NICE guidance

Stimulated graciloplasty 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 stimulated graciloplasty for faecal incontinence is limited, but appears sufficient to support the use of this procedure for carefully selected patients in whom other treatments have failed or are contraindicated, provided that the normal arrangements are in place for consent, audit and clinical governance.

1.2 This procedure should be performed only in specialist units by clinicians with specific training and experience in the assessment and treatment of faecal incontinence.

2 The procedure

2.1 Indications

2.1.1 Stimulated graciloplasty is used to treat refractory faecal incontinence (for example, anorectal atresia) as an alternative to colostomy. Other approaches aimed at establishing continence are insertion of an artificial anal sphincter and sacral nerve stimulation.

2.2 Outline of the procedure

2.2.1 Stimulated graciloplasty involves creating a new anal sphincter using transposed gracilis muscle. Electrodes are implanted in the transposed muscle and connected to an electric pulse generator implanted in the abdominal wall. A

continuous current from the pulse generator gradually alters the character of the gracilis muscle fibres.

2.2.2 The procedure can be performed in one or two stages. In the latter case, the muscle wrapping precedes the electrode implantation stage by a few weeks.

2.3 Efficacy

2.3.1 A systematic review of 37 studies of graciloplasty found that between 42% and 85% of patients became continent after the procedure (different definitions of continence were used and continence was assessed at different time points in the studies). A controlled study found that at 24 months, frequency of incontinence had significantly improved from baseline in 48 patients who had undergone graciloplasty ($p<0.0001$); there was no improvement during this period in patients who were not offered surgery. A case series reported successful outcomes in 72% (144 out of 200) of patients, with 5-year follow-up.

2.3.2 A controlled trial found that quality of life improved more in patients treated with graciloplasty (n=46) than in those not offered surgery who were being medically managed (n=40). The following scales were used to assess quality of life: the Cleveland Clinic Faecal Incontinence Scale ($p=0.001$); the Hospital Anxiety and Depression Scale for anxiety ($p=0.03$) and depression ($p=0.05$); and a validated study-specific scale for psychological wellbeing ($p<0.0001$) and lifestyle characteristics ($p<0.0001$). In a case series of 129 patients who had graciloplasty, patients' quality of life was significantly improved on the SF-36 scale for physical and social functioning at 12 months' follow-up. For more details, refer to the overview.

2.3.3 The Specialist Advisors suggested that this procedure has been largely superseded by sacral nerve stimulation.

2.4 Safety

2.4.1 The most common complication of stimulated graciloplasty is wound infection. In

a systematic review that included 403 patients assessed for safety outcomes, the overall rate of infection was 28%. In a case series of 121 patients, serious infection needing hospitalisation and/or surgery was reported in 15% of patients, and in another series, it occurred in 14% (17 out of 123) of patients.

2.4.2 Electrical or technical problems with the pulse generator leading to hospitalisation occurred in 48% (23 out of 48) of patients who had undergone graciloplasty in a controlled trial at 42 months' follow-up. In a case series of 123 patients, 3 patients (2%) had a deep vein thrombosis, and one patient died following a pulmonary embolism 3 weeks after surgery.

2.4.3 In a comparative study 69% (33 out of 48) of patients had evacuation difficulties or pain requiring hospitalisation following graciloplasty. Disturbed evacuation was reported in 16% (32 out of 200) of patients in a prospective case series. For more details, refer to the overview.

2.4.4 The Specialist Advisors noted that the main reported adverse events were related to the pulse generator, particularly the risk of infection (both in the short and the long term).

3 Further information

3.1 NICE has produced interventional procedures guidance on sacral nerve stimulation for faecal incontinence.

Sources of evidence

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

Information for the public

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

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Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.