Clinical Observation on the Efficacy of Traditional Chinese Medicine Hard Ointment Hot Compress for Knee Osteoarthritis of Qi Stagnation and Blood Stasis Pattern

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Date: 2023-12-26T00:00:00+00:00

Abstract

Objective To investigate the clinical efficacy of herbal plaster hot compress for knee osteoarthritis of qi stagnation and blood stasis pattern. Methods Sixty patients with knee osteoarthritis of qi stagnation and blood stasis pattern were selected as study subjects. Using the random number table method, they were randomly divided into a control group and an observation group with 30 cases each. The control group received conventional treatment, while the observation group received additional herbal plaster hot compress on top of conventional treatment. Both groups were treated once daily for a total of two weeks. The observation indices included the Visual Analogue Scale (VAS) for pain, Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) score, clinical efficacy, erythrocyte sedimentation rate (ESR), and C-reactive protein (CRP). Results Both groups showed significant decreases in VAS, WOMAC scores, ESR, and CRP compared with before treatment ($P<0.05$). Compared with the control group, after treatment, the observation group showed significant reductions in VAS, WOMAC scores, ESR, and CRP ($P<0.05$), and the effective rate was significantly higher ($P<0.05$). Conclusion Herbal plaster hot compress can improve joint function and alleviate pain in patients with knee osteoarthritis of qi stagnation and blood stasis pattern, and can be recommended for clinical application.

Full Text

Preamble

Observation on the Therapeutic Effect of Hot Application of Chinese Herbal Hard Paste on Knee Osteoarthritis of Qi Stagnation and Blood Stasis Pattern

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Abstract

Objective: To investigate the clinical efficacy of hot application of Chinese herbal hard paste in treating knee osteoarthritis (KOA) of qi stagnation and blood stasis pattern. **Methods:** Sixty patients with KOA of qi stagnation and blood stasis pattern admitted to the Pain Department of The First Hospital of Hunan University of Chinese Medicine between September 2022 and September 2023 were enrolled and randomly divided into a control group and an observation group (30 cases each) using the random number table method. The control group received conventional treatment, while the observation group received additional hot compress therapy with Chinese herbal hard paste. Both groups were treated once daily for two consecutive weeks. Outcome measures included the Visual Analogue Scale (VAS), Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) score, clinical efficacy, erythrocyte sedimentation rate (ESR), and C-reactive protein (CRP) levels. **Results:** After treatment, VAS and WOMAC scores, ESR, and CRP levels decreased significantly in both groups compared with baseline ($P<0.05$). The observation group showed significantly greater reductions in VAS and WOMAC scores, ESR, and CRP levels compared with the control group ($P<0.05$), along with a significantly higher effective rate ($P<0.05$). **Conclusion:** Hot application of Chinese herbal hard paste can improve joint function and alleviate pain in patients with KOA of qi stagnation and blood stasis pattern, warranting clinical promotion and application.

Keywords: Hot application of Chinese herbal hard paste; qi stagnation and blood stasis pattern; knee osteoarthritis

Funding: Key Project of Hunan Provincial Administration of Traditional Chinese Medicine (A2023010).

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Introduction

Knee osteoarthritis (KOA) is a chronic joint disease characterized by degenerative changes in knee cartilage and secondary bone hyperplasia [2]. Its pathogenesis remains unclear due to the complexity of the disease, though studies have indicated that its occurrence is associated with age, obesity, inflammation,

trauma, and genetic factors [1]. Symptoms progress gradually over time, leading to knee stiffness, deformity, and in severe cases, complete loss of mobility [3]. With the intensification of population aging in China, the incidence of KOA has increased significantly. Reports indicate that the prevalence of KOA in various degrees exceeds 10% in people over 60 years old, reaching as high as 18% in women. KOA causes tremendous suffering and severely impacts quality of life, representing a serious public health challenge [4].

According to traditional Chinese medicine (TCM) theory, "the knee is the house of tendons," and chronic strain leading to knee pain and limited mobility falls under the category of "knee bi syndrome" [5]. TCM holds that KOA often results from insufficient vital qi, allowing external pathogenic factors such as wind, cold, and dampness to invade the body and obstruct the meridians, causing impaired qi and blood flow. Clinical manifestations include pain, numbness, heaviness, and limited flexion and extension of muscles, bones, and joints [6]. Recent studies have demonstrated that TCM treatments offer unique advantages for KOA. Hot application of Chinese herbal hard paste possesses functions of activating blood circulation to remove stasis, reducing swelling and pain, and relaxing tendons to unblock collaterals. It can improve local microcirculation, promote inflammatory absorption, and alleviate pain, with the benefits of being simple, safe, and well-received clinically [7,8]. Therefore, this study applied hot herbal paste therapy to patients with KOA of qi stagnation and blood stasis pattern to observe its clinical efficacy and explore a better treatment approach.

Methods

1.1 Study Subjects

Sixty patients with KOA of qi stagnation and blood stasis pattern admitted to the Pain Department of The First Hospital of Hunan University of Chinese Medicine from September 2022 to September 2023 were selected as study subjects. Using the random number table method, the 60 patients were randomly divided into a control group and an observation group, with 30 cases in each group.

1.2 Diagnostic Criteria

1.2.1 Western Medicine Diagnostic Criteria Based on the diagnostic criteria from the "Guidelines for the Diagnosis and Treatment of Osteoarthritis (2007 Edition)" by the Orthopedic Branch of the Chinese Medical Association [9]: (1) Recurrent knee joint pain within the past month; (2) X-ray films (standing or weight-bearing position) showing narrowed joint space, subchondral bone sclerosis and/or cystic changes, and osteophyte formation at joint margins; (3) Joint fluid (at least two examinations) clear and viscous, with white blood cell count below 2000/ml; (4) Middle-aged and elderly patients ($ $40 years old); (5) Morning stiffness $ $30 minutes; (6) Bone friction sound (sensation) during movement. Note: Diagnosis of KOA can be established if clinical, laboratory,

and X-ray examinations meet criteria 1+2, or 1+3+5+6, or 1+4+5+6.

1.2.2 TCM Diagnostic Criteria Based on the "Eleventh Five-Year Key Specialty Collaborative Group Knee Bi Syndrome (Knee Osteoarthritis) Diagnosis and Treatment Plan" of the State Administration of Traditional Chinese Medicine [10]: Knee joint pain with aversion to pressure, or swelling and discomfort, or stabbing pain, mild during daytime and severe at night, or persistent and unresolved, with limited mobility or even difficulty turning sideways, dull complexion and dark lips, tongue with hidden cyanosis or petechiae, and a wiry-choppy or thin-rapid pulse. The disease course is prolonged, often with a history of trauma and strain.

1.3 Inclusion Criteria

(1) Met Western medicine diagnostic criteria for KOA; (2) Met TCM diagnostic criteria for qi stagnation and blood stasis pattern; (3) Age: 48-70 years; (4) Provided informed consent.

1.4 Exclusion Criteria

(1) Patients with organ dysfunction or malignant tumors; (2) Patients with eczema, severe skin disease, or broken skin at the knee joint; (3) Patients with mental illness or pregnant women.

1.5 Treatment Protocols

1.5.1 Control Group The control group received oral celecoxib capsules, 0.2 g per dose, once daily, for two consecutive weeks. They also received routine nursing care: (1) Weight control advice, knee protection, and wearing knee pads for warmth; (2) Light, easily digestible diet with increased vegetables and fruits, avoiding raw, cold, greasy, and fried foods; (3) Patient education about disease treatment and rehabilitation, introducing successful cases to help build confidence.

1.5.2 Observation Group The observation group received additional hot application of Chinese herbal hard paste based on the control group treatment. The hospital's research-based blood-activating herbal formula was used (containing Aucklandia root 5g, cinnamon 10g, notopterygium 10g, vinegar-processed cyperus 10g, angelica 15g, dried ginger 3g, salt-processed fennel 6g, papaya 10g, processed aconite 3g, vinegar-processed corydalis 10g, angelica dahurica 15g, ligusticum 10g, aconite lateral root 10g, dipsacus 10g, ginger-processed magnolia bark 6g, Sichuan pepper 6g, processed Sichuan aconite 3g, and safflower 10g). The herbs were ground into powder, mixed with appropriate amounts of edible oil and vinegar to form a paste, applied to local body surface or specific acupoints, and then irradiated with a TDP lamp at a distance of 20-30 cm. Using heat to facilitate herbal vapor penetration through the skin and meridians, this

treatment achieves the effects of dispelling wind and cold, promoting qi and blood circulation, resolving phlegm and unblocking collaterals, and reducing swelling and pain. Each treatment lasted 30 minutes, once daily, with 7 days constituting one course, for a total of two courses. Skin condition, circulation, and swelling were monitored, and treatment was discontinued immediately if skin allergy occurred.

1.6 Outcome Measures

1.6.1 Visual Analogue Scale (VAS) [11] VAS scores were measured before treatment and after two weeks of treatment in both groups. The scale ranges from 0-10 points, with higher scores indicating more severe pain.

1.6.2 Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) [12] This index evaluates three domains: pain, stiffness, and difficulty in daily activities, comprising 24 items scored 0-4 points each, with a total score of 96 points. Higher scores indicate worse joint function.

1.7 Efficacy Criteria

Based on the "TCM Treatment Standards" combined with VAS visual scale [13]: (1) Clinical cure: Complete disappearance of knee pain and swelling, with no discomfort when walking or climbing stairs; (2) Markedly effective: No pain or swelling at rest, occasional pain during activity, no pain while walking, no impact on work or life; (3) Effective: Intermittent knee pain, mild pain while walking, slight inconvenience when climbing stairs, slightly limited joint mobility; (4) Ineffective: No significant improvement in knee pain, swelling, or pain during movement.

1.8 Statistical Methods

All data were analyzed using SPSS 21.0 software. Measurement data were expressed as (mean ± standard deviation). For data with normal distribution and homogeneity of variance, paired t-tests were used for within-group comparisons before and after treatment, and independent t-tests were used for between-group comparisons at the same time point. Non-parametric tests were used when normal distribution or homogeneity of variance was not satisfied. $P<0.05$ was considered statistically significant.

Results

2.1 Comparison of VAS and WOMAC Scores Between Groups

VAS scores in both groups were significantly lower after treatment compared with baseline ($P<0.05$), with the observation group showing significantly lower scores than the control group ($P<0.05$). Similarly, WOMAC scores in both groups decreased significantly from baseline ($P<0.05$), with the observation

group demonstrating significantly greater reduction than the control group (P<0.05). These findings indicate that the intervention had a significant effect on pain reduction. See Table 1 .

Table 1 VAS and WOMAC Scores of Both Groups
Note: Compared with pre-treatment; compared with control group.

2.2 Comparison of Clinical Efficacy Between Groups

After treatment, the total effective rate in the observation group was 95%, significantly higher than the 80% in the control group (P<0.05). See Table 2 .

Table 2 Comparison of Clinical Efficacy Between Groups
Clinical Control (cases) | Markedly Effective (cases) | Effective (cases) | Ineffective (cases) | Total Effective Rate (%)

2.3 Comparison of CRP and Blood Sedimentation Between Groups

Both CRP levels and erythrocyte sedimentation rates decreased significantly in both groups after treatment compared with baseline (P<0.05), with the observation group showing significantly lower values than the control group (P<0.05). See Table 3 .

Table 3 Comparison of CRP and Blood Sedimentation Between Groups
CRP | 19.43$±5.23|28.90±5.29|4.40±1.81|14.90±2.68|20.63±5.43|28.90±5.29|2.87±1.28|12.67±$2.51

Discussion

KOA is characterized by high incidence, high disability rate, and treatment difficulty. The primary clinical goals are to relieve joint pain, improve joint function, and enhance quality of life [14]. Current mainstream treatments include intra-articular sodium hyaluronate injection and oral non-steroidal analgesics such as celecoxib to alleviate pain and improve joint function [15]. Compared with Western medicine, topical TCM therapy for KOA offers better safety profiles with fewer adverse reactions and superior short-term efficacy [16].

In TCM theory, KOA belongs to the category of bone bi syndrome. The pathogenesis is often attributed to qi stagnation and blood stasis, following the principle of "if there is no free flow, there is pain." Therefore, the treatment approach for early- and mid-stage KOA focuses on activating blood circulation to remove stasis [15]. In our herbal formula, vine-type herbs serve as the sovereign ingredients for their functions of relaxing tendons, activating blood, dispelling dampness, and benefiting bone marrow. Processed Sichuan aconite, processed aconite, and angelica dahurica act as ministerial herbs to dispel wind-dampness, resolve exterior cold, benefit joints, and relieve bi syndrome pain. Ligusticum, safflower, and angelica serve as adjuvant and messenger herbs to expel wind, nourish blood, and activate blood circulation. Modern research has confirmed that

multiple active components in this formula possess anti-inflammatory, analgesic, antioxidant, microcirculation-improving, or immunosuppressive effects [17].

Furthermore, the combination of herbal hard paste with TDP irradiation generates abundant medicinal vapor within the paste. The heat promotes local blood circulation, enhances drug penetration, dilates blood vessels, and facilitates drug absorption and distribution, while the medicinal components exert therapeutic effects through skin absorption [18]. Through both pharmacological and thermal actions, hot herbal paste application can regulate organ function, relieve pain, promote inflammatory absorption and resolution, and treat disease. This study demonstrates that compared with the control group, the observation group showed significantly reduced VAS and WOMAC scores, ESR, and CRP levels, indicating superior overall treatment efficacy and a higher effective rate. However, this study has limitations, including a small sample size, and future research should expand the sample size for more in-depth investigation.

Conclusion

In summary, hot application of Chinese herbal hard paste can improve joint function, reduce pain, and enhance clinical efficacy in patients with KOA of qi stagnation and blood stasis pattern, meriting clinical promotion and application.

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