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Protective effect of salvianolic acid B against atherosclerosis: A systematic review and meta-analysis of preclinical studies

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ADMINISTRATIVE INFORMATION

Support - No.

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 5 December 2024 and was last updated on 5 December 2024.

INTRODUCTION

Review question / Objective Atherosclerosis is the main potential pathology of cardiovascular disease. Timely intervention can reduce the risk of cardiovascular and cerebrovascular diseases to a certain extent. However, the existing lipid-lowering anti-inflammatory drugs have some problems such as high side effects and poor medical compliance. Salvianolic acid B is the most soluble component of *Salvia miltiorrhiza*, which can effectively delay the progression of atherosclerosis, but its mechanism is still unclear. Therefore, we will evaluate the efficacy of salvianolic acid B on atherosclerosis through preclinical systematic review and meta-analysis, explore its mechanism of action, and provide scientific basis for clinical application.

Condition being studied Atherosclerosis is a major contributor to cardiovascular disease, which in turn is the leading cause of morbidity and mortality worldwide. The high disability rate of

complications such as myocardial infarction and cerebral infarction also seriously affects people's quality of life. At present, lipid-lowering therapy is the cornerstone of the prevention and treatment of atherosclerosis. However, due to the side effects of some lipid-lowering drugs on patients' liver function and the economic burden brought by long-term drug use, some patients have low medical adherence and it is difficult to achieve the treatment goal. Therefore, it is urgent to find a new and multi-target drug.

METHODS

Search strategy We will search eight databases, including PubMed, Embase, Cochrane Library, Web of Science, China Biomedical Literature Service System, China Science and Technology Journal Database (VIP), CNKI, Wanfang, etc., and search the relevant studies from the self-built database until December 2024. The search strategy was based on the search components "atherosclerosis" and "salvianolic acid B".

Participant or population Rat/mouse models with atherosclerosis, irrespective of modeling method, sex, age, and weight.

Intervention The treatment group could receive any dose, time of administration and treatment mode of Sal B.

Comparator The control group received only the same amount of saline or did not receive any treatment.

Study designs to be included Animal studies investigating the therapeutic effect of Sal B in rat or mouse models of atherosclerosis will be included.

Eligibility criteria The inclusion criteria were as follows: (1) The rat/mouse model of atherosclerosis, with no restrictions on the modeling method; (2) The treatment group could receive any dose, administration time and treatment mode of Sal B; (3) The control group received only the same amount of saline or did not receive any treatment. (4) Main outcome indicators included pathological changes of aortic plaques, lipid levels, and inflammatory markers.

The exclusion criteria are as follows: (1) reviews, conference abstracts, case reports, in vitro studies, clinical trials; (2) Treatment groups receiving salvianolic acid complex or receiving SalB in combination with other treatments; (3) Documents that are not reasonably accessible; (4) There are no predefined outcome indicators; (5) Duplicate data or publications.

Information sources The extracted information will include: (1) first author's name and year of publication; (2) Specific details of the animals in each study, including species, number, sex, age, and weight; (3) molding method and anesthesia method; (4) Information on treatment of Sal B, including dose, mode of administration, duration of treatment, and corresponding information in the control group; (5) Mean and standard deviation (SD) of the results. If the outcome metrics are only presented graphically, we try to contact the authors to obtain the original experimental data. If the author does not answer, use WebPlotDigitizer 4.5 software (<https://automeris.io/WebPlotDigitizer>) to quantify the graphic data processing. If the article presents results from multiple different time points or multiple doses of Sal B, only data from the last time point or the highest dose group is extracted.

Main outcome(s) The main prognostic indicators included pathological changes of aortic plaques, lipid levels and inflammatory markers.

Quality assessment / Risk of bias analysis Two evaluators assessed the quality of included animal studies using a 10-item Risk of Bias (ROB) tool developed by the Center for Systematic Evaluation of Animal Experiments (SYRCLE). The tool evaluates the criteria: (1) sequence generation; (2) baseline characteristics; (3) covert grouping; (4) Animal placement randomization; (5) blinding (blinding animal breeders and researchers); (6) Evaluation of stochastic results; (7) Blind method (result evaluator); (8) Incomplete data report; (9) Selective results report; (10) Other sources of bias. Any differences in the evaluation process are resolved in consultation with the third evaluator.

Strategy of data synthesis Statistical analysis will be performed using STATA software version 15.0. The results of the indicators included in the study are continuous variables; Therefore, the total effect size is expressed by the standardized mean difference (SMD) and 95% confidence interval (95% CI). When the heterogeneity test results of the included studies were $P > 0.05$ and $I^2 < 50\%$, the fixed effect model was adopted. When $P \leq 0.05$ or $I^2 \geq 50\%$, random effects model was adopted. Subgroup analysis and sensitivity analysis were used to explore the sources of heterogeneity. Publication bias will be assessed using Egger regression tests.

Subgroup analysis If there is high heterogeneity in the outcome measures, subgroup analysis will be performed using STATA version 15.0.

Sensitivity analysis If there is high heterogeneity in outcome measures, sensitivity analysis will be performed using STATA version 15.0.

Country(ies) involved China.

Keywords Atherosclerosis; Salvianolic acid B; meta-analysis.

Contributions of each author

Author 1 - Xing Ji - Ji X conceived and designed the study.

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Author 2 - Huanlin Wu - Wu HL will make changes to the problems in the study.

Email: wuhuanlinboshi@aliyun.com

Author 3 - Kailin Huang - Huang KL has contributed to the development of selection criteria and bias risk assessment strategies.

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