Short term urgency outcomes following transobturator midurethral sling placement

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Introduction: *Research suggests that midurethral sling placement may have a beneficial effect on urgency (U) and urge incontinence (UUI). This study examined short term U/UUI outcomes in patients undergoing TVT-O placement.*

Methods: *One hundred patients undergoing TVT-O placement were prospectively assessed using 3 day bladder diary, combined with multiple validated incontinence questionnaires focusing on UUI, U and QoL.*

Results: *At 6 week assessment, improvements in daily pad use (2.6 to 0.9) and incontinence episodes (3.6 to 0.7) were seen ($p < 0.05$, both comparisons). Eighty-two patients reported cure of stress incontinence. Focused outcome scores for UUI improved from 2.0 (± 1.1) to 0.8 (± 1.0) (p value < 0.001), with 39% and 29% of patients reporting score resolution and improvement, respectively. Similarly, mean Urinary Perception Score improved from 10.1 (± 4.4) to 5.8 (± 3.7) (p value < 0.001) with cure/improvement identified in 75%. Eighty-four patients did not require anticholinergics postoperatively. Interestingly, patients reporting residual SUI but improved UUI demonstrated QoL scores only slightly worse than patients with SUI cure and improved or persistent UUI.*

Conclusion: *TVT-O placement is associated with cure/improvement in a significant proportion of patients. In addition, significant improvement in QoL is seen following TVT-O placement.*

Key Words: urgency, urge Incontinence, midurethral sling

Introduction

The development of urgency symptoms following anti-incontinence surgery is a significant concern. The pubovaginal sling (PVS) is associated with postoperative reductions in flow rate and increases in detrusor pressures and postvoid residuals suggesting an obstructive effect.[1] A recent review identified rates of postoperative de novo and worsening urge urinary incontinence (UUI) following PVS to be as high as 18% and 74%, respectively.[2]

Similar concerns existed surrounding the introduction of the midurethral sling (MUS). However, important differences included placement in a tensionless fashion and a midurethral position. Such distinctions hypothetically avoided an obstructive action and the subsequent development of irritative effects on the bladder. Related investigation has demonstrated a low rate of postoperative UUI and urgency (U) to be associated with MUS placement.[2] However, even more promising was the somewhat unexpected finding that MUS placement was associated with significant improvement/resolution of UUI/U.

Several studies have studied the effect of MUS placement on symptoms of urgency and UUI, with the majority evaluating retropubic MUS types.[3-6] Segal et al reported resolution of UUI/U following TVT placement in 63% and 57% of patients, respectively. Also, 58% of patients no longer required anticholinergic medication postoperatively.[4] Duckett and colleagues demonstrated subjective cure of urge symptoms and resolution of

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detrusor overactivity (DO) after TVT placement in 63% and 47% of patients at 6 month follow up, respectively.[5] Limited study has identified similar findings associated with transobturator sling types. Lim and associates examined outcomes 1 year after TVT-O, reporting a decrease in UUI from 59% to 35% with a rate of de novo UUI of 4.8%.[6]

Supporting this effect of the MUS is recent comparative analysis of PVS and MUS types. Accordingly, Botros et al assessed DO and overactive bladder (OAB) symptoms in a series of 340 patients undergoing PVS or MUS.[7] These authors identified a superior rate of DO resolution associated with MUS. In addition, a significantly higher rate of de novo DO was associated with PVS placement.

Despite these studies, limited investigation is present to specifically evaluate the effect of transobturator MUS types on U and UUI. Further, the vast majority of prior studies fail to utilize validated questionnaires to assess both U and UUI in a prospective fashion. The goal of this study was to examine short term U/UUI outcomes following TVT-O using multiple validated questionnaires. Additional goals were to assess quality of life (QoL) following TVT-O placement and to assess for potential differences in these outcomes in patients undergoing versus not undergoing concurrent pelvic organ prolapse (POP) surgery.

Materials and methods

This study comprised a prospective evaluation of 100 consecutive patients undergoing TVT-O (Ethicon Inc., Sommerville, NJ, USA) placement in the treatment of stress predominant mixed incontinence. The presence of urge incontinence was assessed by subjective clinician interview and assisted by formal questionnaire evaluation as described below. All patients underwent anticholinergic therapy prior to TVT-O placement, with a 4 week minimum washout period prior to questionnaire evaluation and/or TVT-O placement. Outcomes were assessed using 3 day bladder diary, combined with multiple validated questionnaires. Institutional review board approval was obtained (#2009-63).

TVT-O placement was done by a single surgeon under general anesthesia using standard technique as previously reported.[8] Patients undergoing concomitant POP repair were admitted for overnight observation. Remaining patients undergoing TVT-O placement alone were treated as outpatients. Foley catheters were removed on the morning following surgery. Patients undergoing outpatient procedures removed the Foley catheter at home. Postvoid residual was assessed at 5-7 days postoperatively in the absence of symptoms of retention in the immediate postoperative period.

Validated questionnaire evaluation comprised the International Consultation on Incontinence Questionnaire-Female Lower Urinary Tract Symptoms (ICIQ-FLUTS short form),[9] the Urgency Perception Score (UPS),[10] and the Incontinence Impact Questionnaire, short form (IIQ-7).[11] The ICIQ-FLUTS (short form) is a patient-completed questionnaire for evaluating female lower urinary tract symptoms and impact on quality of life, derived from the Bristol Female Lower Urinary Tract Symptoms Scored Form. The UPS questionnaire comprises items addressing the abnormal bladder sensation of urgency. The IIQ-7 is an empirically validated instrument assessing QoL that is commonly used in OAB/incontinence research. Additional items assessing patient satisfaction and level of improvement were included. Satisfaction and level of improvement were assessed using a dichotomous (yes/no) questionnaire item and scaled item (0-100%), respectively.

Baseline evaluation comprised full history, general physical examination, pelvic examination, urodynamic evaluation, 3 day bladder diary, and questionnaire administration. Follow up evaluation included abbreviated history, pelvic examination, 3 day bladder diary, and questionnaire evaluation, performed at 6 weeks postoperatively. The need for anticholinergic therapy was assessed on an ongoing basis, with changes in status updated as appropriate.

Data were analyzed with specific focus on changes in symptoms of urgency and related variables. Results were further analyzed based on the presence/absence of concomitant surgery for POP in order to identify differences in outcomes as based on this variable. Urgency and UUI were assessed separately using UPS total and ICIQ domain scores, respectively. Cure was defined in both cases as postoperative responses of 0. Improvement was defined as postoperative improvement in scores given a baseline score of greater than 0. Persistence was defined as a postoperative score being the same as recorded at baseline. De novo was defined as a postoperative score greater than 0, given a baseline score of 0. Patients classified as having de novo symptoms achieved study inclusion because they reported symptoms of urgency despite a ICIQ UUI questionnaire response of 0. Patients reporting complete absence of any SUI episodes were defined as achieving SUI cure.

Statistical analysis of data was performed using T test for dependent variables and Fisher's test. A p value less than 0.05 was considered statistically significant. Data are listed as mean (± standard deviation).

TABLE 1. **Patient demographics and characteristics**

	TVT-O (n = 53)	TVT-O/POP (n = 47)	Combined	p value
Age (y)	59.5 (± 13.6)	65.3 (± 16.6)	63.0 (± 13.2)	0.04
Follow up (m)	10.7 (± 4.6)	9.1 (± 4.8)	10.0 (± 4.7)	ns
Parity (n)	2.3 (± 1.2)	2.3 (± 1.1)	2.3 (± 1.7)	ns
Incontinence episodes (n/d)	4.7 (± 2.5)	2.4 (± 2.5)	3.6 (± 3.1)	< 0.01
Pads (n/d)	3.3 (± 1.9)	1.7 (± 1.9)	2.6 (± 2.5)	< 0.01
Concurrent surgeries (n)				
Cystocele repair		38		
Rectocele repair		11		
Sacrocolpopexy		4		
Hysterectomy		3		

POP = pelvic organ prolapse; ns = not significant (p > 0.05)

Results

One hundred patients were accrued for study analysis, undergoing sling placement between January 2009 and May 2010. Patient demographics are detailed in Table 1. Forty-seven patients underwent concomitant prolapse repair with TVT-O placement. Patients undergoing TVT-O without concomitant prolapse repair had lower mean age, baseline daily incontinence episodes and pad use.

Analysis of overall incontinence outcomes identified significant improvements in multiple outcome measures. Statistically significant improvements in daily pad use (2.6 to 0.9) and incontinence episodes (3.6 to 0.7) were observed (p < 0.001, both comparisons). Ninety-one percent of patients reported being satisfied with their surgery, with a mean subjective improvement of 84%.

Focus on measures of SUI identified 82% of patients that denied SUI under any circumstances. ICIQ-FLUTS domain score for SUI improved from 2.6 to 0.7, with the corresponding bother score improving from 7.0 to 2.0 (p < 0.001, both comparisons). Statistically significant improvement in quality of life was observed, with IIQ-7 scores improving from 9.8 to 2.9 (p < 0.001). Postoperative PVR increased from 24 to 36 cc (p = 0.03).

Analysis of outcomes focused on urgency is detailed in Table 2. Statistically significant improvements in ICIQ-FLUTS domain score for UUI and total UPS scores were observed, in addition to corresponding bother

TABLE 2. **Outcomes following TVT-O placement (n = 100)**

	TVT-O (n = 53)			Concomitant surgery (n = 47)			Combined (n = 100)		
	Preop	Postop	p value	Preop	Postop	p value	Preop	Postop	p value
ICIQ-FLUTS									
Urge	2.2 (± 1.0)	0.8 (± 1.0)	< 0.001	1.8 (± 1.2)	0.7 (± 1.1)	< 0.001	2.0 (± 1.1)	0.8 (± 1.0)	< 0.001
Urge bother	7.3 (± 2.8)	2.6 (± 3.1)	< 0.001	5.3 (± 3.9)	1.3 (± 2.8)	< 0.001	6.4 (± 3.5)	2.0 (± 3.1)	< 0.001
UPS									
Total	10.2 (± 4.1)	5.8 (± 3.2)	< 0.001	9.6 (± 4.6)	5.9 (± 4.2)	< 0.001	10.1 (± 4.4)	5.8 (± 3.7)	< 0.001
UPS bother	7.4 (± 2.0)	4.5 (± 2.9)	< 0.001	6.6 (± 2.9)	3.1 (± 2.9)	< 0.001	7.0 (± 2.5)	3.9 (± 3.0)	< 0.001
IIQ	8.9 (± 6.6)	3.4 (± 4.8)	< 0.001	9.0 (± 5.8)	2.4 (± 3.4)	< 0.001	9.8 (± 6.0)	2.9 (± 4.2)	< 0.001
PPD	3.3 (± 2.7)	1.0 (± 1.5)	< 0.001	1.7 (± 1.9)	0.8 (± 1.5)	0.001	2.6 (± 2.5)	0.9 (± 1.5)	< 0.001
Incontinence episodes	4.7 (± 3.3)	0.9 (± 1.5)	< 0.001	2.4 (± 2.5)	0.5 (± 1.3)	< 0.001	3.6 (± 3.1)	0.7 (± 1.4)	< 0.001

ICIQ-FLUTS = international consultation on incontinence questionnaire-female lower urinary tract symptoms; UPS = urgency perception score; IIQ-7 = incontinence impact questionnaire, short form

scores for each outcome measure. In the analysis of ICIQ-FLUTS domain score for UUI, 39% and 29% of patients reported score resolution (postoperative score = 0) or improvement. Similarly, mean UPS total score cure or improvement was identified in 77%. Based on ICIQ score, two patients met the criterion for de novo UUI. These patients were part of four patients with baseline ICIQ-FLUTS scores of 0 who were included given positive UPS scores and clinician evaluation suggesting the presence of UI. The majority of patients (84%) did not require anticholinergics during the mean follow up period of 10 months.

Statistical comparison of outcomes in patients undergoing concomitant prolapse surgery versus TVT-O alone was performed. No differences in postoperative values were seen in comparison of ICIQ-FLUTS domain score for UUI, in addition to total UPS, IIQ, and overall improvement scores ($p > 0.05$). A similar proportion of patients reporting postoperative satisfaction was observed ($p > 0.05$). Despite the previously described differences in baseline comparisons, no differences in postoperative daily pad use and incontinence episodes were seen ($p > 0.05$).

Analysis of subjective improvement and IIQ scores was performed as dependent on the postoperative presence or absence of SUI and ICIQ UUI outcome, Figure 1. Comparisons were performed in an attempt to assess how UUI status affected subjective improvement and QoL in both patients with or without SUI cure. Interestingly, patients reporting residual SUI but improved UUI demonstrated IIQ scores only slightly worse than those patients with SUI cure and improved or persistent UUI. Similar findings were seen when improvement levels were assessed as stratified by UUI outcomes. Of note, an overall satisfaction rate of 85% was identified in this same cohort of patients experiencing improvement or cure of UUI despite persistent SUI.

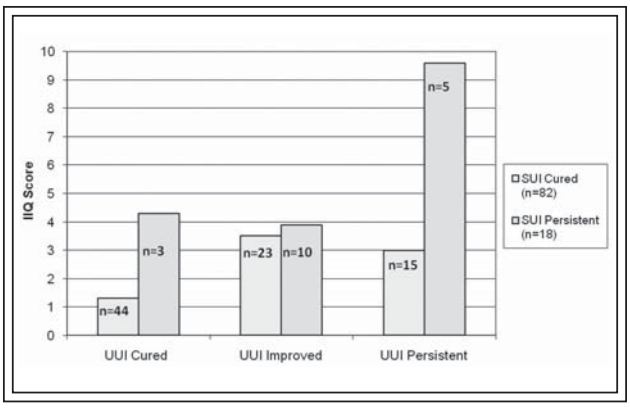

Figure 1. Effect of urge outcomes on IIQ scores.

Discussion

The goal of this study was to examine the short term effect of TVT-O on UUI/U in a prospective fashion using focused and validated outcome measures. These data demonstrate several important findings. Foremost, TVT-O placement appears to have a beneficial effect on UUI/U. In addition to significant improvements in multiple objective and subjective outcome measures, specific focus revealed resolution or cure of UUI and U in 68% and 77% of patients, respectively. Further, less than 10% of patients reported worsening UUI or U. Finally, the vast majority of patients did not require anticholinergic therapy during the follow up period.

These findings confirm previously described studies of MUS types and are important given that the majority of prior investigation comprises retropubic MUS types. Whether transobturator versus retropubic MUS are associated with differing degrees of UUI/U improvement remains to be seen. In a comparative study, Botros et al found that patients undergoing transobturator MUS had a lower rate of de novo UUI in comparison to patients undergoing TVT or SPARC procedures.[6] They did not find a statistically significant difference in resolution of DO or de novo DO. Further comparative study is needed to better assess this issue.

Second, the observed improvement in UUI/U may be associated with improved QoL. As expected, superior subjective improvement and QoL were seen in patients reporting cure of both SUI and UUI. Interestingly, patients reporting residual SUI but improved UUI demonstrated improvement and IIQ scores only slightly worse than those patients with SUI cure and improved or persistent UUI. The finding of satisfaction rates of 85% in this same cohort experiencing improvement or cure of UUI despite persistent SUI underscores the importance of UUI outcomes in patients undergoing surgery for SUI.

The impact of U on outcomes after sling surgery is documented previously. Fulford and colleagues found that only 78% of patients reported subjective satisfaction following PVS placement, despite 97% of these patients reporting cure of SUI.[1] This discrepancy was attributed to persistent urge syndrome. Combined, these findings confirm the importance of patient counseling. Nonetheless, despite the fact that our patients are specifically counseled preoperatively that improvement in UUI/U should not be expected following TVT-O, our data suggests that UUI/U outcome may impact QoL outcomes.

The long term effect of MUS on UUI/U is unknown. Limited study of TVT suggests that the duration of improvement in urge symptoms may not be as durable as SUI outcomes. Holmgren et al report a SUI cure rate of 80%-90% lasting through the 8 year follow up.[12] The reported cure rates in patients with mixed urinary incontinence was 60% and 30% at 3 and 8 year follow up, respectively, a finding attributed to the urge component. Further data is needed to assess this issue.

The mechanism underlying the observed improvement in UUI/U following MUS placement is unclear. Animal study identified the generation of detrusor contractions via saline infusion into the urethra.[13] A decrease in detrusor contractions was seen with cessation of infusion. The authors interpret these data as evidence of an afferent urethral bladder reflex and suggest this as a possible mechanism underlying the relationship between SUI and UUI. In additional study assessing outcomes after TVT in patients with OAB, Choe et al divided patients into cohorts with and without associated baseline DO.[14] They found that patients with DO demonstrated a higher rate of resolution of OAB, suggesting a possible beneficial effect of TVT placement on abnormal detrusor contractions.

However, investigation also demonstrates the lowest rate of persistent DO to be associated with transobturator slings, in comparison with retropubic and PVS types.[15] This finding is interpreted by the investigators to contradict the theory that the relationship between SUI and UUI is explained by a vesicourethral reflex as this would suggest the highest rate of DO resolution to be associated with PVS types. Despite other theories forwarding that superior DO improvement may be associated with the more modest vector of TO sling types, recent investigation does not demonstrate a difference in persistent or de novo UUI in comparison of transobturator (TVT-O and Monarc) versus the retropubic (TVT) slings.[16]

Multiple studies have attempted to identify predictors for persistence of UUI/U after sling procedures, focusing on baseline symptoms, anticholinergic use, urodynamic parameters, and sling type.[2] Accordingly, Gamble et al identified multiple demographic and objective variables associated with persistence of DO following sling placement.[15] These variables included older age, previous hysterectomy, hormone replacement therapy, and lower maximum cystometric capacity. Additional study has found such factors as sling type and videourodynamic findings to be associated with OAB persistence.[2] Conversely, there is a paucity of research specifically investigating predictors for resolution of UUI/U, with the presence of DO being identified as such a predictor.[2]

Several study limitations should be mentioned. First, differences in the baseline characteristics of the patients undergoing TVT-O alone versus with concomitant POP repair were present. The difference in pad and incontinence degree are not unexpected, given that incontinence degree is often less severe in patients undergoing POP repair, as slings may be placed to not only treat existent SUI, but also prevent worsening. Nonetheless, no differences in outcomes were identified in comparison of these groups. Study size also limited our secondary analysis given the small size of study cohorts experiencing persistent SUI. The study has a limited follow up, with most outcomes assessed uniformly at 6 weeks with the exception of anticholinergic use being assessed through the follow up period. However, the study was designed with this intent as we believe that focus on urge outcomes in the immediate postoperative period is important. Further follow up is ongoing and it will be interesting to assess for persistent of the observed benefits at 1 and 2 year endpoints. Further research is also needed to more clearly define the relationship between urge outcomes and other subjective markers such as patient satisfaction and degree of improvement. Despite these limitations, we believe our data contributes significantly to the literature given its prospective design, use of multiple validated questionnaire addressing UUI and U, primary outcome measure focus on UUI/U, and assessment of a transobturator MUS.

Conclusion

TVT-O placement is associated with cure or improvement in a significant proportion of patients. Also seen in this cohort is significant improvement in QoL, even in patients not achieving cure of SUI. Assessed outcomes were not different in patients undergoing versus not undergoing concurrent repair of POP. Longer term follow up is ongoing to assess for a durable effect to the observed improvement in UUI/U. □

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