



Outcomes After Percutaneous Coronary Intervention or Bypass Surgery in Patients With Unprotected Left Main Disease

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ABSTRACT

BACKGROUND Currently available randomized data on the comparison between percutaneous coronary intervention (PCI) and coronary artery bypass graft (CABG) for the treatment of unprotected left main coronary disease (LMD) lacks statistical power due to low numbers of patients enrolled.

OBJECTIVES This study assessed long-term outcomes of PCI and CABG for the treatment of LMD in specific subgroups according to disease anatomic complexity.

METHODS We conducted a pooled analysis of individual patient-level data of the LMD patients included in the PRECOMBAT (Bypass Surgery Versus Angioplasty Using Sirolimus-Eluting Stent in Patients With Left Main Coronary Artery Disease) and SYNTAX (Synergy Between PCI With TAXUS and Cardiac Surgery) trials. Incidences of major adverse cardiac events were assessed at 5 years follow-up.

RESULTS Study population comprised 1,305 patients. The incidence of major adverse cardiac and cerebrovascular events at 5 years was 28.3% in the PCI group and 23.0% in the CABG group (hazard ratio [HR]: 1.23; 95% confidence interval [CI]: 1.01 to 1.55; $p = 0.045$). This difference is mainly driven by a higher rate of repeat revascularization associated with PCI (HR: 1.85; 95% CI: 1.38 to 2.47; $p < 0.001$). The 2 strategies showed similar rates of the safety composite endpoint of death, myocardial infarction, or stroke ($p = 0.45$). In patients with isolated LM or LM + 1-vessel disease, PCI was associated with a 60% reduction in all-cause mortality (HR: 0.40; 95% CI: 0.20 to 0.83; $p = 0.029$) and 67% reduction in cardiac mortality (HR: 0.33; 95% CI: 0.12 to 0.88; $p = 0.025$) when compared with CABG.

CONCLUSIONS In patients with unprotected LMD, CABG, and PCI result in similar rates of the safety composite endpoint of death, myocardial infarction, or stroke. In patients with isolated LM or LM + 1-vessel disease, PCI is associated with lower all-cause and cardiac mortality when compared to CABG. (J Am Coll Cardiol 2016;68:999-1009)
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Revascularization for unprotected left main coronary artery disease (UPLMD) has evolved considerably in the last few years. What was once a forbidden territory for percutaneous coronary intervention (PCI) has now become common practice

in most catheterization laboratories across the globe following the improvement in PCI outcomes (1).

Currently available randomized data on treatment of UPLMD lack statistical power due to low numbers of patients enrolled in randomized controlled trials,



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**ABBREVIATIONS
AND ACRONYMS**

CABG = coronary artery bypass graft

CAD = coronary artery disease

CI = confidence interval

HR = hazard ratio

LM = left main

MACE = major adverse cardiac event(s)

MI = myocardial infarction

PCI = percutaneous coronary intervention

UPLMD = unprotected left main disease

especially for specific subgroup analyses. The PRECOMBAT (Bypass Surgery Versus Angioplasty Using Sirolimus-Eluting Stent in Patients With Left Main Coronary Artery Disease) trial is the largest randomized controlled trial to ever address specifically this population, and included only 600 patients (2). The SYNTAX (Synergy Between PCI With TAXUS and Cardiac Surgery) trial included a slightly larger number (n = 705), but was not specifically designed for UPLMD patients and was subject to the limitations of subgroup analyses, albeit being a pre-specified one (3,4). Both of these trials were underpowered to definitively answer the question of which is the best revascularization strategy for patients with UPLMD, if there is one (5).

of including only population-level data instead of analyzing individual patient-level data (6-8). In the present study we performed a pooled analysis of individual patient-level data from the 2 largest randomized populations available so far. Our objective was to compare long-term clinical outcomes of coronary artery bypass graft (CABG) surgery and PCI for the treatment of UPLMD in the 1,305 patients randomized in the SYNTAX and PRECOMBAT trials and to assess outcomes across several specific subgroups (9,10).

METHODS

The methods and designs of both trials have been previously described elsewhere (2,3). Some differences between them are worth noting and are summarized as the following:

STUDY POPULATION. The SYNTAX trial was a multicenter randomized controlled trial conducted in 17 countries in Europe and the United States that included 1,800 patients with 3-vessel or left main

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Although several meta-analyses have tried to address this statistical power issue, they have the issue

FIGURE 1 Study Flowchart

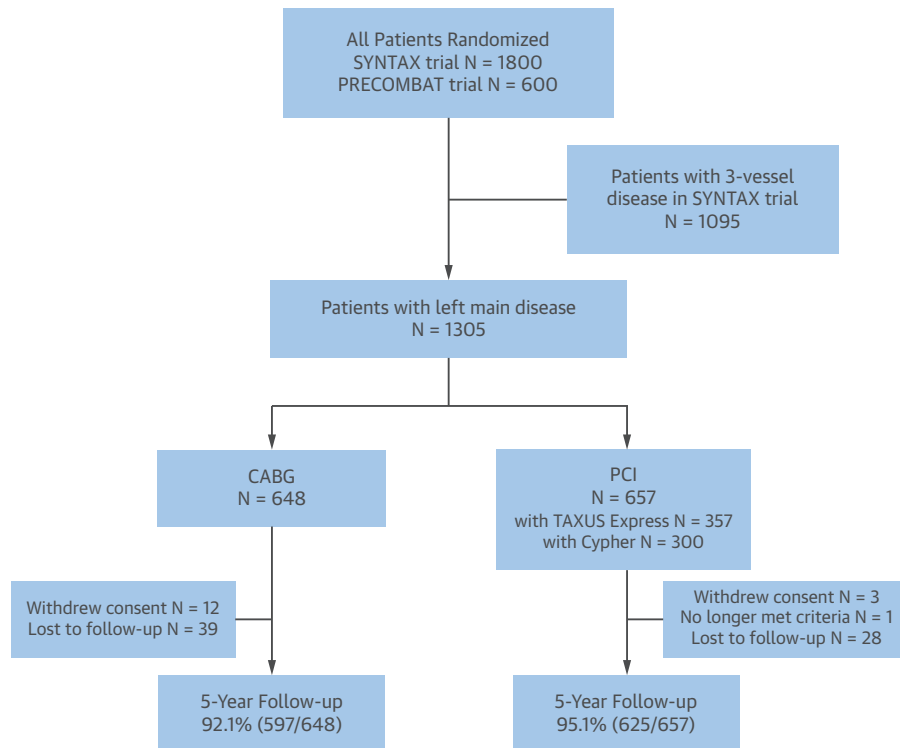


Illustration depicting the patient selection and allocation to treatment randomization arms. Numbers of patients lost to follow-up and complete follow-up rates are shown. CABG = coronary artery bypass graft; PCI = percutaneous coronary intervention; PRECOMBAT = Bypass Surgery Versus Angioplasty Using Sirolimus-Eluting Stent in Patients With Left Main Coronary Artery Disease; SYNTAX = Synergy Between PCI With TAXUS and Cardiac Surgery.

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