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Comparison between bipolar pulsed radiofrequency and monopolar pulsed radiofrequency in chronic lumbosacral radicular pain

A randomized controlled trial

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Abstract

Background: Chronic lumbosacral radicular pain is a challenging medical problem with respect to therapeutic management. Many patients with lumbosacral radicular pain complain of persistent leg pain after transforaminal epidural steroid injection. Nowadays, pulsed radiofrequency (PRF) stimulation on the dorsal root ganglion (DRG) is widely used for controlling lumbosacral radicular pain.

Methods: We evaluated the effect of bipolar PRF on the DRG for the management of lumbosacral radicular pain. In addition, we compared the effect of bipolar PRF to monopolar PRF. Fifty patients with chronic lumbosacral radicular pain were included in the study and randomly assigned to 1 of 2 groups, the bipolar or monopolar PRF group (n = 25 per group). Pain intensity was evaluated using a numeric rating scale (NRS) at pretreatment, and 1, 2, and 3 months after treatment.

Results: When compared to the pretreatment NRS scores, patients in both groups showed a significant decrease in NRS scores at 1, 2, and 3 months after treatment. Reductions in the NRS scores over time were significantly larger in the bipolar PRF group. Three months after treatment, 19 patients (76.0%) in the bipolar PRF group and 12 patients (48.0%) in the monopolar PRF group reported successful pain relief (pain relief of ≥50%).

Conclusion: The use of bipolar PRF on the DRG can be an effective and safe interventional technique for chronic refractory lumbosacral radiculopathy, particularly in patients whose pain are refractory to epidural steroid injection or monopolar PRF stimulation.

Abbreviations: DRG = dorsal root ganglion, NRS = numeric rating scale, PRF = pulsed radiofrequency, TFESI = transforaminal epidural steroid injection.

Keywords: bipolar, chronic pain, dorsal root ganglion, lumbosacral radicular pain, monopolar, pulsed radiofrequency

1. Introduction

Lumbosacral radicular pain secondary to spinal disease is a common and disabling condition.[1] In clinical practice, its therapeutic management is challenging. The chemical inflammatory mechanism and the mechanical compression of the nerve root are 2 major factors that induce radicular pain, which provoke the inflammatory process and increase nociceptive input.[2–4] For the management of lumbosacral radicular pain, clinicians have applied several modalities or procedures to reduce inflammatory response and lessen the excitement of nociceptive nerves.[5–8] Epidural steroid injection through translaminar, transforaminal, or caudal routes was frequently used for the management of lumbosacral radicular pain because it suppresses the expression of various inflammatory cytokines and chemokines and blocks the transmissions in nociceptive C-fibers.[8–10] However, injected steroids can have adverse effects including allergic reaction, flushing, hyperglycemia, immunosuppression, thinning of the skin, and adrenal suppression.[11,12] In addition, many patients treated in this manner continue to complain of persistent neuropathic pain.

Pulsed radiofrequency (PRF), introduced by Sluijter in 1998,[13] is widely used as a safe and efficacious alternative therapy to corticosteroid injection.[7,13–15] PRF works by delivering an electrical field and heat bursts to targeted nerves or tissues and rarely damages these structures.[16–18] Although the mechanism of PRF has not been clearly elucidated, the electrical field produced by PRF is known to alter pain signals.[19–21] So far, several studies have reported that PRF on the dorsal root ganglion (DRG) can effectively manage lumbosacral radiculopathy.[22–28] For PRF stimulation on the DRG, a single PRF cannula is used to produce a therapeutic

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Table 1

Demographic characteristics of patients in the bipolar PRF and monopolar PRF groups.

	Bipolar PRF group	Monopolar PRF group	*P*
Number (n)	25	25	
Age, y	60.4 ± 16.3	60.8 ± 13.2	0.712
Male:female	14:11	12:13	0.571
NRS (pretreatment)	5.1 ± 0.8	4.6 ± 0.8	0.779
Pain duration, month	9.7 ± 5.7	10.9 ± 9.1	0.920
Imaging finding (HLD:LS)	14:11	15:10	0.774
Site of leg pain (right:left)	13:12	12:13	0.777
Treatment level (L4:L5:S1)	1:20:4	2:18:5	

Values are presented as number or mean ± standard deviation. HLD = herniated lumbar disc, LS = lumbosacral stenosis, NRS = numeric rating scale, PRF = pulsed radiofrequency.

electrical field. This method is called monopolar PRF stimulation. We thought that 2 parallel PRF cannulae would produce denser and larger electrical fields compared to a single PRF cannula[29–31]; thus, we proposed that PRF stimulation on the DRG using 2 PRF cannulae tips would be more effective in controlling radicular pain. We called this PRF stimulation method bipolar PRF stimulation.

In the current study, we investigated the effect of bipolar PRF stimulation to the DRG in patients with chronic lumbosacral radicular pain who were unresponsive to transforaminal epidural steroid injection (TFESI). In addition, we compared the effect of bipolar PRF to that of monopolar PRF.

2. Methods

2.1. Patients

From January 2014 to August 2015, a total of 262 patients underwent TFESI for the treatment of lumbosacral radicular pain. We recruited patients who continued to complain of persistent lumbosacral radicular pain after TFESI with 20 mg of triamcinolone under real-time fluoroscopy. Bipolar or monopolar PRF was performed when the patient's radicular pain was rated at least 4 (0 indicating no pain and 10 indicating the worst pain imaginable) on a numeric rating scale (NRS) despite TFESI. Sixty out of the 262 patients reported persistent radicular pain rated at least 4 on the NRS. We retrospectively reviewed data from subjects who had received at least a single procedure of TFESI. From March 2015 to August 2016, we prospectively conducted this study. Out of the 62 patients, 50 patients were included in this study. The inclusion criteria were as follows (Table 1): ≥6-month history of segmental pain of lumbar or sacral origin radiating from the back to the leg; age between 20 and 79 years; ≥50% temporary pain relief following a diagnostic nerve block with 1 mL of 2% lidocaine; unsatisfactory response to at least a single procedure of TFESI (segmental pain of at least 4 on the NRS that radiated to the leg despite TFESI); no interval change in the pain score on the NRS over the 4 weeks immediately after TFESI; and imaging findings (magnetic resonance imaging and/or computed tomography) of herniated lumbar disc or lumbosacral stenosis (lateral recess or foraminal stenosis) compatible with pain symptoms. Exclusion criteria were as follows: previous history of spinal surgery, such as lumbar fusion or laminectomy; bilateral symptoms or involvement of more than 1 segment; myelopathy; infection of the spine; and coagulation disorder.

The Institutional Review Board of Yeungnam University Hospital approved the study, and all patients signed an informed consent form. Fifty patients with chronic lumbosacral radicular pain were randomly assigned to 1 of 2 groups. In the bipolar PRF group, 25 patients received bipolar PRF stimulation on the DRG. In the monopolar PRF group, 25 patients received monopolar PRF stimulation. Randomization was performed using a random table. Treatment was carried out only once for each patient.

2.2. PRF procedures

Aseptic techniques were adopted for the bipolar PRF treatment. For the procedure, the patient was laid in a prone position for C-arm fluoroscopy (Siemens) and two 22-gauge curved-tip cannulae (SMK Pole needle, 100 mm with a 10 mm active tip, Cotop International BV) were placed bilaterally around the DRG (Fig. 1). Two catheter needles (active tip electrodes) were inserted, and a sensory stimulation test was carried out using an RF generator (Cosman G4, Burlington, MA). Each catheter needle was then advanced toward the DRG until the patient reported a tingling sensation and/or dysesthesia at less than 0.3 V. The distance between the 2 catheter needle tips was less than 1 cm but they were not in contact with each needle tip.[32] The PRF treatment was administered at 5 Hz and a 5-ms pulsed width for 360 seconds at 45 V with the constraint that the electrode tip

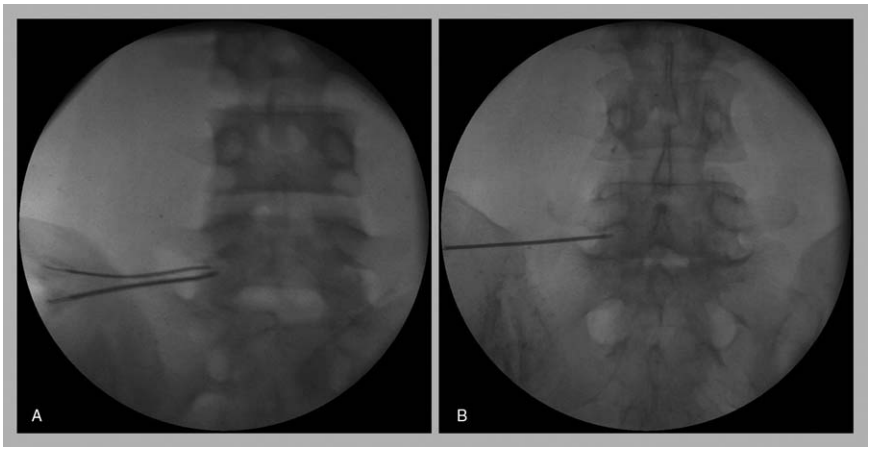

Figure 1. Fluoroscopy-guided bipolar pulsed radiofrequency (left) and monopolar pulsed radiofrequency (right) of the left L5 dorsal root ganglion.

temperature did not exceed 42 °C. In the monopolar PRF group, the preparation steps were identical to the PRF group. A 22-gauge curved-tip cannula (SMK Pole needle, 100 mm with a 10 mm active tip, Cotop International BV) was placed around the DRG (Fig. 1). When the patient reported a tingling sensation and/or dysesthesia at less than 0.3 V, the PRF treatment was administered with the same protocol as the bipolar PRF treatment.

2.3. Outcome measures

The assessments at pretreatment and follow-up periods were performed by 1 investigator; this investigator was blinded to the grouping of the patients and did not participate in any treatments. Pain intensity was assessed using an NRS with values between 0 and 10, with 0 representing "no pain" and 10 representing "the most intense pain imaginable." The NRS scores were measured before treatment, and 1, 2, and 3 months after treatment. Successful treatment was defined as more than 50% reduction in the NRS score at 3 months when compared to the pretreatment NRS score. To validate the change in pain reduction, NRS scores were evaluated by assessing the difference between the pretreatment NRS scores and the 3-month after treatment scores (change in NRS [%] = [pretreatment score − score at 3 months after treatment]/pretreatment score × 100).

2.4. Statistical analysis

Data were analyzed using the Statistical Package for Social Science (SPSS, v. 22.0, IBM Corporation, Armonk, NY). Demographic data and successful pain relief rate were compared between the 2 groups using the Mann–Whitney *U* test and chi-square test. The changes in NRS scores in bipolar and monopolar PRF groups were evaluated using repeated measure 1-factor analysis. Repeated measure 2-factor analysis was used to compare changes between groups over time. Multiple comparisons were obtained following a contrast using the Bonferroni correction. The level of statistical significance was set at $P < 0.05$.

3. Results

All patients completed the study. No adverse events were observed in both groups. No significant intergroup differences were observed for demographic data ($P > 0.05$) (Table 1).

In the bipolar PRF group, the mean NRS decreased after treatment. The pretreatment NRS was 5.1 ± 0.8. At 1 month, the mean NRS was 2.5 ± 1.5, at 2 months, 2.6 ± 1.6, and at 3 months, 2.6 ± 1.7 (Fig. 2). In the monopolar PRF group, the mean NRS decreased from 4.6 ± 0.8 pretreatment to 3.0 ± 1.5 at 1 month, 3.0 ± 1.5 at 2 months, and 3.0 ± 1.5 at 3 months.

Scores on the NRS for each group were significantly different over time ($P = 0.000$). In both groups, scores at 1, 2, and 3 months were significantly decreased when compared to pretreatment scores ($P = 0.000$). Reductions in the NRS scores over time were significantly larger in the bipolar PRF group ($P = 0.037$). In addition, the scores from pretreatment to each evaluation time point was significantly more reduced in the bipolar PRF group compared to the monopolar PRF group (1 month: $P = 0.032$, 2 months: $P = 0.043$, and 3 months: $P = 0.040$). Three months after treatment, 19 patients (76.0%) in the bipolar PRF group and 12 patients (48.0%) in the monopolar PRF group reported successful pain relief (pain relief of ≥50%). The rates of successful pain relief at 3 months after the procedures were significantly different between the 2 groups ($P = 0.041$).

4. Discussion

In the current study, we evaluated the clinical effects of the bipolar and monopolar PRF on the DRG, and compared the effects of both procedures. Our results showed that the severity of pain, which was measured using the NRS score, was significantly reduced after each bipolar and monopolar PRF procedure. Furthermore, we found that their effects were sustained for at least 3 months after each procedure. However, the reduction in the NRS scores was greater in the bipolar PRF group compared to the monopolar PRF group at 1, 2, and 3 months after the PRF stimulation. The rate of successful pain relief (more than 50% reduction of the pain at 3 months after the procedure) of monopolar PRF was 48.0%, which was similar to the results of previous studies. On the other hand, bipolar PRF had a significantly better rate of successful pain relief (76.0%) than monopolar PRF. Our results indicate that bipolar PRF is a more effective method for managing chronic lumbosacral radicular pain compared to monopolar PRF.

Although the mechanism underlying the pain-reducing efficacy of PRF was not clearly elucidated, previous studies suggested some possible mechanisms. Erdine et al[33] reported that PRF stimulation damages the sensory nociceptive axons at a microscopic or subcellular level. These lesions are selectively located in the smaller principal sensory nociceptors (C-fibers, and A-delta fibers), but rarely identified in the larger nonpain-related sensory fibers (A-beta fiber). Higuchi et al[21] found increased c-fos in laminae I and II of the dorsal horn after PRF to the DRG. Increased c-fos expression was suggested to activate some pain inhibition mechanisms. Cho et al[34] reported that PRF of the DRG decreased microglia activity in the spinal dorsal horn of a rat model of lumbar disc herniation. Because microglia releases several cytokines and chemokines that mediate pain signaling, downregulation of microglia activity could possibly control neuropathic pain. In addition, Hagiwara et al[20] reported that the analgesic action of PRF involves the enhancement of noradrenergic and serotonergic descending pain inhibitory pathways. Based on these experimental evidences, monopolar PRF is widely used for controlling neuropathic pain of a spinal nerve root origin. However, compared with monopolar PRF, it has been suggested that bipolar PRF would produce denser and larger electrical fields.[29–31] Shen et al[35] investigated the normal morphologic features of lumbar DRG in humans using 3-dimensional MRI. For the L5 DRG, the mean length was 11.6 mm and the mean width was 6.4 mm. When conventional RF was conducted using a cannula with a 10 mm exposed tip, the mean lesion size after monopolar RF was 12.8 mm × 7.8 mm (length × width).[36] Therefore, depending on the location of the RF stimulation tip around the DRG, monopolar RF may not sufficiently cover the DRG. The mean lesion size of bipolar RF using parallel cannulae spaced 10 mm apart was 15.5 mm × 11.8 mm (length × width),[36] thus bipolar RF can cover the DRG more sufficiently. A direct comparison between conventional RF and PRF would be difficult, but we think similar results can be inferred in the PRF procedure. Based on this idea, we applied bipolar PRF to the DRG of patients with chronic lumbosacral radicular pain. Our study demonstrated superior pain relief from bipolar PRF than from monopolar PRF.

Several studies have demonstrated the efficacy of monopolar PRF to the DRG in managing lumbosacral radicular pain.[7,22–28]

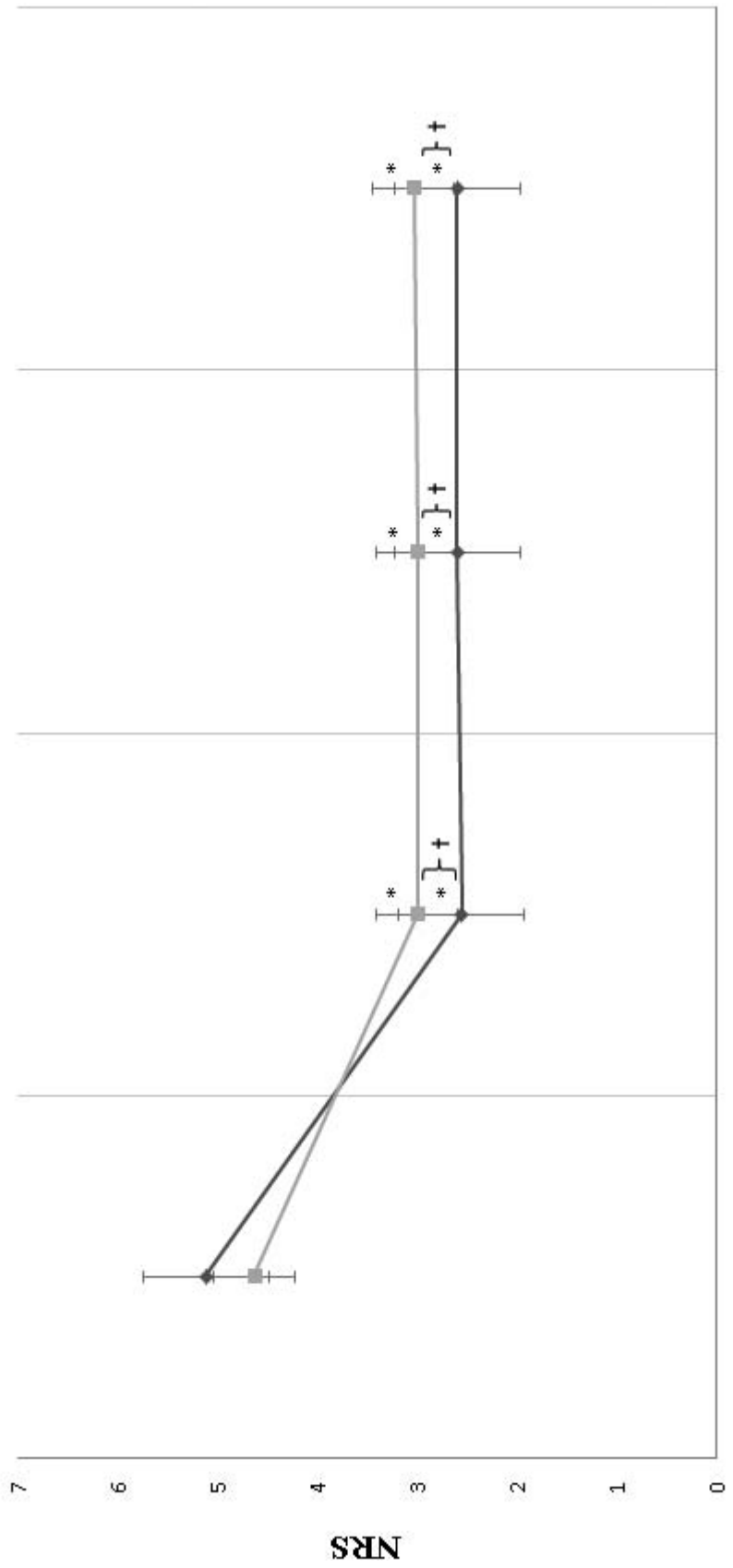

Figure 2. Changes in NRS. When compared to pretreatment NRS scores, both groups showed a significant decrease in scores at 1, 2, and 3 months after treatment. However, 1, 2, and 3 months after the procedures, the NRS score was significantly lower in the bipolar pulsed radiofrequency (PRF) group than in the monopolar PRF group. $^{*}P < 0.05$: intragroup comparison between 1, 2, and 3 months posttreatment, and pretreatment (repeated measure 1 factor analysis). $^{+}P < 0.05$: intergroup comparison in each time point (repeated measure 2 factor analysis). NRS = numeric rating scale, PRF = pulsed radiofrequency.

To the best of our knowledge, 5 studies have been published on the effect of monopolar PRF on chronic lumbosacral radicular pain.[23,24,26–28] In 2008, Simopoulos et al[27] applied monopolar PRF on 37 patients with chronic lumbosacral radicular pain. Three months after the PRF to the DRG, about half of the patients reported successful pain reduction. In the same year, Chao et al[23] recruited 116 patients with lumbar radicular pain following herniated lumbar disc or postlumbar surgery syndrome. At 3 months after PRF to the DRG, approximately 45% of the patients reported pain relief of more than 50%. In 2014, Shanthanna et al[26] reported that 6 out of 16 patients with radicular pain in the leg had a good response to PRF. In 2015, Koh et al[24] reported that 31 patients who received combined PRF and TFESI showed higher treatment efficacies for at least 3 months than 31 patients who received TFESI alone in chronic radicular pain. In the same year, Van Boxem et al[28] performed PRF on the DRG of 65 patients with chronic lumbosacral radicular pain, and 50% to 60% showed a positive treatment response; its effect was sustained for at least 6 months. However, thus far, no study has been conducted to evaluate the therapeutic efficacy of the bipolar PRF in lumbosacral radicular pain.

In conclusion, we found that both monopolar PRF and bipolar PRF stimulation to the DRG significantly relieved chronic lumbosacral radicular pain at 1, 2, and 3 months after the procedure. In addition, we demonstrated superior pain relief from bipolar PRF compared to monopolar PRF. We suggest bipolar PRF as a beneficial treatment option that can safely manage chronic lumbosacral radicular pain, particularly in patients with pain that is refractory to epidural steroid injection or monopolar PRF stimulation. This is the 1st study to evaluate the clinical efficacy of bipolar PRF for managing radicular pain in the leg. However, this study has some limitations. First, we recruited a small number of patients. Second, we did not investigate the long-term effects of bipolar PRF. Last, we are not able to explain why bipolar PRF exhibited a higher pain reducing effect than monopolar PRF. Further studies addressing these limitations are necessary.

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