NICE guidance

Percutaneous intradiscal radiofrequency treatment of the intervertebral disc nucleus for low back pain

Interventional procedures guidance
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www.nice.org.uk/guidance/ipg545

This guidance replaces IPG83.

1 Recommendations

1.1 Current evidence on percutaneous intradiscal radiofrequency treatment of the intervertebral disc nucleus for low back pain raises no major safety concerns. The evidence on its efficacy is limited in quantity and quality. Therefore, this procedure should only be used with special arrangements for clinical governance, consent and audit or research.

1.2 Clinicians wishing to do percutaneous intradiscal radiofrequency treatment of the intervertebral disc nucleus for low back pain should:

- Inform the clinical governance leads in their NHS trusts.
- Ensure that patients understand the uncertainty about the procedure's efficacy and provide them with clear written information. In particular, patients should be informed about other treatment options, about the possibility that the procedure may not relieve their symptoms, and about the risk of a flare-up of their pain after treatment. In addition, the use of NICE's information for the public is recommended.
- Audit and review clinical outcomes of all patients having percutaneous intradiscal radiofrequency treatment of the intervertebral disc nucleus for low back pain (see section 7.2).

1.3 NICE encourages further research into percutaneous intradiscal radiofrequency treatment of the intervertebral disc nucleus for low back pain. Further research should include details of patient selection, the duration of patients' symptoms, and a precise account of the technique used for treatment. Outcome measures should include pain relief and quality of life. Long-term follow-up data should include details of any subsequent procedures.

This replaces previous guidance on percutaneous intradiscal radiofrequency thermocoagulation for lower back pain (NICE interventional procedure guidance 83).

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 may 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 have not responded to

conservative treatment. This can be done by open discectomy or less invasive percutaneous approaches.

2.3 Percutaneous intradiscal radiofrequency treatment of the intervertebral disc nucleus may be used for low back pain caused by contained herniated discs that has not responded to conservative treatment, when open surgery is not suitable.

3 The procedure

3.1 Percutaneous intradiscal radiofrequency treatment aims to enhance the structural integrity of the intervertebral disc. It aims to reduce low back pain by using radiofrequency heat energy to alter the biomechanics of the intervertebral disc and to destroy the nociceptive pain fibres.

3.2 Provocative discography is sometimes used before this procedure, to identify the symptomatic disc. The procedure is done with the patient under sedation in the prone position and using local anaesthesia. A needle is inserted into the disc under fluoroscopic guidance. An electrode or flexible catheter is then passed through the needle and into the centre of the disc nucleus. Once in position, it is slowly heated and kept at the chosen temperature (around 70ºC) for a predetermined time, usually for about 1–2 minutes, before it is removed.

3.3 A recent modification to this procedure uses pulsed radiofrequency, which generates less heat in the disc nucleus but is applied for a longer period of time.

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 randomised controlled trial of 28 patients treated by percutaneous intradiscal radiofrequency thermocoagulation (PIRFT) of the intervertebral disc nucleus (n=13) or sham (n=15) reported treatment

success (defined as a 2-point reduction on a visual analogue scale [VAS] and pain reduction of 50% or more on a 7-point global perceived effect scale ranging from much worse [−3] to total pain relief [+3]) in 1 patient in the PIRFT group and in none in the sham group, 12 months after the procedure (no significant difference between groups).

4.2 A case series of 76 patients treated by pulsed radiofrequency reported good clinical success (defined as 50% or more pain reduction on a 10-point numeric rating scale) in 38% (29/76) of patients at 3 months. It reported moderate clinical success (defined as a minimum of 2 points reduction in pain intensity) in 30% (23/76) of patients at 3 months. Pulsed radiofrequency had no effect on pain symptoms in 29% (22/76) of patients at 3 months. In the group who had 50% or more pain reduction at 3 months, 79% (23/29) of patients still had this effect at 12-month follow-up. The remaining 21% (6/29) reported pain that was the same as at baseline (before the procedure). The same study reported treatment failure (defined as conversion to surgery) in 3% (2/76) of patients at 12-month follow-up.

4.3 The randomised controlled trial of 28 patients treated by PIRFT or sham reported mean changes in pain VAS scores from baseline to 8 weeks of −0.61 in the PIRFT group and −1.14 in the sham group (VAS measured for 4 days and minimum and maximum scores recorded; difference between groups not significant). A randomised trial of 37 patients treated by PIRFT for 120 seconds (group A, n=19) or PIRFT for 360 seconds (group B, n=18) reported significant differences between mean pain scores before the procedure (± standard deviation; SD) and mean pain scores at 1 month in both groups, measured by VAS. The mean pain scores were 6.73±1.55 compared against 3.36±0.89 for group A and 6.27±1.31 compared against 3.33±0.97 for group B; $p<0.05$ for the difference compared against pre-treatment scores. It reported no significant differences from pre-treatment scores at 2-, 3- and 6-month follow-up in either group.

4.4 A non-randomised trial of 31 patients treated by pulsed radiofrequency (n=15) or intradiscal electrothermal therapy (IDET, n=16) reported mean numerical rating scores for pain of 7.2 at baseline and 2.5 at 6-month follow-up in the pulsed radiofrequency group and 7.5 at baseline and 1.7

at 6 months in the IDET group (significant improvements within groups, p<0.01). No significant differences in mean numerical rating scale scores were observed between the groups at 6-month follow-up.

4.5 The randomised controlled trial of 28 patients treated by PIRFT or sham reported mean changes in function scores of −2.62 (measured using the Oswestry disability scale [ODS]; from 0 to 100 with lower scores indicating less disability) in the PIRFT group and −4.93 in the sham group at 8 weeks (p value for the difference between groups was not significant, and no significance test was reported for within group changes). The randomised trial of 37 patients comparing PIRFT for 120 seconds against PIRFT for 360 seconds reported significant differences between mean ODS scores before the treatment and at 1 month (±SD) in both groups (42±9% compared against 26±11% for 120 seconds and 42±10% compared against 24±12% for 360 seconds, p<0.05 for both groups). There were no significant differences at 6 months in either group. The non-randomised trial of 31 patients treated by pulsed radiofrequency or IDET reported Roland Morris disability questionnaire scores (RMDQS; from 0 to 18, with lower scores indicating less disability). In the pulsed radiofrequency group, the reported RMDQS was 10.8 at baseline and 2.3 at 6 months after the procedure. In the IDET group the reported RMDQS was 10.4 at baseline and 2.8 at 6 months (significant improvements within both groups, p<0.01). There were no significant differences in RMDQS between groups at 6-month follow-up (p>0.05).

4.6 A case series of 8 patients treated by pulsed radiofrequency reported that all patients had stopped their regular pain medication after the procedure (no further details provided).

4.7 The specialist advisers listed key efficacy outcomes as reduction of back and leg pain, global improvement, reduction in 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 Flare-up pain lasting from a few days to 6 weeks was reported in a case series of 76 patients with discogenic pain treated by pulsed radiofrequency in the intervertebral disc nucleus. The pain was treated by non-steroidal anti-inflammatory drugs or paracetamol (number of patients not reported).

5.2 Disc herniation was reported in 5% (2/39) of patients in a case series of 39 patients with low back pain treated by percutaneous intradiscal radiofrequency thermocoagulation, but it was unclear whether this was associated with the procedure (timing not reported).

5.3 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 the following anecdotal adverse events: visceral or vascular injury and discitis. They considered that the following were theoretical adverse events: instrument failure; technical failure at L5 or S1 (lumbosacral joints) because of difficult access; needle misplacement through disc to retroperitoneum or behind to dura or spinal canal; damage to other structures including nerve damage; bleeding; infection; instability; infarction; epidural fibrosis; late disc protrusion; and paralysis.

6 Committee comments

6.1 The Committee recognised that low back pain is very common and that it can cause considerable distress and disability. Therefore, if further research were to provide good evidence of efficacy for percutaneous intradiscal radiofrequency treatment of the intervertebral disc nucleus, the procedure might offer benefit to many patients. This supported the recommendation for further research.

6.2 The Committee was advised that pulsed radiofrequency treatment is becoming more commonly used. Therefore, further studies using pulsed radiofrequency, including comparative studies, are encouraged to reduce

the uncertainties about this emerging technique.

6.3 The Committee noted that there was no evidence on the use of percutaneous intradiscal radiofrequency treatment of the intervertebral disc nucleus for the treatment of sciatica; that is why this guidance refers only to its use for low back pain.

6.4 The Committee was disappointed by the lack of new evidence following its specific recommendation for further research on this procedure in NICE's interventional procedure guidance on percutaneous intradiscal radiofrequency thermocoagulation for lower back pain published in 2004.

7 Further information

7.1 For related NICE guidance, see the NICE website.

7.2 This guidance requires that clinicians doing the procedure make special arrangements for audit. NICE has identified relevant audit criteria and has developed an audit tool (which is for use at local discretion).

Information for patients

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

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Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.

Accreditation