



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

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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 <u>assess and reduce the environmental impact of implementing NICE recommendations</u> wherever possible.

1 Recommendations

- The evidence on the safety of Barnett Continent Intestinal Reservoir (modified continent ileostomy) to restore continence after colon and rectum removal shows that 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 <u>shared decision making</u>. In addition, the use of
 MICE's information for the public 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. This guidance requires that
 clinicians doing the procedure make special arrangements for audit. NICE has
 identified relevant <u>audit criteria</u> and has developed an <u>audit tool</u> (which is for
 use at local discretion).
- 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

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, which 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).
- 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 created 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

- 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 overview.
- The specialist advisers and the committee considered the key efficacy outcomes to be: continent ileal pouch and quality of life.
- 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.
- Patients should be offered appropriate counselling about the effect the procedure may have on their quality of life, including about support from stoma nurses.
- 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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Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.