NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional procedure consultation document

Percutaneous transforaminal 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 foramen (a natural opening for the nerve in 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 transforaminal 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 transforaminal 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.

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- 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- The Advisory Committee will then prepare draft guidance which will be the basis for NICE's guidance on the use of the procedure in the NHS.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 transforaminal 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 transforaminal 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 transforaminal endoscopic lumbar discectomy for sciatica should be entered onto the <u>British Spine Registry</u>.

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, or 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 prolapsed disc.

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3 The procedure

3.1 Percutaneous endoscopic lumbar discectomy procedures aim to preserve bony structures and cause less damage to paravertebral muscles and ligaments than open lumbar discectomy, allowing a shorter hospital stay and faster recovery. Percutaneous transforaminal endoscopic lumbar discectomy is done with the patient in the prone or lateral position using local or general anaesthesia. Under fluoroscopic guidance, a needle is inserted through the skin and the appropriate intervertebral foramen into the disc. A small guidewire is placed through the needle and the needle is exchanged for a series of dilators to create a working channel through the muscles, to the ruptured disc. An endoscope and rongeurs are used for piecemeal removal of 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</u> [add URL].

4.1 A systematic review of transforaminal endoscopic surgery for symptomatic lumbar disc herniation reported that the median percentage improvement (measured using a visual analogue scale for pain) in non-controlled studies for leg pain was 88% (7 studies, n=1558) and for back pain was 74% (5 studies, n=1401). There was no significant difference in improvement between intradiscal and intracanal techniques (leg pain 83% versus 88%; back pain 75% versus 70%). The controlled studies found no significant

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difference in leg pain and back pain reduction between transforaminal endoscopic surgery and open lumbar microdiscectomy (leg pain 89% versus 87%; back pain 42% versus -8.3% [1 study, n=200]). A retrospective comparative study of 60 patients comparing transforaminal endoscopic lumbar discectomy (n=30) against interlaminar endoscopic lumbar discectomy (n=30) reported a decrease in mean visual analogue scale scores (ranging from 0 to 10, 0 indicating best and 10 worst scores) for leg and back pain at mean 2.2-year follow-up. For transforaminal discectomy, back pain reduced from 5.2 to 2.4 and leg pain reduced from 7.4 to 1.6, whereas for interlaminar discectomy, back pain reduced from 5.5 to 2.4 and leg pain reduced from 7.6 to 1.7 (no significant differences between the groups).

- 4.2 The systematic review reported that the median improvement in functional status (assessed using the Oswestry disability index questionnaire for low back pain-specific functional disability) for non-controlled studies was 83% (3 studies, n=624). The retrospective comparative study of 60 patients reported improvements in mean Oswestry disability index scores (ranging from 0 to 100, 0 indicating no disability and 100 maximum disability) from 52% to 12% in the transforaminal group and from 51% to 15% in the interlaminar group at mean 2.2-year follow-up (no significant difference between the groups).
- 4.3 The systematic review reported that the median percentage of patients in non-controlled studies who returned to work was 90% (5 studies, n=757). The retrospective comparative study of 60 patients reported that the mean time to return to work was

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- 4.9 weeks for the transforaminal group and 4.4 weeks for the interlaminar group (no significant difference between the groups).
- 4.4 The systematic review reported that the median score in global perceived effect for non-controlled studies was satisfactory in 85% and poor in 6% of patients (15 studies, n=2544). There was no significant difference in median scores between intradiscal and intracanal techniques (85% satisfactory [3 studies, n=279] versus 86% satisfactory [12 studies, n=2292]) or between far lateral herniation (86% satisfactory; 2 studies, n=52); central herniation (91% satisfactory; 1 study, n=71) and all types of herniation (83% satisfactory; 9 studies, n=1810). The controlled studies found no significant difference in median global perceived effect score between transforaminal endoscopic surgery and open lumbar microdiscectomy (84% versus 78% satisfactory; 5 studies, n=1102). The sum of 'excellent' and 'good' scores was reported as 'satisfactory'.
- 4.5 The systematic review reported that the median percentage of patients in non-controlled studies who were satisfied with treatment was 78% (3 studies, n=181).
- 4.6 A case series of 55 patients who had transforaminal endoscopic lumbar discectomy reported that there was significant improvement in many aspects of quality-of-life scores. These were SF-36 scores for physical function, role physical, bodily pain, vitality, social function, role emotional and mental health (all p<0.05 except for general health scores at 6-month and 2-year follow-up, which were 66.4 at baseline, 67.1 at 6 months and 68.5 at 2 years). These improvements correlated with improvements in the North American Spine Society score.

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- 4.7 The comparative study of 60 patients reported incomplete removal of the disc fragments in 3% (1/30) of patients in the transforaminal group and in 7% (2/30) in the interlaminar group. Open surgery was needed in all these patients.
- 4.8 The systematic review reported that the median rate of recurrence in non-controlled studies (13 studies, n=2612) was 1.7% (range 0-12%). Recurrence was defined as reappearance of a symptomatic lumbar disc herniation at the same level within a month or after a pain-free interval of more than a month. There was no significant difference in median recurrence rates between intradiscal (0.7%; 3 studies, n=217) and intracanal techniques (3.2%; 10 studies, n=2395) or between far lateral herniation (2.6%; 2 studies, n=76) and all types of herniation (3.6%; 9 studies, n=2201). The controlled studies found no significant difference in median recurrence rates between transforaminal endoscopic surgery (5.7%) and open lumbar microdiscectomy (2.9%; 4 studies, n=1182). The most common cause of reoperation was persistent symptoms because of missed lateral bony stenosis and remnant fragments.
- 4.9 The systematic review reported that the median reoperation rate in non-controlled studies was 7% (range 0–27%; 28 studies, n=4135). There was no significant difference in median reoperation rates between intradiscal (7.5%; 14 studies, n=1267) and intracanal techniques (74.6%; 15 studies, n=3098); or between far lateral herniation (8.0%; 5 studies, n=214); central herniation (4.6%; 1 study, n=71) and all types of herniation (5.6%; 15 studies, n=2934). The controlled studies found no significant difference in median reoperation rates between transforaminal endoscopic

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- surgery (6.8%) and open lumbar microdiscectomy (4.7%; 15 studies, n=2934).
- 4.10 The specialist advisers listed key efficacy outcomes as reduced back or leg pain, frequency of dysaesthetic pain, relief of sciatic pain, reduced blood loss, reduced incidence of spinal instability, shorter operating time, length of hospital stay, early return to work and patient satisfaction.

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 A systematic review of transforaminal endoscopic surgery for symptomatic lumbar disc herniation reported that the mean percentage of complications in non-controlled studies was 2.8% (28 studies, n=6336). There was no significant difference in median complication rates between intradiscal (5.3%; 12 studies, n=1206) and intracanal techniques (2.1%; 17 studies, n=5362); or between far lateral herniation (5.1%; 5 studies, n=214); central herniation (2.7%; 1 study, n=71) and all types of herniation (4.9%; 15 studies, n=2934). The controlled studies found no significant difference in median complication rates between transforaminal endoscopic surgery (1.5%) and open lumbar microdiscectomy (1.0%; 6 studies, n=1302). Most reported complications were transient dysaesthesia or hypaesthesia.
- 5.2 Post-discectomy pseudocysts (defined as cystic lesions of T2W high and T1W low at discectomy site) were detected on

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postoperative MRI at 2 months in 1% (15/1503) of procedures in a case series of 1406 patients. The mean interval from surgery to detection was 53.7 days. The interlaminar approach significantly correlated with pseudocyst formation (3%; 9/298) compared with the transforaminal approach (1%; 6/1205) (p=0.001). Ten pseudocysts were treated conservatively and 5 were treated surgically. There was no difference in treatment outcome between conservative and surgical management at a mean follow-up of 25 months.

- 5.3 Symptomatic retroperitoneal haematoma was reported in 1.0% (4/412) of patients in a retrospective case series of 412 patients treated by transforaminal endoscopic surgery. Two patients with massive diffuse type retroperitoneal haematomas compressing their intra-abdominal structures needed open haematoma evacuation. The other 2 patients had small localised retroperitoneal haematomas that were treated conservatively. Symptoms improved without any neurological sequelae in 3 patients at a median follow-up of 21 months. One patient had transient hip flexion weakness and mild dysaesthesia on the lateral thigh which improved in 6 months.
- 5.4 Symptomatic dural tears were reported in 1.1% (9/816) of patients in a case series of 816 patients treated by transforaminal endoscopic lumbar discectomy. In 3 patients, dural tears were detected intraoperatively (patients complained of headache with back pain as the cerebrospinal fluid leak occurred). Six patients had delayed diagnosis (clinical findings or by MRI) after an average symptom-free interval of 2.5 days and their condition was unresponsive to conservative management. Two of the delayed diagnosis patients had nerve root herniation causing profound leg

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pain and neurological deficits; 4 had nerve root irritation causing leg pain. All patients had secondary open repair surgery (with a standard microscope-assisted interlaminar approach) without any neurological sequelae. One had subsequent fusion surgery at the same level. At a mean follow-up of 30.8 months, the mean visual analogue scale score of leg and back pain and mean Oswestry disability index improved. The final outcome was poor in 2 patients with unrecognised dural tear with nerve root herniation.

- 5.5 Spondylodiscitis (with or without soft tissue infection) was reported in less than 1% (12/9821) of patients in a retrospective case series of 9821 patients treated by transforaminal endoscopic lumbar discectomy. The average time to diagnosis by MRI was 14.6 days. Four patients were treated with antibiotic therapy only; 2 with surgical debridement; the remaining 6 were unresponsive to initial therapies or surgical drainage, and had anterior lumbar interbody fusion with posterior instrumentation surgery. At a mean follow-up of 31.7 months, the mean Oswestry disability index and visual analogue scale score for leg and back pain improved. Based on the modified MacNab criteria, 58% (7/12) of patients had an excellent or good outcome.
- A sequestered disc post-procedure was reported in 1 patient who had transforaminal endoscopic surgery in a case series of 55 patients. The patient was treated by open discectomy.
- 5.7 'Transitory foot drop' was reported in 1 patient and 'transitory sensibility disturbance' of the foot was reported in 3 patients in a retrospective case series of 255 patients who had transforaminal endoscopic lumbar discectomy (no further details were reported).

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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 listed the following anecdotal adverse event: iliac crest pain during the procedure. They considered that the following were theoretical adverse events: visceral injury, cauda equina syndrome and allergic reactions to local anaesthetic.

6 Further information

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

Bruce Campbell

Chairman, Interventional Procedures Advisory Committee

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