NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional procedures consultation document

Bilateral cervicosacropexy or vaginosacropexy using mesh for pelvic organ prolapse

Pelvic organ prolapse is when 1 or more of the pelvic organs (uterus, bladder or rectum) bulge into the vagina. This may be caused by weakness or stretching of ligaments that support the uterus and hold the organs in place. This procedure is done during or after a hysterectomy. The ligaments are replaced by plastic mesh tapes, using open abdominal or keyhole surgery. The aim is to lift the bladder or rectum back to a normal position.

NICE is looking at bilateral cervicosacropexy or vaginosacropexy using mesh for pelvic organ prolapse.

NICE's interventional procedures advisory committee met to consider the evidence and the opinions of specialist advisers, who are consultants with knowledge of the procedure.

This document contains the draft guidance for consultation. Your views are welcome, particularly:

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

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others.

This is not NICE's final guidance on this procedure. The draft guidance may change after this consultation.

After consultation ends, the committee will:

- meet again to consider the consultation comments, review the evidence and make appropriate changes to the draft guidance

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- prepare a second draft, which will go through a resolution process before the final guidance is agreed.

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

Closing date for comments: 21 November 2019

Target date for publication of guidance: February 2010

1 Draft recommendations

1.1 Evidence on the safety and efficacy of bilateral cervicosacropexy or vaginosacropexy using mesh for pelvic organ prolapse is inadequate in quantity and quality. Therefore, this procedure should only be used in the context of research.

1.2 Further research should include randomised controlled trials, and report details of patient selection, improvement in the prolapse, procedure-related adverse events and patient-reported outcome measures.

2 The condition, current treatments and procedure

The condition

2.1 Pelvic organ prolapse is defined as symptomatic descent of 1 or more of: the anterior vaginal wall, the posterior vaginal wall, the cervix or uterus, or the apex of the vagina (vault or cuff). Symptoms include a vaginal bulge or sensation of something coming down, urinary, bowel and sexual symptoms, and pelvic and back pain. These symptoms affect women's quality of life.

Current treatments

2.2 NICE's guideline on urinary incontinence and pelvic organ prolapse describes its management. Non-surgical management options include lifestyle modification, such as losing weight and minimising heavy lifting, topical oestrogen, pelvic floor muscle training and vaginal pessaries. Surgery may be needed when the prolapse is severe. Different surgical procedures are available using vaginal or abdominal (open, laparoscopic or robotic) approaches. Some procedures involve using mesh, the aim being to provide additional support.

The procedure

2.3 Bilateral cervicosacropexy or vaginosacropexy for pelvic organ prolapse are abdominal mesh procedures. They are done through an open or laparoscopic approach, with the patient under general anaesthesia. If the uterus is still in place, the first step of the procedure is a hysterectomy. A polyvinylidene fluoride (PVDF) mesh ligament-replacement structure is then placed within the peritoneal fold of both the left and right uterosacral ligaments. Anterior fixation of each PVDF structure is done by centrally suturing it to the cervix or vaginal vault with 3 or 4 interrupted, nonabsorbable polyester sutures. For posterior fixation, the PVDF structures are fixed to the left and right prevertebral fascia of the sacral vertebra at the level of S1 and S2, using a fixation device or sutures. The peritoneum above the cervix or vaginal vault is then closed to cover the PVDF structure. The aim is to support the pelvic organs in their correct position, and to improve symptoms associated with the prolapse.

3 Committee considerations

The evidence

3.1 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 5 case series. It is presented in table 2 of the interventional procedures overview. Other relevant literature is in the appendix of the overview.

3.2 The specialist advisers and the committee considered the key efficacy outcomes to be: prolapse resolution, urinary symptoms, sexual function and quality of life.

3.3 The specialist advisers and the committee considered the key safety outcomes to be: intraoperative complications, mesh erosion, new urinary symptoms, chronic pain, need for mesh removal and reintervention rate.

Committee comments

3.4 The committee noted that there was a risk of damage to the sacral plexus veins, and care had to be taken not to damage the sigmoid colon during the procedure.

3.5 The committee noted that this procedure may be done either by open surgery or laparoscopically.

Tom Clutton-Brock
Chair, interventional procedures advisory committee
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