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Effective orifice area and hemodynamic performance of the transcatheter Edwards Sapien 3 prosthesis: short-term and 1-year follow-up

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Aims The Edwards Sapien 3 heart valve prosthesis (S3) is commonly used for transcatheter aortic valve implantation (TAVI) and is available in three sizes. To date no data has been published on the effective orifice area (EOA) and the hemodynamic performance of the three different S3 sizes. The aim of this study was to measure the size-specific EOA and hemodynamic performance of the S3 in short-term and 1-year follow-up.

Methods and results One hundred and thirteen consecutive patients treated by TAVI with a S3 prosthesis at the Heart Clinic Zurich between May 2014 and July 2015 were included. Clinical data were extracted from the Swiss TAVI registry. The EOA was calculated using Doppler echocardiography (peri-interventionally and at discharge) and by 3D-biplane transoesophageal echocardiography (peri-interventionally). Mean transvalvular gradients (dPmean) were additionally calculated with Doppler echocardiography at 30 days and 1 year. Results were analysed separately for the 23 mm ($n = 42$; 37%), 26 mm ($n = 46$; 41%), and 29 mm ($n = 25$; 22%) prostheses. At discharge, the EOAs were $1.6 \pm 0.2\,cm^2$ (23 mm S3), $2.0 \pm 0.2\,cm^2$ (26 mm S3), and $2.7 \pm 0.2\,cm^2$ (29 mm S3), $p < 0.001$. The dPmeans at discharge were 10.9 ± 6.0 mmHg (23 mm S3), 10.4 ± 3.5 mmHg (26 mm S3), and 8.9 ± 2.8 mmHg (29 mm S3), $p = 0.235$, and did not significantly change over time within any of the S3 sizes.

Conclusions Post-TAVI, the EOAs of the three different S3 prosthesis sizes differ significantly, the transvalvular gradients, however, are comparable. Mean transvalvular gradients remain stable over time and document good prosthesis function after 1 year.

Keywords TAVI • Edwards Sapien 3 • effective orifice area • transvalvular gradient • percutaneous aortic valve implantation

Introduction

After mitral regurgitation, aortic stenosis was found the second most common valvular heart disease of people >75 years of age in the USA.[1] Without aortic valve replacement, severe aortic stenosis has a poor prognosis.[2] For patients with a severe aortic stenosis surgical aortic valve replacement is the definitive therapy.[3] However, some of these patients have a high surgical risk due to severe comorbidities and/or high age.[4,5] For these patients the less invasive transcatheter aortic valve implantation (TAVI) is the recommended procedure of choice.[3,6] Furthermore, two recent randomized trials proved that even in patients with an intermediate surgical risk, TAVI has a higher 3-year survival compared with surgical aortic valve replacement.[7,8]

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During follow-up of TAVI patients, assessment of the prosthesis hemodynamic performance and effective orifice area (EOA) is key to assure proper prosthesis function.[9] Due to the prosthesis geometry, the EOA of larger prosthesis is usually bigger and the transvalvular gradients smaller compared with smaller prosthesis, as documented for many surgical valve prostheses.[10] However, for TAVI prostheses, there is a lack of such size specific data even in large randomized trials.[11,12]

One of the latest generations of transcatheter heart valve prosthesis is the balloon-expandable Edwards Sapien 3 (S3). Compared with earlier heart valve prostheses it showed a lower 30-day and 1-year mortality with a lower risk of stroke, vascular complications and paravalvular regurgitation.[13,14] The S3 is available in three sizes (23, 26, 29 mm). To date, however, no data has been published on the EOA and the hemodynamic performance of the different S3 sizes. The aim of this study was to measure the size-specific EOA and hemodynamic performance of the S3 in short-term and 1-year follow-up.

Methods

Patient population

One hundred and thirteen consecutive patients treated by TAVI with the S3 prosthesis between May 2014 and July 2015 at the Heart Clinic Zurich were included. TAVI was performed in patients who had been identified by the heart team of the Heart Clinic Zurich as a moderate or high surgical risk using different risk scores[4,5] and additional parameters such as frailty or age.[15] All patients had a severe aortic stenosis as defined by the current guidelines.[6,16] The appropriate prosthesis size was chosen based on anatomical criteria (described below) and on the recommendation charts provided by Edwards Lifesciences. Clinical data were extracted from the mandatory national Swiss TAVI registry.[17] All patients gave written informed consent for inclusion in the Swiss TAVI registry. The protocol of the Swiss TAVI registry and the protocol of this study were approved by the local ethical committee.

Study design

In this single centre retrospective cohort study we compared the EOA and the transvalvular gradients of the three different Edwards Sapien 3 prosthesis sizes (23, 26, 29 mm) during implantation and at discharge from the hospital, and the transvalvular gradients additionally at 30 days and at 1-year follow-up.

Pre-interventional measurement of annulus diameter and area and aortic valve area

In order to achieve correct prosthetic sizing, the following annular parameters were measured: annulus diameter (D) derived by 2D echocardiography (direct measurement in parasternal long axis view in mid-systole), by CT perimeter ($D = \text{perimeter}/\pi$) and CT area ($D = 2 \times \sqrt{\text{area}/\pi}$). In addition, the annular area was derived by 2D echocardiography [$(D/2)^2 \times \pi$], and direct CT annular measurement. The correct aortic annulus plane on CT was determined using validated software (3mensio Medical Imaging BV, the Netherlands) and current recommendations for CT imaging prior to TAVI.[18] The aortic valve area (AVA) was determined using the continuity equation by transthoracic Doppler-echocardiography.[19]

Measurement of the prosthetic EOA

During peri-interventional assessment, the prosthetic EOA was determined using either Doppler-echocardiography [continuity equation using the velocity-time integral (VTI)][9] or direct planimetry of the orifice during maximum opening in systole using biplane 3D transoesophageal echocardiography (TEE),[20] depending on image quality and contraindications for transgastric imaging. Special care was taken in the correct measurement of the prosthetic annular dimension (diameter of proximal stent-end) to avoid underestimation of the EOA as well as the placement of the Doppler sample volume immediately before the stent (pre-stent) in order to achieve the correct left ventricular outflow tract (LVOT) VTI spectrum (*Figure 1*).[21] The use of both methods was possible in 14 (12%) patients, while in 30 (27%), and in 45 (40%) patients, assessment could only be done by Doppler-echocardiography and by planimetry, respectively. In 24 (21%) patients no quantitative assessment was possible, and good prosthesis function was assumed based on normal leaflet motion and normal transvalvular gradients by invasive measurements. These patients were excluded from the peri-interventional valve gradient data.

For pre-discharge assessment of EOA, only Doppler-echocardiography was used to calculate EOA as described above as image quality was not sufficient for direct planimetry in most cases.

Furthermore the EOA was indexed to the body surface area (EOAi) in order to detect a possible patient prosthesis mismatch (PPM).

Measurement of the hemodynamic performance

To evaluate the hemodynamic performance of the native aortic valve and the valve prosthesis we measured the mean transvalvular gradient (dPmean) by Doppler-echocardiography using the velocity and the modified Bernoulli equation.[19] Parameters influencing the hemodynamic performance such as heart rate, blood pressure, and haemoglobin level were part of the Swiss TAVI registry data.

Statistical analysis

Continuous data are expressed as mean ± standard deviation (SD) or median with range, as appropriate, and categorical data as number and percentage (%). For dependent data we used the repeated measures ANOVA and for independent data the one-way ANOVA. Correlations were analysed with the Pearson product-movement correlation coefficient (r). For the comparison of the 14 patients in whom both methods (VTI, planimetry) to estimate the EOA were possible, linear regression and Bland–Altman analysis were performed. The level of significance was set at a p-value of <0.05. All statistical analyses were performed using SPSS® software (release 23.0, SPSS Inc., Chicago, IL) and Microsoft Excel® (version 2010).

Results

Baseline characteristics

Baseline characteristics are summarized in *Table 1*. 42 (37%) patients received a 23 mm S3, 46 (41%) a 26 mm S3, and 25 (22%) a 29 mm S3. Female patients had smaller BSA compared with men (1.7 and 1.9 m^2, respectively, $p < 0.001$) and were more likely to receive a 23 mm valve ($p < 0.001$).

Baseline anatomical and hemodynamic data

Echocardiography significantly underestimated annular diameters and area as compared with CT measurements (all $p < 0.001$, see *Table 2*). Area derived CT annular diameter was significantly smaller than perimeter derived CT annular diameter ($p < 0.001$). Women had a smaller CT based on annular area compared with men ($p < 0.001$).

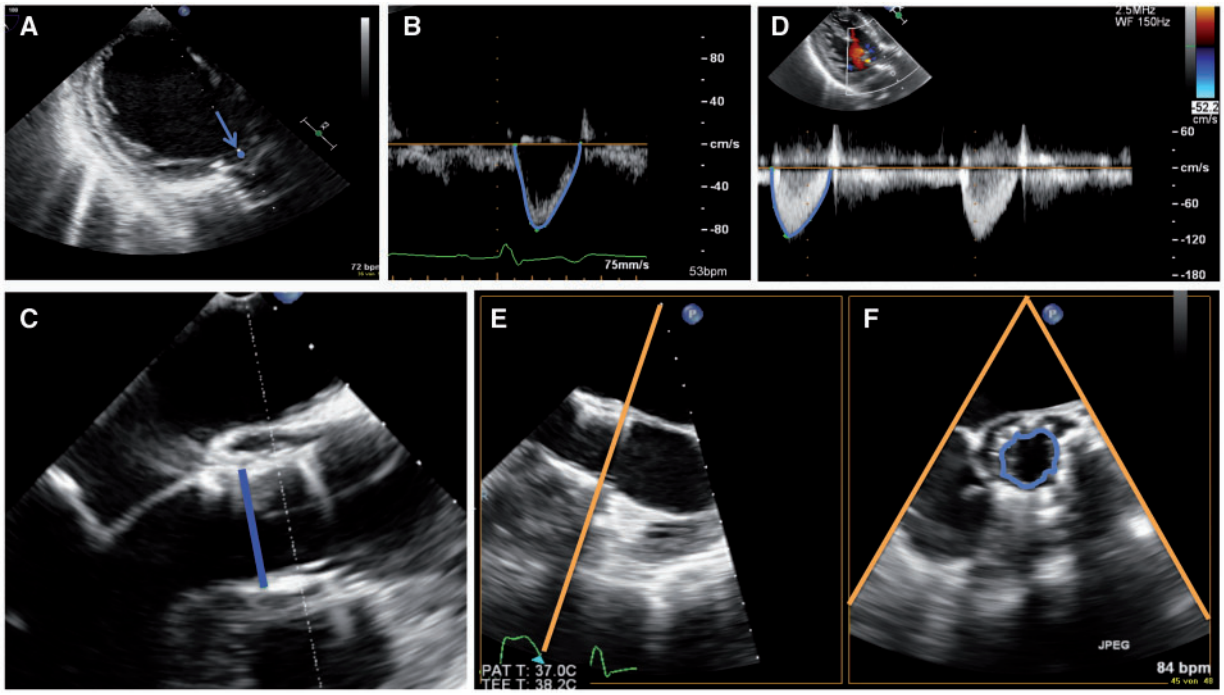

Figure 1 Determination of prosthesis EOA by Doppler- and biplane 3D TEE technology. The annular dimension (in stent diameter at base of leaflet insertion) was established using the higher definition of TEE and then adopted for transthoracic measurement (blue line in *C*). In addition, the sample volume of the pulsed wave Doppler needs to be as close as possible to this annular level (blue arrow and dot in *A*) in order to measure flow at the site of annular dimension. This should result in the largest possible, but still clean-cut envelope just before frazzling of the Doppler-spectrum occurs (*B*). Continuous wave Doppler is used to measure the transvalvular gradient (*D*). When using the planimetry method, the beam for the measuring plane (yellow line) is oriented perpendicular to the leaflet tips and at maximal opening during systole (*E*). The corresponding plane (yellow lines in *F*) then demonstrates the maximal EOA of the prosthesis (blue circular line).

Female gender and small BSA correlated with smaller CT based on annular area (r = -0.398 and 0.408, respectively, both $p < 0.001$).

The baseline AVA and the dPmean are shown in *Table 1*. Baseline AVA and dPmean did not differ significantly between prosthesis groups, and no correlation was found between female gender and AVA or dPmean (r = -0.016 ($p = 0.874$) and -0.077 ($p = 0.435$), respectively). There was a mild correlation between BSA and AVA ($r = 0.308$, $p = 0.002$), but none between BSA and dPmean (-0.028, $p = 0.777$).

EOA and dPmean

Table 3 gives an overview of the EOAs and dPmean of the S3 prosthesis over time.

Peri-interventional results

The mean EOAs of the three different S3 sizes differed significantly among each other during implantation ($p < 0.001$). Despite the differences in EOA among the three available S3 sizes, the dPmean did not differ between prosthetic sizes peri-interventionally ($p = 0.060$). The mean EOA assessed by planimetry tended to be higher than when assessed by continuous equation: 1.8 ± 0.2 cm^2 and 1.7 ± 0.2 cm^2, respectively, for the 23 mm S3, 2.3 ± 0.2 cm^2, and 2.2 ± 0.2 cm^2, respectively, for the 26 mm S3, and 3.1 ± 0.3 cm^2 and 3.0 ± 0.2 cm^2, respectively, for the 29 mm S3. In the subgroup of 14 patients in whom both echocardiographic methods were used to determine the peri-interventional EOA (Doppler-echocardiography using VTI and direct planimetry using 3D TEE), the two measurements correlated well ($r = 0.93$, $p < 0.001$, see *Figure 2*).

Pre-discharge results

The median hospital stay after TAVI was 8.0 days (Range = 57 days). The mean EOAi at discharge was 1.1 ± 0.2 cm^2/m^2 and significantly differed between prosthesis sizes: 0.9 ± 0.2 cm^2/m^2 for S3 23 mm, 1.0 ± 0.2 cm^2/m^2 for S3 26 mm, and 1.4 ± 0.2 cm^2/m^2 for S3 29 mm, $p < 0.001$. 12 (11%) patients had an EOAi < 0.85cm^2/m^2 (mean EOAi was 0.78 ± 0.1 cm^2/m^2). 9 of these 12 patients had received a 23 mm S3, representing 21% of all patients receiving a 23 mm S3. Comparing the patients with a PPM to those without mismatch, the mean transvalvular gradients at discharge were 11 ± 3.4 mmHg vs. 10.2 ± 4.7 mmHg ($p = 0.566$), respectively, and at 30 days 10.7 ± 3.3 vs. 10.5 ± 4.3 ($p = 0.903$), respectively.

The dPmean did not differ between prosthetic sizes at discharge ($p = 0.235$), 30 days ($p = 0.262$), and 1 year ($p = 0.172$). Additionally, dPmean did not significantly differ over time within a given S3 size, ($p = 0.444$ for 23 mm S3, $p = 0.769$ for 26 mm S3, and $p = 0.765$ for 29 mm S3, see *Figure 3*). The mean transvalvular gradients did also not differ significantly over time in patients with a PPM ($p = 0.449$).

Table 1 Baseline characteristics of the study population ($n = 133$)

	Overall ($n = 113$)	23 mm ($n = 42$)	26 mm ($n = 46$)	29 mm ($n = 25$)	*p*-value
Age (years)	83 ± 4.9	83.9 ± 4.6	82.0 ± 4.7	83.4 ± 5.7	0.169
Female sex, *n* (%)	57 (50.4)	38 (90.5)	18 (39.1)	1 (4.0)	<0.001
Euroscore II (%)	4.6 ± 4.5	5.2 ± 3.9	3.3 ± 3.1	5.9 ± 6.7	0.060
STS score (%)	3.8 ± 2.3	4.5 ± 2.7	3.4 ± 2.0	3.2 ± 1.7	0.025
Clinical findings					
Body surface area (m^2)	1.83 ± 0.23	1.70 ± 0.22	1.89 ± 0.19	1.93 ± 0.20	<0.001
Body mass index (kg/cm^2)	26.6 ± 5.1	26.0 ± 5.5	27.1 ± 5.1	26.8 ± 4.5	0.568
Systolic BP (mmHg)	114.8 ± 21.6	117.8 ± 23.8	115.1 ± 17.2	108.4 ± 25.5	0.284
Diastolic BP (mmHg)	57.0 ± 13.3	57.2 ± 15.2	56.6 ± 11.6	57.4 ± 13.6	0.975
Heart rate (bpm)	77.7 ± 21.0	80.9 ± 26.6	77.0 ± 18.1	73.7 ± 13.9	0.380
Atrial fibrillation, *n* (%)	27 (23.9)	6 (14.3)	13 (28.3)	8 (32.0)	0.176
NYHA class III and IV, *n* (%)	76 (67.3)	30 (71.4)	27 (58.7)	19 (76.0)	0.260
Laboratory findings					
GFR (mL/min)	53.2 ± 21.0	46.9 ± 18.9	55.8 ± 20.7	58.4 ± 23.0	0.055
Haemoglobin, g/L	124.5 ± 16.5	121.0 ± 14.6	126.0 ± 17.4	127.4 ± 17.3	0.223
History of					
Diabetes mellitus, *n* (%)	24 (21.2)	7 (16.7)	12 (26.1)	5 (20.0)	0.557
Coronary artery disease, *n* (%)	71 (62.8)	23 (54.8)	33 (71.7)	15 (60.0)	0.249
Myocardial infarction, *n* (%)	12 (10.6)	4 (9.5)	4 (8.7)	4 (16.0)	0.615
Stroke, *n* (%)	14 (12.4)	6 (14.3)	6 (13.0)	2 (8.0)	0.746
Bypass graft surgery, *n* (%)	5 (4.4)	2 (4.8)	0 (0.0)	3 (12.0)	0.063
Percutaneous coronary intervention, *n* (%)	40 (35.4)	11 (26.2)	21 (45.7)	8 (32.0)	0.153
Peripheral artery disease, *n* (%)	13 (11.5)	5 (11.9)	4 (8.7)	4 (16.0)	0.657
Chronic obstructive pulmonary disease, *n* (%)	14 (12.4)	4 (9.5)	5 (10.9)	5 (20.0)	0.424
Pacemaker, *n* (%)	12 (10.6)	3 (7.1)	6 (13.0)	3 (12.0)	0.654
Echocardiographic findings					
≥Moderate mitral regurgitation, *n* (%)	24 (23.1)	10 (26.3)	7 (16.3)	7 (30.4)	0.367
Left ventricular ejection fraction, %	56.1 ± 14.3	57.1 ± 14.3	59.2 ± 12.8	49.0 ± 15.0	0.016
Stroke volume (Doppler), mL	47.8 ± 18.1	40.2 ± 13.3	53.6 ± 21.5	49.9 ± 12.8	0.029
AVA, cm^2	0.8 ± 0.2	0.7 ± 0.2	0.8 ± 0.3	0.8 ± 0.2	0.055
AVA index, cm^2/m^2	0.4 ± 0.1	0.4 ± 0.1	0.4 ± 0.1	0.4 ± 0.1	0.396
Mean transvalvular Gradient, mmHg	39.7 ± 16.1	39.2 ± 15.6	40.0 ± 15.4	40.1 ± 18.7	0.964

STS, The Society of Thoracic Surgeons; BP, blood pressure; NYHA, New York Heart Association; GFR, glomerular filtration rate.

Table 2 Comparison of aortic annulus dimensions with echocardiography and CT

	Echo diameter (mm)	CT (P) diameter (mm)	CT (A) diameter (mm)	*p*-value	Echo (D) area (mm^2)	CT area (mm^2)	*p*-value
Total ($n = 113$)	22.2 (2.2)	24.4 (3.0)	23.8 (2.5)	<0.001	390.0 (76.9)	450.3 (96.4)	<0.001
23 mm S3 ($n = 42$)	19.6 (1.4)	22.1 (1.4)	21.6 (1.3)	<0.001	304.5 (42.7)	369.0 (45.1)	<0.001
26 mm S3 ($n = 46$)	22.9 (1.5)	24.9 (1.6)	24.4 (1.5)	<0.001	413.5 (53.0)	469.1 (55.0)	<0.001
29 mm S3 ($n = 25$)	23.3 (1.4)	28.5 (2.7)	27.5 (1.1)	<0.001	413.5 (53.0)	593.4 (48.9)	0.004

Echo diameter, echocardiography measured annulus diameter; CT (P) diameter, perimeter derived CT annular diameter; CT (A) diameter, area derived CT annular diameter; Echo (D) area, diameter derived echocardiography annular area; CT area, CT measured annular area.

Table 3 Behaviour of EOA and mean transvalvular gradient (dPmean)

	Overall	23 mm S3	26 mm S3	29 mm S3	*p*-value
dPmean					
peri, mmHg (SD)	4.3 (1.9)	4.8 (2.0)	4.3 (1.9)	3.5 (1.6)	0.060
discharge, mmHg (SD)	10.3 (4.6)	10.9 (6.0)	10.4 (3.5)	8.9 (2.8)	0.235
30 days, mmHg (SD)	10.4 (4.3)	11.2 (4.3)	10.3 (4.9)	9.2 (2.4)	0.262
1 year, mmHg (SD)	11.2 (4.6)	12.7 (5.1)	10.5 (4.3)	9.5 (3.4)	0.172
EOA					
peri, cm^2 (SD)	2.3 (0.6)	1.7 (0.2)	2.3 (0.2)	3.1 (0.3)	<0.001
discharge, cm^2 (SD)	2.0 (0.4)	1.6 (0.2)	2.0 (0.2)	2.7 (0.2)	<0.001

peri, peri-interventional, as calculated by continuous equation. See text for further details; SD, standard deviation.

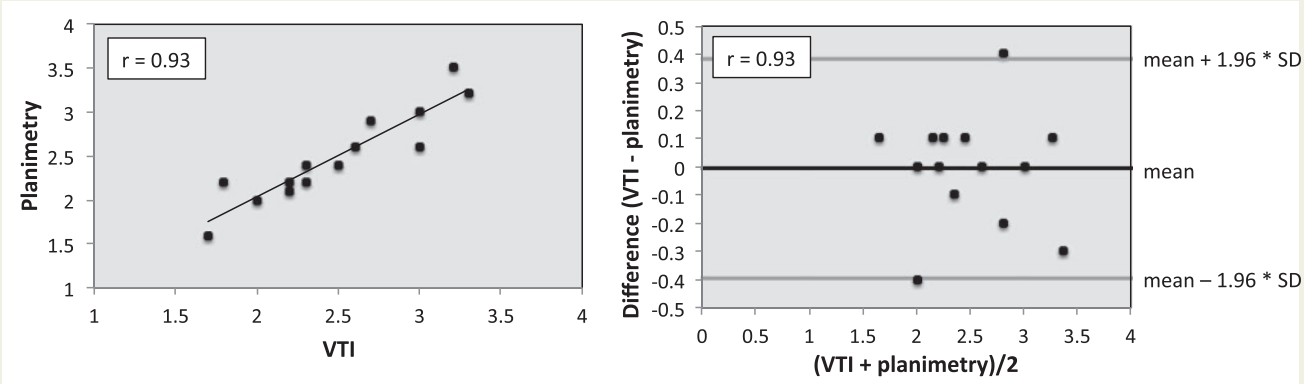

Figure 2 Correlation and differences (Bland–Altman Plot) of EOA measurements using different methods. VTI, EOA calculated using the transaortic velocity-time integral (VTI) measured by Doppler Echocardiography; Planimetry, EOA anatomically measured using planimetry by 3D-biplane transoesophageal echocardiography.

Factors influencing transvalvular gradients

Overall, the left ventricular ejection fraction (LVEF) increased between baseline and discharge (56.1 ± 14.3% and 58.3 ± 14.1%, $p = 0.025$). For patients with an LVEF ≥50% at baseline, the baseline and discharge values were 63.9 ± 7.7%, and 65.1 ± 9.3% ($p = 0.260$), respectively. For those with LVEF <50%, the corresponding values were 38.4 ± 9.8% and 42.5 ± 10.6% ($p = 0.031$), respectively. In patients with a LVEF ≥50% as compared with patients with LVEF <50%, dPmean was significantly higher at baseline (43.6 mmHg vs. 32.5 mmHg, $p < 0.001$), and at discharge (10.9 mmHg vs. 8.4 mmHg, $p = 0.012$). However, no correlations were found between transvalvular gradients and haemoglobin level, heart rate or blood pressure. Except for two cases with moderate paravalvular regurgitation the post-procedural aortic regurgitation was none or trace in all patients and did not correlate with transvalvular gradients.

Discussion

This is the first study to describe the *in vivo* EOA and transvalvular gradients of the Edwards Sapien 3 TAVI prosthesis in short-term and 1-year follow-up differentiated by prosthesis size. While the EOAs significantly differ between the three prosthesis sizes, the transvalvular gradients are comparable. Furthermore, the transvalvular gradient did not differ over time.

Implications for follow-up in daily practice

Regular follow-up of TAVI patients is recommended by current guidelines.[6] In order to assess the prosthesis clinically and by echocardiography and judge upon its proper function, knowledge of the patients specific discharge findings (mean transvalvular gradient, calculated EOA, and nominative EOA as per manufacturing company) are crucial.[9] Our data suggests that as long as the mean transvalvular gradient remains within the given stable range of 10–11 mmHg, stable prosthesis function can be assumed based on this measurement alone. Our results are in line with the recently published 5-year results of the Sapien prosthesis used in the PARTNER 1 trial, showing a dPmean after 5 years of 10.6 mmHg.[11] Interestingly, the larger orifice area in patients receiving a larger prosthesis is compensated by the larger output volume in these typically larger patients, resulting in more or less identical transvalvular gradients for all

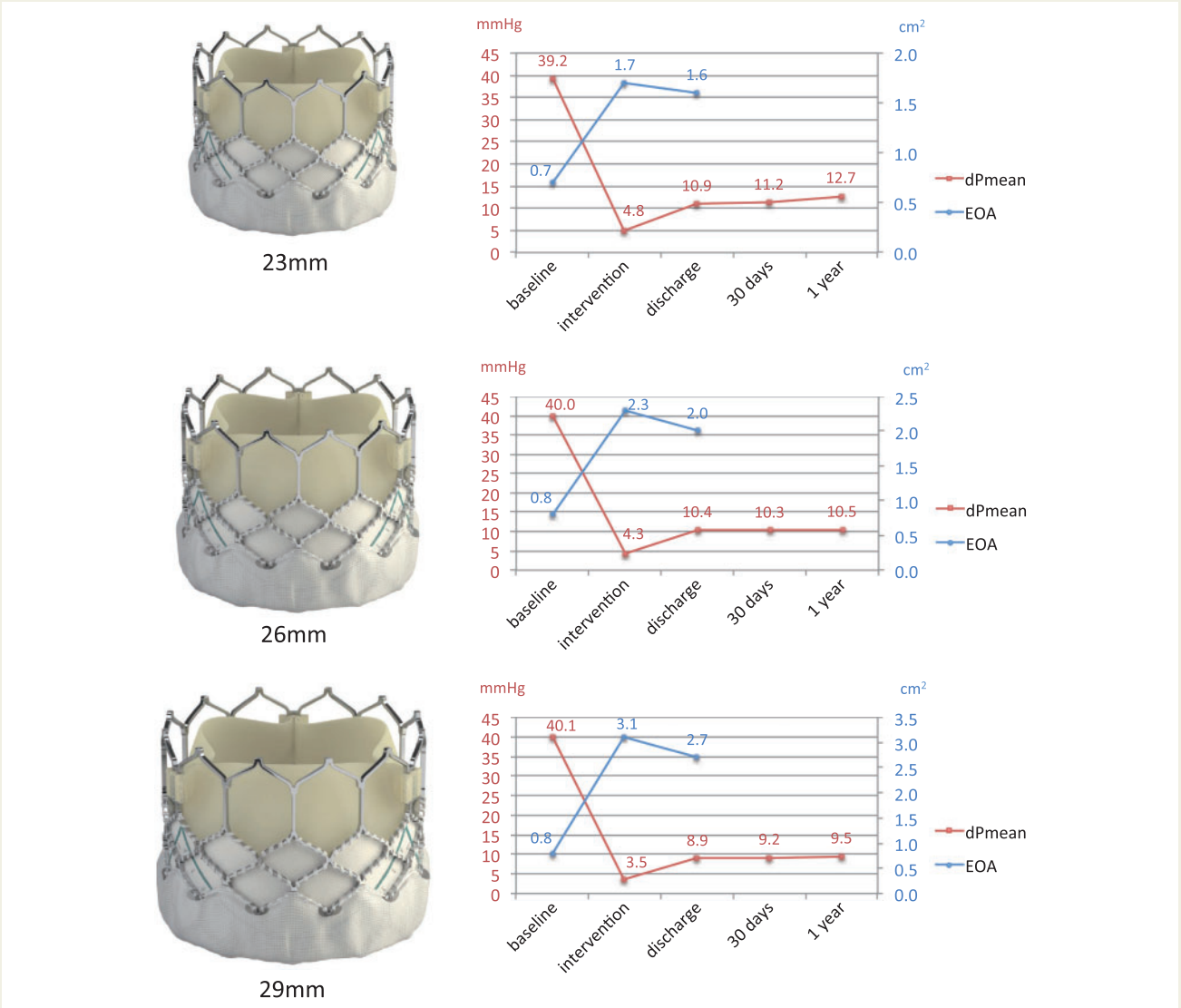

Figure 3 EOA and mean transvalvular gradients over time, separated for the three different sizes of the S3 prosthesis. EOA, effective orifice area; dPmean, mean transvalvular gradient.

three S3 sizes. However, once gradients increase during follow-up, the calculation of the EOA and comparison with discharge values is mandatory in order to confirm true decrease in EOA. Concomitant factors for higher gradients such as change in heart rate, haemoglobin level or high cardiac output have to be ruled out.[22]

Assessment of EOA by echocardiography—not an easy task

Assessing the EOA by echocardiography is part of the clinical routine, but should not be underestimated. Both the direct planimetry as well as the calculation of EOA by Doppler echocardiography are associated with well-known sources of error.[9,19,20] The advantage of using 3D TEE biplane planimetry as in our study is the relative independence of hemodynamic factors as well as of the annular measurement. However, if the measurement plane is not exactly perpendicular to the opening orifice and slightly below the leaflet tips, the EOA will be overestimated for geometric reasons. Despite taking meticulous care in getting the correct plane, angle and time, we cannot exclude that our planimetry results slightly overestimate the true EOA, as indicated by the somewhat smaller results when assessed by Doppler-echocardiography.

In our study peri-interventional transvalvular gradients were lower compared with those measured at discharge and in follow-ups, a phenomenon also reported by others. A recent study compared mean aortic valve gradients in patients undergoing aortic valve replacement for severe aortic stenosis before (using transthoracic echocardiography (TTE)) and during general anaesthesia (by TTE).[23] They found lower transvalvular gradients by a mean of 6.6mmHg during TEE and assumed that pre-operative fluid restriction, the general anaesthesia

itself and the use of positive pressure ventilation lead to a relevant stroke volume reduction. During TAVI, rapid pacing for prosthesis deployment may additionally reduce stroke volumes for some time even after termination of pacing, but the extent of this is currently unknown. Finally, angulation between the Doppler beam and the flow direction is a recognized source of error when measuring transvalvular flow.[19] Assessment of the proper function of the implanted prosthesis can prevent incomplete valve deployment.[22] In addition, unexpectedly high transvalvular gradients may help detecting patients prosthesis mismatch or otherwise underestimated paravalvular regurgitation.

Using TTE, image quality is almost never sufficient for direct planimetry of prosthetic valves. During patient follow-up, EOA thus has to be calculated using Doppler-echocardiography. As we were able to compare the calculated (discharge TTE) to the planimetered EOA (peri-interventional TEE), we were able to optimize the technique of Doppler EOA assessment (see description for *Figure 1*). A similar concept of assessing EOA post-TAVI in Sapien and Sapien XT valves has recently been published, albeit having more accurate results using pre-TAVI LVOT assessment as compared with us using the instant diameter.[24] The importance of correct calculation of EOA is demonstrated in the recently published 5-year results of the PARTNER 1 trial.[11] The EOA in PARTNER 1 with a population of mixed 23 and 26mm Sapien prostheses was continuously calculated at around 1.6 cm^2, which appears rather low and clearly smaller than the results of the recent 3D study measuring a mean EOA of 1.85 cm^2 in Sapien and Sapien XT prostheses.[24]

PPM mismatch in TAVI

The lack of data on valve prostheses size and function provided by manufacturers has been recognized.[12,25] Without the knowledge of the EOA provided by manufacturers, it remains challenging to prevent PPM, an entity associated with reduced survival.[26] In our cohort, the mean prosthesis EAOi was $1.1 \pm 0.2\ cm^2/m^2$, and 11% patients were below the threshold of $0.85\ cm^2/m^2$.[27,28] Interestingly the mean transvalvular gradients in subjects with a PPM were not significantly higher compared with patients without mismatch. One possible explanation for these findings was the somewhat lower stroke volume (in the range of 10 mL) in the mismatch group compared with the non-mismatch group.

A recent meta-analysis revealed a smaller risk of relevant PPM for patients undergoing TAVI compared with surgery with an overall prevalence of 35% (TAVI[29]) and 44% (surgery[26]). Based on our results, especially patients receiving a small prosthesis size appear to be at risk for PPM (75% of mismatch patients had received a 23 mm S3). The risk for insufficient reduction in transvalvular gradients may even increase in patients undergoing valve-in-valve TAVI, where space for proper deployment of the implanted prosthesis is limited.[30] It is thus of concern that most transcatheter prostheses nowadays are launched without knowledge of EOA by prosthesis size.

Limitations

We cannot provide EOA data for 30-days and 1-year follow-up because the cardiologists who perform these follow-up controls on the TAVI patients and contribute their data to the Swiss TAVI registry, mostly do not measure the EOA. One can assume that the EOA of this cohort was more or less stable over time giving the stable transvalvular gradients described above.

Unfortunately, there are no data on the in-vivo EOA of the Edwards Sapien 3 available from Edwards Lifesciences. It would have been meaningful to compare the manufacturer's data with the results from our study.

Furthermore it is important to recognize that there is no gold standard method against which to compare the calculation of the prosthetic EOA.

Conclusion

This is the first study to describe the in vivo EOA and transvalvular gradients of the Edwards Sapien 3 TAVI prosthesis in short-term and 1-year follow-up differentiated by prosthesis size. While the EOAs significantly differ between the three prosthesis sizes, the transvalvular gradients are comparable. Mean transvalvular gradients remain stable over time and document good prosthesis function after 1 year. The results of this study are relevant for clinical follow-up and to avoid PPM.

Conflict of interest: None declared.

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