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Original Article

The comparison of an inexpensive–modified transobturator vaginal tape versus TVT-O procedure for the surgical treatment of female stress urinary incontinence

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Abstract

Objective: To compare the safety and efficacy of an inexpensive–modified transobturator vaginal tape procedure with the transobturator tension-free vaginal tape (TVT-O) procedure for the surgical treatment of female stress urinary incontinence (SUI).
Materials and Methods: Patients with SUI were randomly allocated to either the test group receiving the inexpensive–modified transobturator vaginal tape procedure or the control group receiving the GYNECARE TVT-O procedure. Treatment outcomes and Quality-of-life scores were recorded and analyzed between two groups.
Results: A total of 156 patients were enrolled in this trial. Eighty patients underwent the modified transobturator vaginal tape procedure. Among them 75(93.8%) were cured and 5(6.2%) were improved. The rest of the 76 patients underwent the GYNECARE TVT-O procedure with a 92% (70 of 76) cure rate and an 8% (6 of 76) improvement rate. No inefficient or aggravated cases occurred in both groups. The success rates between groups had no significant statistic difference ($p > 0.05$). The operative time, blood loss, hospital stay, and medical cost were significantly lower in the test group ($p < 0.01$); the increases in Quality-of-life scores were comparable between groups.
Conclusions: The modified transobturator vaginal tape procedure is an efficacious and economic surgical treatment for female SUI.

Keywords: Mesh; Stress urinary incontinence; Surgical treatment

Introduction

Stress urinary incontinence (SUI) is defined as the involuntary loss of urine associated with activities that increase intra-abdominal pressure, such as coughing, sneezing, laughing, squatting, or performing the Valsalva maneuver [1]. Similar to its frequency in Western countries, approximately 22.9% of women aged from 22 years to 99 years suffer from SUI in China according to Zhu' report [2]. The woman with SUI can have a significant social embarrassment and may cause negative changes in their lifestyles and self-esteem. Several surgical treatments for cure of SUI especially transobturator tension-free vaginal tape (TVT-O), have been used clinically and widely in the past decade thanks to the efficacious results [3]. However, the disposable GYNECARE TVT-O procedure may be too expensive to be afforded by many people. Therefore, the introduction of a simple and safe, mini-invasive, and economic anti-incontinence technique is of great importance in China. In this background, Professor Tong from Tongji University, Shanghai, China modified the original TVT-O and made it more acceptable to more people [4]. To compare the safety and efficacy of the modification, we initiated this prospective and randomized trial to compare the two procedures for the treatment of female SUI.

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Materials and methods

Patients enrolled in this study

From January 2006 to December 2007, patients with SUI who fulfilled the inclusion and exclusion criteria were enrolled in this trial and randomly assigned to the groups receiving either the GYNECARE TVT-O group (the TVT-O group) or the inexpensive–modified transobturator vaginal tape group (the test group). All patients were preoperatively informed the detailed techniques, reported efficacy, and complications of both procedures and then an informed consent was signed. The inclusion criteria included age more than 18 years, incontinence at the increase of abdominal pressure for at least 3 months. Patients with persistent urinary retention, a 50 mL or greater postvoid residual, urinary urgency, frequency and odynuria or other urologic diseases, psychiatric disorder, pregnancy or lactation, participation in other clinical trials in the past 3 months, or disability to understand and follow the present trial were all excluded from the study.

All patients were allocated to two groups with the use of stratified randomization based on patients' SUI stages. All the operations have been performed by two experienced surgeons, to minimize the influence on the results as low as possible. Blood routine test, hemagglutination test, serum liver and kidney function test, and electrocardiogram were performed preoperatively.

The modified transobturator vaginal tape procedure

The intimate surgical procedure of the modified transobturator vaginal tape has been reported by Chen et al in 2009 [4]. The instruments used in this procedure including one pair of metallic helical needles and a 1 cm × 15-cm polypropylene mesh has been reported before [4]. The procedures are briefly stated as follows: after the patient was placed in lithotomy position, a 2 cm vertical incision was made medially 1.0–1.5cm away from the urethral meatus on the anterior vaginal wall. Sharp dissection was performed submucosally until reaching the anterior and inferior edge of pubis ramus. Under the guidance of the contralateral index finger, the screw was inserted close to the internal edge of pubis ramus and through the obturator foramen with a minor rotation. A small incision was made bilaterally at the level of clitoris 4 cm lateral to the midline, through which the screw passed from inside to outside. A No.10 silk suture was folded in figure-of-U with the end hanging into the gab under the tip of the screw. Then the screw with the suture was withdrawn slowly from outside to inside. By this maneuver, the end of the folded suture was guided into the vagina. The same procedure was performed on the other side. The mesh was adjusted to an appropriate tension with the retraction of the 4 sutures.

The TVT-O technique

The TVT-O procedures were performed using the TVT Obturator System (Gynecare, Ethicon, Somerville, New Jersey, USA) according to the product's instructions. A 2-cm midline incision was made under the midurethra. The helical device was placed through the suburethral tunnel until the medial surface of the ischiopubic ramus was reached. The device was popped through the obturator membrane and then rotated sharply around the ischiopubic ramus to exit through the skin. The polypropylene sling was then pulled out through the skin incision and held. The procedure is repeated on the opposite side. Finally the plastic sleeves were removed and the skin and vaginal incision closed.

Evaluation of clinical outcomes in two groups

Subjective and objective clinical outcomes were evaluated. SUI grading bases on the severity of SUI inducement, whereby Grade 1 is defined as incontinence during high abdominal pressure (severe coughing, sneezing, etc); Grade 2 as incontinence during moderate abdominal pressure (mild coughing, running, etc.); Grade 3 as incontinence with mild abdominal pressure such as quick walking; and Grade 4 as incontinence during minimum abdominal pressure during changes of the body position [5]. Subjective outcomes are described as follows: *cure* refers to disappearance of incontinent symptoms under Grade 1 inducement; *improvement* refers to disappearance of incontinent symptoms under Grade 2 or lower inducement; *inefficiency* refers to no changes of the symptoms and in *aggravation* the symptoms become more serious after the treatment [6].

Perioperative variables including operative time, blood loss, hospital stay, medical cost, and complications as visceral injures of urinary retention were noted and analyzed. Satisfaction of patients in both groups were asked at 1 month's follow-up.

Quality-of-life (QOL) was measured by self-administered questionnaire (I-QOL)[7]. Three aspects were assessed: activity limitations, psychological influence, and societal dysfunction. Pre- and postoperative QOL scores were compared.

Statistical analysis

Comparison of subjective treatment outcomes was performed with Chi-square test. The *t* test was used to evaluate continuous variables expressed as median and range. All statistical analysis was made using statistical software (SPSS 11.0 for Windows; SPSS Inc, Chicago, IL, USA). A p value <0.05 was considered statistically significant.

Results

Patient characteristics

A total of 156 patients were enrolled in this prospective and randomized trial. Eighty patients with a mean age of 62.6 ± 3.2 years were assigned to the test group and 76 patients with a mean age of 61.4 ± 5.4 years in the control

Table 1
Subjective treatment outcomes

Groups	Cases	Cure	Improvement	Inefficiency	Aggravation
The test group (The modified TVT-O group)	80	75(93.8%)	5(6.2%)	0	0
The control group (The GYNECARE TVT-O group)	76	70(92%)	6(8%)	0	0

$\chi^2 = 0.1609$, $p = 0.688$.
TVT-O = transobturator tensionfree vaginal tape.

group. The ages and SUI stages were well balanced between groups.

Subjective and objective clinical outcomes

All patients were successfully operated and could void after removal of the catheter 6 hours after surgery. Postvoid residual urine volume for more than 100 mL occurred in one patient in both groups, which was improved after 48 hours catheterization.

In the test group 75(93.8%) were cured and 5(6.2%) were improved whereas the TVT-O group had a 92% (70 of 76) cure rate and an 8% (6 of 76) improvement rate (Table 1). No inefficient or aggravated cases occurred in both groups. There was no significant statistic difference between groups in this subjective outcomes ($p > 0.05$). Satisfaction of patients shows no difference between two groups at 1 month's follow-up ($p > 0.05$, Table 2). The operative time, blood loss, hospital stay, and medical cost were significantly lower in the test group ($p < 0.01$) (Table 3).

Assessment of QOL

Patients in both groups noted that the incontinence symptoms were significantly improved, which was demonstrated by the increased postoperative QOL scores. The mean increase of scores was 24.6 ± 3.5 points and 23.9 ± 2.7 points in the test group and the TVT-O group, respectively. The difference had no statistical significance ($p > 0.05$) (Table 4).

Discussion

Theories and TVT-O procedure

The Pelvic Integral Theory states that the pelvic floor is an organic and balanced integrity correlated with muscles, connective tissues, vessels, and nerves, rather than a simple combination of the separate parts [8]. The basis of the theory is that function depends on anatomic structures and the anatomic defect will lead to functional disability. Anatomic restoration can regain function restoration. The Hammock Theory suggests that the maintenance of the urethral closure pressure relies on the effective transmission of the pressure from pubovesical fascia and anterior vaginal supportive tissues to the bladder neck, pubourethral ligament, and paraurethral tissues [9]. The plate of levator ani muscles plays an important role in stabilizing the hammock-like structure. If the support is destroyed, the vaginal pressure to the urethra will attenuate and SUI occurs.

In TVT-O procedure, based on these theories, a sling is placed suburethrally as a hammock to strengthen pubourethral ligament and paraurethral tissues. It emphasizes the integrity of pelvic anatomical complex and maintenance of pelvic integrity and anatomical restoration. During coughing, the urethra will be drawn by the sling as the role of pubourethral ligament [10–12]. It has been confirmed by De Lancy [9] in the cadaver study that the ligament plays a vital role as a mechanical device in urinary continence. The fiber reaction surrounding the TVT-O sling may further strengthen the ligaments and tissues and help to regain urinary continence.

Characteristics of the modified TVT-O procedure

The passage and mechanism of our modified transobturator vaginal tape procedure is identical to the GYNECARE procedure. In 2003, Leval performed studies on cadavers to assess the anatomical associations during a TVT-O, and observed that the pelvic region of vesical wall was completely outside of the surgical field. Therefore, the cystoscopy is not necessary [3]. We have also performed anatomical studies using cadavers recently to identify the exact passage of the needles and tape with our modified TVT-O procedure and confirmed his findings. In our autopsy studies, we performed the modified approach in fresh cadavers. The puncture was exposed after exposure of retropubic space by the dissection of

Table 2
Satisfaction of patients at 1 month's follow-up

Satisfaction of patients (at 1 month's follow- up)	The test group ($n = 80$)	The control group ($n = 76$)	Statistics	p value
Completely satisfied	54(67.5%)	51(67.1%)	$\chi^2 = 0.0202$	0.990
Satisfied	12(15%)	12(15.8%)		
Not satisfied	14(17.5%)	13(17.1%)		

Table 3
The operative time, blood loss, hospital stay and medical cost between the groups

Groups	Operative time (min)	Blood loss (ml)	Hospital stay (d)	Medical cost (RMB)
The test group	24 ± 6	55 ± 5	5 ± 0.5	3052 ± 310
The control group	49 ± 5	70 ± 5	8 ± 0.5	9466 ± 350
t value	−28.1945	−18.7288	−37.4577	−121.3083
p value	<0.0001	<0.0001	<0.0001	<0.0001

Table 4
Changes of QOL scores before and after the surgery (at 1 month's follow-up)

Groups	The increase of QOL scores (point)	*t* value	*p* value
The test group	24.6 ± 3.5	1.3935	>0.05
The control group	23.9 ± 2.7		

QOL = Quality-of-life.

bladder and pelvic fascia. This indicates that the exact passage of the approach was completely outside of the retropubic space, which insured impossibility to cause the vesical injury. We therefore postulate that cystoscopy is not necessary and consequently the operative time can be reduced. Because of the application of specially designed screw and self-tailored polypropylene mesh, rather than the disposable GYNECARE TVT-O device, the surgical cost is reduced to one third of the prior. Furthermore, the operative time, blood loss, and hospital stay are significantly lower with the modified TVT-O procedure. According to our experience, the GYNECARE TVT-O procedure needs to remove the plastic sheath that covers the tape slowly and carefully, so as not to induce excessive tension on the tape or tape distortion caused by over-stretch. So the GYNECARE TVT-O procedure needs to spend more time. The subjective outcomes are comparable between the two procedures. It appears that the modified TVT-O is as effective as the original procedure in relieving incontinence symptoms.

SUI is a nonfatal condition, which influences the quality of life. Improvement of QOL is an important target for the treatment of SUI. It has been widely accepted as an essential measure for treatment outcomes. The present study found that the QOL in both groups had greatly improved after the surgery, whereas the QOL scores between groups had no significant difference. It suggested that the modified TVT-O was comparable to the original procedure in improving the patient's QOL.

In the present study, we found a phenomenon that should be noticed. In the cured or improved patients under the subjective evaluation, satisfaction of patients was not always consistent with the relief of symptoms or the increase of QOL scores. It seemed that there was some defects in the outcome measurements [13]. However, more detailed information could not be provided by our study. Relevant researches and preferable subjective or objective measure system are expected.

In conclusion, the modified transobturator vaginal tape procedure is an efficacious and acceptable surgical treatment for female SUI. It is worthy of further application and study.

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