Impact of Operator Experience and Volume on Outcomes After Left Main Coronary Artery Percutaneous Coronary Intervention

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ABSTRACT

OBJECTIVES The aim of this study was to assess the impact of operator experience on prognosis after left main coronary artery (LM) percutaneous coronary intervention (PCI).

BACKGROUND LM PCI can be technically challenging and potentially risky considering the amount of supplied myocardium.

METHODS Consecutive patients who underwent unprotected LM PCI at a single institution were included and compared according to whether the primary operator was an experienced, high-volume LM operator (defined as an operator who performed at least 15 LM PCIs per year for at least 3 consecutive years) or not. Kaplan-Meier estimates and Cox proportional hazards models are presented.

RESULTS From January 2004 to December 2011, a total of 1,948 patients underwent unprotected LM PCI by 25 operators. Of these, 7 operators (28%) were considered experienced, and 18 (72%) were considered less experienced, with an overall mean experience of 12.0 ± 11.5 LM PCIs per year. LM PCI was performed in 1,422 patients (73%) by experienced operators and in 526 patients (27%) by less experienced operators. Patients treated by experienced operators had more complex and extensive coronary artery disease. Unadjusted and adjusted risks for cardiac death were lower for patients who were treated by experienced operators, both at 30-day (unadjusted hazard ratio [HR]: 0.23; 95% confidence interval [CI]: 0.09 to 0.60; p = 0.003; adjusted HR: 0.22; 95% CI: 0.09 to 0.59; p = 0.003) and 3-year (unadjusted HR: 0.53; 95% CI: 0.32 to 0.89, p = 0.02; adjusted HR: 0.49; 95% CI: 0.29 to 0.84; p = 0.009) follow-up. Discrimination improved when operator experience was added to Cox proportional hazards models containing the SYNTAX (Synergy Between PCI With Taxus and Cardiac Surgery) score (integrated discriminatory index = 0.004, p = 0.03) or SYNTAX score II (integrated discriminatory index = 0.007, p = 0.02). No significant interaction was detected between operator experience and distal bifurcation LM lesion, 2-stent bifurcation stenting, and intravascular ultrasound use (p > 0.10 for all).

CONCLUSIONS Patients who underwent LM PCI by high-volume and experienced operators had better short- and long-term prognoses. Operator experience is an important factor in a complex intervention such as LM PCI. (J Am Coll Cardiol Intv 2016;9:2086–93) © 2016 by the American College of Cardiology Foundation.
Left main coronary artery (LM) percutaneous coronary intervention (PCI) is associated with favorable outcomes compared with coronary artery bypass grafting (CABG) for patients with low or intermediate SYNTAX (Synergy Between PCI With Taxus and Cardiac Surgery) scores (<32) and coronary anatomy suitable for PCI. LM PCI is therefore considered a valid alternative in current guidelines (1-5). Consequently, an increasing number of patients are undergoing LM PCI each year (5). LM PCI may be technically challenging, and given the amount of myocardium at risk, suboptimal results can lead to devastating complications, including death (3). Optimizing these complex procedures is therefore crucial if outcomes are to be improved. Although operator experience and volume have been shown to be associated with improved prognosis in many other surgical and interventional procedures (6-8), the impact of operator experience after LM PCI remains unknown. Herein, we report the impact of operator experience and volume on short- and long-term outcomes in a large cohort of 1,948 patients who underwent LM PCI.

METHODS

STUDY PROTOCOL AND PATIENTS. We included 1,948 consecutive patients who underwent unprotected LM PCI from January 2004 to December 2011 at Fu Wai Hospital, Beijing, China. Clinical, procedural, and outcomes data were recorded in a dedicated database. Follow-up was performed via office visit or telephone contact at 30 days and at 6, 12, 24, and 36 months.

OBJECTIVE AND ENDPOINTS. The study objective was to compare outcomes between patients who underwent LM PCI by experienced, high-volume operators and patients who underwent LM PCI by low-volume operators. Our primary endpoint of interest was cardiac mortality at 3 years after PCI. Our key secondary endpoint was cardiac death at 30 days. Secondary endpoints included the rates of all-cause death, myocardial infarction (MI), stent thrombosis, stroke, and target vessel revascularization (TVR) at 30 days and 3 years.

DEFINITIONS. We defined an experienced and high-volume LM PCI operator as an operator who performed at least 15 LM PCIs per year for at least 3 consecutive years. We defined cardiac death as any death that could not be attributed to a noncardiac cause, MI as creatine kinase concentration >2 times the upper limit of normal, stent thrombosis as any definite or probable Academic Research Consortium-defined stent thrombosis, and TVR as any revascularization within the entire major coronary vessels proximal or distal to a target lesion, including upstream and downstream side branches and the target vessel lesion itself.

STATISTICAL ANALYSIS. Categorical variables are presented as rates or percentages and were compared using the chi-square test. Continuous data are presented as mean ± SD or as median (interquartile range) and were compared using analysis of variance or the Kruskal-Wallis test, as appropriate. Three-year outcomes are presented as Kaplan-Meier estimates and were compared using the log-rank test. Multivariate Cox proportional hazard models were constructed to identify independent predictors of outcomes at 30 days and 3 years. The following variables were included in the model: age, left ventricular ejection fraction, previous MI, intravascular ultrasound (IVUS) use, SYNTAX score, and creatinine clearance. We determined the net reclassification index and integrated discriminatory index associated with operator experience by comparing models that included operator experience as an independent variable against reduced models that did not include operator experience. We performed subgroup analyses by including interaction terms between operator experience and the variable of interest. A p value of <0.05 was considered to indicate statistical significance. Statistical analyses were performed using SAS version 9.1.3 (SAS Institute, Cary, North Carolina).

RESULTS

CLINICAL AND PROCEDURAL CHARACTERISTICS. Among the entire cohort of 1,948 patients, 25 operators performed the LM PCI procedures. Of those patients, 1,422 (73%) were treated by 7 high-volume operators (28%), and 526 (27%) were treated by 18 low-volume operators (72%). Overall, the mean number of LM PCI performed each year per operator was 12 ± 12 and ranged from 1 to 43. High-volume operators performed a mean of 25 ± 8 LM PCI procedures yearly, and low-volume operators performed a mean of 4 ± 3 LM PCIs. Baseline characteristics are presented in Table 1. Patients who underwent LM PCI with high-volume operators had more extensive coronary artery disease and more often had complex lesions, including distal LM bifurcation lesions. Patients who were treated by high-volume operators were also more likely to receive first-generation...
rather than second-generation drug-eluting stents (DES). They also had higher SYNTAX and SYNTAX II scores. High-volume operators more frequently used IVUS to guide their procedures (39.2% vs. 31.7%, p = 0.002).

**30-DAY CLINICAL OUTCOMES.** Mortality within 30 days was 0.6% for patients treated by high-volume operators and 2.1% for patients treated by low-volume operators (p = 0.008) (Table 2, Figure 1). Thirty-day rates of MI, stroke, TVR, and stent thrombosis were nominally lower for patients who were treated by high-volume operators, but these differences were not statistically significant (Table 2). Being treated by a high-volume operator was associated with a lower adjusted risk for cardiac death (adjusted hazard ratio [HR]: 0.22; 95% confidence interval [CI]: 0.09 to 0.59; p = 0.003) (Table 3, Online Table 1) and all-cause mortality (adjusted HR: 0.30; 95% CI: 0.12 to 0.73; p = 0.008) and a trend toward decreased risk for stent thrombosis (adjusted HR: 0.34; 95% CI: 0.11 to 1.06; p = 0.06).

**3-YEAR CLINICAL OUTCOMES.** Complete 3-year follow-up data were available for 1,912 patients (98.2%). When patients were stratified into tertiles on the basis of operator experience, there was a statistically significant trend toward lower risk for cardiac death for patients treated by experienced operators (Figure 2A). The same trend was observed when operators were stratified into tertiles (Figure 2B). Patients who were treated by high-volume operators had a significantly lower risk for the primary endpoint, cardiac death (2.5% vs. 4.6%, p = 0.02),
with a trend toward lower all-cause mortality (3.8% vs. 5.3%, p = 0.15). There were no significant differences in rates of MI, stent thrombosis, or TVR (Table 2).

After adjustment for known cardiovascular risk factors by multivariate Cox proportional hazards regression, being treated by a high-volume operator was associated with an almost halved risk for cardiac death (HR: 0.49; 95% CI: 0.29 to 0.84; p = 0.009) (Tables 4 and 5, Online Table 1). The integrated discriminatory index but not the net reclassification index was significantly improved when operator experience was added to a model adjusted for clinical risk factors (Table 6). The integrated discriminatory index was also significantly improved when operator experience was added to models including either the SYNTAX score or the SYNTAX score II.

**SUBGROUP ANALYSES.** We found no significant difference in the magnitude of effect of operator experience on the risk for cardiac death at 3 years according to whether 1 or 2 stents were used (p = 0.39), whether the target lesion involved the distal LM bifurcation (p = 0.93), and whether IVUS was used (p = 0.47) (Figure 3).

**DISCUSSION**

Drawn from more than 1,900 patients undergoing unprotected LM PCI, the present analysis represents the largest study to assess the impact of operator experience on clinical outcomes after LM PCI. The main findings of our study are as follows: 1) patients treated by experienced, high-volume operators have a significantly reduced risk for cardiac death at short- and long-term follow-up after LM PCI, despite having more extensive and complex coronary artery disease at baseline; 2) operator experience was a strong independent predictor of cardiac death after LM PCI; and 3) incorporating operator experience and volume in an already validated stratification model such as the SYNTAX score and the SYNTAX score II improved the discrimination capability of these score algorithms.

PCI is an alternative to CABG for patients with LM disease who have low (1,2) or intermediate (3,4) SYNTAX scores and/or lesion anatomy that is deemed suitable for PCI (1,2,5). LM PCI is also a good alternative for patients with certain clinical characteristics, such as concomitant chronic obstructive pulmonary disease and presentation with acute...
coronary syndromes (1,9). Recently, subanalysis of 2 large, multicenter, randomized trials demonstrated similar outcomes for patients with LM disease who underwent CABG and PCI at 5 years of follow-up (4,10). Notably, the trials used first-generation DES rather than the superior second-generation DES (11,12). Had contemporary DES platforms been used in these trials, the results may have been different (13).

Two large-scale, multicenter, randomized trials are currently addressing whether contemporary PCI is equivalent or superior to CABG for selected patients with LM disease (NCT01205776, NCT01496651). Data from these trials will soon be available and may provide meaningful information. However, these large international trials have been conducted among many centers, with heterogeneity in operators experience and volume. Quantifying the impact of operator experience within these trials will be challenging, if not impossible, given the large operator-to-patient ratios in these trials.

Multiple studies have identified predictors of worse outcomes after LM PCI (including renal insufficiency, low ejection fraction, concomitant peripheral vascular disease, higher SYNTAX score, presentation with acute coronary syndromes (1,9), and presence of distal bifurcation LM disease) (4,9,14-16); however, to the best of our knowledge, no studies have assessed or considered operator experience when assessing predictors of outcomes after LM PCI. Given that a considerable and increasing number of patients undergo LM PCI each year (5) and that LM PCI is a high-risk procedure (3), every measure should be taken to optimize these procedures and minimize the risk for adverse events for these patients.

### Table 4

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Unadjusted Hazard Ratio (95% Confidence Interval)</th>
<th>p Value</th>
<th>Adjusted Hazard Ratio (95% Confidence Interval)</th>
<th>p Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>All-cause death</td>
<td>0.70 (0.45-1.11)</td>
<td>0.13</td>
<td>0.65 (0.41-1.03)</td>
<td>0.07</td>
</tr>
<tr>
<td>Cardiac death</td>
<td>0.53 (0.32-0.89)</td>
<td>0.02</td>
<td>0.49 (0.29-0.84)</td>
<td>0.009</td>
</tr>
<tr>
<td>MI</td>
<td>0.88 (0.60-1.29)</td>
<td>0.51</td>
<td>0.86 (0.59-1.26)</td>
<td>0.45</td>
</tr>
<tr>
<td>Target vessel revascularization</td>
<td>1.33 (0.86-2.05)</td>
<td>0.20</td>
<td>1.30 (0.84-2.01)</td>
<td>0.24</td>
</tr>
<tr>
<td>Definite/probable ST</td>
<td>0.76 (0.37-1.56)</td>
<td>0.46</td>
<td>0.73 (0.36-1.52)</td>
<td>0.41</td>
</tr>
<tr>
<td>Death/stroke/MI</td>
<td>0.81 (0.59-1.10)</td>
<td>0.17</td>
<td>0.78 (0.57-1.07)</td>
<td>0.12</td>
</tr>
</tbody>
</table>

The following variables were included in each model: age, left ventricular ejection fraction, previous MI, intravascular ultrasound use, SYNTAX score, and creatinine clearance. Abbreviations as in Tables 1 and 2.

### Table 5

<table>
<thead>
<tr>
<th>Predictor</th>
<th>Adjusted Hazard Ratio (95% Confidence Interval)</th>
<th>p Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Experienced operator</td>
<td>0.49 (0.29-0.83)</td>
<td>0.009</td>
</tr>
<tr>
<td>Left ventricular ejection fraction</td>
<td>0.47 (0.35-0.62)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>SYNTAX score</td>
<td>1.03 (1.00-1.07)</td>
<td>0.057</td>
</tr>
<tr>
<td>Previous myocardial infarction</td>
<td>1.79 (1.00-3.22)</td>
<td>0.051</td>
</tr>
<tr>
<td>Age (per 10 yrs)</td>
<td>1.19 (0.84-1.67)</td>
<td>0.33</td>
</tr>
<tr>
<td>Creatinine clearance (per 10 U)</td>
<td>0.95 (0.83-1.09)</td>
<td>0.48</td>
</tr>
<tr>
<td>Intravascular ultrasound use</td>
<td>0.62 (0.34-1.14)</td>
<td>0.13</td>
</tr>
</tbody>
</table>

*To avoid overfitting of the model, the impact of second-generation DES was evaluated by substituting intravascular ultrasound use for it in the model.

Abbreviation as in Table 1.

(A) Patients are grouped into tertiles according to the experience of the operator who performed the procedure. Operator experience was defined as the mean number of left main coronary artery percutaneous coronary intervention procedures performed by the operator per year. (B) Patients are grouped according to tertiles of operators, where the operators are ranked on the basis of their experience, defined as in A. The p values refer to p values for trend across groups. N refers to the number of patients in each group. Presented are also the median and the interquartile range of operator experience for each group.
Our findings demonstrate that operator experience is a major determinant of outcomes after LM PCI. This is an important finding because the impact of operator experience on outcomes after mainstream (simple) PCI is a matter of active debate (17-33). Some PCI procedures are more technically demanding than others. Several patient and lesion characteristics are associated with more difficult procedures and a higher risk for adverse events. It is likely that operator experience has a greater influence on the outcomes of complex PCI procedures than more simple procedures. For example, experienced operators have higher success rates and fewer complications when it comes to PCI of chronic total occlusions, an important high-risk lesion subset (34,35); however, these studies have not been powered for clinical endpoints. Similarly, operator experience has been shown to be important for other more demanding procedures, including transradial procedures, bifurcation PCI, and structural heart (e.g., transcatheter aortic valve replacement, mitral clip) procedures in general (36-40).

Our study has potentially important clinical implications. It is the first study to conclusively show that operator experience affects prognosis after high-risk PCI, in this case LM PCI. We show that operator experience appears to be important regardless of LM PCI type (i.e., proximal lesion vs. distal LM bifurcation lesion and 1 stent vs. 2 stents) and whether IVUS is used to guide the procedure. Importantly, patients who were treated by experienced operators had a better prognosis despite the fact that this group had more advanced coronary artery disease, underwent more technically complex procedures, and were less likely to receive second-generation DES. Furthermore, the excess deaths and stent thromboses that were observed among patients treated by low-volume operators occurred within days of the procedure and are thus most likely related to procedural factors. In contrast, TVR beyond 1 year was more common among patients treated by high-volume operators. The latter finding is not surprising and is most likely related to the more extensive and complex coronary artery disease and higher cardiovascular risk profile present at baseline within the experienced group. Our findings call attention to the need for experienced high-volume operators to be present when LM PCI is performed. Furthermore, our results suggest that operator experience should be considered when choosing between revascularization strategies for patients with LM disease. Currently available algorithms that are used to decide between PCI and CABG (e.g., SYNTAX score, European System for Cardiac Operative Risk Evaluation score, and SYNTAX score II) would benefit of integrating information on operator experience (9). In light of our findings, prospective validation of this concept among patients undergoing complex revascularization (both by PCI or CABG) is warranted.

**STUDY LIMITATIONS.** First, this was a retrospective analysis and, as such, should be considered hypothesis generating.

Second, the event rates were low. This was particularly true for events at 30 days and may have resulted in overfitting of the multivariate Cox models. The adjusted models presented herein should therefore be interpreted with caution. That being said, the adjusted risk estimates were similar between multivariate Cox model analysis and, as such, should be considered hypothesis generating.

Third, this was a single-center study. Its external validity is uncertain. The high-volume PCI operators

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### TABLE 6

<table>
<thead>
<tr>
<th>Reduced Model</th>
<th>Net Reclassification Index (95% Confidence Interval)</th>
<th>p Value</th>
<th>Integrated Discriminatory Index (95% Confidence Interval)</th>
<th>p Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Multivariate model*</td>
<td>-0.03 (-0.1035 to 0.0347)</td>
<td>0.3327</td>
<td>0.014 (0.0038 to 0.0238)</td>
<td>0.007</td>
</tr>
<tr>
<td>SYNTAX score</td>
<td>0.00 (-0.1633 to 0.1601)</td>
<td>0.9846</td>
<td>0.004 (0.0005 to 0.0078)</td>
<td>0.03</td>
</tr>
<tr>
<td>SYNTAX score II</td>
<td>0.05 (-0.0782 to 0.1831)</td>
<td>0.4339</td>
<td>0.007 (0.0011 to 0.0121)</td>
<td>0.02</td>
</tr>
</tbody>
</table>

*This reduced model contained the following covariates: age, left ventricular ejection fraction, previous myocardial infarction, intravascular ultrasound use, SYNTAX score, and creatinine clearance.

**Abbreviation as in Table 1.**

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**FIGURE 3**

**Subgroup Analyses: Primary Endpoint at 3 Years**

<table>
<thead>
<tr>
<th>Hazard Ratio (95% CI)</th>
<th>p for Interaction</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>IVUS used</strong></td>
<td></td>
</tr>
<tr>
<td>IVUS not used</td>
<td>0.42 (0.14, 1.22)</td>
</tr>
<tr>
<td>Non-bifurcation</td>
<td>0.53 (0.29, 0.87)</td>
</tr>
<tr>
<td>Bifurcation</td>
<td>0.50 (0.27, 0.90)</td>
</tr>
<tr>
<td>Two-stent</td>
<td>0.45 (0.13, 1.53)</td>
</tr>
<tr>
<td>One-stent</td>
<td>0.14 (0.03, 0.82)</td>
</tr>
<tr>
<td></td>
<td>0.56 (0.29, 1.08)</td>
</tr>
</tbody>
</table>

Impact of procedural characteristics (multiple stent implantation, distal left main bifurcation percutaneous coronary intervention, and intravascular ultrasound [IVUS] use) on the association between operator experience and the risk for cardiac death at 3 years. CI = confidence interval; HR = hazard ratio.
were very experienced. Whether these results can be extended to differences in operator experience among less experienced operators remains to be explored; however, previous studies imply that learning curves for PCI procedures are steeper in the lower volume ranges and taper off at higher volumes. Although we adjusted the analyses for known cardiovascular risk factors, we cannot rule out the presence of unmeasured confounders.

Last, our primary endpoint, cardiac death, was a rare event. Despite being the largest series of LM PCI, the small number of patients who experienced cardiac death led to low statistical power. This was particularly true for interaction tests. Therefore, we are at risk of committing a type II statistical error.

**CONCLUSIONS**

Patients who underwent LM PCI by high-volume and experienced operators had a better prognosis compared with patients treated by low-volume and less experienced operators. Our findings suggest that high-risk and complex procedures, such as LM PCI, should be reserved to a limited number of experienced operators if outcomes are to be optimized. Alternatively, less experienced operators could perform LM PCI under the close supervision and mentorship of experienced operators until they acquire sufficient skill and technique and become independent.

**REFERENCES**


**PERSPECTIVES**

**WHAT IS KNOWN?** LM PCI is increasingly performed and could be technically challenging and potentially risky considering the large amount of supplied myocardium.

**WHAT IS NEW?** This is the first study to demonstrate the positive impact of operator volume and experience on short- and long-term prognosis after PCI of LM lesions.

**WHAT IS NEXT?** The operator’s experience and annual volume should be integrated with traditional (i.e. SYNTAX score, SYNTAX score II) risk stratification algorithms when debating revascularization strategies (PCI vs. CABG) for a given patient within a given institution. The impact of operator experience on prognosis after other types of high-risk PCI and CABG should be further studied.

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13. Claessen BE, Stone GW, Snits PC, et al. Would SYNTAX have been a positive trial if XIENCE V had been used instead of TAXUS? A meta-analysis of a first-generation vs. a second-generation drug-eluting stent system. Neth Heart J 2010;18:451-3.


**KEY WORDS** left main coronary artery, stents, quality of care, SYNTAX score

**APPENDIX** For a supplemental table, please see the online version of this article.