NICE guidance

Percutaneous electrothermal treatment of the intervertebral disc annulus for low back pain and sciatica

Interventional procedures guidance
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www.nice.org.uk/guidance/ipg544

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 IPG319.

1 Recommendations

1.1 Current evidence on percutaneous electrothermal treatment of the intervertebral disc annulus for low back pain and sciatica raises no major safety concerns. The evidence on efficacy is inconsistent and of poor 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 electrothermal treatment of the intervertebral disc annulus for low back pain and sciatica 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 following treatment. In addition, the use of the information for the public is recommended.
- Audit and review clinical outcomes of all patients having percutaneous intradiscal radiofrequency treatment of the intervertebral disc annulus (see further information).

1.3 NICE encourages further research into percutaneous electrothermal treatment of the intervertebral disc annulus. Further research should document details of patient selection, including the duration of their symptoms. It should report precise details 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.

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.

3 The procedure

3.1 Percutaneous electrothermal treatment aims to relieve back pain and sciatica by applying thermal energy to the annulus of a damaged intervertebral disc in order to stiffen the annulus and disrupt nerve endings within it. Thermal treatment of the annulus can be performed using a variety of techniques which use radiofrequency energy. These include Intradiscal Electrothermal Therapy (IDET), biacuplasty, and Percutaneous Intradiscal Radiofrequency Thermocoagulation (PIRFT). PIRFT can be used to treat the intervertebral disc annulus and/or the disc nucleus. This guidance considers only thermal treatment of the annulus.

3.2 Percutaneous electrothermal treatment is usually done with the patient under

sedation and using local anaesthesia. The damaged disc is identified by lumbar discography. If the patient feels pain when contrast is injected into the disc (provocative discography), this is usually taken as evidence that the disc is symptomatic. Under fluoroscopic guidance, 1 or 2 introducer needles are inserted into the disc. If 1 introducer needle is used, a monopolar electrode or catheter is then passed into the disc and positioned next to its posterior wall. If 2 introducer needles are used, bipolar electrodes are inserted through each introducer into contralateral sides of the disc. Once in position, electrodes heat the annulus for 2 to 15 minutes, depending on the technique being used. The aim is to contract collagen fibres and promote closure of any tears and cracks. In addition, treatment may destroy nociceptive pain fibres.

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 In a systematic review of 17 studies that included patients treated by Intradiscal Electrothermal Therapy (IDET), 13 studies (503 patients) reported visual analogue scale scores for pain (scores ranged from 0 to 10 with lower scores indicating less pain). Meta-analysis revealed that visual analogue scale scores for pain improved by a mean of 2.9 points (95% confidence interval [CI] 2.5 to 3.4; no p value reported). Meta-analysis of 4 studies (n=196 patients) that reported SF-36 bodily pain scores (scores ranged from 0 to 100 with higher scores indicating less pain) showed that scores improved by a mean of 21.1 points (95% CI 13.4 to 28.8; no p value reported).

4.2 In a randomised controlled trial of 59 patients treated by intradiscal biacuplasty (n=29) or sham (n=30), mean numerical rating scale scores for pain (scores ranged from 0 to 10 with lower scores indicating less pain) improved from 7.13 to 4.94 and from 7.18 to 6.58 respectively, at 6-month follow-up (p value between groups=0.014).

4.3 In a non-randomised comparative study of 46 patients treated by Percutaneous Intradiscal Radiofrequency Thermocoagulation (PIRFT) of the annulus (n=31) or

conservative treatment (n=15), mean visual analogue scale scores for pain (scores ranged from 0 to 10 with lower scores indicating less pain) changed from 7.2 to 4.5 (p<0.001) and from 6.2 to 6.3 (not significant) respectively, at 1-year follow-up. No p value for inter-group comparisons was reported.

4.4 In the systematic review of 17 studies that included patients treated by IDET, 3 studies (79 patients) reported Oswestry Disability Index (ODI) scores (scores ranged from 0 to 100 with lower scores indicating less disability). Meta-analysis showed that ODI scores improved by a mean of 7.0 points (95% CI 2.0 to 11.9; no p value reported).

4.5 In the randomised controlled trial of 59 patients treated by intradiscal biacuplasty (n=29) or sham (n=30), mean ODI scores changed from 40.37 to 32.94 and from 40.93 to 41.17 respectively, at 6-month follow-up (p value between groups=0.005).

4.6 In the non-randomised comparative study of 46 patients treated by PIRFT of the annulus (n=31) or conservative treatment (n=15), mean ODI scores improved from 48.1 to 35.5 (p<0.001) and from 46.1 to 46.0 (not significant) respectively, at 1-year follow-up. No p value for inter-group comparisons was reported.

4.7 In the systematic review of 17 studies that included patients treated by IDET, 4 studies (196 patients) reported SF-36 physical function scores (scores ranged from 0 to 100 with higher scores indicating better physical function). Meta-analysis showed that scores improved by a mean of 18.0 points (95% CI 11.9 to 24.1; no p value reported).

4.8 In the randomised controlled trial of 59 patients treated by intradiscal biacuplasty (n=29) or sham (n=30), mean SF-36 physical function scores changed from 47.04 to 62.04 and from 46.03 to 48.67 respectively, at 6-month follow-up (p value between groups=0.012).

4.9 In the randomised controlled trial of 59 patients treated by intradiscal biacuplasty (n=29) or sham (n=30), mean amount of opioids taken each day changed from 52.47 mg to 36.87 mg and from 50.85 mg to 49.48 mg respectively, at 6-month follow-up (not significant).

4.10 Specialist advisers listed key efficacy outcomes as visual analogue scale scores for pain, validated back pain and disability scores, functional outcome scores and measures of social function (for example, productivity at home and the ability to work).

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 Catheter breakage was reported in 19 patients (involving 20 tips which fractured and separated) in a case series of 1675 patients treated by Intradiscal Electrothermal Therapy (IDET). Two broken tips were retrieved using percutaneous methods, 1 was removed surgically, 16 were left in the disc and 1 was left in subcutaneous tissues. None of the cases were associated with any morbidity. A case report of 1 patient treated by IDET described paraesthesia and dysaethesia in the left leg, 6 months after a procedure in which 3 different catheters had to be used because of catheter breakage. On the third attempt, the tip of the catheter broke off inside the disc space and was not retrieved. When the patient reported dysaesthetic symptoms, the tip was surgically removed and the patient reported no symptoms 3 months after removal.

5.2 Transient radiculopathy, which lasted for less than 6 weeks, was reported in 11% (4 of 38) of patients in the IDET group and 5% (1 of 19) of patients in the sham procedure group in a randomised controlled trial of 57 patients.

5.3 Bladder dysfunction was reported in 1 patient in the case series of 1675 patients treated by IDET. During IDET the treating physician noted that the catheter was positioned in the extra-discal space. No further details were provided.

5.4 Type 1 complex regional pain syndrome was reported at 3-month follow-up in a case report of 1 patient treated by Percutaneous Intradiscal Radiofrequency Thermocoagulation (PIRFT) of the annulus. The patient reported that their back pain decreased after receiving PIRFT but both feet became extremely painful and swollen. The patient was treated by medical therapy and a computer

tomography-guided lumbar sympathetic trunk block.

5.5 Increased axial back pain was reported in a case report of 1 patient treated by IDET. Magnetic resonance imaging at 3-month follow-up revealed diffuse 'marrow oedema' of the L2 vertebral body consistent with osteonecrosis; this resolved at 12-month follow-up.

5.6 In a systematic review of 17 studies that included patients treated by IDET, 11 studies (486 patients) reported the incidence of adverse events. Meta-analysis revealed an adverse event rate of 0.8% (95% confidence interval 0.2% to 1.4%). Adverse events included:

- A burning sensation in the leg of 1 patient; this resolved.
- Paraesthesia and numbness in the thighs of 2 patients; both resolved.
- Foot drop in 1 patient; this resolved.
- Increasing lower leg pain in 1 patient; the patient was subsequently lost to follow-up.
- Increasing back and thigh pain in 1 patient; this was treated by spinal fusion.
- Headache in 1 patient; this resolved.
- Increasing radicular pain in 5 patients; pain resolved in 4 patients, 1 patient needed surgery.
- Device failure in 1 patient due to scar tissue around the treatment site; the patient was treated by inter-body fusion.
- Increasing low-back pain in 1 patient; this was treated by spinal fusion.
- Nerve root injury in 1 patient; this resolved.
- Increased disc herniation in 2 patients; both were treated by spinal fusion.
- Decreased anal sphincter tone and faecal incontinence in 1 patient; this resolved.
- Non-dermatomal leg pain in 2 patients; both resolved.

- Discitis in 1 patient; this was treated by spinal fusion.
- Anterolisthesis in 1 patient; this was treated by spinal fusion.

5.7 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: catheter misplacement through the disc to the retroperitoneum and visceral/vascular injury. They considered that the following were theoretical adverse events: excessive bleeding, spinal instability and paralysis.

6 Committee comments

6.1 The committee noted that the literature described a variety of techniques for percutaneous electrothermal treatment of the intervertebral disc annulus for low back pain and sciatica, and that different names were used to describe them. These complicated its consideration of the published evidence.

6.2 The committee was disappointed by the lack of new evidence following its specific recommendation for further research on this procedure in NICE's interventional procedures guidance on percutaneous intradiscal electrothermal therapy for low back pain. It considered that publication of comparative studies would be particularly useful.

6.3 The committee noted that the technology for this procedure is evolving.

7 Further information

7.1 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. 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.