Routine Endovascular Treatment With a Stent Graft for Access-Site and Access-Related Vascular Injury in Transfemoral Transcatheter Aortic Valve Implantation

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Background—Access-site and access-related vascular injury (ASARVI) is still a major limiting factor in transcatheter aortic valve implantation and affects the outcome of patients. Management strategies for ASARVI include manual compression, stent grafts, and vascular surgery. We hypothesized that the standard use of a self-expanding stent graft for the management of ASARVI is feasible and safe.

Methods and Results—Of 407 patients treated by transfemoral transcatheter aortic valve implantation, 110 experienced ASARVI (27.0%). Of these, 96 (87.3%) were managed by the implantation of a self-expanding nitinol stent graft. In the majority of patients, minor vascular complications triggered the implantation of a stent graft (86.5%), mainly because of bleeding (90.6%) and dissection (5.2%) of the common femoral artery with high rates of primary treatment success (97.9%). Patients receiving stent grafts were more often female (62.2 versus 45.6%, P<0.01), had higher body mass indices (27.8±6.7 versus 25.7±4.7, P=0.01), and suffered more often from diabetes mellitus (34.4 versus 24.5%, P=0.04). Angiographic assessment after a median follow-up of 345 days (interquartile range, 23–745 days) revealed only one patient with moderate, asymptomatic instent-stenosis (1.0%). Compared with a propensity score–matched cohort of patients without ASARVI, stented patients had comparable long-term mortality, despite the occurrence of a vascular complication (1-year mortality: 17.7% versus 26.6%; stent versus matched cohort, respectively; P=0.1).


Key Words: aortic valve ■ femoral artery ■ stent ■ TAVI ■ vascular complications

Transcatheter aortic valve implantation (TAVI) has proven to be a valuable treatment option for high-risk patients with severe symptomatic aortic stenosis.1 With the advent of ongoing technical improvements including smaller access-sheath diameters, access-site and access-related vascular injury (ASARVI) have been reduced over time, but are still encountered in ≤17.3% in TAVI patients and are associated with an overall unfavorable outcome.2,3 The majority of these complications affect the common femoral and external iliac artery, and, among others, include access-site bleeding mostly because of closure device failure, vessel dissection, or rupture.4,6 With the lack of specific guidelines, acute management of vascular complications largely depends on the type of complication and the operator’s experience and preference. Possible treatment options range from conservative treatment with manual compression with or without the use of protamine, endovascular approaches with use of balloon occlusion, or implantation of covered stent grafts to open surgical management.7,8

Although surgical management of vascular complications after percutaneous femoral procedures can be performed safely,9 nonsurgical treatment options are desirable because these patients are usually old, frail, and have a high operative risk.

Recently published data on the use of vascular stent grafts in the context of TAVI-associated vascular complications seem to give a valid base for the use of this technique as a bail-out strategy; however, the overall evidence in this field is limited to small cohorts, and the risk of stent fractures in arteries with high exposure to biomechanical forces have been described.10,11
WHAT IS KNOWN

• Despite ongoing technical improvements and clinical experience, vascular complications in transcatheter aortic valve implantation are still common and associated with increased morbidity and mortality.
• With the lack of specific guidelines or a classification of access-site injury, acute management of vascular complications largely depends on the type of complication and the operator’s experience and preference.
• In the context of access-site injury, placement of a covered stent graft has proven safe and efficient; however, the scientific data on this topic are limited.

WHAT THE STUDY ADDS

• The study provides a novel classification of access-site and access-related vascular injury that may be of use to establish standardized treatment for vascular complications.
• Clinical evidence on the feasibility, safety, and efficacy of stent-graft placement in access-site and access-related vascular injury is provided showing excellent clinical outcome and low-rates of instent-restenosis after stent graft treatment.

We hypothesized that the use of a self-expanding nitinol stent graft for the management of vascular complications is feasible, safe, and might affect the outcome of patients experiencing vascular complications during a transfemoral TAVI procedure.

Methods

Patient Population
We assessed 407 high-risk patients undergoing transfemoral TAVI between February 2008 and December 2013. All patients underwent a comprehensive preoperative evaluation, including multidetector computed tomography, transthoracic and transesophageal echocardiography, and left heart catheterization. Aortic valve annuli, access-site diameters, and femoral artery calcification and tortuosity were assessed with the use of reconstructed multidetector computed tomographic images. Peripheral artery disease in our analysis was defined as any known history of peripheral angioplasty or surgery, presence of claudication, an ankle-brachial index of <0.9, and stenosis of the iliofemoral axis >50%. After evaluation, all patients were discussed within the local interdisciplinary heart team. In this analysis, we excluded patients undergoing primary surgical cut down for vessel access and patients undergoing access-site closure with the use of investigational devices.

Patients undergoing TAVI agreed to participate in the local TAVI registry, which was approved by the Ethical Committee of the University Hospital Bonn, and gave written informed consent.

Study Rationale and Study End Points
From 2010, TAVI-associated vascular access-site complications at our center were routinely managed by stent-graft implantation. The decision to implant a covered stent was triggered by significant bleeding at the access-site after contralateral contrast dye injection, significant dissection or occlusion of the vessel. In cases of mild bleeding, manual compression was applied for 10 minutes. If bleeding was still present thereafter, stent implantation was performed.

Primary study end point was 1-year all-cause mortality. Secondary end points included mortality at 30 days, the need for red blood cell transfusion, and the incidence of post-TAVI systemic inflammation and acute kidney injury. Vascular complications, bleeding, myocardial infarction, and stroke as well as acute kidney injury and paravalvular regurgitation were defined as specified by the updated Valve Academic Research Consortium (VARC-2) criteria.

Hereby, unplanned vascular stent graft implantation for any vascular complications during TAVI without other clinical sequelae were considered minor, when criteria for major vascular complications were not met. In our transfemoral-only cohort, based on the VARC-2 criteria, we defined any vascular Access-Site and Access-Related Vascular Injury, excluding aortic dissection, aortic or annulus rupture, or left ventricular perforation, as VARC-2-ASARVI.

ASARVI and thus the reason for stent graft placement were retrospectively stratified into 4 categories according to a modified classification of coronary injury by Ellis et al12: type I, blush or minimal extravasation; type II, moderate extravasation (<5 mm); type III, major extravasation (>5 mm) including vessel perforation/rupture; and type IV, vessel dissection or occlusion (Figure 1).

Primary success for treatment by stent graft use was defined as implantation of one or more stents for the management of ASARVI, resulting in complete resolution of the complication without the need for further therapy (ie, conservative or surgical).

To support the study hypothesis, the above-mentioned outcome parameters were compared in patients who had received a stent graft and a propensity score–matched cohort of patients without VARC-2-defined vascular complications.

Stent Characteristics and Implantation Technique
The Fluency Plus vascular stent graft (C.R. Bard Inc, Murray Hill, NJ) consists of a self-expanding nitinol stent frame encapsulated within 2 layers of expanded polytetrafluoroethylene. Implantation of stent grafts was performed after final access-site angiography in a crossover technique with contralateral approach as previously described.19 After crossover angiographic visualization of the iliofemoral axis, a hydrophilic wire was advanced into the superficial femoral artery. The wire was exchanged for an Amplatzer Extra stiff wire; the access sheath was changed to a 9F sheath, and the stent graft was advanced and implanted. Low-pressure postdilation using a Wanda balloon (Boston Scientific, Marlborough, MA) in a 1:1 stent:balloon ratio was performed when indicated, mostly because of malapposition of the stent due to heavy calcifications. Final selective access-site angiography was performed via the contralateral femoral access with a minimum of 8-ml contrast dye at a rate of 4 ml/s in 2 projections (biplane, anterior-posterior, and left anterior oblique 60–90°) for the final evaluation of bleeding/vascular injury site. Implantation of a second stent graft or secondary surgical management was performed by the discretion of the physician.

Procedural Details
Transfemoral access is the primary approach at our institution, with alternative strategies being reserved for patients with contraindications for the latter (eg, access-limiting peripheral artery disease). TAVI was performed in a fully percutaneous approach under conscious sedation by 3 operators (G.N., N.W., and E.G.) of whom at least 2 were present for all procedures. During the study period, the following prostheses types were used: Medtronic CoreValve, Edwards Sapien XT, Direct Flow Medical, Boston Lotus, and Symetis Accurate TF. After crossover angiography of the contralateral iliofemoral axis, fluoroscopy-guided percutaneous puncture of the common femoral artery (CFA) proximal to the bifurcation (puncture into pigtail technique) was performed. A closure system was introduced for preclosure of the access vessel as previously described. After successful valve implantation, a wire and a pigtail catheter were advanced into the retracted large-bore TAVI sheath.
and, after removal of the sheath, primary access-site closure was performed. Selective access-site angiography was obtained in all patients via the contralateral femoral access with a minimum of 8-mL contrast dye at a rate of 4 mL/s in 2 projections (biplane, anterior-posterior, and left anterior oblique 60–90°). In case of relevant hemorrhage, vessel stenosis/occlusion or dissection, protamine antagonization or stent graft implantation were performed by the discretion of the operator. After the procedure, patients were submitted to an intermediate care/intensive care unit ward for further postoperative invasive monitoring for 24 to 72 hours.

The antithrombotic regimen consisted of dual antiplatelet therapy with loading doses of 500-mg aspirin and 300-mg clopidogrel, which was given the day before the procedure. Intravenous heparin was administered in a dose of 70 IU/kg and added to maintain an ACT of >250 during the procedure. Postinterventionally, heparinization was adjusted in accordance with the individual thrombotic risk. Clopidogrel and aspirin were maintained in a dose of 75 mg and 100 mg once daily, respectively, for 3 to 6 months.

Mortality and survival were investigated with the use of Kaplan–Meier estimates, and log-rank tests were used to determine statistical significance. Propensity score matching was performed with the use of a logistic regression model (nearest-neighbor selection) in a 1:1 ratio. Covariates for matching were chosen on the basis of significantly different baseline variables from univariate analyses (with \( P \leq 0.1 \)). For these variables (body mass index, sex, and logistic EuroScore), propensity score matching was performed without replacement and with a caliper of 0.1 of the SD of the logit of the propensity score (The R project for statistical computing, Vienna, Austria). Comparison of both groups was performed using paired-data analyses, that is, McNemar test for categorical and a paired \( t \) test for continuous variables. Further analyses were conducted with SPSS version 22.0 (IBM Corporation, Somer, NY). Statistical significance was assumed when the null hypothesis could be rejected at \( P \leq 0.05 \). The investigators initiated the study, had full access to and analyzed the data, and wrote the article. All authors vouch for the data and analyses.

Follow-Up
All patients received a routine follow-up including clinical examination and TTE at 30 days, 3, 6, and 12 months at our center. After the first year of follow-up, annual clinical recalls were performed. Patients who were unable to attend clinical visits at our center were followed-up via a standardized telephone interview. Information on survival status was available in all patients.

Angiological follow-up of patients who had received stent grafts was performed at our Department of Angiology. Stent graft restenosis was determined by duplex sonography using an established cutoff of a 2.4-fold elevation of the peak velocity ratio, which is calculated as the intrastenotic peak systolic velocity divided by the peak systolic velocity recorded proximal to the stent.17 All duplex sonography images were obtained with the use of a Philips i33 ultrasound scanner (Philips Medical Systems, Eindhoven, The Netherlands) using a linear probe and were evaluated by experienced angiologists (C.S., S.P., and N.S.).

In patients in whom stent fracture was suspected by duplex sonography, further evaluation for stent fractures was performed by biplanar fluoroscopy according to the classification used by Jaff et al.18 Visualization of stent grafts was performed using the stent-boost technique.

Statistical Analysis
Data are presented as mean±SD if normally distributed. Continuous variables were tested for normal distribution with the use of the Kolmogorov–Smirnov test. Categorical variables are given as frequencies and percentages. For continuous variables, a Student \( t \) test was performed for comparison between the 2 groups. For categorical variables, the \( \chi^2 \) or Fisher exact test were used for further analysis. When comparing \( \geq 2 \) groups, ANOVA or the Kruskal–Wallis test was used.

Results
Between 2008 and 2013, 407 patients with transfemoral TAVI were analyzed at our center. Patients were female in 50.1% and had a mean age of 81±6 years. Society of Thoracic Surgeons predicted risk of mortality (8.8±6.1) and logistic EuroScore (26.6±16.9) indicated a high operative risk in the overall cohort. The incidence of peripheral artery disease was 17.7%, mean CFA diameter was 7.7±1.7 mm with a mean sheath:femoral artery ratio of 0.96±0.22. Further baseline and vascular characteristics are depicted in Table 1.

Patients With and Without Stent Graft Placement
In stented patients, TAVI was predominantly performed with the use of the Medtronic CoreValve (75.6%) and the Edwards Sapien XT prosthesis (17.8%). The Symetis Accurate TF valve was used in 2 patients (2.22%), the Direct Flow Medical valve in 3 (3.3%), and the Evolut R Valve in 1 patient (1.1%). When compared with patients who did not receive a stent graft, patients who received a stent graft were significantly more often female (62.2% versus 45.6%, \( P=0.002 \)) and had higher body mass indices (27.8±6.7 versus 25.7±4.7, \( P=0.01 \)). Furthermore, patients receiving a stent graft had a significantly higher incidence of diabetes mellitus (34.4% versus 24.5%, \( P=0.04 \); Table 1).

Procedure time did not differ significantly between stented patients and those not receiving a stent graft (80±29 minutes versus 74±38 minutes, \( P=0.1 \)), whereas in patients who
received a stent graft more contrast dye was used (187±68 mL versus 171±61 mL, \(P=0.04\)).

**Vascular Complications**

Within the overall cohort, VARC-2–defined major vascular complications occurred in 7.6% of patients (31/407) and minor vascular complications in 22.4% (91/407), resulting in a total incidence of 30.0%. Hereby, VARC-2–ASARVI complications were observed in 27.0% (110/407) of patients, whereas 2.9% (12/407) of patients experienced nonaccess-site or nonaccess–related vascular complications, such as aortic annulus rupture (n=4), left ventricular perforation (n=7), and valve embolization (n=1; Figure 2).

The majority of patients with ASARVI complications (87.3%) were managed by the implantation of a self-expanding nitinol stent graft, accounting for 23.6% (96/407) of all transfemoral TAVI.

Remaining 12.7% (14/110) of patients with ASARVI complications underwent primary conservative (6.4%) or primary surgical treatment (6.4%). Surgical treatment was performed in 2 cases with failed retrieval of the femoral access sheath, in one case of a balloon-expandable sheath. Two patients were surgically treated for persistent bleeding from the CFA, which could not be managed interventionally because of bleeding location. Secondary surgery was performed in 3 patients, of which 2 developed an arteriovenous aneurysm needing surgical repair. In another patient, a retroperitoneal hematoma from a bleeding site in the CFA was surgically removed.

Conservative treatment included prolonged manual compression and heparin antagonization with protamine in 3 patients. In 1 patient, crossover balloon occlusion led to successful therapy of persistent access-site bleeding. Two patients did not undergo specific therapy in a watchful-waiting approach. Hereby, 1 patient had developed a retroperitoneal hematoma (without evidence of active bleeding in CT-angiography) and 1 patient experienced a nonflow-limiting dissection of the CFA.

Table 1. Baseline Characteristics

<table>
<thead>
<tr>
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<th>Overall Cohort</th>
<th>Stent Graft</th>
<th>No Stent Graft</th>
<th>Matching Cohort</th>
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<tr>
<td></td>
<td>n=407</td>
<td>n=96</td>
<td>n=311</td>
<td>n=94</td>
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<tr>
<td><strong>P Value</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Age, y</td>
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<td>81±7</td>
<td>81±6</td>
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<td>Body mass index</td>
<td>26.2±5.3</td>
<td>27.8±6.7</td>
<td>25.7±4.7</td>
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<td>Female, %</td>
<td>50</td>
<td>62</td>
<td>46</td>
<td>&lt;0.01</td>
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<td>Logistic EuroScore, %</td>
<td>26.6±16.9</td>
<td>22.8±14.6</td>
<td>27.8±17.4</td>
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<td>STS-PROM, %</td>
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<td>8.8±6.2</td>
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<td>Ejection fraction, %</td>
<td>50±15</td>
<td>51±13</td>
<td>49±15</td>
<td>0.4</td>
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<td>Chronic obstructive pulmonary disease, %</td>
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<td>26</td>
<td>27</td>
<td>0.5</td>
</tr>
<tr>
<td>Myocardial infarction, %</td>
<td>18</td>
<td>18</td>
<td>18</td>
<td>0.5</td>
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<tr>
<td>Percutaneous coronary intervention, %</td>
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<td>38</td>
<td>38</td>
<td>0.4</td>
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<td>Coronary artery bypass grafting, %</td>
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<td>14</td>
<td>18</td>
<td>0.2</td>
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<tr>
<td>Stroke, %</td>
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<td>17</td>
<td>16</td>
<td>0.5</td>
</tr>
<tr>
<td>Diabetes mellitus, %</td>
<td>27</td>
<td>34</td>
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</tr>
<tr>
<td>Atrial fibrillation, %</td>
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<td>38</td>
<td>34</td>
<td>0.2</td>
</tr>
<tr>
<td>Coronary artery disease, %</td>
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<td>64</td>
<td>66</td>
<td>0.4</td>
</tr>
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<td>Pulmonary hypertension, %</td>
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<td>31</td>
<td>31</td>
<td>0.3</td>
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<tr>
<td>Peripheral artery disease, %</td>
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<td>18</td>
<td>18</td>
<td>0.5</td>
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<tr>
<td>Creatinine, mg/dL</td>
<td>1.5±0.9</td>
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<td>1.4±0.8</td>
<td>0.4</td>
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<tr>
<td>Dialysis, %</td>
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<td>3</td>
<td>4</td>
<td>0.3</td>
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</table>

**Vascular variables**

<table>
<thead>
<tr>
<th></th>
<th>Overall Cohort</th>
<th>Stent Graft</th>
<th>No Stent Graft</th>
<th>Matching Cohort</th>
</tr>
</thead>
<tbody>
<tr>
<td>Common femoral artery, mm</td>
<td>7.7±1.7</td>
<td>7.8±1.6</td>
<td>7.7±1.7</td>
<td>0.3</td>
</tr>
<tr>
<td>External iliac artery, mm</td>
<td>7.5±1.6</td>
<td>7.6±1.4</td>
<td>7.9±1.8</td>
<td>0.4</td>
</tr>
<tr>
<td>Common iliac artery, mm</td>
<td>9.3±2.2</td>
<td>9.2±2.4</td>
<td>9.6±2.1</td>
<td>0.2</td>
</tr>
<tr>
<td>Femoral calcification (0–3)</td>
<td>1.6±0.7</td>
<td>1.6±0.7</td>
<td>1.6±0.7</td>
<td>0.5</td>
</tr>
<tr>
<td>Femoral tortuosity (0–3)</td>
<td>1.4±0.9</td>
<td>1.4±0.8</td>
<td>1.5±0.9</td>
<td>0.7</td>
</tr>
<tr>
<td>Sheath:femoral artery ratio</td>
<td>1.0±0.2</td>
<td>0.9±0.2</td>
<td>1.0±0.3</td>
<td>0.3</td>
</tr>
</tbody>
</table>

Baseline characteristics of the overall cohort, patients with and without stent graft placement, and propensity score–matched patients. Vessel sizes refer to the maximum diameter assessed by computed tomography. STS indicates Society of Thoracic Surgeons predicted risk of mortality.

\*P value for patients with stent grafts vs propensity score matching cohort.
Characteristics and Localization of Stent Graft Placement

Major vascular complications accounted for stent graft implantations in 13 of 96 cases (13.5%). In 83 patients (86.5%), a minor complication triggered the use of a vascular stent graft. Access-site bleeding (type I–III), as the result of incomplete access-site closure, was the leading cause for stent graft implantation (91.7%), especially among minor vascular complications (Figure 1).

Stent grafts were mainly implanted in the CFA (96.9%). Stent placement was necessary in the right external iliac artery in 2 patients (2.1%) and in the left external iliac artery in 1 patient (1.0%). Mean stent graft length was 40.2±2.1 mm with an average diameter of 9.8±1.4 mm. Postdilatation of the stent graft was performed in the majority of patients (86.7%). In 5 patients, implantation of a second stent graft was necessary because of insufficient hemostasis (3 patients), and residual flow-limiting dissection (2 patients). Primary success of stent graft placement was achieved in 96.9% (94/96) of patients. During the early learning phase, 2 patients were submitted to surgical therapy because of very distal stent graft placement and concomitant obstruction of the profound femoral artery. Delayed, secondary stenting on the first postinterventional day was necessary because of persistent, hemodynamically relevant bleeding from the puncture site in another patient.

Angiographic Follow-Up

Duplex sonography was available in 74 of 96 (77.0%) patients with a median follow-up of 345 days (interquartile range, 23–745 days). In 58 of 74 patients, duplex follow-up was performed after >30 days (median follow-up, 527 days; interquartile range, 182–927 days). Ultrasonographic assessment revealed a mean peak velocity ratio of 1.5±0.4 in stented patients. In 1 patient, intrastent peak systolic velocity reached 240 cm/s with a peak velocity ratio of 2.1, indicating moderate instent-restenosis. No clinical symptoms were reported for this patient.

Biplanar fluoroscopy was performed in 22 of 96 patients (22.9%) in whom stent malapposition or fracture were suspected by sonography. Among these patients, no sign of stent fracture was evident at a median follow-up of 369 days (interquartile range, 184–850 days).

Propensity Score Matching

Propensity score matching was performed in a 1:1 manner with patients who had not experienced VARC-2–defined vascular complications (n=285), resulting in a matching cohort of 94 patients. After PSM for univariate predictors for vascular complications, no significant differences in baseline characteristics between the 2 cohorts remained (Table 1). Calibration of the propensity score model was determined using a Hosmer–Lemeshow goodness of fit test. The P value was found to be 0.44 indicating good calibration. Discrimination of the model was assessed using a C statistic and receiver operating characteristic analysis with a 95% confidence interval (receiver operating characteristic, 0.77).

Procedural characteristics between the 2 cohorts did not differ concerning the used valve types, with a majority of Medtronic CoreValve prostheses in both groups (75.6 versus 74.5%, P=0.5).

The primary end point of 1-year mortality was not significantly different between patients treated with a self-expanding stent graft and the matched cohort without complications
(17.7% versus 26.6%, P=0.1). Also, 30-day mortality was found to be similar between both cohorts, with excellent outcome in the stented cohort but low overall incidences (2.1% versus 6.4%).

Secondary end point analysis showed a trend toward absolute (1.5±1.7 versus 1.0±1.3 red blood cells, P=0.07) and a significant difference in the relative need for blood transfusion (60.4% versus 33.3%, P<0.01) in ASARVI patients compared with the matched cohort.

This was accompanied by a significantly increased incidence of post-TAVI systemic inflammatory response (41.6% versus 27.3%, P=0.04). No differences were observed concerning the incidence of TAVI-associated acute kidney injury (26.0% versus 20.8%, P=0.6), the duration of intensive care unit, and overall in-hospital stay between cohorts (6±10 versus 4±5 intensive care unit days; P=0.1 and 21±16 versus 19±15 in-hospital days; P=0.7; Table 2).

**Discussion**

Vascular complications are still a major limiting factor in TAVI and the routine management of ASARVI depends mostly on personal experience. Here we could show that routine use of a self-expanding nitinol stent graft in patients with ASARVI after TAVI leads to a safe and quick repair of the vascular injury without device failure within the observed time period. In addition, we could prove an excellent short- and midterm clinical outcomes in comparison to a propensity-matched cohort without vascular complications.

In our study, VARC-2–defined major vascular complications occurred in 7.6% (31/407) and minor vascular complications in 22.4% (91/407) of patients. Hereby, ASARVI complications were observed in 27.0% (110/407) of patients, whereas 2.9% (12/407) of patients experienced nonaccess-site or nonaccess-related vascular complications. The observed rates of vascular complications are well comparable to previously published studies using the updated VARC-2 criteria with rates for major complications going ≤17.3%. In a recently published report on the use of the Viabahn stent graft, De Backer et al13 reported an incidence of 72 vascular access complications in a cohort of 348 transfemoral TAVI patients (20.7%) with 15.2% major vascular complications (11/72 patients). These data demonstrate that vascular complication rates remain high despite increasing operator experience and technical improvements, such as smaller access sheaths, especially in female patients with small vessel diameters, obese patients, and patients with severe peripheral artery disease.13

**Stent Graft Placement for ASARVI**

Endovascular management is more and more recognized as a primary treatment strategy in peripheral artery disease; however, lesions of the femoral arteries remain a surgical domain. In fact, current guidelines discourage stent graft placement in so-called bending areas such as the hip, where stent grafts are exposed to high extrinsic and intrinsic forces.19 However, as mobility is often limited in the typical TAVI collective, stent grafts at bending areas may be at a lower risk for stent fracture and subsequent restenosis, factors known to be associated with unfavorable outcome,20 theoretically making endovascular treatment a preferable choice in these patients. This hypothesis is further supported by growing scientific evidence on endovascular strategies within the iliofemoral axis, showing low rates of stent fracture and instant-restenosis in primary endovascular treatment for isolated CFA.21,22

Despite the fact that clinical evidence on stent graft placement in the context of TAVI-associated iliofemoral complications is limited, the available results are promising. De Backer et al11 detected virtually no instant-restenosis and no signs of stent fractures in a cohort of 48 patients treated with the Viabahn stent graft for TAVI-related access-site injury over a median follow-up period of ≈1 year. In their study, access-site complications led to acute intervention in 20.3% of patients. Although 25% of patients could be managed by balloon angioplasty, 66.7% were treated by Viabahn stenting, and 8.3% needed surgical intervention.11 Similar to our experience, the majority of these patients were treated by stent graft implantation for residual bleeding, underlining the relevance of suboptimal access-site closure.5 Furthermore, no detrimental impact of stent graft placement on mortality was found in this study,11 which is conclusive with a recent meta-analysis showing that the Viabahn stent graft is a safe and effective option for symptomatic superior femoral artery lesions.23

In our cohort, angiographic assessment after a median follow-up of 345 days revealed only one patient with moderate, asymptomatic instant-stenosis (1.0%). In addition, we could not identify any patient with stent fracture, which goes along with excellent clinical data for nitinol self-expanding stents in femoral disease.24

The main finding of this study is that fast and effective treatment of vascular complications by stent graft placement is safe and feasible. In addition, we were able to demonstrate
that patients receiving a stent graft after TAVI had similar short- and long-term mortality compared with a propensity score–matched cohort of our patients without vascular complications (1-year mortality: 17.7% versus 26.6%; stented versus matched cohort, $P=0.1$). In fact, it seems that stent graft placement, at least in this cohort with predominantly minor vascular complications, prevented the devastating effects on outcome associated with vascular injury and bleeding.

Despite the increased need for blood transfusion in patients receiving stent graft, the overall good outcome in the stented cohort may be attributed to positive effects on patient ambulation, indicated by similar duration of intensive care unit and in-hospital stay in stented patients and the matched cohort. Hereby, the increased use of blood transfusion in patients with stent grafts may have been due to the initial internal policy for TAVI-associated bleeding. Whereas in the early phase of our clinical experience, blood transfusion was already performed in the presence of hemoglobin levels $<10$ g/dL, currently hemoglobin levels $<8$ g/dL or signs of hemodynamic compromise are required before blood transfusion is initiated. Also, a reduction of acute kidney injury, which was only nonsignificantly increased in stented patients compared with the propensity-matched cohort, may play a significant role, which is independent of blood transfusion. Overall in-hospital duration in our cohort was $21\pm16$ days. This needs to be interpreted in the context of the learning curve (eg, time point of pacemaker implantation) and a different standard of care in our health system.

Regardless of these promising results, general recommendations on the first line use of stent grafts cannot be given at this point in time. In our study, implantation of self-expanding stent grafts was safe and feasible but was not systematically compared with manual compression, balloon-only, or surgical repair. Especially, as TAVI is more and more performed in physically more active patients, potential downsides of stent graft placement, for example, stent graft fracture and failure, need to be considered.

**Figure 3.** Step-by-step approach for the management of access-site and access-related vascular injury (ASARVI). Dotted lines indicate possible alternatives in failed primary treatment strategies.
Given the detrimental effects of bleeding complications and blood transfusion on postprocedural outcome, the prevention of ASARVI by thorough preoperative planning and optimal implementation of primary access closure devices should remain the target in transfemoral TAVI. In our clinical practice, additional contralateral angiography and puncture into the pigtail (bull’s eye technique) is the standard approach to ensure anterior puncture of the artery during the procedure. Furthermore, the use of dedicated transfemoral access sheaths in high-risk cohorts and modern closure devices, as well as alternative approaches such as transapical access or direct aortic TAVI, should be taken into consideration when transfemoral TAVI is limited or deemed risky.

However, when access-site injury is encountered, especially incomplete access-site closure, stent graft placement seems to be an effective tool. Given the current clinical evidence, we suggest a step-by-step approach for the management of ASARVI (Figure 3), which should incorporate both clinical and angiographic criteria, as well as the availability of and experience with certain management techniques at a TAVI center. Also, the prospective application of a dedicated angiographic classification, as suggested in our article, might be helpful in this context (Figure 1). Nonetheless, randomized studies comparing a direct stenting strategy with a step-wise approach including crossover balloon occlusion technique are needed to determine the true benefit of a primary stenting strategy especially concerning long-term results including stent graft failure.

Limitations
Limitations of this study include the nonrandomized character of our single-center experience. However, to our knowledge, this is the largest cohort evaluating patients undergoing stent graft placement in the context of TAVI. In addition, although clinical follow-up was close to 100%, incomplete angiographical follow-up because of concomitant comorbidities of the cohort that prevented frequent follow-up visits at the implanting hospital may have led to an underestimation of asymptomatic stent graft failure.

In addition, due to the lack of a prespecified treatment protocol for access-site and access-related vascular complications, patients underwent stent graft placement by physician’s discretion, leading to a certain selection bias in our analysis. In this context, also the impact of a learning curve on both procedures.

Conclusions
Our study suggests that management of access-site–associated injury (ASARVI) by the use of a self-expanding stent graft is a reliable treatment option for vascular complications.

Disclosures
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Routine Endovascular Treatment With a Stent Graft for Access-Site and Access-Related Vascular Injury in Transfemoral Transcatheter Aortic Valve Implantation


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