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Research Article

A COMPARATIVE STUDY ON THE EFFICACY OF DULOXETINE WITH AMITRIPTYLINE IN PATIENTS OF DIABETIC NEUROPATHY

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Abstract:

Aim: To compare efficacy of flap anchoring with suction drains alone after modified radical mastectomy. **Methods:** A total of 200 cases (100 in each group) between the age 20-65 years of any gender, ≥ 5 years' history of diabetes, symptoms of peripheral neuropathy for at least six months, having HbA1c $>7.5\%$ were included while those with co-existing other causes of peripheral neuropathy (porphyria, chronic renal failure, amyloidosis, leprosy, hypothyroidism), pregnant and lactating women and use of Duloxetine or amitriptyline in previous three months were excluded from the study. Randomization was done by computer generated random number table, to allocate patients to either group A (Duloxetine group) or group B (Amitriptyline group). Patients were instructed to take study medication in the morning, with a glass of water for up to 6 weeks. Group A was given 60mg Duloxetine each day and Group B was given 75mg amitriptyline in a single dose. Baseline pain was recorded on VAS. Diary card was provided to all patients at the baseline visit. Each morning during the 1st 3 weeks, patients would be instructed to record the severity of the symptoms in term of reduction in pain score recorded by visual analogue scale. After 3 weeks, an additional three weeks supply of medication was dispensed and patient were scheduled to return at week 6 for the final evaluation that recorded by me in terms of reduction in pain score and also assessed for 50% reduction in pain score from base line that was labeled as reduced. Patients were followed up by keeping telephonic contacts of patients.

Results: In this study, out of 200 cases (100 in each group) 21%(n=21) in Group-A and 17%(n=17) in Group-B were between 20-40 years of age while 79%(n=79) in Group-A and 83%(n=83) in Group-B were between 41-65 years of age, mean \pm sd was calculated as 47.08 ± 11.43 and 48.37 ± 10.83 respectively, 56%(n=56) in Group-A and 49%(n=49) in Group-B were male while 44%(n=44) in Group-a and 51%(n=51) in Group-B were females, comparison of efficacy in both groups was done which shows that 62%(n=62) in Group-A and 35%(n=35) in Group-B were treated effectively, which shows a significant difference between the two groups.

Conclusion: It is concluded that the efficacy of duloxetine as compare to the amitriptyline in terms of reduction in frequency of pain in the management of patients of diabetic neuropathy is significantly higher.

Keywords: Diabetic Neuropathy, Management, Duloxetine, Amitriptyline, Efficacy

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INTRODUCTION:

Presence of signs and symptoms of peripheral nerve dysfunction in diabetics like pain with any of following numbness, tingling and paresthesia in patients with diagnosed diabetes for more than 5 years is known as diabetic peripheral neuropathy (DPN). The commonest diabetic neuropathy is peripheral neuropathy, it is recorded in 47% of the subjects with diabetes mellitus when diagnosed with the help of nerve conduction testing. Diabetic neuropathy symptoms range from mild dysesthesias to severe unremitting pain which may potentially affect the quality of life. Various factors are involved in pathogenesis of DPN including hyperglycemia, dyslipidemia, growth factor deficiencies, oxidative and nitrosative stress, autoimmune damage to nerve fibers and microvascular insufficiency. The management of painful diabetic peripheral neuropathy is difficult and these cases require more attention as compared to those with other types of diabetic neuropathies. Commonly used classes of agents for the management of diabetic peripheral neuropathic pain are anticonvulsants, antidepressants, serotonin norepinephrine reuptake inhibitors and topical medications.

Now a day's first line therapies include TCA, SNRI, or anticonvulsant's considering the fact of cost and comorbidities. TCA like amitriptyline is proposed as a first line therapy for neuropathic pain. The mechanism action is considered to be inhibition of norepinephrine and / or serotonin reuptake within the central nervous system. However, other possible mechanisms include sodium channel effect, alpha-adrenergic blockage, and NMDA-receptor for antagonism. On the other hand, Duloxetine hydrochloride and pregabalin are also used for the relief of pain in diabetic peripheral neuropathy. Blockage of reuptake of serotonin and norepinephrine is the mechanism of this drug. This study was planned to explore the clinical improvement in patients with DPN on duloxetine as compared to amitriptyline. That will help us to modify the treatment of this common disorder resulting in better patient care.

MATERIAL AND METHODS:

A total of 200 cases (100 in each group) between the age 20-65 years of any gender, ≥ 5 years' history of

diabetes, symptoms of peripheral neuropathy for at least six months, having HbA1c $>7.5\%$ were included while those with co-existing other causes of peripheral neuropathy (porphyria, chronic renal failure, amyloidosis, leprosy, hypothyroidism), pregnant and lactating women and use of Duloxetine or amitriptyline in previous three months were excluded from the study. Randomization was done by computer generated random number table, to allocate patients to either group A (Duloxetine group) or group B (Amitriptyline group). Patients were instructed to take study medication in the morning, with a glass of water for up to 6 weeks. Group A was given 60mg Duloxetine each day and Group B was given 75mg amitriptyline in a single dose.

Baseline pain was recorded on VAS. Diary card was provided to all patients at the baseline visit. Each morning during the 1st 3 weeks, patients would be instructed to record the severity of the symptoms in term of reduction in pain score recorded by visual analogue scale. After 3 weeks, an additional three weeks supply of medication was dispensed and patient were scheduled to return at week 6 for the final evaluation that recorded by me in terms of reduction in pain score and also assessed for 50% reduction in pain score from base line that was labeled as reduced. Patients were followed up by keeping telephonic contacts of patients.

RESULTS:

In this study, out of 200 cases (100 in each group) 21%(n=21) in Group-A and 17%(n=17) in Group-B were between 20-40 years of age while 79%(n=79) in Group-A and 83%(n=83) in Group-B were between 41-65 years of age, mean \pm SD was calculated as 47.08 \pm 11.43 and 48.37 \pm 10.83 respectively, 56%(n=56) in Group-A and 49%(n=49) in Group-B were male while 44%(n=44) in Group-a and 51%(n=51) in Group-B were females, comparison of efficacy in both groups was done which shows that 62%(n=62) in Group-A and 35%(n=35) in Group-B were treated effectively, which shows a significant difference between the two groups.

Table 1: Comparison of Efficacy in Both Groups (n=200)

Efficacy	Group-A (n=100)		Group-B (n=100)	
	No. of patients	%	No. of patients	%
Yes	62	62	35	35
No	38	38	65	65
Total	100	100	100	100

P value= 0.000

DISCUSSION:

We planned this study to explore the clinical improvement in patients with DPN on duloxetine as compared to amitriptyline which may help us to modify the treatment of this common disorder resulting in better patient care. In our study, out of 200 cases (100 in each group) 21%(n=21) in Group-A and 17%(n=17) in Group-B were between 20-40 years of age while 79%(n=79) in Group-A and 83%(n=83) in Group-B were between 41-65 years of age, Mean±SD was calculated as 47.08±11.43 and 48.37±10.83 respectively, 56%(n=56) in Group-A and 49%(n=49) in Group-B were male while 44%(n=44) in Group-a and 51%(n=51) in Group-B were females, comparison of efficacy in both groups was done which shows that 62%(n=62) in Group-A and 35%(n=35) in Group-B were treated effectively, which shows a significant difference between the two groups. We found similar findings in a previous study showing 59% of the patients treated with duloxetine having reduction in pain. Another study 41.4% of patients treated with amitriptyline showed reduction in pain.

Duloxetine is reported to be well tolerated in the trials, with fewer withdrawals due to adverse events with 60 mg than with 120 mg. Most adverse events were reported to be mild or moderate, with nausea, somnolence, constipation, decreased appetite and dry mouth frequently mentioned. In stress incontinence duloxetine affects the resting tone and contraction of the urethral striated sphincter muscle. It might be expected to cause symptoms of urinary hesitancy in patients without incontinence, but urinary problems were not reported in any of these trials, or in trials of duloxetine in depression. The results of our study clearly justify the hypothesis of the study that “Duloxetine is more effective in reducing the pain in patients of diabetic neuropathy as compared to amitriptyline” is justified. However, being the limitation of the study, we did not analyze the side effects and withdrawals of the treatment in our study, which is recommended in further trials.

CONCLUSION:

It is concluded that the efficacy of duloxetine as compare to the amitriptyline in terms of reduction in frequency of pain in the management of patients of diabetic neuropathy is significantly higher.

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