



Epiduroscopic lumbar discectomy through the sacral hiatus for sciatica

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www.nice.org.uk/guidance/ipg570

Your responsibility

This guidance represents the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, healthcare professionals are expected to take this guidance fully into account, and specifically any special arrangements relating to the introduction of new interventional procedures. The guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

All problems (adverse events) related to a medicine or medical device used for treatment or in a procedure should be reported to the Medicines and Healthcare products Regulatory Agency using the Yellow Card Scheme.

Commissioners and/or providers have a responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful

discrimination, advance equality of opportunity, and foster good relations. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with those duties. Providers should ensure that governance structures are in place to review, authorise and monitor the introduction of new devices and procedures.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should <u>assess and reduce the environmental</u> impact of implementing NICE recommendations wherever possible.

This guidance replaces IPG300.

1 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. Find out what only in research means on the NICE interventional procedures guidance page.
- 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 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 <u>interventional procedure overview</u>.

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 (ranging from 0 to 10, with lower scores indicating less pain) for radicular 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 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 250 patients, the mean VAS score for leg pain decreased from 7.1 at baseline to 2.6 (p<0.01) and the mean VAS score for back pain decreased from 5.9 at baseline to 2.7 (p<0.01) at 3-month follow-up.

- In the non-randomised comparative study of 98 patients, Roland Morris disability questionnaire scores (ranging from 0 to 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 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). In the case series of 250 patients, the Oswestry Disability Index score (ranging from 0 to 100) improved from 50 at baseline to 12 at 3-month follow-up (p<0.01).
- 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 <u>interventional procedure overview</u>.

- 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 a 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.
- Transient hyperaesthesia was reported in 1 patient in the non-randomised comparative study of 98 patients. The authors did not state which group this patient was in. 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.
- 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 state which groups these patients were in. Headache was reported in 1% (3/250) of patients in a case series of 250 patients.
- 5.4 Epidural pneumocephalus was reported in 1 patient in the case series of 250 patients (no further information given).
- 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 state which groups these patients were in.
- 5.6 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 of the studies did not state which treatment groups these patients were in. Symptoms resolved after bed rest and symptomatic treatment.

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

- The committee noted that in the published evidence many of the included patients had adhesiolysis in addition to discectomy.
- The committee noted that the procedure may have a role in treating pathology at multiple levels of the spine at the same time.

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Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.

Accreditation

