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Intravascular ultrasound assessment of coronary ostia following valve-in-valve transcatheter aortic valve implantation

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Introduction

The "chimney" and "BASILICA" techniques[1,2] were developed to offer safe prevention of coronary artery occlusion (CAO) in case of valve-in-valve transcatheter aortic valve implantation (VIV-TAVI) in degenerated surgical bioprostheses. However, sometimes these lead to unnecessary stenting or may simply not be performed because of unfavourable anatomy. Moreover, when they are not implemented, a reassuring coronary angiogram after valve implantation may hide the risk of delayed CAO, which could occur after the removal of protective wires from coronaries[3].

This study aimed to evaluate the feasibility and usefulness of intravascular ultrasound (IVUS) analysis of the coronary ostia to predict and prevent CAO after VIV-TAVI.

Methods

This prospective observational analysis included 50 patients undergoing VIV-TAVI in degenerated surgical bioprostheses, at the Verona University Hospital, from July 2011 to December 2019. This series is a part of the Verona Valve Registry approved by the local Institutional Review Board.

Except for the first three cases (before 2015), the remaining 47 underwent a meticulous protocol for the risk assessment of CAO[4], taking into consideration the presence of the risk factors shown in **Figure 1**.

Patients presenting ≥2 risk factors were considered at high risk of CAO and underwent coronary protection during the procedure, initially through upfront intracoronary guidewires with eventual bail-out "chimney/snorkelling technique" in case of sudden CAO[2]. From 2019, the bioprosthetic or native aortic scallop intentional laceration to prevent iatrogenic coronary artery obstruction (BASILICA) technique was introduced as an alternative in anatomically suitable cases.

The occurrence of CAO following removal of the protective wire from the left main led the team to consider a new strategy for the assessment of the true risk of CAO despite reassuring coronary angiograms after VIV-TAVI. Thus, IVUS assessment of coronary

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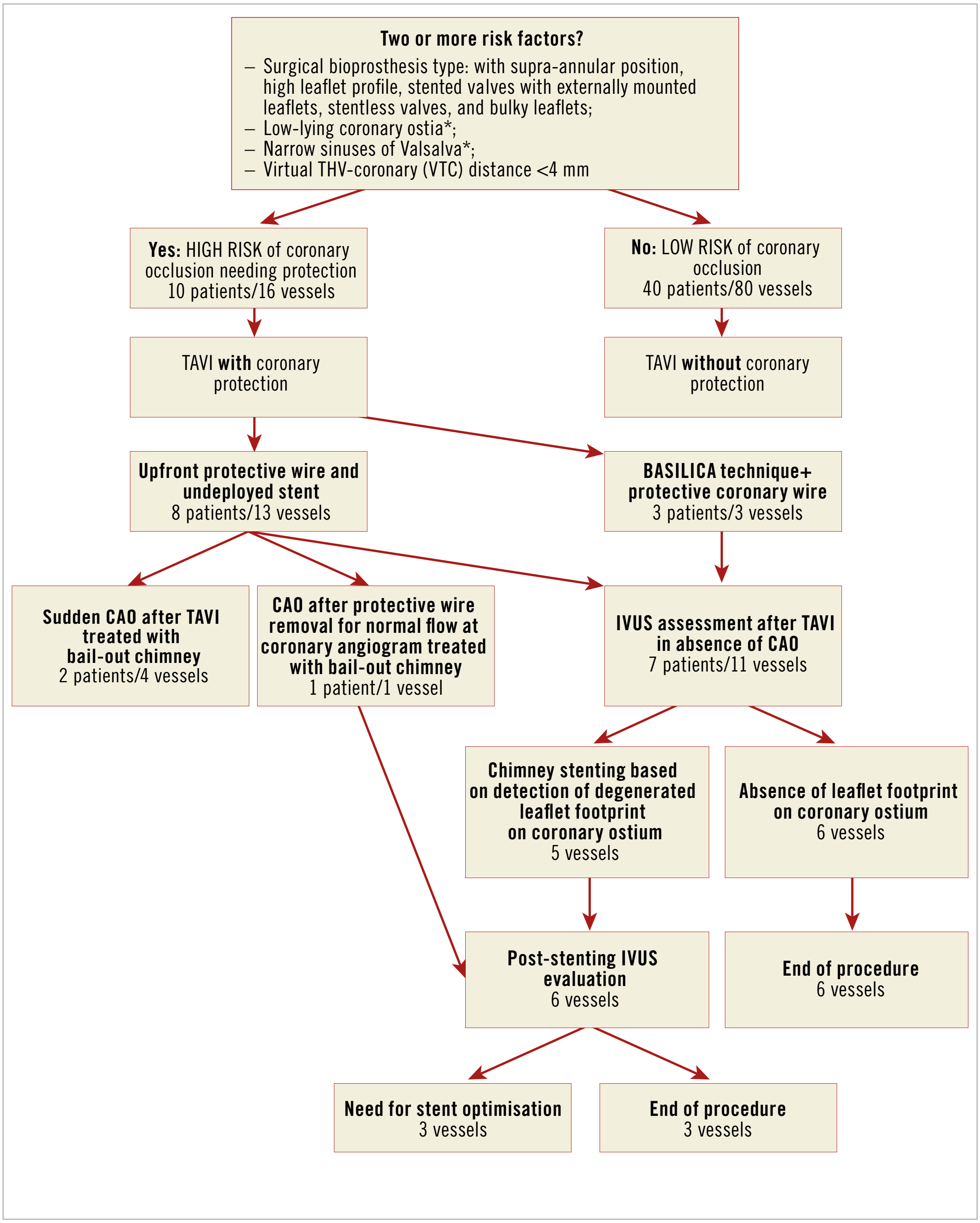

Figure 1. *Management of VIV-TAVI in patients at high risk for CAO, according to the proposed IVUS-guided strategy. *suggested values are: <9 mm from the ostia to the sewing ring and <30 mm by width for Valsalva sinuses. CAO: coronary artery obstruction*

ostia at high risk of CAO following VIV-TAVI was systematically implemented. We hypothesised that IVUS could unmask possible CAO markers, not detectable by angiography (either selective or unselective) and potentially leading to acute or delayed CAO.

In brief, the IVUS strategy consists of the following steps:

– careful IVUS analysis taking into consideration the ostium, its relationship with the degenerated leaflet and any potential interaction with the transcatheter heart valve (THV) frame at the para-ostial space;
– in cases of partial obstruction, IVUS shows the degenerated leaflet footprint on the coronary ostia, considered a marker of an unsafe relationship between them (otherwise undetected by angiography). These findings, suggestive for high risk of acute or delayed complete obstruction, lead to stent implantation

using the elective chimney/snorkel technique **(Supplementary Figure 1, Moving image 1)**;
- conversely, the detection of fully patent ostia, without signs of leaflet footprint, supports the safe removal of the coronary wire, avoiding stent implantation **(Supplementary Figure 2, Moving image 2)**;
- in case of stenting, a further IVUS evaluation is recommended to verify the patency and the correct stent apposition.

Results

Baseline characteristics of the 50 VIV-TAVI cases are available in **Supplementary Table 1**.

Ten patients (16 coronaries), out of the 47 evaluated according to our protocol, were considered at high risk for CAO and therefore underwent coronary protection **(Supplementary Table 2)**. Acute CAO occurred in the first two patients protected with upfront intracoronary wires and undeployed stents, who were successfully treated by bail-out chimney. The third patient presented CAO, but only after the wire removal from the left main, following a misleading coronary angiogram showing a preserved flow after VIV-TAVI **(Supplementary Figure 3)**.

Since then, in the absence of sudden CAO, IVUS was introduced as the primary strategy to assess the actual coronary patency before the wire removal, even after BASILICA (7 patients/11 coronaries) **(Supplementary Table 3)**.

Five out of eleven vessels required stent implantation following IVUS evaluation, based on the presence of the degenerated leaflet footprint on coronary ostia leading to partial obstruction or on an unsatisfactory result of the cusp laceration following BASILICA. Conversely, IVUS allowed avoiding stenting in the remaining six vessels, due to the absence of markers suggestive of CAO.

Of note, none of these cases systematically approached with the IVUS strategy presented either haemodynamic impairment or signs of CAO during the procedure and the hospital stay.

The median hospital stay was 7 days (range 2-27). At the last available follow-up (range 6-108 months), neither myocardial infarction nor cardiac death was reported in any of the patients.

Discussion

To date, chimney/BASILICA techniques represent the only available strategies to prevent or manage CAO. Although studies reported low rates of stent complications after chimney[2], the implantation of stents may render subsequent coronary re-catheterisations difficult. Even relying on wires left in place after VIV-TAVI to assess vessel patency may be misleading, with unexpected CAO and haemodynamic instability occurring after wire removal. Moreover, such complications may happen with a delayed onset, in particular in patients treated with self-expanding devices because of their tendency to expand further after implantation, therefore making a partial obstruction more likely to evolve into a complete CAO hours after the procedure.

Conversely, BASILICA, by avoiding stents, is less prone to complications, including difficulties in re-engaging coronary ostia. However, in some cases, BASILICA may not completely prevent CAO, due to the persistence of partial obstruction by a portion of the lacerated leaflet[5], or because of the unfavourable anatomic relationship between the coronary ostium and the surgical valve commissures, making the laceration useless. Taking into consideration the limitations of these techniques, complementary strategies may be useful to ensure vessel patency better, to avoid unnecessary stenting, or to assess the effectiveness of BASILICA.

In the present report, IVUS showed signs of partial obstruction, not detected by the standard angiogram, in 5 out of 11 evaluated coronary arteries.

Of note, none of the six cases where the IVUS assessment excluded the need for stents suffered acute or delayed CAO, supporting the rationale of this technique.

The overall CAO rate in our series was higher compared to the VIVID registry (6% vs 3.5%)[4]. However, these data are closely related to the type of surgical bioprosthesis. Indeed, the VIVID registry reported a CAO rate of 30% among stentless prostheses, and up to 50% for the Freedom SOLO valves (Sorin Group Inc., Milan, Italy) which were the valves represented most in our series.

Based on these preliminary observational data, we propose the implementation of an "IVUS-assisted decision-making algorithm" in VIV-TAVI procedures **(Figure 1)**, with the following goals:
- to guide the operators in assessing the need for possible stenting following VIV-TAVI;
- to support operators in avoiding unnecessary stenting;
- to expand the safety of BASILICA in difficult anatomies and presence of ambiguous angiographic imaging.

Limitations

Although the present report focuses mainly on the feasibility of this novel strategy, the definition of its efficacy and safety warrants further and larger studies, as well as the identification of a potential quantitative IVUS threshold to guide the operator's decision better. Moreover, IVUS assessment after the valve implantation was performed with the wire into the coronary, that could keep the cusp of the surgical valve away from the coronary ostia.

Conclusion

IVUS assessment of coronary ostia after VIV-TAVI is proposed to detect potential markers of CAO. If validated in dedicated studies, this strategy could be implemented as a complementary tool in the algorithm for CAO prevention in TAVI.

Impact on daily practice

The present study describes an IVUS-guided technique for the assessment of the coronary patency after VIV-TAVI and to support the operator in deciding whether to stent or, conversely, to avoid unnecessary stenting.

Conflict of interest statement

The authors have no conflicts of interest to declare.

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Supplementary data

Supplementary Figure 1. IVUS assessment of coronary ostia after VIV-TAVI.

Supplementary Figure 2. Case example of IVUS confirmation of patent coronary ostium after VIV-TAVI.

Supplementary Figure 3. Case example of CAO despite normal coronary angiogram after non-IVUS-guided VIV-TAVI.

Supplementary Table 1. Demographic characteristics of VIV patients.

Supplementary Table 2. Detailed risk factors of coronary occlusion in patients presenting a high risk for CAO.

Supplementary Table 3. Coronary protection strategies adopted for each high-risk patient.

Moving image 1. Approach to the case reported in Supplementary Figure 1.

Moving image 2. Approach to the case reported in Supplementary Figure 2.

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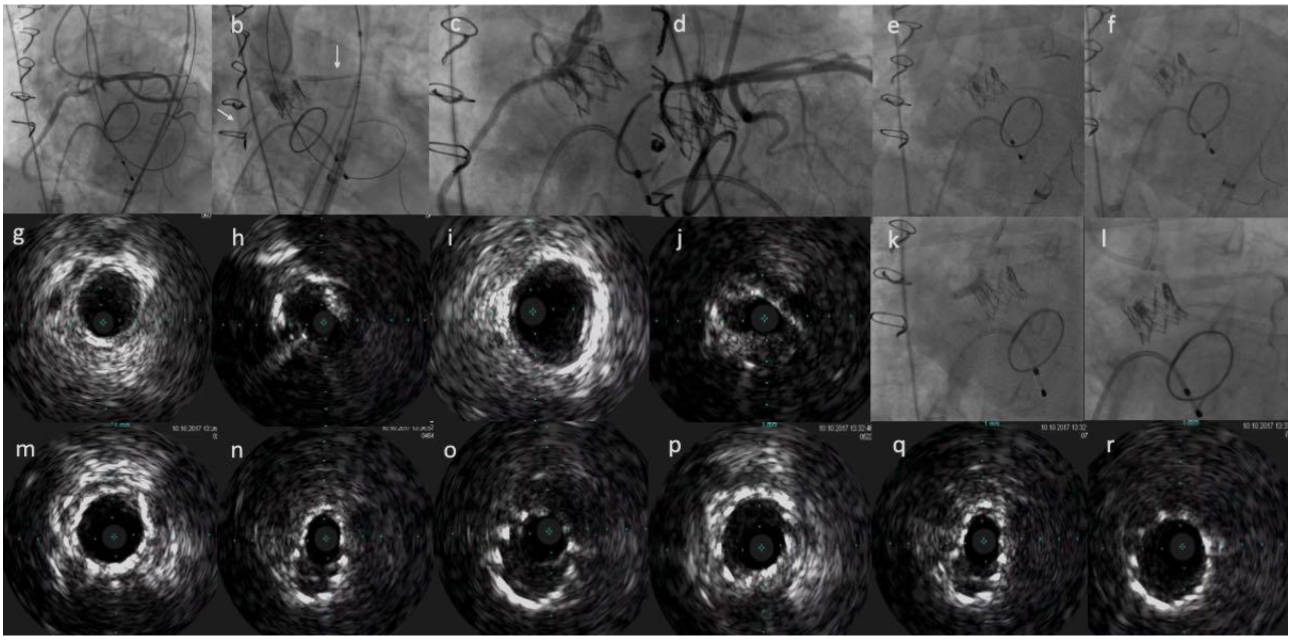
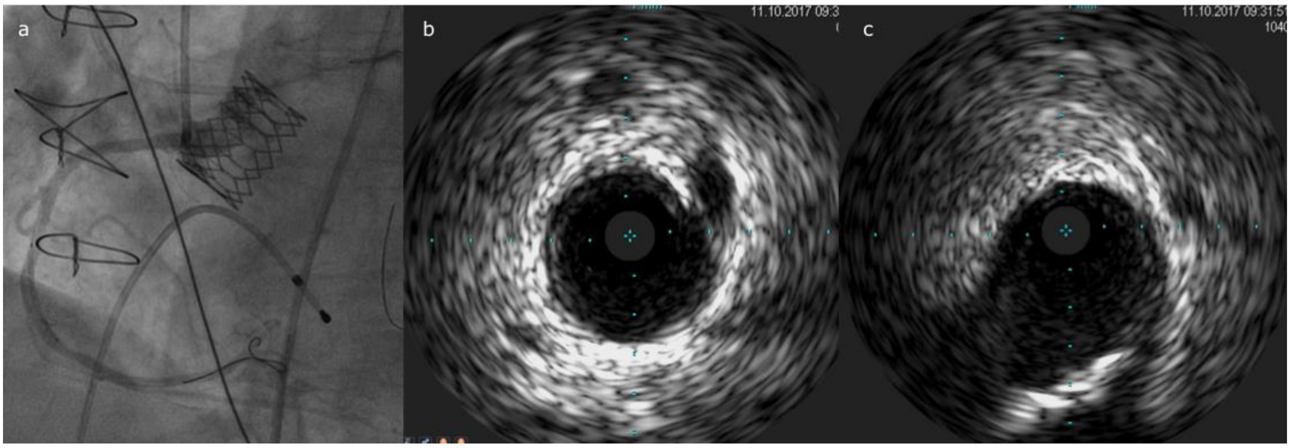
Supplementary data



Supplementary Figure 1. IVUS assessment of coronary ostia after VIV-TAVI.
a) Simultaneous opacification of the right and left coronary arteries showing the low origin of the two ostia.
b) Expanded SAPIEN XT 20 mm valve (Edwards Lifesciences, Irvine, CA, USA), guidewires and undeployed stents in the right and left coronary arteries (arrows).
c) Right coronary angiography showing normal flow.
d) Left coronary angiography showing normal flow.
e) & f) IVUS catheter in the right and subsequently in the left coronary arteries after removal of the undeployed stents.
g) IVUS images of the proximal segment of the RCA.
h) IVUS at the ostium of the RCA that shows a clear footprint by the surgical valve leaflet.
i) IVUS images of the proximal segment of the left main and its ostium that shows a clear footprint by the surgical valve leaflet (j).
Stenting of the right (k) and left coronary artery (l).
m) IVUS of the RCA at the proximal segment.
n) The ostium compressed by the SAPIEN XT valve metallic struts.
o) The edge protruding into the aorta.
p) IVUS images of the left main at the shaft.
q) The ostium compressed by the SAPIEN XT valve metallic struts.
r) The edge protruding into the aorta.

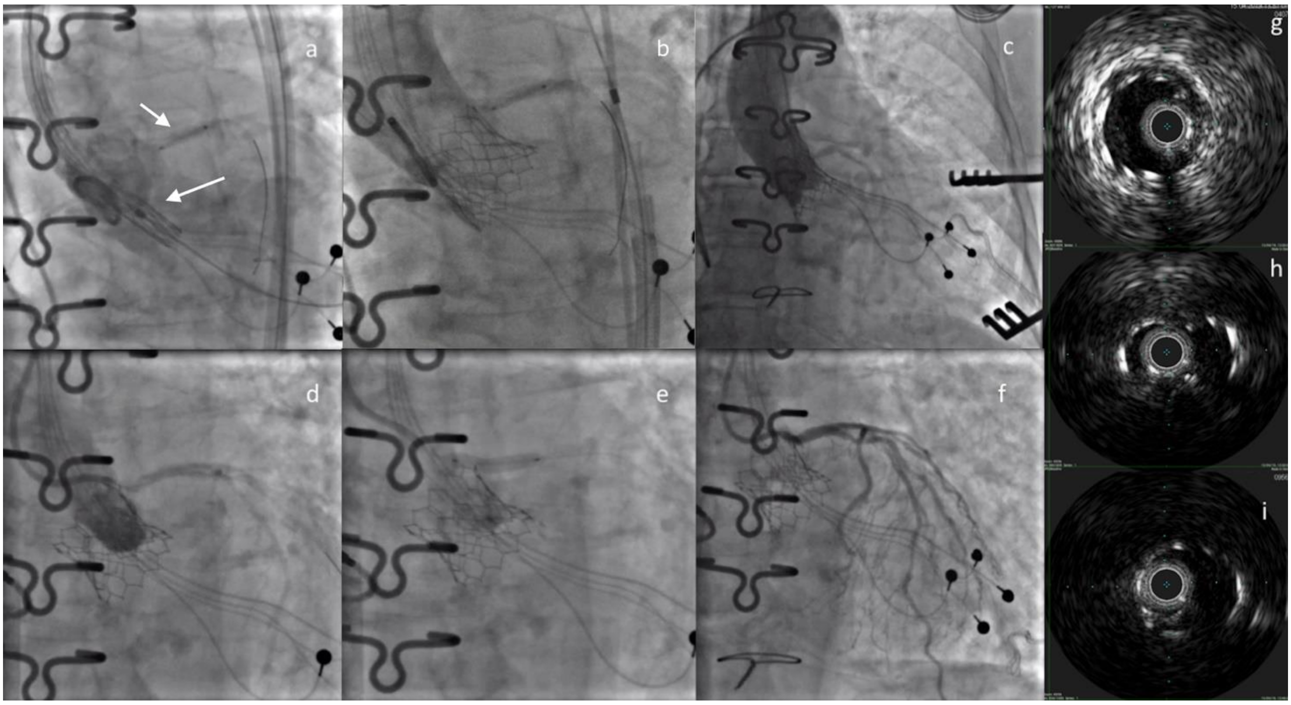


Supplementary Figure 2. Case example of IVUS confirmation of patent coronary ostium after VIV-TAVI.

a) Unselective right coronary angiography, showing normal coronary flow.

b) IVUS image of proximal segment of right coronary showing full vessel patency.

c) IVUS image of right coronary ostium without signs of degenerated leaflet footprint on it, suggesting safe removal of the protective wire and avoidance of stent implantation.



Supplementary Figure 3. Case example of CAO despite normal coronary angiogram after non-IVUS-guided VIV-TAVI**.**

In this patient, not assessed by IVUS after valve implantation, left coronary occlusion and shock occurred after wire retrieval despite an apparently normal flow at the angiogram and haemodynamic stability following the successful valve implantation (Edwards S3, 23 mm). Immediate left main recanalisation after re-wiring allowed flow restoration and haemodynamic recovery after emergency stenting.

a) The undeployed balloon-expandable aortic valve and one undeployed stent in the left coronary artery (arrows).

b) After deployment of the valve, the left coronary artery is patent and haemodynamics are stable but with the wire and the undeployed stent still in place.

c) Left coronary occlusion and sudden shock after the retrieval of the wire and the stent managed by the emergency percutaneous implantation of an extracorporeal membrane oxygenator.

d) Re-wiring of the left coronary artery.

e) Emergency stent implantation in the left coronary ostium.

f) Final angiographic image with normal patency of the left coronary system and rapid haemodynamic recovery.

g) IVUS images of the stent in the left main shaft.

h) The ostium compressed at the level of the aortic valve metallic frames.

i) Protrusion into the coronary sinus.

Supplementary Table 1. Demographic characteristics of VIV patients.

Clinical characteristics	**VIV patients (50)**
Age, years	78 [6]
Logistic EuroSCORE, %	25.3±8.7
EuroSCORE II, %	10 [3]
STS score, %	4 [3]
Male, n (%)	25 (50%)
BMI, kg/m^2	26.6±6.5
GFR <30 mL/min, n (%)	36 (72%)
Anaemia*, n (%)	30 (60%)
Dyslipidaemia, n (%)	28 (56%)
COPD, n (%)	6 (12%)
Diabetes, n (%)	13 (26%)
Hypertension, n (%)	38 (50%)
Previous AMI, n (%)	5 (10%)
Atrial fibrillation, n (%)	23 (46%)
Previous stroke, n (%)	6 (12%)
PVD, n (%)	16 (32%)
CAD, n (%)	33 (66%)
Previous CABG, n (%)	17 (34%)
NYHA Class III or IV, n (%)	50 (100%)
Pure aortic valve stenosis, n (%)	15 (30%)
Pure aortic valve insufficiency, n (%)	14 (28%)
Mixed steno-insufficient valve, n (%)	21 (42%)
Valve type	
Stented with leaflets mounted internally	
Medtronic Hancock, n (%)	18 (36%)
Edwards Perimount, n (%)	10 (20%)
SJM Biocor, n (%)	1 (2%)
Stented with leaflets mounted externally	
SJM Trifecta, n (%)	1 (2%)
Sorin Mitroflow, n (%)	4 (8%)
Stentless	
SJM Toronto, n (%)	2 (4%)
Sorin Pericarbon Freedom, n (%)	3 (6%)
Sorin Freedom SOLO, n (%)	7 (14%)
Bravo 400 stentless xenograft, n (%)	2 (4%)
Edwards Prima Plus, n (%)	2 (4%)

Categorical data are presented as numbers and percentages; continuous data are presented as means±standard deviations for normally distributed variables and as median (interquartile range) otherwise.

*Anaemia: <13 g/dL for males, <12 g/dL for females.

AMI: acute myocardial infarction; BMI: body mass index; CABG: coronary artery bypass graft; CAD: coronary artery disease; COPD: chronic obstructive pulmonary disease; GFR: glomerular filtration rate; NYHA: New York Heart Association; PVD: peripheral vascular disease; STS: Society of Thoracic Surgeons

Supplementary Table 2. Detailed risk factors of coronary occlusion in patients presenting high risk for CAO.

Patient n.	Low-lying coronary ostia: LM/RCA	Narrow Valsalva sinuses	VTC <4 mm: LM/RCA	Unfavourable surgical prosthesis*	LM occlusion risk	RCA occlusion risk
1	+/+	+	- / -	+	+	+
2	+/ -	-	+/-	+	+	-
3	+/+	+	-/-	+	+	+
4	+/+	+	+/+	+	+	+
5	+/+	+	+/+	+	+	+
6	+/+	+	- / -	+	+	+
7	+/ -	-	+/ -	+	+	-
8	+/ -	-	- / -	+	+	-
9	+/ -	-	+/ -	+	+	-
10	+/+	+	- /+	+	+	+

LM: left main; RCA: right coronary artery; VTC: virtual transcatheter valve to coronary
* stentless or stented valve with externally mounted leaflets.
+ presence of the risk factor.
- absence of the risk factor.

Supplementary Table 3. Coronary protection strategies adopted for each high-risk patient.

Patient n.	Coronary	Protection wire + undeployed stent	IVUS assessment	BASILICA	Other strategies	Stent number
1	LM	+	-	-	Bail-out chimney for CA after VIV	1
	RCA	+	-	-	Bail-out chimney for CA after VIV	1
2	LM	+	-	-	Bail-out chimney for CA after VIV	2
	RCA	+	-	-	Bail-out chimney for CA after VIV	1
3	LM	+	-	-	Bail-out chimney for CA **after wire removal**	1
	RCA	-	-	-	-	0
4	LM	+	+	-	-	1
	RCA	+	+	-	-	1
5	LM	+	+	-	-	1
	RCA	+	+	-	-	0
6	LM	+	+	-	-	0
	RCA	+	+	-	-	0
7	LM	+	+	-	-	0
	RCA	-	-	-	-	0
8	LM	-	+	+	-	0
	RCA	-	-	-	-	0
9	LM	-	+	+	-	1
	RCA	-	-	-	-	0
10	LM	-	+	+	-	0
	RCA	+	+	-	-	1

CA: cardiac arrest; LM: left main; RCA: right coronary artery

Moving image 1. Approach to the case reported in Supplementary Figure 1.

A) IVUS pullback from LAD to LM and aorta. At the end of the run, the occlusion of the LM is evident.

B) IVUS pullback from LAD to LM and aorta after stenting. Note the good expansion in the distal third of the stent, the compressed (elliptic) shape of the stent at the level of the ostium, and the round shape of the proximal segment of the stent protruding into the aorta.

Moving image 2. Approach to the case reported in Supplementary Figure 2.

IVUS evaluation after transcatheter valve deployment, showing fully patent right coronary artery ostia. Note the absence of signs of the surgical degenerated leaflet at the ostium.