ORIGINAL ARTICLE

Computed tomography assessment of the aortic root morphology in predicting the development of paravalvular leak following transcatheter aortic valve implantation

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KEY WORDS

aortic root morphology, bicuspid aortic valve, paravalvular leak, transcatheter aortic valve implantation

ABSTRACT

INTRODUCTION Transcatheter aortic valve implantation (TAVI) is an effective treatment of significant aortic stenosis. Paravalvular leaks (PVLs) are one of the most common complications after the procedure.

OBJECTIVES The aim of this study was to assess whether the aortic root morphology affects the occurrence of PVL after TAVI.

PATIENTS AND METHODS We enrolled 50 patients with bicuspid and 50 patients with tricuspid aortic valve who underwent multislice computed tomography (MSCT) and transthoracic echocardiography prior to TAVI. The dimensions of the aortic root were assessed by MSCT. PVL after TAVI was assessed by transthoracic echocardiography. Patients were divided in 2 groups according to the PVL severity: less than moderate PVL (n = 80) and moderate or worse PVL (n = 20), and comparisons between the groups were performed.

RESULTS Patients with at least moderate PVL, compared with those with less than moderate PVL, had greater mean (SD) area (5.2 [1.1] cm^2 vs 4.7 [0.8] cm^2; $P = 0.02$), perimeter (8.4 [0.9] cm vs 7.9 [0.7] cm; $P = 0.01$), and long axis (29.5 [2.7] mm vs 28 [2.7] mm; $P = 0.04$) of the aortic annulus and greater mean (SD) area (5.3 [1.3] cm^2 vs 4.7 [1.1] cm^2; $P = 0.04$) and perimeter (8.6 [1.1] cm vs 8.1 [0.9] cm; $P = 0.02$) of the left ventricular outflow tract. In multivariable analysis, bicuspid aortic valve disease, interventricular septum hypertrophy, greater left ventricular outflow tract, and postdilatation were significant predictors of moderate PVL following TAVI.

CONCLUSIONS The assessment of the aortic root morphology with MSCT can be helpful in predicting PVL after TAVI.

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INTRODUCTION Nowadays, transcatheter aortic valve implantation (TAVI) is an effective treatment of severe aortic stenosis (AS) among patients not only at high[1-3] but also intermediate surgical risk.[4,5] Moreover, TAVI in patients at low-risk was also associated with favorable outcomes.[6,7] However, its widespread use is limited by postinterventional paravalvular leaks (PVLs) which are associated with increased mortality during follow-up.[8,9] Bicuspid aortic valve (BAV) may be one of the risk factors for PVL.[10] For a long time, BAV stenosis have constituted an exclusion criterion from TAVI registries.[1,2] An abnormal cusps fusion, marked aortic annulus asymmetry, fibrotic leaflets, and a calcified raphe can lead to erroneous deployment of

WHAT'S NEW?

Transcatheter aortic valve implantation (TAVI) is an effective treatment of severe aortic stenosis; however, its widespread use is limited by postinterventional paravalvular leaks, which are associated with increased mortality during follow-up. To the best of our knowledge, this is the first study that systematically looked at the aortic root morphology and its impact on paravalvular leaks in patients with bicuspid and tricuspid aortic valve stenosis. Our study revealed that the assessment of the aortic root morphology can be helpful in predicting paravalvular leaks after TAVI and our data may prove useful in improving results of TAVI.

the valve prosthesis and predispose to PVL.[11] Detailed assessment of the aortic root morphology on multislice computed tomography (MSCT) before TAVI may help predict the severity of PVL in patients after TAVI.[12,13] Currently, there is still a paucity of data on the detailed assessment of the aortic root morphology in bicuspid and tricuspid AS and its impact on PVL. Therefore, further studies investigating this are warranted. Moreover, current TAVI practice is largely based on the experiences with TAVI for tricuspid AS. Thus, it is important to understand the impact that the aortic root morphology has on the clinical outcomes of TAVI in bicuspid and tricuspid AS.

The aim of this study was to assess whether the morphology of the aortic root in patients with bicuspid and tricuspid AS affects the occurrence of PVL after TAVI.

PATIENTS AND METHODS The study was conducted in accordance with the 1975 Declaration of Helsinki developed by the World Medical Association. The protocol for the study was reviewed and approved by a local bioethical committee. The study included 100 consecutive patients: 25 women and 25 men with BAV stenosis and 25 women and 25 men with tricuspid aortic valve (TAV) stenosis who underwent MSCT prior to TAVI from 2015 to 2019 at our institute. Baseline clinical characteristics of the study participants are summarized in TABLE 1.

Transthoracic echocardiography (TTE) and MSCT before TAVI and TTE after the procedure were performed in all patients. The aortic valve morphology, both tricuspid or bicuspid valves, was assessed by TTE and MSCT. The aortic root geometry was assessed retrospectively.

Multislice computed tomography Computed tomography (2 × 192 slices with 0.6-mm collimation; gantry rotation time, 250 ms; tube voltage, 70–100 kV; tube current, 320–500 mAs [depending on the patient body mass]; pitch, 0.16–0.3 [depending on the heart rate]) was performed with a dual source scanner, SOMATOM Force (Siemens Healthcare, Forchheim, Germany). A nonenhanced, prospectively electrocardiogram-gated scan (75% of the R-R interval) with a slice thickness of 3 mm was performed to measure the calcium score of the aortic valve according to the modified Agatston method using dedicated calcium scoring software.[14]

After the nonenhanced scan, retrospectively electrocardiogram-gated CT of the thoracic aorta (extending from the tracheal bifurcation to the diaphragm) was performed. Iodinated contrast material (350–370 mg/ml) was injected intravenously at a flow rate of 4.5 ml/s. To minimize radiation exposure, electrocardiogram-gated tube current modulation was applied in all patients. The dataset of the contrast-enhanced scan was reconstructed every 10% of the R-R interval and analyzed using dedicated software, syngo.via (Siemens Healthcare).

We retrospectively assessed the anatomy of the aortic root and the ascending aorta. The aortic annulus was measured in the oblique transversal plane which crossed the level of the most basal attachments of the aortic cusps (FIGURE 1A). The dimensions of the aortic root at the level of the sinotubular junction (STJ) and the widest portion of the sinus of Valsalva were assessed in the oblique transversal plane perpendicular to the course of the aorta.[15]

The sinus of Valsalva was measured at the level of the largest diameter from one sinus to another sinus. The average of 3 sinus-to-sinus measurements was calculated. The sinus of Valsalva height was measured from the annular plain to the highest point of the right and the left sinus of Valsalva (FIGURE 1B).

The following measurements of the aortic root and the aortic valve were made using multiplanar reformated reconstruction: the long axis (maximum) and the short axis (minimum) of the left ventricular outflow tract (LVOT), the aortic annulus, the STJ, and the ascending aorta, the area of annulus (defined as an oval or a circle formed by linking the most basal portions of the leaflet attachments),[15] the perimeter of the annulus, the widest and the highest portions of the sinus of Valsalva diameter, the area and the perimeter of the sinus of Valsalva (FIGURE 2).

The area, the perimeter, and the diameter of the ascending aorta were measured 4.5 cm above the annulus on a transverse double oblique plane perpendicular to the long axis of the ascending aorta. The volume of the aortic root was calculated from the annular plane to the lowest point of the STJ using syngo.via VOI freehand Siemens software (FIGURE 3). The aortic valve calcium score and calcification in the LVOT were assessed.

All diameter measurements were assessed in the systolic phase. The aortic wall and calcifications were included in all dimensions. MSCT images were analyzed by radiologists trained in cardiac CT with more than 10 years of experience and involvement in interpretation of CT scans performed before TAVI procedures (a member of the Heart Team). Before the TAVI procedure, they were blinded and unexposed to other patient characteristics.

TABLE 1 Clinical characteristics of the patients

Characteristics	All (n = 100)	PVL <moderate (n = 80)	PVL ≥moderate (n = 20)	*P* value
Age, y, mean (SD)	76.5 (7.1)	76.7 (6.9)	75.6 (8.5)	0.55
Weight, kg, mean (SD)	78.4 (16.3)	77.7 (17.1)	80.9 (13)	0.45
Height, cm, mean (SD)	165.6 (8.9)	165.1 (9)	167.4 (9)	0.31
BMI, kg/m^2, mean (SD)	28.4 (6.7)	28.6 (6.5)	28.9 (5)	0.84
BSA, m^2, mean (SD)	1.9 (0.2)	1.9 (0.2)	1.9 (0.2)	0.29
Female sex	50 (50)	39 (48.7)	11 (55)	0.62
Hypertension	72 (75)	57 (72.1)	15 (75)	0.79
CAD	70 (70)	57 (71.2)	13 (68.4)	0.81
AF	31 (31)	24 (30)	7 (36.8)	0.56
NYHA class III/IV	42 (42)	32 (40.5)	10 (52.6)	0.34
DM	41 (41)	30 (37.5)	11 (55)	0.16
RI category 3–5	51 (51)	39 (48.7)	12 (60)	0.37
BAV	50 (50)	35 (43.7)	15 (75)	0.01

Data are presented as number (percentage) of patients unless otherwise indicated.

Abbreviations: AF, atrial fibrillation; BAV, bicuspid aortic valve; BMI, body mass index; BSA, body surface area; CAD, coronary artery disease; DM, diabetes mellitus; NYHA, New York Heart Association; PVL, paravalvular leak; RI, renal impairment

FIGURE 1 Multislice computed tomography: **A** – the aortic annulus in the short-axis view. The measurement of the aortic annulus just below the lowest insertion points of the aortic leaflets; **B** – the long axis of the left ventricular outflow tract in the sagittal oblique plane

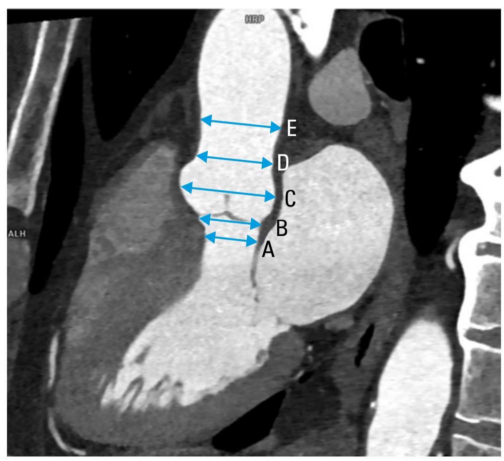


FIGURE 2 The measurements of the aortic root on multislice computed tomography: A, the left ventricle outflow tract; B, the aortic annulus; C, the sinuses of Valsalva; D, the sinotubular junction; E, the ascending aorta

Echocardiography A standard comprehensive TTE was carried out in each patient before and after TAVI. The Vivid S70 and E9 (General Electric Medical Systems, Milwaukee, Wisconsin, United States) were used. Echocardiographic measurements have been done by qualified echocardiographers experienced in the assessment of valvular heart diseases and bioprosthesis function.

According to the current guidelines of the European Society of Cardiology,[16] severe AS was defined as the aortic valve area of less than 1.0 cm^2, mean aortic gradient greater than 40 mm Hg, or aortic jet velocity greater than 4.0 m/s.

The following were assessed on TTE before TAVI: left ventricular end-diastolic diameter, left ventricular end-systolic diameter, interventricular septum thickness at end diastole, end-diastolic posterior wall thickness, and left ventricular ejection fraction. All measurements were made in the parasternal long axis view. Paravalvular leak was quantified by TTE performed mean (SD) 7.6 (10.6) days after TAVI. Paravalvular leaks were categorized from 0 to 3, with 0 indicating none or trivial, 1 indicating mild, 2 indicating moderate, and 3 indicating severe PVL.[17] Based on TTE after TAVI measurements, patients were divided in 2 groups according to the PVL severity: none, trivial or mild PVL (less than moderate PVL), and moderate to severe PVL (moderate or worse PVL).

Procedural data The access site was appointed by the Heart Team based on the evaluation of the size, calcification, and atheroma of the aorto-iliofemoral arteries. TAVI procedures were performed via transfemoral, trans-subclavian, transapical, and transaortic access routes. The early--generation devices (the Sapien XT [Edwards Lifesciences, Irvine, California, United States] and CoreValve [Medtronic, Minneapolis, Minnesota, United States]) or new-generation devices (Evolut R [Medtronic], the Sapien 3 [Edwards Lifesciences], Lotus [Boston Scientific, Natick, Massachusetts, United States] and Acurate THV [Symetis SA, Ecublens, Switzerland]) were implanted.

FIGURE 3 The long axis of the left ventricular outflow tract in the sagittal oblique plane. A measurement of the aortic root volume

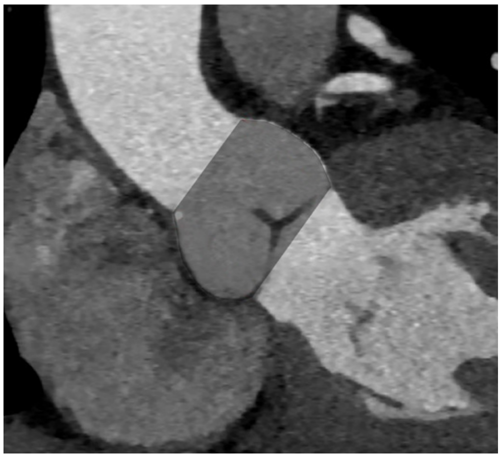


TABLE 2 Echocardiographic data of patients before transcatheter aortic valve implantation

Parameter	PVL < moderate (n = 80)	PVL ≥ moderate (n = 20)	*P* value
LVEDD, mm	48.7 (7.1)	51.7 (6.7)	0.09
LVEDs, mm	31 (7.8)	38.4 (8.9)	0.01
IVS, mm	14.8 (2.5)	16 (2.3)	0.045
POST, mm	11.9 (2.2)	12.7 (2.6)	0.17
LVEF, %	56 (13.1)	50.7 (9.9)	0.10
LA, mm	43 (11.5)	44.4 (5.4)	0.56
AVA, cm^2	0.6 (0.2)	0.6 (0.2)	0.47
GA, mm Hg	53.7 (17.2)	56.4 (17.5)	0.53

Data are presented as mean (SD).

Abbreviations: AVA, aortic valve area; GA, mean transvalvular gradient; IVS, interventricular septum thickness; LA, left atrial dimension; LVEDD, left ventricular end-diastolic diameter; LVEDs, left ventricular end-systolic diameter; LVEF, left ventricular ejection fraction; POST, left venrticular posterior wall thickness; others, see TABLE 1

Statistical analysis Statistical analysis was performed using SAS, version 9.4 (SAS Institute Inc, Cary, North Carolina, United States). All data are presented as absolute values and values indexed to body surface area.

Data distribution was verified by the Shapiro–Wilk test. Variables had a normal or log-normal (CaS, and CaS index) distribution. Continuous data are presented as mean (SD) or median (interquartile range) and qualitative variables are presented as frequency and percentages. We used the *t* test for continuous data and the χ^2 test for categorical variables to compare clinical and echocardiographic characteristics and the morphology of the aortic root and the ascending aorta between patients after TAVI with less than moderate PVL and moderate or worse PVL. Multivariable logistic regressions with backward elimination were used to assess prognostic utility of the occurrence of paravalvular leak based on demographic and clinical factors, morphology of the aortic complex and the ascending aorta, and the procedural data. Receiver operating characteristic (ROC) curves were plotted to assess the importance of the included variables and performance metrics of the final model. All *P* values were 2-tailed and a *P* value of less than 0.05 was considered statistically significant.

RESULTS Echocardiographic data of patients before TAVI are shown in TABLE 2.

A comparison of the aortic annulus, the LVOT, the sinus of Valsalva, the STJ, and the ascending aorta in patients with and without at least moderate PVL after TAVI is shown in TABLE 3. A comparison of procedural data is shown in TABLE 4.

In the multivariable analysis, BAV, postdilation during TAVI, greater interventricular septum hypertrophy, and greater LVOT circumference increased the likelihood of at least moderate PVL. In addition, when left ventricular ejection fraction increases, the risk of PVL decreases. Moreover, the same is true for LVOT circumference, the lager its diameter, the lower the probability of leakage (FIGURE 4A).

The ROC curves for each covariate and the full model are shown in FIGURE 4B. Differences between areas under the ROC curve of each variable and the final model are demonstrated in the graph. The *P* values ranged from 0.001 to 0.02.

Patients with BAV and at least moderate PVL, compared with those with BAV and less than moderate PVL, had larger area (mean [SD], 5.5 [1.3] cm^2 vs 4.7 [1.1] cm^2, respectively; $P = 0.04$) and perimeter (mean [SD], 8.7 [1.0] cm vs 8.0 [0.9] cm, respectively; $P = 0.02$) of the LVOT. Moreover, they had greater hypertrophy of interventricular septum on TTE (mean [SD], 16.2 [2.3] mm vs 14.5 [2.7] mm; $P = 0.04$). No differences were observed in the dimensions of the aortic annulus, the sinus of Valsalva, the STJ, and the ascending aorta. We did not demonstrate any differences in the morphology of the aortic root in patients with TAV with at least moderate PVL and with less than moderate PVL.

DISCUSSION Our study revealed that patients with at least moderate PVL had larger aortic annulus and left ventricle outflow tract compared with patients with less than moderate PVL. In the multivariable analysis, independent predictors of PVL were: BAV, larger perimeter of the LVOT, more pronounced interventricular septum hypertrophy, and postdilatation during TAVI. What is more, the greater area and the perimeter of the LVOT in patients with BAV stenosis were associated with more frequent occurrence of at least moderate PVL.

Paravalvular leaks are significant limitations of TAVI. The overall incidence of mild or greater PVL is ranging from 44% to 77%, while at least moderate PVL is ranging from 3.1% to 21.6%.[18,19] The presence of at least moderate PVL has been considered a strong predictor of mortality after TAVI.[20] Some studies suggested that even mild PVLs are associated with increased mortality within 2 years.[3] Data about PVL risk factors remain controversial. One of the known determinants of PVL is a very deep implantation of

TABLE 3 Comparison of the aortic root morphology between patients with at least moderate paravalvular leak and those with less than moderate paravalvular leak after transcatheter aortic valve implantation

Parameter	Absolute value			Indexed to BSA value		
	PVL < moderate (n = 80)	PVL ≥ moderate (n = 20)	*P* value	PVL < moderate (n = 80)	PVL ≥ moderate (n = 20)	*P* value
CaS, IU	3227 (2098–4675)	4027 (3356–6102)	0.07	1796 (1125–2486)	2164 (1685–3082)	0.11
LVOT calcifications, n (%)	32 (40.5)	13 (65.0)	0.049		–	
Aortic annulus						
Area, cm^2	4.7 (0.8)	5.2 (1.1)	0.02	2.5 (0.5)	2.7 (0.6)	0.12
Perimeter, cm	7.9 (0.7)	8.4 (0.9)	0.01	4.3 (0.5)	4.3 (0.5)	0.50
Long axis, mm	28 (2.7)	29.5 (2.7)	0.04	15.1 (2.1)	15.3 (1.9)	0.60
Short axis, mm	21.7 (2.3)	22.5 (2.9)	0.17	11.7 (1.6)	11.7 (1.8)	0.92
Left ventricular outflow tract						
Area, cm^2	4.7 (1.1)	5.3 (1.3)	0.04	2.5 (0.6)	2.7 (0.7)	0.18
Perimeter, cm	8.1 (0.9)	8.6 (1.1)	0.02	4.4 (0.7)	4.5 (0.6)	0.42
Long axis, mm	29.3 (3.6)	29.9 (4.2)	0.54	15.8 (2.5)	15.6 (2.5)	0.73
Short axis, mm	20.5 (2.7)	21.7 (3.3)	0.11	11 (1.9)	11.3 (1.9)	0.64
Sinus of Valsalva						
RL, mm	33.1 (3.7)	34.5 (5.2)	0.17	17.9 (2.8)	18.2 (3.4)	0.65
LNC, mm	34.9 (4.2)	36.5 (4.3)	0.14	18.8 (3)	19 (2.9)	0.80
RNC, mm	33.6 (3.7)	35.2 (5.2)	0.20	18.1 (2.6)	18.4 (3.4)	0.66
Area, cm^2	8.8 (1.6)	9.7 (2.7)	0.15	4.7 (1)	5 (1.5)	0.35
Perimeter, cm	10.9 (1.1)	11.5 (1.5)	0.13	5.9 (0.8)	6 (1)	0.63
Sinotubular junction						
Diameter, mm	28.9 (3.5)	29.8 (4.1)	0.34	15.6 (2.5)	15.5 (2.5)	0.89
Long axis, mm	30.8 (4)	32 (5)	0.26	16.6 (3)	16.7 (3.1)	0.95
Short axis, mm	28.9 (3.4)	30 (4.2)	0.22	15.6 (2.5)	15.6 (2.5)	0.94
Ascending aorta						
Diameter, mm	35.7 (4.9)	37.1 (4.6)	0.28	19.3 (3.6)	19.3 (3.2)	0.97
Long axis, mm	36.5 (4.7)	38 (4.7)	0.20	19.7 (3.5)	19.8 (3.3)	0.88
Short axis, mm	35.4 (4.7)	36.9 (4.7)	0.21	19.1 (3.5)	19.3 (3.3)	0.88
Aortic root						
Volume, cm^3	18.4 (5.1)	21.1 (8)	0.17	9.9 (2.7)	11 (4.4)	0.30
ARH-L, mm	19.9 (2.8)	20.6 (5)	0.60	10.7 (1.8)	10.7 (2.9)	0.99
ARH-R, mm	20.1 (3.5)	20.2 (4.3)	0.95	10.8 (2.1)	10.5 (2.3)	0.54
RCA, mm	14.9 (3.2)	14.7 (4.3)	0.82	8 (1.8)	7.7 (2.2)	0.45
LCA, mm	14.3 (3.3)	15.1 (4.2)	0.37	7.7 (1.9)	7.9 (2.4)	0.65

Data are presented as mean (SD) and median (interquartile range) unless otherwise indicated.

Abbreviations: ARH-L, distance from the aortic annulus to the sinotubular junction on the left side; ARH-R, distance from the aortic annulus to the sinotubular junction on the right side; CaS, calcium score of the aortic valve; LCA, left coronary artery ostium height; LNC, dimension between the left and noncoronary sinuses of Valsalva; LVOT, left ventricular outflow tract; RCA, distance from the aortic annulus to the right coronary artery ostium; RL, dimension between right and left sinuses of Valsalva; RNC, dimension between the right and noncoronary sinuses of Valsalva; others, see TABLE 1

the device[21] and undersizing of the bioprosthesis.[22] Also, calcifications of the device landing zone are considered predictors of PVL.[23-25] Moreover, a higher incidence of PVL was observed among patients treated with the CoreValve system compared with Sapien bioprostheses.[23] Numerous studies seem to confirm that the improvements introduced in the newer generation valves can reduce PVL occurrence.[10,18,23]

Some studies suggested that also the quantitative assessment of aortic valve calcification may be of value in the prediction of PVL. The volume of the largest calcium block, calcium perimeter, and calcium size showed a strong association with PVL after TAVI.[26] In another study, a multivariable analysis adjusted for aortic annulus size showed that the area of aortic valve calcifications independently predicted paravalvular regurgitation.[27]

To the best of our knowledge, there are limited data reflecting the impact of the aortic root morphology in patients with bicuspid and tricuspid AS on the occurrence of at least moderate PVL.

Our results are partly comparable to earlier investigations.[28,29] More than mild aortic regurgitation was associated with larger aortic annulus dimensions, as measured by TTE or

TABLE 4 Comparison of procedural data between patients with and without at least moderate paravalvular leak

		PVL < moderate (n = 80)	PVL ≥ moderate (n = 20)	*P* value
New-generation devices		66 (82.5)	17 (85.0)	>0.99
Balloon-expandable devices		24 (30.4)	4 (20.0)	0.36
Prosthesis size	Small[a]	18 (23.1)	2 (10.5)	0.43
	Medium[b]	32 (41.0)	8 (42.1)	
	Large[c]	28 (35.9)	9 (47.4)	
Predilatation		49 (62.8)	9 (47.4)	0.22
Postdilatation		16 (20)	11 (55.0)	0.002
Access site	Transfemoral	70 (87.5)	20 (100)	0.43
	Trans-subclavian	5 (6.2)	0	
	Transapical	4 (5.0)	0	
	Transaortic	1 (1.25)	0	

Data are presented as number (percentage).

a Small: 23 mm for Sapien XT / Sapien 3 / Lotus and 26 mm for CoreValve / Evolut R and Symetis S

b Medium: 25 mm for Lotus, 26 mm for Sapien XT / Sapien 3 and 29 mm for CoreValve / Evolut R and Symetis M

c Large: 27 mm for Lotus, 29 mm for Sapien XT / Sapien 3, 31 mm for CoreValve, and 34 mm for Evolut R and Symetis L

Abbreviations: see TABLE 1

transesophageal echocardiography ($P = 0.002$). This can be explained by a higher risk of prosthesis undersizing in patients with a large annulus, resulting in discrepancy between the annulus and the device.[28] On the other hand, TAVI in patients with small aortic annulus may be associated with good postprocedural valve hemodynamics and clinical outcomes.[30] Another study showed that while the rate of at least moderate PVL among patients with small aortic annulus (<18mm) was less than 6%, in the large aortic annulus (≥20 mm) group it was greater than 11% ($P = 0.009$).[29] Moreover, Tang et al[31] demonstrated that a larger LVOT was associated with higher PVL. They hypothesized that the mechanism of PVL is related to a reduced LVOT seal zone. However, they included only 74 patients with extremely large annuli (annular area >683 mm^2) treated with Sapien 3, and only 11 patients (14.9%) had BAV.

The results of our study are in opposition to the investigation which included 108 patients with AS who underwent MSCT and then successful TAVI.[25] In the study, the following were assessed at the level of the annulus, LVOT, and aortic cusps: annular and LVOT dimensions, annulus / LVOT perimeter difference ratio, LVOT to ascending aorta angle, and the calcification of the aortic valve. It was found that only procedure-related prosthesis / annulus sizing ratio was a significant determinant of PVL degree after TAVI, whereas anatomical measurements of the aortic root and the presence of calcifications were not associated with PVL occurrence. However, there was no aortic valve morphology assessment. Also, Pollari et al[23] analyzed preoperative MSCT scans of 539 patients who underwent TAVI. To assess risk factors for PVL, they calculated calcium volume for each aortic cusp in the aortic valve, LVOT, and device landing zone. They also measured the dimensions of the aortic annulus. In multivariable logistic regression, calcification of the device landing zone, and the use of the CoreValve prosthesis were found to be associated with at least mild PVL. Conversely, the degree of oversizing and the use of Sapien 3 with SapienXT as reference were associated with a lower incidence of at least mild PVL. In that study, the authors did not assess LVOT dimensions and patients with BAV were excluded.

One of the first large multicenter analyses of TAVI in patients with severe BAV stenosis or regurgitation demonstrated a high incidence of postimplantation aortic regurgitation grade at least 2 (28.4%).[32] Additionally, a reduction of aortic regurgitation to 17% in those with MSCT-based aortic valve sizing was observed. However, it should be emphasized that only patients with BAV were included, stenosis occurred only in 65.5% of patients, and 33.8% of patients had mixed disease and the aortic root morphology was not assessed.

Some of previous studies showed comparable frequency of PVL after TAVI between patients with BAV and those with TAV; however, the results were based on a small sample size of patients with BAV.[33-35] On the other hand, our results are similar to a few earlier investigations.[10,36] In a large patient cohort from the German TAVI Registry, a higher rate of relevant aortic regurgitation (grade ≥2) after TAVI among patients with BAV (25% vs 15%; $P = 0.05$) was noted. However, only 3% of all patients undergoing TAVI have BAV.[36] Furthermore, an international, multicenter, observational study showed that, compared with patients with tricuspid AS, those with bicuspid AS had more frequent moderate or severe paravalvular leak. Differences were observed only among patients treated with the early-generation devices.[10] However, there was no detailed assessment of the morphology of the aortic root.

Our study revealed that greater area and perimeter of LVOT in patients with BAV stenosis were associated with more frequent at least moderate PVL. To the best of our knowledge, this was the first study that systematically monitored the aortic root morphology and its impact on PVL in patients with BAV stenosis. Further research is necessary and our data may contribute to raising awareness of predictors of PVL after TAVI in BAV stenosis.

Limitations This was a single-center study. Another limitation was a small sample size. The study included only patients at high surgical risk and the complications may be associated with their general health. A longer follow-up is needed to validate the outcomes.

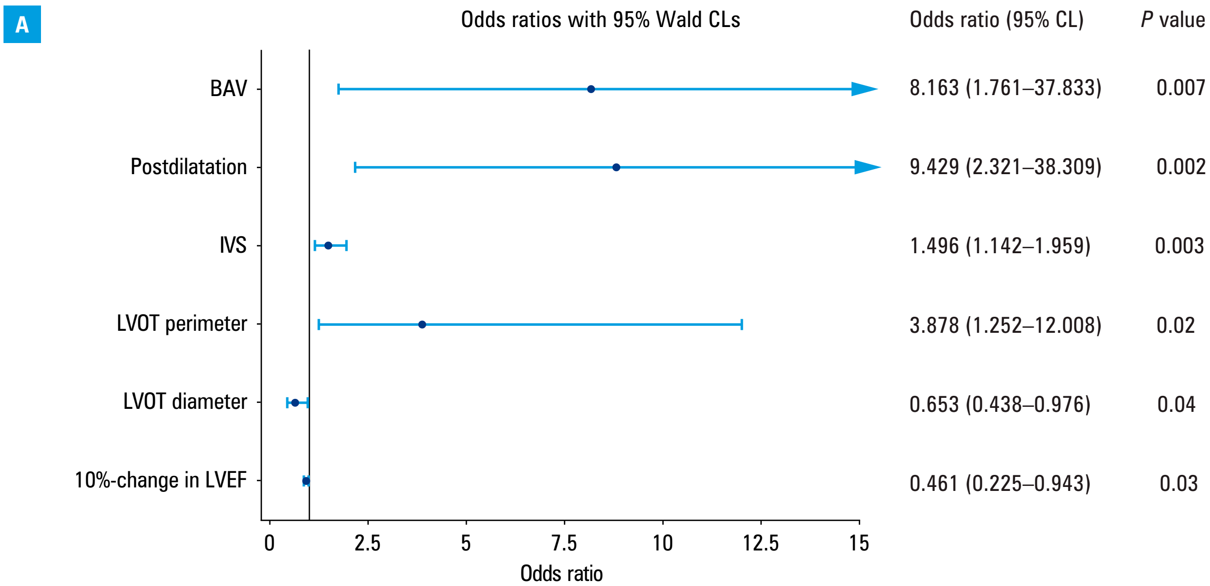
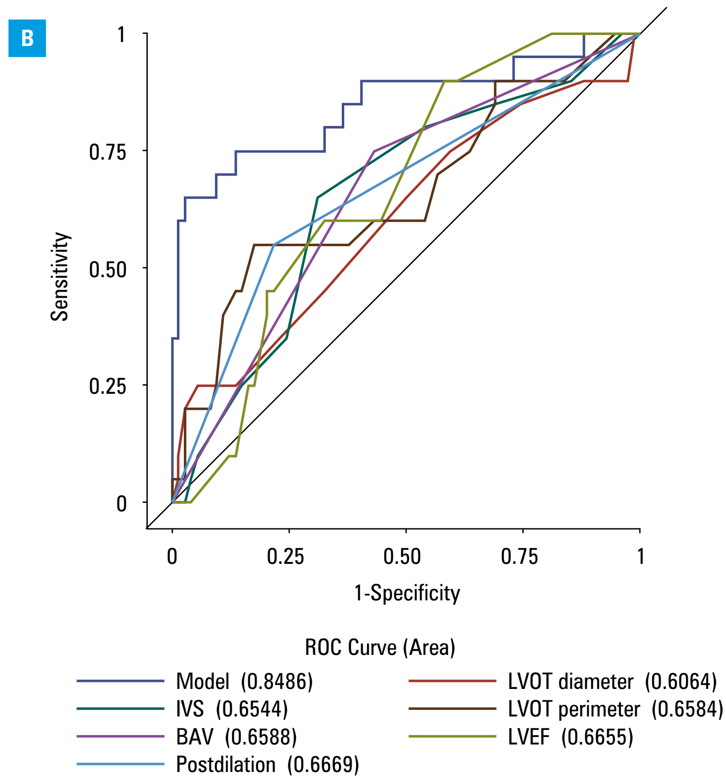


FIGURE 4 **A** – forest plot for multivariable analysis of predictors of at least moderate paravalvular leak after transcatheter aortic valve implantation; **B** – receiver operating characteristic curve analysis for the echocardiographic, morphological, and procedural factors in predicting at least moderate paravalvular leak
Abbreviations: CL, confidence limit; ROC, receiver operating characteristic; others, see **TABLES 1**, **2**, and **3**



Conclusions The assessment of the aortic root morphology can be helpful in prediction of PVL after TAVI. Transcatheter aortic valve implantation in patients with BAV is associated with a higher incidence of at least moderate PVL in short-term follow-up. The occurrence of paravalvular leak after TAVI in patients with BAV is related to the size of the LVOT, not to the dimensions of the aortic annulus.

ARTICLE INFORMATION

CONTRIBUTION STATEMENT MN, KZ, PS, TH, and IM conceived the concept for the study. All authors were involved in data collection. Supervision of the study and interpretation of data: MN, IM. IK was responsible for statistical analysis. All authors edited and approved the final version of the manuscript.

CONFLICT OF INTEREST None declared.

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