

TVT and TOT Compared in American Studies

BY BETSY BATES
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TUCSON, ARIZ. — Three studies presented at the annual meeting of the Society of Gynecologic Surgeons have begun to unravel the advantages and disadvantages of tension-free vaginal tape (TVT) and transobturator tape (TOT) procedures in patients with stress or mixed urinary incontinence.

The introduction of TVT sling procedures in the mid-1990s rapidly took hold worldwide as a simple, minimally invasive alternative to open or laparoscopic Burch colposuspension. They are now the most widely performed procedures in the United States for stress urinary incontinence.

The more recent entry into this arena of hammocklike procedures using TOT avoided the retropubic space and therefore offered a theoretical safety advantage over TVT procedures. Bladder perforation has been reported in as many as 6%-9% of TVT cases; bowel and vascular injuries are very rare but do occur, explained Dr. Matthew Barber of the Cleveland Clinic.

Few studies have directly compared the two approaches in terms of safety and efficacy, or to identify the best candidates for each procedure. The SGS meeting featured comparisons of the following:

► **Perioperative complications and adverse events.** Dr. Barber and associates reviewed safety in 205 patients who underwent a TOT and 213 who underwent a TVT procedure at the Cleveland Clinic between January 2003 and August 2005. Con-

current surgical procedures were performed in 72% of all subjects, but neither the number nor type of procedures differed between the two groups.

The most significant difference in perioperative complications was bladder injury, which occurred in 5.1% of women undergoing TVT and no patient undergoing TOT.

Voiding dysfunction was present in 8.9% of women following TVT surgery and 2.9% of women following TOT procedures. Anticholinergic medications were required beyond 6 weeks postsurgery in 14% of women in the TVT group and 6.3% of those in the TOT group.

Dr. Barber disclosed that he has received grant/research support from American Medical Systems and Eli Lilly, and two of his coinvestigators have served as consultants or received support from Gynecare, American Medical Systems, or Organogenesis, makers of products used in stress incontinence surgery.

► **Efficacy in patients with borderline maximal urethral closure pressure.** Dr. Jay-James Miller and associates at Northwestern University in Evanston, Ill., and Michigan State University in Flint noted that most TOT failures occur in patients with low maximal urethral closure pressures.

They therefore undertook a study of 14-week outcomes in 145 patients (85 who un-

derwent TOT and 60 who underwent TVT), analyzing results based on a cutoff point of maximal urethral closure pressure of 42 cm H₂O or less. With that threshold, the TOT procedure was six times more likely to fail in patients with a borderline maximal urethral closure pressure at baseline. Specifically, failure occurred in 7 of 37 patients meeting that definition who had TOT vs. 1 of 36 patients who had a TVT procedure.

Longer-term follow-up and a prospective, randomized controlled trial would be helpful.

DR. MILLER

Among all patients evaluated at 14 weeks, almost three times as many objective failures were seen with TOT: 8 of 77 vs. 2 of 58 with TVT.

Longer-term follow-up and a prospective randomized controlled trial would be helpful in determining whether this preliminary observation proves true, said Dr. Miller, a fellow at the Evanston Continence Center of Evanston Northwestern Healthcare. If so, routine preoperative evaluation of urethral function may be helpful during preoperative planning so that patients receive the most appropriate surgical procedure, said Dr. Miller.

Dr. Peter K. Sand, director of urogynecology at Evanston Northwestern Healthcare and an investigator on the study has been an advisor, investigator, and lecturer for American Medical Systems (AMS), which makes MONARC transobturator tape. AMS did not fund the study.

► **Detrusor overactivity and urge incontinence following surgery.** Dr. Sylvia M. Botros, also a fellow at Northwestern's Evanston Continence Center, presented a poster detailing postsurgical resolution rates of detrusor overactivity and subjective urge urinary incontinence (UUI) in 276 subjects with urodynamic stress or mixed urinary incontinence.

Patients underwent one of three procedures: TVT (n=99), SPARC (suprapubic arch sling, n=52), or TOT (N=125). Preoperatively, subjective UUI was reported by 66%, 61%, and 64%, and detrusor overactivity was present in 59%, 62%, and 66% of patients undergoing TVT, SPARC, or TOT.

"At 1 year, with follow-up ranging from 54% to 90% in the three groups, 85% Monarc [TOT] vs. 55% TVT vs. 60% SPARC subjectively had no UUI," she said.

Patients in the TOT group had a very low rate of de novo UUI and were three times as likely to have resolution of presurgical UUI as those who underwent retropubic midurethral sling procedures.

"When adjusted for possible confounding factors, the Monarc significantly increased the chance of resolution of UUI over TVT (odds ratio 3.12) or SPARC (odds ratio 3.03) postoperatively."

No differences were seen in detrusor overactivity resolution based on which procedure was performed.

Several of Dr. Botros's co-investigators disclosed consultant or investigator relationships with Boston Scientific or American Medical Systems, makers of TOT products. ■



European/Canadian Results Favor TOT for Ease and Safety

BY JANE SALODOF
MACNEIL
Southwest Bureau

PARIS — A randomized, multicenter trial and two retrospective studies presented at the annual congress of the European Association of Urology found outcomes were similar whether patients had the transvaginal or transobturator sling procedure for urinary stress incontinence.

The investigators agreed that their results favored the newer transobturator tape (TOT) procedure, as it is simpler than constructing midurethral synthetic slings with transvaginal tape (TVT). "Both are the same in my experience. The TOT is easier, and it is inherently safe," Dr. Graeme H. Urwin of the United Kingdom said in a conclusion echoed by investigators from France and Canada.

"My sense is transobturator is a little easier to carry out, so it gave me a little confidence to recommend this," said Dr. Sender Herschorn, professor of urology at the University of Toronto.

Less clear was whether some patients might present with con-

ditions that would be better treated by TVT or TOT. Dr. Herschorn said he did "not know of any specific indications for one over the other."

The French group is continuing to investigate this question. "There might be some specific indications for the retropubic route, but we don't have enough data to support this yet. We are going to do more work," Dr. Emmanuel David-Montefiore of Hôpital Tenon, Paris, said in an interview.

Dr. David-Montefiore reported 3-month data from a multicenter trial in which 88 women with similar demographics and clinical histories were randomized: 42 to a retropubic route (TVT) and 46 to TOT. He said the same tape was used in both groups.

At 3 months, 89.3% of the retropubic cohort and 88.6% of the transobturator group were dry. Satisfaction rates were 90% and 92%. He also reported de novo pollakiuria in 10.7% of the retropubic patients vs. 5.7% of transobturator patients. De novo urgency occurred in 17.9% and 17.1%.

Average hospital stays and overall morbidity were similar

between the two groups. Bladder injuries occurred only in retropubic patients, however: 9.5% vs. 0% of the transobturator patients. The retropubic cohort reportedly had more pain and longer operating times.

Dr. Herschorn reviewed outcomes of 40 women who underwent TVT and 35 in whom TOT was used. A majority of both groups had mixed incontinence, and half had prior surgeries for urinary stress incontinence.

The only statistically significant difference in outcomes was that 8 (20%) of the TVT group vs. 3 (9%) of the TOT cohort had urinary retention after the procedure. Dr. Herschorn reported that all voided within a month.

He also reported three perforations (two bladder and one urethral) with the TVT procedure. Although there were slightly more complications with TVT, he said the difference was not statistically significant.

Most patients who responded to a subjective questionnaire described their condition as cured or improved, regardless of the procedure used.

Dr. Urwin reviewed available

case notes for 73 of 83 TVT patients and 126 of 131 TOT patients at York (England) District General Hospital. He reported that most had preoperative urodynamics and about two-thirds had pure urinary stress incontinence.

Operating times were similar,

while use of regional anesthesia was significantly more common with TVT and general anesthesia was more common with TOT. A learning curve was observed, but it did not significantly affect the complication rate, which was described as low and similar between both groups. ■

Monarc Sling Keeps Providing Symptom Relief for 24 Months

Two years after being implanted with the Monarc transobturator sling, most evaluable patients in an international study had symptom relief and were satisfied with the results, according to a poster presentation at the meeting.

Dr. Dirk Deridder reported that the proportion of patients who had a negative cough test dropped from 94.5% before surgery to 12.4% of 105 patients available for testing at 24 months. Pad use also declined from 3.4 to 0.6 per day, and the av-

erage weight gain per pad fell from 68.7 g/hour to 9.4 g/hour.

"One pad a day is more a security pad than anything else," said Dr. Deridder of the University Hospital KU Leuven (Belgium). The single-arm study enrolled 148 patients at 15 sites in Europe, Canada, and Australia between January 2003 and February 2004.

Dr. Deridder disclosed that the sling's maker, American Medical Systems (AMS) of Minnetonka, Minn., sponsored the study and that he is an AMS advisory board member.