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Research Progress on Modified Banxia Xiexin Decoction for the Treatment of Reflux Esophagitis

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Abstract: ***Reflux esophagitis is a common subtype of gastroesophageal reflux disease and a frequently occurring digestive system disease in clinical practice. It is characterized by a prolonged course, repeated episodes, and persistent complications that are difficult to cure, seriously affecting patients' quality of life. Currently, Western medicine treats this disease with proton pump inhibitors (PPIs) as the preferred treatment. These drugs can significantly suppress gastric acid secretion and quickly improve symptoms such as acid reflux and heartburn. However, long-term or monotherapy with PPIs has certain limitations, as it can lead to various potential complications and adverse reactions. Clinical practice urgently needs to explore safer, more efficient, and more stable treatment options. TCM centers on holistic concepts and syndrome differentiation as its core diagnostic and treatment concepts, offering unique features and advantages in the treatment of chronic and recurrent digestive system diseases. Integrated Chinese and Western therapies have been proven to significantly improve the overall treatment outcomes of reflux esophagitis. Banxia Xiexin Decoction originates from the "Treatise on Cold Damage and Miscellaneous Diseases." It is a classic prescription for regulating the spleen and stomach and balancing cold and heat, with the functions of balancing cold and heat, dispersing masses, and eliminating fullness. Numerous basic experiments and clinical studies have shown that this formula can effectively improve clinical symptoms in patients with reflux esophagitis, repair damaged esophageal mucosa, regulate gastrointestinal function, and intervene in disease progression through multiple targets and pathways. This paper systematically reviews the pharmacological effects of Banxia Xiexin Decoction alone, the application of original formulas and their therapeutic effects, the mechanisms of combined formula synergy, and the research progress in integrated Chinese and Western medicine for the treatment of reflux esophagitis, aiming to provide new reference ideas for standardized clinical treatment and mechanistic research of this disease.***

Keywords: Banxia Xiexin Decoction, Reflux esophagitis, Gastroesophageal reflux disease, Research progress**.**

1. Introduction

Reflux esophagitis (RE) is a common disease of the digestive system, caused by stomach contents flowing back into the esophagus, causing damage to the esophageal mucosa, leading to inflammation. It falls under the category of gastroesophageal reflux, with a relatively high incidence, accounting for 48%~79% of GERD diseases [1]. Patients present clinically with acid reflux, heartburn, pain behind the sternum, and a burning sensation. It may even lead to esophagitis, upper gastrointestinal bleeding, anemia, peptic ulcers, gastrointestinal narrowing, difficulty swallowing, gastric cardia cancer, and Barrett's esophagus, among other complications [2]. It also has a long pathological cycle and is prone to recurrent episodes [3]. Western clinical treatment often uses proton pump inhibitors (PPIs), H2 receptor antagonists, antacids, and promokinetic drugs to reduce gastric acid secretion. Although PPIs can effectively improve clinical symptoms, they are prone to varying degrees of drug resistance and adverse reactions such as pneumonia, intestinal infections (mainly Clostridium difficile), hypomagnesemia, vitamin B12 deficiency, chronic kidney disease, and dementia [4], and also has a relatively high recurrence rate [5]. Therefore, to better treat RE, it is urgent to research drugs with significant efficacy and minimal adverse reactions.

There is no specific disease name for RE in the theoretical system of traditional Chinese medicine, but based on its characteristics, RE can be classified under categories such as "acid reflux," "esophageal stiffness," and "stomach distension." Patients with spleen and stomach deficiency are often harmed by irregular diet and emotional distress, causing imbalance in the ascending and lowering of the spleen and stomach, stomach qi reverses upward, the spleen loses its function and transformation, and the essence of food and drink stagnates in the middle burner. Over time, it becomes stagnant and transforms into heat, resulting in a mix of cold and heat, resulting in acid reflux, heartburn, nausea, pain behind the sternum, and a burning sensation. TCM treatment should focus on strengthening the spleen and stomach, balancing cold and heat, as the main principles [6]. Banxia Xiexin Decoction comes from Article 149 of the 'Treatise on Cold Damage: Differentiation of Taiyang Disease Pulse Syndrome and Treatment Part Two', Section 149, and is indicated for treating syndrome of Pi syndrome caused by mistaken purgation in cold damage: 'If on the fifth or sixth day of cold damage, if there is vomiting and fever, and Chaihu Decoction has symptoms but other medicines are used to purge, then Chaihu Tang is given again.' …If there is fullness without pain, this indicates fullness; if Chaihu is not suitable for treatment, Banxia Xiexin Decoction is appropriate [7]. Pi means blockage and blockage, preventing harmony between upper and lower levels. The spleen and stomach are located in the middle burner and serve as the pivot for ascending and descending. Manifesting weakness and stomach qi rising in rebellion, with cold and heat intermingling, this results in Pi syndrome. Banxia Xiexin Decoction is a classic formula for balancing cold and heat, mainly composed of Scutellaria, Coptis, Banxia, dried ginger, ginseng, honey-fried licorice, and jujube. It has the effects of harmonizing the stomach, descending rebellious qi, dispersing masses, and eliminating fullness. It has significant effects in alleviating symptoms such as acid reflux and heartburn in RE, with promising development prospects and clinical significance.

2. The Basis of the Formula Pattern for Banxia Xiexin Decoction

Traditional Chinese medicine disease names for RE fall under categories such as “esophageal dampness,” “vomiting acid,” and “stomach pain.” The ‘Linzhang Beiyao · Acid Swallowing’ states: “The stomach is generally sour, noisy with a burning sensation, mostly due to liver qi invading the stomach.” “Classified Syndrome Treatment Regulations” states, “When there is rebellion and vomiting, it is because liver qi invades the stomach, or the stomach is weak and the liver overrides” [3]. RE mainly affects the esophagus and stomach. Due to overwork and irregular diet, liver qi is not properly distributed and the spleen and stomach are damaged. Combined with mixed cold and heat in the epigastrium, stomach qi becomes abnormal, causing it to flow upward instead of descending, triggering a series of symptoms such as regurgitation, nausea, acid vomiting, and heartburn [5]. Professor Wang Xingkuan, a nationally renowned TCM doctor, has innovatively proposed the in-depth approach of treating reflux esophagitis from the liver perspective, establishing the core pathogenesis of ‘liver reversal invading the stomach,’ emphasizing the coordinated treatment of the liver, stomach, and lungs, and proposing the treatment method of ‘harmonizing the liver and stomach, with the left side balancing metal’ [8]. Professor Xu Erping pointed out that Banxia Xiexin Decoction treats most diseases in the middle burner, with the core pathogenesis summarized as a mixture of deficiency and excess, coexistence of cold and heat, and dysfunction of qi transformation. For clinical syndrome differentiation, when the pathogenesis is a mixture of deficiency and excess, the base formula from Banxia Xiexin Decoction as described in the Treatise on Cold Damage is used as the base formula with modifications and adjustments; If the main contradiction is pathogenic excess and stagnation, then the Banxia Xiexin Decoction from the Jin Gui Yaolue edition is chosen for treatment [9].

Banxia Xiexin Decoction uses pungent and warm pinellia as the main focus, which can dissolve nodules and dissolve fullness, as well as descend rebellious qi and harmonize the stomach to stop vomiting; Combined with pungent and hot dried ginger to warm the middle burner and disperse cold stagnation in the middle burner, bitter and cold scutellaria and coptis to clear and drain stomach congealed heat, relieve heat and relieve fullness; The combination of ruler and minister, combined cold and heat, balanced yin and yang, established the classic treatment method of pungent opening and bitter descending. In the Qing dynasty, Ye Tianshi explained in “Clinical Guide Medical Cases” that “pungent to open the condition, bitter to descend,” highlighting the mechanism of bitter and pungent combination: bitter flavors descend to clear heat and eliminate dampness, pungent flavors disperse qi and disperse turbidity, fully interpreting the core connotation of the pungent opening and bitter descending treatment method [10]; Banxia Xiexin Decoction also uses ginseng and jujube as adjuncts, sweet, warm, and soothing, tonifying spleen qi; Licorice tonifies the spleen and harmonizes the middle, harmonizing other herbs; The combination of these herbs forms the basic formula for treating central qi deficiency, cold and heat interlocking, and abnormal ascending and descending disorders.

3. Pharmacological Study of Banxia Xiexin Decoction as a Single Herb

Modern pharmacological research confirms that the core active substances effective in Banxia Xiexin Decoction include quercetin, kasanol, baicalin, naringin, and baicalin. Among them, quercetin and kaempol exhibit multiple pharmacological activities such as anti-inflammatory, antioxidant, and antitumor effects; Baicalin can downregulate the activity of gastric mucosa-specific secretion proteins, increasing mucus secretion levels and inhibiting total gastric acid secretion, thereby exerting protective effects on the gastric mucosa; Both baicalin and naringin belong to the flavonoid class, both exhibiting antioxidant and anti-inflammatory pharmacological effects [11]. Combined use can achieve a good therapeutic effect on RE.

Pinellia is pungent, warm, and toxic, entering the lung, spleen, and stomach meridians. It dries dampness and resolves phlegm, descends rebellious qi and stops vomiting, dispels fullness and nodules, and when used externally, it reduces swelling and relieves pain [12]. Modern pharmacology has proven that Pinellia has antitussive and expectorant effects, anti-nausea, anti-inflammatory, anti-tumor, calming and sleep-inducing, anti-aging, immune-boosting, and promoting gastric function [13]. It mainly contains alkaloids, flavonoids, organic acids, and volatile oils [14], among which 10,13-eicosaenoic acid and β-The siltosterol content is relatively high. Wang Lei et al. [15] found that Pinellia inhibits mink vomiting induced by cisplatin and apomorphine, with the mechanism related to central nervous system inhibition.

Coptis originates from the Shennong Bencao Jing, known for its bitter and cold nature, and belongs to the heart, liver, stomach, and large intestine meridians. It has the effect of clearing heat and drying dampness. The main active substance in Coptis is berberine, which can reduce H+-K+-ATPase activity and inhibit gastric acid secretion; It can also increase levels of the anti-inflammatory cytokine interleukin-10 (IL-10), enabling the pro-inflammatory cytokine IL-1β and tumor necrosis factor to αTumor necrosis factor-α, TNF-α), IL-6 levels decrease. This helps restore the balance between inflammatory mediators and anti-inflammatory factors, reducing gastric mucosal damage caused by Helicobacter pylori [34].

Scutellaria is bitter and cold, entering the lung, stomach, gallbladder, and large intestine meridians, and has effects such as clearing heat and drying dampness, cooling the blood, calming the fetus, and clearing upper burner fire. It is composed of main ingredients such as baicalin, baicalin, and baicalin. Baicalin can regulate the gut microbiota, not only reduces the expression of inflammatory mediators such as IL-1β, IL-6, IL-8, and TNF- in the gastric mucosa, α alleviates inflammatory responses [34], it can also promote the secretion of gastric mucus, thereby protecting the gastric mucosa [11].

Dried ginger is pungent and hot. The Shennong Bencao Jing states: “Mainly treats chest fullness, cough, and rebellious qi, warms the middle and stops bleeding, promotes sweating, dispels wind-dampness obstruction, and causes intestinal dysentery and diarrhea.” The living ones are especially good [16]. It has the effects of restoring yang and unblocking the

meridians, warming the lungs and resolving fluids, and warming the middle to disperse [17]. Modern research has shown that the main active ingredients in dried ginger are volatile oils, gingerols, and diphenylhepteneanes [18], which have anti-inflammatory, antioxidant, anticancer, antibacterial, and cardiovascular protective effects [19]. The gingerol, gingerol, and curcumin in dried ginger have various protective effects on the digestive system [20]. Gingerol and gingerol can stimulate the gastric mucosa and pancreas, promoting the secretion of digestive juices and thereby improving digestive function [21]. Curcumin has antibacterial properties and can inhibit the growth of bacteria and fungi. Reduce the proportion of infections [22]. Li Yalan et al. [23] found that dried ginger can also reduce inflammatory factor levels by inhibiting the TLR4/ERK/p38 MAPK signaling pathway in Ly6Chi mononucleus/macrophages.

Ginseng is warm in nature and slightly bitter, entering the spleen and lung meridians [24]. It has effects such as restoring pulse and stabilizing collapse, tonifying the spleen and benefiting the lungs, preventing collapse and stopping sweating, and benefiting the kidneys and enhancing yang [25]. First recorded in the Shennong Hundred Herbal Classics, classified as superior grade, it states: “Sweet and slightly cold in taste, mainly nourishes the five organs, calms the spirit, stabilizes the soul, stops frightening and palpitations, dispels pathogenic qi, improves eyesight, promotes mental health and intelligence, lightens the body and prolongs life with long-term use” [26]. Pharmacological studies have shown that ginseng contains active ingredients such as ginsenosides, ginseng polysaccharides, and ginseng volatile oils. Ginseng volatile oil has antibacterial and calming effects [27], while ginseng polysaccharides help regulate the immune system, have antibacterial and antitumor effects, lower blood sugar, enhance intestinal absorption, and repair the intestinal mucosa [27,28].

Licorice is sweet, neutral, and non-toxic. It has the effects of tonifying the spleen and boosting qi, clearing heat and detoxifying, resolving phlegm and relieving cough, relieving pain relief and harmonizing various medicines [29]. Modern medicine believes that its ginsenosides and ginseng polysaccharides and other triterpene saponins and flavonoids possess antiviral, antibacterial, anti-inflammatory, antioxidant, antitumor, antiulcer, and liver-protective properties, and thus is widely used to treat gastrointestinal diseases [30].

Jujubes are recorded as early as the Shennong Bencao Jing, where they are considered the finest medicinal herbs, and are commonly known among the people as the “longevity fruit.” The main components of jujube are jujube polysaccharides and jujube protein, which are rich in vitamins and have effects such as boosting immunity, inhibiting tumors, providing antioxidant effects, liver protection, and anti-allergy effects [31].

Table 1: Summary of Charts

	Main Components Action	Source
Banxia	Alkaloids, flavonoids	[13] [14] [15]
Coptis	Berberine	[34]
Scutellaria	Baicalin, baicalin	[11] [34]
Dried ginger	Gingerol, gingerol, curcumin	[18] [19]
Ginseng	Ginsenosides and ginseng polysaccharides	[27] [28]
Licorice	Ginsenosides and ginseng polysaccharides	[30]
Jujubes	Jujube polysaccharides and jujube protein	[31]

4. Clinical Study of Banxia Xiexin Decoction

An increasing number of clinical studies have proven that Banxia Xiexin Decoction can effectively improve gastrointestinal function and repair the digestive tract mucosa. Pan Shuang and colleagues found through experiments that Banxia Xiexin Decoction can effectively alleviate esophageal mucosal injury in a rat model of reflux esophagitis and reduce the expression of intercellular adhesion molecule-1 and L-selectin [32]; Experimental studies show that Banxia Xiexin Decoction can lower gastric acid and bile acid concentrations, inhibit gastric reflux, reduce esophageal mucosal damage, and promote gastric motility [33]. Wang Ruoling et al. [34] found that Banxia Xiexin Decoction protects the gastric mucosa, regulates intestinal flora, fights gastrointestinal tumors, and has antidepressant effects. Liang Kun et al. [35] found that Banxia Xiexin Decoction has good antibacterial and bactericidal effects against Helicobacter pylori. Liu Xiaoni et al. [36] found that the mechanism of Banxia Xiexin Decoction in preventing and treating reflux esophagitis may be achieved by downregulating the genes for dining ning and calmodulin binding proteins, increasing the concentration of free calcium within cells, thereby enhancing the contractile ability of esophageal smooth muscle.

4.1 Single-sided Chemical Cutout Application

In clinical practice, Banxia Xiexin Decoction should be flexibly adjusted according to the patient’s specific symptoms, with syndrome differentiation and treatment. Yan Danchun et al. [37] randomly divided patients into two groups of 30 cases each. The control group was treated with pantoprazole sodium enteric-coated tablets and mosapreride citrate tablets, while the observation group was treated with Banxia Xiexin Decoction. The study found that the total effective rate in the observation group was higher than in the control group ($P<0.05$). The use of Banxia Xiexin Decoction is more beneficial for improving clinical symptoms in patients with reflux esophagitis, offering significant advantages in suppressing inflammatory responses. Its therapeutic effects surpass conventional Western medicine treatments, aligning better with the holistic regulation concept of traditional Chinese medicine; Shi Zhengguo et al. [38] randomly divided 80 patients with reflux esophagitis with liver-stomach disharmony syndrome into a study group and a control group, 40 cases each. The control group received conventional treatment, while the study group combined Banxia Xiexin Decoction with modified treatment based on the control group, demonstrating significant efficacy in treating patients with reflux esophagitis combined with acid reflux, markedly improving TCM symptoms and enhancing gastrointestinal motility; Liu Dan et al. [39] randomly divided 68 patients who met the inclusion criteria into a control group and a treatment group. Both groups received omeprazole enteric-coated capsules, and the treatment group received Banxia Xiexin Decoction. The results showed that the treatment group had better clinical efficacy ($P<0.05$). Banxia Xiexin Decoction is more effective than omeprazole enteric-coated capsules for reflux esophagitis with mixed cold and heat, effectively regulating gastrointestinal hormone levels and improving symptoms such as stomach pain, burning, and acid reflux; Yang Shaohua et al. [40] divided 60 patients with reflux esophagitis into a control group and a study group with 30

cases each. The control group received omeprazole enteric-coated tablets, while the study group received modified Banxia Xiexin Decoction. The results showed that the total effective rate (93.33%) in the study group was higher than that in the control group (66.67%). The difference was statistically significant (P<0.05), indicating that the modified Banxia Xiexin Decoction was more effective in treating patients with reflux esophagitis, better for symptom improvement, and lower recurrence rates. In summary, the modified Banxia Xiexin Decoction has good efficacy in treating reflux esophagitis.

4.2 Traditional Chinese Medicine Combined in Formula Application

The causes and mechanisms of RE are complex, and single treatment may be difficult to cope with complex disease changes. Therefore, in clinical practice, formulas are often combined to enhance efficacy. Li Wei et al. [41] studied 100 patients with mixed cold and heat type RE outpatient treatment and divided them into a combination group and a Western medicine group, 50 cases each. The combination group received Banxia Xiexin Decoction combined with Wubei San combined with omeprazole, while the Western medicine group received omeprazole. The results showed that the combination group had a higher efficacy rate, and the difference between groups was statistically significant (P<0.05). Tang Ying et al. [42] randomly divided 100 patients with reflux esophagitis into a control group (n=50) and an observation group (n=50), receiving conventional Western medicine combined with Banxia Xiexin Decoction combined with Si Ni San as a modification. The results showed that the combination of Banxia Xiexin Decoction combined with Si Ni San effectively improved the treatment efficacy of reflux esophagitis and reduced recurrence rates.

4.3 Integrated Chinese and Western Medicine Treatment

With the development of modern medicine, integrated Chinese and Western medicine treatments have become increasingly mature and have achieved good results. Ke Yan et al. [43] randomly divided 60 patients into two groups, 30 cases each. Group G took rabeprazole sodium enteric-coated tablets; In group H, on top of taking rabeprazole sodium enteric-coated tablets, Banxia Xiexin Decoction was added. The results showed that the combination of Banxia Xiexin Decoction with Rabeprazole was highly effective in treating reflux esophagitis, with a low recurrence rate. Luo Qin et al. [44] randomly divided 90 RE patients into control group 1, control group 2, and observation group, each receiving oral omeprazole, Banxia Xiexin Decoction orally, and Banxia Xiexin Decoction combined with omeprazole, respectively. Observational results showed that the observed group showed significantly better efficacy than omeprazole or Banxia Xiexin Decoction alone, making it worthy of clinical promotion and application. Lin Yanfen et al. [45] divided 90 cold-heat interlocking RE patients into a control group and an observation group with 45 cases each according to a random numerical table. The control group received omeprazole enteric-coated capsules and famotidine tablets, while the observation group received Banxia Xiexin Tang as a modification on top of the control group, with continuous treatment for 4 weeks. The results showed: Banxia Xiexin Decoction combined with Western medicine is effective in treating cold-heat interlocking type RE, effectively improving clinical symptoms, reducing esophageal mucosal damage and gastroesophageal reflux, enhancing sleep quality, and offering high drug safety. Ruan Shengren et al. [46] randomly divided 150 RE patients into treatment and control groups. The control group received oral treatment with Xisapilil, while the treatment group received modified Banxia Xiexin Decoction based on the control group. The results showed that the combination of Banxia Xiexin Decoction combined with Xisapreb in RE showed good clinical efficacy. The incidence of adverse reactions is low, and its efficacy and safety may be superior to cesapride alone.

5. Summary

In summary, Banxia Xiexin Decoction and its active components can intervene in reflux esophagitis (RE) through multiple pathways such as regulating gastrointestinal motility and repairing the mucosal barrier of the digestive tract. Their clinical efficacy is definite, clearly demonstrating the unique advantages of TCM in syndrome differentiation and holistic regulation. Whether used alone, combined with traditional Chinese medicine, or combined with Western medicine for coordinated intervention, this formula can provide a safe and reliable diversified treatment plan for reflux esophagitis.

However, existing research still has shortcomings such as unclear interpretation of target mechanisms and incomplete analysis of related signal pathway regulatory networks. Subsequent large-sample clinical observations and in-depth pharmacological mechanisms of Banxia Xiexin Tang modified formulas for RE will continue to further optimize clinical dosing protocols and improve actual diagnostic and treatment outcomes, and help promote the iterative upgrading and innovative development of TCM digestive disease diagnosis and treatment systems.

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