

Sacrocolpopexy using mesh to repair vaginal vault prolapse

Interventional procedures guidance

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Your responsibility

This guidance represents the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, healthcare professionals are expected to take this guidance fully into account, and specifically any special arrangements relating to the introduction of new interventional procedures. The guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

All problems (adverse events) related to a medicine or medical device used for treatment or in a procedure should be reported to the Medicines and Healthcare products Regulatory Agency using the [Yellow Card Scheme](#).

Commissioners and/or providers have a responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with

those duties. Providers should ensure that governance structures are in place to review, authorise and monitor the introduction of new devices and procedures.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

This guidance replaces IPG283.

1 Recommendations

- 1.1 Current evidence on the safety of sacrocolpopexy using mesh to repair vaginal vault prolapse shows there are serious but well-recognised safety concerns. The evidence on efficacy is adequate in quantity and quality. Therefore, this procedure can be used provided that standard arrangements are in place for clinical governance, consent and audit.
- 1.2 During the consent process, clinicians should ensure patients understand that there is a risk of vaginal vault prolapse happening again, and of potentially serious complications, including mesh erosion (for example, into the vagina). Patients should be provided with clear written information about the procedure and its complications. In addition, the use of NICE's information for the public is recommended.
- 1.3 Patient selection and treatment should only be done by clinicians specialising in the management of pelvic organ prolapse and urinary incontinence in women. All clinicians doing this procedure should have specific up-to-date training and do the procedure regularly.
- 1.4 Clinicians should enter details about all patients having sacrocolpopexy using mesh to repair vaginal vault prolapse onto an appropriate registry (for example, the British Society of Urogynaecology database). All adverse events involving the medical devices (including mesh) used in this procedure should be reported to the Medicines and Healthcare products Regulatory Agency.

2 Indications and current treatments

- 2.1 Vaginal vault prolapse is when the upper part of the vagina descends from its usual position, sometimes out through the vaginal opening. It is common after hysterectomy and can affect quality of life by causing pressure and discomfort, and by its effect on urinary, bowel and sexual function.
- 2.2 Treatment is rarely indicated if there are no symptoms. Mild-to-moderate prolapse may be treated with conservative measures such as pelvic floor muscle training, electrical stimulation and biofeedback. Topical oestrogens and mechanical measures such as pessaries may also be used. Surgery may be needed when the prolapse is severe. Different surgical procedures are available for repairing vaginal vault prolapse using vaginal or abdominal (open, laparoscopic or robotic) approaches. Some procedures involve using mesh to provide additional support.

3 The procedure

- 3.1 Sacrocolpopexy using mesh to repair vaginal vault prolapse is done with the patient under general anaesthesia, using an open or laparoscopic abdominal approach. Mesh is attached to the longitudinal ligament of the sacrum, or to the sacrum itself, most often at the level of the sacral promontory. The mesh is then attached to the apex of the vagina and sometimes to the anterior or posterior vaginal wall.
- 3.2 The procedure can be combined with surgery for stress urinary incontinence, such as colposuspension or sub-urethral sling placement. Several different types of meshes or grafts have been used for this procedure, including synthetic meshes, allografts and xenografts. Different types of mesh may have different safety profiles.

4 Efficacy

This section describes efficacy outcomes from the published literature that the committee considered as part of the evidence about this procedure. For more detailed information on

the evidence, see the [interventional procedure overview](#).

- 4.1 In a systematic review and meta-analysis of 3,414 women from 30 randomised control trials (RCTs) comparing surgery for apical pelvic organ prolapse, 16 studies compared surgery for vaginal vault prolapse. In 3 RCTs (n=277) sacrocolpopexy (SCP) had a statistically significantly lower rate of subjective failure than vaginal procedures (7% [10/139] for SCP compared with 16% [22/138] for vaginal procedures, risk ratio [RR] 2.11; 95% confidence interval [CI] 1.06 to 4.21, $I^2=0\%$). The use of mesh or biological graft for SCP did not affect the subjective failure rate. Adding colposuspension to SCP did not alter subjective failure rate in a 7-year follow-up study.
- 4.2 In 4 RCTs (n=390) from the systematic review of 3,414 women, SCP was associated with statistically significantly less recurrent prolapse than vaginal procedures at 1 to 2-year follow-up (19% [35/189] compared with 34% [68/201], RR 1.89; 95% CI 1.33 to 2.70, $I^2=41\%$). The use of mesh or biological graft did not affect the incidence of recurrent prolapse. Recurrent prolapse was not statistically significantly different between SCP and robot-assisted sacrocolpopexy (RASC) when compared with laparoscopic sacrocolpopexy (LSC). Adding colposuspension to SCP did not alter the incidence of recurrent prolapse. In 4 RCTs from a systematic review of 1,176 women, SCP using mesh had statistically significantly better objective cure rates than native tissue vaginal repair (75% [132/177] compared with 62% [119/192], odds ratio (OR) 2.04; 95% CI 1.12 to 3.72, $I^2=31\%$) at 1 to 2.5-year follow-up. In a systematic review and meta-analysis of 1,488 women, all-compartment prolapse was 6% (66/1,029) at a minimum 2-year follow-up. In an RCT of 100 women comparing SCP using polypropylene mesh with SCP using cadaveric fascia lata, overall objective anatomic success was statistically significantly higher in the polypropylene group (93% [27/29]) than in the fascia lata group (62% [18/29], $p=0.02$) at 5-year follow-up. In a case series of 165 women treated by LSC there was recurrent vault prolapse in 5% (7/138) of women, recurrent rectocele in 1% (1/138) and cystocele in 4% (5/138) of women at 8-year follow-up.
- 4.3 In 2 RCTs (n=199) from the systematic review of 3,414 women, the rate of anterior compartment prolapse was statistically significantly less frequent in women treated by SCP than in women treated by vaginal procedures (6% [6/102] compared with 24% [23/97], RR 4.02; 95% CI 1.71 to 9.49, $I^2=22\%$).

- 4.4 In 3 RCTs (n=275) from the systematic review of 3,414 women, apical compartment prolapse was statistically significantly less frequent in women treated by SCP than in women treated by vaginal procedures (2% [3/134] compared with 21% [29/141], RR 8.15; 95% CI 2.71 to 24.49, $I^2=0\%$). In the systematic review and meta-analysis of 1,488 women, apical prolapse rate was less than 1% (2/246).
- 4.5 In 2 RCTs (n=199) posterior compartment prolapse was statistically significantly less frequent in women treated by SCP than in women treated by vaginal procedures (3% [3/99] compared with 12% [12/100], RR 3.43; 95% CI 1.10 to 10.66, $I^2=0\%$) in the systematic review of 3,414 women. In a comparative study included in the systematic review of 1,176 women there was a statistically significantly higher recurrence of posterior wall prolapse after LSC (17% [10/60]) than after sacrospinous ligament fixation (0/51, $p<0.01$).
- 4.6 In the systematic review and meta-analysis of 3,414 women, there was no statistically significant difference in quality of life measured by different types of questionnaires. In 1 RCT (n=110) a statistically significantly better quality of life was reported, as measured by the pelvic floor distress inventory (PFDI-20), in women treated by SCP than in women treated by vaginal procedures (mean difference 7.90; 95% CI 0.70 to 15.10). In a prospective case series of 70 women treated by RASC, 55% (22/40) would recommend the procedure to a relative or friend, 25% (10/40) would probably recommend the procedure and overall satisfaction was 10 (0=not at all successful, 10=very successful) at the median follow-up of 90 months. The average improvement in symptoms was 9 (0=much worse, 10=much better). In the prospective case series of 165 women treated by LSC, 83% (115/138) of women were 'quite satisfied', 12% (16/138) were 'satisfied enough' and 5% (7/138) were 'not satisfied'. In a prospective case series of 101 women treated by LSC, the quality-of-life score improved from 5.6 at baseline to 9.1 at 12 months and 8.3 at 60 months (measured on a visual analogue scale between 1 and 10).
- 4.7 In the prospective case series of 165 women, constipation rates increased from 7% (10/138) before surgery to 13% (18/138) at the end of follow-up. Obstructed defaecation increased from 1% (2/138) to 6% (8/138). Urgency was not reported by any women before surgery and it was reported in 2% (3/138) of women at 43 months. The incidence of pelvic pressure symptoms reduced from 67% (92/

138) to 9% (12/138) at the end of follow-up. Similarly, the incidence of false urge to defaecate reduced from 51% (70/138) of women at baseline to 5% (7/138) at 43 months.

- 4.8 In a systematic review and meta-analysis of 5,954 women from 56 RCTs, in 3 RCTs reduction in postoperative dyspareunia was greater in the SCP group than in the VSC group (16% [7/45] for VSC compared with 36% [22/61] for SCP, RR 0.39; 95%CI 0.18 to 0.86).
- 4.9 The specialist advisers listed the key efficacy outcomes as patient satisfaction, elimination of the bulge in the vagina, and bladder, bowel and sexual function changes.
- 4.10 Fourteen commentaries from women who had experience of this procedure were received, which were discussed by the committee.

5 Safety

This section describes safety outcomes from the published literature that the committee considered as part of the evidence about this procedure. For more detailed information on the evidence, see the [interventional procedure overview](#).

- 5.1 Incidence of death was not statistically significantly different between women treated by abdominal sacrocolpopexy (SCP) using mesh (0/503) and women treated using native tissue (less than 1% [1/582], odds ratio [OR] 0.14; 95% confidence interval [CI] 0.003 to 6.97) in the analysis of comparative studies reported in a systematic review and meta-analysis of 1,176 women. Postoperative admission to intensive care was not statistically significantly different between the SCP using mesh group (1% [3/561]) and the native tissue repair group (0/506, OR 4.64; 95% CI 0.42 to 50.6) in the analysis of comparative studies in the same systematic review.
- 5.2 Deep vein thrombosis or pulmonary embolism was not statistically significantly different between the SCP using mesh group (less than 1% [2/569]) and the native tissue repair group (less than 1% [1/599], OR 1.36; 95% CI 0.14 to 13.7) in the same analysis of comparative studies.

- 5.3 Mesh or suture complications were statistically significantly more frequent in women treated by SCP using mesh (4% [28/650]) than in women who had native tissue repair (1% [6/537], OR 3.26; 95% CI 1.62 to 6.56) in an analysis of comparative studies in the systematic review of 1,176 women. Mesh or suture complications were statistically significantly more frequent in women treated by SCP using mesh (4% [348/7,831]) than in women treated by native tissue repair (less than 1% [13/1,169], $p < 0.001$) in an analysis of 40 SCP compared with 11 native tissue repair non-comparative studies. Mesh erosion was not statistically significantly different between robot-assisted sacrocolpopexy (RASC) and laparoscopic sacrocolpopexy (LSC; OR 1.82; 95% CI 0.51 to 6.45 [n=438], $I^2 = 0\%$, $p = 0.86$) in a systematic review of 1,488 women. Mesh erosion was statistically significantly lower in women treated by RASC with supracervical hysterectomy (0%) than in women treated by RASC after total hysterectomy (14%, $p = 0.008$) in 1 comparative study included in the same systematic review. Mesh erosion was reported in 1% (1/99) of women treated by LSC at 12 months and in 3% (2/85) at 60 months in a prospective case series of 101 women.
- 5.4 Reoperation rates were similar for women treated by SCP or sacrospinous ligament fixation (13% [6/46] compared with 16% [7/43], $p = 0.67$) in an RCT (reported in the systematic review of 1,176 women) with follow-up of 6 to 66 months. Pooled reoperation rates were 7% (46/615) for SCP and 10% (51/511) for native tissue repair (OR 0.76, 95% CI 0.28 to 1.09) in 7 comparative studies from the same systematic review and meta-analysis. Pooled reoperation rates in non-comparative studies were 5% (367/7,218) for SCP and 3% (114/3,872) for native tissue repair ($p = 0.28$) in the systematic review of 1,176 women. The reoperation rate was 3% (23/687) in women treated by RASC in the systematic review and meta-analysis of 1,488 women from 27 studies. A feeling of traction needing reoperation was reported in less than 1% (2/1,118) of the women treated by RASC in the same systematic review. Reoperation for stress urinary incontinence in women treated by LSC was reported in 15% (15/99) and 19% (16/85) of women at 12 and 60 months respectively in the prospective case series of 101 women. Reoperation rates in women treated by RASC were 2%, 5% and 10% at years 1, 3 and 6 respectively in a prospective case series of 70 women.
- 5.5 The vaginotomy rate in women treated by RASC was 1% (14/1,488) in the systematic review and meta-analysis of 1,488 women from 27 studies.

- 5.6 Urinary tract injury was not statistically significantly different in women treated by SCP using mesh (2% [20/1,068]) compared with women treated by native tissue repair (1% [9/1,108], OR 1.68; 95% CI 0.79 to 3.55) in 8 comparative studies from the systematic review of 1,176 women. Urinary tract injury was statistically significantly higher in women treated by SCP using mesh (2% [113/6,894]) compared with native tissue repair (1% [46/5,111], $p < 0.05$) in the analysis of non-comparative studies from the same review. Bladder injury in women treated by RASC was 2% (26/1,488) in the systematic review of 1,488 women. Ureteral injury was less than 1% (1/1,488) in women from the same systematic review.
- 5.7 Bowel injury in women treated by RASC was less than 1% (4/1,488) in the systematic review of 1,488 women.
- 5.8 Stress incontinence in women who had not had it before and who were treated by LSC was 24% (24/99) and 38% (32/85) at 12 and 60 months respectively in the case series of 101 women. Postoperative voiding disorders occurred in 8% (8/99) and 13% (11/85) of women at 12 and 60 months respectively in the same patient group. Urge incontinence in women who had not had it before occurred in 2% (2/99) women at 12 months and in 8% (7/85) at 60 months. The detrusor muscle overactivity rate was 9% (15/165) in a case series of 165 women.
- 5.9 Dyspareunia was statistically significantly lower in women treated by SCP using mesh (5% [23/445]) than in women treated by native tissue repair (12% [46/384], OR 0.42; 95% CI 0.25 to 0.72) from the analysis of 5 comparative studies reported in the systematic review and meta-analysis of 1,176 women. The rate of dyspareunia was similar for SCP using mesh (12% [371/2,986]) and native tissue repair (9% [200/2,180]; $p = 0.48$) in the analysis of non-comparative studies in the same systematic review. Dyspareunia in women who had not had this before who were treated by LSC was 2% (1/47) and 24% (10/41) at 12 and 60 months respectively in the prospective case series of 101 women.
- 5.10 Rectocele and cystocele incidence in women who had not had these before and who were treated by LSC was 12% (16/138) and 8% (11/183) respectively at 8-year follow-up in the case series of 165 women.
- 5.11 Infection rates were not statistically significantly different between women treated by SCP using mesh (3% [17/676]) and women treated by native tissue

repair (1% [9/617] OR 2.01; 95% CI 0.91 to 4.45) in the analysis of comparative studies reported in the systematic review and meta-analysis of 1,176 women. Infection rates were not statistically significantly different between women treated by mesh SCP (2% [114/5,519]) and women treated by native tissue repair (12% [558/4,743], $p=0.6$) in the analysis of non-comparative studies for the same systematic review. Abscess formation in women treated by RASC was less than 1% (3/1,118) in the systematic review of 1,488 women. Peritonitis caused by bowel injury was reported in less than 1% (2/1,118) of women in the same review.

- 5.12 Bleeding rates were not statistically significantly different between women treated by SCP using mesh (3% [43/1,317]) and women treated by native tissue repair (2% [37/1,863] OR 1.00; 95% CI 0.63 to 1.59) in the comparative studies reported in the systematic review of 1,176 women. Bleeding rates were statistically significantly lower in women treated by SCP using mesh (2% [128/6,555]) than in women treated by native tissue repair (5% [367/7,044], $p=0.05$) in the analysis of non-comparative studies in the same systematic review.
- 5.13 Ileus or small bowel obstruction was statistically significantly higher in women treated by SCP using mesh (2% [16/814]) than in women treated by native tissue repair (less than 1% [2/780], OR 9.45; 95% CI 3.39 to 26.4) in the analysis of comparative studies reported in the systematic review of 1,176 women. Ileus or small bowel obstruction was also statistically significantly higher in women treated by SCP using mesh (3% [137/4,168]) than in women treated by native tissue repair (less than 1% [3/1,449], $p<0.01$) in the analysis of non-comparative studies for the same systematic review. Bowel obstruction in women treated by RASC was less than 1% (5/1,118) in the systematic review of 1,488 women. Postoperative constipation in women treated by LSC was 1% (1/99) and 5% (4/85) at 12 and 60 months respectively, in the case series of 101 women.
- 5.14 Lumbosciatica pain was reported in 3% (5/165) of women treated by LSC in the case series of 165 women.
- 5.15 Intraoperative complication rates were not statistically significantly different between women treated by RASC and women treated by LSC (OR 1.05; 95% CI 0.52 to 2.12 [$n=443$], $I^2=0\%$, $p=0.94$) in the systematic review of 1,488 women. Surgical conversion to open surgery was also not statistically significantly different between the RASC and LSC treatment groups (OR 0.89; 95% CI 0.25 to

3.19 [n=443], $I^2=0%$, $p=0.72$). The incidence of all postoperative complications was not statistically significant between RASC and LSC (OR 1.85; 95% CI 0.96 to 3.75 [n=350], $I^2=37%$, $p=0.18$) and this was also true for severe postoperative complications (of grade 3 or higher; OR 0.56; 95% CI 0.36 to 2.83 [n=430], $I^2=24%$, $p=0.73$).

- 5.16 In addition to safety outcomes reported in the literature, specialist advisers are asked about anecdotal adverse events (events which they have heard about) and about theoretical adverse events (events which they think might possibly occur, even if they have never done so). The anecdotal adverse events reported for the procedure were osteomyelitis of the sacrum and haemorrhage from left iliac vein.
- 5.17 Fourteen commentaries from women who had experience of this procedure were received, which were discussed by the committee.

6 Committee comments

- 6.1 There appears to be under-reporting of complications of the procedure to the [Medicines and Healthcare products Regulatory Agency](#).
- 6.2 Registry data collection has been disappointing.
- 6.3 There is a subspecialty training programme in urogynaecology with a General Medical Council approved curriculum for clinicians who wish to do this procedure.
- 6.4 Different mesh materials are used in this procedure.
- 6.5 The 13 out of 14 women who returned the patient questionnaire would recommend this procedure.

7 Further information

NICE has produced information on this procedure for patients and carers ([information for the public](#)). It explains the nature of the procedure and the guidance issued by NICE, and has been written with patient consent in mind.

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Endorsing organisation

This guidance has been endorsed by [Healthcare Improvement Scotland](#).