Egyptian Journal of Radiology and Nuclear Medicine

RESEARCH

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Aortic valve calcium score in prediction of post-TAVI complications in an Egyptian cohort

Mohammed Ali Salem*, Ahmed Shehata Ismail, Ragab Hani Donkol, Mohamed Adam Reyad and Ahmed Mohammed Ramadan

Abstract

Background: Severe symptomatic aortic stenosis is a common disorder in the elderly and is associated with high morbidity and mortality rate. Traditionally, surgical aortic valve replacement has been considered the most effective treatment for advanced disease. Transcatheter aortic valve implantation (TAVI) has been established as a valuable alternative treatment option for inoperable and high-risk patients with symptomatic severe aortic stenosis. Pre-procedure ECG-gated CT aortography study is important in planning the procedure. The aim of the study was to correlate the aortic valve calcium score with the post-TAVI complications.

Results: Thirty patients who were candidates for TAVI procedure were enrolled for ECG-gated CT aortic valve calcium score and CT aortography. The calcium score was calculated. The patients were followed up both clinically and by echocardiography every 3 months for 1 year. Those who developed complications were enrolled for another CT study. Fourteen out of 30 patients (46.7%) presented with post-TAVI complications [9 cases (30%) presented with paravalvular leak (PVL) and 5 cases (16.7%) presented with major adverse cardiac events (MACE), while 16 cases (53.3%) had no complications]. There was a strong correlation between the calcium score and post-procedure complications.

Conclusions: The degree of aortic valve calcification can be considered as a predictor of post-TAVI complications: PVL and MACE.

Keywords: Transcatheter aortic valve implantation (TAVI), Aortic valve calcium score, Complications

Background

Severe symptomatic aortic stenosis (AS) is a common disorder in the elderly and is associated with high morbidity and mortality rate [1].

Aortic valve stenosis is a progressive disease that evolves from a non-symptomatic disease with thickened and calcified leaflets but without hemodynamic repercussions into an increasingly degenerative valve with extensive calcified and immobile leaflets. As the valve stenosis worsens, symptoms progress from mild to severe, with increasing fatigue and shortness of breath invariably leading to heart failure, angina pectoris and syncope [2].

Calcific aortic valve stenosis (CAVS) is the most common cause of aortic valve disease in adults. It shows the same risk factors of atherosclerosis including the male sex, age, hyperlipidemia, smoking, type II diabetes mellitus, obesity, and hypertension. It is to be noted that about 50% of patients with CAVS show associated coronary artery disease (CAD) [3].

Traditionally, surgical aortic valve replacement has been considered the most effective treatment for advanced disease, significantly improving patient symptoms and survival compared with patients who are unwilling or unable to undergo surgery. About 30% of patients with severe aortic stenosis are not eligible for

*Correspondence: masalem55@yahoo.com; malisalem123@gmail.com
Cairo University, 8C Tiba Buildings, Zahraa Al-Maadi, Cairo, Egypt

surgery because of comorbidities that increase surgical mortality [4, 5].

Some patients are not eligible for surgery, as many as 30% of patients with aortic stenosis are not considered surgical candidates because of comorbidities with high surgical mortality risk [4, 5].

Transcatheter aortic valve implantation (TAVI) has been established as a valuable alternative treatment option for inoperable and high-risk patients with symptomatic severe aortic stenosis [1].

The aim of the study is to correlate the aortic valve calcifications assessed by non-contrast multi-detector CT with the post-transcatheter aortic valve implantation (TAVI) complications.

Methods

All procedures performed in this study were in accordance with the ethical standards, approved by the ethics committee of our institute, and complied with the Declaration of Helsinki 1964 and its later amendments. Written informed consent was obtained from all individual participants included in this study.

The study design was prospective observational; it included thirty patients indicated for TAVI. Twenty patients (66.7%) had implanted Sapien valves, while the remaining 10 patients (33.3%) had implanted CoreValve. They were enrolled in a cardiac ECG-gated CT calcium score study and ECG-gated CT aortography between December 2019 and February 2021. Patients with rapid arrhythmia or unstable clinical conditions or those with contraindication to contrast administration (allergy or GFR less than 30 ml/min) were excluded.

Patient preparation and setup

The patients were instructed to fast 4–6 h prior to the study, and medications are not to be discontinued. Before the examination, the heart rate and rhythm were evaluated. All steps of the study were explained in detail for each patient (including the breath-holding instructions).

CT examination

All MSCT examinations were performed using a 256-slice scanner (iCT 256 Philips; Eindhoven, The Netherlands). The heart rate was checked on the monitor. The patient was positioned supine on the table with feet first. ECG leads are fixed at four corners of the pericardium. Calcium score was performed using the prospective ECG gating at 75% of the cardiac cycle, and the CT aortography was performed using the retrospective ECG gating. First, a localization scan (scanogram) was performed yielding an antero-posterior and lateral views of the chest.

1-CT calcium score The field of view was adjusted to cover the aortic root. Aortic valve calcium scoring (AVCS) was performed using (Agatston score) in the cranio-caudal direction while the patient is holding the breath in inspiration. Calcification was considered when CT density was above 130 HU. Acquisition parameters were as follows: ECG gated at 75% of the RR interval, 270 ms gantry rotation, 3 mm collimation, 80 mA, and 120 kV. To minimize the total effective patient radiation dose, the scan was conducted with a relatively low tube current (Fig. 1).

2-CT aortography The field of view was adjusted to cover the entire aorta including the aortic root, thoraco-abdominal aorta, and iliofemoral arteries. Acquisition parameters are as follows: retrospective ECG gating with dose modulation, 270 ms gantry rotation, 256 × 0.6 mm collimation, 330 mA, and 120 kV. The contrast (with an average volume of 80 cc) was injected via a wide bore (18 gauge) cannula in an antecubital vein with a rapid injection rate (5–6 cc/sec) using the automatic dual head injector. The contrast used was a non-ionic low osmolar iodine containing (Ultravist 370 mg/ml, Schering AG, Germany). 40 cc of chasing saline is injected at the same flush rate to make sure of the utilization of all the injected contrast. Image acquisition was done while the patient is holding the breath in inspiration.

Image analysis

An experienced radiologist and cardiologist, with more than 12 years of experience in cardiac CT reporting, both blinded to the clinical data, reviewed all CT studies, including the aortic valve calcium score and the CT aortography, in a consensus interpretation. The analysis was

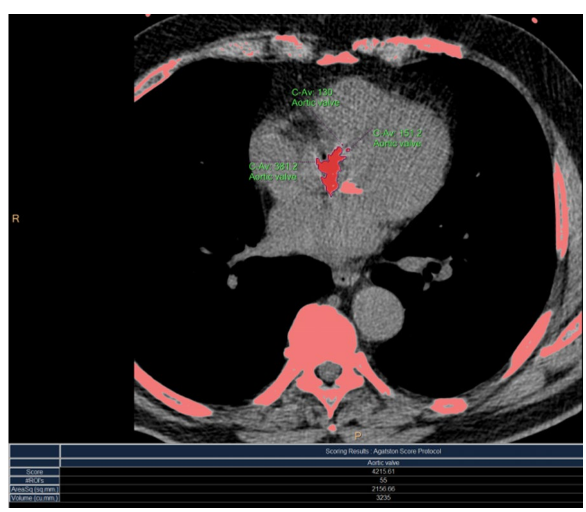

Fig. 1 Calculation of the CT calcium score for the aortic valve showing Agatston score = 4215

performed using a commercially accessible workstation, Vitrea 5 Core workstation (Vital Images, Minnetonka, MN).

Patient follow-up to detect complications

The patients were followed up clinically and by echocardiography every 3 months for 1 year, those who developed complications were enrolled for another CT study. Complications included paravalvular leak (PVL) and major adverse cardiac events (MACE).

MACE include myocardial infarction, heart failure, stroke, and cardiovascular death. They were diagnosed clinically and by different imaging modalities.

Measurements

All measurements were performed manually, using the ECG-synchronized images, during mid-to-end systole (35–45% of cardiac cycle). Initially, the LVOT was examined to exclude obstructing lesions. The aortic annulus was defined as the luminal contour within a virtual plane aligned with the most basal attachment points of the three aortic valve cusps. Quantification of annular diameters, area and perimeter was done manually with the cursor. The coronary ostial height measured in a perpendicular fashion to the annular plane. The STJ diameter was measured on the transverse double oblique. The ascending aorta diameter was measured on transverse double oblique plane at the level of the main pulmonary artery. The minimum diameter of the descending aorta was identified. Comments on the aortic course, tortuosity, and presence of aneurysms or atherosclerotic plaques were done. The minimum cross section diameter of the common iliac, external iliac, and common femoral arteries bilaterally was determined with a comment on tortuosity and calcifications.

Statistical methodology

For quantitative data, median, minimum, and maximum were used, while categorical data were summarized using frequency and relative frequency (%). The sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and diagnostic effectiveness of standard diagnostic indices were computed as reported by Galen [6]. The optimal cutoff value of several parameters for detecting complications was determined using a ROC curve and area under the curve analysis. The nonparametric Mann–Whitney test was used to make comparisons between quantitative variables [7]. The chi-square test was used to compare categorical data. When the anticipated frequency is less than 5, the exact test was utilized instead [7]. Regression analysis was conducted to predict complications [8]. Statistical significance was defined as a *P* value of less than 0.05.

Table 1 Baseline clinical characteristics of the patients

Variables	Median (range) or number (%)
Age (years)	77.5 (56–87)
Gender, male	22 (73%)
Cardiovascular risk factors	
Smoking	17 (56.7%)
Diabetes mellitus	15 (50%)
Hypertension	19 (63.3%)
Hyperlipidemia	14 (46.7%)
Presenting symptoms	
Heart failure symptoms	17 (56.7%)
Chest pain	11 (36.7%)
Palpitations	5 (16.7%)
Syncope	3 (10%)

Table 2 Baseline CT data of the patients

Variables	Median (range) or number (%)
Aortic valve calcium score	3380.0 (413–7448)
Annulus long axis	27.5 (19–36)
Annulus short axis	23.00 (15–33)
Annulus area	315 (340–655)
Annulus perimeter	79.0 (66–90.4)
ST junction short axis	27.5 (18.4–34)
ST junction long axis	28.6 (22.5–34)
Ascending aorta short axis	34.1 (26.5–39)
Ascending aorta long axis	35.3 (29–40)
Distance bet. annulus and right ostium in mm	16 (8–20)
Distance bet. annulus and left ostium in mm	13.1 (6.3–19)
Associated cardiac findings	
LVH	16 (53.3%)
Septal bulge	10 (33.3%)

Results

The study included 30 patients with severe aortic valve stenosis indicated for TAVI. Twenty-two patients were males (37%) with a median age of 77.5 years (ranging between 56 and 87 years). About half of the patients had cardiovascular risk factors, and about half of the patients presented with heart failure symptoms (Table 1).

The calcium score in the studied population ranged from 2120 to 6543; the median calcium score was 3380. The annular and aortic root measurements and the associated cardiac findings are summarized in Table 2.

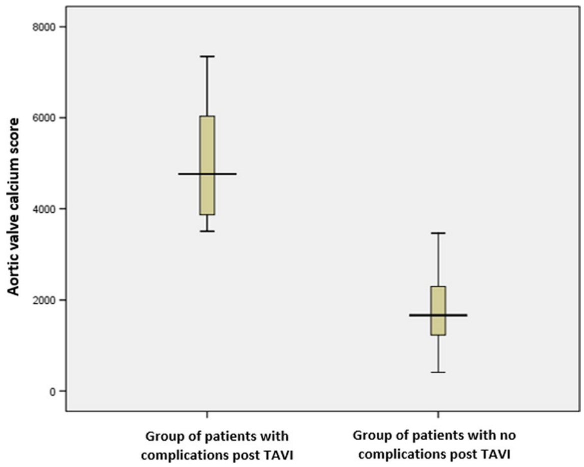

Fig. 2 Comparison between patients who developed complications to those with no complications post-TAVI

Comparison analysis

Post-TAVI complications occurred in fourteen patients (46.3%), nine patients (30%) suffered from paravalvular leak (PVL), and five patients (16.7%) suffered from major adverse cardiac events (MACE). Patients who developed complications were compared to those with no complications regarding the cardiovascular risk factors and aortic valve calcium score (Fig. 2, Table 3).

- Table 4 and Fig. 3 show the statistical relationship between increasing the calcium score values and the occurrence of PVL with sensitivity, specificity, positive predictive value, negative predictive value, and accuracy were 100%,76%,64%,100%, and 83%, respectively, with significant *P* value < 0.001.

Table 3 Comparison between patients who developed complications to those with no complications post-TAVI

	Patients with complication (*n* = 14)	Patients with no complications (*n* = 16)	*P* value
	Median (range)	**Median (range)**	
Age	72 (56–86)	81 (60–87)	0.10
Aortic valve calcium score	4765 (3504–7448)	1666 (413–3460)	**< 0.001**
Annulus long axis	28.6 (19–36)	26.1 (21–31)	**0.03**
Annulus short axis	23.5 (20–33)	22 (18–25)	0.10
Annulus area	496 (340–655)	451 (342–588)	0.23
Annulus perimeter	82.2 (67–90.4)	76 (66–86)	0.07
ST junction short axis	28 (20.1–34)	27.5 (18.4–32)	0.54
ST junction long axis	29 (25–34)	28.2 (22.5–33)	0.58
Ascending aorta short axis	34.5 (28–37)	338 (26–39)	0.5
Ascending aorta long axis	35.6 (29–38)	35.1 (29–40)	0.4
Distance bet. annulus and right ostium in mm	16.5 (12–20)	15 (8–20)	0.28
Distance bet. annulus and left ostium in mm	13 (9–19)	13.6 (6.3–17)	0.72
	Number (%)	**Number (%)**	
Gender, male	12 (85.7%)	10 (62.5%)	0.22
Smoking	8 (57.1%)	9 (56.2%)	0.96
Diabetes mellitus	9 (64.3%)	6 (37.5%)	0.27
Hypertension	7 (50%)	12 (75%)	0.15
Hyperlipidemia	7 (50%)	7 (43.8%)	0.73
Left ventricular hypertrophy	7 (50%)	9 (56.2%)	0.94
Left ventricular septal bulge	5 (35%)	5 (31.2%)	0.093

Table 4 ROC for prediction of PVL with aortic valve calcification

Area under the ROC curve	*P* value	95% confidence interval		Cutoff	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)	Accuracy (%)
		Lower bound	Upper bound						
Calcium score									
0.873	< 0.001	0.748	0.998	3482	100	76.2	64.29	100	83.33

Table 5 ROC for prediction of post-TAVI MACE using calcium score

Area under the ROC curve	*P* value	95% confidence interval		Cutoff	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)	Accuracy (%)
		Lower bound	Upper bound						
Calcium score									
0.832	< 0.001	0.688	0.976	3776	100	76	45.45	100	80

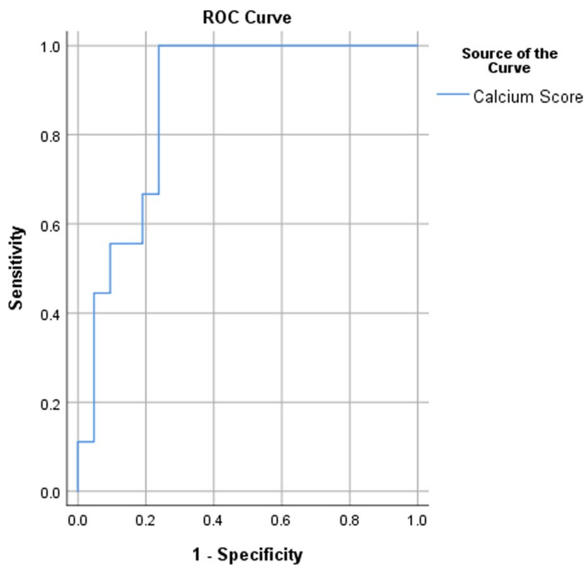

Fig. 3 ROC curve for prediction of PVL with aortic valve calcification

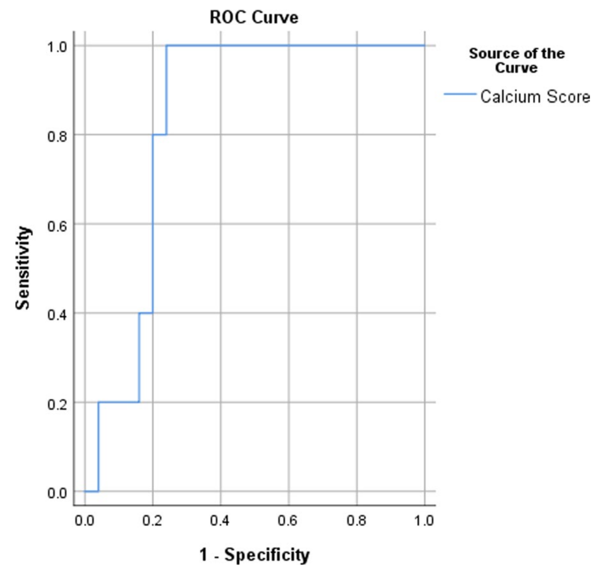

Fig. 4 ROC curve for prediction of post-TAVI MACE using calcium score

- By applying a ROC curve, the calculated cutoff value for the aortic valve calcium score as a predictor of a PVL was 3482, as shown in Table 4.
- Table 5 and Fig. 4 show the statistical relationship between increasing the calcium score values and the occurrence of MACE as post-TAVI complication with sensitivity, specificity, positive predictive value, negative predictive value, and accuracy were 100%,76%,45.5%,100%, and 80%, respectively, with significant *P* value < 0.001.
- By applying a ROC curve, the calculated cutoff value for the aortic valve calcium score as a predictor of a major cardiac events MACE was 3776, as shown in Table 5.

Regression analysis
Conducting regression analysis showed that aortic valve calcium score is a predictor of post-TAVI complications (Table 6).

Table 6 Regression analysis

Variables	*R* = 0.84 Adjusted R square = 0.68, *P* = < 0.001			*P* value
	Unstandardized coefficients		Standardized coefficients	
	B	Std. error	Beta	
Annulus diameter (long axis)	− 0.007	0.08	− 0.048	0.68
Aortic valve calcium score	0.00	0.00	0.85	**< 0.001**

Discussion
In this study, 14 out of 30 patients (46.7%) presented with post-TAVI complications in the form of 9 cases presented with PVL (30%) and 5 cases presented with MACE (16.7%), while 16 cases had no complications (53.3%).

Larroche et al. [9] showed that 6.5% of post-TAVI complications were paravalvular leak and 24.7% were MACE, while Chamandi et al. [10] showed that 21% of post-TAVI complications were paravalvular leak and 15% were MACE.

In the current study, the calcium score ranged from 413 to 7448. The calcium score for the occurrence of post-TAVI complications (mean 5504.43 ± 2824.76 SD) was significantly higher than that for cases without post-TAVI complications (mean 1803.19 ± 835.79 SD) with *P* value =< 0.001 (Fig. 5). A suggested mechanism is that the large plaques of dense calcium prevent good opposition between the deployed valve and the aortic root allowing for PVL, and they also compress the underlying conductive system allowing for MACE to occur [11, 12].

In this study, the calcium score in correlation with the occurrence of PVL ranged from 3504 to 7448 (mean 5767.44 ± 3426.73 SD), it was significantly higher than that for cases without PVL (mean 2571.71 ± 1706.79 SD) with *P* value = < 0.001 (Fig. 6). The calculated cut off value was 3482, with sensitivity, specificity, positive predictive value, negative predictive value, and accuracy being 100%, 76%, 64%, 100%, and 83%, respectively. This matches the results with Larroche et al. [5], who stated that the calcium score was higher in patients with significant PVL (mean calcium score 8608 ± 4212 SD) which was observed in 6.5% of the patients, with *P* value < 0.001.

It also coincides with Ko et al. [13] who stated that one of the predictors of significant PVL in 22.6% of patients was observed in high degree of aortic valve calcium score (mean calcium score (4910 ± 3127 SD) and *P* value < 0.001). In contrast, Guimarães et al. [14] found that low rates of significant aortic regurg were observed irrespective of calcium score, with a mean calcium score of 4607 ± 1424 SD. The different results in the study performed by Guimarães et al. [12] could be attributed to the

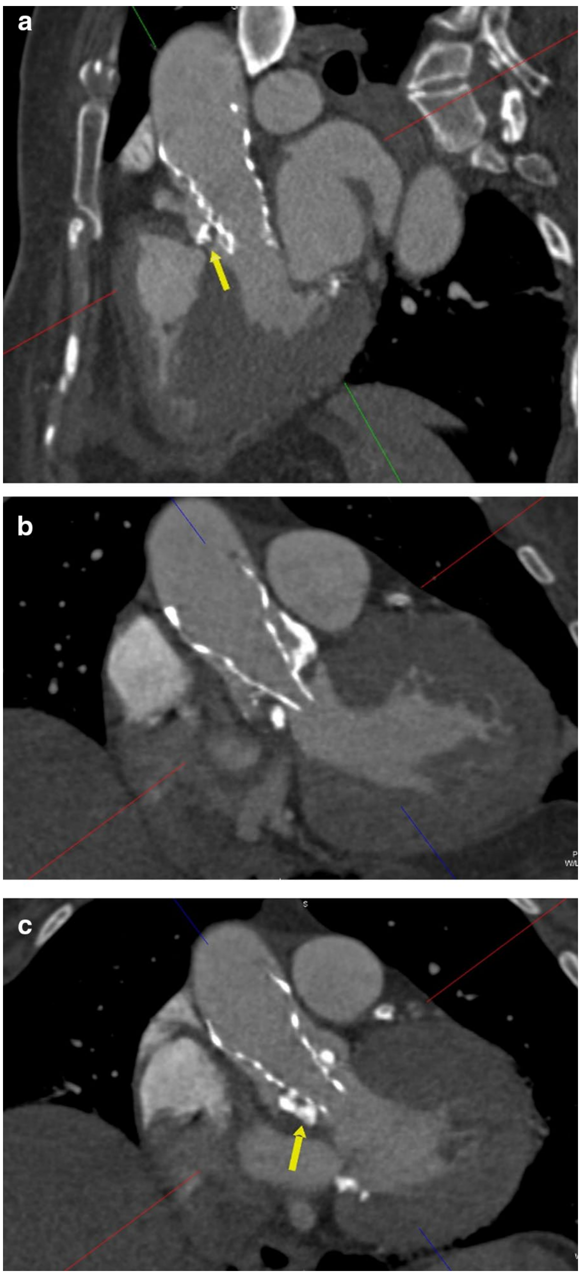

Fig. 5 CT aortography, coronal plane, for patient presented by post-procedure complications showing aortic valve prosthesis not well deployed due to extensive aortic root calcifications (arrows)

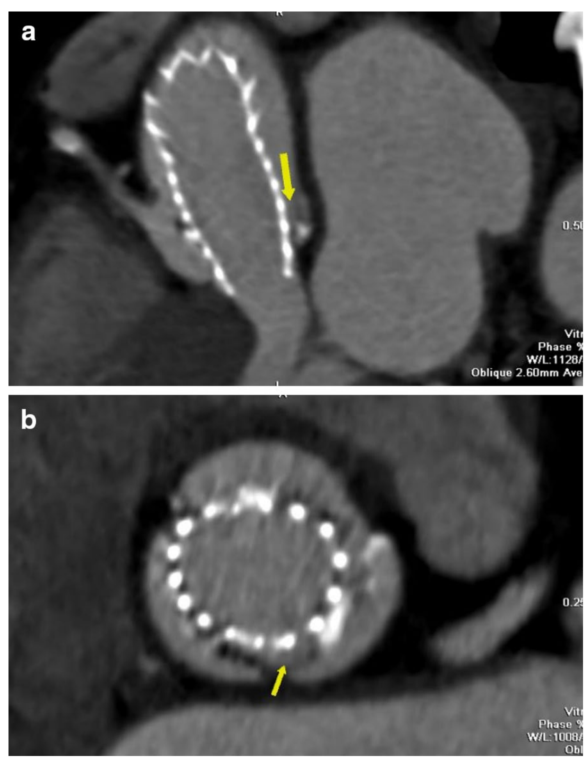

Fig. 6 CT aortography for patient presented by post-procedure complications showing paravalvular leak (arrow)

large cohort of patients undergoing TAVI with a newer generation balloon-expandable transcatheter heart valve (THV, SAPIEN 3 valve, Edwards Lifesciences, Irvine, CA) which provide a better sealing of the aortic annulus further preventing the occurrence of residual PVL and showed that good clinical and valve performance outcomes can be obtained irrespective of the degree of aortic valve calcification severity.

In the current study, the calcium score in correlation with the occurrence of MACE ranged from 3868.00 to 7348.00 (mean 5031 ± 1418.4 SD); it was significantly higher than that for cases without MACE (mean 3230.3 ± 2849.9 SD) with P value $=< 0.001$, and the calculated cutoff value was 3776 with sensitivity, specificity, positive predictive value, negative predictive value, and accuracy being 100%, 76%, 45.5%, 100%, and 80%, respectively.

In contrast to Gamet et al. [15], who stated that the measurement of aortic valve calcium score has no prognostic value regarding mortality, cardiovascular events, or conductive disturbances after TAVI as the aortic valve calcium score was not significantly higher in patients who died or had a major cardiovascular event after implantation (2936 ± 1235 vs. 3051 ± 1440, $P = 0.93$).

However, a similar interpretation was done by Pollari et al. [16], who stated that LVOT calcification is associated with MACE and mortality. It coincides also with Leber et al. [17], who stated that there was a significant correlation between the valve calcium score and the occurrence of MACE, P value 0.027.

Conclusions

Aortic valve calcium scoring is helpful in anticipating TAVI post-procedural complications. It should be calculated in all cases prior to performing the post-contrast CT study.

The degree of aortic valve calcification was a significant predictor for PVL and MACE as post-TAVI complications.

Limitations

The present study is limited by the small sample size of 30 patients, and the follow-up is limited to a period of 1 year. Other limitations are that the distribution of the aortic valve calcifications in the three leaflets and at the annulus as well as the measurements and calcifications of the LVOT were not considered. The absence of correlation between the type of implanted valve and the incidence and type of complications is another limitation of the study.

Abbreviations

AS: Aortic stenosis; CAD: Coronary artery disease; CAVS: Calcific aortic valve stenosis; MACE: Major adverse cardiac events; MSCT: Multislice computed tomography; PVL: Paravalvular leak; STJ: Sinotubular junction; TAVI: Transcatheter aortic valve implantation.

Acknowledgements

Not applicable.

Author contributions

MAS performed and interpreted the CT studies. ASI performed the echocardiographic studies. MAR contributed to the idea of the study and collected the patients. RHD was a major contributor in writing the manuscript. AMR is the contributor in writing the manuscript and was also responsible for data analysis and statistics. All authors read and approved the final manuscript. All authors have approved the manuscript for submission. The content of the manuscript has not been published, or submitted for publication elsewhere.

Funding

No funding was obtained for this study.

Availability of data and materials

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

Declarations

Ethics approval and consent to participate

All procedures performed in this study were in accordance with the ethical standards, approved by the ethics committee of Cairo University Hospitals, and complied with the Declaration of Helsinki 1964 and its later amendments. Written informed consent was obtained from all individual participants included in this study.

The ethics committee reference numbers are not available; as the study started 3 years ago and ended 15 months later, the numbers were not collected at the time of start and could not be reached now.

Consent for publication

All patients included in this research gave written informed consent to publish the data contained within this study.

Competing interests

The authors declare that they have no competing interests.

Received: 3 October 2022 Accepted: 9 December 2022
Published online: 23 December 2022

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