

Comparative study of two integrated traditional Chinese and Western medicine treatment methods on treatment compliance of patients with diabetic peripheral neuropathy

Yongli Qiao¹, Guiying Guo², Jianhua Zhao²

¹College of Nursing, Shanxi University of Chinese Medicine, Shanxi, China, ²Shanxi Hospital of Integrated Traditional Chinese and Western Medicine, Shanxi, China

Folia Neuropathol 2022; 60 (3): 324-328

DOI: <https://doi.org/10.5114/fn.2022.117523>

Abstract

Introduction: This study aims to compare the treatment satisfaction and compliance of two integrated traditional Chinese and Western medicine methods for diabetic peripheral neuropathy (DPN) patients with cold coagulation and blood stasis.

Material and methods: A total of 120 patients with cold coagulation and blood stasis type of distal symmetric polyneuropathy (DSPN), the most common form of diabetic neuropathy, were selected from the urology department of a hospital and randomly divided into a control group (60 patients), who were given external medicinal liquid application with Tangbiling (Magic Diabetic Arthralgia Treating Paste) herbs, and an observation group (60 patients), who were treated with modified Tangbiling herbs (Tangbiling herbs mixed with mud moxibustion substrate) for external medicinal liquid application. Both groups were treated with a TDP therapeutic apparatus at the same time as the external medicinal liquid application. After three courses of treatment (14 days/course of treatment), the efficacy was evaluated by the score of traditional Chinese medicine (TCM), and the questionnaires were used to compare the treatment compliance of the two groups.

Results: After the external medicinal liquid application with modified traditional Chinese medicine, the moulding and cleaning degree of TCM and the symptoms of the two groups were improved. The effective rate of the observation group was 91.7%, which was higher than the control group (86.7%). The compliance of the observation group was higher than the control group, and the differences were statistically significant ($p < 0.05$).

Conclusions: The external medicinal liquid application with modified Tangbiling herbs improved the treatment compliance and satisfaction of DPN patients and effectively improved the symptoms of pain and numbness in the lower limbs of patients, which is worth promoting.

Key words: external medicinal liquid application with Tangbiling herbs, TDP therapeutic apparatus, diabetic peripheral neuropathy, mud moxibustion.

Introduction

Among diabetic peripheral neuropathies (DPN), diabetic distal symmetric sensorimotor polyneuropathy (DSPN) is the most common type. Its clinical manifestations, such as pain, numbness, and abnormal sensations, may appear in the extremities, but mainly in

the lower extremities [13], which eventually leads to diabetic foot, resulting in a high rate of disability and death. At present, the treatment of DPN by Western Medicine is mostly based on the control of blood glucose and the use of drugs for symptomatic treatment. Although this comprehensive measure has a certain

Communicating author:

Guiying Guo, MM, Department of Endocrine, Shanxi Hospital of Integrated Traditional Chinese and Western Medicine, No. 13, Fudong Street, Xinghualing District, Taiyuan City, Shanxi Province, 030013, China, phone: +86-13700545301, e-mail: guoguiying_2021_13@126.com

curative effect on DPN, it lacks specificity and cannot be cured. At the same time, it has side effects and high cost, which increases the economic and spiritual burden of patients [6]. The external treatment of traditional Chinese Medicine in China takes syndrome differentiation and treatment as the guiding ideology, the clinical efficacy of the treatment is accurate by relaxing meridians and activating collaterals, helping Qi and blood run normally and reach the viscera. However, there is still insufficient specificity of the treatment based on syndrome differentiation [8], and little attention is paid to the patient's compliance [12]. Given the limitations of current Western medical treatment and research on the external treatment of Chinese medicine [6,8], the aim of this study is to investigate the effect of external medicinal liquid application with modified traditional Chinese medicine (TCM) on the compliance and efficacy of DPN patients with cold coagulation and blood stasis.

Material and methods

Patients

With the approval of the Ethics Committee, a total of 120 DPN patients with cold coagulation and blood stasis admitted to the endocrinology department of a hospital from January to December 2019 were randomly divided into an observation group (60 cases, 32 males and 28 females, mean 58.02 ± 9.54 years, DPN disease duration 8.22 ± 4.39 years) and a control group (60 cases, 33 males and 27 females, mean 58.3 ± 9.67 years, DPN disease duration 8.62 ± 4.47 years). Inclusion criteria: 1) met the diagnostic criteria of the Guidelines for the Prevention and Control of Type 2 Diabetes in China (2017 Edition) [2] and DPN [12]; 2) complied with the diagnostic criteria and classification of cold coagulation and blood stasis in the Guidelines for TCM Clinical Diagnosis and Treatment of Diabetic Peripheral Neuropathy (2016 Edition) [4]. Exclusion criteria: patients with severe arteriovenous vascular disease; patients with Guillain-Barré syndrome, cervical and lumbar diseases, cerebral infarction; patients with renal insufficiency, and neurotoxic injury caused by chemotherapeutic drugs were excluded. Drop-out criteria: 1) those who withdrew themselves from the trial, 2) those who did not cooperate with the use of drugs.

Methods

Patients in both groups were given conventional drug therapy, mainly symptomatic treatment, such as neurotrophic drugs, thioctic acid and miltiorrhiza polyphenol for improving microcirculation, hypoglycaemic and hypotensive drugs are given according to individual circumstances.

Control group

The TCM (Astragalus membranaceus 30 g, Cinnamonum cassia 15 g, Radix Paeoniae Alba 15 g, Radix Angelicae sinensis 30 g, Asarum 6 g, Tong Cao 10 g, Tong Cao 30 g, Lonicera japonica 30 g, Zingiber officinale 30 g, Jujube 30 g, and Radix Glycyrrhizae 15 g) was ground into powder and mixed with vinegar and heated. Then the external medicinal liquid was applied (temperature 38-40°C) on the itchy and painful areas of the lower limbs of patients.

Observation group

Mud moxibustion substrates, such as volcanic rock and beeswax (10 g each, added or subtracted according to the application area), were added to the mix and implemented in the external medicinal liquid application based on the formula of the control group.

Both groups were treated for 30 min once a day. After 15 minutes of external medicinal liquid application, a TDP therapeutic apparatus was applied for 15 minutes (the light board was 30 cm away from the treatment site), during which the application area was closely observed to prevent infection and burns. Fourteen days was a course of treatment, and the cycle observation care time was three courses of treatment.

Effectiveness evaluation

Efficacy criteria for the clinical efficacy of TCM

The efficacy criteria of TCM syndrome scores need to be formulated with reference to the Guidelines for TCM Clinical Diagnosis and Treatment of Diabetic Peripheral Neuropathy (2016 Edition) [4]. Symptoms such as numbness and tingling in the limbs, cold skin sensation, formication, changes in the tongue and pulse were observed, and symptom scores were recorded as 0 = none, 2 = mild, 4 = moderate, and 6 points = severe. The efficacy criteria were as follows clinical recovery: the symptoms and signs of numbness, coldness, pain, and impotence of the limbs disappeared, and the scores were reduced by ≥ 90%; significantly effective: the subjective symptoms and signs improved significantly, and the scores were reduced by ≥ 70%; effective: the subjective symptoms and signs improved, and the scores were reduced by ≥ 30%; ineffective: the subjective symptoms and signs did not improve significantly, and the scores were reduced by < 30%. The calculation formula was the following: $([\text{pre-treatment score} - \text{post-treatment score}] / \text{pre-treatment score}) \times 100\%$.

Compliance survey

The compliance was assessed using the Morisky Medication Adherence Scale (MMAS) questionnaire [11],

Table I. Clinical efficacy of the two groups evaluated by TCM syndrome scores [n (%)]

Group	n	Clinical recovery	Significantly effective	Effective	Ineffective	Total validity
Control group	60	5	24	23	8	86.7%
Observation group	60	14	30	11	5	91.7%*

Compared with the control group, $\chi^2 = 9.857, p = 0.02, *p < 0.05$.

Table II. Comparison of TCM syndrome scores before and after treatment between the two groups (x ± s, points)

Group	n	Pre-treatment scores	Post-treatment scores
Control group	60	20.78 ± 5.87	7.32 ± 4.83*
Observation group	60	19.13 ± 5.68	5.67 ± 4.11 ^{Δ*}

Compared with the pre-treatment period, * $p < 0.05$; compared with the control group during the same period, ^Δ $p < 0.05$.

which consisted of 8 items, each with a score of 0 or 1 and a total score of 8. If the score was higher, the patient’s adherence was better. A score of 8 indicated high adherence, a score of 6-7.9 indicated moderate adherence, and a score of less than 6 indicated poor adherence.

Statistical methods

SPSS 17.0 statistical software was used for analysis, and the measurement data were expressed as mean ± standard deviation (x ± s). One-way analysis of variance (ANOVA) was used for comparison between groups with a *t*-test. $P \leq 0.05$ was considered a statistically significant difference.

Results

There were no statistically significant differences ($p > 0.05$) between the two groups when comparing their general data such as gender, age, and duration of diabetes mellitus, and they were comparable.

Comparison of clinical efficacy between the two groups

Among the 60 patients in the observation group, 14 were clinical recovery, 30 were significantly effective, 11 were effective and 5 were ineffective. The total validity was 91.7%. The efficacy in only 5 of the 60 pa-

tients in the control group was clinical recovery, 24 – significantly effective, 23 – effective and 8 – ineffective. The total validity was 86.7%. The efficacy of the observation group was significantly higher than the control group, and the difference was statistically significant ($p < 0.05$) (Table I).

Comparison of the TCM syndrome scores between the two groups

After treatment, the TCM syndrome scores were significantly lower in the observation group compared with those before treatment and the control group during the same period ($p < 0.05$) (Table II).

Patient compliance survey

The evaluation results of MMAS questionnaire showed that 54 (90%) in the observation group (60 cases) got the full score (8 points), while only 45 (75%) in the control group (60 cases). In addition, there were 7 in the control group with less than 6 points and only 1 in the observation group. There were 8 in the 6-7.9 points control group and 5 in the observation group. The compliance of the observation group was better than the control group (Tables III, IV).

Safety

The safety of the two groups was good. There were no allergies, skin foaming, or burns.

Discussion

External medicinal liquid application of TCM is also known as TCM fumigation, steaming therapy, and iontophoresis therapy [7], which is a typical external treatment method of TCM. In the Huang Di Nei Jing Su Wen, it is said that “those who have evil, impregnate the form with sweat”, and the external medicinal liquid application of TCM can achieve different therapeutic purposes according to its diverse drug selection [16]. The princi-

Table III. Comparison of the level of patient compliance between the two methods of external medicinal liquid application [n (%)]

Group	n	Low (< 6 points)	Moderate (6-7.9 points)	High (8 points)	Good compliance
Control group	60	7	8	45	75%
Observation group	60	1	5	54	90%*

Compared with the control group, $\chi^2 = 6.01, p = 0.046, *p < 0.05$.

ple is to use the dual effect of heat and herbal medicine on the surface of the limb to stimulate the patient's skin, nerves, and blood vessels, thus achieving the purpose of warming the meridians and dispersing cold, activating blood circulation, and relieving spasms and pain [14]. Several studies [1,9,15] have applied external medicinal liquid application combined with a TDP therapeutic apparatus to DPN patients with knee pain, knee joint effusion, and other pain, and the symptoms were effectively improved. However, there is a relative lack of clinical application of treatment based on syndrome differentiation for DPN. Some patients withdrew from treatment because of the poor compliance caused by the long treatment period and unsuitable treatment methods. A large amount of evidence-based medicine (EBM) also showed that the difference in clinical efficacy between patients with different compliance was significant, and those with good compliance had better clinical efficacy [10]. In this study, for patients with DPN of cold coagulation and blood stasis type, we used external medicinal liquid application combined with a TDP therapeutic apparatus. The treatment process produced a "thermal power effect" through the specific electromagnetic waves of the TDP therapeutic apparatus, which could open the site where the skin and muscle are joined and make the medicine penetrate the local area through the pores. It can regulate the balance mechanism of elements in the body, unblock the meridians and relieve pain [5], and achieve continuous warmth in the treatment process so that the drug efficacy can be effectively exerted continuously, and avoid factors that reduce patient's compliance, such as acupuncture fainting after acupuncture and moxibustion, local skin redness and allergic reactions after application therapy. However, the efficacy of the treatment combination of external medicinal liquid application and the TDP therapeutic apparatus was observed in the early stage of this study. It was found that some patients were not willing to cooperate because the medication at the application site was not easy to clean. Therefore, it is vital to consider the treatment compliance of patients to improve the clinical efficacy while performing syndrome differentiation and formulating treatment plans for DPN patients.

Beeswax has a long history of medicinal use and is quite common for both oral and external use, with the largest amount frequently used to make creams and ointment bases. In this study, a layer of cling film was wrapped around the medicine to prevent scratching and staining the clothes. Volcanic rock and beeswax were added to the formula for the observation group. Patients' compliance in the observation group (7.85 ±0.51) was significantly higher than the control group (7.63 ±0.8) during treatment.

Table IV. Comparison of patient compliance scores between the two methods of external medicinal liquid application ($\bar{x} \pm s$, points)

Group	<i>n</i>	Points
Control group	60	7.63 ±0.8
Observation group	60	7.85 ±0.51 ^A

Compared with the control group, ^A*p* < 0.05.

The reason could be mainly related to the fact that the beeswax matrix containing esters, fatty acids, and other ingredients has excellent plasticity, lubricity, and flexibility, which can not only closely fit with the human body [3,17] but also regulate the viscosity of the medicine, reduce the greasy sensation of the skin, facilitate local skin cleaning after application, and increase the patient's willingness to cooperate. In addition, volcanic rock and beeswax have a large heat capacity and can fully permeate their own therapeutic and TCM therapeutic components into the pores and conduct them to the subcutaneous tissue so that the drugs are directly absorbed through the local site and reach the disease site, making the treatment of promoting blood circulation to remove blood stasis, reducing inflammation, and relieving pain more directly and effectively [3,17]. The results showed that the total treatment effective rate of the observation group was 91.7%, which was significantly higher than the control group (86.7%). The TCM syndrome score of the observation group (5.67 ±4.11) was significantly lower than the control group (7.32 ±4.83), indicating that the modified application method effectively improved the treatment effect.

This study also has some limitations. The sample size is small. There is no age limit when the patients are included. The elderly patients have a longer course of disease and are more difficult to recover, which may affect the test results.

The results of this study showed that the compliance of DPN patients with cold coagulation and blood stasis was significantly improved by the treatment of external medicinal liquid application with Tangbiling herbs mixed with mud moxibustion substrate combined with a TDP therapeutic apparatus, and the clinical efficacy was also improved while giving full play to the efficacy of the TCM Tangbiling.

Funding

The project was supported by the scientific research project fund of Jinzhong science and Technology Bureau of Shanxi Province (Project No. y193005).

Funding project of nursing discipline construction in Shanxi University of Traditional Chinese Medicine (ZBH [2018] No. 1).

Disclosure

The authors report no conflict of interest.

References

1. Chi SS. Clinical observation on diabetic peripheral neuropathy treated with Chinese medicine combined with intermediate frequency diathermy instrument. *Clin J Chinese Med* 2015; 7: 89-90.
2. Chinese Diabetes Society. Guideline for prevention and treatment of type 2 diabetes in China (2017 Edition). *Chinese J Pract Intern Med* 2018; 38: 292-344.
3. Du J. Physical and chemical properties of natural beeswax and purification of its active components. Changchun University of Technology 2015.
4. Fang ZH, Wu YL, Zhao JD. Guidelines for TCM Clinical Diagnosis and Treatment of Diabetic Peripheral Neuropathy (2016 Edition). *J Traditional Chinese Med* 2017; 58: 625-630.
5. Ge Y, Liu J, Huang CB, Zhang WD, Wang Y, Fan HX, Cao YX. Effect of external application of Xiaoyu Jiegu powder combined with electromagnetic spectrum therapy on adjuvant treatment of rheumatoid arthritis and its influence on inflammatory indexes. *Chinese J Clin Healthcare* 2018; 21: 10-14.
6. Li T, Zhang CL, Chen L, Zhao W, long L, Huang Q, Tang LS, Luo KZ. New progress in treatment of diabetic peripheral neuropathy by external therapy of Chinese medicine. *J Guiyang Coll Traditional Chinese Med* 2019; 41: 75-77, 89.
7. Li YX, Yan XL, Xun JP, Xie JS, He YM, Jin BX, Liu XN, Zhao Y. Clinical observation on 30 cases of children with spastic cerebral palsy treated by Chinese materia medica soakage cooperated with wax therapy. *J Pediatr Traditional Chinese Med* 2021; 17: 54-57.
8. Luo KZ, Zhang CL, Chen L, Di TT, Li T, Tang LS. New progress in treatment of diabetic peripheral neuropathy with Chinese medicine. *J Guizhou University Traditional Chinese Med* 2020; 42: 70-73.
9. Nie DQ, Wang CW. Tazi of Chinese medicine decoction with TDP therapy for the treatment of articular cavity effusion. *Jilin J Traditional Chinese Med* 2015; 35: 376-378.
10. Wang MH. Study on the effect of traditional Chinese medicine Juanzi combined with TDP therapeutic instrument on knee joint pain of Bi (rheumatoid arthritis) cold dampness obstruction syndrome. Changchun University of traditional Chinese medicine 2014.
11. Wang X. Investigation on moxibustion compliance of patients with modified Morisky scale. Chengdu University of Traditional Chinese Medicine 2017.
12. Wang XG, Ni Q, Pang GM. Guidelines for diagnosis and treatment of diabetic peripheral neuropathy based on combination of disease and syndromes. *J Traditional Chinese Med* 2021; 62: 1648-1656.
13. Wang XX. Clinical research of integrated therapy of traditional Chinese medicine in the treatment of type 2 diabetes distal symmetry polyneuropathy. Chengdu University of TCM 2020.
14. Wu QF. Observation on the effect of traditional Chinese medicine collapsing stain combined with posture on improving upper limb spasticity in patients with ischemic stroke. Changchun University of Traditional Chinese Medicine 2020.
15. Ying C, Jin Z, Feng XQ, Chen PY. Electroacupuncture combined with warm needling therapy for treatment of diabetic peripheral neuropathy with cold coagulation and blood stasis type. *Mod J Integr Traditional Chinese Western Med* 2015; 24: 1744-1746.
16. Zhu KH. Clinical efficacy of arthroscopy combined with traditional Chinese medicine in the treatment of mid-term knee osteoarthritis. Liaoning University of traditional Chinese medicine 2020.
17. Zhu SF. Clinical study on treating lumbar muscle strain of cold dampness type by hot compress with beeswax and electroacupuncture. Guangzhou University of Chinese Medicine 2020.