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Predictive Factors, Management, and Clinical Outcomes of Coronary Obstruction Following Transcatheter Aortic Valve Implantation

Insights From a Large Multicenter Registry

Henrique B. Ribeiro, MD,* John G. Webb, MD,† Raj R. Makkar, MD,‡ Mauricio G. Cohen, MD,§ Samir R. Kapadia, MD,‖ Susheel Kodali, MD,¶ Corrado Tamburino, MD,# Marco Barbanti, MD,†# Tarun Chakravarty, MD,‡ Hasan Jilaihawi, MD,‡ Jean-Michel Paradis, MD,¶ Fabio S. de Brito, Jr, MD,** Sergio J. Cánovas, MD,†† Asim N. Cheema, MD,‡‡ Peter P. de Jaegere, MD,§§ Raquel del Valle, MD,‖‖ Paul T. L. Chiam, MD,¶¶ Raúl Moreno, MD,## Gonzalo Pradas, MD,*** Marc Ruel, MD,††† Jorge Salgado-Fernández, MD,‡‡‡ Rogerio Sarmento-Leite, MD,§§§ Hadi D. Toeg, MD,††† James L. Velianou, MD,‖‖‖ Alan Zajarias, MD,¶¶¶ Vasilis Babaliaros, MD,### Fernando Cura, MD,**** Antonio E. Dager, MD,†††† Ganesh Manoharan, MD,‡‡‡‡ Stamatios Lerakis, MD,### Augusto D. Pichard, MD,§§§§ Sam Radhakrishnan, MD,‖‖‖‖ Marco Antonio Perin, MD,** Eric Dumont, MD,* Eric Larose, MD,* Sergio G. Pasian, MD,* Luis Nombela-Franco, MD,* Marina Urena, MD,* E. Murat Tuzcu, MD,‖ Martin B. Leon, MD,¶ Ignacio J. Amat-Santos, MD,¶¶¶¶ Jonathon Leipsic, MD,† Josep Rodés-Cabau, MD*

Quebec City, Quebec, Toronto, Ottawa, Hamilton, Ontario, and Vancouver, British Columbia, Canada; Los Angeles, California; Miami, Florida; Cleveland, Ohio; New York, New York; Catania, Italy; Sao Paulo, and Porto Alegre, Brazil; Valencia, Oviedo, Madrid, Vigo, La Coruna, and Valladolid, Spain; Rotterdam, the Netherlands; Singapore; St. Louis, Missouri; Atlanta, Georgia; Buenos Aires, Argentina; Cali, Colombia; Belfast, Northern Ireland; and Washington, DC

Objectives This study sought to evaluate the main baseline and procedural characteristics, management, and clinical outcomes of patients from a large cohort of patients undergoing transcatheter aortic valve implantation (TAVI) who suffered coronary obstruction (CO).

Background Very little data exist on CO following TAVI.

Methods This multicenter registry included 44 patients who suffered symptomatic CO following TAVI of 6,688 patients (0.66%). Pre-TAVI computed tomography data was available in 28 CO patients and in a control group of 345 patients (comparisons were performed including all patients and a cohort matched 1:1 by age, sex, previous coronary artery bypass graft, transcatheter valve type, and size).

Results Baseline and procedural variables associated with CO were older age ($p < 0.001$), female sex ($p < 0.001$), no previous coronary artery bypass graft ($p = 0.043$), the use of a balloon-expandable valve ($p = 0.023$), and previous surgical aortic bioprosthesis ($p = 0.045$). The left coronary artery was the most commonly involved (88.6%). The mean left coronary artery ostia height and sinus of Valsalva diameters were lower in patients with obstruction than in control subjects (10.6 ± 2.1 mm vs. 13.4 ± 2.1 mm, $p < 0.001$; 28.1 ± 3.8 mm vs. 31.9 ± 4.1 mm, $p < 0.001$). Differences between groups remained significant after the case-matched analysis ($p < 0.001$ for coronary height; $p = 0.01$ for sinus of Valsalva diameter). Most patients presented with persistent severe hypotension (68.2%) and electrocardiographic changes (56.8%). Percutaneous coronary intervention was attempted in 75% of the cases and was successful in 81.8%. Thirty-day mortality was 40.9%. After a median follow-up of 12 (2 to 18) months, the cumulative mortality rate was 45.5%, and there were no cases of stent thrombosis or reintervention.

Conclusions Symptomatic CO following TAVI was a rare but life-threatening complication that occurred more frequently in women, in patients receiving a balloon-expandable valve, and in those with a previous surgical bioprosthesis. Lower-lying coronary ostium and shallow sinus of Valsalva were associated anatomic factors, and despite successful treatment, acute and late mortality remained very high, highlighting the importance of anticipating and preventing the occurrence of this complication. (J Am Coll Cardiol 2013;62:1552–62) © 2013 by the American College of Cardiology Foundation

Symptomatic coronary obstruction due to the displacement of the calcified native valve leaflets over the coronary ostia is a potential complication of transcatheter aortic valve implantation (TAVI). However, apart from reporting its incidence (usually <1%) in some TAVI studies (1–7), data on this life-threatening complication have been limited to case reports and very small case series (8), and to date, there has been no large registry evaluating the baseline characteristics of patients suffering this complication, its management, and clinical impact.

We recently conducted a systematic review of the literature on symptomatic coronary obstruction as a complication of TAVI that included 24 cases; all of them reported as case reports or very small case series (8). In that study, reported cases of coronary obstruction following TAVI occurred more frequently in women and patients receiving a balloon-expandable valve, and the left coronary artery (LCA) was the most commonly involved. Percutaneous coronary intervention (PCI) was a feasible and successful treatment in most cases, but hemodynamic support and/or conversion to open heart surgery were frequently needed. This study, however, had the limitations inherent to a review that collects only the information described in publications. In addition to the possible omission of data and the selection bias inherent to published cases (reported cases might tend to have better outcomes than those that are not reported), obtaining data from case reports precluded any comparison with the entire TAVI population at risk and made it difficult to evaluate the baseline and procedural factors associated with this complication. The aim of the present study, therefore, was to evaluate the main baseline and procedural characteristics, management, and clinical outcomes of patients suffering from coronary obstruction following TAVI from a large series of consecutive patients undergoing TAVI.

Abbreviations and Acronyms

CABG = coronary artery bypass graft
CT = computed tomography
IQR = interquartile range
LCA = left coronary artery
logEuroSCORE = logistic European System for Cardiac Operative Risk Evaluation score
PCI = percutaneous coronary intervention
RCA = right coronary artery
SOV = sinus of Valsalva
TAVI = transcatheter aortic valve implantation
TIMI = Thrombolysis In Myocardial Infarction

Methods

The present multicenter registry of coronary obstruction following TAVI collected retrospectively all cases with this complication from 81 centers in North America, Europe, South America, and Asia, from January 2007 to January 2013. Gathered data included the main baseline clinical, echocardiographic, computed tomography (CT), and procedural characteristics of the cases. All information on clinical presentation, diagnosis, and treatment of the coronary obstruction complication, as well as 30-day and late clinical outcomes were entered. The clinical events were defined according to the VARC (Valve Academic Research Consortium)-2 criteria (retrospective

From the *Department of Cardiology, Quebec Heart and Lung Institute, Laval University, Quebec City, Canada; †Departments of Cardiology and Radiology, St. Paul's Hospital, University of British Columbia, Vancouver, British Columbia, Canada; ‡Department of Cardiovascular Intervention Center and Cardiothoracic Surgery, Cedars-Sinai Medical Center, Los Angeles, California; §Cardiovascular Division, Department of Medicine, University of Miami, Miami, Florida; ‖Miller Family Heart and Vascular Institute, Cleveland Clinic, Cleveland, Ohio; ¶Columbia University Medical Center, Center for Interventional Vascular Therapy, NewYork Presbyterian Hospital, New York, New York; #Division of Cardiology, Ferrarotto Hospital, University of Catania, Catania, Italy; **Hospital Israelita Albert Einstein, Sao Paulo, Brazil; ††Department of Cardiac Surgery, University General Hospital of Valencia, Valencia, Spain; ‡‡Division of Cardiology, St. Michael's Hospital, Toronto University, Toronto, Ontario, Canada; §§Department of Cardiology, Thoraxcenter-Erasmus MC, Rotterdam, the Netherlands; ‖‖Department of Cardiology, Asturias University Hospital, Oviedo, Spain; ¶¶Department of Cardiology, National Heart Centre, Singapore; ##Division of Interventional Cardiology, University Hospital La Paz, Madrid, Spain; ***Department of Cardiac Surgery, Vigo University Hospital, Vigo, Spain; †††Division of Cardiac Surgery, University of Ottawa Heart Institute, Ottawa, Ontario, Canada; ‡‡‡Department of Cardiology, A Coruña University Hospital, La Coruña, Spain; §§§Instituto de Cardiologia do Rio Grande do Sul, Porto Alegre, Brazil; ‖‖‖Division of Cardiology, Department of Medicine, Hamilton General Hospital, McMaster University, Hamilton, Ontario, Canada; ¶¶¶Cardiovascular Division, Washington University School of Medicine, St. Louis, Missouri; ###Department of Medicine, Division of Cardiology, Emory University Hospital, Atlanta, Georgia; ****Department of Interventional Cardiology, Instituto Cardiovascular de Buenos Aires, Buenos Aires, Argentina; ††††Department of Cardiology, Angiografia de Occidente S.A., Cali, Colombia; ‡‡‡‡Belfast Heart Centre, Royal Victoria Hospital, Belfast, Northern Ireland; §§§§Interventional Cardiology, MedStar Washington Hospital Center, Washington, DC; ‖‖‖‖‖Sunnybrook Health Sciences Centre, University of Toronto, Toronto, Ontario, Canada; and the ¶¶¶¶Instituto de Ciencias del Corazón (ICICOR), Hospital Clinico Universitario de Valladolid, Valladolid, Spain. Dr. Ribeiro has received funding via a research grant from the Conselho Nacional de Desenvolvimento Científico e Tecnológico, Brasil. Dr. Webb has received consulting fees from Edwards Lifesciences and St. Jude Medical. Dr. Makkar has received research grants from Edwards Lifesciences, Medtronic, Abbott, Capricor, and St. Jude Medical; has served as a proctor for Edwards Lifesciences; and has received consulting fees from Medtronic. Dr. Cohen has served on the Speakers' Bureau of Medtronic; and has received consulting fees from Edwards Lifesciences and St. Jude Medical. Dr. Kodali has received consulting fees from Edwards Lifesciences; has served on the steering committees of Edwards Lifesciences and St. Jude Medical; has served on the Speakers' Bureau of Thubrikar Aortic Valve, Inc.; and has equity in Thubrikar Aortic Valve. Dr. Tamburino has received support from Edwards Lifesciences, Abbott, and CardioKinetix; and has a speaking honorarium with CardioKinetix. 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Dr. Manoharan has received consulting fees from St. Jude Medical. Dr. Lerakis has received consulting fees from Edwards Lifesciences. Dr. Pichard has received consulting fees from and has served as a proctor for Edwards Lifesciences. Dr. Radhakrishnan has received consulting fees from and has served as a proctor for Medtronic. Dr. Perin has received consulting fees from Medtronic. Dr. Dumont has received consulting fees from Edwards Lifesciences. Dr. Leon has received research grants for clinical trials from Edwards Lifesciences. Dr. Amat-Santos was supported by the Instituto de Salud Carlos III (Madrid, Spain) through a contract "Río Hortega" at the ICICOR. Dr. Leipsic has received consulting fees from and has served on the Speakers' Bureau of Edwards Lifesciences. Dr. Rodés-Cabau has received consulting fees from Edwards Lifesciences and St. Jude Medical. All other authors have reported that they have no relationships relevant to the contents of this paper to disclose.

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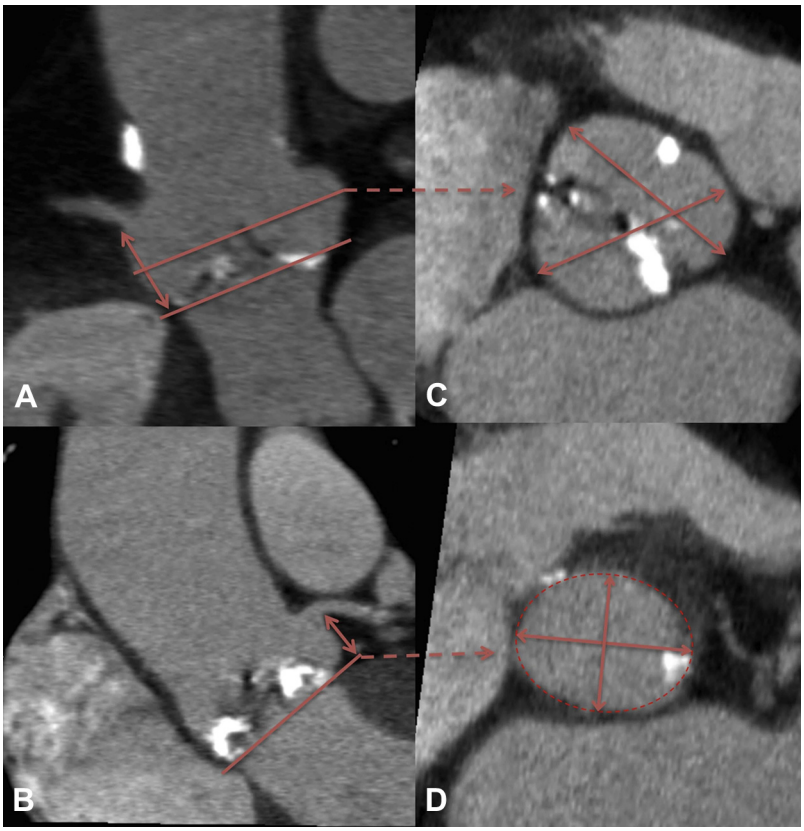

Figure 1 **Multidetector CT Evaluation Pre-TAVI**

Computed tomography (CT) angiographic measurements in the long-axis view for the right **(A)** and left **(B)** coronary artery height. The coronary height was measured from the aortic annulus plane to the lower level margin of the right **(A)** and left **(B)** coronary ostia. While maintaining the orientation, the images are scrolled up to allow for short-axis measurement of the sinus of Valsalva **(C)** and then down to provide measures of the annulus/basal ring **(D)**. TAVI = transcatheter aortic valve implantation.

event assignment) (9). Also, all centers were asked to provide data on the entire population undergoing TAVI with no coronary obstruction in each center; the data included mean age and logistic EuroSCORE (European System for Cardiac Operative Risk Evaluation) (logEuroSCORE), and the percentage of women, and patients with previous coronary artery disease and previous coronary artery bypass graft (CABG). The total number of TAVI cases per center, as well as data on valve type, approach, and valve-in-valve procedures (cases with a previous surgical aortic bioprosthesis) were gathered.

Computed tomography. Data on coronary height, aortic annulus diameter and area, sinus of Valsalva (SOV) diameter, diameter of the sinotubular junction, and severity of valve calcification (Agatston units) were obtained in those patients with CT performed prior to the TAVI procedure. CT exams were evaluated in a central core-lab by 2 investigators (S.P., H.B.R.) and all measurements, but valve calcification severity, were performed with the CT images obtained following contrast injection. The techniques used for all these CT measurements have been described in detail in previous reports (10–12), and are summarized in Figure 1. The CT measurements from patients with coronary obstruction following TAVI were compared with those obtained in a control group (no coronary obstruction) of 345 consecutive patients, obtained from January 2011 to December 2012, in 3 participating centers, with both valve types.

Statistical analysis. Categorical variables are reported as n (%) and continuous variables are expressed as mean ± SD or median (interquartile range [IQR]) depending on variable distribution. Group comparisons were analyzed using the Student *t* test or Wilcoxon rank sum test. The chi-square test and the Fisher exact test were performed for categorical variables. To further evaluate the CT variables associated with coronary obstruction, patients with this complication and without previous surgical bioprosthesis were matched 1:1 with control subjects from a CT cohort of 345 patients using the bootstrap technique (1,000 samples with replacement). The clinical variables used for the match were age ± 2 years, sex, previous CABG, valve type, and size. All analysis were conducted using the statistical package SAS (version 9.2, SAS Institute Inc., Cary, North Carolina).

Results

Of 6,688 patients who underwent a TAVI procedure in 81 centers worldwide, 44 cases (0.66%) of acute symptomatic coronary obstruction occurred following the procedure. The clinical and procedural characteristics of the study population are shown in Table 1, and the main clinical and procedural characteristics of the coronary obstruction cases compared with the rest of the study population are shown in Table 2. Patients who suffered symptomatic coronary obstruction were older and more frequently women ($p < 0.001$ for both), had less frequently a history of CABG ($p = 0.043$), exhibited a higher risk profile as evaluated by logEuroSCORE ($p < 0.001$), more frequently had a previous surgical aortic bioprosthesis ($p = 0.045$), and had more frequently received a balloon-expandable valve ($p = 0.023$ vs. self-expandable valve). The incidence of coronary obstruction according to valve type and the presence of a previous surgical bioprosthesis ("valve-in-valve procedure") are shown in Figure 2. The incidence of coronary obstruction according to the approach is shown in Figure 3.

Clinical presentation, management, and outcomes. Data on clinical presentation and management of coronary obstruction, and 30-day outcomes are presented in Table 3. Coronary obstruction occurred at the ostium of the LCA in most (88.6%) cases and the diagnosis was made by coronary angiography in all patients but 1 (post-mortem). Coronary obstruction was related to the displacement of a calcified native aortic valve leaflet toward the coronary ostium in all patients but 1 (97.7%), who had an aortic valve cusp shearing and migration into the LCA. Most cases (68.2%) presented with severe persistent hypotension, and electrocardiographic changes, mainly ST-segment elevation and ventricular arrhythmias, occurred in 56.8% of the patients.

Coronary revascularization was not attempted in 7 patients (15.9%). In 2 patients who received a CoreValve system (Medtronic, Minneapolis, Minnesota), coronary obstruction was resolved by snaring and removing the transcatheter valve toward the ascending aorta. One patient with partial obstruction of the right coronary artery (RCA) ostium was managed with medical treatment and no coronary revascularization was attempted. Another 3 patients died within the few minutes following a complete coronary obstruction of the LCA, with no time for any coronary revascularization attempt. PCI was attempted in 33 patients (75%), and it was successful (residual stenosis <20% and TIMI [Thrombolysis In Myocardial Infarction] flow grade 3) in 81.8% of them.

Procedural death occurred in 7 patients (15.9%), and among those patients who survived the procedure, 11 had died at 30 days, leading to a 30-day mortality rate of 40.9%. The causes of death in these patients were sepsis (n = 6), cardiogenic shock (n = 4), and hypoxic brain injury (n = 1). The 30-day mortality rate according to the type and results of coronary revascularization treatment is shown in Figure 4. Thirty-day survival was 66.7% among patients who received cardiopulmonary bypass as mechanical support (without CABG). In patients who survived the procedure, the median hospitalization length was 6 (IQR: 3 to 17) days, and echocardiographic data showed

Table 1 Baseline and Procedural Characteristics of the Patients With Coronary Obstruction Following TAVI (n = 44)

Clinical variables	
Age, yrs	83.1 ± 8.0
Female	37 (84.1)
Body mass index, kg/m^2	25.3 ± 6.0
NYHA functional class	
I–II	7 (15.9)
III–IV	37 (84.1)
Diabetes	15 (34.1)
Dyslipidemia	25 (56.8)
Hypertension	41 (93.2)
Coronary artery disease	19 (43.2)
Previous myocardial infarction	6 (13.6)
Prior PCI	9 (20.5)
Prior CABG	4 (9.1)
Patent LIMA/graft to LAD	2 (50)
Complete revascularization prior to TAVI	31 (70.5)
Prior aortic valve surgery	3 (6.8)
Previous pacemaker	8 (18.2)
Cerebrovascular disease	9 (20.5)
Peripheral vascular disease	17 (38.6)
COPD	11 (25.0)
Porcelain aorta	3 (6.8)
eGFR, <60 ml/min	23 (52.3)
logEuroSCORE, %	23.2 ± 16.2
Echocardiographic variables	
Mean aortic gradient, mm Hg	54.5 ± 17.8
Aortic valve area, cm^2	0.53 ± 0.19
LVEF, %	53.5 ± 14.7
Annulus size, mm	20.4 ± 1.5
Procedural variables	
Approach	
Transfemoral	30 (68.2)
Transapical	13 (29.5)
Transaortic	1 (2.3)
Valve-in-valve	3 (6.8)
Prosthesis size, mm	
23	25 (56.8)
26	15 (34.1)
29	3 (6.8)
31	1 (2.3)
Prosthesis type	
Balloon-expandable valve: Sapien/Sapien XT	37 (84.1)
Self-expandable valve: CoreValve	7 (15.9)
Balloon pre-dilation	40 (90.9)
Balloon post-dilation	8 (18.2)

Values are mean ± SD or n (%). Sapien and Sapien XT are products of Edwards Lifesciences (Irvine, California); CoreValve is a product of Medtronic (Minneapolis, Minnesota).

CABG = coronary artery bypass graft; COPD = chronic obstructive pulmonary disease; eGFR = estimated glomerular filtration ratio; EuroSCORE = European System for Cardiac Operative Risk Evaluation; LAD = left anterior descending artery; LIMA = left internal mammary artery; logEuroSCORE = logistic EuroSCORE predicted risk of mortality; LVEF = left ventricular ejection fraction; NYHA = New York Heart Association; PCI = percutaneous coronary intervention; TAVI = transcatheter aortic valve implantation.

Table 2 Main Clinical and Procedural Characteristics, According to the Occurrence of Coronary Obstruction Following TAVI

	Coronary Obstruction (n = 44)	Control Subjects (n = 6,644)	p Value
Clinical variables			
Age, yrs	83.1 ± 8.0	81.0 ± 7.1	<0.001
Female	37 (84.1)	3,408 (51.3)	<0.001
Prior CAD	19 (43.2)	2,270 (55.5)*	0.258
Previous CABG	4 (9.1)	919 (22.5)*	0.043
logEuroSCORE, %	23.2 ± 16.2	18.1 ± 13.6	<0.001
Procedural variables			
Valve type			0.023
Sapien/Sapien XT	37 (84.1)	4,533 (68.2)	
CoreValve	7 (15.9)	2,066 (31.1)	
Others	—	45 (0.7)	
Approach			0.442
Transfemoral	30 (68.2)	4,904 (73.8)	
Transapical	13 (29.5)	1,546 (23.3)	
Transaortic/trans-subclavian	1 (2.3)	194 (2.9)	
Valve-in-valve	3 (6.8)	118 (1.8)	0.045

Values are mean ± SD or n (%). The — indicates that there was no case of coronary obstruction with the other valves. Sapien and Sapien XT are products of Edwards Lifesciences (Irvine, California); CoreValve is a product of Medtronic (Minneapolis, Minnesota). *Data available for 4,386 patients.

CAD = coronary artery disease; other abbreviations as in Table 1.

a mean residual gradient of 10.9 ± 7.9 mm Hg, and a valve area of 1.66 ± 0.36 cm^2. Residual aortic regurgitation was absent/trivial, mild, and moderate in 33.4%, 58.3%, and 8.3% of the patients, respectively.

At a median follow-up of 12 (IQR: 2 to 18) months, 20 patients had died (cumulative mortality rate: 45.5%). Among those patients who survived at 30 days, 2 patients died during the follow-up period of unknown causes. The vast majority of patients (95%) were in New York Heart Association functional class I to II at follow-up. There were no cases of stent thrombosis or repeat revascularization. The Kaplan-Meier survival curves at 1-year follow-up are shown in Figure 5.

CT data. Pre-TAVI CT data were available in 28 of 44 patients with coronary obstruction (63.6%). CT data of the patients with coronary obstruction compared with those of the control group are shown in Table 4. The main clinical characteristics of the CT control group were similar to the overall study population with no coronary obstruction following TAVI (Online Table 1). Patients with coronary obstruction exhibited a smaller aortic annulus area (p = 0.002), SOV diameter (p < 0.001), and sinotubular junction diameter

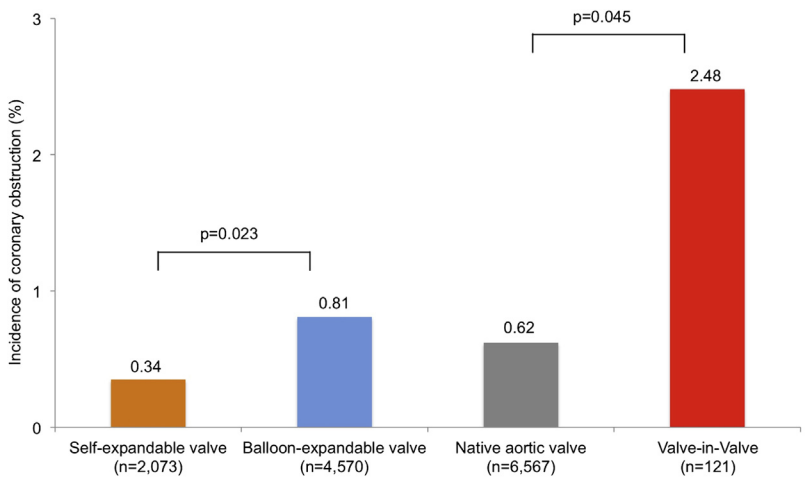

Figure 2 Incidence of Coronary Obstruction According to Valve Type and Valve-In-Valve Procedures

Incidence of coronary obstruction following transcatheter aortic valve implantation with self-expandable or balloon-expandable valves, as well as in native or prosthetic aortic valves.

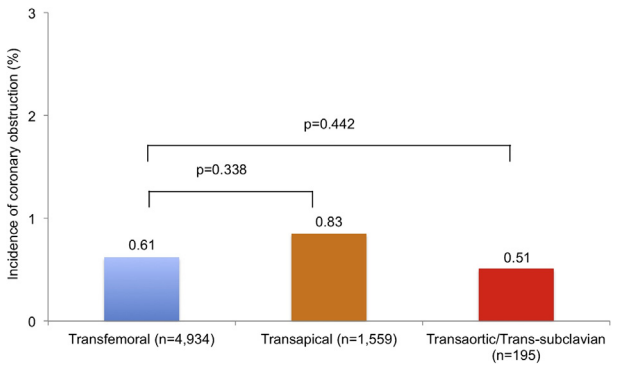

Figure 3 **Incidence of Coronary Obstruction According to the Different Approaches for TAVI**

Incidence of coronary obstruction following transcatheter aortic valve implantation (TAVI) through the transfemoral, transapical, and transaortic/trans-subclavian approaches.

($p = 0.003$), as well as a lower LCA height ($p < 0.001$). As women represented the vast majority of patients in the coronary obstruction group, a separate analysis of the CT data in women only was also performed (Online Table 2).

The results of the case-matched analysis including 27 patients without previous surgical bioprosthesis in both groups are shown in Table 5. The SOV diameter remained smaller in the coronary obstruction group (odds ratio [OR]: 1.37; 95% confidence interval [CI]: 1.13 to 1.66) and LCA height lower as compared with that of control subjects (OR: 2.17; 95% CI: 1.62 to 2.90). The individual data for LCA height and SOV diameters are shown in Figure 6. Up to 86% of the patients who had a coronary obstruction had a LCA height of <12 mm, compared with 26.4% of the patients in the control group ($p < 0.001$). The SOV diameter was <30 mm in 71.4% of the patients who had coronary obstruction compared with 33% of the patients in the control group ($p < 0.001$). Most patients (67.9%) who had coronary obstruction had both a LCA height <12 mm and a SOV diameter <30 mm compared with 13.3% of the patients in the control group ($p < 0.001$).

Discussion

Coronary obstruction and TAVI: incidence and associated factors. Potential concerns about the occurrence of coronary obstruction had been pointed out in the very first experimental models evaluating the TAVI technique (13,14), and the occurrence of this complication was also reported in the first human experiences of TAVI (15). The incidence of this complication in subsequent large TAVI series and registries has been low, nearly systematically lower than 1% (1–7,16). The results of the present study, with a systematic evaluation of this complication in a multicenter cohort including >6,500 TAVI procedures, confirmed an incidence of coronary obstruction of <1% (0.66%).

Whereas the incidence of this complication was low for the 2 transcatheter valve types (balloon-expandable and self-expandable), the coronary obstruction rate was as much as twice as high among patients who received a balloon-expandable valve (0.81% vs. 0.34% among those who received a self-expandable valve). A recent review of TAVI complications including all TAVI studies with ≥100 patients also found a tendency toward a higher incidence of coronary obstruction in patients treated with a balloon-expandable valve (1.1%) compared with those treated with a self-expandable valve (0.4%) (16). This is also consistent with the systematic review of the reported cases of coronary obstruction to date, which involved a balloon-expandable valve in >80% of the cases (8). Differences in both the frame characteristics of the 2 transcatheter valve systems (straight stainless steel or cobalt chromium vs. nitinol with a concave shape at the level of coronary arteries) and the mechanisms for valve implantation (balloon-expandable vs. self-expandable) might partially explain these differences. However, the specific recommendations on SOV diameter and coronary ostia height for the CoreValve system implantation could also have played a role in these differences. In fact, whereas no specific formal recommendation for SOV width and coronary ostia height was provided for the implantation of the Edwards valve (Edwards Lifesciences, Irvine, California), a recommendation of a SOV width of ≥27 mm (for the 26-mm CoreValve) or ≥28 mm (for the 29-mm CoreValve) and a coronary height of ≥14 mm was provided by the manufacturer for the implantation of the CoreValve system. Although these specific recommendations might not have been followed by all CoreValve implanting centers, it may possibly have prevented a significant number of coronary obstructions with the CoreValve system.

The occurrence of coronary obstruction was also more frequent among patients with previous surgical aortic bioprosthesis ("valve-in-valve" procedures). The incidence of coronary obstruction of 2.4% in such patients was close to the 3.5% rate reported in a recent multicenter registry of valve-in-valve TAVI procedures (17). Some types of surgical aortic bioprosthesis such as stentless valves or stented valves with long leaflets have been associated with this complication, and future studies with a much larger number of patients will be needed to further evaluate the factors associated with coronary obstruction in this specific group of patients.

Whereas women represent about 50% of the patients treated with TAVI, the vast majority (>80%) of patients who had coronary obstruction following TAVI were women. This was consistent with previous data from reported cases of coronary obstruction as a complication of TAVI, mainly single case reports or small case series, which involved women in 83% of the cases (8). The association between female sex and coronary obstruction may be due to anatomic differences in aortic SOV dimensions and coronary height according to sex. Previous CT studies have already shown the smaller aortic SOV dimensions and lower coronary ostia takeoff in women, irrespective of the

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Table 3 Clinical Presentation and Management of Coronary Obstruction Following TAVI (n = 44)

Obstructed coronary artery	
Left coronary artery	39 (88.6)
Right coronary artery	2 (4.5)
Both	3 (6.8)
Timing	
After balloon valvuloplasty	4 (9.1)
After valve implantation	31 (70.5)
After balloon post-dilation	4 (9.1)
Within 24 h following TAVI	4 (9.1)
More than 24 h following TAVI	1 (2.3)
Clinical presentation	
Severe persistent hypotension	30 (68.2)
ECG changes	25 (56.8)
ST-segment elevation	14 (56.0)
Ventricular fibrillation	7 (28.0)
Ventricular tachycardia	3 (12.0)
Atrial fibrillation	2 (8.0)
Left bundle branch block	2 (8.0)
Stenosis severity	
Partial occlusion	25 (56.8)
Complete occlusion	19 (43.2)
Treatment	
PCI attempted	33 (75.0)
Successful	27 (81.8)
Stent successfully implanted	25 (75.8)
Guidewire protection only	1 (3.0)
Catheter cannulation only	1 (3.0)
Unsuccessful	6 (18.2)
Coronary cannulation failure	2 (33.3)
Wire crossing failure	2 (33.3)
Stent could not be advanced	1 (16.7)
Stent implanted but no flow	1 (16.7)
Type of stent	
Bare-metal stent(s)	6 (24.0)
Drug-eluting stent(s)	17 (68.0)
Bare-metal and drug-eluting stents	2 (8.0)
Urgent CABG	6 (13.6)
Conversion to open heart surgery	2 (6.1)

Continued in the next column

Table 3 Continued

Procedural complications	
Need for cardiopulmonary resuscitation	18 (40.9)
Need for hemodynamic support	16 (36.4)
CPB	7 (43.8)
IABP	4 (25.0)
Fem-Fem CPB	3 (18.8)
ECMO	1 (6.3)
Impella	1 (6.3)
Inotropes	30 (68.2)
Valve embolization	2 (4.5)
Need for a second valve	3 (6.8)
Cardiac tamponade	3 (6.8)
30-day outcomes	
Myocardial infarction	21 (47.7)
Peak CK-MB, μg/l	82.4 (24.3–240.6)
New Q waves*	5 (35.7)
New left bundle branch block	4 (9.1)
New pacemaker	1 (2.3)
Major vascular complications	5 (11.4)
Major or life-threatening bleeding	7 (15.9)
Acute renal failure	9 (20.4)
Dialysis	2 (4.5)
Stroke	4 (9.1)
Death	18 (40.9)
Hospitalization length, days	6 (3–17)

Values are n (%) or median (interquartile range). *After excluding the patients with procedural death. CK-MB = creatine kinase-myocardial band; CPB = cardiopulmonary bypass; ECG = electrocardiographic; ECMO = extracorporeal membrane oxygenation; Fem-Fem = femoral-femoral bypass; IABP = intra-aortic balloon pump; other abbreviations as in Table 1.

presence of aortic stenosis (11,18), and these sex differences in aortic SOV dimensions and coronary height were also observed in the pre-TAVI CT exams of our control group including >300 patients (33.8 ± 3.9 mm vs. 29.7 ± 3.1 mm for SOV dimensions; 14.1 ± 2.1 mm vs. 12.7 ± 1.8 mm for LCA coronary height in men and women, respectively; $p < 0.001$ for both). It has been shown that coronary obstruction following TAVI is mainly due to the displacement of the calcified native cusp over the coronary ostia, and this was also the mechanism of coronary obstruction in 98% of the patients in the present study. Therefore, it is not surprising that aortic SOV dimensions and coronary height were shown to be important factors associated with the occurrence of coronary obstruction following TAVI in this study. Patients with coronary obstruction exhibited a lower coronary ostia takeoff of the LCA. The mean LCA height in patients with coronary obstruction was of about 11 mm (10 mm in women), as compared with about 13 mm in those patients without coronary obstruction. Importantly, most patients who

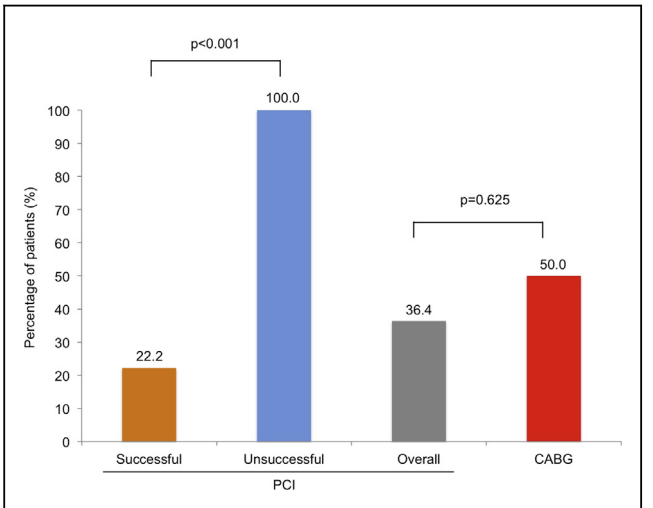

Figure 4 Mortality Rate at 30 Days According to the Type and Results of the Treatment for Coronary Obstruction

Mortality at 30 days following successful percutaneous coronary intervention (PCI), unsuccessful PCI, or coronary artery bypass graft (CABG) after the occurrence of coronary obstruction.

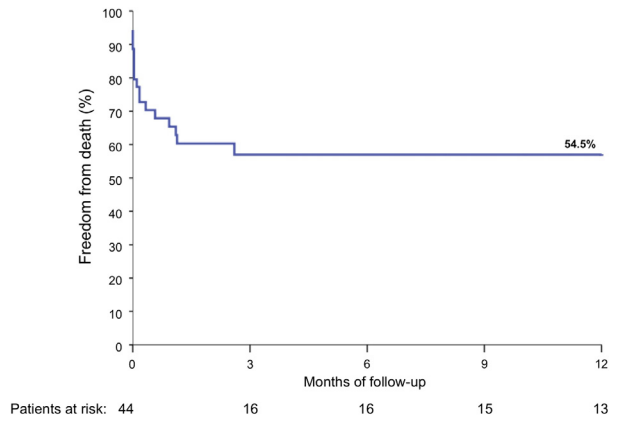

Figure 5 Kaplan-Meier Survival Curves at 1-Year Follow-Up

Survival curve showing a mortality rate of 45.5% at 1-year follow-up after transcatheter aortic valve implantation complicated with coronary obstruction.

suffered coronary obstruction (about 80% overall, 96% of the women) had a LCA height of <12 mm, suggesting that this may be a more accurate cutoff than the 10-mm cutoff suggested by the American College of Cardiology Foundation/American Association for Thoracic Surgery/Society for Cardiovascular Angiography and Interventions/Society of Thoracic Surgeons and the CT-TAVI expert consensus (10,19), and the 14-mm cutoff suggested by the manufacturer regarding the CoreValve implantation. Moreover, the 12-mm cutoff would be in the upper limit of the 95% CI from the coronary obstruction cases and would not be included in the lower limit for the control subjects. The RCA ostia takeoff is usually higher than that of the LCA (11,12), and this is probably the reason why RCA obstruction after TAVI is very infrequent (only 11% of the cases in the present series). Whereas the RCA ostia height was also found to be lower in patients who had RCA obstruction after TAVI, the low number of patients with this complication precluded drawing any reliable conclusions about the RCA cutoff height associated with an increased risk.

Although coronary ostia height is an important factor associated with coronary obstruction following TAVI, a significant number of patients in the coronary obstruction group suffered this complication despite a LCA coronary height of >12 mm (21.4%), indicating that factors other than coronary height are also involved in this complication. A narrow aortic root leaving little room to accommodate the native aortic leaflets may also contribute to coronary obstruction after TAVI. In fact, coronary obstruction was associated with a certain degree of aortic root effacement as compared with that of the control group. Most patients (64.3%) who suffered this complication had an aortic SOV diameter of <30 mm, as compared with about one-third of the patients in the control group. In fact, only a minority of the patients who did not suffer coronary obstruction had both, a coronary height of <12 mm and an aortic SOV diameter of <30 mm (13.3%), meaning that the combination of these 2 anatomic factors has to be taken into account when evaluating the possibility of coronary obstruction due to TAVI. The degree of valve calcification as a global measure was not associated with the occurrence of coronary obstruction in this study, suggesting that this is probably not the main anatomic factor associated with post-TAVI coronary obstruction. However, the presence of bulky calcium nodules was not specifically evaluated, and its role in the occurrence of some cases of coronary obstruction cannot be ruled out.

In those patients considered at high risk for coronary obstruction, we would suggest to implement additional security measures during the TAVI procedure such as simultaneous angiography during balloon valvuloplasty to depict coronary obstruction or coronary protection with a guidewire

Table 4 Computed Tomography Data, According to the Occurrence of Coronary Obstruction Following TAVI

	Coronary Obstruction (n = 28)	Control Subjects (n = 345)	p Value
Annulus diameter, mm	22.9 ± 3.1	24.4 ± 2.9	0.010
Annulus area, mm^2	387 (375–424)	476 (405–560)	0.002
Aortic SOV diameter, mm	28.1 ± 3.8	31.9 ± 4.1	<0.001
Sinotubular junction, mm	25.2 ± 3.1	28.0 ± 3.9	0.003
Relation prosthesis size/annulus	1.09 ± 0.11	1.05 ± 0.09	0.084
Relation SOV/annulus	1.25 ± 0.17	1.31 ± 0.14	0.054
Left coronary height, mm	10.6 ± 2.1	13.4 ± 2.1	<0.001
Right coronary height, mm	12.4 ± 3.2	14.1 ± 2.4	0.003
Left coronary height, mm*	10.4 ± 2.0	13.5 ± 2.0	<0.001
Right coronary height, mm†	11.3 ± 2.1	14.0 ± 2.4	0.048
Calcium score, Agatston units	2,354 ± 1,187	2,872 ± 1,726	0.290

Values are mean ± SD or median (interquartile range). *Cases of right coronary artery obstruction excluded. †Cases of left coronary artery obstruction excluded.

SOV = sinus of Valsalva; other abbreviations as in Tables 1 and 3.

Table 5 CT Data From the Case-Matched Analysis, According to the Occurrence of Coronary Obstruction Following TAVI

	Coronary Obstruction (n = 27)	Control Subjects (n = 27)	OR (95% CI)	p Value
Annulus diameter, mm	23.0 ± 0.6	23.6 ± 0.4	1.15 (0.92–1.45)	0.510
Annulus area, mm^2	410 ± 18	458 ± 17	1.01 (0.99–1.02)	0.126
Aortic SOV diameter, mm	28.3 ± 0.8	31.3 ± 0.6	1.37 (1.13–1.66)	0.011
Relation prosthesis size/annulus	1.08 ± 0.02	1.05 ± 0.02	0.02 (0.01–3.99)	0.315
Relation SOV/annulus	1.26 ± 0.04	1.34 ± 0.03	20.0 (1.28–333)	0.003
Left coronary height, mm	10.7 ± 0.4	13.3 ± 0.3	2.17 (1.62–2.90)	<0.001
Right coronary height, mm	12.7 ± 0.8	14.2 ± 0.4	1.36 (1.10–1.68)	0.047
Calcium score, Agatston units	2,284 ± 318	2,733 ± 313	1.00 (0.99–1.10)	0.333

Values are mean ± SE.

CI = confidence interval; CT = computed tomography; OR = odd ratio; other abbreviations as in Tables 1 and 4.

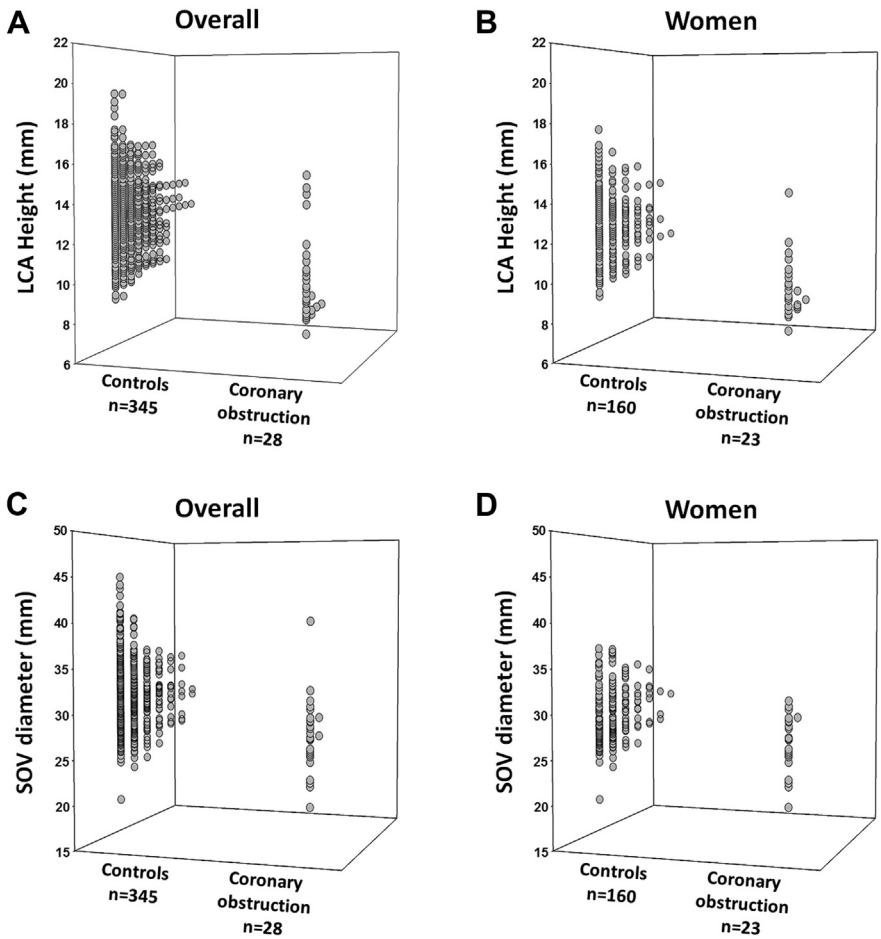

Figure 6 Individual Data for the LCA Height and Aortic SOV Diameter According to the Occurrence of Coronary Obstruction Overall and in Women Only

Individual data on computed tomography from the patients with coronary obstruction and control subjects showing that up to 86% of the patients with coronary obstruction had a left coronary artery (LCA) height of <12 mm, compared with 26% of the patients in the control group **(A)**. In women, up to 96% of the patients with coronary obstruction group had an LCA <12 mm compared with 36% in the control group **(B)**. The sinus of Valsalva (SOV) diameter was <30 mm in 71% of the patients who had coronary obstruction versus 33% in the control subjects **(C)**. In women, up to 78% of the patients in the coronary obstruction group had an SOV <30 mm versus 55% in the control group **(D)**.

in the presence of clinical and anatomical parameters of risk. Finally, the use of a transcatheter valve that can be repositioned or retrieved in case of coronary obstruction following valve implantation should probably be recommended in such cases.

Coronary obstruction following TAVI: management and clinical outcomes. Most of the patients with coronary obstruction presented with persistent severe hypotension, about one-half of them exhibited electrocardiographic changes, mainly ST-segment elevation, and more than one-third had ventricular arrhythmias. These data suggest that in case of persistent hypotension following valve implantation, coronary obstruction should be included in the differential diagnosis irrespective of electrocardiographic changes, and prompt echocardiography to detect new segmental abnormalities and/or coronary angiography to detect coronary obstruction should be performed.

The present study also showed that PCI was the preferred strategy for the treatment of coronary obstruction following TAVI. Importantly, PCI was feasible (attempted in 75% of the patients) and had a success rate of 81.8%. Still, urgent CABG or mechanical hemodynamic support (mainly cardiopulmonary bypass) were needed in 14% and 36% of the patients, respectively, underscoring the importance of performing these procedures in highly experienced centers with cardiac surgery facilities. These results differ from those of a recent systematic review of the literature that included small case series and case reports, where PCI was attempted in 96% of the patients and was successful in 91% of them (8). In fact, the reported patients might have tended to pursue a better outcome than those who were not published ("selection bias"). This is also supported by the fact that our 30-day death rate was as high as 41%, as compared with <10% in the systematic review of reported cases (8). The mortality rate was high after successful PCI (22%) or CABG (50%) and increased to as much as 100% in case of unsuccessful PCI. Whereas these results suggest that PCI as a first attempt for coronary revascularization is a reasonable strategy, it also highlights the importance of both obtaining coronary flow restoration very rapidly and being ready to change the therapeutic strategy (cardiopulmonary bypass, CABG) if coronary flow is not restored within a few minutes of the attempted PCI.

Study limitations. Only cases with symptomatic coronary obstruction were gathered; there might have been cases with previous CABG in which coronary obstruction occurred without clinical symptoms ("graft protection"). Available data from baseline clinical characteristics in the global cohort of TAVI patients were limited to a few clinical variables and logEuroSCORE. Reporting of cases of coronary obstruction cases was done on a voluntary basis, and there was no external monitoring done to verify the accuracy of the data reported by each center. CT data were available in about two-thirds of the coronary obstruction patients and in a control group of 345 patients. Although this was a small control group as compared with the entire TAVI study population, it still represents 1 of the largest series with pre-TAVI CT data to date (8,11,12,20–22). Also, the main clinical characteristics of the control group were similar to the rest of the study population, and both LCA height and SOV diameter remained as associated factors with coronary obstruction after performing a case-matched comparison. Coronary angiograms leading to the diagnosis of coronary obstruction were analyzed by the investigators of each center, with no centralized analyses. Although the present study represents a large series of coronary obstruction cases following TAVI, the relatively low number of events and CT exams precluded the performance of a multivariate analysis to evaluate the independent predictors of coronary obstruction in this population. Future prospective studies with a very large number of patients with systematic CT measurements will be needed to confirm these results.

Conclusions

The present study, which included the largest series of patients with coronary obstruction following TAVI to date, confirmed that this is a rare but life-threatening complication of TAVI that occurred more frequently in women, in patients receiving a balloon-expandable valve, and in those with a previous surgical bioprosthesis. Lower-lying coronary ostium (<12 mm) and shallow SOV (<30 mm) were related anatomic factors, and despite successful treatment (mainly PCI), in most cases, periprocedural mortality remained very high, which highlights the importance of anticipating and preventing the occurrence of this complication.

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Reprint requests and correspondence: Dr. Josep Rodés-Cabau, Quebec Heart and Lung Institute, Laval University, 2725 Chemin Ste-Foy, G1V 4G5 Quebec City, Quebec, Canada. E-mail: josep.rodes@criucpq.ulaval.ca.

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Key Words: coronary obstruction ■ coronary occlusion ■ percutaneous aortic valve replacement ■ percutaneous coronary intervention ■ transcatheter aortic valve implantation.

APPENDIX

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