

Insertion of mesh uterine suspension sling (including sacrohysteropexy) for uterine prolapse repair

1 Guidance

- 1.1 Current evidence on the safety and efficacy of insertion of mesh uterine suspension sling (including sacrohysteropexy) for uterine prolapse repair is inadequate in quantity. Therefore this procedure should only be used with special arrangements for clinical governance, consent and audit or research.
- 1.2 Clinicians wishing to undertake insertion of mesh uterine suspension sling (including sacrohysteropexy) 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, use of NICE's information for patients ('Understanding NICE guidance') is recommended (available from www.nice.org.uk/IPG282publicinfo).
- 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 mesh uterine suspension sling (including sacrohysteropexy) for uterine prolapse repair and

may review the procedure on publication of further evidence on different types of mesh. Future research should include short- and long-term efficacy, safety outcomes (such as mesh erosion in the long term), patient-reported quality-of-life outcomes using validated scales and subsequent successful pregnancy.

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 effects 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.
- 2.1.3 This procedure can also be used for women with cervical prolapse after supracervical hysterectomy.

2.2 Outline of the procedure

- 2.2.1 Uterine suspension sling using mesh for uterine prolapse involves attaching the uterus (or cervix) either to the sacrum (sacrohysteropexy) or to the ileopectineal ligaments. The procedure is performed with the patient under general anaesthesia using an open or laparoscopic abdominal approach. The mesh can be attached to the uterus either in the midline of the posterior cervix or bilaterally, where the uterosacral ligaments join the uterus. Another technique involves attaching the mesh to the front of the cervix and to the ileopectineal ligaments.

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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.

- 2.2.2 This procedure can be combined with surgery for stress urinary incontinence, such as colposuspension or minimally invasive slings.
- 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 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/ip372review

2.3 Efficacy

- 2.3.1 A randomised controlled trial (RCT) of 82 women reported subjective failure (consultation within 1 year because of prolapse symptoms) in 39% (16/41) following sacrohysteropexy compared with 12% (5/41) following hysterectomy. Case series of 30 and 20 women reported prolapse symptoms in 3% (1/30, 3-year follow-up) and 0% (0/20, 6- to 30-month follow-up) respectively.
- 2.3.2 In the RCT, there was no significant difference at 1-year follow-up in objective failure rate between the women who had sacrohysteropexy and those who had hysterectomy (5% [2/38] and 5% [2/40], respectively). Three case series of 30, 19 and 13 women reported objective failure in 3% (1/30), 0% (0/19) and 8% (1/13), respectively, following sacrohysteropexy (4-month to 5-year follow-up).
- 2.3.3 The RCT reported need for further prolapse surgery in 22% (9/41) of women after sacrohysteropexy compared with 2% (1/41) after hysterectomy (1-year follow-up). Further prolapse surgery was required by 3% (1/30) of women in the case series (3-year follow-up) and 0% after sacrohysteropexy (0/36) or sacrocolpopexy following hysterectomy (0/39) in a non-randomised study of 75 women (mean follow-up 51 months).

- 2.3.4 The Specialist Advisers considered key efficacy outcomes to include support of the uterus as measured by the pelvic organ prolapse quantification system (POPQ), prolapse recurrence, and subsequent pregnancy.

2.4 Safety

- 2.4.1 Mesh erosion occurred in 8% (3/39) of women treated by sacrocolpopexy following hysterectomy and in 0% (0/36) treated by sacrohysteropexy in the non-randomised study (mean follow-up of 51 months). The case series of 30 women reported mesh erosion in 3% (1/30) at 2-year follow-up.
- 2.4.2 Mesh infection requiring surgery, postoperative vault abscess and postoperative fever of unknown origin were reported in 5% (2/41), 5% (2/41) and 7% (3/41), respectively, of women treated by sacrohysteropexy in the RCT.
- 2.4.3 Perivesical haematoma or voiding dysfunction occurred in 17% (6/36) of women after sacrohysteropexy in the non-randomised study, compared with 13% (5/39) of women treated by sacrocolpopexy following hysterectomy.
- 2.4.4 The Specialist Advisers considered theoretical adverse events to include mesh erosion, mesh rejection, shrinkage or brittleness; osteomyelitis; bowel obstruction; ureteric, bowel or bladder injury; cellulitis; cervical elongation; sexual dysfunction; and vaginal discharge and bleeding. 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/IPG282publicinfo

Ordering printed copies

Contact NICE publications (phone 0845 003 7783 or email publications@nice.org.uk) and quote reference number N1773 for this guidance or N1774 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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