## **INPLASY**

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# The effect of diabetes mellitus on restenosis after percutaneous transluminal angiography or stenting: A meta analysis

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#### **ADMINISTRATIVE INFORMATION**

Support - Science and Technology Department of Sichuan Province.

**Review Stage at time of this submission -** Formal screening of search results against eligibility criteria.

Conflicts of interest - None declared.

INPLASY registration number: INPLASY202370034

**Amendments -** This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 11 July 2023 and was last updated on 11 July 2023.

#### INTRODUCTION

Review question / Objective Is the target lesion restenosis after balloon angioplasty or stenting associated with diabetes?

Condition being studied Diabetes mellitus is thought to be closely related to arterial stenotic or occlusive disease caused by atherosclerosis. However, there is still no definitive clinical evidence to confirm that patients with diabetes have a higher risk of restenosis.

#### **METHODS**

Participant or population Eligibility criteria: (1) RCTs of patients with or without DM; (2) lesions confined to the coronary arteries or femoralpopliteal artery; (3) endovascular treatment via PTA or stenting. Exclusion criteria: (1) the proportion of patientslost to follow-up was higher than 20%; and (2) a secondary restenosis operation.

Intervention Trials were included if they satisfied the following eligibility criteria: (1) RCTs of patients with or without DM; (2)lesions confined to the coronary arteries or femoral popliteal artery; (3) endovascular treatment via PTA orstenting; and (4) studies had to include an outcome of angiographic follow-up of the lesion site, target lesionrevascularization (TLR) or target vessel revascularization (TVR). The exclusion criteria included the following: (1)the proportion of patients lost to follow-up was higher than 20%; and (2) a secondary restenosis operation.

**Comparator** Patients with or without diabetes who received PTA or Stent.

#### Study designs to be included RCT.

Eligibility criteria Trials were included if they satisfied the following eligibility criteria: (1) RCTs of patients with or without DM; (2)lesions confined to the coronary arteries or femoral popliteal artery; (3) endovascular treatment via PTA orstenting; and (4) studies had to include an outcome of angiographic

follow-up of the lesion site, target lesionrevascularization (TLR) or target vessel revascularization (TVR). The exclusion criteria included the following: (1)the proportion of patients lost to follow-up was higher than 20%; and (2) a secondary restenosis operation.

**Information sources** PubMed/MEDLINE, EMBASE and Cochrane. Searched from 01/1990 to 06/2023.

Main outcome(s) Restenosis. Confirmed by angiography or ultrasound during follow-up time; Measures of effect; RR.

**Quality assessment / Risk of bias analysis** The Cochrane risk of bias assessment tool.

Strategy of data synthesis Two researchers independently scanned the titles and abstracts of the retrieved studies for the topic. Then, the researchers obtained the full texts of potentially eligible studies and examined these texts independently for suitability according to the inclusion and exclusion criteria. In the case of disagreement between the two researchers, a third researcher was consulted to reach a consensus on whether to include the trial or not.

**Subgroup analysis** Restenosis and glycemic control levels.

Sensitivity analysis For dichotomous data (for example, the presence or absence of restenosis), we calculated Mantel-Haenszel relative ratios (RRs) and 95% confidence intervals (Cls). Heterogeneity across studies was assessed by Cochran's Q statistic with a P value set at 0.1. The I² statistic was also taken into account regardless of the P value. An I² of  $\geq$  50% was prespecified as the threshold considered too high to provide consistent analysis. A random effects model was used for the analysis. Tests were two-tailed, and a P value of < 0.05 was considered statistically significant. Funnel plots were used to assess publication bias. STATA 16.0 (Statacorp, USA) was used to analyze the data.

Country(ies) involved China.

Keywords diabetes mellitus, restenosis.

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