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Original article

Predictive factors of bladder outlet obstruction following the tension-free vaginal tape obturator (TVTO) procedure in females treated surgically for stress urinary incontinence



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KEYWORDS

Urethral hypermobility;
SUI;
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Abstract

Objectives: To identify patients at risk for postoperative outlet obstruction after the tension-free vaginal tape obturator (TVTO) procedure in order to allow for better counseling and possible treatment alternatives.
Subjects and methods: This prospective study was carried out on 85 women who underwent the TVTO procedure for treatment of stress urinary incontinence (SUI). Preoperatively, a detailed medical history was taken from all patients, and all were subjected to physical examination, routine labs, abdominal and pelvic ultrasound and urodynamic studies (cystometry and assessment of the detrusor leak point pressure (DLPP), abdominal leak point pressure (ALPP), pressure flow and post-void residual (PVR) urine). The TVTO procedure was carried out by the same surgeon in all cases. Postoperative voiding dysfunction in this study was defined as the subjective feeling of difficult voiding, a weak stream and/or incomplete evacuation, and a PVR urine volume >100 ml, a urine flow rate <15 ml/s or urinary retention on examination. The following risk factors for postoperative bladder outlet obstruction were evaluated: age, history of previous incontinence surgery, parity, menopausal status, type of SUI, grade of SUI, residual urine, Q_{max} and $P_{det}Q_{max}$. Statistical analysis was done using the SPSS package version 1.5.
Results: 75% of our patients were cured. Denovo urgency or urge incontinence developed in 5.8% of the patients. Voiding dysfunction according to our definition developed in 24.7% of the patients. On multivariate analysis, Q_{max} was the only risk factor that could predict postoperative bladder outlet obstruction ($p = 0.002$, odds ratio = 0.658, 95% C.I.).

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Conclusion: Preoperative Q_{\max} is the only independent risk factor for postoperative bladder outlet obstruction in women undergoing TVTO surgery.

Brief summary: TVTO is an effective surgical option for genuine stress incontinence in females. Preoperative Q_{\max} is the only independent risk factor for postoperative bladder outlet obstruction.

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Introduction

Urinary incontinence is a disorder with wide-spread human and social implications, causing discomfort, shame and loss of self-confidence. Stress urinary incontinence (SUI) is one of the most common types of incontinence which mainly occurs in female patients and accounts for 50% of all incontinence cases [1].

SUI is due to urethral hypermobility, an intrinsic sphincteric deficiency or both [2]. Based on the proper understanding of the pathophysiology of female SUI, several surgical techniques for the treatment of this condition have been developed. In 1995, Ulmsten and Petros described the midurethral support concept [3], however, the use of the retropubic tape (TVT) was associated with various peri- and postoperative complications, including bladder perforation, temporary or persistent retention, de-novo instability [4] and injuries to the urethra, vessels, nerves and bowel [5].

In 2001, Delorme described the transobturator tape and its passage from outside to inside (outside-in procedure) [6]. The reported results were very close to those reported for the TVT [7] with no reported vascular, nerve or bowel injuries [8]. Two years later, De Leval described the transobturator passage of the tape from inside to outside (inside-out procedure) [9].

Most methods of incontinence surgery are associated with some degree of urethral obstruction. The risk of postoperative voiding dysfunction is, therefore, an important issue to be addressed. So far, the risk factors for developing voiding dysfunction after incontinence surgery have not been clearly identified, mostly due to the lack of standardized definitions. Identifying patients at risk for postoperative bladder outlet obstruction would allow for an improved counseling and the choice of treatment alternatives.

Subjects and methods

This prospective study conducted between April 2009 and October 2012 was carried out on 85 female patients with pure or mixed stress urinary incontinence. Patients with a history of any pre-operative obstructive symptoms (difficult voiding, weak stream or a sensation of incomplete evacuation), a pre-operative residual urine volume >100 ml or any neurological pathology affecting the bladder or the sphincters were excluded from the study.

After taking a detailed current and past medical history, all patients were subjected to physical examination, laboratory investigations (urine analysis and culture, liver and kidney functions, fasting blood sugar and coagulation profile), real time ultrasonography for the assessment of post void residual (PVR) urine, and urodynamic studies (uroflowmetry, cystometry, detrusor leak point pressure [DLPP], abdominal leak point pressure [ALPP], and pressure flow). An

Ethical/Institutional Review Board Approval was obtained before starting our study.

The patients were admitted to the hospital on the day of surgery, and a written consent was signed by all patients. All patients underwent the TVTO procedure. The urethral catheter and the vaginal pack were removed on the first postoperative day. Patients who were unable to void or had a PVR urine volume >100 ml were catheterized for 1 week. If, after this time, they were still unable to void or had a PVR urine volume >100 ml, they were taught clean intermittent catheterization (CIC).

All patients were assessed after 1 and 3 weeks, as well as after 1, 3 and 6 months by using a urinary symptoms questionnaire and subjecting them to a clinical examination, uroflowmetry and a urinary bladder ultrasound for the assessment of PVR.

The patients were considered cured when there was no subjective or objective evidence of SUI. Post-operative bladder outlet obstruction in our study was defined as the subjective feeling of difficult voiding, a weak stream and/or the sensation of incomplete evacuation, and a PVR urine volume >100 ml, a urine flow rate <15 ml/s or urinary retention on examination. The following risk factors for postoperative bladder outlet obstruction were evaluated: age, history of previous incontinence surgery, parity, menopausal status, type of SUI, grade of SUI, residual urine, Q_{\max} and $P_{\det}Q_{\max}$.

The data were coded and evaluated using the statistical package SPSS version 15. They were then summarized using descriptive statistics. A receiver operating characteristic (ROC) curve analysis was done to validate Q_{\max} for the detection of voiding dysfunction. A logistic regression analysis was done to test for significant predictors of voiding dysfunction. P values ≤ 0.05 were considered statistically significant.

Results

The patients' age ranged from 23 to 61 (mean 41.94) years. The mean number of vaginal deliveries was 4.47 (range 2–11).

75% of our patients were cured. De-novo urgency or urge incontinence developed in 5.8% of the patients. Voiding dysfunction according to our definition developed in 24.7% of the patients. The patients' characteristics are illustrated in Table 1. Table 2 shows the urodynamic features.

Univariate analysis of multiple preoperative clinical and urodynamic factors demonstrated that, out of all the parameters studied, only Q_{\max} and $P_{\det}Q_{\max}$ were associated with postoperative bladder outlet obstruction. The mean Q_{\max} in the patients with bladder outlet obstruction was 15.48 ± 6.12 ml/s vs 23.42 ± 6.03 ml/s in

Table 1 Patient's characteristics among the study group.

Parameter	No. of patients	%
Menopause		
Pre-menopausal	73	85.90
Post-menopausal	12	14.10
Previous surgeries		
No previous surgery	79	92.90
Colposuspension	2	2.35
Hysterectomy	3	3.50
Myomectomy	1	1.18
Type of SUI		
Pure SUI	44	51.80
Mixed SUI	41	48.20
Grade of SUI		
Grade I	53	62.40
Grade II	28	32.90
Grade III	4	4.70
Pelvic organ prolapse		
Cystocele	29	34.12
Grade I	21	72.47
Grade II	8	27.50
Grade III	0	0

the patients without obstruction ($p < 0.001$). The mean $P_{det}Q_{max}$ in the patients without obstruction was 22.76 ± 3.38 cmH₂O vs 28.73 ± 6.47 cmH₂O in the patients with obstruction ($p < 0.001$).

ROC analysis revealed that the pre-operative Q_{max} was a good predictor of obstruction because the area under the ROC curve (AUC of $P_{det}Q_{max}$) was 0.792 (95% C.I. 0.681–0.895, $p < 0.001$).

The cutoff value for Q_{max} of 17.5 ml/s was most valid in predicting postoperative bladder outlet obstruction with a sensitivity of 81% and a specificity of 87.5%. However, the AUC of $P_{det}Q_{max}$ was 0.792 (95% C.I. 0.681–0.895, $p < 0.001$), which indicated that $P_{det}Q_{max}$ was also a good predictor with a sensitivity and specificity of 81% and 69%, respectively, when its value was 25.5 cmH₂O.

On the other hand, multivariate analysis indicated that Q_{max} was the only factor independently related to postoperative bladder outlet obstruction after TVTO ($p = 0.002$, odds ratio = 0.658, 95% CI for odds ratio 0.507–0.855).

Discussion

Stress urinary incontinence defined as the involuntary loss of urine during increases in intra-abdominal pressure [10] has been treated with various surgical techniques. It is generally accepted that

Table 2 Urodynamic features among the study group.

Preoperative Q_{max}	Average 21.46 ml/sec Range 8–46 SD 6.94
Preoperative ALPP	<60 cmH ₂ O 3 patients (3.5%) 60–90 cmH ₂ O 37 patients (43.5%) >90 cmH ₂ O 45 patients (52.9%)
Preoperative $P_{det}Q_{max}$	Mean 27.26 Range 16–47 SD 6.45

anti-incontinence procedures may, to some degree, cause obstruction to the urethra [11], and therefore the risk of postoperative voiding dysfunction needs to be taken into consideration

Carr and Webster stated that postoperative de-novo irritative or obstructing voiding symptoms in addition to urethral hypersuspension on physical examination are the best indicators of obstruction after anti-incontinence procedures [12]. These symptoms are very distressing to the patient, which raises the question of whether postoperative voiding dysfunction could be predicted preoperatively.

For our study we chose a cohort of patients with SUI who underwent the TVTO procedure. The prognostic significance of urinary urgency and preoperative uninhibited detrusor overactivity in urodynamics on the outcome of patients treated with vaginal tapes is still controversial. According to Stamey, preoperative urgency is no contraindication for surgery [13]. To study the effect of preoperative urodynamic parameters on voiding dysfunction, a full urodynamic evaluation was done for all patients in this study.

In our study we defined postoperative bladder outlet obstruction as a development of voiding symptoms (voiding difficulty, weak stream and sensation of incomplete evacuation) with PVR urine >100 ml, a urinary flow rate <15 ml/s or urinary retention. Others use different definitions for this problem, as there is no international consensus on a standard definition. So, the prevalence and predictors of voiding obstruction after various sling procedures have indeed been studied, but they vary according to the definition used in different institutions. While Groutz et al. defined postoperative voiding dysfunction as a maximum flow rate <12 ml/s or PVR urine >100 ml [14], Stanton et al. defined it as a peak flow rate <15 ml/s or PVR urine >200 ml on two or more readings [15]. This is again different from the definition used by Lose et al. who defined it as a peak flow rate <15 ml/s for patients younger than 60 years and <10 ml/s for patients aged 60 years and above [16].

According to our definition, postoperative voiding dysfunction was observed in about 25% of the patients studied. This is more or less comparable to the findings of Jang et al. who performed various midurethral sling procedures (TVT, TVT obturator, TOT, TVT secure) on 625 women and found out that 26% had postoperative bladder outlet obstruction, with Q_{max} being the only independent risk factor for postoperative voiding obstruction [17]. Similarly, Stanton et al. found out that age and preoperative Q_{max} were independent risk factors for post-operative obstruction [15]. In their study, post-operative obstruction was reported in 20 patients (20%) after the TVT procedure. However, De Tayrak et al. reported a smaller incidence of obstructive symptoms after the TOT procedure, ranging from 1.5% to 16.5% [18]. Also, Delorme et al. reported bladder outlet obstruction after TOT in only 1 patient (0.6%) [19]. As mentioned above, the difference in the reported rates can be attributed to different definitions of voiding dysfunction.

Using univariate and multivariate analysis methods, we found an association between preoperative Q_{max} and postoperative bladder outlet obstruction. A $Q_{max} < 17$ ml/s was correlated to postoperative bladder outlet obstruction. An association between $P_{det}Q_{max}$ and postoperative bladder outlet obstruction was only seen on univariate analysis. The other preoperative clinical and urodynamic parameters could not be correlated to postoperative bladder outlet obstruction. This result is in agreement with the report of Cho et al. who found that a $Q_{max} < 15$ ml/s was predictive of postoperative

bladder outlet obstruction [20]. On the other hand, Lemack et al. who studied a group of patients undergoing Burch colposuspension and pubovaginal sling surgeries stated that no preoperative urodynamic features could identify patients at risk for postoperative bladder outlet obstruction [21]. Miller et al., on their part, reported that PVR urine was the only parameter associated with a delayed return to normal voiding [22]. This was not observed in our study because all patients with a large volume of PVR urine were excluded. From a clinical point of view, it has to be emphasized that the above findings do not imply that postoperative bladder outlet obstruction does not occur in patients with a $Q_{\max} > 17$ ml/s or that all patients with a $Q_{\max} < 17$ ml/s will have complaints.

Conclusion

Patients with a lower preoperative Q_{\max} may be at higher risk of developing postoperative bladder outlet obstruction after TVTO. The diagnosis of bladder outlet obstruction in females has gradually evolved, but a standardization of definitions is imperative for an accurate assessment of the problem. We recommend further studies, using other parameters on a larger number of patients and over a longer follow-up period.

Conflict of interest

None declared.

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