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Original Research Article

Efficacy of combined application of traditional Chinese medicine foot bath and mild moxibustion in the treatment of limb pain in diabetic peripheral neuropathy patients

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Abstract

Purpose: *To determine the efficacy of the combination of traditional Chinese medicine (TCM) foot bath and mild moxibustion in the treatment of limb pain in patients with diabetic peripheral neuropathy (DPN).*
Methods: *A total of 120 patients with symptoms of DPN-induced pain who were hospitalized at the Department of Endocrinology in the 903rd Hospital of PLA, from January 2020 to June 2021, were included in this study. They were randomly assigned to a study group and a control group, with 60 patients in each group. Patients in both groups received conventional treatments and nursing care, while those in study group were additionally treated with a combination of TCM foot bath and mild moxibustion. Treatment efficacy in the patients was evaluated using Short-Form McGill Pain Questionnaire (SF-MPQ), pain rating index (PRI), visual analogue scale (VAS), TCM symptom score (TCMSS), and Toronto Clinical Scoring System (TCSS).*
Results: *Compared with control group, there were significant improvements in pain-related scores, namely, SF-MPQ, ($p < 0.05$); PRI, ($p < 0.01$); VAS, ($p < 0.05$); as well as overall efficacy ($p < 0.05$). Similar improvements were also observed with regard to TCMSS ($p < 0.001$) and TCSS ($p < 0.001$) in the study group. However, there were no significant changes in Adjusted Diabetes Quality of Life (A-DQOL) score and blood glucose control in both groups.*
Conclusion: *Relative to the conventional treatment for DPN, limb pain and disease score of patients are significantly reduced by the combination of TCM foot bath and mild moxibustion treatments. Further clinical trials would be required prior to application in clinical practice.*

Keywords: *Traditional Chinese medicine foot bath, Mild moxibustion, Diabetic peripheral neuropathy, Limb pain, Efficacy*

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INTRODUCTION

Diabetes mellitus (DM) is a common metabolic disease. A current estimate shows that there are 537 million DM patients worldwide, a figure which is expected to increase by one-third by 2045, to about 700 million [1]. Diabetic peripheral neuropathy (DPN) is one of the major complications of DM, and it affects about 50 % of DM patients [2]. In addition, DPN is the leading

cause of diabetic foot complications, often contributing to lower-limb amputations. Limb pain is also a major clinical manifestation that greatly affects the quality of life of DPN patients.

Although DPN brings a huge healthcare-related financial burden to society and also affects the life quality of patients, its treatment options are limited. Since the outbreak of COVID-19 pandemic, the international popularity of TCM has been on the rise. Mild moxibustion and TCM foot bath are common external TCM treatments that might be useful in the treatment of limb pain in patients with DPN. This study was carried out to determine the therapeutic effectiveness of the combined use of TCM foot bath and mild moxibustion in the treatment of limb pain in DPN patients.

METHODS

Patients' information

A total of 120 patients hospitalized for DPN-induced pain in the Department of Endocrinology in the 903rd Hospital of PLA from January 2020 to June 2021 were enrolled in this study. The patients were randomly assigned to study group (n = 60) and control group (n = 60), and subjected to different therapeutic regimens. General information and specific data were collected, including fasting blood glucose (FBG) level, hemoglobin A1C (HbA1c) level, and scores in Short-Form McGill Pain Questionnaire (SF-MPQ), pain rating index (PRI), visual analogue scale (VAS), and Toronto Clinical Scoring System (TCSS). Moreover, data was obtained on the assessment of the reliability and validity of Adjusted Diabetes Quality of Life (A-DQOL).

Ethical statement

This study was approved by the Medical Ethics Committee of 903 Hospital (approval no. 20200722/08/01/226). Written informed consent was obtained from each of the patients enrolled in this study. All experiments were carried out in strict compliance with the guidelines of the Declaration of Helsinki [3].

Inclusion/exclusion criteria

Inclusion criteria

Patients in the following categories were included: patients diagnosed with DPN by standard diagnostic procedures, those with VAS ≥ 4 points, patients with pain which started at the corresponding symmetrical part of the foot, with daily pain lasting at least for 6 months; patients who passed preliminary TCSS screening; patients aged 30 - 80 years, with at least complete primary school educational background, or above, and those who voluntarily completed and signed informed consent forms.

Exclusion criteria

Patients in the following categories were excluded from the study: patients with acute complications of DM and severe infections within a month before seeing a doctor; those with non-DPN-induced pain, including pain due to peripheral vascular disease (ischemia-induced pain), phantom limb pain after amputation, or other pain states (e.g. arthritis), and pain due to osteoporosis; patients with severe heart disease, liver disease, kidney disease, coagulation disorders or thrombosis; those with history of epilepsy or with communication disorders, patients with the surgical installation of electronic cardiac pacemakers, or patients allergic to electricity; those having skin diseases, or patients with injury at sites for acupoint-stimulation, and patients enrolled in other studies.

Treatments

Patients in both groups were subjected to conventional treatments for DM. For DPN treatments, oral mecobalamin for nerve nurturing was given at a dose of one 0.5-mg tablet, 3 times daily. Moreover, there was regular nursing care for all patients, with respect to medication, diet, exercise, emotional support, feet care, and health education. In addition to these treatments, patients in the study group were treated with TCM foot bath in combination with mild moxibustion.

The TCM foot bath recipe, a foot bath formulation independently developed by the 903rd Hospital of PLA, enhances blood circulation and removes blood stasis. The prescription comprised common Clubmoss herb (20 g), *Angelica sinensis* (10 g), Ligusticum chuanxiong hort (10 g), peach seed (10 g), *Carthamus tinctorius* L. (safflower, 6 g); red peony root (10 g), *Paeonia suffruticosa* Andr. (10 g), sub-erect spatholobus stem (15 g), Ramulus mori (20 g), Notopterygium root (10 g), Radix angelicae pubescentis (10 g), *Fructus chaenomelis* (20 g), frankincense (*Boswellia carterii*) essential oil (10 g), myrrh (10 g), *Artemisia argyi* Levl. et Vant. (20 g), *guizhi* (*Ramulus cinnamomi*, cinnamon twig, or cassia twig, 20 g); *Fructus liquidambaris* (30 g), *Impatiens balsamina* L. (20 g), and *Buthus martensi* karsch (6 g). These medicinal herbs

were weighed and soaked in 1000 mL of clear water for 30 min, prior to heating to boiling stage, followed by gentle heating for 45 min. Next, 500 mL of the medicinal decoction was put into a homothermal foot basin, and warm water was added to bring up the overall volume to 2000 mL. Then, the patient's feet were immersed in the extract for 30 min, with the temperature kept at 40 - 43 °C. This therapy was administered once a day for 60 consecutive days [4].

Mild moxibustion was given at the acupoints *feishu, pishu, shenshu,* and *zusanli*; in addition to coupling with *quchi* and *waiguan* for patients with symptoms of pain in the upper extremities, or *sanyinjiao* and *yanglingquan* for those with symptoms of pain in the lower extremities. In the pre-treatment preparation, moxa strips of appropriate length were lit and put into the moxibustion box. The patient lay in appropriate positions, with the whole body relaxed, and parts of the body where moxibustion was to be performed were fully exposed. In the method of mild moxibustion, the corresponding acupoints were selected, and holes under the moxibustion box were aligned with the body parts for moxibustion, leaving 3 cm of clearance from the skin.

Then, moxa-moxibustion was performed to the extent that patients felt warm without burning pain, and it was stopped when patients had feelings of obvious burning pain or acupuncture. Local cleaning was done after moxa-moxibustion, to avoid scratching and prevent infection. The treatment lasted 10 min for each acupoint, with local warmth around the acupoints as standard. Each treatment course for mild moxibustion was 20 times, done once every other day, and 3 times a week. Two courses of treatment were used [5].

Evaluation of efficacy with respect to pain

The SF-MPQ was used to determine the PRI, VAS, and current pain status of the patients before and after the intervention. Treatment effectiveness was calculated in terms of pain efficacy index (PI) as shown in Eq 1.

$$PI = \{(At–Bt)/Bt\}100 \quad \text{……} \quad (1)$$

Where At = integration after treatment, and Bt = integration before treatment.

Treatment was classified as markedly effective (pain efficacy index ≥ 20 %); effective (pain efficacy index ≥ 12 %); ineffective (pain efficacy index < 12 %), or pain-aggravating (efficacy index < -12 %).

Evaluation of TCSS

Neurological symptoms, neurological reflexes, and sensory function of the patients before and after intervention were assessed using TCSS.

Assessment of the reliability and validity of A-DQOL

The quality of life of patients were evaluated before and after the intervention, using A-DQOL which had good construct validity, with four factors: degree of satisfaction, degree of influence, anxiety level I, and anxiety level II. There was a total of 46 items. The higher the score, the worse the quality of life of the patient.

Laboratory tests

An automatic biochemical analyzer was used to determine the levels of FBG and HbA1c in patients in the two groups before drug intervention, and 60 days after treatment.

Evaluation of TCMSS

The TCMSS of each patient in the two groups was recorded before and after treatment [6].

Assessment of side effects

All adverse reactions in patients during treatment were carefully recorded.

Statistical analysis

Statistical analysis was performed using SPSS 22.0 statistical software. Measurement data are expressed as mean ± standard deviation (SD). For data that conformed with normal distribution, Student's *t*-test was used for comparison between the two groups, while the rank sum test was used if the data were not consistent with normal distribution. Enumeration data are expressed as absolute numbers and percentages; n (%), and $\chi 2$ test or rank sum test was used for comparison. Values of $p < 0.05$ indicated significant differences.

RESULTS

General patients' information

There were no statistically significant differences in general data between the study group and the control group regarding gender, age, DPN course, limb pain course, body mass index (BMI), HbA1c, FBG, SF-MPQ, PRI, VAS, TCSS, and TCMSS. These data are shown in Table 1.

Effect of combination of TCM foot bath and mild moxibustion on blood glucose-related indicators

There were no significant differences in the levels of FBG and HbAb1c in patients between the two groups before and after treatment (Table 2). Thus, the combined application of TCM foot bath and mild moxibustion had no marked effect on the levels of FBG and HbAb1c in the DPN patients.

Efficacy of combination of TCM foot bath and mild moxibustion on limb pain relief

Table 3 shows that there were significant improvements in pain-related scores i.e. Short-Form McGill Pain Questionnaire (SF-MPQ, $p < 0.05$); pain rating index (PRI, $p < 0.01$); visual analogue scale (VAS, $p < 0.05$), as well as overall efficacy ($p < 0.05$); TCMSS ($p < 0.001$), and Toronto Clinical Scoring System (TCSS, $p < 0.001$) in the study group, when compared with the control group, after treatment. As presented in Table 4, statistical analysis showed that the overall pain efficacy in the study group given a combination of TCM foot bath and mild moxibustion was superior to that of the control group ($p < 0.05$).

Effect of combination of TCM foot bath and mild moxibustion on TCSS, A-DQOL, and TCMSS

The combined use of TCM foot bath and mild moxibustion in study group resulted in significant improvements in TCSS and TCMSS of DPN patients when compared to control group ($p < 0.001$). However, there were no marked changes in A-DQOL between the two groups before and after treatment. These results suggest that the combined treatment with TCM foot bath and mild moxibustion was more effective in reducing the degree of neuropathy and TCM symptoms in DPN patients. These results are shown in Table 5.

Table 1: General information on 120 patients with DPN

Characteristic	Group		t/Fisher	*P*-value
	Control	Study		
N	60	60		
Gender			-	0.051
Male	46	35		
Female	14	25		
Age/years	59.33±9.69	60.65±12.16	0.656	0.513
DPN disease duration /years	4.55±3.36	6.07±5.32	1.866	0.065
BMI (Kg/m^2)	23.86±3.09	24.73±3.60	1.454	0.149
HbA1c (%)	8.51±2.26	8.65±1.90	0.376	0.707
FBG (mmol/L)	9.71±3.05	9.16±3.45	0.928	0.355
SF-MPQ	15.20±3.54	14.53±3.65	1.016	0.223
PRI	7.47±1.83	7.18±1.76	0.865	0.389
VAS	5.65±1.19	5.48±1.31	0.730	0.467
TCSS	7.15±1.44	6.92±1.22	0.957	0.340
A-DQOL	91.93±13.58	95.55±17.92	1.246	0.215
TCMSS	5.48±1.85	5.40±1.42	0.277	0.783

Table 2: Changes in blood levels of glucose-related indicators in the two groups before and after 60 days of treatment (n = 60)

Group	FBG (mmol/L)		HbA1c (%)	
	Before treatment	After treatment	Before treatment	After treatment
Control	9.71±3.05	9.06±2.27	8.51±2.26	8.17±1.83
Study	9.16±3.45	8.79±1.55	8.65±1.90	8.30±1.34
t	0.928	0.743	0.376	0.918
P-value	0.335	0.459	0.707	0.361

Table 3: Comparison of pain-related scores between the two groups of patients before and after 60 days of treatment

Group	SF-MPQ		PRI		VAS	
	Before treatment	After treatment	Before treatment	After Treatment	Before treatment	After treatment
Control	15.20±3.54	13.12±3.88	7.47±1.83	6.45±2.04	5.65±1.19	4.32±1.94
Study	14.53±3.65	11.55±3.09	7.18±1.76	5.38±1.65	5.48±1.31	3.70±1.20
t	1.016	2.447	0.865	3.153	0.730	2.092
P-value	0.223	<0.05	0.389	<0.01	0.467	<0.05

Table 4: Comparison of treatment efficacy in the two groups based on SF-MPQ after 60 days of treatment

Group	Markedly effective	Effective	Ineffective	Deteriorative	Z	*P*-value
Control	25	8	20	7	2.146	0.032
Study	36	7	14	3		

Table 5: Comparison of TCSS, A-DQOL, and TCMSS between the two groups before and after 60 days of treatment

Group	TCSS		A-DQOL		TCMSS	
	Before treatment	After treatment	Before treatment	After treatment	Before treatment	After treatment
Control	7.15±1.44	7.22±1.45	91.93±13.58	89.27±10.91	5.48±1.85	4.23±1.65
Study	6.92±1.22	5.95±1.17	95.55±17.92	89.07±14.91	5.40±1.42	3.13±1.32
t	0.957	5.263	1.246	0.084	0.277	4.031
P-value	0.340	<0.001	0.215	0.933	0.783	<0.001

DISCUSSION

Diabetic peripheral neuropathy (DPN) is one of the most common complications of DM. Studies have revealed that the number of DPN inpatients is more than the total number of inpatients for all other DM complications, which results in a huge economic burden on society [7,8]. Limb pain is one of the most typical symptoms of DPN, and this symptom often starts from the foot and spreads to the proximal end in a length-dependent manner. However, due to the complex pathogenesis of the disease, there are limited treatment options for DPN [9].

It has been reported that impairment of microcirculation in peripheral nerves may be one of the pathophysiological mechanisms of DPN[9]. Microcirculation dysfunction is closely related to peripheral nerve dysfunction: poor microcirculation aggravates nerve injuries. Relative to healthy controls, patients with DM present with increased intraneural capillary density, suggesting that capillary density may respond to DM-induced neuro-ischemia [10]. It has been reported that basement membrane thickening of blood vessels is associated with nerve injury in DPN patients [10]. Studies have reported poor vasodilation of epineurial arterioles in DM rats, and the use of vasodilators ameliorates reduced intraneural blood flow in preclinical models [11]. A study has demonstrated that DM reduces levels of mediators of angiogenesis such as insulin-like growth factor (IGFs), vascular endothelial growth factor (VEGF), nerve growth factor (NGF), and angiopoietin [12]. Overall, these findings suggest that an effective treatment modality may be developed by addressing microvascular problems in DM.

In recent years, the international popularity of TCM has been on the rise. Moreover, it has been revealed that TCM has significant efficacy in the treatment of DPN. Consistent with the clinical manifestations of DPN such as numbness and pain, TCM theory states that “numbness belongs to deficiency syndrome”. Therefore, in TCM, the therapeutic principles in DPN involve dredging of the meridians and enhancement of blood circulation, which are consistent with the principle of improving microcirculation in peripheral nerves.

The DPN-induced limb pain often occurs in the feet. The TCM foot bath is a popular TCM therapeutic method based on the *TCM theory of syndrome differentiation* and the principles of mucocutaneous absorption and physical stimulation in Western Medicine [13]. Chinese herbs that promote blood circulation and remove blood stasis are important components of the herbal cocktail used in the preparation of TCM foot baths. The medicinal decoction which is effective in dredging *meridians* and promoting blood circulation, exerts stimulatory and osmotic effects on the plantar reflex areas and acupoints, thereby enhancing microcirculation in the foot. It

has been reported that TCM foot baths relieved the symptoms of foot ulcers in patients with diabetic foot [14]. Mild moxibustion is one of the moxibustion therapies [15]. It is a TCM therapeutic method in which specific acupoints on the human body are stimulated by heat generated after the ignition of moxa sticks or moxa cones made of *Artemisia argyi* Levl. et Vant. Stimulation of different acupoints produces different effects. A research team has reported that mild moxibustion significantly relieved symptoms of pain in patients with primary dysmenorrhea [16].

In the present study, mild moxibustion was used to stimulate relevant acupoints, including the bladder meridian of the foot (*taiyang*) and the stomach meridian of the foot (*yangming*), and it was effective in dredging meridians, promoting blood circulation and alleviating pain. Stimulation of the bladder meridian of the foot i.e., *taiyang* effectively relieved the symptoms of sciatica, shoulder pain, and backache [17,18]. Moreover, stimulation of the stomach meridian of the foot (*yangming*) effectively alleviated pain and dysfunction caused by lumbar disc herniation [19]. In this study, 120 DPN patients were generally treated with conventional therapy, but patients in the study group were additionally treated with a combination of TCM foot bath and mild moxibustion. It was revealed that pain-related scores in study group were more significantly reduced after treatment than the corresponding scores in control group. Patients in the study group manifested distinct advantages in treatment efficacy. In addition, it was found that TCSS and TCMSS of patients with DPN were mitigated in study group, which indirectly indicated that the combined use of TCM foot bath and mild moxibustion produced definite clinical significance. However, there were no marked differences in blood glucose-related indicators between study group and control group, before and after treatment, suggesting that the efficacy of the combination treatment on limb pain in patients with DPN was not achieved by reducing the levels of blood glucose. The clinical effect of the combination treatment may be related to the improvement of peripheral nerve microcirculation. However, the specific underlying mechanism needs to be unraveled through further studies.

Limitations of this study

Nevertheless, it should also be noted that this study has some inadequacies. In the first place, it was a single-center study with a small sample size, and no basic studies were carried out. However, with advancements in modern medicine, more in-depth studies in the field of TCM will need to be carried out in the future in order to validate the findings reported here, so as to achieve more treatment options and better therapeutic efficacy for DPN patients.

CONCLUSION

This study demonstrates that, relative to conventional treatments for DPN, the use of a combination of TCM foot bath and mild moxibustion is significantly effective in the treatment of limb pain in DPN patients. Large scale, multicenter study would be needed in order to validate the findings of this study and establish its potential for application in clinical practice for the treatment of DPN.

DECLARATIONS

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Ethical approval

None provided.

Availability of data and materials

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

Conflict of Interest

No conflict of interest associated with this work.

Contribution of Authors

The authors declare that this work was done by the authors named in this article and all liabilities pertaining to claims relating to the content of this article will be borne by them.

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