

## Pilot Study

# Output Current and Efficacy of Pulsed Radiofrequency of the Lumbar Dorsal Root Ganglion in Patients With Lumbar Radiculopathy: A Prospective, Double-blind, Randomized Pilot Study

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**Background:** Lumbar radicular pain (LRP) is a common but challenging clinical symptom. Pulsed radiofrequency (PRF), a neuromodulation technique that uses short pulses of radiofrequency current, is effective in treating various pain disorders. However, few studies have been conducted on the effects of PRF and its modifying parameters.

**Objectives:** Our study aimed to determine the intraoperative parameters of PRF of the lumbar dorsal root ganglion (DRG) that are related to clinical effects in patients with LRP unresponsive to transforaminal epidural steroid injections (TFESI).

**Study Design:** Prospective double-blind randomized controlled trial, pilot study.

**Setting:** Single medical center in the Republic of Korea.

**Methods:** Patients were allocated to one of 2 groups, high-voltage (60 V) or standard-voltage (45 V), according to the preset maximum voltage at which the active tip temperature does not exceed 42°C. Intraoperative parameters, such as output current, sensory threshold, and impedance, were measured. The primary outcomes were radicular pain intensity, physical functioning, global improvement and satisfaction with treatment, and adverse events. The assessments were performed up to 3 months postprocedure.

**Results:** The patients in the standard-voltage group showed significant improvements in the Numeric Rating Scale pain score ( $P = 0.007$ ) and Oswestry Disability Index (ODI) ( $P = 0.008$ ) scores at 3 months post-PRF; however, no difference was observed in the high-voltage group. Among the intraoperative parameters, the output current showed a significant negative linear relationship with analgesic efficacy. The output current also showed a significant association with pain intensity ( $P = 0.005$ ,  $R^2 = 0.422$ ) and ODI score ( $P = 0.004$ ,  $R^2 = 0.427$ ) at 3 months postprocedure in a multiple regression analysis. The optimal cut-off value of the output current to lower pain intensity after 3 months was 163.5 mA with a sensitivity of 87.5%, specificity of 100%, and an area under the receiver operating characteristic curve value of 0.92 (95% CI. 0.76 – 1.00).

**Limitations:** Limitations of our study include an imbalance of baseline characteristics, small sample sizes, and short follow-up periods

**Conclusions:** Lower output currents during PRF application to the lumbar DRG were associated with greater analgesic effects in patients who did not respond to therapeutic TFESI.

**Key words:** Lumbar radicular pain, pulsed radiofrequency, dorsal root ganglion

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**L**umbar radicular pain (LRP) is a common but challenging clinical problem (1,2). Patients with LRP who show an unsatisfactory response to treatment may develop chronic nerve irritation or neuropathic pain disorders (1,2). Interventional procedures may be considered if conservative treatment is not effective (2).

Radiofrequency has been used as a therapeutic tool for more than 30 years (3). Pulsed radiofrequency (PRF) is a recently developed non-neurorestorative technique that uses short pulses of radiofrequency current with intervals of longer pauses between the pulse; notably, the exposed needle tip is maintained below a temperature of 42°C (3,4).

Previous studies have shown that applying PRF to the lumbar dorsal root ganglion (DRG) is effective in treating LRP (5,6). However, PRF's effectiveness in treating lumbar DRG remains controversial (7). Therefore, it is necessary to identify the variables that need to be modified during PRF to increase its effectiveness.

There has been a comparative study of the analgesic effects according to the output voltage during PRF in patients with LRP (8). However, the relationships between the clinical effects and other interoperative parameters, except for voltage, were not elucidated.

Our study aimed to investigate the feasibility of assessing the relationship between the clinical effects and intraoperative parameters according to the preset maximum output voltage of PRF during its application to the lumbar DRG in patients with LRP who were unresponsive to transforaminal epidural steroid injections (TFESI).

## METHODS

### Study Design and Registration

This was a prospective, double-blind, randomized pilot study. This study was approved by the Ethics Committee of the Catholic Kwandong University International St. Mary's Hospital (IS22OISE0032) and registered with the Clinical Trial Registry of Korea (CRIS, [www.cris.nih.go.kr](http://www.cris.nih.go.kr)) (Registration number: KCT0007578).

### Patient Recruitment

As reported previously (9), patients with LRP were initially assessed for eligibility and recruitment. This study recruited 20 patients who visited the outpatient pain clinic of the Catholic Kwandong University International St. Mary's Hospital after obtaining written informed consent from the patient.

Patients fulfilling the following criteria were included in this study: 1) age  $\geq$  20 years; 2) pain intensity  $\geq$  5 out of 11 on the Numeric Rating Scale (NRS-11); 3) chronic LRP lasting  $\geq$  12 weeks; 4) no response to conservative management modalities, such as physiotherapy, exercise therapy, or analgesic medications; 5) lumbar spinal stenosis or disc herniation confirmed by magnetic resonance imaging; 6) patients who received conventional fluoroscopy-guided therapeutic TFESI; 7) patients who received at least 2 TFESI in the 3 months preceding PRF treatment; and 8) patients who reported persistent pain (NRS-11 score  $\geq$  5) after receiving TFESI.

Exclusion criteria were: patients with an NRS-11 score  $>$  9 points (unbearable pain) or an NRS-11 score  $<$  4 points; acute pain for  $<$  12 weeks; signs of progressive motor weakness or neurologic deficits; an allergy to steroids or contrast medium dyes; coagulopathy; a history of receiving epidural steroid injections within 4 weeks before reporting to our clinic; systemic infection; an injection site infection; or malignancy. Patients who declined participation were also excluded.

### Randomization and Blinding

Using a computer-generated scheme, the patients were randomized into 2 groups, a standard-voltage (45 V) or a high-voltage (60 V) group at a 1:1 ratio according to the preset maximum voltage at which the active tip temperature does not exceed 42°C. Blinding was performed using a sealed opaque envelope technique, with the physician opening a sequentially numbered opaque envelope containing group assignments immediately before initiating the procedure. All patients were blinded to the group allocation until the study was completed. A single researcher who was blinded to the group allocation collected the postprocedure data.

### Procedures

All procedures were performed by the same physician (SP) under fluoroscopic guidance in an operating room. The patients were placed prone with a pillow supporting the lower abdomen. After sterile preparation of the needle insertion area, 1% lidocaine was infiltrated at the needle-entry site.

For the procedure, 22G, 4-inch RF cannulas with a 10 mm curved active tip were used in both groups. The tip of the cannula was placed on the superoposterior aspect of the intervertebral foramen in the lateral images, and between one-third and the middle of the pedicle in the anteroposterior images. (10) After confirming epidural spread using 1 mL of contrast medium

dye, the stylet was replaced with the RF probe. The probe was then connected to the PRF generator (Radiofrequency Ablation for Pain Management, G4™ RF Generator; Cosman Medical).

The final, definitive location of the RF probe adjacent to the lumbar DRG was determined using the sensory (50 Hz) and motor stimulation thresholds and impedance. The sensory stimulation was set to a threshold of  $\leq 0.4$  V, the motor stimulation threshold (2 Hz) was 1.5-fold greater than the sensory stimulation threshold, and the impedance was less than 400  $\Omega$ . The position of the RF cannula was adjusted slightly after each cycle of treatment.

The maximum output voltage was set to 45 V and 60 V depending on the group; the temperature was maintained at 42°C or lower, the pulse width was 20 milliseconds, the frequency was 2 Hz, and the duration was 120 seconds for 2 cycles. The generator was manipulated by an operating room nurse, and the display was concealed from the patient and physician.

### Outcome Assessment and Follow-up

As part of the baseline data, we collected information regarding the age, gender, height, weight, body mass index, coexisting medical conditions (e.g., diabetes and hypertension), diagnosis, stenosis location (11), total pain duration, the affected nerve root's target level, and the number of prior epidural injections. We also collected intraoperative parameter data regarding output currents, impedance, and sensory and motor thresholds.

The following data were collected: 1) radicular pain intensity, which was assessed using an 11-point NRS-11 scale (0 = no pain, 10 = unbearable pain); 2) physical functioning, which was assessed using the Korean version 10-item Oswestry Disability Index (ODI) questionnaire (range: 0–100; 0 = no disability); 3) global improvement and satisfaction with treatment, which was assessed using a global perceived effect (GPE) score on a 7-point Likert scale; and 4) adverse events during treatment and follow-up that were individually recorded.

The primary outcomes were the NRS-11 and ODI scores at 3 months postprocedure. The secondary outcomes were reduced pain intensity and ODI score compared with the baseline values, GPE, and adverse events.

### Statistical Analysis

Continuous variables are presented as median

(interquartile range) and were compared using the Mann–Whitney U test. Categorical variables are presented as frequency (percentage) and were compared using Fisher's exact test. The Wilcoxon signed-rank test was used to evaluate within-group differences. Repeated-measures analysis of variance was used to evaluate between-group differences. Correlation and multiple regression analyses were performed to examine the relationship between the intraoperative parameters and outcomes. A stepwise method was used in the multiple regression analyses, and age, body mass index, pain duration, stenosis location, and output current were used as covariates. Multicollinearity was assessed using a variance inflation factor. Receiver operating characteristic (ROC) curves were used to assess the optimal cut-off point. Statistical significance was set at  $P < 0.05$ . All statistical analyses were performed using IBM SPSS Statistics 26.0 (IBM Corporation).

### RESULTS

From September 2022 through February 2023, 38 patients who had received at least 2 TFESI in the 3 months preceding their enrollment date were initially recruited in the study. Among them, 20 patients who met the inclusion criteria and agreed to participate were randomized and allocated to either of the 2 groups. Two patients in the high-voltage group and one patient in the standard-voltage group withdrew from follow-up as they decided to undergo surgery; thus, 17 patients were included in the final analysis (Fig. 1).

The mean age of the high-voltage group was 77.0 years (range, 72.3 – 88.0), which was higher than that of the standard-voltage group, which had a mean age of 65 years (range, 60.5 – 75.5). No statistically significant differences were observed in the other baseline characteristics of the groups (Table 1). The standard-voltage group had 4 patients with a herniated nucleus pulposus; This group also had 4 patients with spinal stenosis. The high-voltage group had 2 patients with a herniated nucleus pulposus and 3 patients with spinal stenosis (Table 1). One patient in the standard-voltage group and 3 patients in the high-voltage group had combined herniated nucleus pulposus and spinal stenosis. There was no difference in stenosis location between the 2 groups.

Patients in the standard-voltage group showed significant improvements in the NRS-11 ( $P = 0.007$ ) and ODI ( $P = 0.008$ ) scores during the 3 months post-PRF

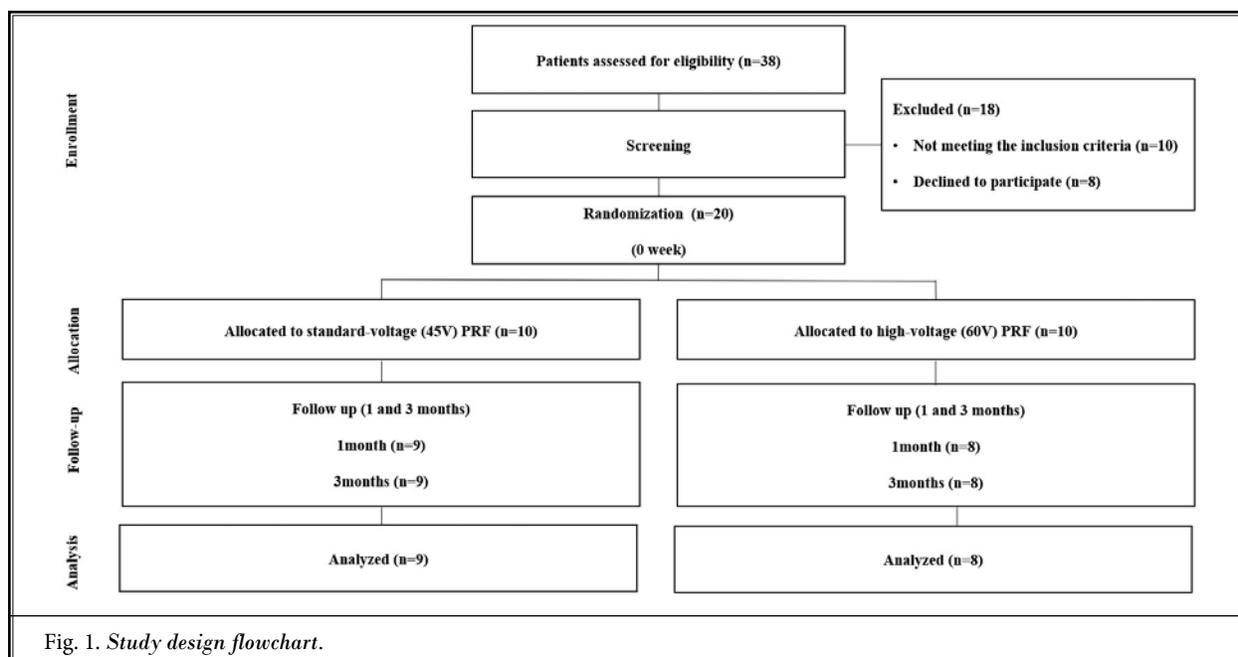


Fig. 1. Study design flowchart.

Table 1. Baseline characteristics and procedural variables.

	Standard-voltage (45 V) (n = 9)	High-voltage (60 V) (n = 8)	P Value
Men (%)	2 (22.2)	3 (37.5)	0.490
Age (years)	64.0 (60.5 – 75.5)	77.0 (72.3 – 83.0)	0.036
Height (cm)	158.0 (150.0 – 166.5)	157.5 (150.6 – 165.0)	0.888
Weight (kg)	68.0 (53.0 – 74.5)	58.5 (51.3 – 67.5)	0.370
BMI (kg/m <sup>2</sup> )	24.9 (21.8 – 28.6)	23.9 (21.9 – 26.4)	0.321
Pain duration (months)	9 (7 – 12)	9 (4 – 14)	0.963
Diagnosis			0.415
HNP	4 (44.4)	2 (25.0)	
Spinal stenosis	4 (44.4)	3 (37.5)	
Combined	1 (11.1)	3 (37.5)	
Location of stenosis			0.390
Central	2 (22.2)	1 (12.5)	
Lateral recess	2 (22.2)	0	
Foraminal	2 (22.2)	1 (12.5)	
Extraforaminal	0	1 (12.5)	
Combined	3 (33.3)	5 (62.5)	
Hypertension (%)	3 (33.3)	3 (37.5)	0.858
Diabetes (%)	6 (66.7)	4 (50.0)	0.486

Data are presented as median (25th percentile, 75th percentile) or frequency (percentage). BMI, body mass index; HNP, herniated nucleus pulposus.

Table 1 cont. Baseline characteristics and procedural variables.

	Standard-voltage (45 V) (n = 9)	High-voltage (60 V) (n = 8)	P Value
Treatment Levels			0.707
1	6 (66.7)	6 (75.0)	
2	3 (33.3)	2 (25.0)	
Treatment side			0.064
Right	1 (11.1)	5 (62.5)	
Left	5 (55.6)	1 (12.5)	
Bilateral	3 (33.3)	2 (25.0)	
Sensory threshold (V)	0.35 (0.30 – 0.40)	0.40 (0.31 – 0.48)	0.370
Motor threshold (V)	0.70 (0.65 – 0.95)	1.03 (0.75 – 1.33)	0.093
Current (mA)			
Initial	155 (139 – 215)	218 (199 – 238)	0.059
Final	143 (135 – 152)	202 (169 – 218)	0.001
Impedance (Ω)			
Initial	305 (295 – 352)	278 (254 – 371)	0.114
Final	311 (293 – 335)	273 (255 – 339)	0.114

Data are presented as median (25th percentile, 75th percentile) or frequency (percentage).

(Supplementary Table S1). However, patients in the high-voltage group showed no significant improvement in the NRS-11 or ODI scores during the 3 months. From 30 minutes post-PRF to 3 months post-PRF, a statistically significant difference was observed between

the NRS-11 scores of the 2 groups (Fig. 2). A significant difference was also observed between the ODI scores of the 2 groups at 3 months postprocedure. Significant differences were observed between the GPE of the 2 groups at one month and 3 months (Supplementary Table S2). Significant time and group interactions were observed in terms of the changes in the NRS-11 ( $P = 0.028$ ) and ODI scores ( $P = 0.010$ ) (Fig. 2).

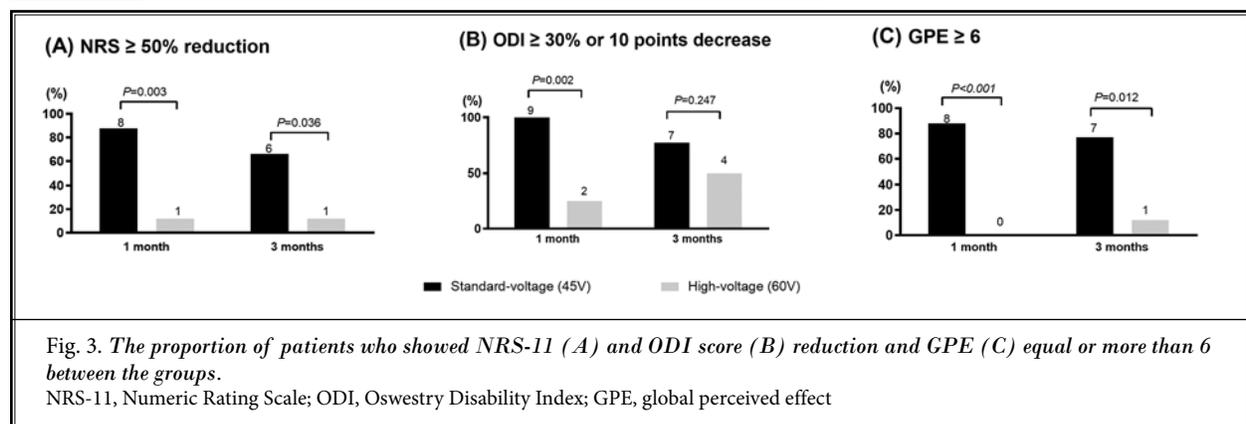
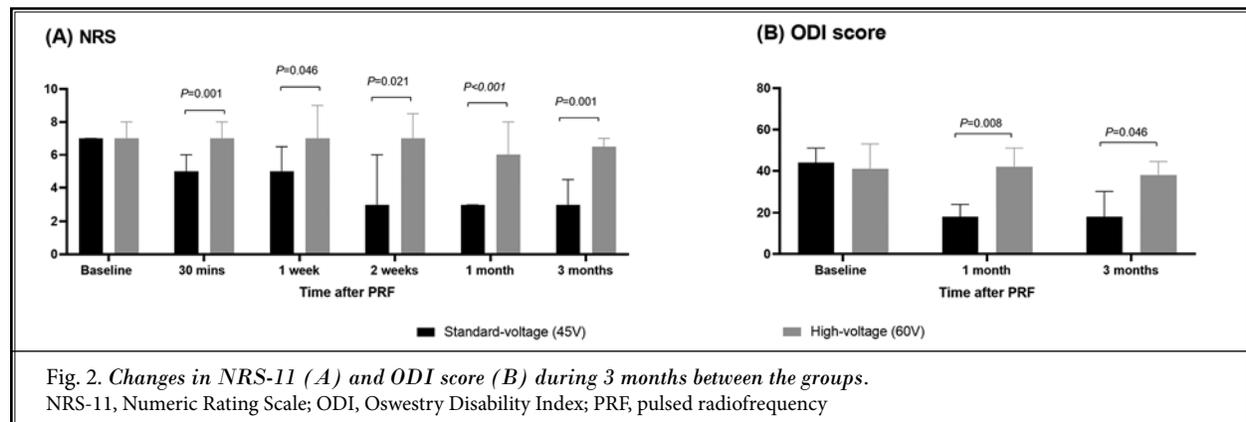
The proportion of patients who showed an NRS-11 reduction of  $> 50\%$  was significantly higher in the standard-voltage group than at baseline, one month ( $P = 0.003$ ), and 3 months ( $P = 0.036$ ) postprocedure (Fig. 3). The proportion of patients who showed an ODI reduction of  $> 30\%$  or 10 points was significantly higher in the standard-voltage group than at baseline and one month postprocedure ( $P = 0.002$ ). The proportion of patients with a GPE  $> 6$  was significantly higher in the standard-voltage group at one month ( $P < 0.001$ ) and 3 months postprocedure ( $P = 0.012$ ).

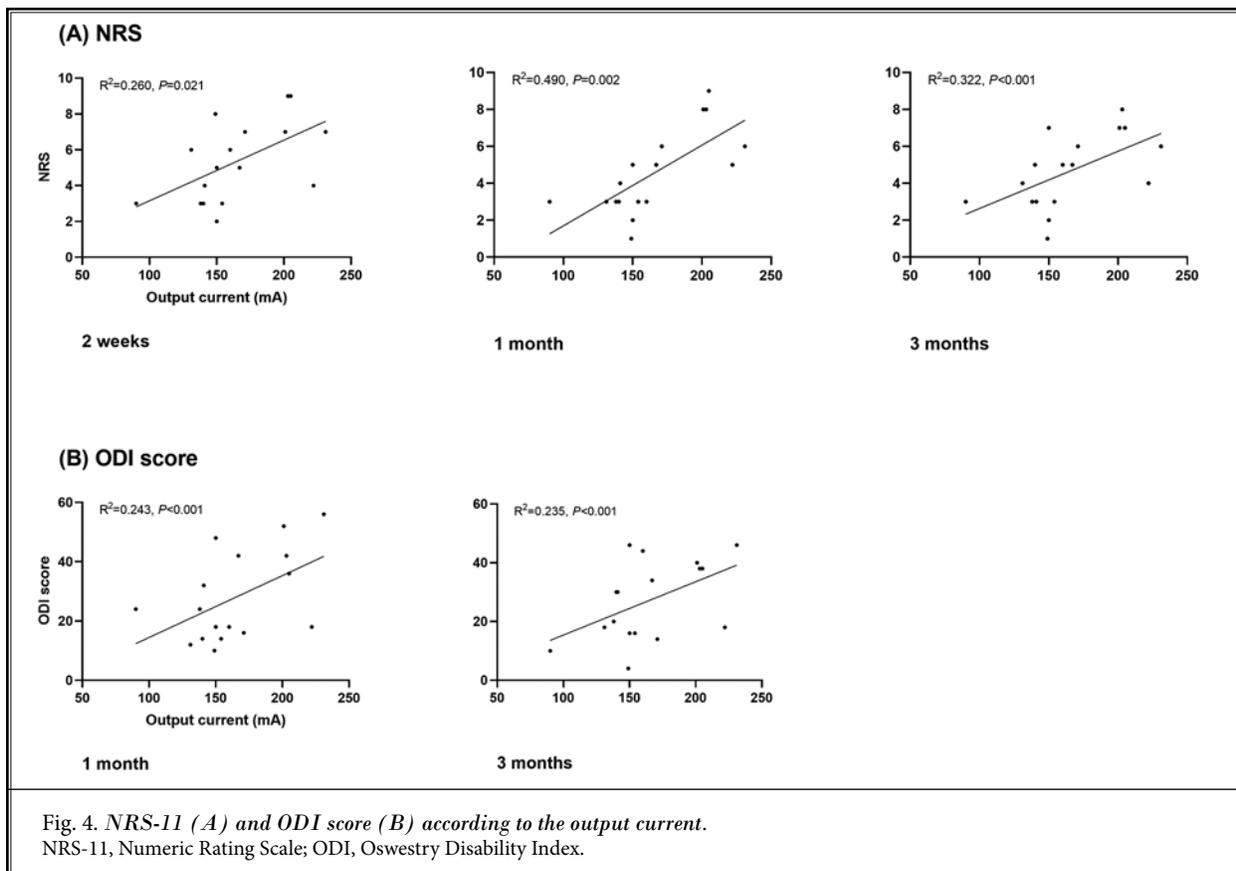
We observed a significant negative linear relationship between the output current and analgesic efficacy. Except at one week post-PRF, pain intensity from 30

minutes to 3 months was positively correlated with the output current (Fig. 4 and Supplementary Table S3). Similarly, significant positive linear relationships were observed between the output current and ODI scores. A multiple regression analysis revealed that the output current was significantly associated with pain intensity ( $P = 0.005$ ,  $R^2 = 0.422$ ) and ODI score ( $P = 0.004$ ,  $R^2 = 0.427$ ) at 3 months postprocedure. There was no significant relationship between the impedance and outcomes.

The ROC analysis indicated that the optimal cut-off value for the output current to lower the NRS-11 score at 3 months postprocedure was 163.5 mA, with a sensitivity of 87.5%, specificity of 100%, and area under the ROC curve (AUC) of 0.92 (95% CI, 0.76 – 1.00). No clinically significant complications were observed in either group.

There were no serious adverse events in either group. A few patients reported transient pain during needling and paresthesia upon sensory stimulation, but none required additional medication or discontinuation of the procedure.





## DISCUSSION

Our study evaluated the analgesic efficacy of applying PRF to the lumbar DRG in patients with LRP who did not respond to therapeutic TFESI. The present study reveals that the analgesic efficacy of PRF in the standard-voltage group was better than that in the high-voltage group. Previous clinical studies have suggested that analgesic efficacy is positively correlated with the voltage during PRF (8,12,13). However, in our study, the standard-voltage group consistently demonstrated low NRS-11 and ODI scores throughout the follow-up period. In addition, among the intraoperative parameters, only the output current showed a statistically significant linear relationship with pain intensity and physical functioning scores during all periods at one week postprocedure.

Erken et al (8) recently published a study conducted with the same preset voltage as our study; however, their results were in opposition to our findings, with the high-voltage (60 V) group showing better efficacy and longer duration of effect in patients with LRP than the standard-voltage (45 V) group.

The discrepancy between the results of the study by Erken et al (8) and our study may be attributed to the patients' age and response to treatment. First, the study population mainly consisted of elderly patients in our study. The average age of the patients in our study was over 70 years; in contrast, the average age was 51 years in the study by Erken et al (8). Second, the patients enrolled in the study by Erken et al (8) had a 75% response after a single diagnostic block with one mL of lidocaine. However, in our study, we only included patients who responded to 2 sessions of therapeutic TFESI but did not continue for more than 2 weeks or those who had an NRS-11 score of  $\geq 5$  even after receiving TFESI twice. Therefore, the patients of this study consisted of patients who did not respond to TFESI and might have had greater disease severity than those in the study of Erkin et al (8).

PRF exerts its therapeutic effects by generating an electric field in the DRG where mechanical compression is present, thereby causing inflammation in the spinal nerve roots and axonal ischemia (14,15). Although the exact mechanism of PRF in pain relief remains unclear,

it is known to be a nondestructive technique. However, some proposed mechanisms for pain relief after applying PRF to the DRG include neuronal cell damage and alteration of synaptic transmission functions.

An experimental study reported that PRF exerts its effects by causing microscopic damage to the DRG's cell morphology and sensory and nociceptive axons (16). In another experimental study, subclinical tissue changes, such as endoneurial edema and collagen deposition in the DRG, were observed when PRF was applied to the DRG of rats, even when the tissue temperature did not exceed 42°C (17). Larger PRF electric fields can be destructive and disruptive to neuronal membranes and their functions (18).

We presume that in elderly patients who did not respond to the treatments included in our study, a larger electric field that exceeded the therapeutic effect may have caused temporary or permanent histological changes in the DRG's ion channels and modifications to the resting and threshold potentials of neurons that transmit pain signals (18,19). We also speculate that a larger electrical field might cause an overreaction, preventing the occurrence of "resilience" despite no thermal damage.

Based on the results of our study, it can be concluded that increasing the preset voltage may not maximize the treatment effect, and that the selection of the current strength should be determined in consideration of pathophysiological evidence and patient characteristics, such as age and disease severity (14). In our study population, the optimal cutoff value of the output current to reduce pain intensity at 3 months postprocedure was 163 mA. Thus far, the optimal PRF output current remains unknown. In future studies, optimal treatment parameters that consider age, responsiveness to existing treatments, and disease severity should be evaluated.

In our study, there were no serious adverse events, but a review study analyzing complications of PRF applied to the DRG reported only minor adverse events, such as transient neuritis and localized pain at the injection site (20). In addition, a review study reporting complications of PRF or thermal RF applied to the dorsal root entry zone complex found no serious adverse events, suggesting that PRF applied to the DRG is a very safe method (10,21). In our study, we performed PRF in patients with an NRS-11 pain score of 5 or higher despite 2 TFESIs within 3 months. We consider PRF to

be a safe treatment option for patients who have difficulty tolerating a steroid or who do not respond to a single TFESI.

### Limitations

A limitation of this study is that the patients in the high-voltage group were older than those in the standard-voltage group. However, based on the results of the multiple regression analysis with age as a covariate, there was a statistically significant relationship between the primary outcome and the output current; the difference between the 2 groups might have been corrected to some extent.

Second, since this was a single-center pilot study, the sample size was small. In addition, histopathological changes, and psychophysical tests, such as quantitative sensory testing, were not compared in this study.

Lastly, the follow-up period of 3 months was short. Despite these limitations, our study attempted to identify the relationship between postoperative outcomes and intraoperative parameters. It should be noted that previous studies (8,12,13) only focused on the preset voltage and did not consider the output current and impedance, leaving a significant gap in the understanding of the relationship between output current and analgesic effect in patients with LRP. Further studies with larger sample sizes considering age and responsiveness to treatment are warranted to support these findings. In addition, further research exploring other PRF parameters, such as varying the duration of PRF application instead of voltage, are necessary to determine how to enhance and sustain analgesic effects.

### CONCLUSIONS

This study compared the efficacy of applying PRF to the lumbar DRG by varying the preset voltage in patients who did not respond to therapeutic TFESI. We found that lower output currents were associated with higher analgesic effects.

### Author Contributions

Park S, Shon JE and Park JH designed the research; Park S, Park JH, and Song YM collected the data; Park S and Jang JN analyzed the data; Park S, Kim DS and Kim YU contributed to the study conception; Jang JN, Park S, and Park S revised the manuscript; and Jang JN and Park S wrote the paper.

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Supplemental Table S1. *Within group changes compared to baseline.*

	<b>Total (n=17)</b>	<b>Standard-voltage (45 V) (n=9)</b>	<b>High-voltage (60 V) (n=8)</b>
	<b>P Value</b>	<b>P Value</b>	<b>P Value</b>
<b>NRS</b>			
30 mins	0.011	0.017	0.317
1 week	0.048	0.024	0.581
2 weeks	0.009	0.020	0.221
1 month	0.002	0.007	0.256
3 months	0.001	0.007	0.072
<b>ODI</b>			
1 month	0.003	0.008	0.400
3 months	0.001	0.008	0.063

NRS-11, Numeric Rating Score; ODI, Oswestry Disability Index

Supplemental Table S2. *Postprocedural outcomes between groups.*

	<b>Standard voltage (45 V) (n = 9)</b>	<b>High-voltage (60 V) (n = 8)</b>	<b>P Value</b>
<b>NRS</b>			
Baseline	7.0 (6.5 - 7.0)	7.0 (7.0 - 8.0)	0.167
30 mins	5.0 (3.5 - 6.0)	7.0 (7.0 - 8.0)	<0.001
1 week	5.0 (3.0 - 6.5)	7.0 (5.5 - 9.0)	0.046
2 weeks	3.0 (3.0 - 6.0)	7.0 (5.0 - 8.5)	0.021
1 month	3.0 (2.5 - 3.0)	6.0 (5.0 - 8.0)	<0.001
3 months	3.0 (2.5 - 4.5)	6.5 (5.3 - 7.0)	0.001
<b>ODI</b>			
Baseline	44.0 (35.0 - 51.0)	41.0 (35.5 - 53.0)	0.888
1 month	18.0 (13.0 - 24.0)	42.0 (22.5 - 51.0)	0.008
3 months	18.0 (13.0 - 30.0)	38.0 (22.0 - 44.5)	0.046
<b>GPE</b>			
1 month (0-7)	6.0 (6.0 - 7.0)	4.5 (4.0 - 5.0)	<0.001
3 months (0-7)	6.0 (5.5 - 7.0)	4.5 (4.0 - 5.0)	0.002
<b>NRS ≥ 50% reduction</b>			
1 month	8 (88.9)	1 (12.5)	0.003
3 months	6 (66.7)	1 (12.5)	0.036
<b>ODI ≥ 10 points decrease</b>			
1 month	9 (100)	2 (25.0)	0.002
3 months	7 (77.8)	4 (50.0)	0.247
<b>GPE ≥ 6</b>			
1 month	8 (88.9)	0	<0.001
3 months	7 (77.8)	1 (12.5)	0.012

Data are presented as median (25th percentile, 75th percentile) or frequency (percent). NRS-11, Numeric Rating Scale; ODI, Oswestry Disability Index; GPE, global perceived effect

Supplemental Table S3. *Output current and outcomes.*

	Output Current		Impedance	
	R <sup>2</sup>	P Value	R <sup>2</sup>	P Value
NRS				
30 mins	0.365	0.010	0.103	0.210
1 week	0.188	0.082	0.101	0.214
2 weeks	0.260	0.021	0.141	0.076
1 month	0.496	0.002	0.140	0.139
3 months	0.322	<0.001	0.054	0.371
ODI				
1 month	0.243	<0.001	<0.001	0.989
3 months	0.235	<0.001	0.029	0.472

NRS-11, numeric Rating Scale; ODI, Oswestry Disability Index; GPE, global perceived effect