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Original Article

Outcomes of concomitant PCI and TAVR versus TAVR alone in patients with severe aortic stenosis: A retrospective study

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ABSTRACT

Background: Severe aortic stenosis (AS) and coronary artery disease frequently coexist, yet the optimal management strategy for patients undergoing TAVR with concomitant CAD remains debated. Our study compared safety outcomes and procedural characteristics of concomitant TAVR and PCI versus TAVR alone in a two-center Indian population with severe AS.

Methods: This retrospective, multi-center, case-control study included 30 consecutive patients undergoing planned concomitant TAVR and PCI and 30 age-, sex-, and valve-type-matched TAVR-alone controls identified from the same study period. PCI was performed for angiographically confirmed proximal coronary stenosis $\geq 70\%$ or as deemed appropriate according to the study protocol. The primary outcome was VARC-3 defined any bleeding or vascular complication through hospital discharge. Secondary outcomes included in-hospital and 30-day mortality, myocardial infarction, stroke, acute kidney injury, pacemaker implantation, fluoroscopy time, and contrast volume.

Results: Thirty concomitant TAVR-PCI patients and 30 matched TAVR-alone controls were included. The primary outcome occurred in 3 patients (10.0%) versus 2 patients (6.7%; $p > 0.99$), with a risk difference of 3.3 percentage points (95% CI, -12.7 to 19.7). No major or life-threatening bleeding events occurred. Fluoroscopy time (38.6 ± 23.2 vs. 26.8 ± 10.0 min; $p < 0.01$) and contrast volume (166.7 ± 65.5 vs. 99.6 ± 37.7 mL; $p < 0.001$) were higher with concomitant PCI. No in-hospital or 30-day deaths or myocardial infarctions occurred in either group.

Conclusion: In this small, retrospective, two-center cohort, concomitant PCI at the time of TAVR was not associated with an observed excess of bleeding or vascular complications compared with TAVR alone. These findings are hypothesis-generating and support the feasibility of a concomitant strategy in carefully selected patients at experienced, high-volume centers; they do not establish safety equivalence.

1. Introduction

Severe aortic stenosis (AS) affects about 3.4% of individuals beyond 75 years,¹ with a co-prevalence of coronary artery disease (CAD) ranging around 50%. Recognizing this cohort of patients remains particularly challenging as both share common symptoms and both affect coronary perfusion.² Additionally, a pathological concordance,

driven by overlapping mechanisms such as chronic inflammation, lipid accumulation, endothelial dysfunction and importantly, calcification, substantially increases periprocedural complexity and carries significant prognostic implications. The coexistence of these two conditions complicates management, requiring a comprehensive understanding of revascularization strategies, including whether to perform revascularization, the timing of revascularization, commissural alignment, and

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coronary re-access after TAVR.³

According to the 2025 European Society of Cardiology/European Association for Cardio-Thoracic Surgery (ESC/EACTS) guidelines, PCI may be considered in patients with a primary indication to undergo transcatheter valve interventions who have coronary artery stenosis $\geq 70\%$ in proximal segments of main vessels (Class IIb recommendation, Level of Evidence B). However, no specific recommendation is provided regarding the optimal timing of PCI.⁴ In accordance with the statement by the guidelines, many studies have been conducted on patients undergoing PCI and TAVR at different time settings^{5–8}; however, the optimal management of CAD in patients undergoing TAVR has remained a subject of considerable clinical debate.

Moreover, real-world outcomes data comparing patients who undergo TAVR with concomitant PCI against those undergoing TAVR alone remain limited, particularly from non-Western, practice settings where patient demographics, lesion complexity, financial ability and institutional protocols may differ substantially from those reported in pivotal European and North American trials. Hence, we planned this study to compare the safety profiles and clinical outcomes of patients undergoing TAVR with concomitant PCI versus TAVR alone.

2. Methods

This is a retrospective, multi-center, investigator-initiated, case-control study which was conducted at two experienced centers with good volume of TAVI and PCI in India. Group 1 comprised patients who underwent planned concomitant TAVR and PCI in the same session, while group 2 comprised age-, sex-, and valve-type-matched patients who underwent TAVR alone during the same study period. The study was approved by the ethics committees of the participating centers, and was conducted in accordance with the Declaration of Helsinki and Good Clinical Practice guidelines. Because of the retrospective design, a waiver of informed consent was obtained.

Patients who underwent TAVR were identified from the institutional databases. All consecutive patients from both institutions who underwent TAVR with planned concomitant PCI during the study period were identified; patients who underwent bailout PCI for coronary occlusion during TAVR were excluded. The concomitant-PCI cohort was selected a priori on the basis of angiographically confirmed proximal coronary stenosis $\geq 70\%$ or lesions where the operator feel clinically important for that patient necessitating PCI. The TAVR-alone controls were identified from the same study period and matched 1:1 for age, sex, and valve type; they were not restricted to patients without CAD. All 30 patients in the concomitant group underwent PCI because angiographically confirmed obstructive CAD was identified at the TAVR work-up. Both centers used comparable access-site management, anticoagulation, and vascular-closure protocols under a shared standard operating procedure, although operator-level variation could not be excluded retrospectively. Both centers followed a common valve-first sequencing protocol, with PCI performed after valve deployment in the same session unless left main disease was present or a self-expanding valve was planned, in which cases PCI was performed before TAVR. Dual anti-platelet strategy was used in all patients with concomitant TAVI and PCI arm. A comprehensive dataset was collected from the existing records, including demographics, comorbidities, prior cardiovascular events, laboratory results, electrocardiogram (ECG), echocardiography, computed tomography findings, and procedural characteristics. For the TAVR procedure, fluoroscopy time, contrast volume, valve type and size, access site, pre- and post-dilatation, and procedural complications were recorded. PCI procedural details were also collected.

Outcomes: The primary outcome was the composite of any bleeding or vascular complication through hospital discharge, defined according to VARC-3.⁹ This composite was selected because bleeding and vascular complications are clinically relevant safety outcomes plausibly influenced by the additional arterial instrumentation, sheath burden, and dual-antiplatelet exposure associated with concomitant PCI, and

because they have been used as safety endpoints in prior PCI/TAVR timing studies. These definitions were adjudicated from the available records.

Secondary outcomes were assessed at prespecified time points and included in-hospital death, all-cause mortality at 30 days, myocardial infarction and stroke within the 30-day follow-up period, acute kidney injury, pacemaker implantation, fluoroscopy time, and contrast volume.

3. Statistical analysis

All collected data were entered into a Microsoft Excel sheet and subsequently imported into statistical software. Descriptive statistics summarized patient characteristics, procedural details, and outcomes. Continuous variables were compared using *t*-tests or non-parametric tests as appropriate based on the distribution. Categorical variables were expressed as numbers and percentages and compared using chi-square or Fisher exact tests, as appropriate. For binary outcomes, exact 95% confidence intervals for proportions were calculated using the Clopper-Pearson method, and absolute risk differences with 95% confidence intervals were calculated using the Newcombe-Wilson method. Formal propensity-score or multivariable adjustment was not performed because the sample size of 30 patients per group was too small to support stable multivariable estimation without substantial risk of overfitting. We used STATA (version 17) (the United States of America) for statistical analysis. A *p*-value of <0.05 was considered significant. No a priori sample-size calculation was performed because this was a time period-based, non-powered study; the sample size reflected all eligible consecutive concomitant-TAVI and PCI cases identified during the study period.

4. Results

A total of 60 patients were included, comprising 30 consecutive patients undergoing concomitant TAVR and PCI and 30 age-, sex-, and valve-type-matched patients undergoing TAVR alone. Matching was limited to age, sex, and valve type; the groups therefore remained inherently different with respect to CAD burden and other factors related to the indication for PCI. The mean age was similar between the concomitant TAVR-PCI and TAVR-alone groups (75.5 ± 6.7 years vs. 75.2 ± 6.6 years; $p = 0.86$), with a predominance of male patients (76.7%) [Table 1](#).

Diabetes mellitus (53.3% vs. 56.7%; $p = 0.26$) and hypertension (76.7% vs. 56.7%; $p = 0.10$) were not significantly different between groups. Known/history of CAD was more frequent in the concomitant TAVR-PCI group than in the TAVR-alone group (26 [86.7%] vs. 18 [60.0%]; $p = 0.04$). Unsurprisingly, all 30 patients in the concomitant group had angiographically confirmed obstructive CAD requiring PCI at the TAVR work-up; 4 patients had newly identified CAD while 26 patients had prior history of CAD as described before. Angina was reported in 9 (30.0%) and 7 (23.3%) patients, respectively. These data illustrate that the control group was not CAD-free and that underlying CAD burden was not fully balanced by the matching strategy.

Baseline echocardiographic parameters were comparable, including mean aortic valve gradient (47 [40–59] mmHg vs. 46 [37–59] mmHg; $p = 0.61$), aortic valve area (0.51 [0.41–0.61] cm² vs. 0.55 [0.41–0.72] cm²; $p = 0.35$), and left ventricular ejection fraction (55 [49–60]% vs. 52 [39–60]%); $p = 0.70$). Surgical risk scores were also similar, including EuroSCORE II (3.45 [1.90–4.75] vs. 3.20 [2.10–4.20]; $p = 0.68$) and STS score (3.43 [2.39–4.81] vs. 2.75 [1.64–3.75]; $p = 0.11$).

Procedural characteristics of TAVR: Pre-dilatation of the aortic valve was performed in 13 patients (43.3%) in the concomitant TAVR-PCI group and 10 patients (33.3%) in the TAVR-alone group ($p = 0.43$). Post-dilatation was more frequent in the concomitant group (23.3% vs. 6.7%; $p = 0.15$), although this difference did not reach statistical significance. Nearly 88% of patients received balloon-expandable valves in the overall population ([Fig. 1](#)). Mean fluoroscopy

Table 1
Baseline characteristics.

Variable	Concomitant TAVR and PCI (n = 30 patients)	TAVR only (n = 30 patients)	p value
Age (years)	75.5 ± 6.73	75.20 ± 6.58	0.86
BMI (kg/m ²)	26.5 ± 3.67	25.8 ± 3.52	0.45
Male, n (%)	23 (76.67)	24 (80)	0.75
Diabetes mellitus, n (%)	16 (53.33)	17 (56.7)	0.259
Hypertension, n (%)	23 (76.67)	17 (56.7)	0.10
Known/history of coronary artery disease, n (%)	26 (86.67)	18 (60)	0.04
Chronic kidney disease, n (%)	4 (13.33)	8 (26.7)	0.33
Prior coronary artery bypass surgery, n (%)	1 (3.33)	6 (20.6)	0.05
Prior percutaneous coronary intervention, n (%)	4 (13.33)	5 (16.7)	0.99
Prior cerebrovascular accident, n (%)	4 (13.33)	2 (6.7)	0.67
Symptoms, n (%)			
Dyspnoea	30 (100)	26 (86.7)	0.04
Angina	9 (30.0)	7 (23.3)	0.56
Syncope	4 (13.3)	2 (6.7)	0.39
NYHA class III-IV, n (%)	25 (83.3)	22 (73.3)	0.35
Hemoglobin (g/dL)	11.4 ± 1.19	11.7 ± 1.46	0.29
Creatinine (mg/dL)	1.11 ± 0.37	1.14 ± 0.35	0.72
Estimated glomerular filtration rate (mL/min/1.73m ²)	65.1 ± 20.2	58.7 ± 23.3	0.25
Mean aortic gradient (mmHg)	47 [40–59]	46 [37–59]	0.61
Aortic valve area (cm ²)	0.51 [0.41–0.61]	0.55 [0.41–0.72]	0.35
Pulmonary hypertension (mmHg)	33.5 [19.0 – 74.0]	34.0 [18.0–62.0]	0.51
Left ventricular ejection fraction (%)	55 [49–60]	52 [39–60]	0.70
EuroSCORE II (%)	3.45 [1.90–4.75]	3.20 [2.10–4.20]	0.68
Society of Thoracic Surgeons score (%)	3.43 [2.39–4.81]	2.75 [1.64–3.75]	0.11
Frailty score	6.5 [4.00–8.25]	5 [4.00–6.00]	0.29

Values are mean ± SD, median [IQR], or n (%).

time was longer with concomitant TAVR-PCI (38.6 ± 23.2 vs. 26.8 ± 10.0 min; $p < 0.01$), and contrast volume was also higher (166.7 ± 65.5 vs. 99.6 ± 37.7 mL; $p < 0.001$) Table 2.

Procedural characteristics of PCI (concomitant TAVR-PCI group): PCI was performed only in the concomitant group; no TAVR-alone patient underwent PCI by study design. PCI procedural

characteristics were comparable between the two participating centers. Fig. 2 demonstrates the target vessels treated. Five patients (16.7%) had left main disease and underwent PCI before TAVR; in the remaining patients, PCI was performed after TAVR deployment within the same session. The majority of patients underwent PCI without adjunctive plaque modification (56.7%). Rotational atherectomy was used in 26.7% of cases, while intravascular lithotripsy and cutting-balloon angioplasty were each used in 6.7%, and IVUS-guided PCI was performed in 3.3%. The mean rotational atherectomy burr size was 1.25 ± 0.49 mm, and the mean IVL balloon size was 2.75 mm. All patients were treated with drug-eluting stents, with a mean of 1.20 ± 0.41 stents implanted per patient. The angiographic figures illustrate representative concomitant PCI and TAVR procedures (see Figs. 3–5).

Outcomes: The primary composite of any bleeding or vascular complication occurred in 3 patients (10.0%) in the concomitant TAVR-PCI group and 2 patients (6.7%) in the TAVR-alone group ($p > 0.99$), corresponding to an absolute risk difference of 3.3 percentage points (95% CI, –12.7 to 19.7). VARC-3 type 2 bleeding occurred in 2 (6.7%) and 1 (3.3%) patients, respectively ($p > 0.99$). No major or life-threatening bleeding occurred. Minor vascular complications occurred in 1 patient (3.3%) in each group ($p > 0.99$), while no major vascular complications were observed. The wide confidence intervals around these estimates are compatible with clinically important differences in either direction.

Postprocedural outcomes were assessed during the index hospitalization and at 30 days, as applicable. No in-hospital or 30-day deaths or myocardial infarctions occurred in either group. One periprocedural transient ischemic attack occurred in the concomitant TAVR-PCI group (3.3%) and none in the TAVR-alone group ($p > 0.99$); one in-hospital stroke occurred in the TAVR-alone group (3.3%) and none in the concomitant group ($p > 0.99$). New-onset atrial fibrillation occurred in 1 patient (3.3%) in each group ($p > 0.99$). Acute kidney injury occurred in 0 and 1 patient (3.3%), respectively ($p > 0.99$). Postoperative infection occurred in 0 patients in the concomitant group and 6 (20.0%) in the TAVR-alone group ($p = 0.02$); infections comprised urinary tract infection, and lower respiratory tract infection during the index hospitalization. Given the small sample and the absence of a biologically plausible causal mechanism, this difference cannot be directly interpreted as a protective effect of concomitant PCI. The postprocedural mean aortic valve gradient was 9.12 ± 4.09 mmHg versus 11.3 ± 3.64 mmHg ($p = 0.04$); this difference may reflect valve type/size selection, procedural sequencing, or measurement variability. Median

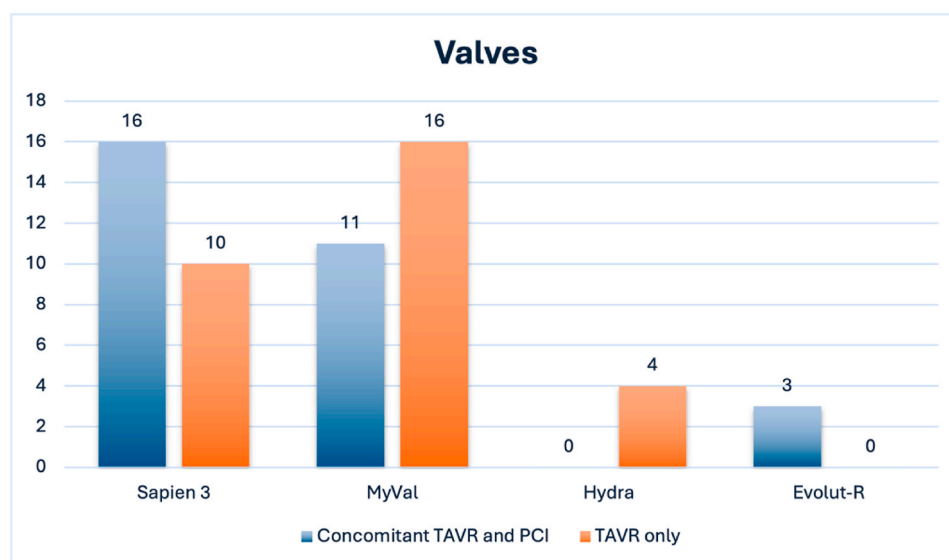


Fig. 1. Disposition of valves utilized in the study.

Table 2

Procedural and postprocedural outcomes.

Variable	Concomitant TAVR and PCI (n = 30 patients)	TAVR only (n = 30 patients)	p value Risk difference (95% CI)
Pre-dilatation (TAVR), n (%)	13 (43.33)	10 (33.33)	0.43
Post-dilatation (TAVR), n (%)	7 (23.33)	2 (6.67)	0.15
Mean fluoroscopy time (min)	38.6 ± 23.2	26.8 ± 10.0	<0.01
Mean procedure time (min)	101.9 ± 54.7	98.0 ± 42.8	0.76
Mean contrast volume (mL)	166.7 ± 65.5	99.6 ± 37.7	<0.001
Any bleeding or vascular complication (through discharge), n (%)	3 (10.0%)	2 (6.7%)	>0.99 RD 3.3% (95% CI, -12.7 to 19.7)
Minor vascular complication, n (%)	1 (3.3%)	1 (3.3%)	>0.99 RD 0.0% (95% CI, -13.6 to 13.6)
Major vascular complication, n (%)	0 (0.0%)	0 (0.0%)	— RD 0.0% (95% CI, NE)
VARC-3 type-2 bleeding (through discharge), n (%)	2 (6.7%)	1 (3.3%)	>0.99 RD 3.3% (95% CI, -10.8 to 18.2)
Periprocedural transient ischemic attack, n (%)	1 (3.3%)	0 (0.0%)	>0.99 RD 3.3% (95% CI, -8.3 to 16.7)
Myocardial infarction (in-hospital/30-day), n (%)	0 (0.0%)	0 (0.0%)	— RD 0.0% (95% CI, NE)
Permanent pacemaker required (index hospitalization), n (%)	2 (6.7%)	2 (6.7%)	1.00 RD 0.0% (95% CI, -15.4 to 15.4)
New-onset atrial fibrillation (index hospitalization), n (%)	1 (3.3%)	1 (3.3%)	>0.99 RD 0.0% (95% CI, -13.6 to 13.6)
Acute kidney injury (index hospitalization/30-day follow-up), n (%)	0 (0.0%)	1 (3.3%)	>0.99 RD -3.3% (95% CI, -16.7 to 8.3)
Postoperative infection (index hospitalization), n (%)	0 (0.0%)	6 (20.0%)	0.02 RD -20.0% (95% CI, -37.3 to -4.5)
Postprocedural mean gradient (index hospitalization, mmHg)	9.12 ± 4.09	11.3 ± 3.64	0.04
Hospital stay (index hospitalization, days)	4 [3–6.25]	3.5 [3–4]	0.05
In-hospital mortality, n (%)	0 (0.0%)	0 (0.0%)	— RD 0.0% (95% CI, NE)
30-day mortality, n (%)	0 (0.0%)	0 (0.0%)	— RD 0.0% (95% CI, NE)
In-hospital stroke, n (%)	0 (0.0%)	1 (3.3%)	>0.99 RD -3.3% (95% CI, -16.7 to 8.3)

Values are mean ± SD, median [IQR], or n (%). For binary outcomes, percentages are accompanied by exact 95% CIs (Clopper-Pearson); NE: Not estimable; RD denotes absolute risk difference in percentage points with 95% CI calculated by the Newcombe-Wilson method.

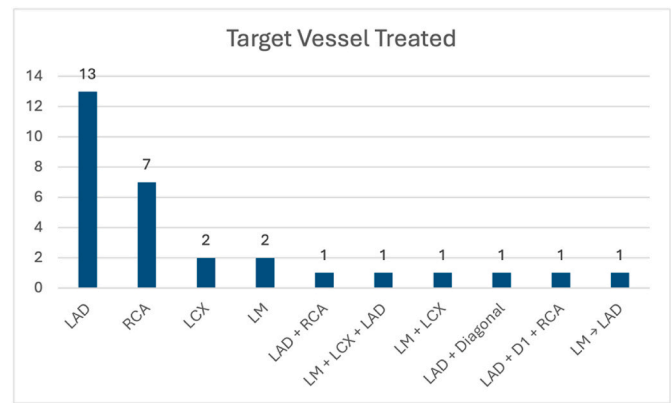


Fig. 2. Bar graph depicting the distribution of coronary vessels intervened. Abbreviations: LAD – left anterior descending artery; RCA – right coronary artery; LCx – left circumflex artery; LM – left main; D1 – Diagonal 1.

hospital stay was 4 [3–6.25] versus 3.5 [3–4] days ($p = 0.05$), a borderline difference of uncertain clinical importance. Median intensive care unit stay was 24 [22.0–31.5] versus 27.5 [22.8–36.0] hours ($p = 0.33$).

5. Discussion

To our knowledge, this is one of the first reports from India/South Asia to compare concomitant TAVR-PCI with TAVR alone in routine practice. In this small retrospective cohort, concomitant PCI was not associated with a statistically significant difference in the observed composite of bleeding or vascular complications. The longer fluoroscopy time and higher contrast volume are expected consequences of performing two interventions in one session and represent procedural burden rather than evidence of clinical harm.

Contemporary randomized evidence highlights the importance of patient selection and timing. In ACTIVATION, PCI before TAVR did not meet the prespecified non-inferiority criterion for death or rehospitalization at 1 year and was associated with more bleeding.⁵ NOTION-3⁶ subsequently reported a lower 2-year composite of death, myocardial infarction, or urgent revascularization with PCI than conservative treatment in selected patients with significant CAD; however, most PCI was performed before TAVR, with a smaller proportion performed during or shortly after TAVR, so the trial does not directly establish the safety or benefit of same-session PCI. More recently, PRO-TAVI reported that deferral of PCI was non-inferior to routine PCI before TAVR for a 1-year composite of death, myocardial infarction, stroke, and major bleeding, supporting a more selective approach to revascularization.¹⁰ Taken together, these studies indicate that the evidence is heterogeneous and that the decision to revascularize, and the timing of PCI, should be individualized.

Performing PCI concomitantly with TAVR presents several procedural challenges, including longer procedure times, greater contrast exposure, potential hemodynamic compromise during rapid ventricular pacing, and antiplatelet-related bleeding risk. A single-session approach may offer operational advantages by avoiding a second procedure and repeat vascular access,³ but these potential logistical benefits were not directly measured in this study and no cost-effectiveness analysis was performed. The higher fluoroscopy time and contrast volume observed in our cohort should therefore be regarded as expected procedural burden.

The VARC-3 type 2 bleeding occurred in 6.7% versus 3.3% of patients, with no major bleeding, while minor vascular complications occurred in 3.3% of each group. This low incidence may reflect careful execution of vascular access, proper wire handling in LV and coronaries contrasting with earlier reports of heightened bleeding in concomitant

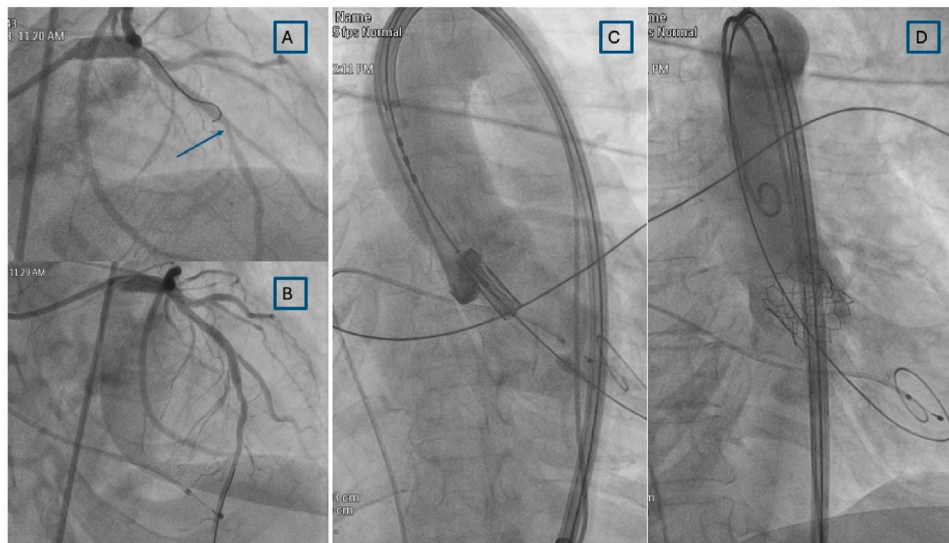


Fig. 3. (A) Selective left coronary angiography with mid LAD 80-90% lesion (blue arrow). (B) Selective left coronary angiography post deployment of drug eluting stent from proximal to mid LAD. (C) Root angiogram after positioning the Edwards Sapien Valve across the aortic valve. (D) Root angiogram post deployment of Edwards Sapien valve.



Fig. 4. (A) Selective right coronary angiogram showing 80-90% mid RCA lesion (blue arrow). (B) Selective right coronary angiogram post successful deployment of drug eluting stent from proximal to mid RCA. (C) Root angiogram after positioning and 80% deployment of Medtronic Evolut Valve across the aortic valve annulus. (D) Root angiogram post deployment of Medtronic Evolut valve.

strategies.^{11,12} However, these findings are descriptive and may reflect operator experience and contemporary access management, but the study was not powered to determine whether concomitant PCI changes the true risk of these events. Similarly, the absence of increased AKI despite greater contrast exposure should not be interpreted as evidence that same-session PCI protects against AKI. Prior observational data have reported differences between concomitant and staged strategies, but residual confounding and patient selection remain important considerations.

A concomitant strategy may be less suitable in patients with chronic kidney disease or a high anticipated contrast burden, complex multi-vessel CAD requiring prolonged or high-risk PCI, or tenuous baseline hemodynamics in whom additional procedural time and rapid-pacing exposure may be poorly tolerated. In such patients, a staged strategy may permit renal recovery, reassessment of coronary anatomy and symptoms, or completion of revascularization under more stable

conditions. Rotablation was performed in more than 1/4th of the patient that signifies that the lesions intervened are not simple lesions. Hence, in carefully selected patients with a clinically significant disease and experienced team/operators, a single-session approach may reduce the logistical burden of a second procedure. Moreover, there are diminished chances of secondary hemodynamic instability due to ischemia attributed to rapid pacing during the intervention, especially in left main disease; besides improvement in NYHA class and quality of life,¹³ it minimizes the waiting period for revascularization, during which patients remain at risk for decompensation from untreated aortic stenosis or CAD. These potential advantages remain unmeasured in the present study.

Limitations: This study has several important limitations beyond its small sample size and retrospective design. First, matching was limited to age, sex, and valve type and did not address CAD burden, frailty, lesion complexity, access choice, renal function, or overall procedural

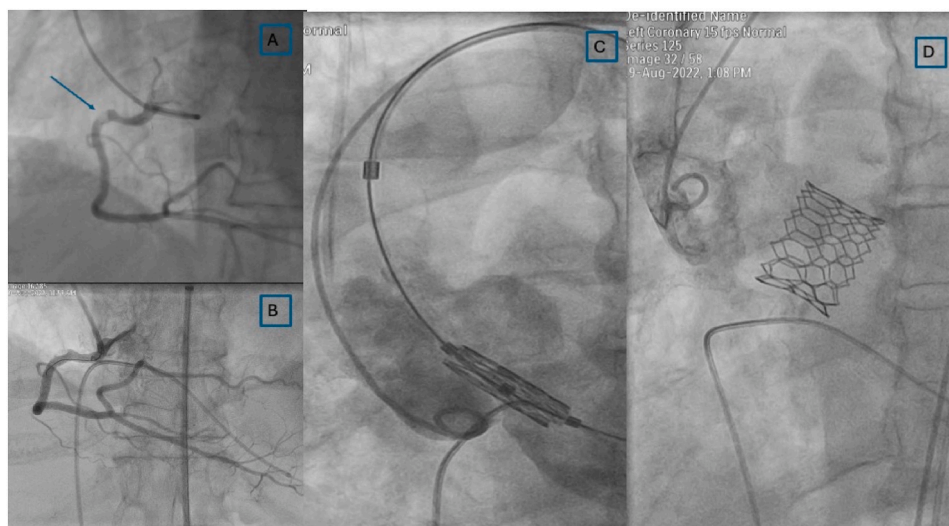


Fig. 5. (A) Selective right coronary angiogram showing 95% calcific lesion in proximal RCA(blue arrow). (B) Selective right coronary angiography post succesful PCI using drug eluting stent. (C) Aortic root angiogram with Meril MyVal positioned across the aortic annulus. (D) Aortic root angiogram after deployment of Meril MyVal.

risk. The concomitant-PCI and TAVR-alone groups were therefore not fully comparable by design, and substantial residual confounding is likely. Second, no propensity-score or multivariable adjustment was performed because the sample size was too small to support reliable model estimation without overfitting. Third, the control group was not restricted to patients without CAD, and granular angiographic information regarding vessel distribution, lesion severity. Fourth, the cohort was limited to two high-volume centers, and operator-level variation cannot be excluded despite shared procedural protocols, limiting generalizability to other settings. Fifth, follow-up was limited to in-hospital and 30-day outcomes, precluding assessment of longer-term ischemic or valve-related events. Finally, the study was not powered to evaluate uncommon outcomes such as death, myocardial infarction, stroke, or AKI; zero observed events do not establish equivalence or a low true event rate.

6. Conclusion

In this small, retrospective, two-center cohort, concomitant PCI at the time of TAVR was not associated with an observed excess of bleeding or vascular complications compared with TAVR alone. These findings are hypothesis-generating and suggest that a concomitant strategy may be feasible in carefully selected patients treated at experienced, high-volume centers. Further larger prospective multicenter studies with longer follow-up are warranted.

Disclosures

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Declaration of competing interest

The authors declare that they have no known competing financial

interests or personal relationships that could have appeared to influence the work reported in this paper.

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