ORIGINAL RESEARCH ARTICLE

Effect of Gabapentin versus Pregabalin on Pain Intensity in Adults with Chronic Sciatica- Prospective Observational Study.

Chandrashekhar V. Gaike[1], Sidharth V. Allahbadia[2] & Shradha D. Kardile[3]

[1]Associate Professor, [2] Junior Resident , [3]Assistant Professor, Department of Orthopedics, MGM Medical College and Hospital, Chatrapati Sambhajinagar, Maharashtra, India.

Received Date: 11-4-2024 Revised Date: 30-5-2024 Accepted Date: 10-06-2024

Abstract:

Objectives: To Study the Effect of Gabapentin (GBP) vs Pregabalin (PGB) on Pain Intensity in Adults with Chronic Sciatica.

Materials & Methods: Over 18 months, we conducted a prospective observational study in a tertiary care hospital. Individuals with Sciatic / radicular pain, verified by magnetic resonance imaging, radiates into only one leg to, at or below, knee level and is brought on by a degenerative condition (e.g., degenerative disc disease, bone spur growth, degenerative scoliosis). The study comprised participants who were either naive to Pregabalin and Gabapentin use, 18 years of age or older, had adequate local language comprehension, or had access to interpretation services to finish the study treatment and assessments. Participants scored 0 to 10 on the visual analogue scale, with 10 denoting the worst possible leg pain and 0 reflecting no leg discomfort.

Results: This prospective observational predefined interim analysis revealed that, although PGB and GBP were both highly effective in lowering pain intensity in chronic sciatica patients, GBP outperformed PGB when evaluated head-to-head. Moreover, regardless of the sequence order, GBP was linked to fewer and milder adverse events.

Conclusion: Both GBP and Pregabalin demonstrated significant efficacy and helped to alleviate the symptoms of chronic sciatic pain. However, when lowering pain intensity, GBP outperformed PGB and correlated with fewer, milder adverse events.

Keywords: Sciatica; Pregabalin; Gabapentin.

Introduction:

Sciatica or sciatic neuralgia is a common type of lumbosacral radiculopathy, characterised by lower back pain that radiates to the leg.Aberrant reflexes, muscular weakness, or sensory loss may also accompany it. Sciatica is a leg pain symptom that is well-localized and has a burning, shooting, or sharp sensation.

Address for correspondence:
Dr. Sidharth V. Allahbadia
Junior Resident,
Department of Orthopedics,
MGM Medical College and Hospital,
Chh Smbhajinagar, Maharashtra, India.
Email ID: sidharth_8@hotmail.com

How to cite this article:
Chandrashekhar V. Gaike, Sidharth V. Allahbadia & Shradha D. Kardile. Effect of Gabapentin versus Pregabalin on Pain Intensity in Adults with Chronic Sciatica- Prospective Observational Study. *International Journal of Current Medical and Applied sciences; 2024, 43(1), 05-08.*

Access this Article Online

Quick Response Code

Website: *www.ijcmaas.com*

Subject:
Medical Sciences

Its distribution along the leg's posterior and lateral sides approximates the sciatic nerve's dermatomal distribution [1] .

It usually goes beyond the boundaries of perceived pain in either a sclerotomal or dermatomal physical way and is frequently coupled with numbness or paraesthesia in the same distribution [2,3].

For patients having spine surgery, effective pain management is crucial to their comfort. Sufficient management of pain following surgery has shown improved results, decreased usage of opioids, shortened hospital stays, and cheaper expenses [4,5]. Currently, the gold standard for managing pain after surgery is multimodal analgesia, and Gabapentinoids are frequently used to reduce neuropathic pain [6,7]. Pregabalin and other Gabapentinoidscan prevent central nervous system sensitization [8]. Recently, a wealth of high-quality research has shown that gabapentinoids are a safe and effective treatment for neuropathic pain that follows spinal cord damage [9,10]. Previous meta-analysis found that both gabapentin and Pregabalinhelped lower postoperative pain and opioid use after spine surgery when compared to placebo. However, new trials with direct comparisons show that the outcomes must be more consistent. The purpose of the current study was to compare the effects of Gabapentin and Pregabalin on the degree of pain experienced by persons with chronic sciatica.

Material and Methods:

Study Centre: Tertiary care hospital.

Study Period: From March 2023 to Feb 2024.

Study Design: Prospective observational Study.

Inclusion criteria:

Patients included were with Sciatica pain (radiating into only one leg too, at or below knee level), verified by magnetic resonance imaging and brought on by a degenerative condition (e.g., degenerative disc disease, bone spur growth, degenerative scoliosis). The study comprised participants who were either naive to PGB and GBP use, 18 years of age or older, had adequate local language comprehension, or had access to interpretation services to finish the study treatment and assessments.

Exclusion criteria:

Patient not willing to give consent.

The study excluded patients with an estimated creatinine clearance of less than 60 millilitres per minute, pregnant or nursing women, women who were planning a pregnancy during the study period, the presence of hypothyroidism, vitamin B12 deficiency, connective tissue disease, amyloidosis, toxic exposure), organ system disease and allergy to either GBP or PGB.

Data collection:

To gather pertinent medical and pharmaceutical history and screen the patient against the eligibility criteria following clearance from the Ethics Committee and acquiring an informed consent form from the patient. The first intervention included the baseline results for the VAS and ODI scale. The trial chemist continued to work independently from the medical staff.

At the start of treatment, each participant was randomly assigned to either PGB or GBP. Due to the crossover design, participants had the rare chance to experience PGB and GBP consecutively.

For the first week, PGB was started at a dose of 75 mg once a day. Depending on the participant's progress and tolerance at each dose level, this was titrated to their optimal dose, up to 300 mg twice daily. During the first week, 100 mg of GBP was administered once daily. Depending on the participant's progress and tolerance at each dose level, this was titrated to their optimal dose, up to 400 mg twice daily. The typical trial dosage schedule included a 4-week titration phase and an additional 4-week period with the participant's maximum tolerated dose. Since both of these drugs have a short half-life (5-7 hours), a week was considered sufficient for the washout interval between treatment phases. The trial's efficacy and adverse events (AEs) may need the study expert and chemist to communicate to modify the dosage of PGB or GBP. For each medicine, the maximum treatment duration was eight weeks.

Participants scored 0 to 10 on the visual analogue scale, with 10 denoting the worst possible leg pain and 0 reflecting no leg discomfort [4].

Based on earlier research, a minimal difference of 1.5 clinically significant points was selected.

Statistical analysis:

Before doing an interim statistical analysis, the data was identified and treated according to intention. Unadjusted means (SDs) were computed and displayed for the population's descriptive statistics. Unpaired t-test was applied to check significant difference between two groups. $\chi 2$ test was applied to check significant association between two attributes. A P-value of less than 0.5 determines statistical significance.

Observations & Results:

In our study, the average age of patients in the GBP and PGB group was 54.65±3.79 years and 55.29±4.13 years, respectively. There was approximately equal sex distribution in the GBP and PGB group, with 36 males (72%) and 14 females (28%) in the GBP group and 35 males (70%) and 15 females (30%) in the PGB group, respectively. Concerning addiction, the GBP group had 20 (40%) smokers and 28 (56%) alcoholic patients; the PGB group had 23 (46%) smokers and 32 (64%) alcoholic patients [Table 1].

Table 1: Demographic profiles of the patients

Parameters	Gabapentin group (n=50)		Pregabalin dosages (n=50)	
	No of cases	Percentage (%)	No of cases	Percentage (%)
Age (Mean±S.D)	54.65±3.79		55.29±4.13	
Smokers	20	40.0	23	46.0
Alcohol Intake	28	56.0	32	64.0
Men	36	72.0	35	70.0
Women	14	28.0	15	30.0
Adverse Event	17	34.0	35	70.0
Efficacy	50	100	50	100.0

Both the groups taken collectively showed a total of Smokers- 43%, Alcohol Intake- 60%. The Incidence of Chronic Sciatic Pain was higher in Men as compared to Women in the given age group. The Gabapentin Group showed fewer adverse events as compared to the Pregabalin Group.

Table 2: Comparison of Efficacy Gabapentin Group and Pregabalin Group.

Groups	Mean±S.D	P value
VAS		
Gabapentin group (n=50)	7.45±1.46	P=0.30 NS
Pregabalin dosages (n=50)	6.98±1.21	
ODI		
Gabapentin group (n=50)	58.23±12.98	P=0.60 NS
Pregabalin dosages (n=50)	58.15±12.25	

The mean VAS score in Gabapentin group was 7.45±1.46 and Pregabalin dosages group was 6.98±1.21. There was not significant difference in mean VAS between Gabapentin group and Pregabalin dosages group (p=0.30).
The mean ODI score in Gabapentin group was 58.23±12.98 and Pregabalin dosages group was 58.15±12.25. There was not significant difference in mean ODI between Gabapentin group and Pregabalin dosages group (p=0.30).
The Both Gabapentin and Pregabalin demonstrated significant efficacy and helped to alleviate the symptoms of Chronic Sciatic Pain as assessed by the Visual Analogue Scale (VAS).

Table 3: Comparison of Adverse Event in Gabapentin Group and Pregabalin Group

Parameters	Gabapentin group (n=50)		Pregabalin dosages (n=50)		P-value
	No of cases	Percentage (%)	No of cases	Percentage (%)	
Nausea, Vomiting, Headache	06	12.0	13	26.0	P=0.04 S
Bowel disturbance	02	4.0	06	12.0	P=0.141 NS
Diplopia, Dysarthria	00	0.0	05	10.0	P=0.021 S
Dizziness	06	12.0	10	20.0	P=0.24 NS
Alertness	03	6.0	01	2.0	P=0.31 NS

Pregabalin Group was observed in 26% Nausea, Vomiting and Headache as compared to In Gabapentin group was observed in 12% of patients. There was significant association between Nausea, Vomiting and Headache and Gabapentin group & Pregabalin groups [p=0.04].
There was significant association between Diplopia, Dysarthria and Gabapentin group & Pregabalin groups [p=0.021].
Nausea, Vomiting and Headache were the most common Adverse Events, followed by Dizziness and Bowel Disturbance. The Gabapentin Group showed fewer adverse events as compared to the Pregabalin Group.

.

Discussion:

This prospective observational predefined interim analysis revealed that, although PGB and GBP were both highly effective in lowering pain intensity in CS patients, GBP outperformed PGB when evaluated head-to-head. Moreover, regardless of the sequence order, GBP was linked to fewer and milder adverse events. Both PGB and GBP, when measured by the ODI, were considerably effective in lowering pain-associated impairment; however, when compared head-to-head, neither was better. The power of this clinical research was sufficient to identify a conservative difference in pain intensity between the medicines, measuring 0.8 out of 10. We recognise that the current clinically significant treatment impact for pain intensity is 1.3 out of 10, and for disability

severity, it is 10 out of 100. According to our findings, the only medicine that demonstrated a clinically significant difference in ODI decrease (mean [SD], 10.59 [8.98]) and VAS reduction (mean [SD], 1.69 [1.11]) was GBP. One expert spine surgeon was involved in recruitment and screening according to the definition of CS. The National Formulary's recommendations changed the drug dose by utilising an escalating titration plan and AE monitoring [11].

Given that PGB and GBP are now regarded as equal, treating chronic sciatica with either PGB or GBP satisfies both requirements. As a result, this clinical trial compares therapies more effectively than would be feasible with a parallel trial design. PGB adverse events (AEs) were more common and severe when taken before GBP. GBP may sensitize tissues some how, such as by lowering their tolerance to PGB. AEs were markedly increased even after washout. If so, potential sensitization to PGB did not impact tissue tolerance to GBP.

Conclusion:

Both Gabapentin Group and Pregabalin demonstrated significant efficacy and helped to alleviate the symptoms of chronic sciatic pain. However, when lowering pain intensity, Gabapentin Group out performed Pregabalin dosages and correlated with fewer, milder adverse events.

References:

1. *Pinto RZ, Maher CG, Ferreira ML, Ferreira PH, Hancock M, Oliveira VC, McLachlan AJ, Koes B. Drugs for pain relief in patients with sciatica: systematic review and meta-analysis. Bmj. 2012 Febeuary 13;344.*
2. *Deyo RA, Rainville J, Kent DL. What can the history and physical examination tell us about low back pain? Jama. 1992 Aug 12;268(6):760-5.*
3. *Clinical Services Advisory Group. Back Pain. London: HMSO; 1994.*
4. *Benzon HT, Huntoon MA, Rathmell JP. Improving the Safety of Epidural Steroid Injections.* JAMA. *2015;313(17):1713–1714..*
5. *Hah JM, Cramer E, Hilmoe H, Schmidt P, McCue R, Trafton J, Clay D, Sharifzadeh Y, Ruchelli G, Goodman S, Huddleston J. Factors associated with acute pain estimation, post-operative pain resolution, opioid cessation, and recovery: secondary analysis of a randomized clinical trial. JAMA network open. 2019 Mar 1;2(3):e190168-.*
6. *Warner NS, Habermann EB, Hooten WM, Hanson AC, Schroeder DR, Sauver JL, Huddleston PM, Bydon M, Cunningham JL, Gazelka HM, Warner DO. Association between spine surgery and availability of opioid medication. JAMA Network Open. 2020 Jun 1;3(6):e208974-.*
7. *Federico CA, Wang T, Doussau A, Mogil JS, Fergusson D, Kimmelman J. Assessment of Pregabalinpost-approval trials and the suggestion of efficacy for new indications: a systematic review. JAMA Internal Medicine. 2019 Jan 1;179(1):90-7.*
8. *Schmidt PC, Ruchinelli G, Mackey SC, Carroll IR. Perioperative Gabapentinoids: choice of agent, dose, timing, and effects on chronic postsurgical pain. Survey of Anesthesiology. 2014 Apr 1;58(2):96-7.*
9. *Tong C, Zhengyao Z, Mei L, Dongpo S, Qian H, Fengqun M. Pregabalin and gabapentin in patients with spinal cord injury-related neuropathic pain: a network meta-analysis. Pain and therapy. 2021 Dec;10:1497-509.*
10. *Davari M, Amani B, Khanijahani A, AkbarzadehA, Shabestan R. Pregabalin and Gabapentin in neuropathic pain management after spinal cord injury: a systematic review and meta-analysis. The Korean Journal of Pain.2020 Jan 1;33(1):3-12.*
11. *About eTG complete. Therapeutic Guidelines https://tgldcdp.tg.org.au/index.*

Conflict of interest: *None declared*
Source of funding: *None declared*