0.075% Capsaicin Lotion for Treatment of Painful Diabetic Neuropathy: A Randomized, Double-blind, Crossover, Placebo-Controlled Trial

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Background: Oral medication demonstrates modest efficacy in relieving painful diabetic neuropathy (PDN). Topical medication has been tested with the same success. We aim to test capsaicin, a vanilloid 1 receptor agonist, with 0.075% lotion for treatment of PDN.

Objectives: To test the efficacy and safety of 0.075% capsaicin lotion for painful diabetic neuropathy.

Methods: We conducted a 20-week, double-blinded, crossover, randomized, two-center study in subjects with PDN. We randomly assigned patients to receive 0.075% capsaicin lotion or placebo for 8 weeks, with a washout period of 4 weeks between the two treatments. Primary endpoint was the measure of change in visual analog scale (0-100 mm) of pain severity. Secondary outcomes were score change in Neuropathic Pain Scale (NPS), short-form McGill Pain Questionnaires (SF-MPQ), the proportion of patients who had pain score reductions of 30% and 50% and adverse events.

Results: A total of 42 subjects were enrolled. Of these, 27 completed at least 8-week treatment period. Intention-to-treat analysis showed no significant improvement in pain control with capsaicin lotion, compared to placebo for visual analog scale (VAS) score (34.3 mm vs 36.3 mm, p = 0.725). No significant difference between the two groups was found in NPS (27.23 vs 25.13, p = 0.595), SF-MPQ (9.07 vs 9.72, p= 0.775). Per-protocol analysis also showed similar results in pain for all measured outcomes. Capsaicin lotion was well tolerated. Its major side effect was skin reaction and without serious adverse events.

Conclusion: In patients with PDN, 0.075% capsaicin lotion does not provide significant pain relief, when compared to placebo. However, it is safe with minor skin reaction.

Keywords: Capsaicin, Neuropathic pain, Diabetic neuropathy, Topical lotion