

Original Article

A Randomized Clinical Trial of the Effectiveness of Photon Stimulation on Pain, Sensation, and Quality of Life in Patients With Diabetic Peripheral Neuropathy

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Abstract

Context. Peripheral neuropathy is one of the most common complications of diabetes.

Objectives. The purpose of this study was to evaluate the effects of photon stimulation on pain intensity, pain relief, pain qualities, sensation and quality of life (QOL) in patients with painful diabetic peripheral neuropathy.

Methods. In this randomized, placebo-controlled trial, patients were assigned to receive either four photon stimulations ($n = 63$) or four placebo ($n = 58$) treatments. Pain intensity, pain relief, and pain qualities were assessed using self-report questionnaires. Sensation was evaluated using monofilament testing. QOL was measured using the Medical Outcomes Study Short Form-36 (SF-36). Multilevel regression model analyses were used to evaluate between-group differences in study outcomes.

Results. No differences, over time, in any pain intensity scores (i.e., pain intensity immediately post-treatment, average pain, worst pain) or pain relief scores were found between the placebo and treatment groups. However, significant decreases, over time, were found in some pain quality scores, and significant improvements in sensation were found in patients who received the

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photon stimulation compared with placebo. In addition, patients in the treatment group reported significant improvements in SF-36 social functioning and mental health scores. Findings from a responder analysis demonstrated that no differences were found in the percentages of patients in the placebo and treatment groups who received 30% or more or 50% or more reduction in pain scores immediately post-treatment. However, significant differences were found in the distribution of the changes in pain relief scores, with most of the patients in the photon stimulation group reporting a slight (28.6%) to moderate (34.9%) improvement in pain relief from the beginning to the end of the study compared with no change in pain relief (43.1%) in the placebo group.

Conclusion. Four treatments with photon stimulation resulted in significant improvements in some pain qualities, sensation, and QOL outcomes in a sample of patients with a significant amount of pain and disability from their diabetes. A longer duration study is needed to further refine the photon stimulation treatment protocol in these chronically ill patients and to evaluate the sustainability of its effects. *J Pain Symptom Manage* 2010;39:88–99. © 2010 U.S. Cancer Pain Relief Committee. Published by Elsevier Inc. All rights reserved.

Key Words

Neuropathic pain, diabetes, photon stimulation, quality of life, pain, sensation

Introduction

Peripheral neuropathy is one of the most common complications of diabetes. The concomitant loss of protective sensation increases the patients' risk for foot ulcers and contributes to the increased incidence of lower-extremity amputations.^{1–3}

The prevalence of painful diabetic peripheral neuropathy (PDPN) ranges between 16% and 26%,^{4–6} and a significant percentage of patients experience moderate to severe pain.⁵ In addition, PDPN is known to have a profound impact on patients' sleep, mood, daily activities, and quality of life (QOL).^{7–12}

A wide variety of analgesic medications (e.g., antidepressants, anticonvulsants, topical agents, opioids) have been evaluated in patients with PDPN.^{13–15} The results of a recent systematic review that defined clinical success as a 50% reduction in pain¹⁶ found that tricyclic antidepressants were the most effective analgesics, followed by traditional anticonvulsants and then newer-generation anticonvulsants. However, the review concluded that the efficacy of most of these pharmacological treatments is limited, because for any particular drug, only 30% of patients treated will experience analgesia. In addition, adverse effects occur frequently with all of these

medications and often cause patients to discontinue treatment.

Based on the limited efficacy of current analgesics available for the management of PDPN, new approaches are needed to reduce pain and improve patient outcomes. One such approach, which has been tested in patients with PDPN, is photon stimulation delivered using light-emitting diodes (LEDs). Photon stimulation is sometimes referred to in the literature as pulsed infrared light therapy or photobiomodulation.^{17,18} In an excellent review,¹⁷ Desmet et al. summarized the clinical and experimental applications of LED photon stimulation. LED arrays were initially developed by the U.S. National Aeronautics and Space Administration for experimental plant growth in space. Their clinical applications began to be evaluated after observations were made that low-energy stimulation of tissues by lasers increased cellular activity during wound healing.^{19,20} LEDs have several advantages over lasers for clinical use. They can be configured to produce multiple wavelengths, can be arranged in large flat arrays to treat a wide three-dimensional surface, and are compact. In addition, because LED light is produced out of phase, it does not emit heat. Therefore, at intensities required to penetrate deeper tissues, there is no risk of heat damage

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