

Traditional suburethral sling operations for urinary incontinence in women (Review)

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[Intervention Review]

Traditional suburethral sling operations for urinary incontinence in women

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ABSTRACT

Background

Traditional suburethral slings are surgical operations used to treat women with symptoms of stress urinary incontinence.

Objectives

To determine the effects of traditional suburethral slings on stress incontinence alone or stress with other types of urinary (mixed) incontinence in comparison with other management options.

Search strategy

We searched the Cochrane Incontinence Group Specialised Trials Register (searched 22 December 2004), The UK National Research Register (Issue 1, 2001) and the reference lists of relevant articles. We hand searched the proceedings of the Brazilian Congress of Urology from 1991 to 2003, inclusive.

Selection criteria

Randomised or quasi-randomised trials that included traditional suburethral slings for the treatment of stress or mixed urinary incontinence.

Data collection and analysis

All three reviewers independently extracted data from included trials onto a standard form and assessed trial methodological quality. The data abstracted were relevant to predetermined outcome measures. Where appropriate, a summary statistic was calculated: a relative risk for dichotomous data and a weighted mean difference for continuous data.

Main results

Thirteen trials were identified including 760 women of whom 627 were treated with suburethral slings. Five compared suburethral slings with open abdominal retropubic colposuspension (Burch/Marshall-Marchetti-Krantz) and one compared suburethral slings with needle suspension (Stamey). In six trials, different types of suburethral sling were compared with each other. Nine types of slings were included (Teflon, polytetrafluoroethylene, prolene used for transvaginal tape (TVT), porcine dermis, lyophilised dura mater, fascia lata,

vaginal wall, autologous dermis and rectus fascia). There were no comparisons of suburethral sling with anterior repair, laparoscopic retropubic suspension, peri-urethral injections or artificial sphincters. One trial compared surgery (including slings) with anticholinergic medication.

There were no statistically significant differences between traditional slings and other types of continence surgery, or between one type of traditional sling and another sling. Confidence intervals around the estimates were wide, reflecting the few data available, and so clinically important differences could not be ruled out.

Authors' conclusions

The data on sub urethral sling operations remain too few to address the effects of this type of surgical treatment. Few trials are reported by authors in a complete fashion and most information came from abstracts presented in annual meetings. The broader effects of suburethral slings could not be established since trials did not include appropriate outcome measures such as general health status, health economics, pad testing, third party analysis and time to return to normal activity level. Data obtained from thirteen trials did not provide reliable estimates because of their sizes, and heterogeneity of designs, populations studied, and types of comparisons made.

Reliable evidence on which to judge whether or not suburethral slings are better or worse than other surgical or conservative management is currently not available.

PLAIN LANGUAGE SUMMARY

traditional sling operations for urinary incontinence in women

Stress urinary incontinence is loss of urine when coughing, laughing, sneezing or exercising. Damage to the muscles that hold up the bladder, and injuries to the nerves during childbirth, may be causes. Traditional sling operations are used to treat women with this condition. They aim to hold up the bladder with a strip of material which may be biological or synthetic. The results showed that there is not enough information on which to judge whether traditional sling operations are better or worse than any other treatments. Long term results are awaited. In this review there were few trials comparing slings with other forms of surgery and only one study comparing sling operations with non-surgical treatment.

BACKGROUND

The prevalence of urinary incontinence in adult women has been estimated to be between 10% to 40% of adult women, which is considered severe in about 3% to 17% (Hunnskaar 2002). This is a potentially debilitating social problem which leads to high health care costs, estimated in billions of dollars in the United States (Fantl 1996).

Continence is achieved through an interplay of the normal anatomical and physiological properties of the bladder, urethra and sphincter, pelvic floor and the nervous system co-ordinating these organs. The active relaxation of the bladder coupled by the ability of the urethra and sphincter to contain urine within the bladder by acting as a closure mechanism during filling, allow storage of urine until an appropriate time and place to void is reached. The role of the pelvic floor in providing support to the bladder and urethra, and allowing normal abdominal pressure transmission to the proximal urethra is also considered essential in the maintenance of continence. Crucial to the healthy functioning of the bladder,

urethra, sphincter and pelvic floor is coordination between them, facilitated by an intact nervous system control.

Incontinence occurs when this normal relationship between the lower urinary tract components is disrupted, resulting from nerve damage or direct mechanical trauma to the pelvic organs. Advancing age, higher parity, vaginal delivery, obesity and menopause are associated with an increase in risk (Wilson 1996).

There are different types of urinary incontinence. Stress urinary incontinence is the most common type (Wilson 1996). The symptom of 'stress incontinence' is the involuntary loss of urine from the urethra during physical activities that increase abdominal pressure, in the absence of a detrusor (bladder wall muscle) contraction or an over-distended bladder (Blaiivas 1997a). Two mechanisms for stress incontinence are recognised: hyper-mobility or significant displacement of the urethra and bladder neck during exertion, and intrinsic urethral sphincter deficiency (Blaiivas 1988). In women, these mechanisms may co-exist (O'Donnell 1994). Few clinical

trials have distinguished between the two conditions, probably because there is no standardised and validated test available to date (Blaivas 1988; McGuire 1993). Women whose incontinence may be due to either of these two mechanisms will be considered together in this review.

The diagnosis of 'urodynamic stress incontinence' requires urodynamic investigation to exclude detrusor overactivity, in addition to history taking, physical examination, frequency/volume charts and urine analysis. Some authors have described women with only the symptom of stress incontinence (diagnosis made on clinical evaluation without urodynamics). Women with stress incontinence both with and without urodynamic investigation will be included in this review.

'Urge incontinence' is the symptom of involuntary loss of urine associated with a sudden, strong desire (urgency) to void. 'Detrusor overactivity' is a diagnosis that denotes involuntary detrusor contractions which are not due to neurological disorders, and diagnosis must be made using urodynamic techniques (Blaivas 1997a). Both women with the symptom and the formal diagnosis of detrusor overactivity will be included in the review only if they have co-existing stress incontinence ('mixed' incontinence).

Women with mixed incontinence included in this review will either have symptoms of stress plus urge incontinence or other urinary symptoms (diagnosed clinically), or urodynamic stress incontinence plus detrusor overactivity (diagnosed using urodynamics).

Treatments for stress urinary incontinence include conservative, pharmacological and surgical interventions. Conservative treatment centres on physical methods, including pelvic floor muscle training, electrical stimulation, biofeedback and weighted cones. Mechanical devices which prevent or reduce urinary leakage are available, such as meatal plugs/patches and urethral and vaginal inserts. Drug therapies, principally oestrogens and less often alpha adrenergic agents, can be used. A trial of conservative therapy is generally undertaken before resorting to surgery. These interventions are the subject of separate Cochrane reviews. Surgical procedures to remedy stress incontinence generally aim to lift and support the urethro-vesical junction. There is disagreement, however, regarding the precise mechanism by which continence is achieved. Choice of procedures is often influenced by co-existent problems, surgeon's preference and the physical features of the person affected.

Numerous surgical methods have been described, but essentially they fall into seven categories:

Open abdominal retropubic suspension (e.g. colposuspension (Burch), Marshall-Marchetti-Krantz (MMK))

Laparoscopic retropubic suspension

Vaginal anterior repair (anterior colporrhaphy - e.g. Kelly, Pacey)

Suburethral slings (including traditional suburethral slings and self fixing slings)

Needle suspensions (e.g. Pereyra, Stamey)

Peri-urethral injections, and

Artificial sphincters.

This review will concentrate on traditional suburethral sling operations.

A traditional suburethral sling operation requires a combined abdominal and vaginal approach. Strips of material are tunneled under the urethra. They are 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 strains. The materials that have been used for slings may be biological or synthetic. Autologous biological materials include: rectus fascia, fascia lata, pubococcygeal muscle, vaginal wall, aponeurosis and pyramidalis fascia. Exogenous biological materials include: ox fascia and porcine dermis. Synthetic materials include: Teflon, Mersilene tape in a silicon tube, lyodura, polytetrafluoroethylene (Gore-Tex), Marlex mesh and silastic. A modification of the suburethral sling procedure is the 'self-fixing' polypropylene mesh applied through a minimally invasive technique (transvaginal tape (TVT), suprapubic arc (SPARC)) in which a prolene tape covered by a plastic sheath is inserted around the mid-urethra without fixation and in some centres under local anaesthesia (Smith 2002). These will be considered in a separate Cochrane review. Only traditional sling operations, applied by open surgeries or fixed with sutures were included in this review.

OBJECTIVES

To assess the effects of traditional suburethral sling procedures for treatment of urodynamic stress urinary incontinence (urodynamic diagnosis), or for symptoms of stress or mixed incontinence (clinical diagnosis) in women.

The following comparisons were made for traditional suburethral sling procedures (abdominal and vaginal).

1. Traditional suburethral sling operation versus no treatment or sham operation for the management of urodynamic stress incontinence (urodynamic diagnosis), and for symptoms of stress or mixed incontinence (clinical diagnosis).
2. Traditional suburethral sling operation versus conservative management (e.g. pelvic floor muscle training, electrical stimulation, cones, biofeedback) for the management of urodynamic stress incontinence (urodynamic diagnosis), or for symptoms of stress or mixed incontinence (clinical diagnosis).
3. Traditional suburethral sling operation versus colposuspension (abdominal surgery) for the management of urodynamic stress

incontinence (urodynamic diagnosis), or for symptoms of stress or mixed incontinence (clinical diagnosis).

4. Traditional suburethral sling operation versus needle suspension (abdominal and vaginal) for the management of urodynamic stress incontinence (urodynamic diagnosis), or for symptoms of stress or mixed incontinence (clinical diagnosis).

5. Traditional suburethral sling operation versus anterior repair for the management of urodynamic stress incontinence (urodynamic diagnosis), or for symptoms of stress or mixed incontinence (clinical diagnosis).

6. Traditional suburethral sling operation versus laparoscopic procedures for the management of urodynamic stress incontinence (urodynamic diagnosis), or for symptoms of stress or mixed incontinence (clinical diagnosis).

7. One type of traditional sling operations versus another type of sling (including self fixing slings) for the management of urodynamic stress incontinence (urodynamic diagnosis), or for symptoms of stress or mixed incontinence (clinical diagnosis).

METHODS

Criteria for considering studies for this review

Types of studies

Randomised or quasi-randomised controlled trials amongst women with urodynamic stress incontinence (urodynamic diagnosis), or symptoms of stress or mixed urinary incontinence (clinical diagnosis), in which at least one trial arm involves traditional suburethral sling procedures.

Types of participants

Adult women with stress urinary incontinence due to hyper-mobility and/or intrinsic sphincter deficiency, diagnosed clinically or with urodynamics, or with mixed incontinence. Classification of diagnoses will be accepted as defined by the trialists.

Types of interventions

At least one arm of a study must involve traditional suburethral sling procedures to treat stress or mixed incontinence. Comparison interventions may include other surgical techniques and non-surgical interventions.

Types of outcome measures

Outcome measures used in this review were selected on the basis of their relevance to the clinical cure or improvement of incontinence. We regard the principal measures of effectiveness as the proportion

of women cured (continent or dry) following surgery, and the proportion of women whose incontinence is improved.

A. Women's observations

1. Perception of cure and improvement in the short term (less than 12 months) and longer term (more than 12 months)

B. Quantification of symptoms

2. Pad changes over 24 hours (from self-reported number of pads used)
3. Incontinent episodes over 24 hours (from self completed bladder chart)
4. Pad tests of quantified leakage (mean volume or weight of urine loss)

C. Clinician's observations

5. Urge symptoms or urge incontinence (clinical diagnosis without urodynamics)
6. Voiding dysfunction / difficulty after three months (with or without urodynamic confirmation)
7. Detrusor overactivity (urodynamic diagnosis)
8. Entero-rectocele
9. Peri-operative surgical complications (e.g. infection, bacteriuria, haemorrhage, bladder perforation)

D. Quality of life

10. General health status measures (e.g. Short Form 36 (Ware 1993)), or specific instruments designed to assess incontinence e.g. the Bristol Female Lower Urinary Tract Symptoms questionnaire (BFLUTS) (Jackson 1996).

E. Socioeconomic measures

11. Costs of interventions
12. Cost-effectiveness of interventions
13. Resource implications

F. Surgical outcome measures

14. Duration of operation
15. Length of inpatient stay
16. Time to return to normal activity level

G. Adverse events

17. Repeat incontinence surgery
18. Later prolapse surgery
19. Surgical complications and other types of adverse event

H. Other outcomes

Non-prespecified outcomes judged important when performing the review

Search methods for identification of studies

This review has drawn on the search strategy developed for the Incontinence Review Group. Relevant trials were identified from the Incontinence Group Specialised Register of controlled trials which is described under the Incontinence Group's details in *The Cochrane Library* (For more details please see the 'Specialized Register' section of the Group's module in *The Cochrane Library*). The register contains trials identified from MEDLINE, CINAHL, the Cochrane Central Register of Controlled Trials (CENTRAL) and hand searching of journals and conference proceedings. Date of the most recent search of the register for this review: 22 December 2004.

The trials in the Incontinence Group Specialised Register are also contained in the Cochrane Central Register of Controlled Trials (CENTRAL). The terms used to search the Incontinence Group Specialised Register are given below:

(TOPIC.URINE.INCON*)

AND

({DESIGN.CCT*} OR {DESIGN.RCT*})

AND

({INTVENT.SURG.SLIN*}

OR

{INTVENT.SURG.SUBURETHRAL SLING.}

OR

{INTVENT.SURG.ABDO.SLING.})

(All searches were of the keyword field of Reference Manager 9.5 N, ISI ResearchSoft).

For this review specific extra searches were performed by one of the reviewers. These are detailed below.

Systematic searches of electronic bibliographic databases:

- PubMed - years searched: 1966 to January 2000, date searched: 30 Jan 2000;
- UK National Research Register - Issue 1, 2001, date searched: May 2001.

Search term used: TVT.

Hand searching of Conference Proceedings: Brazilian Congress of Urology Annual meeting 1991 to 2003 inclusive.

The reference lists of relevant articles were searched for other possibly relevant trials.

We did not impose language or other restrictions on any of these searches.

Data collection and analysis

Trials Selection

The reports of all possibly eligible studies were evaluated for appropriateness for inclusion by the reviewers without prior consideration of the results. Reports of potentially eligible trials were retrieved in full.

Quality assessment

Assessment of methodological quality was undertaken independently by each reviewer using the Incontinence Group's assessment criteria. The system for classifying methodological quality of controlled trials was based on an assessment of the three principal potential sources of bias. These are: selection bias from insecure random allocation of treatments; attrition bias from dropouts or losses to follow-up, particularly if there is a differential dropout rate between groups; and biased ascertainment (detection bias) of outcome where knowledge of the allocation might have influenced the measurement of outcome.

Data Extraction

Data extraction was undertaken independently by the three reviewers using a standard form containing pre-specified outcomes. Where data may have been collected but not reported, clarification was sought from the trialists. Included trial data were processed as described in the Cochrane Reviewers' Handbook (Deeks 2004).

Any differences of opinion related to study inclusion, methodological quality or data extraction were resolved by discussion among the reviewers, and when necessary, referred to a fourth party for arbitration.

Data Analysis

The review was conducted using the standard Cochrane software 'Revman'. Included trial data were processed as described in the Cochrane Reviewers' Handbook (Deeks 2004). Trial data were grouped by type of incontinence - either urodynamic stress incontinence based on a urodynamic diagnosis, or stress or mixed incontinence based upon a symptom classification. Quantitative synthesis was done when more than one eligible study was identified. Where appropriate, a combined estimate of treatment effect across similar studies was calculated for each pre-specified outcome, using relative risks for dichotomous data or weighted mean differences for continuous outcomes. 95% confidence intervals was generated where possible. For categorical (dichotomous) outcomes the numbers reporting an outcome were related to the numbers at risk in each group to derive a relative risk (RR). For continuous variables means and standard deviations was used to derive a weighted mean difference (WMD). A fixed effects approach to the analysis was undertaken unless there was evidence of heterogeneity across studies. A narrative review of eligible studies was undertaken where statistical synthesis of data from more than one study was not possible or considered not appropriate. Data on the number of patients with each outcome event, by allocated treated group, irrespective of compliance and whether or not the patient was later thought to be ineligible or otherwise excluded from treatment or follow-up was sought to allow an intention-to-treat analysis when possible.

Differences between trials was investigated when apparent from either visual inspection of the results or when statistically significant heterogeneity was demonstrated by using the chi squared

test at the 10% probability level or assessment of the I-squared statistic (Higgins 2003). If there was no obvious reason for the heterogeneity (after consideration of populations, interventions, outcomes and settings of the individual trials) or it persists despite the removal of outlying trials, a random effects model was used.

Studies were excluded from the review if they were not randomised or quasi-randomised controlled trials for incontinent women or if they made comparisons other than those pre-specified. Excluded studies are listed in the Tables of Excluded Studies with the reasons for their exclusion.

Any differences of opinion related to study inclusion, methodological quality or data extraction were resolved by discussion between the reviewers.

RESULTS

Description of studies

See: [Characteristics of included studies](#); [Characteristics of excluded studies](#); [Characteristics of ongoing studies](#).

Thirteen randomised or quasi randomised trials were identified that met the inclusion criteria. These trials included 760 women (627 with slings) and sample sizes ranged from 20 to 165 participants.

Participants

Inclusion criteria were not always clearly defined. Only four trials included women with mixed incontinence (Barbalias 1997; Kondo 2003; Osman 2003; Sand 2000). All others were restricted to women with a urodynamic diagnosis of pure stress incontinence. One trial (Henriksson 1978) only included women without previous interventions for incontinence and another (Enzelsberger 1996) only women with recurrent incontinence and vaginal hysterectomy. The others included women with both primary and recurrent stress incontinence. All trials included both pre and postmenopausal women, but none were treated with hormone replacement therapy. One study was restricted to women with vaginal narrowing due to atrophic vaginitis or previous surgical scars (Hilton 1989).

Not all studies reported initial and long term follow up. Four authors (Henriksson 1978; Sand 2000; Osman 2003; Viseshsindh 2003) presented their results at three and/or six month assessment respectively. Four of the studies presented an intermediate follow up (Aurunkalaivanan 2001; Demirci 2001; Lucas 2000; Shin 2001). Three studies described longer but not ideal, follow up (Barbalias 1997; Enzelsberger 1996; Hilton 1989). One trial provided full information in two reports of short and long-term (more than five years) follow-up (Sand 2000).

One trial was designed to study an anticholinergic agent (oxybutynin) in comparison with surgery (Burch or Sling) for mixed urinary incontinence patients (Osman 2003). Only data of sling surgery in comparison with medical treatment were extracted from report and included in tables.

Further characteristics of the trials are reported in the Characteristics of Included Studies table. The trials on transvaginal tape procedures (Halaska 2001; Han 2001; Liapis 2002; Ward 2002) were excluded from this update to be included in the new review on self fixing slings.

Risk of bias in included studies

The reported method of randomisation was secure in two trials (Lucas 2000; Sand 2000). None of the other eleven reported using an adequate method of randomisation. Three used randomisation charts without providing information about the process (Barbalias 1997; Enzelsberger 1996; Hilton 1989). Eight just stated that women were randomised, without any other detail (Arunkalaivanan 2003; Demirci 2001; Fischer 2001; Henriksson 1978; Arunkalaivanan 2003; Osman 2003; Shin 2001; Viseshsindh 2003). In one trial one woman was randomised to one arm of the study in comparison with two randomised for the other intervention (Barbalias 1997). Masking of women or surgeons was not reported, but is unlikely in these circumstances. Baseline comparisons were given in seven trials (Arunkalaivanan 2003; Demirci 2001; Enzelsberger 1996; Hilton 1989; Kondo 2003; Lucas 2000; Sand 2000). One author stated that the two groups were comparable without supplying data (Henriksson 1978), and the others did not mention baseline comparisons between the groups (Barbalias 1997; Fischer 2001; Osman 2003; Shin 2001; Viseshsindh 2003). Third party outcome assessment was not performed in any of the trials.

The definition of cure was not uniform in the identified studies. For example, although Barbalias (Barbalias 1997) considered only the dry patients as cured, he included the improved ones in the success rates, without reporting what "improvement" meant. Others only considered dry patients cured (Enzelsberger 1996). The most detailed description of results were reported by Sand (Sand 2000) and Lucas (Lucas 2000) with data describing both objective (pad tests and urodynamics) and subjective (self reported, voiding diaries) cure rates. Reporting of other outcomes was variable and incomplete.

Effects of interventions

With the exception of the Sand (Sand 2000) trial, in general included trials were small with short follow-up. Five trials compared slings with open abdominal retropubic colposuspension (Demirci

2001; Enzelsberger 1996; Fischer 2001; Henriksson 1978; Sand 2000), one with needle suspension (Hilton 1989) and six compared different types of sling (Arunkalaivanan 2003; Barbalias 1997; Kondo 2003; Shin 2001; Viseshsindh 2003; Lucas 2000). There were no trials comparing suburethral slings with anterior repair, laparoscopic retropubic colposuspension, peri-urethral injections or artificial sphincters. One trial compared sling with oxybutynin in the treatment of mixed urinary incontinence patients (Osman 2003). The types of sling included were: porcine dermis (Arunkalaivanan 2003; Hilton 1989), lyophilised dura mater (Enzelsberger 1996), Teflon (Henriksson 1978), prolene - TVT (Arunkalaivanan 2003; Kondo 2003), rectus fascia (Barbalias 1997; Demirci 2001; Lucas 2000) and polytetrafluoroethylene - PTFE (Barbalias 1997; Sand 2000). One trial (Fischer 2001), reported in abstract form, did not mention the type of material used for the suburethral sling. There were single trials with slings made of vaginal wall (Viseshsindh 2003), fascia lata (Shin 2001) and autologous dermis (Shin 2001). Outcome measures used in this review were not consistently reported in the trials.

Traditional suburethral sling versus open abdominal retropubic colposuspension (comparison 01)

Five trials were identified which compared slings with abdominal retropubic colposuspension (Demirci 2001; Enzelsberger 1996; Fischer 2001; Henriksson 1978; Sand 2000). The extent to which the trials could be considered together was limited, however, because of differences in the procedures compared, the populations studied, the outcomes assessed, and the length of follow-up. There are four trials comparing Burch colposuspension with different slings and one trial comparing Marshall-Marchetti-Krantz colposuspension with sling. One of these (Sand 2000) reported the longest follow-up for more than five years and presented the results in the short and long-term in two full reports.

In three trials (Fischer 2001; Henriksson 1978; Sand 2000) with a total of 86 participants the four women not cured all had colposuspension (RR 0.19; 95% CI 0.02 to 1.53; Comparison 01.01). In three trials (Demirci 2001; Enzelsberger 1996; Sand 2000) with a total of 134 patients reporting longer-term data there was again no statistically significant difference between traditional slings and abdominal retropubic colposuspension (4/66 versus 9/68; RR 0.49; 95%CI 0.17 to 1.42; Comparison 01.02). The data available on voiding dysfunction, detrusor overactivity, prolapse, peri-operative complications and symptoms of urge are also scarce. For example, in three trials with a total of 142 participants eight out of 70 women had detrusor overactivity after a sling procedure compared with three out of 72 after abdominal retropubic colposuspension, again with wide confidence intervals (RR 2.79; 95% CI 0.78 to 10.0). Taken all data together there was no detectable difference in the peri-operative complications overall, but the estimates (confidence intervals) were all compatible with clinically important differences.

Traditional suburethral sling versus needle suspension (comparison 02)

One trial compared porcine dermis sling with Stamey needle suspension (Hilton 1989). This was a small trial with only ten women in each arm. The women were unsuitable for abdominal colposuspension (the author's preferred procedure) because they had vaginal narrowing secondary to either previous interventions or atrophic vaginitis. All women had urodynamic stress incontinence. Groups were comparable for age, parity, previous interventions and hormonal status. Follow up was reported at three and 24 months. Although there were no differences in cure rates in the short or longer term, numbers were small. Late voiding troubles, detrusor overactivity and urge incontinence were also similar but with wide confidence intervals. None of the 10 women who had sling operations had complications compared with two of the 10 who had needle suspension. These included: pyrexia, blood loss, wound infection and pulmonary embolus (Comparison 02.13). The sling group also needed an indwelling catheter for longer, and more adjuvant therapy, resulting in a longer stay in hospital (Comparison 02.14).

One type of traditional suburethral sling versus another sling (including self fixing) (comparison 03)

Six trials comparing different types of sling were identified. Only one trial did not compare a fascial sling (Arunkalaivanan 2003). This study compared Pelvicol (porcine dermis) versus self-fixing transvaginal tape. The other five trials compared different types of sling either with rectus fascia (Barbalias 1997; Kondo 2003; Lucas 2000; Viseshsindh 2003) or with fascia lata (Shin 2001). (A possible reason for this is that the researchers wished to compare new types of material with the most commonly used types of autologous fascia.) Failure rates were similar both in the short and long-term, as was the incidence of detrusor overactivity, but the numbers were small and the confidence intervals wide. In the Barbalias trial (Barbalias 1997) five women in the Goretex group had post-operative complications. These included two women with erosion of the urethra which required removal of the sling more than three years later, but their incontinence did not return. At the twelve month assessment in the Barbalias trial results were said to be similar with both groups improving their health status. Again, the confidence intervals around estimates of differences, where available, were all wide. Another trial compared two types of rectus fascia sling: long and short (Lucas 2000). Outcome was reported in terms of quality of life, clinical indicators (such as immediate post-operative complications, time to first void, pad tests) and health status but often with no standard deviation or other measure of dispersion. Finally, one trial compared Pelvicol (porcine dermis) sling with transvaginal tape (Arunkalaivanan 2003). This was a well designed trial, with intermediate follow up (median 12 months) and a reasonable number of participants. No difference was detected in cure and complications rates and the authors postulated that the Pelvicol, a new manufactured porcine dermis

strip may be more durable than others and are cheaper than the transvaginal tape.

Traditional suburethral sling versus conservative management (comparison 04)

One trial was designed to study mixed urinary incontinence patients treated with oxybutynin or surgery (Osman 2003). The type of surgery was selected according to Valsalva leak point pressure (VLPP) (those with VLPP less than 90cm of water had rectus fascia sling and those with VLPP more than 90cm of water had Burch colposuspension). All patients had SUI and symptoms of urge incontinence but without involuntary contractions on urodynamic examination. Patients were randomised to oxybutynin or surgery by block-randomisation technique (details not reported) and evaluated subjectively and objectively. The author did not report patient characteristics nor stated that groups were comparable. Study population were evaluated for cure of stress urinary incontinence, urgency and urge incontinence symptoms and de novo detrusor instability. The results for the total surgically managed group were similar to those for the subgroup having slings. We therefore included in tables only data from oxybutynin and sling patients. The study suggested that slings are significantly better for treating mixed urinary incontinence than oxybutynin, with a cure rate of 83% for stress urinary incontinence and 93% for urgency/urge incontinence in comparison to 0% and 43%, respectively. One patient treated with sling developed true involuntary contractions on follow up.

DISCUSSION

This updated review includes data from five new trials (Arunkalaivanan 2003; Kondo 2003; Osman 2003; Shin 2001; Viseshsindh 2003), and a new publication of a long-term follow up (Sand 2000). Four trials from the last update were excluded because they will be included in a new review of self fixing slings (Halaska 2001; Han 2001; Liapis 2002; Ward 2002). Most trials compared slings with other types of sling (six trials) or with abdominal retropubic open colposuspension (five trials).

We did not find trials comparing suburethral slings with conservative management such as pelvic exercises or vaginal cones, or with some other surgical operations (anterior repair, laparoscopic retropubic suspension, injections or artificial sphincters). But there was a trial comparing surgery with oxybutynin drug therapy for patients with mixed incontinence symptoms. The trial showed much better results in the group managed surgically. A trial of pubovaginal sling versus periurethral macroplastique for intrinsic sphincteric deficiency patients was excluded from this update because the reference identified by the search was an abstract with

insufficient data to analyse the results. The authors were contacted to obtain further information.

Overall, the review has not shown that slings are more (or less) effective than abdominal retropubic suspension or needle suspension. The same applies to different types of slings, compared with each other.

The limited data available suggest that the overall rates of perioperative and late surgical complications are similar after sling and colposuspension operations. However, the pattern of complications varies. Wound complications were more common after colposuspension. Little could be said about voiding dysfunction and detrusor overactivity in face of the poor description and limited data available. This is a concern for those dealing with surgical treatment of SUI which deserves more attention of authors.

In general, the scientific quality of the trials was poor. In spite of stating that they were randomised, the reports of some trials did not give any detail about randomisation and others mentioned use of random charts, without giving information about the process. Only two authors reported an adequate randomisation method. All trials were done without reference to blinding surgeons or women (although for different types of operation this may not be possible), and none reported external, third party, assessment at follow up. The total number of women enrolled was 760, but in some trial arms was only 10. In addition, several types of slings were compared with different interventions, so that they could not be grouped easily. This meant that the numbers in each comparison were small and the confidence intervals wide.

The populations varied, including women with and without previous surgery, and one study included only women who were deemed not suitable for another procedure (Hilton 1989). Although the majority had urodynamic stress incontinence, some trials included women with mixed incontinence. Baseline comparability of the groups was not reported in all trials. Several trials assessed different types of sling in comparison with autologous fascia, suggesting that the latter were being used as a 'standard' comparator. Although five trials included open abdominal retropubic colposuspension, each used a different type of sling, and three followed up the women for only six months. However this finding reflects the acceptance of Burch colposuspension as an effective treatment for SUI.

In general, most trials reported different outcome measures, often poorly. The principal measure of effectiveness used in most studies was the proportion of women cured (continent or dry) following surgery. In one trial, the proportion of women whose condition was improved or cured was reported, but few researchers have considered other outcomes such as activities of daily living and quality of life. None addressed general health status, economic measures, repeat incontinence surgery, later prolapse surgery and time to return to normal activity level. Satisfaction with, and acceptability of, the treatment were also seldom addressed but are important factors in choice of management.

Some synthetic slings may have a higher incidence of erosion, infections and urge symptoms. There was some evidence that these were more common after Goretex than after Teflon or transvaginal tape. More evidence is needed to compare slings made of autologous materials (e.g. rectus fascia, vaginal wall) with synthetic or exogenous biological materials (e.g. Teflon, polytetrafluoroethylene, porcine dermis, dura mater).

In the trial comparing a sling procedure with a needle suspension procedure which was restricted to women with vaginal narrowing deemed unsuitable for open abdominal retropubic colposuspension (Hilton 1989), there were more complications in the slings group, but it was unclear whether the complications were caused by surgical difficulties due to vaginal narrowing. However, the group managed by needle suspensions did not seem to have the same complications.

AUTHORS' CONCLUSIONS

Implications for practice

The data were too few to address whether the several types of suburethral slings tested were as effective as other slings, open abdominal retropubic suspension or needle suspension. There was limited evidence from one small trial that slings made of Goretex had more complications than slings made of rectus fascia. The broader effects of suburethral slings could not be established since trials did not include appropriate outcome measures such as general health status, health economics, pad testing, third party analysis and time to return to normal activity level, and follow up was limited.

Evidence to clarify whether or not traditional suburethral slings may be better or worse than other surgical or conservative man-

agement options is lacking because no trials addressed these comparisons.

Implications for research

The evidence was limited by the poor quality and small numbers of the included randomised trials. There is an urgent need for further trials of adequate power to assess the effectiveness of suburethral slings in comparison with other surgical techniques, conservative management and different types of slings, and in specific populations (e.g. failed previous surgery, anatomical restrictions etc).

Future research in incontinence treatments should incorporate standardised, validated and simple outcome measures that are relevant to women who have incontinence in order to allow comparison between treatments. In particular, quality of life, psychological and economic outcomes should be incorporated. Surgical trials related to urinary incontinence should systematically address surgical morbidity outcomes such as adverse peri-operative events, length of hospital stay, time to return to normal activities, development of urge symptoms or detrusor overactivity and especially the need for repeat surgery or alternative interventions. Long-term follow-up (at least one year, preferably 5 years or more) is essential for the proper evaluation of incontinence treatments.

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* Indicates the major publication for the study

CHARACTERISTICS OF STUDIES

Characteristics of included studies [ordered by study ID]

Arunkalaivanan 2003

| | | |
|-------------------------|--|--------------------|
| Methods | RCT, randomisation method unclear. Patients demographics were well reported. Procedures were standardised. Follow up was 2-6 months, 12 and 24 months (median 12 m). | |
| Participants | 142 women with urodynamic proven SUI were recruited. Women with detrusor instability was excluded. Groups comparable. | |
| Interventions | Group I: TVT (n=68). Group II: Pelvicol (n=74). | |
| Outcomes | Outcome measures reported were cure rates (subjective, questionnaire-based; pad used - not weighted), levels of morbidity and impact on quality of life, health economic costs and symptom severity. There was not significant difference on cure, satisfaction and complication rates between interventions. Failures: group I = 10 (68); group II = 8 (74). Complications: retention up to 6 weeks 1 (group I) and 6 (group II); release of sling required 2 (group I) and 5 (group II). | |
| Notes | Surgery was only offered after conservative therapy had proved unsuccessful. | |
| Risk of bias | | |
| Item | Authors' judgement | Description |
| Allocation concealment? | Unclear | B - Unclear |

Barbalias 1997

| | | |
|---------------|--|--|
| Methods | RCT. Follow-up at six and 30 months. Women allocated to one of two interventions by a computer generated random table in a 2:1 ratio. All women available at follow-up. | |
| Participants | 48 consecutive women. Inclusion and exclusion criteria not clearly stated, but some patients with mixed incontinence | |
| Interventions | Group I: Goretex sling operation (n=16). Group II: rectus fascia sling (n=32). | |
| Outcomes | Cure defined as complete freedom from SUI (clinically assessed) or improved (persistence or recurrence of SUI, but in lesser intensity). Failure rates I: 2/16 at 6 months and 2/16 at 30 months, II: 6/32 at 6 months and 11/32 at 30 months. Complications: I: 2 cases of erosion of sling and 3 other cases of recurrent UTI. | |
| Notes | Pre operative characteristics reported but no comparisons between groups made; statistical analysis reported for urodynamic parameters pre and post operation. No other statistical comparison between groups reported. Some patients with mixed incontinence, but results not stratified by groups or type of incontinence. | |

Barbalias 1997 (Continued)

| <i>Risk of bias</i> | | |
|-------------------------|--------------------|-------------|
| Item | Authors' judgement | Description |
| Allocation concealment? | Unclear | B - Unclear |

Demirci 2001

| | | |
|---------------|---|--|
| Methods | RCT. Follow-up 12 months. No details of allocation method given. Not all women available in follow-up. | |
| Participants | 46 women recruited, 23 in each arm of the study. 34 women available for follow-up, reasons for loss to follow up not reported. Inclusion and exclusion criteria are well defined | |
| Interventions | Group I: Burch colposuspension (n=17), Group II: Rectus fascia sling (n=17) | |
| Outcomes | Cure defined as dry, symptom-free (subjective= history and objective ultrasonography). Failure rate: I = 1/17; II =0/17. Late complications (1year follow-up) - Group I; 1 instability, 2 dyspareunia and 2 genital prolapse (enteroclece); Group II - 1instability; 3 suprapubic pain and 1 dyspareunia. | |
| Notes | Ultrasonography for measurement of bladder neck mobility was tested in both groups pre and post operatory and showed significant improvement but no significant differences between the groups | |

Risk of bias

| Item | Authors' judgement | Description |
|-------------------------|--------------------|-------------|
| Allocation concealment? | Unclear | B - Unclear |

Enzelsberger 1996

| | | |
|--------------|---|--|
| Methods | RCT. Follow-up at 32 to 48 months. Women allocated to one of two interventions by open random-number chart. All women available to follow-up. | |
| Participants | 72 women recruited, 36 in each arm of the study. Inclusion criteria: all patients with GSI (urodynamic and sonographic diagnosis) had a vaginal hysterectomy and, at least, one previous anterior repair; 57 were postmenopausal without hormone replacement therapy. Exclusion criteria: urinary tract infection, unstable bladder, voiding difficulty and severe cystocele and/or rectocele. Groups were comparable for age, weight, parity, menopausal status, previous surgery and time of follow-up. | |

Enzelsberger 1996 (Continued)

| | | |
|-------------------------|--|--------------------|
| Interventions | Group I : modified Burch colposuspension (two pairs of sutures instead of three) (n=36). Group II: lyophilized dura mater sling operation (n=36). | |
| Outcomes | Cure defined as dry, symptom-free without objective urine loss during stress with bladder filled to 300 ml or positive urethral-closure pressure during stress provocation. Failure rate I: 5/36, II: 3/36 at follow-up at 32-48 months. Urodynamic results reported before and at follow-up. Reported longer hospital stay and suprapubic catheter permanence for group II. Equal frequency pyrexia and bladder laceration. Late complications: enterocele or rectocele I: 5/36, II: 1/36; voiding difficulty I: 1/36, II: 5/36. Both differences statistically significant. Other problems not statistically significant: urgency/urge incontinence (I: 3/36, II: 6/36). Four patients reported in control because of residual urine for group II. Equal good results in sonographic investigation at follow-up. | |
| Notes | | |
| Risk of bias | | |
| Item | Authors' judgement | Description |
| Allocation concealment? | Unclear | B - Unclear |

Fischer 2001

| | | |
|-------------------------|---|--------------------|
| Methods | RCT. Details not given. Follow-up at 6 months | |
| Participants | 22 women with intrinsic sphincter deficiency, 11 in each arm. | |
| Interventions | Group I: Burch retropubic urethropexy Group II: suburethral sling | |
| Outcomes | Cure assessed using Incontinence impact questionnaire (IIQ), Urinary distress inventory (UDI), stress test, voiding dysfunction | |
| Notes | Abstract only. Aim to evaluate the prognostic value of urethral electrodiagnosis | |
| Risk of bias | | |
| Item | Authors' judgement | Description |
| Allocation concealment? | Unclear | B - Unclear |

Henriksson 1978

| | |
|---------------|--|
| Methods | RCT. Details not given. Follow-up at four to six months. |
| Participants | 30 women randomized, 15 in each arm of the study, all with genuine stress incontinence. All age groups of patients but menopausal status not reported. Exclusion criteria: cystocele, uterine prolapse, urge incontinence, neurogenic bladder, urinary tract infections. |
| Interventions | Group I: Teflon sling (Zoedler urethroplasty) (n=15). Group II: MMK urethrocystopexy (n=15). |
| Outcomes | Cure defined as complete freedom from SUI (subjective and objective demonstration). All patients cured in both groups. Complications not reported. Main differences observed in stress closing pressure of urethra, which became positive after surgery in both groups. |
| Notes | Groups stated similar but no comparisons made at baseline. Short follow-up. |

Risk of bias

| Item | Authors' judgement | Description |
|-------------------------|--------------------|-------------|
| Allocation concealment? | Unclear | B - Unclear |

Hilton 1989

| | |
|---------------|---|
| Methods | RCT. Follow-up at 2, 3, 12 and 24 months. Women allocated to one of two interventions by random tables. All women available at follow-up. |
| Participants | 20 women recruited, 10 in each arm of the study. Inclusion criteria: GSI (urodynamic diagnosis), vaginal narrowing, post surgical scar, unsuitable for colposuspension. Exclusion criteria: not stated. Groups comparable for age, parity and number of previous surgical incontinence procedures. Menopausal status not reported. |
| Interventions | Group I: Stamey bladder-neck (needle) suspension (n=10). Group II: porcine dermis sling operation (n=10). |
| Outcomes | Cure stated as objective (urodynamic diagnosis, pad test) at 3 months and subjective at 24 months of follow-up. Failure rates I: 2/10 at 3 months and 3/10 at 24 months, II: 1/10 at 3 months and 1/10 at 24 months. Differences not statistically significant at 3 and 24 months. Post op. complications I: 2/10, II: 9/10 (operative blood loss, pyrexia, infective complications, supra pubic catheter permanence). Hospital stay I: 7 (0.3), II: 20 (12.9). Late complications not reported. Voiding problems at 3 months I:2/10, II: 4/10. Detrusor instability I: 1/10, II: 2/10. Urge incontinence I: 3/10, II: 5/10. No difference in frequency of uninhibited detrusor contractions, residual volume and maximum voiding pressure. Peak flow significantly reduced for group II, although higher than 15 ml/s. |
| Notes | Pad test at 12 and 24 months stated but not reported. |

Risk of bias

Hilton 1989 (Continued)

| Item | Authors' judgement | Description |
|-------------------------|--------------------|-------------|
| Allocation concealment? | Unclear | B - Unclear |

Kondo 2003

| | | |
|---------------|--|--|
| Methods | RCT. Details not reported. Follow-up 3 to 24 months. 54% achieved 24th month visit. | |
| Participants | 57 women, with pure genuine SUI (54) and mixed incontinence (3). | |
| Interventions | Group I: TVT (n = 29) and Group II: rectus fascia (n=28) | |
| Outcomes | Cure rates presented as objective and subjective data. Objective cure was defined as complete continence in response to strong coughs 3 to 4 times in a row in a lithotomy position with intravesical water of 250 to 300 ml. There was an objective cure rate of 68,4% for group I (TVT) and 45,7 for group II. | |
| Notes | Results extracted from an abstract presented in 2003 ICS annual meeting. | |

Risk of bias

| Item | Authors' judgement | Description |
|-------------------------|--------------------|-------------|
| Allocation concealment? | Unclear | B - Unclear |

Lucas 2000

| | | |
|---------------|---|--|
| Methods | RCT. Follow-up at 3, 6 and 12 months. Women allocated to each arm by a central telephone randomisation system. | |
| Participants | 165 women recruited, all with GSI, exclusion criteria: detrusor instability and hypocompliance | |
| Interventions | Group I: sling on a string (n=84); Group II: standard sling insertion (n=81) | |
| Outcomes | Outcome was measured by patient's quality of life, clinical indicators (such as immediate post-operative complications, time to first void, pad tests); administrative indicators, pain scores and patient satisfaction. At 12 month assessment 62 patients were satisfied in group I and 57 in group II. | |
| Notes | Detailed outcome measures at 3, 6 and 12 months were provided. Both groups showed improvement in their quality of life with no significant statistical difference between allocated operation. | |

Risk of bias

| Item | Authors' judgement | Description |
|------|--------------------|-------------|
|------|--------------------|-------------|

Lucas 2000 (Continued)

| | | |
|-------------------------|-----|--------------|
| Allocation concealment? | Yes | A - Adequate |
|-------------------------|-----|--------------|

Osman 2003

| | | |
|---------------|--|--|
| Methods | RCT (block-randomization technique). Follow up reported at six months. Selection criteria were well reported. | |
| Participants | 68 women with mixed incontinence symptoms and a negative cystometrogram for motor detrusor over-activity. All had proved stress urinary incontinence. No details on demographic data were reported. | |
| Interventions | Group I (n=25): anticholinergic treatment. Group II(n=50): surgery (II a - 24 Burch colposuspension, II b - 26 rectus fascia sling). | |
| Outcomes | Patients were evaluated by SEAPI score (subjective and objective) and underwent urodynamic examination pre and post treatment. 21 patients (group I) and 24 (group II b) were available to follow up. Urge symptoms: 57% cured for group I and 88% cured for group II b. SUI: 0 cured for group I and 83% for group IIb. | |
| Notes | The study was designed to investigate anticholinergic therapy in comparison with surgery. Patients allocated to surgery had a sling procedure if the Valsalva leak point pressure was <90cmH2O. We extracted only data on sling in comparison with anticholinergics. | |

Risk of bias

| Item | Authors' judgement | Description |
|-------------------------|--------------------|-------------|
| Allocation concealment? | Unclear | B - Unclear |

Sand 2000

| | | |
|---------------|--|--|
| Methods | RCT by random number table. Follow-up at three months and at 72,6 months (mean) | |
| Participants | 36 women with genuine stress incontinence and a maximum urethral closure pressure ≤ 20 cm H2O. Groups comparable in terms of age, parity, and urodynamic variables, except for detrusor instability (>Burch vs sling) and residual volume (> Burch vs sling) | |
| Interventions | Group I: PTFE sling operation (n=17). Group II: modified (overcorrection) Burch colposuspension (n=19). | |
| Outcomes | Cure defined as objective (urodynamic) and subjective (history). Cure was 100% objective and 84% subjective for sling and 84,6% objective and 93% subjective for Burch (long-term). There were no statistically significant differences in outcome measures. | |

Sand 2000 (Continued)

| | | |
|-------------------------|--|--------------------|
| Notes | The first publication (2000) reported the short-term follow-up and was considered the primary reference. The last publication (2003) reported the long-term results. | |
| Risk of bias | | |
| Item | Authors' judgement | Description |
| Allocation concealment? | Yes | A - Adequate |

Shin 2001

| | | |
|-------------------------|---|--------------------|
| Methods | RCT stated. Details not given in the abstract of trial. Follow-up after first year reported | |
| Participants | 57 women with various types of SUI. Patients characteristics were not reported | |
| Interventions | Group I: autologous dermal graft patch (n=33). Group II: cadaveric fascia lata (n=24) | |
| Outcomes | Outcome measures reported were success rate (dry/improved), de novo detrusor instability. Success rate for group I = 91,6% and for group II = 93,2% | |
| Notes | | |
| Risk of bias | | |
| Item | Authors' judgement | Description |
| Allocation concealment? | Unclear | B - Unclear |

Viseshsindh 2003

| | | |
|---------------------|---|--|
| Methods | RCT. Method not clarified. Only the short-term follow-up reported. | |
| Participants | 26 women with stress urinary incontinence. | |
| Interventions | Group I: vaginal wall sling (n=11); Group II: fascial sling (n=15) | |
| Outcomes | Measures of outcome included SEAPI-QMN questionnaire, presence of SUI at postoperative period, urinary symptoms and hospital stay. Cure rates: SEAPI scores decreased from 6.1 to 0.9 for group I and from 6.3 to 0.8 for group II. | |
| Notes | | |
| Risk of bias | | |

Viseshsindh 2003 (Continued)

| Item | Authors' judgement | Description |
|-------------------------|--------------------|-------------|
| Allocation concealment? | Unclear | B - Unclear |

RCT=randomised controlled trial; SUI=stress urinary incontinence; MMK=Marshall-Marchetti-Krantz

Characteristics of excluded studies [ordered by study ID]

| | |
|----------------------|---|
| Atherton 2000 | Non-randomised. |
| Aurunkalaivanan 2001 | We are not sure about the population studied and it could be the same population as Barrington 2003 and Arunkalaivanan 2003 (included in the review); we have written to the authors to clarify this point. |
| Barrington 2003 | We are not sure about the population studied and it could be the same population as Arunkalaivanan 2001 and Arunkalaivanan 2003 (included in the review); we have written to the authors to clarify this point. |
| Choe 2000 | Allocation score C (patients randomised by alternating fashion). Trial comparing slings made of vaginal wall and of polytetrafluorethylene mesh impregnated with chlorhexidine. |
| Choe 2001 | All patients were randomized to undergo preoperative urodynamic evaluation or not. They then had implantation of suburethral mycromesh sling. Therefore the study analyses the impact on effectiveness of sling if the diagnostic of SUI is made with or without urodynamic evaluation. |
| Chong 2003 | Patients all had TVT operation were randomised to division/no division of tape. |
| Corcos 2001 | Patients were randomized to surgery or collagen injection but those in the surgery arm were selected to sling by patient's option. Three types of operation could be chosen in the surgery group: Burch, sling or bladder neck suspension. Results were reported in terms of collagen versus surgery. |
| Debodinance 1993 | Not all patients had stress incontinence (and allocation score C - patients randomised by birth date). Debodinance 2000 is a ten year follow-up of the first published study. The trial is a comparative study between Bologna (a sling made of strips of vaginal wall) and Ingelman-Sundberg procedure (anterior colporraphy with pubococcygeum muscle). |
| Debodinance 1994 | Not clear how patients allocated. Paper in French need translation. |
| Goldberg 2001 | Prolapse surgery rather than incontinence surgery. |

(Continued)

| | |
|-----------------|---|
| Halaska 2001 | Study comparing transvaginal tape with colposuspension; will be included in a separate review on self fixing slings. |
| Han 2001 | Study comparing transvaginal tape with colposuspension; will be included in a separate review on self fixing slings. |
| Hung 2001 | Not clear how patients were allocated, we have written to the authors. |
| Ishenko 1999 | Randomisation and groups unclear ('randomised by age'). Excluded as attempts to contact authors unsuccessful and insufficient information given in abstract. Interventions: vaginal hysterectomy, modified Pereyra procedure, anterior and posterior repair vs vaginal hysterectomy, sling procedure with mersilen mesh, anterior and posterior repair. |
| Kuo 2001 | Allocation score C (patients randomised by consecutive study entry). Comparison between rectus fascia and polypropylene mesh. |
| Kwon 2002 | Not all patients had stress incontinence; all patients were treated for prolapse but one group received concomitant transvaginal sling (processed fascia lata), one group received an alternate surgery for SUI and the last group, didn't have SUI and were submitted only to treatment of prolapse. |
| Lemieux 1991 | Interventions were on clamping versus non-clamping of catheters post-anti-incontinence surgery. |
| Liapis 2002 | Study comparing transvaginal tape with colposuspension; will be included in a separate review on self fixing slings. |
| Maher 2001 | The study is an abstract and does not mention how many patients are in each arm of the study (pubovaginal sling or transurethral macroplastique). The authors only cited the total number of patients recruited and will be contacted for further information. |
| Meschia 2001 | Surgery for prolapse rather than incontinence. |
| O'Sullivan 2000 | RCT. Patients randomised to colposuspension or transvaginal tape. Outcome measures (collagen metabolism) reported not included in this review. |
| Obrink 1978 | Not clear how patients were allocated. Author written to in October 2001, no reply received. |
| Schostak 2001 | Unclear how patients were allocated. Bone anchoring used. |
| Trezza 2001 | Occult incontinence treated at same time as prolapse repair. |
| Wang 1999 | Randomised to different types of anaesthetic. |
| Ward 2002 | Study comparing transvaginal tape with colposuspension; will be included in a separate review on self fixing slings. |

Characteristics of ongoing studies *[ordered by study ID]*

Hilton 2000

| | |
|---------------------|---|
| Trial name or title | A prospective randomised comparative trial of a tension free vaginal tape (TVT) and fascial sling procedure for 'secondary' genuine stress incontinence |
| Methods | |
| Participants | 146 planned recruitment |
| Interventions | TVT versus fascial sling |
| Outcomes | no information |
| Starting date | |
| Contact information | |
| Notes | |

Lucas 2001

| | |
|---------------------|---|
| Trial name or title | Sling operation for stress urinary incontinence: randomised trial of three operative procedures |
| Methods | |
| Participants | |
| Interventions | TVT versus Pelvicol versus sling on a string |
| Outcomes | |
| Starting date | |
| Contact information | |
| Notes | possibly same as Lucas 2004 |

Lucas 2004

| | |
|---------------------|---|
| Trial name or title | Failure of porcine xenograft sling in a randomised controlled trial of three sling materials in surgery for stress incontinence |
| Methods | |
| Participants | |

Lucas 2004 (Continued)

| | |
|---------------------|--|
| Interventions | TVT versus Pelvicol versus sling on a string |
| Outcomes | |
| Starting date | |
| Contact information | |
| Notes | Interim analysis published ICS Paris 2004 |

DATA AND ANALYSES

Comparison 1. SLING VS OPEN ABDOMINAL RETROPUBLIC SUSPENSION

| Outcome or subgroup title | No. of studies | No. of participants | Statistical method | Effect size |
|---|----------------|---------------------|-------------------------------------|-------------------|
| 1 Number not cured (worse, unchanged or improved) within the first year | 3 | 86 | Risk Ratio (M-H, Fixed, 95% CI) | 0.19 [0.02, 1.53] |
| 1.1 objective/genuine stress incontinence (only) | 3 | 86 | Risk Ratio (M-H, Fixed, 95% CI) | 0.19 [0.02, 1.53] |
| 1.2 subjective/stress urinary incontinence (only) | 0 | 0 | Risk Ratio (M-H, Fixed, 95% CI) | Not estimable |
| 1.3 mixed incontinence | 0 | 0 | Risk Ratio (M-H, Fixed, 95% CI) | Not estimable |
| 2 Number not cured (worse, unchanged or improved) after first year | 3 | 134 | Risk Ratio (M-H, Fixed, 95% CI) | 0.49 [0.17, 1.42] |
| 2.1 objective/genuine stress incontinence (only) | 3 | 134 | Risk Ratio (M-H, Fixed, 95% CI) | 0.49 [0.17, 1.42] |
| 2.2 subjective/stress urinary incontinence (only) | 0 | 0 | Risk Ratio (M-H, Fixed, 95% CI) | Not estimable |
| 2.3 mixed incontinence | 0 | 0 | Risk Ratio (M-H, Fixed, 95% CI) | Not estimable |
| 3 Number not improved (worse or unchanged) within the first year | 0 | 0 | Risk Ratio (M-H, Fixed, 95% CI) | Not estimable |
| 3.1 objective/genuine stress incontinence (only) | 0 | 0 | Risk Ratio (M-H, Fixed, 95% CI) | Not estimable |
| 3.2 subjective/urinary stress incontinence (only) | 0 | 0 | Risk Ratio (M-H, Fixed, 95% CI) | Not estimable |
| 3.3 mixed incontinence | 0 | 0 | Risk Ratio (M-H, Fixed, 95% CI) | Not estimable |
| 4 Number not improved (worse or unchanged) after first year | 0 | 0 | Risk Ratio (M-H, Fixed, 95% CI) | Not estimable |
| 4.1 objective/genuine stress incontinence (only) | 0 | 0 | Risk Ratio (M-H, Fixed, 95% CI) | Not estimable |
| 4.2 subjective/stress urinary incontinence (only) | 0 | 0 | Risk Ratio (M-H, Fixed, 95% CI) | Not estimable |
| 4.3 mixed incontinence | 0 | 0 | Risk Ratio (M-H, Fixed, 95% CI) | Not estimable |
| 5 Pad changes over 24 hours | 0 | 0 | Mean Difference (IV, Fixed, 95% CI) | Not estimable |
| 5.1 objective/genuine stress incontinence (only) | 0 | 0 | Mean Difference (IV, Fixed, 95% CI) | Not estimable |
| 5.2 subjective/stress urinary incontinence (only) | 0 | 0 | Mean Difference (IV, Fixed, 95% CI) | Not estimable |
| 5.3 mixed incontinence | 0 | 0 | Mean Difference (IV, Fixed, 95% CI) | Not estimable |
| 6 Incontinent episodes over 24 hours | 1 | 28 | Mean Difference (IV, Fixed, 95% CI) | Not estimable |
| 6.1 objective/genuine stress incontinence (only) | 1 | 28 | Mean Difference (IV, Fixed, 95% CI) | Not estimable |

| | | | | |
|--|---|-----|-------------------------------------|--------------------|
| 6.2 subjective/stress urinary incontinence (only) | 0 | 0 | Mean Difference (IV, Fixed, 95% CI) | Not estimable |
| 6.3 mixed incontinence | 0 | 0 | Mean Difference (IV, Fixed, 95% CI) | Not estimable |
| 7 Pad test weights | 0 | 0 | Mean Difference (IV, Fixed, 95% CI) | Not estimable |
| 7.1 objective/genuine stress incontinence (only) | 0 | 0 | Mean Difference (IV, Fixed, 95% CI) | Not estimable |
| 7.2 subjective/stress urinary incontinence (only) | 0 | 0 | Mean Difference (IV, Fixed, 95% CI) | Not estimable |
| 7.3 mixed incontinence | 0 | 0 | Mean Difference (IV, Fixed, 95% CI) | Not estimable |
| 8 Health status measures | 0 | 0 | Mean Difference (IV, Fixed, 95% CI) | Not estimable |
| 8.1 objective/genuine stress incontinence (only) | 0 | 0 | Mean Difference (IV, Fixed, 95% CI) | Not estimable |
| 8.2 subjective/stress urinary incontinence (only) | 0 | 0 | Mean Difference (IV, Fixed, 95% CI) | Not estimable |
| 8.3 mixed incontinence | 0 | 0 | Mean Difference (IV, Fixed, 95% CI) | Not estimable |
| 9 Health economic measures | 0 | 0 | Mean Difference (IV, Fixed, 95% CI) | Not estimable |
| 9.1 objective/genuine stress incontinence (only) | 0 | 0 | Mean Difference (IV, Fixed, 95% CI) | Not estimable |
| 9.2 subjective/stress urinary incontinence (only) | 0 | 0 | Mean Difference (IV, Fixed, 95% CI) | Not estimable |
| 9.3 mixed incontinence | 0 | 0 | Mean Difference (IV, Fixed, 95% CI) | Not estimable |
| 10 Voiding dysfunction after three months | 2 | 106 | Risk Ratio (M-H, Fixed, 95% CI) | 5.0 [0.61, 40.70] |
| 10.1 objective/genuine stress incontinence (only) | 2 | 106 | Risk Ratio (M-H, Fixed, 95% CI) | 5.0 [0.61, 40.70] |
| 10.2 subjective/stress urinary incontinence (only) | 0 | 0 | Risk Ratio (M-H, Fixed, 95% CI) | Not estimable |
| 10.3 mixed incontinence | 0 | 0 | Risk Ratio (M-H, Fixed, 95% CI) | Not estimable |
| 11 Detrusor instability (urodynamic diagnosis) | 3 | 142 | Risk Ratio (M-H, Fixed, 95% CI) | 2.79 [0.78, 10.00] |
| 11.1 objective/genuine stress incontinence (only) | 3 | 142 | Risk Ratio (M-H, Fixed, 95% CI) | 2.79 [0.78, 10.00] |
| 11.2 subjective/stress urinary incontinence (only) | 0 | 0 | Risk Ratio (M-H, Fixed, 95% CI) | Not estimable |
| 11.3 mixed incontinence | 0 | 0 | Risk Ratio (M-H, Fixed, 95% CI) | Not estimable |
| 12 Prolapse | 2 | 106 | Risk Ratio (M-H, Fixed, 95% CI) | 0.2 [0.04, 1.11] |
| 12.1 objective/genuine stress incontinence (only) | 2 | 106 | Risk Ratio (M-H, Fixed, 95% CI) | 0.2 [0.04, 1.11] |
| 12.2 subjective/stress urinary incontinence (only) | 0 | 0 | Risk Ratio (M-H, Fixed, 95% CI) | Not estimable |
| 12.3 mixed incontinence | 0 | 0 | Risk Ratio (M-H, Fixed, 95% CI) | Not estimable |
| 13 Peri-operative surgical complications | 2 | 108 | Risk Ratio (M-H, Fixed, 95% CI) | 0.65 [0.18, 2.36] |
| 13.1 objective/genuine stress incontinence (only) | 2 | 108 | Risk Ratio (M-H, Fixed, 95% CI) | 0.65 [0.18, 2.36] |
| 13.2 subjective/stress urinary incontinence (only) | 0 | 0 | Risk Ratio (M-H, Fixed, 95% CI) | Not estimable |
| 13.3 mixed incontinence | 0 | 0 | Risk Ratio (M-H, Fixed, 95% CI) | Not estimable |
| 14 Length of inpatient stay | 2 | 108 | Mean Difference (IV, Fixed, 95% CI) | 2.80 [2.11, 3.49] |
| 14.1 objective/genuine stress incontinence (only) | 2 | 108 | Mean Difference (IV, Fixed, 95% CI) | 2.80 [2.11, 3.49] |

| | | | | |
|--|---|----|-------------------------------------|------------------|
| 14.2 subjective/stress urinary incontinence (only) | 0 | 0 | Mean Difference (IV, Fixed, 95% CI) | Not estimable |
| 14.3 mixed incontinence | 0 | 0 | Mean Difference (IV, Fixed, 95% CI) | Not estimable |
| 15 Time to return to normal activity level | 0 | 0 | Mean Difference (IV, Fixed, 95% CI) | Not estimable |
| 15.1 objective/genuine stress incontinence (only) | 0 | 0 | Mean Difference (IV, Fixed, 95% CI) | Not estimable |
| 15.2 subjective/stress urinary incontinence (only) | 0 | 0 | Mean Difference (IV, Fixed, 95% CI) | Not estimable |
| 15.3 mixed incontinence | 0 | 0 | Mean Difference (IV, Fixed, 95% CI) | Not estimable |
| 16 Repeat incontinence surgery | 0 | 0 | Risk Ratio (M-H, Fixed, 95% CI) | Not estimable |
| 16.1 objective/genuine stress incontinence (only) | 0 | 0 | Risk Ratio (M-H, Fixed, 95% CI) | Not estimable |
| 16.2 subjective/stress urinary incontinence (only) | 0 | 0 | Risk Ratio (M-H, Fixed, 95% CI) | Not estimable |
| 16.3 mixed incontinence | 0 | 0 | Risk Ratio (M-H, Fixed, 95% CI) | Not estimable |
| 17 Urge symptoms or urge incontinence | 1 | 72 | Risk Ratio (M-H, Fixed, 95% CI) | 2.0 [0.54, 7.39] |
| 17.1 objective/genuine stress incontinence (only) | 1 | 72 | Risk Ratio (M-H, Fixed, 95% CI) | 2.0 [0.54, 7.39] |
| 17.2 subjective/stress urinary incontinence (only) | 0 | 0 | Risk Ratio (M-H, Fixed, 95% CI) | Not estimable |
| 17.3 mixed incontinence | 0 | 0 | Risk Ratio (M-H, Fixed, 95% CI) | Not estimable |

Comparison 2. SLING VS STAMEY BLADDER NECK (NEEDLE) SUSPENSION

| Outcome or subgroup title | No. of studies | No. of participants | Statistical method | Effect size |
|---|----------------|---------------------|---------------------------------|-------------------|
| 1 Number not cured (worse, unchanged or improved) within the first year | 1 | 20 | Risk Ratio (M-H, Fixed, 95% CI) | 0.5 [0.05, 4.67] |
| 1.1 objective/genuine stress incontinence (only) | 1 | 20 | Risk Ratio (M-H, Fixed, 95% CI) | 0.5 [0.05, 4.67] |
| 1.2 subjective/stress urinary incontinence (only) | 0 | 0 | Risk Ratio (M-H, Fixed, 95% CI) | Not estimable |
| 1.3 mixed incontinence | 0 | 0 | Risk Ratio (M-H, Fixed, 95% CI) | Not estimable |
| 2 Number not cured (worse, unchanged or improved) after first year | 1 | 20 | Risk Ratio (M-H, Fixed, 95% CI) | 0.33 [0.04, 2.69] |
| 2.1 objective/genuine stress incontinence (only) | 1 | 20 | Risk Ratio (M-H, Fixed, 95% CI) | 0.33 [0.04, 2.69] |
| 2.2 subjective/stress urinary incontinence | 0 | 0 | Risk Ratio (M-H, Fixed, 95% CI) | Not estimable |
| 2.3 mixed incontinence | 0 | 0 | Risk Ratio (M-H, Fixed, 95% CI) | Not estimable |
| 3 Number not improved (worse or unchanged) within the first year | 0 | 0 | Risk Ratio (M-H, Fixed, 95% CI) | Not estimable |

| | | | | |
|---|---|----|-------------------------------------|------------------|
| 3.1 objective/genuine stress incontinence | 0 | 0 | Risk Ratio (M-H, Fixed, 95% CI) | Not estimable |
| 3.2 subjective/stress urinary incontinence (only) | 0 | 0 | Risk Ratio (M-H, Fixed, 95% CI) | Not estimable |
| 3.3 mixed incontinence | 0 | 0 | Risk Ratio (M-H, Fixed, 95% CI) | Not estimable |
| 4 Number not improved (worse or unchanged) after first year | 0 | 0 | Risk Ratio (M-H, Fixed, 95% CI) | Not estimable |
| 4.1 objective/genuine stress incontinence (only) | 0 | 0 | Risk Ratio (M-H, Fixed, 95% CI) | Not estimable |
| 4.2 subjective/stress urinary incontinence (only) | 0 | 0 | Risk Ratio (M-H, Fixed, 95% CI) | Not estimable |
| 4.3 mixed incontinence | 0 | 0 | Risk Ratio (M-H, Fixed, 95% CI) | Not estimable |
| 5 Pad changes over 24 hours | 0 | 0 | Mean Difference (IV, Fixed, 95% CI) | Not estimable |
| 5.1 objective/genuine stress incontinence (only) | 0 | 0 | Mean Difference (IV, Fixed, 95% CI) | Not estimable |
| 5.2 subjective/stress urinary incontinence (only) | 0 | 0 | Mean Difference (IV, Fixed, 95% CI) | Not estimable |
| 5.3 mixed incontinence | 0 | 0 | Mean Difference (IV, Fixed, 95% CI) | Not estimable |
| 6 Incontinent episodes over 24 hours | 0 | 0 | Mean Difference (IV, Fixed, 95% CI) | Not estimable |
| 6.1 objective/genuine stress incontinence (only) | 0 | 0 | Mean Difference (IV, Fixed, 95% CI) | Not estimable |
| 6.2 subjective/stress urinary incontinence (only) | 0 | 0 | Mean Difference (IV, Fixed, 95% CI) | Not estimable |
| 6.3 mixed incontinence | 0 | 0 | Mean Difference (IV, Fixed, 95% CI) | Not estimable |
| 7 Pad tests weight | 0 | 0 | Mean Difference (IV, Fixed, 95% CI) | Not estimable |
| 7.1 objective/genuine stress incontinence (only) | 0 | 0 | Mean Difference (IV, Fixed, 95% CI) | Not estimable |
| 7.2 subjective/stress urinary incontinence (only) | 0 | 0 | Mean Difference (IV, Fixed, 95% CI) | Not estimable |
| 7.3 mixed incontinence | 0 | 0 | Mean Difference (IV, Fixed, 95% CI) | Not estimable |
| 8 Health status measures | 0 | 0 | Mean Difference (IV, Fixed, 95% CI) | Not estimable |
| 8.1 objective/genuine stress incontinence (only) | 0 | 0 | Mean Difference (IV, Fixed, 95% CI) | Not estimable |
| 8.2 subjective/stress urinary incontinence (only) | 0 | 0 | Mean Difference (IV, Fixed, 95% CI) | Not estimable |
| 8.3 mixed incontinence | 0 | 0 | Mean Difference (IV, Fixed, 95% CI) | Not estimable |
| 9 Health economic measures | 0 | 0 | Mean Difference (IV, Fixed, 95% CI) | Not estimable |
| 9.1 objective/genuine stress incontinence (only) | 0 | 0 | Mean Difference (IV, Fixed, 95% CI) | Not estimable |
| 9.2 subjective/stress urinary incontinence (only) | 0 | 0 | Mean Difference (IV, Fixed, 95% CI) | Not estimable |
| 9.3 mixed incontinence | 0 | 0 | Mean Difference (IV, Fixed, 95% CI) | Not estimable |
| 10 Voiding dysfunction after three months | 1 | 20 | Risk Ratio (M-H, Fixed, 95% CI) | 2.0 [0.47, 8.56] |
| 10.1 objective/genuine stress incontinence (only) | 1 | 20 | Risk Ratio (M-H, Fixed, 95% CI) | 2.0 [0.47, 8.56] |
| 10.2 subjective/stress urinary incontinence (only) | 0 | 0 | Risk Ratio (M-H, Fixed, 95% CI) | Not estimable |
| 10.3 mixed incontinence | 0 | 0 | Risk Ratio (M-H, Fixed, 95% CI) | Not estimable |

| | | | | | |
|----|--|---|----|-------------------------------------|--------------------|
| 11 | Detrusor instability (urodynamic diagnosis) | 1 | 20 | Risk Ratio (M-H, Fixed, 95% CI) | 2.0 [0.21, 18.69] |
| | 11.1 objective/genuine stress incontinence (only) | 1 | 20 | Risk Ratio (M-H, Fixed, 95% CI) | 2.0 [0.21, 18.69] |
| | 11.2 subjective/stress urinary incontinence (only) | 0 | 0 | Risk Ratio (M-H, Fixed, 95% CI) | Not estimable |
| | 11.3 mixed incontinence | 0 | 0 | Risk Ratio (M-H, Fixed, 95% CI) | Not estimable |
| 12 | Entero-rectocele | 0 | 0 | Risk Ratio (M-H, Fixed, 95% CI) | Not estimable |
| | 12.1 objective/genuine stress incontinence (only) | 0 | 0 | Risk Ratio (M-H, Fixed, 95% CI) | Not estimable |
| | 12.2 subjective/stress urinary incontinence (only) | 0 | 0 | Risk Ratio (M-H, Fixed, 95% CI) | Not estimable |
| | 12.3 mixed incontinence | 0 | 0 | Risk Ratio (M-H, Fixed, 95% CI) | Not estimable |
| 13 | Peri-operative surgical complications | 1 | 20 | Risk Ratio (M-H, Fixed, 95% CI) | 4.5 [1.28, 15.81] |
| | 13.1 objective/genuine stress incontinence (only) | 1 | 20 | Risk Ratio (M-H, Fixed, 95% CI) | 4.5 [1.28, 15.81] |
| | 13.2 subjective/stress urinary incontinence (only) | 0 | 0 | Risk Ratio (M-H, Fixed, 95% CI) | Not estimable |
| | 13.3 mixed incontinence | 0 | 0 | Risk Ratio (M-H, Fixed, 95% CI) | Not estimable |
| 14 | Length of inpatient stay | 1 | 20 | Mean Difference (IV, Fixed, 95% CI) | 13.0 [5.00, 21.00] |
| | 14.1 objective/genuine stress incontinence (only) | 1 | 20 | Mean Difference (IV, Fixed, 95% CI) | 13.0 [5.00, 21.00] |
| | 14.2 subjective/stress urinary incontinence (only) | 0 | 0 | Mean Difference (IV, Fixed, 95% CI) | Not estimable |
| | 14.3 mixed incontinence | 0 | 0 | Mean Difference (IV, Fixed, 95% CI) | Not estimable |
| 15 | Time to return to normal activity level | 0 | 0 | Mean Difference (IV, Fixed, 95% CI) | Not estimable |
| | 15.1 objective/genuine stress incontinence (only) | 0 | 0 | Mean Difference (IV, Fixed, 95% CI) | Not estimable |
| | 15.2 subjective/stress urinary incontinence (only) | 0 | 0 | Mean Difference (IV, Fixed, 95% CI) | Not estimable |
| | 15.3 mixed incontinence | 0 | 0 | Mean Difference (IV, Fixed, 95% CI) | Not estimable |
| 16 | Repeat incontinence surgery | 0 | 0 | Risk Ratio (M-H, Fixed, 95% CI) | Not estimable |
| | 16.1 objective/genuine stress incontinence (only) | 0 | 0 | Risk Ratio (M-H, Fixed, 95% CI) | Not estimable |
| | 16.2 subjective/stress urinary incontinence (only) | 0 | 0 | Risk Ratio (M-H, Fixed, 95% CI) | Not estimable |
| | 16.3 mixed incontinence | 0 | 0 | Risk Ratio (M-H, Fixed, 95% CI) | Not estimable |
| 17 | Urge symptoms or urge incontinence | 1 | 20 | Risk Ratio (M-H, Fixed, 95% CI) | 1.67 [0.54, 5.17] |
| | 17.1 objective/genuine stress incontinence (only) | 1 | 20 | Risk Ratio (M-H, Fixed, 95% CI) | 1.67 [0.54, 5.17] |
| | 17.2 subjective/stress urinary incontinence (only) | 0 | 0 | Risk Ratio (M-H, Fixed, 95% CI) | Not estimable |
| | 17.3 mixed incontinence | 0 | 0 | Risk Ratio (M-H, Fixed, 95% CI) | Not estimable |

Comparison 3. SLING VS SLING

| Outcome or subgroup title | No. of studies | No. of participants | Statistical method | Effect size |
|---|----------------|---------------------|-------------------------------------|-------------------|
| 1 Number not cured (worse, unchanged or improved) within the first year | 2 | 298 | Risk Ratio (M-H, Fixed, 95% CI) | 0.96 [0.59, 1.55] |
| 1.1 objective/genuine stress incontinence (only) | 2 | 298 | Risk Ratio (M-H, Fixed, 95% CI) | 0.96 [0.59, 1.55] |
| 1.2 subjective/stress urinary incontinence (only) | 0 | 0 | Risk Ratio (M-H, Fixed, 95% CI) | Not estimable |
| 1.3 mixed incontinence | 0 | 0 | Risk Ratio (M-H, Fixed, 95% CI) | Not estimable |
| 2 Number not cured (worse, unchanged or improved) after first year | 3 | 162 | Risk Ratio (M-H, Fixed, 95% CI) | 0.69 [0.41, 1.16] |
| 2.1 objective/genuine stress incontinence (only) | 1 | 57 | Risk Ratio (M-H, Fixed, 95% CI) | 1.16 [0.43, 3.12] |
| 2.2 subjective/stress urinary incontinence (only) | 0 | 0 | Risk Ratio (M-H, Fixed, 95% CI) | Not estimable |
| 2.3 mixed incontinence | 2 | 105 | Risk Ratio (M-H, Fixed, 95% CI) | 0.56 [0.30, 1.04] |
| 3 Number not improved (worse or unchanged) within the first year | 3 | 346 | Risk Ratio (M-H, Fixed, 95% CI) | 0.86 [0.47, 1.59] |
| 3.1 objective/genuine stress incontinence (only) | 2 | 298 | Risk Ratio (M-H, Fixed, 95% CI) | 1.06 [0.56, 2.01] |
| 3.2 subjective/stress urinary incontinence (only) | 0 | 0 | Risk Ratio (M-H, Fixed, 95% CI) | Not estimable |
| 3.3 mixed incontinence | 1 | 48 | Risk Ratio (M-H, Fixed, 95% CI) | 0.15 [0.01, 2.50] |
| 4 Number not improved (worse or unchanged) after first year | 2 | 105 | Risk Ratio (M-H, Fixed, 95% CI) | 1.09 [0.20, 6.03] |
| 4.1 objective/genuine stress incontinence (only) | 1 | 57 | Risk Ratio (M-H, Fixed, 95% CI) | 1.09 [0.20, 6.03] |
| 4.2 subjective/stress urinary incontinence (only) | 0 | 0 | Risk Ratio (M-H, Fixed, 95% CI) | Not estimable |
| 4.3 mixed incontinence | 1 | 48 | Risk Ratio (M-H, Fixed, 95% CI) | Not estimable |
| 5 Pad changes over 24 hours | 1 | 146 | Mean Difference (IV, Fixed, 95% CI) | Not estimable |
| 5.1 objective/genuine stress incontinence (only) | 1 | 146 | Mean Difference (IV, Fixed, 95% CI) | Not estimable |
| 5.2 subjective/stress urinary incontinence (only) | 0 | 0 | Mean Difference (IV, Fixed, 95% CI) | Not estimable |
| 5.3 mixed incontinence | 0 | 0 | Mean Difference (IV, Fixed, 95% CI) | Not estimable |
| 6 Incontinent episodes over 24 hours | 1 | 156 | Mean Difference (IV, Fixed, 95% CI) | Not estimable |
| 6.1 objective/genuine stress incontinence (only) | 1 | 156 | Mean Difference (IV, Fixed, 95% CI) | Not estimable |
| 6.2 subjective/stress urinary incontinence (only) | 0 | 0 | Mean Difference (IV, Fixed, 95% CI) | Not estimable |
| 6.3 mixed incontinence | 0 | 0 | Mean Difference (IV, Fixed, 95% CI) | Not estimable |
| 7 Pad test weight | 1 | 110 | Mean Difference (IV, Fixed, 95% CI) | Not estimable |

| | | | | |
|--|---|-----|---------------------------------------|-------------------|
| 7.1 objective/genuine stress incontinence (only) | 1 | 110 | Mean Difference (IV, Fixed, 95% CI) | Not estimable |
| 7.2 subjective/stress urinary incontinence (only) | 0 | 0 | Mean Difference (IV, Fixed, 95% CI) | Not estimable |
| 7.3 mixed incontinence | 0 | 0 | Mean Difference (IV, Fixed, 95% CI) | Not estimable |
| 8 Health status measure | 1 | 156 | Mean Difference (IV, Fixed, 95% CI) | Not estimable |
| 8.1 objective/genuine stress incontinence (only) | 1 | 156 | Mean Difference (IV, Fixed, 95% CI) | Not estimable |
| 8.2 subjective/stress urinary incontinence (only) | 0 | 0 | Mean Difference (IV, Fixed, 95% CI) | Not estimable |
| 8.3 mixed incontinence | 0 | 0 | Mean Difference (IV, Fixed, 95% CI) | Not estimable |
| 9 Health economic measures | 0 | 0 | Mean Difference (IV, Fixed, 95% CI) | Not estimable |
| 9.1 objective/genuine stress incontinence (only) | 0 | 0 | Mean Difference (IV, Fixed, 95% CI) | Not estimable |
| 9.2 subjective/stress urinary incontinence (only) | 0 | 0 | Mean Difference (IV, Fixed, 95% CI) | Not estimable |
| 9.3 mixed incontinence | 0 | 0 | Mean Difference (IV, Fixed, 95% CI) | Not estimable |
| 10 Voiding dysfunction after three months | 0 | 0 | Peto Odds Ratio (Peto, Fixed, 95% CI) | Not estimable |
| 10.1 objective/genuine stress incontinence (only) | 0 | 0 | Peto Odds Ratio (Peto, Fixed, 95% CI) | Not estimable |
| 10.2 subjective/stress urinary incontinence (only) | 0 | 0 | Peto Odds Ratio (Peto, Fixed, 95% CI) | Not estimable |
| 10.3 mixed incontinence | 0 | 0 | Peto Odds Ratio (Peto, Fixed, 95% CI) | Not estimable |
| 11 Detrusor instability (urodynamic diagnosis) | 2 | 105 | Risk Ratio (M-H, Fixed, 95% CI) | 0.87 [0.36, 2.10] |
| 11.1 objective/genuine stress incontinence (only) | 1 | 57 | Risk Ratio (M-H, Fixed, 95% CI) | 0.58 [0.17, 1.94] |
| 11.2 subjective/stress urinary incontinence (only) | 0 | 0 | Risk Ratio (M-H, Fixed, 95% CI) | Not estimable |
| 11.3 mixed incontinence | 1 | 48 | Risk Ratio (M-H, Fixed, 95% CI) | 1.5 [0.38, 5.91] |
| 12 Entero-rectocele | 0 | 0 | Peto Odds Ratio (Peto, Fixed, 95% CI) | Not estimable |
| 12.1 objective/genuine stress incontinence (only) | 0 | 0 | Peto Odds Ratio (Peto, Fixed, 95% CI) | Not estimable |
| 12.2 subjective/stress urinary incontinence (only) | 0 | 0 | Peto Odds Ratio (Peto, Fixed, 95% CI) | Not estimable |
| 12.3 mixed incontinence | 0 | 0 | Peto Odds Ratio (Peto, Fixed, 95% CI) | Not estimable |
| 13 Peri operative surgical complications | 4 | 412 | Risk Ratio (M-H, Fixed, 95% CI) | 0.95 [0.70, 1.27] |
| 13.1 objective/genuine stress incontinence (only) | 2 | 307 | Risk Ratio (M-H, Fixed, 95% CI) | 0.86 [0.62, 1.20] |
| 13.2 subjective/stress urinary incontinence (only) | 0 | 0 | Risk Ratio (M-H, Fixed, 95% CI) | Not estimable |
| 13.3 mixed incontinence | 2 | 105 | Risk Ratio (M-H, Fixed, 95% CI) | 1.39 [0.68, 2.82] |
| 14 Length of inpatient stay | 2 | 307 | Mean Difference (IV, Fixed, 95% CI) | Not estimable |
| 14.1 objective/genuine stress incontinence (only) | 2 | 307 | Mean Difference (IV, Fixed, 95% CI) | Not estimable |
| 14.2 subjective/stress urinary incontinence (only) | 0 | 0 | Mean Difference (IV, Fixed, 95% CI) | Not estimable |
| 14.3 mixed incontinence | 0 | 0 | Mean Difference (IV, Fixed, 95% CI) | Not estimable |

| | | | | | |
|----|--|---|-----|---------------------------------------|-------------------|
| 15 | Time to return to normal activity level | 0 | 0 | Mean Difference (IV, Fixed, 95% CI) | Not estimable |
| | 15.1 objective/genuine stress incontinence (only) | 0 | 0 | Mean Difference (IV, Fixed, 95% CI) | Not estimable |
| | 15.2 subjective/stress urinary incontinence (only) | 0 | 0 | Mean Difference (IV, Fixed, 95% CI) | Not estimable |
| | 15.3 mixed incontinence | 0 | 0 | Mean Difference (IV, Fixed, 95% CI) | Not estimable |
| 16 | Repeat incontinence surgery | 0 | 0 | Peto Odds Ratio (Peto, Fixed, 95% CI) | Not estimable |
| | 16.1 objective/genuine stress incontinence (only) | 0 | 0 | Peto Odds Ratio (Peto, Fixed, 95% CI) | Not estimable |
| | 16.2 subjective/stress urinary incontinence (only) | 0 | 0 | Peto Odds Ratio (Peto, Fixed, 95% CI) | Not estimable |
| | 16.3 mixed incontinence | 0 | 0 | Peto Odds Ratio (Peto, Fixed, 95% CI) | Not estimable |
| 17 | Urge symptoms or urge incontinence | 1 | 154 | Risk Ratio (M-H, Fixed, 95% CI) | 0.82 [0.56, 1.19] |
| | 17.1 objective/genuine stress incontinence (only) | 1 | 154 | Risk Ratio (M-H, Fixed, 95% CI) | 0.82 [0.56, 1.19] |
| | 17.2 subjective/stress urinary incontinence (only) | 0 | 0 | Risk Ratio (M-H, Fixed, 95% CI) | Not estimable |
| | 17.3 mixed incontinence | 0 | 0 | Risk Ratio (M-H, Fixed, 95% CI) | Not estimable |

Comparison 4. SLING VS CONSERVATIVE MANAGEMENT

| Outcome or subgroup title | No. of studies | No. of participants | Statistical method | Effect size |
|---|----------------|---------------------|---------------------------------|------------------------|
| 1 Number not cured (worse, unchanged or improved) within the first year | 1 | 45 | Odds Ratio (M-H, Fixed, 95% CI) | 387.0 [17.55, 8533.79] |
| 1.1 objective/genuine stress incontinence (only) | 0 | 0 | Odds Ratio (M-H, Fixed, 95% CI) | Not estimable |
| 1.2 subjective/stress urinary incontinence (only) | 0 | 0 | Odds Ratio (M-H, Fixed, 95% CI) | Not estimable |
| 1.3 mixed incontinence | 1 | 45 | Odds Ratio (M-H, Fixed, 95% CI) | 387.0 [17.55, 8533.79] |
| 2 Number not cured (worse, unchanged or improved) after first year | 0 | 0 | Odds Ratio (M-H, Fixed, 95% CI) | Not estimable |
| 2.1 objective/genuine stress incontinence (only) | 0 | 0 | Odds Ratio (M-H, Fixed, 95% CI) | Not estimable |
| 2.2 subjective/stress urinary incontinence (only) | 0 | 0 | Odds Ratio (M-H, Fixed, 95% CI) | Not estimable |
| 2.3 mixed incontinence | 0 | 0 | Odds Ratio (M-H, Fixed, 95% CI) | Not estimable |
| 3 Number not improved (worse or unchanged) within the first year | 0 | 0 | Odds Ratio (M-H, Fixed, 95% CI) | Not estimable |
| 3.1 objective/genuine stress incontinence (only) | 0 | 0 | Odds Ratio (M-H, Fixed, 95% CI) | Not estimable |

| | | | | |
|---|---|----|---------------------------------|--------------------|
| 3.2 subjective/stress urinary incontinence (only) | 0 | 0 | Odds Ratio (M-H, Fixed, 95% CI) | Not estimable |
| 3.3 mixed incontinence | 0 | 0 | Odds Ratio (M-H, Fixed, 95% CI) | Not estimable |
| 4 Number not improved (worse or unchanged) after the first year | 0 | 0 | Odds Ratio (M-H, Fixed, 95% CI) | Not estimable |
| 4.1 objective/genuine stress incontinence (only) | 0 | 0 | Odds Ratio (M-H, Fixed, 95% CI) | Not estimable |
| 4.2 subjective/stress urinary incontinence (only) | 0 | 0 | Odds Ratio (M-H, Fixed, 95% CI) | Not estimable |
| 4.3 mixed incontinence | 0 | 0 | Odds Ratio (M-H, Fixed, 95% CI) | Not estimable |
| 5 Detrusor instability (urodynamic diagnosis) | 0 | 0 | Odds Ratio (M-H, Fixed, 95% CI) | Not estimable |
| 5.1 objective/genuine stress incontinence (only) | 0 | 0 | Odds Ratio (M-H, Fixed, 95% CI) | Not estimable |
| 5.2 subjective/stress urinary incontinence (only) | 0 | 0 | Odds Ratio (M-H, Fixed, 95% CI) | Not estimable |
| 5.3 mixed incontinence | 0 | 0 | Odds Ratio (M-H, Fixed, 95% CI) | Not estimable |
| 6 Urge symptoms or urge incontinence | 1 | 45 | Odds Ratio (M-H, Fixed, 95% CI) | 5.25 [1.19, 23.22] |
| 6.1 objective/genuine stress incontinence (only) | 0 | 0 | Odds Ratio (M-H, Fixed, 95% CI) | Not estimable |
| 6.2 subjective/stress urinary incontinence(only) | 0 | 0 | Odds Ratio (M-H, Fixed, 95% CI) | Not estimable |
| 6.3 mixed incontinence | 1 | 45 | Odds Ratio (M-H, Fixed, 95% CI) | 5.25 [1.19, 23.22] |

WHAT'S NEW

Last assessed as up-to-date: 24 May 2005.

| | | |
|-----------------|---------|---------------------------------|
| 13 October 2008 | Amended | Converted to new review format. |
|-----------------|---------|---------------------------------|

HISTORY

Protocol first published: Issue 3, 1999

Review first published: Issue 3, 2000

| | | |
|------------------|--|--|
| 25 May 2005 | New citation required and conclusions have changed | Substantive amendment. The review was divided into two separate reviews: one on traditional sub-urethral sling operations (current review, updated) and another on sub-urethral self fixing sling operations (to include the new TVT and SPARC procedure) to be prepared. The trials on TVT versus other procedures other than traditional suburethral sling operations (four) were moved to the excluded trials list and will be included in the new review. Five new trials were included. |
| 13 February 2003 | New search has been performed | minor update, five studies added |
| 17 May 2001 | New citation required and conclusions have changed | first update |

CONTRIBUTIONS OF AUTHORS

The review was conceived by CB and HB. CB coordinated the steps of the review process with the help of DJC . Screening papers, appraising their quality and abstracting data were done by CB, HB separately (published data only). The review was written by CB who extracted, analysed and interpreted data with the help of HB. DJC assisted in the update for Feb 2003 by appraising, quality assessing, abstracting data and assisting with interpretation.

DECLARATIONS OF INTEREST

None known

SOURCES OF SUPPORT

Internal sources

- Federal University of Sao Paulo - Sao Paulo, Brazil.
- Faculty of Medicine of Foudation of ABC, Brazil.

External sources

- No sources of support supplied

NOTES

Third update: issue 3, 2005, search updated 20.12.2004. The review is to be divided into two separate reviews: one on traditional sub-urethral sling operations (current review, updated) and another on sub-urethral self fixing sling operations (to include the new TVT and SPARC procedure) to be prepared. The trials on TVT versus other procedures other than traditional suburethral sling operations (four) were moved to the excluded trials list and will be included in the new review. Five new trials were included.

INDEX TERMS

Medical Subject Headings (MeSH)

Polytetrafluoroethylene [therapeutic use]; Randomized Controlled Trials as Topic; Urethra; Urinary Incontinence, Stress [*surgery]; Urologic Surgical Procedures [methods]

MeSH check words

Female; Humans