Symposium: Transcatheter aortic valve implantation

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Guest Editor: Prof. Khalil Fattouch

Prognostic value of the ratio between prosthesis area and indexed annulus area measured by MultiSlice-CT for transcatheter aortic valve implantation procedures

Nicolas Debry[1], Arnaud Sudre[1], Ibrahim Elquodeimat[1], Cédric Delhaye[1], Guillaume Schurtz[1], Antoine Bical[1], Mohamad Koussa[1], Khalil Fattouch[2], Thomas Modine[1]

[1]Heart Team, Lille University Hospital, Lille, France
[2]Department of Cardiovascular Surgery, GVM Care and Research, Maria Eleonora Hospital; Department of Surgery and Cancer, University of Palermo, Palermo, Italy

Abstract

Background   Postprocedural aortic regurgitations following transcatheter aortic valve implantation (TAVI) procedures remain an issue. Benefit of oversizing strategies to prevent them isn't well established. We compared different level of oversizing in our cohort of consecutive patients to address if severe oversizing compared to normal sizing had an impact on post-procedural outcomes. **Methods**   From January 2010 to August 2013, consecutive patients were referred for TAVI with preoperative Multislice-CT (MSCT) and the procedures were achieved using Edwards Sapien® or Corevalve devices®. Retrospectively, according to pre-procedural MSCT and the valve size, patients were classified into three groups: normal, moderate and severe oversizing; depending on the ratio between the prosthesis area and the annulus area indexed and measured on MSCT. Main endpoint was mid-term mortality and secondary endpoints were the Valve Academic Research Consortium (VARC-2) endpoints. **Results**   Two hundred and sixty eight patients had a MSCT and underwent TAVI procedure, with mainly Corevalve®. While all-cause and cardiovascular mortality rates were similar in all groups, post-procedural new pacemaker (PM) implantation rate was significantly higher in the severe oversizing group (P = 0.03), while we observed more in-hospital congestive heart-failure (P = 0.02) in the normal sizing group. There was a trend toward more moderate to severe aortic regurgitation (AR) in the normal sizing group (P = 0.07). **Conclusions**   Despite a higher rate of PM implantation, oversizing based on this ratio reduces aortic leak with lower rates of post-procedural complications and a similar mid-term survival.

1   Introduction

Transcatheter aortic valve implantation (TAVI) is the standard treatment for old patients suffering from severe symptomatic aortic stenosis at high or prohibitive risk for surgery.[1,2] Pre-interventional prosthesis sizing relies on aortic Multislice-CT (MSCT).[3] Incorrect prosthesis sizing may result in adverse outcomes such as moderate-to-severe paravalvular aortic regurgitation (AR)[4] and device embolization in case of undersizing,[5] or aortic root rupture[6] and conduction disorders in case of severe oversizing.[7] Moderate to severe AR has been shown to be an independent predictor of mortality[8] and MSCT can predict AR.[9]

While some studies suggest that oversizing based on area appears to provide the best risk-benefit ratio to reduce post-procedural regurgitation and conduction disorders,[10] the impact of different levels of oversizing of the bioprosthetic valve on the aortic annulus is not well understood.[11] Previous studies report early posprocedural outcomes but impact at 1-year follow-up is unknown.[12]

The aim of this study was to report the prognostic value of different grade of oversizing on the mortality and major advert cardiac and cerebral events (MACCE) at 1-year follow-up but also on the post-procedural Valve Academic Research Consortium (VARC-2) criteria,[13] and in particular on aortic regurgitation.

2   Methods

Between January 2010 and August 2013, consecutive patients undergoing TAVI procedure at our institution were

included in a dedicated prospective database. All patients had severe symptomatic aortic valve stenosis (indexed aortic valve area < 0.6 cm^2/m^2) and multiple comorbidities. The institutional multidisciplinary heart teams agreed each patient should proceed to TAVI. All patients gave written informed consent for the procedures.

Patients' clinical characteristics on admission and during follow-up were collected prospectively. All patients underwent transthoracic echocardiography (TTE), coronary angiography, and aortic MSCT, allowing us to determine the most suitable access. Selection of the bioprosthesis, Edwards SAPIEN (Edwards Lifesciences, Irvine, CA, USA), or Medtronic Corevalve (Medtronic Inc, Minneapolis, MN, USA) was determined following aortic root assessment using MSCT.

2.1 Pre- and post-procedural echocardiography

Comprehensive echocardiography was performed before and after TAVI procedure using commercially available Vivid® 7 or 9 (General Electric Healthcare, USA) or a iE33® (Phillips Medical, The Netherlands), to determine annulus diameter as well as to assess general parameters like pressure gradients, mitral valve, and left ventricular function. AR was reported as recommended in the VARC 2 guidelines (regarding the circumferential extent of prosthetic valve paravalvular regurgitation: mild < 10%, moderate 10%–29%, and severe > 30%).

2.2 Pre procedural MSCT.

We used electrocardiographically synchronized (gated) imaging of the aortic root, to avoid motion-induced artifacts. Reconstruction of the annulus was performed orthogonally in relation to the central axis of the left ventricular outflow tract; to analyze minimal and maximal diameters, circumference, and area (Figure 1). Other parameters were also assessed (heights and width of sinus of valsalva, ascending aorta diameters, calcifications, and septum thickness). We used a commercially available and dedicated post processing software (Philips Medical, Eindhoven, The Netherlands; Trimensio® GmBh).

Retrospectively, according to pre-procedural MSCT and implanted prosthesis size, patients were classified into three groups depending on the ratio between the prosthesis area (diameter × diameter × π) and the annulus area indexed on the body surface area and measured on the preprocedural MSCT (Figure 1). Group 1 was the "Normal sizing group (NS)" with a ratio between 1 and 2, Group 2 was the "Moderate oversizing group (MO)" with a ratio between 2.1 and 2.5, Group 3 was the "Severe oversizing group (SO)" with a ratio between 2.6 and 4.
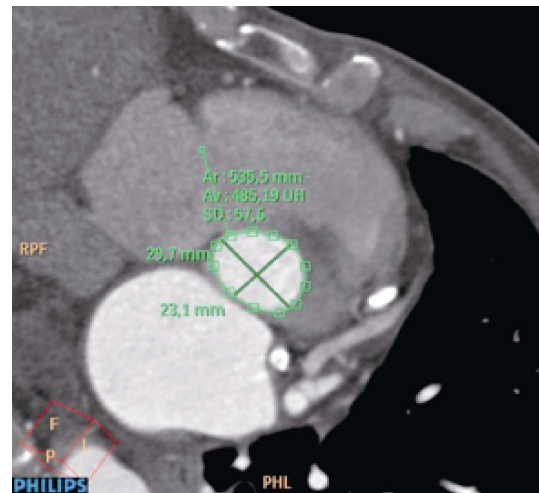

Figure 1. MSCT assessment of annular dimensions (area, short and long diameters). MSCT: MultiSlice-CT.

2.3 TAVI procedure

Standard TAVI implantation technique was followed as previously described.[14] Procedures were performed in a hybrid operative theatre by a multidisciplinary team including anesthesiologists, interventional cardiologists and cardiac surgeons. Patients systematically underwent general anesthesia. Per procedural heparin (0.5 mg/kg) was injected immediately before valve insertion. Deployment of the prosthesis was performed through different access, including femoral, subclavian, carotid, and transapical access. In case of post-deployment angiography showing AR ≥ 2/4, a balloon post-dilation was performed. Significant regurgitations were also sought out through a final control TEE. In case of endovascular procedure, the sheath was removed and the access site closed surgically or thanks to percutaneous closure system.

2.4 Endpoints

The clinical endpoints were defined according to standardized criteria proposed by the Valve Academic Research Consortium updated in 2012 (VARC-2).

The primary endpoints of interest were the 1-year (1) global and (2) cardiovascular mortalities.

Secondary endpoints included long-term survival (ranging from four months to four years) and MACCE at one year (composite of all-cause mortality, major stroke, and myocardial infarction).

Further analyses explored cerebrovascular events (major stroke, minor stroke, transient ischemic attack), myocardial infarction (MI), bleeding (life-threatening and major), acute renal failure, access site complications (major and minor), and new pace-maker implantation.

2.5 Statistical analysis

Statistical analysis was performed by using commercial software (SAS 9.3; SAS Institute, Cary, NC, USA). Results for continuous variables were expressed as means with standard deviations when data were symmetrically distributed or, otherwise, as medians with ranges. The normality of distribution was assessed using Shapiro-Wilk test and normality diagrams. Results for categorical variables were expressed as frequencies and percentages.

Comparative analyses were obtained using the chi-square test for categorical data; when not applicable because of the sample size, the Fisher's exact test was used. For numerical variables, we used the ANOVA test or Kruskal-Wallis test if normality of distribution was not present.

Survivals were calculated by the Kaplan-Meier method, and the differences between groups were compared using the log-rank test. *P* values < 0.05 were considered statistically significant.

3 Results

Between January 2010 and August 2013, *n* = 268 consecutive patients with severe symptomatic aortic valve stenosis were prospectively enrolled in this observational study.

The baseline demographic, clinical, and echocardiographic characteristics of the study population are listed in Table 1.

The mean patient age was 80.6 ± 7.2 years and most 58% (*n* = 156) were female. The average Society of Thoracic Surgeons predicted risk of mortality (STS Prom) score was 6.7% ± 4.8%. There were few differences between the SO group and the two others regarding BMI (*P* < 0.001), STS score (*P* = 0.03) and smaller annulus diameter (*P* < 0.001). Indeed our ratio is calculated with a annulus area indexed on the body surface (STS score take BMI into account).

3.1 Procedural outcomes

General anesthesia was performed in all cases. We had no valve embolization or aortic root rupture. *N* = 201 (75%) Corevalve® devices and *n* = 67 (25%) Edwards Sapien® heart valve were implanted. We used more Corevalve® devices in the SO group than in the other two groups (*P* < 0.001). The series included 7 (2%) cases where a transcatheter valve was placed inside a failing aortic bioprosthesis (*P* = 0.87).

3.2 Post-procedural outcomes

There was a similar in-hospital mortality between groups,

Table 1. Baseline characteristics of the three groups.

	NS (*n* = 89)	MO (*n* = 89)	SO (*n* = 90)	Overall *P* Value
Clinical characteristics				
Age, yrs	82.0 ± 8.1	79.9 ± 7.1	80.1 ± 6.6	0.12
Sex, female	60 (67%)	47 (52%)	49 (54%)	0.09
BMI, kg/m^2	23.5 ± 3.7	26.8 ± 5.6	29.7 ± 6.2$^{\#\$}$	< 0.001*
Euroscore 2, %	5.7 ± 5.0	6.4 ± 7.1	5.9 ± 6.9	0.74
STS score,%	7.7 ± 5.4	6.6 ± 4.7	5.8 ± 4.3$^{\#\$}$	0.03*
Diabetes	22 (25%)	27 (30%)	25 (27%)	0.73
COPD	21 (23%)	23 (25%)	29 (32%)	0.40
NYHA class IV	35 (39%)	26 (29%)	26 (29%)	0.23
Pre procedural PM	10 (11%)	14 (15%)	15 (16%)	0.54
Prior TIA-Stroke	16 (18%)	14 (15%)	10 (11%)	0.40
Prior AF	34 (38%)	39 (43%)	41 (45%)	0.58
Prior renal failure	48 (54%)	51 (57%)	48 (53%)	0.84
Prior Balloon Valvuloplasty	5 (5%)	5 (5%)	9 (10%)	0.44
Prior CABG	10 (11%)	16 (18%)	14 (15%)	0.44
TTE characteristics	-	-	-	-
LVEF, %	53.2 ± 14.7	55.2 ± 13.9	56.8 ± 13.4	0.23
MaxV, m/s	4.33 ± 0.77	4.24 ± 0.67	4.31 ± 0.57	0.69
Aortic valve area, cm^2/m^2	0.43 ± 0.23	0.39 ± 0.11	0.37 ± 0.12	0.34
AR moderate to severe	2 (2%)	2 (2%)	0 (0)	0.35
MSCT characteristic	-	-	-	-
Annulus diameter, mm	25.4 ± 2.9	24.3 ± 2.8	23.7 ± 2.5$^{\#\$}$	< 0.001*

Data are presented as mean ± SD or *n* (%). $^*P$ < 0.05; $^{\#}$SO *vs*. NS, *P* < 0.05; $^{\$}$SO *vs*. MO, *P* < 0.05. AF: atrial fibrillation: BMI: body mass index, CABG: coronary artery bypass graft; COPD: chronic obstructive pulmonary disease; LVEF: left ventricular ejection fraction; MaxV: maximal velocity; MO: Moderate oversizing group; MSCT: MultiSlice-CT; NS: Normal sizing group; NYHA: New York Heart Association; Preproc AR: pre-procedural aortic regurgitation; PM: pace maker; STS: Society of Thoracic Surgeons; SO: Severe oversizing group; TIA: transient ischemic attack; TTE transthoracic echocardiography.

n = 19 (7%) (*P* = 0.10). We found a significant increase in cardiovascular death in the NS group compared to the MO and SO groups (*P* = 0.04). After one month, MACCE occurred more frequently in the NS group (*P* = 0.009). Major bleeding and major vascular complications occurred respectively in 5 (2%) and 18 (6%) patients, with no difference between groups. Cerebrovascular events (transient ischemic attack-TIA and stroke) occurred in 18 patients (6%). New permanent pacemaker was required in 58 (21%), mostly with self-expanding devices (86%). There was also significantly more new pace maker implantation in the SO group than in the NS group (*P* = 0.02). Twenty-nine (10%) patients presented moderate to severe post-procedural aortic regurgitation assessed by TTE, with a significant difference

between SO and NS groups (*P* = 0.03). Aortic regurgitations were similar between Corevalve and Edwards Sapien devices (*P* = 0.70). No prosthesis thrombosis, endocarditis or other valve-associated complications were observed. Post-implantation hemodynamics demonstrated a reduction in transvalvular mean gradient from 42.4 ± 10.1 to 7.5 ± 2.0 mmHg (*P* < 0.001) and an increase in the effective orifice area from 0.80 ± 0.32 cm^2 to 1.74 ± 0.33 cm^2 (*P* < 0.001) with no difference between groups. There were 20 (7%) cases of new onset atrial fibrillation, at the same rate in the three groups (*P* = 0.98).

Interestingly we found more intra hospital-CHF in the NS group (*P* = 0.02). No significant differences between the 3 groups were observed in the incidence of other VARC-defined complications (Table 2).

3.3 Follow-up: mortality and morbidity

Thirty-days mortality was 9% (*n* = 24) with a significant

Table 2. Procedural and in-hospital outcomes.

	NS (*n* = 89)	MO (*n* = 89)	SO (*n* = 90)	Overall *P* value
Procedural characteristics	-	-	-	-
Predilation	83 (93%)	86 (96%)	81 (91%)	0.30
Postdilation	16 (18%)	17 (19%)	16 (18%)	0.98
Femoral access	61 (68%)	60 (67%)	56 (62%)	0.63
Carotid access	12 (13%)	20 (22%)	22 (24%)	0.15
Bioprosthesis diameter, mm	26.8 ± 2.1	27.5 ± 2.1	28.3 ± 1.5$^{#\$}$	< 0.001*
Corevalve® device	53 (59%)	66 (74%)	82 (91%)$^{#\$}$	< 0.001*
Postprocedural outcomes	-	-	-	-
New PM implantation	11 (12%)	23 (25%)	24 (26%)$^{#}$	0.03*
MI	2 (2%)	1 (1%)	0 (0)	0.10
TIA-Stroke	6 (6%)	4 (4%)	8 (9%)	0.53
CHF	11 (12%)	12 (13%)	3 (3%)$^{#\$}$	0.02*
AKI stage 2-3	34 (38%)	34 (38%)	33 (36%)	0.97
Major and minor vascular complications	22 (25%)	25 (28%)	23 (25%)	0.29
All bleedings	25 (28%)	15 (28%)	24 (27%)	0.98
Hospital stay duration, days	12.5 ± 6.4	14.1 ± 8.4	13.5 ± 9.4	0.44
ICU stay duration, days	3.1 ± 3.9	2.6 ± 4.0	3.0 ± 7.4	0.81
Postprocedural TTE	-	-	-	-
AR moderate-severe	15 (15%)	8 (8%)	6 (6%)$^{#}$	0.07
MaxV, m/s	2.01 ± 0.46	2.06 ± 0.52	2.15 ± 0.49	0.20
AVA, cm^2/m^2	1.66 ± 0.41	1.75 ± 0.47	1.82 ± 0.46	0.16

Data are presented as mean ± SD or *n* (%). *P* < 0.05; $^{#}$SO *vs*. NS, *P* < 0.05; $^{\$}$SO *vs*. MO, *P* < 0.05. AKI: acute kidney injury; AVA: aortic valve area; CHF: congestive heart failure; ICU: intensive care unit; LT: life-threatening; MI: myocardial infarction; MO: Moderate oversizing group; NS: Normal sizing group; PM: pace maker; Post-AR: post-procedural aortic regurgitation in angiography; Post-TTE: one week post-procedural transthoracic echocardiography; SO: Severe oversizing group.

increase of mortality in the NS group (*P* = 0.04) and of cardiovascular death in the NS group compared to the oversizing groups (*P* = 0.04). One-month major advert cardiac and cerebrovascular events occurred in 30 patients (11%). We observed more MACCE in the NS group than in the SO group (*P* = 0.01). One MI and two transient ischemic attacks occurred in the NS group. We found no other differences regarding the left and right systolic function (TTE), or new late pacemaker implantation between the three groups (Table 3).

Table 3. One-month outcomes.

	NS (*n* = 89)	MO (*n* = 89)	SO (*n* = 90)	Overall *P* value
Clinical outcomes	-	-	-	-
30-days mortality	13 (15%)	6 (7%)	5 (5%)$^{#}$	0.08
30-days MACCE	16 (18%)	9 (10%)	5 (5%)$^{#}$	0.03*
NYHA class III-IV	5 (6%)	7 (9%)	6 (7%)	0.87
TTE characteristics	-	-	-	-
AR moderate to severe	12 (19%)	7 (10%)	5 (7%)	0.31
MaxV, m/s	1.91 ± 0.46	1.97 ± 0.51	2.03 ± 0.46	0.35
AVA, cm^2/m^2	1.76 ± 0.48	1.78 ± 0.50	1.77 ± 0.49	0.97

Data are presented as mean ± SD or *n* (%). *P* < 0.05; $^{#}$SO *vs*. NS, *P* < 0.05. AR: aortic regurgitation; AVA: aortic valve area; MACCE: major advert cardiac and cerebral event; MaxV: maximal velocity; MO: Moderate oversizing group; Ns: non-significant; NS: Normal sizing group; NYHA: New York Heart Association; TTE; transthoracic echocardiography; SO: Severe oversizing group.

MACCE (*n* = 42, 15%) at 1-year occurred at the same rate between the three groups (*P* = 0.92). One-year global (*n* = 50, 18%) and cardiovascular mortalities (*n* = 39, 14%) were similar in the three groups; *P* = 0.52 and *P* = 0.32, respectively (Figures 1 and 2).

4 Discussions

The impact of different levels of oversizing isn't well understood as it can have positive and side effects on valve implantation and post-procedural outcomes and long-term implications are not known.[15]

This observational study with consecutive patients series evaluate retrospectively the prognostic value of an index reflecting accurately different levels of oversizing on the post-procedural outcomes.

To compare our ratio to previous studies like Blanke, *et al*.[6] were they used the relative difference in diameter between pre-TAVI MSCT mean annulus diameter and nominal diameter of the selected prosthesis, we would have, respectively 6.6% ± 10.4% (NS group), 13.6% ± 9.2% (MO); 20.6% ± 11.4% (SO) with a significant difference
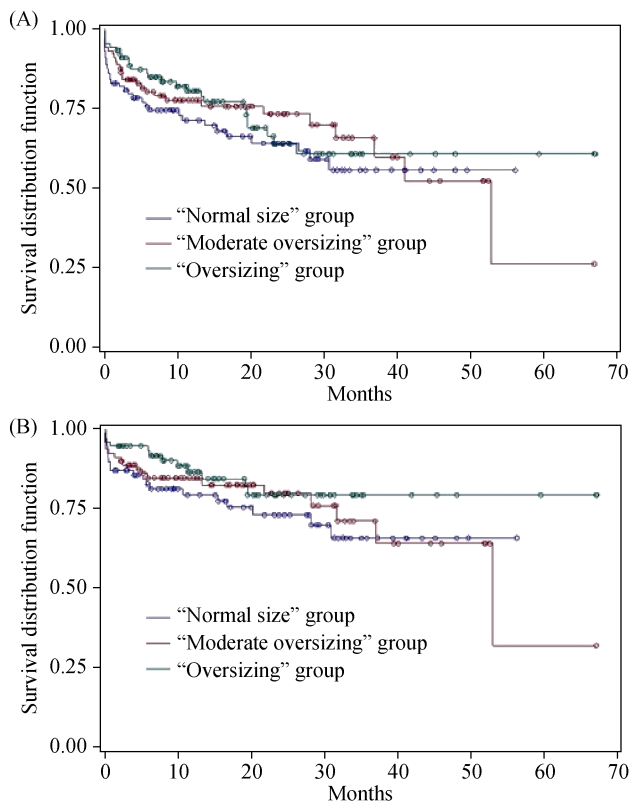
Figure 2. (A) Long-term global mortality; (B) Long-term cardiovascular mortality.

P < 0.0001. Calculated as the relative difference in area between pre-TAVI MSCT mean annulus area and measured valve area of the selected prosthesis, 13.1% ± 17.12% (NS group); 28.7% ± 16.7% (MO); 45.8% ± 39.1% (SO) with *P* < 0.0001.

4.1 Clinical and functional impact

As Hayashida, *et al.*[16] described before, MSCT-guided valve sizing in TAVI significantly reduces the incidence of post-procedural AR compared to TEE sizing, and we tried using such a new index to evaluate retrospectively in our cohort the reality of this assertion.

This is the first study to report the impact of different levels of oversizing on the 1-year mortality and MACCE. We did not observe any differences regarding the global mortality or the cardiovascular mortality whatever the type of valve, reinforcing the idea that oversizing may be a safe and feasible approach in TAVI patients.

Post-procedural new pace-maker implantation rates were significantly higher in the SO group (*P* = 0.02), while we observed more in-hospital congestive heart-failure (*P* = 0.02) in the NS group. We found no aortic root rupture in all groups. We found also more moderate to severe AR in the NS group (*P* = 0.03) as previously reported.[9]

At 1-month the mortality was higher and there was significantly more MACCE in the NS group than in the oversizing groups. Finally we found no differences about the 1-year MACCE (*P* = 0.92) and mortality (*P* = 0.52).

As previously found by Leber, *et al.*[10] aggressive oversizing resulted in decreasing significant AR but induced conductance disorders requiring pacemaker implantations in a significant number of patients. On the other hand, normal sizing was associated with a trend toward higher incidence of immediate post-procedural AR.

The most important finding in the current study is that the incidence of early post-operative complications, except the pace-maker implantation, seems to be higher in the Normal group than in the Oversizing groups, but that benefice tend to fade on the long term with no benefit on the global or cardiovascular mortalities.

4.2 Limitations

First, this non-randomized study reflects the experience of a single center only. We did not compare MSCT to other 3-dimensional imaging techniques like 3D-TEE or MRI.[17] Because this is an MSCT study, the findings may not necessarily be concordant with a TEE study.

Although the MSCT, echographic and clinical data were prospectively collected, this is a retrospective observational study and therefore may be subjected to confounding factors, especially for the long term follow-up. We mostly used Corevalve devices, which are known to provide more complete atrio-ventricular block.[18]

We didn't explore the positioning of the valve, which can impact also on outcomes.

Accurate assessment of paravalvular AR is difficult in the absence of standardized methods and only relies on color flow imaging with direct measures of the number of jets and jet size.

Because of our indexed ratio, we had significantly a lower STS score (take BMI into account), more obese, a bigger prosthesis size and a smaller MSCT annulus area in the oversizing groups.

4.3 Conclusions

Despite higher rate of new PM implantation, severe oversizing (ratio between bioprosthesis area and the annulus area indexed on the body surface measured by MSCT: 2.6 to 4) reduces postprocedural aortic regurgitation and have similar 1-year survival than normal sizing.

Acknowledgments

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