INPLASY

Efficacy and safety of drug-coated balloons in chronic total coronary occlusion recanalization: a systematic review and meta-analysis

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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 08 June 2024 and was last updated on 08 June 2024.

INTRODUCTION

Review question / Objective With advancements in chronic total coronary occlusion (CTO) recanalization techniques and concepts, the success rate of recanalization has been steadily increasing. However, the current data are too limited to draw any reliable conclusions about the efficacy and safety of drug-coated balloons (DCBs) in CTO percutaneous coronary intervention (PCI). Herein, we conducted a meta-analysis to confirm the efficacy of DCB in CTO PCI.

Condition being studied Drug-coated balloons (DCBs), which were first introduced in 2004, have become an alternative treatment option for DESs, without the limitations of permanent metal implant8. Evidences suggest that compared to conventional balloon angioplasty or additional stent implantation with DES, DCBs have a lower incidence of stent restenosis and thrombosis and provide better long-term efficacy for in-stent restenosis (ISR). Considering the high risk of restenosis or thrombosis and the prevalence of CTO, it seems reasonable to study whether the DCB-only method is a feasible option for treating such lesions. However, only a few small sample sizes and short follow-up studies have evaluated the effectiveness of DCB in treating de novo CTO lesions. To shed further light on this issue, we conducted a systematic literature review and meta-analysis to assess the clinical outcomes of DCB treatment for patients with CTO lesions.

METHODS

Participant or population studies with patients treated by DCB in CTO-PCI.

Intervention studies with patients treated by DCB in CTO-PCI.

Comparator None.

Study designs to be included We searched the electronic databases of PubMed, Web of Science and Embase from inception using the keywords ("chronical total occlusion" OR "coronary chronical total occlusion" OR "chronical total coronary occlusion" OR "CTO) AND ("Drug-coated balloon" OR "balloon" OR "DCB").

Eligibility criteria The inclusion criteria were as follows:
(1) studies with patients treated by DCB in CTO-PCI.
(2) Study sample larger than 20 patients with a follow-up of at least 1 month.
(3) Original studies reporting at least one of these outcomes: late lumen enlargement (LLE), target lesion revascularization (TLR), target vessel revascularization (TVR), myocardial infarction (MI) and cardiac death.
(4) Articles written in English.

Information sources We searched the electronic databases of PubMed, Web of Science and Embase from inception.

Main outcome(s) The study endpoints were cumulative MACE, including all-cause death, nonfatal MI, TLR, and TVR.

Additional outcome(s) The follow-up angiographic endpoints were LLE, reocclusion and restenosis.

Quality assessment / Risk of bias analysis The quality of the included studies was assessed using the Newcastle-Ottawa Scale.

Strategy of data synthesis Results were analyzed using a random effects model or a fixed effects model in cases of significant heterogeneity between studies. The I2 statistic was used to quantify heterogeneity between studies. If the results were non-heterogeneous (I250%), a random effects model was used. In addition, 25%, 50%, and 75% indicated low, moderate, and high heterogeneity, respectively. All analyses were performed using Review Manager version 5.4.1 and Stata software version 14.0. A P-value<0.05 was considered statistically significant.

Subgroup analysis Subgroup analysis was utilized to assess the differentialeffects.

Sensitivity analysis sensitivity analysis was performed to determine whether the omittance of a single study result affected the stability of the overall results.

Country(ies) involved China.

Keywords Chronic total coronary; Percutaneous coronary intervention; Drug-coated balloon; Major advent cardiovascular event; Meta-analysis.

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