Low rate secondary surgeries for removal, revision of vaginal mesh slings for stress urinary incontinence

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A follow-up of nearly 60,000 women who received a synthetic vaginal mesh sling for the treatment of stress urinary incontinence finds the risk is low for needing a second surgery for mesh removal or revision (about 1 in 30 women ten years after surgery), according to a study published online by *JAMA Surgery*.

Female stress urinary incontinence (SUI) is a common condition that is often treated with surgery when conservative management options are unsuccessful. An estimated 1 in 7 women will undergo surgery for SUI during their lifetime. Synthetic mesh slings are the most common surgical treatment. However, the U.S. Food and Drug Administration has released warnings related to the safety of vaginal mesh (used for procedures to treat SUI and pelvic organ prolapse). In the United States, more than 50,000 women have joined class action lawsuits for transvaginal mesh complications resulting from SUI and prolapse procedures, according to background information in the article.

Blayne Welk, M.D., M.Sc., of Western University, St. Joseph's Health Care, London, Ontario, and colleagues measured the incidence of mesh removal or revision after SUI procedures and determined whether significant surgeon and patient risk factors exist. The study included all adult women undergoing a procedure for SUI with synthetic mesh in Ontario, Canada, from April 2002 through December 2012 (n = 59,887).

Overall, 1,307 women (2.2 percent) underwent mesh removal or revision a median of 0.94 years after receiving a mesh implant for SUI. Patients of high-volume surgeons (75th percentile of yearly mesh-based procedures) had a significantly lower risk for experiencing the composite outcome (surgical procedures related to removal or revision of mesh slings). Gynecologists were not significantly associated with more complications compared with urologists. Multiple mesh-based SUI procedures increased the risk for complications.

"These findings support the regulatory statements that suggest that patients should be counseled regarding serious complications that can occur with mesh-based procedures for SUI and that surgeons should achieve expertise in their chosen procedure. Multiple mesh-based procedures for SUI are a novel risk factor associated with an almost 5-fold higher rate of mesh removal or revision, and the safety of this practice should be studied further," the authors write.

The researchers note that although the FDA in the past has treated all vaginal mesh implants as equivalent, the intervention rates for mesh-based complications in procedures for SUI appear to be lower than those associated with procedures for pelvic organ prolapse.

"The results of Welk et al suggest that treatment of stress urinary incontinence would be better served by a high-volume surgeon; however, for such a common procedure, this solution may be impractical or impossible," write Christian P. Meyer, M.D., and Quoc-Dien Trinh, M.D., of Brigham and Women's Hospital, Harvard Medical School, Boston.

"Should patients be expected to travel hundreds of miles for surgery by a designated high-volume surgeon? Similarly, if the community urologist or gynecologist is not to perform such procedures, then what are they supposed to do? A more reasonable approach to achieve quality surgical

care for common procedures may come from structured proctoring and/or coaching models and from mandatory outcomes reporting. Although physicians may not openly welcome these initiatives, they ultimately will help to establish surgical audits and improve outcomes. In all likelihood, such programs will be mandatory in the near future and tied to reimbursements. Ultimately, we surgeons should be the drivers for change rather than wait for payers or regulators to impose punitive measures."

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