UROGYNECOLOGY

Findings of universal cystoscopy at incontinence surgery and their sequelae

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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 (MUS) procedures (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.

Key words: cystoscopy, iatrogenic bladder injury, incontinence surgery

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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]

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The Stress Incontinence Surgical Treatment Efficacy Trial (SISTEr), Trial Of Mid-Urethral Slings (TOMUS), and Value of Urodynamic Evaluation (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 populations, 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. Categoric 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