

Consensus Opinions on Diagnosis and Treatment of Functional Dyspepsia with Integrated Traditional Chinese and Western Medicine (Year 2017)

Specialized Committee on Digestive System Disease of Chinese Association of Integrative Medicine

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Functional dyspepsia (FD) is a common and frequently-occurring disease in clinical practice with a relatively high incidence which has seriously affected the health and living quality of our people. The specialized committee has formulated the *Diagnosis and Treatment Protocol of Functional Dyspepsia with Integrated Traditional Chinese and Western Medicine* at the Chongqing Conference on Digestion with Integrated Traditional Chinese and Western Medicine in 2003 and the Diagnosis and Treatment Protocol was discussed and revised twice at the Shanghai Conference in 2008 and the Nanning Conference in 2009. In 2010, this Expert Committee coatingther revised the Diagnosis and Treatment Protocol of FD and *Consensus Opinions on Diagnosis and Treatment of Functional Dyspepsia with Integrated Traditional Chinese and Western Medicine* was officially issued. In recent years, the basic and clinical study on FD both in China and overseas have made new progress, so it is necessary to update the *Consensus Opinions*. Therefore, Specialized Committee on Digestive System Disease of Chinese Association of Integrative Medicine organized specialists in the field of digestion study of traditional Chinese and Western medicine nationwide to summarize the main opinions of the diagnosis and treatment of FD, and the specialists' opinions were consulted using the Delphi Method. Finally, the *Consensus Opinions on Diagnosis and Treatment of Functional Dyspepsia with Integrated Traditional Chinese and Western Medicine* were formed.

1 Concept

FD refers to the symptoms of one or more of postprandial bloating, early satiety sensation, epigastric pain, and epigastric burning sensation, whose causes could not be explained by organic diseases, systemic diseases or metabolic diseases, etc. In traditional Chinese medicine, it belongs to the categories of "bloating syndrome", "Epigastric Pain", "indigestion and stasis". The global prevalence of FD is 10%-30%^[1]. A multi-center study which involved 9 countries and regions in Asia showed that 43% of 1115 patients with unchecked dyspepsia were diagnosed as FD^[2] after gastroscopy. According to the domestic reported results from LI Xiaobo et al^[3] and WU Gailing et al^[4], FD among patients with dyspepsia accounted for 69% and 51% respectively.

2 Western medicine diagnosis

2.1 Clinical manifestation^[5]

FD is manifested as chronic dyspepsia, the onset of the disease is usually slow and the course lasts or is recurrent. Main symptoms: ①abdominal distension after meals: food stays in stomach for relatively long time after meals, which causes the discomfort sensation of gastric distension. ② Sensation of early satiety: discomfort sensation of gastric distension appears after taking food that

is less than the usual amount, and causes the normal meal being unable to be finished. ③ Epigastric pain: subjective pain and discomfort sensation in the upper abdomen. The part is located within the scope of 1-2cm below xiphoid process of central upper abdomen to the upper part of the umbilicus. ④ Epigastric burning sensation: subjective discomfort sensation of epigastric burning. ⑤ Epigastric gassiness, excessive belching, nausea.

FD is usually characterized by one symptom, some of which may overlap with two or more symptoms and may occur simultaneously with gastroesophageal reflux disease (GERD) or irritable bowel syndrome (IBS). The onset and recurrence of some patients may be related to diet, mental and psychological factors. This disease has no obvious signs.

2.2 Relevant examinations

Relevant examinations include Blood, urine, stool routine, fecal occult blood tests, liver and kidney function, blood glucose, serum marker for viral hepatitis and helicobacter pylori, and relevant tumor marker when necessary.

Chest X-ray, electrocardiogram, hepatobiliary and pancreatic color Doppler ultrasound are used as routine examinations. Patients with dyspepsia at preliminary diagnosis shall do routine gastroscopy. Patients who are not willing to or do not adapt to gastroscopy can do double-contrast barium examination of upper digestive tract instead.

Abdominal CT, MRCP or ERCP should be performed in patients with suspected hepatobiliary and pancreatic diseases which cannot be determined by abdominal color Doppler ultrasound.

Nuclide labeling scintillation method, radioopaque marker test meal method and real-time ultrasound, etc. are often used to examine the gastric emptying function. About 50% of FD patients experienced delayed gastric emptying for solid.

Multi-purpose air sac manometry and distal-end-open perfusion catheter manometry are used to measure the pressure in the gastric cavity. Patients with PD usually have proximal end gastric receptive relaxation disability and weakened gastric antrum movement after meals.

Psychological assessment has important reference value for the development of subsequent treatment protocols for patients with ineffective empiric treatment. Therefore, for patients with suspected psychological obstacles such as anxiety and (or) depression, it is recommended to enquire carefully relevant environmental factors, life stress events and affective state. Relevant psychological scale assessment shall be performed when necessary.

It should be noted that abdominal CT, MRCP or ERCP, gastric emptying function measurement, pressure measurement in the gastric cavity, etc. are not necessary for the diagnosis of FD, especially for the latter two, which are just methods to understand whether FD patients have motor function disability, and because of the fact that their correlation with the symptoms of dyspepsia remain controversial, the two methods are not recommended as routine examinations.

2.3 Diagnosis assessment

Assessment of patients with dyspepsia should include whether there is any warning symptoms,

frequency of the symptoms and severity, psychological state, etc.^[6] ① First it should be noticed whether there is warning symptoms, which includes: patients >40 years old with preliminary onset of the disease; emaciation, anemia, epigastric mass, frequent vomiting, hematemesis or black stool, dysphasia, abdominal mass, jaundice; progressive aggravation of dyspepsia symptoms and having family history of tumor, etc. Overall examination of the patients with the warning symptoms shall be performed, so as to exclude organic diseases, systemic diseases or metabolic diseases. ② Assessment of the severity and frequency of the dyspepsia symptoms can provide objective indexes for the evaluation of the impacts of this disease to the life quality of the patients and judgment of the therapeutic effects. ③ Hp test should be performed for dyspepsia patients with ineffective empirical treatment. If part of dyspepsia patients who are Hp positive are in long-term remission(6 months) of the symptoms after successful eradication of Hp, the disease belongs to Hp related gastritis, but not FD^[7]. ④ FD symptoms related duodenum eosinophil increasing and mass cells or lymphocytic duodenitis can be identified through gastroscopy and biopsy. In areas where parasite infection is prevalent, it is recommended to carry out corresponding etiological tests. ⑤ For some FD, IBS and GERD can exist simultaneously. One study result from China shows that 24.8% of 608 FD patients have IBS symptoms^[8]. Another clinical reported result from our country shows that among 910 FD patients, 20.0% of them overlap IBS^[9]. YAO Xin et al in China^[10] found that among 111 FD patients, 21.6% of them have GERD symptoms. Therefore, the judgment whether patients with symptoms of FD overlapped with IBS, GERD symptoms has certain significance for the selection of treatment protocol of this disease and the evaluation of therapeutic effects. ⑥ if organic diseases are excluded and diagnosis criteria for FD are met, it should be coatingther identified whether it is PDS and (or) EPS. The former are dyspepsia symptoms induced by having meals, while symptoms of the latter do not only occur after meals, but also with empty stomach and symptoms even may be improved after meals. If these two types overlap, it may be manifested as dyspepsia symptoms induced by having meals and epigastric pain or epigastric burning sensation.

2.4 Diagnosis criteria^[11]

2.4.1 Diagnosis criteria of FD(Roman IV)

Diagnosis criteria of FD should have one or more following symptoms: ① distension and discomfort after meals; ② sensation of early satiety; ③ epigastric pain; ④ epigastric burning sensation. Moreover there is no evidence of organic diseases (including gastroscopy examination) which can explain the symptoms. Before the diagnosis, the symptoms have appeared for at least 6 months and the above criteria are met in recent 3 months. FD is divided into two sub-types: postprandial distress syndrome (PDS) and epigastric pain syndrome (EPS), and they can overlap.

2.4.2 Diagnosis criteria of sub-type of FD

PDS: one or two following symptoms are necessary: distension and discomfort after meals (daily life is affected); early satiety (cannot finish meals with sufficient food amount). No organic, systemic or metabolic diseases are found in routine examinations (including image, biochemistry and endoscopy). Before diagnosis, there have been at least 6 months' course of the disease and the symptoms appear in the recent 3 months with at least 3 days each week. Conditions supporting the diagnosis: ① epigastric pain or epigastric burning sensation; ② epigastric distension, excessive belching, nausea; ③ vomiting, other diseases should be considered; ④ heartburn is not a symptom of dyspepsia, but it can coexist; ⑤ if symptoms are in remission

after flatus and defecation, they are usually not considered as dyspepsia;⑥GERD, IBS, etc. may also cause symptoms of dyspepsia, they may coexist with PSD.

EPS: one or two following symptoms are necessary: epigastric pain (daily life is affected); epigastric burning sensation (daily life is affected). No organic, systemic or metabolic diseases are found in routine examinations (including image, biochemistry and endoscopy). Before diagnosis, there have been at least 6 months' course of the disease and the symptoms appear in the recent 3 months with at least 1 day each week.

Conditions supporting the diagnosis: ① the pain can be induced or relieved by having meals, or it may occur in empty stomach; ②epigastric distension, excessive belching, nausea after meals may occur; ③vomiting, other diseases should be considered; ④heartburn is not a symptom of dyspepsia, but it can coexist; ⑤the pain does not meet the criteria of biliary tract diseases; ⑥if symptoms are in remission after flatus and defecation, it is usually not considered as dyspepsia; ⑦GERD, IBS, etc. may also cause symptoms of dyspepsia, they may coexist with EPS

2.4.3 Determination of the FD symptom degree^[12]

Main symptoms: such as distension after meals, early satiety, epigastric pain, epigastric burning sensation, etc. The "five-level scoring system" can be used to score (degree + frequency) to determine the degree of symptoms. RomanIV recommends that the severity degree of FD symptoms should be at least ≥ 2 points. 0 point: no symptom, 0 d/week; 1 point: mild, patient can only realize the existence of symptoms when more attention is paid or by being reminded, 1d/week; 2 points: moderate: the symptoms are obvious but work and life are not affected, 2-3 d/week; 3 points: severe, the symptoms are obvious, work and life are affected, 4-5 d/week; 4 points: extremely severe, the symptoms are very obvious and work and life are seriously affected and it continues.

3 TCM Treatment Based on Syndrome Differentiation^[13]

(1) Spleen Deficiency and Qi Stagnation Syndrome

Main Symptoms: ①Abdominal bloating or abdominal pain; ②Lack of food and appetite.

Secondary Symptoms:①Sallow complexion; ②Belching; ③Fatigue; ④Loose stools

Tongue and Pulse: Pale tongue, thin and white coating; thin and thready pulse.

Syndrome Type Determination: 2 Main Symptoms and 1 Secondary Symptom, or Main Symptom ① and 2 Secondary Symptoms.

(2) Liver and Stomach Discord Syndrome

Main Symptoms: ① Abdominal bloating; ②Scurrying pain on two sides, it may be induced or worsened by emotional dissatisfaction.

Secondary Symptoms: ①Belching; ②Dry mouth and bitter mouth; ③Heartburn and acid regurgitation; ④Impatient and irritable.

Tongue and Pulse: Red tongue, white coating; pulse string or thin pulse.

(2) Syndrome Type Determination: 2 Main Symptoms plus 1 Secondary Symptom or Main Symptom ① and 2 Secondary Symptoms

(3) Spleen and Stomach Damp Heat Syndrome

Main Symptoms: ①Abdominal bloating or abdominal pain; ②Lack of food and appetite..

Secondary Symptoms:①Feeling sleepy and heavy in the head and body; ②Bitter mouth and sticky mouth; ③Uncomfortable defecation and stagnation of defecation; ④Short urination with yellow urine.

Tongue and Pulse: Red tongue, yellowish, thick and greasy coating; slippery pulse.

Syndrome Type Determination: 2 Main Symptoms plus 1 Secondary Symptom, or the Main Symptom ① plus 2 Secondary Symptoms.

(4) Spleen and Stomach Deficiency-Cold Syndrome

Main Symptoms:①Cold abdominal pain or abdominal bloating; ②Relieved by warmth and pressing;

Secondary Syndromes:①Vomiting of clear water; ②Lack of food and appetite; ③Mental fatigue; ④Cold limbs; ⑤Loose stools.

Tongue and Pulse: Pale tongue, white coating, thin and weak pulse.

Syndrome Type Determination: 2 Main Symptoms plus 1 Secondary Symptom, or Main Symptom ① plus 2 Secondary Symptoms.

(5) Mixed Cold and Heat Syndrome

Main Symptoms: ① Abdominal bloating or abdominal pain; ② noisy stomach and discomfort; ③preference of warmth and fear of cold of the stomach.

Secondary syndrome: ①Belching; ②Gastric cavity scorching hot; ③Dry mouth and bitter mouth; ④Loose stools.

Tongue and Pulse: Pale tongue, yellow coating, thin or slippery pulse string

Syndrome Type Determination 2 Main Symptoms plus 1 Secondary Symptom, or Main Symptom ① plus 2 Secondary Symptoms.

In clinical practice of FD, the two syndrome types may appear simultaneously, for example, liver and stomach discord and the spleen and stomach deficiency and weakness occur, it can be called Spleen Deficiency and Qi Stagnation Syndrome; the above syndrome types can also be mixed with food accumulation, phlegm-damp or blood stasis. The clinical syndrome should be based on

the differentiation of the Main Symptoms.

4 Treatment

4.1 General treatment

It is to help the patients to know and understand the condition of the disease, guide them to improve their lifestyle, adjust their diet structure and habits, remove the pathogenic factors that may be related to the occurrence of the symptoms and improve patients' ability to cope with the symptoms. Irritating food and drugs should be avoided, as well as food that is spicy, greasy, cold and hard, high-fat diet, coffee, smoking, alcohol and non-steroidal anti-inflammatory drugs (NSAIDs). For patients with early satiety and obvious gastric distension after meals, it is recommended to have more meals with less food each meal.

4.2 Treatment with western medicine

4.2.1 Acid suppression drug

Proton pump inhibitors (PPI) or histamine₂ receptor antagonist(H₂RA) can be the first choice of empirical drug therapy for FD, especially EPS patients. The improvement of the symptoms of FD patients by PPI is superior to the placebo group, however, for the improvement of FD symptoms, the therapeutic effect of large dose of PPI is not superior to the standard dose^[14]. A Meta analysis result shows that PPI has relatively good mitigative effect on the symptoms of FD patients with sub-type of EPS^[15]. It has been reported that H₂RA famotidine can significantly improve the symptoms of FD patients^[16]. The FD guideline formulated by the Japanese Society of Gastroenterology in year 2015 believes that, both PPI and H₂RA can effectively improve the symptoms of FD and their therapeutic effects are equivalent^[17]. *Chinese Guideline for Dyspepsia Diagnosis and Treatment in 2007* puts forward that both H₂RA and small dose of PPI can effectively treat FD^[18]. Other weak alkaline drugs also have certain therapeutic effect, such as sucralfate, hydrotalcite, etc.

4.2.2 Gastrointestinal prokinetic drug

Gastrointestinal prokinetic drug can be the first choice of empirical treatment drug for FD, especially PDS. The result of a prospective, multi-center study in China suggests that itopride is effective in relieving FD symptoms^[19]. There are also studies show that mosapride has the effect of significantly relieving the clinical symptoms of FD patients with PDS and EPS sub-types^[20].

4.2.3 Gastric fundus diastole drug

Acotiamide (Z-388) is a new chemical compound which has the effect of relaxing gastric fundus and promoting gastric motility and is effective to PDS^[21]. Other drugs that have the potential effect of relaxing gastric fundus include tandospirone, 5-HT_{1A} receptor stimulant^[22](it can improve the symptoms of epigastric pain and discomfort) and buspirone, which can significantly reduce the severity of dyspepsia symptoms and improve symptoms such as distension after meals, early satiety, etc.^[23]. However, therapeutic effect of this type of drug still need to be coatingther verified in China.

4.2.4 Digestive enzyme

Compound digestive enzyme preparation can be an adjuvant therapy of FD. However, its

therapeutic effect still need to be verified by more high-quality clinical studies.

4.2.5 Centrally acting drugs

Some studies have shown that the therapeutic effect of fluoxetine for the symptoms of FD patients with depression is obviously superior to that for FD patients without depression^[24]. For FD patients with psychological factors such as depression, anxiety, etc., psychological treatment and drugs such as tricyclic antidepressants amitriptyline and 5-HT/ NorAdrenaline Reuptake Inhibitor can be used. It is recommended to start with small dose and adverse reactions of drugs shall be paid attention to. It is recommended that the drugs are taken under the guidance of a specialist.

4.3 Treatment with traditional Chinese medicine^[25]

4.3.1 TCM Syndrome Differentiation and Treatment

(1) Spleen Deficiency and Qi Stagnation Syndrome

Therapy: **Invigorating the spleen and stomach**, regulating qi and relieving bloating.

Recipe: Modification of Xiangsha Liujunzi Decoction(*Discourse of Recipes of Ancient and Modern Famous Doctors*), **medicinal** codonopsis pilosula, atractylodes, poria, **corydalis**, **tangerine peel**, saussureae, villous amomum fruit, prepared **licorice** root for medical purpose.

Modification: For patients with dizziness and palpitations, codonopsis pilosula should be replaced by ginseng, add white peony root and donkey-hide gelatin should be added for nourishing qi and blood; for patients with abdominal bloating, add caulis perillae and tangerine peel to regulate qi and relieve bloating; for patients with food stagnation, charred triplet and radish seed should be added to promote digestion and resolve accumulation; for patients with spleen deficiency and sinking of middle qi, Buzhong Yiqi Decoction should be selected for modification..

(2) Liver-and Stomach Discord Syndrome

Therapy: Regulating qi to relieve depression, soothing stomach to reduce adverse qi.

Recipe: Modification of Chaihu Liver Soothing Powder (*The Complete Volume of Yue Jing*), medicinal Bupleurum or Bupleurum, Citrus aurantium, Sichuan lovage rhizome, caulis perillae, White Peony, Tangerine Peel, Prepared Pinellia Tuber, Raw Licorice or medicinal Glycyrrhiza uralensis Fisch.

Modification: For patients with belching, vomiting, nausea and regurgitation due to liver and Qi stagnation, add inula flower, raw **ochre**, Chinese eaglewood should be added to calm the adverse-rising energy and soothe the stomach; patients with anorexia, reduced appetite and serious stagnation of food and drinks, medicated leaven, Citrus aurantium, betel nut should be added to promote digestion and remove food stagnation; for patients with gastric upset and acid regurgitation, coptis chinensis, medicinal evodia fruit shall be added to clear liver heat; for

patients with severe stomachache, corydalis should be added.

(3) Spleen and Stomach Damp Heat Syndrome

Therapy: Clearing away heat and dampness, regulating qi and soothing stomach.

Recipe: Modification of Lianpu Drink (*Theory of Cholera*). Drugs: coptis chinensis, ginger magnolia, acorus tatarinowii, rhizoma pinelliae praeparatum, scutellaria baicalensis, tangerine peel, reed rhizome, capillary wormwood herb, **coix seed**.

Modification: For patients who feel heavy in the head and body, ricepaperplant pith and asiatic plantain seed should be added to induce diuresis to drain dampness; for patients with abdominal bloating, add Citrus aurantium and aucklandia lappa to regulate qi and relieve bloating.

(4) Spleen and Stomach Deficiency and Cold Syndrome

Therapy: **Invigorating** the spleen and soothing the stomach, warming the spleen and stomach to dispel cold.

Recipe: Modification of Astragalus Jianzhong Decoction(*Jinkui Yaolue or Synopsis of the Golden Chamber*), medicinal astragalus, white peony root, common ginger root, **licorice** root, Chinese date, Citrus aurantium(stir-fried with bran), villous amomum fruit and Chinese cassia tree for medical purpose.

Modification: For patients who suffer from cold in the abdomen, medicinal evodia fruit and lesser Galangal rhizome should be added to warm the spleen and stomach for dispelling cold.

5) Mixed Heat and Cold Syndrome

Therapy: Pungent dispersion bitter purgation, soothe the stomach and disintegrate the abdominal lumps.

Recipe: Modification of Banxia Xiexin Decoction (*Treatise on Febrile Diseases*), Pinellia Tuber(processed with alum), Scutellaria, coptis chinensis, dried ginger, **Codonopsis**, officinal magnolia bark, medicated leaven, thunberg fritillary bulb, Cuttlefish Bone, raw licorice root for medical purpose.

Modification: For patients with diarrhea and loose stools, Poria, Fried Atractylodes root, Chinese Yam and coix seed should be added to invigorate the spleen and remove dampness and **stop diarrhea**; for patients with gastric upset and acid regurgitation, coptis chinensis, medicinal evodia fruit and arc shell(calcined) should be added to inhibit acidity to relieve pain.

4.3.2 Treatment with Chinese Patent Medicine

- (1) Weisu Granules: Dried tangerine peel, finger citron fruit, nutgrass galangale rhizome, medical citron fruit, Citrus aurantium, perilla stem, betel nut and Gallus gallus domesticus. It has the function of regulating qi and removing the bloating, soothing the stomach and relieving the stomach pain. It is applicable to the Spleen and Stomach Qi

Stagnation Syndrome with the oral dose at 15g/time and 3 times/day.

- (2) Biling Weitong Granules: Citronella, corydalis, coptis chinensis, etc. It has the function of promoting qi to activate blood, soothing the stomach to relieve pain. It is applicable to syndrome of qi stagnation and blood stasis with the dose taken dissolved at 5g/time and 3 times/day.
- (3) Qizhi Weitong Granules: Bupleurum, corydalis, Citrus aurantium, nutgrass galingale rhizome, root of herbaceous peony and prepared licorice root. It has the function of soothing the liver and regulating qi, soothing the stomach to relieve pain. It is applicable to the syndrome of liver qi invading the stomach or the syndrome of stagnation of liver qi. The dose may be taken dissolved at 5 g/time, 3 times/day.
- (4) Zhizhu Kuanzhong Capsule^[26]: the rhizome of large-headed atractylodes, Citrus aurantium, Bupleurum, hawthorn. It has the power of invigorating the spleen and soothing the stomach, regulating qi and disintegrating abdominal lumps. It is applicable to the syndrome of Spleen Deficiency and qi Stagnation Syndrome. 3 capsules/time(0.43g/ capsule), 3 times/day of the drug shall be administered before each meal.
- (5) Dalitong Granules: Bupleurum, Citrus aurantium, common Aucklandia root, tangerine peel, pinellia tuber(processed with alum), dandelion, hawthorn(stir-bake to brown), charred areca seed. It has the function of clearing away the heat and relieving qi depression, reducing the adverse effects of the stomach and relieving stagnation. It is applicable to the Liver and Stomach Heat Stagnation Syndrome . 6 g/time, 3 times/d of the drug shall be administered after dissolved before each meal.
- (6) Xiangsha Liujunzi Pills(Concentrated Pills): Common Aucklandia root, villous Amomum fruit, tangerine peel, rhizoma Pinelliae Preparatum, Codonopsis, the rhizome of large-headed atractylodes, Poria, prepared Licorice root. It has the power of nourishing qi, invigorating the spleen and soothing the stomach. It is applicable to the Spleen Deficiency and Qi Stagnation Syndrome. 6-9 g/time, 2 times/day the drug shall be taken orally.
- (7) Jinghua Weikang Capsule^[27]: Nepeta (Chenopodium ambrosioides) and water ball flower (pilular adina herb). It has the function of regulating qi and dissipating cold, clearing heat and removing blood stasis. . It is suitable for the Liver and Stomach Discord and Blood Stasis Syndrome. 2 capsules/time (160mg), 3 times/d, orally before meals.
- (8) Yueju Pill: nutgrass galingale rhizome(processed with vinegar), Sichuan lovage rhizome, gardenia(stir fried), atractylodes rhizome(stir fried), medicated leaven (stir fried). It has the function of soothing the liver and relieving depression, regulating qi and relieving epigastric distension and disintegrating abdominal lumps. It is suitable for qi stagnation and phlegm obstruction syndrome. 6-9g/time, 2 times/d, orally.
- (9) Shenling Baizhu Granules: Ginseng, Poria, Atractylodes (stir-fried with bran), Chinese yam, white hyacinth bean(stir fried), lotus seeds, coix seed(stir fried), villous Amomum fruit, Platycodon grandiflorum, licorice root. It has the function of strengthening the

spleen and nourishing qi. It is suitable for the Spleen and Stomach Qi Deficiency Syndrome 3 g/time, 3 times/day of the drug shall be taken dissolved.

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- (10) Wenweishu Capsules: Codonopsis, Aconite (prepared), Astragalus (prepared), cinnamon, Chinese yam, prepared common monkshood daughter root(prepared), ;milkvetch root(stir-bake with adjuvant), ;cassia bark, common yam rhizome, desertliving cistanche (prepared), the rhizome of large-headed atractylodes(stir fried), hawthorn(stir fried), dried plum, villous amonnum fruit, dried tangerine peel and psoralea corylifolia. It has the function of warming the stomach, nourishing the stomach yin and promoting qi and relieving pain. It is suitable for the Spleen and Stomach Deficiency and Cold Syndrome. 1.2g/time, 2 times/day, shall be taken orally.
- (11) Jianwei Xiaoshi Oral Liquid: Taizi ginseng (heterophylly falsestarwort root), tangerine peel, common yam rhizome, malt(stir fried) and hawthorn. It has the function of invigorating the stomach and promoting digestion. It is suitable for the spleen deficiency and food accumulation syndrome. 10ml/time, 2 times/day of the drug shall be taken orally during or after meals.
- (12) Sanjiuweitai Granules[28]:evodia lepta, baical skullcap root, murraya jasminorage, shynyleaf pricklyash root, common aucklandia root, Poria, White peony root and Rehmannia glutinosa. It has the function of clearing heat and dampness, promoting qi and blood circulation, soothing the liver and relieving pain, eliminating inflammation and relieving pain, and regulating qi and fortifying the spleen. It is suitable for other syndrome types except spleen and stomach deficiency and cold syndrome. 10g/time, 2 times/day of the drug shall be taken dissolved.
- (13) Deficiency and Cold Stomachache Granules: honey-fried radix Astragalus, Codonopsis, cassia twig, White Peony Root, lesser Galangal rhizome, dried ginger, prepared Licorice root, Jujube or Chinese date. It has the function of nourishing qi to invigorate the spleen, warming the stomach to relieve pain. It is suitable for the Spleen and Stomach Deficiency and Cold Syndrome. 5g/time, 3 times/day of the drug shall be taken after being dissolved.

4.4 Characteristic Therapy of Traditional Chinese Medicine

(1) Acupuncture Therapy^[29]

Empirical Evidence: The acupoints of the Foot Jueyin Liver Meridian and the Foot Yangming Stomach Meridian are the main points, and acupuncture with acupuncture method is used; Zusanli, Tianshu, Zhongwan, Neiguan, Qimen, Yanglingquan are often used.

Deficiency Syndrome: The main points are Backshu, Renmai, Spleen Meridian of Foot Taiyin, and Stomach Meridian of Foot Yangming. Commonly used Pishu, Weishu, Zhongwan, Neiguan, Zusanli, Qihai, etc.

(2)Therapy of Ear Acupoints^[29]

Take acupoints of spleen, stomach, liver, sympathetic, large intestines, small intestines and pressing manipulate for 10 minutes with 2 times/day, 7 days as one course of treatment.

(3)Abdominal massage^[30]

Massage the abdomen clockwise, knead the abdomen, attack the points of middle epigastrium, tianshu, zhangmen and zusanli, kneading manipulate and massage the stomach cavity, attack and press the points of qihai, guanyuan, vibrate the abdomen with 25 minutes each time, once every two days, 3 times/week for 4 weeks continuously.

(4)Moxibustion^[31]

Take the points of middle epigastrium and shenque, with the patient in supine position, cut a piece of ginger about 2 fen thick on each of the two acupoints, puncture several holes in the center, place moxa cone on top and ignite it, stop until the local skin is flushed. Do this one time/day and 10 days is one course of treatment.

4.5 Main points of combined diagnosis and treatment with traditional Chinese medicine and western medicine^[29]

FD, as a kind of recurrent functional gastropathy, is characterized by slow onset, long course and persistent or recurrent attacks. Modern medicine mainly treat it with antacid agents, prokinetics, digestants, HP eradication drugs, etc., whose characteristics are rapid onset, significant effect. However, using long-term or large dose of the above drugs may cause adverse reactions such as headache, general malaise, even leukopenia, increase of serum transaminase in some cases, and the disease is easy to recur after withdrawal of the medicines. The therapeutic effect of traditional Chinese medicine therapy for FD may not be as rapid as western medicines, but it is stable, with less adverse reactions and lower recurrence rate. Therefore, during the treatment of FD, we should fully grasp the type of this disease and its onset characteristics based on the condition and course of disease, so as to give full play of the advantages of traditional Chinese medicine and western medicine and make their respective advantages complementary to each other.

For PDS, whose main symptoms are early satiety, epigastric distension and discomfort after meals, the first choice of western medicine is gastrointestinal prokinetic agents such as mosapride, itopride, etc., so as to eliminate the symptoms rapidly. With traditional Chinese medicine, Xiangsu powder and Bupleurum can regulate qi and relieve distension, or Xiangsha Liujunzi Decoction to invigorate the spleen, regulate qi and relieve distension.

For EPS, whose main symptoms are epigastric burning sensation and epigastric pain, the first choice of western medicine is acid inhibitors such as PPI, H₂RA, ETC. With Chinese medicine, Zuojin Pill combined with Xuanfu Daizhe Decoction can be administered to purge the liver, clear heat, soothe the stomach and calm the adverse-rising energy, and Banxia Xiexin Decoction combined with Xuanfu Daizhe Decoction can be administered for pungent dispersion and bitter purgation, soothing the stomach and calming the adverse-rising energy.

For FD with mild, moderate symptoms of depression and anxiety, Deanxit (Flupentixol and Melitracen Tablets) can be used. For severe patients, Selective Serotonin Reuptake Inhibitors(SSRIs) are often used, such as fluoxetine, paroxetine, citalopram, sertraline and fluvoxamine. They can be used in combination with modifications of Chaihu plus Longgu oyster Decoction, Jiawei Xiaoyao Powder, Chaihu Shugan Powder, etc.

5 Evaluation of Therapeutic effect

5.1 Therapeutic effect evaluation criteria of a single symptom

Record and evaluation of single item of the main symptoms: the main symptoms are distension and discomfort after meals, early satiety, epigastric pain and epigastric burning sensation. The record of main symptoms levels: level 0: no symptoms, record 0 points; level I: symptoms are mild and do not affect daily life, record 1 point; level II: symptoms are moderate and affect daily life partly, record 2 points; level III: the symptoms are serious and affect the daily life, and the patient cannot continue working, record 3 points. Therapeutic effect identification of the symptoms: ① significantly effective: the original symptoms disappear; ② effective: the original symptoms improve to level 2; ③ progress: the original symptoms improve to level 1; ④ ineffective: the original symptoms have no improvement or the original symptoms are aggravated.

5.2 Therapeutic effect evaluation criteria of syndromes

Nimodipine method was used to calculate. Therapeutic effect index=(accumulated points before treatment-accumulated points after treatment)/accumulated points before treatment \times 100%. ① Clinical recovery: main symptoms and signs disappear or basically disappear, the therapeutic effect index \geq 95%; ② significantly effective: main symptoms and signs have improved significantly, $70\% \leq$ the therapeutic effect index $< 95\%$; ③ effective: main symptoms and signs are significantly improved, $30\% \leq$ the therapeutic effect index $< 70\%$; ④ ineffective: there is no significant improvement in the main symptoms or signs, even are aggravated, the therapeutic effect index $< 30\%$.

5.3 Therapeutic effect evaluation criteria of gastrointestinal prokinetics

Currently, it is considered that radionuclide scintillation test for gastric emptying is the golden standard for gastric motility test. Liquid test meal is marked with $^{111}\text{In-DTPA}$, and solid test meal is marked with $^{99\text{m}}\text{Tc}$. By using $^{99\text{m}}\text{Tc}$ -chicken liver solid phase test meal, the content of gastric content marker is measured by γ -camera at different time after meal, and the gastric emptying rate is calculated. Some studies have found that radiopaque marker(ROM)(such as barium gastric emptying method) can be used to measure the gastric emptying. After administering radiopaque marker test meal, the number of markers left in the stomach at different time can be monitored under x-ray, and therefore the emptying condition of the undigested solid in stomach can be obtained. The fact that devices of nuclide stomach emptying method are still not common in many hospitals, and that the test meals and analysis technologies of each center are different make the results not easy to be compared. Radiopaque markers test meal method and real time ultrasonography to test the function of stomach emptying are simple, practicable, stable and reliable. It is recommended to apply them into clinic and scientific studies.

5.4 Evaluation of stomach capacity function and sensation function

The golden standard for the evaluation of proximal stomach function is Barostat testing technology, however, the test is time-consuming and laborious and the patients' tolerance is poor, popularization of this technology is therefore limited. In recent years, it has been put forward to use water load test(WLT) for the evaluation of stomach function. It is found that there is a good correlation between its result and the result of Barostat, and it is closer to physiological status compared to Barostat. However, currently there is still no clear conclusion on the specific

operation method and quantitative criteria of this test. B ultrasound water load test play an important role in the evaluation of proximal stomach function.

5.5 Evaluation criteria of living quality

Traditional Chinese medicine can improve the living quality of patients with dyspepsia. Currently, the Chinese localization version of the health survey scale SF-36 is widely used for evaluation in China. Patient Reported Outcomes(PRO) scale, i.e. PRO scale, is an evaluation indicator developed on the basis of health-related living quality evaluation abroad in recent years. In the field of chronic diseases, from the perspective of patient reported outcome indicators, the scale as a tool to evaluate the clinical efficacy of traditional Chinese medicine has been gradually recognized. Drawing lessons from scale-making principles and methods and developing PRO scale of spleen and stomach diseases with characteristics of traditional Chinese medicine has reference significance to the therapeutic evaluation of dyspepsia.

5.6 Other

About half of the above FD patients have mental and psychological disorders, and the severity of FD symptoms is related to depression, anxiety, etc. Therefore, it is recommended that Hamilton Anxiety(HAMA) and Hamilton Depression (HAMD) scale shall be used for evaluation.

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