Stent versus bypass grafting for the treatment of left main stem disease: a meta-analysis of six randomised controlled trials

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Abstract

Aims: We performed a meta-analysis of all randomised controlled trials to compare percutaneous coronary intervention (PCI) with stents versus coronary artery bypass grafting (CABG) for the treatment of left main stem disease.

Methods and results: We searched PubMed, the Cochrane Library, ClinicalTrials.gov, and major cardiovascular congresses for articles comparing PCI versus CABG for the treatment of left main stem disease. We utilised either fixed or random effects models to calculate the pooled risk ratio (RR) and 95% confidence interval (CI). Six trials with a total of 4,717 patients treated with either PCI (n=2,355) or CABG (n=2,362) were eligible and included. There were no differences in all-cause (RR: 1.03, 95% CI: 0.84-1.25, p=0.78) and cardiac mortality (RR: 1.03, 95% CI: 0.78-1.37, p=0.83) between PCI- and CABG-treated patients at the longest available follow-up. PCI-treated patients had a higher incidence of repeat revascularisation (RR: 1.65, 95% CI: 1.40-1.94, p<0.0001). However, there was no difference in myocardial infarction (RR: 1.36, 95% CI: 0.87-2.12, p=0.17) and stroke (RR: 0.86, 95% CI: 0.44-1.69, p=0.66).

Conclusions: There are no differences in mortality, myocardial infarction and stroke in PCI- or CABG-treated patients with left main stem disease. However, PCI-treated patients are more likely to need repeat revascularisation.

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**Introduction**

The optimal revascularisation strategy for patients with unprotected left main stem (LMS) disease remains debatable. Cohen and Gorlin published a case series of coronary artery bypass grafting (CABG) in unprotected LMS in 1975 showing a long-term mortality benefit. Subsequently, several registries and randomised controlled trials (RCT) confirmed the survival benefit of CABG over medical treatment, especially in moderate- to high-risk groups. Traditionally, percutaneous coronary intervention (PCI) for unprotected LMS has remained a class III indication (i.e., harmful) in the international guidelines. However, with recent technical and technological advances, PCI has challenged the supremacy of CABG and has been the subject of several RCT. European Society of Cardiology (ESC) revascularisation guidelines in 2014 for the first time upgraded PCI for LMS to a class I indication for patients with LMS disease and a SYNTAX score ≤22 (and class IIA for patients with a SYNTAX score 23-32) based on data from the SYNTAX (SYNergy Between PCI With TAXUS and Cardiac Surgery) trial. Two more large clinical trials, NOBLE (Coronary Artery Bypass Grafting Vs Drug Eluting Stent Percutaneous Coronary Angioplasty in the Treatment of Unprotected Left Main Stenosis) and EXCEL (Evaluation of XIENCE Versus Coronary Angioplasty Using Sirolimus-Eluting Stent in Patients with Left Main Coronary Artery Disease) with five-year follow-up, LE MANS (left main stenting) trial with 10-year follow-up, Boudriot et al with one-year follow-up, SYNTAX with five-year follow-up, NOBLE with five-year follow-up, and EXCEL with three-year follow-up. These trials randomised 4,717 patients with unprotected LMS disease to treatment with either PCI with stents compared with CABG in patients with unprotected LMS disease.

**Methods**

**SEARCH STRATEGY AND SELECTION CRITERIA**

Randomised trials comparing PCI with a stent versus CABG were searched in PubMed, the Cochrane Library, and ClinicalTrials.gov, as well as major cardiovascular congresses. The search was limited to the English language. The subject keywords percutaneous coronary intervention, angioplasty, stents, left main stem, bypass grafting and randomised trial were applied to identify studies. The last search was performed in January 2017 by two independent investigators (J-Z. Cai and Y-X. Zhu).

**INCLUSION AND EXCLUSION CRITERIA**

Two investigators independently screened the title and abstract of the retrieved reports and reviewed the full articles of relevant citations in detail. Any discrepancies or disagreements were settled by a third investigator. Only randomised controlled clinical trials comparing clinical outcomes between CABG and PCI using stents for the treatment of unprotected LMS disease and with a fully published status were included. The clinical outcomes of interest were all-cause death, cardiac death, myocardial infarction (MI), stroke, and repeat revascularisation. We evaluated clinical outcomes for each trial at one year as well as at the longest reported follow-up. The risk of bias for individual trials was assessed in accordance with the Cochrane Collaboration’s tool.

**STATISTICAL ANALYSIS**

Risk ratio (RR) and mean differences with 95% confidence interval (CI) were utilised as summary statistics. The Mantel-Haenszel fixed effects model and inverse variance fixed effects model were used for categorical variables and continuous variables, respectively. We performed the F test and chi-square test to evaluate heterogeneity among studies. An I² >50% or p-value <0.10 was considered as significant heterogeneity. A random effects model was performed to calculate the risk estimation if a significant heterogeneity was detected. Sensitivity analyses were carried out by omitting one study at a time. The Egger’s linear regression tests were employed to test for funnel plot asymmetry at the p<0.10 level of significance. All the statistical analyses were performed using Review Manager, Version 5.3 (The Nordic Cochrane Centre, Copenhagen, Denmark) and Stata, Version 13.0 (StataCorp, College Station, TX, USA).

**Results**

Six eligible RCT were identified after the screening process, as illustrated in Figure 1. The trials included were PRECOMBAT (Premier of Randomised Comparison of Bypass Surgery versus Angioplasty Using Sirolimus-Eluting Stent in Patients with Left Main Coronary Artery Disease) with five-year follow-up, SYNTAX with five-year follow-up, LE MANS (left main stenting) trial with 10-year follow-up, Boudriot et al with one-year follow-up, NOBLE with five-year follow-up, and EXCEL with three-year follow-up. These trials randomised 4,717 patients with unprotected LMS disease to treatment with either PCI with stents (n=2,355) or CABG (n=2,362) and are summarised in Table 1.

**ALL-CAUSE AND CARDIAC DEATH**

All-cause mortality was reported in all six trials. The pooled RR showed no significant differences between PCI- and CABG-treated
groups for all-cause mortality at one-year (RR: 0.81, 95% CI: 0.59-1.12, p=0.21; I²=0%) (Figure 2A) or long-term (RR: 1.03, 95% CI: 0.84-1.25, p=0.78; I²=18%) (Figure 2B) follow-up. Cardiac death was reported in only two trials at one-year follow-up leading to statistical heterogeneity (I²=62%), and in four trials at long-term follow-up (I²=25%). Nevertheless, there was no difference in cardiac death at one-year (RR: 1.03, 95% CI: 0.38-2.78, p=0.95) or long-term (RR: 1.03, 95% CI: 0.78-1.37, p=0.83) follow-up.

**MYOCARDIAL INFARCTION**

MI was reported in all six trials, although there were differences in the definition of MI, especially preprocedural MI. There was no significant difference in MI at one-year (RR: 0.86, 95% CI: 0.65-1.14, p=0.30; I²=0%) (Figure 3A) or the longest available follow-up (RR: 1.36, 95% CI: 0.87-2.12, p=0.17; I²=51%) (Figure 3B) between PCI- and CABG-treated patients. However, analysing only non-procedural MI revealed that, whilst there was no difference at one year (RR: 1.17, 95% CI: 0.77-1.76, p=0.46; I²=0%) (Figure 3C), CABG-treated patients had lower rates of MI at long-term follow-up. As the EXCEL trial reported spontaneous (as opposed to non-procedural) MI, sensitivity analysis excluding EXCEL also showed a reduction in MI among CABG-treated patients (RR: 1.79, 95% CI: 1.22-2.62, p=0.003; I²=7%).

Table 1. Study and patient characteristics.

<table>
<thead>
<tr>
<th>Study</th>
<th>Treatment (n)</th>
<th>Follow-up (years)</th>
<th>Definition of primary MACCE</th>
<th>Age</th>
<th>Male</th>
<th>DM</th>
<th>Multivessel</th>
<th>SYNTAX score</th>
</tr>
</thead>
<tbody>
<tr>
<td>LE MANS</td>
<td>BMS/DES (52)</td>
<td>10</td>
<td>Cardiac death, MI, RR, ST, or stroke</td>
<td>61 (11)</td>
<td>61 (8)</td>
<td>60</td>
<td>73</td>
<td>19</td>
</tr>
<tr>
<td>Boudriot et al</td>
<td>SES (100) CABG (101)</td>
<td>1</td>
<td>Death, MI, and RR</td>
<td>66 (n/a)</td>
<td>69 (n/a)</td>
<td>72</td>
<td>77</td>
<td>40</td>
</tr>
<tr>
<td>PRECOMBAT</td>
<td>SES (300) CABG (300)</td>
<td>5</td>
<td>Death, MI, stroke, or ischaemia-driven TVR</td>
<td>62 (10)</td>
<td>63 (10)</td>
<td>76</td>
<td>77</td>
<td>34</td>
</tr>
<tr>
<td>SYNTAX</td>
<td>PES (357) CABG (348)</td>
<td>5</td>
<td>Death, MI, stroke, and RR</td>
<td>65 (10)</td>
<td>66 (10)</td>
<td>72</td>
<td>76</td>
<td>24</td>
</tr>
<tr>
<td>NOBLE</td>
<td>BES/PES/SSES (598) CABG (603)</td>
<td>5</td>
<td>Death, non-procedural MI, RR, or stroke</td>
<td>66 (10)</td>
<td>66 (9)</td>
<td>80</td>
<td>76</td>
<td>15</td>
</tr>
<tr>
<td>EXCEL</td>
<td>EES (948) CABG (957)</td>
<td>3</td>
<td>Death, stroke, MI, or ischaemia-driven revascularisation</td>
<td>66 (10)</td>
<td>66 (10)</td>
<td>76</td>
<td>78</td>
<td>30</td>
</tr>
</tbody>
</table>

Values are mean (SD) or %. BES: biolimus-eluting stents; CABG: coronary artery bypass grafting; DES: drug-eluting stents; DM: diabetes mellitus; EES: everolimus-eluting stents; MI: myocardial infarction; PES: paclitaxel-eluting stents; RR: repeat revascularisation; SES: sirolimus-eluting stents; ST: stent thrombosis; TVR: target vessel revascularisation.

Figure 2. Forest plots of risk ratios for all-cause mortality between PCI- and CABG-treated groups. There was no difference in all-cause mortality at one-year (A) or long-term (B) follow-up. The size of data markers indicates the weight of each trial included in the meta-analysis for all-cause death. CABG: coronary artery bypass grafting; PCI: percutaneous coronary intervention.
STROKE AND REPEAT REvascularisation

Stroke was reported in five trials. There was a lower incidence of stroke in PCI-treated patients at one year (RR: 0.39, 95% CI: 0.21-0.70, p=0.002; I²=0%) (Figure 4A), but there was no difference between revascularisation strategies at long-term follow-up (RR: 0.86, 95% CI: 0.44-1.69, p=0.66; I²=51%) (Figure 4B).

Repeat revascularisation was reported in all trials. PCI-treated patients had a higher incidence of repeat revascularisation at one year (RR: 1.80, 95% CI: 1.35-2.40, p<0.0001; I²=0%) (Figure 4C).
as well as at long-term follow-up (RR: 1.65, 95% CI: 1.40-1.94, p<0.0001; I²=19%) (Figure 4D).

COMPOSITE OF MAJOR ADVERSE CARDIOVASCULAR AND CEREBRAL EVENTS

Major adverse cardiovascular and cerebral events (MACCE) as a composite of all-cause death, MI, stroke and revascularisation could be calculated for all trials despite the differences in definition of MI, revascularisation and incomplete data about stroke. There were no differences in MACCE at one-year follow-up (RR: 0.98, 95% CI: 0.82-1.16, p=0.78; I²=39%) (Figure 5A); however, on long-term follow-up, MACCE rates were much higher in PCI-treated patients (RR: 1.25, 95% CI: 1.12-1.39, p=0.0001; I²=36%) (Figure 5B). Further analysis based on the SYNTAX score was available in five trials and showed that there was no difference in the two revascularisation strategies for a SYNTAX score 1-32.

**Figure 4.** Risk ratios for stroke and repeat revascularisation. Forest plots showing the risk ratio for stroke at one-year (A), stroke at long-term follow-up (B), repeat revascularisation at one-year (C) and repeat revascularisation at long-term follow-up (D) between the PCI- and CABG-treated groups. Size of data markers indicates weight of each trial included in the meta-analysis for stroke and repeat revascularisation. CABG: coronary artery bypass grafting; PCI: percutaneous coronary intervention
There was no publication bias observed with Egger’s linear regression except for cardiac (p=0.081) and all-cause death (p=0.064), which may be attributed to the different follow-up duration of the included studies and not all studies reporting cardiac death (Supplementary Figure 2). Sub-analysis of trials using first-generation (LE MANS, Boudriot, PRECOMBAT, SYNTAX) or predominantly newer-generation stents (NOBLE and EXCEL) did not show a significant difference in risk ratios for MACCE between the PCI- and CABG-treated groups.}

**PUBLICATION BIAS AND SENSITIVITY ANALYSES**

The risk of bias for individual trials was low in accordance with the Cochrane Collaboration’s tool (Supplementary Figure 1). There was no publication bias observed with Egger’s linear regression except for cardiac (p=0.081) and all-cause death (p=0.064), which may be attributed to the different follow-up duration of the included studies and not all studies reporting cardiac death (Supplementary Figure 2). Sub-analysis of trials using first-generation (LE MANS, Boudriot, PRECOMBAT, SYNTAX) or predominantly newer-generation stents (NOBLE and EXCEL) did not show a significant difference in risk ratios for MACCE between the PCI- and CABG-treated groups.

**Figure 5.** Risk ratios for MACCE between the PCI- and CABG-treated groups. Forest plots showing the risk ratio for major adverse cardiovascular and cerebral events (MACCE) at one-year (A), MACCE at long-term follow-up (B), MACCE for SYNTAX score ≤32 (C) and MACCE for SYNTAX score >32 (D). The size of data markers indicates the weight of each trial included in the meta-analysis for MACCE. CABG: coronary artery bypass grafting; PCI: percutaneous coronary intervention.
not show any major differences in MACCE (Supplementary Figure 3). Finally, meta-analysis with the exclusion of the LE MANS trial (as it used both bare metal stents [BMS] and drug-eluting stents [DES]) showed no significant difference in outcomes (Supplementary Figure 4).

Discussion

To date, this is the largest meta-analysis of randomised controlled trials comparing the clinical outcomes of PCI with stent(s) versus CABG for the treatment of unprotected LMS disease. We found no difference in all-cause and cardiac mortality between the two treatment strategies. All MI was similar at one year but higher afterwards in PCI-treated patients. Stroke rates were lower in PCI-treated patients at one year but the difference disappeared on long-term follow-up. Revascularisation rates remained higher in the PCI-treated group.

The trials included in this meta-analysis had differences in inclusion/exclusion criteria, complexity of coronary disease (LMS bifurcation disease, SYNTAX score, etc.), technical aspect of the procedure (type of stent, use of intravascular ultrasound, use of arterial grafts), definition of clinical endpoints, and duration of follow-up. Despite these differences, it is reassuring to see that both PCI and CABG provided effective treatment of unprotected LMS disease with no difference in survival. The LE MANS trial was the first randomised trial of PCI (n=52) vs. CABG (n=53). Only 35% had drug-eluting stents (DES) and 81% had a left internal mammary artery but the primary outcome of major adverse cardiac events (MACE) at one year was similar in the two groups11. This trial now has 10-year follow-up data available showing that mortality (21.6% vs. 30.2%, p=0.41), MI (8.7% vs. 10.4%, p=0.68), stroke (4.3% vs. 6.3%, p=0.58) and repeat revascularisation rates (26.1% vs. 31.3%, p=0.39) were similar between PCI and CABG11. Boudriot et al (n=201) and PRECOMBAT (n=600) compared PCI with sirolimus-eluting stenting versus CABG using predominantly arterial grafts and found no difference in death or MI, whilst revascularisation rates remained high in the PCI arm12. The SYNTAX trial compared PCI with a paclitaxel-eluting stent versus CABG but also went one step further to dissect the relationship of extent/complexity of coronary disease with revascularisation strategy1. It showed that both PCI and CABG may provide optimal revascularisation in the lower and middle terciles of SYNTAX score but, for the high score tercile, CABG was clearly superior12. NOBLE (n=1,201) and EXCEL (n=1,905) have compared PCI with newer-generation DES versus CABG. In NOBLE, there was no difference in mortality (12% vs. 9%, p=0.77) and stroke (5% vs. 2%, p=0.073), but higher rates of non-procedural MI (7% vs. 2%, p=0.004) and revascularisation (16% vs. 10%, p=0.032) in the PCI group4. In EXCEL, there was no difference in mortality (PCI 8.2% vs. CABG 5.9%, p=0.11), cardiac death (PCI 4.4% vs. CABG 3.7%, p=0.48), stroke and MI at three years; however, ischaemia-driven revascularisation was higher in the PCI arm (12.6% vs. 7.5%, p<0.001)5. A recent pooled analysis at the patient level of four registries showed an association of intravascular ultrasound guidance during PCI with better outcomes in patients with left main disease undergoing revascularisation with DES. Although in most patients in the EXCEL, NOBLE and PRECOMBAT trials intravascular ultrasound was performed for guiding stent deployment, the risk of ischaemia-driven revascularisation in the PCI arm was also higher in comparison with CABG.

It is also reassuring to see that the results of RCT and our meta-analysis are consistent with several registries comparing the two revascularisation strategies for the treatment of unprotected LMS disease. In the Bologna registry (n=311), there was no difference in mortality and MI but repeat revascularisation was higher in the PCI group14. The DELTA registry also showed no difference in mortality, MI or stroke between PCI- (n=1,874) and CABG-treated (n=901) patients; however, revascularisation remained higher in the PCI group15. An Italian registry of patients with unprotected LMS stenosis treated with PCI (n=107) or CABG (n=142) reported no difference in mortality (HR: 0.3, 95% CI: 0.055-1.404, p=0.17) at one year. PCI offered a lower composite endpoint of death and/or MI (HR: 0.26, 95% CI: 0.08-0.60, p<0.001) and death, MI, or stroke (HR: 0.38, 95% CI: 0.18-0.82, p=0.01)6. However, repeat revascularisation was 20% in the PCI versus 4% in the CABG group. The non-randomised MAIN-COMpare (Revascularisation for Unprotected Left Main Coronary Artery Stenosis; Comparison of Percutaneous Coronary Angioplasty Versus Surgical Revascularisation) registry assessed 1,138 patients undergoing CABG and 1,102 patients undergoing PCI (318 with BMS, 784 with DES). At three- and five-year follow-up, outcomes among a propensity-matched cohort of patients were comparable in terms of death and MACE, whereas repeat revascularisation was higher in the PCI group7. It would be appropriate to bear in mind that complex distal bifurcation or trifurcation LMS disease requiring multiple stents may affect PCI outcomes16-20. However, a study comparing PCI with DES (n=556) and CABG (n=309) in unprotected LMS bifurcation disease showed similar rates of death (HR: 0.95, 95% CI: 0.62-1.45), a similar composite endpoint of death/MI/stroke (HR: 0.97, 95% CI: 0.64-1.48) and higher repeat revascularisation with PCI (HR: 4.42, 95% CI: 2.39-8.18) at five-year follow-up. The outcomes were comparable between the simple stenting and complex stenting groups except for target vessel revascularisation (HR: 1.94, 95% CI: 1.22 to 3.10)21.

A previous meta-analysis of four trials (without EXCEL and NOBLE) including 1,611 patients showed that PCI, as compared to CABG, was associated with a significant reduction in the risk of stroke, an increased risk of repeat revascularisation, and a similar risk of mortality or MI, resulting in a higher risk of MACE but a similar risk of MACCE22. Similarly, a recent meta-analysis of five trials (excluding LE MANS) showed similar results23. The LE MANS trial was excluded from this meta-analysis due to limited use of DES (35%). However, the LE MANS trial now has 10-year follow-up and provides useful insights into further revascularisation in both the PCI and CABG arms. Furthermore, our sensitivity analysis has shown no difference in outcomes with or without LE MANS or difference in outcomes based on type of
stent used. Due to differences in the primary composite endpoints and definition of endpoints, we have chosen to compare the individual outcomes and focused mainly on mortality, MI and stroke. Our results have therefore conclusively shown comparable hard outcomes between PCI- and CABG-treated patients with significant LMS disease.

It is reassuring to see that both PCI and CABG provide effective treatment of unprotected LMS disease with no difference in survival. There are trends towards less stroke in PCI-treated patients and less MI in CABG-treated patients. The main advantage seen with CABG was a reduction in repeat revascularisation. This difference persisted even with the use of DES. However, one may argue that, without impact on survival, the need for revascularisation is not a hard endpoint and many patients would accept it to avoid the need for CABG.

Limitations
This meta-analysis has several potential limitations. The results are based on trial level data and share the limitations of the original trials. The definitions of clinical endpoints were not identical in all studies. Follow-up data among trials were variable, ranging from one year to 10 years. Finally, the trials included in this meta-analysis used a variety of stent platforms, and most of the available data are from older and non-everolimus-eluting stents. Thus, the pooled event rates, including repeat revascularisation, may not accurately reflect the performance of any one particular stent.

Conclusions
PCI and CABG offer comparable survival in patients with unprotected LMS disease. There were trends towards less MI in the CABG group and less stroke in the PCI group. CABG is associated with a significantly lower risk of repeat revascularisation. The Heart Team should make an individualised revascularisation decision based on the extent of downstream disease (SYNTAX score >32 favouring CABG), surgical risk (high risk favouring PCI), local resources/expertise and patient preference.

Impact on daily practice
The international guidelines, particularly those from the European Society of Cardiology/European Association for Cardio-Thoracic Surgery and American College of Cardiology/American Heart Association, provide a balanced, practical, patient-oriented, and evidence-based approach for coronary revascularisation. We believe future iterations of guidelines should update PCI for LMS to a class I (level of evidence A), at least for patients with a SYNTAX score ≤32. As per guideline recommendations, use of the Heart Team for decision making and intracoronary imaging to guide PCI should remain the standard of care. The final revascularisation decision should be made by the Heart Team and the individual patient after considering the evidence base, international guidelines, contemporary practice, and local resources and expertise.

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Conflict of interest statement
The authors have no conflicts of interest to declare.

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PCI vs. CABG for LMS disease

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**Supplementary data**

**Supplementary Figure 1.** Risk of bias across domains of study quality.

**Supplementary Figure 2.** Publication bias for studies in the meta-analysis.

**Supplementary Figure 3.** Risk ratios for MACCE between PCI- and CABG-treated groups according to stent type.

**Supplementary Figure 4.** Meta-analysis of five trials comparing PCI with DES vs. CABG.

The supplementary data are published online at: www.asiaintervention.org
Supplementary data

Supplementary Figure 1. Risk of bias across domains of study quality.

Proportions of studies classified as having low (green), unclear (yellow), and high (red) risk of bias according to Cochrane Collaboration’s tool.

Supplementary Figure 2. Publication bias for studies in the meta-analysis.

The Egger’s linear regression tests for all-cause death (A), cardiac death (B), myocardial infarction (C), stroke (D), repeat revascularisation (E) and major adverse cardiovascular and cerebral events (F).
Supplementary Figure 3. Risk ratios for MACCE between PCI- and CABG-treated groups according to stent type.

Forest plots showing risk ratio for major adverse cardiovascular and cerebral events (MACCE) at long-term follow-up for trials using first-generation or predominantly newer-generation stents. The size of data markers indicates the weight of each trial included in the meta-analysis for all-cause death.

CABG: coronary artery bypass grafting; PCI: percutaneous coronary intervention
Supplementary Figure 4. Meta-analysis of five trials comparing PCI with DES vs. CABG.

Forest plots showing risk ratio for all-cause death (A), cardiac death (B), myocardial infarction (C), stroke (D) and repeat revascularisation (E) comparing PCI with a drug-eluting stent (DES) versus CABG in PRECOMBAT, Boudriot, SYNTAX, NOBLE and EXCEL trials. The size of data markers indicates the weight of each trial included in the meta-analysis for all-cause death.

CABG: coronary artery bypass grafting; PCI: percutaneous coronary intervention