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ORIGINAL ARTICLE

Factors predictive of post-TVT voiding dysfunction

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Abstract In this study we assessed the incidence of voiding dysfunction in women 6 months after undergoing a tension-free vaginal tape (TVT) procedure. Logistic regression was then used to look for significantly associated factors from a range of patient, urodynamic and surgical variables. From a group of 267 women we identified 22 (8%) who needed to perform daily intermittent self-catheterisation (ISC) as a result of the TVT surgery. When potential predictive factors were examined individually there were three that appeared to be associated with the need to use ISC: menopausal status, previous incontinence surgery and the centile score for average voiding flow rate (as derived from a volume–flow rate nomogram). Following multivariate logistic regression this flow rate centile score showed the strongest association with post-TVT voiding dysfunction, the likelihood of needing ISC increasing as the centile score fell. This factor has not previously been described but is readily assessed pre-operatively and may be useful in case selection for TVT.

Keywords Voiding dysfunction · Tension-free vaginal tape · Urodynamic stress incontinence

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Introduction

The tension-free vaginal tape (TVT) procedure has been widely adopted for the treatment of urodynamic stress incontinence (USI) in women. Objective cure rates for the TVT are comparable with colposuspension [1], and there are now published observational data to suggest ongoing cure at 7 years [2]. As with other operations for USI, post-operative voiding dysfunction can occur after TVT. There are considerable differences, however, in the definitions used for voiding dysfunction in the published literature and hence in the quoted rates with which it occurs.

It is unclear how post-operative voiding dysfunction can be best predicted before surgery. If this were possible then pre-operative counselling could include a specific risk assessment for each individual and be more meaningful. Indeed, a woman advised of an increased likelihood of voiding problems after TVT, possibly requiring self-catheterisation, may decline surgery.

Previous work in this area has failed to identify a consistent means of predicting voiding ability after TVT. Voiding dysfunction has been associated with patient characteristics such as increased age [3], irritative bladder symptoms [4], pre-existing enterocoele and vault prolapse [5] as well as previous incontinence or prolapse surgery [3, 6, 7]. Associations between post-operative voiding dysfunction and the urodynamic variables of reduced peak voiding flow rate and an abnormal uroflowmetry pattern have been made [5, 8]. A concomitant vault suspension at the time of TVT has been linked with voiding problems [5], whereas the use of spinal rather than local anaesthetic has been associated with reduced urinary retention [9]. Other studies have failed to identify significant predictive factors [10, 11]. Much of the published material on predictive

factors for voiding dysfunction has analysed cases relatively early in the post-operative period [7, 8, 15]. Although short-term problems invariably precede long-term voiding difficulty, the majority will resolve and are of less significance.

The aim of this study was to review all TVT procedures carried out in our tertiary urogynaecology unit to provide a large sample for analysis. In addition to auditing local outcomes, we planned to analyse a range of demographic, urodynamic and operative variables to identify those associated with post-operative voiding dysfunction and the need for intermittent self-catheterisation (ISC) 6 months after surgery. Of particular interest was whether centile scores for voiding flow rates might assist in the prediction of voiding dysfunction after TVT. We routinely use the Liverpool nomograms [12] when assessing results of uroflowmetry studies. These charts can be used to calculate centile scores of both maximum and average urine flow rates for any given voided volume.

Materials and methods

The setting for this study was the Urogynaecology Department of a tertiary referral hospital. All TVTs performed in the hospital since its introduction in January 1998 until November 2004 were analysed retrospectively. The end date chosen was to allow for a routine review of all cases 6 months after surgery. Local Research Ethics Committee approval was obtained before the study commenced.

Cases were identified from a coded surgical database and comprised TVTs performed either as a sole procedure or concomitantly with another operation. All women had undergone urodynamic investigations before surgery. These tests included a standardised 1-h pad test [13], uroflowmetry (Urodyn, Dantec Dynamics, Bristol) with ultrasonically assessed post-void residual volume (PVR) and dual-channel subtraction cystometry (Medtronic, Dantec Dynamics, Bristol).

Selected details of history and examination along with urodynamic results were extracted from case notes. Variables were chosen for analysis on the basis of possible influence on the voiding mechanism, either before or after surgery. The uroflowmetry data were compared with the Liverpool voiding nomograms to determine centile values for the maximum and average flow rate in each case.

The TVT procedure was introduced to the hospital in the setting of a randomised controlled trial comparing it with Burch colposuspension, and the technique used was that described by Ulmsten et al. [14] as required for the trial. Initial cases were performed with training and supervision from a visiting expert. Subsequent to this, the consultant urogynaecologists and urogynaecology subspecialty trainees performed all operations.

At the completion of the trial recruitment, the TVT was made available more widely within the department and was also performed in combination with other procedures. Concerns about the effect of sedation and positioning on the reliability of the cough test led to the use of general anaesthesia. Retropubic infiltration with dilute local anaesthetic was continued, however, on the premise that the hydrodissection afforded by this technique was important in reducing bladder injury. More recently, the infiltration has been carried out using sterile water alone to avoid any influence of anaesthetic agents upon urethral function. After cystoscopy to confirm bladder integrity, the tape was pulled through until a size-eight Hegar dilator fitted easily between the tape and urethra. In this way, there was minimal tension applied to the urethra. The bladder was emptied as cystoscopy was completed and post-operative indwelling catheterisation used only when the TVT was combined with additional surgery.

We assessed voiding flow rate and PVR the morning after surgery. A residual volume of more than 100 ml was usually managed with double voiding, but if this was insufficient then the women were taught ISC before discharge. The ISC continued until the residual volume was less than 100 ml on two consecutive occasions. All women were reviewed routinely at 6 weeks and had a final outpatient visit at 6 months, which included a repeat pad-test, uroflowmetry and PVR assessment.

Women were defined as having voiding dysfunction if, at their 6-month review visit, they continued to have a daily requirement for ISC on the basis of voiding ability and urinary symptoms. Although the extent of daily ISC might vary between cases, we felt that this outcome was clinically relevant and one that would be more significant in terms of quality of life than defining voiding dysfunction by an arbitrary flow rate or PVR volume. To concentrate on voiding dysfunction developing after TVT, women were excluded from the analysis if they were already doing ISC before surgery.

All data was anonymously entered into a spreadsheet and analysed using SPSS for Windows 11.0 (SPSS, Chicago, IL).

Univariate logistic regression modelling was used to assess the association between the outcome and each of the predictor variables, whether continuous or categorical. Univariate odds ratios (O.R. with 90% C.I.) and p values were calculated for each variable. Any that were significantly associated with ISC ($p<0.1$) were selected for entry into the multivariate model, and logistic regression was used to assess which of these variables were significant in predicting the outcome when taken in combination. A

backwards-elimination procedure was used to determine the final model (criteria for removal $p>0.05$).

Results

Between January 1998 and November 2004, we performed 294 TVTs. Pre-operative characteristics of the women who underwent surgery are shown in Table 1 along with the grade of operating surgeon, type of anaesthesia and whether the TVT was combined with other surgery.

Follow-up voiding function data were available for 273 (93%) women at 6 months. The women with this data and those without were compared in terms of demographics and aspects of their surgery. The two groups were similar, differing only in that a higher percentage of women with missing data had the TVT as a combined procedure (3 [38%] vs 56 [21%]). Given the small numbers involved, we considered the cases with complete data to be representative of the total TVT group.

At the 6-month post-operative assessment, there were 28 women who needed to perform daily self-catheterisation. Excluding those who were already self-catheterising before surgery meant that 22 of 267 cases (8%) met our criteria for voiding dysfunction. The indication for ISC in most cases (14) was an ongoing PVR of greater than 100 ml with recurrent episodes of cystitis. Five women used ISC to deal with a symptomatic 'slow void' whereas a further three did so only at night to reduce their nocturia. Six of the 22 women had been taught ISC before surgery on the basis of their pre-operative urodynamic assessment.

Table 1 Pre-operative patient characteristics

Characteristic	Value (n=294)
Age (years)	52.2 [10.0]
Parity	2.6 [1.3]
Body mass index	28.4 [4.7]
Menopausal	183 (62.2%)
HRT use	114 (38.8%)
Irrititative symptoms[a]	252 (85.7%)
Previous incontinence surgery[b]	74 (25.2%)
Previous prolapse Surgery	47 (16.0%)
1 h pad loss (g)	21 (8, 45)
Post-void residual volume (PVR) (ml)	36 (12, 68)
PVR>100 ml	45 (16%)
Maximum flow rate below 15 ml/s	23 (8%)
Registrar case	108 (36.7%)
General anaesthetic (no cough test)	260 (88.4%)
TVT with other op.	64 (21.8%)

Data are mean [SD]; median (interquartile range) or number (%)

[a] Women who reported one or more of frequency, urgency or nocturia prior to surgery.

[b] Previous incontinence surgery includes Burch colposuspension, TVT and anterior repair (if performed for incontinence).

The univariate odds ratios for ISC for each of the potential predictor variables are shown in Table 2.

Three variables met statistical criteria for entry into the multivariate logistic regression model. These were menopausal status, previous incontinence surgery and the centile score for average voiding flow rate (QaveCent).

After a backwards elimination of non-significant variables, one remained as being significantly associated with ISC (Table 3).

In addition to the information on voiding dysfunction objective, pad-test results were available for 263 of the cases. As with the voiding function follow-up, there were no differences between women with and without pad-test data, and it is therefore reasonable to consider the observed 6-month cure rate of 207/263 (79%) to be a representative of the total TVT group.

Bladder perforation occurred in six cases (2%); all were detected intra-operatively. In five of these women, the tape was removed and immediately reinserted. The sixth woman had already undergone a failed Burch colposuspension and a previous TVT. The perforating tape was removed, and a repeat colposuspension was successfully performed after a 2-month interval.

Tape division or removal was required in three women. The first, who could not void because of a vaginal haematoma and could not contemplate ISC, underwent clot evacuation and tape removal after 2 days. A second woman developed an abscess around the tape and had it divided and partially removed at 17 months. The third case had her tape divided 8 months after insertion because of extreme tenderness over the mid-urethra. Neither of these women needed to perform ISC at 6 months, but all were wet on pad testing after tape removal. Tape infection was recorded for two further women in the 6 months after surgery. Both resolved with conservative management.

Discussion

In this study of 267 women undergoing TVT, we have identified 22 (8%) who needed to perform ISC on a daily basis 6 months after surgery. We have calculated ISC odds ratios for a range of patient and operative variables to determine those that might be associated with this complication. The statistically significant variables of those studied were: menopausal status, previous incontinence surgery and the centile score obtained for average voiding flow rate (QaveCent) using a recognised volume-flow-rate nomogram. Logistic regression analysis of these three factors showed that QaveCent had the strongest statistical association.

Table 2 Results of univariate analysis

Variable	O.R. for ISC (90% C.I.)	*p* Value
Age	1.04 (1.00, 1.07)	0.11
Parity	0.89 (0.65, 1.22)	0.55
Body mass index	1.02 (0.94, 1.10)	0.70
Menopausal	2.88 (1.13, 7.33)	0.06*
HRT use	1.94 (0.93, 4.05)	0.14
Previous incontinence surgery	2.20 (1.04, 4.68)	0.09*
Previous prolapse surgery	1.14 (0.44, 2.95)	0.82
Pad loss	1.00 (0.992, 1.007)	0.95
Post-void residual	1.04 (0.99, 1.10)	0.18
Maximum. Capacity	1.00 (0.996, 1.002)	0.68
Maximum flow rate (Qmax)	1.00 (0,97, 1.02)	0.85
Average flow rate (Qave)	0.96 (0.92, 1.00)	0.14
Qmax Centile score (QmaxCent)	1.00 (0.99, 1.01)	0.76
Qave Centile score (QaveCent)	0.985 (0.974, 0.996)	0.03*
Overactive bladder at cystometry	1.64 (0.55, 4.85)	0.46
TVT with other op.	1.92 (0.87, 4.27)	0.18
Registrar surgeon	1.52 (0.73, 3.17)	0.35
GA (no cough test)	1.36 (0.39, 4.79)	0.69

*Meet statistical entry criteria for multivariate analysis ($p<0.1$).

Published rates of voiding dysfunction after TVT range from 2.5–26% [5, 15] although comparing results is difficult because of inconsistent definitions of the problem. A figure of 8% needing self-catheterisation is at the upper end of the published range, particularly given that we made our voiding assessment at 6 months, which is longer than in many studies [3, 8, 10, 15]. The case mix seen in a tertiary referral department such as ours may predispose towards a higher rate of post-operative voiding problems. Our cohort included many women undergoing repeat incontinence procedures and several with evidence of sub-optimal voiding before surgery. The use of general anaesthetic for the majority of our cases might suggest that increased voiding dysfunction arises from an inability to adjust the tape using the cough test. In our analysis, the mode of anaesthesia was not a significant influence and other authors have reported that the cough test and choice of anaesthetic have little bearing on voiding outcome [17, 18].

Average pre-operative voiding flow rate has not previously been reported as a predictor of post-TVT voiding dysfunction and certainly not in the form of a flow-rate centile score. Indeed, previous work has produced mixed results perhaps because of variation in methodology with different definitions, timing and methods of analysis. Increasing age and a history of previous continence or prolapse surgery have been associated with delay in establishing normal voiding after TVT [3] whereas elsewhere, previous continence surgery alone has been recognised as a risk factor [7]. A need to catheterise for 3 days or more after surgery has been associated with lower pre-operative peak flow rate, but this failed to take account of the variations in flow rate with voided volume [8]. Despite a small sample size, one study [5] found numerous variables predictive of voiding dysfunction at 3-month follow-up. The definition of voiding dysfunction was based on a combination of urodynamic data and subjective patient reporting, which perhaps explains the high prevalence (26%). The predictive variables were abnormal uroflowmetry pattern, peak flow rate <15 ml/s, pre-operative enterocoele or vault prolapse, combined vault suspension with TVT and post-operative urinary tract infection. Pre-operative irritative symptoms have been found to be predictive [4] in one study.

Table 3 Results of multivariate analysis

Variable	O.R. for ISC (95% CI)	*p* Value
QaveCent	0.985 (0.971, 0.998)	0.029

The large cohort size is a strength of our study with cases including women undergoing primary and repeat surgery, stand-alone and combined procedures. Although the study is a review of cases, the subject data was collected prospectively for both pre-operative factors and voiding outcome. The outcome is one that is clinically relevant and readily understood by both patients and clinicians and is potentially transferable to other patient populations. Being an objective measure reduces the potential for patient recall bias.

We have used multivariate logistic regression to analyse each variable without the influence of potential confounders. This method also enables the analysis of both categorical variables and continuous ones, without unnecessary dichotomisation. The statistical threshold for inclusion was set intentionally low (odds ratio *p* value <0.1). In this way, variables that appear to be predictive of the outcome when analysed in isolation might turn out not to

be so. Conversely, variables that appear less influential might assume increased significance when the effect of another factor is removed.

There are limitations in this study. Any assessment of outcome after surgery should include subjective or quality-of-life data along with objective measurements, and we are now using a validated questionnaire [16] as part of the routine follow-up. The omission of voiding pressure at maximum flow rate (PdetQmax) from the assessed variables weakens our analysis. In 21% of our cases, PdetQmax could not be calculated at cystometry, for technical reasons. To include this variable in the analysis with so many missing results would have risked introducing significant bias. Despite the low statistical threshold for inclusion, there remains the possibility of type II errors with valid variables being rejected. The variable of patient age, which has some biological plausibility and has been associated with poor outcome in other work [3], falls just outside the inclusion threshold of our study. This may not have occurred with a larger cohort.

The ISC odds ratio that has been calculated for QaveCent (0.985) is very close to 1, and although statistically significant, the clinical importance may be questioned. The odds ratio applies to incremental QaveCent changes of a single percentage point and so the influence will be much greater as the centile score changes by larger amounts. The relationship between QaveCent and post-operative voiding function makes intuitive sense. The use of a nomogram to account for the influence of voided volume on average urine flow rate has enabled us to assign each woman a centile score. As expected, with an increase in this 'ranking' of voiding ability, we have seen a reduction in the likelihood of needing ISC.

Although it is tempting to think that this association will enable an exact risk of ISC to be calculated for each woman, based on her pre-operative QaveCent, this is not the case. The relationship between QaveCent and ISC rate is not linear, the number of cases (22) is relatively small, and the statistical model generated from the data is therefore not strongly predictive. Further analysis of the QaveCent scores among our 267 cases is interesting, however, in that it reveals a bimodal distribution with 'clustering' of scores at both the lower and upper ends of the centile scale; at 10 and 80%, respectively. Using values from our logistic regression model, it is possible to calculate an approximate relative risk of needing ISC for women at the tenth centile compared with women at the 80th centile for average flow rate. Doing so suggests that in our study population, there is almost a threefold greater likelihood of needing ISC in women with a QaveCent of 10 than in those with a QaveCent of 80. This is a useful calculation, and a QaveCent of 10 is a potentially relevant clinical figure to use in selecting those women for whom specific counselling and ISC tuition could be given before surgery. It concurs with Haylen's work, in developing the voiding nomograms, where all women with voiding difficulties had urine-flow centiles below 10 and above this level were unlikely to do so [19].

Post-operative voiding dysfunction remains an important complication of the TVT procedure. If women at increased risk are able to be identified before surgery then they can receive more specific counselling, some taught pre-operative self-catheterisation and others advised against the operation. Case selection would be based on better information, and complication rates should decline.

The association of centile scores, from a voiding-flow-rate nomogram, with post-TVT voiding dysfunction has not previously been described. In our study population, a QaveCent of 10 or below is associated with an increased risk of post-operative voiding dysfunction when compared with a QaveCent of 80 or higher. For a given woman, it is easy to plot the average flow rate and voided volume on to the nomogram and thus determine their QaveCent.

Counselling for risk of voiding dysfunction can therefore potentially be individualised, particularly if the QaveCent figure is at either extreme.

Although this association may not apply to other populations undergoing TVT, testing it in a wider setting would not be difficult, particularly given the ease with which centile scores are generated. This is an area in which further study seems warranted.

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