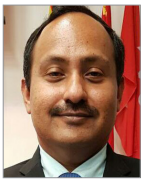
Monochromatic infrared therapy in patients with diabetic peripheral neuropathy: a pilot study



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Neuropathy is the most common microvascular obstacle among patients with diabetes and can involve peripheral, central and/or autonomic nervous systems. Diabetic peripheral neuropathy (DPN) has a lifetime prevalence of approximately 50% and its prevalence increases with the duration of diabetes. DPN places a huge burden on public health and the economy, accounting for a rise in morbidity and mortality following foot ulcers and amputations. This study aims to determine the effect of monochromatic infrared therapy (MIRE) in people with DPN. The study took place in an outpatient setting at the Wound Care Unit, Hospital Kuala Lumpur, Malaysia (WCUHKL), using two participants with long-standing diabetes mellitus who were attending their routine treatment visit. Both patients received an hour of active monochromatic Infrared energy (MIRE) after each dressing follow-up, which was twice a week and continued until wound closure. Pain scores and numbness were documented every Monday, using the Visual Analogue Score (VAS) while neurological examination took place during foot assessment. MIRE is demonstrably effective, especially in managing DPN that includes numbness, which disappeared (along with muscle spasms) in week eight. Wound healing took some time; one healed within 17 weeks whereas the other healed in week 23. There was also an improvement in the ankle brachial systolic index (ABSI) from 0.8 to 0.9 in both patients during the vascular assessment. Therefore, MIRE therapy is an effective adjunctive therapy in managing DPN and helps perfuse the limb. As this was a pilot study, the small sample size was a limitation, and more studies more required to vailidate the result.

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Neuropathy is the most common microvascular obstacle among diabetics and can involve peripheral, central and/or autonomic nervous systems (Callaghan et al, 2012; Papanas and Ziegler, 2012; Tesfaye and Selvarajah, 2012). Diabetic peripheral neuropathy (DPN) has a lifetime prevalence of approximately 50% (Tesfaye and Selvarajah, 2012; Mehra et al, 2014; Juster-Switlyk and Smith, 2016) and its prevalence increases with the duration of diabetes. DPN is a cause of rising morbidity and mortality following foot ulcers and amputations, which places a huge burden on public health and the economy (Ko and Cha, 2012).

The symptoms are usually symmetrical and predominantly sensory, starting distally and gradually spreading proximally in a glove and stocking distribution. People with early DPN usually experience pain that worsens at night, including perceived numbness and a tingling sensation in the feet and hands (Tesfaye and Selvarajah, 2012). Despite the prevalence of DPN, many people are asymptomatic and therefore do not seek help (Gregg et al, 2004). Although there is no definitive intervention for the treatment of DPN, the mainstay generally hinges on rigorous glycaemic control and reduction of pain and paraesthesia by either topical or systemic means (Tesfaye and Selvarajah, 2012). Hence we used adjunctive treatments to improve circulation and reduce pain, alongside other medications.

Monochromatic Infrared energy (MIRE) is

an adjunct therapy to the management of DPN. MIRE was cleared by the United States Food and Drug Administration (FDA) in 1994 for increasing circulation and reducing pain, stiffness and muscle spasm. In a sham-controlled randomised trial, Leonard et al (2004) reported improved sensitivity, less pain and better balance in the limbs of DPN patients treated with the active device. On the other hand, multiple other retrospective and prospective case studies state that MIRE treatment was associated with an improvement in peripheral neuropathy, as measured by changes in sensitivity recorded by the Semmes-Weinstein monofilament (Powel et al, 2004; Prendergast et al, 2004; DeLellis et al, 2005).

Kochman et al (2002) reported the use of skin-contact MIRE in the treatment of 49 patients with DPN and the outcome revealed change in sensation, as measured with a Semmes-Weinstein monofilament. On the basis of Semmes-Weinstein monofilament values, 98% showed improved sensation after six treatments, and all had improved sensation after 12 treatments. Thomasson (1996) reported the outcomes of 563 people treated with skin-contact MIRE who were diagnosed with trapezius tendonitis, splenius capitis tendonitis, temporomandibular capsulitis or myofascial pain. The research confirmed an 88% to 90% improvement rate in patients treated with 1 to 12 sessions of skin-contact MIRE. Horwitz et al (1999) attest that the use of skin-contact MIRE promotes the healing process in five patients with venous leg ulcers, diabetic foot ulcers, and ulcers related to scleroderma. A four-case report shows that MIRE therapy, using the Anodyne Therapy System, enhances the healing of ischaemic foot ulcers in patients with diabetes (Nather et al, 2008).

Objective

To determine the effect of MIRE in people with DPN.

Methods

The study took place in an outpatient setting at the Wound Care Unit, Hospital Kuala Lumpur, Malaysia (WCUHKL). Study participants comprised patients who attended their routine treatment visit.

Patients received an hour of active MIRE after each dressing follow-up, which was done twice a week and continued until wound closure. Pain score and numbness were documented every Monday, using the Visual Analogue Score (VAS) while neurological assessment was done during foot examination.

The ankle brachial systolic index (ABSI) was measured by placing the BP cuff at the ankle while the doppler unit was used to get the arterial flow. The Systolic BP was taken at the brachial area. The ABSI was calculated as per standard protocol

This study conformed to the guidelines set out in the World Medical Association's Declaration of Helsinki for Ethical Principles for Medical Research Involving Human Subjects. The study was approved by the Hospital Review Board (a local institution board) and its objectives and potential risks were explained to the participants in detail. We obtained informed consent and permission to use wound photographs and case details for publication/research purposes.

Devices used in the study

MIRE intervention was administered using the Anodyne® Therapy System, model 480 (Anodyne Therapy, LLC, Tampa, FL). The device consisted of a base power unit and 8 therapy pads, each containing 60 gallium aluminium arsenide diodes. The area of light-emitting diodes per therapy pad was 22.5cm^2, yielding a total intervention area of 180cm^2. The diodes delivered MIRE pulses at 292Hz at a wavelength of 890nm and provided an average energy density of 16joules/cm^2/min.

Treatment

The following protocols for MIRE were followed:

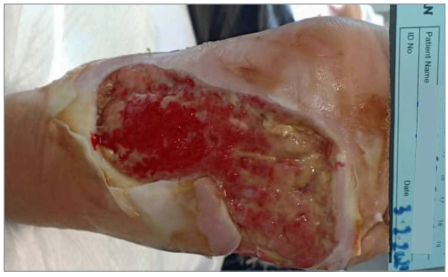
- All patients were treated with MIRE twice a week
- Patients were asked to lie down comfortably on the bed throughout the therapy
- The skin of the intervention area was covered with plastic wrap as a barrier between the skin and the diodes to ensure compliance with infection control procedures
- We placed four non-invasive therapy pads on each leg, i.e. one on each of the medial and lateral side of the gastrocnemius muscle, and two on the dorsal of the foot in a T shape
- The intensity of the MIRE therapy device was adjusted according to the comfort of the patient (maximum of 10 bars)
- The exposure time of the MIRE was an hour, which aimed to deliver an average energy of 16joules/cm^2/min
- The diodes and the plastic wrap were removed at the end of the treatment session
- MIRE therapy was continued for 10 weeks.

Results

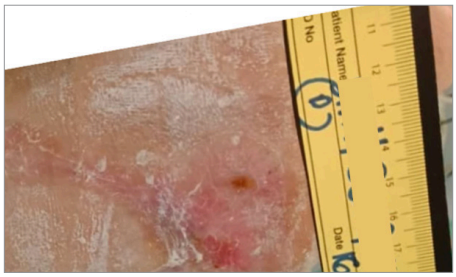
We recruited two people with long-standing diabetes mellitus for this pilot study to assess the effect of MIRE on DPN.

Case 1

Pre-treatment



Post-treatment



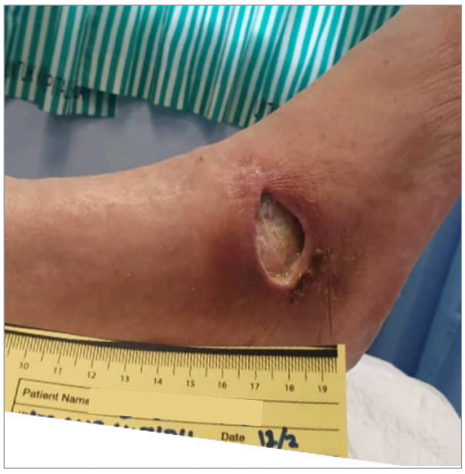
	Wound size (length x width x depth)	Ankle brachial systolic index (ABSI)	
		Left	Right
Pre-treatment (3 February 2020)	12.0cm x 9.5cm x 0.0cm	0.9	0.8
Post-treatment (16 July 2020)	Wound healed	0.9	0.9

Peripheral neuropathy

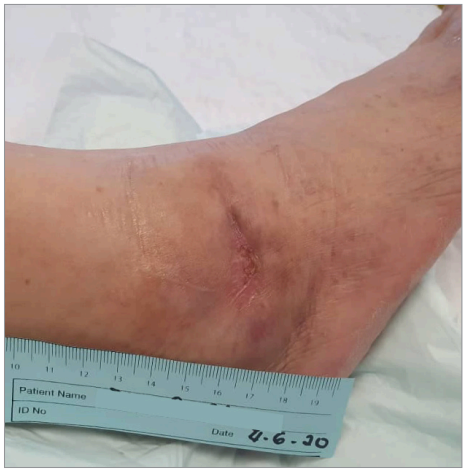
Week	1	4	8	12	16	20	23
Pain score	2	2	2	0	0	0	0
Muscle spasm	Present	Present	Absent	Absent	Absent	Absent	Absent

Case 2

Pre-treatment



Post-treatment



	Wound size (length x width x depth)	Ankle brachial systolic index (ABSI)	
		Left	Right
Pre-treatment (12 February 2020)	2.0cm x 4.0cm x 0.5cm	0.9	0.8
Post-treatment (4 June 2020)	Wound healed	0.9	0.9

Peripheral neuropathy

Week	1	4	8	12	16	17	23
Pain Score	7	6	4	2	0	0	0
Numbness	Present	Present	Absent	Absent	Absent	Absent	Absent

Case 1

A 56-year-old Chinese male with a 15-year history of diabetes mellitus first presented to the foot clinic with an infected diabetic foot ulcer. The wound closed during Week 23. Loss of sensation was confirmed by light touch and neurotip test.

Case 2

A 69-year-old Chinese female with a 21-year history of diabetes mellitus first presented to the foot clinic on 29th January 2020 with wound dehiscence, following excision of right ankle angiolipoma performed on 23rd December 2019. The wound closed at Week 17. Loss of sensation was confirmed by pin-prick test.

Discussion

The Anodyne device was FDA-cleared for increasing circulation and reducing pain. The MIRE technology (890nm infrared energy) stimulates photo-dissociation of nitric oxide (NO) from the endothelial cells at the site of treatment and from haemoglobin in the red blood cells (RBC). The continuous delivery of RBCs sustains the local increase in NO during delivery of Anodyne therapy, resulting in vasodilation that can indirectly relieve pain caused by lack of blood flow (Cheryl, 2001; Noble et al, 2001; Leonard et al, 2004; Powel et al, 2004; Thomasson, 1996). NO acts as vasodilator and neurotransmitter, which significantly increases microcirculation (Horwitz et al, 1999; Mak and Cheing, 2012). NO also induces angiogenesis, acts as an anti-inflammatory and increases osteoblastic cell activity and collagen synthesis, which accelerate wound healing.

As this was a pilot study, the small sample size was a limitation. More studies must be done to validate the result.

Conclusion

We have shown that MIRE therapy is effective, especially in managing DPN that includes numbness. There was also an improvement in the ABSI from 0.8 to 0.9 in both patients during the vascular assessment. Therefore, MIRE therapy helps manage DPN and perfusion of the limb. WAS

Declaration of interest

The authors have no conflicts of interest to declare, and received no funding for this study.

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