Proceedings of Anticancer Research, 2024, Volume 8, Issue 1
http://ojs.bbwpublisher.com/index.php/PAR
ISSN Online: 2208-3553
ISSN Print: 2208-3545

Jianpi Fuzheng Decoction in the Treatment of Gastric Cancer-Related Fatigue

Weiwei Liu[1], Xiaobing Qin[2], Haiyan Wang[1], Xiao Chen[1], Yanqing Liu[3]*

[1]Xuzhou Tongshan Traditional Chinese Medicine Hospital, Xuzhou 221116, Jiangsu Province, China
[2]The Affiliated Hospital of Xuzhou Medical University, Xuzhou 221116, Jiangsu Province, China [3]Yangzhou University, Yangzhou 225001, Jiangsu Province, China

***Corresponding author:** Yanqing Liu, 18752148841@163.com

Abstract: *Objective:* To observe the clinical effects of Jianpi Fuzheng Decoction in patients with gastric cancer and cancer-related fatigue (CRF). *Methods:* Using the random number table method as a reference, 68 cases of gastric CRF were randomly divided into two groups. One group served as the control group and received basic treatment, while the other was the observation group. The observation group, in addition to the control group's treatment, received Jianpi Fuzheng Decoction. The clinical treatment effectiveness, fatigue scores, immune function indicators, and treatment safety were compared between the two groups. *Results:* The total clinical treatment effectiveness of the observation group and the improvement in immune function indicators after treatment were higher than those of the control group. The fatigue score after treatment was lower in the observation group than in the control group ($P < 0.05$). No serious adverse reactions occurred during the treatment in either group. *Conclusion:* Jianpi Fuzheng Decoction can enhance the clinical treatment effectiveness for gastric cancer patients with CRF. It facilitates the acceleration of fatigue symptom improvement and immune function enhancement. The medication's safety is guaranteed, making it worthy of promotion.

Keywords: Jianpi Fuzheng Decoction; Gastric cancer; Cancer-related fatigue; Clinical effect

Online publication: January 26, 2024

1. Introduction

Gastric cancer, a malignant tumor with high clinical incidence, is commonly treated using clinical approaches such as radiotherapy, chemotherapy, and surgery. While these methods offer a certain life-extending effect, they also result in varying degrees of bodily damage. Severe cases of gastric cancer may lead to psychological issues, including cancer-related fatigue (CRF), a fatigue type induced by cancer or its related treatment, negatively impacting daily life. Unlike the fatigue experienced by healthy individuals, CRF is challenging to predict and alleviate, persisting for extended periods. Without timely and effective symptomatic interventions, the prolonged state of CRF can diminish a patient's enthusiasm for treatment, thereby affecting the overall clinical efficacy [1].

In recent years, with the growing attention to traditional Chinese medicine (TCM) in clinical practice,

numerous studies have indicated that it can effectively address CRF by leveraging its ability to treat both the root cause and the symptoms. TCM identifies CRF, based on its clinical manifestations, as belonging to the category of "deficiency." This suggests that the disease's occurrence is primarily influenced by the disharmony of the spleen and stomach, organ deficiency, and insufficient qi and blood. Long-term deficiency leads to fatigue, resulting in persistent weariness. In this context, timely reinforcement of the spleen and stomach, strengthening the body, dispelling "evils," and promoting blood circulation and qi become crucial [2].

Jianpi Fuzheng Decoction is a prescription well-suited for "spleen deficiency." Clinical practices have shown its effectiveness in improving symptoms such as fatigue, loss of appetite, and more. However, the existing research data on the clinical value of this prescription in addressing CRF is still relatively limited. Thus, this article focuses on a study involving 68 cases of gastric CRF, aiming to explore the clinical benefits obtained through the targeted application of Jianpi Fuzheng Decoction during their treatment.

2. Materials and methods

2.1. General information

A total of 68 cases of gastric CRF were enrolled within the specified research timeframe (commencing in March 2020 and concluding in October 2022). Employing the random number table method as a reference, a standardized grouping operation was executed, resulting in 34 cases per group. This control group comprised 18 males and 16 females, with an age range of 35–76 years and an average age of 55.56 ± 8.14 years. The disease duration ranged from 3 to 8 months, with a mean duration of 5.51 ± 2.05 months. Clinical staging distribution was as follows: stage II: stage III: stage IV = 6:18:10.

In the observation group, there were 20 males and 14 females, with ages ranging from 35 to 75 years and an average of 55.51 ± 8.10 years. The disease duration ranged from 2 to 8 months, with an average of 5.22 ± 1.99 months. Clinical staging distribution was as follows: stage II: stage III: stage IV = 5:20:9. After a standardized comparison of data between groups, no significant differences were found ($P > 0.05$).

Inclusion criteria included patients complying with relevant diagnostic standards for gastric cancer in "Internal Medicine" [3] and "Guiding Principles for Clinical Research of New Traditional Chinese Medicines" [4], confirming gastric cancer through clinical pathology, cytology, and other examinations, adhering to the definition of CRF in the 10th edition of the International Classification of Diseases (ICD-10), having stable condition with no missing medical records, having Karnofsky Performance Status (KPS) score > 60 points and an expected survival time of ≥ 3 months, no history of mental, cognitive, or psychological diseases, or cardiovascular and cerebrovascular diseases, as well as informed and voluntarily signing relevant documents.

Exclusion criteria included patients with fatigue symptoms due to poor cardiopulmonary function, pregnant and lactating women, those concurrently undergoing other clinical experiments, individuals intolerant to drugs in this study or experiencing allergic reactions, patients with low compliance, and those who dropped out of the research midway.

2.2. Method

Upon admission to the hospital, both groups underwent basic treatment plans tailored to their individual conditions. This encompassed utilizing oral, graphic, text, and video education to empower patients with disease-related health knowledge. Patients diligently adhered to the doctor's instructions, employed relevant treatment drugs judiciously, and monitored for potential adverse reactions. Additionally, healthcare professionals actively engaged in friendly communication, providing emotional support, mindfulness intervention, family support, social support, and other psychological treatments. Patients were encouraged to cultivate healthy

eating and living habits, engaging in appropriate and effective daily activities. Aerobic exercise therapy was incorporated to enhance physical fitness and regulate negative psychological emotions.

The observation group, comprising 34 enrolled cases, incorporated Jianpi Fuzheng Decoction into their treatment regimen. The basic prescription consisted of 30 g of *Astragalus membranaceus*, 20 g each of *Pseudostellaria heterophylla* root (Pseudostellariae radix) and *Atractylodis macrocephalae* rhizome (Macrocephalae rhizoma), 15 g of *Poria cocos* (Indian Bread or Poria), 10 g each of Longan Arillus, ginseng, *Ziziphus jujuba* seed (spine date seed), *Aucklandia lappa* root (Aucklandiae radix), and *Polygala tenuifolia* root (Polygalae radix), and 5 g of *Glycyrrhiza uralensis* root (Glycyrrhizae radix preparata). This was administered as one dose, boiled with approximately 800 mL of water daily until approximately 400 mL remained. Patients consumed 200 mL of the warm decoction 30 minutes after meals in the morning and evening.

The control group, consisting of 34 enrolled cases, received a Jianpi Fuzheng Decoction simulation agent (drug content ≤ 5%) for treatment. This was administered orally, with one pack (200 mL/pack) taken twice daily, 0.5–1 hour before meals in the morning and evening. Both groups continued medication for two courses, with each course lasting 21 days.

2.3. Observation indicators

(1) Effective clinical treatment: In accordance with the "Guiding Principles for Clinical Research of New Traditional Chinese Medicines," the TCM syndromes of both groups were compared before and after treatment. These syndromes included fatigue and tiredness, poor appetite, abdominal distension after eating, sallow complexion, abnormal stools, light mouth and lack of thirst, edema of limbs, nausea, and vomiting. Each symptom was scored as "0, 1, 2, 3" in the order of "none, mild, moderate, and severe." The higher the points obtained, the more severe the symptom. The reduction rate of TCM syndrome points was calculated using the formula (TCM syndrome points before treatment – TCM syndrome points after treatment) ÷ TCM syndrome points before treatment × 100%. The clinical treatment effectiveness was then evaluated as follows: (i) Markedly effective: Relevant clinical symptoms significantly improved, with a reduction rate of TCM syndrome points > 70%; (ii) Effective: Relevant clinical symptoms relatively improved, with a reduction rate of TCM syndrome points between 30% and 70%; (iii) Ineffective: The content did not meet the above standards.

(2) Level of fatigue: The Revised Piper Fatigue Scale (RPFS) was utilized before and after treatment to scientifically assess the fatigue symptoms of both groups. The form consists of 24 items, with each item scored on a scale of 0–10 points. The score correlates with the level of fatigue.

(3) Immune function indicators: T lymphocyte subpopulations (CD3+, CD4+, CD4+/CD8+) were measured in both groups before and after treatment. The results were compared, and each indicator's normal reference value range was defined as follows: CD3+ cells: 770–2,860 cells/μL; CD4+ cells: 44–1,440 cells/μL; CD4+/CD8+: 0.7–2.87.

(4) Treatment safety: Throughout the treatment period for both groups, regular reviews of blood routine, stool routine, liver and kidney function, etc., were conducted, and the incidence of adverse reactions was meticulously recorded.

2.4. Statistical analysis

Statistical analysis was conducted using SPSS 25.0 for Windows software as the basis. All acquired data were categorized by nature. If the data fell under measurement data, it was presented as mean ± standard deviation (SD), and a parallel *t*-test was performed. For count data, it was presented as %, and the chi-squared test was

performed. A final *P* value less than 0.05 indicated a statistically significant difference.

3. Results

3.1. Comparison of clinical treatment effectiveness between the two groups

Table 1 shows that the total clinical treatment effectiveness of the observation group was significantly higher than that of the control group ($P < 0.05$).

Table 1. Comparison of clinical treatment effectiveness observation results [*n* (%)]

Group	Markedly effective	Effective	Ineffective	Total effective rate
Control group ($n = 34$)	7 (20.59)	18 (52.94)	9 (26.47)	25 (73.53)
Observation group ($n = 34$)	12 (35.29)	20 (58.82)	2 (5.88)	32 (94.12)
χ^2	-	-	-	5.314
P	-	-	-	0.021

3.2. Comparison of fatigue scores between the two groups

As shown in **Table 2**, there was no statistical significance in scoring the fatigue degree between the groups before treatment ($P > 0.05$). However, after treatment, the RPFS score of the observation group was significantly lower than that of the control group ($P < 0.05$).

Table 2. Comparison of RPFS scores (mean ± SD, points)

Group	Before treatment	After treatment
Control group ($n = 34$)	136.98 ± 25.89	155.01 ± 28.78
Observation group ($n = 34$)	135.87 ± 25.04	129.45 ± 20.45
t	0.180	4.221
P	0.858	0.001

3.3. Comparison of immune function indicators between the two groups

Before the treatment, the immune function indicators of both groups were similar ($P > 0.05$), but the observation group had greater improvement after treatment as compared to the control group ($P < 0.05$), as shown in **Table 3**.

Table 3. Comparison of observed values of immune function indicators (mean ± SD)

Group		CD3+ (cells per μL)	CD4+ (cells per μL)	CD4+/CD8+
Control group ($n = 34$)	Before treatment	703.55 ± 85.65	358.32 ± 61.25	1.12 ± 0.38
	After treatment	712.05 ± 90.45	360.28 ± 62.21	1.20 ± 0.42
Observation group ($n = 34$)	Before treatment	703.95 ± 85.99	358.87 ± 61.55	1.14 ± 0.39
	After treatment	775.14 ± 108.65	401.25 ± 69.69	1.55 ± 0.54
t	Before treatment	0.019	0.037	0.214
	After treatment	2.602	22.797	2.983
P	Before treatment	0.985	0.971	0.831
	After treatment	0.011	0.001	0.004

3.4. Comparison of treatment safety between the two groups

After treatment, no serious adverse reactions were observed during the treatment in both groups.

4. Discussion

In China, there are noticeable differences in the incidence of gastric cancer among various regions. Compared with the southern region, individuals in the eastern coastal and northwest regions are more prone to developing this disease, a phenomenon attributed to their penchant for pickled, smoked, and grilled foods. Additionally, numerous studies have affirmed that factors such as genetics, *Helicobacter pylori* infection, long-term heavy smoking, and precancerous lesions significantly contribute to the onset of gastric cancer [5].

Since gastric cancer often lacks apparent clinical symptoms in its early stages, it is frequently overlooked by patients. However, as lesions persist and potentially metastasize to distant areas, they can lead to pain, weight loss, hematemesis, melena, peritoneal irritation, and severe symptoms such as jaundice and anemia, posing a threat to an individual's life.

CRF is an adverse symptom commonly accompanying cancer patients. While the cause and mechanism of its occurrence remain unclear, it is generally believed that the joint effect of cancer and related treatment behaviors plays a pivotal role in its development. In the past, clinical treatments for CRF primarily relied on conventional medication coupled with psychotherapy, diet therapy, exercise therapy, and other methods, yielding minimal overall results [6].

According to the results in **Tables 1** and **2** of this article, the total clinical treatment effectiveness of the observation group reached 94.12%, significantly higher than the 73.53% observed in the control group. The RPFS score of the observation group after treatment was lower, indicating that increased application of TCM can further alleviate patients' fatigue symptoms and significantly enhance the effectiveness of clinical treatment. The analysis reveals that CRF is categorized as a "deficiency" from the perspective of traditional Chinese and Western medicine. Following the principle of "replenishing deficiencies," this article utilizes the method of strengthening the spleen and the body through a decoction. *Astragalus membranaceus* and Longan Arillus, the principal ingredients in the prescription, primarily strengthen the spleen and replenish qi. Ministerial ingredients, such as ginseng, Pseudostellariae radix, and Macrocephalae rhizoma, further contribute to replenishing qi, activating blood circulation, and strengthening the spleen and stomach. Adjuvants such as Aucklandiae radix, Polygalae radix, spine date seed, and Poria calm the mind, nourish and activate blood, stimulate the spleen, and regulate and calm qi. Glycyrrhizae radix preparata, a conducted ingredient, strengthens the principal ingredients' effects and coordinates various components, promoting blood circulation, dispelling blood stasis, removing dampness, promoting qi, strengthening the spleen, and harmonizing the heart [7,8].

From the standpoint of modern pharmacology, the flavonoids, polysaccharides, saponins, and other components in *Astragalus membranaceus* can assist in the rational distribution of T lymphocyte subpopulations, thereby improving immunity. The polysaccharides in Poria can inhibit immune system aging and enhance the function of hematopoietic cells, thus improving physical fitness and nutritional status [9]. **Table 3** confirms that compared with the control group, the immune function indicators of the observation group improved more significantly after treatment, suggesting that Jianpi Fuzheng Decoction can indeed help correct the immune dysfunction caused by CRF and promote effective improvement in patients' physical health.

Applying Jianpi Fuzheng Decoction to patients with gastric CRF alongside conventional treatment can significantly enhance clinical treatment efficiency, accelerate the improvement of fatigue symptoms and immune function, and does not cause serious adverse reactions. It is strongly recommended for vigorous promotion.

Funding

2021 Open Project of the Key Research Office of the State Administration of Traditional Chinese Medicine "Treatment of Toxins and Evils in Gastric Cancer," "Research on the Effect and Related Mechanisms of Jianpi Fuzheng Decoction in Improving Fatigue Related to Advanced Gastric Cancer," (No. 202138); 2022 Xuzhou Key R&D Plan (Social Development) Project - Medical and Health Care, "Research on the Clinical Application of Jianpi Fuzheng Decoction in the Treatment of Cancer-Related Fatigue," (No.: KC22276)

Disclosure statement

The authors declare no conflict of interest.

References

[1] Wang L, Dai Z, 2023, Clinical Study on Jianpi Yangrong Decoction in Treating Cancer-Induced Fatigue in Gastric Cancer. Inner Mongolia Traditional Chinese Medicine, 42(4): 40–41.

[2] Zhu L, Guo L, Mao Z, et al., 2019, Effects of Jianpi Yishen Jiedu Recipe Combined with Chemotherapy on Cancer-Related Fatigue and Immune Function in Patients with Intermediate and Advanced Gastric Cancer. Journal of Microcirculation, 29(3): 39–44 + 48.

[3] Ge J, Xu Y, Wang C, 2018, Internal Medicine. 9th Edition. People's Medical Publishing House, Beijing, 364–367.

[4] Zheng X, 2002, Guiding Principles for Clinical Research of New Traditional Chinese Medicines. China Medical Science and Technology Press, Beijing.

[5] Xie Y, Li L, Miao W, et al., 2020, Effect of Buzhong Yiqi Decoction on Cancer-Related Fatigue and Quality of Life in Patients with Advanced Gastric Cancer. Laboratory Medicine and Clinic, 17(23): 3455–3458.

[6] Wang Y, 2022, Clinical Study on the Treatment of Cancer-Related Fatigue in Gastric Cancer with Spleen Deficiency Type by Jianpi Fuzheng Decoction, thesis, Shandong University of Traditional Chinese Medicine.

[7] Zhuang X, 2022, Effect of Fuzheng Jianpi Decoction Combined with Chemotherapy on Patients with Postoperative Colorectal Cancer. Chinese and Foreign Medical Research, 20(24): 122–126.

[8] Wei B, Liu Y, 2022, Effect of Jianpi Fuzheng Decoction on Immune Function and Quality of Life in Elderly Patients with Advanced Gastric Cancer Undergoing Chemotherapy. Reflexology and Rehabilitation Medicine, 3(23): 16–19.

[9] Yang Y, Wang W, Zeng L, 2019, Effect of Jianpi Fuzheng Decoction on Liver Function and Immune Indicators in Patients with Advanced Primary Liver Cancer. Guizhou Medicine, 43(2): 242–243.