Observation of the clinical effect of the combined therapy of zushima tablet and western medicine in the treatment of rheumatoid arthritis and MRI test results

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Abstract: To evaluate the clinical efficacy of combined therapy of Zushima tablet and western medicine in treatment of rheumatoid arthritis and analyze the MRI test results. A total of 170 patients who had been treated for rheumatoid arthritis at our hospital from August 2016 and June 2018, were enrolled as research objects. They were randomly divided into control group and research group, with 85 patients in each group. The patients in the control group were treated with western medicine, while patients in the research group were treated with combined therapy of Zushima tablet and western medicine. The clinical efficacies of two groups were compared. Results showed that the overall effective rate of the research group was higher than that of the control group (p<0.05). Various clinical symptoms including joint swelling, joint tenderness, duration of morning stiffness for both groups before and after treatment were recorded, and results showed that the improvement of the research group was significantly better than that of the control group (p<0.05). Application of combined therapy of Zushima tablet and western medicine in treatment of rheumatoid arthritis could lead to favorable effects and improvement of the patients’ clinical symptoms.

Keywords: Zushima tablet, western medicine, rheumatoid arthritis, MRI.

INTRODUCTION

Rheumatoid arthritis (RA), as a systemic autoimmune disease, is primarily characterized by chronic aggressive arthritis. Synovitis is the pathological feature of RA, which could result in destruction of articular cartilage and bone, causing causes joint deformity (Nian, 2017; Zhang, 2015). If timely and effective treatments could not be carried out on RA patients, the chance of disability will be greatly increased. According to relevant data, RA is distributed in all parts of the world, with a prevalence rate being 0.18%-1.07% among different populations (Guo and Chen, 2016; Li Sun and Yu, 2016; Wroblewska et al., 2017). There are significant racial differences in the incidence of this disease, for instance the incidence of Indians is higher than that of Caucasians, and the incidence of Caucasians is higher than Yellow race. The total number of RA patients in China has exceeded 5 million. And it occurs in all ages and usually peaks in people with the age of 30-50 years old. Generally, the RA incidence of women is higher than that of men (Abdel et al., 2016; Alvi et al., 2018).

Rheumatoid arthritis (RA for short, as shown in fig. 1 below) is usually classified according to the urgency degree of onset or the affected area at onset. Occult, subacute and sudden onset. According to the number of affected joints at the time of onset, it can be divided into multi-joint, oligoarticular, single joint and extra-articular onset. At present, the cause of RA is still unclear, which is generally considered to be closely related to genetic, environmental, infectious factors. The quality of life and work of the RA patients could be seriously affected. Thus it is of great importance to adopt effective drug treatment to control the disease (Hazra et al., 2018; Tan and Huang, 2018). This study aims to evaluate the clinical efficacy of combined therapy of Zushima tablet and western medicine in treatment of rheumatoid arthritis, and the results are reported as follows.

MATERIALS AND METHODS

General design
A total of 170 RA patients who had been treated at our hospital (Haiyang People's Hospital) from August 2016 to June 2018 were enrolled as research objects. This paper has a rigorous structure, and the conclusion has been approved by relevant ethics and relevant departments. Inclusion criteria are as follow: all patients were definitely diagnosed as RA by relevant clinical examinations and met the classification and diagnostic criteria for rheumatoid arthritis proposed by American society of Rheumatology in 1987, as shown in fig. 2 below. The patients’ condition is active, suffering from joint swelling and pain for more than three months, and morning stiffness lasts for more than 15 minutes. The erythrocyte sedimentation rate of male patients is >20mm/1h, while
Observation of the clinical effect of the combined therapy of zushima tablet and western medicine in the treatment of female patients is >30mm/1h. And the joint function classification is class II-III. Exclusion criteria are as follow: Patients with severe cardiac, liver, kidney diseases and gastroduodenal ulcer disease or with a history of the above diseases. Patients with allergic constitution or with a history of drug allergies; pregnant women and lactating women; people with mental disorders (Ofori-Kwakye et al., 2016; Attari et al., 2016).

Fig. 1: Rheumatoid arthritis

Patients were randomized into research group and control group, with 85 patients in each group. There were 25 male patients and 60 female patients in the research group, with an average age of (40.3±8.5) years, ranging from 28 to 60. The average course of disease in the research group was (4.3±1.2) years, ranging from 3 months to 15 years. In contrast, there were 30 male patients and 55 female patients in the control group, with an average age of (41.8±7.2) years, ranging from 24 to 60. The average course of disease in the control group was (5.2±1.3) years, ranging from 2 months to 14 years. The difference in general data between the two groups was of no statistical significance (p>0.05). All patients and their families had the right to know and signed the informed consent. The study was approved by the hospital ethics association.

Method

The control group and research group were subjected to different treatment schemes. Patients in the control group were treated with western medicine, while patients in the research group were treated with combined therapy of Zushima tablet and western medicine.

The patients in the control group were instructed to take Naproxen sustained-release tablets at dosage of 75mg each time, once a day; to take prednisone at a dosage of 10mg each time for consecutive 2 months before changing to dosage of 5mg each time for one month; to take methotrexate at a dosage of 10mg each time, once a week; and to take sulfasalazine at a weekly dosage of 0.25mg, twice a day for one week, before increasing the dosage by 0.25mg/time per week, and reaching 1.0mg each time since the fifth week, twice a day. During the treatment period, corresponding symptomatic treatment and life guidance were also needed, including healthy diet, high-protein, high-calorie, digestible and light food, avoid eating cold and greasy food; preventing exposure to wind, rain, cold and moisture, keeping warm and conducting proper physical exercises to enhance the body's immunity and resistance (Qin et al., 2016) . On the basis of control group, the patients in the research group were treated with Zushima tablets (Shanhaiqian Pharmaceutical Factory, Qinhuangdao, Hebei Province) at a dosage of 3 tablets each time, three times a day, for consecutive 6 months. After treatment for 6 months for both groups, the patient's therapeutic efficacy of both groups was evaluated.

Fig. 2: The image of a patient with rheumatoid arthritis

Observation indexes

The joint swelling, joint tenderness, duration of morning stiffness for both groups before and after treatment were observed and recorded. The overall effective rates of both groups were compared. The improvement of clinical symptoms was calculated with corresponding formula (Nian, 2017; Ofori-Kwakye et al., 2016; Alvi et al., 2018). The overall efficacy can be divided into three categories, namely significantly effective, effective, and ineffective. Significantly effective treatment is defined when the clinical symptoms and experimental indicators are improved by 75% or more. The effective treatment is defined when clinical symptoms and experimental indicators are improved by 40%-75%. The ineffective treatment is defined when the clinical symptoms and experimental indicators are improved by less than 40%.

STATISTICAL ANALYSIS

Statistical analyses were performed using SPSS21.0. All quantitative data were expressed as mean ± standard variance (x ± s), using t test for inter group comparison. Enumeration data were expressed by natural number (n) and percentage (%), with chi-square test for inter group comparison.
RESULTS

Comparison of the overall effective rate between both groups
As shown in table 1, compared with the control group, the overall effective rate was significantly better in the research group (p<0.05).

Comparison of the changes in clinical symptoms between both groups before and after treatment
As shown in table 2, compared with the control group, the clinical symptoms of the research group were significantly improved after treatment (p<0.05).

Comparison of the MRI test between two groups
Magnetic resonance imaging (MRI) of patients with rheumatoid arthritis treated in this study is shown in fig. 3 below. The clinical manifestations of these patients were mostly joint swelling, which can be divided into single joint swelling and multi-joint swelling. There was foreign body exudation in the wrist joint, which was actually soft tissue swelling. At this time, the T2 signal was fuzzy. Fig. 4 is the image taken after treatment, which showed significant improvement.

DISCUSSION

Rheumatoid arthritis is a common autoimmune disease, and there is no unified understanding of the causes of this disease at present (Safi et al., 2015). Characterized by symmetric erosive synovitis, many RA patients would experience a chronic, progressive, and fluctuating disease process. Although treated, some progressive joint destruction, deformity, disability or even early death would still occur (Hu et al., 2015a; Hu et al., 2015b; Huang et al., 2015). Therefore, early diagnosis, selection of high-efficiency and low-toxic drugs and taking effective and reasonable regimens are the key to control the progress of RA.

There are many types of drugs in western medicine for the treatment of RA, including methotrexate, sulfasalazine, non-steroidal anti-inflammatory drugs, and low-dose prednisone. However, their therapeutic effect varies. The Zushima tablet has the functions of dispelling wind, eliminating dampness, relieving pain and dissipating blood stasis (Daolei et al., 2015; Sarfraz et al., 2016). Extracted from traditional Chinese medicinal herbs, there are two kinds of active ingredients in the Zushima tablet, namely the daphnetin and the Zushima saponin. As a pure Chinese medicine refined by modern technology, Zushima tablet tastes slightly bitter and is warm-natured.

Figure 3: Images of RA (left: joint effusion; right: edema in bone marrow).

Figure 4: Images of RA after treatment (left: Mild enhancement; right: Strong enhancement).

### Table 1: Comparison of the overall effective rate between both groups [n (%)]

<table>
<thead>
<tr>
<th>Group</th>
<th>Number of cases</th>
<th>Significantly effective</th>
<th>Effective</th>
<th>Ineffective</th>
<th>Overall effective rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Research group</td>
<td>85</td>
<td>50</td>
<td>33</td>
<td>2</td>
<td>83 (97.65)</td>
</tr>
<tr>
<td>Control group</td>
<td>85</td>
<td>30</td>
<td>41</td>
<td>14</td>
<td>71 (83.53)</td>
</tr>
<tr>
<td>t</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>6.52</td>
</tr>
<tr>
<td>p</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>&lt;0.05</td>
</tr>
</tbody>
</table>

### Table 2: Comparison of the changes in clinical symptoms between both groups before and after treatment (x±s)

<table>
<thead>
<tr>
<th>Group</th>
<th>Joint swelling (points)</th>
<th>Joint tenderness (points)</th>
<th>Duration of morning stiffness (min)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Before treatment</td>
<td>After treatment</td>
<td>Before treatment</td>
</tr>
<tr>
<td>Research group</td>
<td>14.29±5.10</td>
<td>8.05±6.21</td>
<td>14.20±6.02</td>
</tr>
<tr>
<td>(n=85)</td>
<td></td>
<td></td>
<td>8.33±7.92</td>
</tr>
<tr>
<td>Control group</td>
<td>13.28±5.24</td>
<td>10.29±4.26</td>
<td>14.38±5.28</td>
</tr>
<tr>
<td>(n=85)</td>
<td></td>
<td></td>
<td>11.20±8.94</td>
</tr>
<tr>
<td>t</td>
<td>0.29</td>
<td>9.03</td>
<td>0.34</td>
</tr>
<tr>
<td>p</td>
<td>&gt;0.05</td>
<td>&lt;0.05</td>
<td>&gt;0.05</td>
</tr>
</tbody>
</table>

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which can exert the effects of dispelling wind, eliminating dampness, relieving pain, dissipating blood stasis, warming spleen and stomach for dispelling cold, anti-inflammatory, analgesia as well as sedation. Clinical studies have shown that Zushima tablets have significant analgesic, anti-inflammatory and detumescence effects, thus producing favourable effects on the treatment of rheumatic immune system diseases.

By comparing the overall effective rates of two groups, results showed that the overall effective rate of the research group was higher than that of the control group (P<0.05). Moreover, the improvement of symptoms including joint swelling, joint tenderness, duration of morning stiffness in the research group was significantly better than that of the control group after treatment (p<0.05).

CONCLUSION
In conclusion, the combined therapy of Zushima and western medicine can achieve relatively ideal results in treatment of rheumatoid arthritis, timely improve the clinical indicators of patients, and improve their quality of life. Therefore, it is worth of being popularized and applied.

REFERENCES