

Expert Consensus Opinions on Clinical Application of Shenling Baizhu Powder and Buzhong YiqiDecoction

Buzhong YiqiDecoction

Professional Committee of Spleen and Stomach Diseases, Beijing Association of Chinese Medicine

(Digestive Center of Beijing Hospital of Traditional Chinese Medicine, Capital Medical University, Beijing, 100010, China)

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Corresponding author: ZHANG Sheng-sheng, ZHOU Qiang, Tel: (010) 52176634

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Traditional Chinese medicine holds that the “spleen” is a combination of the structure and function of human digestive system, which is the foundation of acquired nature and constitution, and the source of transformation of qi and blood, governing the movement and transformation of the essence of water and grain, blood circulation, muscles and limbs. The spleen deficiency may induce failure of transformation of water and grain, lack of source of transformation of qi and blood, and dysfunction in rise and fall of qi, thus causing various diseases. The major treatment for spleen deficiency should be spleen invigorating or strengthening. Spleen-invigorating prescriptions can be adopted as the main therapy, of which the representative prescriptions are Shenling Baizhu Powder (granules, pills) and Buzhong Yiqi Decoction (granules, pills). Both of them are classical TCM prescriptions, emphasizing the original dosage of the classic prescription. Both of them are widely used in clinical practice, and have shown unique advantages in the treatment of “spleen-deficiency syndrome” of various diseases, which are safe, effective and have small adverse reactions. So far, many clinical studies and empirical summary papers have been published, but the level of Evidence-based practice varies generally. Therefore, it is extremely necessary to formulate relevant expert consensus opinions to guide the clinical practice.

Shenling Baizhu Powder was first mentioned in the *Taiping Huimin Heji Ju Fang (Prescriptions of the Bureau of Taiping People's Welfare Pharmacy)*, and consists of 10 Chinese herbs, i.e. ginseng, poria, largehead atractylodes rhizome, white hyacinth bean, Chinese yam, glycyrrhiza, lotus nut, fructus amomi, coix seed and platycodon grandiflorum, which together play the effect of invigorating spleen and supplementing qi, draining dampness and checking diarrhea. It is used for the Spleen Deficiency spleen deficiencywith Overabundance of Dampness Syndrome, which is mainly manifested as weakness of spleen and stomach, poor appetite and loose stools, limb weakness, chest and epigastric bloating and distress, sallow complexion, pale tongue, white and greasy coating, etc. In the prescription, ginseng, largehead atractylodes rhizome and poria are monarch drugs, of which ginseng is for tonifying viscera, largehead atractylodes rhizome for fortifying spleen and eliminating dampness, and poria can not only fortify spleen and tonify deficiency, but also clear dampness and promote diuresis. These three Chinese herbs can achieve the effect of replenishing qi to invigorate spleen. In addition, Chinese yam is added for tonifying

spleen and nourishing stomach, coix seed for fortifying spleen and percolating dampness, white hyacinth bean for invigorating spleen and resolving dampness, and lotus nut for tonifying spleen and stopping diarrhea. All of them are ministerial drugs, which can strengthen the effect of invigorating spleen and supplementing qi, draining dampness and checking diarrhea. Fructus amomi is an assistant to enliven spleen and harmonize stomach, promote the circulation of qi and relieve stagnation; platycodon grandiflorum and glycyrrhiza are assistant and guide, of which platycodon grandiflorum is for dispersing the lung and expelling wind, dredging and regulating water passage, and ascending up qi, while glycyrrhiza is for tonifying spleen and regulating the middle warmer, and moderating the property of herbs. The combination of various herbs can make the spleen-qi healthy and the dampness be eliminated.

Buzhong Yiqi Decoction is derived from the *Pi Wei Lun (Treatise on the Spleen and Stomach)* written by Li Dongyuan, a great doctor in Jin Dynasty. It consists of 8 Chinese herbs, i.e. astragalus membranaceus, largehead atractylodes rhizome, tangerine peel, ginseng, angelica sinensis, glycyrrhiza, rhizoma cimicifugae, and radix bupleuri, which together play the effect of tonifying middle-Jiao and qi, ascending up spleen-qi and yang. It is used for the syndrome of depression of qi of middle-jiao or syndrome of qi-deficiency fever, which is mainly manifested as reduced appetite, fatigue, asthenic breathing and laziness to speak, pale tongue, vacuous pulse or rectocele, uterine prolapse, prolonged diarrhea and dysentery, uterine bleeding or general fever and spontaneous perspiration, thirst with a liking for hot drinks, shortness of breath and fatigue, pale tongue, feeble large and weak pulse, etc. Of the Prescription, astragalus membranaceus is the monarch drug, with the effect of tonifying middle-Jiao and qi, invigorating splenic yang and securing the exterior; ginseng and largehead atractylodes rhizome are ministerial drugs, with the effect of invigorating qi and strengthening the spleen. In addition, angelica sinensis is an assistant for replenishing qi and nourishing blood, tangerine peel is an assistant for regulating qi-flowing for harmonizing stomach to make all herbs be supplemented and not sluggish. Moreover, a small amount of rhizoma cimicifugae and radix bupleuri are added in the prescription as guide to enhance spleen-qi and yang, and assist the monarch drug in enhancing the sunken qi of middle-jiao. Glycyrrhiza is the guide to moderate the property of all herbs.

Both Shenling Baizhu Powder and Buzhong Yiqi Decoction have the effect of invigorating qi and strengthening spleen, which have good efficacy in the treatment of symptoms induced by spleen deficiency, and can be widely used in the treatment of diseases of multi systems, such as digestive system, respiratory system, urinary system, pediatrics and gynecology. However, Shenling Baizhu Powder tends to drain dampness and check diarrhea, which is better for treating the Spleen Deficiency with Dampness Syndrome. Buzhong Yiqi Decoction tends to enhance spleen-qi and yang, which is better for treating the syndrome of collapse from qi deficiency. At the same time, Shenling Baizhu Powder has the effect of protecting lungs, which is a typical prescription of “cultivating the earth to produce gold” that has a good efficacy in the treatment of lung injury and consumptive disease. Buzhong Yiqi Decoction has the effect of warming and removing heat, which can treat the syndrome of qi-deficiency fever.

Specialized Committee of Spleen and Stomach Diseases of Beijing Association of Chinese Medicine led the establishment of the drafting group of the *Expert Consensus Opinions on*

Clinical Application of Shenling Baizhu Powder and Buzhong Yiqi Decoction in August 2016. Based on the principles of Evidence-based medicine, the team members collected Evidence-based data extensively. Professor Liu Jianping and Associate Professor Chen Wei from the Centre for Evidence-based Medicine of Beijing Association of Chinese Medicine provided document retrieval. MEDLINE (<http://www.medline.com/>), EMBase (<https://www.embase.com/login>), The Cochrane Library (<https://www.cochranelibrary.com/>), CQVIP (<http://www.cqvip.com/>), Wanfang data (<http://d.wanfangdata.com.cn/>), CNKI (<https://www.cnki.net/>) were searched with computer to collect literature about clinical application of Buzhong Yiqi Decoction, with the retrieval time limit from January 1, 1979 to November 30, 2017. A total of 1,371 pieces of literature about Shenling Baizhu Powder were retrieved, and 784 pieces were obtained after reading the abstract of the literature and eliminating the relevant literature that did not meet the inclusion criteria. According to the literature collected, it was concluded that, with diseases treated with Shenling Baizhu Powder classified, Shenling Baizhu Powder could be used to treat more than 40 diseases in clinical practice, among which the application in the treatment of digestive and respiratory diseases were reported the most; In addition, reports on the treatment of metabolic diseases such as obesity, diabetes and hyperlipidemia with Shenling Baizhu Powder were also concentrated. A total of 1,923 pieces of literature about Buzhong Yiqi Decoction were retrieved, and 561 pieces were obtained after reading the abstract of the literature and eliminating the relevant literature that did not meet the inclusion criteria. According to the literature collected, it was concluded that, with diseases treated with Buzhong Yiqi Decoction classified, Buzhong Yiqi Decoction could be used to treat more than 60 diseases in clinical practice, among which the application in the treatment of digestive and respiratory diseases were reported the most; In addition, reports on the treatment of chronic fatigue syndrome, myasthenia gravis, fever, gastroptosis, hysteroptosis and hernia with Buzhong Yiqi Decoction were also concentrated..

The formulation of this Consensus Opinions is based on the best Evidence available to grade the Evidence with reference to the GRADE standard, including high-level Evidence (A): RCT, observational study with quality increased by two levels; intermediate-level Evidence (B): RCT with quality reduced by one level, observational study with quality increased by one level; Low-level Evidence (C): RCT and observational study with quality reduced by two levels; Very-low-level Evidence (D): RCT with quality reduced by three levels, observational study, serial case observation and case report with quality reduced by one level. At the same time, the relevant experts were organized to discuss, modify and review, and a series of key issues concerning the clinical application of Shenling Baizhu Powder and Buzhong Yiqi Decoction were summarized in full combination with the experience of clinical experts in TCM digestion, respiration, endocrinology, gynecology and skin. As a result, this Consensus Opinions were formed. The full text is now published as follows for the reference of colleagues at home and abroad, and continuous improvement is expected in further application.

1 Digestive System Diseases

- ① Both Shenling Baizhu Powder and Buzhong Yiqi Decoction can be used to treat the diarrhea-predominant Irritable Bowel Syndrome, which can effectively improve the symptoms of diarrhea and abdominal pain^[1-2] (Level of Evidence: A), and Buzhong Yiqi Decoction combined with trimebutine can relieve the concomitant symptoms (loss of appetite, tiredness and fatigue, etc.), anxiety and depression^[3] of patients with Irritable

Bowel Syndrome accompanied by spleen-stomach weakness (Level of Evidence: **C**); for patients with diarrhea-predominant Irritable Bowel Syndrome accompanied by liver depression and spleen deficiency, both Buzhong Yiqi Decoction and Shenling Baizhu Powder can be used in combination with Tongxie Yaofang^[4-7] (Level of Evidence: **C**). ②

Both Shenling Baizhu Powder and Buzhong Yiqi Decoction can effectively improve the chronic diarrhea patients with the spleen deficiency and reduce the frequency of defecation^[8-10] (Level of Evidence: **C**); and both can improve the concomitant symptoms of diarrhea such as abdominal pain accompanied by diarrhea, loss of appetite, fatigue and abdominal bloating, as well as anxiety and depression scores^[11] (Level of Evidence: **D**). For chronic diarrhea, patients with spleen deficiency with overabundance of dampness, Shenling Baizhu Powder^[12] (Level of Evidence: **D**) can be selected, and for patients with depression of qi of middle-jiao, Buzhong Yiqi Decoction^[8-10] (Level of Evidence: **D**) can be selected. ③ For patients with ulcerative colitis in active phase (Spleen and Stomach Deficiency Syndrome), the basic treatment combined with Buzhong Yiqi Decoction or Shenling Baizhu Prescription^[13-15], or a combination of both at the same time, can increase the effective rate of treatment^[13-15] (Level of Evidence: **D**). ④ The application of Shenling Baizhu Powder and Buzhong Yiqi Decoction in the treatment of functional dyspepsia patients with the Spleen and Stomach Deficiency Syndrome, especially in elderly patients, can effectively relieve the symptoms of early satiety, epigastric bloating and pain, poor appetite and anorexia, epigastric burning, etc.^[16-17]. The efficacy of using traditional Chinese medicine alone is significantly superior to that of Western medicine of prokinetics to promote gastrointestinal motility^[18-20]; or the combined use of prokinetic drugs has a synergistic effect^[21-22] (Level of Evidence: **D**). ⑤ Both Shenling Baizhu Powder and Buzhong Yiqi Decoction can be used to treat chronic superficial gastritis^[23-24] (Level of Evidence: **D**), chronic atrophic gastritis^[25-27] (Level of Evidence: **D**), erosive gastritis^[28] (Level of Evidence: **D**) accompanied by the Spleen and Stomach Deficiency Syndrome. With respect to HP eradication, triple or quadruple therapy of Shenling Baizhu Powder and Buzhong Yiqi Decoction combined with Western medicines have a synergistic effect^[29-30] (Level of Evidence: **B**). ⑥ Shenling Baizhu Powder and Buzhong Yiqi Decoction can effectively relieve the symptoms of peptic ulcer, such as epigastric pain, abdominal bloating, acid reflux, heartburn and other symptoms of peptic ulcer (the Spleen and Stomach Deficiency Syndrome) etc. The combination with acid-inhibitory drugs can assist in promoting the healing of ulcer surface, which has synergistic effect, and the efficacy is better than the use of acid-suppressing drugs alone^[31-34] (Level of Evidence: **B**). ⑦ Buzhong Yiqi Decoction can also be used for oral mucosal ulcer (the Spleen and Stomach Deficiency Syndrome)^[35-37] (Level of Evidence: **D**), gastroptosis^[38] (Level of Evidence: **C**), constipation^[39] (Level of Evidence: **D**), anal bulging after anorectal surgery^[40] (Level of Evidence: **C**), malnutrition after gastrointestinal surgery^[41] (Level of Evidence: **C**) accompanied by the Spleen and Stomach Deficiency Syndrome

2 Respiratory Diseases

- ① Shenling Baizhu Powder and Buzhong Yiqi Decoction are used for treating patients with the chronic obstructive pulmonary disease (**COPD**) in remission is a typical prescription for reinforcing earth to generate metal, which can effectively improve the quality of life of patients, improve the lung ventilation function, increase the forced expiratory volume in the first second (FEV₁), effectively reduce the incidence of respiratory failure, improve

remission rate of dyspnea, alleviate the symptoms of cough, expectoration, wheezing, shortness of breath, tiredness and fatigue, lack of food and appetite, etc., with good short-term and long-term efficacy^[42-48] (Level of Evidence: C). ② Shenling Baizhu Powder and Buzhong Yiqi Decoction combined with antibiotics in the treatment of respiratory tract infection can improve the cure rate of pneumonia in the elderly community, improve the bacterial clearance rate, shorten the time of disappearance due to cough, fever and rales, and clear absorption of lung shadows, reduce antibiotic resistance in the treatment of respiratory tract infections, enhance the efficacy of antibiotics; and it has been found that it may be related to the improvement of the patient's immunity and regulation of immune-inflammatory factors^[49-51] (Level of Evidence: C). ③ Buzhong Yiqi Decoction can effectively prevent repeated respiratory infections in the elderly and reduce the frequency of respiratory infections^[52-54] (Level of Evidence: C).

- ④ Shenling Baizhu Powder and Buzhong Yiqi Decoction can improve the body's immunity, regulate the gastroenteric function, help improve the effect of anti-tuberculosis drugs. It has a synergistic and detoxification effect^[55-56], and can reduce the gastrointestinal reactions caused by anti-tuberculosis drugs, such as abdominal bloating, abdominal pain, nausea and vomiting, loss of appetite, etc.^[57-58]. At the same time, Buzhong Yiqi Decoction and Shenling Baizhu Powder can also reduce liver function damage caused by chemotherapeutic drugs for tuberculosis^[59-60] (Evidence level: C). ⑤ Shenling Baizhu Powder and Buzhong Yiqi Decoction can be used for the adjuvant treatment of chronic bronchitis^[61], bronchiectasis^[62-63] in stable phase, chronic cough^[64-65]; Buzhong Yiqi Decoction can also be used for treating the upper airway cough syndrome in children^[66] (Level of Evidence: C).

3 Tumor-Related Diseases

- ① Shenling Baizhu Powder and Buzhong Yiqi Decoction combined with Western medicine of chemotherapy drugs (low-dose cisplatin and 5-fluorouracil) can reduce the systemic side effects of chemotherapy in gastric cancer patients^[67-68], relieve nausea, vomiting, pain, liver function damage, etc. improve the spirit, physical strength, appetite and sleep, etc.^[69-71], as well, improve quality of life of patients^[72-77]; have auxiliary effect on the gastrointestinal function recovery after the gastrointestinal tumor operation^[78-80]; can also alleviate gastrointestinal reactions such as diarrhea and vomiting after surgery in some cancer patients^[81-82] (Level of Evidence: C). ② Buzhong Yiqi Decoction has a certain effect on oral mucosal ulcers caused by tumor radiotherapy and chemoradiotherapy, fever associated with tumor, tumor fatigue syndrome, etc.^[83-84]. (Level of Evidence: C).

4 Metabolic Diseases

- ① Shenling Baizhu Powder and Buzhong Yiqi Decoction can be used for diabetic gastroparesis to relieve symptoms such as vomiting and abdominal bloating^[85-89]; and can be used for diabetic diarrhea to alleviate diarrhea symptoms^[90-96] (Level of Evidence: D). ② Shenling Baizhu Powder can help improve postprandial blood glucose and reduce insulin resistance^[97-98]. It can also be used for the treatment of obesity and hyperlipidemia^[97,99], which can reduce body mass index and triglyceride^[100-101] (Level of Evidence: C). ③ Buzhong Yiqi Decoction can also be used for the treatment of diabetic constipation, diabetic neurogenic bladder^[102-104] (Level of Evidence: C).

5 Kidney Related Diseases

- ① Shenling Baizhu Powder and Buzhong Yiqi Decoction have a certain effect on chronic glomerulonephritis^[105] and nephrotic syndrome^[106], which can effectively alleviate edema,

reduce proteinuria, assist in correcting hypoproteinemia, etc.^[107-108]; or can be combined with Liuwei Dihuang Pills / Zhibai Dihuang Pills for treating the chronic nephritis patients with both qi and yin deficiency^[109] (Level of Evidence: **D**). ② Shenling Baizhu Powder can effectively improve the malnutrition status of uremia patients when receiving hemodialysis, improve the abdominal bloating of dialysis patients, increase appetite, reduce their fatigue and other clinical symptoms, and improve the quality of life of patients^[110-113] (Level of Evidence: **C**).

6 Pediatric Diseases

- ① Both Shenling Baizhu Powder and Buzhong Yiqi Decoction can be used to treat digestive diseases such as autumn diarrhea in children^[114] (Level of Evidence: **C**), anorexia in children^[115-116] (Level of Evidence: **C**), malnutrition in children^[117] (Level of Evidence: **D**), and other diseases of the digestive system. Both Shenling Baizhu Powder and Buzhong Yiqi Decoction can be used to treat respiratory diseases such as repeated respiratory tract infection in children^[118-119] (Level of Evidence: **C**), chronic cough and other respiratory diseases, etc.^[64, 120] (Level of Evidence: **D**). ② Buzhong Yiqi Decoction can also be used for pediatric hernia and recovery after hernia operation^[121]; can also be used in combination with Suoquan Pills to treat enuresis in children^[122]; the combination of Buzhong Yiqi Decoction with prednisone in the treatment of ocular myasthenia gravis in children can improve efficacy, shorten the total dosage amount and duration of using hormones, and reduce the adverse reactions and recurrence rate^[123] (Level of Evidence: **D**).

7 Skin Diseases

- ① Shenling Baizhu Powder and Buzhong Yiqi Decoction can be used to treat skin diseases such as spleen-deficiency type chronic eczema, acne, chronic urticaria, etc.^[124-128] (Level of Evidence: **D**). ② The application of oral Buzhong Yiqi Decoction combined with systemic therapy, local dressing changes and physiotherapy for pressure sores can shorten the wound healing time and improve the cure rate^[129]; Buzhong Yiqi Decoction can also assist in the treatment of recurrent condyloma acuminatum^[130] (Level of Evidence: **C**).

8 Gynecological Diseases

Buzhong Yiqi Decoction can be used for the spleen and stomach weakness patients with gynecological diseases such as uterine prolapse with depression of qi of middle-jiao^[131], habitual abortion, threatened abortion^[132-133], postpartum urinary retention^[134-136], female tension urinary incontinence^[137-139], functional uterine bleeding, etc.^[140-142] (Level of Evidence: **C**).

9 Male Diseases

Buzhong Yiqi Decoction can be used to treat bladder spasm after prostate surgery, retention of urine, etc.^[143]; Buzhong Yiqi Decoction can also be used to treat mild to moderate varicocele, benign prostatic hyperplasia^[144-146] (Level of Evidence: **D**).

10 Others

- ① Shenling Baizhu Powder can be used to treat chronic anemia^[147-149], and Buzhong Yiqi Decoction can be used to treat thrombocytopenic purpura^[150-151]; both can be used to treat leukopenia, etc.^[151-152] (Level of Evidence: **D**). ② Buzhong Yiqi Decoction can be used to

treat neurological deafness and tinnitus ^[153-154] due to insufficient middle Qi (Level of Evidence: **D**). ③ Buzhong Yiqi Decoction can be used to treat non-infectious fever, which can effectively shorten the course of epidemic hemorrhagic fever patients during polyuria period, reduce urine volume ^[155] (Level of Evidence: **D**); used for AIDS fever ^[156] (Level of Evidence: **C**), tumor fever ^[157-158] (Level of Evidence: **C**), post-operative non-infectious fever ^[159-161] (Level of Evidence: **C**), etc., and which can shorten the fever time and reduce the recurrence rate. ④ Buzhong Yiqi Decoction is used for treating hypotension and sinus bradycardia, which can increase heart rate and elevate blood pressure ^[162] (Level of Evidence: **D**). ⑤ Buzhong Yiqi Decoction is used for treating simple fatigue syndrome ^[163], tumor fatigue syndrome ^[164-165], pre-exam syndrome ^[166], which can reduce fatigue and relieve fatigue symptoms (Level of Evidence: **C**). ⑥ Buzhong Yiqi Decoction can regulate the body's immunity ^[167] (Level of Evidence: **C**), and treat chronic Guillain-Barre Syndrome ^[168-169] (Level of Evidence: **D**), AIDS ^[170-171] (Level of Evidence: **C**), myasthenia gravis ^[172-173] (Level of Evidence: **C**), etc.

Project leader: ZHANG Sheng-sheng

Authors of the Consensus: ZHANG Sheng-sheng, ZHOU Qiang

Experts participating in the Consensus (Ranking by surname strokes):

WANG Zhong (Beijing), WANG Feng-yun (Beijing), WANG Chui-jie (Liaoning), YE Bai (Jiangsu), LIU Li (Shaanxi), LIU Feng-bin (Guangzhou), LIU Hua-yi (Tianjin), LIU Qi-quan (Hebei), SUN Liyun (Beijing), LI Junxiang (Beijing), LI Qian-gou (Beijing), LI Hui-zhen (Tianjin), SHI Zhao-hong (Hubei), SHEN Hong (Jiangsu), ZHANG Sheng-sheng (Beijing), ZHANG Ya-li (Heilongjiang), LIN Jiang (Shanghai), YANG Yan (Beijing), YANG Xiao-jun (Chongqing), YANG Sheng-lan (Hubei), YANG Jin-xiang (Beijing), YI Jing-hong (Beijing), ZHOU Zheng-hua (Tianjin), CHEN Wei (Beijing), CHEN Su-ning (Liaoning), CHEN Guo-zhong (Guangxi), ZHAO Wen-jing (Beijing), ZHAO Wen-xia (Henan), ZHAO Lu-qin (Beijing), Qin Dan-ping (Zhejiang), YUAN Hong-xia (Tianjin), TANG Xu-dong (Beijing), HUANG Yu-hua (Beijing), HUANG Shao-gang (Guangdong), HUANG Heng-qing (Fujian), HUANG Hui-ping (Guangdong), CAO Zhi-qun (Shandong), DONG Ming-guo (Guangdong), WEN Yan-dong (Beijing), XIE Sheng (Guangxi), XIE Jing-ri (Heilongjiang)

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About the author: ZHANG Sheng-sheng, male, 54 years old, Doctor, chief physician. Research direction: traditional Chinese medicine, integrated traditional Chinese and Western medicine in the treatment of digestive diseases.

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