

# Recent Advances in the Treatment of Ulcerative Colitis with Shenling Baizhu San

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**Abstract:** *Ulcerative colitis (UC) is an intestinal disorder of unknown aetiology, characterised primarily by chronic, non-specific inflammation of the mucosa of the colon and rectum. The lesions mainly affect the mucosa and submucosa. Clinically, it presents as persistent or recurrent abdominal pain, diarrhoea, and mucoid, purulent or bloody stools. Characterised by a protracted course, recurrent episodes and a high risk of malignancy, it is widely recognised as one of the intractable diseases of the digestive system. Shenling Baizhu San, derived from the "Taiping Huimin Heji Jufang", is a classic formula representing the Traditional Chinese Medicine (TCM) principle of 'strengthening the spleen and draining dampness'. It is widely used in the clinical treatment of UC and has demonstrated proven efficacy. Mechanistic studies have further demonstrated that Shenling Baizhu San treats ulcerative colitis through multiple mechanisms, including promoting the release of anti-inflammatory factors, inhibiting the secretion of pro-inflammatory factors, regulating immune function, repairing the intestinal mucosal barrier, and maintaining the homeostasis of the gut microbiota. In recent years, with the advancement of network pharmacology, multi-omics technologies and molecular biology research, the modern scientific underpinnings of Shenling Baizhu San in the treatment of UC have been progressively elucidated. This paper systematically reviews the theoretical foundations of Traditional Chinese Medicine underlying the use of Shenling Baizhu San for the treatment of UC. It summarises its mechanisms of action from multiple dimensions, including the regulation of inflammatory factors and related pathways, modulation of immune function, repair of the intestinal mucosal barrier, regulation of the gut microbiota, and antioxidant stress. Furthermore, by integrating the latest clinical research advances, the paper explores the value of its use as a monotherapy and in combination therapy, with the aim of providing a reference for the in-depth study and clinical optimisation of this formula.*

**Keywords:** Shenling Baizhu San, Ulcerative colitis, Mechanism of action, Clinical study.

## 1. Introduction

Ulcerative colitis is a non-specific inflammatory condition of the colon and rectum, characterised by persistent damage to the mucosal and submucosal layers. Clinical manifestations include diarrhoea, mucoid, purulent and bloody stools, abdominal pain and tenesmus. With the rapid rise in the incidence of this disease in China in recent years, UC has become one of the most common gastrointestinal disorders [1]. In the treatment of UC, modern medicine primarily employs medications such as aminosalicylate preparations, glucocorticoids, immunosuppressants and biologics. Although these therapeutic measures are effective in inducing and maintaining remission, they are subject to limitations such as significant inter-individual variability in efficacy, numerous adverse effects associated with long-term use, and a high likelihood of relapse following discontinuation [2]. The formula Shenling Baizhu San was first recorded in the Song Dynasty's officially compiled pharmacopoeia, "Taiping Huimin Heji Jufang". The complete formula is composed of a combination of medicinal ingredients including ginseng, poria, white atractylodes, Chinese yam, lotus seed, coix seed, amomum, platycodon, white kidney bean and liquorice. Its core principle lies in tonifying the qi of the spleen and stomach, draining dampness and turbidity, and thereby arresting diarrhoea. Based on the Four Gentlemen Decoction, the formula combines Chinese yam and lotus seed with Atractylodes macrocephala to enhance the spleen-tonifying and qi-nourishing effects; the concurrent use of white kidney bean and coix seed assists Poria in strengthening the spleen and draining dampness. Amomum villosum, pungent and warm in nature, excels at invigorating the spleen, harmonising the stomach, and regulating the qi mechanism of the middle jiao; Platycodon root acts as a carrier to direct the other herbs

upwards, whilst also promoting the flow of lung qi and dispersing the essence. Collectively, the formula achieves the effects of strengthening the spleen, draining dampness, regulating qi, and harmonising the middle jiao. Guided by the principles of Traditional Chinese Medicine, Shenling Baizhu San is widely used in the treatment of ulcerative colitis (UC) characterised by spleen deficiency with excessive dampness. It can effectively reduce levels of inflammatory markers and significantly improve symptoms such as abdominal pain, diarrhoea, and stools containing mucus, pus and blood, demonstrating remarkable clinical efficacy [3]. Relevant studies indicate that Shenling Baizhu San treats ulcerative colitis through multiple mechanisms, including promoting the release of anti-inflammatory factors, inhibiting the secretion of pro-inflammatory factors, regulating immune function, repairing the intestinal mucosal barrier, and maintaining the homeostasis of the gut microbiota. This article provides a systematic review of the TCM theory, mechanisms of action, and clinical application of Shenling Baizhu San in the treatment of UC, offering a reference for the management of this condition.

## 2. The Traditional Chinese Medicine Perspective on Ulcerative Colitis

### 2.1 The Pathogenesis of UC and its Corresponding Categories in Traditional Chinese Medicine

There are no direct references to the term 'ulcerative colitis' in classical texts of Traditional Chinese Medicine. Based on its clinical symptoms, this condition can be categorised and treated within the scope of syndromes such as 'diarrhoea', 'dysentery', 'intestinal diarrhoea' and 'loose stools'. Over the centuries, medical practitioners have continually deepened

their understanding of this condition, gradually reaching a consensus on its core pathogenesis: ‘spleen deficiency as the root cause, and damp-heat and blood stasis-toxin as the secondary manifestations’. The Suwen: Treatise on the Taiyin and Yangming states: “Those who do not regulate their diet or observe regular routines... will, over time, develop intestinal diarrhoea.” This illustrates that irregular diet and disordered daily routines can damage the spleen and stomach; if the condition persists, it develops into intestinal diarrhoea. Zhang Zhongjing’s “Essentials of the Golden Cabinet” includes a dedicated chapter on “Pulse Patterns, Symptoms and Treatment of Diarrhoea”, and the formulas recorded therein, such as Bai Tou Weng Decoction and Tao Hua Decoction, established a model for the treatment of dysentery in subsequent generations. Li Dongyuan, a physician of the Jin and Yuan dynasties, believed that internal injury to the spleen and stomach was the core pathogenesis of diarrhoea and dysentery. He proposed that “once the qi of the spleen and stomach is injured, the original qi cannot be replenished, and this is the source of all diseases”, emphasising that deficiency of the spleen and stomach gives rise to a multitude of ailments. Medical scholars of the Ming and Qing dynasties further enriched the understanding of dysentery. The “Complete Works of Jingyue” states: “All cases of dysentery are often caused by weakness of the spleen and stomach, irregular diet, or external invasion by seasonal pathogens, leading to the accumulation of damp-heat internally,” emphasising the interrelationship between spleen deficiency and damp-heat [5].

Modern scholars hold differing views on the pathogenesis of ulcerative colitis. Modern scholars hold differing views on the pathogenesis of ulcerative colitis. Professor Shen believes that UC primarily affects the large intestine and is often associated with the spleen, stomach, liver and kidneys. A constitutional deficiency of the spleen forms the basis of the condition, which is frequently triggered by dietary indiscretion, exposure to external pathogens, or occasionally emotional disturbances. The disease typically arises when dampness, cold, heat, or stagnant toxins accumulate in the large intestine, leading to impaired transmission and transformation functions and damage to the meridians. Clinically, one must weigh the relative importance of the pathogenic factors and the host’s constitution, identify the location of the disease within the zang-fu organs, and grasp the pathogenesis holistically. Treatment must employ multiple methods simultaneously; only when the formula corresponds to the syndrome can it be considered appropriate [6]. Professor Li Junxiang believes that the aetiology of UC is primarily internal, centring on congenital deficiency, spleen-stomach dysfunction, or factors such as kidney qi deficiency and lung qi imbalance. He proposes that the treatment of UC should be approached from three aspects: treatment based on damp-heat, treatment based on qi and blood, and treatment based on the pivotal mechanisms [7]. Professor Wang Qingguo posits that the core pathogenesis of UC lies in the dysfunction of the ‘pivot mechanism’ and the disharmony of qi, blood, yin and yang within the zang-fu organs. He identifies spleen-kidney yang deficiency as the underlying deficiency, whilst damp-heat, blood stasis and stagnation obstructing the intestines constitute the manifest excess. In clinical practice, he advocates integrating the disease and its manifestations, focusing on the primary disease and symptoms, and

formulating treatments according to the specific presentation. He frequently employs methods that combine warming and clearing, clearing the liver and regulating the spleen, regulating qi and invigorating blood, and treating both internal and external aspects—all of which are ‘unblocking’ and ‘harmonising’ approaches [8].

Based on the discussions of medical scholars throughout history and the consensus of modern medical experts, the pathogenesis of ulcerative colitis (UC) is characterised by an underlying constitution of spleen deficiency, with irregular diet, emotional imbalance and external invasion by damp-heat serving as precipitating factors. Spleen deficiency leads to impaired transport and transformation, resulting in the retention of fluid and dampness within the body. Damp turbidity accumulates and stagnates, transforming into heat; damp-heat and toxic stasis then obstruct the intestines and viscera, damaging the lipid-nourished vessels, causing the decay of flesh and blood, and manifesting as bloody and mucoid diarrhoea. Prolonged illness leads to depletion of qi and blood and impairment of both yin and yang, resulting in a pattern characterised by underlying deficiency and superficial excess, or a mixture of deficiency and excess. Spleen deficiency is a constant factor throughout the course of the disease; it is not only the root cause of the onset but also the key factor in the recurrent and protracted nature of the condition [9].

## **2.2 The Theoretical Basis of Traditional Chinese Medicine for the Treatment of Ulcerative Colitis with Shenling Baizhu San**

UC is fundamentally attributed to spleen deficiency; the spleen governs the transformation and transport of the essence of food and drink. When the spleen functions robustly, dampness does not accumulate, and there is a source for the generation of qi and blood. The Shenling Baizhu San formula uses ginseng, white atractylodes and poria as its principal ingredients to tonify qi and strengthen the spleen, thereby restoring the transformative and transportative functions of the middle jiao [10]. Chinese yam and lotus seed flesh assist the principal herbs in strengthening the spleen and consolidating the qi, whilst also stopping diarrhoea. Poria, coix seed and white kidney bean in the formula gently drain and dispel dampness, guiding water and dampness to be excreted via the urine, in accordance with the principle of ‘promoting urination to solidify the stools’. Amomum, with its aromatic properties, transforms dampness, invigorates the spleen and harmonises the stomach, thereby eliminating dampness and restoring the smooth flow of qi. Platycodon, in this formula, disperses the lungs and promotes the flow of qi, whilst carrying the other herbs upwards, embodying the principle of ‘nourishing earth to generate metal’ in the formulation. When spleen qi is robust, pathogenic dampness has no source from which to arise; when qi and blood are abundant, the intestinal vessels are nourished, and the damaged mucosa can naturally repair itself [11].

## **3. The mechanism of action of Sanling Baizhu San in treating UC**

### **3.1 Modulation of Inflammatory Factors and Inflammation-related Pathways**

One of the key mechanisms underlying the pathogenesis of UC lies in the inflammatory and immune damage to the colonic mucosa caused by an imbalance between pro-inflammatory and anti-inflammatory factors. Shenling Baizhu San exerts an anti-inflammatory effect by intervening in the inflammatory network via multiple targets and regulating immune balance [12].

An imbalance in the inflammatory response is a core pathological feature of UC, manifested as excessive release of pro-inflammatory factors and a relative deficiency of anti-inflammatory factors. Hu M. et al. [13] found that the combined use of acupuncture and Shenling Baizhu San in the treatment of rats with UC activated the Nrf2/HO-1 pathway in the intestinal mucosa, reduced the levels of TNF- $\alpha$ , IL-1 $\beta$ , IL-6 and IL-18, and consequently alleviated intestinal inflammation and oxidative stress. Liu Yuhui et al. [14] found that Shenling Baizhu San could alleviate DSS-induced intestinal inflammatory responses in UC and reduce the extent of colonic tissue damage; its mechanism of action may be related to the formula's regulatory effects on proteins associated with the NLRP3 inflammasome signalling pathway and their downstream inflammatory factors. Research has shown [15] that Shenling Baizhu San can reduce the expression of IL-6 in inflammatory tissue cells, thereby alleviating the inflammatory damage associated with UC. The above studies indicate that Shenling Baizhu San can alleviate intestinal mucosal inflammatory responses and repair damaged mucosa by modulating the expression of inflammatory factors.

### 3.2 Regulation of Immune Function

The onset and progression of UC are closely linked to dysregulation of the immune response; Shenling Baizhu San can alleviate inflammation by enhancing the body's immune function. Research has shown [16] that Shenling Baizhu San can suppress excessive intestinal immune responses by increasing the number and function of regulatory T cells (Tregs) in the intestinal mucosa. The specific mechanism involves increasing the proportion of CD4+CD25+Foxp3+ regulatory T cells in the intestine, thereby enhancing the function of the mucosal immune barrier, alleviating local inflammatory damage, and ultimately promoting the repair of the intestinal mucosa and ulcer healing. Sun Juan et al. [17] found that the anti-UC effect of Shenling Baizhu San may be realised via the TLR4/NF- $\kappa$ B signalling pathway. This formula can inhibit the release of pro-inflammatory mediators such as TNF- $\alpha$  and MIF mediated by this pathway, whilst simultaneously enhancing the expression of anti-inflammatory factors such as IL-10 and EGF. By restoring the pro-inflammatory-anti-inflammatory balance through bidirectional regulation, it alleviates UC-related pathological changes. In a rat model of UC characterised by spleen deficiency with dampness retention, Shenling Baizhu San significantly reduced the protein and mRNA expression levels of NF- $\kappa$ B p65 and I $\kappa$ K $\beta$  in colonic tissue, whilst simultaneously upregulating the protein and mRNA expression of I $\kappa$ B $\alpha$ . By inhibiting the activation of the I $\kappa$ K/I $\kappa$ B/NF- $\kappa$ B signalling pathway, this formula exerts a protective effect on the intestinal mucosa [18]. Recent studies indicate that Shenling Baizhu San can, by inhibiting the activation of the NLRP3 inflammasome, block the release of

pyroptosis-related inflammatory factors such as IL-1 $\beta$  and IL-18, whilst simultaneously activating antioxidant pathways such as Nrf2/HO-1 to enhance the resistance of intestinal epithelial cells to ROS damage. Furthermore, it upregulates the expression of peroxisome proliferator-activated receptor  $\gamma$  to inhibit NF- $\kappa$ B nuclear translocation, thereby establishing a multi-tiered anti-inflammatory mechanism [19].

### 3.3 Modulation of Cell Adhesion Molecules

The adhesion of leukocytes to vascular endothelial cells and their transendothelial migration, mediated by cell adhesion molecules, are key steps in the initiation and maintenance of inflammation in UC. The cell adhesion molecules CD44, CD62p and CD54 are glycoproteins located on the cell membrane; the inflammatory responses they mediate play a key role in the abnormal immune response observed in UC. Shenling Baizhu San can effectively reduce plasma levels of CD44 and CD62p, thereby inhibiting local intestinal inflammatory responses.[20] The repair and reconstruction of the colonic mucosa primarily depend on colonic mucosal stem cells. Shenling Baizhu San can downregulate the expression of ICAM-1 and VCAM-1 in colonic tissue and blood, reducing the infiltration of white blood cells into the site of inflammation, thereby repairing the colonic mucosal tissue and providing a new therapeutic approach for the treatment of UC [21].

### 3.4 Regulating the Gut Microbiota

Disruption of the gut microbiota is closely associated with the onset and progression of UC: beneficial bacteria such as Lactobacillus and Bifidobacterium can regulate microbial balance, repair the mucosal barrier and alleviate inflammation; whereas harmful bacteria such as Escherichia coli can compromise mucosal integrity, induce inflammation and accelerate disease progression. The pathogenesis of UC is primarily characterised by a reduction in beneficial gut bacteria, overgrowth of pathogenic bacteria, and a decline in microbial diversity. Consequently, restoring the homeostasis of the gut microbiota and intestinal barrier function is regarded as a new strategy for the effective treatment of UC [22].

#### 3.4.1 Regulating the balance of the gut microbiota:

Research has confirmed that Shenling Baizhu San, when used to treat ulcerative colitis, targets the gut microbiota as a key intervention point. This formula promotes the proliferation of beneficial bacteria in the gut whilst inhibiting the colonisation and growth of pathogenic bacteria, thereby maintaining the stability of the local gut microenvironment. By protecting the intestinal mucosal barrier and alleviating the inflammatory response, it ultimately promotes recovery from UC [23]. Xu Xia et al. [24] found that Shenling Baizhu San reduces C-reactive protein (CRP) and procalcitonin (PCT), increases inducible nitric oxide synthase (iNOS), and reduces the abundance of pathogenic bacteria such as Clostridium perfringens-9, Bacteroides and Arcobacter, whilst increasing the abundance of beneficial gut bacteria such as Clostridium butyricum (UCG-005) and Lactobacillus. By enhancing the abundance of beneficial bacteria, suppressing that of pathogenic bacteria and protecting the intestinal mucosa, it

promotes the cure of UC. Wei De-feng et al. used 40 Wistar rats as experimental subjects, employing a randomised grouping method and combining traditional Chinese medical aetiology with modern medical aetiology to establish a UC model. Following drug intervention, total bacterial DNA was extracted from colonic contents, and microbial community structure analysis was performed using enterobacterial intergenic repetitive consensus (ERIC-PCR) technology. The results demonstrated that Shenling Baizhu San effectively regulates the colonic microbiota balance in rats with UC presenting with the pattern of spleen deficiency with dampness retention, thereby improving immune function, alleviating inflammatory responses, and promoting ulcer healing [25].

#### 3.4.2 Improving the intestinal barrier:

The progression of ulcerative colitis is closely linked to damage to the intestinal mucosal barrier function. Consequently, repairing and reconstructing damaged colonic mucosal tissue has become a key component in achieving a cure for UC. Zhu Yunfei [26] randomly divided 60 C57BL/6 mice into a control group, a model group, a positive drug group, and groups receiving low, medium, and high doses of Shenling Baizhu San. A mouse model of UC was established using 2% sodium dextran sulphate. Serum cytokine levels were measured by ELISA; serum FITC-dextran fluorescence intensity was assessed following FITC-dextran gavage to evaluate changes in colonic mucosal permeability; and the expression of miR-130a, PPAR $\gamma$  and Occludin was analysed by RT-qPCR and Western blotting. The results indicated that, compared with the model group, levels of IL-1 $\beta$ , IL-6 and TNF- $\alpha$  were reduced in all treatment groups except the low-dose Shenling Baizhu San group, where the reduction in IL-6 was not statistically significant. This suggests that Shenling Baizhu San can improve the intestinal mucosal barrier function in UC mice, and its mechanism of action may be related to the regulation of the miR-130a/PPAR $\gamma$ /Occludin pathway. Shen Lingna et al. [27] found that the combination of Sishen Wan, Shenling Baizhu San and mesalazine effectively alleviated clinical symptoms in patients with UC of the spleen-kidney yang deficiency type; the mechanism is associated with increasing beneficial gut bacteria, regulating the microbial community structure and promoting the repair of the intestinal mucosal barrier.

#### 3.5 Antioxidant

The onset and progression of UC are closely associated with an imbalance in inflammatory homeostasis. Excessive oxidative stress can induce epithelial apoptosis, disrupt the integrity of the intestinal barrier, and lead to the invasion of pathogenic microorganisms into the lamina propria of the intestinal mucosa. Shenling Baizhu San inhibits endoplasmic reticulum stress and modulates multiple pathways, including inflammation and oxidative stress, thereby exerting its therapeutic effect on UC [28]. Zhang Quanhui et al. [29] found that the Shenling Baizhu San group promoted the activation of the Keap-1/Nrf2/ARE signalling pathway, inhibited oxidative stress responses, and alleviated oxidative stress in rats with UC, thereby exerting a protective effect on colonic mucosal damage in these rats. Li Qiankun et al. [30] found that Shenling Baizhu San can inhibit oxidative stress in

the intestine and alleviate intestinal inflammation in CD rats; its mechanism of action may involve inhibiting the ERK/JNK pathway, reducing ROS production, decreasing the release of inflammatory factors such as IFN- $\gamma$ , IL-2 and IL-8, promoting a reduction in CRP levels, and increasing ALB and Hb levels.

#### 3.6 Regulation of Water and Fluid Metabolism

Aquaporins (AQP) significantly enhance cell membrane permeability, mediate transmembrane water transport in various cell types, and maintain the body's fluid balance. Research has shown that Shenling Baizhu San not only promotes the restoration of the spleen's function of 'transporting and transforming fluids' as described in traditional Chinese medicine, thereby improving the body's fluid metabolism, but also significantly modulates the protein and mRNA expression levels of AQP3 and AQP4 in the colonic tissue of rats with spleen deficiency and dampness-obstruction type ulcerative colitis. The molecular mechanism may involve the ERK/p38 MAPK signalling pathway mediating the regulation of AQP expression by this formula.

### 4. Summary and Outlook

In summary, Shenling Baizhu San is a representative formula of the 'tonifying the spleen and draining dampness' approach, and its therapeutic effects on ulcerative colitis (UC) are characterised by multiple targets and pathways. Existing research confirms that this formula exerts its effects through the following mechanisms: regulating inflammatory mediators and their signalling networks; modulating the immune response; interfering with the expression of adhesion molecules; reshaping the gut microbiota; regulating colonic AQP to maintain water metabolism; and scavenging oxygen free radicals. The synergistic integration of these mechanisms forms the pharmacological basis for the formula's ability to alleviate UC symptoms, slow disease progression, and achieve therapeutic effects. It demonstrates significant efficacy in treating UC, effectively relieving clinical symptoms such as diarrhoea, abdominal pain, and mucoid, purulent, or bloody stools, whilst improving intestinal mucosal damage caused by immune dysregulation and inflammatory responses, and enhancing patients' quality of life. In addition to being administered as a single oral formulation, Shenling Baizhu San can be combined with various treatment modalities, including Western medicines, enemas, nutritional support and acupuncture. This approach effectively enhances clinical treatment outcomes, reduces adverse reactions and promotes recovery in UC patients. These interrelated and synergistic mechanisms collectively constitute the scientific basis for the multi-targeted, multi-pathway treatment of UC by Shenling Baizhu San [32]. However, the clinical application of Shenling Baizhu San remains limited by several shortcomings, such as: (1) a lack of standardisation in the construction of UC animal models. Different modelling methods result in varying research focuses; further standardisation of modelling protocols is required to enhance the accuracy of experimental validation. (2) Existing clinical studies often suffer from issues such as small sample sizes, unclear randomisation methods, and highly subjective outcome measures. (3) Although current research has confirmed that Shenling Baizhu San treats UC

via multiple pathways and targets, there remains a lack of systematic and in-depth investigation into the interconnections, synergistic or antagonistic effects, and functional overlaps between these pathways. (4) The pharmacological mechanisms by which the individual herbal ingredients in Shenling Baizhu San exert their therapeutic effects remain unclear, and their precise mechanisms of action have yet to be elucidated. (5) The syndrome patterns of UC are complex and variable; Shenling Baizhu San is primarily indicated for the pattern of spleen deficiency with dampness retention. Further exploration is required regarding how to achieve precise medication administration under the guidance of pattern differentiation and treatment, as well as how to dynamically adjust the formula in response to the evolution of syndrome patterns. Current research on the treatment of UC with Shenling Baizhu San is subject to numerous limitations. In the future, it will be necessary to integrate advanced scientific technologies and research methods to elucidate the mechanisms of action of Shenling Baizhu San in treating UC, thereby providing new theoretical and experimental foundations for the treatment of UC with traditional Chinese medicine.

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