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INPLASY

Systematic Review and Meta-analysis of the Comparative Effectiveness of Sirolimus-Eluting Stents versus Paclitaxel-Coated Balloon Catheters in Treating Coronary In-Stent Restenosis

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ADMINISTRATIVE INFORMATION

Support - No.

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

Conflicts of interest - None declared.

INPLASY registration number: INPLASY202480079

Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 16 August 2024 and was last updated on 16 August 2024.

INTRODUCTION

Review question / Objective To systematically evaluate the therapeutic efficacy differences between paclitaxel-coated balloons and everolimus-eluting stents in the treatment of in-stent restenosis.

Condition being studied In-stent restenosis (ISR) is defined as >50% diameter narrowing within the stent by visual assessment, posing a significant challenge in percutaneous coronary intervention (PCI). Previous studies have shown that treatment commonly involves DCB (drug-coated balloons) or DES (drug-eluting stents), but the relative effectiveness of these treatments across various ISR types remains unclear. This study specifically aims to compare the efficacy of the most commonly used paclitaxel-coated balloon (PCB), a type of DCB, versus the everolimus-eluting stent (EES), a type of DES, in the treatment of ISR, thereby providing critical insights for clinical application.

METHODS

Participant or population In this study, the population comprises patients who have experienced in-stent restenosis (ISR) following percutaneous coronary intervention (PCI).

Intervention The measures implemented include the use of a paclitaxel-coated balloon (PCB) or an everolimus-eluting stent (EES).

Comparator Patients treated with Paclitaxel-Coated Balloons (PCB) or Everolimus-Eluting Stents (EES) for In-Stent Restenosis (ISR) were designated as the control group.

Study designs to be included Randomized Controlled Trials (RCT).

Eligibility criteria The literature screening and data extraction were independently carried out by two researchers.
Inclusion criteria: (1) Study type limited to Randomized Controlled Trials (RCTs); (2) Patients

experiencing ISR post-PCI; (3) Intervention measures include: treatment of ISR using Paclitaxel-Coated Balloons (PCB) or Everolimus-Eluting Stents (EES); (4) Primary outcome measures: one-year mortality, cardiac death, myocardial infarction, target lesion revascularization, target vessel revascularization, and stent thrombosis.
Exclusion criteria: (1) Literature published repeatedly; (2) Studies without relevant outcome measures; (3) Inaccessible original texts; (4) Scientific review articles or letters to the editor; (5) Non-clinical research.

Information sources We conducted searches up to August 2024 in the following databases: PubMed, Cochrane Library, Web of Science, and Embase. The search terms included in-stent restenoses, occlusion of the stent, everolimus-eluting stents, drug-eluting stents, paclitaxel-coated balloons, drug-coated balloons, and drug-eluting balloons.

Main outcome(s) One-year mortality, cardiac death, myocardial infarction, target lesion revascularization, target vessel revascularization, stent thrombosis.

Quality assessment / Risk of bias analysis The risk of bias of the included studies was assessed by two independent reviewers using the revised version of the Cochrane tool for randomized trials . Disagreements were resolved either by consensus or by a third reviewer. Six domains, including bias arising from the randomization process, bias arising from deviations from intended interventions, bias arising from missing outcome data, bias in the measurement of the outcome, and bias in the selection of the reported results were considered in the evaluation process. Finally, the overall bias of studies was identified. Studies were considered to be of “low concern” if all domains were rated to have “low risk”. Once one domain was rated to be of “some concern”, studies were considered to be of “unclear risk of bias” (including not applicable and no information). When more than one domain was rated as “high risk”, the studies were considered to be of “high concern”.

Strategy of data synthesis The risk of bias of the included studies was assessed by two independent reviewers using the revised version of the Cochrane tool for randomized trials . Disagreements were resolved either by consensus or by a third reviewer. Six domains, including bias arising from the randomization process, bias arising from deviations from intended interventions, bias arising from missing outcome data, bias in the measurement of the outcome, and bias in the selection of the reported results were considered in the evaluation process. Finally, the overall bias of studies was identified. Studies were considered to be of “low concern” if all domains were rated to have “low risk”. Once one domain was rated to be of “some concern”, studies were considered to be of “unclear risk of bias” (including not applicable and no information). When more than one domain was rated as “high risk”, the studies were considered to be of “high concern”.

Subgroup analysis If there is high heterogeneity among the included studies, subgroup analysis, sensitivity analysis, and meta-regression are employed to addressit.

Sensitivity analysis Involves the exclusion of individual studies one at a time to evaluate the robustness of the statistical results.

Country(ies) involved The First School of Clinical Medicine at Lanzhou University, China.

Keywords In-stent restenosis; paclitaxel-coated balloon; everolimus-eluting stent; systematic review and meta-analysis.

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