Observation on the Effect of Traditional Chinese Medicine Dressing Combined with Silver Ion Dressing Change in Promoting Diabetic Foot Wound Healing (Postprint)

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Date: 2022-08-17T00:00:00+00:00

Abstract

Objective: To observe the effect of self-prepared traditional Chinese medicine "Shuanghuangdan" dressing and silver ion dressing combined with dressing change in promoting wound healing of diabetic foot, and to evaluate its efficacy and safety. Methods: A total of 45 diabetic foot patients who visited the First Affiliated Hospital of Guizhou University of Traditional Chinese Medicine from March to September 2021 were selected and divided into "Shuanghuangdan" group, silver ion group, and combination group using random number table method, with 15 cases in each group. Based on conventional symptomatic treatment, the three groups received dressing change with self-prepared traditional Chinese medicine "Shuanghuangdan" dressing, silver ion dressing, and combined traditional Chinese medicine "Shuanghuangdan" with silver ion dressing, respectively. The TCM syndrome scores of the three groups were compared, and wound healing status was evaluated. Results: After 4 weeks of treatment, the wound area was lowest in the combination therapy group, and the difference was statistically significant compared with the "Shuanghuangdan" group ($P<0.05$). The VEGF level in the combination therapy group was higher than that in the "Shuanghuangdan" group and silver ion group, and the TCM syndrome score in the combination therapy group was lower than that in the "Shuanghuangdan" group and silver ion group, with statistically significant differences ($P<0.05$). Conclusion: The combination of traditional Chinese medicine "Shuanghuangdan" dressing and silver ion dressing for dressing change can significantly reduce inflammatory response in patients, promote wound healing, and has good safety.

Full Text

Title and Authors

Effect of Chinese Herbal Medicine Dressing Combined with Silver Ion Dressing Change on Promoting Diabetic Foot Wound Healing

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Abstract

Objective: To observe the efficacy and safety of self-made Chinese medicine "Shuanghuangdan" dressing combined with silver ion dressing change in promoting diabetic foot wound healing.

Methods: Forty-five diabetic foot patients treated at The First Affiliated Hospital of Guizhou University of Traditional Chinese Medicine from March to September 2021 were enrolled and randomly divided into three groups (n=15 each): a "Shuanghuangdan" group, a silver ion group, and a combined treatment group. Based on conventional symptomatic treatment, the three groups received dressing changes with self-made Chinese medicine "Shuanghuangdan" dressing, silver ion dressing, and combined "Shuanghuangdan" with silver ion dressing, respectively. Traditional Chinese Medicine (TCM) syndrome scores were compared among groups to evaluate wound healing outcomes.

Results: After 4 weeks of treatment, the combined treatment group showed the smallest wound area, which was significantly different from the "Shuanghuangdan" group ($P<0.05$). The VEGF level in the combined treatment group was higher than that in both the "Shuanghuangdan" and silver ion groups, while the TCM syndrome score was lower than in the other two groups, with statistically significant differences ($P<0.05$).

Conclusion: Chinese medicine "Shuanghuangdan" dressing combined with silver ion dressing change can significantly reduce inflammatory reactions and promote wound healing in diabetic foot patients with good safety profiles.

Keywords: diabetic foot; Chinese herbal medicine dressing; Astragalus membranaceus; rheum officinale; silver ion dressing; wound healing; Traditional Chinese Medicine nursing

Introduction

Diabetic foot is one of the most severe complications of diabetes, predominantly occurring in elderly patients with long disease duration and poor glycemic con-

trol. Infection in diabetic foot directly affects the prognosis of foot ulcers [1]. Literature reports indicate that 4%–10% of patients with type 2 diabetes develop diabetic foot, and the 5-year mortality risk for diabetic foot patients is 2.5 times higher than for patients with diabetes alone [2]. In clinical treatment and nursing care of diabetic foot, besides improving vascular blood supply and peripheral nerve function, a critical component is wound management, particularly the use of debridement and dressings. Conventional treatment involves debridement, povidone-iodine disinfection, antibiotic application, and final bandaging, yet outcomes remain suboptimal.

Silver ion antimicrobial dressings, containing silver ions, exhibit strong antibacterial and antimicrobial effects that eliminate wound bacteria and inhibit fungal and bacterial proliferation, thereby reducing inflammatory responses and promoting wound healing [3-4]. Various dressings are clinically used for diabetic foot wounds, including silver ion dressings, alginate dressings, and foam dressings. In recent years, silver ion dressings have emerged as the "first-choice dressing" for diabetic foot wound management due to their unique anti-infective properties and significant wound healing promotion. However, a major drawback of silver ion dressings is their high cost. Therefore, identifying a treatment approach with clinical efficacy equivalent to or better than silver ion dressings but at significantly lower cost holds substantial clinical significance. This study observed the effects of self-made Chinese medicine "Shuanghuangdan" dressing combined with silver ion dressing change in promoting diabetic foot wound healing and evaluated its efficacy and safety.

Methods

1.1 Diagnostic Criteria

1.1.1 TCM Diagnostic Criteria: Diabetic foot is defined as foot infection, ulceration, and/or deep tissue destruction in diabetic patients resulting from distal lower extremity neuropathy and varying degrees of vascular lesions [5-7]. Diagnostic criteria include: (1) limb ischemic manifestations such as coolness, cold intolerance, numbness, pain, intermittent claudication, pale or purplish skin, nutritional changes, and rest pain; (2) peripheral neuropathy with diminished or absent pain, temperature, and touch sensation, along with atrophic skin and subcutaneous tissue; (3) Doppler ultrasound showing narrowed distal vessels, reduced elasticity, decreased blood flow and velocity causing ischemia or gangrene; (4) angiography confirming vascular stenosis or occlusion with clinical manifestations; (5) electrophysiological examinations showing slowed peripheral nerve conduction velocity or abnormal somatosensory evoked potentials on electromyography. Diagnosis is confirmed by meeting the first two criteria plus any one of the subsequent criteria.

1.1.2 Western Diagnostic Criteria: Referenced from *Wound Nursing Science* (2017 edition) [8]. Criteria include: (1) confirmed diabetes history or positive biochemical tests such as blood glucose, urine glucose, and ketone bodies;

(2) foot ulcers or gangrene, often secondary infection presenting as wet gangrene, with severe cases showing systemic symptoms including fever, lethargy, and poor appetite in addition to local redness, swelling, heat, and pain; (3) weakened or absent posterior tibial and dorsalis pedis pulses, or even weakened popliteal pulses; when upper extremities are involved, weakened radial and ulnar pulses may be present.

1.2 Inclusion and Exclusion Criteria

1.2.1 Inclusion Criteria: (1) Age 18–60 years; (2) meeting diagnostic criteria for diabetes; (3) meeting TCM and Western diagnostic criteria for diabetic foot; (4) wet gangrene-type wounds; (5) Wagner grade 2; (6) wound area <1 cm^2; (7) TCM local syndrome differentiation as yang syndrome; (8) voluntary participation with informed consent and agreement to follow-up.

1.2.2 Exclusion Criteria: (1) Wound area exceeding 1/3 of the affected foot with systemic infection requiring amputation; (2) severe cardiovascular, cerebrovascular, hepatic, renal disease or severe malnutrition; (3) allergy to study medications or allergic constitution; (4) psychiatric disorders preventing treatment cooperation; (5) malignant tumors, autoimmune diseases, or current glucocorticoid therapy; (6) uncontrolled blood glucose or blood pressure and severe anemia.

1.3 Grouping

From March to September 2021, 45 diabetic foot patients at The First Affiliated Hospital of Guizhou University of Traditional Chinese Medicine were enrolled and randomly divided into three groups (n=15 each): a "Shuanghuangdan" group, a silver ion group, and a combined treatment group. Baseline comparisons showed no statistically significant differences among the three groups in gender distribution, age, blood glucose, ABI, BMI, wound area, basic fibroblast growth factor (bFGF), interleukin-6 (IL-6), vascular endothelial growth factor (VEGF), or TCM syndrome scores ($P>0.05$) . This study was approved by the hospital ethics committee, and all patients provided informed consent.

1.4 Interventions

1.4.1 Drug Selection: The "Shuanghuangdan" preparation was produced by the hospital's TCM preparation room, containing equal proportions of Astragalus membranaceus, Rheum officinale, Myrrha, Salvia miltiorrhiza, Aquilaria sinensis, Angelica sinensis, and Sanguisorba officinalis, with Astragalus membranaceus used at double dosage. Silver ion dressings were purchased from Coloplast (China) Medical Products Co., Ltd.

1.4.2 Basic Treatment and Nursing: (1) Basic treatment: blood glucose control (preprandial glucose 4.4–8.0 mmol/L), blood supply improvement (standard use of vasodilators and antiplatelet agents), nerve function improvement (standard use of neurotrophic agents), and blood pressure control. (2) Basic

nursing: pressure offloading and wound protection, wound and wound bed management to promote healing, and family education.

1.4.3 Dressing Change Methods: All groups underwent two phases of treatment. Debridement was performed before each dressing change: povidone-iodine disinfection of periwound skin to 10 cm beyond the wound edge, repeated wound irrigation, and removal of necrotic tissue following the principle of "painless, non-damaging to normal tissue." For patients unable to tolerate one-time debridement, the "nibbling" method was used. Wounds with undermining were longitudinally incised to clear necrotic fascia, muscle, tendon, and bone, followed by removal of aged granulation and fibrous tissue. After debridement, wounds were rinsed with normal saline and dried with sterile gauze.

Shuanghuangdan Group: Phase 1 (first 6 weeks) used Shuanghuangdan dressing covering the wound, secured with adhesive tape or bandage, changed on Mondays, Wednesdays, and Fridays (3 times weekly). Phase 2 (last 6 weeks) changed dressings weekly on Mondays.

Silver Ion Group: Phase 1 (first 6 weeks) used silver ion dressing, changed on Mondays and Thursdays (twice weekly). Phase 2 (last 6 weeks) changed dressings weekly on Mondays.

Combined Treatment Group: Phase 1 alternated dressings—Shuanghuangdan dressing in weeks 1, 3, and 5 (same method as Shuanghuangdan group Phase 1), and silver ion dressing in weeks 2, 4, and 6 (same method as silver ion group Phase 1). Phase 2 continued alternating—Shuanghuangdan dressing in weeks 7, 9, and 11, and silver ion dressing in weeks 8, 10, and 12.

1.5 Outcome Measures

1.5.1 Wound Area: Wounds were photographed before treatment and after 4 weeks of treatment. Wound area was measured using IMAGJ computer photo processing software. Granulation tissue growth was observed and scored using the Lower Extremity Chronic Wound Scoring System.

1.5.2 TCM Syndrome Score: TCM clinical syndrome scores were assessed before and after treatment. The reduction rate was calculated using the Nimodipine method: Reduction rate = (pretreatment score - posttreatment score)/pretreatment score × 100.00%.

1.5.3 Inflammatory Factor Levels: Before treatment and after 4 weeks, 8 mL of fasting peripheral venous blood was collected. Serum levels of basic fibroblast growth factor (bFGF), interleukin-6 (IL-6), and vascular endothelial growth factor (VEGF) were measured by enzyme-linked immunosorbent assay.

1.6 Statistical Analysis

SPSS 22.0 software was used for statistical analysis. Measurement data were expressed as mean ± standard deviation ($\bar{x} \pm s$). Paired t-tests were used

for within-group comparisons before and after treatment. One-way ANOVA was used for multi-group mean comparisons, with LSD-t test for inter-group comparisons. Non-normally distributed data were expressed as median and interquartile range [P50(P25, P75)], analyzed using Mann-Whitney U test for independent samples and Wilcoxon signed-rank test for paired samples. Kruskal-Wallis test was used for multi-group comparisons. The significance level was set at α=0.05, with P<0.05 considered statistically significant.

Results

After intervention, the Shuanghuangdan group, silver ion group, and combined treatment group all showed statistically significant differences in wound area, bFGF, IL-6, VEGF, and TCM syndrome scores compared with pre-intervention values (P<0.05). In post-intervention comparisons among groups, the combined treatment group had the smallest wound area, significantly smaller than the Shuanghuangdan group (P<0.05), but not significantly different from the silver ion group (P>0.05). VEGF levels in the combined treatment group were higher than in both the Shuanghuangdan and silver ion groups, while TCM syndrome scores were lower than in the other two groups, with statistically significant differences (P<0.05) .

Discussion

Diabetic foot results from qi and yin deficiency with blood stasis obstructing collaterals, preventing timely nourishment of muscles and bones and leading to limb numbness, pain, and gangrene [9-11]. This study demonstrates that after intervention, the combined treatment group showed the smallest wound area (P<0.05 vs. Shuanghuangdan group), highest VEGF levels, and lowest TCM syndrome scores compared with the other two groups (P<0.05), indicating faster and better wound healing.

Silver ion dressings maintain a slightly acidic, moist wound environment with broad-spectrum antimicrobial activity that alters bacterial structure, prevents infection, and stimulates fibroblast proliferation to facilitate granulation tissue formation and wound healing [12]. The Chinese medicine components in Shuanghuangdan dressing possess properties of activating blood circulation, removing necrotic tissue, and promoting tissue regeneration. The combination of Shuanghuangdan and silver ion dressings effectively inhibits fungal and bacterial proliferation, reduces IL-6 secretion, alleviates inflammatory reactions, and increases VEGF levels, suggesting that alternating Shuanghuangdan and silver ion dressings promotes diabetic foot wound healing with good safety profiles.

Conclusion

Chinese medicine “Shuanghuangdan” dressing combined with silver ion dressing change significantly reduces inflammatory reactions and promotes wound healing in diabetic foot patients, demonstrating superior efficacy to single-agent

silver ion dressing with high safety. Future studies should increase sample sizes and extend observation periods to evaluate long-term outcomes of this combined treatment protocol, providing further evidence for clinical application.

Conflict of Interest Statement: The authors declare no conflict of interest.

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Note: Figure translations are in progress. See original paper for figures.