NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional procedure consultation document

Percutaneous interlaminar endoscopic lumbar discectomy for sciatica

The tough covering of a spinal disc (annulus) can sometimes break, allowing the soft centre to bulge through. This is called herniation, also known as 'slipped disc'. It may cause pain in the back, pain in the leg (sciatica), and numbness and weakness in the leg. In this procedure, the bulging part of the disc is removed through the interlaminar space (a natural opening between the spinal bones, or vertebrae) using an endoscope (a thin tube with a camera on the end) through a small cut in the back. The aim is to remove the pressure on the nerve to relieve symptoms.

The National Institute for Health and Care Excellence (NICE) is examining percutaneous interlaminar endoscopic lumbar discectomy for sciatica 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 provisional recommendations about percutaneous interlaminar endoscopic lumbar discectomy for sciatica.

This document summarises the procedure and sets out the provisional recommendations made by the Advisory Committee. It has been prepared for public consultation. The Advisory Committee particularly welcomes:

- comments on the provisional 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 provisional 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- The Advisory Committee will then prepare draft guidance which will be the basis for NICE's guidance on the use of the procedure in the NHS.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 <u>Interventional Procedures Programme process</u> 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: 26 January 2016

Target date for publication of guidance: April 2016

1 Provisional recommendations

1.1 Current evidence on the safety and efficacy of percutaneous interlaminar endoscopic lumbar discectomy for sciatica is adequate to support the use of this procedure provided that normal arrangements are in place for clinical governance, consent and audit.

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- 1.2 Percutaneous interlaminar endoscopic lumbar discectomy for sciatica is a procedure that needs particular experience. Surgeons should acquire the necessary expertise through specific training and mentoring. It should only be done by surgeons who do the procedure regularly.
- 1.3 Details about all patients having percutaneous interlaminar endoscopic lumbar discectomy for sciatica should be entered onto the British Spine Registry.

2 Indications and current treatments

- 2.1 Lumbar disc herniation occurs when the nucleus pulposus of an intervertebral disc protrudes through a tear in the surrounding annulus fibrosus. Symptoms include pain in the back or leg, and numbness or weakness in the leg. Serious neurological sequelae including painful foot drop, bladder dysfunction, and cauda equina syndrome, may sometimes occur.
- 2.2 Conservative treatments include analgesics, non-steroidal anti-inflammatory medication, manual therapy and acupuncture. Epidural corticosteroid injections can also be used to reduce nerve pain in the short term. Lumbar discectomy is considered if there is severe nerve compression or persistent symptoms that are unresponsive to conservative treatment. Surgical techniques include open discectomy, microdiscectomy or minimally invasive alternatives using percutaneous endoscopic approaches. The choice of operative technique may be influenced by several factors, including the presenting symptoms and signs, and the location and size of the disc prolapse.

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3 The procedure

- 3.1 Percutaneous endoscopic lumbar discectomy aims to preserve bony structures and cause less damage to paravertebral muscles and ligaments than open discectomy, allowing a shorter hospital stay and faster recovery. An interlaminar approach provides an alternative to the transforaminal approach for treating central or centro-lateral disc extrusions, especially at the L5-S1 level where the transforaminal approach is difficult.
- 3.2 Percutaneous interlaminar endoscopic lumbar discectomy is usually done with the patient in the prone position using local or general anaesthesia. Under fluoroscopic guidance, a guidewire is inserted into the appropriate interlaminar space. Dilators are used to expose the ligamentum flavum and the ruptured disc is accessed through this ligament. An endoscope and rongeurs are used to remove the herniated disc fragments. A laser may also be used to aid removal of the disc. The patient can usually mobilise within a few hours of the 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 <u>interventional procedure</u> <u>overview [add URL]</u>.

4.1 A retrospective study of 60 patients comparing interlaminar endoscopic lumbar discectomy (n=30) against transforaminal endoscopic lumbar discectomy (n=30) reported a significant improvement in mean visual analogue scale (VAS) scores (ranging from 0 to 10 from best to worst), in both groups, for leg and back

IPCD: Percutaneous interlaminar endoscopic lumbar discectomy for sciatica Page 4 of 11 pain from before the procedure to a mean follow-up of 2.2 years. In the interlaminar group, back pain scores changed from 5.5 to 2.4 and leg pain scores changed from 7.6 to 1.7 (level of significance not reported). In the transforaminal group, back pain scores changed from 5.2 to 2.4 and leg pain scores changed from 7.4 to 1.6 (level of significance not reported). There was no significant difference between the interlaminar and transforaminal groups.

- 4.2 A case series of 400 patients treated by interlaminar endoscopic lumbar discectomy reported an improvement in mean VAS scores for back and leg pain from 7.9 before the procedure to 1.5 at 3 months after the procedure; it also reported that the VAS scores improved significantly in 90% of patients when compared against scores before the procedure.
- 4.3 The retrospective comparative study of 60 patients reported significant improvements in mean Oswestry Disability Index (ODI) scores (ranging from 0 to 100, from no disability to maximum disability) from before the procedure to a mean follow-up of 2.2 years; from 51% to 15% in the interlaminar group, and from 52% to 12% in the transforaminal group (no significant difference between groups). A case series of 372 patients treated by percutaneous interlaminar endoscopic discectomy reported improvement in mean ODI score from 79% before the procedure to 21% at 2 years after the procedure (level of significance not stated). The same study reported mean North American Spine Society neurology scores (ranging from 1 to 6, from best to worst) of 3 before the procedure and 2 at 2 years (level of significance not stated).

- A prospective comparative study of 200 patients with disc herniation treated by full-endoscopic discectomy (interlaminar approach, n=59; transforaminal approach, n=41) or microsurgical discectomy (n=100) reported recurrence rates at 2-year follow-up of 6% (3/53) in the interlaminar group, 8% (3/38) in the transforaminal group and 6% (5/87) in the microsurgical group (no significant difference between groups). All patients with recurrence were treated a second time by the same technique; in the transforaminal group, 2 patients had another recurrence.
- 4.5 A prospective comparative study of 100 patients with recurrent lumbar disc herniation treated by full-endoscopic discectomy (interlaminar approach, n=29; transforaminal approach, n=21) or microsurgical discectomy (n=50) reported re-recurrence rates at 2-year follow-up of 4% (1/24) in the interlaminar group, 10% (2/21) in the transforaminal group and 5% (2/42) in the microsurgical group (no significant difference between groups). All patients with re-recurrence were treated a second time by the same technique.
- 4.6 The retrospective comparative study of 60 patients reported recurrence in 7% (2/30) of patients treated by the interlaminar approach and in 3% (1/30) of patients treated by the transforaminal approach within a minimum of 2 years after the procedure (no significant difference between groups). The case series of 400 patients reported recurrence in 2 patients; they were treated again by surgery at 3 and 6 months after the first procedure.
- 4.7 The case series of 400 patients reported conversion to open surgery in 1 patient who had root protrusion after sustaining a dural tear during the procedure; the authors stated that this happened during the period when the surgeons were gaining experience in

IPCD: Percutaneous interlaminar endoscopic lumbar discectomy for sciatica Page 6 of 11 how to do the procedure. A case series of 163 patients (175 procedures) with lumbar disc herniations treated by interlaminar (n=104) or transforaminal (n=71) endoscopic lumbar discectomy reported no conversion to open surgery for either approach.

- 4.8 The retrospective comparative study of 60 patients reported complete removal of the disc fragment in 93% (28/30) of patients treated by the interlaminar approach and in 97% (29/30) of patients treated by the transforaminal approach (no significant difference between groups).
- 4.9 The retrospective study of 60 patients reported that the mean time to return to work was 4.4 weeks for patients treated by the interlaminar approach and 4.9 weeks for patients treated by the transforaminal approach (no significant difference between groups). The case series of 372 patients reported that 98% (247/251) of patients who were not unemployed or retired returned to their occupation or sport activities; 2% (4/251) were not able to return to their occupation because of persistent paresis. Sick leave following hospitalisation ranged from 5 to 33 days (mean of 16 days).
- 4.10 The case series of 400 patients reported good-to-excellent results according to MacNab criteria in 91% (364/400) of patients; poor results were reported in 2% (8/400) of patients (no further details reported). The case series of 372 patients reported that 91% (301/331) of patients reported subjective satisfaction up to 2 years after the procedure and would have the procedure again; 9% (29/331) had a poor result (defined as no reduction in leg pain or having to be retreated by open surgery).
- 4.11 Specialists advisers listed key efficacy outcomes as resolution of leg pain, improvement in disability score, recurrence rate IPCD: Percutaneous interlaminar endoscopic lumbar discectomy for sciatica Page 7 of 11

(reoccurrence of leg pain following an initial resolution of the leg pain), improvement in a generic quality of life measure (such as EQ-5D), return to activity, reduced operating time and hospital length of stay.

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 <u>interventional procedure</u> <u>overview</u> [add URL].

- 5.1 Single-facet injury during the procedure was reported in the first 3 patients in a case series of 400 patients with lumbar disc herniation treated by percutaneous interlaminar endoscopic lumbar discectomy (no further details provided).
- Dural injury was reported in 1 patient who had recurrent lumbar disc herniation after conventional discectomy, treated by interlaminar endoscopic lumbar discectomy in a prospective comparative study of 100 patients treated by full-endoscopic discectomy (interlaminar approach, n=29; transforaminal approach, n=21) or microsurgical discectomy (n=50); it was repaired with fibrin glue. Dural injury was reported in none of the patients in the transforaminal group and in 6% (3/50) of patients in the microsurgical group (no further details provided). Minor dural tear was reported in 2% (7/400) of patients in the case series of 400 patients (no further details provided). Dural tear was reported in 6% (6/104) of procedures using the interlaminar approach in a case series of 163 patients (175 procedures) with lumbar disc herniations treated by interlaminar or transforaminal endoscopic

lumbar discectomy. In 5 procedures, patients were treated IPCD: Percutaneous interlaminar endoscopic lumbar discectomy for sciatica Page 8 of 11

conservatively with 2 additional days of bed rest before mobilisation and discharge. In 1 procedure, an attempt was made to repair the dura by open surgery immediately after the procedure; this was complicated by an open cerebrospinal fluid fistula. The patient needed a second procedure to repair the dura and 5 days of bed rest and lumbar drainage.

- 5.3 Nerve root injury and persistent paraesthesia 2 years after the procedure were reported in 1 patient in the case series of 400 patients (no further details provided).
- Motor deficit was reported in 3% (5/163) of patients (interlaminar approach, n=104 procedures; transforaminal approach, n=71 procedures) in the case series of 163 patients. In 2 of these 5 patients, 2-level discectomy was performed using an interlaminar approach for 1 level and a transforaminal approach for 1 level. In 4 patients these motor deficits were transient and they recovered completely, including the 2 patients who were treated by 2-level discectomies. In 1 patient there was a permanent motor deficit resulting in footdrop (no further details provided).
- 5.5 Transient dysaesthesia was reported in 3% (2/59) of patients with symptomatic lumbar disc herniation treated by interlaminar endoscopic lumbar discectomy in a prospective comparative study of 200 patients treated by full-endoscopic discectomy (interlaminar approach, n=59; transforaminal approach, n=41) or microsurgical discectomy (n=100). In the transforaminal group and in the microsurgical group, transient dysaesthesia was reported in 2% (1/41) and 5% (5/100) respectively (no further details provided). Transient dysaesthesia was reported in 6% (2/29) of patients who had recurrent lumbar disc herniation after conventional discectomy,

IPCD: Percutaneous interlaminar endoscopic lumbar discectomy for sciatica Page 9 of 11 treated by interlaminar endoscopic lumbar discectomy, in the prospective comparative study of 100 patients treated by full-endoscopic discectomy or microsurgical discectomy; it was reported in none of the patients in the transforaminal group and in 10% (5/50) in the microsurgical group (no further details provided). Dysaesthesia was reported in 7% (2/30) of patients with symptomatic lumbar disc herniation treated by interlaminar endoscopic lumbar discectomy and in none of the 30 patients treated by the transforaminal approach in a retrospective comparative study of 60 patients (no further details provided). Transient dysaesthesia was reported in 3 patients treated by interlaminar endoscopic lumbar discectomy in a case series of 372 patients with symptomatic lumbar disc herniation (no further details provided).

- 5.6 Discitis was reported in 1% (2/400) of patients after the procedure in the case series of 400 patients; both patients were treated conservatively (no further details provided).
- 5.7 Pseudocysts were reported in 3% (9/298) of procedures in the group of patients treated by interlaminar endoscopic lumbar discectomy and in 1% (6/1205) of procedures in the group of patients treated by the transforaminal approach, in a case series of 1406 patients with protruded or extruded disc materials compressing the lumbar root (p=0.001 for the comparison between groups). The interval between discectomy and pseudocyst detection on MRI was a mean of 53.7 (11–118) days. Five pseudocysts were treated surgically and 10 were treated conservatively.

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, the specialist advisers did not report any anecdotal adverse events. They considered that the following were theoretical adverse events: bleeding, haematoma and scar tissue.

6 Further information

6.1 For related NICE guidance, see the <u>NICE website</u>.

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December, 2015