

Stress incontinence

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Joseph L Onwude

ABSTRACT

INTRODUCTION: 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. **METHODS AND OUTCOMES:** We conducted a systematic review and aimed to answer the following clinical questions: What are the effects of non-surgical treatments and surgical treatments for women with stress incontinence? We searched: Medline, Embase, The Cochrane Library, and other important databases up to June 2008 (Clinical Evidence reviews are updated periodically, please check our website for the most up-to-date version of this review). We included harms alerts from relevant organisations such as the US Food and Drug Administration (FDA) and the UK Medicines and Healthcare products Regulatory Agency (MHRA). **RESULTS:** We found 97 systematic reviews, RCTs, or observational studies that met our inclusion criteria. We performed a GRADE evaluation of the quality of evidence for interventions. **CONCLUSIONS:** In this systematic review we present information relating to the effectiveness and safety of the following interventions: adrenoceptor agonists, anterior vaginal repair, laparoscopic colposuspension, needle suspension, oestrogen supplements, pelvic floor electrical stimulation, pelvic floor muscle exercises, retropubic colposuspension, selective serotonin reuptake inhibitors (duloxetine), suburethral slings, tension-free vaginal tape, transobturator foramen procedures, and vaginal cones.

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INTERVENTIONS

NON-SURGICAL TREATMENTS

Likely to be beneficial

Pelvic floor electrical stimulation	4
Pelvic floor muscle exercises	6
Serotonin reuptake inhibitors (duloxetine)	3
Vaginal cones	7

Trade-off between benefits and harms

Oestrogen supplements	8
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Unknown effectiveness

Adrenoceptor agonists	10
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SURGICAL TREATMENTS

Beneficial

Laparoscopic colposuspension (similar cure rates to open retropubic colposuspension and tension-free vaginal tape)	11
Open retropubic colposuspension (higher cure rates than non-surgical treatment, anterior vaginal repair, or needle suspension, and similar cure rates to laparoscopic colposuspension, traditional suburethral slings, TOT, and TVT)	12
Suburethral slings other than tension-free vaginal tape (similar cure rates to open retropubic colposuspension,	

TVT and needle suspension, but more perioperative complications than needle suspension)	14
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Likely to be beneficial

Transobturator foramen procedures (similar cure rates to tension-free vaginal tape and open retropubic colposuspension)	19
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Trade-off between benefits and harms

Tension-free vaginal tape (similar cure rates to laparoscopic colposuspension, non-TVT suburethral slings, TOT and open retropubic colposuspension, but associated with more bladder and vaginal perforations)	16
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Unlikely to be beneficial

Anterior vaginal repair (lower cure rates than open retropubic colposuspension but similar cure rates to needle suspension)	21
Needle suspension (lower cure rates and more surgical complications than open retropubic colposuspension)	22

To be covered in future updates

- Peri-ureteric implants/injections
- TVT-like operations

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 incontinence symptoms 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 incontinence frequency at 4–12 weeks compared with placebo, or compared with pelvic floor muscle exercises, but increase adverse effects, such as headache and gastric problems.
- We do not know whether **adrenoceptor 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 non-surgical treatments, **anterior vaginal repair** or **needle suspension** at up to 5 years. Complication rates are similar to those with other surgical procedures.
- **Suburethral slings** and open retropubic colposuspension are equally effective in curing stress incontinence at up to 5 years.
- **Tension-free vaginal tape** may be as effective as open retropubic colposuspension in curing stress incontinence. Complications of tension-free vaginal tape include bladder perforation.
- **Transobturator foramen procedures** may be as effective as open retropubic colposuspension and tension-free vaginal tape.
- **Laparoscopic colposuspension** and open retropubic colposuspension seem equally effective.

DEFINITION Stress incontinence is involuntary leakage of urine on effort or exertion, or on sneezing or coughing.^[1] 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,^[2] 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.^[3] One cross-sectional study (15,308 women in Norway, aged less than 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.^[4]

AETIOLOGY/ RISK FACTORS Aetiological factors include pregnancy, vaginal or caesarean delivery, cigarette smoking, and obesity.^{[4] [5] [6] [7]} One cross-sectional study (15,308 women in Norway) found that, when compared with women who had not borne a child, the risk of stress incontinence was increased in women who had 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).^[4] 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).^[7] The risks associated with obesity are unclear.

PROGNOSIS The natural history of stress incontinence is unclear. 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 *Clinical Evidence* search and appraisal June 2008. The following databases were used to identify studies for this systematic review: Medline 1966 to June 2008, Embase 1980 to June 2008, and The Cochrane Database of Systematic Reviews and Cochrane Central Register of Controlled Clinical Trials 2008, Issue 2 (1966 to date of issue). An additional search was 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). We also searched for retractions of studies included in the review. Abstracts of the studies retrieved from the initial search were assessed by an information specialist. Selected studies were then sent to the contributor for additional assessment, using pre-determined criteria to identify relevant studies. Study design criteria for inclusion in this review were: published systematic reviews of RCTs 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. In the case of three-armed RCT studies, analyses were not included if ANOVA was used to compare results from the three arms. We included systematic reviews of RCTs and RCTs where harms of an included intervention were studied, applying the same study design criteria for inclusion as we did of benefits. In addition we did an observational harms search for specific harms as highlighted by the contributor, peer reviewer and editor. We 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 FDA and the UK Medicines and Healthcare products Regulatory Agency (MHRA), which are added to the reviews as required. To aid readability of the numerical data in our reviews, we round percentages to the nearest whole number. Readers should be aware of this when relating percentages to summary statistics such as relative risks (RRs) and odds ratios (ORs). We have performed a GRADE evaluation of the quality of evidence for interventions included in this review (see table, p 30).

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 at doses of 20 mg, 40 mg, or 80 mg is no more effective at increasing the proportion of women cured, assessed either subjectively or objectively (high-quality evidence).

Incontinence episodes

Compared with placebo Duloxetine at doses of 80 mg or above daily is more effective at reducing the frequency of incontinence episodes in women with predominantly stress urinary incontinence (high-quality evidence).

Compared with pelvic floor exercises Duloxetine seems more effective at reducing the frequency of incontinence episodes in women with predominantly stress urinary incontinence (moderate-quality evidence).

Quality of life

Compared with placebo We don't know whether duloxetine is more effective at improving quality of life in women with predominantly stress incontinence (moderate-quality evidence).

Compared with pelvic floor exercises Duloxetine and pelvic floor exercises are equally effective at improving quality of life in women with predominantly stress incontinence (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 30 .

Benefits:

Serotonin reuptake inhibitors versus placebo or no treatment:

We found one systematic review (search date 2007, 10 RCTs, 3944 women with predominantly stress urinary incontinence),^[8] one additional RCT,^[9] and one subsequent RCT.^[10] The review found no significant difference in the proportion of women “not cured” during treatment with duloxetine 20 mg, 40 mg, or 80 mg daily (assessed either subjectively, or objectively using stress pad test) compared with placebo or no treatment (see table 1, p 27).^[8] However, it found that duloxetine 20 mg, 40 mg, or 80 mg daily significantly increased the proportion of women who “improved” during treatment compared with placebo or no treatment (see table 1, p 27).^[8] The review also found that duloxetine significantly improved quality of life compared with placebo (see table 1, p 27).^[8] Five RCTs^{[11] [12] [13] [14] [15]} identified by the review^[8] 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 27). A sixth RCT^[16] identified by the review

^[8] 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 27). One of the identified RCTs ^[13] found no significant difference in IEF outcomes between duloxetine at a dose of 20 mg and placebo at 12 weeks (see table 1, p 27). Another identified RCT 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 27). ^[12] The additional and subsequent RCTs found that duloxetine (40 mg twice daily for 4 weeks ^[9] and for 8 weeks ^[10]) significantly reduced the IEF outcomes compared with placebo (see table 1, p 27). They found no significant improvement in Incontinence Quality of Life scores with duloxetine compared with placebo (see table 1, p 27). ^[9] ^[10]

Serotonin reuptake inhibitors versus pelvic floor muscle exercises:

We found one systematic review (search date 2007), ^[8] which identified one RCT. ^[17] The RCT (201 people) 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 after 12 weeks (92 women, median decrease in IEF: 57% with duloxetine v 35% with PFMT; P less than 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; $P = 0.98$). ^[17]

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 ^[8] reported that although significantly more adverse effects were associated with duloxetine than with placebo, they were reported as acceptable by the authors of the trial reports (proportion of women with adverse effects: 984/1380 [71%] with duloxetine v 643/1100 [58%] with placebo; RR 1.31, 95% CI 1.24 to 1.39; P less than 0.0001). Five identified RCTs ^[12] ^[13] ^[14] ^[15] ^[16] 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 less than 0.001; ^[12] 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; ^[13] 24% with duloxetine 40 mg twice daily v 4% with placebo; P less than 0.001; ^[14] 22% with duloxetine 40 mg daily v 5% with placebo; P less than 0.001; ^[15] 17% with duloxetine 40 mg twice daily v 2% with placebo; $P = 0.001$ ^[16]). The most common adverse effects with duloxetine were nausea, diarrhoea, headache, dizziness, fatigue, and dry mouth. ^[12] ^[13] ^[14] ^[15] ^[16] ^[17] ^[18] The additional and subsequent RCTs found that treatment-emergent adverse effects (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 less than 0.001; ^[9] 80% with duloxetine v 44% with placebo; P less than 0.001 ^[10]). The RCTs also reported that discontinuation rates because of adverse effects were significantly higher with duloxetine compared with placebo (34% with duloxetine v 8% with placebo; P less than 0.001; ^[9] 27% with duloxetine v 7% with placebo; $P = 0.003$ ^[10]).

Serotonin reuptake inhibitors versus pelvic floor muscle exercises:

The RCT did not report adverse effects separately for each of the four treatment arms. ^[17]

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 in women with incontinence (moderate-quality evidence).

Compared with vaginal cones Pelvic floor electrical stimulation and vaginal cones seem equally effective at preventing episodes of incontinence in women (moderate-quality evidence).

Improvement of incontinence

Compared with no/sham treatment Pelvic floor electrical stimulation may be more effective at increasing the proportion of men and women with improvement or cure of incontinence (very low-quality evidence).

Compared with vaginal cones Pelvic floor electrical stimulation and vaginal cones are equally effective at increasing cure or improvement rates in women with stress incontinence ([high-quality evidence](#)).

Compared with oestrogen supplements Pelvic floor electrical stimulation and oestrogen supplements seem equally effective at increasing cure or improvement rates in women with stress incontinence (moderate-quality evidence).

Adverse effects

Pelvic floor electrical stimulation is associated with tenderness and vaginal bleeding.

For GRADE evaluation of interventions for stress incontinence, [see table , p 30](#) .

Benefits:

Pelvic floor electrical stimulation (PFES) versus no treatment or sham treatment:

We found one systematic review (search date 1998, 1 RCT),^[19] three additional RCTs,^{[20] [21] [22]} and two subsequent RCTs ([see table 2, p 28](#)).^{[23] [24]} 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 28](#)).^[19] 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 28](#)).^[20] 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).^[20] The second additional RCT (33 people with stress incontinence; 5 [15%] men and 28 [85%] women) 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 28](#)).^[21] However, because this RCT included men, the findings might not be fully generalisable to women with stress incontinence.^[21] The third additional RCT (43 women) found that more people receiving PFES reported improvement or cure compared with no treatment ([see table 2, p 28](#)).^[22] 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 28](#)).^[23] The second subsequent RCT (27 women) found that PFES significantly improved Urogenital Distress Inventory Questionnaire scores after 8 weeks ([see table 2, p 28](#)).^[24]

PFES versus vaginal cones:

We found one systematic review (search date 2007, 4 RCTs, 274 women).^[25] The review found no significant difference between PFES and [vaginal cones](#) in self-reported cure rates (1 RCT; failure to cure: RR [for comparison vaginal cones v PFES] 1.00, 95% CI 0.89 to 1.13; absolute numbers not reported), self-reported cure or improvement rates (2 RCTs; failure to improve or cure: 18/55 [33%] with PFES v 24/51 [47%] with vaginal cones; RR [for comparison vaginal cones v PFES] 1.45, 95% CI 0.90 to 2.33), 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 g with PFES v 0.6 g 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).^[26] 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).^[26] 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.^{[19] [20] [21] [22] [23] [24]}

PFES versus vaginal cones:

In one of the RCTs^[27] identified by the review,^[25] adverse effects 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).^[27]

PFES versus oestrogen supplements:

The systematic review reported no information on harms.^[26]

Comment: None.

OPTION PELVIC FLOOR MUSCLE EXERCISES**Improvement in incontinence**

Compared with no treatment/inactive treatments Pelvic floor muscle exercises seem more effective at increasing cure or improvement rates in women with stress incontinence (moderate-quality evidence).

Compared with vaginal cones Pelvic floor muscle exercises and vaginal cones are equally effective after 12 months at increasing cure or improvement rates (high-quality evidence).

Compared with oestrogen supplements Pelvic floor muscle exercises seem more effective at increasing improvement or cure rates (moderate-quality evidence).

Compared with adrenoceptor agonists We don't know whether pelvic floor muscle exercises are more effective compared with adrenoceptor agonists (clenbuterol, phenylpropranolamine) (low-quality evidence).

Incontinence frequency

Compared with no treatment/inactive treatments We don't know whether pelvic floor muscle exercises are more effective at reducing the frequency of incontinence episodes compared with no active treatment (low-quality evidence).

Compared with vaginal cones Pelvic floor muscle exercises seem more effective at reducing the number of daily leakage episodes at 6 months in women with stress incontinence (moderate-quality evidence).

Compared with selective serotonin reuptake inhibitors Pelvic floor exercises are less effective at reducing the frequency of incontinence episodes compared with duloxetine (moderate-quality evidence).

Quality of life

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

Adverse effects

Pelvic floor muscle exercises are associated with discomfort.

For GRADE evaluation of interventions for stress incontinence, see table, p 30 .

Benefits:**Pelvic floor muscle exercises (PFME) versus no treatment or placebo:**

We found one systematic review (search date 2004, 3 RCTs)^[28] and one subsequent RCT.^[17] The review did not pool data because of heterogeneity among studies in diagnosis of incontinence and in outcomes reported. One of the identified studies did not meet our inclusion criteria (as it was only reported as a conference abstract and not as a full text article) and is not discussed further in this review.

The first RCT (122 women with stress incontinence) identified by the review was a four-arm trial comparing pelvic floor muscle exercises (PFME), electrical stimulation, vaginal cones, and no treatment (except for instruction in the use of a continence guard). It found that PFME resulted in significantly higher subjective cure rate (proportion of women stating that the condition was "unproblematic" on a 5-point scale after treatment: 14/25 [56%] with PFME v 1/30 [3%] with no treatment; [reported in review: RR 16.8, 95% CI 2.4 to 119.0]^[28]) and subjective improvement rate (proportion of women reporting being "continent" or "almost continent": 12/25 [48%] with PFME v 1/30 [3%] with no treatment; [reported in review: RR 14.4, 95% CI 2.01 to 103.23]^[28]) after 6 months. It also found a significant improvement in objective assessment (stress pad test) of stress incontinence with PFME after 6 months (mean change in measures of stress incontinence from baseline to 6 months using the stress pad test: -30.2 g with PFME v -12.7 g with no treatment; P = 0.02).^[27] The second RCT (66 women with stress incontinence)^[29] identified by the review found significantly reduced incontinence episode frequency with PFME after 3 months' follow-up (mean number of incontinence episodes over 7 days: from 17.3 to 4.8 with PFME v from 23.1 to 25.3 with no treatment; P less than 0.01). It found a higher proportion of women with subjective cure or improvement in level of incontinence after 3 months' follow-up (proportion of women reporting level of incontinence as improved/cured: 85% with PFME v 0% with no treatment; absolute numbers not reported, significance not assessed) and a higher proportion of women reporting better results in incontinence severity after 3 months' follow-up with PFME compared with no treatment (proportion of patients describing severity of incontinence as "dry" or "only mildly incontinent" at 3 months' follow-up: 20/33 [61%] with PFME v 1/33 [3%] with no treatment; baseline results presented graphically; [reported in review: RR 20.0, 95% CI 2.85 to 140.51]^[28]).^[29]

The subsequent RCT (201 women)^[17] was a four-arm trial comparing PFME plus placebo, placebo plus imitation PFME, duloxetine plus imitation PFME, and PFME plus duloxetine. It found that PFME plus placebo significantly, but only slightly, reduced pad use at 12 weeks compared with

imitation PFME plus placebo (97 women; 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 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, P value not reported).^[17]

PFME versus vaginal cones:

We found one systematic review (search date 2007), which identified eight RCTs (820 women) comparing PFME versus vaginal cones.^[25] It found no significant difference in self-reported cure rates (failure to cure: 4 RCTs; 117/143 [82%] with PFME v 118/145 [81%] with vaginal cones; RR 1.00, 95% CI 0.91 to 1.11), or in self-reported cure or improvement rates (failure to cure or improve: 5 RCTs; 63/170 [37%] with PFME v 63/171 [37%] with vaginal cones; RR 1.00, 95% CI 0.76 to 1.32) between PFME and vaginal cones over 12 months. It found that PFME was significantly better than vaginal cones for leakage episodes per day (3 RCTs; WMD 0.69, 95% CI 0.26 to 1.13; absolute numbers not reported).

PFME versus oestrogen supplements:

We found one systematic review (search date 2002, 2 RCTs, 69 women), which 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).^[26]

PFME versus serotonin reuptake inhibitors:

See benefits of serotonin reuptake inhibitors, p 3 .

PFME versus adrenoceptor agonists:

See benefits of adrenoceptor agonists, p 10 .

Harms:

PFME versus no treatment or placebo:

The first RCT identified by the review reported no adverse effects with PFME.^[27] The adverse effects reported by the second identified RCT were pain when contracting pelvic muscles (1/33 [3%]), an uncomfortable feeling during exercise (3/33 [9%]), and difficulty maintaining motivation for use (2/33 [6%]).^{[28] [29]} The subsequent RCT did not report adverse effects separately for each group.^[17]

PFME versus vaginal cones:

The systematic review gave little information on adverse effects.^[25] Three RCTs identified by the review gave information on adverse effects, all of which were in women using vaginal cones.^[25] In one RCT (29 women), 14/29 (48%) had difficulty using the cones and maintaining motivation for use, 2/29 (7%) had vaginitis, 1/29 (3%) had abdominal pain, and 1/29 (3%) had bleeding. In the second RCT (30 women), 5/30 (17%) said that cones produced an unpleasant feeling, 3/30 (10%) said that cones were time consuming, 2/30 (7%) said that cones were difficult to insert when anxious or in a hurry, 2/30 (7%) said that cones interfered with menstruation, and 2/30 (7%) suffered from muscle fatigue.

PFME versus oestrogen supplements:

The systematic review reported no information on harms.^[26]

PFME versus serotonin reuptake inhibitors:

See harms of serotonin reuptake inhibitors, p 3 .

PFME versus adrenoceptor agonists:

See harms of adrenoceptor agonists, p 10 .

Comment: None.

OPTION

VAGINAL CONES

Improvement of incontinence

Compared with no active treatment Vaginal cones are more effective at increasing self-reported cure or improvement rates at 6–12 months compared with no treatment or advice to use a continence guard (high-quality evidence).

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

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

Incontinence frequency

Compared with no active treatment Vaginal cones are no more effective at decreasing the frequency of incontinence episodes (high-quality evidence).

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

Compared with pelvic floor electrical stimulation Vaginal cones seem equally effective 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 effects, such as vaginitis and abdominal pain, have been reported.

Note

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

For GRADE evaluation of interventions for stress incontinence, see table , p 30 .

Benefits:**Vaginal cones versus no active management aimed at exercising the pelvic floor:**

We found one systematic review (search date 2007, 3 RCTs, 373 women) comparing [vaginal cones](#) with control (no active management aimed at exercising the pelvic floor). Two of the identified RCTs included women with urodynamically proven stress incontinence, one RCT included women with symptoms of incontinence 3-months' postpartum.^[25] The review found that vaginal cones significantly improved the self-reported cure (failure to cure: 3 RCTs; 104/127 [82%] with vaginal cones v 171/200 [86%] with control; RR 0.88, 95% CI 0.79 to 0.98) and self-reported improvement or cure rates (failure to improve or cure: 2 RCTs; 38/106 [36%] with vaginal cones v 55/109 [50%] with control; RR 0.72, 95% CI 0.52 to 0.99) 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 (WMD in daily leakage episodes: 2 RCTs; +0.19, 95% CI –0.40 to +0.77; absolute numbers not reported).

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 no active management aimed at exercising the pelvic floor:**

The systematic review gave little information on adverse effects.^[25] 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 4 .](#)

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 be more effective at improving or curing incontinence (low-quality evidence).

Compared with adrenoceptor agonists Oestrogen supplements and adrenoceptor agonists seem equally effective at improving or curing incontinence (moderate-quality evidence).

Compared with pelvic floor muscle exercises Oestrogen supplements seem less effective after 9 months at improving or curing incontinence (moderate-quality evidence).

Compared with pelvic floor electrical stimulation Oestrogen supplements and pelvic floor electrical stimulation seem equally effective at improving or curing incontinence (moderate-quality evidence).

Incontinence frequency

Compared with placebo Oestrogen supplements seem no more effective 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 rates of stroke 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 30](#) .

Benefits:

Oestrogen supplements versus placebo:

We found one systematic review (search date 2002, 15 RCTs, 718 women), comparing oestrogen supplementation versus placebo, ^[26] and one subsequent RCT. ^[31] The systematic review ^[26] included many small studies with different types of oestrogen, methods of administration, doses, treatment durations, and periods of follow-up. It found that 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 ultra-low-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). ^[31] 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. ^[31]

Oestrogen supplements versus adrenoceptor agonists:

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

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%). ^[26] 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). ^[32] 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). ^[33] 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 comparing unopposed ultra-low-dose transdermal estradiol (0.014 mg/day) with placebo in postmenopausal women over 2 years gave no information on adverse effects. ^[31]

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 We don't know whether adrenoceptor agonists are more effective at improving incontinence (low-quality evidence).

Compared with pelvic floor muscle exercises We don't know whether adrenoceptor agonists are more effective at improving or curing incontinence (low-quality evidence).

Compared with oestrogen supplements Adrenoceptor agonists and oestrogen supplements seem equally effective 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 30 .

Benefits: We found one systematic review (search date 2007) (see table 3, p 29).^[30]

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 29).^[30]

Adrenoceptor agonists versus non-surgical treatments:

The review identified two RCTs comparing adrenoceptor agonists with non-surgical treatments.^[30] 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 29).^[30]

Adrenoceptor agonists versus oestrogen supplements:

The review identified one RCT (20 women), which found no significant difference in subjective cure or improvement rates between phenylpropanolamine and oestrogen (vaginal estriol) (see table 3, p 29).^[30]

Adrenoceptor agonists versus surgical treatment:

The review identified no RCTs.^[30]

Harms: Phenylpropanolamine has been withdrawn from the US market because of an increased risk of haemorrhagic stroke.^[34]

Adrenoceptor agonists versus no treatment or placebo:

The review found that there was a higher incidence of adverse effects with adrenoceptor agonists compared with placebo (4 RCTs; adverse effects: 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).^[30] The most common adverse effects were insomnia, restlessness, and vasomotor stimulation.^[30]

Adrenoceptor agonists versus non-surgical treatments:

One RCT identified by the review found more adverse effects with clenbuterol than with pelvic floor muscle exercises (adverse effects: 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).^[30]

Adrenoceptor agonists versus oestrogen supplements:

The RCT identified by the review gave no information about harms.^[30]

Adrenoceptor agonists versus surgical treatment:

The review identified no RCTs.^[30]

Comment:

The RCTs identified by the review might have lacked power to detect a significant difference in harms. Clenbuterol has anabolic steroid properties and has not been approved by the US FDA.^[35]

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

OPTION LAPAROSCOPIC COLPOSUSPENSION

Improvement of incontinence

Compared with open retropubic colposuspension Laparoscopic colposuspension and open retropubic colposuspension are equally effective at curing stress incontinence in women ([high-quality evidence](#)).

Compared with tension-free vaginal tape Laparoscopic colposuspension using sutures or mesh may be less effective at 18 months at improving objective measures of incontinence in women with stress or mixed urinary incontinence ([moderate-quality evidence](#)).

Adverse effects

The risks of de novo detrusor overactivity and bladder injury may be similar between laparoscopic colposuspension and open retropubic colposuspension. The risks of perioperative complications and de novo detrusor overactivity may be similar between laparoscopic colposuspension and tension-free vaginal tape.

Note

We found no direct information about whether laparoscopic colposuspension is better than no active treatment. We found no clinically important results from RCTs 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 30](#) .

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

We found one systematic review (search date 2007), which identified no RCTs.^[36]

Laparoscopic colposuspension versus anterior vaginal repair:

[See benefits of anterior vaginal repair, p 21](#) .

Laparoscopic colposuspension versus suburethral slings:

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

Laparoscopic colposuspension versus open retropubic colposuspension:

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

Laparoscopic colposuspension versus needle suspension:

We found no RCTs.

Laparoscopic colposuspension versus tension-free vaginal tape:

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

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 21](#) .

Laparoscopic colposuspension versus suburethral slings:

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

Laparoscopic colposuspension versus open retropubic colposuspension:

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

Laparoscopic colposuspension versus needle suspension:

We found no RCTs.

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 non-surgical treatment Open retropubic colposuspension may be more effective at increasing cure rates compared with pelvic floor muscle exercises or electrical stimulation in women with urinary incontinence ([very low-quality evidence](#)).

Compared with laparoscopic colposuspension Open colposuspension and laparoscopic colposuspension are equally effective at curing incontinence ([high-quality evidence](#)).

Compared with anterior vaginal repair Open retropubic colposuspension is more effective at increasing cure rates in women with incontinence ([high-quality evidence](#)).

Compared with suburethral slings Open retropubic colposuspension and suburethral slings are equally effective at increasing cure rates ([high-quality evidence](#)).

Compared with needle suspension Open retropubic colposuspension is more effective at curing incontinence ([moderate-quality evidence](#)).

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

Compared with transobturator foramen procedures Open retropubic colposuspension seems equally effective at 12 months at curing incontinence ([moderate-quality evidence](#)).

Adverse effects

Open retropubic colposuspension is associated 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 from RCTs about whether open retropubic colposuspension is better than no active treatment.

For GRADE evaluation of interventions for stress incontinence, see [table, p 30](#) .

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

We found one systematic review (search date 2004), which identified no RCTs. ^[39]

Open retropubic colposuspension versus non-surgical treatment:

We found one systematic review (search date 2004, 2 RCTs, 97 women) comparing [open retropubic colposuspension](#) versus non-surgical treatments ([pelvic floor muscle exercises](#) alone or [pelvic floor muscle exercises plus pelvic floor electrical stimulation](#)). ^[39] The review did not pool data because of differences in the outcome measures reported. Both RCTs were described as methodologically weak, including non-reporting of method of randomisation and uncertainty about the number of withdrawals. The review 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 21](#) .

Open retropubic colposuspension versus suburethral slings:

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

Open retropubic colposuspension versus laparoscopic colposuspension:

We found one systematic review (search date 2007, 10 RCTs) ^[36] and two additional RCTs. ^[40] ^[41] The review found no significant difference between open retropubic colposuspension and laparoscopic colposuspension in self-reported cure rates at 18 months and between 18 months and 5 years (subjective cure rate at 18 months: 7 RCTs; 433/521 [83%] with open retropubic colposuspension v 394/504 [78%] with laparoscopic colposuspension; RR [for the comparison laparoscopic colposuspension v open retropubic colposuspension] 0.95, 95% CI 0.90 to 1.00; subjective cure rate between 18 months and 5 years: 1 RCT; 71/130 [55%] with open retropubic colposuspension v 73/133 [55%] with laparoscopic colposuspension; RR [for the comparison laparoscopic colposuspension v open retropubic colposuspension] 1.00, 95% CI 0.81 to 1.25). ^[36] The review found that open retropubic colposuspension modestly but significantly increased objective cure rates at 18 months (objective cure rate at 18 months: 6 RCTs, 564 women; 249/289 [87%] with open retropubic colposuspension v 217/275 [79%] with laparoscopic colposuspension; RR [for the comparison laparoscopic colposuspension v open retropubic colposuspension] 0.91, 95% CI 0.85 to 0.99) but there was no significant difference between 18 months and 5 years (objective cure rate between 18 months and 5 years: 2 RCTs, 290 women; 105/142 [74%] with open retropubic colposuspension v 111/148 [75%] with laparoscopic colposuspension; RR [for the comparison laparoscopic colposuspension v open retropubic colposuspension] 1.01, 95% CI 0.88 to 1.16).

The first additional RCT (60 women with stress incontinence) found no significant difference in cure rate at 12 months between open Burch colposuspension compared with laparoscopic colposuspension (objective cure rate: 30/33 [90%] with open colposuspension v 23/27 [85%] with laparoscopic colposuspension; P greater than 0.05). ^[40] The second additional RCT (200 women with urodynamic stress incontinence) found no significant difference between open Burch colposuspension and laparoscopic colposuspension in subjective failure (defined as stress incontinence found at urodynamic assessment) at 6 months' follow-up (subjective failure rate at 6 months: 20/92 [22%] with open colposuspension v 23/83 [28%] with laparoscopic colposuspension; P = 0.22). ^[41]

Open retropubic colposuspension versus needle suspension:

We found one systematic review (search date 2004, 7 RCTs, 570 women). ^[39] 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). ^[39] The studies included in the systematic review used weak methods. ^[39]

Open retropubic colposuspension versus tension-free vaginal tape:

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

Open retropubic colposuspension versus transobturator foramen procedures:

[See benefits of transobturator foramen procedures, p 19](#) .

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

We found no RCTs.

Open retropubic colposuspension versus non-surgical treatment:

The review identified one RCT, which gave information on adverse effects. ^[39] It found that open retropubic colposuspension was associated with more adverse effects than non-surgical treatments (pelvic floor muscle exercises alone or pelvic floor muscle exercises plus pelvic floor electrical stimulation), although this difference was small and significance was not assessed. 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 anterior vaginal repair:

[See harms of anterior vaginal repair, p 21](#) .

Open retropubic colposuspension versus suburethral slings:

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

Open retropubic colposuspension versus laparoscopic colposuspension:

The review ^[36] found a significant increase in perioperative complications with open retropubic colposuspension compared with laparoscopic colposuspension (9 RCTs: 106/587 [18%] with open retropubic colposuspension v 87/595 [14.6%] with laparoscopic colposuspension; RR [for the

comparison laparoscopic colposuspension v open retropubic colposuspension] 0.74, 95% CI 0.58 to 0.96). The review gave no information on the nature or severity of perioperative complications. It found no significant difference in de novo detrusor overactivity between open retropubic colposuspension and laparoscopic colposuspension at 18 months (5 RCTs: 18/261 [7%] with open retropubic colposuspension v 23/251 [9%] with laparoscopic colposuspension; RR [for the comparison laparoscopic colposuspension v open retropubic colposuspension] 1.29, 95% CI 0.72 to 2.30).^[36] The review found no significant difference in incidence of bladder injury between groups, however laparoscopic colposuspension was associated with more cases of bladder injury (7 RCTs; AR of bladder injury: 10/507 [2%] with open Burch colposuspension v 21/521 [4%] with laparoscopic colposuspension; RR [for the comparison laparoscopic colposuspension v open retropubic colposuspension] 1.88, 95% CI 0.93 to 3.83).^[36] The first additional RCT gave no information on adverse effects.^[40] The second additional RCT reported no significant difference in serious perioperative complications between the two treatment groups (1 case of haemorrhage with open Burch colposuspension requiring a blood transfusion and 1 case of haemorrhage with laparoscopic colposuspension that did not require a blood transfusion). There were six cases of suture penetration into the bladder (1 with open Burch colposuspension and 5 with laparoscopic colposuspension; P = 0.11). There was no significant difference in de novo detrusor overactivity on urodynamic testing after 6 months (12 with open Burch colposuspension and 9 with laparoscopic colposuspension; P = 0.67).^[41]

Open retropubic colposuspension versus needle suspension:

We found one systematic review (search date 2002, 7 RCTs, 570 women).^[39] It found that open retropubic colposuspension significantly reduced 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).^[39] The review gave no information on the nature or severity of surgical complications.

Open retropubic colposuspension versus tension-free vaginal tape:

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

Open retropubic colposuspension versus transobturator foramen procedures:

See [harms of transobturator foramen procedures](#), p 19 .

Comment: None.

OPTION

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

Cure of incontinence

Compared with open retropubic colposuspension Suburethral slings and open retropubic colposuspension may be equally effective at increasing cure rates ([high-quality evidence](#)).

Compared with needle suspension Suburethral slings and needle suspension may be equally effective at curing incontinence after 1 year ([low-quality evidence](#)).

Compared with tension-free vaginal tape (TVT) Suburethral slings and TVT may be equally effective at curing incontinence at 6 months (low-quality evidence).

Adverse effects

Suburethral slings may increase perioperative complications compared with needle suspension and anterior vaginal repair. The risk of perioperative complications and severe adverse effects at 2 years may be similar between non-TVT suburethral slings and open retropubic colposuspension.

Note

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

For GRADE evaluation of interventions for stress incontinence, see [table](#), p 30 .

Benefits: We found one systematic review (search date 2004; see comment below).^[38]

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

We found one systematic review (search date 2004), which identified no RCTs.^[38]

Suburethral slings other than TVT versus anterior vaginal repair:

We found one systematic review (search date 2004), which identified no RCTs. ^[38]

Suburethral slings other than TVT versus open retropubic colposuspension:

We found one systematic review (search date 2004, 5 RCTs, 206 women) ^[38] and one subsequent RCT. ^[42] The systematic review did not perform a meta-analysis for non- **tension-free vaginal tape** (non-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 identified by 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%] women cured in both groups; RR and CI not reported). The second RCT identified by 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 identified by the review (34 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 identified by the review (20 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; RR 0.17, 95% CI 0.01 to 3.08). The review reported the short-term results of the fifth RCT (36 women), ^[38] and long-term follow-up was reported in a subsequent publication. ^[35] 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 (failure to cure at 3 months: 0/17 [0%] with sling v 2/19 [10%] with colposuspension; RR 0.22, 95% CI 0.01 to 4.33; failure to cure at 6 years: 0/13 [0%] with sling v 2/15 [13%] with colposuspension; RR 0.23, 95% CI 0.01 to 4.37). The subsequent RCT (655 women) found that non-TVT suburethral autologous sling was significantly more effective than open retropubic colposuspension at 2 years' follow-up (success of overall urinary incontinence measures: 153/326 [47%] with autologous sling v 125/329 [38%] with Burch colposuspension; P less than 0.01; specific urinary incontinence measures: 215/326 [66%] with autologous sling v 161/329 [49%] with Burch colposuspension; P less than 0.001). ^[42]

Suburethral slings other than TVT versus laparoscopic colposuspension:

We found one systematic review (search date 2004), which found no RCTs comparing non-TVT slings versus **laparoscopic colposuspension**. ^[38]

Suburethral slings other than TVT versus needle suspension:

We found one systematic review (search date 2004, 1 RCT, 20 women). ^[38] 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. All women in the RCT had vaginal narrowing secondary to either previous interventions or atrophic vaginitis. ^[38]

Suburethral slings other than TVT versus tension-free vaginal tape:

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

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. ^[45] 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 less than 0.01). ^[45]

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). ^[38] 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). ^[46] 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). ^[38] One subsequent

RCT ^[42] found that the non-TVT suburethral autologous sling was associated with significantly more adverse effects, such as urinary tract infection, difficulty with voiding and postoperative urge incontinence, compared with open retropubic colposuspension (adverse effects at 2 years: 206/326 [63%] with suburethral autologous sling v 156/329 [47%] with open retropubic colposuspension; P = 0.001) but there was no difference in severe adverse effects such as genito-urinary injury, recurrent cystitis, voiding dysfunction leading to surgical revision, and abdominal wound complication requiring surgical intervention (severe adverse effects at 2 years: 42/326 [13%] with suburethral autologous sling v 32/329 [10%] with open retropubic colposuspension; P = 0.2)

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 less than 0.001; wound infection and urinary infection: 7/10 [70%] with sling v 0/10 [0%] with needle suspension; P less than 0.001; pulmonary embolus: 1/10 [1%] with sling v 0/10 [0%] with needle suspension). ^[47]

Suburethral slings other than TVT versus tension-free vaginal tape:

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

Comment: The data presented in the systematic review ^[38] were originally reported in another systematic review, ^[48] which was amended in 2005 and divided into two separate reviews: one on traditional suburethral sling operations, ^[38] which is included in the current review, and another on suburethral self-fixing sling operations (to include the new TVT and SPARC procedure) which has not yet been published.

OPTION TENSION-FREE VAGINAL TAPE

Cure of incontinence

Compared with open retropubic colposuspension Tension-free vaginal tape (TVT) and open retropubic colposuspension may be equally effective at curing incontinence at up to 2 years in women with stress incontinence ([very low-quality evidence](#)).

Compared with suburethral slings Tension-free vaginal tape and suburethral slings may be equally effective at curing incontinence at 6 months in women with stress incontinence ([low-quality evidence](#)).

Compared with transobturator foramen procedures TVT and transobturator foramen procedures are equally effective at curing incontinence in women with stress incontinence ([high-quality evidence](#)).

Improvement of incontinence

Compared with laparoscopic colposuspension TVT may be more effective at 18 months at improving objective measures of incontinence in women with stress or mixed urinary incontinence compared with laparoscopic colposuspension using sutures or mesh ([moderate-quality evidence](#)).

Quality of life

Compared with no treatment TVT may be more effective at improving Incontinence Quality of Life scores in elderly women with stress incontinence ([very low-quality evidence](#))

Adverse effects

TVT is associated with a higher incidence of bladder perforation than open retropubic colposuspension and transobturator foramen procedures, but a lower incidence of postoperative fever than open retropubic colposuspension, and of groin/thigh pain than transobturator foramen procedures. The risks of perioperative complications and de novo detrusor overactivity may be similar between TVT and laparoscopic colposuspension.

Note

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

For GRADE evaluation of interventions for stress incontinence, see [table , p 30](#) .

Benefits: Tension-free vaginal tape (TVT) versus no treatment:

We found one RCT (69 women, aged over 70 years). ^[49] It found a significant improvement in Incontinence Quality of Life (I-QOL) scores in elderly women at 6 months' follow-up following immediate TVT surgery compared with waiting for 6 months with no treatment prior to surgery (58

women; mean change in I-QOL scores from baseline [higher scores indicating better quality of life, maximum score 110]: from 57.8 to 96.5 with TVT v from 58.9 to 61.6 with no treatment; P less than 0.0001; no analysis to treat performed).

TVT versus 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:

We found one systematic review (search date 2002), which found no RCTs, ^[50] and one subsequent RCT. ^[51] The subsequent RCT (53 women) found similar subjective cure rates between 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). ^[51] The RCT was small, so it is possible that it was underpowered to detect a small but clinically important difference in cure rates between groups.

TVT versus open retropubic colposuspension:

We found one systematic review (search date 2002, 2 RCTs). ^[50] The review did not pool the data. The review found no significant difference between TVT and **open retropubic colposuspension** in cure rates at 6 months in one RCT (344 women) (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). ^[50] However, the RCT was weakened by differential withdrawal from the two groups after randomisation (5 in the TVT group v 23 in the open retropubic colposuspension group). ^[50] 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). ^[52] 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 (33%). 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. ^[52] 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). ^[53] 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 less than 0.05). Participants in the RCT were allocated into groups alternately, rather than by true randomisation. ^[53] The review identified two further RCTs, which did not assess cure rates. ^[50]

TVT versus laparoscopic colposuspension:

We found one systematic review (search date 2007, 8 RCTs comparing laparoscopic colposuspension [using sutures or mesh] with newer "self-fixing" sling procedures [TVT or SPARC slings]). ^[36] The review pooled the data for all techniques and materials, and also reported a subgroup analysis for laparoscopic colposuspension using sutures versus TVT, laparoscopic colposuspension using mesh versus TVT and laparoscopic colposuspension versus SPARC. It found no significant difference in self-reported cure rates at 18 months between TVT and laparoscopic colposuspension using sutures, but did find a significant improvement in self-reported cure rates at 18 months with TVT versus laparoscopic colposuspension using mesh (subjective cure rate: 3 RCTs; 74/102 [73%] with TVT v 70/94 [74%] with laparoscopic colposuspension [sutures]; RR [for the comparison laparoscopic colposuspension [sutures] v TVT] 1.01, 95% CI 0.86 to 1.19; subjective cure rate: 1 RCT; 58/70 [83%] with TVT v 30/51 [59%] with laparoscopic colposuspension [mesh]; RR [for the comparison laparoscopic colposuspension [mesh] v TVT] 0.71, 95% CI 0.55 to 0.91). The review found a significant but modest increase in objective cure rates at 18 months with TVT compared with laparoscopic colposuspension using either sutures or mesh (objective cure rate: 179/198 [90%] with TVT v 163/196 [83%] with laparoscopic colposuspension [sutures]; RR [for the comparison laparoscopic colposuspension [sutures] v TVT] 0.92, 95% CI 0.85 to 0.99; objective cure rate: 60/70 [86%] with TVT v 29/51 [57%] with laparoscopic colposuspension [mesh]; RR [for the comparison laparoscopic colposuspension [mesh] v TVT] 0.66, 95% CI 0.51 to 0.86). ^[36]

TVT versus needle suspension:

One systematic review (search date 2002) found no RCTs. ^[50] We found no subsequent RCTs.

TVT versus transobturator foramen procedures:

See [benefits of transobturator foramen procedures, p 19](#) .

Harms:

We found one systematic review (search date 2007) comparing complication rates of tension-free midurethral slings with other surgical procedures and devices.^[44]

TVT versus no treatment:

The RCT reported the following complications in the immediate TVT surgery group: intra-operative complication of bladder perforation (7/31 [23%]), postoperative complication of urinary retention (4/31 [13%]), and other complications of urinary tract infection (1/31 [3%]) and de novo urgency (1/31 [3%]).^[49] Complications were not reported for the no-treatment waiting group.

TVT versus 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 earlier review reported that the principal operative complication with TVT was bladder perforation.^[50] The subsequent RCT^[51] 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). The later systematic review^[44] identified four RCTs, including the subsequent RCT^[51] comparing complication rates with TVT versus pubovaginal slings. The RCTs were all small and described as low quality. The results of only two RCTs were pooled because of heterogeneity between studies and reported complications. The review found that voiding lower urinary tract symptoms and clean intermittent catheterisation were not significantly different between TVT and pubo-vaginal slings (2 RCTs; AR of voiding lower urinary tract symptoms: 9/99 [9%] with TVT v 6/102 [6%] with pubo-vaginal slings; OR 1.57, 95% CI 0.54 to 4.61; AR of clean intermittent catheterisation: 7/99 [7%] with TVT v 4/102 [4%] with pubo-vaginal slings; OR 1.79, 95% CI 0.50 to 6.40).

TVT versus open retropubic colposuspension:

The later systematic review identified 10 RCTs including the two RCTs from the earlier review.^[44] It found that bladder/vaginal perforations were significantly more common with TVT than with open retropubic colposuspension (6 RCTs; AR of bladder/vaginal perforations: 31/333 [9%] with TVT v 5/320 [2%] with open retropubic colposuspension; OR 5.35, 95% CI 2.27 to 12.63) while re-operation rates were significantly less common with TVT than open retropubic colposuspension (2 RCTs; AR of re-operation: 4/211 [2%] with TVT v 16/205 [8%] with open retropubic colposuspension; OR 0.29, 95% CI 0.10 to 0.80). There were no significant differences between procedures in complications such as haematoma formation (4 RCTs; AR of haematoma formation: 5/270 [1.9%] with TVT v 4/263 [1.5%] with open retropubic colposuspension; OR 1.16, 95% CI 0.37 to 3.66), urinary tract infection (5 RCTs; AR of urinary tract infection: 15/337 [4%] with TVT v 9/313 [3%] with open retropubic colposuspension; OR 1.65, 95% CI 0.72 to 3.81), storage lower urinary tract symptoms (7 RCTs; AR of storage lower urinary tract symptoms: 91/396 [23%] with TVT v 74/372 [20%] with open retropubic colposuspension; OR 1.31, 95% CI 0.90 to 1.90) or voiding lower urinary tract symptoms (8 RCTs; AR of voiding lower urinary tract symptoms: 57/428 [13%] with TVT v 63/384 [16%] with open retropubic colposuspension; OR 0.81, 95% CI 0.54 to 1.22).

TVT versus laparoscopic colposuspension:

The review found no significant difference in the proportion of perioperative complications between laparoscopic colposuspension using sutures or mesh and TVT (5 RCTs; 16/170 [9%] with laparoscopic colposuspension [sutures] v 19/180 [11%] with TVT; RR 0.88, 95% CI 0.48 to 1.60; 1 RCT; 7/51 [14%] with laparoscopic colposuspension [mesh] v 5/70 [7%] with TVT; RR 1.92, 95% CI 0.65 to 5.71).^[36] 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 using sutures and TVT (8/165 [5%] with laparoscopic colposuspension [sutures] v 10/161 [6%] with TVT; RR 0.80, 95% CI 0.34 to 1.88).^[36]

TVT versus needle suspension:

We found no RCTs.

TVT versus transobturator foramen procedures:

See [harms of transobturator foramen procedures, p 19](#) .

Observational data:

Observational reports found that complications associated with TVT include death (10 deaths associated with TVT; ^[54] 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, ^[55] ^[56] ^[57] ^[58] ^[59] ^[60] ^[61] ^[62] necrotising fasciitis, ^[63] ^[64] Fournier's gangrene, ^[65] urethrovaginal fistula, ^[66] and nerve injuries, ^[55] ^[63] 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. ^[55] TVT might eventually erode into the bladder, ^[55] ^[67] ^[68] 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 ^[69] ^[70] ^[71] ^[72] ^[73] ^[74] ^[75] incisional hernia of the inguinal canal ^[76] and urethral diverticulum. ^[77]

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 OR TVT-O)**Cure of incontinence**

Compared with tension-free vaginal tape (TVT) Transobturator foramen procedures are as effective as TVT at increasing cure rates (**high-quality evidence**).

Compared with open retropubic colposuspension Transobturator foramen procedures seem as effective at 12 months at curing incontinence (**moderate-quality evidence**).

Adverse effects

Transobturator foramen procedures are associated with a lower incidence of bladder injuries, retropubic haematoma, and voiding difficulties than TVT, but a higher incidence of groin/thigh pain. Transobturator foramen procedures may have similar rates of postoperative complications as open retropubic colposuspension.

Note

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

For GRADE evaluation of interventions for stress incontinence, see table , p 30 .

Benefits: Transobturator foramen procedures versus no treatment or sham treatment:

We found no RCTs.

Transobturator foramen procedures versus tension-free vaginal tape (TVT):

We found two systematic reviews (search date 2006, ^[78] search date 2006 ^[79]). Four RCTs were identified by both reviews. We found three subsequent RCTs. ^[80] ^[81] ^[82]

The first systematic review identified six RCTs (492 women). It found no significant difference in subjective failure of treatment (defined as women reporting being unchanged or worse after the procedure) with **transobturator tape (TOT)** versus **TVT** (5 RCTs; subjective failure: 12/210 [6%] with TOT v 17/217 [8%] with TVT; pooled OR 0.85, 95% CI 0.38 to 1.92). ^[78] The follow-up time varied between studies (from short-term [absolute numbers not reported] to 15 months). The second systematic review (11 RCTs including 4 RCTs identified by the first review, and 1 RCT ^[83] excluded from the first review because it was retracted from the journal because of reason of ethics; ^[84] 1261 women) found no significant difference in subjective cure with transobturator procedures including TOT and **tension-free vaginal tape obturator route (TVT-O)** versus TVT at 2–12 months' follow-up (547/633 [86%] with TOT and TVT-O v 559/630 [89%] with TVT; OR 0.85, 95% CI 0.60 to 1.21). ^[79]

The first subsequent RCT (72 women with stress urinary incontinence) found no significant difference in cure of stress incontinence (defined as no leakage of urine during urodynamic testing) between TVT-O and TVT at 12 months' follow-up (proportion of women cured at 12 months: 33/37 [89%] with TVT-O v 32/35 [91%] with TVT; reported as not significant, P value not reported). ^[80] The second subsequent RCT (148 women) found no significant difference in cure of stress incontinence (defined as "dry" [no leakage during clinical, stress test, reported by patients, or a combination]) between TVT-O and TVT (proportion of women with objective cure at 12 months: 58/75 [77%] with TVT-O v 52/73 [71%] with TVT; P value not reported, reported as not significant). ^[81] The third subsequent RCT (180 women) found no significant difference between TOT and TVT in the composite outcome of abnormal bladder function (incorporating presence of incontinence symptoms,

a positive cough stress test or retreatment for stress incontinence or postoperative urinary retention) at 12 months' follow-up (proportion of women with abnormal bladder function: 35/82 [43%] with TOT v 41/88 [47%] with TVT; absolute mean difference +3.9, 95% CI -11 to +18.6).^[82]

Transobturator foramen procedures versus open retropubic colposuspension:

We found one RCT (101 women).^[43] It found no significant difference between TOT and open retropubic colposuspension in cure of stress incontinence at 1-year' follow-up (subjective cure of stress incontinence: 42/49 [86%] with TOT v 43/51 [85%] with open retropubic colposuspension; P = 0.8; objective cure of stress incontinence: 43/49 [75%] with TOT v 41/51 [80%] with open retropubic colposuspension; P = 0.4).^[43]

Transobturator foramen procedures versus laparoscopic colposuspension:

We found no RCTs.

Transobturator foramen procedures versus other treatments:

We found no RCTs.

Harms:

Transobturator foramen procedures versus no treatment or sham treatment:

We found no RCTs.

Transobturator foramen procedures versus TVT:

The first systematic review found a significantly lower proportion of perioperative complications such as bladder perforations, haematoma and infection with TOT compared with TVT (2/241 [1%] with TOT v 30/246 [12%] with TVT; pooled OR 0.21, 95% CI 0.10 to 0.44).^[78] The second systematic review found that adverse effects such as bladder injuries (0/575 [0%] with TOT v 20/588 [3%] with TVT; OR 0.12, 95% CI 0.05 to 0.33) and voiding difficulties (18/453 [4%] with TOT v 32/455 [7%] with TVT; OR 0.55, 95% CI 0.31 to 0.98) were significantly less common, whereas groin/thigh pain (27/224 [12%] with TOT v 3/219 [1%] with TVT; OR 8.28, 95% CI 2.7 to 25.4) was significantly more common after TOT and TVT-O than TVT at 2–12 months.^[79] There was no significant difference in the incidence of de novo urgency (35/325 [10.8%] with TOT v 37/324 [11.4%] with TVT; OR 0.89, 95% CI 0.54 to 1.46) or vaginal injuries or erosion of mesh (16/578 [3%] with TOT v 7/572 [1%] with TVT; OR 1.51, 95% CI 0.51 to 4.43).

We found another systematic review^[44] (search date 2007, 14 RCTs including 8 RCTs identified by the first^[78] and second^[79] systematic reviews) comparing complication rates of tension-free midurethral slings with other surgical procedures and devices. This systematic review found that bladder/vaginal perforations, retropubic haematoma, storage and voiding lower urinary tract symptoms were significantly less common with transobturator slings compared with retropubic tension-free midurethral slings (TVT and vaginal suburethral slingplasty [SPARC]) (AR of bladder/vaginal perforations: 12/654 [2%] with transobturator sling v 31/661 [5%] with retropubic tension-free midurethral slings; OR [for the comparison retropubic tension-free midurethral slings v transobturator sling] 2.33, 95% CI 1.26 to 4.32; AR of retropubic haematoma: 0/537 [0%] with transobturator sling v 9/547 [2%] with retropubic tension-free midurethral slings; OR [for the comparison retropubic tension-free midurethral slings v transobturator sling] 4.83, 95% CI 1.22 to 19.2; AR of storage lower urinary tract symptoms: 36/417 [7%] with transobturator sling v 53/412 [13%] with retropubic tension-free midurethral slings; OR [for the comparison retropubic tension-free midurethral slings v transobturator sling] 1.81, 95% CI 1.13 to 2.91; AR of voiding lower urinary tract symptoms: 23/422 [6%] with transobturator sling v 46/427 [11%] with retropubic tension-free midurethral slings; OR [for the comparison retropubic tension-free midurethral slings v transobturator sling] 2.30, 95% CI 1.34 to 3.95). There were no significant differences in complications such as urinary tract infection and vaginal erosions. The first subsequent RCT was included in the meta-analysis of this review and is not discussed separately.^[80]

The second subsequent RCT found no significant difference in complications between TVT-O and TVT (overall perioperative complication rates: 14/75 [19%] with TVT-O v 13/73 [18%] with TVT; P value not reported, reported as not significant).^[81] The third subsequent RCT^[82] found that bladder perforations occurred less frequently with TOT compared with TVT (0/82 [0%] with TOT v 7/88 [8%] with TVT; P = 0.02).^[82]

Transobturator foramen procedures versus open retropubic colposuspension:

The RCT^[43] found no significant difference between TOT and open retropubic colposuspension in complications of postoperative urinary retention (defined as greater than 100 mL after day 2) (1/49 [2%] with TOT v 3/51 [6%] with open retropubic colposuspension; P = 0.3), postoperative urinary infection (1/49 [2.0%] with TOT v 1/51 [1.9%] with open retropubic colposuspension; P = 0.9), de novo voiding difficulties (1/49 [2%] with TOT v 3/51 [6%] with open retropubic colposuspension; P = 0.3) and de novo urge incontinence (1/49 [2%] with TOT v 3/51 [6%] with open retropubic colposuspension; P = 0.3) between the two groups.^[43]

Transobturator foramen procedures versus laparoscopic colposuspension:

We found no RCTs.

Transobturator foramen procedures versus other treatments:

We found no RCTs.

Observational data:

Case reports found that TOT was associated with retropubic haematoma,^[85] vulvar haematoma,^[86] urethral erosion and infected obturator haematoma,^[87] tape erosion into the vagina^[88] ^[89] accompanied by ischioanal abscess^[90] or infected mesh and severe leg pain,^[91] bladder erosion,^[92] perineal cellulitis,^[93] large abscesses of the thigh^[94] and psoas muscle,^[95] necrotising fasciitis^[96], and vesico-vaginal fistula.^[97] Case reports found that TVT-O was associated with nerve damage^[98] and osteomyelitis.^[99]

Comment: TOT has been separated from traditional suburethral sling operations and TVT because the operative procedure is substantially different. We found one case report in French of vesico-vaginal fistula with TOT.^[100] We are awaiting translation of this report, and will assess it for potential inclusion after translation.

OPTION	ANTERIOR VAGINAL REPAIR (ANTERIOR COLPORRHAPHY)
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Cure of incontinence

Compared with open retropubic colposuspension Anterior vaginal repair is less effective at up to 5 years at leading to cure of incontinence in women ([high-quality evidence](#)).

Compared with needle suspension Anterior vaginal repair and needle suspension are equally effective at 12 months at curing incontinence in women ([high-quality evidence](#)).

Adverse effects

Overall operative complications are similar between anterior vaginal repair and open retropubic colposuspension in women with incontinence.

Note

We found no direct information about whether anterior vaginal repair is better than no active treatment. We found no clinically important results from RCTs 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 30 .

Benefits: We found one systematic review (search date 2007) on [anterior vaginal repair](#).^[37]

Anterior vaginal repair versus no treatment or sham treatment:

The review identified no RCTs.^[37]

Anterior vaginal repair versus non-surgical treatment:

The review identified one RCT (50 women), comparing 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.^[37]

Anterior vaginal repair versus suburethral slings:

The review identified no RCTs comparing anterior vaginal repair versus [suburethral slings](#).^[37]

Anterior vaginal repair versus open retropubic colposuspension:

The review identified eight RCTs (929 women).^[37] It found that anterior vaginal repair was significantly less effective than [open retropubic colposuspension](#) at 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).

Anterior vaginal repair versus laparoscopic colposuspension:

The review identified no RCTs comparing anterior vaginal repair versus [laparoscopic colposuspension](#).^[36] ^[37]

Anterior vaginal repair versus needle suspension:

The review identified three RCTs (549 women).^[37] It found no significant difference between anterior vaginal repair and [needle suspension](#) in cure rates within 12 months (2 RCTs; 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.^[37]

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).^[37]

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.^[37] An earlier systematic review (search date 1995) found one non-randomised study assessing complications after surgery.^[45] The review reported that anterior vaginal repair caused fewer major complications than needle suspension (no further data reported).^[45]

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****Cure of incontinence**

Compared with open retropubic colposuspension Needle suspension seems less effective at 5 years at curing incontinence ([moderate-quality evidence](#)).

Compared with suburethral slings Needle suspension and suburethral slings seem equally effective after 1 year at curing incontinence ([low-quality evidence](#)).

Compared with anterior vaginal repair Needle suspension and anterior vaginal repair are equally effective at 12 months at curing incontinence ([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 from RCTs 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 30](#) .

- Benefits:**
- Needle suspension versus no treatment, sham treatment, or non-surgical treatment:**
We found one systematic review (search date 2005), which found no RCTs. ^[101]
 - Needle suspension versus anterior vaginal repair:**
See benefits of anterior vaginal repair, p 21 .
 - Needle suspension versus suburethral slings:**
See benefits of suburethral slings, p 14 .
 - Needle suspension versus open retropubic colposuspension:**
See benefits of open retropubic colposuspension, p 12 .
 - Needle suspension versus laparoscopic colposuspension:**
See benefits of laparoscopic colposuspension, p 11 .
 - Needle suspension versus tension-free vaginal tape:**
See benefits of tension-free vaginal tape, p 16 .
- 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 21 .
 - Needle suspension versus suburethral slings:**
See harms of suburethral slings, 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.

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.

Tension-free vaginal tape obturator route (TVT-O) This procedure is similar to transobturator tape (TOT) except that it uses an inside-out insertion technique, rather than the outside-in technique used with TOT; a needle is passed in through a vaginal incision and out through the obturator foramen.

Transobturator foramen procedures (TOT or TVT-O) 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.

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

SUBSTANTIVE CHANGES

Laparoscopic colposuspension Four systematic reviews updated. ^[36] ^[37] ^[38] ^[39] Reporting updated for one systematic review. ^[36] Categorisation unchanged (Beneficial).

Open retropubic colposuspension Four systematic reviews updated. ^[36] ^[37] ^[38] ^[39] One RCT added comparing open retropubic colposuspension versus suburethral slings other than tension-free vaginal tape. It found that non-TVTV suburethral autologous sling improved overall urinary incontinence and specific urinary incontinence measures at 2 years' follow-up compared with open retropubic colposuspension. ^[42] One RCT added, comparing open retropubic colposuspension with transobturator foramen procedures. It found no significant difference in cure of stress incontinence at 1-year' follow-up. ^[43] One systematic review comparing complications with open retropubic colposuspension versus tension-free vaginal tape added. It found that bladder/vaginal perforations were less common while re-operation rates were more common with open retropubic colposuspension. It found no significant differences between procedures in complications such as haematoma formation, urinary tract infection, storage, or voiding lower urinary tract symptoms. ^[44] Categorisation unchanged (Beneficial).

Pelvic floor muscle exercises Four systematic reviews updated. ^[8] ^[25] ^[28] ^[30] One systematic review ^[28] reporting updated and one systematic review ^[25] now includes one further RCT. Categorisation unchanged (Likely to be beneficial)

Tension-free vaginal tape (TVT) One systematic review updated. ^[36] One RCT added, found improved Incontinence Quality of Life scores in elderly women with TVT versus no treatment after 6 months. ^[49] Two systematic reviews ^[78] ^[79] and three RCTs ^[80] ^[81] ^[82] added, found no significant difference in failure of treatment or cure with TVT versus transobturator procedures. One systematic review comparing complications with suburethral slings versus TVT added. It found no significant difference in voiding lower urinary tract symptoms and clean intermittent catheterisation between TVT and pubo-vaginal slings. ^[44] Observational data added to harms section. Categorisation unchanged (Trade off between benefits and harms).

Vaginal cones One systematic review updated ^[25] to now include one further RCT. Categorisation unchanged (Likely to be beneficial).

Non-tension-free vaginal tape/transobturator foramen tape suburethral slings One systematic review updated. ^[38] One RCT added comparing suburethral slings other than tension-free vaginal tape (TVT) versus open retropubic colposuspension, found that non-TVTV suburethral autologous sling improved overall urinary incontinence and specific urinary incontinence measures at 2 years' follow-up compared with open retropubic colposuspension. ^[42] One systematic review added, comparing complications with suburethral slings versus TVT, found no significant difference in voiding lower urinary tract symptoms and clean intermittent catheterisation between TVT and pubo-vaginal slings. ^[44] Categorisation changed (Beneficial).

Serotonin reuptake inhibitors (duloxetine) One systematic review ^[8] updated to now include one further RCT. One subsequent RCT added, which found reduced incontinence episode frequency but no significant improvement in quality of life with duloxetine compared with placebo. ^[10] Categorisation changed (Beneficial to Likely to be beneficial).

Transobturator foramen procedures Two systematic reviews ^[78] ^[79] and three RCTs ^[80] ^[81] ^[82] added, comparing transobturator foramen procedures (TOT or TVT-O) versus tension-free vaginal tape (TVT), found no significant difference between procedures in failure of treatment or cure. One systematic review comparing complications of transobturator foramen procedures (TOT or TVT-O) versus TVT added. ^[44] It found a lower incidence of bladder and vaginal perforations, haematoma, and storage and voiding lower urinary tract symptoms with transobturator foramen procedures (TOT or TVT-O) versus TVT. One RCT added, comparing TOT versus open retropubic colposuspension, found no significant difference between TOT and open retropubic colposuspension in cure of stress in-

continence at 1-year' follow-up.^[43] Observational data added to harms section. Categorisation changed (from Unknown effectiveness to Likely to be beneficial).

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Joseph Loze Onwude

Consultant Gynaecologist and Medical Statistician
Springfield Hospital
Chelmsford
UK

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TABLE 1 Effects of serotonin reuptake inhibitors versus placebo or no treatment for the treatment of stress incontinence (see text).^{[11] [17] [9] [12] [13] [14] [15] [16] [10]}

Reference	Population	Comparison	Timeline	Results
<i>Median percentage decrease in IEF</i>				
[8]	1 RCT, 201 women (total 92 in these comparison groups) ^[17]	Duloxetine 80 mg daily v placebo plus imitation PFME	12 weeks	57% with duloxetine v 29% with placebo; absolute numbers NR; P = 0.05
[8]	1 RCT, 109 women ^[12]	Duloxetine 80 mg daily for 4 weeks v placebo	4 weeks	55% with duloxetine v 26% with placebo; P less than 0.002
[8]	1 RCT, 109 women ^[12]	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 less than 0.001
[8]	1 RCT, 109 women ^[12]	Duloxetine 120 mg v placebo	4 weeks	64% with duloxetine v 26% with placebo; P less than 0.01
[8]	1 RCT, 553 women ^[13]	Duloxetine 20 mg daily v placebo	12 weeks	44% with duloxetine v 40% with placebo; P less than 0.6
[8]	1 RCT, 553 women ^[13]	Duloxetine 80 mg daily v placebo	12 weeks	58% with duloxetine v 40% with placebo; P = 0.04
[8]	1 RCT, 683 women ^[14]	Duloxetine 80 mg daily v placebo	12 weeks	50% with duloxetine v 28% with placebo; P less than 0.001
[8]	1 RCT, 494 women ^[15]	Duloxetine 80 mg daily v placebo	12 weeks	50% with duloxetine v 29% with placebo; P = 0.002
[8]	1 RCT, 458 women ^[16]	Duloxetine 80 mg daily v placebo	12 weeks	54% with duloxetine v 40% with placebo; P = 0.05
[9]	1 RCT, 121 women with predominant urinary stress incontinence	Duloxetine 80 mg daily v placebo	4 weeks	50% with duloxetine v 37% with placebo; P = 0.033
[10]	1 RCT, 121 women with predominant urinary stress incontinence	Duloxetine 80 mg daily v placebo	8 weeks	70% with duloxetine v 43% with placebo; P less than 0.001
<i>Subjective number of women not cured</i>				
[8]	3 RCTs, 1396 women	Duloxetine 80 mg daily v placebo or no treatment	12 weeks	619/694 [89%] with duloxetine v 648/712 [91%] with placebo; RR 0.97, 95% CI 0.93 to 1.00; P = 0.04
[8]	1 RCT, 255 women	Duloxetine 40 mg daily v placebo or no treatment	12 weeks	93/123 [76%] with duloxetine v 112/132 [85%] with placebo or no treatment; RR 0.89, 95% CI 0.79 to 1.01; P = 0.07
[8]	1 RCT, 260 women	Duloxetine 20 mg daily v placebo or no treatment	12 weeks	107/128 [84%] with duloxetine v 112/132 [85%] with placebo or no treatment; RR 0.99, 95% CI 0.89 to 1.09; P = 0.8
<i>Objective number of women not cured (stress pad test)</i>				
[8]	1 RCT, 227 women	Duloxetine 80 mg daily v placebo or no treatment	12 weeks	69/113 [61%] with duloxetine v 72/114 [63%] with placebo or no treatment; RR 0.97, 95% CI 0.79 to 1.18; P = 0.7
[8]	1 RCT, 225 women	Duloxetine 40 mg daily v placebo or no treatment	12 weeks	63/111 [57%] with v 72/114 [63%] with placebo or no treatment; RR 0.90, 95% CI 0.73 to 1.11; P = 0.3
[8]	1 RCT, 224 women	Duloxetine 20 mg daily v placebo or no treatment	12 weeks	75/110 [68%] with duloxetine v 72/114 [63%] with placebo or no treatment; RR 1.08, 95% CI 0.89 to 1.30; P = 0.4
<i>Number of women not improved during treatment</i>				
[8]	4 RCTs, 1733 women	Duloxetine 80 mg daily v placebo or no treatment	8–12 weeks	394/864 [46%] with duloxetine v 534/869 [61%] with placebo or no treatment; RR 0.74, 95% CI 0.68 to 0.81; P less than 0.0001
[8]	1 RCT, 67 women	Duloxetine 40 mg daily v placebo or no treatment	6 weeks	18/33 [55%] with duloxetine v 29/34 [85%] with placebo or no treatment; RR 0.64, 95% CI 0.45 to 0.90; P = 0.01
[8]	1 RCT, 60 women	Duloxetine 30 mg daily v placebo or no treatment	6 weeks	10/26 [39%] with duloxetine v 29/34 [85%] with placebo or no treatment; RR 0.45, 95% CI 0.27 to 0.75; P = 0.002
[8]	2 RCTs, 160 women	Duloxetine 20 mg daily v placebo or no treatment	3–6 weeks	31/89 [35%] with duloxetine v 48/71 [68%] with placebo or no treatment; RR 0.55, 95% CI 0.40 to 0.75; P = 0.0001
<i>Overall improvement in I-QoL scored from 0 = worst to 100 = best possible quality of life</i>				

Reference	Population	Comparison	Timeline	Results
[8]	5 RCTs, 1835 women	Duloxetine 80 mg daily v placebo	8–12 weeks	Absolute data not reported; WMD 4.50, 95% CI 2.83 to 6.18; P less than 0.0001
[10]	1 RCT, 121 women	Duloxetine 80 mg daily v placebo	8 weeks	13.64 with duloxetine v 13.33 with placebo; P = 0.732
[9]	1 RCT, 121 women	Duloxetine 80 mg daily v placebo	4 weeks	14.77 with duloxetine v 8.71 with placebo; P = 0.066
<i>PGI-I status "very much better", "much better", or "a little better"</i>				
[8]	6 RCTs, 1879 women	Duloxetine 80 mg daily v placebo or no treatment	8–36 weeks	522/939 [56%] with duloxetine v 420/940 [45%] with placebo or no treatment; RR 1.25, 95% CI 1.14 to 1.36; P less than 0.0001

IEF, incontinence episode frequency; I-QoL, Incontinence Quality of Life scale; PFME, pelvic floor muscle exercises; PGI-I, Patient Global Impression of Improvement scale; NR, not reported.

TABLE 2 RCTs comparing pelvic floor electrical stimulation versus no treatment or sham treatment for the treatment of stress incontinence (see text, p 4). [19] [20] [21] [22] [23] [24]

Reference	Study design and population	Comparison	Outcomes	Results
[19]	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
[20]	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
[21]	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
[22]	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
[23]	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 less than 0.01 1.2 with PFES v 0 with no treatment; P less than 0.01
[24]	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; UDIQ, Urogenital Distress Inventory Questionnaire.

TABLE 3 Adrenoceptor agonists for the treatment of stress incontinence; results of a systematic review (see text, p 10).^[30]

Study design and population	Comparison	Results for subjective cure or improvement	Overall adverse effects
<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.			

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?										
At least 8 RCTs (at least 2587 people) [8]	Incontinence cure rates	SSRIs v placebo	4	0	0	0	0	0	High	
7 (2519) [11] [12] [13] [14] [15] [16] [17]	Incontinence frequency	SSRIs v placebo	4	0	+1	0	0	0	High	Consistency point added for evidence of dose response
7 (2077) [9] [10]	Quality of life	SSRIs v placebo	4	0	-1	0	0	0	Moderate	Consistency point deducted for conflicting results
1 (92) [17]	Incontinence frequency	SSRIs plus imitation pelvic floor exercises v pelvic floor exercises plus placebo	4	-1	0	0	0	0	Moderate	Quality point deducted for sparse data
1 (92) [17]	Quality of life	SSRIs plus imitation pelvic floor exercises v pelvic floor exercises plus placebo	4	-1	0	0	0	0	Moderate	Quality point deducted for sparse data
2 (112) [19] [23]	Incontinence frequency	Pelvic floor electrical stimulation v no treatment/sham stimulation	4	-1	0	0	0	0	Moderate	Quality point deducted for sparse data
3 (197) [21] [22]	Cure/improvement of incontinence	Pelvic floor electrical stimulation v no treatment/sham stimulation	4	-2	0	-1	0	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) [25]	Episodes of incontinence	Pelvic floor electrical stimulation v vaginal cones	4	-1	0	0	0	0	Moderate	Quality point deducted for sparse data
4 (274) [25]	Cure/improvement of incontinence	Pelvic floor electrical stimulation v vaginal cones	4	0	0	0	0	0	High	
1 (49) [26]	Cure/improvement of incontinence	Pelvic floor electrical stimulation v oestrogen supplements	4	-1	0	0	0	0	Moderate	Quality point deducted for sparse data
3 (165) [28]	Cure/improvement of incontinence	Pelvic floor muscle exercises v no treatment	4	-1	0	0	0	0	Moderate	Quality point deducted for sparse data
2 (163) [17] [29]	Incontinence frequency	Pelvic floor muscle exercises v no treatment	4	-1	-1	0	0	0	Low	Quality point deducted for sparse data. Consistency point deducted for different results
7 (661) [25]	Cure/improvement of incontinence	Pelvic floor muscle exercises v vaginal cones	4	0	0	0	0	0	High	
2 RCTs [25]	Incontinence frequency	Pelvic floor muscle exercises v vaginal cones	4	-1	0	0	0	0	Moderate	Quality point deducted for incomplete reporting of results
1 (69) [26]	Cure/improvement of incontinence	Pelvic floor muscle exercises v oestrogen supplements	4	-1	0	0	0	0	Moderate	Quality point deducted for sparse data
2 (191) [30]	Cure/improvement of incontinence	Pelvic floor muscle exercises v adrenoceptor agonists	4	-1	-1	0	0	0	Low	Quality point deducted for sparse data. Consistency point deducted for different results
2 (252) [25]	Cure/improvement of incontinence	Vaginal cones v no active treatment	4	0	0	0	0	0	High	
2 (252) [25]	Incontinence frequency	Vaginal cones v no active treatment	4	0	0	0	0	0	High	

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
	15 (718) ^[26]	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) ^[31]	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) ^[30]	Cure/improvement of incontinence	Oestrogen supplements v adrenoceptor agonists	4	-1	0	0	0	Moderate	Quality point deducted for sparse data
	4 (276) ^[30]	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?										
	12 (at least 1285 people) ^{[36] [40] [41]}	Cure/improvement of incontinence	Open retropubic colposuspension v Laparoscopic colposuspension	4	0	0	0	0	High	
	8 (at least 515 people) ^[36]	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 (97) ^[39]	Cure of incontinence	Open retropubic colposuspension v pelvic floor muscle exercises/stimulation	4	-3	0	0	0	Very low	Quality points deducted for sparse data, and for non-reporting of method of randomisation and number of withdrawals
	8 (929) ^[37]	Cure of incontinence	Open retropubic colposuspension v anterior vaginal repair	4	0	0	0	0	High	
	5 (206) ^[48]	Cure of incontinence	Open retropubic colposuspension v suburethral sling	4	0	0	0	0	High	
	7 (570) ^[39]	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) ^[50]	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 (101) ^[43]	Cure of incontinence	Open retropubic colposuspension v transobturator foramen procedure	4	-1	0	0	0	Moderate	Quality points deducted for sparse data
	1 (20) ^[48]	Cure of incontinence	Suburethral sling v needle suspension	4	-1	0	-1	0	Low	Quality point deducted for sparse data. Directness point deducted for population restricted to women with vaginal narrowing secondary to either previous interventions or atrophic vaginitis
	1 (53) ^[51]	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
	At least 14 RCTs (at least 1661 people) ^{[78] [79] [80] [81] [82]}	Cure of incontinence	Tension-free vaginal tape v transobturator foramen procedures	4	0	0	0	0	High	

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
	1 (69) ^[49]	Quality of life	Tension-free vaginal tape v no treatment	4	-2	0	-1	0	Very low	Quality point deducted for sparse data and no intention to treat analysis. Directness point deducted for population restricted to elderly women
	2 (469) ^[37]	Cure of incontinence	Anterior vaginal repair v needle suspension	4	0	0	0	0	High	

Type of evidence: 4 = RCT; 2 = Observational
 Consistency: similarity of results across studies
 Directness: generalisability of population or outcomes
 Effect size: based on relative risk or odds ratio

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