Management of Vascular Access in Transcatheter Aortic Valve Replacement
Part 2: Vascular Complications

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The interventional cardiologist must be able to recognize and manage potential vascular complications. Iliofemoral complications are the most frequent vascular complications in transfemoral transcatheter aortic valve implantation. Small vessel dimensions, moderate or severe calcification, and center experience are the major predictors. The traditional treatment for injured arteries has been surgical reconstruction, but endovascular techniques may allow for less invasive but effective management of arterial injuries. Dissection may be treated with prolonged balloon inflation or deployment of a self-expanding or balloon-expandable stent or a surgical graft. Iliofemoral rupture is a serious complication that may lead to retroperitoneal bleeding that can be unrecognized. Rapid insertion of a dilator or sheath or an occlusive balloon is used to achieve hemostasis. Prolonged balloon inflation or implantation of a covered stent or surgical repair should then be considered. Treatment options for failed percutaneous closure include prolonged manual compression, balloon angioplasty, stent implantation, and surgery. Aortic complications are rare, but serious complications are associated with a high mortality rate, even if emergent surgery is performed. There are specific vascular complications associated with alternative access routes such as transapical and transaxillary and direct aortic access. (J Am Coll Cardiol Intv 2013;6:767–76) © 2013 by the American College of Cardiology Foundation

Vascular complications are a major cause of morbidity and mortality in transcatheter aortic valve implantation (TAVI) due to the large-bore catheters required. In this paper, we review the frequency and causes of and treatment options for different vascular complications.

Definitions of Vascular Complications

Most studies have used nonstandardized definitions and thus have yielded a wide range of vascular complication rates. Also, vascular complications are associated with bleeding, which also has had nonstandardized definitions (1,2). In an attempt to allow direct comparison among clinical trials, the Valve Academic Research Consortium (VARC) has proposed standardized definitions for clinical endpoints (3,4). These definitions were recently updated (VARC-2) (5,6). The definitions include all complications that can be caused by a wire, a catheter, or anything else related to vascular access (including left ventricular perforation and pseudoaneurysm). According to the VARC, only major vascular complications are considered important clinical endpoints.

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Clinical Relevance of Vascular Complications

**Frequency.** The frequency of vascular complications in transfemoral TAVI is summarized in Table 1. Reported rates of (major) vascular complications range from 1.9% to 17.3% (7–20).

**Impact on mortality.** Vascular complications have been associated with morbidity, reduced quality of life, and increased costs. Several studies have shown that mortality is higher in patients with vascular complications than in those without (odds ratios ranging from 2.4 to 8.5) (9,20–23).

**Impact on length of hospital stay.** Hospital stay was significantly longer in patients with major complications (16 days) than in those with minor (11 days) or no vascular complications (6 days) (24). Another study yielded similar findings with hospital stays of 17 and 10 days in patients with and without major vascular complications, respectively (20).

Vascular Complications of the Iliofemoral Arteries

Iliofemoral complications are the most common vascular complications in transfemoral TAVI. Studies have identified small vessel dimensions (minimal artery diameter smaller than the external sheath diameter or sheath-to-femoral artery ratio >1.05), moderate or severe iliofemoral calcification, and center experience as major predictors of iliofemoral vascular complications (Table 2) (19,20,24). In our experience, the combination of an iliofemoral artery diameter smaller than the external sheath size and the concomitant presence of moderate or severe calcification is associated with the highest vascular complication rate. In such patients, alternative access routes should be preferred.

Iliofemoral tortuosity was not found to predict vascular complications (20,24). Usually, the artery straightens out as soon as the stiff wire is advanced through the tortuous part of the artery (Fig. 1).

The traditional treatment for injured arteries has been surgical reconstruction (25). Although the success rate for surgical treatment is high, there are often considerable morbidity and mortality (26). Surgical access, in combination with hematoma and various comorbidities, often predisposes to poor wound healing and infection in these often elderly and comorbid patients (27,28). Endovascular techniques may allow for less invasive yet effective management of arterial injuries.

**Iliofemoral dissection.** Dissection of the iliofemoral artery requiring percutaneous or surgical intervention has been reported in 2.0% to 7.4% of patients undergoing transfemoral TAVI with a surgical cutdown and in 1.6% to 21.4% of patients undergoing percutaneous closure (20,23,24,29–36).

Whether a dissection requires treatment depends on the extent and hemodynamic relevance. Usually, prolonged inflation of a balloon with appropriate diameter results in successful apposition of the intima and underlying media. However, more extensive dissection may warrant self-expanding or balloon-expandable stent deployment or a surgical graft (23,28,29,31–34,36).

Several cases of stent thrombosis have been reported after treatment of dissections with stents. Therefore, temporary treatment with heparin (in addition to aspirin and clopidogrel) should be considered in such patients. The mortality of iliofemoral dissection is low.

**Iliofemoral rupture.** Rupture can occur if the delivery sheath is inserted in a small, calcified artery. Rupture of the iliofemoral artery has been reported in both patients undergoing transfemoral TAVI with a surgical cutdown (4.0% to 9.3%) and in patients undergoing percutaneous closure (0.7% to 7.1%) (20,23,24,29–38). Most of the patients reported in literature were treated with surgery, some with a covered stent. Although a detailed outcome was not reported in all, at least 6 of 30 (20%) with ruptured iliac and/or femoral arteries died. Retroperitoneal bleeding after rupture can be unrecognized, and, therefore, in cases with borderline iliofemoral anatomy, angiography should be performed from the ipsi- or contralateral side during or after retrieval of the large sheath.

When rupture or bleeding is detected, options include rapid insertion of a dilator or sheath or, alternatively, an occlusive balloon can be inserted (from the ipsilateral or contralateral femoral) to achieve hemostasis. In case of a smaller perforation, crossover balloon inflation for up to 5 to 10 min may be enough to stop the bleeding (Fig. 2). If there is ongoing bleeding, implantation of a covered stent (Fig. 3) or surgical repair should be considered. If major vascular injury occurs, endovascular occlusion with an occlusion balloon (e.g., Reliant Stent Graft Balloon Catheter, Medtronic, Minneapolis, Minnesota; Berenstein Occlusion Balloon Catheter, Boston Scientific, Natick, Massachusetts; or Coda Occlusion Balloon Catheter, Cook Medical Inc., Bloomington, Indiana) may be life saving (Figs. 4 and 5). These balloons are highly compliant and elongate without undue radial force once they reach the vessel diameter. The degree of inflation is monitored by fluoroscopy. After acute control of the hemorrhage is achieved, definitive therapy with surgical repair or implantation of a covered stent is performed (39).

**Access site infection.** The risk of access site infection after suture-mediated closure has previously been described (40). In TAVI, access site infections were reported in 1.6% to 6.3% of transfemoral cases (11,15,20,30,36,38,41). In the PARTNER 1A (Placement of Aortic Transcatheter Valves) study, 7 of 348 of the patients (2.0%) had a skin infection at the puncture site. This rate was similar to the 2.0% of patients presenting with a sternal wound infection after...
surgical aortic valve replacement (11). Skin infections appear to be more common in patients undergoing a cutdown to expose the femoral artery. Of 19 patients with infection reported in the literature, 16 occurred in patients undergoing a planned surgical cutdown, and only 3 in patients undergoing percutaneous closure. In general, superficial wound infections should respond to local and/or systemic therapy. However, a deep periarterial infection may result in significant morbidity. Death occurred in 2 of 19 patients (10.5%), due to sepsis in 1 patient (20,41).

**Stenosis/thrombosis/occlusion.** Percutaneous closure with either ProGlide Suture-Mediated Closure System or ProStar XL Percutaneous Vascular Surgical System (Abbott Vascular, Abbott Park, Illinois) is usually associated with mild stenosis of the common femoral artery that is clinically asymptomatic (24). Post-dilation of the closure site can be performed in case of a more severe stenosis (32,35). Stenting should rarely be necessary.

Thrombosis can occur after hemostasis, for example, after crossover balloon-inflation. These patients can be treated with surgical revascularization or balloon angioplasty (32), but there is a risk of distal thromboembolization resulting in reduced perfusion of the limb (33).

**Artery avulsion.** Adhesion of the sheath to the iliofemoral artery is an unusual complication (32,42). In patients with borderline iliofemoral arteries, the sheath can adhere directly to the endothelium. The operator feels resistance during sheath withdrawal and sudden hemorrhage may occur. The risk of avulsion is reduced with smaller sheaths, periodic sheath rotation (not advisable with the expandable sheath), and early sheath removal (42). If avulsion is suspected, an occlusion balloon should be placed, and the patient should be prepared for possible surgical repair.

**Pseudoaneurysms.** Pseudoaneurysm formation can occur when the arterial puncture site seals incompletely, resulting in contained bleeding into the soft tissue within a pseudo-capsule (43). The diagnosis should be suspected in a patient with a painful, pulsatile groin mass. A murmur may be heard on auscultation. Risk factors for pseudoaneurysms are increasing sheath size, advanced age, cannulation of an artery other than the common femoral artery, calcification, increased body mass index, female sex, current anticoagulation, combined arterial and venous puncture, and failure to provide appropriate compression (44). Several studies have reported spontaneous closure of pseudoaneurysms in >50% of cases. Therefore, it appears reasonable to observe a pseudoaneurysm if the size is <3.0 to 3.5 cm, there is no associated pain, and no need for oral anticoagulation (45–47). Treatment options are ultrasound-guided compression and ultrasound-guided thrombin injection. In studies investigating both, success rates for ultrasound-guided thrombin injection were consistently higher (93% to 100%) than after

### Table 1. Vascular Access and Complication Rate in Larger Series (>100 Patients) of Predominantly Transfemoral Transcatheter Aortic Valve Implantation

<table>
<thead>
<tr>
<th>First Author (Year)</th>
<th>N</th>
<th>Sheath Size, F</th>
<th>Technique</th>
<th>Vascular Complication Rate, %*</th>
<th>VARC Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Piazza et al. (2008)</td>
<td>646</td>
<td>18–21</td>
<td>Percutaneous, ProStar</td>
<td>1.9</td>
<td>No</td>
</tr>
<tr>
<td>Bleiziffer et al. (2009)</td>
<td>137</td>
<td>18–24</td>
<td>Mostly percutaneous, ProStar</td>
<td>11.7</td>
<td>No</td>
</tr>
<tr>
<td>Webb et al. (2009)</td>
<td>113</td>
<td>22–24</td>
<td>Mostly surgical cutdown</td>
<td>8.0</td>
<td>No</td>
</tr>
<tr>
<td>Leon et al. (2010)</td>
<td>179</td>
<td>22–24</td>
<td>Surgical cutdown</td>
<td>16.2</td>
<td>Yes</td>
</tr>
<tr>
<td>Tamburino et al. (2011)</td>
<td>679</td>
<td>18–24</td>
<td>Mostly percutaneous, ProStar</td>
<td>2.0</td>
<td>No</td>
</tr>
<tr>
<td>Smith et al. (2011)</td>
<td>348</td>
<td>22–24</td>
<td>Surgical cutdown</td>
<td>11.0</td>
<td>Yes</td>
</tr>
<tr>
<td>Gurvitch et al. (2011)</td>
<td>310</td>
<td>18–24</td>
<td>Mostly percutaneous, ProGlide</td>
<td>11.7</td>
<td>Yes</td>
</tr>
<tr>
<td>Lange et al. (2011)</td>
<td>412</td>
<td>18–24</td>
<td>Mostly percutaneous, ProStar</td>
<td>10.2</td>
<td>No</td>
</tr>
<tr>
<td>Hayashida et al. (2011)</td>
<td>130</td>
<td>18–24</td>
<td>Mostly percutaneous, ProStar</td>
<td>17.3</td>
<td>Yes</td>
</tr>
<tr>
<td>Stähli et al. (2011)</td>
<td>130</td>
<td>18–24</td>
<td>Mostly percutaneous</td>
<td>11.5</td>
<td>Yes</td>
</tr>
<tr>
<td>Nuis et al. (2011)</td>
<td>165</td>
<td>18</td>
<td>Mostly percutaneous</td>
<td>15.0</td>
<td>Yes</td>
</tr>
<tr>
<td>Moat et al. (2011)</td>
<td>599</td>
<td>22–24</td>
<td>Not reported</td>
<td>8.4</td>
<td>No</td>
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<tr>
<td>Toggweiler et al. (2012)</td>
<td>137</td>
<td>18–24</td>
<td>Percutaneous, ProGlide</td>
<td>5.6</td>
<td>Yes</td>
</tr>
<tr>
<td>Gilard et al. (2012)</td>
<td>2361</td>
<td>18–24</td>
<td>Not reported</td>
<td>5.5</td>
<td>Yes</td>
</tr>
</tbody>
</table>

*Major vascular complication rate reported in series that used VARC definitions. | ProGlide and ProStar closure systems, Abbott Vascular, Abbott Park, Illinois.

### Table 2. Predictors of Vascular Complications

<table>
<thead>
<tr>
<th>First Author (Year)</th>
<th>N</th>
<th>Predictors</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lange et al. (2011)</td>
<td>412</td>
<td>Center experience, planned surgical cutdown reduced vascular complication rate</td>
</tr>
<tr>
<td>Hayashida et al. (2011)</td>
<td>130</td>
<td>Sheath-to-femoral artery ratio, femoral calcification, center experience</td>
</tr>
<tr>
<td>Toggweiler et al. (2012)</td>
<td>137</td>
<td>Sheath diameter greater than minimal artery diameter, moderate/severe femoral calcification, learning curve</td>
</tr>
<tr>
<td>Généreux et al. (2011)</td>
<td>419</td>
<td>Female sex</td>
</tr>
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</table>
ultrasound-guided compression (0 to 87%) (40,48–54). Ultrasound-guided thrombin injection is considered to be very safe, with complications such as infection, thrombosis, and distal embolization occurring in <1% of cases (44). Patients in whom minimally invasive techniques failed should undergo surgical repair.

**Failed percutaneous closure.** Failed closure with a ProStar or Perclose ProGlide (Abbott Vascular) requiring intervention or surgery or leading to relevant bleeding has been described in 4.4% to 8.7% of cases (18- to 24-F sheaths) (20,32,35–37). Of 30 cases of failed percutaneous closure reported in the literature, 7 (23%) were treated with surgery, 4 (13%) with prolonged manual compression only, 5 (17%) with stent implantation, 3 (10%) with balloon angioplasty, and 1 (3%) with aortic balloon occlusion and manual compression.

**Access site bleeding.** In patients undergoing percutaneous coronary intervention, bleeding has been shown to be associated with prolonged hospital stay, increased need for blood transfusion, and mortality (55–57). Furthermore, blood transfusion has been directly linked with excess mortality (58). The possible mechanisms include prothrombotic effects, impaired oxygen delivery of transfused erythrocytes, microvascular obstruction, and transfusion related immunomodulation (59). In transfemoral TAVI, access site bleeding was reported in 2.2% to 12.5% (20,24,29,37,38,41). A large hematoma can form very quickly despite manual compression and warrants immediate action. A catheter should be advanced from the contralateral side to achieve control of the artery. A smaller injury of the femoral artery can usually be managed with balloon occlusion. If a larger injury occurs, a stent-graft should be

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**Figure 1. Transcatheter Aortic Valve Implantation in Patients With Iliofemoral Tortuosity**

A patient with tortuosity of his external iliac artery (A, arrow) that straightened out after it was crossed with the wire and the sheath. However, the sheath kinked (B, arrow), but the procedure was successfully carried out after the sheath was replaced. Contralateral angiography showed minimal stenosis after closure with ProGlide system (Abbott Vascular, Abbott Park, Illinois) (C). Extensive tortuosity of the external iliac artery (D) that straightened out with an Amplatz Extra Stiff Wire (Cook Medical Inc., Bloomington, Indiana) and an 18-F Edwards sheath (Edwards Lifesciences, Irvine, California) (E). Crossover angiography confirmed a good result after closure (F).
implanted (60). Self-expanding nitinol stents are preferred over balloon-expandable stents because they are more resistant to external compression and bending stress (61).

**Aortic Complications**

Aortic complications such as aortic dissection and perforation have been reported in 0 to 1.9% of patients undergoing transfemoral TAVI (17,20,22,23,30,34,35,62). These serious complications are associated with a very high mortality rate. **Aortic aneurysms.** Aneurysms of the iliac arteries or the abdominal aorta are frequently present in patients undergoing TAVI (Fig. 6). Usually, these aneurysms can be passed with the delivery sheath without any problems. A delayed lethal rupture of the descending aorta has been reported in a patient with a previously stent-treated abdominal aneurysm 4 h after transfemoral TAVI (19). In a minority of patients, iliofemoral access is suitable for transfemoral TAVI, but there is relevant kinking of the aorta. More than slight kinking of the thoracic or abdominal aorta may lead to difficulties when trying to position the valve for implantation (19). In this case, an alternative access route should be preferred. **Aortic rupture.** Acute or delayed aortic annular rupture is a rare but serious complication with a very poor prognosis, even if emergent surgery is performed (31,33,63,64).
Rupture of the descending aorta or the annulus has been reported in 0 to 2.0% of patients undergoing TAVI (11,19,20,24,30,31,33,35). Annular rupture may occur after balloon valvuloplasty or after valve implantation (more frequently with balloon-expandable valves) and lead to acute rupture, cardiac tamponade, or death. Two cases of delayed aortic annulus rupture 24 h and 27 h after implantation of the Medtronic CoreValve (Medtronic, Minneapolis, Minnesota) have been described (19). Meticulous measurement of the annulus with multi-slice computed tomography or...
Patients with iliac (A,B), abdominal (C,D), or both iliac and abdominal (E,F) aneurysms are not infrequent. Careful passage of a guidewire followed by over-the-wire passage of catheters can generally be accomplished with low risk.

Figure 6. Transcatheter Aortic Valve Implantation in Patients With Iliofemoral or Aortic Aneurysms
Alternative Access Routes

Vascular Complications in TAVI

biplane transesophageal echocardiography may reduce the risk of extreme oversizing (65–67). The risk of perforation may be higher in patients with a very calcified valve. On the other hand, an undersized valve may lead to moderate/severe paravalvular regurgitation or embolization of the valve (66). **Aortic dissection.** Aortic dissection has been reported in 0 to 1.9% of transfemoral TAVI cases (11,20,22,24,35,62). Traditionally, the treatment for most patients with injury of the descending aorta has been surgical intervention with graft interposition (68). More recently, endoluminal stent-graft procedures have become increasingly popular and are associated with lower mortality and paraplegia rates than open repair (68).

**Retroperitoneal hemorrhage.** A retroperitoneal bleed can be caused by injury of the aorta, the iliac or proximal common femoral artery, or a small branch vessel such as the inferior epigastric artery. Bleeding may occur after incomplete closure if the sheath is removed from the proximal common femoral artery or the external iliac artery. The diagnosis is often delayed as symptoms are nonspecific (hemodynamic instability, groin/flank/abdominal/back pain) (69). When a retroperitoneal hematoma is suspected, computed tomography or angiography should be performed to confirm the diagnosis.

After TAVI, retroperitoneal hemorrhage has been reported in 0 to 2.2% of cases (17,24,30,33,36,37,41). TAVI patients who often present with poor cardiac reserve and severe comorbidities may be at increased risk of mortality in the context of bleeding.

Most of the retroperitoneal hematomas do not require intervention and can be managed with administration of fluids, normalization of coagulation factors, and blood transfusion (69). If the patient becomes unstable or the hemoglobin does not respond to blood transfusion, angiography may be able to identify the source of bleeding. Temporary balloon occlusion may be enough to achieve hemostasis in cases of smaller injuries. A larger injury of the iliac artery can be treated with a covered stent. Rupture of a small branch such as the inferior epigastric artery may be treated with a coil embolization, balloon tamponade, a covered stent, or surgery. A high groin exposure or retroperitoneal incision is usually performed with direct suture repair of the injury (37,41,43).

**Vascular Complications Associated With Alternative Access Routes**

**Vascular complications associated with transapical access.** The most frequent acute complications are bleeding from the apical puncture site and myocardial tears requiring further surgical repair (70,71). Apical scarring resulting from a hematoma or myocardial sutures may result in local hypokinesis. This may be a problem in patients with a low pre-procedural ejection fraction but preserved apical contraction (72). A puncture close to the left anterior descending coronary artery may lead to tension resulting in flow obstruction (73). Long-term complications include aneurysm formation, chronic pain caused by rib retraction, pleural dissection, and intercostal nerve damage (15,22,31,38,74–76).

**Vascular complications associated with transaxillary access.** Manipulation of a large sheath inside the axillary and subclavian artery can cause vascular injury. Thrombosis of the subclavian artery has been reported after transaxillary TAVI (33). Lange et al. (19) reported the outcomes of 28 patients; 1 patient had a subclavian artery injury during CoreValve implantation, and the vessel was repaired by interposition of a vascular prosthesis. One patient had a asymptomatic subclavian artery dissection after CoreValve implantation. Dissection of the left subclavian artery may be a problem in patients with a patent left internal mammary artery graft (77).

**Vascular complications associated with transaortic access.** In elderly and frail patients, the aortic wall may be fragile, and tearing of the aorta may occur when tightening the sutures. Other specific complications of the direct aortic access include deep wound infection or mediastinitis after partial sternotomy. A right mini-thoracotomy may lead to injury of a right internal mammary graft. Rare complications with transaortic access include laceration of the right ventricle after right mini-thoracotomy and pseudoaneurysm formation of an intercostal artery after mini-sternotomy (72,73,78–82).

**Summary**

Although vascular complications will continue to occur, we believe that with lower profile sheaths, better screening techniques, appropriate choice of access site, and operator experience, lower complication rates will be achieved in future clinical trials and clinical routine. Nevertheless, the interventional cardiologist must be able to recognize and manage potential vascular complications. With increased experience, most of the vascular complications associated with the transfemoral approach may be managed percutaneously.

We believe that specific access site complication rates should be reported rather than overall minor and major vascular complications so that readers may know which issues have improved and which remain a problem as TAVI technology advances.

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Vascular Complications in TAVI


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