

DOI: 10.13288/j.11-2166/r.2017.17.025

## Standard and Specification

# Expert Consensus Opinions on the TCM Diagnosis and Treatment of Spleen Deficiency Syndrome (2017)

Branch of Gastrointestinal Diseases, China Association of Chinese Medicine

## 1 Overview

### 1.1 Understanding of the Spleen in Traditional Chinese Medicine

According to *Plain Questions·Linglan Midian Lun*, “spleen and stomach are the organs of warehouse, where five tastes come from”. According to *Plain Questions·Jingmai Bie Lun*, “after food and drinks come into the stomach, essence qi overflows and wanders up into the spleen, and the spleen qi transports the essence”. The two sentences both described the spleen’s transformation and transportation functions. In *Lingshu·Yingweishenghui*, a sentence goes like this, “middle-jiao is located next to the stomach, after upper-jiao. It receives qi, filters water and food and turns them into essence.....then turns into blood”, pointing out that the generation of qi and blood is accomplished by the coordination of the spleen and the stomach. *Plain Questions·Wei Lun* says, “the spleen governs the muscles of the body”. *Plain Questions·Yuji Zhenzang Lun* says, “the spleen, belonging to the earth, is the only organ to nourish the other organs”, explaining the spleen’s nature as governing the muscles and nourishing extremities and bones. *Synopsis of Golden Chamber* says, “if the spleen is vigorous, pathogen will not invade all year round”, which points out that if the spleen qi is vigorous, then exogenous pathogenic factors cannot invade. *Yangsheng Siyao* says, “receiving water and food and changing them, that’s spleen and stomach yang; transforming the essence qi of the water and food to form qi and blood, that’s spleen and stomach yin”, which indicates that the spleen also can be divided into yin and yang. The above functions of the spleen as “governing the transportation and transformation”, “governing the blood”, “governing the muscle and extremities”, “protecting the body” and “as the source of the generation of qi and blood” not only cover the digestive system of the modern medicine, but are also closely related to the functions of the nervous, endocrine, blood, circulatory, immune, reproductive and motor systems. It is because of the special status of the spleen in the theory of visceral manifestation that the research on the nature of spleen has been long lasting with great progress.

### 1.2 Changes in the Diagnosis and Treatment Criteria of the Spleen Deficiency Syndrome

The Spleen Deficiency Syndrome is an important part of the syndrome study, as well as one of

---

**Fund Program:** Development Plan of Key Medical Specialties of Beijing Municipal Administration of Hospitals - Key Medical Specialties (TCM Spleen and Stomach Diseases): ZYLX201411

**Corresponding Author:** 1) Zhang Shengsheng, Digestion Center of Beijing Hospital of Traditional Chinese Medicine affiliated to Capital Medical University, E-mail: zhss2000@163.com; 2) Hu Ling, Spleen and Stomach Disease Research Institute of Guangzhou University of Chinese Medicine, E-mail: hl.cn@139. Com

the earliest syndromes on which studies have been carried out in China. The exploration of its diagnosis and treatment standards presents a process of continuous sublation and evolution. In the mid-1970s, the Spleen and Stomach Study Group of the former Guangzhou College of Traditional Chinese Medicine first proposed the diagnostic plan for the Spleen Deficiency Syndrome<sup>[1]</sup>. In 1982, the National Specialized Committee on Deficiency Syndrome and Senile Disease Studies with Integrated TCM and Western Medicine developed the diagnostic criteria for the Spleen Deficiency Syndrome based on syndrome differentiation<sup>[2]</sup>: 1) Loss of appetite; 2) Abdominal bloating after eating or in the afternoon; 3) Loose stools; 4) Sallow complexion; 5) Muscle emaciation and weakness. If three of the above five symptoms can be diagnosed, then the diagnosis can be confirmed. Thus, the national diagnostic criteria of the Spleen Deficiency Syndrome based on syndrome differentiation was initially established. In 1986, this Specialized Committee revised the standards based on the Syndrome Differentiation of 1982. Loose stools were listed as the first symptom. The condition of relief was added to the abdominal bloating after eating. Moreover, the urine D-xylose excretion rate (put forward by Beijing Hospital of Traditional Chinese Medicine and Beijing Institute of Traditional Chinese Medicine) and the salivary amylase acid load test (put forward by the former Spleen and Stomach Research Laboratory of Guangzhou College of Traditional Chinese Medicine) were recommended as auxiliary laboratory efficacy reference indicators<sup>[3]</sup>. The relevant standards issued by the former Ministry of Health in 1987 and National Administration of Traditional Chinese Medicine in 1988 both included the Diagnostic and Therapeutic Criteria for the Spleen Deficiency Syndrome<sup>[4-5]</sup>. In 1993, *Guidelines for Clinical Research on TCM New Drugs (Volume I)* was issued by the former Ministry of Health<sup>[6]</sup>, with the diagnostic standards for the Spleen Deficiency Syndrome, classification of the severity of the main symptoms and efficacy criteria. It is a more comprehensive and representative diagnostic and treatment standards for the Spleen Deficiency Syndrome. The standard of diagnosis and treatment has been widely used. In 2002, *Guidelines for Clinical Research on New Drugs of Traditional Chinese Medicine (Trial)*<sup>[7]</sup> formulated the Diagnostic Criteria for the Spleen qi Deficiency Syndrome, quantitative classification of symptoms and relevant efficacy evaluation standards.

### 1.3 Current Research Status of the Spleen Deficiency Syndrome

The clinical Spleen Deficiency Syndrome involves a variety of diseases of TCM and Western medicine, whose symptoms are complex and diverse. The research process will inevitably produce more qualitative pathophysiological data, and the non-linear relationship between them has restricted modern research on the overall picture of Spleen Deficiency Syndrome to a certain extent. Meanwhile, the research on Spleen Deficiency Syndrome mostly focuses on one method or the experience of experts, and there is still a lack of large-sample, multi-center and randomized, controlled evidence-based medical research, and the level of evidence is relatively low. In recent years, some studies have put forward the concept of Spleen Deficiency Syndrome sub-types and made beneficial attempts on gene studies of material and energy metabolism. These studies preliminarily suggested that the Spleen Deficiency Syndrome had subtypes of digestion and absorption dysfunction with the genetic background of related materials and energy metabolism disorders<sup>[8]</sup>. The concept "syndromics" is proposed to explain the complex pathological mechanism of Spleen Deficiency Syndrome through the systematic biological studies<sup>[9]</sup>. On this basis, if the complex clinical manifestations of Spleen Deficiency Syndrome can be decomposed into relatively simple sub-types of digestion and absorption disorders,

gastrointestinal motility disorders, immunodeficiency, and discussed systematically from the perspectives of multi-omics and multi-levels such as perspectives of gene, transcription, protein, metabolism, etc. It can better reflect the characteristics of the pathological changes in a certain syndrome subgroup of Spleen Deficiency Syndrome, making the clinical medicines more targeted.

Throughout the development process of the diagnosis and treatment standards for the Spleen Deficiency Syndrome, high degree of national consensus has not been reached due to the different research objects and disease types selected, or the experience and understanding of the standard setters. Therefore, it is necessary to revise and refine the previous diagnosis and treatment standards of Spleen Deficiency Syndrome to meet the needs of clinical diagnosis and treatment and scientific research.

In August 2014, the Spleen and Stomach Disease Branch of China Association of Chinese Medicine took the lead in establishing the drafting team for the *Expert Consensus on the TCM Diagnosis and Treatment of Spleen Deficiency Syndrome* in Hefei. Members of the drafting team integrated research results of Spleen Deficiency Syndrome in recent years on the basis of the diagnosis and treatment standards of Spleen Deficiency Syndrome issued in the past, widely collected evidence-based data according to the theory of evidence-based medicine, and organized national spleen and stomach experts to summarize and discuss a series of key questions such as syndrome classification of Spleen Deficiency Syndrome, treatment based on syndrome differentiation, process of diagnosis and treatment, efficacy standard, etc. Finally, the first draft of this consensus was formed. After that, three rounds of voting were conducted based on the Delphi method which is widely used internationally. In September 2015, the first round of vote was carried out in Chongqing. The drafting team revised this consensus based on the opinions of the experts. In December 2015, the second round of vote was carried out in Beijing. In June 2016, a manuscript reviewing meeting with core experts was held in Xiamen by the Spleen and Stomach Disease Branch of China Association of Chinese Medicine. More than 20 renowned experts in the spleen and stomach diseases all over China voted for the third time for this consensus (draft), and full discussion and revision were carried out. In July 2016, at the 28<sup>th</sup> National Academic Meeting of Spleen and Stomach Diseases in Harbin, discussion, revision and review were conducted again by the experts. In September 2016, an expert draft-finalizing meeting for this consensus was held in Beijing and this consensus was completed. (Voting Options: ① Fully agree; ② Agree, but with certain reservations; ③ Agree, but with larger reservations; ④ Disagree, but with reservations; ⑤ Completely disagree. If more than 2/3 of people vote for ①, or more than 85% people vote for ① + ②, then it would be passed as a clause). Now, the full article is now published as follows, for reference by colleagues at home and abroad. It's hoped to be continuously improved in the application.

## 2 Etiology and Pathogenesis

### 2.1 Etiology

According to the classic theories of TCM, such as “excessive food and drinks harm the intestines and stomach” in *Plain Question·Bi Lun*, “spleen stores ying qi, mind lives in the ying qi, if spleen qi is deficient, then extremities will lose the ability to move and the five internal organs will not have peace” in *Ling Shu·Ben Shen*, “all dampness, swelling and fullness are because of

the spleen” in *Plain Question·Zhizhenyao Dalun*, “excessive dampness leads to diarrhea” in *Plain Questions·Yinyang Yingxiang Dalun*, “coldness in the visceral causes distension” in *Plain Questions·Yifa Fangyi Lun*, “intestines and stomach are like a market, which receive everything, and everything enters. If one of the wind, coldness, heat, damp and dryness is excessive, it can hurt spleen and stomach as well” in *Theory of Spleen and Stomach·Theory of the Wax and Wane of Spleen and Stomach*, “if spleen earth yin gets hurt, there’s no organ for transportation” in *Danxi's experiential therapy*, “the spleen governs the mind, therefore too many thoughts hurts the spleen yin” in *A Treatise on Blood Troubles*, and, “deficient and waning spleen and stomach cause the inability to lift limbs, then all the pathogens will follow” in *Key to Therapeutics of Children's Diseases*, Spleen Deficiency Syndrome is often due to disorder of hunger and fullness, or overeating greasy, sweet, strong-flavored, raw or cold food, or overfatigue, or over thinking, emotional maladjustment, or long-term vomiting and diarrhea, and damage of spleen earth, or invading of dampness pathogen with spleen earth stuck inside, or insufficiency of natural endowment with innate deficiency and weakness of spleen and stomach, or long-time disease without careful nursing, or lesion of other organs affected the spleen, or overdosing on bitter, cold drugs with potent action, which lead to the damage of spleen stomach qi, blood, yang and yin.

## 2.2 Pathogenesis

From the classic theories of TCM, such as “people with spleen diseases have deficiency, with gastric fullness, borborygmus, loose stool and indigestion” in *Plain Questions·Zangqifa Shilun*, “the spleen governs blood. If the spleen is deficient, the blood cannot be controlled; the spleen transforms the blood, and transportation and transformation fail when the spleen is deficient. Then the blood loses control and escapes” in *Jinguiyi*, “improper diet leads to stomach diseases, ... when the stomach is sick, then the spleen receives nothing and gets sick as well; physical strain leads to spleen diseases. When the spleen is sick, people becomes lazy and lethargic, weak limbs and loose stools; since the spleen is sick, the stomach cannot transport fluids alone and gets sick as well” in *Theory of Spleen and Stomach·Theory of the Wax and Wane of Spleen and Stomach* saying, “if the spleen yang is insufficient, the water and food cannot be digested. If the spleen yin is insufficient, the water and fluid still cannot be digested. It is like cooking rice in a cooking pot, if there’s no fire under the pot, the rice cannot be cooked, and if there’s no water in the pot, the rice cannot be cooked either” in *A Treatise on Blood Troubles*, it is learned that the genesis of Spleen Deficiency Syndrome is closely related to the constitution of the patient and the strength of the pathogenic qi. Although the clinical symptoms of Spleen Deficiency Syndrome is perplexing, its pathogenesis is mainly manifested as the spleen losing control of transportation and transformation, the spleen failing to upbear the clear, the spleen losing general control, deficient and waning spleen yang and insufficient spleen yin, which lead to main pathogenic changes such as abnormality of the transportation and transformation of water, food and essence, insufficiency of the generation of qi and blood, malnutrition of the body; failure of clear-yang to rise, depression of middle-qi, abnormality of the transportation of essence, and failure of the blood to follow the normal route, overflowing outside the vessel, etc.

## 3 Diagnostic Criteria

### 3.1 Diagnostic Criteria of the Syndrome

The Consensus Opinions on the Diagnostic Criteria of Spleen Deficiency Syndrome shall refer to the *Guidelines for Clinical Research on New Drugs of Traditional Chinese Medicine (Volume I)*

<sup>[6]</sup> and *Guidelines for Clinical Research on New Drugs of Traditional Chinese Medicine (trial)*<sup>[7]</sup>, based on the relevant ancient literature, clinical practices and experts' consensus, are divided into three types of syndromes, the Spleen qi Deficiency Syndrome (including 3 Concurrent Syndromes of Spleen Deficiency and Accumulated Dampness, Spleen Failure to Control the Blood and the Depression of Middle qi), the Spleen Yang Deficiency Syndrome and the Spleen Yin Deficiency Syndrome. Details are as follows.

**3.1.1 Spleen Qi Deficiency Syndrome** Main Symptoms: 1) Fatigue and tiredness; 2) Loose stools; 3) Loss of appetite. Secondary Symptoms: 1) Spiritlessness and laziness to talk; 2) Abdominal bloating after eating; 3) Abdominal dull pain, caused by fatigue; 4) Tasteless, but not thirsty; 5) Sallow complexion; 6) Weak bowel movements. Tongue and Pulse: Pale tongue or with tooth marks, white and thin coating; weak and powerless pulse. Diagnosis: Manifestations of tongue and pulse are necessary, plus 2 Main Symptoms and 2 Secondary Symptoms, or manifestations of tongue and pulse are necessary, plus 1 Main Symptom and 3 Secondary Symptoms, then diagnosis can be made.

Diagnosis of Concurrent Syndromes: **On** the basis of the diagnosis of the Spleen Qi Deficiency Syndrome, 1) Patients with loose stools, diarrhea after the meal, sticky and greasy mouth, but not thirsty, white, thick and greasy coating can be diagnosed as the Spleen Deficiency and Accumulated Dampness Syndrome; 2) Patients with hematochezia, or hematemesis, or large menstrual blood volume, or one of the chronic bleeding symptoms such as gingival bleeding, etc. can be diagnosed as spleen failure to control the blood; 3) Discomfort due to the gastric downbearing distension, which aggravate after the meal, standing, or fatigue; downbearing distension and discomfort in crissum or lower abdomen or the waist, which aggravate after standing or fatigue; chronic diarrhea or chronic dysentery. Patients with one of the above symptoms can be diagnosed as Depression of Middle Qi Syndrome.

**3.1.2 Spleen Yang Deficiency Syndrome** Main Symptoms: 1) Loose stools, even with Indigestible food; 2) stomach and abdominal coldness and pain, relieved by warmth and pressing, and the pain intensifies with coldness or hunger; 3) Afraid of chills and cold limbs. Secondary Symptoms: 1) Intestinal regurgitation; 2) Swelling of the mouth and clear salivation in the mouth; 3) Pale complexion; 4) Clear and thin vaginal discharge with large amount. Tongue and Pulse: Pale and fat tongue with tooth marks, white and slippery coating, heavy and slow pulse. Diagnosis: Manifestations of tongue and pulse are necessary, plus 2 Main Symptoms and 2 Secondary Symptoms, or manifestations of tongue and pulse are necessary, plus 1 Main Symptom and 3 Secondary Symptoms, then diagnosis can be made.

**3.1.3 Spleen Yin Deficiency Syndrome** Main Symptoms: 1) Hunger, but with no appetite; 2) Muscle thinness with skin fever. Secondary Symptoms: 1) Dry lips, but with poor appetite for drinking; 2) stomach and abdominal stuffiness and bloating, which intensifies at night and stays tranquil during daytime; 3) Dry stools and weak discharge; 4) Vexing heat in the limbs; 5) Gastric upset and discomfort. Tongue and Pulse: The tongue is tender and moist, with less coating and thin, weak pulse. Diagnosis: Manifestations of Tongue and Pulse are necessary, plus 2 Main Symptoms and 2 Secondary Symptoms, or Manifestations of Tongue and Pulse are necessary, plus 1 Main Symptom and 3 Secondary Symptoms, then diagnosis can be made.

**Table 1 Quantitative Classification Scoring Table of the Main Symptoms of Spleen Deficiency Syndrome**

| Main Symptoms                                   | Level 0<br>(0 point) | Level I<br>(1 point)   | Level II<br>(2 points)  | Level III<br>(3 points)   |
|---|----------------------|--|---|---|
| Loss of appetite                                | N/A                  | Slightly poor appetite, the appetite decreased 1/3 compared to the time before the onset of the disease  | Poor appetite, the appetite decreased 1/2 compared to the time before the onset of the disease  | Basically no appetite, the appetite decreased more than 2/3 compared to the time before the onset of the disease  |
| Fatigue and weakness                            | N/A                  | Low-spirit, no tolerance to labour, still having ability to do daily light physical activities   | The spirit is more tired, fatigue and sleepy, can barely support daily light physical activities  | The spirit is extremely tired, weakness of the body and limbs, unable to do daily light physical activities   |
| Spiritlessness and laziness to talk             | N/A                  | No preference of talking, not asking and not answering questions, able to work   | Laziness of talking, asking lots of questions but not answering questions, decreased working ability  | Drowsiness and no preference of talking, significant decrease in working ability  |
| Sallow complexion                               | N/A                  | Slightly sallow complexion, slightly light lip color   | Sallow complexion, lack of radiance, light lip color  | Sallow complexion, no radiance, pale lips   |
| Stomachache                                     | N/A                  | Gastric dull pain attacks once more than 3 days, sometimes painful sometimes not, the pain decreases after having meal; the pain is relieved within 1 hour; it does not affect work and life | Gastric dull pain attacks once every 2-3 days, preference to warmth and pressing, the pain intensifies during hunger; the pain is relieved within 1-3 hours; it affects work and life | Gastric dull pain or cold pain attacks every day, preference to warmth and pressing, the pain is relieved after more than 3 hours, or the abdominal pain lasts ceaselessly, and attacks when doing labour; it seriously affects work and life |
| Stomach and abdominal stuffiness and distension | N/A                  | It attacks once >3 days, the symptom is obvious after having the meal, sometimes painful, sometimes not, and it is relieved within 1 hour, with no effect to daily life                      | It attacks once every 2-3 days, the symptom is obvious after having the meal, frequently attacks; it is relieved within 1-4 hours, with partial effect to daily life                  | It attacks every day; symptoms are obvious after having the meal, it is relieved after >4 hours, even not relieved for the whole day; with effect on work and life  |
| Hunger but without appetite                     | N/A                  | Occasionally having the feeling of hunger but no appetite  | Sometimes having the feeling of hunger but no appetite  | Often having the feeling of hunger but no appetite  |
| Gastric upset                                   | N/A                  | It attacks once more than 3 days and can be relieved within 1 hour, there is slight gastric upset, and it does not affect daily life   | It attacks once every 2-3 days and can be relieved within 1-3 hours, there is obvious gastric upset, and it affects daily life  | It attacks every day and can be relieved after more than 3 hours and even not relieved for the whole day, and it seriously affects daily life   |

| Main Symptoms                           | Level 0<br>(0 point) | Level I<br>(1 point)  | Level II<br>(2 points)  | Level III<br>(3 points)   |
|---|----------------------|---|---|---|
| Diarrhea                                | N/A                  | Loose stool or hard first then loose, 2 or 3 times/day, it even lasts for about 2 months  | Loose stool or slight diarrhea with undigested food, 3 or 4 times/day, it even lasts for about 2 months   | Diarrhea with undigested food, more than 4 times/day; or even having lienteric diarrhea without ceasing for more than 2 months  |
| Defecation atonia                       | N/A                  | Labored defecation, the stool is soft and not very dry  | Relatively labored defecation, the stool is soft or loose, defecation is only done with great effort  | The defecation is rather labored, the stool is loose, it's still difficult to defecate after going to the toilet for several times  |
| Abdominal pain                          | N/A                  | Abdominal dull pain attacks once more than 3 days, sometimes painful sometimes not; the pain is relieved within 1 hour; it does not affect work and life      | Abdominal dull pain attacks once every 2-3 days, preference to warmth and pressing, the pain increases with coldness; the pain is relieved within 1-3 hours; it affects work and life | Abdominal dull pain or cold pain attacks every day, preference to warmth and pressing; the pain is relieved after more than 3 hours, or the abdominal pain lasts ceaselessly, and attacks when doing labour; it seriously affects work and life |
| Borborygmus                             | N/A                  | ≤3 times/day, the sound of borborygmus is not loud  | 4-9 times/day, borborygmus continuously with rather loud sound  | ≥10 times/day, intestinal gurgling sound, the sound is as loud as the thunder   |
| Tastelessness                           | N/A                  | Occasional tastelessness  | Sometimes tastelessness   | Continuous tastelessness  |
| Sticky mouth, hydroadipsia              | N/A                  | Occasional sense of sticky mouth and hydroadipsia   | Sometimes having the sense of sticky mouth and hydroadipsia   | Continuous sense of sticky mouth and hydroadipsia   |
| Dry lips, lack of thirst                | N/A                  | Occasional sense of dry lips and lack of thirst   | Sometimes having the sense of dry lips and lack of thirst   | Continuous sense of dry lips and lack of thirst   |
| Clear salivation coming up in the mouth | N/A                  | Occasionally, clear salivation comes up in the mouth with small amount  | Sometimes, clear salivation comes up in the mouth with relatively large amount  | Clear salivation often comes up in the mouth with large amount  |
| Chills and cold extremities             | N/A                  | Slight chills, fear of eating raw and cold food, preference to warmth; extremities are occasionally not warm, and there's no need to add clothes or coverings | Chills which decreases when getting warmth; having raw or cold food may get sick; extremities lack warmth, the patient wears more clothes or coverings than normal people             | Significant chills, preference to warmth and pressing; having raw or cold food will easily get sick; extremities are ice-cold, the patient feels necessary to wear more clothes or coverings than normal people                                 |
| Splanchnoptosis                         | N/A                  | Mild drooping of stomach or uterus or kidney; the abdomen is stuffy or  | Moderate drooping of stomach or uterus or kidney; the sense of  | Severe drooping of stomach or uterus or kidney; the sense of abdominal stuffiness   |



| Main Symptoms                | Level 0<br>(0 point) | Level I<br>(1 point)  | Level II<br>(2 points)   | Level III<br>(3 points)  |
|------------------------------|----------------------|---|--|--|
|                              |                      | infra-umbilical downbearing distension appears after having more food; or sense of downbearing distension in the lower abdomen, or sense of downbearing distension in the waist appear after doing labour | abdominal stuffiness infra-umbilical downbearing distension is obvious after having more food; or sense of downbearing distension and discomfort in the lower abdomen, or sense of downbearing distension in the waist appear after activities | infra-umbilical downbearing distension is obvious immediately after having any food; or sense of downbearing distension and discomfort in the lower abdomen, or sense of downbearing distension in the waist appear immediately after activities |
| Proctoptosis                 | N/A                  | Mild drooping of anus, occasionally concurrent by proctoptosis  | Mild drooping of anus, sometimes concurrent by proctoptosis  | Mild drooping of anus, often concurrent by proctoptosis  |
| Hemafecia                    | N/A                  | The stool is soft but with form, its color is dark; 1 or 2 times/day  | The stool is more soft and tarry, bowel sound is hyperactive; 2 or 3 times/day   | The stool is tarry, loose and even watery with dark red color, it is glossy; bowel sound is obviously hyperactive; every day more than 4 times; it may be concurrent by dark brown gastric contents  |
| Large menstrual blood volume | N/A                  | The menstrual blood volume is larger with light color   | The menstrual blood volume is relatively large with light color  | The menstrual blood volume is large with light color and it is dripping without ceasing  |
| Hematemesis                  | N/A                  | Vomiting light brown gastric contents   | Vomiting dark brown gastric contents; may be concurrent by tarry soft black stool, bowel sound is hyperactive  | Vomiting dark red or even red gastric contents; may be concurrent by black, tarry and rotten stool, bowel sound is significantly hyperactive   |
| Gingival bleeding            | N/A                  | Occasional gingival bleeding with light color, there's no obvious red swelling  | Sometimes gingival bleeding appears with light color, there's slight atrophy in local areas  | Gingival bleeding often appears with light color, there's atrophy in local areas   |

Note: for the severity of the above main symptoms, besides using the symptom scoring to identify the quantitative classification, it still needs to be combined with relevant clinical symptoms, signs and individual constitution of the patients. It should be grasped as a whole and it is not suitable to distinguish in a too detailed way.



**Table 2 Quantitative Classification Scoring Table of Tongue Manifestation of the Spleen Deficiency Syndrome**

| <b>Tongue Manifestation</b>                         | <b>Level I (1 point)</b>  | <b>Level II (2 points)</b>   | <b>Level III (3 points)</b>   |
|---|---|--|---|
| Spleen qi deficiency syndrome                       | The tongue quality is with mild light color, thin and white coating   | The tongue quality is light or slightly fat with indentation, thin and white coating     | The tongue quality is light and fat, and is often concurrent by indentation, thin and white coating |
| Spleen Deficiency and Accumulated Dampness Syndrome | The tongue quality is with mild light color, the coating is thin and greasy, or the root part is white and greasy | The tongue quality is light, the middle and root part of the coating is white and greasy | The tongue quality is light and fat with indentation, the coating is white, thick and greasy        |
| Spleen yang deficiency syndrome                     | The tongue quality is mildly light and fat with indentation, the coating is slightly white and slippery           | The tongue quality is light and fat with indentation, the coating is white and slippery  | The tongue quality is light and fat with obvious indentation, the coating is white and slippery     |
| Spleen yin deficiency syndrome                      | The tongue quality is tender with less coating  | The tongue quality is tender and more moist, little coating                              | The tongue quality is tender and moist with obvious lack of coating                                 |

Note: the change of tongue manifestation can be regarded as a vital sign for the efficacy evaluation, however, clinically it still needs to be combined with concurrent symptoms as a whole. It is not suitable to distinguish in a too detailed way. For patients with tongue indentation, it should be identified comprehensively in combination with the relevant symptoms of Spleen Deficiency Syndrome, so as to avoid diagnosis of Spleen Deficiency Syndrome based on the indentation alone.



### 3.2 Quantitative Classification of Main Symptoms and Signs

Different points are assigned based on the weight of each Main Symptom and physical sign in the syndrome score. The Quantitative Classification Scoring Table of the Main Symptoms and Physical Signs of this Spleen Deficiency Syndrome, with reference to *Guidelines for the Clinical Research on New Drugs of Traditional Chinese Medicine (Volume I)*<sup>[6]</sup>, *Guidelines for the Clinical Research on New Drugs of Traditional Chinese Medicine (Trial)*<sup>[7]</sup> and *TCM Symptoms Scoring Table of Gastrointestinal Diseases*<sup>[10]</sup> developed by the Specialized Committee of the Digestive System Diseases of Chinese Association of Integrated Medicine, has been formulated in combination with the clinical practices and the details are as follows.

### 3.3 Diagnostic Criteria for Diseases Involving Western Medicine

In clinic, if different Spleen Deficiency Syndrome involves the Western medicine diseases, the diagnosis of the Western medicine diseases should be conducted based on the corresponding diagnostic criteria and degree of severity recognized at home and abroad.

### 3.4 Reference Indicators for Auxiliary Diagnosis

Low Urine D-xylose excretion rate, Low activity of the load test of salivary amylase.

## 4 Clinical Treatments

### 4.1 Syndrome Differentiation and Treatment

**4.1.1 Spleen Qi Deficiency Syndrome** Treatment Method: Invigorate the spleen and replenish qi.

Main Recipe: Sijunzi Decoction (*Taiping Huimin Heji Ju Fang*). Drugs:

Ginseng, Atractylodes, Poria, prepared licorice root. Treatment of the Concurrent Symptoms: 1)

Spleen Deficiency and Accumulated Dampness Syndrome: Invigorate the spleen and replenish qi, exudate the dampness and stop diarrhea, and use Shenling Baizhu Powder (*Taiping Huimin Heji Ju Fang*) as drugs; 2) Spleen Failure to Control the Blood Syndrome: Replenishing qi and

nourishing the blood, invigorating the spleen and ingesting the blood and the Recipe uses Guipi Decoction (*Recipes for Saving Lives*) as the drug 3) Depression of the Middle Qi Syndrome: Invigorating the spleen and stomach and replenishing qi, invigorating yang and lifting the depression, and use Buzhong Yiqi Decoction (*Theory of Spleen and Stomach*) as the drug.

Modification: For patients with spleen qi deficiency concurrent with chest and diaphragm stuffiness and fullness, add citrus aurantium and tangerine peel to promote qi to soothe the chest; for patients with belching and poor appetite, bloating and diarrhea due to spleen deficiency and qi stagnation, Xiangsha Liujun Decoction should be used to nourish qi and invigorate spleen, regulate qi to soothe the middle; for patients with the Spleen Failure to Control the Blood Syndrome, it should be based on the bleeding site, time, degree of severity and cold or heat. For patients with cold, argy wormwood leaf (carbonized) or paojiangtan should be added appropriately to warm the channel for arresting bleeding. For patients with heat, rehmannia root (carbonized) or trachyearpi carboni status should be added appropriately to cool the blood to stop bleeding. For patients with depression middle qi concurrent with abdominal pain, root of herbaceous white peony should be added appropriately to soften the liver and relieve the pain; for patients concurrent with qi stagnation, Citrus aurantium should be added appropriately to

regulate qi and remove bloating.

**4.1.2 Spleen Yang Deficiency Syndrome Treatment Method:** Warming the middle and dispelling cold, replenishing qi and invigorating the spleen. Main Recipe: Lizhong Decoction (*Treatise on Febrile Diseases*). Drugs: Atractylodes, ginseng, dried ginger, prepared licorice root. Modification: 1) For patients with serious deficiency and cold, add aconite and cinnamon to promote yang and dispel cold; 2) For patients concurrent with qi stagnation and fluid retention, Citrus aurantium and Poria should be added to regulate qi and resolve fluid retention; 3) For patients with gastric dull pain, which intensified with cold or hunger, and the pain was relieved after eating, warmth and pressing, Huangqi Jianzhong Decoction should be used for treatment.

**4.1.3 Spleen Yin Deficiency Syndrome Treatment Method:** The sweet and pale flavors support the spleen. Main Recipe: Shenrou Yangzhen Decoction (*Five Books of Shenrou*). Drugs: Radix Codonopsis, Poria, Atractylodes Astragalus Chinese Yam, Lotus Seeds root of white peony, Schisandra chinensis, Radix Ophiopogonis, prepared licorice root. Modification: 1) For patients with obvious anorexia, add germinated barley (stir-fried) to enliven the spleen and promote the appetite; 2) For patients with obvious dry mouth and lack of fluid, Astragalus should be removed and Potentilla kleiniana should be added, which is not greasy nor dry, can invigorate the spleen and benefit qi; 3) For patients with abdominal bloating which intensify at night time and stay tranquil during daytime, albizia flower which has a sweet taste should be added to relieve depression and calm the nerves, nourish yin and benefit the spleen.

## 4.2 Commonly Used Chinese Patent Medicine

**4.2.1 Sijunzi Pill** It benefits qi and invigorates the spleen. It is applicable to patients with the Spleen and Stomach Qi Deficiency Syndrome, poor stomach intake, poor appetite and loose stools.

**4.2.2 Xiangsha Liujunzi Pills** It benefits qi, invigorates the spleen and soothes the stomach. It is applicable to patients with the symptoms of dyspepsia, belching and poor appetite, abdominal bloating, loose stools due to spleen deficiency and qi stagnation.

**4.2.3 Shenling Baizhu Granules (Pills)** It invigorates the spleen and benefits qi. It is applicable to patients with the symptoms of tiredness, weakness, poor appetite and loose stools.

**4.2.4 Shenling Jianpiwei Granules** It nourishes the spleen and stomach, relieves dampness and stops diarrhea. It is applicable to patients with the symptoms of the spleen and stomach weakness, food indigestion, diarrhea or vomiting, thin appearance and sallow complexion, mental fatigue and weakness.

**4.2.5 Buzhong Yiqi Granules (Pills)** It invigorates the spleen and stomach and replenishes qi, invigorates yang and lifts the depression. It is applicable to patients with the symptoms of spleen and stomach weakness, fatigue and weakness due to depression of middle qi, eating a little and having abdominal bloating, loose stools and long-term diarrhea, anus drooping or proctoptosis, and uterine prolapse.

**4.2.6 GinsengJianpi Pills** It invigorates the spleen and nourishes qi, soothes the stomach and relieves diarrhea. It is applicable to patients with the symptoms of food indigestion, gastric oppression and upset, nausea and vomiting, abdominal pain and loose stools, anorexia, physical weakness and fatigue due to spleen and stomach deficiency and weakness.

**4.2.7 Bupi Yichang Pills**(Nourishing the Spleen and Intestine Pills) Nourishing Qi and tonifying blood, warming yang and promoting qi, and relieving and stopping diarrhea with intestinal astringents. It is applicable to patients with the symptoms of abdominal distension and pain, bowel irritation and diarrhea, mucosanguineous feces due to spleen deficiency and qi stagnation; chronic colitis, ulcerative colitis, allergic enteritis.

**4.2.8 Fuzi Lizhong Pills** It warms the spleen and stomach and invigorates the spleen. It is applicable to patients with gastric and abdominal cold and pain, vomiting and diarrhea, cold limbs due to Spleen and Stomach Deficiency and cold.

**4.2.9 Ginseng Guipi Pills** It benefits qi and replenishes blood, invigorates the spleen and nourishes the heart. It is applicable to patients with palpitations, forgetfulness, insomnia and dreaminess, sallow complexion, body fatigue and less appetite and women with large menstrual volume with light color, dripping without stopping due to deficiency of heart and spleen qi.

#### **4.3 Acupuncture and Moxibustion Therapy**

Regarding the deficiency syndrome, the treatment principles of “treat deficiency by tonification”, “sagging requires moxibustion” should be followed. For patients with deficiency of yang qi, both acupuncture and moxibustion should be used. For acupuncture, method of tonification should be used, and the emphasis is on moxibustion. It is to replenish qi and nourish the blood, encourage the vital qi, strengthen the visceral organs and the function of meridian. For patients with deficiency of yin, generally more acupuncture and less moxibustion should be given to even reinforcing-reducing. For patients with deficiency of spleen qi and spleen yang, the acupoints selected are Foot Taiyin, Foot Yangming Meridian and corresponding Back-Shu acupoint such as Tai Bai, Sanyinjiao, Foot Sanli, Fenglong, Pishu, Weishu, etc. should be focused on. For patients with qi deficiency and depression, acupoints of Qihai, Guanyuan, Baihui should be added and moxibustion should mainly be used. For patients with qi failing to ingest blood, the acupoints of Yinbai, Xuehai, Geshu, should be added and acupuncture should be mainly used. For patients with serious deficiency of yang, the acupoints of Guanyuan and Shenshu should be added and the method of acupuncture should be mainly used. For patients with the Spleen Yin Deficiency, the acupoints of Foot-Tai Yin Meridian, Hand and Foot Yang Ming Meridian and front-mu point of spleen and stomach should be focused on, such as Middle Epigastrium, Zhangmen, Hegu, Liangmen, Foot Sanli, Neiguan, Gongsun, Lianquan, Jin Jin, Yuye, etc.,

#### **4.4 Combined Treatment of Diseases and Syndromes**

Considering that the syndromes of the Spleen Deficiency involve many kinds of diseases of TCM and Western medicine clinically, thoughts for treatment should be given to disease, syndromes and symptoms. Syndromes should be taken as the root, the symptom as the surface and the disease as the pivot to develop the corresponding treatment. The improvement and

elimination of its concurrent symptoms should also be given consideration. The main, associate and adjuvant drugs should be listed separately based on the severity and degree of emergency of the symptoms seen, so as to formulate the recipes reasonably, and give full play to the characteristics of flexible compatibility and treatment of disease and syndrome of traditional Chinese medicine compound recipe<sup>[11]</sup>.

## 5 Efficacy Evaluation

The clinical summary with syndrome as the main body, should focus on the evaluation of a single item of the main symptoms and comprehensive efficacy, as well as the evaluation of the efficacy of syndromes.

### 5.1 Evaluation Standards for the Evaluation of the Main Symptoms Efficacy

**5.1.1 Scoring Standard for a Single Item of the Main Symptoms** It is divided into 4 levels, 0, I, II and III. Level 0: no symptoms, 0 point; level I: symptoms are mild, which do not affect daily life and work, 1 point; level II: symptoms are moderate, which partly affect daily life and work, 2 points; level III: symptoms are severe, which affect daily life and make it difficult to work, 3 points.

### 5.1.2 Efficacy Evaluation Standard for a Single Item of the Main Symptoms

It is divided into 4 levels, clinically recovered, markedly effective, effective and ineffective. Spleen Qi Deficiency Syndrome: Fatigue Strength; loose stools; loss of appetite. Spleen Yang Deficiency Syndrome: Very loose stools., even diarrhea with indigested food; abdominal coldness and pain, relieved by warmth and pressing, and the pain intensifies with coldness or hunger; fear of coldness and cold limbs. The Spleen Yin Deficiency Syndrome showed the symptom of hunger but without appetite; lean with skin fever. 1) Clinically recovered: The original symptoms would disappear. 2) Markedly effective: The original symptoms would improve by 2 levels. 3) Effective: The original symptoms would improve by 1 level. 4) Ineffective: There was no improvement in the original symptoms or the original symptoms would worsen.

### 5.1.3 Evaluation Standard of the Comprehensive Efficacy of the Main Symptoms

According to the Nimodipine method, the Percentage of the Symptom Improvement = [(Total Accumulated Points before the Treatment - Total Accumulated Points after the Treatment)/Total Accumulated Points before the Treatment] X100%. It is divided into 4 levels, clinically recovered, markedly effective, effective and ineffective. The total efficacy rate is calculated by the case number of clinically recovered and markedly effective. 1) Clinically recovered: Symptoms disappear. 2) Markedly effective: The percentage of symptom improvement  $\geq 70\%$ . 3) Effective:  $30\% \leq$  Percentage of Symptom Improvement  $< 70\%$ . 4) Ineffective: There's no significant improvement of symptoms, The percentage of symptom improvement  $< 30\%$ .

## 5.2 Evaluation Criteria for the Efficacy of Syndromes

It is calculated by the Nimodipine method, the Efficacy Index = [(Accumulated Points before the Treatment - Accumulated Points after the Treatment)/Accumulated Points before the Treatment]X100%. It is divided into 4 levels, clinically recovered, markedly effective, effective and ineffective. 1) Clinically recovered: The main symptoms and signs disappear or basically disappear, the Efficacy Index  $\geq 95\%$ . 2) Markedly effective: The main symptoms and signs significantly improve,  $70\% \leq$  the Efficacy Index  $< 95\%$ . 3) Effective: The main symptoms and signs obviously improve favorably,  $30\% \leq$  the Efficacy Index  $< 70\%$ . 4) Ineffective: There's no significant improvement of symptoms and signs, or even worsen. The Efficacy Index is  $< 30\%$ .

### 5.3 Evaluation of Quality of Life

Currently, the Chinese version of the Health Survey Scale SF-36 is widely used for evaluation in China. As an evaluation tool, Patient Reported Outcomes (PRO)'s role of assisting in the evaluation of the clinical efficacy of traditional Chinese medicine in the field of chronic diseases has been gradually recognized. Considering that the PRO Scale of the Chronic Gastrointestinal Diseases<sup>[12]</sup> and PRO Scale of the Spleen and Stomach Diseases<sup>[13]</sup> have referential significance to the evaluation of the corresponding symptoms, overlaps of signs and clinical efficacy of Spleen Deficiency Syndrome of a chronic gastrointestinal disease, evaluation of the life quality of Spleen Deficiency Syndrome can be conducted with reference to the corresponding details.

### 6 Prevention and Adjustment of Intake

The diet should be regular. It is suitable to have food that is easy to digest, and hawthorn and the inner membrane of chicken gizzard can be taken appropriately to help with the digestion. Common yam, lotus seed, lentil beans, Euryale Ferox, *Coix lacryma-jobi*, which are both medicine and food, can invigorate the spleen and benefit qi. Food that is raw, cold, unclean and hard to digest harms the spleen and hurts the stomach. Spicy, alcoholic, fishy and greasy food should be avoided to prevent accumulated dampness and heat on the basis of spleen qi deficiency.

Keep an optimistic and calm attitude. Do not be impatient and irritable and worried, be empathetic, so as to minimize the impact of emotional disorders on the spleen and stomach.

In daily life, we should be careful to prevent the invasion of external pathogen such as cold, dampness and other external evils, etc., and alternate work with rest. We should pay attention to exercise, stick to taking a walk and practice proper health preserving techniques, such as Eight-Sectioned Exercise and Tai Chi, so as to strengthen the healthy qi to improve the body's ability of defending against the external pathogen.

Medication should be used based on syndrome differentiation, and on this basis, the clinical effect will be better if it is properly combined with external treatment of TCM characteristics such as manipulation for benefiting qi, invigorating the spleen and dredging qi movement, acupoint massage or pressure manipulation, spine pinching, application, moxa-wool moxibustion, ear acupuncture, hot medicinal compress, reyanbao therapy, etc.



**Project leader:** ZHANG Shengsheng

**Consensus penners:** HU Ling, LI Ruliu, ZHANG Shengsheng

**Specialists participated in this consensus are as follows (in surname strokes order):**

DING Xia, MA Qun, WANG Fengyun, WANG Bangcai, WANG Ruxin, WANG Chuijie, WANG Chunsheng, WANG Xianbo, WANG Min, NIU Xingdong, YE Song, TIAN Xudong, TIAN Yaozhou, FENG Peimin, ZHU Shengliang, ZHU Ying, REN Shunping, LIU Li, LIU Youzhang, LIU Fengbin, LIU Huayi, LIU Qiquan, LIU Jianshe, LIU Shaoneng, LIU Dexi, QI Yuzhen, JIANG Yuyong, SUN Yuxin, LAO Shaoxian, SUN Juanping, LI Junxiang, LI Yanping, LI Tianguai, LI Yong, LI Zhenhua, LI Qiangou, LI Pei, LI Huizhen, YANG Xiaojun, YANG Shenglan, YANG Jinxiang, YANG Cuilan, SHI Zhaohong, WU Yaonan, HE Xiaohui, YU Zeyun, WANG Longde, WEN Mingqi, SHEN Hong, ZHANG Xiaoping, ZHANG Shengsheng, ZHANG Xuezhi, ZHANG Lei, CHEN Suning, CHEN Diping, LIN Shouning, JI Guang, JIN Xiaojing, ZHOU Zhenghua, ZHOU Xuewen, ZHOU Qiang, ZHENG Yu, SHAN Zhaowei, MENG Lina, ZHANG Wenxia, ZHAO Yuming, ZHAO Luqing, HU Ling, KE Xiao, ZHA Ansheng, QIN Danping, JIANG Liyun, YUAN Hongxia, DANG Zhongqin, XU Jinkang, XU Jianzhong, TANG Xudong, TANG Zhipeng, TAO Lin, HUANG Minghe, HUANG Shaogang, HUANG Guihua, HUANG Hengqing, HUANG Suiping, LIANG Chao, DONG Mingguo, SHU Jing, ZENG Binfang, XIE Sheng, XIE Jingri, LU Guangchao, CAI Min, PAN Yang, XUE Xilin, WEI Wei.

## References

- [1] Spleen and stomach research team, Guangzhou University of Chinese Medicine. Preliminary study on salivary amylase activity in patients with spleen deficiency [J]. Chinese Medical Journal, 1980, 60 (5): 290-292.
- [2] SHEN ZY. Reference Standards for Syndrome Differentiation of Traditional Chinese Medicine [J]. Chinese Journal of Integrated Traditional and Western Medicine, 1983, 3 (2): 117.
- [3] SHEN ZY, WANG WJ. Reference Standards for Syndrome Differentiation of Traditional Chinese Medicine [J]. Chinese Journal of Integrated Traditional and Western Medicine, 1986, 6 (10): 598.
- [4] Ministry of Health of the People's Republic of China. Guidelines of Clinical Study on Treatment of Spleen Deficiency Syndrome with Traditional Chinese Medicine [J]. China Journal of Traditional Chinese Medicine and Pharmacy, 1988, 3 (5): 71-72.
- [5] National Administration of Traditional Chinese Medicine. Efficacy Criteria for Diagnosis and Treatment of Diseases with Traditional Chinese Medicine [M]. Nanjing: Jiangsu Science and Technology Press, 1988.
- [6] Ministry of Health of the People's Republic of China. Guidelines for Clinical Research of New Drugs of Traditional Chinese Medicine: Volume One [M]. Beijing: Ministry of Health of the People's Republic of China, 1993: 91-95.
- [7] ZHENG XY. Guidelines for Clinical Research of New Drugs of Traditional Chinese Medicine (Trial) [M]. Beijing: China Medical Science Press, 2002: 361-364.
- [8] CHEN WW, WANG YF, LAO SX, et al. Study on Gene Differential Expression in Patients with Deficiency of Spleen Qi [J]. Chinese Journal of Pathophysiology, 2008, 24 (1): 148-152.
- [9] WANG Y, XU A. Zheng: A systems biology approach to diagnosis and treatments [J]. Science, 2014, 346(6216): S13-S15.

- [10] Professional Committee on Digestive Diseases, Chinese Association of Integrative Medicine. TCM symptom Score Table for Gastrointestinal Diseases [J]. Chinese Journal of Integrated Traditional and Western Medicine on Digestion, 2011, 19 (1): 66-68.
- [11] LAO SX, HU L. Core of Clinical Thinking in Modern Traditional Medicine: Syndrome is Root, Disease is Pivot and Symptom is Surface [C] // Compiled by National Seminar on the Development Strategy of Integrated Traditional and Western Medicine and Paper Collection of the 30th Anniversary of the Chinese Association of Integrative Medicine. Beijing: Chinese Association of Integrative Medicine, 2011: 202-205.
- [12] TANG XD, WANG P, LIU BY, et al. Compilation and Reliability and Validity Analysis of Clinical Outcome Measurement Scales Based on Reports of Patients with Chronic Gastrointestinal Diseases [J]. Journal of Traditional Chinese Medicine, 2009, 50(1): 27-29.
- [13] LIU FB, WANG WQ. Construction Ideas for the Theoretical Structure Model of PRO Scale for Spleen and Stomach System Diseases [J]. Journal of Guangzhou University of Traditional Chinese Medicine, 2008, 25 (1): 12-14.

(Received date: March 21, 2017; Revised date: April 10, 2017)

[Edited by: Jiao Shuang]