TAVI for Combined CAD

David R. Holmes, Jr., M.D.

Mayo Clinic, Rochester

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Presenter Disclosure Information

David R. Holmes, Jr., M.D.

"TAVI for Combined CAD"

The following relationships exist related to this presentation:

None

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Futility versus Frailty

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Patient Characteristics

Characteristic	Study Cohort N= 5,980
Age (yr) Median (25^{th}, 75^{th})	85 (79, 88)
75-84, n (%)	2,244 (37.5)
85-94, n (%)	2,869 (48.0)
Female, n (%)	3,006 (50.4)
STS PROM Score (25^{th}, 75^{th})	7.1 (4.7, 10.9)
<8% n, (%)	3,405 (57.0)
8-15%	1,844 (30.8)
>15%	729 (12.2)
NYHA Class III/IV Heart Failure, n (%)	4,876 (83.6)
CAD, n (%)	3,564 (61.7)

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CAD in TAVR Patients

Study/registry (no.)	Prevalence of CAD (%)
PARTNER 1 (179)	67.6
FRANCE (244)	41.3
Canadian Registry (339)	69.0
SOURCE/Sapien (1,038)	51.9
German TAVI (697)	60.2
UK TAVI (870)	47.6
GARY (3,875)	55.0
FRANCE 2 (3,195)	48.0
Total = 10,437	Average = 55.08

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10.3. Treatment of Coronary Artery Disease at the Time of Aortic Valve Replacement

Class I

1. Patients undergoing AVR with significant stenoses (greater than or equal to 70% reduction in luminal diameter) in major coronary arteries should be treated with bypass grafting. *(Level of Evidence: C)*

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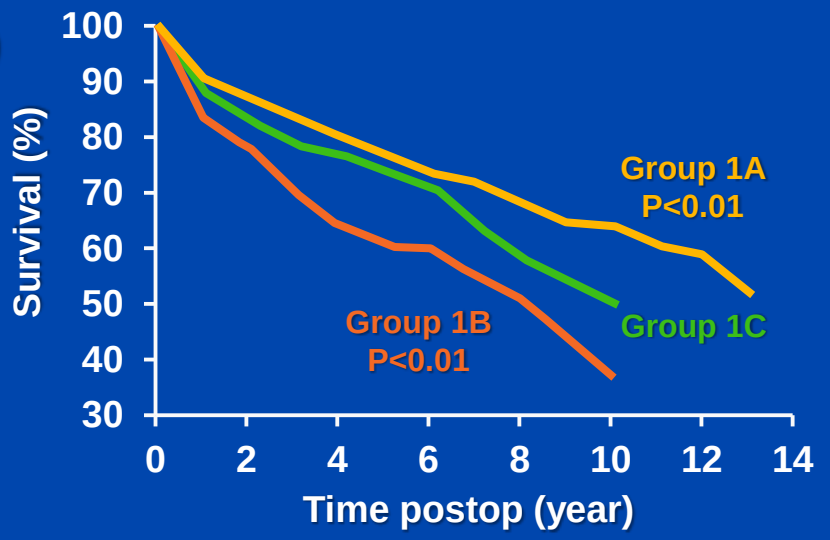
Coronary Artery Disease and Its Management: Influence on Survival in Patients Undergoing Aortic Valve Replacement

CHARLES J. MULLANY, MB, MS, LILA R. ELVEBACK, PHD,* ROBERT L. FRYE, MD, FACC,
JAMES R. PLUTH, MD, FACC, WILLIAM D. EDWARDS, MD, FACC,
THOMAS A. ORSZULAK, MD, LOUIS A. NASSEF, JR., MD, RONALD E. RINER, MD,
GORDON K. DANIELSON, MD, FACC

Rochester, Minnesota

- 1,156 pts at Mayo (1967-1983)
- Three groups
  - 1A – No CAD
  - 1B – CAD, no CABG
  - 1C – CAD + CABG



Mullany et al: J Am Coll Cardiol 10:66, 1987

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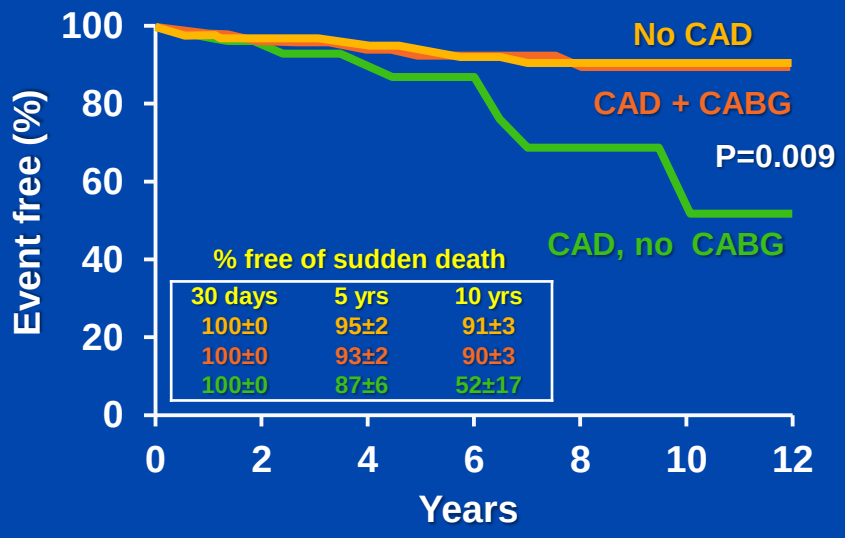
Reduction in sudden late death by concomitant revascularization with aortic valve replacement

Lawrence S. C. Czer, MD, Richard J. Gray, MD, Morgan E. Stewart, PhD,
Michele De Robertis, RN, BA, Aurelio Chaux, MD, and Jack M. Matloff, MD,
Los Angeles, Calif.

- 474 patients
- 1964-89
- Three cohorts
  - No CAD
  - CAD + CABG
  - CAD w/o CABG



Czer et al: JTCVS 390, 1988

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Cause of Death Post-TAVR

PARTNER Trial	SOURCE Registry Data
38% cardiac	25% cardiac
38% non-cardiac	49% non-cardiac
24% unknown	26% unknown

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PARTNER Trial: Gestalt

PARTNER 1

Trial of percutaneous therapy for AS closely mimicking surgical therapy

Degree of revascularization more closely matched

PARTNER 2

Trial of surgical vs percutaneous management of AS patients

Degree of revascularization variable between arms

Pre-randomization revascularization discouraged

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PARTNER Trial Exclusion Criteria

PARTNER 1

"Substantial coronary artery disease requiring revascularization"

"Any therapeutic invasive cardiac procedure performed within 30 days of the index procedure, (or 6 months if the procedure was a drug eluting coronary stent implantation)"

PARTNER 2

"Complex CAD" (Cohort A)

"Any therapeutic invasive cardiac procedure resulting in a permanent implant that is performed within 30 days of the index procedure **(unless part of planned strategy for treatment of concomitant coronary artery disease)**"

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Concomitant CAD and TAVR

- Multicenter Registry
  - 201 high-risk patients enrolled in two international feasibility studies
- Logistic regression to establish association between CAD and survival from TAVI

Dewey TM et al: Ann Thorac Surg 89:758-67, 2010

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Impact of CAD on TAVR Outcomes

Effect of Concomitant Coronary Artery Disease on Procedural and Late Outcomes of Transcatheter Aortic Valve Implantation

Todd M. Dewey, MD, David L. Brown, MD, Morley A. Herbert, PhD, Dan Culica, MD, PhD, Craig R. Smith, MD, Martin B. Leon, MD, Lars G. Svensson, MD, PhD, Murat Tuzcu, MD, John G. Webb, MD, Alain Cribier, MD, and Michael J. Mack, MD

Factor	CAD	No CAD	P
Mortality			
Pooled patients	35.7% (30/84)	18.4% (16/87)	0.01
Transapical	42.1% (11/26)	22.2% (2/9)	0.43
Transfemoral	32.8% (19/58)	18.0% (14/78)	0.04
30-day mortality			
Pooled patients	13.1% (11/84)	1.2% (1/87)	0.002
Transapical	19.2% (5/26)	0	0.03
Transfemoral	10.3% (6/58)	1.3% (1/78)	0.04

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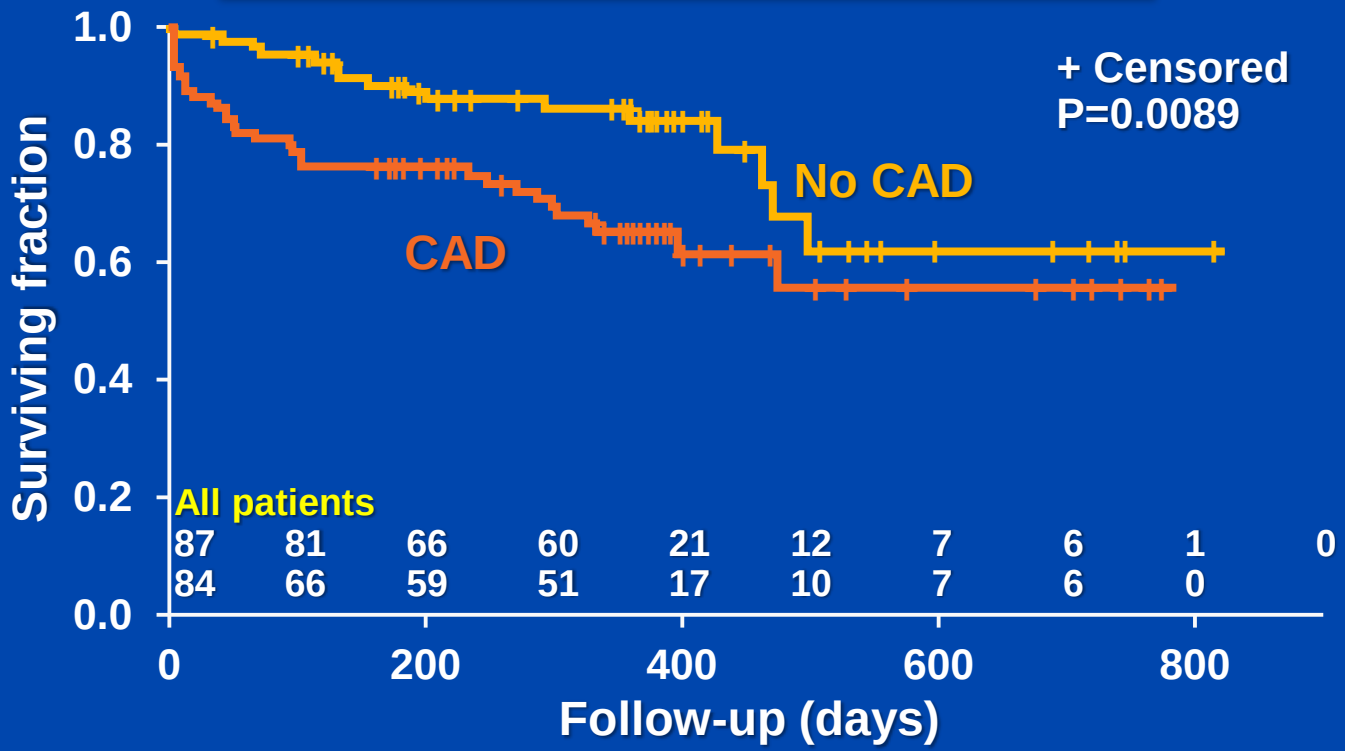

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Medical City Dallas Hospital, Dallas, and Cardiopulmonary Research Science and Technology Institute, Dallas, Texas; Department of Surgery, Columbia Presbyterian Hospital, New York, New York; Department of Thoracic and Cardiovascular Surgery, and Department of Cardiology, Cleveland Clinic [illegible] Columbia, Vancouver, British C[illegible]

Conclusions: Coexisting coronary artery disease negatively impacts procedural outcomes and long-term survival in patients undergoing TAVI, and implies that risk assessment and anticipated outcomes might be inaccurate due to stratification as isolated aortic valve replacement rather than AVR + CABG. Comparison of procedural outcomes, based on operative approach without controlling for unequal distribution of CAD in the cohorts, are like invalid.

Background. Previous co[illegible] increases predicted operativ[illegible] replacement, according to th[illegible] risk algorithm. Additionally[illegible] tery disease (CAD) has be[illegible] procedural risk with convent[illegible] Significant coexisting CAD r[illegible] ous coronary intervention (P[illegible] ation for transcatheter aorti[illegible] This study examined the imp[illegible] bypass grafting or PCI on pr[illegible] survival in patients having T[illegible]

Methods. Two hundred [illegible] were enrolled in two international feasibility studies from December 2005 to February 2008 for the treatment of aortic stenosis using TAVI. Thirty patients were excluded from analysis due to failure to successfully deploy the valve in the aortic annulus. Data were collected concurrently using an ad hoc database that included operative and long-term survival. Previous cardiovascular intervention prior to TAVI was used to identify the existence of concomitant CAD. Logistic regression along with Kaplan-Meier estimates were employed to

Conclusions. Coexisting coronary artery disease negatively impacts procedural outcomes and long-term survival in patients undergoing TAVI, and implies that risk assessment and anticipated outcomes might be inaccurate due to stratification as isolated aortic valve replacement rather than AVR+CABG. Comparison of procedural outcomes, based on operative approach without controlling for unequal distribution of CAD in the cohorts, are likely invalid.

(Ann Thorac Surg 2010;89:758–67)

Impact of CAD on TAVR

- Single center study
  - 136 patients undergoing TAVR
  - Jan 2005 – Dec 2007
- 76.5% had CAD
- Retrospective analysis
  - No CAD
  - CAD – DMJS 0, 2, 4, ≥6
- Study outcomes
  - 30 day and 1 year survival, symptom change, LVEF, MR, Re-revasc

Masson JB et al: Catheter Cardiovasc Interv 76:165-73, 2010

CAD and TAVR
Mortality

	30 Days	P	1 Year
No CAD	6.3	0.56	22.1%
CAD DMJS			NSD
0	14.6		
2	7.1		
4	5.6		
≥6	17.7		

Masson JB et al: Catheter Cardiovasc Interv 76:165-73, 2010

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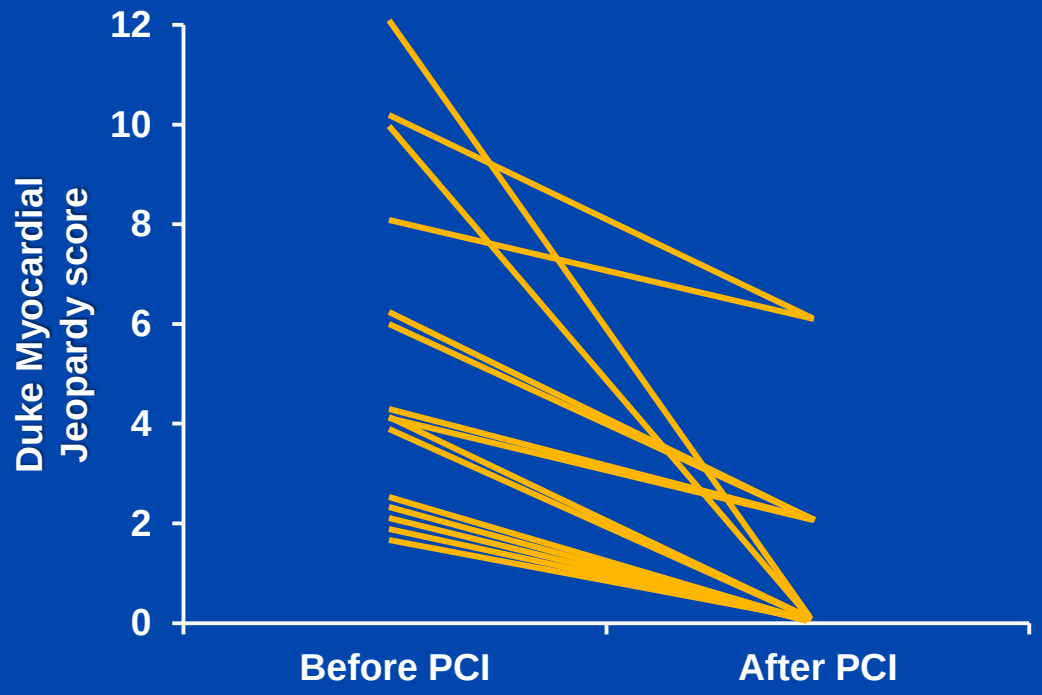
Impact of Coronary Artery Disease on Outcomes After Transcatheter Aortic Valve Implantation

Jean-Bernard Masson, MD, May Lee, MSc, Robert H. Boone, MD, Abdullah Al Ali, MD, Saad Al Bugami, MD, Jaap Hamburger, MD, PhD, G.B. John Mancini, MD, Jian Ye, MD, Anson Cheung, MD, Karin H. Humphries, PhD, David Wood, MD, Fabian Nietlispach, MD, and John G. Webb,* MD



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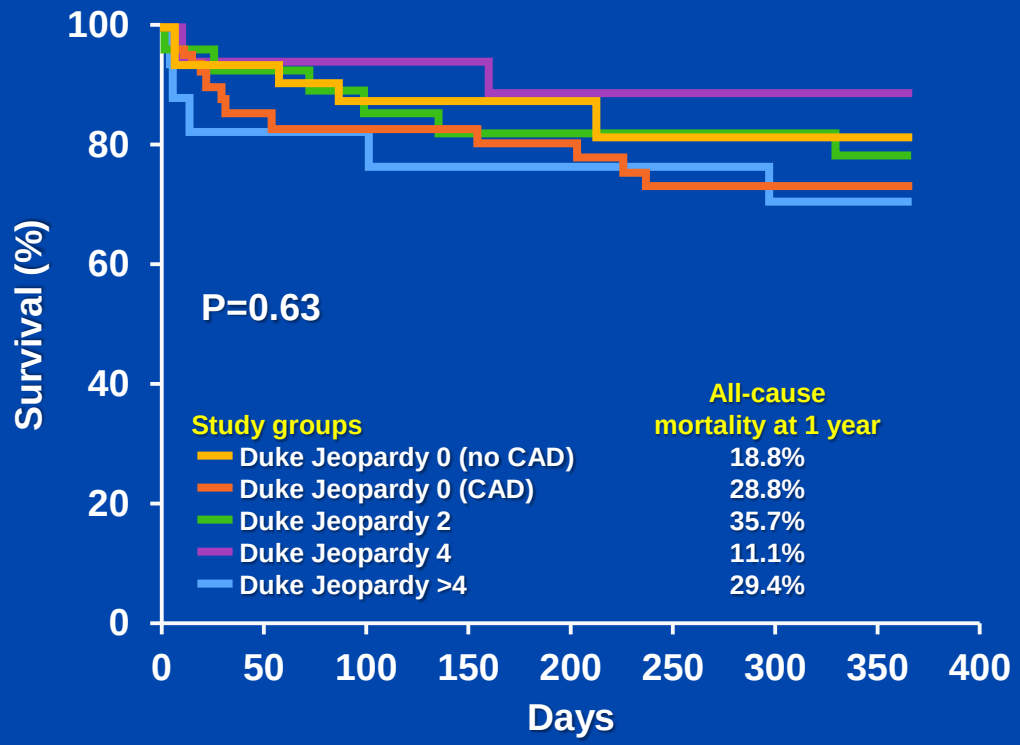

Masson et al: Catheterization and Cardiovasc Interven 76:165, 2010

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Catheterization and Cardiovascular Interventions 76:165–173 (2010)

VALVULAR AND STRUCTURAL HEART DISEASE

Original Studies

Impact of Coronary Artery Disease on Outcomes After Transcatheter Aortic Valve Implantation

Jean-Bernard Masson, MD, May Lee, MSc, Robert H. Boone, MD, Abdullah Al Ali, MD, Saad Al Bugami, MD, Jaap Hamburger, MD, PhD, G.B. John Mancini, MD, Jian Ye, MD, Anson Cheung, MD, Karin H. Humphries, PhD, David Wood, MD, Fabian Nietlispach, MD, and John G. Webb,* MD

Conclusion: The presence of CAD or nonrevascularized myocardium was not associated with an increased risk of adverse events in this initial cohort. On the basis of these early results, complete revascularization may not constitute a prerequisite of TAVI. This conclusion will require re-assessment as experience accrues in patients with extensive CAD.

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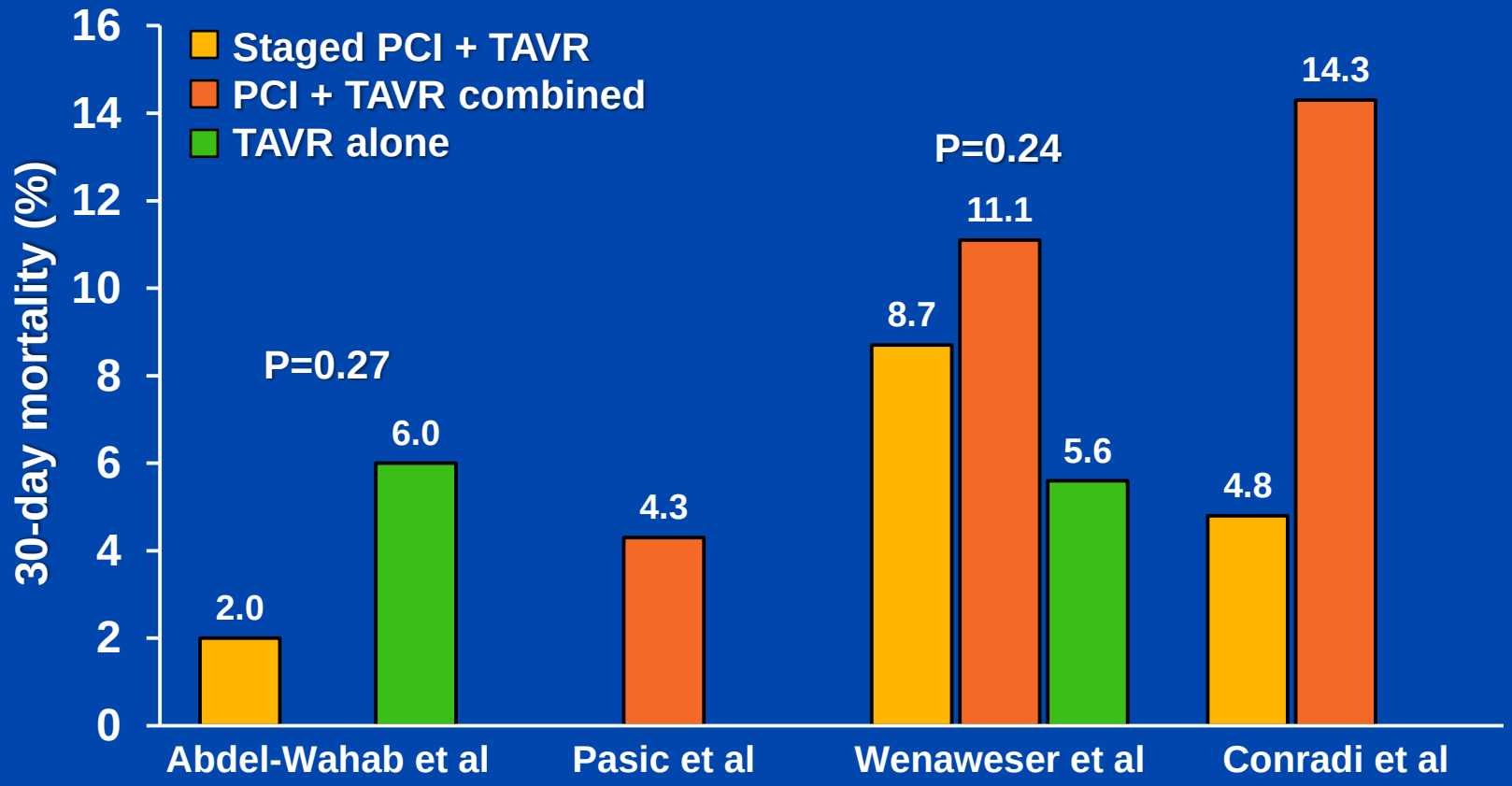
Key words: aortic stenosis; transcatheter valvular intervention; coronary artery disease

PCI Staged or Combined With TAVR



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Safety of PCI in Patients With Severe AS

Percutaneous Coronary Intervention in Patients With Severe Aortic Stenosis

Implications for Transcatheter Aortic Valve Replacement

Sachin S. Goel, MD; Shikhar Agarwal, MD, MPH, CPH; E. Murat Tuzcu, MD; Stephen G. Ellis, MD; Lars G. Svensson, MD, PhD; Tarique Zaman, MD; Navkaranbir Bajaj, MD; Lee Joseph, MD; Neil S. Patel, BS; Olcay Aksoy, MD; William J. Stewart, MD; Brian P. Griffin, MD; Samir R. Kapadia, MD

Predictors of Mortality in Patients With Severe Aortic Stenosis Undergoing Percutaneous Coronary Intervention

Characteristics*	Hazard ratio	95% CI	P
Age	1.07	1.04-1.10	<0.001
Ejection fraction ≤30%	2.83	1.79-4.49	<0.001
Chronic kidney disease	1.82	1.12-2.97	0.02
Diabetes mellitus		1.02-2.10	0.04
Chronic obstructive pulmonary disease		1.18-2.70	0.02

STS >10

Circulation 125:1008, 2012

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Timing of PCI

Before TAVR

Pros

- Simplified access to coronaries
- Decreased risk from rapid pacing
- Spacing contrast load

Cons

- Dual antiplatelet Tx
- Safety of PCI with severe AS

At time of TAVR

Pros

- Avoids waiting for decompensation
- Single arterial access

Cons

- Increased contrast dose

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Conclusions

- Coronary artery disease is common in patients considered for TAVR
- CAD is an adverse prognostic factor in TAVR patients
- TAVR ≠ SAVR
- Optimal treatment strategy for CAD in TAVR patients continues to evolve

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Future Directions: ACTIVATION Trial

- Trial of 310 TAVR patients
  - Prohibitive operative risk
  - >1 proximal coronary lesion with >70% stenosis amenable to PCI
- Randomized to PCI or no PCI prior to TAVR
- Excludes left main disease
- British and European sites

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Case 2

- 74-year-old male with severe AS considered for TAVR
- STS 9.12%
  - CAD – prior CABG (LIMA-LAD, SVG-D1)
  - EF 60%
  - Cerebrovascular disease

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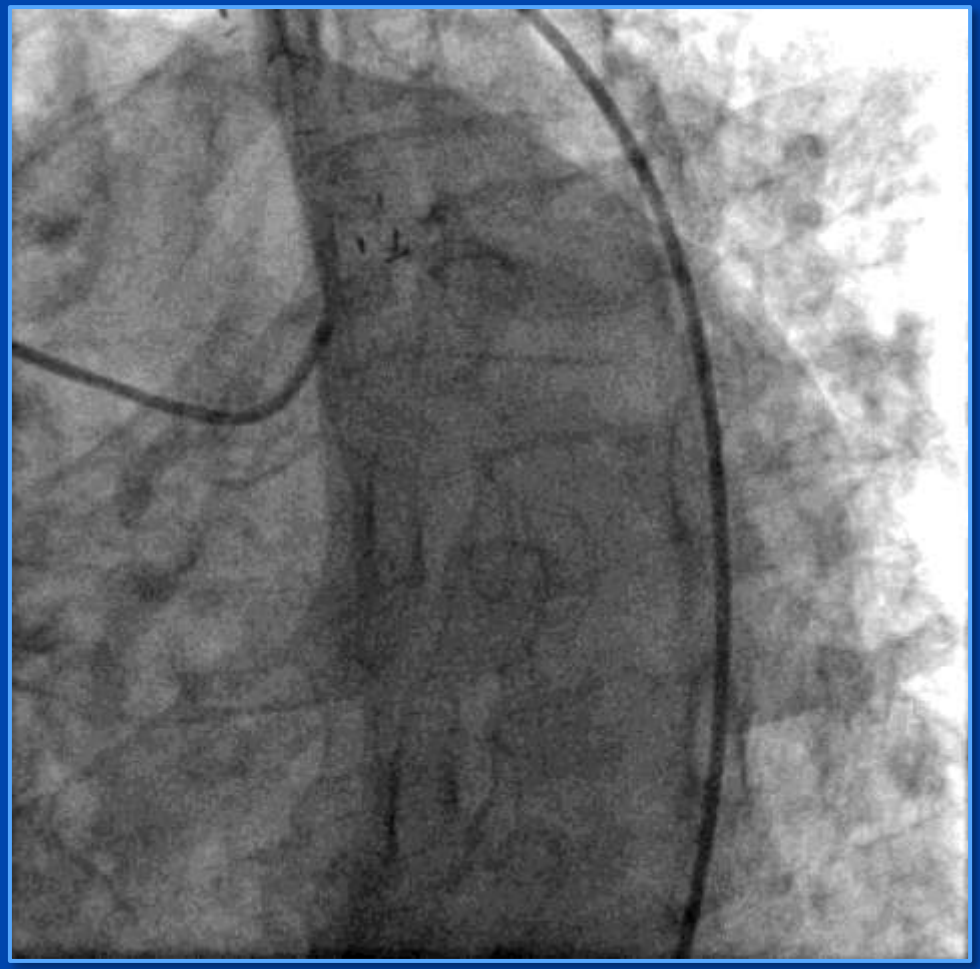
Case 2



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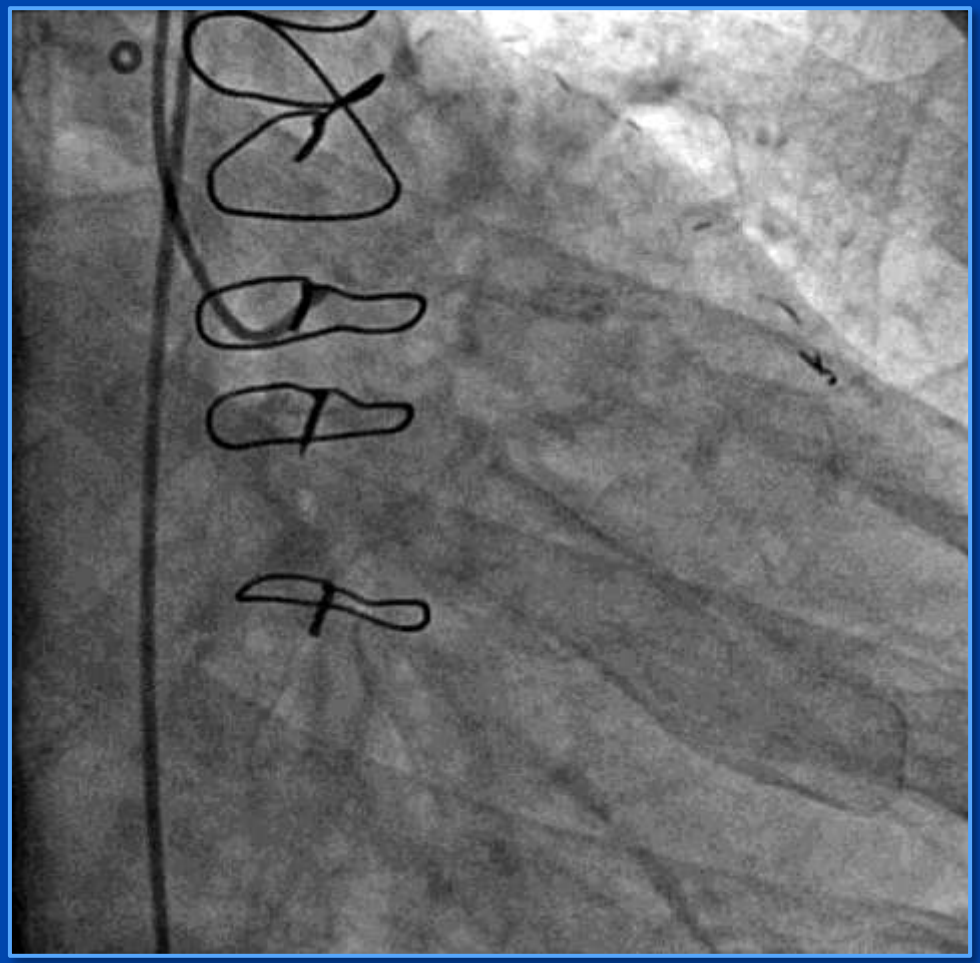

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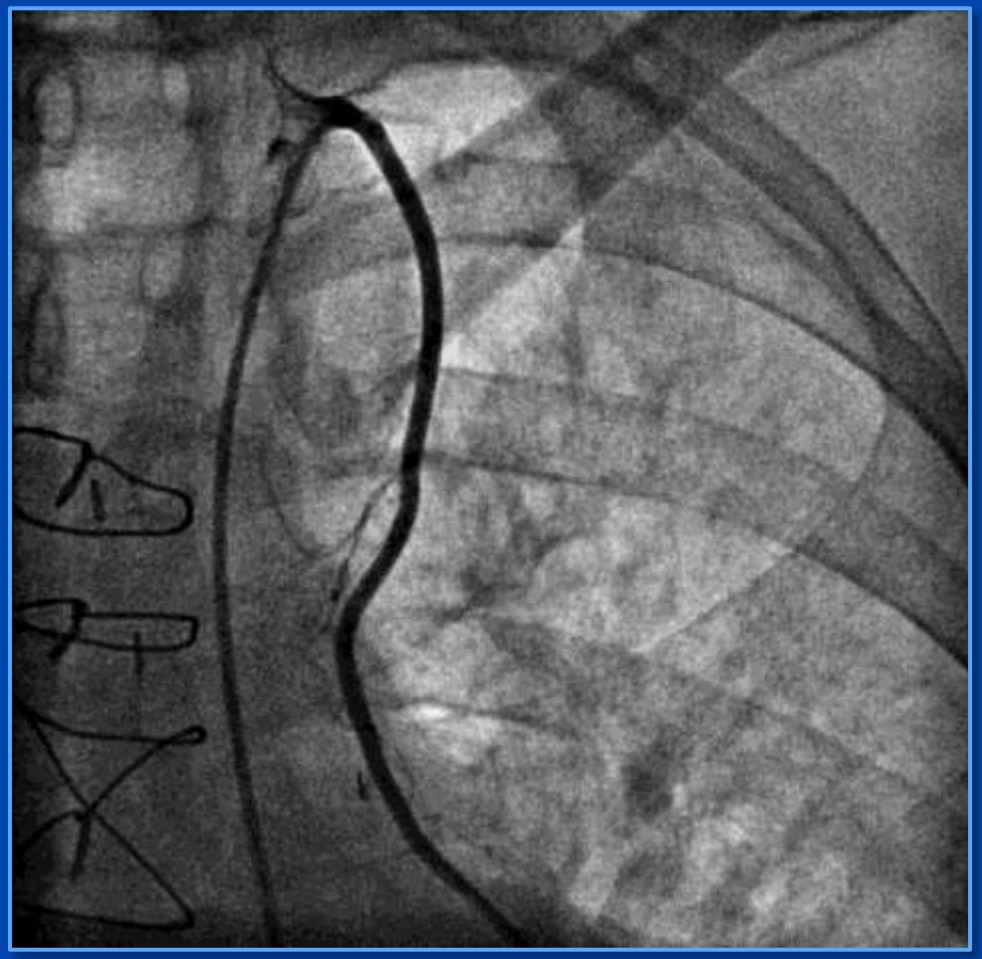
Case 2 – LIMA-LAD



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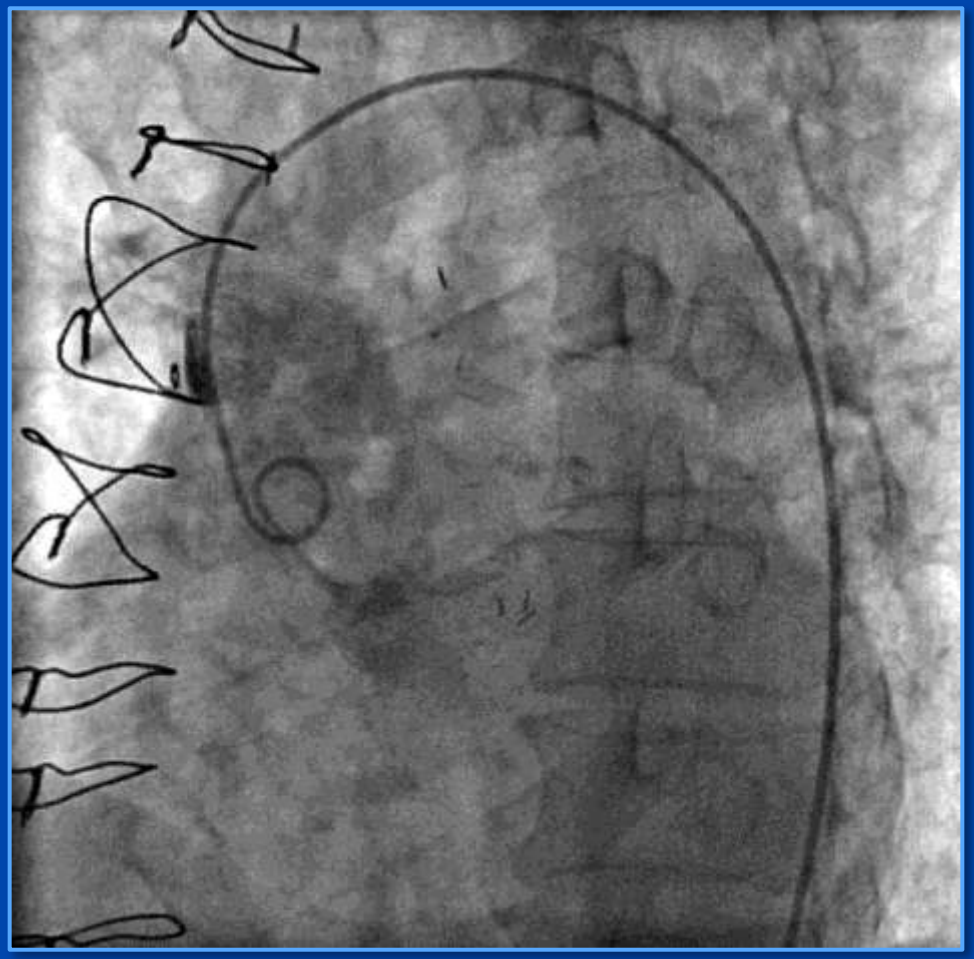
Case 2 – SVG Occluded



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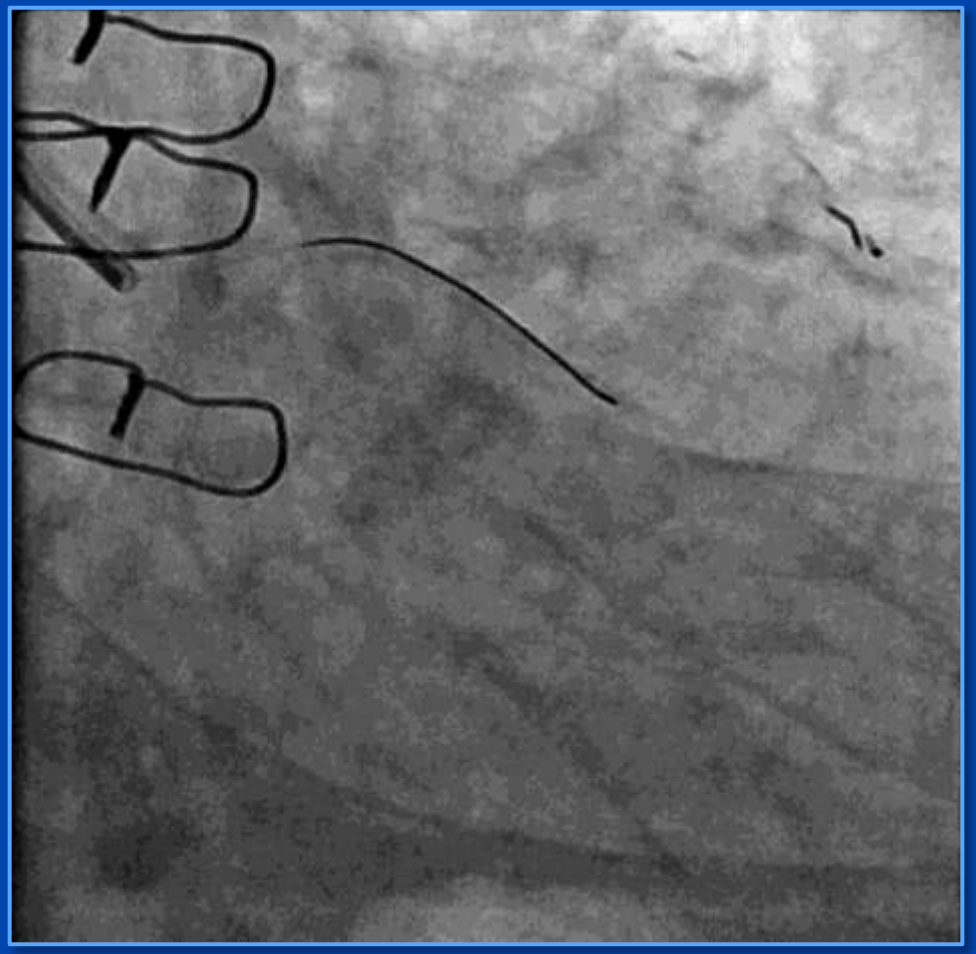
Case 2 – FFR 0.82, Systemic Adenosine



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FFR and LVH

- In LVH myocardial muscle mass outgrows the vascular bed
- Thus the range of physiological reserve of maximum achievable blood flow becomes smaller with increasing severity of LVH
- Therefore, the cut off value to indicate inducible ischemia will be higher with increasing severity of hypertrophy
- In such cases, an FFR >0.75 cannot be used to rule out inducible ischemia

Pijls and De Bruyne: Heart, 1998

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PARTNER Trial: Gestalt

PARTNER 1

Trial of percutaneous therapy for AS closely mimicking surgical therapy

Degree of revascularization more closely matched

PARTNER 2

Trial of surgical vs percutaneous management of AS patients

Degree of revascularization variable between arms

Pre-randomization revascularization discouraged

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Learning Objectives

- Prevalence of coronary disease in TAVR patients is high
- CAD adversely affects outcomes in TAVR patients
- PCI in patients with severe AS can be high risk
- LVH may impact FFR
- Treatment strategy of coronary disease in TAVR patients continues to evolve

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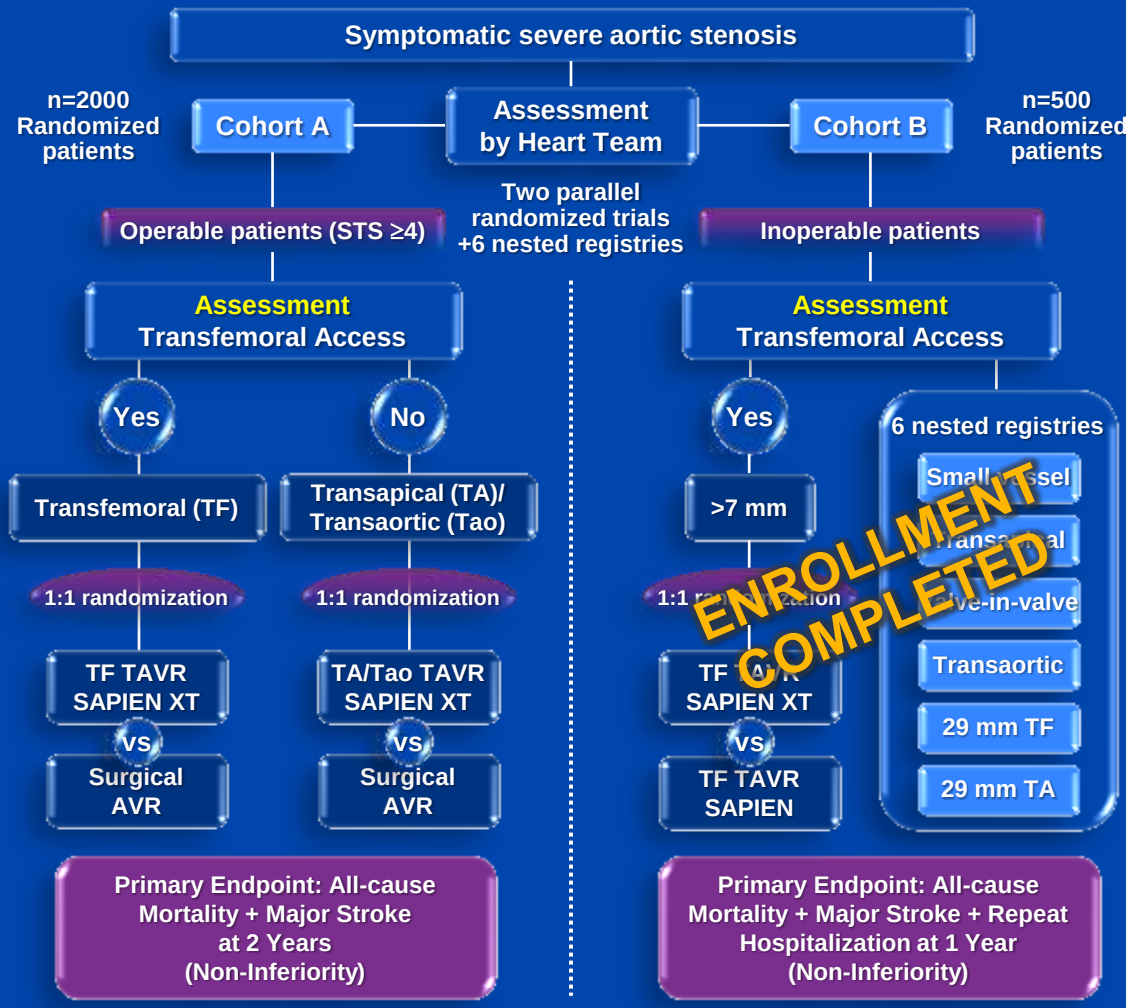
Cause for Confusion



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Combined elective percutaneous coronary intervention and transapical transcatheter aortic valve implantation

Miralem Pasic*, Stephan Dreysse, Axel Unbehaun, Semih Buz, Thorsten Drews, Christoph Klein, Giuseppe D'Ancona and Roland Hetzer

- 46 of 419 patients (11%)
- Single German center
- Transapical TAVR only
- TAVR always before PCI
- Selected only proximal lesions with severe stenosis and large area of myocardium
- 30-day mortality 4.3%
- 100% technical success

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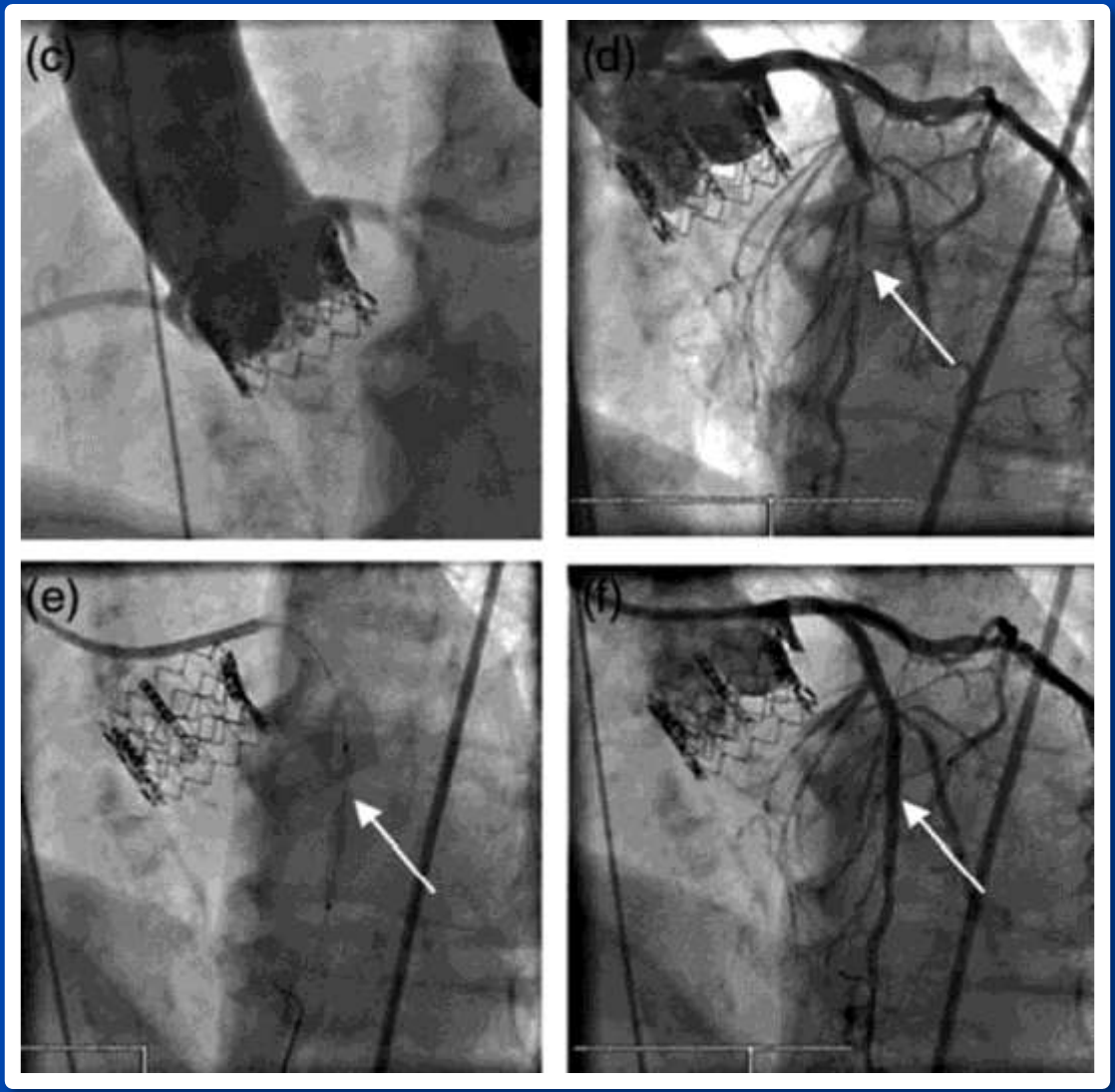

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Combined PCI and TA-TAVR

- Single center registry
  - 419 patients
- Combined elective PCI and TAVR performed in 46 (11%)

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