Commissural Versus Coronary Optimized Alignment During Transcatheter Aortic Valve Replacement



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ABSTRACT

OBJECTIVES The aims of this study were to determine the rate of noncentered coronary ostia and their risk for coronary overlap (CO) and to develop an improved orientation strategy for transcatheter aortic valve replacement (TAVR) devices taking into account anatomical cues to identify patients at risk for CO regardless of commissural alignment and compute an alternative, CO-free TAVR rotation angle for those patients.

BACKGROUND Commissural alignment during TAVR reduces CO risk. However, eccentricity of coronary ostia from the center of the sinus of Valsalva may result in CO even after perfect alignment of TAVR commissures.

METHODS Baseline computed tomography from TAVR candidates helped identify distance from commissures to the right coronary artery (RCA) and the left coronary artery (LCA). Then, for each case, a virtual valve was simulated with ideal commissural or coronary alignment, and the degree of CO was determined. On the basis of the potential BASILICA (bioprosthetic or native aortic scallop intentional laceration to prevent iatrogenic coronary artery obstruction) efficacy, 3 groups were defined: no risk for CO (>35° from neocommissure to coronary ostia), moderate risk (20° - 35°), and severe risk ($\leq 20^\circ$).

RESULTS Computed tomographic studies from 107 patients were included. After excluding 7 patients (poor quality or bicuspid valve), 100 patients were analyzed. The RCA showed greater eccentricity compared with the LCA (18.5° [IQR: $3.3^{\circ}-12.8^{\circ}$] vs 6.5° [IQR: $3.3^{\circ}-12.8^{\circ}$]; P < 0.001). The mean intercoronary angle was $140.0^{\circ} \pm 18.7^{\circ}$ (95% CI: 136.3°-143.7°). Thirty-two patients had moderate to severe risk for CO (\leq 35°) despite ideal commissural alignment. Greater coronary eccentricity (cutoff for RCA, 24.5°; cutoff for LCA, 19°) and intercoronary angle >147.5° or <103° were associated with greater risk for moderate to severe CO despite commissural alignment (area under the curve: 0.97; 95% CI: 0.91-0.99). If optimal coronary alignment was simulated, this prevented severe CO in all cases and reduced moderate CO from 27% to 5% (P < 0.001).

CONCLUSIONS One third of patients would have CO during TAVR-in-TAVR despite commissural alignment; a 6-fold decrease in this risk was achieved with optimized coronary alignment. Coronary eccentricity and intercoronary angle were the main predictors. (J Am Coll Cardiol Intv 2022;15:135-146) © 2022 by the American College of Cardiology Foundation.

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ABBREVIATIONS AND ACRONYMS

AUC = area under the curve

BASILICA = bioprosthetic or native aortic scallop intentional laceration to prevent iatrogenic coronary artery obstruction

CMA = commissural misalignment

- CO = coronary overlap
- CT = computed tomographic
- LCA = left coronary artery
- RCA = right coronary artery

STJ = sinotubular junction TAVR = transcatheter aortic

valve replacement THV = transcatheter heart

valve

growing interest in commissural alignment during transcatheter aortic valve replacement (TAVR) is emerging to circumvent iatrogenic coronary occlusion. Traditionally, and as opposed to surgical aortic valve replacement, alignment of the neocommissures is not considered during TAVR. If one of the commissural posts lands in front of a coronary ostium, reaccess to the coronary artery can be challenging or impossible (1,2), there might be an increased risk for coronary occlusion, and in the eventual need for TAVR-in-TAVR, the risk for coronary occlusion would be increased. This is of special interest given the expansion of TAVR to a younger and lower risk population with a longer life expectancy that could surpass the durability of the TAVR device (which accounts for >10% of valve-in-valve procedures in recent series) (3) and confer increased risk for requiring percutaneous coronary intervention because of worsening or development of coronary artery disease. Therefore, avoiding coronary overlap (CO), and not the commissural alignment by itself, should be the main objective of commissural alignment strategies.

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The geometry of the devices is symmetrical and constant, with neocommissures 120° apart from each other. On the contrary, the geometry of the native aortic valvular cusps is not symmetrical, and consequently the angle between native commissures varies. More important, the coronary ostia are not always centered in the aortic sinus of Valsalva, with the right coronary artery (RCA) being more eccentric than the left coronary artery (LCA) (4,5). Hence, our hypothesis is that the interplay between the device and the native valve to achieve commissural alignment and avoid CO is not constant, and indeed, CO might not be avoided with a perfect commissural aligned implant if severe coronary eccentricity is present. On the basis of pre-TAVR computed tomographic (CT) imaging, we aimed, first, to determine the rate of noncentered coronary ostia and their risk for CO and, second, to develop an improved orientation strategy for TAVR devices taking into account anatomical cues to identify patients at risk for CO regardless of commissural alignment and compute an alternative, CO-free TAVR rotation angle for those patients. This would result in avoiding CO while maintaining reasonable commissural alignment as a way to improve the rate of coronary reaccess if needed and to allow an effective BASILICA (bioprosthetic or native aortic scallop intentional laceration to prevent iatrogenic coronary artery obstruction) technique prior to future TAVRin-TAVR interventions.

METHODS

Analysis of CT images was performed to identify anatomical features and to simulate TAVR orientation and positioning. A total of 107 consecutive patients who underwent pre-TAVR CT imaging between February and December 2020 at our institution were included. Seven patients were excluded because of poor visualization of coronary ostia and/or commissures or bicuspid aortic valve, resulting in a final study population of 100 patients. For each case, a virtual valve was simulated with ideal commissural or coronary alignment, and the degree of CO was determined. Clinical data were prospectively gathered for all patients in a dedicated database after approval from local ethics committees. Written informed consent was obtained from each patient.

CT MEASUREMENT OF COMMISSURE AND CORONARY ARTERY ORIENTATION. In a cross-sectional multiplanar reconstruction of the aortic root, the angular distances between coronary ostium and native commissures were measured using the RCA as the starting point. In a clockface view of the aortic root, the RCA was set at 12 o'clock, and clockwise direction was set as positive (**Central Illustration**).

VIRTUAL VALVE SIMULATION. The Central Illustration depicts the process from CT analysis to parametric modeling and virtual valve implantation and measurements. Measurements from CT scans were transferred to a parametric model of the aortic root of each specific patient (Grasshopper and Rhinoceros, McNeel and Associates). A Python script (Supplemental File 1) was written to simulate a virtual valve implant prosthesis given certain conditions. Two situations were simulated: 1) virtual valve rotation to minimize the distance from the neocommissures to the native commissures (optimal commissural alignment); and 2) virtual valve rotation to maximize the distance from the neocommissures to the coronary ostium (optimal coronary alignment). Optimal coronary alignment corresponds to positioning 1 of the neocommissures at the bisector of the angle between coronary arteries as long as the angle between coronaries is between 60° and 180° (all considered patients fall within these limits, although theoretically it is possible to find an extreme anatomy that does not), which can be easily calculated manually. Then, the 2 simulated virtual valves, 1 with optimal commissural alignment and 1 with optimal coronary alignment, were introduced to the parametric aortic model, in which automatic measurements of commissural misalignment (CMA) and CO were calculated.

CMA was defined as the mean angular distance among the 3 native commissures and neocommissures. The eccentricity of the coronary ostia was measured as the deviation angle from the center of their respective coronary sinus, with 0° as the ideal location for each coronary ostium (Central Illustration).

ESTIMATED PARAMETERS FOR BASILICA TECHNIQUE **EFFICACY.** Considering that the greatest preventive effect of the BASILICA technique is achieved when the coronary ostium is at the center of the leaflet, decreasing as the ostium is shifted towards the commissural post, a gradient of risk for coronary obstruction was estimated as follows: no CO (ostium to neocommissure deviation $>35^{\circ}$ to 60°), moderate CO (>20° to \leq 35°), and severe CO (\leq 20°) (Figure 1). This apparently unequal distribution of risk was selected because of the triangular shape of the split of the leaflet created by BASILICA, since if equal tertiles were used $(20^\circ, 40^\circ, 60^\circ)$ it might lead to an area "free" of occlusion risk narrower than the moderateand high-risk groups (both with a trapezoidal shape) and therefore overestimate the risk.

STATISTICAL ANALYSIS. Continuous variables are reported as median and IQR; normality of distribution was determined using the Kolmogorov-Smirnov test and Q-Q plots. The Mann-Whitney *U* test was used to compare continuous variables. We determined the optimal operating point in the area under the curve (AUC) as the one that equaled sensitivity and specificity regarding moderate to severe risk for CO to coronary eccentricity and the angle between the coronary arteries. We performed statistical analyses using R version 3.6.1 (R Project for Statistical Computing) and MedCalc version 18.9.1 (Med-Calc Software).

RESULTS

NATIVE COMMISSURES AND CORONARY ARTERIES ORIENTATION. A total of 100 pre-TAVR CT studies were analyzed. The orientations of native commissures and coronary ostia and the alternative positions of the neocommissures with optimal commissural alignment and optimal coronary alignment of each case are shown in Supplemental Table 1 and represented in Supplemental Figure 1. The median deviation of the RCA from the ideal centered position within the sinus of Valsalva (RCA eccentricity) was 18.5° (IQR: $3.3^{\circ}-22.8^{\circ}$), greater than the median deviation of the LCA from its centered position (6.5° ; IQR: $3.3^{\circ}-12.8^{\circ}$) (P < 0.001). The mean angle between coronary arteries was $140.0^{\circ} \pm 18.7^{\circ}$ (95% CI: $136.3^{\circ}-143.7^{\circ}$), with a range of 85° to 172° .

EFFECT OF CORONARY ECCENTRICITY ON CO: COMMISSURAL ALIGNMENT VERSUS OPTIMIZED CORONARY ALIGNMENT. In virtual valve simulation with optimal commissural alignment, the mean angle from the RCA ostium to the closest neocommissure was 42.0° (IQR: $33.5^{\circ}-52.0^{\circ}$), significantly lower than the angle from the LCA to the closest neocommissure (52.2° ; IQR: $46.3^{\circ}-55.6^{\circ}$) (P < 0.001). In these simulations, the rate of severe CO was 5% (5 cases), with 4 cases due to RCA ostium overlap and 1 case to LCA ostium overlap. A total of 32 cases had moderate or severe CO: 29 cases with RCA overlap, 3 with LCA overlap, and 1 case with both.

The presence of coronary eccentricity of the RCA was related to an increased risk for moderate or severe CO during virtual commissural alignment implant (AUC: 0.97; 95% CI: 0.91-0.99). A cutoff value of 24.5° yielded 100% sensitivity and 81% specificity to identify patients with moderate to severe CO with the RCA (Figure 2A). LCA eccentricity was also related to increased risk for moderate to severe CO when commissural alignment was simulated for implantation (AUC: 0.99; 95% CI: 0.94-1.00). A cutoff value of 19° yielded 100% sensitivity and 94.8% specificity for classifying patients with moderate to severe CO with the LCA. During simulated commissural alignment implantation, there was a linear correlation among LCA and RCA eccentricity and the degree of CO (Figure 2B).

In the optimal coronary alignment virtual implantation, none of the patients had severe CO, and 5 patients had moderate CO (4 with the RCA and 5 with the LCA) (Figure 2B). There were no significant differences in the distance from each coronary ostium to its closest neocommissure (RCA, 48.35 $^{\circ} \pm 6.88$; LCA, 48.1 $^{\circ}$ \pm 6.95; *P* = 0.783). Although the mean angular distance from the native commissures to the neocommissures with the valve in the optimal coronary alignment orientation was higher compared with commissural alignment strategy (4.3° vs 9.4° in the coronary optimized alignment; P < 0.001), there were no cases of severe CMA with the second strategy. However, there were 2 cases of moderate CMA (cases 59 and 28, with mean CMA of 31.3° and 41.7°) and 7 cases with mild CMA.



EFFECT OF ANGLE BETWEEN CORONARY ARTERIES DURING IMPLANTATION WITH COMMISSURAL ALIGNMENT VERSUS OPTIMIZED CORONARY ALIGNMENT. The influence of the angle between coronary arteries on CO is represented in Figure 3. During commissural alignment implantation, the larger the angle between coronary arteries, the greater the risk for CO for the RCA (AUC: 0.86; 95% CI: 0.78-0.92); conversely, the smaller this angle, the greater the risk for LCA overlap (AUC: 0.76; 95% CI: 0.66-0.84). An angle between coronary arteries >147° identified patients with moderate or severe risk for CO with the RCA (sensitivity 79.3%, specificity 77.5%), and an angle <103° yielded sensitivity of 75.0% and specificity of 96.9% for identifying patients with moderate or severe risk for CO with the LCA.

Optimized coronary-oriented implantation maximized the distance from the coronary ostia to the neocommissures, thus the angle between coronary arteries shows a dual slope correlation with the degree of CO, with an angle of 120° between coronary arteries presenting the largest distance from the coronary ostia to the neocommissure (coronary arteries would be located 60° apart from the neocommissure) and worsening linearly with wider or narrower angles (Figure 3B). With optimized coronary-oriented implantation, the distance between both coronary ostia with the closest neocommissure was equally distributed (48.35° \pm 6.9° for the RCA vs 48.10° \pm 7° for the LCA; P = 0.793). None of the patients would have had severe CO with optimal coronary-oriented implantation, and 5 would have had moderate CO. In all these cases, a large intercoronary angle existed (mean 170.5° \pm 1°-2°).

DISCUSSION

Technological improvements in TAVR devices must go hand in hand with tailored interventions that take into consideration anatomical and physiological patient-specific parameters in order to achieve further improvement in the current outcomes of this

CENTRAL ILLUSTRATION Continued



intervention. The availability of precise imaging assessment before the intervention provides unique opportunities to define new strategies, such as commissural alignment, with plenty of potential beneficial effects that are still being researched. In this study, we aimed to deepen and widen the scope of this promising strategy by means of virtual simulation. Our work supports the concept that adequate commissural alignment does not ensure adequate coronary alignment. Our main findings were as follows: 1) the RCA showed a higher degree of eccentricity compared with the LCA, and the mean angle between coronary arteries was 140.0° \pm 18° but widely varied across cases; 2) a coronary eccentricity of the RCA >24.5°, and of the LCA >19°, detected risk for moderate or severe CO despite ideal commissural alignment during implantation (an angle between coronary arteries >147° or <103° also identified increased risk for moderate or severe CO affecting at least 1 coronary ostium); and 3) the automatic calculation of an optimized coronary alignment for TAVR devices provided an acceptable rate of commissural alignment and, simultaneously, allowed a further decrease from 32% to 5% in the rate of moderate or

(A) Parametric aortic model of an ideally symmetrical aortic root anatomy: right coronary artery (RCA), left coronary artery (LCA) left coronary to non-coronary commissure (LCNC), left coronary to right coronary commissure (LCRC) and right coronary to non-coronary commissure (RCNC). (B) Schematic representation of the measurements for right coronary artery and left coronary artery (LCA) eccentricity and of the angle between coronary arteries. (C) Flowchart of the study. At the left, computed tomographic analysis of case 70: angle between RCA (black dotted line) and LCA (yellow dotted line) and commissure angulations: LCRC commissure (green line), LCNC commissure (red line), and RCNC commissure (blue line). The center top image is the parametric aortic representation of case 70; center bottom image depicts all cases included (n = 100). At the top left, the red triangle represents the position of the neocommissures (vertex of the triangle) in the commissural alignment implantation, and at the bottom left, the green triangle represents the optimized coronary alignment implantation; note how the green triangle (optimized coronary implantation) has the vertices far from the coronary arteries compared with the red triangle. (D) Cutoffs for coronary overlap when optimal commissural alignment. (E) Main findings.



severe CO, with no cases of severe CO. This strategy might be particularly useful for patients with longer life expectancy who may need eventual TAVR-in-TAVR procedures.

FACTORS AFFECTING THE RISK FOR CO. Recently, different factors have been proposed to increase risk for coronary occlusion in TAVR-in-TAVR driven by sinus sequestration. This can occur when the leaflets of the first TAVR are pushed vertically, during implantation of the subsequent TAVR, creating a cylindrical cage that depending on the relative sinotubular junction (STJ) height, distance from the transcatheter heart valve (THV) to the STJ, and mean sinotubular diameter, may isolate the coronary sinuses (6-8) impairing flow to the coronary arteries. The presence of high-risk features for TAVRin-TAVR is not uncommon. A recent study showed that intra-annular THV extending above the STJ occurs in the 21% of cases (29 of 137), increasing to 62.1% (18 of 29) in cases with distance from the STJ to the THV <2 mm. In long-stent THVs, the presence of high-risk features was described by Fovino et al (8), in up to 38.5% of cases with Evolut R (Medtronic) and 41.1% with ACURATE neo (Boston Scientific).





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pointing toward the inner curve in the coronary optimized alignment projection.

If high-risk features for coronary occlusion during TAVR-in-TAVR are present, the BASILICA technique (4) can avoid sinus sequestration. However, the BASILICA technique will not be effective if the laceration created in the leaflet by this procedure is not aligned with the coronary ostium. Thus, a second step in the CT evaluation of TAVR-in-TAVR feasibility in patients with high-risk factors should include the determination of the alignment of the commissural post of the previously implanted TAVR to evaluate the potential effectiveness of BASILICA. A summary of all these factors to be taken into consideration is elaborated in **Figure 4** for different TAVR stent frame designs.

FIGURE 4 Continued

Risk plane (dotted orange line): the level under which the stent frame of the host valve would be covered by its neoskirt. Green line denotes valve-to-sinotubular junction distance (VTSTJ) >2 mm. Red line denotes VTSTJ <2 mm. BA = balloon-assisted; BASILICA = bioprosthetic or native aortic scallop intentional laceration to prevent iatrogenic coronary artery obstruction; CT = computed tomographic; STJ = sinotubular junction; TAVR = transcatheter heart valve replacement.



The feasibility of BASILICA in the presence of highrisk features for coronary occlusion in TAVR-in-TAVR has been reported (9). In vitro tests evaluating BASILICA in TAVR-in-TAVR raised some concerns regarding the effectiveness and repeatability of the technique (10) that have been addressed by different BASILICA-like techniques, including balloon-assisted BASILICA, which allows a wider split of the leaflet before TAVR-in-TAVR (11).

The eccentricity of the RCA and LCA ostia has been investigated previously, with similar findings regarding eccentricity and variability of the ostia. Komatsu et al (5) evaluated the orientation of coronary arteries on pre-TAVR CT imaging, including 40% of cases with prior surgical aortic bioprosthesis. Interestingly, the investigators found that in patients with surgical bioprostheses, the eccentricity of the RCA was lower than in native cases (14.0° [IQR: 3°-20°] vs 19.0° [IQR: $12^{\circ}-26^{\circ}$]; P = 0.004). It is plausible that surgeons performed minor rotations of the bioprosthesis during implantation to avoid CO rather than to perfectly align it with the native commissures. This optimized coronary alignment performed by surgeons is in line with our hypothesis for TAVR.

In our sample, CO was not expected in most patients if commissural alignment implantation was performed (68 of the 100 cases). Two scenarios that may increase the risk for CO, even after commissural alignment, were detected: 1) when the angle between LCA and RCA is extreme (including $<103^{\circ}$ and $>147^{\circ}$); and 2) when there is severe eccentricity of the coronary ostia within the sinuses of Valsalva, including ${>}27^{\circ}$ for the RCA and ${>}19^{\circ}$ for the LCA. Such measurements can be easily calculated during pre-TAVR CT evaluation and used as red flags to alert for potential risk for CO even if commissural alignment strategies are used.

IMPACT OF CO IN BASILICA. The intentional laceration of the leaflets of bioprostheses has been described as a helpful strategy to reduce the risk for coronary obstruction during valve-in-valve procedures (4). The number of TAVR-in-TAVR procedures is expected to rapidly increase in the following years because of the longer life expectancy of TAVR recipients, and thus good alignment of TAVR devices is increasingly relevant. The laceration of the leaflet during BASILICA affects the midportion of the leaflet, creating a triangular uncovered space when the new valve is implanted within (**Figure 1**); the center of the leaflet is the location where the intended effect of BASILICA technique is more effective, but the beneficial effect decreases toward the sides and is minimal where the leaflets are attached to the commissural posts.

Thus, once BASILICA is performed, the risk for coronary occlusion, rather than binary (present or not), could be better represented as a gradient depending on the position of the native coronary ostium within the sinus of Valsalva (Figure 1). This hypothesis is confirmed by recent reports of partial coronary occlusion during BASILICA-facilitated valve-in-valve procedures (12). The investigators reported a rate of complete or partial coronary occlusion of 4.7%, although with lower mortality than cases with this complication and no prior BASILICA (10% vs 40%-50%) (13,14). Importantly, cases were mainly TAVR-in-surgical aortic valve replacement (156 of 214), with only 3 cases of TAVR-in-TAVR, meaning that most of the patients likely had commissural alignment with optimized coronary alignment of their prior prosthetic valves, performed by surgeons during the first replacement (15). Therefore, the adequate outcomes reported with BASILICA to date might not be representative of future outcomes of TAVR-in-TAVR interventions, especially considering that nowadays most TAVR procedures do not incorporate commissural or coronary alignment.

STRATEGIES FOR CORONARY ALIGNMENT AND A POTENTIAL APPROACH. Techniques for commissure alignment of TAVR have been recently described (16-18). The "ACA project" (17) suggests a strategy based on introducing the device within the patient with a previously identified axial rotation on the basis of CT analysis. This strategy still needs to be validated in larger populations with challenging anatomies and simplified for more extended use; however, it represents the most patient-specific approach and could be easily modified to achieve optimal coronary rotation following the same principle. **Figure 5 and** Video 1 illustrates a case of optimal coronary alignment based on the ACA project.

More extended strategies include a method derived from the findings of the ALIGN-TAVR study (18), using the computed tomography-estimated 2-cusp C-arm projection (left coronary cusp to right coronary cusp) to improve and individualize the alignment of the Evolut TAVR platform. Figure 6 summarizes the process for obtaining a modified C-arm projection to guide optimized coronary alignment implantation with most self-expandable devices.

STUDY LIMITATIONS. This was an observational study evaluating the geometric interaction of TAVR devices with the components of the aortic root and proposing an alternative implantation orientation of TAVR that aims to diminish the degree of CO compared with commissural alignment. We hypothesize that the effect of BASILICA can be maximized with this coronary-focused orientation, particularly in the presence of high-risk features for coronary occlusion during TAVR-in-TAVR. However, the interplay of those high-risk features and how they could affect the effectiveness of BASILICA have not been evaluated. The classification in 3 categories of risk leads to a subgroup of moderate risk with ambiguous interpretation, but its inclusion helps more accurately determine actual risk when putting together all the factors influencing the risk for coronary obstruction.

The aforementioned methods for achieving optimal coronary orientation are both based on CT analysis; variations in the position of the patient at the moment of TAVR implantation may affect their accuracy, as for the estimation of coplanar view.

CONCLUSIONS

The efficacy of the BASILICA technique for eventual TAVR-in-TAVR procedures depends of the degree of CO. Despite commissural alignment, moderate or severe CO might affect one third of the patients because of coronary ostial eccentricity within the sinus of Valsalva. A new strategy based on optimized coronary alignment might have avoided severe CO in all cases and minimized the incidence of moderate CO to 5%. Implantation with this new orientation is feasible using concepts that are already being applied for patient-specific commissural alignment.

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PERSPECTIVES

WHAT IS KNOWN? Techniques to perform commissural alignment in TAVR allow the reduction of CO. However, eccentric coronary ostia may decrease the efficacy of the BASILICA technique for eventual TAVR-in-TAVR.

WHAT IS NEW? One third of patients would have had CO during TAVR-in-TAVR despite commissural alignment; a 6-fold decrease in this risk was achieved with optimized coronary alignment. Coronary eccentricity and intercoronary angle varied widely across patients and were the main predictors of moderate or high risk for CO.

WHAT IS NEXT? Both preclinical and clinical studies need to explore the benefits of coronary alignment to achieve safer outcomes if eventual TAVR-in-TAVR is required.

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KEY WORDS BASILICA, commissural alignment, coronary obstruction, TAVI, TAVR

APPENDIX For a supplemental figure, a supplemental table, the Python script for estimation of the commissural position of TAVR devices, and a supplemental video, please see the online version of this paper.