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Analysis of the Effects of the Addition and Subtraction Therapy of Jianpi Jiedu Decoction on T-lymphocyte Subpopulations' Changes in Colorectal Cancer Patients' Clinical Symptoms

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Abstract: *Objective:* To investigate the clinical efficacy of applying the addition and subtraction of Jianpi Jiedu decoction (JPJD) in patients suffering from colorectal cancer and changes in their clinical symptoms. *Methods:* Seventy-two colorectal cancer cases were selected and randomly divided into the control group and the observation group, where both groups received the same comprehensive treatment and chemotherapy intervention after surgery. The observation group received the addition and subtraction therapy of JPJD based on the control group. The Chinese medicine (TCM) symptom scores, the intestinal bacterial flora, and the changes in the T-lymphocyte subsets of the two groups were compared. *Results:* The observation group had lower TCM evidence points, more *Escherichia coli*, less Bifidobacterium and Lactobacillus, and higher T-lymphocyte subpopulation levels than that of the control group after treatment ($P < 0.05$). *Conclusion:* The application of addition and subtraction therapy of JPJD in conjunction with postoperative radiotherapy for colorectal cancer patients further improved the patient's clinical symptoms and intestinal flora environment, and effectively enhanced their immunity. which is worthy of promotion.

Keywords: Jianpi Jiedu formula; Colorectal cancer; Clinical symptoms; T-lymphocyte subpopulation

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1. Introduction

Colorectal cancer is the collective name of colon cancer and rectal cancer. It is a highly prevalent malignant tumor in China with a relatively high fatality rate of about 20% [1]. Currently, surgery with adjuvant radiotherapy is the optimal treatment plan for colorectal cancer. When combined with postoperative radiotherapy, it can continuously inhibit the proliferation of tumors, thus increasing the patient's chance of survival. However, both the invasive damage caused by surgery and a series of toxic side effects caused by radiotherapy can adversely impact the internal environment of the gastrointestinal tract and further exacerbate the symptoms of spleen deficiency. Subsequently, these symptoms prompt a continuous decline in the body's immune system, and

if not effectively intervened promptly, will hinder the recovery process of the patients. In severe cases, the disease may recur again [2]. From the perspective of traditional Chinese medicine (TCM), colorectal cancer is categorized as "blood in stool," "dirty poison," etc. Its occurrence is related to the accumulation of dampness and toxins in the intestines caused by dietary irregularities, emotional disorders, and a weak spleen. Surgery can further exacerbate fluid loss and deplete qi, resulting in the loss of a balanced gastric function. This complicates the production of qi and intestinal bacterial flora, increasing the risk of recurrence [2]. Therefore, this study focused on applying Jianpi Jiedu decoction (JPJD) with additions and subtractions to investigate its effectiveness in treating colorectal cancer patients. 72 cases have been selected as the study subjects. The details have been described in the following [3].

2. Information and methods

2.1. Data

Seventy-two patients with colorectal cancer who were admitted from February 2020 to May 2023 were selected and grouped into a control group and an observation group, with 36 cases each. The control group consisted of 25 males and 11 females aged 48–84 years old, with an average of 66.35 ± 8.92 years. The duration of the disease was 1–6 years, with a mean duration of 3.02 ± 1.21 years. The clinical staging of Stage II: Stage III: Stage IV was in the ratio of 14:20:2. There were 19 and 17 cases of colon cancer and rectal cancer, respectively. The observation group consisted of 24 males and 12 females aged 46–85 years old, with an average age of 65.96 ± 8.84 years. The disease duration was 1–5 years, with a mean duration of 2.99 ± 1.18 years. The clinical staging of Stage II: Stage III: Stage IV was in the ratio of 12:21:3. There were 17 and 9 cases of colon cancer and rectal cancer, respectively. The data between the groups were not significantly different after normalized comparison ($P > 0.05$).

Inclusion criteria: (1) Satisfy the relevant diagnostic criteria of the Chinese Diagnostic and Therapeutic Criteria for Colorectal Cancer (2017 Edition) [4] and the Guidelines for Clinical Research of New Chinese Medicines (for Trial Implementation) [5]; (2) obtained a score of more than 60 in the Kahn's Functional Status Scale (KPS); (3) meet the relevant therapeutic indications of surgery, postoperative radiotherapy, and chemotherapy; (4) have an expected survival time of ≥ 6 months; (5) able to communicate normally; (6) consented. Exclusion criteria: (1) Pregnant and lactating women; (2) distant metastasis; (3) presence of other malignant tumors; (4) hematologic and immune system diseases; (5) serious dysfunction of heart, brain, kidney, and other important organs; (6) contraindications to surgery, radiotherapy, and chemotherapy; (7) intolerance or allergy to the study drugs; (8) low compliance; (9) dropped out of the study halfway.

2.2. Methods

After both groups were admitted to the department, surgical treatment was carried out by the same medical team, and postoperative interventions such as anti-infection, nutritional support, gastrointestinal decompression, etc. were implemented according to the specific conditions of the patients, based on the CapeOX chemotherapy program that was carried out in the two groups. For the control group, on the first postoperative day, 130 mg/m^2 oxaliplatin (injectable preparation, State Drug License: H20094158, Manufacturer: Yangzijiang Pharmaceutical Group Co. Group Co., Ltd, specification: 50 mg) was used for intravenous drip treatment. On the 1st to 14th day, 1000 mg/m^2 capecitabine (tablets, State Drug License: H20133361, manufacturer: Qilu Pharmaceutical Co., Ltd, specification: 500 mg) was taken orally twice daily and the treatment was continued for 3 weeks. The observation group was given the addition and subtraction therapy of JPJD based on the control group. The JPJD decoction consisted of *Astragalus membranaceus* (30 g), Hedyotis diffusa (30 g), dandelion (25 g), Coix

lacryma-jobi (20 g), *Semen coicis* (20 g), *Cynanchum paniculatum* (15 g), fried atractylodes macrocephala (12 g), Poria (12 g), chenpi (6 g), with the addition and subtraction of ingredients according to the disease. For abdominal distension, 12 g of *Citrus sinensis* shells was added; for abdominal pain, 12 g *Corydalis yanhuosuo* was added; for those with loose stool, 12 g *Rhizoma atractylodis* was added. Every day, 800 mL water was added to 1 dose of the prescription decocted until 300 mL, where it was then taken twice a day, 150 mL each time, with warm water for 3 weeks.

2.3. Observation indicators

(1) TCM symptom points

Based on the Guiding Principles for Clinical Research of New Chinese Medicines, points were allocated to the primary symptoms (night sweats, nausea, tiredness of limbs) and secondary symptoms (intestinal sounding, abdominal distension, belching) of the two groups. The primary symptoms were given points of 0, 2, 4, and 6 according to the sequence of "none, mild, moderate, and severe," and the secondary symptoms were given points of 0, 1, 2, and 3 according to the same sequence. The points corresponded to the severity of the related symptoms.

(2) Intestinal flora

Before and after the implementation of the treatment plan, 0.5 g of fresh feces was collected from both groups and placed on a culture medium, and the QXC-500 automatic colony counter was applied to detect the specific number of *Escherichia coli*, Bifidobacteria, and Lactobacillus.

(3) T-lymphocyte subpopulation level

Before and after the therapeutic matters were carried out, 5 mL of fasting venous blood was extracted from both groups, and the specific values of CD3+, CD4+, and CD4+/CD8+ were measured by enzyme-linked immunosorbent assay.

2.4. Statistical analysis

Based on the SPSS 25.0 for Windows software, the observed data were compared normatively. The measurement data were expressed as mean ± standard deviation and compared using the *t*-test. Count data were expressed as % and analyzed using the chi-squared (χ^2) test. Results were considered statistically significant at $P < 0.05$.

3. Results

3.1. Comparison of Chinese medicine symptoms points between the two groups

As shown in **Table 1**, the TCM symptom points of the two groups before treatment were compared, and there was no difference ($P > 0.05$). The total TCM symptom points of the observation group were significantly lower than those of the control group after the treatment ($P < 0.05$).

3.2. Comparison of intestinal flora between the two groups

As shown in **Table 2**, after treatment, the number of *Escherichia coli* in the observation group was significantly higher than that of the control group, and the number of bifidobacteria and lactobacilli was significantly lower than that of the control group ($P < 0.05$).

3.3. Comparison of T-lymphocyte subpopulation levels between the two groups

As shown in **Table 3,** after treatment, the T-lymphocyte subpopulation levels of the observation group were significantly higher than those of the control group ($P < 0.05$).

Table 1. Comparison of the observed results of TCM evidence points (mean ± standard deviation, points)

Group	Period	Primary symptoms	Secondary symptoms	Total points
Control group (n = 36)	Before treatment	14.05 ± 5.28	6.96 ± 2.15	21.06 ± 8.46
	After treatment	8.25 ± 2.69	3.85 ± 0.92	12.21 ± 4.89
Observation group (n = 36)	Before treatment	13.96 ± 5.20	6.85 ± 2.09	20.54 ± 8.29
	After treatment	4.69 ± 1.74	1.85 ± 0.36	6.58 ± 1.88
t	Before treatment	0.073	0.220	0.263
	After treatment	6.667	12.147	6.448
P	Before treatment	0.942	0.826	0.793
	After treatment	0.001	0.001	0.001

Table 2. Comparison of intestinal flora between the two groups (mean ± standard deviation, logCFU/g)

Group	Period	*Escherichia coli*	Bifidobacterium	Lactic acid bacteria
Control group (n = 36)	Before treatment	7.56 ± 2.56	8.55 ± 3.56	8.28 ± 3.24
	After treatment	7.92 ± 3.22	7.59 ± 2.58	6.54 ± 2.18
Observation group (n = 36)	Before treatment	7.59 ± 2.58	8.49 ± 3.49	8.30 ± 3.28
	After treatment	9.74 ± 4.11	5.01 ± 1.45	5.12 ± 1.51
t	Before treatment	0.050	0.072	0.026
	After treatment	2.091	5.231	3.213
P	Before treatment	0.961	0.943	0.979
	After treatment	0.040	0.001	0.002

Table 3. Comparison of T-lymphocyte subpopulations between the two groups (mean ± standard deviation)

Group	Period	CD3+ (%)	CD4+ (%)	CD4+/CD8+
Control group (n = 36)	Before treatment	51.95 ± **5.45**	37.11 ± **2.98**	1.31 ± 0.28
	After treatment	53.85 ± **7.69**	39.38 ± **4.25**	1.42 ± 0.51
Observation group (n = 36)	Before treatment	52.01 ± **5.49**	37.18 ± **3.02**	1.34 ± 0.30
	After treatment	58.62 ± **9.68**	42.12 ± **5.89**	1.78 ± 0.79
t	Before treatment	0.047	0.099	0.439
	After treatment	2.315	2.263	2.297
P	Before treatment	0.963	0.921	0.662
	After treatment	0.024	0.027	0.025

4. Discussion

The occurrence of colorectal cancer is related to many factors, including chronic inflammation of the colon, adenoma or heredity, environment, and poor dietary habits (high-fat and low-fiber diet). During the initial stages, patients usually do not exhibit obvious symptoms and some of them only have slight indigestion or fecal occult blood. However, with the continuous enlargement of the tumor, or even infiltration and distant

metastasis, it can cause abdominal mass, abdominal pain, bloody stool, intestinal obstruction, fever, emaciation, anemia, and other symptoms. At the same time, the corresponding clinical symptoms can be triggered according to the organs involved in the lesion [6]. Surgery is one of the most intuitive and effective interventions for colorectal cancer, which can remove lesions to prevent the continuous progress of the disease. When combined with postoperative chemotherapy programs, it can greatly reduce the risk of disease recurrence and improve the patient's quality of life. Nonetheless, the disease has already caused different degrees of damage to the patient's gastrointestinal system and immune function. If coupled with the stressful trauma of surgery and the toxic side effects of chemotherapy, it may lead to gastrointestinal dysfunction such as tinnitus and abdominal distension, as well as complications such as infections and cystitis, thus greatly reducing the effectiveness of the clinical treatment. Therefore, it is necessary to focus medication usage on improving the clinical symptoms and promoting the recovery of gastrointestinal function [7].

This study showed that the observation group had lower TCM symptom scores and higher levels of intestinal flora and T-lymphocyte subpopulations than the control group, suggesting that the formula of JPJD can help accelerate the improvement of clinical symptoms and immune function. *Vincetoxicum paniculatum* can play the role of clearing heat and removing toxins by acting as an analgesic and expectorant; *Coix lacryma* and *Semen Coicis* can work together to detoxify the liver and stomach, clear heat, and dry dampness; chenpi can regulate qi, tonify the spleen, and dry dampness to strengthen the spleen and eliminate toxins [8,9]. Qiu showed that the JPJD decoction effectively inhibited the mRNA expression of the lesion through mitogen-activated protein kinases (MAPK) and P13K-Akt signaling pathways to regulate the tumor microenvironment better and inhibit the proliferation and metastasis of the tumor cells [10].

5. Conclusion

The application of JPJD in conjunction with postoperative chemotherapy in colorectal cancer patients helped improve their clinical symptoms, intestinal microecology, and immune function. It is recommended to be vigorously promoted.

Disclosure statement

The authors declare no conflict of interest.

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