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Long-term outcomes of extracorporeal shockwave therapy for chronic foot ulcers

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ABSTRACT

Background: Recent studies showed that extracorporeal shockwave therapy (ESWT) is effective in the treatment of chronic foot ulcers in short term. However, the long-term effects of ESWT in chronic foot ulcers are unknown. The purpose of this study was to evaluate the long-term outcomes of ESWT in chronic foot ulcers with 5-y follow-up.
Methods: The study cohort consisted of 67 patients with 72 ulcers including 38 patients with 40 ulcers in the diabetes mellitus (DM) group and 29 patients with 32 ulcers in the non–diabetes mellitus (non-DM) group. Each patient received ESWT to the affected foot twice per week for 3 wk for a total of six treatments. The evaluations included clinical assessment for the ulcer status, local blood flow perfusion, and analysis of mortality and morbidity.
Results: The results showed completely healed ulcers in 55.6% and 57.4% of total series, 48% and 43% of DM group, and 66% and 71% of non-DM group at 1 and 5 y ($P = 0.022$ and $P = 0.027$), respectively. The mortality rate was 15% in total series, 24% in DM group, and 3% in non-DM group ($P = 0.035$). The rate of amputation was 11% in total series, 17% in DM group, and 3.6% in non-DM group ($P = 0.194$). The blood flow perfusion rate significantly increased after ESWT for up to 1 yr but decreased from 1–5 y in both groups. However, the non-DM group showed significantly better blood flow perfusion than the DM group at 5 y ($P = 0.04$).
Conclusions: ESWT appears effective in chronic diabetic and nondiabetic foot ulcers. However, the effects decreased from 1–5 y after treatment.

1. Introduction

Chronic foot ulcers are defined as nonhealing ulcers for >3 mo. The etiologies of chronic foot ulcers are multifactorial. Diabetic ulcers are caused by small vessel occlusion angiopathy associated with poor skin sensation because of peripheral neuropathy and secondary infection. Nondiabetic ulcers are caused by venous stasis with poor venous return because

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of deep vein thrombosis or varicosity that predisposes to tissue edema, skin breakdown and secondary infection, and peripheral arterial disease [1,2]. Managements of chronic foot ulcers require multidisciplinary approaches including diabetic control, antibiotic, shoe wear, wound care, and surgery in selected cases. The results of surgical and nonsurgical treatments are inconsistent, and most studies reported unsatisfactory results [3–5]. Therefore, many adjunctive therapies are designed for the care of chronic foot ulcers including hyperbaric oxygen therapy (HBOT), ultrasound, recombinant human platelet-derived growth factor BB, vacuum-assisted wound closure, and acellular matrix. Some achieved limited success, but none showed universal results [6–13].

Recent study reported positive effects of extracorporeal shockwave therapy (ESWT) in the treatment of acute and chronic wounds [14]. Prior studies showed that ESWT is more effective than HBOT in the treatment of diabetic foot ulcers in short-term follow-up [15]. Other studies demonstrated that ESWT is effective in chronic foot ulcers [16–18]. Furthermore, ESWT was shown to improve the skin flap survival, healing of burn wound, and improvement in blood flow perfusion [19–21]. Yet, the long-term result of ESWT in chronic foot ulcers is unknown. The purpose of this study was to evaluate the long-term effects of ESWT in chronic foot ulcers with 1- and 5-y follow-up. We hypothesized that ESWT may be effective in the treatment of chronic diabetic and nondiabetic foot ulcers in short- and long-term results.

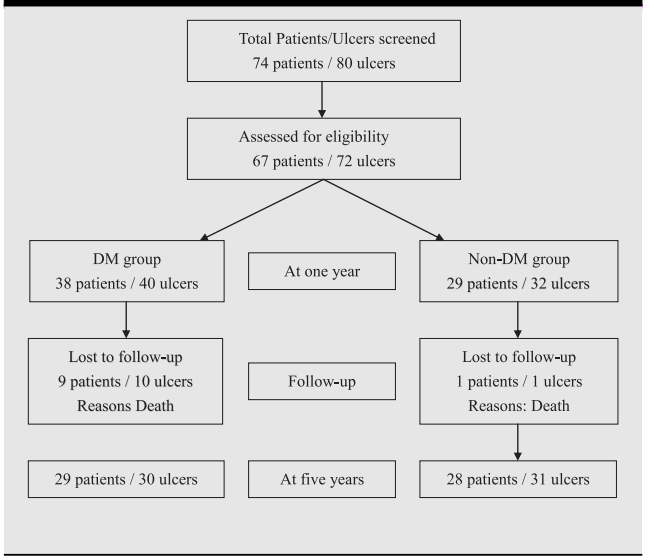
2. Patients and methods

The institutional review board of our institution approved this prospective clinical study. The study was performed in accordance with the standard of the ethical committee, and the declaration of Helsinki protocol was followed. All patients were required to sign an informed consent before participation in the study. The inclusion criteria included patients with recurrent or persistent nonhealing diabetic or nondiabetic ulcers of the foot for >3 mo. The exclusion criteria included patients with cardiac arrhythmia or pacemaker, pregnancy, malignancy or joint sepsis, skeletal immaturity, and poor compliance. Seventy patients with 80 ulcers were initially screened for the study. Among them, 67 patients with 72 ulcers were assessed for eligibility. The study cohort included 38 patients with 40 ulcers in the diabetes mellitus (DM) group and 29 patients with 32 ulcers in the non–diabetes mellitus (non-DM) group. The flow chart of patient recruitment is shown in Table 1, and the patient demographic characteristics are listed in Table 2.

2.1. Shockwave application

All patients received ESWT to the diseased foot. The source of shockwave was from a dermaPACE device (SANUWAVE, Alpharetta, GA). The treatment dosage is ulcer size dependent. The number of impulses = treatment area (cm^2) × 8, but at least 500 shocks at E2 at 4 Hz (equivalent to 0.11 mJ/mm^2 energy flux density) twice/wk for six treatments. During treatment, the treatment head of the device should be gently glided over the entire surface of the wound extending 1.0 cm from the wound perimeter in every direction. The treatment area is calculated as the actual size of the ulcer extending 1.0 cm in each direction.

Table 1 – The flow chart of patient recruitment.



2.2. Complications

There were no systemic or neurovascular complications. There were no device-related problems. None of the ulcers became worse after ESWT. Two patients complained of transient burning sensation around the treatment area that resolved spontaneously within 1–2 d.

2.3. Blood flow perfusion scan

Tissue viability was evaluated by local blood flow perfusion scan preoperatively and at 6 wk, 1 y, and 5 y postoperatively. Local blood flow perfusion was measured using the Peri-Scan PIM II Laser Doppler Perfusion Imager (Perimed AB, Stockholm, Sweden). The object was placed on a light-absorbing background material such as a black or a dark green cloth. The distance between the scanner head and the object was 15 cm. The minimum and maximum values were set at 0 and 5 V, respectively. The perfusion scan image color scale displayed the lowest value in dark blue and the highest value in dark red. The minimal value, the maximal value, and the mean and standard deviation were computer analyzed.

After treatment, all patients received the necessary medical care from the referring physicians, including diabetic control, wound dressing care, and antibiotic, if indicated. The follow-up examinations were performed in 1, 3, 6, and 12 mo and then once a year. The evaluations included clinical assessment of the ulcer status, including the size, shape, and depth with photo documentation, local blood flow perfusion scan, and the mortality and morbidity including the rates of amputation in 1 and 5 y after ESWT.