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# To study the comparison of functional outcomes between pregabalin versus gabapentin in Cases of Low Back Ache with radiculopathy

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## ABSTRACT

***Aims & Objectives: Millions of people have low back pain, which causes more disability than any other health condition. The present study was planned for comparing the functional outcomes between pregabalin versus gabapentin in Cases of Low Back Ache with radiculopathy.***

***Materials & methods: A total of 100 subjects with presence of low back ache with radiculopathy were enrolled. Clinical and MRI examination of all the patients was done. All the 100 patients were divided into two study groups with 50 patients in each group as follows: Gabapentin group and Pregabalin group. Capsule pregabalin 75 mg one time a dayorally and tablet gabapentin 300 mg one timea day was given in the respective groups. Both drugs were given at night time. Pain intensity was assessed at the start of study i.e. at baseline (0 week), at 1 month and three months using VAS. Complications were recorded on each visit. All the results were recorded and analysed by SPSS software.***

***Results: Mean VAS at baseline, one month and three months among patients of group Pregabalin was 8.91, 6.96 and 3.16 respectively. Mean VAS at baseline, one month and three months among patients of group Gabapentin was 8.12, 6.43 and 3.58 respectively. While making intra-group comparison, significant results were obtained. However; while comparing the mean VAS between the two study groups, non-significant results were obtained at different time intervals. Sedation as a side effect was significantly more common in Pregabalin group.***

***Conclusion: Gabapentin was better in comparison to pregabalin in having fewer side effects.***

**Key words: Gabapentin, Pregabalin**

## INTRODUCTION

Millions of people have low back pain, which causes more disability than any other health condition. Most people with low back pain have symptoms resulting from nonspecific causes. About 5% to 10% of people with low back pain have sciatica, in which the leg pain follows the sciatic nerve and can be accompanied by strength, sensory and reflex changes in the leg. A smaller proportion of people have neurogenic claudication, in which the leg pain is associated with spinal stenosis and symptoms are exacerbated with extension activities (e.g., walking) and relieved by flexion (e.g., sitting). Leg pain originating from the lumbar spine is commonly referred to as radicular pain.[1-3]

Anti-convulsant anti-neuropathic agents such as gabapentin (GBP) and pregabalin (PGB) are also widely used to treat NP, including CS. On the basis of 'moderate- to high-quality'

evidence, NICE-UK noted the efficacy of these agents over placebo for NP. Australian prescribing authorities (e.g., ATG) recommend anti-neuropathic agents as second-line agents for NP, even though NICE-UK did not actually favour TCAs over anti-neuropathics as first-line agents (or vice versa). However, NICE-UK states that when introducing second-line agents, 'overlap' with pre-existent regimens should be considered to avoid decreased pain control. A recent literature review provides information on the individual efficacy of PGB and GBP over placebo for CS; however, when compared head-to-head, no firm conclusions can be made.[4- 6]Hence; the present study was planned for comparing the functional outcomes between pregabalin versus gabapentin in Cases of Low Back Ache with radiculopathy.

## MATERIALS & METHODS

The present study was planned for comparing the functional outcomes between pregabalin versus gabapentin in Cases of Low Back Ache with radiculopathy. A total of 100 subjects with presence of low back ache with radiculopathy were enrolled. Clinical and MRI examination of all the patients was done. Ethical approval was obtained. All the 100 patients were divided into two study groups with 50 patients in each group as follows: Gabapentin group and Pregabalin group. Capsule pregabalin 75 mg one timea day orally and tablet gabapentin 300 mg one timea day was given in the respective groups. Both drugs were given at night time. Pain intensity was assessed at the start of study i.e. at baseline (0 week), at 1 month and three months using VAS. Complications were recorded on each visit. All the results were recorded and analysed by SPSS software.

## RESULTS

Mean age of the patients of Pregabalin group and Gabapentin group was 46.9 years and 42.8 years respectively. 56 percent of the patients of the Pregabalin group and 52 percent of the patients of the Gabapentin group were males. Mean VAS at baseline, one month and three months among patients of group Pregabalin was 8.91, 6.96 and 3.16 respectively. Mean VAS at baseline, one month and three months among patients of group Gabapentin was 8.12, 6.43 and 3.58 respectively. While making intra-group comparison, significant results were obtained. However; while comparing the mean VAS between the two study groups, non-significant results were obtained at different time intervals. Sedation as a side effect was significantly more common in Pregabalin group.

**Table 1:** Demographic data

| Variable | | Pregabalin (n=50) | | Gabapentin (n=50) | |
|---|---|---|---|---|---|
| | | Number | Percentage | Number | Percentage |
| Age group (years) | Less than 40 | 21 | 42 | 24 | 48 |
| | More than 40 | 29 | 58 | 26 | 52 |
| Gender | Males | 28 | 56 | 26 | 52 |
| | Females | 22 | 44 | 24 | 48 |

**Table 2:** Comparison to VAS

| Mean VAS | Pregabalin | Gabapentin | Inter group p-value |
|---|---|---|---|
| Baseline | 8.91 | 8.12 | 0.32 |
| One month | 6.96 | 6.43 | 0.42 |
| Three months | 3.16 | 3.58 | 0.76 |
| Intra group p-value | 0.00 (Significant) | 0.00 (Significant) | - |

**Table 3:** Adverse effects

| Adverse effects | Pregabalin | | Gabapentin | | p-value |
|---|---|---|---|---|---|
| | Number | Percentage | Number | Percentage | |
| Sedation | 14 | 70 | 8 | 40 | 0.00 (Significant) |
| Dizziness | 4 | 20 | 5 | 25 | 0.48 |

## DISCUSSION

Chronic low back pain is a prevalent, disabling condition for which there are few effective interventions. Antidepressants, non-steroidal anti-inflammatory agents, and opioids are often employed, but there are questions about their long-term efficacy or safety. Gabapentin has some evidence of efficacy for fibromyalgia, a musculoskeletal pain syndrome, and is recommended as a first line treatment for neuropathic pain in many recent clinical practice guidelines, but the number-needed-to-treat is relatively high for these conditions. Gabapentin is prescribed frequently for chronic back pain syndromes in both primary care and specialty pain clinics, particularly when there is a 'radicular' or neuropathic component with pain radiating into the upper or lower legs.[7- 10]Hence; the present study was planned for comparing the functional outcomes between pregabalin versus gabapentin in Cases of Low Back Ache with radiculopathy.

In the present study, mean age of the patients of Pregabalin group and Gabapentin group was 46.9 years and 42.8 years respectively. 56 percent of the patients of the Pregabalin group and 52 percent of the patients of the Gabapentin group were males. Mean VAS at baseline, one month and three months among patients of group Pregabalin was 8.91, 6.96 and 3.16 respectively. Shaikh H et al compared safety and efficacy of pregabalin and gabapentin in management of pain associated with chronic lumbar radiculopathy. Total 160 patients were enrolled and randomized equally into 2 groups. Group A patients were given capsule pregabalin 75 mg two times a day orally, Group B patients were given tablet gabapentin 300 mg twotimes a day. Pain intensity was assessed at the start of study i.e. at baseline (0 week), at 6 weeks and at 12 weeks of starting the treatment using numeric pain rating scale. There was significant reduction in pain at the end of 12 weeks in both the groups ($p<0.0001$), but there was no significant difference between these two groups. The incidence of adverse effects was also more in group A.[11]

In the present study, Mean VAS at baseline, one month and three months among patients of group Gabapentin was 8.12, 6.43 and 3.58 respectively. While making intra-group comparison, significant results were obtained. However; while comparing the mean VAS between the two study groups, non-significant results were obtained at different time intervals. Sedation as a side effect was significantly more common in Pregabalin group. Shanthanna H et al assessed the effectiveness and safety of gabapentinoids in adult CLBP patients. Electronic databases of MEDLINE, EMBASE, and Cochrane were searched from their inception. Meta-analyses were performed for outcomes reported in 3 or more studies. Outcomes were reported as mean differences (MDs) or risk ratios (RRs) with their corresponding 95% confidence intervals (CIs), and I2 in percentage representing the percentage variability in effect estimates that could be explained by heterogeneity. GRADE (Grading of Recommendations Assessment, Development, and Evaluation) was used to assess the quality of evidence. Out of 1,385 citations, eight studies were included. Based on the interventions and comparators, studies were analyzed in 3 different groups. GB compared with placebo (3 studies, n = 185) showed minimal improvement of pain. Three studies compared PG with other types of analgesic medication (n = 332) and showed greater improvement in the other analgesic group. The GRADE evidence quality was noted to be very low for dizziness and fatigue, low for difficulties with mentation, and moderate for visual disturbances. Functional and emotional improvements were reported by few studies

and showed no significant improvements. Existing evidence on the use of gabapentinoids in CLBP is limited and demonstrates significant risk of adverse effects without any demonstrated benefit.[12]

## CONCLUSION

Gabapentin was better in comparison to pregabalin in having fewer side effects.

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Nil

## AUTHORS' CONTRIBUTIONS

The authors have made considerable contributions to the work reported in the manuscript.

## CONFLICTS OF INTEREST

The authors confirm that this article content has no conflicts of interest.

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## REFERENCES

1. Hoy D, March L, Brooks P, et al. The global burden of low back pain: estimates from the Global Burden of Disease 2010 study. Ann Rheum Dis 2014;73:968–74.
2. Koes BW, van Tulder MW, Peul WC. Diagnosis and treatment of sciatica. BMJ 2007;334:1313–7.
3. Ropper AH, Zafonte RD. Sciatica. N Engl J Med 2015;372:1240–8
4. Konstantinou K, Dunn KM. Sciatica: Review of epidemiological studies and prevalence estimates. Spine. 2008;33(22):2464–72.
5. Lewis R, Williams N, Matar HE, Din N, Fitzsimmons D, Phillips C, et al. The clinical effectiveness and cost-effectiveness of management strategies for sciatica: systematic review and economic model. Health Technol Assess. 2011;15(39): 63- 66.
6. National Institute for Health and Care Excellence (NICE) Neuropathic pain – pharmacological management: the pharmacological management of neuropathic pain in adults in non-specialist settings. NICE Clinical Guideline 173. London: NICE; 2010. p. 155.
7. Waddell G, Main CJ. Assessment of severity in low back disorders. Spine. 1984;9:204–208.
8. Wu YT, Lai MH, Lu SC, Chang ST. Beneficial response to gabapentin portraying with interval change of brain SPECT imaging in a case with failed back surgery syndrome. Journal of Clinical Pharmacy and Therapeutics. 2011;36:525–528.
9. Yaksi A, Ozgonenel L, Ozgonenel B. The efficiency of gabapentin therapy in patients with lumbar spinal stenosis. Spine. 2007;32:939–942.
10. Yildirim K, Sisecioglu M, Karatay S, Erdal A, Levent A, Ugur M, Senel K. The effectiveness of gabapentin in patients with chronic radiculopathy. Pain Clinic. 2003;15:213–218.
11. Shaikh H, Syed MH, Khan IN, Mubeen F. Comparative study of safety and efficacy of pregabalin and gabapentin in management of neuropathic pain associated with chronic lumbar radiculopathy. Int J Basic ClinPharmacol 2019;8:2480-4.
12. Shanthanna H, Gilron I, Rajarathinam M, et al. Benefits and safety of gabapentinoids in chronic low back pain: A systematic review and meta-analysis of randomized controlled trials. PLoS Med. 2017;14(8):e1002369.