CARDIOLOGY

Balloon Sizing for Transcatheter Aortic Valve Implantation Using 3rd Generation Valves, Does It Still Work?

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ABSTRACT

Background: **For transcatheter aortic valve implantation (TAVI), accurate determination of valve size is crucial. Multidetector Computed Tomography (MDCT) is considered gold standard, however sometimes there are conflicting measurements or aortic annulus is ambiguous between 2 prosthesis sizes. In such cases balloon sizing can serve in selecting valve size.**

Methods: **110 patients were prospectively enrolled. Aortic annular diameter was measured by 2D TEE. Balloon sizing was done with balloons equal or 1 mm smaller than TEE measurements. Supra-aortic angiography was performed during balloon inflation. Contrast regurgitation and balloon movement indicated annulus size underestimation, balloon wasting indicated annulus size overestimation. Valve size selection was based on balloon sizing. Agreement between 2D TEE and balloon measurements was calculated. Inhospital outcomes related to valve sizing and routine predilation were determined.**

Results: **TEE was correctly sizing the valve in 81% of patients, oversizing in 17% and undersizing in only 2% compared with balloon sizing. Agreement between 2D TEE and balloon sizing measurement yielded a K value of 0.71. Hemodynamic instability after balloon sizing was observed in 2 patients, valve embolization occurred in one patient, no case of aortic rupture or coronary occlusion was detected. Two patients needed a second valve. Stroke rate was 0.9%, inhospital mortality was 1.8%. At hospital discharge, rate of significant PVL (≥ grade II) was 3.4% and pacemaker implantation rate was 6.4%.**

Conclusions: **Balloon sizing based on 2D TEE annular measurements represents an appropriate approach for selecting valve size with favorable outcomes.**

KEY WORDS

Aortic stenosis, Balloon Valvuloplasty, Evolut PRO, SAPIEN 3, Paravalvular leakage

INTRODUCTION

Over the last few years, transcatheter aortic valve implantation (TAVI) has become the treatment of choice for patients with symptomatic severe aortic stenosis[1]. For TAVI, measurement of the aortic annulus is crucial, since both, over- and underestimation of valve size may lead to deleterious complications like significant paravalvular leakage (PVL), annular rupture, etc.[2].

Multidetector computed tomography (MDCT) is now considered the gold standard[2]. However, there are sometimes discrepancies in MDCT measurements among different softwares and vendors[3], or sometimes measurements of the aortic annulus are ambiguous between 2 different prosthesis sizes[4].

Balloon sizing during balloon aortic valvoplasty (BAV) represents a simple and quite effective method to determine aortic annular size, particularly in ambiguous cases[4]. However BAV is claimed in some studies to be associated with adverse effects, such as haemodynamic instability; embolic events and increasing permanent pacemaker implantation (PPI) but most of these studies lack randomization thus, it is possible that BAV might has been selected for more complex cases and exclusively used balloon expandable valves[5].

In this study, we assessed inhospital outcomes of TAVI procedures exclusively based on a 2D transesophgeal echocardiography (TEE) guided balloon sizing approach and used 3rd generation transcatheter heart valves (THV) including both balloon expandable and self-expandable valves. These outcomes included both primary success and complications potentially related to both sizing and routine BAV like stroke or heart block. In our study, patients were selected randomly.

METHODS

Study population

The study was approved by the local ethics committee. One hundred

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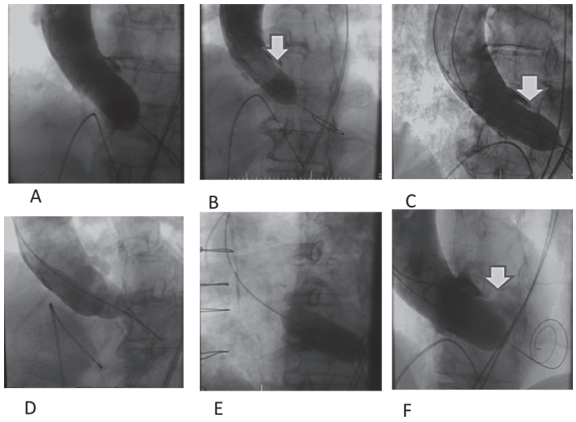

Figure 1: Technique of balloon sizing: A: balloon fits well in annulus with no waist or PVL indicating proper sizing, B &C: shows waist on balloon indicating smaller annulus, D&E: balloon moves up and down indicating larger annulus, F: shows regurgitation around balloon indicating also larger annulus.

and ten consecutive patients with severe symptomatic aortic stenosis receiving transfemoral TAVI at Duisburg Heart Center, Duisburg, Germany, were prospectively enrolled.

TEE measurements

Aortic annular diameters were obtained in the 3-chamber long-axis view at an angle of approximately 120° from junction of the aortic leaflet with septal endocardium anteriorly to the junction of the leaflet with mitral valve posteriorly, measured from inner edge to inner edge[6].

Balloon sizing

The size of the valvuloplasty balloon Edwards® balloon (Edwards Lifesciences Inc., Irvine, California) or VACS® III (OSYPKA, Germany)) was chosen usually equal or 1mm less than annulus size determined by TEE. Balloon inflation was done during rapid ventricular pacing and aortic angiography was performed in a left anterior oblique projection with slight cranial or caudal angulation over a 5-F pigtail catheter. The following parameters were recorded: (I) presence of aortic regurgitation at full balloon inflation ("para-balloon leak"), (II) presence of a waist on the balloon at the level of the annulus, (III) patency of the coronary artery ostia and their relations with the displaced aortic valve cusps[7]. Contrast regurgitation into the left ventricle and free movement of balloon indicated annulus size underestimation by TEE (so the annulus is 1-2 mm larger than TEE measurement), waisting of the balloon indicated annulus size overestimation (so the annulus is 1-2 mm larger than TEE measurement). Balloon size and angiographic features during full inflation were used to determine "true" annular size (Figure 1). Also patency of left main artery (LM) ostium was noted (Figure 2). A cover index according to balloon sizing was defined as 100 x [(prosthesis diameter-annulus diameter determined by balloon sizing) / prosthesis diameter].

Valve size was derived from annular size as specified by the manufacturers. Valve type was chosen randomly and was either balloon expandable SAPIEN 3 (Edwards Lifesciences Inc., Irvine, California) or self-expandable Evolut PRO valve (Medtronic Inc., Minneapolis, Minneapolis). .

PVL assessment

Residual PVL was graded qualitatively by the amount of regurgitating contrast medium during aortic angiography after final device deployment using the Sellers criteria[8] : 0/4 (absent); 1/4 (mild) ; 2/4 (moderate); 3/4 (moderate to-severe); and 4/4 (severe). Invasive measurement of transvalvular pressure gradients was done by pull back technique. The aortic regurgitation index (AR index) defined as the ratio of the gradient between diastolic aortic pressure and left ventricular end-diastolic pressure (LVEDP) to systolic blood pressure x 100 was also calculated[9].

In case of significant PVL ≥ grade II, balloon postdilation using VACS®)III or NUCLEUS balloon (NuMED, NY, USA) was applied.

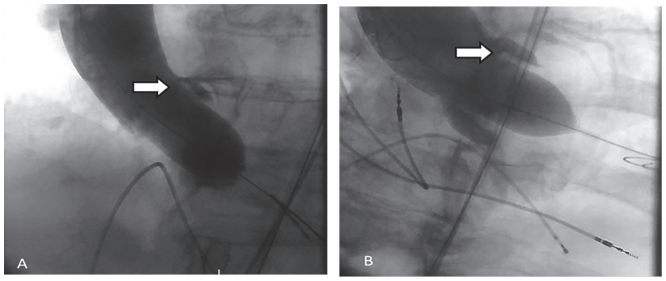

Figure 2: Relation of aortic valve leaflet to LM ostium during BAV: A: native valve leaflet reaches LM ostium without occlusion B: leaflet doesn't reach LM ostium. (LM: left main).

Transthoracic echocardiography was performed predischarge to quantify PVL according to main VARC criteria[10].

Assessment of anatomical factors facilitating complications, especially PVL

All measurements were supported by Philips software (Philips Medical, Eindhoven, Netherlands): *Angle between LVOT and ascending aorta*, i. e., axis of the first 4 cm of the ascending aorta and the LVOT axis (represented by a line perpendicular to the plane of the aortic valve annulus)[11]. Aortic angulation (AA), defined as the angle between the horizontal plane and the plane of the aortic annulus[12]. Both angles were measured in the optimal fluoroscopic deployment position with all three coronary cusps in the same plane. *Depth of valve implantation*: Distance from the native aortic annular margin on the side of both, NCC and LCC to the most proximal edge of the deployed valve on the corresponding side, measured in deployment position on fluoroscopy[13] (Figure 3). *Fluoroscopic aortic root calcification assessment*: none; mild (small isolated calcification spots); moderate (multiple large calcification spots); or severe (extensive calcification)[14]. Presence or absence of LVOT and mitral annular calcification was also noted.

All clinical outcomes/complications were assessed and compiled with the VARC definition criteria[10].

Statistical analysis

SPSS (Statistical Package for the Social Science, version 20, IBM, and Armonk, New York) was used. Continuous data was expressed as mean ± SD or median (range), nominal data as frequency (percentage).

Chi^2 test was used to compare nominal data, continuous data was compared using student's t test. Agreement between TEE and balloon valve sizing was evaluated by Bland-Altman plot and K degree. Univariable and multivariable logistic regression analyses were performed for possible fluoroscopic and procedural predictors of significant immediate PVL. Level of confidence was kept at 95%, p value was considered significant if < 0.05.

RESULTS

Study population

Baseline clinical characteristics of the study group were typical of a TAVI population. Demographic data are summarized in table 1

Baseline electrocardiographic findings

The majority of patients (79%) had no conduction disturbances at baseline. Pre-existing right bundle branch block (8.2%) was somewhat more common than left bundle branch block (3.6%). Eight patients (7.3%) had paced ECG rhythm, 49 (44.5%) were in sinus rhythm and 53 (48.2%) had atrial fibrillation.

Echocardiographic findings

All patients had severe aortic stenosis, mean pressure gradient was 42.6 ± 8.9 mm Hg. Low flow low gradient aortic stenosis was diag-

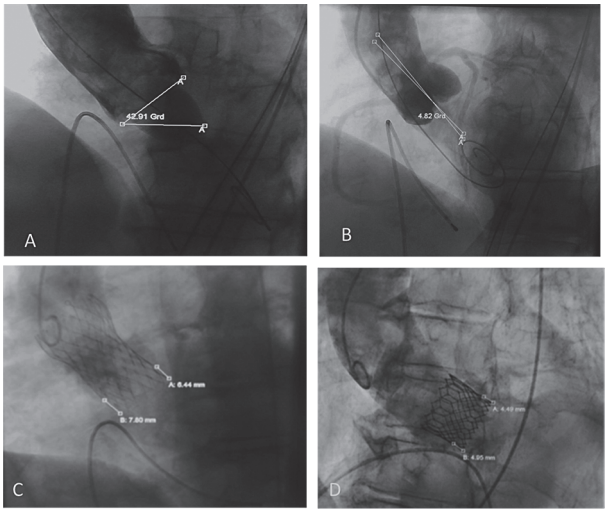

Figure 3: Fluroscopic measurements, A: AA angle, B: LVOT/AO angle, C: depth of implanation of Evolute PRO valve and D: depth of implantation of SAPIEN 3. AA: ascending aorta, LVOT: left ventricular outflow tract, AO: ascending aorta.

Table 1: Baseline clinical characteristics of enrolled patients

	N = 110
Age (years)	81.85 ± 6.12 Range (64-98)
Male gender	63 (57.3%)
Body mass index (kg/m^2)	27.60 ± 4.82
Body surface area (m^2)	1.19 ± 0.29
Hypertension	37 (33.6%)
Diabetes mellitus	55 (50%)
Ischaemic heart disease	58 (52.7%)
Previous revascularization	
CABG	7 (6.4%)
PCI	34 (30.9%)
CABG/PCI	2 (1.8%)
Cerebrovascular stroke	6 (5.5%)
Peripheral artery disease	10 (9.1%)
Previous pacemaker	9 (8.2%)
Chest diseases	
Asthma	1 (0.9%)
COPD	10 (9.1%)
Lung cancer	2 (1.8%)
OSAS	6 (5.5%)
NYHA class	
II	16 (14.5%)
III	89 (81.8%)
IV	4 (3.6%)
STS score	3.66 ± 2.39
STS class	
low	69 (62.7%)
Intermediate	34 (30.9%)
High	7 (6.4%)
Laboratory data	
Hemoglobin (g/dl)	12.04 ± 1.58
Glomerular filtration rate (ml/minute)	60.65 ± 20.94
Creatinine (mg/dl)	1.13 ± 0.52

Data expressed as frequency (percentage), mean (SD). CABG: coronary artery bypass grafting; PCI: percutaneous coronary intervention; COPD: chronic obstructive pulmonary disease; OSAS: obstructive sleep apnea syndrome; STS: society of thoracic surgery risk score

nosed in 30 patients (27.3%). Mean left ventricular ejection fraction was 50 ± 12 %. Twelve patients (10.9%) and 8 patients (7.3%) had moderately and severely impaired left ventricular function respectively. TEE findings are summarized in table 2.

Pre-TAVI fluoroscopic assessment of aortic root

During left and right heart catheterization, no or only mild aortic root calcification was noted in 69.1% of patients, moderate calcification in 27.3% and severe calcification in 3.6%. The LVOT / AO angle was measured at 13.8 ± 5.2 °, the AA angle at 47.0 ± 10.4 °. Mitral annular calcification was found in 17% of patients.

Procedural data

procedural data are summarized in table3.

Agreement between TEE and balloon annular sizing for final valve size selection

TEE correctly sized the valve in 89 (81%) patients, suggested a larger size in 19 (17.2 %) and a smaller size in only two cases. Agreement between 2D-TEE and balloon sizing was strong with K value of 0.71 and mean difference of -0.5mm (Figure 4).

Paravalvular leakage after TAVI

Relevant PVL (≥ grade II) immediately after implantation was relatively uncommon (14 cases, 13%) and usually treated by post-dilatation, leaving 4 patients with grade II and one patient with grade III regurgitation. One patient (Evolut PRO) showed progression of PVL grade I (immediately after procedure) to grade III PVL on the 2nd day and was managed by implantation of second valve (SAPIEN 3). At hospital discharge significant PVL was presented in only 4 patients (3.6%) (3 in Evolut PRO valve and only one in SAPIEN 3 group).

Factors possibly related to PVL

As demonstrated in table (4) moderate and severe valvular calcification, LVOT calcification, LVOT/AO angle and valve type (Evolut PRO valve) seem to be related to PVL. Cover index was larger in patients with ≥ grade I PVL, excluding valve sizing as a contributor to PVL in this patient group. Multivariate regression analysis revealed LVOT/AO angle to be the only predictor for ≥ grade I immediate PVL (odds ratio 1.16, 95% confidence interval 1.03-1.30, $p < 0.001$).

Other inhospital outcomes

Only 7 patients (6.4%) developed complete heart block requiring pacemaker implantation. LBBB occurred in 8 (7.3%). For SAPIEN-3 valves, depth of implantation was significantly higher in patients with conduction defects. No other factors have been found to be associated with conduction defects. Also with multivariate regression analysis, it was noticed that there weren't predictors in the current study for post-procedural conduction defects.

Again there was no significant differences in cover index (%) between 2 groups (14.47 ± 5.90 vs 13.02 ± 5.64, P value = 0.31) according to balloon sizing in patients with and without new onset conduction defects respectively, suggesting that valve sizing was appropriate and not associated with increasing risk of conduction defects.

Other Major complications were infrequent and ranged from acute kidney injury (4.5%), major vascular complications (3.7%), need for 2nd valve (1.8%), stroke (0.9%), valve embolization (0.9%) , inhospital mortality (1.8%). No detected cases of annular rupture.

DISCUSSION

We found that 2D TEE measurements of the aortic annulus match with the results of balloon sizing in about 80%.It was also demonstrated that a routine TAVI approach using 2D TEE, and balloon sizing yields favourable results with a low incidence of complications (eg PVL, heart block, etc..)

Balloon sizing implicates predilatation, and predilatation might increase the risk of stroke, annular rupture and conduction defects. On the other hand, predilatation offers several advantages: it helps to assess

Table 2: Transesophageal echocardiographic findings among enrolled patients

	N= 110
Valve morphology	
Tricuspid	110 (100%)
Aortic measurements	
Aortic valve area (mm)	0.69 ± 0.14
Annulus (mm)	24.15 ± 2.04
Left ventricular outflow tract (mm)	21.39 ± 3.72
Sinus of Valsalva (%)	30.94 ± 3.72
Sinotubular junction (mm/m^2)	26.18 ± 3.29
Ascending aorta (mm)	33.47 ± 3.29
Distance of STJ/LVOT (mm)	19.74 ± 7.49
Basal septal hypertrophy	20 (18.2%)

Data expressed as frequency (percentage), mean (SD). STJ: sinotubular junction; LVOT: left ventricular outflow tract

Table 3: Procedural data among enrolled patients

	N = 110
Route	
Right femoral	66 (60%)
Left femoral	44 (40%)
Type of valve	
SAPIEN 3	59 (53.6%)
Evolut PRO	51 (46.4%)
Annulus by TEE	24.15 ± 2.04
Size of balloon	22.15 ± 1.89
Balloon sizing	23.50 ± 1.86
Final valve size based on balloon sizing	
SAPIEN 3	18 (30.5%)
23	27 (45.8%)
26	14 (23.7%)
29	
Evolut Pro	22 (43.1%)
26	29 (56.9%)
29	
Balloon derived Cover index (%)	13.74 ± 5.72
AR index (%)	29.67 ± 7.64
Depth of implementation (mm)	
Evolut PRO	
LCC	5.75 ± 2.32
NCC	6.25 ± 2.48
SAPIEN 3	
LCC	4.24 ± 1.71
NCC	5.27 ± 1.66
Postdilation	11 (10%)

Data expressed as frequency (percentage), mean (SD). TEE: transoesophageal echocardiography, LCC: left coronary cusp, NCC: non coronary cusp.

the risk of coronary obstruction during TAVI which result from displacement of native valve leaflets over the ostia[15]. So far, there are no definite anatomical criteria to identify patients at high risk of coronary obstruction[16]. Appreciating the functional interaction of the displaced leaflets with the coronary ostia during BAV, the operator may decide to abort the TAVI procedure or consider preventive measures like guidewire engagement of the ostium at risk or selection of a specific type of THV[17]. Predilatation also facilitates deliverability of the valve system and optimal valve deployment, thereby reducing the risk of PVL and the need for postdilatation. Postdilatation carries a risk of device migration or annulus rupture and may affect long-term valve durability[17]. Finally, predilatation may help to identify patients with severe focal calcifications prone to troublesome TAVI procedures. Condado *et al*.[14] found that calcium-related leakage during balloon sizing in spite of complete filling of the sinuses of Valsalva by the balloon may identify patients at higher risk for annular rupture. At present, there are some studies favouring direct TAVI instead of routine predilatation. However, most of these studies were non-randomized and exclusively used balloon expandable valves[5].

Valve size selection

Most studies comparing 2D TEE with MDCT[18] found that 2D TEE underestimates annular dimension. In our study, comparing 2D TEE with balloon sizing, overestimation (17%) was more common in the former than underestimation (1.8%). Similarly, Patsalis *et al*.[4] reported 2D TEE overestimation in 10% of patients. Comparing MDCT measurements with balloon sizing, Condado *et al*.[14] revealed a mismatch in 34.0% of patients, with 20% receiving a smaller valve based on balloon sizing. They also found that differences in LVOT morphology may contribute to discordant measurements. The long and homogenous sealing zone of a tubular LVOT (type A) can be accurately determined by MDCT measurements. When the LVOT is funnel- (type B) or trumpet-shaped (type C), MDCT may overestimate (type B) or underestimate (type C) the size of the landing zone. Wang *et al*.[19] compared aortic annulus size measurements obtained by 2D TEE and MDCT to direct intraoperative measurements and found that MDCT overestimated annulus size in 72% and valve size in 46% of cases, whereas TEE underestimated annulus size in 51% and valve size in 17%. Obviously, TEE does not always undersize inappropriately compared to MDCT and MDCT does not always oversize the annulus appropriately.

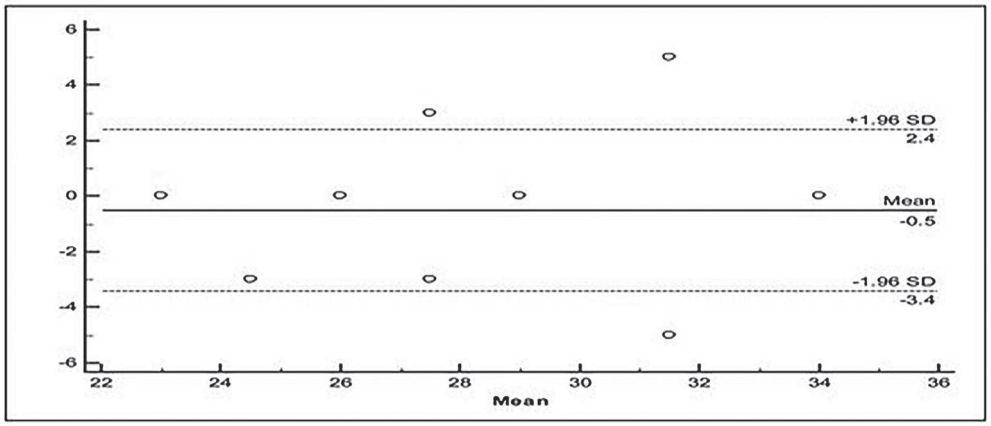

Figure 4: Bland-Altman plot comparing valve size determined by balloon sizing and 2D TEE. Mean difference of -0.50 with limits of agreement of -3.4 to 2.40 (both types of valve). TEE: transesophgeal echocardiography.

Table 4: Anatomical and procedural factors related to paravalvular leakage.

	No/trace (n = 65)	≥ grade I (n = 45)	*P* value
Valvular calcification			**0.03**
Mild	51 (78.5%)	25 (55.6%)	
Moderate	13 (20%)	17 (37.8%)	
Severe	1 (1.5%)	3 (6.7%)	
Sinuotubular calcification	3 (4.6%)	5 (11.1%)	0.17
LVOT calcification	3 (4.6%)	14 (31.1%)	< 0.001
Mitral annular calcification	9 (13.8%)	10 (22.2%)	0.18
LVOT/AO angle (–)	12.64 ± 4.79	15.56 ± 5.20	< 0.001
AA angle (–)	46.78 ± 11.96	47.31 ± 9.36	0.80
Type of valve			**< 0.001**
Evolut- PRO valve	19 (29.2%)	32 (71.1%)	
SAPIEN-3 valve	46 (70.8%)	13 (28.9%)	
Cover index (%) according to balloon sizing	11.50 ± 5.04	15.83 ± 5.63	< 0.001
AR index (%)	31.79 ± 6.67	26.60 ± 7.98	< 0.001
Depth of implementation (mm)			
Evolut PRO			
LCC	5.86 ± 2.46	5.68 ± 2.27	0.79
NCC	6.33 ± 2.37	6.20 ± 2.58	0.85
SAPIEN 3			
LCC	4.15 ± 1.56	4.57 ± 1.57	0.43
NCC	5.21 ± 1.57	5.50 ± 1.99	0.57

Data expressed as frequency (percentage), mean (SD). *P* value was significant if < 0.05.
PVL: paravalvular leakage; LVOT: left ventricular outflow tract; AO: aorta

Paravalvular leakage

In our study, the incidence of PVL was quite low and comparable to similar studies using MDCT for valve sizing. Hagar *et al*.[20] reported an incidence of 5.5% for moderate PVL and of 0.7% for severe PVL, postdilatation was needed in 45% of patients. Condado *et al*.[14] found an overall rate of ≥ moderate PVL of 6.3% for balloon sizing and of 7.3% for MDCT sizing, with a need for postdilation in 46% of cases. More recent studies with the SAPIEN 3 valve described an incidence of PVL ≥ II around 2% at hospital discharge, which is comparable to the SAPIEN 3 subgroup in our study (1.6%)[21]. Importantly, pre-dilation was performed in the majority of cases (98%), and post-dilatation was required in 38%[21]. Thus, balloon predilation may play a role in reducing PVL by optimizing valve deployment beyond optimal sizing.

Predictors of PVL

Based on multivariate regression analysis, the only predictor for ≥ grade I immediate PVL in our study was LVOT/AO angle. Other investigators[20] found calcification volume and prosthesis type (self-expandable versus non-self-expandable) to be independent predictors of ≥ mild PVL after TAVI. However, the majority of patients received a self-expandable prosthesis. Hence, it seems difficult to conclude that a certain prosthesis type predicts PVL. As in our study, Sherif *et al*.[11] observed that LVOT/AO angle predicts significant PVL, in univariate as well as in multivariate analysis. However, different from our study, the depth of implantation also seemed to be of relevance. One might speculate that depth of implantation was appropriate in all our patients and that improved technology of 3rd generation THV with proper sealing skirts reduces the risk of PVL.

Composite of adverse events with the balloon sizing approach

An incidence of 12% regarding the composite of adverse events (annular rupture, PVL, need for 2nd valve, conduction defects requiring pacemaker implantation) in our study compares well to the results of Condado *et al*.[14] who reported an incidence of 14.7% in their balloon sizing group and of 13.9% in their MDCT sizing group.

Theoretically, predilatation could increase the risk of damage to the conduction system and the need for permanent pacemaker implantation (PPI) after TAVI. Still, a PPI rate of 6.4% in our study fits well with comparable studies. When comparing TAVI with and without predilatation, Bonaros *et al*.[22] as well as Schymik *et al*.[5] noticed a similar incidence of conduction defects for both groups.

Predictors of conduction defects

As mentioned before only depth of implantation, in case of SAPIEN-3 valve, correlated significantly to conduction defects in our study in univariate regression analysis but by multivariate regression analysis, there weren't predictors for post-procedural conduction defects. Maeno *et al*.[23] described a higher incidence of PPI with SAPIEN 3 valves compared to SAPIEN XT valves and a significant relation to depth of implantation. However, this finding might have been specific to the type of valves used.

Risk of coronary occlusion

In our study, predilatation was applied in all patients. The relation of the displaced native valve leaflets to the coronary ostia obtained from angiography during full balloon inflation was noticed. We did not observe any coronary occlusion. This is reassuring, keeping in mind that we were primarily unaware of all anatomical details of the aortic root, since preprocedural MDCT was not done.

Risk of stroke

Incidence of clinically evident stroke was 0.9%. Subclinical insults were not excluded by routine MRI. Due to the additional manipulations, predilatation may increase the risk of aortic wall and calcific valve tissue embolization. On the other hand, balloon inflation may fragment calcific debris present on a heavily calcific aortic valve, stabilize such debris through a homogeneous apposition onto aortic leaflets and, thereby, reduce embolization during valve implantation[24]. Studies evaluating cerebral embolic load during TAVI using transcranial Doppler suggest a low incidence of microembolizations during predilatation, but a high embolic load during prosthesis deployment[17]. In general, stroke rates are less with new generation devices, whether using predilatation or not[25].

Hemodynamic instability

Predilatation may lead to acute severe aortic regurgitation leading to hemodynamic instability, a complication occurring in 2 of our patients. This complication can only be handled by rapid preparation and implantation of an aortic valve, indicating that planned exclusive balloon valvuloplasty in a setting not prepared for bail-out valve implantation may carry considerable risk. On the other hand, predilatation facilitates subsequent valve implantation, thereby reducing the risk of haemodynamic instability during valve deployment[26].

Acute kidney injury and mortality

In-hospital mortality (1.8%) and incidence of acute kidney injury (4.5%) in our study were as low as in other series. There is no evidence that the sizing modality (2D TEE, MDCT, balloon sizing) or the TAVI approach (with or without predilatation) affects these parameters. This was shown by Condado *et al*.[14] with respect to MDCT and balloon sizing and by Schymik *et al*.[5] regarding TAVI with or without predilatation.

CONCLUSION

Balloon sizing based on 2D TEE measurements of the aortic annulus constitutes an appropriate approach for transcatheter valve size selection with favorable outcomes especially in the era of 3rd generation THV. This relates to both, balloon expandable and self-expandable THVs. Balloon sizing should at least be considered complementary to MDCT especially in borderline cases and in patients with high risk of LM artery occlusion.

LIMITATIONS

The operators have a long term experience with balloon sizing. Thus, some training with qualified TAVI team is necessary to master this technique. We did not compare balloon sizing with CT which is considered the gold standard. Unblinded CT measurements would have biased our balloon sizing judgement. Blinded CT measurements would have raised ethical questions given the exposure to radiation and additional contrast dye. Not using CT scans, assessment of aortic root calcifications had to depend on fluoroscopy. We exclusively relied on inhospital outcomes, trusting that typical complications related to valve sizing are well reflected within early postprocedural phase.

CONFLICTS OF INTEREST

The authors report no financial relationships or conflicts of interest regarding the content herein.

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