



URINARY INCONTINENCE

Level 1 evidence from the past year on the prophylactic placement of a midurethral sling in vaginal prolapse repair, value of urodynamic testing, and best sling insertion approach for intrinsic sphincter deficiency



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Urinary incontinence affects up to one-half of adult women,¹ with 16% of those women having bothersome symptoms.² The prevalence of urinary incontinence increases with age, and with our aging population (expected to more than double by 2050³), an increased number of women will be presenting for evaluation and treatment.

In 2010, there were approximately 260,000 surgeries performed for stress urinary incontinence (SUI).⁴ In addition, women have up to a 20% lifetime risk of needing surgery to correct pelvic organ prolapse. Surgery to repair prolapse may increase incontinence rates by unmasking urinary leakage in approximately 25% of women.⁵ Clearly, improving the foundation of clinical knowledge surrounding preoperative, operative, and prophylactic management of incontinence is of great value to our patients.

In this article we focus on three key randomized trials published in the last year that provide high quality data to better guide clinical practice:

- A randomized, single-blinded, sham-controlled trial in which investigators studied whether placement of a prophylactic retropubic sling is an effective option to reduce objective measures of post-operative incontinence among patients undergoing a vaginal approach to pelvic reconstructive surgery
- A randomized, noninferiority trial that asked the question, “Does the addition of urodynamic testing provide significant insight or valuable alterations to treatment planning and surgical outcomes in patients with uncomplicated stress-predominant incontinence and a positive cough stress test?” (Note: This trial is also highlighted in a commentary by G. Willy Davila, MD, in Examining the Evidence on page 19 of this issue.)
- A randomized trial in which a retropubic sling was compared with the transobturator (TOT) approach in women with stress incontinence and a diagnosis of intrinsic sphincter deficiency (ISD).

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A prophylactic midurethral sling is an option in vaginal prolapse repair, with increased potential for AEs

Wei JT, Nygaard I, Richter HE, et al. A midurethral sling to reduce incontinence after vaginal prolapse repair. N Engl J Med. 2012;366(25):2358-2367.

Surgical treatment of pelvic organ prolapse can result in de-novo urinary incontinence in women who are continent preoperatively—ie, occult incontinence.

In 2008, CARE (Colpopexy and Urinary Reduction Efforts) trial investigators compared abdominal repairs of prolapse for stage II or greater anterior wall defects with or without the inclusion of a prophylactic bladder-neck suspension.⁶ Postoperative stress incontinence decreased from 44.1% to 23.8% with the inclusion of a retropubic urethropexy. This finding was noted at a planned interim analysis, and the difference was so great that it led to early discontinuation of the trial.

Since then, many surgeons have tried to extrapolate these abdominal data to vaginal repairs of prolapse and retropubic midurethral slings.

Do the data back the practice?

To provide Level 1 evidence to better inform clinical practice, Wei and colleagues investigated whether a prophylactic retropubic midurethral sling placed at the time of vaginal prolapse surgery for stage II or greater anterior wall defects could significantly reduce postoperative rates of incontinence.

Study design. In this multicenter (seven sites), randomized, single-blinded, sham-controlled trial, 337 women were randomly assigned to receive a retropubic midurethral sling or two sham suprapubic incisions with no sling. Primary outcome measures were assessed at 3 and 12 months. At 3 months, bothersome symptoms of incontinence (stress and/or

urge), a cough stress test, and any additional treatment for incontinence were evaluated. At 12 months, urinary incontinence symptoms (stress and/or urge), regardless of interim treatment, were evaluated.

Preoperative evaluation for all participants included: a cough stress test at a bladder volume of 300 mL, a postvoid residual, and quality-of-life questionnaires (Medical Outcomes Study 36-Item-Short-Form Health Survey, Pelvic Floor Distress Inventory, Pelvic Floor Impact Questionnaire, Incontinence Severity Index, Pelvic Organ Prolapse/Urinary Incontinence Sexual Functioning Questionnaire Short Form, visual analog of pain).

Postoperative evaluation included a cough stress test, examination of prolapse, urinalysis, postvoid residual, and the aforementioned quality-of-life questionnaires.

Findings. Three-hundred and six women were available for 3-month follow-up, and 287 for 12-month follow-up. At 3 months, the sling group demonstrated significantly decreased rates of incontinence and treatment for incontinence, compared with the sham group (23.6% vs 49.4%; $P < .001$). At 12 months, incontinence rates were again significantly decreased in the sling group (27.3% vs 43.0% in the sham group; $P = .002$).

While the rates of treatment for incontinence did not differ between the groups at 3 months, by 12 months there was only one additional surgery for incontinence in the sling group and eight additional surgeries in the sham group. The number of women needed to treat to prevent one case of postoperative incontinence was 6.3 at 12 months.

With regard to quality-of-life measures, at 12 months there was greater improvement in the sling group with regard to the Urinary Distress Inventory stress subscale and the Incontinence Severity Index; otherwise there



At 12 months, about 6 prophylactic midurethral slings needed to be placed to prevent 1 case of incontinence resulting from surgery for vaginal prolapse repair

were no significant differences between groups.

Complication rates were higher in the sling group compared with the sham group, including: bladder perforation (6.7% vs 0%), major bleeding (3.1% vs 0%), incomplete emptying (3.7% vs 0%), and urinary tract infection (31.0% vs 18.3%).

At 3 months, women who had a positive preoperative stress test experienced greater benefit with sling placement, compared with those who received a sling after a negative stress test; however, this finding did not maintain significance at 12 months.

WHAT THIS EVIDENCE MEANS FOR PRACTICE

Postoperative stress incontinence after prolapse repair is a frustrating and real entity. This trial demonstrates that retropubic midurethral sling placement in women undergoing vaginal prolapse repair (with at least stage II anterior defects) significantly reduced postoperative incontinence at 12 months. Still, these conclusions cannot be extended beyond 12 months or extrapolated to the use of TOT slings.

This study provides Level 1 evidence that can help surgeons counsel patients on operative risks and postoperative expectations with and without inclusion of a prophylactic retropubic sling. These data do not represent a novel standard of care, nor do they replace the importance of appropriate counseling.

Urodynamic testing can be avoided in some patients with uncomplicated stress-predominant incontinence

Nager CW, Brubaker L, Litman HJ, et al. A randomized trial of urodynamic testing before stress-incontinence surgery. N Engl J Med. 2012;366(21):1987-1997.

Urodynamic testing is commonly used to evaluate urinary incontinence. It is employed to confirm diagnoses and to assess for intrinsic sphincter deficiency, detrusor overactivity, and voiding dysfunction prior to incontinence surgery. A cough stress test is a simple, office-based test used to confirm the diagnosis of stress incontinence. This trial explores the value of urodynamic evaluation in women with uncomplicated stress-predominant incontinence and a positive cough stress test.

Study design. This was a multicenter (11 sites), randomized, noninferiority trial. Preoperatively, 630 women with stress-predominant incontinence (and a positive cough stress test) who desired surgical management were randomly assigned to preoperative office evaluation alone or to the addition of urodynamic testing. Patients then

underwent incontinence surgery as planned (which could have included a retropubic or TOT sling, a mini-sling, a bulking agent, retropubic urethropexy, or a traditional sling).

Outcomes were assessed at 3 and 12 months. Primary outcome measures at 12 months included the Urogenital Distress Inventory (UDI) and Patient Global Impression of Improvement (PGII). Treatment success was defined as 70% improvement from baseline on the UDI, and a response of “much better” or “very much better” on the PGII. The noninferiority margin for office evaluation only was defined as 11 percentage points, based on clinical judgment of what was deemed an acceptable trade-off value. Secondary outcomes included additional quality-of-life questionnaires, complications, and a 12-month postoperative cough stress test.

Findings. Approximately 93% of both groups underwent a retropubic or TOT sling procedure (about 65% and 28%, respectively). Primary outcome measures demonstrated no significant difference in success rates between the evaluation-only and urodynamic

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No significant differences in success rates of incontinence surgery were found between the evaluation-only and urodynamic testing groups

>> See additional commentary on this study in the discussion by G. Willy Davila, MD, on page 19



groups: 77.2% versus 76.9%, respectively (difference of -0.3 percentage points; 95% confidence interval, -7.5 to 6.9). The threshold for noninferiority of the evaluation-only group was met.

Both groups also had similar improvements in quality-of-life measures and satisfaction rates, with no significant differences in adverse outcomes or negative postoperative cough stress test rates: 69.4% in the urodynamic group versus 72.9% in the evaluation-only group.

Although the addition of urodynamic testing led to some changes in surgical planning (12 retropubic slings changed to TOT, and six TOT slings changed to retropubic), these differences were not significant. Urodynamic testing did lead to a lower likeli-

WHAT THIS EVIDENCE MEANS FOR PRACTICE

This clinical trial provides Level 1 evidence that, for a population of women with uncomplicated stress-predominant incontinence, omission of urodynamic testing does not lead to inferior surgical results. Therefore, in this specific patient population, urodynamics may be avoided.

hood of diagnosis of overactive bladder with or without incontinence ($P < .001$, $P = .002$) and suspected ISD ($P = .003$), and a higher likelihood of a voiding dysfunction diagnosis ($P < .001$). This did not alter treatment planning or outcome measures.

Retropubic outperforms TOT midurethral sling in patients with intrinsic sphincter deficiency

Shierlitz L, Dwyer PL, Rosamilia A, et al. Three-year follow-up of tension-free vaginal tape compared with transobturator tape in women with stress urinary incontinence and intrinsic sphincter deficiency. Obstet Gynecol. 2012;119(2 pt 1):321-327.

While the omission of urodynamic testing did not prove inferior in the preoperative evaluation of uncomplicated stress incontinence in the trial by Nager and colleagues (just discussed), a urodynamic diagnosis of ISD may raise additional considerations. ISD is often thought to represent a more severe form of stress incontinence, but its exact definition remains elusive. Midurethral slings remain an effective treatment option for most types of stress incontinence but are generally quoted with lower success rates in women without ISD than in women with ISD.⁷ Still, clear evidence regarding

the choice between a retropubic or TOT approach in such patients has been lacking.

A recent large, randomized, prospective trial demonstrated equivalence between retropubic and TOT slings in all patients who had stress incontinence with and without ISD, but this trial was not powered to assess equivalence specific to patients with ISD.⁸ Shierlitz and colleagues aimed to address this specific issue.

Study design. One hundred sixty-four women with stress incontinence and a diagnosis of ISD (defined as a maximal urethral closure pressure < 20 cm H₂O or leak point pressures < 60 cm H₂O) were randomly assigned to a retropubic ($n = 82$) or TOT ($n = 82$) sling. All except one in the retropubic group received their allocated treatment. Follow-up data were available at 3 years for 72 women from the retropubic group and for 75 from the TOT group.



Shierlitz and colleagues designed their study to adequately address the superiority of retropubic or TOT slings in ISD, which former studies have not been powered to do

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Retropubic approach is best in women with ISD

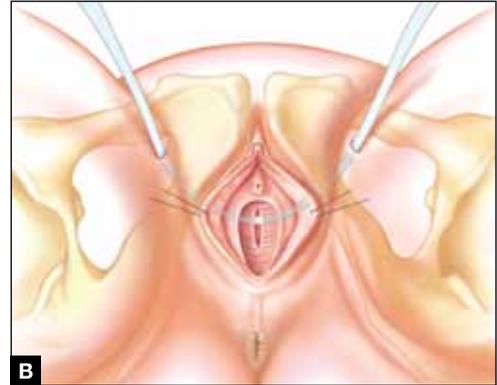


ILLUSTRATION: MAURA FLYNN

Data from the recent randomized trial by Shierlitz and colleagues indicate that, for patients with intrinsic sphincter deficiency and stress urinary incontinence, a retropubic approach to sling insertion (A) reduces the reoperation rate at 3 years to a greater degree, compared with the transobturator approach (B).

The primary outcome was symptomatic stress incontinence requiring reoperation by 3 years. Secondary outcomes included quality-of-life measures.

Findings. At 3 years, one of 72 women (1.4%) in the retropubic group, compared with 15 of 75 women (20%) in the TOT group, required a repeat incontinence procedure ($P<.001$) (FIGURE). If a retropubic approach had been used in all, one in six repeat procedures would have been avoided. Of the 16 women who underwent repeat slings (all were retropubic on reoperation except one), nine were cured, four had minimal leakage, and three were unchanged. With regard to quality-of-life measures, both groups reported high satisfaction rates and, overall, lacked significant differences between them.

WHAT THIS EVIDENCE MEANS FOR PRACTICE

A retropubic approach to midurethral sling insertion for patients with ISD improved postoperative outcomes and significantly reduced reoperation rates at 3 years, compared with the TOT approach. However, this study failed to meet the power calculation of its investigators; it also lacked blinding. Nevertheless, this study provides Level 1 evidence that, for women with urodynamic documentation of ISD, consideration of a retropubic approach may be prudent when planning for incontinence surgery.

FAST TRACK

Although power was not met in this study, 1.4% of retropubic patients versus 20% of TOT patients underwent repeat procedures

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