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A prospective study on clinical efficacy and decisive outcomes of gabapentin versus pregabalin: on pain management in adults with lumbar radiculopathy

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ABSTRACT

Lumbar radiculopathy is a condition where there is pain in the lower back that is radiated down to the leg due to compression of the nerve roots that exit the spine. Radiculopathy is most common in lower back although it can occur in any part of the spine. Gabapentin and pregabalin are being used for treating radiculopathy. A Six- month prospective, comparative study to compare efficacy and pain management of gabapentin and pregabalin in adults with lumbar radiculopathy was conducted at the department of orthopedics at Malla Reddy hospital. The patients were randomly selected and were divided into two groups. Group A was given pregabalin, 75mg + methylcobalamin, 500mcg and group B was given gabapentin,100mg + methylcobalamin, 500mcg. The pain intensity scores has baseline (start of the study), 4th week and 8th week (end of the study) and assessed. In our study, we found that at the end of 8 weeks, pregabalin and gabapentin helped in significantly reducing pain in patients with lumbar radiculopathy. The mean pain score in patients treated with pregabalin reduced significantly from 8.16 to 2.63 and the mean pain score of gabapentin also reduced from 8.25 to 2.41. The effectiveness of pregabalin was 67.7% and that of gabapentin was 68.3%. When intergroup comparison was done between group A (pregabalin) and B(gabapentin), the difference in reduction of mean pain scores were not statistically significant during all the follow ups. It concludes that both pregabalin and gabapentin are equally efficacious in management of pain associated with lumbar radiculopathy.

Keywords: lumbar radiculopathy, pregabalin, gabapentin, pain, efficacy, visual analogue scale.

INTRODUCTION

Sciatica refers to pain that radiates along the path of the sciatic nerve, which branches from L4 through S2 nerve roots which coalesce at the pelvis to form the sciatic nerve. Typically, it affects only one side of the body [1]. Radiculopathy is most commonly seen when a herniated disk, bone spur on the spine or narrowing of the spine (spinal stenosis) compresses part of the nerve. This causes inflammation, pain and often some numbness in the affected leg [1]. It can begin suddenly and symptoms may be intermittent or constant.

There appears to be no gender predominance. Peak incidence is seen in patients of ages 30- 39. Lifetime incidence reported between 10% to 40%. Annual incidence of 1% to 5%. There is no association with body height except in the 50 to 60 years age group. Rarely occurs before age 20 unless traumatic.[2]

Physical activity increases incidence in those with prior sciatica symptoms and decreased in those with no prior symptoms

Lumbar radiculopathy is a manifestation as both pressure and irritation are significant all together for the nerve root are the indications. By definition patients notice emanating torment in the leg. Sciatica is transmitting torment that

follows a dermatomal design. Patients may also report sensory symptoms.

While diagnosing, physical assessment relies upon neurological testing. The most applied examination is the straight leg raising test or it can be called as Lasègue's sign. Patients with sciatica may have low back agony however this is generally less serious than the leg torment. The pooled affectability of the straight leg raising test is evaluated to be 91%, with a relating pooled explicitness of 26%. This test with a high particularity is the crossed straight leg raising test, with a pool of 88% yet affectability of just 29%. If a patient reports the normal transmitting torment in one leg joined with a positive outcome on at least one neurological test showing nerve root pressure or neurological shortfall the finding of lumbar radiculopathy appears justified. [3-4]

VAS:

A Visual Analogue Scale (VAS) is an instrument used to measure a characteristic or that is a range of continuum of values that cannot usually be measured directly. It helps in estimating extent of pain a patient perceives across a continuum from none to an extreme amount of pain.

A simple VAS is a straight horizontal line of usually 100mm length. The ends are the extreme limits of the parameter to be measured such as pain. orientated from the left (worst) to the right best or horizontal scales are orientated from right to left can be used.

In a survey, no difference between horizontal and vertical VAS has been shown. [5-7]

Pregabalin is an analogue of the neurotransmitter GABA. It potently binds to the α2-δ subunit resulting in modulation of Ca channels and reduction in the release of several neurotransmitters, including glutamate, norepinephrine, serotonin, dopamine, calcitonin gene-related peptide and substance P. [8-11]

Pregabalin, which is classified as an anticonvulsant drug is also used for the treatment of several neuropathic pain syndromes

Mechanical compression with or without the local inflammation of the dorsal root ganglia leading to spontaneous neuronal firing, causing a spread of impulses perceived as pain.[12]

Gabapentin is a GABA analogue. It is structurally related to neurotransmitter GABA, but it shows no effect on GABA binding, uptake, or degradation. It interrupts the series of events that lead to the experience of neuropathic pain by effecting the voltage dependent calcium ion channels at the post synaptic dorsal horns. These drugs are usually taken so as to get pain relief and permit the patient to participate in physical therapy. [13-19]

Aim

To compare the efficacy of gabapentin and pregabalin and to evaluate characteristic pain intensity using Visual Analogue Scale (VAS).

Method

Both in and out patients who were willing to participate in the study from orthopedic department in Malla Reddy Hospital, Suraram cross road, Jeedimetla, Hyderabad, Telangana were included. The study was conducted for a period of 6 months in 160 patients which included patients with acute or chronic lumbar radiculopathy taking pregabalin, 75mg (PREGALIN 75,) and gabapentin, 100mg (GABANEURON). The Patients were of age 18 years to 65 years, of either sex. Severity of pain ranging from mild to incapacitating pain was assessed by VAS scale and interviewing them before initiation of the treatment, after 4 weeks, after 8 weeks

METHODOLOGY

Study site: Both in and out patients who were willing to participate in the study from orthopedic department in Malla Reddy Hospital, Suraram cross road, Jeedimetla, Hyderabad, Telangana.

Study period: The study was conducted for a period of 6 months

Sample size: 160 patients

Study design: A prospective, comparative study

Study criteria:

Inclusion criteria

➢ Lumbar radiculopathy with acute and chronic patients taking pregabalin (PREGALIN 75) and gabapentin (GABANEURON).

➢ Patients of age 18 years to 65 years, of either sex.

➢ Patients who are willing to participate in study are included

Exclusion criteria

➢ People who are using steroids.

➢ Avoided in people having any contraindications to those drugs.

➢ Pregnant and lactating women.

➢ Patients with psychiatric and associated medical conditions.

➢ Other severe comorbidities.

➢ Patients with osteomyelitis and neoplastic malignancies.

Statistics

The comparison of two groups was done using ANOVA test, graphs and percentages.

RESULTS AND DISCUSSION

Table1: Gender wise distribution

GENDER	NUMBER OF SUBJECTS (n=160)	PERCENTAGE
FEMALE	102	64%
MALE	58	36%

In the study performed out of 160 patients the prevalence rate of lumbar radiculopathy was found to be high in females (n= 102; females compared to males; n= 58), which shows that females are more prone to lumbar radiculopathy than males.

Table 2: Age wise distribution

Age	Number of subjects (n=160)	Percentage
18-35	48	30%
36-50	67	42%
51-65	45	28%

Out of 160 patients, a greater number of patients were seen among the age groups of 36-50 years n= 67 (42 %) followed by age group of 18- 35 years consisting of n= 48 (30%) and the lesser in age group of 51-65 years n= 45 (28%).

Table 3: Sleep habits

Sleep habits	Number of subjects (n=160)	Percentage
Abnormal	122	76%
Normal	38	24%

In the study performed, the sleep habits of the subjects indicated that a greater number of patients i.e. n=122, had abnormal sleep pattern which consists of 76% and the remaining had normal sleep i.e. n= 38, consisting of 24% of the total number of subjects, which suggests that sleep pattern was disturbed due to discomfort caused by pain.

Table 4: Occupational status

Occupation	Number of subjects (n= 160)	Percentage
Wage worker	36	22%
Farmer	36	22%
Housewife	59	37%
Others	29	19%

In the study performed, out of 160 patients, it was found out that a greater number of patients were house wife (n= 59), followed by farmers (n= 36) and wage workers (n= 36) and other occupations were n= 29 patients.

1) Pain levels

1a) Table 5: Before treatment

Severity	Number of subjects (n=160)	Percentage
Moderate	63	39%
Severe	86	54%
Very severe	11	7%

The study performed, manifests the severity levels of the subject before the initiation of the therapy, as maximum number of subjects experienced severe pain followed by very severe and moderate pain.

1b) Table 6: After treatment

Severity	Number of subjects (n= 160)	Percentage
Mild	112	70%
Moderate	35	22%
Severe	13	8%
Very severe	0	0

In the study, the post treatment pain intensity of most individuals was decreased, with number of subjects with mild pain was n= 112 (70%), followed by n= 35 subjects having moderate pain (22%) and n= 13 subjects having severe pain (8%)

2) Severity of pain based on gender

2a) Table 7: Before treatment

Gender	Mild	Moderate	Severe	Very severe
Male	0	23	31	4
Female	0	40	55	7

from the above study performed, manifests the severity levels of the subject before the initiation of the therapy, based on their gender, as a greater number of female subjects experienced severe pain compared to males.

2b) Table 8: after treatment

Gender	Mild	Moderate	Severe	Very severe
Male	43	11	4	0
Female	69	24	9	0

based on the above chart, it is established that the pain intensity was reduced in both the genders after treatment

3) Pain levels based on drug

3a) Table 9: before treatment

Drug	Mild	Moderate	Severe	Very severe
Pregabalin	0	32	42	6
Gabapentin	0	31	44	5

A greater number of subjects from both the groups had severe pain followed by moderate and very severe**.**

3b) Table 10: after treatment

Drug	Mild	Moderate	Severe	Very severe
Pregabalin	53	20	7	0
Gabapentin	59	15	6	0

as illustrated above, after the treatment, the pain intensity was significantly decreased among both the groups.

4) Pain levels based on gender among group A (pregabalin)

4a) Table 11: before treatment

Gender	Mild	Moderate	Severe	Very severe
Male	0	12	15	2
Female	0	20	27	4

according to the above study, majority of female subjects had higher pain intensity among the group that was given pregabalin.

4b) Table 12: after treatment

Gender	Mild	Moderate	Severe	Very severe
Male	20	7	2	0
Female	33	13	5	0

the above represents the pain severity of the subjects based on their gender post treatment among the subjects of group a. The pain intensity was significantly decreased after treatment.

5) Pain levels based on gender among group B (gabapentin)

5a) Table 13: before treatment

Gender	Mild	Moderate	Severe	Very severe
Male	0	11	16	2
Female	0	20	28	3

according to the above study, majority of female subjects had higher pain intensity among the group that was given gabapentin as the drug.

5b) Table 14: after treatment

Gender	Mild	Moderate	Severe	Very severe
Male	23	4	2	0
Female	36	11	4	0

the above represents the pain severity of the subjects based on their gender post treatment among the subjects of group b. It shows a decrease in pain intensity among the subjects.

5) Table 15: effectiveness of the drug

Drugs	Effective	Non-effective
Pregabalin	54 (67.7%)	26 (32.3%)
Gabapentin	55 (68.3%)	25(31.7%)

as the above chart illustrates, both pregabalin and gabapentin have similar effectiveness (67.7% vs 68%) in decreasing the pain intensity among patients with lumbar radiculopathy. There is no statistically significant difference between them.

6) Table 16: mean vas pain scores

Drug	Baseline	4th week	8th week	Mean reduction in pain score
Pregabalin	8.16	4.8	2.63	5.53
Gabapentin	8.25	4.7	2.41	5.84

The data was analyzed using p- value to assess the significance of the drug therapy. There was a decrease in mean pain scores at the end of the study.

DISCUSSION

80 subjects in each group who completed the 6-month study were evaluated. The incidence of lumbar radiculopathy was more among the females as seen in table 1 and was more common among the individuals of ages 36-50 years as seen in table 2. Most of the subjects had an abnormal sleep pattern (table 3). Many of the subjects consisted of home makers followed my wage workers (table 4). Pain severity was measured using VAS score. In our study, we found that at the end of 8 weeks, pregabalin and gabapentin helped in significantly reducing pain in patients with lumbar radiculopathy. The mean pain score in patients treated with pregabalin reduced significantly from 8.16 to 2.63 and the mean pain score of gabapentin also reduced from 8.25 to 2.41. The effectiveness of pregabalin was 67.7% and that of gabapentin was 68.3%. When intergroup comparison was done between group A (pregabalin) and B(gabapentin), the difference in reduction of mean pain scores were not statistically significant during all the follow ups. This study concluded that both pregabalin and gabapentin are equally efficacious in management of pain associated with lumbar radiculopathy. The mean reduction of VAS pain score in group A from baseline to 8 weeks was 5.53. The mean reduction of VAS pain score in group B from baseline to 8 weeks was 5.84. In intragroup analysis of both the groups, group A subjects, the mean VAS pain scores were 8.16 at the start of the study, 4.8 after 4 weeks and 2.63 at the end of 8 weeks. This signifies that there was a statistically significant decrease in mean pain score ($p<0.0001$). Similarly, in group B the mean VAS pain scores were 8.25 at the start of the study, 4.7 at the end of 4 weeks and 2.41 at the end of 8 weeks which also concludes that there was a statistically significant decrease in mean pain score ($p<0.0001$) in group B.

CONCLUSION

Through this study it can be concluded that both pregabalin and gabapentin are equally efficacious in management of pain associated with lumbar radiculopathy. The pain intensity was significantly decreased after treatment. Based on our studies, eventually the tolerability towards gabapentin was observed more when compared to pregabalin. So, it can be more preferred as a rational therapy option for lumbar radiculopathy.

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