No. 132, August 2003

TENSION-FREE VAGINAL TAPE (TVT) PROCEDURE

This Technical Update has been reviewed by the Sub-Committee on Urogynaecology and approved by Executive and Council of the Society of Obstetricians and Gynaecologists of Canada (SOGC) in March 2003.

PRINCIPAL AUTHOR
Scott A. Farrell, MD, FRCSC, Halifax NS

SUB-COMMITTEE ON UROGYNAECOLOGY
Scott A. Farrell (Chair), MD, FRCSC, Halifax NS
Lo-Ann Beckerson, RN, Toronto ON
Annette Epp, MD, FRCSC, Saskatoon SK
Catherine G. Flood, MD, FRCSC, Edmonton AB
François Lajoie, MD, FRCSC, Sherbrooke QC
J. Barry MacMillan, MD, FRCSC, London ON
Thomas Charles Mainprize, MD, FRCSC, Calgary AB
Magali Robert, MD, FRCSC, Calgary AB

Abstract

Objective: To provide an introduction to the tension-free vaginal tape (TVT) procedure, placing it in the context of minimally invasive surgeries for the treatment of urinary stress incontinence in women, and to provide guidance to surgeons counselling women on the merits of this surgical choice.

Options: This discussion is limited to surgical treatment of urinary stress incontinence in women.

Evidence: A search of both MEDLINE and the Cochrane Library identified the most relevant medical evidence. This document represents an abstraction of the evidence rather than a methodological review.

Values: This update is the consensus of the Sub-Committee on Urogynaecology of the Society of Obstetricians and Gynaecologists of Canada (SOGC).

Benefits, Harms, and Costs: Counselling for the surgical treatment of urinary incontinence should consider the harms-benefits ratios of various options and include a measure of the "weight" of the evidence.

Recommendations:

1. The Burch procedure should be offered as the gold standard. The TVT procedure is promising but currently under evaluation in trials that will establish its efficacy and safety (II-3A).
2. Proper training is recommended prior to performing TVT procedures.
3. Long-term trial results are needed before the TVT procedure can be offered to patients as an equal alternative to the Burch procedure.

Validation: This technical update has been approved by the Sub-Committee on Urogynaecology and Executive and Council of the SOGC.

J Obstet Gynaecol Can 2003;25(8):692–4.

Key Words
Stress incontinence, surgery, minimally invasive

INTRODUCTION

Over 200 surgical procedures designed to treat stress incontinence have been reported in the medical literature. In recent years, the emphasis has shifted toward minimally invasive procedures because of the recognized benefits of rapid recovery and return to work, minimal morbidity, and decreased cost. Although these benefits are achieved with the laparoscopic Burch procedure, which produces results comparable to the open Burch procedure,[1,2] the steep surgical learning curve and the requirement of an OR suite equipped with advanced laparoscopic equipment render this technique unavailable to many women. The tension-free vaginal tape (TVT) procedure, developed by Ulf Ulmsten in the early 1990s, is very similar to the traditional pubovaginal sling procedure.[3] The TVT procedure is performed with a prepackaged kit that permits the surgeon to use very small incisions, resulting in minimal discomfort to the woman and a rapid recovery. This technical update will address the place of the TVT procedure in the management of stress incontinence.

The quality of evidence and classification of recommendations within this technical update are determined using the Evaluation of Evidence criteria outlined in the Report of the Canadian Task Force on the Periodic Health Exam (Table 1).[4]

TVT PROCEDURE

The TVT procedure was originally performed using either local anaesthesia in conjunction with conscious sedation or spinal anaesthetic. The procedure is performed with the woman in the lithotomy position and uses three small incisions: two suprapubic and one on the anterior vaginal wall 1.5 cm proximal to the urethral meatus (i.e., midurethra). The TVT kit consists of two curved stainless steel needles attached to a 1-cm-wide prolene mesh sling sheathed in plastic, a detachable handle to facilitate retropubic passage of the needles, and an obstructor to make a Foley catheter rigid. The needles are passed from the vaginal entry point through the retropubic space to exit through the suprapubic incisions. Cystoscopy is performed after the passage of each of the needles to ensure that bladder perforation has not occurred. Once safe passage of the needles is confirmed and the needles are pulled through, the sling is held suprapubically with hemostats. The bladder is filled with 300 mL of sterile water. With metzenbaum scissors or a kelly clamp placed between the urethra and the sling, as a buttress, the tape is adjusted until it is snug enough to prevent incontinence during coughing. The plastic sheath, which facilitates initial sling placement, is removed, and the excess sling arms are excised suprapubically. The incisions are then closed with sutures. Women are observed postoperatively until a satisfactory postvoid residual will permit discharge home. If a woman is unable to void effectively, a variety of options are available, including short-term catheterization or intermittent self-catheterization.

OUTCOMES

A number of prospective observational trials have been conducted to evaluate the effectiveness of the TVT procedure (Table 2).[5-8] The results of this procedure for the treatment of primary stress incontinence and mixed incontinence are comparable to the published results in the literature for both the Burch[9] and the pubovaginal sling. For women with recurrent incontinence, the results are similar.[6] For women with a fixed urethrovesical junction the outcome is poor, as with other surgical procedures.[8,10] A prospective study comparing the TVT procedure to the open Burch procedure has found, after six months' follow-up, that the effectiveness of the two procedures is the same (TVT, 68%; Burch, 66%).[11]

Intraoperative complications of the TVT procedure include cystotomy and bleeding.[12] Postoperative complications include *de novo* detrusor instability, prolonged urinary retention, and pain.[12] The rates of these complications are comparable to other surgical procedures.[13] Serious complications have been associated with TVT, including injury to large pelvic vessels, such as the internal iliacs,[14] and perforation of the bowel.[15] The rates of these complications seem low (based on case reports and anecdotal information) and most can be avoided by ensuring that anaesthesia is adequate prior to undertaking the surgery.

TABLE 1

QUALITY OF EVIDENCE ASSESSMENT[4]	CLASSIFICATION OF RECOMMENDATIONS[4]
The quality of evidence reported in this document has been described using the Evaluation of Evidence criteria outlined in the Report of the Canadian Task Force on the Periodic Health Exam. I: Evidence obtained from at least one properly randomized controlled trial. II-1: Evidence from well-designed controlled trials without randomization. II-2: Evidence from well-designed cohort (prospective or retrospective) or case-control studies, preferably from more than one centre or research group. II-3: Evidence obtained from comparisons between times or places with or without the intervention. Dramatic results in uncontrolled experiments (such as the results of treatment with penicillin in the 1940s) could also be included in this category. III: Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees.	Recommendations included in this document have been adapted from the ranking method described in the Classification of Recommendations found in the Canadian Task Force on the Periodic Health Exam. A. There is good evidence to support the recommendation that the condition be specifically considered in a periodic health examination. B. There is fair evidence to support the recommendation that the condition be specifically considered in a periodic health examination. C. There is poor evidence regarding the inclusion or exclusion of the condition in a periodic health examination, but recommendations may be made on other grounds. D. There is fair evidence to support the recommendation that the condition not be considered in a periodic health examination. E. There is good evidence to support the recommendation that the condition be excluded from consideration in a periodic health examination.

TABLE 2

LONG-TERM OUTCOMES OF THE TENSION-FREE VAGINAL TAPE (TVT) PROCEDURE

Author	No.	Patient Group	Duration of Follow-Up	Treatment Outcomes
Nilsson[5]	72	Stress incontinence Primary surgical procedure	5 years	85% cured
Rezapour[6]	34	Recurrent stress incontinence	4 years	82% cured
Rezapour[7]	80	Mixed urinary incontinence	4 years	85% cured
Rezapour[8]	49	Intrinsic sphincter deficiency	4 years	74% cured

DISCUSSION

Although the TVT procedure is similar in many ways to other pubovaginal procedures[16,17] the procedure is significantly different in that the sling mesh is placed at the midurethra rather than at the urethrovesical junction, and in that the TVT requires less dissection around the urethra it is therefore less likely to disrupt the blood and nerve supply to the urethra.

Early results using the TVT procedure have been very promising.[5-8] Preliminary results of the current randomized trial comparing TVT to the Burch procedure[11] are that the TVT procedure appears to be as effective in treating stress incontinence. Long-term follow-up of these patients is needed to confirm that the TVT has longevity of effect similar to that of the Burch procedure.

RECOMMENDATIONS

1. The Burch procedure should be offered as the gold standard. The TVT procedure is promising but currently under evaluation in trials that will establish its efficacy and safety (II-3A).

2. Proper training is recommended prior to performing TVT procedures.

3. Long-term trial results are needed before the TVT procedure can be offered to patients as an equal alternative to the Burch procedure.

REFERENCES

1. Summitt RL, Lucente VV, Karram MM, Shull BL, Bent AE. Randomized comparison of laparoscopic and transabdominal Burch urethropexy for the treatment of genuine stress incontinence. Obstet Gynecol 2000;95(Suppl 1):S2.
2. Fatthy H, El Hao M, Samaha II, Abdallah K. Modified Burch culposuspension: laparascopic versus laparotomy. J Am Assoc Gynecol Laparosc 2001;8:99–106.
3. Ulmsten U, Henriksson L, Johnson P, Varhos G. An ambulatory surgical procedure under local anaesthesia for treatment of female urinary incontinence. Int Urogynecol J 1996;7:81–6.
4. Woolf SH, Battista RN, Angerson GM, Logan AG, Eel W. Canadian Task Force on the Periodic Health Exam. Ottawa: Canada Communication Group; 1994. p. xxxviii.
5. Nilsson CG, Kuuva N, Falconer C, Rezapour M, Ulmsten U. Long-term results of the tension-free vaginal tape (TVT) procedure for surgical treatment of female stress incontinence. Int Urogynecol J 2001; (Suppl 2):S5–8.
6. Rezapour M, Ulmsten U. Tension-free vaginal tape (TVT) in women with recurrent stress urinary incontinence – a long-term follow-up. Int Urogynecol J 2001;(Suppl 2):S9–11.
7. Rezapour M, Ulsmsten U. Tension-free vaginal tape (TVT) in women with mixed urinary incontinence – a long-term follow-up. Int Urogynecol J 2001;(Suppl 2):S15–8.
8. Rezapour M, Falconer C, Ulmsten U. Tension-free vaginal tape (TVT) in stress incontinent women with intrinsic sphincter deficiency (ISD) – a long-term follow-up. Int Urogynecol J 2001;(Suppl 2):S12–4.
9. Jarvis GJ. Surgery for genuine stress incontinence. Br J Obstet Gynaecol 1994;101:371–4.
10. Summitt RL, Bent AE, Ostergard DR, Harris JA. Stress incontinence and low urethral closure pressure. Correlation of preoperative urethral hypermobility with successful suburethral sling procedures. J Reprod Med 1990;35:877–80.
11. Ward KL, Hilton P, Browning J. A randomized trial of colposuspension and tension-free vaginal tape (TVT) for primary genuine stress incontinence. Neurol Urodynam 2000;19:386–8.
12. Meschia M, Pifarotti P, Bernasconi F, Guercio E, Maffiolini M, Magatti F, et al. Tension-free vaginal tape: analysis of outcomes and complications in 404 stress incontinent women. Int Urogynecol J 2001; (Suppl 2):S24–7.
13. Vassollo BJ, Kleeman SD, Segal JL, Walsh P, Karram MM. Tension-free vaginal tape: a quality of life assessment. Obstet Gynecol 2002;100:518–24.
14. Zilbert A, Farrell SA. Laceration of the external iliac artery: a complication of the TVT procedure. Int Urogynecol J 2001;12:141–3.
15. Meschia M, Busacca M, Pifarotti P, De Marinis S. Bowel perforation during insertion of tension-free vaginal tape. Int Urogynecol J 2002;13:263–5.
16. Hilton P, Stanton SL. Clinical and urodynamic evaluation of polypropylene (Marlex) sling for genuine stress incontinence. Neurourol Urodyn 1983;2:145.
17. Horbach NS, Blanco JS, Ostergard DR, Bent AE, Cornella JL. A suburethral sling procedure with polytetrflouroethylene for the treatment of genuine stress incontinence in patients with low urethral pressure. Obstet Gynecol 1998;71:648–52.