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Zhao, YF, Wang, ZW, Kuang, SK, Zhang, SX.

Corresponding author:
Shuxin Zhang

zhangshuxin_shxx@126.com

Author Affiliation:
Dongzhimen Hospital, Beijing
University of Chinese Medicine.

ADMINISTRATIVE INFORMATION

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Conflicts of interest - None of the authors have any personal, financial, commercial, or academic conflicts of interest.

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Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 4 July 2025 and was last updated on 4 July 2025.

INTRODUCTION

Review question / Objective This study aims to evaluate the efficacy and safety of acupoint embedding for Functional constipation by meta-analysis.

Condition being studied In recent years, acupuncture, as a component of traditional Chinese medicine (TCM), has demonstrated distinct advantages in the treatment of functional gastrointestinal disorders, attributable to its holistic regulatory effects. Acupoint catgut embedding (ACE), a significant branch of acupuncture, has gained widespread application in the treatment of FC. This method is favoured for its simple operation, lasting efficacy and high patient compliance.

METHODS

Participant or population Patients clearly diagnosed with FC (met Rome (II, III, IV) diagnostic criteria for FC [4]), irrespective of gender or age.

Intervention The experimental group received ACE as a primary intervention, either alone or combined with other treatments.

Comparator The control group was provided with oral Western medicine, standard acupuncture, oral TCM or a placebo.

Study designs to be included The inclusion of RCTs and controlled clinical trials (CCTs) from both domestic and international sources.

Eligibility criteria Inclusion Criteria
To be included in the meta-analysis, studies had to meet the following criteria:
(1) Publication date: RCTs or CCTs on ACE for FC published from inception to November 2024.
(2) Participants: patients clearly diagnosed with FC (met Rome (II, III, IV) diagnostic criteria for FC [4]), irrespective of gender or age.
(3) Interventions: The experimental group received ACE as a primary intervention, either alone or combined with other treatments.

(4) Control measures: The control group was provided with oral Western medicine, standard acupuncture, oral TCM or a placebo.

(5) Outcome measures: At a minimum, the total response rate must be reported (see Table 1). Additional efficacy evaluation indicators may include constipation severity scores using a constipation assessment scale (CAS), defecation frequency, stool consistency scores and quality of life scores using the Patient Assessment of Constipation Quality of Life (PAC-QOL) questionnaire.

Exclusion Criteria

This study excluded literature that met any of the following criteria:

- (1) Constipation caused by organic lesions (e.g. intestinal obstruction, inflammatory bowel disease and tumours).
- (2) Patients with concurrent psychiatric disorders (e.g. severe anxiety and depression).
- (3) Pregnant or lactating women.
- (4) Acupoint catgut embedding was used only as a partial or temporary treatment, or was also used in the control group.
- (5) Studies with incomplete data or studies from which valid data could not be extracted.

Information sources China National Knowledge Infrastructure (CNKI), WanFang Data, VIP, PubMed, Web of Science and Cochrane Library databases.

Main outcome(s) A total of 23 studies involving 1,794 patients were included. The meta-analysis showed that the total effective rate of ACE was significantly higher compared with oral Western medicine (odds ratio [OR]=2.71, 95% confidence interval [CI]: 1.91–3.83, $P<0.00001$), acupuncture (OR=2.90, 95% CI: 1.68–5.01, $P=0.0001$) and placebo groups ($P<0.05$). There was no significant difference between ACE and oral Chinese medicine (OR=2.34, 95% CI: 0.79–6.89, $P=0.12$). The incidence of adverse reactions in the ACE group was low, presenting mainly as mild local discomfort such as soreness, bruising and pain, which were self-limiting.

Quality assessment / Risk of bias analysis

Literature Quality Assessment:

The methodological quality of each literature study included in the current research was evaluated using the modified Jadad scale:

- Studies with a score of 1–3 points were categorised as having poor quality;
- Studies with a score of 4–7 points were classified as having high quality.

The assessment covered aspects such as randomisation, allocation concealment, blinding,

follow-up and dropout rates, ensuring the scientific rigour and reliability of the included literature.

Risk of bias analysis:

The possibility of publication bias was assessed using a funnel plot and Egger's linear regression analysis. Any identified bias was adjusted using the trim and fill method.

Strategy of data synthesis Data analysis was conducted using Review Manager (RevMan 5.4.1) and Stata BE 17 software for meta-analysis and plotting.

(1) Heterogeneity test: The Q test and I^2 statistic were used to assess the heterogeneity between studies:

- The fixed-effect model was used when there was acceptable homogeneity ($P\geq 0.1$ and $I^2<50\%$).

- Otherwise, the random-effect model was selected in case of heterogeneity ($P<0.1$ and $I^2\geq 50\%$). Meanwhile, sensitivity analysis was conducted by sequentially omitting each study to identify the source of heterogeneity.

(2) Categorical data: The odds ratio (OR) was used to assess efficacy alongside the calculation of 95% confidence intervals (95% CI). A $P\leq 0.05$ was considered statistically significant.

Subgroup analysis Not applicable.

Sensitivity analysis Not applicable.

Country(ies) involved China.

Keywords Constipation; functional constipation; slow transit constipation; defecation disorder constipation; functional defecation disorder; catgut embedding at acupoints; randomised; randomised controlled.

Contributions of each author

Author 1 - Yufei Zhao.

Email: zhaoyufei8809@21cn.com

Author 2 - Zhiwei Wang.

Email: wang_zhiwzw@21cn.com

Author 3 - Shangke Kuang.

Email: kuangshang_ke2022@21cn.com

Author 4 - Shuxin Zhang.

Email: zhangshuxin_shxx@126.com