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Predictive Value of R2CHA2DS2-Vasc Score for Short-Term Mortality in Patients Undergoing Transcatheter Aortic Valve Replacement

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ABSTRACT

Background: Transcatheter aortic valve replacement (TAVR) is a popular method of treating severe symptomatic aortic valve stenosis in patients who cannot benefit from surgical aortic valve replacement (SAVR).

Objective: We aimed to evaluate how well the modified R2CHA2DS2-VASc score (M-R2CHA2DS2-VASc) predicts short-term mortality (≤ 30 days) in TAVR patients.

Methods: This observational multi-center study included 70 patients aged > 55 years with symptomatic severe aortic valve stenosis who were assigned to undergo transfemoral TAVR. The R2CHA2DS2-VASc score was estimated for all patients, which comprises persistent kidney disorder and the existence of RBBB or LBBB along with traditional CHA2DS2-VASc score variables. All patients underwent TAVR using transfemoral access, and the decision to choose a valve was made by the heart team. Follow-up was conducted for short-term mortality, defined as all-cause mortality within 30 days after TAVR.

Results: The studied patients had a mean age of 76 ± 4 years, with 58.6% males. The median R2CHA2DS2-VASc score was 4 ranging from 1–9. ROC analysis revealed that the R2CHA2DS2-VASc score had an AUC of 0.911, with a 95% CI of 0.831 - 0.990 (P < 0.001) for predicting the composite endpoint. The best cut-off point for the R2CHA2DS2-VASc score was > 4, with 82.40% sensitivity and 84.90% specificity. In multivariable logistic regression analysis, the R2CHA2DS2-VASc score was a significant predictor of death.

Conclusion: In patients undergoing TAVR, the M-R2CHA2DS2-VASc score is a valuable tool for predicting short-term mortality.

Keywords: Aortic valve, Transcatheter aortic valve replacement, R2CHA2DS2-Vasc score, Mortality.

INTRODUCTION

TAVR has emerged as a viable alternative to SAVR to treat patients with symptomatic severe aortic stenosis (AS) who are at high risk for unfavorable postoperative results or those who cannot undergo surgery [1, 2].

In the absence of a validated scoring system for TAVR, the Logistic European System (LES) for Cardiac Operative Risk Evaluation score, Society of Thoracic Surgeons (STS) Predicted Risk of Mortality (PROM) score, and European System for Cardiac Operative Risk Evaluation II (EuroSCORE II) are most frequently used in the assessment of symptomatic severe AS patients to determine their mortality risk [3, 4]. Although they were created using a patient group unlike the normal cohort of elderly transcatheter aortic valve implantation (TAVI) patients with comorbidities, these alternatives are primarily employed to assess surgical risk before SAVR in clinical practice [5]. Their applicability to TAVR patients is still debatable. Therefore, numerous new TAVR-specific risk models have recently been created, including STS/American College of Cardiology (ACC) transcatheter valve treatment (TVT)-TAVR risk score (TAVR score). However, the lack of external cohort validation for many of these scores has prevented their widespread use in practice [6].

The CHA2DS2-VASc score is a reliable substitute for patients with non-valvular AF to determine their risk of a cerebrovascular accident (CVA). It has been suggested that the CHA2DS2-VASc score and its modified form (R2CHA2DS2-VASc score) can predict mortality within 30 days following TAVR [3, 7].

As far as we know, the newly developed R2CHA2DS2-VASc score's ability to predict short-term mortality in patients having TAVR has not been well-studied. Therefore, this study examined the M-R2CHA2DS2-VASc score ability to predict short-term mortality (30 days) in patients undergoing TAVR.

MATERIAL AND METHODS

Study design: This observational study was carried out at two centers in Egypt; Al-Mokattam and Nasr City Health Insurance Hospitals.

Inclusion criteria: Patients were eligible if they were aged >55 years, had symptomatic severe aortic valve (AV) stenosis, and were assigned to undergo transfemoral TAVI. When the mean pressure gradient exceeds 40 mmHg, the jet velocity exceeds 4.0 m/s, and the valvular orifice area is lower than 1.0 cm^2 or 0.6 cm^2/m^2, severe AS is deemed to exist [8].

Exclusion criteria: Patients undergoing concurrent percutaneous coronary intervention (PCI) and other combined procedures, patients with a life expectancy

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lower than a year, those with severe mental disabilities, and patients with insufficient data were all excluded from this study.

All patients were subjected to the following:

Calculation of R2CHA2DS2-Vasc score: The following items explain what R2CHA2DS2-VASc means and were used in calculation; C stands for congestive heart failure; R2 stands for preexisting kidney dysfunction (eGFR 60 mL/min/1.73 m^2 or serum creatinine > 200 mol/L) or preexisting conduction abnormality such as right bundle branch block (RBBB) or left bundle branch block (LBBB) on preprocedural ECG; H stands for hypertension; A2 for an age of 75 years or more; D for diabetes mellitus; S2 for ischemic stroke or TIA history; V for vascular disease; A for an age of 65 to 74 years; Sc for the female sex. Eleven points are the highest R2CHA2DS2-VASc score that may be achieved.

Full history taking included age, sex, hypertension, congestive heart failure, stroke, diabetes mellitus (DM), transient ischemic attack (TIA), vascular disease (peripheral artery disease, prior MI, or aortic plaque), thromboembolism, and renal disease.

Complete physical examination included (a) signs of heart failure (including shortness of breath while moving or when lying down, weakness and fatigue, swelling in belly, legs, ankles, and feet, rapid or irregular pulse, inability to move, persistent cough or wheezing with blood-tinged white or pink mucus, rapid weight increase owing to fluid retention, chest discomfort if heart failure was brought on by a heart attack, nausea and anorexia, and diminished alertness or trouble concentrating), (b) Assessment of peripheral artery disease and (c) signs of neurological deficit (such as weakness, paralysis, lack of muscle control, involuntary movements, decreased or increased muscle tone, numbness, or paraesthesia).

Surface 12-lead ECG.

Investigations included renal function tests, hematocrit level, WBCs count, platelet count, fasting blood sugar, echocardiography, and CT chest.

The heart team decided on valve selection, and the default access method for TAVR was transfemoral. Under general anaesthesia or sedoanalgesia, the operation was carried out with echocardiography guidance in the cardiac catheterization laboratory. Before the procedure, each patient received 75 mg of aspirin and ≥ 300 mg of clopidogrel, and heparin was used during the procedure. Patients received clopidogrel for at least one month after surgery and continued on aspirin for as long as possible.

Study endpoints:

The endpoint was a composite of all-cause mortality and cerebrovascular events at 6-month follow-up. Al-Mokattam and Nasr City Health Insurance Hospitals obtained the mortality statistics as a part of regular clinical practice. Stroke, bleeding complications, myocardial infarction (MI), acute renal injury, conduction abnormalities, vascular complications, and arrhythmias were categorized as cerebrovascular events [9].

Sample size calculation: MedCalc software version 18.2.1 was employed to determine the sample size based on an expected area under the curve (AUC) of R2CHA2DS2-VASc of 0.862 in predicting short-term mortality. The total sample size calculated was 66 patients (11 non-survivors and 55 survivors). Power and alpha were set at 0.99 and 0.05, respectively [3].

Ethical approval: The study protocol was approved by the Local Ethics Committee at each of the participating centers. Each patient provided a written informed consent for analysis of anonymized data. The study was performed in concordance with the Declaration of Helsinki.

Statistical methods

SPSS version 28 was employed for statistical analysis (IBM, Armonk, New York, United States). Kolmogorov-Smirnov test, Shapiro-Wilk test, and direct data visualization techniques were employed to determine the normality of quantitative data. The quantitative data were illustrated as means and standard deviations (SD) or medians and ranges following the normality assumption. Numbers and percentages were employed to summarize categorical data. According to the occurrence of the composite endpoint, the independent t-test or Mann-Whitney U test was employed to compare quantitative data. Categorical data were contrasted using Fisher's exact Chi-square tests. ROC analyses were done for the R2CHA2DS2-VASc score and EuroScore.

Areas under the curve with 95% confidence intervals (CI), best cut-off points, and diagnostic indices were calculated. De-Long's method compared areas under the curve of the two scores. Correlation analysis was done using Spearman's correlation. Multivariate logistic regression analysis was done for the R2CHA2DS2-VASc score and EuroScore to predict the occurrence of the endpoint, controlling for potential confounders. The odds ratios with 95% confidence intervals were calculated. Kaplan Meier analysis was done for the endpoint occurrence according to the cut-off point of the R2CHA2DS2-VASc score. The long-rank test compared the two Kaplan-Meier curves. Each statistical test has two sides. P values ≤ 0.05 were considered significant.

RESULTS

Demographic, clinical, and laboratory parameters: The mean age of the studied patients was 76 ± 4 years. About two-thirds were males (58.6%). DM and hypertension were observed in 35.7% and 60%, respectively. Only 10% were smokers, and 15.7% had dyslipidemia. Patients showed a history of heart failure (32.9%), cerebrovascular disease (8.6%), and COPD (22.9%). Only 5.7% had AF.

The most frequent NYHA classification was class II (50%), followed by class III (21.4%), I (18.6%), and IV (10%). AV area has a mean value of 0.7 ± 0.1 cm^2. AV gradient has a mean value of 50 ± 5. The mean LVEF was 50 ± 5. The mean PASP was 43 ± 6. The mean eGFR was 56 ± 11. Only 18.6% had bundle branch block. The mean hematocrit was 36 ± 2%. The mean WBCs count was 7.5 ± 2.2. The mean platelet count was 239 ± 46. The median CHA2DS2-VASc score was 3, ranging from 1 – 7.

The median R2CHA2DS2-VASc score was 4, ranging from 1 – 9. The median EuroScore was 2.76, ranging from 1.23 – 10.08.

Patients who experienced the composite endpoint demonstrated significantly higher DM (64.7% vs. 26.4%, P = 0.004), smoking (35.3% vs. 1.9%, P-value < 0.001), dyslipidemia (58.8% vs. 1.9%, P < 0.001), history of heart failure (58.8% vs. 24.5%, P-value = 0.009) and cerebrovascular disease (35.3% vs. 0%, P < 0.001), AF (23.5% vs. 0%, P-value = 0.003), bundle branch block (58.8% vs. 5.7%, P < 0.001), CHA2DS2-VASc score (median = 4 vs. 3, P-value < 0.001), R2CHA2DS2-VASc score (median = 6 vs. 4, P-value < 0.001), and EuroScore II (median = 3.84 vs. 2.46, P-value < 0.001) than patients who did not. No statistically significant differences were detected regarding other parameters (Table 1).

Table (1): Demographic, clinical, and laboratory characteristics according to the composite endpoint

		Composite endpoint		
	Total (n = 70)	**Yes (n = 17)**	**No (n = 53)**	**P-value**
Age (years)	76 ± 4	76 ± 4	76 ± 4	0.636
Gender				
Males	41 (58.6)	12 (70.6)	29 (54.7)	0.248
Females	29 (41.4)	5 (29.4)	24 (45.3)	
Hypertension	42 (60)	13 (76.5)	29 (54.7)	0.111
Diabetes	25 (35.7)	11 (64.7)	14 (26.4)	**0.004***
Smoking	7 (10)	6 (35.3)	1 (1.9)	**<0.001***
Dyslipidemia	11 (15.7)	10 (58.8)	1 (1.9)	**<0.001***
PH of heart failure	23 (32.9)	10 (58.8)	13 (24.5)	**0.009***
PH of cerebrovascular disease	6 (8.6)	6 (35.3)	0 (0)	**<0.001***
PH of COPD	16 (22.9)	2 (11.8)	14 (26.4)	0.211
Atrial fibrillation	4 (5.7)	4 (23.5)	0 (0)	**0.003***
NYHA class				
I	13 (18.6)	2 (11.8)	11 (20.8)	0.604
II	35 (50)	8 (47.1)	27 (50.9)	
III	15 (21.4)	4 (23.5)	11 (20.8)	
IV	7 (10.0)	3 (17.6)	4 (7.5)	
AV area (cm^2)	0.7 ±0.1	0.7 ±0.1	0.7 ±0.1	0.384
Mean AV gradient (mmHg)	50 ±5	49 ±5	50 ±5	0.529
LVEF (%)	50 ±5	50 ±5	51 ±6	0.78
PASP (mmHg)	43 ±6	44 ±6	43 ±6	0.677
eGFR (ml/min)	56 ±11	48 ±12	58 ±10	**0.002***
Bundle branch block	13 (18.6)	10 (58.8)	3 (5.7)	**<0.001***
Hematocrit (%)	36 ±2	35 ±2	36 ±3	0.662
WBCs count (10^3/µl)	7.5 ±1.2	7 ±212	7.7 ±1.2	0.234
Platelets (10^3/µl)	239 ±46	251 ±55	235 ±43	0.206
CHA2DS2-VASc score	3 (1 - 7)	4 (3 - 7)	3 (1 - 5)	**<0.001***
R2CHA2DS2-VASc score	4 (1 - 9)	6 (4 - 9)	4 (1 - 6)	**<0.001***
EuroScore II	2.76 (1.23 - 10.08)	3.84 (2.26 - 10.08)	2.46 (1.23 - 6.12)	**<0.001***

Data are exhibited as mean ±SD, median (min-max), or number (%); * Significant P-value as it is < 0.05; COPD: Chronic obstructive pulmonary disease; LVEF: Left ventricular ejection fraction; NYHA: New York Heart Association; PASP: Pulmonary artery systolic pressure; WBCs: White blood cells; eGFR: estimated glomerular filtration rate.

Procedural and post-procedural findings:

All patients received sedation. Pre-dilatation and post-dilatation were reported in 45.7% and 54.3%, respectively. The mean implantation depth was 5.29 ± 0.45 mm.

Paravalvular leakage was reported in 7.1%. Major vascular complications were reported in 2.9%. Bleeding complications were reported in 4.3%. No pericardial tamponade was reported in the studied patients. Only 8.6% had acute renal failure. A permanent pacemaker was placed in 5.7%. Patients who experienced the composite endpoint showed significantly higher paravalvular leakage (23.5% vs. 1.9%, P = 0.011), bleeding complications (17.6% vs. 0%, P = 0.012), acute renal failure (P = < 0.001), and permanent pacemaker (23.5% vs. 0%, P = 0.002) than those who did not experience the composite endpoint.

The remaining parameters were insignificantly different between patients who experienced the composite endpoint and patients who did not (Table 2).

Table (2): Procedural and post-procedural findings according to the composite endpoint

		Composite endpoint		
	Total (n = 70)	**Yes (n = 17)**	**No (n = 53)**	**P-value**
Conscious sedation	70 (100)	17 (100)	53 (100)	-
Predilatation	32 (45.7)	11 (64.7)	21 (39.6)	0.0781
Postdilatation	38 (54.3)	11 (64.7)	27 (50.9)	0.322
Implantation depth (mm)	5.29 ±0.45	5.27 ±0.48	5.29 ±0.45	0.874
Paravalvular leakage (>2+)	5 (7.1)	4 (23.5)	1 (1.9)	**0.011***
Major vascular complications	2 (2.9)	2 (11.8)	0 (0)	0.056
Bleeding complications	3 (4.3)	3 (17.6)	0 (0)	**0.012***
Pericardial tamponade	0 (0)	0 (0)	0 (0)	-
Acute renal failure	6 (8.6)	6 (35.3)	0 (0)	**<0.001***
Permanent pacemaker	4 (5.7)	4 (23.5)	0 (0)	**0.002***

Data are displayed as mean ±SD or number (%); * Significant P-value.

Correlation between R2CHA2DS2-VASc score and EuroScore:

A significant positive correlation was reported between the R2CHA2DS2-VASc score and EuroScore (r = 0.547, P < 0.001) (Figure 1).

ROC analysis of the R2CHA2DS2-VASc score and EuroScore:

ROC analyses were done for the R2CHA2DS2-VASc score and the EuroScore to predict the composite endpoint. The R2CHA2DS2-VASc score showed a significant AUC of 0.911, with a 95% CI of 0.831 - 0.990 (P < 0.001). The best cut-off point was > 4, with 82.40% sensitivity and 84.90% specificity. The PPV and NPV were 63.60% and 93.70%, respectively. Regarding the EuroScore, it showed a significant AUC of 0.864, with a 95%CI of 0.771 - 0.955 (P < 0.001). The best cut-off point was > 2.9, with 94.10% sensitivity and 77.40% specificity. The PPV and NPV were 57.10% and 97.60%, respectively. No significant difference was reported between the two ROC curves (P = 0.338) (Figure 1).

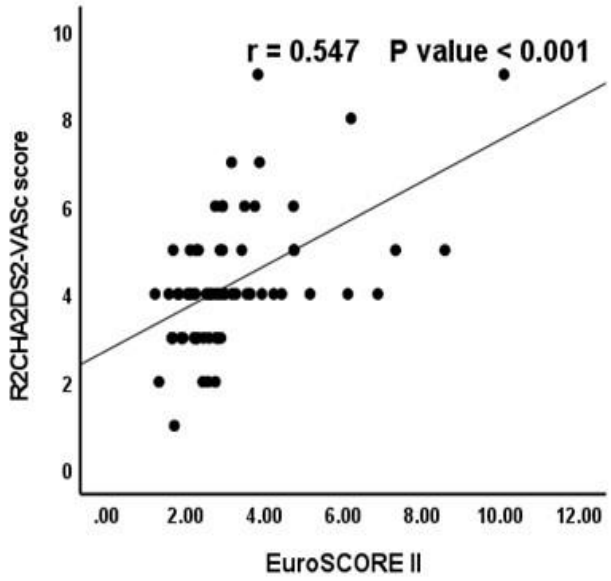

Figure (1): Correlation between R2CHA2DS2-VASc score and EuroScore

Prediction of the occurrence of the composite endpoint:

Multivariate logistic regression analysis was carried out to foresee the occurrence of the composite endpoint using the R2CHA2DS2-VASc score and EuroSCORE II as independent predictors. It revealed that the R2CHA2DS2-VASc score (OR = 7.45, 95% CI = 1.442 – 38.497, P = 0.017) and EuroScore (OR = 2.566, 95% CI = 1.369 – 4.81, P = 0.003) were significant predictors of composite endpoint, controlling for age, gender, DM, hypertension, smoking, and dyslipidemia (Figure 2).

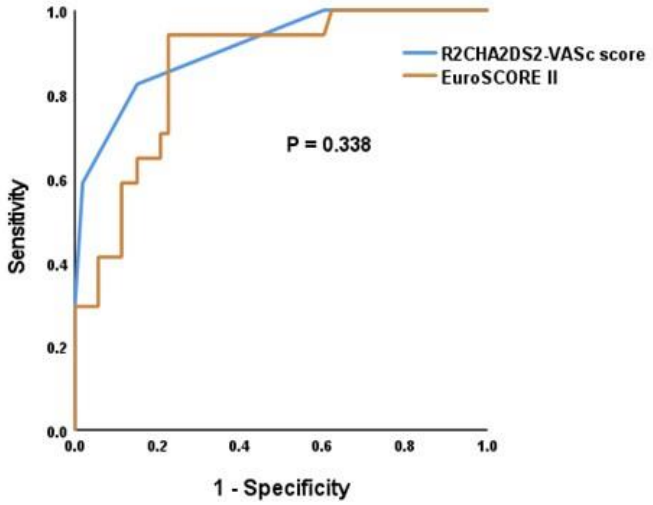

Figure (2) ROC analysis of the R2CHA2DS2-VASc score and EuroScore to predict the occurrence of the composite endpoint.

Kaplan Meier analysis for the occurrence of composite endpoint according to the R2CHA2DS2-VASc score:

Kaplan-Meier analysis was performed for the composite endpoint occurrence according to the R2CHA2DS2-VASc score. Patients were classified according to the cut-off point of the R2CHA2DS2-VASc score. The median time to composite endpoint in patients with R2CHA2DS2-VASc score > 4 was 1.767 months, while the median time in those with R2CHA2DS2-VASc score ≤ 4 was not reached. A significant difference was observed between the two Kaplan-Meier curves (Log-rank P < 0.001) (Figure 3).

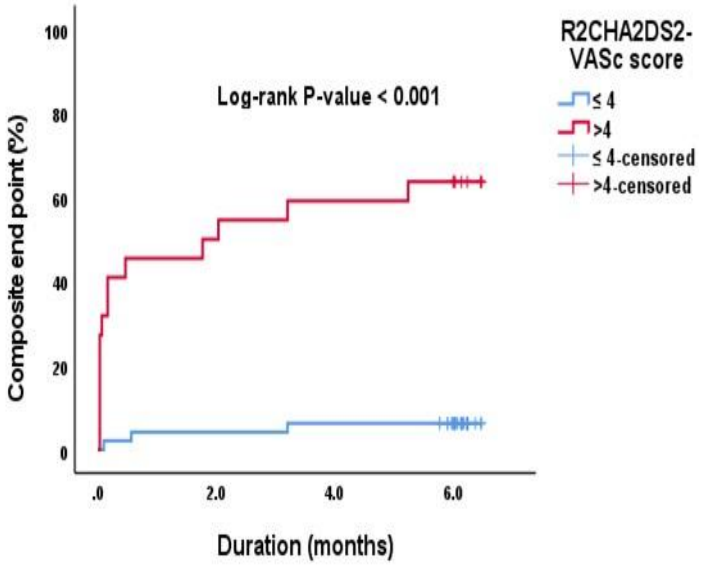

Figure 3. Kaplan Meier analysis for the occurrence of composite endpoint according to the R2CHA2DS2-VASc score.

DISCUSSION

The current study objective was to evaluate the ability of the relatively new R2CHA2DS2-VASc score to predict short-term mortality. This study emphasizes the demand for a novel score incorporating several clinical and surgical factors.

The current study reported that patients who experienced the composite endpoint demonstrated significantly higher DM, smoking, dyslipidemia, history of heart failure and cerebrovascular disease, AF, bundle branch block, CHA2DS2-VASc score, R2CHA2DS2-VASc score, EuroScore II, paravalvular leakage, bleeding complications, acute renal failure, and permanent pacemaker than patients who did not experience the composite endpoint.

In harmony with the current findings, Kalyoncuoglu and Ozturk found that the non-survivors had significantly higher R2CHA2DS2-VASc score and EuroSCORE II than survivors (P <0.001). Additionally, patients who died within 30 days had a higher incidence of major bleeding and acute renal failure (P = 0.005 and <0.001, respectively) [3]. In addition, **Hamid *et al.* [10]** reported that patients with CHA2DS2-Vasc score ≥ 6 and R2CHA2DS2-Vasc score ≥ 7 had a higher proportion of comorbidities, including DM, hypertension, CHF, and peripheral vascular disease and a higher log EuroSCORE. However, smoking, coronary artery disease (CAD), renal impairment, and AF were similar.

The current study reported a significant positive correlation between the EuroScore score and the R2CHA2DS2-VASc score (r = 0.547, P-value < 0.001). Consistently, Kalyoncuoglu and Ozturk demonstrated a significant moderate correlation between the R2CHA2DS2-VASc score and the EuroSCORE II (r = 0.51, P<0.001) [3].

In the current study, ROC analysis revealed that the R2CHA2DS2-VASc score and EuroScore were significant predictors for the composite endpoint (AUC = 0.911 and 0.864, respectively, best cut-off points > 4 and > 2.9, respectively, sensitivity = 82.40% and 94.1%, respectively, specificity = 84.9% and 77.40%, respectively, positive predictive value = 63.60% and 57.10% and negative predictive values = 93.70% and 97.60%, respectively. No significant difference was reported between the two ROC curves (P = 0.338). Consistently, **Kalyoncuoglu and Ozturk [3]** evaluated the performance of EuroSCORE II and R2CHA2DS2-VASc score in mortality prediction. They found that the AUC for 30-day mortality was 0.886 for the EuroSCORE II and 0.862 for the R2CHA2DS2-VASc score, with no significant difference (P-value > 0.05).

In the present study, multivariate logistic regression analysis was performed to predict the occurrence of the composite endpoint using the R2CHA2DS2-VASc score and EuroSCORE II as independent predictors. It revealed that the R2CHA2DS2-VASc score (OR = 7.45, 95% CI = 1.442 – 38.497, P = 0.017) and EuroScore (OR = 2.566, 95% CI = 1.369 – 4.81, P = 0.003) were significant predictors of the composite endpoint, controlling for age, sex, DM, hypertension, smoking, and dyslipidemia.

In parallel, **Katkat *et al.* [11]** tested the R2CHA2DS2-VASc score system efficiency in predicting mortality in COVID-19 patients. They found that the R2CHA2DS2-VASc score was an independent predictor of mortality in hospitalized COVID-19 patients. Additionally, they reported that the predictive ability of the R2CHA2DS2-VASc score was superior to other scores such as CHA2DS2-VASc and CHA2DS2-VASc-HS scores. In contrast, **Yatsynovich *et al.* [12]** showed a poor association between the CHA2DS2-VASC score and 30-day mortality in transapical (TA) and transfemoral (TF) TAVR patients. However, the EuroSCORE exhibited a predictive value for 30-day mortality among all patients who underwent TAVR procedures.

In the current study, Kaplan-Meier analysis was done for the occurrence of the composite endpoint according to the R2CHA2DS2-VASc score. Patients were classified according to the R2CHA2DS2-VASc score cut-off point. The median time to the composite endpoint in cases with R2CHA2DS2-VASc score > 4 was 1.767 months, while the median time in those with R2CHA2DS2-VASc score ≤ 4 was not reached. The two Kaplan-Meier curves showed a significant difference (P < 0.001).

Katkat *et al.* [11] conducted a survival analysis and found that patients with R2CHA2DS2-VASc scores greater than 3 had a higher mortality rate. Furthermore, **Hamid et al. [10]** in their retrospective analysis of patients undergoing TAVI, reported that the R2CHA2DS2-VASc score was a significant predictor for short-term survival (HR = 4.27, 95%CI = 1.51 - 12.07, P = 0.006).

Limitations: The study had some limitations, including being observational with a relatively small sample, limiting the statistical power. Additionally, the study did not include patients whose life expectancy was predicted to be shorter than a year, which may have excluded a significant proportion of patients with severe comorbidities and high mortality risk.

CONCLUSION

The R2CHA2DS2-VASc score can predict short-term mortality in TAVR patients. It is a valuable risk stratification tool that could assist physicians in decision-making and potentially alert patients of their short-term risks.

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- **Author contributions: Ahmed Bendary** and **Mohamed A. Elsayed** conceived, collected, analyzed, interpreted data, authored the manuscript and are the guarantee. **Hisham M. Aboul-Enein** conceived, collected data, interpreted data, critically assessed the work for key intellectual ideas, and is the guarantee. **Yasser H. Abdelrahman** conceived, collected, and interpreted data and critically assessed the work for key intellectual ideas.
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