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Modified chaihu shugan san combined with chemotherapy to treat breast cancer：A systematic review and meta-analysis

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Xie, ZM[1]; Shui, HL[2]; Yang, Z[3]; Wu, WY[4].

Corresponding author:
Zhenming xie

1766309244@qq.com

Author Affiliation:
The First Affiliated Hospital of Guizhou University of Chinese Medicine, Guizhou, China.

ADMINISTRATIVE INFORMATION

Support - Guizhou Traditional Chinese Medicine Tumor Inheritance and Science and Technology Innovation Talent Base(No. Deaf leader [2018] No. 3), Guizhou high-level innovative talent training plan (100 levels) (no. YankeheTalents [2016] no. 4032), TCM graduate school workstation (No. Teaching and research JYSZ-[2014]018).

Review Stage at time of this submission - Preliminary searches.

Conflicts of interest - None declared.

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Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 29 September 2023 and was last updated on 29 September 2023.

INTRODUCTION

Review question / Objective According to the PICOS acronym, the inclusion criteria were as follows: Participants(P): ①All eligible patients must be definitely diagnosed with breast cancer either through pathology or cytology②Approved by the hospital ethics committee, the patient understand and are informed, voluntarily participate in this study and sign the informed consent form③No restrictions by the stage of cancer, gender, age, race, and severity.Intervention(I):Randomized controlled trials of oral modified chaihu shugan san combined with chemotherapy for breast cancer will be eligible, while laboratory studies, qualitative studies, or observational study will be excluded in the research.There are no limitations on language and publication status.Comparison(C):On the basis of the control group, patients in the test group received modified chaihu shugan san preparations.Outcomes(O):Clinical efficacy and safety of modified chaihu shugan san. Study design(S):Randomized controlled clinical trials.

Condition being studied Breast cancer (BRCA) ranks the first among female malignancies. At present, there are about 1.7 million new cases of breast cancer in the world every year, more than 52% of the cases and 62% of the deaths of breast cancer patients occur in some countries of lower income and middle class respectively, posing a serious threat to women's health. BRCA is highly heterogeneous, and treatment measures have their own focuses. When BRCA is in the middle and advanced stages, chemotherapy is often adopted, which can not only reduce the size of breast tumor, but also play a role in inhibiting breast tumor metastasis and relieving symptoms, and has a significant therapeutic effect on patients with middle and advanced breast cancer. Due to BRCA

patients with their own individual differences, exist many chemotherapy drugs, cancer patients have vital qi weakness, combined with chemotherapy drugs can damage the body, the inevitable side effects of chemotherapy is difficult to avoid, will cause cancer, increased risk of infection in patients with increased tumor recurrence, the lower the quality of life, increased mortality, resulting in a series of complications, All kinds of inconvenient effects on patients. Therefore, it is necessary to take reasonable treatment measures. Traditional Chinese Medicine(TCM) has the advantages of multiple channels, multiple directions and multiple targets. It can achieve the purpose of treating diseases by adjusting the balance of the functions of yin, yang, qi, blood and viscera. Studies have shown that TCM combined with chemotherapy in the treatment of BRCA can reduce toxicity and increase clinical efficacy, supporting the positive anticancer, and the application of TCM in the field of tumor has been expanding in recent years.

TCM classifies breast cancer as "breast rock" or "breast stone carbuncle". TCM believes that the incidence of breast cancer is closely related to liver qi stagnation and liver and spleen injuries, and the treatment should emphasize the dredging of liver and regulating qi, promoting blood circulation and removing blood stasis and dispersing constipation. As a famous prescription of TCM, Chaihu shugan san(CHSGS) is good at dredging liver, regulating qi, promoting blood circulation and removing blood stasis. It has a wide range of clinical applications and has definite curative effect. Studies have shown that has the effect of phytoestrogens, which can effectively antagonize human estrogen, reduce the level of estrogen in the body, and achieve the effect of preventing and treating breast cancer. Pharmacologically, CHSGS can induce apoptosis of breast cancer MCF-7 cells by inhibiting the levels of Bcl-2 protein and VEGF factor, it can also increase and down-regulate the expression level of protein kinase C in human TH cells and the differentiation signal of TH cells, thus enhancing the immune system of the body and alleviating bone marrow suppression. The saponins in Chaihu, the main component of CHSGS, can be antitumor, antioxidation and regulate immune function; Chaihu polysaccharide can enhance the phagocytosis ability of macrophages and activate the immune function of the body, so as to improve the toxic and side reaction ability of the body against chemotherapy drugs, and then improve the prognosis. CHSGS has a great effect on soothing the liver, relieving depression and dispersing the organs, and the side effects are small, plays an important role in the treatment of breast cancer, which is common in women.

A systematic review and meta-analysis to evaluate the efficacy of CHSGS combined with chemotherapy in BRCA has not yet been conducted. Therefore, we assess the efficacy and safety of modified CHSGS combined with chemotherapy in the treatment of BRCA to provide clinicians and health policymakers with convincing evidence.

METHODS

Participant or population ①All eligible patients must be definitely diagnosed with breast cancer either through pathology or cytology②Approved by the hospital ethics committee, the patient understand and are informed, voluntarily participate in this study and sign the informed consent form③No restrictions by the stage of cancer, gender, age, race, and severity.

Intervention Oral modified chaihu shugan san combined with chemotherapy.

Comparator Chemotherapy alone.

Study designs to be included ①All eligible patients must be definitely diagnosed with breast cancer either through pathology or cytology②Approved by the hospital ethics committee, the patient understand and are informed, voluntarily participate in this study and sign the informed consent form③No restrictions by the stage of cancer, gender, age, race, and severity.

Eligibility criteria ①repetitive article②non-randomized controlled trials③The literature contains its own before and after cross-controlled experiments④incomplete test results⑤lack of sufficient data.

Information sources Literature search in both international (PubMed, Cochrane Library, EMBASE and Web of Science) and Chinese(CNKI,Wan-fang Database, CBM and VIP) databases will be systematically searched for eligible studies from 2000 to September 1, 2023, were independently conducted by two researchers.

Main outcome(s) The primary outcome included three efficacy measures: (I) short-term clinical efficacy ORR, short-term clinical efficacy according to the World Health Organization (WHO) criteria and Response Evaluation Criteria in Solid Tumors(RECIST), short-term tumor remission including complete remission (CR), partial

remission (PR), stable disease remission (SD), progressive disease remission (PD), ORR, disease control rate ORR was defined as the sum of CR and PR; (II) survival time (median survival time and 5-year survival rate) ,(III)adverse drug reactions, assessed by bone marrow suppression(leukopenia、hemoglobinia、thrombopenia), gastrointestinal reactions (nausea, vomiting, diarrhea).

Additional outcome(s) Secondary outcome included three efficacy measures: (i)quality of life, assessed by (social function、physiological function and emotional function) , (ii)symptom remission rate, (iii)KPS score.

Quality assessment / Risk of bias analysis The Cochrane collaboration's tool, an established and reliable tool for assessing the risk of bias, will be used in studies evaluate the risk of bias for each study by two independent reviewers. In this tool, the risk of bias of a trial is evaluated through 7 items, include random sequence generation (selection bias), allocation concealment (selection bias), blinding of participants and personnel (performance bias), blinding of outcome assessment (detection bias), incomplete outcome data(attrition bias), selective reporting (reporting bias), other bias.The assessment will be classified as "Low risk," "High risk," or"Unclear risk." Disagreements between the 2 reviewers will be resolved by discussion of all reviewers.

Strategy of data synthesis RevMan 5.3 software was used for statistical analysis. For dichotomous variables, the odds ratio(OR) will be applied to analyze. For continuous variables, a mean difference (MD) or a standard mean difference (SMD) will be used for analysis. The confidence intervals (CI) for both dichotomous andcontinuous variables will be set to 95%.Statistical hetergeneity among studies was evaluated by I2and Cochrane X2.In the event of no significant heterogeneity (P>.1 and I2 <50%), the fixed effect model was used for meta-analysis.In cases of statistically significant heterogeneity (P50%), the random effect model was used for meta-analysis.When more than 10 studies are included, the funnel plot is drawn to identify the publication bias.

Subgroup analysis Subgroup analysis was performed according to whether or not combined ch emotherapy was administered.

Sensitivity analysis Sensitivity analysis was performed in Review Manager (version 5.3) to explorethe impact of individual studies on the pooled results by removing one study at a time from the pooled analysis.

Country(ies) involved China.

Keywords Chinese herbal medicine, chaihu shugan san, breast cancer, chemotherapy, meta -analysis.

Contributions of each author

Author 1 - Zhenming Xie - Author 1 Conceptualization、Methodology、Formal analysis and investigation、Writing-original draft preparation、Writing -review and editing and Resources themanuscript.
Email: 1766309244@qq.com
Author 2 - Huili Shui - The author provided statistical expertise Formal analysis and investigation and Writing -review and editing.
Author 3 - Zhu Yang - The author contributed to the Funding acquisition.
Author 4 - Wenyu Wu - The author contributed to the Supervision.
Email: 250005736@qq.com
Author 5 - Dongxin Tang - The author contributed to the Funding acquisition and Supervision.
Email: tangdongxin@msn.com