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**Efficacy and Safety of Jianpi Yiqi method in the
Treatment of low anterior resection syndrome:
A systematic review and meta-analysis**

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ADMINISTRATIVE INFORMATION

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Review Stage at time of this submission - Preliminary searches.

Conflicts of interest - None declared.

INPLASY registration number: INPLASY202570023

Amendments - This protocol was registered with the International
Platform of Registered Systematic Review and Meta-Analysis Protocols
(INPLASY) on 6 July 2025 and was last updated on 6 July 2025.

INTRODUCTION

Review question / Objective Population:
Rectal cancer patients aged ≥ 18 years who
undergo anterior rectal resection may have
postoperative conditions such as diarrhea, fecal
incontinence, increased frequency of defecation,
or abnormal defecation
Intervention: It is treated with the method of
strengthening the spleen and benefiting qi
Comparison: Conventional Western medical
treatment or other nursing measures
Outcome: The main outcome measures were the
recovery rate, the effective rate and the LARS
score. The secondary outcome measures were
Xu's defecation score, adverse reactions, anal
resting pressure, maximum anal systolic pressure,
and maximum tolerated volume
Study design: Randomized controlled study.

Condition being studied Efficacy and Safety of
Jianpi Yiqi method in the Treatment of low anterior
resection syndrome.

METHODS

Search strategy We conducted a search using
Health Sciences Descriptors (MeSH) and Medical
Subject Headings (MeSH terms), with the following
keywords: English search terms "Rectal cancer,
Diarrhea, Fecal incontinence, low anterior resection
syndrome, anterior excision syndrome, low anterior
resection, postoperative defecation disorder of
rectal cancer, post-surgery bowel dysfunction,
LARS, traditional Chinese medicine, herbal
medicine, acupuncture, traditional Chinese
medicine non-drug therapy"; The search language
was limited to Chinese and English. Boolean
operators "AND" and "OR" were used to combine
the keywords. The search covered MeSH entries
and keyword variations. The databases included
CNKI, SinoMed, Wanfang Data Knowledge
Service Platform, VIP, The Cochrane Library,
EmBase, and PubMed, for relevant literature up
to July 26, 2024.

The PubMed search query is as follows: (((Rectal
cancer[Title/Abstract]) OR (Rectal cancer[MeSH
Terms])) AND (((Diarrhea[Title/Abstract]) OR

((Diarrhea[MeSH Terms])) OR (Fecal incontinence[Title/Abstract])) OR (Fecal incontinence[MeSH Terms])) OR (((((((low anterior resection syndrome[MeSH Terms]) OR (anterior excision syndrome[MeSH Terms])) OR (post-surgery bowel dysfunction[MeSH Terms])) OR (anterior excision syndrome[Title/Abstract])) OR (low anterior resection syndrome[Title/Abstract])) OR (low anterior resection[Title/Abstract])) OR (post-surgery bowel dysfunction[Title/Abstract])) OR (LARS[Title/Abstract])) AND (((((((traditional chinese medicine[Title/Abstract]) OR (traditional chinese medicine[MeSH Terms])) OR (herbal medicine[Title/Abstract])) OR (herbal medicine[MeSH Terms])) OR (Acupuncture[Title/Abstract])) OR (Acupuncture[MeSH Terms])) OR (traditional Chinese medicine non-drug therapy[Title/Abstract])) OR (traditional Chinese medicine non-drug therapy[MeSH Terms])).

Participant or population Rectal cancer patients aged ≥ 18 years who undergo anterior rectal resection may have postoperative conditions such as diarrhea, fecal incontinence, increased frequency of defecation, or abnormal defecation.

Intervention It is treated with the method of strengthening the spleen and benefiting qi.

Comparator Conventional Western medical treatment or other nursing measures.

Study designs to be included Randomized controlled study.

Eligibility criteria Inclusion criteria: ① Research subjects: Rectal cancer patients aged ≥ 18 years who underwent anterior rectal resection and had postoperative conditions such as diarrhea, fecal incontinence, increased frequency of defecation, or abnormal defecation. ② The intervention measures include the treatment of strengthening the spleen and benefiting qi. ③ Control measures: Conventional Western medical treatment or other nursing measures. ④ The main outcome measures were the recovery rate, the effective rate and the LARS score; The secondary outcome measures were Xu's defecation score, adverse reactions, anal resting pressure, maximum anal systolic pressure, and maximum tolerated volume. ⑤ Randomized controlled study.

Exclusion criteria: ① Animal experiments ② Possibly duplicate data from the same research center ③ Systematic reviews, meta-analyses, literature reviews, case reports, conference abstracts, and only registration protocols ④

Incomplete or missing analysis data, and no data could be obtained even when contacting the original authors. ⑤ No detailed data.

Information sources Two groups of researchers independently conducted The search. By searching the literatures in each database (CNKI, China Biomedical Literature Analysis System, Wanfang Data Knowledge Service Platform, VIP Network, The Cochrane Library, EmBase and PubMed database) up to July 26, 2024, The English search terms are "Rectal cancer, Diarrhea, Fecal incontinence, low anterior resection syndrome, anterior excision syndrome". low anterior resection, postoperative defecation disorder of rectal cancer, post-surgery bowel dysfunction, LARS traditional chinese medicine, herbal medicine, acupuncture, traditional Chinese medicine non-drug therapy; The Chinese search terms are "rectal cancer, diarrhea, fecal incontinence, increased frequency of defecation, abnormal defecation, LARS, low anterior resection syndrome, anterior resection syndrome, traditional Chinese medicine, traditional Chinese medicine, strengthening the spleen, benefiting qi, strengthening the spleen and benefiting qi, random".

Main outcome(s) The results of this study show that the treatment method of strengthening the spleen and invigorating the qi for LARS can increase the effective rate, reduce the LARS score, improve the score of the Xuzhong method scale, the resting pressure of the anus, the maximum contraction pressure of the anus, and the maximum tolerance capacity, and has better safety.

Quality assessment / Risk of bias analysis

Quality evaluation

Using the GRADE (Grades of Recommendation, Assessment, Development, and Evaluation) evidence classification standard [12] for quality Evaluation of evidence, study into the each end, We judged whether to downgrade based on five aspects: risk of bias, inconsistency, inappropriateness, imprecision and publication bias. Eventually, the certainty of evidence was classified into four grades: "high", "medium", "low" and "very low".

Risk of bias assessment

The Cochrane risk of Bias tool was used to evaluate the quality of randomized controlled trials. The evaluation was conducted from seven aspects: random sequence generation, allocation concealment, blinding of the implementry and research subjects, blind evaluation of the research results, integrity of the result data, selective

reporting, and other biases. Each of these can be rated as "low risk of bias", "high risk of bias", or "uncertain risk of bias".

Strategy of data synthesis Two researchers independently conducted the literature search, screening, data extraction, cross-checking, and quality assessment. In case of any disagreement, a third person would intervene in the discussion and make a decision. The two researchers exported the retrieved literature from various databases to the Endnote X9 literature management software and deleted duplicate ones.

The extracted data included the study type, publication year, first author, patient gender, age, number, intervention measures, outcome indicators, follow-up time, adverse events, generation of random sequence, random concealment, blinding of study subjects, blinding of researchers, blinding of outcome measurers/evaluators, completeness of data, methods for addressing data missingness, and selective reporting of outcomes.

Subgroup analysis According to the intervention measures of the experimental group, it was divided into two subgroups: the first subgroup received the intervention measures of the "Bu Zhong Yi Qi Decoction", while the second subgroup received the intervention measures of the "Self-Designed Qi-Boosting and Spleen-Strengthening Decoction".

Sensitivity analysis If the statistical heterogeneity among the various studies is high, in order to identify the source of the heterogeneity, each study should be excluded one by one for a sensitivity analysis.

Country(ies) involved China.

Other relevant information Liu Bo once received specialized training at the Center for Evidence-Based Medicine (CEBM) of Beijing University of Chinese Medicine. The authors of the papers, Liu Pu, Wang Tianchang, Xue Weicai, Wang Shuling, and Wu Chunxiao, all participated in the relevant training on evidence-based medicine.

Keywords Low anterior resection syndrome LARS; Method of strengthening the spleen and benefiting qi System review Meta-analysis.

Contributions of each author

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