Unexpected Complications With TOT Reported

BY KATE JOHNSON
Montreal Bureau

MONTREAL — Although the complication rate remains low with the use of transobturator tape to treat stress urinary incontinence, unexpected complications are beginning to emerge as this treatment becomes more widely used, according to Sarah Hamilton Boyles, M.D., an instructor and fellow in obstetrics and gynecology at Oregon Health and Science University's Center for Women's Health in Portland.

"There are documented cases of complications that the companies had said could not occur, and it's important that we are all aware of these complications," Dr. Hamilton Boyles said in an interview.

In a study she presented at the annual meeting of the International Continence Society, Dr. Hamilton Boyles searched the Manufacturer and User Facility Device Experience (MAUDE) database to identify all complications reported with the use of three transobturator tape (TOT) techniques available in the United States. These included ObTape (manufactured by Mentor, Minneapolis), Monarc (American Medical Systems, Minnetonka, Minn.), and the TVT Obturator System (Gynecare, Somerville, N.J.).

MAUDE, maintained by the Food and Drug Administration, collects voluntary physician reports and mandatory reports from manufacturers, distributors, and user facilities. A review of published literature revealed that documented complications with TOT are low, and include bladder, urethra, and vaginal perforation; vaginal and urethral erosion; thigh pain; infection; urinary retention; and bleeding of 200-300 cc, she said. In addition, many of these problems were associated with a different TOT (UraTape), which is no longer on the market.

However, her search of MAUDE revealed some other unexpected complications. "Unique complications that are only easily discovered when searching a large surgical database such as MAUDE were found in the categories of infection, neuropathy, and bleeding," she reported.

The study revealed 173 reports of complications in 140 patients from January 2004 to January 2005. Among the complications were 25 cases of infection, 4 cases of neuropathy, and 5 cases of bleeding. A total of 18 of the infection cases were associated with erosion, including one vaginal abscess just below the mucosa and 2 ischiorectal fossa abscesses occurring remote from placement at about 2 months post procedure—both of which required surgical drainage.

There were two other abscesses not associated with erosion. Both of these occurred by the adductor muscle and also required surgical drainage. And five other infections were not specified.

Among the neuropathy cases, two involved gait difficulty, one of these with a confirmed obturator injury. In addition, there was a case of peripheral numbness, and one other case which was not specified.

Among the bleeding cases, the procedure was aborted in one case after an estimated blood loss of 600 cc during urethral dissection.

Another case involved an estimated blood loss of 650 cc during the pass of the right trocar. In addition, there was one injury to the iliac vessel that required embolization, another case involving a hemoglobin drop to 4 g/dL during the procedure, and another case of an unspecified hematoma, Dr. Hamilton Boyles said.

She cautioned that a comparison of complications according to technique is impossible since the MAUDE database records only reported complications and did not record what percentage they represent of the total number of procedures performed.

However, among the 25 infection cases and 105 erosion cases reported to the database, 22 and 99, respectively, occurred with the ObTape. In addition, all three of the urethral injuries, three of the four cases of neuropathy, and eight of the nine reports of pain occurred with the TVT Obturator System.

"Even though the overall rate of complications is low, because so many of these procedures are done, it is societally important to know about them," she said.

A recent survey of members of the International Urogynecology Association revealed that although tension-free vaginal tape is the most popular treatment for stress urinary incontinence, 13% of respondents preferred TOT, she said (Eur Urol. 2005;47:648-52). ■