

## Therapeutic effects of low-frequency phonophoresis with a Chinese herbal medicine versus sodium diclofenac for treatment of knee osteoarthritis: a double-blind, randomized, placebo-controlled clinical trial

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**Supported by** State Administration of Traditional Chinese Medicine ("Eleventh Five-Year" Key Discipline Construction Projects), and Beijing Municipal Administration of Traditional Chinese Medicine (External Treatment Special Fund, No. WZF2012-09)

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**Accepted:** July 22, 2015

### Abstract

**OBJECTIVE:** To evaluate the therapeutic effects of low-frequency phonophoresis with a Chinese herbal medicine (CHM) compared with sodium diclofenac (SD) for knee osteoarthritis (KOA).

**METHODS:** In this double-blind, randomized, placebo-controlled trial, 100 KOA patients were assigned randomly to a placebo group, a CHM group, or SD group. Low-frequency phonophoresis was used to improve the efficiency of drug delivery. Pain at rest [using a visual analog scale (VAS)], pain on movement (VAS), and range of motion (degrees) in the three groups were evaluated using the Western Ontario and McMaster Universities Osteoarthritis Index (WOMACAI) scores. Safety assessments comprised emergency adverse events, as

well as laboratory tests of blood biochemistry, creatinine, blood urea nitrogen, alanine aminotransferase and aspartate aminotransferase.

**RESULTS:** Significant improvements were found after treatment in all outcome measures except stiffness and range of motion in patients in the CHMP group and SDP group ( $P < 0.05$ ). No significant differences in all outcome measures were found between the CHMP group and SDP group.

**CONCLUSION:** CHMP and SDP can show good therapeutic effects for KOA in terms of relieving pain and improving physical function.

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**Key words:** Osteoarthritis, knee; Phonophoresis; Drugs, Chinese herbal; Diclofenac; Ultrasonography

### INTRODUCTION

Osteoarthritis (OA) is a degenerative disease characterized by: chronic pain and stiffness in joints; joint deformity; articular instability; reduction in the range of motion (ROM); limited physical activity; and muscle weakness. It is seen commonly in weight-bearing joints [e.g., knee osteoarthritis (KOA)].<sup>1</sup>

Approximately 250 million people worldwide have KOA.<sup>2</sup> In the USA, it is estimated that 80% of the population aged > 65 years may have radiographic KOA, but only 60% of these subjects may have symptoms.<sup>3</sup> The World Health Organization estimated that the incidence of KOA in China in 2009 was 320-340 per 100 000 inhabitants.<sup>4</sup> With an aging population, the challenge facing China will soon become severe.

The primary aim of KOA management is pain alleviation. Non-steroidal anti-inflammatory drugs (NSAIDs) are the first-line treatment for KOA, but can give rise to gastrointestinal bleeding, cardiac risks, and stroke. Corticosteroids given *via* the oral route are not recommended for KOA treatment because of the: (a) hepatic first-pass effect and (b) high risk of adverse effects. Increasing the efficacy of drugs is one way to avoid (or reduce) these adverse effects.

Phonophoresis (also called "sonophoresis") involves the use of ultrasound to deliver therapeutic compounds through the skin in a non-traumatic manner. In this way, the hepatic first-pass effect and side effects of NSAIDs can be avoided. The NSAID sodium diclofenac (SD) is used for the treatment of acute or chronic conditions involving pain and inflammation. However, its application for KOA may be limited in view of its side effects. According to the literature,<sup>5</sup> phonophoresis using SD is effective for knee-joint pain.<sup>6</sup> However, whether sodium diclofenac phonophoresis (SDP) can relieve knee-joint stiffness and improve physical function is not known.

Chinese herbal medicine (CHM) has been used for thousands of years to treat all types of diseases and disorders, including KOA.<sup>7-9</sup> However, the color, appearance, and taste of CHMs are not particularly attractive for patients. Hence, we screened several CHM prescriptions to find an efficacious recipe and created a gel formulation (Chinese patent number: CN102091158A). The main ingredients of this CHM prescription were Guizhi (cassia twig) and cinnamic aldehyde (C<sub>9</sub>H<sub>8</sub>O).

Previously, we showed that the amount of cinnamic aldehyde that could permeate the skin can be increased by using a low-frequency ultrasound appliance.<sup>10</sup> Whether phonophoresis using this CHM is effective treatment for KOA and how its effects compare with those of SDP are not known.

Based on preliminary studies on SDP and the pure ingredients used for Chinese herbal medicine phonophoresis (CHMP) in KOA treatment in our previous research, we compared the effects of CHMP, SDP, and phonophoresis using 10% sodium chloride (placebo-controlled group (PC) group) for KOA treatment in terms of improvement of pain, ROM, and the Western Ontario and McMaster Universities Osteoarthritis Index (WOMACAI).

## METHODS

### *Ethical approval of the study protocol*

The study protocol was approved by the Ethics Committee of the Third Affiliated Hospital of Beijing University of Chinese Medicine (Beijing, China). All patients provided written informed consent.

### *Research design*

We designed a double-blind, randomized controlled trial. A table of random numbers was generated by a per-

sonal computer. The opaque-envelope method was used to hide this randomization.

All patients were assigned randomly to the CHMP group, SDP group, or PC group. Patients underwent CHMP, SDP, or placebo treatment once a day, five times a week, for 2 weeks. There was a 4-week follow-up observation after treatment cessation.

### *Subjects*

Patients were recruited from January 2010 to November 2013 from the Third Affiliated Hospital of Beijing University of Chinese Medicine. All the patients participated in this research had signed an informed consent. Ultimately, 100 patients (100 affected knees) were recruited.

### *Inclusion criteria*

The first set of criteria that patients had to fulfil was that set by the American College of Rheumatology for KOA:<sup>11</sup> (a) age 40-75 years; (b) symptomatic for ≥ 1 month; (c) primary source of pain did not respond adequately to anti-inflammatory drugs, and the number of leukocytes in synovial fluid was < 2000/mL; (d) a minimum score of 2 on a visual analog scale (VAS); (e) duration of stiffness in the morning ≤ 30 min.

The second set of criteria that patients had to fulfil was for the diagnosis of blood-stasis syndrome used in traditional Chinese medicine: (a) "stabbing" pain, and pain at a fixed location; (b) spotted, blue or purple tongue; (c) "choppy" pulse.

### *Exclusion criteria*

Patients were excluded if they: (a) had severe disease of cardio-cerebral blood vessels, liver, kidneys, hematopoietic systems or a psychiatric disease; (b) were allergic to adhesive plasters, liniments, lotions, or external applications; (c) had received other therapies that could influence indices of the effects measured in this study; (d) were pregnant or lactating; (e) were undergoing glucocorticoid treatment < 4 weeks before study enrollment; (f) were receiving NSAID treatment < 2 weeks before study enrollment.

### *Therapies*

Drug phonophoresis was implemented at points (2 cm in diameter) on the skin of medial and lateral patellar tendons. Participants were asked to suspend all other therapies during the trial.

Simultaneous low-frequency phonophoresis (40 kHz, 5000 Pa) was undertaken for 30 min each time.<sup>12</sup> For the CHMP group, the prescription was Guizhi (*Ramulus Cinnamomi*), Xixin (*Herba Asari Mandshurici*), Taoren (*Semen Persicae*), Baishao (*Radix Paeoniae Alba*), Huajiao (*Pericarpium Zanthoxyli Bungeani*), Honghua (*Flos Carthami*), Niuxi (*Radix Achyranthis Bidentatae*), Caowu (*Radix Aconiti Kusnezofii*), Ruxiang (*Olibanum*), and Moyao (*Myrrh*). Each of these drugs (100 g) was extracted and made into an ointment. Then, the

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