

"U-Method" TVT-Secur Slings: Are they obstructive?

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Cite as: *Can Urol Assoc J* 2012;6(2):e104-107. <http://dx.doi.org/10.5489/cuaj.11124>

Abstract

Introduction: The TVT-Secur, a single incision sling, was introduced in 2006. It is implanted using either the "hammock" or the "U-method" technique. With the latter, the sling is tightened to create a "pillowing effect" on the urethra until a negative stress test is obtained. Short-term results seem promising. However, no study has ever reported on the voiding pattern 12 months after its implantation. Our objective was to assess whether the "U-method" technique creates an obstructive voiding pattern on pressure-flow study (PFS) 12 months after the surgery.

Methods: In this retrospective study, we reviewed the charts of 33 women who underwent the "U-method" TVT-Secur. Patients were evaluated before and 12 months postoperatively with regard to different urodynamic studies (UDS). The incontinence status was also assessed 12 months after surgery.

Results: At 12 months after the operation, 12.5% (4/32) of the patients reported an improvement of their stress urinary incontinence, while 78.1% (25/32) reported being cured from it. The objective cure rate was 63% (19/30). One patient had a suspected bladder outlet obstruction (BOO) based on PFS. Maximal flow rate (Q_{max}) was significantly lower 12 months after surgery (26.0 mL/s [range: 19.0-36.5] vs. 21.5 mL/s [range: 16.0-32.3]). However, median voided volume was lower on the postoperative uroflowmetry (446 mL [range: 348-605] vs. 320 mL [range: 243-502]). Furthermore, none of the patients complained of voiding symptoms after surgery.

Conclusions: Although one patient had findings compatible with BOO, none complained of voiding symptoms. TVT-Secur may result in a lower Q_{max} . However, this finding may be due to a lower voiding volume on the postoperative UDS.

Introduction

Several treatment modalities exist for stress urinary incontinence (SUI), including pelvic floor physiotherapy and surgical interventions. The efficacy of the tension-free vaginal tape (TVT) has been demonstrated^{1,2} and it is now considered the gold standard in the management of SUI. However, because

of the blind passage of the needle through the retropubic space, it is associated with significant potential complications.³ In 2001, transobturator tapes (TOT) were introduced to lower the number of bladder perforations and vascular injuries associated with TVT.⁴ To further decrease the complication rate, the TVT-Secur (Gynecare, Ethicon, Somerville, NJ) was introduced in 2006. Two surgical techniques are presently used for its implantation: the "U-method" and the "hammock" method. A better clinical outcome using the "U-Method" has been reported,⁵ although other studies found no difference between both techniques.^{6,7}

No matter which technique is used, it is recommended to maximally tighten the sling to create a "pillowing effect" on the urethra (filling of the tape pores with suburethral tissue) until obtaining a negative stress test because the tape does not retract as much as its longer counterpart⁸ and is pushed on the tissues rather than pulled.

The short-term results on the safety and efficacy of the procedure seems promising.⁹⁻¹¹ However, no study has assessed the effect of the "U-method" on voiding patterns 12 months after its implantation. The objective of this study was to assess whether the "U-method" creates an obstructive voiding pattern on the urodynamic studies (UDS) 12 months after implantation.

Methods

After institutional review board approval, we reviewed the charts of 33 patients who underwent the implantation of the "U-method" TVT-Secur at our centre between October 2007 and April 2009. Charts were reviewed for incontinence status, urodynamic findings, subjective voiding symptoms and satisfaction rate. Preoperative assessment included a history and physical examination, the evaluation of the Stamey score and the presence of voiding symptoms (Table 1).

Patients were evaluated before and 12 months after the surgery with regard to different UDS parameters, which included a non-intubated uroflowmetry (UFM), postvoid residual urine volume (PVR), filling cystometrogram (CMG), pressure-flow studies (PFS) and valsalva leak point pressures (VLPP).

Definitions and units of urodynamics conformed to the standards of the International Continence Society.¹² UDS were performed with patients in a sitting position; UFM was performed before urethral instrumentation. CMG and PFS were performed through a 6 Fr catheter. VLPP was defined as the lowest intravesical pressure at 200 mL of bladder capacity during valsalva that produced urine leakage. If no urinary leakage was observed, the procedure was repeated at 300, 400 mL or at maximal cystometric capacity. Bladder outlet obstruction (BOO) was defined as a combination of a Maximal flow rate (Q_{\max}) ≤ 12 mL/s and a detrusor pressure (P_{\det}) $Q_{\max} \geq 25$ cm H₂O.¹³

Preoperative SUI was confirmed by UDS and a cough stress test. Urge incontinence (UUI) was defined as any leakage of urine immediately preceded or accompanied by urgency before reaching the toilet. It was rated on a validated Likert scale.

The TVT-Secur was implanted by a single surgeon (LMT) using the "U-Method" technique. Procedures were performed under local anesthesia and light sedation. A cystoscopy was performed at the end of the procedure. A thorough description of this procedure is available.¹⁴ The patients were discharged on the same day after spontaneous voiding.

Routine follow-up was performed after surgery. At 12 months follow-up, patients were evaluated with regard to the occurrence of a complication, their incontinence status, the presence of voiding symptoms and their satisfaction rate (assessed on a scale of 0-100%). UDS was also repeated. The controlled UDS was explained to patients prior to undergoing the surgery as part of the follow-up. It was decided to proceed as such because at the time of installation, the TVT-Secur was a relatively new technique with a limited number of studies. Its maximal tensioning against the urethra and its potential underlying effect on the voiding pattern were worrisome to the surgeon. It was thus decided to proceed to an UDS 1 year after surgery to insure that no patient had a "subclinical" obstruction which could have resulted in serious long-term complications.

The objective cure rate was defined as no leakage at all

during the VLPP studies. Subjective cure rate was defined as no reported SUI at the 12-month visit. while the significant subjective improvement rate was defined as an improvement of more than 75% of the initial symptoms.

SPSS version 17.0 software (SPSS Inc, Chicago, IL) was used to analyze and compare the data. Data were summarized using the adequate descriptive statistics. The baseline and 12-month urodynamic findings were compared using either the Wilcoxon signed-rank test or the Student *t* test for the continuous variables. The McNemar test was used to compare categorical variables. A *p* value of less than 0.05 was considered statistically significant.

Results

The mean age of the population was 63 ± 9 years. SUI was the main diagnosis in 51.5% (17/33). The preoperative mean protections per day were 2.7 ± 1.4 . Six patients had a previous anti-incontinence surgery: 2 Burch urethropexies, 2 Marshall-Marchetti-Krantz procedures, 1 TVT and 1 Mentor ObTape Sling (Table 2).

The 12-month visit was attended by 97% (32/33) of the patients; 1 patient died of an unrelated cause during the follow-up. The median satisfaction rate was 98% (range: 50-100). The subjective cure and improvement rate of the SUI was 78.1% (25/32) and 12.5% (4/32), respectively (Table 3). Fewer patients ($p < 0.001$) complained of UUI in the postoperative group (7/32) than in the preoperative group (16/33). Of the patients with postoperative UUI, 3 had no associated postoperative SUI, while 4 showed an improvement of their SUI. The mean protection per day was reduced to 0.44 ± 0.5 ($p < 0.001$) and 93.8% of the women had an improvement of at least 1 Stamey score 12 months after surgery.

The 12-months UDS was completed by 91% (30/33) of patients. Two patients refused the UDS; one patient was not happy with the surgery and the other moved out of town but reported an improvement. The third patient, as previously stated, died during the evaluation period. The objec-

Table 2. Characteristics of the patients

No. patients	33
Mean age, yr (\pm SD)	63 (\pm 9)
Body mass index, mean (\pm SD)	27 (\pm 4)
Type of incontinence, no.	
• Urodynamic SUI	17/33 (51.5%)
• Mixed urinary incontinence	16/33 (48.5%)
Prior vaginal surgery, no.	
• Anti-incontinence surgery	6/33 (18.2%)
• Pelvic prolapse repair	0/33 (0%)
• Hysterectomy	16/33 (48.5%)
Mean protection per day (\pm SD)	2.7 (\pm 1.4)
OR time, mean in minutes (\pm SD)	35 (\pm 4)

SD: standard deviation; SUI: stress urinary incontinence; OR: operating room.

Table 1. Questions to assess voiding symptoms

How often have you had a sensation of not emptying your bladder completely after you finish urinating?
How often have you had to strain to begin urination?
How often have you found you stopped and started again several times when you urinated?
How often have you had a weak urinary stream?

Table 3. Subjective results at 12 months follow-up

Diagnosis (n)	Overall UI cure rate	SUI cure rate	SUI improvement rate
SUI (17)	13 (76.5)	13 (76.5)	2 (11.8)
MUI (15)	9 (60.0)	12 (80.0)	2 (13.3)
Total (32)	22 (68.8)	25 (78.1)	4 (12.5)

UI: urinary incontinence; SUI: stress urinary incontinence; MUI: mixed urinary incontinence. Data are n (%) unless otherwise indicated.

tive cure rate was 63.3% (19/30). The mean Q_{\max} and the median PVR were lower for the postoperative UDS than for the preoperative UDS ($p = 0.02$ and $p = 0.01$, respectively) (Table 4). However, voided volume during the postoperative UFM was significantly lower ($p = 0.03$). Overall, there was no difference in the mean $P_{\det} Q_{\max}$ before and after surgery. One patient (3.1%) showed UDS parameters compatible with BOO ($Q_{\max} = 7$ mL/s and $P_{\det} Q_{\max} = 34$ cm H₂O) but she did not present a significant PVR (80 mL) nor did she complain of any voiding symptoms. None of the other patients complained of subjective voiding symptoms. Two patients showed de novo detrusor overactivity on the 12-month UDS.

Complications were noted in 9 of the 33 patients (27%). The most common complication was urinary retention, which occurred in 4 (12%) and lasted between 2 to 14 days. Their mean PVR on the controlled UDS was 22.8 mL (range: 0-75). Urinary tract infections occurred in 2 patients (6%). Pain was a complaint in 3 patients (9%) and was treated with narcotics and anti-inflammatory. It resolved spontaneously in 2 patients, while the other patient still complained of atypical generalized pain at the 12-month follow-up visit. Finally, 1 patient complained of de novo UUI. No bladder perforation, urethral erosion or vaginal extrusion was reported.

Discussion

To our knowledge, this is the first study that evaluates the 12-months effect of the 'U-method' on PFS. Even though our results show that the surgery did not alter the $P_{\det} Q_{\max}$, it did lower the Q_{\max} by several millilitres. However, it is important to mention that this could only be the result of a lower voided volume on the controlled UDS as none of the patients complained of diminished urinary flow. No explanation could be found for the lower voided volume and PVR as the same instructions were given to all patients before the UDS.

Krofta and colleagues compared the preoperative and 12-month postoperative UDS of 82 women operated using the "hammock technique."¹⁵ No statistically significant differences were seen between the parameters. Lee and colleagues assessed the UFM of patients operated with TVT-Secur 1 week after surgery and also found no differences between the parameters.¹⁶ Furthermore, Lim and colleagues published their experience with the "U-method." At the 6-month follow-up, they found no significant differences

in the UFM between the postoperative and preoperative parameters.¹⁷ However, 3 of their cases showed postoperative voiding difficulty. These patients may have suffered from BOO, although there is currently no consensus on the definition of BOO in women. Several definitions have been proposed,^{13,15,18-21} but the one most often used is the one proposed by Defreitas and colleagues.¹³ Their definition of BOO is a combination of $Q_{\max} \leq 12$ mL/s and $P_{\det} Q_{\max} \geq 25$ cmH₂O. In our study, 1 patient had findings compatible with BOO. However, she did not complain of voiding symptoms nor did she present with significant PVR. For this reason, it is unlikely that this patient suffered from BOO.

Other studies assessed the effect of the more conventional slings on PFS. Wang and colleagues compared the TOT (Monarc TOT, American Medical Systems, Minnetonka, MN) and the suprapubic arc (Sparc) sling and concluded that both procedures did not result in BOO.²² Natalin and colleagues reported that the incidence of BOO with autologous slings was 0.9%.²³ Hsiao and colleagues compared the preoperative and postoperative UDS in patients who underwent the TVT or TOT (Monarc) procedures.²⁴ No significant differences were observed between both procedures with regard to their impact on bladder voiding and storage functions, although the TOT did lower the Q_{\max} (-2.4 mL/s) on the 12-month follow-up UFM.

The success rate of the TVT-Secur is generally between 58% and 85%,^{6-11,15,16,25} although a success rate as high as 94.6% has been reported.⁹ Its success rate is generally lower than the more conventional slings, with success rates around 90% to 92% for the TVT and between 87% and 90% for the TOT.^{6,15,26} Our subjective success rate (90.6%) is higher than those generally described with the "U-method" TVT-Secur and similar to the other conventional slings. This may be because we only performed the "U-method," although conflicting data exist regarding the better outcome of one technique over the other.^{5-7,16}

No major complications were reported during the procedures. However, there was a higher occurrence of transient urinary retention (12%) than in previous studies,^{6,10,11} which reported rates of less than 1%, but comparable to the other conventional slings.¹¹ Only one patient (3%) reported UUI 12 months after surgery, which is lower than the rates in previous studies which varied from 7% to 12%.^{10,16,25} One patient (3%) was still complaining of pain 12 months after surgery. However, the pain was generalized and unlikely related to the surgery.

Although there are some drawbacks to this study, such as its small number of patients, the high proportion of women suffering from mixed urinary incontinence and its lack of quality of life questionnaires, it does have a 1-year follow-up and compares preoperative and postoperative PFS; to our knowledge, this comparison has never been done before in women who underwent the "U-method" TVT-Secur.

Table 4. Comparison between baseline and 12-month UDS

	Baseline	12-month	P values
PdetQmax (cmH ₂ O)	19.0 (15.3-54.8)	18.0 (5.3-36.0)	0.18
Maximal urethral closure pressure (cmH ₂ O)	33.5 (23.5-39.4)	34.0 (23.0-55.0)	0.31
Voided volume (mL)	446.5 (348.3-605.3)	320 (243.3-502.8)	0.03
Qmax (mL/sec)	26.0 (19.0-36.5)	21.5 (16.0-32.3)	0.02
Postvoiding residual volume (mL)	21.0 (0-38.5)	4.0 (0-25.0)	0.01
Filling cystometrogram			
• Maximal cystographic capacity (mL)	495.0 (±154.0)	485.0 (±143.3)	0.07
• Detrusor overactivity	0/32	2/29	0.22

Qmax: Maximal flow rate; UDS: urodynamic studies, PdetQmax: detrusor pressure maximal flow rate.

Conclusion

TVT-Secur represents an appropriate option for patients suffering from SUI. Despite its tighter placement against the urethra in comparison to its longer counterpart, it did not result in BOO in most cases, although it did lower the Q_{\max} . However, this may be the result of a lower voided volume on the controlled UDS, as none of the evaluated patients complained of obstructive voiding symptoms.

Competing interests: None declared.

This paper has been peer-reviewed.

Acknowledgement: Special thanks to Tania Fayad, PhD.

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