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Safety and efficacy of duloxetine versus gabapentin in painful diabetic polyneuropathy

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ABSTRACT

Objective: To evaluate safety and efficacy of Gabapentin and Duloxetine in patients with painful diabetic neuropathy.

Materials and Methods: This is a prospective randomized double blinded parallel group study done for a period of 12 weeks. Total of 60 patients were enrolled and randomly allocated to two groups with 30 patients each, group A received Duloxetine 30 mg twice daily and group B received Gabapentin 300mg twice daily and followed every 2 weeks. Patients of age 35 to 60 years with painful diabetic peripheral polyneuropathy are included in the study. Primary objective is improvement in pain assessed by NPRS; Secondary objective is improvement in sleep and clinical condition of the patient, assessed by Sleep Interference Score and Clinical Global Impression of Change (CGIC). Assessment was done at beginning and at four, eight and twelve weeks. Data was analysed using SPSS 12.0 version.

Results: Numerical pain rating scores and daily sleep interference scores were reduced significantly with course of treatment within both groups ($p = <0.05$ in both groups), but there was no significant difference observed between two groups at baseline, 4th week, 8th week and 12th week. There is significant reduction in CGIC severity scores with course of treatment within both groups ($p = <0.05$ in both groups), but there was no significant difference observed between groups at baseline and at end of treatment. Common adverse events seen are nausea, dry mouth, dizziness, somnolence and constipation in both groups. There is high incidence of nausea and dry mouth with Duloxetine when compared to Gabapentin.

Conclusion: Monotherapy with either Duloxetine or Gabapentin was equally effective at 12 weeks treatment with minor side effects. In addition, Gabapentin showed fewer side effects. It can be concluded that for preventing side effects, Gabapentin can be used. Further large head to- head comparator and combination trials are required.

1. Introduction

Diabetes has reached epidemic proportions worldwide, with International Diabetes Federation estimating prevalence of 425 million people worldwide in 2017, which will rise to 628 million by 2045.[1] Earliest presenting and most prevalent complication of diabetes is diabetic peripheral neuropathy (DPN) and it is primary cause of diabetic foot disease, including ulceration and non-traumatic amputations.[2] Up to one-third of patients with DPN suffer with neuropathic pain (painful diabetic polyneuropathy, pDPN)[3–5] This condition causes a series of unpleasant symptoms, which often results in sleep disturbance, poor quality of life, depression, and unemployment.[6–9]

In Diabetes Control and Complications Trial (DCCT), prevalence of DPN in conventional treatment arm was ~ 20%, whilst in intensive treatment arm it was 10%

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after 5 years, in those with type 1 diabetes (T1D) who were non-neuropathic at baseline.[10] Epidemiology of Diabetes Interventions and Complications (EDIC) study showed that after approximately 26 years of diabetes, DPN was present in 25% and 35% of patients in the intensive and conventional treatment arms, respectively.[11] The EURODIAB IDDM study showed similar prevalence rates (28% DPN at baseline) with risk factors including age, duration of diabetes, HbA1c and elevated triglycerides.[12] In SEARCH for Diabetes in Youth Study,[13] in those of an age of 20 years or less with a duration of diabetes of greater than 5 years, the prevalence was 7% in patients with T1D and 22% in T2D.[14]

There is paucity of data on the prevalence of pDPN. The reported prevalence has varied from 8 to 26%, depending on the diagnostic criteria and population studied.[15] Prevalence of pDPN in USA is estimated at 20–24% among patients with peripheral neuropathy.[16] There are data to suggest that mortality is higher in patients with severe chronic pain.[17] In a population-based study, prevalence of painful DPN was estimated at 16%; however, of these, 12.5% had never reported symptoms to their doctor and 39% had never received treatment for their pain.[18]

Gabapentin was first $\alpha 2$-δ ligand to receive approval for treatment of neuropathic pain. Its half-life is 6–8 h, consequently drug is typically administered three times daily.[19] Dosing regimen with titration up to 1800 mg and maximum upper dose of 3600 mg is recommended in painful diabetic polyneuropathy.[20]

Duloxetine is one of most widely studied, prescribed and recommended agents for painful diabetic polyneuropathy. It relieves neuropathic pain through inhibition of serotonin and norepinephrine reuptake, which enhances descending inhibition of pain.[21–23] Duloxetine is rapidly absorbed, reaching maximal plasma concentrations approximately 6 h after administration, reaching steady state in bloodstream within 3 days.[22]

Efficacy and safety of Gabapentin and Duloxetine in painful diabetic polyneuropathy management have been studied in many clinical trials, and several studies tried to assess use of these drugs in real-world practice.[24,25] Since relationship between pain and sleep may be bidirectional, some researchers suggest that pain management should also include measures to improve sleep.[26,27] In this study, we evaluated improvement in sleep after giving medications.

To the best of our knowledge, no comparative studies have been carried out between Gabapentin and Duloxetine in painful diabetic neuropathy in South Indian population. Therefore, this study was aimed to evaluate efficacy and safety of Gabapentin and Duloxetine in patients with painful diabetic neuropathy in a tertiary care centre in south India.

2. Materials and Methods

This is a prospective randomized double blinded parallel group study done in a tertiary care hospital, South India. Patients attending medical out-patient of General Medicine department were selected for this study and this study was done for a period of 12 weeks from March 2022 to May 2022. Total of 60 patients were enrolled in study as per selection criteria. They were randomly allocated to two groups with 30 patients each, group A received Duloxetine 30 mg twice daily and group B received Gabapentin 300mg twice daily and followed every 2 weeks.

Patients of age 35 to 60 years with painful diabetic peripheral polyneuropathy from 1 month to 5 years and based on history and clinical examination, HbA1c lower than 10, time frame of diabetes diagnosis was between 1 to 15 years and patients with pain on Numerical pain rating scale (NPRS) of at least 4 are included in the study. Patients having liver or kidney impairment, amputation in their lower limb, symptoms of cognitive impairment, pregnant or lactating, alcohol abusers or drug addicts are excluded from the study.

Medications were first made similar to each other by a doctor and then sufficient amounts were packed into packets A and B. Before commencement of study, side effects of medications were explained to patients and each patient randomly received one of two medications used in the study.

Primary objective is improvement in pain as assessed by NPRS; Secondary objective is improvement in sleep and clinical condition of the patient, assessed by Sleep Interference Score and Clinical Global Impression of Change (CGIC).Though patients were followed every two weeks for any side effects, assessment was done at beginning and at four, eight and twelve weeks, comparison was both intragroup and intergroup, for evaluation of effectiveness of two medications.

NPRS is segmented numeric version of visual analogue scale (VAS) in which respondent selects whole number (0–10 integers) that best reflects intensity of pain.[28,29] Common format is horizontal bar or line. Similar to VAS, NPRS is anchored by terms describing pain severity extremes. 11-point numeric scale ranges from ’0’ representing one pain extreme (e.g. no pain) to ’10’ representing the other pain extreme (e.g. pain as bad as you can imagine)

Daily sleep interference scale (DSIS) has 11-point response scale that asks patients to select number that best describes how much your pain has interfered with your sleep during past 24 hours. Response options range from 0 (Did not interfere with sleep) to 10 (Completely interfered with sleep-unable to sleep due to pain). DSIS is designed to be used in patient daily diary that patients fill out upon awakening each morning.[30]

CGIC[31,32] assesses any changes in patient’s clinical condition and is graded on a seven-point scale. Each point

indicates a specific clinical condition and is defined as follows: 1 shows significant improvement; 2 shows major improvement; 3 shows minimal improvement; 4 shows no change; 5 shows minimal worsening; 6 shows major worsening; and 7 shows significant worsening of clinical condition.

Ethical approval was taken from Institutional Ethical Committee. Informed written consent was taken from each of the participants. They were assured to keep their data confidential and they had full right to withdraw themselves from study at any moment. Compliance regarding medication consumption is assessed by counting used tablet strips returned by patient and patient diary. All adverse events reported by patients during any stage of trial were recorded and assessed for seriousness and relation to study drug. Data was analysed using SPSS 12.0 version. Appropriate statistical methods were used based on the data. A probability value of <0.05 was considered statistically significant.

3. Results

Table 1: Showing baseline mean values of demographic and clinical characteristics of patients included in the study

Characteristic	Group A (Duloxetine)	Group B (Gabapentin)	p value
Age	50.21±5.66	51.32±5.69	>0.05
Male Female	14 16	16 14	>0.05
HbA1c	8.04±1.66	8.03.7±1.67	>0.05
Duration of diabetes in years	7.76±4.26	7.17±3.96	>0.05
Duration of painful diabetic neuropathy in years	3.21±0.66	3.17±1.06	>0.05
Baseline NPRS	6.82±1.16	6.02±0.66	>0.05
Baseline Sleep interference score	7.17±1.63	7.22±1.56	>0.05
CGIC	3.71±0.91	3.61±0.92	>0.05

Table 2: Showing comparison of NPRS between two groups at 4^{th}, 8^{th} and 12 weeks

Numerical pain rating scale	Group A (Duloxetine)	Group B (Gabapentin)	p value
At beginning	6.82±1.16	6.02±0.66	>0.05
At 4^{th} week	2.61±1.16	2.59±1.22	>0.05
At 8^{th} week	1.89±1.06	1.97±1.02	>0.05
At 12^{th} week	1.7±0.96	1.69±1.12	>0.05

Numerical pain rating scores (NPRS) were reduced significantly with course of treatment within both groups (p = <0.05 in both groups), but there was no significant difference observed between the groups at baseline, 4th week, 8^{th} week and at 12th week.

Table 3: Showing comparison of daily sleep interference scale between two groups at 4^{th}, 8^{th} and 12 weeks

Daily sleep interference scale	Group A (Duloxetine)	Group B (Gabapentin)	p value
At beginning	7.17±1.63	7.22±1.56	>0.05
At 4^{th} week	5.86±1.52	5.64±1.74	>0.05
At 8^{th} week	4.62±1.88	4.82±1.01	>0.05
At 12^{th} week	3.63±1.32	3.68±1.62	>0.05

Sleep interference scores were reduced significantly with course of treatment within both groups (p = <0.05 in both groups), but there was no significant difference observed between the groups at baseline, 4th week, 8th week and at 12th week.

Table 4: Showing comparison of clinical global impression of change between two groups at 4^{th}, 8^{th} and 12 weeks

CGIC	Group A (Duloxetine)	Group B (Gabapentin)	p value
At beginning	3.71±0.91	3.61±0.92	>0.05
At 4^{th} week	2.21±0.74	2.22±0.92	>0.05
At 8^{th} week	1.91±0.68	1.87±0.67	>0.05
At 12^{th} week	1.73±0.57	1.73±0.64	>0.05

CGIC severity scores were reduced significantly with course of treatment within both groups (p = <0.05 in both groups), but there was no significant difference observed between the groups at baseline, 4th week, 8th week and at 12th week.

4. Discussion

Neuropathic pain is often associated with diabetic peripheral neuropathy and is defined as pain caused by primary lesion or dysfunction in the nervous system. Major goal of pharmacologic treatment is to control pain. Simple analgesic may provide partial, short-term relief, but more specifically targeted drugs are required for sustained control of pain of neuropathic origin.[33]

Main treatment for all painful diabetic polyneuropathy patients is maintaining glucose concentrations within the normal range.[34] Consensus-based treatment guidelines recommended both Duloxetine and gabapentin for managing painful diabetic polyneuropathy patients as first-line medications.[35]

Limited number of studies has directly (head to head) compared effectiveness of these two medications.[36] Some studies have found duloxetine to have similar or inferior efficacy to pregabalin or gabapentin.[37]

In this study, there was significant reduction in mean Numeric pain rating Scale (NRS) score and daily sleep interference score at the end of the study. However, there was no significant difference observed between study

Table 5: Showing distribution of adverse events in both groups

Adverse event	Group A (Duloxetine)	Group B (Gabapentin)
Somnolence	4	4
Constipation	1	1
Nausea	4	2
Vomiting	0	0
Weight gain	0	0
Dry mouth	2	1
Dizziness	2	2

Common adverse events seen are nausea, dry mouth, dizziness, somnolence and constipation in both groups. There is high incidence of nausea with dry mouth with Duloxetine when compared to Gabapentin.

groups in NRS score, daily sleep interference score and CGIC severity score at 4th week, 8th week, and 12th week of treatment. Study of Devi et al. also reported similar observation at end of study.[36] Similar significant improvement in Gabapentin and Duloxetine taking patients with painful diabetic polyneuropathy was reported in several studies like Quilicis et al.[33] Goldstein et al.,[38] Baron et al.,[39] and Tolle et al.[8]

Study done by Backonja et al.[40] compared gabapentin with placebo, gabapentin-treated patients had lower pain scores with improvements in quality of life, mood and sleep. Ko et al.[41] in terms of VAS score, suggested that duloxetine compared to gabapentin had similar efficacy in alleviating diabetic peripheral neuralgia. Our study showed similar and comparable reduction in pain measured by NPRS scale between two groups. Significant improvement was observed in Clinical Global Impression of Change (CGIC) severity score in both Duloxetine and Gabapentin groups when compared between start and end of the study. Two studies[42] recorded clinical global impression of change at 8 weeks after treatment, showed slightly better clinical global impression of change with Gabapentin when compared with Duloxetine. HbA1c levels did not change significantly during 12 weeks of study and average HbA1c level was 8% or less across treatment groups. No significant differences were found in fasting glucose levels between duloxetine group and gabapentin group. Rates of adverse events in placebo-controlled RCTs are greater for duloxetine than placebo. Most common is nausea with dry mouth, dizziness, somnolence, fatigue, insomnia, constipation, reduced appetite and sweating.[43] Tanenberg et al.[14,25] reported higher adverse effects ($p = 0.04$) in Duloxetine group than Gabapentin group. In order to reduce nausea patients can be advised to take duloxetine with or after food.

Medication compliance was good in both groups; similar medication compliance for both Gabapentin and Duloxetine has been reported in previous studies.[33]

5. Conclusion

Monotherapy with either Duloxetine or Gabapentin was equally effective at 12 weeks treatment in improving NPRS, Sleep Interference Score, and CGIC in patients who had painful diabetic polyneuropathy and both are well tolerated with minor side effects. In addition, Gabapentin showed fewer side effects. It can be concluded that for preventing side effects, Gabapentin can be used. Further well-conducted, large head to- head comparator trials and combination trials are urgently required.

6. Limitations

Limited number of population and limited duration of treatment (only 12 weeks). Outcome measures like sleep interference score, and clinical global impression of change can only be used as secondary ones to supplement and explain results. Need for large-sample, multicenter studies to further improve analysis results.

7. Source of Funding

None.

8. Conflict of Interest

None.

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