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Optimized Screening of Coronary Artery Disease With Invasive Coronary Angiography and Ad Hoc Percutaneous Coronary Intervention During Transcatheter Aortic Valve Replacement

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***Background*—**We sought to describe an optimized approach to coronary artery disease (CAD) screening and management in patients undergoing transcatheter aortic valve replacement (TAVR).

***Methods and Results*—**When invasive coronary angiography showed CAD, the treatment strategy and completeness of revascularization was determined based on coronary anatomy. TAVR was performed in the same setting if percutaneous coronary intervention (PCI) was uncomplicated; otherwise TAVR was postponed. A total of 604 patients undergoing CAD screening at the time of TAVR procedure were prospectively included in this study. Severe CAD was found in 136 patients (22.5%). Among patients with severe CAD, 53 patients (8.8%) underwent uncomplicated PCI. After PCI, TAVR was postponed in 2 patients (0.3%). In 83 patients (13.8%), coronary angiography showed severe CAD that was left untreated. After TAVR, all-cause and cardiovascular 30-day mortality rates were 2.4% and 1.4%, respectively. Disabling stroke, myocardial infarction, and life-threatening bleeding occurred in 0.5%, 0.8%, and 4.0% of patients, respectively. Acute kidney injury II or III rate was 3.3%. At 2 years, all-cause mortality rate was 14.1%. Disabling stroke and myocardial infarction occurred in 2.5% and 1.8% of patients, respectively. Patients undergoing TAVR and PCI in the same session had similar rate of the composite of death, disabling stroke, and myocardial infarction when compared with patients without CAD, and patients with severe CAD left untreated (TAVR+PCI: 10.4%; severe CAD left untreated: 15.4%; no-CAD: 14.8%; *P*=0.765).

***Conclusions*—**In patients undergoing TAVR, screening of CAD with invasive coronary angiography and ad hoc PCI during TAVR is feasible and was not associated with increased periprocedural risks. PCI followed by TAVR in the same session had similar outcomes than TAVR in which PCI was not performed. **(*Circ Cardiovasc Interv*. 2017;10:e005234. DOI: 10.1161/CIRCINTERVENTIONS.117.005234.)**

Key Words: acute kidney injury ■ aortic valve stenosis ■ coronary angiography ■ coronary artery disease ■ myocardial infarction ■ stroke

Coronary artery imaging is always recommended for patients undergoing transcatheter aortic valve replacement (TAVR).[1] Screening of coronary artery disease (CAD) is an important component of the work-up because it may provide information that will influence the conduct of the planned procedure and offer a more accurate risk assessment of patients undergoing TAVR. Invasive coronary angiography (CA) is the gold standard for the screening of coronary anatomy.[2] In the context of TAVR work-up, this is generally performed as a separate procedure within a variable range from a few days up to a month or more before TAVR, according to each center's policy and waiting list.[1]

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In the last years, the extension of TAVR to younger and lower-risk patients is testing the capabilities of TAVR centers to treat a greater number of patients.[3,4] This is the background for the growing interest in a more efficient system for patient assessment.[5–7] Chieffo et al[8] described an original approach,

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From the Division of Cardiology, Ferrarotto Hospital, University of Catania, Italy (M.B., D.T., G.C., G.P., A.P., S.G., P.C., K.L.S., E.D.S., P.D., W.D., A.I., S.C., D.G., S.I., C.T., M.P., S.B., D.C., C.S., C.T.); and ETNA Foundation, Catania, Italy (C.T.).

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Correspondence to Marco Barbanti, MD, Division of Cardiology, Ferrarotto Hospital, University of Catania, Via Citelli 6, 95124 Catania, Italy. E-mail mbarbanti83@gmail.com

WHAT IS KNOWN

- Screening of coronary artery disease is an important component of the work-up in patients undergoing transcatheter aortic valve replacement (TAVR).
- This is generally performed as a separate procedure before TAVR.
- In the last years, the extension of TAVR to younger and lower-risk patients is testing the capabilities of TAVR centers to treat a greater number of patients.

WHAT THE STUDY ADDS

- We described a minimalistic and optimized approach to coronary artery disease screening and management in patients undergoing TAVR.
- Screening of coronary artery disease with invasive coronary angiography and ad hoc percutaneous coronary intervention during TAVR is feasible and was not associated with increased periprocedural risks.
- Percutaneous coronary intervention followed by TAVR in the same session had similar outcomes than TAVR in which percutaneous coronary intervention was not performed.

which foresaw the integration of CAD screening during cardiac computed tomography (CT) for aortic root assessment, reserving invasive CA for patients in whom CT is contraindicated, or when a significant proximal coronary artery lesion is detected at CT CA. However, this approach carries some limitations, and CA was required anyhow in almost 30% of patients.[8]

In this study, we describe a minimalistic and optimized approach to CAD screening and management in patients undergoing TAVR, which foresees performing an invasive CA and ad hoc percutaneous coronary intervention (PCI) at the time of TAVR procedure.

Methods

Study Design and Patients Population

From January 2013, all consecutive patients referred to our Institution and deemed clinically eligible for TAVR by the local Heart Team were potentially considered for this study. Patients who underwent CA within 6 months in our or other hospitals (before indication for TAVR was given) not requiring further CAD assessment by CA were excluded from the present analysis. The preoperative patient-screening flowchart for CAD applied in our center is depicted in Figure 1.

All subjects provided written informed consent before the procedure. The study was conducted according to the principles of the Declaration of Helsinki and Good Clinical Practice. The authors vouch for the integrity of and completeness of the data and analyses.

Screening studies were performed in all patients before the procedure. Sizing of the transcatheter heart valve (THV) was performed by using multidetector CT and an integration of echocardiography (transthoracic transesophageal and transesophageal), angiography, and simultaneous aortography during balloon valvuloplasty, when CT was not available.[9] All patients with severe renal function impairment (estimated Glomerular Filtration Rate <30 mL/min) were pretreated with the RenalGuard system (PLC Medical Systems, Milford, MA).[10]

Procedure and Definitions

TAVR procedures were performed in a standard catheterization laboratory through the transfemoral or alternative approaches (transaxillary or transapical) using the following Conformité Européene-mark approved THVs: Sapien XT and Sapien 3 (Edwards Lifesciences, Irvine, CA), CoreValve and Evolut R (Medtronic Inc, Minneapolis, MN), Acurate neo (Symetis SA, Ecublens, Switzerland), and Portico (St. Jude Medical, Minneapolis, MN).

The catheterization laboratory was initially equipped only for CA. This was performed using the radial or the femoral artery, according to the operator's preference. When the femoral artery was cannulated, this one was contralateral to the common femoral artery eventually selected for large-bore sheath insertion. Typically, 3 views (40° cranial, 30°caudal-30°right, and 50°left-50°caudal) of the left coronary and 1 view (30°cranial-30°right) of the right coronary arteries were obtained with a hand injection technique. Additional views were obtained in case better coronary anatomy or lesions assessment was required. CAD was defined as ≥1 stenosis of ≥70% in a major epicardial artery (≥50% if left main stem or vein graft) found at invasive CA. When no CAD was found, the catheterization laboratory was then equipped for TAVR and the procedure was performed in a standard fashion.

In case of CAD, the treatment strategy and completeness of revascularization was determined based on coronary anatomy: when indication for TAVR was confirmed, severe coronary lesions subtending a large area of myocardium (stenoses of >50% in the left main and stenoses of >70% in the proximal epicardial arteries or large branches) were treated with PCI. Chronic total occlusions, very distal lesions, and coronary stenoses on small vessels (<2.5 mm) were left untreated.

After PCI, operators proceeded with TAVR if all the following criteria were met: (1) PCI was successful and uncomplicated; (2) contrast dye administration was <80 mL (50 mL in case of estimated Glomerular Filtration Rate <60 mL/min); and (3) patient was hemodynamically stable. When at least one of the abovementioned criteria was not met, TAVR was postponed 1 month after PCI.

Before the procedure, patients were treated with 100 mg acetylsalicylic acid and a 600 mg loading dose of Clopidogrel. At discharge, antithrombotic regimen followed that recommended by the most recent European guidelines and consensus documents.[11]

Standardized definitions were used in accordance with the Valve Academic Research Consortium-2 consensus.[12]

Statistical Analysis

Continuous variables are reported as mean and SD, while dichotomous parameters as frequencies and percentages (%). The normal distribution of continuous parameters was tested with the Kolgomorov–Smirnov test. Time to midterm outcomes was described by means of the Kaplan–Meier curve. All data were processed using the Statistical Package for Social Sciences (SPSS), version 20 (IBM, Armonk, NY).

Results

Patient Population

From January 2013 to January 2017, a total of 675 patients underwent TAVR in our Institution. Among them, 604 patients undergoing CAD screening at the time of TAVR procedure were included in this study (Figure 2). Baseline demographic, clinical, and echocardiographic characteristics are presented in Table 1. Median age was 82.0 years (interquartile range, 76–88). The Society of Thoracic Surgery mortality risk score was 4.6±3.2%. All patients had severe symptomatic aortic stenosis (mean transaortic pressure gradient, 47.1±15.0 mm Hg; mean aortic valve area, 0.6±0.4 cm^2). The majority of patients (n=456; 75.5%) were in New York Heart Association functional class 3 or 4 before the procedure. Canadian Society Class 3 or 4 angina was reported in 82 patients (13.6%).

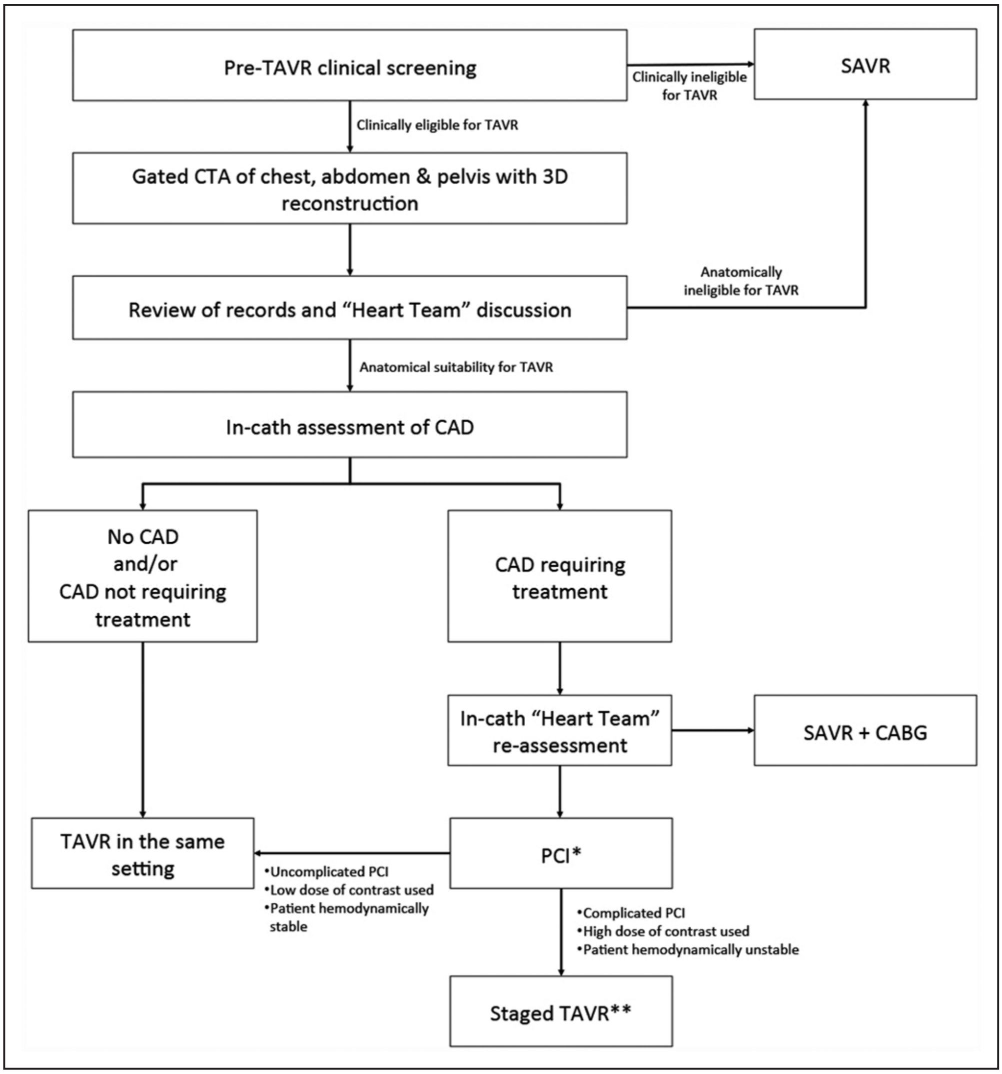

Figure 1. Descriptive algorithm of coronary artery disease (CAD) screening in patients candidate to transcatheter aortic valve implantation (TAVR). *Percutaneous coronary intervention (PCI) strategy is left to operator discretion. **TAVR is postponed of at least 2 wk. CABG indicates coronary artery bypass graft; CTA, computed tomography angiography; and SAVR, surgical aortic valve replacement.

Coronary Artery Screening and PCI Outcomes

The vast majority of patients underwent the CA through the femoral artery (n=600, 99.3%).

No evidence of CAD was encountered in 468 patients (77.5%). CAD of at least 1 main epicardial vessel was found in 136 patients (22.5%). Heart Team reassessment was required in 19 patients (13.9% of CAD group); all of these patients were <80 years old. One patient was eventually switched to surgery for combined aortic valve replacement and coronary bypass. Among patients with severe CAD, 53 patients (8.8% of the overall population) underwent uncomplicated PCI to ≥1 coronary lesions. Table 2 reports details of CAD extension and distribution. Anatomic complete revascularization was achieved in 64.7% of cases. In 7 patients (13.2%), PCI was performed in 2 separate lesions; only 1 patient (1.9%) underwent PCI on 3 separate vessels. A total of 68 stents on 61 lesions were deployed. In the majority of cases, PCI was performed using drug-eluting stents (n=65, 95.6%). Stent deployment was preceded by balloon dilatation in all cases. Cutting balloon was required in 3 cases to prepare moderately calcified lesions. Rotational atherectomy was used in no patient. No PCI-related complications were reported. After PCI, TAVR was postponed of 1 month in only 2 patients (0.3%) because of the large amount of contrast dye administered during PCI.

Overall, in 83 patients (13.8%), CA showed severe CAD that was left untreated. The reasons for not proceeding with PCI in such cases were (1) distal coronary stenoses or stenoses on small vessels (n=41, 49.4%), (2) chronic total occlusions (n=26, 31.3%), (3) very high calcium burden (n=10, 12.0%), and (4) lesions subtending necrotic area (n=6, 7.2%).

TAVR Outcomes

Procedural characteristics are illustrated in Table 3. Among patients undergoing CAD screening in the same setting of TAVR, the transfemoral approach (n=583, 98.1%) was the most frequently used access for THV deployment, followed by the transapical (n=9, 1.5%), transaortic (n=2, 0.3%), and transaxillary (n=1, 0.2%). The vast majority of the procedures (95.6%) were accomplished by using the SAPIEN XT/SAPIEN 3 (Edwards Lifesciences, Irvine, CA) and the CoreValve/Evolut R

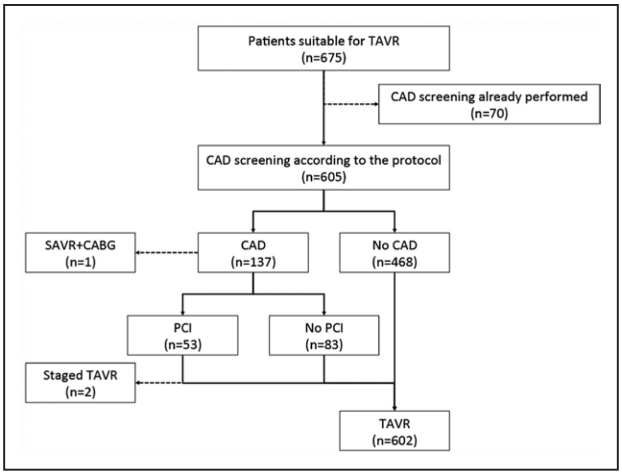

Figure 2. Descriptive flow chart of population groups in our study. CABG indicates coronary artery bypass graft; CAD, coronary artery disease; PCI, percutaneous coronary intervention; SAVR, surgical aortic valve replacement; and TAVR, transcatheter aortic valve replacement.

prostheses (Medtronic Inc, Minneapolis, MN; Table 3). Device success was achieved in 91.2% of cases. The procedure was aborted before THV deployment because of reasons not related with PCI in 3 cases (0.5%). Implantation of 2 THVs was required in 3.7% of cases. One case of right coronary occlusion occurred after CoreValve deployment; this case was effectively treated with bailout stent implantation at the ostium of the right coronary artery. No cases of aortic rupture were reported.

Table 1. Baseline Characteristics

	Overall (n=602)
Clinical variables	
Age, y	81.1±5.2; 82 (79–84)
Female sex, n (%)	347 (57.6)
Diabetes mellitus, n (%)	185 (30.7)
Hypertension, n (%)	519 (86.2)
Permanent AF, n (%)	88 (14.6)
Previous MI, n (%)	69 (11.5)
Previous stroke, n (%)	27 (4.5)
Previous TIA, n (%)	24 (4.0)
Previous CHF, n (%)	192 (31.9)
PVD, n (%)	61 (10.1)
Previous CABG, n (%)	43 (7.1)
COPD, n (%)	136 (22.6)
CRF*	396 (65.8)
Previous PPM, n (%)	61 (10.2)
NYHA III/IV, n (%)	455 (76.6)
STS Score, %	4.7±3.2; 4.3 (3.1–6.5)
Echocardiographic variables	
LVEF, %	53.7±11.3; 57 (48–60)
Mean aortic gradient, mm Hg	48.3±15.0; 46 (40–56)

AF indicates atrial fibrillation; CABG, coronary artery bypass graft; CHF, congestive heart failure; COPD, chronic obstructive pulmonary disease; CRF, chronic renal failure; LVEF, left ventricle ejection fraction; MI, myocardial infarction; NYHA, New York Heart Association; PPM, permanent pacemaker; PVD, peripheral vascular disease; STS, Society of Thoracic Surgery; and TIA, transient ischemic attack.

*Defined as GFR <60 mL/min.

Table 2. Coronary Angiography Findings and PCI Details

	PCI Group (n=51)
CAD distribution	
LM, n (%)	6 (11.8)
LAD, n (%)	22 (44.0)
LCx, n (%)	10 (19.6)
Diagonal branch, n (%)	5 (9.8)
Marginal branch, n (%)	5 (9.8)
RCA, n (%)	25 (49.0)
LIMA, n (%)	1 (1.9)
RIMA, n (%)	0 (0.0)
SVG, n (%)	1 (1.9)
Chronic total occlusion, n (%)	4 (7.8)
PCI variables	
LM, n (%)	5 (9.8)
LAD, n (%)	20 (39.2)
LCx, n (%)	6 (11.8)
Diagonal branch, n (%)	2 (3.9)
Marginal branch, n (%)	3 (5.9)
RCA, n (%)	24 (47.1)
LIMA, n (%)	0 (0.0)
RIMA, n (%)	0 (0.0)
SVG, n (%)	1 (1.9)
Complete revascularization, n (%)	33 (64.7)

Percentages refer to the number of patients treated with PCI (n=51). CAD indicates coronary artery disease; LAD, left anterior descendent; LCx, left circumflex; LIMA, left internal mammary artery; LM, left main; PCI, percutaneous coronary intervention; RCA, right coronary artery; RIMA, right internal mammary artery; and SVG, saphenous vein graft.

In-hospital outcomes are listed in Table 4. All-cause and cardiovascular 30-day mortality rates were 2.4% and 1.4%, respectively. Disabling stroke and myocardial infarction occurred in 3 (0.5%) and 5 (0.8%) patients, respectively. Life-threatening, major, and minor bleeding occurred in 4.0%, 17.9%, and 4.8% of patients, respectively. Major vascular complications occurred in 5.5% of cases. The rate of pacemaker implantation was 10.0%. Acute kidney injury III rate was 3.3%. After TAVR, 1 patient with small left ventricular cavity and severe septum hypertrophy developed systolic anterior movement of the anterior mitral leaflet causing severe dynamic left ventricle outflow tract obstruction and concomitant severe mitral regurgitation. This complication was effectively resolved by implanting a MitraClip (Abbott Vascular, Abbott Park, IL).

At discharge, more than mild paravalvular regurgitation was observed in 5.8% of cases.

Table 3. Transcatheter Aortic Valve Implantation Procedural Variables

	Overall (n=602)
Approach	
Transfemoral, n (%)	591 (98.2)
Transapical, n (%)	9 (1.5)
Transaortic, n (%)	2 (0.3)
THV type	27 (4.5)
SAPIEN XT, n (%)	66 (11.0)
SAPIEN 3, n (%)	126 (20.9)
CoreValve, n (%)	163 (27.1)
Evolut R, n (%)	168 (27.9)
Acurate neo, n (%)	54 (25.8)
Portico, n (%)	12 (2.0)
Lotus, n (%)	3 (0.5)
Device success, n (%)	549 (91.2)
Aborted procedure, n (%)	3 (0.5)
Two THV implanted, n (%)	21 (3.5)
Major vascular complications, n (%)	33 (5.5)
Minor vascular complications, n (%)	51 (8.5)

THV indicates transcatheter heart valve.

Kaplan–Meier curves are depicted in Figure 3. At 2 years, all-cause mortality rate was 12.9%. Disabling stroke and myocardial infarction occurred in 2.5% and 1.8% of patients, respectively. No cases of target lesion and vessel revascularization were reported. The composite end point of all-cause death, disabling stroke, and myocardial infarction occurred in the 14.1% of cases. A sensitivity analysis, including only high-risk patients according to the Society of Thoracic Surgery score (>7%), was also performed (n=190). In-hospital all-cause and cardiovascular death were reported in 3.6% and 1.8% of patients, respectively. Disabling stroke and major vascular complications occurred in 1.1% and 4.7% of cases, respectively.

Comparative outcomes between patients undergoing CAD screening during TAVR (study population) and patients who underwent CAD screening with invasive CA as a separate procedure before TAVR during the same study period are presented in the Tables I through III in the Data Supplement. Comparative outcomes between patients undergoing PCI before TAVR in the same session and patients without severe CAD and with severe CAD left untreated are presented in the Tables IV through VI in the Data Supplement and Figure I in the Data Supplement.

Table 4. In-Hospital Outcomes

	Overall (n=602)
All-cause death, n (%)	14 (2.3)
Cardiovascular death, n (%)	8 (1.3)
Disabling stroke, n (%)	3 (0.5)
Nondisabling stroke, n (%)	1 (0.2)
TIA, n (%)	1 (0.2)
Life-threatening bleeding, n (%)	24 (4.0)
Major bleeding, n (%)	108 (17.9)
PM implantation, n (%)	60 (10.0)
AKI II or III, n (%)	20 (3.3)

AKI indicates acute kidney injury; PM, pacemaker; and TIA, transient ischemic attack.

Discussion

The main findings of this single-center prospective study are the following: (1) CAD screening with invasive CA at the time of TAVR is feasible and was not associated with increased periprocedural risks; (2) in our study population, severe CAD was found in 23% of patients and PCI was performed in same session before THV implantation in 9% of cases; (3) after PCI, TAVR had to be postponed in only 2 cases (0.3%) because of complex PCIs that required large amount of contrast dye administration; (4) the presence of chronic total occlusion was associated with a lower probability to undergo PCI, whereas nonoccluded CAD involving the left anterior descendent or the right coronary artery was more likely to be treated with PCI; and (5) PCI followed by TAVR in the same session had similar outcomes than TAVR in which PCI was not performed.

The reported prevalence of CAD among patients undergoing TAVR ranges from 50% to 75%,[13,14] and reports are mixed about its prognostic implications.[15–19] However, no doubt, identification, and adequate treatment of CAD must be carefully evaluated before the procedure.

Coronary Artery Screening

Today, the majority of centers assess TAVR candidates in the catheterization laboratory by performing an invasive CA, eventually with the addition of PCI when needed, as a separate step before TAVR.[2] Then the patient is usually discussed by the Heart Team and scheduled for TAVR (or surgical aortic valve replacement).

This approach, although it has proved to be very safe, carries 2 limitations: it produces a slowdown of the screening process of TAVR candidates, and it exposes patients to the risk of potential injury to the same vessel intended to be used later during the TAVR procedure.

In this scenario, an optimized and minimalistic approach is then highly desirable.[20] By excluding 1 in-hospital admission for isolate CA, this approach has the potential to improve the cost-effectiveness of a TAVR program and to shorten the assessment time, then reducing the waiting lists of accepted TAVR candidates. Starting from the principle of an optimization of costs and patient care for TAVR candidates, Chieffo et al[8] demonstrated that pre-TAVR coronary artery disease screening can be safely performed through CT CA at the time of cardiac CT scan for aortic root and ilio-femoral arteries assessment. This approach is very interesting, but it must be underlined that the 30% of patients required invasive CA to rule out or confirm severe CAD.

One may argue that performing CAD screening, and eventually PCI, at the time of TAVR could expose the patients to a potential increased risk of contrast nephropathy secondary to the additional dye load during the same procedure. The results of the present analysis tend to support the safety of either simple CA or PCI during TAVR. The rate of acute kidney injury stages 2 and 3 was in line with that reported in many previous series

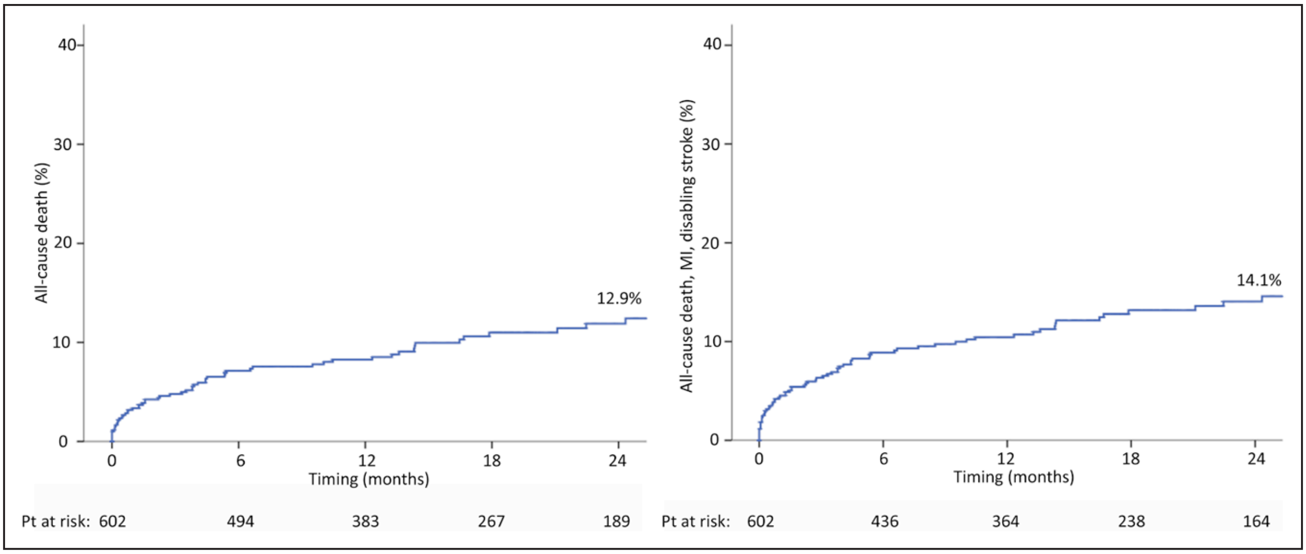

Figure 3. Kaplan–Meier analysis for death and the composite of death, myocardial infarction (MI), and disabling stroke.

and meta-analysis.[21] Similarly, the rates of death and other important periprocedural and midterm complications in our experience compared favorably with these reported in major trials and registries where CAD screening was performed with CA in a separate procedure.[22]

Furthermore, to further increase the safety of this approach, in those situations where PCI was complicated or required large amount of contrast (as specified in the algorithm), TAVR was postponed; in our population, this circumstance occurred only 2×, and TAVR was uneventfully performed in both cases 1 month after PCI.

In our experience, this approach was also logistically sustainable: during the in-cath CAD screening with CA, patient reassessment by the interventional cardiologist and the cardiac surgeon on-call was required in only 19 cases; that mostly happened in younger patients and when patients had left main stenosis or multivessel CAD.

Severe CAD Management

In TAVR candidates with severe CAD requiring revascularization, the PCI can be performed before TAVR or concomitantly as a single-stage procedure with TAVR or be staged after TAVR.[13] All these 3 approaches have been demonstrated to be feasible and safe, and each of them carries potential advantages and drawbacks. However, whether one of these is associated with better outcomes remains unclear because of the lack of studies comparing these different strategies.[13] The results of an additional analysis of this study are in line with those reported by previous small series[23]: in our population, the 51 patients who underwent PCI at same time of TAVR procedure had similar periprocedural outcomes than patients undergoing only TAVR (patients without severe CAD or with severe CAD not requiring revascularization according to the operator's choice). PCI was performed before THV implantation in all cases. No PCI-related complications were described. At midterm follow-up, we did not report in-hospital admissions or complications directly attributable to the PCI performed during TAVR. One single patient who underwent PCI and TAVR in the same session had a myocardial infarction at 6 months; the culprit lesion was a subocclusive stenosis on a proximal left circumflex that was deemed borderline (60%) during the pre-TAVR screening CA. Of note, Griese et al[24] recently showed that concomitant TAVR and PCI were associated with poorer outcomes compared with staged procedures. These discrepancies further underline the need for larger and properly designed studies to provide a definite answer to this important issue.

Study Limitations

This study has several important limitations: first, this is not a randomized trial; second, this is a single-center study, whether this strategy could also be adopted in other centers with different logistic is unknown; third, the SYNTAX score (Synergy Between Percutaneous Coronary Intervention With Taxus and Cardiac Surgery) was not routinely calculated, and data on noninvasive functional assessments of ischemia using nuclear perfusion imaging, echocardiography, or magnetic resonance imaging were not presented; fourth, comparison of outcomes across the 3 groups with this sample size (as presented in the Data Supplement) is subject to Type 2 error; and finally, the impact of revascularization strategies (complete versus incomplete revascularization) was not investigated. However, this was beyond the aims of this work.

Conclusions

In patients undergoing TAVR, screening of CAD with invasive CA and ad hoc PCI during TAVR is feasible and was not associated with increased periprocedural risks. PCI followed by TAVR in the same session had similar outcomes than TAVR in which PCI was not performed.

Disclosures

Dr Barbanti is a consultant for Edwards Lifesciences. Dr Tamburino received speaker honoraria from Medtronic Inc and Symetis. Dr Sgroi is Proctor physician for Edwards Lifesciences and Symetis. The other authors have no conflicts.

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