Taiwanese Journal of Obstetrics & Gynecology 57 (2018) 295–299

Contents lists available at ScienceDirect

Taiwanese Journal of Obstetrics & Gynecology

journal homepage: www.tjog-online.com

Original Article

Did surgical failure and complications affect incontinence-related quality of life in women after transobturator sling procedure?

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ARTICLE INFO

Article history:
Accepted 12 February 2018

Keywords:
Complication
Quality of life
Stress urinary incontinence
Transobturator tape
Urodynamic stress incontinence

ABSTRACT

Objective: To report the objective outcome, subjective measurement of incontinence-related quality of life (QoL) for female urodynamic stress incontinence (USI) after transobturator sling surgery (TVT-O) and to evaluate the effects of surgical failure and complications on QoL.

Materials and methods: We analyzed the data from women who underwent TVT-O for USI and completed two validated QoL questionnaires, the Urogenital Distress Inventory (UDI-6) and Incontinence Impact Questionnaire (IIQ-7) preoperatively and at least 12 months postoperatively. We evaluated the subjective results of QoL questionnaires, objective results and compare the effect of QoL on those with surgical failure and complications after TVT-O surgery.

Results: A total of 78 women were followed for a median of 13.5 months (range 12–15 months) after surgery. Within this group, 75 (96%) were considered subjectively cured or improved after TVT-O. There were significant improvements in the IIQ-7 and total UDI-6 scores postoperatively, as well as in the UDI-6 subscales for urge, stress and voiding dysfunction symptoms. Even the 18 women with objective urodynamic failure had significant improvement in QoL scores. For those with surgical related complications, the QoL scores were also significantly improved.

Conclusions: TVT-O for USI resulted in improvement of incontinence-related QoL including urgency, stress, and voiding dysfunction symptoms. Surgical failure and complications didn't impair postoperative QoL.

Introduction

Stress urinary incontinence is a common problem affecting women's quality of life (QoL) in physical, social as well as hygienic aspects. According to the International Continence Society, stress urinary incontinence is defined as the complaint of involuntary leakage on effort or exertion, or on sneezing or coughing [1]. Women with stress urinary incontinence may suffer from involuntary urine leakage during daily activities. They may not drive or walk for long distances, travel by public transportation, running, and heavy lifting due to the leakage. Their abilities to do household chores are impaired. Women who fear leakage also limit their physical recreation, entertainment, and voluntary participation in social activities. For example, most feel embarrassed during exercise such as swimming, jogging because of the leakage. Outside social events are remarkably limited. They may feel frustrated which impacts their quality of life. Psychological impact is another important issue. The embarrassment, anxiety and physical discomfort pertaining to urinary leakage, urgency and difficulty in emptying bladder make them nervous and depression. In the USA, the prevalence of stress urinary incontinence is estimated to be 31% [2]. This estimate is similar in Asian countries, with a prevalence of 30% in Japanese women [3] and 34% in Chinese-Hong Kong women [4]. In Taiwan, the reported prevalence is 18.7% among women younger than 60 years [5] and 29.8% in those over 60 years [6]. Previous reports suggest that age is the main risk factor for stress urinary incontinence [2,4–6].

The tension-free vaginal tape (TVT) procedure was first introduced by Ulmsten et al., in 1995 [7], and has been proven effective

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https://doi.org/10.1016/j.tjog.2018.02.020

in treating stress incontinence. TVT resulted in a 90% objective cure rate after more than 10 years of follow-up [8], and became a standard surgical procedure for stress incontinence treatment. However, in 2003, de Leval introduced the tension-free vaginal tape-obturator procedure (TVT-O) to avoid complications associated with TVT. TVT-O reportedly has an excellent cure rate of 88.4% at 3 years postoperatively [9,10], and is increasingly accepted as the treatment of choice worldwide.

Depending on methodology and length of follow up, the short-term success of the TVT-O procedure ranges from 80% to 90%. In most studies, urodynamic study with a cough stress test and pad test have been used to determine objective outcomes. The common definition of objective cure of stress urinary incontinence is the absence of urine leakage during urodynamic stress test or negative cough test during pelvic examination and leakage of less than two grams in pad test. Subjective assessment is particularly crucial for a procedure that is performed specifically to improve QoL. Our previous studies reported subjective success rates of 74%–83% after a TVT-O operation [11–13]. In the current study using the same validated QoL questionnaires from previous studies, we further evaluated our data to examine the effect of the TVT-O operation on incontinence-related QoL and to investigate if surgical failure and complications impair postoperative QoL.

Materials and methods

We collect and maintain a database of women who were treated for stress urinary incontinence at the Mackay Memorial Hospital (Department of Obstetrics and Gynecology) in Taipei, Taiwan. For the study, we collected and analyzed data from women who underwent the Gynecare (Somerville, NJ, USA) TVT-O operation for USI. Informed consent for the surgery was obtained from all subjects. This research project was approved by the hospital ethics committee.

History, urinalysis, and pelvic examination with a cough test were performed at an outpatient clinic. Participants underwent preoperative investigation that included a complete multi-channel urodynamic study and a one-hour pad test to confirm the diagnosis and severity of urinary stress incontinence. Urodynamic study is generally used to confirm the diagnosis of urodynamic stress incontinence. Urodynamic study included free uroflowmetry, postvoid residual, filling and voiding cystometry, and a urethral pressure profile. The filling cystometry and urethral pressure profile were performed with 37 °C normal saline similar to body temperature at an infusion rate of 80 ml/min. A stress test was carried out during filling cystometry at which the subject with full bladder were instructed to cough strenuously to provoke leakage in both supine and standing position. Intrinsic sphincter deficiency (ISD) is a form of severe urinary incontinence with leakage and abnormally lower urethral pressure. Intrinsic sphincter deficiency was diagnosed if the Valsalva leak point pressure was less than 60 cm H_2O at a bladder volume of 200 ml. One-hour pad test is widely used to quantify the severity of urinary incontinence with leakage. Subjects were asked to drink approximately 500 mL of water one-hour prior to examination. Pre-weighted sanitary pads were used for the tests of urinary incontinence. Following this, subjects completed a series of activities such as coughing ten times, running in place for one minute, picking up an object from the floor, and washing hands. The urine loss was determined by the difference in the pre-versus post-use weight of the sanitary pads. It is well accepted worldwide that fewer than two grams of leakage in pad test was considered negative because of the sweat and vaginal discharge during the provocative activities mentioned above. More than two grams of leakage in pad test was considered positive for urinary incontinence. Urodynamic data were recorded and analyzed by MMS UD-200 (Medical Measurement System, Enschede, Netherlands). Urinary incontinence-related symptoms were assessed using the short form of the Urogenital Distress Inventory (UDI-6) and the Incontinence Impact Questionnaire (IIQ-7).The urodynamic study and one-hour pad test were performed by the same technician to reduce possible bias. The patients completed the questionnaires during preoperative and at follow-up urodynamic study at least one year after the surgery. If the patients had problems filling the questionnaires, one and the same investigator provided explanations each time.

The TVT-O procedure was performed in the manner described by de Leval [9]. The TVT-O is a minimally invasive anti-incontinence surgery and required approximately ten minutes during the entire procedure. General anesthesia with a laryngeal mask airway was used in women undergoing isolated TVT-O surgery. Postoperative follow-up visits were scheduled one week after discharge and at 3-month intervals within the first year and then yearly thereafter. Pelvic examination with a cough test and one-hour pad test were repeated at least six months after TVT-O and then one year postoperatively. Women were also asked to repeat a complete urodynamic study, although not all agreed to the examination. In addition, they all completed the UDI-6 and IIQ-7 again one year after the procedure.

Sample selection

Women complaining of stress urinary incontinence were offered the TVT-O operation if they had an urodynamic study-confirmed diagnosis of USI and urine leakage of over 10 grams on a one-hour pad test. We excluded women who had mixed incontinence (USI plus detrusor overactivity). For evaluating the effect of TVT-O procedure on QoL, those who underwent both TVT-O and pelvic reconstructive surgery for symptomatic pelvic organ prolapse were excluded. For reducing the selection bias that influenced the interpretation of the results, patients who were less highly educated, older, suffering from comorbid condition were also excluded. Only those who completed both symptom questionnaires and urodynamic study pre- and postoperatively and who were followed postoperatively for at least one year were included in the analysis.

Objective outcome and QoL measures

Objective cure was defined as the absence of urine leakage during an urodynamic study stress test and a negative cough test on pelvic examination. If either was positive, the procedure was deemed to have failed. Subjective cure was defined as the absence of symptomatic urinary leakage reported by a woman after surgery. Subjective improvement was defined as persistent minor incontinence but overall satisfaction with the operation. Women with persistent leakage and dissatisfaction were deemed to have subjective failure. QoL assessment was based on comparison of UDI-6 and IIQ-7 scores before and at least one year after surgery. UDI-6 and IIQ-7 are both incontinence-specific questionnaires [14]. The UDI-6 consists of six items and is divided into three domains with two items in each assessing symptoms of urge, stress, and voiding difficulty. The urge domain assesses the impact on frequent urination, urgent incontinence; the stress domain evaluates stress incontinence, small amounts of leakage; the voiding difficulty focuses on difficulty in emptying bladder, pain or discomfort in lower abdomen or external genitalia. The scores of UDI-6 ranged from 0 to 18. The IIQ-7 consists of seven items and evaluates ability to do household chores, physical recreation, entertainment activities, ability to travel for more than 30 min, social activities, emotional health and feeling frustrated. The scores of IIQ-7 ranged from 0 to

21. Each item of the two questionnaires has a scale that assessed how much the statement described the ability of the respondent: none, slightly, moderately and greatly. On both of these scales, a lower score indicates better QoL. These questionnaires have been previously evaluated to establish evidence of construct validity and test-retest reliability in women who were diagnosed with urinary incontinence [14,15].

Subgroups of patients were identified based on preoperative urodynamic study: those with pure USI and those with ISD. If a surgical complication occurred, this may have negative impact on QoL. Patients who presented with complications were included in the assessment of the effect of peri- and postoperative complications on QoL. Pre- and postoperative QoL scores were compared between subgroups of pure USI and ISD patients as well as patients with objective failure.

Statistics

Data are expressed as mean ± SD. For comparison of preoperative and postoperative variables, Wilcoxon signed rank test was used. The data were analyzed using SPSS 12.0 for Window (SPSS, Inc, Chicago, IL, USA). The level of statistical significance was set at $p < 0.05$.

Results

A total of 151 women had undergone the TVT-O procedure in the study period, of which 78 subjects met inclusion criteria and had adequate data for analysis. The demographic characteristics of subjects included in this study are listed in Table 1. The postoperative QoL questionnaires were completed between 12 and 15 months with a median of 13.5 months after surgery. The pure USI group comprised 60 women. The intrinsic sphincter deficiency group contained 18 women.

Subjective and objective outcomes

Sixty out of 78 subjects reported that they were completely dry after surgery, indicating a subjective cure rate of 76.9%. Another 19.2% (n = 15) had improvement, while the remaining 3.9% (n = 3) had subjective failure and required continuous pad protection postoperatively.

For objective assessment with urodynamic study, 60 out of 78 subjects were completely dry during urodynamic study and the one-hour pad test. This indicates an objective success rate of 76.9%. Of the 18 subjects with objective failure, 8 subjects reported subjective failure. However, the remaining 10 subjects reportedly felt they had satisfactory improvement after the operation. The urinary leakage in pad test was significantly reduced after operation in each study group (Table 2).

Table 1
Demographic characteristics of the subjects included for analysis (N = 78).

Age (years)	54.6 ± 10.9 (34–79)
Parity	3.3 ± 1.5 (1–9)
BMI (kg/m^2)	24.8 ± 2.3 (19.5–29.9)
Post-menopause	49 (62.8%)
Diagnosis	n (%)
Pure USI	60 (76.9)
ISD	18 (23.1)
Previous surgery	n (%)
Anti-incontinence	1 (1.3)
Prolapse	4 (5.2)
Hysterectomy	1 (1.3)

Table 2
Results of the 1-h pad test (gm).

Group	n	Before operation	After operation	P[a]
USI	60	37.2 ± 24.9	2.1 ± 6.4	<0.001
ISD	18	45.1 ± 27.3	7.8 ± 15.7	<0.001
Failure	18	30.3 ± 24.3	10.1 ± 12.3	0.002

[a] Wilcoxon signed rank test, p value < 0.05 was considered statistically significant.

QoL assessment

The QoL scores of IIQ-7 and UDI-6 in all three subscales significantly improved after TVT-O (Table 3). In the urodynamic study-based subgroups, the scores improved significantly (Table 4). Even in the objective failure group, QoL scores showed significant improvement (Table 5).

Complications

Complications occurred in nine patients, including tape extrusion in one and culture-proven urinary tract infection in another. Three had transient postoperative urinary retention, while four had de novo detrusor overactivity. All scores assessed improved significantly, except for the voiding difficulty subscale.

Discussion

Among the urodynamic study-based USI and intrinsic sphincter deficiency subgroups of women who underwent the TVT-O procedure, there was a significant improvement in the QoL scores postoperatively, including the overall IIQ-7 and UDI-6 scores and in the three subscales of the latter. These results are comparable with those from TVT operations reported by Vassallo et al. [16].

Most previous studies of anti-incontinence surgery have focused primarily on objective results. While it is important to ensure that a surgical procedure adequately addresses the anatomic and physiologic problems, women are concerned about the psychological and social effects of incontinence as well as the physical component. UDI-6 and IIQ-7 are both incontinence-specific questionnaires. They are widely used to evaluate the impact of incontinence on perceived quality of life. In the current study, the total IIQ-7 and UDI-6 scores and the three UDI-6 subscales decreased significantly after TVT-O, suggesting a significant improvement in perceived QoL. These results were consistent with the patients' own assessment of satisfaction with the procedure (76.9% indicating subjective cure and 19.2% indicating subjective improvement with a total 96% of satisfaction within the total patient sample group). These findings are consistent with the results of TVT and other transobturator sling procedures reported previously [17–21]. For objective assessment, the leakage was significantly reduced in one-hour pad test after operation in all study groups. This was consistent with the reduction of postoperative

Table 3
Quality of life scores in 78 women before and after surgery for incontinence.

Scale	Pre-op	Post-op	P[a]
IIQ-7[b]	8.6 ± 5.2	2.4 ± 4.5	<0.001
UDI-6[c]	7.8 ± 4.2	2.8 ± 3.1	<0.001
Urge subscale	2.6 ± 1.8	0.9 ± 1.2	<0.001
Stress subscale	3.2 ± 1.6	0.6 ± 1.2	<0.001
Voiding difficulty subscale	1.9 ± 1.6	1.2 ± 1.4	<0.001

[a] Wilcoxon signed rank test, p value < 0.05 was considered statistically significant.
[b] IIQ-7: short form of the Incontinence Impact Questionnaire.
[c] UDI-6: short form of the Urogenital Distress Inventory.

Table 4
Pre- and postoperative quality of life scores in 78 women with subtypes of preoperative urodynamic stress incontinence.

Scale	USI (n = 60)			ISD (n = 18)			with post-operative complications (n = 9)		
	Pre	Post	P[a]	Pre	Post	P[a]	Pre	Post	P[a]
IIQ-7[b]	8.3 ± 5.2	2.5 ± 4.4	<0.001	9.5 ± 5.2	1.9 ± 4.8	0.001	10.7 ± 4.7	2.7 ± 5.9	0.008
UDI-6[c]	7.7 ± 3.8	3.0 ± 2.8	<0.001	8.1 ± 5.5	2.2 ± 4.0	0.002	7.8 ± 4.5	3.3 ± 4.9	0.024
Urge	2.5 ± 1.7	1.0 ± 1.1	<0.001	3.0 ± 2.1	0.7 ± 1.3	0.001	3.3 ± 2.0	1.1 ± 1.6	0.007
Stress	3.3 ± 1.5	0.6 ± 1.0	<0.001	3.0 ± 2.0	0.6 ± 1.7	0.002	3.4 ± 1.8	1.0 ± 1.8	0.011
Voiding difficulty	1.9 ± 1.6	1.3 ± 1.4	0.008	1.9 ± 1.7	0.8 ± 1.0	0.015	1.1 ± 1.4	1.2 ± 1.6	0.799

[a] Wilcoxon signed rank test, p value < 0.05 was considered statistically significant.
[b] IIQ-7: short form of the Incontinence Impact Questionnaire.
[c] UDI-6: short form of the Urogenital Distress Inventory.

Table 5
Pre- and postoperative quality of life scores 18 of 78 women with objective surgical failure.

Scale	Pre-op	Post-op	P[a]
IIQ-7[b]	8.9 ± 6.1	2.1 ± 3.5	<0.001
UDI-6[c]	8.1 ± 3.5	2.6 ± 3.1	<0.001
Urge subscale	2.8 ± 1.4	0.9 ± 1.1	<0.001
Stress subscale	3.6 ± 1.6	1.1 ± 1.6	<0.001
Voiding difficulty subscale	1.6 ± 1.3	0.5 ± 0.8	0.003

[a] Wilcoxon signed rank test, p value < 0.05 was considered statistically significant.
[b] IIQ-7: short form of the Incontinence Impact Questionnaire.
[c] UDI-6: short form of the Urogenital Distress Inventory.

scores which reflected improvement in quality of life during subjective assessment. Even in the failure group, the leakage was reduced as well. The incontinence-related QoL scores were also significantly improved in the failure group. This may explain why the ten objective failure subjects reported satisfaction with the surgery. According to the result, the repeated anti-incontinence surgery is suggested for those with subjective failure and impaired postoperative QoL rather than just objective failure.

The overall subjective success rate (96%) in our study was higher than the objective success rate (76.9%) in the women who underwent postoperative urodynamic study. This objective success rate in our study was lower than that reported in an earlier study by Lim and colleagues [21]. In this earlier study, the objective success rate (95%) was higher than the subjective success rate (92%) after TVT-O [21]. There are several possible reasons for this discrepancy. First, our inclusion criteria were quite strict in that the procedure was only performed in women with more than 10 gm of urine on a one-hour pad test. Similarly, objective success required no leakage during both the urodynamic study stress test and the cough test during pelvic examination. Secondly, both these tests to provoke leakage were quite strenuous, more so than many women would experience during their normal daily activities. Hence, a positive stress test in the clinic did not necessarily indicate that the woman actually had frequent stress incontinence. Thirdly, even women with objective failure had relatively minor leakage and so felt that their QoL had improved after the operation.

All types of anti-incontinence surgery carry the risk of postoperative voiding dysfunction, urinary retention, and de novo urge incontinence. These are considered side effects and may result in a negative impact on QoL. We found, however, that the urge and voiding difficulty subscale scores improved after TVT-O. This suggests that TVT-O may be less likely to cause postoperative voiding dysfunction and de novo lower urinary tract symptoms than other procedures, although such an assertion could only be proved by performing a controlled comparison of procedures that would likely be very difficult to do. At least it is clear that the subjective result in this case was comparable to the objective outcome of de novo detrusor overactivity.

There were some limitations of this study. First, there were only nine patients for QoL assessment in the complication subgroup. According to the result of the nine subjects, 6.0 points of mean difference (effect size) and standard deviation is 5.6, the power reached 80% with alpha set at 0.05 (using software—Sample Power 2.0). Second, because the outcomes were assessed only one year after surgery, follow-up is needed to confirm long-term outcomes.

In conclusion, the TVT-O procedure for stress urinary incontinence had a good subjective outcome in women who were followed for one year after operation. Post-operatively (1 year+), the procedure resulted in subjective and objective improvement for incontinence-related QoL including stress, urgency, as well as voiding dysfunction symptoms. Surgical failure and complications didn't impair postoperative QoL.

Conflicts of interest

The authors have no conflicts of interest relevant to this article.

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