

Chapter 17: Management of Procedural Complications in the Cath Lab / Hybrid OR

Syed Zaid, MD¹, Amit Pawale, MD², Gilbert H. L. Tang, MD, MSc, MBA²

¹Department of Medicine, Westchester Medical Center, New York Medical College, Valhalla, NY, USA

²Department of Cardiovascular Surgery, Mount Sinai Health System, Icahn School of Medicine at Mount Sinai, New York, NY, USA

Introduction

With advances in imaging, valve delivery sheaths and systems, and improvements in implantation techniques, major procedural complications during TAVR have significantly decreased in frequency [1-3]. Nevertheless, when complications do arise they must be managed expeditiously using the combined skill set of the cardiologist and surgeon involved in TAVR. This chapter focuses on the most significant procedural complications in TAVR, with a discussion of associated risk factors, diagnosis and management.

How to Prevent Complications

First and foremost, most complications in TAVR are now preventable. With multidetector computed tomography (MDCT) evaluation now a standard part of pre-case planning, accurate assessment of aortic root morphology, coronary heights, and vascular access options provide a thorough assessment of potential procedural challenges and areas where complications may arise. Intraprocedural complications can be reduced by good team communication, meticulous vascular access techniques, consistent conduct in valve crossing and wire exchanges, and utilizing multimodality imaging including fluoroscopy and echocardiography. Mostly importantly, however, the prevention of intraprocedural complications can be reduced through pre-procedural team briefings or time-outs where the patient's history and diagnostics studies are reviewed with members of the procedural team so that special case considerations can be discussed. Having a contingency plan that is communicated in advance, in cases of complications such as acute pericardial effusion, coronary obstruction, or cardiac failure requiring mechanical circulatory support, may potentially transform a disastrous situation into a successful outcome. In addition, pre-procedural briefings provide an opportunity to ensure that the necessary equipment for managing complications, such as endovascular rescue devices, are in the room and readily available.

Complications

Vascular Access

Risk factors

The severity of femoral and iliac artery calcification, tortuosity and small dimensions can predict vascular injury. Sheath and delivery system sizes relative to the vessel size (sheath-to-artery ratio) have been predictive of vascular complications. The newer generation transcatheter valves, with smaller sheath sizes and delivery systems (Edwards Sapien 3: 14 French eSheath, 5.5 mm minimum for 23 mm and 26 mm valve, 6.0 mm for 29 mm valve; Medtronic Evolut R: 14 French equivalent Inline sheath, 5.0

mm minimum for 23, 26, 29 mm valves, 5.5 mm minimum for 34 mm valve; Medtronic Evolut Pro: 16 French equivalent Inline sheath, 5.5 mm minimum for 23, 26, 29 mm valves), have resulted in reduced major vascular complications [1-3]. Circumferential vessel calcification and anterior femoral artery calcification are especially prone to access site complications (Figure 1). Additionally, caution must be exercised in patients with previous endovascular aortoiliac repairs or unrepaired aortoiliac aneurysms.

Diagnosis

The immediate method of diagnosis is angiography to evaluate vessel perforation, dissection or stenosis. In general, this diagnosis can be made rapidly through re-positioning the pigtail catheter in the aortic annulus to just above the iliac bifurcation. Alternatively, an omni catheter can be placed in the contralateral femoral artery and used for dye injection and potential peripheral intervention. Acute hypotension without other causes may also suggest major bleeding due to a vessel disruption.

Management

Depending on the complication, the management strategy is different. Stenosis can likely be managed by balloon angioplasty to improve luminal flow. Dissection may be conservatively managed if not angiographically significant, or gentle balloon angioplasty can be used to re-approximate the dissection flap to the vessel wall. Disruption or perforation will likely require endovascular stenting with a covered stent to seal off the bleeding site. If endovascular techniques are unable to address the problem, an open cutdown by a vascular surgeon may be necessary. An endovascular rescue device, such as a Coda balloon, placed via the contralateral femoral artery, can be used to occlude flow proximal to the area of vascular injury and control hemorrhage as well as allow for time and planning of definitive endovascular or surgical repair. At the beginning of vascular access, placing a cross-over wire from the contralateral groin to the distal superficial femoral artery of the access side, may enable timely management of access site-related complications [4].

Annular Injury/Rupture

Risk factors

With routine MDCT analysis, the incidence of annular injury has significantly decreased. However, severe annular, LVOT and base of leaflet calcification may increase the risk of annular injury, particularly with balloon-expandable valves, significant valve oversizing, and aggressive balloon post dilatation after valve deployment [5,6] (Figure 2). Nonagenarians and patients on chronic steroids or immunosuppression are also particularly vulnerable to annular injury, given the more delicate tissue quality. In TAVR with a balloon-expandable valve, the sinotubular junction (STJ) dimension and sinus height need to be considered in relationship of the height and size of the transcatheter valve. Significant valve oversizing in a small STJ, may risk balloon and stent frame interaction with the STJ and cause acute aortic injury and dissection. Similarly, in severe annular and LVOT calcification, significant valve oversizing may risk ventricular septal defect, or aorto-ventricular fistula (Figure 3).

Diagnosis

Patients usually develop acute hypotension if there is annular rupture or aortic dissection. TEE is invaluable in assessing for new pericardial effusion or tamponade, aortic root hematoma, and aortic dissection.

Management

High-risk, emergency surgery is usually necessary in these situations to fix the underlying pathology if the patient is a surgical candidate, which, often may not be the case since the patient is undergoing TAVR. In patients with aortic root hematoma but no rupture, permissive hypotension, reversal of heparin, platelet / coagulant factor transfusion and close observation may lead to resolution. In certain circumstances, placing a balloon-expandable transcatheter valve more ventricular in position to seal off the junction between the LVOT and annulus may address the problem [6].

Coronary Obstruction

Risk factors

With MDCT analysis, the risk of coronary obstructive in TAVR in native aortic valve remains low. Left main or right coronary protection in patients with high risk aortic root anatomy has mitigated against such potentially catastrophic complication. Low coronary height, narrow sinus of Valsalva, small STJ, and low sinus height are all risk factors for coronary obstruction (Figure 4). In patients with favorable aortic root anatomy, bulky leaflet calcification, especially at the leaflet tips, combined with an oversized transcatheter valve, may also risk coronary occlusion.

Transcatheter aortic valve-in-valve replacement is at a higher risk of coronary obstruction than TAVR in native aortic valve [7]. This is due to stenting of the leaflets of the surgical prosthesis to create a “cylinder” effect in the aortic root. Insufficient distance between the stented leaflets and the STJ and coronary orifice may risk coronary obstruction. The risk is also higher if the STJ is small and the sinus height is low, potentially compromising diastolic flow to the coronary arteries after valve deployment (Figure 5).

Diagnosis

To minimize the risk of coronary obstruction in native valve TAVR, avoid significant oversizing in the setting of high risk aortic root anatomy, or select a self-expanding valve that allows recapturing and retrieval if coronary obstruction is imminent. In aortic valve-in-valve procedures, pre-procedural semi-selective coronary angiography lining up 2 commissural posts facing the left main orifice gives an idea of the coronary obstruction risk. MDCT can also accurately measure the distance between the surgical prosthesis and STJ and the sinus height to determine coronary obstruction risk.

During the procedure, coronary obstruction will manifest as acute hypotension, ST segment elevation, ventricular arrhythmias, and cardiac arrest. Aortic root and selective coronary angiography provide the diagnosis.

Management

If coronary protection a priori is performed, stenting will be the first option. In situations of hemodynamic instability or collapse, placing the patient emergently on mechanical circulatory support may be life-saving, since this option allows the operators time to intervene on the obstruction. If a wire and coronary stent are unable to pass through the area of obstruction, surgical management is usually necessary. A simple and effective way to surgically address this complication is to resect the offending calcium obstructing the coronary orifice, thereby avoiding coronary artery bypass grafting to restore coronary perfusion [8].

Ventricular Perforation

Risk factors

Perforation of the left ventricle is rare in TAVR and is usually iatrogenic. Aggressive wire and catheter handling inside the left ventricle risks perforation. Aggressive insertion of the temporary transvenous pacing wire can also cause perforation of the right ventricle. Patients with connective tissue abnormalities, on chronic steroids, or on immunosuppression are at higher risk of such a complication.

Diagnosis

Intraprocedural echocardiography will detect a new pericardial effusion and the patient may present with progressive hypotension requiring vasopressor support. Pericardiocentesis with bloody effusion confirms the diagnosis. In patients with right ventricular perforation, diagnosis is usually delayed until after the transvenous pacing wire has been removed and detected on post TAVR echocardiography.

Management

Patients with right ventricular perforation may be managed by reversing anticoagulation, pericardiocentesis and close observation to monitor the patient's hemodynamics and hemoglobin level. If the patient remains stable, the pericardial drain may be removed in 48-72 hours. Anticoagulation should be avoided for at least 7 days to promote healing. Left ventricular perforation usually necessitates immediate drainage of pericardial fluid and surgery to identify the site of injury to undergo primary repair. Patients with hemodynamic instability or in cardiac arrest will require emergency mechanical circulatory support.

Valve Malposition

Risk factors

Malposition of transcatheter valve during TAVR has become rare due to simplified implantation techniques and innovation in some delivery systems to allow device repositioning, recapture and retrieval.

Diagnosis

Acute malposition can be confirmed by aortography and TEE to evaluate transcatheter valve position and confirm valve stability in the aortic annulus. In certain situations, severe paravalvular leak (PVL) or coronary obstruction may result, causing hemodynamic instability.

Management

Self-expanding valves may be snared in the aortic direction if implanted too ventricular or aortic. With the ability to reposition, recapture and retrieve, this complication has become exceedingly rare. In balloon-expandable valves, a second transcatheter valve is usually necessary. However, the risk of coronary obstruction should be assessed prior to implantation. In certain situations, such as extreme ventricular deployment or valve embolization, surgery to extract the prosthesis and conventional aortic valve replacement may be necessary.

Significant Paravalvular Leak

Risk factors

With newer generation transcatheter valves such as Edwards Sapien 3, Medtronic CoreValve Evolut R Pro and Boston Scientific Lotus, the incidence of moderate or greater paravalvular leak (PVL) has significantly decreased. However, challenging aortic root anatomy, such as bicuspid aortic valves or severe leaflet or annular / LVOT calcification, may result in severe PVL necessitating treatment.

Diagnosis

Intraprocedural echocardiography can confirm severity and location of PVL.

Management

Balloon post dilatation is the preferred first-line treatment of severe PVL. In cases of persistent valve under-expansion after post dilatation, a second transcatheter valve implantation within the existing prosthesis may be necessary. Otherwise, surgery is always an alternate solution.

Summary

While the incidence of intra-procedural complications during TAVR has decreased with growing operator experience, device innovation, and pre-procedural imaging, complications still occur and must be managed expeditiously. Complications in TAVR can be minimized through meticulous pre-case planning, good team communication and procedural conduct, and anticipation of potential challenges and their management solutions.

References:

1. Tang GH, Lansman SL, Panza JA. Beyond PARTNER: appraising the evolving trends and outcomes in transcatheter aortic valve replacement. *Cardiol Rev* 2015;23(1):1-10.
2. Herrmann HC, Thourani VH, Kodali SK, Makkar RR, Szeto WY, Anwaruddin S, Desai N, Lim S, Malaisrie SC, Kereiakes DJ, Ramee S, Greason KL, Kapadia S, Babaliaros V, Hahn RT, Pibarot P, Weissman NJ, Leipsic J, Whisenant BK, Webb JG, Mack MJ, Leon MB; PARTNER Investigators. One-year clinical outcomes with Sapien 3 transcatheter aortic valve replacement in high-risk and inoperable patients with severe aortic stenosis. *Circulation* 2016;134(2):130-40.
3. Popma JJ, Reardon MJ, Khabbaz K, Harrison JK, Hughes GC, Kodali S, George I, Deeb GM, Chetcuti S, Kipperman R, Brown J, Qiao H, Slater J, Williams MR. Early Clinical Outcomes After Transcatheter aortic valve replacement using a novel self-expanding bioprosthesis in patients with severe aortic stenosis who are suboptimal for surgery: results of the Evolut R U.S. Study. *J Am Coll Cardiol Interv* 2017;10:268-75.
4. Genereux P, Kodali S, Leon MB, Smith CR, Ben-Gal Y, Kirtane AJ, Daneault B, Reiss GR, Moses JW, Williams MR. Clinical outcomes using a new crossover balloon occlusion technique for percutaneous closure after transfemoral aortic valve implantation. *J Am Coll Cardiol Interv* 2011;4(8):861-7.
5. Barbanti M, Yang TH, Rodès Cabau J, Tamburino C, Wood DA, Jilaihawi H, Blanke P, Makkar RR, Latib A, Colombo A, Tarantini G, Raju R, Binder RK, Nguyen G, Freeman M, Ribeiro HB, Kapadia S, Min J, Feuchtner G, Gurtvich R, Alqoofi F, Pelletier M, Ussia GP, Napodano M, de Brito FS Jr, Kodali S, Norgaard BL, Hansson NC, Pache G, Canovas SJ, Zhang H, Leon MB, Webb JG, Leipsic J. Anatomical and procedural features associated with aortic root rupture during balloon-expandable transcatheter aortic valve replacement. *Circulation*. 2013;128(3):244-53.
6. Pasic M, Unbehaun A, Buz S, Drews T, Hetzer R. Annular rupture during transcatheter aortic valve replacement: classification, pathophysiology, diagnostics, treatment approaches, and prevention. *J Am Coll Cardiol Interv* 2015;8(1):1-9.
7. Paradis JM, Del Trigo M, Puri R, Rodés-Cabau J. Transcatheter valve-in-valve and valve-in-ring for treating aortic and mitral surgical prosthetic dysfunction. *J Am Coll Cardiol*. 2015;66(18):2019-37.
8. Tang GH, Ahmad H, Cohen M, Undemir C, Lansman SL. Calcium resection to relieve left main coronary obstruction in transcatheter aortic valve replacement. *J Card Surg* 2016;31(5):315-7.

Figure 1. Representative examples of difficult femoral access for TAVR. In (A), patient has severe bilateral iliofemoral calcifications with small vessel diameters < 5mm. Balloon angioplasty was required prior to insertion of the 11/19-French balloon-expandable and recollapsible Terumo Solopath introducer sheath (B), followed by successful implantation of Evolut R CoreValve without vascular complication. In another example (B), a patient with prior endovascular aortic repair (EVAR) with Endologix stent graft underwent successful TAVR with CoreValve using the Solopath sheath, given its working length extending beyond the proximal end of the EVAR graft and also the smallest insertion profile of currently available introducer sheaths for TAVR.

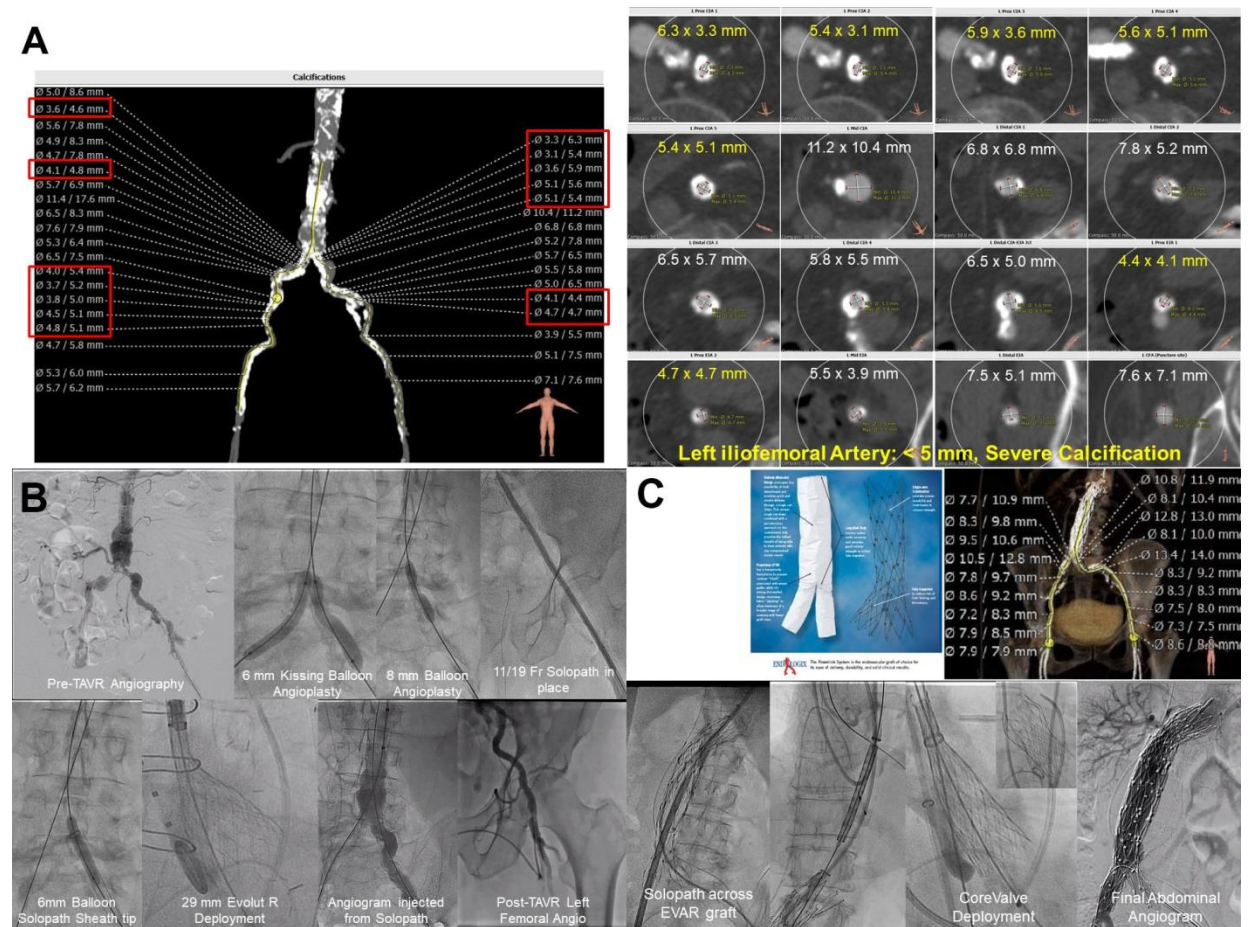


Figure 2. Two representative examples of severe annular and left ventricular outflow tract (LVOT) calcification risking annular injury after TAVR. In patient A, horseshoe calcification at the annulus is seen which can risk injury from aggressive valve oversizing. In patient B, nodular calcification may be less of a concern with newer generation transcatheter valves (Edwards Sapien 3, Medtronic Evolut Pro) with sealing cuffs or wrap, provided the implanted valve is not significantly oversized (<15% by area for Sapien 3) and avoiding aggressive balloon post dilatation. The severe LVOT calcification may make this case more suitable for a self-expanding transcatheter valve given a lower risk of annular and LVOT injury.

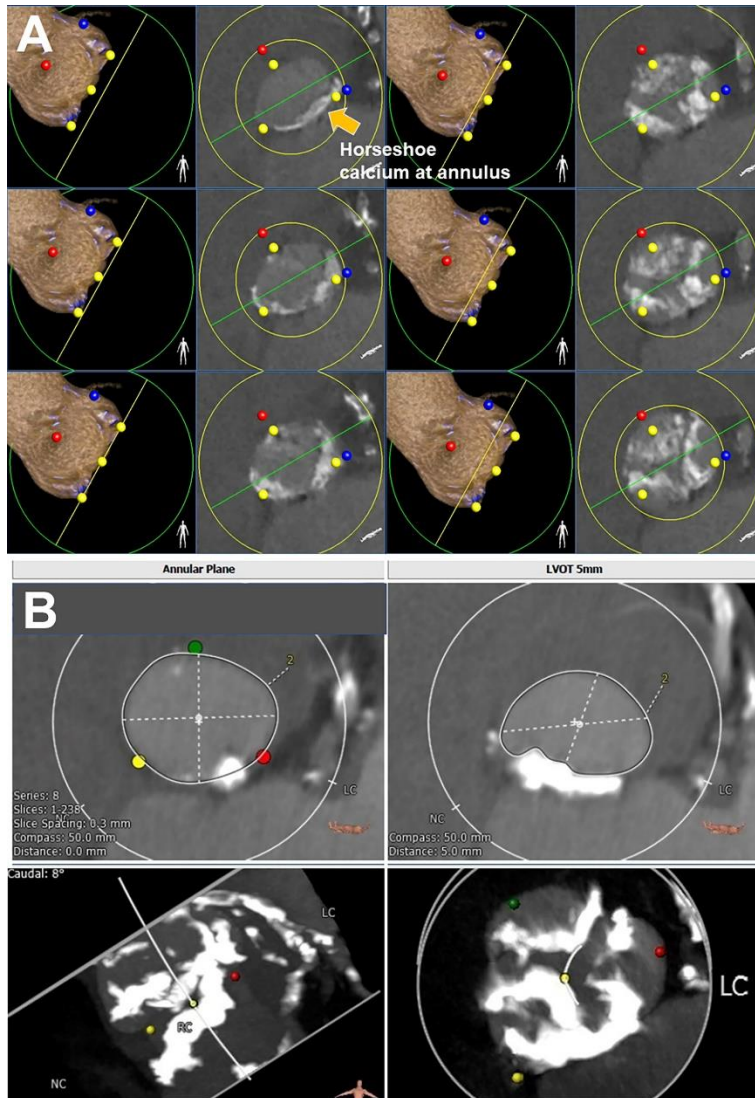


Figure 3. Aorto-ventricular fistula developed after TAVR with an Edwards Sapien 3 valve in a 98 year-old frail patient. Transthoracic echocardiography (A) showed a pan-systolic high-velocity aorto-right ventricular jet and multidetector computed tomography (B) identified the calcium at the base of the right coronary cusp that may have resulted in the fistula formation (red arrow). Blue arrow denoted subclinical leaflet thickening of the non coronary cusp. N = non coronary cusp, RV = right ventricle, LV = left ventricle, LA = left atrium, R = right coronary cusp, L = left coronary cusp.

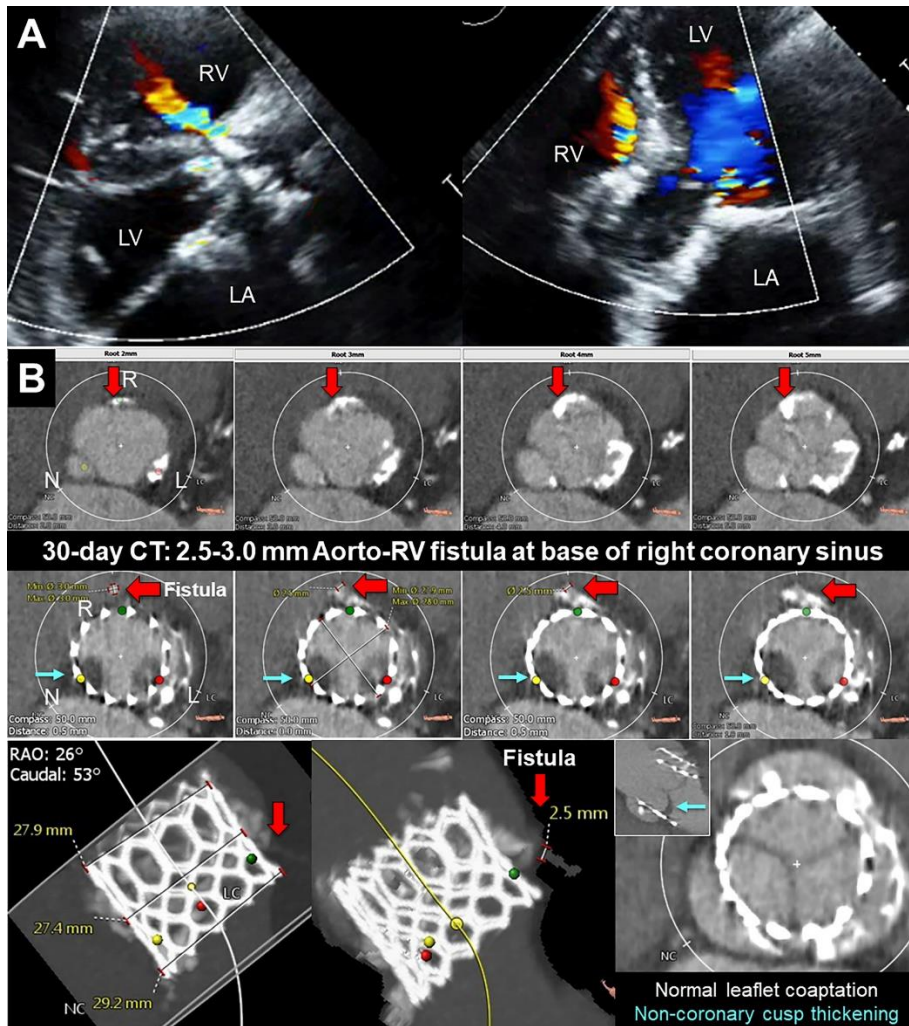


Figure 4. Two examples of left main coronary anatomy at risk of coronary obstruction. Patient A has a low left main height of 7.8 mm and low sinus height of 14.0 mm. Virtual placement of a 20 mm Edwards Sapien 3 valve suggests a high risk of left main occlusion. A prior coronary protection would be recommended in this case. On the other hand, patient B has a normal left main height of 11.5 mm. Because of the bulky calcium at the leaflet tip facing the left sinus (red circle), the risk of left main obstruction remains high especially with a balloon-expandable valve. Left main coronary protection would therefore also be recommended in this case.

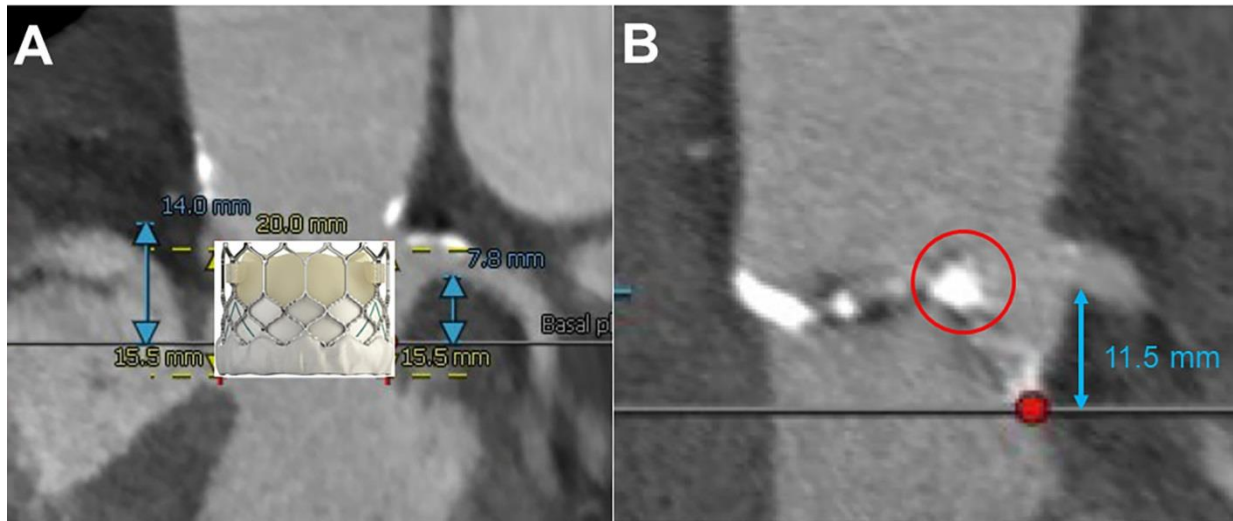


Figure 5. Evaluation of coronary obstruction risk in aortic valve-in-valve (AVIV) TAVR. Dashed yellow lines (A,B) illustrate the projected height and position of the leaflets of the surgical bioprosthesis after transcatheter aortic valve implantation. Semi-selective coronary angiography confirms low (A) vs high (B) coronary obstruction risk, as shown by the dashed red circle. Multidetector computed tomography can determine the virtual valve to sinotubular junction (STJ) distance to evaluate diastolic flow after AVIV TAVR. Drawing a box within the bioprosthetic valve (C,D) to illustrate the prosthetic leaflet height and position, the virtual valve to STJ distance is respectively 4.0 mm (C) and 2.7 mm (D), corresponding to moderate and high risk of coronary obstruction. Using a repositionable and recapturable self-expanding valve allows one to evaluate coronary flow by aortography (blue arrow) before release (E), and determine if coronary protection will be necessary. Following valve release, a completion aortography at the same projection angle confirms coronary patency.

