APPLICATION VALUE OF EXTRACORPOREAL SHOCK WAVE THERAPY OF PATIENTS WITH RECURRENT DIABETIC FOOT ULCER INFECTION

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ABSTRACT

Introduction: *To determine the application value of extracorporeal shock wave therapy (ESWT) in rehabilitation nursing of patients with diabetic foot ulcer (DFU).*

Materials and methods: *Totally 87 patients with DFU admitted between March 2018 and May 2020 were enrolled for in this study for analysis. Among them, 46 patients received ESWT combined with nursing intervention as the research group, while the rest 41 received routine treatment combined with nursing intervention as the control group. Patients in both groups were given routine hypoglycemic and anti-infective treatment and debridement every day. On this basis, patients in the research group were additionally treated with pneumatic ballistic ESWT instrument. Then the two groups were compared in the reduction rate and healing time of wound after treatment, and their exudation, histology and bacterial clearance rate of wound were evaluated. In addition, the clinical efficacy and safety on the two groups were evaluated, and the changes of blood glucose, blood pressure, and inflammatory factors in them were detected before and after treatment. The two groups were followed up for 6 months to understand their life quality.*

Results: *The wound healing of the research group was notably better than that of the control group, in which the healing time, exudation and histological score of the wound of the research group were all superior to those of the control group and the bacterial clearance rate of the former group was higher than that of the latter group (all $P<0.05$). In addition, according to the clinical efficacy results of the two groups, the research group showed a higher total effective rate and a lower incidence of adverse reactions than the control group (both $P<0.05$). Moreover, after treatment, the blood glucose, blood pressure and inflammatory factors in the two groups were all ameliorated, and the amelioration of them in the research group was more notable (all $P<0.05$). According to follow-up results, the research group got higher life quality scores than the control group (all $P<0.05$).*

Conclusion: *ESWT can effectively improve the wound healing of patients with DFU and reduce the risk of infection, so it has a high application value in clinical rehabilitation nursing of such patients.*

Keywords: *ESWT, DFU, wound healing, recurrent infection.*

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Introduction

Diabetes is a global pervasive disease, widely regarded as a new epidemic, which has accumulated influence on almost every country, people of every age group and economy worldwide[1, 2]. According to the latest data survey, diabetes in China has an incidence rising to 11.2% and over 415 million patients suffer from diabetes in the world, so diabetes has become a major public health problem[3,4]. Diabetes is incurable, so most patients with it can only be treated with scientific and reasonable treatment methods to help them live with the same life quality and life span as non-diabetic patients, and most patients are diagnosed as it until they receive physical examination and blood glucose test because of the lack of obvious clinical manifestation in the early stage[5, 6]. In addition, many patients with diabetes do not fully understand their own disease, so the incidence of complications caused by the disease is gradually increasing, which has become a primary factor for the higher mortality of patients with diabetes[7, 8]. As one of its most severe complications, diabetic foot ulcer (DFU) is featured with wound healing difficulty, long treatment period

and high cost, and patients with it are likely to have disability after the disease develops in severe cases, and even has mortal danger, so DFU causes serious burden on patients and families[9, 10].

DFU can aggravate the original diabetes, and diabetes, as a metabolic disease, will seriously slow the healing of wounds[11]. For patients with DFU who have recurrent wound infection and ulcer and blood glucose not brought under control, in addition to effective treatment, nursing intervention is also needed to achieve ideal treatment effect[12].

Extracorporeal shock wave therapy (ESWT) is a novel physical therapy method in the field of orthopedics, which has been approved for the treatment of DFU wounds[13, 14].

However, studies on the treatment of DFU with ESWT are relatively rare. Therefore, this study analyzed the application value of ESWT in nursing of patients with current DFU wound infection, with the aim of offering a reliable theoretical basis for future clinical diagnosis and treatment of such patients.

Materials and methods

General information of the patients

With permission from the Medical Ethics Committee of our hospital, 87 patients with DFU admitted between March 2018 and May 2020 were enrolled in this study for analysis.

Among them, 46 patients received ESWT combined with nursing intervention as the research group, while the rest 41 received routine treatment combined with nursing intervention as the control group.

Exclusion and inclusion criteria

Inclusion criteria:

• Patients meeting the diagnostic criteria of DFU;

• Patients who consented to cooperate with the study;

• Patients with detailed clinical data, and those who and whose families signed informed consent forms.

Exclusion criteria:

• Patients with other wound infections, or heart, liver or kidney dysfunction;

• Patients with other comorbid chronic diseases;

• Patients who had received hormone therapy, and those with unclear consciousness or communication disorder.

Therapy means

Both groups were given routine hypoglycemic and anti-infective treatment, and also given injection of alprostadil injection and lipoic acid for improvement of microcirculation and neurological status. Patients in the control group were given debridement daily, and their abscess cavities were not disinfected with hydrogen peroxide, normal saline and gentamicin-containing normal saline.

Their wounds were compressed and bound with sterile alginate dressing and foam application, and the dressing was changed once every three days. On this basis, patients in the research group were additionally given shock therapy (Swiss pneumatic ballistic ESWT instrument, Swiss DolorClast Smart). The area with the most obvious somatosensory pain and surrounding muscles were given regional point-to-surface ESWT with the following treatment parameter settings: frequency: 9-18Hz, intensity: 2-4 Bar, times of each grade: 4000-6000 times, density: 0.25mJ/mm2. The shock therapy was carried out for each patient 1 time/week for 4-6 weeks in total.

Nursing methods

Patients in both groups were given targeted nursing care against diabetic foot. Specifically, the nursing staff were required to introduce basic treatment knowledge, adjuvant diet and exercise therapy, targeted drug therapy, daily blood glucose monitoring, and self-care and management about diabetic foot treated by lower extremity vascular intervention to patients at their admission. During debridement treatment, the staff were required to pay close attention to the patients' vital signs and condition changes, and establish personal nursing records. In addition, efforts were made to provide psychological counseling and health education about debridement treatment for the patients, and help them master relevant knowledge.

After the debridement, the staff were arranged to inform the patients of their operation outcome, reduce uneasy emotion of the patients, and urge the patients to carry out passive limb movement as much as possible, so as to do a good job of nursing that can promote the blood circulation at the distal end of the lower extremity of the patients. During hospitalization, for patients with initial good treatment outcomes, the staff were required to instruct them to adhere to cooperation and maintain a good attitude to consolidate the treatment effect. For patients with poor treatment effect, the responsible nurse was required to patiently listen to and understand the

patients' illness and psychological state, and actively communicate with clinicians to respond to the patients' clinical effect as early as possible.

Moreover, the patients were encouraged to exchange experiences with other patients in anti-sugar and anti-infection, so as to reduce negative emotions. The nursing staff were also required to develop a suitable exercise, diet and drug treatment plan for each patient at discharge according to the patient's situation, and instruct the patient and his families to carry out rehabilitation training after discharge in strict accordance with the requirements, and the staff were also arranged to conduct a telephone follow-up once a month to understand the patient's post-hospital situation.

Outcome measures

The reduction rate and healing time of wound after treatment; clinical efficacy; incidence of adverse reactions; changes of blood glucose and blood pressure before and after treatment; wound exudation score: The score ranges between 0-3 points, and a higher score indicates more severe exudation; histological type score: The score ranges between 1-3 points, and a higher score indicates more severe situation; changes of inflammatory indicators (high sensitivity C-reactive protein (hs-CRP) (enzyme-linked immunosorbent assay (ELISA), white blood cells (WBC) (automatic biochemical analyzer), transcutaneous oxygen partial pressure (tc PO_2) (300-G blood gas analyzer); bacterial clearance rate of wound; life quality scores.

Statistical analyses

Enumeration data were expressed as (n/%), and measurement data as ($\bar{x}\pm s$). With SPSS24.0, statistical analyses were carried out by the chi-square test, independent-samples T-test, and paired t-test. $P<0.05$ indicates a remarkable difference.

Results

Clinical baseline data of the two groups

As shown in Table 1, the two groups were not greatly different in general data including age, gender, body mass index (BMI), residential environment, course of diabetes, smoking, drinking, exercise habits, ulcer area before treatment, and nationality.

Clinical efficacy on the two groups

As shown in Table 2, according to the clinical efficacy of the two groups, the total effective rate of the research group was notably higher than that of the control group (95.45% vs. 80.49%, $P<0.05$).

	Research group	Control group	t or χ^2	P
Age			0.387	0.700
	57.7±6.6	58.2±5.3		
Gender			0.521	0.470
Male	26 (56.52)	20 (48.78)		
Female	20 (43.48)	21 (51.22)		
BMI (kg/cm^2)			0.071	0.943
	23.52±3.05	23.46±4.72		
Residential environment			0.389	0.533
Town	31 (67.39)	25 (60.98)		
Countryside	15 (32.61)	16 (39.02)		
Course of disease (year)			0.954	0.059
	7.23±3.12	7.19±3.25		
Smoking			0.245	0.620
Yes	26 (56.52)	21 (51.22)		
No	20 (43.48)	20 (48.78)		
Drinking			0.134	0.714
Yes	24 (52.17)	23 (56.10)		
No	22 (47.83)	18 (43.90)		
Exercise habits			0.461	0.497
Yes	18 (39.13)	19 (46.34)		
No	28 (60.87)	22 (53.66)		
Ulcer area before treatment (cm^2)			0.847	0.399
	28.31±3.54	27.66±3.61		
Nationality			0.307	0.580
Han	43 (93.48)	37 (90.24)		
Minority	3 (6.52)	4 (9.76)		

Table 1: General data$^{(n\ (\%))}$.

	Research group	Control group	χ^2	p
Markedly effective				
	26 (56.52)	12 (29.27)		
Effective				
	18 (39.13)	21 (51.22)		
Invalid				
	2 (4.55)	8 (19.51)		
Total effective rate (%)			4.580	0.032*
	42 (95.45)	33 (80.49)		

Table 2: Clinical efficacy$^{(n\ (\%))}$.
**indicates P<0.05.*

Incidence of adverse reactions in the two groups

As shown in Table 3, adverse reactions such as bleeding, pain, redness and reinfection all occurred in both groups after treatment, and the research group showed a notably lower incidence of adverse

reactions than the control group (8.70% vs. 24.39%, P<0.05).

	Research group	Control group	χ^2	p
Bleeding				
	0 (0.00)	2 (4.88)		
Pain				
	3 (6.52)	4 (9.76)		
Redness				
	1 (2.17)	3 (7.32)		
Reinfection				
	0 (0.00)	1 (2.44)		
Incidence of adverse (%)			3.955	0.047*
	4 (8.70)	10 (24.39)		

Table 3: Incidence of adverse reactions(n (%)).
**indicates P<0.05.*

Reduction rate and healing time of wound after treatment in the two groups

As shown in Figure 1, the wound reduction rate (%) of the research group was greatly higher than that of the control group (P<0.05), while the healing time of the former was notably shorter than that of the latter (P<0.05).

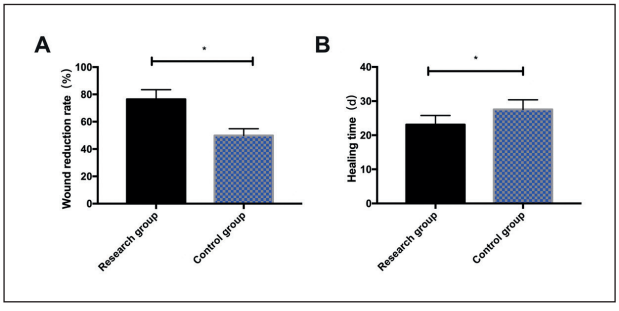

Figure 1: Changes of clinical indicators after treatment in the two groups. A) Comparison of wound reduction rate (%). B) Comparison of wound healing time.
*Note: *indicates P<0.05.*

Wound exudation and histological type scores of the two groups before and after treatment

As shown in Figure 2, before treatment, the two groups were not greatly different in wound exudation score and histological type score (P>0.05), while after it, the scores of both groups decreased, and the scores of the research group were lower (both P<0.05).

Transcutaneous oxygen partial pressure and bacterial clearance rate of wound in the two groups

As shown in Figure 3, after treatment, the transcutaneous oxygen partial pressure (tc PO2) and bacterial clearance rate of wound in the research group were both higher than those in the control group (both P<0.05).

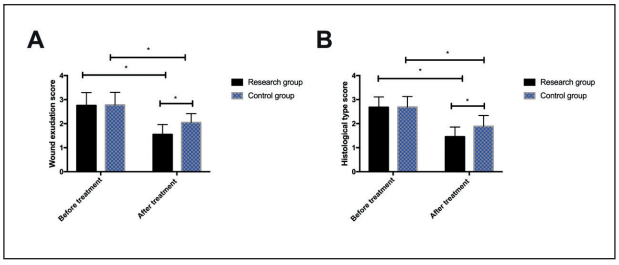

Figure 2: Wound exudation and histological type scores of the two groups before and after treatment. A) Wound exudation score. B) Histological type score.
*Note: *indicates P<0.05.*

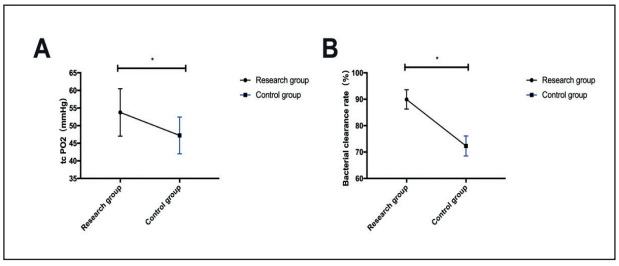

Figure 3: Transcutaneous oxygen partial pressure and bacterial clearance rate of wound in the two groups. A) Transcutaneous oxygen partial pressure of the two groups. B) Bacterial clearance rate of wound in the two groups.
*Note: *indicates P<0.05.*

Changes of clinical indexes in the two groups before and after treatment

As shown in Figure 4, before treatment, no notable difference was found between the two groups in fasting blood glucose (GLU), systolic blood pressure (SBP), and diastolic blood pressure (DBP) (all P>0.05), while after it, GLU, SBP, and DBP of both groups decreased, and the decreases in the research group were more notable (all P<0.05).

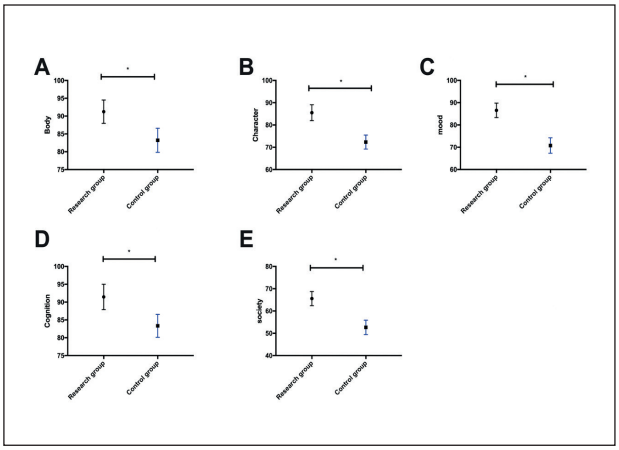

Figure 4: Changes of clinical indexes in the two groups before and after treatment. A) Changes of fasting blood GLU before and after treatment. B) Changes of SBP before and after treatment. C) Changes of DBP before and after treatment.
*Note: *indicates P<0.05.*

Changes of inflammation indexes in the two groups before and after treatment

As shown in Figure 5, before treatment, the two groups were not greatly different in the levels of hs-CRP and WBC (both P>0.05), while after it, the levels of them in both groups decreased, and the decreases in the research group were notably significant (both P<0.05).

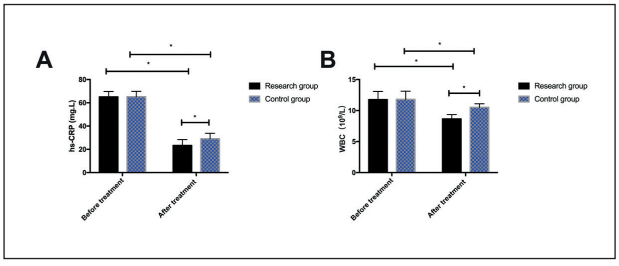

Figure 5: Changes of inflammation indexes in two groups before and after treatment. A) The level of hs-CRP. B) The level of WBC.
*Note: *indicates P<0.05.*

Life quality scores of the two groups

As presented in Figure 6, the life quality scores of the research group were all notably higher than those of the control group in terms of bodily pain, role physical, role emotional, cognition function, and social function (all P<0.05).

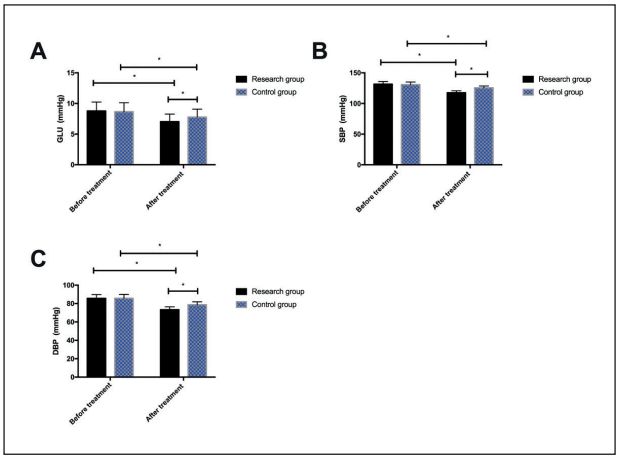

Figure 6: Life quality scores of the two groups. A) Bodily pain score. B) Role physical score. C) Role emotional score. D) Cognition function score. E) Social function score.
*Note: *indicates P<0.05.*

Discussion

Diabetes is a global disease with an extremely high incidence and it is clinically considered to be mainly caused by low insulin level or insufficient insulin efficacy[15]. During the development of diabetes, the long-term high glucose state of the internal environment of patients is likely to induce chronic organ injury, vascular disease, neuropathy and other malignant diseases[16]. As a high-infection complication of diabetes, DFU is mainly caused by limb neuropathy and infection due to the disorder of body function metabolism, which disrupts the normal life of patients[17]. In addition, because of the particularity of diabetes, patients are highly susceptible to infection, so cases of recurrent DFU infection are extremely common in clinical practice[18]. Therefore, effective treatment is the key to ensuring the prognosis and life quality of patients with DFU.

Compared with other treatment methods for tissue injury, ESWT has obvious advantages for its non-invasion, simplicity in use, safety, effectiveness, and low cost, and it is increasingly widely applied in clinical practice[19]. One study has revealed that ESWT can exert biological effects in vivo as a mechanical wave, which can inhibit inflammation and promote cell growth and microvascular formation[20]. The positive electrode is suitable for the treatment of DFU. However, there are few studies on the influence of ESWT on DFU at present, and there is a lack of reliable guidance in clinical practice to popularize the use of ESWT. Therefore, this study that explores the influence of ESWT on DFU is of great significance in clinical practice.

In this study, we firstly evaluated the prognosis of DFU wounds in the two groups. The results showed that the clinical efficacy on and wound healing of the research group were both better than those of the control group, while the incidence of adverse reactions in the research group was notably lower, suggesting that ESWT possesses significant therapeutic effect and high safety for DFU. The application effect of ESWT on venous ulceration of lower extremity in a previous study is also in line with the result of our study[21], which once again verifies the great clinical application value of ESWT in the future. We speculated that the treatment of ESWT for DFU mainly depended on the mechanical stress effect, electro-hydraulic effect and electromagnetic effect of its shock wave[22]. One study by Celik et al.[23] has pointed out that ESWT can inhibit inflammatory factors in arthritis and reduce the incidence of nonunion. One other study by Lin et al.[24] has found that ESWT can promote the release of expansive and angiogenic mediators in bone and muscle tissue and promote the regeneration of pro-inflammatory neuropeptides and neovascularization in local treatment. As we all know, DFU is produced

due to the inhibition of the growth ability of cells and microvessels in a high glucose environment and also due to the continuous diffusion of inflammatory mediators caused by infection and damage to limb tissues[25]. ESWT can effectively curb the development of the previous two situations, so it can exert a remarkable therapeutic effect on DFU.

Subsequently, we further compared the clinical efficacy between the two groups and found that the blood pressure, blood glucose, inflammatory factors, wound exudation and bacterial clearance rate of the research group were improved greatly in contrast to those of the control group. The results once again confirm our above inference and explain the application value of ESWT. Moreover, the follow-up survey for prognosis showed the remarkably improvement of life quality of the research group. Because of the decreased immune function and metabolic disorder of patients with diabetes, their DFU usually has a high possibility of repeated attacks[26]. We speculated that the treatment of ESWT not only effectively promoted the recovery of the wound, but also helped fundamentally change cell viability. The original slow cell growth cycle was activated under electromagnetic shock, which effectively guaranteed the patient's prognosis. This view was also put forward in a research by Li et al.[27], which confirmed the certain molecular regulation ability of ESWT.

Additionally, nursing guidance is also one of the key links of treating DFU[28]. The guidance in self-monitoring of blood glucose can improve patients' understanding to the knowledge of diabetes and their daily precautions, thus accelerating their recovery. The negative psychology and emotion caused by illness and social life can also be alleviated in the nursing process, so that patients can build up confidence in overcoming diseases. Moreover, fully humanized nursing can not only help patients recover from diseases, but also effectively promote harmonious communication between doctors and patients and improve patients' nursing experience.

To sum up, ESWT can effectively improve the wound healing of patients with DFU and reduce the risk of infection, so it has a high application value in clinical rehabilitation nursing of such patients. However, this study has not fully revealed the specific reasons of various adverse reactions in the two groups, and the understanding of them is helpful to effectively control the clinical rehabilitation of patients in the future and reduce the incidence of risk events. In addition, due to the short experimental period, we are unable to evaluate the long-term prognosis of patients. The two aspects are both our future research focus and direction.

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