Prolapse Recurrence after Transvaginal Mesh Removal

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Abbreviations and Acronyms AVWS = anterior vaginal wall suspension ICS = International Continence Society IUGA = International Urogynecological Association MS = mesh sacrocolpopexy POP = pelvic organ prolapse TMR = transvaginal mesh removal

Accepted for publication June 11, 2015. * Correspondence: University of Texas Southwestern Medical Center, 5323 Harry Hines Blvd., Dallas, Texas 75390 (telephone: 214-648-9397; FAX: 214-648-3839; e-mail: <u>Philippe.</u> <u>zimmern@utsouthwestern.edu</u>). **Purpose**: We determined the rate of pelvic organ prolapse recurrence after transvaginal mesh removal.

Materials and Methods: Following institutional review board approval a longitudinally collected database of women undergoing transvaginal mesh removal for complications after transvaginal mesh placement with at least 1 year minimum followup was queried for pelvic organ prolapse recurrence. Recurrent prolapse was defined as greater than stage 1 on examination or the need for reoperation at the site of transvaginal mesh removal. Outcome measures were based on POP-Q (Pelvic Organ Prolapse Quantification System) at the last visit. Patients were grouped into 3 groups, including group 1—recurrent prolapse in the same compartment as transvaginal mesh removal, 2—persistent prolapse and 3—prolapse in a compartment different than transvaginal mesh removal.

Results: Of 73 women 52 met study inclusion criteria from 2007 to 2013, including 73% who presented with multiple indications for transvaginal mesh removal. The mean interval between insertion and removal was 45 months (range 10 to 165). Overall mean followup after transvaginal mesh removal was 30 months (range 12 to 84). In group 1 (recurrent prolapse) the rate was 15% (6 of 40 patients). Four women underwent surgery for recurrent prolapse at a mean 7 of months (range 5 to 10). Two patients elected observation. The rate of persistent prolapse (group 2) was 23% (12 of 52 patients). Three women underwent prolapse reoperation at a mean of 10 months (range 8 to 12). In group 3 (de novo/different compartment prolapse) the rate was 6% (3 of 52 patients). One woman underwent surgical repair at 52 months.

Conclusions: At a mean 2.5-year followup 62% of patients (32 of 52) did not have recurrent or persistent prolapse after transvaginal mesh removal and 85% (44 of 52) did not undergo any further procedure for prolapse. Specifically for pelvic organ prolapse in the same compartment as transvaginal mesh removal 12% of patients had recurrence, of whom 8% underwent prolapse repair.

Key Words: urinary bladder, pelvic organ prolapse, surgical mesh, device removal, recurrence

VAGINAL placement of synthetic mesh for POP repair was introduced as early as 2000.¹ A randomized, controlled trial in 2011 comparing native tissue repair to transvaginal mesh kit placement for POP repair showed superior performance for mesh kits in anatomical and functional outcomes.² However, in this report mesh complications were noted, thus, raising concern for this surgical modality in the long term. Since then, concerns for complications related to transvaginal mesh implantation such as mesh erosion, dyspareunia or pelvic pain have mounted. Escalating numbers of mesh complication reports led to 2 FDA (Food and Drug Administration) warnings in 2008 and 2011, respectively, which cautioned the public on the use of transvaginal mesh for POP.^{3,4}

At our tertiary care center we have been involved in TMR for nearly a decade. We have developed expertise in meshology, a fast-growing field in the management of POP mesh and synthetic midurethral sling complications such as extrusion, pelvic pain, dyspareunia and reoperations.⁵ Recently we reported a series of women who underwent sling and vaginal mesh removal for the sole indication of pain only. Using a visual analog scale administered preoperatively and postoperatively we observed a decrease in the pain level from 7.9 to 0.9 in 69 patients, of whom 67% achieved a pain level of zero postoperatively.⁶

During preoperative counseling patients frequently ask about recurrent POP after TMR and there is a dearth of outcome data on this topic. Furthermore, there is no established standard of care for mesh or biological replacement at the time of TMR. Some argue that it is best to remove the mesh that prompted the complication and let the tissues heal primarily at the risk of having to reoperate to correct secondary or persistent POP later. Others prefer to complete mesh removal and then perform native tissue prolapse repair and/or add a new mesh substitute. Bioabsorbable mesh is generally favored as many of these patients with complications fear replacement with another synthetic material.

Our approach has been to remove the synthetic mesh material and as much as possible of its extension arms without any additional mesh interposition or concurrent prolapse procedures. Based on this decision we reviewed our POP recurrence rate after TMR for all indications of POP mesh removal.

METHODS

This is a retrospective analysis of an institutional review board approved, longitudinally collected database of women who underwent TMR for complications. The database was queried for POP recurrence after TMR. All primary mesh placement was performed elsewhere and all TMR surgeries were performed by a single surgeon at a tertiary referral center. Patients undergoing excision of vaginal mesh (not mesh slings or mid urethral synthetic tapes) via the vaginal approach for mesh related complications were included in study. Patients who had less than 1 year followup and underwent vaginal mesh removal of abdominally placed mesh were excluded. Collected data included patient demographics, type of mesh excised, indications for excision, site and type of excision, concomitant procedures, postoperative complications, time to prolapse recurrence and type of POP reoperation. The recent mesh complication and classification system of IUGA/ICS was used. This is a classification of complications directly related to the insertion of synthetic material with a coding system based on C (category), T (time) in relation to primary surgery and S (site) of the complication.⁷ Note that this review focused on POP compartment recurrence only. Other outcomes such as pelvic pain or dyspareunia are beyond the scope of this report.

The surgical technique of transvaginal mesh excision has already been reported.⁶ Briefly, the procedure included removal of the vaginal mesh as well as the lateral extensions of the mesh arms all the way to the obturator foramen or the sacrospinous ligament fixation sites (see figure). A maximal amount of mesh was removed within reasonable margins of safety to avoid injuries to adjacent organs (bladder, ureter and rectum). Following mesh removal vaginal incisions were closed primarily with no additional biological or mesh interposition. After anterior and/or apical mesh removal cystoscopy was performed to ensure no bladder or ureteral injury. For posterior mesh removal rectal packing was placed at the beginning of the procedure to mold the rectum and digital rectal examination was performed to confirm no rectal injury at the end of the procedure. Each mesh segment removed was photographed and sent to pathology for medicolegal documentation (parts d and eof figure).

Patients were discharged home on the day of surgery or the following day on limited pain medication, preferably without codeine, and with stool softeners to minimize postoperative constipation. Vaginal packing and the Foley catheter were routinely left in place postoperatively and removed prior to discharge on the day of surgery or the following morning. The decision for admission was based on procedure duration, time of day of the procedure, patient age and comorbidities.

Outcomes were measured at serial intervals (6 weeks, 6 months, 1 year and yearly thereafter) and included physical examination and evaluation for possible complications and/or POP recurrence. Anatomical outcomes were assessed using POP-Q. Recurrent POP was defined as greater than stage 1 on examination or the need for reoperation at the site of TMR. Apical vaginal prolapse was defined as any descent of the vaginal cuff or cervix below a point 2 cm less than the total vaginal length about the plane of the hymen. Outcome measures were based on POP-Q at the last visit and compared with POP-Q points preoperatively. Secondary outcomes were tallied, including intraoperative complications such as bleeding requiring transfusion, and bladder, ureteral and rectal injuries. Postoperative complications were reported using the Clavien classification of surgical complications and were inclusive of adverse events within 30 days of TMR.

Based on recent IUGA/ICS POP outcome guidelines⁸ 3 distinct POP recurrence groups were identified. Group 1 (POP recurrence) included patients with symptomatic POP recurrence after TMR that was in the same TMR compartment. Group 2 (POP persistence) included patients who presented with persistent POP despite Download English Version:

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