

The effect of *Astragalus membranaceus* on gut microbiota and chemotherapy related complications in patients with colon cancer undergoing chemotherapy

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Abstract: Background: *Astragalus membranaceus* is a Traditional Chinese Medicine (TCM) often used to modulate intestinal flora. **Objectives:** This study aims to analyze the effects of *Astragalus membranaceus* on intestinal flora and chemotherapy-related complications in patients undergoing chemotherapy for colon cancer through clinical research and to explore the possible mechanism. **Methods:** The study included 86 patients with colon cancer who were assigned to the Chemotherapy (Che) and Astragalus (Ast) groups. The Che group was treated with bevacizumab combined with oxaliplatin and capecitabine and the Ast group was treated with Astragalus granules on the basis of the Che group. The intestinal flora and the incidence of chemotherapy-related complications were compared between the two groups. **Results:** Astragalus granules can reduce a variety of complications during chemotherapy in patients with colon cancer. At the same time, this study detected the feces of patients before and after chemotherapy and found that Astragalus can effectively increase the content of intestinal *Bifidobacterium* and *Lactobacillus* and reduce the content of *Enterococcus* and *Escherichia coli* in patients. In addition, by detecting the serum of patients in this study, it was found that Astragalus granules can increase the level of serum CD4⁺ T cells and reduce the level of CD8⁺ T cells in patients. At the same time, Astragalus granules can also relieve the inflammatory state of patients during chemotherapy. **Conclusion:** TCM formula based on astragalus can effectively regulate the intestinal flora of patients, reduce the complications of chemotherapy and relieve the inflammatory state of the body during the chemotherapy of patients with colon cancer. *Astragalus membranaceus* has significant advantages in effectively improving the imbalance of intestinal flora caused by chemotherapy, improving the immune function of patients and reducing the incidence of chemotherapy-related complications.

Keywords: *Astragalus membranaceus*; Chemotherapy; Colon cancer; Inflammation; Traditional Chinese Medicine

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INTRODUCTION

Colon cancer is a malignant tumor of the digestive tract that occurs in the colon, with most patients being around 50 years old (Guimarães *et al.*, 2024; Bleyer *et al.*, 2025). The treatment of colon cancer primarily involves surgery, supplemented by chemotherapy. Chemotherapy following the radical resection of colon cancer can reduce postoperative recurrence (Lee *et al.*, 2023; Lahaye *et al.*, 2024). However, during chemotherapy, patients may experience a range of complications due to the effects of chemical drugs, such as intestinal flora imbalance, nausea and vomiting, diarrhea, etc., which may lead to the termination of chemotherapy due to intolerance (Lee *et al.*, 2021; Aliseda *et al.*, 2024).

As the largest symbiotic microbial ecosystem in the human body, the intestinal flora plays a role in digestion, substance metabolism, energy conversion, immune regulation and can form "biofilm" to resist foreign pathogenic bacteria (Adnan *et al.*, 2024; Yuan *et al.*, 2024). The normal balance of the intestinal microecology is essential for the healthy functioning of the body's physiological activities, while an imbalance can lead to various systemic diseases. Long-

term clinical trials have demonstrated that the use of TCM monomers or compounds in combination with chemotherapy can enhance efficacy and reduce toxicity. This means they can increase the concentration of chemotherapy drugs in tumor cells and decrease the toxic side effects caused by these drugs (Zhang X *et al.*, 2021; Zhang Y *et al.*, 2021). *Astragalus membranaceus* is effective in treating tumors caused by internal pathogen invasion, qi stagnation and blood stasis and phlegm turbidity and stasis (Tang and Tian, 2024). The main active ingredients of Astragalus, including astragalus polysaccharide, astragaloside, methylisolin-3-O-glucoside and methylisolin (Fig. 1), have been shown to regulate gut microbiota. Additionally, Astragalus can boost the body's immunity and alleviate the body's inflammatory state (Liu *et al.*, 2022; Wu *et al.*, 2021). In conclusion, *Astragalus membranaceus* may ameliorate the adverse effects of chemotherapy on the intestinal flora in patients with colon cancer and may even reduce incidence of chemotherapy-related complications. Astragalus granule is a commonly used traditional Chinese patent medicine and a simple preparation with Astragalus as the main component. However, the efficacy of *Astragalus membranaceus* in mitigating the side effects of chemotherapy for colon cancer patients remains unclear.

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This study aims to investigate the potential value of *Astragalus membranaceus* in enhancing intestinal flora and decreasing complications in patients undergoing colon cancer chemotherapy, thereby providing a reference for improving the treatment outcomes of these patients.

MATERIALS AND METHODS

Study design, sample size selection

Subjects

86 patients with colon cancer who were hospitalized from January 2022 to June 2023 were selected as the research objects.

Inclusion and exclusion criteria

Inclusion criteria

(1) met the diagnostic criteria of colorectal cancer; (2) 18 to 75 years old; (3) receiving chemotherapy after radical resection of colorectal cancer; (4) the patients and their families agreed to participate in this study after understanding the purpose and process of this study and signed the informed consent.

Exclusion criteria

(1) expected survival time was not more than 3 months; (2) allergy to the drugs used in this study; (3) accompanied by serious cardiovascular and cerebrovascular diseases, liver and kidney dysfunction or other serious life-threatening diseases; (4) accompanied by mental diseases; (5) women who are pregnant or lactating.

Basic information about patients

The average age of 86 patients with colon cancer was (61.14±6.05) years old. The patients were divided into chemotherapy (Che) and astragalus (Ast) groups according to their treatment plans. The basic information, such as gender, age and BMI of the different groups, is shown in table 1. The analysis showed that the basic information of the two groups of patients had negligible influence on the treatment effect ($P > 0.05$).

Disease-related information of patients

As shown in table 2, among the 86 colon cancer patients included in the study, the number of patients with stage II, III and IV was 14, 52 and 20 cases, respectively. The analysis showed that the disease-related information of the two groups of patients had negligible influence on the treatment effect ($P > 0.05$).

Treatment methods

The Che group was treated with bevacizumab combined with oxaliplatin and capecitabine: bevacizumab injection (Roche Pharma, Germany, registration number: S20170035, 7.5 mg/kg, the first day) and oxaliplatin injection (Jiangsu Henrui Pharmaceutical Co., LTD., approval number: H20050963, 130 mg /m², the first day), oral capecitabine (manufactured by Jiangsu Henrui Pharmaceutical Co., LTD., approval number: H20133365, 2.5 g/m², qd, day 1-14). The treatment lasted for 14 days,

followed by 7 days of drug withdrawal and 21 days was a course of treatment. On the basis of the above chemotherapy regimen, the Ast group was combined with Astragalus granules (produced by Sichuan Baili Pharmaceutical Company, 4 g/ bag, 3 times/day, 1 bag/time) and the treatment process was shown in Fig. 2.

Observation indicators

(1) Fresh feces (4-6 g) were collected before and after chemotherapy in the two groups and were tested within 30 minutes. After bacterial culture, the content of *Bifidobacterium*, *Lactobacillus*, *Enterococcus* and *Escherichia coli* in stool diluent was calculated.

(2) The occurrence of abdominal distension, diarrhea, vomiting, leukopenia and other complications during treatment was recorded. During treatment, if the patient develops serious complications, symptomatic treatment is required. If the patient had vomiting, ondansetron was used for antiemetic treatment. The patient with hand-foot syndrome was treated with vitamin B6 and Urin cream. Those who developed neutropenia were treated with recombinant human granulocyte stimulating factor.

(3) The immune indexes and inflammatory indexes of patients were detected 3 days before and after chemotherapy, respectively. The immune indexes mainly detected serum CD4⁺ T and CD8⁺ T cells and the inflammatory indexes mainly detected were the levels of tumor necrosis factor (TNF) - α and interleukin-6 (IL-6). The detection of CD4⁺ and CD8⁺ T cells was performed using flow cytometry. The specific steps include: collecting peripheral blood samples from patients, separating peripheral blood mononuclear cells by centrifugation, labeling the cells with fluorescently labeled monoclonal antibodies, incubating, washing with PBS and fixing with 1% formaldehyde and finally detecting by flow cytometry (Beckman Coulter Company, USA, model: EPICSXL) to analyze the percentage of CD4⁺ and CD8⁺ T cells. The inflammatory markers TNF- α and IL-6 were detected using the enzyme-linked immunosorbent assay (ELISA) method. The specific steps include: after sample collection, separating the serum and storing it in a -80°C refrigerator. ELISA testing is strictly carried out according to the instructions of the kit, including the addition of standard and sample, incubation, washing, addition of enzyme labeled secondary antibodies and color reaction steps. Finally, the absorbance was measured using an ELISA reader at a wavelength of 450 nm and the concentrations of TNF - α and IL-6 in the sample were calculated based on the standard curve.

Statistical analysis

SPSS 26.0 software was used for data analysis. Measurement data conforming to normal distribution were expressed in the form of mean \pm standard deviation and comparison between the two groups was performed using the t-test.

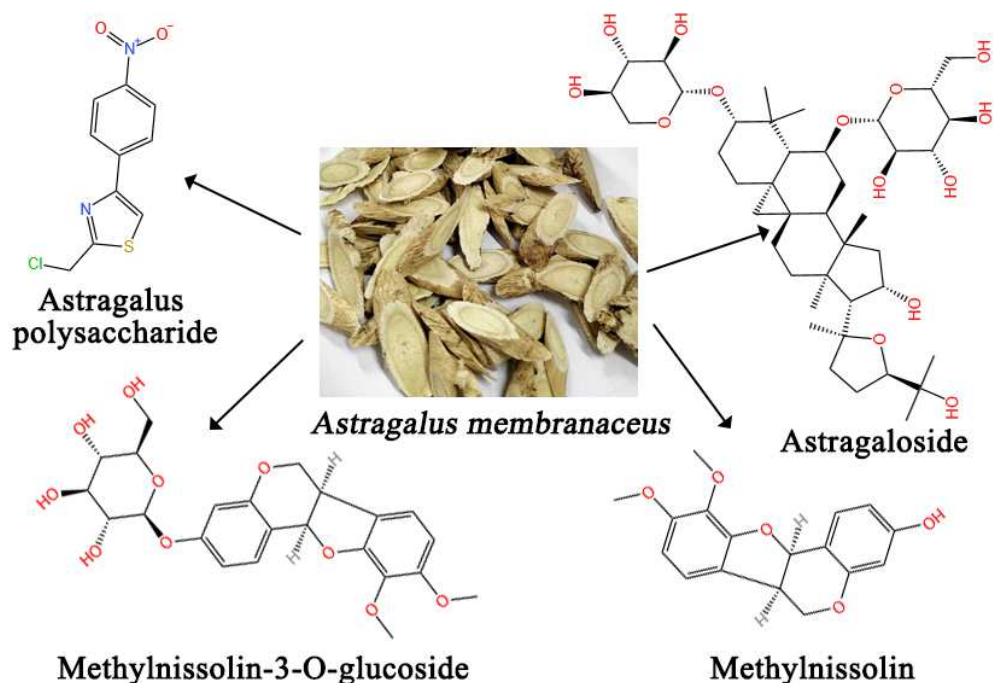


Fig.1: *Astragalus membranaceus* and its major active components.

Table 1: Basic information of patients.

Group	Gender [n(%)]		Age (years)	BMI (kg/m ²)		
	Male	Female		< 18.5	18.5-24.0	> 24.0
Che group	25 (58.14)	18 (41.86)	61.14±6.05	7 (16.28)	26 (60.47)	10 (23.26)
Ast group	22 (51.16)	21 (48.84)	62.47±5.80	9 (20.93)	23 (53.49)	11 (25.58)
t/χ^2	0.422		1.041	0.481		
<i>P</i>	0.516		0.301	0.786		

Table 2: Disease-related information of patients [n(%)]

Group	TNM			Anatomical location of the lesion	
	II	III	IV	Left	Right
Che group	6 (13.95)	28 (65.12)	9 (20.93)	22 (51.16)	21 (48.84)
Ast group	8 (18.60)	24 (55.81)	11 (25.58)	24 (55.81)	19 (44.19)
χ^2	0.793			0.187	
<i>P</i>	0.673			0.665	

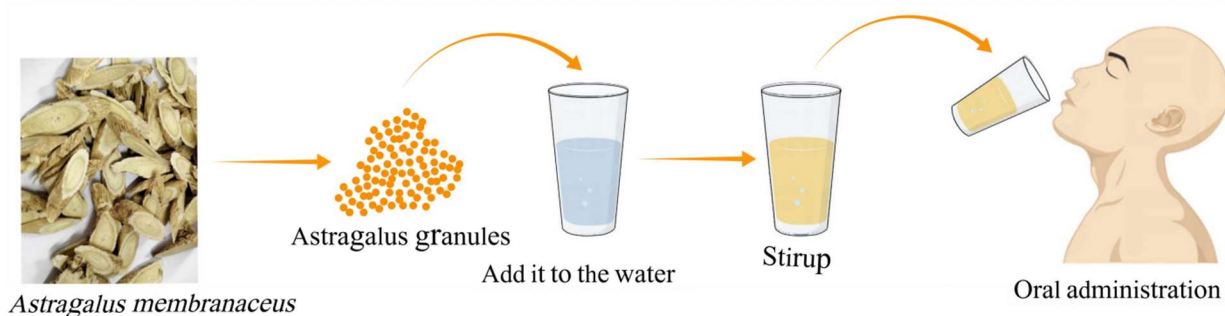


Fig. 2: Flow chart of *Astragalus membranaceus* in the treatment of colorectal cancer.

Count data were expressed as rates and percentages and chi-square test was used for comparison between the two groups. $P < 0.05$ was considered to indicate statistical significance.

RESULTS

Intestinal flora

When exploring the effect of *Astragalus membranaceus* on intestinal flora in patients with colon cancer chemotherapy, it was found that chemotherapy reduced the content of *Bifidobacterium* and *Lactobacillus* in the intestine of colon cancer patients ($P < 0.05$), but did not affect the content of *Enterococcus* and *Escherichia coli*. However, *Astragalus* granules, on the basis of chemotherapy, could improve the adverse effects of chemotherapy on intestinal flora of colon cancer patients, increase the content of intestinal *Bifidobacterium* and *Lactobacillus* and decrease the content of intestinal *Enterococcus* and *Escherichia coli* ($P < 0.05$), as shown in Fig. 3.

Complications

In the analysis of the safety of *Astragalus* granules in patients with colon cancer chemotherapy, it was found that the incidence of common complications such as abdominal distension, diarrhea, vomiting and leucopenia during chemotherapy was as high as 83.72%, while taking *Astragalus* granules on the basis of chemotherapy could effectively reduce the occurrence of related complications ($P < 0.05$), see Fig. 4 for details.

Immune indicators

In the analysis of the effect of Huangqi granule on the immune function of patients with colon cancer chemotherapy, it was found that the immune function of the two groups was similar before chemotherapy and chemotherapy led to a decrease in CD4⁺ and an increase in CD8⁺ ($P < 0.05$). On the basis of chemotherapy, *Astragalus* granules could effectively improve the level of CD4⁺ and reduce the level of CD8⁺ ($P < 0.05$), see Fig. 5 for details.

Inflammatory markers

When analyzing the effect of *Astragalus* granules on the inflammatory state of colon cancer patients undergoing chemotherapy, it was found that there was a serious inflammatory response in the patients before chemotherapy and the inflammatory state of the patients was not significantly improved after chemotherapy (all $P > 0.05$).

On the basis of chemotherapy, *Astragalus* granules could effectively reduce the levels of TNF- α and IL-6 in patients with colon cancer and improve the inflammatory state of the body (all $P < 0.05$), see Fig. 6 for details.

DISCUSSION

Postoperative adjuvant chemotherapy can improve the radical cure rate of colorectal cancer. It should be noted that

while killing cancer cells, chemotherapy drugs also have adverse effects on the rapidly metabolizing gastrointestinal mucosal cells and blood cells in the body, resulting in chemotherapy-related gastrointestinal and bone marrow toxicity (Ishibashi *et al.*, 2021). The main adjuvant chemotherapy regimens for colorectal cancer are fluorouracil or capecitabine combined with oxaliplatin. Common side effects include nausea and vomiting, diarrhea and constipation caused by antiemetics (Pan *et al.*, 2022; Tominaga *et al.*, 2022). Oxaliplatin is a chemotherapeutic drug with moderate emetogenic risk, leading to a high incidence of nausea and vomiting. Fluorouracil induces apoptosis of intestinal mucosal epithelial cells, causes intestinal mucosal injury and often leads to diarrhea in patients. In this study, the incidence of related complications during chemotherapy for colon cancer patients was as high as 86.05%, slightly lower than the 95.5% reported in the latest study (Hiraga *et al.*, 2022). However, this still indicates that chemotherapy not only prolongs the survival time of colon cancer patients but also has a negative impact on their quality of life.

Modern studies suggest that intestinal microecology is closely related to the spleen and stomach. In TCM, the function of the intestinal flora in participating in body metabolism is integrated into the theory of the spleen and stomach and viscera. If the spleen and stomach are dysfunctional, there will be clinical manifestations of TCM spleen and stomach disorders such as anorexia, stagnation and diarrhea (Zhang *et al.*, 2021). Differences in the composition and abundance of intestinal microbes can trigger inflammatory responses in various parts, regulate systemic immunity and affect the risk of malignant transformation, potentially leading to the occurrence of tumors (Liu *et al.*, 2021). Simultaneously, during cancer treatment, different therapies can alter the composition and structure of the intestinal flora, which may also influence the efficacy of various treatments. There are numerous types of intestinal flora, encompassing thousands of different populations and they are highly active, interdependent and restricted with the host, participating in the maintenance of intestinal homeostasis (Mohamed *et al.*, 2021). TCM treatment is characterized by overall regulation and addressing both symptoms and root causes. The multi-target approach of TCM plays a crucial role in regulating the intestinal flora and improving intestinal function (Zou *et al.*, 2024). Guided by the holistic concept, TCM treatment for intestinal flora imbalance focuses on the spleen and stomach to achieve a balance of Yin and Yang in the body (Zou *et al.*, 2024). For colon cancer, TCM follows the principle of strengthening health, eliminating pathogenic factors, balancing attack and supplementation and focusing on the patient as a whole (Zou *et al.*, 2024).

Currently, TCM and its formulations for replenishing qi and astringent properties are frequently utilized in the treatment of colon cancer.

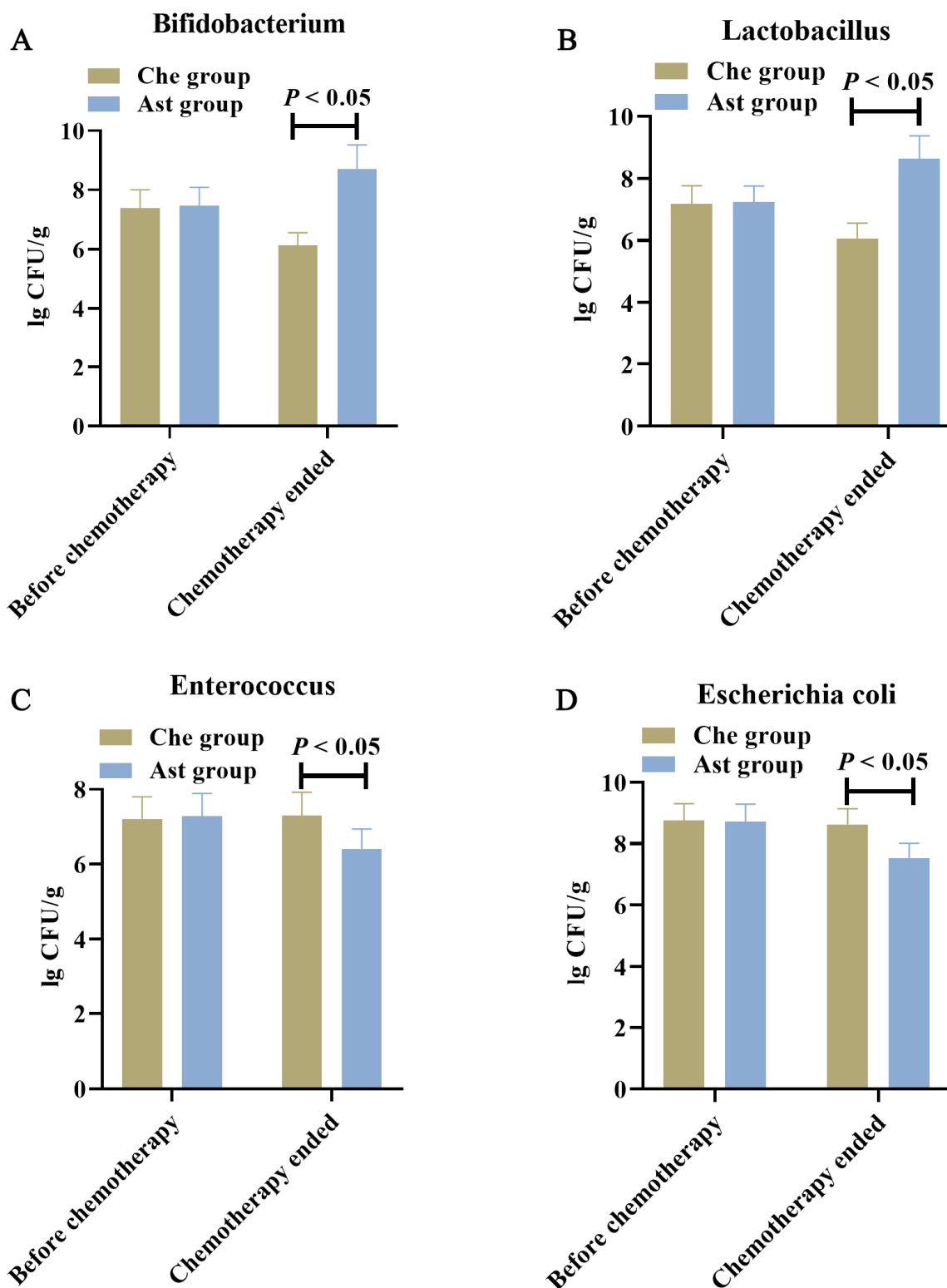


Fig. 3: Effect of *Astragalus granules* on intestinal flora in patients undergoing chemotherapy for colon cancer. (A) the content of bifidobacterium; (B) the content of lactobacillus; (C) the content of enterococcus; (D) the content of escherichia coli.

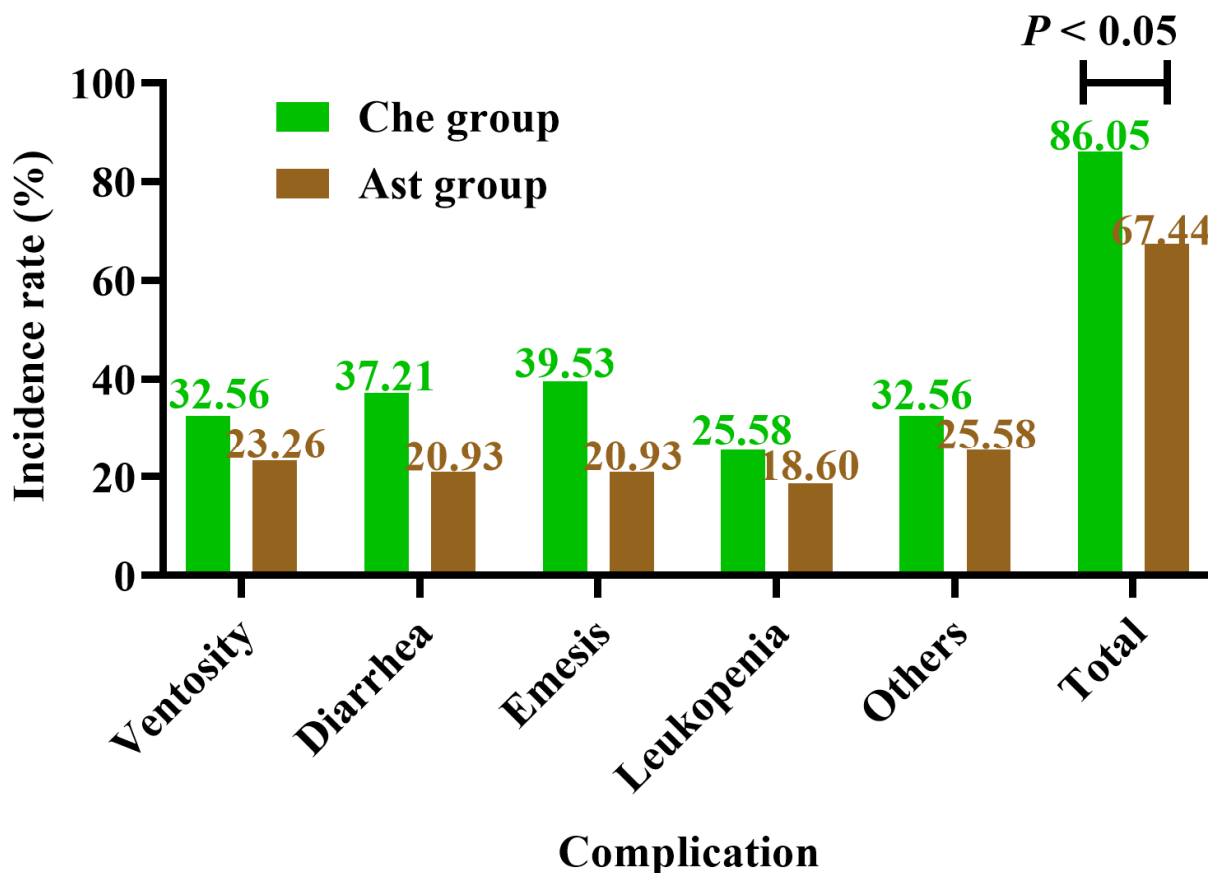


Fig. 4: Occurrence of complications during chemotherapy in patients.

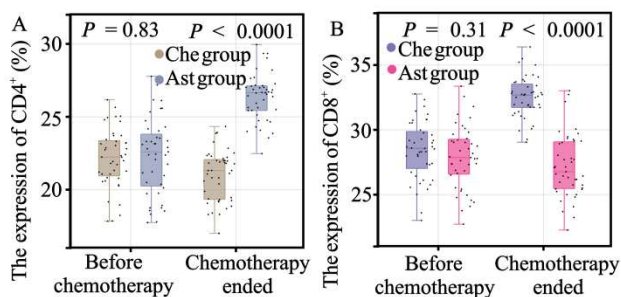


Fig. 5: Effect of Astragalus granules on immune indexes in colon cancer patients undergoing chemotherapy, (A) CD4⁺, (B) CD8⁺.

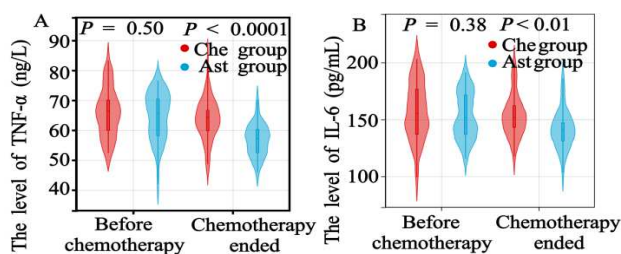


Fig. 6: Effect of *Astragalus granules* on the inflammatory state in colon cancer patients, (A) TNF- α , (B) IL-6.

The aim is to eliminate toxic and pathogenic factors while also strengthening health and supplementing deficiencies, thereby promoting patient recovery.

Astragali Radix is a representative herb in Yiqi solid tablets (Ishibashi *et al.*, 2021). This study discovered that chemotherapy can induce intestinal flora dysbiosis in colon cancer patients and *Astragalus granules* can effectively increase the content of beneficial intestinal bacteria while reducing the content of harmful bacteria during chemotherapy. The study analyzed the safety of *Astragalus granules* in patients undergoing colon cancer chemotherapy and found that the incidence of common complications such as abdominal distension, diarrhea, vomiting and leucopenia reached as high as 86.05%. The administration of *Astragalus granules* in conjunction with chemotherapy could significantly reduce the occurrence of these related complications. The results suggest that *Astragalus membranaceus granules* can help mitigate the side effects of chemotherapy drugs and decrease the incidence of complications during treatment. Furthermore, the study found that chemotherapy led to a decrease in CD4⁺ and an increase in CD8⁺ levels; *Astragalus granules*, when used alongside chemotherapy, could effectively enhance CD4⁺ levels and reduce CD8⁺ levels. Concurrently, taking *Astragalus granules* during chemotherapy could also alleviate inflammation in patients.

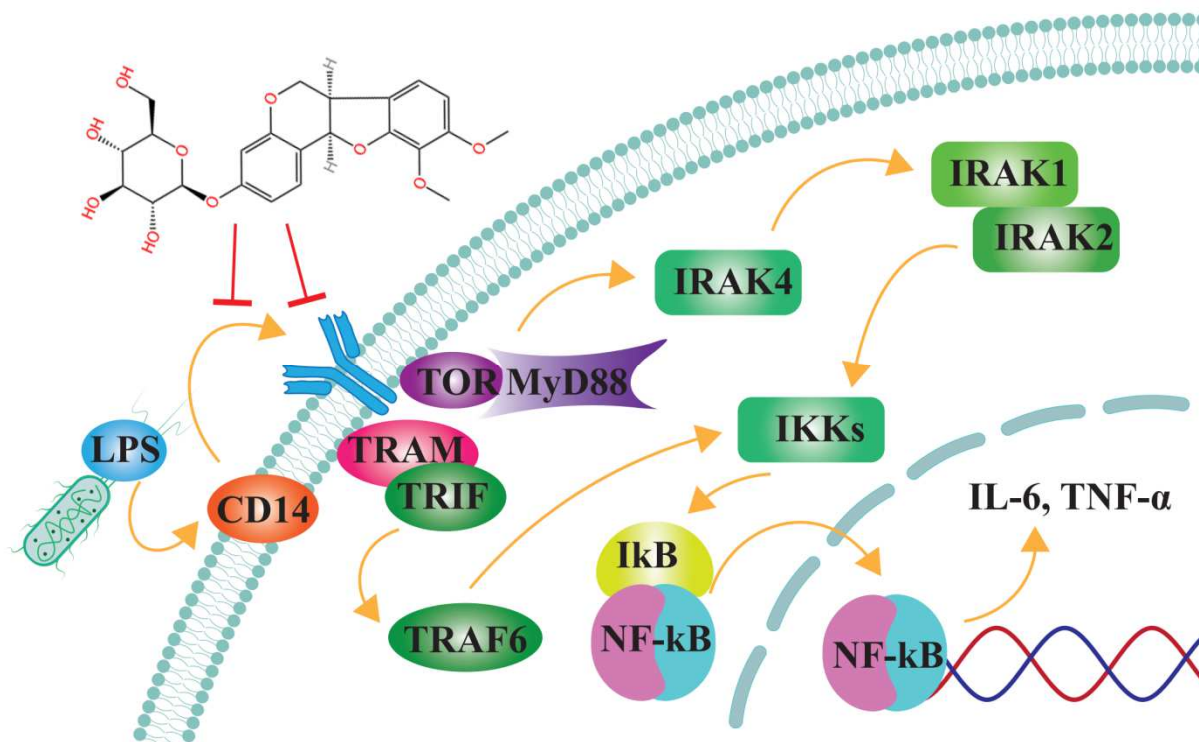


Fig. 7: Possible mechanisms by which Methylnissoin-3-O-glucoside alleviate the inflammatory state of patients by regulating *Escherichia coli*.

Astragalus polysaccharide is the primary active ingredient in the dried root extract of *Astragalus membranaceus*. Studies have demonstrated that astragalus polysaccharide exhibits various effects, including regulating the inflammatory cascade, treating diabetes and its complications, modulating immunity, anti-tumor properties, liver protection and promoting bile production (Li *et al.*, 2022). Astragaloside is the main active component of *Astragalus membranaceus* with effective biological activity and has been proven to possess various pharmacological effects, such as anti-oxidative stress, anti-inflammation, anti-apoptosis and anti-fibrosis (Wang *et al.*, 2023). A previous study (Tian *et al.*, 2021) confirmed that astragaloside can help alleviate the symptoms of inflammatory enteritis. As a class of active substances in *Astragalus membranaceus*, flavonoids exhibit various biological activities. The total flavonoids of *Astragalus membranaceus* have demonstrated significant effects on antioxidant, anti-aging, anti-tumor, anti-diabetic, immune regulatory and cardiovascular protective functions (Gao *et al.*, 2022). These total flavonoids can also inhibit inflammatory responses, reduce oxidative stress injuries, control blood glucose and lipids through multiple pathways and targets and effectively treat diabetes and its complications. Methylnissoin-3-o-glucoside and Methylnissoin are common flavonoids that have been confirmed to possess good anti-inflammatory effects (Gui *et al.*, 2022). *Escherichia coli* is one of the primary pathogens causing the inflammatory state in colon cancer

patients after chemotherapy. LPS, a unique component found in the cell wall of *Escherichia coli*, is the main substance responsible for inducing inflammatory responses in host cells by Gram-negative bacteria. LPS binds to LBP and activates TLR4 through CD14 transduction. The activation of TLR4 can promote the expression of IKK through MyD88-dependent or independent pathways, thereby activating IκB. Inhibited NF-κB can be translocated to the nucleus via phosphorylation, promoting the transcription and expression of inflammatory factors. However, Astragalus granules can down-regulate the content of *Escherichia coli* in the intestine of colon cancer patients undergoing chemotherapy and then inhibit the secretion process of the above inflammatory factors, so as to reduce the secretion of inflammatory factors (Fig. 7 below).

In conclusion, this study retrospectively investigated the effects of *Astragalus membranaceus* on gut microbiota and chemotherapy-related complications in patients undergoing chemotherapy for colon cancer and revealed the underlying mechanism of action. However, this study also has some limitations. First, because of the retrospective design of the study, the randomized, double-blind group assignment was not used, which may partly affect the reliability and generalizability of the study results. Furthermore, the relatively limited sample size and the limitation of the study to a patient population at a single center may limit the generalizability of the findings. In the

future, it is suggested that a larger, multicenter, prospective, randomized, double-blind, controlled study be carried out to further verify the clinical effect of *Astragalus membranaceus* in colon cancer patients undergoing chemotherapy.

CONCLUSIONS

Currently, research into the relationship between TCM and intestinal microorganisms is advancing. The field has evolved from early isolation and culture techniques to mass spectrometry and subsequently to molecular biology and high-throughput sequencing technology. This relationship has garnered increasing attention. Study findings indicate that *Astragalus* granules can effectively regulate the intestinal flora, enhance immune function, mitigate the body's inflammatory state and lower the risk of chemotherapy-related complications in colon cancer patients. The study suggests that *Astragalus*'s regulatory effect on the intestinal flora in colon cancer patients may be associated with its various active components, including astragalus polysaccharide, astragaloside and compounds like methylnissoin-3-o-glucoside and methylnissoin.

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Authors' contributions

BZ and WPC: Conceived and designed the study; HJL, JCZ and XSY: Collected the clinical data and performed the experiments; BZ and HJL: Analyzed the data; BZ: Drafted the manuscript; WPC: Revised the manuscript critically for important intellectual content. All authors read and approved the final version of the manuscript.

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Data availability

The data that support the findings of this study are available from the corresponding author upon reasonable request.

Ethical approval

This study was conducted in accordance with the Declaration of Helsinki. The study protocol was approved by the Ethics Committee of Jinhua People's Hospital (approval number: Jinhua People's Hospital Ethics Review 2025 Research No. 100). Written informed consent was obtained from all patients and their families prior to participation. This study was performed in adherence with the STROBE guidelines. See supplementary file for the STROBE checklist.

Conflict of interest

The authors declare no conflict of interest.

Supplementary data

<https://www.pjps.pk/uploads/2026/06/SUP1782456110.pdf>

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