NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional procedures consultation document

Laparoscopic ventral mesh rectopexy for internal rectal prolapse

Internal rectal prolapse is when the lowest part of the bowel (rectum) telescopes on itself, causing difficulty in emptying the bowel, faecal incontinence or both. In this procedure, a piece of sterile material is used to attach the rectum to the lower back bone using keyhole surgery. The aim is to support the rectum in its natural position.

The National Institute for Health and Care Excellence (NICE) is looking at laparoscopic ventral mesh rectopexy for internal rectal prolapse. 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 May 2018

Target date for publication of guidance: June 2018

1 Draft recommendations

1.1 Current evidence on the safety of laparoscopic ventral mesh rectopexy for internal rectal prolapse shows there are well-recognised, serious but infrequent complications. The evidence on efficacy and safety is limited in quality. Therefore, this procedure should only be used with special arrangements for clinical governance, consent and audit or research.

1.2 Clinicians wishing to do laparoscopic ventral mesh rectopexy for internal rectal prolapse should:

- Inform the clinical governance leads in their NHS trusts.
- Ensure that patients understand the uncertainty about the procedure's efficacy and safety and that there are different types of mesh available, which may have different efficacies and

complications. Patients should be provided with clear written information. In addition, the use of NICE's information for the public is recommended.

1.3 Patient selection should be done by a pelvic floor multidisciplinary team. This should typically include a surgeon, a physician, a radiologist, a nurse specialist, a physiotherapist, a pelvic floor physiologist and, when appropriate, a urogynaecologist.

1.4 This procedure should only be done by surgeons who are trained and experienced in laparoscopic pelvic floor surgery, who have done their initial procedures with an experienced mentor.

1.5 Clinicians should enter details about all patients having laparoscopic ventral mesh rectopexy for internal rectal prolapse onto an appropriate registry (for example, the British Pelvic Floor Society database). The results of the registry should be published.

1.6 Clinicians are encouraged to collect data on patient selection, patient-reported outcomes, mesh-related complications, the type of mesh used, the attachment method and long-term follow-up. NICE may update the guidance on publication of further evidence.

1.7 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.

2 The condition, current treatments and procedure

The condition

2.1 Internal rectal prolapse is when the lowest part of the bowel (rectum) telescopes on itself. It is more common in women who have had children but also occurs in nulliparous women and in men. Factors related to the development of the condition are age, childbirth, constipation and straining. It may be associated with prolapse of other pelvic organs and some people may have a predisposition because of abnormalities in collagen. It is not life threatening but it can be a distressing and demoralising condition, with negative effects on quality of life. Symptoms include discomfort, pain, constipation, difficult evacuation (obstructed defaecation syndrome), faecal incontinence and discharge of mucus or blood. In women it can be associated with vaginal bulge (rectocele), painful intercourse, lower back pain, urinary dysfunction, and vaginal prolapse and enterocele.

Current treatments

2.2 Conservative treatment of internal rectal prolapse may include pelvic floor exercises and advice to improve defaecatory habits, reduce constipation and improve incontinence. These are often termed biofeedback or pelvic floor re-training. Surgical treatment of internal rectal prolapse is classified into perineal (Delorme's operation) and abdominal procedures. Open abdominal surgery and laparoscopic procedures, with or without robotic assistance, use mesh or direct suturing and may involve resection of the sigmoid colon.

The procedure

2.3 Laparoscopic ventral mesh rectopexy (LVMR) is done under general anaesthesia using keyhole surgery in which 3 to 4 small incisions are made in the abdomen. The peritoneum around the rectum is dissected until the muscle coat of the rectum is identified and exposed over the entire anterior rectum, which is mobilised into the rectovaginal or rectoprostatic fascia. The mesh is secured to the rectum anteriorly, as low as possible in the fascia, using sutures, and fixed to the sacral promontory with permanent sutures or small metal tacks. The peritoneum is closed over the mesh to prevent the bowel becoming trapped or adhering to the mesh. In women, LVMR may help control rectocele or enterocele associated with rectal prolapse.

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 9 sources, which was discussed by the committee. The evidence included 2 systematic reviews 1 randomised control trial and 6 case series, and is presented in table 2 of the interventional procedures overview ***[add URL]***. Other relevant literature is included in the Appendix of the overview.

3.2 The specialist advisers and the committee considered the key efficacy outcomes to be: improvement in quality of life and other

patient-reported outcomes, anatomical and functional correction of prolapse, and improvement in pelvic pain.

3.3 The specialist advisers and the committee considered the key safety outcomes to be: perioperative adverse events and mesh-related complications (such as infection and erosion of the mesh).

3.4 Thirteen commentaries from patients who had experience of this procedure were received, which were discussed by the committee.

Committee comments

3.5 The committee was informed that the types of mesh and the techniques used to insert it are evolving.

3.6 The committee was advised that polyester mesh is no longer used because of high erosion rates.

3.7 The committee was informed that all patients should have a period of supervised conservative treatment before surgery is considered.

Tom Clutton-Brock
Chairman, interventional procedures advisory committee
January, 2018

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