Comparison of Frequency of Vascular Complications With Ultrasound-Guided Versus Fluroscopic Roadmap-Guided Femoral Arterial Access in Patients Who Underwent Transcatheter Aortic Valve Implantation

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To compare outcomes of ultrasound guidance (USG) versus fluoroscopy roadmap guidance (FG) angiography for femoral artery access in patients who underwent transfemoral (TF) transcatheter aortic valve implantation (TAVI) to determine whether routine USG use was associated with fewer vascular complications. Vascular complications are the most frequent procedural adverse events associated with TAVI. USG may provide a decreased rate of access site complications during vascular access compared with FG. Patients who underwent TF TAVI between July 2012 and July 2017 were reviewed and outcomes were compared. Vascular complications were categorized by Valve Academic Research Consortium-2 criteria and analyzed by a multivariable logistic regression adjusting for potential confounding risk factors including age, gender, body mass index, peripheral vascular disease, Society of Thoracic Surgeons score and sheath to femoral artery ratio. Of the 612 TAVI patients treated, 380 (63.1%) were performed using USG for access. Routine use of USG began in March 2015 and increased over time. Vascular complications occurred in 63 (10.3%) patients and decreased from 20% to 3.9% during the study period. There were fewer vascular complications with USG versus FG (7.9% vs 14.2%, p = 0.014). After adjusting for potential confounding risk factors that included newer valve systems, smaller sheath sizes and lower risk patients, there was still a 49% reduction in vascular complications with USG (odds ratio 0.51, 95% confidence interval 0.29 to 0.88, p = 0.02). In conclusion, USG for TF TAVI was associated with reduced vascular access site complications compared with FG access even after accounting for potential confounding risk factors and should be considered for routine use for TF TAVI. **(Am J Cardiol 2020;132:93−99)**

Transcatheter aortic valve implantation (TAVI) has become a standard treatment for eligible patients with severe aortic stenosis. Transfemoral (TF) access is the preferred access for TAVI procedures.[1] However, vascular complications associated with TF access occur in approximately 7% of procedures and are associated with increased morbidity and mortality.[1,2] Fluoroscopy roadmap guidance (FG) has been traditionally used to gain controlled access to the common femoral artery (CFA). Ultrasound guidance (USG) for access has previously been used in endovascular aneurysm repair (EVAR), thoracic endovascular aneurysm repair, and in many other percutaneous interventions which utilize large sheath sizes through the CFA. USG CFA cannulation was found to reduce the number of attempted needle punctures and vascular complications during percutaneous coronary intervention when compared with FG in multicenter randomized trials.[3] Furthermore, USG has also been associated with better outcomes compared with FG in patients with TAVI procedures.[4] Given the potential benefits of USG and our experience in EVAR and thoracic endovascular aneurysm repair, our center began using USG for TF-TAVI procedures in March 2015. In this study, we report our experience comparing USG and FG access for TF-TAVI over a period of 6 years. We also evaluated the outcomes of patients who experienced vascular complications between these 2 different guiding techniques.

Methods

A retrospective review of all TF-TAVI procedures performed in a single center between July 2012 and July 2017 was conducted. All patients implanted with both balloon expandable or self-expanding valves were included with sheath size ranging from 14-Fr to 20-Fr. We excluded patients who underwent TF-TAVI with the first generation

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SAPIEN (Edwards Lifesciences, Irvine, CA) due to the larger sheath size and in order to maintain a patient population most representative of contemporary practice. All operators became experienced users with large sheath TAVI before the study period. The choice of using FG or USG to gain access to the CFA during TAVI was at the operator's discretion as was the side of access based on preoperative computerized tomographic (CT) angiography of the iliofemoral vessels. Mode of access, sheath size, and vessel size were collected for all patients. Mortality was assessed using a previously described methodology to ascertain long-term survival status in our patient population.[5]

USG access was confirmed using procedural codes for ultrasound access as well as by reviewing previously archived USG clips for each patient. The technique for USG access using a standard vascular ultrasound probe was standardized across all operators and included identifying the least calcified spot in the CFA above the bifurcation and below the point where the CFA dives into the retroperitoneum. Access was obtained while watching the tip of the needle enter the anterior wall of the CFA at the desired spot on ultrasound (Figure 1). For patients who underwent FG access, access was obtained on the contralateral side using anatomical and fluoroscopic landmarks and an aorto-ilac angiogram was performed (Figure 2). The TAVI access site was then accessed under live fluoroscopic guidance of the roadmap using standard technique (Seimens system). The closure device used in all cases was Perclose Proglide (Abbott Vascular). In 3 cases Angioseal (Terumo Medical) was deployed at the end to treat residual oozing.

Vascular complication data were collected. For commercial TAVI procedures, the Society of Thoracic Surgeons (STS)/American College of Cardiology Transcatheter Valve Therapy Registry was the data source. For patients enrolled in research trials, an adverse events report was requested from each trial sponsor. A final verification was performed by manual chart review of the operative and discharge reports. During this blinded adjudication process

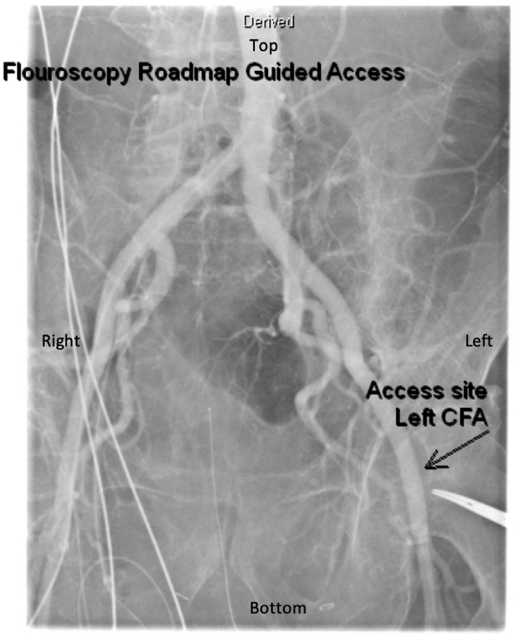

Figure 2. Fluoroscopy roadmap-guided access. CFA = common femoral artery; CFV = common femoral vein. *Double arrow*: needle entering the anterior wall of the artery.

with several of the authors, vascular complications were divided into 3 categories based on Valve Academic Research Consortium (VARC-2) criteria- major, minor, and percutaneous closure device complications. Only access-related vascular complications related to the larger TAVI sheath access site were included in the study. Two patients experienced nonaccess site-related vascular complications; for this reason, these outcomes were not counted as a vascular complication.

The CFA diameters were measured using the preoperative CT scan; if there were multiple measurements, the minimum diameter was used. Preoperatively, peripheral

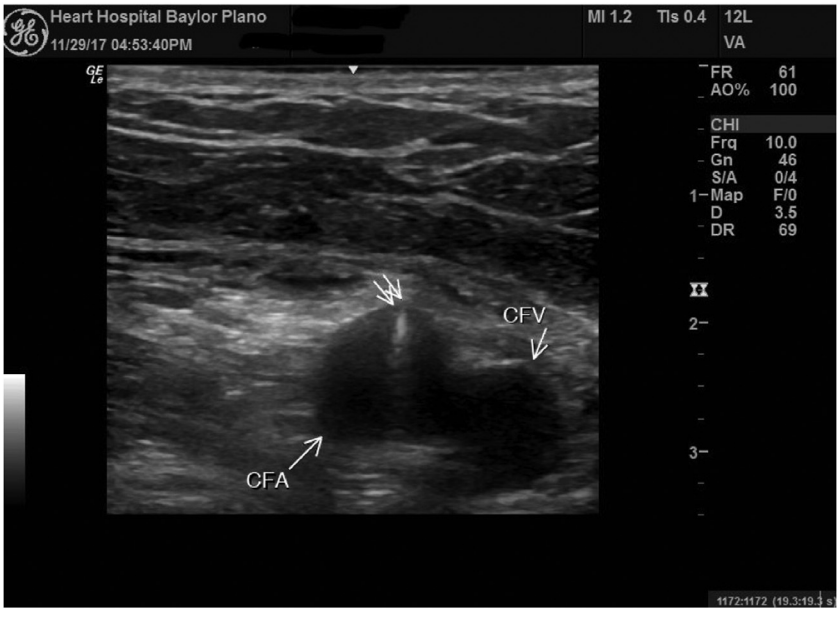

Figure 1. Ultrasound-guided access.

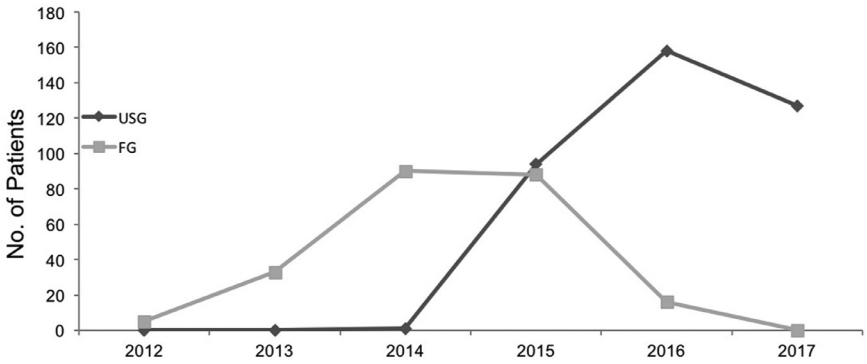

Figure 3. Access method used for TAVI over time at our center.

vascular calcium was also examined through the preoperative CT, but the amount of calcium was not particularly quantified for this study. A sheath to femoral artery ratio (SFAR) was calculated by dividing the sheath size by 3 to derive the sheath diameter in mm and dividing the same by the CFA size to derive the SFAR. Previous studies have shown SFAR to be predictive of vascular complications in patients who underwent TF TAVI and hence SFAR was accounted in our analysis to adjust for differences in sheath sizes and CFA size.

Categorical variables were presented as proportions and continuous variables as mean ± SD/median (range), as appropriate. Differences in baseline characteristics, co-morbidities between USG and FG access were compared using chi-square/Fisher's exact tests for proportions and Student's *t* test/Wilcoxon Rank-Sum test for continuous variables where applicable. To assess whether USG access was associated with a lower risk for vascular complications, a multivariable logistic regression analysis adjusting for different factors was conducted. We adjusted the logistic regression model for patients' health-related factors and anatomy. Three different models were assembled as follows: Model 1 − adjusting for Society of Thoracic Surgeons Predicted Risk of Mortality risk score and SFAR, Model 2 − including factors identified in the literature such as SFAR, age, gender, body mass index (BMI), and peripheral vascular disease, Model 3 − including the factors with a p value of <0.05 in the univariate analysis. Goodness of fit of the models was assessed by Hosmer-Lemeshow goodness of fit tests and the corresponding c-statistic was obtained for each model. The effect of individual operators or operator volume was not included in the models because all operators had similar volume and no difference in complications were seen among them. A sensitivity analysis was then conducted to assess the learning curve for USG access at our center. Only those patients with a TAVI procedure by USG access were included for the sensitivity analysis and a trend test was conducted to evaluate the rates of complication over time. Analyses were done using STATA 14.2 and a 2-sided p value of <0.05 was considered significant.

Results

A total of 612 TAVI patients were included in the study; 380 (62.1%) with USG, and 232 (37.9%) with FG. The year 2015 was the inflection point for access guidance (USG access: 52%; FG access 48%) with higher USG use afterward (Figure 3). Patients who underwent USG access were more commonly female, younger, with lower STS score, and higher BMI (Table 1). The prevalence of diabetes, hypertension, and coronary artery disease were similar between the 2 groups. Patients with USG access had a median CFA diameter of 7.5 mm compared with 7.8 mm in the FG group (p = 0.002). The sheath size used in the USG group was most often 14Fr (68.4%) and 16Fr (24.5%) whereas the FG was more heterogeneous with 14F (35.3%), 16F (30.2%), and 18Fr (23.7%) sheaths being used. The median value of the SFAR was similar between both groups (1.5 vs 1.4, p = 0.09). Most of the patients in the USG access group were implanted with a Sapien 3 (81.1%) valve whereas those in the FG access group received either a Sapien 3 (50.4%) or Sapien XT (46.1%).

There were 63 (10.3%) patients with vascular complications. Table 2 summarizes vascular complications stratified by VARC-2 criteria. The overall unadjusted vascular complication rate was significantly lower in the USG access group (7.9%) as compared with the FG access group (14.2%, p = 0.014). The unadjusted odds ratios (ORs) for the outcome of vascular complications were calculated (Table 3). All of these adjusted models showed us that the USG access was independently associated with reduced vascular complications. SFAR was independently associated with an increase in vascular complications after adjusting for various risk factors (Figure 4). The sensitivity analysis was performed on patients in the period from 2015 through 2017. It included only the USG TAVI patients and showed that the vascular complications decreased consistently over that period (18.1% in 2015 vs 5% in 2016 vs 3.9% in 2017, p <0.001). Follow-up of these patients revealed that 11.6% in the FG group died during the first year after TAVI compared with 9.8% in the USG group (p = 0.52).

Discussion

Our study conducted in a single center, demonstrates that USG access for TAVI is associated with a significant reduction in access-related vascular complications compared with conventional FG access. This association remains significant even after adjusting for various potential

Table 1
Patient demographics and clinical characteristics

Preoperative	FG (n = 232)	USG (n = 380)	p value
Age, median (range) (years)	84.1 (58.6-95.2)	82 (53.8-100.8)	0.001
STS-PROM, median (range)	6.4 (1.3-25.7)	5.6 (0.61-32.2)	0.002
Body mass index, median (range) (kg/m^2)	25.9 (15.4-54.4)	27.7(12.5-59.2)	0.0001
Preop hemoglobin, median (range) (g/L)	11.9 (6.7-16.7)	12.2 (7.2-37.1)	0.11
Preop creatinine, median (range) (mg/dl)	1.2 (0.5-11.7)	1.2 (0.44-12.5)	0.7
Female	95 (40.9%)	190 (50%)	0.03
Hypertension	208 (89.7%)	356 (93.7%)	0.07
Peripheral vascular disease	63 (27.2%)	93 (24.5%)	0.5
Coronary artery disease	139 (59.9%)	210 (55.3%)	0.26
Diabetes mellitus	84 (36.2%)	162 (42.6%)	0.12
Intraoperative	FG (n = 232)	USG (n = 380)	p value
CFA diameter, median (range)	7.8 (3.3-18)	7.5 (2.6-18.1)	0.002
Sheath to femoral artery ratio, median (range)	1.4 (0.62-3.86)	1.5 (0.55-3.39)	0.09
Sheath size			<0.001
14 F	82 (35.3%)	260 (68.4%)	
16 F	70 (30.2%)	93 (24.5%)	
18 F	55 (23.7%)	14 (3.7%)	
20 F	25 (10.8%)	13 (3.4%)	
Valve size (mm)			0.27
20	4 (1.7%)	8 (2.1%)	
23	61 (26.3%)	113 (29.7%)	
26	102 (44.0%)	147 (38.7%)	
29	64 (27.6%)	107 (28.2%)	
31	1 (0.4%)	0 (0.0%)	
34	0	5 (13.2%)	
Valve type			<0.001
Sapien 3	117 (50.4%)	308 (81.1%)	
Sapien XT	107 (46.1%)	33 (8.7%)	
Evolut	8 (3.5%)	39 (10.3%)	

FG = fluoroscopy-roadmap-guidance angiography; USG = ultrasound guidance.

Table 2
Outcomes

	FG (n = 232)	USG (n = 380)	p value
Vascular complication	33 (14.2%)	30 (7.9%)	0.014
Major vascular complication	13 (5.6%)	12 (3.2%)	
Minor vascular complication	16 (6.9%)	15 (3.9%)	
Percutaneous closure device complications	4 (1.7%)	3 (0.8%)	
Mortality			
1 year mortality	27 (11.6)	23 (9.8)	0.52
LOS	2 (0-17)	1 (0-30)	<0.001

FG = fluoroscopy-roadmap-guidance angiography; LOS = length of stay; USG = ultrasound guidance.

Table 3
Vascular complications − univariate analysis

	Unadjusted odds ratio	95% Conf. interval		p value
Ultrasound access	0.52	0.31	0.87	0.01
Female	2.16	1.26	3.7	0.01
Age at time of procedure	1	0.97	1.03	0.91
Body mass index	0.95	0.91	1	0.03
Hypertension	0.65	0.28	1.51	0.31
Coronary artery disease	0.94	0.55	1.58	0.8
Peripheral vascular disease	0.9	0.49	1.67	0.75
Diabetes mellitus	0.91	0.53	1.55	0.72
SFAR	14.61	4.27	50.05	<0.001
STS-PROM	1.03	0.97	1.1	0.35
Pre op creatinine	1.14	0.96	1.36	0.14
Pre op hemoglobin	0.85	0.74	0.99	0.04
Year of surgery				
2012	Ref			
2013	0.55	0.05	6.25	0.63
2014	0.49	0.05	4.87	0.55
2015	0.92	0.1	8.48	0.94
2016	0.22	0.02	2.16	0.19
2017	0.16	0.02	1.75	0.13

SFAR = sheath to femoral artery ratio; STS-PROM = Society of Thoracic Surgeons Predicted Risk of Mortality.

confounders including differences in patient co-morbidities, STS score and SFAR. Our study also showed a decrease in VARC-2 vascular complications over time, with a 3.9% rate of vascular complications with the use of USG access for all cases in 2017.

Vascular complications during TAVI have been linked to increased mortality, morbidity, length of stay, costs, and poorer quality of life,[2,6,7] and their incidence has been steadily declining over the last few years.[2,7,8,9,10] A meta-analysis including 16 studies reported that life-threatening and major bleeding following TAVI occurred in 15.6% and 22.3% of the patients, respectively. All of the studies included in this meta-analysis reported at least 1 VARC defined outcome.[11] VARC major vascular complications have been shown to increase the 30-day mortality in TAVI patients.[2,10] Several risk factors such as female gender,

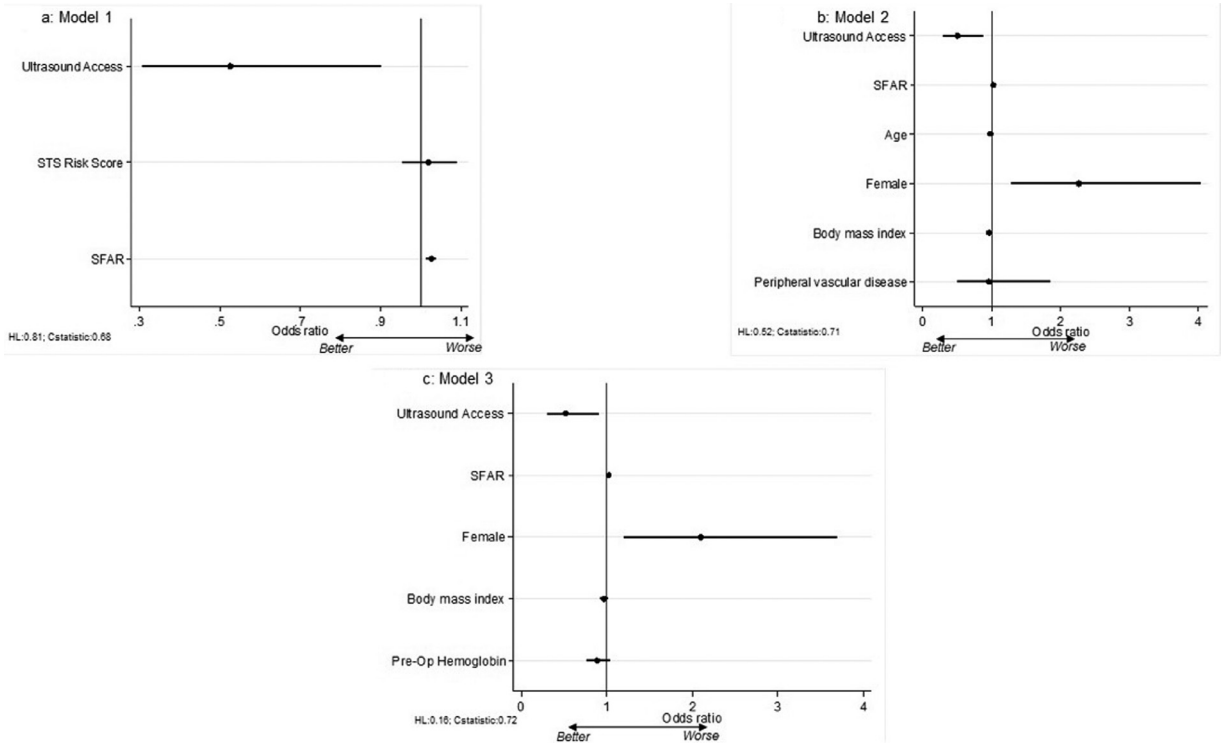

Figure 4. Multivariable logistic regression analysis. (*A*) Model 1: adjusted for STS risk score and SFAR; (*B*) Model 2: adjusted for SFAR, age, gender, body mass index, and peripheral vascular disease; (*C*) Model 3: adjusted for SFAR, gender, body mass index, and preop hemoglobin. SFAR represented as ratio percentage for the forest plot. SFAR = sheath to femoral artery ratio; STS-PROM = Society of Thoracic Surgeons Predicted Risk of Mortality.

peripheral vascular disease, high perioperative risk per the STS score, diabetes mellitus, morbid obesity (BMI >35), peripheral artery disease, small-caliber ilio-femoral vessels, vascular tortuosity, moderate or severe vascular calcification, SFAR, as well as low center experience have been established to be independently associated with vascular complications.[2,7,10,12] In our study, 10.3% of the patients encountered a VARC-2 vascular complication and 4.1% of patients encountered major vascular complications. Female gender and increasing SFAR were independent risk factors for VARC 2 vascular complications.

USG access has been studied in several arterial and venous access procedures including percutaneous coronary interventions,[13,14,15] central venous access,[16,17] as well as large bore procedures including EVAR.[18,19,20] A meta-analysis including 1,422 subjects from 4 prospective randomized controlled trials emphasized that USG was associated with fewer life-threatening vascular complications compared with traditional methods of femoral artery catheterization.[21] The Femoral Arterial Access with Ultrasound Trial included 1,004 patients who underwent coronary angiography and were randomized to USG access or conventional FG femoral arterial access. USG access was associated with reduced vascular complications (1.4% vs 3.4%, p = 0.04), reduced number of attempts (1.3 vs 3.0, p <0.0001), reduced mean time to access (136 s vs 148 s, p <0.003), reduced risk of venipuncture (2.4% vs 15.8%, p <0.0001) as well as increased success in CFA cannulation in patients with high bifurcations (82.6% vs 69.8%, p <0.01).[22] Similar findings have been observed in multiple studies.[23,24,25] The vascular events were lower in Femoral Arterial Access with Ultrasound Trial than our study. This difference was likely due to large sheath access, older patients and that all patients in our study received intervention and anticoagulation.

Despite the large number of studies documenting the safety and efficacy of USG access for CFA cannulation especially with large bore sheaths, the use of USG access for TAVI is not considered standard and there is paucity of data on this subject. One recent study by Elbaz-Greener et al reported 387 patients who underwent TAVI at their institution using conventional landmarks (109 patients) and USG access (278 patients). They noted a significant reduction in composite end points of access-related vascular or bleeding complications and red blood cell transfusions (OR 0.42, 95% CI 0.25 to 0.7; p <0.01) and access-related major vascular or major/life threatening bleeding complication (OR 0.31, 95% CI 0.17 to 0.54, p <0.01).[4] Our study represents the largest study evaluating USG access versus conventional FG access in TAVI patients, is more reflective of contemporary practice (includes only patients with Sapien 3, Sapien XT and Evolut, with >90% of patients who underwent TAVI with 14 to 18Fr sheaths) performed by multiple operators. Even though the patients in the USG access group had a higher BMI, smaller CFA, and higher SFAR, the reduction of vascular complications remained significant. The sensitivity analysis was performed after the inflection point and showed a significant learning curve with use of USG access for TAVI which stresses the

importance of developing a standardized protocol for USG access in all TAVI cases to help increase operator experience.

Our study is limited by the differences in time periods of access technique, with conventional FG access being utilized predominantly in the early years of the study, and USG being the predominant access guidance method in the latter period. Time can only be introduced as a confounder in the sensitivity analysis and not in the regression models. Thus, to minimize time as a possible confounder, we included only those patients who underwent TAVI with a 14 to 20Fr sheaths and adjusted for differences in sheath sizes, Society of Thoracic Surgeons Predicted Risk of Mortality, age, gender, BMI and presence of PVD. Although we have adjusted for these differences, we cannot discount that some of these factors could still contribute to the differences observed in vascular complications with residual confounding. We also did not have specific data on the amount and location of femoral artery calcification in our study. The presence of extensive calcification would have favored USG access by helping target the least calcified location in the anterior wall of the CFA for access. Lastly, this is a single center study and our results need to be validated by additional prospective studies in other centers.

In conclusion, USG access is associated with fewer vascular complications than FG access being approximately 50% lower even after adjusting for various risk factors in patients who underwent TF-TAVI. Additionally, smaller sheath size, operator experience and standardized technique have helped decrease vascular complications. Based on our experience, routine use of USG is recommended for all patients who underwent TF TAVI.

Disclosures

Dr. Srinivasa Potluri is a speaker and on the advisory panel for Boston Scientific, Edwards, Medtrontic, Janssen, and Terumo. The authors declare that they have no known competing financial interests or personal relations that could have appeared to influence the work reported in this study.

Authors' Contribution

Srinivasa P. Potluri, Mohanad Hamandi, Sukhdeep S. Basra: Writing- Original draft preparation, methodology.

Kathryn V. Shinn, Deborah Tabachnick, Anupama Vasudevan, Giovanni Filardo: Data curation and data analysis

J. Michael DiMaio, William T. Brinkman, Katherine Harrington, John J. Squiers, Molly I. Szerlip, David L. Brown, Elizabeth Holper, Michael J. Mack: Writing - Reviewing and Editing.

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