NICE guidance

Reinforcement of a permanent stoma with a synthetic or biological mesh to prevent a parastomal hernia

Interventional procedures guidance
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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 Yellow Card Scheme.

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 assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

1 Recommendations

1.1 The evidence on the safety of reinforcement of a permanent stoma with a synthetic or biological 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. Find out what special arrangements mean on the NICE interventional procedures guidance page.

1.2 Clinicians wishing to do reinforcement of a permanent stoma with a synthetic or biological 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 is recommended.
- Audit and review clinical outcomes of all patients having the procedure. NICE has identified relevant audit criteria and has developed an audit tool (which is for use at local discretion).

1.3 All adverse events involving the medical devices (including the synthetic or biological 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 synthetic or biological 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 synthetic or biological 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, synthetic or biological mesh-associated complications, fistulation, bowel obstruction and bowel adhesion.

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

Committee comments

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

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

3.7 Synthetic or biological mesh is difficult to remove should this be needed, and it is more difficult to repair a parastomal hernia if a mesh is already in place.

3.8 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.

3.9 Synthetic or biological mesh-associated complications may include fistulation and infection.

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Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.