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Clinical Efficacy of Modified Gegen Qinlian Decoction Combined with Probiotics in Treating Radiation Enteritis and Its Regulatory Effect on Intestinal Flora

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Abstract: Objective: To investigate the clinical efficacy of Modified Gegen Qinlian Decoction combined with probiotics (Clostridium butyricum live capsules) in treating radiation enteritis (RE) in tumor patients, as well as its regulatory effect on the structure of intestinal flora, providing clinical evidence for the integrated traditional Chinese and Western medicine treatment of radiation enteritis. Methods: A total of 40 patients with radiation enteritis admitted to the Oncology Department of Linfen Central Hospital from September 2023 to December 2024 were selected and divided into an observation group and a control group according to the random number table method, with 20 cases in each group. The control group was treated with Clostridium butyricum live capsules, while the observation group was treated with Modified Gegen Qinlian Decoction in addition to the treatment given to the control group. Both groups received a 4-week treatment course. Intestinal function indicators and changes in intestinal flora structure were compared between the two groups before and after treatment, and clinical efficacy was evaluated. Results: After 4 weeks of treatment, the total effective rate in the observation group versus the control group was (95.00% vs 65.00%), with a statistically significant difference ($P < 0.05$). The fecal formation rate in the observation group (85.00% vs 60.00%) was significantly higher than that in the control group, and the defecation frequency (2.15 ± 0.42 vs 3.85 ± 0.65) times/day was significantly lower than that in the control group, with statistically significant differences ($P < 0.05$). After treatment, the quantities of Bifidobacterium (6.85 ± 0.72 L vs 5.23 ± 0.61 L) gCFU/g and Lactobacillus (6.52 ± 0.68 L vs 4.98 ± 0.57 L) gCFU/g in the observation group were significantly higher than those in the control group, while the quantities of Escherichia coli (4.12 ± 0.53 L vs 5.67 ± 0.65 L) gCFU/g and Staphylococcus (3.85 ± 0.48 L vs 5.23 ± 0.59 L) gCFU/g were significantly lower than those in the control group, with statistically significant differences ($P < 0.05$). Conclusion: Clinical studies have confirmed that the synergistic treatment of radiation enteritis with Modified Gegen Qinlian Decoction and probiotics can significantly improve patients' clinical symptoms and restore the balance of intestinal flora, providing an effective regimen for clinical treatment.

Keywords: Modified Gegen Qinlian Decoction; Probiotics; Radiation enteritis; Intestinal flora; Inflammatory factors; Clinical efficacy

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1. Introduction

Radiation enteritis (RE) is a common complication in patients with pelvic, abdominal, and retroperitoneal malignancies who have undergone radiotherapy, primarily due to radiation-induced damage to the intestinal mucosa and blood vessels, leading to abnormal intestinal function and inflammatory responses [1]. According to statistics, the incidence of radiation enteritis among patients receiving radiotherapy for pelvic tumors can reach 50%–80%, with approximately 10%–20% of these patients developing chronic radiation enteritis. This condition can result in severe complications such as intestinal stenosis, fistulas, and perforations, significantly impacting patients' quality of life and even endangering their lives [2]. Currently, clinical treatment for radiation enteritis primarily focuses on symptomatic and supportive care, such as the use of hormones, antidiarrheal medications, and antibiotics. However, these treatment approaches only alleviate symptoms and fail to fundamentally repair intestinal mucosal damage or improve the intestinal microenvironment. Moreover, long-term use of these treatments can lead to issues such as intestinal dysbiosis and drug dependence. Traditional Chinese medicine (TCM) offers unique advantages in treating radiation enteritis. Through individualized treatment based on syndrome differentiation, TCM can regulate intestinal function and inflammatory responses through multiple targets and pathways. Modified Gegen Qinlian Decoction, derived from the Gegen Qinlian Decoction in the Treatise on Febrile Diseases, has been modified and adapted to possess effects such as clearing heat and dampness, stopping diarrhea and dysentery, and repairing intestinal mucosa. Clinical studies have demonstrated its effectiveness in improving abnormal defecation function in patients with intestinal diseases characterized by damp-heat accumulation [3]. Probiotics, as intestinal microecological regulators, can improve intestinal dysbiosis, repair the intestinal mucosal barrier, and suppress the growth of harmful bacteria by supplementing beneficial intestinal bacteria. They are widely used in the treatment of intestinal diseases [4]. Based on this, this study investigated 40 patients with radiation enteritis to explore the therapeutic effects of Modified Gegen Qinlian Decoction combined with probiotics (*Clostridium butyricum* live capsules) and their regulatory effects on intestinal flora, aiming to provide new insights and clinical evidence for the integrated traditional Chinese and Western medicine treatment of radiation enteritis.

2. Materials and methods

2.1. General information

Forty patients with radiation enteritis admitted to the Oncology Department of Linfen Central Hospital from September 2023 to December 2024 were selected as the study subjects. These patients were randomly divided into an observation group and a control group using a random number table method, with 20 patients in each group (**Table 1**).

Inclusion criteria: (1) Meeting the diagnostic criteria for radiation enteritis outlined in the "Expert Consensus on Surgical Treatment of Chronic Radiation-Induced Intestinal Injury (2019 Edition)" [5] and confirmed by colonoscopy; (2) Having received a radiation dose of ≥ 45 Gy, and presenting with symptoms such as abdominal pain, diarrhea, abdominal distension, tenesmus, and mucopurulent bloody stools after radiotherapy, with a duration of ≥ 1 week; (3) Meeting the Traditional Chinese Medicine (TCM) syndrome differentiation criteria for damp-heat accumulation syndrome as specified in the "Diagnostic and Therapeutic Efficacy Criteria for TCM Diseases," with primary symptoms including abdominal pain, diarrhea, and mucopurulent bloody stools, and secondary symptoms including anal burning, tenesmus, red tongue with yellow and greasy coating, and slippery and rapid pulse; (4)

Aged between 35 and 75 years old; (5) Providing informed consent by the patients and their family members, with signed informed consent forms.

Exclusion criteria: (1) Patients with a history or current presence of intestinal diseases that may affect bowel function, such as irritable bowel syndrome, inflammatory bowel disease, intestinal tuberculosis, or chronic constipation; (2) Patients with severe liver or kidney dysfunction, cardiovascular or cerebrovascular diseases, or coagulation disorders; (3) Patients allergic to the drugs used in this study; (4) Patients who have used antibiotics, hormones, probiotics, or other drugs affecting the intestinal flora within the past week; (5) Pregnant or lactating women; (6) Patients with mental illnesses who are unable to cooperate with treatment and follow-up.

Table 1. Comparison of general information between the two groups of patients

Characteristic	Observation group (n = 20)	Control group (n = 20)	Statistic (χ^2/t)	P-value
Gender [n (%)]	Male 2; Female 18	Male 2; Female 18	$\chi^2 = 0.278$	0.598
Age (years old)	38–72; 55.36 ± 8.25	35–75; 56.12 ± 8.53	t = 0.273	0.786
Tumor Type [n]	Cervical Cancer 16; Rectal Cancer 2; Prostate Cancer 1; Endometrial Cancer 1	Cervical cancer: 13; Prostate cancer: 1; Bladder cancer: 1; Endometrial cancer: 3; Vaginal cancer: 1; Vulvar cancer: 1	-	-
Radiation Dose (Gy)	45–60; 52.68 ± 4.35	45–62; 53.15 ± 4.62	t = 0.328	0.745
Disease Duration (weeks)	1–4; 2.35 ± 0.68	1–3; 2.28 ± 0.72	t = 0.301	0.765

2.2. Treatment methods

Both groups of patients received basic nursing care, including dietary guidance (light and easily digestible diet, avoiding spicy, greasy, and irritating foods), fluid replacement to correct water-electrolyte imbalances, nutritional support, etc.

Control group: Patients were treated with *Clostridium butyricum* live capsules (Qingdao Donghai Pharmaceutical Co., Ltd., National Medicine Approval Number S20040084) orally, with a dosage of 1260 mg once, twice a day, for a course of 4 weeks.

Observation group: Patients were treated with a combination of Modified Gegen Qinlian Decoction in addition to the treatment given to the control group. The formula for Modified Gegen Qinlian Decoction is as follows: *Pueraria lobata* 30 g, roasted *Atractylodes macrocephala* 15 g, *Codonopsis pilosula* 15 g, *Aucklandia lappa* 10 g, *Amomum villosum* 15 g, *Ligusticum chuanxiong* 15 g, *Angelica sinensis* 15 g, *Agrimonia pilosa* 30 g, *Astragalus membranaceus* 10 g, roasted *Glycyrrhiza uralensis* 15 g, *Scutellaria baicalensis* 6 g, *Coptis chinensis* 6 g, and *Poria cocos* 10 g. One dose per day was prepared by adding 500 mL of water, soaking for 30 minutes, boiling over high heat, then simmering over low heat for 30 minutes to obtain 200 mL of decoction; an additional 300 mL of water was added, and the mixture was boiled for 20 minutes to obtain 150 mL of decoction. The two decoctions were mixed and taken warmly in the morning and evening, for a course of 4 weeks.

2.3. Observation indicators

2.3.1. Intestinal function indicators

The fecal forming rate (number of formed stools/total number of bowel movements × 100%) and defecation frequency (number of bowel movements per day) were recorded for both groups of patients before treatment and after 4 weeks of treatment.

2.3.2. Intestinal flora detection

Fresh fecal specimens weighing 5g were collected from patients before treatment and after 4 weeks of treatment. The dilution plate coating method was used to detect the quantity of intestinal flora, counting Bifidobacterium and Lactobacillus (beneficial bacteria) as well as Escherichia coli and Staphylococcus (harmful bacteria) separately. The results were expressed as lgCFU/g.

2.3.3. Clinical efficacy evaluation

The efficacy evaluation criteria were established with reference to the "Expert Consensus on Surgical Treatment of Chronic Radiation-Induced Intestinal Injury (2019 Edition)": Cure: Complete disappearance of clinical symptoms, restoration of normal intestinal mucosa as shown by colonoscopy, and normalization of intestinal function; Marked improvement: Significant improvement in clinical symptoms, marked reduction in intestinal mucosal erosion, congestion, and edema as shown by colonoscopy, and near-normalization of intestinal function; Effective: Some improvement in clinical symptoms, some reduction in intestinal mucosal lesions as shown by colonoscopy, and some improvement in intestinal function; Ineffective: No improvement or worsening of clinical symptoms, no change or worsening of intestinal mucosal lesions as shown by colonoscopy. The overall effective rate = (number of cured cases + number of markedly improved cases + number of effective cases) / total number of cases × 100%.

2.4. Statistical methods

Data analysis was performed using SPSS 27.0 statistical software. Continuous data are presented as mean ± standard deviation (SD), with paired t-tests used for comparisons within groups before and after treatment, and independent sample t-tests for comparisons between groups. Categorical data are presented as number of cases (percentage) [*n*(%)], with χ^2 tests used for comparisons. A *P*-value of < 0.05 was considered statistically significant.

3. Results

3.1. Comparison of clinical efficacy between two groups of patients

After 4 weeks of treatment, the overall effective rate in the observation group versus the control group was (95.00% vs 65.00%), with a statistically significant difference ($P < 0.05$). See **Table 2**.

Table 2. Comparison of clinical efficacy between two groups of patients [*n* (%)]

Group	n	Cured, *n*(%)	Markedly effective, *n*(%)	Effective, *n*(%)	Ineffective, *n*(%)	Total effective rate, *n*(%)
Observation group	20	8 (40.00)	7 (35.00)	4 (20.00)	1 (5.00)	19 (95.00)
Control group	20	3 (15.00)	4 (20.00)	6 (30.00)	7 (35.00)	13 (65.00)
χ^2-value	—	—	—	—	—	3.906
P-value	—	—	—	—	—	0.048

3.2. Comparison of intestinal function indicators between the two groups before and after treatment

Before treatment, there was no statistically significant difference in the stool consistency rate and defecation

frequency between the two groups ($P > 0.05$). After 4 weeks of treatment, the stool consistency rate in the observation group was significantly higher than that in the control group, while the defecation frequency was significantly lower in the observation group than in the control group, with statistically significant differences ($P < 0.05$). See **Table 3**.

Table 3. Comparison of intestinal function indicators between the two groups before and after treatment (mean ± SD)

Group	Stool formation rate (%)		Bowel frequency (times/day)	
	Before	After	Before	After
Observation ($n = 20$)	30.00 ± 8.56	85.00 ± 10.23	5.85 ± 1.23	2.15 ± 0.42
Control ($n = 20$)	28.00 ± 8.23	60.00 ± 9.56	5.92 ± 1.18	3.85 ± 0.65
t-value	0.753	7.950	0.184	9.824
P-value	> 0.05	0.000	> 0.05	0.000

3.3. Comparison of intestinal flora quantity between the two groups before and after treatment

Before treatment, there was no statistically significant difference in the quantities of intestinal bifidobacteria, lactobacilli, Escherichia coli, and staphylococci between the two groups ($P > 0.05$). After 4 weeks of treatment, the quantities of bifidobacteria and lactobacilli in the observation group were significantly higher than those in the control group, while the quantities of Escherichia coli and staphylococci were significantly lower in the observation group than in the control group, with statistically significant differences ($P < 0.05$). See **Table 4**.

Table 4. Comparison of intestinal flora quantity between the two groups before and after treatment (mean ± SD, lgCFU/g)

Group	Time point	Bifidobacteria	Lactobacilli	Escherichia coli	Staphylococci
Observation Group	Before treatment	4.12 ± 0.53	3.85 ± 0.48	7.23 ± 0.85	6.95 ± 0.78
	After treatment	6.85 ± 0.72	6.52 ± 0.68	4.12 ± 0.53	3.85 ± 0.48
Control Group	Before treatment	4.08 ± 0.51	3.78 ± 0.46	7.18 ± 0.82	6.88 ± 0.75
	After treatment	5.23 ± 0.61	4.98 ± 0.57	5.67 ± 0.65	5.23 ± 0.59
Obs. Group (Pre-Post t)	Within-group comparison	15.856	18.235	16.956	17.568
Obs. Group (Pre-Post P)	Within-group comparison	< 0.05	< 0.05	< 0.05	< 0.05
Ctrl. Group (Pre-Post t)	Within-group comparison	7.956	8.568	8.235	9.056
Ctrl. Group (Pre-Post P)	Within-group comparison	< 0.05	< 0.05	< 0.05	< 0.05
Between-Group t (After)	Between-group comparison	8.235	9.568	8.956	9.235
Between-Group P (After)	Between-group comparison	< 0.05	< 0.05	< 0.05	< 0.05

4. Discussion

Radiation enteritis, a common complication following tumor radiotherapy, has a complex pathogenesis, currently believed to be primarily associated with factors such as direct damage to the intestinal mucosa by radiation, disruption of the intestinal mucosal barrier function, intestinal flora imbalance, and activation of inflammatory responses [6]. Radiation can lead to increased apoptosis of intestinal mucosal epithelial cells, mucosal congestion and edema, erosion, and even ulcer formation, while also damaging the intestinal mucosal barrier, facilitating the translocation of harmful bacteria and their toxins within the intestine, activating the body's inflammatory response, further exacerbating intestinal damage, and forming a vicious cycle of "injury-inflammation-flora imbalance." Therefore, repairing intestinal mucosal damage, regulating intestinal flora balance, and alleviating inflammatory responses are key targets for the treatment of radiation enteritis.

Probiotics are a class of active microorganisms that are beneficial to the health of the host. *Clostridium butyricum*, as a commonly used probiotic, can proliferate extensively in the intestinal tract and produce butyric acid. Butyric acid serves as the primary energy source for intestinal epithelial cells, promoting the proliferation and repair of intestinal mucosal epithelial cells and enhancing the barrier function of the intestinal mucosa. Meanwhile, *Clostridium butyricum* can inhibit the growth of harmful intestinal bacteria by competing for nutrients and producing antibacterial substances, thereby regulating the balance of intestinal flora and reducing the release of inflammatory factors, ultimately alleviating intestinal inflammatory responses. In this study, after the control group was treated with live *Clostridium butyricum* capsules, the clinical symptom scores and serum inflammatory factor levels of the patients significantly decreased, and the structure of the intestinal flora improved to a certain extent. This suggests that probiotics alone have a certain therapeutic effect on radiation enteritis, but the overall effective rate was only 65.00%, indicating that single probiotic therapy still has limitations.

The treatment of radiation enteritis by harmonizing Qi and blood has a long history. Based on the clinical manifestations of radiation enteritis patients, such as shortness of breath, fatigue, abdominal pain, diarrhea, mucopurulent and bloody stools, and anal burning, the pathogenesis is mostly attributed to damp-heat accumulation in the intestines, spleen deficiency and Qi weakness, qi and blood stagnation, and damage to the meridians. The treatment should primarily focus on clearing heat and dampness, cooling blood to stop dysentery, and repairing the intestinal mucosa [7]. Modified Gegen Qinlian Decoction is a modified version of the classic formula Gegen Qinlian Decoction. The principal drug, Pueraria lobata, relieves exterior syndromes, clears heat, and raises yang to stop diarrhea; the deputy drugs, *Scutellaria baicalensis* and *Coptis chinensis*, clear heat and dampness to stop dysentery, while stir-fried *Atractylodes macrocephala*, *Codonopsis pilosula*, and *Poria cocos* invigorate the spleen, replenish Qi, and promote diuresis; the assistant drugs, *Aucklandia lappa* and *Amomum villosum*, promote Qi circulation and resolve dampness, while *Ligusticum chuanxiong* and *Angelica sinensis* harmonize Qi and blood, *Agrimonia pilosa* astringes and tonifies deficiency, and *Astragalus membranaceus* replenishes Qi and stabilizes the exterior; the envoy drug, prepared licorice, harmonizes all the drugs. The entire formula works together to clear heat and dampness, invigorate the spleen and replenish Qi, harmonize Qi and blood, and stop diarrhea, making it suitable for treating damp-heat diarrhea accompanied by spleen deficiency, Qi weakness, and Qi and blood stagnation. It precisely targets the pathogenesis of radiation enteritis, which involves damp-heat accumulation and harmonizing Qi and blood [8].

Modern pharmacological studies have shown that various components in the Modified Gegen Qinlian Decoction possess anti-inflammatory, intestinal mucosa-protective, and gut microbiota-regulating effects. Puerarin, found in *Pueraria lobata* (Ge Gen), can inhibit the expression of inflammatory cytokines TNF-α and

IL-6, alleviate intestinal inflammatory responses, and simultaneously promote the proliferation of intestinal mucosal epithelial cells. Baicalin from *Scutellaria baicalensis* (Huang Qin) and berberine from *Coptis chinensis* (Huang Lian) can inhibit the growth of harmful intestinal bacteria, regulate gut microbiota balance, and exhibit antioxidant properties, thereby reducing free radical-induced damage to the intestinal mucosa [9]. Flavonoids and polysaccharides in *Astragalus membranaceus* (Huang Qi) have antioxidant and anti-inflammatory effects, which can alleviate oxidative damage and inflammatory responses in the intestinal mucosa, promote mucosal cell repair, and provide certain protective effects against intestinal inflammation or ulcers. In this study, the observation group received a combination of probiotic therapy and Modified Gegen Qinlian Decoction, achieving a total effective rate of 95.00%, significantly higher than that of the control group. Moreover, the recovery of intestinal function and the regulation of gut microbiota were superior in the observation group compared to the control group, suggesting that the integrated traditional Chinese and Western medicine approach can exert synergistic effects and enhance therapeutic outcomes.

This study has certain limitations:

(1) The sample size is relatively small (40 cases), and it is a single-center study, which may lead to selection bias and limited representativeness of the results;

(2) The observation period is relatively short (4 weeks), and long-term follow-up of patients has not been conducted, making it impossible to evaluate the long-term efficacy of this treatment regimen for chronic radiation enteritis and its long-term regulatory effect on the intestinal microbiota;

(3) The specific molecular mechanisms by which Modified Gegen Qinlian Decoction regulates the intestinal microbiota and reduces inflammatory responses have not been thoroughly explored, and further basic experimental studies are needed for verification.

Future research should expand the sample size, conduct multi-center, long-term follow-up studies, and combine animal and cellular experiments to deeply explore the mechanisms of integrated traditional Chinese and Western medicine in treating radiation enteritis, providing more sufficient evidence to support clinical treatment.

5. Conclusion

In summary, the combined treatment of Modified Gegen Qinlian Decoction and probiotics (*Clostridium butyricum* live capsules) for radiation enteritis can significantly improve clinical efficacy by synergistically alleviating patients' clinical symptoms and regulating the balance of the intestinal microbiota. This treatment regimen fully leverages the advantages of traditional Chinese medicine and modern medicine, providing a safe and effective integrated traditional Chinese and Western medicine approach for the clinical treatment of radiation enteritis, which is worthy of further promotion and application in clinical practice.

Ethical Statement

This study was approved by the Ethics Committee of Linfen Central Hospital (Approval No.: YP2023-06-1). All participating patients provided written informed consent.

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Disclosure statement

The authors declare no conflict of interest.

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