

A pilot study

Percutaneous intradiscal radio-frequency thermocoagulation in chronic non-specific low back pain

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summary

Five to 10 per cent of patients with low back pain do not respond to any kind of therapy and develop "chronic non-specific low back pain", involving serious disability. Recent studies suggest that the intervertebral disc plays an important part in low back pain, implicating the disc as a target for invasive antinociceptive therapy. A new technique, percutaneous intradiscal radio-frequency thermocoagulation (PIRFT) is described in which an RF-lesion is made in the centre of the disc, using the disc material as vehicle for heat rather than as the target of the lesion.

Twenty unoperated and 19 previously operated (for disc herniation) patients with chronic non-specific low back pain were treated with this procedure. There was an improvement of two points of a four-point scale in 70 per cent of the unoperated patients and in 37 per cent of the operated patients, 8 weeks after treatment. At the end of the follow-up (mean 16 months) these figures were 55 and 27 per cent. There were no untoward effects of the method, magnetic resonance imaging scans made before and after the procedure in 11 patients showed no signs of loss of water content of the disc after the procedure.

Key words: annulus fibrosis; radio-frequency; intervertebral disc; low back pain.

sommaire

5 à 10% des cas de douleur du dos ne réagissent à aucune thérapie et développent le syndrome de "douleur chronique non-spécifique de la région lombaire du dos", comprenant une grave infirmité. Des études récentes suggèrent que le disque intervertébral joue un rôle important dans les douleurs du dos, ce qui implique que le disque est un objectif pour les thérapies anti-nociceptive du type invasif. Une nouvelle technique, la thermocoagulation par radio-fréquence intradiscale percutanée (PIRFT) est décrite dans cet article. Une lésion-RF est effectuée dans le centre du disque, en se servant du matériel du disque comme "véhicule" pour la chaleur plutôt que de conserver le disque comme objectif en soi.

Vingt cas non-opérés et 19 cas opérés dans le passé pour une hernie du disque intervertébral, souffrant de douleur lombaire non-spécifique, furent soumis à cette

の37%に4点スケールで2点の改善が認められた。調査終了の時点で(平均16カ月)、この数字はそれぞれ55%及び27%であった。この治療法による合併症はなく、治療前後で11人に行ったMRIによると治療後椎間板の水量の減少は認められなかった。(高橋 秀則 抄)

キーワード：繊維輪；高周波；椎間板；腰痛

introduction

Low back pain affects a large majority of the normal adult population at some time in their life.¹ In about 90 per cent of the cases pain resolves spontaneously over a period of 7–12 weeks. In contrast, 5–10 per cent of patients do not respond to any kind of therapy and go on to develop “chronic non-specific low back pain”, involving serious disability.²

As the pathogenesis of the syndrome remains obscure, therapy aimed at reducing pain must be symptomatic. Invasive techniques have been developed to modulate neural transmission of stimuli derived from possibly pain-producing tissues in the lumbar region.³ Targets usually are the capsule of the lumbar facetal joints and the outer layer of the (intervertebral) annulus fibrosus, as these are richly neurally innervated and may be a source of pain.^{4,5} Radio-frequency (RF) has been used widely to produce lesions aimed at reducing nociceptive input from the lumbar facetal joint.³ Advantages include optimal controllability by a temperature monitoring electrode system⁶ and minimal patient discomfort.⁷ Moreover, an RF lesion to denervate the lumbar facet joint can be produced without risk of damage to other structures, as these joints are exclusively innervated by the medial branch of the posterior primary rami of the segmental nerves.

Reducing nociceptive input from the intervertebral disc is different in this respect. The innervation of the annulus fibrosus is complex^{8,9} and particularly the posterior part of the intervertebral disc is richly innervated by Von Luschka's recurrent nerve. This nerve cannot be lesioned selectively without serious risk of damage to the segmental nerve. Techniques have been described to reduce nociceptive input from the anterolateral and anterior part of the disc.¹⁰ During the development of similar lesioning procedures in the posterior part of the annulus fibrosus we observed that there was a number of patients with remarkable relief of pain, when in retrospect the electrode had been positioned in the nucleus pulposus and not in the annulus fibrosus as intended at that moment. It appeared that in a number of patients RF-current applied to the nucleus pulposus reduced nociceptive input from the intervertebral disc.

Herein we describe a pilot study of 39 patients with non-specific chronic low back pain treated with percutaneous intradiscal radio-frequency thermocoagulation (PIRFT), demonstrating a favourable outcome in a substantial number of patients.

patients

The study population consisted of 39 consecutive patients with a minimum of 12 months of low back pain with or without sciatica, referred to the Pain Management and Research Center of the University Hospital Maastricht by orthopaedic surgeons, neurologists and neurosurgeons. All patient had a history of unsuccessful conservative treatment involving non-opioid analgesics, physiotherapy and TENS (transcutaneous nerve stimulation). Patients under the age of 25 or over the age of 60 years were excluded. Other exclusion criteria were: presence of clinical or radiological (computerized tomography (CT)/magnetic resonance imaging (MRI)) 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; presence of psychological problems as identified by the SCL-90.^{11,12}

Before entering the study, patients underwent diagnostic blocks (using a local anaesthetic solution) of the dorsal rami innervating the L4/L5 and L5/S1 zygapophyseal joints. Patients with a positive diagnostic block were excluded. To investigate the possible value of discography in predicting the outcome results of the PIRFT procedure, discography was performed at the L4/5 and L5/S1 levels. During these discographies a mixture of local anaesthetic solution and contrast medium (Omnipaque 300) was injected.

methods

Diagnostic anaesthetization of the lumbar disc

With the patient prone on the operating table, the C-arm is adjusted to an approximately 45° oblique projection. The position is then further adjusted along the horizontal axis of the C-arm until there are no more double contours of the endplates of the adjoining lumbar vertebrae (at the L5–S1 level this may result in considerable obliqueness in two planes). An entry point is marked overlying the centre of the intervertebral disc, just lateral to the facet joint. A 22G SMK C15 cannula (Radionics, Burlington, MA, USA) is then introduced using a so-called tunnel vision fluoroscopic technique (Fig. 1A). It is important that the cannula is directed as far medially as possible, as 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 paraesthesiae, a slight redirection medially and caudally was made, sufficient to pass the segmental nerve root without discomfort. On entering the disc itself there was a characteristic “loss of resistance”. The projection is then checked on the transverse and anteroposterior projections and the cannula is advanced, so that its tip is in the centre of the disc (Fig. 1B, C). At the L5–S1 level this may be difficult in the case of a highly projecting iliac crest.



Figure 1A. C-arm in oblique projection, the needle is introduced using “tunnel vision” fluoroscopy.

patients with a "positive" response (i.e. "good relief" or "pain free") went on to undergo a RF-lesion procedure of the involved intervertebral disc. Two adjacent discs (L4–L5 and L5–S1) were tested at weekly intervals, unless there was complete pain relief after the first diagnostic block. If this was the case this level was selected for the RF lesion procedure of the disc.

RF lesion procedure of the disc

The technique for entering the cannula for a RF-disc procedure is identical to the diagnostic block procedure. A 20G C15 cannula with a 10 mm exposed tip is introduced again using tunnel vision fluoroscopy. With the tip of the cannula in the centre of the disc, the stylet of the cannula is replaced by RF probe (Radionics, Burlington, MA, USA). Electrical stimulation is now carried out in order to ensure that the electrode is not positioned near nerve structures. Stimulation at 2 and 50 Hz did not give a response below 2 V. A 90 s 70°C lesion was made. Pilot studies had shown that this lesion is painless and that no local anaesthetic is required. Following the lesion the tip temperature is monitored for 30 s as an indication of the extent of the lesion. There was usually a slow fall to 50–52°C over that period.

Assessment

First patient follow-up was 8 weeks after the procedure. The result was scored on the Likert Scale as indicated above. Long-term results (> 36 weeks) were collected by a disinterested third party. Results from "good" to "pain free" were interpreted as an adequate reduction of pain.

MRI studies

In 10 patients MRI had been performed before the procedure in order to exclude nerve root compression by a herniated disc. A scanning protocol (using a Philips Gyroscan T5) featuring sagittal T1, proton density and T2-weighted images was applied, followed by transverse T1-weighted slices through the lower three lumbar interspaces. In these 10 patients follow-up MRI examinations were performed, using the same scanning protocol. Time after treatment ranged from 3 to 14 months (mean 8.8 months).

results

A total of 129 diagnostic discographies were performed in 77 patients during the period of November 1992 until June 1994. In 38 patients there was no temporary relief of pain following the discography. These patients were not selected to undergo the RF-disc procedure. The remaining 39 patients were entered into the study. Nineteen patients had undergone previous disc surgery, the remaining 20 patients had not been operated upon. Table I gives patient characteristics including sex, age and duration of pain for operated and non-operated patients. In Table II the level of treatment is presented for both groups.

Twenty-one of the 39 patients subjected to a RF-disc procedure (54 per cent) reported an adequate reduction of pain at 8 weeks follow up. This percentage was 41 at the long-term follow-up (mean 16 months). In Table III and IV the reduction of pain (8 weeks and long-term) is shown for operated versus non-operated patients. At 8 weeks follow-up it was found that there were significantly more non-operated patients who reported an adequate pain reduction than operated patients ($\chi^2 = 4.31$, $P = 0.01$). At the long-term follow-up a similar result was found: there were more non-operated

Table I.

Sex, age and duration of pain

	Operated patients		Non-operated patients	
Sex	10 ♀	9 ♂	10 ♀	10 ♂
Age	m = 43.4	SD 6.9	m = 44.1	SD 6.6
Duration of pain in months	m = 100.4	SD 77.7	m = 101	SD 78.1

Table II.

Level of treatment

	Operated patients	Non-operated patients
L3-L4	1	1
L4-L5	12	10
L5-S1	6	9

Table III.

Eight-week follow-up

	Pain reduction	No pain reduction	χ^2	<i>P</i> -value
Operated	7	12	4.31	0.01
Unoperated	14	6		

Table IV.

Long-term follow-up

	Pain reduction	No pain reduction	χ^2	<i>P</i> -value
Operated	5	14	3.31	0.03
Unoperated	11	9		

patients with an adequate reduction of pain than operated patients ($\chi^2 = 3.31$, $P = 0.03$).

Retrospectively, we studied whether the result of treatment could be predicted by some other variables which were measured in the study. Success of a RF-disc procedure could not be predicted reliably by signs of discopathy on a lumbar X-ray nor by pain during forward flexion during physical examination (all $P > 0.14$). Also the number of diagnostic discographies ($\chi^2 = 0.55$), the tip temperature following the lesion ($\chi^2 = 0.62$) or the duration of pain ($\chi^2 = 0.16$) were not related to the outcome of treatment. With respect to sex there was a tendency for men to have a better result at the 8 weeks follow-up ($\chi^2 = 3.12$, $P = 0.08$, two-tailed). At the long-term follow-up, however, this tendency was less clear ($\chi^2 = 0.01$, $P = 0.9$, two-tailed). In the present study patients did not experience complications or adverse events.

Follow-up MRI studies were performed in 10 patients. In seven of these the aspect of annulus fibrosus and nucleus pulposus was unchanged at all levels. In three there was a slight decrease in water signal intensity of the nucleus pulposus at the treated level; however, in one of these a similar decrease could be seen at an untreated level. In one patient a disc herniation was seen at the treated level which had not been present immediately prior to treatment. The herniation was located contralateral to the side of disc puncture, however, and the patient had previously undergone surgery on the same disc. In another patient, treated at the L4-5 level, an L3-4 disc bulge progressed to a herniation with annular rupture. It was concluded that a significant adverse effect of the procedure on the MRI aspect of the annulus fibrosus or nucleus pulposus could not be demonstrated.

discussion

To our knowledge this is the first prospective study of PIRFT in the treatment of chronic non-specific low back pain. It appears that 54 and 41 per cent of the selected patients experience a significant decrease in pain complaints at follow-up at 8 weeks and 16 months, respectively. The 41 per cent of patients showing improvement on a long-term basis is specifically significant, as these are all patients with a chronic pain syndrome in whom all other treatment modalities have failed. These results allow two conclusions. First, chronic non-specific low back pain includes a group of patients in whom nociceptive input from a lumbar intervertebral disc contributes significantly to the syndrome. This accords with recent studies suggesting that the intervertebral disc plays an important part in low back pain.^{8,13} Secondly, a PIRFT procedure reduces pain in this patient group both on a short-term and a long-term basis.

The pathophysiology of a PIRFT procedure is unclear. Theoretically, some of the possibilities are the following. A mechanical effect by the heat resulting in a shrinkage of the disc. This is unlikely as control MRI scans did not show any abnormalities in the intervertebral discs. Another possibility is an effect on the enzyme mechanisms of the disc. It is known that there are differences in enzyme activity between normal and degenerative discs.¹⁴ Some of these enzymes may cause inflammatory reactions,¹⁵ thereby eliciting nociceptive pain. Finally, the antinociceptive effect of PIRFT may be explained by a temperature increase of the free nerve endings in the annulus fibrosus. This hypothesis is intriguing, as an RF lesion in the nucleus pulposus is a lesion made under exceptional circumstances. The nucleus pulposus is an avascular structure. As the "washing-effect" of the circulation in the tissue which surrounds the electrode is an important determinant of the size of RF lesion, the lesion in the nucleus pulposus will be much larger than would be expected elsewhere in the body. Secondly, it appears that the electrical impedance in the nucleus pulposus is much lower than in the annulus fibrosus and in the tissues outside the disc. This is likely to be due to a greater water content inside the nucleus pulposus, resulting in a higher conductance to heat. As conductance to heat¹⁶ is another major factor determining the size of RF lesions this would again tend to increase the size of the lesion in the nucleus pulposus. Thirdly, the low electrical impedance inside the nucleus pulposus has another effect. The energy output from the lesion generator is usually regulated in such a way, that the tip temperature is held constant. In an environment of low electrical impedance the wattage which is required to achieve this is relatively high as the production of heat is proportional to the impedance. On its way to the dispersive electrode this high current passes through the zone of increased impedance outside the nucleus pulposus. In this way heat is generated inside the annulus fibrosus. This effect will not be significant when the electrode tip is too close to the annulus fibrosus due to "back-pressure" of the generated heat on the output level of the generator. Alternatively, it will also not be significant when the electrode tip is too far away from the electrode, as in that case the electrical current is too diluted to have an effect even if the impedance rises sharply. Computer simulation studies indicate that the effect is operational at tip-to-annulus distances of 4–12 mm.¹⁷ This is in accordance with the actual situation during this procedure. Finally, the endplates of the adjoining vertebrae serve as a thermal insulator, tending to keep the generated heat inside the disc. This accords with observations reported in a cadaveric study of the PIRFT procedure.¹⁸ The combined effect of these factors might well result in a rise of temperature in large parts of the annulus fibrosus which is sufficient to affect small nerve endings.

Taken together, both the clinical data and pathophysiological considerations point towards a significant therapeutic effect of PIRFT in chronic non-specific low back pain. However, as a large proportion of patients does, in our hands, not respond to the procedure, the selection of patients remains a problem. In this study we looked for possible criteria with which to diagnose "discogenic low back pain"¹⁹ to define a patient population responding to PIRFT. Diagnostic imaging procedures, such as CT/MRI scans are not conclusive for such a diagnosis as degenerative disc changes and even herniated discs are seen in both asymptomatic and symptomatic patients.²⁰ A diagnosis of discogenic low back pain may therefore be based on clinical symptoms,¹⁹ and either on the provocation of pain during discographies^{21,22} or on temporary relief of pain following an analgesic discography.^{19,23} In our experience it has been difficult to get reliable information from the patient during provocation discography. We therefore studied whether it would be possible to select "discogenic low back pain" patients by an analgesic injection into the putatively symptomatic intervertebral disc. In patients who had previously undergone surgery, analgesic discography was in our hands an inadequate tool to select patients for an RF disc procedure. The number of false positive discographies was unacceptably high. This may be due to the fact that tears in the annulus fibrosus occur more frequently in operated patients. Overflow of analgesic solution, resulting in a false positive block, may have occurred, although this has not been noticed on fluoroscopy.

The overall result of the method showed a good relief of pain in 50 per cent of the treated population. The result was significantly better in patients who had not undergone surgery, in spite of the fact that there were no differences in terms of symptoms and physical examination between the two groups. Although long-term effects of this procedure are not known yet it seems to be an adjunct in the treatment of untractable discogenic pain. The results of this pilot trial justify a prospective, randomized study of PIRFT in chronic non-specific low back pain.

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