

A Combination of Pulsed Radiofrequency Application to Dorsal Root Ganglia and Transforaminal Injection of Autologous Platelet Lysate for Management of Failed Back Surgery Radicular Pain: A Prospective Study

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ABSTRACT

Background: Lumbosacral radiculopathy is often found in people who have back pain.

Objective: This study used a combination of autologous platelet lysate injection and applied pulsed radiofrequency (PRF) to the dorsal root ganglion to treat lumbosacral radicular pain of patients with failed back surgery syndrome.

Methods: This was a prospective study with only one arm. People with failed back surgery radicular pain who were sent to Zanko Private Hospital in Erbil, Iraq, took part. The $22G \times 4$ inch radiofrequency probe tip was brought close to the dorsal root ganglion with the help of a fluoroscope. A temperature of 42° C was used to treat the patients with PRF for 300 seconds.

The venous blood sample (60 mg) was centrifuged (200g) for ten minutes and the supernatant was removed. After freezing at -80°C and defrosting, the samples were centrifuged again and the supernatant was collected. Platelet lysate injection was performed after complete PRF and in the same place under the fluoroscopy guide.

Results: A total of 15 patients with lumbosacral radiculopathy with an average age of 51.06 ± 15.3 years were included in this study; 6 were men (40%) and 9 were women (60%). The most common nerve roots involved were L4 and L5 (93.3%), L3 (66.7%), and S1 (40%), respectively. The side of radiculopathy was right in 40% of cases, bilateral in 33.3%, and left in 26.7%. The average NRS pain score before the interventions was 6.13 ± 1.06 , which reached 6.06 ± 1.27 in the second week after the interventions. According to the results of the paired t-test, there was no statistically significant decrease in the pain score (P=0.865). However, 10 weeks after the intervention, the mean NRS pain score was reported as 2.93 ± 1.16 , which was significantly lower than the pain reported before the intervention and 2 weeks after the intervention (P<0.001). A reduction of more than 50% in the NRS score was observed in no patient during 2 weeks after the intervention and in 11 patients (73.3%) after 10 weeks of the intervention.

Conclusion: In patients with lumbosacral radiculopathy due to failed back surgery syndrome, applying PRF to the dorsal root ganglion along with transforaminal injection of autologous platelet lysate can significantly reduce the patient's pain, at least in the mid-term.

Keywords: Pulsed Radiofrequency, Lumbosacral Radiculopathy, Platelet Lysate

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1. INTRODUCTION

Lumbar radiculopathy is described as pain felt in the legs, originating from the involvement of the lumbar and sacral nerve roots, and is usually associated with changes in related dermatomes and abnormal tendon reflexes (1). A herniated disc and spinal canal stenosis can put pressure on the nerves and cause this problem. Lumbar radiculopathy can also be caused by changes in the body that happen because of injuries, tumors, or some diseases (2). Between 12 and 40 percent of people with low back pain also have lumbosacral radicular pain (2). Failed back surgery syndrome is one of the conditions that can cause back radicular pain. This condition includes pain in the lower back, with or without radiating to the leg, following apparently successful spinal surgeries. Its prevalence is reported between 10-40% and many patients struggle with radicular pain resistant to pharmacotherapy (3, 4). In addition to opioids and drugs, physical therapy, acupuncture, and spinal adjustments are also used to treat radiculopathy pain (2). It is also thought about to use surgery to treat radiculopathy when the cause can be removed medically (5). Sluijter et al. (1998) were the first to write about pulsed radiofrequency (PRF). It is a newer and a little more invasive way to treat a number of painful conditions, like nerve pain (5). In short bursts and at regular times, electrical stimulation is applied to the target regions. So, the temperature of the flesh doesn't rise high enough to hurt or burn it (5). The spinal sense neurons' cell bodies make up the dorsal root ganglion. It has a lot to do with how pain cues get to different parts of the brain (5). Adding PRF to the dorsal root ganglion has been shown to help with radicular pain in studies (5). A new study discovered that average voltage PRF (45 V) can help people with lumbar radiculopathy feel a lot better for up to three months after the treatment (5). However, some studies don't look at whether PRF is better at relieving pain than other methods, like Transforaminal Epidural steroid shots (TFESI) (6). Epidural steroid injections are another widely used approach in the management of radicular back pain, which has been reported to be effective (7, 8). Some studies have introduced the epidural injection of platelet-rich plasma (PRP) as an alternative approach to steroid injection, which lacks its undesirable consequences such as decreased bone mass and increased fracture risk, and probably provides longer-lasting effects (9, 10). Platelet lysate, a more purified product of PRP, has been used in recent years as an alternative in many PRP injection indications (11, 12). Promising results of the application of epidural platelet lysate injection for the treatment of lumbar radiculopathy have been reported (13). However, in none of the previous studies, the effect of the combination approach of PRF and platelet lysate injection has not been investigated. On the other hand, a study showed that using only PRF for failed back surgery could not significantly reduce the pain of patients (14). Therefore, the present study aimed to investigate the results of the management of failed back surgery radicular pain by the combination approach of applied PRF to dorsal root ganglion and transforaminal injection of autologous platelet lysate.

2. METHODOLOGY

This prospective single-arm study was conducted on patients with of failed back surgery radicular pain referred to Zanko Private Hospital, Erbil, Iraq. After the approval of the local ethics committee, this study reached the stage of sample collection. The inclusion criteria included age over 20 years, baseline pain intensity of 5 or more based on numeric rating scale (NRS), presence of lumbar radiculopathy for more than 3 months, lack of response to non-invasive treatments such as pharmacotherapy, physical therapy, and manual therapy. Patients who had received TFESI or any other treatment for lumbar radiculopathy up to 4 weeks before the intervention, subjects with very severe pain at baseline (NRS 9 and above), progressive motor weakness symptoms, and impaired neurologic function, systemic infection, diagnosed cancer and unwillingness to participate were excluded from the study. A written consent form was completed for all patients. All procedures were performed by an expert physician under the guidance of fluoroscopy.

Pulsed radiofrequency

After the initial preparations of the patients in the operating room, they lay prone and the needle entry site was anesthetized using 1% lidocaine. From the lateral view, the tip of the radiofrequency cannula ($22G \times 4$ inches) was placed in the superior-posterior region of the intervertebral foramen, and from the anteroposterior view, it was placed close to the middle of the pedicle. The correctness of the placement was determined by evaluating the epidural expansion through the injection of 1 ml of contrast solution. Then the stylet was replaced

with RF probe the and radio frequency pulses were applied using a radio frequency generator (Cosman G4 version 2.1.0, Cosman Medical, Inc., Burlington, MA, USA). The proper position of the probe tip relative to the dorsal root ganglion was adjusted using the ratio of motor stimulation threshold (2 Hz) to sensory stimulation threshold (50 Hz) equal to 1.5 -2. Patients received PRF treatment for 300 seconds at 42°C.

Transforaminal injection of autologous platelet lysate

The day before the intervention, the patients were called to collect a venous blood sample (60 mg). The samples were centrifuged for ten minutes (200g) and the supernatant was removed. Freezing at -80°C for all samples was done for 5 to 10 minutes and they were centrifuged again after coming out of freezing mode; The supernatant was collected and prepared for injection. Platelet lysate injection was performed after complete PRF and in the same place under fluoroscopy guide.

Outcomes measurement

The age and gender of the patients were initially recorded along with the history of surgery. Before the intervention, their pain level was asked based on NRS. For this purpose, it was explained to each patient that "if the most severe possible pain is 10 and the situation without pain is considered zero, what is the perceived pain score?" The NRS score was also recorded for all patients at 2 and 10 weeks after the intervention. Successful treatment included a 50% or more reduction in NRS score.

Statistical Analysis

The data was entered into the statistical software SPSS version 27 and the changes in the NRS score were analyzed by the paired t-test.

3. RESULTS

A total of 15 patients with failed back surgery radicular pain with an average age of 51.06 ± 15.3 years were included in this study; 6 were men (40%) and 9 were women (60%). The most common nerve roots involved were L4 and L5 (93.3%), L3 (66.7%) and S1 (40%), respectively. In only two patients (13.3%) the L2 nerve root was also involved. The side of radiculopathy was right in 40% of cases, bilateral in 33.3% and left in 26.7%. 53.3% of patients had fixation surgery and 46.7% had discectomy history. The characteristics of the

patients are shown in (**Table 1**). The average NRS pain score before the interventions was 6.13 ± 1.06 , which reached 6.06 ± 1.27 in the second week after the interventions. According to the results of the paired t test, there was no statistically significant decrease in the pain score (P=0.865). During 2 weeks, 7 patients (46.6%) experienced increased pain intensity. However, 10 weeks after the intervention, the mean NRS pain score was reported as 2.93 ± 1.16 , which was significantly lower than the pain reported before the intervention and 2 weeks after the intervention (P<0.001) (**Figure 1**). A reduction of more than 50% in the NRS score was observed in no patient during 2 weeks after the intervention and in 11 patients (73.3%) after 10 weeks of the intervention (**Table 2**). The type of back surgery had no effect on the improvement of patients' pain (**Figure 2**).

No.	Age	Gender	Radiculopathy nerve Root		History of	baseline		
			side	Nerve roots	surgery	NRS	2-W NRS	10-W NRS
1	43	male	Right	L3,L4,L5	Discectomy	7	6	2
2	25	female	Bilateral	L4,L5	Discectomy	6	6	3
3	29	female	Bilateral	L3,L4	Fixation	5	6	2
4	49	male	Right	L4,L5,S1	Fixation	6	4	2
5	58	male	Left	L2,L3,L4,L5,S1	Fixation	8	6	3
6	85	female	Right	L3,L4,L5	Discectomy	7	9	6
7	55	female	Left	L2,L3,L4,L5	Fixation	5	4	2
8	67	female	Right	L3,L4,L5	Discectomy	5	6	4
9	66	male	Left	L4,L5,S1	Fixation	5	6	2
10	50	female	Left	L3,L4,L5,S1	Discectomy	7	5	2
11	36	male	Bilateral	L3,L4,L5	Fixation	6	8	4
12	60	female	Left	L5,S1	Fixation	8	6	4
13	48	female	Bilateral	L3,L4,L5	Discectomy	6	7	2
14	45	male	Left	L3,L4,L5	Discectomy	5	6	3
15	50	female	Bilateral	L4,L5,S1	Fixation	6	6	3

Table 1. Characteristics of the studied cases

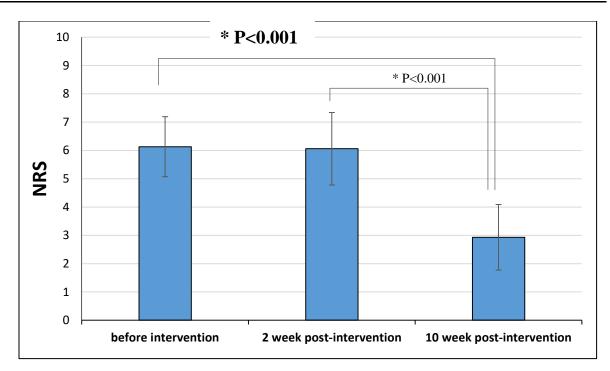


Figure 1. Changes in the average NRS score at the time points examined

Variable	After 2 week		After 10 week		
Variable	No.	%	No.	%	
≥50% NRS reduction	0	0.0	11	73.3	
<50% NRS reduction	15	100.0	4	26.7	

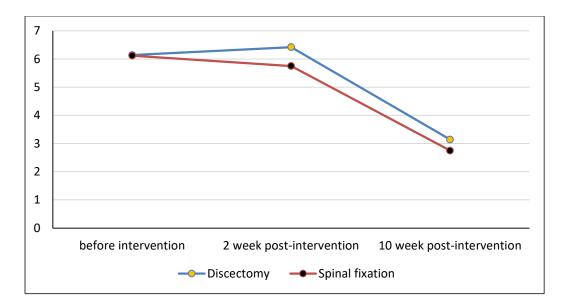


Figure 2. Change in pain score (NRS) according to the type of surgery

4. DISCUSSION

In the present study, the effect of the combined approach of applying PRF to the dorsal root ganglia along with the transforaminal injection of autologous platelet lysate was evaluated in reducing the pain of patients with lumbosacral radiculopathy due to failed back surgery syndrome. The findings indicated that within 2 weeks after the interventions, almost no effect of pain improvement was seen in the patients, but after 10 weeks, the patients revealed a significant reduction in pain. This shows that the immediate effects of this combined treatment approach are not significant, but in the mid-term, the effects are quite promising. PRF has been used for the past two decades to reduce symptoms, especially pain, in various medical conditions (15-17). The application of PRF on the dorsal root ganglion has been investigated in various studies. Lee et al. showed that patients' radicular pain significantly decreased after receiving PRF based on VAS. They showed that the amount of pain reduction in the second week is less and over time up to 3 months after the intervention, the patient's pain decreases to a greater extent (Lee et al., 2016). These findings are in line with our results that the reduction of pain in the tenth week is much more than in the second week. Several other studies also confirmed the effectiveness of applying PRF to the dorsal root ganglion for the treatment of patients with lumbosacral

radiculopathy (18-20). However, in a single-center study by Shanthanna et al., on 350 patients with chronic radicular pain, it was found that there was no significant reduction in VAS pain scores either 4 weeks or 3 months after applying PRF to the dorsal root ganglia (21). This shows that the application of PRF alone cannot be recognized as an approach with definite efficacy in patients with lumbar raln a study on 34 patients with lumbosacral radicular pain, Yang et al. showed that PRF intervention combined with transforaminal epidural steroid injection at a mean follow-up of 9.5 months caused a significant decrease in the average pain score from 6.5 to 2.4 (22). In another study, applying PRF to the dorsal root ganglion along with transforaminal epidural steroid injection resulted in successful treatment (50% or more reduction in NRS score) in 66.6% of patients with radicular pain. In the present study, the success rate was slightly higher and a 50% or more reduction in pain score was observed in 73.3% of patients after 10 weeks (Sinha et al., 2020). This shows that transforaminal injection of autologous platelet lysate in combination with PRF can work even better than the combination of PRF with steroids, even though platelet lysate does not have the harmful effects of steroids, such as reducing bone mass and increasing the probability of future fractures. Another study investigated the effect of PRF administration along with PRP injection in reducing lumbosacral radicular pain. Their results showed that the average pain decreased from 6.75 ± 0.98 at baseline to 3.35 ± 0.78 , 3.17 ± 0.56 , and 3.03 ± 0.57 at months 1, 3, and 6. In the present study, average pain decreased from 6.13±1.06 at baseline to 6.06±1.27 and 2.93±1.16 after 2 and 10 weeks. These findings are consistent with each other and show that platelet lysate, like PRP, can be used in combination with PRF to reduce pain in patients with radicular pain (23). Therefore, the researchers hypothesized that combining it with another treatment process may be able to produce a more significant improvement. The present study reported promising results of a new combined approach for the management of radicular back pain. However, there are limitations that may contribute to the results obtained. The sample size of the present study included 15 patients, which is relatively small, and larger studies are needed to determine the effectiveness of this combined approach. Also, this study was conducted as a single arm, which cannot compare the effectiveness of the studied approach with the approaches examined in previous studies.

Therefore, it is suggested to compare the combined and single approaches introduced in the treatment of radicular pain in future studies.

5. CONCLUSIONS

In patients with lumbosacral radiculopathy due to failed back surgery syndrome, applying PRF to the dorsal root ganglion along with transforaminal injection of autologous platelet lysate can significantly reduce the patient's pain, at least in the mid-term.

Ethical Approval:

All ethical issues were approved by the author. Data collection and patients enrollment were in accordance with Declaration of Helsinki of World Medical Association, 2013 for the ethical principles of researches involving human. Signed informed consent was obtained from each participant and data were kept confidentially.

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