

Relationship of Aortic Annular Eccentricity and Paravalvular Regurgitation Post Transcatheter Aortic Valve Implantation With CoreValve

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ABSTRACT: Background. Significant paravalvular aortic regurgitation (PAR) after transcatheter aortic valve implantation (TAVI) is associated with negative clinical consequences. We hypothesize that increased eccentricity of the aortic annulus is associated with greater PAR. **Methods.** Patients with severe aortic stenosis underwent multidetector computed tomography (MDCT) before successful TAVI with the Medtronic CoreValve bioprosthesis. The smallest ($D_{\min}$) and largest ($D_{\max}$) orthogonal diameters in the basal ring of the aortic annulus were determined. We defined circularity of aortic annulus using the eccentricity index ($1 - D_{\min}/D_{\max}$). The primary endpoint was early occurrence of significant PAR, defined as > grade II PAR by postprocedural aortography. **Results.** Eighty-four patients, mean age 83 ± 4 years with a mean aortic valve area of 0.7 ± 0.2 cm² were included. Twenty patients had postprocedural PAR > grade II. Using a receiver operating characteristic (ROC) analysis, eccentricity index correlated with significant PAR (AUC = 0.834; $P=.034$). A retrospectively determined eccentricity index cut-off of >0.25 was related to significant PAR with a sensitivity of 80%, specificity of 86%, and negative predictive value of 95% ($P<.001$). On univariate logistic regression, eccentricity index of >0.25 ($P<.001$) and device implantation depth ($P=.015$) correlated with significant PAR, while other parameters such as annular calcification and cover index did not. On multivariate analysis including only parameters with $P<.1$ on univariate analysis, eccentricity index >0.25 was the sole independent predictor of significant PAR. **Conclusion.** Eccentricity index is related to significant PAR after TAVI with Medtronic CoreValve. Further larger studies are required to determine the utility of this novel index in screening suitable patients for this procedure.

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Key words: transcatheter aortic valve implantation, computed tomography, paravalvular aortic regurgitation, CoreValve, annular eccentricity

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Transcatheter aortic valve implantation (TAVI) is increasingly being performed as an alternative to surgical aortic valve replacement for severe aortic stenosis in patients with high surgical risk or contraindications to surgery.^{1,2} Paravalvular aortic regurgitation (PAR) is frequent after TAVI using Medtronic CoreValve bioprosthesis (Medtronic), but is usually mild.¹ Nonetheless, significant PAR does occur and may have negative consequences.³⁻⁶ The annulus has previously been shown to be elliptical on multidetector computed tomography (MDCT).⁷ We hypothesize that increased eccentricity of the aortic annulus is associated with greater PAR.

Methods

Subjects. Patients with severe symptomatic aortic stenosis (aortic valve area [AVA] <1 cm² or indexed AVA <0.6 cm²/m²) were recruited and underwent successful transfemoral TAVI using the Medtronic CoreValve bioprosthesis between February 2009 and November 2010. Our clinical and anatomic selection criteria and device size selection were in accordance with the published investigational study for the third-generation (18 Fr) CoreValve device.¹ The technical aspects of the procedure have been previously published.¹ The sizing of the prosthesis was based on a combination of echocardiographic and MDCT measurements at the discretion of the implanting cardiologist. All patients included in this study underwent a preprocedure MDCT. We performed a retrospective analysis of the MDCT measurements and hypothesize that the increased eccentricity of the aortic annulus is associated with greater PAR assessed on aortography immediately after device deployment.

Preprocedure MDCT protocol. CT was performed using one of two systems. Thirty-seven patients underwent CT scan on a 128-detector system (Siemens Definition AS+, Siemens Medical Solutions). The scan of the thorax was acquired during injection of non-ionic iodinated contrast agent, iopromide (Ultravist 370 mg/mL, Bayer Healthcare) in an antecubital vein by a dual injector (Medrad Stellant). Individualized weight-based contrast volumes were injected at 6 mL/s in a triple-phase pattern of pure contrast / 50:50 saline mix / saline. A contrast bolus monitoring technique evaluating time to peak enhancement in the descending aorta was used to determine the scan delay. The entire thorax was scanned using retrospective electrocardiogram gating with tube modulation technique

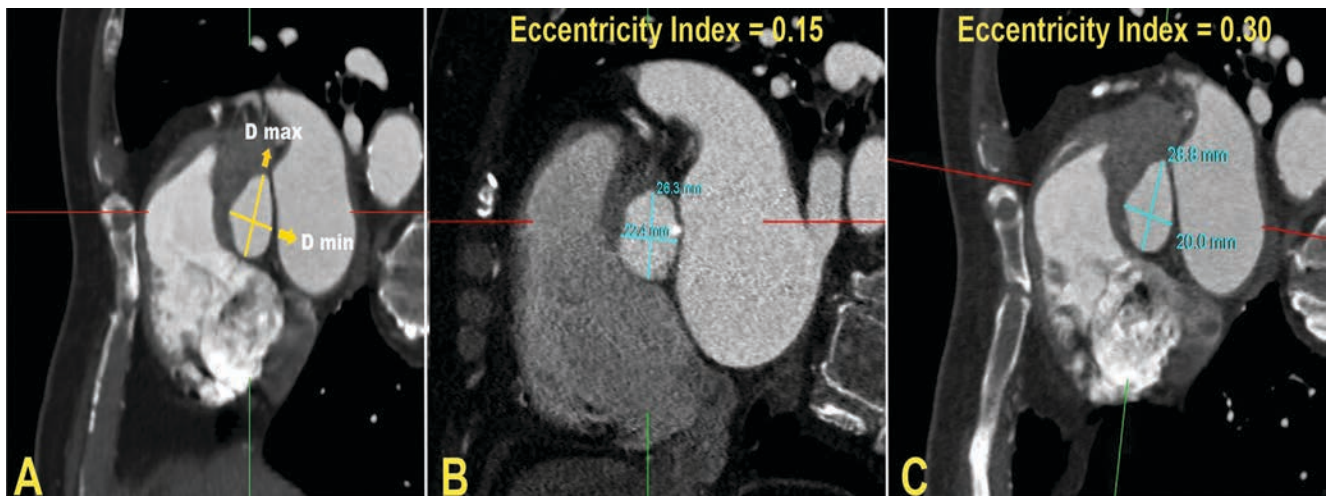


Figure 1. Computed tomography angiography of the aortic root. Computed tomography angiographic double oblique transverse images of the aortic root at the level of the basal ring. (A) The maximal ($D_{\max}$) and minimal ($D_{\min}$) diameter measurements of the basal ring below the hinge point of the aortic valve cusps are shown. (B) An example of a circular annulus with an eccentricity index of 0.15. (C) An example of an elliptical annulus with an eccentricity index of 0.3.

(120 kV; 280-350 mAs; 300 ms gantry rotation time). Images were acquired at 0.6 mm slice thickness at 0.3 mm increments and reconstructed using a medium-smooth kernel (B26, Siemens Medical Solutions) throughout the cardiac cycle at 10% increments of the R-R interval.

Another 47 patients were scanned with a 320-detector CT scanner (Aquilion ONE, Toshiba Medical Systems). The scan of the thorax was acquired during injection of 55 mL of 100% iohexal 56.6g/75 mL (Omnipaque 350) at 5 mL/s, followed by 20 mL of a 30:70 mixture of contrast and saline, followed by 30 mL of saline. Scanning was triggered in the arterial phase using automated contrast bolus tracking with the region of interest placed in the descending aorta, and automatically triggered at 300 Hounsfield units (HU).

Scanning parameters were: detector collimation 320×0.5 mm; tube current 300-500 mA (depending on body mass index [BMI]); tube voltage 120 kV if BMI ≥ 25 (100 kV if BMI < 25); gantry rotation time 350 ms; and temporal resolution 175 ms. Prospective electrocardiogram gating was used covering 70%-80% of the R-R interval. For images acquired at heart rates ≤ 65 beats/min, scanning was completed within a single R-R interval utilizing an 1808 segment. In patients with a heart rate of 65 beats/min, data segments from two consecutive beats were used for multisegment reconstruction with improved temporal resolution of 87 ms.

Definition of the aortic annulus on MDCT. All images were analyzed using a cardiac application on dedicated workstations (Vitrea V4.1, Vital Images) by two independent observers. The best diastolic images at 70 or 80% of R-R interval were used. As previously described,⁷ images were reconstructed using the three multiplanar reformation planes to acquire a modified coronal and modified sagittal view. *Aortic annulus dimension* was defined as the distance between the hinge points of the aortic valve cusps on these views. A transverse cut-plane at the level of the aortic valve hinge point resulted in a true double oblique transverse view of the aortic root. The largest ($D_{\max}$) and the

smallest ($D_{\min}$) basal ring diameters were measured at the most caudal attachments of the aortic valve as shown in Figure 1. *Circularity of aortic annulus* was defined using the eccentricity index derived using the formula $(1 - D_{\min}/D_{\max})$.⁸ The mean (D_{mean}) basal ring diameter was derived by averaging the largest and smallest basal ring diameters.

The degree of aortic valve calcification was semi-quantitatively classified into no calcification, mild calcification (small calcium spots), moderate calcification (larger calcium spots), and severe calcification (extensive calcification).⁹ For assessment of the congruence between the aortic annulus and the device, we calculated a cover index as previously described.¹⁰ We utilized the annulus diameter measured in the modified coronal view on MDCT. The cover index was expressed as a ratio of:

$$100 \times \frac{[\text{prosthesis diameter} - \text{MDCT annulus diameter}]}{\text{prosthesis diameter}}$$

In order to explore the difference between CoreValve prosthesis size and annular size for the prediction of PAR, we measured the difference between the nominal CoreValve bioprosthesis size and mean basal ring diameter as previously described:¹¹

$$\text{prosthesis diameter} - \text{MDCT mean annular diameter}$$

The CoreValve bioprosthesis is deemed undersized when the prosthesis diameter was smaller than the MDCT mean annular diameter and vice versa for the definition of prosthesis oversizing.¹¹

Angiographic evaluation of aortic regurgitation. Aortography immediately after device deployment was performed to evaluate prosthesis position and the degree of aortic regurgitation. Qualitative assessment of PAR severity was performed by two independent observers who were not involved in the TAVI procedure. Aortic regurgitation was classified into 4 grades: absent (0), trace or mild (I), mild-to-moderate (II), moderate-to-severe (III), and severe (IV).¹² Significant PAR was defined as AR $>$ grade II. This was the primary endpoint of our study.

Echocardiographic evaluation of aortic regurgitation and assessment of prosthesis circularity post deployment. Transthoracic echocardiography (TTE) was performed within

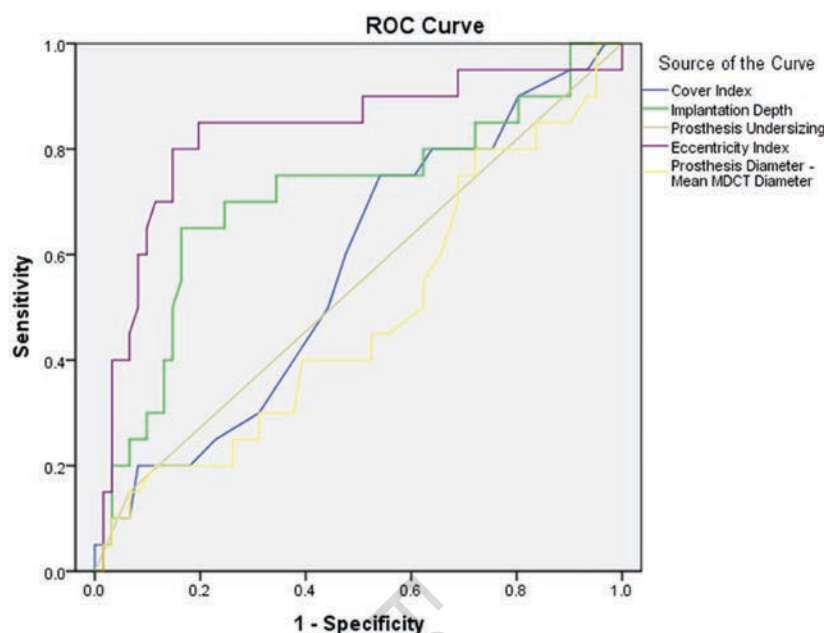


Figure 2. Receiving operating characteristic (ROC) curve of eccentricity index (area under curve [AUC] = 0.834), prosthesis implantation depth (AUC = 0.707), cover index (AUC = 0.57), prosthesis undersizing (AUC = 0.542), and prosthesis diameter – mean multidetector computed tomography diameter (AUC = 0.483) in relation to significant paravalvular aortic regurgitation.

24 hours of TAVI procedure and prior to patient discharge. The concordance of aortic regurgitation between aortography and echocardiography was assessed. When there was discrepancy, a third independent observer graded the aortic regurgitation and a consensus was reached. Short- and long-axis TTE views were used to confirm the location (paravalvular versus central) of AR assessed on angiography.

Evaluation of device position. Using the final aortogram of the deployed bioprosthesis, displaying the aortic valve in optimal alignment with all three leaflets visible in the same plane, we assessed the final device implantation depth position in the left ventricular outflow tract (LVOT). The device implantation depth was defined as the distance from the native aortic annular margin on the side of the non-coronary cusp (NCC) to the most proximal edge on the corresponding side (deepest in the left ventricle) of the deployed stent-frame as previously described.¹³ We also measured the device implantation depth from the annular margin of the left coronary cusp to the corresponding side of the deployed stent-frame.

Statistical analysis. Data were expressed as mean $\pm$ standard deviation or percentage. Comparisons of clinical, MDCT, or procedure-related characteristics of patients according to AR ≤ 2 or AR > 2 used t-test or chi-square as appropriate. Receiver operating characteristic (ROC) analysis was performed to evaluate the diagnostic potential of the eccentricity index in predicting significant PAR. Area under the curve (AUC) was determined and the optimal cut-off value that maximized the sensitivity and specificity was chosen. The sensitivity and specificity of the defined eccentricity index cut-off value was then ascertained. Potential predictors for the occurrence of significant AR, such as eccentricity index, device implantation depth, annulus cal-

cification, cover index, prosthesis diameter, undersizing of prosthesis, baseline AR and ejection fraction, ascending aorta and sinus of Valsalva diameter were studied using univariate logistic regression analysis. Predictors with $P < .1$ on univariate analysis were included in a multivariate logistic regression analysis. Statistical analysis was performed with SPSS 18.0 (SPSS Inc). A P -value $< .05$ was considered statistically significant.

Results

Baseline clinical, MDCT, and procedural characteristics are shown in Table 1. All 84 patients (age, 83 ± 4 years; 57% males) had severe aortic stenosis (mean AVA, 0.73 ± 0.17 cm²).

Assessment of aortic regurgitation after TAVI. Angiographic grading of AR revealed absence of AR in 13 patients (16%), grade I in 33 patients (39%), grade II in 18 patients (21%), and grade III in 20 patients (24%). Therefore, 20 patients (24%) had AR that was defined as ‘significant’ on postprocedural angiography ($>$ grade II). The concordance of AR severity between

postprocedural angiography and TTE was 89% ($P < .001$). In addition, assessment by TTE confirmed that regurgitation was paravalvular rather than valvular in all cases. Five patients with significant PAR on angiography underwent postdilatation of the CoreValve prosthesis, which improved the severity of PAR in 2 patients from grade IV to grade III.

Predictors of significant AR. An eccentricity index of > 0.25 was associated with the occurrence of significant PAR immediately after valve implantation ($P < .001$). On ROC analysis, the AUC was 0.834 (CI, 0.715–0.954; standard error [SE] = 0.061), as shown in Figure 2. The retrospectively determined eccentricity index threshold of 0.25 derived from ROC predicted significant AR with a sensitivity of 80% and specificity of 86% ($P < .001$). On ROC analysis, the AUC for device implantation depth was 0.707, cover index (AUC = 0.57), undersized prosthesis (AUC = 0.542), while prosthesis diameter – mean MDCT annular diameter had an AUC of 0.483 (Figure 2). On univariate logistic regression, device implantation depth was also related to the occurrence of significant PAR ($P = .015$). However, other factors such as cover index, annular calcification, undersizing of prosthesis, prosthesis diameter – MDCT mean annular diameter, and baseline aortic regurgitation were not related to the occurrence of significant PAR (Table 2). There was no significant correlation between eccentricity index and cover index (Figure 3). On multivariate analysis including only parameters with $P < .1$ on univariate analysis, eccentricity index > 0.25 was the sole independent predictor of significant PAR ($P < .001$).

Reproducibility of the eccentricity index. Eccentricity index measurement showed good reproducibility between observers in 10 randomly selected patients. The mean inter-observer

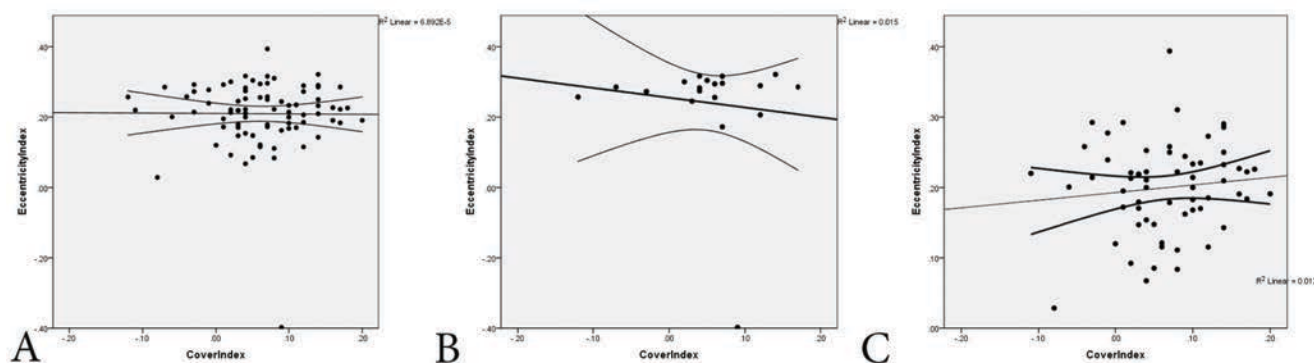


Figure 3. Scatter plots showing the poor correlation between eccentricity index and cover index. (A) The entire study cohort ($r = -0.012$). (B) Patients with significant paravalvular aortic regurgitation (PAR; $r = 0.084$). (C) Patients without significant PAR ($r = 0.066$).

difference (bias) and repeatability coefficient (± 2 standard deviations) was 0.011 ± 0.036 . The intraclass coefficient was 0.959 ($P < .001$).

Discussion

This study shows that significant PAR may occur after TAVI Medtronic CoreValve and that the occurrence of significant PAR is related to the eccentricity extent of the annulus assessed on preprocedure MDCT.

Assessment of aortic regurgitation after TAVI. The assessment of aortic regurgitation after TAVI can be performed with either aortography,¹³ transesophageal echocardiography (TEE), or TTE.^[14] We wanted an assessment that would provide us with the earliest assessment of PAR in the catheterization laboratory. This is because further intervention such as postdilatation or snaring of the prosthesis can be performed based on the severity of PAR on postprocedural aortography. Therefore, we chose postprocedural aortography assessment as our primary endpoint. As intraprocedural TEE assessment was not available for all patients in our study, we could not use this as our primary endpoint. Nonetheless, there are currently no consensus angiographic PAR grading criteria. The authors of the recently published standardized consensus report from the Valve Academic Research Consortium acknowledged that there is a need to develop improved definitions and to better understand the long-term clinical implications of paravalvular prosthetic AR.¹⁴ They further acknowledged that unfortunately, the precise grading of paravalvular AR remains controversial and many echocardiography experts believe that grading schemes for prosthetic central and paravalvular AR should be different.¹⁴ The authors proposed a consensus echocardiographic PAR grading criteria but did not propose a consensus for angiographic PAR assessment. More recently, Sinning and colleagues described an AR index, which was calculated as the ratio of end-diastolic gradient across the valve prosthesis to systolic blood pressure.¹⁵ The authors demonstrated that the AR index decreased stepwise in parallel with increasing severity of PAR and allowed a precise judgment of the degree of PAR. In addition, the AR index also strongly predicted 1-year mortality after TAVI and provided additional prognostic information that was complementary to the echo-

cardiographically assessed severity of PAR. Correlation of eccentricity index with the AR index would have been ideal had the hemodynamic parameters in our cohort been available.

Predictors of significant AR. The 24% incidence of significant PAR ($>$ grade II) on postprocedural aortography found in this study is similar to the at least moderate AR incidence of 7%-20% reported in previous studies.^{1,16,17} This has been shown to be associated with worse short-term outcomes and increased in-hospital mortality.¹⁸ In addition, Tamburino et al recently reported that postprocedural paravalvular aortic regurgitation impacts on late outcomes between 30 days and 1 year post TAVI.⁵ Furthermore, Kodali et al described that even mild PAR is associated with increased late mortality at 2 years.⁶ This highlights the importance of obtaining preprocedure data, which may predict significant PAR in the selection of patients for TAVI. Detaint et al related the occurrence of significant AR to prosthesis/annulus discongruence in patients treated with the Edwards Sapien valve.¹⁰ Meanwhile, Sherif et al suggested that the occurrence of significant AR is strongly related to the angle of LVOT to the ascending aorta and the final depth of the bioprosthesis in patients treated with Medtronic CoreValve bioprosthesis.¹³ Preprocedure MDCT has been used to measure annular size in addition to evaluating access sites before TAVI.^{7,19} In addition, the annulus has been observed to be often oval shaped, in contrast to the circular shape of current devices.⁷ Tops et al reported that the annulus evaluated by MDCT had an oval configuration in approximately 50% of patients evaluated for TAVI, with a mean difference between coronal and sagittal measurements of 3.0 ± 1.9 mm. This was also observed by Delgado et al in 53 patients with severe aortic stenosis.⁹ Schultz et al recently investigated the utility of preprocedure MDCT in predicting mild-to-moderate PAR after TAVI.²⁰ They suggested that improved prosthesis sizing based on mean annulus diameter on MDCT may help to reduce PAR.²⁰ On the other hand, Willson et al have recently described that moderate or severe PAR was associated with prosthesis undersizing (AUC = 0.81) in 109 patients treated with the Sapien XT or Sapien, Edwards LifeSciences prosthesis. This was assessed by calculating the difference between the nominal bioprosthesis size and mean basal ring diameter. The incidence of undersizing reported by the authors based on this criterion of 35.3%

Table 1. Baseline clinical, echocardiographic, angiographic, and procedural characteristics.

Characteristics	All (n = 84)	AR ≤2 (n = 64)	AR >2 (n = 20)	P- Value
Patient characteristics				
Age (years)	83 ± 4	83 ± 4	83 ± 5	.717
Male	48 (57%)	39 (61%)	9 (45%)	.212
Height (cm)	1.6 ± 0.9	1.6 ± 0.1	1.6 ± 0.1	.914
Weight (kg)	73.5 ± 13.2	74.1 ± 12.6	72.1 ± 14.7	.621
Echo parameters				
AVA (cm ²)	0.73 ± 0.17	0.74 ± 0.17	0.72 ± 0.19	.659
Peak pressure gradient (mm Hg)	80.3 ± 24.7	79.4 ± 23.7	83 ± 28.0	.568
Ejection fraction	57.9 ± 11.2	57.2 ± 11.4	60.2 ± 10.6	.298
Baseline AR grade	0.7 ± 0.6	0.7 ± 0.6	0.5 ± 0.5	.16
MDCT parameters				
Annulus (mm)	25.9 ± 2.1	25.9 ± 2.1	26.1 ± 2.2	.066
Severe leaflet calcification	53 (63%)	39 (61%)	14 (70%)	.666
Procedural parameters				
Depth to NCC (mm)	10.7 ± 4.8	4.4 ± 0.57	13.0 ± 5.1	.015
Depth to LCC (mm)	11.2 ± 4.2	10.7 ± 4	12.5 ± 4.4	.11
Valve size				
29 mm	50 (60%)	41 (64%)	9 (45%)	.134
26 mm	34 (40%)	23 (36%)	11 (55%)	.134
AVA = aortic valve area; AR = aortic regurgitation; MDCT = multidetector computed tomography; NCC = non-coronary cusp; LCC = left coronary cusp.				

Table 2. Univariate logistic regression of factors in relation to significant paravalvular aortic regurgitation.

Variable	Univariate		Multivariate	
	Estimated Coefficient, β1	P-Value	Estimated Coefficient, β1	P-Value
Eccentricity index >0.25	-3.2	<.001	-3.037	<.001
Depth to NCC (mm)	0.145	.015	0.113	.119
Depth to LCC (mm)	0.098	.11	—	—
Severe annulus calcification	0.774	.666	—	—
Cover index	-4.6	.24	—	—
Undersized prosthesis	2.515	.256		
(Prosthesis diameter – mean MDCT annular diameter)	0.895	.975		
Prosthesis diameter (mm)	-0.234	.134	—	—
Baseline AR	0.521	.16	—	—
Baseline ejection fraction (%)	0.025	.298	—	—
Ascending aorta diameter (mm)	-0.045	.345	—	—
Sinus of Valsalva diameter (mm)	-0.069	.384	—	—
LCC = left coronary cusp; NCC = non-coronary cusp; AR = aortic regurgitation.				

was significantly higher compared to our study (8.3%). The authors also reported that annular eccentricity was not associated with PAR (AUC = 0.58). This is in contrast to our findings in a cohort of 84 patients treated with CoreValve bioprosthesis. We found that prosthesis undersizing (AUC = 0.483) was not associated with PAR, while annular eccentricity was associated with PAR (AUC = 0.834). We also demonstrated that eccentricity index >0.25 predicted significant AR with a sensitivity of 80% and specificity of 86% ($P<.001$). Therefore, the results of our study have important clinical implications as they highlight that there are different MDCT predictors of PAR for Sapien and CoreValve bioprostheses. This could be explained by the difference in how the bioprostheses are deployed. The Sapien bioprosthesis is a balloon-expandable valve, while the CoreValve bioprosthesis is a self-expanding valve. Mylotte et al presented their view recently that because self-expanding and balloon-expandable valves interfere differently with the aortic annulus, we should not expect similar oversizing principles.²¹ Further larger multicenter studies to evaluate predictors of PAR are therefore required.

We also evaluated other factors that have been shown to predict significant PAR in previous studies such as the cover index,¹⁰ device implantation depth,¹³ and aortic valve area.¹⁸ The mean cover index in our study (6.2%) was similar to that reported by Detaint and colleagues (6.7%),¹⁰ indicating that the incidence of valve undersizing in our report is comparable to previous studies. Although patients with severe PAR had a lower cover index of $5.1 \pm 6.9\%$ compared to those without significant PAR ($6.6 \pm 6.5\%$), this was not statistically significant ($P=.24$). Device implantation depth was also a factor associated with significant PAR in our study; however, eccentricity index >0.25 was the strongest independent factor associated with significant PAR on multivariate analysis. It was feared that severe leaflet or annular calcification might prevent adequate sealing of the annulus by the device, but we did not find this to be a factor in causing paravalvular leaks. Our study lends further credit to the utility of preprocedure MDCT for screening patients suitable

for TAVI. In addition to annular dimension determination and access site evaluation, MDCT assessment may play a role in predicting significant PAR after TAVI, but further studies are required to fully define the clinical utility of the eccentricity index in this context.

Study limitations. The eccentricity index cut-off value of 0.25 was retrospectively determined from ROC curve, which could lead to overestimation of its predictive value. Furthermore, the number of patients with significant PAR was relatively small in this study, which may limit the interpretation of multivariate analysis. We did not assess the circularity of the prosthesis after deployment on postprocedure MDCT since postprocedure MDCT was not standard practice in our centers. We acknowledge that assessment of aortic regurgitation on intraprocedural TEE would be optimal; however, this was not standard practice at our institution. This report, in keeping with previous studies, utilized the severity of PAR evaluated on postprocedural aortography as a primary endpoint;¹³ however, we acknowledge that PAR may improve with the expansion of the CoreValve over time. We assessed CoreValve devices only; therefore, the validation of eccentricity index as a predictor of PAR requires further evaluation before extrapolation of this index to other TAVI devices. Since the completion of our study, a 31 mm CoreValve has become available and extrapolation of data to those who might have received a larger valve is therefore uncertain. Finally, the current study did not assess the utility of area or circumference of the annulus as predictor of PAR, which may offer incremental value. However, the utility of annular mean diameter, which was used in our study, had comparable predictive value to area or circumference of the annulus as demonstrated by Willson et al.¹¹

Conclusion

The eccentricity index, a measure of the eccentricity of the aortic annulus, is related to significant paravalvular aortic regurgitation after TAVI with Medtronic CoreValve. Further larger studies are required to confirm our findings and determine the utility of this novel index in screening patients preprocedurally.

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