

The Predictive Value of PRECISE-DAPT Scores for Thrombogenic Milieu of the Left Atrium in Patients Awaiting AF Ablation

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Abstract

Current guidelines recommend the use of the CHA₂DS₂VAS_c score in the evaluation of thromboembolic risk in patients with atrial fibrillation (AF). In this study, we aimed to evaluate the effectiveness of the PRECISE-DAPT score to predict thrombogenic milieu by comparing it with the CHA₂DS₂VAS_c score in nonvalvular AF patients referred for a TEE before an AF ablation procedure. In the study, 428 patients were included. The presence of grade 2–3 SEC and thrombus in the left atrium and/or left atrial appendage were accepted as thrombogenic milieu. Sixty patients were included to the thrombogenic positive (+) group, while 368 patients were included to the thrombogenic milieu (-) group. In the multivariate logistic regression analysis, the PRECISE-DAPT score was found to be an independent predictor of thrombogenic milieu (OR: 1.145, CI:1.083–1.211, p < 0.001). In our study, the PRECISE-DAPT score was found to be an independent predictor for thrombogenic milieu presented as high-grade SEC and thrombus in patients where TEE was performed before AF ablation, there by thromboembolic risk.

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Introduction

Atrial fibrillation (AF) is a supraventricular tachyarrhythmia characterized by chaotic atrial activation and its associated mechanical dysfunctions.¹ AF is associated with increased risk of thromboembolic events and heart failure leading to recurrent hospitalizations, deterioration in quality of life, and even death. The evaluation of thromboembolic risk and the administration of appropriate anticoagulant therapies play critical roles in the management of AF patients. Current guidelines recommend using the CHA₂DS₂VAS_c (congestive heart failure/ left ventricle dysfunction means LV ejection fraction < 40%, hypertension, age > 75, diabetes mellitus, stroke/transient ischemic attack, vascular disease, age 65–74, sex category i.e. female sex) score to assess thromboembolic risk.² However, the effectiveness of this scoring system has been questioned. The need for more accurate risk categorization necessitates the search for new markers and risk scores.

The PRECISE-DAPT score is a bleeding score that helps to set the optimal DAPT time after coronary stent implantation.

Key Words

AF; SEC; thromboembolism

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The PRECISE-DAPT score predicts out-of-hospital bleeding in patients under DAPT. The PRECISE-DAPT score consists of five items: age, creatinine clearance, hemoglobin, white blood cell count, and history of spontaneous bleeding.³ Although the PRECISE-DAPT score was first proposed as a bleeding risk score to determine the optimal duration of dual antiplatelet use in patients undergoing PCI (percutaneous coronary intervention), recent studies have suggested that this score may also predict thrombotic events.⁴ The PRECISE-DAPT score may help assess the risk of thromboembolic events because it includes well-known thromboembolic risk markers, such as age, creatinine level, leukocyte count, and hemoglobin level, which have been demonstrated as predictors of thromboembolism in AF patients.

Thrombosis and spontaneous echo contrast (SEC), detected by transesophageal echocardiography (TEE) in the left atrium (LA) and left atrial appendix (LAA), are associated with increased thromboembolic events and are indicative of thrombogenic environments. In various studies, high-grade SEC and thrombus are described as thrombogenic milieus and are used to assess the efficacy of thromboembolic risk markers.^{5–7}

This study focused on the evaluation of the efficacy of the PRECISE-DAPT score in comparison to the CHA₂DS₂VAS_c score in predicting

thrombogenic milieu in patients with non-valvular AF who were referred to TEE prior to AF ablation. The aim was also to evaluate the efficacy of the PRECISE-DAPT score in comparison to the $CHA_2DS_2VAS_C$ score in predicting thrombogenic milieu in these patients.

Methods

Study design and population

We assessed the TEE records of 658 patients who had been admitted to the Turkey High Specialization Hospital between April 2014 and January 2019 for symptomatic paroxysmal AF. The patients underwent TEE prior to a planned AF ablation. Patients with symptomatic paroxysmal AF despite at least one antiarrhythmic drug treatment, without structural heart disease and who were hospitalized for the first time to undergo ablation were included in the study.

Exclusion criteria were determined as persistent AF, ejection fraction below 40%, moderate-to-severe heart valve disease, dialysis-dependent renal failure, the presence of malignancies, active infections, and hematologic diseases that may cause hypercoagulability. After the exclusion criteria, 428 patients with the sufficient data to evaluate PRECISE-DAPT scores were included in the study. Based on previous studies, the presence of thrombogenic milieu was assessed by the presence of a thrombus or a grade 2–3 SEC in the LA or LAA. Patients were divided into two groups according to the presence of thrombogenic milieu. Also, three groups, divided by grade 0–1 SEC, grade 2–3 SEC, or thrombi, were formed to evaluate the changes more clearly.

Demographic characteristics, comorbid diseases, medical treatments, laboratory findings, ECG recordings, physical examination findings, cardiovascular disease risk factors, history of stroke and GIS bleeding, and echocardiographic examinations were evaluated for all patients.

Patients' hemoglobin value, white blood cell count, age, creatine clearance, and history of bleeding were entered in the web calculator at www.precisedaptscore.com. Creatine clearance was calculated in ml/min.

All patients underwent TTE (transthoracic echocardiography) before the procedure. In-patients receiving warfarin, who had a $CHA_2DS_2VAS_C$ score of less than 1, whose treatment was continued around INR 2, or who were in DOAC (direct oral anticoagulants) were discontinued 12–24 hours before the procedure, according to the guidelines. If $INR < 2$, subcutaneous enoxaparin at 1mg/kg was administered every 12 hours until the day of the procedure. Enoxaparin was not administered on the morning of the procedure. TEE was performed on the morning of the procedure to exclude the presence of thrombus in the LA and LAA.

All patients underwent TTE before cryoballoon ablation. Parasternal and apical images were obtained in the left lateral position using Vivid 7 (Dimension Cardiovascular Ultrasound Systems, GE Medical Systems, USA).

Transesophageal echocardiography

All patients underwent TEE in the morning of the AF ablation procedure. Vivid 7 (Dimension Cardiovascular Ultrasound Systems,

GE Medical Systems, USA) was used for TEE. The following procedures were used to display the entire LAA:

1. To show two perpendicular windows of the LAA, a smooth LAA image was obtained at 20–60 degrees, and then the LAA was centered on the image, and the image was rotated by 90 degrees to create the image for the second window.
2. The left atrium was scanned slowly and carefully between 0–180 degrees to accurately evaluate its long curvature.

A thrombus was defined as a gelatinous mass that differs from the normal LA wall in density. SEC was characterized as “cigarette smoke-like echo” that swirls in a vortex pattern throughout the entire cardiac cycle. The gain was appropriately modified to optimize the image during the imaging process.

SEC was graded as follows:

1. Grade 0: No change in echogenicity, suggesting SEC in the left atrium.
2. Grade 1 (mild): Occasional SEC seen throughout the cardiac cycle in the main cavity of the LA.
3. Grade 2 (moderate): More intensive SEC during the cardiac cycle seen in the LA cavity and the LAA.
4. Grade 3 (serious): SEC, clearly visible. A sluggish and very dense vortex pattern seen in the entire left atrium.

Laboratory Parameters

Erythrocyte counts were performed with hemoglobin and hematocrit, using an automated hematology analyzer XE-1200 (Sysmex, Kobe, Japan); biochemical measurements were performed with a molecular analyzer (Roche Diagnostics, Mannheim, Germany).

Statistical Method

Continuous variables were expressed as mean \pm standard deviation, and categorical variables were expressed as the number and percentage of patients. The patients in the study were divided into two groups: those with and those without thrombogenic milieu. An independent samples t-test was used for continuous variables, and a chi-square test was used for categorical variables.

Logistic regression analyses were performed to determine the parameters predicting the thrombogenic environment. All variables were first put into a univariate logistic regression analysis. Interactions of any variable with a p-value of less than 0.10 were evaluated by a multicollinearity analysis. When the variable was accepted as a potential risk factor, it was included in a multivariate logistic regression analysis. A new model was created via “backward” elimination, and then a comparison was made with a model created by “forward” elimination. The highest chi-square model with the least independent predictors was selected.

Receiver operating characteristic (ROC) analyses of the PRECISE-DAPT and $CHA_2DS_2VAS_C$ parameters were performed to determine the best predictive point for predicting thrombogenic environment.

A p-value less than 0.05 was considered statistically significant. All statistical analyses were performed with IBM SPSS version 20.

Results

Thirty-six patients had grade 2–3 SECs, and 24 patients had thrombi. A total of 60 patients were treated for thrombogenic milieu (+), and the remaining 368 patients were included in the thrombogenic milieu (-) patient group. The patients in the thrombogenic milieu (+) group were older, and hypertension, diabetes mellitus, stroke prevalence, and anticoagulant use were higher than in the patients within the thrombogenic milieu (-) group. Also, the CHA₂DS₂VAS_C and PRECISE-DAPT scores were higher in the thrombogenic milieu (+) group (Table 1).

The thrombogenic milieu (+) patient group had higher glucose, urea, and creatinine levels, while GFR (glomerular filtration rate) and platelet levels were lower. When the echocardiographic findings were examined, the EF value was lower, LA size was wider, and the SPAP (systolic pulmonary artery pressure) value was higher in the thrombogenic milieu (+) patient group in comparison to the thrombogenic milieu (-) group (Table 2).

A logistic regression analysis was performed to determine the effective parameters for predicting the presence of thrombogenic milieu. In the univariate logistic regression analysis, age, coronary artery disease, hyperlipidemia, diabetes mellitus, presence of stroke, LVEF (left ventricular ejection fraction), LVEDD (left ventricular end diastolic diameter), LA, SPAP, glucose, urea, creatinine, albumin, hemoglobin, platelet count, and CHA₂DS₂VAS_C and PRECISE-DAPT scores were revealed to be significant parameters. Multicollinearity analysis was used to evaluate the interactions of the variables. Diabetes mellitus, LVEF, LA size, albumin level, and PRECISE-DAPT score (OR: 1.145, CI: 1.083–1.211, p < 0.001) were found to be independent variables predicting the presence of thrombogenic milieu (Table 3).

Receiver operating characteristic (ROC) analyses of PRECISE-DAPT and CHA₂DS₂VAS_C parameters were performed to determine the best predictive score for predicting the thrombogenic environment. A PRECISE-DAPT score of 11.9 was the best predictor of thrombogenic environment, with 68.9% sensitivity and 67% specificity (P < 0.001).

Table 2: Evaluation of laboratory and echocardiographic parameters of patients.

Variables	Thrombogenic milieu (-)		Thrombogenic milieu (+)		P value
	Grade 0–1 SEC	Grade 2–3 SEC	Thrombus		
Glucose, mg/dL	99.64 ± 22.21	110.56 ± 38.83	101.79 ± 25.13		0.036
Urea, mg/dL	30.33 ± 7.48	33.26 ± 9.12	39.56 ± 16.81		<0.001
Creatinine, mg/dL	0.86 ± 0.21	0.94 ± 0.22	1.05 ± 0.30		<0.001
GFR, ml/min	86.40 ± 16.86	76.72 ± 15.54	71.49 ± 19.44		<0.001
AST, U/L	22.33 ± 9.23	24.68 ± 10.09	23.45 ± 8.59		0.267
ALT, U/L	27.57 ± 10.83	22.16 ± 12.71	23.55 ± 10.60		0.104
LDL, mg/dL	101.24 ± 30.44	108.69 ± 29.78	106.00 ± 38.90		0.995
Uric acid, mg/dL	4.81 ± 1.12	5.87 ± 4.11	6.41 ± 2.28		0.387
TSH, μ IU/mL	2.93 ± 0.96	1.91 ± 1.29	1.71 ± 0.93		0.850
Hemoglobin, g/dL	14.19 ± 1.46	14.03 ± 2.05	13.52 ± 1.95		0.098
Hematocrit, %	43.30 ± 3.92	44.03 ± 4.39	41.62 ± 5.27		0.698
Platelets, $\times 10^3$ /uL	254.54 ± 58.88	230.36 ± 72.63	242.20 ± 41.77		0.026
Leukocyte, $\times 10^3$ /uL	7.32 ± 2.06	7.35 ± 2.37	7.45 ± 3.60		0.810
EF, %	59.36 ± 5.66	53.91 ± 8.80	57.79 ± 7.06		<0.001
LVEDD, mm	46.42 ± 3.42	48.36 ± 4.88	45.61 ± 4.82		0.093
LA, mm	37.96 ± 4.85	41.96 ± 5.39	42.00 ± 5.56		<0.001
SPAP, mmHg	29.31 ± 5.89	35.67 ± 9.11	34.79 ± 9.27		<0.001

SPAP: systolic pulmonary artery pressure, LA: left atrium, LVEDD: Left ventricular end-diastolic diameter

Table 3: Logistic Regression analysis of parameters predicting the presence of thrombogenic milieu.

Variables	Unadjusted		Adjusted	
	OR (95% CI)	P	OR (95% CI)	P
Age	1.087 (1.053–1.122)	<0.001		
Coronary Artery Disease	2.544 (1.328–4.874)	0.005		
Hyperlipidemia	2.890 (1.572–5.312)	0.001		
Diabetes Mellitus	2.653 (1.308–5.380)	0.008	3.145 (1.083–1.211)	0.014
Stroke	6.667 (2.250–19.749)	0.001		
LVEF	0.932 (0.904–0.961)	<0.001	0.947 (0.900–0.998)	0.008
LVEDD	1.131 (0.990–1.134)	0.095		
LA	1.131 (1.068–1.197)	<0.001	1.103 (1.040–1.171)	0.010
SPAP	1.114 (1.067–1.163)	<0.001		
Glucose	1.010 (1.000–1.020)	0.047		
Urea	1.063 (1.028–1.099)	<0.001		
Creatinine	9.381 (3.060–28.755)	<0.001		
Albumin	3.460 (1.061–11.281)	0.040	6.109 (1.341–13.831)	0.022
Hemoglobin	0.868 (0.733–1.027)	0.099		
Platelets	0.994 (0.989–0.999)	0.026		
CHA ₂ DS ₂ VAS _C	1.504 (1.232–1.8350)	<0.001		
PRECISE-DAPT	1.174 (1.120–1.231)	<0.001	1.145 (1.083–1.211)	<0.001

SPAP: Systolic pulmonary artery pressure, LA: Left atrium, LVEDD: Left ventricular end-diastolic diameter

Table 1: Baseline characteristics of the subjects.

Variables	Thrombogenic milieu (-)		Thrombogenic milieu (+)		P value
	Grade 0–1 SEC n = 368	Grade 2–3 SEC n = 36	Thrombus n=24		
Age	54.19 ± 12.17	62.65 ± 8.0	64.3 ± 8.2		<0.001
Male, n (%)	205 (%55.9)	22 (%61.1)	11 (%45.8)		0.902
Coronary Artery Disease, n (%)	45 (%12.3)	10 (%27.0)	6 (%25)		0.004
Hypertension, n (%)	127 (%34.6)	16 (%43.3)	12 (%50)		0.061
Hyperlipidemia, n (%)	53 (%14.4)	11 (29.7%)	9 (37.5%)		0.001
Diabetes Mellitus, n (%)	34 (%9.3)	8 (%21.6)	5 (%20.8)		0.008
History of stroke, n (%)	7 (%1.9)	4 (%10.8)	3 (%12.5)		0.001
Anticoagulants, n (%)	228 (%64.4)	26 (%76.5)	20 (%87)		0.010
Warfarin, n (%)	96 (%39.7)	7 (%26.9)	10 (%47.6)		0.027
CHA ₂ DS ₂ VAS _C					
0	125 (%34.1)	6 (%16.2)	4 (%16.7)		0.001
1	106 (%28.9)	8 (%21.6)	6 (%25.0)		
≥2.00	136 (%37.1)	23 (%62.2)	14 (%58.3)		
PRECISE-DAPT	9.04 ± 5.82	14.36 ± 6.25	17.46 ± 7.87		<0.001

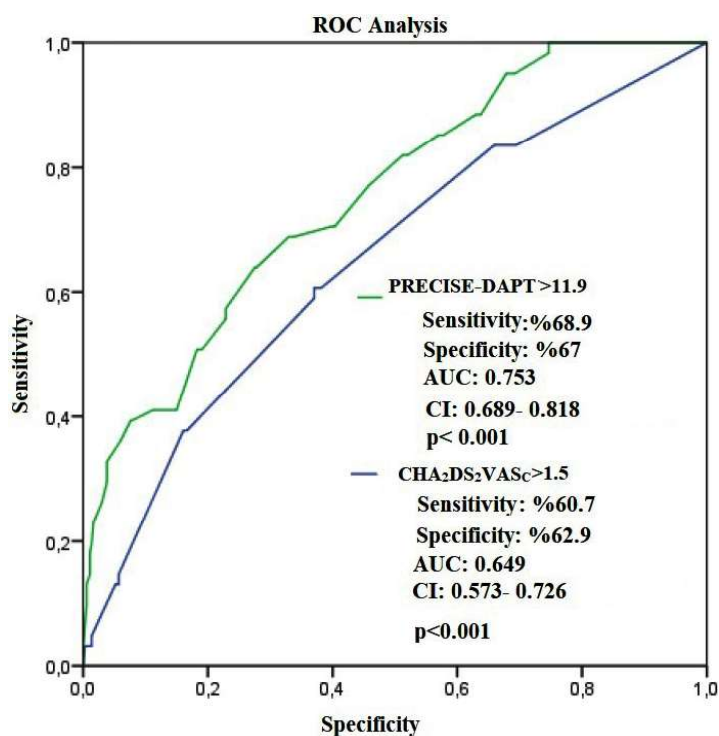


Figure 1: Receiver Operating Curve Analysis.

Compared to the CHA₂DS₂VAS_c score, the area under the curve of the PRECISE-DAPT score was 0.753, which was higher than 0.649 (Figure 1).

Discussion

In this study, the prediction of thrombogenic milieu using the PRECISE-DAPT scores of patients who underwent TEE prior to AF ablation was compared with predictions from the CHA₂DS₂VAS_c scores.

AF increases the risk of ischemic stroke and thromboembolism by approximately 3–5 times. Thus, ischemic stroke prevention is an important part of AF treatment.⁸ TEE is performed as the gold standard method to detect the presence of intracardiac thrombus prior to AF ablation, even if the patient uses oral anticoagulants. Detection of a thrombus and intensive SEC in a TEE is described as thrombogenic milieu. It has been shown that patients with thrombogenic milieu are at increased risk for thromboembolic events.⁹

SEC is seen when the interaction between fibrinogen and erythrocyte increases or activated platelet and leukocyte aggregation occurs.¹⁰ For dense SEC, age, hypertension, congestive heart failure, and thromboembolisms, such as ischemic events, may be predictive as closely related clinical conditions.⁹ For thrombus and dense SEC in the left atrial appendix, hypertension, diabetes mellitus, coronary artery disease, and congestive heart failure independent from other clinical conditions, such as cardiovascular death, are very strong predictors.¹¹ Patients with dense SEC who are not taking anticoagulants have a three-fold increased risk of stroke in TEE

than patients without this finding.¹² In this context, the presence of SEC and thrombi in patients may also be considered an indicator of increased thromboembolic risk.

The risk of thromboembolic events in patients with AF is determined by various risk factors, and anticoagulant therapy should be initiated in patients with increased risk.¹³ In AF patients, advanced age, hypertension, diabetes mellitus, and a history of transient ischemic attacks/ cerebrovascular events have been reported as independent risk factors for stroke.¹⁴ Various AF thromboembolic risk scoring systems have been established to holistically evaluate these risk factors and to easily and effectively assess risk in daily practice. The ATRIA, R₂CHADS₂, ABC, CHADS₂, and CHA₂DS₂VAS_c scores were created for this purpose. The efficacy of these scores to differentiate the thrombotic risk factors detectable in TEE (LAA thrombus, SEC, low LAA velocity, etc.) was investigated. However, the distinctive abilities of these scores remained low to moderate.^{15,16} In the recent studies, there were limitations in the effectiveness of the CHA₂DS₂VAS_c score to predict thromboembolic milieu. For instance, some studies reported that TEE may not have been performed before AF ablation in patients on anticoagulants with CHA₂DS₂VAS_c scores less than two¹⁷ and when thrombus had been found in patients with a CHA₂DS₂VAS_c score of zero or at therapeutic levels of anticoagulation.^{18–20} One of the major limitations of the CHA₂DS₂VAS_c score itself is the lack of biochemical and hematological markers associated with increased thromboembolic risk. New risk scores are needed in this regard.

The PRECISE-DAPT score is a bleeding score that helps set the optimal DAPT time after coronary stent implantation. The PRECISE-DAPT score predicts out-of-hospital bleeding in patients under DAPT. The PRECISE-DAPT score consists of five items: age, creatinine clearance, hemoglobin, white blood cell count, and history of spontaneous bleeding.³ It was found that prolonged DAPT duration did not show an ischemic benefit in patients with a PRECISE-DAPT score of 25 and higher. It has been shown that prolonged treatment provides a reduction in ischemic end points in those with this score below 25, and there is no increase in bleeding.³ Although the PRECISE-DAPT score is a bleeding risk score initially established to adjust the duration of DAPT in PCI patients, recent studies have shown that it can predict thrombotic events associated with poor prognoses. In the 2017 ESC DAPT guidelines,²¹ PRECISE-DAPT is recommended to assist the clinician in determining the duration of DAPT. Previous studies on bleeding or ischemia risk scores have shown that patients at high risk for hemorrhage are also at high risk for ischemic events, and vice versa.^{22–25} In support of these findings, Long et al. showed that DAPT and PRECISE-DAPT scores were associated with the prevalence of coronary artery disease and bleeding in patients with acute coronary syndrome.²⁶ In this study, the PRECISE-DAPT score was shown to be positively and independently associated with the risk of three-vessel disease.²⁶ In another study, the PRECISE-DAPT score was compared with the TIMI score to show in-hospital mortality in patients who had come with STEMI (ST segment elevation myocardial infarction) and underwent primary PCI. When compared with the TIMI score, PRECISE-DAPT was found to

be noninferior. In-hospital mortality was higher in patients with a PRECISE-DAPT score of 25 or greater.²⁶ In another study, the relationship between contrast-induced nephropathy (CIN) risk and the PRECISE-DAPT score was investigated in patients with STEMI who underwent primary PCI. Age, hemoglobin level, number of white blood cells, and creatine clearance in the PRECISE-DAPT score were the major parameters that could lead to CIN development, and it was concluded that the PRECISE-DAPT score could be an independent predictor of CIN risk.²⁷ Saylik et al. demonstrated that the PRECISE-DAPT score was higher in those with high thrombus burden and was an independent predictor of high thrombus burden in patients with STEMI undergoing primary PCI.²⁸ A higher risk of ischemic events in patients with a PRECISE-DAPT score ≥ 25 was shown in a meta-analysis²⁹ (meta analysis). In patients with AMI (acute myocardial infarction), a high PRECISE-DAPT score was associated with higher long-term all-cause mortality.³⁰

In our study, a high PRECISE-DAPT score was found to be an independent predictor of a thrombogenic environment and thromboembolic risk in patients with AF. The parameters included in the PRECISE-DAPT score were age, creatinine level, leukocyte count, and hemoglobin level, which have been shown to cause a thromboembolic risk increase in previous studies. Leukocyte count is a known indicator of acute and chronic inflammation and has been shown to be associated with coronary artery disease, stroke, and all-cause deaths.^{31–35} In addition, it has been reported that inflammation from AF may directly stimulate thrombogenesis.³⁶ Neutrophils release autocoids and induce vasoconstriction and platelet aggregation, and monocyte-derived macrophages are known to contribute to endothelial damage and thrombus formation through cytokine production.^{37,38} In another study, a relationship between leukocyte count and cardioembolic stroke was shown.³⁹ Another parameter of the PRECISE-DAPT score is the hemoglobin value; anemia is a predictor of hemorrhagic complications and mortality in patients with AF. Anemia is also reported to be a strong predictor of thromboembolic events in patients with AF.⁴⁰ Another parameter, advanced age, is part of many thromboembolic risk schemes and is known to have an independent relationship with ischemic stroke.¹² Another parameter of this score is creatine clearance. Furthermore, the independent relationships between impaired renal function, stroke, and systemic embolism have been demonstrated in scientific studies.⁴¹

There are significant findings in our study: LVEF, left atrial size, albumin level, and diabetes mellitus were found to be predictors of a thrombogenic environment. According to this information, demographic features alone are not sufficient in determining thromboembolic risk in AF. Integrating hematological, biochemical values, and echocardiographic findings in a holistic process will provide a more accurate risk assessment.

Clinical Benefits

As previously mentioned, the effectiveness of thromboembolic risk scores in current use remains inadequate. Thrombosis or thromboembolic events, especially in patients with $CHA_2DS_2VAS_C$ scores of 0–1, suggest that additional assessment methods are needed. The PRECISE-DAPT score includes prothrombotic

parameters that have been neglected in other scoring systems but are well known for their association with thromboembolic risk. Inclusion in the decision-making process may be useful when evaluating anticoagulation for treatment, especially in the group at low thromboembolic risk. Although larger studies are needed in this regard, our study constitutes an initial step.

Limitations

The retrospective nature of our study and the lack of follow-up data were the main limitations of this work. Follow-up data of thromboembolic events could have strengthened the findings of our study. Furthermore, patients who underwent TEE only scheduled AF ablation, which did not reflect the entire population, were included in the study.

A particular benefit of the $CHA_2DS_2VAS_C$ score is its ability to vary risk predictions based on the calculated score. A patient with a higher $CHA_2DS_2VAS_C$ score has a higher risk of stroke. However, there are not similar data for the PRECISE-DAPT score.

Since the study group included patients with AF ablation plan, our cut-off value may be relatively low, and higher values may be required for elderly patients.

It could also be useful to evaluate the association of markers such as IL-6 and TNF-alpha with the PRECISE-DAPT score, as these indicate inflammation and activation in the thrombotic processes.

Conclusion

In conclusion, the PRECISE-DAPT score was found to be an independent predictor of thrombogenic environments. Regarding to evaluation of thrombogenic milieu, the PRECISE-DAPT score seems to be more effective than the $CHA_2DS_2VAS_C$ score. On the grounds, this score may contribute to a clearer assessment of thrombogenic environments and risks in patients with AF, thus enabling a more individual and accurate decision about anticoagulation.

Conflicts of Interest

The authors have no conflicts of interest to declare.

Author Note

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