Effects of monochromatic infrared energy therapy on diabetic feet with peripheral sensory neuropathy: a randomised controlled trial

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ABSTRACT

Introduction: Peripheral diabetic neuropathy, which is a cause of increasing morbidity and mortality following foot ulcers and amputations, is a burden to health and the economy. Various adjunct treatments to improve neuropathy have been introduced into the market; one such treatment is monochromatic infrared energy (MIRE) therapy, which claimed to produce promising results. This study aimed to evaluate the effects of MIRE on diabetic feet with peripheral neuropathy.

Methods: A randomised controlled, single-blinded study was conducted at Hospital Universiti Sains Malaysia from February 2008 to October 2008. A total of 30 feet from 24 patients were studied. Neuropathy was screened using the Michigan neuropathy scoring instrument, followed by an assessment of the current perception threshold using a neurometer at frequencies of 2,000 Hz, 250 Hz and 5 Hz. The feet were randomised to receive either daily MIRE or sham treatment for a total of 12 treatments. Each foot was then reassessed using the neurometer at six weeks and three months following treatment.

Results: The data obtained was analysed using a non-parametric test to compare the pre- and post-treatment groups. No significant difference was found between the neuropathic foot of diabetic patients in both the MIRE and sham groups.

Conclusion: No improvement of neuropathy was observed following MIRE treatment in the neuropathic feet of diabetic patients.

Keywords: diabetes complications, diabetic foot, infrared therapy, peripheral neuropathy

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INTRODUCTION

Diabetic peripheral neuropathy is a common complication of long-term diabetes mellitus, which subsequently leads to foot ulceration. Most of these complications result in amputation of part of the foot or leg. It has been estimated that at least 171 million people worldwide would suffer from diabetes mellitus by the year 2030,[1] and around 50% of them would develop peripheral neuropathy.[2] Therefore, prevention and treatment of neuropathy is vital. Until now, however, no appropriate treatment that could treat or reverse neuropathy once it has set in exists. Currently, only education regarding foot care[3] and glycaemic control[4] can help in delaying the onset of neuropathy.[5] Multiple consensus, guidelines and surgical treatment for diabetic neuropathy have been widely described in the literature.[6]

Recently, a few studies have suggested the use of single monochromatic infrared energy (MIRE) as an adjunct treatment to improve the sensation in the neuropathic foot.[7,8] The MIRE technique had been shown to increase blood circulation by 400% over the baseline circulation after 30 minutes of application, as opposed to elevation of skin temperature to the same degree with heat therapy, which increases blood flow by only 40%.[9] Increased circulation possibly accounts for the reported symptomatic reversal of any associated neuropathy.[7,10] Many interventional studies reported in the literature have also shown that MIRE treatment could improve the symptoms of neuropathy. However, few randomised studies have proven the opposite in terms of sensory improvement.[11,12] Lavery et al[11] and Cliff et al[12] used monofilament assessment tools to test and map out the neuropathy. According to this method, the bias would arise due to the examiner, the patients and the material that has been produced commercially by various companies. A 10% variation has been found in association with the various types of monofilaments that are available in the market.[13] Semmes-Weinstein monofilament is a helpful screening tool, although it is not the sole diagnostic tool.[14]

The current study used a neurometer that had an objective assessment with less bias;[15] the neurometer produced a current perception threshold that measured definite sensory deficits in myelinated and unmyelinated nerve fibres at different frequencies, i.e. 2,000 Hz, 250 Hz and 5 Hz, which were the recommended frequencies for the assessment of peripheral neuropathy.[16] The aim of this study was to evaluate the effects of MIRE on diabetic feet with peripheral neuropathy.

Table I. Patient profiles.

Parameter (valid no = 30)	Mean ± SD; range
Age (yrs)	54.43 ± 8.78; 38.0–81.0
Duration of diabetes mellitus (yrs)	12.27 ± 8.03; 0.2–30.0
Height (m)	1.51 ± 0.085; 1.4–1.7
Weight (kg)	56.77 ± 10.37; 43.0–83.0
MNSI (n = 10)	4.08 ± 1.57; 2.0–8.0

SD: standard deviation; MNSI: Michigan Neuropathy Scoring Instrument

METHODS

This was a randomised, controlled, single-blinded study conducted at the orthopaedic ward of Hospital Universiti Sains Malaysia from February 2008 to October 2008. The study subjects were diabetic patients admitted to the orthopaedic ward for various causes. They were selected based on the diagnostic criteria set by the American Diabetic Association. An additional inclusion criterion was a score of 2–8 on the Michigan Neuropathy Scoring Instrument (MNSI) scheme. Patients having concurrent back pain with neurology and/or a history of spinal surgery, those on medications that may induce neuropathy and those who had a history of chronic alcohol intake or renal complications (e.g. uraemia, chronic renal disease) were excluded from the study.

The standard deviations (SDs) for the frequencies of 2,000 Hz, 250 Hz and 5 Hz obtained from the manual of the neurometer were 110, 52 and 34, respectively. A difference of ≥ 120 units in the neurometer readings pre- and post treatments was considered significant. The sample sizes for the frequencies of 2,000 Hz, 250 Hz and 5 Hz were 13, five and three, respectively. To obtain a power of 80% for the study, we found that 13 samples were sufficient to cover the sample size for each of the three frequency groups. With the inclusion of a 10% drop-out rate, 15 samples would be required for each frequency group. A total of 30 samples were thus required for the study.

A total of 30 feet were selected from screened patients admitted to the orthopaedic ward. This study was approved by the ethics committee of the institution. After obtaining informed consent from the patients, information about age, gender, type and duration of diabetes mellitus was obtained. The height and weight of all patients were measured and charted on the data collection sheet. Blood was taken for serum urea estimation and assessment of liver function. The previous blood sugar level was reviewed from the records of patients who were already on treatment for diabetes mellitus. The study required that patients should be able to understand and follow the procedure, especially during measurement with the neurometer. Patients who consented to the study were screened for neuropathy using the MNSI examination sheet.

Each foot was assessed for any abnormalities such as ulcer, callosity or deformities. Vibration perception was checked using a 128-Hz tuning fork at the patient's big toe and compared with the vibration perception at the patient's thumb. If the two measurements of vibration perception were comparable, then the score was marked as 0, and if reduced, it was marked as 0.5 point. Monofilament testing with a 10g Semmes-Weinstein monofilament (Northcoast Medical Inc, Morgan Hill, CA, USA) was used to detect pressure sensation over the big toe. The filament was pressed against the skin for 1–2 seconds. If the patient could not feel the applied pressure at that area, then perception was considered to be absent. If the pressure was perceived to be reduced, it was marked as 0.5. This procedure was repeated for the other foot, and the total points were calculated. Patients who had a score of 2–8 were included in the study.

Both the feet of a single patient were considered if the criteria for inclusion in the study were met. However, since most of the patients were admitted to the hospital due to an infected foot, only the uninfected foot of the patient was included in the study. The neuropathy was then assessed with the Neurometer® Nervscan 2000 (Neurotron Inc, Baltimore County, MD, USA) at three current perception thresholds, i.e. at stimulation frequencies of 2,000 Hz, 250 Hz and 5 Hz.

The feet were randomised into the sham group and the MIRE group using a computer-generated randomisation plan. In the sham group, the pad of the MIRE device was applied to the foot, but the switch was not activated and the patient was blinded to this information. The pads were applied daily for 30 minutes for a total of 12 treatments in both groups. At the end of the treatment, the neuropathy assessment was repeated. This was done after six weeks of treatment and repeated after three months of treatment.

Table II. Differences in neurometer readings before and after the six-week treatment for the sham and MIRE treatment groups.

Frequency (Hz)	Sham group		MIRE group	
	Pre-treatment	Post-treatment	Pre-treatment	Post-treatment
2,000	16.83 ± 7.42	18.67 ± 7.78	15.0 ± 8.78	14.92 ± 9.76
250	18.83 ± 6.83	19.58 ± 5.85	18.38 ± 8.83	19.77 ± 8.20
5	22.83 ± 3.43	23.17 ± 4.30	20.77 ± 7.96	21.92 ± 7.56

Note: Data is presented as the mean ± standard deviation. MIRE: monochromatic infrared energy

RESULTS

All enrolled patients successfully completed the study according to the protocol. A total of 24 patients (30 feet) were enrolled into the study, out of which 16 were female and eight were male. The mean age was 54.4 (range 38–81) years. The mean duration of diabetes mellitus from the time of diagnosis was 12.3 years (range two months to 30 years) (Table I). All patients were diagnosed with Type 2 diabetes mellitus and were admitted for either foot or upper limb infection. As infected feet were excluded, a total of 12 right feet and 18 left feet from the 24 patients were included in the study. The 30 feet were randomised into the sham group (n = 15) and the MIRE treatment group (n = 15). The sham group comprised three right feet and 12 left feet, while the MIRE group consisted of nine right feet and six left feet. Table I shows the diverse profiles of the patients recruited in the study.

Table II shows the mean ± SD of the neurometer score before and after treatment for the sham and MIRE groups at each frequency. Patients in both groups showed a reading of nearly maximum neuropathy at a frequency of 5 Hz, which suggested that this group had profound neurosensory loss in their feet. Mann-Whitney test for non-parametric independent samples, which was used to compare the frequencies (i.e. 2,000 Hz, 250 Hz and 5 Hz) after the MIRE and sham treatment, showed that the improvement with MIRE treatment was not statistically significant.

DISCUSSION

No significant differences were observed between diabetes mellitus patients with peripheral neuropathy who received MIRE and sham treatments. This finding was observed in all perception stimuli of 2,000 Hz, 250 Hz and 5 Hz frequencies. Prendergast et al found some improvement in current perception stimuli at 2,000 Hz and 250 Hz in their single-limb study.[17] However, the current study could not detect any significant improvement after the completion of 12 treatment rounds in both the MIRE and sham groups at the six-week and three-month follow-ups. This finding contradicts the results of previous studies using monofilament assessment.[8,18] The results of the current study were similar to those observed in the studies of Cliff et al[12] and Lavery et al,[11] whose methods of assessment for improvement also made use of monofilaments. In addition, Lavery et al used various other methods of assessment, including vibration perception threshold, nerve conduction velocities and MNSI.[11]

In previous randomised studies, Semmes-Weinstein monofilament was used to assess neuropathy by detecting the areas on the foot with sensory deficit alone. The number and site tested by monofilament varied.[12,19] Each of the commercial type of monofilaments used also had different variability, which was estimated to be around 10%.[13] Since the current study used a neurometer to assess the neuroselective myelinated and unmyelinated nerve fibres in the affected neuropathic foot, it could be considered to be more quantitative and objective. Prendergast et al, who also used current perception threshold in their study to monitor sensory improvement following MIRE treatment, suggested that a neurometer was able to detect significant improvement in large and small myelinated nerves but not in small and unmyelinated nerves.[17] The findings of Prendergast et al were taken into account when interpreting the findings of the current study; however, we obtained contradictory results. The current study did not detect any improvement in the large and small myelinated nerves.

Studies conducted on the effect of MIRE in diabetic patients who did not have current active infection in the body reported an improvement of sensory neuropathy following treatment.[12,17-19] Since most of the patients in this study were admitted due to foot infections, hyperglycaemia during illness or infection could have exaggerated the neuropathy and compromised the effectiveness of the MIRE treatment. Moreover, as most of the subjects already suffered from profound neuropathy, no other treatment method would have improved the disease. The outcome of the study could have been

improved if the patients had only peripheral neuropathy without infection and were warded. However, this was not done due to problems with patient recruitment. The foot assessed, however, did not include the infected foot. In this study, no improvement in neuropathy was observed with MIRE treatment. The improvement reported in previous studies may have been due to various other reasons, as mentioned by Prendergast et al.[17]

A larger group of patients with milder clinical neuropathy would probably have yielded different results. Moreover, the neurometer measurement was tested shortly after the completion of the study and was not repeated. The short duration of treatment in this study may have been responsible for the undetectable nerve recovery. If MIRE therapy had increased circulation around the nerve, the neurometer would have detected any slight differences. Thus, longer and more frequent MIRE therapy sessions may likely show an improvement in the long run; however, this is beyond the scope of the current study. Since none of the previously published randomised studies had used the neurometer to assess neuropathy and its recovery, an attempt to use it in a study with a longer duration would be advisable. Further studies to validate its usefulness and assess its relationship with foot ulcer and amputation incidence rates could be useful.

In conclusion, neuropathy is a common complication of diabetes mellitus worldwide. In the absence of a promising and effective treatment, more and more patients would be living with the morbidity. New methods of treatment should not be adopted without consideration for its cost to patients and the effectiveness of the treatment. Clinicians should be well versed with the different treatment options available so as to decide which option would prove the most useful before recommending it to patients. This study has not found the MIRE treatment to be beneficial to diabetic patients with neuropathy.

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