

NATIONAL INSTITUTE FOR CLINICAL EXCELLENCE

INTERVENTIONAL PROCEDURES PROGRAMME

**Interventional procedure overview of
percutaneous intradiscal thermocoagulation for lower back pain**

Introduction

This overview has been prepared to assist members of the Interventional Procedures Advisory Committee 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 in April 2003. It is based on an earlier overview presented to the committee on Intradiscal Electrothermal Therapy.

Procedure names

Intradiscal Electrothermal Annuloplasty (IDETA)
Intradiscal electrothermal anuloplasty (IDTA)
Intradiscal Electrothermal Therapy (IDET)
Intradiscal Electroannuloplasty (IDEA)
Percutaneous Intradiscal Radiofrequency Thermocoagulation (PIRFT)

Procedure number

181

Specialty society

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

Indication(s)

Chronic back pain is common condition that affects a consideration 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 pain ^[1].

Current Treatment 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 program. Patients who fail to respond to this regime then have the choice to continue with conservative management or to undergo 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 thermocoagulation is a procedure that facilitates 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 lightly sedated and local anaesthetic is applied to the skin above the affected disc. Under fluoroscopic guidance, a needle is inserted into the disc to be treated.

The electrode or flexible catheter is then introduced into the annulus of the disc. Within the literature several variations are described regarding the placement of this electrode or flexible catheter and the placement would seem to be dependent on the device used ^[2].

The most commonly reported placement is the introduction of the flexible catheter into the nucleus which then curls around the back of the disc.

The electrode or flexible catheter is then slowly heated, ranging from 50 –90° C for a short period (again depending on the device used).

Efficacy

- Based on the evidence identified the benefits of intradiscal therapy appeared to be in respect to pain relief and restoration of function (e.g. return to work, increased sitting tolerance). The lack of published comparative data made it difficult to determine what influence the placebo effect had on reported outcomes. Return to work dates should also be viewed with some caution given the patient population included in the studies.
- Specialist Advisors were divided about the benefits of this procedure. Some Advisors felt that while short-term results were promising, long-term results were still unknown. Other Advisors believed that the procedure is ineffective and might not be of benefit to patients.

Safety

- Adverse events associated with intradiscal therapy appeared to be infrequent. None of the studies identified reported complications as a result of this procedure. It is difficult to know whether this is because complications are uncommon or whether complications were not systematically investigated in these studies.

- From the narrative literature on this procedure potential complications from intradiscal therapy include nerve injury, infection, bleeding and burns ^[3]. There has also been one case report of cauda equina and vertebral osteonecrosis due to intradiscal electrothermal therapy ^[4;5].
- Specialist Advisors did not report any particular safety concerns, though persisting pain, puncture of dura and bowel, nerve root damage and infection were noted as potential complications of intradiscal therapy.

Literature review

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 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 comparative studies. Abstracts were excluded where no clinical outcomes were reported; the paper was a review, editorial, technical or animal study. Case reports were excluded Case Series with less than 10 patients were excluded Conference abstracts were also excluded due to the difficulty in appraising methodology.
Patient	Patients with lower back pain
Intervention/test	Percutaneous intradiscal thermocoagulation
Outcome	Articles were retrieved if the abstract contained information relevant to the safety and/or efficacy
Language	Non-english language articles will be excluded unless they are thought to add substantively to the English language evidence base.

List of studies included in the overview

Three relevant health technology assessments (HTAs) were identified on the above procedure. The three assessments included different evidence due to differing inclusion criteria (Table 2). This overview summaries a selection of the published evidence on percutaneous intradiscal thermocoagulation for lower back pain. Emphasis was placed on identifying good quality comparative studies.

Table 2 List of studies identified on percutaneous intradiscal thermocoagulation for lower back pain

First author (year)	No of Pts	Study Design	IPAC Overview	Blue Cross Review	MSAC Review	ASERNIP-S
Barendse et al (2001) ^[6]	28	Double blind placebo randomized trial	X	X		
Pauza et al (2002) ^[7]	63	Double blind placebo randomised controlled trial (unpublished)		X ^a	X ^a	X
Karasek and Bogduk (2000) ^[8]	53	Prospective quasi controlled study	X	X	X	X
Derby et al (2000) ^[9]	32	Prospective Consecutive Case Series	X	X	X	X
Singh (2000) ^[10]	21	Consecutive Case Series		X	X	X
Saal and Saal (2000b) ^[11]	25	Consecutive Case Series		X	X	X
Saal and Saal (2000a) Saal and Saal (2002b) ^{[12] [13]}	58	Consecutive Case Series	X	X	X	X
Endres, Fiedler and Larson (2002) ^[14]	48	Retrospective uncontrolled study			X	
Thompson and Eckel (2001) ^[15]	100	Registry (n=211 for 12 months) (unpublished)		X ^a		X
Totta (2001) ^[16]	400	Registry (unpublished)		X ^a		
Saal et al. (2001) ^[17]	167	Multi-centre study (unpublished)		X ^a		X
Carragee, Khurana & Alamin (2001) ^[18]	50	Historical Control (unpublished)		X ^a		
Spruit & Jacobs (2002) ^[19]	20	Prospective Case Series ^b				
Lutz, Lutz & Cooke (2003) ^[20]	33	Prospective Case Series ^b	X			
Van Kleef et al. 1996 ^[21]	39	Prospective Case Series ^b	X			
Welch, Gerszten & McGrath (2001) ^[22]	23	Prospective Case Series ^b				
McGrath (2001) ^[23]						
Narvani et al. (2003) ^[24]	10	Prospective Case Series ^b				

^a mentioned in Appendix not included in the results section (unpublished studies were excluded from analysis)
^b Additional studies identified in literature review

Authors, date, location, number of patients, length of follow-up, selection criteria	Key efficacy findings	Key safety findings	Comments
<i>Randomised Controlled Trial</i>			
Barendse, van Den Berg, Kessels, Weber, & van Kleef (2001) ^[6]	The treatment was considered a success if patients had a two-point reduction on the VAS scale and at > a 50% pain reduction on global perceived effect	There were no complications reported during or after the procedures.	Electrode tip for placed in the centre of the nucleus 90 seconds at 70°C, slow decrease to 50-52°C
Radionics	Authors state that only '2 successes in the sham group and 1 in the lesion group'		Short-term follow-up. The number of drop-outs remained unclear
13 lesion group: RF current applied 15 sham group: no RF current applied	Mean Pain Visual Analogue, 8 week follow-up RF Group Sham Group Difference -1.14 -0.61 1.25 (not significant)		
Follow-up 8 weeks	Change in Global perceived effect 8 week follow up RF Group Shame Group Difference 0.21 0.09 -0.18 (not significant)		
University Hospital Maastricht Netherlands	No significant differences reported for secondary outcomes		
<i>Non-randomised comparative studies</i>			
Karasek & Bogduk (2000) ^[8] USA	Pain	Not stated	Control group consisted of patients whose insurance company refused to reimburse.
SpineCATH	Mean Pain Visual Analogue, 8 week follow-up IDET Control Group Baseline 8 (7-9) 8 (5-8) 3 months 4 (1-5) 8 (7-8) 6 months 3 (1-6) 12 months 3 (1-7)		Authors stated that control group did not complete full follow-up
36 patients IDET, 17 patients control (rehabilitation).	Improvement <u>Control</u> – 3 months; 1/17 (6%) dramatically improved, 3/17 (18%) modestly improved, 4/17 (24%) no improvement, 9/17 (53%) deteriorated.		Thermal electrode was navigated within the annulus of the disc rather than intradisically
<i>Follow-up:</i> 12 months	<u>IDET</u> – 4/36 (11%) no appreciable relief, 32/36 (89%) obtained varying degrees of relief		Claim that reduction in pain and return to work should be considered a success
<i>Selection criteria:</i> 3 months who underwent discography, unresponsive to conservative management, No evidence disc prolapse, CT discography	Return to work <u>IDET</u> – 8/15 patients not working had returned to work at 6 month, by 12months 9/15 patients. All who were working before procedure continued to work		

Study details	Key efficacy findings	Key safety findings	Appraisal/Comments
<i>Case series</i>			
<p>Saal & Saal (2000a) (2002b) ^[12] SpineCATH</p> <p>58 patients</p> <p><i>Follow-up:</i> minimum 2 years (mean 28 months)</p> <p>30 (48%) of patients treated as a single disc level <i>Selection criteria:</i> Pain > 6 months No improvement following conservative management, normal neurological findings, negative straight leg raising results, negative MRI scan</p>	<p>Mean Pain Visual Analogue Mean ± SD reduction in 10 point pain scale Baseline 6.6 ± 1.9, at minimum 24-month follow-up 3.4 ± 2.0 P<0.01</p> <p>Return to work, all patients 37/38 (97%) of privately paying and 17/20 (83%) of workers compensation patients returned to work</p> <p>SF-36 all patients, 24 month follow-up Physical function subscale, 100-point scale, mean ± SD Baseline 40.5 ± 25.0, 24 months 71.8 ± 22.8 p<0.0001</p> <p>Bodily pain subscale 100-point scale, mean ± SD Baseline 29.8 ± 16.0 24 months 51.7 ± 22.6 p<0.0001</p>	<p>No IDET-treated patient in this study had a complication reported. Transient pain</p>	<p>Potential for bias: 4/58 (7%) patients lost to follow-up. Small study numbers. Saal and Saal are the inventors of the SpineCath catheter and are also cofounders of the manufacturing company Oratec Interventions Inc</p> <p><i>Outcome measures and their validity:</i> Validation of VAS not stated.</p>
<p>Van Kleef et al. (1996) ^[21]</p> <p>Radionics 39 consecutive patients University Hospital Maastricht Netherlands</p> <p>Follow-up: 8 weeks and 16 months</p>	<p>Pain (4 point Likert Scale) 21/39 patients reported an adequate reduction in pain at 8 weeks follow-up 17/39 patients reported reduction in pain at 16 months</p>	<p>No complications were reported.</p>	<p>Preliminary report of later reference^[6] Limited data outcomes</p>
<p>Lutz, Lutz & Cooke (2003) ^[20]</p> <p>SpineCATH</p> <p>33 patients Patients recruited from a academic-affiliated private physiatric practice of one of the authors</p> <p>16 (52%) of patients treated as a single disc level</p>	<p>The treatment was considered a success if patients had a two-point reduction on the VAS and Roland Morris Disability Questionnaire (RMDQ) and a positive North American Spine Society (NASS) response.</p> <p>Mean Pain Visual Analogue Scale (VAS) Mean ± SD reduction in 10 point pain scale Baseline 7.5 follow-up 3.9. Mean change was 3.9 P<0.001</p> <p>Mean Pain Visual Analogue – Lower Extremity (VAS- LE) Mean ± SD reduction in 10 point pain scale Baseline 5.7 follow-up 2.0. Mean change was 3.7 P<0.001</p> <p>Overall VAS scores improved by ≥ 3 in 23/33 (69.6%) of cases</p>	<p>No complications reported of dural puncture or tear, infection or nerve injury were reported</p>	<p>15 were workers compensation or no-fault cases Unclear about return to work for people on workers compensation</p>

Follow-up: mean 15 months

Mean Roland Morris Disability Questionnaire (RMDQ)
Mean Baseline 13.9 follow-up 6.6 Mean change was 7.3 P<0.001

NASS Patient satisfaction, all patients, 12 month follow-up
22/33 (77%) of patients stated the procedure met their expectations and they would undergo it again for the same outcome.

Return to work, all patients
4/8 (50%) of patients who were not working returned to work

Derby, Eek, Chen, O'Neill, & Ryan (2000)
^[9]

Mean Pain Visual Analogue Scale (VAS)
Mean \pm SD improvement from baseline 1.8 \pm 2.4

No complications reported
Transient pain

Authors note that report is a pilot study
Variable electrode heating regime was also used on the first few patients

SpineCATH

Mean Roland Morris Disability Questionnaire (RMDQ)
Improvement from baseline 4.0 \pm 4.8
Patients improved in sitting (41%), standing (50%), walking (45%) and sleeping (41%)

32 patients
California US (single Centre)

Patient satisfaction, all patients, 12 month follow-up
78% of patients stated the procedure met their expectations and they would undergo it again for the same outcome.

Follow-up: 12 months

21 (66%) of patients treated as a single disc level

Self reported overall activity level compared with before the procedure, 53% patients better or much better, 34.4% same, 9.4% worse, 3.1% much worse.

Selection criteria:

Pain > 6 months
No improvement following conservative management, normal neurological findings, negative straight leg raising results, negative MRI scan

Summary Points

- There are three known devices that permit the delivery of heat to the intervertebral disc.
- In this overview evidence is presented on two of these devices.
- This decision was made based on the fact that the devices are intended to be used for the same purpose and that the slight variations in technique did not constitute a new procedure.
- The two devices differ primarily in respect to the temperature applied to the intervertebral disc and the exact technique of inserting the electrode or flexible catheter into the disc. However in the paper by Karasek and Bogduk (2000) ^[8] which used the SpineCATH device, the method of insertion differed to the other papers reporting on the same device suggesting that alternative techniques are continuing to be explored and that this difference may not be of great import.
- For one device (Radionics) there is a published RCT ^[6] and a case series paper ^[21]. The same group of investigators wrote both these papers.
- On the other device (Spine CATH) there is one non randomised comparative study ^[8] and several small case series papers, a number of which are not reported on in this overview.
- It has also been reported that there are a number of ongoing trials on the SpineCATH device.

Validity and generalisability of results

- 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.
- Similarly the lack of comparative data makes it difficult to distinguish between treatment effect and the natural history of this disease.
- As previously mentioned, the temperature applied to the intervertebral disc differed in respect to the two devices. This has the potential to limit the comparability and generalisability of the results.
- In respect to one of the devices a non-controlled study indicated that intradiscal therapy appeared to be of some benefit in the reduction of pain and warranted a prospective randomised controlled trial. In the subsequent randomised controlled trial it was concluded that the current technique was not sufficient to treat discogenic pain. This

highlights the importance of having evidence from good quality trials in respect to this procedure.

- Patients were typically a highly selected group. In the papers by Saal et al quite specific inclusion and exclusion criteria were applied to study participants. Most of the other papers comment that there should be rigorous selection of patients.
- Selection bias would also seem to be an issue. For example in the study by Karasek & Bogduk (2000)^[8] the control group consisted of patients whose insurance company refused to reimburse for the treatment.
- The inclusion of workers compensation cases in the studies may have an influence of the reported results, particularly when interpreting return to work rates.
- Much of the literature is US based and set in private clinics. This has the potential to limit the generalisability of the findings.
- Limited safety data is reported in the studies.

Specialist advisor's opinion / advisors' opinions

- It was noted that skilled clinicians should only undertake the procedure.
- The procedure is relevant to radiologists, orthopaedic surgeons and those versed in interventional pain techniques.
- There is some debate as to the efficacy of this procedure.
- The procedure could potentially have an impact on the way discogenic low back pain is managed.
- One device has more evidence and appears to be better.
- Short-term results appear to be promising.
- A number of trials are underway.

Issues for consideration by IPAC

- There are a number of unpublished studies on this procedure, including results from a randomised controlled trial. The results from unpublished studies were not included in this overview.

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