

NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

INTERVENTIONAL PROCEDURES PROGRAMME

Interventional procedure overview of single-incision sub-urethral short tape insertion for stress urinary incontinence in women

Stress urinary incontinence is the involuntary leakage of urine during exercise or certain movements such as coughing, sneezing and laughing. It is usually due to weak or damaged muscles and connective tissues in the pelvic floor. Single incision sub-urethral short tape insertion involves the insertion of a short synthetic tape under the urethra (the passage through which urine leaves the bladder), through an incision in the vagina. The tape supports the urethra, to reduce the chance of urine leaking when the bladder is put under pressure.

Introduction

This overview has been prepared to assist members of the Interventional Procedures Advisory Committee (IPAC) in making recommendations about the safety and efficacy of an interventional procedure. It is based on a rapid review of the medical literature and specialist opinion. It should not be regarded as a definitive assessment of the procedure.

Date prepared

This overview was prepared in July 2007.

Procedure name

- Interventional procedure overview of single-incision sub-urethral short tape insertion for stress urinary incontinence in women

Specialty societies

- British Association of Urological Surgeons – (Section of Female and Reconstructive Urology)
- British Society of Urogynaecology
- Royal College of Obstetricians and Gynaecologists

Description

Indications

Stress urinary incontinence (SUI) in women

SUI is the involuntary leakage of urine during exercise or movements such as coughing, sneezing and laughing. It is usually caused by weak or damaged muscles and connective tissues of the pelvic floor, or by weakness of the urethral sphincter mechanisms. In women, the most common cause is previous pregnancy, with or without recognised obstetric trauma. Previous urogynaecological or pelvic surgery may also result in SUI.

Current treatment and alternatives

Typically, first-line treatment is conservative and includes lifestyle changes such as weight loss and pelvic floor muscle training. If the condition does not improve, surgery may be employed, most commonly the insertion of synthetic tension-free vaginal tape (TVT). Alternative surgical options are insertion of transobturator tape or other synthetic sling procedures, use of slings made from biological materials, colposuspension or intramural bulking procedures. Very rarely, and if all other surgery has failed, an artificial urinary sphincter may be used. Stress urinary incontinence is a distressing condition and surgical treatment can have a profound effect on the patient's quality of life.

What the procedure involves

The procedure can be undertaken using local anaesthesia (with or without sedation) or general anaesthesia. A catheter is inserted through the urethra to empty the bladder. A single small mid-line incision, about 1.0–1.5 cm long, is made in the vaginal wall, about 1 cm from the external urethral meatus (opening of the urethra). From this incision, two tunnels are dissected and a strip of synthetic mesh (the tape or sling, made from polypropylene) is inserted into the tunnels using an introducer device. Two ways of placing the tape have been described: tapes can be placed either with the ends of the tape inserted into the obturator internus muscle ('hammock' position), or with the ends inserted into the connective tissue behind the pubic bone ('U' position). In each position, the tape lies beneath the mid-urethra. The tape is manufactured with an 'anchor' at each end (a variety of anchoring mechanisms have been used), the intention being that this will grip the tissue and hold the tape in position initially. It is intended that tissue will grow through the pores of the mesh to hold the tape in position in the longer-term. The tension and position of the tape may be tested before the introducer device is withdrawn, leaving the tape in position. If the patient is awake during the procedure, a cough test may be used for this purpose. Cystoscopy may be used to check whether bladder perforation has occurred during the procedure. The vaginal incision is then closed.

Efficacy

Evidence on efficacy was obtained from one peer-reviewed article describing a case series of 15 women,¹ and conference abstracts describing five further case series with efficacy data for 188 women in total.²⁻⁶

Continence

Three case series reported the results of continence stress tests following the procedure.^{2,5,6} A case series reported that 75% (45/60) of women had no leaking on a standing cough test at 5 weeks' follow-up.² Another case series reported that at 1 month's follow-up 67% (20/30) of women had no leaking and 23% (7/30) had 'less' leaking on a stress test compared with baseline.⁵ A third case series reported that 83% of women had a negative stress test, with 44% of women absolutely dry (8/18, median follow-up 18 weeks, range 9–25 weeks). (Results were reported for 18 out of the 24 women who were treated, because 6 were lost to follow-up.)⁶

A case series of 40 women reported that the median frequency of incontinence episodes decreased from 4 per day pre-operatively, to 0 per day at 6 weeks' follow-up.³ Significant improvements were also reported in 24-hour urine leakage, pad usage and nocturia (no statistics given).

In three case series,^{1,3,4} including a total of 95 women, the proportion without SUI following the procedure ranged from 74% (absolute number not stated, total n = 40, 6 weeks' follow-up)³ to 93% (14/15; 1–3 months follow-up).¹ In four case series^{3,4,5,6} (including two of those just described), the proportion of women whose SUI improved (including those with no residual incontinence) ranged from 78% (n = 18 [not including 6 patients lost to follow-up] median follow-up 18 weeks, range 9–25 weeks)⁶ to 90% (36/40; 2 months' follow-up).⁴

The results described above were patient-reported in two studies.^{3,6} The method of assessment was not clearly stated for four of the studies.^{1,2,4,5}

One of the case series,² which used patient-reported symptoms scores ranging from 0 to 10, reported that the score had improved by at least 75% for 83% of women (50/60, 95% confidence intervals 72 to 92%) at 5 weeks' follow-up compared with pre-operative scores.²

Safety

Evidence on efficacy was obtained from one peer-reviewed article describing a case series of 15 women,¹ and conference abstracts describing five further case series of 206 women in total.²⁻⁶

Visceral injury

Bladder perforation occurred in 1 woman in the case series of 72 women.² The case series of 30 women reported bladder perforation in 1 woman and bladder abrasion in another.⁵ Two case series, of 64 women in total, reported that no bowel, bladder or urethral injuries occurred.^{3,6} The remaining two case series did not mention any visceral injuries.^{1,4}

Vaginal injury

'Vaginal button-holing' (inadvertent perforation of the vaginal wall) occurred in 2 women in a case series of 40 women.³ Vaginal primary wound dehiscence occurred in 4 out of 24 women (17%) in one case series.⁶

Tape erosion into the vagina

In a case series of 15 women, vaginal erosion by the tape was reported for one woman.¹ Two other case series, of 72² and 40⁴ women, reported 'tape exposure' in 1 woman each.

Development of de-novo urinary symptoms

A case series reported voiding dysfunction in 2 out of 40 women at 6 weeks' follow-up.³ De-novo dysuria (with a maximum flow rate of less than 15 ml/second) was reported in 5.4% of a total of 40 women, and de-novo urgency in 16%, one of whom developed de-novo urge incontinence.⁴ De-novo urgency was reported in 13% (9/72) of women in another case series, 3 of whom required further treatment as a result.²

Pain

Two case series, including a total of 87 women, each reported pain in 1 woman (at 1-week follow-up in one case series,¹ and at an undefined time point in the other).² Another case series reported pain in 18% (7/40) of women (questioned at 2 months' follow-up; mean duration of pain was 16 days post-operatively, range 4–30).⁴

Haemorrhage

In a case series of 40 women, haemorrhage of 150 ml occurred in one woman.⁴

Literature review***Rapid review of literature***

The medical literature was searched to identify studies and reviews relevant to single-incision sub-urethral short tape insertion for SUI in women. Searches were conducted via the following databases, covering the period from their commencement to 26 June 2007: Medline, PreMedline, EMBASE, Cochrane Library and other databases. Trial registries and the Internet were also searched. No language restriction was applied to the searches. (See Appendix C for details of search strategy.)

The following selection criteria (Table 1) were applied to the abstracts identified by the literature search. Where these criteria could not be determined from the abstracts the full paper was retrieved.

Table 1 Inclusion criteria for identification of relevant studies

Characteristic	Criteria
Publication type	Clinical studies were included. Emphasis was placed on identifying good quality studies. Abstracts were excluded where no clinical outcomes were reported, or where the paper was a review, editorial, or laboratory or animal study. Conference abstracts were also excluded because of the difficulty of appraising methodology.
Patient	Female patients with stress urinary incontinence
Intervention/test	Single-incision sub-urethral short tape insertion
Outcome	Articles were retrieved if the abstract contained information relevant to the safety and/or efficacy.
Language	Non-English-language articles were excluded unless they were thought to add substantively to the English-language evidence base.

List of studies included in the overview

This overview is based on six case series, one of which has been published as a full article in a peer-reviewed journal, and five of which have been described in conference abstracts. The conference abstracts were included to bring safety issues relating to serious adverse events to the attention of IPAC, given the lack of data on safety available from the fully published study.

Other studies that were considered to be relevant to the procedure but were not included in the main extraction table (Table 2) are listed in Appendix A.

Existing reviews on this procedure

No published systematic reviews with meta-analysis or evidence-based guidelines were identified at the time of the literature search.

Related NICE guidance

Below is a list of NICE guidance related to this procedure. Appendix B details the recommendations made in each piece of guidance listed below.

Interventional procedures

'Bone-anchored cystourethropexy (using data from In-Tac and Vesica as specified by SERNIP)'. NICE interventional procedures guidance 18 (2003). Available from <http://guidance.nice.org.uk/IPG18>

'Insertion of extraurethral (non-circumferential) retropubic adjustable compression devices for stress urinary incontinence in women'. NICE interventional procedures guidance 133 (2005). Available from <http://guidance.nice.org.uk/IPG133>

'Intramural urethral bulking procedures for stress urinary incontinence'. NICE interventional procedures guidance 138 (2005). Available from <http://guidance.nice.org.uk/IPG138>

'Insertion of biological slings for stress urinary incontinence'. NICE interventional procedures guidance 154 (2006). Available from <http://guidance.nice.org.uk/IPG154>

Technology appraisals

None ('Stress incontinence – tension-free vaginal tape', TA56, is now obsolete and has been replaced by CG40 [see below]).

Clinical guidelines

'Urinary incontinence: the management of urinary incontinence in women' NICE clinical guideline 40 (2006). Available from <http://guidance.nice.org.uk/CG40>

Public health

None

Table 2 Summary of key efficacy and safety findings on single-incision mid-urethral tape insertion for stress urinary incontinence in women

Abbreviations used: BMI: body mass index; SD: standard deviation; SUI: stress urinary incontinence; TVT, tension-free vaginal tape; UI: urinary incontinence			
Study details	Key efficacy findings	Key safety findings	Comments
<p>Martan et al 2007¹ [Published article]</p> <p>Case series</p> <p>Czech Republic</p> <p>Study period: Sept to Nov 2006</p> <p>n = 15</p> <p>Population: Women previously untreated for SUI; median age 53 years (range 15–74), median BMI 27.7 kg/m² (SD 5.7), median parity 1.9</p> <p>Indications: Pure SUI (not mixed) according to International Continence Society criteria and confirmed by patient history, and physical and urodynamic tests, stress test and pad-weight test. Women with severe cystocele were excluded.</p> <p>Technique: ‘TVT-Secur’ device used, in ‘hammock’ position for 10/15 women and in ‘U’ position for 5/15. Position and mobility of the urethra and bladder neck were assessed by ultrasound pre- and post-operatively, at rest and at maximum Valsalva manoeuvre.</p>	<p>93% (14/15) of women had no complaints following the procedure at 1–3 months’ follow-up.</p> <p>Slight folding of the tape (observed by ultrasound) occurred in 1 woman and was associated with persistent SUI. However, the patient reported that SUI symptoms had improved following the procedure.</p> <p>Ultrasound examination showed that tapes remained in position, 1 mm below the mid-urethral wall (i.e. did not stretch excessively).</p>	<p>Vaginal erosion 7% (1/15)</p> <p>This occurred because of slight folding of the tape (not the same woman as described under efficacy, left). This did not cause SUI to persist. The surgeon planned to remove the tape if the erosion had not resolved at 10 weeks’ follow-up.</p> <p>Vaginal pain 7% (1/15) The woman experienced moderate vaginal pain 1 week after the procedure. The cause was not established, but the pain resolved spontaneously.</p>	<p>This is the only study included in this overview that has been peer-reviewed and published as a full article.</p> <p>The authors concluded that the ‘hammock’ position was better for women with a medium level of urethral mobility, as it is quicker and simpler to perform, while the ‘U’ position was more effective for lower urethral mobility or intrinsic sphincteric deficiency.</p>

Abbreviations used: BMI: body mass index; SD: standard deviation; SUI: stress urinary incontinence; TVT, tension-free vaginal tape; UI: urinary incontinence			
Study details	Key efficacy findings	Key safety findings	Comments
<p>Position and mobility of the tape were assessed by ultrasound post-operatively.</p> <p>Follow-up: 1–3 months</p> <p>Conflict of interest: The study was supported by a grant from the Czech government.</p>			

Abbreviations used: BMI: body mass index; SD: standard deviation; SUI: stress urinary incontinence; TVT, tension-free vaginal tape; UI: urinary incontinence			
Study details	Key efficacy findings	Key safety findings	Comments
<p>Karram et al 2007² [Conference abstract]</p> <p>Case series</p> <p>USA, Finland, Italy</p> <p>Study period: not stated</p> <p>n = 72</p> <p>Indications: SUI, or mixed UI with stress incontinence predominating</p> <p>Technique: Anaesthesia and device placement described only for the 60 patients for whom efficacy data were reported. 'TVT Secur' device used, in 'hammock' position for 31 women and in the 'U' position for 29 women (randomly allocated). Local anaesthesia = 53 (49 of whom were also sedated); spinal/epidural anaesthesia = 4; general anaesthesia = 3</p> <p>Follow-up: 5 weeks</p> <p>Conflict of interest: Study was supported by the manufacturers of the device.</p>	<p>Efficacy data were reported for 60 patients only, and not for the first 12 women treated (see Comments).</p> <p>Patient-reported symptoms using visual analogue scale (0–10) at 5 weeks' follow-up</p> <ul style="list-style-type: none"> ▪ ≥ 50% improvement in symptoms score: 52/60 patients (87%, 95% CI: 75 to 94%) ▪ ≥ 75% improvement in symptoms score: 50/60 patients (83%, 95% CI: 72 to 92%) <p>Urine leakage during standing cough test at 5 weeks' follow-up</p> <ul style="list-style-type: none"> ▪ 25% (15/60) women <p>10 of these had 'hammock' placement and 5 had 'U' placement.</p> <p>Mean urogenital distress inventory (UDI-6) score</p> <ul style="list-style-type: none"> ▪ Baseline: 52.5 ▪ 5-weeks' follow-up: 18.0 <p>Mean pain scores after procedure, using visual analogue scale from 0–10</p> <ul style="list-style-type: none"> ▪ 48 hours' follow-up: 0.9 ▪ 35 days' follow-up: 0.3 <p>King's Health Questionnaire scores (assessing quality of life, n = 60)</p> <ul style="list-style-type: none"> ▪ Improvements observed in all domains between baseline and 5 weeks post-op (no further details provided) <p>Device placement difficulties (not further described)</p> <p>3/72 women</p>	<p>Hypotensive episode related to anaesthesia</p> <p>1% (1/72)</p> <p>Bladder perforation</p> <p>1% (1/72)</p> <p>De-novo urgency</p> <p>13% (9/72) women; 3 required treatment (not further described)</p> <p>Worsening incontinence</p> <p>3% (2/72)</p> <p>Persistent urge</p> <p>1% (1/72)</p> <p>Partial tape exposure</p> <p>1% (1/72)</p> <p>Groin pain</p> <p>1% (1/72)</p>	<p>Six surgeons performed the procedures.</p> <p>"Each surgeon performed two device run-in (DRI) cases (1 'U' and 1 'Hammock')". Efficacy outcomes for these initial 12 patients were not reported in the abstract (hence n = 60 for efficacy) but safety outcomes were reported for all 72 patients. Efficacy estimates reported in this study may not accurately represent the outcomes of the first 12 patients.</p> <p>The authors commented that care must be taken not to loosen the tape when removing the introducer device, as no further tightening can take place once it has been removed.</p> <p>Women were randomised to 'hammock' or 'U' device placement, but results in this abstract were largely presented for all patients combined, as for a case series.</p>

Abbreviations used: BMI: body mass index; SD: standard deviation; SUI: stress urinary incontinence; TVT, tension-free vaginal tape; UI: urinary incontinence			
Study details	Key efficacy findings	Key safety findings	Comments
<p>Marsh & Assassa 2007³ [Conference abstract]</p> <p>Case series</p> <p>UK</p> <p>Study period: 2006</p> <p>n = 40</p> <p>Population: All women had previously undertaken pelvic floor therapies; 9/40 (23%) had previously taken duloxetine (current medical treatment not described). Mean age 54 years (range 33–77)</p> <p>Indications: Pure SUI = 68%; mixed UI = 32%</p> <p>Technique: 24/40 (60%) were treated with 'TVT Secur' device alone; 16/40 (40%) underwent pelvic floor repair at same time as 'TVT Secur' procedure. Local anaesthesia was used for 2 patients and general anaesthesia for 38 patients.</p> <p>Follow-up: 6 weeks</p> <p>Conflict of interest: The authors were not funded by the industry.</p>	<p>Median frequency of incontinence episodes</p> <ul style="list-style-type: none"> ▪ Baseline: 4 per day ▪ 6 weeks' post-op: 0 per day <p>Significant improvements occurred in 24-hour urine loss, pad usage and nocturia (no statistics given).</p> <p>Patient-reported assessment of efficacy (questionnaire, numbers not stated)</p> <ul style="list-style-type: none"> ▪ Cured: 74% ▪ 'Improved' 12% ▪ Unchanged 14% 	<p>Intra-operative complications</p> <p>Vaginal 'button-holing' (perforation of the vaginal wall in the lateral sulcus): 2/40 (5%) women</p> <p>No other intraoperative complications occurred.</p> <p>Post-operative complications</p> <p>'Voiding dysfunction' (not further described): 2/40 women</p> <p>This resolved spontaneously within 6 weeks in one woman but the problem persisted in the other woman.</p>	<p>The authors "audited the introduction of this technique within [their] hospital".</p>

Abbreviations used: BMI: body mass index; SD: standard deviation; SUI: stress urinary incontinence; TVT, tension-free vaginal tape; UI: urinary incontinence			
Study details	Key efficacy findings	Key safety findings	Comments
<p>Debodinance et al 2007⁴ [Conference abstract]</p> <p>Case series</p> <p>France</p> <p>Study period: 2006</p> <p>n = 40</p> <p>Population: Mean age 59 years; mean BMI 26.8 kg/m²; 69% post-menopause; 3/40 women had previously undergone surgery for incontinence, 3 had undergone surgery for pelvic organ prolapse, 7 had undergone hysterectomy.</p> <p>Indications: Pure SUI (26 women, 65%, 9 of whom had sphincteric insufficiency) or mixed UI (14 patients, 35%, 6 of who had sphincteric insufficiency).</p> <p>Technique: 'TVT Secur' device used, in 'hammock' placement only. Anaesthesia: local = 29/40; epidural = 10/40; general = 1/40.</p> <p>Follow-up: 2 months</p> <p>Conflict of interest: None</p>	<p>Continence at 2 months' follow-up (not stated whether assessed by patient or clinician)</p> <p>Women with pure SUI (n = 26) 81% (21/26) 'cured' 15% (4/26) improved 4% (1/26) failed</p> <p>Women with mixed UI (n = 14) 64% (9/14) 'cured' 14% (2/14) improved 21% (3/14) failed</p> <p>All combined (n = 40) 75% (30/40) 'cured' 15% (6/40) improved 10% (4/40) failed</p> <p>Patient satisfaction score 8.2 out of 10 (range 2–0)</p> <p>25% (10/40) of women required bladder catheterisation for 24 hours after the procedure.</p> <p>In the immediate post-op phase, 13% (5/40) women had post-micturition residues of 100–200 ml.</p>	<p>Intra-operative complications</p> <p>Haemorrhage 1/40 women (150 ml blood loss)</p> <p>The device could not be placed successfully in one women (reason not stated) and a TVT obturator procedure was used instead.</p> <p>Complications at 2 months' follow-up</p> <p>Development of de-novo urgency 16% of women (number not stated), with one of these women experiencing de-novo urge incontinence</p> <p>Tape exposure 3% (1/40) women</p> <p>Development of de-novo dysuria (maximum flow < 15 ml/second) 5.4% of women (number not stated)</p> <p>'Lateral vaginal cords' (term not defined) 5% (2/40) women</p> <p>Painful post-operative course 18% (7/40) women, lasting a mean of 16 days (range 4–30)</p> <p>Dyspareunia was not reported by any of the 16 women who were sexually active.</p>	<p>These were the first 40 women treated with this procedure by the authors.</p> <p>Participants were patients at two centres.</p> <p>The authors commented that it was necessary for the surgeon to be 'very cautious' in adjusting the tension of the tape and in disconnecting the introducer device from the tape.</p>

Abbreviations used: BMI: body mass index; SD: standard deviation; SUI: stress urinary incontinence; TVT, tension-free vaginal tape; UI: urinary incontinence			
Study details	Key efficacy findings	Key safety findings	Comments
<p>Han et al 2007 ⁵ [Conference abstract]</p> <p>Case series</p> <p>Singapore</p> <p>Study period: Aug–Dec 2006</p> <p>n = 30</p> <p>Population: 9/30 women had the procedure in conjunction with other vaginal surgery. None had undergone surgery for incontinence previously.</p> <p>Indications: Urodynamically confirmed SUI</p> <p>Technique: ‘TVT-Secur’ device was used (placement not described).</p> <p>Follow-up: 1 month</p> <p>Conflict of Interest: None</p>	<p>Continence at 1-month follow-up (‘Cure’ defined as continent with negative stress test; ‘improvement’ defined as less leaking; ‘failure’ defined as no improvement).</p> <p>Cure: 67% (20/30) Improvement: 23% (7/30) Failure: 10% (3/30)</p> <p>97% of women could void spontaneously after the procedure without need for catheterisation.</p>	<p>Bladder perforation 3% (1/30)</p> <p>Bladder abrasion 3% (1/30)</p> <p>Blood loss ‘Minimal’ in women who underwent TVT-Secur procedure alone</p> <p>No patients experienced fever, urinary tract infection, thigh pain or bruising. No patients had to be re-admitted.</p> <p>No patients had developed de-novo urgency or urge incontinence by 1 month’s follow-up.</p>	<p>Patients were the first 30 women treated with this procedure by the author. The same surgeon performed all the procedures.</p>

Abbreviations used: BMI: body mass index; SD: standard deviation; SUI: stress urinary incontinence; TVT, tension-free vaginal tape; UI: urinary incontinence			
Study details	Key efficacy findings	Key safety findings	Comments
<p>Albrich et al 2007⁶ [Conference abstract]</p> <p>Case series</p> <p>Germany</p> <p>Study period: not stated</p> <p>n = 24</p> <p>Population: mean age 59.7 years (range 41–87); mean BMI 28.7 kg/m² (19.9–39.9)</p> <p>Indications: SUI confirmed by multi-channel urodynamics, stress test and questionnaire</p> <p>Technique: ‘TVT-Secur’ device used (position not described).</p> <p>Follow-up: Median 18 weeks (9–25) weeks</p> <p>Conflict of interest: None</p>	<p>Results are given for the 18 women who were successfully followed up.</p> <p>Patient-reported continence at follow-up (median 18 weeks) Cured or improved: 78% (14/18) No change: 17% (3/18) Felt worse: 6% (1/18)</p> <p>Continence assessed by stress test at follow-up exam Negative stress test: 83%; 44% absolutely dry Positive stress test: 17%</p> <p>3/24 women underwent additional surgery (classic TVT insertion or Burch colposuspension) because the procedure failed.</p>	<p>Vaginal primary wound dehiscence 17% (4/24) women; managed with topical oestrogens.</p> <p>No patient had urinary retention, haematoma, bladder injury or infection.</p>	<p>6 of the 24 women were lost to follow-up.</p>

Validity and generalisability of the studies

- The studies in Table 2 are all small case series, ranging from 15 to 72 women; 221 women in total.
- Results are from short-term follow-up of less than 6 months; in most studies follow up was 2 months or less.
- Three studies included women with mixed UI.²⁻⁴ One study stated that it included only women with pure SUI.¹ The two remaining studies stated that only women with urodynamically confirmed SUI were included.^{5,6}
- Two device positions were used. The device was placed in the 'hammock' position in 81 women and in the 'U' position in 34 women. Placement was not described for 106 women.

Specialist advisers' opinions

Specialist advice was sought from consultants who have been nominated or ratified by their Specialist Society or Royal College.

Dr Anthony Smith, Mr Ash Monga, Dr Paul Fogarty, Mr R Philip Assassa, Mr Mark Speakman, Mr Marcus Drake

- Two Specialist Advisers had performed the procedure, one for around 100 women.
- Five Specialist Advisers considered the procedure to be definitely novel and of uncertain safety or efficacy. One Specialist Adviser said that only the tape-fixing mechanism was novel and that the rest of the procedure is a minor variation on standard TVT procedures.
- Key efficacy outcomes identified by the Specialist Advisers included various subjective and objective measures of SUI (with two Advisers saying that follow-up of at least 1 year is necessary) and quality of life.
- Several Specialist Advisers considered the efficacy data available to be limited or inadequate. Some mentioned the lack of long-term follow-up data and data from comparative studies. One Specialist Adviser commented that, in his experience, outcomes had been poor when the procedure was performed at the same time as anterior vaginal repair. Another considered the combination of this procedure with other surgery (as is commonly undertaken with some alternative sling procedures) to be untested.
- One Specialist Adviser said that he had observed a 'steep learning curve' associated with the procedure, with a much greater risk of complications during a surgeon's first 15 procedures.
- The Specialist Advisers said that in theory adverse events that could occur include injury to the bladder or other organs, urethral injury, perforation of the vaginal wall), haemorrhage, erosion into the vagina, bladder or urethra by the tape, infection, voiding dysfunction, onset of urgency, pain and dyspareunia.

- From their own experience or anecdotally, the Specialist Advisers reported that haemorrhage, bladder injury, erosion by the tape, wound dehiscence, severe voiding dysfunction, pain and dyspareunia had occurred.
- The Specialist Advisers expressed uncertainty about the true risk of bladder injury and the ease of removal of the anchoring part of the tape from the bladder if this injury occurred.
- One Specialist Adviser said that the procedure should be performed as part of research studies.
- The Specialist Advisers were divided in their views about the likely uptake of the procedure in the UK, with some saying it would be undertaken in only a few hospitals and some expecting it to reach most district general hospitals.
- Some Specialist Advisers said it was important that surgeons are supervised and mentored while performing procedures initially. One Specialist Adviser said that ideally surgeons should undertake training with cadavers. One Specialist Adviser said that surgeons should be experienced in inserting standard TVT devices before performing this procedure.

Issues for consideration by IPAC

- All studies in this overview employed one device, the 'TVT Secur' (Gynecare Worldwide, a division of Ethicon, owned by Johnson & Johnson). We are aware that two other devices for single-incision sub-urethral short tape insertion for SUI have received CE marks. These are the MiniArc Single Incision Sling System (Americal Medical Systems Inc.) and the Minitape (Gyne Ideas Ltd.). We did not identify any published literature relating to these devices.
- Johnson & Johnson has informed NICE that an international observational study of Gynecare TVT devices, including TVT Secur, began in Spring 2007. The website www.ClinicalTrials.gov shows that four UK centres are planning to take part in the trial. Total recruitment is intended to be 5000 women globally, with a maximum follow-up of 5 years.
- The same manufacturer has informed NICE that it is supporting three ongoing randomised controlled trials comparing TVT Secur with other Gynecare TVT devices, and expects final results to be released in 2009. One of these trials intends 3 years' follow-up and two intend 1 year's follow-up. A Swedish randomised controlled study (Persson et al) is also ongoing.
- The NICE Clinical Guideline on the management of urinary incontinence in women (see Appendix B) made recommendations relating to the training of surgeons and the submission of data to registries (British Society of Urogynaecology (BSUG) and British Association of Urological Surgeons Section of Female and Reconstructive Urology (BAUS-SFRU)).

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5. Han HC, Shukiman I, Lee LC. (2007) TVT Secur in treating female stress urinary incontinence: early experience. *International Urogynecology Journal* 18 (Suppl 1): S184.
6. Albrich S, Naumann G, Skala C, Koelbl H. (2007) TVT-Secur: a novel approach for the treatment of female genuine stress urinary incontinence. *International Urogynecology Journal* 18 (Suppl 1): S25.

Appendix A: Additional papers on single-incision mid-urethral tape insertion for stress urinary incontinence in women not included in summary Table 2

The following table outlines the studies that are considered potentially relevant to the overview but were not included in the main data extraction table (Table 2). It is by no means an exhaustive list of potentially relevant studies.

Article title	Number of patients/ follow-up	Direction of conclusions	Reasons for non-inclusion in Table 2
Finnegan S, Fogarty PP. (2007) Clinical outcome of the first cases of the TVT Secur in the UK. <i>International Urogynecology Journal</i> 18 (Suppl 1): S222. [Conference abstract]	n = 25 Case series Follow-up at 6 weeks	"Follow-up is at present in its early stages. However, early results look promising."	No efficacy or safety data are given in the abstract.
Han H, Ismail S, Lee LC. (2007) TVT Secur in treating female stress urinary incontinence: early experience. [Abstract presented at the International Continence Society Annual Meeting, August 2007]	This abstract was presented at an earlier conference also, and is included in Table 2 with the earlier citation. ⁵		
Martan A, Masata J, Svabik K, Koleska T. (2007) Initial experience with TVT-Secur system procedure. [Abstract presented at the International Continence Society Annual Meeting, August 2007]	n = 40 Follow-up: patients were at 1–6 months post-op when the abstract was submitted. It is not clear exactly when outcomes were assessed.	87.5% (35/40) of women were 'cured' (no further details given). Folded tape causing persistent SUI: 10.0% (4/40) of women Vaginal erosion by the tape, causing pain: 5.0% (2/40) of women Vaginal pain of unknown cause: 2.5% (1/40) of women [pain lasted 1 week]	It was judged likely that 15 of the women described in this conference abstract were included in the full peer-reviewed article by Martan et al (2007), ¹ included in Table 2. In both pieces, the authors say they are describing their initial experience of the procedure. This abstract and the fully article report the same type of adverse events and a similar degree of efficacy, and so the peer-reviewed full article was selected for inclusion in Table 2.
Martan A, Masata J, Svabik K. (2007) Initial experience with TVT-Secur system procedure and the reason for persistent stress urinary incontinence. <i>International Urogynecology Journal</i> 18 (Suppl 1):S26.	n = 25 Follow-up: patients were at 1–5 months post-op when	This conference abstract appears to report results of the procedure for the first 25 women included in the abstract above.	

Article title	Number of patients/ follow-up	Direction of conclusions	Reasons for non-inclusion in Table 2
[Conference abstract]	the abstract was written.		
<p>Neuman M. (2007) Training TVT SECUR: The first 150 teaching operations. <i>International Urogynecology Journal</i> 18 (Suppl 1):S27.</p> <p>[Conference abstract]</p>	<p>n = 150</p> <p>Case series</p> <p>Follow up: peri-operative data only</p>	<p>3% (5/150) of women required additional tensioning of the tape because of "early therapeutic failure".</p> <p>There were no other failures.</p> <p>In 3% (5/150) women the device was withdrawn and replaced because it did not fully detach from introducer device (all early in the series).</p> <p>"No voiding difficulties, significant pain, or any other patient inconvenience was observed post-operatively."</p> <p>No bowel, bladder or urethral injuries, intra-operative bleeding or post-operative infections occurred.</p>	<p>This case series has been published as a conference abstract only. The authors reported that no serious adverse events occurred and therefore the abstract was not judged to be suitable for inclusion in Table 2.</p>
<p>Neuman M. TVT Secur: 100 teaching operations with a novel anti-incontinence procedure.</p> <p>[Article yet to be submitted for publication. Manuscript supplied to NICE by Johnson & Johnson in August 2007]</p>	<p>n = 100</p> <p>Case series</p> <p>Follow up: 2 – 5 months</p>	<p>Persistence of SUI affecting quality of life: 3% (3/100)</p> <p>Persistent leakage not sufficient to negatively affect quality of life: 7% (7/100)</p> <p>No significant operative bleeding, bladder or intestinal perforation, infection, overactive bladder or bladder outlet obstruction occurred.</p> <p>Inadvertent vaginal wall perforation 4% (4/100)</p>	<p>These data were obtained from a paper that has not yet been published or accepted for publication. Serious adverse events are reported in this case series. However, the safety issues raised in this paper have already been brought to the attention of IPAC in Table 2, which includes published conference abstracts that also report these types of adverse events.</p>

Article title	Number of patients/ follow-up	Direction of conclusions	Reasons for non-inclusion in Table 2
		Tape erosion into vagina: 3% (3/100) Bleeding: One woman was returned to theatre for evacuation of haematoma of 50ml.	
Saltz SM. (2007) Short-term assessment of patients undergoing the new tension free vaginal tape: Secur procedure for treatment of stress urinary incontinence. International Urogynecology Journal 18 (Suppl 1):S27.	n = 77 Case series Follow-up: 6 weeks	Women 'cured' (no SUI after the procedure) 69% (53/77) of women had no SUI after the procedure. 40% of the remaining women reported improvement in symptoms. Voiding dysfunction: 2.6% (2/77)	Pain at 6 weeks' follow-up: 1.3% (1/77) women No tape exposures had occurred at 6 weeks' follow-up.

Appendix B: Related published NICE guidance for single-incision mid-urethral tape insertion for stress urinary incontinence in women

Guidance programme	Recommendation
Interventional procedures	<p>IPG18 Bone-anchored cystourethropexy</p> <p>1 Guidance 1.1 Current evidence of the safety and efficacy of bone-anchored cystourethropexy does not appear adequate to support the use of this procedure without special arrangements for consent and for audit or research. Clinicians wishing to undertake bone-anchored cystourethropexy should inform the clinical governance leads in their Trusts. They should ensure that patients offered it understand the uncertainty about the procedure's safety and efficacy and should provide them with clear written information. In particular patients should be informed that the long-term efficacy of the procedure appears to be poor. Use of the Institute's Information for the Public is recommended. Clinicians should ensure that appropriate arrangements are in place for audit or research. Publication of safety and efficacy outcomes will be useful in reducing the current uncertainty. NICE is not undertaking further investigation at present.</p> <p>IPG133 Insertion of extraurethral (non-circumferential) retropubic adjustable compression devices for stress urinary incontinence in women</p> <p>1 Guidance 1.1 Current evidence on the safety and efficacy of insertion of extraurethral (non-circumferential) retropubic adjustable compression devices for stress urinary incontinence in women does not appear adequate for this procedure to be used without special arrangements for consent and for audit or research.</p> <p>1.2 Clinicians wishing to undertake insertion of extraurethral (non-circumferential) retropubic adjustable compression devices for stress urinary incontinence in women should take the following actions.</p> <ul style="list-style-type: none"> • Inform the clinical governance leads in their Trusts.

	<ul style="list-style-type: none"> • Ensure that patients understand the uncertainty about the procedure's safety and efficacy and provide them with clear written information. Use of the Institute's Information for the public is recommended. • Audit and review clinical outcomes of all patients having insertion of extraurethral (non-circumferential) retropubic adjustable compression devices for stress urinary incontinence. <p>1.3 Publication of safety and efficacy outcomes will be useful. The Institute may review the procedure upon publication of further evidence.</p> <p>IPG138 Intramural urethral bulking procedures for stress urinary incontinence in women</p> <p>1 Guidance</p> <p>1.1 Current evidence on the safety and short-term efficacy of intramural urethral bulking procedures for stress urinary incontinence is adequate to support the use of these procedures provided that normal arrangements are in place for clinical governance and for audit or research.</p> <p>1.2 Clinicians should ensure that patients understand that the benefits of the procedures diminish in the long term and provide them with clear written information. In addition, use of the Institute's Information for the public is recommended.</p> <p>1.3 Further publication of longer-term efficacy outcomes will be useful. Clinicians should submit data to the British Association of Urological Surgeons registry (available from www.baus.org.uk), or the British Society of Urogynaecologists registry (for further information contact BSUG@rcog.org.uk).</p> <p>IPG154 Insertion of biological slings for stress urinary incontinence in women</p> <p>1 Guidance</p> <p>1.1 Current evidence on the safety and short-term efficacy of the insertion of biological slings for stress urinary incontinence in women is adequate to support the use of this procedure provided that normal arrangements are in place for consent and clinical governance.</p> <p>1.2 Data on the long-term efficacy of the insertion of biological slings for stress urinary incontinence in women are limited to autologous slings. Clinicians should therefore audit patients in the</p>
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	<p>longer term. Publication of further audit data and research will be helpful in determining the usefulness of different types of sling for this procedure.</p> <p>1.3 Clinicians should ensure that patients understand that slings made of cadaveric or animal tissue may be implanted, and that the use of such slings is acceptable to the patient.</p>
Technology appraisals	None applicable (TA56: Stress incontinence - tension-free vaginal tape is now obsolete and has been replaced by CG40 (see below).
Clinical guidelines	<p>CG40 Urinary Incontinence: the management of urinary incontinence in women</p> <p>1.3 <i>Surgical management</i></p> <p>1.3.1 Discussion of benefits and risks</p> <p>1.3.1.1 Any woman wishing to consider surgical treatment for UI should be informed about the benefits and risks of surgical and non-surgical options. Counselling should include consideration of the woman's child-bearing wishes.</p> <p>1.3.2 Procedures for OAB [edited out]</p> <p>1.3.3 Procedures for stress UI</p> <p>1.3.3.1 Retropubic mid-urethral tape procedures using a 'bottom-up' approach with macroporous (type 1) polypropylene meshes are recommended as treatment options for stress UI if conservative management has failed. Open colposuspension and autologous rectus fascial sling are the recommended alternatives when clinically appropriate.</p> <p>1.3.3.2 Synthetic slings using a retropubic 'top-down' or a transobturator foramen approach are recommended as alternative treatment options for stress UI if conservative management has failed, provided that women are made aware of the lack of long-term outcome data.</p> <p>1.3.3.3 Synthetic slings using materials other than polypropylene that are not of a macroporous (type 1) construction are not recommended for the treatment of stress UI.</p> <p>1.3.3.4 Intramural bulking agents (glutaraldehyde cross-linked collagen, silicone, carbon-coated zirconium beads, or hyaluronic acid/dextran copolymer) should be considered for the management of stress UI if conservative management has failed. Women should be made aware that:</p> <ul style="list-style-type: none"> • repeat injections may be required to achieve efficacy • efficacy diminishes with time

	<ul style="list-style-type: none"> • efficacy is inferior to that of retropubic suspension or sling. <p>1.3.3.5 In view of the associated morbidity, the use of an artificial urinary sphincter should be considered for the management of stress UI in women only if previous surgery has failed. Life-long follow-up is recommended.</p> <p>1.3.3.6 Laparoscopic colposuspension is not recommended as a routine procedure for the treatment of stress UI in women. The procedure should be performed only by an experienced laparoscopic surgeon working in a multidisciplinary team with expertise in the assessment and treatment of UI.</p> <p>1.3.3.7 Anterior colporrhaphy, needle suspensions, paravaginal defect repair and the Marshall–Marchetti–Krantz procedure are not recommended for the treatment of stress UI.</p> <p>1.3.3.8 Autologous fat and polytetrafluoroethylene used as intramural bulking agents are not recommended for the treatment of stress UI.</p> <p>1.4 <i>Competence of surgeons performing operative procedures for UI in women</i></p> <p>1.4.1 Surgery for UI should be undertaken only by surgeons who have received appropriate training in the management of UI and associated disorders, or who work within a multidisciplinary team with this training, and who regularly carry out surgery for UI in women.</p> <p>1.4.2 Training should be sufficient to develop the knowledge and generic skills documented below. Knowledge should include the:</p> <ul style="list-style-type: none"> • specific indications for surgery • required preparation for surgery, including preoperative investigations • outcomes and complications of the proposed procedure • anatomy relevant to the procedure • steps involved in the procedure • alternative management options • likely postoperative progress. <p>Generic skills should include:</p> <ul style="list-style-type: none"> • the ability to explain procedures and possible outcomes to patients and family and to obtain informed consent • the necessary hand–eye dexterity to complete the procedure safely and efficiently, with appropriate use of assistance • the ability to communicate with and manage the operative team effectively • the ability to prioritise interventions • the ability to recognise when to ask for advice from others
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	<ul style="list-style-type: none"> • a commitment to multidisciplinary team working. <p>1.4.3 Training should include competence in cystourethroscopy.</p> <p>1.4.4 Operative competence of surgeons undertaking surgical procedures to treat UI or OAB in women should be formally assessed by trainers through a structured process.</p> <p>1.4.5 Surgeons who are already carrying out procedures for UI should be able to demonstrate that their training, experience and current practice equates to the standards laid out for newly trained surgeons.</p> <p>1.4.6 Surgery for UI or OAB in women should be undertaken only by surgeons who carry out a sufficient case load to maintain their skills. An annual workload of at least 20 cases of each primary procedure for stress UI is recommended. Surgeons undertaking fewer than five cases of any procedure annually should do so only with the support of their clinical governance committee; otherwise referral pathways should be in place within clinical networks.</p> <p>1.4.7 There should be a nominated clinical lead within each surgical unit with responsibility for continence and prolapse surgery. The clinical lead should work within the context of an integrated continence service.</p> <p>1.4.8 A national audit of continence surgery should be undertaken.</p> <p>1.4.9 Surgeons undertaking continence surgery should maintain careful audit data and submit their outcomes to national registries such as those held by the British Society of Urogynaecology (BSUG) and British Association of Urological Surgeons Section of Female and Reconstructive Urology (BAUS-SFRU).</p>
Public health	None applicable

Appendix C: Literature search for single-incision mid-urethral tape insertion for stress urinary incontinence in women

Search history

IP:		
Database	Date searched	Version searched
Cochrane Library	26/06/2007	Issue 2, 2007
CRD databases (DARE & HTA)	26/06/2007	Issue 2, 2007
Embase	26/06/2007	1980 to 2007 Week 25
Medline	26/06/2007	1950 to 2007 June Week 2
Premedline	26/06/2007	June 25, 2007
CINAHL	26/06/2007	1982 to 2007 June Week 4
British Library Inside Conferences	26/06/2007	1993 to date
NRR	27/06/2007	2007 – Issue 2
Controlled Trials Registry	27/06/2007	-

Search strategy used in Medline

The following search strategy was used to identify papers in Medline. The search strategy was adapted for use in the databases above

1. exp Suburethral slings/
2. (subureth\$ adj3 sling\$).tw.
3. tension-free vaginal tape.tw.
4. (tension adj3 vagin\$).tw.
5. TVT.tw.
6. or/1-5
7. exp urogenital Surgical procedures/
8. exp Urologic Surgical Procedures/
9. (ur\$ adj3 (surg\$ or proced\$ or operat\$)).tw.
10. ((urethra\$ or vagina\$ or bladder\$) adj3 surger\$).tw.
11. or/7-10
12. exp Surgical Procedures, Minimally invasive/

13. (minim\$ adj3 invasiv\$).tw.
14. ((sing\$ or one or once) adj3 (incision\$ or cut or entr\$)).tw.
15. or/12-14
16. 11 and 15
17. 6 and 16
18. exp Urinary Incontinence, Stress/
19. (incont\$ adj3 (urin\$ or stress\$)).tw.
20. (sphincter adj3 (defic\$ or dysfunct\$)).tw.
21. exp Urethra/
22. (urethra\$ adj3 hypermob\$).tw.
23. or/18-22
24. 17 and 23
25. Animals/
26. Humans/
27. 25 not (25 and 26)
28. 24 not 27
29. limit 28 to yr="2003 - 2007"