NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional procedures consultation document

Reinforcement of a permanent stoma with mesh to prevent a parastomal hernia

A stoma is an opening on the front of the abdomen, made to allow faeces or urine to be collected in a bag on the outside of the body. A parastomal hernia happens when part of the intestine bulges around the stoma. This can cause discomfort, difficulties fitting the stoma bag and it can block the stoma. This procedure involves inserting a piece of mesh close to the stoma when it is created. The aim is to strengthen the abdominal wall and prevent a hernia.

The National Institute for Health and Care Excellence (NICE) is looking at reinforcement of a permanent stoma with mesh to prevent a parastomal hernia. 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: 21 March 2019

Target date for publication of guidance: June 2019

1 Draft recommendations

1.1 The evidence on the safety of reinforcement of a permanent stoma with mesh to prevent a parastomal hernia shows there are serious but well-recognised complications. The evidence on efficacy is limited in quantity and quality. Therefore, this procedure should not be used unless special arrangements are in place for clinical governance, consent, and audit or research.

1.2 Clinicians wishing to do reinforcement of a permanent stoma with mesh to prevent a parastomal hernia should:

- Inform the clinical governance leads in their NHS trusts.

- Ensure that patients understand the procedure's safety and efficacy, as well as any uncertainties about these. Provide them with clear written information to support shared decision-making. In addition, the use of NICE's information for the public *[URL to be added at publication]* is recommended.
- Audit and review clinical outcomes of all patients having reinforcement of a permanent stoma with mesh to prevent a parastomal hernia. NICE has identified relevant audit criteria and is developing an audit tool (which is for use at local discretion), which will be available when the guidance is published.

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 could be in the form of randomised controlled trials, observational studies and analysis of registry data. It should report details of patient selection, the type of mesh used, mesh-associated complications and long-term outcomes (at least 3 years). In participating centres, clinicians should encourage patients to take part in the National Institute for Health Research CIPHER study.

2 The condition, current treatments and procedure

The condition

2.1 Stomas are created surgically to divert the contents of the urinary or digestive tract through an opening in the abdominal wall. A parastomal hernia allows protrusion of abdominal contents through the abdominal-wall defect created by the stoma. They are relatively common, usually developing gradually and increasing in size over time. A parastomal hernia may remain asymptomatic, but can

cause problems such as unacceptable physical appearance, poorly-fitting stoma device, bowel obstruction, and bowel ischaemia and strangulation.

Current treatments

2.2 A parastomal hernia can be repaired surgically, using an open or laparoscopic approach. Surgical repair is associated with its own morbidity and there is a high risk of recurrence.

The procedure

2.3 This procedure is done using general anaesthesia, at the same time as the creation of the stoma. A space is formed between the rectus abdominus muscle and the rectus sheath of the abdominal wall, and a piece of mesh is inserted into the space. The bowel or ureter is passed through the mesh and then through the abdominal wall. The mesh and the bowel or ureter are stitched to the abdominal wall. The aim is to strengthen the abdominal wall and prevent parastomal herniation.

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 8 sources, which was discussed by the committee. The evidence included 2 systematic reviews and meta-analyses, 3 randomised controlled trials, 2 non-randomised comparative studies and 1 case series, and 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: occurrence of symptomatic parastomal hernia and quality of life.

3.3 The specialist advisers and the committee considered the key safety outcomes to be: need for reoperation, infection, mesh-associated complications, fistulation, bowel obstruction and bowel adhesion.

Committee comments

3.4 The committee noted that there are different types of meshes including synthetic and biological (some from animal origin) and various techniques for constructing stomas. This makes the evidence difficult to assess.

3.5 The committee noted that most of the evidence comes from colostomy procedures.

3.6 Mesh is difficult to remove should this be needed, and it is more difficult to repair a parastomal hernia if mesh is already in place.

3.7 The committee was informed that there is little evidence to support the use of this procedure for colostomies in patients with inflammatory bowel disease, and that there is a risk of further serious complications in these patients.

3.8 Mesh-associated complications may include fistulation and infection.

Tom Clutton-Brock
Chairman, interventional procedures advisory committee
February, 2019