

Infracoccygeal sacropexy using mesh for vaginal vault prolapse repair

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NICE interventional procedure guidance 281

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1 Guidance

This guidance replaces the previous guidance on posterior infracoccygeal sacropexy for vaginal vault prolapse (Interventional Procedures Guidance no. 125, May 2005).

- 1.1 Current evidence on the efficacy and safety of infracoccygeal sacropexy using mesh for vaginal vault prolapse repair is inadequate in quantity and quality. Therefore this procedure should only be used with special arrangements for clinical governance, consent and audit or research.
- 1.2 Clinicians wishing to undertake infracoccygeal sacropexy using mesh for vaginal vault prolapse repair should take the following actions:
 - Inform the clinical governance leads in their Trusts.
 - Ensure that patients understand the uncertainty about the procedure's safety, including mesh erosion (for example, into the vagina) and the risk of recurrence, and provide them with clear written information. In addition, use of NICE's [information for patients](#) ('Understanding NICE guidance') is recommended.
- 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 The British Society for Urogynaecology runs a [database](#) on urogynaecological procedures, and clinicians should enter details about all patients undergoing this procedure onto this database.
- 1.5 NICE encourages further research into infracoccygeal sacropexy using mesh for vaginal vault prolapse repair, and may review the procedure on publication of further evidence on different types of mesh. Clinicians are encouraged to collect long-term data on clinical outcomes and patient-reported quality-of-life outcomes 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. Several surgical procedures can be used, including hysterectomy, mesh sacrocolpopexy, uterine suspension sling (including sacrohysteropexy) and uterine/vault suspension (without sling). Some of these procedures involve the use of mesh, with the aim of providing additional support.

2.2 Outline of the procedure

- 2.2.1 The procedure is performed with the patient under general anaesthesia. An incision is made in the posterior wall of the vagina and a small puncture incision is made in each buttock. A tape (mesh) is introduced through one buttock and, using a tunnelling device (guided by a finger through the vaginal incision), the tape is passed around the rectum. The tape is then passed up the side of the vagina, across the top, and down the other side, and out through the incision in the other buttock. The tape is sutured to the top of the vagina to act as a tension-free sling that aims to suspend the vaginal vault.
- 2.2.2 This procedure can be combined with a hysterectomy or surgery for stress urinary incontinence, such as a 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.

Sections 2.3 and 2.4 describe efficacy and safety outcomes which were available in the published literature and which the Committee considered as part of the evidence about this procedure. For more detailed information on the evidence, see the [overview](#).

2.3 Efficacy

- 2.3.1 A case series of 93 women treated by infracoccygeal sacropexy reported subjective failure in 9% (8/91) of women (mean follow-up 12 months, 2 women lost to follow-up).
- 2.3.2 A case series of 75 women reported objective failure within 24 months in 10% (4/40) of women (35 patients lost to follow-up). A case series of 20 women reported no objective failure (0/20) at a mean follow-up of 16 months.
- 2.3.3 Case series of 93 and 75 women reported that 2% (2/91) and 30% (12/40) of women, respectively, had further surgery for vault prolapse with a mean follow-up of 12 months, and between 1 and 4.5 years, respectively.
- 2.3.4 The Specialist Advisers considered key efficacy outcomes to include success rates, as measured by the pelvic organ prolapse quantification system (POPQ), and outcomes including resolution of prolapse symptoms and urinary, bowel and sexual function. Three Advisers noted a need for long-term efficacy outcomes.

2.4 Safety

- 2.4.1 Rectal perforation was reported in 1% (1/93) and 3% (2/75) of patients in the case series of 93 and 75 women, respectively (subsequent management and follow-up not stated).

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- 2.4.2 Mesh erosion was reported in 7% (2/30) of women treated by infracoccygeal sacropexy in a randomised controlled trial of 60 women (conference abstract only) at a mean follow-up of 24 months. Four case series of 93, 75, 52 and 15 women reported mesh erosion in 6% (6/93), 5% (4/75), 21% (11/52) and 7% (1/15) of women, respectively, at mean follow-up periods of between 20 weeks and 12 months.
- 2.4.3 Infection was reported in 5% (5/93) and 1% (1/75) of women (urinary tract infection and unspecified infection, respectively) within 1 week of surgery in the case series of 93 and 75 women, respectively.
- 2.4.4 The Specialist Advisers considered theoretical adverse events to include rectal injury, infection/sepsis, mesh erosion or rejection, dyspareunia and functional disturbance of the bowel or bladder. One 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 our [website](#).

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.

4 Other NICE recommendations on the treatment of pelvic organ prolapse

NICE was notified of various procedures for the treatment of pelvic organ prolapse. NICE asked the Review Body for Interventional Procedures to undertake a systematic review of these procedures. The Interventional Procedures Advisory Committee (IPAC) considered the systematic review and have also produced guidance on: [infracoccygeal sacropexy using mesh for uterine prolapse repair](#), [sacrocolpopexy using mesh for vaginal vault prolapse repair](#), [sacrocolpopexy using mesh for uterine prolapse repair](#) and [insertion of uterine suspension sling \(including sacrohysteropexy\) using mesh for uterine prolapse repair](#).

5 About this guidance

NICE interventional procedure guidance makes recommendations on the safety and efficacy of the procedure. It does not cover whether or not the NHS should fund a procedure. Funding decisions are taken by local NHS bodies after considering the clinical effectiveness of the procedure and whether it represents value for money for the NHS. It is for healthcare professionals and people using the NHS in England, Wales, Scotland and Northern Ireland, and is endorsed by Healthcare Improvement Scotland for implementation by NHSScotland.

This guidance was developed using the NICE [interventional procedure guidance](#) process.

It updates and replaces NICE interventional procedure guidance 125.

We have produced a [summary of this guidance for patients and carers](#). Information about the evidence it is based on is also [available](#).

Changes since publication

8 January 2012: minor maintenance

Your responsibility

This guidance represents the views of NICE and 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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