

Infracoccygeal sacropexy using mesh for uterine prolapse repair

1 Guidance

- 1.1 Current evidence on the efficacy and safety of infracoccygeal sacropexy using mesh for uterine 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 uterine 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, the use of NICE's information for patients ('Understanding NICE guidance') is recommended (available from www.nice.org.uk/IPG280publicinfo).
- 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 (www.bsug.net).
- 1.5 NICE encourages further research into infracoccygeal sacropexy using mesh for uterine 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 Uterine prolapse is the protrusion of the uterus down into, and sometimes through, the vagina. 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 incision 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 then out through the incision in the other buttock. The tape is sutured to the top of the vagina and acts as a tension-free sling to suspend the uterus in its natural position.
- 2.2.2 This procedure can be combined with 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.

Interventional procedure guidance 280

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/ip728review

2.3 Efficacy

- 2.3.1 A non-randomised comparative study of 79 women reported objective failure in 3% (1/35) of women after infracoccygeal sacropexy alone and in none (0/44) after infracoccygeal sacropexy combined with hysterectomy at a mean follow-up of 30 months. A case series of 10 women reported that 10% (1/10) had grade 3 uterine prolapse (most of the uterus has descended into the vagina) at a mean follow-up of 16 months. Neither of these studies reported time to failure.
- 2.3.2 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 Mesh erosion was reported in 11% (4/35) of women treated by infracoccygeal sacropexy and 14% (6/44) of women treated by infracoccygeal sacropexy combined with hysterectomy in the study of 79 women (time to occurrence of mesh erosion not reported). Resection of the eroded mesh segment was performed in an outpatient clinic for all women with mesh erosion (final outcome not reported).
- 2.4.2 Mean blood loss of 200 ml was reported in the case series of 10 women; none of the women required blood transfusion.
- 2.4.3 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 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/IPG280publicinfo

Ordering printed copies

Contact NICE publications (phone 0845 003 7783 or email publications@nice.org.uk) and quote reference number N1769 for this guidance or N1770 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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