



SURGICAL TREATMENT OF URODYNAMIC STRESS INCONTINENCE

1. Background and purpose

This guideline is based on recommendations formulated by the 2nd International Consultation on Incontinence, Paris 2001, which provided of a worldwide panel of experts, and a summary of Cochrane and National Institute for Clinical Excellence (NICE) reviews from 2003.

Stress incontinence is a symptom or sign indicating that the woman has involuntary urine loss associated with exertion. Urodynamic stress incontinence (previously known as genuine stress incontinence) is a solely urodynamic diagnosis which occurs when an incompetent urethra allows leakage of urine in the absence of a detrusor contraction.¹

Surgery for stress incontinence of urine has been performed on women for over a century. The anterior vaginal repair was the most popular primary procedure for stress incontinence up to the 1970s, but over the last 20 years the operation has been criticised because of high recurrence rates. More sustained results are obtained from retropubic surgery.

The aim of this guideline is to highlight the evidence for different surgical approaches, since the best chance of surgical 'cure' for stress incontinence is successful primary surgery. Primary surgery should only be considered after a period of conservative treatment from a specialist therapist has been offered and rejected, or has failed. There is evidence from a Cochrane review that pelvic-floor muscle training is effective in patients with stress or mixed incontinence, and that intensive therapy is better than standard pelvic floor training.² The role of conservative therapy following previous continence surgery has not been established.

The literature on surgery for stress incontinence is extensive but is mainly based on case series rather than randomised trials. Cure is defined in many different ways, both subjective and objective. The difficulty of assessing cure rates in studies of continence surgery has been highlighted in a review of stress incontinence surgery.³ Overall, 83% of women reported improvement three months after continence surgery, 5% had no change and 8% reported a worsening in their condition. The impact of complications from bladder-neck surgery has been studied only recently; for example, the occurrence of urge incontinence or voiding difficulty postoperatively can greatly affect the woman's perception of 'cure'. While not underestimating the difficulty in conducting well constructed, prospective, randomised trials of surgical treatment, this review highlights the need for such trials to be performed. In this guideline, we have attempted to provide consistency in definition of cure, using 'continence rate' after surgery to indicate the woman's dryness reported by the surgical team. If objective measurements have been performed, an 'objective continence rate' is quoted. Too few of the available studies provided subjective data on women's perception of continence (such as quality-of-life data), although this is often markedly different from the surgical perception of 'cure.'

2. Identification and assessment of evidence

This guideline is based on recommendations formulated by the 2nd International Consultation on Incontinence, Paris 2001, which provided of a worldwide panel of experts, and a summary of Cochrane and NICE reviews from 2003.

The Cochrane Database of Systematic Reviews and Cochrane Register of Controlled Trials were searched for relevant randomised controlled trials (RCT), systematic reviews and meta-analyses. A search of the Medline (PubMed) electronic database from 1966 to 2002 was also carried out. The date of the last search was May 2002. In addition conference proceedings and relevant abstracts were searched.

The databases were searched using the relevant MeSH terms including all subheadings and this was combined with a keyword search using 'human,' 'female,' 'incontinence,' 'bladder,' 'repair,' 'surgery,' 'sutures,' 'anterior repair,' 'anterior colporrhaphy,' 'Burch colposuspension,' 'retropubic,' 'Marshall–Marchetti–Krantz,' 'paravaginal repair,' 'laparoscopic colposuspension,' 'Stamey,' 'Pereyra,' 'needle suspension,' 'tension-free vaginal tape,' 'sling,' 'Martius,' 'fascia lata,' 'cadaveric,' 'Macroplastique,' 'injectable,' 'collagen,' 'artificial sphincter,' 'randomised controlled trials' and 'meta-analysis'.

The definitions of the types of evidence used in this guideline originate from the US Agency for Healthcare Research and Quality (Appendix). Where possible, recommendations are based on and explicitly linked to the evidence that supports them. Areas lacking evidence are highlighted and annotated as 'Good practice points'.

3. Surgical procedures

3.1 Anterior vaginal repair

A Anterior repair is less successful as an operation for continence than retropubic procedures and has been superseded by sling procedures. Anterior repair still has a role in the treatment of prolapse without incontinence.

The anterior colporrhaphy procedure is perhaps better termed the anterior repair with bladder buttress when relating to surgery for urodynamic stress incontinence. Case report literature indicates a wide range of continence rates following this procedure, ranging between 31% and 100% continence.⁴ Meta-analyses of heterogeneous studies suggest a continence rate of between 67.8–72.0%.^{4,5} Randomised trials including anterior colporrhaphy in one arm and suprapubic surgery in the other show a continence rate of 66%.⁶

The anterior colporrhaphy procedure remains in contemporaneous use largely because of the relatively low morbidity of the procedure and its familiarity for gynaecologists as an operation for prolapse. The 'serious complication rate' is in the region of 1% and the incidence of *de novo* detrusor overactivity is less than 6%. Compared with colposuspension there may be a shorter hospital stay and a 50% decrease in blood loss. The incidence of long-term voiding disorders following this procedure approaches zero.^{7,8} Long-term results decrease with time, such that a 63% continence rate at one year of follow up fell to 37% at five years of follow up.⁹ Long-term follow up beyond the first year was only available in three RCTs.^{10–12} The view of the American Urological Association is that 'anterior repairs are the least likely of the four major operative categories (anterior repair, suburethral sling, colposuspension, long-needle suspension) to be efficacious in the long term'.¹⁵

The literature regarding anterior vaginal repair has been most recently reviewed by the Cochrane Collaboration.¹⁴ Anterior vaginal repair was found to be less effective than open abdominal retropubic suspension. This was based on woman-reported continence rates in eight trials both in the short term (failure rate within first year after anterior repair 29% versus 14%) and long term (after first year, 41% versus 17%). There was evidence from three of these trials that this led to more repeat operations for incontinence (23% versus 2%). These findings held irrespective of the coexistence of prolapse. The correct operation for the woman with stress incontinence in the presence of anterior wall prolapse is currently unclear.

Evidence level Ia

3.2 Burch colposuspension

A Burch colposuspension is the most effective surgical procedure for stress incontinence, with a continence rate of 85–90% at one year. The continence rate falls to 70% at five years; this shows better longevity than other methods of treatment.

Sixteen substantive articles were reviewed. Two studies were prospective randomised trials and nine were prospective nonrandomised studies. Overall, these studies looked at the outcome of a total of 1363 women who underwent Burch colposuspension for stress incontinence, with a mean age of 51 years. Among these women, 267 had undergone previous incontinence surgery. The mean continence rate (based on a combination of subjective and objective evidence) was 79% with an improvement rate of 90%. The follow-up duration was nine months to 16 years. The immediate and long-term results from colposuspension suggest that the procedure remains effective with time. Three studies report five plus years continence rates. Bergman and Elia⁹ reported a 90% continence rate at eight years, while Kjødhede and Ryden¹⁵ reported only 55% continence at 10 years. Alcalay *et al.*¹⁶ reported a gradual decline in continence from 88% at two years to a plateau of 69% once 12 years or longer had been reached.

Voiding difficulty has been reported in a mean of 10.3% of women after colposuspension (range 2–27%). *De novo* detrusor overactivity has been described in a mean of 17% women (range 8–27%). Genitourinary prolapse (enterocele, rectocele) has been reported in colposuspension follow up at five years in an average of 13.6% women (range 2.5–26.7%). Ureteric damage has been reported. There was no reported mortality as a direct consequence of the procedure. The continence rate after Burch colposuspension falls if previous continence surgery has been performed. In one study the continence rate fell from 84% for a primary procedure to 63% for secondary surgery.¹⁷

A Cochrane review¹⁸ has examined the place of Burch colposuspension among other continence procedures and concluded that open colposuspension is the most effective surgical treatment for stress incontinence, especially in the long term. Thirty-three trials involving 2403 women were examined. Burch colposuspension is more effective than needle suspension (14% subjective failure after one year for open colposuspension compared with 26% for needle suspension) and provides a similar subjective continence rate to laparoscopic colposuspension (85–100% after 6–18 months of follow-up). Similarly, when compared with suburethral sling procedures, short-term comparisons only are available for sling procedures, which indicate a similar continence rate to colposuspension.^{19,20} There was no evidence of increased morbidity or complication rate with open colposuspension compared with other techniques, although posterior pelvic-organ prolapse is more common than after anterior colporrhaphy and sling procedures.

Evidence level Ia

3.3 Alternative suprapubic surgery

B The role of other suprapubic operations such as Marshall–Marchetti–Krantz, paravaginal repair and laparoscopic colposuspension, is unclear.

The Marshall–Marchetti–Krantz (MMK) retropubic procedure was a common anti-incontinence procedure between 1950–90s and Krantz described a personal series of 3861 cases with a follow-up of up to 31 years and a 96% subjective continence rate.²¹ The mortality was 0.2%, with a 22% overall complication rate. This operation has now fallen into disuse. A characteristic complication of MMK was osteitis pubis, which occurs in 2.5% of patients who undergo a MMK procedure.²² The operation was less successful than Burch colposuspension at correcting a cystocele. In a Cochrane review¹⁸ of open colposuspension trials, MMK was more likely to fail at five years than Burch colposuspension.

Evidence level Ia

Paravaginal repair was first described by White in 1909.²³ Cohort studies have suggested a subjective continence rate of 97% in women undergoing a paravaginal repair.²⁴ However there is only a single published randomised comparison of colposuspension with paravaginal repair; 36 women randomly

Evidence level III

allocated to treatment by either colposuspension or paravaginal repair using nonabsorbable suture material. At six months follow-up, there was an objective continence rate of 100% for those patients undergoing colposuspension but only 72% for those undergoing paravaginal repair.²⁵ Currently, the importance of recognition or repair of paravaginal defects is uncertain.

Evidence level III

Laparoscopic colposuspension has been the subject of several case series and cohort studies, which show similar continence rates between laparoscopic and open Burch colposuspension. However, the five prospective trials show similar or lower continence rates associated with laparoscopic Burch. Fatty *et al.*²⁶ and Summitt *et al.*²⁷ performed identical procedures by both routes and showed similar continence rates. The main criticisms of Burton's trial²⁸ are that he had not gained sufficient experience with laparoscopic surgery prior to embarking on the study and that the suture used was absorbable with a small needle, which may have included insufficient tissue. Likewise, Su *et al.*²⁹ used three absorbable sutures in the open Burch compared with a single nonabsorbable suture in the laparoscopic procedure. Persson and Wolner Hanssen³⁰ randomised women to a one-suture versus two-suture laparoscopic Burch and found a significantly higher continence rate with the two-suture procedure at one year (83% versus 58%).

A Cochrane review published in 2002³¹ examined eight eligible trials, five of which included 233 women receiving laparoscopic and 254 receiving open colposuspension. Subjective continence rates were similar at 6–18 months (85–100%) but there was some evidence of poorer objective outcomes for the laparoscopic operation (on urodynamic testing there was an additional 9% risk of failure). There were no significant differences for postoperative detrusor overactivity or voiding difficulty. There were trends towards a higher complication rate and longer operative times, lower intraoperative blood loss, less postoperative pain, shorter need for catheterisation, shorter hospital stay and earlier return to normal activities for the laparoscopic procedure.

Evidence level Ia

The important factors appear to be the laparoscopic experience of the surgeon and the type of suture used. There is no logical reason why the success rate of laparoscopic Burch should be different from the open procedure, if they are performed identically. It is important to avoid compromising the procedure by using tacks and mesh or by placing fewer sutures because of the technical difficulty of laparoscopic suturing. Currently, the long-term performance of laparoscopic colposuspension is uncertain. Despite a quicker recovery, the operation takes longer to perform, is associated with more surgical complications and is more expensive. It is likely to become a specialist procedure performed by surgeons highly skilled in both continence and laparoscopic techniques.

3.4 Needle suspension procedures

A Needle suspension procedures should not be performed: initial success rates are not maintained with time and the risk of failure is higher than for retropubic suspension procedures.

Multiple suspension procedures have been described in the past. The first procedure was described by Peyrera³² and numerous procedures have subsequently evolved from this, including the Gittes and the Stamey procedure, using suspending sutures and patch materials. Procedures have evolved to include the percutaneous bladder-neck suspension using bone anchors and a suspending system. The largest experience with these procedures was obtained by Raz *et al.*³³

Long-term follow up of the percutaneous needle procedure was reported by Tebyani *et al.*,³⁴ although only 42/49 patients were available for follow-up. Mean follow-up was 29 months. The reported continence rate was only 5%, with 12% significantly improved and 83% considered the operation a failure. In the only RCT comparing Peyrera-type needle suspension procedures and retropubic surgery, by Karram and Bhatia,³⁵ retropubic operations were found to be associated with a higher continence rate at one year.

Evidence level Ia

A Cochrane review was completed in 2002, based on eight trials and including 327 women having six types of needle suspension and 407 women having comparison interventions. Needle suspensions were more likely to fail than open retropubic procedures and there were more perioperative complications in the needle suspension group (48% compared with 30%). Needle suspensions may be as effective as anterior repair but carry a higher morbidity.²⁰

Evidence level Ia

3.5 Sling procedures

Suburethral sling procedures were developed initially in the 1880s. Numerous authors have subsequently modified these procedures. In 1942, Aldridge³⁶ used rectus sheath strips and reported the technique in one woman, describing the procedure as a salvage-type operation for those women who had failed prior procedures. Used with such an indication, the success rate recorded in the literature would appear to range between 64% and 100%, with a mean continence rate in the region of 86%.^{4,5}

Evidence level III

A Sling procedures, using autologous or synthetic materials, produce a continence rate of approximately 80% and an improvement rate of 90%, with little reduction in continence over time. Only one synthetic sling procedure (tension-free vaginal tape) has been subjected to randomised study to date.

Numerous materials are available for use in a suburethral sling. As a generalisation, autologous material is associated with a greater continence rate and fewer complications than either cadaveric material or synthetic materials.³⁷ Autologous rectus fascia and fascia lata are probably the most common materials in use. Allogenic grafts harvested from a cadaveric donor and porcine dermal implants (Pelvicol®, CR Bard) are also widely used. These do not seem to carry a risk of erosion but there may be a long-term failure rate from this type of material in excess of 20%.³⁸ Synthetic material tends to be associated with a risk of erosion and sinus formation.³⁹ Modifications designed to achieve greater stabilisation, such as anchorage to the pubic bone, are associated with good results in the short term but carry a long-term risk of osteomyelitis at the site of anchorage.⁴⁰ Overall, with all of these materials the risk of vaginal erosion ranges from zero to approximately 16%. Urethral erosion ranges from 0–5%. *De novo* detrusor overactivity ranges from 3.7–66.0%, and procedures requiring sling revision or removal range from 1.8–35% of women included in these studies. Up to 10.8% of women have some voiding disorder symptoms subsequent to the immediate postoperative period.³⁷ Long-term self-catheterisation has been reported in anywhere between 1.5% and 7.8% of patients, although a figure of 2% may be more realistic.^{4,37}

When compared with colposuspension procedures, the suburethral sling carries a similar success rate.⁶ This appears to be true even in patients with low maximal urethral closure pressure.⁴¹ The intermediate and longer-term results for suburethral slings suggest that the ten-year continence rate is not dissimilar from the one-year continence rate.⁶

Evidence level Ia

The American Urological Association considered that ‘Retropubic suspensions and slings are the most efficacious procedures for long-term success based upon cure/dry rate. However, in the panel’s opinion, retropubic suspensions and sling procedures are associated with slightly higher complication rates, including postoperative voiding difficulty and longer convalescence. In patients who are willing to accept a slightly higher complication rate for the sake of long-term cure, retropubic suspensions and slings are appropriate choices’.¹³ The Second International Consultation on Incontinence concluded that suburethral slings represented ‘an effective procedure for genuine stress incontinence in the presence of previous failed surgery.’⁶

The Prolene® (Ethicon) tension-free vaginal tape (TVT) is relatively new, although increasing numbers of cohort studies of its use are being reported. The originator of the procedure reports that, at three years, 86% of women were ‘completely cured,’ while a further 11% were ‘significantly

improved'.⁴² The six-month subjective and objective results of a randomised trial between TVT and Burch colposuspension showed a similar continence rate from both procedures.⁴³ Complete dryness in both groups was 38% and 40% respectively (based on a rigorous definition of cure). Large cohort analysis shows a continence rate of 80% and an improvement rate of 94%.

The majority of women are potentially treatable without general anaesthesia and on a day-case basis.⁴² Somewhere between 3% and 15% of women developed symptoms compatible with the onset of *de novo* detrusor overactivity.⁴⁴ Short-term voiding disorder is described in 4.3% of women, although longer term voiding disorder does not appear to be a specific feature.^{42,44} In the UK RCT, intraoperative bladder perforation was recognised in a mean of 9% of procedures.⁴³ A report from Finland⁴⁵ on 1455 TVT procedures revealed eight cases of significant bleeding, a 3.8% chance of bladder perforation and a 2.3% chance of a voiding disorder. There have been a few individual case reports of urethral erosion, sometimes several years after surgery.^{46,47} There is a need for long-term results for this procedure. It must be emphasised that newer slings based on similar technology to TVT, but using different materials, do not have the same evidence base and should be subjected to RCTs. TVT has received approval from NICE.⁴⁸ The committee considered data from a number of sources and assessed TVT as having similar objective and subjective continence rates to colposuspension with a shorter hospital stay. Despite being more expensive than colposuspension, the reduction in hospital stay makes the procedure cost effective.

Evidence level Ia

A Cochrane review¹⁹ has examined the RCTs available in all types of slings. Seven trials were identified including 682 women: 457 treated with suburethral slings and 225 with other procedures. Four compared suburethral slings with open abdominal retropubic suspensions and one compared suburethral slings with needle suspension. For short-term cure, overall rates are similar to open abdominal retropubic suspension. About 1/11 had a complication during TVT, most commonly bladder perforation, although serious consequences are rare.¹⁹

3.6 Injectable agents

B Injectable agents have a lower success rate than other procedures: a short-term continence rate of 48% and an improvement rate of 76%. Long term, there is a continued decline in continence. However, the procedure has a low morbidity and may have a role after other procedures have failed, e.g. when a diagnosis of intrinsic sphincter deficiency is made.

A number of bulking agents have been used for the treatment of stress incontinence in women. The bulking agents (collagen, Teflon® [Dupont], fat, silicone, Durasphere® [Carbon Medical Technologies]) are injected in a retrograde (more common) or antegrade fashion in the periurethral tissue around the bladder neck and proximal urethra. Among the 18 larger published studies on bulking agents, 14 are on glutaraldehyde cross-linked collagen and eight are prospective nonrandomised studies; 1221 women were included, mean age 61 years. Follow up was between three months and two years, (mean of 12 months). The cure rate, defined as completely dry, was 48%. The success rate (defined as dry or improved) was 76%.

Evidence level III

For silicone (Macropastique®, Urolasty Ltd) Radley *et al.*⁴⁹ showed cure or improvement in 60% in a prospective cohort of women with recurrent stress incontinence on a 19-month follow-up. Detrusor overactivity was an important cause of failures in this study. For both collagen and silicone, efficacy deteriorates with time. Sherrif *et al.*⁵⁰ found success rate at 90% at one month, 75% at three months and 48% at two years. This raises the possibility of either sphincteric function deterioration or absorption or degradation of the injected materials. RCTs are needed for bulking agents. The lack of morbidity associated with the bulking agents leads some people to believe that they should be more meaningfully compared with conservative therapy such as pelvic floor physiotherapy.

3.7 Artificial sphincters

B Artificial sphincters can be successfully used after previous failed continence surgery but have a high morbidity and need for further surgery (17%).

The literature related to the use of an artificial sphincter implanted around the proximal urethra is difficult to interpret since most studies include women with a range of indications for surgery yet do not break down the result by indication. A cure rate of 80% and an improvement rate of 90% can be expected when an artificial sphincter is inserted as a primary procedure for stress incontinence.

There are, however, some studies in which the vast majority of women have undergone recurrent previous surgery for urodynamic stress incontinence. In such women, and provided that there is no detrusor overactivity, high levels of continence can be obtained, at around 92%.⁵¹ These benefits must be balanced with the potential need for further surgery; in the above series, 17% of patients required an average of two revisions each over an eight-year follow-up for either malfunction of the device or cuff erosion.^{51,52}

4. Preoperative management

It is recommended that women undergoing surgery for urodynamic stress incontinence should have urodynamic investigations prior to treatment (including cystometry). There was a paucity of data on urodynamics prior to surgery identified in a 2003 Cochrane review;⁵³ one small study showed that women were more likely to be treated with drugs or surgery as a result of testing. Nevertheless, prior to performing irreversible bladder-neck surgery, it would appear to be beneficial to have assessed objectively the type of incontinence and the presence of any complicating factors such as voiding difficulty or detrusor overactivity, which may affect the surgical decision and provide the basis for informed consent. Surgery should be performed by a surgeon who has been trained in the operation and who has a caseload that enables him or her to provide a suitable level of expertise, especially when any repeat surgery is considered.

5. Auditable standards

Units should monitor the results of incontinence investigations and interventions. The Department of Health has suggested the following initial auditable standards (DH Good Practice 2000):

- rate of anterior repair/needle suspension for urodynamic stress incontinence
- rate of urodynamics/cystometry prior to surgery
- occurrence of repeat continence surgery within two years
- rate of postoperative detrusor overactivity after surgery and clean intermittent self-catheterisation.

References

1. Abrams P, Cardozo L, Fall M, Griffiths D, Rosier P, Ulmsten U, *et al.* The standardization of terminology of lower urinary tract dysfunction: report from the standardization committee of the ICS. *Neurourol Urodyn* 2002; 21: 167-78.
2. Hay-Smith EJ, Bo K, Berhmans LC, Hendriks HJ, de bie RA, van Waalwijk van Doorn ES. Pelvic floor muscle training for urinary incontinence in women. *Cochrane Database Syst Rev* 2003; CD001407.
3. Black NA, Downs SH. The effectiveness of surgery for stress incontinence in women: a systematic review. *Br J Urol* 1996; 78: 497-510.
4. Jarvis GJ. Stress incontinence. In: Mundy AR, Stephenson TP, Wein AJ, editors. *Urodynamics*. Edinburgh: Churchill Livingstone; 1994. p. 299-326.
5. Jarvis GJ. Surgery for genuine stress incontinence. *Br J Obstet Gynaecol* 1994; 101: 371-4.
6. Jarvis GJ. Surgical treatment for incontinence in adult women. In: Abrams P, Khoury S, Wein A, editors. *Incontinence*. Monaco: Health Publication; 1998. p. 637-68.
7. Beck RP, McCormick S, Nordstrom L. A 25-year experience with 519 anterior colporrhaphy procedures. *Obstet Gynaecol* 1991; 78: 1011-8.
8. Jarvis GJ. Detrusor instability, a complication of surgery. *Am J Obstet Gynecol* 1981; 319: 219.
9. Bergman A, Elia G. Three surgical procedures for genuine stress incontinence: five-year follow up of a prospective randomised study. *Am J Obstet Gynecol* 1995; 173: 66-71.
10. Bergman A, Ballard CA, Coonings PP. Comparison of three different surgical procedures for genuine stress incontinence: prospective randomised study. *Am J Obstet Gynecol* 1989; 160: 1102-6.

11. Liapis AE, Asimiadis V, Loglis CD, Pyrgiotis E, Zourlas PA. A randomised prospective study of three operative methods for genuine stress incontinence. *J Gynecol Surg* 1996; 12: 7-14.
12. Colombo M, Vitbello D, Proietti F, Milani R. Randomised comparison of Burch colposuspension versus anterior colporrhaphy in women with stress urinary incontinence and anterior vaginal prolapse. *Br J Obstet Gynaecol* 2000; 107: 544-51.
13. Leach GE, Dmochowski RR, Appell RA, Blaivas JG, Hadley HR, Luber KM, *et al.* Female stress urinary incontinence clinical guidelines. *J Urol* 1997; 158: 875-80.
14. Glazener CM, Cooper K. Anterior vaginal repair for urinary incontinence in women. *Cochrane Database Syst Rev* 2003; CD001755.
15. Kjolhede P, Ryden G. Prognostic factors and long-term results of the Burch colposuspension. *Acta Obstet Gynecol Scand* 1994; 73: 642-7.
16. Alcalay M, Monga A, Stanton S. Burch colposuspension: a 10-20 year follow up. *Br J Obstet Gynaecol* 1995; 102: 740-5.
17. Gallaway NT, Davies N, Stephenson TP. The complications of colposuspension. *Br J Urol* 1987; 60: 122-4.
18. Lapitan MC, Cody DJ, Grant AM. Open retropubic colposuspension for urinary incontinence in women. *Cochrane Database Syst Rev* 2003; CD002912.
19. Bezerra CA, Bruschini H. Suburethral sling operations for urinary incontinence in women. *Cochrane Database Syst Rev* 2002; CD001754.
20. Glazener CM, Cooper K. Bladder neck needle suspension for urinary incontinence in women. *Cochrane Database Syst Rev* 2002; CD003636.
21. Krantz K. The Marshall-Marchetti-Krantz procedure. In: Stanton SL, Tanagho EA, editors. *Surgery of Female Incontinence*. Berlin: Springer Verlag; 1980. p. 47-54.
22. Mainprize TC, Drutz HP. The Marshall-Marchetti-Krantz procedure: a clinical review. *Obstet Gynecol Surv* 1988; 43: 724-9.
23. White GR. Cystocele, A radical cure by suturing lateral sulci of vagina to white line of pelvic fascia. *JAMA* 1909; 21: 1707-10.
24. Shull BL, Baden WF. A six year experience with paravaginal defect repair for stress urinary incontinence. *Am J Obstet Gynecol* 1989; 161: 43-240.
25. Colombo M, Zanetta G, Vitobello D, Milani R. The Burch colposuspension for women with detrusor overactivity. *Br J Obstet Gynaecol* 1996; 103: 255-60.
26. Fathy H, El Hao M, Samaha I, Abdallah K. Modified Burch colposuspension: laparoscopy versus laparotomy. *J Am Assoc Gynecol Laparosc* 2001; 8: 99-106.
27. Summitt RL Jr, Lucente V, Karram M, Shull B, Bent A. Laparoscopic versus open Burch colposuspension: a randomised clinical trial. *Clin Obstet Gynecol* 2000; 43: 584-93.
28. Burton G. A five year prospective randomised urodynamic study comparing open and laparoscopic colposuspension. *Neurourol Urodyn* 1999; 18: 295-6.
29. Su TH, Wang KG, Hsu CY, Wei H, Hong BK. Prospective comparison of laparoscopic and traditional colposuspensions in the treatment of genuine stress incontinence. *Acta Obstet Gynecol Scand* 1997; 76: 576-82.
30. Persson J, Wolner-Hanssen P. Laparoscopic Burch colposuspension for stress urinary incontinence: a randomised comparison of one or two sutures on each side of the urethra. *Obstet Gynecol* 2000; 95: 151-5.
31. Moehrer B, Ellis G, Carey M, Wilson PD. Laparoscopic colposuspension for urinary incontinence in women. *Cochrane Database Syst Rev* 2002; CD002239.
32. Pereyra AJ. A simplified surgical procedure for the correction of stress urinary incontinence in women. *West J Surg Obstet Gynecol* 1959; 67: 223-6.
33. Raz S, Sussman EM, Ericksen DB, Bregg KJ, Nitti VW. The Raz bladder neck suspension; results in 206 patients. *J Urol* 1992; 148: 845-50.
34. Tebyani N, Patel H, Yamaguchi R, Aboseif SR. Percutaneous needle bladder neck suspension for the treatment of stress urinary incontinence in women: long-term results. *J Urol* 2000; 163: 1510-2.
35. Karram MM, Angel O, Koonings P, Tabor B, Bergman A, Bhatia N. The modified Peyrera procedure; a clinical and urodynamic review. *Br J Obstet Gynaecol* 1992; 99: 655-8.
36. Aldridge AH. Transplantation of fascia for the relief of urinary incontinence. *Am J Obstet Gynecol* 1942; 44: 398-411.
37. Bidmead J, Cardozo L. Sling techniques in the treatment of genuine stress incontinence. *BJOG* 2000; 107: 147-56.
38. Singla AK. The use of cadaveric fascia lata in the treatment of stress urinary incontinence in women. *Br J Urol* 2000; 85: 264-9.
39. Duckett JR, Constantine G. Complications of silicone sling insertion for stress urinary incontinence. *J Urol* 2000; 163: 1835-7.
40. Kovac SR, Cruikshank SR. Pubic bone suburethral stabilisation sling for recurrent urinary incontinence. *Obstet Gynecol* 1997; 89: 624-7.
41. Sand PK, Winkler H, Blackhurst DW, Culligan PJ. A prospective randomized study comparing modified Burch retropubic urethropexy and suburethral sling for the treatment of genuine stress incontinence with low pressure urethra. *Am J Obstet Gynecol* 2000; 182: 30-4.
42. Ulmsten U, Johnson P, Rezapour M. A 3 year follow up of tension free vaginal tape for surgical treatment of female stress urinary incontinence. *Br J Obstet Gynaecol* 1999; 106: 345-50.
43. Ward KL, Hilton P, Browning J. A randomised trial of colposuspension and tension free vaginal tape for primary genuine stress incontinence. *Neurourol Urodyn* 2000; 19: 386-8.
44. Moran PA, Ward KL, Johnson D, Smirni WE, Hilton P, Bibby J. Tension free vaginal tape for primary genuine stress incontinence. *Br J Urol* 2000; 86: 39-42.
45. Kuuva, Nilsson. Experience with TVT in Finland. *Neurourol Urodyn* 2000; 19: 364-5.
46. De Ridder D, Deprest J. TVT Erosion: one-step partial excision and replacement by pelvicol. Presented at the International Urogynaecology Association Meeting, 6-8 December 2001, Melbourne, Australia. Abstract.
47. Koelbl H, Stoerer S, Seliger G, Wolters M. Transurethral penetration of a tension-free vaginal tape. *BJOG* 2001; 108: 763-5.
48. National Institute for Clinical Excellence. Guidance on the use of tension-free vaginal tape (Gynecare TVT) for stress incontinence. Technology Appraisal No 56. London: NICE; 2003. [www.nice.org.uk/pdf/56_TVT_full_guidance.pdf] Accessed 28 August 2003.
49. Radley SC, Chapple CR, Mitsogiannis IC, Glass KS. Transurethral implantation of macroplastique for the treatment of female stress urinary incontinence secondary to urethral sphincter deficiency. *Eur Urol* 2001; 39: 383-9.
50. Sheriff MS, Foley S, McFarlane J, Nauth-Misir R, Shah PJ. Endoscopic correction of intractable stress incontinence with silicone micro-implants. *Eur Urol* 1997; 32: 284-8.
51. Webster SD, Perez LM, Khoury JM, Timmons SL. Management of type III stress urinary incontinence using artificial urinary sphincter. *Urology* 1992; 39: 499-503.
52. Richard F, Lefort JM, Bitker MO, Chartier-Kastler E, Chatelain C. Female incontinence with primary sphincter deficiency: results of artificial urinary sphincter (AMS 800) with long-term follow-up. *J Urol* 1996; 155(Suppl): 703A.
53. Glazener CMA, Lapitan MC. Urodynamic investigations for management of urinary incontinence in adults. *Cochrane Database Syst Rev* 2003; CD003195.

APPENDIX

Clinical guidelines are: ‘systematically developed statements which assist clinicians and patients in making decisions about appropriate treatment for specific conditions’. Each guideline is systematically developed using a standardised methodology. Exact details of this process can be found in Clinical Governance Advice No. 1: *Guidance for the Development of RCOG Green-top Guidelines* (available on the RCOG website at www.rcog.org.uk/clingov1). These recommendations are not intended to dictate an exclusive course of management or treatment. They must be evaluated with reference to individual patient needs, resources and limitations unique to the institution and variations in local populations. It is hoped that this process of local ownership will help to incorporate these guidelines into routine practice. Attention is drawn to areas of clinical uncertainty where further research may be indicated.

The evidence used in this guideline was graded using the scheme below and the recommendations formulated in a similar fashion with a standardised grading scheme.

Classification of evidence levels		Grades of recommendations	
Ia	Evidence obtained from meta-analysis of randomised controlled trials.	A	Requires at least one randomised controlled trial as part of a body of literature of overall good quality and consistency addressing the specific recommendation. (Evidence levels Ia, Ib)
Ib	Evidence obtained from at least one randomised controlled trial.		
IIa	Evidence obtained from at least one well-designed controlled study without randomisation.	B	Requires the availability of well controlled clinical studies but no randomised clinical trials on the topic of recommendations. (Evidence levels IIa, IIb, III)
IIb	Evidence obtained from at least one other type of well-designed quasi-experimental study.		
III	Evidence obtained from well-designed non-experimental descriptive studies, such as comparative studies, correlation studies and case studies.	C	Requires evidence obtained from expert committee reports or opinions and/or clinical experiences of respected authorities. Indicates an absence of directly applicable clinical studies of good quality. (Evidence level IV)
IV	Evidence obtained from expert committee reports or opinions and/or clinical experience of respected authorities.		Good practice point Recommended best practice based on the clinical experience of the guideline development group.

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The final version is the responsibility of the Guidelines and Audit Committee of the RCOG.

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