Original Article-Surgery

CMJ

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Complications Following Outside-in and Inside-out Transobturator-Tape Procedures with Concomitant Gynecologic Operations

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This study was undertaken to compare the complications of outside-in transobturator tape procedures (TOT) and inside-out transobturator tape procedures (TVT-O) with concomitant gynecologic surgery for the treatment of female stress urinary incontinence (SUI). A retrospective review of 206 consecutive patients who underwent either TOT or TVT-O with concomitant gynecologic operations between March 2008 and February 2011 was conducted. The incidence of perioperative complications was compared. For statistical analysis, chi-squared tests were used. There were no reports of intraoperative complications such as vaginal injury or bladder perforation. Postoperative complications were noted in 23 procedures (11.2%). These included 6 cases of urinary retention (2.9%), 2 cases of vulva hematoma (1.0%), 7 cases of urinary tract infection (3.4%), 4 cases of de novo urgency (2.9%), and 4 cases of vaginal erosion (2.9%). There were no significant differences in complication rates between the two groups. Our results suggest that inside-out and outside-in procedures are simple and safe techniques that may have a low rate of complications when used with a concomitant gynecologic operation.

Key Words: *Complications; Urinary stress incontinence; Gynecologic surgical procedures*

Article History:
received 3 November, 2011
accepted 30 November, 2011

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INTRODUCTION

Stress urinary incontinence (SUI) affects up to 20% of women and is associated with significant medical complications and social embarrassment. Multiple behavioral and surgical treatments exist; however, the surgical placement of a suburethral mesh named the tension-free vaginal tape (TVT) is becoming the new gold standard for correction of SUI.[1] This mesh is placed without tension between the mid-urethra and the vaginal anterior wall in order to strengthen or even rebuild the pubourethral ligaments and the suburethral vaginal hammock, in accordance with the integral theories described by Petros and Ulmsten.[2] Several reports have confirmed high cure rates by use of the minimally invasive tension-free vaginal tape approach.[3-6] Complications, however, primarily related to the penetration of the retropubic space, have been reported. Although most are minor, such as bladder perforation, other rare but potentially fatal complications such as vessel or bowel injury have been reported.[4-6]

To reduce these complications, an alternative approach, called the transobturator tape (TOT) procedure, was introduced by Delorme[7] in 2001. This tape is also located underneath the midurethra, but runs laterally through the obturator membrane to the upper part of the thigh, from outside to inside. Results show that the success of the operation is comparable with retropubic procedures, but compared to these, the transobturator approach involves far fewer complications.[8,9] In 2003, a novel surgical technique was described by de Leval,[10] with the passage of the tape through the obturator foramens from inside to outside, called tension-free vaginal tape inside out (TVT-O). This procedure permits a lower dissection, a precise and reproducible insertion, and a lower rate of injuries to the urethra and the bladder. These two techniques differ not only in the way the needle is placed and carried forward but also in the designs of the introducer. Recent prospective studies have indicated that TVT-O and TOT are equally effective and

http://dx.doi.org/10.4068/cmj.2011.47.3.165

safe for women with SUI.[11-13]

It has been reported that 41% of women with SUI require concomitant surgical procedures for benign uterine disorders.[14] Therefore, it is pragmatic to question whether concomitant gynecologic operations affect the complication rates of the incontinence procedures for SUI. However, until now, little evidence has been presented that one technique is superior to another when used with a concomitant gynecologic operation. We therefore compared the perioperative complications in two groups of patients who received either TVT-O or TOT procedures with concomitant gynecologic operations.

MATERIALS AND METHODS

1. Patient selection

Between March 2008 and February 2011, 206 consecutive female patients diagnosed with SUI who underwent either the TVT-O (n=61) or TOT (n=145) procedure with a concomitant gynecologic operation were included. Diagnosis of SUI was based on typical subjective symptoms (i.e., involuntary leakage on effort, exertion, coughing, sneezing, or laughing) as recommended in 2002 by the International Continence Society[15] and on objective clinical data from the cough stress test, Q-tip test, or urodynamic studies.

Excluded were women with recurrent and difficult-to-treat urinary tract infections, urge urinary incontinence, or mixed urinary incontinence in which the urge component was predominant, postvoiding bladder retention of more than 150 ml, bladder capacity of less than 100 ml, and physical or mental impairment.

2. Surgical techniques

The Serasis (Serag Wiesner, Germany) tape was inserted through the outside-in route by using the technique recommended by Delorme[7] in 2001. The inside-out procedure was performed as described by de Leval[10] in 2003, and a tape (TVT-O®, Gynecare, Johnson & Johnson, USA) was inserted. We will not describe them here. Both procedures used a monofilament, macroporous polypropylene tape.

All operations were carried out under general anesthesia. Cystoscopy was performed only in the case of encountering bloody urine. Thirty minutes before the scheduled operation, all patients received 1 g cefazolin sodium. A Foley catheter was always inserted. If there was no concomitant anterior colporrhaphy, the catheter was removed on the first postoperative morning. If there was concomitant anterior colporrhaphy, the catheter was maintained for 3 days.

3. Assessment of complications

An assessment of perioperative and postoperative complications was made for each patient. Perioperative complications were recorded after surgery by the surgeon. Immediate and late postoperative complications were also recorded during the patient's hospital stay and by the follow-up visit (after 1 month, 2 months, 1 year, and 2 to 3 years).

4. Statistical analysis

Data from the two groups were compared by using the chi-squared test with a 5% significance threshold. The results are expressed as means +/- standard deviations. Statistical analysis was performed by using SPSS, version 14.0 (SPSS, Chicago, IL, USA).

RESULTS

Patient characteristics are summarized in Table 1. The mean age of the 206 patients was 52.6±10.5 years. Our patients had given birth 2.9±1.4 times on average. All women underwent combined procedures (including abdominal hysterectomy, 14; vaginal hysterectomy with or without colporrhaphy, 145; sacrospinous ligament suspension, 7; colposacropexy, 4; LeFort partial colpocleisis, 10; other, 26). Other procedures included cystectomy of ovarian tumor, myomectomy, or adnexectomy. Ninety-one patients (44.2%)

TABLE 1. Baseline characteristics and concomitant operations

	TOT (n=145)	TVT-O (n=61)	p value
Age, years (mean±SD)	51.26±8.30	53.38±8.50	0.093
Parity (median±SD)	2.7±1.3	2.9±1.4	0.625
Menopause, number (%)	65 (44.8%)	26 (42.6%)	0.085
DM	7 (4.8%)	3 (4.9%)	1.000
Previous incontinence surgery	2 (1.4%)	1 (1.6%)	1.000
Concomitant operations			
Total vaginal hysterectomy with or without anterior and posterior colporrhaphy	101 (69.7%)	44 (72.1%)	0.126
Total abdominal hysterectomy	12 (8.3%)	2 (3.3%)	0.240
Sacrospinous ligament suspension	3 (2.1%)	4 (6.6%)	0.199
Colposacropexy	2 (1.4%)	2 (3.3%)	0.583
LeFort partial colpocleisis	1 (0.5%)	9 (14.8%)	0.000
Others	26 (18.0%)	0 (0%)	0.000

Values are mean±standard deviation. DM: diabetes mellitus, TOT: transobturator tape, TVT-O: tension-free vaginal tape inside out.

TABLE 2. Complication rates

Complications	TOT (n=145)	TVT-O® (n=61)	p value
Intraoperative			
Vaginal injury	0	0	NA
Bladder perforation	0	0	NA
Postoperative			
Urinary retention	4 (2.8%)	2 (3.3%)	1.000
Vulva hematoma	2 (1.4%)	0	1.000
Urinary tract infection	5 (3.4%)	2 (3.3%)	1.000
De novo urgency	3 (2.1%)	1 (1.6%)	1.000
Vaginal erosion	4 (2.8%)	0	0.321
Obturator hematoma or abscess	0	0	NA
Nerve injury	0	0	NA
Dyspareunia	0	1 (0.02%)	0.296
Thigh pain	0	1 (0.02%)	0.296
Total	18 (12.4%)	5 (8.2%)	0.473

TOT: transobturator tape, TVT-O: tension-free vaginal tape inside out, NA: not applicable.

were postmenopausal. There were no significant differences in the baseline characteristics of the patients who underwent TOT or TVT-O. As shown in Table 1, there were significant differences concerning concomitant LeFort partial colpocleisis operations performed between the two groups.

Intraoperative and postoperative complications are presented in Table 2. No major intraoperative complications, such as vaginal injury or bladder perforation, occurred. Urinary tract infections were noted in seven cases (3.4%): five (3.4%) after TOT and two (3.3%) after TVT-O procedures. They were resolved after antibiotic treatment. De novo urgency symptoms developed postoperatively in three TOT (2.1%) and one TVT-O (1.6%) patient (p=NS). All patients with de novo urgency were treated with anti-cholinergic medication and their symptoms were resolved within 1 to 2 months. Urinary retention (postvoiding residual urine volume $>$ 100 ml) was reported in six patients (2.9%): four (2.8%) after TOT and two (3.3%) after TVT-O procedures. Five of the patients with urinary retention required a urethral catheter for 3 days; following removal of the catheter on the 4th day, however, all voided well. In one patient who had persistent urinary retention for more than 1 week, we cut the mesh beneath the urethra and the condition was resolved. During the TOT procedure, there were two cases (1.4%) of vulva hematoma and four cases (2.8%) of vaginal erosion (no case during the TVT-O approach). The vulva hematomas were self-contained on the right side and resolved within 2 to 3 months without surgical intervention. Three cases of vaginal erosion were found within 3 to 4 months, and one case was after 1 year. Three cases of vaginal erosion were situated on the midurethral midline, and one case was on the lateral vaginal sulcus. All vaginal erosions were excised under local anesthesia, and all remained continent afterward. There were no serious complications in either group, such as obturator hematoma/abscess or significant nerve or vessel injury.

In total, 18 (12.4%) complications with the TOT and 5 (8.2%) with the TVT-O procedures were reported. There were no significant differences between the two procedures regarding total complication rates (Table 2).

DISCUSSION

Compared with the retropubic approach (for example, TVT), the transobturator approach (for example, TOT) seems to be safer, because the complications related to the penetration of the retropubic space do not occur. There are two basic techniques for performing TOT: "outside-in" as described by Delorme[7] and "inside-out" as described by Leval.[10] Both procedures have become popular surgical treatments for female SUI[16] and are applied in our department. This report comprises a comparative study of both procedures. The objective of this study was to compare operation-related morbidity for TVT versus TVT-O when used with concomitant gynecologic operations. We found no significant differences in the complication rates between the two approaches. Approximately 11.2% of the women experienced complications.

Although bladder perforation is a common complication occurring during TVT, the transobturator approach reduces the risks of bladder and urethral perforation. Theoretically, the transobturator tape does not penetrate the retropubic space, but the tip of the tunneller can injure the bladder, the bladder neck, or the urethra if its course is misaligned or in an oblique direction.[17] Data from randomized controlled trials in which both groups had cystoscopy showed that no (0 of 232) women had bladder injury in the TVT-O/TOT group.[18-20] Cadaver studies suggest that perioperative cystoscopy is not required, although there are case reports of this complication in the literature.[21-23] Bladder perforation during TOT can be avoided by insertion of an index finger into the vaginal dissection. We had no case of bladder perforation during either procedure, which is consistent with other publications.

After the TOT procedure, two women returned because of hematoma of the vulva. Both cases were treated conservatively only, with nonsteroidal anti-inflammatory drugs and without antibiotics. There was no case of vulvar hematoma after the TVT-O procedure. However, there was no statistically significant difference between the two groups. It seems that the occurrence of postoperative hematoma may be greater after the inside-out procedure because of the fact that the needles go deeper during the inside-out procedure and perforate more muscular tissue, thus increasing the risk for vessel damage.

In a comparative study of two versions of the transobturator tape, TOT using the Obtape (Mentor-Porges, Le Plessis Robinson, France) developed more vaginal erosion than did TVT-O (7.29% vs 1.78%, $p < 0.05$).[24] In a prospective comparative study of the TVT-O and TOT (Monarc®, American Medical Systems, Minneapolis, MN, USA) procedures,

Houwert et al. found a slightly higher erosion rate in the Monarc group.[25] These results disagree with those of But and Faganelj.[12] and Lee et al.[13], which demonstrated that there were no tape erosions with either technique. The data from a meta-analysis of vaginal erosions in both procedures show that there seems to be a slightly higher erosion rate for the outside-in technique, but a significant difference was never reached, mostly because of small patient numbers.[26] In the present study, there were four cases of vaginal erosion in the postoperative period after the TOT procedure (no cases after the TVT-O procedure). However, there was no significant difference between the two groups. Other factors related to vaginal erosion, apart from the surgical technique, such as biomechanical properties of the mesh used, infection, and the properties of tissue, need to be addressed to analyze the tape-erosion pattern. Achtari et al. showed by cadaveric dissection that TVT-O runs more closely to the obturator canal, making TVT-O more prone to possible injury of the obturator nerve and vessels.[27] However, we observed no incidence of obturator nerve or vessel injury with the use of either procedure. Houwert et al. prospectively compared 191 women who underwent either a TVT-O (n= 93) or a TOT (n=96) procedure.[25] They did not find any obturator nerve or vessel injury and suggested that this theoretical risk does not exist in clinical practice.

The drawback of the present study is its retrospective nature and different numbers of patients in each group. Furthermore, in our study, the TOT and TVT-O group differed significantly in the rate of concomitant LeFort partial colpocleisis operations. Despite these limitations, the large sample size, similar demographic variables of the study population, and performance of surgery in a single institution by the same surgical team probably increase the validity and mitigate the weaknesses.

In summary, the results of our study show that the complication rates of TVT-O and TOT with concomitant gynecologic operation were similar.

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