NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional procedure consultation document

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

The tough covering of a spinal disc (annulus) can sometimes break, allowing the soft centre to bulge through. This is called herniation, also known as 'slipped disc'. This may cause pain in the back, pain in the leg (sciatica), and numbness and weakness in the leg. This procedure aims to relieve low back pain and sciatica by inserting a narrow tube into the affected disc and delivering radiofrequency energy to remove excess tissue.

The National Institute for Health and Care Excellence (NICE) is examining percutaneous coblation of the intervertebral disc for low back pain and 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 provisional recommendations about percutaneous coblation of the intervertebral disc for low back pain and sciatica.

This document summarises the procedure and sets out the provisional recommendations made by the Advisory Committee. It has been prepared for public consultation. The Advisory Committee particularly welcomes:

- comments on the provisional 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 provisional 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- The Advisory Committee will then prepare draft guidance which will be the basis for NICE's guidance on the use of the procedure in the NHS.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: 23 October 2015

Target date for publication of guidance: 27 January 2016

1 Provisional 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 includes large numbers of patients with reasonable 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 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 40–70°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 interventional procedure overview.

4.1 A systematic review of 27 studies, including 3211 patients treated by percutaneous coblation, reported that pain measured on a visual analogue scale (VAS; range 0–10, 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.

4.3 The systematic review of 27 studies reported that functional mobility measured 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 mean disability score increased 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 months 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 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 interventional procedure overview.

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, induced by pain, was reported in 1% (4/396) of patients in the case series of 396 patients. Prolonged pain-induced bradycardia led to 1 patient having a convulsive episode.

5.4 Discitis was reported in 1 patient in the case series of 396 patients (no further information given).

5.5 Radicular paraesthesia was reported in <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 spinal canal, instability, paralysis, bleeding, and possibly late disc protrusion (rare).

6 Further information

6.1 For related NICE guidance, see the NICE website.

6.2 This guidance is a review of 'Percutaneous disc decompression using coblation for lower back pain' NICE interventional procedure guidance 173 (2006).

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October, 2015