Contents available at ScienceDirect
Diabetes Research and Clinical Practice
journal homepage: www.elsevier.com/locate/diabres
International Diabetes Federation

Efficacy of shock wave therapy on chronic diabetic foot ulcer: A single-blinded randomized controlled clinical trial

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ARTICLE INFO

Article history:
Received 28 March 2014
Received in revised form
2 July 2014
Accepted 14 September 2014
Available online xxx

Keywords:
Shock wave therapy
Diabetic foot ulcers
Wound bed preparation

ABSTRACT

Objective: This study was conducted to evaluate the efficacy of extracorporeal shock wave therapy (ESWT) on the healing rate, wound surface area and wound bed preparation in chronic diabetic foot ulcers (DFU).

Methods: Thirty eight patients with 45 chronic DFU were randomly assigned into; the ESWT-group (19 patients/24 ulcers) and the control-group (19 patients/21 ulcers). Blinded therapist measured wound surface area (WSA), the percentage of reduction in the WSA, rate of healing and wound bed preparation at baseline, after the end of the interventions (W8), and at 20-week follow-up (W20). The ESWT group received shock wave therapy twice per week for a total of eight treatments. Each ulcer was received ESWT at a frequency of 100 pulse/cm^2, and energy flux density of 0.11 mJ/cm^2. All patients received standardized wound care consisting of debridement, blood-glucose control agents, and footwear modification for pressure reduction.

Results: The overall clinical results showed completely healed ulcers in 33.3% and 54% in ESWT-groups and 14.28% and 28.5% in the control group after intervention (W8), and at follow-up (W20) respectively. The average healing time was significantly lower (64.5 ± 8.06 days vs 81.17 ± 4.35 days, $p < 0.05$) in the ESWT-group compared with the control group.

Conclusion: ESWT-treated ulcers had a significant reduction in wound size and median time required for ulcer healing, with no adverse reactions. So, the ESWT is advocated as an adjunctive therapy in chronic diabetic wound.

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http://dx.doi.org/10.1016/j.diabres.2014.09.024
0168-8227/

Please cite this article in press as: Omar MTA, et al. Efficacy of shock wave therapy on chronic diabetic foot ulcer: A single-blinded randomized controlled clinical trial. Diabetes Res Clin Pract (2014), http://dx.doi.org/10.1016/j.diabres.2014.09.024

1. Introduction

Diabetic foot ulcer (DFU) is a major problem for modern healthcare providers. Research indicated that 15% of people with diabetes will develop foot ulceration in their lifetime, and 5–15% will end up with amputation [1,2].

There is a little research in Saudi Arabia on DFU prevalence, management or cost. However, survey suggested that the incidence of diabetes is 23.7%, and it is extremely high in urban areas [3]. The diabetic foot lesions constitute a major complication, with an overall prevalence of 10.4% [4,5]. Moreover, these lesions are linked with increased health, cost, diminished quality of life and prolong functional disability [6].

Many adjunctive therapies are designed for the care of DFU, involving hyperbaric oxygen therapy [7–9], vacuum-assisted wound closure [10,11], low level laser therapy [12] and electrical stimulation [13]. However, the results from these studies are inconsistent and reported limited success with no conclusive remark on its effect [7–13]. Therefore, the development of new effective noninvasive modalities for the management of diabetic wounds is extremely important to reduce both patients' suffering from chronic wounds and the cost of treatment.

For the past 20 years, extracorporeal shockwave therapy (ESWT) has been used for musculoskeletal disorders [14–16]. Recently, ESWT was shown to be valuable for the treatment of chronic wound, such as bedsores [17], vascular and diabetic ulcers [18–20], burn wounds [21,22] and skin flaps [23]. However, these studies were limited clinical trials with low level of evidence [24]. Moreover, systematic review concluded that lack of evidence, and rigorous study design made it difficult for clinicians and therapists to support using of ESWT in wound healing [25]. Furthermore, clinical trials are required to assess the optimum ESWT treatment parameters, such as duration and frequency of therapy and types of wound remains.

Therefore, this single-blinded, randomized controlled study was conducted to evaluate the efficacy of ESWT on the healing rate, wound surface area and wound bed preparation in chronic diabetic foot ulcers.

2. Materials and methods

2.1. Subjects

This study was a single-blinded, randomized controlled trial. Subjects were recruited from the general surgery department from May 2011 to April 2013. Physical assessment and therapy were conducted in the physical therapy department, King Saud Medical City, Riyadh, Saudi Arabia.

Patients with the following criteria had been enrolled in the study; (1) diagnosis of type I and II diabetes; (2) Grades 1A, and 2A ulcer according to the University of Texas Diabetic Foot Wound Classification System (wound penetrating to tendon or capsule, not involving bone or joint) [26,27]; (3) ulcers had been resisted to conservative treatment $\geq$3 months [19]; (4) ulcer measures $\geq$0.5 cm and $\leq$5 cm at any dimension [20]; (5) patient had peripheral neuropathy (defined by insensitivity to a 10-g monofilament) and (6) patient should be willing to participate in the study and comply with the follow-up.

Patients were excluded if they had: (1) evidence of local infection, acute cellulitis, osteomyelitis or gangrene anywhere in the affected extremity; (2) presence of renal, hepatic, neurologic or malignant diseases; (3) severe protein malnutrition (serum albumin $<$ 2.0 g/dl) or severe anemia (Hgb $<$ 7.0 g/dl) [13,28]; (4) an ankle-brachial index $<$0.7, absence of the dorsalis pedis or posterior tibial artery pulse [20], and (5) pregnancy.

The study was approved by the Research Ethics Committee, King Saud Medical City. All subject signed informed consent form before participation in the study. The trial registration code of this study was ACTRN12613000355774.

Forty four patients with 52 chronic diabetic foot ulcers were assigned into; control-group (n = 22) and ESWT-group (n = 22). Randomization was performed using the computer generator block labels describing the treatment groups. The sample size was estimated to be 38 in both groups and would be increased to 44 for possible dropout. This sample size was estimated to detect 20% difference in wound surface area between groups, with the probability level was set at 0.05 and power of 85%.

2.2. Clinical outcome measurements

Blinded therapist evaluated the patients and measured wound surface area (WSA), and percentage of WSA reduction, and wound bed preparation. These measurements were taken at baseline, after the end of the interventions (W8), and at 20-week follow-up (W20).

2.3. Wound surface area measurement

The percentage of decrease in WSA due to interventions was recorded. The therapist placed sterilized transparency sheet over the wound and traced the wound perimeter using a permanent marking pen [29]. Each wound was traced three times to ensure the reliability of measurement. The tracing was digitized using the A4 G-Note 7100 Tablets with cordless mouse and two stylus pen (KYE systems, Corp, China), and then imported into a specialized software program (Photoshop C4me) to calculate WSA. The percentage of reduction in WSA was determined from the following equation [30]:

$$\%\downarrow \mathrm{WSA} = \frac{[\text{initial WSA}(\mathrm{cm}^2) - \mathrm{WSA}(\mathrm{cm}^2)\ \text{at x weeks}]}{\text{Initial WSA}(\mathrm{cm}^2)} \times 100$$

The percentage of WSA reduction for wounds that had completely healed was detected at each measurement time. The wounds were labeled completely healed only if they clinically closed (100% re-epithelization) without drainage or dressing requirement.

The time to complete healing was recorded as the number of days from the beginning of the treatment on the date in which the wound achieved complete healing. If healing did not occur within the 20 weeks, the patient was considered to be nonhealing and no time was recorded.

2.4. Wound bed preparation, scores

The wound bed preparation, scores and the percentage of granulation and necrotic tissues and the presence of the exudates have been determined. The presence of exudates

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