Use Of Low-Level Laser Therapy In Managing Painful Diabetic Neuropathy

D Ip

Citation

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Abstract

Introduction: This paper reports on the medium-term mean 2-year prospective follow-up of an elderly patient cohort of 21 unselected patients with mean age of 69 years who visited our tertiary referral pain center for painful diabetic neuropathy with history of frequent falls leading to one or more osteoporotic fractures with a view for treatment with low-level laser therapy (LLLT) not only for pain relief, but also to prevent further fall causing possible further fractures.

Materials and methods: All patients in this prospective cohort study had documentation of the diagnosis of bilateral lower limb peripheral neuropathy by nerve conduction studies with both lower limb pain and numbness in glove-and-stocking distribution as well as frequent fall leading to one or more osteoporotic fractures in the past. Low-level laser therapy (LLLT) at a wavelength of 810 nm emitted from a GaAlAs semiconductor laser device with 5.4 J per point and a power density of 20 mW/cm2, was employed to irradiate the bilaterally affected lower limbs of all subjects. The treatment regimen consisted of three sessions of treatment per week for 12 consecutive weeks. Each treatment session lasted 360 seconds for each lower extremity. Serial clinical assessment was undertaken using the Visual Analogue Score (VAS) for pain. Treatment failure was defined as lack of clinical response in terms of decrease in pain and numbness at the 12 week mark. The number of falls if any during the study period was noted.

Results: All subjects showed significant improvement in VAS pain score at the end of 12-weeks' LLLT treatment and, surprisingly, the improvement was found maintained at follow-up assessments at 1 year mark and 2 year mark. Only one subject reported a fall episode during the 2 year subsequent clinical follow up.

INTRODUCTION

The use of low-level laser therapy (LLLT) in the management of deep seated structures such as bony fractures with delayed union had previously been reported by the author in this journal (1), but this technology can also be effective in treating other tissues such as neural structures. As high-lighted previously by the author in published journals, LLLT is a form of non-invasive physical therapy treatment modality that have bio-modulation action as well as anti-inflammatory actions; unlike conventional physical therapy machines such as ultrasound, trans-cutaneous electrical stimulation and so forth which neither have anti-inflammatory action nor bio-modulation actions on body cells. As shown by Chow et al (2) the pain relieving function of LLLT not only stems from its anti-inflammatory actions, but also, by dint of its action on peripheral nerves which is the structure of interest in this study.

This forms the rationale of the author using a scanning mode of LLLT to the whole affected lower third of both lower limbs of all subjects under study. The reader can find the relevant basic science studies on the subject of sciatica in the recently published book chapter written by the author (3).

MATERIALS & METHODS

The study spanned from 2016 to 2019. The study population consisted of a prospective cohort of consecutive unselected 21 patients with mean age of 69 (range: 66–81) years being referred to our tertiary referral pain center previously having failed response to a combination of nonsteroidal anti-inflammatory medications and not fewer than 6 weeks of conventional physical therapy. Nerve conduction studies were used to confirm peripheral neuropathy in both lower limbs. All subjects had long-standing diabetes followed by physicians. Exclusion criteria included patients with

previous history of tumor or ongoing sepsis. We also excluded patients with previous neuromuscular conditions of the affected lower extremity, such as a previous cerebrovascular accident. All patients signed informed consent detailing that they would be treated by LLLT and that only US Food and Drug Administration-approved devices would be used.

All patients received 3 treatment sessions per week for 12 consecutive weeks. Each treatment session consisted of 360 seconds irradiation using the scanning mode to each of the affected lower extremity. None of the subjects consent to the use of sham light source as control.

RESULTS

The male:female ratio of the study population was 2:1 with mean age of 69 (range: 66 to 81 years of age). The mean VAS pain score at study entry was 7 out of 10 (range: 6-9 out of 10). The mean VAS pain score upon completion of the study at the 12 week mark was 2 out of 10 (range 0 to 3 out of 10). All subjects had good clinical response in terms of pain relief and numbness reduction and all were satisfied with the procedure. As none of the subjects agreed to a sham light source as control, a placebo group cannot be arranged in the current scenario. Upon completion of the treatment, each subject was followed up on monthly basis either in the clinic or via telephone interview. At one year mark, the mean VAS pain score was still 2 out of 10 (range 0 to 3 out of 10), and the status was maintained during follow up in the 2 year mark. Analysis of the results using statistical methods showed statistical significance at ($p < 0.5$) and the null hypothesis was rejected.

There was one documented fall incident amongst all 21 subjects during the 2 year follow up. No side effects were documented during the clinical study and follow up period in all subjects.

DISCUSSION

The mechanism of diabetic neuropathy involves diacylglycerol formation causing protein kinase c activation that in turn causes vascular and neural degeneration (4)

The mechanism of pain relief by LLLT is manifold. Firstly, researchers found LLLT mimic the effect of anti-inflammatory medications by inhibition of cyclooxygenase 2 as reported by Sakurai (5). Other workers like Yamamoto have suggested possible role of an increase in endorphin production (6). What is more important in the present context is the possible role of LLLT in increasing the nociceptive threshold resulting in neural blockade., to be more specific: an inhibition of the A and C neural fibres (7). This inhibition can also be brought about by altering axonal flow (3) or via the inhibition of neural enzymes (7). Besides concomitant bio-modulation effects, LLLT can also increase the local blood flow via nitric oxide pathway (8, 9).

The current study represents a prospective clinical study detailing the extremely high success rate of conservative treatment of painful diabetic peripheral neuropathy of the lower extremity. Diabetes incidence is on the rise worldwide. Diabetic patients with neuropathy have x 1.7 fold risk of amputation & x 25-50% higher mortality rate than diabetic patients with no neuropathy, not to mention a higher rate of fall and osteoporotic fractures.

CONCLUSION

While conventional pharmacological treatment of painful diabetic neuropathy involves the use of anti-convulsants, anti-depressants, opoid analgesics, which are usually not too well tolerated by the elderly; this clinical study confirms high clinical efficacy of LLLT treatment of this group of elderly subjects with no side effects, and lasting benefits in terms of pain and numbness prevention, as well as fall prevention.

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Author Information

David Ip
Wellness Pain Centre
Hong Kong