Percutaneous coblation of the intervertebral disc for low back pain and sciatica

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www.nice.org.uk/guidance/ipg543

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

This guidance replaces IPG173.

1 Recommendations

- 1.1 Current evidence on percutaneous coblation of the intervertebral disc for low back pain and sciatica raises no major safety concerns. The evidence on efficacy is adequate and includes large numbers of patients with appropriate follow-up periods. Therefore, this procedure may be used provided that normal arrangements are in place for clinical governance, consent and audit.
- 1.2 As part of the consent process, patients should be informed that there is a range of treatment options available to them and also that further procedures may be needed.

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, pain in the leg (sciatica), and numbness or weakness in the leg. Serious neurological sequelae 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

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considered if there is evidence of severe nerve compression or persistent symptoms that are unresponsive to conservative treatment. Surgical techniques include open discectomy or less invasive alternatives using percutaneous approaches.

2.3 Percutaneous coblation of the intervertebral disc for low back pain may be used for patients with pain caused by contained herniated discs that have not responded to conservative treatment, when open surgery is not suitable.

3 The procedure

3.1 Percutaneous coblation of the intervertebral disc is usually done with the patient under sedation and using local anaesthesia. Using fluoroscopic guidance, an introducer needle is inserted into the affected disc. A small radiofrequency probe is then inserted through the needle and into the disc. The probe delivers radiofrequency energy to create a plasma field at its tip, which causes ablation of the tissue at temperatures of 40 to 70°C. When it has reached a pre-determined depth the probe is removed, coagulating the tissue as it is withdrawn. Around 6 channels are created during the procedure, the number of channels depending on the amount of tissue reduction needed. The aim is to remove tissue from the disc nucleus without damaging surrounding structures.

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>.

A systematic review of 27 studies, including 3211 patients treated by percutaneous coblation, reported that pain measured on a visual analogue scale (VAS; range 0 to 10, where 0 is no pain and 10 is the greatest imaginable pain) decreased after percutaneous coblation from 7.27 (n=971) at baseline to 2.84 at 3 months (n=612, p<0.001), 3.03 at 12 months (n=702, p<0.001), and 3.69 at 24 months (n=92, p<0.001). In patients treated by conservative therapy (in the

comparator groups of the studies), the mean pain score decreased from 6.98 at baseline (n=98) to 3.85 at 12-month follow-up (n=57, p=0.073 compared with percutaneous coblation). A non-randomised comparative study of 160 patients treated by percutaneous coblation or open discectomy reported that the VAS score for pain reduced from 7.9 and 8.0 at baseline to 2.2 and 1.8, respectively, at 12 month follow-up (p values not reported).

- 4.2 A randomised controlled trial (RCT) of 118 patients treated by percutaneous coblation alone, percutaneous coblation combined with nerve root steroid injection, or epidural steroid injection reported that the mean numeric rating scale for pain decreased from 7.15, 7.29 and 7.31 at baseline to 2.27, 2.14 and 3.44, respectively, at 12-month follow-up (p<0.001 for all 3 compared with baseline; p<0.001 for percutaneous coblation compared against epidural injection). A case series of 396 patients reported that 75% of patients had at least a 50% improvement in pain after the procedure (mean follow-up 1 year). A case series of 50 patients reported that 20% (10/50) of patients were asymptomatic after a mean follow-up of 114 months: 54% of patients had mild pain that could be managed with smaller doses of medication than before the procedure.
- The systematic review of 27 studies reported that functional mobility measured 4.3 using the Oswestry Disability Index improved after percutaneous coblation from 58.95 (n=318) at baseline to 18.30 at 3 months (n=153, p<0.001), 24.43 at 12 months (n=264, p<0.001) and 36.98 at 24 months (n=92, p<0.005). In the group of patients treated by conservative therapy, the Oswestry Disability Index worsened from 43 at baseline (n=40) to 49 at 12-month follow-up (n=28)p<0.001 compared with percutaneous coblation). The non-randomised comparative study of 160 patients treated by percutaneous coblation or open discectomy reported improvements in disability of 60% and 78%, respectively, at 12-month follow-up (p value not reported). The RCT of 118 patients treated by percutaneous coblation alone, percutaneous coblation combined with nerve root steroid injection, or epidural steroid injection reported that the mean Oswestry Disability Index scores decreased from 47.73, 47.71 and 48.10 at baseline to 22.73, 22.85 and 27.76, respectively, at 12 month follow-up (p<0.001 for all 3 compared with baseline; p<0.001 for percutaneous coblation compared against epidural injection).
- 4.4 An RCT of 90 patients treated by percutaneous coblation or epidural steroid

injection, which was included in the systematic review of 27 studies, reported that both treatments were associated with significant improvements in quality of life measured using the SF-36 questionnaire: there were significant improvements in components of physical function, bodily pain, the physical components summary, and social function at 6 months. The percutaneous coblation group also had significant improvement for physical and emotional role functioning. There were significant differences between treatment groups in favour of percutaneous coblation for physical function (p=0.0016), bodily pain (p=0.0039), the physical components summary (p=0.004) and social function (p=0.0312).

- 4.5 The RCT of 90 patients reported that 62% of patients treated by percutaneous coblation were extremely or very satisfied at 6-month follow-up compared with 33% of patients treated by epidural steroid injection (absolute numbers and p value not reported). The non-randomised comparative study of 160 patients reported that 67% of patients would recommend percutaneous coblation to other patients, and 32% of patients would not recommend it.
- 4.6 A case series of 1390 patients, which was included in the systematic review of 27 studies, reported that disc bulging (visualised on CT or MRI scan) was eliminated in 34% of patients, significantly reduced in 48% and unchanged in 18% of patients at 6-month follow-up. An RCT of 64 patients treated by percutaneous coblation or conservative therapy reported a decrease in the mean disc bulge from 5.1 mm at baseline to 1.8 mm at 3-month follow-up (p<0.001) in the percutaneous coblation group.
- 4.7 The specialist advisers listed the key efficacy outcomes as reduction of back and leg pain, disability, and work and domestic productivity.

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>.

5.1 Increased radicular pain was reported in 2% (1/45) of patients treated by percutaneous coblation and 13% (5/40) of patients treated by epidural steroid

injection in a randomised controlled trial (RCT) of 90 patients; increased back pain was reported in 2% (1/45) and 10% (4/40) of patients respectively. Acute low back pain with spasms was reported in 1 patient in each group in the same study. Lateralised postural lumbar pain and hypertone (contraction of paravertebral muscles), which lasted up to 10 days after the procedure, were reported in 5% of patients in a case series of 1390 patients (actual numbers not reported). Worsening of pain was reported in 1 patient in a case series of 396 patients.

- 5.2 Muscle tightness or spasms were reported in 4% (2/45) of patients treated by percutaneous coblation and 3% (1/40) of patients treated by epidural steroid injection in the RCT of 90 patients.
- 5.3 Bradycardia, reported by the authors as being related to poor tolerance to minor pain, was reported in 1% (4/396) of patients in the case series of 396 patients.
- Discitis was reported in 1 patient in the case series of 396 patients (no further 5.4 information given).
- 5.5 Radicular paraesthesia was reported in less than 1% (2/396) of patients in the case series of 396 patients.
- 5.6 Increased weakness was reported in 2% (1/45) of patients treated by percutaneous coblation and 0% (0/40) of patients treated by epidural steroid injection in the randomised controlled trial of 90 patients.
- 5.7 Epidural fibrosis, diagnosed by MRI 3 months after percutaneous coblation, was reported in a single case report. The patient had recurrence of pain in the left lower extremity and lower back, which spontaneously resolved after the MRI. No further treatment was needed.
- 5.8 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 visceral injury and vascular injury as anecdotal adverse events. They considered that the following were theoretical adverse events: nerve injury, needle misplacement through the disc to the retroperitoneum or behind the dura or

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spinal canal, instability, paralysis, bleeding, and possibly late disc protrusion (rare).

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Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.

Accreditation

