Introduction

Ankylosing spondylitis (AS) is an autoimmune disease [1] and prototype of spondyloarthropathy [2], generally affecting patients from 16 to 40 years old. Ninety-five percent (95%) of the patients carry the HLA-B27 gene [3]. In Taiwan, the prevalence rate is about 0.2%. HLA-B27 negative patients were found to have higher positive HLA-B60 and B61 in Taiwan [4]. The disease mainly affects the spine, peripheral large
synovial joints, entheses [5], and surrounding soft tissues [6]. Limitations of spinal movement accompanied with morning stiffness are the typical clinical manifestations [3], due to sacroiliitis and spondylitis. About 40% of AS patients had peripheral arthritis involving hips and knee joints. Internal organs such as the heart [7-10], kidneys [3,11-13], and lungs [14-16] could also be affected in AS patients.

The therapies of AS include exercise, rehabilitation, non-steroid anti-inflammatory drugs (NSAIDs) [17], disease-modifying anti-rheumatic drugs (DMARDs) [18], local injection of corticosteroid, pamidronate [19], and anti-tumor necrosis factor-alpha (anti-TNFα) therapies [20-23]. Recently, two open-label trials of thalidomide for AS treatment showed some promising effects [24-26]. Nevertheless, even with NSAIDs or DMARDs therapies, the conditions of about 20% of patients are refractory and required TNF-α antagonist or other alternative therapy.

Traditional Chinese medicine (TCM) is a popular complementary medicine in Taiwan and China, and accounting for around 40% of all healthcare provided in China [27]. A large-scale epidemiology study revealed more than 60% of valid beneficiaries of the National Health Insurance in Taiwan had used TCM [28] and the number of patients was increasing [29]. Herbal remedies were the most commonly used form of TCM [28,29]. Musculoskeletal system problems were the second most reasons of TCM use. Several published clinical studies used TCM for AS [30-34] and rheumatoid arthritis [35-38]. Paeoniae Lactiflorae Radix [33], Angelicae Sinensis Radix, and Cinnamomi Ramulus [31] are the herbs commonly used in TCM formulae for AS treatment. One randomized controlled trial of combination therapy of herbs (Paeoniae Lactiflorae Radix extract) and sulfasalazine was conducted in 67 patients with AS [33], resulting in a significant improvement of pain in the combination therapy group, in comparison to the control group.

TCM, which has been used over thousands of years [27], has a unique theoretical and practical approach to the treatment of diseases. In Taiwan, there are five TCM regimens commonly prescribed by Traditional Chinese physicians to treat AS, according to literature review [39,40] and opinions from TCM physicians, such as: Dang Gui Lian Tong Tang (A), Yi I Ren Tang (B), Gui Zhi Shao Yao Zhi Mu Tang (C), Huang Qi Wu Wu Tang (D), and Qiang Huo Sheng Shi Tang (E). In order to find the TCM formula that has the most potential as an adjuvant for treating AS patients, we conducted a 3-month open pilot study. The most effective TCM formula would be selected for further double blind randomized controlled trial to prove their efficacy.

**Material and Methods**

This was a 3-month open pilot study conducted at a single medical center, the Chung Shan Medical University Hospital, Taichung, Taiwan. This study was approved by the Institutional Review Board (IRB) to perform the study. Written informed consent was obtained from every patient who participated in this study.

**Patients**

Eligible patients were aged 19~75 years old and fulfilled diagnostic criteria for AS, as specified by the 1984 Modified New York criteria for AS [41]. Those patients who matched the serum erythocyte sedimentation rate >10 mm/hour, Bath ankylosing spondylitis disease activity index (BASDAI) >3 points for at least 2 months, and without fulfilling the exclusion criteria, were enrolled. Patients should understand the study procedures and complete the study questionnaires by marking a visual analog scale (VAS) (0-100 mm). In addition, stable dosage of DMARDs (including sulfasalazine, methotrexate, hydroxychloroquine) for at least past 12 weeks was required for all the patients. It had to be no change in the dosage of glucocorticoids during the previous 6 weeks. Patients who received anti-TNFα therapies or joint surgery during the preceding 12 weeks were not enrolled. Supplements such as glucosamine, chondroitin, and methylsulfonylmethane (MSM) were prohibited. Acetaminophen could be used, but should be recorded for daily total amount. For patients who need of cardiovascular protection, aspirin used at daily doses of up to 300 mg was allowed. All blood samples were collected on the day of visit. Patients with creatinine clearance <30 mL/min, serum creatinine (Cr) >1.5 mg/dL, and/or alanine aminotransferase (sGPT) >40 IU/dL at screening, were also excluded. Active serious infections (patients requiring hospitalization and/or intravenous antibiotics) at screening, active tuberculosis by chest X ray or sputum analysis, hypersensitivity to any components of the study drugs, and/or cancer within the past 5 years were likewise excluded. Absolute contraception for female patients was needed during the study period.

**Medications**

All TCM formulae were prepared by Mintong
Traditional Chinese Medicine in AS

Pharmaceutical Limited Company which had received certification from the Australian government for Therapeutic Goods Administration (TGA), Good Manufacturing Practice (GMP) in 1998, and Current Good Manufacturing Practice (cGMP) in 2001 by the FDA of the United States of America. All TCM formulae were extracts of concentrated herb mixtures in powder.

A. Dang Gui Lian Tong Tang (當歸拈痛湯): *Angelicae Sinensis Radix* 2g, *Anemarrhenae Rhizoma* 1.5g, *Notopterygii Rhizoma* 2g, *Artemisiae Capillaris Herba* 2g, *Scutellariae Radix* 2g, *Atractylodis Rhizoma* 1.5g, *Polyporus* 1.5g, *Alismatis Rhizoma* 1.5g, *Atractylodis Rhizoma* 1g, *Saposhnikoviae Radix* 1.5g, *Pueraniae Radix* 1g, *Sophorae Radix* 1g, *Cimicifugae Rhizoma* 1g, and *Glycyrrhizae Radix* 1.5g

B. Yi I Ren Tang (薏苡仁湯): *Coicis Semen* 20g, *Angelicae Sinensis Radix* 3g, *Paeoniae Lactiflorae Radix* 3g, *Ephedra Herba* 1.5g, *Cinnamomi Ramulus* 1.5g, *Atractylodis Radix* 2g, and *Glycyrrhizae Radix* 1.5g

C. Gui Zhi Shao Yao Zhi Mu Tang (桂枝芍藥知母湯): *Cinnamomi Ramulus* 4g, *Paeoniae Lactiflorae Radix* 3g, *Glycyrrhizae Radix* 2g, *Ephedra sinica Stapf* 2g, *ginger* 5g, *Atractylodis Rhizoma* 3g, *Anemarrhenae Rhizoma* 4g, *Saposhnikoviae Radix* 4g, and *Aconiti Lateralis Preparata Radix* 2g

D. Huang Qi Wu Wu Tang (黃耆五物湯): *Astragali Radix* 5g, *Paeoniae Lactiflorae Radix* 5g, *Cinnamomi Ramulus* 5g, *ginger* 5g, and *Zizyphi Fructus* 5g

E. Qiang Huo Sheng Shi Tang (羌活勝濕湯): *Notopterygii Rhizoma* 7g, *Angelicae Tuhou Radix* 7g, *Artemisiae apiaceae herba* 3.5g, *Saposhnikoviae Radix* 3.5g, *Viticis Fructus* 2.0g, and *Ligustici Rhizoma* 3.5g, *Glycyrrhizae Radix* 3.5g

**Procedures**

After patients were enrolled, BASDAI, Bath ankylosing spondylitis functional index (BASFI), and Bath ankylosing spondylitis global index (BAS-G) were recorded at week 0, 4, 8, and 12. Laboratory tests such as complete blood count (CBC), sGPT, Cr, erythrocyte sedimentation rate (ESR), high sensitivity C-reactive protein (CRP), immunoglobulin A (IgA), and urinalysis were performed. Concomitant drugs were recorded. Each patient received one out of five TCM formulae according to their symptom patterns in TCM. A well-trained physician of TCM was involved in identifying the symptom patterns of the patients before they received additional TCM formula for 3 months.

**Outcome measurement**

The primary end point was the number of patients who fulfilled the ASAS-20 response criteria [22], which was defined as ≥20% improvement and an absolute improvement of ≥10 units on a VAS in 3 of the following 4 domains: (1) BASFI, (2) morning stiffness, (3) patient global assessment, and (4) pain. The secondary end points included BAS-G, BASDAI [42], ESR, CRP, and IgA. All adverse events and reasons for dropping out of this study were recorded.

**Statistical analysis**

The primary end point, numbers of patient fulfilling the ASAS-20 response criteria in each TCM formula, was analyzed by the intention-to-treat (ITT) principle. A TCM formula with an ITT result greater than 25% was considered to have potential. Comparison of results (BASFI, BASDAI, BAS-G, ESR, CRP, and IgA) of each TCM formula in week 0 and week 12 visits were analyzed by Wilcoxin Signed Rank Test. Statistical significance was set at a p value ≤ 0.05. Analyses were performed with the use of SPSS software, version 11.

<table>
<thead>
<tr>
<th>Table 1. ITT and PP analysis of 5 TCM formulae in AS</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Patients (n=34)</strong></td>
</tr>
<tr>
<td>A</td>
</tr>
<tr>
<td>B</td>
</tr>
<tr>
<td>C</td>
</tr>
<tr>
<td>D</td>
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<tr>
<td>E</td>
</tr>
</tbody>
</table>

Abbreviation: ITT = Intention to Treat, PP = per protocol, TCM = traditional Chinese medicine, AS = ankylosing spondylitis, ASAS-20 = 20% improvement in the Assessment in AS, A = Dang Gui Lian Tong Tang, B = Yi I Ren Tang, C = Gui Zhi Shao Yao Zhi Mu Tang, D = Huang Qi Wu Wu Tang, E = Qiang Huo Sheng Shi Tang

*Numbers of patients
*Numbers of patients fulfilled the ASAS criteria
Results

A total of 34 patients were enrolled, 6 for Dang Gui Lian Tong Tang (A; n=6), 4 for Yi I Ren Tang (B; n=4), 8 for Gui Zhi Shao Yao Zhi Mu Tang (C; n=8), 6 for Huang Qi Wu Wu Tang (D; n=6), and 10 for Qiang Huo Sheng Shi Tang (E; n=10) (Table 1). The age of patients was between 19 and 55 years old with a male to female ratio of about 5.4:1. Twenty-five patients (n=25) had completed the study and 9 patients dropped out. One patient dropped out from the Huang Qi Wu Wu Tang (D; n=1) and 2 patients each from of the 4 remaining TCM formulae (Table 1). These patients dropped out because of the loss of follow-up instead of lack of efficacy or severe adverse events, and no adverse events were reported after 4 weeks follow-up by telephone contact. Five adverse events were reported by 3 patients, one each from Gui Zhi Shao Yao Zhi Mu Tan (C), Huang Qi Wu Wu Tang (D), and Qiang Huo Sheng Shi Tang (E) groups. These patients were all male and aged from 40 to 44. Diuretic effect was the most common reported adverse event (n=2; one patient in each group C and D) and the others were fatigue (n=1; one patient in group C), weakness (n=1; one patient in group C), and itching over extremities with rash (n=1; one patient in group E). The itching with rash over extremities happened before the patient was enrolled. Results of each TCM formula are revealed as follows.

A. Dang Gui Lian Tong Tang: 6 patients were enrolled, 2 patients dropped out, and 4 patients completed the study. One patient had fulfilled the ASAS-20 response criteria, so the ITT and per protocol (PP) analysis was 16.66% and 25% respectively (Table 1). No adverse event was reported. No statistical differences in the average value of BASFI, BASDAI, BAS-G, ESR, CRP, and IgA were noted between week 0 and week 12 (Table 2).

B. Yi I Ren Tang: 4 patients were enrolled, 2 patients dropped out, and 2 patients completed the study. One patient had fulfilled the ASAS-20 response criteria, so the ITT and PP analysis was 25% and 50% respectively (Table 1). No adverse event was reported. The average value of BASFI, BASDAI, BAS-G, ESR, CRP, and IgA were shown in Table 3. No statistical differences of each parameter were noted between week 0 and week 12.

C. Gui Zhi Shao Yao Zhi Mu Tang: 8 patients were enrolled, 2 patients dropped out, and 6 patients completed the study. Two patients had fulfilled the ASAS-20 response criteria, so the ITT and PP analysis was 25% and 33.3%, respectively (Table 1). A patient reported fatigue, weakness, and diuretic effect. These adverse events were possibly related to the TCM formula and they were diminished after more daily water intake. The average value of BASFI, BASDAI, BAS-G, ESR, CRP, and IgA were shown in Table 4. No statistical differences of each parameter were noted between week 0 and week 12.

D. Huang Qi Wu Wu Tang: 6 patients were enrolled, 1 patient dropped out, and 5 patients completed the study.
study. Two patients had fulfilled ASAS-20 response criteria, so the ITT and PP analysis was 33.3% and 40%, respectively (Table 1). A patient reported a diuretic effect that was diminished after more daily water intake, which was possibly related to the TCM formula. The average value of BASFI, BASDAI, BAS-G, ESR, CRP, and IgA were shown in Table 5. No statistical differences of each parameter were noted between week 0 and week 12, except for the decrease of IgA (p=0.043).

E. *Qiang Huo Sheng Shi Tang*: 10 patients were enrolled, 2 patients dropped out, and 8 patients completed the study. Three patients had fulfilled ASAS-20 response criteria, so the ITT and PP analysis was 30% and 30.75% respectively (Table 1). A patient reported eczema with itching over extremities. Since a diagnosis of contact dermatitis had been made three years previously, this condition was unrelated to the study drug. There were improvements of the BAS-G (p=0.043), BASDAI (p=0.036), and CRP (p=0.050), but IgA was increased in this group (p=0.035) (Table 6). The changes in ESR and BASFI were insignificant.

**Discussions**

Multidisciplinary treatment of a disease, especially autoimmune disease, has become a common modality [43], including: exercises, physical therapies, and medications. Anti-TNFα drugs are now the most effective agents to treat AS. However, their high-cost and lack of long-term safety data were the issues that we needed to be aware of [44]. Although thalidomide was considered to have the inhibitory effects of TNFα [25] and was cheaper than other anti-TNFα drugs, a well designed and double-blind randomized controlled study was needed to better define the role of thalidomide in the treatment of AS. Therefore, we were urged to find a safe, effective, and much affordable complementary and alternative therapy for AS patients.

An epidemiology study of utilization patterns of Chinese medicine and Western medicine under the National Health Insurance Program in Taiwan (1997 to 2003) revealed that the number of TCM users increased every year [29] with a mean increment of 29.2% per year. The increment of female users was higher than male (female: male = 1.13:1) [28] and with a peak distribution of age around 30 years old. Central and Southern part of Taiwan had higher TCM utilization rate. In the study, the age of patients using TCM was younger than the western medicine (WM) group and patients with severe diseases more frequently used WM. This could be a problem in public health issues that some diseases were not well controlled in the beginning. Therefore, large-scale clinical studies of the efficacy and safety of TCM formulae were needed. An open pilot study of TCM is the first step.

TCM has been used for centuries since the time of our ancestors. There were several clinical trials that used TCM or as an add-on therapy in AS [30-34,36]. Cao et al, mentioned that long-term combination therapy of TCM and WM therapy, which has synergic effects, was a practical method in treating AS, with few adverse effects [30]. The identification of the patients’ symptom

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**Table 4. Clinical and laboratory parameters in Gui Zhi Shao Yao Zhi Mu Tang (C)**

<table>
<thead>
<tr>
<th>Weeks</th>
<th>0</th>
<th>4</th>
<th>8</th>
<th>12</th>
<th>Δ12-0</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>ESR</td>
<td>35.3 ± 18.5</td>
<td>36.8 ± 25.5</td>
<td>31.8 ± 15.8</td>
<td>29.2 ± 11.7</td>
<td>-6.2 ± 15.1</td>
<td>0.500</td>
</tr>
<tr>
<td>CRP</td>
<td>1.7 ± 1.9</td>
<td>2.2 ± 2.8</td>
<td>1.3 ± 1.3</td>
<td>1.0 ± 0.6</td>
<td>-0.7 ± 1.5</td>
<td>0.249</td>
</tr>
<tr>
<td>IgA</td>
<td>385.8 ± 134.1</td>
<td>396.8 ± 172.6</td>
<td>383.8 ± 147.5</td>
<td>394.0 ± 159.9</td>
<td>8.2 ± 30.8</td>
<td>0.463</td>
</tr>
<tr>
<td>BAS-G</td>
<td>3.8 ± 2.6</td>
<td>3.8 ± 1.9</td>
<td>2.6 ± 1.8</td>
<td>2.3 ± 1.7</td>
<td>-1.6 ± 2.6</td>
<td>0.249</td>
</tr>
<tr>
<td>BASDAI</td>
<td>4.4 ± 2.0</td>
<td>3.9 ± 1.7</td>
<td>2.7 ± 1.8</td>
<td>2.7 ± 2.0</td>
<td>-1.7 ± 2.4</td>
<td>0.173</td>
</tr>
<tr>
<td>BASFI</td>
<td>2.7 ± 2.6</td>
<td>2.8 ± 2.6</td>
<td>1.3 ± 1.1</td>
<td>1.3 ± 1.0</td>
<td>-1.4 ± 2.1</td>
<td>0.225</td>
</tr>
</tbody>
</table>

**Table 5. Clinical and laboratory parameters in Huang Qi Wu Wu Tang (D)**

<table>
<thead>
<tr>
<th>Weeks</th>
<th>0</th>
<th>4</th>
<th>8</th>
<th>12</th>
<th>Δ12-0</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>ESR</td>
<td>16.8 ± 12.1</td>
<td>16.2 ± 8.0</td>
<td>14.4 ± 5.4</td>
<td>12.0 ± 10.2</td>
<td>-4.8 ± 7.7</td>
<td>0.225</td>
</tr>
<tr>
<td>CRP</td>
<td>0.6 ± 0.6</td>
<td>0.6 ± 0.7</td>
<td>0.7 ± 0.9</td>
<td>0.4 ± 0.2</td>
<td>-0.21 ± 0.48</td>
<td>0.465</td>
</tr>
<tr>
<td>IgA</td>
<td>505.2 ± 320.0</td>
<td>484.8 ± 317.0</td>
<td>476.4 ± 326.9</td>
<td>469.4 ± 320.7</td>
<td>-35.8 ± 27.1</td>
<td>0.043*</td>
</tr>
<tr>
<td>BAS-G</td>
<td>5.8 ± 3.1</td>
<td>5.0 ± 3.2</td>
<td>4.9 ± 2.9</td>
<td>5.1 ± 2.9</td>
<td>-0.7 ± 2.1</td>
<td>0.500</td>
</tr>
<tr>
<td>BASDAI</td>
<td>5.4 ± 3.0</td>
<td>4.1 ± 3.3</td>
<td>4.4 ± 2.8</td>
<td>4.4 ± 2.6</td>
<td>-1.1 ± 1.1</td>
<td>0.080</td>
</tr>
<tr>
<td>BASFI</td>
<td>4.1 ± 2.5</td>
<td>3.5 ± 2.2</td>
<td>3.8 ± 2.8</td>
<td>4.2 ± 2.6</td>
<td>0.1 ± 0.7</td>
<td>0.893</td>
</tr>
</tbody>
</table>

*p<0.05
patterns in TCM was not mentioned in these studies; however, the identification of symptom patterns in TCM, as a daily practice of a TCM physician, should not be ignored. If a patient had no response to a TCM formula prescribed under such rule, doubtless, there was a lack of therapeutic effect. In our study, three symptoms patterns were identified by a TCM physician. The Dang Gui Lian Tong Tang (A) and Gui Zhi Shao Yao Zhi Mu Tang (C) were suitable for patients of “damp-heat and blood stagnation” (濕熱瘀毒型) phenotypes. Yi I Ren Tang (B) and Qiang Huo Sheng Shi Tang (E) were suitable for patients of “damp-cold and blood stagnation” (寒濕瘀阻型) phenotypes. Huang Qi Wu Wu Tang (D) was suitable for patients of “liver and renal Ying deficiency” (肝腎陰虛型) phenotypes.

In our study, Huang Qi Wu Wu Tang (D) (ITT = 33.3%, PP = 40%), and Qiang Huo Sheng Shi Tang (E) (ITT = 30%, PP = 37.5%) were considered to have potential as an adjuvant in treating AS patients. Usually, the placebo effects amounted to about 20% in clinical studies. The Yi I Ren Tang (B) had ITT of 25%, but it was not considered as signifying potential because only 2 patients had completed the study and its power was deemed to be too weak.

The Huang Qi Wu Wu Tang (D) is a TCM formula that includes: Astragali Radix, Paeoniae Lactiflorae Radix, Cinnamomi Ramulus, Ginger, and Zizyphi Fructus [39]. The biological actions of these ingredients were revealed in several studies, such as: inhibition of lymphocyte migration via down-regulating metalloproteinase activity by Notopterygium Rhizoma [49], inhibition of osteoclast formation by Angelicae Tuhou Radix [50], anti-oxidant activities by Artemisiae apioaceae herba [51], and anti-nociceptive effects of Vitici Fructus [52]. As a result, the improvement of the BAS-G (p=0.043), BASDAl (p=0.036), and CRP (p=0.050) with the Qiang Huo Sheng Shi Tang (E) was encouraging. The daily functional status (BASFI = 1.8 ± 1.5) was less affected in this group in comparison to the others. No TCM formula revealed a decrease of serum ESR that was statistical significant in our study. The serum ESR usually takes more time to decrease in regard to chronic inflammatory status. The TCM formula, Qiang Huo Sheng Shi Tang (E), was considered effective as an adjuvant therapy for patients with milder disease activity (BASDAI ≤4) and less functional impairment.

No severe adverse events were observed in this study. No patient dropped out because of adverse events or lack of efficacy according to our records. Nine patients dropped out at the second and third visit because of inconvenience of monthly visits and questionnaire filling, which was time consuming to them. Diuretic effect was the most reported adverse event in the Gui Zhi Shao Yao Zhi Mu Tang (C) and Huang Qi Wu Wu Tang (D) groups, which implied the possible diuretic effect of these 2 TCM formulae. The diuretic effect of Huang Qi Wu Wu Tang (D) was probably related to the lower CRP and IgA. The chronic irreversible mechanical damages to the spine with only mild inflammatory status, compared to the other groups, could be the underlying reason. The decrease of IgA was probably related to the anti-microbial effects of Cinnamomum Ramulus [47] in the bowels.

The Qiang Huo Sheng Shi Tang (E) is a TCM formula that includes: Notopterygii Rhizoma, Angelicae Tuhou Radix, Artemisiae apioaceae herba, Saposhinkoviae Radix, Vitici Fructus, Liquistici Rhizoma, and Glycyrrhize Radix. The biological actions of these ingredients were revealed in several studies, such as: inhibition of lymphocyte migration via down-regulating metalloproteinase activity by Notopterygium Rhizoma [49], inhibition of osteoclast formation by Angelicae Tuhou Radix [50], anti-oxidant activities by Artemisiae apioaceae herba [51], and anti-nociceptive effects of Vitici Fructus [52]. As a result, the improvement of the BAS-G (p=0.043), BASDAl (p=0.036), and CRP (p=0.050) with the Qiang Huo Sheng Shi Tang (E) was encouraging. The daily functional status (BASFI = 1.8 ± 1.5) was less affected in this group in comparison to the others. No TCM formula revealed a decrease of serum ESR that was statistical significant in our study. The serum ESR usually takes more time to decrease in regard to chronic inflammatory status. The TCM formula, Qiang Huo Sheng Shi Tang (E), was considered effective as an adjuvant therapy for patients with milder disease activity (BASDAI ≤4) and less functional impairment.

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natriuresis effect of Astragali Radix [53]. Serum IgA was significantly increased in the Qiang Huo Sheng Shi Tang (E) group (p=0.0467), for an unknown reason.

In conclusion, all TCM formulae were safe in this 12-week open pilot clinical trial. In this study, Qiang Huo Sheng Shi Tang (E) was considered to have potential as adjuvant therapy of AS. However, a large-scale double blind randomized controlled trial is needed to prove their efficacy and long-term safety.

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57
僵直性脊椎炎之中藥方劑輔助治療之先導性試驗

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僵直性脊椎炎，是一種慢性自體免疫疾病。僵直性脊椎炎的西藥治療因為其藥物順從性、副作用及抗腫瘤壞死因子的昂貴價格，使得部份病人的治療效果，仍未能令人滿意。中藥已有數千年的歷史，國人接受度也高，其中必定有其潛力。為了找出可能具有輔助治療潛力的中藥方劑，我們將34例活性期的僵直性脊椎炎病人，在原本治療之藥物維持3個月不變的條件下，依中醫症型分型後，加上濃縮科學中藥方劑，進行此僵直性脊椎炎中藥方劑輔助治療之先導性試驗。本先導性試驗使用了五種中藥方劑，包括當歸拈痛湯、薏苡仁湯、桂枝芍藥知母湯、黃耆五物湯和羌活勝濕湯。三個月後依ASAS 20 response criteria，病人臨床BASDAI, BASFI, BAS-G量表及血清活性指標 (E.S.R, CRP,和IgA)，來評估其效果。中藥方劑輔助治療之效果以意圖治療分析法 (Intention-To-Treat) 分析。結果顯示「黃耆五物湯」組中進入試驗者6人，退出試驗者1人，有效人數為2人。「羌活勝濕湯」組中進入試驗者10人，退出試驗者2人，有效人數為3人。沒有病人因為嚴重副作用或不良反應而退出。本研究中，羌活勝濕湯或許是具輔助治療潛力的中藥方劑，但是必須逐一再以較大規模之隨機雙盲試驗去證實其有效性。

關鍵詞：先導性試驗，中藥，輔助療法，僵直性脊椎炎。