

## ORIGINAL ARTICLE

## Efficiency of Standard Voltage Versus High Voltage Radiofrequency on Unilateral Lower Limb Neuralgia in Patients with Failed Back Surgery Syndrome

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|                   |                                                                                                                                                                                                                                                                                                                                                                                   |
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| <b>Background</b> | Failed back surgery syndrome (FBSS) influences an increasing quantity of patients. As lumbar surgery becomes more common, the incidence of FBSS is also expected to rise. This study aim is to compare the efficiency of standard voltage, pulsed radiofrequency (PRF) mode versus high-voltage long-duration PRF in treating radicular neuralgia following lumbar spine surgery. |
| <b>Methods</b>    | Ninety patients, aged 20 to 60 years, both sexes, presented with FBSS without instrumentation. Patients were categorized into 2 equal groups: Group I established standard low PRF treatment, while Group II established high-voltage long-term PRF.                                                                                                                              |
| <b>Results</b>    | There was a significant decrease in the Oswestry Disability Index (ODI) and the Numerical Rating Scale (NRS) at 1 week, 1 month, and 6 months in relation to pre-procedure values in both groups. Analgesic requirements after one week and six months were significantly higher in group I compared to group II ( $P>0.05$ ).                                                    |
| <b>Conclusion</b> | High-voltage PRF is more operative than low PRF, resulting in enhanced quality of life for patients.                                                                                                                                                                                                                                                                              |
| <b>Keywords</b>   | Failed Back Surgery Syndrome, Oswestry Disability Index, Radiofrequency Ablation.                                                                                                                                                                                                                                                                                                 |
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## INTRODUCTION

Failed Back Surgery Syndrome (FBSS) means a variety of lumbar pain of unidentified cause that is activated or worsened by spinal surgery at the similar anatomical site<sup>[1]</sup>. Research shows that FBSS occurs in 20% to 40% of patients who undergo back surgeries<sup>[2]</sup>.

It is recommended to use multilevel diagnostic approaches to achieve targeted treatment through accurate history, clinical examination, blood tests to check for infections following surgery, Magnetic resonance imaging (MRI) with gadolinium improvement to identify the underlying source of FBSS, such as fibrosis or disc

herniation, 3D MRI to diagnose foraminal stenosis, computed tomography to diagnose fusion mass and disc compression, and diagnostic facet injections assist in diagnosing facet joint arthropathy<sup>[3]</sup>. Psychological, demographic, and socioeconomic factors must be measured when assessing patients with permanent low back pain<sup>[4]</sup>.

Minimally invasive interventional treatments, including selective nerve blocks, pulsed radiofrequency (PRF), epidural adhesiolysis, spinal endoscopy intrathecal drug infusion, and spinal cord electrical stimulation, have become viable treatment options for FBSS<sup>[5]</sup>.

The traditional PRF method typically uses a standard temperature of 42°C. However, patients often do not achieve optimal therapeutic effects because of its short duration (120 seconds), low voltage (40V), and reduced intensity<sup>[6]</sup>. High-voltage, long-duration PRF has been increasingly used to treat neuropathic pain conditions as glossopharyngeal neuralgia, postherpetic neuralgia, and trigeminal neuralgia resulting in favorable outcomes<sup>[7]</sup>.

This study was designed to investigate the efficacy of high-voltage long-duration PRF mode versus standard voltage PRF in the treatment of neuralgia in cases of FBSS.

## PATIENTS AND METHODS

This prospective randomized controlled study was established from December 2022 to December 2024, following approval from our local ethical committee (IRB: 17101963), registration on clinicaltrials.gov (ID: NCT05563636), and obtaining informed consent from the patients arranged for elective adult interventional procedures under local anesthesia. This study pursued the Consolidated Standards of Reporting Trials (CONSORT) guidelines and the regulations of the Declaration of Helsinki. It included ninety patients of both sexes, aged 20 to 60 years, who underwent FBSS without instrumentation, exhibited obvious signs of unilateral lower extremity symptoms, lumbar nerve root irritation, and a positive straight leg elevating test. Patient or relative refusal, mechanical compression to the nerve root, retrosynthesis, spondylodiscitis, spondylolisthesis, coagulopathy, inflammatory low back pain, Lumbar canal stenosis, allergy to local anesthetic and systemic infection were the exclusion criteria.

### Randomization and blinding:

Allocation concealment was ensured using sequentially generated random numbers placed in sealed opaque envelopes, which were only opened by the researcher after patient enrolment. Both the patients and the physician conducting the follow-up were blinded to the type of intervention. Patients, who were categorized as grade I-II by the American Society of Anesthesiologists (ASA), were randomly assigned to 2 equal groups: The standard PRF treatment was administered to Group I ( $N=45$ ) at a, with a frequency of 2Hz temperature of 42°C, voltage of 40V, pulse width of 20ms, and time of 120sec. Group II ( $N=45$ ) was subjected to a high-voltage long-term PRF treatment mode at a temperature of 42°C and an output voltage set within the 70V range. Before the procedure all patients were exposed to complete history taking and were requested to assess their degree of dysfunction by Oswestry disability index (ODI) (self-completed questionnaire) ODI scoring: 0–20 percent: Minimal disability, 21–40 percent: Moderate Disability, 41–60 percent: Severe Disability, 61–80 percent:

Paralyzing back pain, and 81–100 percent: These patients are either have an exaggeration of their symptoms or bed-bound<sup>[8]</sup>.

Patients were also requested to measure their pain before the procedure using NRS established by using a ruler numbered from zero to ten (zero= no pain, one-three= mild pain, four- six= moderate pain, and seven-ten= severe pain)<sup>[9]</sup>. In the operating room, all patients in the two groups were positioned in a prone position, prepped for PRF of the spinal nerve on the affected side, and wrapped in the normal sterile fashion on a radiolucent operative table under fluoroscopic guidance and after alignment of the superior endplate of the vertebral level of the target superior articular process (SAP). An oblique rotation of the fluoroscopic unit to the ipsilateral side of approximately 25° to obtain Scotty dog view, 3ml lidocaine 2 percent was injected at the site of needle insertion after respectable sterilization by Betadine® solution then we used ten cm long, ten mm active tip, 20-gauge, RF cannula (Neurotherm), introduced and steered to the correct location using fluoroscopy. Contrast dye (0.3ml Omnipaque®) was used to confirm needle position (the tip of the puncture needle was positioned beneath the pedicle, and the lateral view showed the tip of the puncture needle was positioned at the posterior 1/2 of the intervertebral foramen). Motor testing was performed at 2Hz up to 2V, and muscle contraction was noticed from the skin at 0.6V; then motor stimulation was elevated to 2V to confirm lumbar root contact or lower limb contraction. Sensory stimulation was performed to verify the needle tip's position at 50Hz, and the patient experienced local back pain at 0.5V. In group I low voltage PRF (frequency: 2Hz, temperature: 42°C, voltage: 40V, pulse width: 20ms, time: 120sec) was done, and in group II high voltage PRF (frequency: 2Hz, temperature: 42°C, voltage: 70V, pulse width: 20ms, time: 360sec). Initially, the patient would experience a severe searing sensation in the initial pain area. The voltage was gradually increased to 70V after the patient had adapted to it. After the needle was retracted from patients in both groups, the injection site was covered with a sterile dressing.

After the procedure, patients in both groups were observed for 1 hour and discharged after meeting the standard discharge criteria. Any interventions or complaints following the procedure, such as local inflammation at the injection site, allergies, muscular spasms or pain, skin discoloration, or any complications related to PRF were also reported.

### Follow up:

All patients were contacted for 6 months, at intervals of 1 week, one month, and 6 months, to rate their ODI and NRS. We also reported the total analgesic consumption and the incidence of any complications (like superficial skin

infections in the injection site, hyperesthesia, mild allergic reaction to the contrast dye or the local anesthetic, damage to adjacent nerves and blood vessels while needle insertion can result, in irreversible neurologic damage, extreme bleeding, long-term tingling, numbness, and heat damage to structures head-to-head to the target nerve).

The primary outcome measure assessed the efficacy of high-voltage PRF using the ODI at one week, one month, and six months following the procedure. The secondary outcomes included NRS, total analgesic requirements, and the occurrence of complications during all follow-up periods.

### Sample size:

This study primary outcome is the ODI 6 months after treatment. Related to a prior study<sup>[10]</sup>. Power calculation estimated that to identify an effect size  $d$  of 0.6 alteration among the ODI of 2 independent groups, with a 80% power and  $p$ -value  $<0.05$ , a sample size of 90 patients was needed (G Power 3.1).

### Statistical analysis:

The Statistical Package for Social Science (SPSS) version 22 was employed to undertake data entry and analysis. To assess the normality of our data distribution, we utilized the Shapiro-Wilk test in conjunction with histograms. Quantitative parametric variables were showed as standard deviations (SD) and means and compared between the 2 study groups applying an unpaired Student's

$t$ -test, with repeated measures ANOVA with Bonferroni correction for within-group associations in each group. Qualitative variables were displayed as percentages and numbers and analyzed utilizing the Chi-square test.  $P$  value  $<0.05$  was assumed to be statistically significant.

## RESULTS

95 patients were evaluated for eligibility in this randomized controlled trial investigation. Five patients were excluded, and 90 patients were randomly assigned to 2 equal groups (45 patients in each) (Figure 1).

The demographic data did not show significant differences between the two groups regarding age, sex, BMI, and ASA classification (Table 1).

ODI scores did not show a statistically significant variance among the groups studied at preoperative values ( $P$  value= 0.205). However, after one week, one month, and 6 months, the ODS showed statistically significantly lower values in group II in comparison with group I ( $P$  value= 0.000). On the other hand, within group II, there was a statistically significant decrease in ODS in 1 week, 1 month, and 6 months in comparison with the preoperative values ( $P$  value= 0.000). The same trend was observed in group I, with a statistically significant decrease in ODS in one week, one month, and 6 months in comparison with the preoperative values ( $P$  value= 0.000) (Table 2).

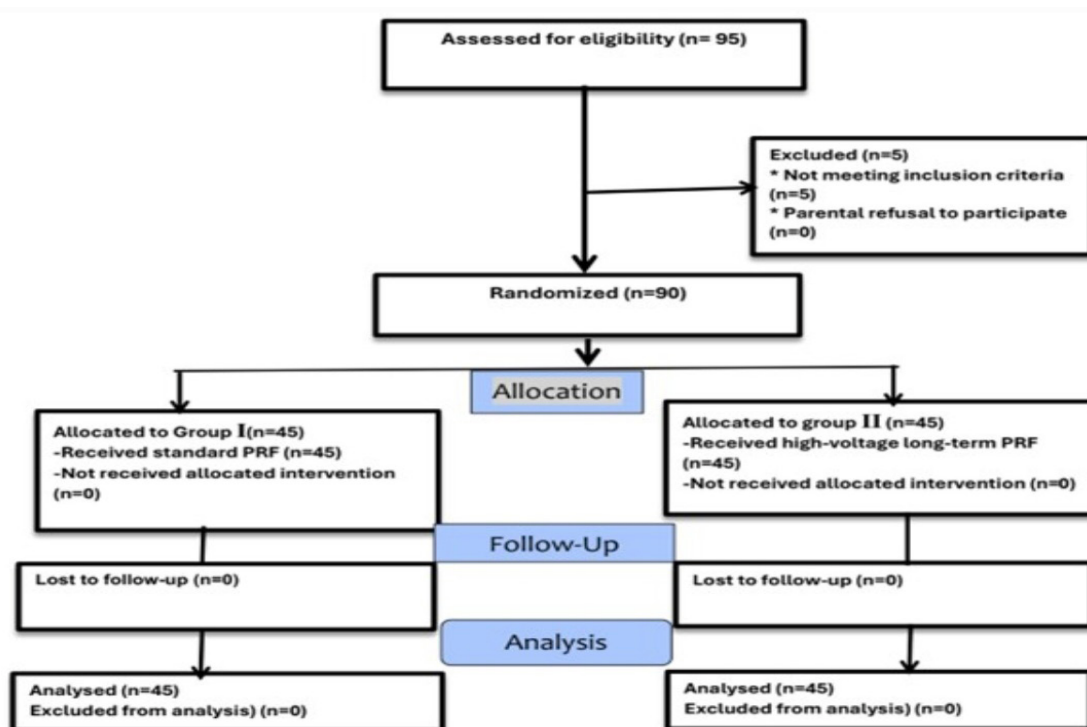


Fig. 1 : Participant Flow diagram.

**Table 1:** Demographic data of the studied groups:

|                          | Group I<br>(n= 45) | Group II<br>(n= 45) | P value |
|--------------------------|--------------------|---------------------|---------|
| Age (years)              | 48.20±5.92         | 49.98±5.36          | 0.139   |
| Sex (Male/Female)        | 26/19              | 26/19               | 1.000   |
| BMI (kg/m <sup>2</sup> ) | 28.85±2.42         | 28.27±2.01          | 0.221   |
| ASA (I/II)               | 28/17              | 24/21               | 0.393   |

Group 1> standard low pulsed radiofrequency (PRF), Group 2> high voltage, long-term PRF; Data presented as mean±SD or as numbers. Abbreviations: SD: Standard deviation; ASA: American Society of Anesthesiologists; BMI: Body mass index; number (N); *P*<0.05 indicates statistically significant differences.

**Table 2:** ODI of the studied groups:

| ODI                  | Group I (n= 45) | Group II (n= 45) | P-value <sup>1</sup> |
|----------------------|-----------------|------------------|----------------------|
| Baseline             | 75.91±4.48      | 74.62±5.07       | 0.205                |
| After 1 week         | 68.73±4.46      | 61.80±4.10       | 0.000*               |
| P-value <sup>2</sup> | 0.000*          | 0.000*           |                      |
| After 1 month        | 63.02±5.29      | 52.16±4.68       | 0.000*               |
| P-value <sup>2</sup> | 0.000*          | 0.000*           |                      |
| After 6 months       | 54.53±5.36      | 40.64±4.69       | 0.000*               |
| P-value <sup>2</sup> | 0.000*          | 0.000*           |                      |
| P-value <sup>3</sup> | 0.000*          | 0.000*           |                      |

Group 1> standard low pulsed radiofrequency (PRF), Group 2> high voltage, long-term PRF; Data presented as mean±SD; *P*-value 1: Comparison between groups; *P*-value 2: Comparison with baseline in each group; *P*-value 3: Comparison among all times in each group; *P*<0.05 indicates statistically significant differences; Abbreviations: ODI: Oswestry disability index.

NRS at preoperative values showed no statistically significant alteration among the studied groups (*P* value= 0.152). However, after one week, one month, and 6 months, the NRS showed statistically significantly lower values in group II in comparison with group I (*P* value= 0.000). On the other hand, within group 1, there was a statistically significant decrease in NRS at one week, one month, and 6 months in comparison with the preoperative values (*P* value= 0.000). The same trend was observed in group II, with a statistically significant decrease in NRS at one week, one month, and 6 months compared to the preoperative values (*P* value= 0.000) (Table 3).

The analgesia requirements of patients in both groups were significantly lower in group II in comparison with group 1 after one week and six months. There were 28 patients in group 1 who required additional analgesics after one week, while 19 needed them after six months. 17 patients in group II required additional analgesics after one week, and 10 patients after six months (*P* value= 0.020 and 0.042) (Table 4).

No post-procedural complications were observed in any patients from either group.

**Table 3:** Numerical Rate Scale (NRS) of the studied groups:

| NRS                  | Group I (n= 45) | Group II (n= 45) | P-value <sup>1</sup> |
|----------------------|-----------------|------------------|----------------------|
| Baseline             | 7.84±0.77       | 7.60±0.84        | 0.152                |
| After 1 week         | 7.44±0.84       | 5.67±1.00        | 0.000*               |
| P-value <sup>2</sup> | 0.000*          | 0.000*           |                      |
| After 1 month        | 6.27±0.65       | 4.96±0.80        | 0.000*               |
| P-value <sup>2</sup> | 0.000*          | 0.000*           |                      |
| After 6 months       | 5.04±0.74       | 3.78±0.64        | 0.000*               |
| P-value <sup>2</sup> | 0.000*          | 0.000*           |                      |
| P-value <sup>3</sup> | 0.000*          | 0.000*           |                      |

Group 1> standard low pulsed radiofrequency (PRF), Group 2> high voltage, long-term PRF; Data presented as mean±SD; *P*-value1: Comparison between groups; *P*-value 2: Comparison with baseline in each group; *P*-value 3: Comparison among all times in each group; *P*<0.05 indicates statistically significant differences.

**Table 4:** Number of patients who require analgesia after PRF in the studied groups:

| Analgesic consumption | Group 1 (n= 45) |       | Group II (n= 45) |       | P-value |
|-----------------------|-----------------|-------|------------------|-------|---------|
| Baseline              | 36              | 80.0% | 35               | 77.8% | 0.796   |
| After 1 week          | 28              | 62.2% | 17               | 37.8% | 0.020*  |
| After 1 month         | 19              | 42.2% | 18               | 40.0% | 0.830   |
| After 6 months        | 19              | 42.2% | 10               | 22.2% | 0.042*  |

Group 1> standard low pulsed radiofrequency (PRF), Group 2> high voltage, long-term PRF. Data presented as numbers and percentages; \*: Significant difference as *P* value ≤0.05; Abbreviation: PRF: Pulsed radiofrequency.

**DISCUSSION**

Our study found that high-voltage long-term PRF led to significant improvements in the ODI, reduction in NRS values, and analgesia requirements in the high-voltage group in comparison with the low-voltage group. These improvements were observed at 1 week, 1 month, and 6 months continuing the process without serious adverse effects in the two groups, indicating the safety of PRF.

Standard PRF treatment provides analgesia near nerve tissue through the field effect created by rapid voltage fluctuations, without causing neurothermal dissociation or disruption of motor nerve function<sup>[10]</sup>.

High-voltage long-term PRF has been utilized in clinical practice with the following treatment parameters: electrode pulse frequency of 2Hz, output voltage ranging from 50 to 90V, pulse width of 20ms, tip temperature set to 42°C, and a treatment duration of 900 seconds. This approach has yielded satisfactory results<sup>[11]</sup>.

In the present study the ODI showed statistically significant improvement at the same follow-up periods in

the 2 studied groups. This improvement was significantly better in the high-voltage group than in the low-voltage group.

Burak Erken *et al.*,<sup>[12]</sup> reported similar findings in their study. They observed that the DOI score improved for both the low-voltage and high-voltage groups from pre-procedure measurements. However, unlike our study, they did not obtain any statistically significant variations in the scores at one month and six months between the two groups ( $p>0.05$ ). This discrepancy may be due to their choice of 60V for the high-voltage group, whereas we used 70V.

In the present study, the NRS demonstrated a statistically significant decrease after PRF, with higher values in the low-voltage group in comparison with the high-voltage group in all follow-up times.

In line with this study, Burak Erken *et al.*,<sup>[12]</sup> reported a decrease in the NRS scores for both groups following PRF treatment, with no statistically significant variation among the groups at the one-month follow-up ( $p>0.05$ ). However, at the six-month mark, the NRS scores were lower in the high-voltage group ( $p=0.016$ ). Also, Jia DL. *et al.*,<sup>[10]</sup> observed the decrease of the VAS of patients at all time points after treatment with either high or low-voltage RF was significantly lower than that before PRF, indicating the efficiency of PRF treatment.

In the present study, the patients in the high-voltage long-term PRF group received stronger electric field stimulation without causing harm to the nerves. As a result, their pain scores after treatment were significantly lower in comparison with those in the standard PRF group. This demonstrates that higher voltage correlates with greater electric field strength, which enhances therapeutic effects.

Jia DL. *et al.*,<sup>[10]</sup> observed that the pain scores and ODI scores decreased significantly at all postoperative time points. However, these scores increased as the time after PRF lengthened. These findings suggest that the neuromodulation PRF is reversible and that the efficacy of PRF diminishes over time. At six months post-PRF, high-voltage long-term PRF proved to be more efficient than standard PRF in terms of pain control and functional improvement. This differs from our results as the pain score and DOI scores did not increase after six months in both groups. The difference may be attributed to the variations in the pain-scoring methods used in our study. Jia DL. *et al.*, employed the Visual Analog Scale (VAS), while our study utilized the Numeric Rating Scale (NRS). Patients in our study were also allowed to use analgesics as needed (acetaminophen, ketorolac, and tramadol in some patients who were not responding), which may contribute to the fact that pain and function scores did not increase over time

after PRF, a factor that was not captured in the study by Jia DL *et al.*,

No significant complications were watched in either group during this study, aligning with the previous studies<sup>[10,12]</sup>.

The limitations of our study include single-center design. To assess the efficacy of PRF, we focused on subjective functional and pain scores. Additionally, we did not document the types and dosages of analgesics that patients used after the procedure. The short follow-up period also means that the safety of this procedure needs to be further evaluated through multicenter studies with longer durations.

## CONCLUSIONS

High pulsed RF compared to low pulsed technique for pain in FBSS patients has lower post-operative ODI, lower NRS, and lower analgesia requirements, denoting better complaint improvement, lesser disability, and better patient satisfaction.

Informed consent is required for participation in this study. This study adhered to the Helsinki Declarations and CONSORT guidelines.

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## CONFLICT OF INTERESTS

There are no conflicts of interest.

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