TOT Complication Rate Similar, Problems Different

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CHAMPIONSGATE, FLA. — Transobturator tape procedures are as likely to result in complications as retropubic tape procedures, but the complications are different, according to Austrian registry data presented at the annual meeting of the Society of Gynecologic Surgeons.

In 2003, transobturator tape became available for correction of stress urinary incontinence in Austria. In 2004, researchers established a registry to track complications and outcomes. They compared performance against retropubic tape data collected in a previous registry.

"Of the intraoperative problems reported to us, increased bleeding was the most common," said Dr. Karl Tamussino, attending obstetrician and gynecologist at the Medical University of Graz (Austria).

Increased bleeding was reported with 3.5% of the 2,436 operations performed at 47 centers.

The surgeons in Austria used a variety of transobturator tape products, including the TVT-Obturator (Gynecare), Monarc (AMS), and Obtape (Mentor-Porges). A meeting attendee asked if there were any significant differences among products. "Bleeding was pretty much the same," Dr. Tamussino replied.

Centers were asked to voluntarily complete a one-page, 15-item questionnaire with each procedure. "The registry is very simple. That is the key to amassing numbers," said Dr. Tamussino, who presented the findings on behalf of the Austrian Urogynecology Working Group. Disclosures for the working group researchers include AMS, Contura, Lilly/Boehringer, and Gynecare.

Other intraoperative complications included 11 bladder perforations, 10 vaginal perforations, and 2 urethral perforations. "Bladder and urethral perforations were more common with systems inserted from the outside," Dr. Tamussino said at the meeting, which was jointly sponsored by the American College of Surgeons.

A total of 51 patients had a tape-related reoperation. Voiding dysfunction was the most common reason; the tape was loosened or cut for 27 patients. An inability to void completely postoperatively "seems to be very similar to what is seen with conventional TVT [tension-free vaginal tape]," Dr. Tamussino said.

Vaginal erosions, abscesses, and pain may be more common with transobturator tape procedures than with retropubic tape procedures.

Vaginal tape erosions in nine patients required reoperations, as did a hematoma in one patient at 14 days postoperatively. In addition, seven patients experienced erosions and/or abscesses. Of these, four occurred with Obtape, which is no longer available in Austria, Dr. Tamussino said. The others occurred with the Monarc, TVT-Obturator, and intravaginal slingplasty systems.

"What we did not expect is these can occur months later," he said.

A meeting attendee asked why erosion and abscesses were reported together. "There were 0.4% erosions alone, and we will separate these out in the [future] randomized trial," Dr. Tamussino said.

Another unexpected postoperative complication was groin pain, with about a 1% incidence, Dr. Tamussino said.

"Unfortunately, we were not expecting the pain issue. We did not have this on the sheet, so we are probably underreporting."

Vaginal erosions, abscesses, and pain may be more common with transobturator than retropubic tape procedures, the authors concluded. "Complications seem more related to the tape materials and not the technique," Dr. Tamussino said.

"These are very important complication data on a very large number of procedures," said study discussant Dr. R. Edward Varner of the department of obstetrics and gynecology at the University of Alabama, Birmingham. "Transobturator tapes seem to be relatively safe, especially in experienced hands."

The registry was voluntary, a potential limitation, Dr. Tamussino said. "We just invited people to participate, we did not motivate them." Dr. Varner agreed that the "reporting of data relies on patients with varying amounts of compulsiveness." ■