

## Incidence of Vascular complications among Egyptian population during trans femoral Aortic Valve Implantation

Mansour Mohamed Moustafa, Islam Shawky Abdelaziz, Moustafa Ibrahim Mokarrab, Ahmad Elsayed Yousef and Mohammed Elsouidi Nasr

Cardiology Department, Faculty of Medicine, Al-Azhar University, Egypt.

[nmohamedsoudy@yahoo.com](mailto:nmohamedsoudy@yahoo.com)

**Abstract: Objectives:** This study sought to evaluate the incidence, impact, and predictors of vascular complications in transcatheter aortic valve implantation (TAVI). **Background:** Vascular complications increase morbidity and mortality in transfemoral TAVI; however, there remains a paucity of data describing these serious events. **Introduction:** Vascular complications are among the most frequent and serious complications of trans femoral TAVI, and have been associated with significantly increased patient morbidity and mortality. De-spite improved patient selection and down-sizing of the delivery system, these complications remain the Achilles' heel of this novel procedure. **Aim of the work:** To describe the incidence of vascular complications in trans femoral TAVI patients, based on the VARC criteria, and to identify predictors of these serious events among the Egyptian population. **Material and methods:** We performed a prospective cohort study of 30 consecutive transfemoral TAVI recipients. Vascular complications were defined by the Valve Academic Research Consortium (VARC) criteria. **Results:** In our cohort of elderly patients (83.3 ± 5.9 years), the logistic Euro Score was 25.8 ± 11.9%. The Edwards valve was used in 3 cases (18- to 24-F) and the Core Valve in 27 (18-F). The minimal femoral artery diameter was 8.17 ± 1.14 mm, and the calcification (0 to 3) and tortuosity scores (0 to 3) were 0.58 ± 0.72 and 0.28 ± 0.53, respectively. The mean sheath diameter was 8.10 ± 0.82 mm, (VARC major: 17.3%, minor: 10.2%), and major vascular complications predicted 30-day mortality (22.7% vs. 7.6%, p 0.049). The SFAR (hazard ratio [HR]: 186.20, 95% confidence interval [CI]: 4.41 to 7,855.11), center experience (HR: 3.66, 95% CI: 1.17 to 11.49), and femoral calcification (HR: 3.44, 95% CI: 1.16 to 10.17) predicted major complications by multivariate analysis. An SFAR threshold of 1.05 (area under the curve 0.727) predicted a higher rate of VARC major complications (30.9% vs. 6.9%, p 0.001) and 30-day mortality (18.2% vs. 4.2%, p 0.016). **Conclusion:** Vascular complications in transfemoral TAVI are relatively frequent. VARC major vascular complications increase 30-day mortality and are predicted by experience, femoral calcification good selection of patient and improvement in size of dilaviry system will improve patient selection for transfemoral TAVI and may improve outcome.

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**Key Words:** aortic stenosis balloon valvuloplasty risk factors transcatheter aortic valve implantation vascular complications.

### 1. Introduction:

Aortic stenosis (AS) is one of the most common cardiac valve pathologies. The prevalence of AS increases with age and population-based studies report a prevalence between 2.8% and 4.6% for patients over 75 years old(1).

Surgical aortic valve replacement (SAVR) is the most effective therapy for AS. However, up to two-thirds of patients with symptomatic AS are excluded from surgical intervention secondary to high perioperative risk profiles (2).

Trans catheter aortic valve implantation (TAVI) has emerged as a promising therapeutic option for patients with severe symptomatic aortic stenosis (AS), who are in eligible for conventional surgical aortic valve replacement (3).

Two trans catheter heart valves, the Edwards SAPIEN valve (Edwards Life sciences, Irvine, California) and the Medtronic Core Valve (Medtronic, Minneapolis, Minnesota), are most commonly used and available in Egypt. The Edwards valve can be implanted via a trans femoral or trans apical approach, and the Core Valve using a trans femoral or trans subclavian approach. Since 2002, more than 30,000 procedures have been performed worldwide. The number of patient who underwent TAVI in Egypt is daily increasing.

Vascular complications are among the most frequent and serious complications of trans femoral TAVI, and have been associated with significantly increased patient morbidity and mortality (4).

The overall survival rate of all patients who underwent TAVI was 83%, with 82.1% for the no

vascular complication group, 88.9% for the major vascular complication group, and 85.7% for the minor vascular complication group at 46 months follow-up.

De-spite improved patient selection and downsizing of the delivery system, these complications remain the Achilles' heel of this novel procedure.

Previous studies have reported on vascular complications in trans-femoral TAVI (5); however, the absence of a uniform definition of what constitutes a major vascular complication has made it difficult to obtain a comprehensive picture of these significant events. To address this problem, the Valve Academic Research Consortium (VARC) have recently developed a consensus on TAVI-related endpoints (1), including a uniform definition of vascular complications.

The VARC major vascular complications are defined as:

- 1) Any thoracic aortic dissection;
- 2) Access site or access-related vascular injury (dissection, stenosis, perforation, rupture, arteriovenous fistula, pseudoaneurysm, hematoma, irreversible nerve injury, or compartment syndrome) leading to either death, significant blood transfusion (>4U), unplanned percutaneous or surgical intervention, or irreversible end organ damage;
- 3) Distal embolization (non-cerebral) from a vascular source requiring surgery or resulting in amputation or irreversible end organ damage.

The VARC minor vascular complications are defined as:

- 1) Access site or access-related vascular injury not requiring unplanned percutaneous or surgical intervention and not resulting in irreversible end organ damage;
- 2) Distal embolization treated with embolectomy and/or thrombectomy and not resulting in amputation or irreversible end organ damage;
- 3) Failure of percutaneous access site closure resulting in interventional or surgical correction and not associated with death, significant blood transfusions, or irreversible end organ damage.

VC were defined by both VARC-1 and VARC-2 criteria and analyzed separately. The difference in frequency of major and minor VC was mainly driven by VARC-2 implementation of major bleeding events. With either VARC definition, patients with minor VC had similar mortality and complications rates as those patients without VC. In multivariate analyses, referenced to patients with minor or no VC, only VARC-1-defined major VC were significantly associated with increased mortality (hazard ratio 3.52; confidence interval 1.5 to 8.4;  $p = 0.005$ ), whereas VARC-2-defined major VC were found to be only marginally significant (hazard ratio 1.9; confidence interval 0.9 to 3.9;  $p = 0.08$ ). In conclusion, the

implementation of the VARC-2 criteria resulted in a higher rate of reported major VC after TAVI compared with VARC-1 criteria, mainly by the inclusion of major bleeding events and a reduced association with patient mortality.

## 2. Material and methods:

This study included (30) patients (males and females) with their ages ranging from 60 to 80 years referred to (Dar-Elfouad hospital),(Ain shams – university hospitals) with low functional capacity, exertional dyspnea and exertional chest discomfort and are evaluated for severity of AS then risk for surgery by EURO and STS score by heart team. the patients undergo.

-pre procedure:

history, examination, echo and CT.

-Then procedure:

According to Type and size of valve, vascular approach, closure devise or cutting down, need to protamine and bl transfusion.

Then follow up patients for 48 h to define vascular complication if occur according to VARC II definition

### Inclusion criteria:

Patients with symptomatic severe AS (valve area<0.8 cm<sup>2</sup>) were considered candidates for TAVI if they had the following Criteriasolute contraindications.

Presence of a 'heart team' and cardiac surgery on the site.

Appropriateness of TAVI, as an alternative to AVR, confirmed by a 'heart team'.

Estimated life expectancy more than 1 year.

Improvement of quality of life by TAVI likely due to absence of comorbidities.

Absence of Severe primary associated disease of other valves with major contribution to the patient's symptoms, that can be treated only by surgery.

Absence of Inadequate annulus size (<18 mm, >29 mm).

Absence of Thrombus in the left ventricle.

Absence of Active endocarditis.

Absence of Elevated risk of coronary ostium obstruction (asymmetric valve calcification, short distance between annulus and coronary ostium, small aortic sinuses).

Absence of Plaques with mobile thrombi in the ascending aorta, or arch.

adequate vascular access (vessel size, calcification, tortuosity). Relativontraindications.

- absence of Untreated coronary artery disease requiring revascularization.

- absence of Haemodynamic instability.

### Exclusion criteria:

Minimal luminal diameter in both femoral arteries. less than 6mm.

All patients were studied along the following scheme:

- I) pre procedural data.
- A) consent: was taken from all patients.
- B) Complete history taking: from every patient included In the study With special emphasis on:-
  - History of dyspnea (Dyspnea was defined by NYHA classification).
  - History of Chest pain (Chest pain defined by candian classification).
  - History of ischemic heart disease (UA, MI, PTCA, CABG.....etc).
  - History of previous aortic intervention ().
  - History of other comorbiditis ().

**C) Clinical examination:**

Full clinical examination was carried out on every patient with special emphasis on the following data:

- 1-Pulse: rate and rhythm.
- 2-Blood pressure: Blood pressure was measured from both upper limbs.
- 3-Head and neck examination for arterial and venous pulsation.
- 4-Upper and lower limb examination for peripheral cyanosis and LL oedema.
- 5-Chest and heart examination for heart sounds, additional heart sounds and murmurs and the back for lung congestion.
- D) Resting 12 lead Electrocardiography: Resting standard 12-leads electrocardiogram searching for rate, rhythm, BBB and chamber enlargement and ischemic changes.

**D) Transthoracic echocardiographic examination:**

All the patients were examined in the left lateral decubitus position, according to standard techniques The following measurements were taken:

- To asses EF, IVS and posterior wall thickness.
- Aortic valve area, and cuspidity.
- Aortic valve mean and peak pressure gradient.
- presence of AR. MR.
- Left ventricular (LV) dimensions and wall thicknesses:
  - Left ventricular Ejection Fraction (EF).
  - Baseline labo-ratory indexes.
  - At least CBC and serum creatinine. INR.
  - coronary angiography.
  - Multislice computed tomography (MSCT) of the aorta and iliofemoral vasculature was performed in patients without significant renal dysfunction.
  - A) To evaluate Vessel tortuosity and calcification.
  - b) To detect level of bifurcation between common femoral artery, superficial femoral and profunda femoris artereries.
  - c) to calculate annular size.

- c) Aortic calcification and porceline aorta.
- d) Identify coronary ostium of left main and Rt coronary arteries. and distance bt them and aortic annulus.

II) Procedural data:

- Type of valve: Edwards SAPIEN valve or Core Valve.
- Type of anaesthesia.
- Side left or right.
- Angiographic guiding.
- Predilation or not.

**3. Results:**

During the enrollment period, a total of 30 patients were deemed eligible for TAVI by the heart team after appropriate screening. Of these patients, were identified as transfemoral TAVI candidates.

Thus, 30 patients underwent transfemoral TAVI using both of the commercially available percutaneous bioprostheses: the Edwards valve (Cribier-Edwards, Edwards-SAPIEN or SAPIEN XT, Edwards Lifesciences), and the CoreValve Revalving system.

**Patient and procedural characteristics.** Patient demographics and procedural characteristics are presented in Tables 1 and 2.

**Table 1. Baseline Characteristics of the Study Population (N 127)**

Age, yrs	83.3 5.9
Female	16 (51.2%)
BMI, kg/m <sup>2</sup>	25.3 4.1
Diabetes	9 (22.8%)
Hyperlipidemia	14 (42.5%)
Hypertension	26 (72.4%)
Current smoker	5 (3.9%)
NYHA functional class III or IV	28 (89.0%)
Coronary artery disease	17 (63.0%)
Previous MI	4 (10.2%)
Previous PCI	9 (35.4%)
Previous CABG	6 (15.7%)
Cerebrovascular disease	7 (15.0%)
COPD	13 (33.9%)
eGFR, ml/min/1.73 m <sup>2</sup>	50.4 23.6
eGFR 60 ml/min/1.73 m <sup>2</sup>	19(63.0%)
Logistic EuroScore, %	25.8 11.9
Pulmonary hypertension	13 (33.1%)
LVEF, %	48.1 14.1
LVEF 40%	14 (35.4%)

Values are mean SD or n (%).

<b>Table 2. Procedural Characteristics of the Study Population (N 127)</b>	
Edwards SAPIEN valve	3(78.7%)
CoreValve	27 (21.3%)
Deep sedation	30 (100%)
Percutaneous femoral artery closure	26 (78.0%)
Sheath size, F	20.8 2.5
18	42 (33.1%)
19	16 (12.6%)
22	37 (29.1%)
24	32 (25.2%)
Introducer sheath diameter, mm	8.10 0.82
Femoral artery MLD, mm	8.17 1.14
SFAR	0.99 0.16
Femoral artery calcification score (0–3)	0.58 0.72
Femoral artery tortuosity score (0–3)	0.28 0.53
Common iliac artery MLD, mm	10.3 2.43
External iliac artery MLD, mm	8.73 1.60
SEIAR	0.98 0.33
Iliac artery calcification score (0–3)	0.96 0.83
Iliac artery tortuosity score (0–3)	0.84 0.75
Values are n (%) or mean SD. MLD minimal lumen diameter; SEIAR sheath to external iliac artery ratio; SFAR sheath to femoral artery ratio.	

The mean age was 83.3 5.9 years, with a logistic EuroScore of 25.8 11.9%, and 63% had renal dysfunction (estimated glomerular filtration rate [eGFR] 60 ml/min/ 1.73 m<sup>2</sup>). The femoral artery MLD was 8.17 1.14 mm, and the mean sheath outer diameter was 8.10 0.82 mm, giving an SFAR of 0.994 0.155 (Fig. 1). The distributions of femoral artery calcification and tortuosity scores are shown in Online Figure 1.

BMI body mass index; CABG coronary artery bypass graft; COPD chronic obstructive pulmonary disease; eGFR estimated glomerular filtration rate; LVEF left ventricular ejection fraction; MI myocardial infarction; NYHA New York Heart Association; PCI percutaneous coronary intervention.

(n 5). In contrast to the femoral artery, all iliac artery complications are classified as VARC major complications. **Vascular complications and death.** Death at 30 days occurred in 13 of 127 (10.2%) patients. Five died due to vascular complications (Table 4). Aortic rupture (n 1), iliac rupture (n 2), iliac dissection (n 1), and femoral artery access site infection (n 1) were directly responsible for these deaths.

**Predictors of VARC major vascular complications and outcomes.** The SFAR (hazard ratio [HR]: 186.20, 95% confidence interval [CI]: 4.41 to 7,855.11, p 0.006), early center experience (HR: 3.66, 95% CI: 1.17 to 11.49, p 0.023), and femoral artery calcium score (HR: 3.44, 95% CI: 1.16 to 10.17, p 0.026) were identified as independent predictors of VARC major vascular complications by multivariate analysis (Table 5).

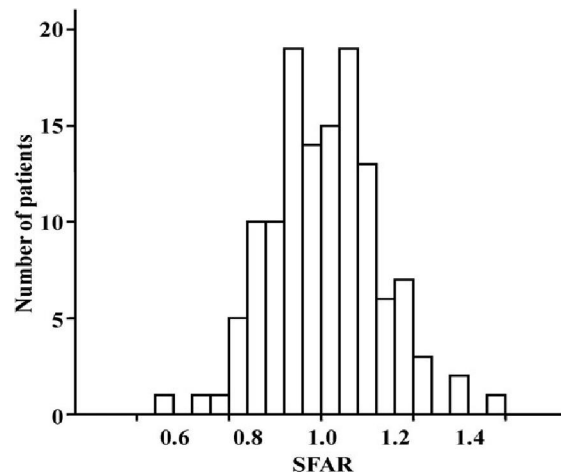


Figure 1. The Distribution of SFAR

The histogram of the sheath to femoral artery ratio (SFAR) showed a normal distribution.

The SEIAR did not predict vascular complications, and although the diameter of the introducer sheath predicted major vascular complications in the univariate analysis (8.7 0.5 mm vs. 8.0 0.9 mm, p 0.010), it was no longer significant after adjustment for other variables (p 0.157). The type of TAVI was significantly associated with vascular complications in univariate analysis, with significantly fewer complications in the CoreValve cohort compared with the Edwards valve cohort (p 0.004). However, the type of device was no longer predictive of vascular complications when adjusted for other variables in the multivariate model (p 0.057). It is likely that the strong association between the type of TAVI with both SFAR (p 0.001) and center experience (p 0.001) are responsible for this result.

Increased rates of in-hospital mortality (27.3% vs. 9.5%, p 0.023), 30-day mortality (22.7% vs. 7.6%, p 0.049), and longer hospital stay (16.5 11.6 days vs. 9.7 6.2 days, p 0.016) were observed in patients with VARC major complications. VARC minor complications were not associated with increased 30-day mortality (7.7% vs. 13.2%, p 0.574) or increased duration of hospital stay (9.8 4.0 days vs. 11.0 8.3 days, p 0.636).

Table 3. Vascular Complications			
	All Patients	VARC Major	VARC Minor
	(N 30)	Complications	Complications
Patients with vascular complications	10 (27.6%)	6 (17.3%)	3 (10.2%)
Femoral artery	7 (18.9%)	2 (8.7%)	3 (10.2%)
Rupture	1 (0.8%)	1 (0.8%)	0
Dissection	3(4.7%)	3 (4.7%)	0
Stenosis/occlusion	3 (2.4%)	3 (2.4%)	0
Pseudoaneurysm	2 (1.6%)	1 (0.8%)	1 (0.8%)
Hematoma	1 (0.8%)	0	1 (0.8%)
Prostar failure	11 (8.7%)	0	11 (8.7%)
Death	1 (0.8%)	1 (0.8%)	0
Iliac artery	13 (10.2%)	13 (10.2%)	0
Rupture	6 (4.7%)	6 (4.7%)	0
Dissection	7 (5.5%)	7 (5.5%)	0
Death	3 (2.4%)	3 (2.4%)	0
Aorta	1 (0.8%)	1 (0.8%)	0
Rupture	1 (0.8%)	1 (0.8%)	0
Death	1 (0.8%)	1 (0.8%)	0
Blood transfusion	8 (6.2%)	7 (7.9%)	1 (0.8%)
Local infection	3 (2.4%)	3 (2.4%)	0
Vascular intervention	9 (21.3%)	9 (15.0%)	8 (6.3%)
Balloon angioplasty	5 (3.9%)	2 (1.5%)	3 (2.4%)
Femoral stenting	8 (6.3%)	3 (2.4%)	5 (3.9%)
Iliac stenting	5 (3.9%)	5 (3.9%)	0
Aortic stenting	1 (0.8%)	1 (0.8%)	0
Emergent vascular surgery	8 (6.3%)	8 (6.3%)	0
Hospital stay (days)	11.0 7.9	16.5 11.6	9.83 4.04
In-hospital mortality	16 (12.6%)	6 (4.7%)	10 (7.9%)
30-day mortality	13 (10.2%)	5 (3.9%)	6 (4.7%)
Values are n (%) or mean SD.			
VARC Valve Academic Research Consortium.			

Table 4. Description of Death Due to Vascular Complications									
No. in				Sheath				Survival,	
Patient #Cohort	Age, yrs	Sex	Vascular Access	Size, F	SFAR	Complication	Treatment	Days	Cause of Death
1 17	84	M	Surgical	24	1.18	Iliac occlusion	Surgery	6	Multiple organ failure
2 24	89	M	Surgical	24	1.21	Femoral access site infection	Surgery	27	Sepsis, multiple organ failure
3 30	70	F	Surgical	24	1.03	Iliac rupture	Surgery	3	Multiple organ failure
4 109	84	M	Percutaneous	24	1.10	Iliac rupture	Surgery	0	Hemorrhagic shock
5 166	86	M	Percutaneous	18	0.74	Thoracic aorta rupture	Covered stent	0	Hemorrhagic shock
F female; M male; SFAR sheath to femoral artery ratio.									

**Table 5. Univariate and Multivariate Analysis of the Clinical and Procedural Characteristics According to the Incidence of VARC Major Vascular Complications**

Multivariate					
Univariate	Odds Variable	p Value	p Value	Ratio	95% CI
Age, yrs	0.069	0.860			
Female	0.937				
BMI, kg/m <sup>2</sup>	0.850				
Diabetes	0.575				
eGFR 60 ml/min/1.73 m <sup>2</sup>	0.222				
Logistic EuroScore, %	0.228				
LVEF 40%	0.212				
Chronic anticoagulation	0.870				
Activated clotting time, s	0.710				
TAVI type	0.004	0.057			
Early center experience	0.007	0.023	3.661	1.17–11.49	
Sheath outer diameter, mm	0.010	0.157			
Femoral artery MLD, mm	0.797				
SFAR	0.001	0.006	186.204	4.1–7,855.11	
Femoral artery calcification (0–3)	0.023	0.026	3.44	1.16–10.17	
Femoral artery tortuosity (0–3)	0.709				
Common iliac MLD, mm	0.419				
External iliac MLD, mm	0.264				
SEIAR	0.577				
Iliac artery calcification (0–3)	0.077				
Iliac artery tortuosity (0–3)	0.459				

Three cases were excluded because of death before valve deployment and access closure. TAVI transcatheter aortic valve implantation; other abbreviation as in Tables 1, 2, and 3.

**SFAR threshold predicts VARC major vascular complications.** The sensitivity–specificity curves identified a threshold SFAR of 1.05, which predicted VARC major vascular complications (Fig. 2). With this cut point, the sensitivity, specificity, and positive and negative predictive values were 66.7%, 65.6%, 40.7%, and 84.7%, respectively, and the area under the receiver-operator characteristic curve was 0.727. Using this SFAR threshold, the minimal femoral artery diameter necessary for the 19- and 18-F introducer sheaths was calculated as 7.1 and 6.9 mm, respectively.

In noncalcified iliofemoral vessels (calcium score 0), the SFAR increased to 1.10 and, conversely, decreased to 1.00 in calcified arteries (calcium score 1 to 3). Using this SFAR threshold, the minimal femoral artery diameter necessary for the 19- and 18-F introducer sheaths was calculated as 6.8 and 6.5 mm, respectively, in noncalcified iliofemoral vessels, and 7.5 and 7.2 mm, respectively, in calcified iliofemoral vessels.

**Clinical outcomes according to SFAR.** Clinical outcomes were compared according to the SFAR cut

point of 1.05 (Table 6). This cut point predicted higher rates of VARC major complications (30.9% vs. 5.6%, p 0.001). An SFAR 1.05 was also associated with an increased incidence of 30-day mortality (18.2% vs. 2.8%, p 0.004).

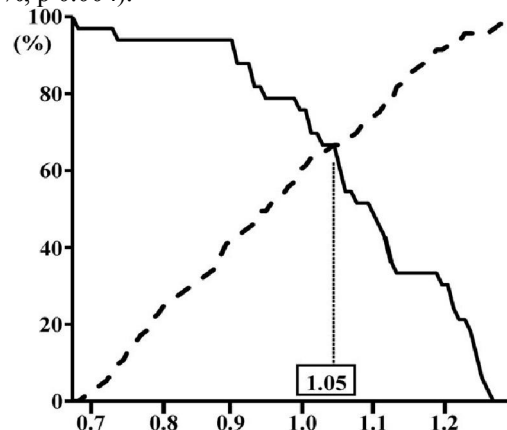


Figure 2. SFAR Threshold Predicts VARC Major Vascular Complications

The sensitivity and specificity curve identified the threshold sheath femoral artery ratio (SFAR) of 1.05 as predictive of VARC major vascular

complications. **Solid line** sensitivity; **broken line** specificity. VARC Valve Academic Research Consortium.

Table 6. Comparison of the Clinical Outcomes According to SFAR Threshold

SFAR			
Variables >1.05 (n 55) <1.05 (n 72)			p Value
Any vascular complication	23 (41.8%)	12 (16.7%)	< <b>0.001</b>
VARC Major	17 (30.9%)	5 (6.9%)	<b>0.001</b>
VARC Minor	6 (10.9%)	7 (9.7%)	0.827
Femoral artery complication	15 (27.3%)	9 (12.5%)	<b>0.035</b>
Iliac artery complication	11 (20.0%)	2 (2.8%)	<b>0.002</b>
In-hospital mortality	11 (20.0%)	5 (6.9%)	<b>0.033</b>
30-day mortality	10 (18.2%)	3 (4.2%)	<b>0.016</b>
Values are n (%). p Values in <b>bold</b> are statistically significant.			
Abbreviations as in Tables 2 and 3.			

#### 4. Discussion:

This study provides description of vascular complications, as defined by the VARC criteria (10), in a large cohort of patients treated by transfemoral TAVI. Our results demonstrate that VARC major vascular complications predict both 30-day and in-hospital mortality. In contrast, VARC minor complications are not associated with increased mortality. Furthermore, we have described the SFAR, a novel tool which predicts VARC major vascular complications, and is strongly associated with clinical outcomes, including mortality.

**Uniform definition of vascular complications with TAVI.** To date, vascular complications have been described in 8% to 30.7% of Edwards valve recipients (1–3,6,8,16,17), and 1.9% to 16% of CoreValve patients (5–7,18). The considerable variation in the reported incidence of these complications arises, in part, from the absence of a standardized definition for vascular complications in TAVI (1–3,5–8, 16–18). Most studies on TAVI have only reported complications that required further percutaneous or surgical intervention (6,9,16), and thus, the true frequency of vascular complications in transfemoral TAVI may have been underestimated. In an effort to standardize the reporting of TAVI data, the VARC have recently developed a consensus on TAVI-related endpoints (9,10,14,15), including a uniform definition of vascular complications. In our series of mixed implant transfemoral TAVI patients, we defined vascular complications according to the VARC criteria, and observed a complication rate of 27.6%, higher than previously described. The rate of major complications in our study was 17.3%, and is comparable to other published series (1,3,8,18); however, the overall rate of complications was

amplified by the addition of VARC minor complications (10.2%). Although the routine application of the VARC criteria for vascular complications will provide reliable, standardized information for TAVI-related research, it is likely to increase the reported rates of complications despite ever-improving operator expertise and device safety.

#### Impact of vascular complications on mortality.

The importance of vascular complications in transfemoral TAVI patients remains unclear (6,8,17). Two small series of Edwards valve (n 15) (8,11,13) and mixed Edwards and CoreValve patients (n 45) (6,12), and a large international registry (n 463) of Edwards valve patients (17,19,20), found no association between vascular complications and mortality. In contrast, in a multicenter cohort of 168 Edwards valve recipients, major vascular complications occurred in 13% of cases and were associated with a mortality rate of 25% (3). In our study, VARC major vascular complications were associated with both in-hospital (27.3% vs. 9.5%, p 0.023) and 30-day mortality (22.7% vs. 7.6%, p 0.049). Consistent with previous reports (3), VARC major vascular complications were associated with a 3-fold increase in the relative risk of death. VARC minor complications were not associated with mortality. The reason for the contrasting reports on the association vascular complications with patient mortality is not known, but may be related to the definition of vascular complications used. The VARC criteria includes factors such as blood transfusion (4 U) and ischemiarelated end organ damage, which may not have been considered vascular complications in previous reports, but nonetheless portend a poor prognosis and thus enhance the association of vascular complications and mortality. For example, the patient

in our cohort who developed a wound infection with subsequent septicemia, multiorgan failure, and ultimately death would not have been classified as a major vascular complication in previous studies. The VARC criteria may therefore represent a more inclusive, representative definition of vascular complications; however, further studies are required to investigate the relationship between VARC major complications and mortality.

### 5. Conclusion:

Vascular complications in transfemoral TAVI are relatively frequent. VARC major vascular complications increase 30-day mortality and are predicted by experience, femoral calcification good selection of patient and improvement in size of dilaviry system will improve patient selection for transfemoral TAVI and may improve outcome.

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