





Comparative study of pregabalin and carbamazepine in painful diabetic peripheral neuropathy at the tertiary care hospital

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Abstract



This study aimed to examine the effectiveness of carbamazepine as well as pregabalin in lowering the degree of pain associated with diabetic peripheral neuropathy. The results revealed noteworthy insights into the comparative effectiveness of these medications. Pregabalin, as a calcium channel modulator, has demonstrated efficacy in numerous neuropathic pain conditions. Beyond pain reduction, these drugs influence various aspects of daily functioning, emotional well-being, and social interactions is crucial for tailoring treatment approaches. The discussion explores Pregabalin medication stands out in improving overall quality of life of the patients. The results presented here indicated that among diabetic patients, age, HbA1c, DR, and the duration of their diabetes are related to considerably higher risks of DPN; however, BMI, smoking, TG, as well as TC did not show any evidence of an increased risk of DPN. The results of the study offer a scientific foundation for a deeper comprehension of the causes of peripheral neuropathy-complicated type 2 diabetes and the outcomes of preventative measures.

Keywords:

Pregabalin,
Carbamazepine,
Diabetic,
Peripheral Neuropathy,
Tertiary Care

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INTRODUCTION

Diabetes is a common metabolic condition that affects people of all ages. There are Five types of diabetes i.e., Type 1, Type 2, Gestational, MODY & LADA. Type 2 is the most common. It is a condition that happens when your carbohydrate metabolism is impaired, thereby high blood sugar leading to other metabolic derangement [1]. It arises when your body is not adequately reacting to the effects of insulin, or when your pancreas produces insufficient amounts of insulin overall.

People of all ages suffer from diabetes. All types of diabetes are treatable with medicine or lifestyle modifications, whereas the majority are chronic. Over time glucose is in your blood stream it needs help—a key to reach its target site. The hormone insulin is crucial here. Hyperglycemia is a condition in which there is an accumulation of glucose in the bloodstream due to insufficient insulin production by the pancreas or improper insulin utilisation by the body. Chronic diabetes, a metabolic condition marked by high blood glucose (blood sugar) levels, can cause major harm to the heart, blood vessels, eyes, kidneys, nerves, and heart over time. Type 2 diabetes is the most prevalent and typically affects adults. It is caused by the body either not producing enough insulin or becoming resistant to it [2].

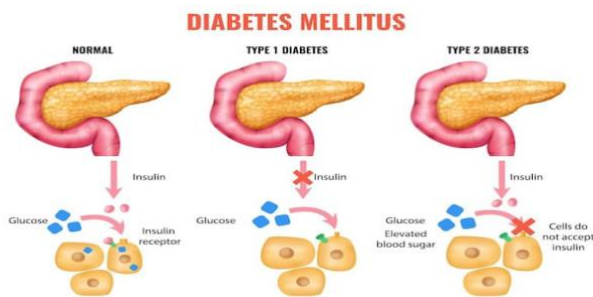


Figure 1: Different Types of Diabetes Mellitus
EPIDEMIOLOGY

As of 2019, the International Diabetes Federation (IDF) [3] reported that 537 million adults worldwide were anticipated to be diabetics. With nearly 2 million deaths each year from diabetes-related kidney disease and other complications, diabetes ranks as the ninth-leading cause of death worldwide in 2020. In addition to heredity, poor nutrition, high blood pressure, alcohol consumption, smoking, as well as elevated BMI are the main causes of type 2 diabetes, which is primarily brought on by food and reduced physical activity. The prevalence of diabetes is rising quickly; estimates from 2019 placed the population at 463 million, with equal distributions across the two genders and a peak incidence at age 55. With population growth expected in every region of the world, the number is predicted to reach 643 million by 2030, or 1079 people per 100,000. Approximately 85%–90% of instances of diabetes are type 2 diabetes. Increases in Type 2 risk factors, such as notably shorter lifespans as well as being overweight or obese, are mostly

responsible for increases in total diabetes prevalence rates [4].

ETIOLOGY

There are two main causes of diabetes mellitus: hereditary and environmental. Reduced physical inactivity, medications and other harmful substances, obesity, viral infections, and geographic location are among the environmental factors that may contribute to the development of diabetes mellitus [5].

Food habits (High calorie diet, junk food, rice).

Type 2 diabetes is mostly caused by genetic predisposition, with concordance in monozygotic twins approaching 100%. Environmental factors may need to alter genetic factors in order for diabetes mellitus to resolve. If environmental circumstances alter the expression of a vulnerable gene, a person having that gene may develop diabetes [6].

TREATMENT

Treated through insulin therapy.

Type 2: Non-Insulin Dependant Diabetes Mellitus (Niddm)

Occurs due to insulin resistance or defective insulin production.

Onset: Adulthood or occur at any age.

Treatment: Managed with life style changes, oral medicines insulin [7].

Gestational Diabetes Mellitus (Gdm)

Develops during pregnancy and usually resolves after child birth.

A disease known as gestational diabetes mellitus occurs when a hormone produced by the placenta impairs the body's ability to use insulin efficiently [8].

Rather than starting out as detected by the cells, glucose accumulates in the circulation. Unlike type 1 diabetes, which is brought on by a shortage of insulin, gestational diabetes is brought on by hormones released during pregnancy that can reduce the effectiveness of insulin—a condition known as insulin resistance.

Women who develop gestational diabetes are at higher risk of developing DM [9].

Mody (Maturity Onset Diabetes of the Young)

Monogenic diabetes, also known as maturity-onset diabetes in young people, is caused by an inherited genetic mutation that modifies the way your body produces and uses insulin. At the moment, MODY comes in more than ten different varieties. It typically runs in families and affects up to 5% of diabetics [10].

LADA (Latent Autoimmune Diabetes In Adults)

Adults with latent autoimmune diabetes (LAD) experience an autoimmune response similar to that of type 1 diabetes, however the development of LADA is significantly slower. Typically, those diagnosed with LADA are older than 30 [11].

PATHOPHYSIOLOGY

Most, but not all, T2DM patients are overweight or obese because obesity affects the sensitivity of tissues to insulin, which in turn influences the development of insulin resistance. Obesity also plays a significant role in the homeostatic regulation of systemic glucose. Obesity's elevated body fat content is such a significant risk factor for type 2 diabetes that it determines the emergence of insulin resistance and, ultimately, hyperglycemia based on both the total quantity and the distribution of body fat [12].

Compared to increased gluteal/subcutaneous fat or peripheral obesity, this kind of diabetes has often been linked to increased abdominal fat or visceral obesity. Patients with type 2 diabetes frequently have multiple cardiovascular risk factors, including hypertension and lipoprotein metabolic abnormalities, which are characterised by elevated triglycerides and low levels of high-density lipoproteins (HDLs). This is because T2DM is strongly associated with increased body fat content or obesity. Owing to its lifelong nature and the many metabolic disturbances that accompany hyperglycemia, type 2 diabetes (T2DM), especially in the middle and later stages of life, is often linked to the emergence of a spectrum of microvascular as well as macrovascular problems [13].

MATERIALS AND METHODS

STUDY SITE

The current study was carried out in the 1000-bed tertiary care teaching hospital, A.C.S.R.

Government Medical College, in Nellore, Andhra Pradesh, in the department of general medicine.

STUDY CRITERIA

PATIENT SELECTION CRITERIA

The inclusion and exclusion criteria were used to determine the patients who were enrolled in the trial.

INCLUSION CRITERIA

1. All the patients aged above 30 years were eligible for inclusion.
2. Individuals diagnosed with either type 1 or type 2 diabetes and exhibiting peripheral diabetic neuropathy were included [14].
3. Patients currently using anti-convulsants were considered.
4. Those with a Visual Analogue Scale (VAS) score of 40-50 or higher were eligible for participation.

EXCLUSION CRITERIA

1. Individuals below the age of 30 were excluded.
2. Participants with a dependency on alcohol or other drugs were not included.
3. Pregnant or lactating individuals and those unable to respond to therapy were excluded from the study [15].

STUDY DESIGN/METHODOLOGY/SCALES

Our study design comprises of Prospective Observational Study [16].

STUDY DURATION

The study was conducted for 6 months from September 2023 to February 2024.

SOURCE OF DATA

Patients case sheet and patients interview.

STUDY POPULATION

The study population contains Type-2 Diabetes Mellitus, Diabetic Peripheral Neuropathy patients.

SAMPLE SIZE

The sample size includes total No. of 175 patients containing both In and out patients [17].

STUDY PROCEDURE

Patients diagnosed with Type 2 Diabetic Mellitus and Diabetic Peripheral Neuropathy have been included in the study [18].

These patients are both In and Out patients of ACSR Govt. General Hospital.

The study is limited for patients who admitted with Type 2 DM and DPN in the General Medicine department with age above 30 years.

Based on inclusion & exclusion criteria we have selected the patients.

Patient demographic details such as age, gender, admission and other details have been collected.

We tried to find out the efficacy of the two drugs belonging to different classes used in treating painful Diabetic Peripheral Neuropathy patients [19].

STATISTICAL ANALYSIS

The statistical method we have used to analyse the data is Mean and Standard deviation.

The mean and standard deviation have been calculated by using MS Excel [20].

RESULTS

In this prospective study, we included 175 subjects based on inclusion and exclusion criteria. Subjects were receiving anticonvulsants therapy.

1. Distribution of Study Population (Gender Wise)

Table 1: Distribution of Study Population (Gender Wise)

MALE	FEMALE
105	70

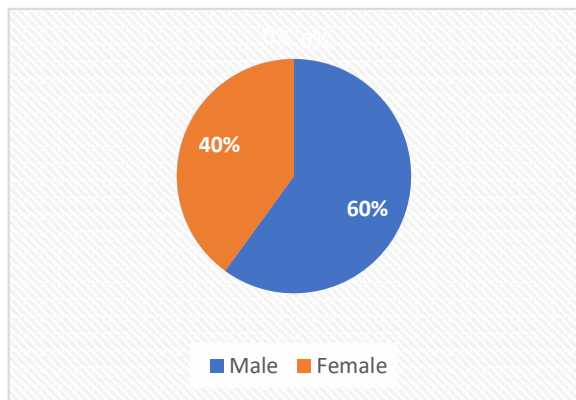


Figure 2: Pie Chart for Gender Wise Distribution of Study Population

Out of 175 prescriptions, Diabetic Peripheral Neuropathy was more found in male than female. The percentage of male and female patients was 60% and 40% respectively.

2. Age - Gender Wise Distribution of Study Population

Table 2: Age - Gender Wise Distribution of Study Population

Age	Male	Female
30-40	10	8
41-50	15	12
51-60	22	18
61-70	28	21
71-80	18	6
Above 81	12	5

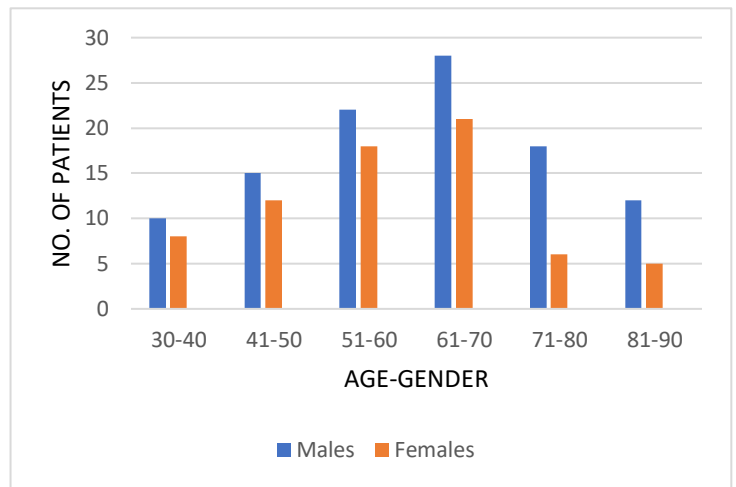


Figure 3: Clustered Column for Age-Gender Wise Distribution

(30-40) males were found to be 10%, females were found to be 8%

(41-50) males were found to be 15%, females were found to be 12%

(51-60) males were found to be 22%, females were found to be 18%

(61-70) males were found to be 28%, females were found to be 21%

(71-80) males were found to be 18%, females were found to be 6%

(81-90) males were found to be 12%, females were found to be 5%

3. Mean And Standard Deviation For Age-Gender Wise Distribution of Population:

Table 3: Mean & SD for Age-Gender Wise Distribution

Age	Males	No. of Females
30-40	10	8
41-50	15	12
51-60	22	18
61-70	28	21
71-80	18	6
ABOVE 81	12	5
Mean	17.5	11.66666667
Standard Deviation	6.68580586	6.592925501

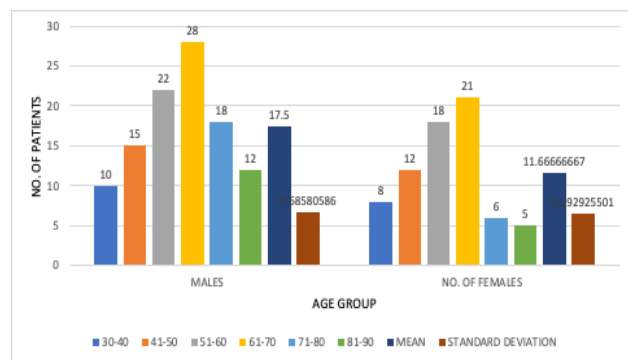


Figure 4: Clustered Column for Age- Gender Wise Distribution

The above graph explains about the following

- ✓ The distribution of drugs is between the age group of 30-90 that includes both men and women.
- ✓ In men, the mean for distribution of drugs is 17.5 and the standard deviation is found to be 6.685.
- ✓ In women, the mean for distribution of drugs is 11.66 and the standard deviation is found to be 6.5929.

4. Drug utilization Patterns In Diabetic Peripheral Neuropathy (Dpn)

Distribution of Drugs In DPN Patients

A. Pregabalin Group

Table 4: Pregabalin Utilization Patterns In DPN Patients

Pregabalin Group	No. of Males	No. of Females
30-40	6	8
41-50	8	9
51-60	18	11

61-70	21
71-80	7
ABOVE 81	5
Mean	10.83333333
Standard Deviation	6.853223086

DRUG UTILIZATION PATTERNS IN MALES

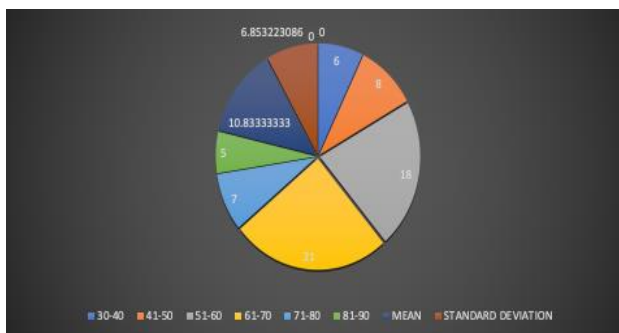


Figure 5: Pie Chart for Pregabalin Utilization Patterns In Males

This pie chart explains about the following:

The drug Pregabalin was prescribed to about 65 male patients as a part of the study.

The mean for male patients taking Pregabalin for diabetic peripheral neuropathy pain is 10.833 and the standard deviation is found to be 6.853.

The mean for female patients taking Pregabalin for diabetic peripheral neuropathy pain is 6.666 and the standard deviation is found to be 3.141.

DRUG UTILIZATION PATTERNS IN FEMALES

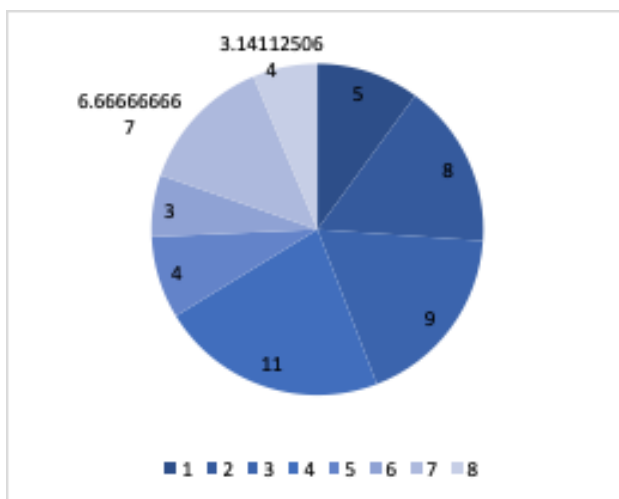


Figure 6: Pie Chart for Drug Utilization of Pregabalin In Females

The above pie chart explains about the following:

The drug Pregabalin was prescribed to about 40 female patients as a part of the study.

The mean for female patients taking Pregabalin for diabetic peripheral neuropathy pain is 6.666 and the standard deviation is found to be 3.141.

B. Carbamazepine Group

Table 5: Carbamazepine Utilization Patterns In DPN Patients

Carbamazepine Group	No. of Males	No. of Females
30-40	3	2
41-50	5	4
51-60	10	6
61-70	12	10
71-80	6	5
Above 81	4	3
Mean	3.559	2.828
Standard Deviation	6.666	5

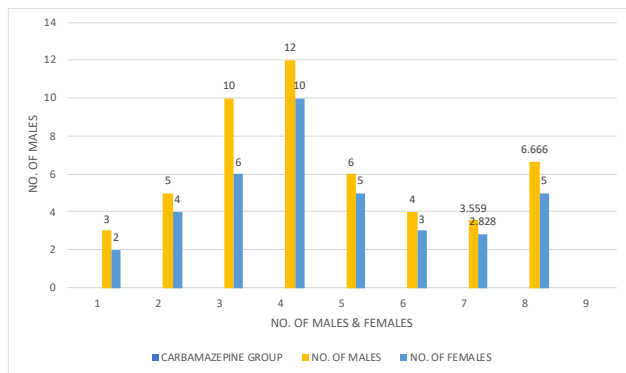


Figure 7: 3d Column Graph for Carbamazepine Utilization Patterns In DPN Patients

The above bar graph explains about the following:

The drug carbamazepine utilization patterns in Diabetic Peripheral Neuropathy patients divided according to their age and gender.

The mean for male patients taking Carbamazepine for diabetic peripheral neuropathy pain is 3.559 and the standard deviation is found to be 6.666.

The mean for female patients taking Carbamazepine for diabetic peripheral neuropathy pain is 2.828 and the standard deviation is found to be 5.

5. Baseline Characteristics and Demographic Details of DPN

Table 6: Baseline Characteristics of DPN Patients

Baseline Characteristics	Pregabalin Group	Carbamazepine Group
Age	30-90	30-90
Males	65	40
Females	40	30
Type 1	0	0
Type 2	110	65
Fbs	175	175
BMI	95	80
Mc Gills Pain Questionnaire	175	175
VAS	175	175
Duration Of Pain	97	78

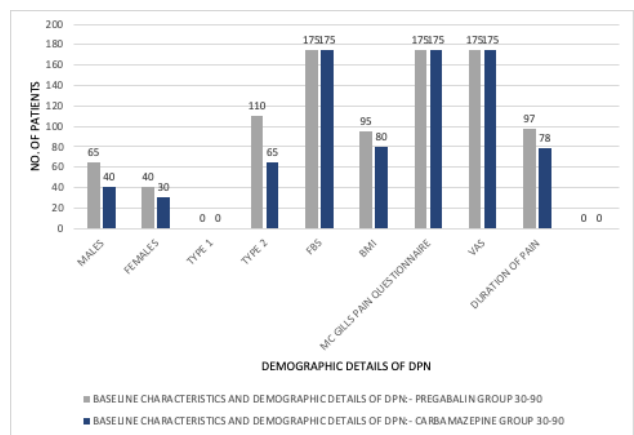


Figure 8: Bar Graph for Baseline Characteristics of DPN Patients

This bar graph explains about the demographic details and baseline characteristics of DPN patients who were divided into two categories such as Pregabalin group and Carbamazepine group.

6. The VAS For Pain by Using the Drugs Pregabalin During days 0, 30, 60, 90 & 120:

Table 7: The VAS Score for Pregabalin at Day 0, 30, 60, 90 & 120

VAS SCORE	DAY 0	DAY 30	DAY 60	DAY 90	DAY 120
0-5	0	3	7	11	16
5-7	8	16	15	4	0
8-9	7	3	0	2	0
9-10	10	2	0	0	0

6. The VAS for Pain by Using the Drugs Carbamazepine During Days 0, 30, 60, 90 & 120:

Table 8: The Vas Score for Carbamazepine at Day 0, 30, 60, 90 & 120

VAS SCORE	DAY 0	DAY 30	DAY 60	DAY 90	DAY 120
0-5	1	2	3	1	1
5-7	3	2	4	4	2
8-9	1	2	0	3	3
9-10	4	7	8	8	11

6.The Mean& Standard Deviation of VAS for Pain By Using the Drugs Pregabalin and Carbamazepine During Days 0, 30, 60, 90 & 120:

Table 9: The Mean & Sd of VAS For Both The Drug Groups

VAS SCORE	DAY 0	DAY 30	DAY 60	DAY 90	DAY 120
Pregabalin	25	24	22	18	16
Mean	7.96	10.5	5.947	5	3.75
Standard Deviation	1.059	15.90	0.848	0.755	0.774
Carbamazepine	9	13	15	14	19
Mean	7.333	7.692	7.6	8	7.666
Standard Deviation	1.5	1.548	1.6818	1.2649	1.4121

60	5.947368421	7.6
90	5	8
120	3.75	7.666666667

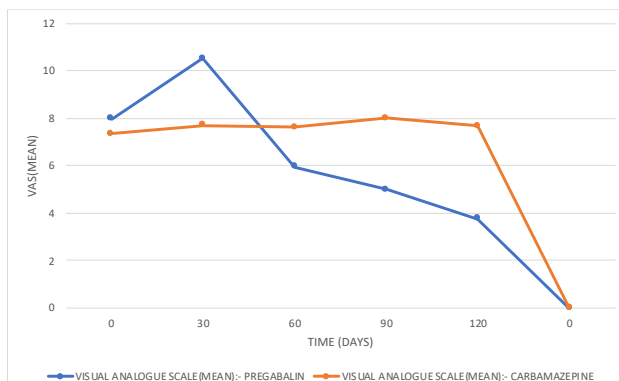


Figure 10: Line with Markers Graph Mean for Day VAS Score of both the Drugs

This graph is type of line with markers graph. It explains about the following, The mean of VAS score for both the Pregabalin and Carbamazepine groups in the time duration of about day 0 (base line), day 30, day 60, day 90, day 120.

The mean score for pregabalin group was found to be highest during day 30 i.e., '10.5'. The mean score for carbamazepine group was found to be highest during day 90 i.e., '8'.

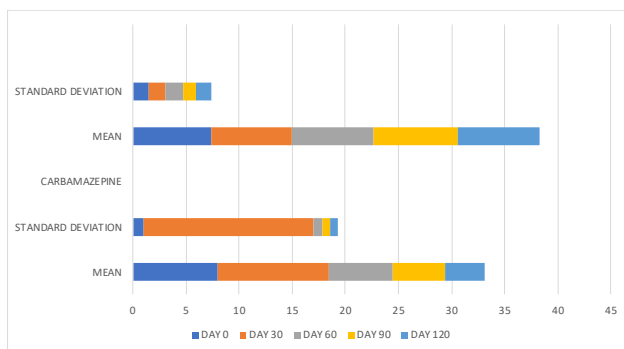


Figure 9: Stacked Bar Graph for Mean & SD of VAS Score

The above stacked bar graph explains about Visual Analogue Scale(VAS) mean score and standard deviation for both Pregabalin and Carbamazepine groups.

6. A Visual Analogue Scale (Mean)

Table 10: Mean for VAS Score of both the Drugs

Time (Days)	Pregabalin Group	Carbamazepine Group
0	7.96	7.333333333
30	10.5	7.692307692

6. B Visual Analogue Scale (Standard Deviation)

Table 11: Standard Deviation for VAS Score of both the Drugs

Time (Days)	Pregabalin	Carbamazepine
0	1.059805834	1.5
30	15.9092823	1.548365557
60	0.848114524	1.681835732
90	0.755928946	1.264911064
120	0.774596669	1.414213562

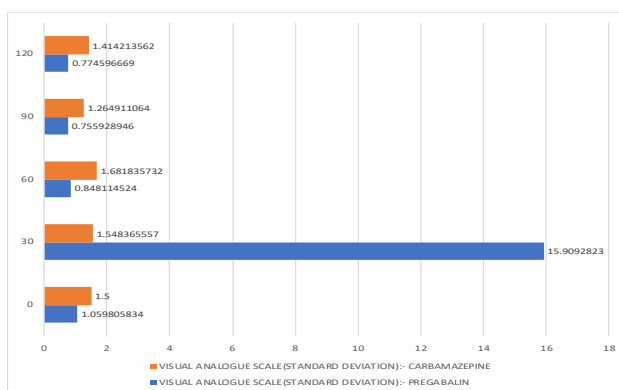


Figure 11: Bar Graph for VAS Score Standard Deviation of Drugs

This bar graph explains about the standard deviation:

The standard deviation for Pregabalin group was found to be highest during day 30 i.e., about 15.909.

The standard deviation for Carbamazepine group was found to be highest during day 60 i.e., about 1.6818.

7. Change In Pain Severity Among Diabetic Peripheral Neuropathy Patients

Table 12: Change In Pain Severity In DPN Patients

Variable	Pregabalin	Carbamazepine
Reduction of VAS $\geq 50\%$	15	10
Reduction of VAS $<50-\geq 30\%$	30	24
Reduction of VAS $<30\%$	50	30
No Change In VAS	4	2
Increase In VAS	6	4
Total	105	70

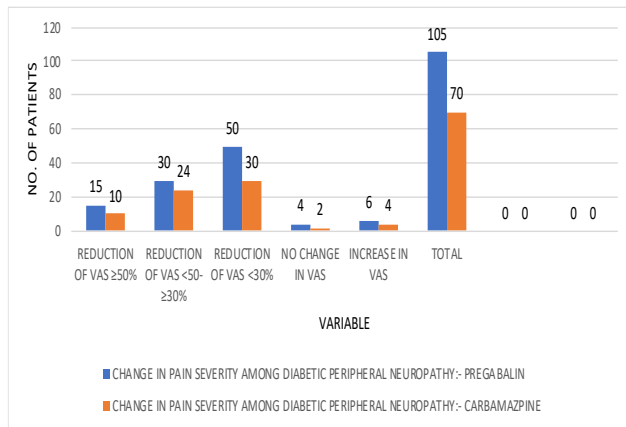


Figure 12: Bar Graph for Change In Pain Severity In DPN Patients

This bar graph explains about changes occurred in pain severity among Diabetic Peripheral Neuropathy patients from day 0 to day 120.

From the above graph we can understand that the change in pain severity has occurred higher in Pregabalin group when compared to Carbamazepine group.

Hence, it is found that Pregabalin is more effective than Carbamazepine in treating DPN.

8. A Side Effects due to Pregabalin

Table 13: Side Effects due to Pregabalin

ADRs	RESULT
Blurred Vision	3
Dizziness	5
Dry Mouth	7
Memory Problems	8
Swelling Of Hands And Feet	9
Anxiety	3
Chest Pain	5
Chills	6
Constipation	5
Headache	15
Depression	10

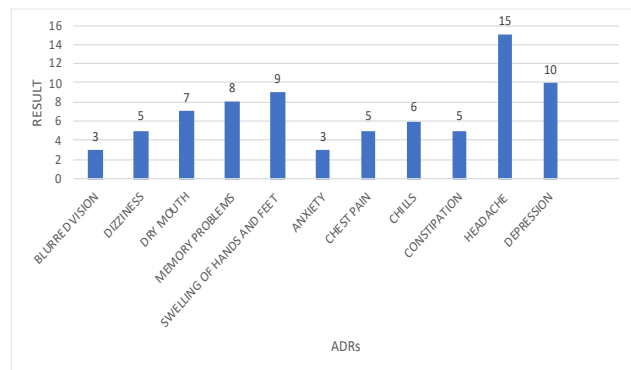


Figure 13: Clustered Column for Side Effects due to Pregabalin

This clustered column explain about side effects due to Pregabalin.

From the above graph it is found that headache and depression are the most common side effects of Pregabalin.

9. B Side Effects due to Carbamazepine

Table 14: Side Effects due to Carbamazepine

ADRs	RESULT
Nausea	14
Vomiting	17
Drowsiness	23
Dizziness	27
Constipation	19
Dry Mouth	16
Skin Irritation	13
Chills	11
Diarrhea	9
Weakness	7
Weight Loss	3

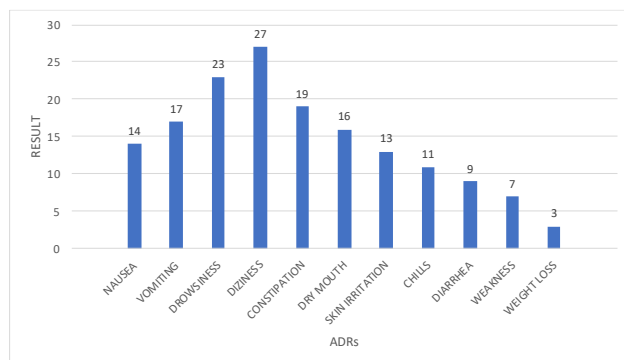


Figure 14: Side Effects due to Carbamazepine

This clustered column explains about side effects due to carbamazepine.

From the above graph it is found that dizziness and drowsiness are the most common side effects of Pregabalin.

DISCUSSION

Diabetic neuropathy (DN) is a prevalent condition characterised by peripheral nerve dysfunction signs and symptoms in a patient with diabetes mellitus (DM) when other potential causes of peripheral nerve dysfunction have been ruled out. India has a greater prevalence of diabetes than the West (1%–2%); it is 4.3% in India. Damage to the peripheral nerves, which are found outside of the brain and spinal cord, results in peripheral neuropathy. This ailment frequently results in discomfort, numbness, and weakness, generally in the hands and feet. It may also have an impact on other bodily parts and processes, such as urination as well as digestion.

This research demonstrates the potential for improving current Nellore treatments by presenting the experiences of individuals with peripheral neuropathy. Physicians are advised to employ a patient-centred approach and to suggest self-management techniques in addition to prescribed medicines. Enhancing quality of life mostly requires coping techniques and self-efficacy, which can be fostered by providing information and assistance on the condition. To raise the standard of care given to patients with peripheral neuropathy, these findings can be applied both locally and worldwide.

Diabetes mellitus is becoming more and more common, approaching epidemic proportions. As a result, the number of patients experiencing its chronic complications—including DPN—will

sharply increase. Preventing diabetic foot syndromes and early diagnosis of the ailment are the main goals of the current DPN therapy approach. Further research is needed to determine whether clinical outcomes like foot ulceration, amputation, and cardiovascular disease can be prevented with routine use of new diagnostic techniques, and whether they can be used as surrogate end points for DPN. These techniques may help the clinical assessment detect clinical and subclinical DPN.

Neuropathy affects as many as 50% of DPN patients. Why some people have excruciating neuropathic symptoms is not well understood. While symptom relief is the goal of our current treatments, in almost one-third of instances, pain ratings are only reduced by 30 to 50% at most. A more customised strategy that uses patient features (such as clinical phenotypes, brain biomarkers, genetics, etc.) to stratify individuals may be more successful in preventing drug trial failure than the empirical use of treatments (14). All of these characteristics have the potential to improve patient outcomes in painful-DPN, but more validation is needed before they can be used for stratification in clinical practice.

Neuropathic pain affects up to 50% of DPN patients. It's unclear why some patients experience excruciating neuropathic symptoms. While the goal of our current treatments is to lessen symptoms, in roughly one-third of instances, the reduction in pain scores is only at best 30–50%. On the other hand, a more customised strategy that uses patient features (e.g., clinical phenotypes, brain biomarkers or genetics, etc.) to stratify individuals may be more effective in preventing drug trial failure (14). While more research is necessary before any of these variables can be taken into account for stratification in clinical practice, doing so could potentially improve patient outcomes for those with painful DPN.

The comparative study of pregabalin and carbamazepine in the context of painful diabetic peripheral neuropathy (DPN) is of paramount importance, considering the prevalence and impact of this condition on patients' lives. This discussion will focus on the key findings, implications, and limitations of the study.

Efficacy in Pain Management

The primary objective of this study was to compare the efficacy of pregabalin and carbamazepine in reducing pain intensity associated with diabetic peripheral neuropathy. The results revealed noteworthy insights into the comparative effectiveness of these medications. Pregabalin, as a calcium channel modulator, has demonstrated efficacy in numerous neuropathic pain conditions. Beyond pain reduction, these drugs influence various aspects of daily functioning, emotional well-being, and social interactions is crucial for tailoring treatment approaches. The discussion explores Pregabalin medication stands out in improving overall quality of life of the patients.

CONCLUSION

Diabetes can lead to a major problem called peripheral neuropathy. There is a significant chance of autonomic dysfunction, trophic alterations, and discomfort with this type of neuropathy.

Hence, PN is a collection of neurological conditions with a wide range of aetiologies, including metabolic, toxic, genetic, and environmental factors. In India, PN caused by diabetes, leprosy, GBS, toxin-like arsenic, as well as TOCP poisoning are frequent due to a variety of ethnic backgrounds and environmental factors. However, there exist other conditions such as hereditary neuropathies, drug-induced neuropathies, and vasculitic neuropathies where adequate research has not been conducted. However, a lot of our series are based in hospitals or clinics, which have inherent bias. To find the true situation in many parts of India, we need to do more community-based research. The studies also point up regional variations, which are crucial to understand in order to choose the right pattern of PN and carry out effective preventive actions. However, it frequently happens that despite thorough inquiry, an etiological diagnosis that calls for ongoing monitoring is not made. In primary care, peripheral neuropathy is frequently encountered. Peripheral neuropathy can be effectively detected or ruled out in patients with systemic diseases like diabetes mellitus by using a mix of vibration and light touch testing.

The majority of peripheral neuropathies are mostly sensory, length-dependent, clinically mild

to moderately severe, and do not significantly impair function. Usually, it is possible to work up and manage these neuropathies successfully. The results presented here indicated that among diabetic patients, age, HbA1c, DR, and the length of their diabetes are related to considerably higher risks of DPN; however, BMI, smoking, TG, and TC did not show any evidence of an increased risk of DPN. The results of the study offer a scientific foundation for a deeper comprehension of the causes of peripheral neuropathy-complicated type 2 diabetes and the outcomes of preventative measures.

There are certain other issues with this research as well. Firstly, the majority of the research kinds were cross-sectional studies, and the causal reasoning was not very strong. Second, although the diagnosis of type 2 diabetes was largely supported by the included studies, the DPN diagnostic criteria did not fully align with the research subjects' inclusion requirements. Third, although a wide range of topics were addressed by the included literature, factors including healthcare levels, ethnicity, as well as economic status were not taken into account. Lastly, as this work contains publication bias, additional research is required to validate our results. Few studies have been conducted to date on the risk factors for DPN in patients with type 2 diabetes; therefore, high-quality prospective cohort studies are required to clarify future trends.

In treating DPN the anticonvulsants like Pregabalin and Carbamazepine are used in which Pregabalin is utilised more for improving the intensity of pain.

In our study we observed that Pregabalin is most effective in treating the DPN based on VAS score, BPI and Mc.Gill's pain questionnaire.

Pregabalin is the most effective drug than Carbamazepine due to occurrence of less complications.

Conflict of Interest

The authors declare no conflict of interest, financial or otherwise.

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