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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.

1. Introduction

Since the first reported human case,[1] 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.[2,3] In patients at high risk for SAVR, transcatheter implantation has demonstrated extremely favorable results.[4] 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.[5–8] Recent trials have demonstrated similar benefits in patients estimated to be at moderate risk.[9–11] 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.[12] 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[6,13] and generally manifest either periprocedurally or early in the postprocedure period. Multiple studies have substantiated higher mortality in patients with vascular complications.[3,14–18] 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.[19] They are associated with increased mortality, increased length of hospital stay, and diminished quality of life.[18,20–22] 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 30.7%.[18,20,23] 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.[24,25]

Table 1 – Vascular access site and access related complications.

Major vascular complications
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
Minor vascular complications
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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Using standard VARC definitions, the incidence of major vascular complications varies between 10% and 20%.[20,21,26] In a large meta-analysis by Genereux et al. using VARC-1 definitions,[13] 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.[20] 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.[27]

4. Impact on clinical outcomes

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

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