Clinical Observation on Curative Effect of Dissolving Phlegm-Stasis on 50 Cases of Knee Osteoarthritis

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Objective: To observe the curative effect of dissolving phlegm-stasis on knee osteoarthritis. Methods: The 100 patients with knee osteoarthritis were randomly divided into two groups. The 50 patients in the treatment group orally took Chinese medicine while the other 50 patients in the control groups orally took Votalin and Vitamin C for one week as a course of treatment. At the end of 2-week treatment, analytic comparison was carried in evaluate the curative effect and the changes in total score of symptoms before and after treatment between the two groups. Results: The total score of symptoms after treatment was significantly lower than that before treatment in both groups \((P<0.01, P<0.05)\). The total score after treatment of patients with X-ray grade I and II in the treatment group was more obviously reduced as compared to the control group \((P<0.05)\). The remarkably effective rate after treatment of patients with X-ray grade I and II in the treatment group was also higher than that in the control group \((P<0.05)\). Conclusion: The treatment of knee osteoarthritis with dissolving phlegm-stasis can effectively improve the clinical symptoms.

Key words: dissolving phlegm-stasis; osteoarthritis; knee joint; Chinese herbal therapy

In order to study the curative effect of dissolving phlegm-stasis on knee osteoarthritis, the authors observed 100 patients conforming to standards for diagnosis and inclusion in the hospital affiliated to Fujian University of Traditional Chinese Medicine from January to December of 2007. The research is reported as follows.

CLINICAL MATERIALS

General Data
The 100 patients with knee osteoarthritis were randomly divided into two groups. Of the 50 cases in the treatment group there were 23 males and 27 females aged 40–70, 52.46±9.86 on average, with illness course 1-28 months, 6.35±5.26 months on average, 13 cases of X-ray grade I, 27 cases of grade II and 10 cases of grade III, 27 cases with the type of damp affecting joint and 23 cases with the type of obstruction by phlegm and stasis. Of the 50 cases in the control group there were 24 males and 26 females aged 40-70, 53.16±10.05 on average, with illness course 0.7-27 months, 6.14±5.53 months on average, 14 cases of X-ray grade I, 27 cases of grade II and 9 cases of grade III, 26 cases with the type of damp affecting joint and 24 cases with the type of obstruction by phlegm and stasis. There was no statistical difference \((P>0.05)\) in age, sex, illness condition, illness course and X-ray grading between the two groups, hence comparability.

Standards for Diagnosis and Inclusion
1. Standard for diagnosis in Western medicine: In reference to the two standards put forward by American College of Rheumatology (ACR) for diagnosing knee osteoarthritis, patients must have either knee joint pain or osteophyte and at least one of the following 3 items: 1) patients are over 40 years old; 2) morning stiffness lasts less than 30 minutes and sound of bony friction can be heard; and 3)
patients have enlarged the tender bone and no obvious heat in joint. Whoever conforms to one of the two standards can be diagnosed.

2. Standard for diagnosis in traditional Chinese medicine: In reference to the standard for diagnosing knee osteoarthritis and dividing its types in the *Directing Principle for Clinical Research of New Chinese Drugs*, the type of damp affecting joint has the symptoms of swelling and accumulated liquid in joints with restricted motion, reddish or pale tongue, thin or thin greasy coating, slippery or taut pulse; and the type of obstruction by phlegm and stasis has the symptoms of thickened joint, lassitude with restricted motion, pale or pink tongue, thin or thin greasy coating, slippery or taut thready pulse.

3. Standard for X-ray grading: Grade 0 means normality, Grade I means that lip-like osteophyte can appear. Grade II means that noticeable osteophyte can narrow joint gap. Grade III means that moderate and multiple osteophyte can obviously narrow joint gap with bony sclerosis and wear. Grade IV means that large osteophyte can obviously narrow joint gap with serious bony sclerosis and obvious bony wear.

**Standard for Exclusion**

Patients are over 70 years old. Women are in pregnancy or lactation. Patients have medical record of medicinal allergy. Patients can not right now stop using other drugs they have taken for a long time. Patients have psoriasis, syphilitic neuropathy, ochronosis, metabolic osteopathy, acute trauma and other diseases affecting joint. Patients have cardiovascular disease, cerebrovascular disease and serious primary diseases of the liver, kidney or hematopoietic system. Patients have mental disease. Patients have been treated with other method which can influence the observation of indexes in this research. Patients give up treatment halfway. Patients are unwilling to objectively fill in indexes in this research.

**METHODS**

**Therapeutic Method**

Patients in the treatment group orally took Chinese medicine for resolving phlegm and removing damp. The recipe consisted of *Zhi Ban Xia* (制半夏 *Rhizoma Pinelliae*) 12g, *Zhi Dan Nan Xing* (制胆南星 *Arisaema cum Bile*) 12g, *Chuan Xiong* (川芎 *Rhizoma Chuanxiong*) 9g, *Dang Gui* (当归 *Radix Angelicae Sinensis*) 9g, *Ba Ji Tian* (巴戟天 *Radix Morindae Officinalis*) 12g, *Hang Bai Shao* (杭白芍 *Radix Paeoniae Alba*) 9g, *Cang Zhu* (苍术 *Rhizoma Atractylodis*) 6g, *Qiang Huo* (羌活 *Rhizoma Fructus Notopterygii*) 6g, *Du Huo* (独活 *Radix Angelicae Pubescentis*) 6g, *Yan Hu Suo* (延胡索 *Rhizoma Corydalis*) 6g, *Huang Qi* (黄芪 *Radix Astragali*) 6g, and *Huai Niu Xi* (怀牛膝 *Radix Achyranthis Bidentatae*) 9g. The decoction was orally taken twice a day, for 2 courses of treatment in succession with one week as a course and a 2-day interval between courses. Patients in the control group orally took Votalin tablet (produced by Beijing Nuohua Pharmaceutical Co. Ltd.) 25 mg each time and Vitamin C (produced by Southwest Pharmaceutical Co. Ltd.) 20 mg each time, 3 times a day, for 2 courses of treatment in succession with one week as a course and a 2-day interval between courses.

**Indexes for Observation**

In the light of reference, 1) Score 0 means no pain or no discomfort felt by the patient when lying in bed at night. Score 1 means pain felt by the patient in motion or in a certain position. Score 2 means pain felt by the patient without motion. 2) Score 0 means no morning stiffness or no aggravation of pain after the patient gets up. Score 1 means that morning stiffness lasts less than 3 minutes. Score 2 means that morning stiffness lasts 3 minutes or more. 3) Score 0 means no pain or no discomfort felt by the patient when walking. Score 1 means pain or discomfort felt by the patient when walking for some distance. Score 2 means pain felt by the patient as soon as he or she walks and pain aggravated after walking. 4) Score 0 means that the patient can stand up from a sitting position without help by hands. Score 1 means that the patient can stand up from a sitting position with help by hands. 5) Score 0 means that the patient can...
walk (perhaps with pain) unrestrictedly. Score 1 means that the patient can walk for more than 1000 m but with restriction. Score 2 means that the patient can walk for 300–1000 m. Score 3 means that the patient can walk for less than 300 m. 6) Score 0 means no lassitude in loin and knees. Score 1 means mild lassitude in loin and knees. Score 2 means severe lassitude in loin and knees. 7) Score 0 means no difficulty in daily activities (including going upstairs or downstairs, squatting, bending knee joints and walking on uneven road). Score 1 means difficulty in daily activities. Score 2 means that the patient can not make daily activities. 8) Score 0 means that the patient can carry out all kinds of activities. Score 1 means that the patient with inflexible joint function can conduct normal activities. Score 2 means that the patient with obviously restricted joint function can only take care of his own life and can not carry out general activities. Score 3 means that the patient with severely restricted joint function is unable to take care of his own life. 9) Mild illness condition means that the total score is 5 points or more. Moderate illness condition means the total score is 6–10 points. Severe illness condition means that the total score is more than 10 points. 10) X-ray examination.

Standard for Curative Effect

In reference to Lyshohn Rating Systems, according to patients’ subjective sensation and their knee joint function, the standard for curative effect is worked out as follows. Excellent curative effect means that symptoms disappear, function returns to normal, and the total score for illness condition is 0–2 points. Very good curative effect means that symptoms basically disappear, function basically returns to normal, the patient can take part in normal activities, and the total score for illness condition is declined by more than 2 / 3 points. Good curative effect means that pain basically vanishes, joint motion basically returns to normal, the patient’s ability to take part in activities is improved, and the total score for illness condition is declined by more than 1 / 3 points. Poor curative effect means that symptoms are not obviously alleviated.

Statistic Method

SPSS11.0 software is used for statistic processing. T test is used for measurement data. Data are expressed as average number ± standard difference (x ±s). χ² is used for count data.

RESULTS

Comparison of Changes in Total Score for Symptoms Before and After Treatment between the Two Groups

As shown in Table 1, there was no statistic difference (P>0.05) in the total score for symptoms before treatment of patients with the same X-ray grading between the two groups. The total score for symptoms obviously declined after treatment in both groups (P<0.01 or P<0.05). The total score for symptoms after treatment of patients with grade I and II declined in the treatment group more obviously than that in the control group (P<0.05).

Table 1. Comparison of Changes in Total Score for Symptoms before and after Treatment between the Two Groups (x ±s)

<table>
<thead>
<tr>
<th>Group</th>
<th>X-ray grading</th>
<th>Cases</th>
<th>Average total score before treatment</th>
<th>Average total score after treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Treatment group</td>
<td>Grade I</td>
<td>13</td>
<td>6.48±2.56</td>
<td>2.83±1.74**</td>
</tr>
<tr>
<td></td>
<td>Grade II</td>
<td>27</td>
<td>8.53±3.71</td>
<td>4.35±2.35**</td>
</tr>
<tr>
<td></td>
<td>Grade III</td>
<td>10</td>
<td>11.46±2.52</td>
<td>8.25±2.34**</td>
</tr>
<tr>
<td>Control group</td>
<td>Grade I</td>
<td>14</td>
<td>6.56±2.65</td>
<td>3.65±1.82**</td>
</tr>
<tr>
<td></td>
<td>Grade II</td>
<td>27</td>
<td>8.32±3.23</td>
<td>5.84±2.64**</td>
</tr>
<tr>
<td></td>
<td>Grade III</td>
<td>9</td>
<td>11.65±2.44</td>
<td>9.63±2.65*</td>
</tr>
</tbody>
</table>

Note: *P<0.05 and **P<0.01 as compared with the datum before treatment in the same group; *P<0.05 as compared with the datum after treatment in the control group.
Comparison of Curative Effect on Patients with X-ray Grading between the Two Groups

As shown in Table 2, the excellent and very good rate of the patients with grade I and grade II after treatment in the treatment group was higher than that in the control group (P<0.05). There was no statistic difference in effective rate between the two groups (P>0.05).

Table 2. Comparison of curative effect between the two groups

<table>
<thead>
<tr>
<th>Group</th>
<th>X-ray grading</th>
<th>Cases</th>
<th>Excellent (cases)</th>
<th>Very good (cases)</th>
<th>Good (cases)</th>
<th>Poor (cases)</th>
<th>Excellent and very good rate (%)</th>
<th>Effective rate (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Treatment</td>
<td>Grade I</td>
<td>13</td>
<td>8</td>
<td>3</td>
<td>1</td>
<td>1</td>
<td>84.62</td>
<td>92.31</td>
</tr>
<tr>
<td></td>
<td>Grade II</td>
<td>27</td>
<td>12</td>
<td>10</td>
<td>3</td>
<td>2</td>
<td>81.48</td>
<td>92.59</td>
</tr>
<tr>
<td></td>
<td>Grade III</td>
<td>10</td>
<td>0</td>
<td>5</td>
<td>2</td>
<td>3</td>
<td>50.00</td>
<td>70.00</td>
</tr>
<tr>
<td>Control</td>
<td>Grade I</td>
<td>14</td>
<td>6</td>
<td>2</td>
<td>5</td>
<td>1</td>
<td>57.14</td>
<td>92.86</td>
</tr>
<tr>
<td></td>
<td>Grade II</td>
<td>27</td>
<td>8</td>
<td>6</td>
<td>9</td>
<td>4</td>
<td>51.85</td>
<td>85.19</td>
</tr>
<tr>
<td></td>
<td>Grade III</td>
<td>9</td>
<td>0</td>
<td>4</td>
<td>3</td>
<td>2</td>
<td>44.44</td>
<td>77.78</td>
</tr>
</tbody>
</table>

Note: *P<0.05 as compared with the datum in the control group.

Comparison of Changes in X-ray on Patients Before and After Treatment between the Two Groups

X-ray manifestation on patients before and after treatment in the two groups was basically identical without obvious change, indicating that treatment with Chinese medicine for dissolving phlegm-stasis and with western medicine Votalin can effectively alleviate the symptoms of knee osteoarthritis but can not improve organic changes which have already taken place.

Adverse Reaction

No adverse reaction of the patients was found during experiment.

DISCUSSION

Osteoarthritis belongs to the category of Gu Bi (bone impediment) in TCM. TCM holds that the disease is based on deficiency of the liver and kidney and importantly linked to blood stasis, deficiency of the spleen and phlegm-damp. Knee osteoarthritis belongs to deficiency in origin and excess of phlegm and stasis in superficiality. Joint cartilage is mainly nourished by synovial fluid which belongs to the category of body fluid in TCM. However, phlegm is a pathological product in metabolism of body fluid. It can thus be conjectured that synovial fluid is inevitably related to phlegm.

It has been discovered during this research that most patients with knee osteoarthritis have fat figure, are fond of motion and have medical record of chronic strain for a long time. In fat old people, the spleen fails to transport, the liver and kidney gradually weaken, the retained water generates phlegm, which can stagnates in internal organs, muscles, bones, the skin and joints. Phlegm mainly originates from deficiency of the spleen and kidney. Deficiency of the kidney makes water accumulate into phlegm. Deficiency of the spleen enables water to retain in the body. Stagnated blood stasis can transform into phlegm. Stagnation of phlegm aggravates blood stasis. Therefore, phlegm is a pathological product and a pathogenic factor as well. It is said that “All diseases are caused by phlegm”. Modern medicine believes that osteoarthritis is a process of change in biomechanics, in which the interaction of biological factor and mechanical factor gives rise to the imbalance between degradation and synthesis of cartilage cells, extracellular matrix, and subchondral bone, thus causing damage to joint cartilage and making liquid accumulate in joints.

Therefore, the pathogenesis of the disease lies in stagnation of phlegm damp and blood stasis. The disease is mainly treated with dissolving phlegm and softening and resolving hard mass with promoting blood circulation to remove blood stasis and
nourishing and clearing collaterals as an auxiliary treatment. In the recipe, Zhi Ban Xia (制半夏 Rhizoma Pinelliae) and Zhi Dan Nan Xing (制胆南星 Arisaema cum Bile) act as monarch drugs to remove damp, dissolve phlegm, soften and resolve hard mass. Chuan Xiong (川芎 Rhizoma Chuanxiong) and Dang Gui (当归 Radix Angelicae Sinensis) act as ministerial drugs to promote blood circulation, remove blood stasis and clear collaterals. Ba Ji Tian (巴戟天 Radix Morindae Officinalis), Hang Bai Shao (杭白芍 Radix Paeoniae Alba), Cang Zhu (苍术 Rhizoma Atractylodis), Qiang Huo (羌活 Rhizoma seu Radix Notopterygii), Du Huo (独活 Radix Angelicae Pubescetis), Yan Hu Suo (延胡索 Rhizoma Corydalis) and Huang Qi (黄芪 Radix Astragali) act as adjuvant drugs to assist monarch drugs. Ba Ji Tian can nourish the kidney and strengthen the bone. Hang Bai Shao can reinforce blood, astringe yin, soothe the liver and stop pain. Cang Zhu can strengthen the spleen and remove dampness. Qiang Huo, Du Huo and Yan Hu Suo can dispel wind, clear collaterals and stop pain. Huang Qi can replenish qi and promote blood circulation. Huai Niu Xi (怀牛膝 Radix Achyranthis Bidentatae) acts as a conductant drug to strengthen the therapeutic effect. The recipe as a whole is mainly warm in nature because “Patients with phlegm should be treated with warm medicine,” and “Blood when heated can be circulated”. Therefore, the recipe can effectively alleviate pain in knee joints, eliminate swelling and improve the scope of motion. The result shows that treatment with dissolving phlegm can effectively alleviate symptoms and signs of patients with knee osteoarthritis, and that the curative effect of dissolving phlegm on patients with grade I and grade II knee osteoarthritis is better than that of Votalin.

This research has further confirmed the rationality of dissolving phlegm in the respect of improving clinical symptoms. The result is confined to near-term curative effect and the long-term curative effect is to be determined in further follow-up visits.

REFERENCES


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