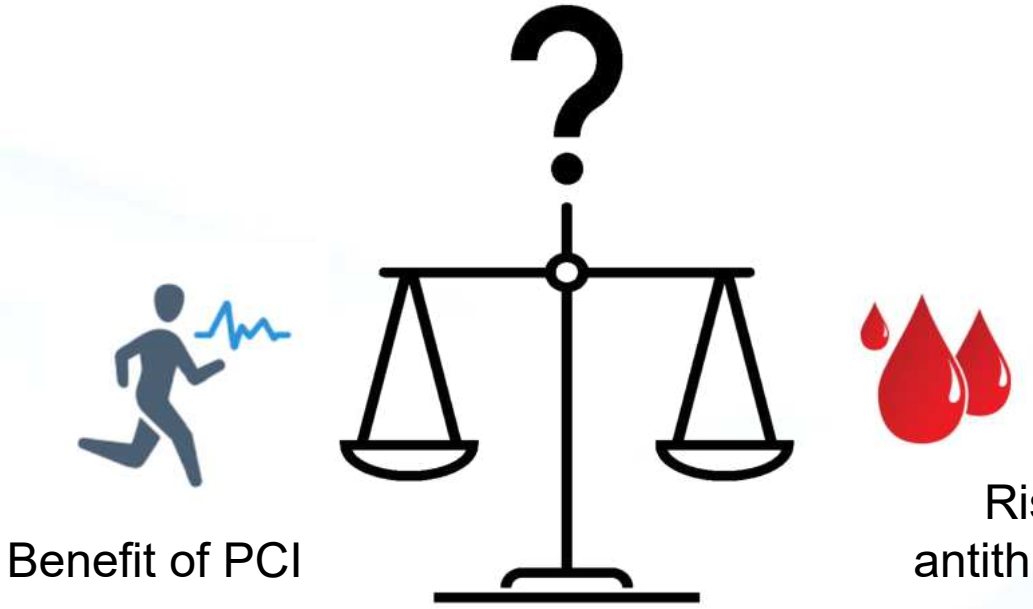
NOTION-3 trial

PCI or not PCI for obstructive CAD before TAVR ?

Flavien Vincent, MD, PhD
CHU Lille

Rationale

- CAD and AS share common etiologic characteristics, risk factors and clinical presentation
- CAD is present in ≈50% of patients undergoing TAVI
- Pre-emptive revascularization for patients with CAD found incidentally during TAVI workup is not well defined.



HIGHTECH

Context

ACTIVATION (PercutAneous Coronary inTervention prIor to transcatheter aortic VAlve implantaTION)

A Randomized Clinical Trial

Tiffany Patterson, PhD,[a] Tim Clayton, MSc,[b] Matthew Dodd, MSc,[b] Zeeshan Khawaja, MBBS,[c] Marie Claude Morice, MD,[d,e] Karen Wilson, MSc,[a] Won-Keun Kim, MD,[f] Nicolas Meneveau, MD,[g,h] Rainer Hambrecht, MD,[i] Jonathan Byrne, PhD,[j] Didier Carrié, MD,[k] Doug Fraser, MD,[l] David H. Roberts, MD,[m] Sagar N. Doshi, MD,[n] Azfar Zaman, MD,[o] Adrian P. Banning, MD,[p] Hélène Eltchaninoff, MD,[q] Hervé Le Breton, MD,[r] David Smith, MD,[s] Ian Cox, MD,[t] Derk Frank, MD,[u] Anthony Gershlick, MD,[v] Mark de Belder, MD,[w] Martyn Thomas, MD,[x] David Hildick-Smith, MD,[y] Bernard Prendergast, MD,[a] Simon Redwood, MD,[a] on behalf of the ACTIVATION Trial Investigators

Procedural Characteristics and Late Outcomes of Percutaneous Coronary Intervention in the Workup Pre-TAVR

Francisco Campelo-Parada, MD,[b] Erika Munoz-Garcia, MD,[c] Luis Nombela-Franco, MD,[d] Donaint, MD,[f] Vicenç Serra, MD,[g] Gabriela Veiga, MD,[h] Enrique Gutiérrez, MD,[i] beri, MD,[k] Ander Regueiro, MD,[l] Lluis Asmarats, MD,[m] Henrique B. Ribeiro, MD,[n] noz-Garcia, MD,[c] German Armijo, MD,[d] Marina Urena, MD,[e] Damien Metz, MD,[f] Maria de la Torre Hernandez, MD,[h] Eduard Fernandez-Nofrerias, MD,[j] es, MD,[l] Dabit Arzamendi, MD,[m] Diego Carter Campanha-Borges, MD,[n] D,[a] Josep Rodés-Cabau, MD[a]

tructive omes after scatheter aortic valve replacement

an Persits [1], Habib Layoun[2], Nicholas P. Kondoleon[1], Nikolaos Spilias[2], Osamah Badwan[1], Joseph Sipko[1], James J. Yun[2], Ankur Kalra [3], Iryna Dykun [4], Larisa G. Tereshchenko[2,5], Amar Krishnaswamy[2], Grant W. Reed[2], Samir R. Kapadia[2], and Rishi Puri [2]*

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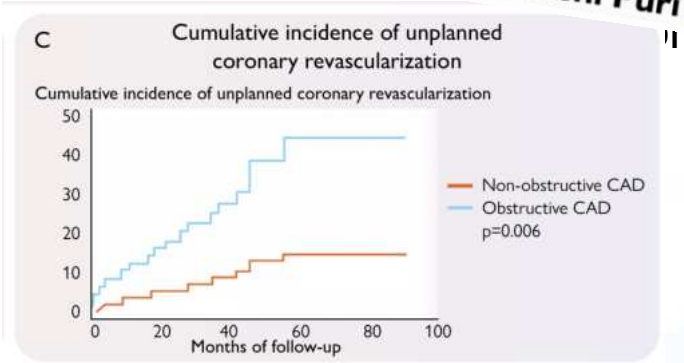

Patterson et al, JACC cardiovas intv 2021

Persits et al, EHJ 2024

Faroux et al, JACC cardio intv 2020

Current ESC guidelines

PCI should be considered in patients with a primary indication to undergo TAVI and coronary artery diameter stenosis >70% in proximal segments.	IIa	C

- PCI of stable significant coronary lesions at the time of TAVI remain common practice
- 10-20% before TAVI have PCI

Vahanian et al, ESC Guidelines for management of valvular heart disease, EHJ 2021

Question of the study

Among patients with coronary and aortic stenosis treated by TAVR :
is PCI superior to medical management ?

VS

Lønborg et AL, NEJM 2024

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Design

Open-blind trial

Inclusion criteria

Symptomatic severe AS
Stable CAD
Diameter stenosis ≥90%
Or FFR≤ 0.80

Lønborg et AL, NEJM 2024

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Artery >= 2.5mm
> 1 CTO
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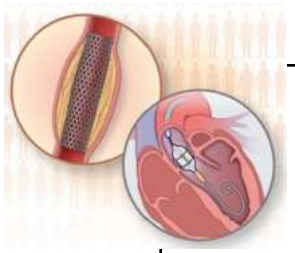

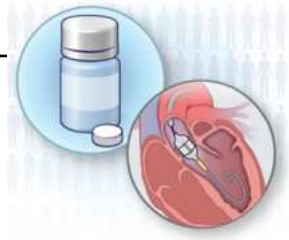

PCI
+ TAVI
n=227

Conservative treatment
+ TAVI
n=228

Lønborg et AL, NEJM 2024

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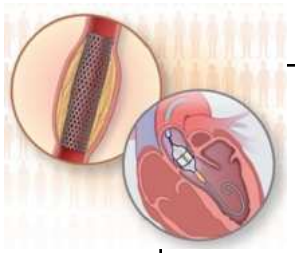

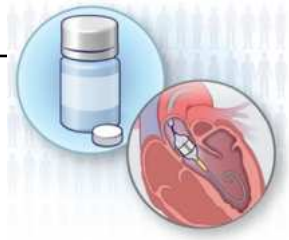

PCI + TAVI
n=227

Conservative treatment + TAVI
n=228

2 years median FU

Primary endpoint : MACE
(death, myocardial infarction, urgent revascularization)

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Population (both arms)

74%

81 year-old

26% diabetes

40% Ballon-expandable valve

STS : 3%

LVEF : 60%

90% median stenosis diameter
80% 1 single disease
60% LAD
Syntax score = 9

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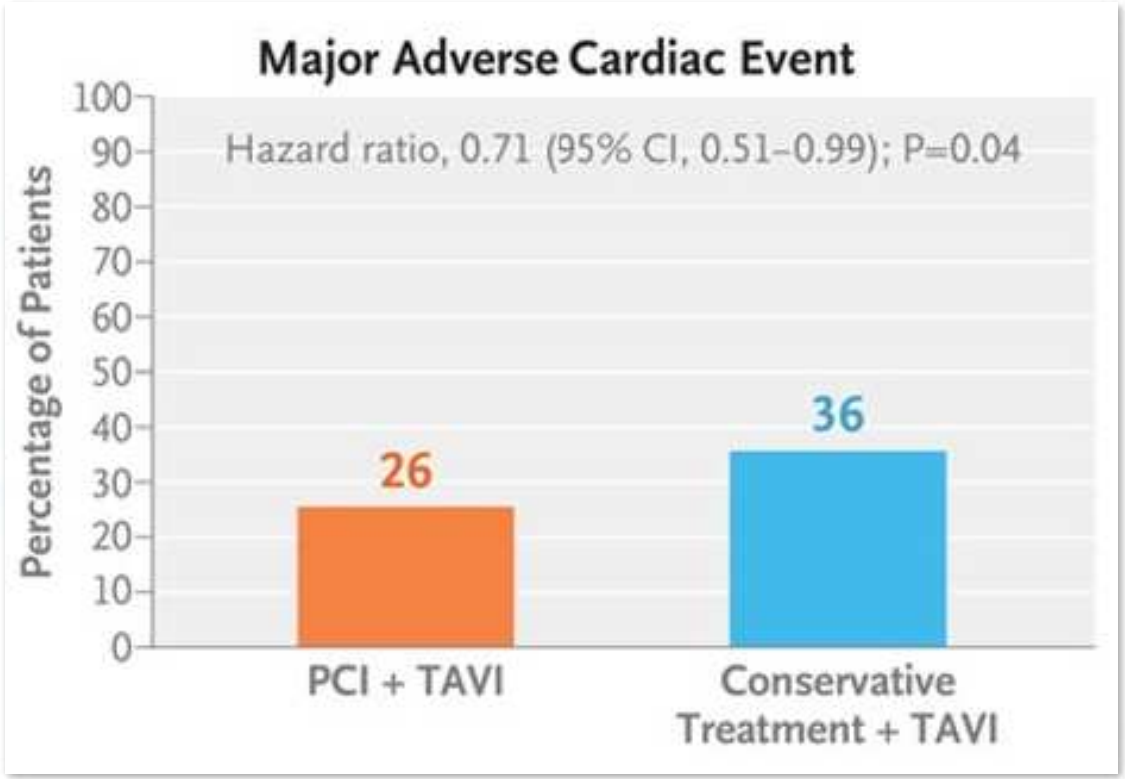
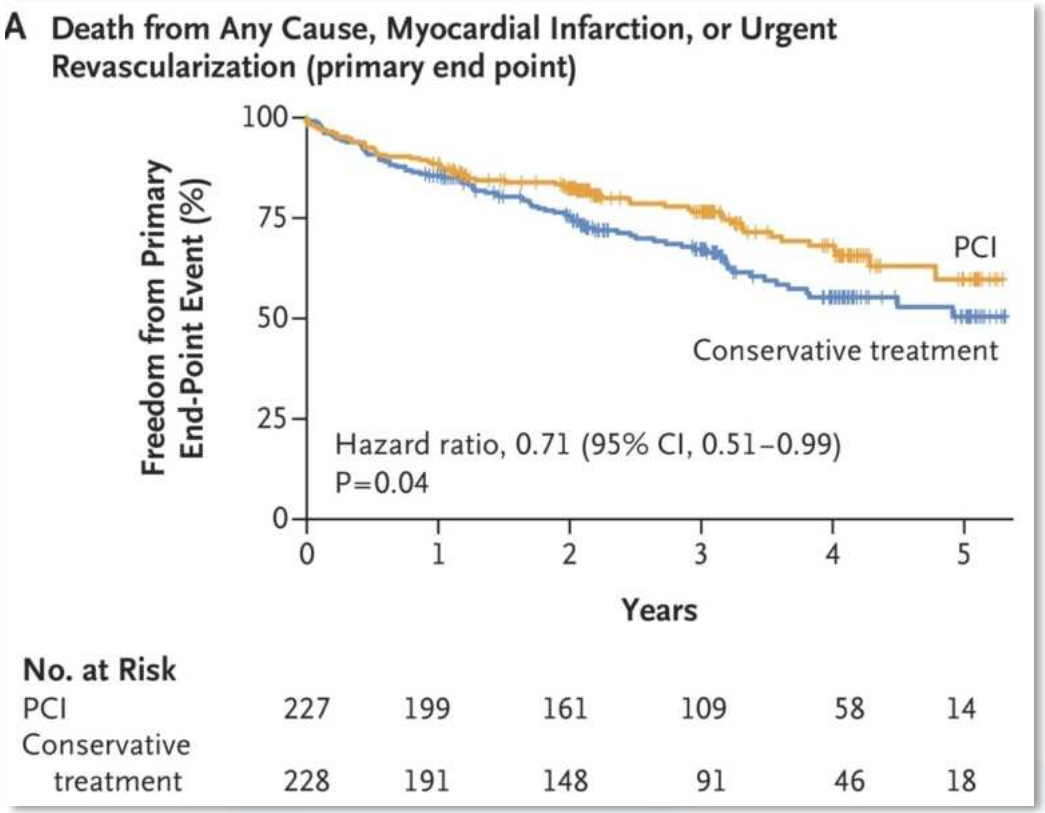
Primary outcomes

29% lower MACE in PCI arm





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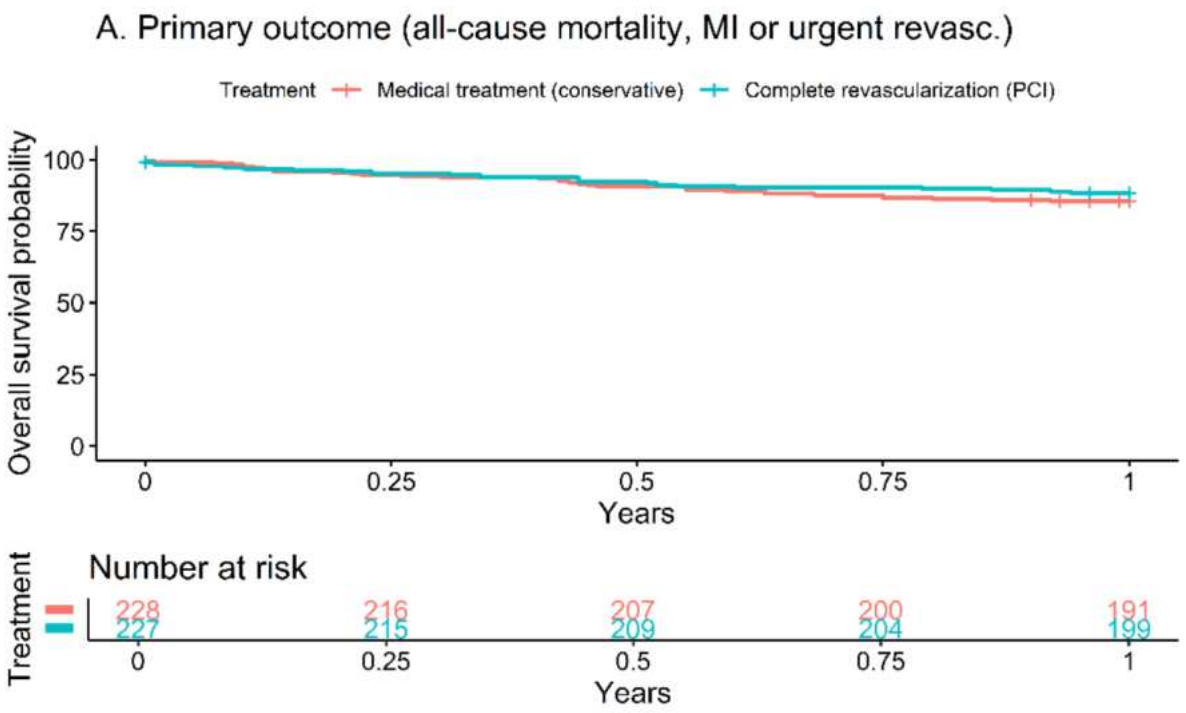
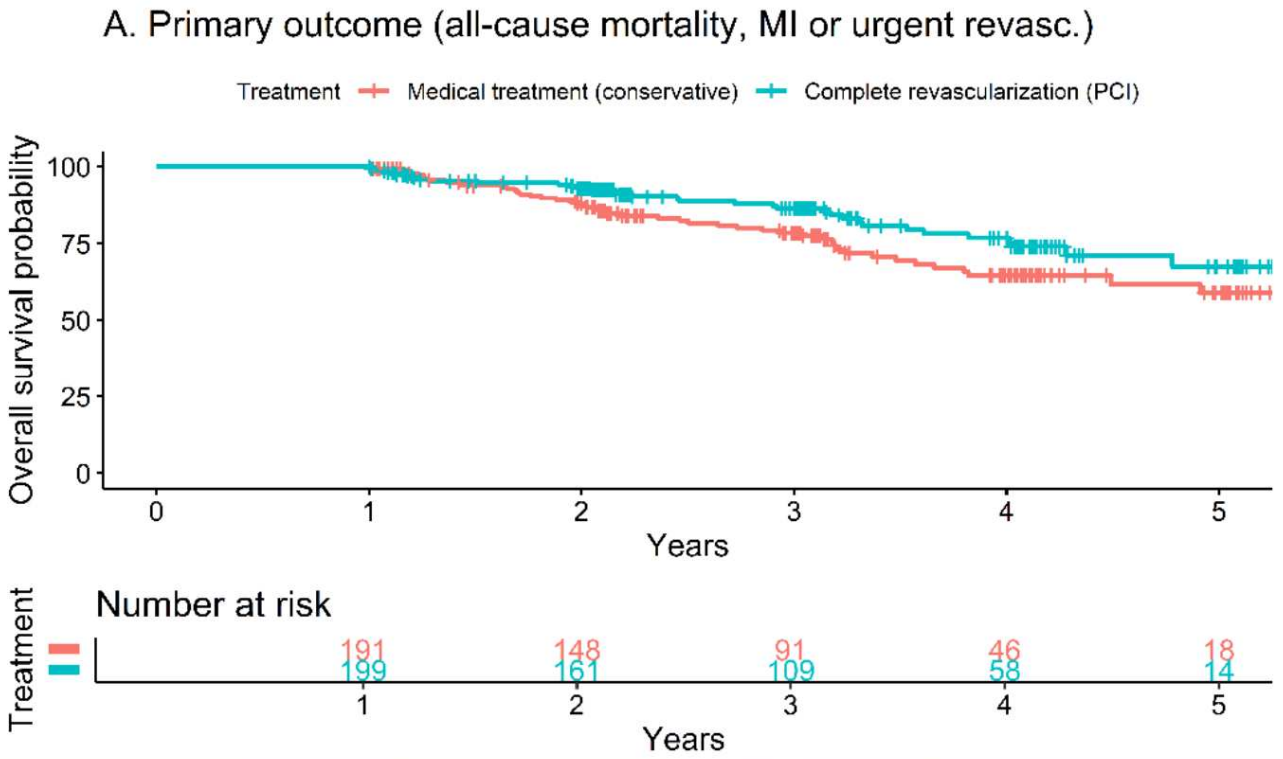
Landmark analysis of primary endpoint





Significant benefit > 1 year

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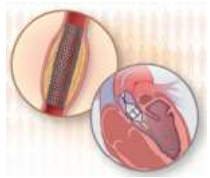
Outcomes



	PCI + TAVI n=227	Conservative treatment + TAVI n=228	
Death from any cause	53 (23)	62 (27)	0.85 (0.59–1.23)
Myocardial infarction‡	17 (7)	31 (14)	0.54 (0.30–0.97)
Urgent revascularization§	5 (2)	25 (11)	0.20 (0.08–0.51)
Death from cardiovascular causes¶	20 (9)	30 (13)	0.67 (0.38–1.19)
Any revascularization	6 (3)	48 (21)	0.12 (0.05–0.27)
Stroke	23 (10)	35 (15)	0.67 (0.39–1.14)

Primary endpoint mainly driven by higher Myocardial infarction and urgent revascularization rate

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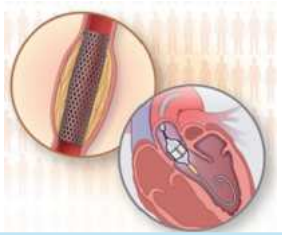
Causes of urgent revascularization



	PCI + TAVI n=227	Conservative treatment + TAVI n=228
Urgent revascularization - no. (%)	**5 (2)**	**25 (11)**
Cardiogenic shock	0 (0)	1 (0)
STEMI	0 (0)	6 (3)
NSTEMI	4 (1)	12 (5)
Unstable angina	0 (0)	6 (3)
Target lesion revascularization	**3 (1)**	**37 (16)**
All revascularization	**6 (3)**	**48 (21)**

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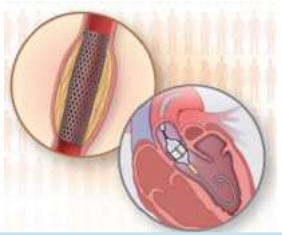

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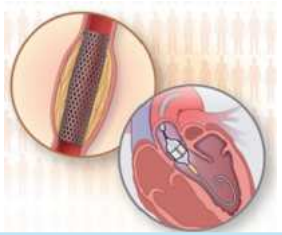

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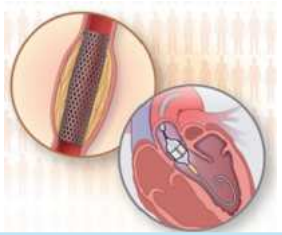

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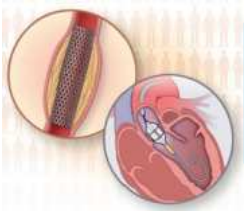
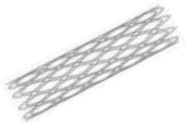
PCI procedural characteristics



PCI + TAVI



74% PCI before TAVI

0% mortality

1% myocardial infarction

< 1% stent thrombosis

0% coronary perforation

1% any bleeding

5% Acute kidney failure

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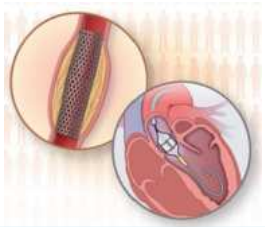
Safety endpoint (bleeding)

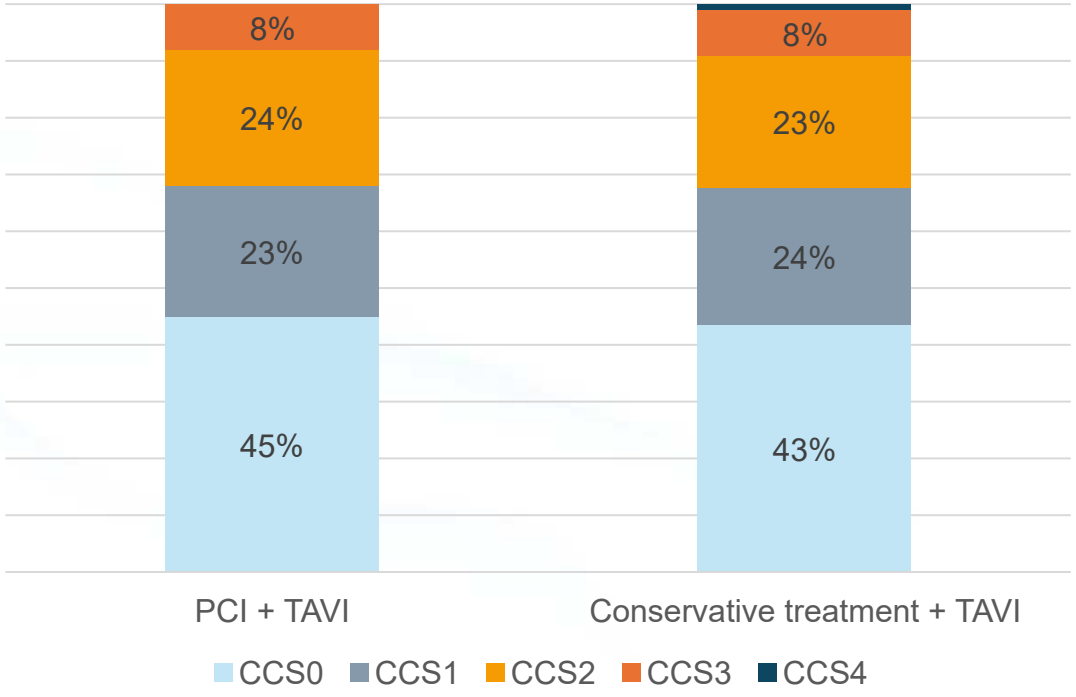


	PCI + TAVI n=227	Conservative treatment + TAVI n=228
Any bleeding no. (%)		
Life-threatening or disabling	64 (28)	45 (20)
Major	26 (11)	22 (10)
Minor	53 (23)	36 (16)

51% higher risk of bleeding in PCI arm (driven by minor bleeding)

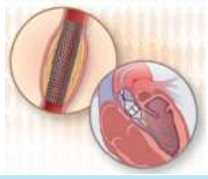
Angina before and after TAVI

PCI + TAVI n=227	Conservative treatment + TAVI n=228



Before TAVI

Angina before and after TAVI



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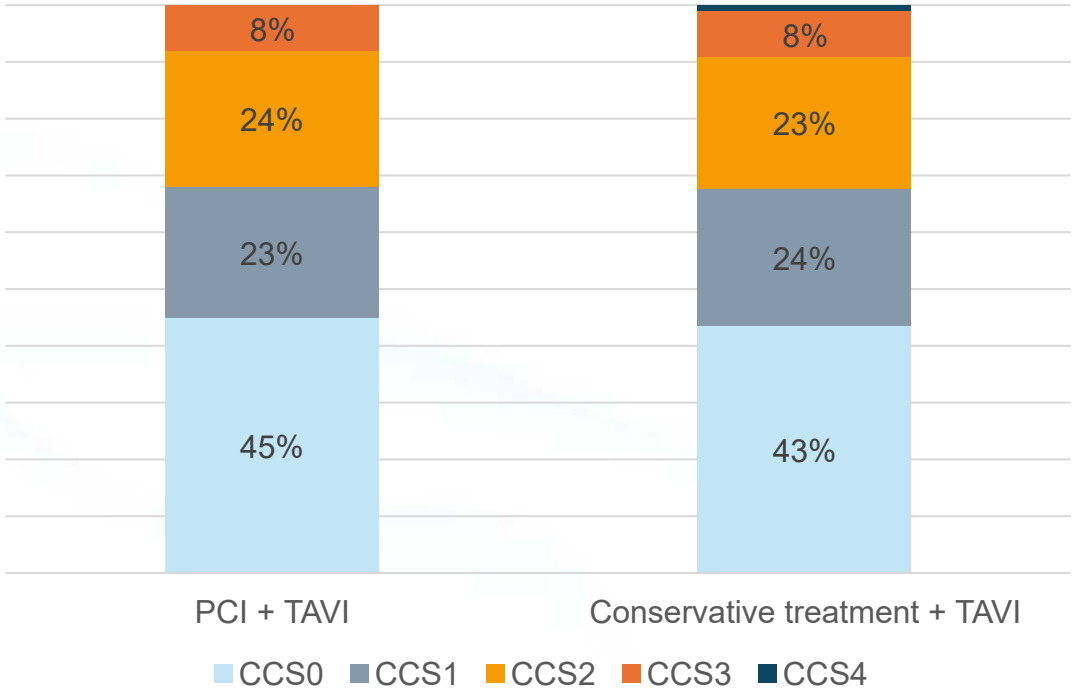

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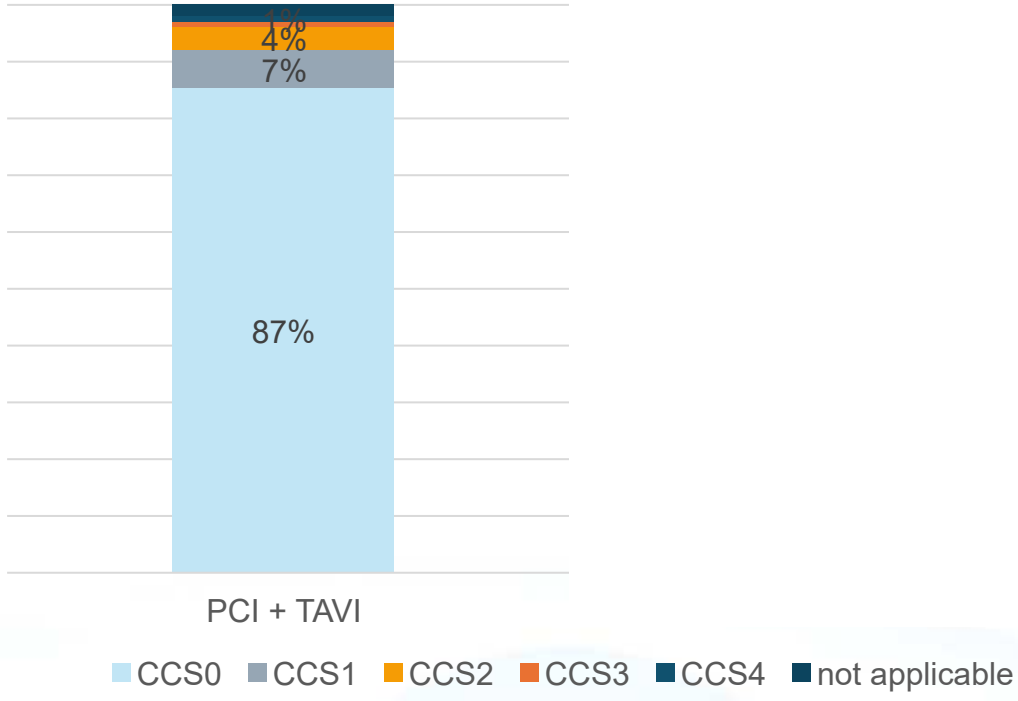
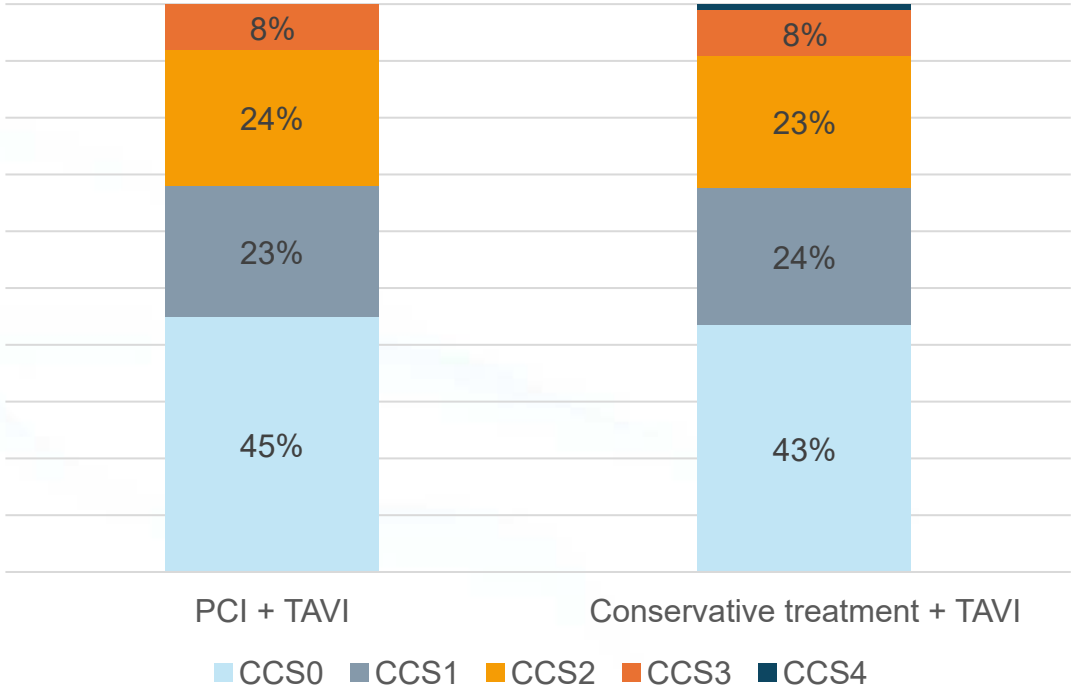


1 month after TAVI

Angina before and after TAVI

PCI + TAVI n=227

Conservative treatment + TAVI n=228



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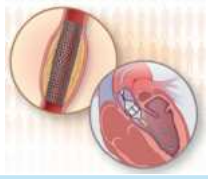

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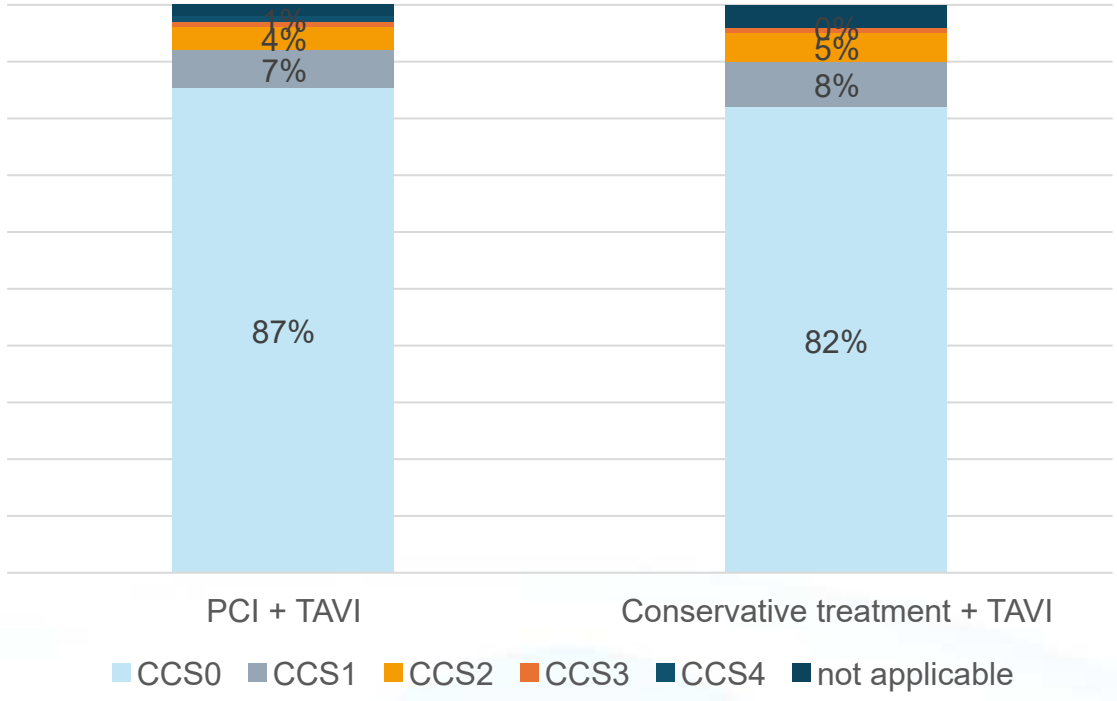
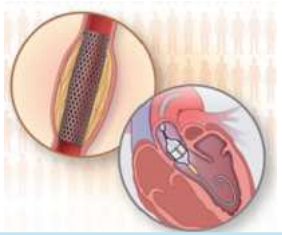


1 month after TAVI

Medical management after TAVI



	PCI + TAVI n=227	**Conservative treatment + TAVI** n=228
Medical treatment- no. (%)		
Statins	171 (78%)	182 (80%)
Long-acting nitrates	13 (6)	27 (12)
Calcium antagonists	67 (30)	79 (35)
Aspirin	142 (56)	140 (61)
Clopidogrel	199 (90)	87 (38)
Oral anticoagulation	82 (3)	71 (31)

Take Home Message

- PCI before the valve was beneficial with reduction in MACE
  - due to a reduction in MI and urgent revascularization>1 year
- PCI for lesions with FFR ≤ 0.80 or diameter stenosis ≥ 90% should be considered in all patients before TAVI

My take home

- Not applicable to all-comer
- 5 years enrollment period
- Very selected patients and lesions
- Very ease and safe PCI
- Single-vessel disease
- Numerical difference of 21 events between the 2 groups for primary endpoint (p=0.04)

My take home

With conservative strategy

- “Only” 10% patients with urgent revascularization and 21% in total at 2-year
- 80% of patients are free of stent; free of DAPT
- Similar TAVR procedural safety
- Similar survival
- Similar symptoms (including angina !)
- MI/urgent revascularization differ from 1 year onward

My take home

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- 80% of patients are free of stent; free of DAPT
- Similar TAVR procedural safety
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We have time to reassess CAD after TAVI !

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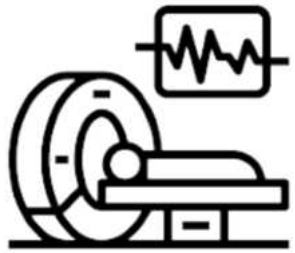
My take home : hybrid strategy is ideal



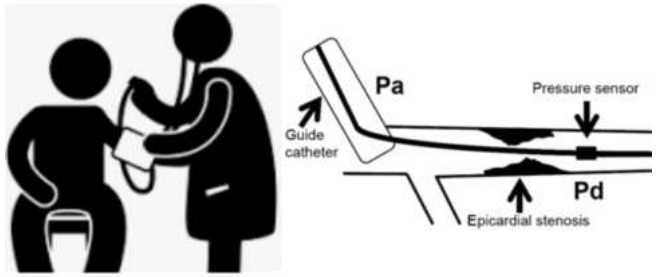
Dx

Obstructive CAD

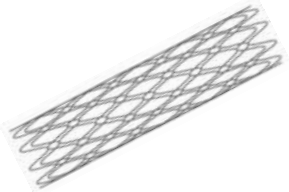
LM stenosis

Multivessel disease

TAVR



Clinical & Invasive assessment



PCI

Ideal management of obstructive CAD in patients treated by TAVI ?

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