

Stimulated graciloplasty for faecal incontinence

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% (144/200) 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 Sources of evidence.
- 2.3.3 The Specialist Advisors suggested that this procedure has been largely superseded by sacral nerve stimulation.

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This guidance is written in the following context

This guidance represents the view of the Institute which was arrived at after careful consideration of the available evidence. Healthcare professionals are expected to take it fully into account when exercising their clinical judgement. This guidance does not, however, override the individual responsibility of healthcare professionals to make appropriate decisions in the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

Interventional procedures guidance is for healthcare professionals and people using the NHS in England, Wales and Scotland.

This guidance is endorsed by NHS QIS for implementation by NHSScotland.

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% (17/123) of patients.
- 2.4.2 Electrical or technical problems with the pulse generator leading to hospitalisation occurred in 48% (23/48) 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% (33/48) of patients had evacuation difficulties or pain requiring hospitalisation following graciloplasty. Disturbed evacuation was reported in 16% (32/200) of patients in a prospective case series. For more details, refer to the Sources of evidence.
- 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 The Institute has produced guidance on sacral nerve stimulation for faecal incontinence (www.nice.org.uk/IPG099).

Andrew Dillon
Chief Executive
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Information for the public

NICE has produced information describing its guidance on this procedure for patients, carers and those with a wider interest in healthcare. It explains the nature of the procedure and the decision made, and has been written with patient consent in mind. This information is available from www.nice.org.uk/IPG159publicinfo

Sources of evidence

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

'Interventional procedure overview of stimulated graciloplasty', June 2005.

Available from: www.nice.org.uk/ip019overview

Ordering information

Copies of this guidance can be obtained from the NHS Response Line by telephoning 0870 1555 455 and quoting reference number N0994. *Information for the public* can be obtained by quoting reference number N0995.

The distribution list for this guidance is available at www.nice.org.uk/IPG159distributionlist

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