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Efficacy and safety of Shexiang Baoxin pill compared with sacubitril/valsartan in the treatment of heart failure: a protocol for a systematic review and network meta-analysis

Wang, YP; Huang, PH; Jin, LL.

Corresponding author:
Yuanping Wang

202021202215@stu.gzucm.edu.cn

Author Affiliation:
The Fifth Clinical Medical College of Guangzhou University of Chinese Medicine.

ADMINISTRATIVE INFORMATION

Support - This work was supported by the National Natural Science Foundation of China (No. 82405259).

Review Stage at time of this submission - The review has not yet started.

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 22 November 2024 and was last updated on 22 November 2024.

INTRODUCTION

Review question / Objective Our study primarily addresses the following questions: (1) Compared to sacubitril/valsartan alone, does the combination of SBP offer greater efficacy in improving clinical symptoms, cardiac function, and quality of life in HF patients? (2) Can the combination of SBP enhance the safety profile of sacubitril/valsartan?

Condition being studied Heart failure (HF) represents a severe and often terminal manifestation of a range of cardiovascular diseases, characterized by persistently high mortality and readmission rates, which position it as an escalating public health challenge.

METHODS

Search strategy The meta-analysis systematically searched four English databases: PubMed, Embase, Cochrane Library, and Web of Science and four Chinese databases: China National Knowledge Infrastructure (CNKI), Wanfang Data Knowledge Service Platform, VIP Chinese Journal Service Platform, and SinoMed. Clinical trials registered in the Chinese Clinical Trial Registry were also included to ensure comprehensive study retrieval. For inaccessible articles, authors were contacted to obtain additional information. The search terms included “Shexiang Baoxin Pill”, “sacubitril/valsartan” and “heart failure”. No language restrictions were applied, and two authors independently conducted the literature search. Detailed search strategies for each database are provided in Supplementary Material S1.

Participant or population The trial subjects were adult patients diagnosed with HF according to internationally recognized diagnostic criteria. There were no restrictions regarding HF type, gender, country, ethnicity, or inpatient/outpatient status.

Intervention The control group of HF patients received standard pharmacological therapy, including diuretics, β-blockers, aldosterone antagonists, and sodium-glucose cotransporter 2 (SGLT2) inhibitors, in combination with sacubitril-valsartan. The experimental group received SBP in addition to standard pharmacological therapy in the control group.

Comparator The control group of HF patients received standard pharmacological therapy, including diuretics, β-blockers, aldosterone antagonists, and sodium-glucose cotransporter 2 (SGLT2) inhibitors, in combination with sacubitril-valsartan. The experimental group received SBP in addition to standard pharmacological therapy in the control group.

Study designs to be included RCTs.

Eligibility criteria Exclusion Criteria - The study is deemed ineligible if it meets any of the following criteria: 1) use of other traditional Chinese medicine interventions (e.g., acupuncture, massage, herbal medicine) as co-interventions; 2) data inaccuracies in the article that could not be resolved after contacting the corresponding author; 3) duplicate reports or conference abstracts.

Information sources This meta-analysis systematically searched four English databases: PubMed, Embase, Cochrane Library, and Web of Science and four Chinese databases: China National Knowledge Infrastructure (CNKI), Wanfang Data Knowledge Service Platform, VIP Chinese Journal Service Platform, and SinoMed. Clinical trials registered in the Chinese Clinical Trial Registry were also included to ensure comprehensive study retrieval. For inaccessible articles, authors were contacted to obtain additional information. The search terms included “Shexiang Baoxin Pill”, “sacubitril/valsartan” and “heart failure”. No language restrictions were applied, and two authors independently conducted the literature search. Detailed search strategies for each database are provided in Supplementary Material S1.

Main outcome(s) The primary outcomes were the left ventricular ejection fraction (LVEF). The secondary outcomes included the clinical efficacy rate, which was defined as a reduction of at least one grade in the New York Heart Association (NYHA) classification for HF patients following treatment. The clinical efficacy rate was calculated as the number of effective cases divided by the total number of cases, multiplied by 100%. Additional secondary outcomes included the left ventricular end-diastolic dimension (LVEDD), left ventricular end-systolic diameter (LVESD), brain natriuretic peptide (BNP), 6-minute walk test (6MWT), and the incidence of adverse drug reactions (ADRs).The primary outcomes were the left ventricular ejection fraction (LVEF).

Quality assessment / Risk of bias analysis Two researchers independently assessed the methodological quality of the included RCTs using the Cochrane Risk of Bias Assessment Tool. Bias was evaluated across several domains, including randomization, allocation concealment, blinding of participants and personnel, blinding of outcome assessment, completeness of outcome data, and selective reporting. Each study was rated as "low risk," "high risk," or "uncertain risk" based on this quality assessment tool. "Low risk of bias" indicates no methodological flaws that could affect the study's outcomes; "high risk of bias" suggests that methodological deficiencies may impact results, while "uncertain risk" indicates insufficient information to make a definitive judgment.

Strategy of data synthesis All statistical analyses were performed using the "meta" package in R version 3.6.1. For dichotomous data, such as clinical efficacy rate and adverse event rates, the risk ratio (OR) was used as the effect measure, while for continuous data, such as LVEF, the mean difference (MD) was employed. All effect sizes were reported with point estimates and 95% confidence intervals (CIs). Statistical significance was set at $p < 0.05$, and results were presented as forest plots. Heterogeneity among study results was assessed using the χ^2 test and I^2 statistic. An I^2 value < 50% was considered acceptable for heterogeneity, and a fixed-effects model was applied; otherwise, a random-effects model was used, accompanied by sensitivity or subgroup analyses to explore sources of heterogeneity. When the number of studies included in the meta-analysis reached 10, funnel plots and Egger’s test were used to assess potential publication bias. The quality of evidence for each outcome in the meta-analysis was evaluated using the GRADE Profiler 3.6.1 system.

Subgroup analysis Subgroup analysis was performed based on the sample size of the RCT (≤ 90 vs. >90) and the duration of the treatment (>1 months vs. ≤ 1) to explore the sources of heterogeneity. Subgroup analyses were conducted based on sample size and treatment duration to explore potential sources of heterogeneity.

Sensitivity analysis Sensitivity analysis was conducted by progressively excluding one study at a time to assess the robustness of the results.

Language restriction Shexiang Baoxin pill; heart failure; GRADE; sacubitril/valsartan; meta-analysis; randomized controlled trials.

Country(ies) involved China.

Keywords Shexiang Baoxin pill; heart failure; GRADE; sacubitril/valsartan; meta-analysis; randomized controlled trials.

Contributions of each author

Author 1 - Yuanping Wang.
Email: 20202120215@stu.gzucm.edu.cn
Author 2 - Lili Jin.
Email: jinlili991@163.com
Author 3 - Peihong Huang.