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Comparison of the Efficacy of Dorsal Root Ganglion Pulsed Radiofrequency for 2 Minutes versus 4 Minutes in the Treatment of Chronic Lumbosacral Radicular Pain

Kronik Lumbosakral Radiküler Ağrı Tedavisinde Dorsal Kök Gangliyonu Darbeli Radyofrekansın 2 Dakikaya Karşı 4 Dakika Süreyle Uygulanmasının Etkinliğinin Karşılaştırılması

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Comparison of the Efficacy of Dorsal Root Ganglion Pulsed Radiofrequency for 2 Minutes versus 4 Minutes in the Treatment of Chronic Lumbosacral Radicular Pain

ABSTRACT

Objective: Pulsed radiofrequency treatment of the dorsal root ganglion has been increasingly used to treat lumbosacral radicular pain in recent decades. However, there is no consensus in the literature regarding issues such as pulsed radiofrequency application duration. This study aimed to determine the efficacy and incidence of adverse events between 2-minute and 4-minute pulsed radiofrequency for lumbosacral radicular pain.

Material and Method: This retrospective study included 160 patients who underwent 2-minute or 4-minute dorsal root ganglion pulsed radiofrequency treatment (Group-2 minutes 82 patients and Group-4 minutes 78 patients). The Numeric Rating Scale and Oswestry Disability Index scores before, 1 and 6 months after the interventions were evaluated to assess the effectiveness of the procedures. The rate of intervention-related adverse events was determined for both durations.

Results: Both the 2-minute and 4-minute procedures provided effective analgesia at 1 and 6 months compared with baseline. There was no difference in the pain scores between the two groups at the measurement times. At the 1-month follow-up, 50% or greater pain relief was achieved in 39% of patients in the 2-minute group compared to 50% in the 4-minute group, with no difference between the groups. There was no significant difference in the rate of procedure-related adverse events between the groups.

Conclusion: Although a higher success rate was achieved with 4-minute pulsed radiofrequency, there was no significant difference, and both 2 and 4-minute pulsed radiofrequency procedures provided safe and effective analgesia compared with baseline. Prospective studies with larger sample sizes are needed.

Keywords: Inflammation, pulsed radiofrequency treatment, radiculopathy.

ÖZET

Amaç: Dorsal kök ganglionunun pulsed radyofrekans tedavisi, son yıllarda lumbosakral radiküler ağrının tedavisinde giderek daha fazla kullanılmaktadır. Ancak pulsed radyofrekansın uygulama süresi gibi konularda literatürde bir fikir birliği bulunmamaktadır. Bu çalışmanın amacı lumbosakral radiküler ağrı tedavisinde 2 dakikalık ve 4 dakikalık pulsed radyofrekans uygulamaları arasındaki etkinliği ve yan etki insidansını karşılaştırmaktır.

Gereç ve Yöntem: Bu retrospektif çalışmaya 2 dakikalık veya 4 dakikalık dorsal kök ganglionu pulsed radyofrekans tedavisi uygulanmış 160 hasta dahil edildi (Grup-2 dakika 82 hasta ve Grup-4 dakika 78 hasta). İşlemlerin etkinliğini değerlendirmek için girişimlerden önce ve girişimlerden 1 ve 6 ay sonra Sayısal Derecelendirme Ölçeği ve Oswestry Engellilik İndeksi skorları değerlendirildi. Girişimlere bağlı advers olayların oranı her iki prosedür için de değerlendirildi.

Bulgular: Hem 2 dakikalık hem de 4 dakikalık pulsed radyofrekans prosedürleri, başlangıca kıyasla 1. ve 6. aylarda etkin analjezi sağladı. Ölçüm zamanlarında iki grup arasında ağrı skorları arasında fark yoktu. 1 aylık takipte, 2 dakika grubundaki hastaların %39'unda, 4 dakika grubundaki hastaların %50'sinde %50 veya daha fazla ağrı rahatlaması sağlandı ve gruplar arasında fark yoktu. Ayrıca işleme bağlı advers olay oranı açısından gruplar arasında anlamlı bir fark yoktu.

Sonuç: Her ne kadar 4 dakikalık pulsed radyofrekans ile daha yüksek bir başarı oranı elde edilmiş olsa da, gruplar arasında anlamlı bir fark yoktu ve hem 2 hem de 4 dakikalık dorsal kök ganglionu pulsed radyofrekans tedavisi, başlangıca kıyasla güvenli ve etkili analjezi sağladı. Daha geniş katılımlı prospektif çalışmalara ihtiyaç vardır.

Anahtar Sözcükler: İnflamasyon, pulsed radyofrekans tedavisi, radikülopati.

Introduction

Lumbosacral radicular pain (LRP) is a common and debilitating condition that affects a significant proportion of the population. Epidemiological studies suggest that LRP has a prevalence rate with annual incidence estimates ranging from 5% to more than 15% and a lifetime prevalence of 60% to 90%. Approximately 10% of acute cases progress to chronic pain (1). While most cases of acute LRP resolve spontaneously, a significant percentage progress to chronic pain, resulting in significant disability and an impact on daily activities (2). Management of chronic LRP remains a challenge, with drug and physical therapy modalities showing variable success rates. Unfortunately, for a subset of patients, these treatments fail to alleviate pain, severely impacting their quality of life (3). Epidural corticosteroid injections provide significant relief for LRP and have demonstrated efficacy in reducing symptoms. However, several studies have indicated that the benefits are predominantly short-term, and the duration of pain relief is often limited (4, 5).

With a limited response to conventional treatments, dorsal root ganglion (DRG) pulsed radiofrequency (PRF) therapy has gained traction in recent decades as an alternative treatment for LRP. PRF therapy involves delivering short bursts of electrical energy to the affected nerve tissue to modulate pain signals without causing significant tissue damage. While the complete mechanism of action for PRF remains elusive, it is thought to impact synaptic transmission, gene expression, and inflammatory mediators without inducing substantial thermal damage or coagulation necrosis in nerve fibers (6). Despite its growing popularity, there is no consensus in the literature regarding the optimal PRF application duration, which often varies at the practitioner's discretion. Practitioners typically apply PRF for 4 or 2 minutes (min) per level (7, 8). However, there are centers that use 6 min or longer (9). Notably, PRF therapy is associated with very few complications, underscoring its potential as a safe treatment modality (10).

The primary aim of this study was to determine the efficacy of two commonly used durations of PRF application, 2 and 4 min, in the treatment of LRP. In addition, our secondary aim was to evaluate and compare the complication rates associated with these different durations. This investigation is intended to contribute to the establishment of evidence-based guidelines for PRF therapy in the treatment of LRP, potentially improving patient outcomes, and reducing the burden of chronic LRP.

Material and Method

Study Design and Participants

This retrospective study involved data collection at a single-center pain clinic in a tertiary-care hospital. Approval was obtained from the Ankara Etlik Şehir Hospital Clinic Research Ethics Committee (Date: 12.07.2023; Decision number: 2023-235). The data of patients who underwent intervention between October 2021 and January 2023 were reviewed. This study was conducted in accordance with the principles of the Declaration of Helsinki.

Inclusion Criteria: Unilateral radicular low back pain extending below the knee; treatment limited to L4, L5, and S1 nerve roots; PRF treatment of the DRG at only two levels (according to magnetic resonance imaging (MRI) and clinical findings) in just one session; numeric Rating Scale (NRS) score ≥6 despite at least 3 months of conservative treatment, including physical therapy and drug combination therapy; compatibility with current clinical and physical examination findings and MRI; and short-term benefit (<1 month) from previous transforaminal epidural injection (TFEI).

Patients are routinely evaluated by neurosurgery, orthopedics, physical therapy and rehabilitation, and rheumatology before consulting us (this is the routine practice of the hospital and these departments are not part of the study), and the exclusion criteria were determined as follows: pain originating from inflammatory or degenerative conditions of the low back, hip, or knee; previous lumbar surgery; one or three levels of DRG PRF treatment; additional intervention in the same session; atypical or bilateral pain radiation; MRI evidence of extruded, sequestered, or migrated discs; presence of motor deficits; relative spinal stenosis (spinal canal sagittal diameter < 13 mm); myelopathy; lumbar fracture; positive piriformis provocation and tenderness; cancer; diabetes mellitus; coagulation disorders; use of antiplatelet or anticoagulant medications; presence of a cardiac pacemaker; psychiatric disorders; and allergies to

drugs used.

Dorsal Root Ganglion Pulsed Radiofrequency Procedure

All procedures were performed by pain specialists with at least five years of fluoroscopy experience. All necessary emergency medications and equipment were made available in the operating room before patient intervention. The patient was placed in the prone position, and a pillow was placed under the patient's abdomen to reduce lumbar lordosis. The C-arm fluoroscope was rotated and tilted to obtain an antero/posterior (A/P) image of the target lumbar vertebra. The C-arm was then rotated toward the affected side to obtain an oblique fluoroscopic image of the target lumbar vertebra. An oblique angle was applied until the spinous process approached the contralateral facet joint.

The inferior medial point of the pedicle was identified as the needle entry point. The skin and subcutaneous tissues were anesthetized with 1 mL of 2% lidocaine using a 27-gauge needle. A 10-mm active and 100-mm radiofrequency (RF) cannula (TOP Nuropole Needle, TOP Corporation, Tokyo, Japan) was advanced from the anesthetized point to the target. The cannula was advanced using a tunnel-vision technique (Figure IA). The depth of the needle was checked with lateral views. In the lateral view, the final depth of the needle was located between the middle and posterior thirds of the intervertebral foramen (Figure IB). An A/P fluoroscopic image of the epidurogram, which could include a nervegram, was obtained. On the A/P image, contrast medium (iohexol, 300 mg iodine/ml; GE Healthcare, Piscataway, NJ, USA) was spread below and medial to the pedicle shadow and outlined the target spinal nerve exiting the foramen (Figure IC). The RF cannula was then connected to an RF generator (TOP Lesion Generator, TOP Corporation, Tokyo, Japan). The tissue impedance was verified to be ≤ 350 Ω. For sensory stimulation, a paresthesia response was sought in the relevant dermatome at a current of 0.5 volt (V) at a frequency of 50 Hz. Subsequently, no contractile response was observed in the relevant myotome at a current of 1-1.5 V at a frequency of 2 Hz. After appropriate responses, PRF was applied at 42 °C for 120 s (Group-2 minutes) or 240 s (Group-4 minutes), depending on the practitioner's clinical approach. Patients were observed for at least 30 min after the procedure for possible complications.

Assessments

Demographic data (including patient age, sex, and relevant medical history), how many seconds (120 s or 240 s) PRF was applied to the patients for each level, and pain and functionality scores were extracted from hospital records.

Pain intensity was quantified using the NRS, in which patients rated their pain on a scale from 0 (no pain) to 10 (the most severe pain). The Oswestry Disability Index (ODI) was also used to measure the impact of pain on daily functioning. The ODI is a percentage scale, ranging from 0% (indicating no disability) to 100% (indicating the maximum possible disability), and is calculated based on patient responses to a series of ten questions about daily activities and pain (11). NRS and ODI scores were collected before the procedure and at follow-up intervals of 1- and 6-months post-treatment. Clinically significant pain relief was defined as a 50% or greater reduction in NRS score.

Adverse event rates were related to the DRG PRF procedure (procedure-related complications or post-procedural effects, with the majority of them being transient and non-serious.) were obtained from patient follow-up records and direct interviews.

Statistical Analysis

All analyses were performed using Jamovi Project (2022, Jamovi version 2.3) (computer software). The results of this study are expressed as frequencies and percentages. Normality analysis was performed using the Shapiro-Wilk test, skewness kurtosis, and histograms. All analyses were conducted using Jamovi Project (2022, Jamovi Version 2.3, Computer Software). Categorical variables are presented as absolute numbers with percentages. Categorical variables were compared using the chi-squared test or Fisher's exact test. Mann-Whitney U tests were used to compare the numerical dependent variables between the groups. Repeated measures were analyzed using Friedman's test with Bonferroni correction for multiple t-tests. Statistical significance was set at $p < 0.05$.

Results

A total of 182 patients, whose medical records were available, were screened for eligibility. After excluding 14 of these patients due to additional facet joint injections in the same session and 8 patients due to caudal epidural injections, the study was completed with 160 patients, and the final analysis included 82 patients in Group 2-minute (120 s PRF) and 78 patients in Group 4-minute (240 s PRF). A patient flowchart is shown in Figure II.

Table I Baseline demographics and clinical characteristics

Variables	Group-2 minutes (n=82)		Group-4 minutes (n=78)		
	Median (min-max)	Mean±SD	Median (min-max)	Mean±SD	*p value*
Age	59 (23-81)	58.8±10.7	55.5 (27-82)	55.2±12.9	*0.074**
Basal NRS	7 (7-10)	7.5±0.65	8 (6-10)	7.6±0.95	*0.354**
NRS-1 month	5 (0-8)	4.5±1.69	4 (1-9)	4.5±2.15	*0.714**
NRS-6 months	6 (2-10)	5.4±1.76	5 (2-9)	5.4±1.83	*0.899**
Basal ODI	50 (44-56)	49.5±2.9	50 (44-56)	49.7±2.6	*0.704**
ODI-1 month	38 (16-54)	33.3±11.6	27 (18-54)	32.4±12.9	*0.906**
ODI-6 months	44 (20-56)	37.2±11.4	31 (20-54)	35.5±11.4	*0.494**
Duration of pain (months)	9.5 (6-17)	10.4±3.4	10 (5-18)	10.6±3.1	*0.319**
Gender n(%)					
Female	38 (46.3)		52 (66.7)		*0.093***
Male	44 (53.7)		26 (33.3)		
Adverse Events n(%)					
None	75 (91.4)		69 (88.5)		*0.938***
Numbness	4(4.9)		5 (6.4)		
Dysesthesia	3 (3.7)		4 (5.1)		
Pain Side n(%)					
Left	39 (47.6)		38 (48.7)		*0.987***
Right	43 (52.4)		40 (51.3)		

Values are presented as mean ± standard deviation, median (min-max), number (%)
PRF: Pulsed radiofrequency; ODI: Oswestry Disability Index; NRS: Numerical rating scale
*: Mann Whitney U Test **: Chi-Square Test

The demographic and clinical characteristics of patients are shown in Table I. The groups were similar with respect to age, gender, duration of pain, and the side of treatment. Although procedure-related adverse events were observed in more patients in Group 4-minute (numbness 5 vs. 4 and dysesthesia 4 vs. 3), this difference was not statistically significant (*p>0.05*). These adverse events resolved spontaneously within one month, with the longest duration requiring no treatment.

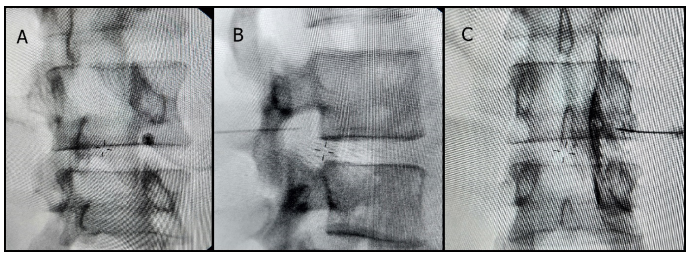

Figure I Fluoroscopy-guided dorsal root ganglion pulsed radiofrequency procedure
(A) shows the tunnel view of the radiofrequency cannula on the oblique fluoroscopic image. (B) shows the tip of the cannula in the foramen intervertebrale on a lateral fluoroscopic image. (C) shows the epidurogram of the existing nerve root.

When the NRS and ODI were evaluated within the groups, their changes over time were statistically significant. At the 1st and 6th month controls, there was a significant improvement in both NRS and ODI scores compared to baseline (*p<0.001*). However, there was no significant difference between the two groups at any time point (*p>0.05*). (Table II).

Table II NRS and ODI scores over time

Treatment Groups		NRS		ODI	
		Median(min-max) / Mean rank	*p value*	Median(min-max) / Mean rank	*p value*
Group-2 minute	Basal	7 (7-8) / 2.84		50 (48-52) / 5.84	
	1 month	5 (3-6) / 1.19	*<0.001*	38 (22-44) / 4.15	*<0.001*
	6 months	6 (4-7) / 1.97		44 (26-48) / 5.01	
Group-4 minute	Basal	8 (7-9) / 2.68		50 (48-52) / 5.72	
	1 month	4 (3-6) / 1.30	*<0.001*	27 (20-46) / 4.27	*<0.001*
	6 months	5 (4-7) / 2.02		31 (24-48) / 5.01	

Friedman test
PRF: Pulsed radiofrequency; ODI: Oswestry Disability Index; NRS: Numerical rating scale; min.-max.: minimum-maximum.

Pain relief of at least 50% was achieved in 39% of patients in Group 2-minute at the 1-month follow-up and in 32.9% at the 6-month follow-up. In comparison,

Group 4-minute exhibited a 50% response rate at the 1-month follow-up and 33.3% at the 6-month follow-up. There was no significant difference in the success rates between the groups at 1 month (*p=0.203*) and 6 months (*p>0.05*).

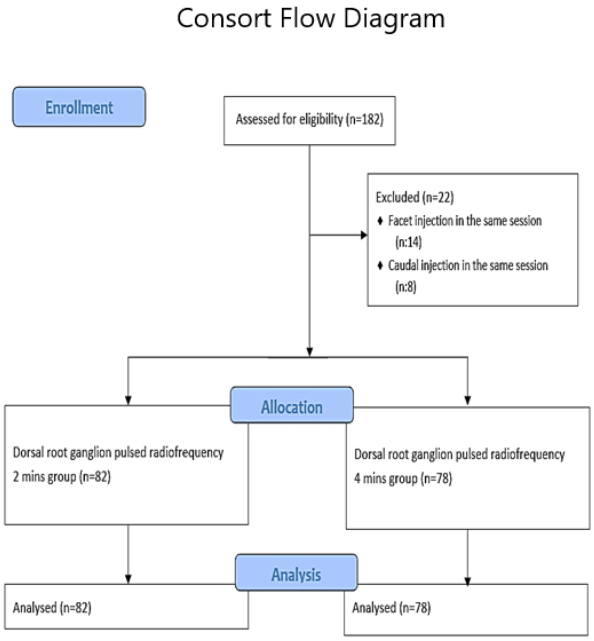

Figure II Patient flow chart

Discussion

In our study, 2-minute and 4-minute DRG PRF applications provided effective analgesia and improved functionality in the management of LRP refractory to conservative treatments, as observed at the first- and sixth-month assessments. Compared to baseline, both the NRS and ODI scores improved. Although there were no statistically significant differences in NRS and ODI between 2 min and 4 min PRF applications, the proportion of patients with 50% or greater pain relief was higher in Group 4-minute, 50% vs. 39% at 1 month, and 33.3% vs. 32.9% at 6 months. Adverse event rates were not significantly different between the groups.

A prospective study by Van Boxem et al. (7), which applied 4-minute DRG PRF per level for LRP, resulted in significant pain relief in 56.9% of patients at six weeks and 55.4% at six months. Conversely, a retrospective study by the same authors (8) using a 2-minute application per level reported a success rate of 22.9% at six months. The authors attributed the difference in results between these studies to the strict inclusion criteria used in the prospective study. In the first study, only patients with pathologies at the lumbar (L) 5 and sacral (S) 1 levels were included, resulting in a higher success rate. Because the L4 dermatome is not very specific, they did not include the L4 level in the study. However, the impact of different durations of PRF, 4-minute versus 2-minute, was not addressed. Our study showed, although not statistically significant, a higher success rate of 50% in Group 4-minute at the 1-month follow-up. In addition, our data included patients who underwent DRG PRF at the L4, L5, and S1 levels, which is more reflective of clinical practice than isolated applications at the L5 and S1 levels.

Another difference between the two studies by Van Boxem et al. is that the retrospective study included only patients with single-level DRG PRF, which had a lower success rate. Elevated levels of chemokine receptor 2 (CLR2), indicating chronic inflammation due to persistent DRG and nerve root compression, were found in both affected and adjacent DRGs (12). This finding suggests that multilevel DRG PRF applications may increase the likelihood of success. Our study included patients who underwent two-level DRG PRF based on clinical and MRI findings. Jyotsna et al. (13) combined 2-minute PRF with 1-minute continuous radiofrequency (CRF) lesioning (mean temperature 56°C ± 8°C for 60 seconds) per level in the treatment of chronic LRP and performed repeated sessions as pain resurged during follow-up. This approach resulted a significant pain reduction for an average of 4.7 months after two sessions in 40 of 50 patients. In the following period, they provided pain relief for an average of 4.3 months with 2-minute PRF+1-minute CRF, which they repeated for five sessions to 18 patients whose pain continued in the following period. In our country, RF applications can be performed only once a year within the framework of social insurance reimbursement, which does not allow for repeated interventions. Our study involved a single PRF session, and the potential for increased success with repeated procedures remains unexplored. Another important detail in this study by Jyotsna et al. (13) is the application of CRF to the DRG, the use of which has always been a reservation for pain specialists. Only one complication was reported in this study, and the patient had numbness that lasted

1 week. This complication was thought to be caused by CRF, rather than PRF.

Although PRF is generally known to have a low adverse event rate (10), one of the largest gaps in the literature is the lack of PRF-related adverse events. In our study, mild numbness was observed in five patients and dysesthesia in four patients in Group-4 minute, while numbness was observed in four patients and dysesthesia was observed in three patients in Group-2 minute, but there was no significant difference between the groups in terms of these adverse event rates. In addition, the longest lasting adverse event in our study was 1 month, which resolved spontaneously without treatment. Koh et al. (9) reported a transient pain increase in six patients in the PRF group and four patients in the sham group in their study comparing 6 mins PRF and sham electrode for LRP and recovered in 2-3 days on average. Although PRF seems to be non-destructive, there are publications indicating that it may cause minor changes in the DRG (14, 15). In the literature, the number of studies in which PRF was applied for 6 min per level is limited and Koh et al. (9) achieved a success rate of 48.4% at 2 months, while this rate was 19.4% in the sham group. At the 3rd month of control, a significant pain relief of 38.7% was observed in the PRF group. The literature gives a wide range of PRF success rates (from 30% to 80%) (8, 16, 17).

The mechanism of action of PRF involves the modulation of pain signals without causing significant nerve tissue damage (18). The predictive factors for PRF efficacy have been investigated. Van Boxem et al. (19) demonstrated in their study that they applied PRF for 4 min that a positive response to the diagnostic block before PRF and an age of 55 years or older may be predictive. Kim et al. (20) also found that short-term positive response to epidural injection prior to PRF was predictive. All participants in our study experienced short-term benefits (<1 month) from TFEI prior to PRF treatment. The absence of comorbid musculoskeletal pain was another predictor highlighted, emphasizing the importance of thorough systemic evaluation prior to interventional treatments, such as PRF, to minimize unnecessary procedures and increase success rates. Our study ensured that the patients underwent comprehensive examinations by orthopedics, neurosurgery, physical therapy and rehabilitation, and rheumatology to rule out non-LRP causes prior to PRF administration. Our study had several limitations. First, the follow-up period was limited to 6 months due to limitations in medical records. Second, we could not evaluate the effects of interventions on drug consumption. Third, our study had a retrospective design.

Conclusion

Although PRF application appears to be generally safe, minor adverse events can be observed, and increasing the duration of application did not increase the incidence of adverse events. A higher success rate was observed with 4-minute PRF application, although this was not clinically significant. Larger, randomized, prospective studies are needed to investigate the effects of varying PRF durations on treatment outcomes.

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