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Peer reviewed

# Outcomes of percutaneous left atrial appendage occlusion device implantation in atrial fibrillation patients based on underlying stroke risk

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## Aims

To determine outcomes in atrial fibrillation patients undergoing percutaneous left atrial appendage occlusion (LAAO) based on the underlying stroke risk (defined by the CHA<sub>2</sub>DS<sub>2</sub>-VASc score).

## Methods and results

Data were extracted from the National Inpatient Sample for calendar years 2016–20. Left atrial appendage occlusion implantations were identified on the basis of the International Classification of Diseases, 10th Revision, Clinical Modification code of O2L73DK. The study sample was stratified on the basis of the CHA<sub>2</sub>DS<sub>2</sub>-VASc score into three groups (scores of 3, 4, and ≥5). The outcomes assessed in our study included complications and resource utilization. A total of 73 795 LAAO device implantations were studied. Approximately 63% of LAAO device implantations occurred in patients with CHA<sub>2</sub>DS<sub>2</sub>-VASc scores of 4 and ≥5. The crude prevalence of pericardial effusion requiring intervention was higher with increased CHA<sub>2</sub>DS<sub>2</sub>-VASc score (1.4% in patients with a score of ≥5 vs. 1.1% in patients with a score of 4 vs. 0.8% in patients with a score of 3, *P* < 0.01). In the multivariable model adjusted for potential confounders, CHA<sub>2</sub>DS<sub>2</sub>-VASc scores of 4 and ≥5 were found to be independently associated with overall complications [adjusted odds ratio (aOR) 1.26, 95% confidence interval (CI) 1.18–1.35, and aOR 1.88, 95% CI 1.73–2.04, respectively] and prolonged length of stay (aOR 1.18, 95% CI 1.11–1.25, and aOR 1.54, 95% CI 1.44–1.66, respectively).

## Conclusion

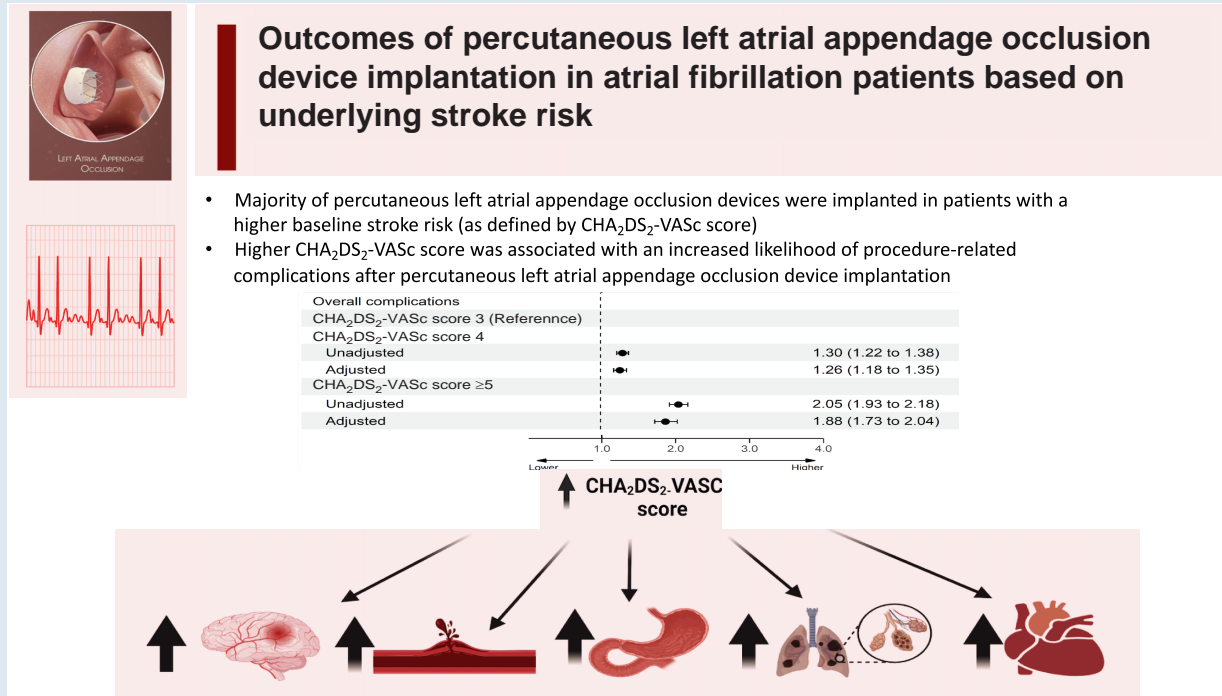
A higher CHA<sub>2</sub>DS<sub>2</sub>-VASc score was associated with an increased risk of peri-procedural complications and resource utilization after LAAO. These findings highlight the importance of patient selection for the LAAO procedure and need validation in future studies.

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## Graphical Abstract



## Keywords

Left atrial appendage occlusion • Stroke risk • CHA<sub>2</sub>DS<sub>2</sub>-VASC score • Outcomes • Complications

## What's new?

- Majority of percutaneous left atrial appendage occlusion (LAAO) device implantations occurred in patients with an elevated baseline stroke risk.
- The prevalence of pericardial effusion requiring intervention was higher in patients with increased CHA<sub>2</sub>DS<sub>2</sub>-VASC score.
- CHA<sub>2</sub>DS<sub>2</sub>-VASC scores of 4 and ≥5 were found to be independently associated with overall complications and prolonged length of stay after percutaneous LAAO device implantation.

## Introduction

Atrial fibrillation (AF) is the most common sustained arrhythmia encountered in clinical practice with an estimated prevalence of 5.2 million in the USA.<sup>1</sup> Patients with AF are at an increased risk of stroke.<sup>2</sup> Current guidelines recommend the CHA<sub>2</sub>DS<sub>2</sub>-VASC score in selecting candidates that would benefit from appropriate oral anticoagulant (OAC) therapy for preventing stroke.<sup>3</sup>

Percutaneous left atrial appendage occlusion (LAAO) is an alternative strategy to minimize the risk of stroke in select AF patients that are unable to tolerate long-term OAC therapy.<sup>4</sup> The majority of the randomized clinical trial evidence supporting the LAAO procedure is limited to patients who are at a lower risk of stroke.<sup>5,6</sup> The landmark PROTECT-AF (percutaneous closure of the LAA vs warfarin therapy for prevention of stroke in patients with atrial fibrillation) trial had almost two-thirds of the patients with a CHADS<sub>2</sub> score of ≤2,<sup>5</sup> whereas less than half of the patients in the

PREVAIL (prospective randomized evaluation of the Watchman LAA closure device in patients with atrial fibrillation vs long-term warfarin therapy) trial had a CHADS<sub>2</sub> score > 2.<sup>6</sup> It is important to examine whether the outcomes of the LAAO procedure observed in patients with a lower stroke risk are similar to those with a higher stroke risk.

To fill these important knowledge gaps, we conducted this retrospective study using a large national US administrative database and compared procedural complications and inpatient outcomes between patients with different baseline risks of stroke as defined by their CHA<sub>2</sub>DS<sub>2</sub>-VASC score.

## Methods

## Data source

Data from the National Inpatient Sample (NIS) were used for the purpose of our current study. We analysed the NIS database from years 2016–20 for LAAO device implantations. 2016 was taken as a start year for our study because the Watchman device was approved by the Food and Drug Administration in March of 2015. The NIS is made possible by a federal-state-industry partnership sponsored by the Agency for Healthcare Research and Quality. The NIS is derived from non-federal hospitals in all states and can be used for computing national estimates of healthcare utilization, costs, and outcomes.<sup>7</sup> The NIS provides discharge weights that are used for estimation of disease and procedure trends nationally. Owing to the de-identified nature of the NIS dataset, the need for informed consent and institutional review board approval is waived. The NIS adheres to the 2013 Declaration of Helsinki for conduction of human research.

### Study population

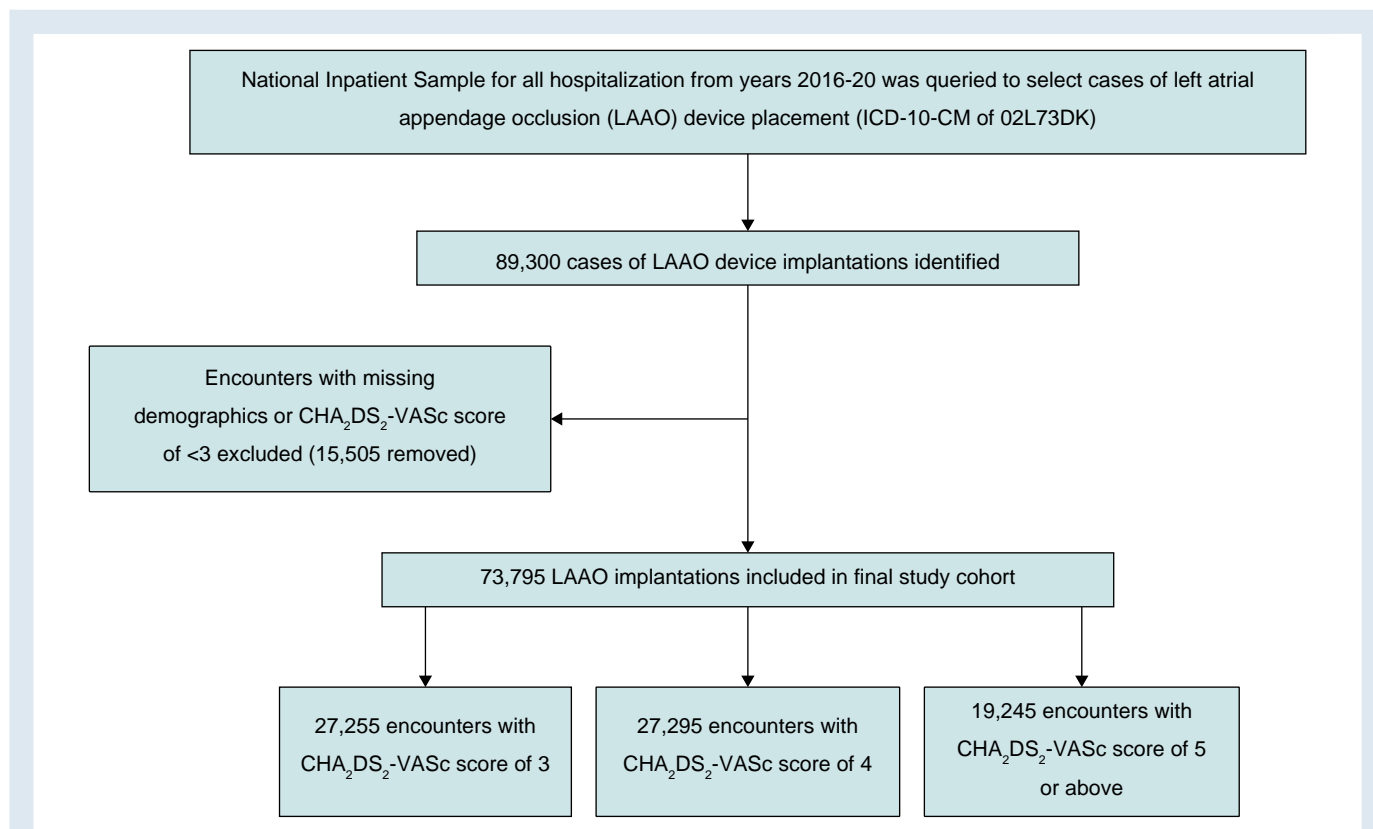
Percutaneous LAAO device implantations were identified using the International Classification of Diseases, 10th Revision, Clinical Modification (ICD-10-CM) code of 02L73DK. This code has been extensively validated in earlier studies for extraction of percutaneous LAAO device implantations from the administrative datasets.<sup>8-13</sup> Patients younger than 18 years and those with missing demographic data were excluded. The study sample was stratified on the basis of the CHA<sub>2</sub>DS<sub>2</sub>-VASc score into three groups (scores of 3, 4, and ≥5). Centers for Medicare and Medicaid Services (CMS) mandates the CHA<sub>2</sub>DS<sub>2</sub>-VASc score of 3 or greater for the purpose of LAAO device reimbursement, and therefore, we excluded patients with a CHA<sub>2</sub>DS<sub>2</sub>-VASc score of ≤2 in the primary analysis (however, supplementary data comparing baseline characteristics and in-hospital outcomes of AF patients undergoing percutaneous LAAO are provided in which stratification was done on the basis of a CHA<sub>2</sub>DS<sub>2</sub>-VASc score of 3 or greater and CHA<sub>2</sub>DS<sub>2</sub>-VASc score < 3

please see [Supplementary material online](#)).<sup>14</sup> Baseline characteristics, procedural complications, and inpatient outcomes including mortality (reported as a distinct categorical variable in the dataset), length of stay, and hospitalization costs were compared in LAAO device recipients based on baseline CHA<sub>2</sub>DS<sub>2</sub>-VASc score. We also analysed independent association of higher CHA<sub>2</sub>DS<sub>2</sub>-VASc score with outcomes of overall complications, major complications (defined as composite of pericardial effusion requiring intervention, cardiac arrest, ischaemic stroke/transient ischaemic attack, haemorrhagic stroke, systemic embolism, myocardial infarction, and peripheral vascular complications, which included arteriovenous fistula, pseudoaneurysm, access site haematoma, retroperitoneal bleeding, and venous thromboembolism), inpatient mortality, prolonged hospital stay (defined as length of stay > 1 day), and increased hospitalization cost (median hospitalization cost > 25 275\$). For computing hospitalization costs, the cost-to-charge ratio files supplied by the Healthcare Cost and Utilization

Project were applied to the total hospital charges and adjusted for inflation to December 2020.

### Statistical analysis

Descriptive statistics are presented as frequencies with percentages for categorical variables and as median with inter-quartile range (IQR) for continuous variables. Baseline characteristics were compared using a Pearson  $\chi^2$  test and Fisher exact test for categorical variables and the Kruskal–Wallis *H* test for continuous variables. For crude comparison of procedural complications and in-hospital outcomes among the study groups, the Pearson  $\chi^2$  test was used. For the assessment of the independent association of CHA<sub>2</sub>DS<sub>2</sub>-VASc scores of 4 and ≥5 with outcomes including overall complications, major complications, inpatient mortality, length of stay > 1 day, and median hospitalization cost > 25 275\$, a single-step multivariable logistic regression model was used. Age, sex, race/ethnicity, and 29 Elixhauser comorbidities (heart failure, valvular disease, pulmonary circulation disease, peripheral vascular disease, paralysis, neurological disorders, chronic pulmonary disease, diabetes without complications, diabetes with chronic complications, hypothyroidism, hypertension, renal failure, liver disease, peptic ulcer, acquired immune deficiency syndrome, lymphoma, metastatic cancer, solid tumour without metastasis, collagen vascular disease, coagulopathy, obesity, weight loss, fluid and electrolyte disorders, chronic blood loss anaemia, deficiency anaemia, alcohol abuse, drug abuse, psychoses, and depression) were used for adjustment. All of these covariates were identified a priori based on prior literature and authors’ best clinical judgement. A *P*-value of <0.05 was considered statistically significant. All statistical analyses were performed using SPSS version 26 (IBM Corp, Armonk, NY) and R version 3.6. Because of the complex survey design of the NIS, sample weights, strata, and clusters were applied to raw data to generate national estimates. The NIS brief on statistical methodology attested that data were missing at random and any such missing data were not imputed in our study.<sup>7</sup>



**Figure 1** Flow sheet showing the process of patient selection.

**Table 1** Baseline characteristics of the study population stratified on the basis of stroke risk

Variable no. (%)	CHA <sub>2</sub> DS <sub>2</sub> -VASc score 3 [n = 27 255 (36.9%)]	CHA <sub>2</sub> DS <sub>2</sub> -VASc score 4 [n = 27 295 (37.0%)]	CHA <sub>2</sub> DS <sub>2</sub> -VASc score ≥ 5 [n = 19 245 (26.1%)]	P-value
Age [median (IQR)] years	75 (71–81)	75 (71–81)	75 (71–81)	<0.01
Females	7740 (28.4)	13 775 (50.5)	13 725 (71.3)	<0.01
Age				
<65	1420 (5.2)	520 (1.9)	175 (0.9)	
65–74	11 325 (41.6)	6045 (22.1)	2575 (13.4)	
≥75	14 510 (53.2)	20 730 (75.9)	16 495 (85.7)	
Race/ethnicity				
White	23 385 (88.6)	23 345 (88.4)	16 100 (86.7)	<0.01
Black	975 (3.7)	1110 (4.2)	865 (4.7)	
Hispanic	1120 (4.2)	1225 (4.6)	950 (5.1)	
Asian or Pacific Islander	350 (1.3)	290 (1.1)	250 (1.3)	
Native American	95 (0.4)	95 (0.4)	65 (0.3)	
Other	465 (1.8)	335 (1.3)	350 (1.9)	
Comorbidities				
Blood loss anaemia	410 (1.5)	630 (2.3)	450 (2.3)	<0.01
Congestive heart failure	5475 (20.1)	11 780 (43.2)	12 790 (66.5)	<0.01
Coagulopathy	1120 (4.1)	1035 (3.8)	710 (3.7)	0.04
Chronic pulmonary disease	5500 (20.2)	6520 (23.9)	5505 (28.6)	<0.01
Coronary artery disease	230 (0.8)	980 (3.6)	5670 (29.5)	<0.01
Diabetes	3420 (12.5)	5535 (20.3)	6605 (34.3)	<0.01
Renal failure	6020 (22.1)	7295 (26.7)	5430 (28.2)	<0.01
Hypertension	23 125 (84.8)	26 145 (95.8)	18 830 (97.8)	<0.01
Liver disease	750 (2.8)	630 (2.3)	485 (2.5)	<0.01
Obesity	4710 (17.3)	4550 (16.7)	3535 (18.4)	<0.01
Peripheral vascular disorders	1125 (4.1)	2390 (8.8)	4190 (21.8)	<0.01
Valvular disease	1300 (4.8)	1810 (6.6)	1450 (7.5)	<0.01
Weight loss	65 (0.2)	125 (0.5)	115 (0.6)	<0.01
Hospital location				
Rural	460 (1.7)	600 (2.2)	480 (2.5)	<0.01
Urban non-teaching	2860 (10.5)	2865 (10.5)	2005 (10.4)	
Urban teaching	23 935 (87.8)	23 830 (87.3)	16 760 (87.1)	
Hospital size				
Small	460 (1.7)	600 (2.2)	480 (2.5)	<0.01
Medium	2860 (10.5)	2865 (10.5)	2005 (10.4)	
Large	23 935 (87.8)	23 830 (87.3)	16 760 (87.1)	
Median income quartile				
0–25th	5565 (20.7)	6005 (22.3)	4435 (23.3)	<0.01
26–50th	6975 (26.0)	7170 (26.6)	5220 (27.4)	
51–75th	7545 (28.1)	7410 (27.5)	5175 (27.2)	
76–100th	6780 (25.2)	6375 (23.6)	4215 (22.1)	

## Results

Out of 89 300 weighted cases of percutaneous LAAO device implantation, a total of 73 795 patients with CHA<sub>2</sub>DS<sub>2</sub>-VASc ≥ 3 and no missing demographic data were included in the final study cohort (please see Figure 1). Of these encounters, 27 255 (36.9%) had a CHA<sub>2</sub>DS<sub>2</sub>-VASc

score of 3, 27 295 (37.0%) had a CHA<sub>2</sub>DS<sub>2</sub>-VASc score of 4, and 19 245 (26.1%) had a CHA<sub>2</sub>DS<sub>2</sub>-VASc score of ≥ 5. Baseline characteristics of the study population are shown in Table 1. In the overall cohort, ~47.8% of patients were women. The approximate breakdown of patients by race is as follows: 85% White, 4% Black, 4.5% Hispanic, 1.2% Asian or Pacific Islander, 0.3% Native American, and 1.6% of other race.

**Table 2** Complications in patients undergoing left atrial appendage occlusion stratified on the basis of stroke risk

Variable no. (%)	CHA <sub>2</sub> DS <sub>2</sub> -VASc score 3 [n = 27 255 (36.9%)]	CHA <sub>2</sub> DS <sub>2</sub> -VASc score 4 [n = 27 295 (37.0%)]	CHA <sub>2</sub> DS <sub>2</sub> -VASc score ≥ 5 [n = 19 245 (26.1%)]	P-value
Overall complications (%)	2015 (7.4)	2560 (9.4)	2710 (14.1)	<0.01
Major complications (%) <sup>a</sup>	1350 (5.0)	1680 (6.2)	1515 (7.9)	<0.01
Any cardiovascular complication	590 (2.2)	850 (3.1)	650 (3.4)	<0.01
Cardiac arrest/CPR procedure code	35 (0.1)	45 (0.2)	35 (0.2)	0.31
Pacemaker implantation	85 (0.3)	95 (0.3)	110 (0.6)	<0.01
ST elevation myocardial infarction	NR	30 (0.1)	NR	NR
Non-ST elevation myocardial infarction	280 (1.0)	415 (1.5)	265 (1.4)	<0.01
Pericardial effusion requiring intervention	215 (0.8)	290 (1.1)	265 (1.4)	<0.01
Cardiac tamponade	105 (0.4)	215 (0.8)	200 (1.0)	<0.01
Pericarditis	30 (0.1)	55 (0.2)	30 (0.2)	<0.01
Cardiogenic shock	55 (0.2)	65 (0.2)	50 (0.3)	0.412
Any systemic complication	25 (0.1)	40 (0.1)	50 (0.3)	<0.01
Anaphylaxis	NR	NR	NR	NR
Arterial embolism	NR	20 (0.1)	35 (0.2)	<0.01
Septic shock	15 (0.1)	NR	NR	NR
Any peripheral vascular complication	360 (1.3)	545 (2.0)	575 (3.0)	<0.01
AV fistula	30 (0.1)	55 (0.2)	30 (0.2)	0.23
Pseudoaneurysm	55 (0.2)	90 (0.3)	110 (0.6)	<0.01
Haematoma	110 (0.4)	140 (0.5)	155 (0.8)	<0.01
Retroperitoneal bleeding	20 (0.2)	15 (0.1)	15 (0.1)	0.58
Venous thromboembolism	50 (0.2)	80 (0.3)	65 (0.3)	<0.01
Dissection	NR	NR	45 (0.2)	NR
Any neurological complication	25 (0.1)	80 (0.3)	555 (2.9)	<0.01
Haemorrhagic stroke	15 (0.1)	40 (0.1)	200 (1.0)	<0.01
Ischaemic stroke	NR	25 (0.1)	200 (1.0)	<0.01
Transient ischaemic attack	NR	15 (0.1)	175 (0.9)	<0.01
Any gastrointestinal (GI) or haematological complication	915 (3.4)	1070 (3.9)	1000 (5.2)	<0.01
GI bleeding	595 (2.2)	630 (2.3)	595 (3.1)	<0.01
Bleeding during the procedure	20 (0.1)	25 (0.1)	20 (0.1)	0.53
Need for blood transfusion	320 (1.2)	465 (1.7)	470 (2.4)	<0.01
Any pulmonary complications	475 (1.7)	690 (2.5)	685 (3.6)	<0.01
Respiratory failure	215 (0.8)	305 (1.1)	400 (2.1)	<0.01
Pneumothorax	5 (0.0)	0 (0.0)	15 (0.1)	<0.01
Pleural effusion	80 (0.3)	95 (0.3)	105 (0.5)	<0.01
Pneumonia bacterial	35 (0.1)	85 (0.3)	95 (0.5)	<0.01
Long-term ventilation requirement	15 (0.1)	25 (0.1)	55 (0.3)	<0.01

Less than 11 data were not reported as per HCUP recommendations and labelled as NR (not reported) where applicable.

<sup>a</sup>Composite of cardiac arrest, ischaemic stroke, haemorrhagic stroke, TIA, arterial embolism, myocardial infarction (NSTEMI & STEMI), major bleeding, pericardial effusion requiring intervention, and peripheral vascular complications.

With an increase in CHA<sub>2</sub>DS<sub>2</sub>-VASc score (3 vs. 4 vs. ≥ 5), there was a corresponding increase in the prevalence of important comorbidities such as renal failure (22.2% vs. 26.7% vs. 28.2%

$P < 0.01$ ), peripheral vascular disease (4.1% vs. 8.8% vs. 21.8%

$P < 0.01$ ), and weight loss (0.2% vs. 0.5% vs. 0.6%

$P < 0.01$ ).

Crude LAO procedure-related complications stratified based on CHA<sub>2</sub>DS<sub>2</sub>-VASc score are shown in Table 2. The prevalence of overall complications increased in AF patients undergoing percutaneous

LAO implantation with increased CHA<sub>2</sub>DS<sub>2</sub>-VASc score (14.1% in patients with a CHA<sub>2</sub>DS<sub>2</sub>-VASc score of ≥5% vs. 9.4% in patients with a CHA<sub>2</sub>DS<sub>2</sub>-VASc score of 4 vs. 7.4% in patients with a CHA<sub>2</sub>DS<sub>2</sub>-VASc score of 3,  $P < 0.01$ ). Similarly, the prevalence of pericardial effusion requiring intervention was also higher with increased CHA<sub>2</sub>DS<sub>2</sub>-VASc score (1.4% in patients with a score of ≥5% vs. 1.1% in patients with a score of 4 vs. 0.8% in patients with a score of 3,  $P < 0.01$ ). The prevalence of any neurological complication was also higher with increased CHA<sub>2</sub>DS<sub>2</sub>-VASc score (2.9% in patients with a

**Table 3** In-hospital outcomes after left atrial appendage occlusion stratified on the basis of stroke risk

Variable no. (%)	CHA <sub>2</sub> DS <sub>2</sub> -VASc score 3 [n = 27 255 (36.9%)]	CHA <sub>2</sub> DS <sub>2</sub> -VASc score 4 [n = 27 295 (37.0%)]	CHA <sub>2</sub> DS <sub>2</sub> -VASc score ≥5 [n = 19 245 (26.1%)]	P-value
Died at discharge	35 (0.1)	35 (0.1)	60 (0.3)	<0.01
Home/routine/self-care	26 790 (98.4)	26 605 (97.6)	18 285 (95.3)	<0.01
Non-home discharges	425 (1.6)	650 (2.4)	895 (4.7)	
Resource utilization, median (IQR)				
Length of stay, days	1 (1–1)	1 (1–1)	1 (1–1)	<0.01
Cost of hospitalization, \$	25 072.57 (19 081–31 683)	25 255.69 (19 751–31 961)	25 677.27 (20 017–32 567)	<0.01

Less than 11 data were not reported as per HCUP recommendations.

score of ≥5% vs. 0.3% in patients with a score of 4 vs. 0.1% in patients with a score of 3,  $P < 0.01$ ).

Crude inpatient outcomes after LAAO device implantation stratified based on CHA<sub>2</sub>DS<sub>2</sub>-VASC score are shown in Table 3. A CHA<sub>2</sub>DS<sub>2</sub>-VASC score of ≥5 was associated with increased mortality at discharge and with non-home discharge compared to CHA<sub>2</sub>DS<sub>2</sub>-VASC scores of 4 or 3 (0.3% vs. 0.1%,  $P < 0.01$ , and 4.7% vs. 2.4% vs. 1.6%,  $P < 0.01$ , respectively).

To analyse the independent association of CHA<sub>2</sub>DS<sub>2</sub>-VASC scores of 4 and ≥5 with important outcomes, multivariable logistic regression models were created by adjusting for potential confounders and are shown in Figure 2. CHA<sub>2</sub>DS<sub>2</sub>-VASC scores of 4 and ≥5 were found to be independently associated with overall complications [adjusted odds ratio (aOR) 1.26, 95% confidence interval (CI) 1.18–1.35, and aOR 1.88, 95% CI 1.73–2.04, respectively] and prolonged length of stay (aOR 1.18, 95% CI 1.11–1.25, and aOR 1.54, 95% CI 1.44–1.66, respectively) after percutaneous LAAO device implantation.

## Discussion

The main findings of our current investigation are as follows: (i) the real-world prevalence of percutaneous LAAO device implantation in patients with an elevated stroke risk was reasonably higher as ~63% of such implantations in our cohort occurred in patients with CHA<sub>2</sub>DS<sub>2</sub>-VASC scores of 4 and ≥5, (ii) the prevalence of important comorbidities was higher in patients with CHA<sub>2</sub>DS<sub>2</sub>-VASC scores of 4 and ≥5, and (iii) a higher CHA<sub>2</sub>DS<sub>2</sub>-VASC score was associated with an increased likelihood of procedure-related complications and increased resource utilization after LAAO device implantation.

Percutaneous LAAO device implantation is a viable strategy to minimize stroke risk in select AF patients who are intolerant to long-term OAC therapy.<sup>15</sup> The pivotal trials comparing percutaneous LAAO device implantation using an earlier-generation Watchman device with warfarin had limited participation of AF patients with an elevated stroke risk.<sup>5,6</sup> In the PROTECT-AF trial, approximately two-thirds of patients had a CHADS<sub>2</sub> score of ≤2. The follow-up PREVAIL trial also primarily involved low stroke risk patients as less than half of the patients enrolled in this trial had a CHADS<sub>2</sub> score > 2. In our real-world cohort of LAAO device implantation from the contemporary US practice, we found that >60% of such implantations occurred in patients with an elevated baseline stroke risk (CHA<sub>2</sub>DS<sub>2</sub>-VASC scores of 4 and ≥5). We also found increased risk of procedural complications after LAAO implantation in patients with elevated CHA<sub>2</sub>DS<sub>2</sub>-VASC score, and implanting physicians should strive to minimize such complications in order to make these devices safer for all patient groups. In fact, studies have shown significant reduction in LAAO procedural complications with increased

operator and institutional experience since its approval in the USA in 2015.<sup>10</sup>

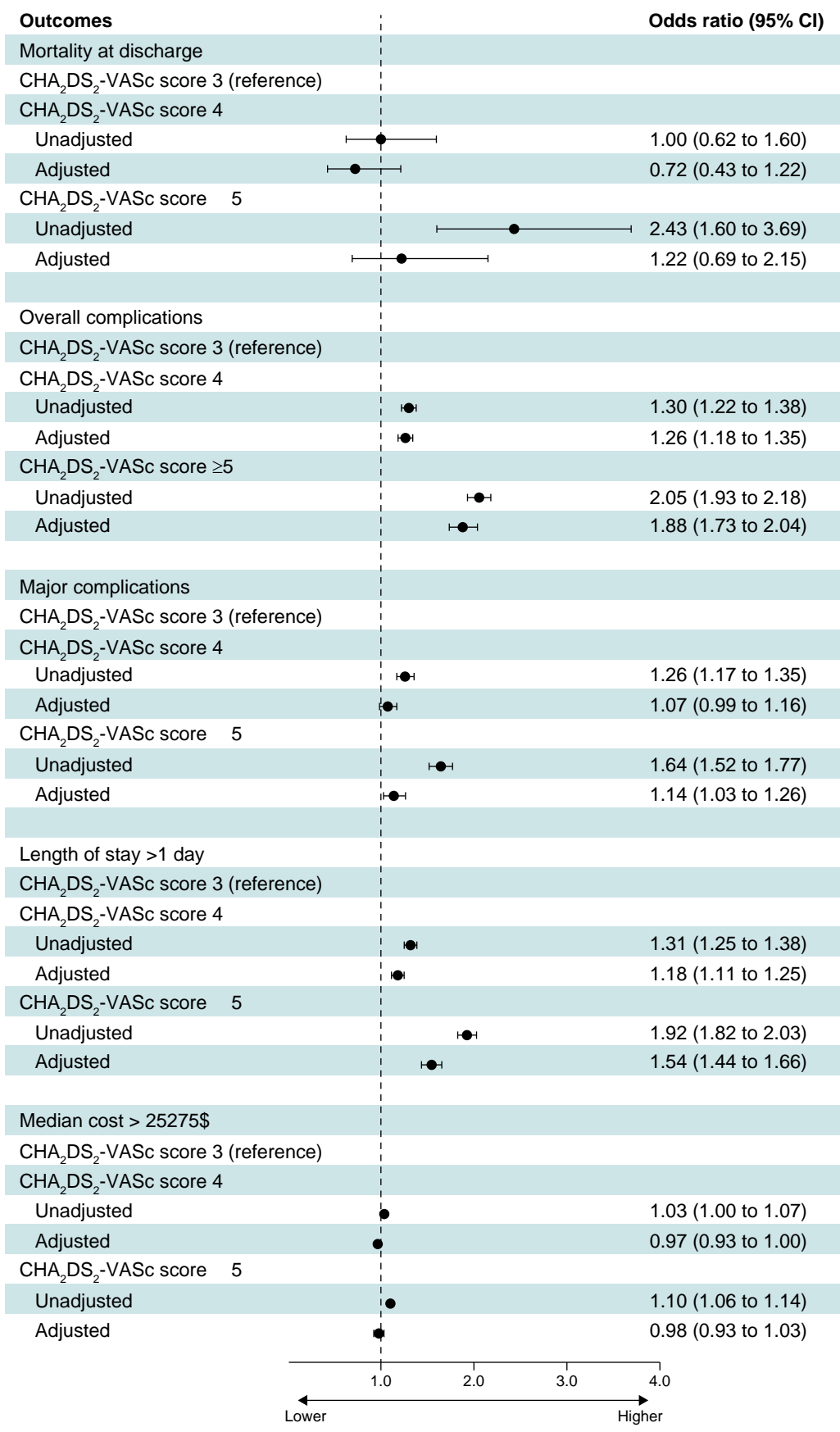
To the best of our knowledge, this is the first large-scale study comparing outcomes after percutaneous LAAO device implantation in AF patients based on the CHA<sub>2</sub>DS<sub>2</sub>-VASC score. Earlier studies have analysed the ability of the CHA<sub>2</sub>DS<sub>2</sub>-VASC score in predicting outcomes after invasive cardiovascular procedures. In a study of 633 consecutive patients undergoing transcatheter aortic valve implantation (TAVI), Orvin et al.<sup>16</sup> demonstrated that the rates of both stroke and mortality were significantly higher with increasing CHA<sub>2</sub>DS<sub>2</sub>-VASC score at 1 year after the index procedure ( $P = 0.012$  and  $P = 0.025$ , respectively). They also demonstrated that each single-point increase in CHA<sub>2</sub>DS<sub>2</sub>-VASC score was associated with a 38% increase in the 1 year combined endpoint of mortality or stroke ( $P = 0.022$

C index 0.615). In another study of >500 patients undergoing percutaneous coronary intervention, Parfrey et al.<sup>17</sup> demonstrated that patients with CHA<sub>2</sub>DS<sub>2</sub>-VASC score ≥ 5 had higher mortality rates at 1 year ( $P = 0.002$ ) and long-term ( $P < 0.001$ ).

Our results also demonstrated that CHA<sub>2</sub>DS<sub>2</sub>-VASC scores of 4 and ≥5 were associated with an increased likelihood of overall complications (aOR 1.26, 95% CI 1.18–1.35, and aOR 1.88, 95% CI 1.73–2.04, respectively) after percutaneous LAAO device implantation. The rate of pericardial effusion requiring intervention was higher in patients with CHA<sub>2</sub>DS<sub>2</sub>-VASC scores of 4 and ≥5 when compared to CHA<sub>2</sub>DS<sub>2</sub>-VASC scores of 3 after LAAO device implantation. Serious pericardial effusion is one of the most dreaded complications of percutaneous LAAO device implantation, and the incidence was close to 5% in the pivotal PROTECT-AF trial.<sup>5</sup> With greater operator experience and improvement in device design, the rate of pericardial effusion requiring intervention continues to decline in contemporary practice after LAAO device implantation.<sup>18</sup> Our dataset is not granular in assessment of causative aetiologies for pericardial effusion in patients with a higher CHA<sub>2</sub>DS<sub>2</sub>-VASC score, and additional studies are needed to determine the mechanism of pericardial effusion in patients with such baseline elevated stroke risk.

## Limitations

The results of our study should be interpreted in the context of the following key limitations. First, the NIS does not contain information on post-LAAO antiplatelet and anticoagulation strategy, which can be variable in patients with different stroke risks. Second, the NIS relies on ICD codes for disease and procedure identification which may be subjected to errors. It is, however, worth pointing out that the NIS has a robust quality control programme that minimizes miscoding and ensures data integrity. Third, the NIS censor outcomes at discharge and patients are not longitudinally followed, and hence, long-term outcomes of stroke and bleeding complications after LAAO implantation



**Figure 2** Unadjusted and adjusted association of CHA<sub>2</sub>DS<sub>2</sub>-VASc scores of 4 and ≥5 with outcomes of mortality, overall complications, major complications, prolonged length of stay, and increased hospitalization costs in patients undergoing percutaneous left atrial appendage occlusion.



cannot be determined from the dataset. Additionally, comparisons cannot be made based on hospital or implanting physician volume as the NIS does not inform on such parameters. Fourth, the NIS only caters to inpatient admissions and does not provide information on outpatient encounters. However, it should be noted that inpatient admission is often required for reimbursement of a LAAO device implantation,<sup>19</sup> and hence, our study constitutes a well-representative national sample of LAAO implantations in the USA in the contemporary period.

## Conclusion

In contemporary real-world US practice, a significant proportion of percutaneous LAAO device implantations occurred in AF patients with baseline elevated stroke risk (CHA<sub>2</sub>DS<sub>2</sub>-VASc scores of 4 and ≥5). A higher CHA<sub>2</sub>DS<sub>2</sub>-VASc score was associated with an increased risk of peri-procedural complications and resource utilization after LAAO device implantations.

## Supplementary material

Supplementary material is available at *Europace* online.

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## Data availability

The data that support the results of this study are available from the corresponding author upon reasonable request.

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