VOIDING DYSFUNCTION AND THE TRANSOBTURATOR APPROACH FOR THE TREATMENT OF FEMALE STRESS URINARY INCONTINENCE (SUI)

Hypothesis / aims of study
Voiding difficulty (VD) is a recognised complication following surgery for SUI. This may occur because of post-operative oedema, haematoma, urinary infection leading to retention, or as a direct result of the continence intervention. Procedures which restore continence by obstruction are associated with higher rates of VD. The placement of a mid-urethral retropubic tape, specifically the TVT™, is associated with significantly lower rates of VD compared to the colposuspension or the traditional pubovaginal sling. The reported rates vary (6.4-60%) depending on the indication (primary or recurrent SUI), the presence of pre-operative VD, and the definition of VD used. It has been suggested that the transobturator approach may be associated with a lower rate of VD compared to TVT but there is currently a paucity of data to support this claim. The aim of this study is to evaluate the impact of the transobturator tape (TOT) on female voiding function (VF) using appropriate subjective and objective parameters.

Study design, materials and methods
Patients presenting to a tertiary urogynaecology unit with urodynamically-proven SUI and a stable bladder were recruited. Those with a ≥ grade 2 were excluded. Patients answered the short form of the Urogenital Distress Inventory questionnaire (UDI-6) and had uroflowmetry, measurement of post-void residual volume (PVR), urethral pressure profilometry (UPP) and 1-hour pad test pre-operatively. The TOT was placed using the outside-in technique. None of the patients were catheterised immediately post-operatively. Approximately 300ml of normal saline was left in the bladder to facilitate trial of void (TOV). Voided volume (vvol) and PVR were recorded. A successful TOV was deemed as two voids >150ml each, with a PVR of <150ml within 6 hours.

At 6 weeks, 6, 12, and 24 months’ follow-up, the uroflowmetry, PVR, 1-hour pad test, and UDI-6 were repeated. UPP was repeated at 6 weeks. Vaginal examination was performed at each visit to exclude complications.

Results
84 women were recruited. Median age was 55(IQR 51-62)y, parity 2(IQR 2-3) and BMI 28(IQR 25-33)kg.m⁻². 76 patients had no previous anti-incontinence surgery. 83(99%) were performed under LA and sedation. Median time to first void was 180(IQR 75-240)min, vvol of 250(IQR 189-400)ml, and PVR 54(IQR 10-156)ml. 5 patients had unsatisfactory TOV and were catheterised for a mean duration of 16(R 12-32)hours after which all had a successful TOV.

The 1-hour pad test demonstrated a significant decrease in urinary loss after surgery (Figure 1). There was also a significant decrease in total UDI-6 scores post-TOT (p<0.05).

Pre-operative voiding cystometry parameters were not influenced by either age or BMI. 23(27%) had symptoms of VD which significantly improved post-TOT (Table 1).

Correlation of pre-operative voiding cystometry parameters to UPP demonstrated a positive correlation between time to maximum flow rate (Qmax), mean maximum urethral closure pressure (MUCP)(0.26) and mean functional urethral length(FUL)(0.24) (p<0.05, Spearman’s test). MUCP and mean MUCP values also correlated with time to void (void)(r = 0.30 and 0.32, p = 0.02 and 0.01), time to flow (ttflow)(r=0.29, 0.31; p=0.02, 0.01), and detrusor pressure at maximum flow (PdetQmax)(r=0.30, 0.32; p=0.02, 0.01). UPP parameters measured pre- and 6 weeks post-operatively demonstrated no significant change in FUL but there was a significant decrease in MUCP at 6 weeks post-surgery.

Figure 1. 1-hr pad test results at the pre-operative visit and on follow-up

Significant difference at p<0.05 using Kendall’s tau-b

Table 1. Voiding function pre-operatively and at follow-up

<table>
<thead>
<tr>
<th>Symptoms of VD</th>
<th>Pre-op</th>
<th>6 w</th>
<th>6 m</th>
<th>12 m</th>
<th>24 m</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients attended (N)</td>
<td>84</td>
<td>81</td>
<td>59</td>
<td>54</td>
<td>37</td>
</tr>
<tr>
<td>Strain to void</td>
<td>6</td>
<td>5</td>
<td>1</td>
<td>3</td>
<td>0</td>
</tr>
<tr>
<td>Poor stream</td>
<td>9</td>
<td>6</td>
<td>1</td>
<td>4</td>
<td>0</td>
</tr>
<tr>
<td>Incomplete emptying</td>
<td>17</td>
<td>5*</td>
<td>3*</td>
<td>2*</td>
<td>0**</td>
</tr>
<tr>
<td>Double voids</td>
<td>11</td>
<td>3**</td>
<td>3</td>
<td>3</td>
<td>0</td>
</tr>
</tbody>
</table>
Post-micturition dribbling 6 2 0 1 0

UDI-6 scores

| Median score (IQR) | 50(34-67) | 14(1-22)* | 6(0-22)* | 11(0-22)* | 6(0-28)* |

*p<0.01, **p<0.05

Uroflowmetry results were analysed using both the cut-off PVR value of 150mls and the Liverpool Nomograms (LN) (Table 2). Both methods did not show a significant change in flow or PVR post-operatively.

Table 2. Uroflowmetry results pre- and post-TOT

<table>
<thead>
<tr>
<th>Uroflowmetry values in patients with voided volume of &gt;150ml</th>
<th>Pre-op (n=84)</th>
<th>6 w (n=81)</th>
<th>6 m (n=59)</th>
<th>12 m (n=54)</th>
<th>24 m (n=37)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients with &gt;150ml (n)</td>
<td>39</td>
<td>61</td>
<td>45</td>
<td>36</td>
<td>25</td>
</tr>
<tr>
<td>Qmax (ml/sec)*</td>
<td>28(22-36)</td>
<td>26(18-34)</td>
<td>32(21-40)</td>
<td>27(21-35)</td>
<td>25(16-31)</td>
</tr>
<tr>
<td>PVR (ml)*</td>
<td>20 (0-30)</td>
<td>10 (0-31)</td>
<td>10 (0-53)</td>
<td>10 (0-42)</td>
<td>10 (0-46)</td>
</tr>
</tbody>
</table>

Uroflowmetry values using the Liverpool Nomogram pre- and post-operatively

| Normal flow | 59 | 59 | 43 | 40 | 22 |

†median values (IQR)

Interpretation of results
Both subjective and objective measures of cure indicate that TOT is an effective treatment for SUI. Although there is a risk of VD in the immediate post-operative period, patients do not require prolonged catheterisation. There does not seem to be a worsening of VF at long-term follow up. In fact, this study suggests that symptoms of VD may indirectly improve after placement of the TOT.

Concluding message
VD is uncommon in patients with SUI. Symptoms of VD based on history are unreliable in diagnosing VD. UDI-6 is a better instrument in detecting VD.

TOT is a safe and effective procedure for the treatment of USI with a low risk of VD. The risk of VD in the immediate post-operative period is short-lived and resolves spontaneously. No deterioration of voiding function is observed at long-term follow-up. Symptoms of VD may improve after TOT.

Specify source of funding or grant
No external funding

Is this a clinical trial?
No

What were the subjects in the study?
HUMAN

Was this study approved by an ethics committee?
Yes

Specify Name of Ethics Committee
Local Ethics Committee of SGHMS

Was the Declaration of Helsinki followed?
Yes

Was informed consent obtained from the patients?
No