

Clinical Efficacy and Safety of Buzhong Yiqi Decoction in Treating Epigastric Pain: A Systematic Review and Meta-Analysis

Jiajing Miao

Nanjing University of Traditional Chinese Medicine, Nanjing, China

19802692965@163.com

Abstract. Epigastric pain is the most common digestive tract symptom in clinical practice without good treatment to intervene at present. Buzhong Yiqi decoction (BYD) is a relatively common traditional Chinese medicine for the treatment of digestive tract diseases now, which can yiqi in the spleen and stomach. Hence, this study aims to explore the clinical efficacy and safety of BYD in the treatment of epigastric pain, so as to provide a reference for the clinical treatment of epigastric pain in the future. Randomized controlled trials of BYD in treating epigastric pain are investigated by searching common databases in Chinese and English. Meta-analysis is conducted by RevMan 5.4. According to the results, compared with the western pharmaceutical treatment, BYD could improve the clinical efficacy of epigastric pain (OR = 4.14, 95% CI [3.22, 5.33], $P < 0.00001$) and mitigate symptoms such as belching (MD = -0.82, 95% CI [-1.15, -0.49], $P < 0.00001$), insufficient appetite (MD = -0.49, 95% CI [-0.65, -0.33], $P < 0.00001$), nausea and vomiting (MD = -0.34, 95% CI [-0.48, -0.19], $P < 0.00001$), abdominal distension (MD = -0.38, 95% CI [-0.55, -0.20], $P < 0.0001$), fullness (MD = -0.51, 95% CI [-0.59, -0.43], $P < 0.00001$) and anorexia (MD = -0.59, 95% CI [-0.70, -0.48], $P < 0.00001$). Meanwhile, BYD could promote quality of life (MD = 7.45, 95% CI [3.91, 10.99], $P < 0.0001$) and reduce the adverse reaction incidence (OR = 0.27, 95% CI [0.13, 0.53], $P = 0.0002$). The results show that the treatment of epigastric pain with BYD has significant clinical effects and strong safety, which can be applied to clinical use.

Keywords: Buzhong Yiqi Decoction, Epigastric Pain, Meta-Analysis, Systematic Review.

Epigastric pain, known as “pain under the heart”, is clinically the main symptom of frequent pain in the upper abdomen near the heart. According to industry standards of traditional Chinese medicine in the People's Republic of China, epigastric pain is often related to gastric and duodenal inflammation, ulcers, spasms and other diseases [1]. Based on statistics from the World Health Organization, the incidence of stomach disease accounts for 80% of the population [2]. With the social progress, there are increasing personal bad living habits and eating habits, which greatly raise the stomach disease incidence, especially among young people [3]. Epigastric pain is the most common in gastric ulcers and gastritis. However, gastric ulcer is a precancerous lesion of gastric cancer, whose treatment urgently needs attention. According to research, about 10% of people have suffered from gastric ulcer [4].

At present, the Western medicines used in the clinical treatment of gastric diseases are mainly proton pump inhibitors, H₂ receptor antagonists, antibiotics, etc., the most common of which is the triple therapy of proton pump inhibitors combined with two antibacterial drugs. However, this therapy often has a high incidence of adverse reactions after drug withdrawal and the disease is prone to recurrence, which is far less effective than combining traditional Chinese medicine [5]. Compared with Western medicine, traditional Chinese medicine has rich methods to treat epigastric pain with great potential advantages. The addition and subtraction of traditional Chinese medicine prescriptions and the listing of traditional Chinese medicine granules have increased the use of traditional Chinese medicine. For example, BYD has a good curative effect in treating epigastric pain. According to studies, BYD can inhibit inflammatory factors, enhance the body's anti-inflammatory effect, and promote the healing of gastric ulcers [6]. Meanwhile, it can increase the number of gastric mucosal glands, relieve the symptoms of gastric mucosal atrophy [7], improve gastrointestinal hormones and reduce the recurrence rate [8].



Although BYD has been confirmed to have gastric mucosal protective effect, there is little clinical research on BYD treatment of epigastric pain currently, with no sufficient advanced evidence. Thus, this study teases out the published literature and conducts meta-analysis to understand the efficacy and safety of BYD, so as to provide a reference for treating epigastric pain in the future.

1. Method

1.1. Inclusion Criteria

1.1.1. Study Types

The published randomized controlled trial (RCT) on the treatment of epigastric pain with BYD is in English and Chinese. There is no limit to the implementation of assignment concealment and blinding.

1.1.2. Study Subjects

All patients with digestive system diseases featuring epigastric pain as the main symptom are clinically diagnosed. Patients have no restrictions on age, sex, course of disease, source of cases or other serious organic lesions of the digestive system.

1.1.3. Interventions

The experimental group is treated only with BYD, while the control group is treated with conventional Western medicine.

1.1.4. Outcome Indicators

(1) Effective rate of clinical treatment. (2) TCM symptom score. (3) Life quality. (4) Incidence of adverse reactions

1.2. Exclusion Criteria

- (1) There are contraindications to drug use and severe organic lesions of the digestive system;
- (2) Studies for which full text is not available are excluded;
- (3) Exclude studies with incomplete or missing data;
- (4) For studies with duplicate data or repeated publications, the one with the most complete data is used;
- (5) Intervention measures such as using combined Chinese and Western medicine or other traditional Chinese medicine measures (such as acupuncture and moxibustion) are excluded;
- (6) The sample size is not less than 25 cases;
- (7) The course of treatment is not less than 2 weeks.

1.3. Retrieval Strategy

1.3.1. Literature Sources

Two researchers searched CNKI, Wanfang database, VIP, SinoMed, PubMed, Cochrane Library, Web of Science, and MEDLINE databases according to the pre-constructed retrieval method to search relevant literature, with the retrieval duration from database construction to February 2024.

1.3.2. Literature Search

Taking CNKI as an example, “BYD AND epigastric pain OR stomachache OR upper abdominal pain OR chronic gastritis OR functional dyspepsia OR peptic ulcer OR gastroesophageal reflux” is used as the retrieval keyword to search in the above-mentioned Chinese and English databases.

1.4. Literature Screening and Data Extraction

First, read the title and abstract of the research for preliminary screening. Then, exclude those studies that did not meet the inclusion criteria. After that, the remaining studies are screened to determine the final included literature, and the literature excluded by the primary screening and re-screening is classified and counted according to the reasons. Through the Excel data extraction table designed in advance, the information and data are extracted from the literature. The extraction content includes the first author, publication year, title, correspondent author and contact information, basic characteristics of the study population, sample size, intervention and control measures, outcome indicators (clinical efficiency, TCM symptom score, adverse reaction incidence and life quality), etc. Two researchers independently conducted literature screening and data extraction based on the screening criteria. If there is any disagreement, the third researcher will make a judgment.

1.5. Quality Assessment

Cochrane as a bias assessment Tool (Rob) 2.0 is used to evaluate the bias risk of each dimension of the included literature. The evaluation of literature quality is implemented independently and simultaneously by two researchers. If there is a disagreement, it will be discussed and resolved with the third researcher.

1.6. Statistical Methods

RevMan 5.4 is used for meta-analysis. Besides, odds ratio (OR) is used for dichotomous variables and mean difference (MD) is used for continuous variables to express effect statistics, with a 95% confidence interval (CI) given. Clinical heterogeneity is assessed according to the characteristics of the study population, the degree of variation in interventions and outcome measures. Methodological heterogeneity is assessed according to the design and risk of bias of included studies. Statistical heterogeneity is assessed based on differences in intervention effects across studies. Heterogeneity is calculated with Cochrane's Q-test and statistically quantified using I^2 . This study stipulates that the size of heterogeneity is judged according to the Cochrane Handbook [9]. $I^2 \leq 50\%$ denotes small heterogeneity and $I^2 > 50\%$ denotes large heterogeneity. If the statistical heterogeneity between studies is small, the fixed effect (FE) model is used for meta-analysis. Otherwise, the random effect (RE) model is used for meta-analysis. For specific outcome measures, when more than 10 studies are included, funnel plots are used to explore the publication bias of research results.

2. Result

2.1. Literature Search Results

According to the inclusion criteria, 463 related literature are retrieved in various databases. 34 literature are left after reading titles and abstracts in initial screening, and 30 literature are left after reading the whole literature to exclude literature lacking the required outcome indicators. The literature screening process and results are shown in Figure 1.

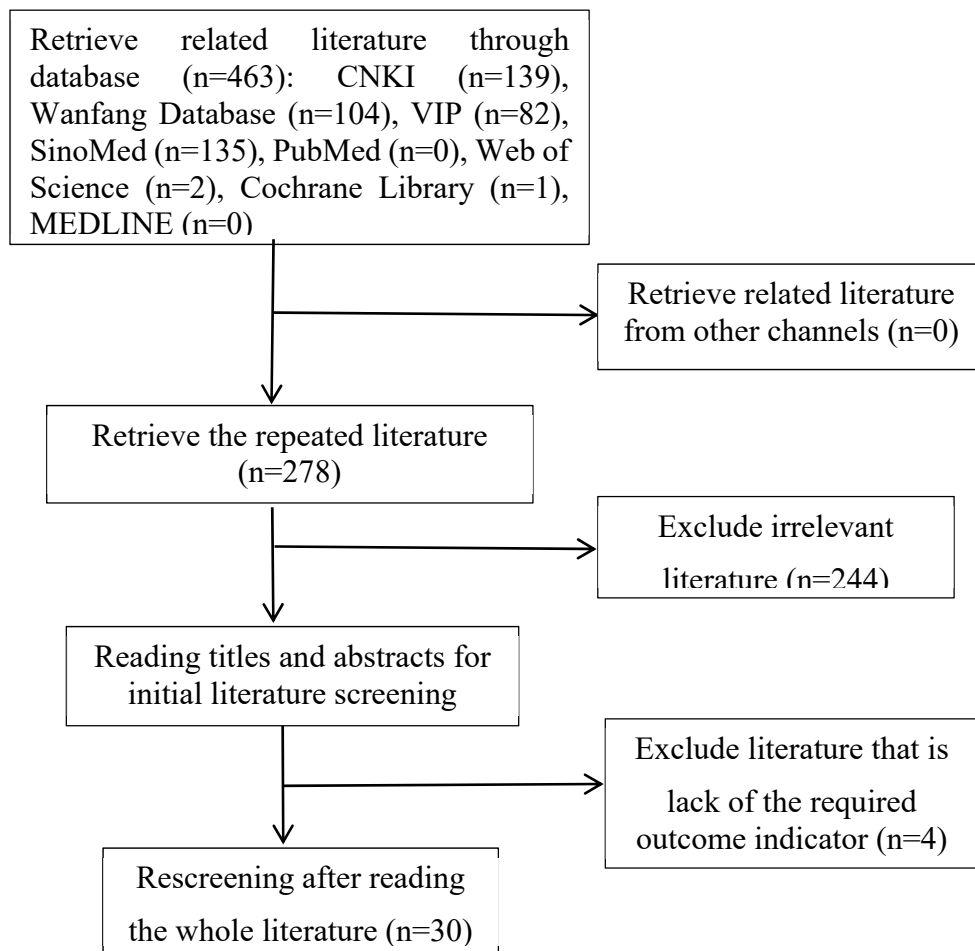


Figure 1. Flowchart of Literature Screening

2.2. General Status and Quality Evaluation of Included Studies

This study includes 30 literature [10-39] with a total of 2796 cases, including 1442 cases in the BYD and 1354 cases in the control group (all using conventional Western medicine). In each study, the daily dosage and frequency of BYD are different, most of which is 1 dose per day and twice a day.

Cochrane risk assessment method is used to evaluate the quality of the final included literature. As for the generation of random sequences, 4 studies [12, 23, 29, 38] use random lottery, 2 studies [13, 39] use random digits and 1 study [32] uses isometric random sampling. Besides, 2 studies have a high risk of selection bias (one adopts the principle of voluntary patients [10], and the other is grouped based on the order of visits [15]). The rest of the studies do not adopt a specific random allocation. Most studies have failed to report distributive concealment or specifically clarify double-blind designs. In terms of baseline characteristics, all 30 literature have comparable baselines. Follow-up visits are conducted in only 2 studies [10, 17]. In terms of loss to follow-up and withdrawal, one study has case dropout [27], and the rest has no loss to follow-up and withdrawal.

2.3. Results of Meta-Analysis

2.3.1. Clinical Response Rate

Twenty-eight literature [10-23, 25, 27-39] report the clinically effective rate of BYD in the treatment of epigastric pain without statistical heterogeneity among the experimental results ($P = 0.81$, $I^2 = 0\%$), so the effect size is combined using a fixed effect model (FE). According to meta-analysis, there is a statistically significant difference between the two groups in terms of clinical efficacy in treating epigastric pain (OR = 4.14, 95% CI [3.22, 5.33], $P < 0.00001$) as seen in Figure 2.

The researchers in this group conducted a funnel plot analysis of the clinical effectiveness of 28 literature (Figure 3) to understand the publication bias. Based on the funnel plot, some included literature are not within the funnel with poor symmetry, suggesting that there is a certain publication bias.

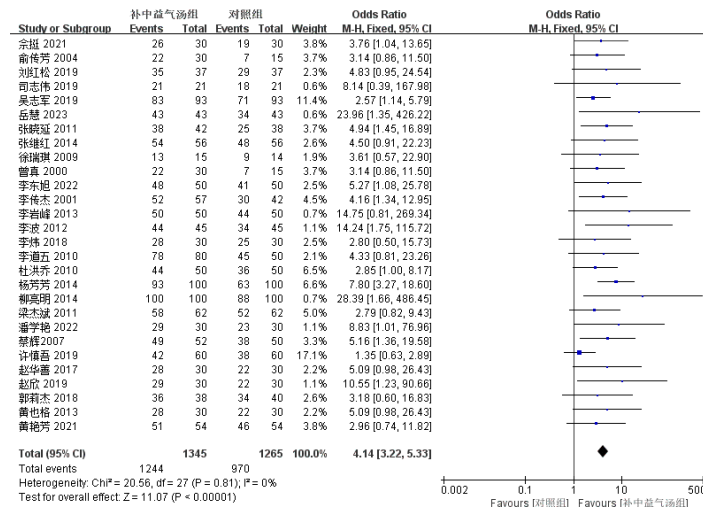


Figure 2. Meta-Analysis of Clinical Response Rate

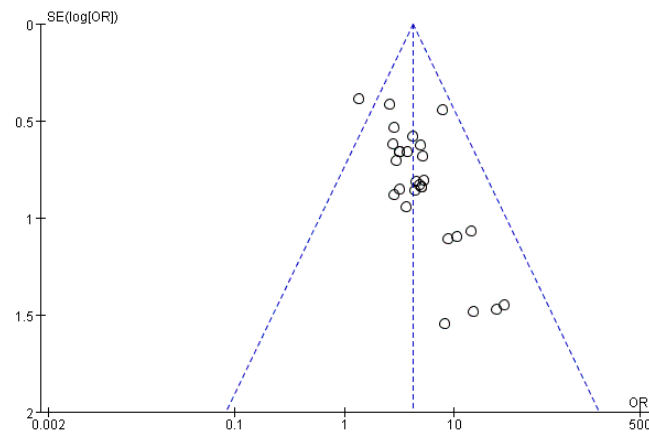


Figure 3. Funnel Plot of Clinical Response Rate

2.3.2. TCM Symptom Score

Belching Symptom Six literature [10, 19-20, 26, 32-33] report the symptom score of belching in treating epigastric pain with BYD. There is statistical heterogeneity among the experimental results ($P < 0.00001$, $I^2 = 97\%$), so the effect size is combined with the random effects model (RE). Meta-analysis results prove statistically significant differences between groups (MD = -0.82, 95% CI [-1.15, -0.49], $P < 0.00001$) in the treatment of belching symptoms in epigastric pain as seen in Figure 4.

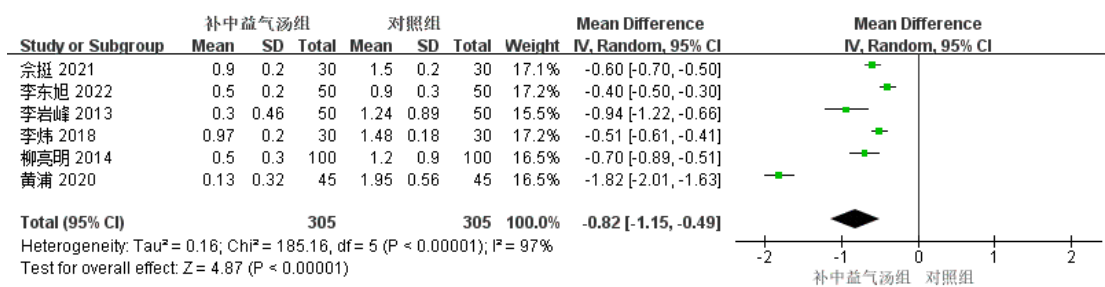


Figure 4. Meta-Analysis of Symptom Score of Belching

Insufficient Appetite Two literature [10, 19] report the symptom score of insufficient appetite in treating epigastric pain with BYD. There is no statistical heterogeneity among experimental results ($P = 0.91$, $I^2 = 0\%$), so the effect size is combined with a fixed effect model (FE). Meta-analysis results prove statistically significant differences between groups (MD = -0.49, 95% CI [-0.65, -0.33], $P < 0.00001$) in treating insufficient appetite due to epigastric pain in Figure 5.

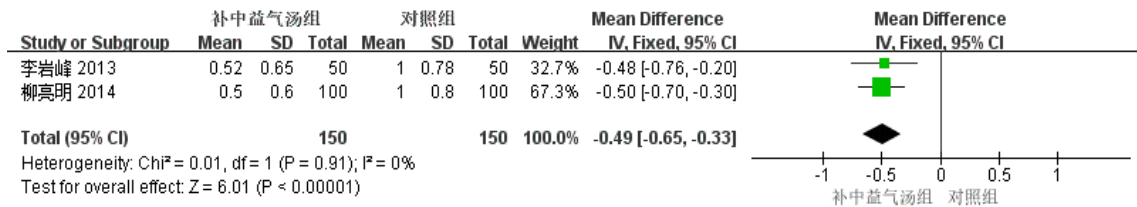


Figure 5. Meta-Analysis of Symptom Score of Insufficient Appetite

Nausea and Vomiting Three literature [10, 19-20] report the symptom score of nausea and vomiting in treating epigastric pain with BYD. There is statistical heterogeneity among the experimental results ($P = 0.04$, $I^2 = 69\%$), so the random effects model (RE) is used to combine the effect sizes. Meta-analysis results show a statistically significant difference in treating nausea and vomiting caused by epigastric pain (MD = -0.34, 95% CI [-0.48, -0.19], $P < 0.00001$) as seen in Figure 6.

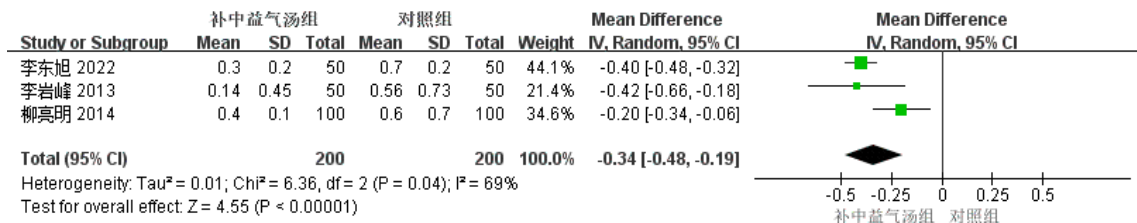


Figure 6. Meta-Analysis of Symptom Score of Nausea and Vomiting

Abdominal distension Five literature [10, 19-20, 32-33] report the symptom score of abdominal distension in treating epigastric pain with BYD. There is statistical heterogeneity among the experimental results ($P < 0.00001$, $I^2 = 86\%$), so the random effects model (RE) is used to combine the effect sizes. Meta-analysis results show statistically significant differences between groups in the treatment of abdominal distension due to epigastric pain (MD = -0.38, 95% CI [-0.55, -0.20], $P < 0.0001$) as seen in Figure 7.

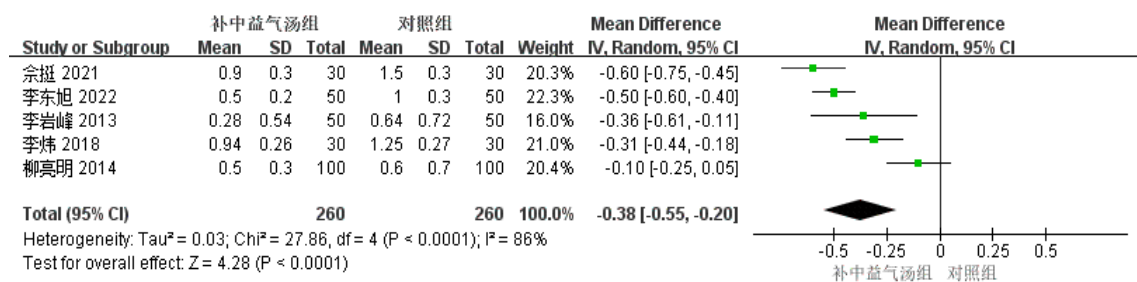


Figure 7. Meta-Analysis of Symptom Score of Abdominal Distension

Fullness Two literature [32-33] report the symptom score of fullness in treating epigastric pain with BYD. There is no statistical heterogeneity among the experimental results ($P = 0.80$, $I^2 = 0\%$), so the effect size is combined with the fixed effect model (FE). Meta-analysis results show statistically significant differences between groups in the treatment of fullness due to epigastric pain (MD = -0.51, 95% CI [-0.59, -0.43], $P < 0.00001$) as seen in Figure 8.

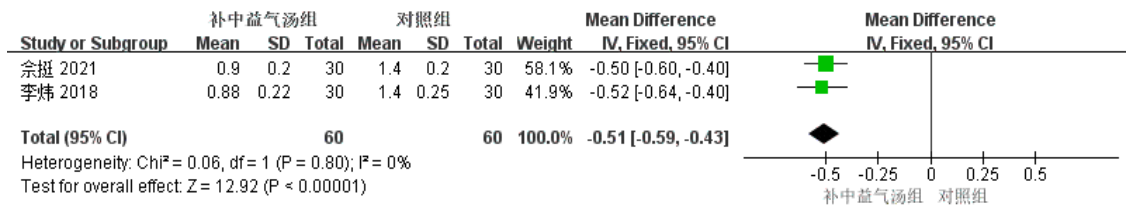


Figure 8. Meta-Analysis of Symptom Score of Fullness

Anorexia Two literature [32-33] report the symptom score of anorexia in treating epigastric pain with BYD. There is no statistical heterogeneity among the experimental results ($P = 0.85$, $I^2 = 0\%$), so a fixed effect model (FE) is used to combine the effect sizes. Meta-analysis results show statistically significant differences between groups (MD = -0.59, 95% CI [-0.70, -0.48], $P < 0.00001$) in the treatment of anorexia due to epigastric pain as seen in Figure 9.

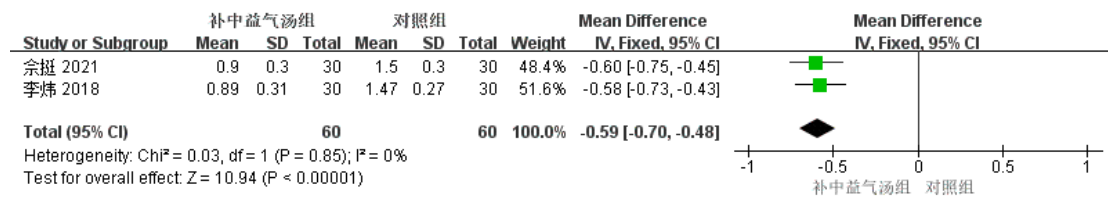


Figure 9. Meta-Analysis of Symptom Score of Anorexia

2.3.3. Life Quality

Two literature [23-24] report the life quality of patients with epigastric pain treated by BYD. There is no statistical heterogeneity among experimental results ($P = 0.58$, $I^2 = 0\%$), so the effect size is combined with a fixed effect model (FE). Meta-analysis results show statistically significant differences between groups in terms of life quality (MD = 7.45, 95% CI [3.91, 10.99], $P < 0.0001$) as seen in Figure 10.

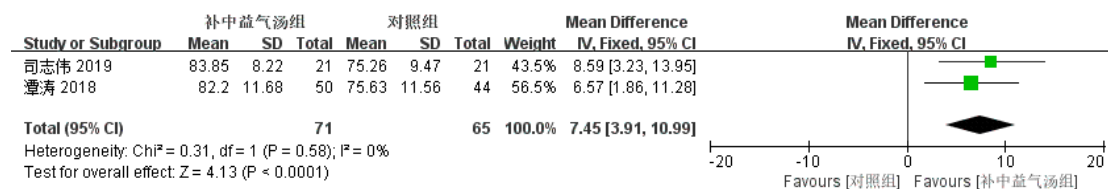


Figure 10. Meta-Analysis of Life Quality

2.3.4. Adverse Reaction Incidence

Four literature [17, 25-26, 39] report the adverse reaction incidence of BYD in treating epigastric pain. There is no statistical heterogeneity among the experimental results ($P = 0.41$, $I^2 = 0\%$), so the effect sizes are combined with a fixed effect model (FE). Meta-analysis results show statistically significant differences between groups (OR = 0.27, 95% CI [0.13, 0.53], $P = 0.0002$) in the adverse reaction incidence of BYD in the treatment of epigastric pain as seen in Figure 11.

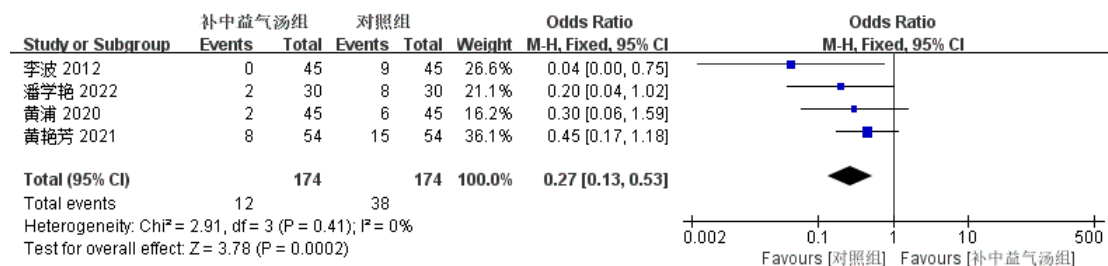


Figure 11. Meta-Analysis of Adverse Reaction Incidence

3. Discussion

Epigastric pain belongs to the spleen system disease of internal medicine of traditional Chinese medicine which has unique advantages. National Administration of Traditional Chinese Medicine and the Chinese Association of Traditional Chinese Medicine even classify refractory *Helicobacter pylori* (Hp)-related gastric disease as a dominant disease of traditional Chinese medicine [40]. BYD is known as one of the eight famous prescriptions of traditional Chinese medicine, which is the representative prescription of the spleen and stomach theory proposed by Li Dongyuan [41]. Astragalus in BYD can yiqi, enhance yang and consolidate physical health, which is deemed as the medicine for the thrones. Compatible with ginseng, roasted licorice, and *Atractylodes macrocephala* to yiqi and the spleen is the medicine for the ministers. Angelica nourishes blood and camp, which cooperates with ginseng and astragalus to yiqi. Tangerine peel regulates qi and the stomach, so that all medicines as adjuvant medicines are nourishing but not stagnant. A small amount of cohosh and *Bupleurum*, being mutually assistive, consolidate the yang and lift the depression. Roasted licorice reconciles all medicines to make medicines, which are used to buzhong and yiqi, uplift yang and cut depression.

According to meta-analysis results, BYD can improve the clinical effective rate of treating epigastric pain (OR = 4.14, 95% CI [3.22, 5.33], $P < 0.00001$), reduce symptoms of belching (MD = -0.82, 95% CI [-1.15, -0.49], $P < 0.00001$), insufficient appetite (MD = -0.49, 95% CI [-0.65, -0.33], $P < 0.00001$), abdominal distension (MD = -0.38, 95% CI [-0.55, -0.20], $P < 0.0001$), nausea and vomiting (MD = -0.34, 95% CI [-0.48, -0.19], $P < 0.00001$), anorexia (MD = -0.59, 95% CI [-0.70, -0.48], $P < 0.00001$) and other TCM syndromes caused by epigastric pain. Meanwhile, BYD can reduce the adverse reaction incidence in the clinical treatment of epigastric pain (OR = 0.27, 95% CI [0.13, 0.53], $P = 0.0002$). Traditional Chinese medicine believes that “the spleen and stomach are the innate foundation and the source of qi and blood biochemistry. Qi deficiency in the spleen and stomach will lead to the imbalance of the stomach's ability to receive decomposed water and grain, thus forming accumulation and stagnation as well as blocking the qi and blood of the viscera, meridians and collaterals, so as to result in epigastric pain. However, BYD is to yiqi and invigorate the spleen. Besides, the spleen and qi can be transported, so that the function of the epigastric cavity can be normal. According to studies, BYD increases the number of CD_3^+ and CD_4^+ positive cells, decreases the number of CD_8^+ positive cells, increases the ratio of CD_4^+/CD_8^+ , and increases the thymus index and spleen index in rats with chronic atrophic gastritis, so as to regulate immune function and promote gastric mucosal repair^[42]. Including 7 studies for meta-analysis, Li Juan et al. found that BYD has an outstanding curative effect in treating epigastric pain caused by reflux esophagitis^[43], which can mitigate patients' clinical symptoms and reduce the adverse reaction incidence. The results are similar to those in this study, which further corroborates the effectiveness and safety of BYD in treating epigastric pain.

The limitations of this study are as follows. (1) Most included studies are small-sample RCT studies with a small sample size and a certain selection bias. (2) Most studies do not use the visual analog scale (VAS) of epigastric pain as an outcome index, so there may be a lack of clinical evaluation of relieving specific epigastric pain. (3) Most studies fail to describe the random grouping, assignment hiding and blinding settings in detail, which may have some random bias and measurement bias.

In conclusion, BYD has a certain curative effect on epigastric pain, which can treat chronic gastritis, peptic ulcer (PU), functional dyspepsia (FD) and other epigastric diseases. However, due to the low quality of original literature, it also has limitations. Future related studies should use unified outcome index measurement standards, emphasize the rigor of study design and implementation as well as heed the clinical safety of BYD, so as to provide more reliable clinical evidence for its use.

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