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Original Research Article

A randomized study to determine the efficacy of pregabalin for the treatment of moderate or severe baseline neuropathic pain at a tertiary care centre in Ganjam, Odisha

Sambit Kumar Panda[1,*], Pradyut Kumar Pradhan[2], Sanjay Kumar Behera[1], Chinmaya Debasis Panda[2]

[1]*Dept. of Orthopaedic Surgery, M.K.C.G. Medical College, Berhampur, Odisha, India*
[2]*Dept. of Pharmacology, M.K.C.G. Medical College, Berhampur, Odisha, India*

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ABSTRACT

Background: Neuropathic pain (NeP) is caused by a disease like lesion; it is the disease of the somatosensory nervous system. NeP also caused some severe health disorders such as diabetic peripheral neuropathy (DPN), postherpetic neuralgia (PHN), and spinal cord injury (SCI). Along with the severe health issues, NeP adversely affects the quality of life (QOL) as well as an economic burden on the infected persons and their family plus society.

Aim: The aim of the study is to define the efficiency of pregabalin for the treatment of moderate or severe baseline neuropathic pain at a tertiary care centre in Ganjam, Odisha.

Materials and Methods: It was a randomized study conducted between August 2019 and January 2020 at the MKCG Medical College Berhampur, Ganjam, Odisha on 700 patients. Simple randomization technique was employed to give patients either pregabalin or placebo. All the patients aged >18 years were selected for the study. The pain was assessed for all the patients using the 11-point numeric rating scale, where 0 = no pain and 10 = worst possible pain. All the patients having pain score >4 were involved in the study. Patients who were below 18 years of age were omitted from the study. Further, the patients whose pain score was below four were also omitted from the study.

Results: It was observed that there were 455 patients in the Pregabalin group, and in the placebo group, there were 245 patients. The patients were also bifurcated as per the severity of their discomfort, in which 513 patients were comprised in the moderate section, whereas 187 patients were encompassed in the severe section. 63-71 years was the median age. In the moderate and severe pain group, standard mean pain scores were equivalent among the pregabalin and placebo treatment groups. There was a statistically significant difference among both the groups with respect to the change in pain score. This implies that pregabalin reduced pain more significantly as compared to the placebo group. The above table also depicted the improvement in mean sleep scores as well. There was a statistically significant difference among both the groups with respect to the sleep scores. The sleep score in the pregabalin group improved from the baseline to endpoint more significantly as compared to the placebo group. In the moderate to severe pregabalin group, 90% of the patients experienced at least one treatment-emergent as compared to 70% in the placebo group. The most common side effects of the AE were weight gain, dizziness, and peripheral edema. The highest discontinuation from the study was observed in the pregabalin group.

Conclusion: It was found that the pregabalin was effective in terms of reducing pain and had greater tolerability with the patients. It was also identified that the patients in the severe pain segment shifted to mild segment with the use of pregabalin dosage.

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1. Introduction

Neuropathic pain (NeP) is caused by the disease of the somatosensory nervous system like lesion. Severe health disorders like diabetic peripheral neuropathy (DPN), postherpetic neuralgia (PHN), and spinal cord injury (SCI) are related with NeP.[1] From the studies, it has also been found that chronic NeP harmfully affects the quality of life (QOL) along with putting a monetary load on the patients, their family and the society.[2] Furthermore, NeP affects the brain neurons, which further impacts the various regions of the body like sensation, integrative processing, pain modulation, emotions and cognition.[3] This, in turn, results in the changes in the behavioural pattern of the patient and might also lead to depression.[4]

It has been reported that there is a prevalence of nearly 29% in the India of NeP.[5] However, it has been established that NeP is often under-diagnosed in the developing as well as developed countries. This results in the delay of treatment. Also, there are discrepancies regarding the treatment regime as well.

Multiple studies have been conducted on analyzing the effect of the NeP over the rising economic burden on the patients, which was found to be positively associated.[6] This implies that the regular visits to the doctor and the treatment regime decreases the productivity of the patients along with overlaying them with an economic burden.[7]

However, Pregabalin is considered to be a reliable treatment drug for the NeP. It is an $\alpha 2$-δ ligand having analgesic properties. It has also been found beneficial in the controlling of anxiety and neuropathic pain related to spinal cord injury.

2. Aim

To determine the usefulness of pregabalin for the treatment of moderate or severe baseline neuropathic pain at a tertiary care centre in Ganjam, Odisha

3. Material and Methods

It was a randomized study conducted between August 2019 and January 2020 at the MKCG Medical College Berhampur, Ganjam, Odisha on 700 patients. Simple randomization technique was employed to give patients either pregabalin or placebo. All the patients aged >18 years were selected for the study. The pain was assessed for all the patients using the 11-point numeric rating scale, where 0=no pain and 10=worst possible pain. All the patients having pain score >4 were included in the study. All the patients below 18 years of age and the patients whose pain score was below four were excluded from the study.

* *Corresponding author*.
E-mail address: drsambitpanda@gmail.com (S. K. Panda).

4. Results

The above table depicts that there were 455 patients in the Pregabalin group, and 245 individual was found in the Placebo group. The patients were also separated based on the severity of their pain, according to which in the moderate group, 513 patients were included, although in the severe group, there were 187 patients included. 63-71 years was the median age. Within the moderate and severe pain cohorts, the standard mean pain scores were comparable between both the group of pregabalin and placebo treatment sections.

Out of 330 patients in moderate and 125 in severe Pregabalin group, only 297 in moderate and 106 in severe group reported on follow-up. Similarly, out of 183 patients in moderate and 62 in severe Placebo group, only 142 in moderate and 48 in severe group reported on follow-up. Thus, overall, 52 and 55 patients were lost on follow-up in Pregabalin and Placebo group respectively. Further, the above table depicts changes in the pain score of the patients in the pregabalin and placebo group on follow-up. There was a statistically significant difference among both the groups with respect to the change in pain score. This implies that pregabalin reduced pain more significantly as compared to the placebo group. The above table also depicted the improvement in mean sleep scores as well. There was a statistically significant difference among both the groups with respect to the sleep scores. The sleep score in the pregabalin group improved from the baseline to endpoint more significantly as compared to the placebo group.

Furthermore, it was observed in the study that nearly 90% of the patients in the moderate to severe pregabalin section go through at least one treatment-emergent as compared to 70% in the placebo group. The most common side effects of the AE were weight gain, dizziness, and peripheral edema. The highest discontinuation from the study was observed in the pregabalin group.

5. Discussion

In the present study, it was found that patients treated with pregabalin were able to tolerate the drug in a better manner. It was also found in the study that the efficacy of pregabalin was found to be more effective in reducing the pain and sleep score of the patients as compared to that of the patients receiving placebo in their treatment regime. Similar results were obtained in the study of Parsons et al., (2019).[8] As per the current study, it was found that the dosage of pregabalin was positively related to the reduction of the pain score and the sleep score. Furthermore, similarly as per the study of the Freeman et al., (2008)[9] it was studied that pregabalin was positively equated with the reduction of sleep score and pain score. Nearly 20% of the patients shifted to mild from severe pain in the pregabalin group related to the 10% in the placebo group; it was identified in the present study. The results were consistent with that of

Table 1: Summary of neuropathic pain studies included in the analysis

Condition (study number/ Clinical Trials.gov identifier)	Total treatment phase/main tenance phase (weeks)	Pregabalin maintenance dose (mg/day)	Administration	No. of participants		
				Placebo	Pregabalin	Total
PHN (A0081120/NCT00394901)	13/12	150, 300, 600[b]	BID fixed dose	97	272	369
DPN (A0081163/NCT00553475)	13/12	300, 600[b]	BID fixed dose	135	179	314
SCI (A0081107/NCT00407745)	16/12	150-600	BID fixed dose	27	32	59

Table 2: Baseline demographic and clinical characteristics

	NeP population: baseline pain			
	Moderate		Severe	
	Pregabalin	Placebo	Pregabalin	Placebo
N	330	183	125	62
Age, years, median (range)	64 (25-90)	63 (30-90)	71 (26-90)	68 (28-88)
Sex, n				
Female	120	50	55	22
Male	210	133	70	40
Duration of NeP-related pain, months, mean (SD)	45.7 (51.5)	50.2 (44.8)	54.9 (66.8)	50.1 (49.8)
Pain score, Mean (SD)	5.6 (1.9)	5.5 (1.5)	9.4 (0.5)	9.0 (0.8)
Sleep score, mean (SD)	3.7 (1.9)	3.6 (1.7)	5.4 (2.9)	5.6 (3.1)

Table 3: Change in mean pain and sleep scores from baseline to endpoint (LOCF analysis)

	Pregabalin		Placebo		Difference from Placebo	
	n	LS mean change	n	LS mean change (SE)	LS mean difference (SE)	p-value
Change in pain score						
NeP						
Moderate	297	-1.65 (0.15)	142	-0.81(0.25)	-0.84 (0.1)	<0.05
Severe	106	-1.65(0.25)	48	-1.15(0.26)	-0.5 (0.01)	<0.05
Change in sleep score						
NeP						
Moderate	297	-1.56 (0.13)	142	-0.56(0.16)	-1.0 (0.03)	<0.05
Severe	106	-1.36(0.20)	48	-0.20(0.21)	-1.16 (0.01)	<0.05

Yamashita et al. (2014).[10] The most common side-effects in the current study were found to be weight gain, dizziness, and peripheral edema. Supporting the current study Farrar et al., (2001)[11] found similar results.

6. Conclusion

In light of the above results, it was found that the pregabalin was effective in terms of reducing pain and had greater tolerability with the patients. It was also identified that the patients in the severe pain segment shifted to mild segment with the use of pregabalin dosage. However, in both severe and moderate groups, the efficacy and tolerability was optimal and helped in achieving pain reduction and sleep improvement.

7. Source of Funding

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8. Conflict of Interest

The authors declare they have no conflict of interest.

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Author biography

Sambit Kumar Panda, Assistant Professor

Pradyut Kumar Pradhan, Assistant Professor

Sanjay Kumar Behera, Assistant Professor

Chinmaya Debasis Panda, Assistant Professor

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