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Clinical Outcomes After Drug-Eluting Stents Versus Coronary Artery Bypass Surgery in High Surgical Risk Patients With Left Main or Three-Vessel Coronary Artery Disease

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Purpose
Previous studies comparing percutaneous coronary intervention (PCI) with coronary artery bypass graft surgery (CABG) in patients with unprotected left main or three-vessel coronary artery disease (LM-3VD) have excluded patients at high surgical risk. We compared clinical outcomes after PCI with drug-eluting stents to CABG in high surgical risk patients with LM-3VD.

Methods
Patients with symptomatic LM-3VD who had Society of Thoracic Surgeons (STS)-predicted operative mortality > 5% and were undergoing either PCI with drug-eluting stents or CABG at a tertiary care center from January 2009 to December 2010 were enrolled in this nonrandomized prospective study.

Results
Mean STS score was 14.5 ± 5.8% for PCI (n=83) versus 13.6 ± 7.1% for CABG (n=187) (P=0.31). After mean follow-up of 37 months, incidence of the composite primary endpoint (death, myocardial infarction or stroke) was 42.2% for PCI and 39.6% for CABG (P=0.69, hazard ratio 1.3, 95% confidence interval 0.5–2.8). There were no differences in the individual components of the primary endpoint between PCI and CABG. Repeat revascularization was 30.1% for PCI versus 9.6% for CABG (P=0.001). Major adverse cardiac and cerebrovascular event rates were similar between PCI and CABG, 50.6% versus 42.2%, respectively (P=0.23). Patients in the PCI group were less likely than those in the CABG group to be discharged to a nursing home (12.1% vs. 47.1%, P<0.001) and had shorter hospital stays (5.6 ± 5.7 days vs. 15.1 ± 10.6 days, P<0.001).

Conclusions
The composite rate of death, myocardial infarction or stroke is similar for PCI and CABG in patients with symptomatic LM-3VD who have STS-predicted operative mortality > 5%.

Keywords
high risk, three-vessel disease, left main, Heart Team, stenting, coronary artery bypass grafting

Left main or three-vessel coronary artery disease (LM-3VD) occurs in 27% of men and 8% of women older than 30 years who undergo coronary angiography for suspected coronary artery disease. Without revascularization, the prognosis is dismal, with 3-year mortality of 24% for three-vessel disease without left main disease and 30–50% when left main disease is present. Coronary artery bypass graft surgery (CABG) is the traditional gold standard for revascularization of LM-3VD. Over the past decade, outcomes of percutaneous coronary intervention (PCI) in complex coronary artery disease have improved due to advances in stent design and other interventional equipment, effectiveness of pharmacotherapy and experience of operators. Recent randomized controlled trials have shown that overall major adverse cardiac and cerebrovascular events (MACCE) are lower with CABG than PCI in patients revascularized for unprotected LM-3VD. However, the outcomes of CABG and PCI were similar in patients who have focal disease with SYNTAX score ≤ 22.

Due to the more invasive nature and higher short-term morbidity of CABG, PCI has been empirically considered a good alternative to CABG in patients with symptomatic LM-3VD who have STS-predicted operative mortality > 5%.
who are deemed a high surgical risk. In clinical practice, surgical risk is defined by different criteria including age,20,21 general frailty22,23 and surgical risk scores.24,25 The latest guidelines for PCI recommend consideration of PCI over CABG in patients with LM-3VD who have favorable coronary anatomy for PCI when Society for Thoracic Surgeons (STS) score predicts operative mortality as > 5%.7 However, this threshold is arbitrary and not based on published data because high surgical risk patients were excluded from major studies comparing PCI to CABG. The aim of this study was to compare clinical outcomes after PCI with drug-eluting stents versus CABG in patients with unprotected LM-3VD who have STS-predicted operative mortality > 5%.

METHODS

Design
This was a nonrandomized prospective study comparing clinical outcomes between high surgical risk patients who underwent PCI versus those who underwent CABG for symptomatic LM-3VD. Local institutional review board approval and signed informed consent from the subjects were obtained for the study.

Patients and Procedures
Consecutive patients who underwent PCI with drug-eluting stents or CABG for symptomatic unprotected LM-3VD at a single tertiary care center from January 2009 to December 2010 were included in the study if they had a baseline STS-predicted operative mortality > 5%. Documentation of ischemia based on symptoms of classic angina, a positive noninvasive test, newly decreased left ventricular ejection fraction or acute coronary syndrome was required. Patients were excluded from the study if they had previously undergone CABG or had a concomitant cardiac pathology that needed treatment at the time of revascularization (e.g. significant valve disease). Patients also were excluded if they had an allergy to aspirin or clopidogrel.

Left main revascularization was performed for angiographic stenosis > 50% or minimal luminal area ≤ 6 mm² as determined by intravascular ultrasound. Other epicardial arteries were revascularized for angiographic stenosis > 70%, minimal luminal area by ultrasound < 4 mm² on proximal segments or fractional flow reserve < 0.8. The choice of revascularization method was at the discretion of the treating physicians and their patients, usually with collaboration from our institution’s multidisciplinary Heart Team. Periprocedural therapies and maintenance treatments were provided according to standard clinical guidelines.

Data Collection
A previously tested and validated data collection questionnaire was used to extract data from patients’ electronic medical records. Baseline sociodemographic and clinical comorbidities as well as indications for revascularization were recorded. Information on equipment used, medications given and grafts used were obtained from procedural reports and case documents. Angiograms were reviewed by two independent cardiologists, and SYNTAX scores were calculated using the online SYNTAX Score Calculator®, Version 2.1 (www.syntaxscore.com).26 Surgical risk scores were calculated for all patients using the online logistic EuroSCORE calculator (www.euroscore.org/calc.html)27 as well as the STS Risk Calculator (riskcalc.sts.org/STSWebRiskCalc273/).28

Endpoints
Endpoints were identified by reviewing data from patients’ medical records. Patients who had no follow-up records were called for a phone interview to inquire about cardiac events. The primary endpoint was a composite of death from any cause, myocardial infarction or stroke, whichever occurred first. Individual secondary endpoints were myocardial infarction, stroke, death from any cause and ischemia-driven repeat revascularization. MACCE constituted a composite secondary endpoint comprising the four individual secondary endpoints. Myocardial infarction was defined as a rise and fall in troponin associated with ischemic symptoms, new ischemic changes on electrocardiogram, new regional wall motion abnormalities or loss of viable myocardium on imaging. Stroke was defined as a new focal neurological deficit lasting > 24 hours or radiological evidence of acute cerebral infarction or hemorrhage. Repeat revascularization was defined as any subsequent PCI or CABG after the index procedure that was performed for definite angina, worsening cardiomyopathy, abnormal noninvasive study or acute coronary syndromes. Out-of-hospital deaths were identified through the National
Death Index. Follow-up time was counted from the date of index revascularization.

Statistical Analyses
Summary descriptive statistics for continuous variables were expressed as means (± standard deviation), and univariate comparisons were made between PCI and CABG groups using the Mann-Whitney U test. Categorical variables were reported as percentages and compared using Fisher’s exact test. Treatment selection bias was overcome by using propensity-matched analysis. A propensity score was calculated for each patient using multivariate binary logistic regression, which was calculated as the probability of undergoing PCI (rather than CABG) as predicted by baseline characteristics, namely age, sex, race, cardiac risk factors, comorbidities, acuity of clinical presentation, presence of left main disease and SYNTAX score. Cumulative event rates were compared using Kaplan-Meier analysis and the log-rank test. Hazard ratios with 95% confidence intervals (CI) were calculated by multivariate Cox regression adjusting for propensity score, STS score, SYNTAX score and left main disease. We assessed the model for overfitting by tracking the trend in the adjusted R²-values and deterioration in the P-values of regression coefficients. Prespecified stratified analyses were performed to determine subgroup differences. All P-values were two-sided.

RESULTS
Of 362 patients revascularized for LM-3VD with a baseline STS score > 5%, 92 patients were excluded (Figure 1). The mean age in our final study sample (n=270) was 77 ± 9 years, and 44% were women. Patients ≥ 80 years old made up 41.9% of the study. There was high prevalence of comorbidities in both study groups (Table 1). The high-risk profile of the study sample is illustrated by the mean STS score of 13.9 ± 6.8%. There were 39.6% of patients with an STS score ≥ 15, which is considered extreme risk. Although there was no difference in the mean STS score between PCI and CABG, more patients revascularized with PCI fell in this extreme risk category (63.9% vs. 28.9%, P<0.001). There was no significant difference in SYNTAX score and number of lesions between the PCI and CABG groups, but left main disease was more common in the PCI group while the average number of arteries revascularized was greater in the CABG group. Other baseline characteristics were similarly distributed between the two groups.

All patients were followed for at least 24 months, with a total mean follow-up of 37 months (range: 24–49 months). There was complete verification of all primary endpoints. Figure 2 shows Kaplan-Meier curves for survival free of the primary endpoint (i.e. composite death, myocardial infarction or stroke). Although there was no significant difference in the incidence of the primary endpoint between both groups, there seemed to be a biphasic trend for lower (but not statistically significant) incidence in the PCI group during the first 9 months and then lower in the CABG group after 9 months. The 1-month incidence of the primary endpoint was 14.5% for PCI versus 19.3% for CABG (P=0.39). The incidence of the primary endpoint at the end of the 3.1-year study period was 42.2% for PCI versus 39.6% for CABG (P=0.69, hazard ratio: 1.3, 95% CI: 0.5–2.8). We performed further analysis to compare the primary endpoint between PCI and CABG within subgroups of patients defined by the presence of predictors of adverse outcomes at baseline (Figure 3). There was no difference in the primary endpoint between PCI and CABG among patients who had left main disease or three-vessel disease. There also was no significant interaction between method of revascularization and either STS score, age, diabetes, previous cardiothoracic surgery, left ventricular ejection fraction or SYNTAX score.
Table 1. Baseline patient characteristics

<table>
<thead>
<tr>
<th>Variable</th>
<th>PCI (n=83)</th>
<th>CABG (n=187)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, years</td>
<td>76.5 ± 9</td>
<td>77 ± 9.6</td>
<td>0.71</td>
</tr>
<tr>
<td>Women</td>
<td>41.0</td>
<td>44.9</td>
<td>0.55</td>
</tr>
<tr>
<td>White</td>
<td>78.3</td>
<td>85.6</td>
<td>0.16</td>
</tr>
<tr>
<td>Diabetes mellitus</td>
<td>50.6</td>
<td>42.2</td>
<td>0.21</td>
</tr>
<tr>
<td>Smoker</td>
<td>51.8</td>
<td>50.3</td>
<td>0.89</td>
</tr>
<tr>
<td>Chronic lung disease</td>
<td>46.3</td>
<td>36.8</td>
<td>0.17</td>
</tr>
<tr>
<td>Renal failure*</td>
<td>23.2</td>
<td>24.7</td>
<td>0.78</td>
</tr>
<tr>
<td>Prior PCI</td>
<td>45.8</td>
<td>26.2</td>
<td>0.001</td>
</tr>
<tr>
<td>Prior cardiothoracic surgery†</td>
<td>60.2</td>
<td>20.3</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>LVEF ≤ 30%</td>
<td>18.1</td>
<td>23.5</td>
<td>0.32</td>
</tr>
<tr>
<td>Clinical presentation</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>STEMI</td>
<td>9.6</td>
<td>8.6</td>
<td>0.82</td>
</tr>
<tr>
<td>Non-STEMI/unstable angina</td>
<td>33.7</td>
<td>30.5</td>
<td>0.67</td>
</tr>
<tr>
<td>Stable coronary disease</td>
<td>56.6</td>
<td>60.9</td>
<td>0.51</td>
</tr>
<tr>
<td>STS score</td>
<td>14.5 ± 5.8</td>
<td>13.6 ± 7.1</td>
<td>0.31</td>
</tr>
<tr>
<td>EuroSCORE</td>
<td>21.8 ± 14</td>
<td>19.8 ± 15</td>
<td>0.24</td>
</tr>
<tr>
<td>SYNTAX score</td>
<td>37.0 ± 12</td>
<td>40.0 ± 15</td>
<td>0.12</td>
</tr>
<tr>
<td>Left main disease</td>
<td>62.6</td>
<td>39.6</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Three-vessel disease</td>
<td>73.5</td>
<td>84.0</td>
<td>0.06</td>
</tr>
<tr>
<td>Number of arteries§</td>
<td>2.5 ± 0.7</td>
<td>2.9 ± 0.3</td>
<td>0.001</td>
</tr>
<tr>
<td>Number of lesions</td>
<td>4.5 ± 2</td>
<td>4.8 ± 1.1</td>
<td>0.35</td>
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<tr>
<td>Discharge medications</td>
<td></td>
<td></td>
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<tr>
<td>Aspirin</td>
<td>92.8</td>
<td>90.3</td>
<td>0.18</td>
</tr>
<tr>
<td>P2Y12 inhibitor</td>
<td>95.2</td>
<td>14.4</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Beta blocker</td>
<td>81.9</td>
<td>75.4</td>
<td>0.31</td>
</tr>
<tr>
<td>Statin</td>
<td>85.5</td>
<td>75.4</td>
<td>0.08</td>
</tr>
<tr>
<td>ACEI/ARB</td>
<td>54.2</td>
<td>25.7</td>
<td>0.001</td>
</tr>
<tr>
<td>Internal mammary artery used</td>
<td></td>
<td>92.5</td>
<td></td>
</tr>
<tr>
<td>Number of grafts per patient</td>
<td></td>
<td>2.7 ± 0.8</td>
<td></td>
</tr>
<tr>
<td>Off-pump surgery</td>
<td></td>
<td>4.3</td>
<td></td>
</tr>
<tr>
<td>Stent type</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Everolimus-eluting</td>
<td>59.0</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Zotarolimus-eluting</td>
<td>21.7</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sirolimus-eluting</td>
<td>18.1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Paclitaxel-eluting</td>
<td>1.2</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Values are percentage or mean ± standard deviation.

*Creatinine > 2 mg/dL.

†Noncoronary cardiothoracic surgery like valves, structural heart disease, thoracic aorta, etc.

§Grouped by main arteries — right coronary, left main, left anterior descending and left circumflex.

ACEI, angiotensin-converting enzyme inhibitor; ARB, angiotensin receptor blocker; CABG, coronary artery bypass graft surgery; LVEF, left ventricular ejection fraction; PCI, percutaneous coronary intervention; STS, Society of Thoracic Surgeons.
Comparisons of secondary endpoints are shown in Table 2. Over the study period the rates of the individual endpoints of death, myocardial infarction and stroke were similar between PCI and CABG. The 30-day mortality was 12.1% for PCI versus 14.4% for CABG (P=0.70). Because our data sources were unreliable in correctly identifying the cause of death, we could not accurately specify cardiac mortality. The incidence of stroke was lower for PCI than CABG during the first year of follow-up only; the difference was not significant thereafter. Stroke rates were 1.2% for PCI versus 7.5% for CABG at 30 days (P=0.038), and 2.4% versus 8.0%, respectively, at 1 year (P=0.08). Unfortunately, the databases we accessed did not have follow-up tracking of stroke or residual disability out to 3 years. Repeat revascularization was the only clinical event with a significant difference. The rate of repeat revascularization was three times greater for PCI than CABG. All repeat revascularizations were performed by PCI. Putting all four individual endpoints together, the rate of MACCE was similar between PCI and CABG over 3.1 years.

We used length of stay as a surrogate for resource utilization during the index hospitalization. Both median length of stay in the intensive care unit and total hospital length of stay were significantly shorter for PCI than CABG (Figure 4). The mean intensive care unit stay was 2.1 ± 3.6 days for PCI versus 7.4 ± 8.8 days for CABG, a mean difference of 5.3 days (95% CI: 3.8–6.8, P<0.001). The mean total length of stay during index hospitalization was 5.6 ± 5.7 days for PCI versus 15.1 ± 10.6 days for CABG, a mean difference of 9.5 days (95% CI: 7.6–11.5, P<0.001). We also compared discharge destinations between the PCI and CABG groups. In the PCI group 85.5% were discharged home and 12.1% went to a specialized nursing/rehabilitation facility versus 41.7% going home and 47.1% going to a

![Figure 2. Kaplan-Meier curves for survival free of the primary endpoint (death, myocardial infarction or stroke) in high surgical risk patients treated with percutaneous coronary intervention (PCI) or coronary artery bypass graft surgery (CABG).](image-url)
specialized nursing/rehabilitation facility after CABG (P<0.0001). Two patients (2.4%) from the PCI group died in the hospital, whereas 21 patients (11.2%) from the CABG group died in the hospital (P=0.017).

**DISCUSSION**

We performed a nonrandomized prospective study to compare the outcomes of PCI using drug-eluting stents and CABG in patients with unprotected LM-3VD who had baseline STS-predicted operative mortality > 5%. Over a mean follow-up period of 3.1 years the composite primary endpoint of death, myocardial infarction or stroke occurred in 42.2% of PCI patients and 39.6% of CABG patients (P=0.69). There was no difference in the primary endpoint among subgroups of patients with left main disease and those with three-vessel disease. The respective individual endpoints were similar between PCI and CABG. Repeat revascularization was more than three times more likely in PCI than CABG but did not lead to a higher rate of MACCE. Length of intensive care unit stay and total duration of index hospitalization was significantly longer for CABG than PCI. Patients treated with CABG were nearly four times more likely to be discharged to a specialized nursing facility than those treated with PCI.

This is the first study to directly compare PCI and CABG in high surgical risk patients. In the SYNTAX trial, the mean EuroSCORE-predicted mortality among randomized patients was 3.8 ± 2.6%. Even in the PCI registry arm, where patients were enrolled due to high surgical risk, the mean EuroSCORE was only 5.8 ± 3.1%. In the LE MANS registry of patients with left main disease treated by PCI, the mean EuroSCORE was 6.0 ± 2.8%, and the observed mortality and MACCE rates were 13.9% and 25.4%, respectively, after a mean follow-up of 3.8 years. The mean EuroSCORE in our study was 21.8%. Advanced age is one of the most important surgical risk factors. In a nonrandomized study of 249 patients ≥ 80 years old that compared PCI to CABG in patients with unprotected left main disease, there was no difference in rates of MACCE between PCI (43.3%) and CABG (35.2%) after a mean follow-up of about 2 years (hazard ratio: 1.11, 95% CI: 0.59–2.0). About 20% of these patients had
concomitant three-vessel disease. Although this study included patients based on only one component of surgical risk, the findings were similar to our study.

High surgical risk patients with LM-3VD present a clinical dilemma. The decision of how to revascularize these patients is even more difficult when SYNTAX score is high. The importance of managing these patients using a comprehensive Heart Team approach cannot be overemphasized.7,8,31 The mortality rate is high in patients with multiple comorbidities who are not revascularized; however, our study shows high mortality even after either surgical or percutaneous revascularization. This finding underscores the importance of taking into account the overall prognosis when considering revascularization in high-risk patients. Our subgroup analysis showed no difference between PCI and CABG irrespective of SYNTAX or STS score category, but the subgroup numbers are too small to draw conclusions. Modifications have been proposed to reduce operative mortality and morbidity in these high-risk patients. Off-pump CABG may reduce operative complications and mortality compared to on-pump CABG, but may not be suitable for complex coronary anatomies.32 Hybrid coronary revascularization is another alternative to traditional CABG or PCI alone in high-risk patients. Surgery is done to graft an internal mammary artery to the left anterior descending artery, then PCI is performed on other coronary arteries.33 Small nonrandomized studies comparing hybrid revascularization to traditional CABG have shown similar short-term results, but long-term outcomes are unknown.33,34 An appropriate discussion to have is when revascularization should be attempted in high-risk patients and how high-risk revascularization compares to optimal medical treatment alone. A third treatment arm of optimal medical therapy would have been informative; unfortunately, such a group with sufficient follow-up data could not be identified for this study.

There are some limitations to our study. Our definition of high surgical risk as STS-predicted mortality > 5% may not be acceptable to everyone. However, this is the value used to quantify high surgical risk in the 2011 PCI guidelines.7 The STS score28 and EuroSCORE27 are the two most commonly used and best validated tools to quantify surgical risk in patients undergoing open heart surgery. Both scores have good predictive accuracy for operative mortality, but STS score may perform slightly better than EuroSCORE.35 Newer scoring methods for PCI that add clinical variables to angiographic characteristics, like the “clinical SYNTAX score” and the “SYNTAX II score,” have shown better accuracy than the angiographic SYNTAX score used in this study in predicting adverse events.36,37 Unfortunately, unlike the angiographic SYNTAX score, these newer scores have not been tested in a study on CABG patients and have not made it into routine clinical practice. In our study it was not entirely clear for all patients how decisions were made to undergo one method of revascularization versus the other. A formal surgical consult was documented in only 45 of the 83 patients treated by PCI. Counting CABG patients, this means 232 (86%) out of all 270 patients were officially assessed by the Heart Team comprised of a surgeon and cardiologist. We believe this study reflects real-life practice in which the cardiologist and patient together decide to skip the surgical consult when there is a strong preference for PCI by the patient. However, it is important to reemphasize here the necessity of a proper Heart Team consultation.7,8,31 Third, our study demonstrated greater upfront resource use and short-term morbidity (based on length of stay and discharge to specialized nursing facility) after CABG than PCI.
in high surgical risk patients with LM-3VD. We, however, did not integrate actual cost data and cannot conclude that any initial cost savings will translate into long-term cost benefit given the greater need for repeat revascularization in the PCI group. Lastly, our study represents the experience of a single center and was not randomized. Our sample size may also be too small to draw definite conclusions.

CONCLUSIONS
In patients with unprotected left main or three-vessel coronary artery disease who have an STS-predicted operative mortality > 5%, the combined rate of death, myocardial infarction or stroke is similar in those revascularized by percutaneous coronary intervention with drug-eluting stents or coronary artery bypass graft surgery. PCI was associated with a higher rate of repeat revascularization than CABG, but this did not translate into a higher rate of major adverse cardiac and cerebrovascular events. Compared to patients who underwent CABG, those who underwent PCI had shorter intensive care unit and hospital stays and were also more likely to be discharged home as opposed to a specialized nursing facility. PCI may be the preferred method of myocardial revascularization over CABG in high surgical risk patients with left main or three-vessel coronary artery disease due to its lower early morbidity but similar long-term clinical outcomes.

Acknowledgments
The authors gratefully acknowledge Brian Miller and Brian Schurrer of Aurora Sinai Medical Center for their help with figures.

Conflicts of Interest
None.

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Patient-Friendly Recap
• As clinical techniques and technology advance, standard treatment recommendations must be continuously reviewed and updated.
• Patients with coronary artery disease in whom bypass surgery is deemed high risk may be better served by a less invasive revascularization procedure, called PCI, that uses drug-eluting stents to improve blood flow.
• The authors compared this type of PCI to surgery in high-risk patients and found similar success rates between the two.
• They also noted that patients who undergo PCI are able to leave the hospital sooner but require a future procedure more often than their counterparts who undergo surgery.

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