Original Article

Clinical efficacy analysis of knee arthralgia external washing prescription combined with acupuncture in treating senile knee osteoarthritis

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Abstract: Objective: The aim of this study was to observe the clinical efficacy of Traditional Chinese Medicine (TCM) rehabilitation therapy in senile knee osteoarthritis (KOA). Methods: A total of 80 patients were divided into a control group and an observation group, according to the random digital table method, each group with 40 cases. The control group was given sodium hyaluronate treatment. The observation group was treated with a combination of knee arthralgia external washing prescription and TCM syndrome differentiation acupuncture treatment. Clinical efficacy and Lequesne comprehensive scores, before and after treatment, were compared between the two groups. Results: The effective rate in the observation group (95.0%) was significantly higher than in the control group (72.5%, P = 0.006). Lequesne scores in the two groups, after treatment, were lower than before treatment (both P<0.001) but the Lequesne score in the observation group was significantly lower than the control group (P<0.001). Conclusion: TCM rehabilitation therapy, including knee arthralgia external washing and TCM syndrome differentiation acupuncture treatment, is effective in the treatment of KOA, significantly improving clinical efficacy.

Keywords: Knee osteoarthritis, Traditional Chinese Medicine rehabilitation therapy, knee arthralgia external washing, acupuncture

Introduction

Knee joint disease is a common and frequently occurring disease among the elderly. Western medicine believes that it is mostly a degenerative disease, causing a series of pathological changes such as articular cartilage slippage, bone hyperplasia, meniscal injury, and synovitis [1]. Knee osteoarthritis (KOA) is an osteoarticular disease with cartilage degeneration of knee joint as core lesions. It involves the bone, synovial membrane, joint capsule, and periarticular structure adhesion, with aseptic inflammation. The main symptoms are joint pain and weight-bearing pain, etc. If not treated in time, it can cause joint swelling, fluid, and movement disorders, seriously affecting patient quality of life [2]. One study has shown that 50% of the population over the age of 60 have x-ray appearance of osteoarthritis, of which 35%-50% have clinical manifestations. Additionally, 80% over the age of 75 show symptoms of osteoarthritis [3].

Relieving symptoms using non-steroidal antiinflammatory drugs or sodium hyaluronate injections remains the main clinical treatment of KOA. However, non-steroidal anti-inflammatory drugs easily lead to gastric bleeding or gastric ulcers and sodium hyaluronate injection treatments requires a longer period, while the condition easily reoccurs [4, 5]. Traditional Chinese Medicine (TCM) believes that TCM rehabilitation therapy has a unique advantage [6]. TCM rehabilitation mainly includes external washing therapy and acupuncture treatment. These treatments have achieved good clinical results. For example, Yu et al. found that the knee arthralgia external washing method combined with sodium hyaluronate injections, in the treatment of KOA, is effective and significantly improves clinical symptoms of patients [7, 8]. Tu et al. found that the effects of warm acupuncture in the implementation of KOA treatment are affirmative, helping eliminate or reduce patient knee pain and improve knee joint function with a better long-term curative

effect [9, 10]. However, there remains a lack of relevant literature reporting on whether combination of the two therapies can be more effective for treatment of KOA.

Therefore, in this study, 40 cases of senile KOA were treated by knee arthralgia external washing method combined with TCM syndrome differentiation acupuncture. Clinical efficacy and Lequesne comprehensive scores, before and after treatment, of the two groups were compared.

Materials and methods

General information

A total of 80 patients with knee osteoarthritis, in Ezhou Central Hospital from January 2016 to June 2017, were selected as research subjects. According to the random number table, patients were divided into a control group and an observation group, with 40 cases in each group.

Inclusion criteria: 1) Consistent with diagnostic criteria of KOA in diagnosis and treatment of KOA, knee joint bone was fricative and joint activities could be heard; long duration of knee pain within the past 1 month; morning stiffness \leq 30 min; existence of osseous hypertrophy of knee joint [11]. Complying with 3 or more would be considered as KOA; 2) Aged 60 or above; and 3) Affected one side of knee joint.

Exclusion criteria: 1) Combined with rheumatism and rheumatoid arthritis, knee joint tumor, or bone tuberculosis and other diseases; 2) History of vascular or nerve injury of affected limb; 3) Stenosis of joint space or with a large number of osteophytes; and 4) Severe knee joint swelling or effusion.

The Ethics Committee of Ezhou Central Hospital approved this research and all patients provided informed consent.

Treatment methods

Control group: Sodium hyaluronate (2.5 mL/25 mg; Shandong Bausch & Lomb Freda Pharmaceutical Co., Ltd.) was given by intra-articular injection. Supine position was taken by patients. Knee injection sites were routinely disinfected with iodine and the effusion was cleaned. Patients were guided with joint activity

3 to 5 times after, intra articular of 2 mL sodium hyaluronate, in order to make injections distribute evenly. They were treated once a day for a total treatment of 4 weeks, as one course.

Observation group: On the basis of the control group, these patients received a combination of knee arthralgia external washing prescription medicine and TCM syndrome differentiation acupuncture treatment.

The knee arthralgia external washing prescription included salvia miltrorrhiza 30 g, safflower 15 g, eucommia 15 g, rhizoma cibotii 15 g, lycopodium clavatum 50 g, spatholobi caulis 30 g, haitongpi 30 g, acanthopanax bark 30 g, rhizoma corydalis 15 g, frankincense 15 g, myrrh 15 g, radix gentianae macrophyllae 10 g, saposhniovia root 10 g, and herba taxilli 12 g. The above medicines were set in a container and were added water to immerse for 1 hour. simmering it after boiling. Affected limbs were fumigated with hot air, then the affected area was rubbed, while keeping away from the wind and cold. The above steps were followed 2 times a day, for about 30 minutes each time, with 4 weeks for one course [7].

For acupuncture treatment, the main acupoints selected in the affected side were Ashi, Yanglingquan, Liangqiu, Xuehai, Weizhong, and inside and outside knee eyes. Qihai, Guanyuan, and Shenyu were added if patients suffered severe pain; Geyu was added to patients with wandering pain; Zusanli, Yinlingquan, and Piyu were added to patients with joint soreness. With a comfortable posture, acupoints area was fully exposed. Appropriate acupuncture needles (Hwato Brand) were used to straightly pierce the acupoints after routine disinfection. Moxibustion was applied on the acupoints of Ashi, Piyu, Shenyu, Guanyuan, Qihai, and Zusanli by 1.5-2.0 cm moxa stick warming acupunctures treatment after needling reaction appeared. Every treatment used 2-3 moxa sticks with needles retained for 15 minutes. These steps were followed once a day, for a total of 4 weeks as one course [12].

Observation indexes

Lequesne scores of the two groups, before and after treatment, were recorded. Scores were given the following 4 aspects, according to Lequesne KOA evaluation standards: any pain

Table 1. Comparison of general data in the two groups of patients ($\bar{\chi} \pm sd$)

Group	Case	Sex (male/female)	Mean age (year)	Mean course of disease (year)	Lequesne score (point)
Control group	40	22/18	66.61 ± 4.37	5.29 ± 1.20	7.93 ± 0.65
Observation group	40	21/19	65.41 ± 3.76	5.17 ± 1.14	7.81 ± 0.91
χ^2/t		0.050	1.316	0.458	1.427
Р		0.823	0.192	0.648	0.158

Table 2. Comparison of clinical efficacy of the two groups of patients

Group	Case	Cure	Improvement	Ineffectiveness	Effective rate (%)
Control group	40	11	18	11	72.5
Observation group	40	18	20	2	95.0
χ^2/t					7.440
Р					0.006

or discomfort while knee flexion, squatting, and kneeling down (0-2 points); any knee joint stiffness in the morning, its severity, and any improvement after exercise (0-2 points); maximum walking distance (0-2 points); and degrees of knee joint pain (0-2 points) [13, 14]. Higher scores indicated a more serious condition.

Assessment of therapeutic effects criteria

With reference to State Administration of Traditional Chinese Medicine *TCM Disease Diagnosis and Efficacy Standards*, therapeutic effects criteria were judged as follows: 1) Cured: swelling and pain of knee joint completely or basically disappeared and joint functional activities completely recovered; 2) Improvement: knee joint pain and swelling reduced and joint functional activities were significantly improved; and 3) Ineffectiveness: knee joint pain and swelling and joint functional activities didn't improve significantly or were aggravated [15]. Efficiency rate (%) = (cure + improvement)/n * 100%.

Statistical methods

SPSS 18.0 statistical software was used to analyze data. Measurement data are expressed as mean \pm standard deviation ($\overline{\chi}$ \pm sd) and t-tests were used for comparison. Counting data are expressed in terms of rate and were compared by χ^2 test. P<0.05 indicates a statistically significant difference.

Results

General information

In the observation group, there were 21 males and 19 females. Ages ranged from 61-78 years old with an average age of 65.41 \pm 3.76 years old. The course of the

disease was 2-7 years while the average course was 5.17 ± 1.14 years. Affected areas of left knee and right knee included 22 cases and 18 cases, respectively.

The control group consisted of 22 males and 18 females. Ages ranged from 60-76 years old with an average age of 66.61 ± 4.37 years old. The course of disease was 3-8 years while the average duration was 5.29 ± 1.20 years. Affected areas of left knee and right knee included 21 cases and 19 cases, respectively.

Differences in patient gender, age, course of disease, knee joint disease, pre-treatment Lequesne scores, and other general information between the two groups were not statistically significant (all P>0.05), but were comparable. See **Table 1**.

Comparison of clinical efficacy of the two groups of patients

Effective rate was 95.0% of the observation group and 72.5% of control group. Clinical efficacy of the two groups was statistically significant (P = 0.006). See **Table 2**.

Comparison of Lequesne scores between the two groups of patients, before and after treatment

Results showed that Lequesne scores of the two groups, after treatment, were lower than those before treatment (both P<0.001). There were no significant differences in Lequesne

Table 3. Comparison of Lequesne scores, before and after treatment, in the two groups of patients ($\overline{x} \pm sd$, score)

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Group	Cases	Before treatment	After treatment	t	P
Control group	40	7.93 ± 0.65	6.19 ± 0.61	13.05	<0.001
Observation group	40	7.81 ± 0.91	5.31 ± 0.58	15.86	<0.001
t		1.155	6.612		
P		0.252	< 0.001		

scores between the two groups before treatment (P = 0.252). After treatment, Lequesne scores of the observation group were significantly lower than the control group (P < 0.001). See **Table 3**.

Discussion

KOA belongs to the categories of "arthralgia" and "arthroncus" of the knee. TCM believes that KOA is related to chronic strain of the elderly resulting from liver-kidney deficiencies. Loss of liver and kidney function in the elderly causes liver blood deficiencies that are unable to support tendons. Tendon and bone relaxation levels are reduced as well as loss of joint lubrication. Kidney deficiency and medulary reduction results in bone malnutrition. Therefore, the main cause of this disease is the loss of liver and kidney function. Treatment should be carried out through tonics and nourishing the liver and kidneys, while promoting blood circulation and collaterals [16].

In the prescription of knee arthralgia external washing, salvia and safflower can promote blood circulation and remove blood stasis. It has the effect of "blood circulation is unobstructed and the pain disappears". Eucommia and Gouji can tonify the liver and kidneys, strengthen bones and muscles, clear water, and dispel wind and eliminate dampness; rhizoma corydalis, frankincense, and myrrh have the effect of activating of Qi and blood circulation and removing blood stasis; gentianae can dispel dampness, clear heat, and relieve arthralgia; herba taxilli can be used to expel wind and dampness, replenish liver and kidneys, and strengthen tendons and bones. Combination of various Chinese medicines provides the effects of expelling wind and cold, removing arthralgia, relaxing tendons and collaterals, and relieving pain [7, 8].

Concerning local acupoints selection, it is important to select acupoints by syndrome dif-

ferentiation in line with patent conditions. Among acupoints, Sanyinjiao, Yin Lingquan, and Xuehai be long to acupoints of the spleen meridian of Foot-Taiyin. Acupuncture of these 3 acupoints can activate meridians to stop

pain, strengthen the spleen, and replenish Qi; Zusanli and Lianggiu belong to acupoints of stomach meridian of Foot-Yangming. The combination of both has the function of supplementing the spleen and stomach and is also effective in treatment of pain. Yang Lingguan is the tendon of eight influential points which can nourish channels, promoting unobstructed meridians and collateral [17, 18]. Inside and outside the knee eyes are extraordinary points with significant effects in treating knee pain. Weizhong is the lower confluent acupoint of the urinary bladder, having a definite effect on pain of the lower extremities. In addition, together with Qihai and Guanyuan, moxibustion can boost body yang and expel cold. Combined with Mingmen, Shenshu, and Pishu, they can complement the spleen and kidneys and reduce joint pain and soreness and weakness of waist and knees. Together with Ashi, they can improve gi and blood circulation, remove stasis, and relieve pain. Combined usage of the above points can treat, both, the symptoms and root cause by clearing and activating channels and collaterals, tonifying the spleen and kidney, removing stasis, and relieving pain [19].

This present study showed that the effective rate of the observation group was 95.0%, while the control group was 72.5%. Differences were statistically significant (P = 0.006). Lequesne scores in both groups, after treatment, were lower than before treatment and Lequesne score of the observation group, after treatment, was significantly lower than the control group (P<0.001). This may be due to knee arthralgia external washing prescriptions used in the observation group combining a variety of traditional Chinese medicines that could improve peroxidase activity, prevents platelet aggregation, enhance immunity, and reduce inflammation and infection, thereby relieving muscle tension around the knee joint, softening and loosening the surrounding soft tissue adhesion and contracture, improving joint

mobility, and promoting cartilage and bone regeneration. In addition, these medicines can assist sodium hyaluronate in reducing the load of knee joints in order to restore stress balance, promote articular cartilage repair and exercise, and enhance the performance of muscles around the knee, thus, achieving the function of relaxing tendons, dredging collaterals, and relieving pain. These factors improve patient knee joint function and quality of life. Moreover, acupuncture has the effect of dredging the channels and collaterals, alleviating pain, thereby enhancing the efficiency of medication treatment [20]. Xiao's study results, regarding local injections of sodium hyaluronate and warm acupuncture treatment in 82 KOA patients, showed that after observation of KOA patient conditions, a reasonable choice of warm acupuncture treatment significantly improved knee joint function and knee pain [19].

In conclusion, TCM rehabilitation therapies such as knee arthralgia external washing prescription and TCM acupoints acupuncture treatment are reliable in the treatment of KOA, significantly improving clinical efficacy for patients. It can be widely applied in clinical work, especially at the grass-roots level. However, due to the limitations of a small sample size and lack of long-term follow up, this topic requires further study to verify treatment effects of TCM rehabilitation therapy on KOA.

Disclosure of conflict of interest

None.

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Efficacy analysis of knee arthralgia external washing combined with acupuncture

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