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Cardiovascular Collapse During Transcatheter Aortic Valve Replacement: Diagnosis and Treatment of the "Perilous Pentad"

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Abstract

Transcatheter aortic valve replacement (TAVR) has, without a doubt, brought an unprecedented excitement to the field of interventional cardiology. The avoidance of a sternotomy by transfemoral or transapical aortic-valve implantation appears to come at the price of some serious complications, including an increased risk of embolic stroke and paravalvular leakage. The technical challenges of the procedure and the complex nature of the high-risk patient cohort make the learning curve for this procedure a steep one, with the potential for unexpected complications always looming. Although most commonly relating to vascular access, these complications can also result from prosthesis-related trauma or malposition, or from unanticipated trauma from the pacing wire or the super stiff wire. Sudden and unexplained hypotension is often the earliest indicator of major complication and must prompt an immediate and detailed exclusion of five major pathologies: retroperitoneal bleeding from access site rupture, aortic dissection or rupture, pericardial tamponade, coronary ostial obstruction, or acute severe aortic regurgitation. In most cases, these can be dealt with quickly, and by percutaneous means, although open surgery may occasionally be necessary. Increased operator and team experience should make prevention and recognition of these catastrophic complications more complete. For this reason, the importance of specific training, such as that provided by the valve manufacturers through workshops and proctorship, cannot be overemphasized. It is essential that all operators, and indeed all members of the implant team, exert extreme vigilance to the development of intraprocedural complications, which could have rapid and potentially lethal consequences. Greater experience with an improved understanding of these risks, along with the development of better devices, deliverable through smaller and less traumatic sheath technology, will undoubtedly improve the safety and, potentially, widen the applicability of TAVR in the future. Forthcoming innovations include a newer generation of the valves with operator-controlled steerability to facilitate negotiation of tortuous aortic anatomy, as well as fully retrievable and resheathable devices to accommodate the events of dislocation or embolization. The fact that Transcatheter aortic valve implantation (TAVI) is new implies learning from experience but also from mistakes. The TAVI team must be vigilant to recognize and diagnose intraprocedure severe hypotension. The "perilous pentad" of catastrophic causes must be constantly borne in mind: retroperitoneal bleeding from access site rupture, aortic dissection or rupture, pericardial tamponade, coronary ostial obstruction, and acute severe aortic insufficiency.

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Key Words

Transcatheter aortic valve replacement · Complications · Aortic valve

Introduction

Transcatheter aortic valve replacement (TAVR) has become a major clinical reality in the management of

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patients with severe aortic stenosis who are deemed to be a high or indeed a prohibitive surgical risk [1,2]. Current understanding of the likely complications associated with this procedure is rapidly evolving. TAVR-adverse events differ markedly from those related to surgical intervention.

Awareness of how complications occur may help in their recognition, management, and ultimately, avoidance, thus improving patient outcomes and facilitating the safe application of this novel therapy.

TAVR continues to be associated with the potential for serious complications [3,4] including vascular injury, stroke, cardiac injury such as heart block, coronary obstruction, cardiac or aortic perforation, paravalvular leak, and valve misplacement.

Within this article we review the complications of TAVR and discuss possible prevention, diagnosis, and management.

Hypotension

Although, most often, relieving aortic stenosis is associated with spontaneous improvement of left ventricular (LV) function and hemodynamics, patients with severe aortic stenosis may be extremely sensitive hemodynamically. This is particularly true in the presence of coronary artery disease and LV systolic or diastolic dysfunction. Whatever the primary cause, hypotension or tachycardia may initiate a downward spiral of ischemia and severe pump failure. Vasopressor agents (phenylephrine or norepinephrine), which maintain adequate perfusion pressure, are often helpful. Chronotropic and inotropic agents should be avoided as they tend to increase myocardial oxygen demands, which may intensify myocardial ischemia and induce a downward spiral which may not be recoverable without cardiopulmonary bypass [5].

Unexplained severe hypotension should prompt consideration for an immediate diagnostic strategy to identify and treat the cause [6] (Table 1), which enumerates the "perilous pentad" of potential catastrophic sources of hypotension during TAVR . This checklist may serve as a useful mental map during the acute hypotensive event.

Retroperitoneal Bleeding from Access Site Rupture

The relatively large diameter of the delivery catheter, the frequent presence of severe arteriosclerosis, along with the common factor of patient fragility can combine to create major vascular problems at the access site. Access for the delivery sheath has proven to be a major limitation of transarterial TAVR. Early systems used 22 gauge to 25 gauge French sheaths (outer diameter 9-10 mm), and in the absence of adequate screening, the incidence of arterial dissection and perforation was relatively high [6,7].

To determine the feasibility of an arterial approach, careful and meticulous assessment of the arterial tree—using multi-slice computed tomography and angiography—is mandatory. The images should be used to evaluate the presence and severity of arterial access pathology and arterial size [8,9].

Minimal lumen diameter, as well as the amount and distribution of atheroma, tortuosity, and calcification, will determine the risk of vascular injury related to sheath insertion. Ideally, the minimal lumen diameter should exceed the diameter of the delivery system.

As a rule, in borderline cases, regarding size or significant pathological findings, one should use access alternatives, which include the apical, subclavian, open iliac, or ascending aorta approaches [9,10]. Another option in such circumstances is reconstruction of the ilio-femoral axis with stents or grafts. Although a large body of knowledge exists for the apical procedure, clinically documented experience with other approaches is still rapidly growing.

After uncomplicated vascular closure, ilio-femoral angiography should be performed from the contralateral femoral access site, which allows rapid identification and, if necessary, ongoing management of vascular complications.

Dissection or perforation of the ilio-femoral arteries may occur in the presence of excessively traumatic sheath insertion. Dissection of the ascending or descending aorta can similarly occur due to catheter trauma. Hypotension, hypovolemia, or cardiac tamponade are the common clinical scenarios whenever a vascular perforation or dissection takes place [11].

Retroperitoneal hemorrhage is one of the dramatic potential complications of TAVR. Successful management requires a high level of suspicion should sudden unexplained hypotension occur [12].

When the large arterial sheath is occlusive, perforation may become evident only after sheath removal. Volume expansion and angiographic assessment should be performed without delay.

Table 1. Causes of Severe Intraoperative Hypotension During TAVR (and Other Less Acute Complications)

Condition	Treatment	Comment
(1) Retroperitoneal bleeding from iliac artery access site rupture	Balloon occlusion Surgical control	Precise imaging of access ileofemoral vessels can decrease the likelihood of this complication
(2) Aortic dissection or rupture	Surgical control will likely be necessary, although this scenario is often lethal	Avoid oversizing, overballooning
(3) Pericardial tamponade	Pericardial drainage or open surgical control may be required, depending on scenario	Causes range from RV wire perforation to LV wire perforation, to aortic or LV rupture
(4) Coronary ostial obstruction	Percutaneous angioplasty may occasionally be of benefit Surgical conversion is often necessary	Components of valve, or, more likely, a bulky leaflet atheroma may overlie and occlude a coronary os
(5) Acute severe aortic insufficiency	A second transcatheter valve may need to be delivered Surgical conversion may be necessary	Usually due to "frozen leaflet"
Apical access site problems	Surgical control	Late pseudoaneurysm may result
Internal cardiac tears (VSD or LV to LA fistula)	Individualized	
Acute mitral insufficiency	Surgery may be required	From chordal tear during antegrade apical approach
Positioning and deployment problems	Individualized	
Stroke	Multifactorial	
Acute kidney injury	Multifactorial	
Conduction disturbances	Close monitoring Pacemaker as needed	More commonly noted with Medtronic CoreValve device
Suicidal LV	Fluid administration	

VSD, ventricular septal defect; LV, left ventricle (ventricular); LA, left atrium.

Immediate reinsertion of the occlusive sheath over a guide wire or placement of a highly compliant occlusion balloon, proximal to the area of suspected perforation, typically provides rapid and relatively reliable control of bleeding, allowing time for definitive management [11].

Covered stents or percutaneous endografts might serve as adequate therapy and should be available in the catheterization laboratory for prompt intervention, although formal surgical repair might be necessary.

Aortic Dissection or Rupture

Unexplained hypotension after balloon dilation or valve expansion should prompt echocardiographic or angiographic assessment of the LV outflow tract and aortic root.

Rupture of the aortic annulus can occur following aortic balloon valvuloplasty or valve deployment. Accurate choice of the valve and balloon size, avoiding excessive balloon dilation and valve oversizing, may decrease the likelihood of this uncommon but deadly complication. Particular attention is required where the annulus and/or subannular tissues are markedly calcified or when the root is unusually small [14,15].

These same traumatic forces during forceful manipulation of the aortic root can produce aortic dissection, with distal propagation from the aortic root. Like aortic rupture, this should be sought and diagnosed from the intraoperative transesophageal echocardiogram. Open surgical correction will usually be required.

Pericardial Tamponade

The reported incidence of tamponade after TAVR varies from 0% to 7%. Typically, pericardiocentesis is adequate; however, thoracotomy might be required. The use of a stiff wire with an appropriately shaped curve and a standard J-curve at the tip is likely to be

the best method to avoid perforation of the LV. Right heart perforation by the transvenous pacemaker is also possible [14].

Coronary Ostial Obstruction

Coronary obstruction may occur if an obstructive portion of the valve frame, or the sealing cuff, is placed directly over a coronary ostium; however, this is exceedingly rare. The presence of open cells over a coronary ostium is well tolerated. Although percutaneous coronary interventions have been performed successfully after valve implantation, it is likely that frame struts will prevent or complicate selective coronary cannulation.

A greater concern is the possibility of displacing an unusually bulky, calcified native leaflet over a coronary ostium.

The diagnosis of coronary ostial obstruction may be reflected in the EKG trace or via sudden depression in left ventricular function on the echocardiogram. The echo may actually demonstrate the displacement of a calcified leaflet onto the coronary os.

Although acute coronary ostial obstruction may well prove fatal, some cases have been successfully managed by immediate percutaneous angioplasty or open bypass surgery. The risk of coronary occlusion is low, but difficult to assess, and most likely depends on the bulkiness of the native leaflets, height of the coronary ostia, and dimensions of the sinus of Valsalva.

Acute Severe Aortic Insufficiency

Acute severe aortic insufficiency after TAVR may produce hypotension and shock. Diagnosis may be suggested by hypotension and a wide pulse pressure on the arterial trace, with failure to maintain a good diastolic pressure after TAVR.

Significant transvalvular regurgitation is rare after TAVR, and is usually related to acute structural valve failure. This may include prosthesis rupture or malfunctioning leaflet ("frozen leaflet"), which is rare but, nevertheless, a possible complication after TAVR. Deployment of a second valve may be necessary. Alternatively, prompt cardiopulmonary bypass and surgical valve replacement may be required to sort out the problem (see below for a discussion of less severe paravalvular aortic regurgitation).

Other Potential Technical Problems

Apical Access Issues

Direct access to the left ventricular apex is achieved through an anterior mini- thoracotomy. The most common concern is chest wall discomfort with the associated potential for respiratory compromise and prolonged ventilation. Identifying the cardiac apex with transthoracic echo or fluoroscopy in two dimensions allows more direct access without the need for rib spreading other than by a soft tissue retractor [13].

On completion of the procedure, the apex is repaired with preinserted pledgeted sutures. A short burst of rapid ventricular pacing (rate between 130 and 140) is used to decrease LV systolic pressure during tying of these sutures.

Postprocedural low-grade bleeding from the access site may result in cardiac tamponade and require further repair and prophylactic use of a biological glue. A pericardial patch cover can reduce this risk. Management of large tears might require institution of cardiopulmonary support [12].

Delayed pseudoaneurysm formation at the site of ventricular repair has been reported. Although pseudoaneurysms might be initially asymptomatic, they are typically progressive and require surgical intervention.

Internal Cardiac Tears

A tear created at the level of the valve inflow can result in either ventricular septal defect or a LV to left atrial shunt.

Mitral Valve Injury

During an antegrade apical approach, a wire can be passed below a mitral chorda, leading to distortion or avulsion of the mitral chordae. This may cause acute mitral regurgitation. Resistance to catheter advancement through the ventricle or transient mitral regurgitation assessed by transesophageal echocardiography should alert the operator to this possibility. Rewiring or use of a balloon flotation catheter may be considered to avoid subchordal passage [15].

Surgical treatment may be required if the mitral regurgitation is acute and severe.

Positioning and Deployment Problems

Improper Positioning

A valve extending excessively into the ventricle or the aorta may be associated with adverse events such as mitral insufficiency, arrhythmia, or aortic injury.

Prosthesis embolization immediately after deployment is generally the result of a gross error in positioning or ejection of the device by an effective ventricular contraction during deployment.

Embolization to the aorta is well tolerated so long as coaxial wire position is maintained, preventing the valve from flipping over and obstructing the antegrade flow. Typically, the valve can be snared or repositioned with a partially inflated valvuloplasty balloon into a stable position in the aorta. A TAVR reattempt is often successful, although an alternative approach might be advisable when the reason for initial failure cannot be identified. Embolization to the LV is far less likely, but in such cases, surgical removal might be the only option available.

Paravalvular regurgitation, due to incomplete annular sealing, is common. Some degree of paravalvular aortic regurgitation is reported in 80-96% of cases. In most cases, the degree of regurgitation is trivial or mild. Grade $\geq$2+ regurgitation is found in 7-24% of patients. Although no trial has directly compared the Edwards SAPIEN and Medtronic CoreValve devices, the rates of regurgitation reported in the literature seem to be similar for the two devices. Appropriate sizing with multiple imaging modalities is one way of reducing this problem, which adversely impacts long-term survival. Sometimes further ballooning may reduce or abolish the aortic regurgitation.

Paravalvular Regurgitation

Mild to moderate paravalvular regurgitation usually does not produce severe, acute hemodynamic derangement. During follow-up, regurgitation is more often reduced, rather than becoming worse. The importance of paravalvular leak has been emphasized in several reports in which grade $\geq$2+ regurgitation has been shown to be an independent predictor of short- and long-term mortality [16].

Stroke

Neurological events are generally mulifactorial, with some related to the procedure. Manipulation of a wire and/or large-diameter catheter through the aortic arch, positioning of the device, performance of balloon aortic valvuloplasty, and inadequate blood flow to the brain during rapid pacing and device deployment are all potential causes of neurologic injury. Factors related to the very elderly patient substrate, in whom the incidence of atrial fibrillation and atherosclerotic disease is high, contribute to the risk of peri-procedural cerebrovascular events. Reported incidence of clinical stroke in the current literature varies between 1.7% and 8.4% [17].

Initially, it was anticipated that stroke associated with TAVR occurred during the procedure, but in-depth analysis of this issue has demonstrated a continuous hazard extending beyond the early phase. This hazard was thought to be higher after Transcatheter aortic valve implantation (TAVI) in comparison with surgical aortic valve replacement (SAVR). However, recent data have shown that although the difference is significant in the first 30 days, the late hazard is in fact similar between TAVI and SAVR.

The role of atrial fibrillation as a potential mechanism for stroke after TAVI has been emphasized in two recent reports, which show a fourfold increased risk of stroke.

There are several embolic protection devices currently under investigation. Reports have not shown a clinical impact on reducing the incidence of overt or silent neurological events after TAVR.

Acute Kidney Injury

The incidence of acute kidney injury (AKI), according to multiple reports, lies around 7-8%. Many of these studies have been consistent in identifying blood transfusion as a predictor of AKI. Transfusions are most likely related to bleeding resulting from the vascular access site. The dye load certainly contributes to kidney injury. Predisposing factors include hypertension, chronic obstructive pulmonary disease, and abnormal baseline renal function. Toggweller S. et al. reported that TAVR patients who had AKI had significantly higher in-hospital mortality and worse long-term survival [18,19].

Conduction Disturbances

It has now been identified that the self-expandable Medtronic CoreValve system (because of the higher and longer-lasting radial forces as well as the deeper implantation site in the left ventricle outflow tract) has a higher rate of pacemaker requirement than the Edwards SAPIEN

system. The incidence is higher in patients who have a left or right bundle branch block prior to implantation.

A recent meta-analysis reported that 28.9% (23-36%) of patients implanted with the Medtronic CoreValve valve and 4.9% (4-6%) of patients implanted with the Edwards SAPIEN valve will require a new permanent pacemaker [19].

Given the variable timing of the possible occurrence of high-degree AV block, continuous postprocedural ECG monitoring should be performed for at least 72 hours for those patients considered to be at increased risk for this complication. Avoiding oversizing and deep implantation in the outflow tract can reduce the incidence of this complication [19].

The "Suicidal LV"

In rare circumstances, after sudden reversal of chronic, severe aortic stenosis, the sudden disappearance of afterload can permit the hypertrophied left ventricle to contract so forcefully and completely that it obstructs forward flow. The subvalvular hypertrophy obstructs outflow from the LV. This has been eloquently termed the "suicidal LV" post-TAVR.

Treatment involves fluid administration and avoidance of diuretics.

Conclusion

TAVR has become the standard of care for those patients for whom the surgical risk is deemed prohibitive. TAVR is also emerging as a reasonable alternative for those selected, operable patients in whom the risk of either mortality or morbidity is "high." Although bleeding and vascular complications are decreasing as TAVR technology improves and continues to miniaturize, significant and potentially catastrophic mechanical complications may still occur. Having a clear, focused, prepared outlook to the recognition and treatment of these TAVR-related catastrophes is essential for the care team. This article has provided a framework for such a perspective.

Conflict of Interest

Adam El-Gamel is a proctor and consultant for Edwards Life Science.

Comment on this Article or Ask a Question

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EDITOR'S COMMENTS AND QUESTIONS:

Editor's Comments:

This excellent article by Dr. El-Gamel provides a clear diagnostic and therapeutic approach for catastrophic complications, which can occur during or immediately after TAVI. Having this clear diagnostic and therapeutic map in mind is likely to save lives. This article is recommended for all teams starting or performing TAVI.

Editor's Questions:

As the indication for TAVI has classified the patients into two different groups—the first being the inoperable AS patients and the second group being the high-risk operable surgical patients, the team has to make an individual call before the procedure if surgical intervention has a place in an individual patient; it makes no sense to perform an emergency procedure on a patient who was rejected for an elective operation (inoperable patient). It is imperative that the Heart Team, the patient, and the patient's family are aware of the limit to the extent of surgery that will be offered in the event of a significant complication. For example, we feel that redo sternotomy and repair of a type A dissection in a nonagenarian is inappropriate and would not be undertaken. Prevention of complications required during TAVI appears to be of critical importance. As the outcome of emergency surgical intervention offers poor outcome, this should be discussed at length with all parties and then documented in the patient's file prior to the procedure.

1. Is it worth operating for rupture of the aortic root from TAVI? Is there any meaningful chance of salvage?

Reported 30-day mortality of TAVI complications needing surgical intervention from the European source registry was high (51.9%) and showed cause-specific differences, with 100% mortality in patients with aortic rupture or cardiac tamponade, 0% death in those with acute aortic regurgitation, and intermediate risk of death or intermediate mortality risk in those with aortic injury or valve embolization/migration. So the experience and data do not support surgery for aortic or cardiac rupture.

2. Is it worth operating for non-ruptured aortic dissection occurring during TAVI?

The decision to operate on acute dissection is complicated by the patient characteristics, pervious operation, and age. For example, we feel that redo sternotomy and repair of a type A dissection in a nonagenarian is inappropriate and would not be undertaken. However, an 80-year-old with no previous history of cardiac surgery, considered operable but high risk for conventional surgery, may be offered surgical repair.

3. Is it worth operating for coronary ostial occlusion occurring during TAVI?

Operating for coronary occlusion and aortic incompetence has the best outcomes, so surgery should be offered in the operable patients who are accepted for TAVI.