NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional procedure consultation document

Epiduroscopic lumbar discectomy through the sacral hiatus for sciatica

The tough covering of a spinal disc can sometimes tear, allowing the soft centre to bulge through. This is called herniation, also known as 'slipped disc'. It may cause pain in the back and leg (sciatica), and numbness and weakness in the leg. In this procedure the bulging part of the disc is removed using an endoscope (a thin, flexible tube with a camera on the end) and other instruments inserted through a small cut between the buttocks and up the spinal canal to the mid back. The aim is to relieve pain by removing parts of the disc that press against the spinal nerve.

The National Institute for Health and Care Excellence (NICE) is examining epiduroscopic lumbar discectomy through the sacral hiatus 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 draft recommendations about epiduroscopic lumbar discectomy through the sacral hiatus for sciatica.

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- The advisory committee will then prepare draft guidance which will be the basis for NICE's guidance on the use of the procedure in the NHS.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: 20 May 2016

Target date for publication of guidance: August 2016

1 Draft recommendations

1.1 Current evidence on the safety and efficacy of epiduroscopic lumbar discectomy through the sacral hiatus for sciatica is limited in quantity and quality. Therefore, this procedure should only be used in the context of research.

1.2 This procedure should only be done by surgeons with expertise in endoscopic spinal surgery and specific training in epiduroscopy through the sacral hiatus.

1.3 NICE encourages further research into epiduroscopic lumbar discectomy through the sacral hiatus for sciatica and may update the guidance on publication of further evidence. Research studies should include details of patient selection, complications and long-term results.

2 Indications and current treatments

2.1 Lumbar disc herniation occurs when the nucleus pulposus of an intervertebral disc protrudes through a weakening or 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 and manual therapy. 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 or minimally invasive alternatives using percutaneous endoscopic approaches. The choice of operative technique may be guided by several factors, including the presenting symptoms and signs and the location and size of the disc involved.

3 The procedure

3.1 Epiduroscopic lumbar discectomy through the sacral hiatus for sciatica is usually done with the patient under sedation and local anaesthesia. Under fluoroscopic guidance, a needle is inserted through the sacral hiatus. Over a guidewire a dilator is used to create a working channel through which a flexible endoscope can be steered into the anterior epidural space. The endoscope can reach nerve roots as high as the mid-lumbar spine bilaterally. When the appropriate disc level is reached, a laser optic fibre is introduced through the working channel of the endoscope to ablate disc tissue. The aim is to relieve pain by removing parts of the disc that press against the spinal nerve.

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 A non-randomised comparative study of 98 patients compared treatment by endoscopic adhesiolysis, foraminoplasty and discectomy (n=78) with endoscopic adhesiolysis and foraminoplasty without discectomy (n=20). Visual analogue scale (VAS) scores for radicular pain (scores range from 0–10, with lower scores indicating less pain) improved from 7.6 to 3.6 with discectomy and from 8.5 to 6.1 without discectomy at final follow-up (p values not reported; mean follow-up periods were 21 and 23 months respectively). A non-randomised comparative study of 57 patients compared treatment by endoscopic adhesiolysis, foraminoplasty and discectomy (n=32) with endoscopic

adhesiolysis and foraminoplasty without discectomy (n=25). The improvement in VAS score for low back pain (scores range from 0–10, with lower scores indicating less pain) was statistically significant with discectomy (from 8.1 to 4.4; p=0.01) but not without discectomy (from 8.5 to 6.7; p=0.12) at 24-month follow-up. The difference between the groups was statistically significant (p<0.01). In the same study, improvements in VAS scores for leg pain were not statistically significant (from 6.2 to 4.7; p=0.07 and from 6.7 to 5.2; p=0.15, respectively) at 24-month follow-up. The difference between the groups was statistically significant (p=0.05). In a case series of 154 patients, there was a statistically significant decrease in VAS score for pain from 7.5 at baseline to 3.4 at follow-up (p<0.005). In a case series of 77 patients, 81.8% (63/77) of patients had improved symptoms at 1-month follow-up.

4.2 In the non-randomised comparative study of 98 patients, Roland Morris disability questionnaire scores (scores range from 0–24, with lower scores indicating less disability) changed from 18.8 to 10.6 with discectomy and from 11.3 to 11.4 without discectomy at final follow-up (p values not reported; mean follow up periods were 21 and 23 months respectively). In the non-randomised comparative study of 57 patients, the change in Roland Morris disability questionnaire scores (scores range from 0–24, with lower scores indicating less disability) was statistically significant with discectomy (from 13.2 to 8.5; p=0.03) but not without discectomy (from 12.6 to 10.4; p=0.09) at 24-month follow-up. The difference between the groups was statistically significant (p<0.01). In the case series of 154 patients, the change in Roland Morris disability questionnaire score was statistically significant, from 18.1 at baseline to 10.3 at follow-up (p<0.005).

4.3 The specialist advisers listed key efficacy outcomes as relief of back or leg pain, improvement in patient-reported outcome measures (such as Oswestry Disability Index), reduced length of hospital stay and reduced time off work.

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 Transient mild motor paralysis was reported in 1 patient from the discectomy group (n=32) in a non-randomised comparative study of 57 patients treated by endoscopic adhesiolysis, foraminoplasty and discectomy or endoscopic adhesiolysis and foraminoplasty without discectomy. Symptoms resolved 1 month after the procedure. Foot drop was reported in 3% (2/78) of patients in the discectomy group in the non-randomised comparative study of 98 patients treated by endoscopic adhesiolysis, foraminoplasty and discectomy (n=78) or endoscopic adhesiolysis and foraminoplasty without discectomy (n=20). Symptoms resolved within 6 months.

5.2 Transient hyperaesthesia was reported in 1 patient in the non-randomised comparative study of 98 patients. The authors did not differentiate between the groups. Paraesthesia was reported in 19% (15/78) of patients treated by endoscopic adhesiolysis, foraminoplasty and discectomy in the same study; symptoms resolved within 6 months.

5.3 Transient headaches were reported in 8% (8/98) and 5% (3/57) of patients in the 2 non-randomised comparative studies of patients

treated by endoscopic adhesiolysis, foraminoplasty and discectomy or endoscopic adhesiolysis and foraminoplasty without discectomy. The authors did not differentiate between the groups.

5.4 Focal infection was reported in 2% (2/98) and 4% (2/57) of patients in the 2 non-randomised comparative studies of patients treated by endoscopic adhesiolysis, foraminoplasty and discectomy or endoscopic adhesiolysis and foraminoplasty without discectomy. The authors did not differentiate between the groups.

5.5 Meningitis was reported in 1 patient each in the 2 non-randomised comparative studies of patients treated by endoscopic adhesiolysis, foraminoplasty and discectomy or endoscopic adhesiolysis and foraminoplasty without discectomy. The authors did not differentiate between the treatment groups. Symptoms resolved after bed rest and symptomatic treatment.

5.6 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 reported no anecdotal adverse events. They considered that the following were theoretical adverse events: cauda equina syndrome, spinal fluid leak, and epidural haematoma.

6 Committee comments

6.1 The committee noted that in the published evidence, many of the included patients had adhesiolysis in addition to discectomy.

6.2 The committee noted that the procedure may have a role in treating pathology at multiple levels of the spine at the same time.

7 Further information

7.1 For related NICE guidance, see the NICE website.

7.2 This guidance is a review of 'Percutaneous endoscopic laser lumbar discectomy' NICE interventional procedure guidance 300 (2009).

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