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Chimney Stenting for Coronary Occlusion During TAVR

Insights From the Chimney Registry

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ABSTRACT

OBJECTIVES The aim of this study was to determine the safety and efficacy of chimney stenting, a bailout technique to treat coronary artery occlusion (CAO).

BACKGROUND CAO during transcatheter aortic valve replacement (TAVR) is a rare but often fatal complication.

METHODS In the international Chimney Registry, patient and procedural characteristics and data on outcomes are retrospectively collected from patients who underwent chimney stenting during TAVR.

RESULTS To date, 16 centers have contributed 60 cases among 12,800 TAVR procedures (0.5%). Chimney stenting was performed for 2 reasons: 1) due to the development of an established CAO (n = 25 [41.6%]); or 2) due to an impending CAO (n = 35 [58.3%]). The majority of cases (92.9%) had 1 or more classical risk factors for CAO. Upfront coronary protection was performed in 44 patients (73.3%). Procedural and in-hospital mortality occurred in 1 and 2 patients, respectively. Myocardial infarction (52.0% vs. 0.0%; $p < 0.01$), cardiogenic shock (52.0% vs. 2.9%; $p < 0.01$), and resuscitation (44.0% vs. 2.9%; $p < 0.01$) all occurred more frequently in patients with established CAO compared with those with impending CAO. The absence of upfront coronary protection was the sole independent risk factor for the combined endpoint of death, cardiogenic shock, or myocardial infarction. During a median follow-up time of 612 days (interquartile range: 405 to 842 days), 2 cases of stent failure were reported (1 in-stent restenosis, 1 possible late stent thrombosis) after 157 and 374 days.

CONCLUSIONS Chimney stenting appears to be an acceptable bailout technique for CAO, with higher event rates among those with established CAO and among those without upfront coronary protection.

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ABBREVIATIONS AND ACRONYMS

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

CAO = coronary artery occlusion

eCAO = established coronary artery occlusion

iCAO = impending coronary artery occlusion

IQR = interquartile range

LMS = left main stem

MSCT = multislice computed tomographic

RCA = right coronary artery

THV = transcatheter heart valve

TAVR = transcatheter aortic valve replacement

VIV = valve-in-valve

VTC = virtual transcatheter valve-to-coronary ostium

Acute coronary artery occlusion (CAO) is a devastating complication during transcatheter aortic valve replacement (TAVR). Although relatively uncommon in contemporary TAVR practice (<1%), specific subsets of patients remain at risk (1). In particular, the reported incidence of CAO during TAVR for degenerated surgical bioprosthetic aortic valves (valve-in-valve [VIV] procedures) is as high as 2.3%, with 30-day mortality rates of up to 50% (1,2). Other predictors of CAO include low coronary ostia, inadequate sinus of Valsalva width, and, in the context of VIV procedures, surgical bioprostheses with externally mounted leaflets or a short virtual transcatheter valve-to-coronary ostium (VTC) distance (**Figure 1**) (2,3). Patients at high risk for CAO can be referred for surgical aortic valve replacement, but prohibitive operative risk often necessitates proceeding with TAVR. In such cases, upfront coronary artery protection can be provided by positioning a coronary guidewire, balloon, undeployed stent, or guide extension in the artery (or arteries) at risk prior to transcatheter heart valve (THV) deployment (4,5). If coronary blood flow is compromised during or after THV expansion, the stent is retracted to extend from the proximal portion of the coronary artery cranially, exterior, and parallel to the THV, and is deployed to create a channel for coronary perfusion between the displaced leaflets and the aortic wall. This "chimney" stenting technique was originally reported in endovascular aneurysm repair procedures in case of coverage of renal or mesenteric vessels and has now been adapted as an important bailout technique during TAVR (6–9).

SEE PAGE 762

Anecdotal evidence suggests that the chimney technique is being used with increasing frequency in the TAVR community, not only to treat new complete obstruction of a coronary ostium, herein described as established CAO (eCAO), but also prophylactically in cases of impending CAO (iCAO). There remains, however, limited information supporting the safety and efficacy of this technique. Moreover, post-discharge outcomes, including risk for chimney stent restenosis or stent thrombosis, are unclear. To address these knowledge gaps, we report the first results of the International Chimney Registry.

METHODS

CHIMNEY REGISTRY DESIGN. The International Chimney Registry was initiated in October 2017 and retrospectively collected data on patients undergoing chimney stenting during TAVR procedures between May 2010 and July 2018 from 16 centers in North America, Europe, and the Middle East. Information on patients with upfront coronary protection but without final delivery of a chimney stent, and on patients with acute CAO but treated using techniques other than chimney stenting (e.g., coronary artery bypass surgery, removal of the THV), was not collected in this database. All data were collected using a dedicated clinical report form encompassing baseline clinical, biological, echocardiographic, and multislice computed tomographic (MSCT) data. Procedural information included THV type and size, the indication for and technique used for chimney stenting, and the clinical outcome. Post-discharge follow-up was performed via outpatient visits and telephonic interview. All data are site reported and were collated into an anonymized patient-level database for analysis. The inclusion of patients in the registry was approved by local or national ethical committees.

PATIENTS. All enrolled patients had symptomatic aortic valve stenosis and/or regurgitation in a native valve or degenerated surgical aortic bioprosthesis. Severe native or bioprosthetic aortic valve stenosis or incompetence was defined according to current guidelines (10). Patients were classified according to their predominant mechanism of aortic valve failure: stenosis or regurgitant. The indication for TAVR was discussed and approved by each institutional heart team.

DEFINITIONS AND ENDPOINTS. An eCAO was defined as angiographic evidence of a new complete

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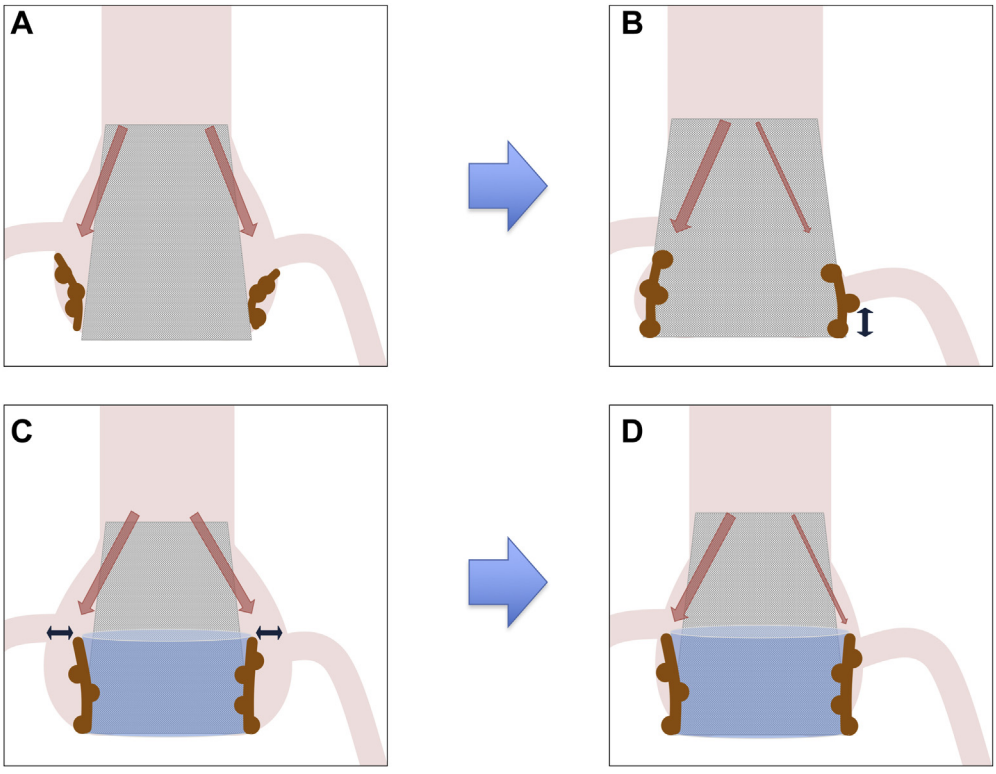
FIGURE 1 Predictors of Coronary Artery Occlusion

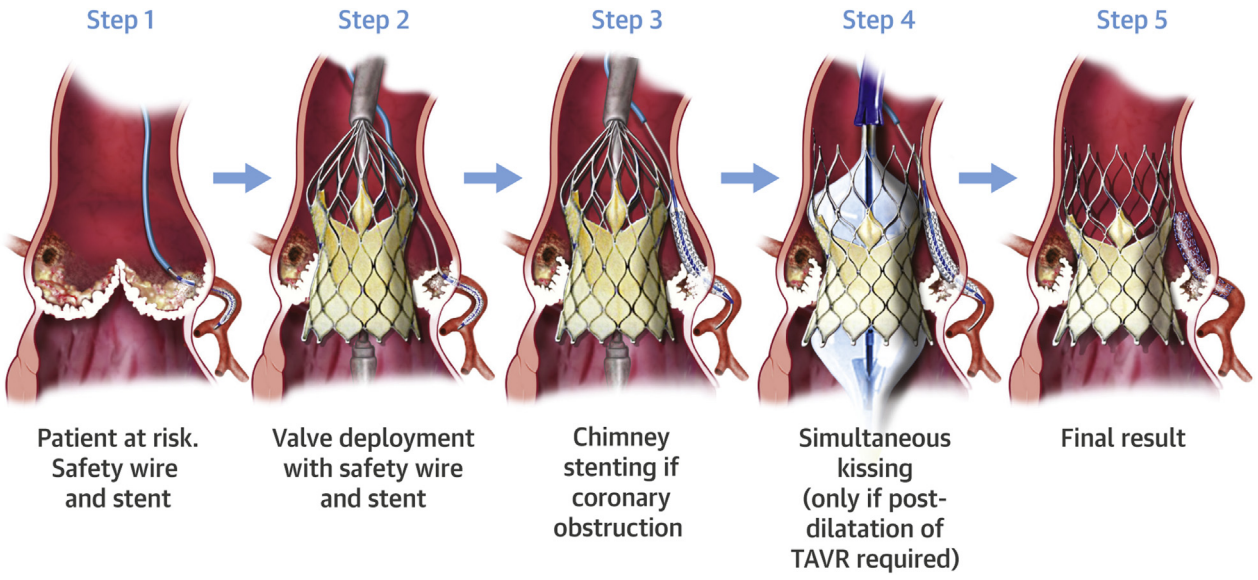


(A) Normal coronary flow after transcatheter aortic valve replacement (TAVR). **(B)** Coronary artery occlusion (CAO) with low coronary height **(black arrow)** or shallow sinuses of Valsalva and/or sinotubular junction. **(C,D)** TAVR for degenerated surgical bioprosthesis (valve-in-valve): surgical bioprosthesis with externally mounted leaflets or a short distance between the coronary ostia and the anticipated final position of the displaced bioprosthetic leaflets after transcatheter heart valve implantation **(black arrows)** are the main determinants of CAO.

obstruction of a coronary ostium during TAVR (11). An iCAO was defined as angiographic evidence of a new partial obstruction of a coronary ostium by displaced aortic leaflet or by structures of the THV itself or reduced coronary flow on aortography or selective coronary angiography during TAVR. Patients undergoing chimney stenting for any other reason (e.g., inability to remove a parked stent) were not included. The decision to perform chimney stenting in this uncontrolled registry was at the operator's discretion. In the case of iCAO, chimney stenting is performed when partial obstruction of a coronary ostium and/or reduced coronary flow is observed with aortography or selective angiography after deployment of the THV. The chimney stenting technique was defined as the deployment of a coronary stent extending from the proximal portion of a coronary artery cranially, exterior and parallel to the THV. Successful chimney stenting implied resolution of CAO with angiographic evidence of stent patency and TIMI (Thrombolysis In Myocardial Infarction) coronary flow grade 3 after stent deployment.

All clinical endpoints were defined according to the updated Valve Academic Research Consortium-2 criteria (11). In particular, periprocedural myocardial infarction was defined as both new ischemic findings (clinical symptoms or new electrocardiographic or imaging abnormalities) and elevation of cardiac biomarkers if measured (>5× elevation of creatine kinase-MB or 15× elevation of troponin within 72 h after the index procedure). Cardiogenic shock was defined as persistent hypotension (systolic blood pressure <90 mm Hg) with typical clinical sequalae. During follow-up, particular attention was given to evidence of in-stent restenosis or stent thrombosis of the chimney stent. In-stent restenosis was defined as an angiographic diameter stenosis ≥70% within the stented segment or ≥50% with associated clinical symptoms or abnormal functional testing. Stent thrombosis was categorized as definite, probable, or

CENTRAL ILLUSTRATION Chimney Stenting Procedural Steps



Mercanti, F. et al. J Am Coll Cardiol Intv. 2020;13(6):751–61.

Step 1: An undeployed coronary stent, appropriately sized for the shaft of the left main coronary artery, and with sufficient length to extend into the ascending aorta to the level of the sinotubular junction, is parked in the mid left anterior descending coronary before transcatheter heart valve (THV) deployment. **Step 2:** During THV implantation, the guide catheter is backed out into the ascending aorta. **Step 3:** If coronary blood flow is compromised, the undeployed stent is carefully retracted beyond the coronary ostium and above the displaced stenotic aortic leaflets and subsequently deployed. **Step 4:** If post-dilatation of the THV is required, simultaneous kissing balloon inflation can be performed between the THV and chimney stent to avoid deformation of the chimney stent. **Step 5:** Final angiographic assessment is mandatory. TAVR = transcatheter aortic valve replacement.

possible and defined according the Academic Research Consortium definition (12). We defined stent failure as post-hospital discharge in-stent restenosis, target lesion myocardial infarction or revascularization, or definite or probable stent thrombosis.

MSCT IMAGING. In all cases, MSCT imaging was performed for valve sizing and for the estimation of CAO risk. Participating centers provided standard MSCT data, including the aortic annular mean diameter, perimeter, and area; the coronary height (measured from the aortic annular plane to the lower level of the right and left coronary ostia); and the diameters of the sinus of Valsalva and sinotubular junction. For VIV procedures, the surgical prosthesis type and size were documented, and VTC distance was measured using MSCT imaging. VTC distance was defined as the distance from a virtual THV to the coronary ostia and considered "high risk" when ≤4 mm (2,3). Low coronary height was defined as a distance of <10 mm between the annular plane and the most inferior aspect of the coronary ostia (13). A sinus of Valsalva diameter <28 mm has previously been identified as a risk factor for CAO (13).

TAVR PROCEDURES AND CHIMNEY STENTING. All TAVR procedures were conducted in accordance with local guidelines using standard techniques. All commercially available valve types were eligible for inclusion in the registry. Clinical follow-up was performed according to the time elapsed from the index procedure to data lock for present analysis. Sequential steps for upfront coronary protection and subsequent chimney stenting are illustrated in the Central Illustration. Post-procedural antiplatelet or antithrombotic strategy was at the operator's discretion.

STATISTICAL ANALYSIS. Categorical variables are reported as counts with percentages and continuous variables as mean ± SD or median (interquartile range [IQR]), according to distribution. Univariate analysis was performed using the chi-square or Fisher exact test for categorical variables and Student's *t*-test for continuous variables. The Kaplan-Meier method was used to estimate cumulative mortality during follow-up. Uni- and multivariate logistic regression were used to identify associated and independent predictors of the combined clinical endpoint of death,

TABLE 1 Baseline Characteristics (N = 60)

Age, yrs	81.6 ± 6.7
Male	15 (25.0)
Body surface area, m^2	1.7 ± 0.2
STS PROM, %	6.9 ± 4.6
Prior myocardial infarction	11 (18.3)
Prior PCI	18 (30.0)
Prior CABG	8 (13.3)
Surgical bioprosthetic valve failure	42 (70.0)
Prior pacemaker	11 (18.3)
Atrial fibrillation	21 (35.0)
Pulmonary hypertension	22 (36.7)
NYHA functional class III/IV	54 (90.0)
Glomerular filtration rate, ml/min	46.8 ± 25.3

Values are mean ± SD or n (%).

CABG = coronary artery bypass grafting; NYHA = New York Heart Association; PCI = percutaneous coronary intervention; STS PROM = Society of Thoracic Surgeons Predicted Risk of Mortality.

TABLE 2 Pre-Procedural Imaging Assessment

Echocardiography (N = 60)	
Left ventricular ejection fraction, %	55.5 ± 10.6
Aortic valve	
Peak gradient, mm Hg	64.1 ± 30.1
Mean gradient, mm Hg	39.8 ± 19.3
Valve area, cm^2	0.9 ± 0.5
Predominant stenosis	23 (38.3)
Predominant regurgitation	11 (18.3)
Mixed disease	26 (43.3)
Pulmonary artery pressure, mm Hg	50.5 ± 17.1
Multislice computed tomography (n = 53)	
Native valve annulus	
Area, mm^2	352.2 ± 97.2
Perimeter, mm	67.1 ± 8.7
Maximum diameter, mm	22.4 ± 4.3
Minimum diameter, mm	19.5 ± 3.2
Mean diameter, mm	20.9 ± 3.6
Native aortic root	
Sinus of Valsalva diameter, mm	28.2 ± 4.1
Sinotubular junction diameter, mm	26.2 ± 3.7
Ascending aorta diameter, mm	31.0 ± 4.6
RCA height, mm	10.2 ± 4.1
LCA height, mm	8.2 ± 3.1
VIV: VTC distance	
LMS to SAV, mm	5.5 ± 2.3
RCA to SAV, mm	5.8 ± 2.9

Values are mean ± SD or n (%).

LCA = left coronary artery; LMS = left main stem; RCA = right coronary artery; SAV = surgical aortic valve; VIV = valve-in-valve; VTC = virtual transcatheter valve-to-coronary ostium.

cardiogenic shock, or myocardial infarction. In the univariate analysis, we included factors that have been previously associated with coronary occlusion during TAVR, and if these variables had p values <0.10, they were included in the multivariate analysis. All statistical analyses were performed using SPSS version 24 (SPSS, Chicago, Illinois). All statistical tests were 2-sided, and p values <0.05 were considered to indicate statistical significance.

RESULTS

BASELINE CHARACTERISTICS. We identified 60 patients from 16 centers with chimney stenting during TAVR. The overall incidence of chimney stenting in these centers was 0.5% (60 among 12,800 TAVR cases). The mean age of the patient population was 81.6 ± 6.7 years, three-quarters were women (n = 45 [75%]), and the mean Society of Thoracic Surgeons Predicted Risk of Mortality score was 6.9 ± 4.6% (Table 1). Notably, more than two-thirds of the patients (n = 42 [70%]) underwent VIV procedures for failed surgical aortic bioprostheses.

Baseline pre-TAVR echocardiographic data were available for all patients (Table 2). Isolated aortic valve stenosis was reported in 23 patients (38.3%) and was more frequent in those with native aortic valve dysfunction (n = 14 [60.1%]). All patients treated for predominant aortic valve regurgitation had undergone previous surgical aortic valve replacement.

Pre-procedural MSCT data were complete in 53 patients (88.3%) and are outlined in Table 2. Pre-TAVR MSCT imaging was not performed in 4 patients, because of renal failure, and in 3 of 42 of the VIV cases. The mean diameter of the aortic valve annulus was 20.9 ± 3.6 mm, with an average diameter of the sinuses of Valsalva of 28.2 ± 4.1 mm. The average heights of left and right coronary arteries were 8.2 ± 3.1 mm and 10.2 ± 4.1 mm, respectively. In 52 patients (92.9%), at least 1 of the following risk factors was identified: coronary height <10 mm, sinus of Valsalva diameter <30 mm, and stentless or stented bioprosthetic valve with leaflets mounted externally. Coronary height <10 mm was present in 73.5% of patients (n = 39), sinus of Valsalva diameter <30 mm in 58.4% (n = 31), and a short VTC distance of ≤4 mm in 33.9% (n = 18). Eight patients (31.7%) had VIV procedures in stentless bioprosthetic valves, and 31 (51.7%) had VIV procedures in stented surgical valves with externally mounted leaflets. Among patients with risk factors for CAO, the rate of coronary protection was 78.8%, and among those without, the rate was 21.1%.

VIV PROCEDURES. Among those patients undergoing TAVR for a degenerative surgical bioprosthesis (n = 42 [70%]), most had a stented bioprosthetic valve design (n = 34 [81.0%]) (Supplemental Table 1). The Sorin Mitroflow valve (Sorin Group, Milan, Italy) was

TABLE 3 Procedural and Post-Procedural Characteristics (N = 60)

Access	
Transfemoral	58 (96.6)
Alternative access	2 (3.4)
General anesthesia	24 (40.0)
TEE guidance	16 (26.6)
Valve type	
Self-expandable valve	43 (71.6)
CoreValve Evolut R or Evolut PRO (Medtronic)	
23 mm	28 (65.1)
26 mm	7 (16.2)
29 mm	4 (9.3)
Portico (St. Jude Medical)	
23 mm	1 (2.3)
29 mm	1 (2.3)
Symetis (Boston Scientific), small	1 (2.3)
Engager (Medtronic), 23 mm	1 (2.3)
Balloon-expandable valve	17 (28.3)
SAPIEN (XT or 3) (Edwards Lifesciences)	
20 mm	5 (29.4)
23 mm	5 (29.4)
26 mm	5 (29.4)
29 mm	2 (11.7)
Pre-dilatation	12 (20.0)
THV reposition	10 (16.6)
Post-dilation	14 (23.3)
Implantation depth, mm	5.32 ± 1.96
Coronary protection	44 (73.3)
Guidewire alone	2 (4.5)
Balloon in LMS/RCA	6 (11.6)
Stent in LMS/RCA	36 (81.8)
Post-procedural echocardiography (n = 53)	
Peak gradient, mm Hg	28 ± 13.5
Mean gradient, mm Hg	15.6 ± 7.9
Effective orifice area, cm^2	1.5 ± 0.35
Paravalvular leak	
None/trivial	41 (68.3)
Mild	13 (22.0)
Moderate	3 (5.0)
Severe	0 (0.0)

Values are n (%) or mean ± SD.

TEE = transesophageal echocardiographic; THV = transcatheter heart valve; other abbreviations as in Table 2.

TABLE 4 Chimney Stenting Procedure (N = 60)

Impending coronary artery occlusion	35 (58.3)
Established coronary artery occlusion	25 (41.6)
Intraprocedural complications	
New ST-segment elevation	15 (25.0)
New left bundle branch block	4 (6.7)
New wall motion abnormality	12 (20.0)
Cardiogenic shock	14 (23.3)
Required CPR and/or defibrillation for VT/VF, ECMO/PVAD/VAD, and/or CPB	12 (20.0)
Immediate procedural death	1 (1.7)
Technical features	
Difficulty engaging LMS/RCA	10 (16.6)
Guide extension required to engage	7 (11.6)
Target coronary artery	
Left main coronary artery	49 (81.6)
RCA	5 (8.3)
LCA and RCA	6 (10.0)
Chimney stent	
Drug-eluting stent	58 (96.6)
Covered stent	1 (1.7)
Bare-metal stent	2 (3.3)
Stent length, mm	19 ± 6.8
Stent diameter, mm	4.1 ± 0.5
Proportion of chimney stent in aorta, %	49.7 ± 16.8
Maximum inflation pressure, atm	16.4 ± 2.7
Incomplete stent expansion	33 (55.0)
Stent post-dilatation	30 (50.0)
Second chimney stent	11 (18.3)
Intraprocedural IVUS/OCT	3 (5.0)
Kissing balloon inflation (chimney and THV)	2 (3.3)
Antithrombotic strategy (n = 59)	
DAPT	42 (71.2)
DAPT + OAC or DOAC agent	9 (15.2)
SAPT + OAC or DOAC agent	8 (13.6)
Length of stay, days	5 (6–11)
Follow-up, days	612 (405–842)

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

CPB = cardiopulmonary bypass; CPR = cardiopulmonary resuscitation; DAPT = dual-antiplatelet therapy; DOAC = direct oral anticoagulant; ECMO = extracorporeal membrane oxygenation; IVUS = intravascular ultrasound; OAC = oral anticoagulant; OCT = optical coherence tomography; PVAD = percutaneous ventricular assist device; SAPT = single-antiplatelet therapy; VAD = ventricular assist device; VF = ventricular fibrillation; VT = ventricular tachycardia; other abbreviations as in Tables 2 and 3.

the most frequently treated bioprosthesis (n = 31 [73.8%]); this is a stented valve design with leaflets mounted externally. The majority of VIV cases (92.9% [n = 39]) had bioprosthetic valve designs that were considered at risk for CAO: 73.8% (n = 31) had stented bioprostheses with leaflets mounted externally, and another 19.0% (n = 8) had stentless bioprosthetic designs (2). The mean labeled size of surgical bioprostheses was 21.9 ± 2.1 mm. Among VIV recipients, the MSCT mean VTC distance was 5.5 ± 2.3 mm to the left main stem (LMS) and 5.8 ± 2.9 mm to the right coronary artery (RCA). The left and right coronary heights were 7.3 ± 2.8 and 8.8 ± 3.2 mm, respectively. VTC distances ≤4 mm were observed in 18 patients (42.9%). Most VIV patients (n = 26 [74.3%]) underwent chimney stenting for iCAO.

PROCEDURAL CHARACTERISTICS. Procedural characteristics are outlined in Table 3. Most patients had transfemoral access (n = 58 [96.6%]) under local anesthesia (n = 36 [60%]) and received self-expanding THVs (n = 43 [71.6%]). Given the high-risk features of this population, nearly three-quarters (n = 44 [73.3%]) of all cases had upfront coronary artery protection prior to THV deployment. In 81.1% (n = 36) and 11.6% (n = 5) of patients, undeployed stents or balloons, respectively, were mounted on a coronary protection wire. In 2 cases (4.5%), coronary guidewires alone, without pre-mounted balloons or stents, were present as preventive measures. CAO was more frequently

diagnosed on aortography (n = 33 [55%]) than selective angiography (n = 7 [45%]).

CHIMNEY STENTING. Data on the chimney stenting procedure are outlined in Table 4. The left main coronary artery was stented most frequently: either only the LMS (n = 49 [81.6%]) or combined with stenting of the RCA consecutively (n = 6 [10%]). Drug-eluting stents were used in most cases (n = 58 [96.6%]), and the average stent length and width were 19 ± 7.8 and 4.1 ± 0.5 mm, respectively. Incomplete stent expansion was frequently encountered (n = 33 [55%]) and necessitated post-dilation (n = 30 [50%]) or placement of a second stent inside the previously sited stent (n = 11 [18.3%]). Post-dilatation of the THV was performed with a kissing balloon technique of the THV and the chimney stent in 2 patients (3.3%).

In more than one-half of the cases (n = 35 [58.3%]), chimney stenting was performed for iCAO. Among these cases, 26 (74.3%) underwent VIV procedures, 28 (80%) received self-expanding valves, 16 (45.7%) had the stent implanted during THV deployment, and 19 (54.2%) had the stent deployed after THV implantation. In the remaining 25 patients (41.6%), chimney stenting was performed for eCAO of the LMS (n = 19 [76%]), RCA (n = 3 [12%]), or both vessels (n = 3 [12%]). No differences in anatomic characteristics were observed between those with iCAO versus eCAO (Supplemental Table 2A).

OUTCOMES. The mean post-procedural transvalvular gradient was 15.6 ± 7.9 mm Hg, and 19 patients (32.2%) had mean gradients ≥20 mm Hg, of whom 90% had VIV procedures. More than mild paravalvular leaks occurred in 3 cases (5.0%) (Table 3).

Total in-hospital mortality occurred in 3 patients (5.0%), all within the eCAO group. One patient was unable to wean from cardiopulmonary bypass (day 1), another died of refractory cardiogenic shock (day 5), and one-third died of septic shock (day 11) (Table 5).

Patients with eCAO had worse clinical outcomes than those with iCAO. No patient with iCAO experienced myocardial infarction, while this was observed in one-half of the patients with eCAO (n = 13 [52%]; 3 with bilateral eCAO and 10 with LMS eCAO). Cardiogenic shock (52% vs. 2.9%; p < 0.01), requirement for mechanical circulatory support or extracorporeal membrane oxygenation (24% vs. 0%; p < 0.01), and cardiopulmonary resuscitation or defibrillation (44% vs. 2.9%; p < 0.01) also occurred more frequently in those with eCAO compared with iCAO (Supplemental Table 2A).

The incidence of eCAO was significantly higher among patients without versus with upfront coronary protection (81.3% vs. 27.3%; p < 0.01) (Supplemental Table 2B). Hence, the absence of coronary protection was associated with adverse outcomes: in-hospital death (18.8% vs. 0%, p = 0.02), myocardial infarction (43.8% vs. 13.6%, p = 0.03), and cardiogenic shock (62.5% vs. 9.1%, p < 0.01). These disparate results were likely due to more difficult revascularization in those without coronary protection: operators reported more difficult engagement of the coronary ostia (50.0% vs. 4.5%; p < 0.01) with frequent requirement for guide catheter extension (31.3% vs. 4.5%, [P = 0.01). Similar trends were also observed in patients with eCAO who had coronary protection compared with patients without (Supplemental Table 2C). On univariate analysis, the absence of coronary protection and the use of a self-expandable THV were associated risk factors for the combined endpoint of cardiogenic shock, myocardial infarction, and death at 30 days. On multivariate analysis, the absence of coronary protection was the sole independent predictor (p < 0.01) for this combined endpoint (Table 6).

TABLE 5 30-Day Clinical Outcomes (N = 60)

		CAO			Coronary Protection		
	Total (N = 60)	iCAO (n = 35)	eCAO (n = 25)	p Value	Present (n = 44)	Absent (n = 16)	p Value
Procedural death	3 (5.0)	0 (0.0)	3 (12.0)	0.07	0 (0.0)	3 (18.75)	0.02
30-day death	3 (5.0)	0 (0.0)	3 (12.0)	0.07	0 (0.0)	3 (18.75)	0.02
MI	13 (21.6)	0 (0.0)	13 (52.0)	<0.01	6 (13.6)	7 (43.8)	0.03
Cardiogenic shock	14 (23.3)	1 (2.9)	13 (52.0)	<0.01	4 (9.1)	10 (62.5)	<0.01
Stroke	1 (1.7)	0 (0.0)	1 (4.0)	–	0 (0.0)	1 (6.2)	–
Major vascular complication	2 (3.4)	1 (2.9)	1 (4.0)	0.7	2 (4.5)	0 (0.0)	0.5
Life-threatening bleeding	1 (1.7)	0 (0.0)	1 (4.0)	–	0 (0.0)	1 (6.2)	–
AKI grade 3	3 (5.0)	1 (2.9)	2 (8.0)	0.4	1 (2.3)	2 (12.5)	0.15

Values are n (%).

AKI = acute kidney injury; eCAO = established coronary artery occlusion; iCAO = impending coronary artery occlusion; MI = myocardial infarction.

FOLLOW-UP. On hospital discharge, dual-antiplatelet therapy with aspirin and clopidogrel or ticagrelor was prescribed in 42 patients (71.2%). The average duration of dual-antiplatelet therapy was 7.5 months (IQR: 6 to 12 months). Nine patients (15.2%) were prescribed dual-antiplatelet therapy combined with oral anticoagulation, and 8 patients (13.5%) were taking a single antiplatelet agent combined with an oral anticoagulant agent.

The chimney stent failure rate, due to either in-stent restenosis or stent thrombosis, was 5.3% after a median follow-up period of 612 days (IQR: 405 to

TABLE 6 Predictors of 30-Day Death, Myocardial Infarction, and Cardiogenic Shock

	Univariate Analysis			Multivariate Analysis		
	Odds Ratio	95% CI	p Value	Odds Ratio	95% CI	p Value
Absence of coronary protection	8.81	2.41–32.16	<0.01	7.39	1.95–27.93	<0.01
No VIV	1.41	0.43–4.67	0.6			
Balloon-expandable THV	3.36	1.01–11.18	0.05	2.18	0.56–8.43	0.26
SOV diameter <30 mm	1.93	0.60–6.23	0.27			
Coronary height <10 mm	2.16	0.41–11.37	0.36			
VTC ≤4 mm*	1.54	0.34–6.93	0.58			

*Univariate analysis in the VIV group (n = 42).
CI = confidence interval; SOV = sinus of Valsalva; other abbreviations as in Tables 2 and 3.

842 days). During follow-up, 9 patients underwent MSCT imaging, and 4 underwent invasive coronary angiography to evaluate the result of the chimney stenting. Selective coronary angiography was feasible in 3 of 4 patients via the chimney stent. One patient with a 23-mm SAPIEN 3 valve (Edwards Lifesciences, Irvine, California) and RCA chimney stenting had in-stent restenosis necessitating coronary artery bypass.

There were 2 deaths (3.5%) between 30 days and 1 year (days 271 and 278), yielding a total 1-year all-cause mortality rate of 8.3%. Five additional deaths (8.7%) beyond 1 year (days 370, 374, 411, 470, and 473) occurred during follow-up (**Figure 2**). The causes of death included 1 case of possible late stent thrombosis: a patient with a 23-mm CoreValve Evolut PRO (Medtronic, Minneapolis, Minnesota) and chimney stenting for established RCA occlusion that was treated with aspirin and clopidogrel post-procedure died suddenly at home at 374 days. The remaining 6 deaths were not cardiac (complications from diabetes, ischemic stroke with hemorrhagic transformation, pneumonia, gastric, and prostate carcinoma).

DISCUSSION

The present study represents data from patients undergoing chimney stenting during TAVR. The salient findings of this registry are as follows: 1) chimney stenting is infrequently required in contemporary practice, accounting for 0.5% of all cases; 2) in the majority of cases (93%), 1 or more classical anatomic risk factors for CAO were present; 3) upfront coronary protection is an important strategy, facilitating rapid restoration of coronary flow, and was associated with lower risk for cardiogenic shock, myocardial infarction, and death; and 4) clinical outcome data suggest that chimney stenting is a successful bailout strategy for treating iCAO or eCAO, but there remain concerns around late stent failure (3.5% at 1 year).

Left main stenting following this chimney stenting technique as a bailout for acute CAO during TAVR was first described in 2013 by Chakravarty et al. (14). Our data suggest that chimney stenting is infrequently performed in modern TAVR practice (0.5% of overall TAVR cases) and revealed that this technique is not only performed for the acute treatment of complete obstruction of coronary flow but also applied when imaging reveals partial obstruction of the coronary ostium or reduced coronary blood flow and an evolution to complete CAO is anticipated. Alternatives for the treatment of acute CAO include snaring and removal of the THV or referral for urgent surgical coronary artery bypass grafting. More recently, a novel technique was developed for the prevention of CAO in at risk patients. The BASILICA (bioprosthetic or native aortic scallop intentional laceration to prevent iatrogenic coronary artery obstruction) technique uses electrocauterization to split a bioprosthetic or native heart leaflet that could obstruct coronary arteries after displacement by TAVR and thus maintain blood flow into the coronary sinuses (15,16). BASILICA has been associated with encouraging early results, but it remains a relatively complex procedure that is not yet widely practiced outside expert centers. BASILICA has advantages over chimney stenting, including the avoidance of placing a coronary stent in the aorta and the consequent risks for reaccessing the coronary arteries, restenosis, and thrombosis. Familiarity with both BASILICA and chimney stenting is advised for those performing TAVR in cases at risk for CAO. However, the efficacy of chimney stenting relative to an alternative management strategy, such as BASILICA or elective deferral to conventional surgical aortic valve replacement, in patients at risk for CAO is unknown.

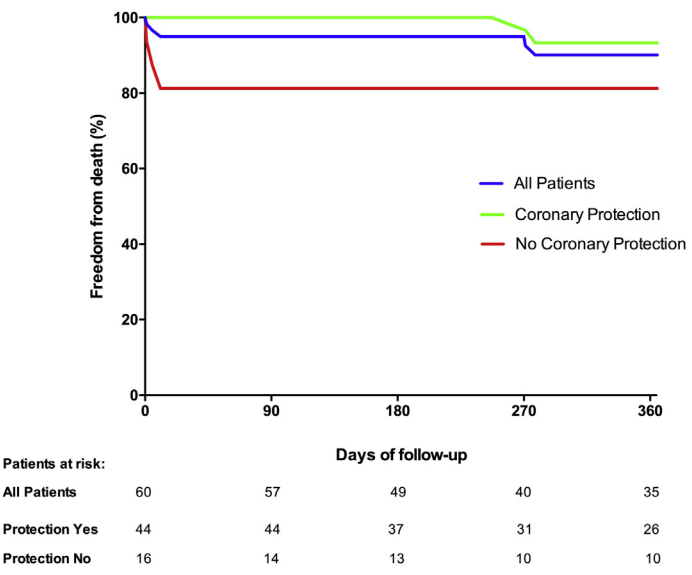
In the present study, 7% of patients did not present "classical risk factors" for CAO on the basis of MSCT analysis or characteristics of the failing bioprosthetic valve for VIV cases. Additional risk factors, such as bulky calcification or thickened leaflets, can heighten CAO risk, and new risk models and tools to better predict CAO are required (5,13). In contrast, upfront coronary protection was used in only 79% in these at-risk cases. The vogue for coronary protection in contemporary TAVR practice stems from the difficulty encountered when trying to cross the struts of a THV in the setting of acute eCAO and the dismal outcomes reported from eCAO (mortality up to 50%) (2). In the present study, which included only successful chimney stenting procedures, the technical feasibility appeared to be greatly facilitated and more expedient when coronary protection was used upfront. Indeed, we observed higher rates of

myocardial infarction (43.8% vs. 13.6%; p = 0.03), cardiogenic shock (62.5% vs. 9.1%; p < 0.01), and in-hospital death (18.8% vs. 0%; p = 0.02) in those without coronary protection. The multivariate analysis suggests that the absence of upfront coronary protection is an important risk factor for adverse outcomes. Although this analysis is limited by its small sample size, we encourage upfront coronary protection in all at-risk cases.

Pre-procedural consideration should be given to the diameter and length of the stent required for a chimney procedure. In this study, the average stent length was nearly 20 mm, illustrating the importance of the "chimney top" being above the displaced aortic leaflets or sinotubular junction. A variety of coronary stents were successfully used in the present series, but the relative safety of any particular stent platform remains unknown. As with any coronary or structural intervention, the result of a chimney stenting procedure should be optimized. Angiographic underexpansion of the chimney stent frequently necessitated high-pressure post-dilatation (50%) or even a second stent (double stent layer; 18.3%) to improve the angiographic appearance. The thrombotic or restenosis risk of a double layer of chimney stent is unknown. A kissing balloon technique was used in 2 cases when post-dilatation of the THV was required. This technique is relevant only when post-dilatation of the THV risks deformation of the chimney stent (9). Anecdotical reports on the use of intravascular ultrasound to evaluate stent expansion have recently emerged and warrant consideration (17,18). Such stent optimization techniques are theoretically considered to lower the risk for stent failure and increase the chances whenever reaccess would be needed. Invasive coronary angiography was performed in only 4 cases during follow-up, and selective intubation of the coronary arteries was feasible in 3 of 4 cases via the chimney stent. Whether future access to the coronary circulation for the management of coronary syndromes is as difficult as predicted requires further study.

To date, clinical follow-up has demonstrated acceptable medium-term (median 612 days) performance of the chimney stenting technique: 1 case of possible late stent thrombosis and 1 stent failure (compression with restenosis). However, in the TAVR-LM registry, 30-day and 1-year mortality was considerably higher in patients who had "unplanned" LMS stenting for a coronary-related complication during TAVR compared with TAVR patients with "planned" LMS stenting (15.8% vs. 3.% [p = 0.01] and 21.1% vs. 8.0% [p = 0.07], respectively) (19). The discrepant outcomes between these studies probably relate to differences in the treated populations and the selection of patients only with chimney stenting in the present study. Persistent turbulent flow across the THV and the coronary stent, local inflammatory processes, and galvanic corrosion between both metallic frames have been proposed as potential mechanisms of chimney stent failure, including the risk for chimney stent thrombosis (15). The optimal antiplatelet or anticoagulant strategy after TAVR is unclear. When chimney stenting is performed, a greater emphasis on dual-antiplatelet therapy is appropriate. Current guideline recommendations of 3 to 6 months of dual-antiplatelet therapy post-TAVR may not be applicable to patients with proximal coronary stenting and with a substantial proportion of the stent protruding into the ascending aorta, which is unlikely to undergo endothelialization (10). Nevertheless, the bleeding risk in this population is considerable, and careful case-by-case management of the antiplatelet strategy is mandatory after chimney stenting. According to these considerations, the median intended duration of antiplatelet or anticoagulant therapy in our cohort was 7.5 months (IQR: 6 to 12 months). Further data collection is required to understand the mechanisms and

FIGURE 2 One-Year All-Cause Death After TAVR With Chimney Stenting



Patients at risk:					
All Patients	60	57	49	40	35
Protection Yes	44	44	37	31	26
Protection No	16	14	13	10	10

Kaplan-Meier curves for 1-year mortality in all patients **(blue)** and those with **(green)** and without **(red)** upfront coronary artery protection. TAVR = transcatheter aortic valve replacement.

frequency of these late events. Until longer-term data on the incidence of stent failure are available, chimney stenting should be considered only as a bailout option for impending or eCAO.

STUDY LIMITATIONS. The small size of the study population limited a more detailed statistical analysis, particularly with respect to the predictors of both CAO and adverse outcomes. It is likely that the mortality rate described in this series (5% procedural mortality) is underestimated relative to that of patients with CAO, as this study included only patients who underwent successful chimney stenting, rather than those that did not survive to receive chimney stenting or were treated in an alternative way. Moreover, the group of patients with iCAO, which probably included some patients who may not have proceeded to frank coronary occlusion, would have lowered the mortality rate in the present study compared with prior studies (1,2). Also, we were unable to collect information on the frequency of upfront coronary protection, in particular data on cases in which coronary protection was removed unused after THV deployment. This information is of relevance to understand the prevalence of coronary protection in contemporary practice and to collate data on the safety and cost-effectiveness of this technique. Site-reported events and the absence of core laboratory analysis of angiographic, echocardiographic, and computed tomographic data represent important limitations of this study as well. Finally, the median follow-up period was short, and extended study of a larger population is required. For these reasons, our results should be interpreted cautiously.

CONCLUSIONS

Chimney stenting is an infrequently used technique to treat or prevent CAO in the setting of TAVR. Acute procedural results are encouraging, especially when risk factors for CAO are recognized preprocedure and coronary protection is prepared upfront. Longer term follow-up is required to understand the frequency and impact of late chimney stent failure.

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PERSPECTIVES

WHAT IS KNOWN? Chimney stenting during TAVR is an important bailout technique for the treatment of acute CAO, but there is little information on post-hospitalization outcomes.

WHAT IS NEW? This study suggests that chimney stenting during TAVR is a reasonable bailout option for CAO with acceptable short- and medium-term clinical outcomes.

WHAT IS NEXT? Longer term follow-up is required to understand the frequency and impact of late chimney stent failure.

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KEY WORDS chimney stenting, coronary artery obstruction, coronary protection, myocardial infarction, transcatheter aortic valve replacement

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