Aortic valve calcium scoring is a predictor of significant paravalvular aortic insufficiency in transapical-aortic valve implantation†

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OBJECTIVE: Transcatheter-aortic valve implantation (TA-AVI) has evolved as routine for selected high-risk patients. However, paravalvular leaks >1+ remain an unsolved issue using current generations of transcatheter valve devices. The purpose of this study was to investigate the impact of native aortic valve calcification on paravalvular leaks and outcomes using the Edwards SAPIEN™ prosthesis.

METHODS: One hundred and twenty consecutive patients (out of 307 TA-AVIs) with preoperative computed tomography aged 82.6 ± 6.2 years, 75.0% female were included. Implanted prosthetic valve sizes were 23 mm (n = 31) and 26 mm (n = 89), respectively. Mean logistic European System for Cardiac Operative Risk Evaluation-Score was 30.1 ± 15.5% and mean Society of Thoracic Surgeons-Score was 12.8 ± 7.9%. Electrocardiographic (ECG)-gated cardiac computed tomography allowed to quantify the amount of calcium in the aortic valve leaflets using a scoring analogous to the Agatston calcium scoring of coronary arteries [Aortic Valve Calcium Scoring (AVCS)]. Paravalvular leaks were assessed intraoperatively by echocardiography and root angiography.

RESULTS: All valves were implanted successfully. The mean AVCS in patients without paravalvular leaks (n = 66) was 2704 ± 1510; with mild paravalvular leaks (n = 31) was 3804 ± 2739 (P = 0.05); and with moderate paravalvular leaks (n = 4) was 7387 ± 1044 (P = 0.002). There was a significant association between the AVCS and paravalvular leaks [odds ratio (OR; per AVCS of 1000), 11.38; 95% confidence interval (CI) 2.33–55.53; P = 0.001] and a trend towards a higher incidence of new pacemaker implantation (OR 1.27; 95% CI 0.85–1.89; P = 0.26). No association was found to 30-day mortality, major cardiac events and stroke rate (OR 1.05; 95% CI 0.84–1.32; P = 0.68; OR 0.92; 95% CI 0.68–1.25; P = 0.57 and OR 0.90; 95% CI 0.41–1.96; P = 0.79, respectively). Overall 30-day mortality was 14.2%.

CONCLUSION: Severe native valve calcifications are predictive for postoperative relevant paravalvular leak. AVCS prior to TA-AVI might serve as an additional tool to reconsider the TAVI indication to reduce the risk of paravalvular leaks especially in so-called operable patients.

Keywords: Transcatheter aortic valve implantation • Calcium score • Transapical

INTRODUCTION

Transcatheter aortic valve implantation (TAVI) has been established as a clinically accepted minimally invasive therapeutic option for selected high-risk patients with symptomatic aortic valve stenosis. Despite a clear benefit of survival and improvement in symptoms [1, 2], TAVI is also associated with the presence of a paravalvular leak in up to 60% of patients [3]. Although efforts have been made to reduce this incidence significantly [4, 5], paravalvular leakage still necessitates additional interventions in a considerable number of patients and hinders TAVI acceptance in others than in high-risk patient populations. A recent study has revealed that patients with paravalvular leaks have a significantly higher mortality rate [6]. Therefore, careful patient selection is of utmost importance to avoid intraoperative complications. However, while an atrioventricular block is relatively easy to identify, early detection of a haemodynamically relevant paravalvular leak is far more challenging, leading potentially to a high number of unrecognized patients. Moreover, while patients are usually stable during and shortly after the procedure, they tend to deteriorate during the following hours and days.

Excessive calcification of the aortic valve cusps, however, may result in a haemodynamically relevant paravalvular leak [4], further sustaining pressure overload, which is poorly tolerated by these patients. As a result, several imaging methods have been routinely established and are of outstanding importance...
in planning the procedure. While the correct size of the aortic annulus is commonly assessed by transoesophageal echocardiography (TOE), an additional multi-slice Electrocardiographic (ECG)-triggered computed tomography allows the measurement of the annular shape and size as well as the distances from the annulus to the coronary ostia. The Dyna-CT technique (Siemens Healthcare, Forchheim, Germany) is used intraoperatively to detect important landmarks like the hinge points of all aortic sinuses, the commissures and the coronary ostia to simulate a three-dimensional view of the entire aortic root [7].

However, despite the encouraging results of TAVI [1, 2], the not well-foreseeable risks of more than a trivial degree of paravalvular leakage, aortoventricular block and comparably high rate of at least minor strokes may negatively impact the outcome [8, 9].

Objectives of this single-centre study were to assess the amount and distribution of calcification of the native aortic cusps and commissures using a scoring system analogous to the Agatston calcium scoring of coronary arteries (AVCS) and according to the presence of paravalvular leaks as well as the association with outcome parameters.

METHODS

Study design

After approval by the local ethics committee of the University of Leipzig, and written consent obtained from each patient, 120 consecutive patients [out of 307 transapical-aortic valve implantation (TA-AVIs)] with preoperative computed tomography were included in this single-centre study. Mean age was 82.6 ± 6.2 years, mean logistic EuroSCORE (European System for Cardiac Operative Risk Evaluation) was 30.1 ± 15.5% and Society of Thoracic Surgeons (STS)-Score was 12.8 ± 7.9%. Overall, 75.0% of the patients were female. Preoperative characteristics of all 120 patients included in the AVCS study

Table 1: Preoperative patient characteristics of all 120 patients included in the AVCS study

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>82.6 ± 6.2 (range 51–95)</td>
</tr>
<tr>
<td>Logistic EuroSCORE (%)</td>
<td>30.1 ± 15.5</td>
</tr>
<tr>
<td>STS-Score (%)</td>
<td>12.8 ± 7.9</td>
</tr>
<tr>
<td>NYHA class</td>
<td>3.0 (3.0–3.0)</td>
</tr>
<tr>
<td>Female (n/%)</td>
<td>90/75.0</td>
</tr>
<tr>
<td>Left ventricular EF (%)</td>
<td>57.1 ± 14.1</td>
</tr>
<tr>
<td>Peripheral vascular disease (n/%)</td>
<td>67/55.8</td>
</tr>
<tr>
<td>Carotid artery stenosis (n/%)</td>
<td>38/31.7</td>
</tr>
<tr>
<td>Chronic lung disease (n/%)</td>
<td>41/34.2</td>
</tr>
<tr>
<td>Mean aortic gradient (mmHg)</td>
<td>46.3 ± 18.9</td>
</tr>
<tr>
<td>Maximum aortic gradient (mmHg)</td>
<td>71.2 ± 24.6</td>
</tr>
<tr>
<td>Effective orifice area (cm²)</td>
<td>0.5 (0.4–0.7)</td>
</tr>
<tr>
<td>Edwards Sapien™ THV</td>
<td>113 (94.2%)</td>
</tr>
<tr>
<td>Edwards Sapien XT™</td>
<td>7 (5.8%)</td>
</tr>
</tbody>
</table>


Commissures using a scoring analogous to the Agatston calcium scoring of coronary arteries (AVCS). Secondary endpoints were AVCS according to the presence of paravalvular leaks and the association with outcome parameters.

Clinical inclusion criteria were age ≥ 75 years, NYHA functional class II or higher, written informed consent and comorbidities leading to a logistic EuroSCORE ≥ 15%. By standard protocol, all patients underwent transthoracic echocardiography and TOE. Echocardiographic inclusion criteria were severe degenerative aortic valve stenosis indicated by an aortic valve area ≤ 1.0 cm² and/or a jet velocity >4 m/s and/or a mean gradient > 40 mmHG.

Transcatheter aortic valve

All treatment options including conventional surgery were discussed in an interdisciplinary Heart Team conference. All patients received the Edwards SAPIEN™ Transcatheter Heart Valve (THV) or SAPIEN XT™ composed of a pericardial xenograft fixed within a stainless steel or cobalt chrome, balloon-expandable stent (Table 1, Edwards Lifesciences, Irvine, CA, USA). Patients with an aortic annulus diameter of 19–22 mm received a 23 mm Edwards SAPIEN™ and patients with an aortic annulus diameter between 22 and 24 mm received a 26 mm prosthesis. To detect the mismatch between the size of the prosthesis and the size of the annulus, we compared the annulus diameter and the normal range recommended for the Edwards Sapien™ prosthesis. In case of a smaller annulus diameter compared with the normal limit for the prosthesis, we defined this as prosthesis greater than annulus mismatch. In case of a larger annulus diameter compared with the normal range for the prosthesis, we defined this as prosthesis lesser than annulus mismatch.

Implantation technique

All procedures were performed under general anaesthesia in a fully equipped hybrid operating room. Prior to skin incision, a femoral ‘safety-net’ was established via a venous guidewire and a 6 Fr arterial sheath to ensure femoral access in case of emergency cannulation for cardiopulmonary bypass (CPB). TA-AVi was performed as previously described in detail [10]. Paravalvular leaks were assessed intraoperatively by echocardiography and root angiography. In case of significant paravalvular leak, the valvuloplasty balloon was introduced again and post-dilatation was performed.

Computed tomography protocol and aortic valve calcium scoring

Preoperative aortic valve calcium scoring (AVCS) was performed by non-contrast cardiac CT on a 64-row CT (Brilliance 64, Philips Medical Systems, Cleveland, OH, USA). All scans were performed in the cranio-caudal direction during inspiratory apnoea with prospective ECG-triggering. ECG-triggering was set at 75% of the RR interval without padding. A collimation of 40 × 0.625 mm at a rotation time of 0.4 s was used. Tube current and voltage were 50 mA and 120 kV, respectively. Images were reconstructed at a slice thickness of 2.5 mm and an increment of 2.5 mm.
To build the AVCS slices with a thickness of 2.5 mm and no overlap, they have been reconstructed from the transverse slices, which were aligned parallel to the aortic valve annulus. These reconstructions were used to generate a total AVCS of the entire aortic valve. Then the image data were divided into three parts along each commissure with no gaps or overlaps to score each cusp separately. The three separate scores were summed and compared with the initially measured total AVCS to eliminate potential errors. In a second attempt, the image data were divided into three parts with a rotation of 60° relative to the previous division to quantify the degree of calcification of each commissure. Again, the three separate scores were summed and compared with the initially measured total AVCS (Fig. 1 a–f and Table 2). Calcifications were attributed to the aortic valve if they were clearly part of the valve cusps. In contrast, supravalvular calcifications and calcifications of the coronary arteries including the ostia were removed carefully by manual segmentation.

All cardiac CTs were assessed in a consensus interpretation by an experienced radiologist (L.L.) and cardiac surgeon (M.H.), both blinded to the clinical data. Aortic valve calcium scores were measured by multiplying the lesion area by an attenuation factor derived from the maximal Hounsfield units within the area as previously described by Agatston et al. (11) using a detection threshold of 130 HU. Data were analysed on a commercially available workstation (Philips Extended Brilliance Workspace, HeartBeat-CS and CT Viewer, Philips Medical Systems, Best, The Netherlands).

**Assessment of paravalvular leak**

Paravalvular leaks were identified after release of the Edwards Sapien™ prosthesis by aortic root angiography according to the Sellers classification [12]. In addition, the degree of a paravalvular leak was assessed by TOE in the mid-oesophageal long-axis view using the vena-tracta width (mild: <0.3; moderate: 0.3–0.6; severe: >0.6 cm) and width of regurgitant jet within the LVOT (<30%; 30–50%; >50%) [13]. The localization was judged in the mid-oesophageal short-axis view. All patients with post-dilatation (n = 10) or a second prosthesis (n = 9) were included in the group of patients with a significant paravalvular leak.

**Statistics**

The 30-day follow-up was 100% complete. All statistical analyses were performed using SPSS, version 16.0 (Chicago, IL, USA).
Continuous variables were analysed by two-tailed Student’s t-test or by the Mann-Whitney U-test for non-normally distributed variables. Logistic regression analysis was used to assess the association for the AVCS and outcome parameters. To analyse the probability for a paravalvular leak depending on the AVCS, a probit analysis was performed. A P-value of less than 0.05 was considered statistically significant. Continuous variables are expressed as mean ± standard deviation for Gaussian-distributed variables and otherwise median values (interquartile range). Categorical data are given as proportions.

RESULTS

Patient characteristics

Valve implantation was successful in all patients. Implanted prosthetic valve sizes were 23 mm (n = 31) and 26 mm (n = 89), respectively. Data on preoperative TOE characteristics are supplied in Table 3.

The mean AVCS was comparable for the entire valve, cusps and commissures (Table 2). In detail, the left coronary cusp revealed a higher degree of calcification (1178 ± 1073) than the right and non-coronary cusps (957 ± 693 and 1135 ± 720, respectively). There was evidence for a significant difference between the right and non-coronary cusp (P = 0.02), but not between the right and left coronary, as well as left and non-coronary cusp (P = 0.13 und P = 0.44). The left non-coronary commissure demonstrated the highest degree of calcification (1245 ± 882).

Impact of aortic valve calcification on paravalvular leaks

The mean AVCS in patients without paravalvular leaks (n = 66) was 2704 ± 1510, with mild paravalvular leaks (n = 31) was 3804 ± 2739 (P = 0.048) and with moderate paravalvular leaks (n = 4) was 7387 ± 1044 (P = 0.002, Fig. 2). There was a significant association between the AVCS and paravalvular leaks (odds ratio (OR), per AVCS of 1000, 11.38, P = 0.001) indicating a limited degree of linear dependence (Table 5). The relationship between the probability for a paravalvular leak and the AVCS is presented in Fig. 3.

When analysing the localization of a paravalvular leak by intraoperative echocardiography, there was a significant association with the AVCS in a separate cusp or commissure. The
mean AVCS was significantly higher in the presence of a paravalvular leak in this region (Table 3).

In detail, the AVCS of the right coronary cusp in patients without a local paravalvular leak \((n = 72)\) was \(811 \pm 542\) compared to patients with a paravalvular leak \((n = 11)\) having an AVCS of \(1189 \pm 882\) \((P = 0.025)\). For the left coronary cusp, the mean AVCS in patients without \((n = 73)\) and with \((n = 10)\) a paravalvular leak was \(919 \pm 644\) and \(1669 \pm 1514\), respectively \((P = 0.001)\). Likewise, the mean AVCS of the non-coronary cusp in patients without a paravalvular leak \((n = 62)\) was \(1013 \pm 671\) and in patients with a paravalvular leak \((n = 21)\) \(1281 \pm 750\) \((P = 0.053)\). This relation between the localization of a paravalvular leak and the AVCS reached statistical significance for the right and left coronary cusp \((OR, 5.64, P = 0.018; OR, 5.43, P = 0.020)\). This, however, was not the case for the non-coronary cusp \((P = 0.56, Table 4)\).

When analysing the three commissures (Tables 3 and 4), the AVCS of the right–left coronary commissure in patients without a paravalvular leak \((n = 70)\) was \(782 \pm 554\) and in patients with a paravalvular leak \((n = 13)\) \(1295 \pm 1071\) \((P = 0.01)\). In contrast, results for the left non-coronary and non-right-coronary commissure were comparable.

### Impact of aortic valve calcification on outcome

There was a significant association between mean AVCS and temporary haemodialysis \((OR 3.73, P = 0.049, Table 5)\). In addition, an association was found for the median ventilation time ≥ 60 h \((OR 7.94, P = 0.005)\). No association was found to 30-day mortality, major cardiac events, postoperative pacemaker implantation and stroke rate \((OR 1.05, P = 0.68; OR 0.92, P = 0.57; OR 1.27, P = 0.26; OR 0.90, P = 0.79)\). Overall 30-day mortality was 14.2%.

### DISCUSSION

TAVI has been established as a minimally invasive procedure to treat symptomatic aortic stenosis for selected high-risk patients [1, 2]. Potential advantages of this truly minimally invasive approach are the avoidance of CPB, avoidance of aortic cross-clamping and cardioplegic cardiac arrest. However, a not well-foreseeable risk of more than a trivial degree of paravalvular leakage may negatively impact the outcome.

In case of a persisting paravalvular leak, the increased end-diastolic volume of the left ventricle causes an increase of myocardial wall stress leading to compensatory eccentric hypertrophy and, eventually, subsequent dilatation associated with a reduced clinical functional status. In untreated patients, a persisting severe paravalvular leak carries the risk of pressure overload and acute pulmonary oedema, potentially leading to cardiac decompensation and death.

The present study is a retrospective, single-centre analysis of aortic valve calcification based on CT prior to TA-AVI in 120 patients. The results suggest that the AVCS of the preoperative CT identifies patients at risk for a relevant paravalvular leak. Thus, AVCS prior to TA-AVI may contribute to an appropriate patient selection for TAVI, especially in less morbid and potentially operable patients. A paravalvular leak was present in more than 29% of patients in the current study. Fortunately, paravalvular incompetence was mild in the vast majority of our patients, and none required re-operation for increasing aortic incompetence after the procedure.
The results of this study showed that the left coronary cusp revealed the highest degree of calcification than the right and non-coronary cusps. The left non-coronary commissure demonstrated the highest degree of calcification (Table 2). One reason might be that these two specific regions may represent the site of greatest mechanical stress for the aortic valve [14, 15]. On the other hand, in aortic stenosis, the left coronary aortic cusp tends to be the largest cusp and is therefore most associated with mechanical stress leading further to calcification [16].

Analysing the impact of aortic valve calcification on paravalvular leaks, there was a significant association between the AVCS and paravalvular leaks, as reported by Koos et al. [17]. Consistent with this report, John and colleagues documented comparable results in 100 patients treated with the CoreValve ReValving prosthesis [18]. Wood et al. [19] in contrast did not find an association between paravalvular leaks and the degree of calcification, which probably was a matter of their small study population.

When analysing the localization of paravalvular leaks, confirmed by TOE, there was also a significant relation to the AVCS in each separate cusp or commissure. We found a significant association for the right and left coronary cusp, and for the right-left and left non-coronary commissure. This association, however, failed to reach statistical significance for the non-right-coronary commissure and non-coronary cusp. One possible reason for this might be the intrinsic weakness of the annulus in this area, leading to an anatomic predisposition to paravalvular leaks [20].

With regard to the impact of aortic valve calcification on the outcome using the Edwards SAPIEN™ prosthesis, both temporary haemodilution as well as median ventilation time were associated with a significantly higher AVCS. More frequently increased AVCS values were observed in those with impaired respiratory function and renal disease, thus, suggesting that these patients are at a higher risk for post-procedural secondary complications and a longer in-hospital stay. Haemodialysis seems to be associated with a higher AVCS as severe aortic stenosis with concomitant heart failure is one reason for impaired glomerular filtration rate [21].

It has been demonstrated recently that patients with a significant paravalvular leak were sicker in general and are prone to considerably higher in-hospital mortality rate [6]. Several risk factors including male gender, aortic valve area, cardiogenic shock and renal failure were independently associated with a higher risk for paravalvular leakage. The authors also found that annulus estimation by TOE was associated with a higher risk most likely due to constant underestimation compared with multi-slice computed tomography.

In our study, preoperative annulus size was comparable whether or not a paravalvular leak was present, while prosthesis mismatch (prosthesis less than annulus in eight patients) was strongly associated with the presence of paravalvular insufficiency. The opposite mismatch, however, prosthesis greater than that of annulus did not play a crucial role. Various studies have proven the association between prosthesis mismatch and paravalvular leaks [22]. Correct sizing of the appropriate prosthesis, therefore, remains of utmost importance, especially when choosing the smaller prosthesis compared to the normal annulus range recommended.

Furthermore, there was a trend towards a higher incidence of new pacemaker implantation and reintubation with increasing AVCS, but, most likely, because of the small number of patients, this trend did not reach a significance level. In contrast to a previously published study [23], the AVCS was not a predictor of 30-day mortality, major cardiac events and stroke in our experience.

Regarding the 30-day mortality in our study population using STS-Score and Logistic EuroSCORE (12.8 ± 7.9 and 30.1 ± 15.5%), the 30-day mortality rate of 14.2% seems acceptable. We could demonstrate in a previous trial that a trend towards lower mortality rates was seen with time, considering that these patients had several comorbidities and the study group included some of the early procedures at the beginning of our TA-AVI programme [24].

Current limitations of transcatheter valves became of particular interest and need to be addressed accurately. Future devices with a cuff, as used for clinical valve-in-a-valve implantation, may lead to better sealing. Recently, a novel Sapien™ valve with an added outer cloth has been introduced [4]. It is designed to reduce paravalvular leaks by creating a seal, improve resistance to migration with better ‘fit’ and promote tissue ingrowth, which further decreases paravalvular leakage. However, the best way to treat these high-risk patients with a heavily calcified aortic stenosis has not been established yet. Moreover, the limited number of different valve sizes available at the moment does not allow to ideally adapt the prosthesis sizes to an individual patient anatomy.

LIMITATIONS

Despite a relatively broad experience with TA-AVI, the number of patients with a multi-slice ECG-triggered computed tomography was still limited. Further limitations are the retrospective and the single-centre design of the study, although data were collected prospectively using medical records and a computerized database. Since we used only the Edwards Sapien™ prosthesis, it may be inappropriate to compare our results with other transcatheter valve devices. The cardiac CT-based AVCS was not cross-validated with the intraoperative TOE. However, the TOE might definitely add information to better understand the morphology of the native calcified valve as recently reported by Colli et al. [25]. Finally, to detect a significant risk for a paravalvular leak, the AVCS was not performed routinely in our institution.

CONCLUSION

In summary, the AVCS identifies patients at risk for a relevant paravalvular leak. AVCS prior to TA-AVI might serve as an additional tool to reconsider the TAVI indication and valve size to reduce the risk of paravalvular leaks. Consideration of the AVCS demonstrated that patients with a high AVCS should not be selected for TAVI, but rather for surgical valve replacement at an early stage. Clinically, we especially consider patients with a borderline EuroSCORE of 15–20% and at the same time a high calcium burden as ‘non-TAVI candidates’. In contrast, patients with a low AVCS might truly benefit from TAVI with a foreseeable good functional result. Further prospective, randomized trials are necessary to investigate the advantage of a certain AVCS cut-off score, particularly in high-risk subgroups such as patients with advanced aortic disease. Because the AVCS indicated a significantly higher risk for a paravalvular leak, higher operative risk and potential sub-optimal outcome should be discussed with
the patient including to consider a conventional approach in operable patients.

Conflict of interest: none declared.

REFERENCES


APPENDIX. CONFERENCE DISCUSSION

Dr T. Walthr (Bad Nauheim, Germany): I wanted to ask you two things. Did you look at the echo in parallel, because earlier on from the same kind of subset, we did some analysis from the transoesophageal echo data on the symmetry and the amount of calcium. Could you correlate that, the TOE results with the CT, and did you look at the eccentricity of the annulus in relation to paravalvular leak? And the other thing is, would you really set a cutoff at some point? As you mentioned, the higher calcium just from CT leads to conventional surgical.

Dr Hansig: We used intraoperative transoesophageal echocardiography data for our analysis regarding the leaks and we didn’t really compare it with the CTS intraoperatively. So this might be an additional point we have to look at in the future. But we found that eccentric calcification didn’t have a significant impact on leaks at all in our analysis. So this was one reason why we didn’t include it in our final results.

What we found interesting was, for example, the prosthesis-annulus mismatch, which showed that patients having a borderline annulus and receiving a bigger valve, that means for example, the 26 mm Sapien, had a significant higher risk. This was one point.

Regarding the second question, it is probably hard to decide where you can make a cutoff for the calcium score. I think patients having a borderline EuroSCORE, a borderline STS score, which might be between 15 and 20, could be patients that might be operated conventionally if they have a high calcium burden.

Dr M. Amin (Cairo, Egypt): When you see a lot of calcium and paravalvular leak during operation, do you place additional sutures or re-replace the valve? Secondly, what do you do during the operation when faced with a small aortic annulus? And thirdly, did you see cases where it was very difficult to remove the cusps and, if so, what did you do?

Dr Hansig: We didn’t remove the cusps during the TAVI procedure, but I think what you mean is when we had patients with a high calcium burden. We had two patients in our study where the decision was made to operate conventionally because the calcium load was extremely high. I didn’t find that patients having a small aortic annulus posed a higher risk for paravalvular leaks. In fact, patients receiving a 23 mm Sapien valve didn’t have a higher risk for leaks, but the patients with a larger annulus were even more prone to leaks. This might even have been because we didn’t have the 29 mm Sapien available at the time, but now we have it.

Dr F. Mohr (Leipzig, Germany): In general I think this is a very interesting score helping us to define preoperatively what we should do, and it is too tough for a resident to decide whether we would go surgical or not. I think we still have the option of surgery. And it really shows us a kind of direction, even in the older patients, that in some situations, for example in small annuluses, we would rather go for a root replacement to dissect out the whole calcium. So we don’t shy away from doing surgery still. It just shows, and it is just focusing right now on the balloon-expandable valve, which I think is important. If you would do a re-evaluation on the self-expanding valve such as the CoreValve and others which don’t have the same force, it may even play a major role, and the significance of a lot of calcium, and even more impact on the postoperative result in terms of the persistence of aortic regurgitation.
I think if we can predict somehow whether these patients will have regurg or not, and this is one way to do it, it will in the future help us to define the best valve for a given patient or the best procedure.

Dr von Segesser (Lausanne, Switzerland): I think this is a very nice study because it tells us about the decision-making as just outlined before. The problem is, of course, that those patients who have most of the calcium are exactly those we don’t want to operate on, because it is the patient on dialysis that has calcium everywhere, not only in the valve but in the coronaries, and we may discuss with the family in a better way because we know that the risk is higher. And the point was made about the valve choice, but probably we will still go for a transfemoral or transapical procedure then. What do you think?

Dr Hänsig: Well, I think the same pretty much. These are the high-risk patients, even the high-risk patients in TAVI procedures, and it is hard to decide what to do in these patients. It seems a little bit of a paradox, but they have a higher mortality, even in TAVI patients. So I think we have to find maybe new approaches for these patients.

Dr C. Huber (Bern, Switzerland): Intuitively I would have thought that more calcium would also predict more strokes. I am quite surprised by the number. But I do understand this was all balloon-expandable devices. Do you have any data comparing balloon-expandable and self-expanding devices in terms of stroke and calcium scoring preoperatively?

Dr Hänsig: We don’t have any data regarding calcium scoring, but we have some data from the second generation valve devices regarding the stroke rate. At the moment the patient number is too low to decide if there is a higher or lower stroke rate, but the trend is towards a lower stroke rate actually, for these devices.

Dr R. Mueller (Siegburg, Germany): We did the same with the transfemoral CoreValve design, and what we found was that eccentric calcification is a predictor of regurgitation and pacemaker implantation. Did I understand you correctly that you didn’t see this?

Dr Hänsig: We didn’t find a significant impact of eccentric calcification on pacemaker implantation or on leaks, actually.