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Vascular Complications and Procedures Following Transcatheter Aortic Valve Implantation☆

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WHAT THIS STUDY ADDS

Transcatheter Aortic Valve Implantation (TAVI) is an excellent option for patients with aortic valve insufficiency. However, the rate of vascular complications is relatively high and should be a consideration in decision making. Involvement of vascular surgery early for recommendations regarding access site, side preference, and anatomical considerations may be beneficial in these patients.

Objectives: Vascular complications (VCs) remain a significant cause of morbidity in transcatheter aortic valve implantation (TAVI) patients and are associated with worse outcomes. This research analysed the incidence, impact, and predictors of VCs in transfemoral cases.

Methods: A retrospective chart review was performed of 388 consecutive TAVI patients between January 2007 and April 2015, which included 237 transfemoral cases. Major and minor VCs were characterised according to the Valve Academic Research Consortium (VARC) guidelines. Logistic regression was completed to identify predictors of VCs.

Results: While VCs occurred in 68 (28.7%) cases, only seven (3.38%) were classified as major complications. Twenty-six (10.9%) of these complications occurred intra-operatively, with four being major (1.6%) and 22 minor (9.3%). Post-operative VCs occurred in 42 cases (17.2%), with three (1.3%) being major. Procedures to correct VCs occurred in 10 (4.2%) cases, with the majority (90%) being surgical and the remainder being treated by endovascular techniques. Nine surgical procedures, predominantly embolectomy, were performed to correct post-operative complications. Female gender was a predictor of all major VCs ($B = -2.1$, $p < .006$). Further, a logistic regression analysis found that when the largest sheath was located on the left side, there were increased minor post-operative complications ($B = -0.99$, $p = .007$). Dissections and haematomas made up the majority of VCs. Thirty day mortality was six patients ($n = 2.5\%$), and peri-operative VCs were significantly correlated with 30 day mortality ($p = .001$, $R = 0.21$). The 30 day readmission rate comprised nine patients (3.8%), with three (1.3%) due to VCs, including haematomas and groin infections.

Conclusions: VCs contribute to operative morbidity in TAVI patients. This study demonstrated low major VC rates over an eight year period. Left sided location of largest sheath size and female gender were predictors of VC.

Keywords: TAVI, Vascular complications, Procedures, Percutaneous
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INTRODUCTION

Symptomatic severe aortic stenosis has a 50% two year mortality rate if left untreated.[1,2] Until recently, open surgical valve replacement has been the only effective treatment; however, up to one third of patients are considered ineligible for this procedure.[3] Transcatheter aortic valve implantation (TAVI) is an emerging treatment option for these patients.[3,4]

Between 2007 and 2011, there were 17 712 new TAVI candidates in Europe and 9 189 in the United States.[5] Different access routes have been suggested for TAVI, with percutaneous transfemoral access being preferred. VCs as a result of large bore delivery catheters remain a significant clinical issue, particularly with respect to the elderly

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patient population. Complications reported include arterial dissection, perforation, pseudoaneurysm, rupture, and haematoma, among others.[5–13] The incidence of major VCs in previous studies ranges from 10% to 17%.[5–13] VCs, along with annular rupture, coronary occlusion, heart block, and renal failure are the leading causes of adverse events in TAVI patients.[14]

Major VCs are associated with poor clinical outcomes, including a higher incidence of major haemorrhage, cardiac and all cause mortality.[15–17] VCs may require urgent surgical or endovascular repair, resulting in greater length of stay in the hospital.[18] In Toronto General Hospital, a multidisciplinary model is used, with cardiologists and cardiac surgeons working side by side to implant TAVI, with the additional involvement of vascular surgery, most commonly for assessment in high risk vascular access patients and management of post-operative complications.

There is a need to adequately characterise VCs in order to mitigate adverse outcomes. While it is a rapidly emerging technology with promise, there is limited literature exploring vascular related adverse events and their effect on mortality and procedural morbidity. The present study analyses a single centre TAVI experience with respect to complications, as defined by the Valve Academic Research Consortium (VARC) 2 guidelines (Table 1),[19] as well as their predictors, management, and 30 day outcomes in patients undergoing transfemoral TAVI procedures.

Table 1. Alternative clinical conditions for major and minor vascular complications based on Valve Academic Research Consortium (VARC) criteria and VARC 2 consensus on vascular complications[19]

Major vascular complications
Any aortic dissection, aortic rupture, annulus rupture, left ventricle perforation, or new apical aneurysm/pseudoaneurysm
Access site or access-related vascular injury (dissection, stenosis, perforation, rupture, arterio-venous fistula, pseudoaneurysm, haematoma, irreversible nerve injury, compartment syndrome, percutaneous closure device failure) *leading to* death, life-threatening or major bleeding, visceral ischemia, or neurological impairment
Distal embolization (non-cerebral) from a vascular source requiring surgery or resulting in amputation or irreversible end-organ damage
The use of unplanned endovascular or surgical intervention *associated* with death, major bleeding, visceral ischaemia or neurological impairment
Any new ipsilateral lower extremity ischaemia documented by patient symptoms, physical exam, and/or decreased or absent blood flow on lower extremity angiogram
Surgery for access site-related nerve injury
Permanent access site-related nerve injury
Minor vascular complications
Access site or access-related vascular injury (dissection, stenosis, perforation, rupture, arterio-venous fistula, pseudoaneuysms, haematomas, percutaneous closure device failure) *not leading to* death, life-threatening or major bleeding, visceral ischaemia, or neurological impairment
Distal embolization treated with embolectomy and/or thrombectomy and not resulting in amputation or irreversible end-organ damage
Any unplanned endovascular stenting or unplanned surgical intervention not meeting the criteria for a major vascular complication
Vascular repair or the need for vascular repair (via surgery, ultrasound-guided compression, transcatheter embolization, or stent-graft)

METHODS

Study population

A retrospective cohort study was conducted at the institution, which included 388 consecutive patients undergoing TAVI between January 2007 and April 2015. Devices implanted included CoreValve (Metronic CV, Irvine, CA, USA), and Edwards Sapien (Edwards Life sciences, Irvine, CA, USA). The delivery sheath diameters for CoreValve and Edwards were 18 F and 22/24 F, respectively. The patient cohort comprised patients who received TAVI via the transfemoral approach. All patients had severe symptomatic aortic stenosis as confirmed by transthoracic echocardiography (mean gradient $>$ 40 mmHg or aortic valve area $<$1.0 cm^2). Of these patients, those who were deemed unsuitable for open valve replacement were considered for TAVI. A multidisciplinary team with interventional cardiologists, cardiac anaesthetists, cardiac surgeons, radiologists, and vascular surgeons (for those high risk vascular access cases identified at TAVI rounds) were involved in patient selection and treatment. Vascular access vessels were evaluated by multislice computed tomography (CT) and arterial duplex studies. It is important to note that during the study period, not all TAVI patients received a pre-operative vascular surgery consultation. All transfemoral cases were completed by interventional cardiology or cardiac surgery and any vascular concerns were discussed with one of six vascular surgeons. Institutional ethics board approval for the study was received (13—6384).

TAVI procedure

After patient selection by the TAVI team, the procedural approach was determined to be transapical, transfemoral, or direct aortic. The access route was selected based on a consensus opinion during a weekly multidisciplinary meeting. CT angiography (CTA) and ultrasound were evaluated before deciding on an optimal approach. Factors such as tortuosity, calcification, diameter, plaque, and aneurysms were considered. Cardiologists evaluated CTA scans by measuring the narrowest common femoral artery (CFA) diameter on axial slices along with patient comorbidities to decide whether a referral to vascular surgery was needed. Patients who were referred to vascular surgeons were further evaluated with CTA via axial and coronal slices to make recommendations. The transfemoral (TF-TAVI) approach was considered the default option unless contraindicated. TAVI was performed based on standard instructions for use that have been outlined previously.[20,21] Sheath sizes varied between an outer diameter of 18 F and 24 F depending on the system used to deliver the valve. TF-TAVI was performed initially in the cardiac catheterisation laboratory but latterly in a hybrid

operating room under fluoroscopic guidance with percutaneous closure. There were no image fusion techniques or specific guidance software used by the operators. Cases that necessitated open cut down or closure of the groins were performed by vascular surgeons. Percutaneous closure was performed using the Perclose ProGlide Suture Mediated Closure System (Abbott Vascular, Santa Clara, CA, USA).[22]

Outcomes and study endpoints

Data collection included patient demographics and comorbidities, peri- and post-operative use of vascular consultations, 30 day mortality, procedures, length of hospital admission, and 30 day readmissions. The primary endpoint of the study was the presence of VCs, divided into peri-operative and post-operative and then further into major and minor complications as defined by the VARC 2 criteria (Table 1). Peri-operative VCs were defined as those that occurred in the operating room and within 24 h of surgery, consistent with VARC 2 guidelines.[19] The secondary endpoints included length of stay, procedural and 30 day mortality. A multidisciplinary team composed of cardiologists, vascular surgeons, and allied healthcare professionals were involved in patient selection and treatment.

Vascular complications

VCs were stratified into major vs. minor, according to the VARC 2 guidelines (Table 1). Vascular surgeons and cardiologists carried out the surgical and interventional management of all VCs. Bleeding secondary to incomplete arteriotomy closure was managed by manual compression, protamine administration, balloon occlusion, and/or stent deployment variably, as dictated by severity and response. Occlusive dissections were treated by angioplasty and/or nitinol stents. Pseudoaneurysms were initially managed by compression, and depending on location and size, treated by thrombin injections. Haematomas resolved with expectant and supportive management. Lacerations and vessel ruptures were treated surgically.

Statistics

Categorical data were expressed as number of patients and frequencies (%), and were compared using Pearson correlations, chi-square analyses, or Fisher exact test. Continuous variables were expressed as mean ± standard deviation (95% CI) and compared using Mann–Whitney U tests (MWU). Demographics, comorbidities, intra-operative, and post-operative characteristics were compared between patients who sustained a VC against those who were complication free. All comparisons were two sided, and $p < .05$ was considered significant. Logistic regression analyses identified factors associated with peri-operative and post-operative VCs. Multivariable analysis of factors associated with VCs in univariable analysis was undertaken to identify independent predictors of VCs using hierarchical logistic regression with bootstrapping. Variables found to be significantly related to complications in univariable analysis ($p < .05$) were included in the final regression model. With regard to VCs over time, curve estimation was used to conduct a simple time series analysis. Normal assumptions for this analysis were met. All statistical analyses were performed using SPSS V. 23 (IBM Corporation, Armonk, NY, USA).

Mortality analysis between the two groups was performed using Spearman correlation and Kaplan–Meier with events compared using the log rank test ($p < .05$).

RESULTS

Patient population

Three hundred and eighty eight patients received TAVI between 2007 and 2015 and a total of 237 (61%) patients were treated via the transfemoral approach (Fig. 1). The remainder of the patients received TAVI by way of the transapical ($n = 146$) or direct aortic ($n = 5$) method. Baseline characteristics and comorbidities of the transfemoral patients are presented in Table 2.

Vascular complications over time

Time series analysis failed to show a significant relationship between the proportion of complications and time from 2007 to 2015. This included both cut down (2007–2009) and percutaneous (2010 onwards) cases. In order to better examine change in complications over time using percutaneous access, VCs from 2010 onwards were explored too. There was neither a significant linear nor a quadratic relationship between the proportion of VCs and year (2010–2015, $p = .24$ (linear) and .26 (quadratic); Fig. 2). In 2010 there were few cases, and no cases with complications. Thus, a relationship was sought between the years 2011 and 2015, excluding the year 2010 as a potential outlier. Both linear and quadratic relationships continued to fail to meet significance in this model ($p = .08$).

Vascular complications

There was a total of 68 VCs (28.7%), with 42 (17.9%) occurring during the post-operative period and the remainder ($n = 26$, 11.4%) during the peri-operative period (Fig. 1). These included haematomas (22), arterial dissections (20), pseudoaneurysms (14), common femoral artery laceration (1), rupture (5), thrombus (4), and fistula (2). Dissections mainly occurred in the femoral system, with 60% (12) being at the level of the common femoral artery and the remainder in the superficial femoral and iliac systems. TAVI patients sustained a total of seven major VCs (3%; Table 3), with all requiring endovascular or open repair. Perforations and lacerations were managed by arterial cut down and primary repair. In certain cases, occlusion balloons were advanced to control bleeding prior to gaining proximal and distal control. It is important to note that ventricular perforations can be treated by both endovascular and open methods, and

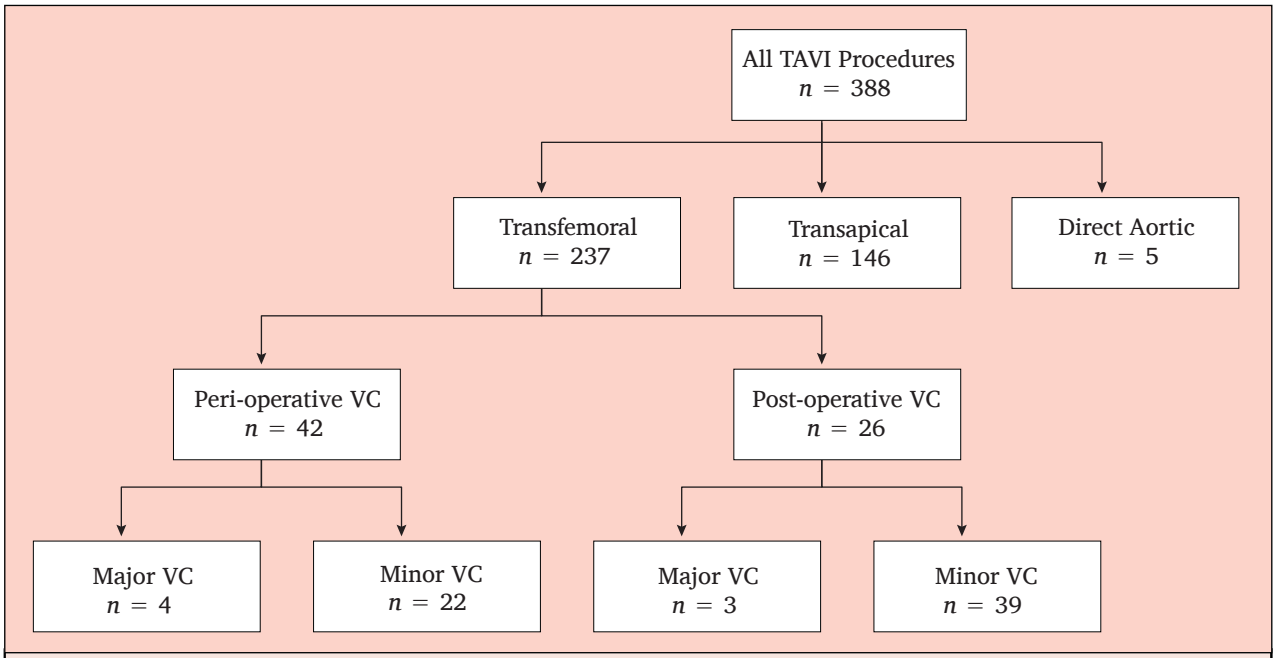

Figure 1. Flowchart of 388 patients receiving transcatheter aortic valve implantation (TAVI) through transfemoral approach ($n = 237$) and their vascular complications (VC). TAVI = transcatheter aortic valve implantation.

it is important to maintain a high index of suspicion in patients who are haemodynamically unstable. Lastly, arterial embolisation was treated by cut down and balloon embolectomy.

Most minor VCs occurred post-operatively (16.5% vs. 9.3%; Fig. 3). In the peri-operative period, the majority of complications were the result of dissections while post-operatively haematomas and pseudoaneurysms were the main causes.

Procedures and length of stay

VCs resulted in 17 procedures, with surgical repair being the most common peri-operatively, and thrombin injections post-operatively (Table 4). Vascular surgeons performed all procedures. This constituted 7% of the TAVI population and 25% of patients who sustained a VC.

Length of stay (LOS) was not related to either major or minor VCs in a multivariable analysis. Patients who had a major post-operative complication had an average stay of 13 days (SD = 12). Patients with a minor complication had an average stay of 10.4 days (SD = 8.6).

Predictors of vascular complications

Owing to the low number of events ($n = 6$), major VCs were analysed without separation into peri- and post-operative subcategories (Table 5). Female gender and dyslipidaemia were univariable predictors of major complications. In the final multivariable regression, male gender was found to be protective against major VCs ($B = -2.1$; $p = .023$). Dyslipidaemia was not sufficiently powered and further studies will be necessary to determine its role.

In minor peri-operative complications, age was a significant predictor of minor peri-operative complications (Table 6; MWU, $p = .039$). The average age in those with minor peri-operative complications was 84 years compared with 81 in those without complications.

Univariable predictors of minor post-operative VC included side (R vs. L) of the largest sheath size ($p = .03$; $p = .008$) (Table 6). There was a higher than expected number of minor complications in those where the largest sheath was on the left.

Mortality

There were nine deaths during a median follow up period of 65 months (>5 years). A variable was created to represent any mortality within a 30 day timeframe (procedural mortality, in hospital mortality and 30 day mortality). This variable was significantly correlated with the experience of a peri-operative VC (Spearman's $R = 0.212$, $p = .001$).

DISCUSSION

TAVI is an evolving treatment option that is becoming more available as the standard of care in high risk patients with severe symptomatic aortic stenosis. Based on results from the PARTNER 1 and 2 trials, TAVI is now also becoming an attractive option for intermediate risk patients.[3,4] VCs remain an important source of potential morbidity and mortality in this patient population. This study demonstrated an overall VC rate of 26% in TAVI patients with a majority of these complications being minor, and occurring during the post-operative period. Vascular surgery was involved in all VC cases with an intervention performed in 25% of these patients. Location of largest sheath and female gender were independent predictors of VCs.

Table 2. Baseline characteristics of patients receiving transcatheter aortic valve implantation (TAVI) through transfemoral approach

Characteristic	Patients (n = 237)
Age − y	81.0 ± 8.6
Male	147 (62.0)
Body mass index	27.85 ± 6.3
Aortic valve area	0.76 ± 0.30
LVEF − %	55.7 (13.7)
NYHA	
Class III	208 (87.8)
Class IV	11 (4.64)
Logistic EuroScore	12.9 (9.3)
Past smoker	97 (41)
Current smoker	14 (6)
Hypertension	187 (79)
Diabetes	79 (33.3)
Coronary artery disease	165 (70)
Dyslipidaemia	170 (72)
Previous aneurysm	7 (3)
Previous PCI	77 (32)
Previous CABG	63 (27)
Past myocardial infarction	41 (17)
Cerebrovascular disease stroke	34 (14.3)
Stroke	14 (5.9)
COPD	41 (17.3)
Pulmonary hypertension	91 (38.3)
Renal	
Creatinine	120.5 ± 105
MDRD GFR	57.4 ± 20

Data are given as n (%) or mean ± standard deviation (SD). Logistic EuroScore is the risk stratification score including age, gender, COPD, extracardiac arteriopathy, neurological dysfunction, creatinine, previous cardiac surgery, critical state, active pericarditis, LV function, unstable angina, recent myocardial infarction, pulmonary hypertension. CABG = coronary artery bypass graft; COPD = chronic obstructive pulmonary disease; GFR = glomerular filtration rate; LVEF = left ventricular ejection fraction; MDRD = modification of diet in renal disease; NYHA = New York Heart Association; PCI = percutaneous coronary intervention.

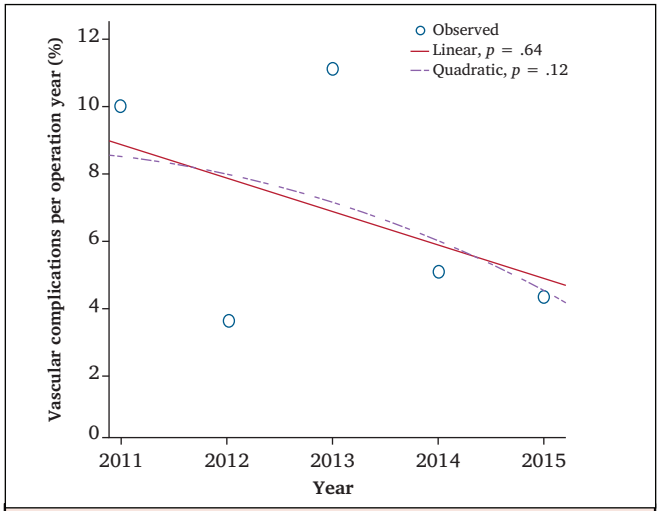

Figure 2. Vascular complications per year (2010-15) of transcatheter aortic valve implantation (TAVI) through transfemoral approach. There was no relationship between the year of operation and vascular complications.

Table 3. Treatment of major vascular complications in patients receiving transcatheter aortic valve implantation (TAVI) through transfemoral approach[a]

Vascular complication (major)	Treatment
Ventricular perforation	Endovascular vascular plug and pericardiocentesis
Iliac and femoral dissection	Hybrid repair
Femoral and cardiac laceration	Surgical repair
Femoral perforation	Surgical repair
Iliac perforation (n = 2)	Surgical repair
Distal embolisation	Embolectomy

[a] 3% of all transcatheter aortic valve implantation patients sustained a major vascular complication. All patients needed >2 units of blood and operative management.

Interestingly, even with the high survival rate in this patient population, peri-operative VCs were correlated with short-term mortality.

VC rates after TAVI have been reported previously at 1.9—51.6%.[5—13,16—18] The wide range is secondary to varying VC definitions, as well as the evolving safety of the technology. Results from the recent multicentre PARTNER 2 trial reported the rate of major VCs was 8.6%. The present study reports lower rates of major VCs, with a rate of 3%. Given that the patient population is similar to the trials reported above, the lower rates of major VC could be related to the multidisciplinary model with input from cardiology, cardiac surgery, vascular surgery, and allied healthcare. The majority of the patients (69%) were seen by a vascular surgeon prior to surgery, reflecting the subset of patients with a worse atherosclerotic disease burden. Consultations aided in decisions about approach (transapical vs. transfemoral) and site (right vs. left femoral) with use of advanced imaging technologies including centreline measurements and 3D reconstruction. Finally, all procedures were completed in the multidisciplinary vascular suite allowing immediate access for any potential repairs.

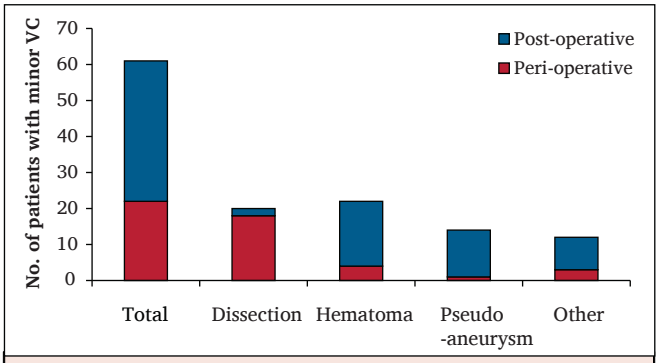

Figure 3. Minor peri- and post-operative vascular complications (VC) in 237 patients receiving transcatheter aortic valve implantation (TAVI) through transfemoral approach. The majority of minor vascular complications occurred post-operatively and consisted of haematomas and pseudoaneurysms. The remainder occurred peri-operatively and consisted predominantly of dissections.

Table 4. Peri- and post-operative procedures to treat vascular complications (VCs) (n = 68) of 237 patients receiving transcatheter aortic valve implantation (TAVI) through transfemoral approach[a]

Procedure	Patients (n = 237)
Peri-operative	26 (11)
Surgical repair (with vascular cut down)	5 (2)
Primary vascular closure	2 (1)
Balloon angioplasty	1 (0.5)
Post-operative	42 (18)
Thrombin injections	6 (3)
Embolectomy	1 (0.5)
Arterial repair	1 (0.5)
Thrombectomy	1 (0.5)

Data are given as n (%). [a] 25% of all patients who sustained a VC needed a procedure to alleviate symptoms. Surgical repair was the most common procedure performed peri-operatively, while thrombin injections were common post-operatively. VC = vascular complication.

Table 5. Predictors of major peri-operative and post-operative vascular complications (VC) in 237 patients receiving transcatheter aortic valve implantation (TAVI) through transfemoral approach

Predictor	Patients with no major VC (n = 231)	Patients with major VC (n = 6)	p
Age − y	80.9 ± 8.64	85.2 ± 6.2	.17
Gender − male	145 (63)	1 (16.7)	.03
BMI	27.9 ± 6.32	25.5 ± 2.66	–
Creatinine	116.3 ± 76.2	91.8 ± 23.1	.50
GFR	57.5 ± 20.5	56.7 ± 16.3	–
Past smoker	83 (36.2)	–	.14
Current smoker	13 (5.7)	1 (16.7)	–
Diabetes	78 (33.9)	1 (16.7)	.67
Hypertension	183 (79.6)	4 (66.7)	
CAD	163 (70.9)	2 (33.3)	.70
Dyslipidaemia	169 (73.5)	1 (16.7)	.01
Previous MI	41 (17.8)	0 (0)	.59
Previous PCI	76 (33.2)	1 (16.7)	–
Previous CABG	63 (27.5)	0 (0)	.20
No. of cardiac procedures	0.82 ± 0.87	0.17 ± 0.41	.07
Previous aneurysm	7 (3.1)	0 (0)	–
Chronic AF	84 (36.7)	1 (16.7)	.42
Permanent pacemaker	35 (15.3)	0 (0)	–
AVA velocity	0.76 ± 0.3	0.69 ± 0.1	–
Intra-operative variables			
Largest sheath size (ID) − cm	18.4 ± 1.8	19.0 ± 2.5	–
Side of the largest sheath			
Right	123 (56.2)	2 (33.3)	.40
Left	96 (43.8)	4 (66.7)	

Data are given as n (%) or mean ± standard deviation (SD). Female gender and lack of dyslipidaemia were univariable predictors of major vascular complications. In the multivariable model, male gender was found to be protective against vascular complications. BMI = body mass index; GFR = glomerular filtration rate; CAD = coronary artery disease; MI = myocardial infarction; PCI = percutaneous coronary intervention; CABG = coronary artery bypass graft; AF = atrial fibrillation; AVA = aortic valve area; ID = inner diameter; VC = vascular complication.

Ventricular perforations remain one of the most challenging complications post TAVI. Their management depends on type of injury, location, and patient comorbidities. Clinically, they present as a rapid pericardial effusion followed by cardiac tamponade. Diagnosis is made during the procedure with an angiogram in the setting of tamponade physiology. First line management of LV perforation is by use of an endovascular vascular plug with percutaneous mediastinal drainage. The backup option would involve emergency sternotomy and surgical repair.

Interestingly, while sheath sizes have decreased over the years, the rate of VC has not changed over time. There are three possible explanations: floor effect, learning curves, and no relationship. Floor effect refers to the concept that complication rates are generally low enough so that it is difficult to show a further decrease. Next, all procedures have a learning curve followed by plateau, wherein a minimum number of procedures must be done every year to maintain acceptable rates of procedural complications.[23,24] The number of procedures has yet to be established for TAVI and would be an interesting future study. Finally, it is possible that due to ongoing evolution of the delivery systems and devices, there is no relationship between time, experience, and VCs.

There have been a number of studies exploring predictors of VC and have implicated a variety of factors. These include sheath diameter, sheath to femoral artery ratio (SFAR), early centre experience, peripheral artery disease, female sex, sheath diameter, and learning curves.[7,12,13,17] The present study adds location of largest sheath as a new predictor. It was found that left sheath size was specifically predictive of VC. Sina et al.[28] have previously identified that there is a relationship between access side used to deliver EVAR and speed of cannulation. They believe this is due to anatomical differences in the origin of the iliac artery. This could account for the differences in sides noted in the current study. Alternatively, this could be related to the handedness of the operator or simply due to increased vascular disease burden.

Consistent with the literature, patients in this cohort who sustained a peri-operative VC had a higher incidence of procedural, in hospital, and 30 day mortality.[12,16,25] Thus, initiatives to reduce VCs have the potential to reduce peri-operative mortality and improve the safety of the TAVI procedure. While there were only nine cases of short-term mortality, two of them were secondary to haemorrhage. Unlike previously published studies, TAVI patients with VC were not found to be at increased risk of life threatening and major bleeding events.[26,27]

The present study has the limitations of a retrospective analysis, and was hypothesis driven. The strengths of the present single centre study include the consistent strategies in patient selection, operative procedure, and post-operative care. The study centre serves a wide catchment area and is the one of the largest TAVI centres in the country, thus it is believed that the findings from the

Table 6. Predictors of minor peri-operative and post-operative vascular complications (VC) in 237 patients receiving transcatheter aortic valve implantation (TAVI) through transfemoral approach

Predictor	Patients without minor peri-operative VC (n = 213)	Patients with minor peri-operative VC (n = 22)	p	Patients without minor post-operative VC (n = 211)	Patients with minor post-operative VC (n = 39)	p
Age − y	80.7	84.3	.04	81.1	80.5	–
Gender − male	134 (62.6)	12 (54.5)	.46	126 (64)	20 (51.3)	–
BMI	27.9 ± 6.3	27.8 ± 6.24	.99	28.0	27	–
Creatinine	122.8 ± 110	98.9 ± 39	.08	123.2	107.3	–
GFR	57 ± 20.8	60.8 ± 15.8	–	57.6	48.0	–
Past smoker	89 (41.8)	8 (36.4)	.62	80 (40.8)	17 (43.6)	–
Current smoker	14 (6.6)	0	.37	12 (6.1)	2 (5.1)	–
Diabetes	70 (32.7)	9 (40.9)	.44	67 (34)	12 (30.8)	–
Hypertension	170 (79.4)	17 (77.3)	.79	155 (78.7)	32 (82.1)	–
CAD	152 (70.1)	13 (59.1)	.25	136 (69)	29 (74.4)	–
Dyslipidaemia	155 (72.4)	15 (68.2)	.67	141 (71.6)	29 (74.4)	–
Previous MI	36 (16.7)	5 (22.7)	.49	32 (16.2)	9 (23.1)	.30
Previous PCI	68 (31.6)	9 (40.9)	.39	63 (32.1)	14 (35.9)	–
Previous CABG	57 (26.8)	6 (27.3)	.96	50 (25.5)	13 (33.3)	.31
Previous aneurysm	7 (3.3)	0	.90	4 (2.1)	3 (7.7)	.90
Chronic AF	73 (34.3)	12 (54.5)		69 (35.2)	26 (41)	–
Permanent pacemaker	33 (15.5)	2 (9.1)		30 (15.2)	5 (12.8)	–
AVA	0.77 ± 0.30	0.65 ± 0.14	.08	0.77 ± 0.31	0.71 ± 0.17	.62
Intra-operative variables						
Largest sheath size (ID) − cm	6.91 ± 0.41	6.97 ± 0.46	.16	6.90 ± 0.39	7.0 ± 0.5	.44
Side of the largest sheath						
Right	116 (56.9)	11 (50)	.65	113 (60.1)	14 35.9	.01
Left	88 (43.1)	11 (50)		75 (39.9)	24 (63.2)	

Data are given as n (%) or mean ± standard deviation (SD). Female gender and lack of dyslipidaemia were univariable predictors of major vascular complications. In the multivariable model, male gender was found to be protective against vascular complications.
BMI = body mass index; GFR = glomerular filtration rate; CAD = coronary artery disease; MI = myocardial infarction; PCI = percutaneous coronary intervention; CABG = coronary artery bypass graft; AF = atrial fibrillation; AVA = aortic valve area; ID = inner diameter; VC = vascular complication.

patient population could be generalised to the general TAVI population. This study provided detailed analysis of VCs, predictors, and procedures that could not be sufficiently addressed in multicentre studies. Finally, self assessments of quality of life would have provided a much needed patient perspective.

CONCLUSION

VCs continue to expose significant morbidity and mortality to TAVI patients. The present study found that 29% of all TAVI patients sustained a VC. Three percent of these patients experienced a major complication while the remaining 26% sustained a minor VC. One quarter of these patients required vascular surgery procedures to correct a VC. This study demonstrated that location of largest sheath size was a predictor of VCs. Finally, VCs were associated with procedural, in hospital, and 30 day mortality. A multidisciplinary TAVI team, involving cardiologists, cardiac surgeons, and vascular surgeons, has the potential to improve patient outcomes.

CONFLICTS OF INTEREST

None.

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