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DOES CONCOMITANT REPAIR AT THE TIME OF MIDURETHRAL SLING AFFECT RECURRENCE RATES OF INCONTINENCE?

Hypothesis / aims of study

Pelvic organ prolapse (POP) and urinary incontinence occur together about 60% of the time [1]. It is imperative that patients presenting for one problem are also evaluated for the other. When surgery is done for both incontinence and prolapse concurrently, it is important to note how this concomitant surgery affects surgical outcomes for sling procedures. Our objective was to compare continence and lower urinary tract symptoms after placement of midurethral slings with and without concurrent repair for prolapse.

Study design, materials and methods

We performed a cohort study of women who underwent midurethral sling (MUS) procedures between April 2002 and October 2005. The exposed group had concurrent repair for prolapse and the unexposed group had MUS only. Medical records were reviewed for patient characteristics, history, physical examination, urodynamic test results and operative reports. Outcomes were assessed from responses to mailed validated questionnaires including the Incontinence Severity Index (ISI) and the Urogenital Distress Inventory-6 (UDI-6), as well as review of the electronic medical record. The Kaplan-Meier method was used to calculate survival free of any, severe, and stress-specific incontinence. These outcomes were defined as any report of urinary leakage on the follow-up survey, an ISI score ≥ 6, or leakage associated with activities, respectively. Patients who required repeat surgery for incontinence were counted as having all three outcomes. Associations between incontinence and concurrent repair were evaluated by fitting Cox proportional hazards models. Patients were considered to have lower urinary tract symptoms (LUTS) at follow-up if they indicated on the UDI-6 that they experience, and if so, are moderately or greatly bothered by frequent urination, urine leakage related to a feeling of urgency, or difficulty emptying the bladder. Associations between the presence of each LUTS and concurrent repair were evaluated by fitting logistic regression models, adjusted for duration of follow-up.

Results

A total of 285 (90%) of the 317 women who had a MUS between April 2002 and October 2005 completed a postoperative survey. Of these 285 women, 122 (43%) had concurrent repair and 163 (57%) had only MUS. Of the women with concurrent repair, 74 (61%) had anterior or apical prolapse stage 3 or greater, and 30 (25%) had a preoperative diagnosis of occult incontinence. During the follow-up period (median 2.7 years), 93 were noted to have any incontinence, 38 had severe incontinence and 42 had stress-specific incontinence. After 3 years, survival free of any, severe, and stress-specific incontinence between the repair group and MUS only group was similar overall and after adjusting for age and body mass index (BMI) (Figures 1-3 and Table 1). Furthermore, there was no increased risk for any of the incontinence outcomes between the subgroups of women with stage 3 or greater anterior or apical prolapse or with preoperative occult incontinence. The odds ratios for frequent urination, urge urinary incontinence, and difficulty emptying the bladder among those with versus without concurrent repair were 1.48 (p=0.13), 1.04 (p=0.90), and 1.83 (p=0.06) respectively (Table 2). When looking specifically at the group with concurrent repair for advanced prolapse, there was a trend towards increased difficulty emptying the bladder among those with concurrent repair and a significant difference for frequent urination (OR 2.00, p=0.02). Similarly, there was an overall trend for increased risk of requiring urethrolysis among those with repair (OR 4.17, p=0.08), which achieved statistical significance in the group with advanced anterior and apical prolapse (OR 6.12, p=0.03).

Figures 1-3: Survival curves for overall outcomes

Figure 1 - Any incontinence

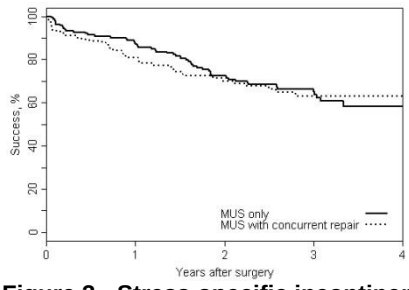

Figure 2 - Severe incontinence

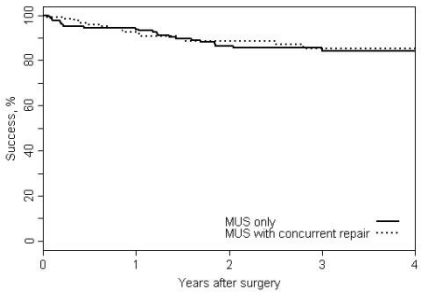

Figure 3 - Stress-specific incontinence

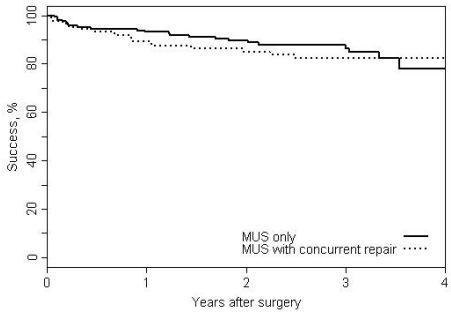

Table 1- Adjusted Hazard Ratios for MUS with repair compared to MUS alone

Type of incontinence	Adjusted HR* (95% CI)
Any	1.05 (0.69 – 1.61)
Severe	0.84 (0.43 – 1.66)
Stress-specific	1.33 (0.71 – 2.51)

*Adjusted for age at surgery and BMI

Table 2 – Lower Urinary Tract Symptoms

UDI-6 Question	MUS only,	MUS with	OR*	P value

	n(%)	concurrent repair, n(%)	(95% CI)	
Frequent urination	47 (29%)	46 (38%)	1.48 (0.89 – 2.44)	0.13
Urine leakage related to feeling of urgency	41 (25%)	31 (25%)	1.04 (0.60 – 1.78)	0.90
Difficulty emptying the bladder	22 (14%)	27 (22%)	1.83 (0.98 – 3.41)	0.06

*Adjusted for duration of follow-up

Interpretation of results

There was no difference between the overall and adjusted survival free of any, severe, and stress-specific incontinence between women having isolated MUS and those who had concomitant repairs. We also found a trend towards higher rates of LUTS and need for urethrolysis when you add prolapse repair to a simple MUS procedure, especially among the group with advanced prolapse.

We provide evidence that concomitant POP repair does not diminish the efficacy of MUS. Although no objective measures were used, our composite outcome of no interval treatment and lack of subjective complaints has been shown to provide similar continence rates to those in which formal cough stress test was done [2]. Furthermore, the 90% response rate to the survey greatly diminishes the possibility of non-respondent bias. Lastly, this type of study is not conducive to a randomized control trial. Nevertheless, it provides information to aid practitioners in counseling patients. Specifically, although the MUS procedure is highly effective in controlling urinary incontinence, many patients with advanced prolapse will continue to have LUTS and are at an increased risk of urethrolysis.

Based on the number of women with and without concurrent repair and the total number of women noted to have any incontinence, this study had 80% power to declare a HR >1.8 as statistically significant, based on a two-sided logrank test with a type I error of 5%.

Concluding message

Recurrent urinary incontinence rates for women undergoing midurethral sling procedures were no different for women who had concomitant prolapse repair. However, there was a trend towards increased symptoms suggestive of lower urinary tract dysfunction and urethrolysis among women who had concomitant prolapse repair.

References

1. Bai SW, MJ Jeon, JY Kim, KA Chung, and KH Park. Relationship between Stress Urinary Incontinence and Pelvic Organ Prolapse. Int Urogynecol J 2002; 13: 256-60
2. Trabuco EC et al. Medium-term comparison of continence rates after rectus fascia or midurethral sling placement. Am J Obstet Gynecol. 2009; 200:300.e1-6

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Is this a clinical trial?	**No**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**Yes**
Specify Name of Ethics Committee	**Mayo Clinic Institutional Review Board**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**