National Institute for Health and Clinical Excellence

Sacrocolpopexy with hysterectomy using mesh for uterine prolapse repair

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1 Guidance

1.1 Current evidence on the safety and efficacy of sacrocolpopexy with hysterectomy 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 sacrocolpopexy with hysterectomy 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, 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 sacrocolpopexy with hysterectomy using mesh for uterine prolapse repair, and may review the procedure on publication of further evidence on different types of mesh. Future research should address short- and long-term efficacy, erosion rates and patient-reported quality-of-life outcome measures 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, infracoccygeal sacropexy, 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 Sacrocolpopexy with hysterectomy using mesh for uterine prolapse is performed with the patient under general anaesthesia. An open or laparoscopic approach is used, following on from a concomitant hysterectomy. Mesh is attached to the apex of the vagina and may also be attached to the anterior and/or posterior vaginal wall, with the aim of preventing future vaginal vault prolapse.

2.2.2 This 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.

> 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 non-randomised study that compared 36 women treated by mesh sacrohysteropexy with 39 women treated by hysterectomy followed by sacrocolpopexy reported no objective failure (defined as prolapse at less than 6 cm above the hymen) in either group (0/36 and 0/39) at a mean follow-up of 51 months.

2.3.2 The same study reported that none of the 75 women required a further operation for recurrent or de novo prolapse at a mean follow-up of 51 months.

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 Mesh erosion was reported in 4% (1/23) of women treated by hysterectomy followed by sacrocolpopexy in a randomised controlled trial (RCT) of 47 women (available as a conference abstract; mean follow-up 33 months). The non-randomised comparative study of 75 women reported no mesh erosion (0/36) in the sacrohysteropexy group and mesh erosion in 8% (3/39) of women in the hysterectomy and sacrocolpopexy group (mean follow-up 51 months); all women with mesh erosion required further surgery. Another non-randomised comparative study of 104 women reported erosion rates of 11% (8/76) in women having total hysterectomy followed by sacrocolpopexy and 4% (1/28) in women having supracervical hysterectomy followed by sacrocolpopexy (median follow-up 4 months); 4 of the 8 women in the first group required further surgery for mesh erosion. A case series of 324 women reported that 7% (7/101) of women had mesh erosion after hysterectomy followed by sacrocolpopexy at a median follow-up of 8.4 months (range 1.4–13 months).

2.4.2 Wound infection was reported in 8% (3/39) of women treated by hysterectomy and sacrocolpopexy in the non-randomised comparative study of 75 women.

2.4.3 Perivesical haematoma or voiding dysfunction were reported in 17% (6/36) of women treated by sacrohysteropexy and 13% (5/39) of women who had hysterectomy followed by sacrocolpopexy in the non-randomised comparative study of 75 women (time of occurrence not reported).

2.4.4 The Specialist Advisers considered theoretical adverse events to include osteomyelitis, bleeding from local 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 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 for 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: sacrocolpopexy using mesh for vaginal vault prolapse repair, infracoccygeal sacropexy using mesh for vaginal vault prolapse repair, infracoccygeal sacropexy 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.

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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