Agri 2024;36(1):38–44
doi: 10.14744/agri.2022.60234

ORIGINAL ARTICLE

Evaluation of the efficacy of pulsed radiofrequency therapy in patients with lumbosacral radicular pain: An analysis of single-center data

Lumbosakral radiküler ağrılı hastalarda pulsed radyo frekans tedavisinin etkinliğinin değerlendirilmesi: Tek merkez verilerinin analizi

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Summary

Objectives: Lumbosacral radicular pain (LRP) is one of the most common causes of neuropathic pain. This pain often arises from inflammation in the dorsal root ganglia (DRG) or spinal nerves. Despite various treatment modalities, success rates are not very high in chronic LRP cases. Pulsed radiofrequency (PRF) therapy, frequently applied to the DRG, is widely used, but its effectiveness is often questioned in various studies. The primary aim of our study is to evaluate the effectiveness of PRF treatment in 154 patients.

Methods: Patients with LRP for longer than 3 months, treated with PRF, were included in this study. To assess the efficacy of PRF treatment, numerical rating scale (NRS) scores were evaluated at the 4th-week and 6th-month follow-ups.

Results: The NRS scores were significantly lower at the 4th-week and 6th-month follow-ups compared to pre-treatment levels ($p<0.001$). However, there was no significant difference between the mean NRS scores at the 4th week and 6th month.

Conclusion: Success in interventional pain procedures is often considered as at least a 50% reduction in pain scores. The success rate for PRF treatment for LRP in the literature varies between 30% and 60%, which is similar to our findings at the 4th week and 6th month. PRF treatment is widely used due to its low side-effect profile and cost-effectiveness in the long term. There is no fully standardized practice regarding procedural aspects, such as the duration of the application, and prospective studies with larger participation are needed.

Keywords: Dorsal root ganglia; lumbosacral radicular pain; low back pain; neuropathic pain; pulsed radio frequency treatment.

Özet

Amaç: Lumbosakral radiküler ağrı (LRA), nöropatik ağrının en sık sebeplerinden biridir ve genellikle dorsal kök gangliyonu (DRG) veya spinal sinirlerdeki inflamasyon sonucu ortaya çıkar. Kronik LRA durumunda, tüm tedavi yöntemlerine rağmen başarı oranları genellikle yüksek değildir. DRG'ye uygulanan pulsed radyofrekans (PRF) tedavisi sıkça tercih edilir, ancak etkinliği üzerine çeşitli araştırmalar mevcuttur. Çalışmamızın amacı, kliniğimizde yaygın olarak uyguladığımız PRF tedavisinin 154 hastanın verileri üzerinden etkinliğini ortaya koymaktır.

Gereç ve Yöntem: Üç aydan uzun süren LRA'sı olan ve PRF tedavisi uygulanan hastalar incelendi. Tedavinin etkinliğini değerlendirmek için 1. ay ve 6. ay kontrollerinde nümerik ağrı skorları (NRS) değerlendirildi.

Bulgular: Tedavi öncesine göre 4. hafta ve 6. ay kontrollerinde NRS'ler anlamlı şekilde düşük bulundu ($p<0.001$). Ancak, 4. hafta ile 6. aydaki ortalama NRS'ler arasında fark bulunamadı.

Sonuç: Girişimsel ağrı yöntemlerinde başarı, ağrı skorlarında en az %50'lik bir düşüş olarak kabul edilir. Literatürde LRA'da PRF tedavisinin başarı oranları %30 ile %60 arasında değişmektedir, bu da çalışmamızdaki 4. hafta ve 6. aylık sonuçlarla uyumludur. PRF tedavisi, düşük yan etki profili ve uzun vadede düşük maliyetiyle yaygın olarak kullanılmaktadır. Bununla birlikte, uygulama süresi gibi prosedürel konularda tam olarak standartlaştırılmış bir uygulama henüz yoktur ve geniş katılımlı prospektif çalışmalara ihtiyaç duyulmaktadır.

Anahtar sözcükler: Bel Ağrısı; darbeli radyo frekans tedavisi; dorsal kök gangliyonu; lumbosakral radiküler ağrı; nöropatik ağrı.

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Submitted *(Başvuru):* **30.11.2021** **Accepted *(Kabul):*** **19.12.2022** **Available online *(Online yayımlanma):*** **28.12.2023**

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Introduction

The annual prevalence of lumbosacral radicular pain (LRP) in the general population ranges from 9.9–25%.[1,2] Low back pain syndromes, including LRP, are the most common cause of neuropathic pain. Inflammation and irritation in the spinal nerves and dorsal root ganglia (DRG) are shown as the causes of pain.[3,4]

The pain usually disappears within 12 weeks in 60% of patients with acute LRP. In 30% of the remaining patients, the pain persists between 12 weeks and 1 year, while it becomes chronic in 10%.[2]

Despite all treatment modalities, success rates are not very high in chronic LRP. If adequate analgesia and functional capacity cannot be achieved with oral medications and physical therapy modalities, interventional pain treatments may be considered.[2] Interventional pain management methods have an important role in the treatment of chronic LRP. One of the treatment methods used in LRP patients is pulsed radiofrequency (PRF) treatment applied to DRG. This method is widely used due to its low side-effect profile and relatively low cost in the long term.[1] Although studies have been conducted to support the effectiveness of PRF in LRP, various studies also question its effectiveness.[5–8]

The primary aim of our study is to reveal the effectiveness of DRG PRF treatment applied to LRP patients in our clinic, based on the data of 154 patients. For this reason, the numerical rating scale (NRS) was evaluated before treatment, at the 4th week, and 6th month after treatment. The secondary aim of our study is to compare the efficacy of DRG PRF treatment between patients with or without a history of lumbar surgery and to reveal procedural complications.

Materials and Methods

Our study was designed as a single-center, retrospective study, and ethical committee approval was obtained from the ethics committee of our hospital, dated 07.07.2021 and numbered E1/1792/2021. The study was conducted in accordance with the Declaration of Helsinki. Records of patients who had undergone DRG PRF for LRP between January 2019 and December 2020 in our clinic were reviewed. Patients older than 18 years, with LRP lasting longer than 3 months, and who did not respond to medical treatment and physiotherapy were included in the study. Only patients with root compression and LRP due to disc herniation shown with magnetic resonance imaging (MRI) were included. Patients whose pain was reduced with transforaminal anterior epidural steroid injection (TFES) for LRP, but still reported NRS >5 and Douleur Neuropathique 4 (DN 4) score ≥4, and for whom DRG PRF treatment was administered just once at one or two levels according to the levels affected, were accepted as inclusion criteria. Targeting and needle positioning were performed similarly to the technique described by Simopoulos et al.[9] Appropriate sensory stimulation with 50 Hz (0.4–0.6 V), and motor stimulation at 2 Hz were used to avoid placement near the anterior nerve root. All procedures were performed by the same team with at least 10 years of experience in interventional pain management. The exclusion criteria were PRF treatment for reasons other than LRP and the inability to access patients' records through the hospital system. A 10-point scale of 0 (no pain) to 10 (pain of highest intensity bearable) was used for NRS.

Demographic data (age, gender), duration of LRP, and history of surgery before or after the procedure were obtained from hospital records. NRS scores, routinely recorded in our clinic for pain assessment, were evaluated before the procedure and at the 4th week and 6th month after the procedure. A 50% or more pain reduction in NRS is accepted as a clinically significant improvement in interventional procedures. It was revealed that 50% or more pain reduction was achieved at 4 weeks and 6 months after DRG PRF treatment. Additionally, NRS scores at the 4th week and 6th month were compared between patients who had undergone surgery for LRP before the procedure and those who had not.

Statistical Analysis

The data obtained in the study were evaluated using the statistical package program SPSS (Statistical Package for the Social Sciences) (version 15.0). Descriptive data were presented as number, percentage, mean, median, standard deviation, and extreme (min.–max.) values. The conformity of the data to the normal distribution was evaluated with the Kolmogorov-Smirnov test. The Chi-square test

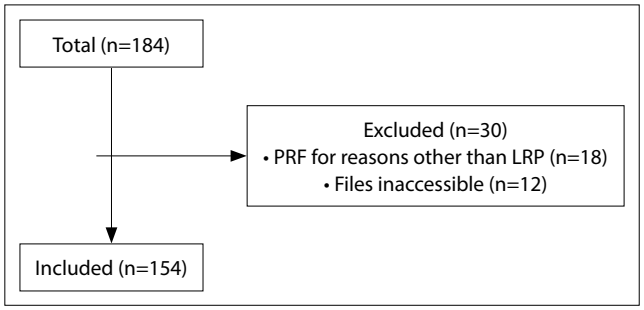

Figure 1. Patient flow chart.

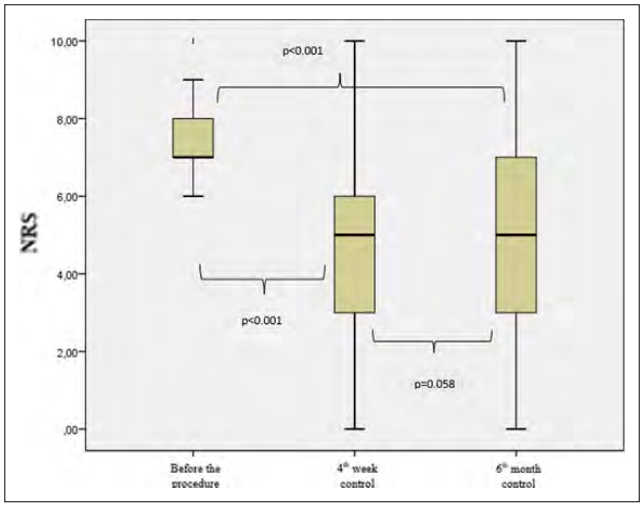

Figure 2. The evaluation of the NRS scores of the patients.

was used to compare categorical data between groups. In the evaluation of the data, the Mann-Whitney U test was used for independent samples according to their conformity to normal distribution. The Friedman test was used for independent samples. Statistical significance value was accepted as $p \leq 0.05$.

Results

Of the 154 patients included in the study, 54.5% (n=84) were female and 45.5% (n=70) were male. The patient flow chart is shown in Figure 1.

The ages of the patients ranged from 23.0 to 86.0 years, with a mean (SD) of 58.02 (12.07) and a median of 59.0. The distribution of the patients according to gender, side of pain, duration of pain, and surgery history is given in Table 1.

DRG PRF was performed on the right side in 48.7% (n=75) of the patients, on the left side in 43.5% (n=67), and bilateral DRG PRF in 7.8% (n=12). The duration of pain in the study group ranged from 1.0 to 15.0 years, with a mean (SD) of 3.27 (2.0) and

Table 1. Distribution of patients in the study group according to some variables

Variable	n	%
Gender		
Female	84	54.5
Male	70	45.5
Side of pain		
Right	75	48.7
Left	67	43.5
Bilateral	12	7.8
Duration of pain (years)		
1–3	104	67.5
4 or more	50	32.5
Surgery history		
No	108	70.2
Yes, before the procedure	40	25.9
Yes, after the procedure	6	3.9
Total	154	100.0

a median of 3.0. The pre-procedural NRS scores of the patients ranged from 6.0 to 10.0, with a median of 7.0, and at the 4th week and 6th month controls, the values ranged between 0.0 and 10.0, with a median of 5.0. It was found that the NRS score medians of the patients decreased at the 4th week control after the procedure compared to the scores before the procedure ($p<0.001$), and the NRS score medians did not change at the 6th month control compared to the 4th week control. No minor or major complications related to PRF treatment were observed in any patient. The evaluation of the NRS scores of the patients before the procedure, at the 4th week, and the 6th month, is given in Figure 2.

In our study, the number of patients with more than 50% reduction in NRS scores at the 4th week and the 6th month control was 56 (36.4%) and 53 (34.4%), respectively, and the number of patients with less than 50% reduction in NRS scores was 98 (63.6%) and 101 (66.6%), respectively. There was no relationship between >50% NRS score reduction and parameters like age, gender, previous lumbar surgery history, duration of pain, operation side, and level. The comparison of the NRS scores of the patients at the 4th week and 6th month evaluation according to some variables is given in Table 2 and Table 3.

Table 2. Comparison of the changes in the NRS scores in the 4th week evaluation according to some variables

	Evaluation of patients' NRS values at 4th week				SA, X^2; p
	50% or more reduction		Less than 50% reduction		
	n	%	n	%	
Age [average (SD)]	57.2	11.3	58.4	12.5	0.765; 0.444
Gender					1.423; 0.233
Female	27	32.1	57	67.9	
Male	29	41.4	41	58.6	
Side of pain					4.648; 0.098
Right	33	44.0	42	56.0	
Left	18	26.9	49	73.1	
Bilateral	5	41.7	7	53.8	
Duration of pain (years)					2.386; 0.122
1-3	33	31.7	71	68.3	
4 or more	23	46.0	27	54.0	
Surgery history					1.049; 0.592
No	40	37.0	68	63.0	
Yes, before the procedure	15	37.5	25	62.5	
After the procedure	1	16.7	5	83.3	
Total	56	100.0	98	100.0	

NRS: Numerical rating scale; SD: Standard deviation; SA: Statistical analysis.

Discussion

In our study, NRS scores were found to be significantly lower at the 4th week and 6th month compared to pre-treatment ($p<0.001$). However, no difference was observed between the mean NRS scores at the 4th week and 6th month. There was a 50% or more decrease in NRS scores of 56 (36.4%) patients at the 4th week follow-up compared to the pre-treatment period. A 50% or more decrease in the NRS scores was detected in 53 (34.4%) patients at the 6th month follow-up.

The use of PRF therapy in chronic pain is a relatively novel method, and it is based on placing cannulas producing a 500 kHz high-frequency electric current close to neuronal structures.[10] After a short-term current lasting 20 milliseconds, no current is given during the silence period lasting 480 milliseconds.[6] Thus, the temperature in the target tissue is prevented from rising above 42 °C. Since the critical temperature of 42 °C is not exceeded, neuron damage is prevented. The mechanism of action of PRF therapy has not yet been clearly demonstrated, but there are various theories. Damage to the DRG, which contains the cell bodies of neuronal fibers carrying sensory stimuli from the periphery to the spinal cord, causes neuronal excitability and ectopic stimuli. This is one of the important sources of pain.[11] One of the mechanisms of action of PRF therapy is that the electromagnetic field created by the electrode placed close to the damaged DRG affects the transmission of special unmyelinated C fibers that transmit pain. Strengthening the inhibitory pathways by increasing the level of C-fos in lamina 1 and 2 in the dorsal horn is another suggested mechanism.[12] In addition, it has been shown that proinflammatory cytokines such as TNF-α and IL-1 decrease with PRF treatment.[13]

While epidural steroid injections for LRP seem to be effective in the short term, discussions about long-term outcomes continue. In a randomized controlled study, PRF treatment was found to be superior to TFES in terms of long-term efficacy, and it was suggested that this might be due to immune modulation in the spinal nerve and DRG.[14]

Table 3. Comparison of the changes in NRS scores at 6th month evaluation according to some variables

	Evaluation of patients' NRS values at 6th mont				SA, X^2; p
	50% or more reduction		Less than 50% reduction		
	n	%	n	%	
Age [average (SD)]	56.9	12.3	58.6	12.0	0.765; 0.444
Gender					0.673; 0.412
Female	26	31.0	58	69.0	
Male	27	38.6	43	61.4	
Side of pain					2.663; 0.264
Right	28	37.4	47	62.7	
Left	19	28.4	48	71.6	
Bilateral	6	50.0	6	50.0	
Duration of pain (years)					0.689; 0.406
1–3	33	31.7	71	68.3	
4 or more	20	40.0	30	60.0	
Surgery history					3.292; 0.193
No	39	36.1	69	63.9	
Yes, before the procedure	14	35.0	26	65.0	
After the procedure	0	0.0	6	100.0	
Total	53	100.0	101	100.0	

NRS: Numerical rating scale; SD: Standard deviation; SA: Statistical analysis.

In a retrospective study of 135 patients, it was reported that the group in which PRF was applied after TFES had a longer benefit compared to the group that received only TFES.[15] The patients included in our study were also patients who had previously undergone TFES. Considering all these factors, we believe that adding PRF to TFES treatment may be an appropriate option to prolong efficacy. It has been reported that complication rates can be up to 10% with epidural steroid injections.[16] For all these reasons, PRF treatment, with its low side-effect profile, has represented a very effective alternative in recent years. No complication related to PRF treatment was observed in any patient included in our study.

Most of the studies on the efficacy of PRF treatment for LRP are retrospective. It is observed that the number of participants in prospectively designed studies is quite low. In one of the few prospective studies, Shanthanna et al.[6] compared the data of 16 patients in the PRF group and 15 patients in the placebo group in which they only inserted the needle. NRS scores were found to be lower in the PRF group at the 2-month follow-up compared to pretreatment. However, in the PRF group, the rate of patients with a 50% decrease in the NRS score at the 2nd month control was 37.5% (6/16). In our study, consisting of 154 patients, the rates of patients with a statistically significant decrease of pain with 50% or more reduction at the 4th week and 6th month were 36.4% (56/154) and 34.4% (53/154), respectively. In another prospective observational study, when the data of 65 patients were analyzed, a success rate of over 50% was found at the 6th month.[17] It is noteworthy that in this study, the inclusion criteria were strictly limited. For example, patients with pain in the lumbar 5 (L5) and sacral 1 (S1) dermatomal distribution were included in the study due to more specific dermatomal spread, while patients with pain in the L4 dermatome were excluded because it was less specific. The high success rate at 6th month was attributed to these strict inclusion criteria. In the literature, the success rates of PRF treatment for LRP vary between 30% and 60%.[15] Whether PRF treatment should be performed at

single or multiple levels is another debate. In a retrospective study in which 61 patients who underwent PRF at a single lumbar level were analyzed, the 2nd month success rate was 29%, while the success rate decreased to 13% in the 12th month follow-up.[2] The low success rates found in this study were attributed to the single-level PRF application and the single-session procedure. They recommended the application of 2 levels of PRF treatment since inflammation may occur in neighboring DRGs over time. Higher success rates can be achieved with repeated PRF treatments. In the same study, in parallel with our study, no significant difference was found between patients who underwent surgery for LRP and those who did not, in terms of NRS scores after PRF. Different results have been reported in the literature regarding the success of post-surgical PRF treatment. Abejon et al.[18] found PRF to be effective in unoperated patients with LRP caused by disc herniation but stated that pain scores did not change in patients with previous surgery. On the other hand, Chao et al.[19] found no difference in terms of efficacy in unoperated patients with LRP due to disc herniation and PRF applied after previous surgery.

In the literature, in most studies on PRF treatment for LRP, PRF was applied for 120 seconds per level. There is no clear information about the relationship between PRF treatment duration and success rates.[16] All patients included in our study underwent PRF for 120 seconds per level, in line with the literature.

Limitations

There were several limitations in our study. For the patients included from the hospital registry system, we could not evaluate longer-term results beyond the 6th month due to the unavailability of data. Additionally, due to incomplete records, we were unable to assess how functionality in daily activities of patients was affected after PRF treatment.

Conclusion

Fully standardized medical practice details about PRF treatment are not yet established in the literature. More randomized controlled studies with large sample groups are needed. We believe that well-planned studies should be conducted on issues such as patient selection and PRF application time.

Ethics Committee Approval: The Ankara Bilkent City Hospital Clinical Research Ethics Committee granted approval for this study (date: 07.07.2021, number: E1/1792/2021).

Conflict-of-interest issues regarding the authorship or article: None declared.

Financial Disclosure: This study has no funding or sponsor.

Peer-rewiew: Externally peer-reviewed.

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