Clinical Study on Treatment to Ankylosing Spondylitis with Fengshi Qutong Capsule-Diclofenac Sodium Combination

Haibin Wang¹, Ying Wang²*, Xin Tian³, Shizhang Liu¹, Le Ji¹

¹ Shaanxi Provincial People's Hospital, Xi’an 710068, Shaanxi Province, China
² The Fifth Hospital of Xi’an City, Xi’an 710082, Shaanxi Province, China

Abstract

Objective: To discuss the clinical study on Fengshi Qutong capsules combined with diclofenac sodium in the treatment of ankylosing spondylitis. Methods: 80 patients who were treated for ankylosing spondylitis from June 2019 to June 2020 were selected and divided into two groups. The experimental group was treated with Fengshi Qutong capsules combined with diclofenac sodium, and the control group was treated with sulfasalazine enteric-coated tablets. Results: The treatment efficacy, VAS score, BASDAI score, BASFI score, CRP level, TNF-α level, IL-β level, and the incidence of adverse reactions between the two groups were significantly different (P<0.05). Conclusion: The application of Fengshi Qutong capsules combined with diclofenac sodium in the treatment of patients with ankylosing spondylitis is beneficial to improve the treatment efficacy, reduce the levels of CRP, TNF-α, and IL-β, reduce the incidence of adverse reactions, and reduce the VAS, BASDAI and BASFI scores, rendering it of important clinical value.

Key words: Fengshi Qutong capsule; Diclofenac sodium; Ankylosing spondylitis

1 Introduction

Ankylosing spondylitis is a common rheumatic disease[1]. After the onset, symptoms such as joint pain and thoracolumbar stiffness will appear. As the disease worsens, the patient will develop spinal fibrosis and sacroiliac joint fibrosis. Symptoms of joint deformity and stiffness may occur in the late stage[2]. The Fengshi Qutong capsules combined with diclofenac sodium has better effects in its treatment, which has the effects of promoting blood circulation, removing blood stasis, dredging collaterals and relieving pain, and improving clinical symptoms[3]. In this paper, 80 patients who were treated for ankylosing spondylitis from June 2019 to June 2020 were selected. The specific report is as follows.

2 General information and methods

2.1 General information

80 patients who were treated for ankylosing spondylitis from June 2019 to June 2020 were selected. Among them, the experimental group: 20 males and 20 females. The age range / average age were: 38 to 72 years old, (45.72 ± 1.29) years old. Control group: 21 males and 19 females, the age range / average age were: 37 to 73 years, (46.88 ± 1.91) years old. This study was approved by the hospital ethics committee. Inclusion criteria: Patients diagnosed with ankylosing spondylitis ("Guidelines for the diagnosis and treatment of ankylosing spondylitis") were admitted. The patients agreed to participate after learning about the study.

2.2 Methods

The selected patients all required conventional treatment, mainly carried out pain relief, functional exercise, diet guidance, etc. In the control group, diclofenac sodium (National Medicine Zhunzi: H20000656; manufacturer: Hainan Puli Pharmaceutical Co., Ltd.) was used for the treatment, and it was taken orally, once a day, with 0.1 g
each time. Fengshi Qutong capsules combined with diclofenac sodium was administered in the experimental group, and the diclofenac sodium treatment method was the same as that of the control group. In the treatment with Fengshi Qutong Capsules, taken 3 times a day, 5 capsules each time, each capsule has 0.3 grams. Patients in both groups had to undergo 8 weeks of treatment.

### 2.3 Observation standards

The treatment efficacy, VAS score (Visual Analog Scale), BASDAI score (Bath Ankylosing Spondylitis Disease Activity Index), BASFI score (Bath Ankylosing Spondylitis Function Index), CRP (C-reactive protein) level, TNF-α (Tumor Necrosis Factor-α) level, IL-1β (Interleukin-1β) level, and the incidence of adverse reactions of the two groups were observed. Efficacy assessment criteria: markedly effective: After treatment, the patient's back and joint pain symptoms have basically disappeared, and the morning stiffness time has been significantly shortened, joint activity has been enhanced, and joint function improved. Effective: After treatment, the patient's back and joint pain symptoms are significantly improved, and the morning stiffness time is reduced, joint activity is enhanced, and joint function is improved. Ineffective: After treatment, the patient's clinical symptoms did not improve. The pain scoring was performed using Visual Analog Scale. There are a total of 10 points in the Bath Ankylosing Spondylitis Disease Activity Index, and the lower the score, the better the improvement of the condition. There are a total of 10 points in the Bath Ankylosing Spondylitis Function Index, and the lower the score, the better the improvement of the condition.

### 2.4 Statistical method

SPSS22.0 software was used to perform statistical analysis, measurement data, T-test; count data, chi-square test. P<0.05 indicates the difference is significant.

### 3 Results

#### 3.1 The status of treatment efficacy of the two groups

Comparing the treatment efficacy of the two groups, there was a big difference (P<0.05).

**Table 1. The status of treatment efficacy of the two groups**

<table>
<thead>
<tr>
<th>Group</th>
<th>No. of Cases</th>
<th>Markedly Effective</th>
<th>Effective</th>
<th>Ineffective</th>
<th>Total Efficacy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Experimental</td>
<td>40</td>
<td>31 (77.50%)</td>
<td>8 (20.00%)</td>
<td>1 (2.50%)</td>
<td>97.50%</td>
</tr>
<tr>
<td>Control</td>
<td>40</td>
<td>22 (55.00%)</td>
<td>10 (25.00%)</td>
<td>8 (20.00%)</td>
<td>80.00%</td>
</tr>
<tr>
<td>X2</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>13.634</td>
</tr>
<tr>
<td>P</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>&lt;0.05</td>
</tr>
</tbody>
</table>

#### 3.2 The status of VAS, BASDAI, and BASFI scores of the two groups before and after treatment

Compared with the pre-treatment VAS scores, BASDAI scores, and BASFI scores, the difference between the two groups was small (P>0.05). The VAS scores, BASDAI scores, and BASFI scores after treatment of the two groups were significantly different (P<0.05).

**Table 2. The status of VAS, BASDAI, and BASFI Scores of the two groups before and after treatment**

<table>
<thead>
<tr>
<th>Group</th>
<th>No. of Cases</th>
<th>Time</th>
<th>VAS Scores</th>
<th>BASDAI Scores</th>
<th>BASFI Scores</th>
</tr>
</thead>
<tbody>
<tr>
<td>Experimental</td>
<td>40</td>
<td>Before Treatment</td>
<td>6.48±1.26</td>
<td>6.07±1.05</td>
<td>5.98±1.12</td>
</tr>
<tr>
<td></td>
<td></td>
<td>After Treatment</td>
<td>1.85±0.78</td>
<td>1.95±0.66</td>
<td>1.75±0.88</td>
</tr>
<tr>
<td>Control</td>
<td>40</td>
<td>Before Treatment</td>
<td>6.49±1.66</td>
<td>5.98±0.57</td>
<td>6.02±1.52</td>
</tr>
<tr>
<td></td>
<td></td>
<td>After Treatment</td>
<td>3.08±1.85</td>
<td>3.05±0.66</td>
<td>2.88±0.66</td>
</tr>
</tbody>
</table>

#### 3.3 The status of CRP, TNF-α and IL-1β Levels of the two groups before and after treatment

The pre-treatment CRP levels, TNF-α levels, and IL-1β levels of the two groups had relatively small differences (P>0.05). The CRP levels, TNF-α levels, and IL-1β levels after treatment between the two groups were significantly different (P<0.05).

**Table 3. The status of CRP, TNF-α and IL-1β Levels of the two groups before and after treatment**
3.4 The status of incidence of adverse reactions of the two groups
In the control group, 5.00% of patients had dizziness, 7.50% of patients had elevated blood pressure, 12.50% of patients had constipation, and 7.50% of patients had abdominal pain; in the experimental group, 2.50% of patients had dizziness and 2.50% of patients had elevated blood pressure, 5.00% of patients had constipation, and 2.50% of patients had abdominal pain; the difference was large (P<0.05).

Table 4. The status of incidence of adverse reactions of the two groups

<table>
<thead>
<tr>
<th>Group</th>
<th>No. of Cases</th>
<th>Abdominal Pain</th>
<th>Constipation</th>
<th>Elevated Blood Pressure</th>
<th>Dizziness</th>
<th>Incidence (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Experimental</td>
<td>40</td>
<td>1 (2.50%)</td>
<td>2 (5.00%)</td>
<td>1 (2.50%)</td>
<td>1 (2.50%)</td>
<td>5 (12.50%)</td>
</tr>
<tr>
<td>Control</td>
<td>40</td>
<td>3 (7.50%)</td>
<td>5 (12.50%)</td>
<td>3 (7.50%)</td>
<td>2 (5.00%)</td>
<td>13 (32.50%)</td>
</tr>
</tbody>
</table>

Χ² 9.862
P <0. 05

4 Discussion
Ankylosing spondylitis is a common disease. After the onset, inflammation will affect cartilage joints, tendons, synovial joints, tendon ends, etc., which can lead to bony ankylosis and fibrosis[4]. If it cannot be treated in time, multiple complications are prone to occur, such as cervical subluxation, amyloidosis, etc[5]. In the application of the combination therapy of Fengshi Qutong capsules with diclofenac sodium, diclofenac sodium can improve limb pain and relieve inflammation[6]. The prescription of Fengshi Qutong Capsules mainly contains Cortex Phellodendri, Weilingxian, suberect Spatholobus stem, atracylodis rhizome, etc. The combination of multiple drugs can achieve the effects of dispelling numbness, dispelling wind, dredging collaterals, and replenishing qi and activating blood[7]. The combination of the two drugs can reduce inflammatory factors, inhibit the activation of macrophages, and improve the ability of the patient's body to scavenge oxygen free radicals.

In this paper, 80 patients who were treated for ankylosing spondylitis from June 2019 to June 2020 were selected. The treatment efficacy of patients who received Fengshi Qutong capsules combined with diclofenac sodium was significantly higher than that of patients who received sulfasalazine enteric-coated tablets. The experimental group patients’ VAS score, BASDAI score, BASFI score were lower, CRP level, TNF-α level, and IL-1β level were lower, and the incidence of adverse reactions was lower.

In summary, the administration of Fengshi Qutong capsules combined with diclofenac sodium treatment in patients with ankylosing spondylitis is beneficial to improve the treatment efficacy, reduce the level of CRP, TNF-α, IL-1β, reduce the incidence of adverse reactions, and reduce the VAS score, BASDAI score, BASFI score, therefore is worthy of clinical application and promotion.

References

