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Clinical Efficacy and Mechanism Exploration of Rougan Jianpi Decoction in Treating IBS-D with Liver Depression and Spleen Deficiency Syndrome

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Abstract: ***Objective: To observe the clinical efficacy and therapeutic mechanism of Rougan Jianpi Decoction in the treatment of IBS-D with liver depression and spleen deficiency type. Methods: A total of 120 patients with IBS-D who visited the Gastroenterology Department of Xi'an Affiliated Hospital of Shaanxi University of Chinese Medicine from August 2022 to September 2024 were selected as the research subjects. They were randomly divided into the experimental group and the control group. The control group was treated with pirenzepine tablets combined with Clostridium pasteurianum live bacteria tablets; The experimental group was treated with the Rougan Jianpi Decoction. After 4 weeks of treatment, the clinical efficacy, TCM syndrome scores, anxiety level, depression level, serum NPY level, inflammatory factor level, and adverse reaction occurrence of the two groups were compared. Results: The total effective rate of the experimental group (89.66%) was higher than that of the control group (78.95%) (P < 0.05); the reduction level of TCM syndrome scores in the experimental group was higher than that in the control group (P < 0.05); the reduction levels of Hamilton Anxiety Scale (HAMA) score and Hamilton Depression Scale (HAMD) score in the experimental group were higher than those in the control group (P < 0.05); the increase level of serum NPY in the experimental group was higher than that in the control group (P < 0.05); the decrease level of serum inflammatory factors in the experimental group was higher than that in the control group (P < 0.05); there was no statistically significant difference in the occurrence of adverse reactions between the two groups (P > 0.05). Conclusion: Rougan Jianpi Decoction can significantly improve the clinical symptoms of IBS-D patients with liver depression and spleen deficiency type. Its mechanism of action may be related to regulating the brain-gut axis function of patients and reducing the inflammatory response of the body.***

Keywords: Rougan Jianpi Decoction, Liver depression and spleen deficiency, IBS-D, NPY, IL-6, IL-8, TNF-α.

1. Introduction

Irritable bowel syndrome (IBS) is a disorder characterized by abdominal pain accompanied by changes in bowel habits, and the results of colonoscopy indicate no organic lesions, presenting as a disorder of intestinal function [1]; among them, diarrhea-predominant IBS (IBS-D) is the most common type, accounting for more than 45% of all IBS cases [2]. Currently, the pathogenesis of IBS-D has not been fully elucidated. With the development of medicine, it has been found that the occurrence and development of IBS-D are closely related to the dysfunction of the brain-gut axis and chronic inflammation of the intestine [3-4]. In terms of treatment, most cases are treated based on the symptoms of patients with measures such as stopping diarrhea and promoting gastrointestinal motility. Due to the long course and persistence of this disease, and in recent years, with increased work pressure, changes in lifestyle and dietary habits, and accelerated pace of life, the incidence and number of visits for IBS-D have been increasing year by year, not only seriously affecting the daily life and work of patients, but also increasing the medical expenses of families and society to a certain extent [5-6]. Traditional Chinese medicine can classify IBS-D under categories such as "abdominal pain" and "diarrhea", and its core pathogenesis is liver depression and spleen deficiency [7]. Under the overall view of traditional Chinese medicine, by soothing the liver and strengthening the spleen, promoting yang and stopping diarrhea, the body can reach a state of "yin and yang in balance". Professor Qiao Huixia, the chief physician, has clinically formulated the Rougan Jianpi Decoction to treat IBS-D of the type with liver depression and spleen deficiency, and has achieved satisfactory therapeutic effects. However, the treatment mechanism of this formula for IBS-D is unclear, so this study aims to explore the clinical efficacy and mechanism of action of Rougan Jianpi Decoction in treating IBS-D of the type with liver depression and spleen deficiency. The research plan is detailed as follows.

2. Objectives and Methods

2.1 Research Subjects

The research subjects were selected from patients with liver qi stagnation and spleen deficiency type IBS-D who visited the Gastroenterology Department Outpatient Clinic of Xi'an Affiliated Hospital of Shaanxi University of Chinese Medicine from August 2022 to September 2024. A total of 120 cases were included. They were randomly divided into the control group and the experimental group, with 62 cases in each group. In the end, there were 57 cases in the control group (2 cases dropped out due to no follow-up and 1 case due to non-compliance with medication); 58 cases in the experimental group (1 case dropped out due to non-compliance with medication and 1 case due to no follow-up). There was no significant difference in the general data between the two groups (P > 0.05), and they were comparable. See Table 1. This study was approved by the Ethics Committee of Xi'an Hospital of Traditional Chinese Medicine (Approval Number: LLSCPJ2022086).

Table 1: Comparison of General Information

Group	Gender (cases)		Age	Disease duration
	Male	Female	($\bar{x} \pm s$, Years)	($\bar{x} \pm s$, Months)
Control group	30	27	39.21±11.99	17.54±1.10

(n=57)				
Experimental group (n=58)	27	31	42.22±13.43	17.34±1.12
Statistical value	$\chi2$=0.425		t=-1.269	0.961
P	0.514		0.207	0.338

2.2 Inclusion Criteria

(1) Meets the diagnostic criteria for IBS as defined by the American Gastroenterological Association (ACG) [8] or the Chinese Medical Association [9], and also conforms to the IBS-D classification criteria in the Rome IV [10]; (2) Meets the diagnosis of liver qi stagnation and spleen deficiency syndrome as stipulated in the "Expert Consensus on Traditional Chinese Medicine Diagnosis and Treatment of Irritable Bowel Syndrome (2017)" [11]; (3) Age 18-75 years old; (4) Good compliance; (5) Voluntarily participates in this trial and signs the informed consent form.

2.3 Exclusion Criteria

(1) Received drug treatment for IBS-D within 2 weeks prior to inclusion; (2) Liver and kidney function indicators exceed the upper limit of normal values by more than twice; (3) Has a clear history of abdominal surgery; (4) Has metabolic or endocrine system diseases, such as diabetes, hyperthyroidism, etc.; (5) Is in a special physiological stage such as pregnancy, lactation, or within 12 months postpartum; (6) Is participating in other research projects.

2.4 Treatment Methods

Control group: Treated with pirenzepine tablets combined with Clostridium sporogenes live bacteria tablets for 4 weeks. Pirenzepine tablets (Beijing Fuyuan Pharmaceutical Co., Ltd., specification: 50mg/tablet, National Drug Approval Number H20133036), taken orally, 3 times/day, 50mg/time; Clostridium sporogenes live bacteria tablets (Qingdao Donghai Pharmaceutical Co., Ltd., specification: 350mg/tablet, National Drug Approval Number S20050032), taken orally, 3 times/day, 1050mg/time.

Experimental group: Treated with Rougan Jianpi Decoction for 4 consecutive weeks. Prescription: Stir-fried White Peony Root (Baishao, Paeoniae Radix Alba) 15g, Stir-fried Largehead Atractylodes Rhizome (Baizhu, Atractylodis Macrocephalae Rhizoma) 15g, Dried Tangerine Peel (Chenpi, Citri Reticulatae Pericarpium) 12g, Divaricate Saposhnikovia Root (Fangfeng, Saposhnikoviae Radix) 10g, Pilose Asiabell Root (Dangshen, Codonopsis Radix) 15g, Indian Bread (Fuling, Poria) 30g, Villous Amomum Fruit (Sharen, Amomi Fructus) 6g, Stir-fried Coix Seed (Yiyiren, Coicis Semen) 30g, Hyacinth Bean (Biandou, Lablab Semen Album) 10g, Stir-fried Common Yam Rhizome (Shanyao, Dioscoreae Rhizoma) 15g, Raw Liquorice Root (Gancao, Glycyrrhizae Radix et Rhizoma) 6g, Mongolian Milkvetch Root (Huangqi, Astragali Radix) 15g, Cimicifuga Rhizome (Shengma, Cimicifugae Rhizoma) 10g, Golden Thread (Huanglian, Coptidis Rhizoma) 3g, Fennel (Xiaohuixiang, Foeniculi Fructus) 10g, Gordon Euryale Seed (Qianshi, Euryales Semen) 15g, Medicine Terminalia Fruit (Hezi, Chebulae Fructus) 15g. Boil with water until 400mL. Take in two warm doses before each meal in the morning and evening.

2.5 Observation Indicators

2.5.1 Clinical Efficacy

The efficacy evaluation is based on the "Clinical Disease Diagnosis and Efficacy Judgment Criteria" [12], and is assessed through the Efficacy Index (EI); EI = (pre-treatment score - post-treatment score) / pre-treatment score × 100%. The efficacy grading standards are as follows:

Recovery: Symptoms and signs basically disappear, EI ≥ 95%;

Marked Improvement: Symptoms and signs significantly improve, 70% ≤ EI < 95%;

Effective: Symptoms and signs improve slightly, 30% ≤ EI < 70%;

Ineffective: Symptoms and signs do not improve or even worsen, EI < 30%.

The total effective rate = (number of recovery cases + number of marked improvement cases + number of effective cases) / total number of cases × 100%.

2.5.2 TCM Syndrome Score

The scoring criteria are formulated according to the "Expert Consensus Opinion on TCM Diagnosis and Treatment of Irritable Bowel Syndrome (2017)" [11]. The syndrome scores of patients before and after treatment are evaluated. The main symptom scoring standard: normal (0 points), mild (2 points), moderate (4 points), severe (6 points); secondary symptom scoring standard: normal (0 points), mild (1 point), moderate (2 points), severe (3 points); tongue and pulse are used as diagnostic evidence and are not scored. The total syndrome score = main symptom score + secondary symptom score, the highest score is 21 points; the higher the score, the more severe the symptoms.

2.5.3 Anxiety and Depression State Scores

Anxiety and depression state scores were evaluated using the Hamilton Anxiety Scale (HAMA) and the Hamilton Depression Scale (HAMD). The HAMA scale consists of 14 items, while the HAMD scale has 17 items. Both scales use a 5-point rating system (0-4 points/item), and a score of less than 7 indicates normality. The scores are positively correlated with the severity of anxiety and depression.

2.5.4 NPY and Inflammatory Factor

Before the first diagnosis and treatment and after the completion of the treatment cycle, 4 ml of venous blood samples were collected from the patients in the morning in an empty stomach state. The samples were left at room temperature to stand for 30 minutes, and then centrifugation was performed at 3000 rpm for 10 minutes (centrifugal radius 10 cm) to obtain the serum. The concentration of neuropeptide Y (NPY), interleukin-6 (IL-6), interleukin-8 (IL-8), and tumor necrosis factor-α (TNF-α) in the serum was analyzed using enzyme-linked immunosorbent assay (ELISA) with a

full-wavelength microplate reader (Molecular Devices SpectraMax 190 model from the United States). (The reagents were provided by Xi'an Haofang Biotechnology Co., Ltd., batch number: 202410)

2.5.5 Adverse Reactions

Detailed records were made of the adverse reactions that occurred in the two groups of patients during the treatment period.

2.6 Statistical Methods

Data were processed using SPSS 26.0. Quantitative data (such as age, disease duration, TCM syndrome score, anxiety and depression scale score, serum NPY indicators, etc.) were expressed as ($\bar{x} \pm s$), and paired sample t-tests were used for within-group comparisons, while independent sample t-tests were used for between-group comparisons; Count data (such as gender, clinical efficacy, occurrence of adverse reactions) were expressed as %, and $\chi 2$ tests were used for group comparisons; $P < 0.05$ indicated statistically significant differences.

3. Research Results

3.1 Clinical Efficacy

After the treatment, through the chi-square test, it was found that the total effective rate of the experimental group was higher than that of the control group ($P < 0.05$), as shown in Table 2.

Table 2: Comparison of Clinical Efficacy (Cases)

Group	n	Recovery	Marked Improvement	Effective	Ineffective	Total Effective Rate (%)
Control group	57	8	19	18	12	78.95
Experimental group	58	14	30	8	6	89.66
$\chi 2$						9.944
P						0.019

3.2 TCM Syndrome Score

After treatment, through t-test, the TCM Syndrome Score of each group were significantly lower than those before treatment ($P < 0.05$), and the test group was lower than the control group ($P < 0.05$). See Table 3.

Table 3: TCM Syndrome Score (points)

Group	n	TCM Syndrome Score	
		Before treatment	after treatment
Control group	57	17.21±2.66	6.75±4.41[a]
Experimental group	58	17.34±2.56	4.41±3.47[ab]

a: $P < 0.05$ vs. pre-treatment within the same group; b: $P < 0.05$ vs. control group after treatment.

3.3 Anxiety and Depression Scale Scores

After treatment, through t-test, the anxiety and depression scale scores of each group were lower than those before treatment ($P < 0.05$), and the scores of the experimental group were lower than those of the control group ($P < 0.05$), as shown in Table 4.

Table 4: Anxiety and Depression Scale Scores (points)

Group	n	Anxiety Scale score		Depression Scale score	
		Before treatment	after treatment	Before treatment	after treatment
Control group	57	13.18±2.59	9.39±1.32[a]	14.93±1.64	10.14±1.37[a]
Experimental group	58	13.40±2.57	8.76±1.61[ab]	14.74±1.61	9.10±0.91[ab]

a: $P < 0.05$ vs. pre-treatment within the same group; b: $P < 0.05$ vs. control group after treatment.

3.4 NPY and Inflammatory Markers

After treatment, through t-test, the serum NPY levels in each group were found to be higher than those before treatment ($P < 0.05$), and the test group had a higher level than the control group ($P < 0.05$), as shown in Table 5; the serum inflammatory marker levels in each group were lower than those before treatment ($P < 0.05$), and the test group had a lower level than the control group ($P < 0.05$), as shown in Table 6.

Table 5: NPY (pg/ml)

Group	n	NPY	
		Before treatment	after treatment
Control group	57	43.48±5.72	62.30±6.02[a]
Experimental group	58	43.34±5.22	63.75±5.91[ab]

a: $P < 0.05$ vs. pre-treatment within the same group; b: $P < 0.05$ vs. control group after treatment.

Table 6: Inflammatory indicators (ng/ml)

Group	n	IL-6		IL-8		TNF-α	
		Before treatment	after treatment	Before treatment	after treatment	Before treatment	after treatment
Control group	57	12.01±2.67	5.56±2.33[a]	13.79±2.49	4.69±1.63[a]	16.78±2.89	6.89±1.41[a]
Experimental group	58	12.03±2.48	4.61±1.98[ab]	14.17±2.04	3.74±1.49[ab]	16.49±2.66	5.26±1.94[ab]

a: $P < 0.05$ vs. pre-treatment within the same group; b: $P < 0.05$ vs. control group after treatment.

3.5 Adverse Reactions

During the study period, the incidence of adverse reactions in the control group was 3.51% (1 case of nausea and vomiting, 1 case of constipation), which was higher than that in the experimental group (3.45%, 1 case of constipation, 1 case of loss of appetite), but the difference was not statistically significant ($P > 0.05$).

4. Discussion

IBS-D can be classified under the category of "diarrhea" in traditional Chinese medicine. Its causes are mostly due to emotional imbalance and improper diet. Master Xu Jingfan attributed its onset to the liver and spleen meridians [13]. Modern medical experts also believe that its main pathogenesis is liver depression and spleen deficiency [14]. Based on this, the chief physician Qiao Huixia proposed that the pathogenesis of IBS-D should be centered on "spleen deficiency as the foundation, spleen deficiency leading to depression, and both the body and mind being ill simultaneously". The following is a summary and elaboration of the clinical experience of the mentor: The spleen governs the transformation and transportation of water and dampness. Its qi is healthy when it ascends. If the spleen is deficient from birth, water and dampness will accumulate internally, and the ascending of clear qi will be impaired. The water and grain

essence, as well as the fluids, cannot be transported upward, but instead, they follow the dampness and turbidity and descend towards the intestines, resulting in diarrhea. Therefore, it is believed that IBS-D has its onset based on spleen deficiency. When the spleen is deficient, water and dampness accumulate internally, and the middle jiao becomes congested with dampness and turbidity, which then leads to imbalance of the liver and causes "earth congestion and wood depression". The "Clinical Guidebook of Diagnosis and Treatment" states: "Dampness obstructs the middle jiao, and the qi mechanism is blocked, with the wood not being able to extend." Moreover, IBS-D has the characteristics of recurrent and intermittent attacks, which seriously affect the quality of life of patients, causing psychological symptoms such as anxiety and depression [15]. This is known as "chronic depression". Ultimately, spleen deficiency leads to liver depression, and liver disease can then spread to the spleen, making the spleen deficiency even worse, and thus the condition worsens. The two are intertwined, with both the body and mind being ill simultaneously. The essence is "body and spirit being diseased".

Therefore, when treating this disease, the mentor advocated nourishing the spleen earth to relieve wood depression, transforming dampness to unblock the qi mechanism, and formulating the Rougan Jianpi Decoction. In the formula, Atractylodes is bitter and warm, being the "first essential herb for nourishing the spleen and strengthening the spleen". It is combined with Astragalus to tonify qi and lift yang. The two herbs are the main ingredients, achieving the effect of strengthening the spleen and qi, and stopping diarrhea and promoting digestion. The secondary ingredients include Poria, Chinese yam, aduki beans, and leucanthemum, which nourish earth and control water. Additionally, Foshan is used to dispel wind and relieve liver depression, and Bai Shao is used to nourish the liver and nourish blood. Inspired by the method of "softening the liver and strengthening the spleen" in the Pain Relief Formula, Fennel is added to further promote the balance of liver and spleen. One purpose is to warm the center and relieve pain, and the other is to assist Foshan and Bai Shao in harmonizing liver and spleen. To prevent the spleen from being undermined, Perilla is added. One purpose is to warm and lift yang qi, and the other is to prevent the accumulation of tonifying herbs and generating heat. Dong Yuan's theory of "sweet and warm to eliminate heat" is followed. If diarrhea is excessive and uncontrollable, immediate treatment should be given with Ho Zi to stop diarrhea, and the treatment should stop once the condition is under control to prevent the accumulation of tonifying herbs. Licorice is used to harmonize the herbs and Huanglian is selected for its ability to thicken the intestines and reduce inflammation. The light dosage is added to the tonifying formula to prevent the accumulation of tonifying herbs and generate heat, and to clear the latent dampness and heat in the intestines. The combination of cold and hot therapies is used to enhance the therapeutic effect and help reduce the inflammatory response in the body.

Studies have shown that the serum levels of IL-6, IL-8, and TNF-α in patients with IBS-D are significantly elevated [16]. This confirms that IBS-D patients have a chronic low-grade inflammatory response. In this study, the serum levels of IL-6, IL-8, and TNF-α in all groups decreased, and the decrease in the experimental group was higher than that in the control group. The reasons for this are that the full formula of the Rougan Jianpi Decoction achieves the effects of lifting yang and stopping diarrhea, and strengthening the spleen and soothing the liver. It can strengthen the body's immunity and reduce the inflammatory response. In addition, Poria polysaccharides have anti-inflammatory and antioxidant effects [17], Foshan can relieve fever, relieve pain, and reduce inflammation and enhance immunity [18], and Huanglian can upregulate the expression of AQP3 and AOP4 and reduce inflammatory damage to the intestinal mucosa [19]. All of these can enhance the therapeutic effect and help reduce the inflammatory response in the body.

Abnormal function of the brain-gut axis is recognized as one of the causes of IBS-D. NPY is widely distributed in the central nervous system and peripheral tissues. It not only affects the emotional regulation of the central nervous system but also directly acts on the intestinal function of the periphery. It is a key node connecting the brain-gut axis. The decline in its level can reflect the abnormalities in functions such as vascular constriction, enhanced stress response, and increased intestinal motility, which are closely related to the occurrence of IBS-D. Therefore, NPY can be used as a biomarker reflecting the brain-gut axis function in IBS-D patients [20]. In this study, the serum NPY levels of patients in each group were higher than those before treatment, and the levels in the experimental group were higher than those in the control group, which was similar to the results of Cai Linkun et al. [21]. Combined with modern pharmacological research, the main component of peony, peony total glycosides, can inhibit the synthesis and release of prostaglandin E2 in the body [22], reduce visceral sensitivity and relieve pain; and peony combined with licorice can inhibit the contraction of small intestinal smooth muscle, acting through multiple targets and pathways on spastic diseases [23]; the volatile oil of atractylodes can regulate the synthesis and release of 5-HT, and promote the synthesis of 5-HT in the brain, correcting the abnormal brain-gut axis in chronic unpredictable stress model mice [24]; and fritillaria can enhance the immune system function. Thus, the Rougan Jianpi Decoction can improve the secretion of neurotransmitters in the brain-gut axis through multiple pathways and targets, and increase the serum NPY level in patients with liver depression and spleen deficiency type IBS-D.

NPY is one of the most widely distributed and abundant neuropeptide substances in the body, mediating the secretion of inflammatory factors, which can enhance the secretion of TNF-α, IL-6, etc. by macrophages and monocytes, promoting inflammatory reactions, and also induce the transformation of macrophages to the M2 type, exerting anti-inflammatory effects [25].

In conclusion, the Rougan Jianpi Decoction has a significant therapeutic effect on liver depression and spleen deficiency type IBS-D, can significantly improve the clinical symptoms of patients, relieve anxiety and depression, and its mechanism of action may be related to regulating the brain-gut axis function and reducing the inflammatory response of the body.

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