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Clinical Study

Clinical study on mild moxibustion for knee osteoarthritis

温和灸治疗膝骨关节炎临床研究

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Abstract

Objective: To observe the clinical effect of mild moxibustion for knee osteoarthritis (KOA) and to explore the role of mild moxibustion in relieving pain, reducing stiffness and improving joint dysfunction in patients with KOA.

Methods: Eighty patients with KOA were randomly allocated into either a moxibustion group or a medication group by the random number table, with 40 cases in each group. The moxibustion group used mild moxibustion at Neixiyan (EX-LE 5), Dubi (ST 35), Xuehai (SP 10) and Liangqiu (ST 34), 30 min each time, 3 times a week; the medication group was given celecoxib capsule (celebrex), 0.2 g each time, once a day. Both groups were treated for 4 weeks. The visual analog scale (VAS) and Western Ontario and McMaster Universities osteoarthritis index (WOMAC) scores were evaluated before and after treatment. The efficacy of the two groups was compared after treatment.

Results: After treatment, the overall efficacy of the moxibustion group was significantly different from that of the medication group (P<0.05). The VAS and WOMAC scores of the two groups were lower than those before treatment (both P<0.01). The changes in the VAS and WOMAC scores after treatment in the moxibustion group were significantly different from those in the medication group (both P<0.05). After treatment, in single item of WOMAC, the changes in pain and joint dysfunction in the moxibustion group were more statistically significant than those in the medication group (both P<0.05).

Conclusion: Mild moxibustion and oral celebrex can reduce the VAS and WOMAC scores of patients with KOA. Mild moxibustion is superior to oral celebrex in relieving pain and improving joint function.

Keywords: Moxibustion Therapy; Moxa Stick Moxibustion; Osteoarthritis, Knee; Pain Measurement; Visual Analog Scale; Quality of Life

【摘要】目的:观察温和灸治疗膝骨关节炎(KOA)的临床疗效,探讨温和灸在减轻KOA患者疼痛、僵硬及改善关节功能障碍方面的作用。方法:将80例KOA患者采用随机数字表法分为艾灸组和药物组,每组40例。艾灸组采用艾条温和灸内膝眼、犊鼻、血海和梁丘,每次30 min,每周3次;药物组口服塞来昔布胶囊(西乐葆),每次0.2 g,每日1次。两组均治疗4周。治疗前后进行视觉模拟量表(VAS)和西安大略与麦克马斯特大学骨关节炎指数(WOMAC)评分。治疗后比较两组疗效。结果:治疗后,艾灸组整体疗效与药物组差异有统计学意义(P<0.05);两组VAS及WOMAC评分均较治疗前下降(均P<0.01),艾灸组VAS、WOMAC治疗前后评分差值与药物组有统计学差异(均P<0.05)。治疗后,在WOMAC单项评分方面,艾灸组疼痛及关节功能障碍治疗前后评分差值与药物组比较有统计学差异(均P<0.05)。结论:温和灸及口服西乐葆均能降低KOA患者的VAS及WOMAC评分,温和灸在减轻疼痛、改善关节功能方面优于口服西乐葆。

【关键词】灸法; 艾条灸; 骨关节炎, 膝; 疼痛测评; 视觉模拟量表; 生活质量

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Knee osteoarthritis (KOA) is a chronic osteoarticular disease caused by hyperplasia of the knee joint cartilage, also known as proliferative osteoarthritis or degenerative arthritis. KOA belongs to bone Biimpediment in traditional Chinese medicine. With the aging of the population, the incidence of KOA has been increasing in recent years^[1]. In Western medicine, it

focuses on symptomatic treatment and pain relief for KOA. Non-steroidal anti-inflammatory drugs (NSAIDs) are routinely used, but it is not suitable for long-term use because of its side effects. Severe cases require surgical treatment, but surgeries will increase pain and put financial burden to patients.

Acupuncture is a common treatment method for KOA and has certain advantages^[2]. This study evaluated the effect of mild moxibustion on knee pain and knee dysfunction in KOA by observing the changes in visual analog scale (VAS) and Western Ontario and McMaster

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Universities osteoarthritis index (WOMAC) scores after treatment. The report is given as follows.

1 Clinical Materials

1.1 Diagnostic criteria

1.1.1 Western diagnostic criteria^[3]

According to the diagnostic criteria of the Osteoarthritis Treatment Guide (2007 edition) formulated by the Chinese Orthopedics Association: 1 repeated knee pain in the past one month; ② X-ray (standing position) examination showing narrowing of the joint space, subchondral bone sclerosis and/or cystic changes, formative osteophytes; ③ synovial fluid (at least 2 times) clear, sticky, white blood cell count (WBC) < 2 000/mL; 4 middle-aged patients (≥40 years); ⑤ morning stiffness ≤30 min; 6 crepitus on active motion.

Comprehensive consideration of clinical, laboratory and X-ray examinations, KOA can be diagnosed with 1+2 or 1+3+5+6 or 1+4+5+6.

1.1.2 Classification of KOA severity by X-ray examination $^{[4]}$

The severity of KOA was classified by X-ray with reference to the Kellgren-Lawrence system.

Grade 0: no radiographic features of OA; grade 1: doubtful joint space narrowing (JSN) and possible osteophytic lipping; grade 2: definite osteophytes and possible JSN on anteroposterior weight-bearing radiograph; grade 3: multiple osteophytes, definite JSN, sclerosis, possible bony deformity; grade 4: large osteophytes, obvious JSN, severe sclerosis and definite bony deformity.

1.2 Inclusion criteria

Age between 40 and 70 years old; conforming to the above diagnostic criteria of KOA; conforming to the above classification criteria grade 0 to 3; be able to accept the treatment and willing to participate and sign the informed consent.

1.3 Exclusion criteria

Patients with unconsciousness, unable to express subjective symptoms; mental illness; patients with progressive malignant tumors or other severely wasting diseases, susceptible to infection and bleeding; combined with severe primary cardiovascular, hepatic, renal, digestive, hematopoietic system diseases; pregnant women and lactating women; long-term use of other drugs that may affect efficacy and safety, or accept comprehensive treatment; rheumatoid arthritis, arthritic diseases such as gouty arthritis, and other diseases affecting lower limb function.

1.4 Elimination and shedding

The patients who didn't meet the inclusion criteria but were included by mistake; received other treatments during the experiment privately or failed to

follow the treatment due to other conditions; quitted the research automatically or disappeared; experienced adverse events during the treatment.

1.5 Statistical methods

The data were processed using the SPSS version 21.0 software. Measurement data that conformed to the normal distribution were described as mean \pm standard deviation (\overline{x} $\pm s$). Paired sample t-test was used for intra-group comparison, and independent sample t-test was carried out for inter-group comparison. Non-parametric test was used when data were of non-normal distribution and non-homogeneity variance. Wilcoxon test was used for intra-group comparison, and Mann-Whitney test was carried out for inter-group comparison. The comparisons of count data and rate were performed by Chi-square test. Rank-sum test was carried out for ranked data. P<0.05 indicated statistically significance.

1.6 General data

A total of 80 subjects, admitted to Acupuncture Department of Longhua Hospital, Shanghai University of Traditional Chinese Medicine or Acupuncture and Injury Department of Pujiang Community Health Service Center of Minhang District, Shanghai between August 2015 and December 2017 were enrolled. A random number table was used to create a randomized distribution card containing serial numbers, random numbers and groups. Patients were randomly assigned cards according to the order of treatment, and were randomly assigned to a moxibustion group or a medication group, with 40 cases in each group. During the study, 2 patients in the moxibustion group and 4 patients in the medication group were lost to follow-up (the 6 patients all withdrew voluntarily), and a total of 74 patients completed all treatments. The flow chart is shown in Figure 1.

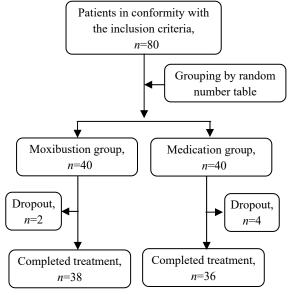


Figure 1. The flow chart of study

There were no statistical differences in gender, age and duration between the two groups (all P>0.05), indicating that the two groups were comparable (Table 1).

Table 1. Comparison of general data between the two groups

C	n	Gender (case)		Mean age	Mean duration	
Group		Male	Female	$(\overline{x} \pm s, year)$	$(\overline{x} \pm s, month)$	
Moxibustion	38	13	25	55.8±7.1	59.8±25.0	
Medication	36	12	24	57.7 ± 8.0	62.1 ± 23.8	

2 Treatment Methods

2.1 Moxibustion group

Acupoints: Neixiyan (EX-LE 5), Dubi (ST 35), Xuehai (SP 10) and Liangqiu (ST 34).

Method: Acupoints were referred to *Science of Acupuncture and Moxibustion*^[5]. The patient took a supine position and naturally placed the affected lower limbs. The ignited moxa (Nanyang Hanyi Moxa Wool Co., Ltd., China) was placed above the acupoint, about 3 cm away from the skin, so that the patient did not feel burning, 30 min for each time, 3 times a week. The effect was observed after 4 weeks of treatment.

2.2 Medication group

Oral celecoxib capsule (celebrex, Pfizer Pharmaceutical Co., Ltd.), 0.2 g each time, once a day. The effect was observed after 4 weeks of continuous administration.

3 Therapeutic Efficacy Observation

3.1 Observation items

VAS and WOMAC were evaluated before and after the treatment.

3.1.1 VAS^[6]

Used a straight 10-centimeter line, with one end marked '0', indicating no pain with 0 point; the other end with '10', representing extreme pain and 10 points. The patient marked a number on the straight line according to his or her feeling of pain, and this number was the VAS score.

3.1.2 WOMAC scale^[7]

WOMAC scale evaluates the structure and function of the knee joint from three aspects: pain, stiffness, and physical function of the joints, including 5 items for pain, 2 items for stiffness, and 17 items for functional limitation. Grading criteria: No difficulty is 0 points; slight is 1 point; moderate is 2 points; very is 3 points; extreme is 4 points. The total score is 0-96 points, the pain score is 0-20 points, the stiffness score is 0-8 points, and the joint function score is 0-68 points. A higher score indicates more severe symptoms.

3.2 Criteria for clinical efficacy

Referring to the *Guiding Principles for Clinical Study of New Chinese Medicine*^[8], the nimodipine method was used to calculate the WOMAC total score reduction. WOMAC total score reduction rate = (Pre-treatment total score – Post-treatment total score) \div Pretreatment total score × 100%.

Recovery: Pain or other symptoms disappeared, joint function was normal; WOMAC total score reduction rate ≥95%; X-ray examination showed normal.

Marked effect: Pain basically disappeared; unlimited joint function; WOMAC total score reduction rate ≥70%, but <95%; X-ray examination showed a significant improvement.

Improvement: Pain basically disappeared; mild limitation of joint function; WOMAC total score reduction rate ≥30%, but <70%, X-ray examination showed improvement.

Failure: Symptoms such as pain and joint function did not improve significantly, WOMAC total score reduction rate <30%, and X-ray examination showed no change.

3.3 Treatment results

3.3.1 Comparison of clinical effect

The overall efficacy between the two groups showed a statistically significant difference (*P*<0.05), indicating that the moxibustion group had a better curative effect than the medication group (Table 2).

3.3.2 Comparison of VAS score

There was no statistical difference in VAS score between the two groups before treatment (P>0.05). After treatment, the scores of VAS in both groups were significantly decreased (both P<0.05). The score in the moxibustion group was lower than that in the medication group, and the difference between the two groups was statistically significant (P<0.05), (Table 3).

3.3.3 Comparison of WOMAC score

There was no statistical difference in WOMAC score between the two groups before treatment (P>0.05). After treatment, the scores of WOMAC in both groups were significantly decreased (both P<0.01). The score in the moxibustion group was lower than that in the medication group, and the difference between the two groups was statistically significant (P<0.05), (Table 4).

Table 2. Comparison of clinical efficacy between the two groups (case)

Group	n	Recovery	Marked effect	Improvement	Failure
Moxibustion	38	2	18	16	2
Medication	36	1	9	23	3

Table 3. Comparison of VAS score ($\bar{x} \pm s$, point)

Group	n	Before treatment	After treatment	Difference value
Moxibustion	38	5.51±1.02	$2.48\pm1.03^{1)}$	$3.03\pm0.97^{2)}$
Medication	36	5.79±1.29	$3.62\pm1.23^{1)}$	2.17 ± 0.89

Note: Intra-group comparison before and after treatment, 1) P < 0.01; inter-group comparison, 2) P < 0.05

Table 4. Comparison of WOMAC score ($\overline{x} \pm s$, point)

Group	n	Before treatment	After treatment	Difference value	
Moxibustion	38	45.99±11.78	17.05±6.98 ¹⁾	28.94±6.48 ²⁾	
Medication	36	47.91±13.87	$24.42\pm7.87^{1)}$	23.49±6.31	

Note: Intra-group comparison before and after treatment, 1) P<0.01; inter-group comparison, 2) P<0.05

3.3.4 Comparison of single item of WOMAC

There were no statistical differences in scores of items in WOMAC between the two groups before treatment (all P>0.05). After treatment, all the scores of items in WOMAC in both groups were significantly decreased (all P<0.01). The difference values of scores of pain and joint dysfunction in the moxibustion group were statistically different from those in the medication group (both P<0.05), (Table 5).

Table 5. Comparison of single item of WOMAC

		Stiffness			Pain			Joint dysfunction		
Group	n	Before treatment	After treatment	Difference value	Before treatment	After treatment	Difference value	Before treatment	After treatment	Difference value
Moxibustion	38	3.98±1.11	2.23±0.73 ¹⁾	1.75±0.63	9.27±3.45	$3.69\pm1.18^{1)}$	5.58±1.86 ²⁾	32.74±10.76	11.13±3.92 ¹⁾	21.61±8.34 ²⁾
Medication	36	4.03±1.06	$2.25{\pm}0.69^{1)}$	1.78 ± 0.71	9.60±3.04	$5.04{\pm}1.67^{1)}$	4.56 ± 1.82	34.28±13.65	17.13±5.15 ¹⁾	17.15±5.61

Note: Intra-group comparison before and after treatment, 1) P<0.01; inter-group comparison, 2) P<0.05

4 Discussion

KOA is a common disease in orthopedics. According to domestic research data, about 60% of people older than 55 years old have an imaging manifestation of KOA, and 85% of people aged above 65 years old experience KOA^[9]. The prevalence of KOA is positively correlated with age. There is a high disability rate as 53% if patients don't receive active treatments^[3].

NSAIDs are often prescribed in clinical practice, but they also bring many adverse effects, such as gastrointestinal reactions, high risk of cardiovascular and cerebrovascular diseases. As a result, NSAIDs are not suggested for long time use. Severe cases require surgeries, and the operations can be risky and costly, which will increase the financial burden for families and society^[10].

Moxibustion can warm meridians to disperse cold, activate blood flow and dissolve stasis, and relieve rigidity of muscle and activate collaterals. Moxibustion has obvious curative effect for KOA due to cold stagnating in the meridians syndrome [11], since it can reduce pain, relieve joint stiffness and improve joint dysfunction in KOA patients [12-13]. There are many clinical reports of moxibustion as an effective intervention for patients with KOA [14-16]. Studies have shown that mild moxibustion can effectively reduce serum interleukin-1 (IL-1) and tumor necrosis factor (TNF)- α levels in patients with KOA [17]. Another study

showed that moxibustion had more health and economic value than electroacupuncture through cost-effectiveness analysis for KOA patients^[18]. Experimental studies have shown that moxibustion can release a large amount of infrared waves, so that the diseased cells can be activated by resonance, and the absorption of inflammation by local lymphatic vessels can be promoted. As a result, the circulation of body fluids would accelerate, the intraosseous pressure would reduce, and the local soft tissues can obtain more nutrients^[19]. Moxibustion can also inhibit the apoptosis of chondrocytes^[20].

Neixiyan (EX-LE 5) and Dubi (ST 35) have the effect of promoting blood circulation, unblocking collaterals and repairing joints. Xuehai (SP 10) can dispel stasis to promote regeneration, relieve pain, benefit qi and unblock the meridian. Liangqiu (ST 34) is the Xi-Cleft point of the Stomach Meridian, where qi and blood accumulate deeply. It can dispel wind and dampness, and unblock the meridian. Literature studies have shown that the above acupoints are high-frequently used acupoints for the treatment of KOA^[21]. Mild moxibustion with moxa stick above these acupoints can warm the meridians and move qi and relieve pain.

The results of this study showed that both mild moxibustion and celebrex can reduce the VAS and WOMAC scores of KOA patients, indicating that both treatments can alleviate pain and improve joint function in KOA patients. The moxibustion group was superior to

oral celebrex in reducing pain and improving knee dysfunction. The two treatments played a similar role in reducing joint stiffness. The above results suggested that mild moxibustion can effectively alleviate the pain and improve the joint function of KOA patients, but its mechanism still needs further study.

Conflict of Interest

The authors declared that there was no potential conflict of interest in this article.

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Statement of Informed Consent

Informed consent was obtained from all individual participants in this study.

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