

Interspinous distraction procedures for lumbar spinal stenosis causing neurogenic claudication

1 Guidance

1.1 Current evidence suggests there are no major safety concerns associated with interspinous distraction procedures for lumbar spinal stenosis causing neurogenic claudication, but evidence of efficacy is limited and is confined to the short and medium term. These procedures should only be used in the context of special arrangements for consent, audit and research.

1.2 Clinicians wishing to undertake interspinous distraction procedures for lumbar spinal stenosis causing neurogenic claudication should take the following actions.

- Inform the clinical governance leads in their Trusts.
- Ensure that patients understand that the procedure is not curative, and that further surgery may be needed. Patients should be provided with clear written information. In addition, use of the Institute's *Information for the public* is recommended (available from www.nice.org.uk/IPG165publicinfo).
- Audit and review clinical outcomes of all patients having interspinous distraction procedures for spinal stenosis causing neurogenic claudication in the lumbar spine.

1.3 Publication of long-term efficacy data will be useful. The Institute may review the procedures upon publication of further evidence.

2 The procedure

2.1 Indications

2.1.1 Lumbar spinal stenosis is a narrowing of the spinal canal in the lower part of the back. Unlike disc rupture, lumbar spinal canal stenosis does not

normally cause pain in the legs at rest.

Characteristically, discomfort in the form of nerve pain, tingling, numbness or sometimes weakness occurs when standing or walking any distance (extension), and is relieved by sitting or leaning forwards (flexion). Because this is a degenerative condition, spontaneous resolution is uncommon, and persistence of symptoms or progressive reduction of standing time and walking distance is common.

2.1.2 Non-surgical therapy commonly includes conservative treatment with medication. Non-steroidal anti-inflammatory medication may help to relieve symptoms.

2.1.3 Surgical treatment most commonly involves laminectomy in which the nerve roots are decompressed by opening the spinal canal. Sometimes, when bony instability or severe back pain are particular problems, laminectomy may be supplemented by stabilisation.

2.2 Outline of the procedure

2.2.1 Implants are placed between adjacent spinous processes to act as physical blocks to extension (and thus lumbar canal narrowing) on standing or walking, relieving pressure on the nerves. These procedures may have a role between medical symptom control and the more invasive procedure of laminectomy.

2.2.2 The patient is positioned with the spine flexed, and the operative level (or levels) is confirmed by X-rays. A midline incision is made over the appropriate spinal level and deepened to display the spinous processes and their intact joining (interspinous) ligament. The blocking device is sized and positioned in the space between the flexed spinous processes.

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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.

2.3 Efficacy

- 2.3.1 A multicentre randomised controlled trial (RCT) compared interspinous implants with non-surgical care in patients with or without back pain, but with leg pain relieved by flexion and spinal stenosis confirmed by computed tomography or magnetic resonance imaging. At 2 year follow-up there was a 45% improvement in symptom severity from baseline in patients who had the implants, compared with a 7% improvement in the control group ($p < 0.001$). Physical function scores improved by 44% in patients treated with an implant whereas the scores for those treated medically deteriorated by 0.4% ($p < 0.001$).
- 2.3.2 In the same study, patients who received implants had significantly improved quality of life outcomes at 6 weeks, 6 months and 1 year postoperatively. At 1 year, 59% of patients who received implants had clinically successful outcomes as assessed by improvements in symptom severity, physical function score and post-treatment satisfaction score ($n = 88$). Of those who had non-surgical treatment, 12% had a clinically successful outcome ($n = 68$) (these figures were derived from charts presented in the publication).
- 2.3.3 In a case series of 10 patients with mild to moderate symptoms undergoing interspinous implant insertion, symptom severity improved in 40% (4/10) of patients, and 10% (1/10) showed significant improvement in physical function at a median follow-up of 11 months. For more details, refer to the Sources of evidence.
- 2.3.4 The Specialist Advisors noted that, given the fluctuating symptoms associated with this condition, the assessment of outcomes in clinical studies may be unreliable. Some Advisors questioned the long-term efficacy of the procedure.

2.4 Safety

- 2.4.1 In an RCT, 6% (5/88) of patients treated needed re-operation during the first year after implantation. At 2 years' follow-up, there had been one case in 100 patients who had

undergone interspinous implantation of each of the following: respiratory distress, ischaemic episode, pulmonary oedema, wound dehiscence, wound swelling, haematoma and incision pain. There was one incident each of the following: implant misplacement, implant migration, spinous fracture and increased pain at the implant level. For more details, refer to the Sources of evidence.

- 2.4.2 The Specialist Advisors noted concerns about additional pain in adjacent levels, device migration and potential infection.

2.5 Other comments

- 2.5.1 It was noted that all the evidence was based on a single type of device.

3 Further information

- 3.1 The Institute is developing guidance on non-rigid stabilisation procedures for the treatment of low back pain (www.nice.org.uk/ip_306).

Andrew Dillon
Chief Executive
March 2006

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/IPG165publicinfo

Sources of evidence

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

'Interventional procedure overview of interspinous distraction procedures for spinal stenosis causing neurogenic claudication in the lumbar spine', July 2005.

Available from: www.nice.org.uk/ip191overview

Ordering information

Copies of this guidance can be obtained from the NHS Response Line by telephoning 0870 1555 455 and quoting reference number N1002. *Information for the public* can be obtained by quoting reference number N1003.

The distribution list for this guidance is available at www.nice.org.uk/IPG165distributionlist

Published by the National Institute for Health and Clinical Excellence, March 2006; ISBN 1-84629-173-9

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