Predicting In-Hospital Mortality in Patients Undergoing Percutaneous Coronary Intervention

Brief title: In-Hospital Mortality Risk Prediction for PCI

Yulanka S. Castro-Dominguez, MD[a,b] , Yongfei Wang, MS[b], Karl E. Minges, PhD, MPH[a,b], Robert L. McNamara, MD, MHS[a], John A. Spertus, MD, MPH[c], Gregory J. Dehmer, MD[d], John C. Messenger, MD[e], Kimberly Lavin, MSN, RN, MPH[f], Cornelia Anderson, MSN, RN, CPHQ[f], Kristina Blankinship, MSN, FNP[f], Nestor Mercado, MD, PhD[g], Julie M. Clary, MD, MBA[h], Anwar D. Osborne, MD, MPM[i], Jeptha P. Curtis, MD[a,b], Matthew A. Cavender, MD, MPH[j]

[a] Department of Medicine (Cardiology), Yale School of Medicine, New Haven, CT
[b] Center for Outcomes Research and Evaluation, Yale-New Haven Hospital, New Haven, CT
[c] Cardiovascular Research, Saint Luke's Mid America Heart Institute/UMKC, Kansas City, MO
[d] Department of Medicine (Cardiology), Virginia Tech Carilion School of Medicine, Roanoke, VA
[e] Department of Medicine (Cardiology), University of Colorado Anschutz Medical Campus, Aurora, CO
[f] American College of Cardiology, Washington, DC
[g] Division of Cardiology, University of New Mexico Health Sciences Center, Albuquerque, NM
[h] Division of Cardiology, Indiana University School of Medicine, Indianapolis, IN
[i] Department of Emergency Medicine, Emory University, Atlanta, GA
[j] Department of Medicine (Cardiology), University of North Carolina, Chapel Hill, NC

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Address for correspondence:
Matthew A. Cavender, MD, MPH
160 Dental Circle, CB #7075
Chapel Hill, NC 27599
Phone: (919) 843-5214
Fax: (919) 966-1743
matt.cavender@unc.edu
Twitter: @YSCastroMD - New CathPCI model accurately predicts mortality after PCI with inclusion of new clinical variables that account for acuity, risk, and frailty.

Abstract
Background: Standardization of risk is critical in benchmarking and quality improvement efforts for percutaneous coronary interventions (PCI). In 2018, the CathPCI Registry was updated to include additional variables to better classify higher-risk patients.
Objectives: We sought to develop a model for predicting in-hospital mortality risk following PCI incorporating these additional variables.
Methods: Data from 706,263 PCIs performed between 7/2018-6/2019 at 1,608 sites were used to develop and validate a new full and pre-catheterization model to predict in-hospital mortality, and a simplified bedside risk score. The sample was randomly split into a development (70%, n=495,005) and validation cohort (30%, n=211,258). We created 1,000 bootstrapped samples of the development cohort and used stepwise selection logistic regression on each sample. The final model included variables that were selected in at least 70% of the bootstrapped samples and those identified *a priori* due to clinical relevance.
Results: In-hospital mortality following PCI varied based on clinical presentation. Procedural urgency, cardiovascular instability, and level of consciousness after cardiac arrest were most predictive of in-hospital mortality. The full model performed well, with excellent discrimination (c-index: 0.943) in the validation cohort and good calibration across different clinical and procedural risk cohorts. The median hospital risk-standardized mortality rate was 1.9% and ranged from 1.1% to 3.3% (interquartile range: 1.7%-2.1%).
Conclusions: The risk of mortality following PCI can be predicted in contemporary practice by incorporating variables that reflect clinical acuity. This model, which includes data previously not captured, is a valid instrument for risk stratification and for quality improvement efforts.

Condensed Abstract
We sought to develop and validate a new CathPCI Registry risk model incorporating new variables to predict in-hospital mortality risk following PCI. Data from 706,263 PCIs performed between 7/2018-6/2019 at 1,608 sites were used to develop and validate an in-hospital mortality risk model using logistic regression. Procedural urgency, cardiovascular instability, and level of consciousness after cardiac arrest were predictive of in-hospital mortality. The full model performed well with excellent discrimination (c-index: 0.943) and calibration across different cohorts. The median hospital risk-standardized mortality rate was 1.9% (range: 1.1%-3.3%). This model is a valid instrument for risk stratification and for quality improvement.

Keywords: percutaneous coronary intervention, risk-standardized mortality rates, hierarchical logistic regression model

Abbreviations:
ACC = American College of Cardiology
CI = confidence interval
CVI = cardiovascular instability
EF = ejection fraction
DCFv5 = Version 5 of CathPCI Registry data collection form
GFR = glomerular filtration rate
NCDR = National Cardiovascular Data Registry
PCI = percutaneous coronary intervention
OR = odds ratio

STEMI = ST-segment elevation MI

Introduction

The National Cardiovascular Data Registry (NCDR) CathPCI Registry was developed to characterize the quality of care provided to patients undergoing percutaneous coronary interventions (PCI) (1). Risk-adjusted models allow for the consideration of patients' pre-procedural risk factors when estimating PCI-associated mortality rates, a cornerstone of quality assessment (2). The CathPCI Registry risk-adjusted mortality prediction models have been important tools used in clinical decision making, quality improvement, research, and have potential use in public reporting programs by allowing appropriate comparison of site-specific outcomes that account for differences in case mix (3).

Prior mortality models from the registry included a full model used for risk adjustment, a pre-catheterization model developed to understand risk prior to performing diagnostic angiography, and a simplified 8-variable risk score designed to be used at the bedside (4). In 2013, these models were updated to account for patients undergoing high-risk PCI (5, 6). All prior models had excellent performance in contemporary clinical practice; however, concerns were raised that the risk-adjustment models may not adequately account for risk in extreme risk patients or lower volume centers, and that clinicians and hospitals treating a greater number of high-risk patients may have worse risk-adjusted mortality ratings (7, 8). Appropriate risk adjustment is necessary to prevent potential risk-adverse behaviors that may negatively affect patients who are at highest risk, particularly those with cardiogenic shock and cardiac arrest, who may benefit the most from revascularization (9, 10).

The CathPCI mortality risk model plays an important role as public reporting and incorporation of outcomes measures into payment programs continues to evolve in the United States. Given the impact on public perception and practice patterns, improvements in the model

and evaluation of the model's performance across the spectrum of risk are paramount. The CathPCI Registry released an updated version 5 data set in 2018 which introduced new variables including: frailty, cardiovascular instability type, level of consciousness after cardiac arrest, and decision for PCI with surgical consult. We sought to 1) develop a new hierarchical mortality model that incorporates these new variables and accounts for case-mix and hospital volume; 2) evaluate the performance of this new mortality model across different risk cohorts; and 3) identify unique cohorts suitable for internal quality improvement and potentially public reporting.

Methods

Data Sources

The CathPCI Registry is a national clinical registry program of the American College of Cardiology (ACC) with partnering support from the Society for Cardiovascular Angiography and Interventions. Description of the registry and the development of its risk mortality prediction models have been previously reported (4, 11). The registry collects data on patient demographics, procedural and clinical characteristics, hospital characteristics, and in-hospital outcomes for PCIs from more than 1600 participating hospitals in the United States. Data are monitored through a comprehensive data quality program that includes a data quality report, a set of internal quality assurance protocols, and a yearly independent auditing program (12).

Study Population

All patients undergoing PCI at any of the 1,608 participating hospitals submitting data to the CathPCI Registry between July 2018 and June 2019 were included. Consistent with prior CathPCI mortality models, only the first procedure per admission was included and patients were excluded if they were transferred to another facility after the index procedure. The study

population was randomly allocated into a model development cohort (70% of total) and a validation cohort (30% of total).

Variable Definitions

The v5 data collection form (DCFv5) integrated a series of new variables that further characterize patients' clinical status. To better characterize cardiovascular instability, new variables included ventricular arrhythmias, acute heart failure symptoms, hemodynamic instability without cardiogenic shock, cardiogenic shock, and refractory cardiogenic shock (defined as persistent hypotension despite mechanical or pharmacologic vasopressor support). A composite ordinal variable was created combining the components of cardiovascular instability with the procedural status, assigned into 6 mutually exclusive categories in decreasing order of procedural urgency and mortality risk: 1) salvage PCI or refractory shock, 2) cardiogenic shock (not refractory) without salvage, 3) cardiovascular instability [CVI] (includes hemodynamic instability, acute heart failure symptoms and ventricular arrhythmia in the absence of shock) without salvage, 4) emergency PCI without shock or CVI, 5) urgent PCI without shock or CVI, and 6) elective PCI without shock or CVI.

The new frailty variable included in DCFv5 was based on the Canadian Study of Health and Aging clinical frailty scale (13). Patients were classified as non-frail, intermediately frail (mild and moderate frailty) and severely frail (severe, severely frail, and terminally ill). Per the data definitions for DCFv5, frailty was based on the clinical condition prior to the start of the procedure which could lead to patients presenting with cardiac arrest, cardiogenic shock or salvage being coded as severely frail irrespective of their baseline status before admission. For purposes of the model, only those patients without cardiac arrest, shock, or undergoing salvage

PCI were eligible to considered as severely frail and were compared to all other patients (non-severe frailty).

A new variable that captured level of consciousness at start of PCI in patients who have suffered cardiac arrest was also incorporated. Patients were categorized as unresponsive if they were not responsive to verbal or painful stimuli or if their level of consciousness was unable to be assessed (e.g., patients who are intubated and sedated). In addition, surgical evaluation prior to PCI was also integrated as new variable. Patients were considered to be a surgical turndown in those cases where a cardiac surgical consult was obtained before engaging in PCI, but surgery was not recommended. Aortic stenosis severity as an indication for cath lab visit was also a newly collected variable. The definitions for number of diseased vessels have been updated to include not only angiographically significant stenosis but also fractional flow reserve and instantaneous wave-free ratio values indicative of ischemia. Finally, estimated glomerular filtration rate (GFR) was calculated based on the Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) equation. CKD was classified according to latest guideline-recommended definition: stage 3a, GFR 45-60 mL/min/1.73 m^2; stage 3b, GFR 30-44 mL/min/1.73 m^2; stage 4, GFR 15-29 mL/min/1.73 m^2; stage 5, GFR <15 mL/min/1.73 m^2 or dialysis (14). The full definitions of the data elements in the registry are available on the NCDR website (15).

Variable Selection

The NCDR established a Risk Adjusted Mortality work group of ACC volunteers to oversee model development and provide input on variable selection and considerations for the model. Candidate variables were screened and selected by the workgroup based on their clinical relevance, association with outcomes from prior research, and importance in model development.

For final variable selection, bootstrap analysis was performed. First, the development sample was used to create 1,000 "bootstrap" samples. For each sample, we ran a logistic regression that included the candidate variables using stepwise selection method (entry = 0.0005, exit = 0.0001). We then calculated the percentage of times each of the variables was selected in each of the 1,000 samples. The variables that were selected in at least 70% of bootstrap samples were then included in the final model. All clinical variables that had been identified *a priori* as being clinically relevant met this threshold except patients turned down for surgery. Given that this variable represents a unique population that may be clustered at certain facilities and high-risk patients with limited treatment options, it was forced into the final model.

Missing data

The rates of missing data were very low (<1%) for all variables, except for ejection fraction (EF) (24%) and GFR (2.5%). For cases with missing information, the following imputation rules were used: 1) for variables related to past medical history, presence of stent thrombosis, and highest risk coronary lesion, missing data was imputed to "no"; 2) for body mass index (BMI), missing values were imputed to the gender-specific median; 3) for GFR, missing values were imputed to the gender-, prior renal failure-, and ST-elevation MI (STEMI)-specific median; and 4) for EF, missing data was imputed to the strata-specific median based on a history of congestive heart failure (CHF), prior myocardial infarction (MI), pre-procedural cardiogenic shock, and the presence of STEMI. These imputation rules have been used in prior models and have generated results similar to those using multiple imputation methods (4, 5).

Statistical analysis

Graphical functions were evaluated for all continuous variables to test for a linear relationship with mortality. For non-linear relationships the variable was transformed using

spline functions. Extreme values for continuous variables were set to outer limits based on clinical judgment. A multivariate logistic regression model linking mortality to the selected variables was fitted. Three models were developed, including: 1) a full model which included all the candidate variables; 2) a pre-cath model, that excluded the angiographic data; and 3) a simplified bedside risk score, which included a reduced number of variables that explained >90% of the risk model. The regression coefficients for these variables were converted to an integer score to create a bedside mortality risk score. To account for the natural clustering of observations within hospitals, a hierarchical logistic regression model was fitted linking mortality to the selected variables with a hospital-specific random effect. Hospital-specific risk-standardized mortality rates (RSMR) for each hospital were calculated using the regression coefficients from the hierarchical model. RSMR were obtained as the ratio of hospital-specific predicted mortality to the hospital-specific expected mortality, multiplied by the mortality rate in the study cohort. The expected number of deaths for each hospital was calculated by summing over the predicted mortality risks for all patients in the hospital using the average of all hospital-specific intercepts, and the predicted number of deaths was calculated in the same manner but using an estimated intercept that is specific for that hospital. This ratio was then multiplied by the mortality rate in the study cohort to calculate RSMR for that particular site (16, 17). The Human Investigation Committee of the Yale University School of Medicine approved the use of a limited data set from the NCDR for research purposes without requiring informed consent because all of the data were deidentified and maintained centrally by the NCDR.

Model performance

After development, the three models were applied to the validation sample. Model discrimination was assessed using the c-index, and model calibration was evaluated by rank-

ordering patients from lowest to highest predicted mortality and comparing predicted versus observed mortality rates within deciles of risk. In addition, discrimination and calibration were further assessed among the following cohorts: 1) all PCI patients excluding cardiogenic shock and cardiac arrest patients, 2) all PCI excluding STEMI patients and 3) all STEMI patients excluding cardiogenic shock and cardiac arrest.

Results

Patient Characteristics

During the study period between July 2018 and June 2019, 1,303,3283 consecutive procedures were recorded in the NCDR CathPCI Registry. After applying exclusion criteria, including visits not associated with a PCI (n=550,586), 706,263 total PCI cases from 1,608 sites were included in the overall sample (**Figure 1**).

The clinical, demographic, and angiographic features of those patients in the development (n=495,005) and validation (n=211,258) cohorts were similar (**Table 1**). The mean patient age was 66 years, 30.8% were female, 85.0% were white, 40.8% had a history of diabetes, and 41.0% had prior PCI. Elective procedures represented 39.2% of procedures performed, while 1.3% were in patients who were unresponsive after cardiac arrest, and 0.5% were in patients with salvage PCI or refractory shock. In the overall sample, 4.0% of the patients were thought to be severely frail, but when considering only patients without cardiac arrest, salvage PCI or shock 2.7% were categorized as severely frail. Aortic stenosis (at least moderate) was noted as an indication for the cath lab visit in 1.9% of the patients, while 3.2% had a documentation of surgery not being recommended after a cardiac surgery consultation.

In-Hospital Mortality Rates

In-hospital mortality following PCI was 1.9% and was similar in both the development and validation cohorts. The unadjusted rates of in-hospital mortality according to clinical characteristics such as age, gender, frailty, and the presence of diabetes (**Table 2)**. In-hospital mortality rates increased with worsening clinical instability – 0.2% for elective procedures without cardiovascular instability or shock, 5.1% in those who were surgical turndowns, 51.7% for patients with cardiac arrest and unresponsiveness, and 62% in salvage PCI or refractory shock cases (**Table 2**).

In-Hospital Mortality Model

The full model contains 22 variables that were consistent predictors of in-hospital mortality in multiple bootstrap samples (**Table 3**). Procedural urgency, cardiovascular instability, age, and responsiveness following cardiac arrest were the variables most predictive of in-hospital mortality. The presence of clinical instability before PCI was a strong predictor in the multi-variable model with those patients who were the most unstable having the highest odds of mortality when compared with patients undergoing elective PCI: salvage PCI or refractory shock (OR 92.77; 95% CI 80.83-106.47), cardiogenic shock without salvage (OR 41.74; 95% CI 37.13-46.92), cardiac instability without shock or salvage (OR 11.25; 95% CI 10.07-12.57), emergency PCI without shock or cardiac instability (OR 7.68; 95% CI 6.84-8.62) and urgent PCI without shock or cardiac instability (OR 3.29; 95% CI 2.97-3.65). New variables associated with in-hospital mortality include unresponsiveness following cardiac arrest (OR 11.36; 95% CI 10.62-12.15), severe frailty for patients without cardiac arrest/shock/salvage (OR 3.12; 95% CI 2.91-3.34), aortic stenosis that is at least moderate in severity (OR 1.52; 95% CI 1.34-1.72), and surgical turndown (OR 1.23; 95% CI 1.13-1.34). The bedside risk score model contains the variables (age, CKD, clinical instability, cardiac arrest) that had the strongest association with

mortality and that in combination explained >90% of the risk model **(Table 4, Supplemental Figure 1).**

Model performance

The full, pre-cath, and bedside risk adjustment models performed well with excellent discrimination in the validation samples (c-indexes, full model: 0.943; pre-cath model: 0.940; bedside risk score: 0.925; **Table 5**). The full model performed well in important cohorts including those undergoing PCI without cardiac arrest or shock (c-index: 0.883), all PCI without STEMI (c-index: 0.926), and patients with STEMI without cardiogenic shock or cardiac arrest (c-index: 0.859) **(Supplemental Figure 2)**. The performance of the full, pre-cath, and bedside risk adjustment models in other cohorts and subgroups are shown (**Table 5)**.

Most patients had a relatively low predicted risk of mortality (90% of the population had a predicted risk of mortality rate that was <1.6%). There was high concordance between model predicted risk and observed mortality in the development and validation cohorts (**Figure 2**). The model was also well calibrated across the different categories of clinical instability (**Supplemental Figure 3**), pre-specified cohorts (**Supplemental Figure 4**), and across the top quintile of predicted risk (**Supplemental Figure 5**). The receiver operator curves for the full model, pre-catheterization model, and the bedside risk score are shown **(Supplemental Figure 6, Supplemental Figure 7)**.

Risk-Standardized Mortality Rates

Hospital RSMR for the overall sample and for the cohort of patients without cardiogenic shock and cardiac arrest are shown in **Figure 3**. The median hospital RSMR in the overall sample was 1.9% (interquartile range [IQR]: 1.7- 2.1%), and in the cohort of patients without cardiogenic shock and cardiac arrest was 0.8% (IQR: 0.7-0.9%). The distribution of hospital

RSMR in the cohort of patients without STEMI and the cohort of STEMI patients without cardiogenic shock or cardiac arrest are shown (**Supplemental Figure 8)**.

Discussion

As the techniques for PCI continue to evolve, as does patient selection, it is important to continually update risk models used to benchmark healthcare quality. In this analysis, we found that contemporary in-hospital mortality rate after PCI is 1.9% and increases with worsening clinical instability. Patients with cardiogenic and refractory shock, patients undergoing salvage PCI, and patients who are unresponsive after cardiac arrest account for a minority of the overall PCI population; yet these patients carry the highest risk of mortality. We found that consideration of newly captured data elements, including frailty, aortic stenosis, refractory shock, and level of consciousness after cardiac arrest add important prognostic information when predicting the risk of in-hospital mortality for patients undergoing PCI (**Central Illustration**). Including these variables improves the discrimination from prior models and enables further stratification of risk in patients undergoing PCI.

The CathPCI registry is the largest and most widely utilized quality improvement registry for patients undergoing PCI in the United States. The risk-adjusted mortality model was last updated in 2013 to specifically improve the ability of the model to account for patients undergoing high risk PCI (5). Since these initial efforts to develop models that predict in-hospital risk associated with PCI, there have been considerable changes in PCI including advances in available equipment, adoption of alternative access sites, and changes in the indications and characteristics of patients who undergo PCI. Furthermore, there have also been improvements both in the methods used to appropriately model risk and the quantity, quality, and relevance of data captured in version 5 of the CathPCI registry. Use of hierarchical models has been shown to be

more accurate and improve upon classic regression models. These models allow for variations in the overall mortality rates at a specific site while at the same time standardizing the patient level factors associated with risk (16, 18).

To date, risk prediction models have not included frailty in the risk assessment of patients undergoing PCI. In studies with prospective evaluation and measurement of physical frailty, over two thirds of patients over age 65 undergoing PCI have some degree of frailty (19, 20). After PCI, frail patients are at increased risk for hospital mortality and cardiovascular complications, but PCI remains an important treatment option (21). Given this, CathPCI registry began collecting outcomes on patient frailty in DCFv5, designated based on the clinical status at the time of PCI. Depending on the measurement tool, a patient's frailty status can vary over time from the baseline status before admission to the time of PCI, particularly in patients hospitalized with acute illness. For this analysis, we elected to only consider frailty for the model in those patients who did not have cardiac arrest, shock, or undergoing salvage PCI. This was done since the current definition of frailty would be reflective of their acute illness rather than the patients baseline frailty. In our multivariate model, frailty was an important predictor that improved the discriminatory ability of the model. While assessment of frailty can be subjective, this model incorporates a standardized definition and is monitored by the CathPCI Registry data monitoring and audit programs.

The new model also considers patient characteristics found to be predictors of particularly poor outcomes, including unresponsiveness following cardiac arrest and refractory cardiogenic shock. Inclusion of high-risk features is necessary as public reporting of outcomes following cardiovascular procedures has become increasingly common. It is possible that public reporting can serve as a powerful driver of quality improvement for hospitals and allow patients to have

more insight into the institutions in which they receive healthcare. Public reporting has been associated with improved PCI outcomes (22). However, studies have also suggested that public reporting may result in risk aversion by providers due to concerns that it may affect individual operator and institutional outcomes, resulting in patients who are at high risk not being offered procedures in which they could potentially benefit (7, 8, 23). Thus, risk prediction models, particularly those which are going to be used in public reporting, must fully account for variables associated with extreme risk and monitor for and mitigate potential to lead to risk aversion.

In this new model, inclusion of level of consciousness following cardiac arrest and refractory cardiogenic shock will allow for the accounting of these particularly high-risk features in such a way as to not penalize providers and sites from being willing to offer high risk patients treatment. The 2013 ACC/AHA guidelines recommend that immediate angiography and PCI should be considered in resuscitated out-of-hospital cardiac arrest patients whose initial ECG shows STEMI (24). While the care of patients with out-of-hospital cardiac arrest has improved over time, outcomes in this population are extremely poor with mortality rates of approximately 50%, primarily driven by non-cardiovascular sequalae (10, 25). There are multiple factors that impact mortality in this high-risk cohort, including time to cardiopulmonary resuscitation, time to defibrillation, total ischemic time, as well as neurological status; the latter shown to enhance mortality risk prediction when considered (26). This new model accounts for level of consciousness following cardiac arrest, which was significantly associated with mortality. We also found that further description of the persistence or "refractoriness" of the cardiogenic shock improves characterization of risk within this extreme risk cohort. These patients also have extremely high mortality rates which are often a reflection of the acuity of illness rather than direct effects of the coronary intervention. Moving forward, consideration should also be given

to the exclusion of patients with prior cardiac arrest or cardiogenic shock from publicly reported outcome measures (27).

Documented surgical ineligibility is associated with increased long-term mortality in patients undergoing PCI even after accounting for common risk factors. Many of these patients have higher anatomical complexity, prohibitive comorbidities or are severely frail, and many are treated with PCI as salvage cases or compassionate use (28). Current guidelines recommended utilizing a heart team approach for handling difficult cases to ensure a multidisciplinary approach that considers a broad range of treatment options in an attempt to optimize care. For the first time, consideration of the heart team decisions will be included in the risk modeling. Patients in whom surgery was not recommended were at increased risk of mortality even after controlling for other potential confounders. Inclusion of this data will improve risk adjustment and help account for the differences in risk that is undertaken by physicians when treating these high-risk cases.

These findings should be considered considering some important limitations. First, this model has excellent discrimination and calibration in the cohorts in which it was developed and validated. However, both the development and validation cohorts were taken from the same overall dataset with variables that are specific to the CathPCI Registry. Participation in the registry is voluntary and individual sites may participate based upon external requirements, therefore results from this model may not be generalizable to smaller or non-US practices. However, it is estimated that CathPCI collects data from >90% of all PCI centers and >90% of all PCIs performed in the U.S (1). The presence of a CTO was a significant predictor of risk; however, the registry does not collect detailed angiographic or procedural variables which have been associated with higher rates of successful revascularization (29). The reasons behind the

recommendation against surgery in the surgical turndown group were out of the scope for this study and should be explored in further research. Finally, although variables in the registry have clearly delineated data definitions, there may be some variation in coding across sites. To address this, the registry counts with a data quality and auditing program, which monitors for accuracy of data collected.

Conclusion

In conclusion, this new in-hospital mortality model incorporates contemporary variables that are reflective of clinical acuity and allows for the accurate prediction of risk of mortality following PCI. Utilization of this model, both in public reporting and in quality improvement efforts, will help standardize the assessment of risk associated with PCI both for hospitals and patients.

Perspectives

Competency in Patient Care and Procedural Skills: In patients undergoing PCI, unresponsiveness after cardiac arrest, refractory cardiogenic shock, salvage and severe frailty are predictive of in-hospital mortality.

Translational Outlook: This updated risk model for in-hospital mortality in patients undergoing PCI can enhance risk stratification of patients considered for PCI, identify opportunities for quality improvement, and improve public reporting of procedural outcomes.

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Figure Legends

Figure 1 - Study Cohort

Between July 2018 and June 2019, 1,303,3283 consecutive procedures were recorded in the NCDR CathPCI Registry. Following exclusions, 706,263 total patients undergoing PCI from 1,608 sites were included in the model development and validation cohorts.

NCDR = National Cardiovascular Data Registry, PCI= percutaneous coronary intervention

Figure 2 - Calibration of the Full Model in the Development and Validation Cohorts

Observed versus predicted mortality estimates for each decile of predicted patient risk in the A) development and B) validation cohorts. There was high concordance between model predicted risk and observed mortality in the development and validation cohorts.

Figure 3 - Distribution of Hospital Risk-Standardized Mortality Rates

Hospital-specific risk-standardized mortality rates for A) All patients cohort and b) All PCI excluding cardiogenic shock/cardiac arrest cohort, determined using the hierarchical logistic regression model.

Central Illustration – Predicting Mortality in Patients Undergoing PCI: Full Model and Bedside Risk Score

Using data from the CathPCI Registry, a multivariate hierarchical logistic regression model was developed to predict in-hospital mortality of patients undergoing PCI, including new updated variables (A). Observed vs predicted mortality rates for equally sized groups are shown (B). (C) A simplified bedside risk score included a reduced number of variables that explained >90% of the risk model. (D) Observed mortality rates varied substantially by risk score.

CLD = chronic lung disease; CVD = cerebrovascular disease; CVI = cardiovascular instability; CKD = chronic kidney disease; GFR = glomerular filtration rate; LAD = left anterior

descending; LVEF = left ventricular ejection fraction; NYHA = New York Heart Association; PAD = peripheral arterial disease; PCI = percutaneous coronary intervention; SBP = systolic blood pressure; STEMI = ST- elevation myocardial infarction

Table 1 - Patient Clinical Characteristics

	Overall (n=706,263)	Development (n=495,005)	Validation (n=211,258)
Patient characteristics			
Age, yrs	66.3 (11.7)	66.3 (11.7)	66.3 (11.7)
Female	30.8	30.7	30.8
Race			
White	85.0	85.0	85.0
Black	8.5	8.5	8.4
BMI	30.2 (6.5)	30.2 (6.5)	30.8 (6.5)
Comorbidities			
Diabetes	40.8	40.8	40.9
Cerebrovascular disease	14.3	14.3	14.3
Peripheral arterial disease	11.8	11.8	11.8
Chronic lung disease	15.7	15.7	15.6
Prior myocardial infarction	28.0	28.0	28.0
Prior PCI	41.0	41.0	41.0
Prior CABG	16.2	16.2	16.3
CKD stage			
Stage 3a (GFR 45-60)	14.9	14.9	15.0
Stage 3b (GFR 30-45)	7.3	7.3	7.4
Stage 4 (GFR 15-29)	2.0	2.0	2.0
Stage 5 (GFR <15 or dialysis)	3.5	3.5	3.5
Frailty scale			
Not frail	77.9	77.9	77.9
Intermediately frail	17.8	17.8	17.8
Severely frail	4.0	4.0	4.0
Aortic stenosis (at least moderate)	1.9	1.9	1.9
Family history of premature CAD	17.4	17.5	17.4
LVEF, %	51.5 (13.0)	51.5 (13.0)	51.6 (13.0)
NYHA class			
Class IV	2.9	2.9	3.0
Class I/II/III	20.7	20.7	20.7
No CHF	76.4	76.4	76.3
Clinical presentation			
Systolic blood pressure, mmHg	148 (26.4)	148 (26.4)	148 (26.4)
STEMI	16.3	16.3	16.2
Treated with thrombolytics	0.6	0.6	0.6
Clinical instability			
Salvage PCI or refractory shock	0.5	0.5	0.5
Cardiogenic shock without salvage	1.8	1.8	1.8
Cardiovascular instability without salvage	4.3	4.3	4.3
Emergency PCI without shock/CVI	14.4	14.4	14.3
Urgent PCI without shock/CVI	40.3	40.2	40.3
Elective PCI without shock/CVI	38.8	38.8	38.8
Cardiac arrest			
Responsive	1.4	1.4	1.4

Unresponsive	1.3	1.2	1.3
Surgery Not Recommended	3.2	3.2	3.2
Procedural characteristics			
Highest risk coronary segment treated			
Left main	3.5	3.5	3.6
Proximal LAD	20.1	20.1	20.0
Number of diseased vessels			
1	52.4	52.5	52.3
2	29.7	29.7	29.8
3	16.8	16.7	16.8
TIMI flow grade 0	15.2	15.2	15.1
Subacute in-stent thrombosis	0.3	0.3	0.3
In-stent restenosis	10.8	10.7	10.9
Chronic total occlusion treated	4.1	4.1	4.1
Bypass graft treated	5.1	5.1	5.1
Type C lesion	63.0	63.0	62.9
Bifurcation lesion	12.0	12.0	12.0

Values are % or mean (SD).

BMI = body mass index; CABG = coronary artery bypass graft; CAD = coronary artery disease; CVI = cardiovascular instability; CHF = congestive heart failure; CKD = chronic kidney disease; GFR = glomerular filtration rate; LAD = left anterior descending; LVEF = left ventricular ejection fraction; MI = myocardial infarction; NYHA = New York Heart Association; PCI = percutaneous coronary intervention; STEMI = ST-elevation myocardial infarction; TIMI = Thrombolysis In Myocardial Infarction.

Table 2 - Unadjusted In-Hospital Mortality Rate

	Overall (n=706,263)
Overall population	1.91
Demographic group	
Women	2.40
Men	1.70
>70 years	2.71
≤ 70 years	1.43
Diabetes	2.06
No diabetes	1.82
Severely frail excluding shock/cardiac arrest/salvage	6.92
Surgery Not Recommended	5.11
No cardiogenic shock or cardiac arrest	0.80
MI status	
STEMI	6.56
No STEMI	1.01
STEMI without cardiac arrest/shock	2.23
Cardiac arrest	
Responsive	7.30
Unresponsive	51.7
Clinical Instability Status	
Salvage PCI or refractory shock	62.01
Cardiogenic shock without salvage	35.61
Cardiovascular instability without salvage	7.26
Emergency PCI without shock/CVI	2.18
Urgent PCI without shock/CVI	0.70
Elective PCI without shock/CVI	0.17

Values are %.

CVI = cardiovascular instability; MI = myocardial infarction; STEMI = ST-elevation myocardial infarction; PCI = percutaneous coronary artery intervention.

Table 3 - Full and Pre-Cath Mortality Models

	Full Model			Pre-Cath Model		
	Chi-square	**OR**	**95% CI**	**Chi-square**	**OR**	**95% CI**
Intercept	152.67					
Age*						
<45 yrs	2.70	0.84	0.69-1.03	2.28	0.86	0.70-1.05
≥45 yrs	1526.13	1.51	1.48-1.55	1692.42	1.54	1.51-1.57
Female	271.70	1.46	1.39-1.52	210.03	1.39	1.33-1.45
Cerebrovascular disease	39.95	1.20	1.13-1.27	52.58	1.23	1.16-1.30
Peripheral arterial disease	68.75	1.29	1.22-1.37	98.82	1.36	1.28-1.44
Chronic lung disease	62.93	1.24	1.18-1.31	51.59	1.22	1.15-1.28
Prior PCI	72.25	0.81	0.77-0.85	73.95	0.81	0.77-0.85
Diabetes	32.62	1.14	1.09-1.20	210.03	1.19	1.14-1.25
CKD stage‡						
Stage 3a (GFR 45-60)	181.78	1.49	1.40-1.57	186.29	1.49	1.41-1.58
Stage 3b (GFR 30-44)	558.65	2.15	2.02-2.29	565.32	2.15	2.02-2.29
Stage 4 (GFR 15-29)	912.39	3.65	3.36-3.97	916.07	3.65	3.35-3.96
Stage 5 (GFR 0-14 or dialysis)	951.47	3.53	3.26-3.82	1000.75	3.61	3.34-3.91
Severe Frailty without shock/cardiac arrest/salvage	1021.15	3.12	2.91-3.34	1082.36	3.20	2.99-3.43
Aortic stenosis (at least moderate)	43.20	1.52	1.34-1.72	44.01	1.52	1.34-1.72
LVEF†						
<55%	359.29	0.90	0.89-0.91	496.82	0.88	0.87-0.89
≥55%	4.07	1.04	1.00-1.08	2.38	1.03	0.99-1.07
Not measured	76.00	1.27	1.21-1.34	74.03	1.27	1.20-1.33
Systolic blood pressure*						
<90 mmHg	3.72	0.96	0.92-1.00	3.20	0.96	0.92-1.00
90-180 mmHg	951.20	0.86	0.85-0.87	981.35	0.86	0.85-0.86
>180 mmHg	23.63	1.11	1.06-1.16	22.35	1.11	1.06-1.15
STEMI	190.46	1.58	1.48-1.68	127.30	1.44	1.35-1.54
Clinical instability§						
Salvage PCI or refractory shock	4151.99	92.77	80.83-106.47	4509.11	108.75	94.84-124.70
Cardiogenic shock without salvage	3909.06	41.74	37.13-46.92	4242.80	47.87	42.61-53.78
CVI without shock/salvage	1829.11	11.25	10.07-12.57	1957.76	12.09	10.83-13.51
Emergency PCI without shock/CVI	1184.62	7.68	6.84-8.62	1284.30	8.28	7.38-9.30
Urgent PCI without shock/CVI	515.76	3.29	2.97-3.65	549.14	3.41	3.08-3.78
Heart failure¶						
NYHA class 1/2/3	6.61	0.93	0.87-0.98	2.13	0.96	0.90-1.02
NYHA class 4	59.45	1.32	1.23-1.42	93.65	1.42	1.32-1.52
Cardiac arrest**						
Responsive	193.41	1.94	1.77-2.13	190.26	1.92	1.75-2.11
Unresponsive	4963.69	11.36	10.62-12.15	4861.57	10.91	10.20-11.67
Surgery Not Recommended	22.83	1.23	1.13-1.34			
In-stent thrombosis	42.75	1.96	1.60-2.40			
Highest risk lesion						
Proximal LAD vs. other	166.17	1.38	1.32-1.45			
Left main vs. other	246.75	1.89	1.74-2.04			
Number of diseased vessels						

2 vs. 1	111.76	1.32	1.25-1.39
3 vs. 1	371.49	1.73	1.64-1.83
Chronic total occlusion	43.42	1.39	1.26-1.53

*Per 10-unit increase. † Per 5-unit increase. ‡ Versus GFR >60. § versus elective PCI without shock/CI. ¶ versus no heart failure within 2 weeks. ** vs no cardiac arrest.

CVI = cardiovascular instability; CKD = chronic kidney disease; GFR = glomerular filtration rate; LAD = left anterior descending; LVEF = left ventricular ejection fraction; NYHA = New York Heart Association; PCI = percutaneous coronary intervention; STEMI = ST- elevation myocardial infarction

Table 4 - CathPCI Registry Bedside Risk Score

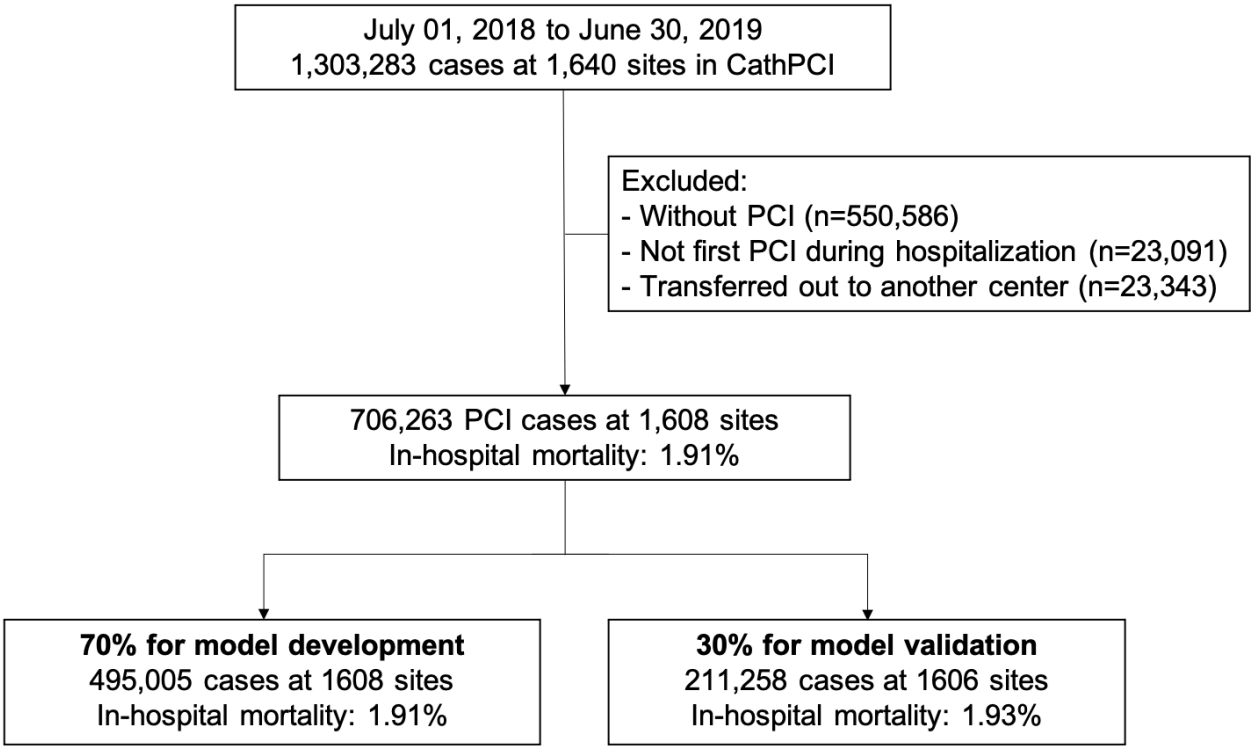
Scoring Response Categories		Points	Total Points	In-hospital Mortality %
			≤5	0.04
Age, yrs.	10 to 19	1	6	0.07
	20 to 29	2	7	0.12
	30 to 39	3	8	0.19
	40 to 49	4	9	0.27
	50 to 59	5	10	0.55
	60 to 69	6	11	0.85
	70 to 79	7	12	1.28
	80 to 89	8	13	2.28
	90 to 99	9	14	4.04
	≥ 100	10	15	6.38
			16	10.01
CKD stage			17	14.92
GFR > 60		0	18	22.72
Stage 3a (GFR 45-60)		1	19	33.76
Stage 3b (GFR 30-44)		2	20	38.89
Stage 4 (GFR 15-29)		3	21	45.73
Stage 5 (GFR 0-14 or dialysis)		3	22	53.00
			23	63.57
Clinical Instability			24	69.22
Salvage PCI or refractory shock		13	25	75.39
Cardiogenic shock (not refractory) without salvage		11	26	78.63
CVI without shock/salvage		7	27	85.48
Emergency PCI without shock/CVI		6	28	87.85
Urgent PCI without shock/CVI		3	29	91.67
Elective PCI without shock/CVI		0		
Cardiac arrest				
No		0		
Responsive		1		
Unresponsive		5		

CVI = cardiovascular instability; CKD = chronic kidney disease; GFR = glomerular filtration rate; PCI = percutaneous coronary intervention.

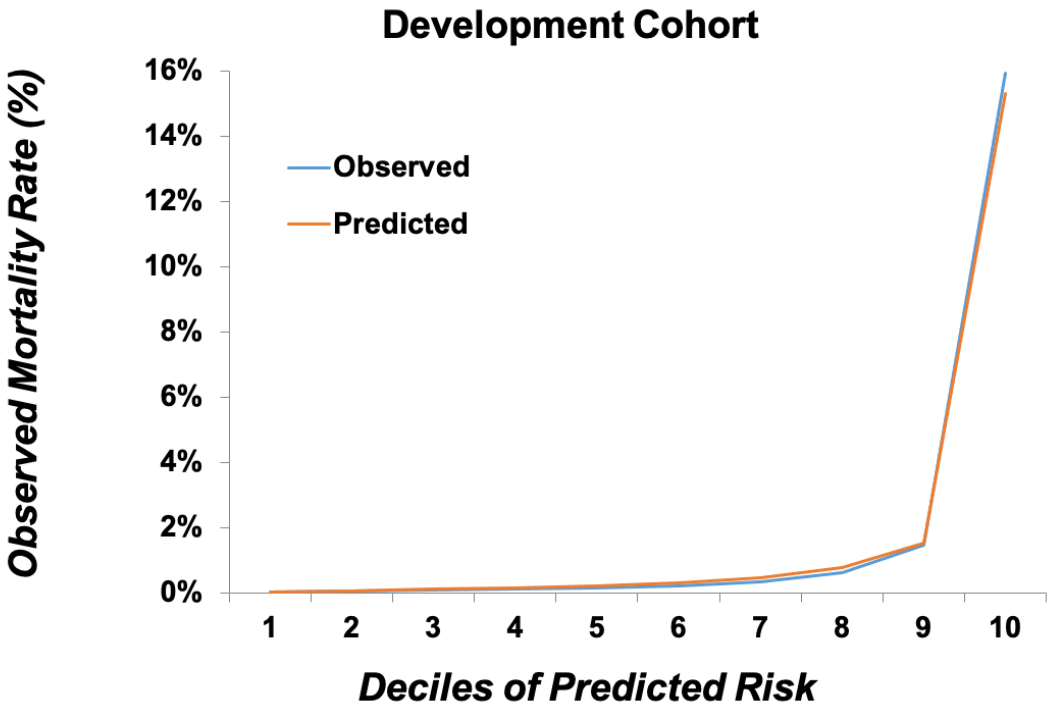
Table 5 – Discrimination in the Full and Pre-Cath Models

	Sample, n	Full Model	Pre-Cath Model	Bedside Risk Score
Development cohort	495,005	0.943	0.940	0.924
Validation cohort	211,258	0.943	0.940	0.924
Cohorts				
All PCI except cardiogenic shock/cardiac arrest	678,347	0.883	0.841	0.843
All PCI except STEMI	591,015	0.926	0.921	0.898
All STEMI except shock/cardiac arrest	98,170	0.859	0.849	0.784
Subgroups				
STEMI	115,248	0.927	0.924	0.903
Female	217,228	0.929	0.924	0.908
Male	489,035	0.949	0.946	0.933
Age >70	267,418	0.925	0.950	0.900
Age ≤70	438,845	0.952	0.922	0.935
Diabetes	288,391	0.942	0.941	0.920
Without diabetes	417,872	0.945	0.938	0.928
Cardiogenic shock/cardiac Arrest	27,916	0.845	0.841	0.822

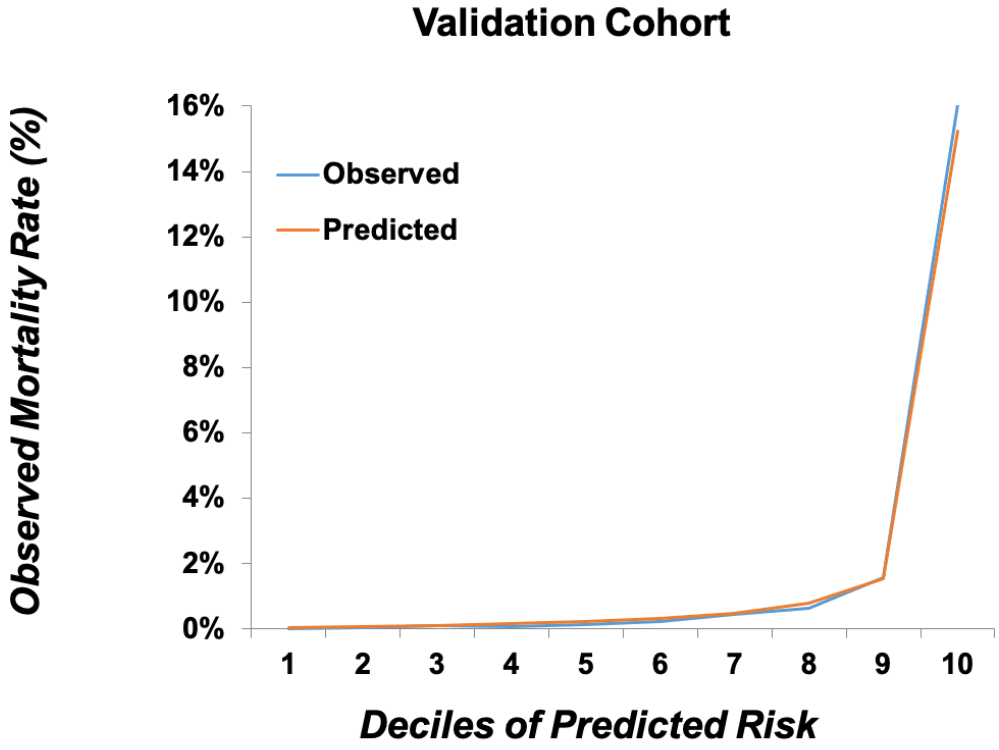
STEMI = ST- elevation myocardial infarction


July 01, 2018 to June 30, 2019
1,303,283 cases at 1,640 sites in CathPCI
Excluded:
- Without PCI (n=550,586)
- Not first PCI during hospitalization (n=23,091)
- Transferred out to another center (n=23,343)
706,263 PCI cases at 1,608 sites
In-hospital mortality: 1.91%
70% for model development
495,005 cases at 1608 sites
In-hospital mortality: 1.91%
30% for model validation
211,258 cases at 1606 sites
In-hospital mortality: 1.93%

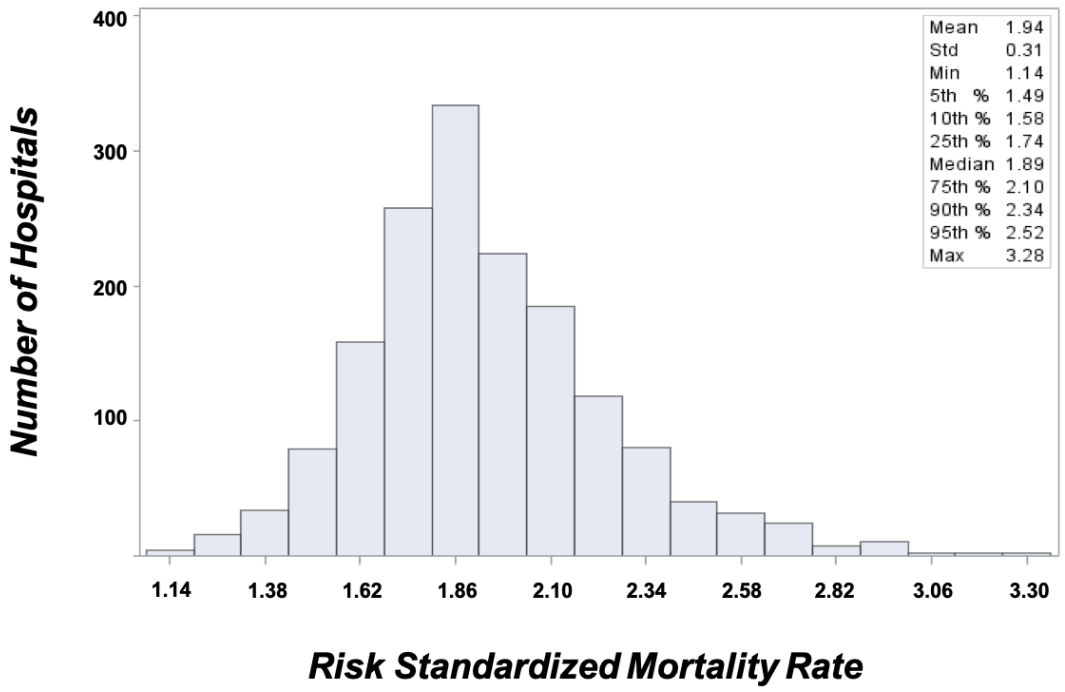
A)


Development Cohort
Observed Mortality Rate (%)
16%
14%
12%
10%
8%
6%
4%
2%
0%
Observed
Predicted
1
2
3
4
5
6
7
8
9
10
Deciles of Predicted Risk

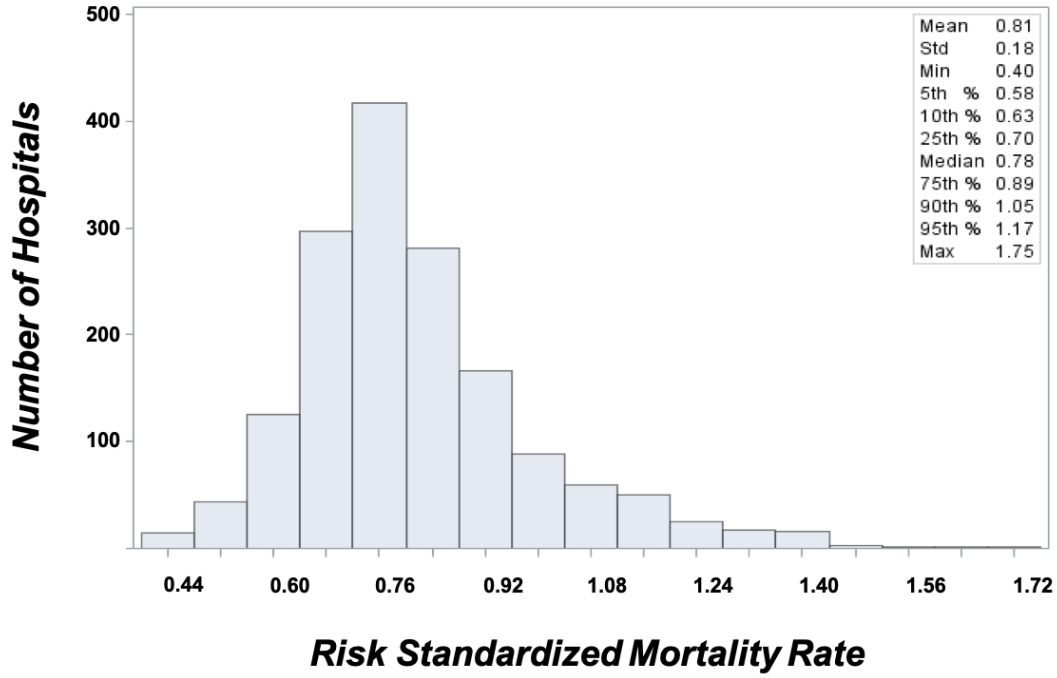
B)


Validation Cohort
Observed Mortality Rate (%)
16%
14%
12%
10%
8%
6%
4%
2%
0%
Observed
Predicted
1
2
3
4
5
6
7
8
9
10
Deciles of Predicted Risk

A)

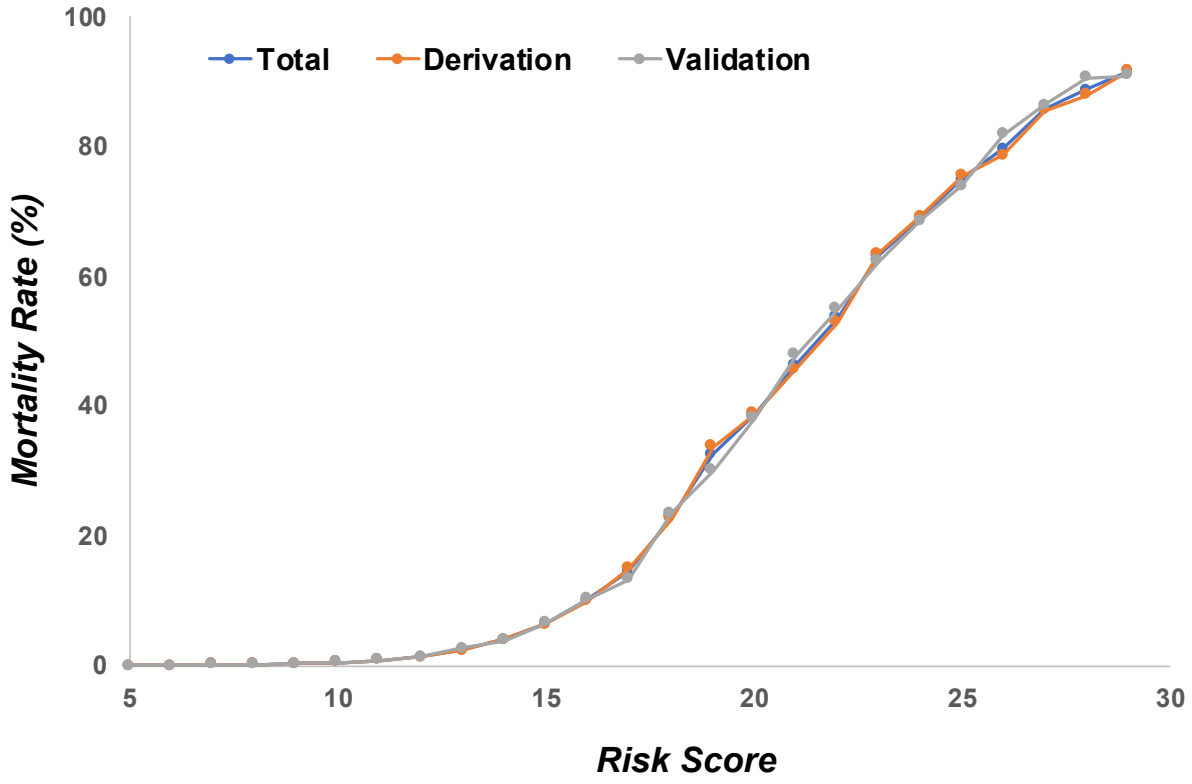

Number of Hospitals
400
300
200
100
Mean 1.94
Std 0.31
Min 1.14
5th % 1.49
10th % 1.58
25th % 1.74
Median 1.89
75th % 2.10
90th % 2.34
95th % 2.52
Max 3.28
1.14
1.38
1.62
1.86
2.10
2.34
2.58
2.82
3.06
3.30
Risk Standardized Mortality Rate

B)


Number of Hospitals
500
400
300
200
100
Mean 0.81
Std 0.18
Min 0.40
5th % 0.58
10th % 0.63
25th % 0.70
Median 0.78
75th % 0.89
90th % 1.05
95th % 1.17
Max 1.75
0.44
0.60
0.76
0.92
1.08
1.24
1.40
1.56
1.72
Risk Standardized Mortality Rate

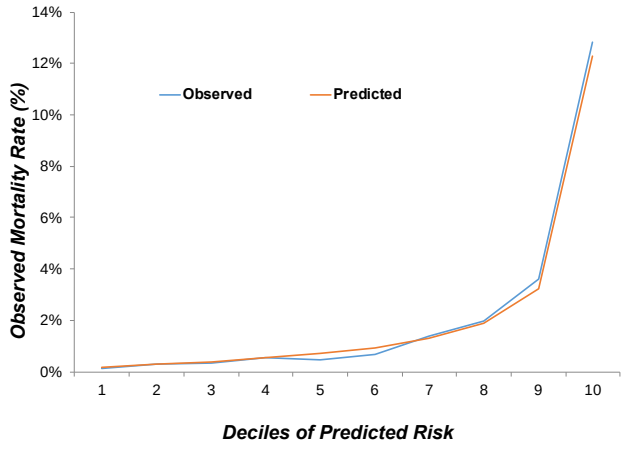
Supplemental Data

Supplemental Figure 1 - Distribution of CathPCI Bedside Risk Score and In-Patient Mortality in All Patients

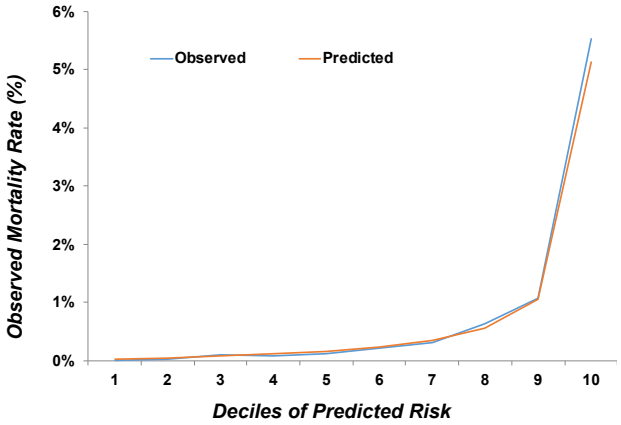


Supplemental Figure 2 - Calibration of the Full Model in Patients for A) All PCI Patients without Cardiogenic Shock/Cardiac Arrest, B) All PCI Patients without STEMI and C) all STEMI Patients without Cardiogenic Shock/Cardiac Arrest

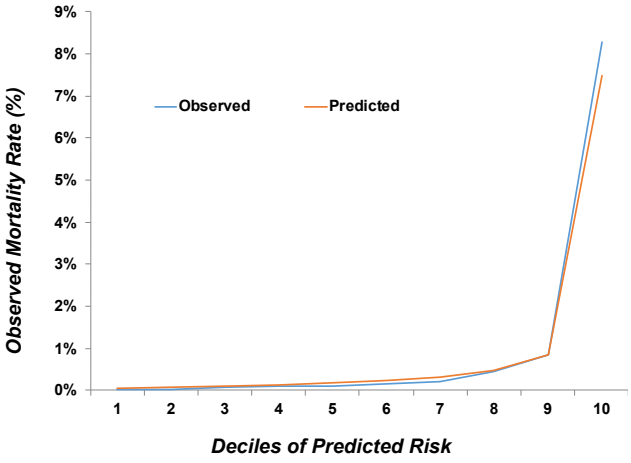
A)



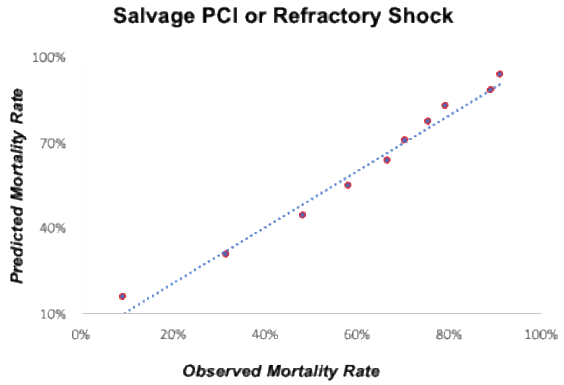
B)

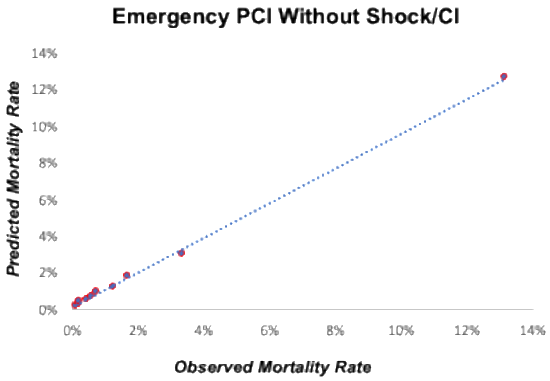


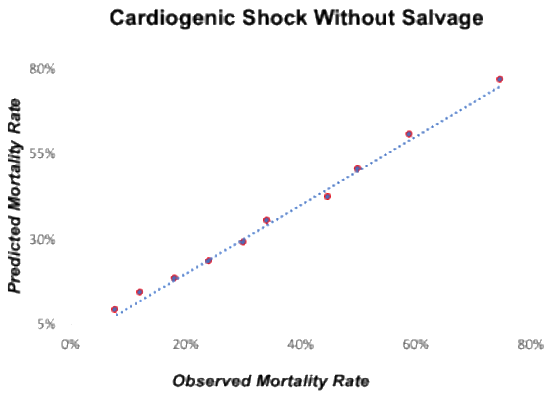
C)

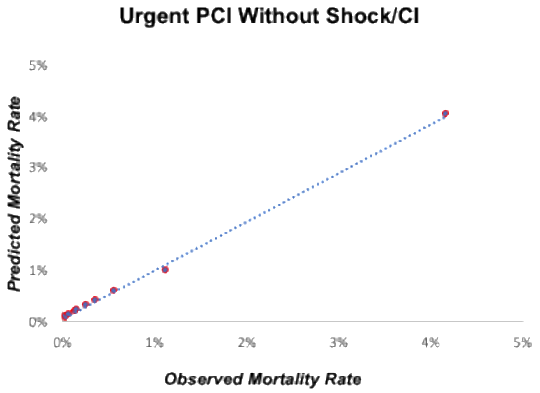


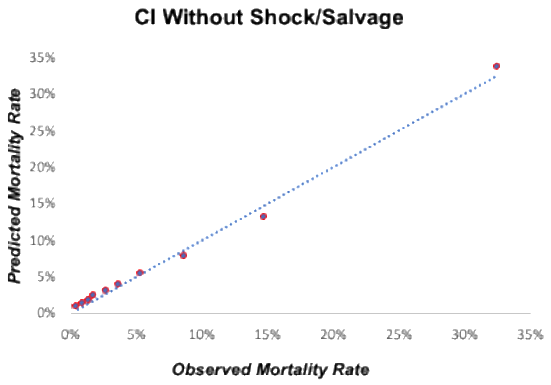
Supplemental Figure 3 - Calibration of the Full Model for Mortality Risk Across Cohorts of Clinical Instability

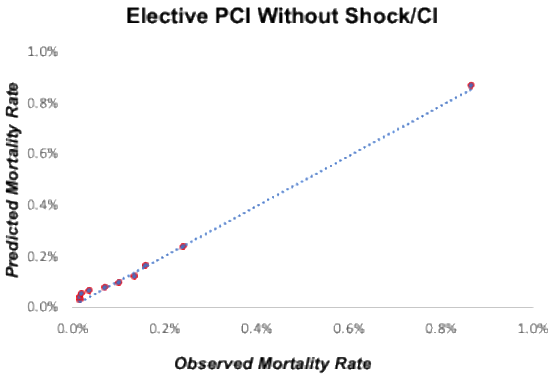




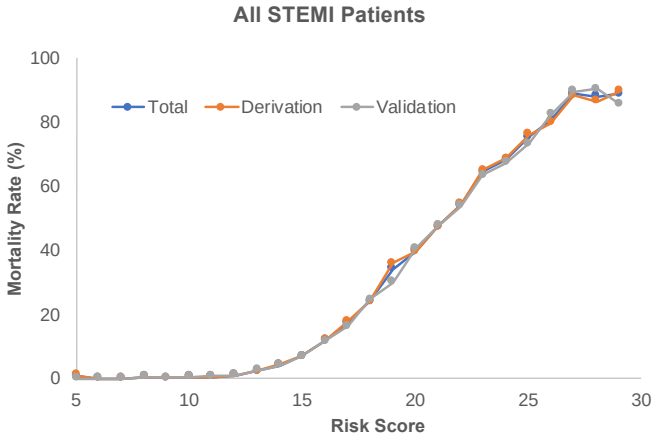


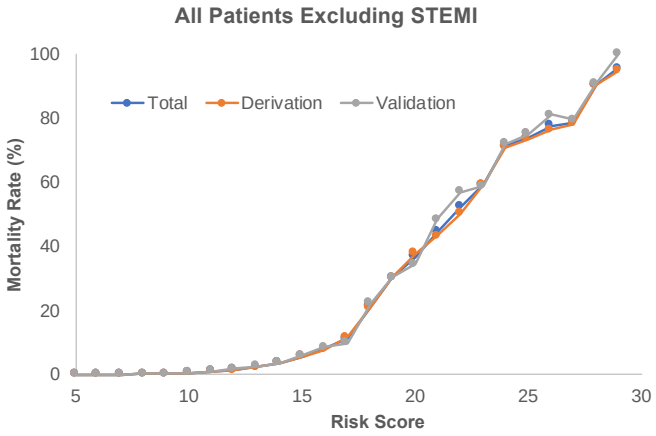


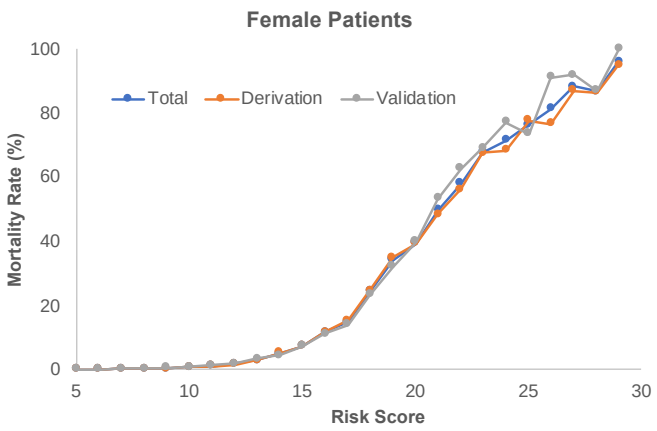


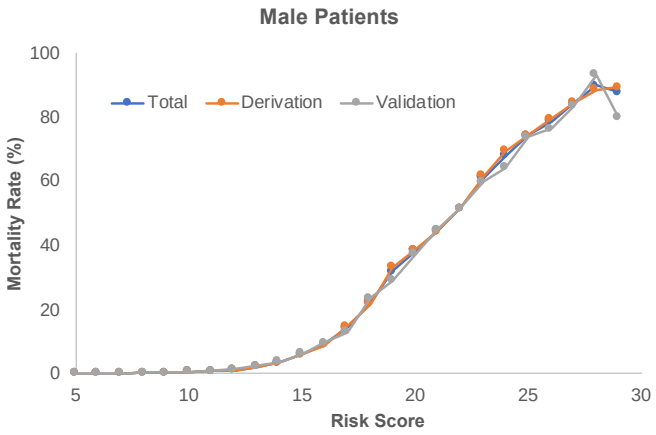


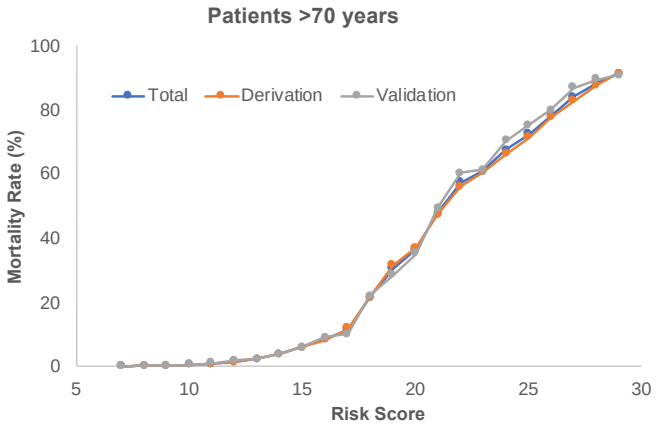
Supplemental Figure 4 - Distribution of CathPCI Bedside Risk Score and In-Patient Mortality in Subgroups

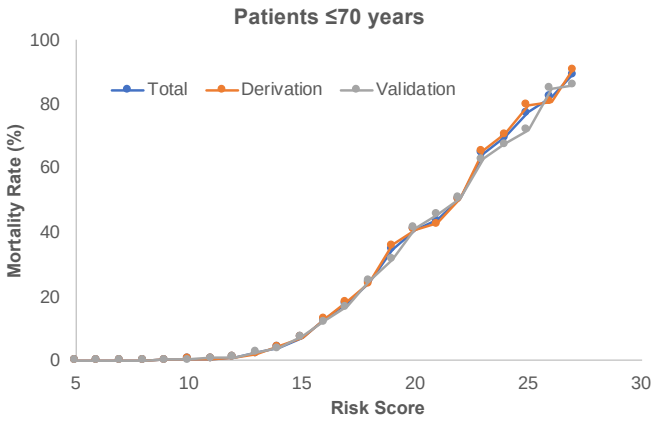




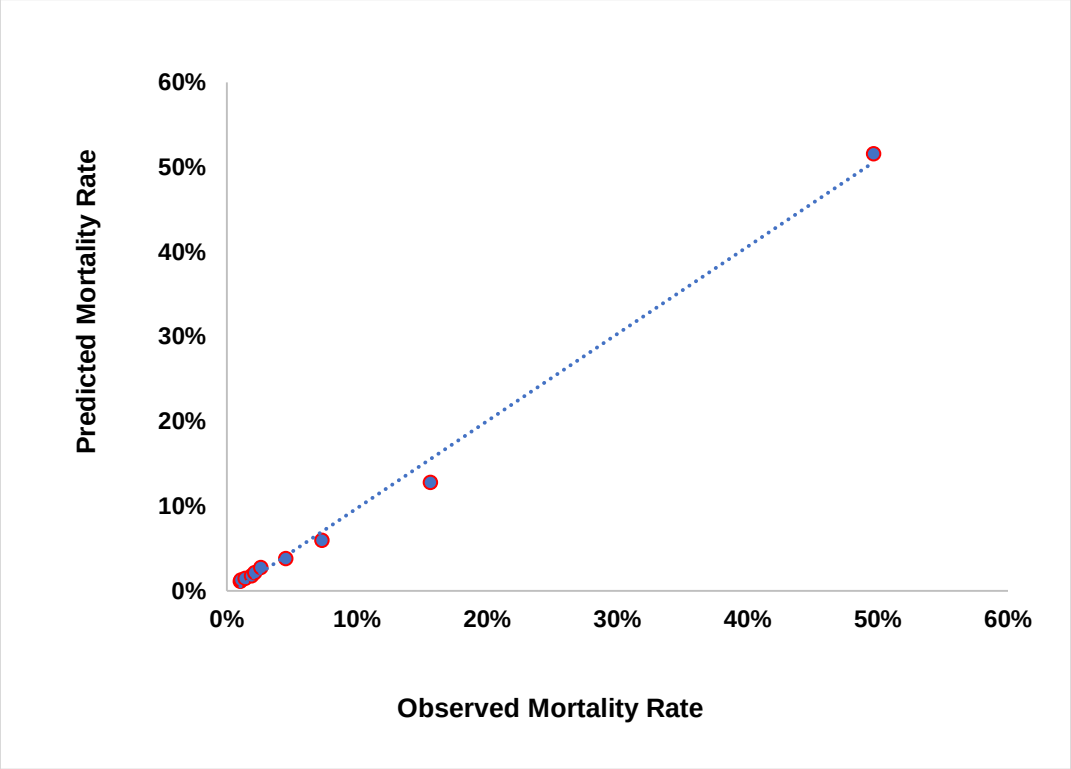




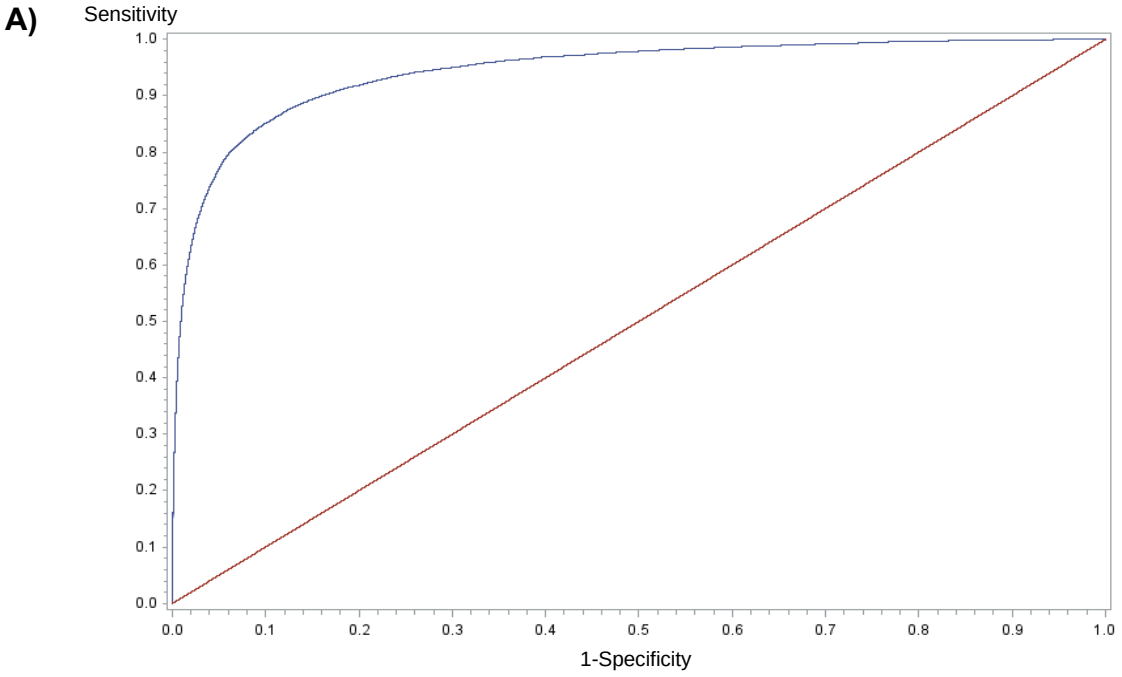


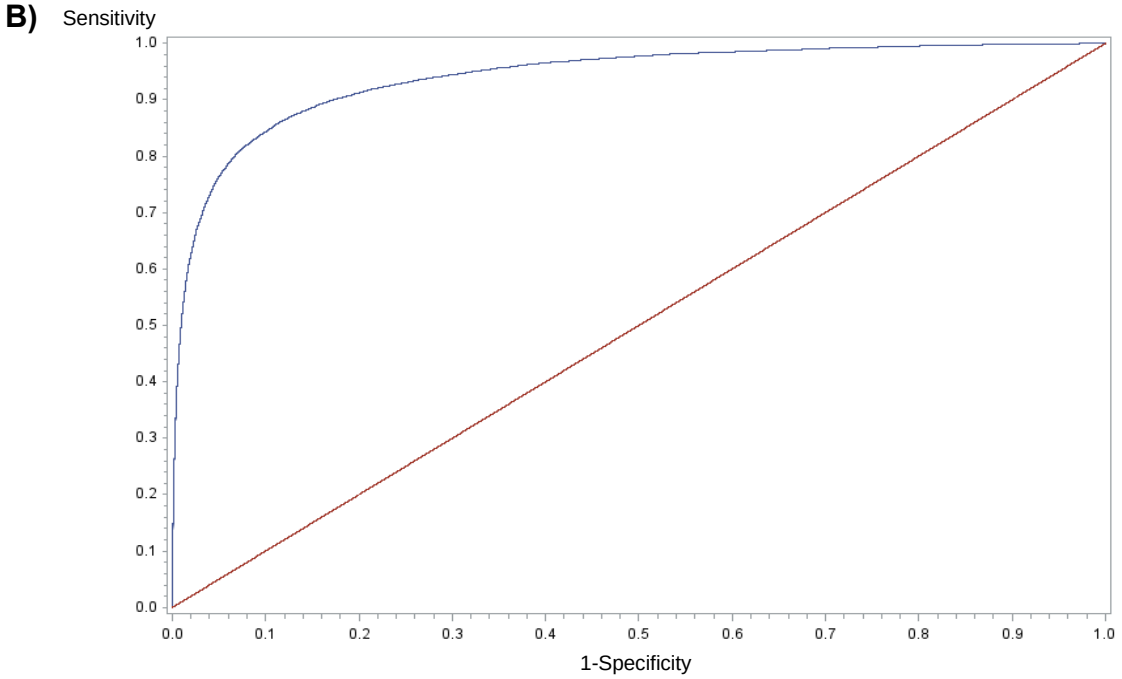


Supplemental Figure 5 - Calibration of the Full Model Across the Top Quintile of Predicted Risk

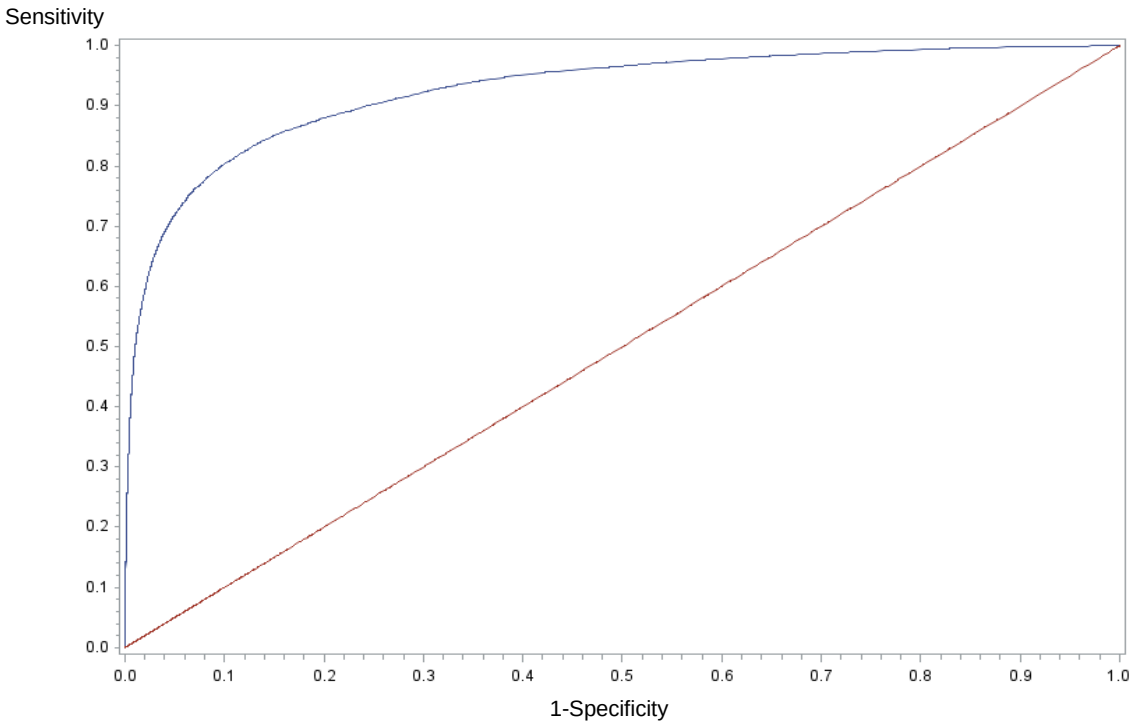


Supplemental Figure 6 - Receiver Operator Curves For the A) Full and B) Pre-Catheterization Models



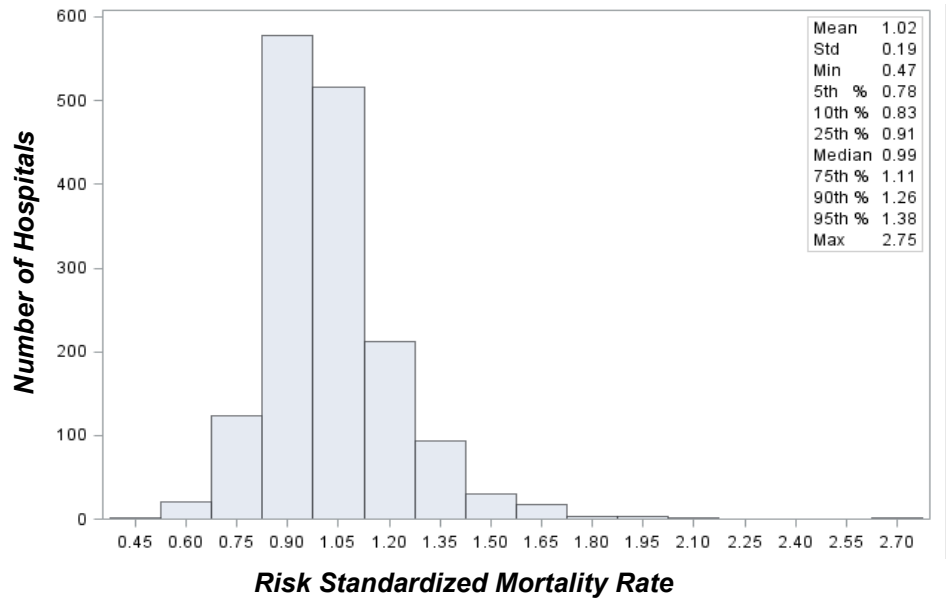


Supplemental Figure 7 - Receiver Operator Curve for the Bedside Risk Score



Supplemental Figure 8- Distribution of Hospital Risk-Standardized Mortality Rates for A) All PCI Patients without STEMI and B) All STEMI Patients without Cardiogenic Shock/Cardiac Arrest

A)



B)