NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

INTERVENTIONAL PROCEDURES PROGRAMME

Interventional procedure overview of percutaneous intradiscal radiofrequency treatment of the intervertebral disc nucleus for low back pain

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', and may cause pain in the back and leg. This procedure aims to relieve low back pain by inserting a needle into the centre of the damaged disc to deliver heat energy to relieve low back pain.

Introduction

The National Institute for Health and Care Excellence (NICE) has prepared this interventional procedure (IP) overview to help members of the Interventional Procedures Advisory Committee (IPAC) make recommendations about the safety and efficacy of an interventional procedure. It is based on a rapid review of the medical literature and specialist opinion. It should not be regarded as a definitive assessment of the procedure.

Date prepared

This IP overview was prepared in March 2015.

Procedure name

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

Specialist societies

- British Association of Spinal Surgeons
- British Pain Society Interventional Pain Management Special Interest Group
- British Society of Interventional Radiologists.

Description

Indications and current treatment

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 or leg. Serious neurological sequelae may sometimes occur.

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.

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

What the procedure involves

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.

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.

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

Literature review

Rapid review of literature

The medical literature was searched to identify studies and reviews relevant to percutaneous intradiscal radiofrequency treatment of the intervertebral disc nucleus for low back pain. The following databases were searched, covering the

period from their start to 27 March 2015: MEDLINE, PREMEDLINE, EMBASE, Cochrane Library and other databases. Trial registries and the Internet were also searched. No language restriction was applied to the searches (see appendix C for details of search strategy). Relevant published studies identified during consultation or resolution that are published after this date may also be considered for inclusion.

The following selection criteria (table 1) were applied to the abstracts identified by the literature search. Where selection criteria could not be determined from the abstracts the full paper was retrieved.

Table 1 Inclusion criteria for identification of relevant studies

Characteristic	Criteria
Publication type	Clinical studies were included. Emphasis was placed on identifying good quality studies. Abstracts were excluded where no clinical outcomes were reported, or where the paper was a review, editorial, or a laboratory or animal study. Conference abstracts were also excluded because of the difficulty of appraising study methodology, unless they reported specific adverse events that were not available in the published literature.
Patient	Patients with low back pain.
Intervention/test	Percutaneous intradiscal radiofrequency treatment of the intervertebral disc nucleus
Outcome	Articles were retrieved if the abstract contained information relevant to the safety and/or efficacy.
Language	Non-English-language articles were excluded unless they were thought to add substantively to the English-language evidence base.

List of studies included in the IP overview

This IP overview is based on 285 patients from 1 randomised controlled trial (RCT)[1], 1 randomised uncontrolled trial[2], 1 non-randomised comparative study[3], and 6 case series[4-9].

Other studies that were considered to be relevant to the procedure but were not included in the main extraction table (table 2) have been listed in appendix A.

Table 2 Summary of key efficacy and safety findings on percutaneous intradiscal radiofrequency treatment of the intervertebral disc nucleus for low back pain

Study 1 Barendse GA (2001) - *included in 2004 overview*

Details

Study type	**RCT**
Country	Netherlands
Recruitment period	1994-1996
Study population and number	n=**28 (13 radiofrequency [RF] versus 15 sham)** patients with a history of at least 1 year of chronic low back pain
Age and sex	Mean 43 years; 64% (18/28) female
Patient selection criteria	Inclusion criteria: patients with chronic non-specific low back pain for more than 1 year, a history of unsuccessful conservative treatment and patients with at least 50% temporary pain relief 30 minutes after an analgesic discography. Exclusion criteria: clinical radiculopathies and other neurologic abnormalities, patients younger than 30 years of age and older than the age of 65 years, spinal stenosis, spondylolisthesis, multilevel burnt out disc lesions, coagulation disturbances, pregnancy, and initial "high" visual analogue score less than 5, patients with diabetes mellitus, patients with more than 1 pain syndrome and patients with multilevel discogenic pain.
Technique	Electrode tip placed in the centre of the nucleus 90 seconds at 70°C, slow decrease to 50-52°C. Sham group: the patients were treated by the same procedure but without use of RF current.
Follow-up	**8 weeks**
Conflict of interest/source of funding	Not reported.

Analysis

Follow-up issues:

- From 195 patients, only 28 patients were found to be eligible (after discography).
- The number of dropouts remained unclear.
- Unclear whether any losses to follow-up.

Study design issues:

- Double-blind.

Study population issues:

- One patient who was allocated to the sham therapy accidentally received an RF disc lesion. Intention-to-treat analyses were conducted. Analyses were done with the data of this patient in the sham group (unadjusted results) and also in the RF group (adjusted results).

Other issues:

- The authors suggested that the method of diagnosis of discogenic pain (analgesic discography) was responsible for false-positive responses.
- In 4 patients in the present study, 2 in the RF group and 2 in the control group, the position of the needle was not optimal because of the iliac crest.
- It has been suggested in other studies that the method used in this study did not provide enough heat in the nucleus to be effective (Azulay 2008).

Key efficacy and safety findings

<table>
<tr><th>Efficacy</th><th>Safety</th></tr>
<tr><td>
Number of patients analysed: 28 (13 RF versus 15 sham)

• Treatment success
The treatment was considered a success if patients had a 2-point reduction on the VAS scale and a > 50% pain reduction on global perceived effect.

<table>
<tr><th>Follow-up</th><th>RF group</th><th>Control group</th></tr>
<tr><td>3 months</td><td>8% (1/13)</td><td>13% (2/15)</td></tr>
<tr><td>6 months</td><td>8% (1/13)</td><td>7% (1/15)</td></tr>
<tr><td>12 months</td><td>8% (1/13)</td><td>0</td></tr>
</table>
Difference between groups not significant

• Mean change in pain VAS (0-10), 8-week follow-up
VAS measured for 4 days and min and max recorded.
RF group Sham group Difference adjusted (90% CI)
-0.61 -1.14 1.25 (-0.55–3.06)
Difference between groups not significant

• Mean change in global perceived effect (-3 worst to +3 best) 8-week follow-up
RF group Sham group Difference adjusted (90% CI)
0.09 0.21 -0.18 (-1.28–0.91)
Difference between groups not significant

• Mean change in function improvement (Oswestry Disability Scale), 8-week follow-up
RF group Sham group Difference adjusted (90% CI)
-2.62 -4.93 3.28 (-7.54–14.11)
Difference between groups not significant

• Mean change in COOP/WONCA quality of life (5-point scale, 1 = best, 5 = worst), 8-week follow-up
RF group Sham group Difference adjusted (90% CI)
-1.85 -0.21 -1.06 (-3.88–1.77)
Difference between groups not significant
</td><td>The authors report that there were no complications reported during or after the procedure.</td></tr>
<tr><td colspan="2">Abbreviations used: CI, confidence interval; NS, not significant; RF, radiofrequency; VAS, visual analogue scale.</td></tr>
</table>

Study 2 Ercelen B (2003) - *included in 2004 overview*

Details

Study type	**Randomised trial**
Country	Turkey
Recruitment period	2000-2001
Study population and number	n=**37 (19 Group A [radiofrequency for 120 s] versus 18 Group B [radiofrequency for 360 s])** patients with discogenic pain
Age and sex	Mean 39 years; 59% (22/37) female
Patient selection criteria	Inclusion criteria: Patients with persistent chronic low back pain who previously received conservative treatment for at least 2 years and with signal intensity decreases in L4-L5, L5-S1, or in both locations on magnetic resonance imaging and a positive provocative discography. Exclusion criteria: nerve compression, spinal stenosis, instability, spondylolisthesis, diabetes mellitus, tumour infiltration, coagulation disorders, clinical radiculopathy, other neurologic abnormalities or systemic inflammatory diseases.
Technique	For the radiofrequency, a 20-gauge RFK C 15 cannula (Radionics) was used after intravenous administration of a sedative (1-2 mg midazolam) and an antibiotic (1 g cefazolin). The cannula was placed in the centre of the disc and then replaced by the radiofrequency probe. After injection of a mixture of 1-2 ml of dye (Omnipaque 300) and local anaesthetic (bupivacaine 0.05%), 80ºC radiofrequency lesioning was done for 120 s in Group A and 360 s in Group B. The tip temperature was monitored until it decreased to 40ºC and the cannula was removed. Radiofrequency heating was done with Radionics RFG-3C plus lesion generator (Radionics).
Follow-up	**6 months**
Conflict of interest/source of funding	None reported.

Analysis

Follow-up issues:

- Pain was assessed with a visual analogue scale (VAS) before the procedure, immediately after, at 1 and 2 weeks and at 1, 3 and 6 months after the procedure.
- Oswestry disability scale (ODS) scores were assessed before the procedure and at 1 and 6 months after the procedure.
- Two patients were excluded from the study: one who had discitis and another who did not return for follow-up.

Study design issues:

- Uncontrolled study.
- Unclear how patients were selected.
- The patients were randomised by computer.
- VAS assessed by a pain nurse.

Study population issues:

- From 60 selected patients only 39 patients were found to be eligible (after discography).
- Group A: there were 9 L4-L5 discogenic pain and 14 L5-S1 discogenic pain.
- Group B: there were 8 L4-L5 discogenic pain and 12 L5-S1 discogenic pain.
- Group A: 24 PIRFT done in 20 patients
- Group B: 21 PIRFT done in 19 patients.

Other issues: None.

Key efficacy and safety findings

<table>
<tr><th>Efficacy</th><th>Safety</th></tr>
<tr><td>Number of patients analysed: 37 (19 Group A [radiofrequency for 120 s] versus 18 Group B [radiofrequency for 360 s])

Pain (Visual Analogue Scale [VAS]: 1–10 where 10 is the worst)

<table>
<tr><th></th><th colspan="2">Group A</th><th colspan="2">Group B</th></tr>
<tr><td>Time</td><td>Mean ± SD</td><td>% improve</td><td>Mean ± SD</td><td>% improve</td></tr>
<tr><td>Pre</td><td>6.73 ±1.55</td><td></td><td>6.27 ±1.31</td><td></td></tr>
<tr><td>Immediate</td><td>1.21 ± 0.97*</td><td>82</td><td>0.94 ± 1.05*</td><td>85</td></tr>
<tr><td>1 week</td><td>2.68 ± 0.94*</td><td>60</td><td>2.55 ± 1.24*</td><td>59</td></tr>
<tr><td>2 weeks</td><td>3.15 ± 0.76*</td><td>53</td><td>3.05 ± 1.21*</td><td>50</td></tr>
<tr><td>1 month</td><td>3.36 ±0.89*</td><td>47</td><td>3.33 ±0.97*</td><td>47</td></tr>
<tr><td>2 months</td><td>5.26 ±2.40</td><td>22</td><td>4.94 ±2.36</td><td>21</td></tr>
<tr><td>3 months</td><td>5.31 ±2.35</td><td>21</td><td>5.00 ±2.61</td><td>20</td></tr>
<tr><td>6 months</td><td>5.42 ±2.43</td><td>19</td><td>4.83 ±2.14</td><td>23</td></tr>
</table>
*p < 0.05 for the difference versus pre-treatment scores.

Function improvement (ODS)

<table>
<tr><th></th><th>Group A</th><th>Group B</th></tr>
<tr><td>Time</td><td>ODS%</td><td>ODS%</td></tr>
<tr><td>Pre</td><td>42 ± 9</td><td>42 ± 10</td></tr>
<tr><td>1 month</td><td>26 ± 11*</td><td>24 ± 12*</td></tr>
<tr><td>6 months</td><td>39 ±14</td><td>38 ± 14</td></tr>
</table>
*p < 0.05 for the difference versus pre-treatment scores.

Authors report that there were no statistical differences between the final (6 months) and the pre-treatment VAS and ODS values in both groups.</td><td>The authors made no statements regarding safety in the report.</td></tr>
<tr><td colspan="2">Abbreviations used: ODS, Oswestry disability scale; PIRFT, percutaneous intradiscal radiofrequency thermocoagulation; SD, standard deviation.</td></tr>
</table>

Study 3 Fukui S (2012)

Details

Study type	**Non-randomised comparative study**
Country	Japan
Recruitment period	2003 to 2011
Study population and number	Patients with chronic discogenic low back pain n=**31 (15 Pulsed radiofrequency to the nucleus versus 16 IDET to the annulus)**
Age and sex	Mean age: Pulsed-radiofrequency group, 39.3 years ; IDET group, 41.7 years Sex: Pulsed-radiofrequency group, 33% (5/15) female versus IDET group 31% (5/11) female
Patient selection criteria	Inclusion criteria: patients with chronic discogenic low back pain that lasted for more than 6 months and was unresponsive to conservative treatment (including corticosteroid injections, physical therapy and oral anti-inflammatory medication) were included. Pain decreased considerably, for more than 3 days, after administration of 1ml of 2% lidocaine. Exclusion criteria: patients with disc extrusion or a sequestered fragment, severe spinal canal narrowing, segmental instability, localised infection (at the treatment site), systemic infection, chronic lower extremity radiculopathy or a history of opioid abuse were excluded.
Technique	All procedures were performed under fluoroscopic guidance. Pulsed radiofrequency was performed by placing the Diskit II needle (Neurotherm) centrally into the degenerated disc using a posterior oblique approach. Pulsed radiofrequency was applied at a frequency of 5 Hz, pulse width of 5 seconds, amplitude of 60 V, and a maximum temperature of 40ºC, for a duration of 15 minutes. Authors do not describe the technique in which IDET was performed.
Follow-up	**6 months**
Conflict of interest/source of funding	Not reported

Analysis
Follow-up issues: none identified
Study design issues: Analysis was performed by retrospectively reviewing the records of patients treated at 1 pain medical centre.
Study population issues: none identified
Other issues:

- Numerical rating scale scores for pain ranged from 0 to 10 with lower scores indicating less pain.
- Roland Morris disability questionnaire scores ranged from 0 to 18 with lower scores indicating less disability.

Key efficacy and safety findings

<table>
<tr><td>Efficacy</td><td>Safety</td></tr>
<tr><td>Number of patients analysed: 31 (15 Pulsed-radiofrequency versus 16 IDET)

Mean numerical rating scale and Roland Morris Disability Questionnaire scores
<table>
<tr><td></td><td colspan="3">Pulsed radiofrequency</td><td colspan="3">IDET</td></tr>
<tr><td>Outcome measure</td><td>Baseline</td><td>3 months</td><td>6 months</td><td>Baseline</td><td>3 months</td><td>6 months</td></tr>
<tr><td>Numerical rating scale scores for pain</td><td>7.2</td><td>2.6</td><td>2.5</td><td>7.5</td><td>3.1</td><td>1.7</td></tr>
<tr><td>Roland Morris Disability Questionnaire scores</td><td>10.8</td><td>2.9</td><td>2.3</td><td>10.4</td><td>5.8</td><td>2.8</td></tr>
</table>

Significant improvements in numerical rating scale scores and Roland Morris disability questionnaire scores were observed within groups (p values<0.01).
No significant differences in numerical rating scale scores and Roland Morris disability questionnaire scores were observed between groups at 6-month follow-up (p values>0.05).
The mean Roland Morris disability questionnaire scores in the pulsed-radiofrequency group were significantly lower than the scores in the IDET group 3 months after the procedure (p<0.01).
An increase in the amount (amount not reported) or type of pain medication was reported in none of the patients in the pulsed-radiofrequency group and in 87.5% of patients in the IDET group within 8 weeks of treatment.
</td><td>Pain flare-up after the procedure was reported in none of the patients in the pulsed-radiofrequency group and in 87.5% (14/16) in the IDET group.</td></tr>
<tr><td colspan="2">Abbreviations used: IDET, Intradiscal electrothermal therapy.</td></tr>
</table>

Study 4 Rohof O (2012)

Details

Study type	**Case series**
Country	Netherlands
Recruitment period	Not reported
Study population and number	n=**76** patients with discogenic pain
Age and sex	Age not reported; 64% (49/76) female
Patient selection criteria	Inclusion criteria: patients older than 18 years with low back pain of minimum 6 months duration that was refractory to pharmacological treatment and physical therapy. Exclusion criteria: tumours, infections, fractures and nerve compressions.
Technique	Patients were consciously sedated with alfentanyl 0.5 mg and midazolam 1-2 mg. Diskit needle was placed into the middle of the nucleus of the affected disc. Discography was done with a 5 ml syringe filled with 3 ml of omnipaque 240, 1 ml lidocaine 2% and prophylactic antibiotic (1ml) per disc. Pulsed radiofrequency was applied at a frequency of 2, 10 ms pulse width and 60 V for 15 minutes (Neurotherm 1100 lesion generator). At the end of the procedure, a protective dose of antibiotic was injected. Physiotherapy was started at the earliest, 4 weeks after the procedure.
Follow-up	**12 months**
Conflict of interest/source of funding	The author has been a consultant for Neurotherm for the development of the Diskit.

Analysis
Follow-up issues:
- Patients were assessed at 3 and 12 months after the procedure.
- At 12 months' follow-up, patients in the groups with no effect and with moderate effect may have received an additional intervention according to the results of additional clinical examination that revealed another pain source.

Study design issues:
- Pain was measured on a 10-point numeric rating scale (NRS) where 0=no pain and 10=the worst imaginable pain.
- Clinical success was described as moderate when a minimum of 2 points reduction in pain intensity was reported and good when 50% or more pain reduction was reported.
- Treatment failure was defined as a conversion to surgery.
- Changes in medication and changes in the tenderness over the spinous processes at physical examination were also assessed.

Study population issues:
- 34% (26/76) of patients were treated by pulsed radiofrequency at 3 levels, 42% (32/76) at 2 levels and 21% (16/76) at 1 level.
- Some patients had additional pain foci: hip, sacroiliac joint, radicular pain and facet joint pain.

Other issues: None.

Key efficacy and safety findings

<table>
<tr><th>Efficacy</th><th>Safety</th></tr>
<tr><td>Number of patients analysed: 76

Clinical success
<table><tr><th></th><th>At 3 months</th></tr><tr><th>Effect of pulsed radiofrequency</th><th>Number of patients</th></tr><tr><td>No effect</td><td>29% (22/76)</td></tr><tr><td>Moderate</td><td>30% (23/76)</td></tr><tr><td>Good</td><td>38% (29/76)</td></tr></table>
In the group who experienced >50% pain relief at 3 months, 79% (23/29) of patients still had this effect at 12-month follow-up and 21% (6/29) reported a pain condition that was not different from baseline.

Treatment failure at 12 months
3% (2/76) of patients were treated by surgery after the procedure.</td><td>• Flare-up pain lasting from a few days up to 6 weeks treated by NSAIDs or paracetamol was reported (number of patients not given).</td></tr>
<tr><td colspan="2">Abbreviations used: NSAID, non-steroidal anti-inflammatory drug.</td></tr>
</table>

Study 5 Van Kleef M (1996) - *included in 2004 overview*

Details

Study type	**Case series**
Country	Netherlands
Recruitment period	1992-1994
Study population and number	n=**39** consecutive patients with a minimum of 12 months of low back pain
Age and sex	Mean 44 years; 51% (20/39) male
Patient selection criteria	Inclusion criteria: history of unsuccessful conservative treatment, temporary pain relief after discography. Exclusion criteria: patients under 25 or over 60 years old, clinical or radiological signs of a herniated disc with nerve root compression, spinal stenosis, extensive multi-level spondylosis or 'burned out' disc lesions, previous surgery involving spinal fusion, psychological problems as identified by the SCL-90, patients with a positive diagnostic block.
Technique	90 second 70°C lesion. Tip of the RF probe in the centre of the disc. No local anaesthetic was used.
Follow-up	**Mean 16 months**
Conflict of interest/source of funding	Not reported.

Analysis
Follow-up issues: 77 patients had diagnostic discographies performed during the recruitment period; in 38 patients, there was no temporary relief of pain and the remaining 39 patients were entered in the study.
Study design issues:
- Independent person assessed outcomes.
- Limited data outcomes.

Study population issues:
- 19 patients were previously treated by surgery.
- Level of treatment: L3-L4, 5% (2/39); L4-L5, 56% (22/39) and L5-S1, 38% (15/39).

Other issues: None.

Key efficacy and safety findings

<table>
<tr><th>Efficacy</th><th>Safety</th></tr>
<tr><td>Number of patients analysed: 39

Pain (4-point Likert Scale)

• 8 weeks follow-up
<table>
<tr><th></th><th>Pain reduction</th><th>No pain reduction</th><th>χ^2</th><th>p value</th></tr>
<tr><td>Operated (n=19)</td><td>37% (7/19)</td><td>63% (12/19)</td><td>4.31</td><td>0.001</td></tr>
<tr><td>Unoperated (n=20)</td><td>70% (14/20)</td><td>30% (6/20)</td><td></td><td></td></tr>
<tr><td>Total (n=39)</td><td>54% (21/39)</td><td>46% (18/39)</td><td></td><td></td></tr>
</table>
• Mean 16 months follow-up
<table>
<tr><th></th><th>Pain reduction</th><th>No pain reduction</th><th>χ^2</th><th>p value</th></tr>
<tr><td>Operated (n=19)</td><td>26% (5/19)</td><td>74% (14/19)</td><td>3.31</td><td>0.003</td></tr>
<tr><td>Unoperated (n=20)</td><td>55% (11/20)</td><td>45% (9/20)</td><td></td><td></td></tr>
<tr><td>Total (n=39)</td><td>41% (16/39)</td><td>59% (23/39)</td><td></td><td></td></tr>
</table></td><td>Two reports of herniation but unclear whether associated with procedure.</td></tr>
</table>

Study 6 Jung YJ (2012)

Details

Study type	**Case series**
Country	Korea
Recruitment period	2008-2010
Study population and number	n=**26** patients with chronic back pain refractory to active rehabilitative management.
Age and sex	Mean 43.2 years; 77% (20/16) female
Patient selection criteria	Inclusion criteria: chronic discogenic low back pain of over 4 on a visual analogue scale and over 30% on an Oswestry disability index, pain lasting for more than 6 months that is non-responsive to conservative medical management, pain provoked by prolonged sitting, normal lower extremity neurologic examination and concordant pain provocation by low pressure (<50 psi) discography at the affected level. Exclusion criteria: severe disc degeneration at 1 or more levels (disc height loss greater than 50%) evidenced from plain lateral lumbar X-ray, extruded or sequestered herniated nucleus pulposus, previous back surgery, chronic lower extremity radiculopathy, spinal canal stenosis evidenced by MRI, spondylolisthesis or any translational instability of any lumbar segmental level, and psychiatric diseases such as depression and somatoform disorder.
Technique	Intradiscal PRF was conducted within 7 days after discography. A 20-gauge SMK C15 cannula with a 15-mm active tip (Cotop International BV) was placed at the centre of the affected disc. The parameters applied for PRF using an RF generator RFG-1A (COSMAN Medical Inc.) were: frequency 2, 20 milliseconds pulse width, and 60 V for 20 minutes.
Follow-up	**Minimum 1 year**
Conflict of interest/source of funding	This study was supported by a grant of the Korea Health care technology R&D Project, Ministry for Health, Welfare & Family Affairs, Republic of Korea.

Analysis

Follow-up issues:

- Patients had follow-up at 3, 6 and 12 months after the procedure.

Study design issues:

- Single-centre study
- Successful clinical outcome was described as moderate when there was over a 2-point reduction in VAS to below 50% pain reduction, and good when 50% or more pain reduction was reported.

Study population issues:

- Mean (±SD) duration of the low back pain before the procedure: 26.8±19.7 months.
- 46% (12/26) of patients received intradiscal PRF at 1 spinal level, 46% (12/26) had intradiscal PRF at 2 spinal levels, and 8% (2/26) at 3 spinal levels.
- Modic I changes were seen in 8% (2/26) of patients, Modic II changes in 35% (9/26) and Modic III changes in none of the patients. In 58% (15/26) patients, there were no Modic changes evident.

Other issues: This study used automated pressure-controlled discography before the procedure. The authors say that 'Contrary to the possibility of over diagnosis of discogenic pain via manual discography reportedly used in previous studies, there might be a possibility of underdiagnosed discogenic pain among untreated discs in our study due to a small 25-gauge needle, slow injection speed (0.02 cc/sec), and 50 psi as cut-off pressure.' This might explain the differences in clinical outcomes between this study and the Teixeira and Rohof studies.

Key efficacy and safety findings

<table>
<tr><th>Efficacy</th><th>Safety</th></tr>
<tr><td>
Number of patients analysed: 26

Pain
<table>
<tr><th>Follow-up</th><th>Mean VAS (± SE)</th><th>p</th></tr>
<tr><td>Baseline</td><td>6.4 ± 1.1</td><td></td></tr>
<tr><td>1 month</td><td>4.1 ± 1.8</td><td><0.01</td></tr>
<tr><td>3 months</td><td>4.1 ± 1.9</td><td><0.01</td></tr>
<tr><td>6 months</td><td>4.2 ± 2.0</td><td><0.01</td></tr>
<tr><td>12 months</td><td>4.4 ± 1.9</td><td><0.01</td></tr>
</table>
p values are for change over baseline at each follow-up

Clinical success outcome at follow-up
<table>
<tr><th>Follow-up</th><th>Good</th><th>Moderate</th><th>No improvement</th></tr>
<tr><td>3 months</td><td>39% (10/26)</td><td>19% (5/26)</td><td>42% (11/26)</td></tr>
<tr><td>6 months</td><td>38% (10/26)</td><td>12% (3/26)</td><td>50% (13/26)</td></tr>
<tr><td>12 months</td><td>35% (9/26)</td><td>7% (2/26)</td><td>58% (15/26)</td></tr>
</table>
Disability
<table>
<tr><th>Follow-up</th><th>Mean ODI score (± SE)</th><th>p</th></tr>
<tr><td>Baseline</td><td>47.3 ± 15.4</td><td></td></tr>
<tr><td>1 month</td><td>33.7 ± 18.3</td><td><0.001</td></tr>
<tr><td>3 months</td><td>32.4 ± 18.5</td><td><0.001</td></tr>
<tr><td>6 months</td><td>34.0 ± 18.1</td><td><0.001</td></tr>
<tr><td>12 months</td><td>36.7 ± 19.5</td><td><0.001</td></tr>
</table>
p values are for change over baseline at each follow-up

Sitting tolerance time
<table>
<tr><th>Follow-up</th><th>Mean sitting tolerance time (± SE, minutes)</th><th>p</th></tr>
<tr><td>Baseline</td><td>27.8 ± 20.4</td><td></td></tr>
<tr><td>1 month</td><td>70.8 ± 43.2</td><td><0.05</td></tr>
<tr><td>3 months</td><td>78.5 ± 42.2</td><td><0.05</td></tr>
<tr><td>6 months</td><td>71.5 ± 42.2</td><td><0.05</td></tr>
<tr><td>12 months</td><td>71.5 ± 42.2</td><td><0.05</td></tr>
</table>
p values are for change over baseline at each follow-up
</td><td>No complications were reported.</td></tr>
<tr><td colspan="2">Abbreviations used: MRI, magnetic resonance imaging; PRF, pulsed radiofrequency; RF, radiofrequency; SD, standard deviation; SE, standard error; VAS, visual analogue scale.</td></tr>
</table>

Study 7 Fukui S (2013)

Details

Study type	**Case series**
Country	Japan
Recruitment period	2009-2012
Study population and number	n=**23** patients who were diagnosed with discogenic low back pain by analgesic disc block
Age and sex	Mean 35.3 years; 35% (8/23) female
Patient selection criteria	Inclusion criteria: chronic low back pain of at least 6 months continuous duration; lack of satisfactory improvement with a comprehensively applied non-operative care programme including the following: epidural corticosteroid injection, a trial of physical therapy and oral anti-inflammatory medication; normal neurologic examination findings; negative SLR results; a magnetic resonance scan that did not demonstrate a neural compression lesion; concordant pain at low pressurisation during discography of the concerned disc. Intradiscal administration of 1 ml of lidocaine 2% diminished pain more than 70%. Exclusion criteria: disc extrusion or a sequestered fragment; severe spinal canal narrowing; segmental instability or psychological issues; systemic infection or localised infection at the anticipated needle entry sites; previous lumbar surgery; chronic lower extremity radiculopathy and history of opioid abuse.
Technique	Under fluoroscopic guidance, the Diskit II needle (NeuroTherm,20G, 15cm length, 20mm active tip, with radiopaque marker active tip) was percutaneously advanced and placed in the centre of the damaged disc. Intradiscal PRF was applied at a frequency of 5Hz, pulse width of 5 ms, amplitude of 60V, and a maximum temperature of 40°C, for a duration of 15 minutes, by the NT1100 generator (NeuroTherm). Intradiscal PRF was performed on an outpatient basis. Prophylactic intravenous antibiotics were administered 15 – 40 minutes before the beginning the procedure. After an hour of bed rest, patients were allowed to leave the outpatient room.
Follow-up	**1 year**
Conflict of interest/source of funding	None reported

Analysis

Follow-up issues:

- Patients had follow-up at 1, 3, 6 and 12 months after the procedure.

Study design issues:

- A successful clinical outcome was described as moderate when there was over a 2 point reduction in NRS to below 50% pain reduction and good when 50% or more pain reduction was reported.

Study population issues:

- 13% (3/23) of patients had 2 discs treated.
- 23 patients received 26 procedures: 9 were at L4-5, 10 were at L5-S1, 1 was at L5-6, 2 had procedures at both L4-5 and L5-S1, and 1 had procedures at both L2-3 and L4-5.

Other issues: The diagnosis of discogenic low back pain was made using discoblock (not discography).

Key efficacy and safety findings

<table>
<tr><th>Efficacy</th><th>Safety</th></tr>
<tr><td>
Number of patients analysed: 23

Pain
<table>
<tr><th>Follow-up</th><th>Mean NRS scores</th><th>p</th></tr>
<tr><td>Baseline</td><td>7.47</td><td></td></tr>
<tr><td>1 month</td><td>3.87</td><td><0.01</td></tr>
<tr><td>3 months</td><td>3.47</td><td><0.01</td></tr>
<tr><td>6 months</td><td>3.21</td><td><0.01</td></tr>
<tr><td>12 months</td><td>3.13</td><td><0.01</td></tr>
</table>
p values are for change over baseline at each follow-up

Clinical success outcome at follow-up
<table>
<tr><th>Follow-up</th><th>Good</th><th>Moderate</th><th>No improvement</th></tr>
<tr><td>3 months</td><td>17% (4/23)</td><td>65% (15/23)</td><td>17% (4/23)</td></tr>
<tr><td>6 months</td><td>22% (5/23)</td><td>61% (14/23)</td><td>17% (4/23)</td></tr>
<tr><td>12 months</td><td>17% (4/23)</td><td>65% (15/23)</td><td>17% (4/23)</td></tr>
</table>
Disability
<table>
<tr><th>Follow-up</th><th>Mean RMDQ scores</th><th>p</th></tr>
<tr><td>Baseline</td><td>11.4</td><td></td></tr>
<tr><td>1 month</td><td>5.00</td><td><0.01</td></tr>
<tr><td>3 months</td><td>4.05</td><td><0.01</td></tr>
<tr><td>6 months</td><td>3.30</td><td><0.01</td></tr>
<tr><td>12 months</td><td>2.90</td><td><0.01</td></tr>
</table>
p values are for change over baseline at each follow-up
</td><td>The report stated that no safety events occurred.</td></tr>
<tr><td colspan="2">Abbreviations used: NRS, numeric rating scale; RMDQ, Roland Morris Disability Questionnaire; SLR, straight leg raising.</td></tr>
</table>

Study 8 Azulay N (2008)

Details

Study type	**Retrospective case series**
Country	France
Recruitment period	2003-2005
Study population and number	n=**17** patients with low back pain
Age and sex	Mean 43.2 years; 53% (9/17) female
Patient selection criteria	Inclusion criteria: Persistent low back pain for at least 6 months, failure of non-surgical treatments, normal neurological exam including a negative straight-leg-raising sign, history of unsuccessful conservative treatments, bulging or herniated discs if not associated with radicular pain, presence of a positive provocative discography done on at least 1 spinal level during the procedure, and presence of a complete follow-up history. Exclusion criteria: Inflammatory arthritis, spinal stenosis, non-spinal conditions that could mimic low back pain, medical or metabolic disorders that would preclude appropriate participation, previous symptomatic surgery, when more than 50% of the disc had collapsed, and patients under 20 or over 60 years old, those with a history of lumbar surgery and pregnant women.
Technique	Patients received prophylactic antibiotic therapy with a single 1g dose of pristinamycine 1 hour before the procedure. After a discography, a needle was placed in the disc and the nucleus pulposus was punctured. An electrode was then inserted through the needle and 2 electrical stimulations were applied. To evaluate the disc integrity, 0.5 ml of contrast media was first injected followed by 1 ml of saline solution (0.9% NaCl). The power of the radiofrequency generator was controlled to be between 4.5-6.5 Watts. The frequency of the alternating current was 295 kHz. Patients were under neuroanalgesia. For each disc, 6 coagulation units (CU) were applied (a CU was defined as the maximum energy delivered to maintain 90ºC over a period of 4 minutes, which corresponds to a delivery of 650-1100 Joules). During each CU, 1ml of saline solution was infused through the needle to prevent energy increase. Patients underwent a rehabilitation programme after the procedure.
Follow-up	**6 months after the procedure**
Conflict of interest/source of funding	None reported

Analysis

Follow-up issues:

- Patients had follow-up at 1, 3 and 6 months after the procedure.
- There were 45 patients treated during the study period and 17 were finally included in the study. Of the 28 patients excluded from the study, 20 lacked follow-up, 10 did not have a positive provocative discography and 5 did not receive a discography during the procedure.

Study design issues:

- Disability was assessed by the Oswestry disability score (scored from 0 to 100, 0 indicating no disability and 100 maximum disability).
- The effectiveness of the treatment was determined by changes in the Oswestry score.
- Treatment success was defined as global pain reductions of at least 50%. All other changes were classified as treatment failures.
- A Mann-Whitney test was done to compare continuous variables and a chi-square test or a Fisher test if necessary were used to test for differences between categorical variables.
- Disc selection was not blinded.

Study population issues:

- Mean duration of the low back pain: 50.6 months (range 6-168 months).
- 6 patients received treatment at 2 spinal levels.
- The pre-therapeutic MRIs indicated an annular tear in 7 cases and degenerative lesions in 16 cases.

Other issues: None.

Key efficacy and safety findings

<table>
<tr><th>Efficacy</th><th>Safety</th></tr>
<tr><td>
Number of patients analysed: 17

A total of 23 discs were treated: 1 L3-L4, 12 L4-L5 and 10 L5-S1.

Disability
<table>
<tr><th>Follow-up</th><th>Oswestry score (mean ± SD)</th><th>p</th></tr>
<tr><td>Baseline</td><td>50.29 ± 9.60</td><td></td></tr>
<tr><td>1 month</td><td>17.29 ± 9.54</td><td><0.001</td></tr>
<tr><td>3 months</td><td>20.94 ± 12.52</td><td><0.05</td></tr>
<tr><td>6 months</td><td>20.53 ± 13.43</td><td><0.05</td></tr>
</table>
p values are for change over baseline at each follow-up

Treatment success at follow-up
<table>
<tr><th>Follow-up</th><th>Success rates</th></tr>
<tr><td>1 month</td><td>88% (15/17)</td></tr>
<tr><td>3 months</td><td>53% (9/17)</td></tr>
<tr><td>6 months</td><td>71% (12/17)</td></tr>
</table>
Treatment success and spinal level treated at 6 months
<table>
<tr><th>Spinal level</th><th>Success rates</th></tr>
<tr><td>L3-L4</td><td>0% (0/1)</td></tr>
<tr><td>L4-L5</td><td>66% (8/12)</td></tr>
<tr><td>L5-S1</td><td>70% (7/10)</td></tr>
</table>
The time between the onset of low back pain and the procedure was significantly longer in the successful treatment group: 64 months versus 30 months in the treatment failure group (p=0.01).
</td><td>
- No complications or technical failures were reported in the 17 included patients.

- Of the total 45 patients treated, 7% (3/45) needed needle reinsertions; 2 because of positioning too close to the vertebral plate, 1 because of contrast extravasation.
</td></tr>
<tr><td colspan="2">Abbreviations used: SD, standard deviation.</td></tr>
</table>

Study 9 Teixeira A (2006)

Details

Study type	**Case series**
Country	Portugal
Recruitment period	Not reported
Study population and number	n=**8** consecutive patients with single-level discogenic pain
Age and sex	Mean 50 years; 37.5% (3/8) female
Patient selection criteria	Continuous back pain without referral to the legs for a minimum of 6 months. Exclusion criteria: facet pain.
Technique	Sedation was not used. Patients were treated on an outpatient basis. A 15-cm, 20-gauge needle with a 15-mm active tip (Cotop International) was placed centrally in the disc. Pulsed radiofrequency was applied for 20 minutes at a setting of 2X20 ms/s and 60V. The mean final tip temperature was 41.0 ± 2.0ºC. At the end of the procedure, 100 mg of Cefamezin (cefazolin) was injected into the disc to prevent discitis. Patients were told to avoid heavy work and strenuous exercise, and to stop physiotherapy for 2 weeks.
Follow-up	**Range 6-25 months**
Conflict of interest/source of funding	Not reported

Analysis
Follow-up issues:
- Daily numeric rating scale scores over the first week were available for 6 patients.
- A follow-up of 12.8 months (range 6-25, median 9 months) was available for 62.5% (5/8) of patients.

Study design issues: None.
Study population issues:
- Mean duration of pain was 6.3 years (range 0.5-16 years, median 4 years).
- Mean score for pain before the procedure (measured on a 0-10 numeric rating scale with 0 indicating no pain and 10 the worst possible pain): 7.75 (range 5-9).
- 87.5% (7/8) of patients were taking medication before the procedure such as non-steroidal anti-inflammatory drugs, cyclo-oxygenase-inhibitors, diazepam, amitryptyline and tramadol. One patient had stopped all medication.
- 83% (5/6) of patients having a profession had stopped working because of their back pain.
- Narrowing of the height of the affected disc of up to 30% was found in 87.5% (7/8) of patients; in 1 patient there was 60% narrowing of the disc space.
- 25% (2/8) of patients were previously treated by disc surgery for a herniated disc. In 1 of them, the pain originated from the operated level; in the other from the level cranial to the level of operation.

Other issues: None.

Key efficacy and safety findings

Efficacy	Safety
Number of patients analysed: **8** **Pain** • There was a significant fall in the numeric rating scale (NRS) scores over the 1st week after the procedure (n=6, p<0.0001). • There was a significant fall in the NRS scores over the first 3 months after the procedure (n=8, p<0.0001). All patients had a fall in the NRS score of at least 4 points at 3 months. • At 12.8 months, 80% (4/5) of patients were pain free; 1 patient had an NRS score of 2. **Medication** All patients stopped their regular medication after the procedure. **Professional activity** • 80% (4/5) of the patients who had stopped working went back to work after a mean period of 34.5 days (range 7-90 days). • 20% (1/5) of the patients who had stopped working lost their job because of frequent absenteeism during the pre-treatment period.	There was no reporting of adverse events.
Abbreviations used: NSAID, nonsteroidal anti-inflammatory drug.	

Efficacy

Treatment success

An RCT 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)[1].

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 [NRS]) 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].

A case series of 26 patients treated by pulsed radiofrequency reported clinical success (either good or moderate) in 58% (15/26) of patients at 3-month follow-up and in 42% (11/26) at 12 months[6].

A case series of 23 patients treated by pulsed radiofrequency reported clinical success (either good or moderate) in 82% (19/23) of patients at 3-month and at 12-month follow-up[7].

A retrospective case series of 17 patients treated by radiofrequency thermocoagulation with instillation of saline solution into the disc nucleus reported treatment success (defined as global pain reductions of at least 50% on the Oswestry disability score) in 88% (15/17) of patients at 1 month, in 53% (9/17) at 3 months and in 71% (12/17) at 6 months. The time between the onset of low back pain and the procedure was significantly longer in the patients with successful treatment (64 months versus 30 months in the patients with treatment failure, p=0.01)[8].

Pain

The RCT of 28 patients treated by PIRFT or sham reported mean changes in pain scores from baseline to 8 weeks of −0.61 in the PIRFT group and −1.14 in the sham group (difference between groups not significant)[1].

A randomised trial of 37 patients treated by for 120 seconds (group A, n=19) or PIRFT for 360 seconds (group B, n=18) reported significant differences between mean pain scores at 1 month (± standard deviation; SD) and mean pain scores before the procedure in both groups, measured by VAS. The mean pain scores were 3.36±0.89 compared against 6.73±1.55 for group A and 3.33±0.97 compared against 6.27±1.31 for group B; $p<0.05$ for the differences 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[2].

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[3].

A case series of 39 patients treated by PIRFT reported pain reduction (measured on a 4-point Likert scale) in 54% (21/39) of patients at 8 weeks and in 41% (16/39) at 16 months (p values not reported)[5].

The case series of 26 patients reported mean (±standard error, SE) VAS scores of 6.4±1.1 at baseline and 4.4±1.9 after 12 months ($p<0.01$)[6].

The case series of 23 patients reported mean NRS scores of 7.47 at baseline and 3.13 after 12 months ($p<0.01$)[7].

A case series of 8 patients treated by pulsed radiofrequency reported a significant fall in the NRS scores over the first week after the procedure (n=6, $p<0.0001$) and over the first 3 months after the procedure (n=8, $p<0.0001$). All patients had a fall in the NRS score of at least 4 points at 3 months. At 12.8 months, 80% (4/5) of patients were pain free and 1 patient had an NRS score of 2[9].

Function

The RCT of 28 patients treated by PIRFT or sham reported mean changes of −2.62 in function scores (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 not significant)[1].

The randomised trial of 37 patients comparing PIRFT for 120 seconds against PIRFT for 360 seconds reported significant differences between mean ODS scores at 1 month (±SD) and pre-treatment scores in both groups (26±11% compared against 42±9% for 120 seconds and 24±12% compared against 42±10% for 360 seconds, $p<0.05$ for both groups). There were no significant differences at 6 months in either group[2].

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, $p<0.01$). No significant differences in RMDQS were observed between groups at 6-month follow-up ($p>0.05$)[3].

The case series of 26 patients reported mean (±SE) ODI scores of 47.3±15.4 at baseline and 36.7±19.5 after 12 months ($p<0.001$). The same study also reported mean sitting tolerance times (±SE) of 27.8±20.4 minutes at baseline and 71.5±42.2 minutes after 12 months ($p<0.05$)[6].

The case series of 23 patients reported a mean RMDQS of 11.4 at baseline and 2.9 after 12 months ($p<0.01$)[7].

The retrospective case series of 17 patients treated by radiofrequency thermocoagulation with instillation of saline solution into the disc nucleus reported ODS scores (mean ±SD) of 50.29±9.60 at baseline, 17.29±9.54 at 1 month, 20.94±12.52 at 3 months and 20.53±13.43 at 6 months (significant difference versus baseline; $p<0.001$ at 1 month and $p<0.05$ at 3 and 6 months)[8].

Medication use

The 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)[9].

Safety

Pain

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)[4].

Disc herniation

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].

Validity and generalisability of the studies

- All the studies included in table 2 involved radiofrequency thermocoagulation of the disc nucleus. Three[1, 2, 5] studies used PIRFT, 5 studies used pulsed radiofrequency[3, 4, 6, 7, 9] and 1 study[8] used PIRFT with saline solution.
- Only 3 comparative studies[1-3] were included. One of these studies[2] compared 2 different temperatures for PIRFT.
- Three of the 9 studies were already included in the previous overview[1,2,5].
- The maximum follow-up reported was 25 months[6].
- The studies included a limited number of patients (minimum 8, maximum 76).
- Different methods were used for the diagnosis of discogenic low back pain.

Existing assessments of this procedure

- A systematic review of the evidence on non-surgical interventional therapies for low back pain was published by the American Pain Society in 2009[10]. It states:

  > 'There is good or fair evidence from randomized trials that prolotherapy, facet joint injection, intradiscal steroid injection, and PIRFT thermocoagulation are not effective.'

- A systematic review of the evidence on percutaneous thermocoagulation intradiscal techniques for discogenic low back pain was published in 2007[11]. It states:

  > 'The available evidence does not support the clinical use of PIRFT or IDET, and potentially serious adverse events have been reported.'

Related NICE guidance

Below is a list of NICE guidance related to this procedure. Appendix B gives details of the recommendations made in each piece of guidance listed.

Interventional procedures

- Insertion of an annular disc implant at lumbar discectomy. NICE interventional procedure guidance 506 (2014). Available from http://www.nice.org.uk/guidance/ipg506
- Peripheral nerve-field stimulation for chronic low back pain. NICE interventional procedure guidance 451 (2013). Available from http://www.nice.org.uk/guidance/ipg451
- Transaxial interbody lumbosacral fusion. NICE interventional procedure guidance 387 (2011). Available from http://www.nice.org.uk/guidance/ipg387
- Non-rigid stabilisation techniques for the treatment of low back pain. NICE interventional procedure guidance 366 (2010). Available from http://www.nice.org.uk/guidance/ipg366
- Percutaneous intradiscal laser ablation in the lumbar spine. NICE interventional procedure guidance 357 (2010). Available from http://www.nice.org.uk/guidance/ipg357
- Lateral (including extreme, extra and direct lateral) interbody fusion in the lumbar spine. NICE interventional procedure guidance 321 (2009). Available from https://www.nice.org.uk/guidance/ipg321
- Percutaneous intradiscal electrothermal therapy for low back pain. NICE interventional procedure guidance 319 (2009). This guidance is currently under review and is expected to be updated in 2015. For more information, see: http://www.nice.org.uk/guidance/ipg319
- Prosthetic intervertebral disc replacement in the lumbar spine. NICE interventional procedure guidance 306 (2009). Available from http://www.nice.org.uk/guidance/ipg306
- Percutaneous endoscopic laser lumbar discectomy. NICE interventional procedure guidance 300 (2009). This guidance is currently under review and is expected to be updated in 2015. For more information, see: http://www.nice.org.uk/guidance/ipg300
- Percutaneous disc decompression using coblation for low back pain. NICE interventional procedure guidance 173 (2006). This guidance is currently

under review and is expected to be updated in 2015. For more information, see: http://www.nice.org.uk/guidance/ipg173

- Automated percutaneous mechanical lumbar discectomy. NICE interventional procedure guidance 141 (2005). Available from http://www.nice.org.uk/guidance/ipg141
- Percutaneous intradiscal radiofrequency thermocoagulation for lower back pain. NICE interventional procedure guidance 83 (2004). This guidance is currently under review (this overview) and is expected to be updated in 2015. For more information, see: http://www.nice.org.uk/guidance/ipg83

NICE guidelines

- Low back pain: Early management of persistent non-specific low back pain. NICE clinical guideline 88 (2009). This guidance is currently under review and is expected to be updated in 2016. For more information, see: http://www.nice.org.uk/guidance/cg88

Specialist advisers' opinions

Specialist advice was sought from consultants who have been nominated or ratified by their Specialist Society or Royal College. The advice received is their individual opinion and is not intended to represent the view of the society. The advice provided by Specialist Advisers, in the form of the completed questionnaires, is normally published in full on the NICE website during public consultation, except in circumstances but not limited to, where comments are considered voluminous, or publication would be unlawful or inappropriate. Three Specialist Advisor Questionnaires for percutaneous intradiscal radiofrequency treatment of the intervertebral disc nucleus for low back pain were submitted and can be found on the NICE website [INSERT HYPER LINK TO MAIN IP PAGE].

Patient commentators' opinions

NICE's Public Involvement Programme was unable to gather patient commentary for this procedure.

Issues for consideration by IPAC

- Ongoing study: NCT02343484 Intradiscal Gelified Ethanol and Pulsed Radiofrequency Versus Gelified Ethanol Injection for Discogenic Low Back Pain. Location: Greece. Ongoing. Enrolment: 40 patients. Estimated Completion Date: March 2018.

References

1. Barendse GA, van Den Berg SG, Kessels AH et al. (2001) Randomized controlled trial of percutaneous intradiscal radiofrequency thermocoagulation for chronic discogenic back pain: lack of effect from a 90-second 70°C lesion. Spine 26(3):287-92.
2. Ercelen O, Bulutcu E, lu T et al. (2003) Radiofrequency lesioning using two different time modalities for the treatment of lumbar discogenic pain: a randomized trial. Spine 28(17):1922-7.
3. Fukui S, Nitta K, Iwashita N et al. (2012) Results of intradiscal pulsed radiofrequency for lumbar discogenic pain: comparison with intradiscal electrothermal therapy. The Korean journal of pain 25:155-160.
4. Rohof O. (2012) Intradiscal pulsed radiofrequency application following provocative discography for the management of degenerative disc disease and concordant pain: a pilot study. Pain Practice 12(5):342-349.
5. Van Kleef M, Barendse GAM, Wilmink JT et al. (1996) Percutaneous intradiscal radio-frequency thermocoagulation in chronic non-specific low back pain. Pain Clinic 9(3):259-68.
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7. Fukui S, Nitta K, Iwashita N et al. (2013) Intradiscal pulsed radiofrequency for chronic lumbar discogenic low back pain: a one year prospective outcome study using discoblock for diagnosis. Pain Physician 16:E435-E442.
8. Azulay N, Forgerit M, Alava EG et al. (2008) A novel radiofrequency thermocoagulation method for treatment of lower back pain: thermal conduction after instillation of saline solution into the nucleus pulposus--preliminary results. Acta Radiologica 49:934-939.
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10. Chou R, Atlas SJ, Stanos SP et al. (2009) Nonsurgical interventional therapies for low back pain: a review of the evidence for an American Pain Society clinical practice guideline. Spine 34:1078-1093.
11. Urrutia G, Kovacs F, Nishishinya MB et al. (2007) Percutaneous thermocoagulation intradiscal techniques for discogenic low back pain. Spine 32:1146-1154.

Appendix A: Additional papers on percutaneous intradiscal radiofrequency treatment of the intervertebral disc nucleus for low back pain

The following table outlines the studies that are considered potentially relevant to the IP overview but were not included in the main data extraction table (table 2). It is by no means an exhaustive list of potentially relevant studies.

Article	Number of patients/follow-up	Direction of conclusions	Reasons for non-inclusion in table 2
Gautam S, Rastogi V, Jain A et al. (2011) Comparative evaluation of oxygen-ozone therapy and combined use of oxygen-ozone therapy with percutaneous intradiscal radiofrequency thermocoagulation for the treatment of lumbar disc herniation. Pain Practice 11:160-166.	RCT n=84 (43 Ozone-PIRFT versus 41 Ozone only) FU=1 year	Ozone-PIRFT was more efficacious than ozone alone in reducing pain scores, analgesic consumption, improving functional outcome, and satisfaction of patients with contained lumbar disc herniation.	Paper studied a combination treatment of PIRFT combined with oxygen-ozone injection. There was no PIRFT-only intervention group.

Appendix B: Related NICE guidance for percutaneous intradiscal radiofrequency treatment of the intervertebral disc nucleus for low back pain

Guidance	Recommendations
Interventional procedures	**Percutaneous intradiscal radiofrequency thermocoagulation for lower back pain. NICE interventional procedure guidance 83 (2004).** **(Current guidance)** 1.1 Current evidence on the safety and efficacy of percutaneous intradiscal radiofrequency thermocoagulation for lower back pain does not appear adequate to support the use of this procedure without special arrangements for consent and for audit or research. 1.2 Clinicians wishing to undertake percutaneous intradiscal radiofrequency thermocoagulation for lower back pain should take the following actions. • Inform the clinical governance leads in their Trusts. • Ensure that patients understand the uncertainty about the procedure's efficacy and provide them with clear written information. Use of the Institute's information for the public is recommended. • Audit and review clinical outcomes of all patients having percutaneous intradiscal radiofrequency thermocoagulation for lower back pain. 1.3 Further research will be useful in reducing the current uncertainty and clinicians are encouraged to collect longer-term follow-up data. The Institute may review the procedure upon publication of further evidence. **Automated percutaneous mechanical lumbar discectomy. NICE interventional procedure guidance 141 (2005).** 1.1 Current evidence suggests that there are no major safety concerns associated with automated percutaneous mechanical lumbar discectomy. There is limited evidence of efficacy based on uncontrolled case series of heterogeneous groups of

	patients, but evidence from small randomised controlled trials shows conflicting results. In view of the uncertainties about the efficacy of the procedure, it should not be used without special arrangements for consent and for audit or research. 1.2 Clinicians wishing to undertake automated percutaneous mechanical lumbar discectomy should take the following actions. • Inform the clinical governance leads in their Trusts. • Ensure that patients understand the uncertainty about the procedure's efficacy and provide them with clear written information. In addition, use of the Institute's information for the public is recommended. • Audit and review clinical outcomes of all patients having automated mechanical percutaneous lumbar discectomy. The Institute may review the procedure upon publication of further evidence. **Percutaneous disc decompression using coblation for low back pain. NICE interventional procedure guidance 173 (2006).** **(Current guidance)** 1.1 Current evidence suggests that there are no major safety concerns associated with the use of percutaneous disc decompression using coblation for lower back pain. There is some evidence of short-term efficacy; however, this is not sufficient to support the use of this procedure without special arrangements for consent and for audit or research. 1.2 Clinicians wishing to undertake percutaneous disc decompression using coblation for lower back pain should take the following actions. • Inform the clinical governance leads in their Trusts. • Ensure that patients understand the uncertainty about the procedure's efficacy and provide them with clear written information. Use of the Institute's information for the public is recommended. • Audit and review clinical outcomes of all patients having percutaneous disc decompression using coblation for lower back pain.

	1.3 Further research will be useful in reducing the current uncertainty, and clinicians are encouraged to collect long-term follow-up data. The Institute may review the procedure upon publication of further evidence. **Percutaneous endoscopic laser lumbar discectomy. NICE interventional procedure guidance 300 (2009).** **(Current guidance)** 1.1 Current evidence on the safety and efficacy of percutaneous endoscopic laser lumbar discectomy is inadequate 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 undertake percutaneous endoscopic laser lumbar discectomy should take the following actions. • Inform the clinical governance leads in their Trusts. • Ensure that patients and their carers understand the uncertainty about the procedure's safety and efficacy and provide them with clear written information. In addition, the use of NICE's information for patients ('Understanding NICE guidance') is recommended. • Audit and review clinical outcomes of all patients having percutaneous endoscopic laser lumbar discectomy. 1.3 Surgeons undertaking this procedure should have specific training in the use of lasers and in endoscopy of the spinal canal. 1.4 NICE encourages further research into percutaneous endoscopic laser lumbar discectomy and may review the procedure on publication of further evidence. Research studies should provide long-term outcome data. **Prosthetic intervertebral disc replacement in the lumbar spine. NICE interventional procedure guidance 306 (2009)** 1.1 Current evidence on the safety and efficacy of prosthetic intervertebral disc replacement 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 A multidisciplinary team with specialist expertise in the

	treatment of degenerative spine disease should be involved in patient selection for prosthetic intervertebral disc replacement in the lumbar spine. The procedure should only be carried out in patients for whom conservative treatment options have failed or are contraindicated. 1.3 The current evidence includes studies with a maximum follow-up of 13 years, but the majority of evidence is from studies with shorter durations of follow-up. NICE encourages clinicians to continue to collect and publish data on longer-term outcomes, which should include information about patient selection and the need for further surgery. **Percutaneous intradiscal electrothermal therapy for low back pain. NICE interventional procedure guidance 319 (2009).** **(Current guidance)** 1.1 Current evidence on the safety and efficacy of percutaneous intradiscal electrothermal therapy for low back pain is inconsistent. Therefore this procedure should only be used with special arrangements for clinical governance, consent and audit or research. 1.2 Clinicians wishing to undertake percutaneous intradiscal electrothermal therapy for low back pain should take the following actions. • Inform the clinical governance leads in their Trusts. • Ensure that patients and their carers understand the uncertainty about the procedure's safety and efficacy and provide them with clear written information. In addition, the use of NICE's information for patients ('Understanding NICE guidance') is recommended. • Audit and review clinical outcomes of all patients having percutaneous intradiscal electrothermal therapy for low back pain. 1.3 NICE encourages further research into percutaneous intradiscal electrothermal therapy for low back pain. Research should describe patient selection, use validated measures of long-term pain relief and quality of life, address the role of the procedure in avoiding major surgery, and measure long-term safety outcomes.

	Lateral (including extreme, extra and direct lateral) interbody fusion in the lumbar spine. NICE interventional procedure guidance 321 (2009). 1.1 Current evidence on the safety and efficacy of lateral (including extreme, extra and direct lateral) interbody fusion in the lumbar spine is inadequate 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 undertake lateral interbody fusion in the lumbar spine should take the following actions. • Inform the clinical governance leads in their Trusts. • Ensure that patients and their carers understand the uncertainty about the procedure's safety and efficacy and provide them with clear written information. In addition, the use of NICE's information for patients ('Understanding NICE guidance') is recommended. • Audit and review clinical outcomes of all patients having lateral interbody fusion in the lumbar spine. 1.3 This procedure should only be carried out by surgeons with specific training in the technique, who should perform their initial procedures with an experienced mentor. 1.4 NICE encourages further research into lateral interbody fusion in the lumbar spine. Research outcomes should include fusion rates, pain and functional scores, quality of life measures and the frequency of both early and late complications. NICE may review the procedure on publication of further evidence. **Percutaneous intradiscal laser ablation in the lumbar spine. NICE interventional procedure guidance 357 (2010).** 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. **Non-rigid stabilisation techniques for the treatment of low back pain. NICE interventional procedure guidance 366 (2010).** 1.1 Current evidence on the efficacy of non-rigid stabilisation techniques for the treatment of low back pain shows that these procedures are efficacious for a proportion of patients with intractable back pain. There are no major safety concerns. Therefore these procedures may be used provided that normal arrangements are in place for clinical governance, consent and audit. 1.2 Patient selection should be carried out by specialist spinal surgeons who are able to offer patients a range of surgical treatment options. **Transaxial interbody lumbosacral fusion. NICE interventional procedure guidance 387 (2011).** 1.1 Current evidence on the efficacy of transaxial interbody lumbosacral fusion is limited in quantity but shows symptom relief in the short term in some patients. Evidence on safety shows that there is a risk of rectal perforation. Therefore this procedure should only be used with special arrangements for clinical governance, consent and audit or research. 1.2 Clinicians wishing to undertake transaxial interbody lumbosacral fusion should take the following actions. • Inform the clinical governance leads in their Trusts. • Ensure that patients and their carers understand the uncertainty about the procedure's efficacy and its risks, specifically including the small risk of rectal perforation in patients with higher bowel disease, or a history of pelvic disease or previous pelvic surgery. They should provide patients with clear written information. In addition, the use of NICE's information for patients ('Understanding NICE guidance') is recommended. • Audit and review clinical outcomes of all patients having transaxial interbody lumbosacral fusion. 1.3 This procedure should only be carried out by surgeons with expertise in the surgical management of spinal disease and specific training in the technique. They should perform their initial procedures with an experienced mentor.

	1.4 NICE encourages further research into transaxial interbody lumbosacral fusion. Research outcomes should include fusion rates, pain and functional scores, quality of life measures and the frequency of both early and late complications. NICE may review this procedure on publication of further evidence. **Peripheral nerve-field stimulation for chronic low back pain. NICE interventional procedure guidance 451 (2013).** 1.1 Current evidence on the efficacy of peripheral nerve-field stimulation (PNFS) for chronic low back pain is limited in both quantity and quality, and duration of follow-up is limited. Evidence on safety is also limited and there is a risk of complications from any implanted device. Therefore this procedure should only be used with special arrangements for clinical governance, consent and audit or research. 1.2 Clinicians wishing to undertake PNFS for chronic low back pain should take the following actions. • Inform the clinical governance leads in their Trusts. • Ensure that patients understand the uncertainty about the procedure's safety and efficacy and provide them with clear written information. In addition, the use of NICE's information for the public is recommended. 1.3 Patient selection for treatment using PNFS for chronic low back pain should be done by a multidisciplinary team, including specialists in pain management and neurosurgery. 1.4 Clinicians should enter details about all patients undergoing PNFS for chronic low back pain onto the UK Neuromodulation Register when it is available. They should audit and review clinical outcomes locally. 1.5 NICE encourages collaborative data collection and publication of comparative studies on PNFS for chronic low back pain. Outcomes should include measures of pain, function and quality of life, particularly in the long term. Full details of any complications and adjunctive or subsequent treatments should be recorded. **Insertion of an annular disc implant at lumbar discectomy. NICE interventional procedure guidance 506 (2014).** 1.1 Current evidence on the safety and efficacy of insertion of an annular disc implant at lumbar discectomy 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 undertake insertion of an annular disc implant at lumbar discectomy should take the following actions: • Inform the clinical governance leads in their NHS trusts. • Ensure that patients and their carers understand the uncertainty about the procedure's safety and efficacy and provide them with clear written information. In addition, the use of NICE's information for the public is recommended. 1.3 NICE encourages further research on insertion of an annular disc implant at lumbar discectomy, particularly comparative trials. All studies should report details of patient selection and recurrence rates. 1.4 Clinicians should enter details about all patients undergoing insertion of an annular disc implant at lumbar discectomy onto the British Spine Registry and review clinical outcomes locally.
NICE guidelines	**Low back pain: Early management of persistent non-specific low back pain. NICE clinical guideline 88 (2009).** **(Current guidance)** 1.5 Other non-pharmacological therapies **Electrotherapy modalities** 1.5.1 Do not offer laser therapy. 1.5.2 Do not offer interferential therapy. 1.5.3 Do not offer therapeutic ultrasound. **Transcutaneous nerve stimulation** 1.5.4 Do not offer transcutaneous electrical nerve simulation (TENS). **Lumbar supports** 1.5.5 Do not offer lumbar supports. **Traction** 1.5.6 Do not offer traction. 1.6 Invasive procedures 1.6.1 Consider offering a course of acupuncture needling

	comprising up to a maximum of 10 sessions over a period of up to 12 weeks. 1.6.2 Do not offer injections of therapeutic substances into the back for non-specific low back pain. **1.9 Referral for surgery** 1.9.1 Consider referral for an opinion on spinal fusion for people who: have completed an optimal package of care, including a combined physical and psychological treatment programme (see section 1.7) and still have severe non-specific low back pain for which they would consider surgery. 1.9.2 Offer anyone with psychological distress appropriate treatment for this before referral for an opinion on spinal fusion. 1.9.3 Refer the patient to a specialist spinal surgical service if spinal fusion is being considered. Give due consideration to the possible risks for that patient. 1.9.4 Do not refer people for any of the following procedures: • Intradiscal electrothermal therapy (IDET) • Percutaneous intradiscal radiofrequency thermocoagulation (PIRFT) • Radiofrequency facet joint denervation.

Appendix C: Literature search for percutaneous intradiscal radiofrequency treatment of the intervertebral disc nucleus for low back pain

Databases	Date searched	Version/files
Cochrane Database of Systematic Reviews – CDSR (Cochrane)	27/03/2015	Issue 3 of 12, March 2015
HTA database (Cochrane)	27/03/2015	Issue 1 of 4, January 2015
Cochrane Central Database of Controlled Trials – CENTRAL (Cochrane)	27/03/2015	Issue 2 of 12, February 2015
MEDLINE (Ovid)	27/03/2015	1946 to March Week 4 2015
MEDLINE In-Process (Ovid)	27/03/2015	March 25, 2015
EMBASE (Ovid)	27/03/2015	1974 to 2015 Week 12
PubMed	27/03/2015	n/a
BLIC (Dialog DataStar)	27/03/2015	n/a

Trial sources searched on 27/03/2015

- Clinicaltrials.gov

Websites searched on 27/03/2015

- Australian Safety and Efficacy Register of New Interventional Procedures – Surgical (ASERNIP – S)
- General internet search

The following search strategy was used to identify papers in MEDLINE. A similar strategy was used to identify papers in other databases.

1	Low Back Pain/
2	LBP.tw.
3	(low* adj4 back pain*).tw.
4	(low* adj4 back ache*).tw.
5	(low* adj4 backache*).tw.
6	(chronic* adj4 back pain*).tw.
7	Intervertebral Disk Displacement/
8	(Intervertebr* adj4 (Disk* or disc*) adj4 Displace*).tw.
9	((slipped or hernia* or prolaps*) adj4 (disc* or disk*)).tw.

10	((discogenic* or diskogenic*) adj4 pain*).tw.
11	Sciatica/
12	sciatica*.tw.
13	Intervertebral Disc Degeneration/
14	(intervertebr* adj4 (disc* or disk*) adj4 degenerat*).tw.
15	(radicular adj4 pain*).tw.
16	Radiculopathy/
17	(lumbar adj4 radiculopath*).tw.
18	((disc* or disk*) adj4 nucleus).tw.
19	or/1-18
20	(intradisc* or intradisk*).tw.
21	Electrocoagulation/
22	electrocoagulat*.tw.
23	Electric Stimulation Therapy/
24	(electric* adj4 stimulat* adj4 therap*).tw.
25	Catheter Ablation/
26	(catheter adj4 ablation).tw.
27	Electrodes/
28	electrode*.tw.
29	electrotherm*.tw.
30	(electroannuloplast* or electroanuloplast* or anuloplast* or annuloplast*).tw.
31	(thermocoag* or thermomodulat*).tw.
32	Radio Waves/
33	(Radiofrequenc* or radio-frequenc*).tw.
34	RF.tw.
35	lesion*.tw.
36	percutaneous.tw.
37	IEA.tw.
38	or/21-37
39	20 and 38
40	PIRFT.tw.
41	39 or 40
42	19 and 41
43	(radionics adj4 catheter*).tw.
44	DiscTRODE*.tw.

45	or/42-44
46	Animals/ not Humans/
47	45 not 46