

Sacrocolpopexy using mesh for vaginal vault prolapse repair

This document replaces previous guidance on mesh sacrocolpopexy for vaginal vault prolapse (Interventional Procedure Guidance 215).

1 Guidance

- 1.1 Current evidence on the safety and efficacy of sacrocolpopexy using mesh for vaginal vault prolapse repair appears adequate to support the use of this procedure provided that normal arrangements are in place for clinical governance and audit.
- 1.2 During the consent process, clinicians should ensure patients understand that there is a risk of recurrence of vaginal vault prolapse after any prolapse repair procedure, and that there is also a risk of complications, including mesh erosion (for example, into the vagina), and provide them with clear written information. In addition, use of NICE's information for patients ('Understanding NICE guidance') is recommended (available from www.nice.org.uk/IPG283publicinfo).
- 1.3 The procedure should only be carried out by surgeons specialising in the management of pelvic organ prolapse and female urinary incontinence.
- 1.4 Evidence on safety and efficacy outcomes is limited to 5 years. Evidence on outcomes beyond 5 years and on different types of mesh would be useful. Further research should include patient-reported quality-of-life outcome measures using validated scales.

2 The procedure

2.1 Indications and current treatments

- 2.1.1 Vaginal vault prolapse can occur in women who have had a hysterectomy. The uppermost part of the vagina descends from its normal position, sometimes out through the vaginal opening. It can affect quality of life by causing symptoms of pressure and discomfort, and by its effect on urinary, bowel and sexual function.
- 2.1.2 Current treatment options include pelvic floor muscle training, use of pessaries and surgery. Some surgical procedures involve the use of mesh, with the aim of providing additional support.

2.2 Outline of the procedure

- 2.2.1 Sacrocolpopexy using mesh for vaginal vault prolapse repair is performed with the patient under general anaesthesia, using an open or laparoscopic abdominal approach. Mesh is attached to the apex of the vagina and may also be attached to the anterior and/or posterior vaginal wall.
- 2.2.2 The procedure can be combined with surgery for stress urinary incontinence, such as colposuspension or suburethral sling placement.
- 2.2.3 Several different types of synthetic and biological mesh are available, which vary in structure and in their physical properties such as absorbability.

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Interventional procedures guidance makes recommendations on the safety and efficacy of a procedure. The guidance does not cover whether or not the NHS should fund a procedure. Decisions about funding are taken by local NHS bodies (primary care trusts and hospital trusts) after considering the clinical effectiveness of the procedure and whether it represents value for money for the NHS.

Interventional procedures guidance is for healthcare professionals and people using the NHS in England, Wales, Scotland and Northern Ireland. This guidance is endorsed by NHS QIS for implementation by NHSScotland.

Sections 2.3 and 2.4 describe efficacy and 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 systematic review, available at www.nice.org.uk/ip311review

2.3 Efficacy

- 2.3.1 A randomised controlled trial (RCT) of 95 women comparing sacrocolpopexy (mesh) with sacrospinous colpopexy (no mesh) reported no difference in subjective failure rate at 24 months (7% [3/46] and 9% [4/43] respectively) (6 women lost to follow-up). A non-randomised study of 111 women comparing sacrocolpopexy (mesh) with sacrospinous colpopexy (no mesh) also reported no difference in subjective failure rates at 34 months (22% [13/60] and 12% [6/51] respectively).
- 2.3.2 The RCT of 95 women reported an objective failure rate of 4% (2/46) for sacrocolpopexy (mesh) and 19% (8/43) for sacrospinous colpopexy (no mesh), respectively (mean follow-up 24 months) (6 women lost to follow-up).
- 2.3.3 The Specialist Advisers considered key efficacy outcomes to include improvement in symptoms and sexual function. One Specialist Adviser also considered long-term success of more than 5 years to be an important outcome.

2.4 Safety

- 2.4.1 The RCT of 95 women reported an incidence of damage to surrounding organs of 2% (1/47) for sacrocolpopexy (mesh) and 2% (1/48) for sacrospinous colpopexy (no mesh). The non-randomised comparative study of 111 women reported an incidence of damage to surrounding organs of 7% (4/60) for sacrocolpopexy (mesh) and 4% (2/51) for sacrospinous colpopexy (no mesh).
- 2.4.2 A non-randomised comparative study of 117 women that compared laparoscopic with open sacrocolpopexy reported bowel obstruction in 2% (1/56) of women in the laparoscopic group and 3% (2/61) of women in the open group.

- 2.4.3 An RCT that compared sacrocolpopexy (mesh) with sacrospinous colpopexy (no mesh) reported mesh erosion after sacrocolpopexy in 2% (1/47) of women (mean follow-up 24 months). In an RCT that compared sacrocolpopexy (non-absorbable mesh) with a biological graft, mesh erosion occurred in 4% (2/54) of women treated by sacrocolpopexy compared with 0% (0/46) of women who received a biological graft (1-year follow-up). In a non-randomised study of 45 women treated by sacrocolpopexy, mesh erosion requiring further operation was reported in 9% (4/45) (follow-ups of 4–20 months).
- 2.4.4 De novo prolapse (cystocele) occurred in 31% (10/32) of women in the sacrocolpopexy group and 14% (4/28) of women in the sacrospinous colpopexy group (no mesh) (mean follow-up 34 and 38 months, respectively), in the non-randomised comparative study (n = 111).
- 2.4.5 In the RCT of 95 women, postoperative de novo stress urinary incontinence was reported in 9% (2/22) of women treated by sacrocolpopexy (mesh) compared with 33% (8/24) of women treated by sacrospinous colpopexy (no mesh) (mean follow-up 24 months), out of a total of 46 women who had no previous urinary symptoms.
- 2.4.6 The Specialist Advisers considered theoretical adverse events to include osteomyelitis, bleeding from major vessels, bladder or bowel perforation, urinary incontinence, bowel obstruction, mesh infection or rejection and dyspareunia. One Specialist Adviser commented that the development of new types of mesh means that current mesh-related complication rates may be lower than those available in the evidence.

3 Further information

- 3.1 NICE has published interventional procedures guidance on a number of procedures for uterine prolapse repair and vaginal vault prolapse repair. For more information go to www.nice.org.uk

Information for patients

NICE has produced information on this procedure for patients and carers ('Understanding NICE guidance'). It explains the nature of the procedure and the guidance issued by NICE, and has been written with patient consent in mind. See www.nice.org.uk/IPG283publicinfo

Ordering printed copies

Contact NICE publications (phone 0845 003 7783 or email publications@nice.org.uk) and quote reference number N1775 for this guidance or N1776 for the 'Understanding NICE guidance'.

This guidance represents the view of NICE, which was arrived at after careful consideration of the available evidence. Healthcare professionals are expected to take it fully into account when exercising their clinical judgement. This guidance does not, however, override the individual responsibility of healthcare professionals to make appropriate decisions in the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

Implementation of this guidance is the responsibility of local commissioners and/or providers. Commissioners and providers are reminded that it is their responsibility to implement the guidance, in their local context, in light of their duties to avoid unlawful discrimination and to have regard to promoting equality of opportunity. Nothing in this guidance should be interpreted in a way which would be inconsistent with compliance with those duties.

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