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Curative Effect of Xiangsha Liujunzi Decoction Combined with Weifuchun Tablet in Functional Dyspepsia

Xiaoyang Chen^{1,*}, Chenfei Huang²

- ^{1.} Department of Traditional Chinese Medicine, Yongjia County People's Hospital, 325100 Wenzhou, Zhejiang, China
- ^{2.} Department of Rehabilitation and Acupuncture, Yongjia County People's Hospital, 325100 Wenzhou, Zhejiang, China

Keywords

Xiangsha Liujunzi Decoction Weifuchun Tablet Functional dyspepsia Inflammatory factor

* Correspondence

Xiaoyang Chen Department of Traditional Chinese Medicine, Yongjia County People's Hospital, 325100 Wenzhou, Zhejiang, China E-mail: 502314343@qq.com

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Abstract

Background: Our study aims to investigate the curative effect of Xiangsha Liujunzi Decoction combined with Weifuchun Tablet in functional dyspepsia. Methods: 45 patients with functional dyspepsia treated with Xiangsha Liujunzi Decoction combined with Weifuchun Tablet for 8 weeks from February 2022 to February 2023 in our hospital were selected into the observation group, and 45 patients with functional dyspepsia treated with Weifuchun tablet for 8 weeks were selected into control group during the same period. The clinical efficacy and adverse reactions of the two groups were compared, and the changes of TCM symptom score, gastric dynamics parameters, and inflammatory factor (CRP, TNF-a, and IL-6) levels in serum before and after treatment were observed. Results: The total effective rate of clinical efficacy in observation group was significantly higher than that in control group ($\rho < 0.05$). After treatment, the levels of TCM symptom score, half-empty time, 2 h retention rate, C-reactive protein, tumor necrosis factor-a, and Interleukin-6 in both groups were obviously reduced, and those in the observation group was visibly lower than those in the control group ($\rho < 0.05$). The emptying rate in the two groups was strikingly increased, and that in the observation group was remarkably higher than that in the control group ($\rho < 0.05$). There was no significant difference in the occurrence of diarrhea, vomiting, and nausea between the two groups ($\rho > 0.05$). Conclusion: Xiangsha Liujunzi Decoction combined with Weifuchun Tablet has a good clinical effect in the treatment of patients with functional dyspepsia, which can alleviate clinical symptoms, improve gastric motility, reduce inflammation, and has good safety.



1 Introduction

Functional dyspepsia is a common functional gastrointestinal disease, caused by microinflammation, gastrointestinal infections, and gastroduodenal motility disorder. It is often characterized by clinical symptoms such as epigastric pain, burning pain, and early satiety. In severe cases, patients' quality of life will be dramatically affected [1,2]. Although antibiotics, acid-suppressants, prokinetics, probiotics, and neuromodulators have been applied into clinical drug treatment for functional dyspepsia, the majority of individuals cannot avoid to stay from significant negative effects of the available medicines [3,4].

According to traditional Chinese medicine (TCM), functional dyspepsia belongs to the category of "distention and fullness" and "epigastric pain", which is caused by emotional upset, dietary disorders, and invasion of pathogenic factors, causing the dysfunctional operation of the spleen and stomach and stagnation of qi. The treatment should be mainly based on smoothing qi, calming the adverse-rising energy, and eliminating the accumulation [5]. Research shows that TCM has a good therapeutic effect in the treatment of functional dyspepsia [6]. Weifuchun Tablet is a kind of Chinese patent medicine, and its main ingredients include Ginseng Rubra Radix and Rabdosia amethystoides which has the effects of strengthening spleen, benefiting qi, promoting circulation of gi to relieve pain, preventing vomiting, and dissolving phlegm [7]. Animal studies by Chen et al demonstrated that Weifuchun Tablet had the effect of improving gastrointestinal function in rats with functional dyspepsia [8]. Xiangsha Liujunzi Decoction is a kind of TCM soup, which is made by decocting Pinellia ternate, Radix Aucklandiae, and Poria. It mainly strengthens the spleen, benefits gi, and harmonizes the stomach, improves clinical symptoms such as gastric distension, indigestion, and loss of appetite, and reduces inflammatory response [9].

Animal studies by Zhang [10] and Zhao [11] et al. concluded that Xiangsha Liujunzi Decoction can improve gastric motility and reduce inflammatory response in rats with functional dyspepsia. The efficacy of single drug on patients with functional dyspepsia is limited.

Based on this, in our study, Xiangsha Liujunzi Decoction combined with Weifuchun Table was applied in patients with functional dyspepsia. We observed the clinical efficacy and adverse reactions, and compared the specific effects of this treatment on gastric dynamics and inflammatory response of the patients, to explore the value of its application in the treatment of functional dyspepsia.

2 Data and methods

2.1 General data

45 patients with functional dyspepsia treated with Xiangsha Liujunzi Decoction combined with Weifuchun Tablet from February 2022 to February 2023 in our hospital were selected into the observation group, and 45 patients with functional dyspepsia treated with Weifuchun tablet were selected into control group during the same period.

There was no statistically significant difference between the two groups of patients in terms of gender, age, duration, and type of disease ($\rho > 0.05$). These data were comparable, as shown in Table 1.

2.2 Inclusion and exclusion criteria

2.2.1 Inclusion criteria

(1) Patients met the diagnostic criteria for functional dyspepsia in *Comparing diagnostic performance of Cantonese-Chinese version of Rome IV criteria and a short Reference Standard for functional dyspepsia in China* [12]. (2) Patients met the diagnostic criteria for functional dyspepsia in *development of clinical trial of new drugs of traditional Chinese medicines* [13], with the primary symptoms being gastric stuffiness or

distension, indigestion and loss of appetite, and the secondary symptoms being belching and loose stool. (3) Patients who have not taken gastric mucosal protector, gastric motivation promoter, or acid-suppressing drugs within 4 weeks before enrollment.

2.2.2 Exclusion criteria

(1) Patients with organic diseases of the digestive

system such as peptic ulcer. (2) Patients with endocrine system diseases such as diabetes mellitus. (3) Patients with severe insufficiency of heart, liver, and kidneys. (4) Patients with previous digestive system-related surgeries. (5) Patients with mental disorder and poor treatment adherence. (6) Patients who were allergic to the drugs used in this study. (7) Pregnant and lactating women.

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		Sex (case)				Type of disease (cases)			
Group	Case	Male	Female	Age (year old)	Duration of disease (year)	Epigastric pain syndrome	Postprandial discomfort syndrome	Epigastric pain syndrome overlapping postprandial discomfort syndrome	
Observation group	45	25	20	67.31 ± 6.22	3.47 ± 0.81	23	11	11	
Control group	45	23	22	66.64 ± 6.18	3.29 ± 0.76	24	10	11	
X²/t		0	.179	0.510	1.072		0.06	9	
p		0	.673	0.611	0.287		0.96	6	

2.3 Treatment measures

2.3.1 Control group

Weifuchun Tablet (Hangzhou Huqingyutang Pharmaceutical Holding Co., Ltd., National Medical Products Administration (NMPA) Approval No.: Z20040003, specification: 0.36 g/tablet) were taken orally, 4 tablets/times, 3 times/day, for 8 weeks of treatment.

2.3.2 Observation group

Based on the treatment in control group, Xiangsha Liujunzi Decoction (formula: 10 g *Pinellia ternate*, 10 g Radix Aucklandiae, 20 g *Poria*, 12 g Citri Reticulatae Pericarpium, 20 g Codonopsis Radix, 20 g *Atractylodes macrocephala* Koidz, 12 g *Amomi fructus*, and 5 g Glycyrrhizae Radix et Rhizoma) was decocted in water to 500 mL, and given to the patients in the morning and evening. Treatment duration was 8 weeks.

2.4 Observational indicators

2.4.1 Clinical efficacy

The clinical efficacy was evaluated after collecting the TCM symptom score of treatment before and after 8 weeks.

Evaluation criteria: Cured: clinical symptoms were basically disappeared, and the reduction of TCM symptom score was \geq 95%; Significantly effective: clinical symptoms were significantly improved, and the reduction of TCM symptom score was 70-94%; Effective: clinical symptoms were improved, and the reduction of TCM symptom score was 30-69%; Ineffective: clinical symptoms were not improved or even aggravated, and the reduction of TCM symptom score was \leq 30%. Total clinical effective rate = (cured + significantly effective + effective) number of cases / total number of cases \times 100%.

2.4.2 TCM symptom score

Before and after 8 weeks of treatment, the TCM

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symptom score was assessed according to the patients' primary symptoms (gastric stuffiness or distension, indigestion and loss of appetite) and secondary symptoms (belching, loose stools) by referring to the *Guidelines for Clinical Research of New Traditional Chinese Medicine* [13]. The degree of absence, mildness, moderateness, and severity of the symptoms were scored as 0, 2, 4, and 6 points and 0, 1, 2, and 3 points for the primary and secondary symptoms, respectively, with higher scores indicating more severe symptoms.

2.4.3 Gastric dynamics parameters

Before and after 8 weeks of treatment, gastric half-emptying time, emptying rate, and 2-h retention rate were examined by radionuclide imaging using a Symbia T single photon emission computed tomography purchased from Siemens AG, Germany.

2.4.4 Inflammatory factor

Before and after 8 weeks of treatment, 5 mL of fasting peripheral venous blood was extracted from the two groups of patients in the early morning, left to stand at room temperature for 30-60 min, centrifuged at 3000 r/min for 10 min, and then the serum was separated and stored at -20 $^{\circ}$ C for measurement. C-reactive protein (CRP), tumor necrosis factor (TNF)- a , interleukin (IL)-6 levels were measured by enzyme-linked immunosorbent assay, with the use of the kits (ml092609/ml077385/ml028583) purchased from Shanghai Enzyme-linked Biotechnology Co., Ltd. All operations are carried out with strict reference to the instructions.

2.4.5 Adverse reactions

The occurrence of diarrhea, vomiting, and nausea in both groups was counted.

2.5 Statistical methods

Statistical analysis was performed using SPSS 20.0. Counting data was represented by examples (%), and comparison was made using X² tests. Measurement data were expressed as mean \pm standard deviation. Comparison between the two groups was performed using the independent samples t-test, and comparison between different time points in the same group was performed using the paired samples t-test. Differences were considered statistically significant at $\rho < 0.05$.

3 Results

3.1 Comparison of clinical efficacy between the two groups

The total effective rate of clinical efficacy in the observation group was significantly higher than that in the control group ($\rho < 0.05$), as seen in Table 2.

3.2 Comparison of TCM symptom score between the two groups before and after treatment

Before treatment, there was no statistically significant difference in the comparison of TCM symptom score in the two groups of patients ($\rho > 0.05$). After treatment, the TCM symptom score in the two groups of patients was decreased obviously ($\rho < 0.05$), and that in the observation group was visibly lower than that in the control group ($\rho < 0.05$). The results were shown in Table 3.

3.3 Comparison of gastric kinetic parameters between the two groups before and after treatment

Before treatment, comparison of half-emptying time, emptying rate, and 2 h retention rate had no significant difference between the two groups ($\rho >$ 0.05). After treatment, the half-emptying time and 2 h retention rate in the two groups were significantly lower than those in the control group ($\rho < 0.05$), and those in the observation group were obviously lower than those in the control group ($\rho < 0.05$). The emptying rate in the two groups was markedly higher ($\rho < 0.05$), and that in the observation group was visibly higher than that in the control group (ρ < 0.05). The results were displayed in Table 4.

3.4 Comparison of inflammatory factor levels between the two groups before and after treatment

Before treatment, there was no statistically significant difference in the levels of CRP, TNF- a , and IL-6 between the two groups ($\rho > 0.05$). After treatment, the levels of CRP, TNF-a, and IL-6 in the two groups

were obviously lower ($\rho < 0.05$), and those in the observation group were visibly lower than those in the control group ($\rho < 0.05$). The results were depicted in Table 5.

3.5 Comparison of adverse reactions between the two groups

There was no statistically significant difference in the occurrence of diarrhea, vomiting, and nausea between the two groups (p > 0.05), as seen in Table 6.

Group	Case	Cured	Significantly effective	Effective	Ineffective	Total effective rate			
Observation group	45	19 (42.22)	18 (40.00)	6 (13.33)	2 (4.45)	43 (95.55)			
Control group	45	11 (24.44)	14 (31.15)	11 (24.44)	9 (20.00)	36 (80.00)			
X ²						5.075			
p						0.024			
							-		

Table 2 Comparison of clinical efficacy between the two groups [cases (%)]

Table 3 Comparison of TCM symptom score between the two groups before and after treatment (means ± standard deviation).

Croup	Case	Gastric stuffines	s or distension	Indigestion and loss of appetite		
Group	Case	Before treatment	After treatment	Before treatment	After treatment	
Observation group	45	3.91 ± 1.59	0.89 ± 1.01 *	3.82 ± 1.53	0.80 ± 0.99 *	
Control group	45	3.78 ± 1.66	$1.56 \pm 1.85 *$	3.87 ± 1.62	1.64 ± 1.77 *	
t		0.388	2.121	0.134	2.789	
p		0.699	0.037	0.894	0.007	
Group	Casa	Belching		Loose stools		
Group	Case	Before treatment	After treatment	Before treatment	After treatment	

		Before treatment	After treatment	Before treatment	After treatment	
Observation group	45	1.98 ± 0.50	0.31 ± 0.47 *	2.16 ± 0.74	0.40 ± 0.50 *	
Control group	45	2.07 ± 0.77	0.78 ± 0.97 *	2.07 ± 0.69	0.69 ± 0.79 *	
t		0.488	2.603	0.592	2.073	
p		0.627	0.011	0.556	0.041	

Note: Comparison with the same group before treatment, * ρ < 0.05.

Table 4 Comparison of gastric kinetic parameters between the two groups before and after treatment (means \pm standard deviation).

	Case	Half-emptying time (min)		Emptying r	ate (%/min)	2 h retention rate (%)		
Group		Before	After treatment	Before	After	Before	After	
		treatment	Alter treatment	treatment	treatment	treatment	treatment	
Observation	45	103 45 + 13 56	84 21 + 10 04 *	0 33 + 0 10	0 54 + 0 22 *	49 21 + 6 19	35 13 + 2 20 *	
group	75	105.45 ± 15.50	04.21 ± 10.04	0.55 ± 0.10	0.34 ± 0.22	49.21 ± 0.19	55.15 - 2.20	
Control group	45	100.87 ± 12.53	93.84 ± 11.12 *	0.30 ± 0.09	$0.41 \pm 0.15 *$	47.81 ± 5.98	$40.10 \pm 3.51 *$	
t		0.937	4.312	1.496	3.275	1.091	8.048	
p		0.351	0.000	0.138	0.002	0.278	0.000	

Note: Comparison with the same group before treatment, * ρ < 0.05.

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Table 5 Comparison of inflammatory factor levels between the two groups before and after treatment (means \pm standard deviation).

		CRP (mg/L)		TNF-c	ι (μg/L)	IL-6 (μg/L)		
Group	Case	Before	After	Before	After treatment	Rofero trootmont	After treatment	
		treatment	treatment	treatment	Alter treatment	Before treatment	After treatment	
Observation	45	7 55 ± 1.40	1 49 + 1 67 *	276 21 + 72 65	140.95 ± 21.94 *	140 56 + 54 12	6E 11 ± 27 9E *	
group	45	7.55 ± 1.40	4.46 ± 1.02	270.21 ± 72.05	140.85 ± 51.84	140.50 ± 54.15	05.11 ± 27.85	
Control group	45	7.13 ± 1.82	5.99 ± 1.31 *	289.47 ± 85.32	187.43 ± 52.41 *	132.47 ± 40.12	87.10 ± 34.12 *	
t		1.227	4.862	0.794	5.095	0.806	3.349	
p		0.223	0.000	0.430	0.000	0.423	0.001	

Note: Comparison with the same group before treatment, * ρ < 0.05.

Table 6 Comparison of adverse reactions between the two groups.

Group	Case	Diarrhea (cases)	Vomiting (cases)	Nausea (cases)	Incidence rate (%)
Observation group	45	1	1	1	6.67
Control group	45	2	2	1	11.11
X ²					0.137
p					0.711

4 Discussion

To investigate the clinical efficacy of Xiangsha Liujunzi Decoction combined with Weifuchun Tablet in functional dyspepsia, this study compared the clinical efficacy of Xiangsha Liujunzi Decoction combined with Weifuchun Tablet or single use of Weifuchun Tablet in the treatment of patients with functional dyspepsia. The results demonstrated that their combined treatment had better effect.

The TCM syndrome score is a scale that assesses the severity of a patient's condition through clinical symptoms, with a higher score indicating a more severe condition. Half-empty time, 2 h retention rate, and emptying rate are commonly used to assess gastric motility in patients [14]. A longer half-emptying time, higher 2 h retention rate, and lower emptying rate indicate poorer gastric motility in patients. In a multi-center randomized double-blind placebo-controlled clinical study, it has been reported that patients treated with Xiangsha Liujunzi granules demonstrated a significant improvement in their TCM symptom score, gastric emptying and other indicators when compared to the placebo group [15]. In line with

can improve clinical symptoms and gastric motility in patients with functional dyspepsia. It is more effective compared to the use of Weifuchun Tablet alone. The main ingredients of Weifuchun Tablet include Ginseng Rubra Radix, Isodon, etc., in which Ginseng Rubra Radix has the effects of reinforcing vital energy, tonifying gi, and controlling blood, and its main ingredient also has the effect of preventing or arresting vomiting [15]. Isodon can exert effects of promoting gi and blood circulation, clearing away heat and toxic material, and promoting the regeneration of gastric mucous membrane. Aurantii Fructus has the effects of relieving distension to eliminate abdominal mass, regulating qi, reducing phlegm, relaxing the blood vessels of intestine, and promoting gastrointestinal motility [16,17]. The ingredients of Xiangsha Liujunzi Decoction include Pinellia ternate, Radix Aucklandiae, Poria, etc., of which Pinellia ternate, Poria, Citri Reticulatae Pericarpium, Codonopsis Radix, and Atractylodes macrocephala Koidz can benefit the spleen and stomach, promote dampness, and replenish gi. Amomi Fructus, Aucklandiae Radix, and

this, the results of this study showed that Xiangsha Liujunzi Decoction combined with Weifuchun Tablet Glycyrrhizae Radix et Rhizoma have the effects of removing stagnation, dissipating dampness, moving qi to alleviate pain, and promoting digestion to eliminate stagnation [18]. Meanwhile, modern pharmacological studies have shown that *Pinellia ternate* can suppress vomiting, inhibit gastric secretion, and reduce gastrointestinal motility. *Amomum villosum* can reduce gastrointestinal stimulation and alleviate symptoms of functional dyspepsia in patients. Codonopsis Radix can promote gastric mucosal repair [19-21]. From this, it was obvious that Xiangsha Liujunzi Decoction combined with Weifuchun Tablet has a certain effect in alleviating clinical symptoms and improving gastric motility in patients with functional dyspepsia.

A study has demonstrated that pro-inflammatory cytokine levels are elevated in patients with functional dyspepsia during the onset and persistence of symptoms, suggesting that patients with functional dyspepsia have higher levels of pro-inflammatory cytokines than the healthy people [22]. CRP, TNF-a, and IL-6 are common clinical inflammatory factors, and higher levels of all three indicate a more severe inflammatory response in the patient's body [23,24]. Interestingly, a recent study has been revealed that Xiangsha Liujunzi Decoction significantly decreased levels of inflammatory factors including IL-6 and TNFa of rat models of functional dyspepsia, and improved their survival rate [25]. This verified the inhibitory role of Xiangsha Liujunzi Decoction on inflammatory reaction in functional dyspepsia. Consistently, our study has uncovered that combination of Xiangsha Liujunzi Decoction and Weifuchun Tablet can alleviate inflammation in patients with functional dyspepsia, and its effect is better compared to using Weifuchun Tablet alone. Among the ingredients of Weifuchun Tablet, Ginseng Rubra Radix can reduce the inflammatory response of the body by inhibiting the activity of NF-KB pathway and reducing the secretion of inflammatory mediators and cytokines. The

coumarins in Aurantii Fructus have analgesic, anti-inflammatory, antibacterial, and antitoxic effects [25,26]. In the composition of Xiangsha Liujunzi Decoction, Pinellia ternate has the effect of inhibiting the secretion of IL-6 and TNF-a, Aucklandiae Radix can reduce the infiltration of inflammatory cells and synovial hyperplasia, and decrease the levels of inflammatory factors such as CRP, and poria total triterpenoids in Poria has a significant inhibitory effects on both acute and chronic inflammation [27-31]. These results have shown that Xiangsha Liujunzi Decoction combined with Weifuchun Tablet provides more anti-inflammatory compositions compared with the use of Weifuchun Tablet alone, thereby displaying a greater inhibition of inflammatory factors, leading to significantly reduced inflammatory reaction in patients with functional dyspepsia.

In addition, the results of this study have revealed that the occurrence of diarrhea, vomiting, and nausea is similar in both groups, indicating that Xiangsha Liujunzi Decoction combined with Weifuchun Tablet has good safety in patients with functional dyspepsia, and can be promoted in the clinic.

In conclusion, Xiangsha Liujunzi Decoction combined with Weifuchun Tablet has a good clinical effect in the treatment of patients with functional dyspepsia, which can alleviate clinical symptoms, improve gastric motility, reduce inflammation, and has good safety. Due to the limited clinical samples collected and observation time in this study, there may be some constraints. In order to further study the clinical efficacy of Xiangsha Liujunzi Decoction combined with Weifuchun Tablet in the treatment of patients with functional dyspepsia, there is still a need to expand the sample size and extend the observation time in the later stage. In addition, this study did not conduct a dialectical analysis of patients, thus it is unclear which syndromes the Xiangsha Liujunzi Decoction combined with Weifuchun Tablet applies to functional dyspepsia.

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Conflicts of Interest

The authors declare no conflicts of interest.

Author Contributions

Conceptualization, X.C. and C.H.; Data curation, X.C.; Formal analysis, C.H.; Methodology, X.C.; Writing-original draft, X.C. and C.H.; Writing-review and editing, X.C. and C.H. All authors have read and agreed to the published version of the manuscript.

Ethics Approval and Consent to Participate

This study was approved by the Ethics Committee, and patients were informed and consented.

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Availability of Data and Materials

The data presented in this study are available on request from the corresponding author.

Supplementary Materials

Not applicable.

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