

# INPLASY PROTOCOL

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**Support:** None.

**Review Stage at time of this submission:** Preliminary searches.

**Conflicts of interest:**  
None.

## Impact of time factor and patient characteristics on the efficacy of PCI vs. CABG for left main coronary disease: a meta-analysis

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**Review question / Objective:** The impact of time factor and patient characteristics on the efficacy of percutaneous coronary intervention (PCI) with drug-eluting stents vs. coronary-artery bypass grafting (CABG) for left main coronary disease is unclear.

**Condition being studied:** This meta-analysis will evaluate the impact of important factors including time factor and the factors related to patient characteristics on the efficacy of PCI vs. CABG for the endpoint of major adverse cardiac or cerebrovascular events (MACCE) in patients with left main coronary artery disease.

**INPLASY registration number:** This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 04 June 2020 and was last updated on 04 June 2020 (registration number INPLASY202060017).

### INTRODUCTION

**Review question / Objective:** The impact of time factor and patient characteristics on the efficacy of percutaneous coronary intervention (PCI) with drug-eluting stents vs. coronary-artery bypass grafting (CABG) for left main coronary disease is unclear.

**Condition being studied:** XThis meta-analysis will evaluate the impact of important factors including time factor and

the factors related to patient characteristics on the efficacy of PCI vs. CABG for the endpoint of major adverse cardiac or cerebrovascular events (MACCE) in patients with left main coronary artery disease.

### METHODS

**Participant or population:** Patients with left main coronary artery disease.

**Intervention:** PCI with drug-eluting stents.

**Comparator:** CABG.

**Study designs to be included:** RCTs assessing the efficacy of PCI vs. CABG for left main coronary disease.

**Eligibility criteria:** PICOS being mentioned above.

**Information sources:** We will search PubMed and Embase from December 2000 through June 2020 for relevant articles reporting randomized controlled trials (RCTs), using a pre-defined search strategy.

**Main outcome(s):** MACCE, defined as a composite of death from any cause, myocardial infarction, stroke, or repeat revascularization. If this composite outcome is not reported in primary articles, we will use other composite outcome similar with this outcome instead. To evaluate the impact of time factor on the efficacy of PCI vs. CABG for MACCE using hazard ratios (HRs) reported at multiple time points in individual trails. To evaluate the impact of important factors related to patient characteristics on the efficacy of PCI vs. CABG for MACCE using HRs reported at the five-year time point in individual trails. If HRs are not available in original articles, risk ratios (RRs) or odds ratios (ORs) will be used instead.

**Data management:** The articles identified by electronic databases will be firstly assessed for relevance in accordance with their titles and abstracts, and those articles potentially eligible to be included will be then assessed for final eligibility in accordance with the inclusion/exclusion criteria. Two authors will use a standardized Excel data extraction sheet to independently extract pre-specified data from the articles eligible to be included. The pre-specified data items to be collected include important patient characteristics, type of intervention and control, study outcomes at different time points in different subgroups, and study design. Any disagreements in the process

of data extraction will be addressed via discussion with a third author.

**Quality assessment / Risk of bias analysis:** Two authors will independently assess the risk of bias of included RCTs using the Cochrane risk of bias tool. Any disagreements in the process of risk of bias assessment will be addressed via discussion with a third author.

**Strategy of data synthesis:** We will perform random-effects meta-analysis to synthesize HRs and 95% confidence intervals (CIs) based on trial-level survival data (i.e., HRs and 95% CIs extracted from included trials). Heterogeneity across included studies will be measured using  $I^2$  statistic. Random-effects meta-regression will be performed to explore the impact of follow-up duration on the efficacy of PCI vs. CABG for MACCE. Statistical analyses will be done using Stata (version 15.1).

**Subgroup analysis:** Subgroup analyses will be conducted to explore the subgroup effects of PCI vs. CABG for five-year MACCE, stratified by the following seven factors related to patient characteristics: 1. Age: <67,  $\geq$ 67 years; 2. Sex: Male, Female; 3. Diabetes: Yes, No; 4. Non-left main diseased coronary arteries: 0, 1, 2, 3; 5. Acute coronary syndrome (ACS): Yes, No; 6. Distal left main coronary stenosis: Yes, No; 7. SYNTAX score:  $\leq$ 22, 23-32,  $\geq$ 33. Meanwhile, random-effects meta-regression will be performed to explore the statistical significance of these subgroup effects. P value <0.05 denotes statistical significance.

**Sensibility analysis:** Not pre-planned.

**Country(ies) involved:** China.

**Keywords:** left main coronary disease; major adverse cardiac or cerebrovascular events; PCI; CABG.

**Contributions of each author:**

Author 1 - Mei Qiu.

Author 2 - Ying-Xi Tang.

Author 3 - Liang-Liang Ding.