Original Article

Fluoroscopy-guided Bipolar Radiofrequency Thermocoagulation Treatment for Discogenic Low Back Pain

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Abstract

Background: The efficacy of percutaneous intradiscal radiofrequency thermocoagulation (PIRFT) for the treatment of discogenic low back pain (LBP) remains controversial. However, all the PIRFT studies utilized monopolar radiofrequency thermocoagulation (RFTC). The aim of this study was to investigate the safety and efficacy of bipolar RFTC for the treatment of discogenic LBP.
Methods: A total of 23 patients with discogenic LBP were treated with single-level bipolar RFTC. The patients were assessed before the procedure and at 1 week, 1 month, 3 months, 6 months, and 1 year after the procedure. The primary outcome included the visual analog scale (VAS) score and the Oswestry Disability Index (ODI) score. The secondary outcome included pain relief, reduction of analgesic dose, and patient satisfaction.
Results: The VAS and ODI scores were significantly decreased after bipolar RFTC treatment at all time points of follow-up ($P < 0.05$). Bipolar RFTC treatment also resulted in a significant change in all secondary measures, such as pain relief, reduction of analgesic dose, and patient satisfaction. No serious complications or neurological sequelae were observed in any of the patients.
Conclusions: Bipolar RFTC treatment can significantly attenuate pain and improve the function of patients with discogenic LBP.

Key words: Bipolar Radiofrequency Thermocoagulation; Discogenic Low Back Pain; Efficacy; Safety

Introduction

Intervertebral discogenic pain is the most common low back pain (LBP) and requires extensive medical attention. Discogenic LBP often persists and can severely affect the patient quality of life. Treatment of patients with discogenic LBP continues to be a challenge. Radiofrequency thermocoagulation (RFTC) is a viable alternative treatment for LBP.[1] A study utilized percutaneous intradiscal radiofrequency thermocoagulation (PIRFT) to treat LBP in 1994.[2] In this study, an electrothermal cannula was placed into the center of the disc, and the device was activated to generate heat. The objective of the technique was to shrink collagen fibrils by coagulating neural and inflammatory tissues of the disc, thus decreasing nociceptive input from the painful disc. However, more recent studies have found that the efficacy of PIRFT for the treatment of discogenic LBP remains controversial.[3,4] The available evidence does not support the effectiveness of PIRFT for the treatment of discogenic LBP.[5,6] Patients do not benefit from the PIRFT-induced radiofrequency (RF) lesion, and the reduction of nociceptive input generated by the single electrode is insufficient to relieve the LBP.

Recently, bipolar RFTC has been developed as an alternative treatment to improve clinical results and decrease adverse events. Bipolar RFTC has been successfully used to treat plantar fasciotomy,[7] and the successful clinical outcome rate was 87.5% at 4 weeks following the operation. Previous reports, which utilized bipolar RFTC for synovial joints such as the sacroiliac joint and the thoracic facet joint, provide evidence that this technique is a more effective mode of treatment.[8-10] An

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ex vivo study utilizing porcine spinal tissue samples confirmed that heating the two electrodes simultaneously appeared to coagulate a wider area and potentially achieved better results in less time.[11] Based on these findings, we hypothesized that bipolar RFTC will be more efficacious than PIRFT in generating effective RF lesions and decreasing nociceptive input in discogenic LBP patients. In this study, we modified the routine method of PIRFT by inserting two cannulas into the center and last third of the disc, followed by heating of the two cannulas simultaneously. We observed 23 patients with discogenic LBP over a period of 1 year to evaluate their pain relief and functional improvement.

Methods

Materials

This study was approved by the Hospital Ethics Committee and was registered at the Chinese Clinical Trial Registry with the identifier ChiCTR-OPC-15006556. Patients with discogenic LBP who underwent bipolar RFTC between October 2013 and May 2015 were enrolled in the study. All patients provided written informed consent for the study. The RFTC devices and cannulas were purchased from Cosman Medical, Burlington, USA. The C-arm fluoroscope was purchased from GE Company, Pittsburgh, USA. The contrast agent delivery system was purchased from Merit Medical, Utah, USA. Iohexol was purchased from GE Healthcare AS, Oslo, Norway.

Inclusion criteria

Patients were included if they met the following criteria: (1) LBP with or without pseudoradicular referral for at least 6 months; (2) lack of satisfactory improvement after adequate conservative therapy; (3) concordant pain upon provocative discography in the affected disc but not in the control discs; (4) LBP exacerbated by sitting; (5) disc height >50% of the control disc; (6) high-intensity zones (HIZs) in the affected disc detected by magnetic resonance imaging (MRI) scans; (7) single-level disc disease without evidence of additional degenerative changes in other discs; (8) the absence of neural compression lesions; and (9) normal neurological examination findings.

Exclusion criteria

We excluded patients with compressive radiculopathy, an extruded or sequestered disc, calcification of the extruded disc, bony spinal canal stenosis, more than two symptomatic levels, previous surgery at the symptomatic level, severe scoliosis, spondylolisthesis, spinal tumor, fracture, infection, segmental instability, coagulation dysfunction, serious cardiopulmonary dysfunction, drug abuse, psychological issues by exam or history, beck depression inventory >20, or pregnancy.

Provocative discography

All provocative discographies were performed under C-arm fluoroscopy in a sterile operating room. Thirty minutes before the intervention, the patients were administrated 2 mg midazolam for relaxation and 1 g cefuroxime intravenously for the prevention of discitis. A discogram was performed using a standard posterolateral approach with the two-needle technique (19-gauge outer and 25-gauge inner). Under fluoroscopy, the final location of the needle was verified in the center of the discs, and then the needle was connected to a contrast agent delivery system. Iohexol (2 ml) was injected into the nuclei at a rate of <0.05 ml/s. We first examined 1 or 2 adjacent levels. The suspicious level was stimulated last. Patients were assessed for pain response during the injection. The pain visual analog scale (VAS) score was at least 6. Only patients with concordant pain at the suspicious level, and with no pain or discordant pain at the adjacent levels were included in the study. Furthermore, the concordant pain was reproduced by the application of pressure of l <15 psi above the opening pressure.

Bipolar radiofrequency thermocoagulation techniques

The procedure was performed 2–4 weeks after the discography. The patients were laid on a fluoroscopy table in the prone position. A cushion was placed under the lower abdomen to reduce lumbar lordosis. All the procedures were performed under strict aseptic conditions and local anesthesia by two pain physician specialists. The blood pressure, electrocardiogram, and SpO_2 were continuously monitored. The affected discs were selected based on previous discograms and MRI analysis. Only a single-level disc with both positive provocative discography and HIZs on the T2-weight MRI was chosen. The treatment level and entry point were localized by C-arm fluoroscopy. The proper disc level and placement of the needle were confirmed with an anteroposterior fluoroscopic view, and the depth of the needle was confirmed with a lateral fluoroscopic view.

Two 20-gauge 15 cm RF cannulas, each containing a 10 mm active tip, were, respectively, placed inside the disc near the medial border utilizing a facet joint approach and/or a posterolateral oblique approach. The distance between the two needle tips was <6 mm. The main electrode was inserted near the side of the pseudoradicular referral. Needle placements were confirmed using anteroposterior and lateral fluoroscopic views. The confirmation of the correct positions of the RF needles was monitored by stimulation at 2 Hz (motor stimulation) and 50 Hz (sensory stimulation), which was not expected to produce a response at <2 V. The impedance measurements were lower than 400 Ω. The bipolar RFTC was performed at 85°C with the two needle electrodes heated simultaneously for 180 s utilizing an RFG-1A Radiofrequency Generator (Cosman Medical, Burlington, USA). The cannulas were withdrawn after the tip temperature decreased to 40°C. The patients were prescribed oral antibiotics for 1 day and bed rest for 24 h.

Data collection

The data collection and follow-up were performed before the procedure and at 1 week, 1 month, 3 months, 6 months, and 1 year after the procedure. Demographic variables such as age, gender, disease duration, disc level treated, and puncture approach were collected. Changes in pain intensity and disability were the primary outcome. Pain intensity

was evaluated using the VAS score (0–10). Disability was assessed using the Oswestry Disability Index (ODI) score.[12] Pain relief, reduction of analgesic dose, and patient satisfaction (very satisfied, satisfied, or unsatisfied) were the secondary outcome. Satisfied patients included the two groups of patients who reported that they were either very satisfied or satisfied with the procedure. A reduction in the daily dosage of analgesics reduced to 50% or less was considered to be significant. The analgesic dose data were expressed as the chronic morphine equivalent dose.

Statistical analysis

Statistical analysis was performed utilizing the Statistical Package for the Social Science version 17.0 (SPSS Inc., Chicago, IL, USA). Data were tested for normal distribution using the Kolmogorov-Smirnov test. The Wilcoxon rank-sum test was used to evaluate the differences in VAS score, ODI scores, and morphine equivalents before and after the procedure. A $P < 0.05$ was considered statistically significant.

Results

A total of 41 eligible patients were identified to undergo provocative discography. Twenty-five patients with concordant pain were enrolled; however, two of these were lost to follow-up for no identifiable reason. Finally, 23 patients with HIZs on the T2-weight MRI and positive provocative discography at a single suspicious level were selected. The demographic and clinical features of the patients are listed in Table 1. There were eight females and 15 males. The mean age of the patients who had discogenic LBP was 43.0 ± 7.8 years. The mean disease duration was 73.6 ± 42.5 months. Twenty-three patients were subjected to bipolar RFTC therapy in L4/L5 or L5/S1 spinal levels according to their symptoms and dermatome distribution.

The treatment levels and puncture approaches are listed in Table 2. Bipolar RFTC was performed at L4/L5 in 7 patients, and at L5/S1 in 16 patients. Considering the evaluation of the imaging data and whether these patients had a pseudoradicular referral, different approaches were adopted. At the L4/L5 level, five patients with pseudoradicular referral were treated by the median border of the facet joint and the posterolateral oblique (MB + PL) approach [Figure 1a and 1b], while two patients without pseudoradicular referral were treated by the bilateral median border of the facet joint (MB + MB) approach [Figure 1c and 1d]. At the L5/S1 level, four patients were treated by the MB + PL approach, and 12 patients were treated by the MB + MB approach.

The follow-up period was from 1 week to 1 year after the operation. The mean preoperative VAS score was 6.74 ± 1.29 (0–10). The mean preoperative ODI score was 43.8 ± 9.9. The VAS and ODI scores at 1 week, 1 month, 3 months, 6 months, and 1 year after procedure were significantly decreased when compared to the baseline ($P < 0.05$) [Figures 2 and 3]. Bipolar RFTC also resulted in a significant change in all secondary measures at all points of follow-up [Table 3]. The

Table 1: Patient demographic and clinical data of this study

Items	Data
Patients, *n*	23
Age (years), mean ± SD (range)	43.0 ± 7.8 (30–67)
Female, *n* (%)	8 (34.8)
Male, *n* (%)	15 (65.2)
Disease duration (months) , mean ± SD	73.6 ± 42.5
Disc level treated, *n* (%)	
L4/L5	7 (30.4)
L5/S1	16 (69.6)
Puncture approach, *n* (%)	
MB + MB	14 (60.9)
MB + PL	9 (39.1)

MB: The medial border of the facet joint approach; PL: The posterolateral oblique approach; SD: Standard deviation.

Table 2: Treatment levels and puncture approaches used in this study (*N* = 23)

Puncture approach	MB + MB, *n* (%)	MB + PL, *n* (%)
Disc level treated		
L4/L5	2 (8.7)	5 (21.7)
L5/S1	12 (52.2)	4 (13.4)

MB: The medial border of the facet joint approach; PL: The posteorlateral oblique approach.

Table 3: Secondary outcome measures (*N* = 23, absolute numbers)

Time point	Patients with ≥50% pain relief	Patients with reduced analgesic dose	Number of satisfied patients
1-week	15	16	17
1-month	17	18	19
3-month	18	19	20
6-month	19	19	21
1-year	20	20	21

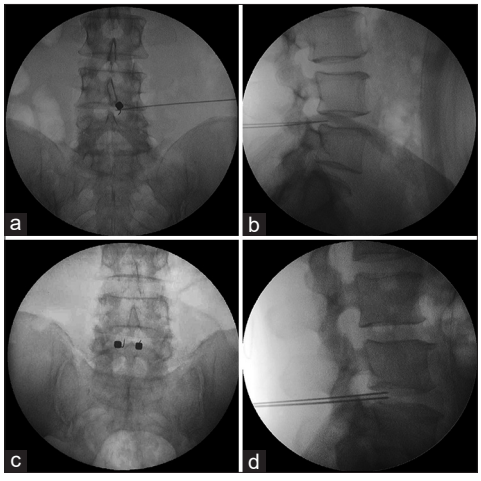

Figure 1: Anteroposterior and lateral views of different approaches. (a) Anteroposterior view of L4/L5 by the MB + PL approach. (b) Lateral view of L4/L5 by the MB + PL approach. (c) Anteroposterior view of L4/L5 by the MB + MB approach. (d) Lateral view of L4/L5 by the MB + MB approach. MB + PL: The median border of the facet joint and posteorlateral oblique approach; MB + MB: The bilateral median borders of the facet joint approach.

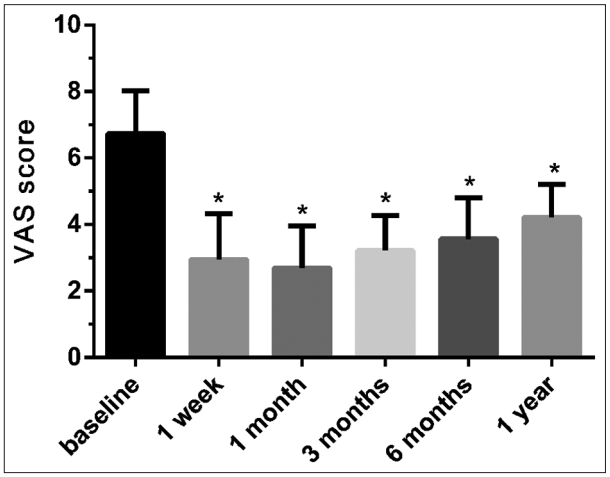

Figure 2: Significant differences were found between baseline and 1 week, 1 month, 3 months, 6 months, and 1 year postoperation in the VAS score during 1-year follow-ups. *$P < 0.05$ during comparison of different values with baseline. VAS: Visual analog scale.

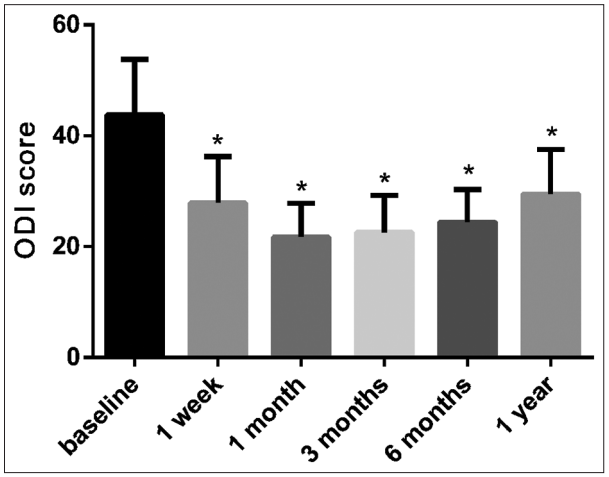

Figure 3: Significant differences were found between baseline and 1 week, 1 month, 3 months, 6 months, and 1 year postoperation in the ODI score during 1-year follow-ups. *$P < 0.05$ during comparison of different values with baseline. ODI: Oswestry Disability Index.

daily analgesic dose was expressed in morphine equivalents, and bipolar RFTC contributed to a significant reduction of analgesic dose [Figure 4]. Three patients suffered from mild short-term postdural puncture headache (PDPH), but the symptom disappeared within 1 week. No serious complications, such as nerve injuries, discitis, and hematoma, occurred in any of the patients. Furthermore, we did not observe any neurological sequelae during the follow-up.

Discussion

LBP is one of the most common public health problems, which limits activity, causes significant disability, and creates a heavy social burden.[13] Internal disk disruption (IDD) characterized by degradation of the nucleus and disruption of the inner lamella of the annulus fibrosus is thought to be the major cause of chronic LBP.[14-16] The diagnosis of discogenic LBP due to IDD is difficult and controversial because of a lack of specific features. Provocative discography, which aims to reproduce the patients' symptoms by stimulating the suspicious disc but not the adjacent discs, is considered to be a main diagnostic test for IDD-induced LBP.[16] However, provocative discography can generate false-positives.[17,18] Recently, several studies reported that the presence of HIZs in the affected disc on MRI scans contributed to the effective diagnosis of discogenic LBP.[19,20] In our study, patients were selected by provocative discography and HIZs in the T2-weight MRI. Only patients with single-level temporary pain were enrolled in the study.

During the last few decades, minimally invasive techniques have been developed as an alternative to treat discogenic LBP. Among those, monopolar RFTC methodologies have also been explored. Monopolar RFTC uses a grounding pad and an uninsulated cannula to heat surrounding tissue around the exposed tip. However, the effectiveness of traditional monopolar RFTC techniques for treatment of discogenic pain is still controversial. A randomized controlled trial performed by Barendse e*t al*.[5] found that an RF-induced lesion (generated by a straight RF probe inserted into the center of the disc and heated to 70°C for 90 s) was not effective in reducing discogenic LBP. Ercelen *et al*.[6] conducted another prospective randomized trial utilizing RF at 80°C for 120 s or 360 s and found that the increased duration of PIRFT failed to improve the effectiveness of treating patients with LBP. The reasons for the poor treatment efficacy are likely very complex. The PIRFT strategy of inserting a single catheter (monopolar RFTC) into the center of the disc will likely only produce limited tissue destruction surrounding the tip of the treatment cannula. The resulting RF lesion may be limited and heating the center of the nucleus might not destroy enough nociceptive fibers in the annulus.

Bipolar RFTC is emerging as an alternative treatment to improve clinical results and decrease adverse events. In contrast to monopolar RFTC, bipolar RFTC utilizes two cannulas, which are heated simultaneously and complete the circuit. The large current provides a second site of tissue coagulation, and a wider coagulation area is produced in the intervening tissue. A possible mechanism of bipolar RFTC therapy was indicated by a cadaver spine study, which demonstrated that a bipolar RF electrode inserted into the intervertebral disc destroyed a portion of the nucleus pulposis after the application of an RF current.[21] Several studies have utilized bipolar RFTC to treat a variety of conditions. First, David utilized bipolar RFTC for the treatment of mid back pain of thoracic facet origin and found that 66% of patients had a significant pain relief with a mean VAS reduction of 80.4%.[10] Second, chronic plantar fasciitis has also been treated with bipolar RFTC, which was shown to be an effective and safe surgical option.[7,22] Third, bipolar RFTC has been recently described as an alternative treatment for the management of chronic spinal pain syndromes.[10] Taken together, these reports suggest that bipolar RFTC may be a promising strategy to treat multiple chronic pains.

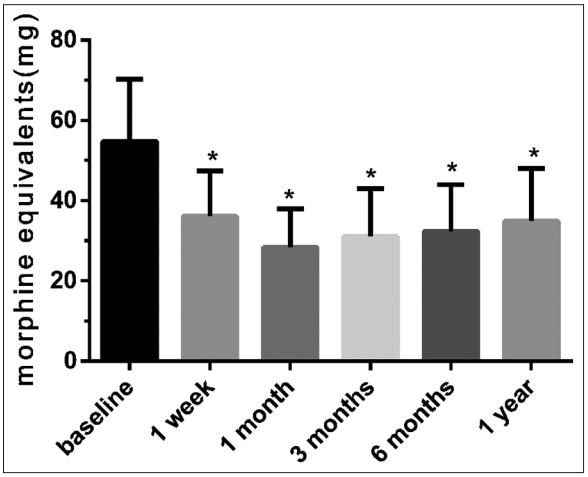

Figure 4: Significant differences were found between baseline and 1 week, 1 month, 3 months, 6 months, and 1 year postoperation in the morphine equivalents during 1-year follow-ups. *$P < 0.05$ during comparison of different values with baseline. Daily analgesic dose was expressed in morphine equivalents.

In the present study, we hypothesized that bipolar RFTC would generate a more effective RF lesion than monopolar RFTC and would result in a greater reduction of nociceptive input for the treatment of discogenic LBP patients. Bipolar RFTC was performed by inserting two adjacent needles into the periphery of the disc not at the center, respectively, with the last third of the disc most common, aiming at reducing discogenic pain by dealing with the nerve fibers accompanying neovascularization through annular tore. The target was located in the tore annulus fibrosis, where neovascularization displayed HIZs on T2-weight MRI. Different from monopolar RFTC which failed to show remarkable improvement in VAS scores, ODI scores and global perceived effect,[5] we observed that bipolar RFTC resulted in a significant improvement in VAS scores, pain relief, analgesic consumption, patient satisfaction, and ODI scores. We achieved >50% pain relief at a 1-year follow-up in 86.9% of the patients. Similarly, the mean VAS scores and mean ODI scores at all points of follow-up were significantly reduced after the bipolar RFTC treatment (mean VAS score at 1 year = 2.71; mean ODI score at 1 year = 22.5). The bipolar RFTC technique can increase the volume of tissue included within the heating radius of the exposed tips, minimize technical failure due to incomplete coagulation and prolong the duration of relief. Thus, heating the two adjacent cannulas simultaneously appears to create a more extensive RF lesion and potentially achieve better outcomes in less time.[23,24] A previous study has shown that an RF temperature >65°C can destroy the nociceptive fibers (A-delta and C fibers) which are richly innervated in the superficial annulus of the disc. Furthermore, in the degenerated or damaged disc, there is more extensive innervation associated with the centripetal growth of nerve fibers.[25] Taken together, bipolar RFTC can provide faster pain relief than the traditional monopolar RFTC techniques (PIRFT) for patients with discogenic LBP.

The efficacy of bipolar RFTC depends on several considerations. First of all, the operational skill of the clinician is very important. An experienced pain clinician guided by a standard protocol performed all the punctures in this study. Second, the distance between the two needle tips should be <6 mm. Pino *et al*.[26] evaluated the morphology of the lesions generated with bipolar RF electrodes placed 2–10 mm apart in egg whites and found that the electrodes should be placed ≤6 mm apart to create a continuous lesion. Similarly, Richael *et al*.[11] confirmed the distance in porcine spinal tissue. Third, the RF temperature and the duration of the exposure to the RF electrodes may play important roles in the efficacy of the procedure. The optimal RF temperature and precise duration of the exposure to the RF electrodes remain unknown. What is known is that the coagulation size increased with higher RF temperature and longer exposure. Previous research indicated that heat produced a tissue color change at 65°C in egg albumin and between 45°C and 50°C in liver.[27] We performed the bipolar RFTC at 85°C for the duration of 180 s. Future studies include a careful analysis of the temperature and duration required for effective treatment. Fourth, the puncture approaches were adopted according to the symptoms, image materials, and the disc level. At the L4/L5 disc level, the MB + MB approach was adopted for patients without pseudoradicular referral. In contrast, the MB + PL approach was adopted for patients with pseudoradicular referral. At the L5/S1 disc level, we preferred the MB + MB approach to accommodate a higher iliac crest. Only four patients with a lower iliac crest were subjected to the MB + PL approach due to unilateral symptoms. A few studies found that the risk of PDPH increased after dural puncture.[28,29] In our study, three patients suffered from mild short-term PDPH, and the symptom disappeared within 1 week. The low incidence of PDPH in our study was possibly associated with fewer patient cohorts, fewer females, older age, expert operators, accurate puncture, late mobilization, prophylactic bed rest in the horizontal position, and adequate hydration. Further investigations regarding the incidence of PDPH following bipolar RFTC treatment are required.

Some limitations of the study should be mentioned. It was not a randomized controlled clinical trial, and the sample size was relatively small. Our results should thus be considered preliminary rather than definitive. We have submitted this report for publication because we found that treatment of discogenic LBP with bipolar RFTC is safe and effective. Further studies including the comparison between different methods of groups should be carried out to investigate the effectiveness of bipolar RFTC in patients with discogenic LBP and the incidence of short-term PDPH. Large patient cohorts are also needed.

In conclusion, in the present study, based on the improved functional capacity, superior pain relief, reduced analgesic dose, decreased pain scores, and increased patient satisfaction, our results suggest that bipolar RFTC may be an effective minimally invasive procedure for the treatment of discogenic LBP.

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Conflicts of interest

There are no conflicts of interest.

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