

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional procedure consultation document

Lateral interbody fusion in the lumbar spine for low back pain

As a person gets older, the discs that support the vertebrae (back bones) can deteriorate. Sometimes this causes such severe pain and disability that surgery is needed.

Lateral interbody spinal fusion involves removing all, or part, of the damaged disc and inserting a supporting structure. It aims to join the 2 back bones together to prevent the painful joint moving. The procedure is done through a cut in the person's side.

The National Institute for Health and Care Excellence (NICE) is examining lateral interbody fusion in the lumbar spine for low back pain and will publish guidance on its safety and efficacy to the NHS. NICE's interventional procedures advisory committee has considered the available evidence and the views of specialist advisers, who are consultants with knowledge of the procedure. The advisory committee has made draft recommendations about lateral interbody fusion in the lumbar spine for low back pain.

This document summarises the procedure and sets out the draft recommendations made by the advisory committee. It has been prepared for public consultation. The advisory committee particularly welcomes:

- comments on the draft recommendations
- the identification of factual inaccuracies
- additional relevant evidence, with bibliographic references where possible.

Note that this document is not NICE's formal guidance on this procedure. The recommendations are provisional and may change after consultation.

The process that NICE will follow after the consultation period ends is as follows.

- The advisory committee will meet again to consider the original evidence and its draft recommendations in the light of the comments received during consultation.
- The advisory committee will then prepare draft guidance which will be the basis for NICE's guidance on the use of the procedure in the NHS.

For further details, see the [Interventional Procedures Programme process guide](#), which is available from the NICE website.

Through its guidance NICE is committed to promoting race and disability equality, equality between men and women, and to eliminating all forms of discrimination. One of the ways we do this is by trying to involve as wide a range of people and interest groups as possible in the development of our interventional procedures guidance. In particular, we aim to encourage people and organisations from groups who might not normally comment on our guidance to do so.

In order to help us promote equality through our guidance, we should be grateful if you would consider the following question:

Are there any issues that require special attention in light of NICE's duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations between people with a characteristic protected by the equalities legislation and others?

Please note that NICE reserves the right to summarise and edit comments received during consultations or not to publish them at all where in the reasonable opinion of NICE, the comments are voluminous, publication would be unlawful or publication would otherwise be inappropriate.

Closing date for comments: 18 November 2016

Target date for publication of guidance: February 2017

1 Draft recommendations

- 1.1 Current evidence on the safety of lateral (including extreme, extra and direct lateral) interbody fusion in the lumbar spine for low back pain shows there are serious but well-recognised complications. Evidence on efficacy is adequate in quality and quantity. Therefore, this procedure may be used provided that standard arrangements are in place for clinical governance, consent and audit.
- 1.2 This procedure should only be done by surgeons with specific training in the technique, who should carry out their initial procedures with an experienced mentor.
- 1.3 Clinicians should enter details about all patients having lateral interbody fusion in the lumbar spine for low back pain onto the [British Spine Registry](#).

2 Indications and current treatments

- 2.1 Chronic low back pain may result from degenerative changes in the intervertebral discs or spinal facet joints. Conservative treatments include analgesics, non-steroidal anti-inflammatory medication and manual therapy.
- 2.2 For people with severe, life-limiting, chronic low back pain that does not respond to conservative treatments, surgery may be appropriate. This may include bony fusion of vertebrae (to immobilise segments of the vertebral column thought to be responsible for back pain, using either a posterior or anterior approach) or inserting a prosthetic intervertebral disc (which preserves lumbar mobility to reduce the risk of degenerative changes in adjacent intervertebral disc spaces). Other surgical alternatives include non-rigid stabilisation techniques.

3 The procedure

- 3.1 The aim of lateral interbody fusion in the lumbar spine is to achieve spinal fusion by a lateral approach, to avoid the major muscle groups in the back (posterior approach) or the organs and blood vessels in the abdomen (anterior approach).
- 3.2 The procedure is done with the patient under general anaesthesia. A probe is inserted laterally through the psoas muscle, under fluoroscopic guidance, to lie alongside the affected disc. A posterior incision is also sometimes made, to allow 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. A bone graft (usually from the hip) is inserted between the 2 vertebrae, sometimes with additional support from screws, plates or rods. The

procedure may be done at more than 1 level during the same operation. A recent variation of this procedure is oblique lateral interbody fusion, which involves retroperitoneal access anterior to the psoas. It may take a few months before patients are able to return to their normal activities after the procedure.

3.3 There are a number of different devices used for this procedure.

4 Efficacy

This section describes efficacy 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 [interventional procedure overview](#).

4.1 In a systematic review of 237 articles on lateral lumbar interbody fusion, the weighted average for the rate of fusion in all patients was 94% (n=907 patients, 22 study arms).

4.2 In the systematic review of 237 articles, the weighted average for improvement in pain, measured on a visual analogue scale, was 60% (n=2,097 patients, 41 study arms). In a non-randomised comparative study of 202 patients treated by extreme lateral interbody fusion (XLIF) or open anterior lumbar interbody fusion (ALIF), low back pain scores, measured on a scale of 0–10, improved from 7.5 at baseline in both groups (n=95) to 2.4 and 2.6 respectively at 12-month follow-up (n=61; p<0.001 compared with baseline; p=not significant for between group comparison). Mean leg pain, measured on a scale of 0–10, improved from 5.8 in the XLIF group and 5.4 in the ALIF group at baseline (n=95) to 1.6 and 2.0 respectively at 12-month follow-up (n=61), in the same study (p<0.001 compared with baseline; p=not significant for between group comparison).

- 4.3 In the systematic review of 237 articles, the weighted average for improvement in disability, measured on the Oswestry Disability Index (ODI), was 48% (n=1,234 patients, 29 study arms). In the non-randomised comparative study of 202 patients treated by XLIF or ALIF, the ODI improved from 59% at baseline in both groups (n=95) to 23% and 24% respectively at 12-month follow-up (n=61; $p < 0.001$ compared with baseline; $p =$ not significant for between group comparison). In a case series of 160 patients, the ODI improved from 44% at baseline to 23.5% at the last follow-up (mean follow-up 18.5 months; p value not reported).
- 4.4 In the systematic review of 237 articles, the weighted average for patient satisfaction was 89% (n=491 patients, 9 study arms); 85% of patients said that they would have the procedure again if their outcome had been known in advance. In a randomised controlled trial (RCT) and non-randomised comparative study of 55 patients treated by XLIF or transforaminal interbody fusion (TLIF), 91% and 80% of patients respectively were satisfied with their outcome at 24-month follow-up ($p = 0.393$) and 100% and 90% of patients respectively would be willing to have the same procedure had their outcome been known in advance ($p = 0.210$). In a non-randomised comparative study of 208 patients treated by XLIF or ALIF, 95% (198/208) of patients were satisfied with the procedure and reported improvement; 10 patients did not improve or worsened (radiological and clinical results were similar in both groups).
- 4.5 In the RCT and non-randomised comparative study of 55 patients treated by XLIF or TLIF, mean quality-of-life scores for the SF-36 physical component improved from 37.7 and 39.5 respectively at baseline to 61.4 and 64.9 at 24-month follow-up ($p < 0.05$ compared with baseline); mean quality-of-life scores for the SF-36 mental component improved from 51 and 52.2 respectively at baseline to 67.2 and 69.2 at 24-month follow-up ($p < 0.05$ compared with baseline). In the case series of 160 patients, the SF-36 physical

component score improved from 30.9 at baseline to 43.2 at the last follow-up (mean follow-up 18.5 months; p value not reported).

- 4.6 The specialist advisers listed the key efficacy outcomes as patient reported outcome measures, including reduced pain, and radiological outcomes, including fusion of the lumbar spine and restoration of the disc height.

5 Safety

This section describes 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 [interventional procedure overview](#).

- 5.1 In a systematic review of 237 articles, the weighted averages for thigh side effects, hip flexion weakness and motor neural deficits were 26% (n=2,772), 21% (n=1,360 patients, 22 study arms) and 3% (n=1,568, 14 study arms) respectively. In a systematic review of 34 studies, neurological adverse events (transient motor weakness, hypoaesthesia, transient or persistent thigh symptoms, injury to lumbosacral plexus, injury to femoral nerve) were reported. These occurred in 9% (209/2,342) of patients treated by extreme lateral interbody fusion (ELIF) compared with 5% (27/544) of patients treated by anterior lumbar interbody fusion (ALIF) when Food and Drug Administration (FDA) reports were excluded (p=0.0015) and 9% (130/1,379) of patients treated by ALIF when FDA reports were included (p=0.605). In the ELIF group, 43% (90/209) of the neurological adverse events resolved within 3 months of the procedure, 16% (33/209) lasted between 3 months and 2 years or throughout the last follow-up; there was no information on the remaining 41% (86/209) of complications.
- 5.2 Sensory deficit was reported in 27% (585/2,160) of patients treated by lateral lumbar interbody fusion (LLIF) compared with 20%

(380/1,885) of patients treated by minimally-invasive transforaminal lumbar interbody fusion (MI-LIF, $p < 0.0001$) in a systematic review of 96 studies (9,714 patients). Temporary neurological deficit was reported in 9% (278/2,957) of patients treated by LLIF and 2% (30/1,349) of patients treated by MI-LIF ($p < 0.0001$). Permanent neurological deficit was reported in 3% (62/2,525) and 1% (14/1,382) of patients respectively ($p = 0.002$), in the same study.

- 5.3 Postoperative hip flexion weakness was reported in 31% (9/29) of patients treated by extreme lateral interbody fusion (XLIF) and in no patients treated by transforaminal interbody fusion (TLIF) in a randomised controlled trial (RCT) and non-randomised comparative study of 55 patients ($p < 0.001$); all resolved within 6 months. Postoperative distal motor weakness was reported in 3.5% (1/29) and 0% (0/26) of patients respectively ($p = 1.00$) and sensory deficit was reported in 10% (3/29) and 8% (2/26) of patients respectively ($p = 1.00$), in the same study; all resolved within 12 months.
- 5.4 A partial and transient injury to the L5 nerve root during implant insertion at level L4–5 was reported in 1 patient treated by XLIF in a non-randomised comparative study of 208 patients; intraoperative nerve monitoring was not yet being used.
- 5.5 The weighted average for reoperations was 6% ($n = 2,080$ patients, 24 study arms) in the systematic review of 237 articles. A secondary surgical procedure (revisions, supplemental fixations, reoperations) was reported in 2% (40/2,342) of patients treated by ELIF compared with 5% (25/544) of patients treated by ALIF when FDA reports were excluded ($p = 0.0002$) and 9% (121/1,379) of patients treated by ALIF when FDA reports were included ($p < 0.0001$) in the systematic review of 34 studies.
- 5.6 Laceration of the abdominal aorta was reported in 1 patient in a case series of 900 patients; this was repaired through an

exploratory laparotomy. Segmental vessel lacerations were reported in less than 1% (4/900) of patients in the same study; all were ligated under direct visualisation without further extension of the incision and no clinical sequelae. Major vascular injury was reported in a case report; a detachable retractor blade caused extensive damage to the iliac veins, the patient had massive blood loss and died a few weeks later from multiple organ failure secondary to septic shock. Lumbar artery pseudoaneurysm, which was successfully treated by embolisation, was reported in 1 patient in a case report.

- 5.7 Wound-related complications (psoas haematoma, infection) were reported in less than 1% (15/2,342) of patients treated by ELIF, in less than 1% (7/544) of patients treated by ALIF when FDA reports were excluded ($p=0.1438$) and in 2% (26/1,379) of patients treated by ALIF when FDA reports were included ($p=0.00067$) in the systematic review of 34 studies.
- 5.8 Gastrointestinal complications (ileus, gastric volvulus, bowel injury) were reported in 1% (25/2,342) of patients treated by ELIF, in less than 1% (3/544) of patients treated by ALIF when FDA reports were excluded ($p=0.2771$) and in 8% (116/1,379) of patients treated by ALIF when FDA reports were included ($p<0.0001$) in the systematic review of 34 studies. Ileus was reported in 7% (2/29) of patients treated by XLIF and in no patients treated by TLIF in the RCT and non-randomised comparative study of 55 patients. Bowel perforation after extreme lateral interbody fusion was described in a case report: the patient had a temporary colostomy for 3 months before making a full recovery.
- 5.9 Renal complications (urinary tract infection or urinary retention) were reported in 1% (12/2,342) of patients treated by ELIF, in no patients treated by ALIF when FDA reports were excluded ($p=0.09$)

and in 1% (10/1,379) of patients treated by ALIF when FDA reports were included ($p=0.4214$) in the systematic review of 34 studies.

- 5.10 Vertebral body fracture or remote compression fracture was reported in 1% (18/2,342) of patients treated by ELIF, in no patients treated by ALIF when FDA reports were excluded ($p=0.0274$) and in less than 1% (3/1,379) of patients treated by ALIF when FDA reports were included ($p=0.0262$) in the systematic review of 34 studies.
- 5.11 Hardware failure (cage subsidence or breakage, intraoperative pedicle fracture, implant bone interface failure) was reported in 1% (31/2,342) of patients treated by ELIF, in 3% (17/544) of patients treated by ALIF when FDA reports were excluded ($p=0.0065$) and in 3% (47/1,379) of patients treated by ALIF when FDA reports were included ($p<0.0001$) in the systematic review of 34 studies. Graft migration and graft subsidence at 24-month follow-up were reported in 0% (0/29) and 3% (1/29) of patients treated by XLIF and in 5% (1/21) and 10% (2/21) of patients treated by TLIF respectively in the RCT and non-randomised comparative study of 55 patients.
- 5.12 Complex regional pain syndrome was reported in 1 patient in a case report. The symptoms were treated conservatively and resolved within 8 weeks. Lumbar post-sympathectomy syndrome was reported in 5% (4/88) of patients treated by XLIF in the non-randomised comparative study of 208 patients (including at level L4/5 in 3 patients and at level L5/6 in 1 patient).
- 5.13 In addition to safety outcomes reported in the literature, specialist advisers are asked about anecdotal adverse events (events which they have heard about) and about theoretical adverse events (events which they think might possibly occur, even if they have never done so). For this procedure, specialist advisers noted that

spinal cord injury was an anecdotal adverse event. They considered that kidney injury was a theoretical adverse event.

6 Committee comments

6.1 The committee noted that there are a number of different approaches used for this procedure, which are associated with different risk profiles. These include the possibility of damage to major blood vessels.

6.2 The committee noted that nerve monitoring is increasingly being used with the intention of reducing neurological injury.

7 Further information

7.1 For related NICE guidance, see the [NICE website](#).

7.2 This guidance is a review of NICE's interventional procedure guidance on [lateral \(including extreme, extra and direct lateral\) interbody fusion in the lumbar spine](#).

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