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# COMPLICATIONS AT THE TIME OF TRANSCATHETER AORTIC VALVE IMPLANTATION

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**Abstract**

Transcatheter aortic valve implantation (TAVI) improves the prognosis of patients with severe aortic stenosis who are deemed too high risk for surgical valve replacement.[1] However, this evolving technology is associated with a wide range of potential complications — some specific to TAVI, some often fatal. Prevention, early recognition, and effective treatment of these complications will significantly improve the outcome of this procedure and are essential prerequisites before the therapy is extended to lower-risk patient subsets.

## Introduction

Complications at the time of transcatheter aortic valve implantation (TAVI) can be classified as cardiac vs. non-cardiac. Furthermore, some of these complications may be specific to TAVI as for example, valve malposition, paravalvular aortic regurgitation, and coronary obstruction or not specific to TAVI as vascular access complications and cardiac perforation/tamponade seen with also others endovascular interventions. Proper patient selection is essential to maintain a heightened awareness for possible complications that may occur during particular steps of the procedure. Operators must have an in-depth knowledge of the implantation technique and be familiar with techniques and materials required for bail-out procedures. In addition, each hospital should identify a heart team (specifically, an interventional cardiologist and cardiac surgeon); this is crucial for a successful outcome and for managing potential complications that may arise during implantation of the CoreValve ReValving System (Medtronic, Inc.). Among the possible cardiac complications of aortic stenosis repair, this manuscript will describe only those more specific to TAVI and will not discuss the less-specific vascular access complications.

## Valve Malposition

Deployment of the Medtronic CoreValve prosthesis is performed in a controlled and step-wise manner. Even so, valve positioning remains one of the most challenging steps of the procedure, since valve malposition may still occur even after all necessary precautions have been taken. Normally, the CoreValve prosthesis should be positioned approximately 4-6 mm below the "aortic valve annulus." A "too-low" implantation is defined as the distal edge of the valve frame (commonly referred to as the "inflow" aspect) positioned more than 12 mm below the annulus, into the left ventricular outflow tract (LVOT). A "too-high" implantation is defined as the inflow aspect positioned above the annulus level.

### *Low Implantation*

Except in cases of severe left ventricular hypertrophy, a low implantation is generally associated with moderate (Grade II) to severe (Grade III-IV) degrees of aortic regurgitation (AR) on contrast aortography. Transesophageal echocardiography (TEE) can confirm the nature of the regurgitation (i.e., paravalvular vs. central).

In the case of "too-low" positioning associated with significant AR and hemodynamic instability, the first objective would be to manually reposition the valve using a "goose-neck" catheter (i.e., the "Lasso" technique). If unsuccessful, the second option would be to implant a second valve inside the first one (i.e., valve-in-valve technique) but positioned slightly higher.

### *Primary option: The "Lasso" Technique*

The choice of projection on fluoroscopy is crucial and is dictated by the valve frame, which should be aligned as perfectly as possible. This will provide a reliable reference line when repositioning the valve. With this option, the operator advances a regular 20-35 mm "goose-neck" catheter alone or through a 7-Fr guiding catheter to engage one of the "loops" of the implanted valve. At this stage it is critical to understand that the success of this maneuver depends on applying torsion to the frame ("unscrewing the valve") rather than applying direct axial force, which frequently results in ejection of the valve into the ascending aorta. It is for this reason that the simultaneous use of two "goose-neck" catheters is strongly discouraged. Upon "loop" engagement, the operator applies gentle and slowly increasing torsion/traction to the "goose-neck" catheter under constant fluoroscopic guidance. After confirming mobilization of the valve with hemodynamic analysis, angiogram, and TEE, the "goose-neck" catheter is carefully detached and retrieved.

### *Alternative option: The Valve-in-Valve Technique*

If the previously described technique of repositioning the valve is unsuccessful or is deemed too dangerous, correction of the severe AR can still be obtained using a second CoreValve implanted inside the first one in a slightly higher position. As with the previous technique, the correct projection is crucial and is dictated by the frame of the valve, which should be aligned as perfectly as possible. The operator advances the second valve into the previously implanted valve and calculates the position for

implantation with regard to the patient´s anatomy. In the case of complex anatomy (as per vertical aortic root), the operator secures the previously implanted valve using a "goose-neck" catheter, as previously described, to avoid dislodging the first valve into the left ventricular cavity when advancing the second valve. The operator then measures the overlap distance of the two valves to better understand the position of the second valve that will be implanted.

Certain steps can be taken to improve the accuracy of implantation. While focusing on the distal (inflow) aspect, the operator can release the second valve until it is one-third deployed, then focus on the proximal (outflow) aspect of the second valve and determine the optimal distance between the frame loops of the first and second valves. For this part it is important not to focus on the distal aspect (inflow) of the valves, because the "criss-cross" appearance of the struts will make it difficult to differentiate the individual valve frames. Once optimal distance between the outflow tips is determined, the operator can deploy the remainder of the valve while strictly maintaining the prescribed distance between the two frames.

After complete release of the second valve, it is likely that there will be no significant AR observed and, as a result, no need for balloon aortic valvuloplasty (BAV) post-implantation. When AR (grade ≥2) is observed, or when tortuous anatomies challenge the implantation of the second valve, the operator should assess for incomplete expansion and axialization of the second valve's frame using control TEE or rotational fluoroscopy. If this is confirmed, BAV post-implantation should be considered

### *High Implantation*

With the possibility of full valve retrieval up to four-fifths of the way through the deployment process, such a situation should rarely occur except in cases of technical mistakes during the last steps of the procedure. Examples include (A) failure to notice incomplete disengagement of both frame loops from the delivery catheter before withdrawing the catheter; (B) failure to manage the distal tip of the delivery catheter (i.e., nose cone) through the prosthesis after successful valve deployment, resulting in tip displacement of the valve frame; (C) post-implant dilatation without the use of rapid pacing, or rapid pacing terminated too early relative to balloon inflation, resulting in ejection of the balloon-valve unit into the ascending aorta.

Unfortunately, a high implantation does not offer the same attractive options for correction as a low implantation. However, it is important to first clearly define the criteria for acceptable parameters despite a "too-high" implantation. To a certain extent, the sealing effect of the native calcified aortic valve around the frame (similar to a chimney above the annulus) can make a "too-high" implantation perfectly compatible with a good result, with no to mild or moderate AR. The control angiogram and the hemodynamic analysis provide the criteria for an acceptable result: (1) AR grade ≤2; (2) no ventricular-aortic gradient; and (3) no coronary occlusion. The last criteria, being the most important to analyze, may require additional aortograms in different projections and/or eventually selective catheterization of the coronary ostia to ensure coronary flow.

In cases where valve implantation is definitively "too high" and incompatible with an acceptable result, the valve can be repositioned into the ascending aorta. The primary goal is to ensure a safe area for the implantation of a second valve. As a result, the operator must reposition the first implanted valve high in the ascending aorta to avoid jeopardizing the functioning of the second valve by (1) severely restricting second-valve expansion, and (2) potentially compromising coronary arterial flow by creating a long skirt — a potential consequence of two valves placed in continuation.

Because the CoreValve prosthesis measures approximately 50-53 mm in height depending on valve size, a safe distance of >50 mm above the annulus level is optimal. Note that the "Lasso" technique for frame loop engagement to achieve higher repositioning of the valve has been previously described. In small anatomies, this technique may not be feasible due to lack of space in the ascending aorta that can nullify any axial force exerted through the frame loop. In such a case, the "goose-neck" catheter can be advanced through the struts of the frame towards the inflow aspect and "hooking" at that point. This allows for effective retrieval of the valve when pulling on the "goose-neck" catheter. Finally, and again for additional safety, the first valve should be secured in the correct position high in the ascending aorta with the use of the "goose-neck" catheter when a second valve is advanced through the first valve.

## Paravalvular Regurgitation

Albeit not a true complication, AR grade ≥2 on a control angiogram or TEE is not rare (>20% of overall cases). This can occur for the following reasons: (1) Low implantation of the valve; (2) under-expansion of the frame in a severely calcified aortic valve; or (3) under-evaluation of annulus measurement. Severity of the AR should be evaluated carefully, but specific guidelines on how to quantify and classify the severity of paravalvular regurgitation in the context of TAVI are lacking.

Minimum basic rules should be followed. Transesophageal echocardiography requires longer duration of the regurgitant signal, eccentricity of the jet, and extension of the jet signal deep into the left ventricular cavity. Aortography requires a minimum of 20 ml of contrast media injection, right anterior oblique projection, and position of the pigtail catheter slightly above the functioning portion of the implanted valve for the angiogram to reflect an accurate AR evaluation. Despite adherence to these rules, different parameters can influence the degree of AR, such as blood pressure, heart rate, and LV dysfunction. Therefore, there is still the risk of underestimating the severity of the regurgitation at the time of implantation and having to face — during follow-up and under different hemodynamic conditions — a more severe AR. Also, the experience with TAVI does not differ from BAV in aortic valve disease, where grade III AR could be well-tolerated in the presence of left ventricular hypertrophy or previous AR and grade II AR not tolerated in the presence of poor left ventricular function.

Therefore, in addition to TEE and aortogram to evaluate the severity of AR, it is recommended that a hemodynamic analysis be added to assess the tolerance of AR.

As a result, one should always measure LV and aortic pressures before and after valve implantation to better define the strategy when facing AR grade ≥2 after CoreValve implantation. Simple criteria can be proposed to establish the potentially bad hemodynamic tolerance of AR grade ≥2 after valve implantation that could lead to a discussion of BAV. Examples of such criteria include: (1) ≥10 mmHg elevation of the LV end-diastolic pressure above the value prior to the implantation, or an absolute value above 25 mmHg; (2) ≥10 mmHg decrease of the diastolic pressure below the value prior to the implantation for a similar systolic pressure, or an absolute diastolic pressure value below 50 mmHg; (3) no "dicrotic notch" on the aortic pressure tracing; and (4) tachycardia.

The decision to perform BAV after CoreValve implantation should always be evaluated carefully with regard to the potential consequences of BAV, such as dislodgement of the valve and structural damage to the valve tissue, which may not become evident before mid- or even long-term follow-up. Although to date nothing is known about the effect of BAV on long-term durability of the valve, a conservative approach is mandatory.

## Pericardial Effusion/Pericardial Tamponade

The causes of pericardial effusion are multifactorial. It is important to note that an effusion can occur promptly during valve implantation or it can be delayed. The source of bleeding can be the right or left ventricle, the aortic root, or the ascending aorta. Injury of the right ventricle may result from perforation of the transient pacemaker wire. Injury of the left ventricle may result from perforation of the stiff guide wire or of the catheters after valve passage. Aortic root rupture may occur after balloon valvuloplasty or after valve implantation, especially in elderly women with fragile tissue where bulky calcifications can perforate the aortic root. Some preventive strategies can help to avoid those injuries; for example, to prevent aortic root rupture, meticulous annulus measurements should be performed by computed tomography, TEE, and transthoracic echocardiography to avoid oversizing of the balloon or prosthesis.

The following describes an algorithm for managing pericardial effusion. As a standard of care, all patients should undergo echocardiography to identify possible pericardial effusion at the end of the implantation procedure. Small effusions <10 mm without hemodynamic impairment should be monitored echocardiographically at close intervals. Patients with rapidly increasing effusions and effusions with hemodynamic impairment (central venous pressure increase, blood pressure decrease, tachycardia) should undergo pericardial puncture. If improvement of symptoms is not achieved, an emergent surgical sternotomy should be performed.

## Low Cardiac Output/Cardiogenic Shock

Intraprocedural circulatory depression may occur in up to 20% of patients during implantation. Cardiac depression with low cardiac output may follow long periods of rapid pacing or may be the consequence of inadequate coronary perfusion due to low intra-aortic pressure. Coronary perfusion may also be impaired when the remaining aortic valve orifice is partially or completely occluded during the placement of the catheter-mounted valve. Another reason for cardiac depression may be the sudden onset of severe bradycardia or third-degree AV block following balloon dilatation of the aortic valve or deployment of the valve prostheses. Furthermore, obstruction of coronary ostia or severe AR after balloon dilatation or after deployment of the valve prosthesis may also cause severe cardiac depression.

To prevent or react adequately to this complication, it is mandatory that anesthesiologists keep in close communication with the implant team. In cases of bradycardia or sudden onset of third-degree AV block, ventricular pacing may quickly improve the circulatory condition. In other cases, if mild hypotension does not resolve spontaneously, it may easily be treated with bolus injections of catecholamines or a continuous infusion of low-dose dopamine or dobutamine. In cases of a more severe blood pressure drop, the management of norepinephrine, milrinone and/or levosimendan should be determined by the anesthesiologist. Intraprocedural ventricular fibrillation is treated by electrical conversion followed by cardiopulmonary resuscitation. If those measures do not help to restore circulation, emergency institution of extracorporeal circulation is the only safe rescue therapy. In those cases, implantation of the valve should be continued during extracorporeal circulation so that the patient is weaned with the valve prostheses already in place.

## Coronary Obstruction

Coronary obstruction during implantation is a rare entity, occurring in less than 1% of patients. The reasons for this potentially catastrophic event include (1) displacement of calcium deposits or large native aortic valve leaflets in front of the coronary ostia during valve deployment; (2) embolization of calcium debris into one of the coronary arteries; (3) aortic dissection with continuity of the rupture into the intima of one of the coronary ostia with resultant obstruction; and (4) a valve prosthesis that is implanted too high. In addition, coronary air embolism can lead to myocardial ischemia. The first reason described may be more frequent in the setting of a low-lying coronary artery and small coronary sinus diameters and may lead to subacute coronary occlusion. Except in cases of subacute obstruction, the first clinical sign of coronary obstruction is usually ST-segment elevation in the EKG recording or rhythm disturbances such as sudden third-degree AV block or ventricular fibrillation. In those cases, severe cardiac depression usually ensues, and the patient may go into cardiogenic shock. In cases of suspected coronary obstruction, a bolus angiogram of the aortic root may reveal which coronary vessel is involved. After that, selective intubation of the vessel ensues, followed by balloon dilatation or stenting of the coronary ostium. If the valve is implanted too high and coronary flow is impaired by the valve skirt, the prostheses must be immediately retracted into the ascending aorta to relieve the obstruction. The majority of coronary obstruction cases result in emergency cardiopulmonary bypass. If interventional measures fail to reconstitute coronary flow, emergent coronary artery bypass grafting or open removal of a malpositioned valve prosthesis is required.

## Conduction Abnormalities

Considering the anatomic proximity of the conduction system to the aortic valve, it is not surprising that conduction abnormalities such as AV or bundle-branch block are known complications of TAVI even in the absence of surgical excision of valve or annulus tissue. The requirement for permanent pacing has been described as necessary in up to 20% of patients. The occurrence of new-onset left bundle-branch block (LBBB) during the procedure may occur in up to 40% of patients. Possible explanations include transient periprocedural inflammation, edema, and mechanical stress due to balloon or stent trauma or myocardial necrosis in the basal interventricular septum due to ischemia. In addition, this population of elderly patients, all with underlying organic heart disease, frequently exhibit pre-existing conduction abnormalities that are known to be associated with aortic stenosis.

There are no definitely known risk factors for peri- and postprocedural complete heart block; however, the occurrence of intraprocedural complete heart block, even when it is transient, and the presence of right bundle-branch block seem to be predisposing factors. In addition, relatively low positioning of the

valve within the left ventricular outflow tract and efforts to oversize the implanted prosthesis to securely fix it within the aortic annulus and thus minimize paravalvular regurgitation might play a role.

Prior to the implantation procedure, conduction abnormalities should be thoroughly documented by a 12-lead ECG to diagnose pre-existing AV block or left and right bundle-branch block. Intra- and postprocedural monitoring with a 3-lead rhythm strip has to be done continuously up to 5 days after the procedure since there have been case reports describing the late occurrence of complete heart block after TAVI. Other pre-existing episodes of bradycardia such as sinus node disease or symptomatic bradyarrhythmia may have been undetected in some patients before the procedure and are unrelated to TAVI. If there is an indication for a pacemaker implantation postoperatively, it is important to distinguish between a new-onset high-grade AV block, which may be related to TAVI, and other pre-existing bradycardias unrelated to TAVI.

A new-onset LBBB is not an indication for the implantation of a permanent pacemaker; the clinical implications of new-onset LBBB are currently unknown, but its occurrence after surgical aortic valve replacement is associated with 1-year mortality. Taking care not to implant the prosthesis too deeply may help to prevent the occurrence of high-grade AV block. Adequate sizing of the balloon and valve are mandatory to avoid serious complications such as valve migration or severe paravalvular leak. As with the use of relatively larger valve sizes, the risk of damage to the conduction system due to balloon and frame trauma might be higher; therefore, the balance between the anticipated complications must be considered carefully. Whether or not immediate pacemaker implantation is indicated even in cases of intermittent AV block is the subject of ongoing debate. In our opinion, with this population of elderly patients, all with underlying organic heart disease, we opt for patient safety.

## Rhythm Disturbances

Patients scheduled for TAVI are considered to be a high-risk population with multiple comorbidities. One-half of these patients have coronary artery disease, one-third have atrial fibrillation, and up to one-fifth have left ventricular dysfunction and concomitant valve disease.

### *Atrial Fibrillation*

Atrial fibrillation (AF) is known to increase the risk of stroke, which makes it difficult to distinguish between TAVI-related cerebrovascular accident (CVA) and AF-induced thromboembolic stroke. Keeping the higher stroke risk in mind, specific attention should be paid to anticoagulation management with Coumadin and recommended antiplatelet therapy. So far, there are no data concerning the optimal combination or duration of antiplatelet therapy and anticoagulation after the implantation of a catheter-based aortic bioprosthesis, especially in a population with a high risk of major bleeding events. When there is an indication for Coumadin intervention after TAVI, we first ensure that no bleeding complications have occurred (i.e., pericardial tamponade, bleeding at the vascular access site) and that the antiplatelet loading dose has been administered before initiating Coumadin. Patients who warrant anticoagulation therapy only receive aspirin in combination with Coumadin because we consider the risk of Coumadin therapy combined with a dual antiplatelet therapy to be too high.

### *Ventricular Tachycardia (VT), Ventricular Fibrillation (VF)*

Considering the incidence of left ventricular dysfunction and significant coronary artery disease in these patients, spontaneous and sustained ventricular tachycardia (VT) and ventricular fibrillation (VF) occur rather seldom during TAVI procedures (1-2%). Short self-limited VT is common, especially when manipulating the guide wire loop within the left ventricle. Sustained VT or even VF can follow the iatrogenic VT induced by rapid ventricular pacing, particularly in patients with preoperatively compromised left ventricular function. Of course, VT or VF can always be indicative of severe coronary ischemia during the intervention. Patients who have received an implantable cardioverter defibrillator prior to TAVI should have the antitachycardia algorithms turned off during the intervention so as not to interfere with the episodes of rapid ventricular pacing.

## Conclusion

While TAVI is a promising therapy for high-risk patients who are not candidates for traditional open surgery, the procedure has inherent challenges that must be overcome before it can be considered a truly safe alternative. It is the responsibility of the heart team to collectively work towards decreasing the complication rate of TAVI and ensuring a safe and effective alternative therapy for patients.

**Conflict of Interest Disclosure:** All authors have completed and submitted the *Methodist DeBakey Cardiovascular Journal* Conflict of Interest Statement and the following was reported: Dr. Laborde is a consultant for Medtronic, Inc.

**Funding/Support:** The authors have no funding disclosures.

**Keywords:** transcatheter aortic valve implantation, TAVI, TAVR, aortic stenosis, Medtronic CoreValve, Lasso technique, paravalvular regurgitation

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