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Evaluation of the efficacy and safety of gabapentin in treatment of lumbar radiculopathy; A randomized clinical trial

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Abstract: Purpose: The aim of this study was to evaluate the efficacy of gabapentin in combination with standard treatment (an NSAID) compared with the control group in the course of lumbar radiculopathy.
Materials and Methods: In this single-blind randomized clinical trial study, patients with lumbar radiculopathy referred to Baqiyatallah Hospital in Tehran, Iran in 2014 were divided into two groups of 28 people. Group 1 was treated with naproxen 250mg every 12 hours and placebo of gabapentin 900 mg daily (300 mg, 3 times a day). In another group, patients were treated with naproxen 250 mg twice a day and gabapentin 900 mg daily (300 mg, 3 times a day).A visual analog scale (VAS) pain assessment was used for evaluation of pain severity .
Results: Pain severity before and after treatment showed no significant decrease in the both groups. (P value = 0.079) The ability to walk before and after treatment in the both groups increased significantly, but there was no significant difference between the two groups. (P value = 0.054)
Conclusion: Gabapentin in combination with NSAID consumption is more effective compared to NSAID use only in patients with lumbar radiculopathy of spinal origin.
Keywords: *Gabapentin, Low back pain, NSAID, Radiculopathy, Spinal*

I. INTRODUCTION

Lumbar radiculopathy is a common consequence of spinal pathology characterized by back pain and lower extremity numbness, paresthesia, or muscle weakness that restricts patients' quality of life[1-4]. Disk herniation is the most common cause of radicular pain[5] when the resulting effect on the nerve root causes radiculopathy[6]. Another important cause of radicular pain is spinal stenosis, a result of degenerative processes caused by age-related changes[5]. Back pain is the most important debilitating disease in America under the age of 45 years with an annual incidence of about 5 percent[7]. The treatment currently used for these patients includes protective measures such as exercise, weight loss, and physiotherapy. In case of failure or impairment of daily activities due to pain, another treatment options include medication, supplements and surgery[8]. Among drug treatments, NSAIDs (Non- Steroidal Anti- Inflammatory Drugs) are known as first-line treatment for acute low back pain[9]. Naproxen as a non-selective NSAID in compared with other NSAIDs has lower risk of complications such as gastrointestinal, renal and cardiovascular problems[10]. Opioids, muscle relaxants, anticonvulsants, anesthetics, steroid injections, electrical nerve stimulation, surgery, and other treatments are also effective in relief of low back pain[11, 12]. Gabapentin of anticonvulsant and analgesic drugs, is one of the treatments effective in pain reduction and enhancing quality of life in patients with chronic radicular pain. However, there are not many studies on the effect of gabapentin on acute radicular pain[13].
The aim of this study was to evaluate the efficacy of gabapentin in combination with standard treatment (an NSAID) in compared with the control group in treatment of lumbar radiculopathy.

II. MATERIALS AND METHODS

In this single-blind randomized clinical trial study, after receiving the ethics approval and patient informed consent, 56 patients with lumbar radiculopathy referred to Baqiyatallah Hospital in Tehran, Iran in 2014 were selected by simple random sampling. Radiculopathy was diagnosed by a neurosurgeon with 10 years of experience. Patients were randomized into two groups with 28 members according to a computer- generated randomization list. The first group received common treatment including : naproxen 250 mg every 12 hours with placebo of gabapentin 900 mg daily (300 mg, 3 times a day) .The second group received naproxen 250 mg twice a day and gabapentin 900 mg daily (300 mg ,3 times a day). The both groups received treatment for 8 weeks. Some previous studies reported safety of more dose of these drugs (1200 and 3600 mg for gabapentin

and 500 mg for naproxen)(14, 15). The efficacy and safety of gabapentin was compared with standard treatment with concomitant use of it and naproxen . Visual analogue scale (VAS)was used to measure the pain severity.
We considered ages 25 -55 years and diagnosis of lumbar radiculopathy based on clinical examination and magnetic resonance imaging (MRI) as inclusion criteria. Cases with duration of diagnosis less than 3 months, treatment discontinuation for more than 3 weeks, progression of the disease and the need for surgery, and creation of psychiatric disorders such as depression were excluded from the study.
Individuals were asked to sign an informed consent form before answering the questionnaire. All the personal information remained anonymous.
Data were analyzed using statistical package for social sciences (SPSS) version 16 (SPSS Inc. Chicago, IL) for windows. Normal distribution variables (approved by one-sample Kolmogorov–Smirnov test) were compared using independent sample t-test between the groups and paired sample t-test within the groups. Chi square test also was used to compare categorical variables in the two groups. P value < 0.05 was considered statistically significant.

III. RESULTS

Eventually 56 cases (30 males and 26 females) with the mean age of group 1= 46.35± 8.03 versus group 2=45.1 ± 7.9 years underwent analysis. The both groups included of 15 males and 13 females. There was no significant difference between the two groups in term of gender. (P=0.12)Age distribution was similar in the two groups and there was no significant difference between the two groups. (P=0.19) Weight average was 76.1± 8.27 Kg and 76.03± 9.7 Kg in group 1 and 2 ,respectively and there was no significant difference between the two groups. (P=0.12)
Table 1 shows distribution of underlying disease in the patients. According to this table, distribution of underlying disease in the two groups showed no significant difference. (P > 0.05)
In the both groups, 27 patients had radicular pain and one patient was with burning pain and also in the both groups in 22 patients, pain continued for 1 hour and in 6 patients pain continued for more than 1 hour. There was no significant difference between the two groups. (P>0.05)
Evaluation of side effects in the both groups showed that in group one, one patient had headache, 2 patients reported abdominal pain and 25 were also uncomplicated. In group 2, three patients were with headache, 2 patients reported abdominal pain and 23 were also uncomplicated. Distribution of side effects in the two groups showed no significant difference. (P > 0.05)
Table 2 shows ability to walk (meter) in the two groups before and after treatment. There was a significant difference in ability to walk before and after treatment in the both groups. But difference was not significant between the groups. (P=0.07)
The average pain score in the group 1 before and after treatment was 5.46 ± 1.52 and 5.03 ± 1.48, respectively. There was no significant difference. (P=0.076) The average pain score in the group 2 before drug treatment was 5.34 ± 1.39 and was 4.68 ± 1.25 after that. The comparison of the average pain score before and after treatment showed no significant difference. (P=0.08) In comparing the two groups, the difference was not significant. (P=0.79)

IV. DISCUSSION

We found that pain severity after treatment in the both groups significantly decreased. But the two groups compared with each other, were not significantly different. It seems that pain relieved not as expected in those who received gabapentin. As well as the ability to walk after treatment in the both groups significantly increased. But there was no significant difference between the two groups. It seems that gabapentin may increase the amount of walking not as expected.
Kasimgan et.al[1] concluded that gabapentin alone can significantly reduce pain compared to baseline values and increase ability to walk in patients with radiculopathy due to lumbar disc herniation and spinal stenosis. This was not in line with our study. We concluded that gabapentin could not relieve as expected.
Levin et.al[14] showed that gabapentin was effective in the treatment of acute lumbosacral radiculopathy if it was administered early (less than one month from the start of pain). Our findings did not confirm this.
Yaksi et.al[13] demonstrated that in nervous intermittent claudication, gabapentin for 4 months, increases the ability to walk, eliminates the pain and sensory deficits significantly.
Gray J et.al [15] reported that gabapentin had a minor effect on radicular pain that was consistent with our study.

V. CONCLUSION

We concluded that effectiveness of gabapentin in combination with NSAID is more effective in reducing pain and increasing the amount of walking and activity ability compared to NSAID use alone in

patients with lumbar radiculopathy of spinal origin. Finally further studies with a larger sample size are suggested to confirm the results of this study.

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Table 1 - Underlying Disease

Groups	Hypertension	Digestive	Diabetes	Renal	Cardiac	Thyroid	Psychiatric	Others
One	2	0	4	1	1	0	0	1
Two	2	1	4	0	0	2	1	1

Table 2- Ability to walk (meter)

		0-100 m	100-500 m	500-1000 m	>1000 m	P Value
Group 1	Before	2	9	6	11	0.04
	After	0	8	7	13	
Group 2	Before	4	8	6	10	0.02
	After	0	7	10	11	

m=meters