

INPLASY PROTOCOL

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None declared.

Meta-analysis of rotational atherectomy combined with cutting balloon in the treatment of moderate and severe coronary artery calcification

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Review question / Objective: We systematically evaluate the efficacy and safety of rotational atherectomy(RA) combined with cutting balloon(CB) in treating moderate and severe coronary artery calcification.

Eligibility criteria: Included criteria:(1)Randomized controlled trials.(2)The control group was pretreated with RA combined with SB, and the observation group was pretreated with RA combined with CB. Exclusion criteria:(1)Observational studies, non-randomized controlled studies, and case reports. (2)Literatures that are excluded contain incomplete data, incorrect data, and incorrect intervention methods, among other things.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 20 September 2022 and was last updated on 20 September 2022 (registration number INPLASY202290095).

INTRODUCTION

Review question / Objective: We systematically evaluate the efficacy and safety of rotational atherectomy(RA) combined with cutting balloon(CB) in treating moderate and severe coronary artery calcification.

Rationale: As an effective and safe treatment for coronary artery diseases, percutaneous coronary intervention(PCI) is widely used in clinical practice. However, it remains a big challenge for coronary artery calcification. Compared to conventional SB, the cutting balloon(CB) surface has three or four microblades

arranged in longitudinal radial pattern. This ensures an orderly circumcission of the vessel intimal and medial plaque with the RA as it expands, reducing vessel circumferential stress and elastic recoil resulting in better lumen access. Therefore, this study systematically evaluated the efficacy and safety of intravascular ultrasound (IVUS) guided RA combined with CB in the treatment of moderate and severe calcified coronary artery lesions.

Condition being studied: percutaneous coronary intervention; rotational atherectomy; cutting balloon; coronary artery calcification; efficacy; safety.

METHODS

Search strategy: A computer will be used to retrieve the following databases: CNKI, Wanfang, VIP, SinoMed, PubMed, Embase, Cochrane Library and Web of Science published before September 4, 2022. In the search, key terms were identified, including "Rotational atherectomy", "Cutting balloon", "Coronary artery", "Calcification", and synonyms for the terms. We will use a combination of subject terms and free words to conduct our search. Furthermore, all references listed in relevant original papers and review articles were checked.

Participant or population: Patients undergoing PCI.

Intervention: The control group was pretreated with RA combined with SB, and the observation group was pretreated with RA combined with CB. The control group was pretreated with RA combined with SB.

Comparator: The control group was pretreated with RA combined with SB, and the observation group was pretreated with RA combined with CB.

Study designs to be included: (1) Randomized controlled trials. (2) The control group was pretreated with RA combined with SB, and the observation

group was pretreated with RA combined with CB.

Eligibility criteria: Included criteria: (1) Randomized controlled trials. (2) The control group was pretreated with RA combined with SB, and the observation group was pretreated with RA combined with CB. Exclusion criteria: (1) Observational studies, non-randomized controlled studies, and case reports. (2) Literatures that are excluded contain incomplete data, incorrect data, and incorrect intervention methods, among other things.

Information sources: A computer will be used to retrieve the following databases: CNKI, Wanfang, VIP, SinoMed, PubMed, Embase, Cochrane Library and Web of Science published before September 4, 2022. In the search, key terms were identified, including "Rotational atherectomy", "Cutting balloon", "Coronary artery", "Calcification", and synonyms for the terms. We will use a combination of subject terms and free words to conduct our search. Furthermore, all references listed in relevant original papers and review articles were checked.

Main outcome(s): (1) Immediate lumen diameter acquisition; (2) Immediate lumen cross-sectional area acquisition; (3) In-stent minimal lumen diameter; (4) In-stent minimum lumen cross-sectional area; (5) The residual cross-sectional area; (6) Repeat vascular reconstruction.

Quality assessment / Risk of bias analysis: We assessed randomised trials' bias risk assessment tool developed by the Cochrane Collaboration, which consists of follow 7 points: Random sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessment, incomplete outcome data, selective reporting and other bias. Each entry is divided into 3 levels: low risk, unclear risk and high risk.

Strategy of data synthesis: We used Revman 5.4.1 software for data analyses. We represented counting data as relative risk (RR) and its 95% CI, and measurement

data as mean difference(MD) and its 95%CI.We will use the I² test to identify heterogeneity among studies.According to our criteria,I²<50% indicates low heterogeneity;I²=50-75% indicates moderate heterogeneity;I²>75% indicates high heterogeneity.In studies with low or moderate statistical heterogeneity (I²=25,25%-50%), we used a fixed effects model, and in studies with high statistical heterogeneity(I²>50%),we used a random effects model.We used a p-value of less than 0.05 to determine significance.

Subgroup analysis: If there is high heterogeneity, we will find the potential sources of heterogeneity by using the methods of subgroup analysis.

Sensitivity analysis: If there was high heterogeneity, sensitivity analyses were conducted.

Country(ies) involved: China.

Keywords: percutaneous coronary intervention; rotational atherectomy; cutting balloon; coronary artery calcification; efficacy; safety.

Contributions of each author:

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