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Percutaneous Management of Vascular Complications in Patients Undergoing Transcatheter Aortic Valve Implantation

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Objectives This study sought to investigate the feasibility and safety of percutaneous management of vascular complications after transcatheter aortic valve implantation (TAVI).

Background Vascular complications after TAVI are frequent and outcomes after percutaneous management of these adverse events not well established.

Methods Between August 2007 and July 2010, 149 patients underwent transfemoral TAVI using a percutaneous approach. We compared outcomes of patients undergoing percutaneous management of vascular complications with patients free from vascular complications and performed duplex ultrasonography, fluoroscopy, and multislice computed tomography during follow-up.

Results A total of 27 patients (18%) experienced vascular complications consisting of incomplete arteriotomy closure (n = 19, 70%), dissection (n = 3, 11%), arterial perforation (n = 3, 11%), arterial occlusion (n = 1, 4%), and pseudoaneurysm (n = 1, 4%). Percutaneous stent graft implantation was successful in 21 of 23 (91%) patients, whereas 2 patients were treated by manual compression, 2 patients underwent urgent surgery, and 2 patients required delayed surgery. Rates of major adverse cardiac events at 30 days were similar among patients undergoing percutaneous management of vascular complications and those without vascular complications (9% vs. 8%, p = 1.00). After a median follow-up of 10.9 months, imaging showed no evidence of hemodynamically significant stenosis (mean peak velocity ratio: 1.2 ± 0.4). Stent fractures were observed in 4 stents (22%, type I [6%], type II [16%]) and were clinically silent in all cases.

Conclusions Vascular complications after TAVI can be treated percutaneously as a bailout procedure with a high rate of technical success, and clinical outcomes are comparable to patients without vascular complications. Stent patency is high during follow-up, although stent fractures require careful scrutiny.
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Transcatheter aortic valve implantation (TAVI) for treatment of severe aortic stenosis improves survival compared with medical treatment alone among patients considered not suitable candidates for surgery (1) and is noninferior to surgical aortic valve replacement in terms of survival among selected very high-risk patients (2). Pre-operative evaluation of the vascular access site aims to define vessel size, tortuosity, and extent of calcification to identify the best vascular access site and to minimize the risk of complications. Notwithstanding, vascular injury and access site complications remain the most frequent adverse event occurring in 12% to 30% of cases (1,3,4), which may result in life-threatening bleeding and require surgical or interventional treatment in most cases. Moreover, major vascular complications among patients undergoing TAVI have been identified as predictors of mortality underscoring the serious nature of this adverse event (1,3).

Surgical repair of vascular complications is common practice, but it is associated with patient discomfort, treatment delay, prolonged hospitalization, and the risk of wound infections (5,6). A percutaneous treatment strategy, including the implantation of covered stent grafts for secondary vessel closure in case of incomplete arteriotomy closure, vessel perforation, rupture, or dissection is effective to rapidly stop severe bleeding, thereby mitigating the consequences of this complication. However, there is concern that covered stent grafts implanted into the iliofemoral artery may be prone to stent fracture and flow obstruction due to the superficial anatomical location with risk of external compression and exposure to bending forces. Therefore, the purpose of the present study was to evaluate the feasibility and safety of percutaneous management of vascular complications during transfemoral TAVI.

Abbreviations and Acronyms

CT = computed tomography

TAVI = transcatheter aortic valve implantation

VARC = Valvular Academic Research Consortium

Methods

Patient population. Between August 2007 and July 2010, 149 high-risk patients with symptomatic, severe aortic valve stenosis underwent transfemoral TAVI using a purely percutaneous approach at a single institution. Figure 1 summarizes the flow of patients included into the present study. All patients underwent comprehensive evaluation before TAVI using a standardized protocol during a short hospitalization, including left and right heart catheterization, aortography, transthoracic and transesophageal echocardiography, and computed tomography (CT) angiography of the chest, abdomen, and pelvis before the procedure as previously described (7,8). An interdisciplinary team of cardiac surgeons and interventional cardiologists reviewed the cases and agreed on subsequent treatment allocation. The registry was approved by the local medical ethics committee, and all patients signed informed, written consent.

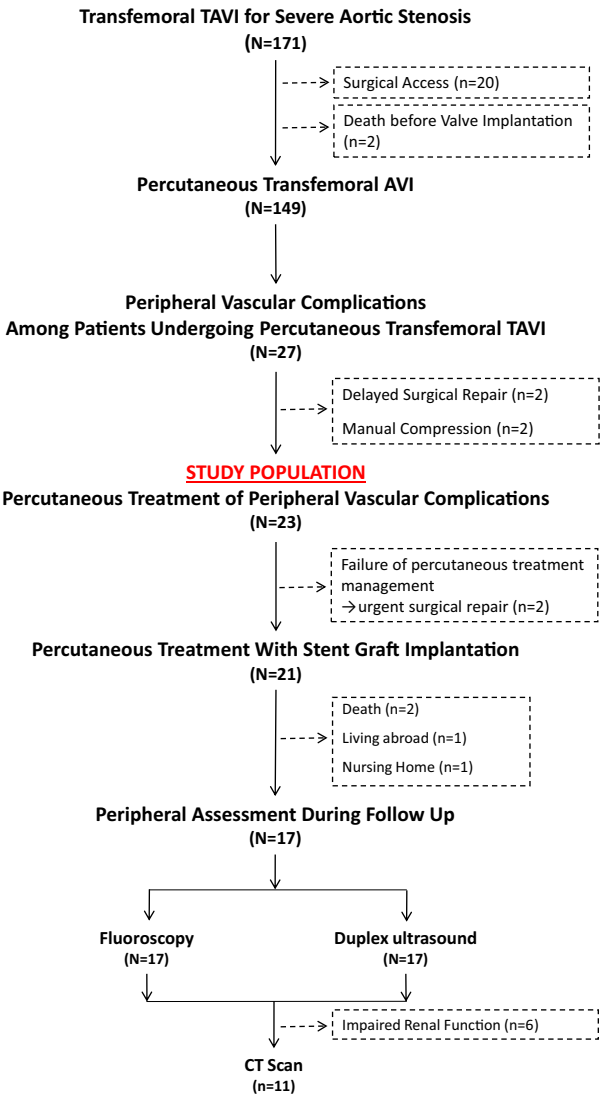

Figure 1. Patient Flow

Patient flow of patients included into the present study. AVI = aortic valve implantation; CT = computed tomography; TAVI = transcatheter aortic valve implantation.

Procedure. Transfemoral TAVI was performed using either the Medtronic CoreValve (Medtronic, Inc., Minneapolis, Minnesota) or the Edwards Sapien valve (Edwards Lifesciences, Irvine, California). Vascular access was obtained by puncture of the common femoral artery under fluoroscopic guidance. After pre-dilation of the vessel with a 9-F vascular sheath, a 10-F ProStar XL closure device (Abbott Vascular Devices, Redwood City, California) was inserted, sutures deployed, needles removed, and sutures secured using the

pre-closure technique (9). Following this, an 18-F delivery sheath was inserted in case of the CoreValve bioprosthesis (26 and 29 mm) and a 22- or 24-F sheath was inserted in case of the Sapien valve (23 and 26 mm). More recently, the delivery sheath of the Sapien valve was reduced to 18- and 19-F with the advent of the Edwards Sapien XT device (Edwards Lifesciences).

After successful transfemoral valve implantation, catheters were removed and access site closure was completed. In the first 65 transfemoral patients, the access site was closed by unprotected tightening of the pre-closed knot of the ProStar device (Abbott Vascular Devices). Subsequently, we adopted the systematic use of a crossover technique as described by Sharp et al. (10). In brief, a stiff wire (Magic Torque Guide-wire, 0.035 inch, Boston Scientific Corp., Natick, Massachusetts, or Terumo Stiff Radifocus Guidewire, 0.035 inch, Terumo Medical Corporation, Terumo, Somerset, New Jersey) was advanced from the contralateral groin into the ipsilateral delivery sheath using a 5-F Judkins right or short-tipped pigtail catheter. Then, an appropriately sized peripheral vascular balloon (6 to 10 mm) was advanced through a 6- to 7-F crossover sheath (e.g., Terumo Destination Guiding Sheath) and placed in the common iliac artery just proximal to the introducer sheath. Low-pressure balloon inflation was performed to occlude the iliac vessel and provide a bloodless dry field for access site closure. Following this, the vascular access sheath was removed and the pre-laid sutures of the ProStar device (Abbott Vascular Devices) were tied in place. The result was checked by contrast angiography via the crossover sheath.

In case of vessel rupture, dissection, and incomplete suture closure, the guidewire was advanced across the site of vascular injury into the distal superficial femoral artery to allow for prolonged balloon occlusion of the vessel. In case of persistent bleeding, rupture, or flow-limiting dissection, percutaneous treatment with a self-expandable covered (Fluency Plus, Bard Peripheral Vascular, Tempe, Arizona) or uncovered stent graft (Cristallo Ideale, Self Expanding Stent System, Medtronic, INVAtec, Roncadelle, Italy) was performed. The covered stent graft consists of a self-expanding nitinol stent platform, encapsulated with 2 ultrathin expanded polytetrafluoroethylene layers. Covered stent grafts were available in lengths between 40 and 80 mm and diameters between 7 and 10 mm, constrained in an 8- to 10-F delivery system designed to accept a 0.035-inch guidewire. The stent graft was placed through a 9-F intravascular sheath following removal of the peripheral vascular balloon and crossover sheath. Then, the stent graft was advanced over the stiff guidewire and placed under fluoroscopic guidance using anatomic landmarks.

Patients undergoing TAVI received a loading dose of clopidogrel (300 mg) and acetylsalicylic acid (100 mg) the day before the intervention. Clopidogrel was maintained at a dose of 75 mg/day for the duration of 6 months after TAVI and acetylsalicylic acid 100 mg was prescribed indefinitely. Patients requiring oral anticoagulation for various indications also received acetylsalicylic acid 100 mg indefinitely.

Endpoint definitions. Clinical adverse events were adjudicated by a team of interventional cardiologists and cardiac surgeons according to the Valvular Academic Research Consortium (VARC) endpoint definitions described in detail elsewhere (11). Vascular complications were defined as major whenever vascular injury, leading to death, transfusion of more than 4 blood units, unplanned percutaneous or surgical intervention, or irreversible end organ damage occurred. Minor vascular complications were defined as any vascular injury requiring blood transfusions <4 U not resulting in unplanned percutaneous or surgical intervention, as well as percutaneous access site closure failure resulting in interventional or surgical correction. Bleeding events were assessed as life-threatening or disabling: 1) in case of bleeding into a critical area or organ; 2) bleeding causing hypovolemic shock or requiring vasopressors or surgery; or 3) with an overt source of bleeding with a decrease in hemoglobin ≥ 5 g/dl or packed red blood cells transfusion ≥ 4 U. Major bleeding was considered in the setting of overt bleeding associated with a decrease in the hemoglobin level of at least 3.0 g/dl. For the definition of death, myocardial infarction, stroke, and kidney injury, we refer to previous reports. Major adverse cerebrocardiovascular events were defined as death, myocardial infarction, or major stroke (7,8).

Data collection and follow-up. Adverse events were assessed in hospital, and regular clinical follow-up was performed at 1, 6, and 12 months, and yearly thereafter by means of a clinical visit or a standardized telephone interview. All suspected events were adjudicated by an unblinded clinical event committee. Baseline clinical and procedural characteristics and all follow-up data were entered into a dedicated database, held at an academic clinical trials unit (CTU Bern, Bern University Hospital, Switzerland) responsible for central data audits and maintenance of the database.

All patients with percutaneous management of vascular complications underwent follow-up assessment of the peripheral vascular site by clinical assessment, fluoroscopy, and duplex ultrasonography. In addition, multislice CT angiography was scheduled in all patients without renal failure (glomerular filtration rate <40 ml/min/1.73 m^2). Cine images were obtained by use of biplane radiography of the vascular access site with at least 2 orthogonal projections. Implanted stents were visualized using the stent boost technique under high magnification ($15\times$) to detect stent fractures. All images were evaluated by a team consisting of a peripheral vascular disease specialist and an interventional cardiologist to grade the presence of stent fractures according to the classification of Jaff et al. (12). Duplex ultrasonography was performed in all patients under fasting conditions

to assess patency and flow across the implanted stent grafts. Restenosis was defined as peak velocity ratio (calculated as intrastenotic peak systolic velocity divided by proximally recorded peak systolic velocity) ≥2.4 (13). Multislice contrast CT angiography allowed assessment of stent integrity and patency.

Statistical analysis. Continuous variables are presented as mean ± SD and were compared using Student *t* test analysis. Categorical data are expressed as frequency (percentages), and Fisher exact tests or Pearson chi-square tests were used for baseline and procedural comparisons. Outcome data were compared using univariate logistical regression analysis, and in case of no (0) events, relative risks were computed with a continuity correction of 0.5 along with respective p values. All statistical analyses were performed using SPSS statistical package (version 17.0, SPSS Inc., Chicago, Illinois). All p values are the results of 2-tailed tests and values <0.05 were considered statistically significant.

Results

Patient population. Between August 2007 and June 2010, 149 patients underwent transfemoral TAVI using a purely percutaneous technique and are subject of the present report (Fig. 1). A total of 27 (18%) patients suffered from at least 1 vascular complication, and 23 patients attempted to undergo percutaneous treatment with covered or uncovered stent implantation. Baseline clinical characteristics of patients with and without percutaneous vascular complication management are shown in Table 1. With the exception of a higher body mass index (27 ± 4 kg/m^2 vs. 25 ± 4 kg/m^2, p = 0.04) and logistic EuroSCORE (European System for Cardiac and Cerebrovascular Events) (31 ± 19% vs. 22 ± 15%, p = 0.02), as well as trend toward a higher prevalence of patients in New York Heart Association functional class III (70% vs. 48%, p = 0.07) among patients with percutaneous vascular complication management, there were no signif-

Table 1. Baseline Clinical Characteristics

	Percutaneous Vascular Complication Management (n = 23)	No Vascular Complication (n = 122)	p Value*
Age, yrs	85 ± 4	84 ± 5	0.16
Female	15 (65)	72 (59)	0.65
Body mass index, kg/m^2	27 ± 4	25 ± 4	0.04
Cardiac risk factors			
Diabetes mellitus	2 (9)	30 (25)	0.11
Hypercholesterolemia	12 (52)	68 (56)	0.82
Hypertension	19 (83)	99 (81)	1.00
Past medical history			
Previous myocardial infarction	6 (26)	21 (17)	0.38
Previous CABG	5 (22)	22 (18)	0.77
Previous PCI	4 (17)	25 (21)	1.00
Previous cerebrovascular event	1 (4)	12 (10)	0.69
Peripheral vascular disease	3 (13)	20 (16)	1.00
Chronic obstructive lung disease	2 (9)	23 (19)	0.37
Symptoms			
NYHA functional class I	2 (9)	14 (12)	1.00
NYHA functional class II	4 (17)	37 (30)	0.31
NYHA functional class III	16 (70)	58 (48)	0.07
NYHA functional class IV	1 (4)	13 (11)	0.70
Risk assessment			
Logistic EuroSCORE, %	31 ± 19	22 ± 15	0.02
STS score, %	6.2 ± 3	6.3 ± 6	0.89
Cardiac catheterization			
Coronary artery disease	13 (57)	72 (59)	0.82
Left ventricular ejection fraction, %	48 ± 15	52 ± 14	0.19
Aortic valve area, cm^2	0.58 ± 0.2	0.54 ± 0.2	0.43
Mean transaortic gradient, mm Hg	45 ± 16	45 ± 16	0.89

Values are mean ± SD or n (%). *Continuous variables were compared using Student *t* test and categorical variables using Fisher exact test.
CABG = coronary artery bypass graft; EuroSCORE = European System for Cardiac Operative Risk Evaluation; NYHA = New York Heart Association; PCI = percutaneous coronary intervention; STS = Society of Thoracic Surgeons.

icant differences between the 2 groups in terms of cardiac risk factors, past medical history, and aortic valve stenosis severity.

Procedural characteristics and outcome. The type and management of all 27 vascular complications are summarized in Table 2. They consisted of incomplete arteriotomy closure (n = 19, 70%), vascular dissection (n = 3, 11%), arterial perforation (n = 3, 11%), arterial occlusion (n = 1, 4%), and pseudoaneurysm (n = 1, 4%) and were classified as VARC major in 9 (6%) and as VARC minor vascular complications in 18 (12%) patients. VARC major complications were more common among patients undergoing TAVI using 22- or 24-F delivery sheaths (n = 3, 25%) as compared to those treated through 18- or 19-F delivery sheaths (n = 6, 4%; $p < 0.0001$) (Fig. 2A). After the systematic implementation of the vascular crossover technique, the rate of VARC major vascular complications decreased from 12% (n = 8) to 1% (n = 1) (Fig. 2B).

Percutaneous stent graft implantation was successful in 21 of 23 (91%) attempted cases, but failed in 2 patients due to excessive tortuosity with inability to crossover from the contralateral site, and those patients underwent urgent

Table 2. Vascular Complications After Percutaneous Transfemoral TAVI

Patient #	Sheath Size, F	Type of Vascular Complication	Severity (VARC)	Site	Crossover Technique for Closure	Treatment Strategy	Comments
1	18	Common femoral artery perforation	Major	Access site	No	Delayed surgery	Uneventful percutaneous access site closure. Hemodynamic instability 1 h after the intervention. Detection of perforated common femoral artery on CT angiography. Urgent surgical repair.
2	5	Common femoral artery occlusion	Major	Contralateral site	No	Percutaneous	Uncovered stent implantation 6 × 30 mm
3*	18	Incomplete arteriotomy closure	Major	Access site	No	Percutaneous	Covered stent implantation 8 × 40 mm
4	18	Common femoral artery dissection	Major	Access site	No	Percutaneous	Uncovered stent implantation 8 × 30 mm
5	18	Common femoral artery dissection	Major	Access site	No	Percutaneous	Covered stent implantation 10 × 60 mm
6	18	Incomplete arteriotomy closure	Minor	Access site	No	Percutaneous	Covered stent implantation 8 × 40 mm
7	18	Incomplete arteriotomy closure	Minor	Access site	No	Percutaneous	Covered stent implantation 8 × 40 mm
8	24	Incomplete arteriotomy closure	Minor	Access site	No	Percutaneous	Covered stent implantation 8 × 60 mm
9	22	Incomplete arteriotomy closure	Minor	Access site	No	Percutaneous	Covered stent implantation 8 × 40 mm
10	24	Common iliac artery perforation	Major	Access site	No	Urgent surgery	Perforation of iliofemoral artery. Unsuccessful crossover due to severe tortuosity. Urgent surgical repair.
11	18	Common iliac artery dissection	Major	Access site	No	Urgent surgery	Dissection and active bleeding of common iliac artery. Unsuccessful crossover due to severe tortuosity. Urgent surgical repair.
12	18	Incomplete arteriotomy closure	Minor	Access site	No	Percutaneous	Covered stent implantation 8 × 40 mm
13	24	External iliac artery perforation	Major	Access site	No	Percutaneous	Covered (8 × 40 mm) and uncovered (8 × 40 mm) stent implantation
14	18	Incomplete arteriotomy closure	Minor	Access site	Yes	Compression	Manual compression
15	18	Incomplete arteriotomy closure	Minor	Access site	Yes	Percutaneous	Covered stent implantation 8 × 40 mm
16	24	Incomplete arteriotomy closure	Minor	Access site	Yes	Percutaneous	Covered stent implantation 8 × 40 mm
17	18	Incomplete arteriotomy closure	Minor	Access site	Yes	Compression	Manual compression
18	18	Incomplete arteriotomy closure	Minor	Access site	Yes	Percutaneous	Covered stent implantation 7 × 40 mm
19	18	Incomplete arteriotomy closure	Minor	Access site	Yes	Percutaneous	Covered stent implantation 8 × 40 mm
20	18	Incomplete arteriotomy closure	Minor	Access site	Yes	Percutaneous	Covered stent implantation 8 × 40 mm
21	18	Incomplete arteriotomy closure	Minor	Access site	Yes	Percutaneous	Covered stent implantation 8 × 40 mm
22	24	Pseudoaneurysm	Major	Access site	Yes	Delayed surgery	Spontaneous large hematoma in right groin on day 17. Detection of a large pseudoaneurysm. Successful surgical repair.
23	22	Incomplete arteriotomy closure	Minor	Access site	Yes	Percutaneous	Covered stent implantation 8 × 40 mm
24	18	Incomplete arteriotomy closure	Minor	Access site	Yes	Percutaneous	Covered stent implantation 8 × 40 mm
25	18	Incomplete arteriotomy closure	Minor	Access site	Yes	Percutaneous	Covered stent implantation 10 × 40 mm
26	18	Incomplete arteriotomy closure	Minor	Access site	Yes	Percutaneous	Covered stent implantation 8 × 40 mm
27	19	Incomplete arteriotomy closure	Minor	Access site	Yes	Percutaneous	Covered stent implantation 8 × 40 mm

*Patient #3 had life-threatening bleeding leading to VARC major access site complication.
TAVI = transcatheter aortic valve implantation; VARC = Valvular Academic Research Consortium.

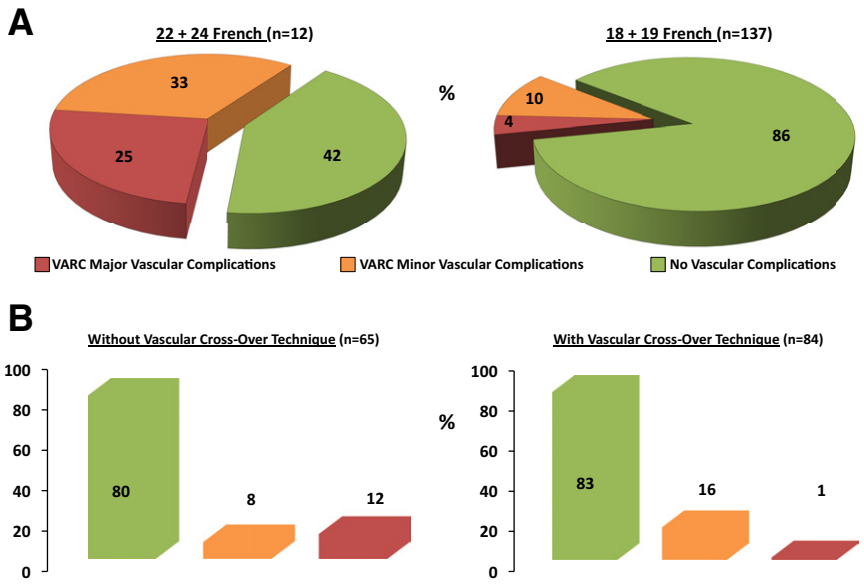

Figure 2. Vascular Complications According to VARC

Occurrence of vascular complications according to vascular access sheath size **(A)** and by vascular closure crossover technique **(B).** VARC = Valvular Academic Research Consortium.

surgical repair. Two other patients underwent delayed surgery due to development of a retroperitoneal hematoma on day 1 and a pseudoaneurysm on day 17, respectively, and 2 patients were treated by manual compression. Percutaneous management of vascular complications was performed ad hoc in 20 patients, whereas 1 patient was treated 1 day after TAVI. This patient, requiring delayed treatment the day after the procedure, experienced sudden occlusion of the left femoral artery that likely was related to a bioresorbable closure device (Angio-Seal, St. Jude Medical, St. Paul, Minnesota) that had been implanted upon removal of a 5-F diagnostic sheath. Following recanalization of the occluded vessel, an uncovered self-expanding stent was implanted at the site. The remaining 20 patients experienced ipsilateral

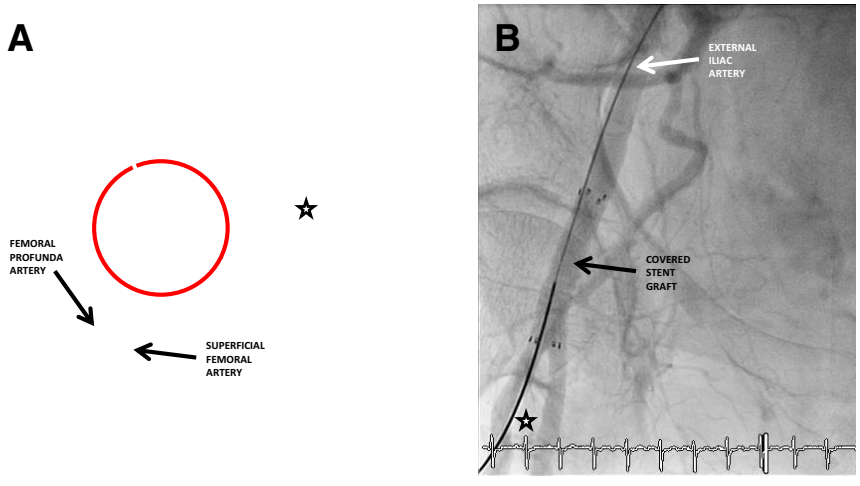

Figure 3. Treatment of Vascular Access Site Complication

(A) Arteriotomy closure failure with use of the ProStar suture device (Abbott Vascular Devices) **(red circle)** resulting in brisk bleeding from the arterial access site. **The star** indicates extravasation. **(B)** Secondary vessel closure after implantation of a Fluency Plus (Bard Peripheral Vascular, Tempe, Arizona) covered stent graft. **The star** indicates Magic Torque Wire (Boston Scientific Corp., Natick, Massachusetts) placed in the superficial femoral artery.

Table 3. Procedural Characteristics

	Percutaneous Vascular Complication Management (n = 23)	No Vascular Complication (n = 122)	p Value*
Procedure time, min	78 ± 20	84 ± 37	0.30
Fluoroscopy time, min	25 ± 9	21 ± 8	0.02
Amount of contrast, ml	296 ± 109	266 ± 100	0.20
Anesthesia	8 (35)	31 (25)	0.44
Valve type			0.003
Medtronic CoreValve	16 (70)	114 (93)	
Edwards Sapien THV	7 (30)	8 (7)	
Sheath size			0.02
18- and 19-F	18 (78)	116 (95)	
22- and 24-F	5 (22)	6 (5)	
Revascularization			
Concomitant PCI	3 (13)	19 (16)	1.00
Staged PCI	3 (13)	14 (12)	0.74
Blood transfusions			
Number of PRBC ≥2 U	4 (17)	8 (7)	0.10

Values are mean ± SD or n (%). *Continuous variables were compared using Student *t* test and categorical variables using Fisher exact test.

PCI = percutaneous coronary intervention; PRBC = packed red blood cell transfusion; THV = transcatheter heart valve.

access site complications and were treated by implantation of a self-expandable covered stent graft (Fluency Plus, Bard Peripheral Vascular) (Fig. 3). One patient received an additional uncovered stent to reconstruct a femoral artery dissection. Balloon dilation after self-expandable stent graft placement was performed in 5 patients (24%) to ensure full stent expansion.

Procedural characteristics are summarized in Table 3. There were no differences in terms of type of anesthesia and need for blood transfusions between patients requiring percutaneous vascular complication management and those without complications. We observed a significant difference in fluoroscopy time (25 ± 9 min vs. 21 ± 8 min, p = 0.02) without differences in procedural time or contrast media use among patients requiring percutaneous vascular complication management.

Clinical outcome. The in-hospital course was similar for patients with percutaneous vascular complication management and for those without in terms of hospital duration (9.9 ± 7 days vs. 9.5 ± 4 days, p = 0.76) and need for packed red blood cell transfusion transfusions (0.4 ± 0.9 U vs. 0.2 ± 0.7 U, p = 0.33). Clinical outcome at 30 days is summarized in Table 4. There were no differences between patients with percutaneous vascular complication management and those without for any VARC-defined endpoint, including mortality, myocardial infarction, stroke, and renal failure. A significant difference in terms of life-threatening bleeding (17% vs. 4%, p = 0.04) was mainly driven by the 2 patients with unsuccessful percutaneous treatment of vascular complication following urgent surgical repair of the vascular access site. Major vascular complications as part of the VARC combined safety endpoint were more prevalent in the percutaneous vascular complication management group. When excluding major vascular complications from the VARC combined safety endpoint (modified combined safety endpoint), numerical differences between both groups were less pronounced.

Follow-up imaging of vascular complications. After a median follow-up of 10.9 months (interquartile range: 6.8 to 22.6 months), 17 of 21 patients with implanted peripheral stent grafts underwent clinical assessment, biplane fluoroscopy, and duplex ultrasonography of the intervened site (Fig. 4). Multislice CT of the vascular region of interest was performed in the absence of chronic renal failure in 11 of 17 patients. Duplex ultrasonography showed patency of all stent grafts and the absence of restenosis within the stent as determined by a peak velocity ratio of ≥2.4 in all patients. One patient showed a stenotic flow pattern (V_{max} = 4.05 m/s) in the deep femoral artery distal to the implanted covered stent graft. However, multislice CT revealed a patent femoral artery bifurcation distal to the stent, and the patient did not experience intermittent claudication or other symptoms. Biplane fluoroscopy revealed full stent integrity without signs of fractures in 14 of 18 stent grafts (78%). A grade I fracture was observed in 1 stent (6%), and a grade II fracture was present in 3 stent grafts (16%) according to the classifi-

Table 4. Clinical Outcome at 30 Days

	Percutaneous Vascular Complication Management (n = 23)	No Vascular Complication (n = 122)	p Value*
All-cause mortality	1 (4)	9 (7)	0.60
Cardiovascular mortality	0 (0)	6 (5)	0.55
Myocardial infarction	0 (0)	4 (3)	0.74
Stroke			
Major	1 (5)	6 (5)	0.98
TIA	0 (0)	1 (1)	0.77
MACCE	2 (9)	10 (8)	1.00
Bleeding			
Life-threatening	4 (17)	5 (4)	0.04
Major	8 (35)	30 (25)	0.31
Kidney injury			0.96
None	21 (91)	108 (89)	
Stage 1	2 (9)	10 (8)	
Stage 2	0 (0)	1 (1)	
Stage 3	0 (0)	3 (2)	
VARC-combined safety endpoint	7 (30)	16 (13)	0.06
VARC-modified combined safety endpoint	5 (22)	16 (13)	0.33

Values are n (%). *Outcome variables were compared using logistical regression analysis and in case of no (n = 0) events, respective p values were calculated after correction for continuity of 0.5.

MACCE = major adverse cardiac and cerebrovascular event(s); TIA = transient ischemic attack; VARC = Valvular Academic Research Consortium.

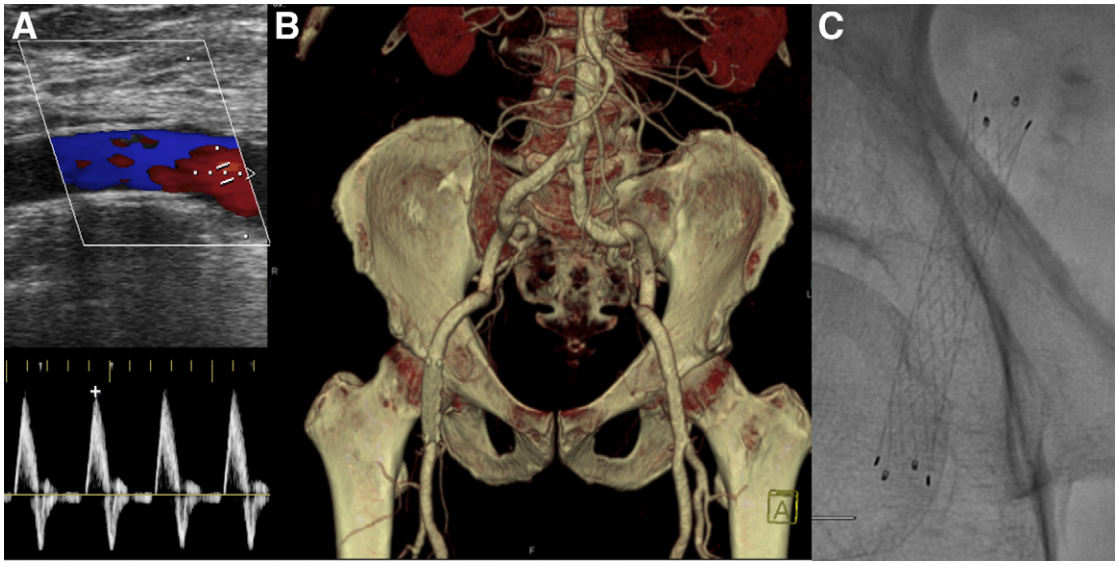

Figure 4. Imaging Follow-Up Assessment

Imaging follow-up assessment of vascular injury site by duplex ultrasonography **(A)** and multislice computed tomography **(B)** showing patency of the stent graft and the absence of restenosis. Biplane fluoroscopy showing no evidence of stent fractures **(C)**.

cation proposed by Jaff et al. (12). There were no grades III, IV, or V fractures. Multislice CT confirmed stent patency in 12 of 12 stent grafts (100%) without evidence of angiographic restenosis.

Discussion

The results of the present study indicate that percutaneous treatment of vascular complications after TAVI is feasible and is associated with high technical success. Clinical outcome of patients undergoing percutaneous management of vascular complications is comparable to those without vascular complications, and follow-up imaging shows patent stent grafts in all patients without need for reintervention during follow-up.

Vascular complications remain a principal limitation of TAVI as they may result in life-threatening bleeding and hemodynamic compromise among patients considered high risk for the procedure itself. The serious nature of major vascular complications is further underscored by the increased risk of mortality in recent studies (1). The incidence of vascular complications amounted to 18% consisting of VARC major in 6% of patients and VARC minor vascular complications in 12.1% of patients in this transfemoral cohort. Vascular complications were more common among patients treated using larger (22- or 24-F) delivery sheaths, but they were reduced with the implementation of the systematic crossover technique with temporary balloon occlusion of the common iliac artery during vascular closure of the access site (Fig. 2).

The frequency of vascular complications in the present study compares well with previous reports using the VARC endpoint definitions in predominantly high-risk patient populations (14,15). Recently published data from the PARTNER B (Placement of Aortic Transcatheter Valves [Cohort B]: Transfemoral TAVI vs. Medical Management) trial observed any vascular complication in 30.7% and major vascular complication in 16.2% of patients considered inoperable (1), whereas patients enrolled into the transfemoral cohort of PARTNER A (Placement of Aortic Transcatheter Valves [Cohort A]: TAVI vs. Surgical AVR) trial experienced any vascular complications in 23% and major vascular complications in 14% of patients in the as-treated analysis (2). Of note, patients included into the PARTNER trials were treated with 22- to 24-F access sheaths and did not benefit from the newer generation devices currently available. Gurvitch et al. (14) reported vascular access site complications in 18.5% of 205 patients undergoing transfemoral TAVI with the Edwards Sapien prosthesis with VARC major in 9.8% and VARC minor access site complications in 8.8% of patients. In this study, major vascular access site complications were attributed to the need for blood transfusions of ≥4 U in 84% of cases. Conversely, only 1 patient had a VARC major access site complication due to bleeding and blood transfusion of ≥4 packed red blood cell transfusions in the present study, whereas vessel perforation, dissection, and occlusion were the causes of VARC major access site complications in the remaining patients (Table 2).

Percutaneous treatment of vascular complications is able to decrease in-hospital complications, such as wound infection, femoral neuropathy, and lymphatic fistula formation (6,16); increases patient comfort; and seems to be more cost-effective than surgical arterial cut down, due to rapid mobilization and earlier hospital discharge (5,6). Currently available devices for suture-mediated percutaneous closure of the arteriotomy achieve high rates of technical success in up to 90% of patients, even among elderly populations undergoing TAVI using large-bore catheters (17). However, failure of arteriotomy closure and other vascular complications, including vessel perforation, dissection, and occlusion remain matters of concern. The high prevalence of peripheral arterial disease in conjunction with potent anticoagulation and antiplatelet regimens during the procedure further increases the risk of these complications. Accordingly, techniques to prevent or mitigate these adverse events are of clinical importance and constitute an integral part of any TAVI procedure. The crossover technique with temporary balloon occlusion from the contralateral access site allows a more controlled removal of TAVI delivery sheaths (10) by lowering perfusion pressure and providing immediate access for percutaneous intervention in case of incomplete arteriotomy closure.

Major vascular complications after percutaneous catheterization procedures are usually corrected by surgical treatment, which is associated with high procedural success, low morbidity, and low mortality (18). However, a percutaneous technique with rapid repair of vascular injury repair is desirable, especially among elderly high-risk patients undergoing TAVI, as it minimizes blood loss and the risk of wound infections and allows for rapid mobilization and earlier hospital discharge. Notwithstanding, the use of covered stent grafts for secondary arteriotomy closure should only be considered as a bailout procedure as vascular access for future percutaneous catheterization procedures might be impaired or limited to the contralateral site. Moreover, the use of covered stent grafts for treatment of vascular complications remains controversial due to unresolved questions relating to long-term patency and stent integrity. Stent implantation for secondary vessel closure after TAVI is performed in a vascular segment that not only is exposed to biomechanical stress during physical motion of the extremities, but also is amenable to external compressive forces. Endovascular stent fractures, particularly when implanted into arteries that cross flexion points, have been well documented in the literature and remain an issue of concern (19,20). Especially the popliteal as well as common femoral arteries are subject to forces, including compression, torsion, and elongation, and the cumulative incidence of stent fractures has been reported ranging from 15% to 28% (21,22). We observed evidence of stent fractures in 4 of 18 stents (22%) in the present study. However, fractures were minor and limited to Jaff class I (n = 1, 6%) and class II (n = 3, 16%) fractures with no single case of high-grade stent fractures. Moreover, investigation by duplex ultrasonography and multislice CT showed patent stent grafts without evidence of restenosis in any patient (23). Furthermore, none of the patients was symptomatic or required additional surgical or interventional therapy after secondary vessel closure.

Study limitations. The present report summarizes the experience of a single institution with only a limited number of patients undergoing percutaneous management of vascular complications following TAVI. Therefore, the results are exploratory and require confirmation in larger studies during longer term follow-up. However, the rates of VARC-defined vascular complications as well as clinical outcomes are comparable with previous reports. The inclusion of patients from the very early experience may have resulted in an overestimation of the rate of vascular complications due to an ongoing learning curve. Thus, we did not systematically use the vascular crossover technique during the first 65 patients of the present cohort. This resulted in a higher frequency of VARC major vascular complications among patients in whom crossover-assisted arteriotomy closure had not been used. Finally, the study does not address the changing incidence and type of vascular access site complications due to the advent of novel and smaller vascular access sheaths.

Conclusions

Vascular complications after TAVI can be treated percutaneously as a bailout procedure with a high rate of technical success and clinical outcomes comparable to patients without vascular complications. Stent patency and integrity is high during follow-up, although stent fractures require careful scrutiny.

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