Preoperative Valsava Leak Point Pressure May Not Predict Outcome of Mid-Urethral Slings. Analysis from a Randomized Controlled Trial of Retropubic versus Transobturator Mid-Urethral Slings

Elisabetta Costantini, Massimo Lazzeri, Antonella Giannantoni, Vittorio Bini, Alberto Vianello, Ervin Kocjancic, Massimo Porena

Department of Medical and Surgical Specialties and Public Health, Section of Urology and Andrology (EC, ML, AG, AV, MP), and Department Internal Medicine (VB), University of Perugia, Perugia, Italy and Department of Urology (EK), University of Udine, Udine, Italy

ABSTRACT

Objective: To test the hypothesis that preoperative Valsalva leak point pressure (VLPP) predicts long-term outcome of midurethra slings for female stress urinary incontinence (SUI).

Materials and Methods: One hundred and forty-five patients with SUI were prospectively randomized to two mid-urethra sling treatments: Tension free vaginal tape (TVT) or transobturator tape (TOT). They were followed-up at 3, 6, 12 months post-operatively and then annually for the primary outcome variable, i.e. dry or wet and secondary outcome variables such as scores on the urogenital distress inventory (UDI-6) and the impact of incontinence on quality of life (IIQ-7) questionnaire as well as patient satisfaction as scored on a visual analogue scale (VAS). Preoperative VLPP was correlated with primary and secondary outcome variables.

Results: Mean follow-ups were 32 ± 12 months (range 12-55) for TVT and 31 ± 15 months (range 12-61) for TOT. When patients were analyzed according to VLPP stratification, 95~(65.5%) patients showed a VLPP $> 60~\text{cm}~\text{H}_2\text{O}$ and 50~(34.5%) patients had a VLPP $\leq 60~\text{cm}~\text{H}_2\text{O}$. The overall objective cure rates were 75.8% for patients with VLPP $> 60~\text{cm}~\text{H}_2\text{O}$ and 72% for those with VLPP $\leq 60~\text{cm}~\text{H}_2\text{O}$ (p < 0.619). No significant differences in objective cure rates emerged when patients were stratified for pre-operative VLPP and matched for TOT or TVT procedures: VLPP $> 60~\text{cm}~\text{H}_2\text{O}$ (82 % vs. 68.9% p < 0.172); VLPP $\leq 60~\text{cm}~\text{H}_2\text{O}$ (68% vs. 76% p < 0.528).

Conclusions: When patients were stratified for preoperative VLPP (\leq or > of 60 cm H_2O), preoperative VLPP was not linked to outcome after TVT or TOT procedures.

Key words: urinary incontinence; Valsalva leak point pressure; tension free vaginal tape; transobturator tape **Int Braz J Urol. 2008**; **34**: 73-83

INTRODUCTION

Since the tension-free vaginal tape (TVT) procedure was first described by Ulmsten et al. in

1996 (1), mid-urethral sling procedures have been established as safe and effective in the treatment of female stress urinary incontinence (SUI) (2). Long-term follow-ups showed high cure rates ranging from

81% to 95% for TVT and the recently introduced tension free transobturator tape (TOT) procedures (3 - 6). Although most studies analyzed the safety and the efficacy of mid-urethra slings, outcomes, and the complication rate, a few tried to address the issue of factors predicting long-term outcome.

Urethral integrity was first investigated as outcome predictor in patients who underwent mid urethral sling operations for SUI. Miller et al. found at 3 months after surgery that TOT was nearly 6 times more likely to fail than TVT in subjects with a preoperative maximum urethral closure pressure at or below 42 cm H₂O (7). The Valsalva Leak Point Pressure (VLPP), which the International Continence Society (ICS) defined as the intravesical pressure at which urine leakage occurs due to increased abdominal pressure generated by a Valsalva maneuver, is considered an objective parameter for SUI severity (8). In 1993, McGuire et al. demonstrated that leakage pressure during the Valsalva maneuver was a reliable method for assessing the urethral sphincter mechanism (9). These findings were confirmed by Feldner Jr. et al. and Albo et al. (10, 11), and indeed Albo et al. concluded that the VLPP might be a good measure of urethral sphincter dysfunction even though it was not associated with symptom severity, quantity of urine loss, or its effect on the patient's Quality of Life (QoL).

Patients with a low VLPP on preoperative urodynamic assessment were reported to have increased risk of treatment failure (12, 13). In a recent investigation into preoperative VLPP as a predictor of outcome after distal urethral sling procedures, Rodriguez et al. reported the VLPP was useful for diagnosing SUI, but, at a 14-month follow-up, appeared to be of minimal importance in predicting outcome (14). On the other hand, in patients who underwent midurethra slings, O'Connor reported excellent results in patients with a VLPP > 60 cm H₂O but not in those with a low VLPP ($\leq 60 \text{ cm H}_{2}O$) (15). As both these studies had short follow-ups and did not match outcomes for different types of surgery, the role of VLPP in predicting the risk of failure at long-term follow-up remains an open issue.

The present study investigated the prognostic value of VLPP for mid-urethral sling outcomes using data from a randomized controlled study of 145 women

with stress or mixed urinary incontinence that were treated with either TVT or TOT (16).

MATERIALS AND METHODS

From May 2002 to November 2005, 145 patients affected by SUI as defined by ICS (8) and who were candidates for the mid-urethral sling procedure were prospectively randomized by a predetermined computer-generated randomization code, to the retropubic approach (TVT) or the transobturator route (TOT). Randomization was done using sealed, opaque, numbered envelopes, which contained the randomized allocation. The Regional Ethics Committee approved the study protocol and all patients gave written informed consent.

Inclusion criteria were stress or mixed urinary incontinence defined according to ICS guidelines and associated with urethral hypermobility. Hypermobility was defined as a Q-tip test $> 30^{\circ}$ (our cut-off). Exclusion criteria were > grade II prolapse in any vaginal compartment, previous incontinence surgery, urine retention, neurogenic bladder and psychiatric disorders. The pre-operative work-up included a detailed case history, clinical, neurological and urogynecological examination using the Half-Way system (17), the POP-Q system classification (18), and a pelvic static ultrasound scan. All patients underwent a stress test in the supine position at physiological maximum bladder capacity. Urethral hypermobility was evaluated not only by the Q-tip test but also by perineal ultrasound, which is routinely performed at our Institution. During the scan the distance was measured between the bladder neck and a line at right angles to the pubic bone plane. A cut-off value > 7 was indicative of a hypermobile urethra (19). Urinary incontinence was classified as recommended by the International Consultation on Incontinence and graded according to the Ingelman Sunderberg classification (20). All patients completed two validated questionnaires on quality of life, i.e. the Urogenital Distress Inventory (UDI-6) and the Impact Incontinence Quality of life (IIQ-7) before surgery, at 3, 6, 12 months postoperatively and then annually. Patient satisfaction was scored by inviting patients to mark the grade of satisfaction on a VAS scale from 0-10, on which 10 was maximum satisfaction and zero no satisfaction. Before surgery patients performed a 1-h pad test and completed a bladder diary for three days.

All patients underwent a preoperative urodynamic assessment, which included uroflowmetry, provocative cystometry and urethral profilometry. In accordance with ICS guidelines, filling cystometry was performed in all patients with saline solution at a flow rate of 25 mL/min by a double lumen 8F catheter (one lumen was used to fill the bladder while the other lumen was connected to a pressure transducer to measure intravesical pressure); a balloon catheter was placed in the rectum to record abdominal pressure. The VLPP was determined at a bladder volume of 200 mL. Patients were instructed to perform several Valsalva maneuvers with a gradual increase in abdominal pressure and urine leakage was recorded as previously described (21). Patients were stratified by VLPP > 60 cm H_2O or VLPP \leq 60 cm H_2O .

Standard operating techniques were, respectively, the Ulmsten (1) (TVT® - Ethicon) and Delorme techniques (5); no concomitant procedure was performed. The trans-obturator tape was a fusion-welded, non-woven, non-knitted polypropylene tape (Obtape® Mentor-Porges). No preoperative choice between general and regional anesthesia was made. In both procedures, a Foley catheter was always inserted for 24 hours. After the catheter was removed, if post-void residual volume was more than 50% of bladder volume, intermittent catheterization was proposed. The surgeons were blinded to preoperative VLPP results.

The primary outcome variable was continence status: dry or wet as deduced by clinical examination, stress test and patient interview. Patients were classified in two categories: dry (no leakage during clinical examination and/or stress test and/or reported by patients) vs. wet. Wet patients were then subdivided into "improved" (more than 50% reduction in incontinence episodes) or "failure". Secondary outcome variables were scores on the quality of life questionnaires and the VAS scale.

Patients were followed-up at 3, 6, 12 months post-operatively and then annually, and at each check-up a blinded assessor measured primary and

secondary outcome variables. Terminology followed ICS guideline (8).

VLPP was analyzed retrospectively using data from a randomized controlled study (16) which was accordingly powered. The Mann-Whitney test compared ordinal and non-normally distributed continuous variables. Deviations from Gaussian distribution were checked using the Kolgomorov-Smirnov test with the Lilliefors method. Categorical data were analyzed by the chi-square test or Fisher's exact test, as appropriate. The level of statistic significance was set at P<0.05. All calculations were carried out with SPSS release 13.0, SPSS Inc., Chicago, USA, 2004.

RESULTS

Table-1 shows the two groups (TVT vs. TOT) were well balanced demographically. No patient was lost during follow-up. Preoperative urodynamic parameters were similar in the two groups, except for detrusor overactivity, which was more frequent in patients who received TOT (Table-2).

The overall median follow-up was 35 months with a mean follow-up of 32 ± 12 months (range 12-55) for the TVT group and 31 ± 15 months (range 12-61) for the TOT procedure. 110 patients (75.9%) had a follow-up ≥ 24 months. Table-3 summarizes the operating data. The overall objective cure rates (dry) were 71.4% for TVT and 77.3% for TOT. When dry patients were grouped with the "wet but improved" the success rates rose to 90% and to 90.6% respectively.

VLPP was > 60 cm $\rm H_2O$ in 95/145 patients (65.5%). TOT was performed in 50 of these 95 patients (52.6%), and in 25/50 patients (50%) with VLPP \leq 60 cm $\rm H_2O$. TVT was performed in the others: 45 patients (47.4%) with a VLPP > 60 cm $\rm H_2O$ and 25/50 patients (50%) with VLPP \leq 60 cm $\rm H_2O$. The overall objective cure rates were 75.8% for patients with VLPP > 60 cm $\rm H_2O$ and 72% in patients with VLPP \leq 60 cm $\rm H_2O$ (p < 0.619). No significant differences emerged in objective cure rates when VLPP-stratified patients were matched for TOT or TVT procedures (VLPP > 60 cm $\rm H_2O$: 82 % TOT vs. 68.9% TVT; p < 0.172; VLPP \leq 60 cm $\rm H_2O$: 68%

Table 1 – Preoperative characteristics of patients.

	TVT (70 pts)	TOT (75 pts)	p Value	
Age (yr.)*	61.8 ± 10.7	60.6 ± 10	NS	
Parity	2 (0-5)	2 (0-4)	NS	
Body mass index (Kg/m ²)°	26.9 (21.4-39.0)	26.7 (19.5-38.0)	NS	
Menopause (n)	61	64	NS	
Previous hysterectomy (n)	27	34	NS	
Mean duration of SUI (yr.)*	3.7 ± 2	4.0 ± 3.1	NS	
Stress incontinence (N)	42	41	NS	
Mixed incontinence (N)	28	34		
SUI grade - Ingelman sundemberg (N))			
Gl	3	8		
G2	51	54	NS	
Œ	16	11		
Mean Q-tip test	58.4 ± 13.5	57.9 ± 14.1		
_	(range 45 - 90)	(range 43 - 89)		
Ultrasound measurements				
Pad test (g)	30 (0-350)	37.5 (0 - 145)	NS	
Voiding symptoms (N)	11	16	NS	
Storage symptoms (N)	36	39	NS	
UDI-6 Questionnaire (score)	8 (0 - 19)	10 (2 - 21)	NS	
IIQ-7 Questionnaire (score)	8 (0 - 16)	8 (0 - 18)	NS	
Sexually active women(N)	51	50	NS	
Dyspareunia (N)	12	16	NS	

 $TVT = tension\ free\ vaginal\ tape;\ TOT = or\ transobturator\ tape;\ * = mean \pm\ SD;\ median\ and\ range.$

Table 2 – Preoperative urodynamic values (median and range).

	TVT (70 pts)	TOT (75 pts)	p Value
Maximum cystometric capacity (mL)	400 (170-606)	414 (177-630)	NS
Opening detrusor pressure (cm H ₂ O)	10 (1-28)	10 (2-35)	NS
Maximum detrusor pressure (cm H ₂ O)	19 (2-99)	18 (2-60)	NS
Pdet Qmax (cm H ₂ O)	15 (1-49)	14(1-58)	NS
Qmax (mL/sec)	23 (5.7-49)	24 (9.8-41)	NS
MUCP (cm H ₂ O)	39 (0-100)	44 (11-84)	NS
Detrusor overactivity (N)	4	14	< 0.05
VLPP	63 (38-89)	66 (42-88)	NS
Post-void residue (N)	3	5	NS

 $TVT = tension\ free\ vaginal\ tape;\ TOT =\ transobturator\ tape;\ Pdet\ Qmax =\ detrusor\ pressure\ at\ maximal\ flow\ rate;\ MUCP =\ maximum\ urethral\ closure\ pressure;\ VLPP =\ Valsava\ leak\ point\ pressure.$

TOT vs. 76% TVT p < 0.528). Data are shown in Table-4. Table-5 reports outcomes in patients with mixed incontinence. No significant difference was observed.

Postoperative changes in questionnaire scores were not significant (p > 0.05) when patients were stratified for VLPP and type of procedure. In patients with VLPP > 60 cm H_2O , the mean post-operative

Table 3 – Operative data and postoperative morbidity (median and range).

	TVT (70 pts)	TOT (75 pts)	p Value
Follow-up (months) mean	32±12	31 ± 15	NS
Median and range	33 (12-55)	34 (12-61)	
Operating time (minutes)	30 (20-60)	20 (20-55)	NS
Hospital stay (days)	1.5 (1-10)	1.3 (1-10)	NS
Intra-operative complications (N)			
Bladder injury	2	1	
Vaginal injury	-	4	
Early complications (N)			
Retropubic hematoma	1	-	
Transient voiding dysfunction (urgency,	3	2	NS
frequency and nocturia for 7-10)			
Transient complete urinary retention	1	1	
Late complications (N)			
Vaginal erosion	-	3	
Voiding dysfunction	3§	3	
Wound discomfort	1	-	
Foreign body granuloma	1**	-	
Paraincisional hernia	1	-	

 $TVT = tension\ free\ vaginal\ tape;\ TOT =\ transobturator\ tape;\ ** =\ removal\ of\ suprapubic\ mesh\ edges;\ \S = 1\ patient\ performed\ urethrolysis.$

scores were 2.24 for TOT and 2.56 for TVT (UDI-6) and 1.94 for TOT and 1.93 for TVT (IIQ-7). In patients with VLPP \leq 60 cm $\rm H_2O$, the mean postoperative scores were 2.08 for TOT and 1.36 for TVT (UDI-6) and 1.72 for TOT and 1.52 for TVT (IIQ-7). Table-6 reports mean changes of the

questionnaire values. All questionnaire scores were significantly lower than the preoperative value reported in Table 1 (p = 0.001). Mean post-operative VAS scores were 8.68 for TOT and 8.24 for TVT in patients with VLPP > 60 cm $_{2}$ O and 7.88 for TOT and 8.44 for TVT in patients with VLPP \leq 60 cm $_{2}$ O (p = NS).

Table 4 - Outcome stratified according Valsava leak point pressure (VLPP) in patients who received TOT or TVT.

	Cured	Failure	Total	p Value
$VLPP > 60 \text{ cm H}_{2}O$	41 (82%)	9 (18%)	50 (100%)	
VLPP≤60 cm H ₂ O	17 (68%)	8 (32%)	25 (100%)	
Total	58 (77.3%)	17 (22.7%)	75 (100%)	> 0.05
Tension Free Vaginal T	Cape (TVT)			
	Cured	Failure	Total	
VLPP>60 cm H ₂ O	Cured 31 (68.9%)	Failure 14 (31.1%)	Total 45 (100%)	
VLPP>60 cm H ₂ O VLPP≤60 cm H ₃ O				

TVT = tension free vaginal tape; TOT = transobturator tape.

Table 5 – Outcome of patients with mixed incontinence.

		Preoperati	ive Stress Incontinence		
Total = 84	Postoperative Results Dry 70 Improved 7 Unchanged 7	TVT =43	Postoperative Results Dry = 36 Improved = 5 Unchanged = 2	TOT =41	Postoperative Results Dry = 34 Improved = 2
			TVT vs. TOT, p	=NS	
		Preoperati	ive Mixed Incontinence		
Total = 61	Dry 38 Improved 16 Unchanged 7	TVT =27	Dry = 14 Improved = 8 Unchanged = 5	TOT =34	Dry = 24 Improved = 8 Unchanged = 2
			TVT vs. TOT, p	=NS	

TVT = tension free vaginal tape; TOT = transobturator tape.

COMMENTS

The present study seems to indicate preoperative VLPP has no bearing on outcomes after mid-urethral slings as treatment of SUI because when patients were stratified for pre-operative VLPP values we found no difference in cure rates, independently of whether TOT or TVT was used as a treatment or not.

Several authors who used the VLPP to choose treatment in patients with SUI suggested it might provide prognostic information (12 - 15, 22, 23). For example, in a series of 43 patients with SUI, O'Connor et al. (15) reported 77% of patients with a preoperative VLPP > 60 were cured compared with 25% of patients

with VLPP \leq 60 cm H₂O. Rodriguez et al., evaluated 174 patients who underwent distal-urethral sling procedures, dividing them into four groups according to VLPP values (group 1: no leakage; group 2: VLPP > 80 cm H₂O group 3: VLPP from 30 to 80; group 4: VLPP < 30). Regardless of the VLPP, overall objective cure rates were similar in all groups (95%, 92%, 93% and 92% respectively) as were patient-reported outcomes and the number of daily pads, even though patients with low VLPP had used more pads per day before surgery (14). These results were confirmed by Cetinel et al. in an investigation into seventy-five consecutive patients with urodynamically proven SUI who underwent TVT (24). When stratified according to preoperative VLPP, 36 patients (48%) had \leq 60

Table 6 – Mean changes of questionnaire values (basal values minus postoperative values).

		TOT	TVT	p Value	
VLPP>60					
	UDI-6	6.00	4.73	NS	
	IIQ-7	5.60	5.60	NS	
VLPP≤60					
	UDI-6	6.28	7.20	NS	
	IIQ-7	6.32	7.08	NS	

TVT = tension free vaginal tape; TOT = transobturator tape.

cm H_2O and 39 patients (52%) had > 60 cm H_2O . When cure rates were compared with preoperative VLPP, no significant difference emerged at a mean follow-up of 21.6 months (89.7% vs. 88.9% respectively). Abdel-Hady investigated the efficacy of tension-free vaginal tape (TVT) in 80 women with a low VLPP (\leq 60 cm H_2O) in a series of 658 patients (25) and reported an 86% cure rate (dry) and a 14% improved rate (wet but improved) at 6 months, concluding that the high efficacy of TVT makes it the first choice treatment for women with SUI – including those with low VLPP.

Although the findings in the present study concur with several reports, one weakness in our study design is the mix of TVT and TOT that could have partly biased results as TOT seems more suitable than retropubic TVT for SUI with urethral hypermobility (26). Secondly, dividing patients arbitrarily into two groups on the basis of a VLPP cut-off of 60 cm $\rm H_2O$ may have been a bias. Recently Guerette et al. found that the cut-off values of VLPP > 60 cm $\rm H_2O$ and Maximum Urethral Closure Pressure > 40 cm $\rm H_2O$ were the most predictive factors of surgical success, showing a sensitivity of 83% and specificity of 79% (27).

Although most surgeons recognize that outcome assessment tools are often debatable, the issue assumes marked significance after operations that are designed to decrease the impact of specific signs and symptoms such as incontinence, and outcomes are correlated with preoperative outcome predictors at urodynamics. In the present study we tried to address issues related to outcome after midurethra sling placement and validation of VLPP as an objective parameter for assessing outlet region function using established, generally accepted criteria. However, increasing evidence suggests with urodynamic findings that the patient's condition and specific quality of life could be dissociated (28). Although studies reporting urinary incontinence as outcome and analyzing outcome predicting factors can never develop the level of evidence seen for other symptoms or disease states such as oncologic outcome reporting, investigating pre-operative predictive factors remains mandatory so as to avoid overuse or misuse of mid-urethra slings and improve quality of care. Minimal requirements for predictor reporting include not only preoperative VLPP as in our case, but also peri-operative complications, hospital stays and length of follow-up data, which seems insufficient in many studies. The 3-year follow-up, which is presented here, may be a step forward in this direction. Finally, we cannot forget the individual's response to surgery for SUI and the impact that other variables have on single outcome criterion, which make it difficult to discuss the pathophysiological significance of the VLPP.

CONCLUSION

Preoperative VLPP, which was stratified for preoperative VLPP (\leq or > of 60 cm $\rm H_2O$), was not dependent on outcome after TVT or TOT. Further studies remain mandatory to confirm these data and to investigate other outcome independent variables.

CONFLICT OF INTEREST

None declared.

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Correspondence address:

F-mail: lazzeri.m@tiscali.it

Dr. Massimo Lazzeri Section of Urology and Andrology Via Brunamonti 51 06100 Perugia, Italy Fax: +39075572-6123

EDITORIAL COMMENT

The cure of female stress urinary incontinence should be based on proper patient selection in order to improve the outcome and accurately predict the therapeutic results. Over the years, there have been various proposals for therapy design regarding the existence or absence of overactive bladder concomitantly with stress urinary incontinence, urethral hypermobility or hypomobility, intrinsic sphincter deficiency, etc. The Valsava leak point pressure (VLPP) was previously advocated as an important cure rate predictor for the mid-urethral sling operations,

and this may influence the surgeon to elect other operations, such as one of the tension free vaginal tape (TVT) like ones. This might lead the patient to lose the overall TVT benefits and suffer some of the previously used operative modalities. This study evaluates the real value of the VLPP for the prediction of success rate with both TVT and transobturator tape (TOT), with clear and objective tools. Even though being retrospective, the additional information provided here for the urogynecologist practitioner makes the selection of operations for patient free of bias.

Dr. M. Neuman

Urogynecology, Department of Gynecology Shaare Zedek Medical Center Ben-Gurion University of the Negev Jerusalem, Israel E-mail: neuman@szmc.org.il

EDITORIAL COMMENT

Preoperative urodynamic evaluation is common in women undergoing stress incontinence surgery. Urodynamic observations have been used to confirm the diagnosis of urodynamic stress incontinence (USI) by observing transurethral urine loss at the moment of increased abdominal pressure in the absence of a detrusor contraction. In addition to this general diagnostic finding, urodynamic criteria

are also used to inform surgical decision-making. The concept of intrinsic sphincter deficiency (ISD) or type III incontinence was introduced by McGuire to characterize a urethra that no longer has a functioning sphincter (1). Commonly used measures to evaluate urethral sphincter integrity are Valsalva leak point pressure (VLPP) and maximal urethral closure pressure (MUCP); low values have been associated with poor surgical results. Previous studies have demonstrated a higher failure rate of the Burch procedure in patients with a MUCP lower than 20 cm $H_2O(2, 3)$. This cut off value of MUCP ≤ 20 cm H_2O has been used arbitrarily as an indicator for ISD. Other reports have evaluated sphincter function on the basis of the VLPP, the lowest abdominal pressure to cause urinary leakage as recorded during a slowly performed Valsalva maneuver. In the original report by McGuire et al. (4), the VLPP was performed with the patient standing under fluoroscopy. Their results demonstrated that 75% of patients with type III incontinence had a low VLPP. A low VLPP less than 60 cm H₂O was thought to be associated with type III incontinence, which is characterized by an open bladder neck at rest and an immobile urethra with proximal damage

The value of urethral sphincter functioning as a predictor for the success rate of tension free vaginal tape (TVT) and transobturator tape (TOT) is controversial (6-8). Most published studies have a small number of participants and are under-powered (6-8). Dr. Costantini and her group should be commended for attempting to answer a clinically relevant question regarding the prognostic value of VLPP for the success of midurethral slings. The presented study is an ancillary part of a randomized study which compared TVT vs. TOT for treatment of stress urinary incontinence (9). All patients underwent standardized multi-channel urodynamic testing prior to the surgery. VLPP values were obtained at a bladder volume of 200 mL. The patients were randomized to either TVT or TOT irrespective of the urodynamic results. Overall there were no differences in the cure rate of patients who had VLPP \leq 60 cm H₂O to those who had VLPP > 60 cm H₂O. A major limitation of this study is the relatively narrow distribution and low median VLPP of the participants. The median values for TOT and TVT were 61 and 66 cm H₂O respectively. Since a VLPP around 60 cm H₂O is regarded as low, the authors might have found more significant differences in a group of patients with a wider distribution of VLPPs. In addition, further evaluation of the recorded MUCP data as it relates to surgical cure rates could also be useful. In summary, the ability of urodynamics to predict the success of SUI surgery is not yet fully recognized and more studies are needed to elucidate the role of preoperative urodynamics.

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Dr. Lior Lowenstein

Division of Female Pelvic Medicine & Reconstructive Surgery Dep. of Obstetrics & Gynecology and Urology Loyola University Medical Center Maywood, Illinois, USA E-mail: llowenstein@lumc.edu

EDITORIAL COMMENT

The current study, "Preoperative Valsava Leak Point Pressure May Not Predict Outcome of Mid-Urethral Slings. Analysis from a Randomized Controlled Trial of Retropubic versus Transobturator Mid-Urethral Slings" by Costantini et al is a well designed, randomized controlled trial attempting to address a valuable clinical issue.

Overall, the use of a trans-obturator approach (TOT) for mid-urethral sling can minimize the risk of injury to the lower urinary tract. It has been found to be equally efficacious compared to the retropubic approach (TVT) in the management of stress urinary incontinence for patients with normal urethral function. If this were also true for patients with poor urethral function, or intrinsic sphincteric deficiency (ISD), universal use of the trans-obturator approach may be preferable.

However, the current study must be evaluated critically, and its potential flaws recognized. The optimal definition of ISD is disputed. Many clinicians prefer the use of static maximum urethral closure pressure (MUCP); studies have shown a wide discrepancy between MUCP and VLPP. Additionally, the study is underpowered. With only 50 patients in the ISD group, and an 8% difference in objective cure with TVT showing superiority, any definitive conclusions cannot be reached.

The authors' study is a valid first attempt to address a vital clinical issue in how best to triage and manage our at-risk patients undergoing anti-incontinence surgery. Though the universal use of the potentially lower-risk TOT may indeed prove true, the practice warrants further study before being widely adopted.

Dr. Kenneth Powers

Associate Professor Obstetrics & Gynecology
Albert Einstein College of Medicine
Chief of Urogyneocology
Montefiore Medical Center
Bronx, New York, USA
E-mail: hoppowers@aol.com