

PREGABALIN FOR THE TREATMENT OF PAINFUL DIABETIC NEUROPATHY OF THE FOOT AND ANKLE AND POSSIBLE PREVENTION OF NEUROPATHIC ULCERATION

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Painful diabetic peripheral neuropathy (DPN) is a common complication of long-standing diabetes. Symptoms of DPN may range from tingling, burning sensations to frank numbness of the distal extremities. Lack of sensation in combination with increased time and pressure to the foot and ankle may lead to ulceration, infection, and eventual amputation. Any therapeutic intervention that will decrease the degree of obtunded sensation may ultimately decrease the rate of amputation. A clinical trial was conducted to evaluate the efficacy of pregabalin in alleviating DPN symptoms of the foot and ankle and increasing overall proprioception and stability in gait. Inclusion criteria for the study were a clinical diagnosis of diabetes mellitus with neuropathy, palpable pedal pulses, no acute infection, and no contraindications to taking pregabalin as prescribed. Forty consecutive patients were included in the study and prescribed pregabalin at a dose of 75 mg twice daily for 4 weeks. The mean duration of DPN symptoms was 6.2 years (range 2 months to 10 years). The average daily pain score was assessed using a visual analog scale (0 = no pain, 10 = worst pain possible). The treatment group was compared to a placebo group studied by Rosenstock et al. All 40 patients complied with the aforementioned study protocol. The average reduction in pain from baseline was 2 visual analogue scale points (range 0 to 7), with 45% of patients having a reduction of 50% of their pain. Numbness was assessed via 5.07 g Semmes-Weinstein monofilament test and improved in 66% of patients. The most common side effects were somnolence, dry mouth, and blurred vision. Four percent of patients discontinued the treatment due to side effects. Twenty two percent of patients stated that they had an improved balance and stability of their foot and ankle. Twenty five percent of the patients had a prior history of a Grade 1 or 2 ulceration, and the remainder had a history of pre-ulcerative lesions. Clinical evaluation at 3 months showed no sign of ulcerative breakdown in any of the study participants.

Perspective: Pregabalin is effective in the treatment of painful DPN of the foot and ankle. It is an efficacious and safe treatment that may ultimately decrease the rate of ulceration, infection, and amputation associated with DPN. Long-term follow-up will be necessary to determine if pregabalin may aid in possible prevention of neuropathic ulceration.

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