NICE guidance

Endoscopic radiofrequency therapy of the anal sphincter 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 The evidence on endoscopic radiofrequency therapy of the anal sphincter for faecal incontinence raises no major safety concerns. There is evidence of efficacy in the short term, but in a limited number of patients. Therefore, this procedure should only be used with special arrangements for clinical governance, consent and audit or research.

1.2 Clinicians wishing to undertake endoscopic radiofrequency therapy of the anal sphincter for faecal incontinence should take the following actions.

- Inform the clinical governance leads in their Trusts.
- Ensure that patients and their carers understand the uncertainty about the procedure's 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 endoscopic radiofrequency therapy of the anal sphincter for faecal incontinence (see section 3.1).

1.3 This procedure should only be carried out in units specialising in the assessment and treatment of faecal incontinence, as one of a range of treatment options.

1.4 Further research into endoscopic radiofrequency therapy of the anal sphincter for faecal incontinence should clearly define the patient groups being treated. It should also report the clinical impact in terms of quality of life and long-term outcomes. NICE may review the procedure on publication of further evidence.

2 The procedure

2.1 Indications and current treatments

2.1.1 Faecal incontinence occurs when a person loses the ability to control their anal sphincter and bowel movements, resulting in leakage of faeces. Causes include neurological disease and perineal injury during vaginal delivery (a relatively common cause in women).

2.1.2 First-line treatment is conservative, with measures such as dietary management or antidiarrhoeal medication. If these are not successful, pelvic floor muscle or anal sphincter training (sometimes including biofeedback therapy) may be used.

2.1.3 If conservative treatments have been unsuccessful, surgical options include sphincter repair, sacral nerve stimulation, stimulated graciloplasty (creation of a new sphincter from other suitable muscles), anorectal or transabdominal implantation of an artificial anal sphincter, or permanent colostomy.

2.2 Outline of the procedure

2.2.1 The aim of endoscopic radiofrequency therapy of the anal sphincter for faecal incontinence is to cause a degree of fibrosis, so tightening the ring of muscle that forms the sphincter. It is intended to be less invasive than alternative surgical treatments.

2.2.2 The procedure is usually done with the patient under sedation and local anaesthesia. Under direct visualisation, a specially designed transparent catheter which houses needle electrodes is inserted into the anus. The needle electrodes deliver heat generated by radiofrequency energy to the anal sphincter muscle under temperature feedback control via temperature sensors. Radiofrequency energy is typically applied to each quadrant sequentially, starting at about the level of the dentate line and repeating this at 3 to 5 levels approximately 1 cm apart. Chilled water is used to cool the mucosa.

2.3 Efficacy

Sections 2.3 and 2.4 describe efficacy and safety outcomes from the published literature that 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 50 patients reported improved mean scores in all components of the Fecal Incontinence Quality of Life (FIQL) questionnaire (29 questions on lifestyle, coping, depression, and embarrassment, scored from 1 to 4; higher score indicates better quality of life) from baseline to 6-month follow-up (per protocol analysis: lifestyle, 2.5 to 3.1; coping, 1.9 to 2.4; depression, 2.8 to 3.3; and embarrassment, 1.9 to 2.5; $p \leq 0.0001$ for each). A case series of 19 patients reported a significant improvement in mean scores in all components of the FIQL questionnaire from baseline to 5-year follow-up (lifestyle, 2.43 to 3.16, $p<0.00075$; coping, 1.73 to 2.6, $p<0.00083$; depression, 2.24 to 3.15, $p<0.0002$; and embarrassment, 1.56 to 2.51, $p<0.0003$).

2.3.2 The case series of 50 patients reported no differences in resting or squeeze pressure, rectal sensation, pudendal nerve motor latency, or sphincter defects on endoanal ultrasound at 6-month follow-up.

2.3.3 The Specialist Advisers listed key efficacy outcomes as improvement in faecal continence and improved quality of life.

2.4 Safety

2.4.1 The case series of 50 patients reported mucosal ulceration in 2 patients, 2 to 3 weeks after treatment. In 1 patient this was superficial and settled with local care: continence was improved. In the other patient the ulceration did not involve the underlying muscle but nevertheless caused anal pain: continence was worse at 6-month follow-up.

2.4.2 The case series of 50 patients reported constipation in 2% (1 out of 50) of patients (treatment and outcome not described).

2.4.3 The case series of 50 and 19 patients reported secondary haemorrhage in 2% (1

out of 50) and 32% (6 out of 19) of patients respectively. Both required suture ligation to control the bleeding (not otherwise described).

2.4.4 The case series of 50 patients reported postoperative anal pain in 10% (5 out of 50) of patients.

2.4.5 The case series of 24 patients reported constipation and diarrhoea in 1 patient each. The first patient was treated with laxatives, and the diarrhoea in the second patient resolved spontaneously.

2.4.6 The Specialist Advisers listed anecdotal adverse events to include haemorrhage (acute or secondary) and anal stenosis.

2.5 Other comments

2.5.1 The Committee recognised both the serious impact that faecal incontinence can have on quality of life and the potential benefits of new treatment options for carefully selected patients, provided that their efficacy has been properly demonstrated.

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 has developed an audit tool (which is for use at local discretion).

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.