

Efficacy of urodynamic studies in predicting long-term outcomes of the transobturator tape: do they augment clinical assessment?

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Introduction Some controversy exists regarding necessity for urodynamic evaluation prior to surgical management of stress urinary incontinence (SUI). We aimed to interrogate the role of pre and post-operative urodynamic studies versus clinical assessment in predicting long-term patient reported outcomes of transobturator tape (TOT) placement.

Material and methods A 100 patient cohort of women post TOT insertion for stress/mixed urinary incontinence 2005–2010, under a single surgeon, was identified. Results of pre and post-operative clinical assessment and urodynamic studies were retrospectively evaluated. Long-term patient reported outcome measures (PROMs) were assessed using the International Consultation on Incontinence Questionnaire (ICIQ) Short Form, Patient Global Impression of Severity (PGI-S) and Patient Global Impression of Improvement (PGI-I) questionnaires. The role of urodynamic studies in predicting postoperative voiding dysfunction, and long-term procedure outcomes was analysed. Statistical correlations were performed using SPSS.

Results Questionnaire response rate was 76/100 (76%) at mean follow-up 9.4 years (7.25–12.75). Mean ICIQ score was 6.32 (1–20). No significant correlations between preoperative pDet QMax and postoperative uroflow/duration of intermittent self catheterisation (ISC), or between preoperative leak-point pressures and outcome were observed. Postoperative urodynamic tests did not reliably predict long-term success in SUI cure. Preoperative clinical urgency was a more reliable predictor of long-term clinical urgency than urodynamic detrusor overactivity. Whilst patients with mixed urinary incontinence at long-term follow-up tended to have the highest (worst) overall ICIQ-SF and ICIQ quality of life score, no studied variables on preoperative CMG were significantly correlated with long-term PROMs.

Conclusions Whilst urodynamic studies provide important baseline bladder function data, prior to mid-urethral sling placement, this study finds no specific value of either pre or postoperative urodynamics in predicting long-term patient reported outcomes of transobturator tape placement.

Key Words: transobturator tape ↔ mid-urethral sling ↔ stress urinary incontinence ↔ long-term outcomes ↔ urodynamics ↔ cystometrogram ↔ predicting outcome ↔ patient reported outcome measures

INTRODUCTION

Surgical management offers the potential of cure to women with stress urinary incontinence (SUI): the complaint of involuntary leakage of urine on effort, exertion, sneezing or coughing [1, 2]. Mid-ure-

thral tapes, be they retropubic (TVT) or transobturator (TOT), had become the gold standard for SUI treatment until recently. A number of uncertainties now surround the use of mid-urethral slings, most notably related to their long-term safety and efficacy profile [3–6, 7, 8], but also concerning the optimal

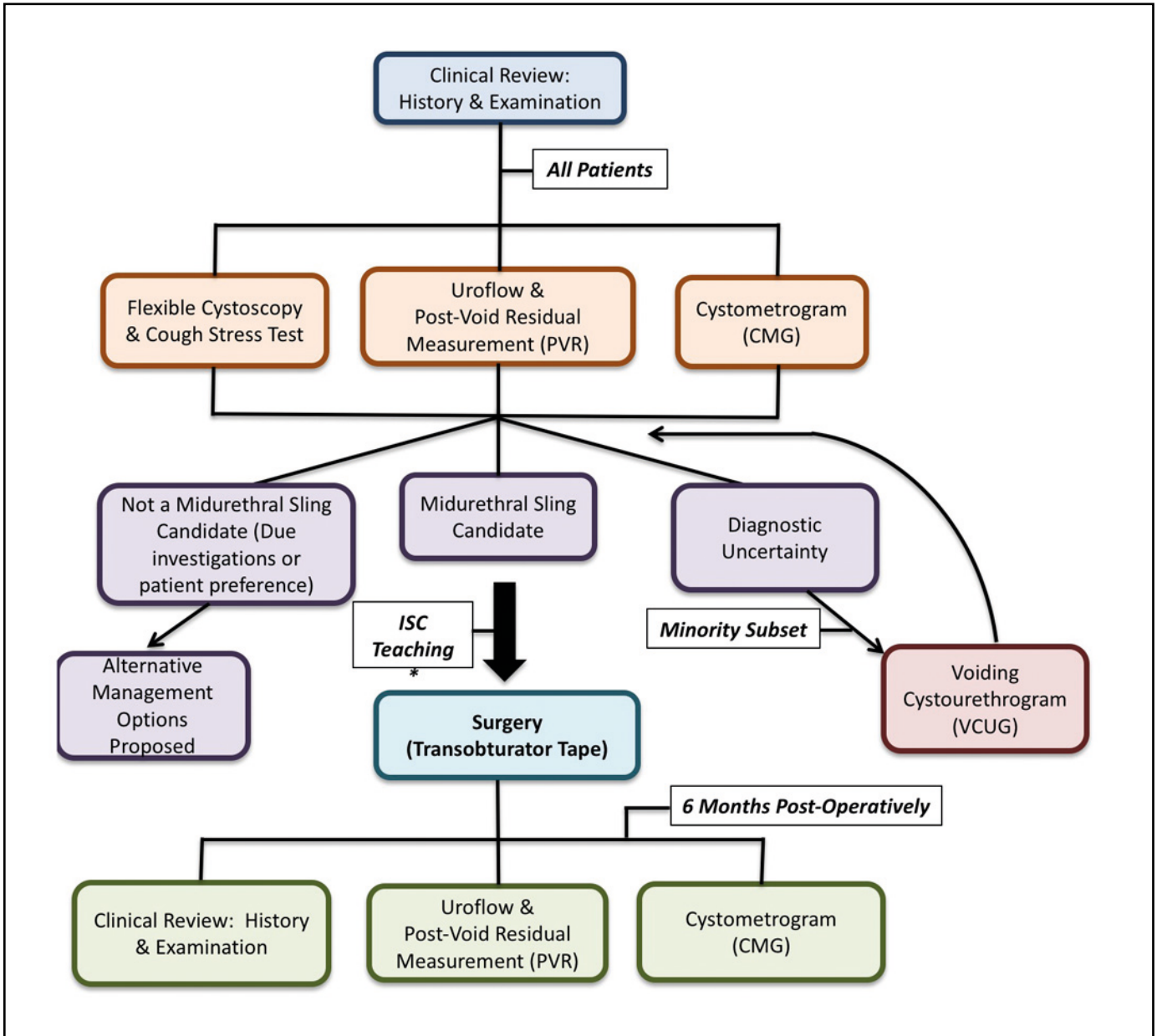


Figure 1. Standard peri-operative investigative algorithm for TOT insertion

*intermittent self-catheterisation; TOT – transobturator; PVR – post-void residual volume; CMG – cystometrogram; ISC – intermittent self catheterisation; VCUG – voiding cystourethrogram

work-up algorithm and the necessity for pre-procedure urodynamic studies [9, 10]. We have recently reviewed our transobturator tape outcomes at 10 year follow-up. We aimed to ascertain the predictive role of pre and post-procedure cystometrogram, as an adjunct to clinical assessment, in determining both short and long-term outcomes of the transobturator tape. There is no published data of which we are aware analysing this relationship at long-term follow-up. We feel that given the current controversies, careful patient selection and

personalised counselling in the work-up of stress urinary incontinence has assumed greater importance than ever before.

MATERIAL AND METHODS

A cohort of 100 female patients who underwent transobturator tape (TOT) insertion for stress or stress-predominant mixed urinary incontinence, over a 5-year timeframe (2005–2010) was identified. This was a consecutive series of all patients with avail-

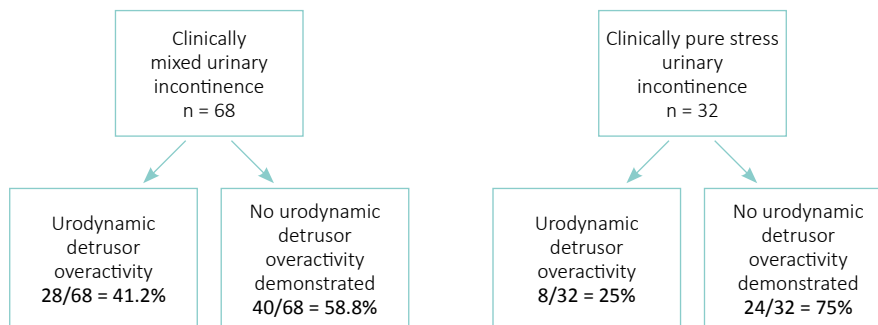
able urodynamic data (two patients operated on over the timeframe were excluded as cystometrograms had been performed elsewhere and results were unavailable). A single surgeon, the senior author, performed patient work-up and TOT placement in all cases.

The standard peri-procedure assessment algorithm used in our institution during the studied time period is outlined in Figure 1. Patients routinely completed a voiding diary as part of assessment in our institution. Formal pad tests were not routinely used, but the patients' perceptions of urinary incontinence (UI) severity was evaluated, along with an estimation of their daily pad usage. Cough stress test was performed at flexible cystoscopy – on completion of procedure, with bladder filled to a volume producing a moderate desire to void, patients were asked to cough in both supine and standing positions, and

observation for leakage was performed. All patients operated on had a positive cough stress test. Two patients in this cohort did not demonstrate stress urinary incontinence at the time of cystometrograms despite having had a positive cough stress test. These two patients underwent voiding cystourethrogram (VCUG) to clarify the diagnosis and to assess the degree of bladder neck descent. Following initial work-up, patients that were deemed suitable candidates for a transobturator tape, who chose to pursue this route, proceeded to TOT placement, using the Monarc® subfascial hammock (Advanced Medical Services, AMS), using an 'outside-in' technique, under general anaesthesia. Following transobturator tape insertion, routine ward care included monitoring for voiding dysfunction with post-void residual volumes (PVRs) assessed with a portable bladder

Table 1. Population characteristics

Mean age	51.7 years (33–75)		
Mean symptom duration	7.44 years (0.75–34)		
Previous pelvic surgery	34/100 (34%)	Hysterectomy +/- BSO	18/34
		Hysterectomy in combination with repair or Marshall Marchetti Krantz	8/34
		Stamey ras	1/34
		Manchester repair	1/34
		Oophorectomy	2/34
		Tubal ligation	1/34
		Rectovaginal fistula repair	1/34
		Shirodkar cervical incompetence	1/34
		Pubovaginal sling	1/34
		Parity	
Para 1	7/100		
Para 2	26/100		
Para 3	27/100		
Para ≥4	20/100		
Unknown	15/100		



scanner. Patients were instructed to perform temporary intermittent self-catheterisation if PVRs exceeded 100 ml. Postoperative evaluation comprised clinical review, as well as uroflow, PVR and cystometrogram (CMG) performed at approximately 6 months post-procedure. As such, all patients underwent cystometrogram both pre and postoperatively. Retrospective chart review was performed and evaluation of the findings of pre and postoperative clinical assessment and investigations for all patients conducted. Long-term patient reported outcome measures (PROMs) were then sought from the study cohort. Patients were telephoned, and verbal consent to participation requested. Willing patients were sent a Patient Global Impression of Severity (PGI-S) and Patient Global Impression of Improvement (PGI-I) measures and the International Consultation on Incontinence Questionnaire (ICIQ-Short Form), [11] along with freetext boxes for the recording of complications, urological medications, and unstructured feedback, via conventional post with a stamped addressed envelope for return. Both PGI-S and PGI-I tools have displayed strong correlations with frequency of incontinence episodes, stress pad test and incontinence quality of life questionnaires [12]. Initial investigations, including the pre and postoperative urodynamic studies were reviewed for each individual patient in the context of her long-term functional outcome. The role of urodynamic studies in predicting both short and long-term outcomes of the TOT, alongside clinical assessment alone, was interrogated, with statistical analysis applied to hypotheses set a priori. Statistical correlations were performed using SPSS.

RESULTS

Population characteristics

A total of 100 female patients were included in the study. Long-term patient reported outcome measures (PROMs) were obtained at mean 9.4 years (7.25–12.75), with a questionnaire response rate of 76/100 (76%).

Patient characteristics are outlined in Table 1.

Short-term outcomes

Short-term outcomes are presented in Table 2.

Patient reported outcomes at long-term follow-up

At mean 9.4 years long-term follow-up, 59% subjectively had sustained cure of SUI, and 81.57% (62/76) described their urinary condition at long term follow

Table 2. Short-term outcomes

Stress urinary incontinence			
	Cure	Cure or significant improvement	
Clinical SUI	91/100 (91%)	98/100 (98%)	
Urodynamic SUI	68/100 (68%)	93/100 (93%)	
Urgency			
Improvement/Cure of clinical urgency	58/68 (85.29%)		
De novo urgency	1/100 (1%)		
De novo detrusor overactivity	1/100 (1%)		
Voiding dysfunction			
	Preoperative	Postoperative	Statistically significant?^
Need for ISC	N/A	44/95 (46.32%) Median 3 days (2–84)	–
Mean PVR*	95.83 ml (0–400 ml)	79.8 ml (0–400 ml)	No, p = 0.08
Mean uroflow QMax	32.07 ml/sec (5–76)	25.08 ml/sec (2–55)	Yes, p <0.00001

*Mean PVR of 92 patients able to voluntarily void for uroflow

^Paired t-test

SUI – stress urinary incontinence; ISC – intermittent self catheterisation; N/A – not applicable; PVR – post-void residual volume

Table 3. Long-term outcomes

Long-term patient reported outcome measures	
Current ICIQ score	Mean score 6.32
Patient global impression of severity: current urinary condition	‘Normal’ or ‘mild’ 56/76 (73.68%)
Patient global impression of improvement: current urinary condition	‘Much better’ or ‘very much better’ 62/76 (81.57%)
Stress urinary incontinence	Sustained Cure 45/76 (59%)
Urge incontinence	Current – any 51/76 (67%)

ICIQ – Consultation on Incontinence Questionnaire

up as ‘much better’ or ‘very much better’ than prior to surgery. The mean ICIQ score at long-term follow-up was 6.32 (1–20) (Table 3).

Complications at long-term follow-up

No new complications, or symptoms suggestive of these, were identified at long-term follow-up. Two patients reported some degree of dyspareunia that

had been investigated post TOT insertion and had not worsened over time.

Urodynamic predictors of voiding

Clinically, no patient reported symptoms of obstructed voiding prior to TOT placement. Analysis of the relationship between preoperative detrusor pressure at maximum flow during voiding (pDetQMax) and postoperative voiding efficiency, determined by post-void residual volume and number of days of intermittent self catheterisation (ISC) required was performed (Figures 2 and 3). Correlations between pDetQMax and postoperative uroflow PVR ($r = 0.06$) or duration of ISC ($r = 0.043$) were not significant, using Pearson's correlation coefficient.

Urodynamic predictors of persistent / recurrent stress urinary incontinence

We evaluated whether lower abdominal leak point pressures would correlate with TOT treatment failure in management of SUI. No statistically significant difference was observed in outcome (Mann-Whitney U Test), when looking at either short-term or long-term recurrence/persistence of stress urinary incontinence, with lower preoperative abdominal leak point pressures, including when patients with leak point pressures <40 cmH₂O were evaluated in isolation (Figures 4 and 5).

We also analysed the relationship between short-term clinical and urodynamic outcome and long-term persistence or recurrence of stress urinary incontinence. Whilst it was noted that more patients with a degree of residual stress urinary incontinence on postoperative urodynamic studies had long-term clinical SUI (11/20) than patients who had no residual SUI on postoperative CMG (20/55), this did not reach statistical significance (Fisher exact test statistic 0.18). Similarly, review of the small number of patients ($n = 6$) who reported SUI to be clinically improved, but not cured, at short-term follow-up and who provided long-term PROM response, showed no significant correlation between short term 'failure to completely cure' and long-term recurrence/persistence (Fisher exact test statistic 0.68).

Urodynamic predictors of urge and urge incontinence

We evaluated the role of preoperative cystometrograph and its assessment of detrusor overactivity in predicting long-term urge/urge incontinence post transobturator tape insertion. To interrogate this, we divided patients into four groups (A–D) based

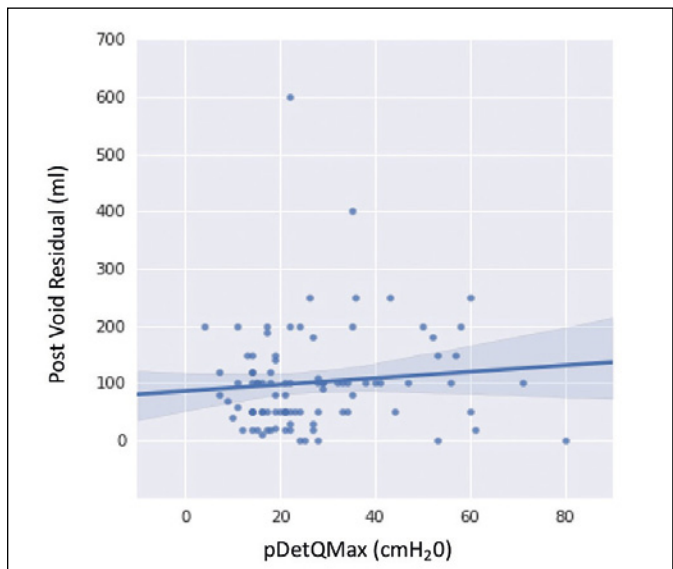


Figure 2. Postoperative PVRs vs. preoperative pDet QMax.

PVRs – post-void residual volumes; pDetQMax – maximum flow during voiding

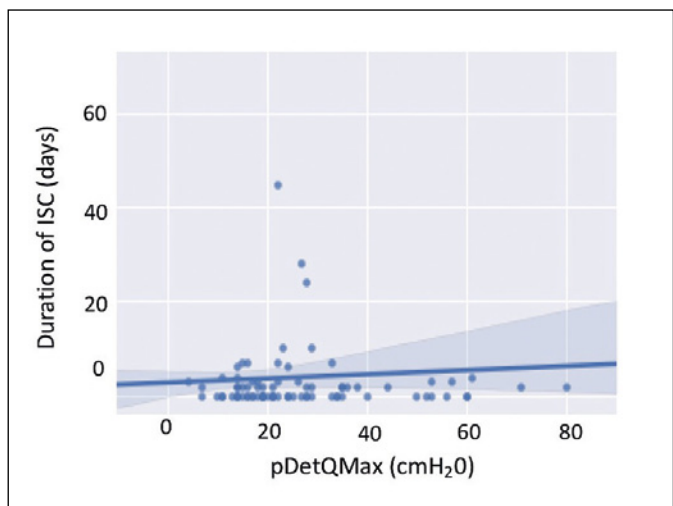


Figure 3. Duration of ISC (days) vs. preoperative pDet QMax.

pDetQMax – maximum flow during voiding; ISC – intermittent self catheterisation

on their preoperative clinical symptoms of urgency and CMG evidence of detrusor overactivity (Table 4). We found, using chi-squared and fisher exact test, the only predictor of postoperative urgency/urge incontinence (both short and long-term) to be preoperative clinical urgency (Figure 6). Detrusor overactivity (DO) on preoperative urodynamics was not a statistically significant predictor of postoperative clinical urgency in this patient cohort. The presence of DO on preoperative urodynamics did not influence the chance of improvement of clinical urgency post TOT placement.

Table 4. Patient groupings

Group	Clinical urgency	Detrusor overactivity	
A	No	No	
B	Yes	No	'Unexplained urge'
C	No	Yes	'Silent detrusor overactivity'
D	Yes	Yes	

Urodynamic predictors of long-term patient satisfaction

We analysed the potential relationship between a number of pre-procedure urodynamic variables and long-term patient reported satisfaction. We assumed 'severe' SUI to be manifest as low abdominal leak point pressures or low bladder volume at first urodynamic evidence of stress urinary incontinence, and interpreted long-term patient satisfaction as PGI-I result of current urinary condition being 'much better' or 'very much better' than originally. No significant correlation was seen between pre-procedure abdominal leak point pressure <40 cmH₂O, or bladder volume <200 ml at first SUI, and long-term satisfaction (Figure 7). Similarly, the absence of urodynamic detrusor overactivity on work-up cystometrogram did not show significant correlation with long-term patient satisfaction (Figure 7).

An overview of the relationship between the current type of urinary incontinence experienced, and the patient's ICIQ-SF overall score, and ICIQ 'quality of life score' alone is presented in Figure 8 and Figure 9. A wide distribution around the mean is seen for all groups of patients with incontinence, with the highest scores reached by those with mixed incontinence. Patients without urinary incontinence reported the lowest scores.

DISCUSSION

This is one of a limited number of papers reporting on long-term outcomes of the transobturator tape, and it is also relatively unusual in the availability of postoperative urodynamic data. To our knowledge, it is the first paper evaluating the predictive value of urodynamic testing in foreseeing long-term patient outcomes.

Urodynamic predictors of voiding

We hypothesized that patients with lower preoperative detrusor pressures at maximum flow (pDetQ-Max) on preoperative uroflow would be most likely

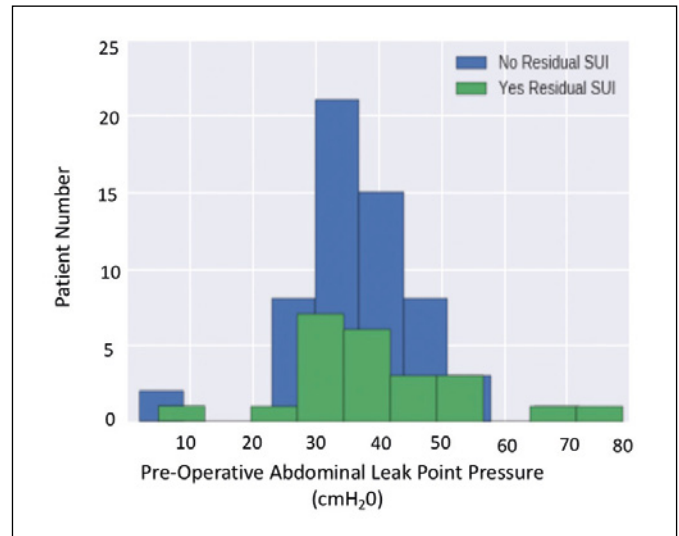


Figure 4. Association of preoperative abdominal leak point pressures with urodynamic SUI at short-term follow-up.

SUI – stress urinary incontinence

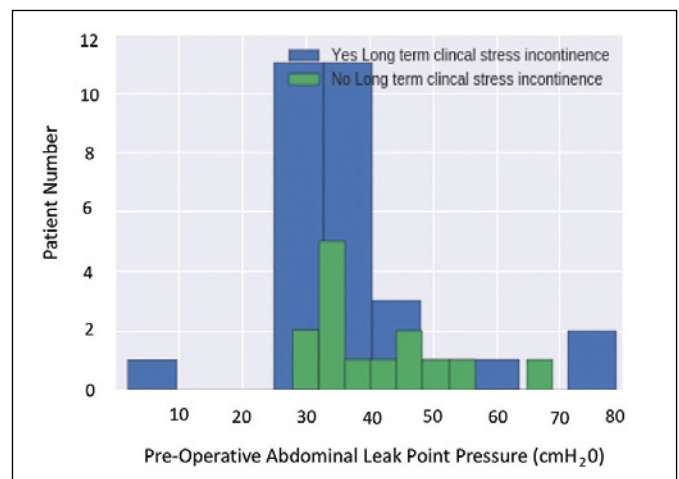


Figure 5. Association of preoperative abdominal leak point pressures with clinical SUI at long-term follow-up.

SUI – stress urinary incontinence

to suffer postoperative voiding dysfunction. Miller et al. had previously studied a cohort of women post cadaveric fascial pubo-vaginal sling and noted all cases of postoperative retention had preoperative detrusor contraction of ≤12 cmH₂O on urodynamic studies [13].

We did not, however, observe any such correlation in our cohort of TOT patients. This is similar to the findings of Kim et al., who assessed correlation between low preoperative flow rate with postoperative retention and concluded no strong relationship existed [14]. We therefore feel that surgical factors, predominantly the positioning and tensioning

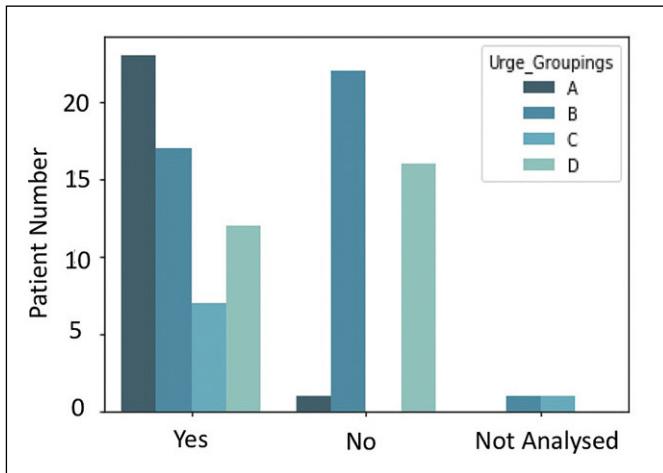


Figure 6. Relationship of Table 4 subgroupings with clinical urgency following transobturator tape insertion.

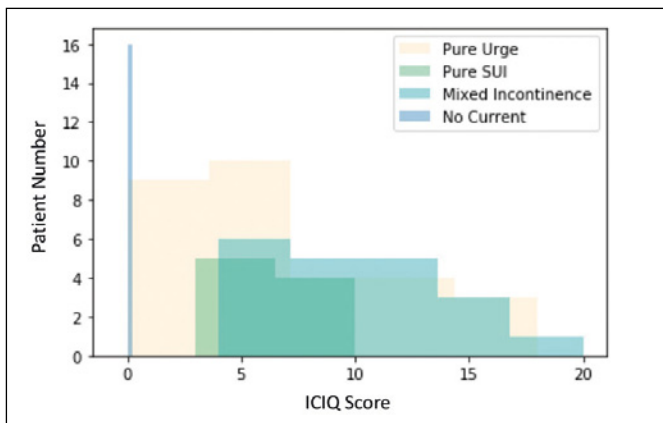


Figure 8. ICIQ-SF scores at long-term follow-up related to presence & type of current incontinence.

SUI – stress urinary incontinence; ICIQ – International Consultation on Incontinence Questionnaire

of the mid-urethral sling (MUS) are likely to be the greatest factors governing resumption of normal postoperative voiding.

Urodynamic predictors of success

Women with lower abdominal leak point pressures, classified as having intrinsic sphincter deficiency, may benefit less from TOT placement [15]. Whilst our patients were carefully selected by the senior author (GL) and typically had urethral hypermobility on exam, a number did demonstrate SUI at abdominal leak point pressures ≤ 40 cmH₂O. We assessed the outcomes of TOT placement related to abdominal leak point pressure, and found that the latter was not a useful predictor of failure/cure of SUI. This is in keeping with several studies

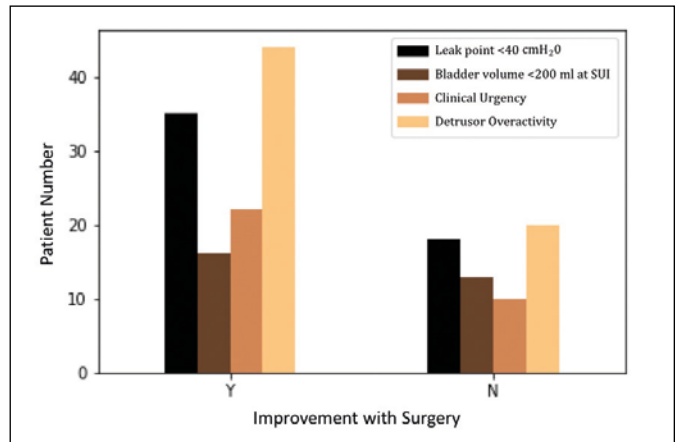


Figure 7. Distribution of preoperative factors across patients who did and did not report improvement with surgery.

SUI – stress urinary incontinence

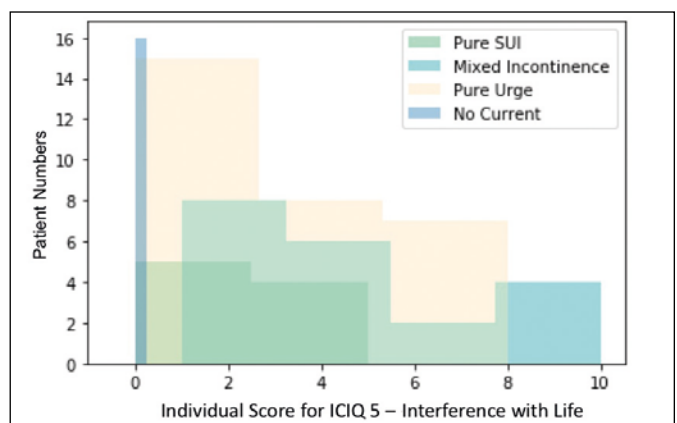


Figure 9. ICIQ QoL scores at long-term follow-up related to presence & type of current incontinence.

ICIQ – International Consultation on Incontinence Questionnaire; QoL – quality of life

and review papers demonstrating the inability of preoperative abdominal/Valsalva leak point pressure to predict outcome in surgical management of SUI [9, 16, 17, 18]. We add to this literature by demonstrating poor predictive ability of preoperative cystometrograms in foreseeing long-term outcomes of TOT placement.

Urodynamic predictors of urgency

We found the only predictor of urgency or urge incontinence at both short and long-term follow-up to be preoperative clinical urgency, which was a more reliable predictor than the presence or absence of detrusor overactivity on CMG. This raises the question of whether urodynamic studies are required prior to SUI surgery, particularly when SUI surgery

may be considered an option for patients with stress-predominant mixed urinary incontinence [19].

Urodynamic predictors of long-term patient satisfaction

Patient-reported satisfaction is one of the most important long-term goals in functional and reconstructive urology. We hypothesized that patients with the most severe stress urinary incontinence in the first instance might have the greatest subjective 'improvement' rating (PGI-I) at long-term follow-up. We also proposed that patients with the absence of DO on preoperative CMG would have higher long-term satisfaction than their counterparts with urodynamic DO. However, in our patient cohort, these factors were not reliable predictors of long-term PROMs.

Overall utility of urodynamics

Our results do not demonstrate any convincing predictive ability of preoperative urodynamics in anticipating long-term patient reported outcomes of the transobturator tape. Previously, a number of other authors have concluded that findings of preoperative urodynamics are unlikely to change patient management or the short-term outcomes of surgery for SUI, although they may increase physician confidence [9, 18, 20].

Study limitations

We do recognise a number of limitations to our study. As we studied an SUI surgical cohort, we cannot deduce from our experience whether other potential surgical candidates were managed differently, non-operatively or with a different surgical procedure, based on their initial urodynamic studies. We cannot, therefore, comment on the role of urodynamic testing in initial patient selection, and believe that larger, prospective trials are warranted to address this question. We offer SUI surgery to patients with clinically mixed UI who demonstrate a prominent stress

component, and therefore wished to study a representative population sample. Analysis is therefore of a population with both pure SUI and mixed urinary incontinence. We feel that this approach allows more clinically-relevant questions to be addressed, particularly surrounding the long-term outcomes of patients with mixed UI, and is further supported by the poor correlations between clinical urgency and urodynamic DO in the preoperative patient cohort (Table 1). This approach, does, however, result in greater heterogeneity of the population, with greater subgrouping of the cohort and lower sample sizes within each group for statistical analysis.

CONCLUSIONS

We did not find any clear advantage to performing preoperative or postoperative urodynamic studies in this patient cohort. We found the presence of clinical urgency preoperatively to be the best predictor of long-term urgency and therefore useful for patient counselling. We did not identify any predictive value to urodynamic testing as an adjunct to clinical assessment in foreseeing long-term patient outcomes of the transobturator tape. We conclude that routine postoperative urodynamic studies are of negligible value, and have since removed them from our practice. Having, however, evaluated a surgical cohort rather than an undifferentiated patient cohort presenting with incontinence, we cannot conclude from our experience whether or not preoperative urodynamic studies were helpful in patient selection. Irrespective of predictive value, urodynamic studies provide important baseline data against which possible postoperative or future bladder dysfunction may be evaluated. Given the current concerns surrounding the use of mid-urethral slings, physicians more than ever have a responsibility to ensure careful, objective patient selection, and in this regard, preoperative CMG is likely to remain a feature in the surgical selection of patients with SUI.

CONFLICTS OF INTEREST

The authors declare no conflicts of interest

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