Computed Tomographic Angiography-Derived Risk Factors for Vascular Complications in Percutaneous Transfemoral Transcatheter Aortic Valve Implantation

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Transfemoral aortic valve implantation (TAVI) has become a viable alternative to surgical valve implantation, particularly for higher risk patients; however, vascular complications (VCs) remain a concern in transfemoral TAVI. We aimed to determine clinical and computed tomographic angiography-derived risk factors associated with Valve Academic Research Consortium (VARC)-2 criteria VCs in patients who underwent TAVI. From 2011 to 2017, 481 patients underwent percutaneous transfemoral TAVI at the Minneapolis Heart Institute and were screened for procedural and postprocedural access-related VC according to VARC-2 criteria. Clinical and clinical and computed tomographic angiography-derived data were collected to establish risk factors for VC. A total of 99 (21%) patients had VARC-2 VCs. Closure device failure (CDF) occurred in 56 of 99 (57%), minor VCs in 37 of 99 (37%), and major VCs occurred in 6 of 99 (6%). Access site-related VCs were preceded by CDF in 18 of 43 (42%) patients and the risk of major/minor VCs was 14 times greater in patients who experienced closure complications. The incidence of CDF was higher in common femoral artery (CFA) access sites with circumferential vessel wall calcification of more than 90̄ ($p = 0.02$) and when skin-surface to CFA access-site distance at an optimal access angle of 45̄ exceeded 80 mm ($p = 0.03$). In conclusion, both the degree of circumferential CFA access site calcification and distance to skin surface at an optimal access angle may improve risk stratification of access planning in patients who underwent percutaneous transfemoral TAVI. **(Am J Cardiol 2019;124:98−104)**

Transcatheter aortic valve implantation (TAVI) is an established alternative to surgical aortic valve implantation, particularly for high- or intermediate surgical risk patients.[1−5] A transfemoral (TF) approach has become the preferred vascular access site, as it has been associated with better outcomes than non-TF approaches.[6] Despite increasing implementation of TF access, major and minor vascular complications (VCs) continue to account for significant morbidity and mortality.[7−9] Multiple factors have previously been shown to be associated with higher rates of VCs, including patient demographics (such as female gender), co-morbid conditions (peripheral artery disease [PAD] and kidney disease), as well as vessel characteristics (calcification).[8−10] Procedural factors have also been associated with VCs, including operator experience, the sheath to femoral artery ratio (SFAR), and the sheath to external iliac artery ratio (SEIAR).[10] Although procedural characteristics are often established using quantitative thresholds, many of the anatomic features that have been reported to be associated with VCs have been described using qualitative measures (e.g., scores of vessel calcification or tortuosity).[10−13] We sought to investigate the role of traditional and novel quantitative CTA-derived risk factors for VCs, including closure device failure as well as major and minor VCs in patients who underwent TF TAVI at our institution.

Methods

Demographic data on all patients who underwent TF TAVI with percutaneous closure performed at Abbott Northwestern Hospital, Minneapolis, Minnesota from January 1, 2011 to March 20, 2017 were collected from the Electronic Medical Record System (Epic Systems Corporation, Verona, Wisconsin). Patients without valid Minnesota Medical Records Authorization were excluded. The study was approved by the Allina Health Institutional Review Board.

The patient population included in this study was included in the retrospective chart review for procedural and postprocedural (before hospital discharge) TF TAVI access-related VCs according to VARC-2 criteria, including major VCs, minor VCs, and percutaneous closure device failure.[14] Patients were identified as having a closure complication if they experienced an access-related VC, which included hematoma, the use of additional devices, switch to surgical cutdown, retroperitoneal bleed, closure

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device failure, inadequate closure, arterial dissection, and thrombosis. Society of Thoracic Surgeons (STS) risk score mortality and morbidity for aortic valve implantation was calculated using the Online STS Adult Cardiac Surgery Risk Calculator based on the STS Adult Cardiac Surgery Database, version 2.81.[15]

CTAs were interpreted in 440 (91%) of the patients by 2 independent readers; the uninterpretable CTAs were all from patients who did not have VCs and were limited by various imaging artifacts (e.g., streaking artifact related to knee replacements). Patients with uninterpretable CTAs were excluded from the data analysis. CTA measurements of the common femoral artery (CFA) and external iliac artery (EIA) were taken with Vitrea imaging software (Vital Images, Inc., Minnetonka, Minnesota) through double oblique multiplanar reconstruction ipsilateral to the leg where vascular access was obtained. The sites for CFA and EIA measurements were defined as 1 cm below and 2 cm above the inferior epigastric artery, respectively. Minimum and maximum luminal diameters, as well as position, circumference, and thickness of calcification in the artery when present were measured at the CFA and EIA sites. Tortuosity (in degrees per centimeter) was measured with Vitrea's tortuosity tool. SFAR and SEIAR were defined as the ratio of the sheath diameter (in millimeters) to the minimum luminal diameter (in millimeters) at the CFA and EIA, respectively.[10] Several novel CTA measurements were also introduced to the study in an effort to characterize vascular access depth from skin and vessel calcification (Figure 1). Depth of the CFA was measured as the distance 90° vertically from the anterior skin surface to the CFA site. Distance from skin surface to CFA site at 45° was also measured as an approximation of the distance

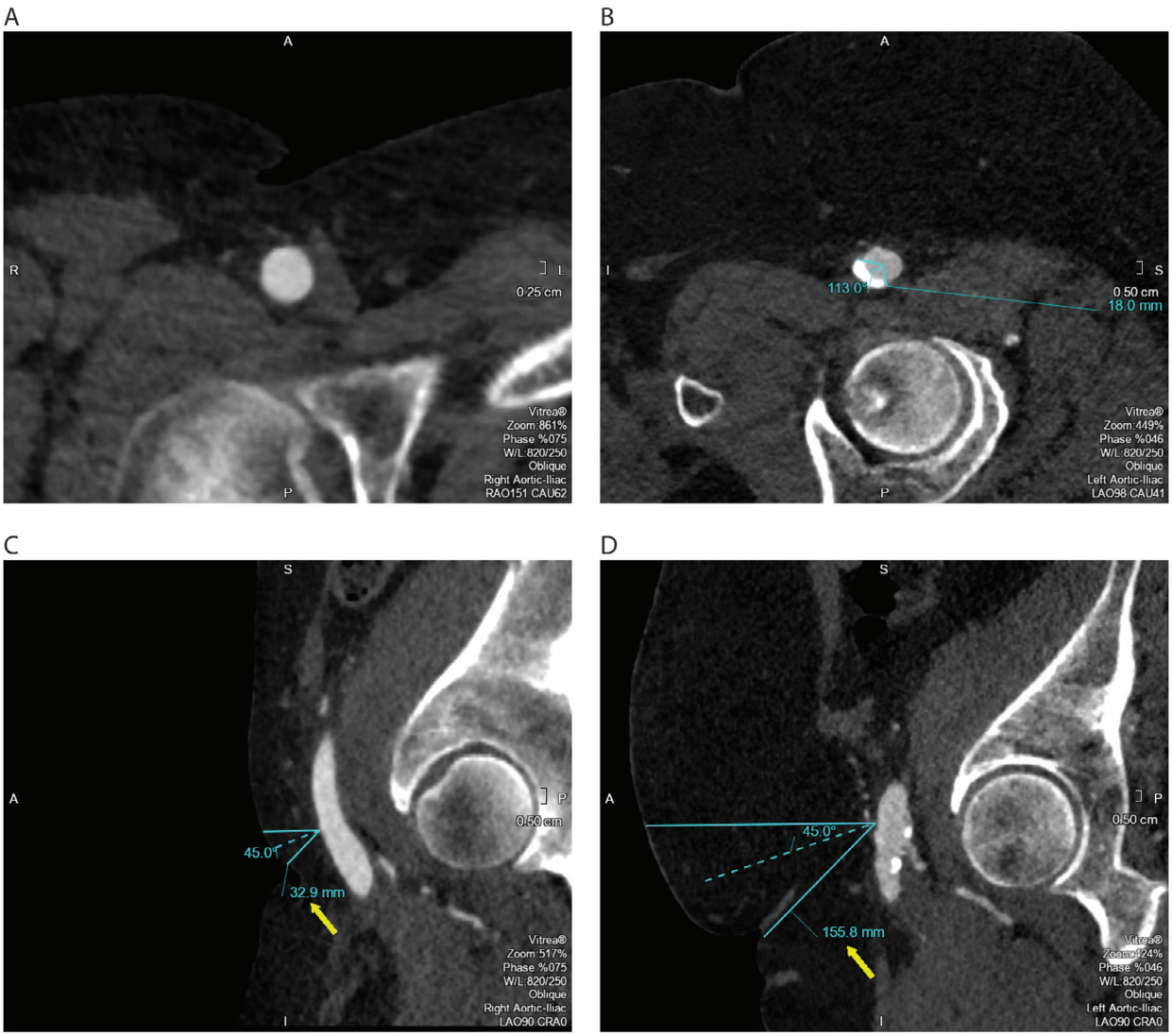

Figure 1. CTA measurements at the common femoral artery.
Representative images of common femoral artery in cross section (*A*) and with depth measured at 45° from skin surface (*C*) from a patient without vascular complication. Panels B and D are from a patient who experienced closure device failure, and represent vessel calcification and depth at 45° from skin surface, respectively. Yellow arrows indicate the measurements taken from each panel. Color version of figure is available online.

Table 1
Classification of vascular access site complications

Vascular access site complication	Number of patients (n = 99)
Major vascular*	6 (6%)
Minor vascular†	37 (37%)
Percutaneous closure device failure	56 (57%)
Conversion to surgical cutdown	13 (13%)
With closure device failure	9 (9%)
With major/minor vascular complication	4 (4%)

* Major vascular complications included ischemia (n = 3, 3%), major retroperitoneal bleeding (n = 1, 1%), vessel dissection (n = 1, 1%), and rupture (n = 1, 1%) at the access site.

† Minor vascular complications included minor hematoma (n = 26, 26%), occlusion (n = 3, 3%), pseudoaneurysm (n = 3, 3%), thrombosis (n = 2, 2%), vessel dissection (n = 1, 1%), retroperitoneal bleed (n = 1, 1%), and claudication (n = 1, 1%) at the access site.

for vascular access at an ideal access angle. Degree of calcification was obtained using Vitrea's angle tool.

Statistical analyses were performed using R 3.4.3 (R Foundation for Statistical Computing, Vienna, Austria) in RStudio 1.1.442 (RStudio, Inc., Boston, Massachusetts).[16,17] Categorical variables are reported as count (%); continuous, symmetrically distributed variables are summarized by average ± standard deviation (median); and median and interquartile range are used for continuous, skewed variables. Categorical variables between groups were compared using Pearson's chi-square test; Fisher's exact test was used for small counts. For continuous variables, Student's *t* tests were used to compare group averages for symmetric distributed variables, and Wilcoxon's rank sum tests were used to compare the distributions of the skewed variables. The relative changes in risk of CDF with respect to CT parameters were estimated using Poisson regression with a canonical log-link and a robust variance estimator. The model was adjusted for age, gender, TAVI sheath size, CFA site tortuosity, and history/presence of cardiac-related events or diagnoses (atrial fibrillation/flutter, previous myocardial infarction, previous coronary bypass, previous AV or non-AV procedures, and PAD). The relative risk of VCs associated with closure complications was estimated using a Poisson model adjusted for age, gender, previous or current cardiac events as above, and medication use on admission (P2Y12 inhibitor and aspirin or anticoagulant). The estimated risk ratios and the corresponding 95% confidence intervals are reported.

Results

Of the 481 patients who underwent percutaneous TF TAVI within the study period, 21% were identified to have VARC-2 access-related VCs. VCs were categorized by CDF, major VCs, and minor VCs, according to VARC-2 definitions. In patients who required conversion to surgical cutdown for vascular access, 69% also had CDF and 31% had major/minor VCs (Table 1). Within the major/minor VC group, 42% had preceding closure complications. In the adjusted model, the risk of major/minor VCs was 14 times greater in patients who experience closure complications (Table S1, Supplementary Material). CDF accounts for 73% of patients identified as having a closure complication.

Table 2
Baseline characteristics between TF TAVI patient groups

Variable	No access-related VARC-2 vascular complications (n = 382)	Access-related VARC-2 vascular complications (n = 99)	p value	Closure device failure (n = 56)	Major/minor vascular complications (n = 43)	p value
Age (years)	82 ± 8 (83)	82 ± 8 (83)	0.830	82 ± 7 (83)	82 ± 8 (83)	0.61
Men	229 (60%)	64 (65%)	0.460	37 (66%)	27 (63%)	0.83
Body mass index (kg/m^2)	28.8 ± 6.1 (27.8)	29.8 ± 7.0 (28.5)	0.220	30.6 ± 7.3 (29.8)	28.6 ± 6.4 (26.6)	0.15
Atrial fibrillation	174 (46%)	46 (46%)	1.000	24 (43%)	22 (51%)	0.42
Diabetes mellitus	135 (35%)	31 (31%)	0.410	19 (34%)	12 (28%)	0.66
Peripheral artery disease	26 (7%)	16 (16%)	**0.010**	12 (21%)	4 (9%)	0.17
Previous aortic valve procedure	42 (11%)	9 (9%)	0.710	6 (11%)	3 (7%)	0.73
Previous non-aortic valve procedure	12 (3%)	5 (5%)	0.370	3 (5%)	2 (5%)	0.07
Previous coronary bypass	91 (24%)	27 (27%)	0.600	18 (32%)	9 (21%)	0.26
Previous myocardial infarction	93 (24%)	37 (37%)	**0.020**	28 (50%)	9 (21%)	**0.004**
Society of Thoracic Surgeons aortic valve implantation mortality score (%)	6.0 ± 3.9 (5.1)	5.4 ± 3.0 (4.8)	0.170	5.6 ± 3.1 (5.0)	5.2 ± 2.9 (4.4)	0.35
Society of Thoracic Surgeons aortic valve implantation morbidity score (%)	24.9 ± 9.4 (22.5)	25.5 ± 8.8 (23.6)	0.420	26.0 ± 7.7 (25.1)	24.9 ± 10.1 (22.6)	0.32
Aspirin	271 (71)	75 (76)	0.610	44 (79%)	31 (72%)	0.49
Anticoagulants	135 (35)	39 (39)	0.560	22 (39%)	17 (40%)	1.000
P2Y12 inhibitors	73 (19)	35 (35)	**0.002**	17 (30%)	18 (42%)	0.29
Creatinine	1.3 ± 0.9 (1.1)	1.2 ± 0.4 (1.1)	0.910	1.2 ± 0.4 (1.2)	1.1 ± 0.3 (1.0)	**0.02**
Transcatheter aortic valve implantation sheath size (French)	16.4 ± 2.7 (18.0)	16.8 ± 2.5 (16.0)	0.140	17.0 ± 2.8 (18.0)	16.6 ± 2.1 (16.0)	0.47

Table 3
CTA and procedural characteristics between TF TAVI patient groups

Variable	No access-related VARC-2 vascular complications (n = 341)	Access-related VARC-2 vascular complications (n = 99)	p value	Closure device failure (n = 56)	Major/minor vascular complications (n = 43)	p value
Calcification anywhere along common femoral artery	245 (64%)	91 (92%)	**<0.001**	53 (95%)	38 (88%)	0.29
Calcification at common femoral artery access site	96 (25%)	42 (42%)	**0.010**	27 (48%)	15 (35%)	0.22
Anterior calcification of common femoral artery access site*	17 (18%)	16 (38%)	**0.020**	11 (41%)	5 (33%)	0.75
Circumference of common femoral artery access site calcification (°)*	68.7 (40.5, 89.0)	85.9 (58.2, 107.9)	0.230	93.2 (77.1, 120.3)	62.0 (35.9, 88.2)	**0.03**
Width of common femoral artery access site calcification (mm)*	2.0 (1.5, 2.5)	1.9 (1.4, 2.6)	0.450	1.8 (1.4, 2.5)	2.0 (1.4, 2.5)	0.52
Common femoral artery minimum lumen diameter (mm)	7.8 ± 1.3 (7.7)	7.5 ± 1.2 (7.3)	**0.04**	7.5 ± 1.2 (7.4)	7.4 ± 1.2 (7.3)	0.81
Common femoral artery maximum lumen diameter (mm)	9.1 ± 1.3 (9.0)	8.5 ± 1.4 (8.4)	**<0.001**	8.6 ± 1.4 (8.4)	8.4 ± 1.3 (8.3)	0.54
Common femoral artery tortuosity (°/cm)	6.1 ± 3.2 (6.0)	6.4 ± 3.2 (6.0)	0.390	6.0 ± 3.1 (6.0)	6.8 ± 3.2 (6.0)	0.11
90° depth to common femoral artery (mm)	54.4 ± 25.8 (48.6)	57.2 ± 27.4 (54.2)	0.470	62.3 ± 28.1 (57.4)	50.6 ± 25.4 (46.3)	**0.04**
45° approach distance to common femoral artery (mm)	57.6 ± 21.4 (54.6)	67.5 ± 27.3 (66.7)	**0.002**	73.2 ± 27.3 (70.0)	60.1 ± 25.8 (56.8)	**0.02**
Calcification at external iliac artery access site	180 (47%)	52 (53%)	1.000	31 (55%)	21 (49%)	0.55
Anterior calcification of external iliac artery access site*	6 (3%)	8 (15%)	0.004	4 (13%)	4 (19%)	0.7
Circumference of external iliac artery access site calcification (°)*	61 (38, 88)	95(56, 148)	0.37	131(72, 148)	65 (37, 141)	0.33
Width of external iliac artery access site calcification (mm)*	1.70 (1.40, 2.10)	1.50(1.37, 1.72)	0.57	1.60 (1.45, 2.00)	1.45 (1.37, 1.52)	0.16
External iliac artery minimum lumen diameter (mm)	8.0 ± 1.2 (7.8)	7.9 ± 1.2 (7.7)	0.430	7.9 ± 1.2 (7.8)	7.8 ± 1.2 (7.7)	0.54
External iliac artery maximum lumen diameter (mm)	9.1 ± 1.3 (8.9)	8.7 ± 1.3 (8.7)	**0.004**	8.8 ± 1.2 (8.7)	8.5 ± 1.3 (8.4)	0.13
External iliac artery tortuosity (°/cm)	6.4 ± 3.1 (6.0)	6.9 ± 3.6 (6.5)	0.870	7.0 ± 3.8 (7.0)	6.8 ± 3.5 (6.0)	0.77
Sheath to femoral artery ratio	0.7 (0.6, 0.8)	0.7 (0.6, 0.9)	**0.002**	0.8 (0.6, 0.9)	0.7 (0.6, 0.8)	0.8
Sheath to external iliac artery ratio	0.7 (0.6, 0.8)	0.7 (0.6, 0.8)	**0.012**	0.7 (0.6, 0.8)	0.7 (0.6, 0.8)	0.99

* Only assessed in patients who had otherwise calcified arteries.

There were no statistically significant differences in patients with and without VCs except for a more frequent history of previous myocardial infarction and PAD in the VC group. VC patients were also more likely to be on P2Y12 inhibitors before the procedure, although the use of aspirin or oral anticoagulants was not associated with VCs. CDF patients had a higher incidence of previous MI and have higher baseline creatinine levels than those with major/minor VCs (Table 2). The subset of patients who required a switch to surgical cutdown was more likely to have had a previous MI and PAD (Table S2, Supplementary Material).

For the CFA, CTA data revealed that VC patients were more likely to have calcification along the CFA than non-VC patients, as well as higher a higher incidence of calcification at the CFA access site. Although calcification tended to be more anterior in VC patients, there was no difference in width or circumference of calcification at the CFA access site. CFA maximal diameter was also significantly smaller in VC patients than non-VC patients. For the EIA, smaller maximum vessel diameter and presence of anterior calcification among VC patients with calcified arteries were similarly associated with access-related VCs. Higher SFAR and SEIAR were also associated with a greater rate of access-related VCs, but did not differ between CDF and major/minor VC patients (Table 3). Within the VC group, CDF occurred more frequently than major/minor VC if over 90° of the CFA vessel wall was calcified (27% vs 7%, p = 0.02, Figure 2). In an adjusted risk model, the risk of CDF is 2.66 times higher (95% confidence interval = 1.53, 4.63) in patients with CFA calcification that exceeds this 90° threshold (Table S3, Supplementary Material).

Although depth to the CFA at 90° from skin surface was not associated with VCs, when depth from the skin surface to the CFA was measured using an optimal access angle of 45°, access-related VCs occurred more frequently in patients with longer approach distances

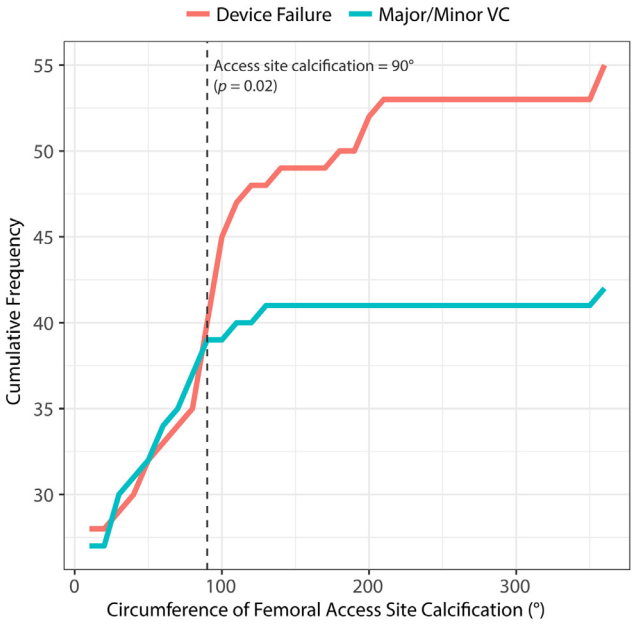

Figure 2. Cumulative frequency of vascular complications is related to the degree of calcification at the common femoral artery access site. Calcification >90° is correlated with higher rates of device failure. VC stands for vascular complication.

(Table 3). Furthermore, CDF complications occurred more frequently than major/minor VCs when the distance from skin to CFA at 45° exceeded 80 mm (39% vs 19%, p = 0.03, Figure 3).

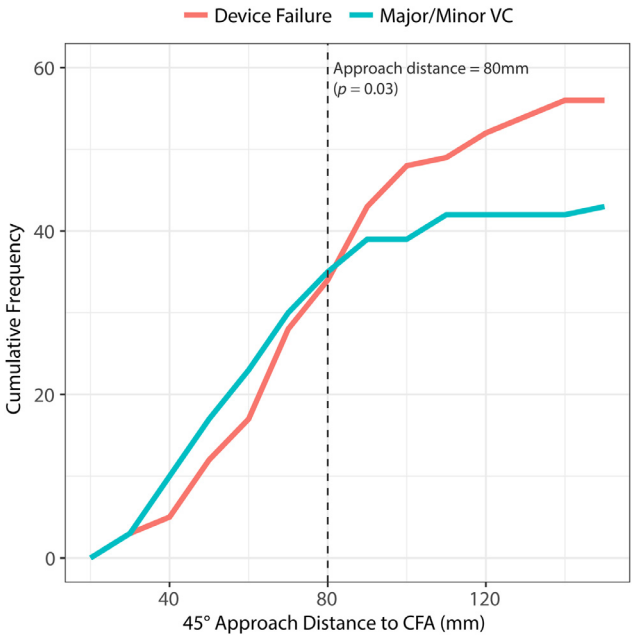

Figure 3. Cumulative frequency of vascular complications is related to the distance from skin surface at 45° to the common femoral artery access site. Complication rates are correlated with distance from skin surface at 45° to common femoral artery, an approximation of access angle and approach distance to vasculature. Distances >80 mm are correlated with higher rates of device failure.
CFA = common femoral artery; VC = vascular complication.

In the switch to cutdown subgroup, there was no difference in the incidence of CFA calcification (including when calcification exceeds 90°), although there was a trend toward higher incidence of common femoral arteries >80 mm from the skin surface at 45° in the SCD group (54% vs 27%, p = 0.06, Table S2, Supplementary Material).

Although there was no statistically significant difference in complication rates over the study period, there was a trend toward a lower rate of device failure and a higher rate of VCs (Table S4, Supplementary Material). STS mortality and morbidity scores during this study period decreased in the overall patient population, as well as in the major/minor VC and CDF groups (Figure S1, Supplementary Material).

Discussion

By evaluating both demographic and clinical patient characteristics as well as comprehensive CTA-derived data, this study has the following main findings: (1) the incidence of VC with percutaneous TF TAVI is high (21%) with the majority being CDFs (57%) and minor VCs (37%); (2) a high percentage (42%) of patients with major or minor VCs has preceding CDF, and the risk of major/minor VCs was 14 times greater in patients who experience closure complications (73% of which are attributed to CDF); (3) in addition to traditional CTA-derived risk factors, the degree of CFA access site calcification as well as skin-to-access-site-distance at 45° appear to be independent risk factors of CDF and may be helpful in preprocedural planning.

It has been reported previously that 64% of major VCs can be attributed to CDF,[18] and our study estimated that 42% of patients with either major or minor VC had preceding CDF. Rates of device failure may be decreasing with time (as our data suggest), which may be the result of increasing operator experience and improved device technology, although there is still a strong association between closure complications and subsequent VCs. Our study revealed that closure complications, the majority of which are attributed to VARC-2 defined CDF, are associated with an increase in the relative risk of major or minor VCs.

Although the link between CDF and VCs has been established, the anatomical risk factors associated with these complications have previously been qualitative in nature using various grading scales. This study offers several novel, quantitative anatomical features that are associated with CDF and major/minor VC. Our preprocedural CTA data showed an association between vessel calcification and VCs (including both CDF and major/minor VCs), particularly when the calcification involves the anterior wall of the CFA. Furthermore, CDF seems to occur more frequently when calcification involves a greater extent of the vessel circumference (over 90° of the vessel wall) and when there is a longer approach distance to the vessel (as measured by the distance to the vessel wall at 45° from the skin surface, particularly once this distance exceeds 80 mm). However, although these 2 novel metrics appear to be predictive of device failure, they are not significantly associated with major/minor VCs on univariate or multivariate analyses.

Periprocedural device-related complications and VCs after TF TAVI remain common, although certain patient

factors and vessel characteristics may prove useful in the risk stratification of patients before the procedure. Our data confirmed previously established factors associated with VCs related to TF TAVI, including vessel calcification, history of PAD, as well as SFAR and SEIAR.[5–7] Our study did not find a link between gender or renal failure with VCs, as described in previous studies.[5–7,19] However, we did find an association between previous MI as well as the use of P2Y12 inhibitors and VCs, which may prove to be of clinical utility if corroborated with further studies.

This study is a retrospective, observational study based on a single-center experience, and the novel CTA-derived risk factors (circumferential vessel wall calcification and the skin-surface to CFA access-site distance) should be validated in other TAVI populations. The measurements used in this study were obtained from preprocedural images using standardized anatomical landmarks, and there may be limitations in the reproducibility and applicability of these measurements in light of possible interobserver differences in measurement as well as the possible deviation of actual puncture site from the area defined in preprocedural planning. Although the majority of CTAs were able to be interpreted and used in the results outlined in our study, the uninterpretable CTAs were from the group of patients without VCs may disproportionately increase the incidence of VCs reported. Additionally, whereas this study identified associations between various factors and VCs, the study was not powered to differentiate between the characteristics that may distinguish between major and minor VARC-2 complications. Furthermore, the analyses of the device-related complications did not take into account for device types and procedural differences between operators.

In conclusion, this study used demographic and clinical patient characteristics as well as comprehensive CTA-derived data to evaluate risk factors for VCs in percutaneous TF TAVI. Our results suggest that the incidence of VC with percutaneous TF TAVI remains high, with the majority being CDFs and minor VCs. A high percentage of patients with major or minor VCs has preceding CDF, and the risk of major/minor VCs was 14 times greater in patients who experience closure complications (73% of which are attributed to CDF). In addition to traditional CTA-derived risk factors, the degree of CFA access site calcification as well as skin-to-access-site distance at 45° appear to be independent risk factors of CDF and may be helpful in preprocedural planning.

Disclosures

Dr. Sorajja is a consultant for Edwards, Abbott Vascular, Medtronic, Admedus, Boston Scientific, and Pipeline, and also works in research and speaks for Edwards, Abbott Vascular, Medtronic, and Boston Scientific.

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Supplementary materials

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