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Effects of Concomitant Surgeries during Mid-Urethral Slings (MUS) on Post-operative Complications, Voiding Dysfunction, Continence Outcomes, and Urodynamic Variables

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Abstract

Objectives—To determine whether concomitant surgeries affected outcomes in a randomized trial comparing retropubic (RMUS) versus transobturator midurethral slings (TOMUS).

Methods—Subjects (n=597) were stratified into 4 groups based on type of concomitant surgeries: Group I had anterior/apical with or without posterior repairs (n=79, 13%), Group II had posterior repairs or perineorrhaphy only (n=38, 6%), Group III had non-prolapse procedures (n=34, 6%) and Group IV had no concomitant surgeries (n=446, 75%). Complication rates, voiding dysfunction, objective and subjective surgical failure rates and changes in urodynamic (UDS) values (post-op minus pre-op) were assessed and compared in these 4 groups.

Results—There were no differences in complications, voiding dysfunction and subjective failure outcomes between these 4 groups. Group I had lower odds ratio (OR) of objective surgical failure compared to Group IV (OR 0.38, 95% CI 0.18–0.81, p=0.05). The OR of failure of all undergoing concomitant surgeries (Groups I–III) was lower than Group IV (OR 0.57, 95% CI 0.35–0.95, p=0.03). The change in Pdet@Qmax (from pressure-flow) was significantly higher in Group III versus IV (p=0.01). The change in Qmax (from uroflowmetry) was significantly less in Group I and II versus Group IV (p=0.046 and 0.04, respectively).

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Conclusions—Concomitant surgeries did not increase complications. Subjects who underwent certain concomitant surgeries had lower failure rates than those undergoing slings only. These data support safety and efficacy of performing concomitant surgery at the time of mid-urethral slings.

Keywords

midurethral slings; stress urinary incontinence; outcomes; concomitant surgery; complications; urodynamics

INTRODUCTION

Pelvic floor disorders, including urinary incontinence, fecal incontinence and pelvic organ prolapse affect between 12% and 42% of adult women, and it is estimated there will be nearly 44 million symptomatic American women by 2050 (1). There is a high co-occurrence of pelvic floor disorders. Approximately 80% of women with stress urinary incontinence (SUI) or overactive bladder (OAB), 69% with pelvic organ prolapse (POP), and 48% with anal incontinence report at least one other pelvic floor disorder (2). As such, reconstructive pelvic surgeons are increasingly performing concomitant surgeries for concurrent pelvic floor disorders. Some recommend that a Burch anti-incontinence surgery be performed concurrently in women with SUI undergoing abdominal sacrocolpopexy (3). However, there is little data evaluating the influence of concomitant pelvic surgery in a group of stress incontinent women at time of mid-urethral sling (MUS).

Several studies reported good outcomes and low complications following vaginal POP surgery and concurrent pubovaginal sling. (4–6). However, less is known about the influence of concomitant POP surgery performed at the time of MUS. Huang et al evaluated the efficacy of pelvic reconstructive surgery with the tension-free vaginal tape in women with urodynamic stress incontinence (7). With a mean follow-up of 25 months, the postoperative complications included persistent urinary urgency in 50%, de novo detrusor overactivity in 8%, dysfunctional voiding in 12%, and mesh erosion in 1.3%.

The Trial of Mid-Urethral Slings (TOMUS) was a randomized multicenter trial comparing continence outcomes from retropubic (RMUS) versus transobturator midurethral (TMUS) polypropylene slings in women with predominant SUI. Twenty-five percent of the cohort required concomitant pelvic surgery, providing a well-characterized cohort with extensive pre and post-operative objective and subjective outcomes and urodynamic data. The objectives of this study were to compare the effects of concomitant non-mesh pelvic surgery performed in conjunction with MUS on multiple post-operative outcomes including MUS failure (incontinence), voiding dysfunction, complications and urodynamic changes.

MATERIALS AND METHODS

This is a secondary analysis of data from TOMUS, in which 597 women with predominant SUI were randomized to either RMUS or TMUS, with or without concomitant vaginal surgery. Details of the trial design, inclusion/exclusion criteria and primary outcomes were previously reported (8, 9). TOMUS was an equivalence trial powered to measure an equivalence margin between RMUS and TMUS of $\pm 12\%$ in outcomes. Women seeking surgery for SUI who were 21 years of age or older, had at least a 3-month history of stress predominant urinary incontinence and had a positive stress test at a bladder volume < 300 ml were eligible for the study. Concomitant POP surgery was allowed only if it was performed vaginally and without the use of synthetic graft material. Additionally, no other graft material was permitted in the anterior compartment. To explore the impact of surgery to the anterior vaginal compartment on bladder symptoms and continence outcomes after MUS,

we stratified subjects into four groups based on the type of concomitant surgeries done at time of MUS: those who underwent anterior/apical with or without posterior repair (Group I); those who underwent only posterior repair or perineorrhaphy (Group II), those who underwent non-POP procedures (Group III), and those who did not have a concomitant procedure with their MUS (group IV). Group III concomitant procedures included: vulvar/perineal dermatological procedures (10), colpocleisis (7), bladder biopsy/retrograde pyelogram (5), hysteroscopy/D&C (3), urethral dilation (2), cervical biopsy (2), breast augmentation (1), hemorrhoidectomy (1), salpingectomy (1), IUD replacement (1), and abdominal hysterectomy (1).

We compared multiple postoperative variables in these 4 groups, including rates of: objective and subjective continence, development of voiding dysfunction, complications and urodynamic changes (12 month post-operative urodynamic (UDS) data values minus pre-operative UDS data values). Objective failure was defined as having any one of these parameters: positive stress test at 300 cc bladder volume, a 24 hour pad test > 15 grams, or the need for any retreatment such as behavioral, pharmacologic, or surgical intervention. Subjective failure was based upon self-reported symptoms of stress-type incontinence, as assessed with the use of the Medical, Epidemiological and Social Aspects of Aging (MESA) questionnaire (10), a 3-day voiding diary, and report of retreatment of SUI.

Complications were divided into adverse events (AEs) and serious adverse events (SAEs), with SAEs categorized according to the Dindo classification system. SAEs included: wound related events (mesh exposure or erosion, infection, granulation tissue); genitourinary events (urethral injury, bladder perforation, vaginal epithelial perforation and recurrent cystitis); vascular or hematologic events (pulmonary embolus or postoperative bleeding); neurologic symptoms, and voiding dysfunction. Voiding dysfunction was defined as a complication if a catheter or medical therapy was needed to facilitate bladder emptying at or beyond 6 weeks, or surgical intervention was needed to facilitate bladder emptying at any time after the TOMUS surgery. Subjects were evaluated at 2 weeks, 6 weeks, and 6, 12 and 24 months postoperatively.

Pre- and post-operative UDS included non-instrumented uroflowmetry (NIF), filling cystometry (CMG), and a pressure flow study (PFS) in accordance with International Continence Society guidelines. The change in urodynamic variables (post-operative minus preoperative UDS values) were determined for peak flow (Q_{max}), maximum detrusor pressure at peak flow (P_{det@Q_{max}}), post void residual volume (PVR) and bladder outlet obstruction index (BOOI = P_{det@Q_{max}} – 2Q_{max}) (4). There were n=499 women who had post-operative UDS measures. There were a total of 32 patients that dropped out of the study (18 in the RMUS arm, 14 in the TMUS arm).

We used logistic regression to examine the association of concomitant surgeries (stratified into Groups I, II and III) with complications, voiding dysfunction, bladder obstruction and failure outcome. Odds ratios (OR) were calculated in the 4 groups controlling for treatment. Pair-wise comparisons were done to compare OR of each outcome in Groups I–III individually versus Group IV. Linear regression analysis was used to compare the delta-changes in UDS variables and to test differences among the 4 groups controlling for treatment. Analyses were performed using SAS version 9.2 (SAS Institute, Inc. Cary, NC). An alpha=0.05 of two-sided significance level was used for all statistical testing.

RESULTS

A total of 597 women were randomized to either RMUS (n=298) or TMUS (n=299) with concomitant procedures being performed in 151 subjects (25%): 79 (13%) in Group I, 38

(6%) in Group II, and 34 (6%) in Group III. The remaining 446 participants (75%) had no concomitant procedures (i.e. MUS only, Group IV). Comparing these four groups, there were no significant differences in demographic/anthropometric characteristics (age, race, marital status, body-mass index, number vaginal deliveries), clinical history (prior surgery for urinary incontinence or POP, menopausal status, current hormone replacement use), or urodynamic characteristics (urodynamic stress incontinence, Valsalva leak-point pressure, maximum urethral closure pressure, detrusor overactivity) at baseline (data not shown). The baseline demographic and clinical parameters of these 597 have been published (9).

As previously reported (9) when no stratification into different concomitant categories was performed, complications (SAEs and AEs) were observed significantly more frequently in the participants undergoing RMUS compared with TMUS (OR 1.62, 95% CI 1.13–2.33, $p=0.009$). Using logistic regression to control for type of treatment, we found no difference in the complication rates between subjects receiving concomitant surgeries (Groups I, II, III combined) compared to MUS alone (Group IV) (OR 1.37 95% CI 0.92–2.05, $p=0.13$). However, for individual group comparisons as shown in Table 1, the complication rates do appear to be marginally different for Group II and Group III compared to Group IV.

As previously reported (9) without stratification of subjects into different concomitant surgery categories, there was increased voiding dysfunction in those who underwent RMUS compared with TMUS (OR 4.23 95% CI 1.40–12.83, $p=0.01$). With stratification into concomitant versus no concomitant surgery, and controlling for treatment type (RMUS or TMUS using logistic regression), no difference was found in rate of voiding dysfunction between subjects undergoing concomitant surgeries (Groups I, II, and III combined) compared to MUS alone (Group IV) (OR 1.68 95% CI 0.65–4.31, $p=0.29$). Too few subjects with voiding dysfunction were in Groups II ($n=1$) and III ($n=0$) to allow for meaningful pair-wise comparisons.

When stratified to concomitant versus no concomitant surgery, and controlling for type of treatment, there was no difference in subjective failure rate between all subjects undergoing concomitant surgeries (Groups I, II, and III combined) compared to MUS alone (Group IV) (OR 0.89 95% CI 0.61–1.30, $p=0.55$) (Table 2a, 4th column). Table 2a also shows non-significant pair-wise comparison p -values for subjective failure rates in each individual group versus Group IV. In contrast, when stratified to concomitant versus no concomitant surgery, and controlling for type of treatment, there was a significantly lower OR of objective failure rate 12 months after surgery in subjects receiving concomitant surgeries (Groups I, II, and III combined) compared with MUS alone (Group IV) (OR 0.57 95% CI 0.35–0.95, $p=0.03$) (Table 2b, 4th column). There did not appear to be any significant differences in the pair-wise comparisons although comparison between Group I and Group IV was marginally significant, $p=0.05$ (Table 2b, 1st column).

Table 3 shows changes in UDS values and corresponding p -values. When analyzing pressure-flow data, change (Δ) in Pdet at Qmax was significantly higher in Group III (11.38 cm water) compared to Group IV (3.03 cm water) with $p=0.01$. When analyzing noninvasive uroflowmetry, Δ Qmax was significantly less in Groups I ($p=0.046$) and II ($p=0.04$) compared with Group IV. Δ PVR was significantly different comparing Group III (where PVR decreased 25.67 cc) to Group IV (where PVR increased 6.01 cc) subjects with $p=0.02$. In fact, in all Groups except Group III, PVR increased postoperatively, whereas in Group III it decreased.

DISCUSSION

Our data suggest that concomitant surgery both for vaginal POP and non-POP indications at the time of MUS do not result in higher rates of post-operative complications and may also result in lower objective failure rates. These findings are important given that a significant proportion of women undergoing treatment for one pelvic floor disorder likely have another pelvic floor disorder (11) and may benefit from concomitant treatments. An analysis of Medicare claims of women who underwent sling procedures from 1999–2001 reported that women who underwent a concomitant POP repair were less likely to undergo re-operation for SUI (4.7% versus 10.2%, $p=.0005$) or POP (OR 0.31, 95% CI 0.22–0.44) in the first year after surgery (12). Our prospectively collected data in a large well-characterized cohort of women undergoing MUS procedures seem to support these data, suggesting women with SUI planning MUS should be evaluated and treated for POP (at least vaginally) at the same setting.

These findings are especially relevant to current practice in light of the updated FDA warning, issued on July 13, 2011 (13), about complications of transvaginal mesh surgeries for POP and SUI. While this warning does not sufficiently distinguish between differences in insertion of mesh intended to repair POP versus SUI, and because of the increased amount of mesh required to repair POP versus SUI, the risks (and severity) of mesh complications would be expected to be higher for mesh used to repair POP compared to SUI. Therefore, it is likely that future use of transvaginal mesh for POP repair will diminish whereas use of transvaginal mesh slings for SUI may not change. Because this trial did not allow for use of transvaginal mesh for POP repairs, those who did receive POP repair (Group I) may more closely represent the population of patients who will undergo non-mesh transvaginal POP repairs concomitant with SUI repair with mesh slings. Thus the findings of this study are highly relevant to the current practice situation.

We categorized concomitant colpocleisis into Group III, rather than in Group I (anterior/apical with or without posterior repair) or Group II (posterior repair or perineorrhaphy), because colpocleisis is an ablative procedure and not a compartment repair, so it did not fit in either Group I nor Group II concomitant procedures. The finding that group III subjects had significantly decreased PVR volume 12-months after surgery (decrease of 26 cc, $p=0.02$) may be due to the 7 colpocleisis subjects in group III. It was shown that colpocleisis significantly decreased the incidence of elevated PVR compared to pre-operative incidence of elevated PVR (14).

A drawback of this study is the relatively low numbers of subjects with POP in this TOMUS cohort. While TOMUS was designed to allow concomitant POP repair, a smaller percentage of subjects underwent concomitant POP surgery in this study compared to our previous SISTER study (15). In SISTER, 51% of subjects underwent POP repair whereas in TOMUS only 20% underwent POP repair. The criterion of not allowing abdominal POP repairs was intentional to limit potential confounding effects of these repairs on self-reported pain outcome which was considered a critical secondary outcome variable in TOMUS. Additionally TOMUS study surgeons were not allowed to place graft (mesh) material in the anterior vaginal compartment and were not allowed to use any other synthetic graft material for transvaginal POP repair. These restrictions may be a reason why a lower percentage of the TOMUS cohort had stage 3 POP compared to SISTER (8% versus 16%, respectively). In another contemporary MUS trial (16), the number of subjects with POP “beyond the hymen” (stage 3) was 21%. Also, in this study, the percentage of subjects undergoing MUS alone was 39% (compared to 75% in TOMUS); however these subjects were allowed to undergo transvaginal mesh repair for POP unlike this trial. Our study was not designed with a primary outcome to answer the question of whether MUS and concomitant surgeries

can be done safely and effectively. However, this secondary analysis did allowed ad hoc comparisons between groups of subjects who underwent MUS alone versus MUS with concomitant surgeries.

Analysis of changes in urodynamic changes after surgery revealed that Pdet at Qmax was higher after concomitant non-prolapse surgery (Table 3). Non-invasive (non-catheterized) uroflowmetry revealed less decrease in Qmax in those undergoing concomitant POP repair; whereas PVR decreased more in subjects undergoing non-prolapse surgeries, perhaps due to the colpocleisis ablative procedure (see explanation above). Overall, the significance of the urodynamic and uroflow changes is questionable as the differences in the values of these variables are probably not clinically significant.

Conclusions

Concomitant surgeries at time of midurethral slings did not increase complication rates. Furthermore, continence outcomes were not adversely affected by concomitant surgeries. On the contrary, subjects receiving concomitant surgeries had a significantly lower risk of objective failure after MUS. These findings are reassuring and support performing concomitant surgeries, if required, at time of midurethral slings.

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Table 1

Complication (adverse and serious adverse events) rates

	Anterior/Apical +/- Posterior Repair (Group I, n=79)	Posterior Repair or Perineorrhaphy Only (Group II, n=38)	Non Prolapse Surgeries (Group III, n=34)	Group I, II, III Combined (n=151)	MUS only (Group IV, n=446)
No complication	51 (65%)	31 (82%)	20 (59%)	102 (68%)	329 (74%)
Any complication	28 (35%)	7 (18%)	14 (41%)	49 (32%)	117 (26%)
OR	1.56	0.63	2.08	1.37	na
95% CI	0.94, 2.60	0.27, 1.46	1.01, 4.29	0.92, 2.05	na
p-value* (vs Group IV)	0.24	0.053	0.056	0.13	na

* pair-wise comparisons after logistic regression controlling for treatment

Table 2

12-month subjective (a) and objective (b) failure rates

(a)	Anterior/Apical +/- Repair (Group I, n=79)	Posterior Repair or Perineorrhaphy Only (Group II, n=38)	Non Prolapse Surgeries (Group III, n=34)	Groups I, II, III Combined (n=151)	MUS only (Group IV, n=446)
Subjective success	50 (63%)	22 (58%)	20 (59%)	92 (61%)	260 (58%)
Subjective failure	29 (37%)	16 (42%)	14 (41%)	59 (39%)	186 (42%)
OR	0.81	1.02	0.95	0.89	na
95% CI	0.49, 1.33	0.52, 2.00	0.47, 1.94	0.61, 1.30	na
p-value [*] (versus Group IV)	0.47	0.76	0.97	0.55	na
(b)					
Objective success	71 (90%)	31 (82%)	27 (79%)	129 (85%)	344 (77%)
Objective failure	8 (10%)	7 (18%)	7 (21%)	22 (15%)	102 (23%)
OR	0.38	0.77	0.86	0.57	na
95% CI	0.18, 0.81	0.33, 1.79	0.36, 2.03	0.35, 0.95	na
p-value [*] (versus Group IV)	0.05	0.82	0.58	0.03	na

* pair-wise comparisons after logistic regression controlling for treatment

Table 3

Changes in urodynamic study parameters from baseline to 12 months after surgery

	Anterior/Apical +/- (Group I, n=79)	Posterior Repair (Group II, n=38)	Non Prolapse Surgeries (Group III, n=34)	MUS only (Group IV, n=446)
Pressure Flow Study				
Δ Pdet at Qmax, cm water (SD)	3.22 (10.2)	5.21 (14.0)	11.38 (23.96)	3.03 (10.98)
p-value (versus Group IV)	0.97	0.5	0.01	na
Δ Qmax, cc/sec (SD)	-0.90 (8.0)	-2.76 (8.45)	-1.71 (6.73)	-2.90 (11.75)
p-value* (versus Group IV)	0.21	0.94	0.65	na
Δ BOO-I (SD)	4.46 (18.38)	11.11 (25.60)	13.52 (28.48)	5.16 (25.48)
p-value* (versus Group IV)	0.87	0.38	0.24	na
Noninvasive Uroflowmetry				
Δ Qmax, cc/sec (SD)	-2.18 (10.92)	-0.82 (16.65)	-0.67 (11.99)	-5.87 (12.78)
p-value* (versus Group IV)	0.046	0.04	0.07	na
Δ PVR, cc (SD)	11.27 (67.75)	7.81 (54.09)	-25.67 (55.01)	6.01 (44.65)
p-value* (versus Group IV)	0.47	0.84	0.02	na

* pair-wise comparisons after logistic regression controlling for treatment