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Application of Stone Needle Therapy Based on Blood Stasis Theory in the Treatment of 36 Cases of Knee Osteoarthritis in Early and Middle Stage

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Abstract

Objective: To evaluate the clinical efficacy of stone needle therapy based on blood stasis theory for different traditional Chinese medicine (TCM) syndrome types of patients with knee osteoarthritis in early and middle stage.

Methods: Totally 36 patients with knee osteoarthritis were enrolled in the orthopaedic ward between March 2016 and December 2017, and diagnosed as qi stagnation and blood stasis syndrome, cold dampness and stasis syndrome, or phlegm and stasis syndrome according to TCM syndrome differentiation. After treatment, stone needle was used for ironing on the different meridian acupoints according to different syndrome. The efficacy of patients with the above three syndromes was respectively evaluated, and the visual analogue scale (VAS) score and western ontario and mcMaster universities arthritis Index (WOMAC) score of the three groups were calculated before treatment, 2 weeks, and 4 weeks after treatment.

Results: The effective rates of the three groups were 86.67%, 81.82%, and 80.00%, respectively. After 2 weeks and 4 weeks of treatment, the VAS and WOMAC scores of the three groups decreased significantly compared to treatment before ($P < 0.05$).

Conclusion: Stone needle therapy for ironing on the acupoints around the knee joint has a good therapeutic effect on knee osteoarthritis of different syndrome types, which is worthy of further application.

Key words: Blood stasis theory; Stone needle; Knee osteoarthritis; Treatment based on syndrome differentiation

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Introduction

Knee osteoarthritis belongs to the category of “Bi” syndrome in traditional Chinese medicine (TCM) which is mainly manifested as pain and limited mobility^[1-2]. As Su Wen--Discussion on Bi syndrome mentioned, “Bi syndrome is formed by the mixture and combination of three Qi--the wind, cold, and wet”. Therefore, the clinical common syndrome types of knee osteoarthritis patients are mainly qi stagnation and blood stasis syndrome, cold dampness and stasis syndrome, and phlegm stasis syndrome^[3-5]. In the Qing Dynasty, Wang Qing-Ren clearly stated in the *Medical Correction* that “there is blood stasis” and pointed out the treatment by promoting blood circulation and removing blood stasis. Stone needle therapy, a new method that combines modern technology with needle stone, not only contains traditional physiotherapy effects of stone needle but also has a thermotherapy effect. Electro-heating stone needle therapy has the effect of promoting blood circulation, warming yang and dispelling cold, and the infrared radiation and thermotherapy effect generated during heating process can effectively improve local microcirculation, and ironing on different meridian points in the process of treatment makes the curative effect more effective. Based on those advantages, it is widely used in the clinical treatment of various diseases, especially in the diseases with blood stasis syndrome at the department of orthopedics^[6]. Therefore, we included 36 patients with knee osteoarthritis in this study to explore the therapeutic effect of stone needle for ironing on different acupoints of patients with different syndrome types, so as to provided reference to the clinical application of stone needle therapy in osteoarthritis.

Materials and Methods

General information

All patients were hospitalized in the Department of Orthopaedics, the Third Affiliated Hospital of Beijing University of Chinese Medicine from March 2016 to February 2017. All patients were diagnosed by imaging (KL grade 2-3) and had early symptoms of clinical symptoms. A total of 36 patients with knee osteoarthritis were enrolled. There were 9 males and 27 females, with average age of (56±8) (ranging from 53 to 75 years old). The hospital stay was averaged (14.5±7.8) months (ranging from 2 to 36 months). 21 cases involved in bilateral knees and 15 in unilateral knee. According to TCM syndrome differentiation, there were respectively 15 cases of qi stagnation and blood stasis syndrome, 11 cases of cold dampness and stasis syndrome and 10 cases of phlegm stasis syndrome. There was no significant differences in the general data of age, gender, and hospital stay among the three groups ($P>0.05$), which was comparable (Table 1).

Diagnostic criteria

Western medicine diagnostic criteria: According to the *Guidelines for the Diagnosis and Treatment of Osteoarthritis (2007 edition)*^[8], the clinical and radiological classification criteria for knee osteoarthritis revised by the Chinese Medical Association Orthopedics Branch is set as follows: (1) Repeated knee pain in the past 1 month; (2) X-ray films (standing or weight position) shows narrowing of the joint space, hardening of the subchondral bone, and/or cystic changes, formation of osteophyte; (3) Joint fluid (at least 2 times) clear, sticky, WBC<2,000/mL; (4) Middle-aged patients (age≥40 years); (5) Morning stiffness≤3 min; (6) Bone friction sound (sensation) during activity.

Table 1 General data of patients ($\bar{x} \pm s$)

| Groups | Cases | Age ($\bar{x} \pm s$, years) | Gender (number) | |
|---|-------|--------------------------------|-----------------|--------|
| | | | Male | Female |
| Qi stagnation and blood stasis syndrome | 15 | 60.13± 13.7 | 4 | 11 |
| cold dampness and stasis syndrome | 11 | 64.36±6.77 | 2 | 9 |
| Phlegm stasis syndrome | 10 | 64.5±6.02 | 3 | 7 |

The condition that comprehensive clinical, laboratory and X-ray examinations was in line with (1)+(2) or (1)+(3)+(5)+(6) or (1)+(4)+(5)+(6), can be diagnosed as knee osteoarthritis.

Chinese medicine diagnostic criteria refer to the diagnosis of “Bi syndrome of bone” in the *Diagnostic and Efficacy Standards for TCM Syndrome* issued by the State Administration of Traditional Chinese Medicine in 1995^[9], there were mainly three Bi syndromes including Qi stagnation and blood stasis syndrome, cold dampness and stasis syndrome, and phlegm stasis syndrome. Qi stagnation and blood stasis syndrome was mainly marked by joint deformity, stabbing pain but relief after rest and exacerbation after exertion and fatigue, darkish complexion, dull purple tongue, and deep and uneven pulse. Cold dampness and stasis syndrome was mainly marked by joint deformity, severe pain, and exacerbation with cold air, reduced with the temperature raised, waist with heavy pain, light-colour tongue with white and greasy fur, and deep pulse. Phlegm stasis syndrome was mainly marked by joint deformity, widespread pain, especially painful around the anserinus tendon, unfavorable flexion and extension of knee joint, chest tightness, excessive phlegm, dull purple tongue with ecchymosis and white and greasy fur, wiry and uneven pulse.

Case inclusion criteria: (1) patients who comply with the diagnostic criteria of Chinese and Western medicine for knee osteoarthritis; (2) Aging between 40 and 75 years old; (3) VAS score: VAS score \geq 4; (4) X-ray films K-L grade II and III; (5) Voluntarily signing informed consent.

Case exclusion criteria: (1) Patients with severe cardiovascular (such as myocardial infarction, heart failure, severe heart failure, etc.), lung (such as pulmonary insufficiency), liver, kidney, hematopoietic system or other severe diseases; (2) The related diseases affects the joints, such as psoriasis, syphilitic neuropathy, brownish yellow disease, metabolic bone disease, acute trauma, etc; (3) Other non-regressive knee arthritis such as rheumatoid arthritis, gouty arthritis; (4) Breast-feeding pregnant women or the one with mental illness; (5) Those with traumatic and ruptured skin at the knee; (6) Those who

received anticoagulant therapy within 61 weeks; (7) The researchers believe that other reasons are not suitable for clinical trials.

Case withdrawal criteria: (1) If the condition worsened or may occur or has serious adverse events, according to the doctor's judgment, the clinical research should be stopped, that is, the clinical study of the case should be suspended. (2) During the treatment, the patient was withdrawn because he or she had certain complications or special cases, his or her physiological changes may not be suitable for continuing to participate in the research. (3) The patient was unwilling to continue the clinical research during the clinical research process, and asked the competent doctor to withdraw from the clinical research. The case should be withdrawn from clinical research.

Case rejection criteria: (1) Patient did not cooperate with the treatment; (2) Patient selection violated the inclusion/exclusion criteria; (3) Patient compliance was poor, unable to follow; (4) Patient received other treatment during the observation period.

Treatment

Stone needle ironing: The electric-heating Bian-stone instrument (model DRB-4A, size 9cmX 10cmX 2cm, Beijing Hai Ao Sikai Technology Development Co., Ltd. [Beijing Pharmaceutical Supervision (standard) word 2008 No. 1270207]) were turned on for 20 minutes in advance, and then the stone surface temperature were set to constant temperature of 50 °C. According to three Bi syndrome types of knee osteoarthritis, different acupoints are selected, and ironed on for 10-15 minutes each time for each syndrome, twice a week.

Acupoints for qi stagnation and blood stasis syndrome: Yanglingquan, Dubi, Liangqiu, Weiyang, Zusanli, Sanyinjiao.

Acupoints for cold and dampness and stasis syndrome: Xuehai, Yinlingquan, Weizhong, Zusanli, Sanyinjiao.

Acupoints for phlegm stasis syndrome: Liang Qiu, Weizhong, Zusanli, Sanyinjiao.

Observation indicators

Visual analogue pain score: The visual analog scale for pain (VAS) was used to score the degree of knee pain before treatment, 2 weeks and 4 weeks after treatment. The degree of pain: 0 indicates no pain. The higher the number, the greater the pain intensity, 10 indicates the most severe pain.

WOMAC Rating Scale: The West Ontario and McMaster University Osteoarthritis Index scores (WOMAC) was used, including scores for pain (5 items in total), stiffness (2 items in total), and functional activities (17 items in total)^[10]. They were evaluated before treatment, 2 weeks and 4 weeks after treatment.

Efficacy criteria: Referring to the “Diagnostic and Efficacy Standards for TCM Syndrome” issued by the State Administration of Traditional Chinese Medicine in 1994^[9], the efficacy index $n \geq 70\%$ is markedly effective, joint pain disappears, swelling, activity function and physical signs are significantly improved; $30\% \leq n < 70\%$ is effective, joint pain is obviously relieved, swelling, activity function and physical signs are obviously improved; when $n < 30\%$ is ineffective, though pain is relieved, but swelling, activity function and physical signs are unchanged. The overall efficacy evaluation was calculated by score (nimodipine method). After 4 weeks of treatment, it was calculated according to the following formula.

Efficacy index $n = [(\text{pre-treatment score} - \text{post-treatment score}) / \text{pre-treatment score}] \times 100\%$

Total effective rate = $(\text{markedly effective} + \text{effective}) / n \times 100\%$

Statistical analysis

The data analysis was performed by SPSS20.0 statistical

software. The results of the measurement data were expressed by the mean \pm standard deviation ($\bar{x} \pm s$). The comparison between the groups with the normal distribution was performed. The homogeneity of the variance was first tested. When the variances were equal, the differences between the groups were compared using independent sample t test, and difference between before and after treatment was compared using the paired t test. The composition ratio and the ratio of the count data were expressed in percentage (%), and the difference of efficacy among the groups were analyzed by Kruskal-Wallis test. The inspection level was $\alpha = 0.05$. $P < 0.05$ was considered statistically different.

Results

Comparison of the efficacy of three groups

The total effective rate was 86.67% for patients with qi stagnation and blood stasis syndrome, 81.82% for patients with cold and dampness resistance syndrome, and 80% for patients with phlegm stasis syndrome, respectively, but no difference was found among those groups ($\chi^2 = 0.193$, $P = 0.908$).

Comparison of VAS scores

There was no statistical difference among three group in VAS scores among groups before and after treatment ($P > 0.05$). but 2 weeks and 4 weeks after treatment, a significant decrease was found in three groups compare with treatment before ($P < 0.01$).

Comparison of WOMAC scores

There was no statistical difference among three group in WOMAC scores among groups before and after treatment ($P > 0.05$), but a significant decrease was found in three groups 2 weeks and 4 weeks after treatment when compare with treatment before ($P < 0.001$).

Table 2 Comparison of the efficacy of three groups

| Groups | Cases | Markedly effective | Effective | Invalid | Total effective rate |
|---|-------|--------------------|-----------|---------|----------------------|
| Qi stagnation and blood stasis syndrome | 15 | 6 | 7 | 2 | 86.67% |
| Cold dampness and stasis syndrome | 11 | 4 | 5 | 2 | 81.82% |
| Phlegm stasis syndrome | 10 | 5 | 3 | 2 | 80% |

Table 3 Comparison of VAS pain scores of three groups ($\bar{x} \pm s$)

| Groups | Cases | Time | VAS score |
|---|-------|------------------------|------------|
| Qi stagnation and blood stasis syndrome | 15 | Before treatment | 7.33±1.11 |
| | | 2 week after treatment | 4.80±1.15* |
| | | 4 week after treatment | 3.06±1.22* |
| Cold dampness and stasis syndrome | 11 | Before treatment | 6.55±0.93 |
| | | 2 week after treatment | 4.64±0.92* |
| | | 4 week after treatment | 3.27±1.00* |
| Phlegm stasis syndrome | 10 | Before treatment | 6.92±1.13 |
| | | 2 week after treatment | 4.44±0.99* |
| | | 4 week after treatment | 3.47±1.58* |

Note: * $P < 0.01$ when compared with treatment before.

Table 4 Comparison of WOMAC scores in each group of patients ($\bar{x} \pm s$)

| Groups | Cases | Time | Pain | Stiffness | Functional activities |
|---|-------|------------------------|-------------|-------------|-----------------------|
| Qi stagnation and blood stasis syndrome | 15 | Before treatment | 13.93±1.67 | 5.87±1.25 | 49.4±4.85 |
| | | 2 week after treatment | 8.93±1.22** | 3.33±1.18** | 32.33±4.29** |
| | | 4 week after treatment | 5.87±3.27** | 2.53±1.19** | 19.87±7.76** |
| Cold dampness and stasis syndrome | 11 | Before treatment | 13.63±2.01 | 5.91±1.04 | 51.18±7.67 |
| | | 2 week after treatment | 8.54±2.16** | 3.73±1.19** | 28.73±4.58** |
| | | 4 week after treatment | 5.36±2.46** | 2.64±1.29** | 21.91±6.925** |
| Phlegm stasis syndrome | 10 | Before treatment | 14.30±1.49 | 5.80±1.03 | 50.20±6.16 |
| | | 2 week after treatment | 8.20±1.55** | 3.30±0.48** | 28.5±4.65** |
| | | 4 week after treatment | 5.10±2.96** | 2.2±0.63** | 20.30±7.51** |

Note: ** $P < 0.001$ compared with treatment before.

Discussion

The motor function of the knee joint is mainly achieved by the muscles, tendons, ligaments, fascia, synovium and other tissues around the joints, that is, the maintenance of the tendons (aponeurotic channel) in the theory of TCM. If the function of the tendons is normal, the joints are smooth,

with favourable flexion and extension. If the function is abnormal, the joint is unstable and its activity is limited. Therefore, As “*Su Wen--Discussion on Pulse-taking*” mentioned, “Knee is the house of tendon, if knee can not stretch, one can not move, the tendon will be disused.”

The distribution of tendons around the knee joint is closely related to the six foot tendons according to the TCM theory of tendons. The foot Yangming tendon, the foot Taiyang tendon, the foot Shaoyang tendon, the foot Taiyin tendon, the foot Shaoyin tendon and foot Jueyin tendon are respectively travelling through the front and back of, outside and inside the knee joint. According to the relationship between the clinical anatomy and the circulation of the tendons^[11], the patellar ligament below the patella, the infrapatellar fat pad, and the lateral retinaculum of the patella are the travelling parts of the foot Yangming tendon. The lateral collateral ligament and end point of tractus iliotibialis of knee joints are the travelling parts of the foot Shaoyang tendon. The starting points of medial head and lateral head of the musculus gastrocnemius are the circumscribing part of the foot Taiyang tendon. The medial space, the bursa of the anserinus, and the nodules of adductor femoris muscle of the knee joint are the pathway that the foot three Yin tendons pass through. Therefore, it is crucial to pay attention to syndrome differentiation of tendons around the knee joints in the process of clinical treatment of knee osteoarthritis. According to clinical manifestations combined with the four diagnostic methods of TCM, we can divide the common syndromes of knee arthritis into qi stagnation and blood stasis syndrome, cold dampness and stasis syndrome, and phlegm stasis syndrome.

Since ancient times, Chinese medicine treatment has been integrated into concept of “doctors, pharmacists and nurses”^[12]. According to the syndromes diagnosed by doctor, the nurses selected different acupoints to apply the stone needle for treatment. Patients with qi stagnation and blood stasis syndrome were ironed on Yanglingquan, Dubi, Liangqiu, Weiyang, Zusanli and Sanyinjiao; patients with cold and dampness syndrome were ironed on Xuehai, Yinlingquan, Weizhong, Zusanli and Sanyinjiao; Patients with phlegm stasis syndrome were ironed on Liangqiu, Weizhong, Zusanli and Sanyinjiao. After 2 weeks and 4 weeks of treatment, the VAS scores and WOMAC scores of the three groups decreased significantly compared with the pre-treatment VAS scores ($P < 0.01$), but there was no statistical significance among the three groups ($P > 0.05$). After four weeks of treatment, the effective rates of

treatment in the three groups were 86.67%, 81.82%, and 80%, respectively.

Electro-heating stone needle therapy is a new type of moxibustion equipment developed in recent years. Its source is the Sibin pumice stone with special biophysical properties. Studies have shown that the Sibin stone needle itself has an inductive warming effect, because it has an very broad far-infrared radiation spectrum, and the unique biophysical effects such as dense ultrasonic pulses can also be generated in the process of friction treatment^[13]. After heating, the Sibin pumice stone has the important physiotherapy effects such as dredging meridians, regulating qi and promoting blood circulation, thus making the treatment effect more significant^[14]. Therefore, using electro-heating stone needle therapy for ironing on acupoints has the effect of removing phlegm, cold and dampness, relaxing muscles and tendons, and promoting blood circulation. The application of electro-heating stone needle on the acupoints is better than the treatment effect of acupuncture alone.

Knee osteoarthritis belongs to the category of Bi syndrome in TCM. According to the pathogenesis theory of knee osteoarthritis, “both obstruction and lack of nutrition lead to pain”. Qi and blood deficiency, kidney qi loss, qi stagnation due to cold congealing, and dampness-heat obstruction can cause tendon and vessel malnutrition and unsmooth qi and blood circulation, resulting in joint and muscle pain and inactivity^[15]. Stone needle hot ironing promotes qi and blood circulation through the thermal effect, thereby achieving the purpose of treating knee osteoarthritis when combined with the therapeutic effect of the acupoints itself.

From the perspective of modern medicine, the so-called “obstruction” in TCM is the change in blood flow velocity. In the study of treatment of osteoarthritis, it is positive to improve local blood flow^[16]. For example, whether it is local physiotherapy, hot compress, massage, topical drugs, or taking drugs such as promoting blood circulation to remove blood stasis and dredging meridians, the disease is treated from the perspective of improving blood flow of blood vessels^[17-18].

In short, the effect of stone needle hot ironing on the acupoints around the knee joints has a good therapeutic effects on knee osteoarthritis of different syndrome types, worthy of further promotion and application.

Declaration

The authors of this article declare that they have no conflict of interest.

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