NICE guidance

Lateral (including extreme, extra and direct lateral) interbody fusion in the lumbar spine

Interventional procedure guidance
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nice.org.uk/guidance/ipg321

1 Guidance

1.1 Current evidence on the safety and efficacy of lateral (including extreme, extra and direct lateral) interbody fusion in the lumbar spine is inadequate in quantity and quality. Therefore this procedure should only be used with special arrangements for clinical governance, consent and audit or research.

1.2 Clinicians wishing to undertake lateral interbody fusion in the lumbar spine 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 safety and efficacy and provide them with clear written information. In addition, the use of NICE's information for patients ('Understanding NICE guidance') is recommended.
- Audit and review clinical outcomes of all patients having lateral interbody fusion in the lumbar spine (see section 3.1).

1.3 This procedure should only be carried out by surgeons with specific training in the technique, who should perform their initial procedures with an experienced mentor.

1.4 NICE encourages further research into lateral interbody fusion in the lumbar spine. Research outcomes should include fusion rates, pain and functional scores, quality of life measures and the frequency of both early and late complications. NICE may review the procedure on publication of further evidence.

2 The procedure

2.1 Indications and current treatments

2.1.1 Chronic low back pain may result from degenerative change of the intervertebral discs and/or spinal facet joints.

2.1.2 Conservative treatments include education and advice, posture and exercise training, manual therapies, analgesics, non-steroidal antiinflammatory medication and acupuncture. For cases of severe life-limiting chronic low back pain that is refractory to conservative interventions, surgery may be appropriate, such as bony fusion of vertebrae, insertion of a prosthetic intervertebral disc or non-rigid stabilisation techniques.

2.1.3 Although degenerative spinal disease is likely to be the most common indication for procedures of this type, the lateral approach may also be used for the treatment of scoliosis, discovertebral infection and trauma.

2.2 Outline of the procedure

2.2.1 The aim of lateral interbody fusion in the lumbar spine is to achieve a spinal fusion procedure via a lateral approach in order to avoid the major muscle groups in the back (posterior approach) or the organs and blood vessels in the abdomen (anterior approach).

2.2.2 The procedure is carried out with the patient under general anaesthesia. A probe is inserted under fluoroscopic guidance through the psoas muscle, to lie alongside the affected disc, via a lateral approach. A posterior incision is also sometimes made, to allow digital access for manipulation of the probe. Nerve monitoring is recommended by many specialists and is described in several of the studies. Dilators are inserted around the probe and a retractor is positioned to give the surgeon direct access to the spine. A discectomy is carried out and a

cage implant inserted to hold the vertebrae in position, maintaining correct disc height and spine alignment. A bone graft (usually from the hip) is inserted between the two vertebral bodies, sometimes with additional support from screws, plates or rods. The procedure may be done at more than one level during the same operation.

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 case series of 21 patients reported that mean pain score (assessed on a 10-point visual analogue scale; higher score indicates greater pain) improved from 8.3 points (range 6–10 points) at baseline to 3.2 points (range 0–5 points) at a minimum of 6 months follow-up (significance not stated).

2.3.2 A case series of 13 patients with low back pain refractory to 6 months of conservative treatment, treated by lateral interbody spinal fusion, reported that most patients were mobile on the first postoperative day (absolute figures not stated).

2.3.3 The Specialist Advisers listed key efficacy outcomes as fusion rates, pain scores, functional ability, walking distance and duration of hospital stay.

2.4 Safety

2.4.1 In a non-randomised controlled trial of 98 patients (58 treated by lateral interbody spinal fusion), there was no significant difference in the total complication rate between patients treated by lateral interbody spinal fusion (22.4%) and those treated by an open posterolateral approach (22.5%) (mean follow-up 15 months, absolute figures and significance not stated).

2.4.2 In the non-randomised controlled trial of 98 patients, ipsilateral nerve root damage (L4) was reported in 3% (2/58) of patients treated by the lateral approach; residual motor disturbances were reported in both patients at 1-year follow-up. Persistent paraesthesia in the groin and thigh area was reported in 5% (1/20) of patients at 11-month follow-up in the case series of 21 patients.

2.4.3 Further degeneration at an adjacent level was reported in 5% (1/20) of patients in the case series of 21 patients (the patient was scheduled for a further fusion procedure) (follow-up not stated).

2.4.4 In the non-randomised controlled trial of 98 patients, mean estimated blood loss was reported as 136 ml in patients treated with a lateral approach and 489 ml in patients treated by an open posterolateral approach ($p < 0.0001$).

2.4.5 The Specialist Advisers stated that anecdotal adverse events included lower limb dysaesthesia from nerve damage. Theoretical adverse events included cerebrospinal fluid leak, infection and failure of the spine to fuse. A consultee reported one case of bowel perforation (no further details provided).

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 developed audit support (which is for use at local discretion).

3.2 For related NICE guidance see our website.

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.

We have produced a summary of this guidance for patients and carers. Tools to help you put the guidance into practice and information about the evidence it is based on are also available.

Changes since publication

5 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