

Research Article

Comparison of Efficacy of Duloxetine with Carbamazepine in the Management of Patients of Painful Diabetic Neuropathy

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ABSTRACT

Background: Painful diabetic neuropathy is one such disabling condition with a negative impact on quality of life of the patient. Strict glycemic control is the most essential step in management of painful diabetic neuropathy. Duloxetine is being used as one of the first line treatment options for painful diabetic neuropathy. Carbamazepine is also used for treatment of painful diabetic neuropathy. There is no head to head comparison trial is available.

Objective: Our objective was to compare the efficacy of carbamazepine and duloxetine in painful diabetic neuropathy in terms of reduction of pain score.

Subjects & Methods: Two hundred (200) patients of painful diabetic neuropathy and diabetes mellitus of more than 5 years duration and HbA1C more than 7.5% were included in the study. Duloxetine group was given duloxetine 60mg capsule once a day in the morning and carbamazepine group was given tab carbamazepine 200mg twice daily. Patient's baseline visual analogue score was noted. Patients were scheduled to visit at 3 months and their pain was evaluated using visual analogue pain score. 50% reduction in visual analogue score from baseline was taken as significant reduction.

RESULTS: The overall sample of $n = 200$ patients comprised 128 (64%) males and 72 (36%) females. There were 62 (62%) males and 38 (38%) females in duloxetine group and 66 (66%) males and 34 (34%) females in carbamazepine group. Comparison of efficacy was done for both groups which showed that 58% efficacy at 3 months in duloxetine group and 38% efficacy in carbamazepine group (p -value 0.005). Stratification was done for gender which showed no significant difference (p -value = 0.689)

Keywords: Painful Diabetic Neuropathy, Duloxetine, Carbamazepine

INTRODUCTION:

Diabetes Mellitus is an ever-increasing epidemic of modern times. It is prevalent in 8.5% of adults over 18 years of age until 2014.¹ It is responsible for microvascular and macrovascular complications like neuropathy, nephropathy, retinopathy, ischemic heart disease, stroke and peripheral vascular disease. Painful diabetic neuropathy is one such disabling condition with a negative impact on quality of life of the patient². Diabetic Neuropathy is a disease of peripheral nerves presenting with excruciating, burning, stabbing or intractable type of pain along with numbness

or tingling or paresthesia in patients of diabetes mellitus.³ Diabetic Neuropathy is a very common complication of long-standing diabetes mellitus with a lifetime prevalence of up to 50%.⁴

It can present with tingling, burning, numbness, excruciating stabbing or intractable pain associated with paresthesia or hyperesthesia in feet or hands. It is a length dependent neuropathy in which distal parts of feet are affected first followed by hands resulting in glove and stocking sensory loss. These symptoms are predominantly nocturnal and

effectpatient’s quality of life,sleep, movement, mood, work, and social interactions. ⁵

Strict glycemc control is the most essential step in management of painful diabetic neuropathy. Several classes of agents are used for management of this condition including antidepressants, anticonvulsants like Carbamazepine and Lacosamide, Serotonin norepinephrine reuptake inhibitors (SSRIs), Selective Norepinephrine Reuptake Inhibitors (SNRIs) like Duloxetine, gabapentin, pregabalin and topical medications like capsaicin.⁶Despite of many treatment options, management of painful diabetic neuropathy has always remained challenging.

Duloxetine is being used as one of the first line treatment options for painful diabetic neuropathy⁷.Carbamazepine is also used for treatment of painful diabetic neuropathy. There is no head to head comparison trial is available. Current study was conducted to make a comparison of efficacy of carbamazepine and duloxetine in treatment of painful diabetic neuropathy.

Objective: Our objective was to compare the efficacy of duloxetine and carbamazepine in painful diabetic neuropathy in terms of reduction of pain score.

Subjects & Methods. This cross-sectional-observational study was conducted at outpatient clinic, Neurology Department, Sir Ganga Ram Hospital Lahore from March to August, 2018. Two hundred (200) patients of painful diabetic neuropathy (burning, jabbing, shooting, stabbing, excruciating along with numbness or paresthesia in patients of diabetes mellitus in glove and stocking pattern) including males and

females with age between 18 and 65 years and diabetes mellitus of more than 5 years duration and HbA1C more than 7.5% were included in the study using non-probability consecutive sampling technique while Pregnant females, lactating mothers and patients with co-existingcauses of peripheral neuropathy (like porphyria,chronic renal failure, amyloidosis, leprosy,hypothyroidism) and who have used Duloxetine or carbamazepine in previousthree months were excluded from the study. Patients were allocated to duloxetine group and carbamazepine group using computer generated random number table. Duloxetine group was given duloxetine 60mg capsule once a day in the morning and carbamazepine group was given tab carbamazepine 200mg twice daily. Patient’s baseline visual analogue score was noted. Patients were scheduled to visit at 3 months and their pain was evaluated using visual analogue pain score. 50% reduction in visual analogue score from baseline was taken as significant reduction.

RESULTS

The overall sample of $n = 200$ patients comprised 128 (64%) males and 72 (36%) females. There were 62 (62%) males and 38 (38%)females in duloxetine group and 66 (66%) males and 34 (34%) females in carbamazepine group. Comparison of efficacy was done for both groups which showed that 58%efficacy at 3 months in duloxetine group and 38% efficacy in carbamazepine group (p-value 0.005). Stratification was done for gender which showed no significant difference (p-value = 0.689)

Table I: Comparison of efficacy of duloxetine and carbamazepine in treatment of painful diabetic neuropathy using chi square test

		Group		Total
		Duloxetine n=100	Carbamazepine n =100	
Efficacy	Yes	58	38	96
	No	42	62	104
Total n=200		100	100	200
Chi squarre value		8.013		
p-value		0.005		

Table 2: Stratification of efficacy with respect to gender in duloxetine and carbamazepine group.

Group			Efficacy		Total
			Yes	No	
Duloxetine Group N=100	Gender	Male	35	27	62
		Female	23	15	38
	Total		58	42	100
Carbamazepine Group N=100	Gender	Male	28	38	66
		Female	10	24	34
	Total		38	62	100
Total N=200	Gender	Male	63	65	128
		Female	33	39	72
	Total		96	104	200
Chi square value			0.161		
p-value			0.689		

DISCUSSION:

Painful diabetic neuropathy is a disabling condition which is uniquely challenging to treat and affects quality of life⁸. Duloxetine and Carbamazepine both are commonly used drugs for treatment of painful diabetic neuropathy. Duloxetine is regarded as first line medication but no randomized trial has made a head to head comparison of these two drugs in treatment of painful diabetic neuropathy⁹. Duloxetine is costly than carbamazepine so it is need of the hour to compare these two drugs in painful diabetic neuropathy. Availability of fewer data on this subject makes it worthwhile to further look into it and establish firm grounds on which solid recommendations can be given for management of painful diabetic neuropathy with duloxetine and carbamazepine.

This was a small study in which 200 patients were enrolled. There was no significant difference in efficacy in males or females in both groups. Comparison of efficacy was done for both groups which showed 58% efficacy at 3 months in duloxetine group and 38% efficacy in carbamazepine group (p-value 0.005).

A systematic review was conducted for duloxetine in treatment of painful diabetic neuropathy in which six trials were included. Trials were found to be consistent, and showed an overall 41% patients achieving 50% pain relief with any dose of duloxetine compared

with 24% with placebo. This supports the results of our study though 58% patients in our study achieved 50% relief in visual analogue pain score which is higher than this systematic review¹⁰.

In one study by Mahmood R et al., carbamazepine was used to treat painful diabetic neuropathy. It was shown to decrease neuropathic pain by 50% on visual analogue pain score scale in 30.31% of patients. It supports the findings of our study in which carbamazepine have provided 50% pain relief in 38% patients.

In another study, carbamazepine was found to provide more than 50% pain relief in 41.2% patients. It is also in agreement with our study results.

Though it is a small-scale study with only 200 patients enrolled and there is a need to conduct large scale trials comparing these two important drugs, still implications are great and recommendations can be given based on these results.

Conclusion and Recommendations:

Duloxetine is more effective in treatment of painful diabetic neuropathy as compared to carbamazepine though both have been found to be significantly effective in treating this condition.

It is recommended that duloxetine should be first line medication in treatment of painful

diabetic neuropathy and if it is not effective carbamazepine should be given later.

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