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Delayed Coronary Obstruction After Transcatheter Aortic Valve Replacement

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ABSTRACT

BACKGROUND Delayed coronary obstruction (DCO) is an uncommon and barely reported complication following transcatheter aortic valve replacement (TAVR).

OBJECTIVES The aim of this study was to describe the incidence and pathophysiological features of DCO after TAVR, obtained from a large international multicenter registry.

METHODS Data were retrospectively collected from an international multicenter registry consisting of 18 centers between November 2005 and December 2016.

RESULTS During the study period, 38 DCO (incidence 0.22%) cases were identified from a total of 17,092 TAVR procedures. DCO occurred more commonly after valve-in-valve procedures (0.89% vs. 0.18%; $p < 0.001$) and if self-expandable valves were used during the index procedure (0.36% vs. 0.11% balloon expandable; $p < 0.01$). DCO was most likely to occur ≤24 h after the TAVR procedure (47.4%; n = 18); 6 (15.8%) cases occurred between 24 h and ≤7 days, with the remaining 14 (36.8%) at ≥60 days. The most frequent presentation was cardiac arrest (31.6%; n = 12), followed by ST-segment elevation myocardial infarction (23.7%; n = 9). The left coronary artery was obstructed in most cases (92.1%; n = 35). Percutaneous coronary intervention was attempted in the majority of cases (74.3% left main; 60% right coronary), and stent implantation was successful in 68.8%. The overall in-hospital death rate was 50% (n = 19), and was higher if DCO occurred ≤7 days from the index procedure (62.5% vs. 28.6%; $p = 0.09$).

CONCLUSIONS DCO following TAVR is a rare phenomenon that is associated with a high in-hospital mortality rate. Clinicians should be aware that coronary obstruction can occur after the original TAVR procedure and have a low threshold for performing coronary angiography when clinically suspected. (J Am Coll Cardiol 2018;71:1513–24)

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ABBREVIATIONS AND ACRONYMS

CABG = coronary artery bypass grafting

CT = computed tomography

DCO = delayed coronary obstruction

LCA = left coronary artery

PCI = percutaneous coronary intervention

RCA = right coronary artery

SOV = sinus of Valsalva

STEMI = ST-segment elevation myocardial infarction

TAVR = transcatheter aortic valve replacement

ViV = valve-in-valve

Transcatheter aortic valve replacement (TAVR) is now an established treatment option for intermediate- and high-risk surgical patients with severe aortic stenosis (1,2). Although there are numerous recognized and relatively common complications related to the TAVR procedure, including vascular injury and the development of conduction disturbances requiring permanent pacemaker implantation, much rarer complications have been described by using data gathered from large international multicenter registries (3,4). Coronary obstruction has long been a recognized potential complication of TAVR and is generally understood to occur in the seconds or minutes after valve deployment (5). However, a few case reports have described the development of delayed coronary obstruction (DCO) occurring in the hours and days following the procedure (6–11). Therefore, to better understand and characterize this phenomenon, we gathered data and analyzed cases of DCO from a large international multicenter registry.

SEE PAGE 1525

METHODS

This international multicenter registry included all cases of DCO following TAVR obtained from 18 centers (8 countries) in North America, Europe, and the Middle East from November 2005 to December 2016 (Online Table 1). DCO was defined as: 1) obstruction of the left main or ostial right coronary artery (RCA) occurring after a patient has left an operating room in a stable condition following successful TAVR; 2) diagnosis by angiogram, surgery, or autopsy at the time of the event; and 3) not solely related to the progression of pre-existing coronary artery disease or in-stent restenosis.

Data were collected including baseline clinical, echocardiographic, and procedural characteristics of the index procedure. Additionally, data on clinical presentation, diagnosis, and management of the DCO complication, as well as in-hospital, early, and late clinical outcomes were gathered. Clinical events were defined as per the VARC (Valve Academic Research Consortium)-2 criteria (12).

Each center also provided information on the total number of TAVR cases performed during the study period, as well as valve type implanted and approach (e.g., femoral, apical, or subclavian).

The investigators at each center were required to input the aforementioned data into a patient-level database, and sent the anonymized data to the study coordinators (R.J., A.T.) for analysis. Source verification and query generation from the coordinating center to the participating sites were undertaken to partly account for the unavoidable bias of site-reported event adjudication.

All available dedicated TAVR computed tomography (CT) scans were evaluated centrally (Milan, Italy) in a uniform manner by 2 operators (R.J., A.T.), and data on coronary heights, aortic annulus diameter/perimeter/area, sinus of Valsalva (SOV)/sinotubular junction diameter, distance between the implanted valve and sinus of Valsalva, and severity and distribution of valve calcification were recorded. In addition, device implantation depth was assessed as previously described (13,14). First, a straight line was traced from the inferior border of each side of the device to the aortic annulus (or surgical valve ring in valve-in-valve [ViV] cases). The 2 values were then averaged giving the final implantation depth. High

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implantation was defined as <4 mm for CoreValve and <3 mm for CoreValve Evolut R (Medtronic, Minneapolis, Minnesota). For Sapien XT/S3 (Edwards Lifesciences, Irvine, California), a high implantation was defined as an aorto-ventricular ratio of 60/40. For ViV cases, a >90/10 aorto-ventricular ratio was deemed as high implantation with balloon-expandable valves and ≤5 mm for self-expandable valves (13,14). Aortic valve calcification and left ventricular outflow tract calcification were graded semi-quantitatively as described previously (15).

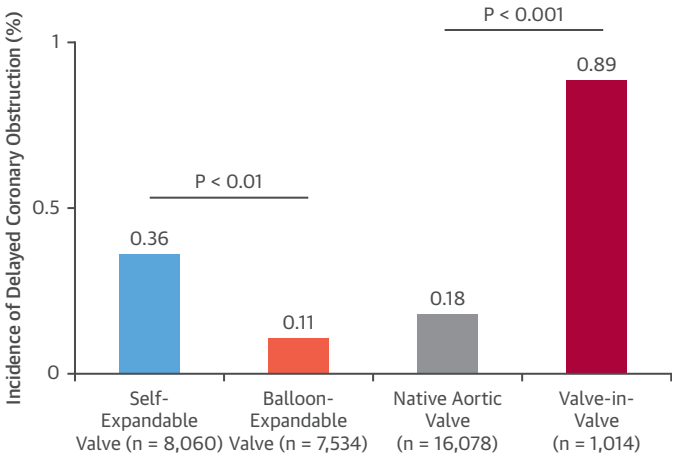
STATISTICAL ANALYSIS. Categorical variables are reported as n (%), and continuous variables are expressed as mean ± SD or median (interquartile range). Group comparisons were analyzed using the Mann-Whitney *U* test. The Fisher exact test was performed for categorical variables. Cumulative event rates were calculated by Kaplan-Meier methods. All analyses were performed using the SPSS 21.0 software package (SPSS, Chicago, Illinois).

RESULTS

INCIDENCE AND BASELINE CHARACTERISTICS. Of 17,092 patients (14,729 [86.2%] femoral access) who underwent TAVR procedures in 18 centers from Europe, North America, and the Middle East between November 2005 and December 2016, 38 cases of DCO (0.22% incidence) occurred. DCO occurred more commonly after ViV procedures (0.89% vs. 0.18%; $p < 0.001$) and if self-expandable valves were used during the index procedure (0.36% vs. 0.11% balloon expandable; $p < 0.01$) (**Figure 1**). The baseline clinical characteristics of the patients who experienced DCO are described in **Table 1**. The mean age of patients presenting with DCO was 81.8 ± 9.5 years, 23.7% (n = 9) were male, mean Society of Thoracic Surgeons score was 6.1 ± 3.9, and 23.7% (n = 9) had a previous bioprosthetic aortic valve implanted. One patient had a prior history of coronary artery bypass graft surgery (CABG). Baseline echocardiographic and angiographic characteristics are described in **Table 2**. The mean ejection fraction of the cohort was 56.3 ± 11.1%, mean aortic valve gradient was 49.9 ± 20.9 mm Hg, and peak gradient was 79.9 ± 29.6 mm Hg. Thirteen (34.2%) patients had a baseline level of aortic regurgitation ≥ moderate. All patients underwent either coronary or CT angiography prior to TAVR, and no patient had significant ostial left main or RCA disease or prior stent implantation before TAVR.

COMPUTED TOMOGRAPHY. Pre-implantation CT scans were analyzed in 27 (71.1%) patients, and the results are described in **Table 3**. The mean annulus diameter was 22.8 ± 2.4 mm (maximum 24.9 ± 2.5 mm; minimum 20.8 ± 2.9 mm), and mean SOV diameter was 29.2 ± 3.5 mm. Nineteen (82.6%) patients with a native valve had aortic valve

FIGURE 1 Incidence of Delayed Coronary Obstruction According to Valve Type and TAVR Procedure



Delayed coronary obstruction occurred more commonly if self-expanding valves were used during the index procedure as opposed to balloon-expandable devices (0.36% self-expandable vs. 0.11% balloon-expandable; $p < 0.01$). Valve-in-valve procedures were associated with a higher incidence of delayed coronary obstruction (0.89% vs. 0.18%; $p < 0.001$). TAVR = transcatheter aortic valve replacement.

TABLE 1 Baseline Patient Characteristics (N = 38)

Age, yrs	81.8 ± 9.5
Male	9 (23.7)
Body mass index, kg/m^2	27.1 ± 4.5
Hypertension	32 (84.2)
Diabetes	8 (21.1)
Dyslipidemia	21 (55.3)
Smoking history	8 (21.1)
Previous myocardial infarction	4 (10.5)
Prior coronary artery bypass grafting	1 (2.6)
Prior percutaneous coronary intervention	9 (23.7)
Prior stroke or transient ischemic attack	4 (10.5)
Prior pacemaker	2 (5.3)
Prior aortic valve replacement*	9 (23.7)
History of congestive heart failure	13 (34.2)
Chronic obstructive pulmonary disease	5 (13.2)
Peripheral artery disease	6 (15.8)
Porcelain aorta	1 (2.6)
Creatinine, mg/dl	1.13 ± 0.52
NYHA functional class I/II/III/IV	0/7/27/4
STS score, %	6.1 ± 3.9
Logistic EuroSCORE, %	17.1 ± 12.0

Values are mean ± SD, n (%), or n. *Bioprosthetic.
NYHA = New York Heart Association; STS = Society of Thoracic Surgeons.

TABLE 2 Baseline Information Regarding Coronary Artery Disease and Echocardiographic Data (N = 38)

Coronary artery disease	
Left main ostial disease (≥50%)	0 (0.0)
Prior left main ostial stent	0 (0.0)
Right coronary ostial disease (≥50%)	0 (0.0)
Prior right coronary ostial stent	0 (0.0)
Left anterior descending artery disease	8 (21.1)
Left circumflex artery disease	9 (23.7)
Right coronary artery disease	6 (15.8)
Complete revascularization prior TAVR	9 (23.7)
Echocardiogram	
Aortic regurgitation: no or trivial/mild/moderate/severe	8/17/7/6
Mean AV gradient, mm Hg	49.9 ± 20.9
Peak AV gradient, mm Hg	79.9 ± 29.6
AVA, cm^2	0.75 ± 0.34
LVEF, %	56.3 ± 11.1

Values are n (%), n, or mean ± SD.

AV = aortic valve; AVA = aortic valve area; LVEF = left ventricular ejection fraction; TAVR = transcatheter aortic valve replacement.

TABLE 3 CT Measurements Before TAVR

CT Data Available	Overall (n = 27)	Early (0–7 Days) (n = 16)	Late (>7 Days) (n = 11)	p Value
Annulus				
Area, mm^2	365 (347–443)	368 (350–476)	352 (312–385)	0.21
Perimeter, mm	73.4 ± 7.7	73.5 ± 7.8	73.3 ± 8.0	0.82
Mean diameter, mm	22.8 ± 2.4	22.8 ± 2.7	22.9 ± 2.2	0.75
Minimum diameter, mm	20.8 ± 2.9	20.8 ± 2.9	20.8 ± 3.0	0.87
Maximum diameter, mm	24.9 ± 2.5	24.8 ± 2.9	25.0 ± 1.8	0.79
Mean SOV diameter, mm	29.2 ± 3.5	28.9 ± 3.5	29.7 ± 3.7	0.58
<30 mm	15 (55.6)	9 (56.3)	6 (54.5)	1.0
Mean SOV/annulus diameter	1.28 ± 0.07	1.27 ± 0.05	1.30 ± 0.08	0.37
Mean ST junction diameter, mm	25.2 ± 2.6	25.3 ± 2.9	25.1 ± 1.8	1.0
Ascending aorta, mm	32.9 ± 4.8	31.3 ± 4.1	35.4 ± 5.2	0.04
LCA height, mm	12.0 ± 3.3	10.8 ± 2.7	13.8 ± 3.4	0.03
<10 mm	7 (25.9)	6 (37.5)	1 (9.1)	0.18
<12 mm	13 (48.1)	10 (62.5)	3 (27.3)	0.12
RCA height, mm	14.2 ± 3.1	13.7 ± 3.4	15.0 ± 2.6	0.34
<10 mm	2 (7.4)	2 (12.5)	0 (0.0)	0.50
<12 mm	4 (14.8)	3 (18.8)	1 (9.1)	0.62
Occluded coronary height <12 mm	13 (48.1)	10 (62.5)	3 (27.3)	0.12
SOV – THV size, mm	2.7 ± 2.6	2.7 ± 2.9	2.7 ± 2.4	0.75
≤3 mm	16 (59.3)	10 (62.5)	6 (54.5)	0.71
Aortic valve calcification				
None/mild/moderate/severe	2/2/10/9	1/1/4/7	1/1/6/2	
Surgical valve	4	3	1	
LVOT calcification				
None/mild/moderate/severe	12/12/3/0	9/5/2/0	3/7/1/0	

Values are median (interquartile range), mean ± SD, n (%), or n.

CT = computed tomography; LCA = left coronary artery; LVOT = left ventricular outflow tract; RCA = right coronary artery; SOV = sinus of Valsalva; ST = sinotubular; TAVR = transcatheter aortic valve replacement; THV = transcatheter heart valve.

calcification ≥ moderate. The mean left and right coronary heights were 12.0 ± 3.3 mm and 14.2 ± 3.1 mm, respectively.

Of the 27 CT scans available for central analysis, 15 (55.6%) patients had mean SOV diameter <30 mm, 13 (48.1%) had left coronary artery (LCA) height <12 mm, and 4 (14.8%) had RCA height <12 mm from the aortic annulus. A total of 24 DCO cases (88.9%) involved the left main trunk, and 11 (45.8%) had LCA height <12 mm from the aortic annulus. By contrast, 8 (29.6%) DCOs involved the RCA, and in 3 (37.5%) cases, the RCA height was <12 mm from the aortic annulus. A total of 66.6% (n = 18 of 27) of patients had at least 1 well known classical risk factor for coronary obstruction (ViV procedure, SOV <30 mm, or RCA or LCA <12 mm).

ORIGINAL TAVR PROCEDURES. The details of the original TAVR procedures of the 38 DCO cases are depicted in Table 4. The femoral access route was most commonly used (97.4%; n = 37). Nine cases were ViV procedures (6 Mitroflow [Sorin Group, Milan, Italy], 1 Toronto SPV [St. Jude Medical, Minneapolis, Minnesota], 1 Perimount [Carpentier-Edwards; Edwards Lifesciences, Irvine, California], and 1 Elan [Vascutek, Inchinnan, Renfrewshire, Scotland]), and self-expandable valves were most commonly implanted (76.3%; n = 29). More specifically, the valves used included CoreValve/Evolut R (68.4%; n = 26), Sapien XT/3 (21.1%; n = 8), Portico [St. Jude Medical] (7.9%; n = 3), and Lotus (Boston Scientific, Marlborough, Massachusetts) (2.6%; n = 1). Balloon pre- and post-dilation occurred in 24 (63.2%) and 5 (13.2%) patients, respectively. The left main was protected (with a coronary guidewire during valve implantation) in 9 (23.7%) cases, and left main stent implantation after TAVR deployment was performed in 7 (18.4%) patients. In 2 patients, a second valve was needed immediately after the first valve was deployed due to severe aortic regurgitation caused by high implantation. In total, 47.4% (n = 18) of TAVR devices were deemed to have a high implantation depth, which equated to 48.3% (14 of 29) of the self-expandable and 50% (4 of 8) of the balloon-expandable valves used. A total of 59.3% (n = 16) of patients had ≤3 mm difference between SOV dimension and size of TAVR device implanted. Acute coronary obstruction was ruled out by selective coronary angiography/aortography in 97.4% (n = 37) of patients, and all 38 patients left the operating room in a hemodynamically stable condition without clinical suspicion/ischemic ECG features suggestive of coronary obstruction.

TIME OF OCCURRENCE, CLINICAL PRESENTATION, MANAGEMENT, AND OUTCOME OF DCO. Details and management of DCO are presented in Table 5. DCO

TABLE 4 TAVR Procedure

	Overall (N = 38)	Early (0-7 Days) (n = 24)	Late (>7 Days) (n = 14)	p Value
Approach				1.00
Transfemoral	37 (97.4)	23 (95.8)	14 (100.0)	
Transapical	1 (2.6)	1 (4.2)	0 (0.0)	
Valve-in-valve	9 (23.7)	8 (33.3)	1 (7.1)	0.12
Valve type				0.21
CoreValve/Evolut R	26 (68.4)	15 (62.5)	11 (78.6)	
Portico	3 (7.9)	1 (4.2)	2 (14.3)	
Sapien XT/3	8 (21.1)	7 (29.2)	1 (7.1)	
Lotus	1 (2.6)	1 (4.2)	0 (0.0)	
Valve size, mm				
20	1 (2.6)	1 (4.2)	0 (0.0)	
23	7 (18.4)	7 (29.2)	0 (0.0)	
25	2 (5.3)	0 (0.0)	2 (14.3)	
26	17 (44.7)	11 (45.9)	6 (42.9)	
27	1 (2.6)	1 (4.2)	0 (0.0)	
29	10 (26.3)	4 (16.7)	6 (42.9)	
Procedural details				
Pre-dilation	24 (63.2)	11 (45.8)	13 (92.9)	0.005
Post-dilation	5 (13.2)	5 (20.8)	0 (0.0)	0.14
Left main protection	9 (23.7)	6 (25.0)	3 (21.4)	1.0
Left main stenting	7 (18.4)	2 (8.3)	5 (35.7)	0.08
Right coronary artery protection	0 (0.0)	0 (0.0)	0 (0.0)	-
Right coronary artery stenting	0 (0.0)	0 (0.0)	0 (0.0)	-
Aortogram post implantation	37 (97.4)	24 (100.0)	13 (92.9)	0.37
Selective coronary cannulation	5 (13.2)	4 (16.7)	1 (7.1)	0.63
Second valve implant	2 (5.3)	1 (4.2)	1 (7.1)	1.00
New permanent PM implantation	0 (0.0)	0 (0.0)	0 (0.0)	-
Major VARC2 vascular complication	1 (2.6)	1 (4.2)	0 (0.0)	1.00
≥ Major VARC2 bleeding	2 (5.3)	2 (8.3)	0 (0.0)	0.52

Values are n (%).

PM = pacemaker; TAVR = transcatheter aortic valve replacement; VARC2 = Valve Academic Research Consortium 2.

TABLE 5 Delayed Coronary Obstruction Details

	Overall (N = 38)	Early (0-7 Days) (n = 24)	Late (>7 Days) (n = 14)
Timing			
Within 24 h	18 (47.4)	18 (75.0)	-
After 24 h ≤7 days	6 (15.8)	6 (25.0)	-
8 to <30 days	0 (0.0)	-	0 (0.0)
30 to <60 days	0 (0.0)	-	0 (0.0)
60 to <180 days	5 (13.2)	-	5 (35.7)
180 to <360 days	6 (15.8)	-	6 (42.9)
≥360 days	3 (7.9)	-	3 (21.4)
Clinical presentation*			
Cardiac arrest	12 (31.6)	9 (37.5)	3 (21.4)
STEMI	9 (23.7)	9 (37.5)	0 (0.0)
NSTEMI	8 (21.1)	4 (16.7)	4 (28.6)
Unstable angina	6 (15.8)	2 (8.3)	4 (28.6)
Stable angina	3 (7.9)	0 (0.0)	3 (21.4)
Asymptomatic	0 (0.0)	0 (0.0)	0 (0.0)
Initial diagnosis			
Angiogram	35 (92.1)	21 (87.5)	14 (100.0)
Direct CABG	1 (2.6)	1 (4.2)	0 (0.0)
Autopsy	2 (5.3)	2 (8.3)	0 (0.0)
Coronary obstruction			
LMT	35 (92.1)	21 (87.5)	14 (100.0)
RCA	10 (26.3)	7 (29.2)	3 (21.4)
Both LMT/RCA	7 (18.4)	4 (16.7)	3 (21.4)
LM obstruction	35	21	14
Complete	6 (17.1)	5 (23.8)	1 (7.1)
Partial	29 (82.9)	16 (76.2)	13 (92.9)
RCA obstruction	10	7	3
Complete	6 (60.0)	5 (71.4)	1 (33.3)
Partial	4 (40.0)	2 (28.6)	2 (66.7)
LM revascularization	35	21	14
PCI	26 (74.3)	17 (81.0)	9 (64.3)
Successful	21 (80.8)	14 (82.4)	7 (77.8)
Unsuccessful	5 (19.2)	3 (17.6)	2 (22.2)
CABG	6 (17.1)†	2 (9.5)	4 (28.6)
Not attempted	4 (11.4)	2 (9.5)	2 (14.3)
RCA revascularization	10	7	3
PCI	6 (60.0)	4 (57.1)	2 (66.7)
Successful	1 (16.7)	1 (25.0)	0 (0.0)
Unsuccessful	5 (83.3)	3 (75.0)	2 (100.0)
CABG	3 (30.0)‡	1 (14.3)	2 (66.7)
Not attempted	3 (30.0)	3 (42.9)	0 (0.0)
Outcome			
In-hospital death	19 (50.0)	15 (62.5)§	4 (28.6)§

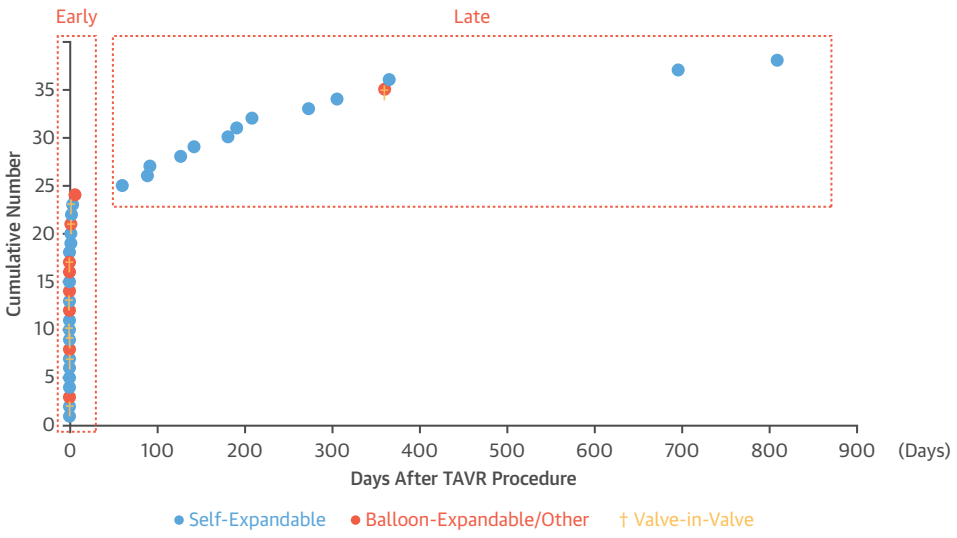
Values are n (%) or n. *p value (early [≤7 days] vs. late) = 0.004. †1 of 6 was after unsuccessful PCI. ‡2 of 3 were after unsuccessful PCI. §p = 0.09.

CABG = coronary artery bypass grafting; LM = left main; LMT = left main trunk; NSTEMI = non-ST-segment elevation myocardial infarction; PCI = percutaneous coronary intervention; RCA = right coronary artery; STEMI = ST-segment elevation myocardial infarction.

occurred most commonly within 24 h of the index TAVR procedure (n = 18); 6 cases occurred from 24 h to 7 days; and 14 cases after 60 days (**Figure 2**). Notably, there were no cases of DCO between 7 and 59 days. The most common presentation was cardiac arrest (31.6%; n = 12), followed by ST-segment elevation myocardial infarction (STEMI) (23.7%, n = 9) and non-STEMI (21.1%; n = 8). Diagnosis was initially made by coronary angiography in 35 (92.1%) patients and by autopsy in 2 (5.3%) patients.

The left coronary artery was obstructed in most cases (92.1%; n = 35), right coronary in 26.3% (n = 10), and both in 18.4% (n = 7). Percutaneous coronary intervention (PCI) was the most common management option (74.3% left main [n = 26 of 35]; 60% right coronary [n = 6 of 10]), and stent implantation was more successful if left main PCI (n = 21; 80.8%) was attempted when compared with RCA PCI (n = 1; 16.6%). A total of 7 patients proceeded to undergo emergency CABG. Overall, the in-hospital death rate was 50%

FIGURE 2 Timing of Delayed Coronary Obstruction Events Following TAVR Procedure



Delayed coronary obstruction occurred most commonly within 24 h of the index transcatheter aortic valve replacement (TAVR) procedure (n = 18); 6 cases occurred from 24 h to 7 days; and 14 cases after 60 days. Notably, there were no cases of delayed coronary obstruction between 7 and 59 days. Nine cases were valve-in-valve procedures († indicated valve-in-valve index procedure).

(n = 19) (Figure 3). There was a similar survival rate between CABG and PCI (57.1% [4 of 7] vs. 59.2% [16 of 27]). The median follow-up of the survivors following DCO was 375 days (interquartile range: 35 to 1,026 days), and no case of stent thrombosis or death occurred in any patient who survived to hospital discharge. One patient underwent target-vessel revascularization during the follow-up period.

FIGURE 3 Kaplan-Meier Curve of All-Cause Death After DCO

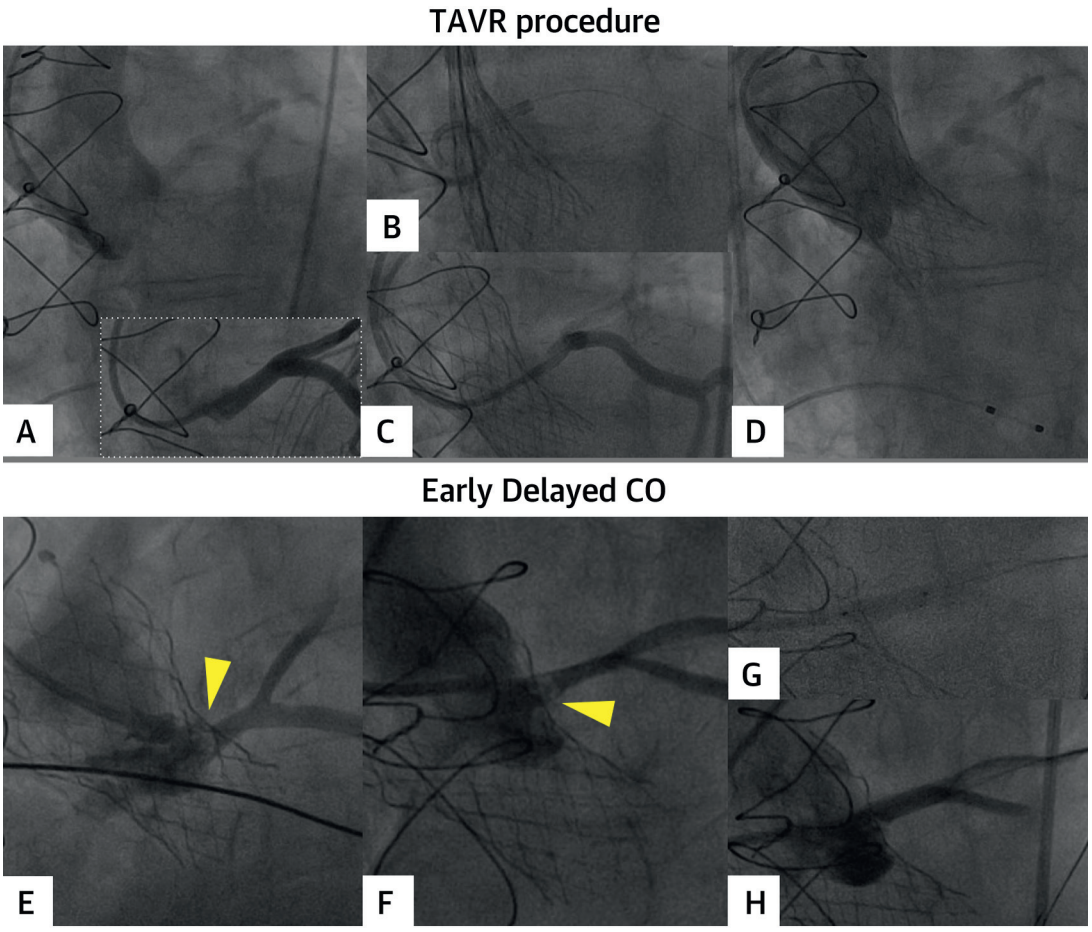
The in-hospital death rate was 50% (n = 19). The median follow-up of the survivors following delayed coronary obstruction (DCO) was 375 days (interquartile range: 35 to 1,026 days), and no case of stent thrombosis or death occurred in any patient who survived to hospital discharge. One patient underwent target-vessel revascularization during the follow-up period.

EARLY (≤7 DAYS) VERSUS LATE (>7 DAYS) OBSTRUCTION. The study population was dichotomized into those patients in whom obstruction occurred less than (n = 24) or later than 7 days (n = 14) from the index TAVR procedure (Figure 2). Procedurally, there were no significant differences between the type of valve prosthesis used and timing of DCO event (early versus late; p = 0.21). Eight (88.9%) of the ViV DCO cases occurred within 7 days.

Patients presenting within 7 days of the index procedure were more likely to present in either cardiac arrest/STEMI (75% vs. 21.4%). In contrast, DCO cases presenting >7 days after the index procedure were more likely to present with stable or unstable angina (50% vs. 8.3%). Of the 27 analyzed CT scans, DCO cases ≤7 days had lower mean LCA height (10.8 ± 2.7 mm vs. 13.8 ± 3.4 mm; p = 0.03) and prognostically DCO cases ≤7 days had a higher in-hospital mortality rate than those after 7 days (62.5% vs. 28.6%; p = 0.09) (Table 5).

POTENTIAL MECHANISMS OF CORONARY OBSTRUCTION. Early (≤7 days). A representative case of early delayed coronary obstruction is shown in Figure 4. Among the 24 cases that occurred within 7 days, 91.7% (n = 22) were thought to be related to

FIGURE 4 Representative Case of Early Delayed Coronary Obstruction

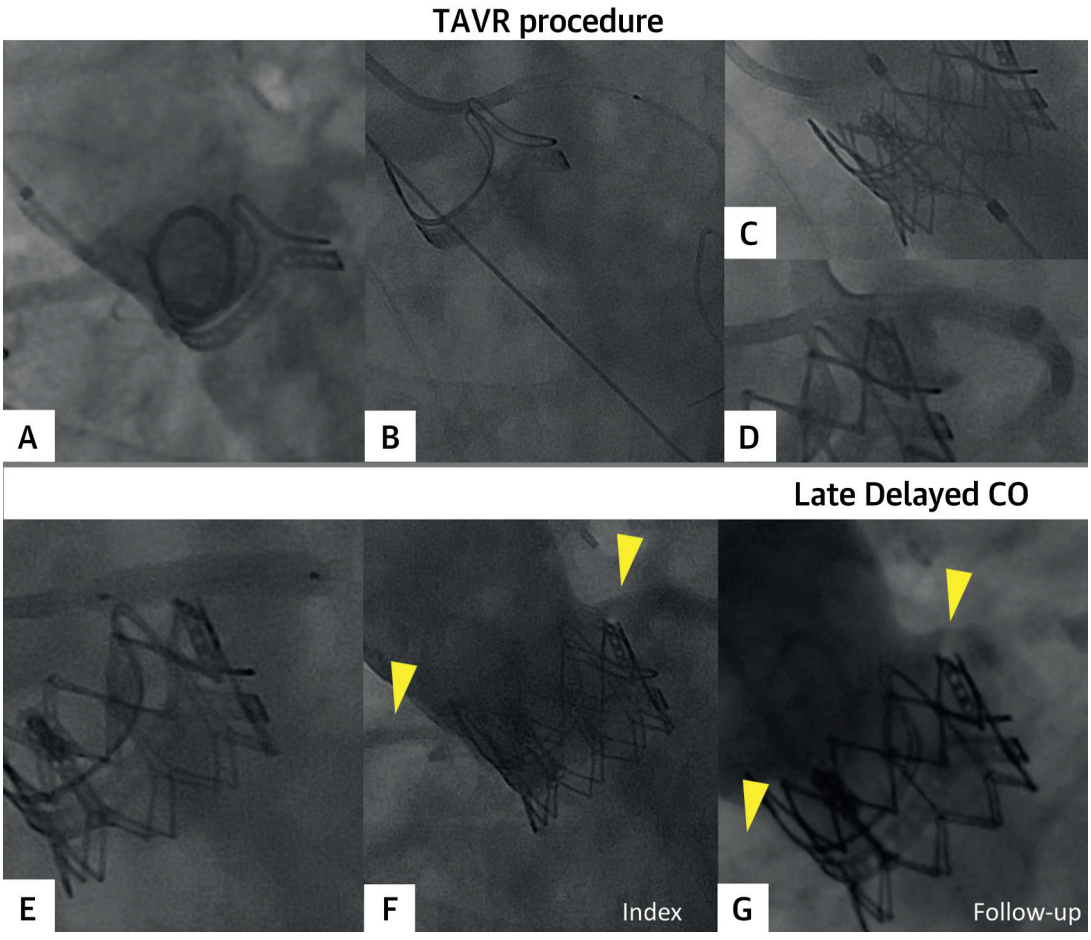


A 70-year old woman with previous history of aortic bioprosthetic valve (23-mm Elan, Vascutek, Terumo) implantation underwent transcatheter aortic valve replacement (TAVR). Pre-implantation computed tomography indicated low left coronary ostial height (7 mm). Baseline aortography and coronary angiography revealed no significant disease of the left main trunk **(A)**. A 23-mm Evolut R (Medtronic) was implanted with guidewire protection of left system **(B)**. Final angiogram and aortography confirmed lack of obstruction **(C and D)**. At day 3 post-TAVR, the patient experienced chest pain and then developed cardiac arrest. Coronary angiogram revealed partial left main obstruction **(E and F)**. A 3.5- × 12-mm bare-metal stent was implanted at the left main ostium **(G)**. An acceptable final angiogram was obtained **(H)**; however, the patient died 90 min following the onset of cardiac arrest. **Yellow arrowheads** indicate probable native leaflet occluding the left main coronary artery.

the displacement of a calcified native valve leaflet or surgical valve leaflet. In 1 patient, a minor left main ostium dissection due to selective cannulation just after valve deployment, which then extended, was suspected as the main cause of DCO. In another patient, a highly implanted valve resulted in severe aortic regurgitation, and consequently a second valve (Portico) was implanted. At 30 min after the end of the procedure, the patient developed STEMI, complete RCA obstruction was diagnosed by angiography, the RCA was unable to be engaged, and the patient subsequently died. Valve leaflet obstruction was confirmed by autopsy.

Late (>7 days). A representative case of late delayed coronary obstruction is shown in Figure 5. Among the 14 remaining cases that occurred after 7 days, the predominant mechanism of DCO (n = 12; 85.7%) was thought to be related to bioprosthetic valve endothelialization with some degree of obstruction caused by either the native or bioprosthetic valve leaflet. In 2 cases, embolization of unknown thrombus located on the TAVR valve (including 1 with thrombus in sinus of Valsalva) caused the development of DCO. The first patient was an 83-year-old female who underwent transfemoral TAVR (Portico 25 mm). During the index procedure, the valve became

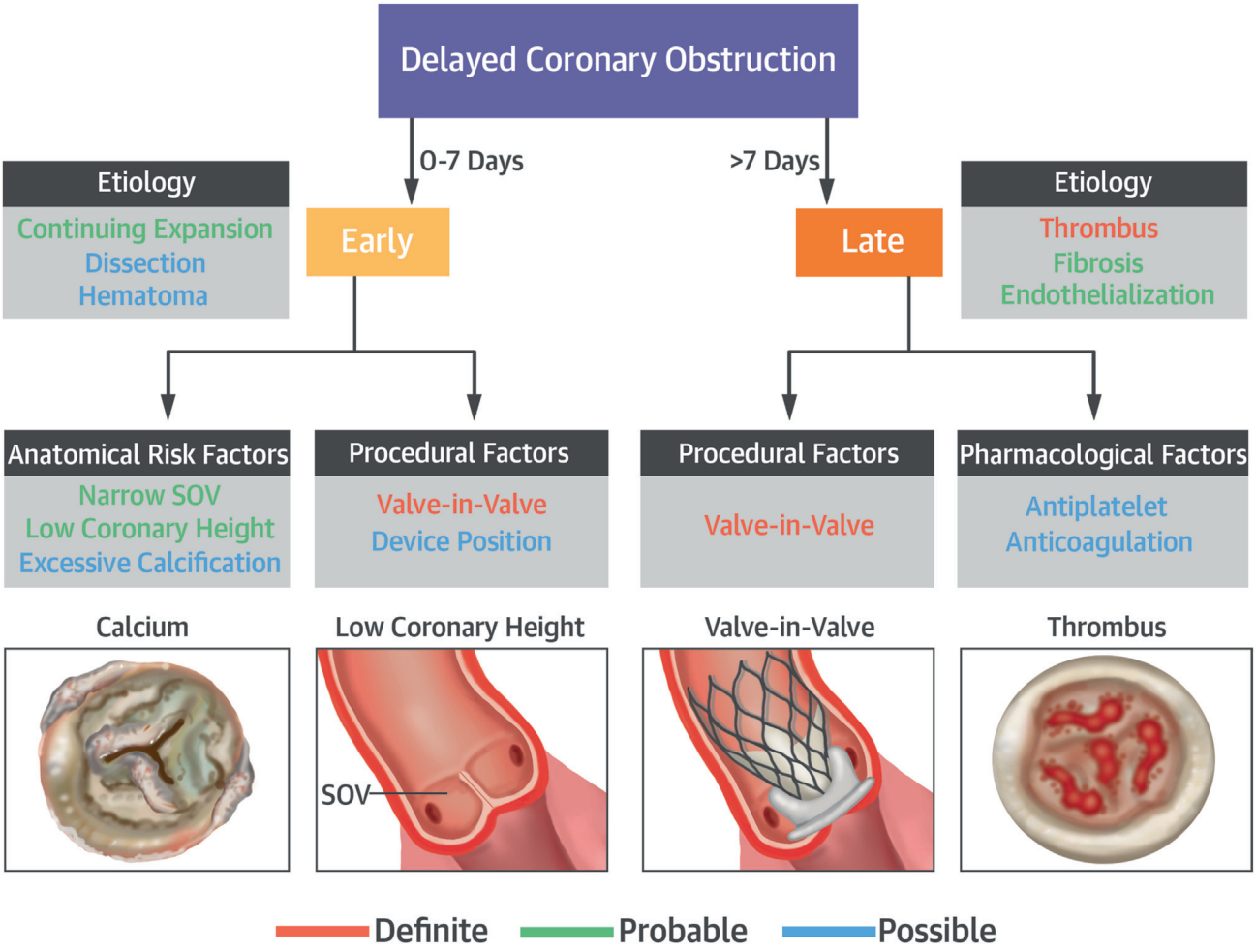
FIGURE 5 A Representative Case of Late Delayed Coronary Obstruction



A 79-year-old man with a history of aortic bioprosthetic valve (Perimount 25 mm) **(A)** underwent transfemoral transcatheter aortic valve replacement (TAVR) with a 26-mm Sapien XT valve (Medtronic). The left main was protected during the index procedure, and a stent was placed after deployment **(B to E)**. Post-procedural aortography revealed a patent stent and flow in the right coronary artery (RCA) **(F)**. The patient represented at 360 days post-procedure with unstable angina. Coronary angiography revealed that the left main was severely stenosed, and the RCA was occluded as well **(G)**. RCA percutaneous coronary intervention was attempted, but it could not be wired. The patient therefore underwent surgery, and it became evident that the left main stent was partially obstructed by the surgical valve leaflet and RCA was completely occluded by the surgical valve leaflet. **Yellow arrowheads** indicate left and right coronary arteries. CO = coronary obstruction.

malpositioned, and therefore, a second portico valve was implanted. The procedure was uncomplicated after the second portico valve was implanted, and the patient had an uncomplicated in-hospital stay. The patient was discharged on dual antiplatelet therapy (aspirin and clopidogrel). At 60 days post-discharge (still on dual antiplatelet therapy), the patient developed cardiac arrest and was admitted to the hospital. An emergency angiogram and a CT scan confirmed obstruction due to a large thrombus in the sinus of Valsalva/on the prosthetic valve. The patient died in-hospital from cardiogenic shock. The second patient was an 81-year-old woman who underwent transfemoral TAVR with a 25-mm Portico valve. The initial procedure was uncomplicated, and the patient was discharged on dual antiplatelet therapy (aspirin and clopidogrel) for 6 months after TAVR, which was followed by aspirin monotherapy. The patient remained stable and asymptomatic for 2 years post-TAVR. The patient then presented to the hospital with ST-segment elevation and cardiogenic shock. An urgent coronary angiogram revealed a thrombotic

CENTRAL ILLUSTRATION **Etiology and Risk Factors for Delayed Coronary Obstruction**



Jabbour, R.J. et al. J Am Coll Cardiol. 2018;71(14):1513-24.

Delayed coronary obstruction can be divided into 2 groups: early (≤7 days) versus late (>7 days). Early delayed coronary obstruction may be due to continuing expansion of the implanted valve, or a dissection or hematoma that expands, causing obstruction. In contrast, thrombus or valve stent endothelization (fibrosis) may cause late delayed coronary obstruction. Late expansion may be a possible additional cause. Valve-in-valve procedures are risk factors for both types of delayed coronary obstruction. Anatomical factors are primarily a risk factor for early delayed coronary obstruction cases. Pharmacological factors may influence the development of delayed coronary obstruction if the etiology is due to thrombus. Definite causes/risk factors are in **orange**, probable in **green**, and possible in **blue**. SOV = sinus of Valsalva.

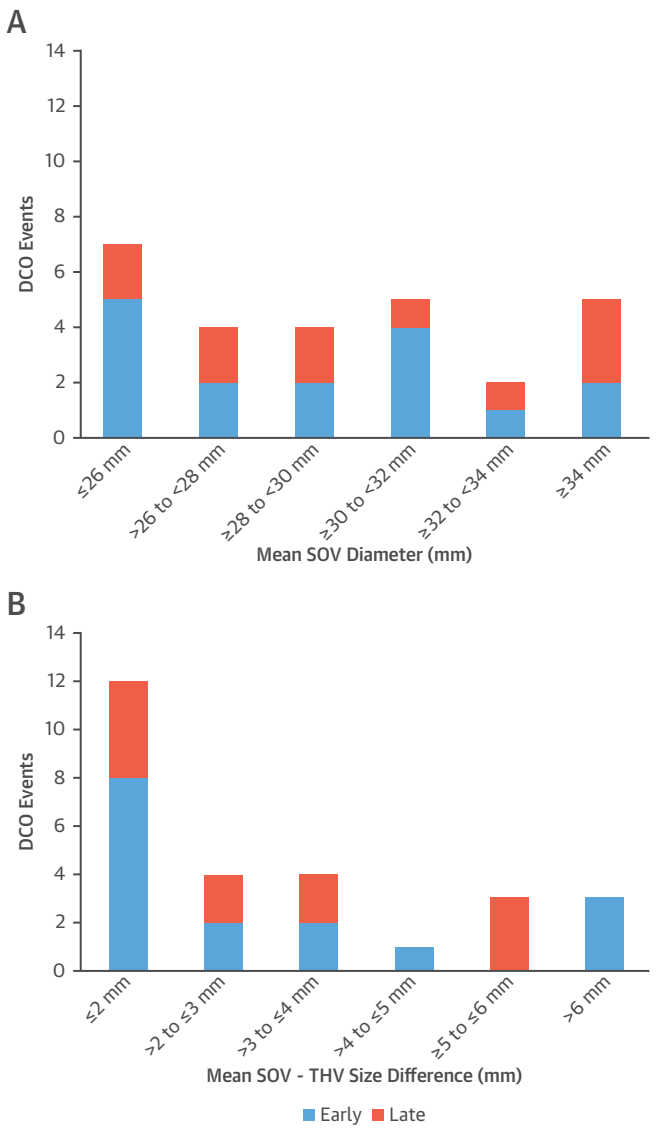
of occlusion of the left main trunk and a large thrombus on the Portico valve. Despite stent implantation, thrombolytic therapy, and prolonged cardiopulmonary resuscitation, the patient unfortunately died in the catheter laboratory from cardiogenic shock.

DISCUSSION

The main findings of this study are that DCO: 1) is a rare complication after TAVR and is associated with a high in-hospital mortality rate; 2) occurred more commonly when self-expanding valves were used during the index procedure; and 3) can be broadly classified into 2 types: those that occur within hours to a few days from the index procedure, and those that occur in the months or years following the procedure (Central Illustration).

Although acute coronary obstruction during TAVR has long been a concern beginning from preclinical development, thankfully, the incidence of acute coronary obstruction determined from large

FIGURE 6 Frequency of Delayed Coronary Obstruction Events According to Mean Sinus of Valsalva Diameter and Transcatheter Heart Valve Size/Sinus of Valsalva Diameter Difference



(A) Incidence of delayed coronary events (DCO) related to mean sinus of Valsalva (SOV) diameter. Computed tomography (CT)–derived mean SOV diameters (n = 27) stratified into groups and plotted against incidence of DCO events (early: ≤7 days from index procedure; late: >7 days from index procedure). **(B)** Relationship between incidence of DCO events and difference between SOV diameter/size of transcatheter heart valve (THV) implanted. Cases were stratified according to the difference between mean SOV diameter/size of the THV implanted and plotted against incidence of DCO events (early: ≤7 days; late: >7 days from index procedure). A total of 59.3% of DCO events (n = 16 from 27 with CT scan data available for central analysis) occurred in patients with a ≤3-mm difference between mean SOV diameter and size of valve implanted.

international multicenter registries has been reported to be below 1% (5,16,17). Data obtained from ViV registries have described a higher rate of between 2.5% and 3.5% (5,18-20). By contrast, the development of obstruction occurring in the hours, weeks, or months after the procedure has barely been described.

In this case series, we describe the development of coronary obstruction after successful TAVR, without any signs or suggestions of any impending serious cardiac complications occurring. Notably, post-implant aortography or selective cannulation of both coronary arteries confirming lack of obstruction was performed in nearly all cases (37 of 38), making delayed presentation unlikely. The incidence of DCO (0.22%), was even more rare than acute coronary obstruction (5), but the real DCO incidence may be higher, because confirmation (angiography/autopsy) needed to be included in this registry in comparison with a diagnosis based on clinical suspicion (e.g., STEMI prior to sudden cardiac death). In contrast, selection bias may have occurred and overestimated DCO incidence, because only centers with DCO cases were included. Notably, patients with early coronary obstruction had more serious presentations than late coronary obstruction. However, sudden cardiac death outside of hospital may be the first manifestation of DCO and may therefore go undiagnosed if no autopsy was performed.

Approximately 50% of patients included in randomized trials and large TAVR registries are female (21,22). By contrast, a higher proportion of women developed DCO (n = 29; 76.3%) in this registry, a finding previously similarly reported from acute coronary obstruction registries. This may be due to anatomical differences in aortic SOV dimensions and coronary height according to sex, because women tend to have smaller aortic SOV dimensions and lower coronary ostia heights independent of aortic stenosis (16). In our cohort, we observed that women had lower left and right coronary heights (left: 11.6 mm vs. 12.4 mm; p = 0.02; right: 13.7 mm vs. 15.5 mm; p = 0.03) and smaller SOV dimensions (28.6 mm vs. 31.3 mm; p = 0.11). Although it is well known that acute coronary obstruction is more common with balloon-expandable valves, we found a higher incidence of DCO with self-expandable valves (16). Self-expandable valves are nitinol based and continue to expand after deployment. The continuing expansion of the valve may be 1 factor as to why it was found to be higher when compared with balloon-expandable valves. Notably, ViV procedures in general are associated with a relatively greater risk of acute coronary obstruction, with the Mitroflow valve at a particularly high risk. In our cohort, the Sorin valve was the most common surgical valve prior to TAVR (n = 6; 66.7%).

In this registry, left main artery DCO occurred most commonly. A 10-mm cut off has been considered a risk factor for coronary obstruction, the mean left main coronary height determined from 27 CT scans was 12.0 ± 3.3 mm. Notably, however, in the largest TAVR registry regarding acute coronary obstruction, approximately 80% of patients in the acute coronary obstruction arm of the study had mean left coronary height below 12 mm, leaving the authors to suggest that this is a more accurate cut-off (5). The mean LCA height was lower in cases of DCO ≤7 days after index procedure (10.8 ± 2.7 mm vs. 13.8 ± 3.4 mm; p = 0.03) possibly indicating that known risk factors for CO have a more important role in the relatively acute setting (16). Narrow aortic SOV dimension is another known risk factor for coronary obstruction and was present in over 50% of patients in our cohort (<30 mm, n = 15 [55.6%]), which is similar to the largest acute coronary obstruction registry (64.3%) (16). In addition, 59.3% (n = 16) of patients had a relatively small (≤3 mm) distance between the size of TAVR device inserted and SOV dimension. In these cases, there may be a greater propensity for the native leaflets to obstruct the coronary ostia after deployment of the transcatheter valve (**Figure 6**). Implantation depth may be a factor in the development of DCO in patients with concomitant low coronary ostia heights or narrow SOV dimensions, due to prosthetic (or native) valve leaflet obstruction of the low-lying coronary ostia. In our case series, 47.4% (18 of 38) of TAVR devices had a high implantation depth. Of those 18 cases, 10 (55.6%) had narrow SOV dimensions (<30 mm) and 7 (38.9%) LCA ostia <12 mm. Other possible mechanisms include a dissection or hematoma that expands after deployment leading to obstruction, or a heavily calcified valve that can occupy space in the sinus of Valsalva causing obstruction.

The present study showed that PCI was the preferred strategy for the treatment of coronary obstruction after TAVR. It is noteworthy that successful stent implantation was achieved in 68.8%; it was higher if left main PCI was attempted in comparison with RCA (80.8% vs. 16.7%). A total of 70% of RCA obstructions occurred with self-expanding prostheses and PCI was unsuccessful in all cases indicating that RCA cannulation may be more difficult with SE valves. Therefore, clinicians should have a low threshold for performing coronary angiography and PCI if necessary if any clinical concern exists.

LATE DELAYED CORONARY OBSTRUCTION. In cases of coronary obstruction that occur in the months and years following the procedure, bioprosthetic valve endothelialization and some degree of obstruction caused by either the native or bioprosthetic valve leaflet was the presumed predominant mechanism. Several proposed mechanisms have also been put forward. For example, the persistence of turbulent flow across a bioprosthesis could lead to intimal thickening and fibrosis near the aortic root, or the persistence of a low-grade inflammatory reaction to the foreign body could also cause fibrosis or endothelialization (23). Thrombus embolization resulted in DCO in 2 cases (11). Valve leaflet thrombosis is an area of intense research, and ongoing studies are investigating the most appropriate antiplatelet/anticoagulant regime post-TAVR. Clinicians should be aware of the possibility of DCO occurring many months or even years after TAVR, even if the index procedure was uncomplicated, and the patient does not have the classical risk factors for DCO. If the presentation is stable, coronary CT angiography may be a suitable first-line investigation to investigate for a coronary cause. In patients with known risk factors for coronary obstruction (ViV, low coronary heights, narrow SOV dimensions), clinicians should be aware that delayed coronary obstruction could occur, and more intensive monitoring pre- (e.g., CT before discharge) and post-discharge may be advisable. Notably, DCO can occur even if an ostial coronary stent was deployed during the index procedure. Therefore, the placement of a protruding "chimney" stent or using stents with greater radial strength are possible solutions that require evaluation. For ViV procedures, novel interventions on the pre-existing valve prior to TAVR (e.g., BASILICA [Bioprosthetic Aortic Scallop Intentional Laceration to prevent Iatrogenic Coronary Artery obstruction for valve in valve procedures) require evaluation (24).

STUDY LIMITATIONS. First, because coronary obstruction had to be confirmed by angiography, surgery, or autopsy, the real incidence of this condition may be under-reported and, hence, underestimated in this registry-based study. However, definitive evidence was needed to characterize this phenomenon as accurately as possible. In contrast, selection bias from centers reporting DCO may have influenced the true incidence. Second, the reporting of DCO cases was performed voluntarily by the investigators at each center, with no external monitoring to verify the accuracy of the data reported by each center. Third, there was no matched control group, so we could not compare our sample with a

matched sample to identify predictors of this rare complication.

CONCLUSIONS

DCO following TAVR is a rare phenomenon that is associated with a high in-hospital mortality rate. Clinicians should be aware that DCO can occur after the original TAVR procedure and have a low threshold for performing coronary angiography when clinically suspected.

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PERSPECTIVES

COMPETENCY IN PATIENT CARE AND PROCEDURAL SKILLS: DCO is a rare but potentially catastrophic complication of TAVR that is associated with a high mortality rate.

TRANSLATIONAL OUTLOOK: Future studies should explore prosthesis design or delivery options for patients undergoing TAVR for either initial valve replacement or ViV successive replacement procedures that reduce the occurrence of iatrogenic coronary ostial obstruction.

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KEY WORDS coronary obstruction, TAVI, TAVR, transcatheter aortic valve replacement

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