Randomized Controlled Trial of Percutaneous Intradiscal Radiofrequency Thermocoagulation for Chronic Discogenic Back Pain

Lack of Effect From a 90-Second 70 C Lesion

Gerard A.M. Barendse, MD, Suzanne G.M. van den Berg, MA, Alfons H.F. Kessels, MD, Wim E.J. Weber, MD, PhD, and Maarten van Kleef, MD, PhD

Study Design. A prospective double-blind randomized trial in 28 patients.

Objectives. To assess the clinical effect of percutaneous intradiscal radiofrequency thermocoagulation for reducing pain, functional disability, and physical impairment in patients with chronic discogenic low back pain.

Summary of Background Data. Chronic discogenic low back pain is a challenging problem in western countries. A treatment option is radiofrequency heating of the affected disc. Its clinical efficacy has never been formally tested in a controlled trial.

Methods. Twenty-eight patients with a history of at least 1 year of chronic low back pain were selected on the basis of a diagnostic anesthetization of the lower intervertebral discs. Only patients with one putative painful level were selected and randomly assigned to one of two treatment groups. Each patient in the radiofrequency treatment group (n = 13) received a 90-second 70 C lesion of the intervertebral disc. Patients in the control group (n = 15) underwent the same procedure, but without use of radiofrequency current. Both the treating physician and the patients were blinded to the group assignment. Before treatment, physical impairment, rating of pain, the degree of disability, and quality of life were assessed by a blinded investigator.

Results. Eight weeks after treatment, there was one success in the radiofrequency group (n = 13) and two in the control group (n = 15). The adjusted and unadjusted odds ratio was 0.5 and 1.1, respectively (not significant).

Conclusions. Percutaneous intradiscal radiofrequency thermocoagulation (90 seconds, 70 C) is not effective in reducing chronic discogenic low back pain. [Key words: discogenic low back pain, percutaneous radiofrequency thermocoagulation, randomized trial] Spine 2001;26:287–292

Low back pain affects a large number of the normal adult population at some point in their lives. In the majority of patients, pain improves spontaneously within several months. In a substantial proportion of patients, even after specific causes of low back pain, such as spondylolisthesis, herniated discs, osteoporosis, spinal stenosis, fractures, and tumors have been excluded, the pain becomes chronic. A recent study reported chronic pain in 72% and serious disability in 14% of patients 1 year after the first onset of acute low back pain.34

There is increasing evidence that in a large percentage of patients, a degenerated intervertebral disc may be the source of chronic low back pain.4,5,23 Clinically, discogenic back pain is supposed to be nonradicular pain in the absence of spinal deformity, instability, and neural tension signs.10 The diagnosis can be confirmed by means of provocative or analgesic discography, although there is a growing concern about the validity of discography as a diagnostic tool.6 The natural history of this disorder is not known. Because the pathogenesis of this syndrome remains unclear, therapy aimed at reducing pain must be symptomatic.

Invasive techniques have been developed to modulate neural transmission of nociceptive stimuli derived from structures in the lumbar region.2,12,18,24,30,31 Radiofrequency (RF) lesions targeted at the medial branches of the dorsal rami of the segmental nerves of L3, L4, and L5 have been shown to be effective in reducing pain from lumbar facet joints.12,30 Reducing nociceptive input from a painful intervertebral disc is different in this respect. The innervation of the disc is complex. It has been demonstrated that intervertebral discs are surrounded by a continuous network of nerve fibers innervating the outer and inner anulus fibrosis.1,7,8 This network of fibers is connected with Von Luschka’s recurrent nerve on the posterior side of the disc. The network of nerve fibers on the lateral and ventral side of the disc is connected with the segmental nerves, the rami communicants, and the sympathetic fibers.Selective denervation of these nerves is not possible because of their complex anatomy. It has been suggested that percutaneous intradiscal radiofrequency thermocoagulation (PIRFT) might be used to reduce nociceptive input from the intervertebral disc.25 With this technique, an RF-lesion is made in the center of the disc using the disc material as vehicle for heat. It has been speculated that the antinociceptive effect of PIRFT is caused by a temperature increase of the free nerve endings in the outer anulus fibrosis.

A prospective study performed by our group suggested the effectiveness of PIRFT in 70% of patients with discogenic low back pain at 8 weeks of follow-up evaluation.31 Also, at a longer follow-up evaluation (mean, 16
months), 55% of these patients reported pain relief. For patients who had undergone a disc operation before PIRFT, the pain relief was 37% at 8 weeks and 27% on a long-term basis.

In the present study, the hypothesis that PIRFT is more effective than a placebo procedure in reducing pain, functional disability, and physical impairment in patients with discogenic low back pain was tested. A double-blind, randomized, controlled trial was performed to examine the results of PIRFT for discogenic low back pain using pain scores, disability, physical impairment, and quality of life as outcome measures.

Methods

Patient Selection. The study was conducted in the Pain Management and Research Center of the University Hospital Maastricht in the Netherlands. It was approved by the University Hospital Ethics Review Board, and all patients gave written informed consent before entering the trial. The study group was recruited from patients with chronic nonspecific low back pain for more than 1 year. All patients had been referred by various medical specialists (neurologists, neurosurgeons, and orthopedic surgeons) and had had extensive diagnostic assessment. They had a history of unsuccessful conservative treatment involving nonopioid analgesics, physiotherapy, and transcutaneous electrical nerve stimulation (TENS). Patients were examined by a staff neurologist (WW) to exclude clinical radiculopathies and other neurologic abnormalities. Patients younger than 30 years of age and older than the age of 65 years were excluded from the study. Other exclusion criteria were: spinal stenosis, spondylolisthesis, multilevel burnt out disc lesions, coagulation disturbances, pregnancy, and initial “high” visual analogue score less than 5.0. Patients with diabetes mellitus and patients with more than one pain syndrome were also excluded. Patients underwent a diagnostic block of the median branch of the primary dorsal rami of the segmental nerves of L3, L4, and L5 first to exclude zygapophysial joint pain. Patients with a positive response were selected for another trial and were excluded from this study.

The remaining patients were selected for this study by means of an analgesic discography at L4–L5 and L5–S1. These blocks were performed in different sessions. Only patients with at least 50% temporary pain relief 30 minutes after an analgesic discography were selected for the study. Patients with multilevel (two or more) discogenic pain also were excluded.

Diagnostic Anesthetization of the Lumbar Disc. With the patient prone on the operating table, the C-arm was adjusted to an approximately 45° oblique projection. The position then was adjusted further along the horizontal axis of the C-arm until there were no more double contours of the endplates of the adjoining lumbar vertebrae (at L5–S1, this may result in considerable obliqueness in two planes). An entry point was marked overlying the center of the intervertebral disc, just lateral to the facetal joint. A 22-gauge SMK C15 cannula (Radiomics, Burlington, MA, USA) then was introduced using a so-called tunnel vision fluoroscopic technique (Figure 1A). It is important that the cannula is directed as far medially as possible, because this ensures passage medial to the exiting segmental nerve root. The cannula was advanced very slowly when in the vicinity of the nerve root. When the patient reported par-

Treatment Allocation and Evaluation. The trial was a double-blind, randomized study. Patients who fulfilled the study criteria and who consented to participate were randomized to two treatment groups by computer program through a disinterested third party (AK). One group (lesion group) was treated with a 90-second 70 C lesion, whereas the control group (sham group) was treated in an identical way, but no RF current was applied. Treating physicians left the operating room after ensuring that the electrode was properly positioned (after test stimulation). The radiofrequency current was applied by a disinterested third-party physician after opening of the randomization envelope. Data were obtained by an investigator (SvdB) blinded for the allocation of the patient. Rating of pain was assessed by averaging three daily measurements of the visual analogue scale (VAS), ranging from 0–10 cm, for 4 days. During these 4 days, the minimum and maximum scores were reported as VAS-low and VAS-high, respectively. Global perceived effect was scored by the patient on a 7-point scale (ranging from much worse, -3; to 0, no change; to total pain relief, +3). Before treatment, there was an objective clinical evaluation of physical impairment. Scores obtained from patients ranged from 0 (indicating no impairment) to 7 (maximum impairment). Analgesic intake, predominantly non-steroidal anti-inflammatory drugs, was monitored simultaneously with the VAS scores in the same diary.
Disability was assessed by the Oswestry disability scale, which is a questionnaire containing 10 items on limitations in various daily activities. The Dartmouth COOP Functional Health Assessment Charts/World Organization of Primary Care Physicians (COOP/WONCA) chart, a quality-of-life questionnaire divided into seven items to be scored on a 5-point scale, also was used.

The patients were assessed before treatment and 8 weeks after treatment. Only for patients with at least a 2-point reduction on the VAS scale (VAS-mean or VAS-high) and at least a 50% pain reduction on global perceived effect was the treatment scored as a success. In all other patients, the treatment was classified as a failure. Success patients also were assessed at 3, 6, and 12 months. Success patients who showed at least a 2-point reduction on the VAS on each follow-up measurement remained in the study. Each treatment with less than a 2-point reduction on the VAS was scored as a failure, and the patient was taken out of the study for ethical reasons. These patients subsequently were offered different treatment options (e.g., pain management program or clinical rehabilitation).

**Statistical Analysis.** The primary outcome was the percentage of successes at 8 weeks. To compare the success rates between the lesion and sham groups, odds ratios (OR) and their 90% confidence interval (CI) were calculated with a logistic regression model. All analyses also were performed adjusted for gender, age, duration of pain before treatment, the average pretreatment pain intensity, and Likert scores after diagnostic nerve blocks. As secondary outcomes, the differences between the sham and lesion group changes in VAS pain intensity scores (impairment according to Waddell), Oswestry disability scale, use of analgesic tablets, and COOP/WONCA quality of life and their 90% confidence intervals (CI) were calculated. This was performed unadjusted by using Student’s t test and adjusted by using a linear regression model with the same covariants as mentioned.

**Figure 1.** A, Oblique view of L4 and L5. The cannula is inserted just lateral of the processus articularis superior of L5. B, Anteroposterior view of L4–L5. The cannula is inserted until the tip is in the center of the disc. C, Lateral view of L4–L5.
Table 1. Pretreatment Characteristics by Allocated Treatment

<table>
<thead>
<tr>
<th>Variables</th>
<th>Sham Group (n = 15)</th>
<th>Lesion Group (n = 13)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sex</td>
<td>5 M, 10 F</td>
<td>5 M, 8 F</td>
</tr>
<tr>
<td>Age, mean (SD) (yr)</td>
<td>45.2 (8.4)</td>
<td>40.8 (7.5)</td>
</tr>
<tr>
<td>Months of pain, median (range)</td>
<td>38 (10–300)</td>
<td>60 (8–204)</td>
</tr>
<tr>
<td>Pretreatment, mean (SD)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>VAS mean</td>
<td>5.5 (1.1)</td>
<td>6.5 (1.3)</td>
</tr>
<tr>
<td>VAS high</td>
<td>8.0 (1.3)</td>
<td>8.6 (1.1)</td>
</tr>
<tr>
<td>VAS low</td>
<td>2.7 (1.6)</td>
<td>4.4 (1.7)</td>
</tr>
<tr>
<td>Impairment according to Waddell, median (range)</td>
<td>3 (1–6)</td>
<td>4 (2–6)</td>
</tr>
<tr>
<td>No. of analgesic tablets per 4 days, median (range)</td>
<td>5 (0–15)</td>
<td>3 (0–19)</td>
</tr>
<tr>
<td>Oswestry Disability Scale, mean (SD)</td>
<td>40.7% (9.5)</td>
<td>43.7% (11.6)</td>
</tr>
<tr>
<td>Coop Wonca, mean (SD)</td>
<td>23.6 (2.9)</td>
<td>23.1 (4.8)</td>
</tr>
<tr>
<td>Level of discogenic pain</td>
<td></td>
<td></td>
</tr>
<tr>
<td>L4–L5</td>
<td>6</td>
<td>4</td>
</tr>
<tr>
<td>L5–S1</td>
<td>9</td>
<td>9</td>
</tr>
</tbody>
</table>

M = men; F = women. VAS = visual analogue scale.

patients in the lesion (n = 13) and the sham (n = 15) groups. There were no significant group differences in these variables. The pain duration in the lesion group was longer, and these patients scored higher on the VAS. According to Waddell’s physical impairment assessment, all patients were impaired. According to the radiographs, needle position was suboptimal in four patients (two in the lesion group and two in the sham group) at L5–S1. The temperature measured in the disc 30 seconds after the disc lesion ranged from 47 to 56 C. The anesthesia was adequate during the procedure. The patient could not determine whether he or she had received the radiofrequency or sham treatment. There were no complications during or after the procedures.

Effect of Treatment

One patient who was allocated to the sham therapy accidentally received an RF disc lesion. Intention-to-treat analyses were conducted. Analyses were performed with the data of this patient in the sham group and also in the lesion group. The results of the latter analyses are presented. Eight weeks after treatment, there were two treatment successes in the sham group and one in the lesion group (unadjusted odds ratio 0.5 with a 90% confidence interval of 0.06–4.2, and an adjusted odds ratio of 1.1 with a 90% confidence interval of 0.04–33.3).

Table 2 shows the results of the two experimental groups at 8 weeks. There also was no statistically significant difference between the two groups in the secondary outcome variables. If the misallocated patient (see above) was included in the lesion group, the adjusted change in VAS-mean increased from 0.53 to 0.60, and the adjusted odds ratio increased from 1.10 to 1.12. After 3, 6, and 12 months, the number of successes in the sham and lesion group were 2 and 1, 1 and 1, and 0 and 1, respectively. The log-rank test showed no statistically significant difference.

Discussion

This prospective randomized controlled study demonstrated that PIRFT is not better than the placebo procedure in reducing pain and disability for patients with presumed discogenic low back pain. This study involved a small number of patients with relatively wide confi-
idence intervals of changes in effect parameters. Although the theoretical probability of a beneficial effect of PIRFT still exists, the number of successes in both groups was low, and the trend of absence of effect was found in all outcome parameters. This study did not confirm the findings of the pilot study. Because selection and treatment of patients were identical in both studies, this difference in outcome probably illustrates the limitation of uncontrolled clinical studies. This negative study, however, does not refute the concept of discogenic low back pain and its treatment by intradiscal RF heating.

The prevalence of this type of chronic low back pain has been reported to be 39%. In clinical practice, both analgesic and provocative discography are used to diagnose discogenic pain. The analgesic discography was, to the authors’ knowledge, the best available tool in making the diagnosis at the time this study was designed in 1994. The limitation of provocative and analgesic discographies is that both are liable to false-positive findings of the pilot study. Because selection and treatment of patients were identical in both studies, this difference in outcome probably illustrates the limitation of uncontrolled clinical studies. This negative study, however, does not refute the concept of discogenic low back pain and its treatment by intradiscal RF heating.

The prevalence of this type of chronic low back pain has been reported to be 39%. In clinical practice, both analgesic and provocative discography are used to diagnose discogenic pain. The analgesic discography was, to the authors’ knowledge, the best available tool in making the diagnosis at the time this study was designed in 1994. The limitation of provocative and analgesic discographies is that both are liable to false-positive responses, as was convincingly shown recently. This problem is also the major limitation of this study. Recently, several publications have appeared suggesting that the effectiveness of discography for diagnosing discogenic back pain may be improved by combining the procedure with vibrator pain provocation, or the presence of high-intensity zones in the affected disc on magnetic resonance imaging (MRI). These new findings may improve the selection criteria for discogenic low back pain in the future.

In the present study, analgesic discography has been proven to be more reliable than provocative discography. Therefore, patients were selected for the present study by analgesic discography. Patients with clinically presumed discogenic low back pain were selected by means of a diagnostic anesthetization of the lower two lumbar discs. Only patients with temporary pain relief at one level were selected.

Besides improvements in the diagnosis of discogenic pain, the technique of PIRFT itself may be improved. In the present study, patients with chronic low back pain emanating from degenerative intervertebral discs were included. In degenerative and “painful” discs, it has been found that free nerve endings grow even into the inner areas of the disc—namely, deeper than the outer third of the anulus fibrosis. In these patients, however, the PIRFT at L5–S1 is more difficult for technical reasons (on this level, the iliac crest sometimes prevents adequate positioning of the needle). In four patients in the present study, two in the RF group and two in the control group, the needle position was not perfect because of the iliac crest.

Presumed pain relief after an intradiscal radiofrequency heating is based on the assumption that the procedure gives a temperature increase of the free nerve endings in the anulus fibrosis. A temperature increase in these free nerve endings above the range of 42–50 °C is supposed to be cytotoxic to nerve fibers. A recent study by Houpt et al demonstrated that, using 90-second 70 °C RF current therapy of the intervertebral disc in an experimental situation, temperature changes at distances further than 11 mm from the thermistor tip were insufficient to increase the temperature above the 42 °C needed for neuronal cell death. Although it is difficult to extrapolate data from an in vitro study, their data correlates with the present in vivo data. A study performed by Troussier et al showed that a bipolar RF electrode introduced in the intervertebral disc can destroy a portion of the nucleus pulposis in a cadaver spine when applying RF current. One could argue that a lesion of this size is required to reduce discogenic pain by blocking the release of inflammatory mediators such as phospholipase A2.

Another research group has reported that intradiscal heating with a longer duration was effective for a substantial number of patients with discogenic low back pain.

The results of the present study show that a 90-second 70 °C monopolar RF intradiscal lesion was not sufficient to treat discogenic pain. Clearly, a future trial should include more rigorous selection of patients with discogenic pain and a significantly improved technique of PIRFT.

### Key Points
- To assess the clinical effect of percutaneous intradiscal radiofrequency thermocoagulation for reducing pain, 28 patients were selected on the basis of a diagnostic anesthetization of the lower intervertebral discs.
- Each patient in the radiofrequency treatment group (n = 13) received a 90-second 70 °C lesion of the intervertebral disc; 15 control subjects underwent the same procedure without radiofrequency current.
- Eight weeks after treatment, visual analog scores for pain, global perceived effect, and the Oswestry disability scale showed no differences between the two groups.
- Percutaneous intradiscal radiofrequency is not effective in reducing chronic discogenic low back pain.

### Acknowledgment
The authors thank Mrs. P. Moonen-Florax for helpful secretarial assistance and Dr. I. Francis, consultant anesthetist, for his helpful comments on the manuscript.

### References

Address reprint requests to
Maarten van Kleef, MD
Pain Management and Research Centre
Dept. of Anesthesiology
University Hospital Maastricht
PO Box 5800
6202 AZ Maastricht
The Netherlands
E-mail mvk@sane.azm.nl