

Clinical Efficacy of Modified Duhuo Jisheng Decoction in Treating Knee Osteoarthritis and Its Effects on Clinical Symptoms and Joint Function

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Abstract: Objective To investigate the intervention effect of modified Duhuo Jisheng Decoction on knee osteoarthritis (KOA). Methods Eighty KOA patients were enrolled and randomly divided into two groups (40 cases each). The control group received oral glucosamine sulfate, while the observation group was additionally treated with modified Duhuo Jisheng Decoction. The treatment course lasted 12 weeks. Traditional Chinese medicine (TCM) syndrome scores, VAS, WOMAC scores, total effective rate, and adverse events were compared. Results The reduction in each score was significantly greater in the observation group than in the control group ($P < 0.05$). The total effective rate in the observation group (92.50%) was higher than that in the control group (75.00%) ($P < 0.05$). The incidence of adverse reactions in the observation group (5.00%) was lower than that in the control group (20.00%) ($P < 0.05$). Conclusion Modified Duhuo Jisheng Decoction as an adjunctive treatment for KOA can effectively alleviate symptoms, promote joint function recovery, and has good safety.

Keywords: Duhuo Jisheng Decoction; knee osteoarthritis; clinical symptoms; joint function; safety

1. Introduction

Knee osteoarthritis (KOA) is a chronic disease characterized by degeneration of articular cartilage. It is highly prevalent in middle-aged and elderly populations, with a prevalence rate of approximately 18% in China. Although conventional Western medicine treatments (e.g., nonsteroidal anti-inflammatory drugs, cartilage protective agents) can relieve symptoms, they are prone to cause adverse reactions in the gastrointestinal tract, liver, and kidneys. In TCM, KOA is classified as "arthralgia syndrome" (Bi Zheng) or "bone arthralgia" (Gu Bi), with pathogenesis involving liver and kidney deficiency, invasion by wind-cold-dampness pathogens, and blood stasis obstructing meridians. Duhuo Jisheng Decoction, originating from Qian Jin Yao Fang (Essential Prescriptions Worth a Thousand Gold), has the effects of tonifying the liver and kidney, dispelling wind and dampness, and dissipating cold to relieve pain. This study adopted a randomized controlled design to evaluate the clinical efficacy and safety of its modified formula for KOA.

2. Materials and Methods

2.1 General Data

Eighty KOA patients from our hospital from 2020 to 2025 were enrolled and randomly divided into an observation group and a control group, with 40 cases each. The two groups were balanced and comparable in terms of gender, age, disease duration, and affected side ($P > 0.05$). All patients signed informed consent, and the protocol was approved by the ethics committee.

2.2 Diagnostic Criteria

Western medicine diagnosis adhered to the 2018 Guidelines for the Diagnosis and Treatment of Osteoarthritis by the Orthopaedics Branch of the Chinese Medical Association. TCM syndrome differentiation was classified as liver-kidney insufficiency with wind-cold-dampness pathogen, referring to the Expert Consensus on the Diagnosis and Treatment of Knee Arthralgia Disease (2024).

2.3 Inclusion and Exclusion Criteria

Inclusion: meeting the above diagnostic criteria, age 40-80 years, no relevant treatment in the past month, signed informed consent. Exclusion: other types of arthritis, history of knee surgery, severe organic diseases, pregnancy or lactation, allergies, inability to complete the trial.

2.4 Treatment Methods

Control group: Glucosamine Sulfate Capsules (0.314 g/capsule), 2 capsules each time, 3 times daily, for 12 weeks. Observation group: additionally received modified Duhuo Jisheng Decoction based on the same regimen. Base formula:

Duhuo (*Angelicae pubescentis radix*) 15g, Sangjisheng (*Taxilli herba*) 20g, Qinjiao (*Gentianae macrophyllae radix*) 12g, Fangfeng (*Saposhnikoviae radix*) 10g, Xixin (*Asari radix et rhizoma*) 3g, Chuanxiong (*Chuanxiong rhizoma*) 10g, Danggui (*Angelicae sinensis radix*) 12g, Shudihuang (*Rehmanniae radix praeparata*) 15g, Chishao (*Paeoniae radix rubra*) 12g, Duzhong (*Eucommiae cortex*) 15g, Niuxi (*Achyranthis bidentatae radix*) 12g, Fuling (*Poria*) 15g, Guizhi (*Cinnamomi ramulus*) 10g, Dangshen (*Codonopsis radix*) 15g, Gancao (*Glycyrrhizae radix et rhizoma*) 6g. Modifications based on symptoms: for predominant wind-cold-dampness, add Weilingxian (*Clematidis radix et rhizoma*) 15g, Qianghuo (*Notopterygii rhizoma et radix*) 12g, Zhi Fuzi (*Aconiti lateralis radix praeparata*) 6g; for blood stasis obstruction, add Danshen (*Salviae miltiorrhizae radix et rhizoma*) 15g, Taoren (*Persicae semen*) 10g, Honghua (*Carthami flos*) 6g; for liver-kidney deficiency, add Shanzhuyu (*Corni fructus*) 12g, Xuduan (*Dipsaci radix*) 15g; for damp-heat accumulation, remove Guizhi and Xixin, add Huangbai (*Phellodendri chinensis cortex*) 10g, Yiyiren (*Coicis semen*) 20g, Cangzhu (*Atractylodis rhizoma*) 10g. One dose daily, decocted in water to 400 ml, divided into two warm doses, for 12 weeks. Both groups were prohibited from using analgesics, nonsteroidal anti-inflammatory drugs, and high-intensity activities.

2.5 Outcome Measures

(1) TCM syndrome score (knee pain, swelling, flexion-extension limitation, knee and lumbar soreness, 0-6 points each, total 24 points). (2) VAS pain score (0-10). (3) WOMAC joint function score (0-96). (4) Clinical efficacy: cured, markedly effective, effective, ineffective; total effective rate = (cured + markedly effective + effective)/total cases × 100%. (5) Safety: blood and urine routine, liver and kidney function, electrocardiogram, and adverse events.

2.6 Statistical Methods

SPSS 26.0. Measurement data expressed as mean ± standard deviation; paired t-test for within-group comparisons, independent t-test for between-group comparisons; count data using chi-square test; effect size Cohen's d. $P < 0.05$ was considered statistically significant.

3. Results

3.1 TCM Syndrome Score

No difference between groups before treatment. After treatment, the observation group (5.24 ± 2.18) was lower than the control group (9.46 ± 3.05), $P < 0.05$.

3.2 VAS Score

After treatment, the observation group (2.36 ± 0.87) was lower than the control group (3.94 ± 1.12), $P < 0.05$.

3.3 WOMAC Score

After treatment, the observation group (28.53 ± 6.74) was lower than the control group (37.86 ± 7.58), $P < 0.05$. Cohen's $d = 1.30$ (95% CI 0.81–1.79), indicating a large effect.

3.4 Clinical Efficacy

Total effective rate was 92.50% (37/40) in the observation group and 75.00% (30/40) in the control group, $P < 0.05$.

3.5 Safety

Two cases of adverse reactions (5.00%) occurred in the observation group: one case of mild gastrointestinal discomfort and one case of dry mouth. Eight cases (20.00%) occurred in the control group: digestive tract reactions (5 cases), dizziness (2 cases), skin allergy (1 case). All adverse events were mild and transient. Between-group comparison $P < 0.05$.

4. Discussion

The pathology of KOA involves cartilage wear, synovitis, etc. The total effective rate of Western medicine using glucosamine sulfate alone is only 75%, showing limited efficacy. TCM considers KOA as "root deficiency and branch excess" — root deficiency refers to liver and kidney deficiency, branch excess refers to wind-cold-dampness pathogens and blood stasis/phlegm turbidity. In Duhuo Jisheng Decoction, Duhuo serves as the sovereign herb, warming meridians, dispelling cold, and relieving arthralgia pain; Sangjisheng, Duzhong, and Niuxi tonify the liver and kidney and strengthen bones and tendons; Qinjiao, Fangfeng, and Xixin dispel wind and cold; Chuanxiong, Danggui, Shudihuang, and Chishao harmonize qi and blood; Dangshen and Fuling support the upright qi and consolidate the root. The whole formula regulates yin-yang and qi-blood, targeting the pathogenesis appropriately.

This study showed that after adding Duhuo Jisheng Decoction, the observation group had significant improvements

in TCM syndrome scores, VAS, and WOMAC, with a total effective rate of 92.50% and an effect size $d=1.30$, indicating definite efficacy. Regarding safety, the adverse reaction rate in the observation group was only 5.00%, much lower than the 20.00% in the control group. Modern pharmacological studies indicate that this formula can inhibit signaling pathways such as TLR4/NF- κ B and JAK2-STAT3, reduce IL-6 and TNF- α , inhibit chondrocyte apoptosis, and protect articular cartilage. The modifications based on symptoms reflect the individualized advantage of TCM pattern differentiation and treatment.

Limitations of this study: single-center, small sample size (80 cases), no blinding, observation period of only 12 weeks, lack of long-term follow-up and objective biochemical indicators. Future multi-center, large-sample, long-term follow-up studies are needed for further validation.

5. Conclusion

Modified Duhuo Jisheng Decoction in the treatment of KOA can significantly improve clinical symptoms such as pain, swelling, morning stiffness, and joint mobility limitation, reduce TCM syndrome scores, VAS and WOMAC scores, and increase the overall treatment effective rate to 92.50%. Moreover, the incidence of adverse reactions in this regimen is only 5.00%, far lower than the 20.00% in the Western medicine alone group, and all reactions are mild and transient, indicating good safety. Modern pharmacology suggests that this formula may exert multi-target therapeutic effects by regulating TLR4/NF- κ B, JAK2-STAT3 and other signaling pathways, inhibiting the release of inflammatory factors, reducing chondrocyte apoptosis, and maintaining extracellular matrix metabolic balance. In summary, modified Duhuo Jisheng Decoction combined with glucosamine sulfate for knee osteoarthritis not only embodies the individualized advantages of TCM pattern differentiation and modification but also has definite efficacy and reliable safety, making it worthy of clinical promotion in primary and specialized medical institutions.

References

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