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Predicting Major Adverse Events in Patients Undergoing Transcatheter Left Atrial Appendage Occlusion

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Abstract

Background: The National Cardiovascular Data Registry (NCDR) Left Atrial Appendage Occlusion (LAAO) Registry includes the vast majority of transcatheter LAAO procedures performed in the United States. The objective of this study was to develop a model predicting adverse events among patients undergoing LAAO with Watchman FLX.

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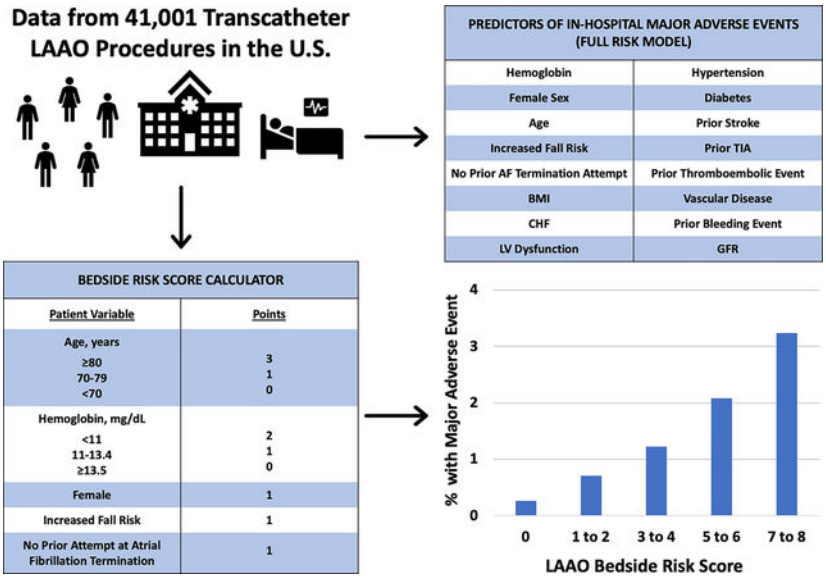
Methods: Data from 41,001 LAAO procedures with Watchman FLX from 7/2020–9/2021 were used to develop and validate a model predicting in-hospital major adverse events (MAE). Randomly selected development (70%, n = 28,530) and validation (30%, n = 12,471) cohorts were analyzed with 1,000 bootstrapped samples, using forward stepwise logistic regression to create the final model. A simplified bedside risk score was also developed using this model.

Results: Increased age, female sex, low pre-procedure hemoglobin, no prior attempt at atrial fibrillation termination, and increased fall risk most strongly predicted in-hospital MAE and were included in the final model along with other clinically relevant variables. The median in-hospital risk-standardized adverse event rate was 1.50% (range: 1.03% to 2.84%; interquartile range 1.42% to 1.64%). The model demonstrated moderate discrimination (development C-index 0.67 [95% CI 0.65–0.70] and validation C-index 0.66 [95% CI 0.62–0.70]) with good calibration. The simplified risk score was well calibrated with risk of in-hospital MAE ranging from 0.26% to 3.90% for a score of 0 to 8, respectively.

Conclusions: A transcatheter LAAO risk model using NCDR LAAO Registry data can predict in-hospital MAEs, demonstrated consistency across hospitals and can be used for quality improvement efforts. A simple bedside risk score was similarly predictive and may inform shared decision-making.

Graphical Abstract



Keywords

left atrial appendage occlusion; outcomes; quality; risk prediction; atrial fibrillation

Introduction

Atrial fibrillation is estimated to affect more than 5 million individuals in the United States and is associated with an approximately five-fold increased risk of ischemic stroke.[1–3] Oral anticoagulation is the standard of care for stroke prevention among patients with

atrial fibrillation with moderate to high risk for stroke,[4] though more than half of such patients may not receive anticoagulation due to factors such as high bleeding risk.[5, 6] Transcatheter left atrial appendage occlusion (LAAO) provides an alternative to long-term oral anticoagulation, with initial approval of the Watchman LAAO Device (Boston Scientific, Natick, Massachusetts) by the U.S Food and Drug Administration in 2015.[7–10] The National Cardiovascular Data Registry (NCDR) LAAO Registry was subsequently developed to measure and improve the quality of care related to utilization and outcomes associated with transcatheter LAAO in clinical practice, and captures the vast majority of LAAO procedures performed in the U.S.[11]

Though LAAO has been increasingly adopted in clinical practice, there is currently no single benchmark that can be reliably used to assess and compare LAAO procedural outcomes across hospitals. There is also very limited evidence to guide clinicians and patients on individual risk of adverse events during LAAO. Risk-standardized models allow for more direct comparisons between hospitals and serve as important tools for quality improvement both locally and nationally.[12–18] Given the novelty and rapid rise in use of transcatheter LAAO, a standardized risk model for in-hospital major adverse events (MAE) is needed. In this analysis we used data from the NCDR LAAO Registry to create a novel, validated risk model that can be employed nationally to assess in-hospital outcomes for transcatheter LAAO. A simplified bedside risk score was also developed to help predict in-hospital MAE and inform shared decision-making in individuals undergoing LAAO.

Methods

Data Overview

The NCDR LAAO Registry is a national clinical registry operated by the American College of Cardiology (ACC). The registry was initially launched in December 2015 as part of a formal post-market surveillance effort required by the Food and Drug Administration (FDA) for the Watchman device, and incorporated input from multiple stakeholders including the NCDR, Society for Coronary Angiography (SCAI), FDA, Centers for Medicare and Medicaid Services (CMS), and Boston Scientific.[11] In order to qualify for Medicare reimbursement, all U.S. hospitals were required to submit data on LAAO procedures to the NCDR LAAO Registry beginning on April 1, 2016.

The LAAO Registry collects information on patient, provider, and facility characteristics; LAAO indications; periprocedural details including LAA size, devices used, reasons for aborted/cancelled procedures, residual leak size, and imaging guidance used; and procedure-related complications and other adverse events that occur during the hospitalization in which LAAO is performed and through two years of follow-up. All data is collected locally at hospital sites by trained data abstractors and submitted to a centralized, secure database overseen by the ACC. In order to ensure data accuracy, external audits are performed annually at randomly selected sites; the most recent audit demonstrated >93% agreement between registry-reported data and source document review.[11] Quality improvement data reports are sent from the ACC to participating sites via an interactive dashboard and data are updated weekly. A novel adjudication system using both automatic computer-based and

manual adjudication of major adverse events has also been developed and validated for the LAAO Registry.[19]

The current analysis was planned and implemented by the NCDR LAAO Registry Risk Model Workgroup with extensive review by the NCDR LAAO Steering Committee, NCDR Metric and Reporting Methodology Subcommittee and NCDR Science and Quality Oversight Committee. Additional feedback was provided during a one-month public comment period. All statistical analyses were performed at the Yale Center for Outcomes Research and Evaluation (CORE) Data Analytic Center using SAS version 9.4 (SAS Institute, Cary, North Carolina). This study was approved by the Human Investigation Committee of the Yale University School of Medicine of the Yale University School of Medicine without requiring informed consent because all data were deidentified and maintained by the NCDR. The data that support the findings of this study are available from Yale CORE upon reasonable consent with approval by the NCDR.

Study Cohort

This study included procedures for adults ≥18 years of age and enrolled in the NCDR LAAO Registry who underwent an initial procedure for placement of a Watchman FLX device from July 2020 through September 2021. All procedures with same-day discharges as well as overnight hospitalizations were included. Patients with a previously reported LAAO procedure (n = 42), a cancelled procedure without adverse events prior to vascular access (n = 3,349), and who received an LAAO device other than Watchman FLX (primarily the first-generation Watchman device) during the study period were excluded (n = 91,535). Only procedures with the second-generation Watchman FLX device were included because the first-generation Watchman device is no longer commercially available and had a higher risk of adverse events.[20, 21] At this time other transcatheter LAAO devices are either rarely used currently or not yet approved for use in the U.S. The final number of LAAO procedures included for analysis was 41,001 (Supplemental Figure 1).

Variable and Outcome Definitions

Candidate variables for potential inclusion in the final risk model were selected by the LAAO Registry Risk Model Workgroup based on review of all baseline characteristics reported on the NCDR LAAO Registry data collection form. Variables were selected based on clinical relevance and those with high rates of missingness (>5% of procedures) were not considered. The following candidate variables were analyzed in model development: age, sex, body mass index (BMI), individual components of the CHA_2DS_2-VASc score (history of congestive heart failure, left ventricular dysfunction, hypertension, diabetes mellitus, stroke, transient ischemic attack, thromboembolism, and vascular disease), fall risk (defined as having two or more falls in the prior 12 months, presenting with an acute fall on admission, or difficulty with walking or balancing), systolic blood pressure (SBP) > 180mmHg or < 90mmHg, prior antiplatelet use, clinically relevant prior bleeding, prior attempt at atrial fibrillation termination, hemoglobin, and glomerular filtration rate (GFR) calculated using the Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) 2021 updated definition.[22]

The primary outcome was a composite of all in-hospital MAE and included the following: death, cardiac arrest, myocardial infarction, pericardial effusion requiring intervention, systemic arterial embolism, device embolization, adjudicated stroke (hemorrhagic, ischemic, or undetermined), transient ischemic attack, intracranial hemorrhage, major vascular complication, and major bleeding. All major bleeding events were adjudicated and defined as any event that required a blood transfusion, invasive intervention, resulted in a hemoglobin decrease of ≥3 g/dL, or resulted in death. Specific definitions for all other outcomes are described in detail on the NCDR LAAO Registry Coder's Data Dictionary (version 1.4).[23]

Variable Selection

For risk model creation, a randomly selected development (testing) sample consisting of 70% of the total cohort (n = 28,530 at 694 hospitals) was used. Forward selection with logistic regression was performed with inclusion of all candidate variables (entry p value = 0.10, exit p value = 0.05) on 1,000 full-size bootstrapped samples with replacement. We calculated the percentage of times each variable was selected across 1,000 samples. All variables that were selected in ≥50% of bootstrap samples were included in the final risk model. Among variables not selected with this method, the following were subsequently included into the final model due to clinical relevance based on prior literature showing an association between these variables and MAE: BMI, individual components of the CHA_2DS_2-VASc score, prior bleeding event, and GFR.

Model Performance

To assess model performance after development, the final risk model was applied to the randomly selected validation sample consisting of 30% of the total cohort (n = 12,471 at 681 hospitals). Model discrimination was evaluated using the C-index in the validation sample. Discrimination was also assessed in the total cohort based on subgroups by age (≤75 and > 75 years) and sex. Calibration was assessed by comparing predicted vs. observed adverse event rates within ranked deciles of risk. Distributions of risk-standardized adverse event rates at the hospital level were also determined for the development and validation samples.

Hospital-Level Risk-Standardized Major Adverse Event Rate

We used hierarchical logistic regression to estimate the hospital-specific risk-standardized major adverse event rate (RSER) as a function of the risk model, accounting for within-hospital correlation of patient outcomes and differences in patient case mix across hospitals. This approach models the log odds of a patient experiencing a major adverse event as a function of patient demographics and clinically relevant comorbidities with an intercept for the hospital-specific random effect.

The hospital-specific RSER is calculated as the ratio of a hospital's "predicted" number of adverse events to the "expected" number of events based on patient case mix multiplied by the event rate of the total cohort. The predicted number of events for a specific hospital is determined using a hierarchical model which applies the estimated regression coefficients to the observed patient characteristics and adds the hospital-specific intercept. The expected

number of events is determined similarly, but alternatively adds the average hospital-specific intercept for all hospitals.[12, 13]

Bedside Risk Score

In order to help facilitate clinical and shared decision-making for LAAO among clinicians and patients, a simplified bedside risk model was developed using only variables selected in the bootstrapped analyses. Continuous variables were converted to clinically relevant categories to help make the score easier to use. A logistic regression model was created using selected variables, and integer points were assigned based on regression coefficient values such that a higher number of points represented greater risk of MAE. Predicted risk of MAE was determined based on total assigned points.

Results

Patient Characteristics

Between July 2020 and September 2021, 41,001 consecutive patients undergoing an initial transcatheter LAAO procedure with a Watchman FLX device from 697 sites were included in the total sample. Consistent with prior studies from the LAAO Registry,[11, 24, 25] patients were primarily older adults with a median age of 77 (standard deviation [SD] 8) years. In this cohort 41.1% were women, 59.9% had a prior history of a clinical bleeding event, the mean (SD) CHA_2DS_2-VASc score was 4.6 (1.4) and the mean (SD) HAS-BLED score was 2.8 (1.1). Characteristics among the randomly selected development and validation samples were similar (Table 1).

In-Hospital Adverse Event Rates

In-hospital MAE occurred in 1.53% of all procedures, with similar rates for the development (1.54%) and validation (1.52%) samples. In-hospital mortality occurred in 0.13% of procedures. The most common adverse outcomes were major bleeding (1.21%) and pericardial effusion requiring intervention (0.53%). Occurrence of other adverse events was very low (Supplemental Table 1). Across all hospital sites, the unadjusted MAE rate ranged between a minimum of 0.00% and 20.00% at the 99th percentile (median 0.00%; interquartile range 0.00% to 2.44%).

In-Hospital Risk Model and Model Performance

The model contained 5 variables (age, sex, pre-procedure hemoglobin, no prior attempt at atrial fibrillation termination, and increased fall risk) which were selected based on inclusion in ≥50% of bootstrapped models in the development sample. An additional 11 variables were included in the final model based on prior literature showing an association between these variables and MAE (BMI, individual components of the CHA_2DS_2-VASc score, clinically relevant prior bleeding, and GFR). The adjusted OR for MAE in the development sample for all variables are shown in Table 2. The final risk model had a C-statistic of 0.659 in the validation sample and was well calibrated across deciles of predicted risk in the validation sample (Figure 1). Model performance in the total cohort was similar across subgroups based on age and sex (Table 3).

Risk-Standardized Major Adverse Event Rates

The median hospital RSER in the total cohort was 1.50% (interquartile range: 1.42% to 1.64%). The full range of RSER was 1.03% to 2.84% with the vast majority between 1% and 2% (5^{th} percentile 1.27% to 95^{th} percentile 1.97%); the distribution of RSER across all hospitals is shown in Figure 2. Hospital RSER distributions were similar in the development and validation samples (Supplemental Table 2).

Bedside Risk Score

Based on results from the bootstrapped analyses, the simplified bedside risk model included age, sex, pre-procedure hemoglobin, no prior attempt at atrial fibrillation termination, and increased fall risk. Integer points for each variable were assigned to create a total score ranging from 0 to 8 (Table 4). The C-statistic of the simplified logistic regression model was 0.672 in the development sample and 0.623 in the validation sample (Table 3). The model was well calibrated in the full cohort, with a stepwise increased risk of in-hospital MAE ranging from 0.26% to 3.90% for a score of 0 to 8, respectively (Figure 3, Supplemental Table 3).

Discussion

In this study we used the NCDR LAAO Registry to develop and validate a novel, standardized risk model to predict in-hospital major adverse events in patients who undergo transcatheter left atrial appendage occlusion. In the entire study cohort we found that in-hospital MAE occurred in 1.53% of procedures, with the most common events being major bleeding and pericardial effusion. Older age, female sex, low pre-procedure hemoglobin, no prior attempt at atrial fibrillation termination, and increased fall risk were the most significant predictors of MAE in the final model. This model can be used to benchmark and compare outcomes among hospitals performing transcatheter LAAO nationally and can guide quality improvement efforts. A simplified bedside risk score was also created to help evaluate individual patient risk and inform shared decision-making.

Transcatheter LAAO with the Watchman device has been studied in two large randomized clinical trials,[7–9] leading to formal FDA approval of the device in 2015. The NCDR LAAO Registry was launched soon after approval, and has since demonstrated a relatively rapid rise in use of the procedure nationally.[11] The second-generation Watchman FLX device was subsequently introduced into clinical practice and demonstrated lower incidence of adverse events along with very high rates of procedural success in a large single arm prospective U.S. study.[20] A subsequent study using the LAAO Registry showed that the rates of MAE associated with LAAO procedures have decreased over time, particularly with adoption of the Watchman FLX.[21]

Given the relative novelty of the Watchman device, no standardized risk model has previously been created to compare transcatheter LAAO performance among hospitals. Standardized risk models accounting for patient characteristics and inter-hospital variation have previously been developed for other NCDR registries,[13, 14, 16–18] and can serve as critical tools for quality improvement and post-marketing surveillance over time. Our

study showed that the risk-standardized adverse event rate for the cohort was 1.50% with the vast majority of hospitals having risk-standardized event rates between 1–2%, demonstrating remarkable consistency across hospitals that vary widely in size, setting and procedure volumes. This consistency indicates that the specific patient variables included in the standardized model adequately capture procedure-related risk for elective transcatheter LAAO procedures regardless of site. Our results thus support ongoing nationwide participation in the NCDR LAAO Registry and use of this risk model among current and potential future sites.

In the final risk model for LAAO hospitalizations, older age, female sex, and lower pre-procedure hemoglobin were all associated with increased risk of MAE. Given that the majority of MAE related to LAAO were bleeding events, these risk factors are consistent with prior studies evaluating bleeding risk related to transcatheter procedures.[14, 15, 17, 24, 26–28] Increased age, particularly ≥80 years, most strongly predicted to risk of MAE and reinforces the importance of shared-decision making and quality of life considerations in this higher-risk population. Among women, pericardial effusion in particular has been shown to be more common following LAAO, with possible reasons for this including anatomical differences and comorbidities in women undergoing the procedure.[15] The association between low hemoglobin and increased procedural risk with transcatheter LAAO is a novel finding, however it remains unknown whether pre-procedural interventions such as blood transfusion would impact outcomes. Increased fall risk was also a significant predictor of MAE, and presumably reflects the increased risk of bleeding and other adverse outcomes associated with frailty.[29–31] Lack of prior attempt at atrial fibrillation termination was also a predictor of MAE, and may be a proxy for other factors such as overall health status and access to regular healthcare.

Strengths of this analysis include the very large size of the LAAO Registry, since participation is required for CMS reimbursement and the vast majority of U.S. LAAO procedures are therefore included. Detailed data collection is performed by trained abstractors, and national auditing has demonstrated extremely high data accuracy for collected variables. Data from nearly 700 sites was included, adding to robustness of the predicted model including the RSER which can be determined for individual hospitals. The C-index for model performance was noted to be less than for risk models developed in other NCDR registries, such as the mortality risk models for the CathPCI and Chest Pain-Myocardial Infarction registries.[16, 18] However, unlike the risks associated with acute myocardial infarction, LAAO is an elective outpatient procedure with overall low rates of MAE. Further work on data collection and quality assurance will be needed to improve and refine the LAAO risk model as it is implemented in clinical practice.

This analysis also developed and validated a simplified clinical risk score inclusive of the five most predictive variables in the risk-standardized model. The score was designed to be quickly and easily calculated in the clinic, demonstrated good calibration, and can be used to help predict risk of MAE for individual patients being considered for LAAO. The risk of in-hospital MAE increased continuously from 0.26% to 3.90% for a score of 0 to 8, respectively, and may serve as a shared decision-making tool for healthcare providers and their patients. Though not directly evaluated in our analysis, this risk score in conjunction

with procedural details may also help guide clinicians in assessing appropriateness of same-day discharge vs. overnight observation after the LAAO procedure.

This study has several limitations. We intended to identify patient factors that predict major in-hospital adverse events, and these associations do not necessarily represent causal relationships. Analyses were also limited to variables reported on the LAAO Registry data collection form, and other variables such as left atrial appendage anatomic details were not available. The MAE risk model was developed using recent data available from the LAAO Registry, though selected variables and model performance could change over time as national procedure volumes increase. Notably, we did not include periprocedural medication use as candidate variables in our model. Medications are not typically incorporated into risk-standardized models for hospital quality assessment, and were not included in our analysis due to significant patient and hospital variability in periprocedural antithrombotic strategies as well as potential issues with confounding by indication. Significant variability in antithrombotic treatment following transcatheter LAAO has been demonstrated in a prior analysis from the LAAO Registry.[25]

Importantly, this model was also developed using data specifically for the Watchman FLX device because the great majority of commercial LAAO implants in the US are currently performed with this device. However, the most common major adverse events after LAAO have been consistent across all transcatheter LAAO devices, and we anticipate our predictive model would likely be relevant to all devices. Reporting of registry events may vary across hospitals, though all outcomes are based on specified NCDR definitions and prior external data audits have demonstrated extremely high accuracy compared to external review of source documents. The analyzed LAAO cohort is also predominantly of white race, and further assessment of risk among racial and ethnic minority groups will be needed as nationwide LAAO volumes increase. The LAAO Registry only includes procedures performed in the U.S., and therefore findings are not necessarily generalizable to sites outside the U.S. Lastly, only in-hospital major adverse events were included in this analysis and therefore the model should not be used for assessment of risk after hospital discharge, which could be dependent on the procedure or other patient factors such as long-term risk for death, stroke and bleeding.

Conclusions

In this study a risk model was developed and validated to predict in-hospital major adverse events during transcatheter LAAO hospitalization. This model is based on clinical characteristics routinely collected in the NCDR LAAO Registry, and can be used to benchmark hospital performance, inform future quality improvement efforts, and help assess individual patient risk with a simple bedside risk score for transcatheter LAAO in the U.S.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Nonstandard Abbreviations and Acronyms

ACC	American College of Cardiology
LAAO	left atrial appendage occlusion
NCDR	National Cardiovascular Data Registry

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What Is Know

- The National Cardiovascular Data Registry (NCDR) Left Atrial Appendage Occlusion (LAAO) includes the vast majority of LAAO procedures performed in the United States.
- No single benchmark has previously been developed to reliably assess and compare transcatheter LAAO procedural outcomes across hospitals, and there is limited evidence to guide clinicians and patients on individual risk of adverse events during elective LAAO hospitalization.

What the Study Adds

- A comprehensive model was developed using data from 41,001 transcatheter LAAO procedures to evaluate in-hospital risk-standardized adverse event rates, and included age, female sex, pre-procedure hemoglobin, no prior attempt at atrial fibrillation termination and increased fall risk as the most predictive variables.
- The NCDR LAAO Registry risk model helps predict in-hospital major adverse events, demonstrated consistency across hospitals and can be used for quality improvement efforts.
- A simplified bedside risk score was also predictive of in-hospital major adverse events and can be used to inform shared decision-making for transcatheter LAAO.

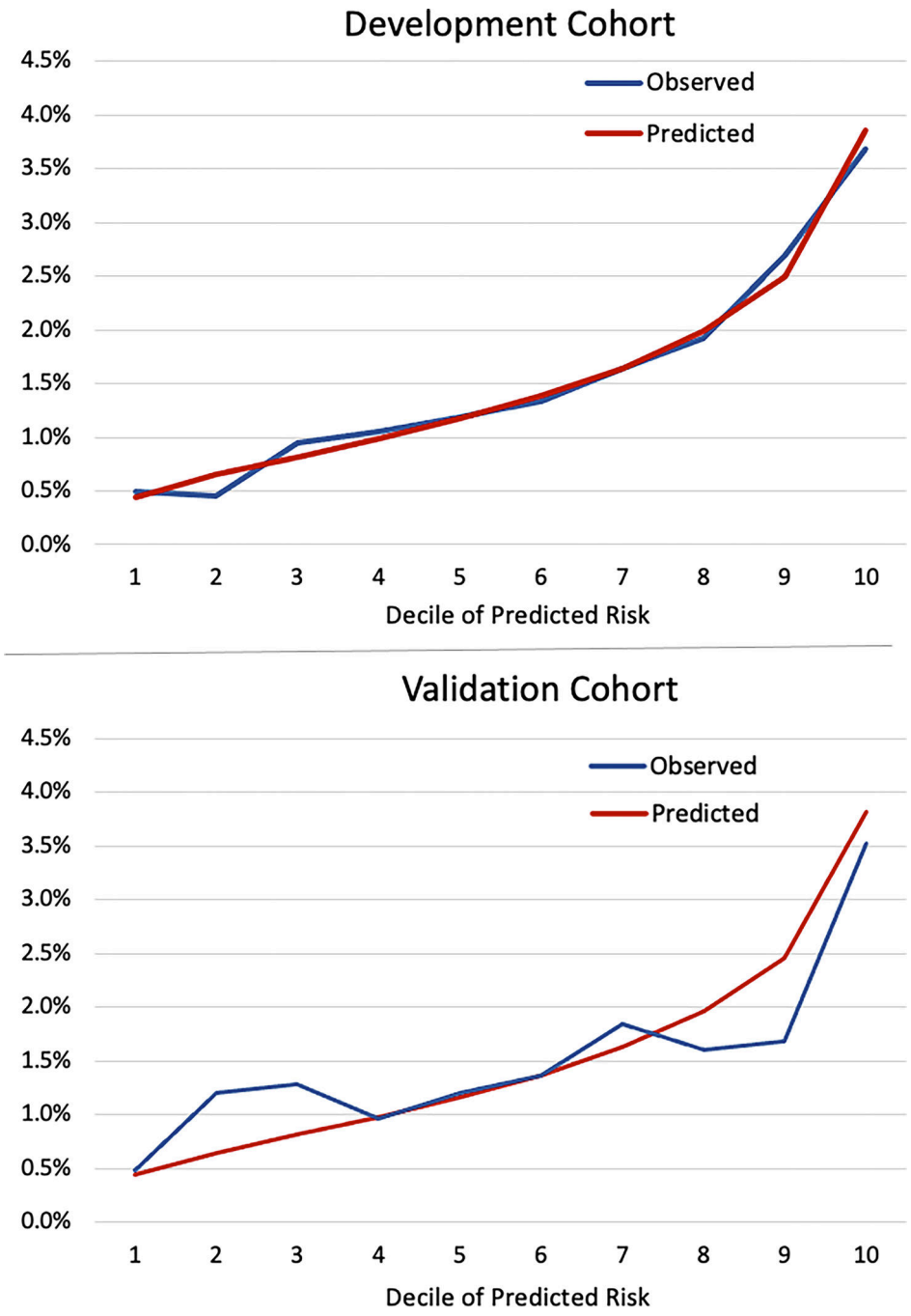

Figure 1.

Calibration Plot for In-Hospital Major Adverse Events in Patients Undergoing Transcatheter Left Atrial Appendage Occlusion. Observed in-hospital major adverse event rates and rates predicted using the risk-standardized model are shown across deciles of predicted risk.

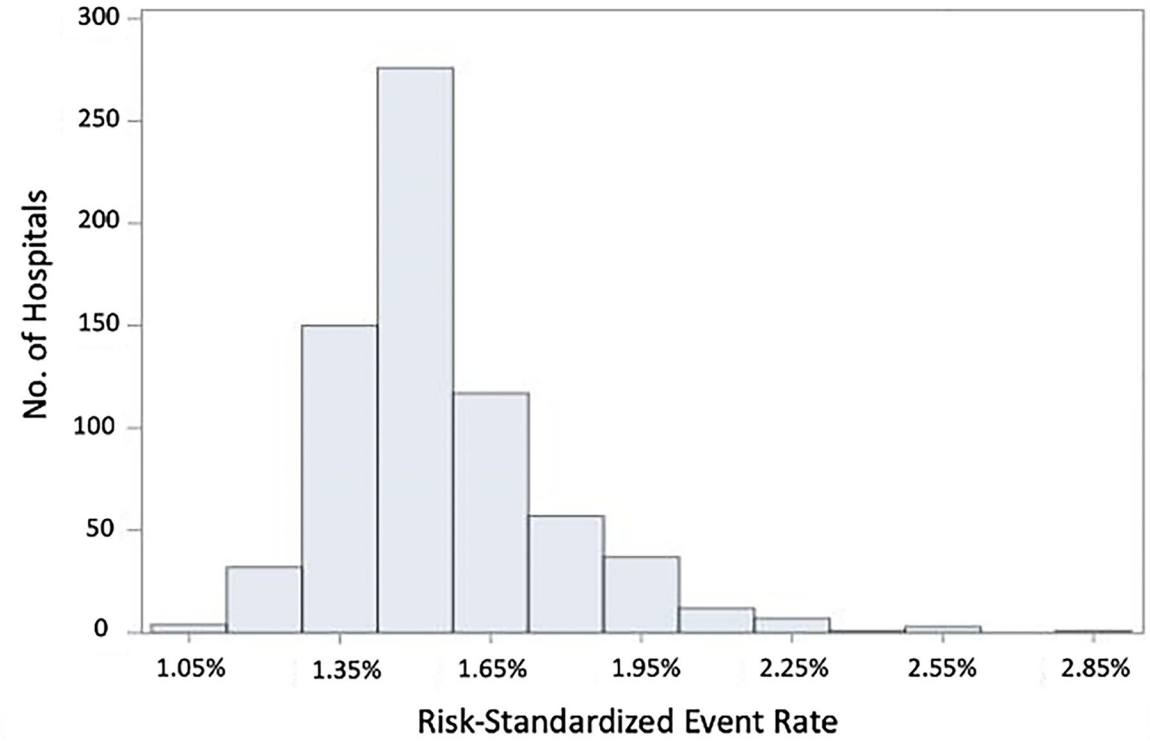

Figure 2.

Transcatheter LAAO Risk-Standardized Event Rates Across Hospitals. Predicted risk-standardized event rates are shown across 697 hospital sites included in model development and validation (41,001 total LAAO procedures). LAAO = left atrial appendage occlusion.

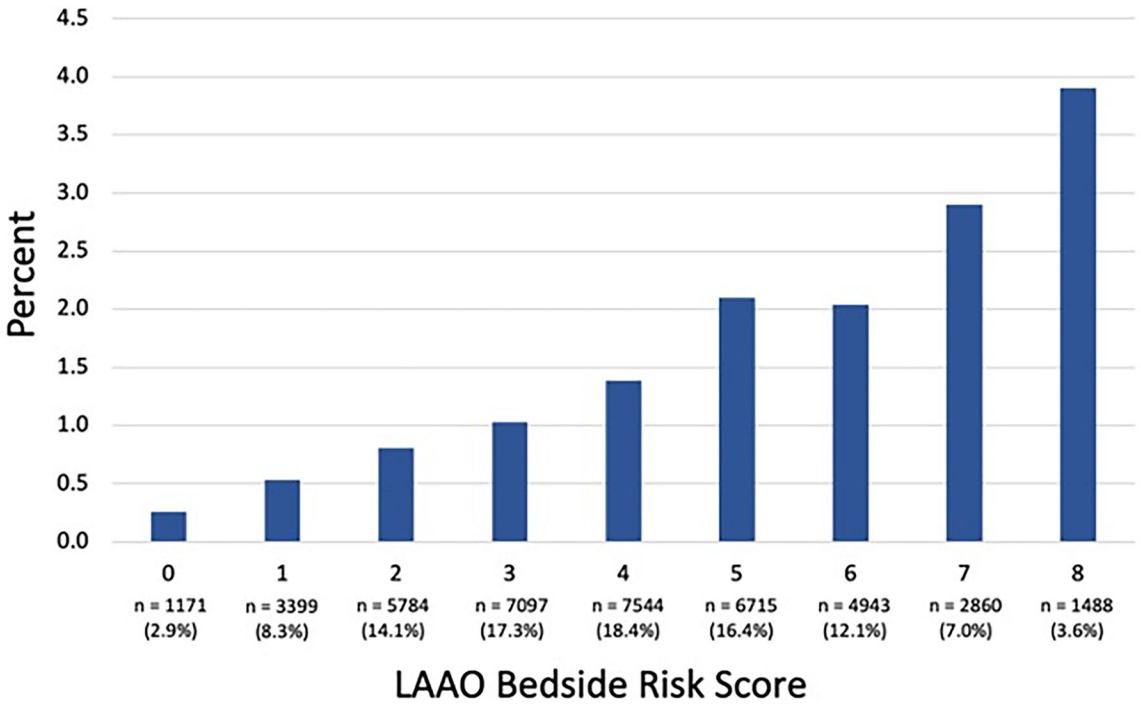

Figure 3.

Observed In-Hospital Major Adverse Event Rates By Bedside Risk Score. The simplified LAAO Bedside Risk Score ranged from 0 to 8 based on points assigned for age, sex, hemoglobin, prior atrial fibrillation termination attempt and fall risk. The percentage of patients with each score are shown. LAAO = left atrial appendage occlusion.

Table 1.

Patient Clinical Characteristics

Patient Characteristics	Overall (n = 41,001)	Development (n = 28,530)	Validation (n = 12,471)
Age	76 (8)	76 (8)	76 (8)
Female	16803 (41.0)	11787 (41.3)	5016 (40.2)
Race			
White	38195 (93.2)	26544 (93.0)	11651 (93.4)
Black	1720 (4.2)	1202 (4.2)	518 (4.2)
Asian	473 (1.2)	342 (1.2)	131 (1.1)
Other	193 (0.5)	138 (0.5)	55 (0.4)
Hispanic Ethnicity	420 (1.0)	304 (1.1)	116 (0.9)
Primary Insurance Payer			
Medicare/Medicaid	30683 (74.8)	21313 (74.7)	9370 (75.1)
Private Health Insurance	21845 (53.3)	15172 (53.2)	6673 (53.5)
Other	6546 (16.0)	4583 (16.1)	1963 (15.7)
Body Mass Index, kg^2/m^2	29.9 (9.3)	29.9 (9.8)	29.8 (8.1)
CHA2DS2-VASc Score	4.6 (1.4)	4.6 (1.4)	4.6 (1.5)
Congestive Heart Failure	15848 (38.7)	11098 (38.9)	4750 (38.1)
Cardiomyopathy	8203 (20.0)	5672 (19.9)	2531 (20.3)
Hypertension	37545 (91.6)	26124 (91.6)	11421 (91.6)
Diabetes Mellitus	14532 (35.4)	10125 (35.5)	4407 (35.3)
Prior Stroke	8841 (21.6)	6083 (21.3)	2758 (22.1)
Prior Transient Ischemic Attacked	4934 (12.0)	3440 (12.1)	1494 (12.0)
Prior Thromboembolic Event	6170 (15.1)	4297 (15.1)	1873 (15.0)
Coronary Artery Disease	18672 (45.5)	12962 (45.4)	5710 (45.8)
Peripheral Artery Disease	4349 (10.6)	3056 (10.7)	1293 (10.4)
Chronic Lung Disease	8224 (20.1)	5785 (20.3)	2439 (19.6)
Obstructive Sleep Apnea	12168 (29.7)	8455 (29.7)	3713 (29.8)
Glomeruler Filtration Rate, $mL/min/1.73m^2$	64.0 (22.9)	63.9 (22.9)	64.2 (22.8)
HAS-BLED Score	2.8 (1.1)	2.8 (1.1)	2.8 (1.1)
Clinically Relevant Prior Bleeding	24576 (59.9)	17082 (59.9)	7494 (60.1)
Intracranial	3821 (9.3)	2634 (9.2)	1187 (9.5)

Patient Characteristics	Overall (n = 41,001)	Development (n = 28,530)	Validation (n = 12,471)
Epistaxis	2393 (5.8)	1669 (5.8)	724 (5.8)
Gastrointestinal	14337 (35.0)	9986 (35.0)	4351 (34.9)
Other	8069 (19.7)	5609 (19.7)	2460 (19.7)
Increased Fall Risk	16625 (40.5)	11521 (40.4)	5104 (40.9)
Arrhythmia History			
Atrial Fibrillation Type			
Paroxysmal	24946 (60.8)	17323 (60.7)	7623 (61.1)
Persistent (> 7 days)	8433 (20.6)	5971 (20.9)	2462 (19.7)
Long-Standing Persistent (>1 year)	2378 (5.8)	1615 (5.7)	763 (6.1)
Permanent	4913 (12.0)	3390 (11.9)	1523 (12.2)
Atrial Flutter Type			
Typical	7329 (17.9)	5153 (18.1)	2176 (17.4)
Atypical	1970 (4.8)	1353 (4.7)	617 (4.9)
Prior Afib Termination Attempt	18618 (45.4)	12907 (45.2)	5711 (45.8)

Table 2.

Full Risk Model for In-Hospital Major Adverse Events During LAAO Hospitalization in Total Cohort

Variable	Beta Coefficient*	OR (95% CI)	P Value
Hemoglobin, per 1 mg/dL decrease	0.2029	1.23 (1.17–1.44)	<0.001
Female Sex	0.3962	1.49 (1.26–1.75)	<0.001
Age, per 1 year increase	0.0158	1.02 (1.00–1.03)	0.001
Increased Fall Risk	0.2161	1.24 (1.05–1.47)	0.011
No Prior Atrial Fibrillation Termination Attempt	0.203	1.22 (1.03–1.43)	0.018
Body Mass Index			
18.5–39.9	-	Ref	-
<18.5	0.2601	1.30 (0.74–2.28)	0.37
≥ 40	0.0568	1.06 (0.78–1.44)	0.72
Congestive Heart Failure	0.0964	1.10 (0.93–1.31)	0.27
Left Ventricular Dysfunction	−0.0498	0.95 (0.72–1.27)	0.73
Hypertension	0.1717	1.19 (0.87–1.62)	0.28
Diabetes Mellitus	0.0068	1.01 (0.85–1.20)	0.94
Prior Stroke	0.1568	1.17 (0.95–1.45)	0.15
Prior Transient Ischemic Attack	0.1768	1.19 (0.95–1.50)	0.13
Prior Thromboembolic Event	0.0639	1.07 (0.84–1.36)	0.61
Vascular Disease	0.0151	1.02 (0.86–1.20)	0.86
Clinically Relevant Prior Bleeding	0.048	1.05 (0.88–1.25)	0.59
Glomerular Filtration Rate, per mL/min/1.73m^2 increase	−0.0038	1.00 (0.99–1.00)	0.048

*Model intercept = −3.1795. LAAO = left atrial appendage occlusion.

Table 3.

Discrimination of LAAO Registry Major Adverse Event Risk Model

	Sample, n	C-Index (95% CI)	
		Full Model	Bedside Risk Score
Total Cohort	41001	0.661 (0.640–0.682)	0.647 (0.633–0.675)
Development Cohort	28530	0.673 (0.648–0.698)	0.672 (0.648–0.697)
Validation Cohort	12471	0.659 (0.620–0.697)	0.623 (0.583–0.663)
Subgroups			
Female	16803	0.623 (0.592–0.654)	0.606 (0.575–0.637)
Male	24198	0.667 (0.635–0.699)	0.656 (0.624–0.689)
Age >75 years	17786	0.652 (0.624–0.681)	0.639 (0.611–0.667)
Age ≤ 75 years	23215	0.675 (0.641–0.708)	0.663 (0.628–0.697)

LAAO = left atrial appendage occlusion.

Table 4.

LAAO Registry Bedside Risk Score Calculator

Patient Variable	Points
Age, years	
≥ 80	3
70–79	1
<70	0
Female	1
Hemoglobin, mg/dL	
<11	2
11–13.4	1
≥13.5	0
No Prior Atrial Fibrillation Termination Attempt	1
Increased Fall Risk	1

Increased fall risk is defined as the following: two or more falls in the prior 12 months, presenting with an acute fall on admission, or difficulty with walking or balancing. LAAO = left atrial appendage occlusion.