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ORIGINAL RESEARCH PAIN MANAGEMENT

Effectiveness of pulsed radiofrequency in chronic lumbosacral radicular pain

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Abstract

Background: Lumbosacral radicular pain is one of the most common clinical features which accounts for more than 10% of the hospital visits annually. Multiple treatment strategies have been in use to manage it. This study aimed to assess the efficacy of pulsed radiofrequency (PRF) in treating pain and physical disturbances in chronic lumbosacral radicular pain.

Methodology: Forty patients, suffering from lumbosacral neuropathic pain were treated by PRF at the corresponding level (ranging from L3 to S1). Outcome measures included the pain intensity score on a 0-10 numeric rating scale (NRS) at pretreatment, after two months and six months post-treatment.

Results: A significant reduction in pain scores was observed in mean NRS at two and six month duration ($p < 0.001$). The NRS after treatment with PRF was significantly reduced compared to that before PRF treatment (3.28 vs. 8.38 and 4.25 vs. 8.38 respectively) after two and six months.

Conclusion: The PRF is effective in the treatment of chronic lumbosacral radicular pain of neuropathic features.

Key words: Pulsed radiofrequency; Chronic lumbosacral pain; Radicular pain; Numeric pain score

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1. Introduction

Low back pain (LBP) has been divided into three categories based upon the duration of the symptoms; acute, subacute and chronic.[1] A primary goal in the management of LBP may be temporary alleviation of pain to enable the patient to become fully engaged in a physical therapy and rehabilitation program aimed at improving strength and body mechanics to minimize physical stress and provide more long term relief.[2]

Lumbosacral radiculopathy is defined as the dysfunction of a spinal nerve root emerging from the lumbosacral spine and commonly accompanied by a disc herniation. It manifests itself as pain, numbness, reflex changes, and/or weakness in a specific radicular pattern.[3]

Since the 1950s, the RF has been used and practiced to create quantifiable and predictable thermal lesions.[4] The first report appeared in the early 1970s, which included the use of conventional radiofrequency current (CRF) to create a thermal lesion.[5] PRF has maximized the delivery of electrical currents by allowing application of higher voltages in a pulsatile way, allowing time for the heat to dissipate in between RF pulses.[6] The laboratory studies have shown neuronal activation,[7,8] cellular stress,[9] and cellular

substructure damage[10] after PRF application. Several experimental studies showed the observed cellular injury from PRF application is predominantly a function of thermal injury.[11,12] Although the exact mechanism remains unclear, there is ample evidence in the form of randomized controlled preclinical and clinical trials, that suggest it may be efficacious in individuals with neuropathic pain.[13,14] During the classic procedure, the currents are applied for 20 msec for 120 sec duration. Thus for the majority of lesioning duration (480/500 msec) and the voltage is controlled in a manner such that the high electrode temperature achieved remains below 42°C.[15] PRF has been applied for 4, 8, and 20 min by some investigators,[16] and there is evidence from preclinical and clinical studies that longer treatment cycles may be associated with increased effectiveness.

Here we assessed the safety and clinical efficacy of PRF in reducing pain, functional disability and physical impairment in patients with chronic lumbosacral radicular pain and neuropathic nature.

2. Methodology

2.1. Study design

A prospective study was carried out on 60 ASA 1 and 2 patients aged 18-40 y at our institution. All patients included in the study had detailed history, physical examination, and multimodal radiographic imaging. The study was approved by the Arab Board Council Ethics Committee and written informed consent was obtained from each patient.

2.2. Inclusion criteria

Patients with a more than 6 month history of segmental pain of lumbosacral origin radiating from the back into the lower extremity, in which radicular pain could be elicited with more than one positive provoking test (e.g. straight leg raising test) were included. MRI evidence of nerve root involvement or spinal canal narrowing and/or radiculopathy suggested by electromyographic test was sought in every patient.

2.3. Exclusion criteria

Patients with progressive motor deficit, or significant sensory deficit or those in need of an urgent open surgical intervention were excluded. MRI evidence of nerve root involvement or spinal canal narrowing and/or radiculopathy suggested by electromyographic test also precluded inclusion in the study. Following conditions were ruled out from the study subjects; hypersensitivity to the injected material e.g., local anesthetic, contrast, and corticosteroid; coagulopathy; significant psychopathology; pregnancy and reported allergy to anesthesia

2.4. Procedure

In the operating room, basic monitoring (pulse rate, SpO_2, non-invasive blood pressure) was attached, and the patient was put in prone position. Sacral hiatus was identified by linear probe. Local infiltration by 3 to 5 ml of lidocaine 2% was done, Cosman introducer needle 18 gauge was passed through it, Cosman catheter 40 cm long, blunt end, 2 mm diameter passed epidurally in the spinal canal and pushed to the target level guided by fluoroscope. Hydrodissection and adhesolyses of fibrosis by normal saline maximum of 30 ml was done while, steering the catheter according to the targeted root. Methylprednisolone (Depo-Medrol™) 80 mg, triamcinolone (Kenacort™) 40 mg diluted with 6-8 ml saline injection was injected after contrast confirmation, then pulsed radiofrequency was used to 40 °C for 4 min for each targeted level and target root. For motor part a maximum of 3 volts, 5 HZ frequency and for sensory burst stimulation from 5-20 bursts in maximum of 3 volts and 200 HZ was used at the damaged root in case of neurological deficit and timing depend on the severity of neurological deficit. The procedure time ranged from 30- 45 min.

2.5. Follow-up

All patients were treated with the non-steroidal anti-inflammatory drug for 4-6 weeks after the procedure and underwent physiotherapy treatment for one month. We used the numeric rating scale (NRS) for evaluating the pain before and post-intervention. The patients were considered to be pain-free result when the pain level decreased by at least 50%; and no effect was defined as less than 30% decrease in pain on NRS.

2.6. Statistical analysis

The data were analyzed using Statistical Package for Social Sciences (SPSS) version 25. The data presented as mean, SD, and ranges. Categorical data presented as frequencies and percentages. Paired t-test was used to compare the continuous variables before and after PRF treatment. A $p < 0.05$ was considered significant.

3. Results

Patients' age ranged from 29 to 75 y with a mean of 49.92±10.86 y. The highest proportion of the patients (19, 48.7%) were aged more than 50 y (Figure 1). The females were more than males (59% versus 41%), with a female to male ratio of 1.44:1. The mean NRS scores before and after PRF intervention were as follows: pre-intervention 8.38, after 2 months 3.28, and after 6 months 4.25 (Figure 2).

The comparison in the mean NRS between the study patients before and after PRF treatment revealed that the NRS after 2 months and 6 months of treatment with PRF was significantly reduced compared to that before PRF treatment (3.28 versus 8.38, p= 0.001 and 4.25 versus 8.38, p= 0.001, respectively). After 6 months of treatment with PRF, we observed a significant increase in the NRS compared to that after 2 months of intervention (4.25 versus 3.28, p= 0.001) (Table 1).

Concerning the comparison in the NRS according to the age of the study patients, a statistically significant difference ($p < 0.05$) was found in the NRS of the study patients before and after PRF treatment. NRS was significantly decreased after 2 months and 6 months of PRF treatment compared to pre-treatment NRS. A significant rise in the NRS was seen after 6 months of PRF treatment compared to the NRS after 2 months of intervention with PRF (Table 2).

The comparison in the NRS according to the gender of the study patients showed that, after 2 months and after 6 months of PRF treatment, the NRS was significantly decreased ($p < 0.05$) compared to pre-treatment NRS. A significant difference was found between the NRS of the recruited patients, 6 months and 2 months after PRF treatment (Table 3).

Table 1: Comparative NRS between the study patients pre, 2 months, and 6 months after PRF treatment

NRS (Mean ± SD)			P-Value
Pre - PR	2 months after PRF	6 months after PRF	
8.38 ± 1.53	3.28 ± 1.12		**0.001**
	3.28 ± 1.12	4.25 ± 1.11	
8.38 ± 1.53		4.25 ± 1.11	

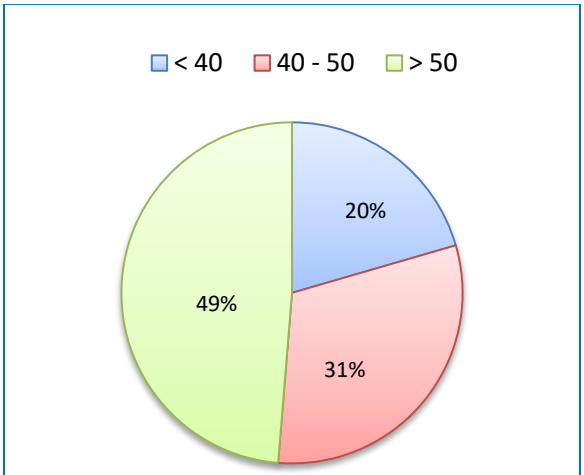

Figure 1: Distribution of the patients by age (y)

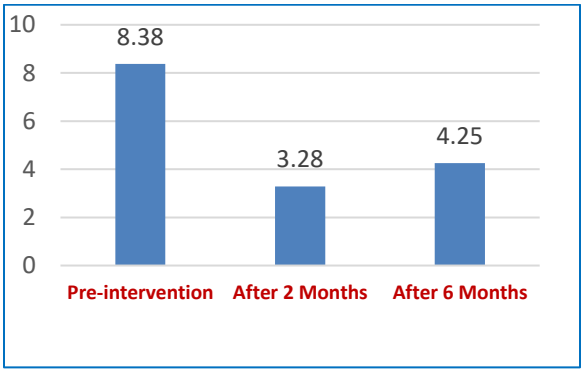

Figure 2: Distribution of the study patients employing NRS, before and after PRF

5. Discussion

This study explored the effectiveness of flexible electro catheter-mediated PRF on lumbosacral radicular pain with neuropathic features. Pain reduction to less than 50% is reported as a good outcome in many works of literature, so reduction to less than 30% can reliably considered as significant for clinical trials, especially in the presence of neuropathic features. [8, 11-13]

The exact mechanism of action of PRF and its therapeutic effects are still being debated. It is supposed that the electric field generated may enhance microstructural changes in neural tissues leading to blocked pain transmission. [14]

Dorsal root ganglia direct excitation has been found to decrease neuronal excitability which may exert an

Table 2: Comparison in NRS according to the age, before and after PRF treatment.

Age Group	NRS (Mean ± SD)			p-value
	Pre - PRF	2 months after PRF	6 months after PRF	
< 40 y	8.87 ± 1.35	2.75 ± 1.03		**0.001**
	8.87 ± 1.35		4.12 ± 1.24	**0.001**
		2.75 ± 1.03	4.12 ± 1.24	**0.001**
40 - 50 y	8.58 ± 1.62	3.16 ± 1.19		**0.001**
	8.58 ± 1.62		3.91 ± 1.08	**0.001**
		3.16 ± 1.19	3.91 ± 1.08	**0.005**
> 50 y	8.05 ± 1.54	3.57 ± 1.07		**0.001**
	8.05 ± 1.54		4.52 ± 1.07	**0.001**
		3.57 ± 1.07	4.52 ± 1.07	**0.001**

analgesic effect by suppressing action potentials generation and propagation.[7] Previous studies documented an increased level of ultrastructural damage in small-diameter neurons exposed to radiofrequency fields. [17]

The radiofrequency of the ganglia showed an immunomodulating effect, that led to a shift in the immune system balance, decreased production of pro-inflammatory cytokines, and raised anti-inflammatory status.[18] Recently, PRF showed the activation of

Table 3: Comparison in NRS according to the gender, before and after PRF treatment

Gender	NRS (Mean ± SD)			p-value
	Pre - PRF	2 months after PRF	6 months after PRF	
Male	8.43 ± 1.54	3.50 ± 1.09		**0.001**
	8.43 ± 1.54		4.25 ± 1.12	**0.001**
		3.50 ± 1.09	4.25 ± 1.12	**0.018**
Female	8.34 ± 1.55	3.13 ± 1.14		**0.001**
	8.34 ± 1.55		4.26 ± 1.13	**0.001**
		3.13 ± 1.14	4.26 ± 1.13	**0.001**

descending anti-nociceptive adrenergic and serotoninergic pathways as well as a significant modulation of microglial expression. [19, 20]

Unfortunately, few randomized controlled studies about PRF are available with the non-univocal result and variable effectiveness in chronic lumbar pain. [5] Most of the studies featured a 120 sec treatment, whereas this duration might be prolonged up to 480 sec. One important issue to be considered in PRF is the time of stimulation, which also is an important factor in neuromodulation and synaptic plasticity.[14, 21] Therefore, we considered 240 sec more appropriate stimulation periods.

The use of a multifunctional flexible electrode has several advantages when compared with the rigid ones, including a closer stimulation of the dorsal root ganglia and a chance to infuse medication into the epidural space. [5] The geometric and structural features of the probe can focus the electric field on the side rather than in front of the tip, which should allow significant neuromodulation with lower tissue healing and injury. [22, 23]

Continuous radiofrequency is contraindicated in neuropathic pain but PRF has shown promising results. [24] Recent experimental models of lumbosacral neuropathic pain have shown significant effects of radiofrequency in reduction of tactile and mechanical allodynia, suggesting it as an important therapeutic tool. [12, 25, 26] Therefore, we considered it important to evaluate the treatment only in a patient with probable neuropathic pain features. The significant relief of

symptoms reported by our patients acquires even greater significance because neuropathic pain treatment still remains challenging for most of the physicians. [27]

A recent work published by Shanthanna et al. [28] was the first randomized controlled trial testing the effectiveness of PRF treatment for chronic lumbar radicular pain. Their results highlighted a small effect of the treatment at 4 weeks and 3 months, not significantly different from the patients in the placebo group. Nevertheless, the treatment was once again performed with a needle rather than a flexible probe, and the duration of the treatment was only 120 sec. In our opinion, these features may have affected the results, minimizing the potential effectiveness of PRF.

6. Conclusion

The PRF has a beneficial role in treating patients with chronic lumbosacral radicular pain with neuropathic features. The complication rates and side effects of this procedure are relatively small in the expert hands and the patients benefit from a long-term pain relief.

7. Conflict of Interest

The authors declare no conflict of interest.

8. Authors' contribution

JNM: Study design, manuscript writing, literature review, statistical analysis

MAJ: Methodology, statistical analysis

MAH: Manuscript writing, Methods

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