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## Review Article

# Vascular complications post-transcatheter aortic valve procedures

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## ABSTRACT

Transcatheter aortic valve replacement (TAVR) has rapidly emerged as the standard of care for severe symptomatic aortic stenosis in patients whose comorbidities put them at prohibitive risk for surgical aortic valve replacement (SAVR). Several trials have demonstrated superior outcomes with TAVR compared to medical management alone. TAVR has also shown favorable outcomes in patients at high risk for SAVR. TAVR can be associated with significant vascular complications, which adversely impact outcomes, and operators should be cognizant of their early recognition and appropriate management. In this article, we review the major vascular complications associated with TAVR, along with optimal prevention and management strategies.

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## 1. Introduction

Since the first reported human case,<sup>1</sup> transcatheter aortic valve replacement (TAVR) has rapidly emerged as a viable strategy for treatment of subsets of patients with severe aortic stenosis (AS). There is strong evidence that in patients deemed “inoperable” or “extreme risk” for conventional cardiac surgery (surgical aortic valve replacement, SAVR), TAVR is associated with significant improvements in mortality, morbidity, and quality of life compared to medical therapy alone.<sup>2,3</sup> In patients at high risk for SAVR, transcatheter implantation has demonstrated extremely favorable results.<sup>4</sup> In the United States, TAVR with the balloon-expandable Edwards Sapien

valve (Edwards Lifesciences Inc., Irvine, CA) and the self-expanding Medtronic Core Valve system (Medtronic, Minneapolis, MN) are approved by the Federal Drugs Administration (FDA) as acceptable treatment options for patients with severe AS who cannot undergo surgery (inoperable). More recently, the FDA has approved Medtronic CoreValve Evolut systems (which use 14 F inline sheath-<http://www.mddionline.com/article/fda-approves-medtronic's-evolut-r-tavr-06-24-15>) and Sapien 3 valve systems (which uses an expandable e-sheaths <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm451678.htm>). These devices have already been available in other markets including Europe. TAVR is also an acceptable alternative for patients deemed to be at high risk for SAVR as

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adjudicated by a multidisciplinary Heart Valve team.<sup>5-8</sup> Recent trials have demonstrated similar benefits in patients estimated to be at moderate risk.<sup>9-11</sup> Compared to initial TAVR procedures, which were performed via an antegrade trans-septal approach, the favored access method is via a transfemoral approach (TF-TAVR). Increasingly, it is less common to access via a transapical approach (TA-TAVR). TA-TAVR is an independent predictor of adverse outcomes from TAVR, and when feasible, a transarterial approach is preferred.<sup>12</sup> Other access routes, such as axillary artery, subclavian artery, carotid artery, transcaval, or direct aortic access, are also utilized but constitute only a minority of the cases.

TAVR is associated with several procedure-specific risks that significantly contribute to peri- and postprocedural, as well as long-term morbidity and mortality. These include vascular complications, embolic events (neurological complications, such as cerebrovascular accidents), renal failure, paravalvular leaks, and conduction system disturbances necessitating permanent pacemaker (PPM) implantation. However, with the possible exception of PPM with self-expanding prosthesis, vascular complications are by far the most common<sup>6,13</sup> and generally manifest either periprocedurally or early in the postprocedure period. Multiple studies have substantiated higher mortality in patients with vascular complications.<sup>3,14-18</sup> Increasingly, endovascular specialists are called on for diagnosis and management of these complications. For successful outcomes, these procedures require a cohesive well-functioning multidisciplinary Heart Team. In this article, we aim to provide a broad overview of vascular complications including their incidence, risk factors, and diagnosis, along with optimal prevention and management strategies.

## 2. Clinical relevance

TF-TAVR involves directing a crimped valve prosthesis (balloon mounted or self-expanding) retrograde through the aortic valve over a stiff guidewire positioned in the left ventricular cavity. This requires placement of large-sized sheaths via the femoral vessels. Patients require careful assessment of the pelvic vasculature, usually with the help of a preprocedure contrast-enhanced CT or pelvic angiography to ensure suitability of the pelvic vessels to accommodate the large sheaths. Despite this, vascular complications are common and are major impediments to successful outcomes.<sup>19</sup> They are associated with increased mortality, increased length of hospital stay, and diminished quality of life.<sup>18,20-22</sup> They also predispose to other complications, such as renal failure, infection, and neuropathies. As TAVR undergoes rapid and widespread adoption, members of the heart team must be aware of these complications, recognize them early, and initiate timely and appropriate management.

## 3. Incidence of vascular complications post-TAVR

Assessing accurate incidence of vascular complications from earlier trials is limited by initial lack of standard definitions and reported rates have varied widely from 1.9% to

**Table 1 – Vascular access site and access related complications.**

<b>Major vascular complications</b>
Any aortic dissection, aortic rupture, annulus rupture, left ventricle perforation, or new apical aneurysm/pseudoaneurysm OR
Access site or access-related vascular injury (dissection, stenosis, perforation, rupture, arterio-venous 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 (noncerebral) 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
<b>Minor vascular complications</b>
Access site or access-related vascular injury (dissection, stenosis, perforation, rupture, arterio-venous fistula, pseudoaneurysms, hematomas, 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)

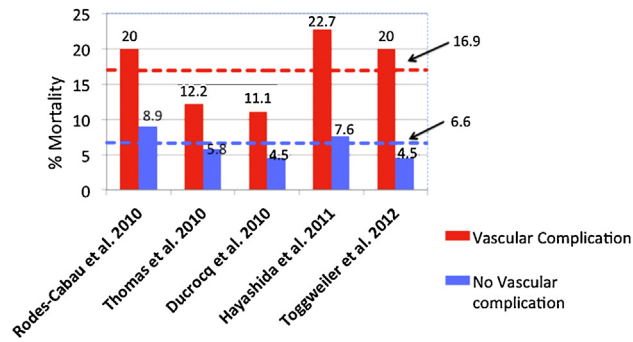
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30.7%.<sup>18,20,23</sup> The risk increases with the size of the valve delivery system. Valve Academic Research Consortium (VARC) has established standard definitions for TAVR-related complications (Table 1), grouping them into major and minor complications.<sup>24,25</sup>

Using standard VARC definitions, the incidence of major vascular complications varies between 10% and 20%.<sup>20,21,26</sup> In a large meta-analysis by Genereux et al. using VARC-1 definitions,<sup>13</sup> the incidence of major vascular complications was 11.9% with major bleeding occurring in 15.6% of the patients. Another study utilizing VARC definitions noted that major vascular complications occurred in 17.3% and minor vascular complications occurred in 10.2% of the patients.<sup>20</sup> Earlier studies have shown that the incidence of major vascular complications is lower with Medtronic core valves compared to earlier-generation Edwards Sapien valves, but more recent literature with newer-generation Edwards Sapien devices have shown the rate of major vascular complications to be similar across the two-valve devices.<sup>27</sup>

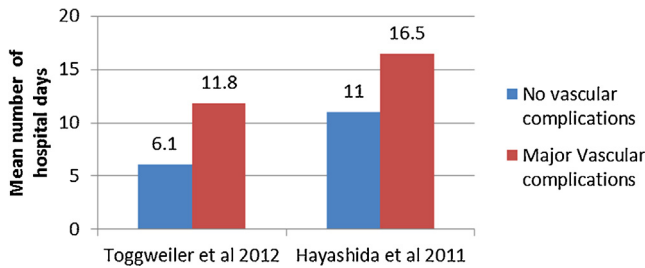
## 4. Impact on clinical outcomes

The occurrence of vascular complications is strongly associated with worse overall clinical outcomes. These patients



**Fig. 1 – Impact of vascular complications on 30-day mortality.** Mortality was consistently higher in those with vascular complications [16.9% (red dotted line) in those with and 6.6% (blue dotted) without].<sup>28</sup>

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**Fig. 2 – A comparison of mean hospital length of stay in patients without (blue) and with (red) major vascular complications.**

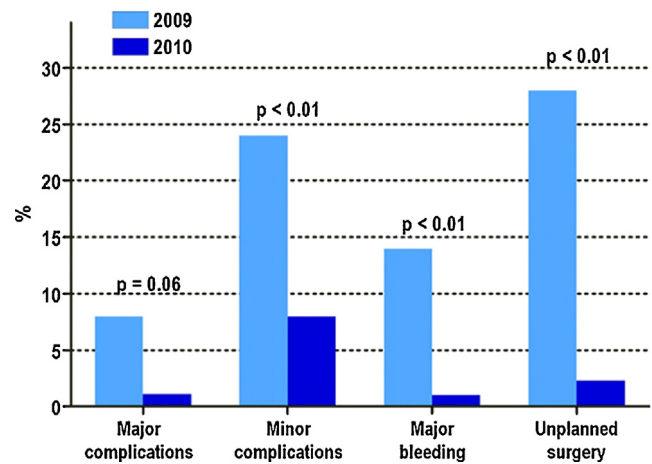
typically have worse 30-day and 1-year mortality.<sup>14,15,20,23,28,29</sup> The estimated 30-day mortality is 16.9% in those with major vascular complications compared to 6.6% in those without (Fig. 1).<sup>14,15,20,23,29</sup> These patients also have significantly more hospital days adding to the total cost of the procedure (Fig. 2). Thus, vascular complications are a major deterrent to successful outcomes in patients undergoing TAVR.

## 5. Risk factors

Several risk factors (Table 2) are associated with an increased risk of vascular complications. Center experience, sheath-to-femoral artery ratio of >1.05, pelvic vessel calcification (especially circumferential calcification), peripheral vascular

**Table 2 – Risk factors for vascular complications from TAVR.**

Female gender
Center and operator inexperience
Sheath to femoral arterial ratio of >1.05
Moderate to severe vascular calcification
Peripheral arterial disease
Sheath size > 19 F
External sheath diameter more than minimal arterial diameter



**Fig. 3 – Complication rates with increasing operator experience (vascular complications, major bleeding, and unplanned surgery declined as operators gained experience).**<sup>23</sup>

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disease, female gender, and external sheath diameter more than minimal arterial diameter are established as independent predictors in multiple studies.<sup>18,20,23,28,30</sup> The rate of vascular complications decreases with increasing operator experience (Fig. 3),<sup>23,31</sup> use of smaller size sheaths, and better patient selection.<sup>15,23,31</sup> Systems using >19 F sheaths have been associated with increased risk of major vascular complications.<sup>21,32</sup> The Medtronic Core Valve has been associated with a lower risk of vascular complications compared to the older-generation Edward Sapien devices that required sheaths with an inner diameter of 22–24 F (outer diameter 25–28 F).<sup>23</sup> Similarly, the newer-generation lower profile Sapien XT valves (18 or 19 F delivery systems) and Edward Sapien valve 3 systems (with even smaller delivery systems) have a decreasing incidence of major vascular complications compared to the first-generation Edward Sapien valves.<sup>32</sup> A large multicenter registry from Europe showed markedly improved vascular complication rates, 3.1% from all access sites combined and 2.9% from the transfemoral access site.<sup>33</sup> Most patients were treated with either 18 F Edwards Sapien XT or the Medtronic Core Valve. There was no difference in the rate of vascular complications from Medtronic Core Valve versus Edwards Sapien XT valves (2.8% vs. 3.3%;  $p = 0.66$ ). These results highlight the importance of operator and center experience, as well as sheath size, toward occurrence of vascular complications. With the recent approval of Medtronic core valve Evolut systems, which use 14 F sheath and Edward Sapien valve 3 systems, which use a 14 F expandable sheath, the real-world incidence of vascular complications is expected to decline.

## 6. Specific vascular complications

The common femoral artery is the more commonly used access site during TAVR with ~70% of the procedures being

performed by this route worldwide.<sup>34</sup> Vascular complications using this approach include aortic dissection, aortic rupture, pelvic vessel dissection, pelvic vessel rupture, access site hematoma, and pseudoaneurysm formation. When vascular injury is suspected, general supportive measures, such as volume resuscitation, should be promptly initiated to prevent precipitous hemodynamic decline. The reason for a change in patient's clinical status should be aggressively pursued as conditions other than vascular complications, such as coronary artery obstruction, paravalvular leaks, and acute valve dysfunction, may present similarly. Once recognized, endovascular treatment is the mainstay of managing vascular complications.

## 7. Aortic dissection

Aortic dissection is a relatively rare but potentially deadly complication from TAVR, with reported incidence between 0.6% and 1.9%.<sup>29,35</sup> Depending on route of access (transfemoral, transapical, subclavian, or direct aortic), any segment of the aorta (from the ascending aorta to abdominal aorta) is a potential site for iatrogenic injury.<sup>36</sup>

The signs and symptoms may not manifest until after the procedure. At most centers, TAVR is performed under concurrent transesophageal echocardiographic guidance and it is routine to assess the ascending aorta post valve deployment to exclude Stanford type A dissections. If diagnosis is suspected peri-procedurally, angiography is generally diagnostic. If unrecognized until the postprocedure period, patients may complain of sharp chest pain if they develop Stanford type A or B dissection, or abdominal pain if the dissection involves the abdominal aorta. With extension into other vascular beds, there may be additional symptoms, such as neurological compromise (from carotid artery involvement), mesenteric ischemia (from involvement of mesenteric arteries), or renal dysfunction. Patients may also manifest differential blood pressure measured between the two arms or the arms and legs. Postprocedure, CT, transesophageal echocardiography, or MRI may be utilized depending on institutional expertise and availability for diagnosis.

The management of aortic dissection in the setting of TAVR is the same as spontaneous aortic dissection, and depends on the site of dissection and the presence of branch vessel compromise. If the patients are hypertensive, aggressive control of blood pressure with  $\beta$ -blockers (or nondihydropyridine calcium channel blockers in patients with contraindication to  $\beta$ -blockers) is required. Direct arterial vasodilators, such as hydralazine, should be avoided. If the patients are hypotensive, fluids should be administered to maintain a MAP of  $\geq 70$  mm of Hg. Urgent surgical consultation should be obtained. Patients with Stanford type A aortic dissection and those patients who are hypotensive without alternative explanations should undergo surgical repair. Hemodynamically stable patients with Stanford type B dissection may be candidates for medical management or, rarely, endovascular repair. Medical management involves appropriate blood pressure and heart rate control with close follow-up.

## 8. Aortic rupture

Aortic rupture is a rare occurrence (<1%) but generally catastrophic.<sup>37</sup> Infrequently, the patient may present subacutely due to an initial aortic injury that may gradually enlarge in size leading to serious bleeding. Rupture can occur from puncture of the aorta by the delivery catheter, especially if the device is inadvertently advanced without a guidewire, or if excessive force is applied when trying to advance around an acute angulation in a tortuous aorta. The diagnosis requires a high index of suspicion and should be considered in any patient undergoing TAVR who develops hemodynamic compromise.

Aortic rupture leads to rapidly progressing hemorrhagic shock with hypoperfusion of the extremities and vital organs. The patients develop signs and symptoms of volume loss, such as hypotension, tachycardia, and lactic acidosis. Depending on the size and location of the tear, there may be gradual or sudden decompensation of hemodynamics. In stable patients with contained rupture, the diagnosis can be confirmed by angiography or CT angiography (CTA).

Aortic rupture is a life-threatening emergency. The management options include surgical versus endovascular repair with covered stent grafts and depend on the site of injury. Despite appropriate interventions, mortality remains high.

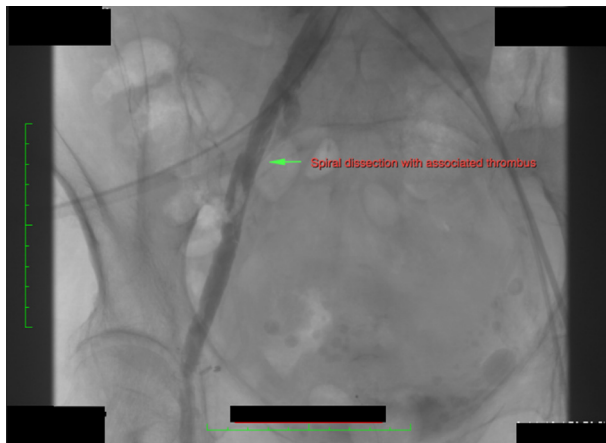
## 9. Pelvic vessel dissection

Pelvic vessel dissection is the most common vascular complication in patients undergoing TAVR via the transfemoral route and has been reported to occur in about 6.5% of the patients.<sup>18</sup> The most frequent vessel dissected is the external iliac artery. Injury typically occurs during initial placement of the delivery sheath but is generally not apparent until the sheath is withdrawn.

Typically, pelvic vessel dissections are recognized after sheath removal, on routine angiography either retrograde through the delivery sheath or more commonly antegrade from an angiography catheter inserted from the contralateral groin. Extensive dissections may compromise vascular flow to the lower extremity and predispose to rupture. Small dissections may be initially unrecognized but may lead to vascular compromise in the postprocedure period, either from abrupt closure due to thrombus formation or collection of significant amount of blood in the false lumen with a resultant compression of the surrounding neurovascular structures. Diagnosis can be confirmed by either invasive angiography (Fig. 4) or CTA or vascular Doppler.

The natural history of small nonflow-limiting retrograde dissections is benign, and if the dissection is small with no neurovascular compromise, then watchful waiting and close monitoring is preferred to allow spontaneous healing. In patients with vascular compromise or with extensive or expanding dissections, intervention is generally warranted.

Endovascular repair is associated with good outcomes and is the preferred treatment modality.<sup>32,38</sup> Treatment is with either angioplasty alone or with adjunctive stent placement if

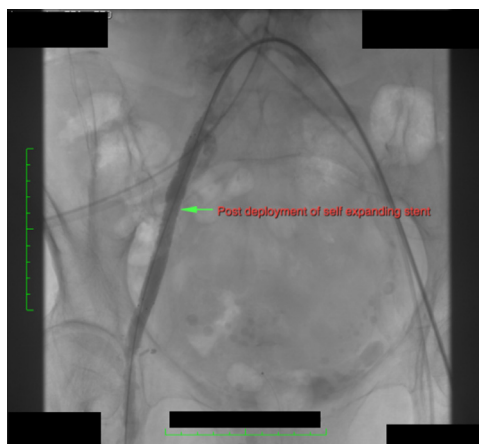


**Fig. 4 – Postprocedure invasive angiography showing external iliac artery dissection with thrombus (green arrow).**

needed, and is the definitive therapy in most cases. Angioplasty involves prolonged balloon inflation with an appropriately sized balloon that may be sufficient to seal the dissection flap. If significant compromise to flow persists despite prolonged balloon inflation, self-expanding stents are useful (Fig. 5). If not technically feasible or unsuccessful, surgical repair may be infrequently required. Patients should be followed closely after repair and clinical exam and duplex ultrasonography are helpful to ensure vascular healing and patency.

## 10. Pelvic vessel rupture

Pelvic vessel rupture is a potentially fatal complication of TAVR. Historically, it has been reported to occur in about 3–5% of the patients and is associated with high mortality. With the



**Fig. 5 – External iliac artery postdeployment of self-expanding stent for management of arterial dissection showing resolution of dissection and return of normal flow. (Green arrow points to the site of previous dissection.)**



**Fig. 6 – Postprocedure retrograde angiogram showing contrast extravasation from right external iliac artery, which is diagnostic of perforation and rupture (red arrow). An occlusive balloon is noted proximal to the site of vessel injury (green arrow).**

advent of low-profile delivery systems, the incidence of pelvic vessel rupture has declined. Pelvic vessel rupture typically manifests after the sheath is withdrawn; as while the sheath is present, it acts as seal for the tear.<sup>39</sup> These patients can decompensate very rapidly and exsanguinate unless prompt intervention is undertaken.

Careful attention to hemodynamics at the time of sheath removal is mandatory. Depending on the severity of bleeding, patients may manifest immediate hemodynamic instability, or in a delayed fashion several hours later. Patients may develop transient hypotension associated with return of circulation to an ischemic limb (due to large sheath sizes, it is common for the limb to have very little blood flow while the delivery sheath is in place). Other causes of acute hemodynamic compromise should be excluded. In most centers, it is routine to perform pelvic angiography upon sheath withdrawal (leaving the guidewire in place) with the tip positioned in the common femoral artery, which may show extravasation of the contrast material into extravascular space in addition to localizing the site of rupture (Fig. 6).

The immediate treatment involves re-advancing the sheath and the dilator to the abdominal aorta that can serve to tamponade the rupture site. This allows time for initiation of supportive measures, such as rapid volume resuscitation (normal saline, packed red cell transfusion), reversal of periprocedural anticoagulation, and advancement of a proximal occlusion balloon, typically from the contralateral access site. In some cases, the tear may seal-off after prolonged balloon inflation and reversal of periprocedural anticoagulation. Definitive therapy includes a covered stent that leads to complete resolution in most cases.<sup>32</sup> Rarely, if vascular anatomy is unfavorable, injury at multiple sites is suspected, or when endovascular treatment is unsuccessful, direct vascular repair may be necessary.

## 11. Access site hematoma and pseudoaneurysm

Access site hematomas are common, occurring either immediately or within several hours to days of TAVR. The incidence is declining due to increasing operator experience, meticulous access technique, and decreasing sheath sizes. Generally, they are benign, with spontaneous resolution over time. However, they increase the risk of secondary infection and rapidly expanding hematomas may be associated with significant comorbidity from compression of the surrounding structures and blood loss.

The patients generally complain of persistent pain and swelling at the access site and diagnosis is established based on the clinical exam. Duplex ultrasound can be helpful to evaluate the size (especially in obese patients) and exclude femoral pseudoaneurysms.

In most instances, hematomas can be managed conservatively with close monitoring as long as there is no active bleeding from the access site. If active bleeding is present, this should be managed with manual digital compression. Reversal of anticoagulation (typically unfractionated heparin is used periprocedurally) should be considered. Once active bleeding is controlled, hematomas resorb over a period of few days to weeks. Supportive measures, such as pain control, generally suffice. Care must be taken to prevent secondary infection. Surgical evacuation may be considered in large hematomas and hematomas that are associated with compressive symptoms, such as painful neuropathy. Pseudoaneurysms are managed in most cases with ultrasound-guided compression or direct thrombin injection. Surgical repair may be needed if these therapies are unsuccessful.

## 12. Prevention

As vascular complications are such a major determinant of ultimate outcome from TAVR, all possible steps must be taken to prevent them. Great attention should be paid toward a meticulous access technique to avoid any possible vessel injury. Knowledge of the patient's vascular anatomy and appropriate patient selection is critical and preprocedural CTA plays a major role in procedural planning.

## 13. Role of CTA in preventing vascular complications

Preprocedure CTA is now the standard of care and is used routinely in planning for patients being considered for TAVR.<sup>7</sup> CTA provides a road map of the aorta and the pelvic vessel anatomy to the operators.<sup>40</sup> A consensus statement by the Society of Cardiovascular CT outlines the recommendations for assessment of access site and aorta in patients for whom TAVR is being planned (Tables 3 and 4).<sup>41</sup> The image acquisition is typically gated and extends from the arch of the aorta to below the femoral head.

CT allows for measurement of the aortic annulus and appropriate sizing of the valve, thereby reducing the risk of

**Table 3 – Recommendations for assessment of access route by CT before TAVI/TAVR.**

CT imaging should be performed for vascular access assessment (pelvic arteries and aorta) when not contraindicated
CT examinations should be performed with iodinated contrast medium
Manual multiplanar reformation or semi-automated centerline reconstruction should be used to achieve cross-sectional visualization for measurement of vessel dimensions. From these reconstructed images, the minimal luminal diameter along the course of the vascular access should be determined
Qualitative assessment of vascular tortuosity should be performed
Qualitative assessment of vascular calcification should be performed
Consideration to varied thresholds of vessel size (sheath/femoral artery ratio) should be contemplated, depending on the presence and extent of vascular calcification
The left ventricle should be evaluated for the presence of thrombus and, if a transapical access route is planned, for geometry and position of the apex

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**Table 4 – Recommendations for assessment of aorta.**

The entire aorta should be imaged and evaluated, unless a transapical access is planned
Severe elongation and kinking of the aorta, dissection, and obstructions caused by thrombus or other material should be reported

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rupture of the aortic annulus or undersizing of the valve that predisposes to paravalvular leaks. Aortic dissection, aneurysms, calcifications, and atheroma are easily recognized on CTA. Similarly, pelvic vessel diameters are measured by CT with careful attention to assessment of tortuosity, calcification (specially horseshoe or circumferential calcification), and kinking. This information is vital to guide the choice of access route and appropriate sheath and device selection. Most TAVR centers have well-established protocols for pre-TAVR assessment, typically interpreted by a radiologist with close familiarity with the device and in-depth understanding of the procedural components. At our institution, a dedicated chest radiologist and interventional radiologist are members of the Heart Team and regularly participate in adjudicating the suitability of patients for a transcatheter procedure in a multidisciplinary valve listing conference.

## 14. Future directions

As larger size catheters are associated with an increased risk of complications, there is strong impetus toward development of devices that can be delivered through smaller sheaths. Technological advances continue to allow development of lower profile devices. Sheath technology has also undergone significant enhancements. Expandable sheaths (Edwards eSheath) allow for transient sheath expansion during valve delivery. Immediately after the transcatheter heart valve passes through the sheath, the sheath is designed to return to a low-profile diameter. This reduces the time the access vessel

is expanded, thereby minimizing the risk of vascular trauma. The Edward Sapien 3 system and Medtronic's CoreValve Evolut R systems, approved in the US in 2015, are steps in this direction. Both catheter systems have sheath profiles <18 F and are expected to significantly reduce vascular complications from TAVR, leading to more optimal patient outcomes.

## 15. Summary

Since first performed in 2002 via trans-septal puncture, TAVR has undergone rapid evolution. The indications for this procedure are expanding and there are several possible access sites (transfemoral, transapical, transaxillary, subclavian, or direct aortic). CTA plays a key role in preprocedure planning and the appropriate access site is chosen based on patient's anatomy, risk factors, and available institutional expertise. Regardless, meticulous vascular access is critical. Vascular injury is amongst the commonest complications of this life-saving procedure. Prompt recognition and early treatment are vital to prevent significant morbidity and mortality.

## Conflicts of interest

The authors have none to declare. Dr Gupta is a consultant for Biotronik. He is also an investigator for the PORTICO trial.

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