

5.4.4 Risk/Case-Mix Adjustment Modeling and/or Stratification Results

As described above, bivariate analyses were done to identify candidate variables that differed significantly between those with and without a clinically important bleeding event. Multivariable, hierarchical logistic regression analyses were then performed to retain those with a statistically significant association with bleeding ($p < 0.05$ for each). Table 10 Predicted Probability of Bleeding in Section 5.1.4 demonstrates the difference between those with and without bleeding events.

Table 17. Model Variables

Variable	Variable Type	Elements
Age	Number	DOB (2050) and Arrival Date/Time (3001)
Female	Boolean (yes or no)	Sex (2060)
BMI (kg/m ²)	Number	BMI=Weight*10000/(Height*Height) Height (6000) and Weight (6005)
Cerebrovascular Disease	Boolean (yes or no)	Cerebrovascular Disease (4551)
Peripheral Arterial Disease	Boolean (yes or no)	Peripheral Arterial Disease (4610)
Chronic Lung Disease	Boolean (yes or no)	Chronic Lung Disease (4576)
Prior PCI	Boolean (yes or no)	Prior PCI (4495)
Glomerular filtration rate (mL/min/1.73 m ²)	Number	$eGFR = 141 \times \min(SCr/\kappa, 1)^{\alpha} \times \max(SCr/\kappa, 1)^{-1.209} \times 0.993^{Age} \times 1.018$ [if female] $\times 1.159$ [if Black]; $\kappa = 0.7$ (females) or 0.9 (males), $\alpha = -0.329$ (females) or -0.411 (males). Pre-procedure creatinine (6050), Age ((Birth Date (2050) and Arrival Date/Time (3001))), sex (2060)
Severe Frailty	Boolean (yes or no)	CSHA Clinical Frailty Scale (4561) = one of the following: severely frail, very severely frail or terminally ill <u>and none</u> of the following: Cardiogenic Shock (7415), Refractory Cardiogenic Shock (7415), Cardiac Arrest (4630, 4635, or 7340) or Salvage PCI (7800)
NYHA: No Heart Failure (reference) NYHA IV NYHA I, II, III	Categories	NYHA Class (4011)
Heart Failure Type	Number	Heart Failure Type (4013)

Variable	Variable Type	Elements
Systolic Blood Pressure (SBP) splines: SBP < 90 SBP 90-180 SBP > 180	Number	Systolic Blood Pressure (6016)
PCI Status and Clinical Instability	Categories	<p>Six mutually exclusive groups:</p> <ol style="list-style-type: none"> 1. Salvage PCI (7800) or Refractory Shock (7415) 2. Cardiogenic Shock (7415) without Salvage PCI (7800) 3. Cardiovascular instability* without shock (7415) <u>or</u> salvage PCI (7800) 4. Emergency PCI (7800) without shock or cardiac instability* (7415) 5. Urgent PCI (7800) without shock <u>or</u> cardiovascular instability* (7415) 6. Elective PCI (7800) without shock <u>or</u> cardiovascular instability* (7415), reference group 7. Other, reference group <p>* Cardiovascular Instability defined as 7415 = Cardiovascular Instability Type of Hemodynamic instability, or Acute Heart Failure symptoms, or Ventricular arrhythmia; but without shock.</p>
Cardiac Arrest No (reference) Yes and Responsive Yes and Non-responsive	Categories	Cardiac arrest out of healthcare facility (4630) <u>or</u> Cardiac arrest at transferring facility (4635) <u>or</u> cardiac arrest at this facility <u>and</u> Responsive (LOC (7810) = alert, pain or verbal) or Unresponsive (LOC (7810) = Unresponsive or Unable to assess)
Decision for PCI with Surgical Consult	Boolean	Decision for PCI with surgical Consult (7815)
Pre-surgery Evaluation: Non-Cardiac Surgery	Boolean	Pre-surgery Evaluation (7465)
ST-segment elevation MI	Boolean	<p>Percutaneous Coronary Intervention Indication (7825) = <u>any</u> of the following:</p> <p>STEMI - Immediate PCI for Acute STEMI, STEMI - Stable (<=12 hrs from Symptom onset), STEMI - Stable (>12 hrs from Symptom onset), STEMI - Unstable (>12hrs from Symptom onset), STEMI (after successful lytics), STEMI - Rescue (after unsuccessful lytics)</p>
Concomitant Procedure	Number	Concomitant Procedure Performed (7065) and Procedure Type (7066) (<u>without</u> Peripheral Intervention (3081), Peripheral Angiogram (3615), Biopsy of heart (3657), or Procedure Type Not Listed (3738))
Highest Risk Lesion treated with PCI Left Main Proximal LAD Other (reference)	Categories	<p>Left Main = segment number (8001) = 11a, 11b or 11c Proximal Left Anterior Descending = segment number (8001) = 12 Other = segment number (8001) = any other segment (not 11a, 11b, 11c or 12)</p>

Variable	Variable Type	Elements
TIMI Flow (Pre-Intervention)	Number	TIMI flow (pre-intervention) (8007)
Lesion Complexity	Number	Lesion Complexity (8019)
In-stent Thrombosis	Boolean (yes or no)	In-stent Thrombosis (8012) within 30 days of prior PCI calculated as difference between prior PCI data (8009) and procedure data (7000)

Table 18. Model Coefficients for All PCI with No Prior Cardiac Arrest or Cardiogenic Shock

Variable	Weight	Standard Error	Odds Ratio, 95% CI, p-value
Intercept	-4.9795	0.0739	
Age	0.0188	0.0007	1.019 (1.018, 1.02) p<0.0001
Female	0.7045	0.0138	2.023 (1.969, 2.079) p<0.0001
BMI	-0.0232	0.0011	0.977 (0.975, 0.979) p<0.0001
Cerebrovascular Disease	0.1259	0.0173	1.134 (1.096, 1.173) p<0.0001
Peripheral Arterial Disease	0.2630	0.0188	1.301 (1.254, 1.35) p<0.0001
Chronic Lung Disease	0.2064	0.0171	1.229 (1.189, 1.271) p<0.0001
Prior PCI	-0.1673	0.0151	0.846 (0.821, 0.871) p<0.0001
GFR	-0.0132	0.0003	0.987 (0.986, 0.987) p<0.0001
Severe Frailty	0.6191	0.0271	1.857 (1.761, 1.958) p<0.0001
PCI Status: Urgent PCI and neither cardiogenic shock nor cardiovascular instability	0.5579	0.0201	1.747 (1.68, 1.817) p<0.0001
PCI Status: Emergency PCI and neither cardiogenic shock nor cardiovascular instability	1.1375	0.0255	3.119 (2.967, 3.279) p<0.0001
PCI Status: No Salvage PCI and cardiovascular instability	1.2130	0.0272	3.363 (3.189, 3.548) p<0.0001
NYHA class within 2 weeks: 4 (NYHA4)	0.2709	0.0303	1.311 (1.235, 1.391) p<0.0001
Heart Failure Type: Diastolic heart failure	0.2423	0.0212	1.274 (1.222, 1.328) p<0.0001
Heart Failure Type: Systolic heart failure	0.1657	0.0194	1.18 (1.136, 1.226) p<0.0001
Pre-surgery Evaluation: Non-Cardiac Surgery	0.5399	0.0534	1.716 (1.545, 1.905) p<0.0001
Concomitant Procedure	0.5423	0.0203	1.72 (1.653, 1.79) p<0.0001
Systolic Blood Pressure < 90	0.4454	0.0591	1.561 (1.39, 1.753) p<0.0001
Decision for PCI with Surgical Consult	0.6014	0.0227	1.825 (1.745, 1.908) p<0.0001

Variable	Weight	Standard Error	Odds Ratio, 95% CI, p-value
PCI Indication: STEMI - Unstable (>12 hours from symptom onset)	0.5228	0.0531	1.687 (1.52, 1.872) p<0.0001
PCI Indication: STEMI - Rescue (After unsuccessful lytics)	-0.3343	0.0371	0.716 (0.666, 0.77) p<0.0001
PCI Indication: New Onset Angina	-0.1350	0.0207	0.874 (0.839, 0.91) p<0.0001
In-stent Thrombosis within 1 month (THROM)	0.5963	0.0802	1.815 (1.551, 2.124) p<0.0001
Highest risk lesion – proximal LAD	0.1164	0.0169	1.123 (1.087, 1.161) p<0.0001
Highest risk lesion – Left Main	0.7686	0.0244	2.157 (2.056, 2.262) p<0.0001
TIMI Flow Pre-Intervention: No perfusion	0.3408	0.0193	1.406 (1.354, 1.46) p<0.0001
Lesion Complexity: Non-High/Non-C Lesion	-0.1776	0.0159	0.837 (0.812, 0.864) p<0.0001