ORIGINAL ARTICLE

The efficacy of pulsed radiofrequency intervention of the lumbar dorsal root ganglion in patients with chronic lumbar radicular pain

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ABSTRACT

Introduction: In recent years, pulsed radiofrequency (PR) has been used as a minimally invasive pain intervention. However, various studies on the efficacy of PR as modalities for the treatment of radicular pain in lumbar disc herniation have had varied results. Objective: This study aims to determine the efficacy of PR in reducing radicular pain among lumbar disc herniation patients compared with conservative treatment.

Methods: This study was conducted using the before-and-after quasi experimental design. There were 50 subjects that fulfilled the inclusion and exclusion criteria and they were divided into an intervention group (n=25) and control group (n=25). The intervention group was given once PR in the dorsal root ganglion. All subjects were assessed for Visual Analog Scale (VAS) and Oswestry Disability Index (ODI) before treatment, at 1- , 2- and 4-week after treatment.

Results: At1-, 2- and 4-week, the VAS reduction in the intervention group was statistically significant compared to the control group. Four weeks after the intervention, the VAS score decreased in the intervention group (mean VAS -78.5, SD 16.8) more significantly compared to the control group (p<0.001). The ODI score decreased in the intervention group (mean ODI -61.8, SD 20.1) more significantly than in the control group (p<0.001).

Conclusion: Finding showed that at1- , 2- and 4-weekPR was more efficacious in reducing radicular pain among lumbar disc herniation patients compared to the conservative therapy.

KEY WORDS:
Efficacy, lumbar disc herniation, pulsed radiofrequency, radicular pain

INTRODUCTION

Almost 80% of peopleexperienced at least one episode of lower back pain (LBP) in theirlifetime. Due toits high prevalence and significant contribution to cause disability, lower back pain United States of America has spentmore than 100 billion dollars annually.[1] Lumbar disc herniation is one of the most common causes of lower back pain. Its specific diagnostic and therapy assessment need to be followed up properly.[2]

The prevalence of lumbar disc herniation is about 1 to 3% of the world population with the most frequent incidence among the 30-50 years olds. The prevalence is 3.6% at the age of less than 35 years and 22% at the age of 45-54 years with a male to female ratio of 2:1. In the study of lumbar disc herniation, more than 90% of cases are most often found at the L4-L5 and L5-S1 vertebral level. In younger patients, disc herniation occurs more frequently at the L5-S1 level. The proportion of disc herniation at higher lumbar levels increases with aging.[3]

Conservative therapy (pharmacotherapy or physiotherapy) is effective in 60% of cases, while the rest of cases progressinto chronic pain. This results in a high degree of disability and ending with higher medical expenses.[2]

Surgical therapy has surgical side effects, such as neurological trauma, slow recovery time, spinal instability, adhesion and scarring, and even surgical failure in severe cases. Pain technique therapy is developed for lumbar disc herniation with minimally invasive and smaller complications.[4]

Radiofrequency therapy is a medical procedure that is used to reduce pain with low complication rates (<1%), ease of application, and low medical costs. In this procedure electric current that is generated by radio waves is used to heat a small area of nerve tissue. It inhibits or reduces pain signals from certain areas. In the last fiveyears, radiofrequency has been developed in the field of this disease related to functional spinal units.[2] Research on the effectiveness of radiofrequency therapy in lumbar disc herniation is still limited.[5] The purpose of this study is to evaluate the efficacy of usage of radiofrequency compared to conservative intervention in lumbar disc herniation patients.

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MATERIALS AND METHODS

Study Design

This study was conducted using the before-and-after quasi experimental with control design, taken with consecutive sampling and no randomisation in this study. This study was donefrom January to March 2019 at Dr. Soeradji Tirtonegoro General Hospital, Klaten, Indonesia. The study subjects were diagnosed with lumbar disc herniation (clinical and MRI)and fulfilled the inclusion criteria. The inclusion criteriawere: 1) Lumbar disc herniation patients with chronic radicular pain (>3 months); 2)18-65 years old;3) Visual Analog Scale (VAS)>50mm and the exclusion criteria are 1) patients with severe organ dysfunction (renal failure, heart failure, severe respiratory diseases); 2) patients with comorbidities that affected the assessment of pain score (post-stroke, central neuropathic pain, diabetic mellitus, cancer, dementia). Subjects who met the inclusion and exclusion criteria were then divided into twogroups, intervention group and control group. Group allocation was shown in Figure 1.

Pulsed Radiofrequency Procedures

The intervention group was given a one time pulsed radiofrequency (PRF) therapy. All subjects in the intervention group were given radiofrequency therapy on the dorsal root ganglion using the same tools and procedures by the same operator. The tools used were Cosman and CC type CR needles, 10cm cannula, and 10mm active tip. It used 100-200ohms impedances, 50Hz, 0.3-0.5V sensory stimulation, and 2Hz, 0.9-1.5V motor stimulation. After stimulation was confirmed, denervation was carried out by heating at a temperature not exceeding 42°C for 120 seconds which was divided into twocycles. The control group was given oral therapy of sodium diclofenac 50mg per 12 hours for four weeks, taken in the morning and evening, after meals.

Outcome Measurements

The clinical outcome was assessed by VAS for radicular pain, before intervention, at 1-, 2- and 4-week after intervention. The VAS score arranged from 0 until 100 milimetres. ODI was obtained to evaluate functional disabilities associated with lumbar radicular pain, respectively, at the same times.

Adverse events

Adverse effects were carefully evaluated during each visit to detect pain flare-up and newly developed neurologic deficits after the procedures.

Sample size

The size of the sample required for this study is assessed using large sample formula to test hypotheses against the two independent populations mean value, with the results as follows:

$$n1 = n2 = 2\left[\frac{([X\alpha+Z\beta)\ S)}{(X1 - X2))}\right]^2$$

Details:
S = standard deviation of the two groups (from literature)
X1-X2 = desired clinical differences(clinical judgement)
α = type I error
β = type II error

Based on the sample calculation above, as well as the anticipation of drop outs, the number of patientsrecruted in this study were 25subjects in each group.

Statistical Analysis

Data was identified using SPSS and considered significant if the *p-value* is <0.05.

RESULTS

Characteristics of Subjects

There were 50 subjects with lumbar disc herniation who met the inclusion and exclusion criterias and they were divided into twogroups; 25 subjects in the intervention group and 25 subjects in the control group. All of data distribution were normal. There were no differences in the characteristics between theintervention and control group (p>0.05) (Table I).

The Differences of VAS and ODI Improvement between Intervetion Group compared with Control Groups.

After analysing the changes in VAS and ODI in each group, the subsequent analysis was carried out to determine the differences in the VAS and ODI improvement between intervention groupscompared with the control group.

From the results of the Mann Whitney test (Table II), it was found that there was a difference in the decrease of VAS in the intervention group which was statistically significant compared to the control group with p value (p<0.001), at 1-, 2- and 4-week of intervention. The VAS score progression was shown in Figure 2.

From the results of the Mann Whitney test (Table II), it was found that there was a difference in the decrease of ODI in the intervention group which was statistically significant compared to the control group with p value (p<0. 001), after 1 week, 2 weeks and 4 weeks of intervention. The ODI score progression was shown in Figure 3.

DISCUSSION

This study showed that there were statistically significant differences in the decrease in VAS and ODI scores in the intervention group compared to the control group fourweeks after intervention. This result was in accordance with the result of research conducted by Teixera et al., Khalifa and Saadalla and Boxem et al., where PRF therapy effectively reduced radicular pain scores in lumbar disc herniation.[6-8]

This study resultwas contrast to the study by Shanthanna et al. In their study of 41 subjects, the PRF therapy in the dorsal root ganglion did not provide a significant deterioration in VAS and ODI at fourweeks and three months after intervention compared with the placebo group. The study by Lee, Ahn and Lee also showed the similar results.[5,9] A systematic review of three trials found that NSAIDwas no more effective than placebo in reducing pain or disability in radicular pain. However, there was a statistically significant increase in global improvement related to NSAID usage compared with placebo in short-term follow-up (up to three weeks; n=753, risk ratio1.14; 95% confidence interval 1.03, 1.27). It should be noted that the overall quality of the

Table I: Characteristics of research subjects and homogeneity tests

Characteristics	Intervention Group		Control Group		*p* value
	n	(%)	n	(%)	
Age	57.4		57.1		0.8
Gender					0.6
Male	10	40	8	32	
Female	15	60	17	68	
Body Mass Index (BMI)					n.s.
Normal	12	48	12	48	
Overweight	13	52	13	52	
Number of lesion					1.0
Single	24	96	22	88	
Multiple	1	4	3	12	
Level of HNP					0.2
L3-4	1	4	3	12	
L4-5	20	80	14	56	
L5-S1	3	12	6	24	
L4-5, L5-S1	1	4	2	8	
Duration of Complaints					0.3
≤ 12 months	21	84	21	84	
> 12 months	4	16	4	16	

Table II: The differences of VAS and ODI score in the intervention group compared to the control group at 1-, 2- and 4-week after intervention

Follow up		Mean	SD	p value
Week 1				
VAS	Intervension	-49.2	9.1	≤0.001*)
	Control	-19.6	14.1	
ODI	Intervension	-58.8	21.5	≤0.001*)
	Control	-17.6	14.4	
Week 2				
VAS	Intervension	-65.2	6.2	0.004*)
	Control	-46.9	7.6	
ODI	Intervension	-59.5	4.7	≤0.001*)
	Control	-28.5	7.5	
Week 4				
VAS	Intervension	-78.5	16.9	≤0.001*)
	Control	-41.4	13.3	
ODI	Intervension	-61.8	20.1	≤0.001*)
	Control	-38.6	16.5	

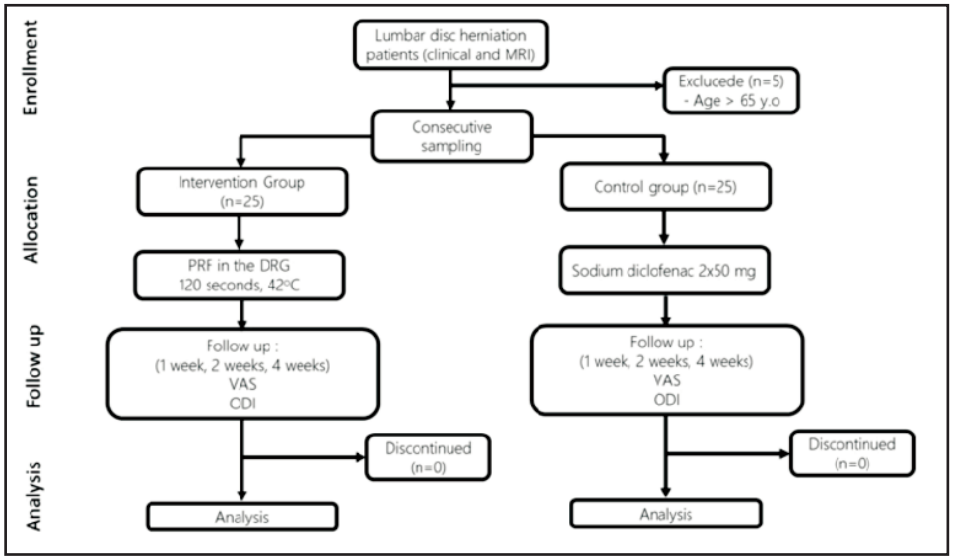

Fig. 1: Non-randomized, conservative intervention controlled, quasi trial study flowchart.

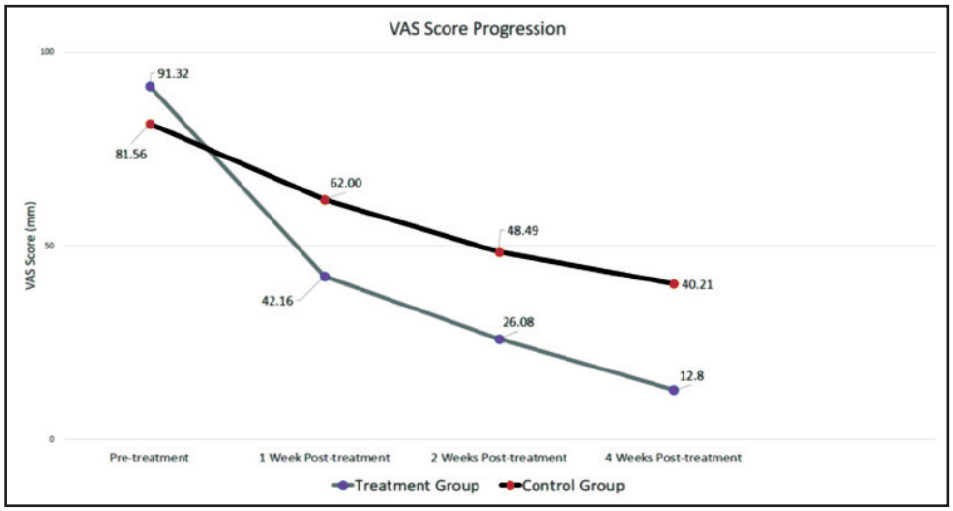

Fig. 2: The VAS improvement in the intervention group and control group.

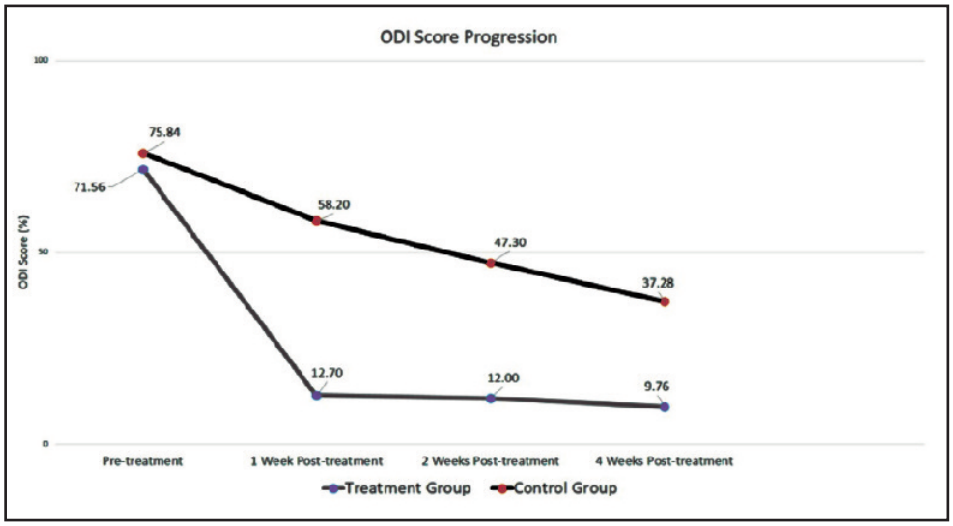

Fig. 3: The ODI improvement in the intervention group and control group.

evidence using the GRADE approach for these results varied from low to very low. Evidence from four trials showed an increased risk of side effects when using NSAIDs compared to placebo. Most side effects reported were mild and consisted of headaches, dizziness and digestive problems, such as nausea, dyspepsia, epigastric burning, and abdominal pain.[10]

This study showed that the PRF intervention group had better efficacy in reducing radicular pain scores in subjects with significant lumbar disc herniation compared to conservative therapy. Although the theory of the PRF working mechanism is still under discussion, PRF therapy is thought to be an effective therapy in reducing the intensity of neuropathic pain, namely radicular pain in disc herniation. This was in accordance to study by Chang who showed that PRF therapy was an effective therapy in reducing the intensity of neuropathic pain, namely radicular pain in disc herniation, post-herpetic neuralgia and occipital neuralgia.[11]

Chang showed that PRF therapy is an effective therapy in reducing the intensity of neuropathic pain, post-herpetic neuralgia and occipital neuralgia. Although the PRF therapy mechanism is still unclear, various studies have sought to uncover the underlying process.[11] Erdine et al evaluated ultra structure lesions in sensory nociceptic axons that occurred after PRF therapy using electron microscopy.[12] They asserted that selective PRF therapy resulted in wider lesions in smaller primary sensory nociceptics such as the Aδ and C fibers compared to larger non-pain sensory fibers. Study by Hagiwara et al showed that PRF therapy activated descending noradrenergic and serotoninergic pain inhibition pathways and inhibited the excitatory nociceptic C fibers.[13]

A study by Cho et al showed that administration of PRF therapy in the dorsal root ganglion can reduce microglial activity in the dorsal horn of the spinal cord. A decrease in microglial activity may prevent the development of chronic neuropathic pain where microglia can cause chronic neuropathic pain through the release of various types of cytokines and chemokines associated with pain signals transmition.[14] Meanwhile, Vallejo et al stated that non-inflammatory cytokines, tumor necrosis factor-α and interleukin-6 decreased after PRF therapy.[15]

We suggest that any new study should be done with longer follow-up time, or comparison with the other treatment of choices such as surgery or regenerative treatment.

CONCLUSION

Finding demonstrated that pulsed radiofrequency was more efficacious in reducing radicular pain among lumbar disc herniation patients than conservative therapy.

AUTHORS' CONTRIBUTION

ANI conceived the study, participated in its design, reviewed, performed statistical analyses, wrote the paper and reference review, manuscript review and edits manuscript. SR carried out patient selection consisting of history taking, physical examination and MRI evaluation, explained the study to the patients and obtained the' informed consent from patients, performed all the radiofrequency treatment, collected intraoperative study data, reviewed and edited the paper. RS collected preoperative data including demographic data, pre-intervention post-intervention data, and prepared the manuscript. YD and BG co-ordinated the study design with all the authors and reviewed the manuscript. IP, IS and CT reviewed the manuscript. All the authors have read and approved the final manuscript.

CONFLICTS OF INTEREST

The authors declare that there is no conflict of interest regarding the publication of this paper.

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ETHICAL APPROVAL

Ethical approval has been given by medical and health research ethics committee (MHREC) Faculty of Medicine Gadjah Mada University/ Dr. Sardjito General Hospital. The reference number is KE/FK/0043/EC/2019.

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