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Clinical Efficacy Analysis of Buyang Huanwu Tang in Preventing and Treating Postoperative Recurrence of Advanced Adenomatous Polyps in the Large Intestine

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Abstract: Objective: To investigate the efficacy of Buyang Huanwu Decoction in preventing the recurrence of advanced colonic adenomatous polyps after surgery. Methods: A total of 160 patients who underwent endoscopic treatment for advanced adenomatous polyps of the large intestine at the First People's Hospital of Jintan, Changzhou, between March 2022 and March 2024 were enrolled in this study. The patients were randomly divided into an intervention group and a control group using a random number table. The control group received routine postoperative care, while the intervention group received Buyang Huanwu Decoction, starting one month after surgery. The decoction was administered warm, twice daily (200 ml per dose), one dose per day, for a total treatment duration of three months. Results: Before the intervention, there were no significant differences between the two groups in terms of TCM syndrome scores, and serum levels of G-17, IL-18, IL-6, COX2, and CRP (P > 0.05). After the intervention, both groups showed a decrease in TCM syndrome scores and serum levels of G-17, IL-18, IL-6, COX2, and CRP compared to pre-intervention values. The intervention group demonstrated a significantly greater reduction (P < 0.05). Three months after the intervention, there was no significant difference in polyp recurrence rates between the two groups (P > 0.05). However, six and twelve months after the intervention, the recurrence rates in the intervention group were significantly lower than those in the control group (P < 0.05). The incidence of adverse reactions was compared between two groups of patients. The intervention group had an incidence of 12.5%, while the control group had an incidence of 6.25%, with no statistically significant difference (P > 0.05). Conclusion: Buyang Huanwu Decoction has significant efficacy in preventing the recurrence of advanced colonic adenomatous polyps after surgery. It improves TCM syndrome scores, reduces oncogenic and inflammatory factors, significantly lowers postoperative polyp recurrence rates, and demonstrates good safety. It is a promising treatment for clinical promotion and application.

Keywords: Buyang Huanwu Decoction; Adenomatous polyps; Colorectal adenoma; Traditional Chinese Medicine syndrome score

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1. Introduction

Adenomatous polyps of the large intestine are considered precancerous lesions for colorectal cancer, and their progression typically follows a gradual "adenoma-carcinoma" sequence [1]. In recent years, with the increasing incidence of colorectal cancer, early detection and removal of adenomatous polyps have become important measures to reduce the incidence of colorectal cancer. However, the recurrence rate of polyps after surgery remains high [2]. The existing postoperative management plan mainly focuses on regular follow-up and lifestyle interventions, but the actual implementation rate and effectiveness of these measures are limited. Drug intervention, as an important means of preventing recurrence after surgery, mainly focuses on the application of non-steroidal anti-inflammatory drugs (NSAIDs) such as aspirin. However, the long-term use of NSAIDs may cause adverse reactions such as gastrointestinal bleeding, limiting their widespread application in prevention [3,4]. Therefore, exploring safe and effective postoperative recurrence prevention measures, especially intervention programs for high-risk progressive adenomatous polyps, has important clinical value. As an important part of traditional Chinese medicine, Chinese herbal medicine has achieved good results in the field of cancer prevention and treatment and has accumulated rich experience. Buyang Huanwu Decoction is a classic prescription created by Wang Oingren, a medical expert in the Oing Dynasty. In recent years, significant progress has been made in the research of cerebrovascular disease, chronic inflammation, and cancer prevention and treatment [5-8]. The author has achieved good results in preventing the recurrence of postoperative advanced adenomatous polyps of the large intestine with Buyang Huanwu Decoction. The report is as follows.

2. Clinical data

2.1. General information

160 patients who underwent endoscopic treatment for advanced adenomatous polyps of the large intestine in the gastroenterology department of Changzhou Jintan First People's Hospital from March 2022 to March 2024 were selected as the research subjects. They were randomly divided into an intervention group and a control group using a random number table, with 80 patients in each group. Among them, there were 36 males and 24 females in the intervention group, with an average age of 53.28 ± 6.52 years old. In the control group, there were 38 males and 22 females, with an average age of 53.33 ± 6.48 years old. There was no statistically significant difference in general information between the two groups (P > 0.05), indicating comparability. This experiment was approved by the Medical Ethics Committee of Changzhou Jintan First People's Hospital (Approval No.: 2022006).

2.2. Diagnostic criteria

- (1) Western medicine diagnostic criteria: The diagnosis of colorectal adenomatous polyps refers to "The Consensus on Pathological Diagnosis of Gastrointestinal Adenomas and Benign Epithelial Polyps" [9]. Colonoscopy and pathology suggest a diagnosis.
- (2) TCM diagnostic criteria: Refer to the "National Administration of Traditional Chinese Medicine's TCM Diagnosis and Treatment Plan for Colorectal Polyps (Colon Polyps)" [10] to develop. The main symptoms include abdominal pain, changes in bowel movements or stool characteristics, difficulty in defecation, hematochezia, abdominal distension, etc. Combined with tongue imagery, the tongue is dark red, the tongue coating is thin and white, and the pulse is taut or astringent. The main dialectic is (Qi deficiency and blood stasis syndrome).

2.3. Inclusion and exclusion criteria

Inclusion criteria: (1) Age between 18 and 75 years old, no gender restriction. (2) Diagnosed with colorectal polyps through endoscopy and have undergone complete endoscopic resection. (3) Postoperatively confirmed by pathology as having advanced adenomatous polyps of the large intestine (adenoma diameter \geq 10 mm; villous structure \geq 25% (including tubular villous adenoma); accompanied by high-grade intraepithelial neoplasia; or number of adenomas \geq 3), and have undergone complete endoscopic resection. (4) Good patient compliance, voluntarily signing the informed consent form.

Exclusion criteria: (1) Those with a history of other gastrointestinal tumors or malignant diseases. (2) Postoperative presence of serious complications (such as perforation, massive bleeding, etc.) or long-term use of immunosuppressants, non-steroidal anti-inflammatory drugs. (3) Those with severe cardiac, liver, or kidney dysfunction or other life-threatening chronic diseases. (4) Those allergic to the ingredients of Buyang Huanwu Decoction or with a history of adverse drug reactions. (5) Pregnant or lactating women. (6) Those participating in other clinical trials or unable to guarantee cooperation during the study period.

3. Treatment methods

Control group: Routine postoperative management measures were provided, including dietary guidance, hemostasis, analgesia, and anti-infection treatment. Intervention Group: On the basis of the control group, Buyang Huanwu Decoction was administered one month after surgery. The medicinal composition and dosage of Buyang Huanwu Decoction are: Astragalus 30 g, Angelica 10 g, Chuanxiong 6 g, Dilong 6 g, Chishao 10 g, Taoren 10 g, Honghua 6 g. Add 1500 mL of water to the above medicinal materials, soak for 30 minutes, then simmer over low heat for about 40 minutes, take the liquid medicine to 400 mL, and take it warm twice a day, morning and evening, 200 mL each time. One dose per day for 3 consecutive months. Strictly follow the medicinal material handling specifications during the cooking process to ensure the full release of medicinal effects, while regularly monitoring patient compliance and adverse reactions to ensure the safety and effectiveness of the intervention.

4. Observation indicators

- (1) TCM syndrome score: A scoring table was developed based on references ^[11]. TCM syndromes such as abdominal pain, bowel frequency, constipation, hematochezia, dry mouth and bitter taste, anal burning, and physical heaviness were scored as 0, 1, 2, and 3 based on the absence, mild, moderate, and severe levels of symptoms, respectively. The total score is the sum of the scores of each TCM syndrome.
- (2) Determination by Enzyme-Linked Immunosorbent Assay (ELISA): Kits were purchased from Shanghai Saipeisen Biotechnology Co., Ltd. The levels of G-17 and IL-18 were measured before and 12 weeks after intervention.
- (3) Serum Inflammatory Factors: The levels of IL-6, COX2, and CRP were measured before and 12 weeks after intervention.
- (4) Polyp recurrence rates at 3, 6, and 12 months after intervention [12–14].
- (5) Comparison of adverse reactions.

4.1. Statistical methods

Data were analyzed using SPSS 26.0 software. Count data were expressed as cases (%), and the chi-square test was used for comparison. Measurement data were expressed as mean \pm standard deviation (SD), and the *t*-test was performed. P < 0.05 was considered statistically significant.

4.2. Results

4.2.1. Comparison of TCM syndrome scores between the two groups

There was no significant difference in TCM syndrome scores between the two groups before intervention (P > 0.05). After intervention, the TCM syndrome scores (abdominal pain, bowel frequency, constipation, dry mouth and bitter taste) and total scores of both groups were lower than before intervention, and the reduction in the intervention group was greater. The difference was statistically significant (P < 0.05).

Table 1. Comparison of TCM syndrome scores between two groups of patients (mean \pm SD)

Syndrome	Group	Before intervention	After intervention	Within-group t-value	Within-group <i>P</i> -value	Between- group <i>t</i> -value	Between- group <i>P</i> -value
Abdominal pain	Control group	1.93 ± 0.68	1.54 ± 0.61	3.819	< 0.001	0.452	0.652
	Intervention group	1.98 ± 0.72	1.24 ± 0.45	7.795	< 0.001	3.540	0.001
Stool frequency	Control group	1.89 ± 0.57	1.65 ± 0.49	3.450	0.001	-0.214	0.831
	Intervention group	1.87 ± 0.61	1.23 ± 0.34	8.197	< 0.001	6.230	< 0.001
Constipation	Control group	1.37 ± 0.38	1.21 ± 0.23	3.222	0.002	-0.316	0.753
	Intervention group	1.39 ± 0.42	0.98 ± 0.18	8.025	< 0.001	7.404	< 0.001
Hematochezia	Control group	1.55 ± 0.43	1.21 ± 0.28	6.025	< 0.001	-0.378	0.736
	Intervention group	1.53 ± 0.31	1.26 ± 0.33	5.334	< 0.001	1.033	0.303
Dry & bitter mouth	Control group	1.31 ± 0.31	1.11 ± 0.19	4.920	< 0.001	-0.412	0.689
	Intervention group	1.33 ± 0.32	0.85 ± 0.16	12.371	< 0.001	9.452	< 0.001
Total score	Control group	7.12 ± 2.14	6.25 ± 1.86	2.744	0.007	0.087	0.931
	Intervention group	7.15 ± 2.21	5.62 ± 1.42	5.210	< 0.001	2.408	0.017

4.2.2. Comparison of serum G-17 and IL-18 levels between the two groups of patients

Before intervention, there was no significant difference in serum G-17 and IL-18 levels between the two groups of patients (P > 0.05). After intervention, the serum G-17 and IL-18 levels in both groups decreased compared to before intervention, and the intervention group showed a greater reduction. The difference was statistically significant (P < 0.05).

Table 2. Comparison of serum G-17 and IL-18 levels between the two groups of patients (mean \pm SD)

	G-17 (pmol/L)				IL-18 (pg/mL)			
Group	Before Intervention	After Intervention			Before Intervention	After Intervention		
Control group $(n = 80)$	26.28 ± 5.38	16.87 ± 2.78	t	13.803	528.29 ± 53.42	254.82 ± 19.39	t	43.040
			p	< 0.001			p	< 0.001
Intervention group $(n = 80)$	26.23 ± 5.41	10.82 ± 1.98	t	23.925	519.32 ± 52.52	143.59 ± 13.92	t	61.852
			p	< 0.001			p	< 0.001
t	0.059	15.855			1.071	41.680		
p	0.953	< 0.001			0.286	< 0.001		

4.2.3. Comparison of serum IL-6, COX2, and CRP levels between the two groups of patients

Before intervention, there was no significant difference in serum IL-6, COX2, and CRP levels between the two groups (P > 0.05). After intervention, the serum IL-6, COX2, and CRP levels in both groups decreased compared to before intervention, and the intervention group showed a greater reduction. The difference was statistically significant (P < 0.05).

Table 3. Comparison of serum IL-6 and COX2 levels between the two groups

	IL-6 (pg/mL)			COX2 (pg/mL)				
Group	Before intervention	After intervention			Before intervention	After intervention		
Control group $(n = 80)$	15.32 ± 3.57	12.76 ± 2.34	t	5.364	8.29 ± 1.52	7.21 ± 1.38	t	4.705
			p	< 0.001			p	< 0.001
Intervention group $(n = 80)$	15.28 ± 3.61	8.28 ± 1.87	t	15.340	8.35 ± 1.47	4.15 ± 0.92	t	21.662
			p	< 0.001			p	< 0.001
t	0.072	15.237			0.254	17.852		
p	0.943	< 0.001			0.800	< 0.001		

Table 3. Comparison of serum CRP levels between the two groups

Croup	CRP (mg/L)					
Group	Before intervention	After intervention				
Control group $(n = 80)$	9.73 ± 2.21	6.21 ± 1.74	t	11.193		
			p	< 0.001		
Intervention group $(n = 80)$	9.82 ± 2.28	4.31 ± 1.43	t	18.311		
			p	< 0.001		
t	0.254	7.545				
р	0.8	< 0.001				

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4.2.4. Comparison of polyp recurrence rates between the two groups of patients

Three months after intervention, there was no significant difference in polyp recurrence rates between the two groups (P > 0.05). However, the polyp recurrence rates in the intervention group were significantly lower than those in the control group at 6 and 12 months after intervention. The difference was statistically significant (P < 0.05).

Table 4. Co	mparison (of pol	yp recurrence rates l	petween the two grou	ıps
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C	Recurrence cases (Rate/Cases, %)					
Group —	After 3 months	After 6 months	After 12 months			
Control group $(n = 80)$	3 (3.75)	9 (11.25)	14 (17.5)			
Intervention group $(n = 80)$	2 (2.5)	2 (2.5)	4 (5)			
χ^2	0.21	4.78	6.26			
P	0.650	0.028	0.012			

4.2.5. Comparison of adverse reaction rates between the two groups of patients

No liver or kidney damage was observed in either group. In the intervention group, 5 patients experienced nausea and vomiting, and 5 patients developed a rash. The incidence of adverse reactions was 12.5%. All patients recovered after symptomatic treatment without discontinuing medication. In the control group, 2 patients experienced nausea and vomiting, and 3 patients developed a rash. The incidence of adverse reactions was 6.25%. All patients recovered after symptomatic treatment. There was no statistically significant difference in the incidence of adverse reactions between the two groups ($\chi^2 = 1.84$, P = 0.175).

5. Discussion

The term "polyp" first appeared in the ancient Chinese medical text "Ling Shu: Evil Qi, Zang-Fu Organs, and Disease Manifestations," which states, "When the lung meridian is excessively tense, it causes convulsions; when slightly tense, it causes lung heat and cold, lethargy, coughing up blood, and pain in the waist, back, and chest, or nasal polyps causing obstruction." Both nasal polyps and colonic polyps share a high degree of overlap in their pathological characteristics, as they are both protrusions of tissue mucosa growing into the lumen. Therefore, some scholars [15] have proposed "large intestine polyp" as a traditional Chinese medicine disease name based on the naming conventions of Chinese medicine. Advanced adenomatous polyps of the large intestine, which are usually larger and have a longer duration, are precancerous lesions of colorectal cancer. The main pathological factors in Chinese medicine are phlegm and blood stasis. Where do phlegm and blood stasis come from? Referring to the theory of collateral diseases, Ye Tianshi stated in his "Medical Records of Clinical Guidelines: Accumulation" that "initially, there is Qi stagnation in the meridians, and over time, there is blood stasis and heat entering the collaterals." In his "Medical Records of Clinical Guidelines: Masses," he also noted that "prolonged illness enters the collaterals, affecting both Qi and blood," and he believed that collateral diseases can be divided into excess and deficiency types.

For excess types, gentle dredging and pungent herbs for purgation are recommended; for deficiency types, tonifying and dredging the collaterals is recommended. Wang Qingren had a deep understanding of the theory of collateral diseases and created the Buyang Huanwu Decoction, which tonifies Qi and activates blood, resolves blood stasis, and dredges the collaterals. Various factors, such as external pathogens, unclean diet, and emotional

imbalances, can cause a series of conditions, such as spleen and stomach damp-heat, liver Qi stagnation, and intestinal obstruction. Initially, there is "Qi stagnation in the meridians," and over time, Qi stagnation and blood stasis occur, along with Qi stagnation and dampness obstruction. With the depletion of healthy Qi, phlegm and blood stasis intermingle, and "prolonged illness enters the collaterals," manifesting as advanced adenomatous polyps of the large intestine. The core of Buyang Huanwu Decoction is "tonifying Qi and activating blood," which can improve local blood circulation, promote tissue repair, and exert anti-tumor effects by regulating immune function and inhibiting chronic inflammation. Modern research has found that the occurrence and recurrence of colorectal adenomas are closely related to chronic inflammation and immune disorders, and the herbs in Buyang Huanwu Decoction, such as *Astragalus membranaceus* and *Angelica sinensis*, have significant anti-inflammatory and immunomodulatory effects [16,17]. For example, polysaccharides and flavonoids in *Astragalus membranaceus* can protect the intestinal mucosal barrier by inhibiting inflammatory factors and free radical levels, while Angelica sinensis and Chuanxiong can slow down malignant changes in the tumor microenvironment by improving microcirculation and inhibiting platelet aggregation. These mechanisms together support the role of Buyang Huanwu Decoction in preventing and treating the recurrence of advanced adenomatous polyps of the large intestine after surgery.

Modern pharmacological research on traditional Chinese medicine has shown that Buyang Huanwu Decoction (BYHWD) exhibits various biological effects such as anti-inflammation, anti-oxidation, immune modulation, and microcirculation improvement. This provides a theoretical basis for its application in preventing the recurrence of advanced adenomatous polyps in the large intestine after surgery. Furthermore, the treatment concept of "strengthening the body's resistance to eliminate pathogenic factors" in traditional Chinese medicine aligns with the goals of "improving the intestinal microenvironment" and "enhancing immune function" in modern medicine. This also offers the possibility of involving traditional Chinese medicine in the prevention of precancerous lesions. However, the clinical efficacy of BYHWD in preventing the recurrence of advanced adenomatous polyps in the large intestine after surgery remains unclear. Therefore, this study aims to clarify the efficacy and safety of BYHWD in the prevention of recurrence through clinical research. The results indicate that compared with conventional postoperative management measures, BYHWD significantly reduces postoperative TCM syndrome scores and improves symptoms such as abdominal pain and abnormal bowel frequency.

Additionally, patients in the intervention group showed significant reductions in levels of cancer-promoting factors (such as G-17 and IL-18) and serum inflammatory factors (such as IL-6, COX2, and CRP) after the intervention. The recurrence rate of polyps was also significantly lower in the intervention group compared to the control group at the 12-month follow-up. These findings suggest that BYHWD not only has significant advantages in symptom improvement but may also reduce the risk of polyp recurrence after surgery through various mechanisms, such as anti-inflammation and inhibition of cancer-promoting factors. This is consistent with the traditional efficacy and modern pharmacological research results of BYHWD [18,19], providing a new potential intervention strategy for postoperative management. This study is the first to systematically explore the role of BYHWD in preventing the recurrence of advanced adenomatous polyps in the large intestine after surgery, offering a new research perspective and clinical evidence in this field.

The role of BYHWD in reducing recurrence rates may be closely related to its multi-target regulatory mechanism. This study found that cancer-promoting factors (G-17 and IL-18) significantly decreased in patients after BYHWD intervention. As a gastrointestinal hormone, G-17 is closely associated with the occurrence and development of colorectal cancer, and its decreased level may indicate a reduced risk of progression of

precancerous lesions in the intestine ^[20,21]. IL-18, on the other hand, is a pro-inflammatory cytokine whose role in inflammatory bowel disease and the tumor microenvironment has been widely studied. The reduction in IL-18 levels in this study further validates the anti-inflammatory effect of BYHWD ^[22]. Furthermore, BYHWD significantly improves patient symptoms and the intestinal environment, suggesting that it may provide a new approach for preventing postoperative recurrence by improving the intestinal microenvironment.

6. Conclusion

In summary, this study initially confirms the efficacy and safety of BYHWD in preventing the recurrence of advanced adenomatous polyps in the large intestine after surgery. It offers a new option for managing high-risk populations after surgery and is worthy of clinical promotion. However, further multicenter, large-sample randomized controlled trials are needed to verify its long-term efficacy and mechanism. Additionally, modern research methods such as gut microbiota and metabolomics can be combined to deeply explore the molecular mechanisms of BYHWD's intervention in colorectal precancerous lesions and improve its action network.

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Disclosure statement

The authors declare no conflict of interest.

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