Laparoscopic ventral mesh rectopexy for internal rectal prolapse

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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 <u>Yellow Card Scheme</u>.

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</u> <u>impact of implementing NICE recommendations</u> wherever possible.

1 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. Find out <u>what special</u> <u>arrangements mean on the NICE interventional procedures guidance page</u>.
- 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 <u>NICE's</u> <u>information for the public on laparoscopic ventral mesh rectopexy</u> is recommended.
- 1.3 Patient selection should be done by a pelvic floor multidisciplinary team. This should typically include a surgeon, an urogynaecologist, a radiologist, a nurse specialist, a physiotherapist, a pelvic floor physiologist and, when appropriate, a gastroenterologist.
- 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.
- Clinicians are encouraged to collect data on patient selection, patient-reported 1.6 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 happens 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 guality 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.

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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 over the rectum is dissected, exposing the muscle coat which is mobilised into the rectovaginal septum in females and the level of the seminal vesicles in males. 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. 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 Thirty eight 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.
- 3.8 The committee was pleased to receive patient commentary from women who had experience of this procedure. The responses were mixed, some patients found the procedure helpful and some found they had significant complications which can be serious and have life-changing consequences.

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Endorsing organisation

This guidance has been endorsed by <u>Healthcare Improvement Scotland</u>.

Accreditation

