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CHA2DS2-VASc Score for Risk Stratification After Endovascular Therapy in Patients With Symptomatic Peripheral Artery Disease

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Abstract

Objective: Risk stratification after endovascular therapy (EVT) for symptomatic peripheral artery disease (PAD) remains clinically important, particularly in patients with multiple comorbidities. The CHA2DS2-VASc score is a simple clinical score that incorporates major cardiovascular risk factors, but its prognostic utility after EVT for PAD has not been well established. This study evaluated the association between the CHA2DS2-VASc score and 3-year mortality in patients undergoing EVT for symptomatic PAD.

Methods: This multicenter retrospective study included 1584 patients who underwent EVT for symptomatic PAD between 2018 and 2020. Patients were classified into low, intermediate, and high CHA2DS2-VASc score groups. The primary outcome was all-cause mortality at 3 years. Kaplan-Meier analysis and multivariable Cox proportional hazards models were used to assess the association between the score and mortality. Subgroup analyses were additionally performed according to atrial fibrillation (AF) status and PAD severity, including intermittent claudication (IC) and chronic limb-threatening ischemia (CLTI).

Results: The rates of 3-year all-cause mortality increased stepwise across the low, intermediate, and high-score groups (4.4%, 17.2%, and 25.3%, respectively; log-rank $P < .001$). After adjustment for PAD-specific clinical factors, the CHA2DS2-VASc score remained independently associated with all-cause mortality (hazard ratio per 1-point increase, 1.31; 95% CI, 1.21-1.43; $P < .001$). This association was evident in patients without AF and was also observed in both IC and CLTI subgroups.

Conclusions: In patients undergoing EVT for symptomatic PAD, a higher CHA2DS2-VASc score was independently associated with increased 3-year mortality. This widely available score may serve as a simple adjunctive tool for initial risk stratification after EVT and may complement established PAD-specific prognostic assessments.

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Clinical Impact

Patients undergoing endovascular therapy (EVT) for symptomatic peripheral artery disease remain at substantial risk of long-term mortality. In this multicenter study, the CHA_2DS_2-VASc score was independently associated with 3-year mortality across a broad spectrum of symptomatic PAD, including intermittent claudication and chronic limb-threatening ischemia. Although PAD- and CLTI-specific prognostic models provide superior discrimination, the CHA_2DS_2-VASc score is simple, universally recognized, and immediately available without disease-specific assessments. It may serve as an adjunctive tool for initial risk stratification and complement established prognostic models in routine clinical practice.

Keywords

peripheral artery disease, endovascular therapy, chronic limb-threatening ischemia, CHA2DS2-VASc score, risk stratification

Introduction

Peripheral artery disease (PAD) is associated with a high risk of cardiovascular morbidity and mortality, even after successful revascularization.[1,2] Endovascular therapy (EVT) has become a widely adopted treatment strategy for symptomatic PAD; however, long-term prognosis remains poor, particularly in patients with multiple comorbidities.[3-5] Therefore, simple and practical risk stratification tools are needed to identify high-risk patients and guide post-procedural management.

The CHA2DS2-VASc score was originally developed to estimate stroke risk in patients with atrial fibrillation (AF).[6,7] Because this score incorporates several established cardiovascular risk factors, it has recently been applied to predict adverse outcomes beyond AF, including in patients with coronary artery disease and heart failure.[8-10] However, its prognostic value in patients with PAD undergoing EVT has not been fully established.

Although several risk models have been proposed for patients with PAD and chronic limb-threatening ischemia (CLTI),[11,12] many require detailed anatomical or wound-related variables, limiting their immediate use in routine EVT practice. A simple clinical score that can be calculated before or shortly after EVT may help identify patients who require closer follow-up and more intensive secondary prevention. Therefore, this study aimed to evaluate the prognostic utility of the CHA2DS2-VASc score for 3-year mortality after EVT in patients with symptomatic PAD, with additional analyses according to AF status and PAD severity.

Methods

Study Population and Design

SETers (retrospective study of prognosis and various factors in the endovascular therapy performed patients with symptomatic lower extremity artery disease) is a multicenter, retrospective study involving 13 institutions. We retrospectively enrolled 1685 patients who underwent EVT for symptomatic lower extremity arterial disease, defined as Rutherford classes 2 to 6, between January 2018 and December 2020. The study flow chart is shown in Figure 1. Patients with missing left ventricular ejection fraction data were excluded from the analysis. After applying the exclusion criterion, a total of 1584 patients were included in the final analysis. The study was approved by the institutional review board of Kurashiki Central Hospital (reference no. 4622).

EVT Procedures

Endovascular therapy was performed according to standard clinical practice at each participating hospital. Procedures included balloon angioplasty using drug-coated balloons and stent implantation at the discretion of the treating operators. The antiplatelet drug administered was aspirin (100 mg/d) with clopidogrel (75 mg/d) and/or cilostazol (100 or 200 mg/d), and its duration was dependent on the patient's background, lesion characteristics, and intervention results. At least 1 antiplatelet drug was maintained after EVT for all patients.

Outcome Measures

The primary outcome was all-cause mortality at 3 years after EVT. Follow-up information was obtained from hospital records and scheduled outpatient visits, and vital status was confirmed by telephone when necessary.

Statistical Analysis

Continuous variables are expressed as mean ± standard deviation and were compared using Student *t*-test for normally distributed data or expressed as median values with interquartile ranges and compared using the Wilcoxon rank-sum test for non-normally distributed data. Categorical variables were presented as frequencies and percentages and compared using the χ^2 test or Fisher exact test as appropriate.

Time-to-event analyses were performed using the Kaplan-Meier method and compared using the log-rank test. Cox proportional hazards regression analysis was used to assess

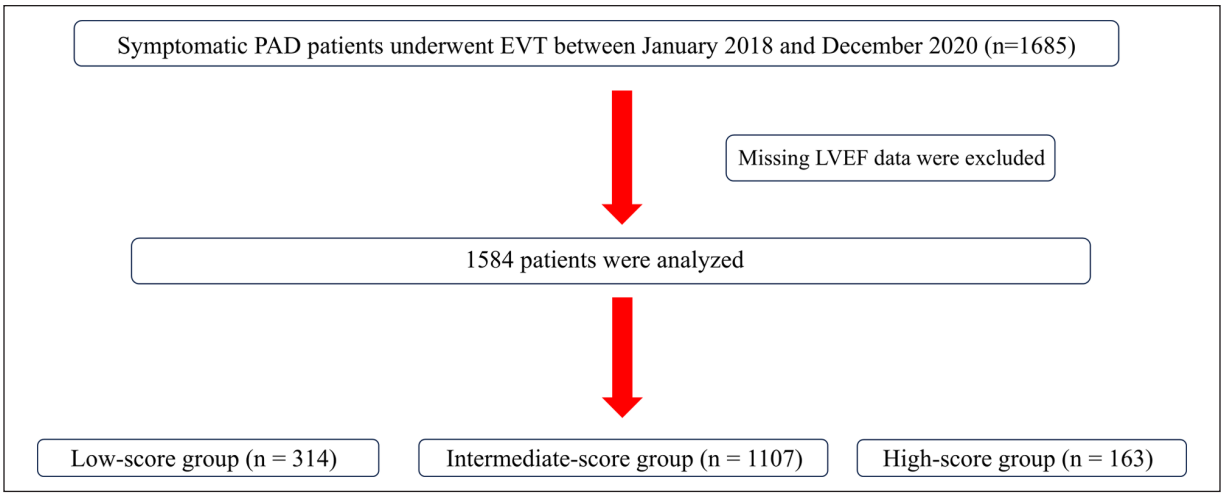


Figure 1. Study flow chart. A total of 1685 patients who underwent endovascular therapy (EVT) for symptomatic peripheral artery disease (PAD) between 2018 and 2020 were screened. After excluding patients with missing left ventricular ejection fraction data, 1584 patients were included in the final analysis.

the association between the CHA2DS2-VASc score and all-cause mortality. To avoid overadjustment and collinearity, variables directly included in the CHA2DS2-VASc score were not entered separately into the multivariable model. Instead, clinically relevant PAD-specific factors not included in the score, including sex, CLTI, hemodialysis, hypoalbuminemia, and statin use, were selected a priori. To evaluate discriminatory performance, Harrell's C-index was calculated for the CHA2DS2-VASc score in the overall cohort and in patients with CLTI. In addition, the predictive performance of the CHA2DS2-VASc score was compared with that of the Soga mortality prediction score, a prognostic model specifically developed for patients with CLTI.[13] Statistical analysis was performed using JMP (version 18.0; SAS Institute, Cary, North Carolina).

Results

Baseline and Procedural Characteristics

Patients were divided into 3 groups based on their CHA2DS2-VASc scores: low (1–3; n = 314), intermediate (4–6; n = 1107), and high (7–9; n = 163). Patients in the high-score group were older and more likely to have diabetes mellitus, hemodialysis, heart failure, and coronary artery disease (Table 1). The prevalence of CLTI increased stepwise with increasing CHA2DS2-VASc score.

Clinical Outcomes

During the 3-year follow-up period, a clear stepwise increase in all-cause mortality was observed across increasing CHA2DS2-VASc score categories. Higher CHA2DS2-VASc scores were associated with increased rates of all-cause mortality (4.4% vs 17.2% vs 25.3%, log-rank $P < .001$; Figure 2), and this association remained significant after multivariable adjustment.

The Cox proportional hazard model was used to examine the prognostic value of the CHA2DS2-VASc score (Table 2). After adjustment for clinically relevant PAD-specific risk factors, the CHA2DS2-VASc score remained independently associated with all-cause mortality (hazard ratio [HR] per 1-point increase, 1.31; 95% CI, 1.21-1.43, $P < .001$). Male, CLTI, hypoalbuminemia, and hemodialysis were also independently associated with increased mortality, even after adjustment for clinically relevant covariates.

The discriminatory performance of the CHA2DS2-VASc score was additionally evaluated using Harrell's C-index. In the overall cohort, the C-index of the CHA2DS2-VASc score was 0.599 (standard error [SE] = 0.013). Among patients with CLTI, the C-index was 0.610 (SE = 0.021). For comparison, the Soga mortality prediction score demonstrated a higher discriminatory performance in the CLTI cohort, with a C-index of 0.665 (SE = 0.022).

Figure 3 shows the Kaplan-Meier curves for mortality rates with and without AF. In patients without AF, the CHA2DS2-VASc score showed a clear stepwise increase in mortality (3.6% vs 14.7% vs 25.1%, log-rank $P < .001$). In contrast, the association was attenuated in patients with AF, possibly due to the smaller sample size (12.3% vs 28.5% vs 25.6%, log-rank $P = .22$).

Figure 4 shows the Kaplan-Meier curves for mortality rates according to the PAD status. When stratified by disease severity, the CHA2DS2-VASc score was significantly associated with increased mortality in both patients with intermittent claudication (IC) and those with CLTI. Among the 230 deaths observed during follow-up, cardiac death

Table 1. Baseline Characteristics.

	Low	Intermediate	High	*P* value
Patients, n	314	1107	163	
Age, y	67.1 ± 8.4	76.1 ± 8.1	78.1 ± 6.9	<.001
Male, No. (%)	270 (85.9)	741 (66.9)	100 (61.3)	<.001
BMI, kg/m^2	22.4 ± 3.5	22.5 ± 3.6	22.3 ± 3.7	.79
Ambulation status, No. (%)				
Independent	304 (96.8)	950 (85.8)	119 (73.0)	<.001
Wheelchair bound	10 (3.2)	137 (12.4)	36 (22.1)	<.001
Bedbound	0 (0)	20 (1.8)	8 (4.9)	.001
Hypertension, No. (%)	173 (55.3)	981 (88.6)	154 (94.5)	<.001
Hyperlipidemia, No. (%)	194 (61.8)	649 (58.6)	110 (67.5)	.079
Diabetes mellitus, No. (%)	83 (26.4)	676 (61.1)	119 (73.0)	<.001
Smoking history, No. (%)	236 (75.2)	648 (58.6)	90 (55.2)	.016
Hemodialysis, No. (%)	38 (12.1)	245 (22.1)	47 (28.8)	<.001
Heart failure, No. (%)	25 (8.0)	502 (45.4)	111 (68.1)	<.001
Cerebrovascular disease, No. (%)	1 (0.32)	145 (13.1)	163 (100.0)	<.001
Coronary artery disease, No. (%)	80 (25.5)	435 (39.3)	78 (47.9)	<.001
Atrial fibrillation or flutter, No. (%)	28 (8.9)	206 (18.6)	51 (31.3)	<.001
LVEF (%)	64.3 ± 8.0	60.6 ± 10.8	59.4 ± 12.1	<.001
Serum albumin, g/dL	3.9 ± 0.5	3.7 ± 0.56	3.6 ± 0.55	<.001
BNP, pg/mL	65.9 ± 267.5	183.6 ± 320.3	298.8 ± 504.4	<.001
ABI	0.64 ± 0.20	0.62 ± 0.23	0.57 ± 0.24	.0057
Rutherford class, No. (%)				<.001
2	154 (49.0%)	154 (49.0%)	154 (49.0%)	
3	98 (31.2%)	98 (31.2%)	98 (31.2%)	
4	17 (5.4%)	17 (5.4%)	17 (5.4%)	
5	40 (12.7%)	40 (12.7%)	40 (12.7%)	
6	5 (1.6%)	5 (1.6%)	5 (1.6%)	
CLTI, No. (%)	62 (19.8)	393 (35.5)	76 (46.6)	<.001
Aspirin, No. (%)	230 (73.3)	827 (74.7)	114 (69.9)	.41
P2Y12i, No. (%)	267 (85.0)	899 (81.2)	134 (82.2)	.3
Cilostazol, No. (%)	64 (20.4)	194 (17.5)	23 (14.1)	.22
Oral anticoagulant, No. (%)	33 (10.5)	182 (16.5)	48 (29.5)	<.001
β-blocker, No. (%)	63 (20.1)	405 (36.6)	68 (41.7)	<.001
ACEi/ARB, No. (%)	120 (38.2)	606 (54.7)	83 (50.9)	<.001
MRA, No. (%)	8 (2.6)	75 (6.8)	18 (11.0)	<.001
Statin, No. (%)	217 (69.1)	709 (64.1)	93 (57.1)	.031

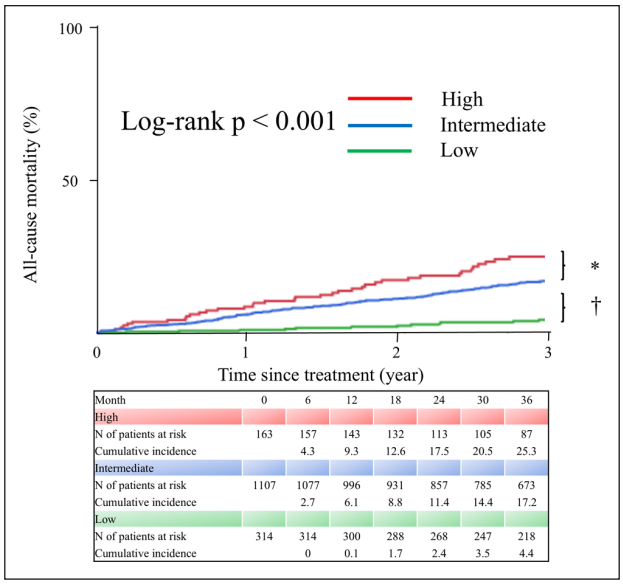
Values are mean ± SD or numbers (%), unless otherwise specified.
Abbreviations: BMI, body mass index; LVEF, left ventricular ejection fraction; BNP, brain natriuretic peptide; ABI, ankle brachial index; CLTI, chronic limb-threatening ischemia; ACEi, angiotensin-converting enzyme inhibitor; ARB, angiotensin II receptor blocker; MRA, mineralocorticoid receptor antagonist.

was the most frequent cause (99 deaths, 43.0%), followed by infection-related death (53 deaths, 23.0%) and cancer-related death (27 deaths, 11.7%).

In a sensitivity analysis excluding patients with Rutherford class 6 disease, the association between the CHA_2DS_2-VASc score and all-cause mortality remained significant (HR per 1-point increase, 1.21; 95% CI, 1.09-1.34; $P = .0005$). The discriminatory performance also remained similar (Harrell's C-index 0.598).

Discussion

In this multicenter retrospective study of patients undergoing EVT for symptomatic PAD, the CHA2DS2-VASc score was independently associated with 3-year all-cause mortality. The main findings were as follows: first, mortality increased stepwise with increasing CHA2DS2-VASc score; second, the score remained independently associated with mortality after adjustment for PAD-specific risk factors; and third, its



Month	0	6	12	18	24	30	36
High							
N of patients at risk	163	157	143	132	113	105	87
Cumulative incidence		4.3	9.3	12.6	17.5	20.5	25.3
Intermediate							
N of patients at risk	1107	1077	996	931	857	785	673
Cumulative incidence		2.7	6.1	8.8	11.4	14.4	17.2
Low							
N of patients at risk	314	314	300	288	268	247	218
Cumulative incidence		0	0.1	1.7	2.4	3.5	4.4

Figure 2. Kaplan-Meier curves for all-cause mortality according to CHA2DS2-VASc score groups. Patients were stratified into 3 groups based on their CHA2DS2-VASc scores: low (1-3), intermediate (4-6), and high (7-9). Higher CHA2DS2-VASc scores were associated with increased rates of all-cause mortality.

Standard errors of the Kaplan-Meier estimates calculated using the Greenwood formula remained below 10% throughout the displayed follow-up period in all groups. EVT indicates endovascular therapy; PAD, peripheral artery disease.

*$P < .05$ for high versus intermediate. **$P < .05$ for intermediate versus low.

prognostic value was observed not only in patients without AF but also across PAD severity, including both IC and CLTI. These findings suggest that the CHA2DS2-VASc score may serve as a simple bedside tool for risk stratification after EVT.

The CHA2DS2-VASc score incorporates several established cardiovascular risk factors, including advanced age, heart failure, diabetes mellitus, and prior cerebrovascular disease.[6,7] These factors are also strongly associated with adverse outcomes in patients with PAD.[8-10] Therefore, the score may reflect the overall systemic atherosclerotic burden and comorbidity profile rather than a disease-specific mechanism. Notably, cardiac death was the most frequent cause of death and accounted for 43.0% of all deaths in the present study. This substantial contribution of cardiovascular mortality may partly explain why the CHA_2DS_2-VASc score, although originally developed for stroke risk assessment in AF, was associated with mortality after EVT. Our findings suggest that this simple and widely available scoring system may be useful for risk stratification in patients undergoing EVT.

Importantly, the prognostic value of the CHA2DS2-VASc score was observed even in patients without AF, suggesting that its utility extends beyond stroke risk assessment in AF. Although the association appeared attenuated in patients with AF, this finding should be interpreted cautiously. In addition to the limited sample size, it is possible that other prognostic factors associated with AF itself, including advanced comorbidity burden and competing cardiovascular risks, may have attenuated the relative contribution of the CHA_2DS_2-VASc score in this subgroup.

The prognostic association of the CHA2DS2-VASc score was observed in both IC and CLTI populations. In patients with CLTI, the score demonstrated a clearer gradient of mortality risk, consistent with the advanced systemic disease burden in this population. These findings suggest that the score may help facilitate risk stratification across a broad spectrum of symptomatic PAD.

We additionally compared the discriminatory performance of the CHA2DS2-VASc score with the Soga mortality prediction score, which was specifically developed for patients with CLTI. As expected, the Soga score demonstrated superior discrimination (Harrell's C-index 0.665 vs 0.610 for the CHA2DS2-VASc score). This finding is not surprising because the Soga score incorporates several CLTI-specific clinical variables and was designed for mortality prediction in this population. Nevertheless, the CHA2DS2-VASc score showed acceptable prognostic performance despite requiring no detailed limb-related assessments, wound evaluation, or anatomical staging. Therefore, the CHA_2DS_2-VASc score may serve as a simple and widely available adjunctive tool for initial risk stratification in routine EVT practice. It should be considered complementary to, rather than a replacement for, established PAD- or CLTI-specific prognostic models.

Interestingly, statin use decreased across increasing CHA_2DS_2-VASc score categories despite the higher cardiovascular risk profile of these patients. Although the reasons for this observation cannot be determined from the present study, it may reflect older age, greater frailty, or historical underutilization of lipid-lowering therapy in patients with multiple comorbidities.

Risk stratification after EVT for PAD remains clinically challenging. Although several prognostic models for CLTI have been proposed, many require detailed anatomical or wound-related assessments that may limit routine applicability.[14] In contrast, the CHA2DS2-VASc score is simple, widely available, and can be calculated immediately at the bedside without additional testing. Our findings suggest that this score may help identify high-risk patients who require closer follow-up and more intensive secondary prevention after EVT.

Limitations

This study has several limitations. First, due to its retrospective observational design, residual confounding

Table 2. Independent predictors of all-cause mortality.

	Multivariate	
Variable	Hazard ratio (95% CI)	*P* value
CHA2DS2-VASc score (per 1-point increase)	1.31 (1.21-1.43)	<.001
Male	1.61 (1.20-2.17)	.001
CLTI	3.11 (2.27-4.25)	<.001
Albumin <3.0 g/dL	2.41 (1.73-3.35)	<.001
Hemodialysis	2.31 (1.76-3.04)	<.001
Statin use	0.72 (0.55-0.94)	.016

Abbreviations: CI, confidence interval; CLTI, chronic limb-threatening ischemia.

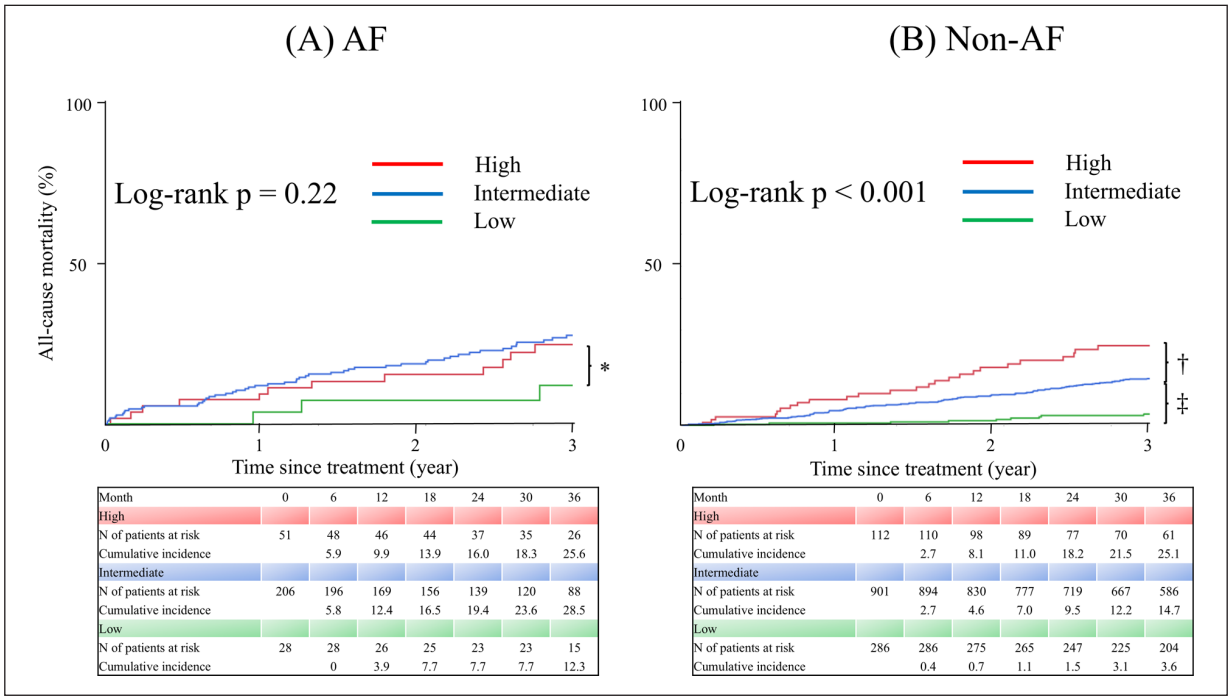
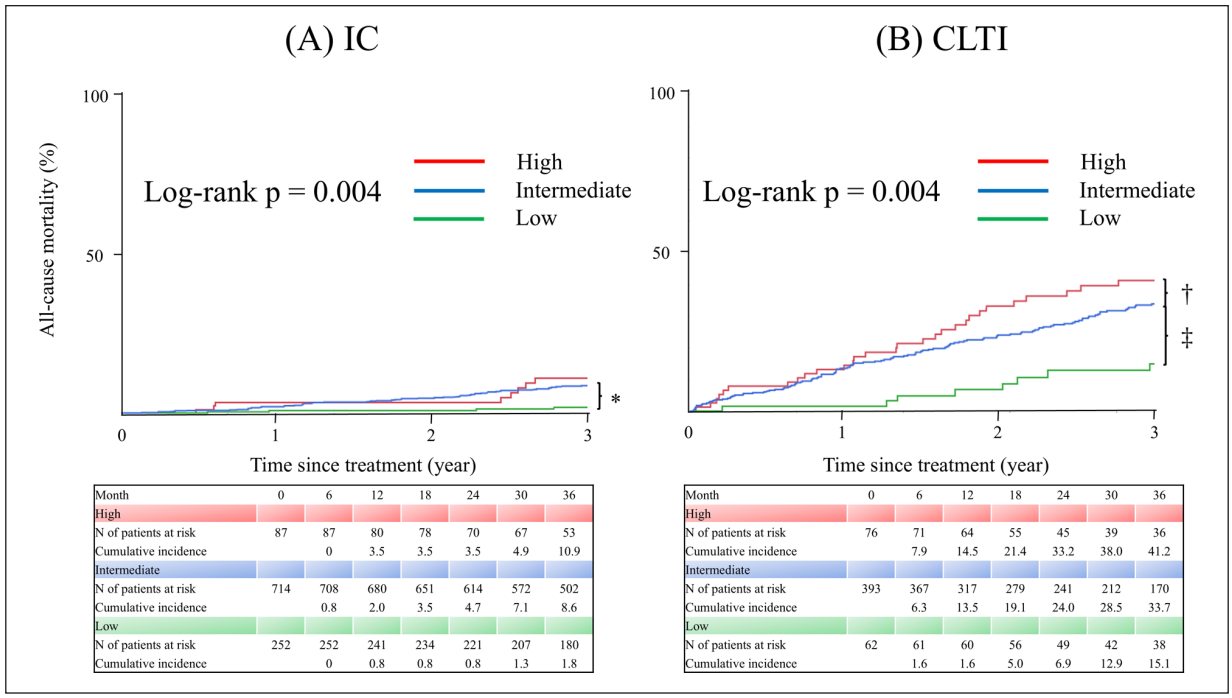


Figure 3. Kaplan-Meier curves for all-cause mortality stratified by atrial fibrillation or flutter status. (A) Patients with AF. (B) Patients without AF. A stepwise increase in mortality was observed in patients without AF, whereas the association was attenuated in those with AF.

Standard errors of the Kaplan-Meier estimates calculated using the Greenwood formula exceeded 10% after approximately 24 months in 1 AF subgroup. AF indicates atrial fibrillation or flutter.

*$P < .05$ for high versus low. **$P < .05$ for high versus intermediate. ***$P < .05$ for intermediate versus low.



Month	0	6	12	18	24	30	36
High							
N of patients at risk	87	87	80	78	70	67	53
Cumulative incidence		0	3.5	3.5	3.5	4.9	10.9
Intermediate							
N of patients at risk	714	708	680	651	614	572	502
Cumulative incidence		0.8	2.0	3.5	4.7	7.1	8.6
Low							
N of patients at risk	252	252	241	234	221	207	180
Cumulative incidence		0	0.8	0.8	0.8	1.3	1.8

Month	0	6	12	18	24	30	36
High							
N of patients at risk	76	71	64	55	45	39	36
Cumulative incidence		7.9	14.5	21.4	33.2	38.0	41.2
Intermediate							
N of patients at risk	393	367	317	279	241	212	170
Cumulative incidence		6.3	13.5	19.1	24.0	28.5	33.7
Low							
N of patients at risk	62	61	60	56	49	42	38
Cumulative incidence		1.6	1.6	5.0	6.9	12.9	15.1

Figure 4. Kaplan-Meier curves for all-cause mortality according to peripheral artery disease severity. (A) Patients with intermittent claudication. (B) Patients with chronic limb-threatening ischemia. Higher CHA2DS2-VASc scores were associated with increased mortality in both groups.

Standard errors of the Kaplan-Meier estimates calculated using the Greenwood formula remained below 10% throughout the displayed follow-up period in all groups. IC indicates intermittent claudication; CLTI, chronic limb-threatening ischemia.

*$P < .05$ for intermediate versus low. **$P < .05$ for high versus intermediate. ***$P < .05$ for intermediate versus low.

cannot be excluded. Second, detailed data on heart failure etiology, biomarkers, and medication adherence were not uniformly available. Third, procedural strategies and device selection were at the discretion of the treating physicians. Fourth, the CHA2DS2-VASc score was analyzed as a clinical risk marker, and this study did not evaluate whether use of the score improves clinical decision-making or outcomes. Fifth, detailed limb-related variables, including wound severity, infection status, WIfI stage, anatomical complexity, and post-EVT patency, were not uniformly available. These factors are known to be strongly associated with prognosis in patients with CLTI and may have contributed to residual confounding despite adjustment for available clinical variables. Therefore, the CHA_2DS_2-VASc score should be interpreted as a systemic risk stratification tool rather than a substitute for comprehensive limb-specific assessment. Finally, as this study was conducted in a Japanese population, the generalizability of our findings to other populations requires further validation. Future studies are warranted to determine whether integration of the CHA2DS2-VASc score into post-EVT management strategies can improve clinical outcomes.

Conclusion

In patients undergoing EVT for symptomatic PAD, a higher CHA2DS2-VASc score was independently associated with increased 3-year all-cause mortality. This simple and widely available score may serve as an adjunctive tool for initial risk stratification after EVT and may complement, rather than replace, established PAD-specific prognostic assessments in routine clinical practice.

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Ethical Considerations

This study was approved by the Institutional Review Board of Kurashiki Central Hospital (reference no. 4622) and was conducted in accordance with the principles of the Declaration of Helsinki.

Consent to Participate

The requirement for individual informed consent was waived because of the retrospective nature of the study. Information regarding the study was disclosed to patients, who were given the opportunity to opt out of participation.

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Declaration of Conflicting Interests

The authors declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

Data Availability Statement

The data sets used and/or analyzed during the current study are available from the corresponding author upon reasonable request.*

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