

## Original Article

# Effects of ankle joint injection combined with massotherapy on function recovery and quality of life of ankle joint osteoarthritis patients

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**Abstract:** Objective: To investigate the effect of ankle joint injection combined with the massotherapy of traditional Chinese medicine (TCM) on functional recovery and quality of life of ankle joint osteoarthritis patients. Methods: A total of 48 patients with ankle pain accompanied by functional disorders who were admitted to Beijing University of Chinese Medicine Third Affiliated Hospital from May 2016 to December 2017 were randomly selected into the study group and the control group, 24 cases each. The control group was given a local drug injection therapy. The study group was given a local drug injection combined with the massotherapy of TCM. Observe and compare the efficacy of the two groups, including pain score of ankle joint, Mazur's functional ankle score, the Kellgren and Lawrence classification under X-ray (KLC) and quality of life score. Results: At 7, 14, and 28 days after treatment, the scores of pain, tenderness, swelling, and dysfunction of the two groups were significantly lower than before treatment (all  $P < 0.01$ ), and the scores of the study group after treatment were significantly lower than the control group (all  $P < 0.05$ ). After the treatment, the ankle pain scores of the two groups were significantly improved (both  $P < 0.05$ ), but there was no significant difference in post treatment pain scores of patients of KLC grade I and II in two groups ( $P > 0.05$ ). After the treatment, patients of KLC grade III and IV in the study group both had lower post treatment pain scores than those patients of same KLC grade in the control group (both  $P < 0.05$ ). Besides, the good rate by Mazur's functional ankle score in the study group was 70.83%, which was significantly higher than that in the control group (41.67%) ( $P < 0.05$ ). In addition, the scores of the quality of life of the two groups were higher than before treatment, and the scores of the study group were significantly higher than that of the control group (all  $P < 0.05$ ). Conclusion: Ankle Joint Injection combined with the massotherapy of TCM can promote the recovery of ankle joint function and improve the quality of life of patients with ankle joint osteoarthritis; it has a high promotional value.

**Keywords:** Ankle joint osteoarthritis, injection, the massotherapy of TCM, ankle joint function, quality of life

## Introduction

Degenerative ankle joint disease is a common clinical degenerative osteoarthritis, occurs in the elderly population, mostly caused by obesity, excessive exercise, repeated sprains and other factors, the clinical joint swollen deformity, pain, rigidity and limitation of motion are main performance. If not treated in time, it can lead to articular cartilage damage, synovial inflammation, calcification of the tendon-bone joint, muscle atrophy and other pathological changes, seriously affecting the patient's joint function and quality of life [1-5]. The current clinical treatments of ankle joint osteoarthritis include surgical treatment, intra-articular injection,

etc [6]. However, surgical treatments are limited due to the trauma and potential risks, and effect of simple physical therapy is not satisfactory [7].

Intra-articular injection of drugs is a common treatment for osteoarticular disease and it can achieve a certain effect, the medical ozone and other drugs are commonly used [8]. Traditional Chinese medicine (TCM) has accumulated rich experience in the treatment of joint diseases. The massotherapy of TCM has the effect of promoting blood circulation and sliding joints [9].

In this study, the usage of the massotherapy of TCM was summarized as an adjuvant therapy

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**Table 1.** Comparison of general information in two groups

Group	N	Gender		Age	Course (years)	The Kellgren and Lawrence classification under X-ray (cases)			
		M	F			I	II	III	IV
Study group	24	10	14	63.9±4.8	6.0±1.3	3	3	11	7
Control group	24	11	13	62.8±4.3	5.9±1.5	3	4	10	7
$\chi^2/t/H$ value		0.085*		0.836**	0.247**		0.153***		
P value		0.771		0.407	0.806		0.878		

Note: \* $\chi^2$  value, \*\*t value, \*\*\*H value.

for intra-articular injection of drugs in treatments of osteoarthritis patients.

## Materials and methods

### General information

A total of 48 patients with ankle pain accompanied by functional disorders were selected, and the screening time was from May 2016 to December 2017.

**Inclusion criteria:** Patients with age <80; duration of joint pain >8 weeks, aggravation after the activity; tenderness around the affected joints and pain score  $\geq 3$  points; no anti-inflammatory drugs used within 1 week; informed consent form signed [6].

**Exclusion criteria:** Patients suffered from ankle injury or bone tumor; gout, tuberculosis, or rheumatoid arthritis; ankle surgery or intra-articular injection in the past six months; congenital varus or valgus deformity; pregnancy; mental disorder or disturbance of consciousness.

**Grouping method:** A total of 48 patients were randomly divided into study group and control group using random number table method, 24 cases in each group. The study group included 10 males and 14 females, aged 58 to 82, with an average age of 63.9±4.8 (mean  $\pm$  sd), the duration ranged from 10 months to 20 years, with an average duration of 6.0±1.3 years; The Kellgren and Lawrence classification under X-ray (KLC): There were 3 cases in grade I, 3 cases in grade II, 11 cases in grade III and 7 cases in grade IV. In the control group, there were 11 males and 13 females, aged 59 to 80, with an average age of 62.8±4.3, the duration ranged from 9 months to 18 years, with an average duration of 5.9±1.5 years; The Kellgren and Lawrence classification under X-ray: There

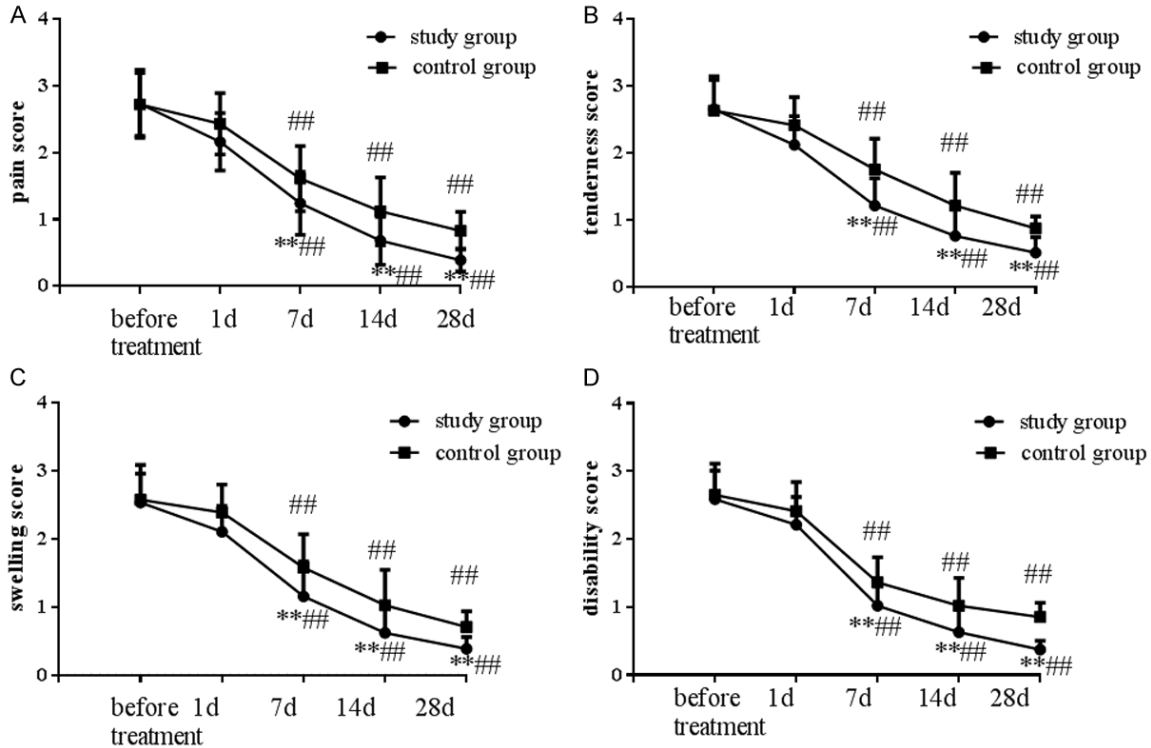
were 3 cases in grade I, 4 cases in grade II, 10 cases in grade III and 7 cases in grade IV. This study has been approved by the Medical Ethics Committee of Beijing University of Chinese Medicine Third Affiliated Hospital and all patients have signed informed consent.

### Methods

The patients in the control group were treated with an injection of ankle joint cavity. The specific method was to take the supine position, placing the affected limb on the treatment bed, after regular disinfection and placing sterile drapes, taking the anterolateral aspect of the ankle joint, and 2 cm above the lateral malleolus as the puncture point, punctured the ankle joint in posteromedial direction. After draining the effusion, injected a mixture of 0.5% lidocaine (Chengdu First Pharmaceutical Co., Ltd., approval number: H51021661) 2-3 mL, methylprednisolone (Pfizer Manufacturing Belgium NV, approval number: H20130301) 10 mg and ozone (40  $\mu$ g/mL) 3 mL into the ankle joint cavity once a week, a total of 4 times [10].

The patients in the study group were given drug injections in the ankle joint cavity combined with the massotherapy of TCM and rehabilitation exercise. The drug administration method was the same as that of the control group and massotherapy was performed once a day. The specific method is to take the patient in sitting position and place the affected limbs flat on bed, press Sanyinjiao, Shangqiu, Shuiquan, Kunlun and other acupoints around the ankles, use the method to loosen the tendons and muscles around the ankle, and to relax before subsequent exercise. Next, pull the ankle in extension position as much as possible and relax after 10-15 seconds, repeat for 10 times in total. Then pull the ankle in plantar flexion position as much as possible and relax after 10-15 seconds, repeat for 10 times in total.

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**Figure 1.** Comparison of symptoms and signs before and after treatment in two groups. Compared with the control group at the same time point, \*\* $P < 0.01$ ; compared with the same group before treatment, ## $P < 0.01$ . A: Pain score; B: Tenderness score; C: Swelling score; D: Dysfunction score.

Then pull the ankle in varus position as much as possible and relax after 10-15 seconds, repeat for 10 times in total. Then pull the ankle in ecstrophy position as much as possible and relax after 10-15 seconds, repeat for 10 times in total. Finally, rotate the ankle joint clockwise and counterclockwise for 10 times in total. Both groups were treated for one month.

### Observation indicators

**Main outcome indicators:** Comparison of symptoms and physical signs: Changes in pain, tenderness, swelling, dysfunction and other symptoms and physical signs before treatment and 1, 7, 14 and 28 days of treatment were observed, including local pain (0 point, no pain; 1 point, slight pain, but tolerable; 2 points, moderate pain, more pronounced; 3 points, severe pain), local tenderness (0 point, no pain under heavy pressure; 1 point, pain under heavy pressure, but without limb retraction; 2 points, pain under heavy pressure, with significant limb retraction; 3 points, pain under mild pressure, with significant limb retraction), swelling (0 points, no swelling; 1 point, slight swelling, skin

texture slightly shallow but identifiable; 2 points, moderate swelling, skin texture blurred; 3 points, severe swelling, skin texture disappeared, even with joint effusion) and dysfunction (0 point, no dysfunction; 1 point, mild dysfunction; 2 points, moderate dysfunction; 3 points, severe dysfunction) [11].

**Pain severity assessment:** Visual analogue scale (VAS) was used to assess the degree of pain and the pain was divided into 0-10 points, where 0 means no pain and the higher the score, the more severe the pain [12]. The 0 point in VAS represented no pain, 1 to 3 points represented mild pain, 4 to 6 points represented moderate pain, and 7 to 10 points represented severe pain.

The Kellgren and Lawrence classification under X-ray: a normal joint is grade 0; a suspicious stenosis of the joint space and a possible osteophyte in X-ray represent grade I; a suspicious stenosis of the joint space and an osteophyte in X-ray represent grade II; an explicit stenosis of the joint space with partial bone sclerosis, a moderate osteophyte, and suspect-

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**Table 2.** Comparison of pain scores in two groups in grade I-II of KLC (mean ± sd)

Group	n	Before treatment	After treatment	t value	P value
Study group	6	7.89±3.25	3.21±1.66	3.141	0.010
Control group	7	8.13±2.18	4.79±1.21	3.544	0.004
t value		0.159	1.983		
P value		0.877	0.073		

Note: KLC, the Kellgren and Lawrence classification under X-ray.

**Table 3.** Comparison of pain scores in two groups in grade III of KLC (mean ± sd)

Group	n	Before treatment	After treatment	t value	P value
Study group	11	7.37±3.29	3.15±1.82	3.723	0.001
Control group	10	7.32±3.17	4.95±1.22	2.206	0.041
t value		0.035	2.633		
P value		0.972	0.016		

Note: KLC, the Kellgren and Lawrence classification under X-ray.

ed malformation represent grade III; a huge osteophyte, explicit stenosis in joint space, severe bone sclerosis, and the presence of malformation represent grade IV [13].

Mazur's ankle function score: including joint pain, activity and pain, the score  $\geq 90$  was excellent, score of 80-89 was good, score of 60-79 was normal, and score  $\leq 59$  was poor, the good rate = (excellent + good)/24\*100% [14].

*Secondary indicators:* Quality of life assessment: 30 items from the EORTC QLQ-30 scale were used to measure the quality of life. Assessment items included cognition, role, emotions, social and physical, the higher the better [15].

### Statistical analysis

The data obtained in this study were analyzed using SPSS 19.0 statistical software. Measurement data were expressed as mean ± standard deviation (mean ± sd). The mean of the two groups was compared using two independent sample t-tests. The paired t test was used before and after the group intervention. The count data is represented by n, and the rate comparison is performed using the  $\chi^2$  test and Fisher's exact probability method. Rank variables used the rank-sum test, denoted by H. The mapping was done with Prism 6.0 software.  $P < 0.05$  is considered statistically significant.

## Results

### Comparison of general information

As shown in **Table 1**, there was no significant difference in general data such as sex composition, average age, mean course of disease, and KLC grading between the two groups (all  $P > 0.05$ ).

### Comparison of scores of symptoms and physical signs

As shown in **Figure 1**, there was no statistically significant difference in joint pain, tenderness, swelling, and dysfunction scores between the two groups ( $P > 0.05$ ) before treatment. One day after treatment, the pain, tenderness, swelling and dysfunction scores of the two groups were slightly lower than before treatment, but the difference was not statistically significant ( $P > 0.05$ ). On the 7th, 14th and 28th days of treatment, the scores of pain, tenderness, swelling and dysfunction in both groups were significantly lower than before treatment (all  $P < 0.01$ ), and the scores of the study group after treatment were significantly lower than those of the control group (all  $P < 0.01$ ).

### Comparison of pain scores in two groups in grade I-II of KLC

As shown in **Table 2**, there was no significant difference in the pain scores between the two groups before treatment ( $P > 0.05$ ). After treatment, both groups were significantly lower than before treatment (both  $P < 0.05$ ), but there was no significant difference in the KLC grade I-II pain score between the two groups ( $P > 0.05$ ).

### Comparison of pain scores in two groups in grade III of KLC

As shown in **Table 3**, there was no significant difference in the pain scores between the two groups before treatment ( $P > 0.05$ ). After treatment, both groups were significantly lower than before treatment (both  $P < 0.05$ ), and the pain scores in the study group were significantly lower than those in the control group ( $P < 0.05$ ).

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**Table 4.** Comparison of pain scores in two groups in grade IV of KLC (mean  $\pm$  sd)

Group	n	Before treatment	After treatment	t value	P value
Study group	7	7.21 $\pm$ 2.59	2.05 $\pm$ 1.53	4.538	0.001
Control group	7	7.34 $\pm$ 2.75	4.36 $\pm$ 2.07	2.291	0.041
t value		0.091	2.374		
P value		0.929	0.035		

Note: KLC, the Kellgren and Lawrence classification under X-ray.

**Table 5.** Comparison of Mazur's functional ankle score in two groups

Group	n	Excellent	Good	Medium	Poor	Good rate n, (%)
Study group	24	7	10	6	1	17 (70.83)
Control group	24	2	8	9	5	10 (41.67)
$\chi^2$ value						4.148
P value						0.042

### *Comparison of pain scores in two groups in grade IV of KLC*

As shown in **Table 4**, there was no significant difference in the pain scores between the two groups before treatment ( $P>0.05$ ). After treatment, both groups were significantly lower than before treatment (both  $P<0.05$ ), and the pain scores in the study group were significantly lower than those in the control group ( $P<0.05$ ).

### *Comparison of Mazur's functional ankle score in two groups*

As shown in **Table 5**, the good rate by Mazur's functional ankle score after treatment in the study group was 70.83%, which was significantly higher than that in the control group (41.67%), with statistical significance ( $P<0.05$ ).

### *Comparison of quality of life before and after treatment*

As shown in **Table 6**, there was no significant difference in the scores of the quality of life before treatment between the two groups (all  $P>0.05$ ). After treatment, the scores of the quality of life of the two groups were significantly higher (all  $P<0.05$ ), and the increase rate of the study group was significantly greater than that of the control group (all  $P<0.05$ ).

## Discussion

Ankle joint osteoarthritis is mainly seen in middle-aged and elderly people. The disease

can cause varying degrees of pain on the medial or lateral side of the ankle joint and joint dysfunction [16]. With the progression of the disease, serious deformities can be caused, and the symptoms are particularly significant during sitting and climbing movements, which seriously affect the quality of life of patients [17, 18]. The clinical examination shows abnormal flexion and extension of the diseased joints, dysfunction of the internal and external valgus, and tenderness. The X-rays shows abnormal joint space and osteophyte formation. Many clinical treatments such as conservative treatment, surgical treatment, etc. are commonly used [19-21].

Conservative treatment includes oral glucosamine, intra-articular injection of drugs and exercise, rehabilitation and physical therapy. In recent years, with the development of arthroscopic techniques, minimally invasive surgery has also been applied to the treatment of ankle joint osteoarthritis. However, several studies have shown that minimally invasive treatment and conservative treatment have no significant difference in the pain improvement and functional recovery of degenerative ankle joint osteoarthritis, and their therapeutic effects are quite similar [22, 23]. Therefore, conservative treatment including intra-articular drug injection is still an important treatment. Intra-articular injection of drugs allows the drug to act directly on the lesions, which can better reduce the level of inflammatory mediators in the joint cavity and achieve the protection of articular cartilage. The effect is relatively satisfactory [24]. Rehabilitation therapy can also significantly improve the patient's pain score and improve ankle function [25]. As a characteristic therapy of the traditional Chinese medicine, massotherapy has the effects of promoting blood circulation, sliding joints, and reducing swelling and pain. It has been reported that the use of traditional Chinese medicine combined with acupuncture and massage can improve the clinical symptoms of patients and reduce the content of matrix metalloproteinases MMP1 and MMP3 in synovial fluid [26]. Therefore, this study attempted to use the massotherapy of traditional Chinese medicine com-

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**Table 6.** Scores for each item in quality of life scores of two groups

Group	n		Emotions	Social	Cognition	Role	Physical
Study group	24	Pre	62.7±7.3	63.4±5.8	59.9±5.3	55.9±5.2	71.7±6.5
		Post	93.0±4.1*#	88.6±6.2*#	88.9±4.1*#	70.6±3.8*#	92.8±6.3*#
Control group	24	Pre	63.1±7.7	63.2±5.4	60.3±5.7	56.3±5.1	72.3±6.9
		Post	85.4±4.8*	75.9±5.9*	76.5±4.7*	63.9±4.4*	85.9±6.6*

Note: Intra-group comparison, \*P<0.05, compared with control group, #P<0.05, pre: pretreatment, post: post treatment.

bined with local drug injection in the treatment of ankle joint osteoarthritis, to observe its therapeutic value and provide reference for the treatment of this disease.

In this study, lidocaine, methylprednisolone, and ozone were injected into the joints. Lidocaine was used as an analgesic and anti-inflammatory agent to relieve joint pain [27]. Methylprednisolone is a glucocorticoid and its main role is to promote the dissipation of edema, accelerate the absorption of fluid in the joint cavity, and improve the state of tissue congestion, thereby reducing inflammatory substances and relieve pain [28, 29]. Ozone can inhibit the release of kinins in joints, reduce the production of inflammatory factors, thereby reducing pain. At the same time, it can increase the production and release of immunogenic agents, reduce the local immune response, improve the environment of the joint cavity, and promote repair and regeneration of joint [30, 31]. However, ankle joint osteoarthritis could also have the dislocation of the ankle joint space and joint disorder, and simple drug treatment cannot correct the disorder of the joint structure. According to the theory of "combining first with separation" of traditional Chinese medicine, this study used the massotherapy of traditional Chinese medicine, ankle joint traction, rotation and other rehabilitation movements to extend the medial or lateral ligaments and joint capsules of the ankle joint, and to correct the slight dislocation of the ankle joint and prevent scar adhesions and ligament injuries around the joint. At the same time, to stimulate the acupoints around the ankle joints, such as shuiquan, kunlun and other related meridians and collaterals, can play a role in promoting blood circulation, sliding joints and reducing pain, and improve treatment effects.

In this study, the patients in the study group were treated with intra-articular injection of drugs combined with the massotherapy of TCM. The results showed that the patients in the

study group had significantly lower scores for joint pain, tenderness, swelling, and dysfunction after treatment, which was better than the results in control group, suggesting that the intra-articular injection of drugs combined with the massotherapy of TCM can effectively relieve joint pain symptoms, reduce swelling, and promote joint function recovery. At the same time, the pain scores of all KLC grades in the study group were significantly decreased, and the degree of decline was better than that of the control group, suggesting that the pain relief effect of the study group was better. After treatment, the good rate of the Mazur's functional ankle score in the study group was 70.83%, which was significantly higher than that of the control group (41.67%), indicating that the study group had better ankle function improvement than the control group and further improved the patient's quality of life. Therefore, the ankle joint injection combined with the massotherapy of TCM can better promote the recovery of ankle joint function and improve the patient's quality of life for patients with ankle joint articular osteoarthritis. The therapeutic effect is better than the single injection of joint cavity. However, the small sample size in this study requires further studies with larger sample size.

In summary, ankle joint injection combined with the massotherapy of TCM can promote the recovery of ankle joint function and improve the patient's quality of life.

### Disclosure of conflict of interest

None.

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