Systematic evaluation and meta-analysis of Chinese medicine in the treatment of centrally mediated abdominal pain syndrome

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Abstract

Background: This study aimed to evaluate the clinical efficacy of Chinese medicine for the treatment of centrally mediated abdominal pain syndrome (CAPS) using a meta-analysis system.

Methods: Six databases, including China National Knowledge Infrastructure, Vendor Information Pages, Chinese Biomedical Database, Wanfang, PubMed, and Embase were searched for randomized controlled trials related to the treatment of CAPS with traditional Chinese medicine. The bias risk assessment tool and RevMan5.3 software (Copenhagen, The Nordic Cochrane Centre, The Cochrane Collaboration) were used to conduct quality assessment and meta-analysis, and the GRADE grading system was used to evaluate the quality of evidence for outcome indicators.

Results: Fifteen articles were included in this study. Meta-analysis results showed that the treatment group was more effective in terms of the total effective rate (relative risk = 1.27; 95% confidence interval [CI], 1.19–1.34; P < .00001), Behavioral Rating Scale-6 pain score (mean difference [MD] = −0.79; 95% CI, −0.99 to −0.59; P < .00001), and traditional Chinese medicine (TCM) symptom score (MD = −1.74; 95% CI, −2.23 to −1.26; P < .00001) than the control group (P < .05). However, in terms of numerical rating scale pain score (MD = 0.79; 95% CI, −1.70 to 0.12; P = 0.09), the efficacy was comparable between the two groups, and the difference was not statistically significant (P > .05). In terms of verbal rating scale pain, depression, and anxiety scores, the data could not be combined due to inconsistent scoring criteria, and only descriptive analysis was performed. The results showed that the treatment group was slightly better than the control group in terms of relieving verbal rating scale pain and improving anxiety and depression (P < .05).

Conclusion: Chinese medicine can effectively improve the pain and TCM clinical symptoms of patients with CAPS and relieve patients’ anxiety and depression with fewer adverse effects, which has certain therapeutic advantages. However, because of the low methodological quality assessment of the included literature, the quality of GRADE evidence for outcome indicators is of mostly low and very low quality, the strength of recommendation is weak, and the credibility of the conclusion is average. More rigorous, larger sample, and higher-quality clinical trials are required to provide a higher level of evidence-based medicine for the development of TCM treatment standards for CAPS.

Abbreviations: BRS-6 = Behavioral Rating Scale-6, CAPS = centrally mediated abdominal pain syndrome, CI = confidence interval, MD = mean difference, NRS = numerical rating scale, RR = relative risk, TCM = traditional Chinese medicine, VAS = visual analog scale, VRS = verbal rating scale.

Keywords: centrally mediated abdominal pain syndrome, Chinese medicine, efficacy, meta-analysis, systematic evaluation

1. Introduction

Centrally mediated abdominal pain syndrome (CAPS), also known as functional abdominal pain syndrome (FAP), is a functional disorder with persistent or recurrent abdominal pain symptoms, with a duration of >6 months, and with or without varying degrees of anxiety, depression, restlessness, and other psychological disorders. The epidemiology of CAPS is poorly studied, and according to previous studies, the prevalence of CAPS in North America is approximately 0.5% to 1.7%, whereas in China, CAPS is only reported in adolescents and officers and soldiers, with a higher prevalence in adolescents...
than in officers and soldiers. The pathogenesis of CAPS is not fully understood, and studies have suggested that may be related to increased visceral sensitivity, abnormal brain–gut interactions, intestinal flora disturbances, and psychosomatic factors. Recent studies have found that the central nervous system plays an important role in the pathogenesis of CAPS, possibly related to the limbic system and pain downregulation mechanisms, and the renaming of FAPs to CAPS in the 2016 book Rome IV: Functional Gastrointestinal Disorders redefines the role of the central nervous system in the pathogenesis of CAPS. Since the pathogenesis of CAPS is unclear, it is considered a clinically difficult disease. Western medicine treatment methods for CAPS are limited, and modern medical treatment is mainly based on antianxiety drugs, antidepressants, painkillers, and psychotherapy. However, its efficacy is poor, with certain forces the role of the central nervous system in the pathogenesis of CAPS. Since the pathogenesis of CAPS is unclear, it is considered a clinically difficult disease. Western medicine treatment methods for CAPS are limited, and modern medical treatment is mainly based on antianxiety drugs, antidepressants, painkillers, and psychotherapy. However, its efficacy is poor, with certain adverse reactions, taking up medical resources and increasing patients’ economic burden. With the prolongation of the disease, many patients cannot correctly perceive the condition. As the disease progresses, many patients feel stigmatized by their own or others’ inability to properly recognize their condition. As a treatment system with a long history of inheritance in China, traditional Chinese medicine (TCM) has made certain achievements in the study of this disease, both in terms of internal and external Chinese medicine. To further evaluate the clinical efficacy and safety of TCM in the treatment of CAPS, this study used a meta-analysis system to evaluate relevant studies on TCM in the treatment of CAPS, thereby providing a high-level evidence-based basis for the clinical treatment of CAPS.

2. Materials and Methods

2.1. Literature search

Regarding the computer search of relevant databases in Chinese and English, Chinese databases included China National Knowledge Infrastructure, Vendor Information Pages, Chinese Biomedical Database, and Wanfang Data. Foreign language databases included PubMed and Embase, and the search time was from the time each database was established to May 1, 2021. The search terms were as follows: centrally mediated abdominal pain syndrome, CAPS, functional abdominal pain syndrome, FAPs, traditional Chinese medicine, Chinese medicine, acupuncture, Chinese medicine enema, acupoint application, ear beans, acupoint massage, acupoint embedding, acupoint cupping, massage, and Chinese medicine package.

2.2. Inclusion criteria

Study type: Studies that were clinical randomized controlled trials (RCTs) written in Chinese or English; Subjects: Studies with subjects meeting the diagnostic criteria for CAPS in Rome IV: Functional Gastrointestinal Diseases, and aged 18 years, regardless of sex; Interventions: Studies with the control group treated with conventional Western medicine and the treatment group receiving TCM intervention with or without a control group; Outcome indicators: Studies with the following outcome indicators: total effective rate and pain, TCM symptom, depression, and anxiety scores.

2.3. Exclusion criteria

The exclusion criteria were as follows: non-RCT studies, such as reviews and conferences, studies that are repeatedly published and have similar content and poor quality literature, animal or in vitro experiments, and studies in children with functional abdominal pain syndrome.

2.4. Literature quality evaluation

The methodological quality of the included studies was evaluated using the risk of bias assessment tool provided by the Cochrane Handbook as the evaluation criteria, including the randomized method, allocation concealment, blinded method, incomplete outcome, selective outcome, and other biases. The results of each literature evaluation were expressed as a low risk of bias, high risk of bias, and bias not judged according to the content. The evaluation was completed through a crossover between the 2 investigators.

2.5. Statistical methods

Meta-analysis of the data was performed using the RevMan5.3 software (Copenhagen, The Nordic Cochrane Centre, The Cochrane Collaboration). Relative risk was used for dichotomous variables and mean difference (MD) for continuous variables, both with 95% confidence intervals (CIs). Descriptive analysis was performed if the data could not be combined. The heterogeneity of the included literature was tested, and when $P$ was >0.1 and $I^2$ was <50%, there was no heterogeneity among the literature, which was analyzed by a fixed-effects model. When $P$ was <0.1 and $I^2$ was >50%, there was heterogeneity among the literature, which was analyzed by subgroup or sensitivity analysis to determine the source of heterogeneity. If the source of heterogeneity could not be identified, it was analyzed using a random-effects model. Funnel plots were used to analyze the presence of publication bias when >10 papers were included as outcome indicators.

2.6. GRADE evidence quality evaluation

The quality of evidence for the outcome indicators was evaluated using the GRADE grading system, which includes 5 aspects: risk bias, inconsistency, indirectness, imprecision, and publication bias. The quality of evidence for the outcome indicators was classified into 4 grades according to the evaluation results: high, medium, low, and very low quality, in that order.

2.7. Ethical review instructions

Although the specimens taken are human (or animal), this is a secondary analysis of the article and does not involve ethical issues.

3. Results

3.1. Literature search results

Relevant databases were searched, and 1620 literatures were retrieved. After excluding duplicate literature; reading the title, abstract, and full text of the literature; and performing other relevant screenings, 15 studies were finally included, all of which were written in Chinese. The literature screening process is illustrated in Figure 1.

3.2. Basic characteristics of the included literature

A total of 1224 patients were included in the 15 included studies, including 617 and 607 in the treatment and control groups, respectively. The interventions in the control group in the included literature were all Western medicine treatments, whereas 10 of the treatment groups studies had TCM + Western medicine interventions and 5 studies had TCM intervention alone. There were no statistical differences between the 2 groups in terms of age, sex, and mean duration of illness. The basic characteristics of the included studies are presented in Table 1.

3.3. Results of the quality evaluation of the included literature

One of the 15 included studies used the random number table method and was therefore evaluated as having a low risk of bias; the remaining 14 studies mentioned the word random but
did not describe the randomization method and were therefore evaluated as undetermined risk. None of the studies mentioned whether the random assignment method was concealed and whether they were blinded to the implementer, subject, or outcome assessor. Thus, they were all evaluated as unable to judge the risk. One study had shedding cases and was therefore evaluated as having a high risk of bias; the remaining 14 studies were evaluated as having a low risk of bias. All studies reported outcomes consistent with the original protocol and were therefore evaluated as having a low risk of bias. Other biases were evaluated by the baseline information of patients, and the 15 included studies showed comparable baseline information in both groups; therefore, it was evaluated as having a low risk of bias (for details, see Fig. 2 and Table 2).

3.4. Meta-analysis results

3.4.1. Total effective rate. A total of 13 studies reported the total effective rate, including 532 and 522 cases in the treatment and control groups, respectively. The heterogeneity test suggested little heterogeneity among the studies ($I^2 = 33\%$); therefore, a fixed-effects model was used for analysis. The results of the meta-analysis showed that the treatment group was superior to the control group in improving the overall effective rate, and the difference was statistically significant ($relative\ risk = 1.27; 95\%\ CI, 1.19–1.34; P < .00001$) (for details, see Fig. 3).

3.4.2. Pain score. Nine studies mentioned the pain scores of 297 and 288 patients in the treatment and control groups, respectively. Four studies were based on numerical rating scale (NRS) scores, 4 studies were based on Behavioral Rating Scale (BRS)-6 scores, and 1 study was based on visual analog scale (VAS) scores. The data could not be combined because of inconsistent scoring criteria; therefore, meta-analysis was performed separately.

3.4.2.1. Numerical rating scale pain score. Four studies evaluated pain scores using NRS scores and the heterogeneity test suggested heterogeneity among the studies ($I^2 = 91\%$). Therefore, a random-effects model was used for analysis. The results of the meta-analysis showed comparable efficacy in relieving pain symptoms between the 2 groups, with no statistical difference ($MD = −0.79; 95\%\ CI, −1.70 to 0.12; P = .09$). When sensitivity analysis was performed after excluding the study by Chen, the heterogeneity disappeared ($I^2 = 0\%$), indicating that this study may be the source of heterogeneity. Exclusion from this study followed by analysis using a fixed-effects model had the following results: $MD = −1.10; 95\%\ CI, −1.44 to −0.76; P < .00001$, with the treatment group outperforming the control group (see Fig. 4 for further details).

3.4.2.2. Behavioral Rating Scale-6 pain score. Four studies evaluated pain scores using the BRS-6 score as a criterion, and a test of heterogeneity suggested heterogeneity among studies ($I^2 = 79\%$). Therefore, a random-effects model was used to analyze them. After meta-analysis, the BRS-6 pain scores of the 2 groups were statistically different and the treatment group outperformed the control group ($MD = −0.79$;
95% CI, −0.99 to 0.59; \( P < .00001 \). Excluding individual studies on a piecewise basis followed by sensitivity analysis, heterogeneity was greatly reduced when excluding the study by Xu and Chen \( ^{[21]} \) (\( P = .32, I^2 = 13\% \)), suggesting that this study may be a source of heterogeneity. The exclusion of this study was then analyzed using a fixed-effects model (MD = 0.70; 95% CI, −0.81 to −0.60; \( P < .00001 \), with the treatment group outperforming the control group (see Fig. 5 for further details).

### 3.4.3. Traditional Chinese medicine symptom score

Six \( ^{[14,15,17–19,23]} \) studies reported TCM symptom scores, with 200 and 199 patients in the treatment and control groups, respectively. The heterogeneity test suggested heterogeneity among studies (\( P = .05, I^2 = 54\% \)); therefore, a random-effects model was used for analysis. After meta-analysis, the treatment group was superior to the control group in terms of improving TCM symptoms (MD = 1.74; 95% CI, −2.23 to −1.26; \( P < .00001 \)). When a sensitivity analysis was performed after excluding the study by Zhang Cong (2013), \( ^{[23]} \) the heterogeneity disappeared (\( P = .68, I^2 = 0\% \)), suggesting that this study may be a source of heterogeneity. Exclusion from this study followed

#### Table 1

| Literature                | Cases (T/C) | Gender (M/F) | Age | Interventions | Outcome indicators |
|---------------------------|-------------|--------------|-----|---------------|-------------------|
| Li \( ^{[11]} \)          | 40/40       | 17/23        | 20/20 | Acupoint cupping + C | Total effective rate |
| Chen \( ^{[12]} \)        | 30/30       | 14/16        | 13/17 | Acupoint catgut embedding + C | Total effective rate |
| Zhao and Jiang \( ^{[13]} \) | 30/30      | 12/18        | 14/16 | Tiaogan Ningxin soup + C | Pain score |
| Wang and Cao \( ^{[14]} \) | 40/40       | Not mentioned | 41.20 ± 8.40 | Chaihu shigan powder + C | Pain score |
| Tang \( ^{[15]} \)        | 48/48       | 24/24        | 26/22 | Banxueixin soup + C | Pain score |
| Dong et al \( ^{[16]} \)  | 55/55       | 21/34        | 25/30 | Ciwujia + C | Pain score |
| Tang \( ^{[17]} \)        | 41/40       | 26/15        | 25/15 | Wumei pills | Pain score |
| Wang and Wu \( ^{[18]} \) | 30/30       | 10/20        | 16/14 | Shiyouqiangcao soupgan-maidazao decoction | Pain score |
| Zhao and Zhang \( ^{[19]} \) | 53/51      | 19/35        | 32/38 | Preservation enema, Oral medicine TCM packet | Pain score |
| Zhang and Cao \( ^{[20]} \) | 55/55       | 34/21        | 35/20 | Oral medicine, acupuncture | Pain score |
| He et al \( ^{[21]} \)    | 48/42       | 23/25        | 20/22 | Tongxieyaofang soup + C | Pain score |
| Meng et al \( ^{[22]} \)  | 41/40       | 20/21        | 18/22 | Acupoint sticking | Pain score |

Note: ①: total effective rate; ②: pain score; ③: TCM symptom score; ④: depression score; ⑤: anxiety score.

C = control group, T = treatment group, TCM = traditional Chinese medicine.
by analysis using a fixed-effects model had the following results: MD = −2.00; 95% CI, −2.35 to 1.66; \( P < .00001 \), with the treatment group outperforming the control group (see Fig. 6 for further details).

### 3.4.4. Depression and anxiety scores

Three\[12,14,18\] studies reported depression scores, and 4\[12,14,16,18\] studies reported anxiety scores. The data could not be combined because of their different scoring criteria; therefore, descriptive analysis was performed. The raw data showed that the treatment group was slightly better than the control group in relieving depression and anxiety symptoms (see Tables 3 and 4 for further details).

### 3.5. Publication bias

A funnel plot of the outcome indicators (total effective rate) for the included literature of >10 articles was produced and analyzed for publication bias, and the funnel plot is shown in Fig. 7.
The results showed that the distribution of scattered points in the plot was not completely symmetrical, indicating the possibility of publication bias in the included studies.

3.6. GRADE system evaluation results

Relevant outcome indicators were evaluated according to the GRADE grading system, including the total effective rate and NRS pain, BRS-6 pain, and TCM symptom scores. The results showed that the total effective rate, BRS-6 pain score, and TCM symptom score were evaluated as low-quality evidence, whereas the NRS pain score was evaluated as very low-quality evidence. The quality level of evidence was not high; thus, clinical references should be integrated according to physicians’ clinical experience when drawing on them (see Table 5 for further details).

4. Discussion

CAPS is a medical condition characterized by abdominal pain as its main clinical manifestation. According to its symptoms, TCM can classify the disease into abdominal pain. There are many records of “abdominal pain” in ancient Chinese literature, and its name was first used in Huangdi Neijing. For example, “Suwen·QiJiaobiandalun” stated the following: “When the earth is too much in the year, the rain and dampness are prevalent, and the kidney water is affected by the evil, the people suffer from abdominal pain.” Moreover, “Lingshu·Wuxia” also stated the following: “If the evil is in the spleen and stomach, then the disease is muscle pain. If the yang energy is insufficient and the yin energy is surplus, then the cold in the intestines will cause abdominal pain.” The etiology of abdominal pain is summarized in the book “Bingyinmaizheng Futong” as external and internal injuries. The external causes of abdominal pain include wind, cold, summer dampness, dryness, and fire. The internal causes of injury include cold condensation, heat accumulation, gas stagnation, blood stasis, food accumulation, phlegm accumulation, worm accumulation, and qi and blood deficiencies.

In general, the overall etiology of abdominal pain can be summarized into the following 6 points: cold, heat, deficiency, reality, qi, and blood. The above pathological factors often interact with each other. The disease is located in the abdomen, and the internal organs involved are the spleen, stomach, liver, gall bladder, appendix, and large and small intestines. The basic pathological mechanism is that the above pathological factors are blocked, the internal organs are not conducive to qi, the meridians do not run smoothly, and the internal organs do not pass pain. Abdominal pain disease to “pass” is the principle of treatment, based on the identification of Chinese medicine as the basis for treatment.

According to Medical Biography: Abdominal Pain, “unobstruction is not painful.” However, the methods of unobstruction are different. When regulating qi with blood and regulating blood with qi, if it goes down, it should go up. If it is blocked in the middle, then it goes sideways. Weak people help it, and cold people warm it. In summary, it involves replenishment.
of deficiency, clearing of heat, warming in cold, slowing in qi, and dissipating in blood stasis.\[^26\] Regarding the treatment of CAPS, Western medicine is limited, and its side effects are significant and at risk of recurrence. In addition to the common internal use of Chinese medicine, there are many external treatments, such as Chinese medicine enema, acupuncture point compression, auricular pressure bean, acupressure, acupuncture point massage, acupuncture point buried wire, acupuncture point cupping, and Chinese medicine sealing package. In recent years, the treatment of CAPS has achieved good results and fewer adverse reactions, involves simple and convenient operations, and has a greater therapeutic advantage. The clinical use of Chinese medicine has increased; therefore, an increasing number of clinics are using Chinese medicine to treat CAPS.\[^27\]

A total of 15 papers on TCM for CAPS were included in this study, systematic evaluation and meta-analysis of the literature were performed, and the quality of GRADE evidence was evaluated for relevant outcome indicators. The results showed that TCM could effectively improve the overall efficiency of patients with CPAS, reduce the BRS-6 pain score, and alleviate the clinical symptoms of TCM, but there was no significant difference between TCM and Western medicine treatment in reducing the NRS pain score. In the analysis of verbal rating scale pain, depression, and anxiety scores, the data could not be combined due to inconsistent scoring criteria. Thus, only descriptive analysis could be performed, and the analysis results showed that the treatment group was better than the control group in relieving verbal rating scale pain and improving anxiety and depression. However, the quality of evidence was insufficiently high to form evidence for meta-analysis, and more clinical studies are required to verify its effectiveness. The heterogeneity test of the included literature in the outcome indicators whose data could be combined showed no heterogeneity among the literature for total effective rate and showed heterogeneity among the included literature for NRS pain, BRS-6 pain, and TCM symptom scores. For sensitivity analysis after excluding the literature one by one, when excluding the studies of Chen,\[^12\] Xu,\[^21\] and Zhang and Cao,\[^23\] the heterogeneity was changed, suggesting that the heterogeneity might originate from the above studies. After careful review of the literature, it was concluded that the

![Figure 7. Total efficiency funnel chart.](image)

| Table 5  | GRADE evidence evaluation of outcome indicators for centrally mediated abdominal pain syndrome treated with Chinese medicine |
|----------|----------------------------------------------------------------------------------------------------------------------|
| **Outcome indicators** | **Literature number** | **Research type** | **Risk of bias** | **Inconsistencies** | **Indirect** | **Inaccuracy** | **Other factors** | **Events/ Sample size (T)** | **Events/ Sample size (C)** | **Effect of the amount (95%CL)** | **Quality classification** | **Importance** |
| Total effective rate | 13 | RCT | Serious\(^1\) | No serious | No serious | No serious | Strongly suspected\(^a\) | 488/532 (91.7%) | 379/522 (72.6%) | RR = 1.2 (1.19, 1.34) | Low | Low importance |
| NRS pain score | 4 | RCT | Serious\(^1\) | Serious\(^2\) | No serious | Serious\(^3\) | No | 130 | 130 | MD = 0.79 (−1.7, 0.12) | Very low | Very low importance |
| BRS-6 pain score | 4 | RCT | Serious\(^1\) | Serious\(^2\) | No serious | No serious | No | 177 | 168 | MD = −0.79 (−0.99, −0.59) | Low | Low importance |
| TCM symptom score | 6 | RCT | Serious\(^1\) | Serious\(^2\) | No serious | No serious | No | 255 | 254 | MD = −1.74 (−2.23, −1.26) | Low | Low importance |

Note: 1 = blinded and allocation concealment missing; 2 = heterogeneity > 50%; 3 = insufficient sample size and wide confidence interval; 4 = presence of publication bias.

BRS-6 = Behavioral Rating Scale-6, C = control group, MD = mean difference, NRS = numerical rating scale, RCT = randomized controlled trial, RR = relative risk, T = treatment group, TCM = traditional Chinese medicine.
heterogeneity of Chen study might be related to single inter-
ventions in the treatment group and low-quality evaluation of 
the literature. Xu heterogeneity might be related to insuf-
ficient sample size, and Zhang heterogeneity was considered 
to be caused by several types of Western drug treatments in 
the control group. According to the GRADE quality evalu-
ation, the total effective rate, BRS-6 pain score, and TCM 
symptom score were evaluated as low-quality evidence, and 
the NRS pain score was evaluated as very low-quality evi-
dence. Therefore, they should be considered comprehensively 
according to physicians’ experience when used as a clinical 
reference.

In conclusion, TCM can effectively improve the pain and 
TCM clinical symptoms of patients with CAPS, relieve patients’ 
anxiety and depression, and improve patients’ cognition and 
treatment compliance to a certain extent with few adverse 
effects, which have certain therapeutic advantages. However,
because the methodological quality of the included literature 
was low and the quality of the GRADE evidence for outcome 
indicators was mostly of low or very low quality, the strength 
of recommendation was weak. The reasons for this are related 
to the small sample size of the included literature studies, insuf-
cient study period, rigorous randomization methods, lack of 
blinding and allocation concealment, and excessive heterogene-
ity. Therefore, in future studies, more rigorous, larger sample, 
and higher-quality clinical trials are required to determine the 
effectiveness of TCM treatment for CAPS to provide a higher 
level of evidence-based medicine for the development of TCM 
treatment standards for CAPS.

Acknowledgments

Thanks to Mr. Xu and all the authors for their assistance in 
writing this manuscript.

Author contributions

XRF, QL, and SX conducted the study design, participated in 
data interpretation, and prepared the manuscript. JH, SYH, 
and MLW participated in coordination and acquisition of data. 
XRF, QL, YPJ, and SX participated in data analysis and acquisi-
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