Peer reviewed article

Is the cough test necessary at TVT insertion?
A case control series

Abstract

The tension-free vaginal tape (TVT) was originally described using a cough test for tape adjustment. More recently, the usefulness of this technique has been questioned and the authors performed a case control series to address this issue. Patients after TVT performed with (n=52) or without cough test (n=54) were invited for review. Matching of the groups was undertaken for age, pre-existing urge incontinence, preoperative maximum flow rate (MFR) centile, concomitant anterior repair and length of follow up. There were no significant differences between groups for subjective cure, satisfaction, subjective symptoms of incontinence, frequency or nocturia. There were more symptoms of voiding dysfunction after cough test (p=0.019). Postoperative flowmetry did not differ significantly, but ultrasound data indicate that the cough test results in a tighter tape. In conclusion, avoiding the cough test seems to have no negative effect on patient satisfaction or subjective symptoms of stress incontinence in the short-term.

Introduction

The tension-free vaginal tape (TVT) [Gynecare] is probably the most successful new anti-incontinence procedure of the last decade. The original technique relies on a cough test in the conscious patient to adjust sling tension. However, alternative suburethral implants and techniques do not consistently use this technique yet seem to result in good success rates. Recently published data suggest that the type of anaesthetic (and consequently performance or non-performance of the cough test) does not seem to significantly affect outcome.

In this case control series of patients after TVT insertion, the authors compared two adjustment techniques. One surgeon (AR) used a technique without the cough test (Group A), leaving enough space between implant and urethra to pass Metzenbaum scissors at rest. The other (PDW) utilised the cough stress test as in the originally described technique (Group B), continuing to adjust the tape until just a drop of leakage was present on repeated coughing at a bladder volume of 300ml.

Methods

Patients after TVT surgery performed by one of the two senior authors were invited for review in the context of external postoperative audits conducted by the first author. Follow up appointments consisted of a standardised interview, free flowmetry, and translabial ultrasound for estimation of residual urine, position and mobility of tape and bladder neck relative to the inferoposterior margin of the symphysis pubis (Figure 1). The ultrasound technique has recently been shown to have good interobserver repeatability (%CV 0.08-0.26 for tape position and %CV 0.12 for total tape mobility).

Pre- and intraoperative data (such as preoperative symptoms and flow rate, anaesthetic management and concomitant surgery) were retrieved from hospital records. Matching was undertaken for age, pre-existing urge incontinence, preoperative maximum flow rate (MFR) centile, concomitant anterior repair and length of follow up.

As far as the authors were aware, this was the first such study to evaluate the effect of different tape adjustment methods on symptoms, flowmetry indices and ultrasound measures of tape position and mobility.

Data were obtained in the context of two clinical research projects for which ethics committee approval had been obtained, and for which other results have been published elsewhere. For statistical analysis we used Minitab Version 13 [Minitab Inc., State College, PA, USA]. Comparative statistics were performed after normality testing (histogram analysis and/ or Kolmogorov-Smirnov testing). Two sample t-tests and X2 statistics were employed to compare continuous and categorical variables between groups. A p<0.05 was considered statistically significant.
Results

A total of 54 women in Group A were compared to 52 women in Group B. Matching resulted in well balanced groups. Table 1 shows basic demographic data and other parameters used for matching. In Group A, all patients underwent a general anaesthetic for tape insertion, with the exception of one who was operated on under spinal anaesthesia. No cough test was performed. In Group B, all women had undergone TVT insertion under local or spinal anaesthesia, with the exception of six who had requested a general anaesthetic despite local or spinal analgesia having been suggested. In three cases, local anaesthesia for tape insertion was followed by spinal or general anaesthesia to allow prolapse surgery.

In Group B, a cough stress test was attempted in all cases (except those six mentioned above), although it was not documented in the notes as to whether leakage was observed at any time. There were a number of concomitant procedures such as vaginal hysterectomies, anterior and posterior repairs and sacrospinous colpopexy, although only anterior repairs were performed in more than 10 women in total and were used for matching.

There were no significant differences between groups for subjective cure as defined by the patient (77% in Group A vs 83% in Group B), satisfaction rate (83% vs 84%), subjective symptoms of stress (20% vs 19%) or urge incontinence (63% vs 64%), frequency and nocturia. There were less symptoms of voiding dysfunction overall in Group A (46% vs 69%, p=0.019); see Table 2 for a breakdown of symptoms. The incidence of recurrent urinary tract infection was similar in both groups.

Postoperative independent flowmetry indices did not differ significantly. In both groups there was a reduction in MFR centiles, and although this was more marked in Group B (-17.3 vs -13.1 centile points), this difference was not significant. Data on residual urine were incomplete and therefore not analysed. Table 3 gives parameters of tape position and mobility which differed significantly – patients in Group B (i.e. those with cough test), showed a tape that was slightly inferior and closer to the

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Group A (n=54)</th>
<th>Group B (n=52)</th>
<th>p</th>
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<tbody>
<tr>
<td>Age (years)</td>
<td>57.8 (12.3)</td>
<td>58.2 (13.3)</td>
<td>NS</td>
</tr>
<tr>
<td>Pre-existing urge incontinence</td>
<td>38/53</td>
<td>40/ 52</td>
<td>NS</td>
</tr>
<tr>
<td>Preoperative MFR centile</td>
<td>25.6 (23.6)</td>
<td>36.2 (31.2)</td>
<td>NS</td>
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<tr>
<td>Concomitant anterior repair</td>
<td>17/54</td>
<td>13/52</td>
<td>NS</td>
</tr>
<tr>
<td>Length of follow up (years)</td>
<td>0.74 (0.32)</td>
<td>0.65 (0.23)</td>
<td>NS</td>
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</tbody>
</table>

Table 1. Results of matching.

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Group A (n=54)</th>
<th>Group B (n=52)</th>
<th>p</th>
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<tbody>
<tr>
<td>Hesitancy</td>
<td>6/54</td>
<td>13/52</td>
<td>0.062</td>
</tr>
<tr>
<td>Poor stream</td>
<td>13/54</td>
<td>32/52</td>
<td>0.028</td>
</tr>
<tr>
<td>Stop-start voiding</td>
<td>8/54</td>
<td>18/52</td>
<td>0.018</td>
</tr>
<tr>
<td>Straining to void</td>
<td>3/54</td>
<td>4/52</td>
<td>NS</td>
</tr>
<tr>
<td>Sensation of incomplete emptying</td>
<td>11/54</td>
<td>20/52</td>
<td>0.041</td>
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Table 2. Symptoms of voiding dysfunction, X2 test.

Figure 1. Determination of tape position by translabial ultrasound. The distance between tape and inferoposterior margin of the symphysis pubis is measured at rest (left) and on Valsalva (right).
symphysis at rest and moved much less on maximal Valsalva (1.56 vs 2.04 cm, p<0.001).

Discussion

The original descriptions of TVT insertion all report a cough stress test as an original and important aspect of adjusting tensioning. The pioneers of this type of surgery performed their new procedure under local anaesthesia, mainly to allow for tensioning with the help of a cough stress test at a defined bladder volume. While this appears to be a reasonably reproducible process, local anaesthesia is sometimes undesirable or inconvenient (such as when a TVT is part of more complex prolapse surgery), and some patients prefer general or regional anaesthesia. In addition, it is a common observation during urodynamic testing that women are more likely to leak when standing, and some TVT candidates will never leak when supine on the operating table. This has led to considerable clinical uncertainty. It is only very recently that researchers have been able to establish that a TVT procedure performed under other forms of anaesthesia carries a similar likelihood of success compared to those under local anaesthesia. 

If it is true that the anaesthesia mode has no significant effect on outcomes, then one would assume that omitting the cough test (regardless of anaesthesia mode) should also have no effect on cure rates. It has been clearly shown that suburethral tapes can have an obstructive effect on voiding which potentially could expose the patient to an increased risk of future symptoms of detrusor overactivity. Any modification of current technique that would reduce this obstructive effect without compromising success/cure rates would be of major clinical interest.

We therefore undertook a case control series comparing data obtained in the context of clinical research projects on patients who had been operated on by two different surgeons using different insertion techniques. Surgeon AR (Group A) adjusted tapes by leaving enough room under the urethra to pass Metzenbaum scissors and did not use the cough test. Surgeon PDW (Group B) utilised the cough stress test, continuing to adjust the tape until just a drop of leakage was present on repeated coughing at a bladder volume of 300ml.

In order to reduce the effect of confounders, we decided to analyse data according to 'intention to treat', i.e., we compared the intention to adjust the TVT by cough test (regardless of the actual occurrence or effectiveness of such a test) with the intention to omit the cough test. In fact, none of the 54 patients in Group A had a cough test, and 46 of 52 women in Group B did have a cough test for adjustment, although the success of this manoeuvre was not documented and may have varied between spinal and local analgesia. It is acknowledged that this may constitute a confounding factor that we are unable to control for due to lack of data.

Another confounding factor was the effect of muscle relaxants on pelvic floor support. In theory, pharmacological relaxation of pelvic musculature in the context of a general or spinal anaesthetic may result in increased downwards displacement of the anterior vaginal wall, resulting in a lower and more mobile tape (as tape mobility is likely to be associated with preoperative anterior vaginal wall elasticity or descent). Despite the obvious shortcomings of a retrospective case control series, we have been able to show that TVT adjustment by cough test is associated with a relatively higher prevalence of symptoms of voiding dysfunction and reduced tape mobility. Tape mobility is, in the opinion of the authors, a measure of ‘tightness’; a loose tape will be displaced further on Valsalva than one that has been tightened more. While differences in MFR centiles were non-significant, the cough test did result in a greater reduction than was observed in the group without cough test. Subjective outcomes such as cure, satisfaction, subjective symptoms of stress or urge incontinence, frequency and nocturia did not vary significantly between groups.

Our results imply that using a cough test for tape adjustment during TVT insertion may result in unnecessary tightening of the tape. Avoiding the cough test and placing the TVT more loosely than originally described seems to have no negative effect on patient satisfaction or subjective symptoms of stress incontinence. There may even be a benefit in terms of reducing symptoms of voiding dysfunction, although independent flowmetry parameters did not vary significantly in this study. However, follow up in this study was relatively short (mean 0.74 years in Group A, 0.65 years in Group B). Longer assessment, and ideally a randomised controlled trial, will be required before more definite conclusions can be drawn regarding tape adjustment methods. The data obtained in this study may become useful in providing data for power calculations for such a trial.

In conclusion, individual variations in technique such as the use of the cough stress test for tape adjustment may have a significant

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<tbody>
<tr>
<td>x-r</td>
<td>1.10 (SD 0.59)</td>
<td>0.72 (SD 0.73)</td>
<td>0.005</td>
</tr>
<tr>
<td>y-r</td>
<td>1.67 (SD 0.36)</td>
<td>1.63 (SD 0.36)</td>
<td>NS</td>
</tr>
<tr>
<td>x-s</td>
<td>-0.69 (SD 0.47)</td>
<td>-0.47 (SD 0.59)</td>
<td>0.038</td>
</tr>
<tr>
<td>y-s</td>
<td>0.83 (SD 0.58)</td>
<td>0.81 (SD 0.54)</td>
<td>NS</td>
</tr>
<tr>
<td>Tape mobility</td>
<td>2.04 (SD 0.64)</td>
<td>1.56 (SD 0.65)</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

Table 3. TVT position and mobility on ultrasound (2-sample T test). X-r, y-r: vertical and horizontal distance between tape and inferoposterior symphyseal margin at rest, x-s and y-s, same parameters on Valsalva. Tape mobility: difference between positions at rest and on Valsalva.
impact on symptoms and tape position and mobility, with use of
the cough test resulting in tighter tapes. However, success rates
and patient satisfaction do not seem to be greatly affected, a
finding that again emphasises the wide range of clinical safety
and efficacy of modern suburethral slings.

Acknowledgements

Part of the data used in this study was obtained in a clinical audit
project part-funded by a grant from Johnson & Johnson, New
Zealand.

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Australian news

CFA National Office welcomes
Jacqueline Lodewyke

Jacqueline Lodewyke will be replacing Nives Zerafa at the CFA
National Office this as Promotions Manager month, as Nives leaves
the CFA to have her first baby.

Jacqueline is a registered nurse with post graduate qualifications
in marketing and health service administration. Jacqueline completed her management residency
programme with the Australian College of Health Service Executives in 2004, after which she was employed as a project
officer/communications officer at Mercy Hospital for Women. Jacqueline brings both a clinical and consumer perspective to
this role and looks forward to joining the CFA team.

Kidsflix

Kidsflix is a fundraising initiative between the Continence
Foundation of Australia and Arthritis Foundation of South
Australia.

Kidsflix will be rolled out in Victoria in June 2006, and involves
free entertainment and a movie for children with a disability/
special needs and their family. The Arthritis Foundation
of South Australia successfully run Kidsflix in New South
Wales and South Australia, with an established call centre for
fundraising located at their head office.

The management of Kidsflix Victoria will be undertaken by the
Arthritis Foundation of Australia. Indicative financials show that
the CFA should receive a reasonable income stream per annum
by the third year of the venture. All profits from Kidsflix will
support promotion and research into paediatric incontinence.

Christchurch 2006 Joint Conference

Online registration for the International Continence Society
36th Annual Meeting being held in conjunction with the
Continence Foundation of Australia and the New Zealand
Continence Association is available at www.ics2006.co.nz

As a joint meeting CFA and NZCA members are reminded that they qualify for the ICS member’s registration fee. All
members who wish to receive their discount for registration
for the conference must have renewed their membership or
have joined by 1 August 2006. The Final Announcement brochure and invitation from Associate Prof Ted Arnold,
Chairman, ICS 2006 has been sent to all members. The CFA’s
Annual General Meeting will be held in New Zealand during
the conference on Thursday 30 November 2006 at 12.30pm.