NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional procedures consultation document

Barnett Continent Intestinal Reservoir (modified continent ileostomy) to restore continence after colon and rectum removal

When the large intestine (colon) and rectum are surgically removed, waste from the small intestine has to exit the body through an opening (stoma) created in the abdominal wall (an ileostomy). The waste is continuously collected in a bag worn over the stoma. In this procedure, a pouch is created on the inside of the abdominal wall using the last part of the small intestine (ileum). The waste from the small intestine collects in the pouch and is drained by inserting a tube (catheter) into the stoma, usually only 2 or 3 times a day. It avoids the need for a bag on the outside of the abdomen to collect the waste.

The National Institute for Health and Care Excellence (NICE) is looking at Barnett Continent Intestinal Reservoir (modified continent ileostomy) to restore continence after colon and rectum removal. 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 November 2018

Target date for publication of guidance: February 2019

1 Draft recommendations

1.1 The evidence on the safety of Barnett Continent Intestinal Reservoir (modified continent ileostomy) to restore continence after colon and rectum removal shows there are serious but well-recognised safety concerns. Current evidence on its efficacy is limited in quantity and 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 Barnett Continent Intestinal Reservoir (modified continent ileostomy) to restore continence after colon and rectum removal 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. They should 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, review and publish clinical outcomes of all patients having Barnett Continent Intestinal Reservoir (modified continent ileostomy) to restore continence after colon and rectum removal. 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 The procedure should only be done by experienced colorectal surgeons with training and mentoring in the specific technique.

1.4 Further research should include details of patient selection, durability, and the incidence of complications. Outcomes should be published.

2 The condition, current treatments and procedure

The condition

2.1 Various groups of patients may need surgery to remove the colon and sometimes the rectum. They include patients with: ulcerative colitis that is unresponsive to medical treatment or who cannot tolerate the treatment; familial adenomatous polyposis; Crohn's disease; or cancer-related problems. An ileostomy is then needed

to allow intestinal contents to exit the body through a stoma on the abdominal wall.

Current treatments

2.2 There are different surgical techniques for creating an ileostomy, including: a Brooke ileostomy (this involves creating a standard stoma that empties intestinal contents continuously into an external ileostomy bag); or a Kock continent ileostomy (this involves creating an internal ileal reservoir connected through the abdominal wall that is drained intermittently by the patient). In patients with good anal sphincter control, a long-term ileostomy may be avoided by creating an ileal pouch reservoir connected directly to the anus (ileal pouch-anal anastomosis).

2.3 The Barnett Continent Intestinal Reservoir is a type of continent ileostomy and may be considered as an option for some patients.

The procedure

2.4 The Barnett Continent Intestinal Reservoir procedure is done under general anaesthesia, usually through a midline incision. It may be done as a primary procedure, when the colon and rectum are removed, or to modify a pre-existing ileostomy. A pouch incorporating a collar and an isoperistaltic valve is made using the last 60 cm of the ileum. The valve is made by intussuscepting a segment of small bowel and fixing it to the pouch wall with staples. This valve functions in the opposite direction to that in a Kock pouch, ensuring the bowel's normal peristaltic action keeps intestinal contents in the pouch rather than expelling them. The collar is formed by wrapping a segment of small bowel around the top of the pouch and valve. It holds the valve in place and provides further continence when the pouch is full and under high pressure. The flat stoma opening is located just above the pubic area and covered with a small adhesive dressing.

2.5 When there is a sensation of fullness, the patient drains the pouch by inserting a catheter through the stoma and valve into the pouch. This is typically done 2 or 3 times a day, but the patient determines the exact frequency.

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 2 sources, which was discussed by the committee. The evidence included 2 retrospective case series and is presented in table 2 of the interventional procedures overview.

3.2 The specialist advisers and the committee considered the key efficacy outcomes to be: continent ileal pouch and quality of life.

3.3 The specialist advisers and the committee considered the key safety outcomes to be: faecal peritonitis, infection, valve slippage, fistula formation, intestinal obstruction, stoma stenosis and bleeding.

3.4 Patient commentary was sought but none was received.

Committee comments

3.5 The committee noted that the ileum needs to rest for 3 weeks after the procedure. In the published evidence reviewed by the committee, this was done by keeping the patient nil by mouth and using intravenous nutrition. The committee was informed that an alternative approach would be to create a defunctioning ileostomy at the time of the procedure, which would subsequently be reversed.

3.6 Patients should be offered appropriate counselling about the effect the procedure may have on their quality of life, including support from stoma nurses.

3.7 The committee was informed that there is information from patients who have had the BCIR procedure available on the internet.

3.8 The committee was informed that the procedure is primarily for patients with ulcerative colitis, and is commonly done after failure of an ileal pouch-anal anastomosis.

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Chairman, interventional procedures advisory committee
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