

Vascular Complications Among Patients Undergoing TAVR

Contemporary concepts facing operators in this challenging patient population.

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The advent of transcatheter aortic valve implantation (TAVR) has revolutionized the treatment of valvular heart disease and has offered an alternative treatment to inoperable or selected high-risk patients with degenerative, severe aortic stenosis.¹ TAVR is less invasive compared to surgical aortic valve replacement and offers early ambulation and a reduction in overall length of hospital stay while achieving favorable hemodynamic and clinical outcomes.^{2,3} After 10 years of experience with transcatheter heart valve systems, the advantages of this technology outweigh the uncertainty of heart valve durability and the concerns about paravalvular regurgitation and procedural complications. At this point in time, contemporary guideline recommendations restrict the use of TAVR, as did the US Food and Drug Administration (FDA) by approving TAVR only for selected high-risk or inoperable patients, given the available evidence from randomized controlled trials.⁴ The treatment of low-risk patients with symptomatic severe aortic stenosis using contemporary TAVR devices is not justified, due to several limitations that remain for this novel procedure. TAVR is associated with low rates of cerebrovascular events, acute renal failure, and myocardial infarction; however, conduction disturbances and vascular access site complications combined with bleeding events

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represent the most-frequently observed problems in the periprocedural phase.⁵ The need for large-diameter bore catheters for valve delivery and device placement, as well as the high-risk patient population currently treated with TAVR, increase the risk for vascular access site complications, which in turn may result in life-threatening bleeding and worse clinical outcome.⁶

PREPROCEDURAL VASCULAR ACCESS SITE SCREENING

During conventional aortic valve replacement, cardiac surgeons are able to directly assess the individual anatomical characteristics of the aortic root; by using this information, they are able to select the appropriate prosthesis type and size. In contrast, TAVR demands a detailed preprocedural planning process using meticulous imaging of the aortic annulus and the peripheral

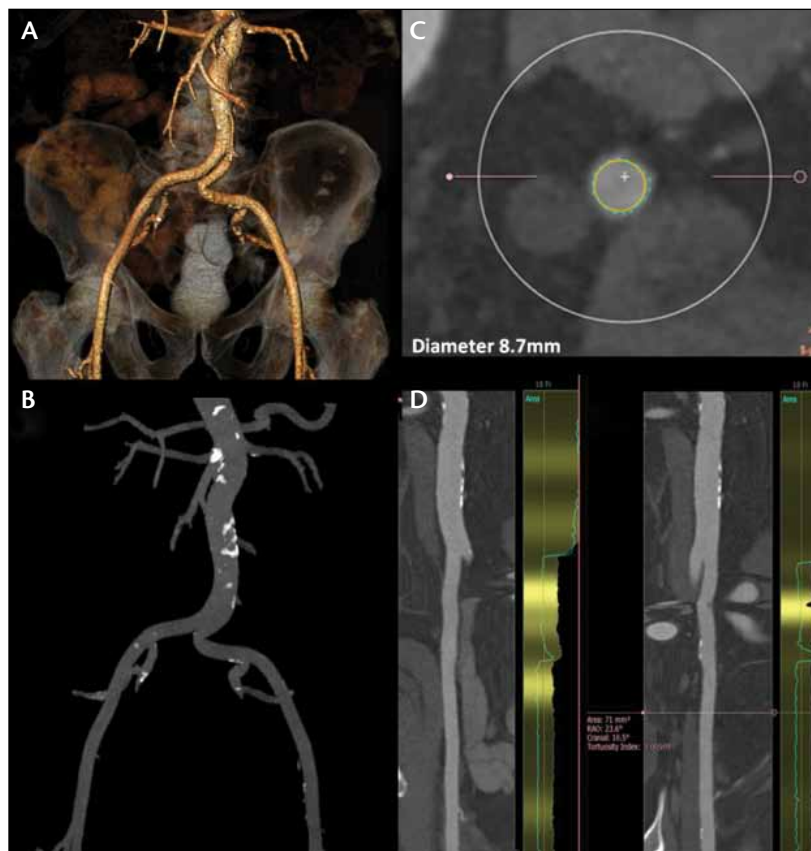


Figure 1. Preprocedural imaging assessment of the peripheral vasculature using 3mensio postprocessing imaging software (3mensio Medical Imaging BV, Bilthoven, The Netherlands). A three-dimensional overview on vascular dimension and tortuosity (A). Information on the degree and distribution of calcification (B). An axial view of the common femoral artery and assessment of vascular dimension (C). The insertion of a virtual 18-F delivery sheath in a stretched view of the peripheral vasculature (D).

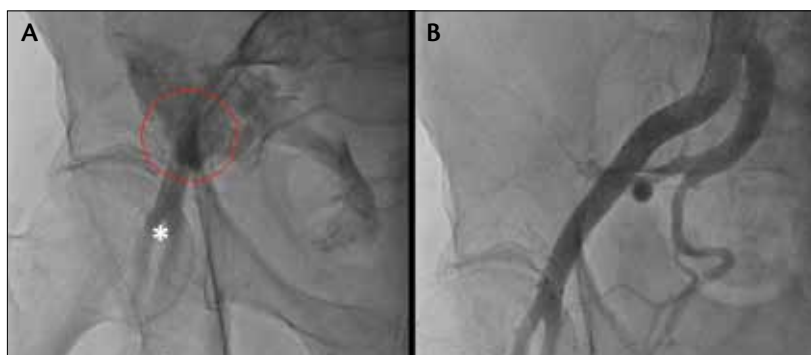


Figure 2. Vascular access closure failure with retroperitoneal bleeding. A high femoral bifurcation followed by a puncture of the external iliac artery (asterisk). Extravasation and severe bleeding into the retroperitoneal space (red circle) caused by arteriotomy closure failure with the use of the ProStar preclose suture device (A). Secondary access site closure by using a Fluency covered stent graft (B; Bard Peripheral Vascular, Tempe, AZ).

vasculature. In addition to coronary angiography for the assessment of relevant coronary artery disease, angiography of the iliac and femoral arteries is recommended to pre-select patients according to their vessel diameter for a transfemoral TAVR procedure. Because two-dimensional imaging techniques fall short in appreciating the entirety of anatomical information required for appropriate access route selection, multislice computed tomography imaging is recommended with a three-dimensional reconstruction of the aortic root and access site.^{7,8} Different, fully automated postprocessing imaging software assists physicians in planning the procedure and allows for a quantitative and qualitative assessment of annular and vascular anatomy, including modeling of virtual transarterial access sheaths and virtual valve templates in the aortic annulus (Figure 1).

Detailed information on access vessel diameter, grade and distribution of calcification, and vessel tortuosity are required for appropriate access route and TAVR delivery system selection. During the early experience of TAVR, transfemoral delivery catheters were introduced through large-diameter arterial delivery sheaths (24 and 22 F), requiring femoral vascular diameters of at least 9.2 mm and 8.4 mm, respectively.^{9,10} Delivery catheter and TAVR valve design have improved over time, bringing vascular access sheath diameters for contemporary TAVR systems down to 16 to 19 F, which require femoral vessel diameters of 6.6 to 7.5 mm, respectively. At this point in time, the 14-F Edwards expandable introducer sheath (eSheath; Edwards Lifesciences, Irvine, CA), which is used for the Edwards Sapien 3 bioprosthesis (23 mm), represents the smallest available sheath design for transfemoral TAVR, with an external sheath diameter of 5.9 mm. Because the incidence of vascular

TABLE 1. VALVE ACADEMIC RESEARCH CONSORTIUM-2 STANDARDIZED ENDPOINT DEFINITIONS**Vascular Access Site and Access-Related Complications**

Major vascular complications

- Any aortic dissection, aortic rupture, annulus rupture, left ventricular perforation, or new apical aneurysm/pseudoaneurysm OR
- Access site or access-related vascular injury (dissection, stenosis, perforation, rupture, arteriovenous fistula, pseudoaneurysm, hematoma, irreversible nerve injury, compartment syndrome, percutaneous closure device failure) leading to death, life-threatening or major bleeding,* visceral ischemia, or neurological impairment OR
- Distal embolization (non-cerebral) from a vascular source requiring surgery or resulting in amputation or irreversible end-organ damage OR
- The use of unplanned endovascular or surgical intervention associated with death, major bleeding, visceral ischemia, or neurological impairment OR
- Any new ipsilateral lower extremity ischemia documented by patient symptoms, physical exam, and/or decreased or absent blood flow on lower extremity angiogram OR
- Surgery for access-site-related nerve injury OR
- Permanent access-site-related nerve injury

Minor vascular complications

- Access site or access-related vascular injury (dissection, stenosis, perforation, rupture, arteriovenous fistula, pseudoaneurysm, hematoma, percutaneous closure device failure) not leading to death, life-threatening or major bleeding,* visceral ischemia, or neurological impairment OR
- Distal embolization treated with embolectomy and/or thrombectomy and not resulting in amputation or irreversible end-organ damage OR
- Any unplanned endovascular stenting or unplanned surgical intervention not meeting the criteria for a major vascular complication OR
- Vascular repair or the need for vascular repair (via surgery, ultrasound-guided compression, transcatheter embolization, or stent graft)

Percutaneous closure device failure

- Failure of a closure device to achieve hemostasis at the arteriotomy site, leading to alternative treatment (other than manual compression or adjunctive endovascular ballooning)

*Refers to VARC bleeding definitions

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injury is directly related to the delivery sheath diameter, a significant decrease in vascular access site complications is expected with newer-generation TAVR devices.

VASCULAR ACCESS SITE COMPLICATIONS ACCORDING TO VARC

With the intention to provide uniform and comparable endpoint definitions for transcatheter aortic valve interventions, the Valve Academic Research Consortium (VARC) created a consensus manuscript, which was first published in 2011.¹¹ Appropriate clinical endpoints were defined, reflecting device-related, procedure-related, and patient-related safety and efficacy. After the first experience in assessing these stan-

dardized endpoint definitions and by comparing the results from observational studies with each other, certain definitions were found to be unsuitable or out of date. For this reason, the VARC criteria for appropriate TAVR endpoint assessment were revisited and adapted according to the growing body of experience with this technique. Table 1 provides a detailed overview of vascular access site and access-related complications according to the VARC-2 endpoint definitions.¹²

INCIDENCE OF VASCULAR ACCESS SITE COMPLICATIONS

In contemporary clinical practice, femoral access is the most frequently used access route for TAVR,¹³ and

a fully percutaneous procedure under local anesthesia and mild conscious sedation is common practice. Commercially available percutaneous suture devices (ProStar, PerClose; Abbott Vascular, Santa Clara, CA) are used for access site closure. By means of a preclosure technique, they provide high rates of closure success.¹⁴

As early-generation TAVR devices required catheter and sheath dimensions as large as 24 F for the femoral access route, surgical cutdown was frequently performed to allow for direct visualization of the iliac artery during catheter insertion and to ensure appropriate vascular closure after successful valve delivery. Because the hazard of vascular complications is directly related to the size of the delivery catheter, an incidence rate of up to 34% has been reported for patients treated with early-generation TAVR devices.^{15,16} During the last few years, several device and catheter modifications were realized and brought into clinical practice. With the reduction of delivery sheath diameter sizes to 16 F, the rate of vascular access site complications was reduced to 9%.¹⁷ Aside from the advantages of valve and catheter designs that allow for downsizing of required sheath dimensions, innovations in sheath technology might also have contributed to this decrease of vascular complications in recent TAVR series. While expandable access delivery sheaths (ie, Edwards eSheath technology) are able to minimize wall stress of the femoral and iliac access vessels because complete sheath expansion is only provided during the short passage of the TAVR prosthesis, dedicated balloon-expandable sheath designs (SoloPath; Terumo Interventional Systems, Somerset, NJ) may even serve as dilators of the borderline peripheral vasculature and facilitate vascular access for transfemoral TAVR.¹⁸

TYPE OF VASCULAR ACCESS SITE COMPLICATIONS

According to VARC, vascular complications include all complications or vascular injury that may be caused by a guidewire, vascular sheath, delivery catheter, or any balloon used for aortic valve predilatation. Apart from wire perforations of the left ventricle, aortic annulus rupture, or aortic dissection, vascular complications mainly include and are not limited to vascular dissection, vascular perforation, arteriovenous fistula, pseudoaneurysm formation, retroperitoneal hemorrhage, or incomplete arteriotomy closure. Particularly, major vascular complications are associated with life-threatening or major bleeding, red packed blood cell transfusion, and increased mortality. In contrast, minor vascular complications appeared to have no impact on clinical outcomes.³ Independent predictors of major vascular

complications have been identified and include the early experience of operators or cardiovascular centers performing TAVR, female gender, peripheral vascular disease, femoral artery calcification, and a sheath-to-femoral artery ratio of > 1.05 .¹⁹

VASCULAR ACCESS AND TREATMENT OF ACCESS SITE COMPLICATIONS

TAVR using the transfemoral access route has become the default access in many experienced TAVR centers, as it is considered the least invasive approach. To keep the procedure as minimally invasive as possible, a purely percutaneous procedure is desired, which makes a step-by-step approach to minimize the risk of vascular access site complications compulsory. The identification of the puncture site to gain vascular access is very important. The femoral bifurcation is identified by contrast injection from the contralateral site. The femoral artery is then punctured under fluoroscopic or ultrasound guidance in a segment with little or no calcification. After successful predilatation of the vessel, insertion of a preclose suture device, and placing of preclosed sutures, the vascular access sheath is introduced, guided by a stiff wire. After successful TAVR and delivery catheter removal, a contralateral crossover technique to facilitate vascular access closure might be considered.²⁰ A peripheral vascular balloon is used to block the external or common iliac artery by advancing a stiff guidewire into the TAVR delivery sheath and inserting a 7-F crossover sheath. This maneuver allows for safe removal of the TAVR access sheath and tightening of the preclosed sutures of the percutaneous closure device. After deflating the peripheral vascular balloon and contrast injection through the crossover sheath, residual bleeding or other vascular access site complications can immediately be investigated. In cases of vascular injury or incomplete closure of the access artery, the stiff guidewire and the peripheral vascular balloon are advanced to the site of injury. In this situation, the implantation of a covered stent graft is often performed (Figure 2), which is successful in covering the vascular defect and provides high rates of patency during long-term follow-up.²¹

SUMMARY

In contemporary clinical practice, TAVR is preferably performed as a fully percutaneous procedure using the femoral access route. However, major vascular complications are the most frequent complications during a transfemoral TAVR procedure and are associated with worse clinical outcomes. Recent advances in the design and size of the device and delivery catheter provide a

substantial technical improvement. Additional procedural modifications, such as the crossover closure technique, contribute to the reduction of the occurrence of vascular injury during a transfemoral TAVR procedure, leading to favorable clinical outcomes. ■

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