CLINICAL REPORT

Results of pulsed radiofrequency technique with two laterally placed electrodes in the annulus in patients with chronic lumbar discogenic pain

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Abstract Discogenic pain is an important cause of low back pain (LBP). We have developed a pulsed radiofrequency (P-RF) technique, using two electrodes placed bilaterally in the annulus, for applying radiofrequency current in the disc (bi-annular P-RF disc method). The purpose of this study was to investigate the effect of the biannular P-RF disc method, using Diskit needles (Neurotherm, Middleton, MA, USA) in patients with discogenic LBP. The subjects were 15 patients with a mean age of 37.3 ± 8.63 years with chronic discogenic lower back pain that was not responsive to aggressive nonoperative care. Two Diskit II needles (15-cm length, 20G needles with a 20-mm active tip) were placed bilaterally in the annulus in the disc. Pulsed radiofrequency was applied for 12 min at a setting of 5 \times 50 ms/s and 60 V. The pain intensity scores on a 0-10 numeric rating scale (NRS) and the Roland-Morris Disability Questionnaire (RMDQ) were measured pretreatment, and at 1 week and 1, 3, and 6 months posttreatment. The mean pain severity score (NRS) improved from 7.27 ± 0.58 pretreatment to 2.5 ± 0.94 at the 6-month follow-up (p < 0.01). The RMDQ showed significant (p < 0.01) improvement, from 10.70 \pm 2.35 pretreatment to 2.10 ± 1.85 at the 6-month follow up (p < 0.01). The bi-annular P-RF disc method with consecutive P-RF 5/5/60 V, 12-min (with Diskit needle),

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Orbis Medisch Centrum, Pain Management Clinic, Dr. H. Vanderhoffplein, 1, 6162 BG Sittard, Geleen, The Netherlands e-mail: o.rohof@orbisconcern.nl appears to be a safe, minimally invasive treatment option for patients with chronic discogenic LBP.

Keywords Pulsed radiofrequency · Discogenic pain · Intradiscal procedures · Chronic low back pain

Introduction

Discogenic pain is estimated to occur in approximately 40 % of all patients with low back pain (LBP) [1]. Clinically the patients complain of chronic LBP often radiating into the buttock and the leg, uni- or bilaterally but without significant radicular pain. The pain is worse with rotation, extension, and side bending movements. The pain is often provoked by cumulative loading. Patients also experience sitting intolerance. Typically the patient arises from a flexed position in an odd, biphasic manner [2]. Neurological examination does not show severe neurological deficit, and the straight leg raising (SLR) test often gives equivocal results.

Discogenic pain is attributed to degenerative changes in the intervertebral disc due to aging or to traumatic events. The healthy adult disc has few nerves, and these are mainly restricted to the outer lamellae.

In degenerated discs, nerves have been found to penetrate into deeper intradiscal structures as far as the the outer part of the annulus, creating nociceptive information from within the disc itself [3]. Discogenic pain occurs when nerve receptors located in the bilateral posterior outer part of the annulus are irritated.

Intradiscal electrothermal therapy (IDET) has been used as a minimally invasive procedure for managing chronic discogenic LBP in patients for whom conservative treatments fail [4–6].

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However, meta-analyses of the available documented evidence of the efficacy of IDET, in which the annulus is coagulated using flexible catheters, yields controversial conclusions [4–6]. Complications of IDET include catheter breakage, nerve root injury, post-IDET disc herniation, cauda equina syndrome, infection, epidural abscess, and spinal cord damage [6].

In recent years, there has been a general trend in interventional treatment away from radiofrequency thermocoagulation toward pulsed radiofrequency (P-RF) as a less invasive treatment. The use of P-RF in the disc relies on the electric field generated, and the electric field is assumed to induce changes in the tissue that may explain changes in pain conduction and possibly induce a healing process [7, 8]. Teixeira and Sluijter [9] reported that high-voltage, long-duration intradiscal P-RF, achieved by means of an electrode placed in the center of the nucleus pulposus, in patients with discogenic LBP produced excellent to good outcomes in 8 cases.

We have developed a bi-annular P-RF technique using two electrodes placed bilaterally in the annulus, for applying a radiofrequency current to the irritated nerve receptors located in the outer part of the bilateral posterior annulus.

The purpose of this study was to evaluate the efficacy of bi-annular P-RF of the intervertebral disc in a procedure with Diskit needles (Neurotherm, Middleton, MA, USA) in terms of pain relief and reduction of disability.

Patients and methods

Fifteen patients with discogenic pain who underwent biannular P-RF of the intervertebral disc between October 2009 and April 2011 were enrolled in the study.

All patients (10 male, 5 female) met the criteria for the bi-annular P-RF and had one treated disc. The mean age of the patients was 37.3 ± 8.63 years (range 29–51 years). Of the total 15 discs treated, 7 were at L5–S1, 7 were at L4–L5, and 1 was at L2–L3.

All patients had had continuous back pain for a minimum of 6 months. All patients had been taking a variety of medications, including various nonsteroidal anti-inflammatory drugs (NSAIDS) and cyclooxygenase (COX) inhibitors. After the bi-annular P-RF treatment, none of the patients increased the amount of medication, and none increased the types of medication taken.

The criteria for inclusion in our study of bi-annular P-RF were the following: (1) chronic LBP of at least 6 months' continuous duration. (2) Lack of satisfactory improvement with a comprehensively applied non-operative care program including the following: epidural corticosteroid injection, a trial of physical therapy, and oral anti-inflammatory

medication. (3) Normal neurologic examination findings. (4) Negative SLR results. (5) A magnetic resonance scan that did not demonstrate a neural compression lesion. (6) Concordant pain at low pressurization (low volume less than ≤ 1.25 mL contrast medium) during discography of the concerned disc. Intradiscal administration of 1 mL of lidocaine 2 % diminished pain by more than 70 % for more than 3 days [10].

The exclusion criteria were: (1) disc extrusion or a sequestered fragment. (2) Severe spinal canal narrowing. (3) Segmental instability, or psychological issues. (4) Systemic infection or localized infection at the anticipated needle entry sites. (5) Previous lumbar surgery. (6) Chronic lower extremity radiculopathy. (7) History of opioid abuse.

The study protocol was approved by the Human Ethics Committee of Shiga University of Medical Science Hospital. The procedure and associated potential complications, such as nerve root injuries, epidural space bleeding, and discitis were explained to the patients, and informed consent was obtained before treatment.

The bi-annular P-RF disc technique was performed with patients who were lying on a fluoroscopy table in the prone position. The discs treated were selected on clinical grounds according to the level of provocative discography.

Local anesthetic was injected into the skin at the needle entry point, which was a little more medial than the entry point for the discography.

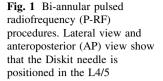
Under fluoroscopic guidance, by a posterior oblique approach the Diskit II needle (20G, 15-cm length, 20-mm active tip, with radiopaque marker active tip; Neurotherm) was percutaneously advanced to the posterior annulus of the disc that was responsible for the symptoms (Fig. 1). Proper placement of the introducer needle was confirmed with anteroposterior, oblique, and lateral fluoroscopic projections. The second needle was placed contralaterally in the disc in the same way (Fig. 1).

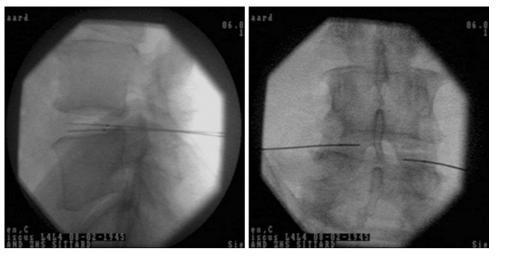
We applied bi-annular P-RF at a frequency of 5 Hz, pulse width of 5 ms, amplitude of 60 V, and a maximum temperature of 40 $^{\circ}$ C, for a duration of 12 min using the "two electrodes technique," with the NT1100 generator (Neurotherm).

Bi-annular P-RF was performed on an outpatient basis. Prophylactic intravenous antibiotics were administered 15–40 min prior to beginning the procedure. After an hour of bed rest, patients were allowed to leave the outpatient room.

The intensity of the pain was assessed using the pain intensity score on a 0–10 numeric rating scale (NRS) preprocedure, and at 1 week and 1, 3, and 6 months after the procedure. In addition, the Roland–Morris Disability Questionnaire (RMDQ) score [11] was measured preprocedure, and after 1 week and at 1, 3, and 6 months.

The Wilcoxon signed-rank test was applied to evaluate the differences in NRS and RMDQ scores before and after





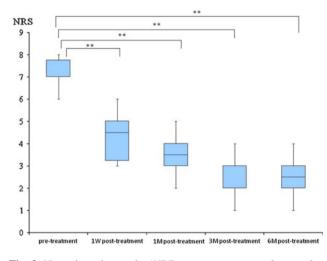


Fig. 2 Numeric rating scale (*NRS*) scores at preprocedure, and at 1 week (*W*) and 1, 3, and 6 months (*M*) post-procedure. Data are presented as median and lower limit, 25th, 75th and upper limit percentiles. Wilcoxon signed-rank test, **p < 0.01

the procedure. p values of <0.01 were considered statistically significant.

Results

The mean preoperative NRS score was 7.27 ± 0.58 (range 6–8). The mean NRS score decreased significantly, from 7.27 at pre-treatment to 4.43 ± 1.16 (range 3–6) at 1 week post-treatment, 3.43 ± 0.85 (range 2–5) at 1 month post-treatment, 2.57 ± 0.94 (range 1–4) at 3 months post-treatment, and 2.5 ± 0.94 (range 1–4) at 6 months post-treatment (Fig. 2). There were statistically significant decreases in NRS scores (p < 0.01, Wilcoxon signed-rank test) when compared to the pre-operative value (Fig. 2).

The mean RMDQ score improved from 10.70 ± 2.35 (range 8–14) to 6.00 ± 2.35 (range 3–11) at 1 week post-

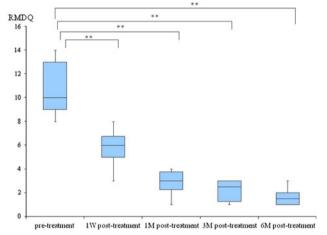


Fig. 3 Roland–Morris Disability Questionnaire (*RMDQ*) scores preprocedure and at 1 week and 1, 3, and 6 months post-treatment. Data are presented as median and lower limit, 25th, 75th and upper limit percentiles. Wilcoxon signed-rank test, **p < 0.01

treatment, 3.11 ± 1.73 (range 1–7) at 1 month post-treatment, 2.60 ± 1.77 (range 1–7) at 3 months post-treatment, and 2.10 ± 1.85 (range 1–7) at 6 months post-treatment (Fig. 3). These decreases in RMDQ scores were statistically significant (p < 0.01, Wilcoxon signed-rank test) when compared to the preoperative value (Fig. 3).

There were no complications of nerve root injuries, epidural space bleeding, discitis, or infection related to the procedures. There were no cases of worsening motor or sensory status.

Discussion

Teixeira and Sluijter [9] first reported on P-RF treatment for discogenic pain. However, there have been no investigations of intradiscal P-RF with Diskit needles in patients with discogenic pain. In the present study, the pain intensity scores (NRS and RMDQ scores) showed significant (p < 0.01) improvement at 1 week after bi-annular P-RF treatment and at 1, 3, and 6 monthsafter the treatment.

The Diskit needles are thin (20G), allowing the treatment of discs with a residual height as low as 10-25 % of the original height, while IDET electrodes are up to 17G and treatment can only be performed in discs that still have at least 50 % of the original height.

Based upon our results, bi-annular P-RF appears to be an effective and promising non-operative treatment for discogenic pain. Bi-annular P-RF is also an outpatient procedure, only local anesthesia is needed, and the procedure takes a very short time.

The exact mechanism by which bi-annular P-RF reduces discogenic pain is uncertain; however, bi-annular P-RF is thought to decrease discogenic pain by two different mechanisms. First, the high-voltage P-RF current applied intradiscally by means of Diskit needles may cause very strong electric fields and these could potentially have a biological effect on the nerve endings in the disc [7–9]. The electric field generated is assumed to induce changes in the tissue that may explain changes in pain conduction [7, 8]. The second effect could possibly reflect an action of the electric field on immune cells, thus influencing the production of anti-inflammatory cytokines, resulting in increased levels of pro-inflammatory cytokines such as interleukin (IL)-1b, tumor necrosis factor- α , and IL-6 [12, 13].

Carefully selected patients with discogenic LBP, nonresponsive to conservative care and with definitive provocative discography and disc block [10] seem to benefit clinically from bi-annular P-RF in terms of pain reduction and also in terms of functional and quality-of-life improvement.

Although the bi-annular P-RF disc method appears to be a safe, minimally invasive procedure for discogenic pain, further research is needed to define the optimal time and the proper setting conditions for applying P-RF current with the latest equipment such as the NT1100 generator (Neurotherm), in which pulse width, pulse frequency, voltage, force, and time can be changed freely.

Bi-annular P-RF appears to be a safe, minimally invasive treatment option for carefully selected patients with chronic lumbar discogenic pain who have not responded to aggressive non-operative care.

Further randomized placebo-controlled studies with longer follow up periods are needed to elucidate the effects of bi-annular P-RF.

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