Development of 2 Registry-Based Risk Models Suitable for Characterizing Hospital Performance on 30-Day All-Cause Mortality Rates Among Patients Undergoing Percutaneous Coronary Intervention

Jeptha P. Curtis, MD; Lori L. Geary, MPH; Yongfei Wang, MS; Jersey Chen, MD, MPH; Elizabeth E. Drye, MD, SM; Laura M. Grosso, PhD; John A. Spertus, MD, MPH; John S. Rumsfeld, MD, PhD; William S. Weintraub, MD; Frederick A. Masoudi, MD, MSPH; Ralph G. Brindis, MD MPH; Harlan M. Krumholz, MD, SM

Background—Variation in outcomes after percutaneous coronary interventions (PCI) may reflect differences in quality of care. To date, however, we lack a methodology to monitor and improve national hospital 30-day mortality rates among patients undergoing PCI.

Methods and Results—We developed hierarchical logistic regression models to calculate hospital risk-standardized 30-day all-cause PCI mortality rates. Due to differences in risk, patients were divided into 2 cohorts: those with ST-segment elevation myocardial infarction or cardiogenic shock, and those with no ST-segment elevation myocardial infarction and no cardiogenic shock. The models were derived using 2006 data from the CathPCI Registry linked with administrative claims data, and validated using comparable 2005 data. In the derivation cohort of the ST-segment elevation myocardial infarction or shock model (n=15123), the unadjusted 30-day mortality rate was 9.2%. The final model included 13 variables with the observed mortality rates ranging from 1.4% to 40.3% across deciles of the predicted patient mortality rates. The 25th and 75th percentiles of the risk-standardized mortality rate were 8.5% and 9.7%, with 5th and 95th percentiles of 7.6% and 11.0%. In the derivation cohort of the no ST-segment elevation myocardial infarction and no shock model (n=110529), the unadjusted 30-day mortality rate was 1.4%. The final model included 16 variables with the observed predicted mortality rates ranging from 0.1% to 7.0% across deciles of the predicted patient mortality rates. The 25th and 75th percentiles of the risk-standardized mortality rate across 612 hospitals were 1.3% and 1.6%, with 5th and 95th percentiles of 1.0% and 2.0%.


Key Words: percutaneous coronary intervention ■ coronary artery disease ■ health policy ■ quality of health care
PCI hospitals. To create an infrastructure for monitoring PCI outcomes while minimizing the associated administrative burden, we developed models of PCI mortality using information already collected by many PCI hospitals through their participation in the American College of Cardiology (ACC) National Cardiovascular Data Registry’s (NCDR) CathPCI Registry. The registry captures detailed information about patients undergoing cardiac catheterization and PCI at more than 1100 hospitals, representing more than half of the hospitals that currently perform PCI.

Previous investigators have used the CathPCI Registry to develop risk models that accurately predict patient risk, but these models are not suitable for public reporting.\textsuperscript{1-5} As articulated in an American Heart Association Scientific Statement, risk models used to compare hospital performance must adhere to a core set of attributes including establishing a standard period of assessment and using an analytic approach that takes into account differences in case mix and volume.\textsuperscript{6}

To address this gap, the Centers for Medicare and Medicaid Services (CMS), in partnership with the NCDR, merged the clinical data from the CathPCI Registry with the administrative claims data to develop hierarchical logistic regression models that produce hospital-specific risk standardized 30-day PCI mortality rates. The mortality estimates from these models reflect the outcomes achieved by the systems of care that are involved with patients who undergo PCI. As such, this information can be used to understand and improve the overall quality of care and outcomes achieved by hospitals that perform PCI.

WHAT IS KNOWN

- The outcomes of patients undergoing percutaneous coronary intervention vary by the quality of care provided.
- To date, the United States has not had a national effort to monitor or report percutaneous coronary intervention mortality rates, in part due to the absence of mechanisms for systematically collecting and analyzing the data needed to adjust for differences in case mix across institutions that perform percutaneous coronary intervention.

WHAT THE STUDY ADDS

- Two models of 30-day percutaneous coronary intervention mortality that leverage the clinical information collected by percutaneous coronary intervention hospitals through the National Cardiovascular Data Registry’s CathPCI Registry.
- The models produce hospital specific estimates of risk-standardized 30-day mortality rates for patients undergoing percutaneous coronary intervention.
- These models are consistent with the consensus standards for publicly reported outcomes measures and have been approved by the National Quality Forum for this purpose.
patients with STEMI (ie, Primary PCI centers). This methodology is consistent with that adopted by Massachusetts’ program to publicly report PCI mortality.2

Outcome
The outcome for each cohort was 30-day all-cause mortality, measured as death due to any cause within 30 days from the date of the index PCI procedure. Vital status was determined through the Medicare EDB.

Candidate and Final Variables
A preliminary list of candidate variables for risk adjustment was proposed by a team of clinicians and vetted by an external panel of experts convened by the ACC. Variables were not considered candidates for risk adjustment if they could represent a complication of care (eg, vessel dissection, use of an intra-aortic balloon pump, final TIMI flow), were inconsistently reported (eg, medications, results of noninvasive testing), or deemed inappropriate to include in a model developed to assess procedural quality (eg, race, ethnicity, admission pathway). The final variables included age, sex, 15 history and risk factor variables, 4 cardiac status variables, and 5 procedural variables (online-only Data Supplement Appendix A).

Missing Data
The percentage of missing values was <1% for all categorical variables. For these variables, the most common value was imputed. Among continuous variables, 3 had significant numbers of missing values: body mass index, glomerular filtration rate, and left ventricular ejection fraction. For body mass index, we stratified by gender and imputed the missing values to the median of the corresponding group. For glomerular filtration rate, we stratified patients into 5 categories: <30, 30–59, 60–89, ≥90, and not measured. For left ventricular ejection fraction, we stratified patients into 4 categories: ≤30%, 31–45%, >45%, and “not measured.”

Analysis
The models were developed using data on PCIs performed in 2006 and validated using comparable data from 2005. In both the STEMI or shock and no STEMI and no shock cohorts, we conducted analyses of model performance using logistic regression models. To create a parsimonious model consisting of the variables most strongly associated with 30-day mortality, we selected variables using backward stepwise selection (entry $P<0.05$; retention $P<0.01$) taking into consideration the direction and magnitude of the regression coefficients. Variable selection was further confirmed repeating the selection process using bootstrap analyses with 1000 iterations. Variables were retained in the final model if they were selected in at least 80% of the iterations. To assess model performance at the patient level, we calculated the area under the receiver operating characteristic curve (AUC), explained variation as measured by the generalized $R^2$ statistic, and calculated the observed readmission rates in the lowest and highest deciles on the basis of the predicted readmission probabilities. To visually assess the calibration of the model (predictive ability), we grouped patients into deciles of predicted 30-day mortality and examined observed mortality across the deciles.
Table 1. Comparison of CathPCI Patients who did and did not Match With Administrative Claims Data (2006 Cohort)

<table>
<thead>
<tr>
<th>Description</th>
<th>Total</th>
<th>Not Matched</th>
<th>Matched</th>
<th>% Standardized Difference</th>
</tr>
</thead>
<tbody>
<tr>
<td>No.</td>
<td>%</td>
<td>No.</td>
<td>%</td>
<td>No.</td>
</tr>
<tr>
<td>184570</td>
<td>57962</td>
<td>126608</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Demographics

| Age: Mean (SD) | 74.42 | 6.51 | 73.94 | 6.45 | 74.65 | 6.53 | <0.001 | –10.83 |
| Female | 75798 | 41.07 | 23028 | 39.73 | 52770 | 41.68 | <0.001 | –3.97 |

History and risk factors

| BMI: Mean (SD) | 28.53 | 5.76 | 28.58 | 5.74 | 28.50 | 5.77 | 0.12 | 0.77 |
| CHF: Previous history | 25 | 755 | 13.95 | 7648 | 13.19 | 18107 | 14.30 | <0.001 | –3.19 |
| Previous valvular surgery | 2842 | 1.54 | 835 | 1.44 | 2007 | 1.59 | 0.02 | –1.17 |
| Cerebrovascular disease | 29 | 121 | 15.78 | 8643 | 14.91 | 20 | 478 | 16.17 | <0.001 | –3.46 |
| Peripheral vascular disease | 28378 | 15.38 | 8456 | 14.59 | 19922 | 15.74 | <0.001 | –3.18 |
| Chronic lung disease | 33935 | 18.39 | 9978 | 17.21 | 23957 | 18.92 | <0.001 | –4.41 |
| Diabetes mellitus /control | 0.02 |       |       |       |       |       |       |       |
| No | 124179 | 67.28 | 38861 | 67.05 | 85318 | 67.39 | <0.001 | –0.73 |
| Noninsulin requiring diabetes mellitus | 41976 | 22.74 | 13403 | 23.12 | 28573 | 22.57 | 1.33 |
| Insulin requiring diabetes mellitus | 18415 | 8.38 | 5698 | 9.83 | 12717 | 10.04 | <0.001 | –0.71 |
| GFR* Mean (SD) | 65.13 | 25.56 | 65.52 | 25.57 | 64.95 | 25.55 | <0.001 | 2.25 |
| Previous PCI | 67408 | 36.52 | 20606 | 35.55 | 46802 | 36.97 | <0.001 | –2.94 |

Cardiac status

| CHF: Current status | 22910 | 12.41 | 6764 | 11.67 | 16146 | 12.75 | <0.001 | –3.29 |
| NYHA | <0.001 |
| Class I | 59457 | 32.21 | 18579 | 32.05 | 40878 | 32.29 | <0.001 | –0.50 |
| Class II | 42984 | 23.29 | 13965 | 24.09 | 29019 | 22.92 | 2.78 |
| Class III | 49988 | 27.08 | 15326 | 26.44 | 34662 | 27.38 | <0.001 | –2.11 |
| Class IV | 32141 | 17.41 | 10092 | 17.41 | 22049 | 17.42 | <0.001 | –0.01 |
| Cardiogenic shock | 3659 | 1.98 | 1153 | 1.99 | 2506 | 1.98 | 0.89 | 0.07 |

Symptoms on presentation

| No angina | 28253 | 15.31 | 9192 | 15.86 | 19061 | 15.06 | 2.23 |
| Atypical chest pain | 13973 | 7.57 | 4641 | 8.01 | 9332 | 7.37 | 2.41 |
| Stable angina | 32453 | 17.58 | 10660 | 18.39 | 21793 | 17.21 | 3.10 |
| ACS: Unstable angina | 63593 | 34.45 | 19716 | 34.02 | 43877 | 34.66 | <0.001 | –1.35 |
| ACS: Non-STEMI MI within 24 h | 18424 | 9.98 | 5492 | 9.48 | 12932 | 10.21 | <0.001 | –2.47 |
| ACS: STEMI within 24 h | 17002 | 9.21 | 4895 | 8.45 | 12107 | 9.56 | <0.001 | –3.86 |
| ACS: Non-STEMI after 24 h | 9029 | 4.89 | 2783 | 4.80 | 6246 | 4.93 | <0.001 | –0.61 |
| ACS: STEMI after 24 h | 1843 | 1.00 | 583 | 1.01 | 1260 | 1.00 | 0.11 |

Cath laboratory visit

| Ejection fraction percentage | <0.001 |
| Missing | 56336 | 30.52 | 18827 | 32.48 | 37509 | 29.63 | <0.001 | 6.20 |
| Mean (SD) | 52.44 | 13.35 | 52.77 | 13.40 | 52.30 | 13.32 | <0.001 | 3.57 |

PCI procedure

| PCI status | <0.001 |
| Elective | 96862 | 52.48 | 30897 | 53.31 | 65965 | 52.10 | 2.41 |
| Urgent | 65772 | 35.64 | 20475 | 35.32 | 45297 | 35.78 | <0.001 | –0.94 |
| Emergency | 21517 | 11.66 | 6436 | 11.10 | 15081 | 11.91 | <0.001 | –2.52 |
| Salvage | 395 | 0.21 | 143 | 0.25 | 252 | 0.20 | 1.03 |

Highest risk lesion: SCAI lesion class

| I | 98784 | 53.52 | 31029 | 53.53 | 67755 | 53.52 | 0.04 |
| II | 63020 | 34.14 | 19160 | 33.06 | 43860 | 34.64 | <0.001 | –3.35 |
| III | 7766 | 4.21 | 2540 | 4.38 | 5226 | 4.13 | 1.27 |
| IV | 15000 | 8.13 | 5233 | 9.03 | 9767 | 7.71 | 4.81 |

(Continued)
Table 1. Continued

<table>
<thead>
<tr>
<th>Description</th>
<th>Total</th>
<th>%</th>
<th>Not Matched</th>
<th>%</th>
<th>Matched</th>
<th>%</th>
<th>P Value</th>
<th>% Standardized Difference</th>
</tr>
</thead>
<tbody>
<tr>
<td>In-hospital mortality</td>
<td>2864</td>
<td>1.55</td>
<td>932</td>
<td>1.61</td>
<td>1932</td>
<td>1.53</td>
<td>0.19</td>
<td>0.66</td>
</tr>
<tr>
<td>Length of stay (days); Mean (SD)</td>
<td>3.21</td>
<td>6.09</td>
<td>3.33</td>
<td>9.09</td>
<td>3.15</td>
<td>4.03</td>
<td>&lt;0.001</td>
<td>2.97</td>
</tr>
</tbody>
</table>

ACS indicates acute coronary syndrome; BMI, body mass index; CHF, congestive heart failure; CMS, Centers for Medicare and Medicaid Services; GFR, glomerular filtration rate; NCDR, National Cardiovascular Data Registry; NYHA, New York Heart Association; PCI, percutaneous coronary intervention; SCAI, Society for Coronary Angiography and Interventions; SD, standard deviation; and STEMI, ST-segment elevation myocardial infarction.*Calculated using Modification of Diet and Renal Disease equation.

Model Validation
We compared the model performance in the derivation sample with its performance in the validation cohort derived from PCI patients discharged in 2005. We calculated overfitting indices that quantify overfitting through logistic regression model in the validation sample on the basis of the risk score using the regression estimates from our derivation model. A risk score coefficient that is far from 1 and an intercept different that is far from 0 are indicative of overfitting. We also recalibrated the model in the validation set and reassessed the model performance using the metrics described above.

Risk-Standardized Mortality Rate
We combined data from the development and validation cohorts to calculate hospital-specific risk-standardized 30-day mortality rates. To handle clustering of patient admissions within hospitals (our unit of inference), we estimated risk-standardized mortality rates (RSMRs) using hierarchical logistic regression models.7 This approach reflects our assumption that after adjusting for patient risk and differences in procedural volume, the remaining variation is attributable to hospital quality. These rates are obtained as the ratio of the number of predicted to expected deaths, multiplied by the national rate. The predicted number of deaths in each hospital is estimated given its own patient mix and using its own hospital-specific intercept. The expected number of deaths in each hospital is estimated using its own patient mix and the average hospital-specific intercept based on all hospitals in our sample. This is a form of indirect standardization.

Analyses were conducted using SAS version 9.1.3 (SAS Institute Inc, Cary, NC). We estimated the hierarchical models using the GLIMMIX procedure in SAS. The Human Investigation Committee at the Yale School of Medicine approved an exemption for the authors to use a limited data set consisting of both NCDR CathPCI data and CMS claims data for research analyses and publication.

Results
Among PCI admissions for older patients (age ≥ 65 years) in the registry, 68% were successfully matched to CMS claims data in the derivation cohort and 71% were successfully matched to CMS claims data in the validation cohort. Results of the match were similar when we varied matching criteria (eg, removing discharge date as a linking field). Within hospitals that participated in the CathPCI Registry, the characteristics of patients who matched were comparable to those of patients who did not match (Table 1, 2006 data).

Model Development and Validation
Figure 1 presents the total number of patients discharged after PCI in 2006, the proportion excluded as a result of individual exclusion criteria, and the number included in the final sample as index admissions. The development sample for the STEMI or shock cohort consisted of 15123 admissions at 602 hospitals. The median hospital volume of STEMI or shock cases was 20 (interquartile range, 9–35), and the overall 30-day mortality rate was 9.2%. The development sample for the no STEMI and no shock cohort consisted of 110529 admissions at 602 hospitals. Median hospital PCI volume in the no STEMI and no shock cohort was 133 (interquartile range, 55–244) and the national 30-day mortality rate was 1.4%.

STEMI or Shock Model
The final risk-adjustment model for the STEMI or shock cohort included 13 variables. The variable descriptions, Wald χ², and odds ratios are shown in Table 2. The development model had excellent discrimination, calibration, and fit (Table 3). The patient-level observed mortality rate ranged from 1.4% in the lowest decile of the predicted mortality to 40.3% in the highest decile of the predicted mortality, with a range of 38.9%. The area under the ROC curve was 0.83. In addition, there was an excellent correlation between the predicted and the observed mortality in the derivation cohort (Figure 2). We compared the model performance in the development sample with its performance in a similarly derived validation sample from 12052 PCI patients at 458 hospitals discharged in 2005. The validation sample had a crude mortality rate of 9.0%, and model performance was not substantively different in this validation sample (ROC=0.84), as compared with the development sample. The model in the validation sample was well calibrated through the overfitting indices of (−0.03, 1.01) (Table 3).

No STEMI and No Shock Model
The final risk-adjustment model for the no STEMI and no shock cohort included 16 variables (Table 4). The development model has excellent discrimination, calibration, and fit (Table 5). The patient-level observed mortality rate in the development cohort ranges from 0.1% in the lowest decile of the predicted mortality to 7.0% in the highest decile of the predicted mortality, with a range of 6.9% (Figure 3). The area under the ROC curve was 0.82. We compared the model performance in the development sample with its performance in a similarly derived validation sample of 88630 PCI patients without STEMI or Shock discharged in 2005 at 457 hospitals. The validation sample had a crude mortality rate of 1.4%. Model calibration in the validation cohort was good with overfitting indices of (−0.14, 0.95). Model performance metrics were not substantively different in the validation sample (Table 5).
30-Day Mortality Rate Distribution With and Without Risk-Adjustment

Figure 4A and 4B display the frequency distributions of the hospital-specific 30-day mortality rates, with and without risk-adjustment for the 2005 to 2006 combined STEMI or shock cohort. The observed mortality rate ranged from 0% to 100% across the 614 hospitals (Figure 4A). After adjusting for patient and clinical characteristics, the risk-standardized rates were found to be more normally distributed (Figure 4B). The 25th and 75th percentiles of the RSMRs across 614 hospitals were 8.5% and 9.7%, with 5th and 95th percentiles of 7.6% and 11.0%. The variance of the random effects was 0.1024, and the odds of all-cause 30-day mortality rates for a hospital whose random effect is 1 standard deviation above average was 1.9 times that of a hospital whose random effect is 1 standard deviation below average.

Figure 5A and 5B display the frequency distributions of the hospital-specific 30-day mortality rates, with and without risk-adjustment for 2005 to 2006 combined no STEMI and no Shock cohort. The observed mortality rate ranged from 0% to 50% across the 612 hospitals (Figure 5A). After adjusting for patient and clinical characteristics, the risk-standardized rates were again more normally distributed (Figure 5B). The 25th and 75th percentiles of the RSMRs across 612 hospitals were 1.3% and 1.6%, with 5th and 95th percentiles of 1.0% and 2.0%. The variance of the random effects was 0.1325, and the odds of all-cause 30-day mortality rates for a hospital whose random effect is 1 standard deviation above average was 2.1 times that of a hospital whose random effect is 1 standard deviation below average.

Discussion

We present 2 hierarchical logistic regression models for 30-day mortality after PCI among patients >65 years of age using data from the CathPCI Registry merged with CMS administrative data. The 2 cohorts consist of distinct PCI populations that have different outcomes allowing for valid estimates of hospital performance. The methodological approach to develop the mortality measures was designed to reflect accepted standards for publicly reported outcomes measures.6 We derived the models using risk-adjustment variables that excluded potential complications so that the estimated risk-adjustment for the 2005 to 2006 combined STEMI or shock cohort. The observed mortality rate ranged from 0% to 100% across the 614 hospitals (Figure 4A). After adjusting for patient and clinical characteristics, the risk-standardized rates were found to be more normally distributed (Figure 4B). The 25th and 75th percentiles of the RSMRs across 614 hospitals were 8.5% and 9.7%, with 5th and 95th percentiles of 7.6% and 11.0%. The variance of the random effects was 0.1024, and the odds of all-cause 30-day mortality rates for a hospital whose random effect is 1 standard deviation above average was 1.9 times that of a hospital whose random effect is 1 standard deviation below average.

Figure 5A and 5B display the frequency distributions of the hospital-specific 30-day mortality rates, with and without risk-adjustment for 2005 to 2006 combined no STEMI and no Shock cohort. The observed mortality rate ranged from 0% to 50% across the 612 hospitals (Figure 5A). After adjusting for patient and clinical characteristics, the risk-standardized rates were again more normally distributed (Figure 5B). The 25th and 75th percentiles of the RSMRs across 612 hospitals were 1.3% and 1.6%, with 5th and 95th percentiles of 1.0% and 2.0%. The variance of the random effects was 0.1325, and the odds of all-cause 30-day mortality rates for a hospital whose random effect is 1 standard deviation above average was 2.1 times that of a hospital whose random effect is 1 standard deviation below average.

Table 2. Logistic Regression Model for 30-Day Mortality in the STEMI or Shock Development Cohort (2006 Derivation Cohort)

<table>
<thead>
<tr>
<th>Name</th>
<th>Wald $\chi^2$</th>
<th>Odds Ratio</th>
<th>95% Confidence Interval</th>
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<td>Intercept</td>
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<td></td>
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<td>Age/10 y</td>
<td>117.3</td>
<td>1.64</td>
<td>1.50–1.79</td>
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<tr>
<td>BMI/5</td>
<td>7.3</td>
<td>0.89</td>
<td>0.82–0.97</td>
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<tr>
<td>Cerebrovascular disease</td>
<td>29.1</td>
<td>1.56</td>
<td>1.33–1.83</td>
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<tr>
<td>Chronic lung disease</td>
<td>40.6</td>
<td>1.61</td>
<td>1.39–1.87</td>
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<td>Glomerular filtration rate*</td>
<td>15.1</td>
<td>1.64</td>
<td>1.28–2.10</td>
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<td>&lt;30</td>
<td>132.2</td>
<td>3.54</td>
<td>2.86–4.40</td>
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<td>30–59</td>
<td>31.9</td>
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<td>60–89</td>
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<td>0.98</td>
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<td>Previous PCI</td>
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<td>Heart failure on admission</td>
<td>30.8</td>
<td>1.51</td>
<td>1.31–1.75</td>
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<td>Cardiogenic shock on admission</td>
<td>477.3</td>
<td>4.59</td>
<td>4.00–5.26</td>
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<td>Symptoms present on admission</td>
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<tr>
<td>No MI</td>
<td>0.1</td>
<td>0.96</td>
<td>0.76–1.22</td>
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<td>MI within 24 h</td>
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<tr>
<td>MI after 24 h</td>
<td>5.8</td>
<td>1.31</td>
<td>1.05–1.62</td>
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<td>Left ventricular ejection fraction</td>
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<td>&gt;45%</td>
<td>Reference</td>
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<td>31–45%</td>
<td>38.1</td>
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<td>≤30%</td>
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<td>Not measured</td>
<td>68.2</td>
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<td>PCI status</td>
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<td>Elective</td>
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<tr>
<td>Urgent</td>
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<td>1.38</td>
<td>0.96–1.99</td>
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<td>Emergency</td>
<td>23.1</td>
<td>2.31</td>
<td>1.64–3.25</td>
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<tr>
<td>Salvage</td>
<td>65.5</td>
<td>6.92</td>
<td>4.33–11.06</td>
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<tr>
<td>Highest risk lesion segment</td>
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<tr>
<td>Proximal RCA, proximal circumflex, or mid LAD</td>
<td>0.1</td>
<td>1.03</td>
<td>0.89–1.19</td>
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<tr>
<td>Proximal LAD</td>
<td>8.6</td>
<td>1.29</td>
<td>1.09–1.52</td>
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<td>Left main</td>
<td>25.7</td>
<td>2.65</td>
<td>1.82–3.86</td>
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<td>Other</td>
<td>Reference</td>
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<tr>
<td>Highest risk lesion: SCAL classification</td>
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<td></td>
</tr>
<tr>
<td>Class 1</td>
<td>Reference</td>
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<td></td>
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<tr>
<td>Class 2 or 3</td>
<td>5.1</td>
<td>1.24</td>
<td>1.03–1.49</td>
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<tr>
<td>Class 4</td>
<td>32.9</td>
<td>1.72</td>
<td>1.43–2.07</td>
</tr>
</tbody>
</table>

BMI indicates body mass index; CHF, congestive heart failure; CMS, Centers for Medicare and Medicaid Services; LAD, left anterior descending; NYHA, New York Heart Association; PCI, percutaneous coronary intervention; RCA, right coronary artery; SCAL, Society for Coronary Angiography and Interventions; SD, standard deviation; and STEMI, ST-segment elevation myocardial infarction.

*Calculated using Modification of Diet and Renal Disease equation.

Table 3. 30-Day Mortality Model Performance for the STEMI or Shock Cohort: Results Based on the Logistic Regression Models

<table>
<thead>
<tr>
<th>Data Source</th>
<th>Calibration</th>
<th>Discrimination</th>
</tr>
</thead>
</table>
|             | (Intercept, Slope) R-Square* | Predictive Ability†%
|             | (Lowest Decile %, Highest Decile %) | AUC |
| Development sample | 2006 | N=15 123 | 0.27 (1.4, 40.3) | 0.83 |
| Validation sample | 2005 | N=12 052 | 0.29 (0.8, 40.4) | 0.84 |

AUC indicates area under the receiver operating characteristic curve.

*Max-rescaled $R^2$.

†Observed rates.

30-Day Mortality Rate Distribution With and Without Risk-Adjustment

Figure 4A and 4B display the frequency distributions of the hospital-specific 30-day mortality rates, with and without risk-adjustment for the 2005 to 2006 combined STEMI or shock cohort. The observed mortality rate ranged from 0% to 100% across the 614 hospitals (Figure 4A). After adjusting for patient and clinical characteristics, the risk-standardized rates were found to be more normally distributed (Figure 4B). The 25th and 75th percentiles of the RSMRs across 614 hospitals were 8.5% and 9.7%, with 5th and 95th percentiles of 7.6% and 11.0%. The variance of the random effects was 0.1024, and the odds of all-cause 30-day mortality rates for a hospital whose random effect is 1 standard deviation above average was 1.9 times that of a hospital whose random effect is 1 standard deviation below average.

Figure 5A and 5B display the frequency distributions of the hospital-specific 30-day mortality rates, with and without risk-adjustment for 2005 to 2006 combined no STEMI and no Shock cohort. The observed mortality rate ranged from 0% to 50% across the 612 hospitals (Figure 5A). After adjusting for patient and clinical characteristics, the risk-standardized rates were again more normally distributed (Figure 5B). The 25th and 75th percentiles of the RSMRs across 612 hospitals were 1.3% and 1.6%, with 5th and 95th percentiles of 1.0% and 2.0%. The variance of the random effects was 0.1325, and the odds of all-cause 30-day mortality rates for a hospital whose random effect is 1 standard deviation above average was 2.1 times that of a hospital whose random effect is 1 standard deviation below average.

Discussion

We present 2 hierarchical logistic regression models for 30-day mortality after PCI among patients >65 years of age using data from the CathPCI Registry merged with CMS administrative data. The 2 cohorts consist of distinct PCI populations that have different outcomes allowing for valid estimates of hospital performance. The methodological approach to develop the mortality measures was designed to reflect accepted standards for publicly reported outcomes measures.6 We derived the models using risk-adjustment variables that excluded potential complications so that the estimated risk...
of mortality was based on characteristics prior to, rather
than during or after, the procedure. The 30-day time period
provides a standardized period of assessment. To calculate
RSMRs, we used a hierarchical logistic regression model, a
statistical approach that takes into account the clustering of
patients within hospitals and differences in sample size across
hospitals.

The variables included in the risk models are consistent
with those of previously published models of in-hospital PCI
mortality, but the c statistics for our models are modestly
lower. This is due in part to the longer period of assessment
(30 day versus in-hospital mortality), as well the decision to
stratify the cohort of patients undergoing PCI into 2 distinct
populations based on the presence or absence of 2 prognosti-
cally important variables: STEMI and cardiogenic shock. As
discussed, the decision to split the population is warranted due
to profound differences in expected mortality and the fact that
a significant number of hospitals are only approved to per-
form primary PCI. However, this results in greater homoge-
neity within each cohort and reduces model discrimination.
In addition, we excluded a number of covariates including
potential complications, patient race, socioeconomic sta-
tus, and admission path (eg, admission from nursing home).
Although these factors could improve model performance,
they should not be included in risk models used to compare
hospital performance.

The measures use a 30-day period for determining mor-
tality after PCI. A fixed outcome period is preferable to in-
hospital outcomes in that variation in length of stay (LOS)
does not affect performance and minimizes the opportunity
for misrepresentation through mechanisms such as trans-
fering patients. In addition, the 30-day period of assessment
may be a more clinically meaningful timeframe for patients,
reflecting not only the outcomes of inpatient processes of
care but also the transition of care to the outpatient setting.
Consequently, a 30-day mortality measure may stimulate
better collaboration between hospitals and their surround-
ing medical communities aimed at reducing mortality rates.

These activities may include ensuring patients are clinically
appropriate for discharge; improving communication among
providers in transitions of care; and encouraging strategies
that promote disease management principles and educate
patients on what symptoms to monitor, whom to contact with
questions, and where and when to seek follow-up care. In
this manner, information about 30-day mortality rates after
PCI could be used to supplement existing quality improve-
mement efforts.

Although the models we developed are suitable for charac-
terizing the quality of care achieved by hospitals performing
PCI, additional steps may be necessary before implementa-
tion. The models were derived from a population of elderly,
fee-for-service Medicare patients undergoing PCI at programs
that participated in the CathPCI Registry. Although the vari-
bles included in the models have face validity, the models
will need to be tested in the broader population of patients
undergoing PCI, including non-Medicare patients and the
growing population of patients undergoing PCI under an
outpatient or observation status. Nevertheless, the variables
and explained variation of our models are similar to those of
prior efforts to model in-hospital mortality after PCI, and it is
unlikely that model performance would differ substantially in
the broader population.

We developed the models from a dataset that linked
CathPCI Registry data with Medicare FFS administra-
tive data. As a result, 30% of eligible PCI in the NCDR
were excluded from measure development. This was due in
large part to the fact that 19% of patients ≥65 years of age
are enrolled in Medicare Advantage and are absent from
the FFS claims data (Medicare Fact Sheet). Other con-
tributing factors include patients ineligible for Medicare (eg
non-US citizens), patients who were not admitted to the
hospital (observation stay PCI), patients with nongov-
ernmental insurance, and inaccuracies in linking fields.
The fact that the characteristics and in-hospital outcomes
of patients who did and did not match were similar sup-
ports the generalizability of the risk models. Nevertheless,
the use of direct patient identifiers such as social security number to link to external databases such as the Social Security Death Index or National Death Index would be necessary to ensure the accurate determination of the vital status of all PCIs, not simply those performed on Medicare FFS patients.

More than a third of hospitals that perform PCI in the United States do not currently participate in the CathPCI Registry. Accordingly, public reporting would require the development of mechanisms to collect and merge data from all hospitals either through CathPCI or other mechanisms. In addition, any effort to publicly report hospital PCI outcomes requires that the data submitted by hospitals be complete, consistent, and accurate. As such, public reporting would need to be accompanied by efforts to ensure data completeness and quality such as surveillance for systematic variation in case mix (eg unexpectedly high proportion of salvage PCI or cardiogenic shock), confirmation of the accuracy of submitted data through targeted chart abstraction, and, potentially, systematic adjudication of cases that are vulnerable to misclassification.9

Certain aspects of our analysis warrant further consideration. First, there may be unmeasured factors that could impact hospitals’ RSMRs. Examples of this include hemoglobin, functional status, and prehospital delays for STEMI patients, none of which are routinely collected in version 3 of the CathPCI Registry. All of these factors have been found to be significantly associated with patient outcomes after PCI, but the impact on hospital-level estimates of PCI outcomes is not known. Additional work will be necessary to identify ways to improve the risk models if and when such variables become available. In addition, we will need to update the risk models to incorporate alternative methods of handling missing data such as multiple imputation, and retaining continuous variables such as body mass index and LVEF as continuous variables rather than categorizing them. We plan on pursuing these activities when the measures undergo re-endorsement evaluation by the NQF. Finally, the risk models do not include hospital characteristics such as procedural volume that are associated with differences in mortality after PCI.
These factors may account for variation in the quality of care as reflected by hospitals’ RSMR, and adjusting for them could obscure important differences between hospitals.

In summary, we present 2 registry-based models that produce estimates of hospital risk-standardized 30-day mortality rates for patients undergoing PCI and can be used to evaluate...
quality of care. These models are consistent with the consensus standards for publicly reported outcomes measures and have been approved by the National Quality Forum.

Acknowledgments
We would like to acknowledge the support of our colleagues affiliated with the American College of Cardiology and the National Cardiovascular Data Registry. Without their support, this project would not have been possible. CathPCI Registry is an initiative of the American College of Cardiology Foundation and The Society for Cardiovascular Angiography and Interventions.

Sources of Funding
The analyses on which this publication is based were performed under Contract Number HHSM-500-2005-C0001C, entitled Utilization and Quality Control Quality Improvement Organization for the State (commonwealth) of Colorado, funded by the Centers for Medicare & Medicaid Services, an agency of the US Department of Health and Human Services. The content of this publication does not necessarily reflect the views or policies of the Department of Health and Human Services, nor does mention of trade names, commercial products, or organizations imply endorsement by the US Government. The authors assume full responsibility for the accuracy and completeness of the ideas presented. This research was supported by the American College of Cardiology Foundation’s National Cardiovascular Data Registry (NCDR). The views expressed in this manuscript represent those of the author(s), and do not necessarily represent the official views of the NCDR or its associated professional societies identified at www.ncdr.com.

J.P.C., L.L.G., Y.W., E.E.D., L.M.G., and H.M.K. receive support from the Centers of Medicare and Medicaid Services (CMS) to develop and maintain performance measures that are used for public reporting. W.S.W. has no conflicts of interest to disclose. J.A.S. is president of Outcomes Instruments, LLC and a board member and founder of Health Outcomes Sciences. J.S.R. discloses that he is the Chief Science Officer for the NCDR. F.A.M. discloses that he has contracts with the American College of Cardiology Foundation and The Society for Cardiovascular Angiography and Interventions. H.M.K. discloses that he chairs a Cardiac Scientific Advisory Board for UnitedHealth.

Disclosures
None.

References


Development of 2 Registry-Based Risk Models Suitable for Characterizing Hospital Performance on 30-Day All-Cause Mortality Rates Among Patients Undergoing Percutaneous Coronary Intervention


_Circ Cardiovasc Qual Outcomes_. 2012;5:628-637; originally published online September 4, 2012;
doi: 10.1161/CIRCOUMES.111.964569
_Circulation: Cardiovascular Quality and Outcomes_ is published by the American Heart Association, 7272 Greenville Avenue, Dallas, TX 75231
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Print ISSN: 1941-7705. Online ISSN: 1941-7713

The online version of this article, along with updated information and services, is located on the World Wide Web at:
http://circoutcomes.ahajournals.org/content/5/5/628

Data Supplement (unedited) at:
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SUPPLEMENTAL MATERIAL

Appendix A. Candidate Variables

Description

Demographic
  Age
  Female

History and Risk Factors
  BMI
  Previous MI
  CHF-previous history
  Previous valvular surgery
  Cerebrovascular Disease
  Peripheral Vascular Disease
  Chronic Lung Disease
  Diabetes
    None
    Non-Insulin Diabetes
    Insulin Diabetes
  Glomerular Filtration Rate (GFR)
    Not measured
    <30
    30-59
    60-89
    ≥90
  Renal Failure-Dialysis
  Hypertension
  History of tobacco use
  Family history of CAD
  Previous PCI
  Previous CABG

Cardiac Status
  Heart Failure - Current Status
  NYHA
    Class I, II, or III
    Class IV
  Cardiogenic Shock
  Symptoms present on admission
    No MI
    MI within 24 hours
    MI after 24 hours

Cath Lab Visit
  Ejection Fraction Percentage
    Not measured
    ≤30
    30-45
    >45

PCI Procedure
  PCI Status
    Elective
Urgent
Emergency
Salvage

Highest Lesion Location
Proximal right coronary artery/mid LAD/proximal circumflex
Proximal LAD
Left Main
Other

Highest pre-procedure TIMI flow: none

Highest Risk Lesion: SCAI Lesion Class
I
II or III
IV