INPLASY PROTOCOL

To cite: Weng et al. Efficacy of Shexiang Baoxin Pills Combined with Statins on Blood Lipid Profile in Patients with Coronary Heart Disease: A systematic review and meta-analysis. Inplasy protocol 202290100. doi: 10.37766/inplasy2022.9.0100

Received: 21 September 2022

Published: 21 September 2022

Corresponding author:
Jieqiong Weng

weng_jieqiong@163.com

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

Support: **China.**

Review Stage at time of this submission: **Data extraction.**

Conflicts of interest:
None declared.

Efficacy of Shexiang Baoxin Pills Combined with Statins on Blood Lipid Profile in Patients with Coronary Heart Disease: A systematic review and meta-analysis

Weng, JQ[1]; Zhang, JF[2]; Xu, K[3]; Yuan, MF[4]; Yao, TT[5]; Wang, XY[6]; Shen, XX[7].

Review question / Objective: **P（Population）：Patients with coronary heart disease; I（Intervention）: Statins treatment in combination with Shexiang Baoxin pill; C（Comparison): Statins alone; O（Outcome）: Improvement of symptoms and blood lipids; S（Study design）：Clinical randomized trials.**

Eligibility criteria: **To be included, trials were required to meet the following criteria: (1) patients were included in the studies according to diagnostic criteria of coronary heart disease established by the WHO, InternationalSociety of Cardiology and Association (ISCA), Internal Medicine, 7th edition (IM-7th), Practice of InternalMedicine, 14th edition (PIM-14th), Guidelines for the Diagnosis of Cardiovascular Diseases in InternalMedicine, 3rd edition (GIM-3rd) or conventional diagnostic criteria (CDC) including assessment of anginapectoris and electrocardiogram (ECG) results; (2) the study was conducted as a randomized controlled trial.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 21 September 2022 and was last updated on 21 September 2022 (registration number INPLASY202290100).

INTRODUCTION

Review question / Objective: **P（Population）：Patients with coronary heart disease; I（Intervention）: Statins treatment in combination with Shexiang Baoxin pill; C（Comparison): Statins alone; O（Outcome）: Improvement of symptoms and blood lipids; S（Study design）：Clinical randomized trials.**

Rationale: **Shexiang Baoxin Pill (SBP) is a classic patent medicine derived from the TCM formula Suhexiang Pill of the Song Dynasty in China, which has been extensively used for the prevention and treatment of CVDs, especially coronary**

heart disease (CHD). Emerging pharmacological studies have revealed that SBP displays pleiotropic roles in protecting the cardiovascular system. From the perspective of preclinical studies, SBP has demonstrated therapeutic effects on CHD via various beneficial mechanisms, such as improving lipid metabolism and mitigating dyslipidemia. In terms of clinical practice, the randomized controlled trials on the treatment of SBP for CVDs have proved the efficacy and safety of SBP. The use of SBP combined with conventional therapy is a widely applied strategy in China, and a nuanced understanding of whether SBP could exert certain effects in regulating blood lipids is a vital step in the evaluation of the risks and benefits of this supplementation to adequately inform clinicians about the potential benefits or lack of efficacy in regulating blood lipids given the relatively wide application of SBP.Shexiang Baoxin Pill (SBP) is a classic patent medicine derived from the TCM formula Suhexiang Pill of the Song Dynasty in China, which has been extensively used for the prevention and treatment of CVDs, especially CHD. It is composed of Moschus, Radix Ginseng, Calculus Bovis, Cortex Cinnamomi, Styrax, Venenum Bufonis, and Borneolum Syntheticum. Emerging pharmacological studies have revealed that SBP displays pleiotropic roles in protecting the cardiovascular system. From the perspective of preclinical studies, SBP has demonstrated therapeutic effects on CHD via various beneficial mechanisms, such as improving lipid metabolism and mitigating dyslipidemia. In terms of clinical practice, the randomized controlled trials on the treatment of SBP for CVDs have proved the efficacy and safety of SBP . The use of SBP combined with conventional therapy is a widely applied strategy in China, and a nuanced understanding of whether SBP could exert certain effects in regulating blood lipids is a vital step in the evaluation of the risks and benefits of this supplementation to adequately inform clinicians about the potential benefits or lack of efficacy in regulating blood lipids given the wide application of SBP. The current research focuses on determining whether supplementation with SBP improved overall effects and blood lipid profile in CHD patients. For the first time, we systematically summarize the lipid mitigation effects of SBP on patients with CHD and quantify a suitable dosage for SBP, thus providing evidence-based advice from clinical perspectives.

Condition being studied: Shexiang Baoxin Pill (SBP) is a classic patent medicine derived from the TCM formula Suhexiang Pill of the Song Dynasty in China, which has been extensively used for the prevention and treatment of CVDs, especially coronary heart disease (CHD). Emerging pharmacological studies have revealed that SBP displays pleiotropic roles in protecting the cardiovascular system. From the perspective of preclinical studies, SBP has demonstrated therapeutic effects on CHD via various beneficial mechanisms, such as improving lipid metabolism and mitigating dyslipidemia. In terms of clinical practice, the randomized controlled trials on the treatment of SBP for CVDs have proved the efficacy and safety of SBP. The use of SBP combined with conventional therapy is a widely applied strategy in China, and a nuanced understanding of whether SBP could exert certain effects in regulating blood lipids is a vital step in the evaluation of the risks and benefits of this supplementation to adequately inform clinicians about the potential benefits or lack of efficacy in regulating blood lipids given the relatively wide application of SBP.

METHODS

Search strategy: The Cochrane Library, PubMed, Embase, Chinese Biomedical Literature Database (CBM), Chinese National Knowledge Infrastructure (CNKI), Chinese Scientific Journal Database (VIP), and the Wanfang database will be searched, and keywords involving “Coronary heart disease", "Statin", “Shexiang Baoxin pill", “Shexiang Baoxin tablet", “Shexiang Baoxin", and “blood lipids”.

Participant or population: (1) patients were included in the studies according to diagnostic criteria of coronary heart

disease established by the WHO, InternationalSociety of Cardiology and Association (ISCA), Internal Medicine, 7th edition (IM-7th), Practice of InternalMedicine, 14th edition (PIM-14th), Guidelines for the Diagnosis of Cardiovascular Diseases in InternalMedicine, 3rd edition (GIM-3rd) or conventional diagnostic criteria (CDC) including assessment of anginapectoris and electrocardiogram (ECG) results; (2) the study was conducted as a randomized controlled trial.

Intervention: Statins in combination with shexiang baoxin pill.

Comparator: Statin monotherapy.

Study designs to be included: Randomized controlled trials.

Eligibility criteria: To be included, trials were required to meet the following criteria: (1) patients were included in the studies according to diagnostic criteria of coronary heart disease established by the WHO, InternationalSociety of Cardiology and Association (ISCA), Internal Medicine, 7th edition (IM-7th), Practice of InternalMedicine, 14th edition (PIM-14th), Guidelines for the Diagnosis of Cardiovascular Diseases in InternalMedicine, 3rd edition (GIM-3rd) or conventional diagnostic criteria (CDC) including assessment of anginapectoris and electrocardiogram (ECG) results; (2) the study was conducted as a randomized controlled trial.

Information sources: The Cochrane Library, PubMed, Embase, Chinese Biomedical Literature Database (CBM), Chinese National Knowledge Infrastructure (CNKI), Chinese Scientific Journal Database (VIP), and the Wanfang database.

Main outcome(s): Improvement of symptoms and blood lipids.

Quality assessment / Risk of bias analysis: The methodological quality assessment was carried out using the Cochrane Handbook for Systematic Reviews of Interventions.

Strategy of data synthesis: Statistical analysis was performed by Review Manager 5.3 software. For measurement data, the dichotomous Variables were presented as risk ratios (RR), while continuous outcomes were presented as the mean difference (MD) with 95% confidence intervals (CIs). The I^2 statistic was used to assess heterogeneity as a quantitative measure of inconsistency. A fixed effect model was performed for minor heterogeneity when I^2 was 50%. Potential publication bias was evaluated using funnel plot analyses.

Subgroup analysis: Subgroup analysis was used to evaluate the 2 combination therapy schedules of the control group and different dosages.

Sensitivity analysis: The sensitivity analysis was performed to evaluate the reliability of the meta-analysis results.

Country(ies) involved: China.

Keywords: Shexiang Baoxin Pill, statin, coronary heart disease, blood lipid profile, meta-analysis.

Contributions of each author:

Author 1 - Jleqiong Weng - Study Design.
Email: wengjieqiong2022@gmail.com
Author 2 - Jingfang Zhang - Study Design.
Email: 18609915406@163.com
Author 3 - Ke Xu - Data synthesis.
Email: xuke0127@163.com
Author 4 - Mengfei Yuan - Data Extraction and data Synthesis.
Email: yuanmengfei2021@163.com
Author 5 - Tingting Yao - Data Extraction.
Email: 18742548013@163.com
Author 6 - Xinyu Wang - Software analysis.
Email: 18810502529@163.com
Author 7 - Xiaoxu Shen - Software analysis.
Email: doctorshen_paper@sina.com