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Clinical

Incidence, Technical Safety, and Feasibility of Coronary Angiography and Intervention Following Self-expanding Transcatheter Aortic Valve Replacement

Akihito Tanaka [a], Richard J. Jabbour [a], Luca Testa [b], Mauro Agnifili [b], Federica Ettori [c], Claudia Fiorina [c], Marianna Adamo [c], Giuseppe Bruschi [d], Cristina Giannini [e], Anna Sonia Petronio [e], Marco Barbanti [f], Corrado Tamburino [f], Francesco De Felice [g], Bernhard Reimers [h], Arnaldo Poli [i], Antonio Colombo [a], Azeem Latib [a,j,k,*]

[a] Interventional Cardiology Unit, San Raffaele Scientific Institute, Milan, Italy
[b] Coronary Revascularisation Unit, IRCCS Policlinico S. Donato, S. Donato Milanese, Italy
[c] Cardiothoracic Department, Spedali Civili Brescia, Brescia, Italy
[d] "De Gasperis" Cardio Center ASST Niguarda Metropolitan Hospital, Milan, Italy
[e] Catheterisation Laboratory, Cardiothoracic and Vascular Department, University of Pisa, Pisa, Italy
[f] Cardio-Thoracic-Vascular Department, Ferrarotto Hospital, University of Catania, Catania, Italy
[g] Interventional Cardiology Unit, S. Camillo Forlanini Hospital, Rome, Italy
[h] Department of Cardiovascular Medicine, Humanitas Clinical and Research Center, Rozzano, Milan, Italy
[i] Interventional Cardiology Unit, ASST Ovest Milanese, Legnano Hospital, Milan, Italy
[j] Division of Cardiology, Department of Medicine, University of Cape Town, Cape Town, South Africa
[k] Department of Cardiology, Montefiore Medical Center, New York, USA

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ABSTRACT

Background: Transcatheter aortic valve replacement (TAVR) is a well-established treatment option for severe aortic stenosis (AS). AS and coronary artery disease frequently coincide, and therefore some patients may require coronary angiography (CAG) and/or intervention (PCI) post-TAVR. Due to valve stent design, most self-expanding prostheses always cover the coronary ostium, and therefore may hinder future access. The objective of this research was to evaluate the incidence, safety and feasibility of CAG/PCI in patients with prior self-expanding TAVR valves.
Methods: Among 2170 patients (age 82 ± 6 years, 43% male) who underwent TAVR with Corevalve or Evolut prostheses, as part of the Italian CoreValve ClinicalService® framework (data from 13 Italian centers), the occurrence of CAG/PCI following TAVR and periprocedural characteristics were examined.
Results: During median follow-up of 379 days, 41 patients (1.9%) required CAG and/or PCI (total 46; 16 CAG, 14 PCI, 16 both PCI/CAG). 56.5% of the procedures were performed under emergency/urgency settings. Left system coronary angiography was successfully performed in most cases (28/32, 87.5%), while right coronary angiography was successful only in 50.0% (16/32). PCI procedures (20 for left system, 3 for right system, 4 for graft) were successfully performed in 93.3% (28/30) of the procedures. No CAG/PCI procedure-related complications including prosthesis dislodgment or coronary ostium dissection occurred.
Conclusions: CAG and PCI procedures following CoreValve TAVR is safe and mostly feasible, although the success rate of selective right coronary angiography was relatively low when compared to the left system. Further investigations are required to explore this issue.

1. Introduction

Aortic stenosis (AS) and coronary artery disease (CAD) frequently coincide [1–3]. When patients with known CAD undergo transcatheter aortic valve replacement (TAVR), percutaneous coronary intervention (PCI) is generally performed prior to valve implantation [4,5]. However, some patients may require coronary angiography (CAG) and/or PCI after TAVR, for example due to the progression of pre-existing CAD, or acute or delayed coronary obstruction [6,7]. To date the incidence, technical safety and feasibility have not been fully elucidated. This is especially important as recently there has been a shift towards intermediate and low-risk patients undergoing the procedure in real-world practice [8–12].

* Corresponding author at: Department of Cardiology, Montefiore Medical Center, New York, USA.
E-mail address: alatib@gmail.com (A. Latib).

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On account of the prosthesis design, some self-expanding valves always cover the coronary ostium, and therefore may hinder future access [13]. This study investigates the incidence, technical safety and feasibility of CAG/PCI following self-expanding TAVR.

2. Material and methods

Data were examined from 2170 patients who underwent TAVR with 18 Fr CoreValve or 14 Fr CoreValve Evolut R prostheses (Medtronic,

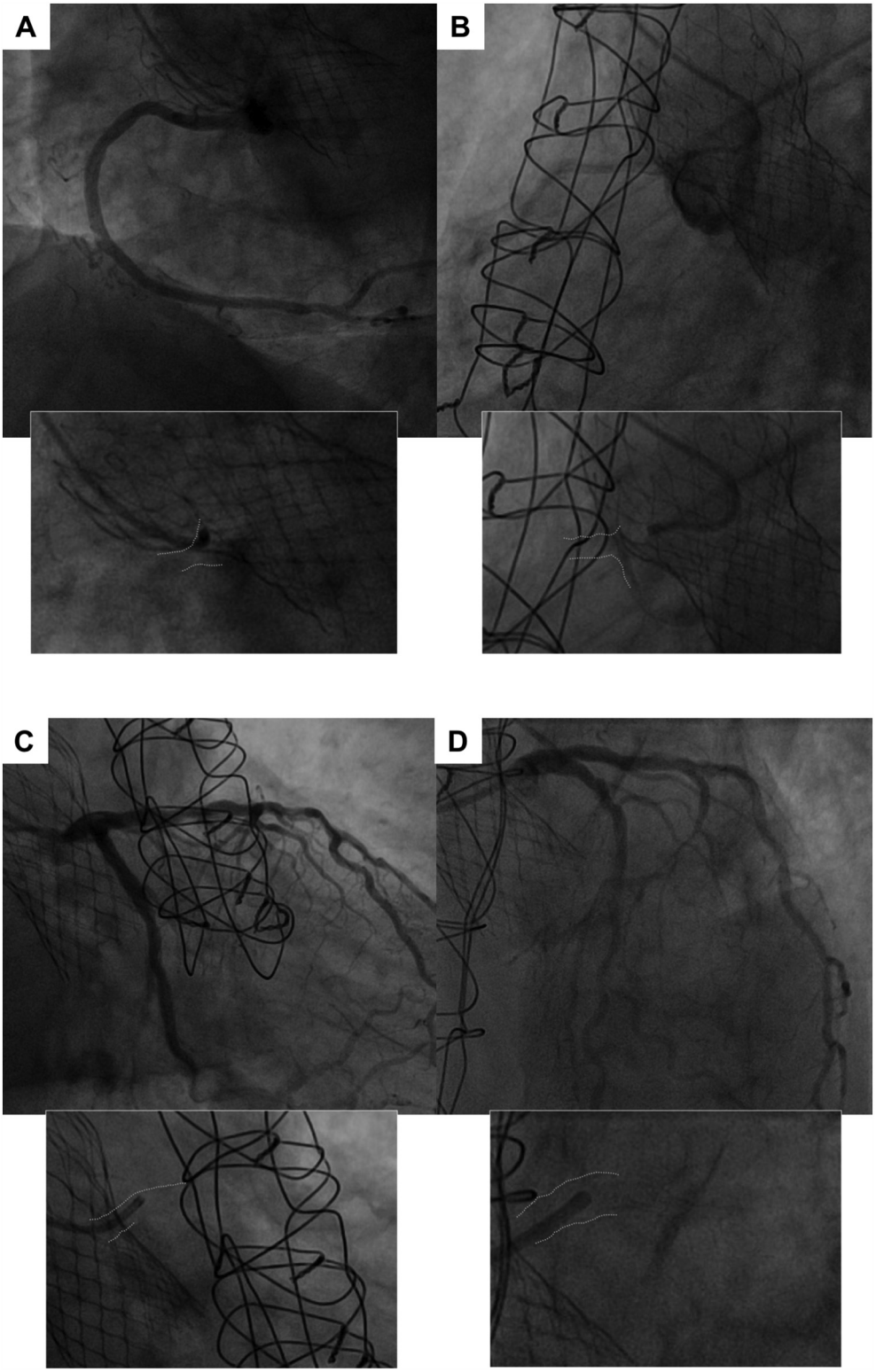

Fig. 1. Representative cases of coronary angiography and percutaneous coronary intervention through the Corevalve prosthesis. A: Selective angiography of right coronary artery with engaged JR 4.0 catheter. B: Assessment with floating AL1.0 catheter after failure with JR 4.0 catheter. C: Selective angiography of left coronary artery with engaged JL5.0 catheter. D: Percutaneous coronary intervention with engaged XB3.5 guiding catheter.

Minneapolis, MN, USA), between June 2007 and May 2016, as part of the Italian CoreValve Clinical Service framework (data from 13 Italian centers) (http://clinicaltrials.gov/ct2/show/NCT01007474). This is a nation-based clinical data repository and medical care project aimed at describing and improving the use of implantable devices in Italian clinical practice. The project was approved by each site's institutional review board or medical director and conforms to the principles outlined in the Declaration of Helsinki. Each patient signed an informed consent for data collection and analysis. For this project, the occurrence of CAG/PCI during follow-up post-TAVR was examined. Data regarding the details of CAG/PCI procedure including clinical presentation, number/type of used catheters, and success were also examined.

CAG success was defined as successfully obtaining the images with sufficient quality for assessment by selective coronary angiography, independent of whether the catheter was well engaged or floating (Fig. 1). Assessment of coronary artery by aortography with a pigtail catheter was not considered "CAG success". PCI success was defined as accomplishment of the PCI procedure with angiographic success. Complications related to CAG/PCI including valve dislodgment, fracture, and coronary ostial dissection, were also assessed.

Data are presented as mean ± SD or median (interquartile range). Categorical variables are expressed as number and percentages. All statistical analyses were performed using SAS 9.4 software (SAS Institute Inc., Cary, NC, USA).

3. Results

During median follow-up of 379 days (interquartile range, 83–1045 days), 41 patients (1.9%) underwent CAG and/or PCI (out of 2170 patients).

Table 1 shows baseline clinical characteristics during the index TAVR procedure in patients with or without CAG and/or PCI during follow-up. In the patients with CAG/PCI, mean age was 79 ± 7, 39.0% had diabetes, and 48.8% prior history of PCI. 5 patients had a history of surgical aortic valve replacement. 18 Fr CoreValves were implanted in 90% and 14 Fr Evolut R in 10%. Valve sizes were 23 mm in 7.5%, 26 mm in 45%, 29 mm in 40%, and 31 mm in 7.5% of patients.

Table 1
Baseline characteristics in patients with or without coronary angiography/percutaneous coronary intervention.

	CAG/PCI (+)	CAG/PCI (−)
	$n = 41$	$n = 2129$
Age (years)	79 ± 7	82 ± 6
Male	21 (51.2%)	919 (43.2%)
Body mass index (kg/m^2)	26 ± 5	26 ± 5
Hypertension	34 (82.9%)	1727 (81.4%)
Diabetes mellitus	16 (39.0%)	614 (29.0%)
Prior MI	13 (31.7%)	356 (16.9%)
Prior PCI	20 (48.8%)	548 (26.0%)
Prior CABG	9 (22.0%)	309 (14.5%)
eGFR <60 mL/min/1.73m^2	23 (59.0%)	968 (47.6%)
Severe COPD	7 (17.1%)	445 (20.9%)
STS score	8 (4–11)	6 (4–10)
Logistic EuroScore (%)	22 (13–36)	18 (11–28)
Valve type[a]		
Corevalve	36 (90%)	1837 (86.7%)
Evolut R	4 (10%)	281 (13.3%)
2nd valve implantation	2 (4.9%)	66 (3.2%)
Valve size[a]		
23 mm	3 (7.5%)	86 (4.1%)
26 mm	18 (45.0%)	943 (44.5%)
29 mm	16 (40.0%)	920 (43.4%)
31 mm	3 (7.5%)	171 (8.1%)

Values are n (%), mean ± SD or median (interquartile range), calculated with available sample data. CAG = coronary angiography, PCI = percutaneous coronary intervention, CVA = cerebrovascular accident (Stroke or Transit ischemic attack), MI = myocardial infarction, CABG = coronary artery bypass grafting, eGFR = estimated glomerular filtration rate, COPD = chronic obstructive pulmonary disease, STS = Society of Thoracic Surgeons.
[a] Detailed valve data were available in 40 out of 41 patients with CAG/PCI patients.

Table 2
Numbers and timing of CAG/PCI procedures following TAVR.

	Total	CAG only	PCI only	Both CAG and PCI
Overall	46	16	14	16
Before discharge	19	4	4	11
After discharge	27	12	10	5
Clinical presentation				
Stable angina/silent ischemia	13 (28.3%)	4 (25.0%)	4 (28.6%)	5 (31.3%)
Unstable angina	7 (15.2%)	4 (25.0%)	1 (7.1%)	2 (12.5%)
NSTEMI	10 (21.7%)	4 (25.0%)	3 (21.4%)	3 (18.8%)
STEMI	12 (26.1%)	4 (25.0%)	2 (14.3%)	6 (43.8%)
Emergency/urgency setting	26 (56.5%)	9 (56.3%)	4 (28.6%)	11 (68.8%)

STEMI = ST-segment elevation myocardial infarction, NSTEMI = non-STEMI.

Table 2 shows the numbers and timing of CAG/PCI procedures following TAVR. A total of 46 procedures were performed: 16 CAG only, 14 PCI only, and 16 both CAG/PCI. 19 procedures were performed before discharge, and 27 after discharge. Majority of procedures (26/46, 56.5%) were performed in the emergency/urgency setting. In 15 patients who received PCI before discharge, all cases were performed for coronary obstruction (11 cases on the same day of TAVR, 2 next day, 1 after 2 days, and 1 after 9 days), without pre-existing significant coronary stenosis.

The details of CAG procedures are shown in Table 3 ($n = 32$). Right coronary artery (RCA) angiography was successfully performed in 50% of cases (16/32), mainly achieved with Judkins Right catheter. Mean number of used catheters was 1.2 ± 0.4, and the catheter was floating during contrast injection in about half of successful cases. Left coronary artery (LCA) angiography was successfully performed in most cases (87.5%; 28/32), and mainly achieved with a Judkins Left catheter. Mean number of used catheters was 1.8 ± 1.5, and the final successful catheter was fully engaged in majority of cases. Complications related to CAG procedure involving the TAVR prosthesis, such as THV dislodgment, fracture and coronary ostial dissection, were not observed.

The details of PCI procedures are shown in Table 3 ($n = 30$). Target vessel was LCA in most cases ($n = 20$), and RCA in only 3 cases. Mean number of guiding catheters used was 1.9 ± 1.8. The final guiding catheter was fully engaged before wiring in most cases, but engaged after wiring or floating through the whole procedure in some cases. PCI procedures were accomplished in all except 2 cases (6.7%), experiencing cardiac arrest due to coronary obstruction during TAVR procedure after valve deployment. In one patient with valve-in valve procedure (a 26 mm Corevalve in another 26 mm Corevalve), RCA occlusion was suspected by urgent aortography, but selective guiding catheter engagement failed. In the other patient LCA CAG was performed and showed an obstruction of left main trunk, but then it was not possible to position the guiding catheter. Another death occurred due to a left main obstruction 2 days after TAVR. PCI for left main trunk was successfully performed, but the patient did not recover from cardiac arrest. No death was caused by CAG/PCI procedures and no procedure-related complications involving THV prosthesis occurred.

4. Discussion

The main findings of this research are: 1) CAG and/or PCI was required in 1.9% of patients during a median follow-up of about 1-year after TAVR; 2) CAG/PCI procedures following CoreValve/Evolut R implantation were mostly feasible, although the success rate of selective RCA angiography was relatively low; 3) CAG/PCI procedures through CoreValve/Evolut R prostheses were safe as no complications involving the implanted prosthesis occurred.

In this study, the incidence rate of CAG and/or PCI was low (1.9% of patients) during a median follow-up of approximately 1-year after

Table 3
Details of CAG and PCI procedures.

CAG	N = 32
RCA angiography	
Number of used catheters	1.2 ± 0.4
RCA angiography success	16 (50.0%)
Final successful catheter ($n = 16$)	
Judkins Right	14
Others	2
Final successful catheter situation	
Engaged	5
Floating	7
Unavailable	4
LCA angiography	
Number of used catheters	1.8 ± 1.5
LCA angiography success	28 (87.5%)
Final successful catheter ($n = 28$)	
Judkins Left	21
Others	6
Unavailable	1
Final successful catheter situation	
Engaged	16
Floating	7
Unavailable	5
Complication related to CAG procedure	
THV dislodgment	0
Coronary ostial dissection	0
Any other complication	0
PCI	**N = 30**
Target vessel	
Left coronary artery	20
Right coronary artery	3
Graft	4
Unavailable	3
Number of used catheters	1.9 ± 1.8
PCI success	93.3% (28/30)
Final successful catheter situation	
Engaged	15
-Before wiring	11
-After wiring	3
-Unavailable	1
Floating throughout procedure	4
Unavailable	9
PCI success	93.3% (28/30)
Complication related to PCI procedure	
THV dislodgment	0
Coronary ostial dissection	0
Any other complication	0

STEMI = ST-segment elevation myocardial infarction, NSTEMI = non-STEMI, THV = transcatheter heart valve.

TAVR. Recently, TAVR procedures have been expanded to lower risk and younger patients [8–12], resulting in an increase of post-TAVR patients with a longer life expectancy after TAVR. Therefore, in clinical practice, there will be more post-TAVR patients who require CAG/PCI. This is important for the non-TAVR interventionalist since they may not appreciate the complexity of performing post TAVR PCI.

The self-expanding CoreValve prosthesis is designed for deployment in a supra-annular position, which always covers the coronary ostia [13]. Therefore, future access to the coronary artery is through a valve stent frame, and therefore technically demanding [14]. To date, only a few single-center reports have described the feasibility of selective CAG/PCI following CoreValve implantation [14–16]. In this multicenter observational project, LCA angiography was successfully achieved in most cases, whilst the success rate of RCA angiography was relatively low (50.0%). A prior report showed a similar result [14], and RCA angiography may be more challenging due to the different anatomical take off of the ostium and relationship to the TAVR prostheses. Furthermore, the majority of cases were performed in an emergency setting in our cohort. In such situations, operators theoretically have less time to perform different maneuvers to fully engage the coronary ostium, and may use aortography for assessment. In this report, majority of PCI target vessels was LCA, therefore the low success rate for RCA angiography may be partially due to the lower interest by the operator to gain full information regarding the vessel. Mean number of catheters used for RCA angiography was lower (1.2 ± 0.4), which may support this hypothesis. Of note, other single-center experiences have reported relatively higher success rates using additional technical efforts including guidewire assisted CAG [15–17], and therefore success rates may be improved using additional catheters (e.g. multipurpose and amplaz) and/or technical efforts [18], especially in stable conditions. Furthermore, in the current era of TAVR procedures expanding to patients with a longer life expectancy, more efforts are required to facilitate coronary access, including considering commissure to commissure alignment when implanting valves with a tall stent frame and the development of more transcatheter valves that don't cover the coronary ostium with their stent frames [18].

Regarding safety of CAG/PCI procedures, complications related to post-TAVR condition were not observed, including valve dislodgement, fracture, and aortic/coronary ostial dissection, although some patients subsequently died but not due to the CAG/PCI procedure. Therefore, in conjunction with the results of other reports [14–16], we can consider that to try CAG/PCI following Corevalve implantation is safe.

This study had several limitations. First, this report is from a large database (the Italian CoreValve ClinicalService® framework), including 13 centers. The experiences of TAVR and CAG/PCI following TAVR might be varied among centers. Second, the details of CAG/PCI procedural information could not be obtained in some cases. Third, as described above, the success rates of CAG may partially depend on the operators' interest to gain full information regarding the vessel. Therefore, some caution should be paid when interpreting the results of this report. Forth, the number of CAG/PCI procedures was relatively small. Further accumulation of data regarding this issue is required. Fifth, follow-up duration was relatively short. In this era of TAVR expansion into lower risk patients, further data with longer follow-up is required. Sixth, data were collected at each center, and site monitoring was absent. Therefore, we cannot exclude that under-reporting of the prevalence CAG/PCI may have occurred. Seventh, the low success rate of RCA angiography in this study should be carefully interpreted because it could be dependent on the clinical condition/situation – for example, in emergency settings by non-TAVR interventionalists with a clear LCA culprit. Further investigations are required to address this technical issue.

5. Conclusions

In conclusion, CAG/PCI procedure following CoreValve TAVR is safe and mostly feasible, although the success rate of selective right coronary angiography was relatively low when compared to the left system. Post-TAVR patients requiring CAG/PCI procedures will increase, and further investigations are required to explore this issue.

Conflict of interest

Dr. Latib is a consultant for Medtronic, Speaking Honoraria from Abbott Vascular, Research grants from Medtronic & Edwards Lifesciences. Dr. Ettori is a consultant for Medtronic. Dr. G. Bruschi is a consultant for Medtronic and Abbott. Prof. Petronio is a consultant for Boston Scientific, Medtronic, and Abbott. Prof Tamburino is a consultant for Edwards Lifesciences, Medtronic, CeloNova, and Abbott. All other authors have reported that they have no relationships relevant to the contents of this paper to disclose.

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