NICE guidance

Transabdominal artificial bowel sphincter implantation for faecal incontinence

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 Guidance

1.1 Current evidence on the safety and efficacy of transabdominal artificial bowel sphincter implantation for faecal incontinence is based on a small number of patients and is inadequate in quantity. Therefore, this procedure should only be used with special arrangements for clinical governance, consent and audit or research.

1.2 Clinicians wishing to undertake transabdominal artificial bowel sphincter implantation for faecal incontinence should take the following actions.

- Inform the clinical governance leads in their Trusts.
- Ensure that patients understand the uncertainty about the procedure's safety and efficacy and provide them with clear written information. In addition, the use of NICE's information for the public is recommended.
- Audit and review clinical outcomes of all patients having transabdominal artificial bowel sphincter implantation for faecal incontinence (see section 3.1).

2 The procedure

2.1 Indications and current treatments

2.1.1 Faecal incontinence is caused by a variety of conditions that can affect either the

anatomy or function of the anal sphincter. These conditions include perineal injury during childbirth, neurological or spinal disease/injury (for example, stroke, multiple sclerosis or spinal cord injury), congenital anorectal dysfunction, pelvic organ prolapse, colonic resection or anal surgery, or pelvic radiotherapy.

2.1.2 First-line treatment for faecal incontinence is usually conservative and includes dietary management and antidiarrhoeal medication. This may be followed by pelvic floor muscle training, biofeedback therapy and electrical stimulation. If conservative treatments fail, local surgery to repair the sphincter may be recommended. If local surgery proves inadequate, alternatives include sacral nerve stimulation, graciloplasty (creation of a new sphincter from other suitable muscles) or implantation of an artificial anal sphincter (anorectal or transabdominal). The most severe cases may require a permanent colostomy.

2.2 Outline of the procedure

2.2.1 Artificial bowel sphincters are usually implanted into the perineum. However, complications (such as infections and erosion of the implant into surrounding tissue) are common at this site, often resulting in surgical revision or removal of the device. Transabdominal implantation aims to achieve a lower rate of complications. Usually with the patient under general anaesthesia, a lower mid-line incision is made to allow the inflatable sphincter cuff (consisting of an expander and a gel-filled pillow) to be placed at the anorectal junction and held in place by a strap. A subcutaneous pouch is then created for the control pump, usually in the right iliac fossa. A balloon reservoir is placed within the peritoneal cavity in the pelvis. The connecting tubes from the sphincter cuff and the balloon reservoir are connected to the control pump and the abdomen is closed.

2.2.2 When inflated, the cuff keeps the anal canal closed. To evacuate the bowel, the patient presses the control pump's button against the abdominal wall. This deflates the cuff and opens the sphincter by pumping fluid from the sphincter cuff into the balloon reservoir. On completion of defaecation, the patient closes the sphincter by pressing the button on the pump again. This opens the pump, allowing fluid to return to the cuff and producing angulation between the rectum and the anal canal.

2.3 Efficacy

Sections 2.3 and 2.4 describe efficacy and safety outcomes which were available in the published literature and which the Committee considered as part of the evidence about this procedure. For more detailed information on the evidence, see the overview.

2.3.1 A case series of 12 patients reported that 75% (9 out of 12) of patients had a functioning implant at a median follow-up of 59 months (range 30 to 72 months). Five of the 9 (56%) required surgical revision (4 to replace the pump and 1 because of strap disruption). In the same study, the median Cleveland Clinic Incontinence Score (in which the maximal faecal incontinence score is 20) improved from 16 (range 7 to 20) before the procedure to 3 (range 0 to 7) after the procedure in the 10 patients whose faecal incontinence could be assessed.

2.3.2 The Specialist Advisers stated that key efficacy outcomes include restoration of faecal continence, absence of mucus leakage and improved quality of life.

2.4 Safety

2.4.1 The case series of 12 patients reported that 25% (3 out of 12) of patients required removal of the device because of complications, including infection after revision surgery in 2 patients and pseudomembranous colitis during the perioperative period in the third patient.

2.4.2 The Specialist Advisers stated that theoretical adverse events include infection, migration of the device within the pelvis, disturbance of the blood supply to the bowel, and rectal injury caused by pressure from the artificial sphincter. One Adviser stated that surgical revision of this procedure is likely to be more difficult than surgical revision after perineal implantation.

2.5 Other comments

2.5.1 The Committee noted that the technology was modified during the single small case series that reported on this procedure and that further development and

modifications are likely to occur.

3 Further information

3.1 This guidance requires that clinicians undertaking the procedure make special arrangements for audit. NICE has identified relevant audit criteria and developed audit support (which is for use at local discretion).

3.2 NICE has published a guideline on faecal incontinence in adults and interventional procedures guidance on stimulated graciloplasty, injectable bulking agents, sacral nerve stimulation and artificial anal sphincter implantation (perineal approach), all for faecal incontinence.

Sources of evidence

The evidence considered by the Interventional Procedures Advisory Committee is described in the overview.

Information for patients

NICE has produced information for the public on this procedure. It explains the nature of the procedure and the guidance issued by NICE, and has been written with patient consent in mind.

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Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.