

Meta-analysis of Xiaochaihu Decoction in the Treatment of Gastroesophageal Reflux Disease

Fu Fangzhi^{1,2}, Yin Shuang², Zhou Qing^{1*}

¹. *The First Affiliated Hospital of Hunan University of Chinese Medicine, Changsha 410007, China*

². *Hunan University of Chinese Medicine, Changsha 410208, China*

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Abstract: Objective: To systematically evaluate the efficacy and safety of Xiaochaihu decoction in the treatment of gastroesophageal reflux disease (GERD). Methods: The databases of CNKI, VIP, WanFang, PubMed and the Cochrane Library were searched to find out the clinical studies of Xiaochaihu decoction in the treatment of gastroesophageal reflux disease and conduct a meta-analysis. And the time limit was from the establishment of the database to September 2021. Results: A total of 10 studies with a total of 1173 patients were included. Meta-analysis results showed that, compared with conventional western medicine, Xiaochaihu decoction can significantly improve the clinical cure rate, gastroscopy cure rate, clinical total effective rate and total gastroscopy total effective rate of GERD, and reduce the recurrence rate and rate of adverse reactions. Conclusion: Xiaochaihu decoction has superior efficacy and safety in the treatment of GERD.

1. Introduction

The symptoms or complications of reflux of gastric contents into the esophagus are called gastroesophageal reflux disease (GERD) [1]. The main clinical manifestations of GERD are reflux, heartburn, and esophageal mucosal damage under endoscopy. The goals of GERD treatment are tantamount to cure esophagitis, relieve symptoms, and reduce complications. According to reports, traditional Chinese medicine has excellent clinical efficacy in the treatment of GERD, and has gradually become a research hotspot due to its advantages such as low recurrence rate. Therefore, this study took Xiaochaihu decoction as the experimental group and conventional western medicine as the control group to evaluate the efficacy and safety of Xiaochaihu decoction in GERD by means of meta-analysis, so as to provide evidence-based basis for the clinical application.

2. Method

The databases of CNKI, VIP, WanFang, PubMed and the Cochrane Library were searched to find out the clinical studies of Xiaochaihu decoction in the treatment of gastroesophageal reflux disease and conduct a meta-analysis. And the time limit was from the establishment of the database to September 2021. Two researchers independently screened the literature, organized the data,

evaluated the literature quality and statistical analysis, and any objections were adjudicated by the third researcher.

Inclusion criteria: (1) Randomised controlled trials; (2) Included objects: met the diagnostic criteria for gastroesophageal reflux disease [2]; (3) Intervention measures: the experimental group was given modified Xiaochaihu decoction, and the control group was given antacids and/or prokinetic drugs; (4) Outcome indicators: clinical cure rate, Gastroscopy cure rate, total clinical effective rate, total gastroscopy effective rate, recurrence rate, rate of adverse reactions.

Meta-analysis was performed using RevMan 5.3 software. For categorical variables, the relative risk (RR) and its 95% confidence interval (CI) were used as efficacy analysis statistics. The chi-square test was utilized to test the heterogeneity of the results of each study. If the results of the chi-square test showed that the heterogeneity among the included studies was small ($P > 0.1$, $I^2 < 50\%$), a fixed effect model was used for meta-analysis. Otherwise, a random-effects model was used for meta-analysis.

3. Results

A total of 177 relevant literature were detected, and after layer-by-layer screening, 10 studies were finally included [3-12]. All included literature was in Chinese, including 1173 patients, 590 in the experimental group and 583 in the control group. Depending on the 7-point Jadad scale, 8 articles were scored 3 points, and 2 articles were scored 4 points (Table 1).

Table 1 Basic characteristics of the included studies

Author and year	Sample size (T/C)	Experimental group (T)	Control group (C)	Course of treatment	Outcomes	Jadad score
Jiang G 2008[3]	30/30	Xiaochaihu decoction	Omeprazole+Domperidone	2month	①②③④⑥	3
Li X 2008[4]	30/29	Xiaochaihu decoction	Famotidine+Domperidone	8week	①②③④	3
Li Z 2011[5]	49/43	Xiaochaihu decoction	Omeprazole+Domperidone	4week	③④⑤	3
Zeng J 2013[6]	30/30	Xiaochaihu decoction	Pantoprazole	4week	①②③④⑤⑥	3
Wu L 2014[7]	50/50	Xiaochaihu decoction	Rabeprazole+Domperidone	3month	①②③④⑤	3
Deng S 2016[8]	30/30	Xiaochaihu decoction	Omeprazole	8week	①③	3
Tan X 2017[9]	38/38	Xiaochaihu decoction	Rabeprazole+Domperidone	Not stated	⑥	4
Chen Z 2019[10]	23/23	Xiaochaihu decoction	Rabeprazole+Domperidone	Not stated	⑥	3
Wang Y 2019[11]	60/60	Xiaochaihu decoction	Omeprazole+Domperidone	4month	①②③④⑥	4
Gao P 2020[12]	250/250	Xiaochaihu decoction	Rabeprazole+Domperidone	Not stated	⑥	3

① represents the clinical cure rate; ② represents the cure rate of gastroscopy; ③ represents the total clinical effective rate; ④ represents the total effective rate of gastroscopy; ⑤ represents recurrence rate; ⑥ represents the rate of adverse reactions.

Meta-analysis results showed that compared with conventional western medicine, Xiaochaihu decoction could significantly improve the clinical cure rate [RR=1.45, 95%CI=(1.08, 1.96), P=0.01], and the cure rate of gastroscopy [RR=1.43, 95%CI=(1.06, 1.95), P=0.02], total clinical effective rate [RR=1.29, 95%CI=(1.18, 1.41), P<0.00001], total effective rate of gastroscopy [RR=1.26, 95%CI=(1.15, 1.37), P<0.00001], reducing the recurrence rate [RR=0.35, 95%CI=(0.21, 0.58), P<0.0001] and the rate of adverse reactions [RR=0.19, 95%CI=(0.12, 0.32), P<0.00001] in the treatment of GERD (Table 2).

Table 2 Meta-analysis results

Outcome	Heterogeneity	Model	RR(95%CI)	P
the clinical cure rate	P=0.70, I2=0%	FEM	1.45(1.08,1.96)	0.01
the cure rate of gastroscopy	P=0.57, I2=0%	FEM	1.43(1.06,1.95)	0.02
total clinical effective rate	P=0.41, I2=2%	FEM	1.29(1.18,1.41)	<0.00001
total effective rate of gastroscopy	P=0.26, I2=23%	FEM	1.26(1.15,1.37)	<0.00001
the recurrence rate	P=0.90, I2=0%	FEM	0.35(0.21,0.58)	<0.0001
the rate of adverse reactions	P=0.44, I2=0%	FEM	0.19(0.12,0.32)	<0.00001

4. Discussion

The results of Meta-analysis showed that Xiaochaihu decoction had higher clinical and gastroscopy cure rate and total effective rate and lower recurrence rate compared with conventional western medicine in the treatment of GERD. Therefore, the effectiveness of Xiaochaihu decoction is preferable to that of conventional western medicine. The rate of adverse reactions of Xiaochaihu decoction group was lower, so the safety of Xiaochaihu decoction was better than that of conventional western medicine. To sum up, the efficacy and safety of Xiaochaihu decoction in the treatment of GERD are better than conventional western medicine.

The limitations of this study are as follows: ①All the included studies are domestic literatures, leading to possible publication bias; ②The total number of samples is small, which may reduce the reliability of the results; ③There are 10 literatures that do not describe the concealment method, which may lead to the possibility of selection bias; ④There are 10 articles that do not describe blinding, which may lead to possible implementation bias; ⑤There are differences in the basic prescriptions and addition and subtraction methods of Xiaochaihu decoction involved in the experimental group, and the types and doses of the drugs in the control group are also different, which has a certain influence on the analysis results.

To sum up, Xiaochaihu decoction has considerable curative effect due to the multi-integrated comprehensive treatment method unique to Chinese medicine, and has advantages over conventional western medicine in terms of efficacy and safety. Therefore, referring to the analysis results of this meta-study, it is recommended to apply Xiaochaihu decoction according to syndrome differentiation in the treatment of GERD. Owing to the influence of the quality and quantity of the included research literature in this study, the above conclusions need to be further verified by a large-sample randomized double-blind trial.

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