NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional procedures consultation document

Laparoscopic mesh pectopexy for apical prolapse of the uterus or vagina

Apical prolapse happens when the womb (uterus), cervix or vaginal vault slips down from its usual position. A vaginal vault is formed at the top of the vagina after surgery to remove the womb and cervix (hysterectomy). This procedure involves inserting a mesh inside the abdomen using several small cuts (keyhole surgery). Each end of the mesh is attached to a ligament at either side of the pelvis. It acts like a sling to support the uterus or the top of the vagina.

The National Institute for Health and Care Excellence (NICE) is looking at laparoscopic mesh pectopexy for apical prolapse of the uterus or vagina. NICE's interventional procedures advisory committee has considered the evidence and the views of specialist advisers, who are consultants with knowledge of the procedure.

The committee has made draft recommendations and we now want to hear your views. The committee particularly welcomes:

- comments on the draft recommendations
- information about factual inaccuracies
- additional relevant evidence, with references if possible.

This is not our final guidance on this procedure. The recommendations may change after this consultation.

After consultation ends:

- The committee will meet again to consider the original evidence and its draft recommendations in the light of the consultation comments.
- The committee will prepare a second draft, which will be the basis for NICE's guidance on using the procedure in the NHS.

For further details, see the Interventional Procedures Programme process guide.

Through our guidance, we are committed to promoting race and disability equality, equality between men and women, and to eliminating all forms of discrimination. One of the ways we do this is by trying to involve as wide a range of people and interest groups as possible in developing our interventional procedures guidance. In particular, we encourage people and organisations from groups who might not normally comment on our guidance to do so.

To help us promote equality through our guidance, please consider the following question:

Are there any issues that require special attention in light of NICE's duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations between people with a characteristic protected by the equalities legislation and others?

Please note that we reserve the right to summarise and edit comments received during consultations or not to publish them at all if in the reasonable opinion of NICE, there are a lot of comments, of if publishing the comments would be unlawful or otherwise inappropriate.

Closing date for comments: 22 December 2017

Target date for publication of guidance: March 2018

1 Draft 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.

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 long-term outcomes.

2 The condition, current treatments and procedure

The condition

2.1 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 4 sources, which was discussed by the committee. The evidence included 1 randomised controlled trial (in 2 publications), 1 case series and 1 case report, and is presented in table 2 of the interventional procedures overview ***[add URL]***. Other relevant literature is in appendix A of the overview.

3.2 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.

Committee comments

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

Tom Clutton-Brock

Chairman, interventional procedures advisory committee

October 2017

ISBN: