

Research Progress on the Treatment of Ulcerative Colitis with Shenling Baizhu Powder

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Abstract: *Ulcerative colitis (UC) is a chronic nonspecific inflammatory bowel disease characterized by recurrence, difficulty in curing, and the risk of accelerated colon cancer. Shenling Baizhu Powder, from “Prescriptions People’s Welfare Pharmacy”, is a classic prescription for treating diarrhea of spleen deficiency and dampness accumulation type, with the core therapeutic principle of “tonifying qi and strengthening the spleen, removing dampness and stopping diarrhea”, and is a commonly used prescription for treating UC. Through a multi-dimensional review of the clinical research and mechanism of action of Shenling Baizhu Powder for the treatment of UC, it is concluded that Shenling Baizhu Powder can be applied through the original formula, combined with Western medicine, compound, etc. In regulating gut microbiota, promoting tight junctions between intestinal epithelium, promoting mucin secretion, regulating immune response, alleviating oxidative stress, regulating water metabolism, inhibiting Toll-like receptor-4 (TLR4)/pro-inflammatory transcription factor nuclear transcription factor-KB (NF- κ B), TLR-5/myeloid differentiation factor (MyD88)/NF- κ B, β 2-epinephrine The receptor (β 2AR)/arrestin2/NF- κ B signaling pathways act, providing a theoretical basis for the clinical application of Shenling Baizhu Powder in the treatment of UC.*

Keywords: Ulcerative colitis, Shenling Baizhu Powder, Clinical application, Mechanism of action.

1. Introduction

Ulcerative colitis (UC) is a chronic, diffuse, nonspecific inflammatory disease of unknown cause, which is clinically characterized by abdominal pain, diarrhea, mucus, and bloody stools, and falls within the category of inflammatory bowel disease [1]. In recent years, the global incidence of ulcerative colitis (UC) has been on the rise, especially in developing and emerging economies [2]. The chronic inflammatory microenvironment caused by UC can accelerate the risk of colorectal cancer, and the chronic persistence and recurrent refractory nature of UC also have a significant impact on the quality of life of patients. The current clinical treatment for UC mostly involves aminosalicylic acid preparations, immunosuppressants, biologics, and new small-molecule drugs to relieve symptoms, which have the limitations of being chronic, lifelong, and prone to recurrence [3]. Traditional Chinese medicine prescriptions have fewer adverse reactions and are characterized by multiple levels, multiple targets, and multiple pathways. Based on this background, integrated treatment that combines the advantages of traditional Chinese and Western medicine, builds a more stable intestinal environment, and restores intestinal function, has become one of the future research directions.

Shenling Baizhu Powder, from Taiming Huimin Heji Jufang, consists of 10 ingredients: ginseng, poria, Atractylodes, yam, lotus seed meat, coix seed, amomum villosum, platycodon grandiflorum, white hyacinth bean, and glycyrrhiza uralensis. All ingredients except Atractylodes are traditional Chinese medicines that are both food and medicine, making clinical use safer and more convenient. Although most of the ingredients in the formula are food and medicine, it does not affect its superior efficacy in the treatment of digestive system diseases.

Of course, it is also highly effective in alleviating symptoms

such as diarrhea and abdominal pain caused by UC. Therefore, it is widely used in the treatment of UC and has good research value and development prospects. Therefore, this article provides a multi-dimensional review of the clinical research and mechanism of action of Shenling Baizhu Powder in the treatment of UC, aiming to provide a scientific basis and theoretical foundation for the analysis of UC pathological mechanisms and precise treatment strategies.

2. Clinical study of Shenling Baizhu Powder

2.1 Modifications to the Original Formula

Shenling Baizhu Powder has received extensive clinical attention in the treatment of UC with spleen deficiency and dampness stagnation due to its advantages of safe administration and relief of core symptoms and pathogenesis. It has achieved remarkable therapeutic effects in several studies and demonstrated superior improvement potential and clinical value. Sun Hongtao [4], through the formulation improvement of Shenling Baizhu Powder combined with heat-clearing detoxifying, hemostatic and antidiarrheal drugs, in the 8-week enema course of 120 patients, the total effective rate of treatment in the observation group (92.31%) was higher than that in the control group (72.73%), and it could reduce erythrocyte sedimentation rate (ESR), C-reactive protein (CRP), interleukin-6 (IL-6), substance P (SP), It increased prostaglandin-E2 (PGE2), vasoactive peptide (VIP), epidermal growth factor (EGF), and regulated the gut microbiota (increased bifidobacterium and lactobacillus, decreased enterobacterium and enterococcus), suggesting that it may improve the dysbiosis of the gut microbiota through immunomodulatory effects and exert therapeutic effects in combination of internal and external. Gao Liang [5] added Shenling Baizhu Powder to an enteral nutrition supplement. After 4 weeks of treatment, the nutritional indicators of the patients increased significantly. Further, the Inflammatory Bowel Disease Quality of Life Questionnaire (IBDQ)

confirmed that traditional Chinese medicine had an overall improvement effect on the multi-dimensional quality of life of the patients.

2.2 Combined with Western Medicine

In recent years, the combination of traditional Chinese and Western medicine has been widely used in the treatment of UC. Multiple RCTS have shown that this therapy not only effectively alleviates symptoms but also has unique advantages in reducing inflammation levels, regulating gut microbiota, reducing the incidence of adverse reactions, and providing clinical economic benefits. Li et al [6]. Randomly divided 82 UC patients into two groups to compare the efficacy of mesalazine monotherapy with Shenling Baizhu Powder. The results showed that the total effective rate (95.12%) of the combined treatment group was higher than that of the control group (80.49%), and the symptom disappearance time was shorter, and the Mayo, DAI, and IBDQ scores were better. It also reduced the levels of inflammatory factors TNF- α , IL-8, and IL-17, and decreased the incidence of adverse reactions. Wang Fuzhong [7] found in RCTS of 60 patients with mild to moderate UC due to spleen deficiency and dampness accumulation that the combination therapy could regulate the gut microbiota, reduce the pathogenic bacteria Enterococcus and Escherichia coli, and increase the abundance of Lactobacillus and Bifidobacterium. In addition, Deng et al [8] focused on the economic aspect of the treatment of UC with Shenling Baizhu Powder. In RCTS of 30 patients with spleen deficiency damp-heat type UC, they found that the combined treatment not only had superior efficacy, but also could reduce hospital stays and costs, ultimately achieving the maximum benefit at the minimum cost.

2.3 Combining with Other Prescriptions

Since the causes of UC are complex, a single prescription is often difficult to fully control the condition. Shenling Baizhu Powder has unique advantages in tonifying qi and strengthening the spleen, promoting dampness, and stopping diarrhea. Therefore, Shenling Baizhu Powder combined with different prescriptions for the treatment of UC is mainly based on strengthening the spleen and stopping diarrhea, supplemented by warming the kidney and consolidating astringency, soothing the liver and relieving depression, balancing cold and heat, to achieve comprehensive intervention for UC with spleen deficiency and dampness stagnation. Studies have shown that when combined with various traditional Chinese medicine prescriptions such as Tongxie Yaofang, Shaoyao Decoction, and Sishen Pills, the clinical efficacy is better, the recurrence rate is lower, and it has unique advantages such as balancing intestinal flora, repairing intestinal mucosa, and regulating inflammatory factors. Shen Lingna [9] found that the combination of Sishen Pill and Shenling Baizhu Powder has a better effect on regulating the intestinal flora and promoting the repair of the intestinal mucosal barrier, and can also reduce serum endothelin (ET), D-lactic acid (DLA), and diamine oxidase (DOA) levels. Liu Fan [10] showed that the combination of the pain-relieving medicine formula and Shenling Baizhu Powder had an advantage in alleviating anxiety; no clinical adverse reactions were observed, the efficacy was definite,

and it could also reduce ESR, CPR, and PCT levels, improve TCM syndromes, and improve Mayo, Baron endoscopy scores, etc. Luo Leilei's [11] research shows that the modified treatment of Shao Yao Decoction combined with Shen Ling Bai Zhu Powder has an advantage in reducing the recurrence rate. The recurrence rate in the treatment group (11.54%) was lower than that in the control group (37.04%), suggesting that it may have potential value in long-term management, which can be verified by increasing the sample size later. In addition, Shenling Baizhu Powder combined with Taohua Decoction [12], Buzhong Yiqi Decoction [13], and Liushen Pills [14] also showed good clinical efficacy in the treatment of UC with spleen deficiency and dampness stagnation.

The above studies show that Shenling Baizhu Powder, when used alone or in combination with Western medicine and prescriptions, can enhance the efficacy of UC. Its spleen-strengthening, moisture-draining, and diarrhea-stopping effects can regulate the intestinal flora, repair the intestinal mucosal barrier, and regulate the immune response; Combined with mesalazine, it can enhance the anti-inflammatory effect, increase the remission rate, and save costs; When combined with pain-relieving prescriptions, peony decoction, etc., it can reduce recurrence, relieve anxiety and improve quality of life.

3. Study on the Mechanism of Shenling Baizhu Powder in the Treatment of UC

3.1 Protect the Intestinal Mucosal Barrier

The human intestinal barrier is the first line of defense against pathogen invasion and is mainly composed of the biological barrier, mechanical barrier, chemical barrier, and immune barrier. A large number of studies have shown that patients with UC have a significant increase in intestinal permeability, so protecting the intestinal mucosal barrier is crucial for the treatment of UC.

3.1.1 Regulate the gut microbiota to maintain the biological barrier

The gut microbiota is a core component of the gut biological barrier. If the gut microbiota is out of balance, with a decrease in beneficial bacteria such as Bifidobacterium and Lactobacillus and an increase in pathogenic bacteria such as Escherichia coli and Clostridium difficile, it will lead to increased intestinal permeability, intestinal immune imbalance, and eventually the occurrence of UC [15]. Therefore, regulating the balance of the gut microbiota could be a new strategy for treating UC. Experiments by Jiao [16] showed that UC patients treated with Shenling Baizhu Powder combined with mesalazine changed the abundance of the gut microbiota while also promoting the microbial level of tryptophan metabolites, thereby promoting mucosal healing and alleviating colonic damage. Lv et al [17] further confirmed that Sanling Baizhu Powder could regulate Bacteroides, Bifidobacterium, and Ruminococcus, thereby altering the structure of the gut microbiota and activating the expression of aromatic hydrocarbons receptor (AhR) and Cyp1A1 by regulating the tryptophan metabolism of the gut microbiota, and promoting the expression of IL-10 anti-inflammatory factor, in the colon. Xu Xia [18] confirmed

through 16S rDNA analysis that Shenling Baizhu Powder inhibits the growth of pathogenic bacteria by promoting the abundance of beneficial bacteria, reduces CPR and PCT, and increases iNOS, indicating that Shenling Baizhu Powder can inhibit the inflammatory response by regulating the balance of intestinal flora. Luo [19] observed in the UC model of spleen deficiency and dampness accumulation that the abundance of actinomycetes and their subordinate bacteria in the intestinal tract of rats increased after intervention with Shenling Baizhu Powder, and the study also suggested that Shenling Baizhu powder has anti-inflammatory and gut microbiota regulating effects in the treatment of UC, while mesalazine does not have such effects. However, when combined with Mesalazine, the improvement in intestinal flora diversity was better than when used alone, confirming the superiority of integrated traditional Chinese and Western medicine treatment.

3.1.2 Promote tight junctions between intestinal epithelial cells to maintain the mechanical barrier

Tight junctions between epithelial cells (TJ) are one of the most critical structures of the mechanical barrier. Tight junctions are mainly composed of the transmembrane protein Claudin family, Occludin, Tricellulin, junctional adhesion molecules (JAM), scaffold protein ZO, and regulatory protein tyrosine kinase, small GTP-binding protein [20]. Mechanical barriers prevent pathogenic microorganisms in the lumen from entering the lamina propria of the mucosa and avoid abnormal activation of the immune system. Therefore, maintaining tight link proteins plays an important role in the treatment of UC. Li [21] has shown that Shenling Baizhu Powder can increase the protein and mRNA expression of Occludin and ZO-1, reduce structural damage to the gut microbiota, regulate galactose metabolism, and alleviate colonic damage. XiaYubin [22] showed that Shenling Baizhu Powder could improve colon length and DAI score in UC mice by inhibiting the classical pyroptosis pathway of cysteine aspartate protease (caspase-1), reducing the protein expression of NLRP3, GSDMD-N, and c-caspase1, and increasing the levels of ZO-1 and Occludin. It improves intestinal tight junctions and reduces the invasion of exogenous inflammatory factors, alleviating colon injury.

3.1.3 Promote mucin secretion to maintain the chemical barrier

Chemical barriers mainly refer to the chemical substances present in the intestine that have antibacterial, antiviral, inactivating toxins, or tissue pathogen adhesion, and these substances are mainly derived from the intestinal mucosal layer and cover the surface of the intestinal mucosal layer or exist in the intestinal lumen. The intestinal mucosa is mainly composed of mucin (MUC) secreted by goblet cells in the intestine, which is mainly MUC2 type in the intestine [23]. Multiple studies have shown that in both UC patients and UC mice, the number of intestinal mucosal goblet cells is reduced, the total expression of MUC2 is decreased, and the changes in the thickness and composition of the mucous layer are closely related to the severity of UC [24-26]. Rao et al [27] found through colonic tissue of UC rats that the number of goblet cells in rats treated with Shenling Baizhu Powder increased, and the expression level of MUC2 mRNA was significantly elevated. Wang et al [28] further demonstrated that a medium

dose of Shenling Baizhu Powder could significantly upregulate the mRNA expression levels of MUC2 and trefoil factor (TFF3), indicating that Shenling Baizhu Powder could accelerate goblet cell remodeling, promote mucin secretion, and repair the intestinal mucus barrier.

3.1.4 Regulate immune responses to maintain the immune barrier

The immune barrier is mainly composed of gut-associated lymphoid tissue (GALT), immune cells, secretory IgA (SIgA), and its core immune barrier depends on the function of immune cells. By regulating the immune response, balancing the function of the immune system, and suppressing excessive inflammatory responses, the therapeutic effect of UC is achieved. Sun Juan [29] identified 25 differentially expressed genes between the Shenling Baizhu Powder group and the mesalazine group through high-throughput transcriptome sequencing technology, mainly concentrated in biological processes such as immunoglobulin-mediated immune response and CD4+αβT cell differentiation. The study showed that Shenling Baizhu Powder is mainly involved in regulating signaling pathways such as cytokine-cytokine receptor interaction, primary immune deficiency, and IgA synthesis in the field network, and alleviates intestinal inflammation through multiple pathways and multiple targets. Starting from the helper T cell 17 (Th17)/regulatory T cell (Treg) axis, Cao Xia [30] suggested that Shenling Baizhu Powder restores immune homeostasis by reducing the ratio of Th17/Treg, promoting the levels of IL-10 and TGF-β, and inhibiting the expression of IL-6 and IL-17. Chen Tianjie [31] confirmed in their study based on the β2AR/β-arrestin2/NF-κB signaling pathway that Shenling Baizhu powder can activate the β2AR/β-arrestin2 signaling pathway, reduce the expression of NF-κB p65 protein, and decrease the release of inflammatory factors, thereby achieving the effect of repairing intestinal damage and reducing recurrence rate. This is also a representation of neuro-immune interaction. Bone marrow mesenchymal stem cells (BMSCs), which have the potential to immunomodulate, home to injured tissue, and promote tissue regeneration, are an important source of colonic mucosal stem cells. Liu Xiping [32] found in UC rats that the proliferation ability of BMSCs derived from peripheral blood in the model group was inhibited, while Shenling Baizhu Powder had the effect of reducing the proportion of G1 phase cells and increasing the proportion of S phase cells of BMSCs derived from bone marrow and peripheral blood, promoting the growth and proliferation of BMSCs derived from bone marrow and peripheral blood. Li [21] showed that Shenling Baizhu Powder could promote the homing of endogenous BMSCs to colon tissue, increase the protein and mRNA expression of occludin and ZO-1, reduce the protein and mRNA expression of SDF-1 and CXCR4 in the colon, and have a stronger restorative effect on intestinal permeability function. It also has a regulatory effect on gut microbiota structure and galactose metabolism, forming a network system of gut microbiota-metabolism-bone marrow.

3.2 Relieve Intestinal Inflammation

UC is closely associated with the inflammatory response, and its occurrence and development can be predicted by the levels

of inflammatory markers. The pharmacological mechanism by which Shenling Baizhu Powder reduces intestinal inflammatory response in UC through multi-target, comprehensive intervention has gradually been widely studied. Sun Juan [33] found that Shenling Baizhu Powder reduced the secretion of tumor necrosis factor and macrophage migration inhibitory factor in colon tissue of UC mice by inhibiting the TLR4/NF- κ B pathway, and promoted the expression of IL-10 and EGF to facilitate injury repair at the ulcer site. Other studies have shown that in a rat model of spleen deficiency and dampness accumulation, Shenling Baizhu Powder can reduce the expression of TLR2, MyD88, COX-2 protein surface and mRNA, thereby reducing the levels of inflammatory factors [34]. Rao [27] further verified this mechanism of action and found that Shenling Baizhu Powder reduced the cytokines that MyD88 signals by inhibiting the expression of key molecules in the TLR-5/MyD88/NF- κ B signaling pathway, inhibiting the expression of apoptosis-related proteins, reducing the release of pro-inflammatory factors CRP, IL-6, IL-17A, IL-1 β , and TNF- α , and blocking the inflammatory cascade response. Liu Yuhui [35] found that Shenling Baizhu Powder could inhibit the NLRP3 inflammasome signaling pathway, reduce the release of inflammatory factors, and the inhibition of IL-1 β and the repair of colonic length reduction caused by colonic injury were more obvious in the medium-dose group, and the effect of reducing IL-18 levels to strengthen intestinal epithelial tight junctions was better in the high-dose group.

3.3 Alleviating Oxidative Stress

Oxidative stress causes damage to the intestinal wall by generating abnormally high levels of reactive oxygen species (ROS) and reactive nitrogen species (RNS), activating inflammatory signaling pathways, promoting the release of pro-inflammatory factors, and inhibiting the activity of antioxidant enzymes, further intensifying inflammation to form a vicious cycle [36]. Gu [37] found through a UC rat model that Shenling Baizhu Powder can significantly reduce MPO levels and increase catalase (CAT) activity, thereby enhancing antioxidant capacity and repairing damaged intestinal mucosa. Zhang Xiuchai [38] further explored the protective effect of Shenling Baizhu Powder on intestinal mucosa. Their study showed that Shenling Baizhu Powder enhanced the antioxidant response by regulating the nuclear factor E2-related factor 2 (Nrf2)/heme oxygenase 1 (HO-1) signaling pathway and promoting the expression of antioxidant genes such as HO-1, quinone oxidoreductase-1 (NQO-1), and SOD. It inhibits the release of lipid peroxide product MDA and serum inflammatory factors TNF- α , IL-1 β , IL-6, ultimately achieving the purpose of alleviating UC symptoms.

3.4 Regulate Water Metabolism

In traditional Chinese medicine, dampness is considered the root cause of diarrhea, while in Western medicine, aquaporin (AQPS) levels are closely related to the transport and absorption of water in the gut [39]. Studies have shown that the expression of AQP3, AQP4, and AQP8 is decreased in the colon of UC mice [40, 41], demonstrating the importance of AQPS in the development of UC. In experiments on UC rats with spleen deficiency and dampness accumulation, Li Huizi

[42] found that Shenling Baizhu Powder could increase the expression of AQP3 and AQP4 through the extracellular signal-regulated kinase /p38 mitogen-activated protein kinase (ERK/p38MAPK) signaling pathway. Zhang Qi [43] further confirmed that Shenling Baizhu Powder could increase the expression levels of AQP3 and AQP8 in the colonic tissue of diarrhea-type rats, thereby achieving therapeutic purposes.

4. Summary and Outlook

Shenling Baizhu Powder has the effects of tonifying the spleen and stomach, benefiting lung qi, eliminating dampness and turbidity, and stopping diarrhea. It is a common prescription for treating UC. Clinical studies have shown that when combined with various treatment methods, Shenling Baizhu Powder can maintain the balance of intestinal flora, regulate immune responses, improve inflammatory indicators, reduce recurrence, and improve the quality of life of patients. The active ingredients in each group of Shenling Baizhu Powder have anti-inflammatory effects, regulate gut microbiota, restore mucosal barrier function, and improve clinical symptoms of patients. Meanwhile, Basic experiments have found that Shenling Baizhu Powder can regulate the gut microbiota by inhibiting signaling pathways such as TLR4/NF- κ B, TLR-5/MyD88/NF- κ B, β 2AR/ β -arrestin2/NF- κ B, promoting tight junctions between intestinal epithelium, promoting mucin secretion, regulating immune responses, alleviating oxidative stress, and regulating water metabolism. Prevention and treatment of ulcerative colitis through multiple pathways.

Research on the application of Shenling Baizhu Powder in the treatment of UC with spleen deficiency and dampness accumulation has progressed from clinical observation to molecular mechanism analysis and achieved good results, but there are still the following limitations: (1) The current clinical studies are mostly small-sample single-center studies, lacking multi-center, large-scale, standardized RCTS. The course of treatment is mostly from 4 to 12 weeks. There are a few clinical studies with follow-up observations, and the follow-up time is mostly insufficient. There is a lack of long-term efficacy observation, and there are significant differences in the severity of symptoms and self-perception among UC patients. Clinical UC symptom improvement scores are difficult to estimate accurately, and clinical trial data are not rigorous enough. (2) There are relatively few studies that use Shengli Bai Zhu San alone or in combination with external treatment methods as the control group. (3) The existing experimental models are mostly DSS-induced mouse or rat models, and there is no unified standard established for UC models of TCM syndrome types. And there are certain differences between animal models and clinical symptoms. (4) Experimental studies have confirmed that Shenling Baizhu Powder involves multiple pathways and targets in the treatment of UC, but the synergistic effects among the mechanisms have not been further clarified. Therefore, in view of the current limitations, the following suggestions are made: (1) At the clinical research level, increase the sample size of the experiment, adopt multi-center, large-scale RCT studies, improve TCM syndrome scoring, conduct regular follow-ups, dynamic observations, and record long-term efficacy, recurrence rate, etc. (2) More research is needed on the treatment of UC using modified Shenling Baizhu Powder,

combined with other formulas, and combined with external therapy methods. (3) Develop animal models of the spleen deficiency and dampness accumulation type UC that are closer to clinical practice and establish a standard evaluation system for the syndrome type. Based on animal experiments of the spleen deficiency and dampness accumulation type UC, integrate the joint mechanisms among signaling pathways and identify the targets of action.

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