INPLASY PROTOCOL

To cite: Chen et al. Efficacy and safety of external stenting for saphenous vein grafts in coronary artery bypass grafting: a systematic review and meta-analysis. Inplasy protocol 2022100029. doi: 10.37766/inplasy2022.10.0029

Received: 07 October 2022

Published: 07 October 2022

Corresponding author:
Zhong Wang

wangzhong761@163.com

Author Affiliation:
First Affiliated Hospital of Soochow University.

Support: **Grants No.BK20200203.**

Review Stage at time of this submission: **Completed but not published.**

Conflicts of interest:
None declared.

Efficacy and safety of external stenting for saphenous vein grafts in coronary artery bypass grafting: a systematic review and meta-analysis

Chen, HR[1]; Si, K[2]; Wang, ZL[3]; Wu, XX[4]; Ni, HY[5]; Tang, YB[6]; Liu, W[7]; Wang, Z[8].

Review question / Objective: **a) Participants: eligible patients were scheduled for on-pump multi-vessel CABG, with the use of 2 or more SVGs to the native vessels; b) Intervention and comparison: each patient was randomized to receive one external stent device to a single SVG, one or more SVGs remained non-stented and served as the control group; c) Outcomes: efficacy outcomes including intimal hyperplasia area, lumen diameter uniformity, graft failure (≥50% stenosis), intimal hyperplasia thickness, SVG occlusion and ectasia(>50% initial diameter); safety outcomes including major cardiac and cerebrovascular events (MACCE) and other adverse events.; d) Study type: RCT.**

Condition being studied: **Autologous saphenous vein grafts (SVGs) remains the universal bypass conduits in coronary artery bypass grafting (CABG) with multivessel coronary artery disease. Though the external stenting for SVGs showed promising clinical outcomes to prevent intimal hyperplasia, the reduction of grafts failure rates remains controversial.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 07 October 2022 and was last updated on 07 October 2022 (registration number INPLASY2022100029).

INTRODUCTION

Review question / Objective: **a) Participants: eligible patients were scheduled for on-pump multi-vessel CABG, with the use of 2 or more SVGs to the native vessels; b) Intervention and comparison: each patient was randomized to receive one external stent device to a single SVG, one or more SVGs remained non-stented and served as the control group; c) Outcomes: efficacy outcomes including intimal hyperplasia area, lumen**

diameter uniformity, graft failure (≥50% stenosis), intimal hyperplasia thickness, SVG occlusion and ectasia(>50% initial diameter); safety outcomes including major cardiac and cerebrovascular events (MACCE) and other adverse events.; d) Study type: RCT.

Condition being studied: Autologous saphenous vein grafts (SVGs) remains the universal bypass conduits in coronary artery bypass grafting (CABG) with multivessel coronary artery disease. Though the external stenting for SVGs showed promising clinical outcomes to prevent intimal hyperplasia, the reduction of grafts failure rates remains controversial.

METHODS

Search strategy: Two independent investigators (ZLW and HRC) performed a comprehensive literature search in MEDLINE, EMBASE, Cochrane Library, and ClinicalTrial.gov to identify relevant studies published up to 31 August 2022. The following search strategy was presented in supplementary material. Additionally, the reference lists of RCTs, relevant systematic reviews and meta-analyses were also screened independently and manually to ensure a more comprehensive search.

Participant or population: Eligible patients were scheduled for on-pump multi-vessel CABG, with the use of 2 or more SVGs to the native vessels.

Intervention: Each patient was randomized to receive one external stent device to a single SVGeach patient was randomized to receive one external stent device to a single SVG.

Comparator: One or more SVGs remained non-stented and served as the control group.

Study designs to be included: Randomized controlled trial.

Eligibility criteria: We set the exclusion criteria as follows: a) language: only available in English; b) retrospective studies, cohort studies, case review, case reports and commentary; c) active control (i.e. that is known to be effective treatment as opposed to a placebo).

Information sources: MEDLINE, EMBASE, Cochrane Library, and ClinicalTrial.gov.

Main outcome(s): Efficacy outcomes including intimal hyperplasia area, lumen diameter uniformity, graft failure (≥50% stenosis), intimal hyperplasia thickness, SVG occlusion and ectasia(>50% initial diameter).

Additional outcome(s): Safety outcomes including major cardiac and cerebrovascular events (MACCE) and other adverse events.

Quality assessment / Risk of bias analysis: The risk of bias plot for individual studies was assessed with Review Manager 5.3 software (version 5.3). The uniform criteria to assess risk of bias for RCTs of the Cochrane Collaboration was applied, which included: selection bias, performance bias, detection bias, attrition bias, reporting bias and other potential bias, each of which was classified as “low”, “high” or “unclear”. Two investigators performed the assessment independently (ZLW and HRC). Disagreements were solved between the two investigators by consensus or by another independent investigator (KS).

Strategy of data synthesis: All statistical analyses were performed using the Review manager software (version 5.3). The Meta-Analyses were based on a fixed-effects model or random-effects model. Mean difference (MD) and 95% confidence interval (CI) were calculated for the continuous outcomes. Risk ratio (RR) and 95% CI were used for the dichotomous outcomes. Cochrane’s Q test and I2 index were calculated to explore heterogeneity across included studies. For all the analysis, two-tailed tests were performed, and $P < 0.05$ was considered to be statistically significant.

Subgroup analysis: NA.

Sensitivity analysis: To assess the stability of the results, a sensitivity analysis was conducted by removing each individual study in turn from the total and reanalyzing the remainder.

Language restriction: English.

Country(ies) involved: China.

Keywords: saphenous vein grafts, coronary artery bypass grafting, external stenting,meta-analysis.

Contributions of each author:
Author 1 - Huiru Chen.
Author 2 - Ke Si.
Author 3 - Zilan Wang.
Author 4 - Xiaoxiao Wu.
Author 5 - Hanyu Ni.
Author 6 - Yanbing Tang.
Author 7 - Wei Liu.
Author 8 - Zhong Wang.