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Prosthesis/annulus discongruence assessed by three-dimensional transoesophageal echocardiography: A predictor of significant paravalvular aortic regurgitation after transcatheter aortic valve implantation

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Aims Paravalvular aortic regurgitation (AR) is common after transcatheter aortic valve implantation (TAVI). This study aimed to assess the prosthesis/aortic annulus discongruence by three-dimensional (3D) transoesophageal (TOE) planimetry of aortic annulus and its impact on the occurrence of significant AR after TAVI.

Methods and results We included 33 patients who underwent TAVI with a balloon expandable device for severe aortic stenosis. To appraise the prosthesis/annulus discongruence, we defined a 'mismatch index' expressed as: annulus area − prosthesis area. The aortic annulus area was planimetered with 3D TOE, and approximated by circular area formula (πr^2) using annulus diameter obtained by two-dimensional (2D) TOE. After TAVI, 13 patients (39.3%) developed significant AR ($\geq$2/4). The occurrence of significant AR was associated to the 3D planimetered annulus area ($P = 0.04$), and the 'mismatch index' obtained through 3D planimetered annulus area ($P = 0.03$), but not to 'mismatch index' derived of 2D annulus diameter. In multivariate analysis, 'mismatch index' for 3D planimetered annulus area was the only independent predictor of significant AR (odds ratio: 10.614; 95% CI: 1.044–17.21; $P = 0.04$). The area under the receiver operating characteristic curve for the 'mismatch index' by the 3D planimetered annulus area was 0.76 (95% CI: 0.54–0.92), whereas for 'mismatch index' obtained by the 2D circular area was 0.36 (95% CI: 0.17–0.55). Using the 3D planimetered annulus area as the reference parameter to decide the prosthetic size, the choice would have been different in 21 patients (63%).

Conclusion Three-dimensional TOE planimetry of aortic annulus improves the assessment of prosthesis/annulus discongruence and predicts the appearance of significant AR after TAVI.

Keywords Annular geometry • Three-dimensional transoesophageal echocardiography • Transcutaneous aortic valve implantation • Aortic regurgitation

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Introduction

Transcatheter aortic valve implantation (TAVI) has been demonstrated to be a feasible therapeutic alternative for high-risk surgical patients with symptomatic aortic stenosis.[1–3] Paravalvular aortic regurgitation (AR) is a common complication after TAVI, with an incidence of mild AR ranging from 40 to 72%, and more than mild from 7 to 40%.[4–9] This complication has been shown to be a predictor of in-hospital mortality[8] and, to decrease the frequency of AR, appropriate aortic annulus measurements were critical. Non-invasive cardiac imaging plays a central role in TAVI.[10–12] Pre-operative accurate measurements of aortic annular sizes are crucial for the selection of appropriate prosthesis sizes. Currently, aortic annular dimensions are usually assessed by two-dimensional (2D) transthoracic or transoesophageal echocardiography (TOE). In a previous study, it was reported that the prosthesis/annulus discongruence measured by 2D echocardiography is a predictor of significant AR post-TAVI.[9] However, compared with three-dimensional (3D) echocardiography and multislice computed tomography, 2D echocardiography underestimates the aortic annulus dimensions.[13–15] Planimetry of aortic annulus by 3D TOE has been suggested to improve pre-TAVI annulus measurements, showing the best agreement with multislice computed tomography.[14]

This study aimed to assess the prosthesis/aortic annulus discongruence by 3D TOE planimetry of aortic annulus, and its impact on the occurrence of significant AR after TAVI. We compared the results with those obtained by the circular area calculated from 2D aortic annulus diameter. We also evaluated the theoretical impact of aortic annulus planimetry on the prosthesis size used.

Methods

Study population

Thirty-three patients with severe symptomatic aortic stenosis who underwent TAVI with balloon expandable Edwards–Sapien prostheses (Edwards Lifesciences, Inc., Irvine, CA, USA) in our centre were included in this study. All these patients underwent TAVI as a result of excessive surgical morbidity and mortality risks from conventional aortic valve replacement. All patients underwent transthoracic and TOE before TAVI. All patients gave written informed consent, and experiments were carried out in accordance with a protocol approved by the institutional review board.

Transthoracic echocardiography

Transthoracic echocardiography was performed <48 h before the TAVI procedure, with the patient in the left lateral decubitus position using a commercially available, fully sampled, matrix-array transthoracic transducer and equipment (S5-1, X5-1 probes; Philips Medical Systems, Andover, MA, USA). All images were digitally stored on hard disks for a later offline analysis (X celera, Philips Medical Systems). A complete 2D, colour, pulsed, and continuous-wave Doppler echocardiogram was performed according to standard techniques. The severity of aortic stenosis was assessed by the aortic mean gradient and the aortic valve area, which was calculated with the continuity equation.[16] The left ventricular end-diastolic volume index, the end-systolic volume index, and the derived left ventricular ejection fraction were obtained using the Simpson biplane method.

Transoesophageal echocardiography

All the patients underwent TOE immediately before valve implantation, under general anaesthesia, to check aortic annulus diameters. TOE was performed using a commercially available fully, sampled, matrix-array TOE transducer and ultrasound system (X7-2t Live 3D TOE transducer, iE33, Philips Medical Systems, Andover, MA, USA). All images were digitally stored for a later offline analysis (QLAB cardiac 3DQ, Philips Medical Systems). During images acquisition, gain and compression settings were optimized to display a magnified, zoomed image of the aortic root in the 30° short-axis or the 120° long-axis view. Two-dimensional TOE aortic annular diameters were determined in the three-chamber long-axis view at ~120° angle. The aortic annulus diameter was measured at the point of insertion of the aortic cusps during early systole. We also assessed the opening of the aortic valve (central or eccentric), the presence of large eccentric calcifications (>5 mm), the thickness of right coronary and non-coronary cusps, and the distance between annulus and right coronary ostium. Cropping of the 3D aortic root data sets was performed using three multiplanar reconstruction tool (MPR) planes during early systole (*Figure 1*). Cropping of the images was first performed using two orthogonal MPR planes bisecting the long axis of the left ventricular outflow tract in parallel, and then a third transverse plane bisecting the aortic annulus just below the lowest insertion points of all three aortic cusps to obtain the short-axis view of aortic annulus. From the 2D and 3D TOE images, the following measurements were obtained: 2D annulus diameter (and derived circular annular area approximated by πr^2) and 3D planimetered annulus area (from the 3D TOE MPR short axis).[14] To appraise the prosthesis/annulus discongruence, we defined a 'mismatch index' expressed as: annulus area − prosthesis area. This index was calculated for the 2D circular annulus area and the 3D planimetered area. The prosthesis circular area was approximated by the formula $A = \pi r^2$ (diameter derived from manufacturer's characteristics, 23 and 26 mm). Major and minor annular axes were obtained by 3D images. The major-to-minor annular axis ratio was also calculated to assess the influence of circularity.

TAVI procedures

TAVI was performed by transfemoral access in all patients, using previously described methods.[4,17–19] Prosthesis size selection was based on 2D TOE aortic annulus diameter, as usually recommended.[10] According to the manufacturer's recommendations, a 23-mm device was implanted when the diameter of the aortic annulus was >18 and ≤ 21 mm, and a 26-mm device was implanted when the diameter of the aortic annulus was >21 and ≤ 25 mm.

Evaluation of post-procedural AR

The degree of post-procedural AR was evaluated after removal of the catheter and guidewire, using short- and long-axis TOE views, approximately at 30° and 120°. The AR grading was based on colour flow Doppler imaging. The vena contracta width and the ratio of the jet to left ventricular outflow tract cross-sectional area were measured as previously described.[20] AR was classified into four grades: absent (0), mild (1/4), mild to moderate (2/4), moderate to severe (3/4), and severe (4/4). Significant AR was defined as AR $\geq 2/4$.

Statistical analysis

Continuous variables are expressed as means $\pm$ SD. Categorical data are presented as absolute number or percentages. Differences between groups for continuous variables were analysed using Student's *t*-test (when group distributions were symmetrical and mounded) or Mann–Whitney *U* test (when group distributions were skewed).

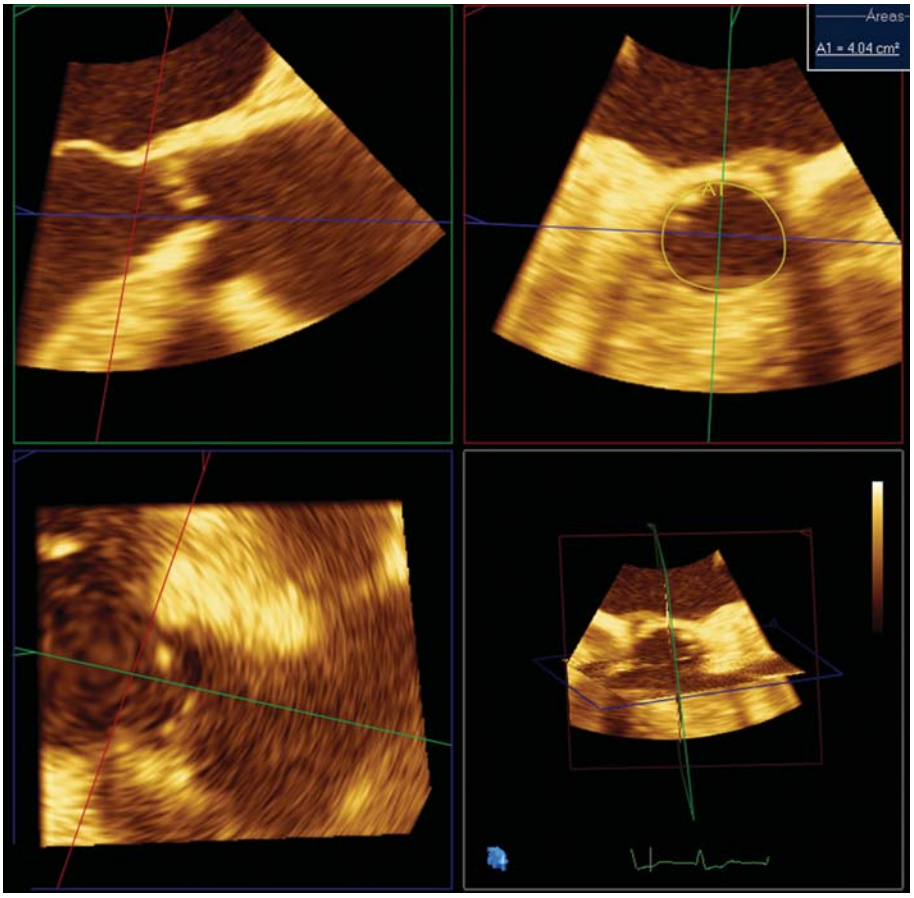

Figure 1 Transoesophageal three-dimensional aortic annulus planimetry, using multiplanar reconstruction tools (MPR) to obtain the short-axis view of aortic annulus.

The χ^2 test (when all expected cell counts were >5) or Fisher's exact test (when any expected cell count was <5) was used to determine the significance of differences in categorical variables. Uni and multivariate logistic regression analyses were used to analyse the predictors of significant AR post-TAVI. Receiver operating characteristic (ROC) curves were plotted to assess the predictive value of the different parameters. The results were considered significant when the *P*-value was <0.05. Inter- and intra-observer reproducibility were evaluated by means of the intraclass correlation coefficient (ICC). Differences were considered statistically significant at $P < 0.05$ (two-sided). Statistical analysis was performed with the SPSS 15.0 (SPSS, Inc., Chicago, IL, USA).

Results

Patient data

Clinical and echocardiographic characteristics of 33 patients studied are summarized in *Table 1*. The mean age was 82.2 ± 6.2 years, and 42.4% were male. The mean heart rate was 80 ± 12 bpm during transthoracic echocardiography and 82 ± 12 bpm during TOE. Neither the systolic blood pressure (123 ± 24 vs. 125 ± 21 mmHg) nor the diastolic blood pressure (73 ± 6 vs. 72 ± 4 mmHg) differed significantly between transthoracic and transoesophageal studies. The median value for the aortic valve area was 0.61 ± 0.15 cm^2 and for the mean gradient was 49 ± 19 mmHg. The mean ejection fraction was 56 ± 17%. Overall, 18 patients (54.5%) received a 23-mm prosthesis, and 15 patients (45.5%) received a 26-mm prosthesis.

Early AR after TAVI

We found no AR in 9 patients (27.2%), mild (1/4) AR in 11 patients (33.3%), mild to moderate (2/4) in 9 patients (27.2%), and moderate to severe (3/4) in 4 patients (12.1%). No severe AR (4/4) was observed. Thus, significant AR (≥2/4) occurred in 13 patients (39.3%). Post-procedural significant AR was associated with larger 3D planimetered annulus areas ($P = 0.04$) and the positive 'mismatch index' for the 3D planimetered annulus area ($P = 0.03$) (*Table 1*). *Table 2* shows the results of the univariate and multivariate logistic regression analyses to detect the predictors of post-TAVI significant AR. In the univariate analysis, the 3D planimetered annulus area ($P = 0.04$) and the 'mismatch index' for the 3D planimetered annulus area ($P = 0.03$) were the predictors of post-TAVI significant AR. Nevertheless, there were no statistically significant differences in other variables, including 2D annulus

Table 1 Clinical and echocardiographic characteristics of the population as a function of significant AR occurrence after TAVI

Variables	Overall (n = 33)	AR <2/4 (n = 20)	AR ≥2/4 (n = 13)	P-value
Clinical characteristics				
Mean age (years)	82.2 ± 6.2	82.1 ± 7	82.4 ± 5	0.9
Gender (male) (%)	14 (42.4)	9 (45)	5 (38.4)	0.7
Weight (kg)	69.5 ± 13.1	71.4 ± 11	66 ± 16	0.4
Height (cm)	161.2 ± 7.2	161 ± 6	160 ± 8	0.6
BSA (m^2)	1.6 ± 0.1	1.7 ± 0.1	1.6 ± 0.2	0.4
Echocardiographic characteristics				
Peak gradient (mmHg)	84 ± 28	88 ± 28	79 ± 29	0.4
Mean gradient (mmHg)	49 ± 19	51 ± 19	46 ± 18	0.4
Aortic valvular area (cm^2)	0.61 ± 0.15	0.59 ± 0.12	0.63 ± 0.18	0.2
Large eccentric calcifications (>5 mm) (%)	9 (27.3)	5 (25)	4 (30.7)	0.3
EDV (mL)	99 ± 48	91 ± 48	111 ± 48	0.3
ESV (mL)	49 ± 37	42 ± 38	60 ± 34	0.3
Ejection fraction (%)	56 ± 17	58 ± 18	53 ± 15	0.4
2D annulus diameter (mm)	21.7 ± 2.5	21.7 ± 2.3	21.7 ± 2.7	0.9
2D circular annulus area (cm^2)	3.64 ± 0.76	3.65 ± 0.74	3.63 ± 0.83	0.9
3D planimetered annulus area (cm^2)	4.84 ± 1.2	4.5 ± 1.1	5.4 ± 1.1	0.04
Major annular axis (3D)	25.0 ± 1.9	24.3 ± 2.3	26.2 ± 1.9	0.12
Minor annular axis (3D)	21.3 ± 1.7	21.4 ± 1.8	21.2 ± 2.6	0.8
Major-to-minor annular axis ratio (3D)	1.17 ± 0.2	1.14 ± 0.2	1.23 ± 0.3	0.11
Prosthesis size (26 mm) (%)	15 (45.4)	8 (40)	7 (53.8)	0.4
Mismatch index for 2D circular area	−1.02 ± 0.42	−0.96 ± 0.46	−1.13 ± 0.32	0.2
Mismatch index for 3D planimetered area	0.19 ± 0.89	−0.06 ± 0.88	0.65 ± 0.75	0.03

Data presented are n (%) of patients or mean ± SD. AR, aortic regurgitation; BSA, body surface area; EDV, end-diastolic volume; ESV, end-systolic volume; TAVI, transcatheter aortic valve implantation; 2D, two-dimensional; 3D, three-dimensional.

diameter, 2D circular area and derived 'mismatch index', the presence of large eccentric calcifications, or the major-to-minor annular axis ratio obtained by 3D images. In multivariate logistic regression analysis, only the 'mismatch index' for the 3D planimetered annulus area was found to be an independent predictor of significant AR post-TAVI (odds ratio: 10.614; 95% CI: 1.044–17.21; $P = 0.04$). The area under the ROC curve for the 'mismatch index' by the 3D planimetered annulus area was 0.76 (95% CI: 0.54–0.92), whereas for the 'mismatch index' obtained by the 2D circular area, it was 0.36 (95% CI: 0.17–0.55) (*Figure 2*).

The theoretical impact of 3D planimetered annulus area on the prosthesis size

Using the 3D planimetered annulus area as a reference parameter, to decide the prosthetic size the choice would have been different in 21 patients (63%). In seven patients (21%) a larger size of Edwards–Sapien prosthesis would have been implanted and in two patients (6%) a smaller size. Twelve patients (36%) would not have undergone the TAVI procedure because of a too large aortic annulus area except the availability of a larger prosthesis size (*Table 3*). Eight of these twelve patients (66.6%) developed significant AR after TAVI.

Reproducibility

To assess the effect of observer variability and the reproducibility, 2D annulus diameter and 3D planimetered annulus area were measured at a separate time by a second independent blinded observer in all cases. Both investigators were experienced in 2D and 3D TOE. Intra-observer variability was assessed by comparing the measurements given by the same observer after an interval of more than a week between the two measurements. Good intra- and inter-observer agreement for 2D annulus diameter measures was shown (intraclass correlation coefficient of 0.88 and 0.84, respectively), whereas it was excellent for the 3D planimetered aortic annulus area (intraclass correlation coefficient of 0.99 and 0.98, respectively).

Discussion

Our study shows that the 'mismatch index' obtained by TOE 3D planimetry of aortic annulus is the best parameter to assess the prosthesis/annulus discongruence, and it is an independent predictor of significant AR post-TAVI. The 3D TOE planimetry overcomes the limitations of a 2D approach in the assessment of aortic annulus dimensions. To our knowledge, this is the first study in

Table 2 The predictors of post-TAVI significant AR (AR ≥2/4)

	OR	95% CI	*P*-value
Univariate			
Age	1.005	0.892–1.132	0.93
Sex (men)	0.764	0.184–3.169	0.71
Weight	0.966	0.892–1.048	0.4
Height	0.964	0.833–1.116	0.62
BSA	0.129	0.001–32.94	0.46
Peak gradient	0.988	0.961–1.016	0.38
Mean gradient	0.983	0.942–1.025	0.42
Aortic valve area	2.186	0.531–4.540	0.25
Large focal calcifications (>5 mm)	1.627	0.467–5.456	0.31
EDV	1.006	0.990–1.022	0.47
ESV	1.008	0.987–1.029	0.45
Ejection fraction	0.978	0.932–1.027	0.36
2D annulus diameter	0.999	0.750–1.331	0.99
2D circular annulus area	0.979	0.388–2.466	0.96
3D planimetered annulus area	196.36	1.304–295.7	0.03
Major annular axis (3D)	1.16	0.990–1.22	0.13
Minor annular axis (3D)	1.008	0.607–1.49	0.8
Major-to-minor annular axis ratio (3D)	1.325	0.937–1.814	0.11
Prosthesis size (26 mm)	1.627	0.477–5.546	0.43
Mismatch index for 2D circular area	0.323	0.045–2.300	0.25
Mismatch index for 3D planimetered area	3.213	1.073–9.626	0.03
Multivariate			
Age	1.231	0.923–1.826	0.11
Mean gradient	0.924	0.812–1.028	0.19
Aortic valve area	1.651	0.924–2.444	0.12
Large focal calcifications (>5 mm)	1.427	0.347–5.856	0.37
Major-to-minor annular axis ratio (3D)	1.521	0.971–1.977	0.13
Mismatch index for 2D circular area	0.067	0.004–1.644	0.14
Mismatch index for 3D planimetered area	10.614	1.044–17.21	0.04

Results of uni and multivariate logistic regression analysis for detecting.
AR, aortic regurgitation; BSA, body surface area; EDV, end-diastolic volume; ESV, end-systolic volume; OR, odds ratio; TAVI, transcatheter aortic valve implantation; 2D, two-dimensional; 3D, three-dimensional.

which TOE 3D planimetry of aortic annulus is used to assess the prosthesis/annulus discongruence.

In our study, the incidence of significant AR after TAVI was 39.3%. This result is in line with those of the previous studies using the same device where it ranged from 22 to 40%.[7,9] Paraprosthetic AR is also common after conventional surgical valve replacement, but it is usually small, and has a benign course.[21] With surgical valve replacement, the annulus can be measured intraoperatively with sizers. By the interventional approach, it is not possible, and imaging techniques are needed to assess the annulus dimensions pre-procedurally. However, annulus sizing is complex because it is oval rather than being circular.[14] Two-dimensional echocardiography, widely used for the pre-procedural assessment, can provide only a 2D sagital view of the left ventricular outflow tract.[13–15] Two-dimensional-derived diameter is often the minor diameter of an elliptical-shaped annulus, resulting in a significant underestimation of the true aortic annulus area.[14] Three-dimensional TOE can avoid this geometric assumption limitation, allowing direct planimetry of the cross-sectional annular area, which has important clinical implications such as the selection of an appropriate prosthetic valve size. Therefore, 3D TOE is an ideal preoperative imaging modality before TAVI.

In the present study, we demonstrated that circular assumption of aortic annulus with 2D echocardiography leads to a significant underestimation (approximately in 1.2 cm^2) of the 3D planimetered area. To demonstrate the clinical impact and possible correlation with the AR post-procedure, we elaborated the 'mismatch index' that integrates the aortic annulus area and the prosthesis area. Only the 'mismatch index' calculated for the 3D planimetered area was found to be an independent predictor of significant AR post-TAVI. Our data suggest that the choice of the prosthesis size based on 2D annulus diameter may lead to the implantation of undersized valves. The use of the 3D planimetered annulus area in the pre-procedural evaluation would have changed the

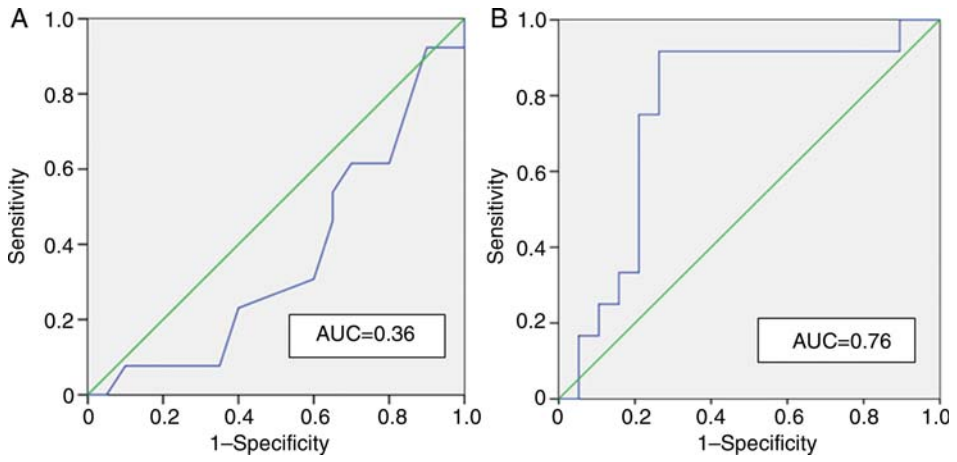

Figure 2 ROC curves for post-TAVI significant AR prediction obtained by 'mismatch index' derived from 2D circular area (*A*) and 3D planimetered area (*B*). AUC, area under the receiver operating characteristic curve; AR, aortic regurgitation; ROC, receiver operating characteristic; TAVI, transcatheter aortic valve implantation; 2D, two-dimensional; 3D, three-dimensional.

Table 3 The impact of the method to assess aortic annulus measurement on the prosthesis size chosen

Echocardiographic measurements	TAVI strategy		
	23-mm prosthesis	26-mm prosthesis	No implantation
2D TOE aortic annulus diameter	18 (54.5%)	15 (45.4%)	0
3D TOE planimetered aortic annulus area	12 (36.4%)	9 (27.2%)	12 (36.4%)

Data presented as number (%) of patients. TAVI, transcatheter aortic valve implantation; TOE, transoesophageal echocardiography; 2D, two-dimensional; 3D, three-dimensional.

TAVI strategy in a substantial number of patients (63%). In addition, 12 patients (36%) would not have undergone the TAVI procedure because of a too large aortic annulus area, most of whom developed significant AR after TAVI (66.6%). This further stresses the importance of avoiding any undersizing of the prosthesis. This problem can be currently overcome, since Edwards has recently made available a 29 mm device. Our data suggest that pre-TAVI assessment by 3D TOE would improve the prosthesis size selection and its use in clinical practice, concomitant with the availability of larger prosthesis sizes and the increase in the balloon inflation volume might reduce the incidence or significant AR post-procedure, leading to a better outcome of patients undergoing TAVI.

Study limitations

Several limitations of this study should be mentioned. It is a descriptive study of retrospective nature in a single centre. The relatively small number of patients studied ($n = 33$) is a limitation. Conclusions of the present study were obtained with a balloon expandable prosthesis and might not be valid with other devices. We did not perform multislice computed tomography, which is considered 'the gold standard' method to assess the aortic annulus area. Nevertheless in a previous study, the 3D planimetered aortic annulus area has been showed to have a good agreement with that obtained by multislice computed tomography.[14]

Conclusions

This study shows that the lack of congruence between the prosthesis and annulus size, assessed by 3D TOE annulus planimetry, is a strong determinant of paravalvular AR after TAVI. The circular area obtained by 2D TOE annulus diameters leads to a significant underestimation of the actual aortic annulus area. Pre-TAVI assessment by 3D TOE may improve the prosthesis size selection and its use in clinical practice associated with the availability of larger prosthesis sizes might reduce the incidence or significant AR post-TAVI.

Conflict of interest: none declared.

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