Since introduction of the TVT technique by Ulmsten and colleagues in 1996, mid-urethral tension-free sling procedures have become the most commonly performed anti-incontinence operations in the world, rapidly replacing Burch colposuspension as the first choice for women who have urodynamically confirmed SUI.[1] In 2004, a prospective, randomized trial by Ward and Hilton demonstrated that the TVT was equal and perhaps even superior to the Burch procedure.[2] The same year, Paraiso and associates reported on a two-center prospective randomized trial of laparoscopic Burch colposuspension versus TVT.[3] Although that trial was underpowered, the investigators found a higher rate of objective urodynamic SUI and subjective urinary incontinence 1 year after laparoscopic Burch colposuspension, compared with TVT.[3] The study by Jelovsek and colleagues represents the long-term follow-up of this cohort, 4 to 8 years after the original operation.

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FDA alert: Transvaginal placement of surgical mesh carries serious risks

Infection, pain, urinary problems, and erosion of mesh through vaginal epithelium are some of the most frequent complications associated with transvaginal placement of surgical mesh to treat pelvic organ prolapse and stress urinary incontinence, according to an October 2008 US Food and Drug Administration (FDA) alert.

These complications have been documented in more than 1,000 reports from nine surgical mesh manufacturers over the past 3 years. Besides the complications described above, they include:

- recurrent prolapse or incontinence (or both)
- bowel, bladder, and blood-vessel perforation during insertion
- vaginal scarring.

In many cases, additional surgery was required, as were intravenous therapy, blood transfusion, and drainage of hematoma or abscess.

Who is at risk?

Although the FDA has not determined whether specific patient characteristics increase the risk of complication, it notes that poor health overall and low estrogen levels may contribute. Other potential variables include the specific mesh material (as well as its size and shape), the surgical technique used, and whether concomitant procedures were undertaken.

The FDA advises physicians to…

- obtain specialized training for each mesh-placement technique
- watch for potential adverse events, especially erosion and infection
- watch for complications associated with surgery itself, such as bowel perforation
- tell the patient that surgical-mesh implantation is permanent, and warn her of potential complications, including the possible need for additional surgery
- give each patient a written copy of patient labeling from the surgical mesh manufacturer.

FOR MORE INFORMATION, VISIT

- www.fda.gov/cdrh/safety/102008-surgicalmesh.html (health-care providers)
- www.fda.gov/cdrh/consumer/surgicalmesh-popsui.html (consumers)

Also, return here in January 2009, when OBG MANAGEMENT features a roundtable on using mesh in prolapse repair, moderated by Mickey M. Karram, MD.

FAST TRACK

Infection, pain, urinary problems and other complications associated with transvaginal mesh placement have been documented in more than 1,000 reports over the past 3 years