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ORIGINAL ARTICLE
Valvular heart disease

Clinical outcomes of percutaneous coronary interventions after transcatheter aortic valve replacement

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Aims The number of patients undergoing percutaneous coronary interventions (PCI) after transcatheter aortic valve replacement (TAVR) is expected to increase, but their prognosis remains poorly understood.

Methods and results Consecutive PCI patients with prior TAVR were compared to patients without prior TAVR between 2008 and 2023. The Kaplan–Meier method was used to estimate the 1-year incidence of major adverse cardiovascular events (MACE), defined as a composite of cardiovascular death or myocardial infarction. An entropy balance approach was implemented to adjust for imbalances in patient and procedural characteristics. Adjusted hazard ratios (HRs) were estimated using weighted Cox

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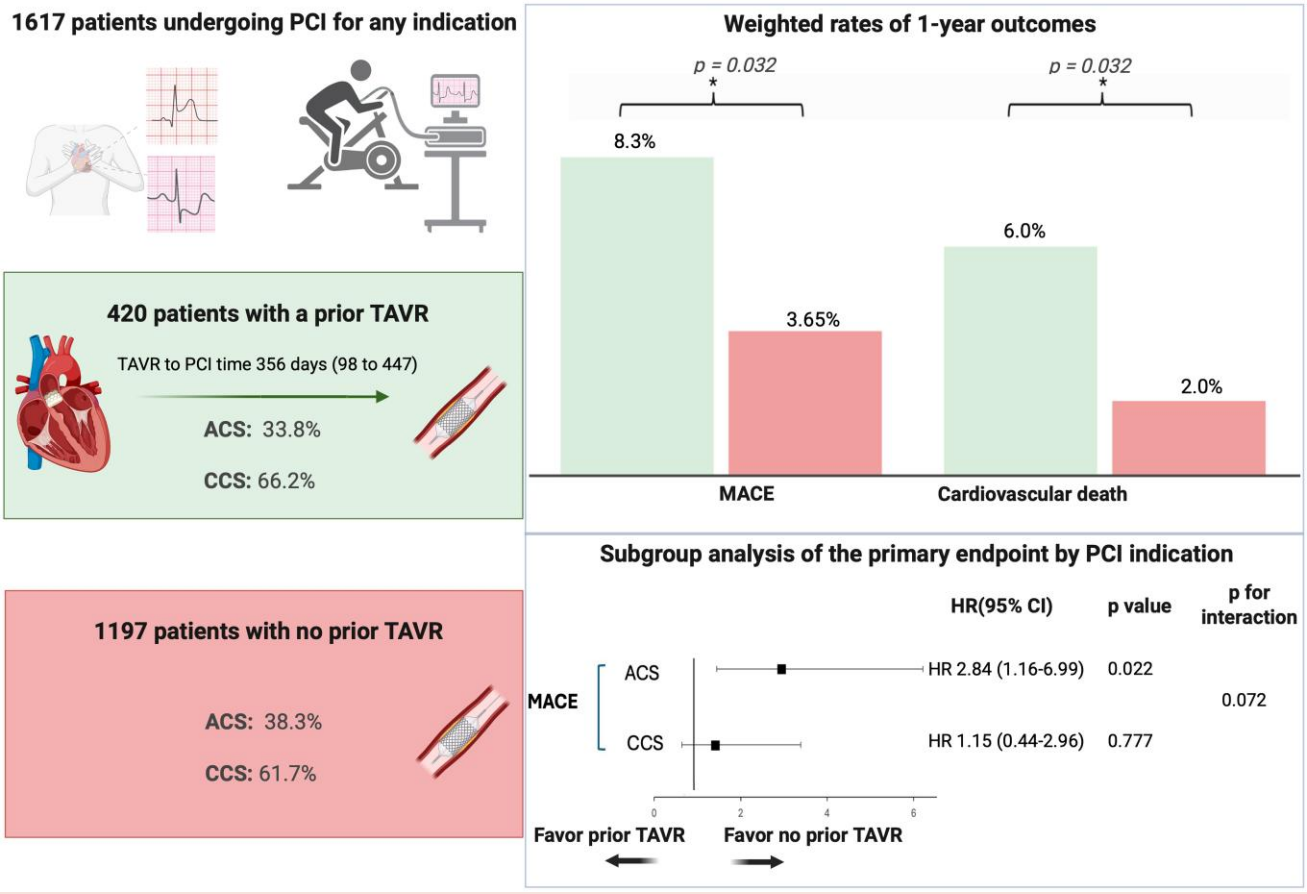
regression models. Comparing 420 PCI patients with prior TAVR (mean age 80.8 years, 37.1% women) to 1197 without (mean age 70.4 years, 24.6% women), 1-year MACE was higher in the prior TAVR group (8.7 vs. 3.7%; unadjusted HR 2.35, 95% CI 1.49–3.69; $P < 0.001$). After adjustment for clinical and procedural characteristics, prior TAVR remained associated with an increased risk of MACE (adjusted HR 2.36, 95% CI 1.08–5.16; $P = 0.032$). This was primarily driven by higher cardiovascular death (adjusted HR 3.12, 95% CI 1.10–8.79, $P = 0.032$), while the association with myocardial infarction was attenuated post-adjustment and no longer statistically significant.

Conclusion Patients undergoing PCI after TAVR experience a higher incidence of MACE compared to those undergoing PCI without prior TAVR, underscoring the importance of accurate patient selection before performing PCI in patients with chronic coronary syndrome and history of TAVR.

Graphical Abstract



Keywords Aortic stenosis • Coronary artery disease • PCI • TAVR

Introduction

Coronary artery disease (CAD) affects ~50% of patients undergoing transcatheter aortic valve replacement (TAVR) for severe aortic stenosis.[1] The coexistence of these conditions poses significant challenges in both the assessment and management of CAD, as their symptoms often overlap, making clinical management more complex. A key question revolves around the optimal timing and necessity of coronary revascularization, as balancing the treatment of both aortic stenosis and CAD requires careful consideration.

Current guidelines advocate for percutaneous coronary intervention (PCI) before TAVR in patients with significant CAD, especially those involving the proximal coronary segments or the left main artery.[2] However, these recommendations are mainly based on observational studies, and recent randomized controlled trials have yielded conflicting results regarding the benefits of pre-TAVR PCI.[3,4] Additionally, some observational studies suggest that in stable CAD patients without predominant coronary symptoms, PCI may safely be deferred until after TAVR, raising questions about whether upfront revascularization is necessary for all patients.[5–9]

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As TAVR is increasingly being used in younger and lower-risk patients with longer life expectancy, the need for post-TAVR is expected to rise.[10,11] Despite this trend, there is limited data on the long-term outcomes of PCI in patients after TAVR. Existing studies have mostly focused on acute coronary syndromes (ACS) following TAVR and have reported worse outcomes compared to patients experiencing ACS without prior TAVR. However, these studies may be confounded by older age and higher comorbidity burdens in the TAVR population, and few studies have appropriately adjusted for these factors.[12–16]

To help address these gaps, we designed the Revascularization after Aortic Valve Implantation (REVIVAL) study, a multicentre, international registry aimed at evaluating the long-term risk of adverse events in patients undergoing PCI after TAVR.

Methods

Study design and population

We compared the clinical outcomes of patients undergoing PCI after TAVR to those undergoing PCI without a prior TAVR by pooling individual participant data from different PCI registries. The institutional review board of each centre approved the protocols of corresponding studies, which were conducted following the ethical principles of the Declaration of Helsinki. Participants provided written informed consent before participating in each study.

The REVIVAL registry (NCT03283501) included consecutive patients undergoing PCI after TAVR in 21 centres across Europe from 2008 to 2023 (see Supplementary material online, *Table S1*). Both TAVR and PCI procedures were performed according to standard techniques, with device choice based on operator preference. Antithrombotic therapy and duration were left to the discretion of the treating physician, based on patient risk profiles. Individual participant data on baseline characteristics, PCI and TAVR procedures, antithrombotic regimen after PCI, and clinical outcomes were collected by each participating centre in a preformatted extraction sheet. These data were anonymized and merged into a core study dataset.

Patients undergoing PCI without prior TAVR were obtained by pooling the individual participant data of two multicentre PCI registries, namely, the POEM and RUDI-FREE studies. Details on the design of these studies have been published elsewhere.[17,18] Of note, both included patients undergoing PCI with the implantation of a new-generation drug-eluting stent (DES) and had very few exclusion criteria, such as cardiogenic shock, cardiac arrest, or acute decompensated heart failure. Accordingly, patients with cardiogenic shock, cardiac arrest, or acute decompensated heart failure were also excluded from the current analysis of the prior TAVR group. Finally, we excluded patients with missing data on pivotal clinical and procedural aspects (namely, left ventricular function, indication for PCI, and antithrombotic therapy).

Endpoints

The primary endpoint was major adverse cardiovascular event (MACE), defined as the composite of cardiovascular death or myocardial infarction (MI) at 1-year follow-up. Secondary outcomes included cardiovascular death, all-cause death, MI, target vessel revascularization (TVR), stroke, and definite or probable stent thrombosis at 1 year. Outcome definitions can be found in the Supplementary material online, *Table S2*.

Statistical analysis

Continuous variables were reported as mean ± standard deviation (SD) or median ± interquartile range (IQR), while categorical variables were expressed as absolute numbers and percentages. Patients undergoing PCI with prior TAVR (REVIVAL registry) were compared with those without prior TAVR (POEM and RUDI-FREE registries). Covariate balance between the two groups was assessed using the standardized mean difference (SMD), with an SMD less than 0.1 indicating good balance.

To estimate the effect of prior TAVR on clinical outcomes of patients undergoing subsequent PCI, we first performed unadjusted Cox regression to determine the crude effect. To control for confounding variables, we employed an entropy balance, a reweighting method that ensures covariates were balanced across the two groups at the time of PCI. Unlike propensity score weighting, which relies on estimated probabilities of treatment assignment, entropy balance directly incorporates knowledge of the covariate distributions into the reweighting process, aiming to achieve near-perfect balance in pre-specified covariates.[19] We selected entropy balance because it allows for a more flexible and precise adjustment of baseline differences, particularly in the presence of small sample sizes or substantial initial imbalances. This approach creates a weighted population in which key clinical and procedural characteristics are well matched before weight truncation, enhancing the validity of comparisons. Final weights were truncated at the 1st and 99th percentiles to reduce the influence of extreme weights and improve precision.

We computed three types of weighted models: one weighted for clinical confounding variables, a second weighted for procedural confounding variables, and a third weighted for both.

We estimated the 95% confidence intervals (CIs) using a robust variance estimator to account for potential correlations introduced by weighting. The effect of prior TAVR was estimated using weighted Cox regression models, including covariates that remained unbalanced after weight truncation, specifically age and clinical indication for PCI in models with clinical confounders. The Kaplan–Meier method was used to estimate both crude and weighted cumulative incidences.

Clinical variables included age, gender, hypertension, diabetes, dyslipidaemia, prior coronary revascularization (percutaneous or surgical), left ventricular ejection fraction (LVEF), chronic kidney disease, indication for PCI, and use of oral anticoagulation. Procedural variables encompassed the number and vessel location of treated lesions per patient (left main or left anterior descending artery), use of drug-coated balloons, calcified coronary disease (defined from the angiographic appearance), American College of Cardiology/American Heart Association (ACC/AHA) lesion complexity, and complex PCI (defined as at least one of the following: ≥3 vessels treated, ≥3 lesions treated, or bifurcation).

We performed a subgroup analysis according to clinical indication to PCI [chronic coronary syndrome (CCS) vs. ACS], after accounting for baseline imbalances in clinical and procedural characteristics in the different subpopulations. A formal interaction test was performed on the association between prior TAVR and MACE by clinical indication. Moreover, to better evaluate the impact of clinical indication for PCI on MACE in patients with prior TAVR, we employed multivariable Cox regression models, adjusting for clinical and procedural confounding variables.

Lastly, we calculated the *E*-value to assess how strongly an unmeasured confounder would need to be associated with both exposure to prior TAVR and the primary outcome to nullify the observed association. In other words, a larger *E*-value indicates a lower likelihood that unmeasured confounding has biased the observed adjusted HR. All analyses were performed using R (version 4.3.1).

Results

Out of 464 patients in the REVIVAL registry and 1547 patients in the POEM and RUDI-FREE registries, 420 patients in the prior TAVR group and 1197 patients in the PCI-only group were included in the analysis, mainly due to relevant missing data (LVEF, indication for PCI, antithrombotic therapy, Supplementary material online, *Figure S1*). The median time from TAVR to PCI was 356 days (IQR 98–447). There was a clear upward trend in the number of PCIs performed post-TAVR across the participating centres throughout the study period, with the median number of cases per centre increasing from one in 2008 to four in 2022 (*Figure 1*). As shown in Supplementary material online, *Table S3*, 48.8% of patients received a balloon-expandable valve, while 46.4% were implanted with a self-expandable valve. Two patients underwent TAVR in the setting of a valve-in-valve procedure (0.5%). Successful PCI in the prior TAVR occurred in 96.9% of the patients and complete revascularization in 69.2%.

Table 1 reports clinical and procedural characteristics in the prior TAVR and no prior TAVR cohorts in the crude population (before weighting) and weighted population (after weighting for clinical and procedural confounders).

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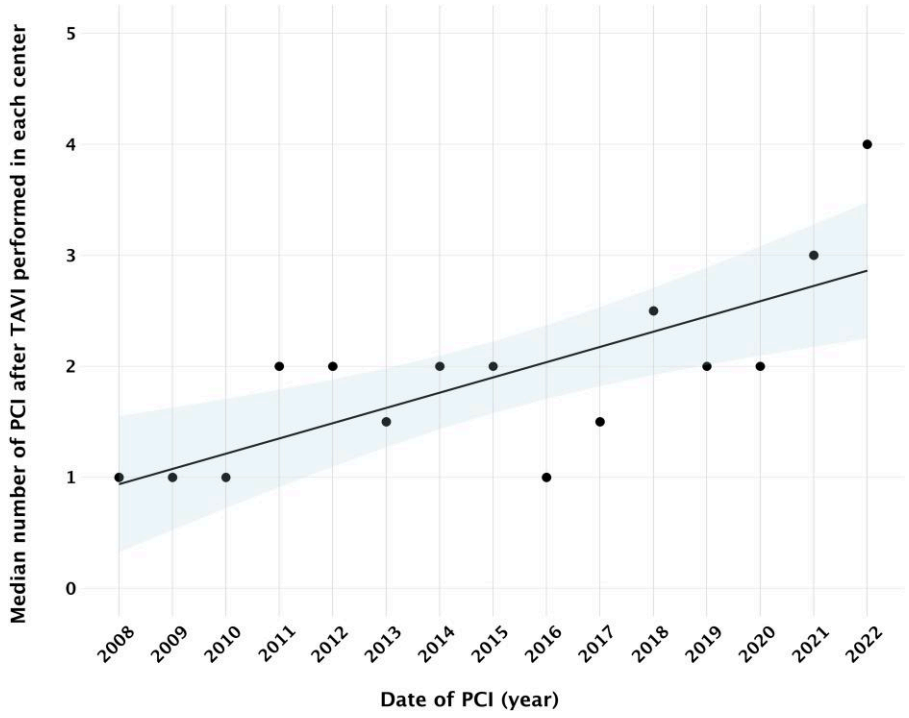

Figure 1 Temporal trend of PCI performed after TAVR across the participating centres from 2008 to 2022. The dots represent the median number of patients undergoing percutaneous coronary intervention (PCI) after transcatheter aortic valve replacement (TAVR) at each centre over the years. The black line represents the regression line illustrating the association between the median PCI count post-TAVR and time. The shaded blue area depicts the 95% confidence interval (CI) for the linear model.

Before weighting, prior TAVR patients were older (mean age 80.84 ± 6.06 vs. 70.41 ± 11.11 years, SMD = 1.165) and more likely to be women (37.1 vs. 24.6%, SMD = 0.273), to have been diagnosed with hypertension (90.2 vs. 81.2%, SMD = 0.260) and chronic kidney disease (21.0 vs. 15.2%, SMD = 0.106), and have had prior PCI (41.9 vs. 28.2%, SMD = 0.291), compared to those without prior TAVR. The prevalence of diabetes (31.4 vs. 32.3%, SMD = 0.019) and number of complex PCI (27.6 vs. 29.3%, SMD = 0.038) were similar in the two cohorts. Patients with a prior TAVR underwent PCI more frequently for CCS (66.2 vs. 61.7%, SMD = 0.234). Moreover, prior TAVR patients had higher rates of increased procedural complexity, with more severe coronary calcifications (24.3 vs. 16.8%, SMD = 0.186), left main PCIs (16.2 vs. 4.7%, SMD = 0.383), and ACC/AHA B2 to C lesions (70.0 vs. 64.6%, SMD = 0.116). Drug-coated balloon was used more frequently in the prior TAVR group (8.1 vs. 0.7%, SMD = 0.369).

After weighting, clinical and procedural characteristics were balanced between groups. However, truncation at the 1st and 99th percentiles resulted in an imbalance for age (SMD 0.250) and type of indication for PCI (SMD 0.175) (see Supplementary material online, *Figure S2*).

Outcomes before weighting

The median follow-up was 360 (IQR 353–360) days. The 1-year crude cumulative incidence of MACE was 8.7% in the prior TAVR group vs. 3.7% in the no prior TAVR group (HR 2.35, 95% CI 1.49–3.69, $P < 0.001$; *Table 2* and *Figure 2*). Similarly, prior TAVR patients had a higher risk of cardiovascular death (5.6% vs. 2.2%, HR 2.58, 95% CI 1.44–4.60, $P < 0.001$), MI (4.2% vs. 1.8%, HR 2.30, 95% CI 1.20–4.41, $P = 0.012$), all-cause death (9.5% vs. 6.6%, HR 1.56, 95% CI 1.04–2.32, $P = 0.030$), stroke (2.9% vs. 0.4%, HR 6.74, 95% CI 2.34–19.40, $P < 0.001$), and TVR (6.8% vs. 1.9%, HR 3.57, 95% CI 2.01–6.33, $P < 0.001$) as compared with no prior TAVR patients (*Table 2* and *Figure 2*).

Outcomes after weighting

Following weighting for clinical and procedural covariates, the primary endpoint remained significantly higher in the prior TAVR population with a 1-year MACE rate of 8.3% vs. 3.7% in the no prior TAVR population (HR 2.36, 95% CI 1.08–5.16, $P = 0.03$) (*Table 2* and *Figure 3*). The *E*-value analysis for the primary analysis suggested that an unobserved confounder would need to be associated with prior TAVR and MACE risk with a relative risk of 4.14 above and beyond the adjusted confounders, to explain the observed HR of 2.36.

Prior TAVR patients still had a higher risk of cardiovascular death (6.0 vs. 2.0%, HR 3.12, 95% CI 1.10–8.79, $P = 0.032$) as compared to no prior TAVR patients (*Table 2* and *Figure 3*). Conversely, MI, all-cause death, stroke, and TVR rates did not differ significantly between the two populations (MI, 3.15 vs. 2.0%, HR 1.55, 95% CI 0.64–3.76, $P = 0.331$; all-cause death, 10.4 vs. 6.1%, HR 1.75, 95% CI 0.85–3.58, $P = 0.129$; stroke, 1.8 vs. 0.6%, HR 2.90, 95% CI 0.55–15.28, $P = 0.209$; TVR, 4.6 vs. 2.7%, HR 1.73, 95% CI 0.76–3.94, $P = 0.192$) (*Table 2*). Supplementary material online, *Figure S3* visualizes the association between prior TAVR and 1-year clinical outcomes across all models: the first unadjusted, the second adjusted for clinical confounders, the third adjusted for procedural confounders, and the fourth adjusted for both.

Subgroup analysis by clinical presentation

In the subgroup analysis by indication for PCI, the crude analysis indicated that patients with prior TAVR were at a higher risk of MACE

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Table 1 Clinical and procedural characteristics in patients with and without prior TAVR before/after weighting

	Crude population			Weighted population[a]		
	Prior TAVR (n = 420)	No prior TAVR (n = 1197)	SMD	Prior TAVR (n = 343)	No prior TAVR (n = 1197)	SMD
Age, years	80.84 ± 6.06	70.41 ± 11.11	1.165	75.32 ± 6.95	73.12 ± 10.36	0.250
Women sex	156 (37.1)	297 (24.6)	0.273	100 (29.1)	334 (27.9)	0.024
Medical history						
Hypertension	379 (90.2)	972 (81.2)	0.260	292.2 (85.3)	999.9 (83.5)	0.047
Diabetes mellitus	132 (31.4)	387 (32.3)	0.019	119.6 (34.9)	384.0 (32.1)	0.060
Dyslipidaemia	308 (73.3)	766 (64.0)	0.202	217.1 (63.4)	795.0 (66.4)	0.064
Prior PCI	176 (41.9)	337 (28.2)	0.291	94.9 (27.7)	379.6 (31.7)	0.088
Prior CABG	63 (15.0)	95 (7.9)	0.223	36.6 (10.7)	116.8 (9.8)	0.030
LVEF, %	54.69 ± 11.80	50.03 ± 9.83	0.429	51.40 ± 12.74	51.24 ± 9.44)	0.014
Indication for PCI			0.234			0.175
CCS	278 (66.2)	738 (61.7)		234.2 (68.3)	751.9 (62.8)	
Unstable angina	84 (20.0)	195 (16.3)		39.7 (11.6)	206.5 (17.3)	
STEMI	22 (5.2)	124 (10.4)		26.8 (7.8)	108.1 (9.0)	
Non-STEMI	36 (8.6)	140 (11.7)		42.0 (12.3)	130.3 (10.9)	
eGFR < 45 mL/min/1.73m^2	88 (21.0)	201 (16.8)	0.106	59.0 (17.2)	213.9 (17.9)	0.017
Oral anticoagulation	106 (25.2)	182 (15.2)	0.252	64.2 (18.7)	213.0 (17.8)	0.024
Procedural characteristics						
Complex PCI[b]	116 (27.6)	351 (29.3)	0.038	102.3 (29.9)	345.7 (28.9)	0.021
Left main PCI	68 (16.2)	56 (4.7)	0.383	30.5 (8.9)	91.6 (7.7)	0.045
LAD PCI	184 (43.8)	654 (54.6)	0.218	186.8 (54.5)	620.3 (51.8)	0.054
No. of lesions per patient	1.38 ± 0.75	1.53 ± 0.89	0.183	1.53 ± 0.92	1.50 ± 0.85	0.041
Drug-coated balloon	34 (8.1)	8 (0.7)	0.369	8.4 (2.5)	30.9 (2.6)	0.008
Calcified lesion	102 (24.3)	201 (16.8)	0.186	65.9 (19.2)	224.3 (18.7)	0.012
ACC/AHA B2/C lesion	294 (70.0)	773 (64.6)	0.116	218.0 (63.6)	789.7 (66.0)	0.049

Values are mean ± SD or n (%).
ACC/AHA, American College of Cardiology/American Heart Association; CABG, coronary artery bypass grafting; CCS, chronic coronary syndrome; LAD, left anterior descending artery; eGFR, estimated glomerular filtration rate; LVEF, left ventricular ejection fraction; PCI, percutaneous coronary intervention; SD, standard deviation; SMD, standardized mean difference; STEMI, ST-elevation myocardial infarction; TAVR, transcatheter aortic valve replacement.
[a]The weighted model is presented which includes both clinical and procedural characteristics. Weights are truncated at the 1st and 99th percentiles.
[b]Complex PCI was defined as at least one among ≥3 vessels treated, ≥3 lesions treated, or bifurcation.

compared to those without prior TAVR, regardless of whether they presented with CCS (HR 1.77, 95% CI 0.90–3.47, $P = 0.094$) or ACS (HR 3.27, 95% CI 1.76–6.09, $P < 0.001$; P for interaction = 0.184). However, after adjusting for clinical and procedural confounders, we observed a trend towards interaction with clinical presentation (P for interaction = 0.072), where the association between prior TAVR and MACE was stronger in the ACS subgroup (HR 2.84, 95% CI 1.16–6.99, $P = 0.022$) compared to the CCS subgroup (HR 1.15, 95% CI 0.44–2.96, $P = 0.777$).

The multivariable Cox regression analysis assessing the association between PCI indication and MACE in patients with prior TAVR confirmed a higher risk of MACE in those with ACS (adjusted HR 2.20, 95% CI 1.26–3.81, $P = 0.005$) compared to CCS. Among all the clinical and procedural variables included in the model, only PCI failure was strongly associated with MACE (adjusted HR 4.34, 95% CI 1.41–14.29, $P = 0.01$).

Discussion

This study represents the largest and most comprehensive analysis to date on long-term clinical outcomes of PCI after TAVR. Our findings reveal an increasing number of patients with prior TAVR undergoing PCI across Europe. These patients are at a significantly higher risk of MACE at 1-year follow-up. After comprehensive adjustment for clinical and procedural confounders, this heightened risk was primarily driven by an increase in cardiovascular death, while the association with myocardial infarction was attenuated. We find these findings of particular clinical relevance since they underscore the need for careful patient selection prior to performing PCI in patients with CCS and a history of TAVR.

The poorer outcome of patients undergoing PCI with prior TAVR is likely multifactorial. One key factor is patient complexity; the prior TAVR group was older, with a higher burden of comorbidities such as chronic kidney disease and prior revascularization, all associated with worse cardiovascular outcomes. However, after adjusting for these variables, the risk for MACE of prior TAVR compared to no prior TAVR remained relatively constant, suggesting that other factors are contributing to the increased risk.

The clinical characteristics of prior TAVR patients—including advanced age, higher comorbidity burden, and myocardial remodelling due to severe aortic stenosis—may account for a higher proportion of patients presenting in unstable clinical conditions and with higher Killip classes compared to those without prior TAVR, as reported in

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Table 2 One-year clinical outcomes in patients with and without prior TAVR before/after weighting

	Before weighting				After weighting			
	Prior TAVR ($n = 420$)	No prior TAVR ($n = 1197$)	HR (95% CI)	*P*-value	Prior TAVR ($n = 343$)	No prior TAVR ($n = 1197$)	HR (95% CI)	*P*-value
MACE	8.7%	3.7%	2.35 (1.49–3.69)	< 0.001	8.3%	3.7%	2.36 (1.08–5.16)	0.032
All-cause death	9.5%	6.6%	1.56 (1.04–2.32)	0.030	10.4%	6.1%	1.75 (0.85–3.58)	0.129
CV death	5.6%	2.2%	2.58 (1.44–4.60)	< 0.001	6.0%	2.0%	3.12 (1.10–8.79)	0.032
MI	4.2%	1.8%	2.30 (1.20–4.41)	0.012	3.1%	2.0%	1.55 (0.64–3.76)	0.331
Stroke	2.9%	0.4%	6.74 (2.34–19.40)	< 0.001	1.8%	0.6%	2.90 (0.55–15.28)	0.209
Stent thrombosis	1.6%	1.3%	1.20 (0.46–3.09)	0.708	1.0%	1.5%	0.88 (0.32–2.42)	0.807
TVR	6.8%	1.9%	3.57 (2.01–6.33)	< 0.001	4.6%	2.7%	1.73 (0.76–3.94)	0.192

Results from the weighted model adjusting for both clinical and procedural characteristics are presented. Weights are truncated at the 1st and 99th percentiles.
CI, confidence interval; HR, hazard ratio; CV, cardiovascular; MACE, major adverse cardiovascular events; MI, myocardial infarction; TAVR, transcatheter aortic valve replacement; TVR, target vessel revascularization.
Incidence rates are Kaplan–Meier estimates in the crude and weighted population at 1-year follow-up.

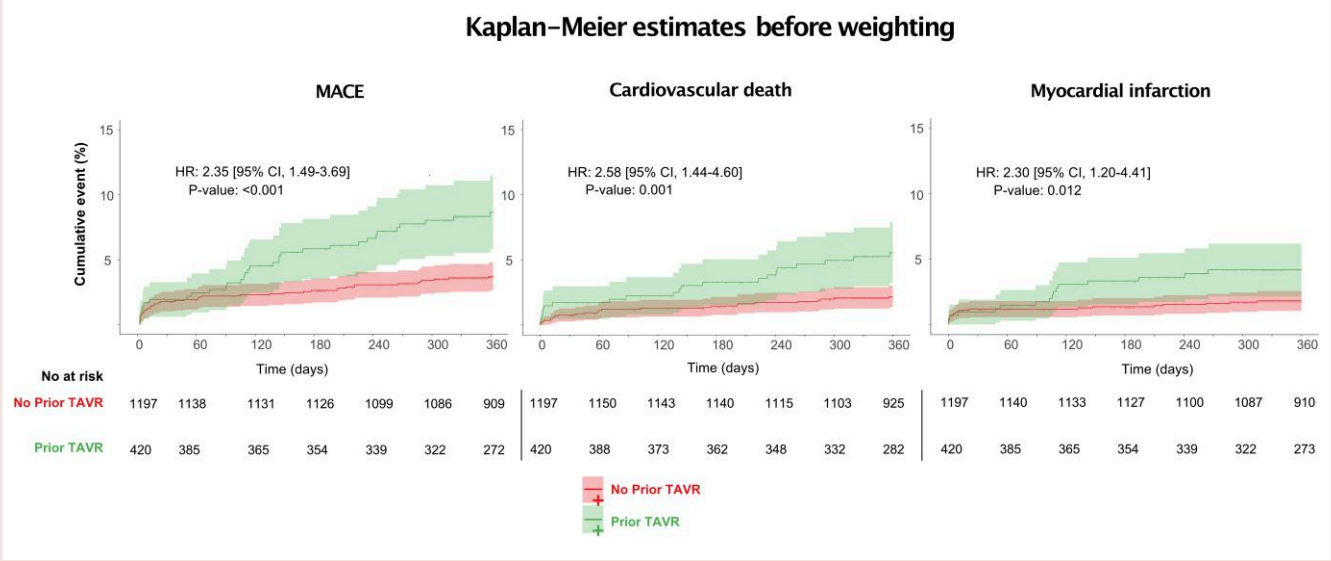

Figure 2 Kaplan–Meier estimates of 1-year clinical outcomes in the crude population. CI, confidence interval; CV, cardiovascular; HR, hazard ratio; MACE, major adverse cardiovascular events; MI, myocardial infarction; TAVR, transcatheter aortic valve replacement.

the literature.[13,20] Procedural challenges also play a significant role. Accessing coronary arteries post-TAVR is complicated by the presence of the transcatheter valve, which can obscure the coronary ostia and hinder catheter engagement.[21–23] Consequently, higher PCI failure rates, longer door-to-balloon times, increased use of fluoroscopy time, more contrast, higher femoral access rates, the need for multiple guide catheters during PCI, and increased haemodynamic instability have been reported in post-TAVR patients compared to those without prior TAVR.[13] These issues are particularly critical in the context of STEMI, potentially explaining why prior studies found that PCI after TAVR was associated with worse outcomes in this setting.[13,15] Conversely, non-STEMI patients with prior TAVR have been associated with better outcomes than those without prior TAVR.[15] It is noteworthy that in these studies, about half of the patients did not undergo PCI, follow-up was limited to in-hospital events or a median of seven months, and data on patients undergoing PCI for CCS were lacking.

Our subgroup analysis showed that the risk of MACE was particularly pronounced in patients with ACS who had undergone prior TAVR. After adjusting for clinical and procedural variables, the association between prior TAVR and MACE remained significant in the ACS group (HR 2.84, 95% CI 1.16–6.99, $P = 0.022$), while it was attenuated in patients presenting with CCS (HR 1.15, 95% CI 0.44–2.96, $P = 0.777$; P for interaction = 0.072). This suggests that the TAVR population is more vulnerable to adverse outcomes in the acute setting, possibly due to the greater haemodynamic instability and anatomical challenges in accessing coronary arteries post-TAVR.[13]

Future iterations of prosthetic valve profiles, alongside new techniques such as commissural and coronary alignment, intentional leaflet laceration,

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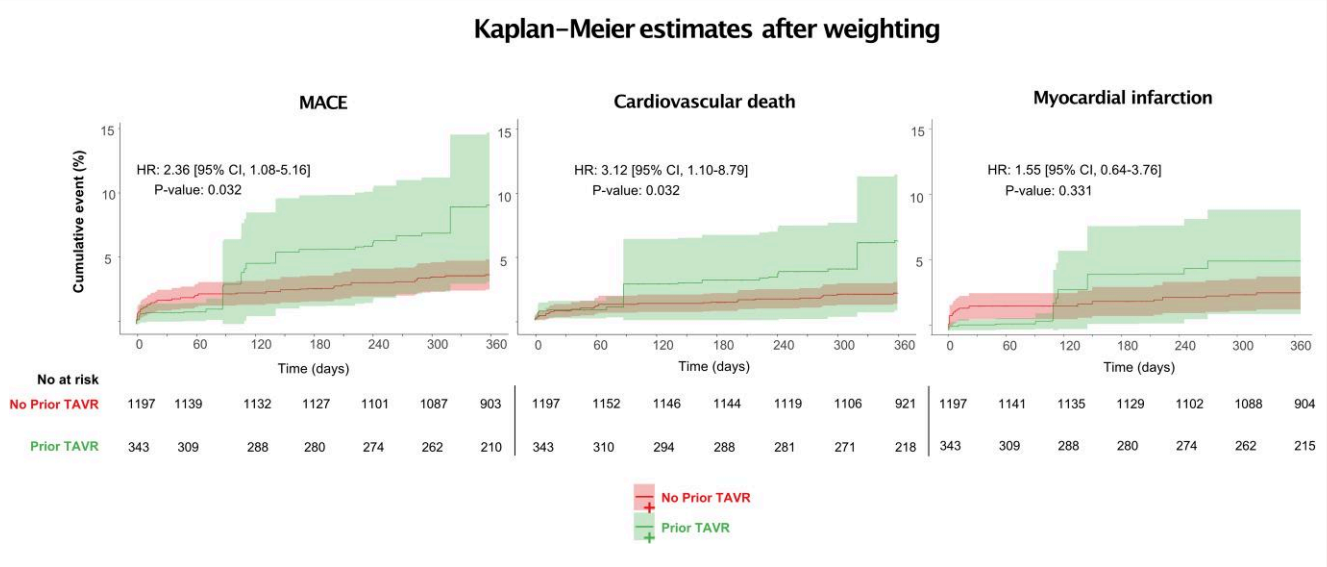

Figure 3 Kaplan–Meier estimates of 1-year clinical outcomes after adjusting for clinical and procedural characteristics. CI, confidence interval; CV, cardiovascular; HR, hazard ratio; MACE, major adverse cardiovascular events; MI, myocardial infarction; TAVR, transcatheter aortic valve replacement.

and advanced pre-procedural planning—including CT-guided PCI—may alter this landscape and improve outcomes for these patients.[21–31]

Limitations

The primary limitation of our study is its observational design, which inherently prevents the elimination of bias from residual confounding. Furthermore, as with all observational studies relying on registry data and re-weighting methodologies like entropy balancing, the accuracy of our results is contingent upon the quality and completeness of the data collected by participating centres and the assumption that recorded covariates accurately reflect the patient characteristics. To address potential unmeasured confounding, we calculated an E-value, which indicates that any unmeasured confounder would need a risk ratio of at least 4.14 associated with both prior TAVR exposure and the primary endpoint to nullify our observed adjusted HR of 2.36. However, it is important to acknowledge that while the E-value provides a useful measure of sensitivity to unmeasured confounding, it does not account for other potential sources of bias, such as selection bias or measurement error, nor does it address the theoretical possibility of bias amplification, where statistical adjustment could, under certain conditions, interact with unmeasured confounders.

A second key limitation is the potential for selection bias. REVIVAL investigators at each centre voluntarily reported cases of PCI after TAVR without external monitoring to verify data accuracy. This could explain the high PCI success rate of 96.9% observed in the TAVR group, although this rate aligns with other studies less susceptible to such bias, which reported success rates ranging from 93 to 99%.[32,33] If this potential selection bias led to an overestimation of PCI success rates, our study might underestimate the true risk of MACE in a more generalizable post-TAVR PCI population, suggesting our primary finding is conservative.

Third, while this is the largest study to date on this topic, the sample size remains relatively modest. This increases the risk of type II error, particularly for some secondary outcomes and subgroup analyses, leading to wider confidence intervals. The extended data collection period from 2008 to 2023, necessary due to the low incidence of PCI after TAVR, also encompasses significant evolution in both TAVR and PCI technologies and operator experience, representing a potential source of unmeasured temporal confounding. Consequently, our findings require validation with more recent, larger databases as they become available.

Finally, the follow-up period was limited to 1 year. While the 1-year follow-up is standard for many PCI studies, it may not fully capture the complete long-term event trajectories. This is particularly relevant in the heterogeneous post-TAVR PCI population, where the risk profiles and outcomes for different PCI indications (e.g. ACS early post-TAVR vs. CCS late post-TAVR) might diverge significantly beyond this initial year. Future studies with extended follow-up are essential to elucidate these longer-term patterns and the potential differential impact of prior TAVR across these subgroups over time.

Conclusions

Patients undergoing PCI after TAVR face a higher incidence of MACE compared to those without prior TAVR. These findings highlight the importance of thorough coronary artery disease management before and during TAVR, as well as the added complexity of post-TAVR PCI, particularly in acute settings. Further research is essential to refine revascularization strategies and improve long-term outcomes in this expanding patient population.

Lead author biography

Carlo Andrea Pivato completed medical training at Vita-Salute San Raffaele University (Milan), followed by a cardiology residency at Humanitas University (Milan). He conducted a research fellowship at the Icahn School of Medicine at Mount Sinai (New York) and obtained a PhD in Data Science and Medicine from Humanitas University (Milan), including a research period at the Health Data Science Center, Human Technopole (Milan). He specialized in echocardiography at

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Humanitas Research Hospital and currently practices as a cardiologist at Humanitas Research Hospital and Humanitas Mater Domini.

Data availability

The data underlying this article will be shared on reasonable request to the corresponding author.

Supplementary material

Supplementary material is available at *European Heart Journal Open* online.

Author contributions

Carlo Andrea Pivato (Project administration, Conceptualization, Methodology, and Writing—review & editing), Ottavia Cozzi (Writing—original draft), Nicole Fontana, Francesca Ieva (Formal analysis, Methodology, and Writing—review & editing), Gianluigi Condorelli (Supervision and Writing—review & editing), Cosmo Godino, Bernhard Reimers, Masaaki Nakase, Karsten Hug, Antonio Munoz-Garcia, Victor Alfonso Jimenez Diaz, Alfonso Ielasi, Marco Barbanti, Luigi Biasco, Darren Mylotte, Tobias Rheude, Massimo Leoncini, Jose Maria de la Torre Hernandez, Giorgio Quadri, Angelo Anzuini, Diego Lopez, Philippe Garot, Jorn Brouwer, Antonio Mangieri, Damiano Regazzoli, Ferdinando Varbella, Luca Testa, Daijiro Tomii, Alaide Chieffo, Michael Joner, Gennaro Sardella, Enrico Cerrato, Luis Nombela-Franco, Jorge Sanz Sanchez, Thomas Pilgrim (Investigation and Writing—review & editing), and Giulio Stefanini (Supervision and Writing—review & editing)

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