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TVT and TVT-Obturator: Comparison of two operative procedures

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Abstract

Aim: To compare two anti-incontinence operations: the tension-free vaginal tape (TVT) and the TVT-Obturator for the first two 75-patient groups.
Methods: One surgeon operated on two patient groups with urodynamically proven urinary stress incontinence. The first 75-patient group in 1998 included the first TVT procedures performed according to Ulmsten [Ulmsten U, Henriksson L, Johnson P, Varhos G. An ambulatory surgical procedure under local anesthesia for treatment of female urinary incontinence. Int Urogynecol J 1996;7:81–6]. Follow-up lasted for 5–6 years. The second 75-patient group in 2004 included the first TVT-Obturator operations performed according to [De Leval J. Novel surgical technique for the treatment of female stress urinary incontinence: transobturator vaginal tape inside-out. Eur. Urol. 2003;44:724–30]. Follow-up lasted for 6–13 months.
Results: The two patient groups were similar from the demographic and therapeutic points of view. The TVT-Obturator procedure required neither bladder catheterization nor intra-operative diagnostic cystoscopy. TVT-related bladder penetration (8.0%), post-operative voiding difficulties (5.0%), intra-operative bleeding (4.0%), post-operative field infection (2.7%), and post-operative pelvic floor relaxation (1.3%) were not noted with the TVT-Obturator. The early therapeutic failure rates were 2.7% for the TVT and 1.3% for the TVT-Obturator, and neither bowel nor urethral injuries were recorded.
Conclusions: The surgeons' learning curves of these two minimally invasive surgical procedures for the treatment of female urinary stress incontinence are comparable. The safety and cost-effectiveness of the TVT are well-established. The TVT-Obturator, a novel mid-urethral sling, was designed to overcome some of the TVT-related operative complications. The TVT-Obturator patients seem to have less intra-operative and post-operative surgical complications than the TVT patients. However, long-term comparative data collection is required prior to drawing solid conclusions concerning the superiority of one of these two operative techniques.

Keywords: TVT; TVT-Obturator

1. Introduction

Tension-free vaginal tape (TVT) is a well-established surgical procedure for the treatment of female urinary stress incontinence (USI). The operation, described by Ulmsten in 1996 and based on a mid-urethral Prolene tape support, is accepted worldwide as an easy-to-learn, effective and safe surgical technique. Being minimally invasive and providing high success rates and low complication rates, it has rapidly become very popular [1–6].

Some typical TVT operative complications have been reported which concern the operating surgeons. Among these is bladder penetration—a rather frequent complication of little prognostic influence, yet necessitating intra-operative cystoscopy and occasional TVT needle re-insertion as well as an extended post-operative period of bladder catheterization [2,3,6,7]. Post-operative urinary outlet obstruction is also a well-known TVT complication and can have a deleterious influence on patient rehabilitation [2,3,6,9]. The occurrence of TVT failure was earlier reported and discussed with regard to the preferable therapeutic approach [2,3,6,10]. Other TVT-related complications are bowel penetration, intra-operative bleeding and post-

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operative infections [2,3,6–10]. The last three complications, which can be related to poor surgical technique, entail the potential risk of severely harming health. Against this background, De Leval was encouraged to design a novel mid-urethral sling procedure—the TVT-Obturator [11]. The TVT needle passes through the retropubic area, which is proximal to the neighboring bladder, bowel and blood vessels. The newly reported TVT-Obturator needle route runs through the relatively safe medial compartment of the obturator fossa area, far from the pelvic viscera and vessels, 2.5–3 cm medially to the obturator vessels and nerve [11]. The aim of this analysis was to compare two minimally invasive anti-incontinence procedures: the TVT and the TVT-Obturator.

2. Patients and methods

Patients suffering from urinary stress incontinence, diagnosed both clinically and urodynamically, were referred for corrective surgery. Between April 1998 and June 2005, 582 TVT procedures were performed; between May 2004 and June 2005, 178 TVT-Obturator procedures were performed. The first two 75-patient series of these two different types of procedures, both performed by the same surgeon and entailing the ''surgeons' learning curves'', are reported. The TVT operations were performed according to Ulmsten [1] and the TVT-Obturator were performed according to De Leval [11], using an inside-out technique. All were given 1 g Monocef (Cefonicid, Beecham Healthcare) intravenously, 1 h prior to surgery [8]. All patients had an iodine antiseptic prophylactic vaginal wash before commencement surgery. The mode of anesthesia depended on the patient's request. A Foley urethral catheter was installed with the members of the TVT group for 24 h, but not with any of the TVT-Obturator group except for those who had a hysterectomy performed. Diagnostic cystoscopy was carried out in the TVT group in order to rule out bladder penetrating TVT needles, but not for the TVT-Obturator group. Patients presenting with other significant features of pelvic floor relaxation included anterior and posterior colporrhaphy, or vaginal hysterectomies, concomitant with the anti-incontinence surgery. Intra-operative and post-operative complications within these two patient series were prospectively recorded. Patients had an interview and a pelvic examination in the 1st and 6th post-operative months and yearly thereafter. The TVT group patients were followed for 5–6 years and the TVT-Obturator patients for 6–13 months. Subjective data regarding urgency, frequency, stress and urge incontinence of urine and feces, sexual function impairments, voiding habits and pelvic pain and bulging were prospectively recorded. The clinical findings on physical pelvic examination, regarding urine and feces leakage, relaxation and prolapse of pelvic floor and organs were also prospectively collected according to the ICS standard terminology. All statistical analyses were performed with SPSS 10.1.4 (SPSS Inc., Chicago, IL). The *T*-test was used for quantitative variance analysis, while the Fisher's exact test and the Chi-square test were used for categorical variance. All statistical tests were evaluated at the $P = 0.05$ level of significance.

3. Results

Patients' age, parity, menopause, bladder over-activity, previous anti-incontinence surgery and chronic illness (Table 1) are similar in the two patient groups. The tabulated operative details (Table 2) show statistical differences between the groups concerning concomitant

Table 1
Patient demographics

	TVT ($N = 75$)	TVT-Obturator ($N = 75$)	*P*-value
Age (mean and range)	54 (39–81 years)	53 (40–85 years)	0.7
Parity (mean and range)	3.0 (1–12 deliveries)	3.3 (1–9 deliveries)	0.9
Post-menopause	56 patients (75%)	40 patients (53%)	0.6
O.A.B.	17 patients (23%)	26 patients (35%)	0.2
Previous U.S.I. corrective surgery	8 patients (11%)	2 patients (3%)	0.1
Background chronic illness	18 patients (24%)	24 patients (32%)	0.18

O.A.B., over-active bladder; U.S.I., urinary stress incontinence.

Table 2
Operative details

	TVT ($N = 75$)	TVT-Obturator ($N = 75$)	*P*-value
Operation time (mean and range)	30 min (19–48 min)	17 min (12–27 min)	0.001
Total concomitant corrective operations	27 patients (36%)	39 patients (52%)	0.03
Anterior colporrhaphy	24 patients	33 patients	
Posterior colporrhaphy	6 patients	9 patients	
Vaginal hysterectomy	2 patients	6 patients	

Table 3
Complication rates

	TVT ($N = 75$)	TVT-Obturator ($N = 75$)	P-value
Bladder penetration	6 patients (8.0%)	0 patients (0.0%)	0.014
Intra-operative bleeding > 200 ml	3 patients (4.0%)	0 patients (0.0%)	0.5
Bowel and/or urethral injury	0 patients (0.0%)	0 patients (0.0%)	
Operative field infection	2 patients (2.7%)	0 patients (0.0%)	0.5
Early therapeutic failure (in the 6th post-operative month)	2 patients (2.7%)	1 patient (1.3%)	0.5
Post-operative voiding difficulties (>24 h)	4 patients (5.0%)	0 patients (0.0%)	0.06
Post-operative pelvic floor relaxation	1 patient (1.3%)	0 patients (0.0%)	0.5

operations (27 TVT patients versus 39 TVT-Obturator patients; most of the additional operations were anterior colporrhaphies). The intra- and post-operative complications were tabulated (Table 3). Bladder penetration, occurring significantly more with the TVT (six TVT patients versus no TVT-Obturator patients), was dealt with by retrieval and re-insertion and verified by cystoscopy. Operative bleeding (loss of more than 200 ml of blood: three TVT patients and no TVT-Obturator patients) was managed with surgical hemostatic sutures via the vaginal approach [13] and no blood transfusion was needed. Operative field post-operative infections (two TVT patients and no TVT-Obturator patients) were managed by percutaneous aspiration of the retropubic accumulated pus and intravenous administration of broad spectrum antibiotics [12]. The TVT patients were followed up for 5–6 years and the TVT-Obturator patients for 6–13 months. Seven patients of the TVT group (9.3%) and none of the TVT-Obturator group were lost to follow-up. Therapeutic failure diagnosis was made in the 6th post-operative month, according to patient report, confirmed by stress test and proven by repeated urodynamic studies. This was treated by tape readjustment in the operating theater [10] with two TVT patients (2.7%) and one TVT-Obturator patient (1.3%). Accordingly, the early cure rate was 97.3% for the TVT procedure and 98.7% for the TVT-Obturator procedure. One TVT group patient was diagnosed with early sub-clinical post-operative relaxation of the anterior compartment of the pelvic floor, which did not necessitate any further surgical measures [8]. No other cases of objective post-operative genital prolapse, such as cystocele, rectocele, uterine prolapse or subjective de novo bladder over-activity, were recorded. Early post-operative partial outlet obstruction was treated with bladder catheterization for up to 3 weeks (four TVT patients—5.3%), while complete obstruction required tape resection (three TVT patients—4%) [9]. No outlet obstruction was noted among the TVT-Obturator patients.

4. Discussion

Since being described by Ulmsten in 1996, the TVT procedure has become very popular. Common complications of former operations for the treatment of urinary stress incontinence, such as intra-operative blood loss, pelvic and abdominal organ injury, post-operative de novo Detrusor instability, dyspareunia and urethral erosion, are rare in the TVT era [1–5]. Prospective randomized multicenter studies, comparing TVT and the former gold standard Burch colposuspension, demonstrated similar therapeutic impact for both. However, TVT had a higher intra-operative complication rate while colposuspension had a higher post-operative complication rate and a longer recovery period [14–18]. Among the well-documented typical TVT complications are bladder penetration, intra-operative bleeding, post-operative field infection and bowel injury [1–3,5]. Against this background, De Leval described a novel TVT-related procedure [11]. This new operation enables mid-urethral support for the treatment of female stress urinary incontinence, without coming close to the bladder, the femoral blood vessels or the bowel. This is achieved by using the obturator fossa, rather than the retropubic space, as a route for the Prolene tape. The demographic characteristics are similar in the two patient groups. The concomitant operation rate differences between the two groups are in favor of the TVT group (36% versus 52%). Most of these operations were anterior colporrhaphies; this might contribute to the reduction of potential urethral kinking and accordingly to the reduction of the post-operative voiding difficulty rate as well. The short-term data presented here agree in general with the previously reported efficacy of both the TVT and the TVT-Obturator, regarding early cure as well as intra-operative and early post-operative complication rates. These comparative study results might be biased, as the author performed the observations and data collection alone. At the same time, the surgeons' learning curves for these two operations, reflected by the cure and surgical complication rates, seem to be promising. Although not proven by cystoscopy, but rather clinically presumed, the TVT-Obturator is found to be statistically less related to bladder penetration and less time-consuming than the TVT. Bladder penetration was previously reported in relation to an ''outside-in'' trans-obturator designed mid-urethral tape procedure (TOT), but never with an ''inside-out'' trans-obturator procedure [19,20] which was exerted in this study as well. Hence, although diagnostic cystoscopy was not used for the TVT-Obturator patients, the author has assumed that no bladder perforation occurred in the TVT-Obturator group, as no signs suggesting bladder perforation (such as urinary leakage through surgical abdominal or vaginal cuts) was

recorded. Intra-operative bleeding, post-operative field infection and voiding difficulties are also less frequent with the TVT-Obturator, even though this is not statistically significant. This might be partially due to the relatively short follow-up period for the recently launched TVT-Obturator procedure, as well as to the relatively small study sample size and the accumulated surgical experience with mid-urethral sling placement since the TVT surgeons' learning curve took place. Nevertheless, that set forth above shows the TVT-Obturator procedure to be potentially superior to the worldwide well-known TVT. This potential, however, requires further appropriate comparative randomized prospective longitudinal studies in order to be definitively established. The TVT-Obturator is easier and simpler for both surgeons and patients, as it does not require urethral catheterization or diagnostic cystoscopy during surgery.

5. Conclusion

The TVT-Obturator, a novel mid-urethral sling operation for the treatment of female stress urinary incontinence, seems to be an effective and safe procedure. Intra-operative diagnostic cystoscopy and bladder catheterization are not mandatory with this newly launched surgical approach. The TVT and TVT-Obturator operations are compared. The TVT-Obturator procedure had fewer complications than the TVT, both intra-operatively and early post-operatively. This included reduced occurrence of operative bleeding and post-operative field infections and voiding difficulties. Randomized controlled trials and long-term follow-up will be needed in order to determine which of those two surgical anti-incontinence techniques is better.

References

[1] Ulmsten U, Henriksson L, Johnson P, Varhos G. An ambulatory surgical procedure under local anesthesia for treatment of female urinary incontinence. Int Urogynecol J 1996;7:81–6.
[2] Olsson I, Kroon U. A three-year post-operative evaluation of tension-free vaginal tape. Gynecol Obstet Invest 1999;48(4):267–9.
[3] Kuuva N, Nilsson CG. A nationwide analysis of complications associated with the tension-free vaginal tape (TVT) procedure. Acta Obstet Gynecol Scand 2002;81:72–7.
[4] Paraiso MFR, Muir TW, Sokol AI. Are midurethral slings the gold standard surgical treatment for primary genuine stress incontinence? J Am Assoc Gynecol Laparosc 2002;9(4):405–7.
[5] Groutz A, Gordon D, Wolman I, Jaffa AJ, David MP, Lessing JB. Tension-free vaginal tape for stress urinary incontinence: is there a learning curve? Neurol Urodynamics 2002;21:470–2.
[6] Waetjen LE, Subak LL, Shen H, et al. Stress urinary incontinence surgery in the United States. Obstet Gynecol 2003;101:671–6.
[7] Neuman M. Tension-free vaginal tape bladder penetration and long-lasting transvesical prolene material. J Pelvic Med Surg 2004; 10(6):307–9.
[8] Neuman M. Low incidence of post TVT genital prolapse. Int Urogynecol J Pelvic Floor Dysfunction 2003;14:191–2.
[9] Neuman M. Post tension-free vaginal tape voiding difficulties—prevention and management. J Pelvic Med Surg 2004;10:19–21.
[10] Neuman M. Trans vaginal tape readjustment after unsuccessful tension-fee vaginal tape operation. Neurourol Urodynamics 2004;23: 282–3.
[11] De Leval J. Novel surgical technique for the treatment of female stress urinary incontinence: transobturator vaginal tape inside-out. Eur Urol 2003;44:724–30.
[12] Neuman M. Infected hematoma following tension-free vaginal tape implantation. J Urol 2002;168(6):2549.
[13] Neuman M. Transvaginal suture placement for bleeding control with the tension-free vaginal tape procedure. Int Urogynecol J Pelvic Floor Dysfunct 2006;17(2):176–7.
[14] Liapis A, Bakas P. Creatsas G: Burch colposuspension and tension free vaginal tape for the management of stress incontinence in women. Eur Urol 2002;41:469–73.
[15] Ward KL, Hilton P, United Kingdom and Ireland Tension-Free Vaginal Tape Trial Group. A prospective multicenter randomized trail of tension-free vaginal tape and colposuspension for primary urodynamic stress incontinence: two-year follow-up. Am J Obstet Gynecol 2004; 190:324–31.
[16] Grise P, Lobel B, Grall J. Les complicasions du TVT. Prog Urol 2003;13(1):144–6.
[17] Cody J, Wyness L, Wallace S, et al. Systemic review of the clinical effectiveness and cost-effectiveness of TVT for the treatment of urinary stress incontinence. Health Technol Assess 2003; 7(21):1–189.
[18] Nygaard IE, Heit M. Stress urinary incontinence. Obstet Gynecol 2004;104:607–20.
[19] Hermieu JF, Messas A, Delmas V, et al. Bladder injury after TVT transobturator. Prog Urol 2003;13(1):115–7.
[20] Minaglia S, Ozel B, Klutke C, et al. Bladder injury during transobturator sling. Urology 2004;64(2):376–7.