Transcatheter aortic valve implantation (TA VI) is increasingly used in patients with severe aortic stenosis who are denied to conventional aortic valve replacement due to severe comorbidities and a perceived high risk of perioperative mortality. Preinterventional prosthesis sizing relies on noninvasive imaging modalities such as echocardiography or multislice computed tomography (MSCT). Incorrect sizing may result in adverse outcomes such as paravalvular regurgitation, device embolization, or even aortic root rupture in the case of severe oversizing.

Although there is no uniform standard for prosthesis sizing with dissenting results among different image modalities, MSCT is increasingly used because of its capability of 3-dimensional assessment of the complex aortic root anatomy. Recent studies suggest that MSCT might be more suitable to assess the aortic annulus size than 2-dimensional echocardiography.

With the introduction of TAVI, performing physicians and surgeons may encounter incidents and complications different from those in conventional aortic valve surgery, such as annulus or aortic root rupture and pseudoaneurysm formation of the aortic root. These complications may be evident while performing the procedure or may be apparent at follow-up studies. However, data are limited and risk factors for these entities have not been investigated thoroughly yet.

The aim of this study was to investigate the potential cause of contained rupture of the aortic root in balloon-expandable TAVI by means of pre- and postinterventional multislice computed tomography.

**Methods**

**Study Population**

This retrospective study was approved by the institutional review board and complies with the Declaration of Helsinki. Between June 2008 and May 2011, 107 patients with severe symptomatic aortic stenosis underwent TAVI, of whom 35 patients received a self-expandable prosthesis and 72 patients a balloon-expandable prosthesis. The study population consisted of the 72 consecutive patients with balloon-expandable TAVI, who underwent either pre-TAVI or post-TAVI multislice computed tomography.
transapical (n=59) or transfemoral (n=13) implantation of the Edwards SAPIEN Transcatheter Heart Valve (Edwards Lifesciences LLC, Irvine, CA). All patients were referred for diagnostic workup before TAVI including an electrocardiography-gated dual-source MSCT of the heart as part of their assessment. Transesophageal echocardiography and transesophageal echocardiography (TEE) were performed within a time span of 1 week, usually before MSCT.

Of the 72 patients, 19 patients received a 23-mm prosthesis, 50 received a 26-mm prosthesis, and 3 patients received a 29-mm prosthesis (available since April 2011). The technique of transapical and transfemoral implantation of the Edwards SAPIEN Transcatheter Heart Valve has been described previously. Precutting of the balloon valvuloplasty was performed using a size 20 mm×50 mm balloon (ZMed, NuMed) filled with 1:4 diluted contrast during a brief episode of rapid ventricular pacing. According to the manufacturer’s instructions for use, the bioprosthesis was deployed by inflating the balloon with the entire volume in the inflation device.

In the first 31 patients, selection of prosthesis size (23 mm or 26 mm) was a case-to-case decision based on pre- and intraoperative TEE: The 23-mm prosthesis was implanted for annulus sizes ≤21 mm, the 26 mm for annulus sizes between 22 and 24 mm, according to contemporary manufacturers recommendations. In the succeeding 41 patients’, prosthesis sizing was based on the calculated average annulus diameter (CAAD) as follows: CAAD=2π√CSA/π

Echocardiography
Multiplanar TEE was performed by an experienced cardiologist using a Philips iE33 echocardiography system (Philips Healthcare, Best, The Netherlands). The aortic annulus diameter was assessed on the midesophageal long-axis view (≈120°) of the ascending aorta and aortic valve at end-systole, according to the American Society of Echocardiography guidelines. Diameter was determined as the distance between the depicted hinge points of the aortic valve leaflets, using the inner edge-to-inner edge technique, including annulus calcifications.

Post-TAVI MSCT Assessment and Definition of Contained Rupture
Similar to the initial MSCT examinations, we reconstructed coronal-oblique and sagittal-oblique views through the aortic valve prosthesis, with the intersection of both views representing the axis of the unfolded stent. The position of the resulting double-oblique transverse view was adjusted to the ventricular stent ending. CSA was obtained by means of planimetry (Figure 1E–1H). Contained rupture of the aortic root was defined as discernible contrast-filled cavities, that is, pseudoaneurysms, in the immediate vicinity to the aortic root.

Oversizing
For retrospective analysis, CAAD was defined as the standard of reference. Selection oversizing was defined as selection of a 26-mm prosthesis by means of TEE in the setting of a MSCT-based CAAD <22 mm.
Relative oversizing was calculated as the relative difference in diameter between pre-TAVI CAAD and nominal diameter of the selected prosthesis. Relative change in CAAD between pre-TAVI MSCT and post-TAVI MSCT was calculated.

**Statistical Analysis**
Continuous variables are reported as means±1 standard deviation when normally distributed as assessed by Kolmogorov–Smirnov tests. Nonnormally distributed variables are reported as the median and interquartile range. Pearson correlation analysis and modified Bland–Altman plots,22 with the assessment of systematic bias and confidence limits for a single prediction, were used to assess agreement for anatomic measurements by TEE and MSCT. Paired t tests were used to test for significant differences between TEE and MSCT measurements. One-way ANOVA was used to test for differences of the eccentricity index (EI) between subgroups. Unpaired t test was used to compare relative oversizing between patients with and without contained rupture. All statistical analyses were performed using SPSS software (SPSS 17.0, SPSS Inc, Chicago, IL). A P value <0.05 was considered statistically significant. To quantify the degree of deviation of both, the virtual ring shape and the shape of the cross section of the unfolded stent from a perfect circle, we calculated an EI, where EI = 1−(minimal diameter/maximum diameter). 23 Using this index, an EI of 0 represents a perfect circle, with higher EI indicating elliptical geometry. Noncircular was defined as EI>0.1.

**Results**

**Study Population**
Patient characteristics are listed in Table 1. Pre-TAVI MSCT data acquisitions and TEE were successfully performed in all 72 patients. Follow-up MSCT was performed at median 10 days (interquartile range, 12 days) after TAVI. One patient declined follow-up MSCT. Three patients died before follow-up MSCT. Three patients were deferred from follow-up MSCT because of renal failure. Post-TAVI MSCT data sets were thus available in 65 patients. Of them, 18 patients received a 23-mm Edwards SAPIEN valve, 45 patients received a 26-mm valve, and 2 patients received a 29-mm valve. Average heart rate and heart rate variability during data acquisition was 68.3±12.4 bpm and 4.8±6.1 bpm for pre-TAVI data acquisition and 70.5±11.7 bpm and 5.1±6.4 bpm for post-TAVI data acquisition. Average estimated radiation dose for ECG-gated CTA of the entire thorax was 15.4±4.2 mSv.

**Procedural Results**
Device success (defined as stable device placement and adequate function in the first attempt as assessed by angiography and intraoperative echocardiography) was 100%. Acute procedural success (defined as device success with the absence of peri-procedural major cardiovascular events including death, tamponade, and coronary artery occlusion in the first 24 hours after device implantation) was 98.6% (71/72). In-hospital mortality rate was 6.9% (5/72), and 1-month mortality rate was 11.1% (8/72).

**Contained Rupture**
Signs of contained rupture of the aortic root were observed in 3 of 65 patients (5%). In these patients, contrast-filled cavities were found on follow-up MSCT adjacent to the stent struts with Hounsfield units equivalent to the lumen of the left ventricular outflow tract, not present on initial pre-TAVI MSCT. In all cases,

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**Table 1. Clinical and Echocardiographic Characteristics of the Study Population**

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>All Patients (n=72)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, y*</td>
<td>81.6±6.8</td>
</tr>
<tr>
<td>Male/female†</td>
<td>16/56</td>
</tr>
<tr>
<td>Body surface area*, m²</td>
<td>1.78±0.2</td>
</tr>
<tr>
<td>Euro score*</td>
<td>21.8±12.5</td>
</tr>
<tr>
<td>Echocardiographic findings</td>
<td></td>
</tr>
<tr>
<td>Peak transvalvular aortic gradient*, mm Hg</td>
<td>68.7±21.0</td>
</tr>
<tr>
<td>Mean transvalvular aortic gradient*, mm Hg</td>
<td>41.6±13.5</td>
</tr>
<tr>
<td>Aortic valve area†, cm²</td>
<td>0.69±0.19</td>
</tr>
<tr>
<td>Ejection fraction*, %</td>
<td>48.6±11.1</td>
</tr>
</tbody>
</table>

*Mean=standard deviations.
†Data are numbers of patients.
‡Aortic valve area as per continuity equation.
the resulting pseudoaneurysm was located adjacent to the left aortic sinus. Annulus and sizing characteristics are listed in Table 2. In all patients, the prosthesis was deployed without technical complications with no abnormal findings on postimplantation intraoperative angiography and intraoperative TEE. There was no postimplantation dilatation in any of the 3 patients.

Two of these patients, both elderly females, had received a 26-mm prosthesis. Both patients were sized by means of TEE (both 22 mm). However, retrospectively performed CAAD assessment revealed diameters of 19.9 mm and 21.2 mm with a relative increase in CAAD of 15.6% and 20.6% post-TAVI (Figure 2). Both patients were discharged on 100 mg aspirin per day. One patient underwent a second follow-up CT 6 months later, which showed the disappearance of the pseudoaneurysm (Figure 3). The other patient (Figure 4) did not undergo a second follow-up CT. She died after being admitted to a community hospital for a traumatic humerus fracture 844 days postimplantation. The cause of death was acute hypoxia most likely related to pulmonary embolism. Autopsy was not performed because of lacking consent by the next of kin.

The third patient, also an elderly female, was sized by means of CAAD and had received a 23-mm prosthesis, given a CAAD of 19.2 mm. Relative increase in CAAD was 9.4%. She died 15 days postimplantation because of respiratory failure after sustained retroperitoneal hematoma and prolonged intubation.

Aortic Annulus Dimensions
The median CSA at the level of the basal attachments of all 3 aortic valve cusps was 420.9 mm² (range, 301–564 mm²); the corresponding mean CAAD was 23.1±1.8 mm (19.6–26.8 mm). Mean minimal diameter was 20.2±2.3 mm (15.8–26.2 mm) and mean maximal diameter 26.3±1.9 mm (21.6–30.0 mm).

TEE Versus MSCT
Mean annulus diameter as assessed with TEE was 21.9±1.7 mm and significantly lower than mean CAAD (23.1±1.8 mm; \(P<0.001\)). Mean difference between CAAD measurements on MSCT and midesophageal long-axis view on TEE was 1.2±1.7 mm (range −3.1 to 4.6 mm). Limits of agreement according to Bland–Altman analysis were −2.2 mm and 4.6 mm (Figure 5).

Post-TAVI Dimensions and Relative Change in CAAD
The stent’s mean CSA was 413.6±47.7 mm² (range, 302–546 mm²); the corresponding mean CAAD 22.9±1.3 mm (range, 19.6–26.4 mm). The stent’s CSA was close to a perfect circle (EI<0.1) in 43 patients (66%) and elliptical in the other 22 (34%). Mean EI was 0.10±0.04. None of the prostheses unfolded to its nominal diameter.

Overall, median relative change in CAAD during pre-TAVI and post-TAVI was −0.5% (interquartile range, 3.6%; range −10.4% to 20.6%). Figure 6A depicts the distribution of relative change in CAAD. A relative increase of 5% to 10% was observed in 4 patients, of whom 1 patient demonstrated signs of contained rupture of the aortic root. A relative increase of >10% was found in 2 patients, both with contained rupture.

Valve Selection and Oversizing
In the first 31 patients, prosthesis choice was TEE based: 11 patients had received a 23-mm prosthesis and 20 patients had received a 26-mm prosthesis. Retrospective comparison

### Table 2. Annulus Characteristics of Patients With Contained Rupture

<table>
<thead>
<tr>
<th>Sex, Age, y</th>
<th>Implanted Prosthesis, mm</th>
<th>Sizing</th>
<th>Pre-TAVI TEE, mm</th>
<th>Pre-TAVI CSA/CAAD</th>
<th>Post-TAVI CSA/CAAD</th>
<th>Relative Oversizing, %</th>
<th>Relative Increase in CAAD, %</th>
</tr>
</thead>
<tbody>
<tr>
<td>♂️, 77</td>
<td>26</td>
<td>TEE</td>
<td>22</td>
<td>312 mm²/19.9 mm</td>
<td>452 mm²/24.0 mm</td>
<td>30.7</td>
<td>20.6</td>
</tr>
<tr>
<td>♂️, 84</td>
<td>26</td>
<td>TEE</td>
<td>22</td>
<td>353 mm²/21.2 mm</td>
<td>472 mm²/24.5 mm</td>
<td>22.6</td>
<td>15.6</td>
</tr>
<tr>
<td>♂️, 89</td>
<td>23</td>
<td>CAAD</td>
<td>19</td>
<td>291 mm²/19.2 mm</td>
<td>346 mm²/21.0 mm</td>
<td>20.4</td>
<td>9.4</td>
</tr>
</tbody>
</table>

CAAD indicates calculated average annulus diameter; CSA, cross-sectional area; TAVI, transcatheter aortic valve implantation; TEE, transesophageal echocardiography.

♀ indicates female sex.
of implanted prosthesis size (23 or 26 mm) with preoperative CAAD measurements revealed that selection oversizing had occurred in 5 of the 20 patients with a 26-mm prosthesis (CAAD<22 mm). All these patients had follow-up MSCT available, and in 2 patients, contained rupture was diagnosed (relative increase in CAAD 15.6% and 20.6%). The other 3 patients with selection oversizing showed a relative increase in CAAD between 6.4% and 7.4% without the evidence of contained rupture.

Average change of CAAD in patients with contained rupture, in patients with selection oversizing but no rupture, and in patients without selection oversizing was 15.2%±5.6%, 7.0%±0.5%, and −1.6%±3.4%, respectively (P<0.001).

Distribution of relative oversizing by comparison of nominal stent diameter and CAAD is depicted in Figure 6B. Mean relative oversizing was 9.8%±7.3% (range −4.6% to 30.7%). Relative oversizing ≥10% occurred in 27 patients. Relative oversizing ≥20% occurred in 6 patients, of whom 3 showed evidence of contained rupture. Oversizing was significantly higher in patients with contained rupture compared to patients without contained rupture (24.6±5.4% versus 9.1%±6.6%; P<0.001).

Eccentricity
The mean calculated EI was 0.23±0.09 (range, 0.11–0.40). The annulus shape was elliptical (EI>0.1) in all patients. Average EI in patients with contained rupture, in patients with selection oversizing but no rupture, and in patients without selection oversizing was 0.24±0.10, 0.25±0.13, and 0.24±0.07 (P=0.944), respectively.

Paravalvular Regurgitation
Moderate, but not severe, paravalvular regurgitation was observed in 3 patients immediately after the intervention by intraoperative TEE and by TTE at time of discharge. There was no paravalvular regurgitation in the 3 patients with contained rupture and in the 3 remaining patients with selection oversizing but without contained rupture.

Discussion
With TAVI, the occurrence of uncontained and contained aortic annulus rupture, the latter also referred to as pseudoaneurysm formation of the left ventricular outflow tract, has been described previously. It is caused by either the forces of the preceding valvuloplasty or the actual TAVI procedure. In the study presented, we found 3 cases of contained rupture of the aortic root by means of MSCT. Contained rupture occurred only in patients with pronounced increase in CAAD between pre-TAVI and post-TAVI MSCT data sets and relative oversizing >20%.

The balloon-expandable Edwards SAPIEN Heart Valve is available with 23 mm and 26 mm in size, and since recently with 29 mm. Current manufacturer’s recommendations for valve sizing are TEE based. Furthermore, in the majority of recent single- and multicenter studies, valve size selection is based on measurements by TEE. As described by Walthier et al, patients with an aortic annulus diameter <21 mm receive a 23-mm prosthesis whereas patients with an aortic anulus
diameter between 22 and 24 mm receive a 26-mm prosthesis. In their opinion, some oversizing of ≈ 10% is essential to avoid severe paravalvular leakage, but in the presence of a rigid aortic root, too much oversizing should be avoided. However, according to Webb et al, an annulus diameter of 18 to 22 mm assessed by echocardiography is considered appropriate for the 23-mm prosthesis and 21 to 25 mm for the 26-mm prosthesis, creating a twilight zone between 21 and 22 mm.

Unfortunately, the aortic annulus is not a true ring. The semilunar hinges of the aortic leaflets take the form of a 3-pronged coronet rather than a circle. Furthermore, the annulus is rather elliptical than round when viewed axially. Given this complex and ovoid geometry, different imaging modalities as well as measurement planes will yield dissenting results. We found that 2-dimensional-TEE systematically underestimated annulus dimensions by 1.2±1.7 mm when compared with CAAD. This can be partially attributed to the ovoid annulus anatomy and the midesophageal long-axis view orientation, transecting through the right and noncoronary cusps, more closely resembling the short annulus axis. Given this complex and ovoid geometry, different imaging modalities as well as measurement planes will yield dissenting results. We found that 2-dimensional-TEE systematically underestimated annulus dimensions by 1.2±1.7 mm when compared with CAAD. This can be partially attributed to the ovoid annulus anatomy and the midesophageal long-axis view orientation, transecting through the right and noncoronary cusps, more closely resembling the short annulus axis. Furthermore, limits of agreement were rather wide with patients having smaller but, importantly, also larger diameters in TEE than in CT. Larger intraindividual diameters in TEE than in MSCT may be due to the varying diameter of the aortic root, which is widest at the midpoints of the sinuses and smaller at the basal attachment of the leaflets. The leaflets’ hinges extend from the basal attachment to the sinotubular junction, following the varying root caliber. With TEE, hinge-to-hinge measurements from the basal attachment of 1 leaflet to the depicted hinge point across the lumen may take a diagonal path in relation to the aortic root’s axis, thus yielding a larger value, further augmented by the aortic root’s wider diameter toward the midpoint of the sinuses. In contrast to the elliptical annulus anatomy, devices for balloon-expandable TAVI are circular when viewed axially.
As recently demonstrated, the Edwards SAPIEN Transcatheter Heart Valve expands to an almost circular shape in most patients, thereby altering the annulus configuration, that is, reducing eccentricity toward a more circular shape while the CSA remains constant. In the study presented, the median relative change in CAAD was −0.5% when comparing pre- and post-TAVI data sets. An increase of ≥5% was observed in only 6 of 65 patients, and an increase of >10% in only 2 patients. Although increase in CAAD was significantly higher in patients with contained rupture, contained rupture was not observed in patients with only moderate increase in CAAD.

Furthermore, relative oversizing, expressing the mismatch of CAAD and nominal prosthesis diameter, was significantly higher in patients with contained rupture. Contained rupture was only found in patients with relative oversizing >20%. We identified 2 reasons for pronounced relative oversizing:

1. Selection oversizing by choosing a larger prosthesis because of borderline TEE measurements; and
2. Small annulus anatomy by choosing the smallest prosthesis currently available.

Given the systematic difference in annulus dimensions obtained by TEE and MSCT, TEE-based sizing guidelines cannot be simply adopted to MSCT. Considering the ovoid nature of the annulus and the circular nature of the ideally unfolded Edwards SAPIEN prosthesis, it becomes apparent that the recommended TEE-based oversizing by 10% as stated by Walther et al does not necessarily imply oversizing in terms of CAAD. Instead, the recommended oversizing by 10% compensates for the intrinsic bias of the midesophageal long-axis view on TEE, yielding smaller values than the CAAD. For the CAAD-based sizing approach, which is now routinely applied at our institution, we deliberately chose 22 mm as the cutoff value for selection between the 23-mm and 24-mm prosthesis sizes.

Figure 6. Distribution of relative change in CAAD between pre-TAVI and post-TAVI data sets (A) and distribution of relative oversizing by comparison of nominal stent diameter and CAAD (B). Histogram intervals are 5%, n=65. CAAD indicates calculated average annulus diameter; TAVI, transcatheter aortic valve implantation.
and the 26-mm prosthesis as we learned that neither of both unfolds to the nominal diameter. Since recently, the 29-mm prosthesis is chosen for CAAD of 25 to 28 mm. However, given the results of this study, it is unclear how to treat patients with a small annulus (eg, <20 mm).

Despite >30 000 TAVI procedures performed worldwide, literature on pseudoaneurysm formation and contained rupture is limited to case reports, as follow-up MSCT is not routinely performed. However, uncontained annulus rupture with cardiac tamponade and fatal outcome has been observed in larger studies. Thus, pseudoaneurysm formation might represent the lower end of the spectrum of manifestations with uncontained rupture and cardiac tamponade on the upper end. In fact, in real world single-center (eg, Pasic et al,1 1 of 194 patients; Lange et al,24 and 1 of 129 patients) or multicenter registries (Elch gymnoff et al,27 1 of 95 patients), the rate of uncontained aortic annulus rupture ranges between 0.5 % and 1%.

As patients included into this study underwent TAVI as they did not qualify for open surgery in the first place due to a perceived high risk of perioperative mortality, the 3 patients with contained rupture underwent conservative management only. Although the clinical impact of untreated contained rupture is unknown, it appears conceivable that the occurrence of contained rupture as an assumed prestige to uncontained rupture should be avoided. Interestingly, in all 3 cases observed in the present study, as well as in the 2 cases described in literature so far,13,15 contained rupture occurred adjacent to the left coronary sinus. This leads to the assumption that the tissue adjacent to the left coronary sinus represents a Locus minoris resistentiae. Furthermore, all 3 patients were elderly women, concordant with observations by others.24

Study Limitations

This study is limited by its relatively small patient cohort and the rare incidence of pseudoaneurysm formation. However, as to our knowledge, this is the largest patient series with systematic follow-up MSCT to date. Furthermore, the time span from TAVI to follow-up varied between 3 and 66 days. Thus, smaller alterations might have been missed in some patients, as pseudoaneurysm may regress with time. Finally, because this study focused on patients with balloon-expandable TAVI, the presented concept cannot be readily applied for self-expanding devices.

Optimal sizing can be thought of being in-between excessive oversizing with subsequent rupture and undersizing with subsequent paravalvular regurgitation. Our MSCT-based sizing regimen results in relative oversizing of 4% to 21% for CAAD of 19 to 28 mm using the 3 currently available prosthesis sizes of 23, 26, and 29 mm (Europe). However, our retrospective study was not designed to investigate the optimal amount of oversizing.

Planimetry is one of the few different measurement techniques for the assessment of annulus dimensions with MSCT. Others are caliper measurements. However, planimetry followed by calculation of an average diameter has been shown to be the most reproducible measurement among different measurement techniques with MSCT.28 Importantly, data reconstruction was deliberately chosen at 300 ms past the R-peak to ensure proper image quality, even in patients with atrial fibrillation.

Conclusion

Contained rupture of the aortic root in balloon-expandable TAVI is associated with severe prostheses oversizing. MSCT-based assessment of aortic annulus dimension in conjunction with adapted sizing guidelines may reduce the incidence of prosthetic oversizing.

Disclosures

None.

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Prosthesis Oversizing in Balloon-Expandable Transcatheter Aortic Valve Implantation Is Associated With Contained Rupture of the Aortic Root

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