Pelvic organ prolapse in a cohort of women treated for stress urinary incontinence

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OBJECTIVE: The aim of our study was to observe pelvic organ prolapse (POP) over time, treated and untreated, in a group of highly characterized women being followed up subjectively and objectively over 5-7 years following continence surgery.

STUDY DESIGN: We measured baseline prolapse symptoms and anatomic prolapse in subjects enrolled in the trial of midurethral sling (TOMUS) and E-TOMUS, and measured these same parameters annually for 5-7 years after the index surgery. Additional information about subsequent treatment for POP was also recorded.

RESULTS: In all, 597 women were randomized to 1 of 2 midurethral sling procedures in the TOMUS; concomitant vaginal procedures for POP were allowed at the surgeon's discretion. Stage 2 POP was present at baseline in 291 subjects (49%). Symptoms of POP were reported in 67 (25%). Of the asymptomatic women, 34 of 223 (15%) underwent a concomitant POP repair at the time of index sling surgery. Anatomic progression of prolapse in women with asymptomatic, unoperated stage 2 POP over the next 72 months was infrequent and occurred in only 3 of 189 subjects (2%); none underwent surgery for POP. Most symptomatic women (47/67 [70%]) underwent a concomitant repair for POP at the index sling surgery. Three of the 47 women who had undergone concomitant repair for symptomatic stage 2 POP underwent repeat POP surgery (2 at 36 months and 1 at 48 months.)

CONCLUSION: For patient populations similar to the TOMUS and E-TOMUS populations, surgeons may counsel women with asymptomatic stage 2 POP that their prolapse is unlikely to require surgery in the next 5-7 years.

Key words: asymptomatic cystocele, midurethral sling, stress urinary incontinence, urogynecology

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Pelvic organ prolapse (POP) is a common finding in women age >60 years and likely to become even more common with an aging population. It is estimated that >40 million women will have POP or another pelvic floor disorder by 2050.[1] Symptomatic patients may be offered intervention with pessary or surgery to improve prolapse symptoms. However, not all POP will progress and many patients, particularly with lower stages of POP (stage ≤2), may be safely observed over time.[2]

EDITORS' ★ CHOICE

A Medicare claims study concluded that patients undergoing surgery for stress urinary incontinence (SUI) may be at fairly high risk for requiring subsequent prolapse surgery within the first year after their SUI procedure.[3] This alarming finding suggests that patients with moderate POP (stage 2) should be counseled to consider corrective surgery at the time of SUI surgery to avoid a subsequent additional procedure in the near future. These findings may be

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explained by study methodology using claims data, may be due to a failure to address potentially asymptomatic POP at the time of SUI surgery, or may be due to the possibility of accelerated progression of POP following SUI surgery.

The trial of midurethral sling (TOMUS) study and extension trial of the same cohort (E-TOMUS) were carried out to assess efficacy and safety of transobturator and retropubic midurethral slings (MUS).[4] This was a highly characterized group of women with SUI who underwent surgery and agreed to further questioning and exams regarding their outcome and symptom progression for 5-7 years following continence surgery. The current study was a planned secondary analysis that focused on women with stage 2 prolapse at baseline in the TOMUS. The aim of our study was to observe POP, symptoms, anatomic progression, and treatment over time in this group of women.

Materials and Methods

This was a planned secondary analysis of uterine and vaginal support after MUS surgery conducted on data from subjects enrolled in TOMUS. TOMUS was a multicenter, randomized equivalence trial comparing the retropubic MUS with the transobturator MUS in women for the treatment of SUI. Study details and the 12- and 24-month postoperative outcomes have been published.[4,5] Notably, the protocol allowed concomitant procedures for POP, but restricted these procedures to those performed vaginally; additionally, no graft material was permitted in the anterior compartment and the use of synthetic mesh was not permitted at all. Although baseline information was collected as to the bothersomeness and degree of prolapse, the decision as to whether the concomitant procedure for prolapse should be undertaken was an individual decision between the surgeon and the patient.

To gain further insight into the longer-term functional and anatomic outcomes after MUS, the Urinary Incontinence Treatment Network recruited all subjects who had not been surgically retreated for SUI since their TOMUS surgery to an extended follow-up study, E-TOMUS. Consented E-TOMUS participants attended annual in-person study visits for a minimum of 5 years post-surgery to report their continence, any retreatment for urinary incontinence, any treatment for POP, and any complications. Patients completed a panel of condition-specific quality-of-life and satisfaction questionnaires. Symptoms of POP were ascertained on the Urogenital Distress Inventory[6] questions that asked about seeing or feeling a bulging in the vaginal area. Symptomatic prolapse was defined as a response of "somewhat," "moderately," or "quite a bit" on either of these prolapse questions of the Urogenital Distress Inventory.

As part of the annual in-person study visits, participants underwent a pelvic exam for prolapse as well as visual or palpable evidence of mesh exposure. The POP quantification (POP-Q) exam was performed by research staff other than the study surgeon, and anatomic prolapse was categorized by POP-Q ordinal stages. In this system,[7] for example, the maximum descent of the anterior vaginal wall (or point Ba) is measured relative to the fixed point of the hymenal ring; a value of −2 cm indicates that the maximal descent of the anterior vaginal wall is no more than 2 cm above the hymenal ring, while a value of +1 cm indicates the maximal descent of the anterior vaginal wall is no more than 1 cm beyond the hymenal ring. We followed the stage of prolapse over time of each of the following anatomical points: most dependent part of the anterior wall (point Ba), the most dependent part of the posterior wall (point Bp), and the cervix or vaginal cuff (point C). Stage 2 in the POP-Q system is defined as the most dependent part of any pelvic organ at 1 cm above or beyond the hymenal ring; in stage 0-1 the prolapse is above this level, and in stage 3 and 4 the prolapse is beyond this level.

As this was a multiyear extension of a randomized trial initially slated to follow up all participants for 2 years after the index surgery, we allowed some flexibility in follow-up. Women who could not attend clinic in person for the annual assessment were surveyed by mail and telephone for new treatments including surgery, and for any new or ongoing symptoms using the same standardized questionnaires.

Statistical methods

Frequency distributions and percentages were used to describe the pattern of prolapse at successive visits for the women enrolled in TOMUS and E-TOMUS. This analysis focuses on women who had stage 2 prolapse prior to their TOMUS surgery but whose prolapse was not repaired during surgery. Analyses were performed with the use of statistical software (SAS, version 9.2; SAS Institute, Cary, NC). An institutional review board at each of the 9 clinical sites and the coordinating center approved the study protocol. Written informed consent was obtained from all participants.

Results

In all, 597 women were randomized to 1 of 2 MUS procedures in the TOMUS study, and baseline POP stage for the group is shown in Table 1. Stage 2 POP was present at baseline in 291 cases (49%); of these 246 (85%) involved the anterior wall and 174 (60%) were limited to the anterior wall. Table 2 demonstrates the relationship of POP stage and symptoms to POP surgery at the time of MUS surgery. For women with stage 2 POP, 67 (25%) reported symptoms while 223 (75%) were asymptomatic. Most symptomatic women (47/67 [70%]) underwent a concomitant repair for POP at the index sling surgery, and 20 (30%) did not. Concomitant surgeries were distributed across all sites, as would be expected in a randomized trial. As reported elsewhere,

TABLE 1
Frequency of POP stage at baseline

Overall POP stage	n	%
Stage 3 at any location	37	6.2
Stage 2 at any location (no stage 3)	291	48.7
Stage 0-1 at all locations	269	45.1
Total	597	

POP, pelvic organ prolapse.

Norton. Natural history of POP. Am J Obstet Gynecol 2014.