NICE guidance

Interspinous distraction procedures for lumbar spinal stenosis causing neurogenic claudication

Interventional procedures guidance
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www.nice.org.uk/guidance/ipg365

This guidance replaces IPG165.

1 Guidance

This document replaces previous guidance on interspinous distraction procedures for lumbar spinal stenosis causing neurogenic claudication (interventional procedure guidance 165).

1.1 Current evidence on interspinous distraction procedures for lumbar spinal stenosis causing neurogenic claudication shows that these procedures are efficacious for carefully selected patients in the short and medium term, although failure may occur and further surgery may be needed. There are no major safety concerns. Therefore these procedures

may be used provided that normal arrangements are in place for clinical governance, consent and audit.

1.2 Patient selection should be carried out by specialist spinal surgeons who are able to offer patients a range of surgical treatment options.

2 The procedure

2.1 Indications and current treatments

2.1.1 Lumbar spinal stenosis is most often caused by degenerative disease of the lumbar vertebrae and their associated joints. Neurogenic claudication can then result from compression of spinal nerves by inward buckling of the ligamentum flavum. The principal symptom is leg pain when standing or walking, which is relieved by sitting or by flexing the spine.

2.1.2 Conservative treatments include non-steroidal anti-inflammatory drugs and rest. For patients with refractory symptoms, surgery may be performed to decompress the spinal nerve roots (laminectomy or ligamentectomy). Spinal fusion may also be performed.

2.2 Outline of the procedure

2.2.1 Interspinous distraction procedures involve placing an implant between the spinous processes of the affected vertebrae (usually L4/5) with the aim of limiting extension and so preventing or reducing leg pain when standing or walking.

2.2.2 These procedures are normally carried out with the patient under local anaesthesia and conscious sedation, but general anaesthesia may be used. The patient is positioned with their spine flexed: operative level(s) are usually confirmed by fluoroscopy. The vertebral spinous processes and their interspinous ligament are exposed through a midline incision. An implant of appropriate size is positioned through the supraspinous ligament, which helps to hold the implant in place between the flexed spinous processes of adjacent vertebrae. More than one spacer may be

inserted for multiple-level disease.

2.2.3 Various devices are available for these procedures.

> 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 Efficacy

2.3.1 A randomised controlled trial (RCT) of 191 patients treated by interspinous distraction (n = 100) or conservatively (n = 91) reported improvements in symptom severity (measured using the Zurich Claudication Questionnaire) of 45% and 7% respectively at 2-year follow-up ($p < 0.001$).

2.3.2 A non-randomised controlled study of 61 patients treated by interspinous distraction (n = 30, mean follow-up 40.4 months) or posterior lateral interbody fusion (n = 31, mean follow-up 38.4 months) reported a significant improvement in visual analogue scores (0–10 scale) for low back pain (from 4.7 to 2.4 and from 5.5 to 3.3 respectively) and for leg pain (from 6.9 to 2.4 and from 6.5 to 2.6 respectively; $p < 0.001$ from baseline to follow-up for all scores but no significant difference between groups).

2.3.3 The non-randomised study of 61 patients reported a significant decrease in the Oswestry Disability Index (0–100 scale, 100 being greatest disability) for patients treated by interspinous distraction and those treated by interbody fusion, from 23% to 11% and from 21% to 11% respectively; $p < 0.001$; no significant difference between groups (mean follow-up 40.4 months and 38.4 months respectively).

2.3.4 The RCT of 191 patients reported that subsequent laminectomy because of unresolved stenosis was required in 6% (6/100) of patients who had interspinous distraction and 26% (24/91) of patients in the control group (time of conversion not stated).

2.3.5 The RCT of 191 patients showed significantly better Short Form-36 scores for physical function, health-related physical limitations, bodily pain, energy levels, social functioning and mental health for patients treated by interspinous distraction compared with those who had conservative treatment at 2-year follow-up.

2.3.6 The Specialist Advisers listed key efficacy outcomes as relief of claudication pain in the leg and functional improvement.

2.4 Safety

2.4.1 The RCT of 191 patients reported 1 case of implant malpositioning (not otherwise described) and 1 of implant migration after a fall, requiring removal without sequelae. An RCT of 75 patients reported that 1 of the 42 patients treated by interspinous distraction had implant malpositioning, detected on 6-month radiographic examination (not otherwise described). A case series of 69 patients (92 implantations) reported 4 cases of device dislocation (3 patients) at 4-day, 6-day and 2-week follow-up. The same study reported device malpositioning in 1 patient at 6-week follow-up. All 4 patients had revision surgery.

2.4.2 The non-randomised study of 61 patients reported device fracture in 1 of the 30 patients treated by interspinous distraction (time of occurrence and further details not stated).

2.4.3 A case series of 69 patients reported spinous process fracture in 1 patient intraoperatively and 3 patients postoperatively (at 1 week, 4 months and 6 months). The postoperative fractures were treated by revision surgery. One was caused by trauma.

2.4.4 An unpublished abstract of 69 patients treated by interspinous distraction reported that 27% (18/66) of patients required removal of the spacer and revision surgery (timing of events not stated). A case series of 175 patients reported that 5% (8/175) of patients required removal of the device because the effect of the procedure was unsatisfactory.

2.4.5 The Specialist Advisers considered anecdotal adverse events to include infection and movement of the implant after placement.

3 Further information

Information for patients

NICE has produced information on this procedure for patients and carers ('Understanding NICE guidance'). It explains the nature of the procedure and the guidance issued by NICE, and has been written with patient consent in mind.

4 About this guidance

NICE interventional procedure guidance makes recommendations on the safety and efficacy of the procedure. It does not cover whether or not the NHS should fund a procedure. Funding decisions are taken by local NHS bodies after considering the clinical effectiveness of the procedure and whether it represents value for money for the NHS. It is for healthcare professionals and people using the NHS in England, Wales, Scotland and Northern Ireland, and is endorsed by Healthcare Improvement Scotland for implementation by NHSScotland.

This guidance was developed using the NICE interventional procedure guidance process.

It updates and replaces NICE interventional procedure guidance 165.

We have produced a summary of this guidance for patients and carers. Information about the evidence it is based on is also available.

Changes since publication

3 January 2012: minor maintenance.

Your responsibility

This guidance represents the views of NICE and 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.

Implementation of this guidance is the responsibility of local commissioners and/or providers. Commissioners and providers are reminded that it is their responsibility to implement the guidance, in their local context, in light of their duties to avoid unlawful discrimination and to have regard to promoting equality of opportunity. Nothing in this guidance should be interpreted in a way which would be inconsistent with compliance with those duties.

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Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.

Accreditation