

## A MULTI-CENTER RANDOMIZED TRIAL COMPARING THE TRANSOBTURATOR TAPE WITH TENSION-FREE VAGINAL TAPE FOR THE SURGICAL TREATMENT OF STRESS URINARY INCONTINENCE

### Hypothesis / aims of study

The aim of this study was to compare the safety and efficacy of the Monarc® transobturator tape (TOT) to tension free vaginal tape (TVT®) in the treatment of stress urinary incontinence in patients with and without concurrent pelvic organ prolapse.

### Study design, materials and methods

This study complies with the recommendations of the CONSORT group. Women with urodynamic stress incontinence with and without concurrent pelvic organ prolapse were invited to participate in this clinical trial from three academic medical centers. Subjects with detrusor overactivity or previous sling surgery were excluded. Subjects were randomized to receive TVT or TOT on the day of surgery. Randomization was stratified by clinical site and the presence or absence of pelvic organ prolapse beyond the hymen. Subjects completed a standardized evaluation including a standing cough stress test (300ml), 3-day bladder diary, the Incontinence Severity Index (ISI) and validated health-related quality of life (HRQOL) questionnaires including the Pelvic Floor Distress Inventory-20 (PFDI-20), Pelvic Floor Impact Questionnaire-7 (PFIQ-7) and SF-36 as well as a sexual function questionnaires (PISQ-12) at baseline, 1-year and 2-years after surgery. The ISI, PFDI-20 and PFIQ-7 were also completed 6 and 18 months after surgery. The primary outcome was the presence or absence of "abnormal bladder function," a composite outcome defined as the presence of *any* the following: incontinence symptoms-any type (ISI>0), a positive cough stress test, re-treatment for stress urinary incontinence (SUI) or postoperative urinary retention assessed 1-year after surgery. This study is a non-inferiority study design. A sample size of 162 women provides an 80% power to test the hypothesis that TOT is not inferior to TVT by more than 15% using a two-group large-sample normal approximation test of proportions with a one-sided 0.05 significance level. Anticipating a 10% loss to follow-up and/or drop out rate over the period of the study, the total enrolment goal was 180 subjects.

### Results

Of 180 subjects who enrolled in the study, 170 underwent surgery and 166 (92%) returned for follow-up, with a mean follow-up of 15.5 ± 5 months. TVT or TOT alone was performed in 65 subjects (39%) while the remainder received additional surgical procedures. Mean operating time, blood loss, length of stay and postoperative pain scores were similar between the two groups. Bladder perforations occurred more frequently in the TVT group (7% vs. 0%, p=.02), otherwise the incidence of peri-operative complications was similar between the two groups. TOT was not inferior to TVT for the primary outcome or any of the secondary efficacy outcome measures. The primary outcome, abnormal bladder function, occurred in 46% of TVT subjects and 42% of TOT subjects [mean difference: 4% favoring TOT, 95% CI (-11% to +18%), p=.64]. One year after surgery, a negative cough stress test was demonstrated in 91% and 90% of subjects in the TVT and TOT groups respectively (p=.88). SUI symptoms were reported postoperatively in 15% of both groups, p = .92. Using the ISI classification, 58% of subjects were classified as "dry" (ISI=0) in each group, while 14% had "slight" incontinence and 28% had "moderate" or "severe" incontinence, p=.90. Urinary retention (catheterization ≥ 6 weeks after surgery or need for sling release or urethrolisis) occurred in 6% of the TVT group and 3% of the TOT group, p=.31. Re-treatment for SUI (surgery or bulking agent injection) occurred in 5% and 3% respectively, p=.49. HRQOL and sexual function improved in both groups with no differences between the groups.

### Interpretation of results

Although several studies have previously compared TVT to TOT, none have had adequate sample size or length of follow-up to evaluate the equivalency or non-inferiority of these two techniques. This multi-center trial demonstrates that TOT is not inferior to TVT by more than 15% with a mean follow-up of over 1 year. The primary outcome measure used in this study "abnormal bladder function" was chosen a priori in order to provide a measure that captures both efficacy and common lower urinary tract adverse events (e.g. prolonged urinary retention, de novo urge incontinence) consistent with the goals of the U.S. National Institute of Health consensus guidelines.[1] TOT demonstrated non-inferiority for this primary outcome measure as well as more standard measures including a standardized cough stress test, bladder diary measures and several validated symptom severity and HRQOL questionnaires. Peri-operative complications were infrequent and similar between the two groups with the exception of bladder perforations which occurred more frequently in those who received a TVT.

### Concluding message

The Monarc® TOT is not inferior to TVT for the treatment of urodynamic stress urinary incontinence and results in less bladder perforations.

### References

1. Int Urogyn J (2001) 12:178:186.

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**CLINICAL TRIAL REGISTRATION:** This clinical trial has not yet been registered in a public clinical trials registry.

**HUMAN SUBJECTS:** This study was approved by the Institutional Review Boards of the Cleveland Clinic, Good Samaritan Hospital, Cincinnati OH, and Greater Baltimore Medical Center, Baltimore MD and followed the Declaration of Helsinki. Informed consent was obtained from the patients.

