

Original Article

Clinical efficacy of *Tiaoqi Jiangni* decoction in the treatment of functional dyspepsia and its influence on life quality

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Abstract: Objective: To observe clinical effects of *Tiaoqi Jiangni* Decoction combined with mosapride citrate tablets in the treatment of functional dyspepsia and its impact on quality of life. Methods: Seventy-six patients with functional dyspepsia were admitted to Cangzhou Central Hospital of Hebei Province from September 2019 to June 2020. They were selected and randomized into a treatment group and a control group (38 cases in each group). Both groups received mosapride citrate tablets (5 mg/time, 3 times/d). The treatment group was additionally given *Tiaoqi Jiangni* Decoction. Results: The total effective rate of the treatment group was higher than that of the control group ($P < 0.05$). After treatment, the sub-scores of each symptom and the overall score of traditional Chinese medicine (TCM) syndrome in the treatment group were significantly lower than those in the control group (all $P < 0.05$). The overall and sub-item scores of the Functional Digestive Disorders Quality of Life Questionnaire (FDDQL) of both groups saw an increase after treatment (all $P < 0.05$). There was no significant disparity in sleep and stress between the two groups. The treatment group presented a better performance in other aspects than the control group (all $P < 0.05$). Before treatment, the two groups showed no significant disparity in the gastric emptying rate of barium bar and mental and psychological state. The two indexes were observed with a rise after treatment, with superior results in the treatment group to those in the control group ($P < 0.05$). No adverse reactions were observed in the two groups. One month after treatment, the treatment group obtained a lower recurrence rate as compared to the control group ($P < 0.05$). Conclusion: *Tiaoqi Jiangni* Decoction in combination with mosapride citrate tablets in the treatment of FD yields a significant clinical effect by substantially alleviating patients' clinical symptoms and improving their quality of life, with no adverse reactions, high safety, and low recurrence rate, which merits further clinical application. Clinical trial registration: The name of the registry: Chinese Registry of Clinical Trials. Trial Registration Number: ChiCTR2100063542. Trial URL: <http://www.chictr.org.cn/showproj.aspx?proj=6354283>.

Keywords: *Tiaoqi Jiangni* decoction, functional dyspepsia, symptom score, functional digestive disorders quality of life questionnaire

Introduction

Functional dyspepsia (FD) is a common digestive disease in the clinic. The main symptoms include postprandial fullness, upper abdominal burning sensation, anorexia, nausea, and belching. Currently, the general therapeutic approach for FD in clinical western medicine is symptomatic treatment with pro-gastrointestinal motility drugs, anti-acid drugs, and anti-anxiety and depression drugs [1-3]. Despite its certain efficacy, the western approach fails to yield an ideal effect for the long run. The pro-

pensity of FD for repeated occurrence severely hinders the patients' quality of life [4]. TCM boasts a unique theoretical system and rich clinical experience in the treatment of FD. In TCM, functional dyspepsia can be categorized as "fullness", "stomach pain", and "poor appetite". This disease is mostly induced by improper diet, emotional imbalance, and excessive fatigue, with the pathogenesis mainly attributed to spleen deficiency. The spleen and stomach are the foundation for nutrient acquisition, with close coordination and interplay in terms of pathogenesis between the two viscera. In-

sufficient and abnormal spleen function results in the inability of the body to absorb nutrients, which increases the burden on the viscera and leads to poor appetite, impeded digestive ability, and gastric blockade, further exacerbating the disease condition [5]. Tiaoqi Jiangni Decoction has the effects of regulating qi, promoting blood circulation, and relieving depression, which is used for the treatment of functional dyspepsia with significant efficacy. In this study, the efficacy of Tiaoqi Jiangni Decoction was compared with that of mosapride citrate.

Data and methods

General data

A total of 76 patients with FD of either sex (aged 18-60 years) who were enrolled in the National Medical Hall and the Department of TCM of Cangzhou Central Hospital, Hebei Province, from September 2019 to June 2020, were selected and randomly divided into a control group (38 cases) and a treatment group (38 cases) using the random number table method. In the control group, there were 16 males and 22 females with an average age of (41.28±10.43) years old (range: 24-59). In the treatment group, there were 19 males and 19 females with an average age of (40.76±8.43) years old (range: 26-59) ($P > 0.05$). This protocol was approved by the ethics committee of Cangzhou Central Hospital (2019-089-01).

Diagnostic criteria

Western medicine criteria refer to Roman III diagnostic criteria for FD [6]: Patients had symptoms including post-prandial discomfort, early satiety, upper abdominal pain, and burning sensation in the upper abdomen for more than half a year without evidence of organic diseases for the above symptoms. The symptoms of the patients in the past 3 months were consistent with the above description.

TCM diagnostic criteria refer to the consensus on the diagnosis and treatment of FD in integrative medicine (2017) [7]: Main symptoms included conscious upper abdominal fullness and discomfort, early satiety, and upper abdominal pain, related to diet, emotion, daily life, and temperature, which recurred for more than three months. In the clinic, FD, with two

or more types of manifestations, may also be accompanied by symptoms of phlegm-dampness, food stagnation, and blood stasis. Its diagnosis should be based on the differentiation of main syndromes for FD.

Inclusion criteria

Patients met the relevant diagnostic criteria in both traditional Chinese and western medicine. The patients and their families voluntarily participated in the study with good compliance after being informed of the purpose and process of the study. Those whose timely treatment and follow-up could be guaranteed.

Exclusions criteria

Patients under 18 or over 60 years old; those not in compliance with relevant diagnostic criteria in western medicine and traditional Chinese medicine; pregnant and lactating women; those with the allergic constitution, heart, brain, liver, kidney, endocrine system, hemorrhagic diseases or mental diseases.

Treatment

The control group was given western medicine routine treatment, with patients orally administered with mosapride citrate tablets (produced by Jiangsu Haosen Pharmaceutical Group Co., LTD., SFDA approval No.: H19990315, specifications: 0.5 mg), three times a day, 5 mg each time, 30 min before meals. On the basis of the control group, the treatment group was additionally treated with *Tiaoqi Jiangni* Decoction (10 g Pericarpium Citri Reticulatae, 10 g Rhizoma Pinelliae Preparatum, 15 g Poria, 10 g Caulis Bambusae in Taenia, 10 g Radix Paeoniae Rubra, 15 g Flos inulae, 30 g calcined ochre, 10 g Radix Linderae, 10 g Radix Curcumae, and 15 g Rhizoma Acori Tatarinowii). For patients with obvious stomach vomiting, 6 g ginger was added. For those with obvious anorexia, 10 g burnt Massa Medicata Fermentata and 5 g Fructus Amomi were added. For those with an obvious burning sensation in the stomach, 6 g Rhizoma Coptidis and 15 g Herba Taraxaci were added. For those with poor insomnia, 30 g Caulis Polygoni Multiflori and 30 g Cortex Albiziae were added. For those with obvious acid reflux, 6 g Rhizoma Coptidis and 6 g Fructus Evodiae were added. The TCM decoction was uniformly pre-

pared by the National Medical Hall, TCM Pharmacy of Cangzhou Central Hospital. One dose (300 ml) was prepared every day, divided into two bags, 150 ml for each, and then taken by the patients half an hour after breakfast and dinner, respectively. Other drugs were strictly prohibited during the treatment. Patients in the above two groups took medicine for 4 weeks.

Observation indicators

(1) Overall clinical efficacy in the two groups; (2) Scores of overall TCM syndrome and sub-item of main symptoms in the two groups before and after treatment; (3) FDDQL scale: Scores of the two groups before and after treatment were recorded and organized by the professional and technical personnel. Life quality of the two groups was evaluated based on the scores; (4) Adverse reactions: The occurrence time, symptoms, the severity of adverse reactions, and treatment plan during the whole treatment process and one month after the treatment in two groups were recorded; (5) Recurrence rate: Patients in the two groups were followed up for one month after the treatment, and their symptoms were inquired in detail to understand and record the recurrence of the disease according to the facts.

Efficacy criteria

According to the Guiding Principles for Clinical Research on New Drugs of TCM [8]: The criteria for efficacy were formulated with four classes: Cured (main symptoms and physical signs disappeared or basically disappeared, and the total score was reduced by $\geq 95\%$). Markedly effective (main symptoms and physical signs were markedly alleviated. The total score was reduced by $\geq 70\%$). Effective (main symptoms and physical signs were alleviated. The total score was reduced by $\geq 30\%$). Ineffective (there was no alleviation or aggravation of main symptoms and signs. The total score was reduced by $< 30\%$). Efficacy index (nimodipine method) = $[(\text{score before treatment} - \text{score after treatment}) \div \text{score before treatment}] \times 100\%$. Total effective rate = $[\text{cases of cured, markedly effective and effective} \div \text{total cases}] \times 100\%$.

TCM syndrome score: The table was formulated with reference to the Guiding Principles

for Clinical Research on New Drugs of TCM [8]. Four grades-no symptom, mild, moderate, and severe symptoms - were classified, 0 scores for no symptom; 1 for mild symptoms that have not disrupted daily life; 2 for moderate symptoms with limited impacts on daily life; and 3 for serious symptoms that have impeded patients' daily life, resulting in their inability to work. Patients in the two groups were scored before and after treatment.

Evaluation criteria of life quality with reference to FDDQL [9]: The scale included eight aspects: daily activity (DA), anxiety (AN), diet (DI), sleep (SL), discomfort (DT), healthy feeling (HP), disease control (CD), and stress (IS), with a total of 43 items. Patients in the two groups filled in the form carefully according to their conditions before and after treatment. The treatment was evaluated according to changes in the FDDQL scale before and after treatment. The score is positively correlated with life quality.

Gastric emptying rate of barium bars: Food and water were forbidden after 18 p.m the day before the examination. On the day of examination, 20 barium bars were taken with breakfast at 6 a.m. Then 1 bag of the foaming agent was given 5 h later. Afterward, a plain abdominal X-ray was performed to assess the gastric emptying rate of barium bars, on which the gastric emptying rate was calculated. Draining less than 10 barium bars was considered as a delayed condition and that more than 10 as normal.

Mental state and gastrointestinal function assessment: The Hamilton Anxiety Scale (HAMA) and Hamilton Depression Scale (HAMD) were used to assess the mental state of patients, and the Nipin Dyspepsia Symptom Index (NDSI) and Gastrointestinal Symptom (GIS) to evaluate the digestive function of patients.

Adverse reactions: Patients in both groups were evaluated in terms of abnormal reactions such as drug allergy, chest stuffiness and shortness of breath, and abdominal pain during the treatment. If one of the above-mentioned symptoms appeared, the data such as occurrence time, severity, and duration were recorded. If necessary or in compliance with the patients' wishes, the clinical trial could be terminated and the patients would be fol-

Table 1. Comparison of clinical effects between the two groups after four weeks of treatment (%)

Group	Number of cases	Cured	Markedly effective	Effective	No effect	Total effective rate
Treatment group	38	10 (26.3)	17 (44.7)	8 (21.1)	3 (7.9)	35 (92.1)*
Control group	38	5 (13.2)	13 (34.2)	11 (28.9)	9 (23.7)	35 (76.3)

Note: *Compared with the control group, P < 0.05.

Table 2. Comparison of scores of Chinese medicine syndrome between the two groups before and after treatment ($\bar{x} \pm s$, scores)

Group	Number of cases	Total scores	
		Before treatment	After treatment
Treatment group	38	25.03±6.33	7.55±6.00*#
Control group	38	25.79±5.42	9.65±7.96*

Note: *Compared with that before treatment in the same group, P < 0.05;

#Compared with the control group, P < 0.05.

ment, the overall scores of TCM syndromes in both groups declined (P < 0.05). The score of the treatment group declined more sharply (P < 0.05), suggesting that the treatment group enjoyed a better efficacy than the control group. See **Table 2**.

Comparison of sub-items of main symptoms between the two groups before and after treatment

Before treatment, there was no statistical difference in the scores of abdominal distension, anorexia, nausea and vomiting, and drowsiness between the two groups (all P > 0.05). After treatment, both groups showed a declining trend in the scores of these four symptoms (all P < 0.05), which demonstrated the scores in the treatment group showed a sharper decline (all P < 0.05). See **Table 3**.

Comparison of overall scores of life quality between the two groups before and after treatment

There was no significant difference in the overall scores of life quality between the two groups before treatment (P > 0.05). After treatment, the overall scores of both groups presented a rising trend (P < 0.05), indicating that the patients' life quality in both groups were improved. The treatment group presented a more notable increase (P < 0.05), suggesting that the treatment group garnered better results than the control group. See **Table 4**.

Comparison of sub-item scores of life quality between the two groups before and after treatment

In terms of the FDDQL scale, there was no significant difference in eight items including daily activity, anxiety, diet, sleep, discomfort, healthy feeling, disease control, and stress between the two groups before treatment (all P > 0.05). After treatment, both groups showed a significant increase in the scores of the above eight aspects (all P < 0.05), sug-

lowed up regularly until their conditions were stable.

Recurrence rate: One month after the treatment, patients in the two groups were followed up, and recurrence in both groups was observed. Recurrence rate = (number of relapses ÷ number of follow-up visits) × 100%.

Statistical analysis

SPSS19.0 was used to analyze the data. Measurement data were described with $\bar{x} \pm s$, and compared by the t-test. The count data were compared with the χ^2 test and the rank data by the rank-sum test. The intra-group comparison before and after treatment was performed using the paired-sample t-test and inter-group comparison by the independent sample t-test. P < 0.05 indicates a statistically significant difference.

Results

Comparison of clinical effects between the two groups after treatment

After treatment, the treatment group yielded a total effective rate of 92.1%, much higher than 76.3% of the control group (P < 0.05). See **Table 1**.

Comparison of overall scores of TCM syndromes between the two groups before and after treatment

Before treatment, the two groups obtained similar TCM syndromes (P > 0.05). After treat-

Table 3. Comparison of scores of main symptoms between the two groups before and after treatment ($\bar{x} \pm s$, scores)

Group	Number of cases	Abdominal fullness and distension		Anorexia		Nausea and vomiting		Heavy and sleepy	
		Before treatment	After treatment	Before treatment	After treatment	Before treatment	After treatment	Before treatment	After treatment
Treatment group	38	2.08±0.63	0.76±0.59* [#]	1.95±0.73	0.69±0.53* [#]	1.76±0.85	0.63±0.34* [#]	0.84±0.59	0.39±0.18* [#]
Control group	38	2.29±0.61	1.05±0.73*	1.95±0.61	0.59±0.52*	1.68±0.74	0.68±0.57*	0.82±0.57	0.59±0.31*

Note: *Compared with that before treatment in the same group, P < 0.05; [#]Compared with the control group, P < 0.05.

Table 4. Comparison of total scores of life quality between the two groups before and after treatment ($\bar{x} \pm s$, scores)

Group	Number of cases	Total scores	
		Before treatment	After treatment
Treatment group	38	56.88±8.18	80.23±7.85* [#]
Control group	38	57.86±7.70	70.36±8.80*

Note: *Compared with that before treatment in the same group, P < 0.05; [#]Compared with the control group, P < 0.05.

gesting that treatment in both groups was effective. The results of inter-group comparison demonstrated that the two groups were significantly different in the scores of daily activity, anxiety, diet, discomfort, health feeling, and disease control (all P < 0.05), but they were not significantly different in the scores of sleep and stress (both P > 0.05), indicating that TCM decoction combined with western medicine is more effective in improving patient's daily activity, anxiety, diet, discomfort, health feeling, and disease control, while less effective in optimizing sleep and stress. See **Table 5**.

Comparison of gastric emptying rate of barium bar between the two groups

No significant difference was found in the gastric emptying rate of barium bar between the two groups before treatment (P > 0.05). After treatment, the gastric emptying rates of barium bars in both groups showed a notable rising trend (P < 0.05), indicating that the gastric emptying abilities of patients in both groups were improved. The emptying rate in the treatment group showed a more notable increase (P < 0.05), suggesting that the treatment group got better treatment than the control group. See **Table 6**.

Comparison of mental states between the two groups

Scores of HAMA and HAMD between the two groups were leveled (both P > 0.05) before

treatment, but plummeted after treatment. Lower scores in the treatment group than those in the control group were observed (both P < 0.05). See **Table 7**.

Comparison of NDSR scores between the two groups

Before treatment, there was no significant difference in NDSI scores between the two groups (P > 0.05). After treatment, the NDSI scores in the treatment group were significantly higher than those in the control group (P < 0.05). See **Figure 1**.

Comparison of GIS scores between the two groups

Before treatment, there was no significant difference in GIS scores between the two groups (P > 0.05). After treatment, both groups showed a surging trend (P < 0.05). See **Figure 2**.

Adverse reactions in the two groups

No adverse reactions such as drug allergy and palpitation occurred in the patients of both groups during the treatment.

Comparison of recurrence rates between the two groups after one month of drug discontinuation

According to follow-up, the recurrence rate of the treatment group was 8.57%, with three cases of recurrence identified. That of the control group was 31.03%, with nine cases identified (P = 0.028 by the chi-square test, P < 0.05), suggesting that the treatment group had a much lower recurrence rate than the control group. See **Table 8**.

Table 5. Comparison of sub-item scores of life quality between the two groups before and after treatment ($\bar{x} \pm s$, scores)

Item	Treatment group		Control group	
	Before treatment	After treatment	Before treatment	After treatment
Daily life	59.38±8.49	84.13±8.90*.#	63.00±10.67	75.33±9.43*
Anxiety	57.78±13.08	80.53±10.58*.#	59.60±10.99	70.39±11.35*
Diet	52.41±12.50	75.58±11.35*.#	48.57±12.49	64.47±9.28*
Sleep	66.23±16.43	85.75±9.47*	73.03±13.90	81.80±11.44*
Discomfort	55.78±11.19	83.33±11.19*.#	59.43±10.95	72.00±13.02*
Health sensation	49.78±9.54	70.39±10.69*.#	51.54±12.38	63.05±12.97*
Disease control	62.71±18.86	87.50±12.81*.#	54.60±18.45	71.71±18.23*
Pressure	65.79±18.66	82.24±11.49*	60.97±18.89	79.39±12.67*

Note: *Compared with that before treatment in the same group, $P < 0.05$; #Compared with the control group, $P < 0.05$.

Table 6. Comparison of gastric emptying rate of barium bar between the two groups

Group	Number of cases	Pre-treatment	After treatment
Treatment group	38	5 (13.12)	30 (78.95)
Control group	38	6 (15.79)	26 (68.42)

Discussion

FD, a common digestive and non-lethal disease in clinical practice, with a prolonged course, inflicts negative effects on patients' daily life. At present, the pathogenesis of FD has not been fully clarified. In terms of treatment, gastrointestinal motility-promoting drugs, acid inhibitors, anti-anxiety, and depression drugs are mostly used against different clinical symptoms of FD, which can substantially alleviate the symptoms of the disease. The above clinical efficacy such as the alleviation of symptoms is considered superficial in terms of radical treatment and a resounding elimination of the negative impact of FD. TCM has a long history in the treatment of spleen and stomach diseases, with a unique theoretical system and advantages [10-12].

The results of this study showed that the treatment group showed a remarkably higher total effective rate and gastric emptying rate of barium bars than the control group, indicating that *Tiaoqi Jiangni* Decoction combined with mosapride citrate tablets could improve the clinical efficacy and the gastric emptying rate as well in the treatment of FD. The two groups demonstrated a falling score in abdominal distension, anorexia, nausea and vomiting, and

drowsiness after treatment. The lower scores of the control group than those of the treatment group demonstrated that the combination of TCM decoction and mosapride could significantly ease the clinical symptoms of patients and restore the function of the spleen and stomach.

According to different clinical symptoms, it can be classified into "fullness", "stomach pain" and "poor appetite" in TCM. Opinions from an array of medical institutions suggest *Qi* disorder as the basic pathogenesis of FD. It is stated in the *On Jutong Lun* that "all diseases are secondary to the disorder of *Qi*" [13]. The ascending, descending, exiting, and entering of *Qi* are the basic forms of human life activities. *Qi* movement disorder can disturb human life activities. In the *Canon of Internal Medicine*, *Qi* movement disorder is regarded as the basic pathogenesis of a majority of diseases, by which FD, a common and typical disease, is triggered. In TCM, the understanding of this disease is mostly expounded from *Qi* [14-16]: Unfavorable *Qi* movement leads to disorder of spleen and stomach ascending and thus compromises people's health. Phlegm-dampness, stagnation, and blood stasis with the development of FD can aggravate the disease [17]. In view of its basic pathogenesis, *Tiaoqi Jiangni* Decoction was used in the present study to treat FD by "regulating *Qi*". This recipe is an empirical one derived from the ancient recipe *Erchen* decoction combined with inula and ochre decoction. *Erchen* Decoction, derived from *Hejiju Recipes*, has been used for eliminating dampness and phlegm, regulating *Qi*, and harmonizing the internal environment. In the prescription, *Rhizoma Pinelliae* is used for

Table 7. Comparison of mental states between the two groups

Group	Number of cases	HAMA score		HAMD score	
		Before treatment	After treatment	Before treatment	After treatment
Treatment group	38	24.16±3.28	11.25±1.47*.#	22.15±3.22	8.26±1.32*.#
Control group	38	23.36±4.42	8.22±1.34*	23.98±4.01	5.88±1.06*

Note: *Compared with that before treatment in the same group, P < 0.05; #Compared with the control group, P < 0.05.

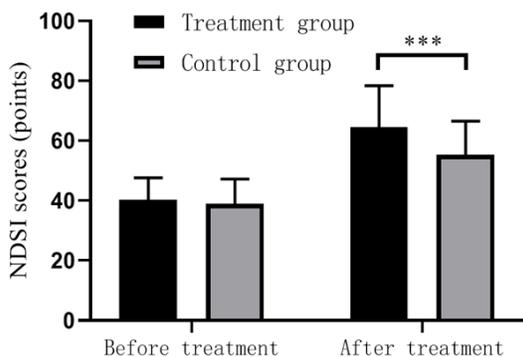


Figure 1. Comparison of NDSI scores between the two groups; *** represents P < 0.001.

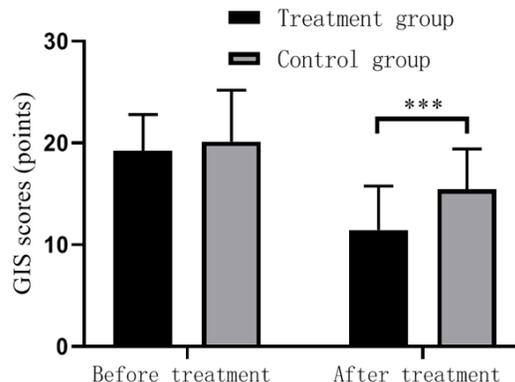


Figure 2. Comparison of GIS scores between the two groups; *** represents P < 0.001.

drying dampness, activating spleen, and stopping vomiting, Pericarpium Citri Reticulatae for regulating Qi and resolving stagnation, drying dampness, and resolving phlegm in combination with Rhizoma Pinelliae, and Poria cocos and Spleen-Strengthening herbs are used to stem the source of phlegm and the power of draining dampness to help resolve phlegm. The combination of the three herbs demonstrated the efficacy of Qi regulation and phlegm resolving. Inula and ochre decoction derived from Article 161 of *Treatise on Febrile and Miscellaneous Diseases* included inula flower, ochre, and pinellia tuber. Inula flower is used to reduce stress and eliminate phlegm, and calcined ochre to reduce stress. The two drugs are combined with Rhizoma Pinelliae to harmonize the stomach and mitigate stress. Modern pharmacological research has pointed out the effectiveness of inula and ochre decoction in the promotion of gastrointestinal motility, inhibiting acid, and relieving vomiting [18]. Bamboo shavings can clear away heat and dissolve phlegm to stop vomiting and relieve restlessness. Radix Paeoniae Rubra can clear away heat and cool blood, dispersing blood stasis and thus relieving pain and activating blood, without damaging the internal environment [19]. Radix Linderae is effective for Qi movement and pain relief, as mentioned in the

Compendium of Materia Medica that “it can be used for patients suffering unpleasant feeling in the chest and abdomen”. Radix Curcumae can take effect in blood activation, pain, and depression relief, liver and gallbladder dredging, and Qi movement. Acorus gramineus soland is beneficial to intelligence and the mind and dissolves dampness and stimulates appetite. The combined use of all these herbs can alleviate Qi inversion, activate blood, and dissipate mass, playing a role in invigorating the spleen, harmonizing the stomach, sorting Qi movement, and restoring the function of the spleen and stomach.

The basis of functional dyspepsia lies in the weakness of the spleen and stomach, with the pathogenesis of the stagnation of liver Qi. Delayed or missed treatment may result in the recurrence of the disease which impairs the normal body function for the long run. Specifically, the invasion of the evil of damp-heat from the body surface in the initial stage or the liver-Qi stagnation offends the spleen and stomach, which are considered excess syndromes. Prolonged treatment will lead to the weakening and even deficiency and coldness of the spleen and stomach. The comorbidity with external evils or Qi stagnation, the defi-

Table 8. Comparison of recurrence rates between the two groups after one month of drug discontinuation

Group	Number of cases	Recur times	Recurrence rate (%)	P value
Treatment group	35	three	8.57	0.028
Control group	29	nine	31.03	

ciency-excess in complexity, the cold-heat in complexity, give rise to gastric pain and burning sensation, flatulence after meals, hyperacidity, loss of appetite, nausea and vomiting, sallow complexion, and cold limbs, which is formidable for full recovery [20]. The use of Tiaoqi Jiangni Decoction can soothe the liver and regulate the Qi, invigorate the spleen and stomach, clear away heat and dispel dampness, and treat functional dyspepsia according to the principle of holistic concept, which is essential for improving the symptoms of patients with functional dyspepsia [21]. This study showed that the quality of life, sleep, stress, and mood of the patients in the study group are significantly better than those in the control group, which proves the promising treatment efficacy of Tiaoqi Jiangni Decoction on patients' physical diseases and a contributory effect for solving psychological problems, which is consistent with previous research results. There was no adverse reaction in the two groups, indicating the safety of the combined treatment. For recurrence rate, the treatment group showed a significantly lower one than the control group, verifying better effectiveness of the combined treatment for the long run.

In summary, *Tiaoqi Jiangni* Decoction combined with mosapride citrate tablets yields a promising clinical effect in the treatment of FD, as it ensures milder clinical symptoms, faster recovery, higher quality of life, and lower recurrence rate, without adverse reactions. This study is limited by the small number of cases included in this study and the lack of a large sample and multi-center clinical research, which requires more cases included in future clinical studies to observe the long-term efficacy.

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Disclosure of conflict of interest

None.

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