

RESEARCH ARTICLES

**Effects of Ban Xia Xie Xin Decoction on GERD of Cold and Heat in Complexity Syndrome**

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**Abstract:** Gastroesophageal Reflux Disease (GERD) presents significant diagnostic challenges and diminishes quality of life. This study evaluates the efficacy of Ban Xia Xie Xin Decoction on patients with GERD exhibiting "Cold and Heat in Complexity Syndrome." A one-group pretest-posttest design was conducted at the Jiangxi University of Chinese Medicine Affiliated Hospital from January to February 2025. This research aims to study the Effects of Ban Xia Xie Xin Decoction on GERD of Cold and Heat in Complexity Syndrome. Ten respondents were selected via purposive sampling based on strict inclusion criteria. Data normality was assessed using the Shapiro-Wilk test, while treatment effects were analysed using the Wilcoxon signed-rank test ( $\alpha=0.05$ ). Primary outcomes were measured using the Reflux Disease Questionnaire (RDQ) and Chinese Medicine Evaluation Report (CMER) scores. Statistical analysis revealed a significant decrease in symptom severity ( $\alpha = 0.005 < 0.01$ ), leading to the rejection of the null hypothesis. Post-intervention mean scores decreased by 18.70 for RDQ and 13.00 for CMER, indicating a substantial reduction in acid reflux and epigastric pain. Ban Xia Xie Xin Decoction significantly alleviates symptoms in GERD patients with Cold and Heat in Complexity Syndrome. These findings support the integration of traditional decoctions in managing chronic gastrointestinal disorders.

**Keywords:** GERD, ban xia xie xin decoction, cold and heat complexity, rdq, traditional chinese medicine.

## INTRODUCTION

Gastroesophageal Reflux Disease (GERD) is a common gastrointestinal disease with the main symptoms of heartburn and acid reflux. GERD is characterised by chronic reflux of stomach contents into the oesophagus, which poses significant diagnostic and therapeutic challenges and often affects patients' overall quality of life and health. The global prevalence of GERD is 13.9%. Prevalence varies by region, ranging from 8.7% to 33.1% in the Middle East, 8.8% to 25.9% in Europe, and 2.5% to 7.8% in East Asia.<sup>1</sup> Meanwhile, in China, the prevalence is around 19.89%.<sup>2</sup>

Common treatments such as proton pump inhibitors (PPIs), surgery, and lifestyle changes are the main treatment options for GERD.<sup>3</sup> However, given the many factors contributing to the pathogenesis of GERD, there is a need to seek treatments that go beyond those currently available for multitarget therapy to treat this disease. Traditional Chinese Medicine (TCM), with a history of more than 2000 years, is known for its holistic approach to treating the human body.<sup>4</sup>

GERD in TCM is often referred to as “Tu Suan”. The main clinical manifestations of GERD are acid reflux and heartburn, accompanied by chest pain, abdominal pain, belching, dysphagia, and other symptoms, which seriously affect the quality of life of patients. GERD is divided into 6 syndromes: Liver and Stomach Disharmony, Stagnation and Heat in the Liver and Stomach, Middle

Jiao Deficiency Causing Qi Reversal, Qi and Phlegm Obstruction, Qi Stagnation and Blood Stasis, and Cold and Heat in Complexity.<sup>5</sup> There are several symptoms to note for determining the cold and heat in complexity syndrome. Primary symptoms: (1) Burning discomfort behind the sternum or in the abdominal and epigastric regions; (2) Acid reflux or vomiting of water; (3) Vague pain in the abdominal and epigastric regions, with a preference for warmth and pressure. Secondary symptoms: (1) Loss of appetite; (2) Fatigue; (3) Bowel sounds and diarrhoea; (4) Cold hands and feet. Tongue and pulse: red tongue, white coating, weak pulse. Determination of syndrome: 2 of the primary symptoms and 1 or 2 of the secondary symptoms, referring to the tongue and pulse.<sup>6</sup>

Ban Xia Xie Xin Decoction first appeared in Shang Han Lun. The original text reads: “If there is vomiting and intestinal noise, Ban Xia Xie Xin Decoction is the main formula”. It is used to treat cold and heat in complexity syndromes. The composition of Ban Xia Xie Xin Decoction consists of Pinellia Tuber (Ban Xia) 10g, Radix Scutellariae (Huang Qin) 10g, Rhizoma Coptidis (Huang Lian) 6g, Dried Ginger (Gan Jiang) 6g, Pilose Asiabell Root (Dang Shen) 15g, Jujube (Da Zao) 10g, Licorice Root (Gan Cao) 6g.<sup>7</sup>

This research aims to study the Effects of Ban Xia Xie Xin Decoction on GERD of Cold and Heat in Complexity Syndrome.

## METHOD

This study used a one-group pretest-posttest design, which aimed to determine the effectiveness of Ban Xia Xie Xin Decoction in treating the symptoms of GERD, Cold and Heat in Complexity Syndrome.

The sample in this study consisted of 10 outpatients with GERD Cold and Heat in Complexity Syndrome at the Jiangxi University of Chinese Medicine Affiliated Hospital. The sampling technique used in this study was purposive sampling. The data source was obtained from the patient history list at the hospital. Patient data was collected using questionnaires to determine changes that occurred in patients during the study. In addition, sampling was also based on inclusion and exclusion criteria:

### a. Inclusion criteria:

1. Patients who came for treatment at the Jiangxi University of Chinese Medicine Affiliated Hospital with complaints of GERD, Cold and Heat in Complexity Syndrome.
2. Patients aged 18 to 65 without gender limitation.
3. Patients without pathological findings of gastric ulcers, hyperplasia, or cancerous lesions.
4. Patients who have not taken any medication that affects gastrointestinal function within 1 week.
5. Patients willing to participate in this study follow the Traditional Chinese

Medicine treatment procedures and sign an informed consent form.

6. Patients without other comorbidities.

### b. Exclusion criteria

1. Patients with GERD with Liver and Stomach Disharmony Syndrome, Stagnation and Heat in the Liver and Stomach, Middle Jiao Deficiency Leading to Qi Reversal, Qi and Phlegm Obstruction, or Qi Stagnation and Blood Stasis.
2. Patients with pathological findings of gastric ulcers, hyperplasia, or cancerous lesions.
3. Pregnant patients.
4. Withdrawal as a research subject.
5. Failure to complete the treatment period, i.e., not taking the herbal formula for 4 weeks.
6. Taking medical drugs or undergoing other interventions.

Collect frequency distribution data from sample characteristics, mean, and mode of GERD Cold and Heat in Complexity Syndrome symptom scores before and after intervention. Testing data normality using the Shapiro-Wilk normality test and testing data hypotheses using the Wilcoxon analysis. Processing data obtained through recording and typing using SPSS version 26 to facilitate data analysis.

This study assessed GERD symptoms using two scales: (1) the Reflux Disease Questionnaire (RDQ) scale and (2) the

Chinese Medicine Evidence Rating (CMER) scale.

The RDQ scale assessed eight items divided into symptom frequency and symptom level (acid reflux, heartburn, non-cardiac chest pain, food reflux), each with six scoring options (absent = 0, not obvious = 1, between obvious and not obvious = 2, obvious = 3, between obvious and very obvious = 4, very obvious = 5).

The CMER scale assessed eight items divided into main symptoms (acid reflux, heartburn) and minor symptoms (poststernal burning pain, epigastric burning pain, stomach distension and fullness, belching or food reflux, irritability, susceptible to hunger), each with four scoring options (for main symptoms absent = 0, occasionally = 2, sometimes = 4, frequently = 6, for minor symptoms absent = 0, occasionally = 1, sometimes = 2, frequently = 3).

## RESULT

This study was conducted from January 2025 to February 2025. The researchers used purposive sampling with a total of 10 samples. All research subjects who met the inclusion criteria were asked to sign an informed consent form. Ban Xia Xie Xin Decoction therapy was administered according to the agreed schedule. The formula therapy was taken twice a day for 28 days.

**Table 1. The General Characteristics of the Patients**

Variables	
Characteristic	
Mean age $\pm$ SD, year	55.90 $\pm$ 7.62
Sex ratio (male: female)	4:6

**Table 2. RDQ and CMER scores**

Variables	Before	After	P Values
Patient RDQ scores	24.50 $\pm$ 2.92	5.80 $\pm$ 7.35	P < 0.01
Patient CMER scores	17.70 $\pm$ 3.06	4.80 $\pm$ 4.66	P < 0.01

## DISCUSSION

The analysis of Table 1 shows that the majority of people with GERD are female (60%) and male (40%). Gender also influences a person's susceptibility to GERD. Women are more prone to GERD due to the influence of estrogen and progesterone hormones, one of whose functions is to relax the LES.<sup>8,9</sup> However, men are more likely to experience pathological changes.<sup>10</sup> The age range of GERD sufferers is mostly between 56 and 65 years old; the older a person is, the more susceptible they are to GERD.<sup>11</sup>

Although Western medicine plays an important role in relieving symptoms and controlling the disease, Western treatment methods tend to be limited and monotonous. Long-term use of PPIs has been associated with a spectrum of potential adverse effects and drug interactions. These include an increased susceptibility to enteric, respiratory, and urinary tract infections.

Metabolic consequences can involve micronutrient deficiencies such as iron, calcium, magnesium, and vitamin B12. Furthermore, PPIs may elevate cardiovascular risk and have been linked to bone fractures. There is also concern regarding their potential to increase the risk of gastrointestinal malignancies; this is thought to occur through mechanisms like hypergastrinemia and by facilitating gastric pan-colonisation of *Helicobacter pylori*, which can promote gastric preneoplastic and neoplastic lesions. Consequently, the association between long-term PPI use and an increased risk of gastric cancer is a significant consideration in ongoing treatment.<sup>12,13,14,15,16</sup>

On the other hand, TCM, as a complementary and alternative treatment method, offers additional perspectives and approaches in managing GERD. TCM has significant advantages over conventional treatment in managing GERD. Jian Ming Yi Gong notes, "All acid reflux is caused by heat. Acid reflux caused by cold occurs when the stomach is injured by cold, hard, or frozen food." This shows that both cold and heat syndromes can cause acid reflux. In elderly patients or patients suffering from chronic diseases, there is often a mixture of cold and heat. This is caused by a weakened spleen, leading to deficiency and a combination of cold and heat syndromes. Therefore, the main principle of treatment should be to v, eliminate cold and heat, calm the stomach, and reduce vomiting.<sup>17,18</sup>

## CONCLUSION

We conclude that Ban Xia Xie Xin Decoction may offer symptomatic improvements in patients with GERD. In this study, Ban Xia Xie Xin Decoction was shown to have effects in the management of GERD. Further studies are needed to determine the precise mechanisms of action.

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