



Transobturator mid-urethral sling in females with stress urinary incontinence and detrusor underactivity: effect on voiding phase

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Received: 11 October 2018 / Accepted: 3 January 2019 / Published online: 4 February 2019
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Abstract

Introduction and hypothesis To assess whether detrusor underactivity (DU) is a risk factor for voiding dysfunction (VD) after transobturator tape (TOT) and if a detrusor pressure at maximum flow (PdetQmax) value predicts postoperative VD in DU patients. Also, we examined uncomplicated patients for postoperative VD.

Methods This is a prospective long-term study on SUI patients who underwent TOT. Exclusion criteria were preoperative POP stage ≥ 2 , previous anti-incontinence surgery and comorbidities.

Patients were grouped by detrusor contractility using the projected isovolumetric pressure (PIP) index (PdetQmax + maximum flow rate) with values of 30–75 cmH₂O indicating normal contractility.

Follow-up was at 1, 3, 6 and 12 months, and then annually. All patients underwent a stress test and responded to the Urogenital Distress Inventory questionnaire and to the King's Health Questionnaire. The subjective cure was evaluated using the Patient Global Impression of Improvement.

We determined the diagnostic accuracy of PdetQmax levels using ROC curve analysis, with a cut-off point calculated for optimal sensitivity and specificity.

Results In 2007–2013, 118 patients underwent TOT. We included 50 in the undercontractility group (G1) and 50 in the normocontractility group (G2).

Continence rates were 82% in G1 and 84% in G2 (mean follow-up 76 months). VD increased from 18 to 36% ($p < 0.05$) in G1 and from 14 to 16% ($p = 0.198$) in G2. De novo VD was 28% in G1 and 2% in G2.

In the G1 group PdetQmax ≤ 12 cmH₂O predicted postoperative VD with 71.4% specificity and 80.0% sensitivity.

Conclusions DU adversely affects the voiding phase of micturition after TOT. In DU patients, PdetQmax ≤ 12 cmH₂O predicts postoperative VD.

Keywords SUI surgery · Detrusor underactivity · Voiding dysfunction · Urodynamics · Uncomplicated SUI patients · Long-term follow-up · Trans-obturator mid-urethral sling · Projected isovolumetric pressure · Quality of life

The results of this study were presented at the 46th Annual International Continent Society Congress, Tokyo, 13–16 October 2016 (Natale F, La Penna C, Illiano E, Balsamo R, Rossi De Vermandois J, Costantini E. Effect of transobturator mid-urethral sling on the voiding phase in women with stress urinary incontinence and detrusor underactivity *Neurol Urodyn*, 35: S261-262, 2016)

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Introduction

Midurethral sling (MUS) surgery is the most frequently performed procedure for treating stress urinary incontinence (SUI) in women. Although incontinence is resolved in most patients, some experience voiding dysfunction (VD) [1]. Symptoms of VD may vary in type and severity from a feeling of incomplete emptying, low stream, acute urinary retention that requires transient catheterisation and prolonged urinary retention requiring reoperation. The reported incidence of voiding dysfunction following MUS procedures ranges from approximately 3 to 10% [2, 3].

Patient age, medical history and voiding parameters including urodynamic study parameters [reduced peak flow rate (Qmax) and increased postvoid residual (PVR)] are risk factors for postoperative urinary retention after tension-free vaginal tape (TVT) [4–6]. However, no study has evaluated detrusor undercontractility (DU) as a risk factor in the new onset of VD after trans-obturator tape (TOT).

DU indicates a condition that contributes significantly to the manifestation of lower urinary tract symptoms (LUTS). The International Continence Society report in 2002 used the term DUA to describe a urodynamic abnormality. This was defined as “a contraction of reduced strength and/or duration, resulting in prolonged bladder emptying and/or failure to achieve complete bladder emptying within a normal time span” [7]. However, the parameters for the length and strength of contraction and prolonged voiding to define what is normal have not yet been established.

There has been some debate about whether a symptom complex is associated with DUA, referred to by some as underactive bladder (UAB), which is rather analogous to detrusor overactivity (DO) and overactive bladder (OAB) symptom complex. UAB manifests itself as prolonged urination time with or without a sensation of impaired bladder emptying, usually with hesitancy, reduced sensation on filling and a slow stream. In contrast to overactive bladder (OAB) and detrusor overactivity (DO), UAB and DU have remained largely unrecognised and poorly researched. There is a paucity of data on the pathogenesis (neurogenic or myogenic) and treatment of DU, and the definition of UAB remains vague, with a variety of definitions (detrusor areflexia, hypotonic bladder, atonic bladder, detrusor failure, impaired detrusor contractility) and of diagnostic criteria found in the literature [8]. This lack of uniformity creates difficulties in characterising UAB, researching its effects and evaluating possible treatments.

We set out to evaluate whether preoperative DU is a predictor of voiding dysfunction following anti-incontinence surgery.

The primary objective of this study was to observe voiding phase outcomes after TOT insertion in patients with and without DU to assess whether DU is a risk factor for voiding dysfunction after TOT insertion.

Our secondary objective was to compare other postoperative urinary symptoms and QoL in the two groups for differences and to assess whether detrusor pressure at maximum flow rate (PdetQmax) can predict which patients with DU are most likely to develop postoperative VD and, if so, at what level and with what degrees of sensitivity and specificity. Also, we wanted to examine the subgroup of uncomplicated patients (as defined in the FIGO working group report [9]) in our sample to see if preoperative DU was associated with postoperative VD. The uncomplicated SUI patient is characterised by a history of leaking urine associated with physical exertion (sneezing or jumping) in the absence of urgency or voiding symptoms (retention, difficulty emptying, etc.), prior anti-incontinence, POP or radical pelvic surgery, recurrent urinary tract infections and medical conditions that can affect the lower urinary tract.

Materials and methods

This is a prospective study performed in a high-volume urogynaecological centre on women who underwent TOT for SUI with a long-term follow-up (minimum 4 years).

Inclusion criteria were patients who had undergone out-in TOT (Monarc® Subfascial Hammock, American Medical Systems, Minnetonka, MN) for clinical and urodynamic SUI between May 2007 and October 2013 and who were ≥ 18 years of age at surgery.

Exclusion criteria were VLPP < 60 cmH₂O, preoperative presence of pelvic organ prolapse (POP) \geq stage 2, previous POP or anti-incontinence surgery, and comorbidities such as diabetes or neurological disease.

Patients were divided into two groups according to detrusor contractility, which was assessed using the projected isovolumetric pressure (PIP) index [PdetQmax + maximum flow rate (Qmax)] with values of 30–75 cmH₂O indicating normal contractility [10]. The reasons why we chose these criteria are set out in the discussion. Patients with preoperative SUI and DU were enrolled in group 1 (G1) and those with SUI and normal detrusor contractility in group 2 (G2).

Preoperatively, all patients underwent a standardised preoperative urogynaecological work-up including: urogynaecological history, pelvic examination using the POP-Q classification [11], a standardised cough stress test (CST) performed in the standing position at a bladder volume of 300 ml or at maximum cystometric capacity if it was < 300 ml [12] and conventional urodynamic study (according to ICS criteria).

The device used for urodynamics was a Medtronic Dantec Duet with water-charged transducers. Bladder pressure was measured using an 8-F two-way transurethral catheter at a filling rate of 50 ml/min. Abdominal pressure was measured using a catheter with a small PVC balloon.

Urinary symptoms were evaluated using a structured questionnaire and the standardised UDI-6 questionnaire [13]. In

particular, the voiding phase was evaluated in the structured questionnaire in terms of yes-no questions on hesitancy, slow-stream, intermittency, straining to void and feeling of incomplete emptying and in UDI-6 question 5, which gives 4 degrees of difficulty in voiding. SUI was defined according to ICS standardisation and classified according to the Ingelmann-Sundberg scale [14]. The King's Health Questionnaire (KHQ) was used to evaluate quality of life (QoL) [15].

“Methods, definitions, and units conform to the standards jointly recommended by the International Urogynecological Association and the International Continence Society, except where specifically noted” [16].

TOT surgery was performed according to the technique described by Delorm [17] by expert surgeon (E.C.).

A Foley catheter was removed 24 h after surgery and the post-void residual was monitored. If PVR was > 100 ml for > 48 h, it was considered ‘persistent high PVR’ and patients underwent intermittent catheterisation.

Patients were followed up at 1, 3, 6 and 12 months and thereafter annually. At follow-up, urinary symptoms were evaluated with the same questionnaires used in the preoperative evaluation. We considered VD to be present when a patient answered at least two structured questionnaire questions affirmatively and also answered ‘moderately’ or ‘greatly’ to question 5 of UDI-6. The postoperative rate of continence was evaluated objectively using the CST. The subjective cure rate was evaluated using the Patient Global Impression of Improvement (PGI-I). The KHQ was again used to evaluate QoL. The urodynamic testing was performed after 1 year.

Follow-up assessments were performed by blinded physicians.

The study was approved by the Ethics Committee of our institution (CEAS registry no. 2566). All patients signed an informed consent.

We used the Fisher exact test for categorical variables, t-test for continuous parametric variables and Mann-Whitney test for continuous non-parametric variables ($p < 0.05$ statistically significant). The diagnostic accuracy of PdetQmax levels in predicting VD in patients with DU was determined using receiver-operating characteristic (ROC) curve analysis, with a cut-off point calculated for optimal sensitivity and specificity.

Results

Between 2007 and 2013, we performed TOT to treat 118 patients for SUI.

At the last follow-up, 3 patients had died, and 15 others were lost for other reasons. The remaining 100 patients were included in this study: of these 50 were enrolled in the undercontractility group and 50 in the normocontractility group.

We observed no significant preoperative differences between the groups in terms of demographic or clinical data or in urodynamic findings unrelated to DU (Table 1).

Immediately following the operation, nine patients in G1 and two in G2 had VD associated with persistent high PVR (defined as > 30% of voided volume) and thus underwent intermittent catheterisation.

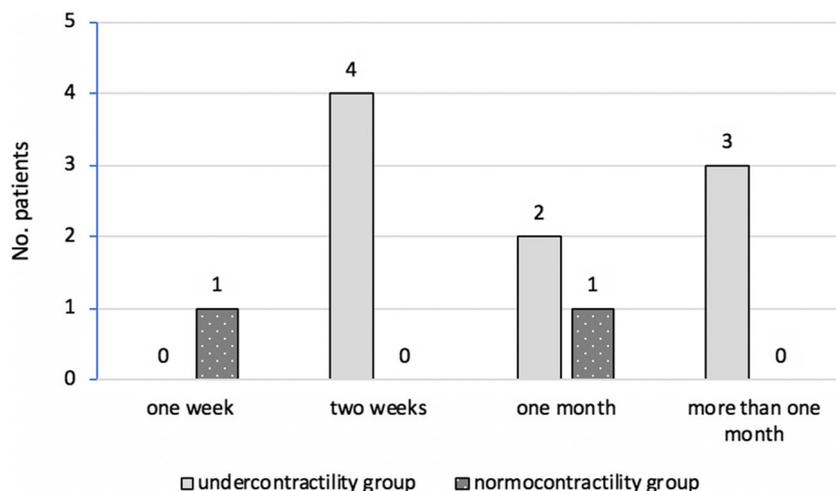
In G1, in three patients, persistent VD and high PVR lasted > 1 month: two underwent mesh incision; one had mesh removal. Following this secondary surgery, VD resolved spontaneously and PVR reduced to < 50 ml in all three cases. In the other six patients VD resolved and PVR reduced to < 50 ml: four in 2 weeks and two in 1 month.

In G2, in both patients VD resolved spontaneously and PVR reduced to < 50 ml in 7 days and 1 month, respectively (Fig. 1).

Table 1 Demographic data in the undercontractility group (G1) and normocontractility group (G2)

	G1 (N = 50)		G2 (N = 50)		P
Age, years mean \pm SD	60.19 \pm 10.80		58.30 \pm 10.56		0.3776
Parity, median (range)	2 (0–4)		2 (0–6)		0.0872
BMI, mean \pm SD	26.43 \pm 4.18		26.43 \pm 4.16		0.9978
Menopause, no. (%)	37 (74)		32 (64)		0.7640
SUI, no. (%)	Grade 0	0	Grade 0	0	1.0000
	Grade 1	10 (20)	Grade 1	5 (10)	
	Grade 2	31 (62)	Grade 2	27 (54)	
	Grade 3	9 (18)	Grade 3	18 (36)	
Wet OAB, no. (%)	23 (46)		33 (66)		0.4908
Dry OAB, no. (%)	29 (58)		36 (72)		0.1024
Voiding dysfunction, no. (%)	9 (18)		7 (14)		1.0000
Mean cystometric capacity, ml (\pm SD)	381.8 (\pm 79)		345.8 (\pm 63.4)		0.7841
DO, no. (%)	4 (8)		5 (10)		0.9943
Mean PdetQmax, cmH ₂ O (\pm SD)	10.6 (\pm 5.2)		28.5 (\pm 2.8)		< 0.005
Mean Qmax, cmH ₂ O (\pm SD)	15.2 (\pm 4.6)		27.8 (\pm 5.9)		< 0.005
PIP	26.1 (\pm 2.8)		49.6 (\pm 4.5)		< 0.005

Mean PdetQmax, cmH₂O (\pm SD); Mean Qmax, cmH₂O (\pm SD); PIP are statistically significant

Fig. 1 Duration of high PVR

At final follow-up (mean 76 months; range 48–120 months), 82 and 84% of women were continent in G1 and G2, respectively; dry OAB resolved in 69% of women in G1 and 84% in G2; wet OAB disappeared in 65% of patients in G1 and 66% in G2. VD showed a statistically significant increase from 18 to 36% in G1; the 19 uncomplicated patients in this group showed analogous results, with six patients (31.6%) having postoperative VD, which was 12% of all incidences. In G2 we had an increase in VD from 14 to 16%, which was not statistically significant. Lastly, G1 had an incidence of de novo VD of 28% and G2 an incidence of 2% (again these results were statistically significant in G1 but not in G2).

Table 2 compares the clinical results of both groups at final follow-up.

The pre- and postoperative urodynamic data of both groups are compared in Table 3.

In both groups PdetQmax and PIP increased after TOT treatment, and no obstruction was observed according to the Blaivas-Groutz nomogram.

One of our secondary objectives was to evaluate whether it is possible to predict postoperative VD in patients with DU using urodynamic parameters. From the baseline values of PdetQmax, we determined that a cut-off ≤ 12 cmH₂O predicted postoperative VD with 71.4% specificity and 80.0 sensitivity (Fig. 2). Note that this applies only to DU patients, so PIP is always ≤ 30 . Even if we were not able to establish a cut-

off for Qmax, the range of possible values is limited by the low PIP.

The KHQ showed a statistically significant improvement in all domains of QoL in both groups.

Table 4 shows the PGI-I scores for both groups.

We observed no statistically significant differences in PGI-I between the two groups.

Discussion

Our study demonstrates that there are no statistically significant differences in objective and subjective cure rates of SUI or other filling symptoms comparing women with DU and those with normal detrusor contractility.

By contrast, de novo VD after TOT surgery and also the reoperation rate for treating partial urinary retention are both higher in women with DU (PIP value < 30) than in women with normal detrusor contractility.

Preoperatively, we did not find significant differences in the incidence of VD between the two groups, which is probably explained by the weakness of the urethral sphincter in incontinent patients. This weakness causes SUI and reduces peripheral resistance so lower values of detrusor pressure during micturition are needed. Postoperatively, TOT produces

Table 2 Clinical results in the undercontractility group (G1) and normocontractility group (G2) at final follow-up

	G1 (N = 50)	G2 (N = 50)	P
Objective cure for SUI, no. (%)	41 (82)	42 (84)	1.0000
Subjective cure for SUI, no. (%)	39 (78)	42 (84)	0.1075
Wet OAB, no. (%)	9, of which 2 were de novo (18)	6, of which 1 was de novo (12)	0.5791
Dry OAB, no. (%)	13, of which 3 were de novo (26)	13, of which 1 was de novo (26)	0.9841
VD, no. (%)	18 (36)	8 (16)	0.0339
De novo VD, no. (%)	14 (28)	1 (2)	0.0016

VD, no. (%); De novo VD, no. (%) are statistically significant

Table 3 Pre- and postoperative urodynamic data in the undercontractility group (G1) and normocontractility group (G2)

	G1 (N= 50)			G2 (N= 50)		
	Preop	Postop	<i>p</i>	Pre-op	Postop	<i>p</i>
Uroflowmetry						
Mean Qmax, ml/s (±SD)	22.1 (± 6.7)	21.6 (± 9.6)	0.8264	34.1 (± 14.9)	27.5 (± 10.2)	0.7891
Mean voided volume, ml (± SD)	373.4 (± 144.7)	388.6 (± 106.1)	0.9172	358.6 (± 133.1)	379.3 (± 187.1)	0.9622
Cystometry and pressure/flow study						
Mean cystometric capacity, ml (± SD)	381.9 (± 79.1)	365.1 (± 59.8)	0.4245*	345.8 (± 63.4)	355 (± 79.8)	0.5532
DO, no. (%)	4 (8)	3 (6)	0.5637	5 (10)	7 (14)	0.2123
Mean PdetQmax, cmH ₂ O (± SD)	10.6 (± 5.2)	17.6 (± 9)	0.0016*	28.5 (± 2.8)	18.2 (± 11.2)	0.0022
Mean Qmax, ml/s (± SD)	15.2 (± 4.6)	15.5 (± 6.2)	0.1599*	27.8 (± 5.9)	25.6	0.4539
PIP	26.1 (± 2.8)	33.8 (± 9.7)	0.0009*	49.6 (± 4.5)	52.87	0.0038

Mean PdetQmax, cmH₂O (± SD); PIP are statistically significant

higher detrusor pressure during micturition in both groups, but there is a greater incidence of postoperative VD and de novo VD only in the G1 where PdetQmax is lower.

This difference in the incidence of postoperative VD between patients with and without DU demonstrates that evaluating symptoms alone is not sufficient to predict how the operation will affect the voiding phase and that this can be overcome by evaluating preoperative detrusor contractility. We note that this also applies to ‘uncomplicated’ SUI patients, which many researchers exclude from preoperative urodynamic studies. Therefore, our results indicate that performing these studies on uncomplicated patients allows their outcomes to be predicted more accurately, and this will have particular importance in

counselling such patients on what results they can expect in terms of postoperative symptoms.

It is known that VD may occur after MUS. Deval et al. reported VD after TVT as occurring in approximately 2 to 15% of patients with a substantial impact on patient satisfaction in these cases [18]. Bullock et al. reported postoperative retention rates of 2.3–19.5% following TVT and 2.0–5.4% after trans-obturator tape (TOT) [19].

However, there is a lack of high-level evidence supporting the assertion that urodynamics are able to predict the complications of surgery.

Some studies have demonstrated that some preoperative urodynamic parameters—high preoperative PVR, low preoperative PFR and low detrusor pressure during a pressure-flow study—can be used to predict postoperative voiding dysfunction after anti-incontinence surgery [20, 21].

Nevertheless, other studies have failed to demonstrate urodynamic predictors of post-MUS voiding dysfunction. Ahn et al. found that preoperative urodynamic parameters did not predict voiding dysfunction for 449 patients who were evaluated after undergoing TOT [22]. Cocci et al. demonstrated that the preoperative flow rate did not correlate with the occurrence of early voiding dysfunction after TVT-O surgery [23]. Linder et al. found that no urodynamic parameters were associated with the risk of sling release; the parameters they evaluated included

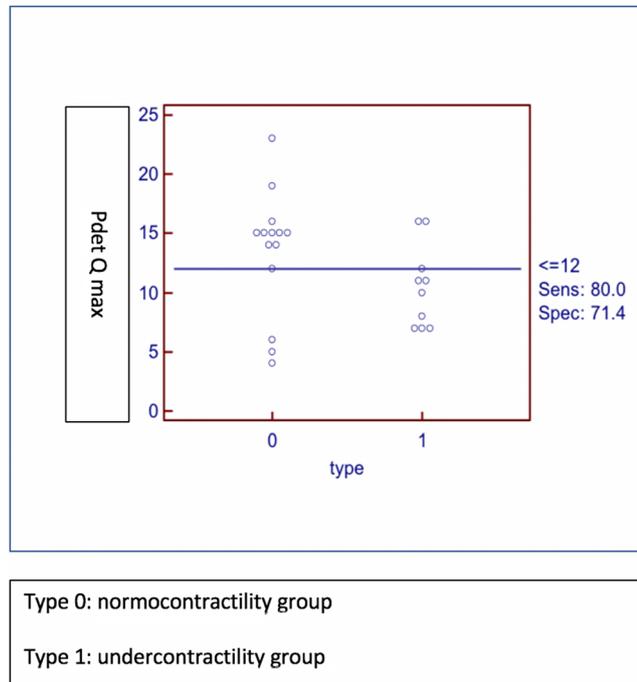


Fig. 2 ROC curve to determine the PdetQmax cut-off in DU patients

Table 4 PGI-I scores for the undercontractility group (G1) and normocontractility group (G2)

PGI-I score, no. (%)	G1 (N= 50)	G2 (N= 50)
1: Very much better	25 (50)	26 (52)
2: Much better	13 (26)	14 (28)
3: A little better	10 (20)	7 (14)
4: No change	2 (4)	3 (6)
5–7: Worse–very much worse	0 (0)	0 (0)

peak flow rate ($P=0.20$), postvoid residual volume ($P=0.37$), voiding without detrusor contraction ($P=0.96$) and detrusor pressure at maximal flow ($P=0.23$) [24]. Significantly, none of these papers evaluated detrusor contractility.

One problem that we encountered was deciding which parameters to use to establish the presence of DU. A precise understanding of how best to diagnose and quantify DU in women is currently lacking and defining parameters vary slightly from study to study [25–27].

In particular, there is need for a consensus on which urodynamic criteria to use to diagnose detrusor contractility. The urodynamic estimation of detrusor contractility is based on the detrusor pressure required to expel urine through a patent urethra. However, it is likely to underestimate contractility because the contraction generates both flow and pressure [28]. To compensate, methods were developed that attempted to estimate ‘isovolumetric detrusor pressure’ during uninterrupted or interrupted voiding [10]. Most of these methods are based on the bladder outlet relation (BOR), namely the inverse relation between pressure and flow [29]. Schafer proposed assessing the maximum isovolumetric pressure using the point Pdet/Qmax when the angle and curvature of the BOR are known [30]. To do this, the BOR is simplified to a straight line with a fixed angle (K). The isovolumetric pressure is then estimated by projecting back to the y-axis (Pdet) in a line parallel to the BOR represented by this formula:

$$\text{PIP} = \text{Pdet@Qmax} + \text{KQmax}$$

where PIP is the projected isovolumetric pressure.

Abrams used this formula to devise the bladder contractility index (BCI) [31]. His studies were on men with BPH and he used a value for K of 5 cmH₂O/ml/s. However, K will vary according to the study populations. For women, K = 1 cmH₂O/ml/s was found by Griffith to be more accurate.

Following Griffith, we chose to use the formula $\text{PIP} = \text{Pdet@Qmax} + 1 \text{ Qmax}$ to evaluate bladder contractility, with values of 30–75 cmH₂O indicating normal contractility.

This is one of the few papers to evaluate the effect of DU after SUI surgery. The other strengths of our study are the prospective design, the presence of a control group, the assessment of symptoms with pre- and postoperative validated questionnaires, the sufficiently long follow-up and the absence of missing subjective data. The most important strength is our identification of a cut-off value of PdetQmax in undercontractility patients below which postoperative VD is more frequent.

The chief limitation of this study is that there is no agreement on the parameter values used to define DU, which means that our results cannot be compared with other studies that used alternative values.

In conclusion, in DU patients with SUI, TOT gives good outcomes in terms of continence but results in a higher rate of VD compared with patients with normal detrusor contractility.

In particular, in DU patients with SUI, $\text{PdetQmax} \leq 12$ cmH₂O is a predictive factor for postoperative VD. Consequently, preoperative urodynamics are useful to discriminate DU patients with SUI and $\text{PdetQmax} \leq 12$ cmH₂O to counsel them better on their risks of VD and de novo VD and the reoperation rate.

Acknowledgements We thank David Nicholson for his invaluable help with and revision of the English in this paper.

Compliance with ethical standards

Conflicts of interest None.

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