5.4.2 Conceptual Model Rationale

Table 15. Risk-Standardized Bleeding Variables with Associated Odds Ratios

A hierarchical logistic regression model was created for this model, with the relevant variables and odds ratios posed below in Table 15. The data definitions are available on the NCDR website (https://cvquality.acc.org/NCDR-Home/registries/hospital-registries/cathpci-registry). The beta coefficients and covariance matrix are available from NCDR upon request.

Table 15. Risk-Standardized Bleeding Variables with Associated Odds Ratios

Label	OR	LOR	UOR
	.	.	.
Age	1.019	1.018	1.020
Female	2.023	1.969	2.079
BMI	0.977	0.975	0.979
Cerebrovascular disease	1.134	1.096	1.173
Peripheral artery disease	1.301	1.254	1.350
Chronic Lung disease	1.229	1.189	1.271
Previous PCI	0.846	0.821	0.871
GFR	0.987	0.986	0.987
Severe Frailty	1.857	1.761	1.958
Clinical Instability: Urgent PCI and Neither shock nor CI	1.747	1.680	1.817
Clinical Instability: Emergency PCI and Neither shock nor CI	3.119	2.967	3.279
Clinical Instability: No Salvage PCI and CI	3.363	3.189	3.548
NYHA class within 2 weeks: IV	1.311	1.235	1.391
Heart Failure Type: Diastolic heart failure	1.274	1.222	1.328
Heart Failure Type: Systolic Heart Failure	1.180	1.136	1.226
Pre-surgery Evaluation: Non-Cardiac Surgery	1.716	1.545	1.905
Concomitant Procedure (excluding *Peripheral Intervention, Peripheral Angiogram, Biopsy of heart, or Procedure Type Not Listed)*	1.720	1.653	1.790
Proc SBP < 90	1.561	1.390	1.753
Decision for PCI with surgical Consult	1.825	1.745	1.908
Percutaneous Coronary Intervention Indication: STEMI - Unstable (>12 hours from symptom onset)	1.687	1.520	1.872
Percutaneous Coronary Intervention Indication: STEMI - Rescue (After unsuccessful lytics)	0.716	0.666	0.770
Percutaneous Coronary Intervention Indication: Other PCI Indication	0.874	0.839	0.910
At least 1 previously treated lesion within 1 month with in-stent thrombosis	1.815	1.551	2.124
Highest risk lesion -- pLAD	1.123	1.087	1.161
Highest risk lesion -- Left Main	2.157	2.056	2.262
TIMI Flow Pre-Intervention: No perfusion	1.406	1.354	1.460
Lesion Complexity: Non-High/Non-C Lesion	0.837	0.812	0.864

*Empty cells left intentionally blank

We believe that social factors did not need to be included as variables in risk-adjustment for peri-procedural

bleeding after PCI. This was predicated on the feasibility of patient-level social factors. The belief that the consequence of adverse social factors (e.g. leading to greater rates of obesity, hypertension, smoking or other comorbidities) would be directly captured by our rich clinical data, and that the short duration of follow-up (72 hours, during which the patient was hospitalized), would negate potential barriers to healthcare access and treatment that might be more relevant with longer-term outcomes. Accordingly, we feel that in this model of in-hospital risk-adjusted bleeding rate, given the rich clinical data available through the NCDR CathPCI registry, that social risk factors, which are not readily available, would not likely improve this particular risk model.

There was an extensive process to develop the face and content validity of the measure. To ensure our model achieved its purported goals, an expert panel was assembled to assess inclusion criteria, definitions, and risk-adjustment methodology. After settling on the outcome definition and candidate variables, categorical variables were summarized as frequencies and percentages and compared with Pearson chi-squared tests. Continuous variables were summarized as medians (interquartile range) and compared using Wilcoxon rank-sum tests. Ordinal variables were tested using a chi-square test based on the rank of the group mean score. The study population was then randomly split into a development sample consisting of 70% of PCI procedures and a validation sample consisting of the remaining 30% of admissions.

Due to high rates of missing data and possible biased data as a result, the following variables were forced out of the model: stress test results; Seattle Angina Questionnaire (SAQ) results; Rose Dyspnea Scale (RDS) results; assessment of chest pain symptoms; new antiarrhythmic therapy. Desire to exclude variables possibly related to physician choice and decision-making, as opposed to intrinsic patient-level risk, led to forcing out the following variables from the model: concomitant peripheral intervention, peripheral angiogram, heart biopsy, or procedure type not listed; arterial access site; arterial cross over; venous access; multivessel procedure type; pre-procedure hemoglobin; procedure medications. Of note, the original model selected the following variables into the risk model: right heart catheterization, mitral valve or percutaneous replacement of aortic valve using fluoroscopic guidance, insertion of temporary cardiac pacemaker, and arch aortogram. To make the model more parsimonious, we combined concomitant procedures into one yes/no variable. The following variables without clear clinical meaning were forced out: BMI unknown; GFR unknown; heart rate unknown; Troponin I unknown; Troponin T unknown; Ejection Fraction unknown; Systolic Blood Pressure unknown; Closure method not documented. Finally, to account for various metrics of clinical instability and procedural status, a “clinical instability” composite variable was created to reduce compounding effects of the following multiple associated variables: cardiogenic shock; ventricular support; pharmacologic vasopressor support; mechanical ventricular support; level of consciousness; STEMI; PCI status; hypothermia induced; hypothermia induction timing. Instead, the following composite variables of “clinical instability” were created: elective PCI without any cardiovascular instability; urgent PCI without any cardiovascular instability; emergency PCI without any cardiovascular instability; any cardiovascular instability without salvage PCI; cardiogenic shock (not refractory) without salvage PCI; refractory shock or salvage PCI; other. Ultimately, at the discretion of the workgroup members, no variables were identified that required “forcing in” to the model.

Stepwise selection logistic regression was used on 1,000 bootstrapped samples from the development cohort. 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.

The C-statistic was used to describe the discrimination of the model. All statistical analyses were performed using SAS software (version 9.3, SAS Institute, Cary, NC).