

NATIONAL INSTITUTE FOR CLINICAL EXCELLENCE

INTERVENTIONAL PROCEDURES PROGRAMME

Interventional procedures overview of percutaneous intradiscal radiofrequency thermocoagulation for lower back pain

Introduction

This overview has been prepared to assist members of the Interventional Procedures Advisory Committee (IPAC) in making 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 overview was prepared by NICE in April 2003.

Procedure names

- Percutaneous intradiscal radiofrequency thermocoagulation (PIRFT).
- Percutaneous radiofrequency thermomodulation.

Specialty societies

- British Orthopaedic Association.
- Association of Anaesthetists of Great Britain and Ireland.
- British Society of Skeletal Radiology.

Description

Indications

Chronic back pain is a common condition that affects a considerable proportion of the population. In the majority of individuals, pain resolves spontaneously within several months. However, for some people pain persists despite specific causes of back pain – such as herniated discs, osteoporosis and fractures – being excluded. Increasingly this pain is being attributed to degeneration of the intervertebral disc, and referred to as discogenic back pain¹.

Current treatments and alternatives

Few treatment options exist for individuals with chronic back pain. First-line treatment is typically a conservative management strategy, consisting of pharmacotherapy and/or a multidisciplinary programme. Patients who fail to respond to this regime then

have the choice of continuing with conservative management or undergoing surgery (spinal fusion).

Potential candidates for intradiscal therapy are those with persistent low back pain, lack of improvement with conservative management, proven internal disc disruption and no evidence of neural compressive lesions on MRI.

Summary of procedure

Percutaneous intradiscal radiofrequency thermocoagulation is a procedure that allows the controlled delivery of heat to the intervertebral disc via an electrode or coil. Controlled heating is thought to contract collagen fibres and destroy the nerves within the disc, thereby diminishing pain.

Patients are sedated and local anaesthetic is applied to the skin over the affected disc. Under fluoroscopic guidance, a needle is inserted into the disc.

The electrode or flexible catheter is then introduced into centre of the nucleus and is slowly heated to 50–80°C for 90–360 seconds.

Before undergoing this procedure, some patients may need to have a provocative discography in order to assess pain response.

Efficacy

In one uncontrolled study of 39 patients there was a reported improvement in pain at a mean follow up of 16 months. Two subsequent studies, including one randomised controlled trial of 28 patients comparing percutaneous intradiscal radiofrequency thermocoagulation with placebo, reported no statistically significant differences between preoperative pain levels and pain levels at final follow up.

All three studies were small; with short-term follow up, and two were uncontrolled. It is therefore unlikely that a clinically significant result could be detected.

The natural history of this condition, the difficulty in assessing pain and the potential for a placebo effect all present problems when interpreting the evidence and trying to determine the benefits of this procedure.

The Specialist Advisors expressed uncertainty regarding the efficacy of this procedure. The Advisors felt that the current published evidence had not demonstrated the benefits of the procedure.

Safety

Adverse events associated with this procedure appear to be uncommon. In the one randomised controlled trial of this procedure the authors state that no complications were observed during or after the procedure. It is difficult to know, however, whether this is because complications are uncommon or whether complications were not systematically investigated in these studies.

Complications following a similar procedure using electrothermal therapy rather than radiofrequency appear to be infrequent.⁶ Case reports of cauda equina and vertebral osteonecrosis due to intradiscal electrothermal therapy have been reported,⁷⁻¹⁰ however, it is unclear whether such reports are relevant to this procedure.

The Specialist Advisors did not report any particular safety concerns. Potential adverse events included infection and nerve root damage.

Literature reviews

Rapid review of literature

The medical literature was searched to identify studies and reviews relevant to percutaneous intradiscal thermocoagulation for lower back pain. Searches were conducted via the following databases from their commencement to February 2003: MEDLINE, PREMEDLINE, EMBASE, Cochrane Library and Science Citation Index. Trial registries and the Internet were also searched. No language restriction was applied to the searches.

The following selection criteria (Table 1) were applied to the abstracts identified by the literature search. Where these 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 included. Emphasis was placed on identifying good-quality published studies. Abstracts were excluded where no clinical outcomes were reported, or the paper was a review, editorial, laboratory or animal study. Case reports were excluded. Case series with fewer than 10 patients were excluded. Conference abstracts were also excluded because of the difficulty of appraising methodology.
Patient	Patients with lower back pain.
Intervention/test	Percutaneous intradiscal radiofrequency thermocoagulation.
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 overview

This overview is based on three clinical studies.²⁻⁴

Two of the studies were conducted by the same study group.^{2,4} The first is a preliminary report on the procedure,⁴ the results of which led the investigators to establish a randomised controlled trial.²

No additional case reports were identified describing complications following this procedure.

Appendix A includes a list of studies not included in the summary tables.

Existing reviews of the procedure

Two relevant reviews were also identified. These findings of these reports are outlined below.

Systematic review: Cochrane review *Radiofrequency denervation for neck and back pain*⁵

Literature search date: February 2002

The review reports on one study² relevant to patients with discogenic low-back pain. The other studies included in this review report on radiofrequency treatment in other indications.

Conclusions: The reviewers conclude “there is limited evidence that intradiscal radiofrequency thermocoagulation is not effective in relieving chronic discogenic low-back pain.”

HTA Review: Blue Cross Blue Shield Association *Percutaneous intradiscal radiofrequency thermocoagulation for chronic discogenic low back pain.*⁶

Literature search date: July 2002

This review reports on one relevant study² using percutaneous radiofrequency ablation for patients with discogenic low back pain. The other studies included report on electrothermal therapy.

Conclusions: The reviewers conclude “whether thermal treatment of collagen tissue brings about later changes in the disc or surrounding tissues that may be harmful has not been determined.... The evidence does not permit conclusions on whether percutaneous intradiscal radiofrequency thermocoagulation for chronic discogenic low back pain improves health outcomes or is as beneficial as established alternatives.”

Study details	Key efficacy findings	Key safety findings	Comments																																																
<p>Barendse, van Den Berg, Kessels, Weber, & van Kleef (2001)²</p> <p>Randomised controlled trial</p> <p>July 1994–September 1996.</p> <p>University Hospital Maastricht Netherlands</p> <ul style="list-style-type: none"> 13 lesion group: RF current applied 15 sham group: no RF current applied <p>Follow up: 8 weeks</p>	<p>Outcomes reported: pain, functional improvement (disability)</p> <p>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</p> <p>Authors state that only “2 successes in the sham group and 1 in the lesion group”</p> <p>Mean Pain Visual Analogue (VAS) (0-10), 8-week follow up VAS measured for 4 days and min and max recorded.</p> <table border="1"> <thead> <tr> <th>RF Group</th> <th>Sham group</th> <th>Difference</th> </tr> </thead> <tbody> <tr> <td>-1.14</td> <td>-0.61</td> <td>1.25 (-0.55–3.06)</td> </tr> </tbody> </table> <p>Change in global perceived effect (-3 worst to +3 best) 8-week follow up</p> <table border="1"> <thead> <tr> <th>RF Group</th> <th>Sham group</th> <th>Difference</th> </tr> </thead> <tbody> <tr> <td>0.21</td> <td>0.09</td> <td>-0.18 (-1.28–0.91)</td> </tr> </tbody> </table> <p>Function improvement (Oswestry Disability Scale: ODS)</p> <table border="1"> <thead> <tr> <th>RF Group</th> <th>Sham group</th> <th>Difference</th> </tr> </thead> <tbody> <tr> <td>-4.93</td> <td>-2.62</td> <td>3.28 (-7.54–14.11)</td> </tr> </tbody> </table> <p>No significant differences reported for secondary outcomes</p>	RF Group	Sham group	Difference	-1.14	-0.61	1.25 (-0.55–3.06)	RF Group	Sham group	Difference	0.21	0.09	-0.18 (-1.28–0.91)	RF Group	Sham group	Difference	-4.93	-2.62	3.28 (-7.54–14.11)	<p>Complications:</p> <p>The authors report that there were no complications reported during or after the procedure.</p>	<p>Double-blind.</p> <p>From 195 patients only 28 patients were found to be eligible (after discography).</p> <p>Electrode tip for placed in the centre of the nucleus 90 seconds at 70°C, slow decrease to 50-52°C.</p> <p>Short-term follow up. The number of dropouts remained unclear.</p> <p>Limited information on outcomes – unclear whether any losses to follow up.</p>																														
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<p>Ercelen, B (2003)³</p> <p>Uncontrolled</p> <p>January 2000–March 2001.</p> <p>Study is a randomised controlled trial of two different time modalities – but for purpose of efficacy defined as an uncontrolled study.</p> <p>Patients were treated with 120 seconds or 360 seconds at 80°C</p> <ul style="list-style-type: none"> Group A: 19 patients, mean age 39.05 years Group B: 18 patients, mean age: 38.5 years 	<p>Outcomes reported: pain, functional improvement (disability)</p> <p>Pain (Visual Analogue Scale[VAS]: 1–10 where 10 is the worst)</p> <table border="1"> <thead> <tr> <th rowspan="2">Time</th> <th colspan="2">Group A</th> <th colspan="2">Group B</th> </tr> <tr> <th>Mean</th> <th>% improve</th> <th>Mean</th> <th>% improve</th> </tr> </thead> <tbody> <tr> <td>Pre</td> <td>6.73 ±1.55</td> <td></td> <td>6.27 ±1.31</td> <td></td> </tr> <tr> <td>1 month</td> <td>3.36 ±0.89</td> <td>46.66</td> <td>3.33 ±0.97</td> <td>46.88</td> </tr> <tr> <td>2 month</td> <td>5.26 ±2.40</td> <td>21.84</td> <td>4.94 ±2.36</td> <td>21.21</td> </tr> <tr> <td>3 month</td> <td>5.31 ±2.35</td> <td>21.09</td> <td>5.00 ±2.61</td> <td>20.25</td> </tr> <tr> <td>6 month</td> <td>5.42 ±2.43</td> <td>19.46</td> <td>4.83 ±2.14</td> <td>22.96</td> </tr> </tbody> </table> <p>Function improvement (Oswestry Disability Scale: ODS)</p> <table border="1"> <thead> <tr> <th rowspan="2">Time</th> <th>Group A</th> <th>Group B</th> </tr> <tr> <th>ODS%</th> <th>ODS%</th> </tr> </thead> <tbody> <tr> <td>Pre</td> <td>42.4 ±9.3</td> <td>41.9 ±10.2</td> </tr> <tr> <td>1 month</td> <td>26.3 ±10.9</td> <td>24.1 ±12.1</td> </tr> <tr> <td>6 month</td> <td>38.8 ±14.4</td> <td>37.6 ±13.9</td> </tr> </tbody> </table>	Time	Group A		Group B		Mean	% improve	Mean	% improve	Pre	6.73 ±1.55		6.27 ±1.31		1 month	3.36 ±0.89	46.66	3.33 ±0.97	46.88	2 month	5.26 ±2.40	21.84	4.94 ±2.36	21.21	3 month	5.31 ±2.35	21.09	5.00 ±2.61	20.25	6 month	5.42 ±2.43	19.46	4.83 ±2.14	22.96	Time	Group A	Group B	ODS%	ODS%	Pre	42.4 ±9.3	41.9 ±10.2	1 month	26.3 ±10.9	24.1 ±12.1	6 month	38.8 ±14.4	37.6 ±13.9	<p>Complications:</p> <p>The authors made no statements regarding safety in the report.</p>	<p>Randomised by computer.</p> <p>Unclear how patients were selected.</p> <p>From 60 selected patients only 39 patients were found to be eligible (after discography).</p> <p>Two patients were excluded from the study: one who had discitis and another who did not return for follow up.</p> <p>VAS assessed by a pain nurse.</p> <p>ODS – questionnaire containing 10 items designed to measure activities of daily life.</p>
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Study details	Key efficacy findings	Key safety findings	Comments
Follow up: 6 months	Authors report that there were no statistical differences between the final (6 months) and the pre-treatment VAS and ODS values in both groups.		
<p>Van Kleef et al. (1996) 4 case series</p> <p>University Hospital Maastricht Netherlands</p> <p>39 consecutive patients Minimum of 12 months low back pain.</p> <p>90 second 70°C lesion.</p> <p>19 had treatment previously with surgery.</p> <p>Follow up: 8 weeks and 16 months (mean)</p>	<p>Outcomes reported: pain</p> <p>Pain (4 point Likert Scale)</p> <p>21/39 patients (54%) reported an adequate reduction in pain at 8 weeks follow-up (7 previous operation [37%], 14 no operation [70%])</p> <p>16/39 patients (41%) reported reduction in pain at 16 months (5 previous operation [26%], 11 no operation [55%])</p>	<p>Complications:</p> <p>Two reports of herniation but unclear whether associated with procedure.</p>	<p>Preliminary report of later reference. (2)</p> <p>Unclear on the consecutive nature of patient selection.</p> <p>Independent person assessed outcomes.</p> <p>Limited data outcomes.</p>

Validity and generalisability of the studies

- There is limited information available on this procedure at present.
- The three studies included were small (total patients n = 89). Therefore it is unlikely that a clinically significant result could be detected.
- Only one study followed patients for longer than 12 months. This is important because the efficacy of the procedure seems to decrease with time.
- The primary end point in the studies is pain relief. Given the lack of comparative data it is difficult to determine what influence the placebo effect has on reported outcomes. However, all three studies did use an independent/blinded person to measure pain.
- Similarly, the lack of comparative data makes it difficult to distinguish between treatment effect and the natural history of this disease.
- Controlled trials are the ideal study design for this procedure, given these limitations. The one randomised controlled trial on this procedure was small (results were reported with wide confidence intervals) and had a follow up of 8 weeks.
- Although selection of patients was identical in two of the studies,^{2,4} the authors note the difficulty of relying on analgesic and provocative discography to diagnose discogenic pain.
- In one of the studies³ the temperature applied was higher and the duration of heating was longer than in the other two studies – it is unclear what impact this has on the generalisability of the results.
- Limited safety data is reported in the studies.

Specialist Advisor's opinions

Specialist advice was sought from consultants who have been nominated or ratified by their Specialist Society or Royal College.

- The procedure is relevant to radiologists, orthopaedic surgeons and those versed in interventional pain techniques.
- Only skilled clinicians should undertake the procedure.
- There is some debate as to the efficacy of this procedure.
- There is limited evidence.

References

- 1 Wetzel FT, McNally TA. New directions and interventions: Intradiscal electrothermal annuloplasty to treat chronic discogenic low back pain. *Current Opinion in Orthopedics* 2002; 13(3):172-7.
- 2 Barendse GA, van Den Berg SG, Kessels AH, Weber WE, et al. Randomized controlled trial of percutaneous intradiscal radiofrequency thermocoagulation for chronic discogenic back pain: lack of effect from a 90-second 70°C lesion. *Spine* 2001; 26(3):287-92.
- 3 Ercelen O, Bulutcu E, lu T, Sasani M, et al. Radiofrequency lesioning using two different time modalities for the treatment of lumbar discogenic pain: a randomized trial. *Spine* 2003; 28(17):1922-7.

- 4 van Kleef M, Barendse GAM, Wilmink JT, Lousberg R, et al. Percutaneous intradiscal radio-frequency thermocoagulation in chronic non-specific low back pain. *Pain Clinic* 1996; 9(3):259-68.
- 5 Niemisto L. Radiofrequency denervation for neck and back pain. A systematic review of randomized controlled trials. *Cochrane Database of Systematic Reviews* 2003; 1.
- 6 Blue Cross Blue Shield Association. Percutaneous intradiscal radiofrequency thermocoagulation for chronic discogenic low back pain. 17 (11). 2002. Technology Evaluation Centre Assessment Report.
- 7 Scholl BM, Theiss SM, Lopez-Ben R, Kraft M. Vertebral osteonecrosis related to intradiscal electrothermal therapy: a case report. *Spine* 2003; 28(9):E161-4.
- 8 Ackerman III WE. Cauda equina syndrome after intradiscal electrothermal therapy. *Reg Anesth Pain Med* 2002; 27(6):622.
- 9 Djurasovic M, Glassman SD, Dimar JR, Johnson JR. Vertebral osteonecrosis associated with the use of intradiscal electrothermal therapy: a case report. *Spine* 2002; 27(13):E325-8.
- 10 Hsia AW, Isaac K, Katz JS. Cauda equina syndrome from intradiscal electrothermal therapy. *Neurology* 2000; 55(2):320.

Appendix A: Additional references not included in the summary table

Study details	Patients/ follow up	Comments
Troussier B, Lebase JF, Chiroseel JP, Peoc'h M, et al. Percutaneous intradiscal radio-frequency thermocoagulation – a cadaveric study. <i>Spine</i> 1995; 20: 1713–8		Cadaveric study

Appendix B: Literature search

The following search strategy was used to identify papers in Medline. A similar strategy was used to identify papers in EMBASE, Current Contents, PredMedline and all EMB databases.

For all other databases a simple search strategy using the key words in the title was employed.

	Search History
1	intradiscal.mp.
2	exp Catheter Ablation/
3	thermocoagulation.mp. or *Electrocoagulation/
4	Electrothermal Therapy.mp.
5	Electrothermal Anuloplasty.mp.
6	intradiscal adj2 radiofrequency
7	PIRFT.tw
8	or/2-7
9	exp Low Back Pain/
10	exp Intervertebral Disk Displacement/
11	1 and 2
12	9 or 10
13	8 and 12
14	11 or 13