ACC.26

Deferral of PCI in Patients Undergoing TAVI (PRO-TAVI)

an Investigator-Initiated, Multicenter, Open-Label, Noninferiority, Randomized Controlled Trial

Prof. M. Voskuil, MD, PhD

Interventional Cardiologist – UMC Utrecht, The Netherlands

On behalf of the PRO-TAVI Investigators

AMERICAN COLLEGE of CARDIOLOGY

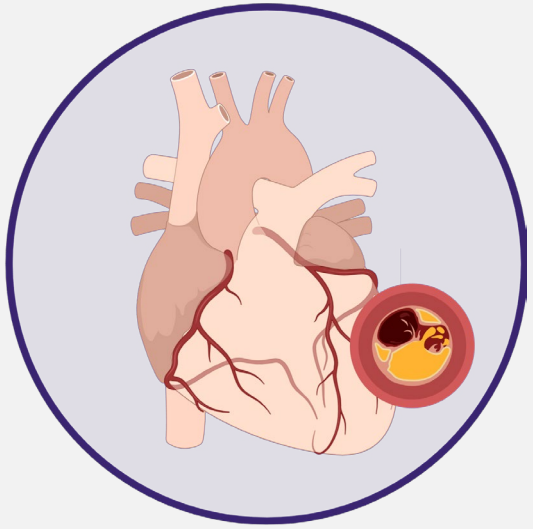
Financial disclosures to declare

Personal disclosures

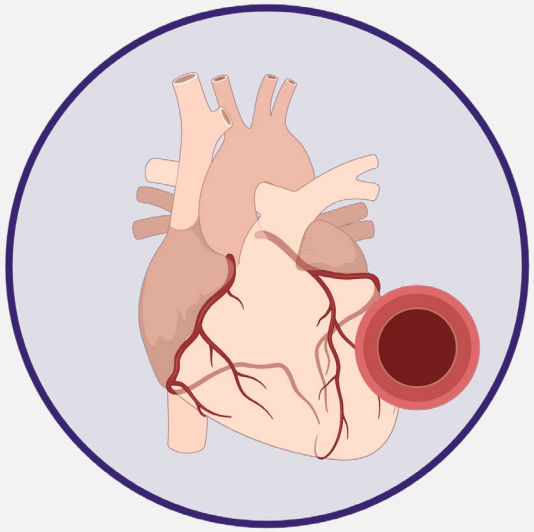
Nothing to declare

Funded by

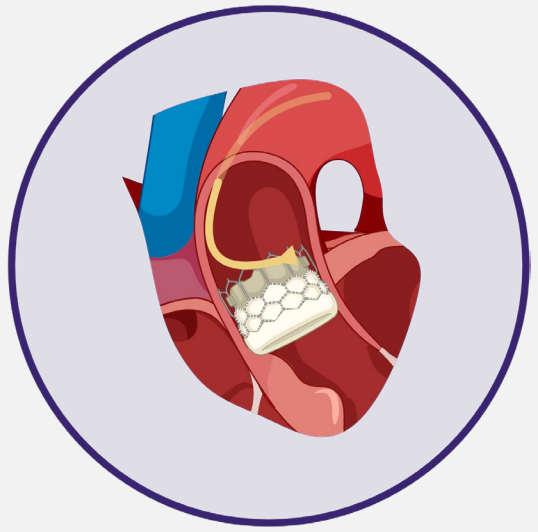
Coronary artery disease in TAVI



Coronary artery disease is common in patients undergoing TAVI



Complete revascularization reduces risk of procedural myocardial infarction



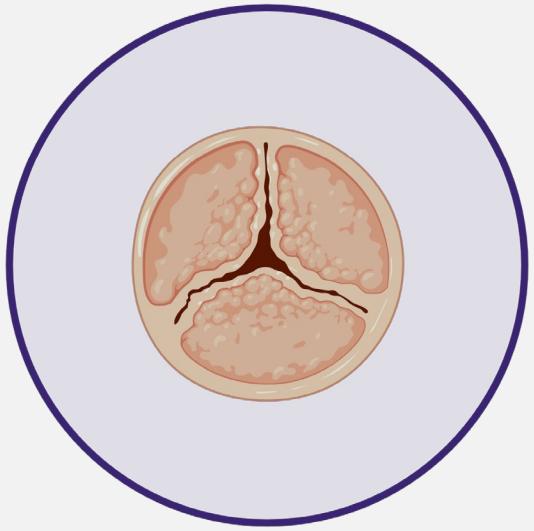
Coronary access after TAVI may be technically challenging

Current guideline recommendations

2020 ACC/AHA Guidelines[1]	2a	C-LD	In patients undergoing TAVI with significant left main or proximal CAD with or without angina, revascularization by PCI before TAVI is reasonable.
2025 ESC/EACTS Guidelines[2]	IIb	B	PCI may be considered in patients with a primary indication to undergo TAVI and coronary artery stenosis ≥70% in proximal segments of main vessels.
2025 ESC/EACTS Guidelines[2]	IIa	B	PCI should be considered in patients with a primary indication to undergo TAVI and ≥90% coronary artery stenosis in segments with a reference diameter ≥2.5 mm.

[1]Otto, C. M., et al. (2021). Circulation
[2]Praz, F., et al. (2025) European Heart Journal

TAVI with prior PCI



Severe aortic stenosis during PCI

Increased bleeding risk with dual antiplatelet therapy

Patient burden and healthcare cost

Trial aim

The PRO-TAVI trial investigates the noninferiority of deferral of PCI in patients undergoing TAVI

Trial design

Investigator-initiated, multicenter randomized controlled trial in the Netherlands

Primary composite end point at one-year follow-up

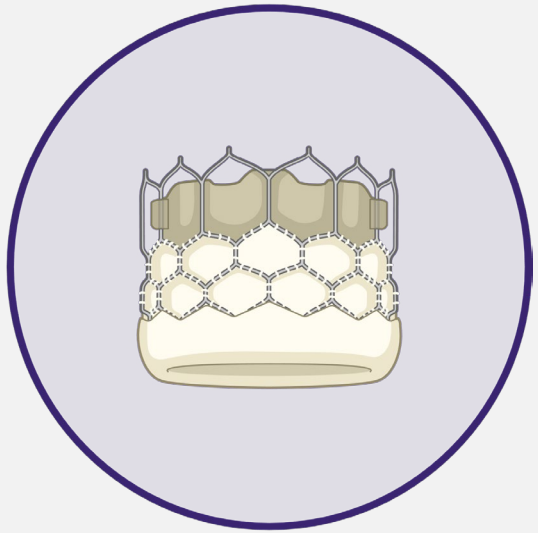
All-cause mortality
Myocardial infarction
Stroke
Major bleeding (type 2 to 4)

In accordance with VARC-3

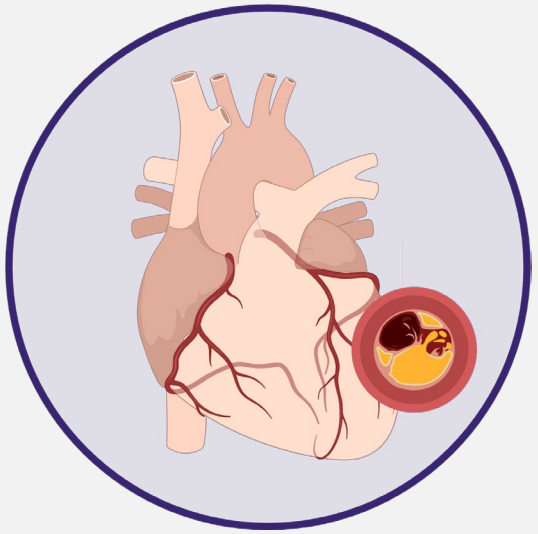
Total sample size 466 patients

Event rates:	15%
Noninferiority margin:	11%
Power:	90%
Alpha:	2.5%
Loss to follow-up:	5%

Eligibility criteria



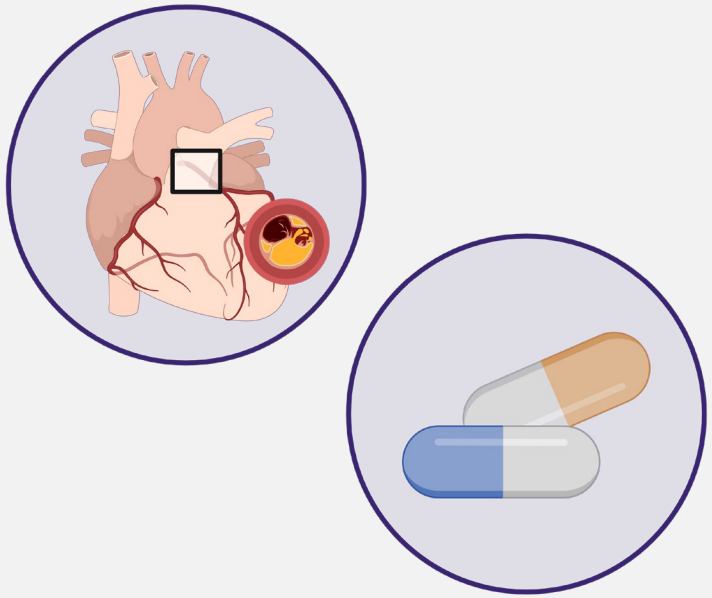
Indication for TAVI



Coronary artery disease

Stenosis 70-99%

Stenosis 40-70% with positive physiological parameter

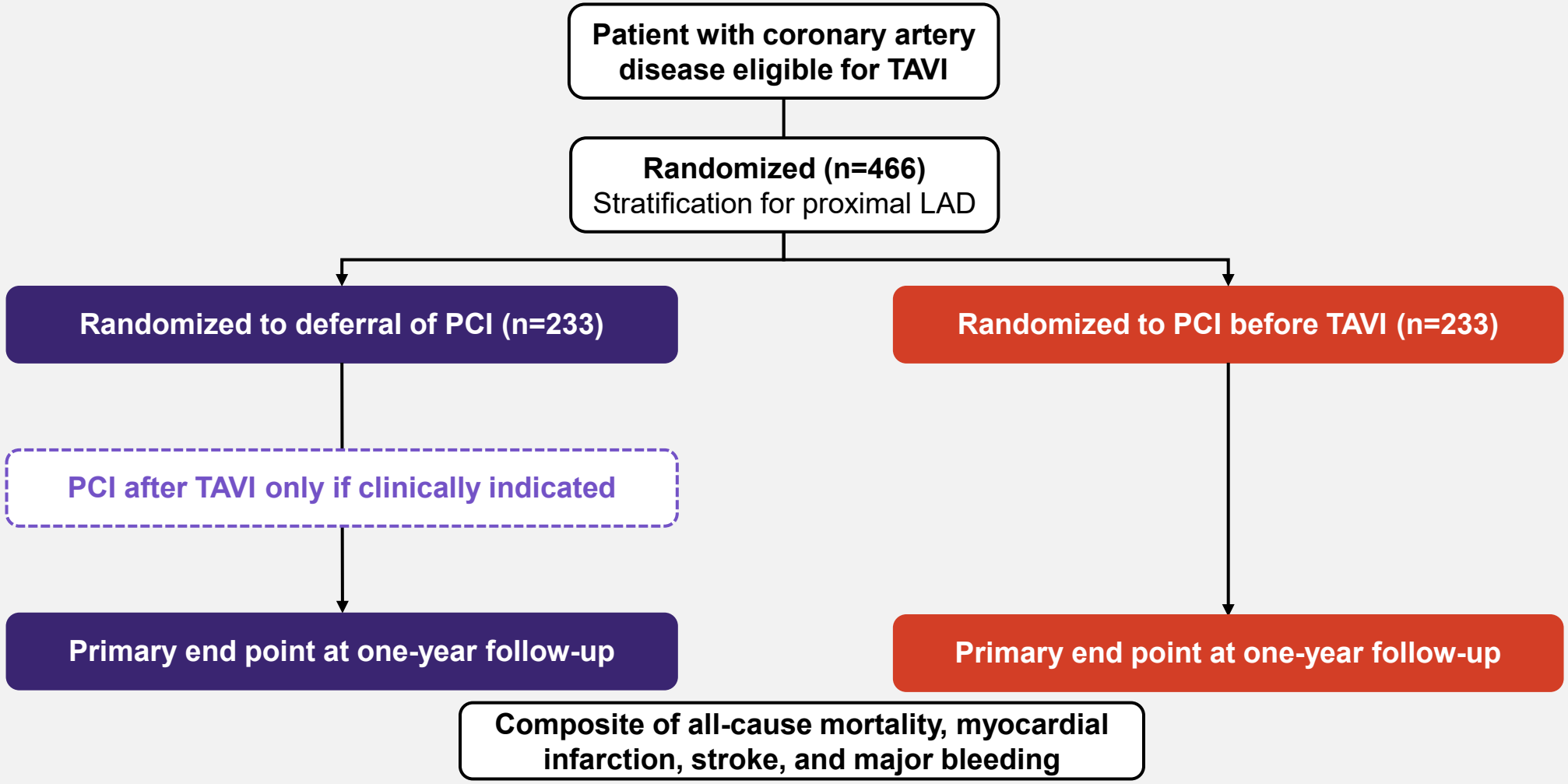


Key exclusion criteria

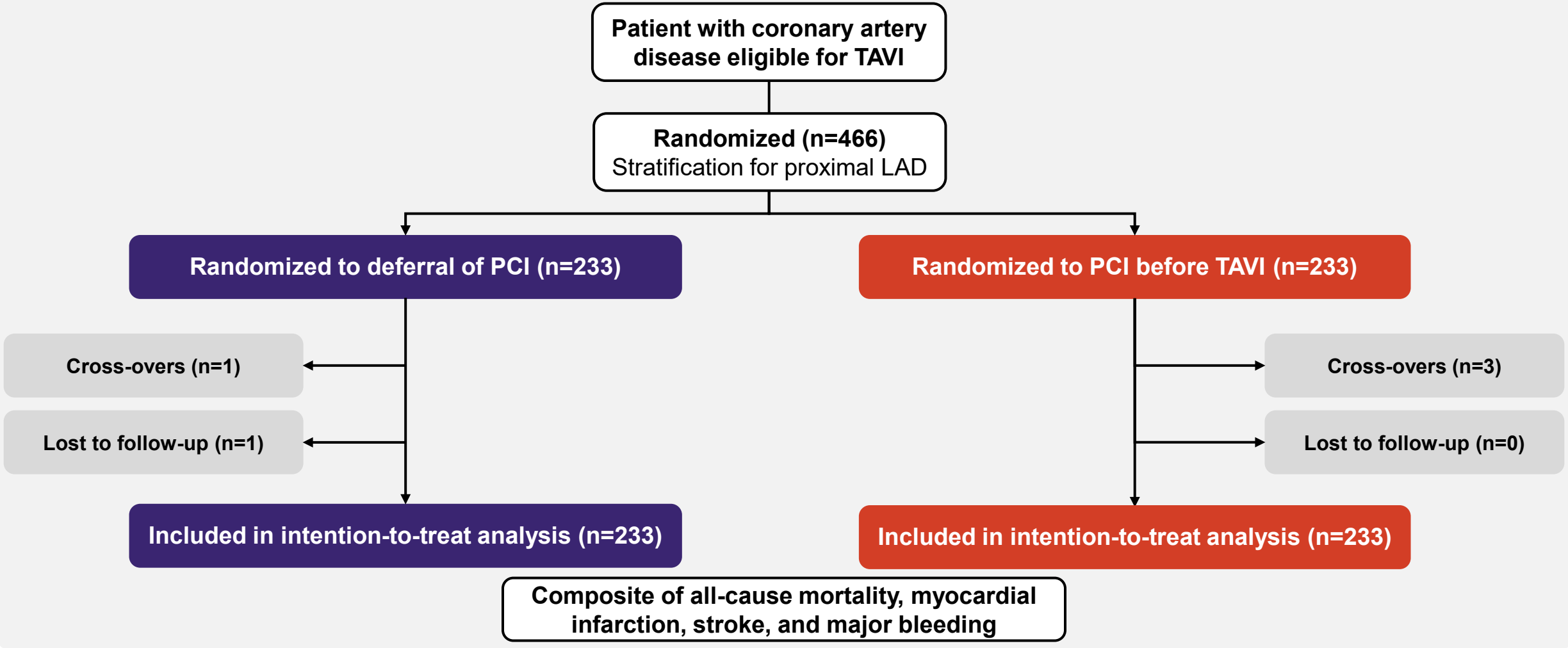
Unprotected left main stenosis

Contraindication for dual antiplatelet therapy

Trial flow


Patient with coronary artery disease eligible for TAVI
Randomized (n=466)
Stratification for proximal LAD
Randomized to deferral of PCI (n=233)
Randomized to PCI before TAVI (n=233)
PCI after TAVI only if clinically indicated
Primary end point at one-year follow-up
Primary end point at one-year follow-up
Composite of all-cause mortality, myocardial infarction, stroke, and major bleeding

Trial flow


Patient with coronary artery disease eligible for TAVI
Randomized (n=466)
Stratification for proximal LAD
Randomized to deferral of PCI (n=233)
Randomized to PCI before TAVI (n=233)
Cross-overs (n=1)
Lost to follow-up (n=1)
Cross-overs (n=3)
Lost to follow-up (n=0)
Included in intention-to-treat analysis (n=233)
Included in intention-to-treat analysis (n=233)
Composite of all-cause mortality, myocardial infarction, stroke, and major bleeding

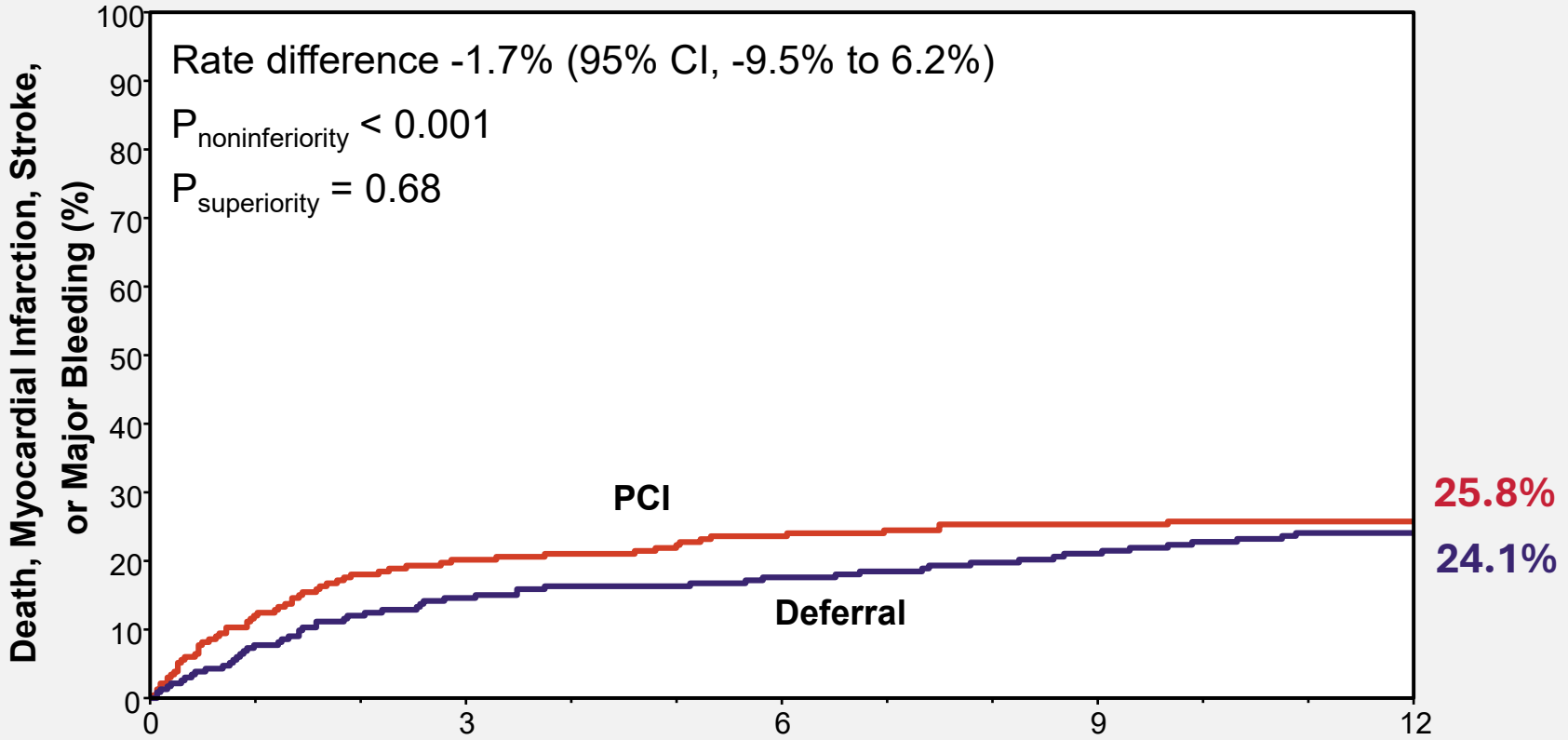
Baseline characteristics

	Deferral (n=233)	PCI (n=233)
Age, years	81 (77-84)	81 (78-84)
Female sex	84 (36)	82 (35)
Anginal complaints	85 (36)	103 (44)
Cardiac History		
Previous PCI	47 (20)	51 (22)
Previous CABG	13 (6)	19 (8)
Previous SAVR	5 (2)	8 (3)
Atrial fibrillation	80 (34)	82 (35)
Risk score		
STS-PROM score	3.1 (1.9-4.9)	3.1 (2.0-5.2)
Echocardiographic variables		
Aortic valve area, cm^2	0.8 (0.7-0.9)	0.8 (0.7-0.9)
Peak pressure gradient, mmHg	68 (55-84)	66 (52-78)
Preserved ejection fraction (≥50%)	175 (75)	166 (71)

Angiographic and procedural characteristics

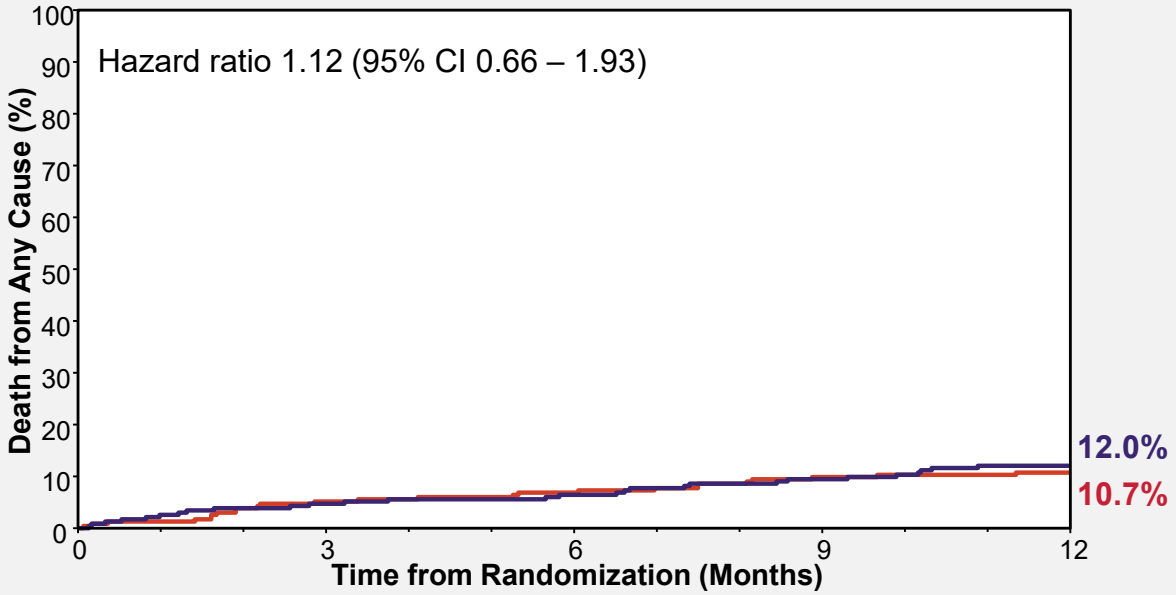
	Deferral (n=233)	PCI (n=233)
Angiographic variables		
SYNTAX score	10 (6-17)	10 (5-17)
Invasive physiological assessment	32 (14)	33 (14)
Proximal LAD	50 (21)	50 (21)
PCI characteristics		
Median no. of days from randomization to PCI	..	13 (6-23)
Before TAVI procedure	..	213 (93)
Residual SYNTAX score	..	0 (0-6)
TAVI characteristics		
TAVI performed	229 (98)	230 (99)
Median no. of days from randomization to TAVI	25 (12-43)	31 (14-47)
Transfemoral access route	214 (93)	214 (93)
Balloon-expandable transcatheter heart valve	125 (55)	117 (51)
Cerebral protection	6 (3)	3 (1)

Primary end point

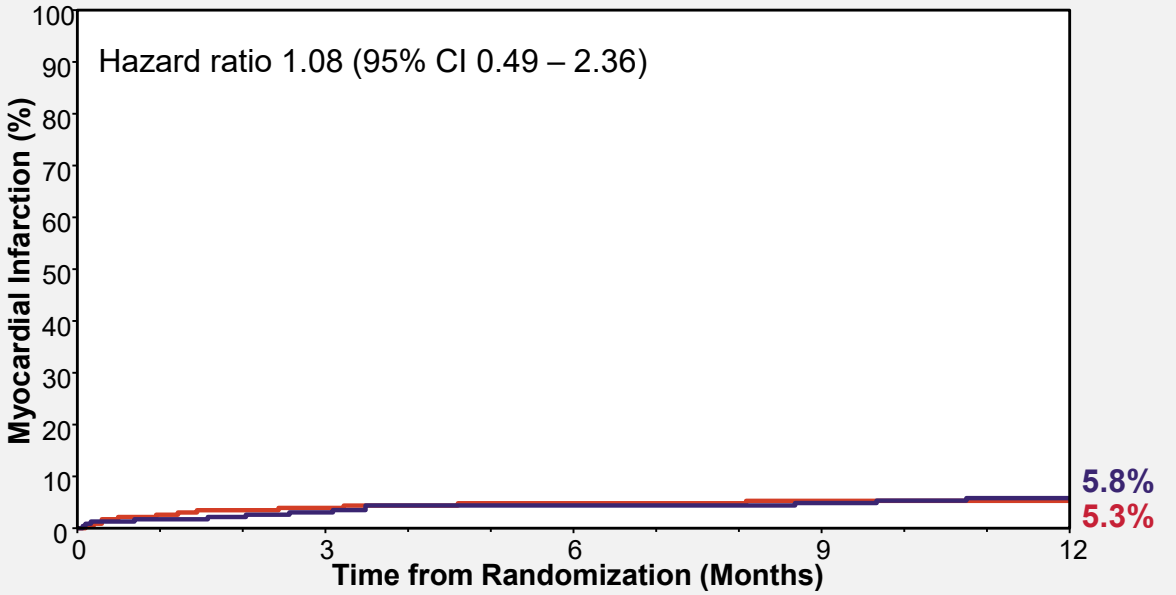


No. at risk					
PCI	233	186	178	174	173
Deferral	233	199	191	183	176

Death from Any Cause



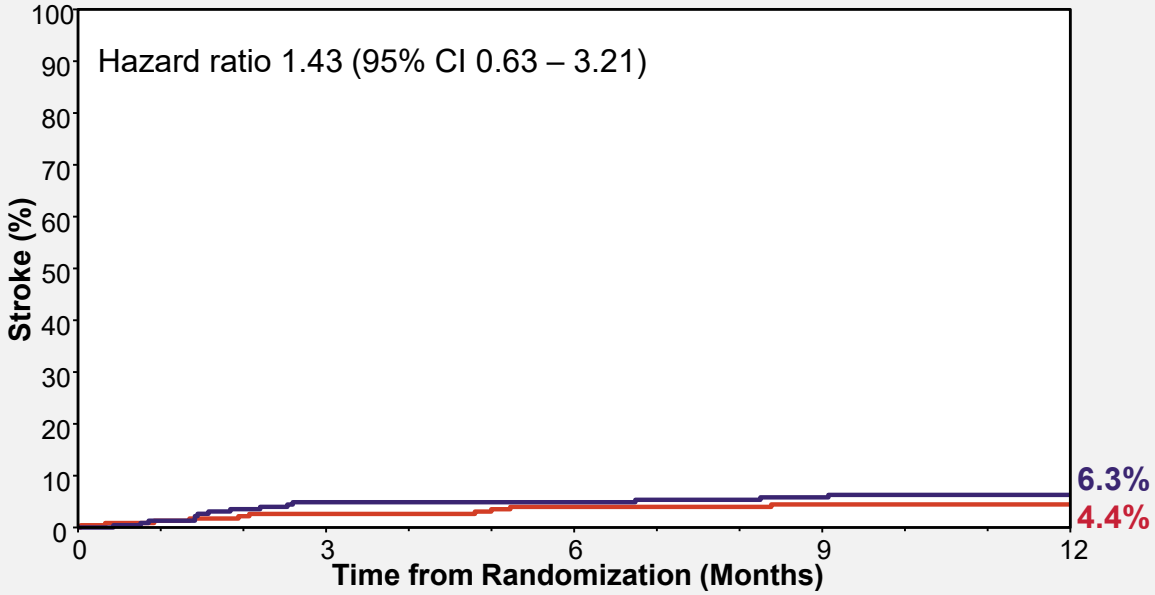
Myocardial Infarction



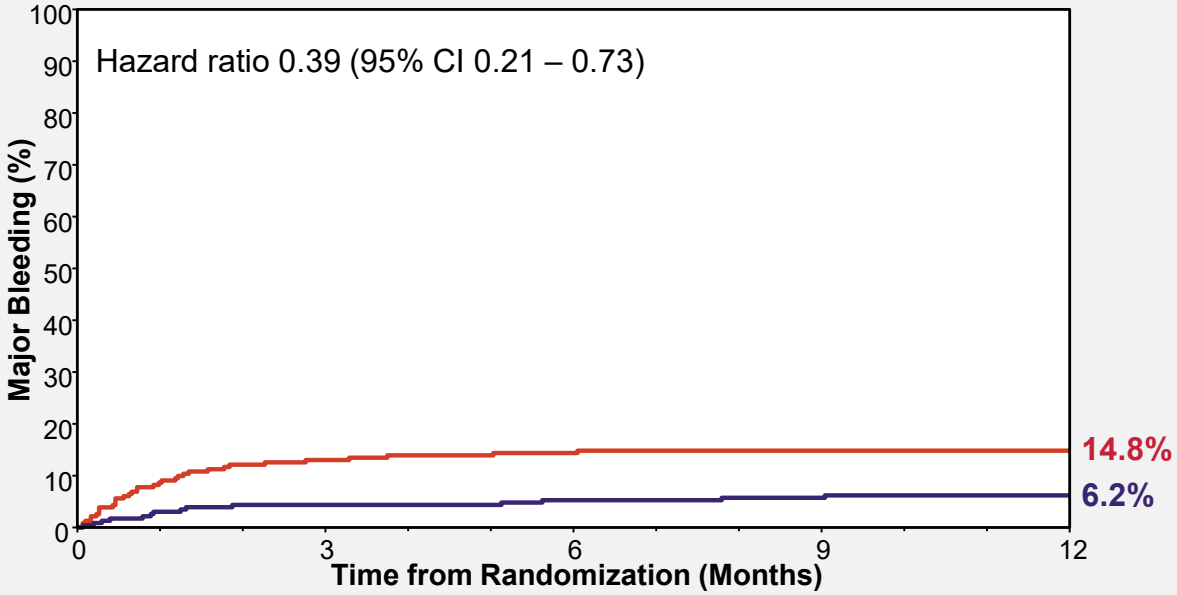
PCI

Deferral

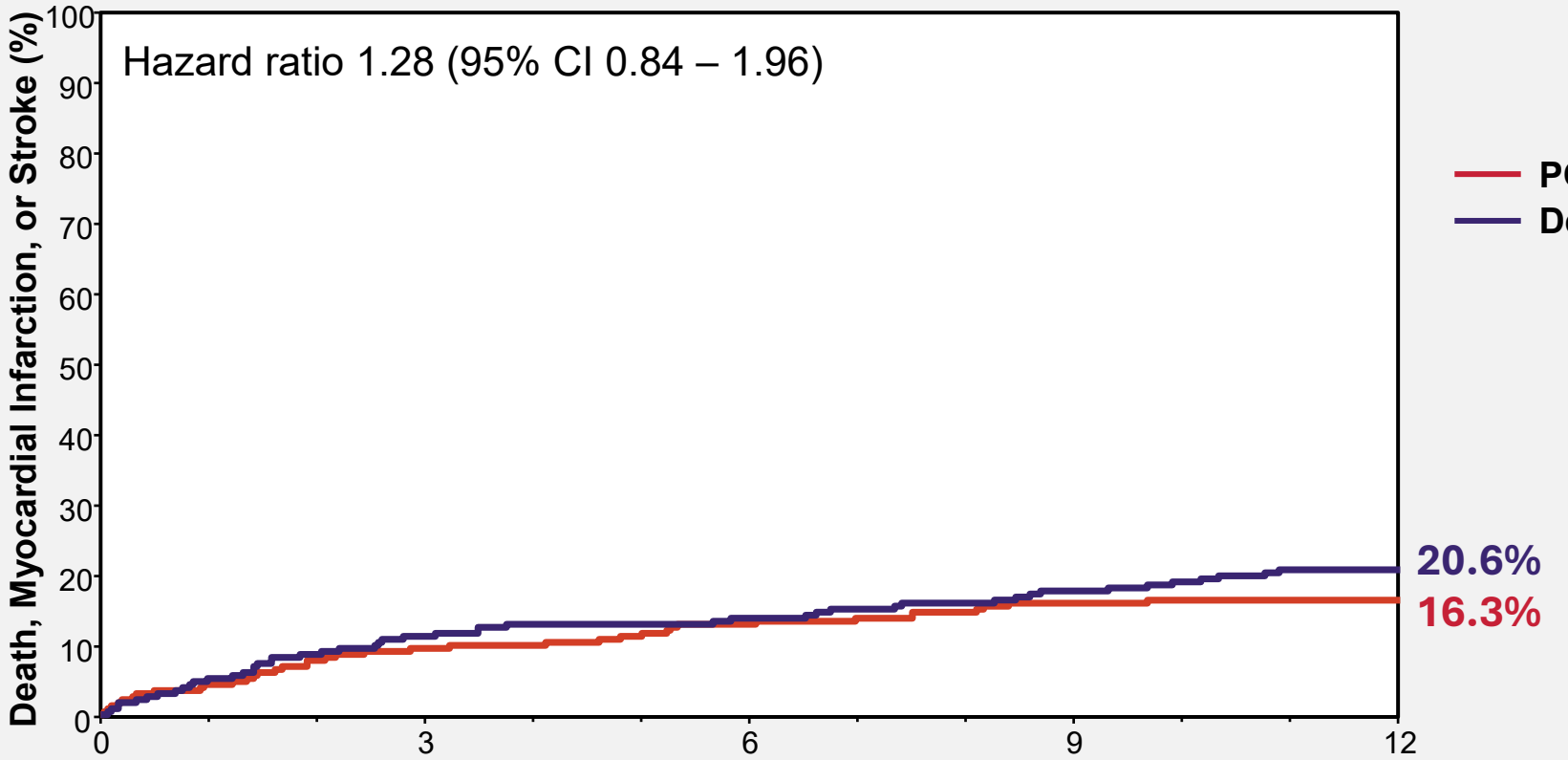
Stroke



Major Bleeding



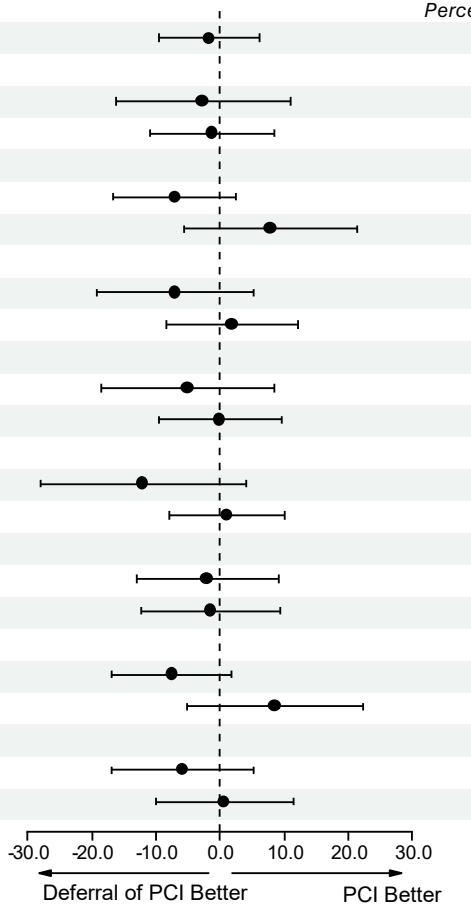
Ischemic end point



No. at risk					
PCI	233	211	203	196	195
Deferral	233	207	200	191	184

Subgroup analyses

Subgroup	Deferral (n=233)		PCI (n=233)		Rate difference (95% CI)
	No. of events / total no.	*Event rate (%)*	*No. of events / total no.*	*Event rate (%)*	*Percentage points*
All patients	56/233	24.1	60/233	25.8	-1.7 (-9.5 to 6.2)
Age					
<80	17/75	22.7	19/75	25.3	-2.7 (-16.3 to 11.0)
≥80	39/158	24.7	41/158	25.9	-1.2 (-10.8 to 8.4)
Sex					
Male	30/149	20.1	41/151	27.2	-7.0 (-16.6 to 2.6)
Female	26/84	31.1	19/82	23.2	7.9 (-5.5 to 21.4)
Angina					
Yes	18/85	21.2	29/103	28.2	-7.0 (-19.3 to 5.3)
No	38/148	25.8	31/130	23.8	1.9 (-8.3 to 12.1)
Left ventricular ejection fraction					
<50%	16/71	22.6	24/87	27.6	-5.0 (-18.5 to 8.6)
≥50%	40/162	24.7	36/146	24.7	0.0 (-9.6 to 9.7)
Proximal LAD					
Yes	8/50	16.0	14/50	28.0	-12.0 (-28.1 to 4.1)
No	48/183	26.3	46/183	25.1	1.1 (-7.8 to 10.1)
Diameter of stenosis					
<90%	18/98	18.5	20/98	20.4	-2.0 (-13.0 to 9.1)
≥90%	38/135	28.1	40/135	29.6	-1.5 (-12.3 to 9.3)
STS-PROM score					
<4%	27/149	18.2	38/148	25.7	-7.5 (-16.9 to 1.9)
≥4%	29/84	34.5	22/85	25.9	8.6 (-5.1 to 22.4)
Transcatheter heart valve					
Balloon-expandable	30/125	24.1	35/117	29.9	-5.8 (-17.0 to 5.3)
Self-expanding	21/103	20.4	22/112	19.6	0.7 (-10.0 to 11.5)



Revascularization

	Deferral (n=233)		PCI (n=233)		Hazard Ratio (95% CI)
	No. of Events	*Event Rate (%)*	*No. of Events*	*Event Rate (%)*	
Any revascularization	24	10.8	11	4.8	2.20 (1.08 – 4.50)
Urgent revascularization	13	5.8	7	3.1	1.86 (0.74 – 4.66)
Study lesion revascularization	18	8.1	7	3.1	2.59 (1.08 – 6.21)

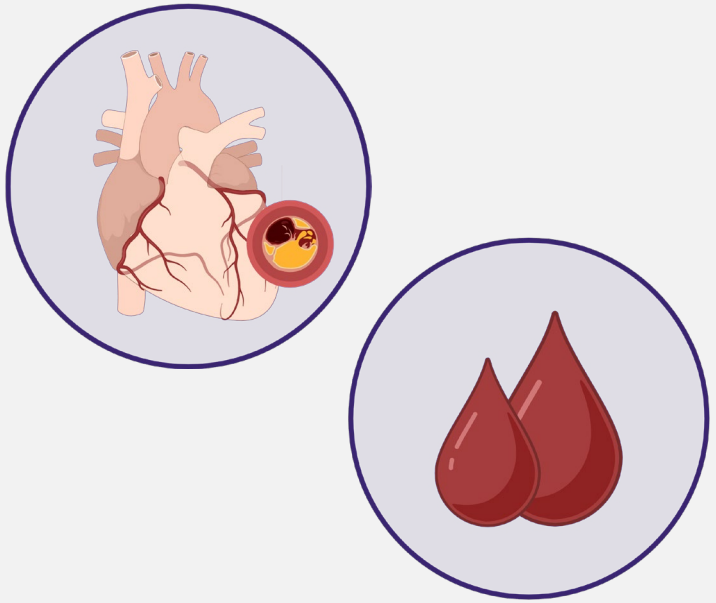
All PCI procedures after TAVI were performed without major periprocedural complications

Discussion

Open-label design

Applicable to study population

Excluding unprotected left main coronary artery disease



Composite primary end point with ischemic and bleeding events

Summary

PRO-TAVI

First trial to show noninferiority of deferral of PCI in TAVI

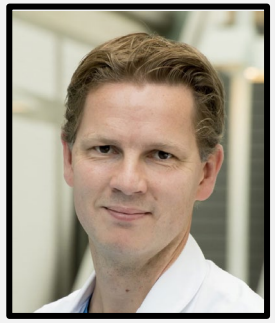
Deferral of PCI before TAVI leads to substantial reduction in major bleeding

Comprehensive assessment of bleeding and ischemic risk by Heart Teams

Longer-term follow-up is awaited

Acknowledgements

Principle investigators



Michiel Voskuil

Ronak Delewi

Coordinating investigators

Hugo M. Aarts

Gijs M. Broeze

Data safety and monitoring board board

Freek W.A. Verheugt

Karel T. Koch

Jan G.P. Tijssen

Site investigators

Jurriën M. ten Berg

Niels van Royen

Pim A.L. Tonino

Carl E. Schotborgh

Martijn Meuwissen

Gert K. van Houwelingen

Giovanni Amoroso

Joanna J. Wykrzykowska

Tessel N. Vossenberg

Pieter A. Vriesendorp

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Deferral of percutaneous coronary intervention in patients undergoing transcatheter aortic valve implantation (PRO-TAVI): an investigator-initiated, multicentre, open-label, non-inferiority, randomised controlled trial

Ronak Delewi, Hugo M Aarts*, Gijs M Broeze, Kimberley I Hemelrijk, Dirk Jan van Ginkel, Geert A A Versteeg, Maik J Grundeken, Bimmer E P M Claessen, Pim A L Tonino, Carl E Schotborgh, Martijn Meuwissen, Gert K van Houwelingen, Joanna J Wykrzykowska, Giovanni Amoroso, Tessel N Vossenberg, Pieter A Vriesendorp, Niels van Royen, Jurriën M ten Berg, Jan G P Tijssen, Michiel Voskuil, on behalf of the PRO-TAVI trial investigators*

Summary

Background Coronary artery disease is common in patients undergoing transcatheter aortic valve implantation (TAVI). We aimed to assess whether deferral of percutaneous coronary intervention (PCI) is non-inferior to routine PCI before TAVI in patients with coronary artery disease.

Methods In this investigator-initiated, open-label, randomised controlled trial, done at 12 hospitals in the Netherlands, TAVI patients with coronary artery disease were randomly assigned in a 1:1 ratio to deferral of PCI or PCI before TAVI. Randomisation was done by use of a web-based system with random block sizes of 2 and 4, and stratification by presence of coronary artery disease involving proximal left anterior descending artery. The primary endpoint was a composite of all-cause mortality, myocardial infarction, stroke, and major bleeding at 1 year. Non-inferiority testing was done in the intention-to-treat population against the prespecified margin of 11 percentage points. The study is registered with ClinicalTrials.gov (NCT05078619) and long-term follow-up is ongoing.

Findings Between Oct 7, 2021, and Nov 19, 2024, 466 patients were enrolled: 233 were assigned to deferral of PCI and 233 to PCI before TAVI. Median age was 81 years (IQR 78–84), and 166 (36%) of 466 patients were female. The primary endpoint occurred in 56 (24%) of 233 patients in the deferral group as compared with 60 (26%) of 233 patients in the PCI group (rate difference −1·7% [95% CI −9·5 to 6·2]; hazard ratio 0·89 [95% CI 0·62–1·28]; p=0·0008 for non-inferiority; p=0·68 for superiority).

Interpretation In patients with coronary artery disease undergoing TAVI, deferral of PCI was non-inferior to PCI before TAVI for the 1-year composite of all-cause mortality, myocardial infarction, stroke, and major bleeding. These findings suggest that an initial conservative strategy can be appropriate in selected patients, although patient-tailored treatment decisions remain essential.

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*Contributed equally

Department of Cardiology, Amsterdam University Medical Centres, Amsterdam, Netherlands (Prof R Delewi MD PhD, H M Aarts MD, G M Broeze MSc, K I Hemelrijk MD, M J Grundeken MD PhD, B E P M Claessen MD PhD, Prof J G P Tijssen PhD); **Department of Cardiology, University Medical Centre Utrecht, Utrecht, Netherlands** (H M Aarts, Prof M Voskuil MD PhD); **Department of Cardiology, St Antonius Hospital, Nieuwegein, Netherlands** (D J van Ginkel MD, Prof J M ten Berg MD PhD); **Cardiovascular Research Institute Maastricht, Maastricht, Netherlands** (Prof J M ten Berg); **Department of Cardiology, Radboud University Medical Centre, Nijmegen, Netherlands**

THE LANCET

Address for correspondence: prof. dr. R. Delewi, MD, PhD | r.delewi@amsterdamumc.nl | Department of Cardiology, Amsterdam UMC, Amsterdam, the Netherlands