

ORIGINAL STUDY

Role of Pulsed Radiofrequency in Management of Chronic Discogenic Lumbosacral Radicular Pain

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Abstract

Background data: Lumbosacral radicular pain is the most common neuropathic pain and is secondary to multiple pathologies, mostly disc herniation. Despite conservative treatment, about 10% of patients still suffer from chronic pain. Previous clinical studies reported promising results of using pulsed radiofrequency (PRF) for 2–4 min.

Purpose: This study aims to evaluate the efficacy and safety of (PRF) for 8 min in managing chronic discogenic lumbosacral radicular pain.

Study design: A prospective descriptive clinical case series.

Patients and methods: This study was conducted on 30 patients with lumbosacral discogenic radicular pain diagnosed clinically and radiologically. All patients underwent PRF for corresponding dorsal root ganglia for 8 min under fluoroscopy with 1-, 3-, and 6-month postprocedural follow-up regarding pain relief using the numerical rating scale (NRS). The patient satisfaction index (PSI) was used to assess the outcomes and responses to PRF 6 months after the procedure, and all results were analyzed.

Results: The preprocedural mean NRS was 7.7, which dropped after the procedure at 1-, 3-, and 6-month follow-up to 2.7, 2.8, and 3, respectively. Therefore, the average improvement at the 6-month follow-up was 4.7, which means a 61% average decline of the mean NRS of pain intensity after PRF at the 6-month follow-up. The success of PRF, as defined by at least a 50% reduction of NRS, was 90%, 86.7%, and 80% after 1-, 3-, and 6-month follow-ups, respectively (P -value = 0.001). The most important factor predicting the outcome was the degree of nerve root compression (P -value = 0.002).

Conclusion: Pulsed radiofrequency for 8 min is a safe and effective minimally invasive procedure in the short-term management of chronic lumbosacral discogenic radicular pain, especially in mild and moderate nerve root compression.

Keywords: Dorsal root ganglia, Lumbosacral radicular pain, Pulsed radiofrequency

Introduction

Lumbosacral radicular pain is the most common neuropathic pain, with an incidence of 13%–40% in the general population [1,2]. Disc herniation, ligamentum flavum hypertrophy, and epidural scar after previous spine surgeries are the most common causes of lumbosacral radicular pain, while infection and tumors are rare causes [3]. Radicular pain is thought to be caused by a complex combination of mechanical compression,

inflammatory, and immune mechanisms affecting the dorsal root ganglion (DRG), which is a critical hyperexcited structure responsible for pain sensation and transmission [4].

Although most patients with acute lumbar discogenic radicular pain recover within three months with conservative treatment such as bed rest, medications, and physiotherapy, few patients (10%–15%) experience chronic pain [1,5]. Transforaminal epidural steroid injections (TESI) were used as an adjunct in reducing radicular pain, with success

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rates ranging from 35% to 75% [6–8]. However, this is of short-term effect and associated with side effects such as endocrine changes like glucose intolerance, adrenal suppression, and rarely spinal cord infarction [3]. Surgical treatment of lumbar disc herniation (open, microscopic, and endoscopic discectomy) has a long-term success rate ranging from 60% to 90%. Nevertheless, the most feared complication is failed back surgery syndrome, with an incidence of about 20% [1,9–12].

These statistics highlight the need for alternative therapeutic interventions with a similar success rate but lower complication rates. Due to these shortcomings, pulsed radiofrequency (PRF) has emerged as a novel technique that may be more effective with fewer side effects. The first PRF procedure on a lumbar DRG was performed in 1996 [13].

Unlike the conventional continuous heat-destructive radiofrequency technique conducted between 65 °C and 80 °C, the PRF technique uses an electromagnetic field generated in a pulsed way with a maximum temperature of 42 °C [14,15]. Previous clinical studies reported promising results of PRF for 2–4 min in patients with lumbosacral radicular pain [16].

This work aims to assess the efficacy and safety of PRF for 8 min in managing chronic discogenic lumbosacral radicular pain.

Patients and methods

This prospective clinical study was conducted from June 2021 to February 2022. It included 30 patients with a postprocedural follow-up period of 6 months. All included patients had the main complaint of significant leg pain rather than back pain that did not respond to at least 3-months of conservative management in the form of medical treatment and physiotherapy; their history, physical examination, and pain pattern were consistent with lumbar radicular pain; and the magnetic resonance imaging (MRI) of the lumbosacral spine (LSS) showed lumbar disc herniation with nerve root compression at that level. The exclusion criteria included those aged >18 years, those with progressive neurologic deficit, those pregnant, those with normal MRI findings of LSS, and those who had previous lumbar surgery, LSS instability, low back pain more symptomatic than radicular pain, uncorrected bleeding tendency and/or psychological problems.

This study was approved by the Research Ethics Committee (REC) of the Neurosurgery Department, Faculty of Medicine, Beni Suef University, in April 2021. All patients included signed informed consent for the procedure. All the procedures involving humans were in accordance with the ethical

standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards.

We studied certain predictive factors to investigate their relationship with the success rates of the PRF. Those included pain intensity and duration, the body mass index, lumbar disc herniation level, site of disc herniation (foraminal, posterolateral, central), radiculopathy level, and degree of nerve root compression (abutment, mild; displacement, moderate; entrapment, severe), as described by Choi et al. [17] This study included 17 males and 13 females, aged from 29 to 75 years, with the mean age was 48.6 ± 11.2 years. The average duration of symptoms was 9.6 ± 3.4 months. Twenty patients had single-level lumbar disc prolapse, while 10 patients had two levels of herniation. The most common anatomical site of disc herniation was posterolateral (21, 52.5%), followed by foraminal (11, 27.5%), and the least site was central (8, 20%). Most patients suffered from unilateral radicular pain 22/30 (73.3%), while eight patients had bilateral symptoms.

The numerical rating scale (NRS) score was used to assess the degree of pain, with 0 as no pain and 10 as the worst imaginable pain. Grades from 1 to 3, 4–6, and 7–9 represented mild, moderate, and severe pain, respectively [18]. The NRS was documented before the procedure and at 1, 3, and 6 months after the procedure. PRF is considered successful when NRS was reduced for at least 50% at 1-, 3-, and 6-month follow-ups.

The patient satisfaction index (PSI) was used to assess the outcome and response to PRF 6 months after the procedure, where grade 1 (the procedure met my expectations) and grade 2 (the procedure improved my condition significantly so that I would repeat it again for the same outcome) considered as a satisfying outcome, whereas grade 3 (the procedure helped me but I would not repeat it again for the same outcome) and grade 4 (same or worse outcome compared to before procedure) indicated a dissatisfied outcome [19].

Technique and devices

All patients were lying prone, and a grounding pad was applied and connected to an RF machine, and they were monitored for heart rate, blood pressure, and oxygen saturation. IV slow injection of midazolam was given by the anesthesiologist for sedation if the patient was anxious.

After level confirmation using C-arm fluoroscopy, the skin was sterilized and draped; then the fluoroscope was tilted to ipsilateral oblique view by

approximately 20°–30° until the tip of the superior articular process of lower vertebra bisects the pedicle of interest. After infiltration using lidocaine hydrochloride 1% to numb the skin and subcutaneous tissue, then 20 G, 10 cm RF cannula (NeuroTherm, Morgan Automation Ltd., Liss, Hants, UK) with a 10 mm curved active tip was advanced just inferior to the targeted pedicle (Fig. 1). At the posteroanterior view, the RF cannula should be directed medially, not passing the 6 o'clock position of the targeted pedicle. Then, the C-arm was rotated to the lateral view, and the needle gradually progressed toward the posterosuperior quadrant of the intervertebral foramen. For the S1 nerve root, the 1st posterior sacral foramen was targeted. A 0.5–1 mL of contrast medium (iohexol 350 mg I/ml) was injected under live fluoroscopy to confirm the needle position and the periradicular flow (see Fig. 2).

After appropriate radiological positioning of the RF cannula, the stylet was replaced with the RF probe, and the probe was connected to the Diros OWL URF-3AP RF lesion generator with Multilesion adapter, Canada. The needle position was further adjusted electrically to be adjacent to the DRG via sensory stimulation of 50 Hz at 0.4–0.7 V to induce paresthesia corresponding to the same distribution of the patient's radicular pain (for a few seconds), followed by motor stimulation of 2 Hz at 0.8–1.3 V, which is about double the sensory threshold, on the affected nerve roots resulting in visible leg muscle contractions (for a few seconds). The PRF generator

was adjusted to give one cycle of 8 min of PRF at 45 V with a maximum temperature of 42 °C with an impedance of less than 400 Ω (Fig. 2). Finally, 8 mg dexamethasone and 1 mL of lidocaine hydrochloride 1% were injected before needle removal.

The patients were observed and discharged from the hospital after 6 h, and nonsteroidal anti-inflammatory medication was prescribed for one week for postprocedure pain.

Statistical analysis

Data are statistically described as mean ± standard deviation (±SD), median and range, or frequencies and percentages when appropriate. Mann–Whitney *U* test for independent samples was done to compare numerical variables between success and failure groups. Wilcoxon signed-rank test for paired (matched) samples was done for group comparison of numerical variables. χ^2 test was performed to compare categorical data. The exact test was used when the expected frequency was less than 5. Analysis of variance (ANOVA) test was applied as tests of significance in more than two groups, and post hoc analysis was utilized to detect significant differences among groups. *P* values > 0.05 are considered statistically significant. We used the computer program IBM SPSS (Statistical Package for the Social Science; IBM Corp, Armonk, NY, USA) release 22 for Microsoft Windows for all statistical calculations.



Fig. 1. (A) RF cannula 20 G, 10 cm with 10 mm curved active tip; (B) the Diros OWL® URF-3AP RF lesion generator, with Multilesion Adapter 4.

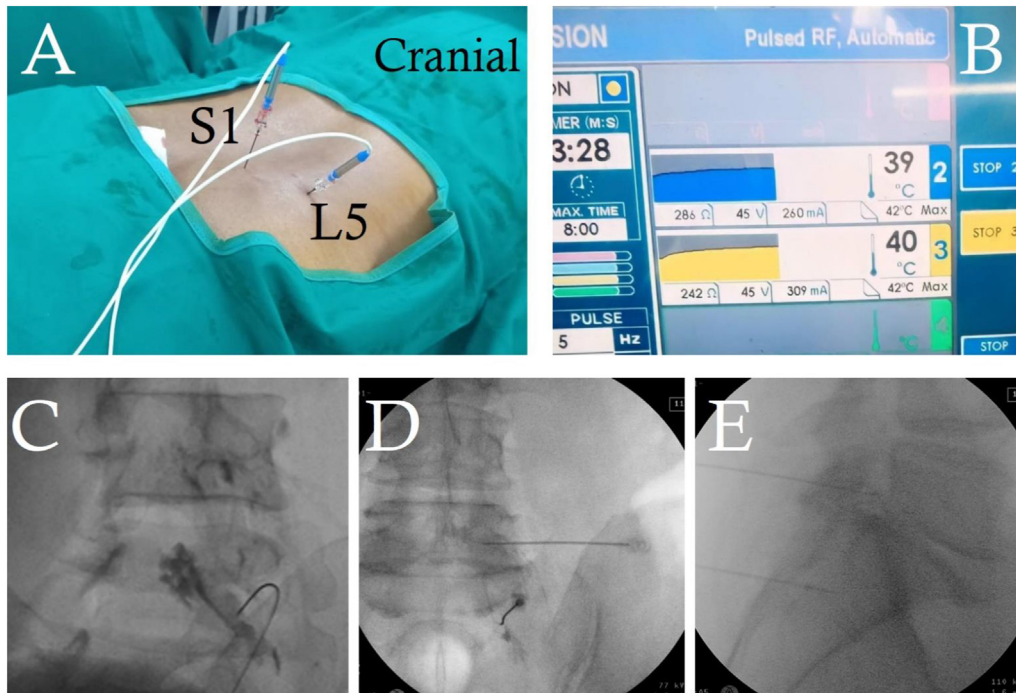


Fig. 2. Steps of lumbosacral PRF procedure: (A) the position of right side L5, S1 cannulas, (B) the RF machine controlling two cables adjusted at pulsed RF mode with a maximum temperature of 42 °C for an 8-min single cycle; (C) right oblique view showing L5 root after contrast injection; (D) posteroanterior view showing RF L5 cannula directed medially not passing the 6 o'clock position of L5 pedicle and S1 cannulae; (E) Lateral view showing RF L5 and S1 cannula passing through their corresponding foramina.

Results

The total number of dorsal root ganglia treated was 48, with an average of 1.6 DRG per patient. The most common affected root was L5 (23/48 = 47.9%), followed by L4 (13/48 = 27.1%), then S1 (9/48 = 18.75%), and lastly L3 roots (3/48 = 6.25%). Most of the patients suffered from mild to moderate degree of nerve root compression (22/30 = 73.3%), while severe entrapment was evident in 8 cases (26.7%) (Table 1). Patients with multiple nerve root compression were classified according to the most severe degree of nerve root compression. The procedure duration ranged from 15 to 35 min, with an average duration was 22.5 ± 5.2 min.

There were no major complications or death during or after the procedure. Two patients had minor complications. One patient suffered from a transient vasovagal attack resolved with atropine and completed the procedure. In contrast, the other patient had postprocedural numbness attributed to transforaminal local anesthetic injection, which resolved within 2 h.

The preprocedural mean of NRS was 7.7 ± 0.83 , which dropped at 1-, 3-, and 6-month postprocedural follow-ups to 2.77 ± 1.5 , 2.83 ± 1.2 , and 3 ± 1.2 , respectively. Thus, the average improvement at the 6-month follow-up was 4.7, which means a 61% decline in the mean NRS of pain after PRF at the 6-month follow-up (Table 2).

Success of PRF, as defined by at least a 50% reduction of NRS, was 90% (27/30), 86.7% (26/30), 80% (24/30) after 1-, 3-, and 6-month follow-up, respectively. The PSI at 6 months after the procedure was grade 1 in 9 (30%) patients, grade 2 in 16 (53.3%) patients, representing a satisfied outcome in (25/30) 83.3% of patients, while it was grade (3) in 5 (16.7%) patients denoting dissatisfied outcome. No patient reported PSI grade 4 (same or worse outcome compared to before the procedure).

The most important factor predicting the outcome was the degree of nerve root compression (P -value = 0.002). Five out of eight patients (62.5%) who had severe nerve root entrapment failed at 6-month follow-up and were referred for discectomy. Other factors such as gender, age, body mass index, duration of symptoms, laterality of symptoms, number of affected levels, and site of pathology were found statistically insignificant to affect the outcome.

Discussion

The most common neuropathic pain is lumbosacral radicular pain, with a lifetime incidence of up to 40% in the general population. The annual incidence of sciatica ranges between 1% and 5% [2]. Among 30 patients with lumbosacral discogenic radicular pain who underwent 8-min PRF in this study, 24 patients (80%) experienced a $\geq 50\%$

Table 1. The characteristics of patients reported in the study (n = 30).

Parameters	Results
Sex	
Males	17
Females	13
Age	
29-	5
40-	19
60-	6
Pathology level	
Single level	20: 10, L4-L5; 5, L5-S1; 4, L3-L4; 1, L2-L3 (16 unilateral, 4 bilateral) (total: 24 roots)
Double level	10: 6, L4- L5+L5-S1; 4, L3-L4+L4-L5 (6 unilateral affecting 12 roots, 4 bilateral affecting 3 roots) (total: 24 roots)
Symptoms laterality	
Unilateral	22: left, 12; right, 10
bilateral	8: single level, 4; double level, 4
Site (40 discs)	
Posterolateral	21
foraminal	11
Central	8
Root compression	
Displacement	21 (11 patients)
Abutment	19 (11 patients)
entrapment	8 (8 patients)
Roots affected (n = 48)	
L5	23
L4	13
S1	9
L3	3

reduction in their NRS score, and 25 patients (83.3%) had a high satisfaction level (grade 1 or 2) at the 6-month post-procedure follow-up.

Radiofrequency ablation (RFA) has been used successfully for thermal tissue ablation in several organs as the heart conduction system, varicose vein, and tumor ablation in the liver, uterine fibroid, osteoid osteomas, and metastatic bony lesions, as well as treatment of trigeminal neuralgia. Regarding the spine field, this conventional radiofrequency (CRF) was applied to treat cervicogenic headaches secondary to the cervical facet joint, lumbar discogenic or facet pain, and pain associated with the sacroiliac joint [20]. CRF employs a continuous electrical current to raise the temperature surrounding the needle tip (between 60 °C and 80 °C), coagulating the nociceptive sensory fibers [13]. On the other hand, PRF is a novel minimally invasive technique that uses intermittent

high-frequency current to allow heat to dissipate to surrounding tissues while avoiding temperature rise above the critical level of 42 °C, the level of protein denaturation. Therefore, PRF appears to be a relatively safe technique. Unlike CRF, which has been linked to the risk of motor impairments and deaf-ferentation syndrome, PRF appears to have few side effects. In fact, no significant complications have been published regarding PRF procedures [14,20–22].

The mechanism of the analgesic effect of PRF is currently undergoing extensive histopathological studies in animal models. Most studies point toward a temperature-independent neuromodulatory effect on DRG. Transient mild endoneurial edema was observed after PRF, in contrast to Wallerian degeneration caused by thermal injury after CRF [23]. PRF may reduce pain signal transmission in the dorsal horn by increasing C-fos gene expression in the superficial lamina [24,25] and inducing ATF3 selective expression at small-diameter nociceptive fibers [8,26]. Finally, PRF may facilitate descending inhibitory cortico-spinal pathways as its effect is reversed by serotonin and alpha-adrenergic antagonists [27]. All these studies confirm the real biological effects of PRF.

The clinical results of PRF in patients with radicular pain showed a “dose-dependent” effect, with clinical success directly proportional to the total duration of PRF treatment. Van Boxem et al. [28] reported a 29.5% and 22.9% success rate at two months and at six months, respectively, after PRF for 2 min. De et al. [29] reported success rates of 96%, 72%, and 28% at 2, 3, and 6 months, respectively, using PRF for 3 min. In a second clinical study, Van Boxem et al. reported a success rate of 55.4% after the 6-month follow-up after PRF for 4 min, which is significantly higher than their earlier study, with only a 22.9% success rate at six months [16]. The success rate in these three clinical studies was defined as $\geq 50\%$ pain relief of lumbar radicular pain.

Regarding the direct impact of PRF on surgical indications for patients with lumbar radicular pain, two clinical studies were published. In a retrospective study of 12 patients scheduled for lumbar discectomy, Teixeira et al. [30] used PRF for 3 min and 11 patients reported good results (91.7%) and declined surgery during a follow-up period ranging from 11 to 23

Table 2. Preprocedural NRS score and its changes at 1, 3, and 6 months post-PRF.

Evaluation time	Study group (30)	P-value	P1/preprocedural	P2/1 mo postprocedural	P3/3 mos postprocedural
Pre-PRF	7.73 ± 0.83	<0.001			
1 mo post-PRF	2.7 ± 1.15		<0.001		
3 mos post-PRF	2.8 ± 1.12		<0.001	0.52	
6 mos post-PRF	3.03 ± 1.12		<0.001	0.21	0.8

Post hoc analysis revealed that there was a statistically significant difference (P -value <0.001) between NRS score pre-PRF and 1 month, 3 months, and 6 months after the procedure. There was a statistically nonsignificant difference (P -value >0.05) between 1 month, 3 months, and 6 months after the procedure, and, in addition, there was a statistically nonsignificant difference (P -value >0.05) between 3 months after the procedure and 6 months after the procedure.

months. Trinidad et al. [31] used PRF for 6 min in 19 patients (76%), conventional RF of the medial branch in three patients (12%), and combined technique in three patients (12%) of his 25 patients who were scheduled for spinal surgery. After treatment, 76% of patients rejected spinal surgery for 12 months. It is worth mentioning that cases with significant mechanical compression were excluded from this study.

The obvious effect of “PRF dose” in these clinical studies is consistent with a recent animal study investigating the effect of PRF on neuropathic pain in rats. The analgesic effect of PRF was significantly greater when PRF exposure was increased from 2 to 6 min [32].

The current study confirms the superior results of PRF of lumbosacral DRG for 8 min compared to previous studies reporting a shorter duration of 2–4 min of stimulation [16,28,29]. Further animal and clinical studies are required to assess the efficacy and safety of gradual extension of the duration of PRF and higher voltage until a plateau response is reached.

The main limitation of the current study is the lack of a control group with sham electrodes. However, establishing a control group with sham electrodes raises an ethical dilemma for not offering them a true therapeutic option and exposing them to the hazards of radiation and injections. A second limitation is the need for a longer follow-up of 12–24 months to assess the long-term effect of PRF. Nevertheless, this study confirmed the superior efficacy and safety of PRF for 8 min in patients with chronic lumbosacral discogenic radicular pain with 6 months of follow-up.

Conclusion

Pulsed radiofrequency for 8 min is a safe and effective minimally invasive procedure in the short-term management of chronic lumbosacral radicular discogenic pain, especially in mild and moderate nerve root compression. A randomized comparative study with a control sham group and a longer duration of follow-up is recommended for future studies.

Ethics Information

The article does not contain information about medical device(s)/drug(s).

Conflict of Interest

The authors report no conflicts of interest.

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List of Abbreviations

DRG	Dorsal root ganglion
LSS	Lumbosacral spine
TESI	Transforaminal epidural steroid injections
MRI	Magnetic resonance imaging
CRF	Conventional radiofrequency
NRS	Numerical rating scale
PRF	Pulsed radiofrequency
PSI	Patient satisfaction index

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