Original Research

Calcium Load in the Aortic Valve, Aortic Root, and Left Ventricular Outflow Tract and the Risk for a Periprocedural Stroke

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ABSTRACT

Background: Periprocedural stroke during transcatheter aortic valve implantation is a rare but devastating complication. The calcified aortic valve is the most likely source of the emboli in a periprocedural stroke. The total load and distribution of calcium in the leaflets, aortic root, and left ventricular outflow tract varies from patient to patient. Consequently, there could be patterns of calcification that are associated with a higher risk of stroke. This study aimed to explore whether the pattern of calcification in the leaflet, aortic root, and ascending aorta can be used to predict a periprocedural stroke.

Methods: Among the 3282 consecutive patients who received a transcatheter aortic valve implantation in the native valve in Sweden from 2014 to 2018, we identified 52 who had a periprocedural stroke. From the same cohort, a control group of 52 patients was constructed by propensity score matching. Both groups had one missing cardiac computed tomography, and 51 stroke and 51 control patients were blindly reviewed by an experienced radiologist.

Results: The groups were well balanced in terms of demographics and procedural data. Of the 39 metrics created to describe calcium pattern, only one differed between the groups. The length of calcium protruding above the annulus was 10.6 mm (interquartile range 7-13.6) for patients without stroke and 8 mm (interquartile range 3-10) for stroke patients.

Conclusions: This study could not find any pattern of calcification that predisposes for a periprocedural stroke.

ABBREVIATIONS

CPD, cerebral protection device; CT, computed tomography; LCC, left coronary cusp; LVOT, left ventricular outflow tract; NCC, noncoronary cusp; RCC, right coronary cusp; SAVR, surgical aortic valve replacement; SWEDEHEART, Swedish Web-system for Enhancement and Development of Evidence-based care in Heart Disease Evaluated According to Recommended Therapies; SWENTRY, SWEdish traNscatheter cardiac intervention registTRY; TAVR, transcatheter aortic valve replacement.

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Introduction

Treatment of aortic stenosis is changing rapidly as more evidence becomes available on the safety and efficacy of transcatheter aortic valve replacement (TAVR).1-4 Despite the fact that TAVR is as safe as surgical aortic valve replacement (SAVR), and in some cases leads to improved outcome compared with SAVR, severe complications still occur.1,2 The most prevalent complications are the need for a pacemaker, puncture site bleeding, renal impairment, and residual paravalvular leak. All these complications are manageable, often with little impact on patient outcome or quality of life. However, a periprocedural stroke is a potentially devastating complication that quickly offsets the benefits of the intervention. The frequency of periprocedural strokes during TAVR has been reported between 1% and 5%,5-8 and the 1-year survival after stroke is 40% to 46%.9,10 Given the negative impact of a periprocedural stroke on not only patient morbidity and mortality but also hospital systems, out-of-hospital care facilities, and emotional trauma to relatives, it is imperative to reduce the incidence of this complication.

Recently, different cerebral protection devices (CPDs) have been introduced11-13 as a way to mitigate the risk of a periprocedural stroke. A reduction in stroke rate by CPD has only been shown in propensity-matched studies or meta-analyses.11,14-16 Therefore, uncertainty exists as to whether CPD should be introduced to all patients, no patients, or to a subgroup of patients at high risk for periprocedural stroke. Several reports have found patient-specific risk factors for developing a stroke,5,8 where the most frequent are previous stroke, age, reduced renal function, atrial fibrillation, high body mass index, and female sex. However, none of the studies have considered the calcium load and distribution in the aortic valve and left ventricular outflow tract (LVOT). Only a few studies have looked at the possible linkage between calcium distribution in the aortic root and the risk for stroke,17,18 but these studies were performed on a small number of stroke patients.

Therefore, the aim of the present study was to determine whether radiological characteristics of the LVOT, annulus, and aortic valve can predispose patients to periprocedural stroke.

Material and Methods

Study Design

This is a retrospective, nationwide follow-up study of all patients who underwent TAVR in Sweden from January 2014 to September 2018. During this period, a CPD was not used in Sweden. The data set and data sources have been described earlier.19 The initial data source was the national TAVR registry SWENTRY (SWEdish trAnscatheter cardiac intervention regisTRY), which is a part of the SWEDHEART registry (Swedish Web-system for Enhancement and Development of Evidence-based Care in Heart Disease Evaluated According to Recommended Therapies) and contains information on all TAVR procedures performed in the country.20 During the study period, a total of 3282 patients received a TAVR in a native valve (valve-in-valve procedures were excluded), and 52 (1.6%) of them developed a stroke during the procedure and were included in the stroke cohort (Table 1). A propensity score matching was performed based on 6 variables: age, gender, hypertension, peripheral vascular disease, atrial fibrillation, and myocardial infarction within the last 3 months; with the nearest neighbor method used to create a control group of 52 patients (Figure 1).

The study was approved by the National Ethical Review Board in Sweden (registration number 2017/595 and EPN 2019/0584).

Radiological Analysis

We turned to all 8 centers performing TAVR in Sweden and asked for the multidetector computed tomography images of the heart and aorta performed before the TAVR for both the case and the control group. The images were electronically transferred to a local server in our hospital. Image analysis was performed by one (A.P.) thoracic radiologist blinded to the outcome (stroke/no stroke). Image storage, assessment, reconstruction, and semi-quantitative analysis were performed for all cases using Sectra IDS7 (Sectra AB, Linköping, Sweden). Quantitative analysis of calcium burden was assessed using a modified routine within the cardiac workflow in Syngo.Via (Siemens Health, Erlangen, Germany).

Relevant computed tomography (CT) series were identified: submillimeter slices of electrocardiogram-gated iodine contrast-enhanced imaging of the aorta root in 1 or 2 time points within the cardiac cycle, 3-mm thick slices of non-contrast-enhanced electrocardiogram-gated imaging of aorta root for standard calcium scoring according to Agatston, and submillimeter slices of imaging of the whole aorta.

Semi-quantitative analysis of the device landing zone was performed on a 1 mm thick slice reconstructed to have the aortic annulus and left ventricular outflow tract (LVOT). Only a few studies have looked at the possible linkage between calcium distribution in the aortic root and the risk for stroke,17,18 but these studies were performed on a small number of stroke patients.

Table 1

<table>
<thead>
<tr>
<th>Center</th>
<th>Cases</th>
<th>Stroke</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>443</td>
<td>3 (0.7%)</td>
</tr>
<tr>
<td>2</td>
<td>99</td>
<td>1 (1.0%)</td>
</tr>
<tr>
<td>3</td>
<td>386</td>
<td>3 (0.8%)</td>
</tr>
<tr>
<td>4</td>
<td>487</td>
<td>13 (2.7%)</td>
</tr>
<tr>
<td>5</td>
<td>931</td>
<td>21 (2.3%)</td>
</tr>
<tr>
<td>6</td>
<td>302</td>
<td>2 (0.7%)</td>
</tr>
<tr>
<td>7</td>
<td>433</td>
<td>5 (1.2%)</td>
</tr>
<tr>
<td>8</td>
<td>201</td>
<td>4 (2.0%)</td>
</tr>
<tr>
<td>Total</td>
<td>3282</td>
<td>52 (1.6%)</td>
</tr>
</tbody>
</table>

For the largest calcification, the extent above and under the annulus plane was measured on dedicated longitudinal reconstructions. Commissure calcifications were assessed on image series consisting of axial reconstructions of the aortic root (Figure 2).

Total calcium volume in the valve leaflets and LVOT were quantified using a modified calcium scoring protocol as described by Bettinger et al.21 (Figure 3). Briefly, a threshold for separating calcium from the iodine was defined as 150 HU + the average attenuation in the lumen at annulus level, and the volume of voxels with higher attenuation was defined as calcium.

Statistical Analysis

A Shapiro–Wilk’s test was performed to test distribution of data, and depending on the result, either a Student’s t-test or Mann-Whitney U-test was performed for continuous data. For dichotomous data, a Fisher’s exact test was used. Data are presented as mean ± SD, number (percentage), or median with interquartile range (interquartile range [IQR]). A p-value <0.05 was considered statistically significant. Data analyses were performed using Stata version 14.2 (StataCorp LLC, College Station, TX).

Results

Of the 104 patients included in the study, 2 did not undergo a CT examination of the heart, yielding 51 patients for both the case and the control group (Figure 1). The case and control groups were well balanced, with no significant differences in the demographic profile and comorbidities (Table 2). There were no significant differences in the distribution of strokes between centers during study period.
differences in intraprocedural relevant variables: access (transfemoral 92% for control group and 88% for stroke group), predilatation (49% for both groups), valve type (55% SEV for control group and 57% SEV for stroke group), and postdilatation (14% for control group and 16% for stroke group; Table 2). There were no differences between the groups for the postoperative outcome in terms of new permanent pacemaker, new dialysis, bleeding complications, infection, or new atrial fibrillation (Table 2). The group with stroke had, however, a higher 30-day mortality (17.3% vs. 3.8%; p = 0.026).
Total Calcium Load

There were no differences in total calcium load of the aortic valve described as volume (867.5 [IQR 628-1272] mm$^3$ for the no stroke group vs. 798.5 [IQR 488-1365] mm$^3$ for the stroke group, $p = 0.53$; Table 3).

Annular Calcium Load

In the comparison of all annuli in both groups, there were no differences in the amount of calcium (Table 3). When the annuli with calcification were analyzed separately, only the length that calcium was protruding above the annulus differed with 10.6 mm [IQR 7-13.6] for patients without stroke and 8 mm [IQR 3-10] for stroke patients ($p = 0.012$; Table 4).

LVOT Calcium Load

In the analysis of LVOT, there was no difference in calcium load between patients. When the patients with LVOT calcifications were compared, there also was no noted difference (Table 5).
In this study, we sought to find a pattern of calcification in the aortic valve and aortic root that predisposed patients to a periprocedural stroke. Despite a detailed analysis of calcium distribution, the study failed to find any radiological signs that could help us categorize patients as high risk or low risk for a periprocedural stroke.

Only one significant finding was made in our comparison, and it was the length that the calcium extended above the aorta annulus. Interestingly, this metric was higher in the control group than in the stroke group. Our interpretation of this finding is that it is a type I error, especially because we did not adjust for multiple testing in this study, and the finding has no clinical relevance. The presence of calcium in the LVOT was found in 55% of stroke patients and 37% in the control group.
IQR, interquartile range.

Table 3

<table>
<thead>
<tr>
<th>Measurement</th>
<th>All (n = 102)</th>
<th>No stroke (n = 51)</th>
<th>Stroke (n = 51)</th>
<th>p level</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean ± SD</td>
<td>Median [IQR]</td>
<td>Mean ± SD</td>
<td>Median [IQR]</td>
</tr>
<tr>
<td>Total calcium load mm³</td>
<td>1106 ± 1028</td>
<td>840.5 [552-1329]</td>
<td>1079 ± 865</td>
<td>867.5 [628-1272]</td>
</tr>
</tbody>
</table>

Notes. Calcium volume presented for the entire cohort and the 2 groups expressed as mm³.

IQR, interquartile range.

Table 4

<table>
<thead>
<tr>
<th>Measurement</th>
<th>All (n = 102)</th>
<th>No stroke (n = 51)</th>
<th>Stroke (n = 51)</th>
<th>p level</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean ± SD</td>
<td>Median [IQR]</td>
<td>Mean ± SD</td>
<td>Median [IQR]</td>
</tr>
<tr>
<td>Commissural Ca bridge</td>
<td>21% (21)</td>
<td>25% (13)</td>
<td>16% (8)</td>
<td>0.327</td>
</tr>
<tr>
<td>Ca in annulus</td>
<td>53% (54)</td>
<td>51% (26)</td>
<td>55% (28)</td>
<td>0.843</td>
</tr>
<tr>
<td>No. of calcifications</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Annulus</td>
<td>0.53 ± 0.5</td>
<td>1 [0-1]</td>
<td>0.88 ± 1.03</td>
<td>0 [0-1]</td>
</tr>
<tr>
<td>RCC</td>
<td>0.14 ± 0.37</td>
<td>0 [0-0]</td>
<td>0.1 ± 0.3</td>
<td>0 [0-0]</td>
</tr>
<tr>
<td>LCC</td>
<td>0.41 ± 0.63</td>
<td>0 [0-1]</td>
<td>0.31 ± 0.55</td>
<td>0 [0-1]</td>
</tr>
<tr>
<td>NCC</td>
<td>0.28 ± 0.59</td>
<td>0 [0-0]</td>
<td>0.27 ± 0.49</td>
<td>0 [0-1]</td>
</tr>
</tbody>
</table>

Notes. Upper part all 102 CT examinations. Lower part only the 54 examinations with calcifications in the annulus.

IQR, interquartile range; LCC, left coronary cusp; NCC, noncoronary cusp; RCC, right coronary cusp.

(p = 0.074). It could be argued that this is type II error and that a larger cohort would have detected a difference. But the absolute difference is 18%, so it would not be a strong predictor that could be useful in determining whether to use a CPD or not.

Relation to Previous Studies

At least 2 other studies have tried to explore a relation between aortic valve morphological and the risk for a periprocedural stroke. Pollari et al.18 found that the amount of calcium in LVOT of RCC correlated with stroke. However, in their study, they analyzed all in-hospital strokes, not only periprocedural strokes. Moreover, the study covered only 9 cases of stroke and 572 patients without stroke, making it challenging to draw conclusions regarding high-risk anatomical features. Spaziano et al. 17 found that LVOT calcium predisposed patients for a composite outcome of death and stroke at 1 year in women. Aggarwal et al.22 used transcranial doppler in a series of 63 patients and found a correlation between the number of high-intensity transient signals and calcium load of the aortic valve and aortic root measured as Agatston score. A similar finding was done by Vlastra et al. 23 when they correlated magnetic resonance imaging findings with calcium burden. They found that aortic valve calcium volume correlated to new cerebral white matter hyperintensity. However, no such correlation was found for calcium burden in the ascending aorta and LVOT. To summarize these findings, one study found that LVOT calcium correlated with clinical stroke, whereas 2 studies found a correlation between embolic load and aortic valve calcium but not with LVOT calcium. Given the disparate results of these studies with different designs and weaknesses, no clear pattern can be established between calcium burden in the aorta/aortic valve/LVOT and the risk of periprocedural stroke. The findings of the present study further strengthen the notion that no strong correlation exists.

Clinical Perspective

The main driver and rationale for this study were to identify anatomical signs in CT imaging that could help us identify patients at high risk for a periprocedural stroke and who would benefit most from a CPD. The scientific data supporting the adoption rate of CPD in practice is currently limited. Although randomized studies have shown no or even negative effects 16,24 of CPD, meta-analysis and pooled data have been able to find a benefit in terms of stroke reduction.16,24 Therefore, the question of if and when to use CPD is still unanswered. This question is being addressed in 2 smaller ongoing studies (Clinicaltrials registration numbers: NCT02895737 and NCT04704258) and 1 larger ongoing study (Clinicaltrials registration number: NCT04149535). The large study includes a wide selection of TAVR patients and will include 3000 patients and have any type of stroke as its primary endpoint.
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setting the threshold to discern between calcium and iodine contrast,

image acquisition parameters. This has an impact on the accuracy of

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examinations with the granularity used in this study. Another limitation

would be an almost insurmountable task to review more than 3000 CT

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Limitations and Strengths

The present study has both some limitations and strengths. Among

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native would be to use the entire cohort as a control group. However, it
would be an almost insurmountable task to review more than 3000 CT
examinations with the granularity used in this study. Another limitation
is the relatively small cohort of 52 patients with a periprocedural
stroke. A larger cohort could potentially detect differences that we
could not find in the current cohort. However, we could not discern any
obvious trend in this study, and therefore, even if a larger cohort would
yield a positive result, the difference between the groups would be
small. As we did not have CT of the brain for stroke patients, we could
do not discern between calcific and thrombotic emboli, where the former
presumably originates from the aortic valve and the latter from the aorta
delivery system. This is a registry-based study and reporting of the
occurrence of cerebral events or not was performed by the
clinicians responsible for the care of the patients. A structured neuror-
logical examination with a CT would have increased the accuracy of the
stroke diagnosis but would need to be assessed in the same manner for
the entire cohort to yield equal groups and thus impossible to have as a
clinical routine. But as it is a all-comers study for all TAVR patients
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Notes. Upper part all 102 CT examinations. Lower part only the 47 examinations with calcifications in the LVOT.
IQR, interquartile range; LCC, left coronary cusp; LVOT, left ventricular outflow tract; NCC, noncoronary cusp; RCC, right coronary cusp.

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Table 5

<table>
<thead>
<tr>
<th>Measurement</th>
<th>All (n = 102)</th>
<th>No stroke (n = 51)</th>
<th>Stroke (n = 28)</th>
<th>p level</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean ± SD</td>
<td>Median (IQR)</td>
<td>Mean ± SD</td>
<td>Median (IQR)</td>
</tr>
<tr>
<td>Ca in LVOT</td>
<td>46% (47)</td>
<td>37% (19)</td>
<td>55% (28)</td>
<td>0.074</td>
</tr>
<tr>
<td>Number of calcifications</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Aneurysm</td>
<td>0.61 ± 0.82</td>
<td>0 [0-4]</td>
<td>0.49 ± 0.73</td>
<td>0 [0-3]</td>
</tr>
<tr>
<td>RCC</td>
<td>0.05 ± 0.22</td>
<td>0 [0-1]</td>
<td>0.06 ± 0.24</td>
<td>0 [0-1]</td>
</tr>
<tr>
<td>LCC</td>
<td>0.34 ± 0.59</td>
<td>0 [0-3]</td>
<td>0.25 ± 0.48</td>
<td>0 [0-2]</td>
</tr>
<tr>
<td>NCC</td>
<td>0.22 ± 0.41</td>
<td>0 [0-1]</td>
<td>0.18 ± 0.39</td>
<td>0 [0-1]</td>
</tr>
</tbody>
</table>

Patients with calcification in LVOT

<table>
<thead>
<tr>
<th>Sector with Ca (arc degree)</th>
<th>All (n = 47)</th>
<th>No stroke (n = 19)</th>
<th>Stroke (n = 28)</th>
<th>p level</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean ± SD</td>
<td>Median (IQR)</td>
<td>Mean ± SD</td>
<td>Median (IQR)</td>
</tr>
<tr>
<td>RCC</td>
<td>1.6 ± 5.5</td>
<td>0 [0-0]</td>
<td>2.7 ± 7.8</td>
<td>0 [0-0]</td>
</tr>
<tr>
<td>LCC</td>
<td>13.5 ± 14.6</td>
<td>10.1 [0-18.2]</td>
<td>14.3 ± 15.1</td>
<td>10.3 [0-21.4]</td>
</tr>
<tr>
<td>NCC</td>
<td>8.1 ± 10.5</td>
<td>0 [0-14.5]</td>
<td>10 ± 12.5</td>
<td>0 [0-18.4]</td>
</tr>
<tr>
<td>Area of Ca per cusp (mm²)</td>
<td>0.9 ± 3.2</td>
<td>0 ± 0.0</td>
<td>1.5 ± 4.6</td>
<td>0 [0-0]</td>
</tr>
<tr>
<td>LCC</td>
<td>7.3 ± 10.1</td>
<td>3.5 [0-8.7]</td>
<td>7.3 ± 8.9</td>
<td>6 [0-9]</td>
</tr>
<tr>
<td>NCC</td>
<td>3.3 ± 4.3</td>
<td>0 [0-6.4]</td>
<td>3.2 ± 4.3</td>
<td>0 [0-6.4]</td>
</tr>
</tbody>
</table>

Notes. Upper part all 102 CT examinations. Lower part only the 47 examinations with calcifications in the LVOT.
IQR, interquartile range; LCC, left coronary cusp; LVOT, left ventricular outflow tract; NCC, noncoronary cusp; RCC, right coronary cusp.

Conclusions

In this study, we could not find any patterns of calcium load on CT imaging that predisposes patients to periprocedural stroke and, conse-
quently, were unable to identify a population at higher risk for a peri-
procedural stroke.

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Ethics Statement

The study followed the Declaration of Helsinki for studies in human
subjects and was approved by the National Ethical Review Board in
Sweden (registration number 2017/995 and EPN 2019/0584).

Funding

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Boston Scientific.

Disclosure statement

H. Bjursten has served as a consultant for Boston Scientific and
Edwards Lifesciences. N. Samano received honorarium from Edwards
Lifesciences. A. Rück has served as a consultant and received research
support from Boston Scientific and Edwards Lifesciences. S. James
received procuring fees from Medtronic. M. Settergren has served as a
consultant and advisory boards for Boston Scientific, Edwards
Lifesciences, Abbott Vascular, and WL Gore. M. Göteborg has served as a consultant for Boston Scientific. The other authors had no conflicts to declare.

Acknowledgments

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References