Are single-incision mini-slings the new gold standard for stress urinary incontinence?

Authors of a UK noninferiority multicenter randomized controlled trial **determined single-incision mini-slings to be noninferior to standard full-length slings in women with stress urinary incontinence** (adjusted risk difference, 4.6 percentage points; 95% CI, -2.7 to 11.8; *P*<.001 for noninferiority). Of 596 women enrolled, 79.1% assigned to the mini-sling arm (212/268) compared with 75.6% in the full-length sling arm (189/250) had patient-reported responses of very much better or much better at 15 months.

Abdel-Fattah M, Cooper D, Davidson T, et al. Single-incision mini-slings for stress urinary incontinence in women. N Engl J Med. 2022;386:1230-1243.

EXPERT COMMENTARY
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A joint society position statement by the American Urogynecologic Society and the Society of Urodynamics, Female Pelvic Medicine and Urogenital Reconstruction published in December 2021 declared synthetic midurethral slings, first cleared for use in the United States in the early 1990s, the most extensively studied anti-incontinence operation and the standard of care for the treatment of female stress urinary incontinence.[1] Full-length retropubic and transobturator (out-in and in-out) slings have been extensively evaluated for safety and efficacy in well-conducted randomized trials.[2] Single-incision mini-slings (SIMS) were first cleared for use in 2006, but they lack the long-term safety and comparative effectiveness data of full-length standard midurethral slings (SMUS).[3] Furthermore, several iterations of the mini-slings have come to market but have been withdrawn or modified to allow for adjustability.

The SIMS trial by Abdel-Fattah and colleagues, published recently in the *New England Journal of Medicine,* is one of the few randomized trials with long-term (3 year) subjective and objective outcome data based on comparison of adjustable single-incision mini-slings versus standard full-length midurethral slings.

Details of the study

The SIMS trial is a noninferiority multicenter randomized controlled trial funded by the National Institute for Health Research at 21 hospitals in the United Kingdom that compared adjustable mini-sling procedures performed under local anesthesia with

FAST TRACK

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full-length retrotropubic and transobturator sling procedures performed under general anesthesia. Patients and surgeons were not masked to study group assignment because of the differences in anesthesia, and patients with greater than stage 2 prolapse were excluded from the trial.

The primary outcome was Patient Global Impression of Improvement (PGI-I) based on a 7-point Likert scale, with success defined as very much improved or much improved at 15 months and failure defined as all other responses (improved, same, worse, much worse, and very much worse). A noninferiority margin was set at 10 percentage points at 15 months.

Secondary outcomes and adverse events at 36 months included postoperative pain, return to normal activities, objective success based on a 24-hour pad test weight of less than 8 g, and tape exposure, organ injury, new or worsening urinary urgency, dyspareunia, and need for prolonged catheterization.

A total of 596 women were enrolled in the study, 298 in the mini-sling arm and 298 in the standard midurethral sling arm. Baseline characteristics were similar in both groups with most sling procedures being performed by general consultant gynecologists (>60%) versus subspecialist urogynecologists.

Results. Success at 15 months, based on the PGI-I responses of very much better or much better, was noted in 79.1% of patients in the mini-sling group (212/268) versus 75.6% in the full-length sling group (189/250). The authors deemed mini-slings noninferior to standard full-length slings (adjusted risk difference, 4.6 percentage points; 95% confidence interval [CI], -2.7 to 11.8; $P<.001$ for noninferiority). Success rates declined but remained similar in both groups at 36 months: 72% in the mini-sling group (177/246) and 66.8% (157/235) in the full-length sling group.

More than 70% of mini-incision slings were Altis (Coloplast) and 22% were Ajust (CR Bard; since withdrawn from the market). The majority of standard midurethral full-length slings were transobturator slings (52.9%) versus retropubic slings (35.6%).

While blood loss, organ injury, and 36-month objective 24-hour pad test did not differ between groups, there were significant differences in other secondary outcomes. Dyspareunia and coital incontinence were more common with mini-slings at 15 and 36 months, reported in 11.7% of the mini-sling group and 4.8% of the full-length group ($P<.01$). Groin or thigh pain did not differ significantly between groups at 36 months (14.1% in mini-sling and 14.9% in full-length sling group, $P = .61$). Mesh exposure was noted in 3.3% of those with mini-slings and 1.9% of those with standard midurethral slings. The need for surgical intervention to treat recurrent stress incontinence or mesh removal for voiding dysfunction, pain, or mesh exposure also did not differ between groups (8.7% of the mini-sling group and 4.6% of the midurethral sling group; $P = .12$).

Study strengths and limitations

The strengths of this pragmatic randomized trial are in the use of clinically important and validated patient-reported subjective and objective outcomes in an adequately powered multisite trial of long duration (36 months). This study is important in demonstrating noninferiority of the mini-sling procedure compared with full-length slings, especially given this trial's timing when there was a pause or suspension of sling mesh use in the United Kingdom beginning in 2018.

Study limitations include the loss to follow-up with diminished response rate of 87.1% at 15 months and 81.4% at 36 months and the inability to adequately assess for the uncommon outcomes, such as mesh-related complications and groin pain.

Further analysis needed

The high rate of dyspareunia (11.7%) with mini-slings deserves further analysis and consideration of whether or not to implant them in patients who are sexually active. Groin or thigh pain did not differ at 36 months but reported pain coincided with the higher percentage of transobturator slings placed over retropubic slings. Prior

randomized trials of transobturator versus retropubic midurethral slings have demonstrated this same phenomenon of increased groin pain with the transobturator approach.[2] Furthermore, this study by Abdel-Fattah and colleagues excluded patients with advanced anterior or apical prolapse, but one trial is currently underway in the United States.[4]

In conclusion, this trial suggests some advantages of single-incision mini-slings—ability to perform the procedure under local anesthesia, less synthetic mesh implantation with theoretically decreased risk of bladder perforation or bowel injury, and potential for easier removal compared with full-length slings. Disadvantages include dyspareunia and mesh exposure, which could be significant trade-offs for patients. ●

WHAT THIS EVIDENCE MEANS FOR PRACTICE

In the IDEAL framework for evaluating new surgical innovations, the recommended process begins with an idea, followed by development by a few surgeons in a few patients, then exploration in a feasibility randomized controlled trial, an assessment in larger trials by many surgeons, and long-term follow-up.[5] The SIMS trial falls under the assessment tab of the IDEAL framework and represents a much-needed study prior to widespread adoption of single-incision mini-slings. The higher dyspareunia rate in women undergoing single-incision mini-slings deserves further evaluation.

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