NICE guidance

Percutaneous intradiscal laser ablation in the lumbar spine

Interventional procedures guidance
Published: 22 September 2010

www.nice.org.uk/guidance/ipg357

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 assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

This guidance replaces IPG27.

1 Guidance

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

1.2 Patients selected for the procedure should be limited to those with severe pain refractory to conservative treatment, in whom imaging studies show bulging of an intact disc, and who do not have neurological deficit requiring surgical decompression.

2 The procedure

2.1 Indications and current treatments

2.1.1 Symptomatic herniation (prolapse) of a lumbar intravertebral disc is a common cause of chronic low back pain and sciatica. Disc herniation is a result of the protrusion of the nucleus pulposus through a tear in the annulus fibrosus. The annulus fibrosus may rupture completely, resulting in an extruded disc, or it may remain intact but stretched, resulting in a contained (bulging) disc prolapse. Protruding discs may compress one or more nerve roots, resulting in pain and numbness in the leg.

2.1.2 Conservative treatment options include rest, analgesic or anti-inflammatory medication, epidural injection and physical therapies. Current surgical treatment options include microdiscectomy, percutaneous intradiscal electrothermal therapy, percutaneous intradiscal radiofrequency thermocoagulation and percutaneous disc decompression using coblation. Surgical decompression is considered when there is nerve compression causing weakness or persistent symptoms that are unresponsive to conservative treatment.

2.2 Outline of the procedure

2.2.1 The aim of percutaneous intradiscal laser ablation (also commonly referred to in the literature as percutaneous laser disc decompression) is to vaporise part of a prolapsed disc. It can only be carried out if the prolapse is contained (that is, the disc is bulging but the nucleus pulposus has not extruded through the annulus fibrosus).

2.2.2 The procedure is usually carried out under local anaesthesia and sedation, with the patient in the prone position. Under fluoroscopic guidance, a spinal needle is inserted through the annulus fibrosus into the nucleus pulposus, and an optical fibre is introduced through the needle. Laser energy is then delivered through the optical fibre to vaporise part of the nucleus pulposus.

2.2.3 Several types of laser are available for this procedure.

2.3 Efficacy

Sections 2.3 and 2.4 describe efficacy and 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 overview.

2.3.1 A non-randomised comparative study of 1,000 patients reported 'excellent' or 'good' MacNab criteria scores (pain relieved by 50% or more and improved motor function) in 84% (419 out of 500) of patients treated by the procedure and 86% (428 out of 500) of patients treated by microdiscectomy at mean 2-year follow-

up (significance not stated).

2.3.2 A non-randomised comparative study of 106 patients reported 'excellent' MacNab criteria scores (pain relieved by 75% or more and no limitation of motor function) in 48% (29 out of 60) of patients treated by the procedure compared with 48% (22 out of 46) of patients treated by automated percutaneous lumbar discectomy (APLD; follow-up not stated; difference reported as not significant).

2.3.3 A case series of 518 patients reported an overall success rate (using MacNab criteria; not otherwise described) of 75% (absolute figures and follow-up not stated).

2.3.4 The non-randomised comparative study of 1,000 patients reported reoperation for herniation or persistent leg or back pain in 3% (16 out of 500) of patients treated by the procedure and 7% (35 out of 500) of patients treated by microdiscectomy at a mean 2-year follow-up.

2.3.5 A case series of 576 patients reported that 61% of patients were satisfied with the overall outcome of the procedure (absolute figures and follow-up not stated).

2.3.6 The Specialist Advisers listed key efficacy outcomes as recurrence rate, reoperation rate, leg and back pain score, Oswestry Disability Index score and successful decompression.

2.4 Safety

2.4.1 Aseptic discitis (post-procedural inflammatory pain) requiring up to 3 days of hospitalisation with steroid treatment was reported in 2 patients treated by the procedure in a non-randomised comparative study of 81 patients. Case series of 576 and 518 patients reported aseptic discitis in 4 and 2 patients respectively. In the second series both patients developed aseptic discitis up to 4 days after the procedure (not otherwise described) and were treated successfully with bed rest and analgesics.

2.4.2 Septic discitis 3 days after the procedure (confirmed by magnetic resonance imaging [MRI] and needle puncture culture, which was positive for

Staphylococcus aureus) was reported in 2 patients in the case series of 518 patients. Both patients were treated with parenteral vancomycin for 6 weeks. Intervertebral disc infection (not otherwise described) was reported in no patients treated by the procedure and 1 patient treated by APLD in the non-randomised comparative study of 106 patients (timing of event not stated).

2.4.3 Subchondral vertebral osteonecrosis (confirmed by MRI) was reported in 2% (4 out of 182) of patients in the case series of 182 patients: 1 patient underwent surgical treatment for persistent severe back pain, which resolved 1 year after the initial procedure, and 3 patients had conservative management of their pain which had diminished at 2-year follow-up after the initial procedure.

2.4.4 A case series of 10 patients who required salvage operations after the procedure to address herniated discs reported that all patients showed evidence of heat-induced cell necrosis and carbonisation, with herniating masses completely compressing and adhering to nerve roots.

2.4.5 The Specialist Advisers stated that bowel perforation was described in the literature. They considered theoretical adverse events to include dural tear, heat damage due to incorrect placement of the probe, recurrent protrusion of disc, nerve damage, infection, vertebral body collapse, loss of disc height and perineural scarring.

3 Further information

Sources of evidence

The evidence considered by the Interventional Procedures Advisory Committee is described in the overview.

Information for patients

NICE has produced information for the public on this procedure. It explains the nature of the procedure and the guidance issued by NICE, and has been written with patient consent in mind.

ISBN: 978-1-4731-6351-5

Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.