

It is, therefore, important that every health professional is aware of these distressing conditions and takes the woman's complaints seriously. Although it is a rare phenomenon in common clinical practice, PGAD warrants further research and a careful medical and psychologic work-up.

Conflicts of interest: The author has nothing to disclose.

References

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Re: FDA Public Health Notification: Serious Complications Associated with Transvaginal Placement of Surgical Mesh in Repair of Pelvic Organ Prolapse and Stress Urinary Incontinence
Schultz DG

US Food and Drug Administration Web site. <http://www.fda.gov/cdrh/safety/102008-surgicalmesh.html>. Updated October 21, 2008.

Re: Complications of Mid Urethral Slings: Important Outcomes for Future Clinical Trials
Daneshgari F, Kong W, Swartz M

J Urol 2008;180:1890–7

Expert's summary:

In a recent communication, Dr Daniel Schultz, director of the US Food and Drug Administration's (FDA's) Center for Devices and Radiological Health, issued a warning on higher-than-expected complications reported for use of mesh in transvaginal surgeries, including surgeries for pelvic organ prolapse (POP) and for stress urinary incontinence (SUI). In the FDA warning, Dr Schulz states: "Over the past three years, FDA has received over 1,000 reports from nine surgical mesh manufacturers of complications that were associated with surgical mesh devices used to repair POP and SUI. ... The most frequent complications included erosion through vaginal epithelium, infection, pain, urinary problems, and recurrence of prolapse and/or incontinence. There were also reports of bowel, bladder, and blood vessel perforation during insertion. In some cases, vaginal scarring and mesh erosion led to a significant decrease in patient quality of life due to discomfort and pain, including dyspareunia."

In a review of SUI complications, our group has recently reviewed all of the short- and long-term complications associated with midurethral slings (Daneshgari et al, 2008). This report indicates continuation of short- and long-term complications associated with these minimally invasive anti-incontinence procedures.

Dr Schulz further states in the above-noted FDA report: "Specific characteristics of patients at increased risk for complications have not been determined. Contributing factors may include the overall health of the patient, the mesh material, the size and shape of the mesh, the surgical technique used, concomitant procedures undertaken (e.g. hysterectomy), and possibly estrogen status."

Similarly, review of the literature by our group does not reveal a conclusive picture of who is at risk for increased complications associated with midurethral sling procedures.

Expert's comments:

Daneshgari et al's review of literature published since the introduction of transvaginal tape (TVT) in the mid-1990s indicates that the complications of slings continue to exist at bothersome levels. Intriguingly, in the era of the traditional pubovaginal sling and the first American Urological Association guidelines for surgical management of SUI in women, Leach and colleagues [1] reported that pubovaginal slings carry a higher rate of morbidity among then-popular anti-incontinence procedures, such as needle suspension.

With a focus on the new generation of midurethral slings, our recent review indicates that the new sling procedure carries the following distribution of complications:

- **Acute complications (1–5%):** These complications include perioperative, immediate, and short-term postoperative complications. Perioperative complications include bladder perforation, bleeding, and damage to other vital organs. The most bothersome immediate and short-term complications include urinary retention or severe voiding dysfunction.
- **Short-term complications (up to 1 yr; 5–11%):** These complications include voiding dysfunction, infection, pain, and mesh erosion.
- **Long-term complications (5–20%):** These complications include more subtle and often unrecognized complications such as changes in voiding habits, mild voiding dysfunction, dyspareunia, and increased risk (as high as 30%) of acquiring urinary tract dysfunction up to 5 yr following the sling procedure [2].

There is no question that midurethral slings have made the surgical treatment of SUI an easier task for both the physician and the patient; however, in view of the comparable effectiveness of the two main types of midurethral sling (TVT and TOT), our group recommends that in future clinical trials, studies of complications may have to serve as the primary outcome of surgical trials and not the secondary outcomes. In such trials, the superiority of the surgical technique would be assessed primarily based on its complication rate. Design and implementation of such trials would allow us to know whether, when treating quality-of-life issues such as SUI or POP, we really do improve the quality of life of our patients or simply trade one set of symptoms (SUI, POP) with another set (voiding dysfunction, mesh erosions, and need for further treatments including surgery).

Studies of complications associated with use of mesh in female pelvic surgery present a unique opportunity for introduction of translational research tools into our fields. Use of animal models in a setting with careful experimental design would allow us to address specific clinically relevant research questions; such models are potent tools that have not yet been fully utilized in female pelvic surgery [3].

Appendix

Recommended reading:

Chaikin DC, Groutz A, Blaivas JG. Predicting the need for anti-incontinence surgery in continent

women undergoing repair of severe urogenital prolapse. *J Urol* 2000;163:531–4.

Daneshgari F, Paraiso MF, Kaouk J, Govier FE, Kozlowski PM, Kobashi KC. Robotic and laparoscopic female pelvic floor reconstruction. *BJU Int* 2006; 98(Suppl 1):62–8.

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Conflicts of interest: The author has nothing to disclose.

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