

PREGABALIN AND GABAPENTIN A STUDY FOR MANAGEMENT IN NEUROPATHIC PAIN WITH CHRONIC LUMBAR RADICULOPATHY

Dr.Ranjeet Kumar Jha¹,

1. Assistant professor, Department of neurosurgery, SSMC Medical College, Rewa, M.P.

*Corresponding author – **Dr.Ranjeet Kumar Jha**

Email id – ranjeetjha20@gmail.com

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ABSTRACT

Background: Chronic lumbar radiculopathy is a medical terminology which covers back and leg pain associated with sensory, reflex, or motor deficits in the area of nerve distribution lasting for > 12 weeks. The lumbar radiculopathy has reported to be 5.3% in men and 3.7% in women. Pregabalin and gabapentin, which is a new category of drugs called as alpha-2-delta ($\alpha 2\delta$) modulators, have discovered to be good in the treatment of neuropathic pain related. So this study was done for comparison of effectiveness and safety profile of pregabalin and gabapentin in the pain management along with chronic lumbar radiculopathy. **Materials and Methods:** This was a randomized trial with comparative prospective study. Total 160 study participants were enrolled for the study and randomized into 2 equal groups. Study participants of group I had received capsule pregabalin 75 mg bd orally, Study participants of group II had received tablet gabapentin 300 mg bd orally. Assessment of pain was done at 0 week (start of study), at 6 weeks and after 12 weeks of onset of the treatment according to numeric pain rating scale. **Results:** There was significant improvement in pain after 12 weeks of onset of the treatment among both the study groups ($p < 0.0001$), there was no statistically significant difference among the groups. The reported adverse effects were found more in study group I. **Conclusions:** Both the drugs are having approximate efficacy but tolerability of gabapentin is more among such cases.

Keywords: Lumbar radiculopathy, Pregabalin, Gabapentin.

INTRODUCTION

Depression Lumbar radiculopathy is a process in which the lumbar nerve roots that results in the radicular symptoms in the lower limbs. The nerve root pathology is due to direct neural compression which have various causative factors like herniated or displaced disc, bony spurs, foraminal stenosis, central stenosis, or hypermobility of a vertebral segment.(1) Chronic lumbar radiculopathy is elaborated as a condition in which covers back and leg pain along with reflex, sensory or motor deficits around the area of nerve root distribution which is lasting for more than 12 weeks.(2-5) The whole life prevalence of lumbar radiculopathy reported is 5.3% in men and 3.7% in women.(6) Lumbar radiculopathy from prolapsed disc improves spontaneously in 23-48% of patients, but up to 30%

go on have symptoms after 1 year, 20% will be out of work, and 5-15% will undergo surgery.(7) Patients whom have symptom like leg pain, conservative management like physical therapy, use of pain killer medicines and epidural steroid injections, along with surgical intervention like lumbar discectomy have shown as helpful.(8) Pregabalin and gabapentin, are counted in to a new category of medicines known as alpha-2-delta ($\alpha 2\delta$) modulators, have discovered to be good in the improvement of neuropathic pain. Given their potency in multiple types of neuropathic pain, these medicines are likely to be good in neuropathic pain associated with nerve root compression, no randomized controlled study has revealed their potency exclusively in this condition.

MATERIAL AND METHODS

The study was conducted in the outpatient department of neurosurgery at SSMC medical college, Rewa. This study was carried out from December 2018 to December 2019. It was a 12 weeks randomized comparative trial with prospective study. Patients of both sex and age (18 to 65 years) and judged as cases of chronic lumbar radiculopathy according to symptoms, clinical examination, X-ray and MRI scan of lumbosacral spine and whom want to participate in the study and gave written along with informed consent were counted in the study. Patients whom had hypersensitivity to the medicines or had taken the medicines previously within past one month, had history of diabetes, tuberculosis, psychiatric disorders and radiculopathy secondary to tumors were not included in study. Patients who had impaired immunity status, heart disease, kidney disease and liver diseases were excluded from the present study. Pregnant and lactating mothers were also excluded from the present study. Total 160 study participants were enrolled for the study and randomized into 2 equal groups. Study participants of group I had received capsule pregabalin 75 mg bd orally, Study participants of group II had received tablet gabapentin 300 mg bd orally. Assessment of pain was done at 0 week (start of study), at 6 weeks and after 12 weeks of onset of the treatment according to numeric pain rating scale. Out of the total 160 study participants, 150 participants completed the study. Total 5 subjects (3 in group A, 2 in group B) were lost to follow up. 5 subjects (2 in group I, 3 in group II) whom had developed neuro-deficit in lower extremities during the course of study were not included and referred for immediate surgical intervention. Therefore 75 subjects in each group who completed the 12 weeks study were evaluated.

RESULT

Out of 160 patients, 150 patients completed the study. Total 5 subjects (3 in group I, 2 in group II) were lost to follow up. 5 subjects (2 in group I, 3 in group II) who developed neuro-deficit in lower extremities along the duration of study were not included and referred for immediate surgical intervention. Therefore 75 subjects in each group who completed the 12 weeks study were checked. The mean reduction of NPRS pain score in group I from baseline to 12 weeks was 4.3. The mean reduction of NPRS pain score in group II from baseline to 12 weeks was 4.38. In intragroup analysis of both the groups, group I subjects, the

mean NPRS pain scores were 8.17 ± 1.34 at the beginning of the study, 6.31 ± 1.99 after 6 weeks and 3.87 ± 3.24 after the end of 12 weeks. This results that there was a statistically significant decrease in mean pain score ($p < 0.0001$) after the end of 12 weeks. Similarly, in group II the mean NPRS pain scores were 8.27 ± 1.18 at the start of the study, 6.76 ± 1.56 at the end of 6 weeks and 3.89 ± 2.99 at the end of study i.e. 12 weeks. There was a statistically significant lowering in mean pain score ($p < 0.0001$) after the end of 12 weeks in group II also. During the study adverse effects were seen with the use of study drugs. 19 (25.33%) patients from group I and 7 (9.3%) patients from group II complained of sedation. The p value came out to be statistically significant ($p = 0.0165$). 8 (10.7%) patients from group I and 5 (6.7%) patients from group II complained of dizziness, but the difference between two groups was not significant ($p = 0.5633$).

DISCUSSION

Various studies reported that Chronic lumbar radiculopathy is among painful medical condition of back and leg region characterized with reflex, sensory or motor deficits around the area of nerve root distribution which is lasting for more than 12 weeks. The medical management consists of medicines like NSAIDs, corticosteroids, gabapentin, pregabalin, duloxetine, tricyclic antidepressants and epidural steroids etc. Pregabalin and gabapentin are one of the important medicines in curing all types of neuropathic pain including radiculopathy. Pregabalin is a analog of gamma-amino butyric acid (GABA) selectively binds the $\alpha 2\text{-}\delta$ subunit, of voltage-dependent calcium channels, which have analgesic, anxiolytic, and antiepileptic properties.⁸ Gabapentin have agonistic action on GABAB receptors which negatively modifies the $\alpha 2\delta\text{-}1$ subunit of voltage gated Ca^{2+} channels, inwardly rectifying K^{+} channels, blocks Ca^{2+} and Na^{+} channels and open K^{+} channels which results in inhibition of the abnormal activity and hyper-excitability of sensory neurons, thereby resulting in reduction of pain. In our study, we found that after the end of 12 weeks, pregabalin was good in reduction of pain of chronic lumbar radiculopathy. The mean pain score among patients treated with pregabalin reduced significantly to 3.87 from 8.17. This finding was in match to study conducted by Baron et al.⁽⁹⁾ Gabapentin reduced chronic lumbar radiculopathy pain significantly after the end of 12 weeks. Among study participants treated with gabapentin, the mean pain score reduction was statistically significant to 3.89 from 8.27. This finding was in match to the study

results obtained by Kasimcan et al.(10) Pain reduction in study participants treated with pregabalin was 52.63%, and 52.96% in study participants treated with gabapentin after end of 12 weeks. Hence, pregabalin reported to be approximate pain reduction in comparison to gabapentin [52.63% vs. 52.96%] after the end of 12 weeks study and results were comparable. Moreover, the incidence of adverse effects like sedation and dizziness was more in subjects treated with pregabalin as compared to those treated with gabapentin.

CONCLUSION

Through this study we conclude that both pregabalin and gabapentin are equally efficacious for the treatment of pain associated with cases of chronic lumbar radiculopathy.

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