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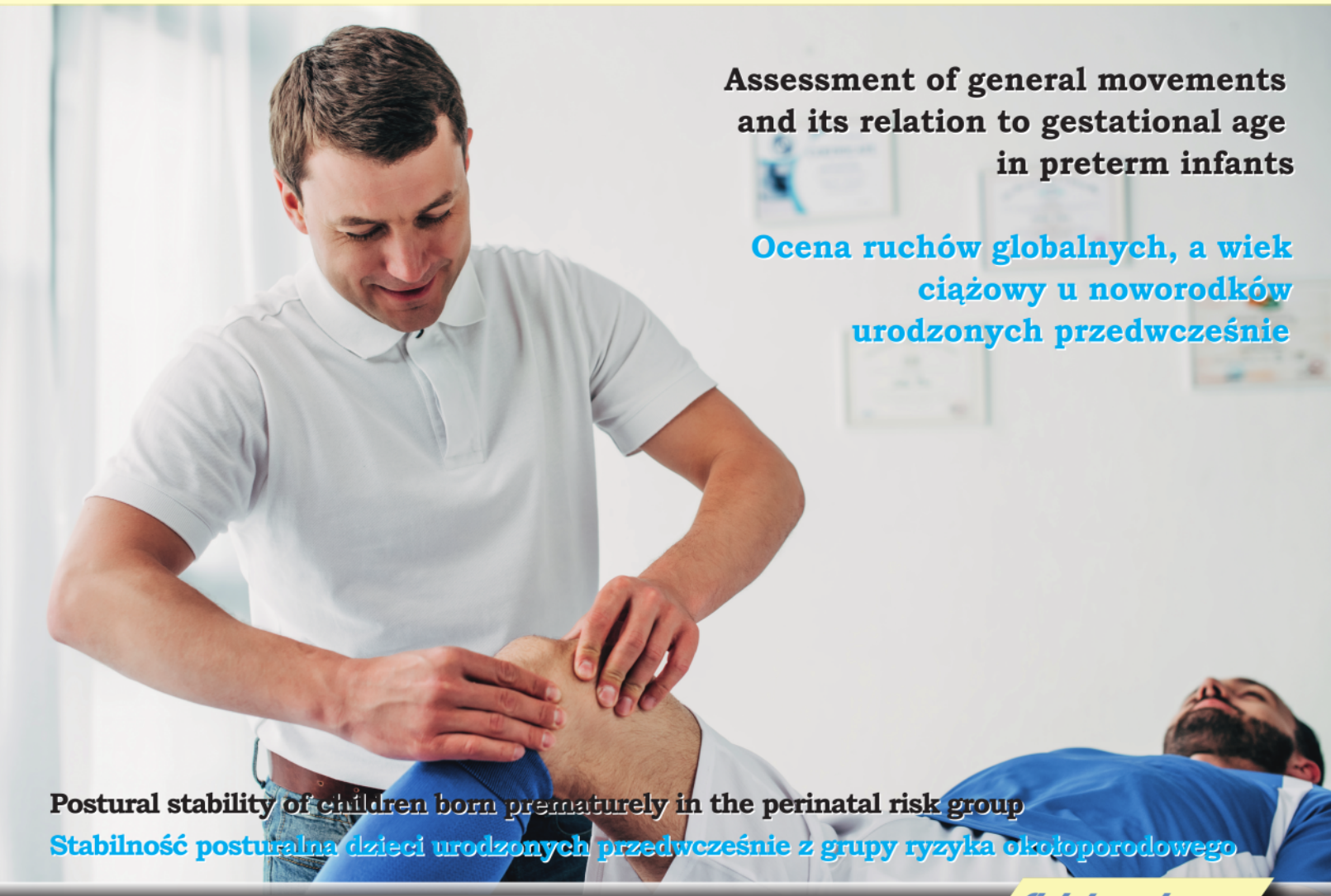

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# Potential effects of extracorporeal shock wave therapy and photobiomodulation in the treatment of older adults with diabetic foot ulcer. A randomized clinical trial

*Potencjalne skutki terapii pozaustrojowej falą uderzeniową i fotobiomodulacji w leczeniu osób starszych z owrzodzeniem stopy cukrzycowej. Randomizowane badanie kliniczne*

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## Abstract

Purpose of the study. To compare between the effectiveness of extracorporeal shock wave therapy (ESWT), photobiomodulation(PBMT) and patients receiving routine physical therapy(PT) on tissue viability, pain, and quality of life in older adults with diabetic foot ulcer.

Methods. Forty-five older adults with diabetic foot ulcer (age, 62-70 years) were enrolled into a randomized control trial with parallel group design, assigned into three equal groups; two study groups (ESWT group and PBMT group), and control group (CG). All the groups received the routine PT program, in addition, ESWT group received ESWT and PBMT group received LLLT. Tissue viability, pain, and quality of life (QoL) were assessed pre- and immediately post-treatment.

Results. Non-significant differences in the outcome measures between groups pre-treatment($P > 0.05$). Regarding the post-treatment, the study groups showed significant improvements in the study outcome measures ($P < 0.001$), whereas the control group did not show significant changes ($p > 0.05$).

Conclusion. ESWT and PBMT produced similar effects on tissue viability, pain, and QoL in older adults with DFU.

**Key words:**

diabetic foot ulcer, extracorporeal shock wave therapy, photobiomodulation, older adults

## Streszczenie

Cel badania. Porównanie skuteczności pozaustrojowej terapii falą uderzeniową (ESWT), fotobiomodulacji (PBMT) i rutynowej fizjoterapii (PT) na żywotność tkanek, ból i jakość życia u osób starszych z owrzodzeniem stopy cukrzycowej.

Metody. Czterdzieści pięć osób starszych z owrzodzeniem stopy cukrzycowej (w wieku 62-70 lat) zostało włączonych do randomizowanego badania kontrolnego. Uczestników przydzielono do trzech równych grup; dwie grupy badawcze (grupa ESWT i grupa PBMT) oraz grupa kontrolna (CG). Wszystkie grupy realizowały rutynowy program fizjoterapii, dodatkowo grupa ESWT była poddawana ESWT, a grupa PBMT była poddawana terapii LLLT. Żywotność tkanek, ból i jakość życia oceniano przed i bezpośrednio po leczeniu.

Wyniki. Różnice w pomiarach wyników między grupami przed leczeniem były nieistotne ($P > 0,05$). W odniesieniu do okresu po leczeniu, grupy badane wykazały znaczną poprawę w pomiarach wyników badania ($p < 0,001$), podczas gdy grupa kontrolna nie wykazała istotnych zmian ($p < 0,05$).

Wniosek. ESWT i PBMT wywierały podobny wpływ na żywotność tkanek, ból i jakość życia u osób starszych z owrzodzeniem stopy cukrzycowej.

**Słowa kluczowe**

owrzodzenie stopy cukrzycowej, pozaustrojowa terapia falą uderzeniową, fotobiomodulacja, osoby starsze

## Introduction

Diabetes mellitus (DM) is an increasing disease not only in developing countries but also in developed countries [1, 2]. The increased prevalence of DM is associated with an increased prevalence of its complications such as foot ulceration and lower limb amputation [3]. The lifetime risk of a diabetic person to develop an ulcer in the foot is 25% [4]. Chronic diabetic foot ulcers (DFUs) are thought to be caused by microangiopathy (small vessel occlusion) and are combined with peripheral neuropathy and infection. Foot ulceration is responsible of about 85% of lower limb amputations in diabetics, as well as it increases the rate of morbidity and mortality among diabetics [5].

Delayed wound healing of DFUs are a common cause for hospitalization and amputation that negatively affects Health-Related Quality of Life (HRQoL) in patients because of mobility reduction and consequently the ability to perform daily living activities and higher dependence on others. In addition, the perceived stress related to healing of ulcer and recurrence, the fear regarding amputation of the foot both increase the negative mood and lead to sleep disturbance in patients with diabetic foot. Moreover DFU affects psychological wellbeing, contributing to depression and placing financial strain on individuals, families, and healthcare systems [1,6]. Neuropathic pain is often experienced by DFU patients and it was reported when walking even short distances and during dressing changes [7, 8].

Both surgical and non-surgical treatments' results for healing of DFU are unsatisfactory. Therefore, many additional therapies are used for the care of chronic DFU including, ESWT, hyperbaric oxygen therapy, PBMT, negative pressure wound therapy, and ultrasound. Shock waves are biphasic high-energy acoustic waves and recently, ESWT is used as a therapeutic approach for improving healing of chronic wounds as chronic DFU, with encouraging early results in short-term follow-up [9–14].

PBMT is a mechanism that endogenous chromophores absorb nonionizing Optical Radiation from the spectrum of visible and near-infrared (NIR) in various biological scales to create photo physical and photochemical impacts without causing thermal harm [14-20]. PBMT has shown good results in accelerating healing for chronic wounds and diabetic ulcers and is characterized as photon therapy based on PBM concepts using lasers or LEDs to enhance tissue recovery, minimize pain and inflammation. It has been shown to be effective in the treatment of a variety of medical conditions and pathologies, including chronic wounds and DFUs [9, 21].

Studies regarding the influence of ESWT and PBMT on tissue viability, pain, and HRQoL in diabetic patients with foot ulceration are still scarce in literatures. So there is a need for further researches to develop a rapid, productive, cost-effective, and appropriate therapy to facilitate healing of DFUs. Regarding that, our study was conducted to find out the effectiveness of ESWT wave versus PBMT on tissue viability, pain, and quality of life (QoL) in older adults with DFU hypothesizing that ESWT and PBMT have the same effect on tissue viability, pain, and QoL among older adults with DFU and hypothesized that both types of interventions may improve tissue viability, pain, and QoL in those patients.

## Subjects and methods

### Study design

This Randomized control trial with parallel group design was carried out between October 2019 and November 2020. It was conducted at the outpatient physiotherapy clinic at Prince Sattam bin Abdul-Aziz University (PSAU). The ethical clearance was attained from the local institution review board of the physiotherapy department (No: RHPT/019/048). All procedures were fulfilled in accordance with the ethical standards of the 1964 Declaration of Helsinki and its updates.

### Participants

Sixty older adult diabetic patients (type I or type II) of both gender were recruited from the department of internal medicine, King Khalid Hospital and other hospitals referring these cases. The included patients age ranged from 62 to70 years and their BMI between 30 -34.9 Kg/ m2, had DFU exposed up to subcutaneous tissue. The diabetic patients who had exposed foot ulcer up to muscle and bone, received other type of dressing, with other complication were excluded. In addition, previous LLLT, circulatory disorders, and dermatological or inflammatory diseases in the area to be radiated.

An angiologist assessed the patients then referred them after classifying the ulcer to the physiotherapy clinic for a new assessment of the treatment. After that the patients were randomly assigned into three groups equal in number (each consisted of 20 patients). Study Group 1, ESWT Group treated with ESWT in addition to the routine physical therapy program; Study Group 2: PBMT group treated with LLLT and routine physical therapy program and Group 3: control group (CG) treated by routine physical therapy program.

### Randomization and blinding

The sixty older adults were randomized by simple random sampling technique before starting the study procedures using SPSS version 22 (IBM Corp., Armonk, NY, USA) into two study groups that received ESWT and photobiomodulation in addition to the routine physical therapy program and the control group that received routine physical therapy program (Figure 1). The procedures of the study were informed to participants and a consent form was signed by them before initiating the study. The assessor was blinded to the group allocation.

### Sample size estimation

Sample size is estimated by using the pain as the main outcome in the research. The present research demanded 48 patients for the three study groups based on this difference in prior studies [15, 16] and the study target of achieving 80% power with type I error of 0.05. Therefore, to compensate for the 20% dropout, the study included sixty patients.

### Outcome measures

Pain, tissue viability and quality of life were measured prior to the treatment and immediately post- treatment by blinded assessment by an independent researcher.

***The viability of tissue*** was investigated by scanning of the local blood flow perfusion. Intact skin at the wound or ulcer bor-

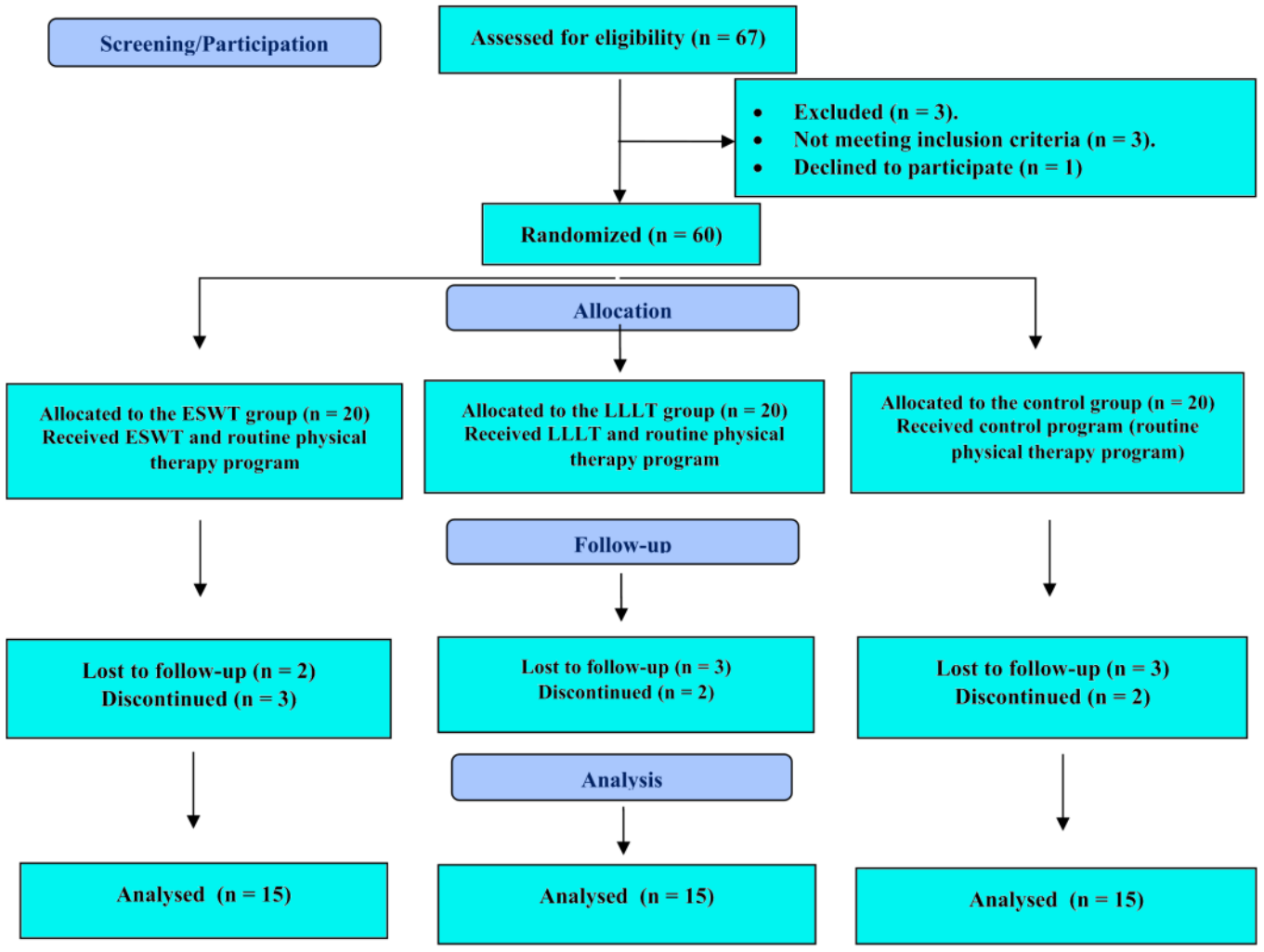


**Figure 1. The flow chart of the study participants**

der with laser Doppler (LD) flux sensors (Angled probe 401, Perimed, Järfälla, Sweden) in conjunction with sources of the laser light at 780 nm (PF 4001 and PF 4002 Satelite, Perimed, Järfälla, Sweden) to examine the microcirculation [17].

***The intensity of pain*** was analyzed by means of visual analogue scale (VAS), that was validated by the previous researchers for the pain measurement in diabetic foot ulcer studies. It is a single dimensional measurement tools utilized extensively in different population of adults. It is one horizontal or vertical line 100 mm in length. The participants are told to physiotherapist "no pain" as a 0 and "worst pain possible" worst imaginable pain as 100 [18,19].

***Quality of life*** was assessed using the SF-36 which entails 36 questions that check 8 domains: general health, physical status, physical role limitations, bodily pain, vitality, social functions, role limitations during emotional state, and mental health. Moreover, one item evaluates previous year health changes. This valid and reliable instrument has been indicated for those participants with persisting ulcers [20]. The previously validated Arabic version of the SF-36 was used [21]. Physical component (PC) and mental component(MC) were evaluated.

**Intervention**

Participants were briefed the use only sodium chloride (saline solution 0.9%), regarding the daily asepsis of the ulcer. Pretest, the dressing was taken out; the wound was thoroughly cleansed by normal saline to remove the remnant local applicant ointments, any pus or debris present; and then gauze were dried. Post session the participant's ulcer area was cleaned and sterile with normal saline. They could thereafter took followed the wound care regime and antibiotic treatment as a when required as per the physician advice.

***Study group 1***

Extracorporeal shock wave therapy (HB-ESWT-01, Zhanjiang Haibin Medical Equipment Co., Ltd, Zhanjiang, Guangdong, China), was applied at 0.23mJ/mm2 the energy flux density, two sessions per week for 6 weeks. There was no anesthesia given to the participants on the ulcer site. The ulcer was covered with a sterile cellulose barrier. The aqua sonic gel is applied on the shockwave head applicator prior to the impulses

delivered. 500 impulses were given at an average rate of 4 shocks per seconds [9].

***Study group 2***

The low level laser therapy (The device Laser He-Ne Plasmax IV, LHN 9709 (KLD Biossistemas ®), Helium-neon, 632.8 nm wavelength and density of 4 J/cm2 applied for 80 seconds each session, as the treatment was divided into two sessions/ week for 6 weeks. Both participant and therapist were given special protective goggles [22].

***Control group***

Physical Therapy program in the form of Burger-Allen exercises was applied, where these exercises are typically meant for improvement of vascular system. The participants were asked to lie down on his/her back with the straight leg raise for 3 minutes. Thereafter, once blanching occurs in the feet and sole the participants asked to sit on the edge of the bed with the legs dangled and with both the feet's: participants did flexion, extension, pronation and supination. The pink color should appear while exercising but if in case they become blue or painful, then the participants were asked to raise his/her feet to a higher ground again and rest. The last step for this exercise the participants is asked to lie down on his/her back again for 5 minutes without raising the feet. The limbs especially the feet were covered with the cloth to keep them warm for better circulation. The exercise regime was taught to the participants in the three groups as home exercise program and it includes 30-50 minutes each session, around 150 minutes per session [23, 24].

***Statistical analysis***

SPSS for window (V. 22, IBM Corp., Armonk, NY, USA) was utilized for analyzing the collected data. Data showed normal distribution when tested for normality. Results are expressed as mean and standard deviation. Mixed design ANOVA was used to compare mean scores within and among the three groups for tissue viability, pain, and quality of life. Significance was accepted as P-value < 0.05.

## Results

Table 1 shows characteristics associated with study participants, there were non-significant differences regarding age, sex, BMI, HbA1c, duration of ulcer total, unilateral /bilateral lesion, and DM complication (p > 0.05).

**Table 1. Baseline characteristics of the study**

| Variable | ESWT group (n = 15) | PBMT group (n = 15) | CG group (n = 15) | p-value |
|---|---|---|---|---|
| Age, [years], x ± SD | 62.13 ± 4.30 | 62.20 ± 6.02 | 61.46 ± 4.85 | 0.910 |
| Sex, M/F, No. | 10 / 5 | 9 / 6 | 9 / 6 | 0.910 |
| BMI [kg/m$^2$], mean ± SD | 30.86 ± 3.24 | 30.33 ± 2.74 | 29.26 ± 2.46 | 0.301 |
| HbA1c [%], mean ± SD | 7.90 ± 0.94 | 7.78 ± 1.12 | 7.89 ± 0.73 | 0.935 |
| Duration of ulcer [months], mean ± SD | 7.06 ± 2.63 | 8.26 ± 2.89 | 8.40 ± 3.18 | 0.393 |
| Affected side, unilateral/bilateral, No. | 9 / 6 | 8 / 7 | 10 / 5 | 0.757 |
| DM complication duration [years], mean ± SD | 5.26 ± 2.37 | 5.66 ± 1.67 | 6.66 ± 2.12 | 0.177 |

**Significant at P-value < 0.05 Data showed as Means ± SD and frequency (percentages); ESWT: extracorporeal shock wave therapy, PBMT: photobiomodulation, CG: control group; BMI: body mass index, HbA1c: glycated haemoglobin, DM: diabetes mellitus*

Table 2 displays the comparison of clinical parameters within each group before and after intervention. Within ESWT group a statistically highly significant difference was observed between pre intervention and post intervention for tissue viability, pain, QoL (PC) and QoL (MC) (p < 0.001). Similar result was observed for PBMT group for all clinical parameters (P < 0.001). The CG Group also showed similar result except for the MC of the QoL which showed non significant change (P = 0.023). Comparison of the means of the tissue viability, pain, and QoL (PC, MC) among the three groups at the pre intervention revealed non significant differences (P > 0.05) which changed into significant differences when comparing the post-treatment levels among the three groups (P = 0.001).

**Table 2. Comparison between outcome variables within and among groups pre and post intervention**

| Variables | | ESWT group (n = 15) Mean ± SD | PBMT group (n = 15) Mean ± SD | CG group (n = 15) Mean ± SD | F (2.55) | P-value |
|---|---|---|---|---|---|---|
| Tissue viability | Pre | 1.83 ± 0.23 | 1.75 ± 0.38 | 1.88 ± 0.37 | 2.468 | 0.17 |
| | Post | 2.80 ± 0.29 | 2.60 ± 0.33 | 2.10 ± 0.25 | 6.074 | 0.001* |
| | F-value | 10.18 | 11.03 | 4.04 | | |
| | P-value | < 0.001** | 0.001** | < 0.001** | | |

| Variables | | ESWT group (n = 15) Mean ± SD | PBMT group (n = 15) Mean ± SD | CG group (n = 15) Mean ± SD | F (2.55) | P-value |
|---|---|---|---|---|---|---|
| Pain | Pre | 8.40 ± 0.98 | 8.60 ± 1.12 | 8.80 ± 0.76 | 2.547 | 0.08 |
| | Post | 5.20 ± 1.14 | 5.33 ± 1.75 | 6.40 ± 1.12 | 5.874 | 0.001* |
| | F-value | 9.79 | 10.87 | 7.856 | | |
| | P-value | < 0.001** | < 0.001** | < 0.001** | | |
| QoL (PC) | Pre | 37.20 ± 3.58 | 36.60 ± 4.06 | 37.13 ± 3.66 | 2.918 | 0.09 |
| | Post | 44.06 ± 4.78 | 43.33 ± 3.90 | 39.13 ± 3.44 | 6.134 | 0.001* |
| | F-value | 7.683 | 5.84 | 4.019 | | |
| | P-value | < 0.001** | < 0.001** | 0.001* | | |
| QoL (MC) | Pre | 42.26 ± 4.84 | 42.13 ± 5.27 | 41.80 ± 4.05 | 2.823 | 0.07 |
| | Post | 48.06 ± 2.91 | 48.13 ± 3.83 | 44.13 ± 3.37 | 6.064 | 0.001* |
| | F-value | 4.190 | 7.93 | 2.554 | | |
| | P-value | 0.001** | < 0.001** | 0.023 | | |

*ESWT: extracorporeal shock wave therapy, PBMT: photobiomodulation, CG: control group; QoL: Quality of life; PC: Physical component, MC: Mental component. **HS, *S*

## Discussion

DFU is the most disabling complication in diabetic patients, that is if untreated leads to serious consequences including amputation. Therefore, seeking an effective therapy to prevent theses consequences is essential. The present study was proposed to assess the effects of ESWT and PBMT in the form of LLLT on pain, tissue viability, and QoL in older adults with diabetic foot ulcers and to compare the effectiveness of these two modalities with that of the routine physical therapy care. It is hypothesized that there is no difference between extracorporeal shockwave therapy, photobiomodulation effect and the routine physical therapy care on pain, tissue viability, and QoL in older adults with diabetic foot ulcers.

The results showed that within each group ESWT and PBMT in the form of LLLT as well as the routine physical therapy care induced significant decrease in pain score, increase in tissue viability, and QoL scores.

Regarding ESWT group, the results have shown that the ESWT resulted in an increase in tissue viability, decrease in pain score, enhance QoL scores in older adults with diabetic foot ulcers. The improvement in tissue viability observed in the present study, as evident by increased the local blood flow perfusion rate, induced as a result of the action of ESWT in diabetic foot ulcers, as documented in previous studies, which works through applying high energy acoustic waves inducing mechanical stimulation of the tissues that results in therapeutic effects through complex biological pathways to stimulate new angiogenesis, increase growth factor production as endothelial nitric oxide synthase (eNOS), vascular endothelial growth factor (VEGF) and proliferating cell nuclear antigen (PCNA), and decrease inflammation within the ulcer and the nearby tissues. All these changes subsequently result in improvement in blood perfusion and acceleration of cell proliferation conducing to tissue regeneration in the ulcer. Application of ESWT induced immediate increase in wound perfusion [25-28].

The study's findings are confirmed by an earlier study conducted by Wang et al. [25] as they found marked increase in local blood flow perfusion rate by the effects of application of ESWT twice weekly for six treatments in chronic diabetic foot ulcers. This increase in the local perfusion rate of blood flow was detected within 6 weeks of treatment and persisted for 1 year but decreased from 1 to 5 years. Therefore, they recommended repetitive ESWT treatment to maintain tissue viability. When comparing the effects of ESWT treatment and hyperbaric oxygen therapy in chronic DFUs, the local blood flow perfusion rate was markedly improved by ESWT than hyperbaric oxygen therapy [29].

The results of Jeppesen et al., [30] run in line with the findings of the present study as they found significant increase in transcutaneous oxygen tension in areas close to the diabetic foot ulcers treated with ESWT although this increase is a short lasting and they attributed this effect to be mediated by vasodilatation.

Regarding the DFU pain, the results of the current study showed significant reduction in pain score after ESWT application which may result from the increased blood flow to the ulcer area and accordingly removal of the metabolites and waste products stimulating nociceptors.

The effects of ESWT on pain reduction may be also attributed to the nature of the shock waves which produce fine and repetitious stimulations in the tissues that suppress the nociceptors, [31] or the activation of small diameter nerve fibers by the shock waves which stimulate the serotonin system responsible for regulating the transmission of pain stimuli resulting in increased the patient's pain threshold [32].

On the other hand, the results of Jeppesen et al. [30] found that ESWT has no additional effect on ulcer related pain than the

standard care but they attributed this to the inclusion of many patients in their study who suffered from neuropathy and did not experience ulcer related pain.

An important finding of the current study is the increased QoL scores after application of ESWT which could be due to the achieved improvement in tissue viability and decreased the ulcer related pain that is reflected functionally in terms of increased the capacity to perform everyday living tasks and decreased the dependence on others and hence increased the QoL.

Concerning the group received PBMT therapy, in the form of LLLT the results showed significant increase in tissue viability, decrease in pain score, and increase in quality of life after treatment. The documented effects of PBMT therapy on tissues are principally pain reduction, alleviation of inflammation, activation of immune system, and stimulation of tissue healing and repair. These biologic effects result from the photochemical and photo physical reactions induced within the cells without thermal injury. Such effects work through acting on cellular mitochondria that result in increased adenosine triphosphate (ATP) synthesis, and oxygen consumption. Increased reactive oxygen species (ROS) production, and release of nitric oxide (NO) from intracellular stores leading to vasodilatation. In addition, increased ATP production is followed by subsequent physiological changes at the molecular level which result in growth factor production and increased cell proliferation and migration that contribute to tissue healing and repair [33-35]. LLLT also has a stimulatory effect on the release of cytokines and growth factors into the circulation which is responsible for vasodilatation and formation of new blood vessels [36,37], that contribute to the improved tissue viability.

The reduction in pain score as a result of LLLT is a documented effect of LLLT in DFU [23, 24]. The mechanisms proposed for pain reduction by the effect of LLLT are stimulation of serotonin system [15], increase the local blood supply and removal of waste products [23], and increased the microcirculation to the periphery [15].

As the pain may cause avoidance of social and recreational activities in older adults with a consequent poor quality of life [24], reduction in the pain after the LLLT treatment resulted in higher QoL. The results of the current study supported by previous trials [17,18] who revealed decreased pain score and increased QoL after LLLT in patients with neuro-ischemic diabetic foot ulcers [17], and in older adults with type 2 diabetes and peripheral neuropathic pain [16].

When comparing the results of the three groups at the end of the study the outcomes were significantly improved in ESWT and PBMT groups than in the group received only exercise physical therapy while the results of ESWT and PBMT groups were comparable indicating that both ESWT and LLLT can similarly inducing improvement in the tissue viability, reduction in the pain scores, and increase in the QoL in older adults with DFUs. To the author 's knowledge, the current research is the first randomized, controlled trial to compare the effects of ESWT against that of PBMT in the form of LLLT on pain, tissue viability, and QoL in older adults with DFUs.

### Study limitations

The current research is constrained by a variety of factors that may impact the findings as the small number of patients and the lack of long-term evidence concerning the sustainability of the obtained results. In addition, the viability of the tissue was assessed by scanning local blood perfusion without the use of direct measuring processes such as fluorescent angiography or indirect methods such as transcutaneous tissue $O_2$ and direct $O_2$ saturation measurements.

## Conclusion

Regarding the results of the current study and the previous studies which reported absence of adverse or side effects associated with application of ESWT [29], and also photobiomodulation [35] in DFU, it is recommended that ESWT and PBMT therapy can be used in the treatment of diabetic foot ulcer as they improved the tissue viability, reduced the pain, and improved the quality of life of the patients hence, will lead to avoidance of further complications.

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