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Comparative Evaluation of Pregabaline, Gabapentine, Sertraline And Du*l*oxetine in Painful Diabetic Non Insulin-Dependent Neuropathy

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Abstract

There are numerous studies that compare different drugs in painful diabetic neuropathy (Bansal, 2009; Goldstein, 2005; Morello, 1999; Wernicke, 2007) but our study tries to make a comparison between all four drugs and evaluate the associated depression. The study shows the results of drug therapy for painful diabetic non-insulin-dependent neuropathy after 6 months. Four drugs are compared for their efficiency and also the global perception of change by the patients. Another aspect is the reduction in depression symptoms caused by unsuccessful therapy before using the drugs used in this study. The study shows how the drugs are similar in efficiency in pairs of two, one pair of drugs being more efficient than the other.

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Keywords: pregabaline; gabapentine; sertraline, duloxetine

1. Objective

To compare the efficacy of pregabaline, gabapentine, sertraline and duloxetine in painful diabetic neuropathy (PDN).

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2. Research design and methods

In this observational trial, 28 patients received pregabaline, gabapentine, sertraline and duloxetine orally once daily at bedtime for duloxetine and twice in the morning at 8 a clock and at the bedtime, each for 6 months with optional dose uptitration (divided in four groups, each group has 7 patients). Pain relief was measured by the patient's global assessment of efficacy, using a visual analogue scale (0–10). Treatment goals include restoring function and improving pain control. Patients were randomly selected, the common factor being the presence of PDN. Patients of either sex with type 2 diabetes, aged between 25 and 83 years, who were on stable glucose-lowering medications during the preceding 3 month and who had PDN for at least 1 month were begin to be treated. Patients who had a pain score of >5, as assessed by visual analogue scale (VAS), were enrolled in our observation. PDN was confirmed by *1*) the patient's medical history, *2*) a diabetic neuropathy symptom and increased thresholds on the vibration perception test and monofilament test. Patients were excluded if they had any clinically significant or unstable medical or psychiatric illnesses. Patients with other causes of neuropathy; renal dysfunction , liver disease; psychiatric illness; uncontrolled hypertension; those taking anticonvulsants, antidepressants, local anaesthetics, or opioids; those who were pregnant; lactating women; or those being treated with any investigational drug within the last 30 days were excluded from this observation. All patients underwent 6 months of treatment with one drug and, at the end of 6 months, patients underwent clinical evaluation. One dose each of sertraline (50 or 100 mg once daily at bed time), gabapentine 400 mg three times daily with increasing the dose till 2400 mg, 75 pregabaline twice daily with increasing the dose till 300 mg two times a day and duloxetine (30 or 60 mg once daily at bed time) were used in the study. Treatment was started with the lowest dose of either drug, with fortnightly assessments with optional uptitration. The primary end point of the study was the reduction of the average pain score from initial results, as assessed by the patient's global assessment of efficacy by the VAS (0–10 points). Secondary end points included the 24-point Hamilton Rating Scale for Depression; and patient self-evaluation of overall change on the basis of patient global impression of change scale. Demographic characteristics were noted and all the parameters were measured before and after treatment with all four drugs and compared. Patients were not allowed any other pain medication.

3. Results and discussion

The study was conducted between January 2012 and June 2012. Population and samples: Total population was 28 participants randomly selected, divided into 4 groups of 7. Age varies between 25 and 83 years old, mean age 53.42 (SD 15.75), 12 male patients and 16 female patients, with duration of diabetes between 3 and 17 years, mean duration 3.90 (SD 11.03).

4. Gathered data analysis

Table 1. Values reported on visual analogue scale (VAS) by patients measuring pain.

	Sertraline Group		Gabapentine Group		Pregabaline Group		Duloxetine Group	
	Before Sertraline	After Sertraline	Before Gabapentine	After Gabapentine	Before Pregabaline	After Pregabaline	Before Duloxetine	After Duloxetine
Patient 1	5	3	6	5	9	5	8	2
Patient 2	6	5	7	6	8	2	9	1
Patient 3	5	3	8	6	7	1	10	3
Patient 4	7	7	5	5	6	3	8	3
Patient 5	6	6	9	8	7	5	7	2
Patient 6	9	8	8	7	9	5	9	1
Patient 7	8	8	7	6	10	3	10	4

All data collections in above table have been tested for normality of distribution using Shapiro-Wilk normal distribution test, and Normal Q-Q Plots. All data collections have been found to have normal distribution.