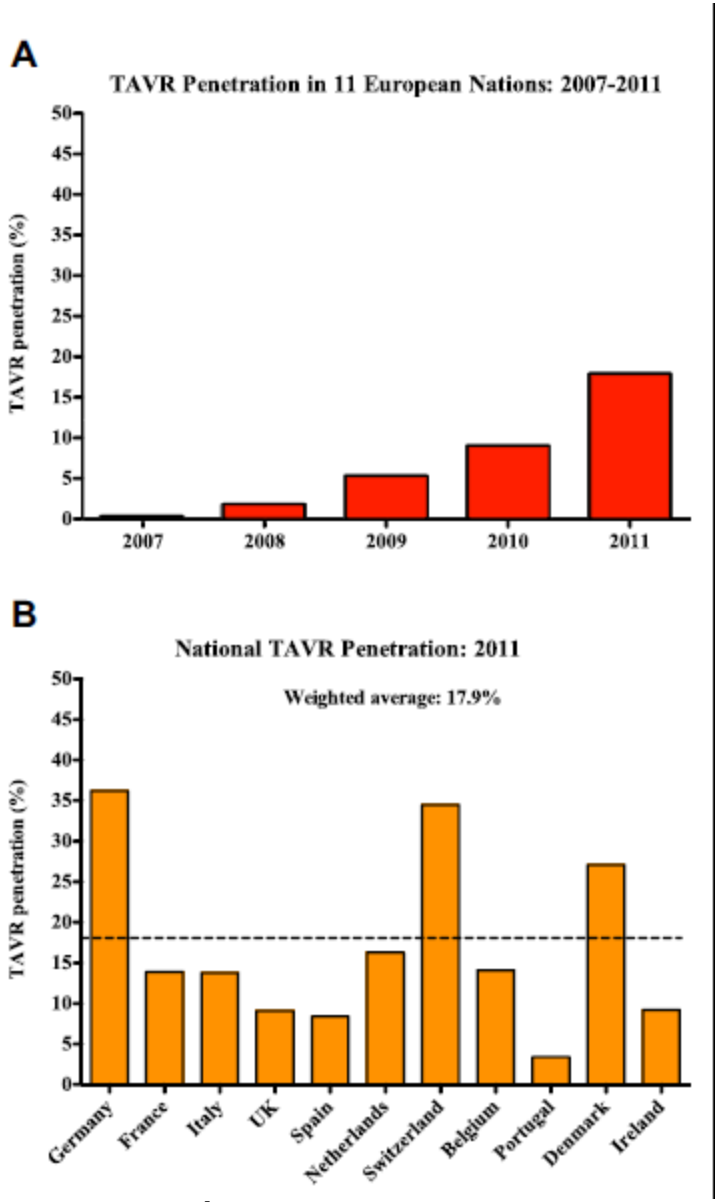
TAVR: Where are we Heading in 2014?

Neal Kleiman, MD
Houston Methodist DeBakey Heart and Vascular Institute

Methodist
DeBakey Heart
& Vascular Center

Estimated TAVR Penetration Among Eligible Patients in Europe

- Despite a 33 fold growth in the first five years, there is still tremendous variability among penetration in different countries

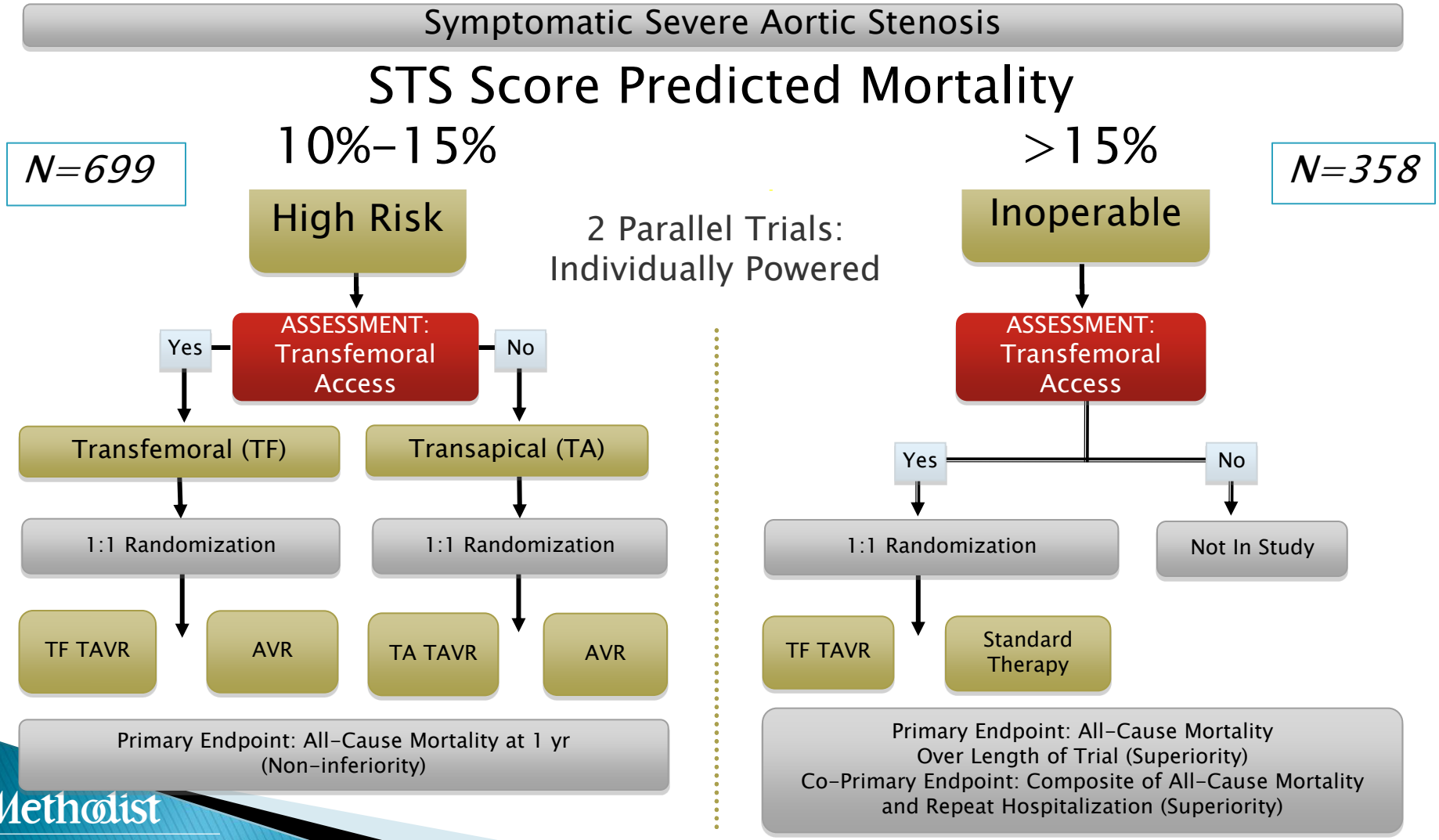


Mylotte: JACC 2013; 62:210

TAVR Directions

1. Patient Selection
2. New Groups
3. New Devices

PARTNER Study Program Design *(Edwards Sapien Valve)*



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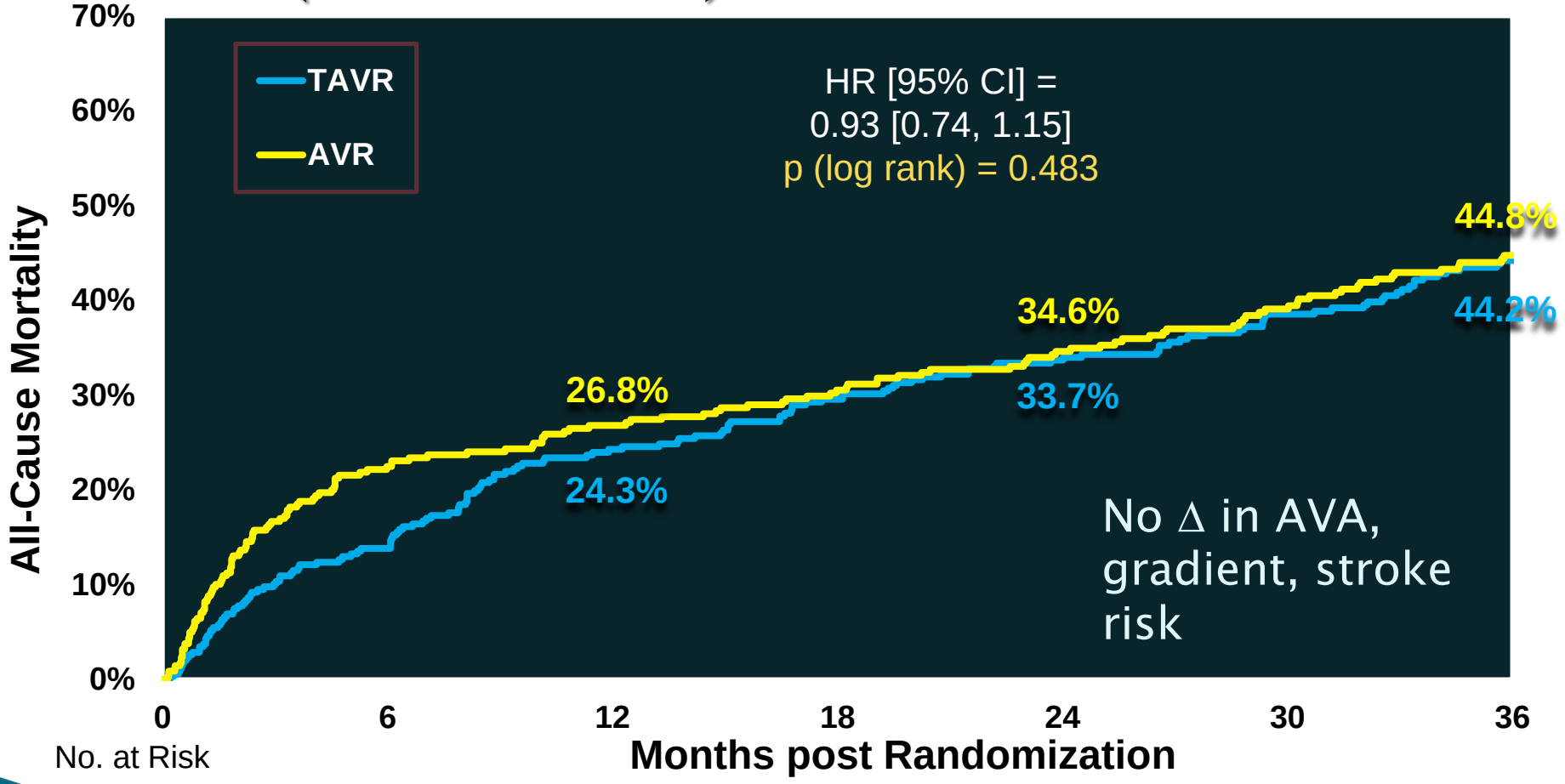
In High Risk But Operable Patients, TAVR and SAVR are Equivalent at Three Years (PARTNER A)



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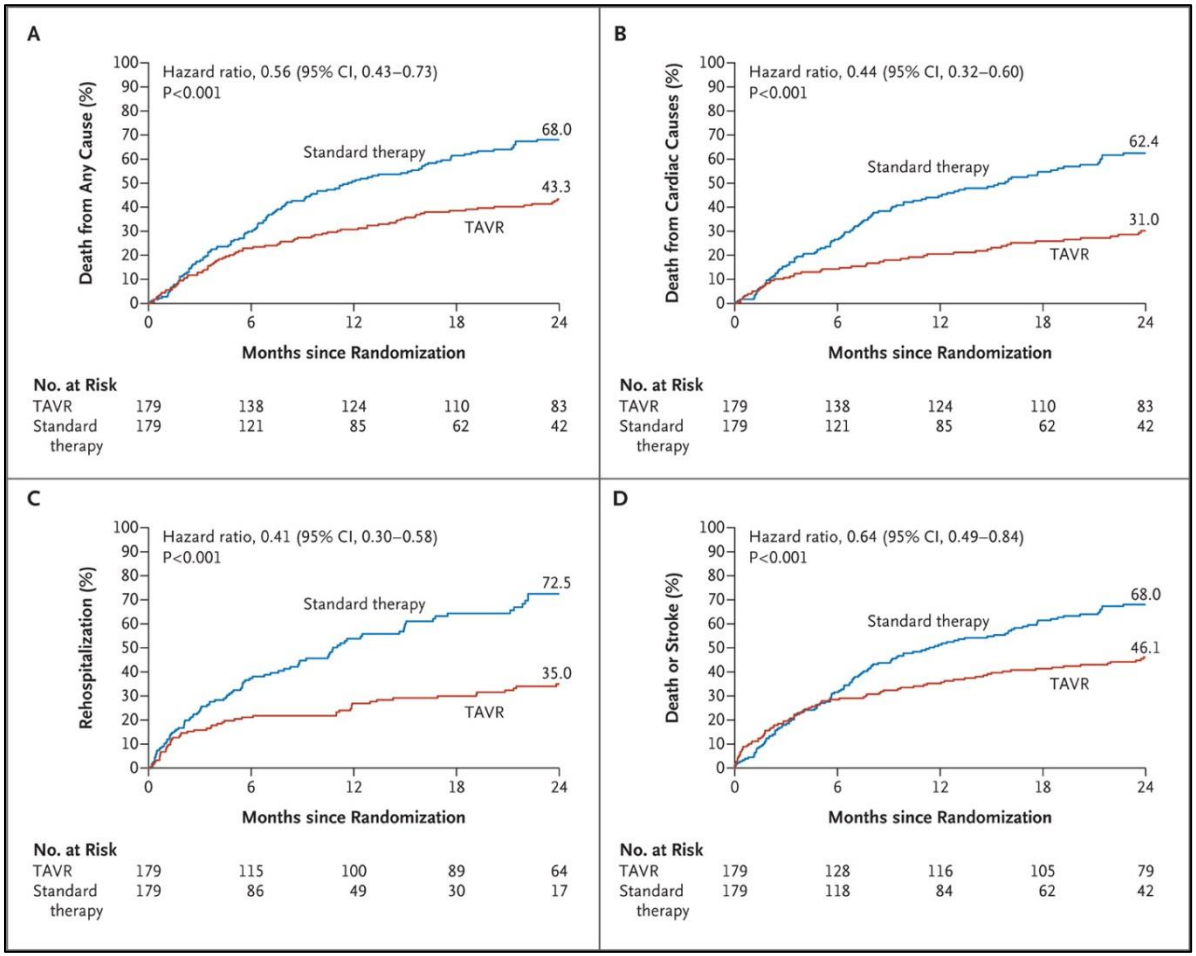
PARTNER B: Two Year Follow-up (in Patients Judged to be "Inoperable")

NNT=4



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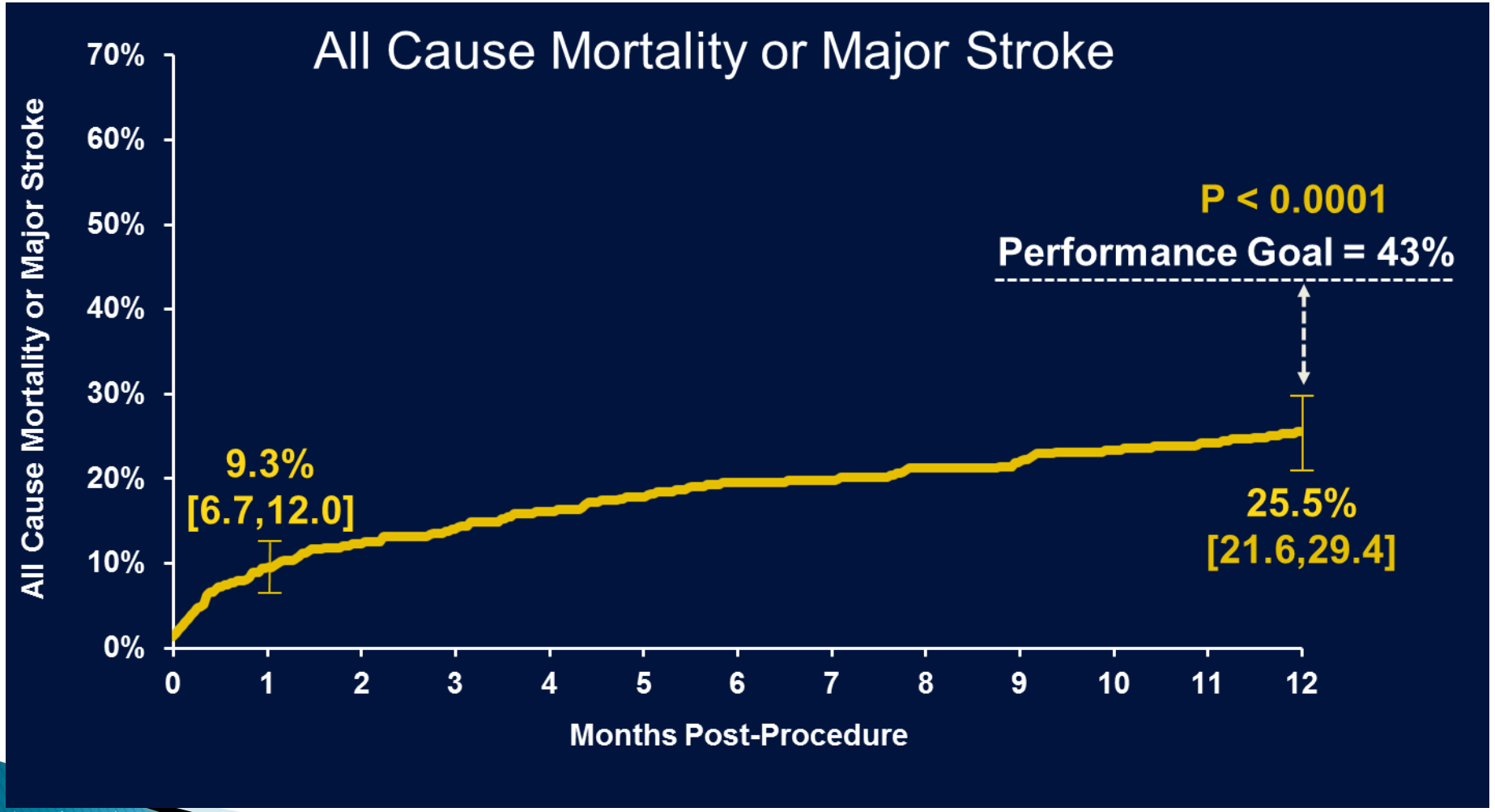
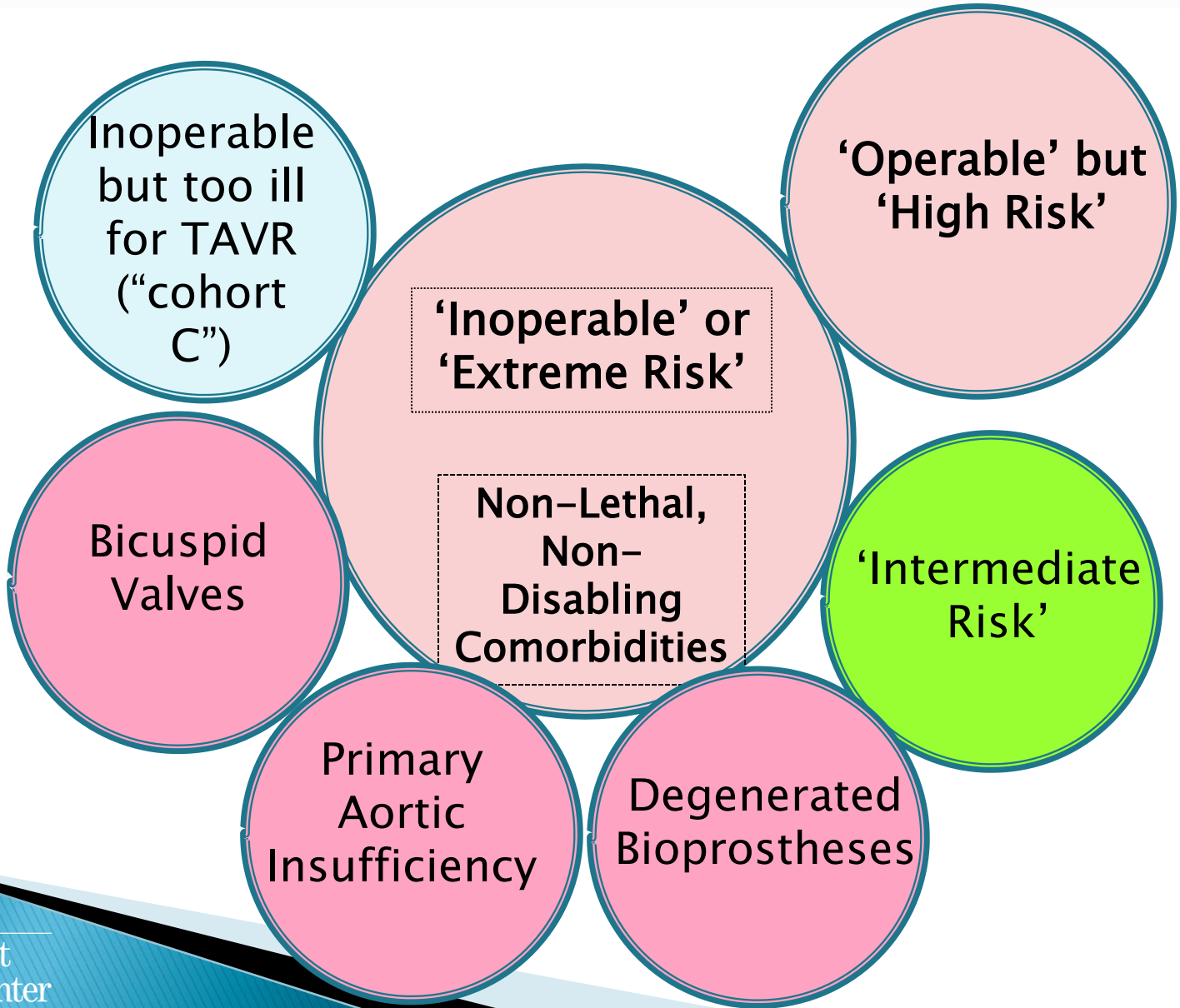
Makkar RR et al. N Engl J Med 2012;366:1696-1704.

CoreValve USIDE Extreme Primary Endpoint



TAVR: The Core and the Fringes



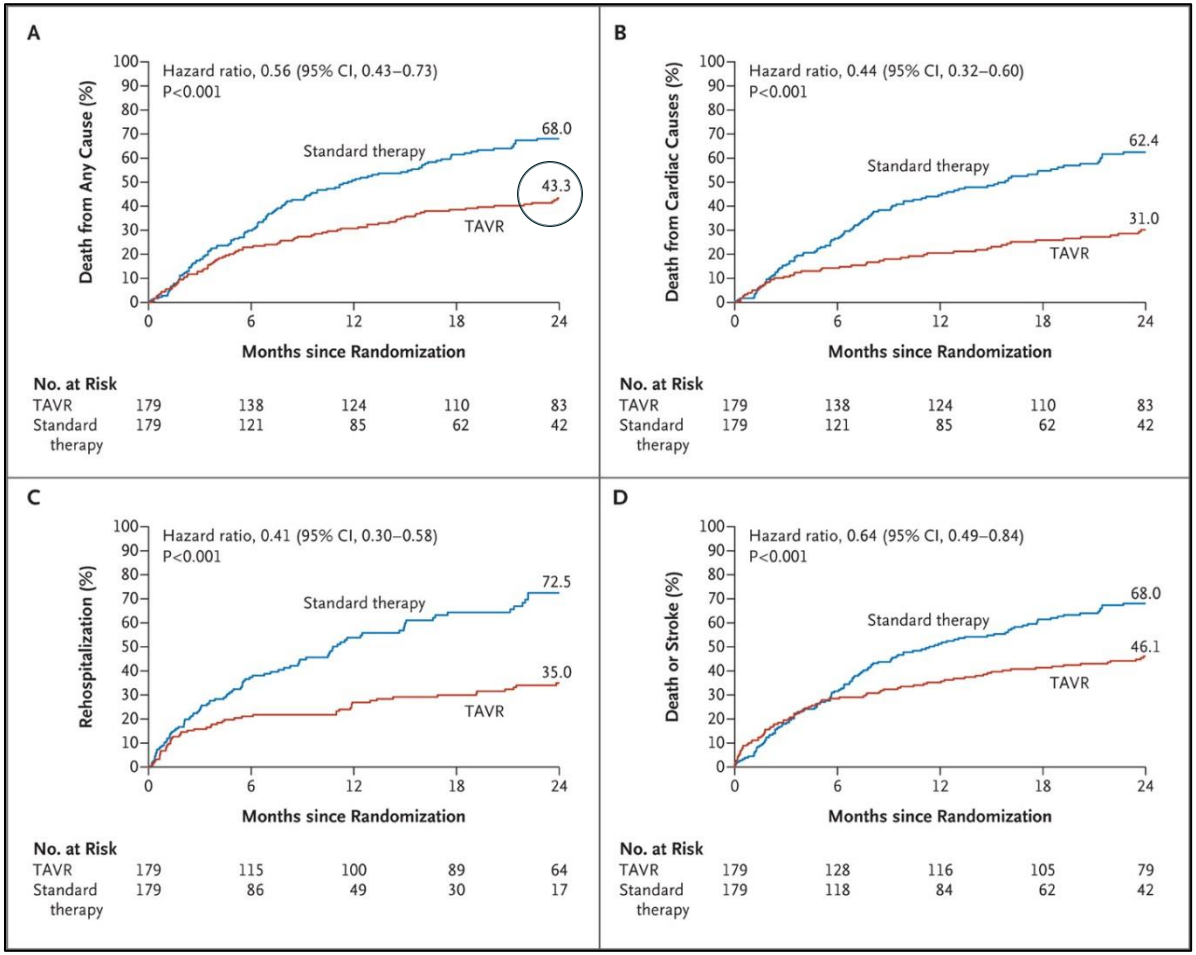
Comparison Between PARTNER COHORT B and STS 2006 Baseline Characteristics for Isolated sAVR:

	PARTNER Cohort B	STS 2006 *(N=15,397)*
Age (y)	83.3	70
Male (%)	82%	57%
NYHA III or IV	92.2%	54%
Prior MI	19%	10%
COPD	41.3%	19.9%
LVEF	53.3%	56%
PAD	30%	8.2%
Creat. > 2 mg/dL	5.6%	5.4%
Prior CABG	37%	9%

(13% > 80y)

Leon, MB. NEJM. 2010;363:1597
Brown, JM. J Thorac Cardiovasc Surg.2009;137:82
Edwards, F. J Am Coll Cardiol. 2001;37:885

PARTNER B: Two Year Follow-up (in Patients Judged to be "Inoperable")



Makkar RR et al. N Engl J Med 2012;366:1696-1704.

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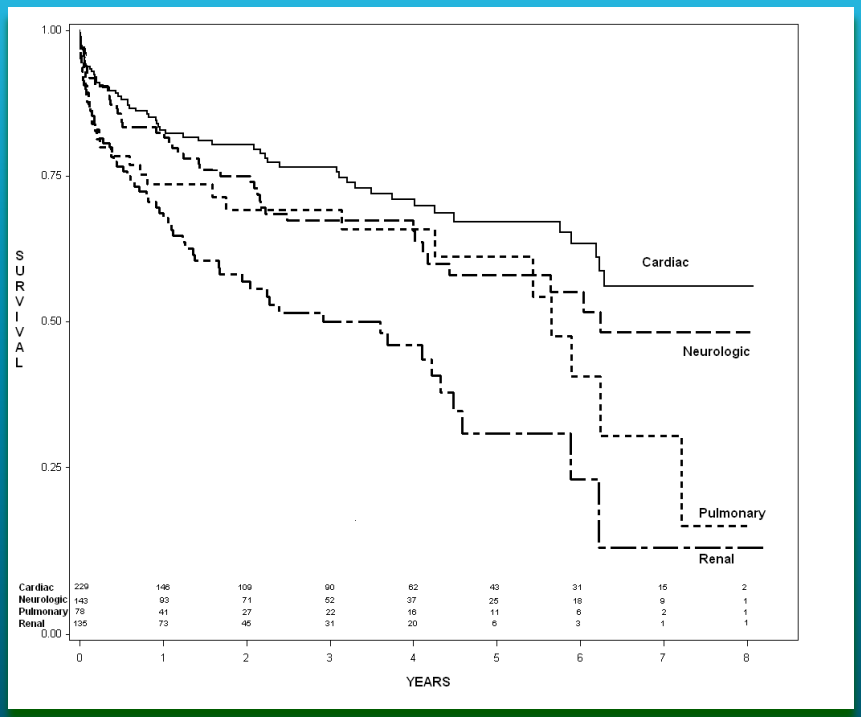
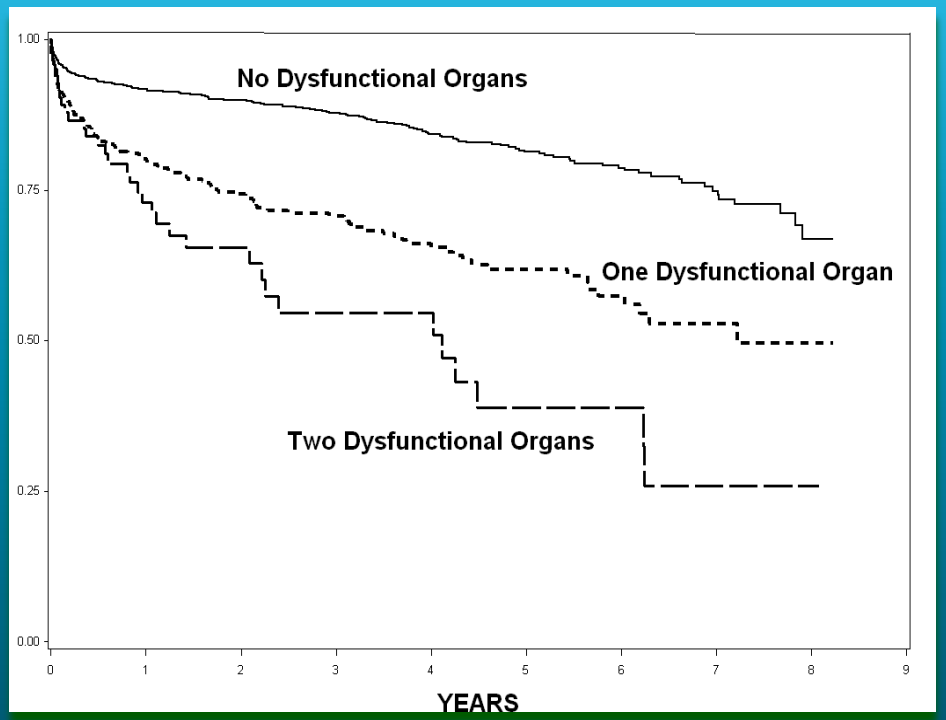
Mortality After SAVR in Patients with Co-Morbidities





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Thourani, Ann Thorac Surg. 2013; 95:838

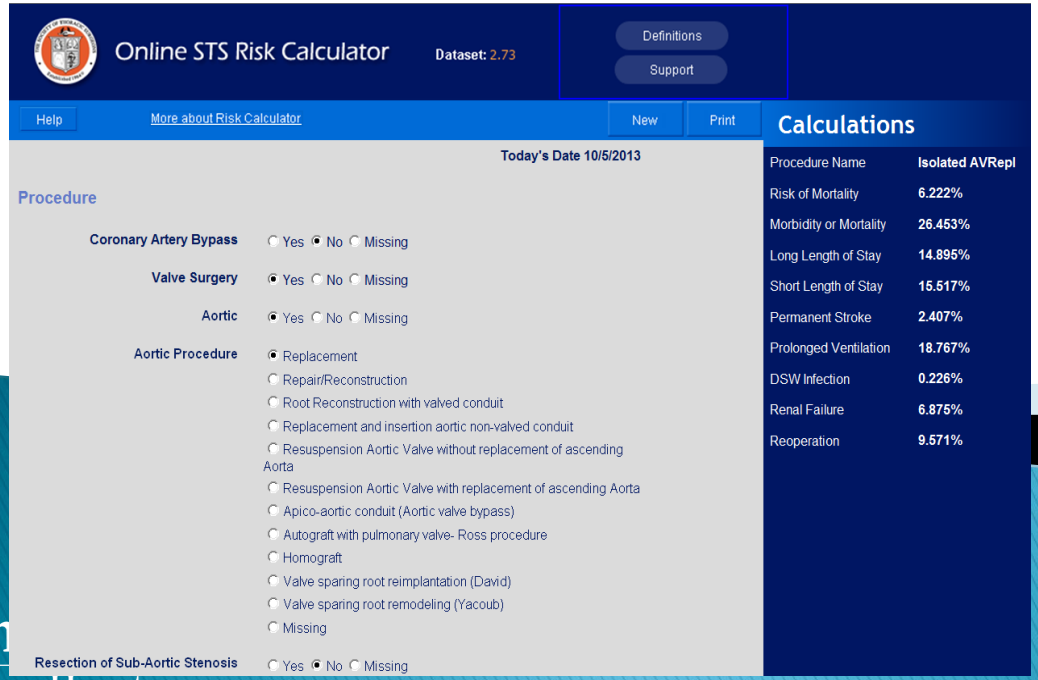
The Society of Thoracic Surgeons National Database Status Report

Richard E. Clark, MD

Chairman, Ad Hoc Committee* to Develop a National Database for Thoracic Surgery

This report describes the development of the first known national surgical database designed for the practicing community cardiothoracic surgeon. Acceptance by members of The Society of Thoracic Surgeons has been gratifying. The number of patients on the system has grown from 116,109 at the end of 1991 to an anticipated 350,000 to 450,000 by the end of 1993. At the time of this report, 842 surgeons were participating, and more than 1,200 will be on the system by the end of 1993. A risk stratification system has been incorporated into the software, which predicts each patient's risk based on the individual surgeon's past experience. Trend analyses demonstrate a substantial increase in the number of patients at increased risk for perioperative death for coronary artery bypass operations over the past 5 years, while observed mortality has remained relatively constant. Programs are available for adult and congenital heart disease, lung cancer, and esophageal cancer, and modules for mediastinal tumors, pleural disorders, and benign pulmonary disease will soon be added. We anticipate that growth will continue as the need for practice profile data increases because of reimbursement issues.

(Ann Thorac Surg 1994;57:20–6)



Trial Guidelines

- PARTNER B, CV Extreme Risk: *STS PROM > 15*
- PARTNER A, CV High Risk: *STS PROM >10*

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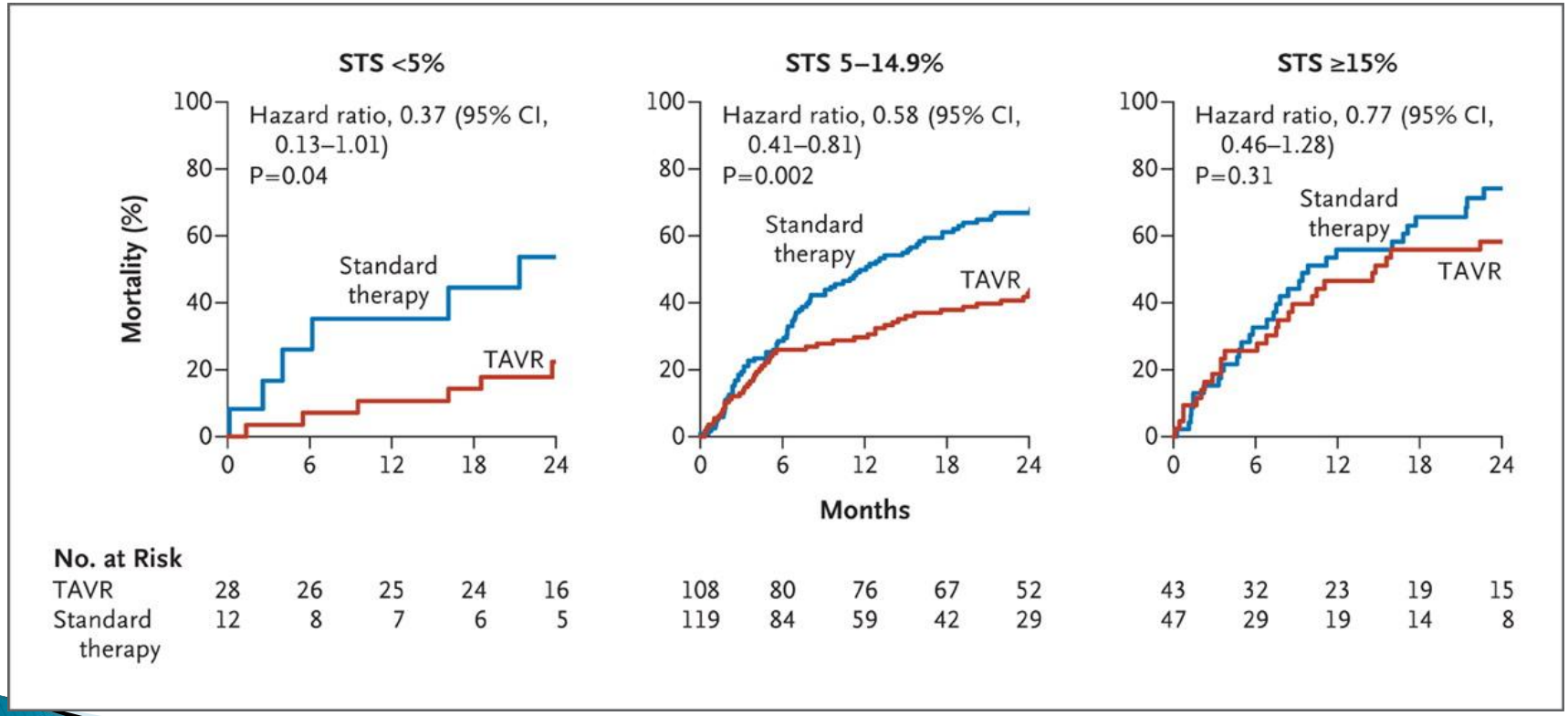
Two-Year Mortality, Stratified According to the Society of Thoracic Surgeons (STS) Risk Score



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Makkar RR et al. N Engl J Med 2012;366:1696-1704.

A Realistic Expectation?

Frailty Assessment

Patient A **vs.** **Patient B**

Same age and predicted risk
One passes the "eyeball test" – one does not

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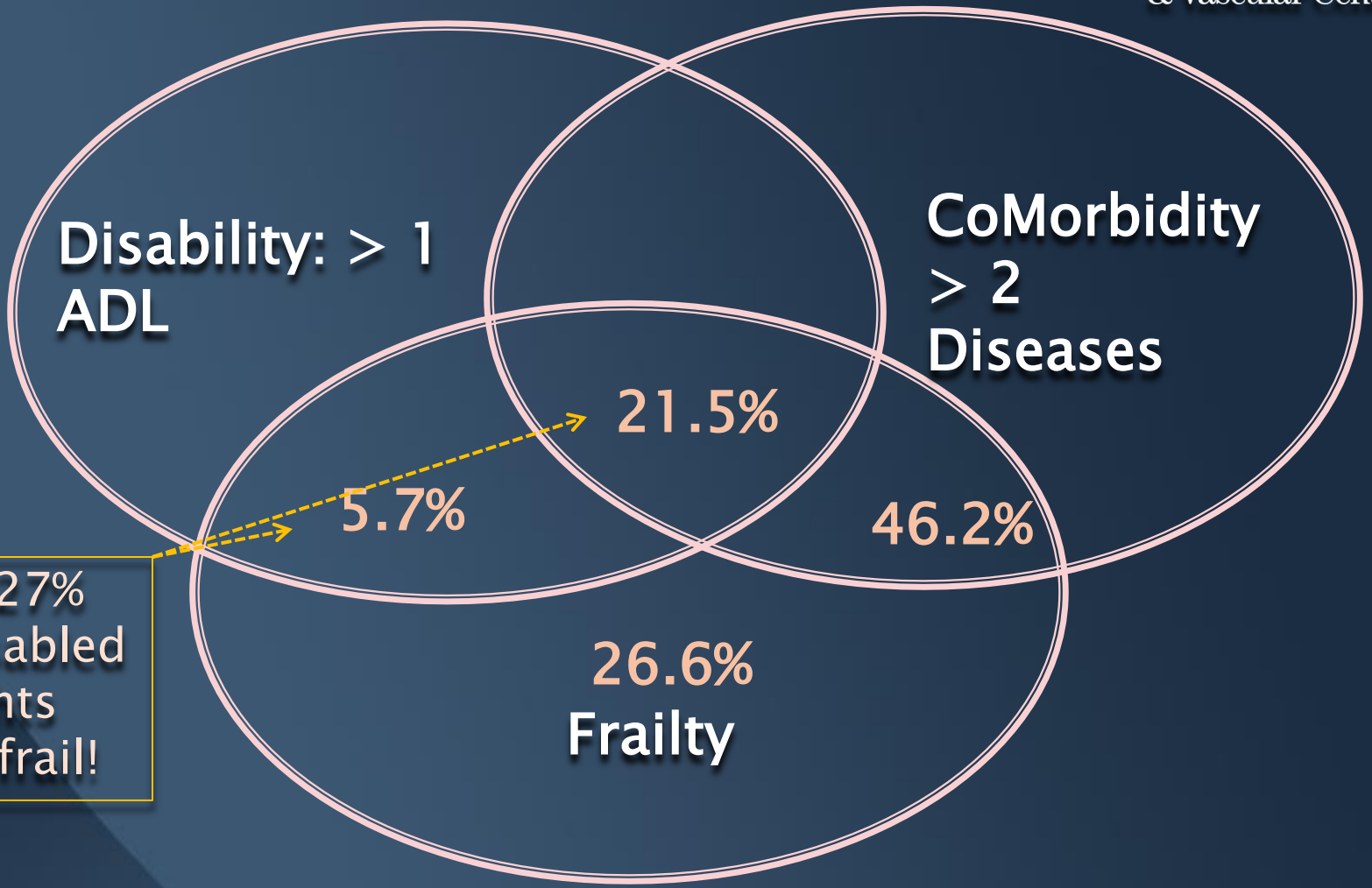
Photos courtesy of Michael J. Mack, MD
Medical City Dallas

Core Valve USIDE Extreme Risk: Frailty Assessment

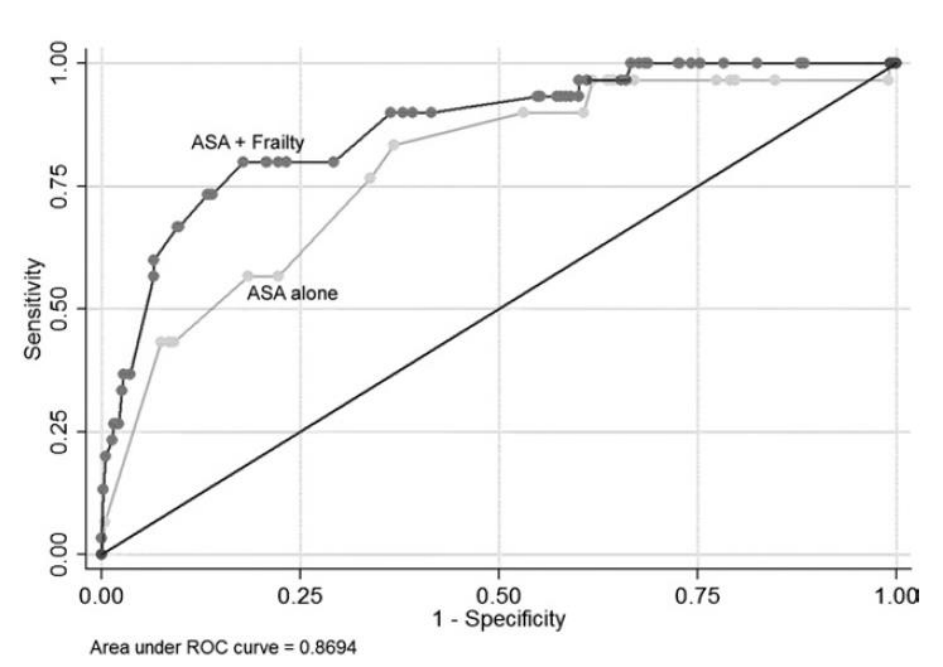
Frailty Characteristic	N=471
Anemia With Prior Transfusion, %	22.9
BMI < 21 kg/m^2, %	7.6
Albumin < 3.3 g/dL, %	18.5
Unplanned Weight Loss > 10 pounds, %	16.9
Falls in Past 6 Months, %	17.8
5 Meter Gait Speed > 6 secs, %	84.2
Grip Strength < Threshold, %	67.6

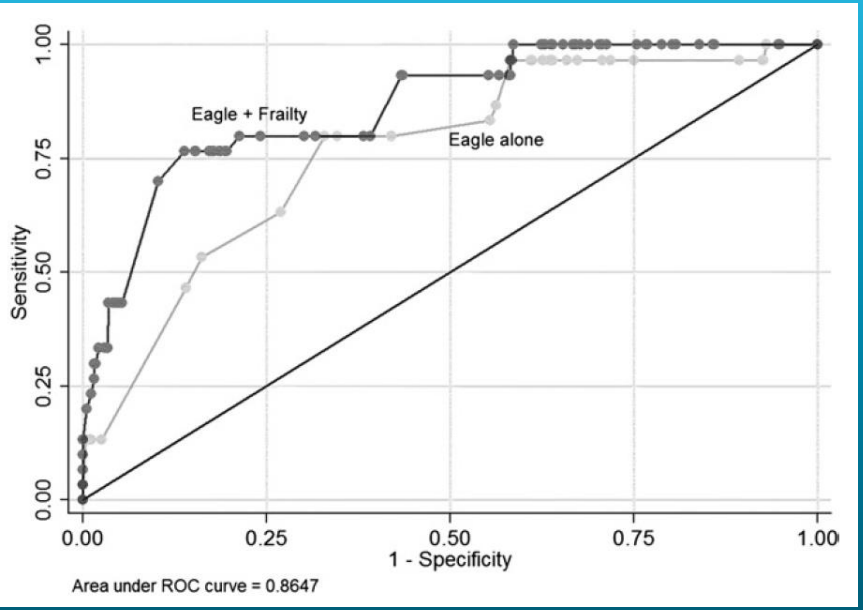


Only 27% of disabled patients were frail!

Fried, L. J Geront. 2001;56A:M146

Incremental Ability of the Frailty Score to Predict Outcomes After General Surgery





Makary. J Am Coll Surg. 2010; 210:901

Treatments for Symptomatic Severe Aortic Stenosis

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All Patients with Symptomatic Severe AS

Lowest Risk

Highest Risk

25%

10

Surgical Population

Partner A CoreValve High Risk

Partner B CoreValve Extreme Risk

Treatments for Symptomatic Severe Aortic Stenosis

Methodist DeBakey Heart & Vascular Center

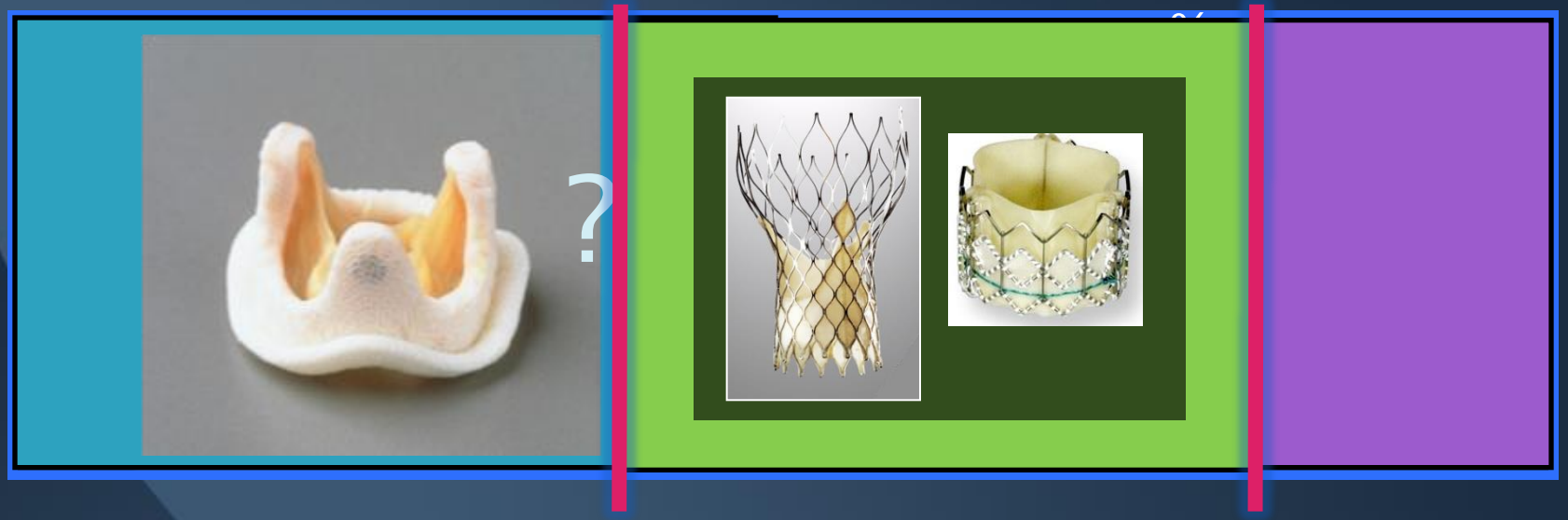
All Patients with Symptomatic Severe AS

Lowest Risk

Highest Risk

25%

10



Surgical Population

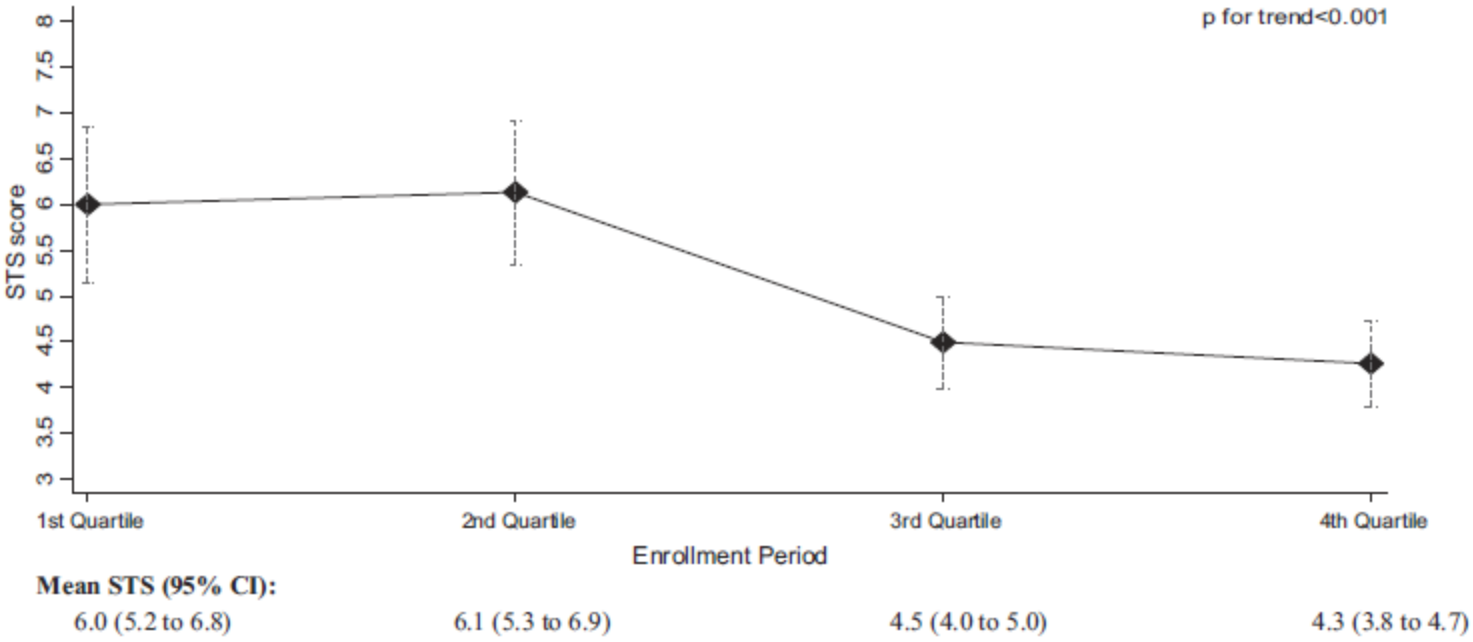
Partner IIA SurTAVI

Partner A CValve High Risk

Partner B Valve Extreme

"Partner C" Futile

Decreasing STS Score in a Multicenter Population



Piazza: JACC 2013;6:443

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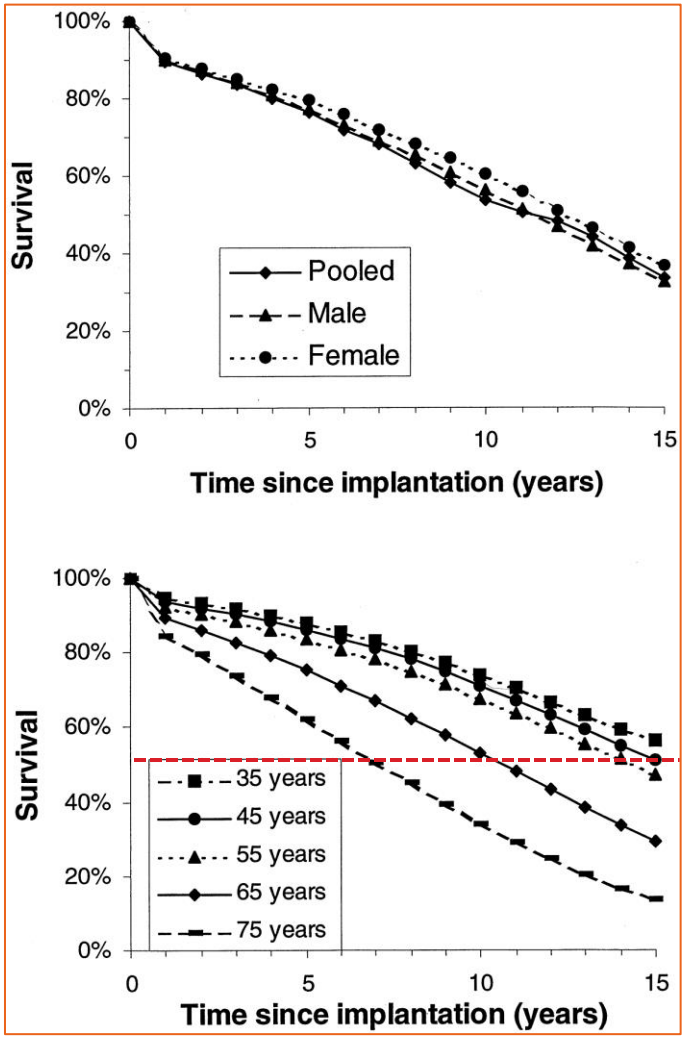
Intermediate Risk Population: Major Considerations

- Durability of the valve
- Consequences of aortic insufficiency
- Stroke risk

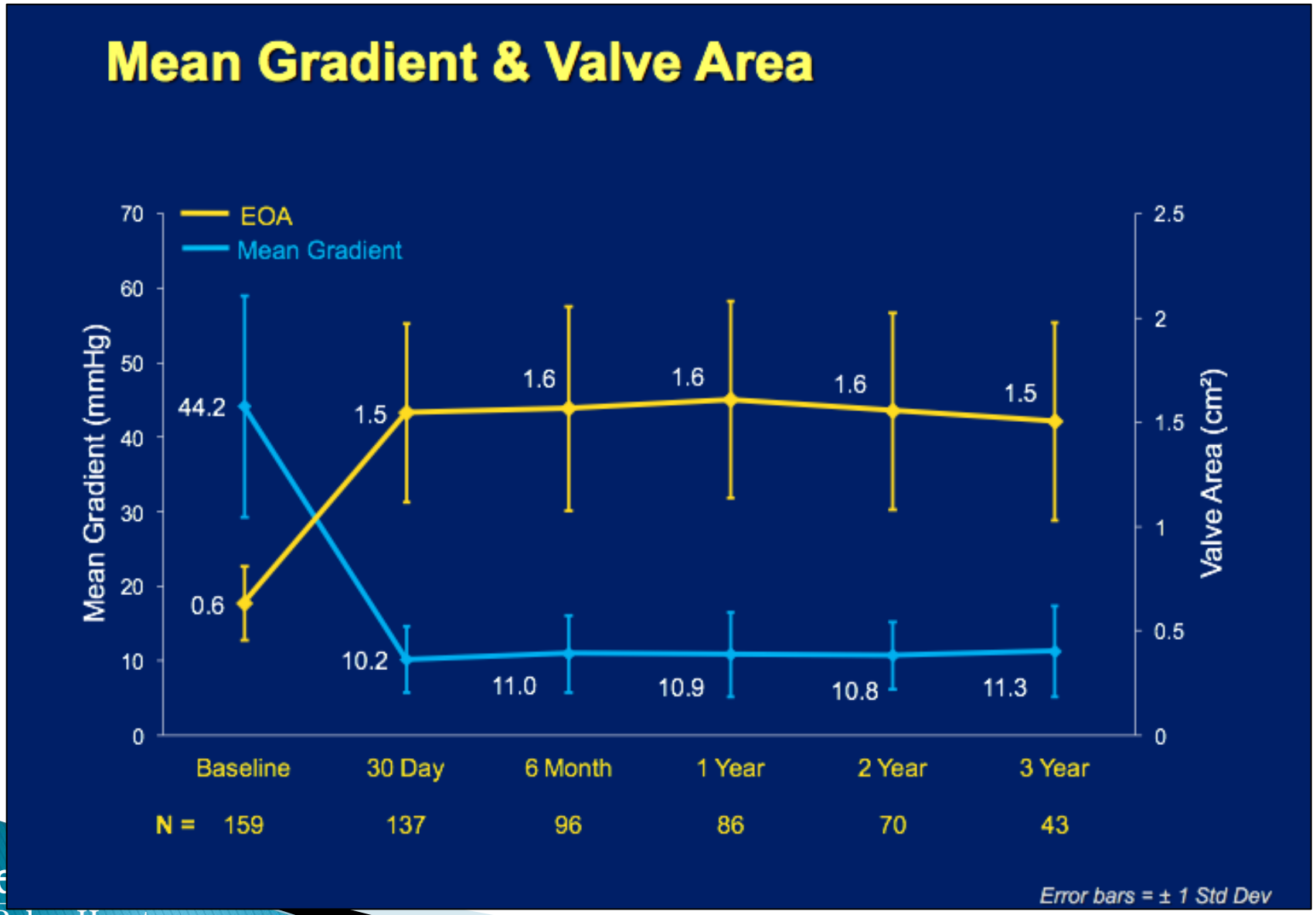
Expected Survival After Bioprosthetic SAVR

- Metanalysis of 9 studies
- 5,837 valve recipients with 31,874 years of follow-up
- Standardized definitions of events
- Microsimulation model producing 10,000 life histories



Puvimanasinghe J P A et al. Circulation 2001;103:1535-1541

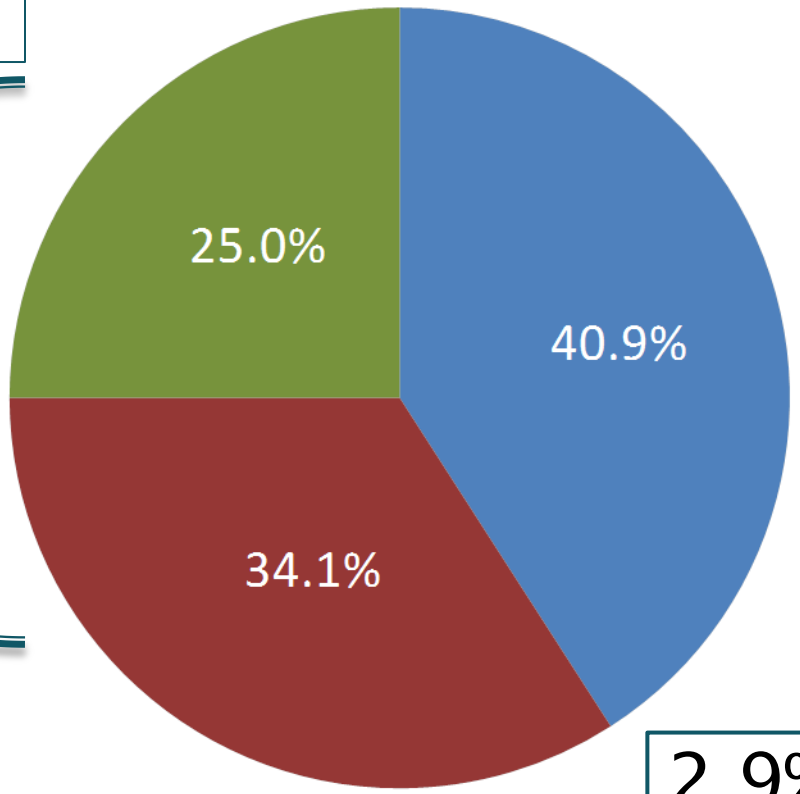
Partner B


Mean Gradient & Valve Area
EOA
Mean Gradient
Mean Gradient (mmHg)
Valve Area (cm²)
70
60
50
40
30
20
10
0
2.5
2
1.5
1
0.5
0
44.2
1.5
1.6
1.6
1.6
1.5
0.6
10.2
11.0
10.9
10.8
11.3
Baseline
30 Day
6 Month
1 Year
2 Year
3 Year
N = 159 137 96 86 70 43
Error bars = ± 1 Std Dev

Stroke and TAVR

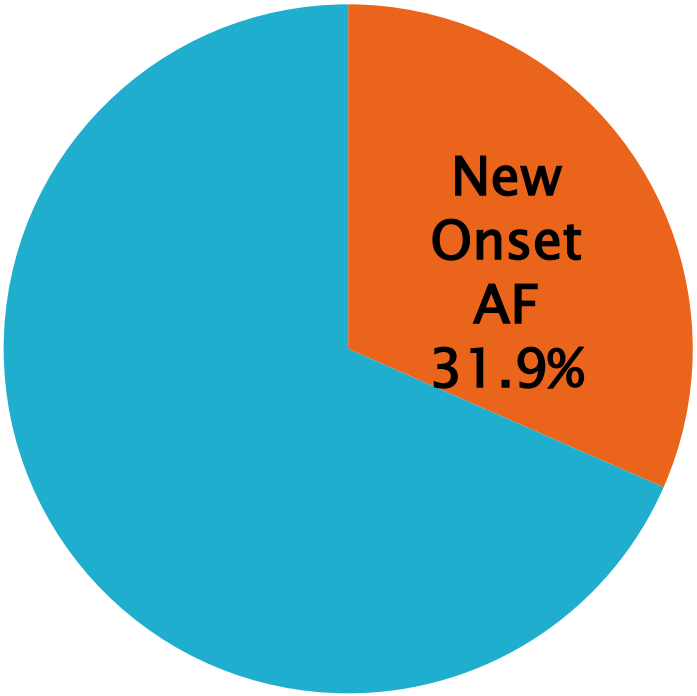
Timing of Stroke/TIA in the ADVANCE Registry

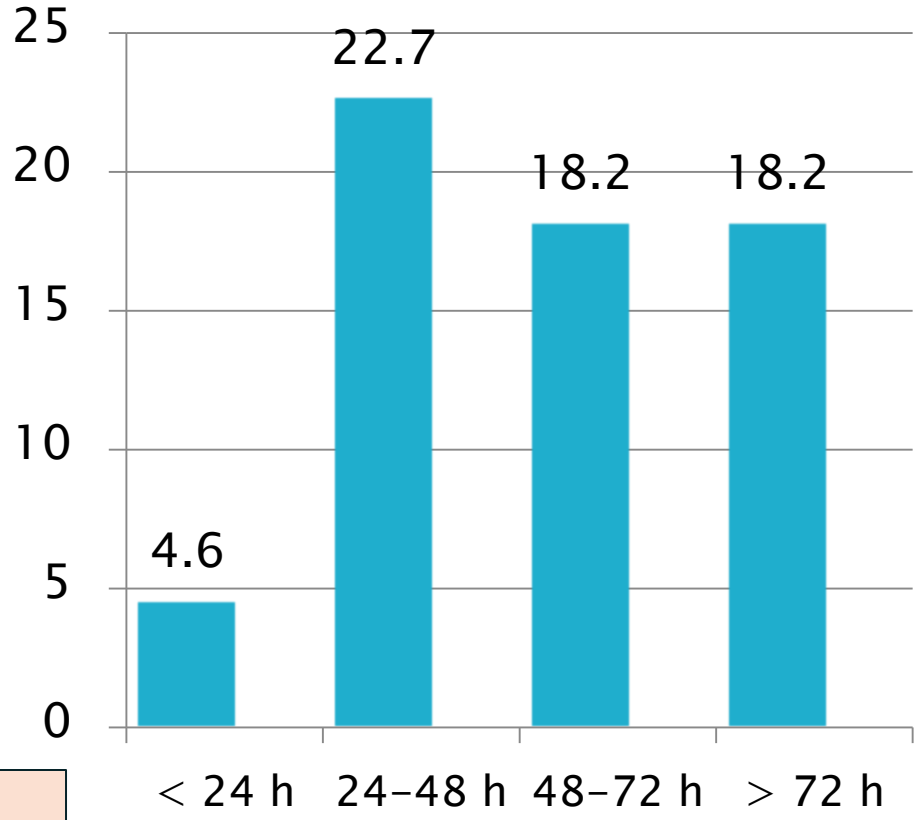
59% occur > 48h AFTER the procedure



2.9% at 30 (days)
{2.4% in CV US IDE trial}

Atrial Fibrillation is Already There: Quebec Experience

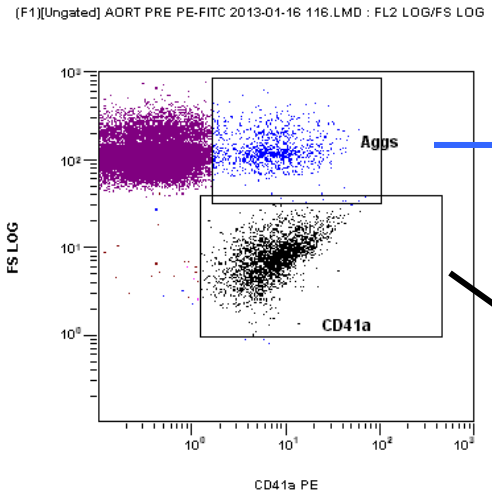


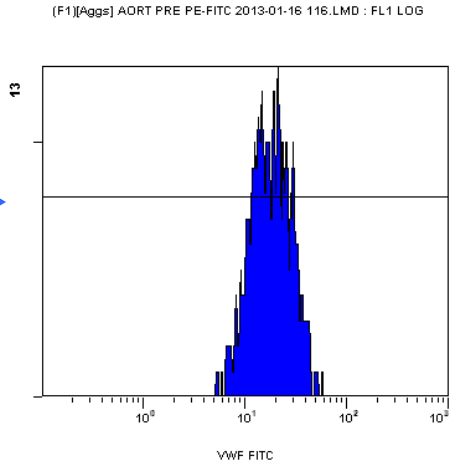


Predictors:
Large LA (OR = 1.21/mm/m²);
Transapical Approach (OR = 4.08)

Amat Santos. JACC. 2012;50:178

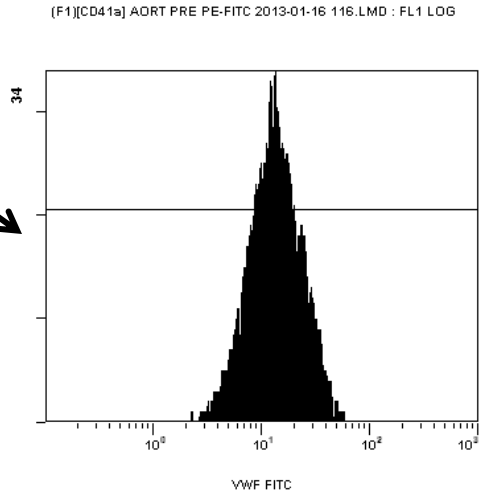
Von Willebrand Factor and Platelet Aggregates after TAVR





MFI=22%

Aortic blood Pre valve implant



MFI = 16%

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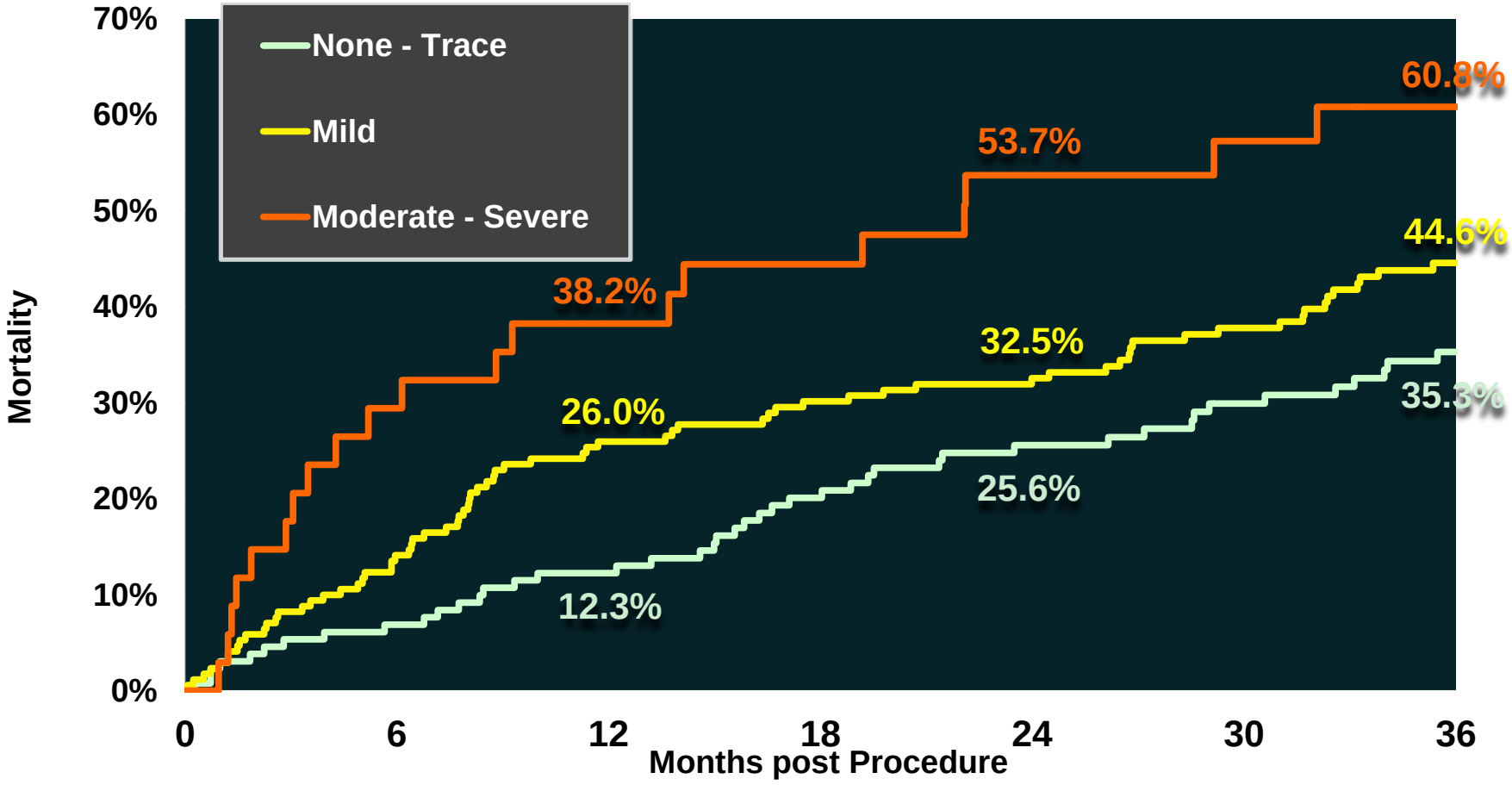
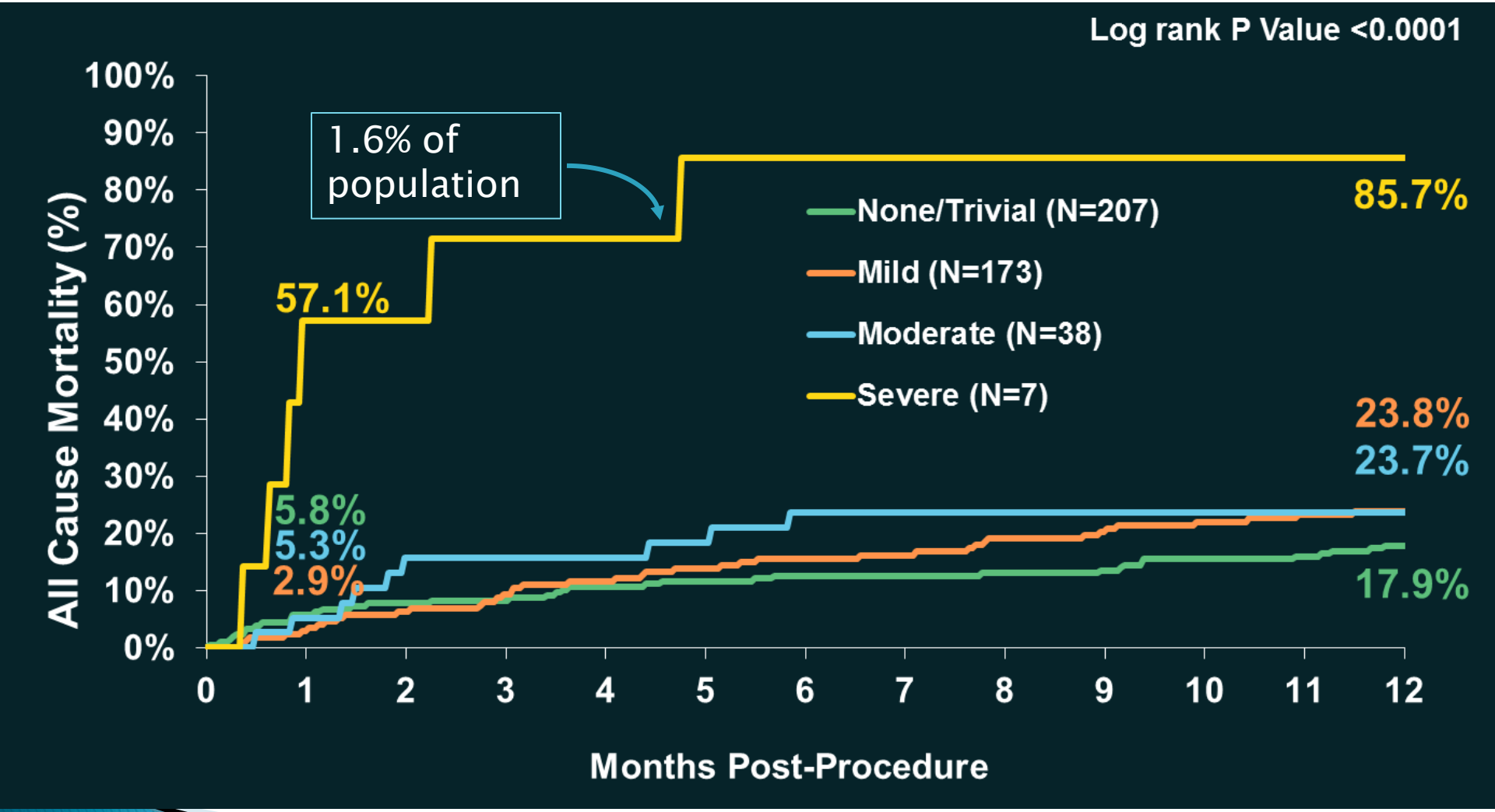
PARTNER 2A: Impact of Total Aortic Insufficiency on Mortality



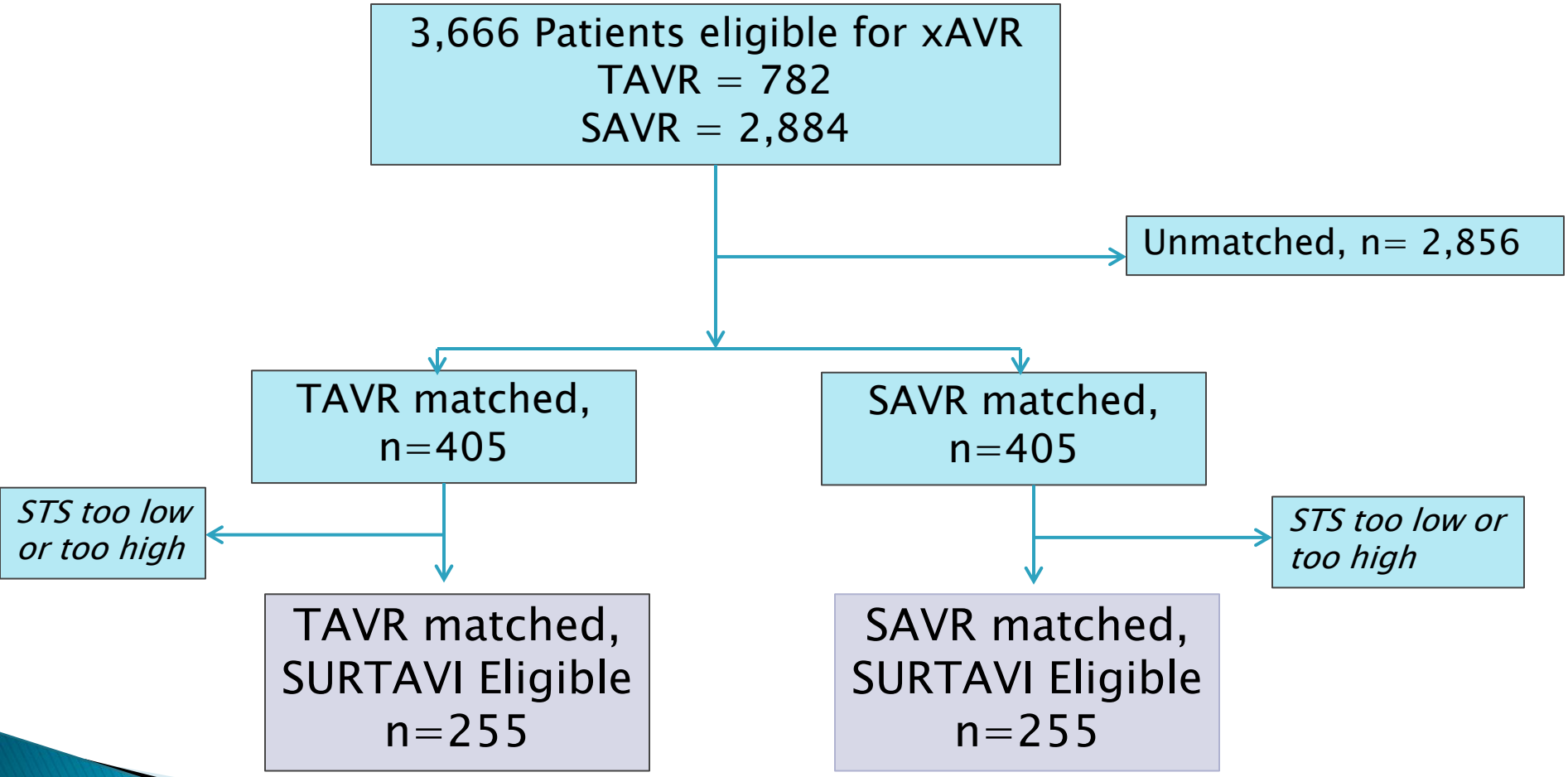
None–Tr	114	102	93	80	63
Mild	125	117	110	94	62
Mod-Sev	21	18	15	12	9

Association Versus Causation

CoreValve USIDE Trial: Impact of PVL on Late Mortality

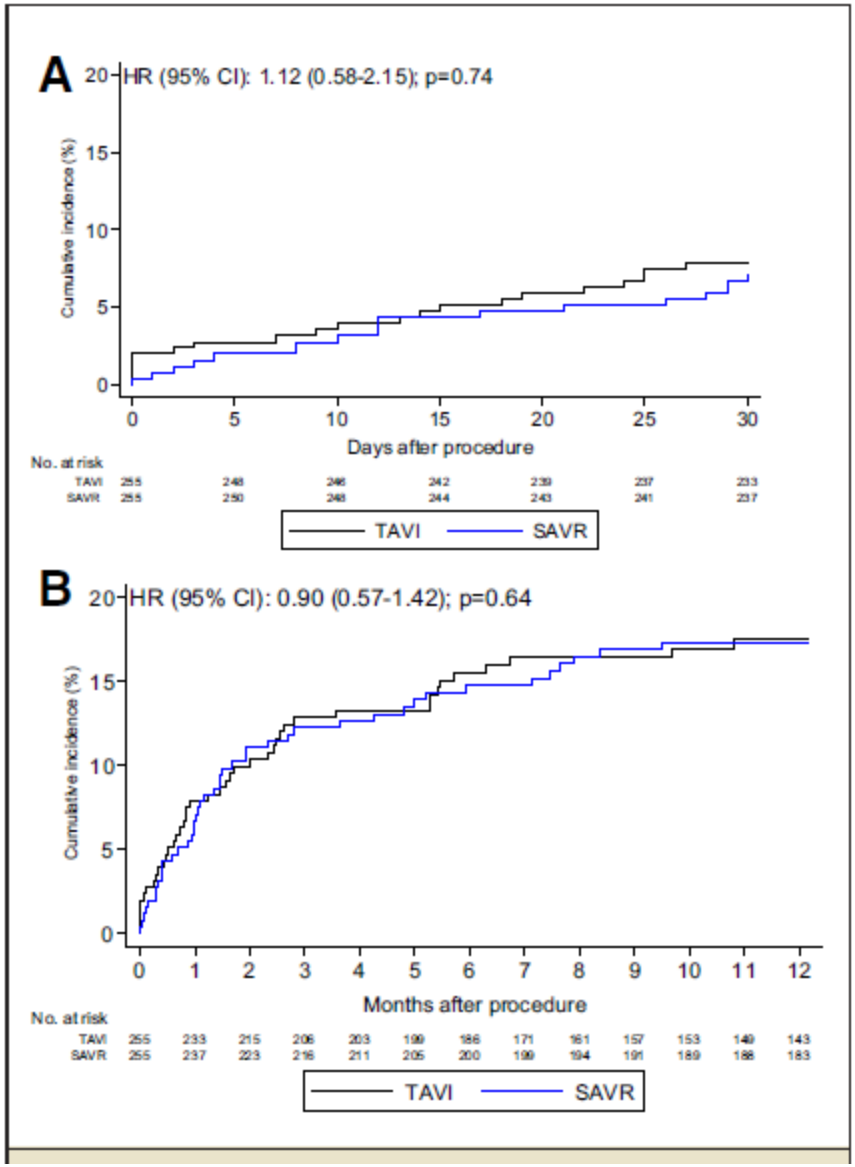


Intermediate Risk – Propensity Matched Outcomes for xAVR



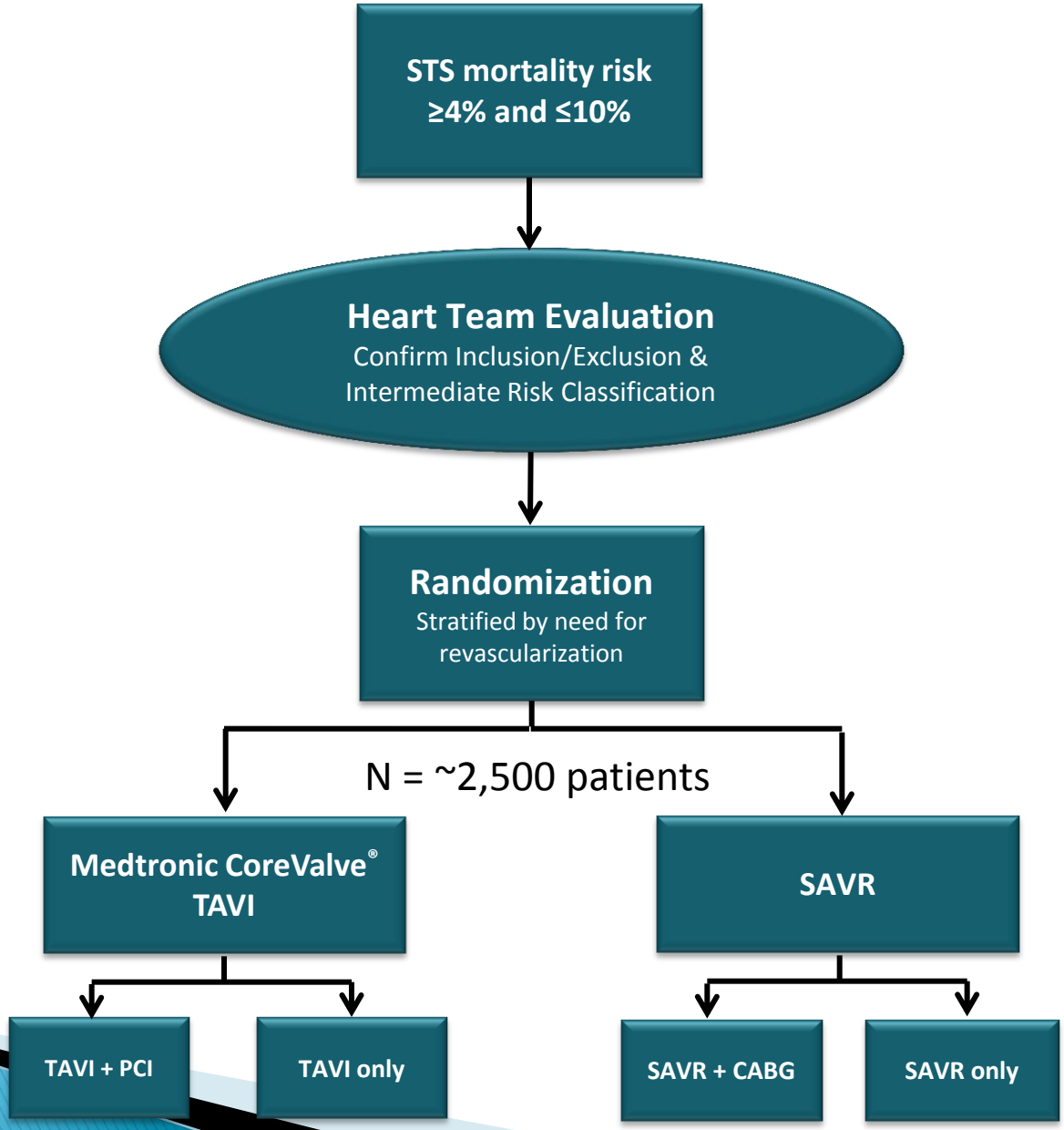
Piazza: JACC 2013;6:443

Matched Population: All Cause Mortality



Piazza: JACC 2013;6:443

CoreValve® SURTAVI Trial



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Staged Percutaneous Treatment of Mitral Paravalvular Leak and Aortic Valve Pathology in Rheumatic Heart Disease

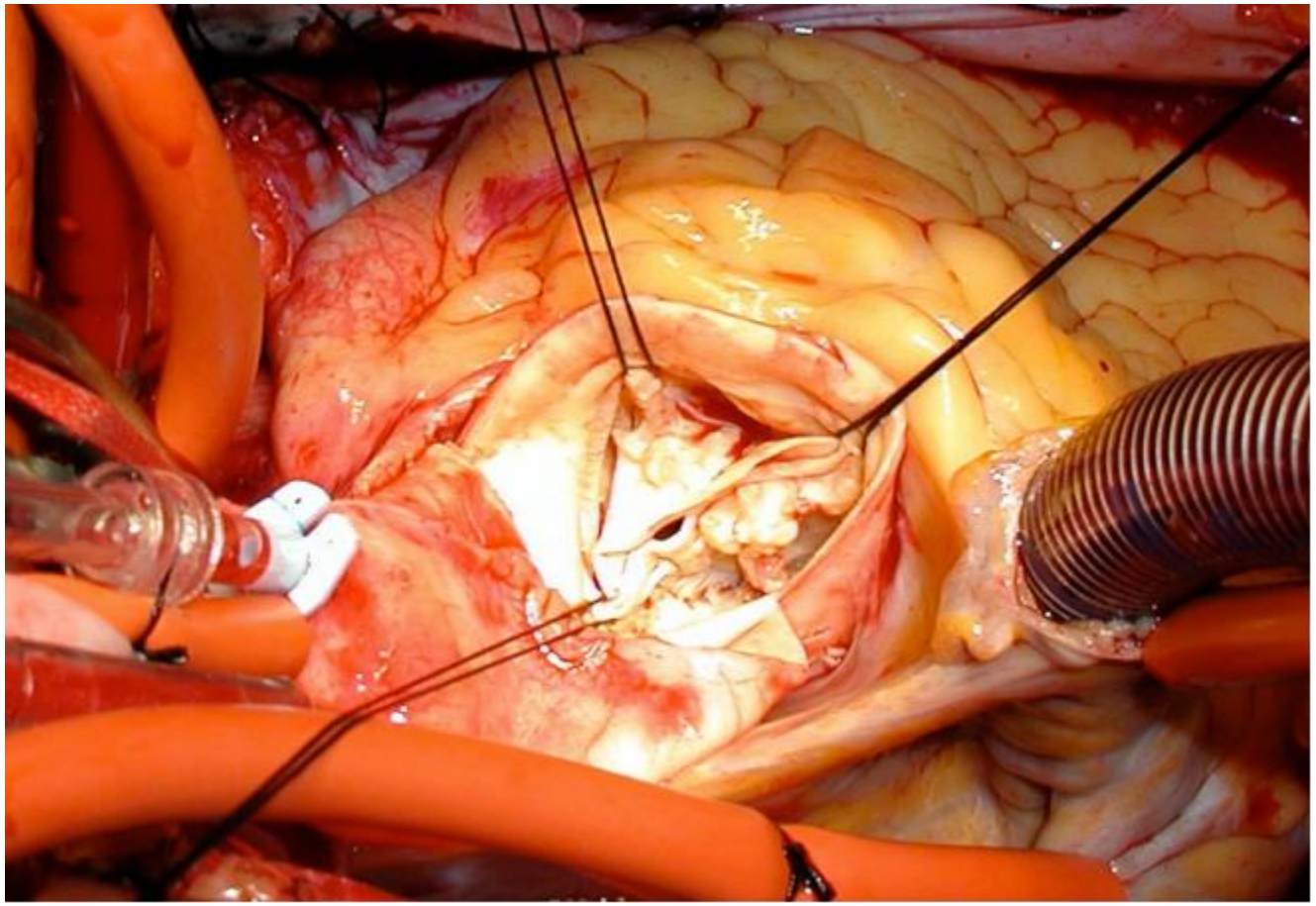
First Case Description.

Kunal Sarkar (1) Francesco Romeo(1) Gian Paolo Ussia(1)

1) Department of Cardiovascular Disease, Tor Vergata University of Rome, Rome, Italy

Address for Correspondence:

Bicuspid Aortic Valve



Transcatheter Aortic Valve Implantation for Patients With Severe Bicuspid Aortic Valve Stenosis

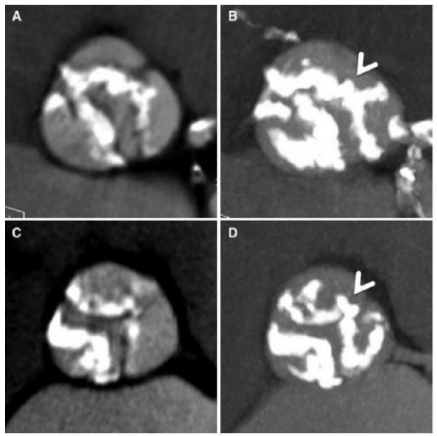
Kentaro Hayashida, MD, PhD, FESC; Erik Bouvier, MD; Thierry Lefèvre, MD, FSCAI, FESC; Bernard Chevalier, MD, FSCAI, FESC; Thomas Hovasse, MD; Mauro Romano, MD; Philippe Garot, MD, FESC; Yusuke Watanabe, MD; Arnaud Farge, MD; Patrick Donzeau-Gouge, MD; Bertrand Cormier, MD; Marie-Claude Morice, MD, FESC

Background—Bicuspid aortic valve (BAV) is regarded as a relative contraindication to transcatheter aortic valve implantation attributable to the risk of uneven expansion of the bioprosthesis. The purpose of this study was to evaluate the efficacy and safety of transcatheter aortic valve implantation in patients with BAV.

Methods and Results—Of 470 patients included in our prospective transcatheter aortic valve implantation database (October 2006–January 2012), 229 consecutive patients undergoing both echocardiography and multidetector computed tomography were analyzed. We compared clinical outcomes in patients with vs patients without BAV. In this series of 229 patients, BAV was detected by multidetector computed tomography in 21 patients (9.2%). BAV was identified by transthoracic and transoesophagal echocardiography in only 9 of these 21 patients. Patients were 83.1±6.6 years old, and European system for cardiac operative risk evaluation score was 20.0%±11.4%. The BAV group was similar to the non-BAV group except for diabetes mellitus (4.8% vs 24.0%; *P*=0.05). The aortic annulus diameter in BAV patients was not significantly larger by multidetector computed tomography (24.7±3.0 vs 23.7±1.9 mm; *P*=0.07). The CoreValve was used more frequently in the BAV group (47.6% vs 16.3%; *P*=0.002). There was no significant difference in device success (100% vs 92.8%; *P*=0.37), risk of annulus rupture (0% vs 1.4%; *P*=1.00), or valve migration (0% vs 1.4%; *P*=1.00) in BAV patients compared with non-BAV patients. Postprocedural mean gradient (10.0±3.4 vs 9.7±4.1 mm Hg; *P*=0.58), aortic regurgitation ≥2 of 4 (19.0% vs 14.9%; *P*=0.54), 30-day mortality (4.8% vs 8.2%; *P*=1.00), and 30-day combined safety end point (14.3% vs 13.5%; *P*=1.00) were also similar in both groups.

Conclusions—In selected BAV patients, transcatheter aortic valve implantation may be associated with low complication rate, efficacy, and acceptable outcomes similar to those in non-BAV patients. (***Circ Cardiovasc Interv*. 2013;6:284-291.**)

Key Words: aortic stenosis ■ bicuspid aortic valve ■ computed tomography ■ echocardiography ■ transcatheter aortic valve implantation



Transcatheter aortic valve implantation (TAVI) for treatment of aortic stenosis (AS) in high-risk patients has emerged as a promising therapeutic alternative to conventional surgical aortic valve replacement. Although the basic technique is reaching relative maturity, there is a paucity of data regarding patients who have not been included in recent clinical trials.

Bicuspid aortic valve (BAV) is a relatively common anomaly that is reported in 0.5% to 2.0% of the general popula-

Although initial TAVI experience in patients with BAV has been described in several reports,[6–8] few data are available on the comparative feasibility and efficacy of TAVI in BAV compared with non-BAV.

The purpose of this study was to evaluate the efficacy and safety of TAVI in patients with the anatomic variation of the aortic valve described as BAV (in patients with BAV anatomy).

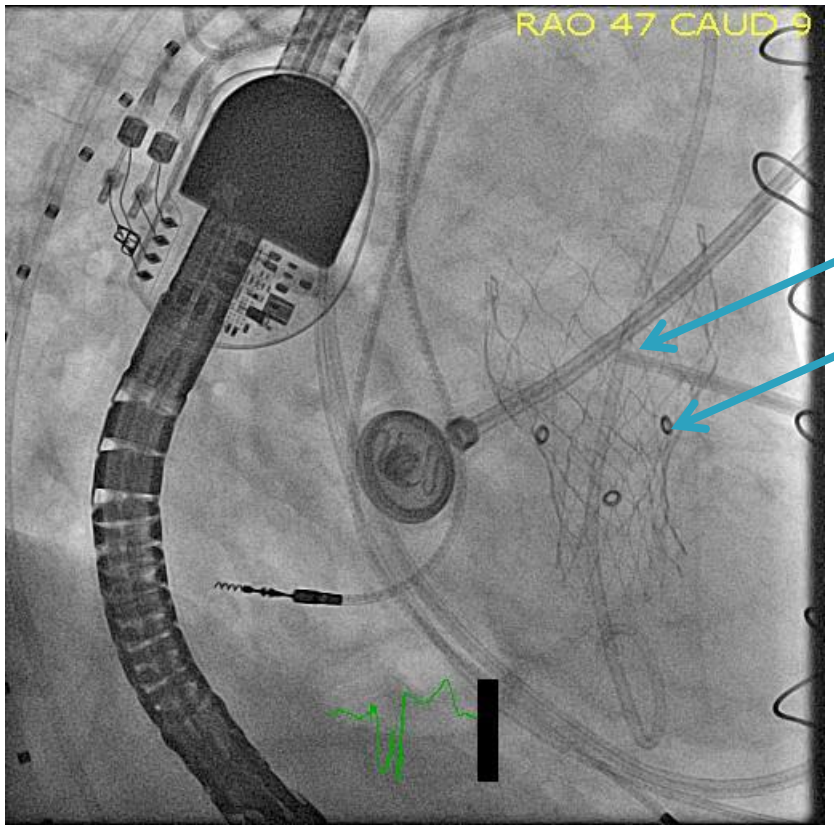
Methods

Outcomes After TAVR for Bicuspid Aortic Valves

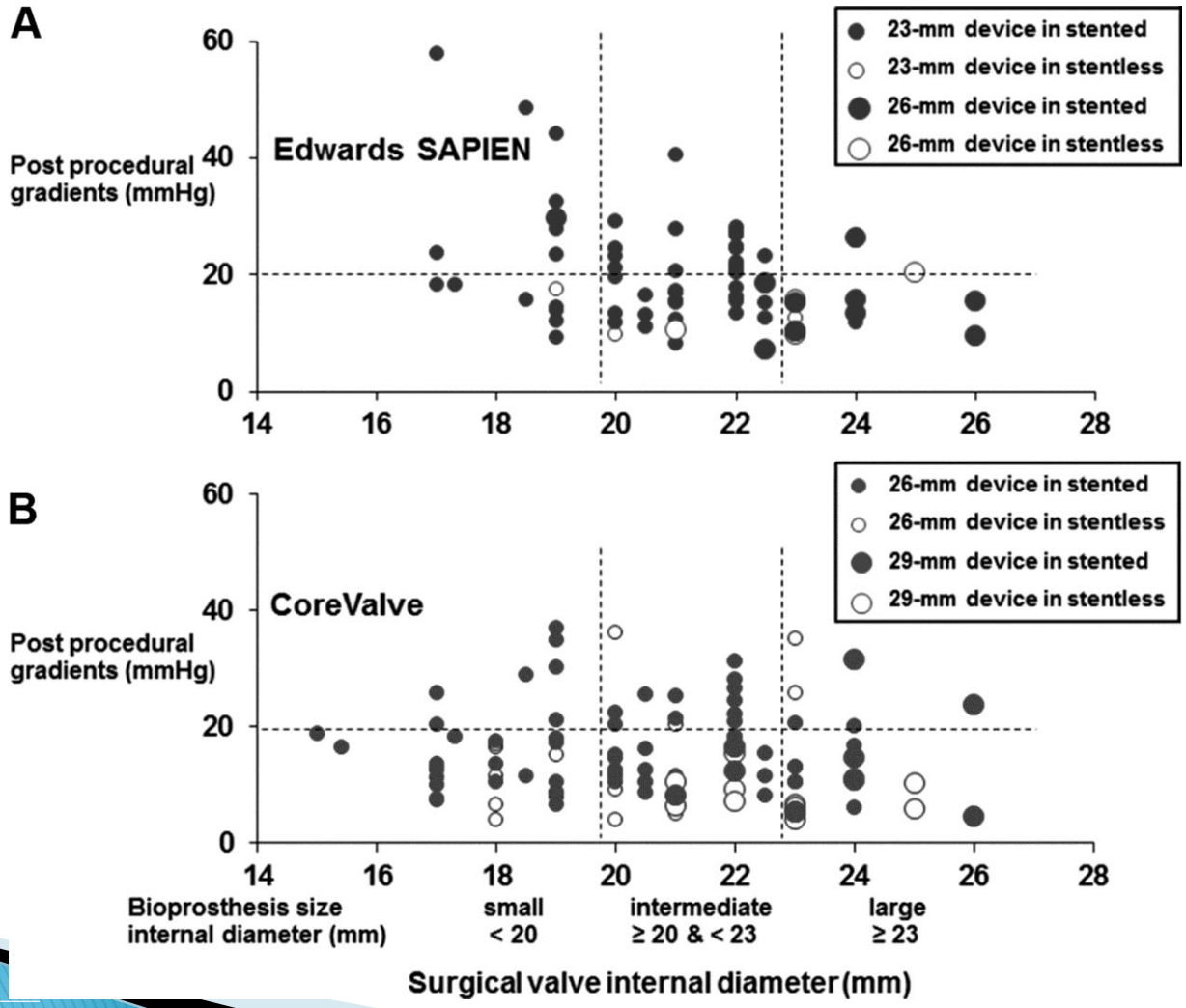
	BAV (n=21)	Non-BAV (n=208)
Perioprocedural MI (%)	0	0.5
Periprocedural Stroke (%)	0	2.9
Annular Rupture (%)	0	1.3
Valve Migration (%)	1.3	1.4
Coronary Occlusion (%)	4.8	1.9
Aortic Regurgitation $\geq$ 2 (%)	19.0	14.9
Aortic Regurgitation $\geq$ 3 (%)	0	1.0
30 Day mortality (%)	14.3	13.5

Hayashida. Circ Interventions 2013;6:284

Valve in Valve



TransValvular Gradients After Valve in Valve Implant for Degenerated Bioprostheses



Dvir D et al. Circulation 2012;126:2335-2344

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St. Jude Medical Portico

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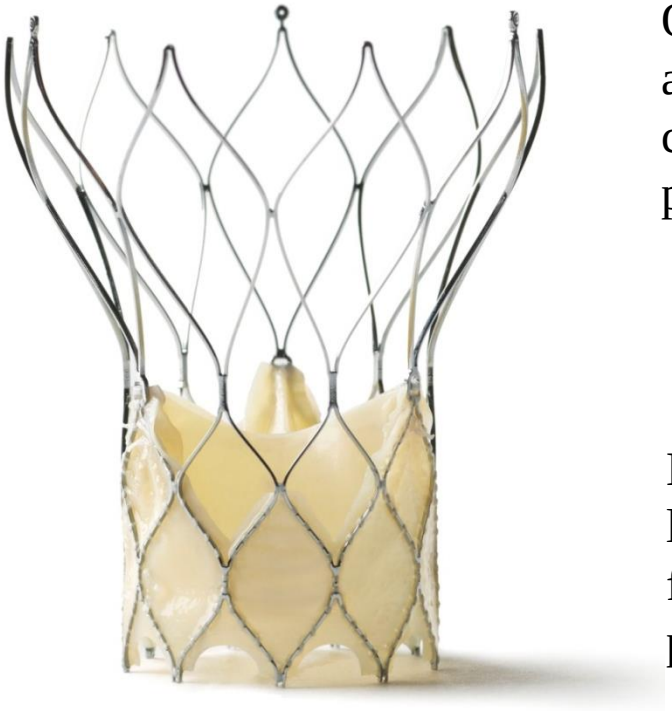
Unique self expanding stent design provides the ability to…
Re-sheath*
Reposition
Retrieve*
… the valve at implant site

Bovine and porcine pericardial valve with
Linx Anti-calcification technology **

LinxAC technology is used on SJM Epic™ and Trifecta™ surgical aortic valves



Open stent cell design allows access to coronaries and low crimp profile

Tissue cuff designed to minimize PV leak

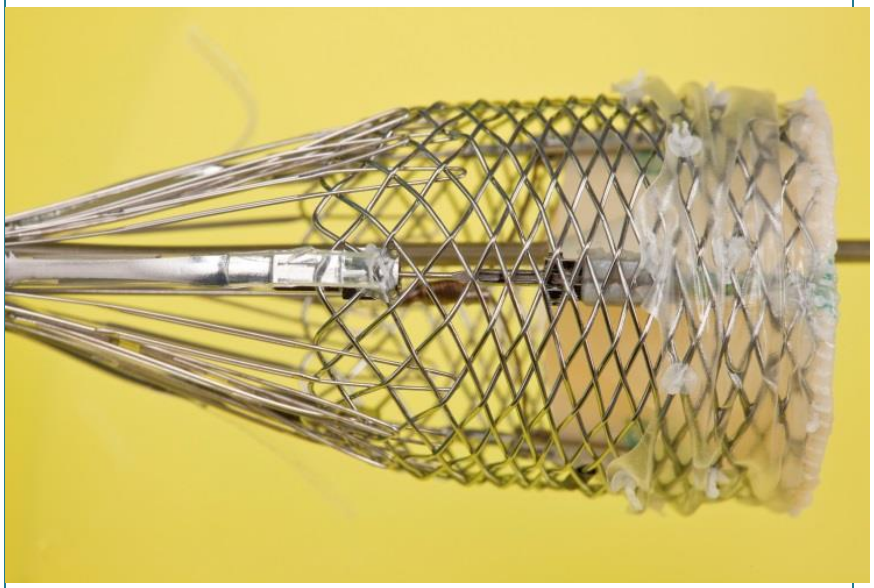
Low placement of leaflets/cuff within the stent frame allows for minimal protrusion into the LVOT

CE Mark Trial Q4 2011
US/IDE Q3 2012

Until fully deployed

** There is no clinical data currently available that evaluates the long-term impact of anticalcification tissue treatment in humans.

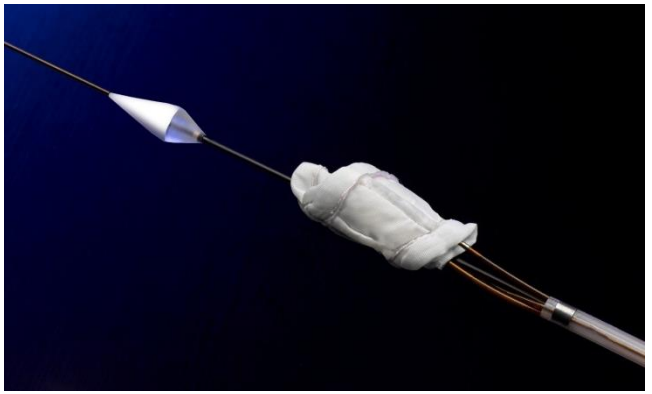
BSC Lotus Valve



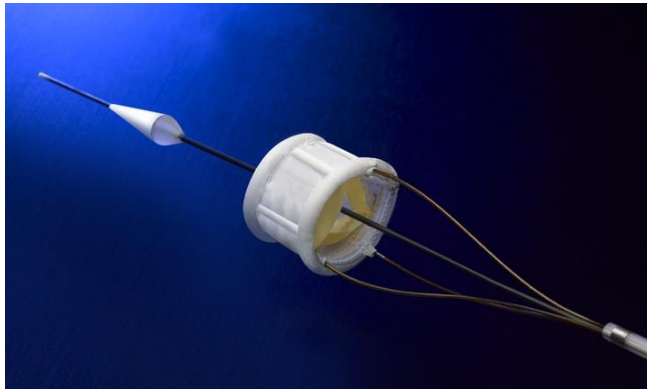
Direct Flow Medical

Transcatheter Aortic Valve System

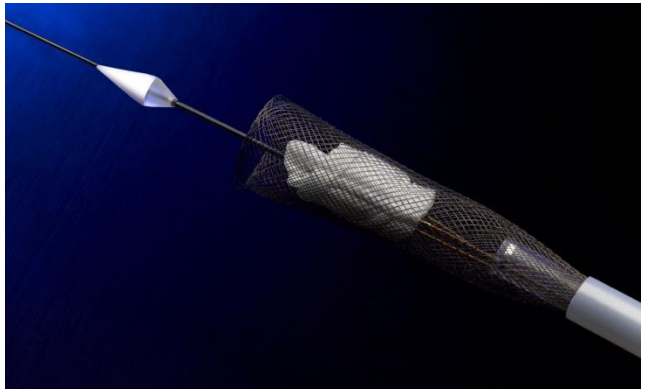
Valve loaded in Delivery System



Valve Unsheathed



Valve Inflated & Steering System



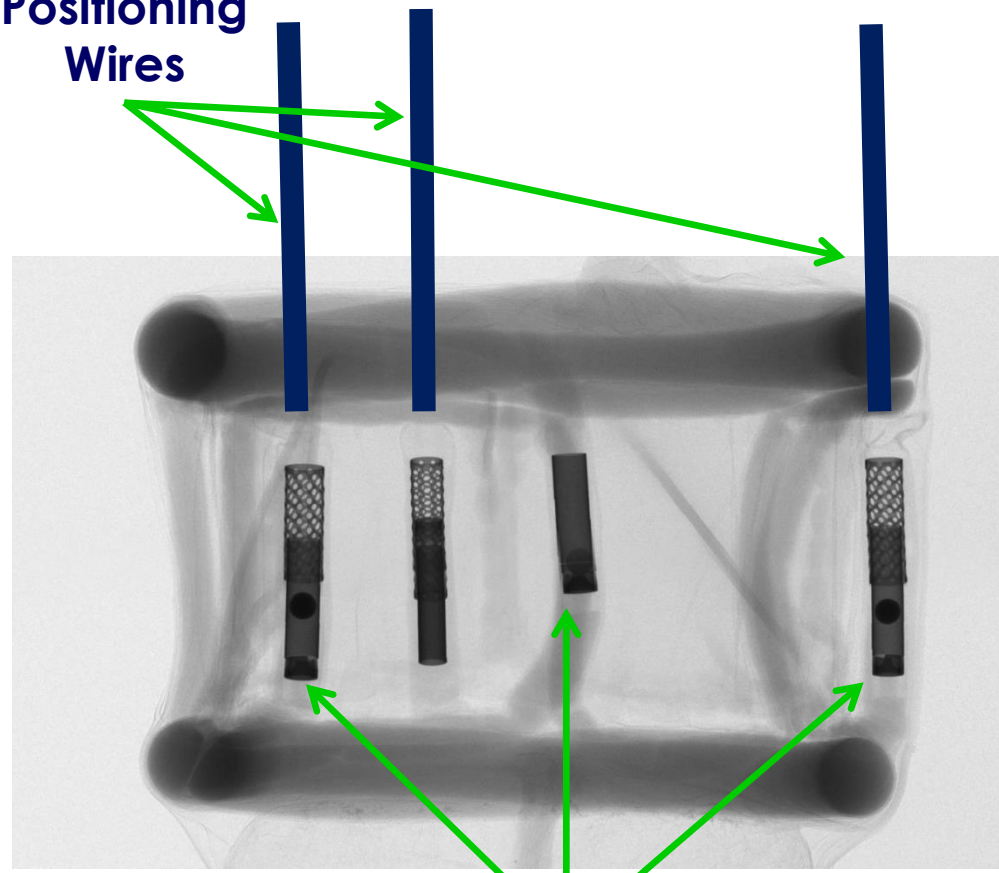
Valve in Retrieval Basket

Investigational device not for sale in or outside the United States

Aortic Ring

Ventricular Ring

Positioning Wires



Check Valves

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