Transobturator and retropubic tape procedures in stress urinary incontinence: a systematic review and meta-analysis of effectiveness and complications

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Background Various types of suburethral tapes inserted via the transobturator route (tension-free vaginal tape obturator route [TVTO] and transobturator tape [TOT]) have been widely adopted for treatment of stress urinary incontinence (SUI) before proper evaluation of their effectiveness and complications.

Objectives To assess the effectiveness and complications of TOTs as treatment of SUI by means of a systematic review.

Search strategy MEDLINE, EMBASE, CINAHL, LILACS (up to September 2006), CENTRAL (The Cochrane Library, Issue 3, 2006), MetaRegister of Controlled Trials, The National Library for Health, the National Research Register and Google Scholar were searched using various relevant search terms. The citation lists of review articles and included trials were searched, and contact with the corresponding author of each included trials was attempted.

Selection criteria Randomised controlled trials (RCTs) that compared the effectiveness of TVTO or TOT with synthetic tension-free vaginal tape (TVT) by retropubic route (Gynecare; Ethicon Inc., NJ, USA) for the treatment of SUI in all languages were included.

Data collection and analysis Two reviewers extracted data on participants’ characteristics, study quality, population, intervention, cure and adverse effects independently. The data were analysed in the Review Manager 4.2.8 software.

Main results There were five RCTs that compared TVTO with TVT and six RCTs that compared TOT with TVT. When compared by subjective cure, TVTO and TOT at 2–12 months were no better than TVT (OR 0.85; 95% CI 0.60–1.21). Adverse events such as bladder injuries (OR 0.12; 95% CI 0.05–0.33) and voiding difficulties (OR 0.55; 95% CI 0.31–0.98) were less common, whereas groin/thigh pain (OR 8.28; 95% CI 2.7–25.4), vaginal injuries or erosion of mesh (OR 1.96; 95% CI 0.87–4.39) were more common after tape insertion by the transobturator route.

Author’s conclusions The evidence for short-term superiority of effectiveness of TOTs is currently limited. Bladder injuries and voiding difficulties are lower, but the risk of vaginal erosions and groin pain is higher with TVTO/TOT. Methodologically sound and sufficiently powered RCTs with long-term follow up are needed, and the results of continuing trials are awaited.

Keywords Incontinence, meta-analysis, transobturator tape.

Introduction Stress urinary incontinence (SUI) is defined as the complaint of involuntary urine leakage on effort or exertion or on sneezing or coughing without rise in detrusor pressure. It is estimated to affect up to one-third of women older than the age of 18 years, with a median age of 45 years. Tension-free vaginal tape (TVT) is a standard minimally invasive procedure used to treat urinary stress incontinence since 1995 when it was first described by Ulmsten. There have been more than 1 200 000 procedures performed worldwide, and it is shown to have similar effectiveness in the medium term to colposuspension but with fewer complications. Although success ranges from 84 to 95%, complications described include bladder, bowel and major blood vessel injuries as well as postoperative voiding difficulties and de novo urgency and urge incontinence.

In 2001, Delorme described a new method of inserting the tape, which passes through the obturator foramen (term
transobturator tape [TOT]), thus theoretically avoiding some of the complications such as bladder perforation. In this (outside–in) technique, after the initial anterior vaginal incision and dissection, the tape is introduced from the skin of the groin into the obturator foramen and comes out in the vaginal incision. Gynecare (Ethicon Inc., Somerville, NJ, USA) introduced a modified technique, termed the tension-free vaginal tape obturator route (TVTO). With the TVTO technique, the needle is passed in a reverse route, i.e. in through vaginal incision and out through the obturator foramen (inside–out). In the preliminary study, Delorme showed that there was a high success rate, no bladder perforations and few perioperative complications via the transobturator route, and this procedure was subsequently widely adopted before proper evaluation of its effectiveness and complications. There have been several noncomparative studies that have reported good short-term9,10 to medium-term11 success rates with TOTs of either route.

The objectives of this review were to determine the effectiveness of tension-free obturator tapes (both TOT and TVTO) when compared with TVT in randomised controlled trials (RCTs) and to explore the rates of adverse events.

Methods

A prospective peer-reviewed protocol for this review was prepared a priori.

Sources

All reports that describe (or might describe) RCTs of midurethral slings by obturator route in the treatment of SUI were obtained. MEDLINE (1966 to September 2006), EMBASE (1980 to September 2006), CINAHL (1982 to September 2006), LILACS (up to September 2006), the Cochrane Menstrual Disorders and Subfertility Group Trials Register (19 September 2006), CENTRAL (The Cochrane Library, Issue 3, 2006), National Library of Health, Google Scholar, MetaRegister of Controlled Trials, the citation lists of review articles and included trials were searched, and contact with the corresponding author of each included trial abstract was attempted. The following keywords were used for the search as text words or subject headings without language restriction using OVID software: ‘stress urinary incontinence, transobturator tape, continence surgery, tension free tape and mid urethral sling’. In addition, hand searches of the bibliographies and citation lists of all relevant reviews and primary studies to identify articles not captured by electronic searches as well as the proceedings of the international urogynaecological association and international continence society (ICS) of the past 2 years were performed. In most cases, the first or corresponding authors of included trials were contacted for additional information.

Study selection

All prospective RCTs comparing synthetic vaginal tape by obturator route (TOT or TVTO) with TVT for women with urodynamic stress incontinence (USI) were selected. In the suprapubic arch sling technique, the needles are passed from suprapubic incision into the vagina via retropubic route (above to downwards). It was not included as an alternative control for TVT because of controversy about differences in complications such as vaginal erosion, return to theatre for loosening of tape and lower subjective cure rates than TVT.12-14 Two authors (P.L. and R.F.) performed the selection of trials for inclusion after using the search strategy described previously.

Data abstraction and quality assessment

All assessments of the quality of trials and data extraction were performed independently by two authors of the review (P.L. and R.F.) using forms designed according to Cochrane guidelines. Data on characteristics of the study participants including details of previously administered treatments, interventions used and methods used to measure success (or definitions of cure/failure) and adverse events were extracted. The following quality criteria and methodological details were assessed: method of randomisation, quality of allocation concealment until randomisation, blinding to treatment allocation after randomisation, power calculation, intention-to-treat (ITT) analysis and numbers lost to follow up.

Data synthesis

The studies used different objective measures such as negative cough stress test on urodynamics study (UDS)15-17 and 1-hour pad test <1 g18 for cure. Objective improvement was defined in one study as negative cough stress test on UDS and <5 g on 1-hour pad test.18 Different subjective measures such as visual analogue scales (VAS), simple questionnaires and validated questionnaires were also used. The subjective cure rates were used to pool the results as these are of prime importance to patients and clinicians alike.19

Statistical analyses were performed according to the statistical guidelines of the Cochrane Collaboration20 using the RevMan 4.2.8 software. Data from ITT analyses were used where available. For the dichotomous data, results of each study were expressed as a Peto odds ratio with 95% confidence intervals and combined for meta-analysis using the Peto-modified Mantel–Haenszel method.21

Results

Figure 1 summarises the flow for study selection in the systematic review and meta-analyses. RCTs involving TOT as treatment for SUI were identified as potentially relevant. Six trials
Methodological quality of included studies

Figure 2 gives details of various quality criteria assessed for this systematic review. Two of the trials reported adequate concealment before allocation. Four studies had computer-generated randomisation, while two studies were quasi-randomised. Two studies had blinded participants. Power calculation was performed in 5 of 11 studies, and ITT analysis was performed in 4 of 11 of the included studies. Follow up was adequate in 7 of 11 trials and was unclear in the others (abstracts). In all trials, less than 15% of randomised participants withdrew or were lost to follow up.

Effectiveness and adverse events

When compared with TVT, the subjective cure of SUI was slightly worse in the TVTO group (OR 0.69; 95% CI 0.42–1.14) and equivalent in the TOT group (OR 1.05; 95% CI 0.64–1.70), although both were statistically insignificant. Figure 3 provides a summary of the effectiveness of the two tapes (TVTO and TOT) in comparison with TVT. Bladder injury (OR 0.13; 95% CI 0.06–0.27) and voiding difficulty (OR 0.56; 95% CI 0.32–0.99) were less for combined TVTO and TOT tapes. The vaginal injuries/erosion were reported twice as much in the transobturator group (OR 2.08; 95% CI 0.89–4.95). When vaginal extrusion rate only was considered, it was still higher in the TOTs group (OR 1.51; 95% CI 0.51–4.43). On subgroup analysis, the erosion was seen more in the TOT group (OR 2.37; 95% CI 0.53–10.63) and less in the TVTO group (OR 0.86; 95% CI 0.17–4.35) when compared with TVT. The pain in groin/thigh was higher in obturator tapes than in TVT (OR 9.34; 95% CI 3.02–28.9). De novo frequency and urgency symptoms were equivalent (OR 0.89; 95% CI 0.54–1.86). Figure 4 quantifies the risks of various complications by the type of tapes. The funnel plot indicated symmetrical distribution of the studies, indicating a low likelihood of publication or reporting bias (Figure 5).

Discussion

To the best of our knowledge, this systematic review, with the data that were used, summarises all the RCTs that exist on this topic. The two techniques of inserting vaginal tape by obturator or retropubic route were not significantly different in effectiveness. The TOTs had fewer complications of bladder injury and voiding difficulty but more groin pain and vaginal mesh erosion.

There are several strengths of this review. The search was thorough and systematic without language restrictions. Two reviewers independently performed the study selection and data extraction to minimise errors. We attempted to contact authors of published and unpublished studies to obtain further details. We adhered to the QUOROM checklist while reporting the meta-analyses. We have presented the results in two different subgroups by the tapes inserted by inside–out versus outside–in technique, as they traverse slightly different paths.
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| **TVTO (intervention) vs TVT (control)**
<p>| Oliveira et al.19 | 58 women: 28 TVTO vs 17 TVT (retro) vs 13 TVT (prepubic); inclusion criteria: women with SUI unsuccessful with conservative treatment. Mean age: 53.9 years for entire study population; study duration: October 2004 to March 2006 | Allocation concealment and randomisation method: not stated. Blinding and power calculation: not performed; ITT analysis: yes; FU &gt; 85%; yes; median follow up: 10 months (1–16 months) | Cure rates at 10 months: TVTO: 24 (85.7%) vs 17 TVT (100%) vs 2 (15.4%) TVT (prepubic); Improvement rates: TVTO, 2 (7.1%); TVT (prepubic), 5 (38.5%); failure rate: TVTO, 2 (7.1%) vs 6 (46.1%) TVT (prepubic) | Erosion: TVTO 1 (3.6%) vs TVT (retropubic) 1 (5.9%) and TVT prepubic 2 (15.4%); thigh pain: 4 (14.3%) vs 1 (5.9%); UTI: 5 (17.8%) vs 2 (11.8%); urgency: 8 (26.6%) vs 2 (11.8%) vs prepubic TVT 2 (15.4%); urge incontinence: 6 (21.4%) vs 3 (17.6%) vs 8 (61.5%) prepubic TVT; urinary retention: 1 (3.6%) vs 3 (17.6%) Bladder perforation: 0 vs 1; vaginal perforations: 3 vs 2; haematoma: TVT 1; blood loss: 46 vs 55 ml; return to normal voiding: 9 vs 6 hours; hospital stay: 17 vs 14 hours; groin/thigh pain: 21 vs 2; UTE: 17 vs 11 |
| Laurikainen et al.16 | 267 women: 131 TVTO vs 136 TVT; inclusion criteria: history of SUI, positive cough test; validated detrusor instability scores of &lt;8, operation indicated. Mean age: 54.7 ± 11.9 vs 53.6 ± 12.5 years; BMI: 25.2 ± 4.3 vs 24 ± 3.2; parity: 2.3 ± 0.8 vs 2.0 ± 0.8; no significant difference. April 2004 to November 2005 | Allocation concealment and blinding: no; randomisation method: computer generated; power calculation: yes; ITT analysis: yes; follow up: 6–12 weeks; long-term follow up (5 years) continuing; both groups had local anaesthesia and cystoscopy | Improvement rates: TVTO, 267 vs 262 (99.5%); TVT; Patient satisfaction score (VAS): 6 vs 7; theatre time: 64 vs 62 minutes; mean op time: 29 minutes for both | No severe complications occurred. Residual of urine &gt;100 ml on day 2: 4 (14%) vs 3 (11%) |
| Zhu and Lang19 | 55 women (27 TVTO vs 28 TVT); inclusion and exclusion criteria: not mentioned; Participants had either a prolapse repair or vaginal hysterectomy simultaneously | Allocation concealment and blinding: not stated; randomised method: not stated. Power calculation: no; ITT analysis: unclear; follow up: 12.5 months average | Hospital stay and mean blood loss was the same in both groups. Time for procedure: 16 vs 43 minutes; subjective cure: 25/27 (92.9%) vs 26/28 (92.6%); improvement: 1 (7.1%) vs 1 (7.4%) | TVTO: shorter operation time; bladder perforation: 0 vs 5; voiding difficulty: 7 vs 12; recurrent UTI: 5 vs 8; vaginal erosion: 1 vs 0 |
| Meschia et al.15 | Multicentre RCT with seven hospitals; inclusion criteria: participants with primary USI and urethral hypermobility. Exclusion criteria: not mentioned; 231 enrolled; number of women randomised: 177 TVTO vs 114 TVT; number of women analysed: 218 at 12 months; no differences between groups in demographic, clinical and urodynamic parameters; duration: December 2004 to September 2005 | Allocation concealment: not stated; randomisation: centralised computer generated; blinding: yes; power calculation: performed; ITT analysis: no; FU &gt; 85%; yes; mean follow up: 9 ± 3 months; FU: 3, 6, 12 and 24 months | Objective cure defined as negative cough stress test on UDS and 1-hour pad test &lt; 1 g; objective cure: 90 vs 85%; objective improvement (negative cough stress test on UDS and &lt; 5 g on 1-hour pad test): 7.6 vs 6.5%; failure (positive cough stress test and pad test &gt; 5 g): 2.5 vs 4.3%; subjective cure: 33 vs 34; subjective improvement: 7 vs 10 and failure: 3 vs 2 (simple questionnaire) | Prolonged catheterisation (10 days): one in TVT group; Hb loss: 0.9 (SD 0.4) g/dl vs 1.0 (SD 0.5) g/dl—NS; haemorrhage (EBL &gt; 500 ml) one in TVT group; bladder perforation: three in TVT group; de novo DO postop: 5 (10.8%) vs 4 (8.6%); vaginal erosion: one in TVT group |
| Liapis et al.18 | Number of women randomised: 91 (Drop-outs/withdrawals: 2); number of women analysed: 89 at 12 months (43 vs 46); inclusion criteria: all participants had USI; informed consent; exclusion criteria: women with DO, any other gynaecological disease requiring hysterectomy or other gynaecological operation and participants with previously failed surgical treatment; Mean age ± SD: 52 ± 10.2 vs 53 ± 9.1 years; BMI: 27.2 (SD 4.1) vs 26.5 (SD 3.8); parity: 2.4 (SD 1.1) vs 2.3 (SD 1); postmenopausal 26 vs 22; HRT: 4 vs 3; duration of SUI: 4.4 (SD 3.4) vs 4.7 (SD 3.4) years. Duration: November 2003 to October 2004 | Allocation concealment: not stated; randomisation: in alternating fashion from the outpatients department of the hospital; blinding: yes; power calculation: yes; ITT analysis: no; FU &gt; 85%; yes; follow up: 12 months; first ten women in TVTO group had cystoscopy | Similar short-term success but different complications | (continued) |</p>
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<td><strong>TOT (intervention) vs TVT (control)</strong></td>
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<td>Riva et al.Updated</td>
<td>n = 180 recruited; results on 131 participants reported (65 TOT and 66 TVT); inclusion criteria: USI with urethral hypermobility, age 40–85 years, urethra cecale of grade 0–2; exclusion criteria: previous prolapse orcontinence surgery, vaginal wall repair with mesh</td>
<td>Allocation concealment and blinding: not stated; randomisation method and power calculation: not stated; ITT analysis: no; FU &gt; 85% at 1 year: yes</td>
<td>Gynaecological examination, UDS, KHQ and voiding diary; cure at 1 year: subjective, 91 vs 94%; objective, 91.3 vs 91.4%; KHQ score range 6–27 vs 2–25</td>
<td>Retention: 2 vs 1; bladder injury: one in TVT group; sling repositioning: 2 vs 1; no haematomas; thigh pain: two in TOT group; vaginal erosion: 2 vs 1; voiding difficulty: 0 vs 1; frequency: 6.9 vs 6.5%; urgency: 13.8 vs 22.7%; urge incontinence: 7.6 vs 4.5%; reoperation for SUI: two in TOT group; fever: one in TVT; no significant difference in frequency, urge incontinence, recurrent SUI and KHQ</td>
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<td>Enzelsberger et al. Number of women randomised and analysed: 105 at 12–17 months (53 vs 52); inclusion criteria: all patients who had USI without DO on cough stress test and cystometry and gave informed consent; dropouts/withdrawals: none; exclusion criteria: previous continence surgery, genital prolapse, mixed or urge incontinence, renal or metabolic disorders; participants: age 35–71 years; BMI 19–30, parity 0–3. The groups were comparable for duration of incontinence, menopause, hysterectomy status and other variables</td>
<td>Allocation concealment and blinding: no; randomisation: quasi by week of examination; those seen in weeks 1, 3, 5 and 7 were randomised to TVT and weeks 2, 4 and 6 to TOT; power calculation: not performed; ITT analysis: performed; FU &gt; 85%: yes; follow up: 12–17 (median 15) months; TOT group: only first 20 participants had cystoscopy</td>
<td>Cure defined as negative cough stress test or no loss of urine during coughing on standing and semi-reclined position with bladder filled to 300 ml at cystometry 45/53 (84%) vs 45/52 (86%); failure: 8 vs 7; UPP showed a significant improvement in Dep. Q (P &lt; 0.05)</td>
<td>Haemorrhage (EBL &gt; 100 ml)/haematoma: 0 vs 7 in TVT group; Bladder perforation: 0 vs 7; voiding difficulties: 3 vs 4; de novo urgency: 6 vs 5; vaginal erosion: one in each group; operation time significantly shorter in the TOT group (15 vs 26 minutes)</td>
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<td>de Tayrac Number of women: analysed: 61 at 12 months (30 vs 31); inclusion criteria: all participants had USI on UDS and failed conservative therapy; exclusion criteria: participants with predominant urge incontinence, DOI or prolapse; no significant differences in the two groups for age; BMI and previous history of surgery for incontinence or prolapse; mean age ± SD: 54.7 ± 11.9 vs 53.6 ± 12.5 years; BMI: 24 (SD 3.21) vs 25.2 (SD 4.3); Parity: 2.3 (SD 0.8) vs 2.0 (SD 0.8); postmenopausal 18 vs 16; HRT: 13 vs 10; duration of SUI: 4 (SD 4.3) vs 3.1 (SD 1.4); Duration: January 2002 to November 2002</td>
<td>Allocation concealment: opaque sealed envelopes; randomisation: computer-generated random allocation 1:1 in balanced blocks of 10; blinding: no; power calculation: performed; ITT analysis: no; FU &gt; 85%: yes; follow up: 6 weeks, 6 months and 12 months &amp; performed by two independent physicians; IV indigo carmine to recognise bladder injury in TOT (Uratape; Mentor-Proges) group</td>
<td>Objective cure defined as negative cough stress test on UDS and no complaint of SUI; objective cure: 27 (90%) TOT vs 26 (83.9%) TVT; objective improvement (positive cough stress test on UDS but no complaint of SUI): 2 (3.3%) vs 3 (9.7%); failure (positive cough stress test and pad test &gt;5 g): 2 (6.5%) vs 2 (6.5%); subjective cure: 18 (60%) vs 20 (64.5%); subjective improvement: 8 vs 10; failure: 4 vs 1 (evaluated by participants as very satisfied, satisfied, not satisfied)</td>
<td>Prolonged retention (PVR &gt; 100 ml); day 1: 4 vs 8; day 2: 3 vs 2; day 3: 1 vs 0; Hb loss: 1.1 (SD 0.6) g/dl vs 1.2 (SD 0.5) g/dl—NS; bladder perforation: 0 vs 3; vaginal erosion: zero in both groups; urethral erosion: 0 vs 1; obturator haematoma: 1 vs 0</td>
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<td>Mansoor et al. Number of women randomised: 102; number of women analysed: 48 TOT and 54 TVT; inclusion criteria: participants with SUI with or without prolapse; exclusion criteria: not stated; participants said to be comparable for age, history and associated surgery in the two groups</td>
<td>Allocation concealment: opaque sealed envelopes; randomisation: not stated; blinding: no; power calculation: no; ITT analysis: yes; FU &gt; 85%: not stated; cystoscopy performed in both groups</td>
<td>One-hour pad test, uroflowmetry and self-filled questionnaire: cure not defined but stated as 46 (96%) vs 50 (93%); Urge incontinence cured in 40 (80%) vs 30 (60%)</td>
<td>Urinary retention requiring lateral section of the tape: 1 vs 5; bladder perforation: 0 vs 5; urethral laceration: 0 vs 1; vaginal erosion: zero in both groups; haematoma: 0 vs 0; de novo UUI: 2 (4%) vs 4 (7%)</td>
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<td>David-Montefiore et al.</td>
<td>88 women randomised over 14 months (46 TOT vs 42 TVT); inclusion criteria: SUI; mean age: 53.4 ± 10 vs 56.8 ± 12 years; parity: 2 ± 1 vs 2 ± 0.9 years; BMI: 26 ± 4 vs 25 ± 4; prior hysterectomy 26.1 vs 21.4%, prior surgery for SUI 3 (6.5%) vs 3 (7.1%); duration: March 2004 to May 2005; follow up: 24 months</td>
<td>Allocation concealment: not stated; randomisation: computer generated; blinding: not used; power calculation: performed; ITT analysis: yes; cystoscopy performed in both groups</td>
<td>Dry 43 (93.5%) vs 39 (92.9%), improved 1 (2.2%) vs 2 (4.8%) and failed 2 (4.3%) vs 1 (2.4%); questionnaires, UDI: no significant difference; TOT 62 ± 53 preop; 5.7 ± 25.2 postop; TVT 64.2 ± 54.3 preop; 5.4 ± 20.3 postop; IQ: no sign difference; TOT 25.7 ± 43.5 preop; 6.1 ± 24.6 postop; TVT 32.6 ± 57.6 preop; TVT 0.6 ± 3.2 postop; the objective functional results were similar in the two groups at 1, 3, 6 and 12 months; QOL, was similarly improved in the two groups</td>
<td>Mean op times (minutes) significantly longer in TVT group: 17 ± 6.6 vs 21.9 ± 9.5; bladder catheterisation (days) 0.8 ± 0.5 vs 1 ± 1; residual volume 28 ± 49 vs 23 ± 45; overall morbidity: 5 (10.9%) vs 8 (19%); bladder injury 0 vs 4 (9.5%); vaginal injury 5 (10.9%) vs 0%; Haematoma 0 vs 2 (4.8%); pelvic abscess 0 vs 1 (2.4%); de novo nocturia 1 (2.2%) vs 3 (7.1%) and urgency 4 (8.7%) vs 2 (4.8%); hospital stay (days), no significant difference: 1.4 ± 0.5 vs 1.8 ± 1.7; pain scores were significantly lower in the TOT group</td>
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<td>Porena et al.</td>
<td>90 consecutive women; 42 TOT vs 47 TVT analysed; inclusion criteria: stress or mixed incontinence, positive Bonney test; exclusion criteria: grade 1 prolapse in any compartment; mean age: 61 ± 10.4 vs 60.9 ± 10.4 years; BMI: 25.8 vs 27.7; parity: 2 (0–4) vs. 2 (0–5); previous hysterectomy 28 vs 20; mean duration of incontinence (months) 37.9 ± 38.2 vs 38.8 ± 38.9; no significant difference between the two groups; 89% (80) had Spinal, 11% (9) had general anaesthesia; duration of trial: January 2002 to September 2004</td>
<td>Allocation concealment and blinding: not stated; randomisation method: not stated; power calculation: not performed; follow up: 13 months</td>
<td>Blood loss was less than 100 ml; no significant difference in hospital stay, intra and postop complications. Hospital stay (days): 1.5 (1–6) vs 2 (1–8); bladder perforations: 0 vs 1; recovery to normal micturition (days) 1.3 (1–4) vs 1.5 (1–7); fever: 2 vs 0; retropubic haematoma: 0 vs 2; vaginal erosion: 2 vs 0; voiding dysfunction: 1 vs 3; wound discomfort: 0 vs 1; foreign body granuloma: 0 vs 1; paracervical hernia: 0 vs 1; de novo urgency: 1 (2.4%) vs 5 (10.6%); mean op time sign shorter with TOT but not significant: 20 (15–60) vs 25 (20–80) minutes</td>
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BMI, body mass index; Dep. Q; depression quotient; DO, detrusor overactivity; EBL, endoscopic band ligation; FU, follow up; Hb, haemoglobin; HRT, hormone replacement therapy; ICI-SF, incontinence inventory-short form; IQ, incontinence impact questionnaire; IV, intravenous; KHQ, king’s health questionnaire; mean op, mean operation; NS, not significant; PGI-I Q, patient global impression of improvement questionnaire; PGI-S, patient global impression of severity; preop, preoperation; postop, post operation; PVR, post void residual; QOL, quality of life; UPP, urethral pressure profile; UTI, urinary tract infection; UUI, urge urinary incontinence; vs, versus; W-IPSS, international prostate symptom score.
The quality of RCTs included is variable, with 2 of 11 studies fulfilling all the criteria apart from blinding. A potential objection to some readers would be inclusion of one of the studies that was retracted after publication because of reasons of ethics. However, we feel that, as the participants who were involved gave permission at the time, it would be unethical to ignore the data collected to guide future treatment and research. The definition and duration at assessments of cure and adverse events such as urgency or detrusor activity were different in the included studies. These issues, together with the variable quality of the included RCTs, reduce the belief in the estimates of effectiveness. The funnel plot for subjective cure, however, was evenly distributed, indicating a less likelihood of publication bias and giving more confidence in the results. We did not assess operating times required for the two procedures as one of our outcomes. We could not get more details on some of the abstracts inspite of attempting to contact the authors.

Figure 2. Methodological quality of studies included in the systematic review of effectiveness of TOT in SUI (data presented as 100% stacked bars; figures in the stacks represent number of studies).

Figure 3. Meta-analysis of subjective cure of SUI with vaginal tapes by transobturator versus retropubic routes.
The reduced risk of voiding difficulty may appear to make the TOT preferable in women with borderline flow rates, although this has not been investigated specifically in this subgroup of women. The low risk of bladder injury might make TOT an option of choice in women who have had previous operations such as colposuspension where the bladder could be tethered. The bladder injuries were reported by a variety of methods, in that some trials performed cystoscopy in both groups, whereas some used indigo carmine test and some did not perform cystoscopy in TOT group, with a potential to miss a bladder perforation easily. The data from RCTs where both groups had cystoscopy show that no (0 of 232) women had bladder injury in TVTO/TOT group versus 10 of 238 in the TVT group (OR 0.13; 95% CI 0.02–0.69). The cadaver studies suggest that perioperative cystoscopy is not required, although there are case reports of this complication in the literature. If clinicians are to perform TVTO/TOT procedures, then data must be collected for audit purposes. In the UK, we would advocate all clinicians collect data prospectively using the BSUG database (www.rcog.org.uk/bsug) to enable the best chance of collection of robust observational data at a national level.

To help resolve the issue of medium- to long-term effectiveness and complications, clinicians may initiate good quality and adequately powered trials with long-term follow up or participate in continuing robustly designed multicentre trials. The main issues are sample size and trial methodology. An individual patient data meta-analysis may address the uncertainty by combining raw data from various studies included in this review and the data from continuing studies.
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References


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