Ventral calcification in the common femoral artery: A risk factor for major transcatheter aortic valve intervention access site complications

Dawid L. Staudacher MD1 | Katrin Braxmeier MS1 | Peter Stachon MD1 | Ingo Hilgendorf MD1 | Christopher Schlett MD2 | Manfred Zehender MD1 | Constantin von zur Mühlen MD1 | Christoph Bode MD1 | Timo Heidt MD1

1Department of Cardiology and Angiology I, University Hospital Freiburg and Faculty of Medicine, University of Freiburg, Freiburg, Germany
2Department of Radiology, University Hospital Freiburg and Faculty of Medicine, University of Freiburg, Freiburg, Germany

Correspondence
Timo Heidt, Department of Cardiology and Angiology I, University Hospital Freiburg, University of Freiburg, Hugstetterstr. 55, Freiburg 79106, Germany.
Email: timo.heidt@uniklinik-freiburg.de

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Abstract
Objectives: We aimed to identify risk factors for major transcatheter aortic valve intervention (TAVI) access site complications based on detailed analysis of the preprocedural computed tomography angiogram (CTA).

Background: Transfemoral TAVI has become the treatment of choice for severe aortic stenosis in elderly patients, especially with increased perioperative risk. Frailty, however, favors complications at the vascular access site due to the large bore vascular sheath devices necessary for valve deployment.

Methods: In this monocentric study, we retrospectively analyzed the preprocedural CTA of 417 consecutive patients that received transfemoral TAVI between 2015 and 2019 to quantify vessel diameter, calcification volume and calcified plaque location in detail within 10 cm proximal to the femoral bifurcation.

Results: The mean age of the study cohort was 81.4 ± 6.5 years with a STS of 8 ± 5.2 representing a population at increased periprocedural risk. 54.4% of patients were female. Major vascular access site complications occurred in 8.2% of patients. Major vascular complications correlated statistically with a sheath-to-vessel diameter (SFAR) when measured 1 cm proximal to the femoral bifurcation using a line-derived diameter and ventral calcification within the first 5 cm proximal to the bifurcation. In contrast, overall calcification volume had no influence.

Conclusions: Transfemoral TAVI harbors a considerable risk for vascular access site complications especially if vessel diameter is too small to comfortably host the sheath diameter at the area of the femoral bifurcation. Preprocedural TAVI planning and risk assessment, location of calcification, especially if located ventrally, seems to be more relevant than consideration of overall calcification alone.

Keywords: aortic valve replacement, computed tomography angiogram, risk assessment
1 | INTRODUCTION

Transfemoral transcatheter aortic valve intervention (TAVI) has become the treatment of choice for severe symptomatic aortic valve stenosis in elderly patients, especially with increased periprocedural risk. This development is driven by significant reductions in mortality, stroke and renal failure across transfemoral TAVI patients owing to the decreased invasiveness of the procedure as compared to surgical aortic valve replacement (SAVR). Nonetheless, age and frailty of TAVI patients bears the risk for periprocedural complications, especially at the vascular access site due to the large bore arterial access needed for valve deployment. Management of these complications may again be associated with a prolonged hospital stay and an increasing risk for secondary complications, thus considerable health care costs.

While the incidence of major access site complications has subsequently decreased by improvements in sheath design, major access site bleeding is still a relevant periprocedural complication resulting from vascular injury, dissection or failure of the vascular closure device. For standardized assessment of these events the Valve Academic Research Consortium (VARC) and the Bleeding Academic Research Consortium (BARC) have defined specific criteria for classification of bleeding after vascular interventions.

Looking for risk factors that predict periprocedural vascular complications, previous studies identified a mismatch in the sheath-to-femoral-artery ratio (SFAR) to correlate with major access site complications. Also, extensive calcification, especially of circumferential extent, or female sex have been reported to be risk factors for adverse events. While these findings have been generally accepted, data were retrieved from several individual studies. Where to analyze SFAR exactly or how to quantify the extent or location of calcification often remained unclear. In this study, we performed extensive analysis of the TAVI access vessel to define the vascular area for measurement of SFAR and calcification in order to predict vascular outcome.

2 | METHODS

2.1 | Study cohort

Datasets of 417 consecutive patients that underwent transfemoral TAVI at University Heart Center Freiburg between May 2015 and September 2019 were included in the study. All patients received a contrast enhanced-multislice computed tomography to plan the procedure and assess the vascular anatomy at the access site. Decision on TAVI versus surgery, type of prosthesis used and vascular access site was to the courtesy of an interdisciplinary heart team. Patients who presented with iliofemoral vascular pathology not suitable for transfemoral TAVI access were excluded from this study. Available balloon-expandable or self-expandable valves were implanted without a prespecified preference (Edwards \(n = 282\)), Medtronic \(n = 83\), DirectFlow \(n = 45\), Symmetis \(n = 6\), JenaValve \(n = 1\)). Clinical data were retrieved from the hospital’s database.

![Vessel assessment](overview.png)

**FIGURE 1** Vessel assessment. Femoral and iliac arteries were reconstructed and segmented from CTA data depicting the vascular anatomy from the aorta to the femoral bifurcation. The bifurcation of the femoral artery was set as baseline and diameters as well as vessel calcification was assessed every 1 cm up to 10 cm proximal to baseline (base).
2.2 CT data analysis

Contrast enhanced – cardiac gated multi-slice computed tomography scans were performed for TAVI procedural planning. The vascular access site was digitally reconstructed with a slice thickness of 1 mm. For image analysis a dedicated software program (3mensio Structural Heart©; 3mensio Medical Imaging and Pei Medical Imaging, Netherlands) was used (Figure 1).

Exact matching of the actual puncture site from angiography with CTA was not possible. We, therefore, defined the vascular access site as the vessel section covering 10 cm proximal to the femoral bifurcation. After identification of the region of interest, the vessel was subdivided into 10 sections at a distance of 1 cm each starting at the femoral bifurcation. Anatomical specifications were assessed based on the vessel’s centerline. For each section the minimal and mean vessel diameter was measured based on the cross-sectional area. Sheath-to-femoral-artery ratio (SFAR) was calculated as the minimum vessel diameter as measured or calculated from minimum vessel area at the access site and the outer diameter of the delivery sheath as specified by the vendor. Vessel calcification was measured by calcification volume (mm$^3$) using an elevated calcification threshold of 600 HU to avoid registration of artifacts.

### TABLE 1  Baseline characteristics of the study population

|                         | Whole cohort | Major complication | No-major complication | p-value group 2 vs. 3 |
|-------------------------|--------------|--------------------|-----------------------|----------------------|
| Group                   | 1            | 2                  | 3                     |                      |
| Number of patients      | 417          | 34                 | 383                   |                      |
| Female gender           | 227 (54.4%)  | 20 (58.8%)         | 207 (54.0%)           | 0.720                |
| Age (years)             | 81.4 ± 6.5   | 80.5 ± 6.7         | 81.5 ± 6.5            | 0.410                |
| Hypertension            | 339 (81.3%)  | 25 (73.5%)         | 314 (82.0%)           | 0.250                |
| Diabetes mellitus       | 130 (31.2%)  | 12 (35.3%)         | 118 (30.8%)           | 0.568                |
| Hypercholesterinemia    | 288 (69.1%)  | 24 (70.6%)         | 264 (68.9%)           | 1.000                |
| Coronary artery disease | 294 (70.5%)  | 28 (82.4%)         | 266 (69.5%)           | 0.168                |
| Peripheral artery disease| 44 (10.6%)   | 2 (5.9%)           | 42 (11.0%)            | 0.559                |
| Cerebral artery disease | 97 (23.3%)   | 8 (23.5%)          | 89 (23.2%)            | 1.000                |
| Atrial fibrillation     | 200 (48.0%)  | 26 (76.5%)         | 174 (45.4%)           | 0.001                |
| Current smoker          | 84 (20.1%)   | 8 (23.5%)          | 76 (19.8%)            | 0.655                |
| Preexisting CAD stent   | 178 (42.7%)  | 19 (55.9%)         | 159 (41.5%)           | 0.147                |
| Preexisting CABG        | 22 (5.3%)    | 2 (5.9%)           | 20 (5.2%)             | 0.698                |
| Valve in valve procedure| 17 (4.1%)    | 1 (2.9%)           | 16 (4.2%)             | 1.000                |
| NYHA score before TAVI  | 2.9 ± 0.9    | 3.0 ± 0.8          | 2.9 ± 0.9             | 0.578                |
| STS score               | 8.0 ± 5.2    | 9.6 ± 6.5          | 7.8 ± 5.0             | 0.063                |
| AVA (cm$^2$)            | 0.7 ± 0.2    | 0.8 ± 0.2          | 0.7 ± 0.2             | 0.534                |
| dPmean (aortic valve) (mmHg) | 42.3 ± 14.2 | 39.8 ± 14.4       | 42.5 ± 14.2           | 0.295                |
| dPmax (aortic valve) (mmHg) | 71.5 ± 23.3 | 69.2 ± 22.5       | 71.7 ± 23.4           | 0.580                |
| LVEF (%)                | 50.2 ± 10.5  | 49.9 ± 11.3        | 50.3 ± 10.4           | 0.842                |
| TAVI side               |              |                    |                       |                      |
| TAVI via right femoral  | 361 (86.6%)  | 30 (88.2%)         | 331 (86.4%)           | 1.000                |
| Diameter minimal 1–10 cm (mm) | 6.9 ± 1.3 | 6.6 ± 1.6          | 7.0 ± 1.3             | 0.105                |
| Diameter minimal 1–10 cm (area) (mm) | 7.7 ± 1.2 | 7.5 ± 1.5          | 7.7 ± 1.2             | 0.323                |
| Calcification           | 79.9 ± 146.4 | 111.2 ± 263.4     | 77.1 ± 131.4          | 0.193                |
| Non-TAVI side           |              |                    |                       |                      |
| Diameter minimal 1–10 cm (mm) | 6.9 ± 1.4 | 6.6 ± 1.9          | 6.9 ± 1.3             | 0.159                |
| Diameter minimal 1–10 cm (area) (mm) | 7.6 ± 1.3 | 7.3 ± 1.5          | 7.6 ± 1.3             | 0.241                |
| Calcification           | 82.9 ± 156.9 | 122.8 ± 282.5     | 76.2 ± 129.4          | 0.078                |
| Deceased 30 days        | 11 (2.6%)    | 3 (8.8%)           | 8 (2.1%)              | 0.052                |
| Complication major      | 34 (8.2%)    | 34 (100%)          | 0 (0%)                | 0.001                |
| Complication minor      | 94 (22.5%)   | 0 (0%)             | 94 (24.5%)            | 0.001                |
| BARC 3–5 access site bleeding | 25 (6.0%) | 25 (73.5%)       | 0 (0%)                | 0.001                |
| Closure device failure  | 44 (10.6%)   | 23 (67.6%)         | 21 (5.5%)             | 0.001                |
In addition, the location of vessel calcification was assessed (ventral, posterior, or balanced).

### 2.3 | End point definition

Major complications were defined as access site complications documented either in the implantation protocol or in the electronic patient files of the intensive care unit (where all patients after TAVI are routinely monitored for at least 24 h) requiring any form of intervention, including prolonged manual compression of the access site, large hematoma but also shock and vascular occlusion or false aneurysm requiring any form of intervention. Any other form of documented complication was considered minor.

### 2.4 | Ethics

For this study, patients’ records and CT data of hospitalized TAVI patients were retrospectively analyzed at the University Heart Center Freiburg covering the years May 2015 to September 2019. Data analysis was blinded to patient identity. This study was approved by the local ethics committee (Ethics Committee of Albert-Ludwigs University of Freiburg).

### 2.5 | Statistics

For statistics, SPSS (version 25, IBM Statistics) or Prism (version 8, GraphPad) was used to plot relevant study data in standardized tables. Data are shown as n (%), mean ± SD or odds ratio (OR) with 95% confidence interval (CI). For analysis, Student’s t-test, Fisher’s exact test/Chi-square test and Mantel-Cox test was applied. A p < 0.05 was considered statistically significant. Multivariate regression analysis was performed to check for interactions and to estimate magnitude of predictors (p < 0.05).

### 3 | RESULTS

#### 3.1 | Study population

Table 1 illustrates the baseline characteristics of our study population. Between 2015 and 2019, a total of 417 patients underwent

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**FIGURE 2**  Vessel contour analysis. (A) CTA-reconstruction of the stretched iliac and femoral artery and contour analysis. (B) Diagram depicts the mean minimal vessel diameter and SD of all reconstructed vessels according to distance to bifurcation, assessed on TAVI and non-TAVI side (above). Distribution pattern of vessel diameters of the common femoral artery across all vessels analyzed (below). (C) Distribution pattern of the vessel diameter of the common femoral artery 1 cm proximal to the bifurcation. (D) Statistical correlation of minimal vessel diameter or sheath-to-minimal-diameter ratio to major complications in the TAVI access vessel dependent on location of and mode of the measurement.
transfemoral TAVI at our department at University Heart Center Freiburg. The mean age was 81.5 ± 6.5 years, with 54.4% female patients. 48% of patients had atrial fibrillation, thus were on oral anticoagulation. The mean STS score was 8.0 ± 5.2 representing a TAVI cohort at increased perioperative risk. Other cardiovascular risk factors were representative for a corresponding TAVI study population. Of note, peripheral artery disease was prevalent in 10.6% of all patients. For TAVI implantation the right femoral artery was preferred in 86.6%. Major TAVI access site complications occurred in 8.4% of patients, minor non-relevant complications were reported in 22.4%. A summary of all major TAVI access site complications is provided as a supplementary table (Table S1).

3.2 Vessel contour analysis of TAVI and non-TAVI access site

We performed a detailed analysis of the TAVI access vessel as well as the contralateral non-TAVI side to define the distribution of the minimal diameter across all sections (Figure 2(A)). Within 10 cm proximal to the femoral bifurcation, the distribution of the minimal vessel diameter was comparable for the TAVI and non-TAVI vessel and displayed a normal distribution with a minimal diameter of 6.9 ± 1.3 by line or 6.1 ± 0.5 when derived from vessel area (Figure 2(B)). Taking into account only the minimal vessel diameter at 1 cm proximal to the bifurcation, the diameter was larger than the average with 8.0 ± 1.7 or 8.7 ± 1.6, respectively (Figure 2(C)). Comparing the minimal TAVI access vessel diameter of patients with major vascular complications to those of patients without major complications (no major complication), only the diameter reported at 1 cm proximal to the bifurcation by line diameter assessment correlated statistically significant. The same was true for the assessment of the sheath-to-minimal-vessel-diameter ratio (Figure 2(D)).

3.3 Assessment of access site calcification in the TAVI vessel

To assess the impact of calcification in the TAVI access vessel on complications, we recorded the calcification volume and distribution across 10 cm proximal to the femoral bifurcation. Among all forms, ventral calcification within the first 5 cm (1–5 cm) proximal to the bifurcation was significantly associated to postinterventional major complications. Total calcification volume, however, did not correlate statistically with major complications after TAVI. This was individually assessed for the full distance as well as for the first section (1–5 cm) and second section (6–10 cm) in relation to the femoral bifurcation (Figure 3).

![Figure 3](image.png)

**FIGURE 3** Complications according to vessel calcification. Correlation of calcification volume and location with occurrence of major complications in the TAVI access vessel.

| Group               | Whole cohort | Major complication | No major complication | p-value group 2 vs 3 |
|---------------------|-------------|--------------------|-----------------------|---------------------|
| Number of patients  |             |                    |                       |                     |
| Calcification mm³   |             |                    |                       |                     |
| 1-5cm               | 35.1±102.7  | 53.4±187           | 33.4±91.8             | 0.278               |
| 6-10cm              | 124.7±214.6| 169.1±349.5        | 120.7±198.6           | 0.208               |
| 1-10cm              | 79.9±146.4  | 111.2±263.4        | 77.1±131.4            | 0.193               |
| Calcification, ventral |           |                    |                       |                     |
| 1-5cm               | 96 (23.0%)  | 13 (38.2%)         | 83 (21.7%)            | 0.034               |
| 6-10cm              | 32 (7.7%)   | 3 (8.8%)           | 29 (7.6%)             | 0.737               |
4 | DISCUSSION

In this retrospective analysis, we performed detailed analysis of the preprocedural CTA and correlated major vascular access site complications after transfemoral TAVI with distinct access vessel characteristics in an elderly population at increased periprocedural risk. Major access site complications have previously been reported in 6%–10% of cases in transfemoral aortic valve implantations and are relevant drivers of morbidity and mortality. The rate of major TAVI access site complications of 8.4% as seen in our study therefore blends well into published literature (Table S1).

The relevance of SFAR had been reported elsewhere and a cut-off SFAR of 1.05 was described to correlate with access site complications and 30-day mortality. However, existing data is not consistent in this regard. A recent publication, for example, suggested that sheath size had no impact on femoral complications. A possible explanation for this opposing data might be that the evaluation of the access vessel, a crucial component to SFAR, is not well standardized. In our study, we found that sheath-to-vascular-access ratio (SFAR) correlated with major access site complications only when assessed approximately 1 cm proximal to the femoral bifurcation using a line-derived diameter while no relevant difference for SFAR was observed when using an area-derived diameter. While differences between groups were small, it seems plausible that the distal tip of the common femoral artery may be the most sensitive segment to indicate unfavorable size characteristics of the access vessel which may prompt implanters to consider an alternative access site for transcatheter valve implantations in patients at risk.

Next to SFAR, access site calcification has been reported to correlate with periprocedural complications. Again, literature provides conflicting evidence stating both relevance or non-relevance of calcifications on postprocedural outcome. Intriguingly, we found that ventral calcification in particular correlated with major access site complications, while overall calcification volume was non-predictive. This finding might best be explained by that fact that closure device failure, which is another major driver of complications, is more likely to occur in calcified vessels, especially if the calcification is close to the suture.

4.1 | Limitations

Limitations apply to the retrospective character of this study. Interdisciplinary heart team decision making based on respective guideline recommendations for TAVI introduced a patient selection bias. Only patients with suitable valve anatomy and an anticipated uncomplicated access vessel were selected for TAVI. Therefore, patients with very small femoral vessel diameters or heavy, circumferential calcifications may have been precluded from this study. Furthermore, advanced age and STS score represent a frail study population at increased periprocedural risk, while low-risk patients are under-represented. In addition, anticoagulation due to atrial fibrillation may add further complexity to frailty. Indeed, atrial fibrillation and anticoagulation were more frequent in patients with major access site complications and BARC 3–5 bleeding thus need to be acknowledged as relevant confounders.

5 | CONCLUSION

Small vessel diameter and severe calcification often causes worries about vascular complications in TAVI procedures. In this registry, we confirm previous data on the predictive value of SFAR for major adverse access site events. We demonstrate that SFAR should be assessed within 2 cm proximal to the femoral bifurcation and ventral calcification of the access vessel should be avoided, if possible. Detailed analysis of the TAVI access vessel helps risk stratification to prevent major adverse events that may affect overall outcome especially within the elderly TAVI population.

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DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

ORCID

Dawid L. Staudacher https://orcid.org/0000-0002-9423-9682
Peter Stachon https://orcid.org/0000-0002-3796-1476
Timo Heidt https://orcid.org/0000-0002-9607-7963

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SUPPORTING INFORMATION
Additional supporting information may be found online in the Supporting Information section at the end of this article.

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