

# Stress incontinence

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## Key Points

- Stress incontinence, involving involuntary leaking of urine on effort, exertion, sneezing, or coughing, affects 17–45% of adult women.  
Risk factors include pregnancy (especially with vaginal delivery), smoking, and obesity.
- Pelvic floor muscle exercises improve symptoms and reduce incontinence episodes compared with no treatment. Pelvic floor electrical stimulation and vaginal cones are also effective compared with no treatment.  
Pelvic floor electrical stimulation can cause tenderness and vaginal bleeding, whereas vaginal cones can cause vaginitis and abdominal pain. Pelvic floor muscle exercises can cause discomfort.
- Oestrogen supplements increase cure rates compared with placebo, but there are risks associated with their long term use. They can be less effective at reducing incontinence compared with pelvic floor muscle exercises.
- Serotonin reuptake inhibitors (duloxetine 80 mg/day) reduce stress incontinence compared with placebo at 4–12 weeks, or compared with pelvic floor muscle exercises, but increase the risk of adverse effects, such as headache and gastric problems.
- We do not know whether adrenergic agonists improve incontinence compared with placebo or with other treatments, but they can cause insomnia, restlessness, and vasomotor stimulation. Phenylpropanolamine has been withdrawn from the US market because of an increased risk of haemorrhagic stroke.

- Open retropubic colposuspension may be more likely to cure stress incontinence than anterior vaginal repair or needle suspension at 1–5 years. Complication rates are similar to those with other surgical procedures, but are higher than with non-surgical treatments.

Suburethral slings, including tension free vaginal tape, are as effective as open retropubic colposuspension in curing stress incontinence over 5 years. Complications of tension free vaginal tape include bladder perforation.

Transobturator foramen procedures may be as effective as tension free vaginal tape.

- Laparoscopic colposuspension seems to be as effective over 2–5 years as open retropubic colposuspension or tension free vaginal tape.

**DEFINITION** Stress incontinence is involuntary leakage of urine on effort or exertion, or on sneezing or coughing.<sup>[1]</sup> Stress incontinence predominantly affects women, and can cause social and hygiene problems. Typically, there is no anticipatory feeling of needing to pass urine. Under urodynamic testing, urodynamic stress incontinence is confirmed by demonstrating loss of urine when intravesical pressure exceeds maximum urethral pressure, in the absence of a detrusor contraction. A confirmed diagnosis of urodynamic stress incontinence is particularly important before surgical treatment,<sup>[2]</sup> given that the symptoms of stress incontinence can occur in people with detrusor overactivity, which is confirmed by the demonstration of uninhibited bladder contractions. This review deals with stress incontinence in general.

**INCIDENCE/ PREVALENCE** Stress incontinence is a common problem. Prevalence has been estimated at 17–45% of adult women in resource rich countries.<sup>[3]</sup> One cross-sectional study (15 308 women in Norway, aged < 65 years) found that the prevalence of stress incontinence was 4.7% in women who had not borne a child, 6.9% in women who had had caesarean deliveries only, and 12.2% in women who had had vaginal deliveries only.<sup>[4]</sup>

**AETIOLOGY/ RISK FACTORS** Aetiological factors include pregnancy, vaginal or caesarean delivery, cigarette smoking, and obesity.<sup>[4] [5] [6] [7]</sup> One cross-sectional study (15 308 women in Norway) found that, when compared with women who have not borne a child, the risk of stress incontinence was increased in women who have delivered by caesarean section (age adjusted OR 1.4, 95% CI 1.0 to 2.0) or by vaginal delivery (age adjusted OR 3.0, 95% CI 2.5 to 3.5).<sup>[4]</sup> The risk of stress incontinence was also increased in women who had a vaginal delivery compared with women who had a caesarean section (adjusted OR 2.4, 95% CI 1.7 to 3.2). One case control study (606 women) found that the risk of “genuine”, now called “urodynamic”, stress incontinence, was increased in former smokers (adjusted OR 2.20, 95% CI 1.18 to 4.11) and in current smokers (adjusted OR 2.48, 95% CI 1.60 to 3.84).<sup>[7]</sup> We found no reliable data measuring the risks associated with obesity.

**PROGNOSIS** We found no reliable data about the natural history of stress incontinence. Untreated stress incontinence is believed to be a persistent, lifelong condition.

**AIMS OF INTERVENTION** To improve quality of life and social function; to reduce embarrassment; and to reduce frequency and volume of involuntary urine leakage, with minimal adverse effects.

**OUTCOMES** **Primary outcomes:** quality of life, social functioning, subjective reduction in urine loss, and adverse effects of treatment. **Secondary outcomes:** reduced urine leakage on urodynamic testing, and pad tests for objective demonstration of leakage. **Excluded proxy/surrogate outcomes:** pelvic floor strength, tension, contractility, physiological measures, and perineometry.

**METHODS** *BMJ Clinical Evidence* search and appraisal December 2006. The following databases were used to identify studies for this review: Medline 1966 to December 2006, Embase 1980 to December 2006, and The Cochrane Database of Systematic Reviews and Cochrane Central Register of Controlled Clinical Trials 2006, Issue 4. Additional searches were carried out using these websites: NHS Centre for Reviews and Dissemination (CRD) — for Database of Abstracts of Reviews of Effects (DARE) and Health Technology Assessment (HTA), Turning Research into Practice (TRIP), and National Institute for Health and Clinical Excellence (NICE). Abstracts of the studies retrieved from the initial search were assessed by an information specialist. Selected studies were then sent to the author for additional assessment, using predetermined criteria to identify relevant studies. Study design criteria for inclusion in this review were: published systematic reviews and RCTs in any language, at least single blinded, and containing more than 20 individuals, of whom more than 80% were followed up. There was no minimum length of follow up required to include studies. We excluded all studies described as “open”, “open label”, or not blinded, unless blinding was impossible. We excluded RCTs that reported only within group comparisons (e.g. change from baseline within a group). We have included only RCTs that stated that more than half of the participants had stress incontinence. We also searched for prospective/retrospective cohort, case control, case,

and cross-sectional survey data on harms of tension free vaginal tape (TVT) and transobturator foramen procedures. We excluded studies comparing different techniques within a single intervention type (e.g. high intensity v low intensity pelvic floor muscle training, or Burch colposuspension v Marshall–Marchetti–Krantz urethropexy). In addition, we use a regular surveillance protocol to capture harms alerts from organisations such as the US Food and Drug Administration (FDA) and the UK Medicines and Healthcare products Regulatory Agency (MHRA), which are added to the review as required. We have performed a GRADE evaluation of the quality of evidence for interventions included in this review ( see table, p 26 ).

**QUESTION** What are the effects of non-surgical treatments for women with stress incontinence?

**OPTION** SEROTONIN REUPTAKE INHIBITORS (DULOXETINE)

### Cure of incontinence

*Compared with placebo* Duloxetine does not increase the proportion of people cured of stress incontinence compared with placebo ( [high-quality evidence](#) ).

### Incontinence episodes

*Compared with placebo* Duloxetine at doses of 80 mg or above daily improves the frequency of incontinence episodes compared with placebo ( [high-quality evidence](#) ).

*Compared with pelvic floor exercises* Duloxetine improves the frequency of incontinence episodes compared with pelvic floor exercises ( [moderate-quality evidence](#) ).

### Quality of life

*Compared with placebo* Duloxetine improves quality of life compared with placebo in people with stress incontinence ( [high-quality evidence](#) ).

*Compared with pelvic floor exercises* Duloxetine is as effective as pelvic floor exercises at improving quality of life ( [moderate-quality evidence](#) ).

### Adverse effects

Duloxetine is associated with more adverse effects, including nausea, diarrhoea, headache, dizziness, fatigue, and dry mouth, compared with placebo.

**For GRADE evaluation of interventions for stress incontinence, see table, p 26 .**

### Benefits:

#### Serotonin reuptake inhibitors versus placebo or no treatment:

We found one systematic review (search date 2005, 9 RCTs, 3327 adults with predominantly stress urinary incontinence),<sup>[8]</sup> which included one conference report of an RCT<sup>[9]</sup> that was subsequently published in full,<sup>[10]</sup> and one subsequent RCT.<sup>[11]</sup> The review found no significant difference in the proportion of people “not cured” during treatment (assessed either subjectively, or objectively using stress [pad test](#)) with duloxetine 20, 40, or 80 mg daily compared with placebo or no treatment ( [see table 1, p 23](#) ).<sup>[8]</sup> However, it found that duloxetine 20, 40, or 80 mg daily significantly increased the number of people who “improved” during treatment compared with placebo or no treatment ( [see table 1, p 23](#) ).<sup>[8]</sup> The review also found that duloxetine significantly improved quality of life compared with placebo. Five RCTs<sup>[9]</sup> <sup>[12]</sup> <sup>[13]</sup> <sup>[14]</sup> <sup>[15]</sup> included in the review<sup>[8]</sup> found that duloxetine (at doses of 40–120 mg/day) significantly reduced incontinence episode frequency (IEF) compared with placebo at between 4 and 12 weeks ( [see table 1, p 23](#) ). A sixth included RCT<sup>[16]</sup> also found that duloxetine 80 mg daily reduced IEF at 12 weeks, although this result was not significant (P = 0.05) ( [see table 1, p 23](#) ). One of the included RCTs<sup>[13]</sup> found no significant difference in IEF outcomes between duloxetine at a dose of 20 mg and placebo at 12 weeks ( [see table 1, p 23](#) ). Another included RCT (109 women) found that in women with severe urinary stress incontinence, duloxetine (40 mg twice daily initially for 4 weeks, escalating to 60 mg twice daily for 4 weeks) significantly reduced the frequency of incontinence and improved quality of life compared with placebo at 8 weeks ( [see table 1, p 23](#) ).<sup>[12]</sup> The subsequent RCT (121 women) found that in women with predominant urinary stress incontinence, duloxetine (40 mg twice daily for 4 weeks) significantly reduced the IEF outcomes compared with placebo ( [see table 1, p 23](#) ).<sup>[11]</sup>

#### Serotonin reuptake inhibitors versus pelvic floor muscle exercises:

We found one systematic review (search date 2005, 1 RCT),<sup>[8]</sup> which identified one RCT reported in two publications.<sup>[9]</sup> <sup>[10]</sup> The RCT (201 people)<sup>[9]</sup> identified by the review<sup>[8]</sup> was a four arm trial comparing duloxetine 80 mg daily plus imitation [pelvic floor muscle training \(PFMT\)](#), PFMT plus placebo, duloxetine 80 mg daily plus PFMT, and placebo plus imitation PFMT. It found that duloxetine (80 mg daily) plus imitation PFMT significantly reduced the frequency of incontinence compared with PFMT plus placebo (92 women, median decrease in IEF: 56.5% with duloxetine v

34.7% with PFMT;  $P < 0.004$ ). It found no significant difference between the two treatments in quality of life scores (mean increase in Incontinence Quality of Life score from baseline [baseline range: 59.8 to 61.4]: 8.3 with duloxetine v 7.8 with PFMT;  $P < 0.98$ ).<sup>[10]</sup>

#### **Serotonin reuptake inhibitors versus non-surgical treatment (other than pelvic floor muscle exercises) or other forms of drug treatment:**

We found no RCTs.

#### **Harms:**

##### **Serotonin reuptake inhibitors versus placebo or no treatment:**

The systematic review<sup>[6]</sup> reported that although significantly more adverse effects were associated with duloxetine than with placebo, they were reported as acceptable (number of people with adverse events: 899/1276 [71%] with duloxetine v 585/1003 [58%] with placebo; RR 1.30, 95% CI 1.23 to 1.38;  $P < 0.00001$ ). Five RCTs<sup>[12] [13] [14] [15] [16]</sup> reported nausea as the most common reason for treatment discontinuation (discontinuation rates: 18/55 [33%] with duloxetine 80 mg daily v 3/54 [6%] with placebo;  $P < 0.001$ ;<sup>[12]</sup> 9% with duloxetine 20 mg v 12% with duloxetine 40 mg v 15% with duloxetine 80 mg v 5% with placebo;  $P = 0.04$  overall;<sup>[13]</sup> 24% with duloxetine 40 mg twice daily v 4% with placebo;  $P < 0.001$ ;<sup>[14]</sup> 22% with duloxetine 40 mg daily v 5% with placebo;  $P < 0.001$ ;<sup>[15]</sup> 17.2% with duloxetine 40 mg twice daily v 1.7% with placebo;  $P = 0.001$ <sup>[16]</sup>). The most common adverse events with duloxetine were nausea, diarrhoea, headache, dizziness, fatigue, and dry mouth.<sup>[10] [12] [13] [14] [15] [16] [17]</sup> The subsequent RCT found that treatment emergent adverse events (nausea, dizziness, anorexia, fatigue, lethargy, abdominal discomfort, and constipation) were reported more frequently with duloxetine compared with placebo (82% with duloxetine v 32% with placebo;  $P = 0.001$ ). The RCT also reported that discontinuation rates because of adverse effects were 34% with duloxetine and 8% with placebo ( $P$  value not reported).<sup>[12]</sup>

##### **Serotonin reuptake inhibitors versus pelvic floor muscle exercises:**

The RCT did not report adverse effects separately for each of the four treatment arms.<sup>[9] [10]</sup>

##### **Serotonin reuptake inhibitors versus non-surgical treatment (other than pelvic floor muscle exercises) or other forms of drug treatment:**

We found no RCTs.

**Comment:** None.

## **OPTION PELVIC FLOOR ELECTRICAL STIMULATION**

### **Incontinence frequency**

*Compared with no/sham treatment* Pelvic floor electrical stimulation is more effective at reducing the frequency of incontinence episodes compared with no treatment or sham pelvic floor electrical stimulation ( [moderate-quality evidence](#) ).

*Compared with vaginal cones* Pelvic floor electrical stimulation seems to be as effective as vaginal cones at preventing episodes of incontinence (moderate-quality evidence).

### **Improvement of incontinence**

*Compared with no/sham treatment* Pelvic floor electrical stimulation may increase the proportion of people reporting improvement or cure of incontinence compared with no treatment or sham treatment ( [very low-quality evidence](#) ).

*Compared with vaginal cones* Pelvic floor electrical stimulation is as effective as vaginal cones at leading to improvement or cure of incontinence ( [high-quality evidence](#) ).

*Compared with oestrogen supplements* Pelvic floor electrical stimulation seems to be as effective as oestrogen supplements at improving or curing incontinence (moderate-quality evidence).

### **Adverse effects**

Pelvic floor electrical stimulation is associated with higher rates of tenderness and vaginal bleeding than vaginal cones.

**For GRADE evaluation of interventions for stress incontinence, see table, p 26 .**

#### **Benefits:**

##### **Pelvic floor electrical stimulation versus no treatment or sham treatment:**

We found one systematic review (search date 1998, 1 RCT),<sup>[18]</sup> three additional RCTs,<sup>[19] [20] [21]</sup> and two subsequent RCTs ( [see table 2, p 24](#) ).<sup>[22] [23]</sup> The RCT identified by the review (52 women) found that [pelvic floor electrical stimulation](#) (PFES) significantly reduced the number of weekly incontinence episodes compared with sham PFES ( [see table 2, p 24](#) ).<sup>[18]</sup> The first additional RCT (121 women; 60 [50%] with stress incontinence, 28 [23%] with [urge incontinence](#) , and 33 [27%] with mixed incontinence) found limited evidence that PFES significantly increased the

proportion of women with self reported improvement in symptoms after 6 weeks compared with sham PFES ( see table 2, p 24 ).<sup>[19]</sup> However, limitations in the methods used make it difficult to draw conclusions from these results, in that the RCT enrolled 148 women, but only 121 (82%) completed the study, and it did not perform an intention to treat analysis. It found no significant difference in withdrawal rates between PFES and sham treatment (14% with PFES v 21% with sham treatment; P = 0.27).<sup>[19]</sup> The second additional RCT (33 people with stress incontinence; 5 [15%] men and 28 [85%] women; see comment below) found that PFES significantly increased the proportion of people with self reported improvement in symptoms and reduced urine loss (measured using a 1 hour pad test) over 4 weeks compared with sham PFES ( see table 2, p 24 ).<sup>[20]</sup> However, because this RCT included men, the findings might not be fully generalisable to women with stress incontinence.<sup>[20]</sup> The third additional RCT (43 women) found that more people receiving PFES reported improvement or cure compared with no treatment ( see table 2, p 24 ).<sup>[21]</sup> The first subsequent RCT (60 women) found that PFES significantly reduced the frequency and severity of incontinence after 6 weeks compared with no treatment ( see table 2, p 24 ).<sup>[22]</sup> The second subsequent RCT (27 women) found that PFES significantly improved Urogenital Distress Inventory Questionnaire scores after 8 weeks ( see table 2, p 24 ).<sup>[23]</sup>

#### PFES versus vaginal cones:

We found one systematic review (search date 2003, 4 RCTs, 274 women).<sup>[24]</sup> The review found no significant difference between PFES and vaginal cones in self reported cure rates (failure to cure: 50/55 [91%] with PFES v 47/51 [92%] with vaginal cones; RR 0.99, 95% CI 0.88 to 1.12), self reported cure or improvement rates (failure to improve or cure: 18/61 [30%] with PFES v 24/60 [40%] with vaginal cones; RR 0.74, 95% CI 0.45 to 1.22), daily leakage episodes (1 RCT; 0.57 with PFES v 1.17 with vaginal cones; P = 0.1), or grams of daily leakage (after 6 months: 1 RCT; 0.8 with PFES v 0.6 with vaginal cones; P = 0.6) after treatment over 4 weeks to 12 months. The review might have lacked power to detect a clinically important difference in outcomes.

#### PFES versus oestrogen supplements:

We found one systematic review (search date 2002, 1 RCT, 49 women).<sup>[25]</sup> It found no significant difference in objective cure or improvement rates between PFES and oestrogen supplements at 6 weeks (8/25 [32%] with PFES v 3/24 [13%] with oestrogen; RR 2.56, 95% CI 0.77 to 8.33).<sup>[25]</sup> The RCT included in the review might have lacked the power to detect a clinically important difference.

#### Harms:

##### PFES versus no treatment or sham treatment:

The RCTs gave no information on harms.<sup>[18] [19] [20] [21] [22] [23]</sup>

##### PFES versus vaginal cones:

In one of the RCTs<sup>[26]</sup> included in the review,<sup>[24]</sup> adverse events included tenderness and vaginal bleeding (1/25 [4%]) and discomfort (1/25 [4%]) in the PFES group, and abdominal pain (1/27 [4%]), vaginitis (2/27 [7%]), and vaginal bleeding (1/27 [4%]) in the vaginal cones group. Motivation problems and difficulty with use were more frequent in the vaginal cones group (8/25 (32%) with PFES v 14/27 (52%) with vaginal cones).<sup>[26]</sup>

##### PFES versus oestrogen supplements:

The systematic review reported no information on harms.<sup>[25]</sup>

**Comment:** None.

## OPTION PELVIC FLOOR MUSCLE EXERCISES

### Improvement in incontinence

*Compared with no treatment/inactive treatments* Pelvic floor muscle exercises increase cure or improvement rates compared with no treatment, placebo, or inactive treatments ( moderate-quality evidence ).

*Compared with vaginal cones* Pelvic floor muscle exercises are as effective as vaginal cones at improving or curing incontinence after 12 months ( high-quality evidence ).

*Compared with oestrogen supplements* Pelvic floor muscle exercises lead to greater improvement or cure rates compared with oestrogen supplements ( moderate-quality evidence ).

*Compared with adrenoceptor agonists* The effects of pelvic floor muscle exercises compared with adrenoceptor agonists (clenbuterol, phenylproprandamine) are unclear ( low-quality evidence ).

### Incontinence frequency

*Compared with no/inactive treatment* Pelvic floor muscle exercises do not reduce the frequency of incontinence episodes compared with no active treatment ( high-quality evidence ).

*Compared with vaginal cones* Pelvic floor muscle exercises reduce the number of daily leakage episodes at 6 months compared with vaginal cones (moderate-quality evidence).

*Compared with selective serotonin reuptake inhibitors* Pelvic floor exercises are less likely to improve the frequency of incontinence episodes compared with duloxetine (moderate-quality evidence).

### Quality of life

*Compared with selective serotonin reuptake inhibitors* Pelvic floor exercises are as effective as duloxetine at improving quality of life (moderate-quality evidence).

### Adverse effects

Pelvic floor muscle exercises are associated with discomfort. Phenylproprandamine has been withdrawn from the US market because of increased risks of haemorrhagic stroke.

**For GRADE evaluation of interventions for stress incontinence, see table, p 26 .**

**Benefits:** We found one systematic review (search date 2005)<sup>[27]</sup> and one subsequent RCT (201 women).<sup>[10]</sup> The subsequent RCT was a four arm trial comparing [pelvic floor muscle exercises](#) (PFME) plus placebo, placebo plus imitation PFME, duloxetine plus imitation PFME, and PFME plus duloxetine.

#### PFME versus no treatment, placebo, or inactive control treatments:

The review identified three RCTs (165 women) comparing PFME versus no treatment, placebo, or inactive control treatments.<sup>[27]</sup> It found that PFME significantly improved perceived cure (1 RCT; 14/25 [56%] with PFME v 1/30 [3%] with no treatment, placebo, or inactive control treatments; RR 16.8, 95% CI 2.4 to 119.0) and patient-perceived cure or improvement (3 RCTs; 56/80 [70%] with PFME v 16/85 [19%] with no treatment, placebo, or inactive control treatments; RR not reported).<sup>[27]</sup> The subsequent RCT (201 women)<sup>[10]</sup> found that PFME plus placebo significantly, but only slightly, reduced pad use compared with imitation PFME plus placebo at 12 weeks (median pad use/week: 8.6 with PFME plus placebo v 9.8 with imitation PFME plus placebo; P = 0.028), and found no significant difference between the two groups in incontinence episode frequency (incontinence episode frequency/week: 22.0 with PFME plus placebo v 18.9 with imitation PFME plus placebo) or Incontinence Quality of Life scores (61.4 with PFME plus placebo v 64.9 with imitation PFME plus placebo; reported as not significant).<sup>[10]</sup>

#### PFME versus vaginal cones:

One systematic review (search date 2003) identified seven RCTs (661 women) comparing PFME versus [vaginal cones](#).<sup>[24]</sup> It found no significant difference in self reported cure rates (failure to cure: 3 RCTs; 41/63 [65%] with PFME v 46/66 [70%] with vaginal cones; RR 0.93, 95% CI 0.72 to 1.16), or in self reported cure or improvement rates (failure to cure or improve: 4 RCTs; 30/90 [33%] with PFME v 35/92 [38%] with vaginal cones; RR 0.87, 95% CI 0.58 to 1.28) between PFME and vaginal cones over 12 months. It found that PFME significantly reduced the number of daily leakage episodes at 6 months compared with vaginal cones (2 RCTs; P = 0.008; pooled absolute numbers not reported, WMD reported graphically).

#### PFME versus oestrogen supplements:

One systematic review (search date 2002, 2 RCTs, 69 women) found that PFME significantly improved objective cure or improvement rates compared with oestrogen supplements at 9 months (21/34 [62%] with PFME v 3/35 [9%] with oestrogen; RR 5.9, 95% CI 2.2 to 16.7).<sup>[25]</sup>

#### PFME versus serotonin reuptake inhibitors:

[See benefits of serotonin reuptake inhibitors, p 3 .](#)

#### PFME versus adrenoceptor agonists:

[See benefits of adrenoceptor agonists, p 9 .](#)

### Harms:

#### PFME versus no treatment, placebo, or inactive control treatments:

Three RCTs identified by the review specifically reported adverse events and two did not report any in the PFME group. The adverse events reported by one RCT were pain when contracting pelvic muscles (1/33 [3%]), an uncomfortable feeling during exercise (3/33 [9%]), and difficulty in complying with treatment (2/33 [6%]).<sup>[27]</sup> The subsequent RCT did not report adverse events separately for each group.<sup>[10]</sup>

#### PFME versus vaginal cones:

Three RCTs identified by the review gave information on adverse events, all of which were in women using vaginal cones.<sup>[24]</sup> In one RCT (29 women), 14 women (48%) had difficulty using the cones and maintaining motivation for use, two (7%) had vaginitis, one (3%) had abdominal pain,

and one (3%) had bleeding. In the second RCT (30 women), five women (17%) said that cones produced an unpleasant feeling, three (10%) said that cones were time consuming, two (7%) said that cones were difficult to insert when anxious or in a hurry, two (7%) said that cones interfered with menstruation, and two (7%) suffered from muscle fatigue.

**PFME versus oestrogen supplements:**

The systematic review reported no information on harms. <sup>[25]</sup>

**PFME versus serotonin reuptake inhibitors:**

See harms of serotonin reuptake inhibitors, p 4 .

**PFME versus adrenoceptor agonists:**

See harms of adrenoceptor agonists, p 10 .

**Comment:** None

OPTION	VAGINAL CONES
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**Improvement of incontinence**

*Compared with no active treatment* Vaginal cones improve self-reported cure or improvement rates compared with no treatment or advice to use a continence guard over 6–12 months ( [high-quality evidence](#) ).

*Compared with pelvic floor muscle exercises* Vaginal cones are as effective as pelvic floor muscle exercises at improving or curing incontinence after 12 months (high-quality evidence)

*Compared with pelvic floor electrical stimulation* Vaginal cones are as effective as pelvic floor electrical stimulation at improving or curing incontinence (high-quality evidence)

**Incontinence frequency**

*Compared with no active treatment* Vaginal cones do not decrease the frequency of incontinence episodes compared with no active treatment (high-quality evidence)

*Compared with pelvic floor muscle exercises* Vaginal cones are less effective than pelvic floor muscle exercises at reducing the number of daily leakage episodes at 6 months ( [moderate-quality evidence](#) ).

*Compared with pelvic floor electrical stimulation* Vaginal cones seem to be as effective as pelvic floor electrical stimulation at preventing episodes of incontinence (moderate-quality evidence).

**Adverse effects**

The most common adverse effect associated with vaginal cones is difficulty maintaining motivation for use, but a small number of more serious events, such as vaginitis and abdominal pain, have been reported.

**Note**

We found no direct information about vaginal cones compared with oestrogen supplements in women with stress incontinence.

**For GRADE evaluation of interventions for stress incontinence, see table, p 26 .**

**Benefits:**

**Vaginal cones versus control:**

We found one systematic review (search date 2003, 2 RCTs, 252 women) comparing [vaginal cones](#) versus control (no treatment or advice to use a continence guard). <sup>[24]</sup> It found that vaginal cones significantly improved the self reported cure (failure to cure: 2 RCTs; 32/48 [67%] with vaginal cones v 98/121 [81%] with control; RR 0.74, 95% CI 0.59 to 0.93) and self reported improvement or cure rates (failure to improve or cure: 1 RCT; 10/27 [37%] with vaginal cones v 29/30 [97%] with no treatment; RR 0.38, 95% CI 0.23 to 0.63) over 6–12 months compared with control. It found no significant difference in the number of daily leakage episodes over 6–12 months between vaginal cones and control (mean daily leakage episodes: 1.17 with vaginal cones v 1.07 with control; P = 0.8).

**Vaginal cones versus pelvic floor muscle exercises:**

See benefits of pelvic floor muscle exercises, p 6 .

**Vaginal cones versus pelvic floor electrical stimulation:**

See benefits of pelvic floor electrical stimulation, p 4 .

**Vaginal cones versus oestrogen supplements:**

We found no systematic review or RCTs.

**Harms:****Vaginal cones versus control:**

The systematic review gave little information on adverse effects. <sup>[24]</sup> It gave some reasons for withdrawal from RCTs in women using vaginal cones, including motivation problems, unpleasant sensation, aesthetic dislike, discomfort, bleeding, and vaginal prolapse.

**Vaginal cones versus pelvic floor muscle exercises:**

See harms of pelvic floor muscle exercises, p 6 .

**Vaginal cones versus pelvic floor electrical stimulation:**

See harms of pelvic floor electrical stimulation, p 5 .

**Vaginal cones versus oestrogen supplements:**

We found no RCTs.

**Comment:**

None.

**OPTION****OESTROGEN SUPPLEMENTS****Improvement of incontinence**

*Compared with placebo* Short-term treatment with oestrogen supplements may improve cure or improvement rates compared with placebo (low-quality evidence).

*Compared with adrenoceptor agonists* Oestrogen supplements seem to be as effective as adrenoceptor agonists at improving or curing incontinence ( moderate-quality evidence ).

*Compared with pelvic floor muscle exercises* Oestrogen supplements are less likely than pelvic floor muscle exercises to improve or cure incontinence after 9 months (moderate-quality evidence).

*Compared with pelvic floor electrical stimulation* Oestrogen supplements seem to be as effective as pelvic floor electrical stimulation at improving or curing incontinence (moderate-quality evidence).

**Incontinence frequency**

*Compared with placebo* Oestrogen supplements seem to be no better than placebo at reducing frequency of incontinence episodes (moderate-quality evidence).

**Adverse effects**

There are concerns about the safety of long-term oestrogen use. Oral oestrogen supplements may increase the risk of strokes in postmenopausal women without a uterus at 6 years, and unopposed oestrogen has been associated with an increased risk of endometrial cancer in women with a uterus.

**Note**

We found no direct information about the effects of oestrogen supplements compared with vaginal cones in women with stress incontinence.

For GRADE evaluation of interventions for stress incontinence, see table, p 26 .

**Benefits:****Oestrogen supplements versus placebo:**

We found one systematic review (search date 2002, 15 RCTs, 718 women), which compared oestrogen supplementation versus placebo, <sup>[25]</sup> and one subsequent RCT. <sup>[28]</sup> The systematic review <sup>[25]</sup> included many small studies with different types of oestrogen, methods of administration, doses, treatment durations, and periods of follow up. It found that, in the short term, oestrogen supplements significantly improved cure or improvement rates compared with placebo at 11 weeks to 9 months (6 RCTs; 46/107 [43%] with oestrogen v 29/109 [27%] with placebo; RR 1.62, 95% CI 1.15 to 2.28). The review did not give information on whether the benefits of oestrogen treatment were sustained after treatment was stopped. The subsequent RCT (417 women) found that, in postmenopausal women with at least one weekly episode of incontinence, unopposed ultralow dose transdermal estradiol (0.014 mg/day) did not significantly worsen their incontinence frequency compared with placebo (10% worsening with estradiol v 9% worsening with placebo; OR 1.52, 95% CI 0.79 to 2.93). <sup>[28]</sup> Although this RCT commented on outcomes in 376 women at 2 years' follow up, the results are presented for only 40 women; therefore, the conclusions reached might have limited value. <sup>[28]</sup>

**Oestrogen supplements versus adrenoceptor agonists:**

See benefits of adrenoceptor agonists, p 9 .

**Oestrogen supplements versus pelvic floor muscle exercises:**

See benefits of pelvic floor muscle exercises, p 6 .

**Oestrogen supplements versus pelvic floor electrical stimulation:**

See [benefits of pelvic floor electrical stimulation, p 4](#) .

**Oestrogen supplements versus vaginal cones:**

We found no systematic review or RCTs comparing oestrogen supplements and [vaginal cones](#) .

**Harms:****Oestrogen supplements versus placebo:**

The review found that common adverse effects with oestrogen were vaginal bleeding (AR about 25%) and breast tenderness (AR about 20%).<sup>[25]</sup> There are concerns about the safety of long term oestrogen use. One RCT (10 739 healthy postmenopausal women without a uterus) found that, after an average follow up of 6.8 years, oestrogen increased the risk of stroke (HR 1.39, 95% CI 1.10 to 1.77), but not of breast cancer (HR 0.77, 95% CI 0.59 to 1.01), coronary heart disease (HR 0.91, 95% CI 0.75 to 1.12), or pulmonary embolism (HR 1.34, 95% CI 0.87 to 2.06).<sup>[29]</sup> One meta-analysis of observational studies found that unopposed oestrogens were associated with an increased risk of endometrial cancer (RR 2.3, 95% CI 2.1 to 2.5).<sup>[30]</sup> However, this meta-analysis should be interpreted with caution, because it is based on observational studies only, which might be subject to bias and confounding. It is not clear whether these harms are associated with short term oestrogen treatment. The subsequent RCT of unopposed ultralow dose transdermal estradiol (0.014 mg/day) compared with placebo in postmenopausal women over 2 years gave no information on adverse effects.<sup>[28]</sup>

**Oestrogen supplements versus adrenoceptor agonists:**

See [harms of adrenoceptor agonists, p 10](#) .

**Oestrogen supplements versus pelvic floor muscle exercises:**

See [harms of pelvic floor muscle exercises, p 6](#) .

**Oestrogen supplements versus pelvic floor electrical stimulation:**

See [harms of pelvic floor electrical stimulation, p 4](#) .

**Oestrogen supplements versus vaginal cones:**

We found no RCTs.

**Comment:**

None.

**OPTION****ADRENOCEPTOR AGONISTS****Improvement in incontinence**

*Compared with placebo* The effect of andrenoceptor agonists on incontinence compared with placebo is unclear ([low-quality evidence](#) )

*Compared with pelvic floor muscle exercises* The effect of adrenoceptor agonists on improvement or cure rates for incontinence compared with pelvic floor muscle exercises is unknown ([low-quality evidence](#))

*Compared with oestrogen supplements* Adrenoceptor agonists seem to be as effective as oestrogen supplements at improving or curing incontinence ( [moderate-quality evidence](#) )

**Adverse effects**

Phenylpropanolamine has been withdrawn from the US market because of an increased risk of haemorrhagic stroke.

**Note**

We found no direct information about the effects of adrenoceptor agonists compared with surgery.

For **GRADE** evaluation of interventions for stress incontinence, [see table, p 26](#) .

**Benefits:**

We found one systematic review (search date 2005) ( [see table 3, p 25](#) ).<sup>[31]</sup>

**Adrenoceptor agonists versus no treatment or placebo:**

The review identified four RCTs comparing adrenoceptor agonists with placebo. Pooled results for two RCTs found no significant difference in subjective cure or improvement rates between phenylpropanolamine and placebo. Two RCTs found that adrenoceptor agonists (midodrine or clenbuterol) significantly increased subjective cure or improvement rates compared with placebo ( [see table 3, p 25](#) ).<sup>[31]</sup>

**Adrenoceptor agonists versus non-surgical treatments:**

The systematic review identified two RCTs comparing adrenoceptor agonists versus non-surgical treatments.<sup>[31]</sup> The first RCT found that phenylpropanolamine significantly increased subjective

cure or improvement rates compared with [pelvic floor muscle exercises](#) . The second RCT found no significant difference in subjective cure or improvement rates between clenbuterol and pelvic floor muscle exercises ( [see table 3, p 25](#) ).<sup>[31]</sup>

**Adrenoceptor agonists versus oestrogen supplements:**

The review identified one RCT (20 women), which no significant difference in subjective cure or improvement rates between phenylpropanolamine and oestrogen (vaginal estriol) ( [see table 3, p 25](#) )<sup>[31]</sup>

**Adrenoceptor agonists versus surgical treatment:**

The review identified no RCTs.<sup>[31]</sup>

**Harms:**

Phenylpropanolamine has been withdrawn from the US market because of an increased risk of haemorrhagic stroke.<sup>[32]</sup>

**Adrenoceptor agonists versus placebo:**

The review found that there was a higher incidence of adverse events with adrenoceptor agonists compared with placebo (4 RCTs; adverse events: 22/77 [29%] with phenylpropanolamine v 13/78 [17%] with placebo, RR 1.72, 95% CI 0.92 to 3.20; 1 RCT: 16/26 [62%] with midodrine 10 mg v 8/24 [33%] with placebo, RR 1.85, 95% CI 0.97 to 3.51; 1 RCT: 13/82 [16%] with clenbuterol v 12/93 [13%] with placebo, RR 1.23, 95% CI 0.59 to 2.54; see comment below).<sup>[31]</sup> The most common adverse events were insomnia, restlessness, and vasomotor stimulation.<sup>[31]</sup>

**Adrenoceptor agonists versus non-surgical treatments:**

One RCT identified by the review found more adverse events with clenbuterol than with pelvic floor muscle exercises (adverse events: 2/15 [13%] with clenbuterol v 0/19 [0%] with pelvic floor muscle exercises; RR 6.25, 95% CI 0.32 to 121.14; see comment below).<sup>[31]</sup>

**Adrenoceptor agonists versus oestrogen supplements:**

The RCT identified by the review gave no information about harms.<sup>[31]</sup>

**Comment:**

The RCTs identified by the review might have been underpowered to detect a significant difference in harms. Clenbuterol has anabolic steroid properties and has not been approved by the US Food and Drug Administration.<sup>[33]</sup>

**QUESTION**

What are the effects of surgical treatments for women with stress incontinence?

**OPTION**

LAPAROSCOPIC COLPOSUSPENSION

**Improvement of incontinence**

*Compared with open retropubic colposuspension* The effects of laparoscopic colposuspension are unclear compared with open retropubic colposuspension ( [low-quality evidence](#) ).

*Compared with tension-free vaginal tape* Laparoscopic colposuspension may be less likely to improve objective measures of incontinence compared with tension-free vaginal tape at 18 months ( [moderate-quality evidence](#) )

**Note**

We found no direct information about whether laparoscopic colposuspension is better than no active treatment. We found no clinically important results about the effects of laparoscopic colposuspension compared with non-surgical treatment, anterior vaginal repair, suburethral slings, or needle suspension.

For GRADE evaluation of interventions for stress incontinence, [see table, p 26](#) .

**Benefits:**

**Laparoscopic colposuspension versus no treatment, sham treatment, or non-surgical treatment:**

We found one systematic review (search date 2006), which identified no RCTs.<sup>[34]</sup>

**Laparoscopic colposuspension versus anterior vaginal repair:**

[See benefits of anterior vaginal repair, p 18](#) .

**Laparoscopic colposuspension versus suburethral slings:**

[See benefits of suburethral slings, p 13](#) .

**Laparoscopic colposuspension versus open retropubic colposuspension:**

[See benefits of open retropubic colposuspension, p 11](#) .

**Laparoscopic colposuspension versus needle suspension:**

We found no RCTs.

**Laparoscopic colposuspension versus tension free vaginal tape:**

See [benefits of tension free vaginal tape, p 15](#) .

**Harms:****Laparoscopic colposuspension versus no treatment, sham treatment, surgery, or non-surgical treatments:**

We found no RCTs.

**Laparoscopic colposuspension versus anterior vaginal repair:**

See [harms of anterior vaginal repair, p 18](#) .

**Laparoscopic colposuspension versus suburethral slings:**

See [harms of suburethral sling, p 14](#) .

**Laparoscopic colposuspension versus open retropubic colposuspension:**

See [harms of open retropubic colposuspension, p 12](#) .

**Laparoscopic colposuspension versus tension free vaginal tape:**

See [harms of tension free vaginal tape, p 16](#) .

**Comment:**

None.

**OPTION****OPEN RETROPUBLIC COLPOSUSPENSION****Cure of incontinence**

*Compared with laparoscopic colposuspension* The effects of open colposuspension compared with laparoscopic colposuspension are unclear ( [low-quality evidence](#) ).

*Compared with pelvic floor muscle exercises or stimulation* Open retropubic colposuspension increases cure rates compared with pelvic floor muscle exercises or electrical stimulation ( [moderate-quality evidence](#) ).

*Compared with anterior vaginal repair* Open retropubic colposuspension is more likely to lead to cure of incontinence compared with anterior vaginal repair ( [high-quality evidence](#) ).

*Compared with suburethral slings* Open retropubic colposuspension is as effective as suburethral slings at curing incontinence ( [high-quality evidence](#) ).

*Compared with needle suspension* Open retropubic colposuspension is more likely to cure incontinence compared with needle suspension ( [moderate-quality evidence](#) ).

*Compared with tension-free vaginal tape* Open retropubic colposuspension may be as effective as tension-free vaginal tape at curing incontinence ( [very low-quality evidence](#) ).

**Adverse effects**

Open retropubic colposuspension is associated with more adverse effects than non-surgical treatment, but with fewer surgical complications than needle suspension. Open retropubic colposuspension is associated with a lower incidence of bladder perforation than tension-free vaginal tape, but a higher incidence of postoperative fever.

**Note**

We found no direct information about whether open retropubic colposuspension is better than no active treatment.

**For GRADE evaluation of interventions for stress incontinence, see [table, p 26](#) .**

**Benefits:****Open retropubic colposuspension versus no treatment or sham treatment:**

We found one systematic review (search date 2002), which identified no RCTs. <sup>[35]</sup>

**Open retropubic colposuspension versus non-surgical treatment:**

We found one systematic review (search date 2002, 2 RCTs, 120 women) comparing [open retropubic colposuspension](#) versus non-surgical treatments ( [pelvic floor muscle exercises](#) alone or pelvic floor muscle exercises plus [pelvic floor electrical stimulation](#) ). <sup>[35]</sup> It found that open retropubic colposuspension significantly improved self reported failure to cure (1 RCT; 3/16 [19%] with open retropubic colposuspension v 10/13 [77%] with conservative treatments; RR 0.24, 95% CI 0.08 to 0.71) and objective cure rates (1 RCT; 6/24 [25%] with open retropubic colposuspension v 42/44 [96%] with conservative treatments; RR 0.26, 95% CI 0.13 to 0.53) at 1 year compared with non-surgical treatment.

**Open retropubic colposuspension versus anterior vaginal repair:**

See [benefits of anterior vaginal repair, p 18](#) .

**Open retropubic colposuspension versus suburethral slings:**

See [benefits of suburethral slings, p 13](#) .

**Open retropubic colposuspension versus laparoscopic colposuspension:**

We found one systematic review (search date 2006, 9 RCTs, 564 women).<sup>[34]</sup> It found no significant difference between [laparoscopic colposuspension](#) and open retropubic colposuspension in self reported cure rates at 18 months (subjective cure rate: 6 RCTs; 352/456 [77%] with laparoscopic colposuspension v 375/459 [82%] with open retropubic colposuspension; RR 0.95, 95% CI 0.89 to 1.01).<sup>[34]</sup> The review also found that open retropubic colposuspension significantly increased objective cure rates at 18 months but found no significant difference in objective cure rates at 5 years (objective cure rate at 18 months: 8 RCTs; 378/487 [78%] with laparoscopic colposuspension v 423/492 [86%] with open retropubic colposuspension, RR 0.90, 95% CI 0.88 to 0.96; objective cure rate at 5 years: 2 RCTs; 111/148 [75%] with laparoscopic colposuspension v 105/142 [74%] with open retropubic colposuspension, RR 1.01, 95% CI 0.88 to 1.16).<sup>[34]</sup> We found three subsequent RCTs.<sup>[36]</sup> <sup>[37]</sup> <sup>[38]</sup> The first subsequent RCT (200 women with stress incontinence) found no significant difference between open colposuspension and laparoscopic colposuspension in objective cure rates at 24 months (82/117 [70%] with open colposuspension v 98/123 [80%] with laparoscopic colposuspension; OR 1.65, 95% CI 0.74 to 3.67).<sup>[36]</sup> The second subsequent RCT (60 women with stress incontinence) found that open Burch colposuspension significantly increased cure rate at 12 months compared with laparoscopic colposuspension (objective cure rate at 12 months: 30/33 [90%] with open colposuspension v 23/27 [85%] with laparoscopic colposuspension;  $p > 0.05$ ).<sup>[38]</sup> The third subsequent RCT (240 women with urodynamic stress incontinence) found that open colposuspension significantly reduced subjective stress incontinence symptoms at 24 months compared with laparoscopic colposuspension (proportion with occasional symptoms: 18/90 [20%] with open colposuspension v 24/77 [31%] with laparoscopic colposuspension;  $p = 0.38$ ).<sup>[37]</sup>

**Open retropubic colposuspension versus needle suspension:**

We found one systematic review (search date 2002, 7 RCTs, 570 women).<sup>[35]</sup> It found that open retropubic colposuspension significantly improved self reported and objective cure rates at 5 years compared with [needle suspension](#) (self reported failure to cure: 6 RCTs; 38/278 [14%] with open retropubic colposuspension v 66/291 [23%] with needle suspension, RR 0.56, 95% CI 0.39 to 0.81; objective failure to cure: 5 RCTs; 32/248 [13%] with open retropubic colposuspension v 57/271 [21%] with needle suspension, RR 0.59, 95% CI 0.40 to 0.88).<sup>[35]</sup>

**Open retropubic colposuspension versus tension free vaginal tape:**

See [benefits of tension free vaginal tape, p 15](#) .

**Harms:****Open retropubic colposuspension versus anterior vaginal repair:**

See [harms of anterior vaginal repair, p 18](#) .

**Open retropubic colposuspension versus non-surgical treatment:**

The review identified one RCT, which gave information on adverse effects.<sup>[35]</sup> It found that open retropubic colposuspension was associated with more adverse events than non-surgical treatments (pelvic floor muscle exercises alone or pelvic floor muscle exercises plus pelvic floor electrical stimulation). These included retropubic pain (1/16 [6%] with open retropubic colposuspension v 0/24 [0%] with non-surgical treatment; CI not reported), detrusor overactivity (1/16 [6%] with open retropubic colposuspension v 0/24 [0%] with non-surgical treatment; significance not reported), and persistent dyspareunia with loss of libido (1/16 [6%] with open retropubic colposuspension v 0/24 [0%] with non-surgical treatment; CI not reported).

**Open retropubic colposuspension versus suburethral slings:**

See [harms of suburethral slings, p 14](#) .

**Open retropubic colposuspension versus laparoscopic colposuspension:**

We found one systematic review (search date 2006, 9 RCTs, 564 women).<sup>[34]</sup> It found a significant increase in perioperative complications with open retropubic colposuspension compared with laparoscopic colposuspension (8 RCTs: 62/520 [12%] with laparoscopic colposuspension v 86/538 [16%] with open retropubic colposuspension; RR 0.54, 95% CI 0.54 to 0.97). The review gave no information on the nature or severity of perioperative complications. It found no significant difference in *de novo* detrusor overactivity between laparoscopic colposuspension and open retropubic colposuspension at 18 months (5 RCTs: 23/251 [9%] with laparoscopic colposuspension v 18/261 [7%] with open retropubic colposuspension; RR 1.29, 95% CI 0.72 to 2.30). One subsequent RCT<sup>[36]</sup> found that laparoscopic colposuspension was associated with more bladder injury (AR of bladder injury with laparoscopic colposuspension 4/144 [3%] versus 1/147 [1%] for open Burch colposus-

pension; p value not reported) and bowel injury (AR of bowel injury with laparoscopic colposuspension 1/144 [1%] versus 0/144 [0%] for open Burch colposuspension; p value not reported), whereas open Burch colposuspension was associated with more wound infections (AR of wound infections with open Burch colposuspension 11/147 [8%] versus 1/144 [1%] for laparoscopic colposuspension; p value not reported). Two further subsequent RCTs gave no information on adverse effects.<sup>[37]</sup><sup>[38]</sup>

#### Open retropubic colposuspension versus needle suspension:

We found one systematic review (search date 2002, 7 RCTs, 570 women).<sup>[35]</sup> It found that open retropubic colposuspension significantly reduced the risk of surgical complications compared with needle suspension (3 RCTs: 23/77 [30%] with open retropubic colposuspension v 36/75 [48%] with needle suspension; RR 0.66, 95% CI 0.46 to 0.94). The review gave no information on the nature or severity of surgical complications.<sup>[35]</sup>

#### Open retropubic colposuspension versus tension free vaginal tape:

See harms of tension free vaginal tape, p 16 .

**Comment:** The studies included in the systematic review comparing colposuspension versus needle suspension used weak methods.<sup>[35]</sup>

### OPTION SUBURETHRAL SLINGS OTHER THAN TENSION FREE VAGINAL TAPE AND TRANSOBTURATOR FORAMEN TAPES

#### Cure of incontinence

*Compared with open retropubic colposuspension* Suburethral slings are as effective as open retropubic colposuspension at curing incontinence ( [high-quality evidence](#) ).

*Compared with needle suspension* Suburethral slings seem to be as effective as needle suspension at curing incontinence after 1 year ( [moderate-quality evidence](#) ).

*Compared with tension-free vaginal tape* Suburethral slings may be as effective as tension-free vaginal tape at curing incontinence at 6 months ( [low-quality evidence](#) ).

#### Adverse effects

Suburethral slings may increase perioperative complications compared with needle suspension.

#### Note

We found no direct information about whether suburethral slings are better than no active treatment. We found no clinically important results about the effects of suburethral slings compared with non-surgical treatment, anterior vaginal repair, or laparoscopic colposuspension.

For GRADE evaluation of interventions for stress incontinence, [see table, p 26](#) .

**Benefits:** We found one systematic review (search date 2002; see comment below).<sup>[39]</sup>

#### Suburethral slings other than tension free vaginal tape versus no treatment, sham treatment, or non-surgical treatment:

We found one systematic review (search date 2002), which identified no RCTs.<sup>[39]</sup>

#### Suburethral slings other than tension free vaginal tape versus anterior vaginal repair:

We found one systematic review (search date 2002), which identified no RCTs.<sup>[39]</sup>

#### Suburethral slings other than tension free vaginal tape versus open retropubic colposuspension:

We found one systematic review (search date 2002, 5 RCTs, 206 women).<sup>[39]</sup> The systematic review did not perform a meta-analysis for [non-tension free vaginal tape](#) (TVT) [suburethral sling](#) procedures. None of the RCTs found a significant difference in outcome between non-TVT suburethral sling techniques and [open retropubic colposuspension](#) . The first RCT included in the review (30 women) found no significant difference between non-TVT suburethral slings (Teflon sling) and open retropubic colposuspension groups in cure rate at 4–6 months' follow up (15/15 [100%] participants cured in both groups; RR and CI not reported). The second RCT included in the review (72 women) found no significant difference between non-TVT suburethral slings (lyophilised dura mater) and open retropubic colposuspension in cure rate at up to 2 years (failure to cure: 3/36 [8%] with sling v 5/36 [14%] with colposuspension; RR 0.60, 95% CI 0.15 to 2.33). The third RCT included in the review (46 women) found no significant difference between suburethral slings (rectus fascial sling) and open retropubic colposuspension in cure rate (failure to cure: 1/17 [6%] with sling v 2/17 [12%] with colposuspension; RR 0.50, 95% CI 0.05 to 5.01). The fourth RCT included in the review

(22 women) found no significant difference between non-TVT suburethral slings (type not specified) and open retropubic colposuspension in cure rate at 6 months (failure to cure: 0/11 [0%] with sling v 2/9 [22%] with colposuspension; reported as not significant). The review reported the short term results of the fifth RCT (36 women),<sup>[39]</sup> and long term follow up was reported in a subsequent publication.<sup>[33]</sup> The RCT found no significant difference between non-TVT suburethral slings (polytetrafluoroethylene sling) and open retropubic colposuspension in cure rate at 3 months or 6 years (cure rate at 3 months: 100% with sling v 90% with colposuspension, P = 0.49; cure rate at 6 years: 100% with sling v 85% with colposuspension, P = 0.17).

#### **Suburethral slings other than TVT versus laparoscopic colposuspension:**

We found one systematic review (search date 2002), which found no RCTs comparing non-TVT slings versus [laparoscopic colposuspension](#).<sup>[39]</sup>

#### **Suburethral slings other than TVT versus needle suspension:**

We found one systematic review (search date 2002, 1 RCT, 20 women).<sup>[39]</sup> The RCT included in the review found no significant difference in cure rate at 1 year between non-TVT suburethral slings (porcine dermis sling) and [needle suspension](#) (failure to cure: 1/10 [10%] with suburethral slings v 3/10 [30%] with needle suspension; RR 0.33, 95% CI 0.04 to 2.69), but it might have lacked power to detect a clinically important difference.<sup>[39]</sup>

#### **Suburethral slings other than TVT versus TVT:**

See [benefits of tension free vaginal tape](#), p 15 .

### **Harms:**

#### **Suburethral slings other than TVT versus no treatment, sham treatment, or non-surgical treatment:**

We found no RCTs.

#### **Suburethral slings other than TVT versus anterior vaginal repair:**

We found no RCTs. An earlier systematic review (search date 1995) identified one retrospective study assessing complications after surgery.<sup>[40]</sup> It found that significantly more women had perioperative complications, including residual urine, urinary retention, and uterine prolapse, with non-TVT suburethral slings than with [anterior vaginal repair](#) (P < 0.01).<sup>[40]</sup>

#### **Suburethral slings other than TVT versus open retropubic colposuspension:**

One RCT included in the review found no significant difference in the incidence of perioperative complications between non-TVT suburethral slings and open retropubic colposuspension (3/36 [8%] with sling v 4/36 [11%] with colposuspension; RR 0.75, 95% CI 0.18 to 3.11).<sup>[39]</sup> Another RCT included in the review also found no significant difference in the incidence of perioperative complications between groups (0/17 [0%] with sling v 1/19 [5%] with colposuspension; difference reported as not significant). The same study found that the long term complications of non-TVT suburethral slings were partial sling erosion (2 people) and prolonged urinary retention (1 person).<sup>[41]</sup> In a third RCT included in the review, five people from both groups had late complications (including genital prolapse, detrusor instability, dyspareunia, and suprapubic pain).<sup>[39]</sup>

#### **Suburethral slings other than TVT versus laparoscopic colposuspension:**

We found no RCTs.

#### **Suburethral slings other than TVT versus needle suspension:**

The RCT included in the review found more complications with non-TVT slings than with needle suspension (bladder injury: 1/10 [10%] with sling v 2/10 [20%] with needle suspension; postoperative pyrexia: 8/10 [80%] with sling v 0/10 [0%] with needle suspension, P < 0.001; wound infection and urinary infection: 7/10 [70%] with sling v 0/10 [0%] with needle suspension, P < 0.001; pulmonary embolus: 1/10 [1%] with sling v 0/10 [0%] with needle suspension).<sup>[42]</sup>

#### **Suburethral slings other than TVT versus TVT:**

See [harms of tension free vaginal tape](#), p 16 .

### **Comment:**

After the date of the *BMJ Clinical Evidence* search, the systematic review<sup>[39]</sup> was amended, and the amended version only assesses traditional types of sling.

## **OPTION**

## **TENSION FREE VAGINAL TAPE**

### **Improvement of incontinence**

*Compared with laparoscopic colposuspension* Tension-free vaginal tape may be more likely to improve objective measures of incontinence compared with laparoscopic colposuspension at 18 months ( [moderate-quality evidence](#) ).

*Compared with open retropubic colposuspension* Tension-free vaginal tape may be as effective as open retropubic colposuspension at curing incontinence at up to 2 years ( [very low-quality evidence](#) ).

*Compared with suburethral slings* Tension-free vaginal tape may be as effective as other types of suburethral slings at curing incontinence at 6 months ( [low-quality evidence](#) ).

*Compared with transobturator foramen procedures* Tension-free vaginal tape seems to be as effective as transobturator foramen procedures at curing incontinence at 12 months (moderate-quality evidence).

### Adverse effects

Tension-free vaginal tape is associated with a higher incidence of bladder perforation, but a lower incidence of postoperative fever compared with open retropubic colposuspension. The risks of perioperative complications and *de novo* detrusor overactivity seem to be similar between tension-free vaginal tape and laparoscopic colposuspension.

### Note

We found no direct information about whether or not tension-free vaginal tape is better than no active treatment. We found no clinically important results about the effects of tension-free vaginal tape compared with non-surgical treatment, anterior vaginal repair, or needle suspension.

For GRADE evaluation of interventions for stress incontinence, [see table, p 26](#) .

**Benefits:** **Tension free vaginal tape versus no treatment, sham treatment, or non-surgical treatment:**  
We found no RCTs.

**Tension free vaginal tape versus anterior vaginal repair:**  
We found no RCTs.

**Tension free vaginal tape versus other types of suburethral slings:**  
We found one systematic review (search date 2002), which found no RCTs, <sup>[43]</sup> and one subsequent RCT. <sup>[44]</sup> The subsequent RCT (53 women) found similar subjective cure rates between [tension free vaginal tape](#) (TVT) and autologous fascial sling at 6 months (26/28 [93%] with TVT v 23/25 [92%] with autologous fascial sling; P value not reported). <sup>[44]</sup> The size of the study was small, so the possibility that a small difference in cure rates could remain undetected could not be excluded.

**TVT versus open retropubic colposuspension:**  
We found one systematic review (search date 2002, 2 RCTs). <sup>[43]</sup> The first RCT (344 women) identified by the review found no significant difference between TVT and [open retropubic colposuspension](#) in cure rates at 6 months (AR for subjective cure: 103/159 [65%] with TVT v 90/127 [71%] with open retropubic colposuspension, RR 0.91, 95% CI 0.78 to 1.07; AR for objective cure: 128/156 [82%] with TVT v 109/131 [83%] with open retropubic colposuspension, RR 0.99, 95% CI 0.89 to 1.10; analysis not by intention to treat). <sup>[43]</sup> However, the RCT was weakened by differential withdrawal from the two groups after randomisation (5 in the TVT group v 23 in open retropubic colposuspension group). <sup>[43]</sup> At later stages of the trial, the number of women withdrawing was similar in both groups. The reasons for the differential withdrawals were not reported. In addition, the trial was smaller than planned, so the non-significant result cannot exclude the possibility of a difference in cure rates of less than 10% between the groups. An update of this RCT, published after 2 years' follow up, found no significant difference in cure rates of stress incontinence defined by a negative 1 hour [pad test](#) (AR of cure: 117/137 [85%] with TVT v 86/108 [80%] with colposuspension; RR 1.09, 95% CI 0.59 to 2.09). <sup>[45]</sup> Although 233/344 (68%) women completed the 1 hour pad test at 2 years' follow up, the RCT reported on 245/344 (71%) women. This analysis has been weakened by this high withdrawal rate (32.7%). As in the 6 month analysis, the non-significant result cannot exclude the possibility of a difference in cure rates of less than 10% between the groups. <sup>[45]</sup> The second RCT (quasi-randomised, 71 women) identified by the review found no significant difference in cure rate between TVT and open retropubic colposuspension at 24 months (AR: 30/36 [83%] with TVT v 30/35 [86%] with open retropubic colposuspension; P value reported as not significant). <sup>[43]</sup> It also found that return to normal activities was significantly shorter with TVT than with open retropubic colposuspension (10 days with TVT v 21 days with open retropubic colposuspension; P < 0.05). Participants in the RCT were allocated into groups alternately, rather than by true randomisation. <sup>[46]</sup> The review identified two further RCTs, which did not assess cure rates. <sup>[43]</sup>

**TVT versus laparoscopic colposuspension:**  
We found one systematic review (search date 2006, 8 RCTs). <sup>[34]</sup> It found no significant difference between [laparoscopic colposuspension](#) and TVT in self reported cure rates at 18 months (subjective cure rate: 5 RCTs; 121/172 [70%] with laparoscopic colposuspension v 158/205 [77%] with TVT; RR 0.91, 95% CI 0.80 to 1.02). The review found that laparoscopic colposuspension significantly decreased objective cure rates at 18 months, either with sutures (163/196 [83%] with laparoscopic

colposuspension using sutures v 179/198 [90%] with TVT; RR 0.91, 95% CI 0.80 to 1.02) or with mesh (29/51 [57%] with laparoscopic colposuspension using mesh v 60/70 [86%] with TVT; RR 0.66, 95% CI 0.51 to 0.86).<sup>[34]</sup>

#### **TVT versus needle suspension:**

One systematic review (search date 2002) found no RCTs.<sup>[43]</sup> We found no subsequent RCTs.

#### **TVT versus transobturator foramen procedures:**

See [benefits of transobturator foramen procedures, p 17](#) .

### **Harms:**

#### **TVT versus no treatment, sham treatment, or non-surgical treatment:**

We found no RCTs.

#### **TVT versus anterior vaginal repair:**

We found no RCTs.

#### **TVT versus other types of suburethral slings:**

The review reported that the principal operative complication with TVT was bladder perforation.<sup>[43]</sup>

The subsequent RCT found similar rates of adverse effects (*de novo* detrusor overactivity: 0/28 [0%] with TVT v 1/25 [4%] with [suburethral slings](#) , P value not reported; wound pain: 2/28 [7%] with TVT v 7/25 [28%] with suburethral slings, P value not reported).<sup>[44]</sup>

#### **TVT versus open retropubic colposuspension:**

The first RCT identified by the systematic review found that bladder perforation was significantly more common with TVT, whereas postoperative fever was significantly less common with TVT than with open retropubic colposuspension (AR for bladder perforation: 15/170 [9%] with TVT v 3/146 [2%] with open retropubic colposuspension, RR 4.29, 95% CI 1.27 to 14.54; AR for fever: 1/170 [1%] with TVT v 7/146 [5%] with open retropubic colposuspension, P = 0.03).<sup>[43]</sup> It found no significant difference between groups in the incidence of postoperative urinary tract infection (UTI) or wound infection (AR for UTI in the first 6 weeks after operation: 38/170 [22%] with TVT v 46/146 [32%] with open retropubic colposuspension, P = 0.07; wound infection: 4/170 [2%] with TVT v 10/146 [7%] with open retropubic colposuspension, P = 0.06). The second RCT identified by the review<sup>[43]</sup> found that bladder perforation and postoperative UTI were more common with TVT, whereas haematoma was more common with open retropubic colposuspension (AR for bladder perforation: 4/36 [11%] with TVT v 0/35 [0%] with open retropubic colposuspension; UTI: 5/36 [14%] with TVT v 2/35 [6%] with open retropubic colposuspension; haematoma: 0/36 [0%] with TVT v 2/36 [6%] with open retropubic colposuspension; P values not reported). It found no significant difference between groups in the proportion of women with new detrusor overactivity at 6 months (3/36 [8%] with TVT v 5/35 [14%] with open retropubic colposuspension; RR 1.17, 95% CI 0.39 to 3.48).

#### **TVT versus laparoscopic colposuspension:**

We found one systematic review (search date 2006, 8 RCTs).<sup>[34]</sup> It found no significant difference in perioperative complications between laparoscopic colposuspension and TVT (16/170 [9%] with laparoscopic colposuspension v 19/180 [11%] with TVT; RR 0.88, 95% CI 0.48 to 1.60). The review gave no information on the nature or severity of perioperative complications. It also found no significant difference in *de novo* detrusor overactivity between laparoscopic colposuspension and TVT (8/165 [5%] with laparoscopic colposuspension v 10/161 [6%] with TVT; RR 0.80, 95% CI 0.34 to 1.88).

#### **TVT versus needle suspension:**

We found no RCTs.

#### **TVT versus transobturator foramen procedures:**

See [harms of transobturator foramen procedures, p 17](#) .

#### **Observational data:**

Observational reports found that complications associated with TVT include death (10 deaths associated with TVT ;<sup>[47]</sup> from unrecognised bowel perforation in 8/10 [80%] cases and haemorrhagic complications in 2/10 [20%] cases). Case reports of serious complications included bowel injuries,<sup>[48] [49] [50] [51] [52] [53] [54] [55]</sup> necrotizing fasciitis,<sup>[56] [57]</sup> Fournier's gangrene,<sup>[58]</sup> urethrovaginal fistula,<sup>[59]</sup> and nerve injuries,<sup>[48] [56]</sup> which might cause problems even after removal of the TVT. The most common complications were urethral injuries during surgery, and urethral erosion up to 5 years later.<sup>[48]</sup> TVT might eventually erode into the bladder,<sup>[48] [60] [61]</sup> which might require surgical opening of the bladder to rectify. Other surgical complications reported in prospective and retrospective cohort studies include bladder perforation, injury to iliac vessels, bleeding, urinary

tract infection, retropubic haematoma, and vaginal tape erosion ( see table 4, p 25 ).<sup>[62] [63] [64] [65] [66] [67] [68]</sup>

**Comment:** TVT has been separated from traditional suburethral sling operations and **transobturator foramen procedures** because the operative procedure is substantially different.

## OPTION TRANSOBTURATOR FORAMEN PROCEDURES (TOT)

### Cure of incontinence

*Compared with tension-free vaginal tape* Transobturator foramen procedures seem to be as effective as tension-free vaginal tape at curing incontinence at 12 months ( **moderate-quality evidence** ).

### Note

We found no direct information about whether transobturator foramen procedures are better than no active treatment. We found no clinically important results about the effects of transobturator foramen procedures compared with non-surgical treatment, anterior vaginal repair, non-tension-free vaginal tape, suburethral slings, open retropubic colposuspension, laparoscopic colposuspension, or needle suspension.

**For GRADE evaluation of interventions for stress incontinence, see table, p 26 .**

**Benefits:** We found no systematic review.

**Transobturator foramen procedures versus no treatment or sham treatment:**  
We found no RCTs.

### Transobturator foramen procedures versus tension free vaginal tape:

We found one RCT.<sup>[69]</sup> The RCT (110 women) found no significant difference in cure rates between **transobturator foramen (TOT) procedures** and **tension free vaginal tape** (TVT) at 12 months (45/53 [85%] with TOT v 45/52 [87%] with TVT; P > 0.05.)<sup>[69]</sup> **TOT procedures versus other treatments.** We found no RCTs.

### Harms: TOT procedures versus TVT:

The RCT reported higher intraoperative complication rates for TVT and TOT (haemorrhage: 3/52 [6%] with TVT v 0/53 [0%] with TOT) but similar postoperative complication rates at 2 days (urinary retention: 4/52 [8%] with TVT v 3/53 [6%] with TOT; *de novo* urgency: 5/52 [10%] with TVT v 6/53 [11%] with TOT; urethral erosion: 1/52 [2%] with TVT v 1/53 [2%] with TOT).<sup>[69]</sup>

### Observational data:

Case reports found that TOT was associated with retropubic haematoma,<sup>[70]</sup> vulvar haematoma,<sup>[71]</sup> urethral erosion and infected obturator haematoma,<sup>[72]</sup> tape erosion into the vagina<sup>[73] [74]</sup> accompanied by ischiorectal abscess<sup>[75]</sup> or infected mesh and severe leg pain,<sup>[76]</sup> bladder erosion,<sup>[77]</sup> perineal cellulitis,<sup>[78]</sup> and large abscesses of the thigh<sup>[79]</sup> and psoas muscle.<sup>[80]</sup>

**Comment:** TOT has been separated from traditional suburethral sling operations and TVT because the operative procedure is substantially different. We also found another RCT comparing TOT versus TVT,<sup>[81]</sup> which was subsequently retracted<sup>[82]</sup> and has not therefore been included in this review.

## OPTION ANTERIOR VAGINAL REPAIR (ANTERIOR COLPORRHAPHY)

### Cure of incontinence

*Compared with open retropubic colposuspension* Anterior vaginal repair is less effective at leading to cure of incontinence compared with open retropubic colposuspension at up to 5 years ( **high-quality evidence** ).

*Compared with pelvic floor muscle exercises* The effects of anterior vaginal repair compared with pelvic floor muscle exercises are unclear ( **low-quality evidence** ).

*Compared with needle suspension* Anterior vaginal repair is as effective as needle suspension in curing incontinence at 12 months (high-quality evidence).

### Adverse effects

Overall operative complications are similar between anterior vaginal repair and open retropubic colposuspension.

### Note

We found no direct information about whether anterior vaginal repair is better than no active treatment. We found no clinically important results about the effects of anterior vaginal repair compared with suburethral slings, laparoscopic colposuspension, or tension-free vaginal tape.

For GRADE evaluation of interventions for stress incontinence, see table, p 26 .

**Benefits:** We found one systematic review (search date 2004) on [anterior vaginal repair](#) .<sup>[83]</sup>

**Anterior vaginal repair versus no treatment or sham treatment:**

The review identified no RCTs.<sup>[83]</sup>

**Anterior vaginal repair versus non-surgical treatment:**

The review identified one RCT (50 women), which compared anterior vaginal repair versus [pelvic floor muscle exercises](#) . Only 16 women were suitable for anterior vaginal repair (7 received anterior repair and 9 received pelvic floor muscle exercises), so no reliable conclusions could be drawn.<sup>[83]</sup>

**Anterior vaginal repair versus suburethral slings:**

The review identified no RCTs comparing anterior vaginal repair and [suburethral slings](#) .<sup>[83]</sup>

**Anterior vaginal repair versus open retropubic colposuspension:**

The review identified eight RCTs (929 women).<sup>[83]</sup> It found that anterior vaginal repair was significantly less effective than [open retropubic colposuspension](#) in increasing cure rates at 12 months or 5 years (failure to cure at 12 months: 82/279 [29%] with anterior repair v 50/346 [15%] with open retropubic colposuspension, RR 1.89, 95% CI 1.39 to 2.59; failure to cure at 5 years: 49/128 [38%] with anterior repair v 31/145 [21%] with open retropubic colposuspension, RR 2.02, 95% CI 1.36 to 3.01; see comment below).

**Anterior vaginal repair versus laparoscopic colposuspension:**

The review identified no RCTs comparing anterior vaginal repair and [laparoscopic colposuspension](#) .<sup>[83]</sup>

**Anterior vaginal repair versus needle suspension:**

The review identified two RCTs (469 women).<sup>[83]</sup> It found no significant difference between anterior vaginal repair and [needle suspension](#) in cure rates at 12 months (failure to cure: 33/134 [25%] with anterior vaginal repair v 31/132 [24%] with needle suspension; RR 1.05, 95% CI 0.69 to 1.59).

**Anterior vaginal repair versus tension free vaginal tape:**

We found no RCTs comparing anterior vaginal repair versus [tension free vaginal tape](#) .

**Harms:**

**Anterior vaginal repair versus no treatment or sham treatment:**

We found no RCTs.

**Anterior vaginal repair versus non-surgical treatment:**

The RCT identified by the review gave no information on harms.<sup>[83]</sup>

**Anterior vaginal repair versus suburethral slings:**

We found no RCTs.

**Anterior vaginal repair versus open retropubic colposuspension:**

One RCT identified by the review reported more positive urine cultures after anterior vaginal repair than after open retropubic colposuspension. Another RCT identified by the review found one bladder perforation in the open retropubic colposuspension group. A third RCT identified by the review reported more intraoperative complications in women receiving open retropubic colposuspension, but more postoperative pyrexia and bleeding in women receiving anterior vaginal repair. It found no significant difference in overall operative complications between anterior vaginal repair and open retropubic colposuspension (14/73 [19%] with anterior repair v 12/91 [13%] with open retropubic colposuspension; RR 1.57, 95% CI 0.84 to 2.95).<sup>[83]</sup>

**Anterior vaginal repair versus laparoscopic colposuspension:**

We found no RCTs.

**Anterior vaginal repair versus needle suspension:**

The systematic review gave no information on adverse effects.<sup>[83]</sup> An earlier systematic review (search date 1995) found one non-randomised study assessing complications after surgery.<sup>[40]</sup> The review reported that anterior vaginal repair caused fewer major complications than needle suspension (no further data reported).<sup>[40]</sup>

**Anterior vaginal repair versus tension free vaginal tape:**

We found no RCTs.

**Comment:** **Long term adverse effects:**  
None of the RCTs we found assessed longer term complications associated with surgery for stress incontinence, such as voiding dysfunction, new onset overactive bladder or [urge incontinence](#), and development of prolapse.

OPTION	NEEDLE SUSPENSION
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**Cure of incontinence**

*Compared with open retropubic colposuspension* Needle suspension is less likely to cure incontinence compared with open retropubic colposuspension at 5 years ( [moderate-quality evidence](#) ).

*Compared with suburethral slings* Needle suspension seems to be as effective as suburethral slings at curing incontinence after 1 year (moderate-quality evidence).

*Compared with anterior vaginal repair* Needle suspension is as effective as anterior vaginal repair in curing incontinence at 12 months ( [high-quality evidence](#) ).

**Adverse effects**

Needle suspension is associated with fewer perioperative complications than suburethral slings, but with more surgical complications than open retropubic colposuspension.

**Note**

We found no direct information about whether needle suspension is better than no active treatment. We found no clinically important results about the effect of needle suspension compared with non-surgical treatment, tension-free vaginal tape, or laparoscopic colposuspension.

**For GRADE evaluation of interventions for stress incontinence, [see table, p 26](#) .**

**Benefits:** **Needle suspension versus no treatment, sham treatment, or non-surgical treatment:**  
We found one systematic review (search date 2003), which found no RCTs. <sup>[84]</sup>

**Needle suspension versus anterior vaginal repair:**  
[See benefits of anterior vaginal repair, p 18](#) .

**Needle suspension versus suburethral slings:**  
[See benefits of suburethral slings, p 13](#) .

**Needle suspension versus open retropubic colposuspension:**  
[See benefits of open retropubic colposuspension, p 11](#) .

**Needle suspension versus laparoscopic colposuspension:**  
[See benefits of laparoscopic colposuspension, p 10](#) .

**Needle suspension versus tension free vaginal tape:**  
[See benefits of tension free vaginal tape, p 15](#) .

**Harms:** **Needle suspension versus no treatment, sham treatment, or non-surgical treatment:**  
We found no RCTs.

**Needle suspension versus anterior vaginal repair:**  
[See harms of anterior vaginal repair, p 18](#) .

**Needle suspension versus suburethral slings:**  
[See harms of suburethral sling, p 14](#) .

**Needle suspension versus open retropubic colposuspension:**  
[See harms of open retropubic colposuspension, p 12](#) .

**Needle suspension versus laparoscopic colposuspension:**  
[See harms of laparoscopic colposuspension, p 11](#) .

**Needle suspension versus tension free vaginal tape:**  
[See harms of tension free vaginal tape, p 16](#) .

**Comment:** None.

## GLOSSARY

**Anterior vaginal repair (anterior colporrhaphy)** The vaginal mucosa below the urethra is dissected, ending just in front of the cervix. Sutures are placed in the periurethral tissue and the pubocervical fascia to support and elevate the bladder neck. Excess vaginal tissue is removed and then the dissected area is closed. The operation can be performed under general, regional, or local anaesthetic.

**Laparoscopic colposuspension** An endoscope is inserted into or through the abdominal wall to view abdominal and pelvic organs. Sutures are inserted into the paravaginal tissues on either side of the bladder neck and then attached to the ileopectineal ligaments on the same side. The operation is performed under general anaesthetic.

**Needle suspension** To support the bladder neck, a needle threads sutures from the vagina to the anterior abdominal fascia through the paraurethral tissue of the bladder neck. The operation is performed under general or regional anaesthetic.

**Open retropubic colposuspension** Involves lifting the tissues near the bladder neck and proximal urethra in the area of the pelvis behind the anterior pubic bones through an incision over the lower abdomen. The operation is performed under general or regional anaesthetic.

**Pad test** After the placement of a preweighed sanitary pad, the woman is asked to exercise. The pad is then reweighed to determine the amount of urine loss.

**Pelvic floor electrical stimulation** A recurrent electrical pulse is delivered by vaginal probe to stimulate pelvic floor muscle contractions.

**Pelvic floor muscle exercises** Repetitive contraction exercises designed to strengthen the pelvic floor muscles, based on the rationale that a strong, fast pelvic floor muscle contraction will clamp the urethra, thus increasing the intraurethral pressure, preventing leakage during abrupt increases in intra-abdominal pressure.

**Pelvic floor muscle training (PFMT)** the subject is instructed to cross her legs at the ankles, with her knees and hips flexed, while sitting or supine, and to abduct the hips, holding the contraction for 6–8 seconds while the therapist palpates the hip abductors and abdominal muscles and confirms that the abductors are contracted without dominant contractions of the abdominal muscles. Once proper contractions are confirmed, the subject receives written instructions and a training log. Three sets of 10 long and two sets of 10 rapid contractions 4 days a week are recommended.

**Suburethral slings** Strips of material are tunnelled under the urethra, attached either to the rectus muscle or the ileopectineal ligaments, resulting in a tightening of the sling and increased bladder support every time the woman contracts her rectus muscles. The operation is performed under general or regional anaesthetic.

**Tension free vaginal tape (TVT)** A minimal access surgical sling procedure, in which a tape is passed beneath the urethra, aiming to restore the urethra to its normal position. The TVT is placed with minimal tension, and support is thought to be achieved by causing a tissue reaction with a subsequent collagen scar. The operation is performed under general or regional anaesthetic.

**Transobturator foramen (TOT) procedures** These procedures use tape similar to tension-free vaginal tape, but the tape is inserted differently. Although it avoids the space behind the pubic bone (the retropubic space), the tape is positioned without tension beneath the urethra, in order to maintain its correct position.

**Urge incontinence** Urge incontinence is typically caused by a spontaneous or inappropriately provoked involuntary bladder contraction (detrusor instability). Urge incontinence, unlike stress incontinence, is associated with a feeling of needing to void. It can exist alone, or more commonly as mixed urinary incontinence, when it is combined with stress incontinence.

**Vaginal cones** A woman inserts a weighted cone into the vagina. When she can successfully retain that cone while standing, moving around, and coughing, she will move onto the next heaviest cone, and so on.

**High-quality evidence** Further research is very unlikely to change our confidence in the estimate of effect

**Low-quality evidence** Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.

**Moderate-quality evidence** Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.

**Very low-quality evidence** Any estimate of effect is very uncertain.

## SUBSTANTIVE CHANGES

**Oestrogen supplements** One subsequent RCT added. <sup>[28]</sup> Benefits and harms sections enhanced; categorisation unchanged (Trade off between benefits and harms).

**Open retropubic colposuspension** One systematic review updated <sup>[34]</sup> and three subsequent RCTs added. <sup>[36]</sup> <sup>[37]</sup> <sup>[39]</sup> Benefits and harms sections enhanced; categorisation unchanged (Beneficial).

**Pelvic floor muscle exercises** One systematic review updated. <sup>[27]</sup> Benefits and harms sections enhanced; categorisation unchanged (Likely to be beneficial).

**Serotonin reuptake inhibitors (duloxetine)** One subsequent RCT added. <sup>[11]</sup> Benefits and harms sections enhanced; categorisation unchanged (Beneficial).

**Tension free vaginal tape** One systematic review updated <sup>[34]</sup> and one case report added. <sup>[59]</sup> Benefits and harms section enhanced; categorisation unchanged (Trade off between benefits and harms).

**Transobturator foramen procedures** Seven observational studies added. <sup>[71]</sup> <sup>[74]</sup> <sup>[75]</sup> <sup>[76]</sup> <sup>[77]</sup> <sup>[79]</sup> <sup>[80]</sup> Harms section enhanced; categorisation unchanged (Unknown effectiveness).

## REFERENCES

1. Abrams P, Cardozo L, Fall M, et al. The standardisation of terminology in lower urinary tract function. *Neurourol Urodyn* 2002;21:167–178. [PubMed]
2. Garnett S, Abrams P. The role of urodynamics. In: MacLean A, Cardoso L, eds. *Incontinence in women*. London: RCOG Press, 2002: 61–72.

3. Jolleys JV. Reported prevalence of urinary incontinence in women in a general practice. *BMJ* 1988;296:1300–1302. [PubMed]
4. Rortveit G, Daltveit AK, Hannestad YS, et al; Norwegian EPINCONT Study. Urinary incontinence after vaginal delivery or cesarean section. *N Engl J Med* 2003;348:900–907. [PubMed]
5. Wilson PD, Herbison RM, Herbison GP. Obstetric practice and the prevalence of urinary incontinence three months after delivery. *Br J Obstet Gynaecol* 1996;103:154–161. [PubMed]
6. Bump RC, Sugerman HJ, Fantl JA, et al. Obesity and lower urinary tract function in women: effect of surgically induced weight loss. *Am J Obstet Gynecol* 1992;167:392–397. [PubMed]
7. Bump RC, McClish DK. Cigarette smoking and urinary incontinence in women. *Am J Obstet Gynecol* 1992;167:1213–1218. [PubMed]
8. Mariappan P, Ballantyne Z, N'Dow JMO, et al. Serotonin and noradrenaline re-uptake inhibitors (SNRI) for stress urinary incontinence in adults. In: The Cochrane Library: Issue 3, 2005. Chichester, UK: John Wiley & Sons, Ltd. Search date 2005; primary sources Cochrane Incontinence Group specialised register, Medline, Premedline, and the reference lists of relevant articles.
9. Van Leeuwen JH, Freeman R, Ghoniem G, et al. Controlled trial of duloxetine alone, pelvic floor muscle training alone, combination treatment, and no treatment in women with stress urinary incontinence (SUI). 19th Congress of the European Association of Urology, Istanbul, Turkey, 2004.
10. Ghoniem GM, Van Leeuwen JS, Elser DM, et al. A randomized controlled trial of duloxetine alone, pelvic floor muscle training alone, combined treatment and no active treatment in women with stress urinary incontinence. *J Urol* 2005;173:1647–1653. [PubMed]
11. Mah SY, Lee KS, Choo MS. Duloxetine versus placebo for the treatment of Korean women with stress predominant urinary incontinence. *Korean J Urol* 2006;47:527–535.
12. Cardozo I, Drutz HP, Baygani SK, et al. Pharmacological treatment of women awaiting surgery for stress urinary incontinence. *Obstet Gynecol* 2004;104:511–519. [PubMed]
13. Norton PA, Zinner NR, Yalcin I, et al. Duloxetine versus placebo in the treatment of stress urinary incontinence. *Am J Obstet Gynecol* 2002;187:40–48. [PubMed]
14. Dmochowski RR, Miklos JR, Norton PA, et al. Duloxetine versus placebo for the treatment of North American women with stress urinary incontinence. *J Urol* 2003;170:1259–1263. [Erratum in: *J Urol* 2004;171:360] [PubMed]
15. van Kerrebroeck P, Abrams P, Lange R, et al. Duloxetine versus placebo in the treatment of European and Canadian women with stress urinary incontinence. *BJOG* 2004;111:249–257. [PubMed]
16. Millard RJ, Moore K, Rencken R, et al. Duloxetine vs placebo in the treatment of stress urinary incontinence: a four-continent randomized clinical trial. *BJU Int* 2004;93:311–318. [PubMed]
17. Kinchen KS, Obenchain R, Swindle R. Impact of duloxetine on quality of life for women with symptoms of urinary incontinence. *Int Urogynecol J Pelvic Floor Dysfunct* 2005;16:337–344. [PubMed]
18. Berghmans LCM, Hendriks HJM, Bo K, et al. Conservative treatment of stress urinary incontinence in women: a systematic review of randomized clinical trials. *Br J Urol* 1998;82:181–191. Search date 1998; primary sources Medline, Excerpta Medica, database of the Dutch National Institute of Allied Health Professions, database of the Cochrane Field in Therapies and Rehabilitation, and hand searches of references. [PubMed]
19. Brubaker L, Benson JT, Bent A, et al. Transvaginal electrical stimulation for female urinary incontinence. *Am J Obstet Gynecol* 1997;177:536–540. [PubMed]
20. Yamanishi R, Yasuda K, Sakakibara R, et al. Pelvic floor electrical stimulation in the treatment of stress incontinence: an investigation study and a placebo controlled double-blind trial. *J Urol* 1997;158:2127–2131. [PubMed]
21. Preisinger E, Hofbauer J, Nurnberger N, et al. Possibilities of physiotherapy for urinary stress incontinence. *Z Phys Med Bain Med Klim* 1990;19:75–79.
22. Sung MS, Choi YH, Back SH, et al. The effect of pelvic floor muscle exercises on genuine stress incontinence among Korean women – focusing on its effects on the quality of life. *Yonsei Med J* 2000;41:237–251. [PubMed]
23. Jeyaseelan SM, Haslam EJ, Winstanley J, et al. An evaluation of a new pattern of electrical stimulation as a treatment for urinary stress incontinence: a randomized, double-blind, controlled trial. *Clin Rehabil* 2000;14:631–640. [PubMed]
24. Herbison P, Plevnik S, Mantle J. Weighted vaginal cones for urinary incontinence. In: The Cochrane Library: Issue 1, 2002. Oxford, UK: Update Software. Search date 2003; primary sources Cochrane Incontinence Group specialised register, Medline, Cinahl, and reference lists of relevant articles.
25. Moehrer B, Hextall A, Jackson S. Oestrogens for urinary incontinence in women. In: The Cochrane Library: Issue 1, 2002. Oxford, UK: Update Software. Search date 2002; primary sources Cochrane Incontinence Group specialised register, Medline, Cinahl, Cochrane Controlled Trials Register, and hand searches of journals.
26. Bo K, Talseth R, Holme I. Single blind, randomised controlled trial of pelvic floor exercises, electrical stimulation, vaginal cones, and no treatment in management of genuine stress incontinence in women. *BMJ* 1999;318:487–493. [PubMed]
27. Hay-Smith EJC, Dumoulin C. Pelvic floor muscle training versus no treatment, or inactive control treatments, for urinary incontinence in women. Cochrane Database of Systematic Reviews: Issue 1, 2006.
28. Waetjen LE, Brown JS, Vittinghoff E, et al. The effect of ultralow-dose transdermal estradiol on urinary incontinence in postmenopausal women. *Obstet Gynecol* 2005;106:946–952. [PubMed]
29. WHI Steering Committee. Effects of conjugated equine estrogens in postmenopausal women with hysterectomy. *JAMA* 2004;291:1701–1712. [PubMed]
30. Grady D, Gebretsadik T, Kerlikowske K, et al. Hormone replacement therapy and endometrial cancer: a meta-analysis. *Obstet Gynecol* 1995;85:304–313. [PubMed]
31. Alhasso A, Glazener CMA, Pickard R, et al. Adrenergic drugs for urinary incontinence in adults. In: The Cochrane Library: Issue 3, 2005; date of most recent substantive amendment: 25 May 2005. Oxford, UK: Update Software. Search date 2002; primary sources Cochrane Incontinence Group specialised register, Medline, Cinahl, and reference lists of relevant articles.
32. US Food and Drug Administration website. Phenylpropranolamine information page. <http://www.fda.gov/cder/drug/infopage/ppa/default.htm> > (last accessed 18 May 2005).
33. Holroyd-Leduc JM, Straus SE. Management of urinary incontinence in women: scientific review. *JAMA* 2004;291:986–995. [PubMed]
34. Dean NM, Ellis G, Wilson PD, Herbison GP. Laparoscopic colposuspension for urinary incontinence in women. In: The Cochrane Library: Issue 4, 2006. Chichester, UK: John Wiley & Sons, Ltd. Search date 2006.
35. Lapitan MC, Cody DJ, Grant AM. Open retropubic colposuspension for urinary incontinence in women. In: The Cochrane Library: Issue 3, 2006. Chichester: John Wiley & Sons, Ltd. Search date 2002.
36. Kitchener H C, Dunn G, Lawton V, et al. Laparoscopic versus open colposuspension — results of a prospective randomised controlled trial. *BJOG* 2006; 113: 1007–1013. [PubMed]
37. Carey MP, Goh JT, Rosamilia A, et al. Laparoscopic versus open colposuspension: a randomised controlled trial. *BJOG* 2006;113:999–1006. [PubMed]
38. Tuygun C, Bakirtas H, Eroglu M, et al. Comparison of two different surgical approaches in the treatment of stress urinary incontinence: open and laparoscopic burch colposuspension. *Turk Uroloji Dergisi* 2006;32:248–253.
39. Bezerra CA, Bruschini H, Cody DJ. Suburethral sling operations for urinary incontinence in women. In: The Cochrane Library: Issue 3, 2001. Oxford, UK: Update Software. Search date 2002; primary sources the Cochrane Incontinence Group trials register, Medline, Cinahl, Cochrane Controlled Trials Register, and hand searches of journals.
40. Black NA, Downs SH. The effectiveness of surgery for stress incontinence in women: a systematic review. *Br J Urol* 1996;78:497–510. Search date 1995; primary sources Medline, Embase, Science Citation Index, British Library Information Index, and reference lists of relevant articles. [PubMed]
41. Culligan PJ, Goldberg RP, Sand PK. A randomized controlled trial comparing a modified Burch procedure and a suburethral sling: long-term follow-up. *Int Urogynecol J Pelvic Floor Dysfunct* 2003;14:229–233. [PubMed]
42. Hilton P. A clinical and urodynamic study comparing the Stamey bladder neck suspension and suburethral sling procedures in the treatment of genuine stress incontinence. *Br J Obstet Gynaecol* 1989;96:213–220. [PubMed]
43. Cody J, Wyness L, Wallace S, et al. Systematic review of the clinical effectiveness of tension-free vaginal tape for treatment of urinary stress incontinence. *Health Technol Assess* 2003;7:1–189. Search date 2002, primary sources Medline, Embase, Dane, Cochrane Incontinence Review Group, references lists, conference proceedings, and contact with experts in the area.
44. Wadie BS, Edwan A, Nabeeh AM. Autologous fascial sling vs polypropylene tape at short-term followup: a prospective randomized study. *J Urol* 2005;174:990–993. [PubMed]
45. Ward KL, Hilton P. A prospective multicenter randomized trial of tension-free vaginal tape and colposuspension for primary urodynamic stress incontinence: two-year follow-up. *Am J Obstet Gynecol* 2004;190:324–331. [PubMed]
46. Liapis A, Bakas P, Creatsas G. Burch colposuspension and tension-free vaginal tape in the management of stress urinary incontinence in women. *Eur Urol* 2002;41:469–473. [PubMed]
47. Adverse Event Reporting System (AERS). Available online at: <http://www.fda.gov/cder/aers/default.htm>. Last accessed 4 October 2006.
48. Patry G, Bolduc S, Martineau G, et al. Colovaginal fistula: an unusual complication of the tension-free vaginal tape procedure. *J Urol* 2004;172:972–973. [PubMed]
49. Meschia M, Busacca M, Pifarotti P, et al. Bowel perforation during insertion of tension-free vaginal tape (TVT). *Int Urogynecol J Pelvic Floor Dysfunct* 2002;13:263–265. [PubMed]
50. Fourie T, Cohen PL. Delayed bowel erosion by tension-free vaginal tape. *Int Urogynecol J Pelvic Floor Dysfunct* 2003;14:362–364. [PubMed]
51. Leboeuf L, Mendez LE, Gousse AE. Small bowel obstruction associated with tension-free vaginal tape. *Urology* 2004;63:1182–1184.
52. Amna MB, Randrianantenaina A, Michel F. Colic perforation as a complication of tension-free vaginal tape procedure. *J Urol* 2003;170:2387. [PubMed]
53. Bafghi A, Iannelli A, Trastour C, et al. Bowel perforation as late complication of tension-free vaginal tape. *J Gynecol Obstet Biol Reprod (Paris)* 2005;34:606–607. [In French] [PubMed]
54. Brink DM. Bowel injury following insertion of tension-free vaginal tape. *S Afr Med J* 2000;90:450–452.
55. Peyrat L, Boutin JM, Bruyere F, et al. Intestinal perforation as a complication of tension-free vaginal tape procedure for urinary incontinence. *Eur Urol* 2001;39:603–605. [PubMed]
56. Johnson DW, ElHajj M, O'Brien-Best EL, et al. Necrotizing fasciitis after tension-free vaginal tape (TVT) placement. *Int Urogynecol J Pelvic Floor Dysfunct* 2003;14:291–293. [PubMed]
57. Connolly TP. Necrotizing surgical site infection after tension-free vaginal tape. *Obstet Gynecol* 2004;104:1275–1276. [PubMed]
58. Riedler I, Primus G, Trummer H, et al. Fournier's gangrene after tension-free vaginal tape (TVT) procedure. *Int Urogynecol J Pelvic Floor Dysfunct* 2004;15:145–146. [PubMed]
59. Siegel AL. Urethral necrosis and proximal urethro-vaginal fistula resulting from tension-free vaginal tape. *Int Urogynecol J* 2006;17:661–664.
60. Irer B, Aslan G, Cimen S, et al. Development of vesical calculi following tension-free vaginal tape procedure. *Int Urogynecol J Pelvic Floor Dysfunct* 2005;16:245–246. [PubMed]
61. Al-Badr A, Fouda K. Suprapubic-assisted cystoscopic excision of intravesical tension-free vaginal tape. *J Minim Invasive Gynecol* 2005;12:370–371. [PubMed]
62. Schraffordt Koops SE, Bisseling TM, Heintz AP, et al. Prospective analysis of complications of tension-free vaginal tape from The Netherlands Tension-free vaginal tape study. *Am J Obstet Gynecol* 2005;193:45–52. [PubMed]
63. Meschia M, Pifarotti P, Bernasconi F, et al. Tension-free vaginal tape: analysis of outcomes and complications in 404 stress incontinent women. *Int Urogynecol J Pelvic Floor Dysfunct* 2001;12:S24–S27. [PubMed]

64. Niemczyk P, Klutke JJ, Carlin BI, et al. United States experience with tension-free vaginal tape procedure for urinary stress incontinence: assessment of safety and tolerability. *Tech Urol* 2001;7:261–265. [PubMed]
65. Bodelsson G, Henriksson L, Osser S, et al. Short term complications of the tension-free vaginal tape operation for stress urinary incontinence in women. *BJOG* 2002;109:566–569. [PubMed]
66. Abouassaly R, Steinberg JR, Lemieux M, et al. Complications of tension-free vaginal tape surgery: a multi-institutional review. *BJU Int* 2004;94:110–113. [PubMed]
67. Tsivian A, Kessler O, Mogutin B, et al. Tape related complications of the tension-free vaginal tape procedure. *J Urol* 2004;171:762–764. [PubMed]
68. Tsivian A, Mogutin B, Kessler O, et al. Tension-free vaginal tape procedure for the treatment of female stress urinary incontinence: long-term results. *J Urol* 2004;172:998–1000. [PubMed]
69. Enzelsberger H, Schalupny J, Heider R, et al. TVT versus TOT – A prospective randomized study for the treatment of female stress urinary incontinence at a follow-up of 1 year. *Geburtshilf Frauenheilkd* 2005;65:506–511.
70. Rajan S, Kohli N. Retropubic hematoma after transobturator sling procedure. *Am J Obstet Gynecol* 2005;105:1199–1202.
71. FJ Richards SR, Balalosi SP. Vulvar hematoma following a transobturator sling (TVT-O). *Int Urogynecol J* 2006;17:672–673.
72. Game X, Mouzin M, Vaessen C, et al. Obturator infected hematoma and urethral erosion following transobturator tape implantation. *J Urol* 2004;171:1629. [PubMed]
73. Khunda A, Calvert SM. Tape erosion into the vagina. *J Obstet Gynaecol* 2005;25:413. [PubMed]
74. Yamada B S, Govier F E, Stefanovic K B et al. High rate of vaginal erosions associated with the mentor ObTape. *J Urol* 2006;176:651–654. [PubMed]
75. Babalola EO, Famuyide AO, McGuire LJ, et al. Vaginal erosion, sinus formation, and ischioanal abscess following transobturator tape: ObTape implantation. *Int Urogynecol J Pelvic Floor Dysfunct* 2006;17:418–421. [PubMed]
76. Mahajan ST, Kenton K, Bova DA, et al. Transobturator tape erosion associated with leg pain. *Int Urogynecol J Pelvic Floor Dysfunct* 2006;17:66–68. [PubMed]
77. Parekh MH, Minassian VA, Poplawsky D. Bilateral bladder erosion of a transobturator tape mesh. *Obstet Gynecol* 2006;108:713–715. [PubMed]
78. Caquant F, Collinet P, Deruelle P, et al. Perineal cellulitis following trans-obturator sub-urethral tape Uratape. *Eur Urol* 2005;47:108–110. [PubMed]
79. Goldman HB. Large thigh abscess after placement of synthetic transobturator sling. *Int Urogynecol J Pelvic Floor Dysfunct* 2006;17:295–296. [PubMed]
80. Agostini A, De Lapparent T, Bretelle F. Abscess of the thigh and psoas muscle after transobturator suburethral sling procedure. *Acta Obstet Gynecol Scand* 2006;85:628–629. [PubMed]
81. deTayrac R, Deffieux X, Droupy S, et al. A prospective randomized trial comparing tension-free vaginal tape and transobturator suburethral tape for surgical treatment of stress urinary incontinence. *Am J Obstet Gynecol* 2004;190:602–608. [PubMed]
82. Retraction in *Am J Obstet Gynecol* 2005;192:339 of deTayrac R, Deffieux X, Droupy S, et al. A prospective randomized trial comparing tension-free vaginal tape and transobturator suburethral tape for surgical treatment of stress urinary incontinence. *Am J Obstet Gynecol* 2004;190:602–608. [PubMed]
83. Glazener CMA, Cooper K. Anterior vaginal repair for urinary incontinence in women. In: The Cochrane Library: Issue 4, 2006. Chichester: John Wiley & Sons, Ltd. Search date 2004.
84. Glazener CMA, Cooper K. Bladder neck needle suspension for urinary incontinence in women. In: The Cochrane Library: Issue 2, 2004. Chichester, UK: John Wiley & Sons, Ltd. Search date 2003; primary sources the Cochrane Incontinence Trials Register, Medline, Cinahl, Cochrane Controlled Trials Register, and hand searches of journals and reference lists of relevant articles.

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**TABLE 1** Results of a systematic review<sup>[8]</sup> of RCTs comparing serotonin reuptake inhibitors (duloxetine) versus placebo or no treatment for the treatment of stress incontinence (see text).<sup>[9]</sup>  
<sup>[10]</sup> <sup>[11]</sup> <sup>[12]</sup> <sup>[13]</sup> <sup>[14]</sup> <sup>[15]</sup> <sup>[16]</sup>

Ref	Population	Comparison	Timeline	Results
<i>Median percentage decrease in IEF</i>				
<sup>[11]</sup>	1 RCT, 121 women	Duloxetine 80 mg daily v placebo	4 weeks	50% with duloxetine v 37% with placebo; absolute numbers NR; p = 0.33
<sup>[9]</sup> <sup>[10]</sup>	201 women (total 92 in these comparison groups)	Duloxetine 80 mg daily v placebo plus imitation PFME	12 weeks	57% with duloxetine v 29% with placebo; absolute numbers NR; P < 0.001
<sup>[8]</sup>	1 RCT, 109 women <sup>[11]</sup>	Duloxetine 80 mg daily for 4 weeks v placebo	4 weeks	55% with duloxetine v 26% with placebo; P < 0.002
<sup>[8]</sup>	1 RCT, 109 women <sup>[12]</sup>	Duloxetine 80 mg daily for 4 weeks, then escalating to 120 mg daily for 4 weeks v placebo for 8 weeks	8 weeks	60% with duloxetine v 27% with placebo; P < 0.001
<sup>[8]</sup>	1 RCT, 109 women <sup>[12]</sup>	Duloxetine 120 mg v placebo	4 weeks	64% with duloxetine v 26% with placebo; P < 0.01
<sup>[8]</sup>	1 RCT, 553 women <sup>[13]</sup>	Duloxetine 20 mg daily v placebo	12 weeks	44% with duloxetine v 40% with placebo; P = 0.6
<sup>[8]</sup>	1 RCT, 553 women <sup>[13]</sup>	Duloxetine 80 mg daily v placebo	12 weeks	58% with duloxetine v 40% with placebo; P = 0.04
<sup>[8]</sup>	1 RCT, 683 women <sup>[14]</sup>	Duloxetine 80 mg daily v placebo	12 weeks	50% with duloxetine v 28% with placebo; P < 0.001
<sup>[8]</sup>	1 RCT, 494 women <sup>[15]</sup>	Duloxetine 80 mg daily v placebo	12 weeks	50% with duloxetine v 29% with placebo; P = 0.002
<sup>[8]</sup>	1 RCT, 458 women <sup>[16]</sup>	Duloxetine 80 mg daily v placebo	12 weeks	54% with duloxetine v 40% with placebo; P = 0.05
<i>Subjective number of people not cured</i>				
<sup>[8]</sup>	3 RCTs, 1396 people	Duloxetine 80 mg daily v placebo or no treatment		619/694 [89%] with duloxetine v 648/712 [91%] with placebo; RR 0.97, 95% CI 0.93 to 1.00; P = 0.04
<sup>[8]</sup>	1 RCT, 255 people	Duloxetine 40 mg daily v placebo or no treatment		93/123 [76%] with duloxetine v 112/132 [85%] with control; RR 0.89, 95% CI 0.79 to 1.01; P = 0.07
<sup>[8]</sup>	1 RCT, 260 people	Duloxetine 20 mg daily v placebo or no treatment		107/128 [84%] with duloxetine v 112/132 [85%] with control; RR 0.99, 95% CI 0.89 to 1.09; P = 0.08
<i>Objective number of people not cured (stress pad test)</i>				
<sup>[8]</sup>	1 RCT, 227 people	Duloxetine 80 mg daily v placebo or no treatment		69/113 [61%] with v 72/114 [63%] with control; RR 0.97, 95% CI 0.79 to 1.18; P = 0.7
<sup>[8]</sup>	1 RCT, 225 people	Duloxetine 40 mg daily v placebo or no treatment		63/111 [57%] with v 72/114 [63%] with control; RR 0.90, 95% CI 0.73 to 1.11; P = 0.3
<sup>[8]</sup>	1 RCT, 224 people	Duloxetine 20 mg daily v placebo or no treatment		75/110 [68%] with duloxetine v 72/114 [63%] with control; RR 1.08, 95% CI 0.89 to 1.30; P = 0.4
<i>Number of people not improved during treatment</i>				
<sup>[8]</sup>	4 RCTs, 1733 people	Duloxetine 80 mg daily v placebo or no treatment		394/864 [46%] with duloxetine v 534/869 [61%] with control; RR 0.74, 95% CI 0.68 to 0.81; P < 0.00001
<sup>[8]</sup>	1 RCT, 67 people	Duloxetine 40 mg daily v placebo or no treatment		18/33 [55%] with duloxetine v 29/34 [85%] with control; RR 0.64, 95% CI 0.45 to 0.90; P = 0.01
<sup>[8]</sup>	1 RCT, 60 people	Duloxetine 30 mg daily v placebo or no treatment		10/26 [39%] with duloxetine v 29/34 [85%] with control; RR 0.45, 95% CI 0.27 to 0.75; P = 0.002
<sup>[8]</sup>	2 RCTs, 106 people	Duloxetine 20 mg daily v placebo or no treatment		31/89 [35%] with duloxetine v 48/71 [68%] with control; RR 0.55, 95% CI 0.40 to 0.75; P = 0.0001
<i>Overall improvement in I-QoL</i>				
<sup>[8]</sup>	4 RCTs, 1739 people	Duloxetine 80 mg daily v placebo		Absolute data no reported; WMD 4.50, 95% CI 2.83 to 6.18; P < 0.00001
<i>PGI-I status "very much better", "much better", or "a little better"</i>				

Ref	Population	Comparison	Timeline	Results
[8]	5 RCTs, 1784 people	Duloxetine 80 mg daily v placebo or no treatment		495/889 [56%] with duloxetine v 401/895 [45%] with control; RR 1.24, 95% CI 1.14 to 1.36; P < 0.00001

IEF, incontinence episode frequency; I-QOL, Incontinence Quality of Life scale (scored from 0 = worst to 100 = best possible quality of life); PFME, pelvic floor muscle exercises; PGI-I, Patient Global Impression of Improvement scale; NR, not reported; Ref, reference.

**TABLE 2** RCTs comparing pelvic floor electrical stimulation versus no treatment or sham treatment for the treatment of stress incontinence ( see text, p 4 ). [18] [19] [20] [21] [22] [23]

Ref	Study design and population	Comparison	Outcomes	Results
[18]	Systematic review (1 RCT, 52 women)	PFES v sham PFES	Mean reduction of episodes/week after 4 weeks	-4.1 with PFES v + 6.9 with sham PFES; P = 0.009
[19]	RCT, results not analysed by ITT; 121 women; 60 (50%) with stress incontinence, 28 (23%) with urge incontinence, and 33 (27%) with mixed incontinence	PFES v sham PFES	Proportion of women with self reported improvement in symptoms after 6 weeks	35% with PFES v 17% with sham PFES; P = 0.03
[20]	RCT, 33 men and women with stress incontinence	PFES v sham PFES	Proportion of people with self reported improvement in symptoms over 4 weeks Proportion of people with self reported reduced urine loss (measured with the 1 hour pad test) over 4 weeks	60% with PFES v 8% with sham PFES; P = 0.005 Absolute data not reported; P = 0.008
[21]	RCT, 43 women	PFES v no treatment	Proportion of people with self reported improvement or cure at 10–12 weeks	27% with PFES v 0% with no treatment; P value not reported; reported as significant
[22]	RCT, 60 women	PFES v no treatment	Mean reduction in BUSQ frequency of incontinence score (scale from 1 [not a problem] to 5 [very serious problem]) after 6 weeks Mean reduction in BUSQ severity of incontinence score (scale from 1 [not a problem] to 5 [very serious problem]) after 6 weeks	0.97 with PFES v 0 with no treatment; P < 0.01 1.2 with PFES v 0 with no treatment; P < 0.01
[23]	RCT, 27 women	PFES v sham PFES	Percentage change in UDIQ score (score measured from 0 [no distress] to 100 [greatest distress]) after 8 weeks	-31% with PFES v + 9% with sham PFES; P = 0.01

BUSQ, Bristol Urinary Symptoms Questionnaire; ITT, intention to treat, PFES, pelvic floor electrical stimulation; Ref, reference; UDIQ, Urogenital Distress Inventory Questionnaire.

**TABLE 3** Adrenoceptor agonists for the treatment of stress incontinence; results of a systematic review ( see text, p 9 ).<sup>[31]</sup>

Study design and population	Comparison	Results for subjective cure or improvement	Overall adverse events
<i>Adrenoceptor agonists v placebo</i>			
2 RCTs, 63 women	Phenylpropanolamine v placebo	15/30 [50%] with phenylpropanolamine v 10/33 [30%] with placebo; RR 1.58, 95% CI 0.87 to 2.85	4 RCTs, 22/77 [29%] with phenylpropanolamine v 13/78 [17%] with placebo; RR 1.72, 95% CI 0.92 to 3.20
1 RCT, 48 women	Midodrine v placebo	22/26 [85%] with midodrine v 12/22 [55%] with placebo; RR 1.55, 95% CI 1.02 to 2.35	1 RCT, 16/26 [62%] with midodrine v 8/24 [33%] with placebo; RR 1.85, 95% CI 0.97 to 3.51
1 RCT, 165 women	Clenbuterol v placebo	36/77 [47%] with clenbuterol v 21/88 [24%] with placebo; RR 1.96, 95% CI 1.26 to 3.05	1 RCT, 13/82 [16%] with clenbuterol v 12/93 [13%] with placebo; RR 1.23, 95% CI 0.59 to 2.54
<i>Adrenoceptor agonists v non-surgical treatments</i>			
1 RCT, 157 women	Phenylpropanolamine v PFME	54/75 [72%] with phenylpropanolamine v 42/82 [51%] with PFME; RR 1.41, 95% CI 1.09 to 1.81	
1 RCT, 34 women	Clenbuterol v PFME	10/15 [67%] with clenbuterol v 10/19 [53%] with PFME; RR 1.27, 95% CI 0.73 to 2.21	2/15 [13%] with clenbuterol v 0/19 [0%] with PFME; RR 6.25, 95% CI 0.32 to 121.14
<i>Adrenoceptor agonists v oestrogen supplements</i>			
1 RCT, 20 women	Phenylpropanolamine v vaginal estriol	8/10 [80%] with phenylpropanolamine v 4/10 [40%] with vaginal estriol; RR 2.00, 95% CI 0.88 to 4.54	NR

NR, not reported; PFME, pelvic floor muscle exercises; Ref, reference.

**TABLE 4** RCTs comparing tension free vaginal tape versus laparoscopic colposuspension for the treatment of stress incontinence ( see text, p 14 ).<sup>[38] [42] [43] [44] [45]</sup>

Ref	Study design and population	Outcomes	Results
[38]	Systematic review (1 RCT, 113 women)	Subjective cure rate at 3 months	100% with TVT v 100% with laparoscopic colposuspension
		Subjective cure rate at 6–24 months	53/57 [93%] with TVT v 45/56 [80%] with laparoscopic colposuspension; RR 1.16, 95% CI 1.00 to 1.34
[42]	RCT, 128 women	Objective cure rates at 6 weeks	65/70 [92.9%] with TVT v 45/51 [88.2%] with laparoscopic colposuspension; RR and P value NR, reported as not significant
[43]	RCT, 46 women	Subjective cure rates at 12 months	19/23 [82.6%] with TVT v 19/23 [82.6%] with laparoscopic colposuspension; NR and P value NR, reported as not significant
[44]	RCT, 128 women; 120 operated on; 58% in TVT group v 42% in laparoscopic colposuspension group	Objective cure rates (assessed using a 48 hour pad test)	51/70 [72.9%] with TVT v 30/51 [58.8%] with laparoscopic colposuspension; P = 0.105
[45]	RCT, 72 women	Objective treatment failure rates at 12 months	1/31 [3.2%] with TVT v 6/32 [18.8%] with laparoscopic colposuspension; RR 1.19, 95% CI 1.00 to 1.42, P = 0.056

ARR, absolute risk reduction; Ref, reference; RR, risk reduction; TVT, tension free vaginal tape

**TABLE GRADE evaluation of interventions for stress incontinence**

Important outcomes	Quality of life, social functioning, self reported improvement/cure, episodes of urine loss, adverse effects									
	Number of studies (participants)	Outcome	Comparison	Type of evidence	Quality	Consistency	Directness	Effect size	GRADE	Comment
What are the effects of non-surgical treatments for women with stress incontinence?										
7 (2519) <sup>[9]</sup> <sup>[10]</sup> <sup>[11]</sup> <sup>[12]</sup> <sup>[13]</sup> <sup>[14]</sup> <sup>[15]</sup> <sup>[16]</sup>	Incontinence frequency	Selective serotonin reuptake inhibitors v placebo	4	0	+1	0	0	High	Consistency point added for evidence of dose response	
9 (3327) <sup>[8]</sup>	Quality of life	Selective serotonin reuptake inhibitors v placebo	4	0	0	0	0	High		
9 (3327) <sup>[8]</sup>	Incontinence cure rates	Selective serotonin reuptake inhibitors v placebo	4	0	0	0	0	High		
1 (92) <sup>[9]</sup>	Incontinence frequency	Selective serotonin reuptake inhibitors plus imitation pelvic floor exercises v pelvic floor exercises plus placebo	4	-1	0	0	0	Moderate	Quality point deducted for sparse data	
1 (92) <sup>[10]</sup>	Quality of life	Selective serotonin reuptake inhibitors plus imitation pelvic floor exercises v pelvic floor exercises plus placebo	4	-1	0	0	0	Moderate	Quality point deducted for sparse data	
2 (112) <sup>[18]</sup> <sup>[22]</sup>	Incontinence frequency	Pelvic floor electrical stimulation v no treatment/sham stimulation	4	-1	0	0	0	Moderate	Quality point deducted for sparse data	
3 (197) <sup>[19]</sup> <sup>[20]</sup> <sup>[21]</sup>	Cure/improvement of incontinence	Pelvic floor electrical stimulation v no treatment/sham stimulation	4	-2	0	-1	0	Very low	Quality points deducted for sparse data and poor follow-up. Directness point deducted for inclusion of men into one RCT	
1 (less than 274 women) <sup>[24]</sup>	Episodes of incontinence	Pelvic floor electrical stimulation v vaginal cones	4	-1	0	0	0	Moderate	Quality point deducted for sparse data	
4 (274) <sup>[24]</sup>	Cure/improvement of incontinence	Pelvic floor electrical stimulation v vaginal cones	4	0	0	0	0	High		
1 (49) <sup>[25]</sup>	Cure/improvement of incontinence	Pelvic floor electrical stimulation v oestrogen supplements	4	-1	0	0	0	Moderate	Quality point deducted for sparse data	
3 (165) <sup>[27]</sup>	Cure/improvement of incontinence	Pelvic floor muscle exercises v no treatment	4	-1	0	0	0	Moderate	Quality point deducted for sparse data	
1 (201) <sup>[9]</sup>	Incontinence frequency	Pelvic floor muscle exercises v no treatment	4	0	0	0	0	High		
7 (661) <sup>[24]</sup>	Cure/improvement of incontinence	Pelvic floor muscle exercises v vaginal cones	4	0	0	0	0	High		
2 RCTs <sup>[24]</sup>	Incontinence frequency	Pelvic floor muscle exercises v vaginal cones	4	-1	0	0	0	Moderate	Quality point deducted for incomplete reporting of results	
1 (69) <sup>[25]</sup>	Cure/improvement of incontinence	Pelvic floor muscle exercise v oestrogen supplements	4	-1	0	0	0	Moderate	Quality point deducted for sparse data	
2 (191) <sup>[31]</sup>	Cure/improvement of incontinence	Pelvic floor muscle exercises v adrenoceptor agonists	4	-1	-1	0	0	Low	Quality point deducted for sparse data. Consistency point deducted for conflicting results	
2 (252) <sup>[24]</sup>	Cure/improvement of incontinence	Vaginal cones v no active treatment	4	0	0	0	0	High		
2 (252) <sup>[24]</sup>	Incontinence frequency	Vaginal cones v no active treatment	4	0	0	0	0	High		

Quality of life, social functioning, self reported improvement/cure, episodes of urine loss, adverse effects									
Important outcomes	Outcome	Comparison	Type of evidence	Quality	Consistency	Directness	Effect size	GRADE	Comment
Number of studies (participants)									
15 (718) <sup>[25]</sup>	Cure/improvement of incontinence	Oestrogen supplements v placebo	4	-1	0	-1	0	Low	Quality point deducted for differences in RCT design. Directness point deducted for differences in treatments
1 (417) <sup>[28]</sup>	Incontinence frequency	Oestrogen supplements v placebo	4	-1	0	0	0	Moderate	Quality point deducted for poor reporting of long-term follow-up
1 (20) <sup>[31]</sup>	Cure/improvement of incontinence	Oestrogen supplements v adrenoceptor agonists	4	-1	0	0	0	Moderate	Quality point deducted for sparse data
4 (276) <sup>[31]</sup>	Cure/improvement of incontinence	Adrenoceptor agonists v placebo	4	0	-1	-1	0	Low	Consistency point deducted for conflicting results. Directness point deducted for inclusion of withdrawn and unlicensed treatments
What are the effects of surgical treatments for women with stress incontinence?									
11 (824) <sup>[34]</sup> <sup>[36]</sup> <sup>[38]</sup>	Cure/improvement of incontinence	Laparoscopic colposuspension v open retropubic colposuspension	4	0	-1	-1	0	Low	Consistency point deducted for conflicting results. Directness point deducted for different results after different endpoints
8 (at least 515 people) <sup>[34]</sup>	Cure/improvement of incontinence	Laparoscopic colposuspension v tension-free vaginal tape	4	0	-1	0	0	Moderate	Consistency point deducted for different results for objective v subjective assessment of outcomes
2 (120) <sup>[35]</sup>	Cure of incontinence	Open retropubic colposuspension v pelvic floor muscle exercises/stimulation	4	-1	0	0	0	Moderate	Quality point deducted for sparse data
8 (929) <sup>[83]</sup>	Cure of incontinence	Open retropubic colposuspension v anterior vaginal repair	4	0	0	0	0	High	
5 (206) <sup>[39]</sup>	Cure of incontinence	Open retropubic colposuspension v suburethral sling	4	0	0	0	0	High	
7 (570) <sup>[35]</sup>	Cure of incontinence	Open retropubic colposuspension v needle suspension	4	-1	0	0	0	Moderate	Quality point deducted for weak methodology of included RCTs
2 (415) <sup>[43]</sup>	Cure of incontinence	Open retropubic colposuspension v tension-free vaginal tape	4	-3	0	0	0	Very low	Quality points deducted for randomisation flaws, poor follow-up and other methodological flaws
1 (20) <sup>[39]</sup>	Cure of incontinence	Suburethral sling v needle suspension	4	-1	0	0	0	Moderate	Quality point deducted for sparse data
1 (53) <sup>[44]</sup>	Cure of incontinence	Suburethral sling v tension-free vaginal tape	4	-2	0	0	0	Low	Quality points deducted for sparse data and incomplete reporting of results
1 (110) <sup>[69]</sup>	Cure of incontinence	Tension-free vaginal tape v transobturator foramen procedures	4	-1	0	0	0	Moderate	Quality point deducted for sparse data
1 (50) <sup>[83]</sup>	Cure of incontinence	Anterior vaginal repair v pelvic floor muscle exercises	4	-2	0	0	0	Low	Quality points deducted for sparse data and allocation flaws
2 (469) <sup>[83]</sup>	Cure of incontinence	Anterior vaginal repair v needle suspension	4	0	0	0	0	High	

Type of evidence: 4 = RCT; 2 = Observational; 1 = Non-analytical/expert opinion. Consistency: similarity of results across studies. Directness: generalisability of population or outcomes.