Prospective Study

The Effect of Bipolar Pulsed Radiofrequency Treatment on Chronic Lumbosacral Radicular Pain Refractory to Monopolar Pulsed Radiofrequency Treatment

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Background: Patients with lumbosacral radicular pain may complain of persisting pain after monopolar pulsed radiofrequency (PRF) treatment.

Objective: We evaluated the effect of bipolar PRF stimulation of the dorsal root ganglion (DRG) in patients with chronic lumbosacral radicular pain who were unresponsive to both monopolar PRF stimulation of the DRG and transforaminal epidural steroid injection (TFESI).

Study Design: This is a prospective observational study.

Setting: The outpatient clinic of a single academic medical center in Korea.

Methods: We retrospectively reviewed data from 102 patients who had received monopolar PRF to the DRG for management of lumbosacral radiculopathy. Of these, 32 patients had persistent radicular pain that was scored at least 5 on a numeric rating scale (NRS). Twenty-three of them were included in this study and underwent bipolar PRF of the DRG. The outcomes after the procedure were evaluated using the NRS for radicular pain before treatment and 1, 2, and 3 months after treatment. Successful pain relief was defined as ≥ 50% reduction in the NRS score compared with the score prior to treatment. Furthermore, at 3 months after treatment, patient satisfaction levels were examined. Patients reporting very good (score = 7) or good results (score = 6) were considered to be satisfied with the procedure.

Results: The NRS scores changed significantly over time. At 1, 2, and 3 months after bipolar PRF, the NRS scores were significantly reduced compared with the scores before the treatment. Twelve (52.2%) of the 23 patients reported successful pain relief and were satisfied with treatment results 3 months after bipolar PRF. No serious adverse effects were recorded.

Limitations: A small number of patients were recruited and we did not perform long-term follow-up.

Conclusion: We believe the use of bipolar PRF of the DRG can be an effective and safe interventional technique for chronic refractory lumbosacral radiculopathy. It appears to be a potential option that can be tried before proceeding to spinal surgery.

Key words: Bipolar, pulsed radiofrequency, lumbosacral radicular pain, chronic pain, dorsal root ganglion, spinal stenosis, herniated disc

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Lumbosacral radicular pain is the most frequently occurring neuropathic pain, affecting 10 – 25% of the general population (1). Patients with lumbosacral radicular pain may experience reduced functional ability and quality of life (2). Lumbosacral radicular pain is a form of neuralgia that results from irritation or damage to the sensory nerve roots of the lumbosacral spine (3). Radicular pain in the

lower extremity is caused by ectopic firing of action potentials in the lumbosacral nerve roots or other neuropathic mechanisms (4,5). It radiates along the leg in the area innervated by the affected nerve with a sharp, shooting, and stabbing character. The most common causes of this pain are stimulation of inflammatory processes, mechanical compression by a herniated lumbar disc (HLD), and peripheral foraminal stenosis (6,7). About 3 quarters of patients with acute lumbosacral radicular pain can recover considerably within a few months (8); however, the prognosis of persistent chronic radicular pain is not favorable (9).

For the management of chronic lumbar radicular pain following HLD or foraminal stenosis, several medications and techniques have been utilized (10-12). Pulsed radiofrequency (PRF), a technique introduced by Sluijter (11) in 1997, is known to be safe and effective in alleviating pain and works by delivering an electrical field and heat bursts to targeted nerves or tissues without damaging these structures (13-15). Continuous radiofrequency (CRF) exposes target nerves or tissues to a continuous electrical stimulation and ablates the structures by increasing the temperature around the RF needle-tip (16). In contrast to CRF, PRF applies a brief electrical stimulation followed by a long resting phase. Thus, PRF does not produce sufficient heat to cause structural damage (17). The proposed mechanism of PRF is that the electrical field produced by PRF can alter pain signals (18-20). To date, several studies have reported that PRF stimulation of the dorsal root ganglion (DRG) can successfully manage lumbosacral radicular pain (10,21-27). However, many patients with lumbosacral radicular pain continue to complain of uncontrolled pain after PRF. In all the previous PRF studies, a single cannula (i.e., monopolar PRF) was used to control lumbosacral radicular pain. We have tried to overcome this limitation of conventional monopolar PRF stimulation by using a bipolar PRF stimulation technique that applies 2 electrode tips to the DRG. We believed that bipolar PRF would be more effective than monopolar PRF because bipolar PRF may produce denser and lager electrical fields.

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

Methods

Patients

From January 2014 to June 2015, a total of 102 patients received monopolar PRF stimulation of the DRG for the treatment of lumbosacral radicular pain, and we recruited patients who continued to complain of persistent lumbosacral radicular pain after a monopolar PRF procedure under real-time fluoroscopy. Monopolar PRF was performed when the patient's radicular pain was scored at least 5 (0 indicating no pain and 10 indicating the worst pain imaginable) on a numeric rating scale (NRS), despite at least a single procedure of TFESI. Thirty-two of the 102 patients reported persistent radicular pain rated at least 5 on the NRS. We retrospectively reviewed data from patients who had received monopolar PRF procedures. From January 2015 to March 2016, we prospectively conducted this study. Out of the 32 patients, 23 patients (mean age: 60.3 ± 12.5 years, range 22 – 74 years) were included in this study and underwent bipolar PRF treatment after applying the following inclusion criteria (Table 1):

1. ≥ 6-month history of segmental pain of lumbar or sacral origin radiating from the back to the leg
2. Age between 20 and 79 years
3. ≥ 50% temporary pain relief following a diagnostic nerve block with 1 mL of 2% lidocaine
4. Unsatisfactory response to monopolar PRF stimulation of the DRG (segmental pain of at least 5 on the NRS that radiated to the leg despite monopolar PRF stimulation of the DRG
5. No interval change in the pain score on the NRS over the 4 weeks after monopolar PRF
6. Imaging findings (magnetic resonance imaging and/or computed tomography) of HLD or lumbosacral stenosis (lateral recess or foraminal stenosis) compatible with pain symptoms.

Exclusion criteria were as follow:

1. Previous history of spinal surgery, such as lumbar fusion or laminectomy
2. Bilateral symptoms or involvement of more than one segment
3. Myelopathy
4. Infection of the spine
5. Coagulation disorder.

The Institutional Review Board of our hospital approved the study, and all patients provided a signed informed consent form.

Table 1. *Demographic data for each patient.*

Case No.	Gender	Age (yr)	Imaging Finding	Duration from Pain Onset to Bipolar PRF	Treatment Level
1	M	22	Herniated lumbar disc	6	Rt. S1
2	M	70	Herniated lumbar disc	34	Rt. L5
3	M	45	Herniated lumbar disc	6	Rt. L5
4	M	68	Herniated lumbar disc	36	Rt. L5
5	M	66	Herniated lumbar disc	9	Lt. L5
6	M	68	Herniated lumbar disc	15	Rt. L5
7	F	68	Lumbosacral stenosis	14	Lt. L5
8	M	65	Lumbosacral stenosis	14	Lt. S1
9	M	70	Lumbosacral stenosis	6	Rt. L5
10	F	64	Herniated lumbar disc	6	Lt. L4
11	M	62	Lumbosacral stenosis	8	Rt. L5
12	M	70	Lumbosacral stenosis	10	Lt. L5
13	M	52	Herniated lumbar disc	6	Rt. L5
14	F	58	Lumbosacral stenosis	23	Lt. L5
15	M	59	Herniated lumbar disc	7	Rt. L5
16	F	62	Herniated lumbar disc	6	Rt. S1
17	F	68	Lumbosacral stenosis	19	Rt. S1
18	M	55	Herniated lumbar disc	12	Lt. L5
19	M	72	Herniated lumbar disc	24	Lt. L5
20	F	74	Lumbosacral stenosis	6	Lt. L5
21	M	40	Herniated lumbar disc	10	Rt. S1
22	M	65	Lumbosacral stenosis	17	Rt. L5
23	M	44	Herniated lumbar disc	8	Lt. L3
Average		60.3		13.1	

PRF = pulsed radiofrequency; M = male; F = female; Rt = right; Lt = left

Bipolar 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, Munich, Germany) and 2 22-gauge curved-tip cannulae (SMK pole needle, 100 mm with a 10 mm active tip, Cotop International BV, Amsterdam, Netherlands) 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, Cosman Medical, 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 without being in contact with each needle-tip (28). 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 temperature did not exceed 42°C.

Outcome Measurements

Pain intensities were assessed using the NRS for radiating pain in the leg before treatment and 1, 2, and 3 months after treatment. The patients were asked to report their pain using a NRS with 0 indicating no pain and 10 indicating the worst pain imaginable. Successful pain relief was defined as ≥ 50% reduction in the NRS score compared with the score prior to treatment. Change in the NRS score was also calculated by the difference between pretreatment and 3 months after treatment in order to validate the degree of change in pain reduction (change in NRS [%] = [pretreatment score - scores at 3 months after treatment]/ pretreatment score × 100).

After 3 months, the patient global perceived effect was assessed using a 7-point Likert scale (Table 2) (29,30). Patients reporting very good (score = 7) or good results (score = 6) were considered to be satisfied with the procedure.

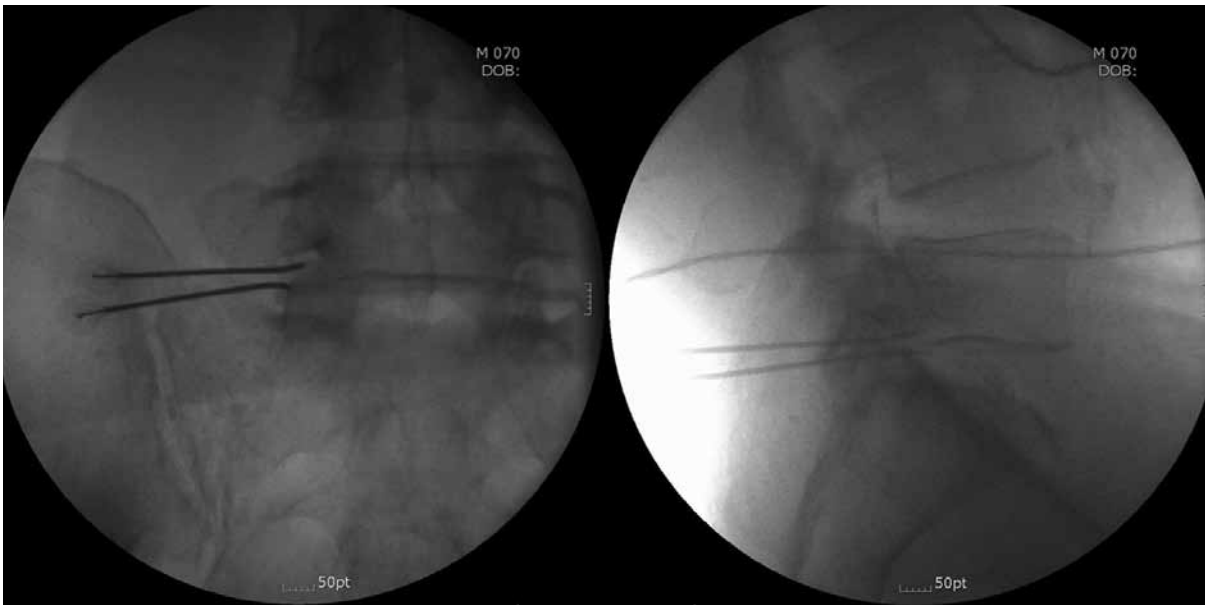

Fig. 1. *Fluoroscopy-guided bipolar PRF of the left DRG.*

Adverse Events

Adverse effects were evaluated at each visit in order to detect flare-ups of pain and newly developed neurologic deficits after the procedure.

Statistical Analysis

Data were analyzed using the Statistical Package for Social Sciences (SPSS) Version 22.0 (IBM Corporation, Armonk, NY). The summary of characteristic variables was performed using descriptive analysis, with the mean ± standard deviation presented for quantitative variables and frequency (percent) for qualitative variables. The overall change in NRS scores over time was evaluated using a repeated measures one-factor analysis. Multiple comparison results were obtained following a contrast under Bonferroni correction. A P-value of less than 0.05 was considered to indicate statistical significance.

Results

There were no drop-outs in this study. The average NRS of the lumbar radicular pain declined from 6.0 ± 0.9 pretreatment to 3.5 ± 1.9 at one month, 3.6 ± 2.0 at 2 months, and 3.5 ± 2.2 at 3 months after bipolar PRF. The NRS scores significantly changed over time ($P < 0.001$) (Fig. 2). 1, 2, and 3 months after bipolar PRF, the NRS scores were significantly reduced compared with the scores before bipolar PRF ($P < 0.001$) (Fig. 2). Twelve patients (52.2%) of the 23 patients reported successful pain relief (pain relief of ≥ 50%) 3 months after bipolar PRF.

On the 7-point Likert scale, very good results (score = 7) were seen in 6 patients (26.1%). Good (score = 6) and fairly good results (score = 5) were observed in 6 (26.1%) and 2 patients (8.7%), respectively. However, no change in results (score = 4) was observed in 9 patients (39.1%). Accordingly, 12 patients, 52.2% of all included patients, were satisfied with the results 3 months after bipolar PRF procedure. Fairly bad (score = 3), bad (score = 2), and very bad (score = 1) results were not reported.

One patient complained of temporarily aggravated radicular pain 14 days after the bipolar PRF, without any motor or sensory changes.

Discussion

In this study, we evaluated the effect of the application of pulsed bipolar PRF of the DRG in patients with chronic lumbosacral radicular pain who were refractory to both monopolar PRF of the DRG and TFESIs. After the bipolar PRF of the DRG, the radicular pain was significantly reduced, and the effect was sustained for at least 3 months. Furthermore, 52.5% of the patients showed successful pain relief and satisfaction with the results following bipolar PRF.

The mechanisms of how PRF reduces pain remain unclear. However, Higuchi et al (18) demonstrated increased c-fos in laminae I and II of the dorsal horn following PRF to the DRG. Increased c-fos expression is known to cause sustained activation of some pain-inhibition mechanisms. Cho et al (19) reported that PRF of the DRG decreased microglia activity in the spinal dorsal horn of a rat model of lumbar disc herniation. Since microglia contribute to the development of chronic neuropathic pain by releasing several cytokines and chemokines that mediate pain signaling, downregulation of microglia could possibly prevent progression to chronic neuropathic pain. In addition, Hagiwara et al (20) reported that the electromagnetic field of the PRF enhances the noradrenergic and serotonergic descending pain inhibitory pathways and the inhibition of excitatory C-fibers. Currently, monopolar PRF is widely used for controlling neuropathic pain of a spinal nerve root origin. However, it has been suggested that bipolar RF would be more effective than monopolar RF (31-33). Monopolar RF produces a small prolate spheroid lesion around the uninsulated cannula tip. Bipolar RF generates a lesion between and around 2 closely positioned uninsulated cannula tips. Therefore, bipolar RF is proposed to produce denser and larger electrical fields (31-33). Based on this idea, we applied bipolar PRF to the DRG in patients with lumbosacral radicular pain who did not show a satisfactory response to monopolar PRF. We found that the radicular pain was significantly reduced at 1, 2, and 3 months after bipolar PRF, and over half of the patients were satisfied with the application of bipolar PRF to the DRG.

The average duration between symptom onset and bipolar PRF procedure was 13.1 months and all patients were more than 6 months after the onset of pain. Considering these facts, we believe that our patients' pain had reached a plateau state, and the reduced pain after the bipolar PRF was not a result of the natural process of lumbosacral radicular pain. Therefore, although we did not conduct a comparison between bipolar PRF outcomes with controls, our results seem to demonstrate the usefulness of applying bipolar PRF to the DRG in patients with chronic radicular pain refractory to monopolar PRF and TFESI.

The mean period of time between conducting bipolar PRF and onset of radicular pain was 13.1 months. Furthermore, we applied bipolar PRF to the DRG in patients with intractable radicular pain who did not show good responsiveness to monopolar PRF and TFESI. Previous studies have reported that the early treatment of neuropathic pain can be more effective in reducing neuropathic pain (34,35). Thus, if we recruited patients with a shorter period between symptom onset and bipolar PRF or if we did not only recruit patients with intractable pain, the outcomes of the bipolar PRF may be improved.

Regarding the side effects of the bipolar PRF, one patient presented with temporary aggravated radicular pain after bipolar PRF that resolved after 2 weeks. Although theoretically PRF does not produce significant heat that could induce tissue damage, several cases of post-procedural neuropathy have been reported clinically (10,36). Several animal studies reported microscopic changes in neural structures following PRF (37-39). It was reported that the internal ultrastructural components of the axon and myelin showed microscopic damage, such as morphological change, in the mitochondria and disruption of the microfilaments and microtubules. Considering these findings, the temporary radicular pain appears to be the result of microscopic damage to the DRG that may be due to the heat generated at the electrode tip.

Table 2. *Global perceived effect according to a Likert scale.*

Score	% Change	Description
7	≥ 75 improvement	Very good
6	50 - 74 improvement	Good
5	25 - 49 improvement	Fairly good
4	0 - 24 improvement or worse	Same as before
3	25 - 49 worse	Fairly bad
2	50 - 74 worse	Bad
1	≥ 75 worse	Very bad

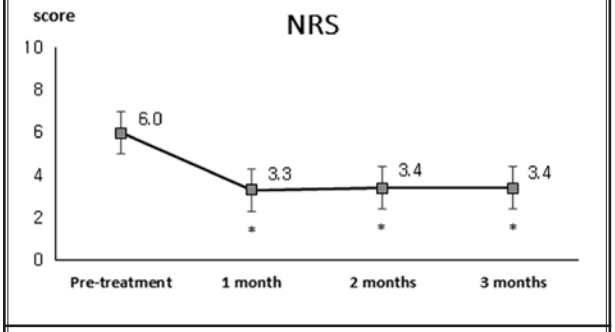

Fig. 2. *Changes in NRS score for lumbosacral radicular pain over the assessment period. The NRS scores significantly reduced from 6.0 prior to treatment to 3.3 at 1 month, 3.4 at 2 months, and 3.4 at 3 months after bipolar treatment.*
* Indicates a significant result ($P < 0.05$).

Thus far, several studies have reported the efficacy of applying monopolar PRF to the DRG in alleviating lumbosacral radicular pain (10,20-27). As for chronic lumbosacral radicular pain, to the best of our knowledge, 5 studies have been reported. In 2008, Simopoulos et al (26) recruited 37 patients with lumbosacral radicular pain who were not responsive to conservative treatment, including interlaminar epidural steroid injections. Half of the patients showed a successful reduction in pain intensity at 3 months after the application of PRF to the DRG. In the same year, Chao et al (22) investigated 116 patients with lumbar radicular pain due to a HLD or previous failed surgery. At 3 months after PRF to the DRG, about 45% of the patients had pain relief of more than 50%. In 2014, Shanthanna et al (25) reported a low success rate for PRF in chronic lumbosacral radiculopathy; 6/16 patients showed a positive response at 3 months after PRF. However, this study was not considered applicable due to its small sample size and inclusion of various pathologies causing radicular pain. In 2015, Koh et al (23) reported that 31 patients who received combined PRF and TFESI showed higher treatment efficacies than 31 patients who received TFESI alone in chronic radicular pain lasting more than 4 months. In the same year, Van Boxem et al (27) reported that in a group of 65 patients with lumbosacral radicular pain for more than 3 months, 50 – 60% showed successful treatment at 6 weeks, 3 months, and 6 months. When combined, except for Shanthanna et al's study (25), which seems to be confounded by a small number of included cases and wide inclusion criteria, 45 – 60% of patients with chronic lumbosacral radicular pain showed good effects following monopolar PRF to the DRG. The present study is the first to demonstrate the usefulness of bipolar PRF to the DRG after the failure of monopolar PRF in managing chronic lumbosacral radicular pain.

Conclusion

In summary, we found that chronic lumbosacral radicular pain refractory to monopolar PRF on DRG and TFESI was significantly reduced at 1, 2, and 3 months after bipolar PRF on DRG. The rate of successful pain relief and patient satisfaction at 3 months after bipolar PRF were found to be 52.5%. Clinically, if monopolar RF or repeated TFESI cannot successfully control chronic radicular pain, clinicians often consider spinal operations as the next intervention. Based on our results, we think bipolar PRF on DRG can be one of the beneficial treatment options that can be safely tried before resorting to surgery. However, some limitations of this study should be considered. First, this study was conducted without a control or a placebo group. However, in the clinical setting, if both monopolar PRF of the DRG and TFESI cannot successfully control chronic lumbosacral radicular pain, clinicians have limited options to manage the pain conservatively. Therefore, it was difficult to choose an appropriate procedure for control group. Also, the recruitment of placebo or sham group is complicated with ethical issues. Second, a small number of patients was recruited. Third, we did not evaluate the long-term effects of bipolar PRF. Therefore, further studies addressing these limitations are necessary.

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