



Laparoscopic mesh pectopexy for apical prolapse of the uterus or vagina

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www.nice.org.uk/guidance/ipg608

Your responsibility

This guidance represents the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, healthcare professionals are expected to take this guidance fully into account, and specifically any special arrangements relating to the introduction of new interventional procedures. The guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

All problems (adverse events) related to a medicine or medical device used for treatment or in a procedure should be reported to the Medicines and Healthcare products Regulatory Agency using the Yellow Card Scheme.

Commissioners and/or providers have a responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful

discrimination, advance equality of opportunity, and foster good relations. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with those duties. Providers should ensure that governance structures are in place to review, authorise and monitor the introduction of new devices and procedures.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should <u>assess and reduce the environmental impact of implementing NICE recommendations</u> wherever possible.

1 Recommendations

- 1.1 Current evidence on the safety and efficacy of laparoscopic mesh pectopexy for apical prolapse of the uterus or vagina is insufficient in quality and quantity. Therefore, this procedure should only be used in the context of research. Find out what only in research means on the NICE interventional procedures guidance page.
- 1.2 The procedure should only be done by surgeons experienced and trained in laparoscopic urogynaecological surgery.
- 1.3 All adverse events involving the medical devices (including the mesh) used in this procedure should be reported to the Medicines and Healthcare products Regulatory Agency.
- 1.4 Further research should include details of patient selection and longterm outcomes.

2 The condition, current treatments and procedure

The condition

Apical prolapse is the descent of the uterus, cervix, or vaginal vault.

Vaginal vault prolapse is when the upper part of the vagina descends from its usual position, sometimes out through the vaginal opening. It is

common after hysterectomy. Apical prolapse can affect quality of life by causing pressure and discomfort, and by its effect on urinary, bowel and sexual function.

Current treatments

2.2 Treatment is rarely indicated if there are no symptoms. Mild-to-moderate prolapse may be treated with conservative measures such as pelvic floor muscle training, electrical stimulation and biofeedback. Topical oestrogens and mechanical measures such as pessaries may also be used. Surgery may be needed when the prolapse is severe. Several surgical procedures are available including hysterectomy, mesh sacrocolpopexy, uterine suspension sling (including sacrohysteropexy) and uterine or vault suspension (without sling). Some procedures involve using mesh to provide additional support.

The procedure

- 2.3 Laparoscopic mesh pectopexy is done with the patient under general anaesthesia. Using a laparoscopic approach, a polyvinylidene fluoride (PVDF) monofilament mesh is inserted into the abdominal cavity. The ends of the mesh are attached to the iliopectineal ligaments on each side of the pelvis, using nonabsorbable suture material. The cervical stump or vaginal apex is elevated to the intended tension-free position and sutured to the central part of the mesh. The mesh is then completely covered with peritoneum, secured using absorbable suture material, so that no mesh is visible in the abdominal cavity.
- 2.4 This procedure may offer an alternative to laparoscopic sacrohysteropexy when access to the sacral promontory is limited, for example because of abnormal anatomy, obesity, adhesions, or previous surgery.

3 Committee considerations

The evidence

- 3.1 To inform the committee, NICE did a rapid review of the published literature on the efficacy and safety of this procedure. This comprised a comprehensive literature search and detailed review of the evidence from 5 sources, which was discussed by the committee. The evidence included 1 randomised controlled trial (in 2 publications), 2 case series and 1 case report, and is presented in table 2 of the interventional procedures overview.
- The specialist advisers and the committee considered the key efficacy outcomes to be: repair of prolapse and reduction of symptoms.
- 3.3 The specialist advisers and the committee considered the key safety outcomes to be: pain, infection and mesh erosion into the vagina, bladder, urethra or bowel.
- 3.4 Patient commentary was sought but none was received.

Committee comments

3.5 There is more than 1 mesh available for use in this procedure.

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Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.