

Diabetic Peripheral Neuropathy Controlled by Diametrol

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Type-2 Diabetes Mellitus (T2DM) is a life-long disease that affects metabolism of glucose with an increasing worldwide incidence. Health complications caused by T2DM such as peripheral neuropathy in both diabetic and pre-diabetic patients has a major impact on quality of life. As such, T2DM is a global health problem affecting approximately 422 million individuals globally and increasing progressively as pre-diabetes almost 3 times more than diabetes [1]. Despite development of effective controller medications such as metformin, a substantial proportion of patients continue to have side effects [2]. One of metformin side effects is neuropathy, created by vitamin B₁₂ deficiency in diabetic patients [3]. Consequently, part of the current high unmet medical need in T2DM is treatment for nerve pain using second controller medications such as gabapentin (Gralise, Neurontin), pregabalin (Lyrica) and carbamazepine (Carbatrol, Tegretol). However, these medications have limited effectiveness on patients and side effects must be weighed against the benefits they offer [4]. Several alternative therapies, like capsaicin cream (Made from chili peppers), physical therapy or acupuncture may relieve pain, but with limited success.

Recently, an alternative product, Diametrol[®], composed of several natural ingredients, was introduced as a Functional Food for diabetics and pre-diabetics patients. The Food Drug Administration (FDA) certified Diametrol[®] as a nutraceutical for its consumption nationally and internationally. In a randomized double blind case-control preliminary study on non-ambulatory diabetic (Type 2) patients conducted in the clinics of a reputed hospital (BIRDEM, Bangladesh) Diametrol[™] was found to be significantly anti-inflammatory and capable of lowering blood sugar in patients with uncontrolled blood sugar even when treated with a combination of several hypoglycemic drugs. Diametrol[®] was also found to lower the fasting insulin significantly in pre-diabetic patients, thus controlling the Insulin Resistance (IR), a hallmark of T2DM.

The purpose of this observational study was to measure the effects of Diametrol[®] on T2DM patients with severe peripheral neuropathy in terms of debilitating diabetic nerve pain. Five patients volunteered for a 1 month study and who were provided with documentations that clearly stated the purpose of the study, as well as given literature on previous Diametrol[®] studies. In conformity with the word limitation, the patient narratives are reported briefly below:

Case No: 1

Treatment: Diametrol[®]

Demographics: 76 year-old Asian-American female

Event: T2DM

Concurrent medications: Metformin

Patient has a history of tingling and numbness in legs and feet, including leg cramps and spasms at night. Intense pain induced contortions in her feet which had to be straightened by family members and lowered her quality of life. Patient began Diametrol[®] treatment, 2 tablets twice a day as recommended. After one week, patient reported an overall feeling of wellness. After 2 weeks patient reported improvement in her leg cramps, having had one episode since beginning Diametrol[®] treatment. Patient reported tingling sensation improvement as well. Blood sugar levels were controlled.

Case No: 2

Treatment: Diametrol[®]

Demographics: 82 year-old Caucasian female

Event: T2 DM, hypertension and anxiety disorder

Concurrent medications: Metformin

Patient presented with complaints of burning sensation in her hands and legs, which affected her sleep and caused anxiety due to the discomfort. Patient began Diametrol[®] treatment, 2 tablets twice a day as recommended. At the end of 2 weeks, patient reported moderate improvement in burning and tingling sensations. Sleeping was much improved which lead the patient to feel less anxious:

Case No: 3

Treatment: Diametrol[®]

Demographics: 65 year-old Caucasian female

Event: T2DM, hypertension, and depression

Concurrent medications: Metformin

Patient presented with complaints of pain and cramps in her legs and feet over a year, which affected her sleep. Patient discontinued taking Diametrol[®] after 5 days of treatment due to diarrhea-like symptoms. The patient was unclear as to whether Diametrol[®] caused her diarrhea-like symptoms. Therefore, conclusions could not be drawn on the efficacy of Diametrol[®]:

Case No: 4

Treatment: Diametrol[®]

Demographics: 58 year-old African American male

Event: T2DM, hypercholesterolemia

Concurrent medications: Metformin

Patient complained of burning sensation in his feet and legs along with night cramps for 6 months and was taking metformin for more than a year. The patient began Diametrol[®] treatment, 2 tablets twice a day as recommended. After 3 weeks, the patient reported moderate improvement of his symptoms of neuropathy and leg cramps:

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Case No: 5

Treatment: Diametrol[®]

Demographics: 66-year-old African American female

Event: T2DM, hypertension, hypercholesterolemia and depression

Concurrent medications: Metformin

The patient presented with complaints of difficulty sleeping due to restlessness, tingling, and cramping in her legs, which caused severe daytime fatigue. The patient began Diametrol[®] treatment, 2 tablets twice a day as recommended. The patient reported moderate improvement of leg cramps and burning sensation in her feet within 4 weeks.

The study was conducted well with respect to study protocol, study drug exposure, and prospective monitoring of the quality of patient life improvement. Patients have shown overall improvement of peripheral neuropathy and leg cramps. Interestingly, none of the patients, except one, reported any undesirable side effects, rather most of them expressed

satisfactions in terms of their gain in energy and wellness. Therefore, further clinical trials are recommended for statistically verifiable results.

References

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