

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

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[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-1 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-1 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

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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 \pm 1.29) years old. Control group: 21 males and 19 females, the age range / average age were: 37 to 73 years, (46.88 \pm 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-1 β (Interleukin-1 β) 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

Group	No. of Cases	Markedly Effective	Effective	Ineffective	Total Efficacy
Experimental	40	31 (77.50%)	8 (20.00%)	1 (2.50%)	97.50%
Control	40	22 (55.00%)	10 (25.00%)	8 (20.00%)	80.00%
X2					13.634
P					<0.05

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

Group	No. of Cases	Time	VAS Scores	BASDAI Scores	BASFI Scores
Experimental	40	Before Treatment	6.48 \pm 1.26	6.07 \pm 1.05	5.98 \pm 1.12
		After Treatment	1.85 \pm 0.78	1.95 \pm 0.66	1.75 \pm 0.88
Control	40	Before Treatment	6.49 \pm 1.66	5.98 \pm 0.57	6.02 \pm 1.52
		After Treatment	3.08 \pm 1.85	3.05 \pm 0.66	2.88 \pm 0.66

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

The pre-treatment CRP levels, TNF- α levels, and IL-1 β levels of the two groups had relatively small differences

($P > 0.05$). The CRP levels, TNF- α levels, and IL-1 β levels after treatment between the two groups were significantly different ($P < 0.05$).

Table 3. The status of CRP, TNF- α and IL-1 β Levels of the two groups before and after treatment

Group	No. of Cases	Time	CRP(mg/l)	TNF- α (ng/l)	IL-I β (pg/ml)
Experimental	40	Before Treatment	27.15 \pm 3.08	133.26 \pm 15.08	5.06 \pm 1.02
		After Treatment	13.18 \pm 3.16	69.33 \pm 12.25	2.11 \pm 0.95
Control	40	Before Treatment	27.55 \pm 3.51	135.98 \pm 16.28	4.99 \pm 1.45
		After Treatment	19.08 \pm 3.33	98.01 \pm 11.55	3.48 \pm 1.25

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

Group	No. of Cases	Abdominal Pain	Constipation	Elevated Blood Pressure	Dizziness	Incidence (%)
Experimental	40	1 (2.50%)	2 (5.00%)	1 (2.50%)	1 (2.50%)	5 (12.50%)
Control	40	3 (7.50%)	5 (12.50%)	3 (7.50%)	2 (5.00%)	13 (32.50%)
X ²						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, atractylodes 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-I β 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-I β , reduce the incidence of adverse reactions, and reduce the VAS score, BASDAI score, BASFI score, therefore is worthy of clinical application and promotion.

References

- [1] Hu D. Analysis on the efficacy of alendronate combined with diclofenac sodium meloxicam and calcium carbonate D3 in the treatment of ankylosing spondylitis [J]. Chinese Remedies & Clinics, 2020, 20(24):4110-4112.
- [2] Niu XY, Zhang XS. Effect of addition or subtraction of Simiaowan combined with diclofenac sodium enteric-coated capsules on symptoms and matrix metalloproteinase-9 level in patients with ankylosing spondylitis of damp-heat type [J]. International Medicine & Health Guidance News, 2020(04):542-545.
- [3] Luo L, Wu GH, Luo S, et al. Clinical Study on Fengshi qutong capsules combined with diclofenac sodium in the treatment of ankylosing spondylitis [J]. China Pharmaceuticals, 2019, 28(14):50-52.

- [4] Han ZJ. Clinical effect of tumor necrosis factor antagonist on refractory ankylosing spondylitis related hipjoint lesions [J]. Chinese Journal of Practical Medicine, 2018, 45(04):106-109.
- [5] Wang XG, Huang L, Lin Q et al. Therapeutic effect of Juanbi Tongluo Decoction combined with diclofenac sodium enteric-coated sustained-release capsules in the treatment of ankylosing spondylitis [J]. Shaanxi Journal of Traditional Chinese Medicine, 2017, 38(10):1435-1436.
- [6] Zhao CW, Wen H, Li ZH et al. Clinical observation of the effect of Zhuanggu Shenjin Formula on ankylosing spondylitis [J]. China Journal of Traditional Chinese Medicine and Pharmacy, 2016, 31(02):740-741.
- [7] Liu BH. The Clinical effect of bu-shen tong-pi tang combined with Western medicine in treatment of ankylosing spondylitis [J]. Journal of Practical Traditional Chinese Internal Medicine, 2015, 29(09):70-72.