Transobturator sling with intraoperative cough test is effective for patients with low valsalva leak point pressure

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ANAST JW, SKOLARUS TA, YAN Y, KLUTKE CG. Transobturator sling with intraoperative cough test is effective for patients with low valsalva leak point pressure. The Canadian Journal of Urology. 2008;15(4):4153-4157.

Objective: *The transobturator sling (TOS) is safe and effective for the treatment of female stress urinary incontinence (SUI). Controversy exists regarding its efficacy in patients with low valsalva leak point pressure (VLPP), a marker of intrinsic sphincter deficiency (ISD). We review our experience of TOS in the treatment of women with SUI and low VLPP.*

Methods: *Patients diagnosed with stress or mixed incontinence treated with TOS were identified by retrospective review. All procedures were performed with local anesthesia and intravenous sedation. Stress incontinence and VLPP were determined preoperatively with urodynamic testing. Chart review identified demographics, perioperative variables, complications, and subjective cure. Low VLPP was defined as VLPP less than 60 cm H_2O.*

Results: *From November 2003 to February 2006, 151 consecutive women underwent TOS. Twenty-seven patients were excluded who exhibited incontinence with cough but not valsalva on preoperative urodynamic testing. Of the remaining 124 patients, 29% had low VLPP and 71% had higher VLPP. There was no difference in subjective cure between patients with low (94%) and higher VLPP (84%) overall ($p = 0.12$) or in patients with 12 months or more of follow-up (93% versus 79%, $p = 0.40$). Patients with low VLPP were more likely to be older ($p = 0.036$), and have pure SUI ($p = 0.019$).*

Conclusions: *TOS is effective for patients with low VLPP. Women with SUI and ISD without a fixed urethra should be considered candidates for TOS. The use of intravenous sedation during sling placement allows the surgeon to perform an intraoperative cough test, permitting tensioning of the TOS in relation to the patient's ISD.*

Key Words: stress urinary incontinence, Trans-Obturator Tape, conscious sedation, treatment outcome

Introduction:

Stress urinary incontinence (SUI) is a common condition in females, with a 10%-35% lifetime incidence.[1] Over the past decade, the mid-urethral sling has become the primary treatment for female SUI. The transobturator sling (TOS) is a recent evolution of the mid-urethral sling that has proven to be safe and effective for the treatment of SUI.[2] Controversy exists regarding the efficacy of the TOS for patients with low valsalva leak point pressure (VLPP), a predictor of intrinsic sphincter deficiency (ISD).[3] We review our experience of TOS in the treatment of women with SUI and low VLPP.

Accepted for publication June 2008

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Materials and methods

Female patients diagnosed with stress or mixed incontinence treated with TOS treated between November 2003 and February 2006 were identified by retrospective review. Patients were not offered a sling if they had a fixed urethra (defined as less than 15 degrees mobility on a cotton swab test), severe urge incontinence, or urinary retention. Institutional review board approval was obtained. Preoperatively, all patients underwent urodynamic testing. Cystometry was performed using sterile saline at a constant infusion

medium filling rate of 60 ml/min through a double lumen 7 FR catheter with rectal pressure monitoring and the patient sitting in a position of reverse Trendelenburg. Presence or absence of stress incontinence with cough was noted at 100 ml bladder volume increments. VLPP was measured at 150 ml of bladder filling. "Low VLPP" was defined as VLPP less than 60 cm of water.[4]

After obtaining informed consent, patients underwent woven prolene mesh TOS placement via the "outside-in" technique (ObTape, Coloplast Surgical, Humlebaek, Denmark). Patients received intravenous (IV) sedation consisting of 2 mg intravenous midazolam in the preoperative holding area, 100 mcg intravenous fentanyl during positioning on the operative table, followed by a propofol infusion at the onset of the procedure. Patients were placed in the hyper-lithotomy position, and 10 ml of 0.25% ropivacaine was injected along the anticipated anterior vaginal and medial thigh incisions. Incisions were made vertically on the anterior vaginal wall in the middle third of the urethra, and on both medial thighs. Local anesthetic consisting 20 ml of 0.25% ropivacaine was then injected into the intervening soft tissue between the anterior vaginal wall and each perineal exit site through the obturator foramen. The paraurethral space was bluntly dissected, and the introducer needle was passed from the medial thigh through the obturator foramen and out the vaginal incision. The sling was attached to the introducer and rotated out the medial thigh incision. The passage of the introducer needle and sling was then repeated on the contralateral side. Next, the patient's bladder was filled with saline (either 250 ml or the volume the patient demonstrated leak during urodynamic testing, whichever was greater) and the patient was placed in reverse Trendelenburg position and instructed to vigorously cough while the sling tension was slowly increased by advancing the sling through the thigh incisions. The tension on the sling was increased up to the point at which the patient no longer leaked with coughing. If blood was noted in the urine after sling placement or if sling placement was technically difficult, flexible cystoscopy was performed, and the sling was replaced if bladder penetration by the sling had occurred.

Statistical analysis was performed with SAS System software (SAS Institute, Cary, North Carolina). Comparison between the two groups was performed with the chi-square test, Fisher's exact test for categorical variables and Student t-test or non-parametric Wilcoxon test for continuous variables when appropriate.

Chart review identified demographic data, perioperative variables, complications, and subjective cure. Patients were followed at 1 month, 6 months, and then yearly after surgery. Postoperative post-void residuals were not routinely checked unless the patient was symptomatic (urinary retention, slower stream, or new onset urgency/frequency). "Cure" was defined as no subjective leakage of urine with cough or strain and no use of pads. "Improvement" was defined as some subjective improvement in leakage with cough or strain or decreased number of pads.

Results

One hundred fifty-one consecutive women underwent TOS for SUI. Twenty-seven patients could not be categorized who exhibited incontinence with cough but not with valsalva on preoperative urodynamic testing, leaving 124 patients for further analysis. Demographic data is listed in Table 1. Thirty-six (29%) patients had low VLPP (< 60 cm H_2O) and 88 (71%) patients had

TABLE 1. **Demographic and operative data**

	VLPP < 60 cm H_20	**VLPP > 60 cm H_20**	**p value**
Patients treated	36	88	
Age, (years, mean, +/- 95% CI)	60 +/- 4.5	55 +/- 2.3	0.036
Mixed incontinence	7/35 (20%)	37/87 (43%)	0.019
Prior vaginal delivery	23/36 (63%)	53/88 (60%)	0.84
Prior hysterectomy	21/36 (58%)	51/88 (58%)	0.97
Prior pelvic surgery	6/36 (17%)	22/88 (25%)	0.32
Prior incontinence surgery	12/36 (33%)	19/88 (22%)	0.17
Blood loss (ml, mean +/- 95% CI)	27 +/- 4	32 +/- 3	0.06
Intraoperative complication	1/36 (3%)	5/88 (6%)	0.67

TABLE 2. **Postoperative and follow-up data**

	VLPP < 60 cm H_20	VLPP > 60 cm H_20	p value
Patients cured at 1+months follow-up	34/36 (94%)	74/88 (84%)	0.12
Patients cured at 12+months follow-up	13/14 (93%)	26/33 (79%)	0.40
Patients improved or cured at 1+ months follow-up	35/36 (97%)	80/88 (91%)	0.22
Patients improved or cured at 12+ months follow-up	13/14 (93%)	30/33 (91%)	0.83
Postoperative complication	4/36 (11%)	25/88 (29%)	0.017
Second procedure performed	2/36 (6%)	10/88 (11%)	0.51
Follow-up, months, mean (range)	10.3 (1-33)	11.7 (1-33)	0.40

higher VLPP, Table 1. Patients with low VLPP were more likely to be older (60 versus 55 years, p = 0.036). Prior pelvic and incontinence surgery rates were similar between both groups. Patients with higher VLPP were more likely to have mixed urge and stress incontinence prior to treatment (43% versus 20%, p = 0.019).

There was a non-significant trend for patients with low VLPP to have less surgical blood loss (27 versus 32 ml, p = 0.06). Intraoperative complications were rare and limited to bladder penetration by the sling introducer needle in six cases with no difference between the low and higher VLPP groups (3% versus 6%, p = 0.67). In each case, a Foley catheter was left indwelling for 1 to 5 days, followed by removal and no additional complaints.

There was no difference in the subjective cure rates between patients with low (94%) and higher VLPP (84%) (p = 0.12) at a mean of 10.7 months postoperatively, Table 2. Likewise, for patients followed for 12 months or more, there was also no difference in subjective cure rate (93% versus 79%, p = 0 .40). Patients reporting either cure or improvement in stress leakage were similar in both groups (97% for low VLPP versus 91% for higher VLPP, p = 0.22). Patients followed for 1 year or longer also had similar rates of either improvement or cure (93% for low VLPP versus 91% for higher VLPP, p = 0.83). In a subset analysis of the low VLPP group, all 15 patients with VLPP less than 30 cm H_20 reported subjective cure.

Postoperative complications were minor in both groups and are summarized in Table 3 (11% for low VLPP vserus 29% for higher VLPP, p = 0.017). Vaginal extrusion of tape was treated by excision of the exposed portion of the tape in the operating room. There was no difference in the rate of urinary retention between the two groups (0% for low VLPP versus 5% for higher VLPP, p = 0.56). Urinary retention or significantly worse urinary urgency and/or frequency was managed with sling loosening in the immediate postoperative period (< 10 days) in all three cases.

TABLE 3. **Postoperative complications**

	VLPP < 60 cm H_20	VLPP > 60 cm H_20	p value
Urinary tract infection	1 (3%)	8 (9%)	0.45
Yeast infection	1 (3%)	6 (7%)	0.67
Urinary retention	0 (0%)	3 (5%)	0.56
Vaginal extrusion of sling	1 (3%)	8 (9%)	0.45
Prolonged pain	1 (3%)	4 (5%)	0.99
Sling infection	0 (0%)	1 (1%)	0.29
Vulvar irritation	0 (0%)	1 (1%)	0.29
Any complication	4/36 (11%)	25/88 (29%)	0.017

Comments

Mid-urethral slings are hypothesized to treat stress incontinence by providing a backboard of support upon which the urethra is able to compress during episodes of stress, increasing urethral closure pressure despite increased intra-abdominal pressure.[5] ISD, also known as type 3 stress urinary incontinence, is a condition characterized by an open bladder neck and proximal urethra at rest.[6] ISD is more common in women who have previously undergone hysterectomy or previous incontinence surgery and in older women,[7] which may be related to mucosal atrophy and loss of urethral function due to post-menopausal estrogen deficiency.[8]

VLPP less than 60 cm H_2O is predictive of the presence of ISD,[4] and is a reliable indicator of intrinsic sphincteric function. More precisely, lower VLPP is related to lower efficiency of the urethral sphincteric mechanism,[9] leading to more severe SUI symptoms.[10] Intuitively, the mid-urethral sling should help correct the underlying anatomical defect of ISD. Earlier reports examining outcomes in patients with low VLPP report cure rates greater than 80%, comparable to those seen in patients with higher VLPP, Table 4. More recently, however, studies have reported worse outcomes in women with low VLPP receiving TVT (trans-vaginal tape)[11] or TOS[3] slings and have cautioned against their use in these patients.

Complications occurred in 11% and 29% of the low and high VLPP group patients, respectively. There was no significant difference in complications between the two groups. The majority of patients experienced either no or minimal complications, such as yeast infection, bladder infection, or vulvar irritation. The few patients with more significant complications, such as vaginal extrusion of mesh or sling infection, were all successfully managed with a second procedure.

Our study supports the use of TOS slings in women with low VLPP. We utilized local anesthesia with intravenous sedation as our method of anesthesia. We believe this choice of anesthesia is ideal for TOS sling placement. The surgeon is able to place the sling with minimal discomfort to the patient, while also allowing tensioning of the sling, allowing precise, individualized placement of the sling, particularly in patients with low VLPP who may likely require a tighter sling to compensate for ISD. Too much sling tension can lead to obstructive voiding symptoms or urinary retention. In our study, low VLPP patients did not develop urinary retention, suggesting that our method of sling tensioning is appropriate even for patients with ISD. Additionally, even patients with VLPP less than 30 cm H_20 had excellent outcomes, suggesting that this group of women can be effectively treated with TOS despite severe ISD.

We did not treat patients with a fixed urethra on preoperative physical exam since these patients traditionally have higher rates of sling failure.[12] Since many of these patients likely also have ISD, excluding these patients from treatment may additionally explain why our results appear more favorable than outcomes reported in other studies. TOS sling placement in women with stress incontinence and low VLPP is equally effective and has similar outcomes to patients with higher VLPP. Intraoperative and postoperative complications are similar in both groups, and need for an additional procedure was low.

Shortcomings of our study include the retrospective and non-blinded nature of our study. Additionally, only subjective patient reported cure was analyzed. Finally, follow-up data greater than 12 months was

TABLE 4. **Sling outcomes in previous studies stratified by VLPP**

Study	Patients with VLPP < 60 cm H_20	Subjective cure in patients with VLPP < 60 cm H_20	Patients with VLPP > 60 cm H_20	Subjective cure in patients with VLPP > 60 cm H_20	p value
TVT					
Paick, 2004[11]	61	82%	160	93%	0.013
Abdel-Hady, 2005[13]	80	87%	-	-	
Ghezzi, 2006[14]	35	91%	-	-	
TOS					
O'Connor, 2006[3]	13	25%	43	77%	0.003
Juma, 2007[15]	63	91%	52	91%	0.71
Current study	36	94%	88	84%	0.12

not available for all patients. Despite these criticisms, this study provides evidence that TOS can be beneficial regardless of VLPP.

Conclusion

TOS is effective for patients with low VLPP without a fixed urethra. Women with SUI and ISD should be considered candidates for TOS. The use of local anesthesia and intravenous sedation during sling placement allows the surgeon to perform an intraoperative cough test, permitting tensioning of the TOS in relation to the patient's ISD. □

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