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THE PRESENT AND FUTURE

STATE-OF-THE-ART REVIEW

Coronary Angiography and Percutaneous Coronary Intervention After Transcatheter Aortic Valve Replacement

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ABSTRACT

Transcatheter aortic valve replacement (TAVR) has revolutionized the management of patients with symptomatic severe aortic stenosis, and indications are expanding towards treating younger patients with lower-risk profiles. Given the progressive nature of coronary artery disease and its high prevalence in those with severe aortic stenosis, coronary angiography and percutaneous coronary intervention will become increasingly necessary in patients after TAVR. There are some data suggesting that there are technical difficulties with coronary re-engagement, particularly in patients with self-expanding valves that, by design, extend above the coronary ostia. The authors review the challenges of coronary angiography and percutaneous coronary intervention post-TAVR and examine the geometric interactions between currently approved transcatheter aortic valves and coronary ostia, while providing a practical guide on how to manage these potentially complex situations. (J Am Coll Cardiol 2018;71:1360–78) © 2018 by the American College of Cardiology Foundation.

Transcatheter aortic valve replacement (TAVR) has revolutionized the treatment of symptomatic severe aortic stenosis (AS). It is now the standard of care for patients who are not surgical candidates, and is comparable to surgical aortic valve replacement in high- and intermediate-risk patients (1–6). The prevalence of coronary artery disease (CAD) in patients with severe AS is high (7). Even in the most recent randomized trials comparing TAVR to surgery in intermediate-risk patients, >60% have coexisting CAD (5,6). The prognostic significance and optimal management of CAD in this population remain controversial (7,8). The recent appropriate use criteria guidelines suggest that it is reasonable to offer revascularization before TAVR, even if there is no evidence of ischemia and only low-risk, noninvasive findings (9).

Furthermore, management of symptomatic CAD after TAVR has not been systematically examined. As TAVR indication expands to lower-risk patients who have better long-term prognoses, there will be an increasing need for repeat coronary angiography and percutaneous coronary intervention (PCI) due to progressive CAD and development of acute coronary syndrome.

This paper aims to: 1) provide an overview of the incidence and management of CAD in patients undergoing TAVR; 2) summarize the worldwide experience with coronary angiography and PCI in patients after TAVR; 3) analyze the 3-dimensional geometric relationship among U.S. Food and Drug Administration-approved transcatheter valves (Medtronic CoreValve self-expanding valve [Medtronic, Galway, Ireland] and Edwards Sapien 3 balloon-expandable valve

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[Edwards Lifesciences, Irvine, California]), the aortic root, and coronary ostia; and 4) provide a practical and systematic approach to coronary angiography and PCI in patients after TAVR.

MANAGEMENT OF CAD IN PATIENTS WITH SEVERE AS UNDERGOING TAVR

PREVALENCE AND PROGNOSTIC SIGNIFICANCE OF CAD IN PATIENTS WITH AS. The prevalence of CAD in patients with severe AS undergoing TAVR ranges from 40% to 75% (7). Given its high prevalence, it is paramount to first ascertain the prognostic significance of CAD and second define the optimal way to manage CAD in patients undergoing TAVR. To date, however, there is no clear consensus on either clinical question, despite several reviews on the topic (7,8,10,11).

The heterogeneity in the definition of CAD across randomized trials and observational studies in patients undergoing TAVR is a major limitation in determining its prognostic significance (12). In a meta-analysis of 2,472 patients from 7 observational studies, CAD was evident in 52% of patients and was defined as: a history of previous PCI or bypass surgery in 4 studies; presence of 50% stenosis in ≥1 epicardial vessel in 2 studies; or a combination of previous revascularization or 50% coronary stenosis in 1 study. With this limitation, the presence or absence of CAD was not associated with an increased risk of death (odds ratio [OR]: 1.0; 95% confidence interval [CI]: 0.67 to 1.50) at a median follow-up of 452 days.

SYNTAX SCORING IN PATIENTS UNDERGOING TAVR. Using the SYNTAX score (SS) to more accurately define CAD has provided further insight into the association between baseline CAD, post-PCI residual CAD, and clinical outcomes, but not all studies were uniformly consistent. Stefanini et al. (13) showed a linear relationship between SS and major adverse cardiovascular events (MACE) at 1 year in patients undergoing TAVR; this was predominantly driven by higher cardiovascular mortality (no CAD 12.5%, low SS 16.1%, high SS 29.6%; p = 0.016). Interestingly, patients with a higher SS (>22) received more incomplete revascularization, and those with a residual SS in the higher tertile (>14) had significantly higher MACE rates (13). In another retrospective analysis from the United Kingdom, the angiographic presence or absence of CAD (>70% epicardial artery stenosis and/or >50% left main stenosis) was not associated with adverse outcomes after TAVR (14). However, when stratified by SS, patients with a score >33 experienced a higher risk of death at both 30 days and 12 months when compared with those with intermediate and low SS (14). Furthermore, after a receiver-operating curve analysis, patients with an SS >9 were identified as having a higher risk of death (14). In the largest (N = 1,270) and most recent study, Witberg et al. (15) added weight to the association between SS and clinical outcomes. Severe CAD, defined as SS >22, was associated with increased mortality at a median follow-up of 1.9 years, even after multivariate analysis (hazard ratio: 2.09; 95% CI: 1.14 to 3.84; p = 0.02). In agreement with the 2 previous studies, incomplete revascularization (residual SS >8) was an independent predictor of mortality (hazard ratio: 1.72; 95% CI: 1.05 to 2.81; p = 0.03). Contrary to these positive studies, Paradis et al. (16) showed that when SS was assessed by a core laboratory, there was no longer a positive association with higher rates of MACE (mortality, myocardial infarction [MI], or stroke) at either 30 days or 1 year. In the small number of patients who underwent PCI (54 of 377), complete revascularization, defined as a residual SS <8, was also not associated with improved outcomes (16).

APPROPRIATE USE CRITERIA IN PCI BEFORE TAVR. Despite the inconsistent findings on the prognostic significance of CAD and effect of revascularization before TAVR, even when using SS, the 2017 appropriate use criteria deemed revascularization before TAVR predominantly appropriate (9). Consequent to these recommendations, a systematic review and meta-analysis of revascularization before TAVR found that of 3,858 patients from 9 studies with CAD, defined as coronary stenosis ranging from 50% to 90%, only 983 (25.5%) received revascularization before TAVR (10). There was no significant clinical benefit derived from revascularization with respect to 30-day cardiovascular death (OR: 1.03; 95% CI: 0.35 to 2.99), MI (OR: 0.86; 95% CI: 0.14 to 5.28), or stroke (OR: 1.07; 95% CI: 0.38 to 2.97). There was, however, an increase in 30-day all-cause mortality (OR: 1.42; 95% CI: 1.08 to 1.87; p = 0.01) with PCI, but this was no longer evident at 1 year (OR: 1.05; 95% CI: 0.71 to 1.56). More importantly, there was also a significant increase in major vascular complications in patients who underwent PCI (OR: 1.86; 95% CI: 1.33 to 2.6; p < 0.001).

It is clear that there is clinical equipoise regarding management of CAD before TAVR. The ACTIVATION (Percutaneous Coronary Intervention Prior to Transcatheter Aortic Valve Implantation; ISRCTN75836930) trial is currently randomizing patients with CAD and severe AS to either pre-TAVR PCI or no

ABBREVIATIONS AND ACRONYMS

AR = Amplatz right
AS = aortic stenosis
CAD = coronary artery disease
CI = confidence interval
CT = computed tomography
JL = Judkins left
JR = Judkins right
LCA = left coronary artery
MACE = major adverse cardiovascular events
MI = myocardial infarction
PCI = percutaneous coronary intervention
RCA = right coronary artery
SS = SYNTAX score
STJ = sinotubular junction
TAVR = transcatheter aortic valve replacement

TABLE 1 Summary of the Largest Published Studies (N > 5 Patients) on Coronary Angiography and PCI After TAVR

First Author (Ref. #), Year Published	No. of Patients (Valve Used)	Study Summary on Feasibility of Coronary Angiography and PCI	Catheters Used
Chetcuti et al. (18), 2016	169 (CoreValve [Medtronic, Galway, Ireland])	190 coronary angiography or PCI; PCI attempted in 113 cases 75 cases in 72 patients with both catheterization reports and angiography reviewed Successful coronary angiography: • 97.9% (186 of 190) possible in overall group • 96.0% (72 of 75) possible from catheterization reports and angiography reviewed Successful PCI: • 91.2% (103 of 113) possible in overall group • 81.6% (31 of 38) possible among the 75 cases reviewed	LCA (N = 74): • Judkins 59.5% • FL4 4.1% • EBU 4.1% • Amplatz 1.4% • Other 6.8% • Unknown 24.3% RCA (N = 70): • Judkins 42.9% • Amplatz 5.7% • Williams 1.4% • FR4 1.4% • EBU 1.4% • Unknown 47.1%
Zivelonghi et al. (19), 2017	66 41 (Sapien 3 [Edwards Lifesciences, Irvine, California]) 25 (Evolut R [Medtronic])	Angiogram and FFR assessed pre- and post-TAVR Successful coronary angiography: • 98.0% (65 of 66) successful diagnostic angiogram performed (6 semiselective angiograms requiring wiring [2 cases with Sapien 3 and 4 cases with Evolut R) • 1 nondiagnostic angiogram with Evolut R (presumed due to high valve implantation) Successful PCI: • 100% (17 of 17 [5 Evolut R, 12 Sapien 3) with 5 cases requiring rotational atherectomy (3 Evolut R, 2 Sapien 3)	• Initial strategy was to use EBU and JR catheters Sapien 3: • standard catheters used Evolut R: • 6 of 25 cases needed a change of catheter (from EBU to JL) • Generally, a smaller catheter was used (JL3.5 instead of JL4 and EBU3.0 instead of EBU3.5) • For horizontal aorta: JL3.5 and 3DRC
Blumenstein et al. (20), 2015	35 19 (Sapien XT) 10 (CoreValve) 4 (Symetis Acurate [Boston Scientific, Marlborough Massachusetts]) 1 (Portico [Abbott, Lake Bluff, Illinois]) 1 (JenaValve [Irvine, California])	• 3.5% (35 of 1,000) patients required angiography and/or PCI post-TAVR • 33.0% (10 of 35) had angiography during index hospitalization • 76.0% (23 of 30) with delayed angiography had known CAD pre-TAVR. • 80.0% femoral access Successful coronary angiography: • Sapien XT: 100% (19 of 19) selective angiograms • Jena Valve: 100% (1 of 1) selective angiograms • CoreValve: 90.0% (9 of 10): 3 selective angiograms (1 used usual catheters, 2 required different catheter); 6 were nonselective angiograms; 1 nondiagnostic angiogram post-valve-in-valve procedure • Portico: 100% (1 of 1) nonselective due to interference between catheter and stent mesh. Needed microcatheter to stabilize system for PCI • Symetis Acurate: 100% (4 of 4): 2 selective angiograms; 2 nonselective angiograms due to prosthesis being too high Successful PCI: • 100% (10 of 10 [8 Sapien XT, 1 Portico, 1 Symetis Acurate]); no self-expanding valve patient required PCI	Sapien XT: • Standard catheters used CoreValve: • LCA: JL3.5 • RCA: AR1 Portico: • LCA: JL3.5 • RCA: AR 1 Symetis Acurate: • LCA: AL2 • RCA: AR1
Htun et al. (21), 2017	28 (CoreValve)	43 coronary angiographies in 28 patients: Successful coronary angiography: • 97.0% selective engagement of LCA • 90.0% selective engagement of RCA Successful PCI: • 29 of 29 (100%) lesions	LCA: • JL (86.0%), EBU, AL2, GuideLiner RCA: • JR4 (93.0%), 3DRC, IM
Allali et al. (22), 2016	17 (CoreValve)	24 PCI procedures to 29 lesions Indication: STEMI 8.3%; NSTEMI 20.8%. Median time: TAVR to PCI = 17.7 months (range: 1–72 months) Successful PCI: • Procedural success 95.8% (1 periprocedural death) • 9 of 15 cases required different guides to pre-TAVR PCI • 4 cases: suboptimal support • 1 case: rotational atherectomy	LCA: • JL (95.0%) • EBU (5.0%) RCA: • JR4.0/JR4.5 (67.0%) • AR2 (33.0%)
Boukantar et al. (23), 2017	16 (CoreValve)	Indications: Angina: 3 NSTEMI: 7 Silent ischemia: 3 Worsening left ventricular function: 3 Successful coronary angiography: • 9 of 16 successful angiograms (no patient had selective engagement of both coronary arteries; only 2 had selective RCA engagement) Successful PCI: • 6 of 7, one failed PCI due to poor backup support related to nonselective LM cannulation	LCA: • EBU3.5/3.75 for all RCA: • No RCA PCI performed

Continued on the next page

TABLE 1 Continued

First Author (Ref. #), Year Published	No. of Patients (Valve Used)	Study Summary on Feasibility of Coronary Angiography and PCI	Catheters Used
Chakravarty et al. (24), 2016	9 4 (CoreValve) 5 (Sapien)	Left main PCI post-TAVR Indication: 7 of 9: NSTEMI 2 of 9: stable angina Successful PCI: • 9 of 9 (100% cases)	No details

3DRC = 3-dimensional right coronary; AL = Amplatz left; AR = Amplatz right; CAD = coronary artery disease; EBU = extra backup; FFR = fractional flow reserve; FL = femoral left; FR = femoral right; IM = internal mammary; JL = Judkins left; LCA = left coronary artery; LM = left main; NSTEMI = non-ST-segment elevation myocardial infarction; PCI = percutaneous coronary intervention; RCA = right coronary artery; STEMI = ST-segment elevation myocardial infarction; TAVR = transcatheter aortic valve replacement.

pre-TAVR PCI (17). Until the results of this trial are available, patients with CAD undergoing TAVR will need to be evaluated by a multidisciplinary heart team and receive individualized management based on their clinical and angiographic findings.

MANAGEMENT OF CAD IN PATIENTS AFTER TAVR

TAVR indications are expanding. In the past year in the United States, both balloon-expandable and self-expanding valves have been approved in patients at intermediate surgical risk (5,6). Furthermore, there are ongoing trials assessing TAVR in low-risk patients (PARTNER 3 [Placement of Aortic Transcatheter Valves (P3); NCT02675114] and the Medtronic Transcatheter Aortic Valve Replacement in Low Risk Patients trials [NCT02701283]), whereas the EARLY TAVR (Evaluation of Transcatheter Aortic Valve Replacement Compared to SurveilLance for Patients With AsYmptomatic Severe Aortic Stenosis; NCT03042104) trial compares TAVR to routine surveillance in patients with asymptomatic severe AS.

As previously discussed, the incidence of CAD in patients undergoing TAVR is high, even in those who are at intermediate risk (5,6). Given the progressive nature of CAD, a significant proportion of these patients will require coronary angiography and possibly PCI. However, there is a paucity of data documenting the feasibility of either coronary angiography and/or PCI after TAVR (**Table 1**) (18–24). Success rates have varied with challenges reported particularly with the self-expanding supra-annular valve.

CORONARY REACCESS IN SELF-EXPANDING VERSUS BALLOON-EXPANDABLE VALVES. In the largest observational study, Zivelonghi et al. (19) reported the feasibility of angiography in 66 patients immediately after TAVR (25 CoreValve Evolut R valves [Medtronic], 41 Sapien 3 [Edwards Lifesciences]). In 4% of vessels, selective angiography required positioning of a guidewire in the vessel and only 1 artery could not be engaged due to high implantation of the Evolut R. In this case, it was hypothesized that the leaflet base of the supra-annular valve landed at the level of origin of the coronary ostium. PCI was successful in all 17 patients, including in 6 with Evolut R. Encouragingly, rotational atherectomy was successfully performed in patients with both valves.

Blumenstein et al. (20), however, reported more difficulty with coronary angiography, particularly with self-expanding valves. Of 1,000 consecutive patients, only 35 (3.5%) required coronary angiography after TAVR at their center. This was feasible in all patients who received a balloon-expandable valve (n = 19) with only 1 patient requiring a different catheter for engagement. PCI was successfully performed in 5 patients. In the 10 patients with a self-expanding valve, only 3 patients had selective intubation of both coronary ostia, and 6 had semi-selective, but diagnostic angiograms with different catheters or an aortogram. In 1 patient, the coronary arteries could not be visualized due to the implantation of 2 self-expanding valves during the index case. None of these patients required PCI.

Boukantar et al. (23) also reported difficulty with the self-expanding valve, as only 9 of 16 patients had successful selective engagement of both coronary ostia. Furthermore, only 2 patients had selective engagement of the right coronary artery (RCA). PCI was consequently indicated in 7 patients, but was only successful in 6. The predominant issue with failed reaccess was a lack of guide catheter support. Given the difficulties encountered, it was not surprising that the investigators reported significantly higher fluoroscopic times, radiation dosage, and contrast medium use when compared with coronary angiography performed before TAVR.

Allali et al. (22) found 5.7% (n = 17) of patients post-TAVR with a self-expanding valve required PCI at a median follow-up of 17.7 months, the indication being acute coronary syndrome in 37.5% of cases. Of the 15

patients who also had interventions before TAVR, 9 required a different guiding catheter after TAVR. Of note, in almost all (18 of 19) left coronary lesions, a Judkins left (JL) catheter was used. In 1 case, a patient with known low right coronary ostia (9 mm) had an inferior ST-segment elevation MI complicated by ventricular fibrillation 2 days post-TAVR. The aortogram showed ostial RCA occlusion, but the artery could not be opened. It is plausible that the valve prosthesis was responsible for the occlusion, and the interplay with the ostium, which usually makes engagement challenging, was impossible in the context of hemodynamic instability and cardiopulmonary resuscitation. Less dramatic, but equally noteworthy, was the recurring issue of inadequate guide support reported in 4 cases. Although not universally used, a guide extension catheter (e.g., GuideLiner, Vascular Solutions, Minneapolis, Minnesota), has proven to be a helpful adjunct to PCI after TAVR (25).

Htun et al. (21) more recently showed that coronary angiography through a self-expanding valve was feasible with the selective engagement of the left coronary artery (LCA) and RCA in 97% and 90% of cases, respectively. Furthermore, PCI was successful in 29 lesions, and there were no issues reported with the use of intravascular ultrasound or instantaneous wave-free ratio. Notably, in 2 cases, a guide extension catheter was used to facilitate engagement and subsequent PCI.

Chetcuti et al. (18) previously presented results of 169 (4.5%) patients from the CoreValve US Trial program who required angiography ± PCI post-TAVR (18). Coronary access was achieved in 97.9% of cases, and PCI was only successful in 103 of 113 (91.2%). Of the 75 cases where coronary angiography and reports were reviewed independently, coronary reaccess was possible in 96.0% and PCI was successful in 31 of 38 (81.6%) cases.

Data from the TAVR-LM (Transcatheter Aortic Valve Replacement and Left Main Stenting) registry showed the feasibility of performing left main PCI in 9 cases at a median of 368 days after TAVR. Although full technical details were not described, it was worth noting that procedural success was achieved in patients with both balloon-expandable and self-expanding valves (24).

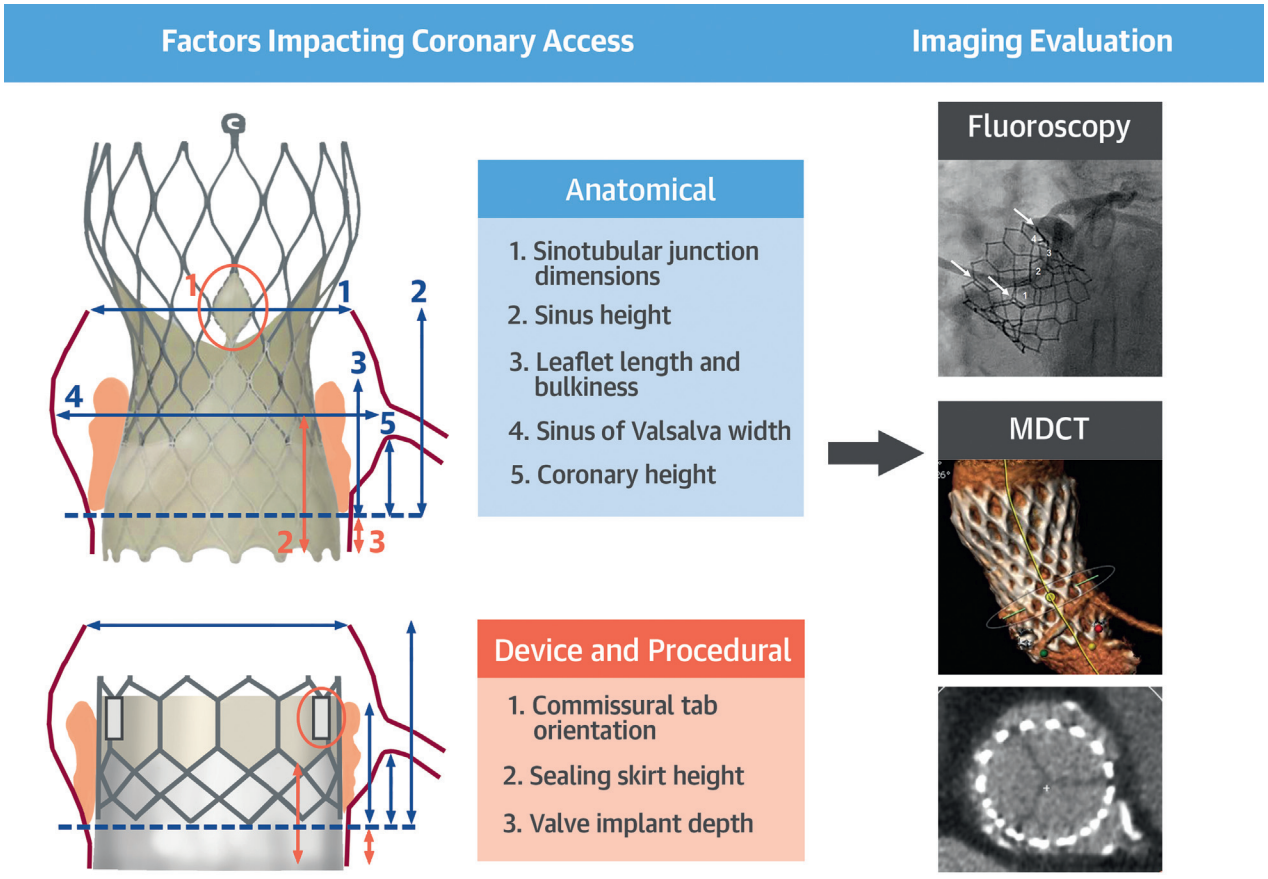
Since the first case report highlighting successful coronary angiography and PCI post-TAVR with a balloon-expandable valve in 2007, there have been numerous case reports and small case series published (Online Table 1) (25-40). The major themes of these case reports are the difficulties with a self-expanding valve regarding coronary engagement, guide support, and the need to use different catheters and/or guide extensions to optimize guide support. Despite these challenges, PCI appears feasible, even in complex disease such as chronic total occlusions (34). However, it should be noted that an extra backup catheter has caught on the stent frame in 2 cases, 1 directly contributing to a patient's death (34,35).

In patients with balloon-expandable valves, there have been recent case reports highlighting difficulties with selective coronary engagement (39,40). As the Sapien 3 valve becomes more widely used, it is possible that more coronary access issues will be encountered due to its higher frame height. Even in cases where the top of the valve frame was partly or completely positioned above the ostium, PCI was feasible (41). In 1 case where selective engagement was not possible, a coronary wire was used to enter the coronary artery, but neither the guide catheter nor a guide extension catheter could be advanced through the struts (40). Engagement was finally possible using balloon-assisted tracking of a guide extension catheter.

With limited published studies regarding coronary access and interventions in patients with prior TAVR, it is nearly impossible to estimate the incidence, feasibility, and success rates of coronary angiography and PCI in this patient population. However, it is evident that valve design matters in terms of ease of reaccess, because the self-expanding valve is associated with greater challenges in coronary angiography and PCI post-TAVR. Given the possibility of coronary reaccess in patients with established or intermediate CAD lesions, especially in younger and lower-risk patients, a heart team discussion on the management of CAD in patients with severe AS would be valuable. An individualized approach on: 1) the treatment of both diseases (e.g., PCI then TAVR vs. surgery); 2) which coronary lesions to intervene before TAVR; and 3) valve selection, which may affect coronary reaccess, is recommended.

Post-TAVR multidetector computed tomography (CT) can be helpful to determine the anatomy and approach to coronary reaccess. However, several practical limitations in using this imaging modality as common practice exist: 1) CT cannot be performed in urgent situations, such as acute coronary syndrome, when urgent cardiac catheterization or PCI is necessary; 2) it can be a logistical challenge to schedule a CT before an elective catheterization, especially in terms of the intravenous contrast medium load in patients with renal insufficiency; and 3) motion artifact and image quality may limit the ability to visualize leaflet orientation of the transcatheter valve

CENTRAL ILLUSTRATION Coronary Reaccess After TAVR



Yudi, M.B. et al. J Am Coll Cardiol. 2018;71(12):1360–78.

Summary of factors impacting coronary access and imaging evaluation after TAVR. MDCT = multidetector computed tomography; TAVR = transcatheter aortic valve replacement.

relative to the coronary ostia, making it difficult to determine whether the commissural post may impede the ability to reaccess coronaries. Nonetheless, it remains essential to understand the 3-dimensional geometric interaction among the valve prosthesis, the aortic root, and coronary ostia to help predict and prepare for potential challenges of coronary reaccess in these patients (Central Illustration).

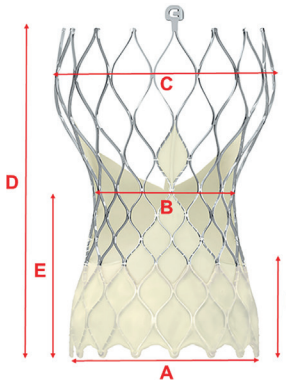
GEOMETRIC INTERACTION BETWEEN SELF-EXPANDING AND BALLOON-EXPANDABLE VALVES AND CORONARY OSTIA

Pre-procedural planning predominantly focuses on predicting the likelihood of acute coronary obstruction because of the life-threatening nature of this rare complication (42). However, to date, there has not been any emphasis on factors that will affect future coronary reaccess, such as valve design and selection, positioning during deployment, as well as potential interactions between the transcatheter valve and the native aortic valve leaflets, coronary ostia height, and sinus of Valsalva diameter and height.

SELF-EXPANDING VALVE. The CoreValve self-expanding valve is composed of 2 parts; the self-expanding nitinol support frame with diamond cell configuration and the trileaflet porcine pericardial tissue valve. The frame has 3 levels:

1. The inflow exerts a high radial expansive force that secures the frame across the annulus.

FIGURE 1 Repositionable Self-Expanding Valves With and Without an External Pericardial Wrap: Features and Dimensions



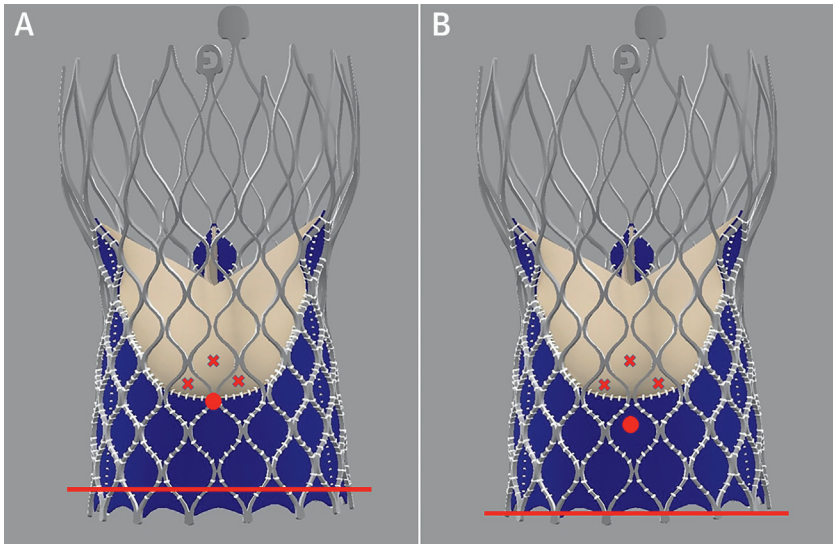
	23mm Evolut R / PRO	26 mm Evolut R / PRO	29mm Evolut R / PRO	34mm Evolut R
A. Inflow Diameter	23 mm	26 mm	29 mm	34 mm
B. Waist Diameter	20 mm	22 mm	23 mm	24 mm
C. Outflow Diameter	34 mm	32 mm	34 mm	38 mm
D. Frame height	45 mm	45 mm	45 mm	46 mm
E. Commissure Height	26 mm	26 mm	26 mm	26 mm
F. Skirt Height	13 mm	13 mm	13 mm	14 mm

Various dimensions of the Evolut-R and Evolut-PRO CoreValve (Medtronic, Galway, Ireland) are listed for comparison.

2. The concave central portion allows the frame to avoid contact with the coronary ostia.
3. The outflow is the largest part of the frame and rests in the ascending aorta.

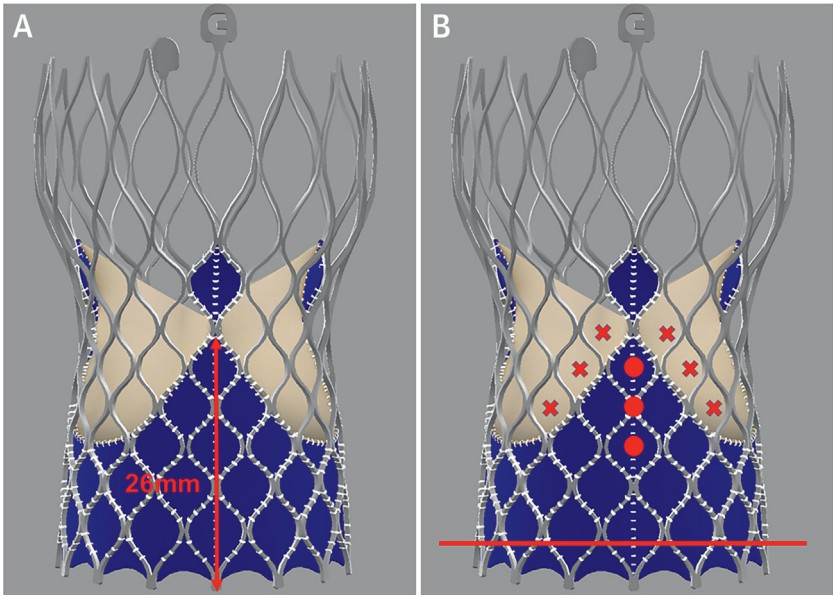
The dimensions of Evolut-R and Evolut-PRO (Medtronic) repositionable self-expanding valves are shown in Figure 1. There are several important considerations regarding coronary reaccess. First, it is important to consider the depth of implantation, particularly in patients with low coronary ostia. Due to their design, these self-expanding valves extend beyond the coronary ostia, but the narrow waist in appropriately large sinuses ensures that the risk of acute coronary obstruction is low (42). To optimize future coronary reaccess, implantation depth is critical, especially if the ostia is <10 mm, as shown in Figure 2. Because the skirt height of the Evolut-PRO is

FIGURE 2 Self-Expanding Valve and Coronary Access Depending on Level of Implantation Across the Annulus



Red dot represents the location of the coronary ostium in relation to the valve frame, and the **red line** represents the annular plane. The **red x's** depict the closest diamonds that can be used to access the coronary ostium. An optimally positioned Evolut-R (Medtronic, Galway, Ireland) **(A)** would make coronary access potentially easier than one with a higher implant **(B)**.

FIGURE 3 Self-Expanding Valve and Coronary Access If Ostia Lines Up With Commissural Post



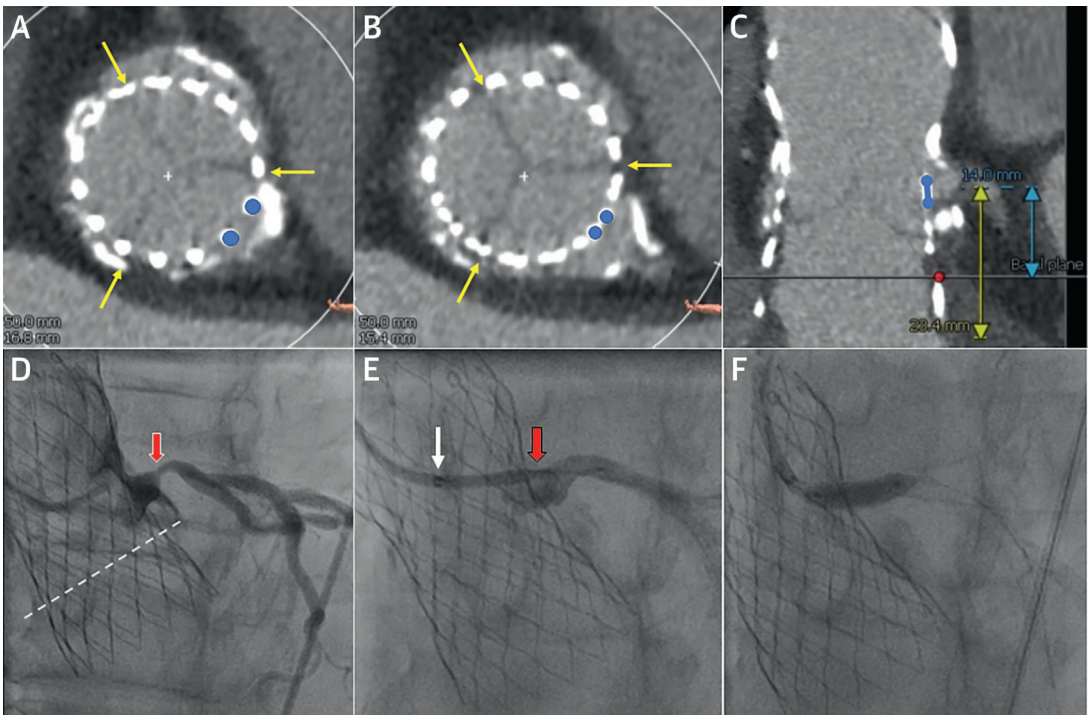
Red line represents the annular plane. The 3 **red dots** depict coronary ostia heights of approximately 10, 14, and 18 mm above the annular plane, respectively. The **red x's** depict the closest diamonds that can be used to access the coronaries. The commissural post of an Evolut-R (Medtronic, Galway, Ireland) is 26 mm in height **(A)**. Depending on the height of coronary ostia, a different catheter and approach is necessary for coronary reaccess, when the ostium faces the side of the commissural post **(B)**.

13 mm, we need to implant at least 4 mm below the annular plane to ensure the skirt is not overlaying the coronary artery. Because the Evolut-R and Evolut-PRO are recapturable when partially deployed, it is possible to position the valve with such precision. In this optimal position, it is feasible to engage the coronary artery in a coaxial manner, assuming the native aortic valve leaflets will not interfere with the path to the coronary ostium (Figure 2A). If the valve is deployed high, as seen in Figure 2B, coronary obstruction would not occur due to the narrow waist of the valve and sufficient sinus of Valsalva width. However, selective coronary angiography would be difficult in this scenario and would have to occur from a diamond above the ostium, given that the supra-annular valve and its covered segment (e.g., sealing skirt) would be above the level of the ostium. A straighter catheter with a short tip, such as a Judkins right (JR) 4, could be used in this scenario, even for left main artery engagement.

Second, during TAVR, there is no reliable and consistent way to assess the position of the transcatheter valve commissures in relation to those of the native aortic valve. This is different from surgical aortic valve replacement, where surgeons usually align the commissural frame posts to the native commissures. With the repositionable Evolut-R self-expanding valve, the commissure with the paddle (with the letter *C* on the tab) is introduced facing the anterior part of the ascending aorta, but because the delivery system traverses the aorta and crosses the native valve, it is not possible to determine its final position until after the valve has been released. Theoretically, a commissure can end up positioned directly in front of the coronary ostium. As there are 3 commissures, and the valve has 15 rows of diamonds, there is a significant chance that this may occur. Although the circumferential sealing skirt is 13 mm in height (14 mm in the 34-mm Evolut-R), it rises up to 26 mm at the commissural insertion point (Figure 3A). In this scenario, coaxial engagement of the coronary ostia would be challenging, if not impossible.

Figure 3B shows a theoretical scenario where a repositionable Evolut-PRO self-expanding valve is positioned 4 mm below the annular plane, consistent with the recommended implantation depth of 3 to 5 mm, and the commissure lines up with the coronary ostia. The 3 red dots depict coronary ostia heights of approximately 10, 14, and 18 mm above the annular plane, respectively. The cross (X) depicts the closest diamonds that can be used to access the coronaries. It is important to note the width of the sinus of Valsalva determines the space between the valve frame and

FIGURE 4 CT Analysis Pre-Left Main Intervention



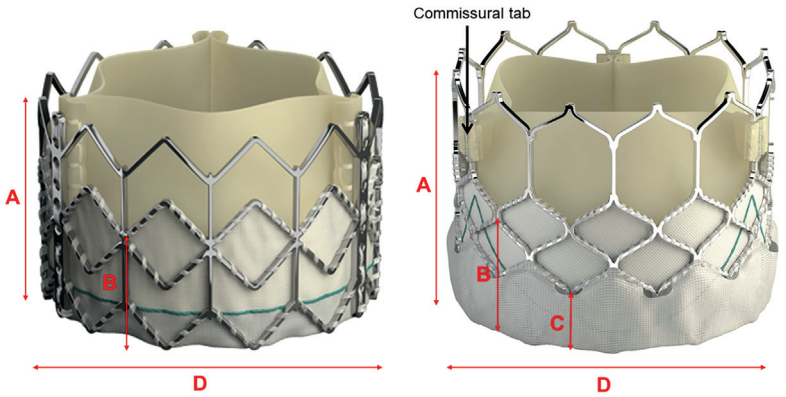
(A) The commissural posts **(yellow arrows)** are clearly not in front of the left main coronary artery, and the diamond is open at the top of the left main orifice **(2 blue dots)**. **(B)** The diamond narrows down at the base of the left main orifice **(blue dots)**. **(C)** The left main coronary artery origin is 14.0 mm from the annular plane **(blue double-headed arrows)** and 23.4 mm from the base of the Evolut-R (Medtronic, Galway, Ireland) **(yellow double-headed arrows)**; thus, the skirt (13 mm in height) will not interfere with left main engagement. **(D)** Nonselective, but diagnostic angiogram was performed using JR4 catheter showing left main stenosis **(red arrow)**. **(E)** An Ikari Right 1.0 guide **(white arrow)** was used with a guide extension catheter **(red arrow)** for extra support to perform the left main PCI. **(F)** Post-dilation of the implanted left main stent was performed with a 4.0-mm balloon, which extended through valve diamonds to ensure that the ostium was treated optimally. CT = computed tomography; JR = Judkins right; PCI = percutaneous coronary intervention.

the coronary ostia; the wider the sinus the more room there is to manipulate a catheter toward the coronary ostia, particularly in the scenario shown in Figure 3. A narrow sinus would require a very acute angle for the catheter to be pointing toward the ostia for a nonselective coronary angiogram. If selective engagement is required, a coronary wire would have to be manipulated into the coronary artery, and the guide, or a guide extension catheter, would then have to be railed into the ostium. This represents the most difficult scenario: a valve commissure overlying a low coronary ostium in a patient with a narrow sinus of Valsalva. Of course, this description has not accounted for the native aortic leaflet height and severity of calcification facing the left and right sinuses. A tall and bulky leaflet may extend beyond the 13- or 14-mm sealing skirt of the repositionable Evolut-PRO self-expanding valve and would likely further add to the challenge of coronary reaccess based on these scenarios.

Third, the repositionable Evolut-R self-expanding valve has a concave central portion ("waist") that measures 20 to 24 mm, depending on the valve size. Clearly, this is narrower than native aortic root dimensions; therefore, it is not surprising that smaller catheters, such as a JL3.5 or JL3, have frequently been used to engage the LCA. On the contrary, engagement of the RCA can usually be managed with a JR4 catheter. If the sinus width is large, there is a larger distance from the valve frame to the ostium, and thus a longer catheter tip would be required. In this circumstance, JR4.5, JR5, Amplatz right (AR) 2 catheters would be more suitable.

CT analysis post-TAVR with the self-expanding valve can aid in identifying potential issues of coronary reaccess, such as the relationship between skirt

FIGURE 5 Balloon-Expandable Valves: Features and Dimensions

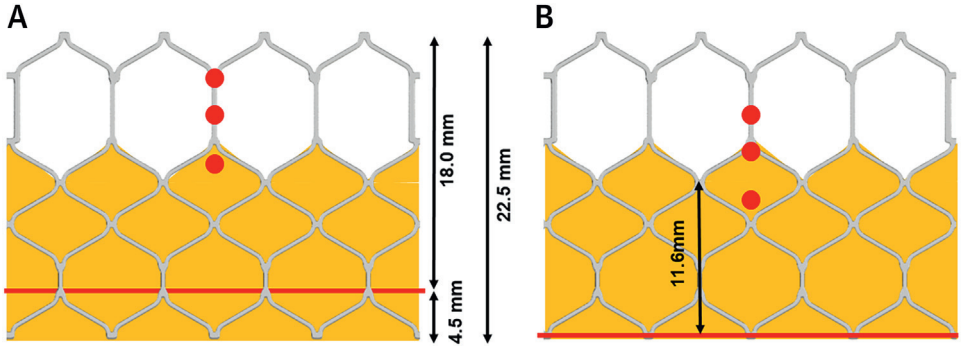


	23 mm Sapien XT	26 mm Sapien XT	29 mm Sapien XT	20 mm Sapien 3	23 mm Sapien 3	26 mm Sapien 3	29 mm Sapien 3
A. Frame Height	14 mm	17 mm	19 mm	15.5 mm	18 mm	20 mm	22.5 mm
B. Inner Skirt Height	6.7 mm	8.7mm	11.6 mm	7.9 mm	9.3 mm	10.2 mm	11.6 mm
C. Outer Skirt Height	N/A	N/A	N/A	5.2 mm	6.6 mm	7.0 mm	8.1 mm
D. Valve Diameter	23 mm	26 mm	29 mm	20 mm	23 mm	26 mm	29 mm

Various dimensions of the Sapien XT and Sapien 3 valves (Edwards Lifesciences, Irvine, California) are listed for comparison.

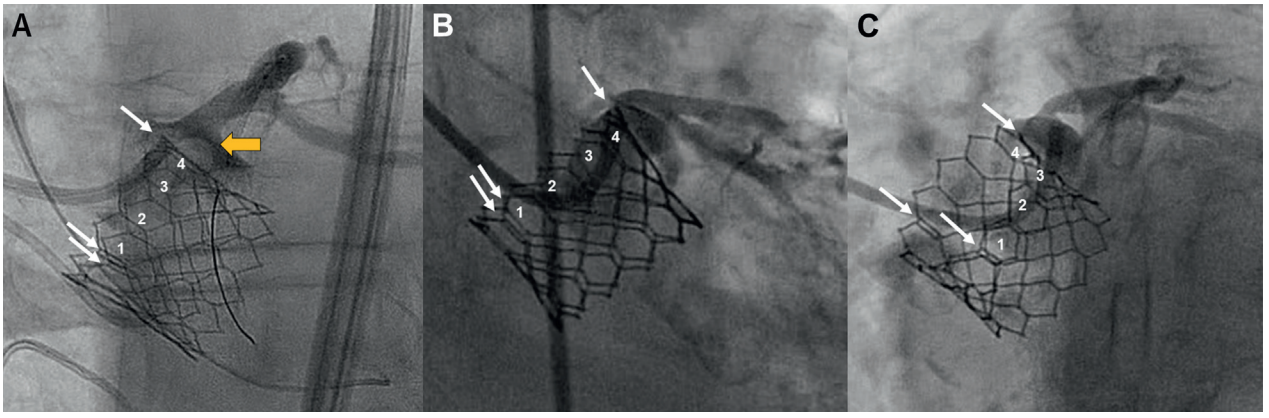
height and the coronary ostia, as well as the position of the commissural posts. In Figure 4, we highlight a case of left main PCI post-TAVR with a 29-mm repositionable Evolut-R self-expanding valve. CT analysis clearly revealed that the commissural posts were away from the coronary ostia and the skirt (13 mm) was well below the left main coronary artery (23.4 mm from base of the valve). As the diamond narrowed towards the center of the left main artery, coronary engagement was achieved by coming from

FIGURE 6 Balloon-Expandable Valve and Coronary Ostia Based on Depth of Implant



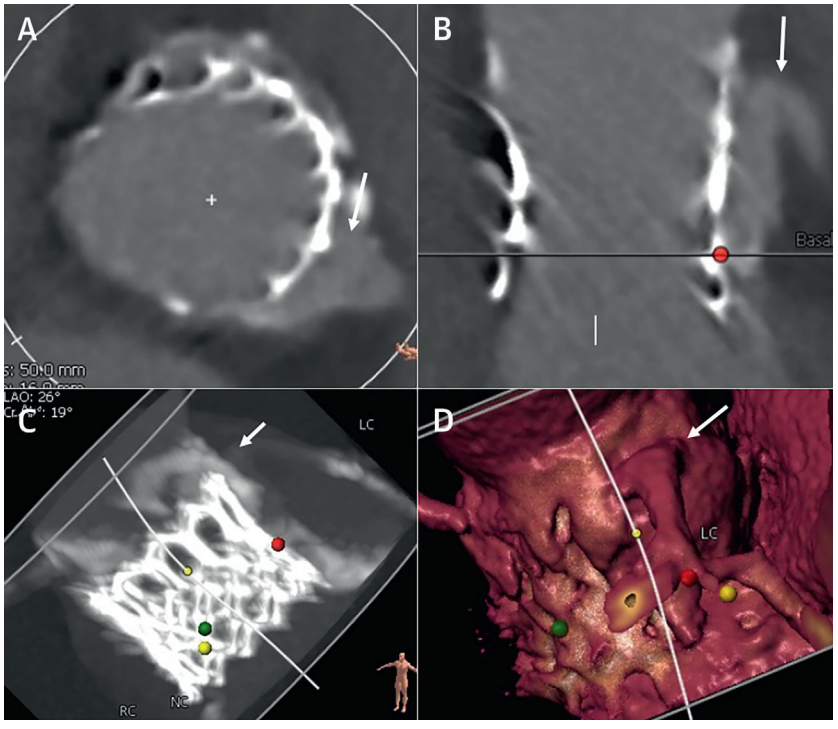
Red dots represent the different locations of the coronary ostium in relation to the valve frame of a 29 mm Sapien 3 valve (Edwards Lifesciences, Irvine, California), and the **red line** represents the annular plane. An optimally positioned Sapien 3 valve (Edwards Lifesciences, Irvine, California) **(A)** would make coronary access potentially easier than one with a higher implant **(B)**, where the coronary ostium will be located below the seal skirt. Tall native leaflet or bulky calcium at the leaflet tip may further increase difficulty of coronary access in a high valve implant.

FIGURE 7 Coronary Reaccess in a Patient After TAVR With a Balloon-Expandable Valve



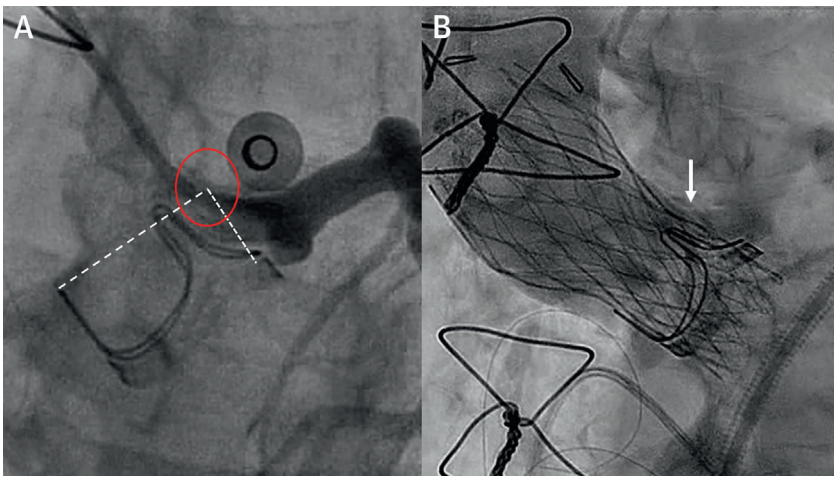
White arrows depict the commissural tabs visible on fluoroscopy, and the **numbers 1 to 4** refer to the open cells separating the commissural tabs. Bulky calcium **(orange arrow)** and the height of the Sapien 3 valve frame (Edwards Lifesciences, Irvine, California) can make advancement of a guide catheter into the left main orifice challenging **(A)**. A narrow sinotubular junction, and the presence of a commissural tab facing the left main orifice, can make coronary access difficult, requiring the guide to be placed on either side of the commissural tab to access the sinus of Valsalva for a semiselective injection **(B and C).** TAVR = transcatheter aortic valve replacement.

FIGURE 8 CT Analysis of Coronary Anatomy After TAVR



CT shows the stent frame of a Sapien 3 balloon-expandable valve (Edwards Lifesciences, Irvine, California) extending above the left main coronary ostium **(white arrow)** in axial **(A)**, coronal **(B),** and reconstructed views **(C and D)**. Colored dots approximately depict the respective nadir of the non **(yellow)**, right **(green)**, and left **(red)** coronary cusp forming the annular plane. Abbreviations as in Figures 4 and 7.

FIGURE 9 Valve-in-Valve TAVR and Coronary Artery Relationships



Small sinotubular junction and short sinus height in the presence of a surgical bioprosthesis predicts high coronary obstruction risk with valve-in-valve TAVR **(A)**. The **dashed lines** depict the position of the bioprosthetic valve leaflets (virtual valve) after valve-in-valve TAVR, and the **red circle** shows near obliteration of the space necessary for coronary perfusion. After implantation of a repositionable self-expanding valve, coronary perfusion remained adequate **(white arrow)**, likely due to its self-expanding nature preventing overexpansion of the transcatheter valve frame toward the sinotubular junction **(B)**. TAVR = transcatheter aortic valve replacement.

above, rather than in a coaxial manner. Consequently, a guide extension catheter was used to optimize engagement. PCI was then successfully undertaken, and during post-dilation of the left main ostium, there was overhang of a 4-mm balloon through the valve frame, emphasizing the area of diamond, which can easily accommodate a 10-F guide, as per the manufacturer.

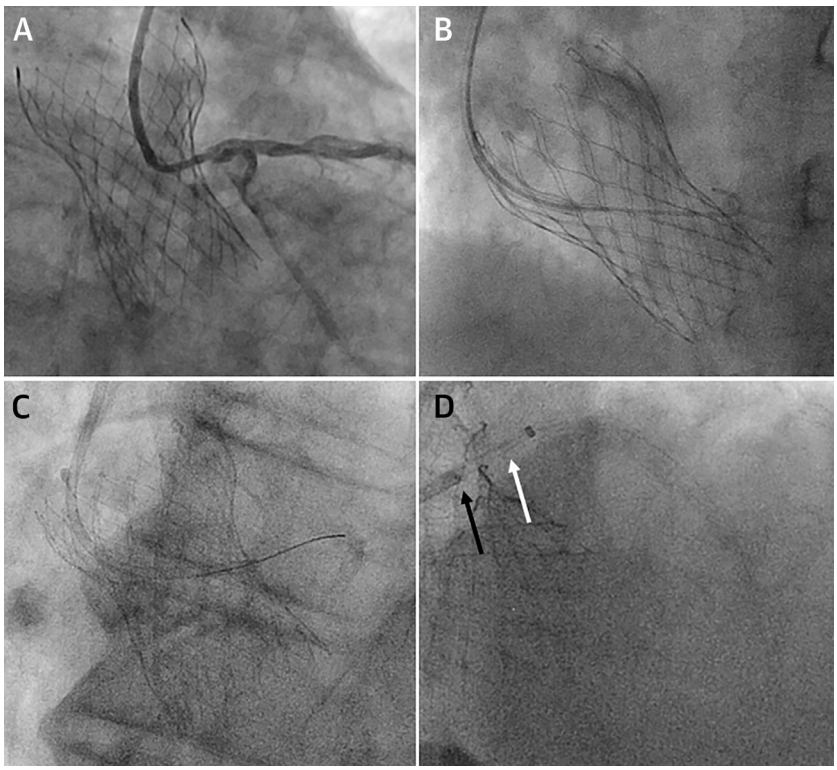
BALLOON-EXPANDABLE VALVES. The design of balloon-expandable valves differs significantly from that of self-expanding valves. It is well documented that acute coronary obstruction is more prevalent with balloon-expandable valves (42); however, significant issues with coronary access post-TAVR have not been documented. This is despite the balloon-expandable valve frames frequently ending up above the coronary ostia (41,43). In a CT analysis of patients post-TAVR with Sapien and Sapien XT valves (Edwards Lifesciences), partial (>1 mm) or complete coverage of the left coronary ostium was evident in 33.6% and 2.1% of cases, respectively (41). The right coronary ostium was partially or completely covered in 42.3% and 7.7% of cases, respectively, whereas in 2.1% of cases, both ostia were completely covered. There were no reported issues with patients who subsequently required coronary reaccess or PCI. Another CT study similarly showed a high proportion of patients with balloon-expandable valves having at least partial coverage of the left main (71%) or RCA (29%) (43).

Figure 5 shows the dimensions of the Sapien XT and Sapien 3 valves (Edwards Lifesciences). The newer-generation Sapien 3 valve is taller, and thus more likely to extend above the coronary ostia and potentially interfere with coronary access. However, it is also important to note that the cells in the upper row of the Sapien 3 valve are 38% larger in area than those of the Sapien XT valve.

The Sapien 3 valve has 12 open cells on its frame, 3 of which contain the commissures and leaflet attachment, along with a 3-mm pledget in the middle of the upper row of cells (Figure 5). Thus, it is possible that the commissure may end up directly in front of a coronary ostium after valve deployment. Another important consideration more pertinent to the balloon-expandable valves is the sinotubular junction (STJ) diameter and height. Because it does not have a narrowed waist like the self-expanding valve, the balloon-expandable valve frame, especially Sapien 3, can extend beyond the STJ, making future coronary access from above the valve more challenging or impossible.

Similar to our theoretical model with the self-expanding valve, in Figure 6, we show a 29-mm balloon-expandable Sapien 3 valve with the commissural post over the coronary ostia at heights of approximately 10, 14, and 18 mm, respectively, with the valve deployed optimally at 80% aortic position.

FIGURE 10 Representative Technique to Reaccess the LCA After TAVR With a Self-Expanding Valve



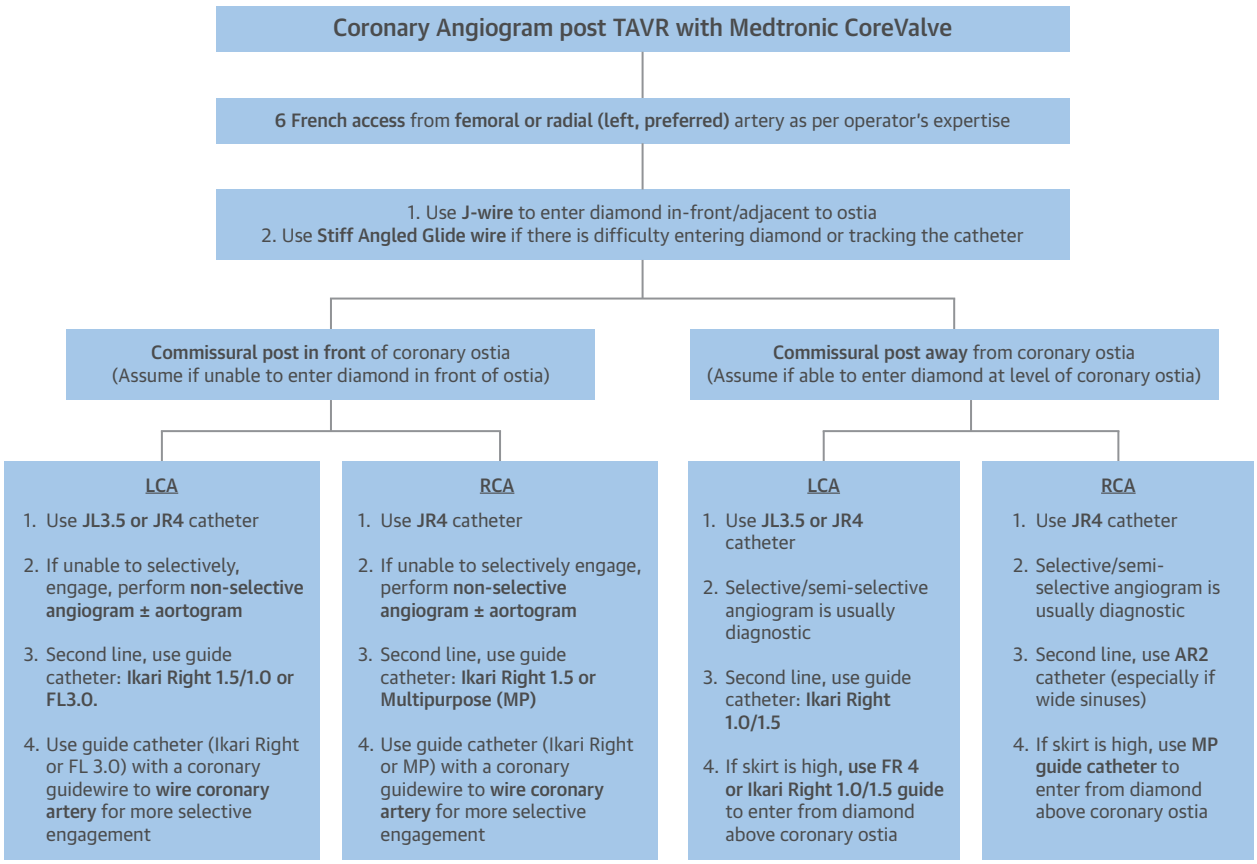
(A) JR4 used to successfully engage the left main coronary artery. **(B)** J-wire use to cross the lowest diamond above the skirt. **(C)** Coronary wire positioned in the coronary artery before railing the guide for selective engagement. **(D)** The guide could not cross the valve frame **(black arrow)**, so a guide extension catheter **(white arrow)** was used to selectively engage the coronary artery. LCA = left coronary artery; other abbreviations as in Figures 4 and 7.

In this position, only low coronary arteries (<10 mm) would cause any concern, as the skirt on the frame would be around this level. If the valve is deployed in a more aortic position, with the inflow near the level of the annulus, this would complicate engagement further, as the skirt is well above the ostia. Of course, this model has not taken the native aortic valve leaflets into account. A tall and bulky leaflet may create an even higher barrier for coronary access, given the bulky calcium would be in the way (Figure 7A). Coronary angiography and PCI may be undertaken in 2 ways. First, if the catheter is placed just above the skirt through the upper row of cells, only a nonselective angiogram is likely to be achieved, and PCI would require a coronary wire to engage the artery with a railing technique to engage the catheter. Second, if the STJ is high enough above the valve, a catheter can be used to engage the coronary artery from above the Sapien 3 valve. Coaxial engagement from this position would depend on the sinus of Valsalva width. If the sinuses are effaced, there will be a relative lack of room to manipulate the catheter and engagement of the artery would be more difficult. In cases where the commissural tab faces the coronary ostium and the top of the Sapien 3 valve frame is in contact with the STJ, it may be necessary to engage from the open cell on either side of the commissural tab to reaccess the coronary artery (Figures 7B and 7C)

CT analysis post-TAVR with the balloon-expandable valve is also useful in identifying whether the stent frame extends partially or completely over the coronary ostia (Figure 8). Three-dimensional reconstruction is able to depict the location of the ostia in relation to the stent frame. However, it is limited by the inability to visualize the commissural posts.

In a proof-of-concept study, Blumenstein et al. (44) used DynaCT-guided (Siemens, Erlangen, Germany) rotation of the Sapien XT valve to ensure the commissural posts were not positioned in front of the

FIGURE 11 Algorithm on Coronary Angiography Post-TAVR With a Self-Expanding Valve



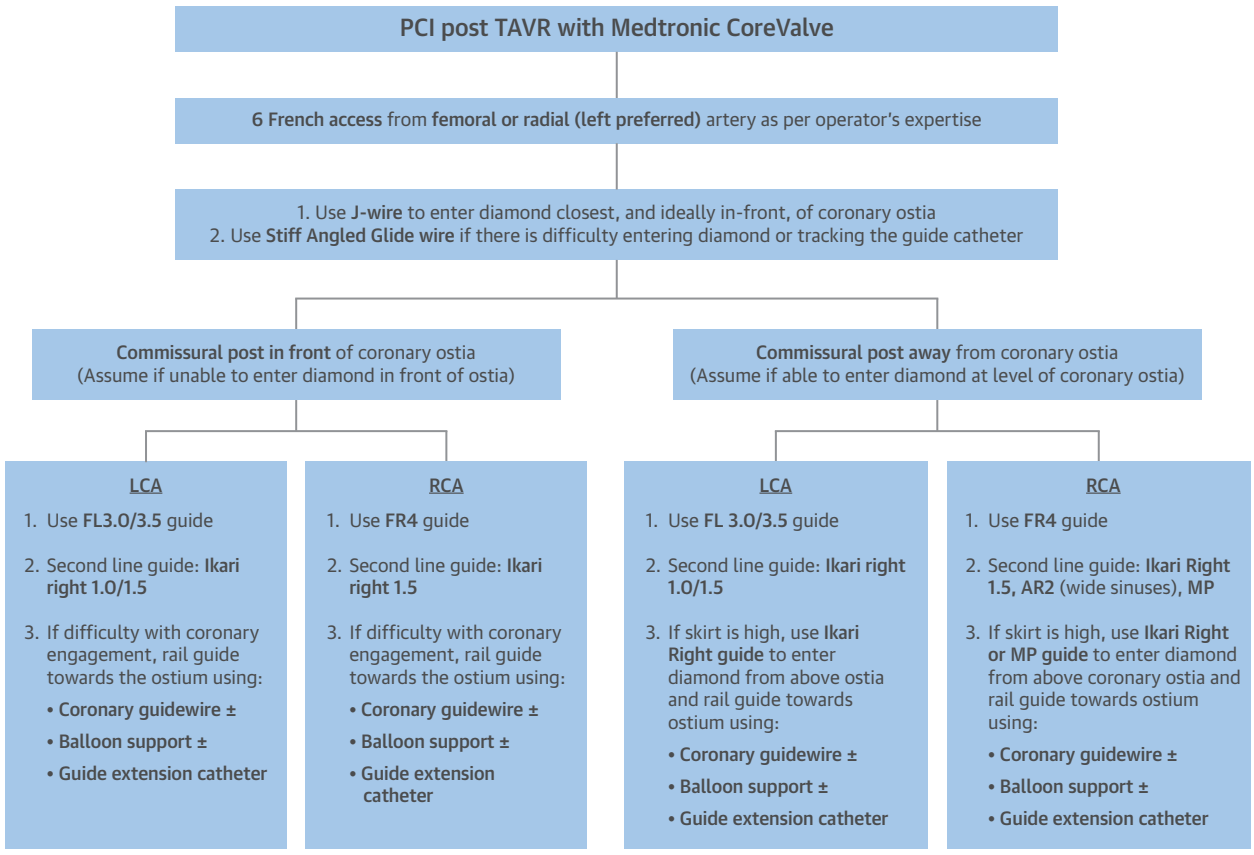
Recommendations on specific catheters used in coronary angiography after CoreValve (Medtronic, Galway, Ireland) implantation is proposed. AR = Amplatz right; FL = femoral left; FR = femoral right; JL = Judkins left; MP = multipurpose; RCA = right coronary artery; other abbreviations as in Figures 7 and 10.

coronary ostia. Unfortunately, this was used during transapical TAVR, and does not appear to be feasible with transfemoral or subclavian approaches, due to the longer distance from the access site to the aortic valve and the inability of the delivery system to be adjusted during positioning and deployment (44).

VALVE-IN-VALVE TAVR. The risk of acute coronary obstruction is higher in valve-in-valve TAVR when compared with those with native aortic valves (45). In the VIVID (Valve-in-Valve International Data) registry, 3.5% experienced this catastrophic complication, which lead to death in >50% of the cases (45). The risk is similar across both valve designs, but is dependent on the characteristics of the surgical bioprosthesis and the relationship of its leaflets with the coronary ostia, STJ, and sinus of Valsalva (Figure 9). As surgical valve commissural posts are usually aligned with those of the native valve, they are remote from the coronary ostia and do not usually interfere with coronary access unless the ostium is located closer to one of the commissural posts (e.g., bicuspid valve). However, in valve-in-valve TAVR, the commissural posts and bioprosthetic valve leaflets can be deflected outward by the transcatheter valve, especially with balloon-expandable valves, reducing the distance between the surgical bioprosthetic valve leaflets and coronary ostia, and potentially compromising coronary flow (45). Self-expanding valves may also risk coronary obstruction, but due to their conformation to the bioprosthetic leaflets and the surgical valve frame, the risk may potentially be lower (Figure 9). Stenotic bioprosthetic valves, due to thickening and calcification of the leaflets, may also increase the risk of coronary obstruction over regurgitant valves.

The feasibility of coronary angiography and PCI in patients after valve-in-valve TAVR who did not have

FIGURE 12 Algorithm on PCI Post-TAVR With a Self-Expanding Valve



Recommendations on specific catheters used in PCI after CoreValve (Medtronic, Galway, Ireland) implantation are proposed. Abbreviations as in Figures 4, 10, and 11.

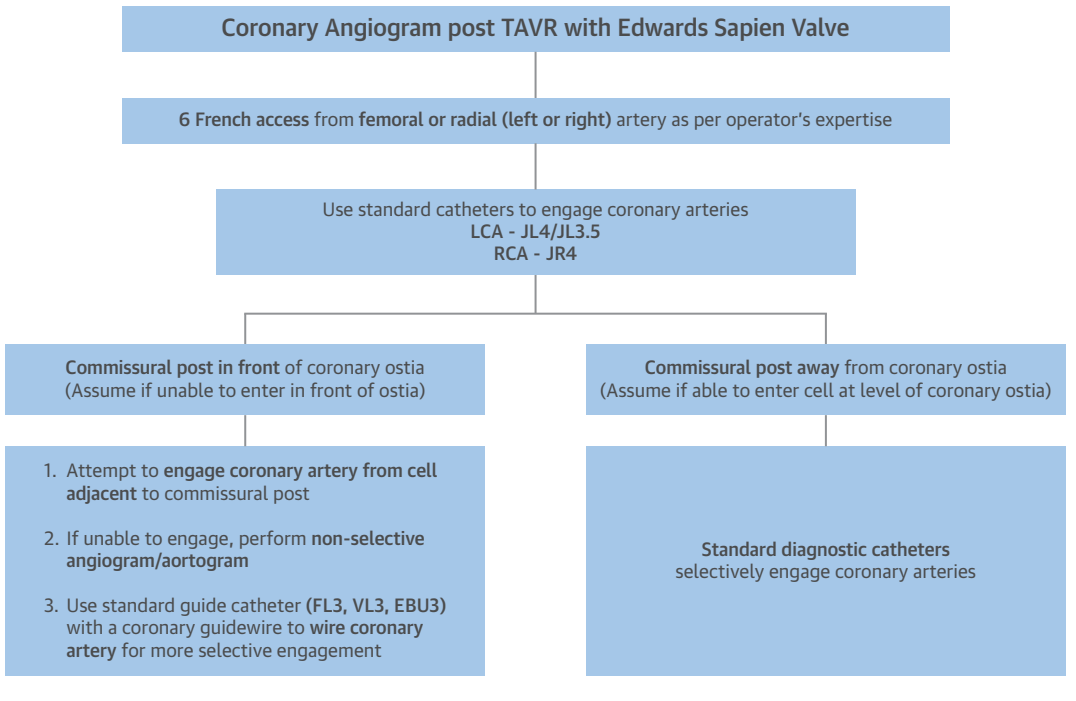
acute coronary obstruction has not been described. Full description of each bioprosthetic aortic valve and the interaction with a transcatheter valve are beyond the scope of this paper. However, the same principles we describe in this review should apply to valve-in-valve TAVR as to TAVR in a native aortic valve.

CORONARY ACCESS IN PATIENTS AFTER TAVR

Undoubtedly, there will be an increasing number of patients with TAVR valves presenting with progressive CAD or acute coronary syndrome in the coming years. This will occur at both major tertiary centers and at community hospitals with limited exposure to transcatheter valve interventions. It is therefore essential for diagnostic and interventional cardiologists to understand the potential challenges of coronary angiography and PCI in this patient population and to have an algorithm to aid with troubleshooting. This would be particularly useful in time-critical scenarios, such as ST-segment elevation MI.

SELF-EXPANDING VALVE TROUBLESHOOTING. Catheter selection. Given the design of CoreValve, particularly its narrow waist, engagement of the LCA typically requires a smaller catheter than usual. For LCA engagement, JL3.5 and JL3.0 catheters can be used for femoral and radial access, respectively. A JR4 can also be used to troubleshoot the narrow waist and engage the LCA (Figure 10A). An essential component to consider is the position of the commissural post, which usually necessitates entering through the valve from a diamond superior and/or lateral to the coronary ostia. Consequently, and due to its design, our recommended second-line catheter of choice for left coronary engagement is the Ikari right guide catheter. Furthermore, using a guide catheter as a second-line strategy allows the possibility of coronary wiring if more selective

FIGURE 13 Algorithm on Coronary Angiography Post-TAVR With a Balloon-Expandable Valve



Recommendations on specific catheters used in coronary angiography after Sapien valve (Edwards Lifesciences, Irvine, California) implantation are proposed. EBU = extra backup; VL = Voda left; other abbreviations as in Figures 4, 7, 10, and 11.

engagement is required to perform a diagnostic angiogram.

For RCA engagement, JR4 is the catheter of choice. When the sinus of Valsalva is wide, longer-tipped catheters, such as an AR2 (preferred), JR4.5, JR5, or an Ikari right guide provide more adequate engagement. If a commissural post is in front of the coronary ostium, a multipurpose catheter or an Ikari right guide is preferred.

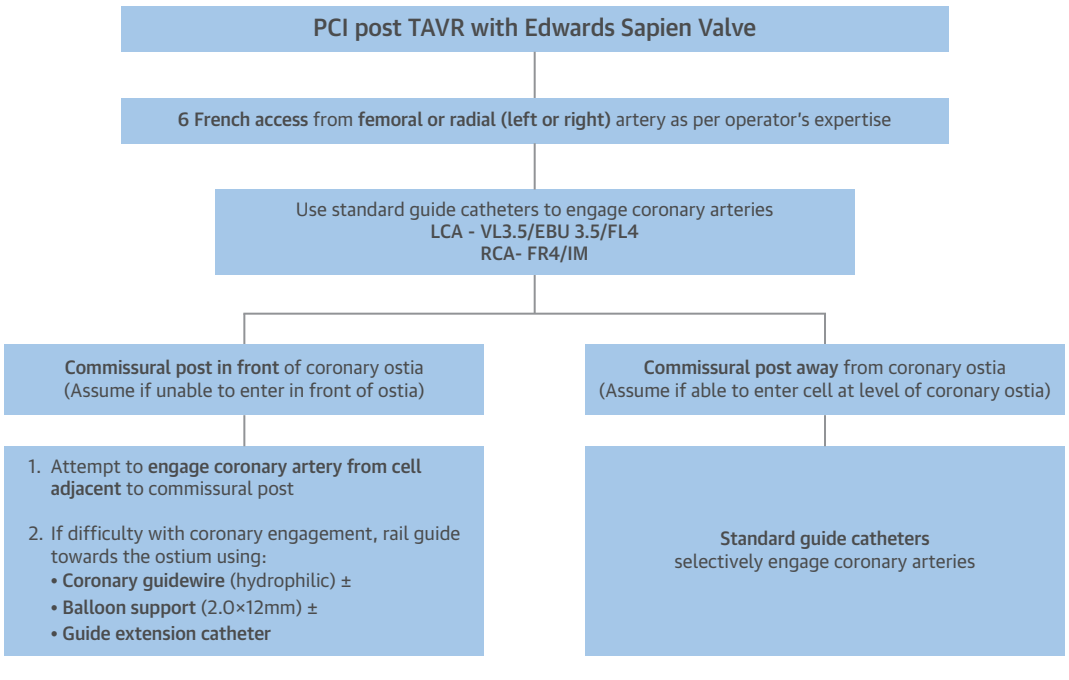
A femoral left 3.5/3.0 guide catheter is the preferred guide for left coronary intervention. Extra backup catheters have been associated with kinking and should be used with extreme care (35). A JR4 guide catheter is preferred for right coronary interventions, whereas an AR2 guide is the preferred choice when there is significant room between the valve frame and the ostia due to a wide sinus of Valsalva.

On occasions when the coronary ostia can only be accessed from above, a downward pointing catheter, such as a multipurpose guide, can also be used, especially for RCAs.

Catheter engagement. Selective catheter engagement can be difficult, depending on the position of the skirt and commissural posts relative to the coronary ostia. If possible, cannulation should be performed in a coaxial manner through the diamond directly in front of the ostia. Engaging from a diamond below the ostia has been associated with kinking of the guide and the inability to remove it (35). Operators have found it useful to cannulate at the fifth alternating diamond above the base of the frame, so as not to be hindered by the pericardial tissue that extends from the base or native valve leaflets. A J-wire is very useful in finding the diamond closest to the ostia, and the catheter can be railed over it for engagement and angiography (**Figure 10B**). If this fails, a stiff, angled glide wire (Terumo Cardiovascular Systems, Elkton, Maryland) can be used for the same purpose. As it is more lubricious, it can more easily enter the diamond of the valve frame close to the ostium, while its stiffness allows the catheter to be straightened as it is railed across the diamond. Although the angled tip provides a degree of safety, it should always be used with care, given the proximity of the left main coronary artery.

If selective engagement continues to be problematic, a coronary wire can be used to enter the coronary artery from the aorta, and then it can act as a rail for the guide (**Figure 10C**). If guide engagement and support is still suboptimal, a 2.0 mm × 12-mm balloon

FIGURE 14 Algorithm on PCI Post-TAVR With a Balloon-Expandable Valve



Recommendations on specific catheters used in PCI after Sapien valve (Edwards Lifesciences, Irvine, California) implantation are proposed. IM = internal mammary; other abbreviations as in Figures 4, 7, 10, and 13.

can be placed in the left main coronary artery for extra support while attempting to rail the guide over it. If this fails, a guide extension catheter can be used (**Figure 10D**), with balloon-assisted tracking in the most difficult cases (40).

Catheter disengagement. Care should be taken when disengaging the guide, as it can kink during the procedure (35). Thus, the guide should be disengaged from the ostium, preferably over a wire, before withdrawal through the diamond of the valve frame. If this becomes problematic, using excessive force should be avoided, as it can kink, or even break, the catheter over the valve frame. If necessary, the use of a balloon may further facilitate disengagement and withdrawal from the valve frame.

BALLOON-EXPANDABLE VALVE TROUBLESHOOTING. Coronary angiography technique does not have to be modified significantly in the presence of a balloon-expandable valve. Even in cases where the valve frame extends above the coronary ostia, as seen on CT, selective angiography is usually feasible. The occurrence of a balloon-expandable valve frame extending beyond the coronary ostia is likely to increase with the use of the newer and taller balloon-expandable valve.

If there is a problem with selective coronary engagement, the most likely cause is the position of the commissural tab in front of the coronary ostia. In this scenario, placement of the catheter across the adjacent frame is recommended and nonselective angiography is usually diagnostic. If PCI is indicated, a coronary wire can be used to enter the coronary artery from the aorta, and it can then act as a rail for the guide. Furthermore, a guide extension catheter can be used if guide engagement and support remain suboptimal. Balloon-assisted tracking of the guide catheter extension has been successfully reported with the Sapien 3 valve (40).

In the rare (and yet undescribed) clinical scenario where the deployment is high and the skirt is in front of the coronary ostia without causing acute coronary obstruction, direct ostial engagement would be difficult. Using a downward-pointing catheter, such as a multipurpose 1, would facilitate engagement from either a cell above the ostia or from the space between the valve frame and the STJ.

Practical algorithms for coronary angiography and PCI for both the self-expanding and balloon-expandable valves are shown in **Figures 11 to 14**.

FUTURE DIRECTIONS

It is essential to consider future coronary access in patients undergoing TAVR. At present, there is no reliable way to control the transcatheter valve commissural orientation in relation to the coronary ostia, nor is there an easy way to orient the valve to optimize future coronary access. Theoretically, when the self-expanding valve is 80% deployed, transesophageal echocardiographic views can determine the commissural position, but the constrained valve frame before release may cause acoustic shadowing and limit the ability to determine leaflet orientation. In addition, it is not practical to recapture the valve and move it to the descending aorta to reorient it before attempting deployment again.

In the future, it would be advantageous if the commissural tabs can be easily identified on fluoroscopy and there is a simple mechanism to align the prosthetic valve commissures with those of the native valve, thus optimizing its placement in relation to the coronary arteries. There may also be a role for specifically designed catheters to engage the coronary arteries through self-expanding valves.

CONCLUSIONS

Coronary angiography and PCI in patients after TAVR can be challenging. Intricate knowledge of the valve design and its relationship with the coronary ostia, sinus of Valsalva, and STJ anatomies can help predict the difficulty in coronary reaccess and identify a strategy to manage these patients. Proposed algorithms on cardiac catheterization and PCI may aid troubleshooting in the management of these complex clinical scenarios.

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APPENDIX For a supplemental table, please see the online version of this paper.