A meta analysis of TCM syndrome differentiation and treatment combined with biofeedback in the treatment of functional constipation

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Abstract: Objective: To systematically evaluate the efficacy of TCM syndrome differentiation and treatment combined with biofeedback in the treatment of functional constipation. Methods: All the clinical randomized controlled trials (RCTs) of TCM syndrome differentiation and treatment combined with biofeedback in the treatment of functional constipation, which were published in September 2022, were retrieved by computer from CNKI, VIP, Wanfang, The Cochrane Library, Pubmed and Embase and other databases. Use RevMan5.3 software for meta analysis. Results: Totally 937 patients were included in 16 clinical randomized controlled trials. Meta analysis showed that traditional Chinese medicine based on syndrome differentiation and treatment combined with biofeedback treatment for functional constipation had more advantages than conventional biofeedback treatment in terms of effective rate (RR=1.21, 95% CI (1.13, 1.30), Z=5.61, P<0.0001) and improvement of constipation symptom score (SMD=-0.31, 95% CI (-0.53, -0.10), Z=2.82, P=0.005), and the negative rate was higher in balloon ejection test (RR=1.26, 95% CI (1.05, 1.50), Z=2.48, P=0.01), It plays a role in reducing anal systolic pressure (MD=15.56, 95% CI (8.59, 22.53), Z=4.38, P<0.0001), but it has no statistical significance in reducing anal resting pressure (MD=-1.25, 95% CI (-15.75, 13.25), Z=0.17, P=0.87), It also played a very good role in reducing anxiety score (MD=-5.04, 95% CI (-7.16, -2.92), Z=4.66, P<0.00001) and depression score (MD=-5.85, 95% CI (-7.93, -3.77), Z=5.52, P<0.00001), and had a greater advantage in reducing follow-up recurrence rate (RR=0.39, 95% CI (0.25, 0.60), Z=4.27, P<0.0001). In terms of adverse reactions, there was no significant difference between the treatment group and the observation group (P=1.00). Conclusion: TCM syndrome differentiation and treatment combined with biofeedback has more advantages than conventional biofeedback treatment.

Keywords: TCM syndrome differentiation; biofeedback; functional constipation; meta analysis

1. Introduction

Constipation refers to a group of symptoms related to excretion disorders. Functional constipation (FC) refers to constipation caused by non-organic causes [1]. According to the characteristics of colonic dynamics, it can be divided into three types: slow transit constipation, outlet obstructive constipation and mixed constipation [2], and outlet obstructive constipation can be divided into multiple subtypes. The main types are basin floor relaxation type and basin floor relaxation type [3]. In recent years, epidemiology has shown that the prevalence of functional constipation in adults is between 2.5% and 79% [4], and gradually increases with age, with the characteristics of more women than men [5]. The pathogenesis of FC is mainly related to colorectal motility disorder, pelvic floor dysfunction, socio-psychological factors and gastrointestinal regulatory dysfunction [6]. Long-term constipation can cause anorectal diseases, gastrointestinal nerve dysfunction, induce and aggravate various cardio-cerebrovascular diseases, and even induce colorectal cancer, hepatic encephalopathy, etc. [7]. At present, the treatment methods of FC mainly include: TCM treatment based on syndrome differentiation, acupuncture and moxibustion, acupoint application, acupoint catgut embedding and other TCM characteristic therapies; And western medicine therapies such as western medicine,

micro-ecological preparations, biofeedback and surgery [8].

Biofeedback training can adjust physiological response by establishing internal and external condition feedback channels between the brain and target organs, so that patients can perceive and correct physiological activities deviating from the normal range, thus achieving the purpose of treating diseases [9]. Traditional Chinese medicine plays a significant role in the treatment of functional constipation. According to the symptoms and individual differences of traditional Chinese medicine, it is necessary to carry out the syndrome differentiation treatment of traditional Chinese medicine, supplement its deficiency, and adjust yin and yang to achieve the effect of treating both symptoms and symptoms. The combination of TCM syndrome differentiation and biofeedback training in the treatment of functional constipation is a combination of traditional medicine and modern medicine. In recent years, relevant clinical studies have been emerging, but the accuracy of the efficacy needs to be verified. In order to further observe the effect of the combined treatment of the two, this study adopts a systematic evaluation method to conduct a meta-analysis of the previous clinical research literature, providing further evidence for clinical work, and laying a foundation for the further convergence and development of traditional medicine and modern medicine.

2. Data and Methods

2.1. Inclusion criteria

(a) Research type: randomized controlled trial (RCT) published at home and abroad. (b) Subjects: Patients with FC diagnosis, regardless of gender, age and occupation. (c) Intervention measures: the experimental group was treated with TCM syndrome differentiation combined with biofeedback treatment, while the control group was treated with conventional biofeedback treatment. (d) Outcome measures: effective rate of treatment, difficulty of defecation, balloon force test, anal resting pressure, anal systolic pressure, anxiety score, depression score, and follow-up recurrence rate.

2.2. Exclusion criteria

(a) The trial design does not meet the requirements, such as clinical review, experience summary, case control and other studies. (b) The subjects were non-FC patients. (c) The intervention measures were inconsistent. The experimental group did not use TCM syndrome differentiation and treatment combined with biofeedback, while the control group did not use biofeedback research. (d) Repeated research published at home and abroad as well as documents that cannot obtain complete information.

2.3. Retrieval strategy

All the clinical randomized controlled trials (RCTs) of TCM syndrome differentiation and treatment combined with biofeedback treatment for functional constipation, which were published in September 2022, were retrieved by computer from CNKI, VIP, Wanfang, The Cochrane Library, Pubmed and Embase and other databases. The retrieval strategy is to combine subject words with free words, taking Wanfang database as an example: subject: ("traditional Chinese medicine" OR "traditional Chinese medicine" OR "traditional Chinese medicine") AND ("biofeedback") AND ("constipation" OR "defecation disorder" NOT "incontinence").

2.4. Document quality evaluation and data extraction

Two evaluators independently screen the retrieved documents and exclude the documents that do not meet the inclusion criteria. In case of different opinions, the third party will participate in the discussion to reach the final judgment. The quality of the included literature was evaluated according to Cochrane bias risk assessment criteria, including: (1) the generation of random sequence; (2) Distribution hidden; (3) Participant blind method; (4) Outcome blind method; (5) Completeness of outcome data; (6) Selective report; (7) Other biases. The extracted data include the name of the first author, year of publication, sample size, average age of patients, intervention measures, treatment cycle, and outcome indicators.

2.5. Statistical analysis

RevMan5.3 software was used for meta-analysis of the data required in this study, and the relative

risk (RR) and 95% confidence interval (CI) were used to analyze the binary variables; Continuous variables were analyzed using weighted mean difference (WMD) or standardized mean difference (SMD) combined with 95% confidence interval (CI). I2 statistics is used to test the heterogeneity. When I2>50%, the heterogeneity is large. The random effect model is used, and sensitivity analysis and subgroup analysis are conducted to find out the source of heterogeneity. When I2 is less than 50%, the heterogeneity is small, and the fixed effect model is used, and the difference is statistically significant with P<0.05. If the data cannot be consolidated for other reasons, descriptive analysis shall be used [10]. The funnel chart is used to display the publication bias. The horizontal axis is the effect value, and the vertical axis is the sample size. If there is no publication bias, the inverted funnel chart is symmetrical from left to right, and vice versa.

3. Results

3.1. Basic characteristics of search results and included research

Table 1: Basic features of the included literature

Included studies	Cases(n)		Age(Year)		Trial group intervention measures	Course of treatment/day	outcome indicator
	Trial group	Control group	Trial group	Control group			
Zheng Fengping 2009[11]	30	30	54.57±10.58	55.83±9.54	Jiawei Zengye decoction combined with biofeedback	28	(1)(2)
Sun Guangjun 2010[12]	30	30	48.26±10.18	47.32±9.83	Yichang tongmi decoction combined with biofeedback	30	(1)(8)
Wang Aihua 2012[13]	20	22	68	66	Jiawei Zengye decoction combined with biofeedback	28	(1)
Lin Yinglan 2014[14]	20	20	37.65±12.35	37.3±13.17	Jieyu Tongyou decoction combined with biofeedback	20	(1)(2)(6)(7)(8)
Qiao sha 2015[15]	30	30	42.43±12.24	43.27±12.03	TCM syndrome differentiation combined with biofeedback	30	(1)(2)(3)(4)(5)
Bao Xinkun 2016[16]	30	30	57.48±10.26	57.48±10.26	Guiqi huoxuetong secret recipe combined with biofeedback	28	(1)(2)(8)
Ke Xiao 2017[17]	32	30	51.37±11.29	49.97±10.91	TCM syndrome differentiation combined with biofeedback	28	(1)
Xiao Qiuping 2017[18]	40	40	53.00±1.13	53.07±1.93	Changrun formula combined with biofeedback	28	(1)
Zheng Chunju 2017[19]	25	25	52.08±7.91	52.32±8.97	Jiangu Yiqing decoction combined with biofeedback	28	(2)
Dong Qingjun 2018[20]	36	36	52.86±14.77	50.81±14.75	Heying tongluo method combined with biofeedback	28	(1)(2)(8)
Feng fuming 2019[21]	30	30	53.9±5.8	53.9±5.8	Jichuan decoction combined with biofeedback therapy	28	(1)(6)
Hou Jiangtao 2019[22]	20	21	48.10±13.53	45.53±14.12	Buqi Huoxue recipe combined with biofeedback	20	(1)(2)(4)(5)(6)(7)
Wang Chao 2019[23]	30	30	47.6±6.2	46.2±6.5	Chaihu Shugan powder combined with biofeedback	20	(1)(4)(6)
Wang Donghong 2019[24]	40	40	46.98±9.65	47.36±8.56	Self made traditional Chinese medicine prescription combined with biofeedback	30	(1)(2)
Zheng Yong 2019[25]	25	25	51.17±5.49	50.29±5.31	Jiangu Yiqing decoction combined with biofeedback	20	(2)
Jiang Liyong 2020[26]	30	30	51.59±11.12	50.47±14.00	Modified Huangqi decoction combined with biofeedback	20	(1)(2)(3)(4)(5)

Note: The intervention measures in the control group are "biofeedback". (1) Effective rate of treatment (2) Degree of difficulty in defecation (3) Balloon forcing test (4) Anal resting pressure (5) Anal systolic pressure (6) Anxiety (SAS) score (7) Depression (SDS) score (8) Follow-up recurrence rate.

1940 articles were found in the database, and were finally included in 16 clinical randomized controlled trials [11-26] after censoring, reading the abstract of the title and reading the full text. The literature screening process is shown in Figure 1, with a total of 937 patients. The characteristics of the included. (Table 1)
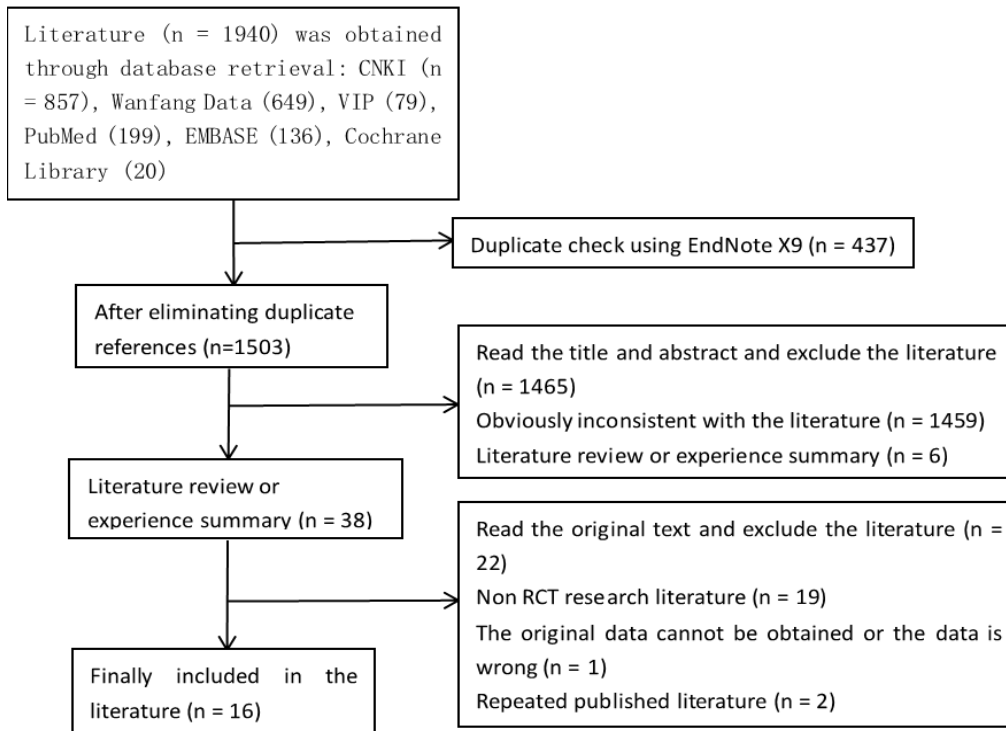
Figure 1: Screening process of literature

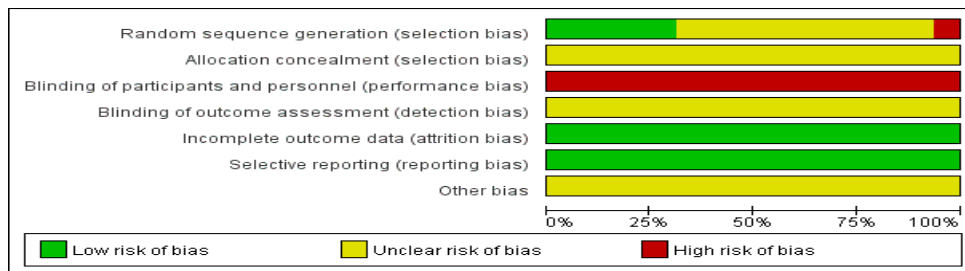### 3.2. Included in the quality evaluation of research methodology
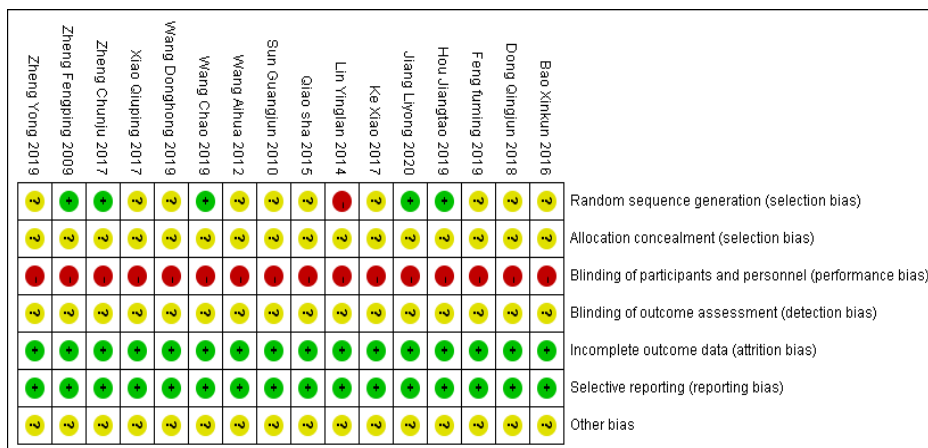

Figure 2: Bias risk map

Figure 3: Included study bias risk assessment diagram

The 16 included studies all referred to random allocation, of which 5 studies [11, 19, 22, 23, 26] used the "random number table method", and 2 studies [14, 18] used the "pseudorandom method" (numbered by stratification, segmentation and admission order). All studies did not mention the allocation concealment and blinding method, and two studies [17, 18] mentioned the cases of shedding and

explained the reasons for shedding (patients taking other drugs in the midway, loss of follow-up). The outcome data of all included studies are complete, but it is not clear whether there are selective outcome reports and other biased sources. See Fig. 2 and Fig. 3.

3.3. Meta-analysis results

3.3.1. Meta-analysis of treatment effectiveness

There are 14 papers [11-18, 20-24, 26] with the effective rate as the index, and the heterogeneity test indicates that the heterogeneity between the studies is small (P=0.04, I² = 43%), using the fixed effect model, the meta-analysis results showed that the experimental group was superior to the control group, with a statistically significant difference (RR=1.21, 95% CI (1.13, 1.30), Z=5.61, P<0.0001). It shows that the effective rate of TCM syndrome differentiation and treatment combined with biofeedback treatment for FC is higher than that of conventional biofeedback treatment, as shown in Figure 4.
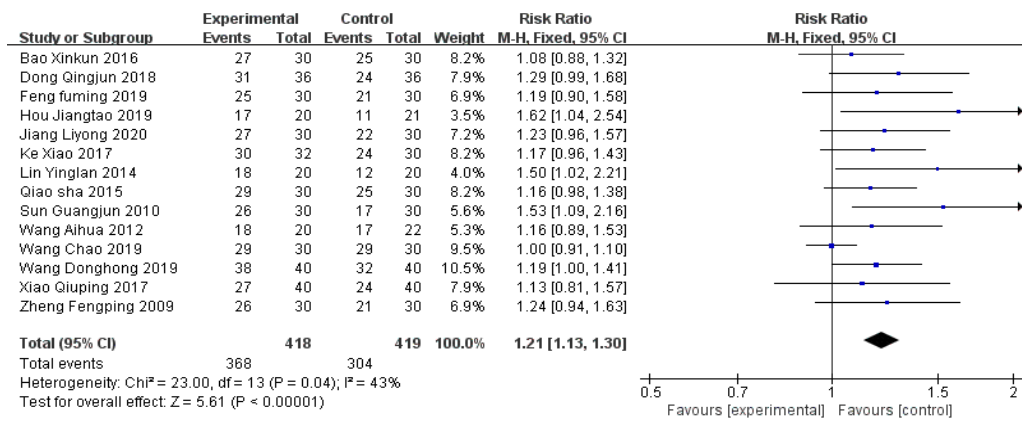

Figure 4: Forest map of efficient meta-analysis

3.3.2. Meta-analysis of dysdefecation symptom score

Nine papers [11, 14, 16, 19, 20, 22, 24-26] reported the score of dysdefecation symptoms, with high heterogeneity among the studies (P<0.00001, I² = 81%), after sensitivity analysis, 7 studies were included [11, 14, 19, 20, 22, 25, 26]. According to the average age of patients, 7 studies were divided into two subgroups, and the heterogeneity of the 41-60 years group was small (P=0.34, I² = 12%), the meta-analysis results showed that SMD=-0.31, 95% CI (-0.53, -0.10), Z=2.82, P=0.005, and the difference was statistically significant. See Figure 5 for details.
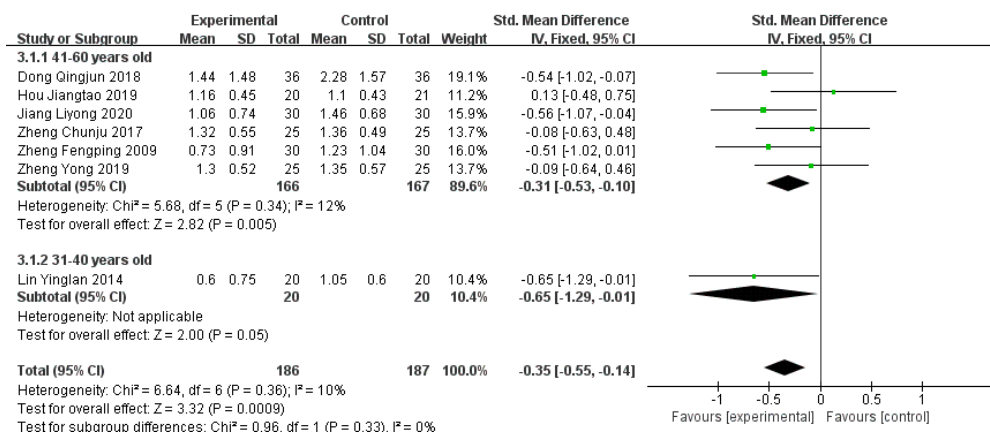

Figure 5: Forest map of meta-analysis of defecation difficulty symptom score

The two excluded studies [16, 24] are the sources of the increase in overall heterogeneity. After the meta-analysis of the original data of the two studies, the results showed that the difference was statistically significant (P<0.00001), suggesting that the combination of TCM syndrome differentiation and treatment with biofeedback may be better than biofeedback in reducing the score of dysdefecation symptoms.

3.3.3. Meta-analysis of the negative rate of balloon extrusion test

There are 2 articles [15, 26] with the negative rate of balloon extrusion test as the outcome index, and there is no heterogeneity among the studies (P=0.88, I² = 0%), so the fixed effect model was used. The results of meta-analysis showed that the negative rate of balloon ejection test in the treatment group was higher than that in the control group, and the difference was statistically significant (RR=1.26, 95% CI (1.05, 1.50), Z=2.48, P=0.01), as shown in Figure 6.

Figure 6: Meta-analysis forest map of balloon forced test negative rate

3.3.4. Meta-analysis of anal resting pressure

There are 4 articles [15, 22, 23, 26] taking anal canal resting pressure as the outcome index, because of the high heterogeneity among the studies (P<0.00001, I² = 93%), according to the average age of patients, the subgroup analysis was carried out, and the results showed that the heterogeneity of the 41-50-year-old group was large (P<0.00001, I² = 95%), the MD value was -1.25, 95% CI (-15.75, 13.25), Z=0.17, P=0.87, and the difference was not statistically significant, indicating that the combination of TCM syndrome differentiation and treatment with biofeedback has obvious advantages over biofeedback in reducing anal canal resting pressure, as shown in Figure 7.
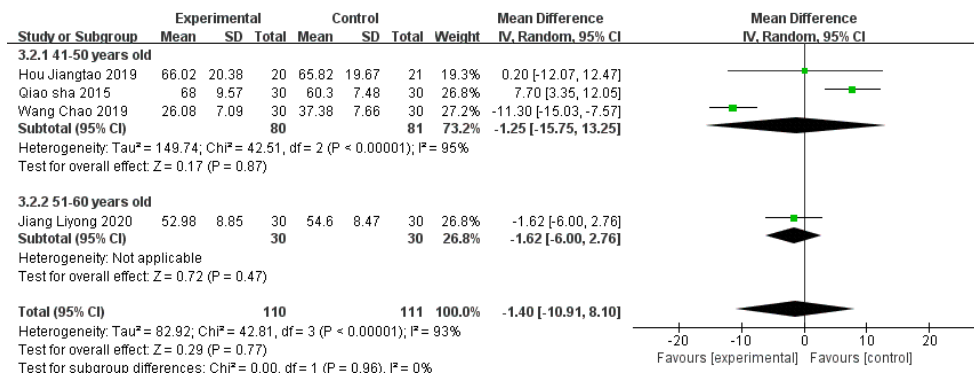

Figure 7: Meta-analysis of anal resting pressure

3.3.5. Meta-analysis of anal canal systolic pressure

There are 3 articles [15, 22, 26] taking anal canal systolic pressure as an index, and the heterogeneity between the studies is low (P=0.23, I² = 33%), so using the fixed effect model, the meta-analysis results showed that the difference was statistically significant (MD=15.56, 95% CI (8.59, 22.53), Z=4.38, P<0.0001). It shows that the effect of TCM syndrome differentiation and treatment combined with biofeedback is better than that of conventional biofeedback treatment in reducing anal canal systolic pressure, as shown in Figure 8.
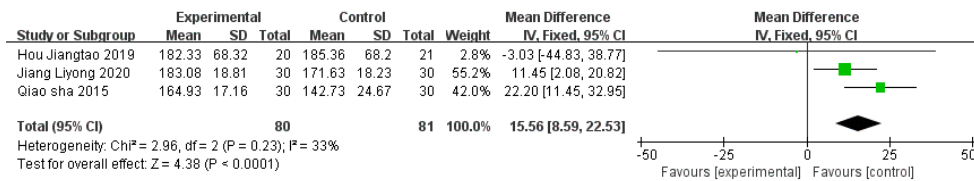

Figure 8: Meta-analysis of anal systolic blood pressure

3.3.6. Meta-analysis of anxiety (SAS) score

There are 4 articles [14, 21, 22, 23] with anxiety (SAS) score as the index, and the heterogeneity between the studies is low (P<P=0.48, I² = 0%), using the fixed effect model for meta-analysis, the MD value is -5.04, 95% CI (-7.16, -2.92), Z=4.66, P<0.00001, the difference is statistically significant, indicating that the combination of TCM syndrome differentiation and treatment with biofeedback has more

advantages than conventional biofeedback in reducing anxiety scores, see Figure 9.
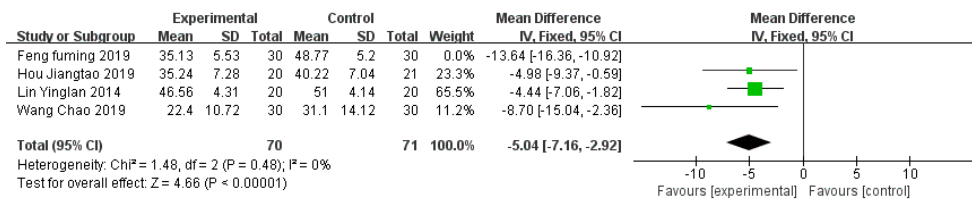

Figure 9: Meta analysis forest diagram of anxiety (SAS) score

3.3.7. Meta-analysis of depression (SDS) score

There are 2 articles [14, 22] with depression (SDS) score as the index, and there is no heterogeneity among the studies (P=0.85, I ² = 0%), so using the fixed effect model, the meta-analysis results showed that the difference was statistically significant (MD=-5.85, 95% CI (-7.93, -3.77), Z=5.52, P<0.00001). It shows that the combination of TCM syndrome differentiation and treatment with biofeedback is more effective than conventional biofeedback in reducing depression scores, as shown in Figure 10.
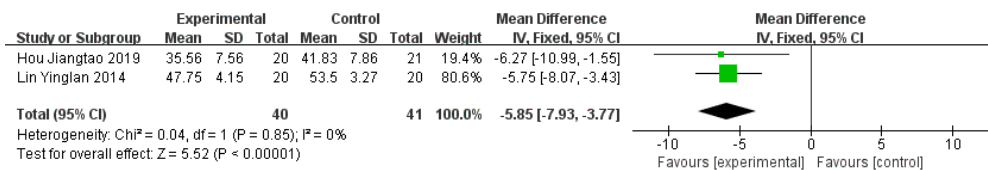

Figure 10: Meta analysis forest map of depression (SDS) score

3.3.8. Meta-analysis of follow-up recurrence rate

There are 4 articles [12, 14, 16, 20] with the follow-up recurrence rate as the index, and there is no heterogeneity among the studies (P=0.89, I ² = 0%), so the fixed effect model was used. The results of meta-analysis showed that the recurrence rate of follow-up in the experimental group was lower than that in the control group, and the difference was statistically significant (RR=0.39, 95% CI (0.25, 0.60), Z=4.27, P<0.0001, see Figure 11).
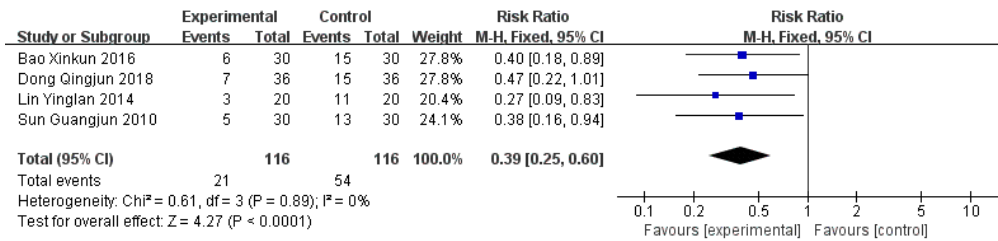

Figure 11: Meta analysis forest chart of follow-up recurrence rate

3.4. Adverse reactions

Three papers [17,18,24] recorded adverse reactions during the trial, including mild abdominal pain, diarrhea and other symptoms. The results of meta-analysis showed that there was no statistically significant difference between the treatment group and the observation group (P=1.00).

3.5. Bias analysis

The publication bias of the treatment effectiveness rate was evaluated. The two sides of the inverted funnel were basically symmetrical, suggesting that there might be no publication bias, as shown in Figure 12.
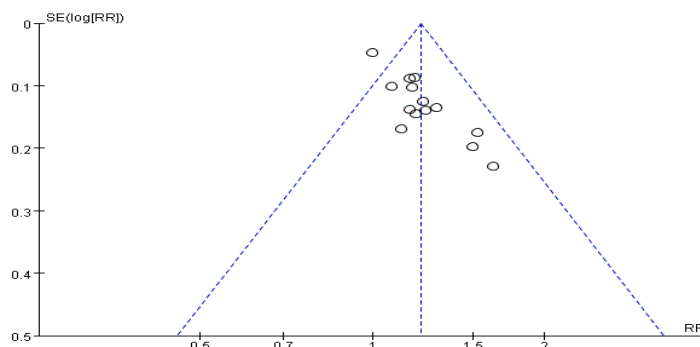
Figure 12: Funnel plot of publication bias of included literature

4. Discussion

Constipation was first seen in the Yellow Emperor's Classic of Internal Medicine [27], which called constipation "unfavourable" and "difficult to defecate" [28]. Doctors of the past dynasties believed that the main location of constipation was in the large intestine, which was closely related to lung, spleen, stomach, liver and kidney. Yan Yonghe divided constipation into five types for the first time in "Ji Sheng Fang" [29], namely, wind constipation, qi constipation, wet constipation, cold constipation and heat constipation, and summarized the treatment principles of "dryness moistens", "dampness smoothes", "constipation unblocks", and "cold warms". When treating constipation, traditional Chinese medicine fully takes into account the characteristics of adjusting measures to the time, place and people. It is not a generalization. Its theories and methods of syndrome differentiation and treatment have been continuously accumulated and verified in the long river of history, with significant curative effect and high safety [30].

Biofeedback therapy is the use of instruments and equipment to display some normal or abnormal physiological phenomena in the human body in the form of images and sounds. With the guidance of therapists, patients can correctly grasp physiological events and properly control pelvic floor muscles to achieve the purpose of treatment [31]. In 1987, Bleijenberg et al. [32] first carried out the study of biofeedback therapy for the treatment of basin achalasia constipation. After more than 30 years of experiments and continuous improvement, the short-term effect of this therapy for functional constipation is higher than that of most other therapies [5], but the long-term effect is controversial, and significantly lower than the short-term effect [33]. The TCM syndrome differentiation treatment of functional constipation has the characteristics of lasting efficacy and low long-term recurrence rate [34]. Whether it can play the role of learning from each other's strengths and complementing each other's weaknesses in combination with biofeedback therapy is the purpose of this study.

Based on the comprehensive analysis of previous relevant literature, the meta-analysis results of various outcome indicators show that the treatment of functional constipation with TCM syndrome differentiation and biofeedback has more advantages in efficiency and improvement of constipation symptom score than the conventional biofeedback treatment. The negative rate is higher in the balloon forcing test, which plays a role in reducing anal systolic pressure, but has no statistical significance in reducing anal resting pressure. TCM syndrome differentiation and treatment combined with biofeedback has also played a good role in reducing anxiety score and depression score while treating functional constipation, and its follow-up recurrence rate is also significantly lower than biofeedback treatment. The combination of the two gives full play to their respective advantages, plays a role in complementing the short board of low long-term efficacy of biofeedback, and reflects the characteristics of long-term efficacy, wide range of action, significant efficacy, and high safety of traditional Chinese medicine.

Due to the low quality of clinical trial methods and reports of TCM syndrome differentiation and treatment combined with biofeedback in the treatment of functional constipation, the evidence provided by the conclusion of Guben study for clinical practice still has deficiencies. This study still has the following limitations: (1) The quality of the included research methodology is generally low, and the number of included documents is small. All studies have not implemented blind method, and have not explained whether to use allocation concealment. The shortcomings of the above research methods are likely to affect the accuracy of the results, leading to bias in the results. (2) Interventions are different. In the aspect of TCM syndrome differentiation and treatment, the experimental group adopted Chinese

herbal decoction orally, but some of them were added or subtracted by classics, some were empirical formulas, and some of the decoction did not indicate the source, resulting in the diversification of intervention measures. Therefore, the conclusion was the overall effect of TCM syndrome differentiation and treatment, and the conclusion of specific prescriptions could not be drawn. (3) The outcome indicators included in the study are not uniform, and some subjective outcome indicators are used, such as stool symptom score, anxiety score and depression score, so the results may be affected by human factors. (4) In terms of adverse reactions, only a few studies mention and record the treatment methods, which may have a certain impact on the research evidence.

To sum up, in the overall efficacy of treating functional constipation, TCM syndrome differentiation and treatment combined with biofeedback has more advantages than conventional biofeedback treatment, but there is no statistical difference between the two in reducing the anal canal resting pressure. In the future, more comprehensive and rigorous high-quality research should be carried out to provide strong evidence support for clinical practice.

Acknowledgement

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