



Automated percutaneous mechanical lumbar discectomy

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www.nice.org.uk/guidance/ipg141

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 <u>Yellow Card Scheme</u>.

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 impact of implementing NICE recommendations</u> wherever possible.

1 Guidance

- 1.1 Current evidence suggests that there are no major safety concerns associated with automated percutaneous mechanical lumbar discectomy. There is limited evidence of efficacy based on uncontrolled case series of heterogeneous groups of patients, but evidence from small randomised controlled trials shows conflicting results. In view of the uncertainties about the efficacy of the procedure, it should not be used without special arrangements for consent and for audit or research.
- 1.2 Clinicians wishing to undertake automated percutaneous mechanical lumbar discectomy should take the following actions.
 - Inform the clinical governance leads in their Trusts.
 - Ensure that patients understand the uncertainty about the procedure's efficacy and provide them with clear written information. In addition, use of NICE's information for the public is recommended.
 - <u>Audit</u> and review clinical outcomes of all patients having automated mechanical percutaneous lumbar discectomy. NICE may review the procedure upon publication of further evidence.

2 The procedure

2.1 Indications

2.1.1 Lumbar radicular pain, also known as sciatica, refers to pain that begins in the

lower back and radiates down the leg. It is commonly caused by a herniated (or prolapsed) lumbar intervertebral disc. The herniation is a result of a protrusion of the nucleus pulposus through a tear in the surrounding annulus fibrosus. The annulus fibrosus may rupture completely, resulting in an extruded disc, or may remain intact but stretched, resulting in a contained disc prolapse. This may then compress one or more nerve roots, causing pain, numbness or weakness in the leg.

- 2.1.2 Conservative treatments include the use of analgesics, non-steroidal anti-inflammatory medicines, physical therapy and hot or cold compresses. Epidural injections of corticosteroid may also be used. Surgery to remove disc material may be considered if there is nerve compression or persistent symptoms that are unresponsive to conservative treatment.
- 2.1.3 Alternative surgical treatments include open discectomy and minimally invasive microdiscectomy.

2.2 Outline of the procedure

2.2.1 Automated percutaneous mechanical lumbar discectomy is performed using local anaesthetic with or without conscious sedation. Under fluoroscopic guidance, a cannula is placed centrally within the disc using a posterolateral approach on the symptomatic side. A probe connected to an automated cutting and aspiration device is then introduced through the cannula. The disc is aspirated until no more nuclear material can be obtained.

2.3 Efficacy

In a randomised controlled trial (RCT) of 71 patients, 29% (9 out of 31) had a successful outcome after automated percutaneous lumbar discectomy, compared with 80% (32 out of 40) of patients after microdiscectomy (p<0.001). In a second RCT, 41% (7 out of 17) of patients had an 'excellent' or 'good' outcome after automated percutaneous lumbar discectomy, compared with 40% (4 out of 10) of patients after conventional discectomy. A third RCT compared automated

percutaneous lumbar discectomy with chemonucleolysis and found that significantly more patients had a successful result after chemonucleolysis (61% [44 out of 72] versus 43% [30 out of 69], p<0.05).

- Two large case series reported that 68% (707 out of 1,047) and 82% (1,216 out of 1,474) of patients had an 'excellent' or 'good' result at 6 months and 1 year, respectively. A third case series reported an overall success rate of 45% (52 out of 115) after a mean follow-up of 55 months. In two further case series reports, 94% (47 out of 50) and 52% (95 out of 182) of patients were satisfied after mean follow-ups of 6 months and 2.5 years, respectively. For more details, refer to the overview.
- 2.3.3 The Specialist Advisors stated that there was some uncertainty about the efficacy of the procedure.

2.4 Safety

- Few complications were reported. Three studies reported discitis in between 0.2% (2 out of 1,146) and 1% (2 out of 182) of patients. Two studies reported haematoma in 0.1% (1 out of 1,146) and 1.4% (1 out of 69) of patients. Other complications included back muscle spasms, minor bleeding, minor radicular injury and vasovagal syncope. For more details, refer to the <u>overview</u>.
- 2.4.2 The Specialist Advisors stated that vascular and nerve damage, discitis and infection were potential adverse effects of the procedure.

3 Further information

3.1 NICE has also published <u>interventional procedures guidance on percutaneous</u> intradiscal laser ablation in the lumbar spine.

Sources of evidence

The evidence considered by the Interventional Procedures Advisory Committee is

described in the overview.

Information for the public

NICE has produced <u>information for the public on this procedure</u>. It explains the nature of the procedure and the decision made, and has been written with patient consent in mind.

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Endorsing organisation

This guidance has been endorsed by <u>Healthcare Improvement Scotland</u>.