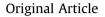
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Did surgical failure and complications affect incontinence-related quality of life in women after transobturator sling procedure?



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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 uro-dynamic 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.

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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

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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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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 shortterm 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 H₂O 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 3month 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 studyconfirmed 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 Download English Version:

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