type of antiincontinence procedure, LUT injury was identified most often at Burch retropubic urethropexy and retropubic midurethral sling procedures (6.4% each) and less often at autologous pubovaginal sling procedures (1.7%) and transobturator midurethral sling procedures (0.4%).

We examined select patient and procedure characteristics as well as surgeon trainee involvement to identify factors that were associated with abnormal cystoscopy. Data for women with LUT injury were compared with data for all other women who underwent the same procedure (ie, abnormal cystoscopy not because of injury and those with normal cystoscopy). Results from univariate analyses are reported in Table 2. Of those women who underwent a Burch retropubic urethropexy, older age women, those who experienced a greater number of vaginal deliveries, and greater intraoperative blood loss were more likely to have LUT injury; increasing body mass index approached significance. Former smokers and older women were at increased risk for LUT injury among those who underwent an autologous pubovaginal sling procedure. We found no demographic or intraoperative factors that correlated with increased risk of LUT injury among women who underwent trocar-based retropubic and transobturator midurethral sling procedures. Previous SUI surgery, concomitant surgery for prolapse or other gynecologic indications, type of anesthesia, and trainee participation were not associated significantly with bladder or urethral injury for any of these 4 procedures. Trocar perforations were recognized in the bladder of 14 TOMUS subjects: 11 perforations were seen laterally, and 4 perforations were at the dome (1 patient sustained 2 trocar perforations). There were no perforations at the trigone. These were all managed exclusively by removal and replacement of the trocar. In both instances of urethral perforation, surgeons removed and replaced the trocar additionally and reported imbricating the urethral defect.

Noninjury bladder abnormalities were identified by cystoscopy in 23 of 1830 women, of which 17 abnormalities were detailed for SISTER and ValUE participants. These included urothelial abnormalities ($n = 8$), inflammation, atypical vessels, bleeding glomerulations ($n = 5$), polyp ($n = 1$), duplicated right ureteral orifice ($n = 2$), and carcinoma in situ ($n = 1$). There were no foreign bodies or invasive cancers identified. When demographic and perioperative factors were compared in women with noninjury abnormalities to all other women (those with normal cystoscopy and those with findings of iatrogenic injury), only a history of cesarean delivery was found to have a significant association. Eight of 23 women (34.8%) with abnormal cystoscopy had a previous cesarean delivery compared with 230 of 1807 women (12.7%) with normal cystoscopy ($P = .01$).

We investigated all postprocedural adverse events from each trial, screening for those that plausibly could be attributable to a missed diagnosis of injury at the time of surgery. The adverse events were reported up to 12 (ValUE) and 24 months (SISTER and TOMUS) after

the operation. In those respective intervals, there were no reported cases of urinary tract fistulas, foreign bodies (suture, mesh, or stone) in the bladder, hydronephrosis, renal failure, or malignancies.

The ValUE and TOMUS protocols did not specify voiding management after trocar perforation. Trocar injuries were identified in 16 TOMUS participants and 29 ValUE participants. Table 3 shows the type and frequency of bladder management strategies at discharge that were used by the UITN study surgeons in both trials. Compared with those women with normal cystoscopy, the women found to have urinary trocar perforations were significantly more likely to be discharged with an indwelling Foley catheter (55.6% vs 18.5%, respectively; $P < .001$). Of the 16 participants with urinary trocar perforations (14 bladder, 2 urethra) in TOMUS, 5 women (32.25%) underwent voiding trials at discharge. All 5 women passed and were discharged voiding spontaneously. When compared with those women without urinary trocar injury, the women with injury were as likely to pass their voiding trials (75.7% vs 100%, respectively; $P = .34$).

Sequelae of urinary trocar perforations were investigated by a comparison of the postoperative functional outcomes with those outcomes of women with normal cystoscopy in the ValUE and TOMUS trials. There were no statistically significant differences between the women with recognized trocar perforations vs normal cystoscopy in overall success, TOMUS (6 women [40.0%] vs 296 women [54.4%]), ValUE (22 women [78.6%] vs 358 women [79.2%]), in voiding dysfunction (4 women [9.3%] vs 53 women [5.2%]), in recurrent urinary tract infections (defined as ≥ 3) during the first 12 months after surgery (0 vs 18 [1.7%]), or in symptoms of persistent or de novo urgency urinary incontinence (15 [34.9%] vs 332 [33.0%], respectively).

Discussion

The general tenets regarding LUT injury at the time of stress incontinence surgery are prevention, recognition, treatment (if needed), and postoperative care tailored to the injury. Optimal surgical technique is the key for prevention of LUT injury; however, variations in patient anatomy or previous surgery can predispose a patient to an iatrogenic injury. Knowledge of patient risk factors for iatrogenic bladder injury can alert the surgeon to this risk. Compared with detected and appropriately managed injuries, unrecognized injuries are associated with increased morbidity. Therefore, intraoperative detection with universal safety cystoscopy at the time of sling procedures is considered to be a standard safety measure.¹³

We found that the rate of iatrogenic bladder injury varied by choice of SUI procedure; the highest rate of 6.4% was for both retropubic midurethral sling procedures and Burch urethropexies. The autologous sling (1.7%) and transobturator midurethral sling (0.4%) had lower rates of cystoscopically detected iatrogenic injury, but none of these procedures were entirely free of injury risk. In addition, we found limited utility in preoperative prediction to triage “routine” vs “selective” cystoscopy. Thus, it seems reasonable to provide the same safety measures to all women who are at risk, that is, who undergo SUI surgery. Stav et al⁷ reported that surgeon inexperience was associated with iatrogenic bladder injury, but we

found that trainee participation did not significantly increase iatrogenic injury for any of the 4 procedures. A much larger sample size that randomly assigned trainee participation would be needed to increase the certainty of this finding.

Our finding that older women were at increased risk for intraoperative injury, especially during fascial sling procedures, deserves further consideration, because it is not intuitive the reason that age alone would increase injury rates. It is certainly possible that age is a biologic proxy for some unmeasured intraoperative or demographic variable, such as tissue integrity or scarring from previous surgery.

An important finding is that iatrogenic bladder injury with a trocar, when immediately identified with intraoperative cystoscopy, was not associated with a difference in surgical outcome. Clinicians and patients can be reassured that a bladder perforation by trocar is not likely to influence continence outcomes or to increase the risk for de novo or worsening urgency symptoms, for voiding dysfunction or postoperative recurrent urinary tract infections despite repeated intraoperative cystoscopy, or for subsequent management with longer catheterization. Further studies would need to confirm the reassuring finding that, when given the opportunity, women with trocar injury are as likely to pass a voiding trial and be discharged voiding spontaneously.

This analysis contains the largest number of randomized trial participants to undergo stress incontinence surgery and routine intraoperative cystoscopy, with classification of adverse events with the use of a validated tool. Despite the size of this sample, the specific numbers of unique noninjury findings do not permit further analysis, thus limiting our ability to comment on predictors or risk factors for such abnormalities. We cannot comment on the sequelae of “missed” abnormalities because we did not intentionally “miss” any abnormalities, which is in keeping with the highest ethical standards of human subject research and patient care.

Based on the important findings of this analysis, we conclude that there is a minimum rate of abnormal cystoscopy regardless of stress incontinence procedure type or iatrogenic LUT injury. We observed that approximately 1 in 100 women will have a noninjury abnormality detected in the bladder at the time of surgical cystoscopy. It seems prudent to survey the bladder at the time of SUI surgery because these lesions may cause urgency and/or urgency incontinence that could be attributed to the surgical intervention. When these noniatrogenic findings are combined with the iatrogenic abnormalities (4%), there is strong rationale for routine cystoscopy as a safety measure.

The American Urological Association panel consensus suggests cystoscopy after sling surgery,¹³ and we suggest that women who have any SUI surgery have cystoscopy at the time of their index surgery. Surgeons will detect an abnormality in approximately 1 in 20 women, which includes noninjury- and injury-related abnormalities. Given the safety and efficiency of intraoperative cystoscopy, it is prudent to provide this safeguard to all patients.

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APPENDIX

SISTER

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TABLE 1

Distribution of patients with abnormal cystoscopic exams by surgery type

Variable	Abnormal cystoscopy because of injury (n = 72)	Abnormal cystoscopy not because of injury (n = 23)	Total subjects undergoing antiincontinence procedure, n
Autologous pubovaginal sling	6	6	347
Burch retropubic urethropexy	21	3	329
Retropubic midurethral sling	43	10	676
Transobturator midurethral sling	2	4	460
Other ^a	0	0	18
Total			1830

^a Includes “mini-sling” midurethral sling (n = 10), allogenic pubovaginal sling (n = 2), other retropubic urethropexy (n = 2), and periurethral bulking injection (n = 4).

TABLE 2

Comparison of patients with and without lower urinary tract injury diagnosed by cystoscopy during incontinence procedures

Characteristic	Autologous pubovaginal sling			Retropubic urethropexy			Retropubic midurethral sling			Transobturator midurethral sling		
	Injured (n = 6)	Uninjured (n = 341)	P value	Injured (n = 21)	Uninjured (n = 308)	P value	Injured (n = 43)	Uninjured (n = 633)	P value	Injured (n = 2)	Uninjured (n = 458)	P value
Age, y ^a	62.9 ± 12.0	51.4 ± 9.9	.02	56.9 ± 10.3	51.9 ± 10.5	.04	52.8 ± 11.6	52.0 ± 10.5	.55	54.0 ± 6.0	52.2 ± 10.8	.66
Body mass index, kg/m ^{2a}	26.5 ± 4.6	30.3 ± 6.1	.13	32.2 ± 7.3	29.6 ± 6.0	.06	28.6 ± 6.5	29.7 ± 6.5	.18	27.7 ± 4.9	29.8 ± 6.2	.65
Parity, n ^a	2.7 ± 1.8	3.3 ± 1.7	.42	3.6 ± 1.4	3.3 ± 1.8	.23	3.0 ± 1.8	2.9 ± 1.6	.86	2.5 ± 0.7	3.1 ± 1.7	.59
Vaginal deliveries, n ^a	2.2 ± 1.3	2.5 ± 1.5	.60	3.1 ± 1.0	2.6 ± 1.6	.04	2.3 ± 1.2	2.1 ± 1.3	.24	2.5 ± 0.7	2.3 ± 1.4	.71
Hormone therapy/ menopausal status, n (%)												
No	4 (66.7)	112 (33.5)	.17	8 (38.1)	109 (35.4)	.26	11 (32.4)	117 (24.1)	.52	1 (50.0)	115 (29.8)	> .99
Yes	2 (33.3)	111 (33.2)		10 (47.6)	107 (34.7)		10 (29.4)	145 (29.8)		0	110 (28.5)	
Premenopausal	0	111 (33.2)		3 (14.3)	92 (29.9)		13 (38.2)	224 (46.1)		1 (50.0)	161 (41.7)	
Smoking status, n (%)												
Never	1 (16.7)	173 (50.7)	.04	15 (71.4)	179 (58.1)	.19	26 (60.5)	367 (58.0)	.54	2 (100)	269 (58.7)	.64
Former	5 (83.3)	112 (32.8)		6 (28.6)	90 (29.2)		14 (32.5)	183 (28.9)		0	140 (30.6)	
Current	0	56 (16.4)		0	39 (12.7)		3 (7.0)	83 (13.1)		0	49 (10.7)	
Stage of prolapse, n (%)												
Stage 0 & 1	1 (20.0)	75 (23.4)	> .99	10 (47.6)	75 (24.3)	.06	7 (46.7)	123 (43.5)	.13	1 (100)	136 (45.6)	.54
Stage 2	3 (60.0)	189 (59.1)		10 (47.6)	185 (60.1)		5 (33.3)	139 (49.1)		0	138 (46.3)	
Stage 3 & 4	1 (20.0)	56 (17.5)		1 (4.8)	48 (15.6)		3 (20.0)	21 (7.4)		0	24 (8.1)	

Characteristic	Autologous pubovaginal sling			Retropubic urethropexy			Retropubic midurethral sling			Transobturator midurethral sling		
	Injured (n = 6)	Uninjured (n = 341)	P value	Injured (n = 21)	Uninjured (n = 308)	P value	Injured (n = 43)	Uninjured (n = 633)	P value	Injured (n = 2)	Uninjured (n = 458)	P value
Medical, Epidemiological, and Social aspects of Aging questionnaire urge index at baseline (••) ^d	33.2 ± 30.7	35.4 ± 21.8	.80	42.8 ± 19.9	36.1 ± 21.8	.11	34.7 ± 25.0	33.0 ± 21.5	.86	27.5 ± 7.8	34.2 ± 22.2	.71
Any urinary incontinence surgery, n (%)	1 (20.0)	42 (13.1)	.51	6 (28.6)	44 (14.3)	.11	3 (20.0)	35 (12.4)	.42	0	41 (13.8)	> .99
Previous urinary incontinence surgery, n (%) ^b												
1	1 (100.0)	35 (83.3)	> .99	6 (100.0)	33 (75.0)	.67	3 (100.0)	28 (80.0)	> .99	0	33 (80.5)	Not available
2	0	6 (14.3)		0	9 (20.4)		0	5 (14.3)		0	8 (19.5)	
3	0	1 (2.4)		0	2 (4.6)		0	1 (2.9)		—	—	
4	—	—		—	—		0	1 (2.9)		—	—	
Previous Burch, n (%)	0	4 (1.2)	> .99	0	1 (0.3)	> .99	2 (13.3)	7 (2.5)	.07	0	7 (2.3)	> .99
Previous sling, n (%)	1 (20.0)	6 (1.9)	.10	0	8 (2.6)	> .99	1 (6.7)	8 (2.8)	.38	0	6 (2.0)	> .99
Previous cesarean delivery, n (%)	0	40 (11.7)	> .99	0	33 (10.7)	.25	7 (16.3)	83 (13.1)	.49	0	69 (15.0)	> .99
Anesthesia, n (%) ^c												
General	3 (60.0)	251 (78.4)	.30	16 (76.2)	261 (84.7)	.35	12 (80.0)	202 (71.4)	.57	1 (100)	212 (71.1)	> .99
Spinal/epidural	2 (40.0)	79 (24.7)	.60	7 (33.3)	55 (17.9)	.09	1 (6.7)	17 (6.0)	> .99	0	19 (6.4)	> .99
Sedation/local	—	—		—	—		3 (4.5)	64 (95.5)	> .99	0	69 (23.2)	> .99
Estimated blood loss, mL ^d	175 ± 185	239 ± 319	.44	393 ± 521	218 ± 317	.01	87 ± 100	76 ± 118	.43	200 ± ^d	67 ± 124	.13

Characteristic	Autologous pubovaginal sling			Retropubic urethropexy			Retropubic midurethral sling			Transobturator midurethral sling		
	Injured (n = 6)	Uninjured (n = 341)	P value	Injured (n = 21)	Uninjured (n = 308)	P value	Injured (n = 43)	Uninjured (n = 633)	P value	Injured (n = 2)	Uninjured (n = 458)	P value
Concomitant surgery, n (%)	2 (33.3)	197 (57.8)	.41	9 (42.9)	175 (56.8)	.26	8 (18.6)	133 (21.0)	.85	0	98 (21.4)	> .99
Surgeon experience fellow assistance, n (%)	3 (50.0)	132 (38.7)	.68	6 (28.6)	110 (35.7)	.64	26 (60.5)	461 (72.8)	.11	0	304 (66.4)	.11

^aData are presented as mean±SD;

^bThe numbers of patients who had any urinary incontinence surgery were used as the denominator;

^cPrimary anesthesia type as reported by the surgeon; only midurethral sling procedures were performed under local sedation;

^dData were available for only 1 of the 1 subjects; therefore, a standard deviation could not be computed.

TABLE 3

Type of voiding management at discharge for women with and without trocar injuries in the TOMUS and ValUE studies

Trocar injury	Type of voiding management at discharge, n (%)			
	Urethral catheter	CISC	Self-voiding	Total
No	199 (18.5)	61 (5.7)	817 (75.9)	1077
Yes	25 (55.6)	3 (6.7)	17 (37.8)	45
Total	224	64	834	1122

Probability value to compare the overall difference: < .001