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EDITORIAL

Transcatheter aortic valve implantation with complex, high-risk indicated PCI

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The management of severe aortic stenosis (AS) with concomitant coronary artery disease (CAD) is one of the most challenging questions posed to the Heart Team. Once the decision for aortic valve intervention is made, which patients should undergo revascularisation and when this should be performed remain open to debate[1].

Concomitant CAD and AS is present in more than half of the transcatheter aortic valve implantation (TAVI) population and is associated with worse outcomes than AS in isolation. Such patients tend to exhibit more comorbidities, have challenging vascular access and reduced left ventricular function. The ACTIVATION trial failed to show any benefit from pre-TAVI percutaneous coronary intervention (PCI), but it did show a significant increase in bleeding in the comorbid TAVI population[2]. NOTION-3 demonstrated that in a less comorbid population, pre-TAVI PCI in patients with single vessel disease reduced the rate of post-TAVI urgent revascularisation[3]. However, these were patients with predominantly single vessel CAD, with significant left main stem (LMS) disease excluded.

Armed with this evidence, the decision to perform PCI often resides with the TAVI operator, taking into account the risk of acute kidney injury, bleeding with dual antiplatelet therapy, concomitant atrial fibrillation and therefore combined anticoagulation strategies, symptoms and acuity of presentation, and the ischaemic burden posed by PCI. The presence of complex CAD and/or need for high-risk PCI further adds to this complex treatment paradigm, and data are lacking.

In this issue of EuroIntervention, Montalto et al[4] report the findings of the observational, multicentre, international registry of Aortic Stenosis with COmplex PCI (ASCoP). The aim of the registry was to define current practice over a 10-year period, including prevalence, patient characteristics, procedural strategies and predictors of outcome in patients in whom a decision for complex PCI and TAVI had been made with comparison of concomitant versus staged PCI.

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Complex, high-risk and indicated PCI (CHIP) was defined as unprotected LMS or equivalent, only remaining coronary, proximal bifurcation, calcium debulking, lesion length ≥30 mm, severe left ventricular systolic dysfunction or need for mechanical haemodynamic support **(Table 1)**. Of 18,333 patients treated with TAVI (both balloon-expandable and self-expanding platforms), 519 (2.8%) CHIP patients were identified. Of these, 156 (30.1%) underwent concomitant PCI, and 363 (69.9%) were staged, the vast majority of which were prior to TAVI. In terms of lesion characteristics, one-third underwent LMS PCI, and just under half of patients underwent bifurcation PCI or extensive stenting with one-quarter requiring calcium modification. Only 15% presented with acute coronary syndrome, and only 3.5% of cases necessitated haemodynamic support.

The majority (99%) were discharged alive with technical success achieved in 95%; however, in-hospital complications were high: 10% vascular complications and 7% acute kidney injury with bleeding rates threefold higher in the concomitant PCI group compared to the staged PCI group. For the primary endpoint of death or heart failure hospitalisation, there was no difference between the concomitant or staged PCI groups; however, major adverse cardiac and cerebrovascular event rates were more than double in the first 30 days in the concomitant PCI group (16% vs 6%), driven by bleeding and vascular complications. Predictors for poor outcome included left ventricular ejection fraction, platelet count and baseline renal function.

The ASCoP registry presents us with invaluable data regarding the increased risk associated with TAVI and concomitant PCI compared to staged PCI. Although limited by its retrospective observational nature, there is a clear signal towards a higher risk of vascular complications and bleeding

Table 1. Characteristics of ACTIVATION, NOTION-3 and the ASCoP registry.

Feature	ACTIVATION	NOTION-3	ASCoP
Symptoms	CCS 3-4: <1% NYHA III-IV: 61% ACS within 30 days excluded	CCS 3-4: 8% NYHA III-IV: 46% ACS within 14 days excluded	CCS 3-4: 21% NYHA III-IV: 54% ACS 15%
No. of participants	TAVI+PCI: 109 (52%) TAVI only: 102 (48%) Total: 211	TAVI+PCI: 227 (50%) TAVI only: 228 (50%) Total: 455	Staged (before): 352 (64%) Concomitant: 156 (30%) Staged (after): 33 (6%) Total: 519
Median follow-up	1 year	2 years	1 year
Lesion characteristics	≥70% stenosis or ≥50% if protected LMS LMS excluded	>90% stenosis or FFR <0.80 LMS excluded	LMS: 33% Bifurcation: 37% Calcium modification: 25% Extensive stenting >30 mm: 40% MCS: 3.5% ≥2 CHIP features: 62%
No. of vessels for intervention	1 vessel: 71% 2 vessels: 24% 3 vessels: 2%	1 vessel: 80% 2 vessels: 17% 3 vessels: 4%	1 vessel: unknown 2 vessels: 37% 3 vessels: 27%
% of patients with a balloon-expandable THV	89-94%	40-42%	31%
Timing of PCI	Before: 100%	Before: 74% Concomitant: 17% After: 9%	Before: 64% Concomitant: 30% After: 6%
Mortality	PCI vs TAVI only: 13.4% vs 12.1% (HR 1.00, CI: 0.49-2.06)	PCI vs TAVI only: 8.4% vs 7.3% (HR 0.85, CI: 0.59-1.23)	Concomitant vs staged: 8.8% vs 8.8%
Primary endpoint*	PCI vs TAVI only: 42% vs 44% (Absolute diff: –2.5%; 1-sided 95% CI: 8.5%)	PCI vs TAVI only: 26% vs 36% (HR 0.71, CI: 0.51-0.99)	Concomitant vs staged: 36.1% vs 36.7%
MACCE**	PCI vs TAVI only: 19.3% vs 19.0% (HR 1.22, CI: 0.74-2.02)	Primary endpoint	Concomitant vs staged: 25.8% vs 17.4%
Bleeding	PCI vs TAVI only: 26% vs 18% (HR 1.44, CI: 0.83-2.51)	PCI vs TAVI only: 28% vs 20% (HR 1.51, CI: 1.03-2.22)	Concomitant vs staged: 10.9% vs 3.9%

*Primary endpoints: ACTIVATION: all-cause mortality or rehospitalisation; NOTION-3: all-cause mortality, MI, urgent revascularisation; ASCoP: all-cause mortality and first unplanned hospitalisation for cardiovascular cause. **MACCE endpoints: ACTIVATION: all-cause mortality, MI, stroke, AKI; NOTION-3: primary endpoint; ASCoP: all-cause mortality, stroke, MI, major bleeding, major vascular complication, unplanned revascularisation. ACS: acute coronary syndrome; AKI: acute kidney injury; CCS: Canadian Cardiovascular Society; CHIP: complex, high-risk and indicated PCI; CI: confidence interval; FFR: fractional flow reserve; HR: hazard ratio; LMS: left main stem; MACCE: major adverse cardiac and cerebrovascular events; MCS: mechanical circulatory support; NYHA: New York Heart Association; PCI: percutaneous coronary intervention; TAVI: transcatheter aortic valve implantation; THV: transcatheter heart valve

in a fragile, elderly cohort of patients. The post-TAVI staged PCI group was small; thus, the benefit was driven by the pre-TAVI staged PCI. However, the question remains as to whether complex, high-risk PCI in TAVI patients is in fact indicated.

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Conflict of interest statement

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