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JOIN EAE/SIEC TEACHING COURSE
UPDATE IN VALVULAR HEART DISEASES:
From clinical imaging to therapeutic innovations

Milano, 8-9 maggio 2012

Aortic Valve Stenosis

TAVI: from compassionate to high-surgical-risk patient treatment

Speaker – 15'

Antonio Colombo

Centro Cuore Columbus and
S. Raffaele Scientific Institute, Milan, Italy

Milestones in TAVI/TAVR

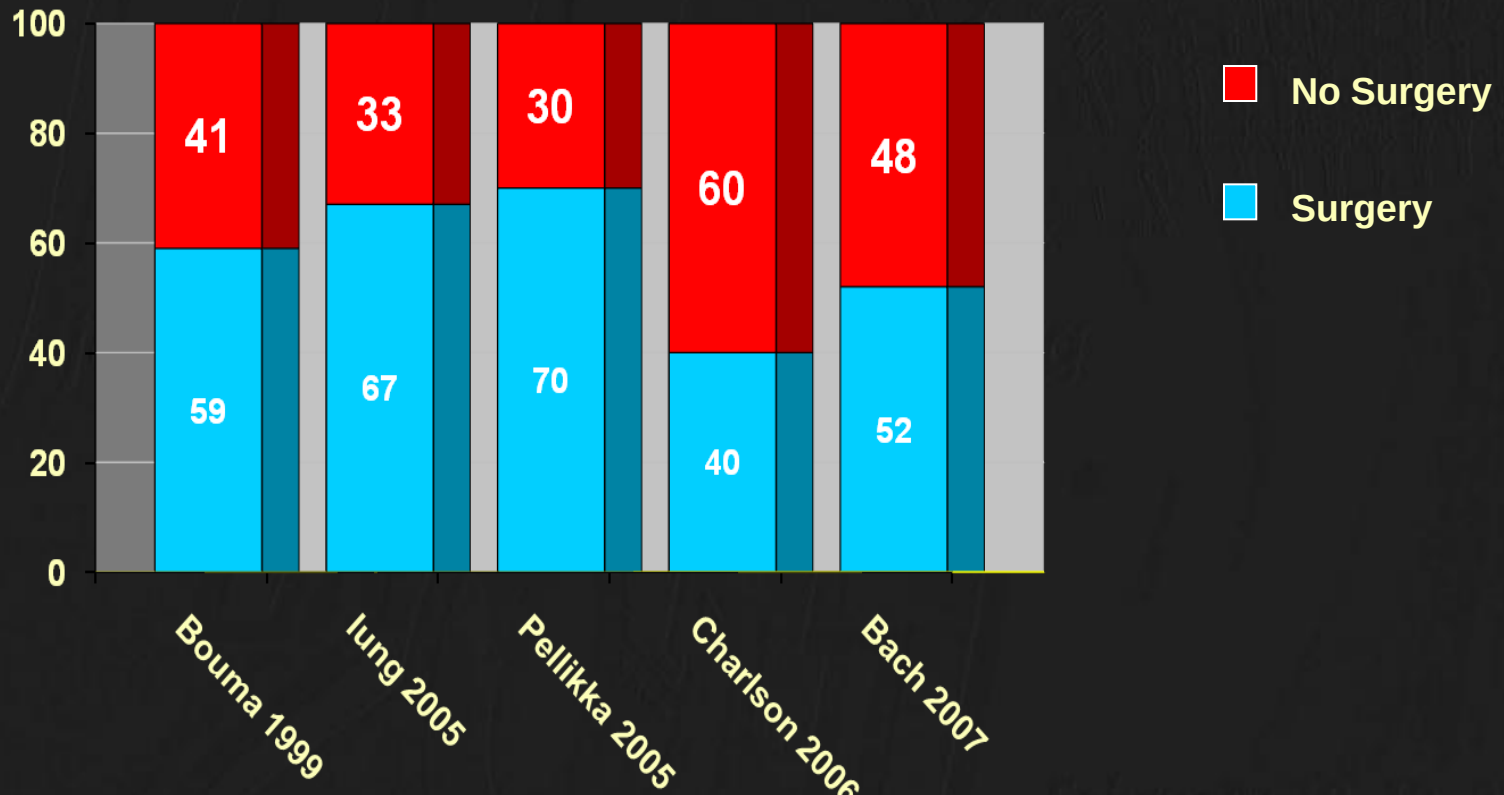
2002 Alain Cribier, 1st TAVI, Circul 2002

2004 Alain Cribier reports 6 cases anterograde (balloon expandable valve), JACC 2004

2005 Eberhard Grube, 1st case of retrograde TAVI (self expandable valve), Circul 2006

2006 John Webb reports 18 cases of retrograde TAVI (balloon expandable valve), Circul 2006

Actual Practices: > 30% of patients are not referred for surgery



Bouma et al. Heart 1999;82:143-148
Iung et al. Eur Heart J 2005;26:2414-2720
Pellikka et al. Circulation 2005;111:3290-3295
Charlson et al. J Heart Valve Dis 2006;15:312-321
Bach et al. J Am Coll Cardiol 2007;50:2018-2019

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Evaluation of Patients With Severe Symptomatic Aortic Stenosis Who Do Not Undergo Aortic Valve Replacement

The Potential Role of Subjectively Overestimated Operative Risk

David S. Bach, MD; Derrick Siao, MD; Steven E. Girard, MD, PhD; Claire Duvernoy, MD; Benjamin D. McCallister, Jr, MD; Sarah K. Gualano, MD

***Circ Cardiovasc Qual Outcomes*. 2009;2:533-539**

- Of 369 patients with severe AS, **191 (52%) did not undergo AVR**. Of these, 126 (66%, 34% of total) had symptoms consistent with AS.

- The most common reasons cited for absent intervention were comorbidities with high operative risk (61 patients [48%]), patent refusal (24 patients [19%]), and symptoms unrelated to AS (24 patients [19%]).

- Operated patients had a lower Society of Thoracic Surgery– calculated perioperative mortality risk than unoperated patients (1.8% [interquartile range, 1.0 to 3.0%] versus 2.7% [interquartile range, 1.6 to 5.5%], *P*0.001).

- However, 28 (24%) of 126 unoperated symptomatic patients had a calculated perioperative risk less than the median risk for patients who underwent AVR.

- Only 57 (30%) of 191unoperated patients were evaluated by a cardiac surgeon.

Two questions are sequentially answered

Is TAVI

Appropriate ?

Feasible ?

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Is TAVI Appropriate ?

- ✓ Surgical aortic valve replacement in Centers with 30 days mortality < 2% remains the gold standard because it garantees "proven durability of the valve" and "no residual aortic insufficency". In some high risk patients mortality is high or very high.
- ✓ **TAVI is usually feasible at an acceptable risk in patients with 30 days surgical mortality of 10% or higher.**
- ✓ Regarding patients with a lower risk the debate is still open.

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Is TAVI Appropriate ?

Cardiologist
Interventional Cardiologist
Anestesiologist
Cardiac Surgeon

Medical Team

Patient
Family

Patient Team

Is TAVI Appropriate ?

The Medical Team will evaluate the risk benefit of standard surgical procedure vs. TAVI taking into account the "limitations and advantages of each of them"

- *the main reason not to perform standard surgical replacement will be the surgical risk (death or complications) and theimpact of the procedure on the future quality of life*

- *the main reason to perform TAVI is that the risk of death or complications are estimated lower than standard surgical risk.*

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Is TAVI Appropriate ?

Except for "specific" situations the Patient/Family team should not over rule the suggestions of the Medical Team

Explaining

↓

Understanding

↓

CONSENSUS

Risk profile: Clear Cut for TAVI

85 yrs old lady, severe COPD; prior CABG (LIMA+SVG), creatinine 2 mg/100ml, 75 kg., 165 cm., no diabetes, no prior CVA, stable angina.

Standard Euroscore: 16;
Logistic Euroscore: 66%

STS score: mortality 8%, mortality and morbidity 31%, length of stay 20 days, risk of stroke 2.5%, postprocedure renal failure 6%, prolonged ventilation 28%.

Not captured by EuroScore or STS score: Porcelain aorta, General Frailty, Dementia etc.

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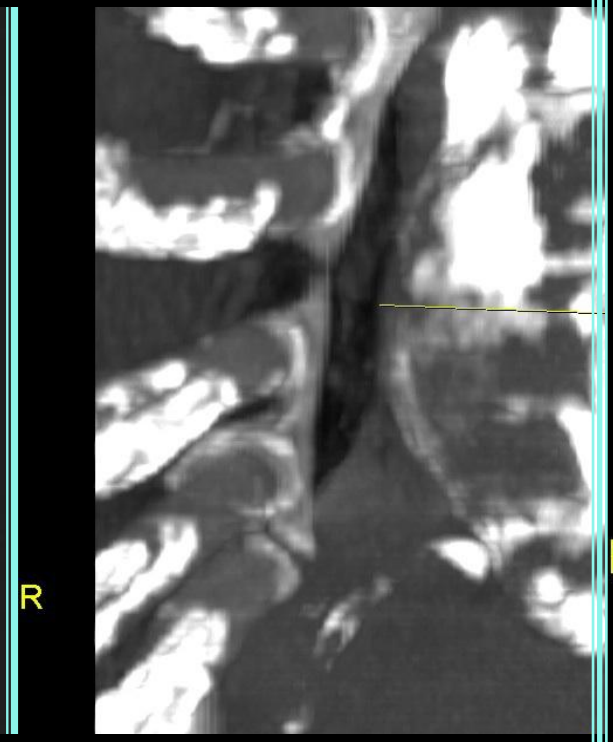
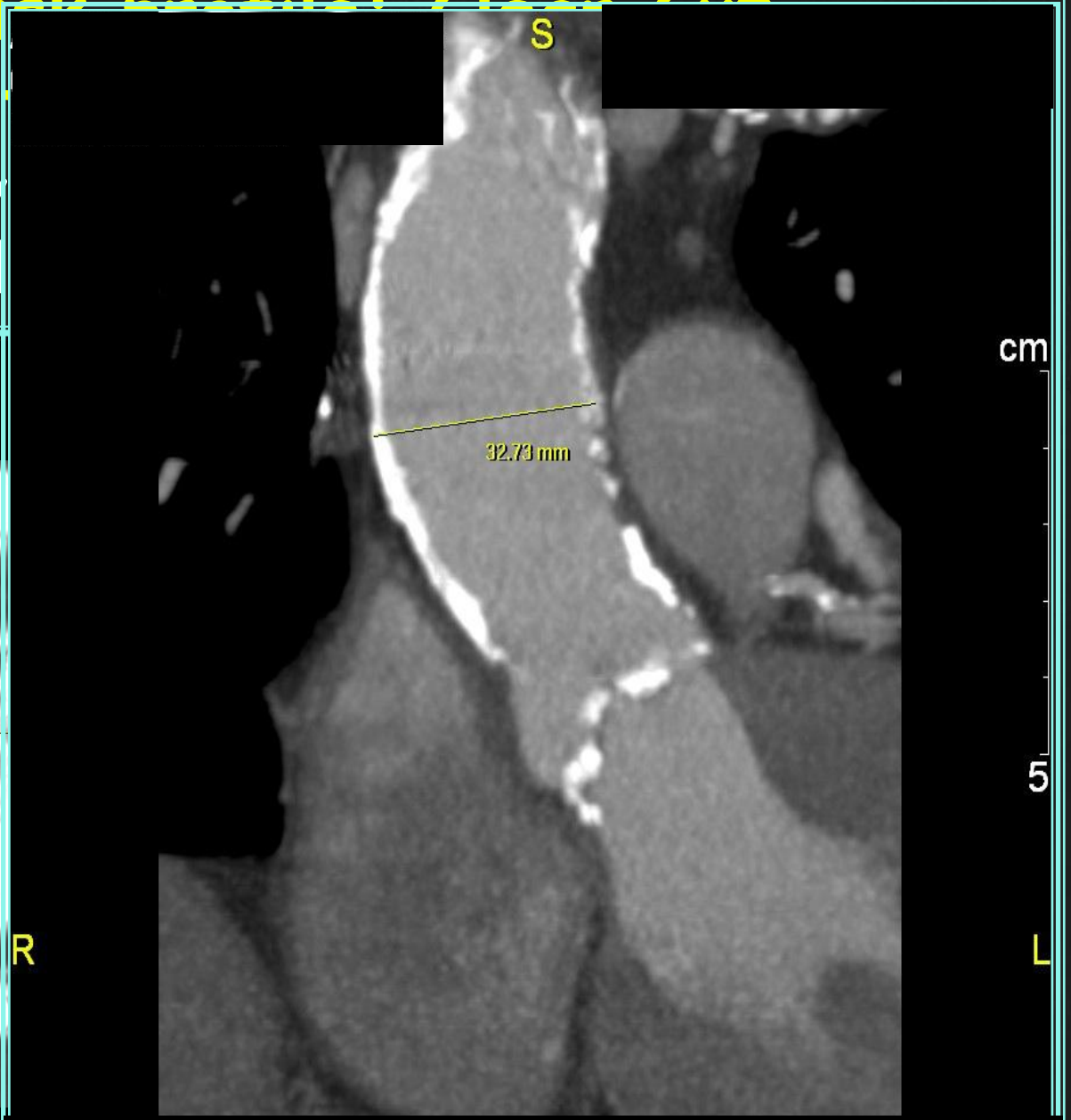
Ri… …fil… …

but no…

85 yrs old lady…

COPD, no rena…





Risk Profiles: Debatable

- 95 yrs old lady, no prior surgery, no diabetes, no COPD, no renal failure, no prior CVA, 65 kg., 165 cm., stable angina.

- 75 yrs old lady, no prior surgery, no diabetes, no COPD, no renal failure, no prior CVA, 65 kg., 165 cm., stable angina. SEVERE DEMENTIA at home assisted by the Family.

- 90 yrs old lady, no prior surgery, no diabetes, no COPD, no renal failure, no prior CVA, 65 kg., 165 cm., stable angina. SEVERE DEMENTIA in a Nursing Home since 5 yrs.

Is TAVI Feasible ?

① Suitability of the patient to undergo an invasive procedure

② Size of the aortic annulus: more than 18 mm and less 25-27 mm;

③ Size and condition of femoral or axillary vessels: 18/19 French introducer

④ Transapical (Sapien) or Supraaortic (Core Valve) alternative approaches when vascular access is inadequate: Need for general anesthesia

Screening and decision making

Multislice CT with ecg-gating and contrast injection to evaluate: annulus, coronaries, aorta, iliacs and femorals arteries

Transesophageal echo to evaluate: annulus, ventricular function

Coronary arteriography when needed

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The variation in annulus size measurements made in the same patient using different investigative modalities.

TTE: Parasternal long-axis view

24 mm

B

TEE: Left ventricular long-axis view

25 mm

C

MSCT: Sagittal view

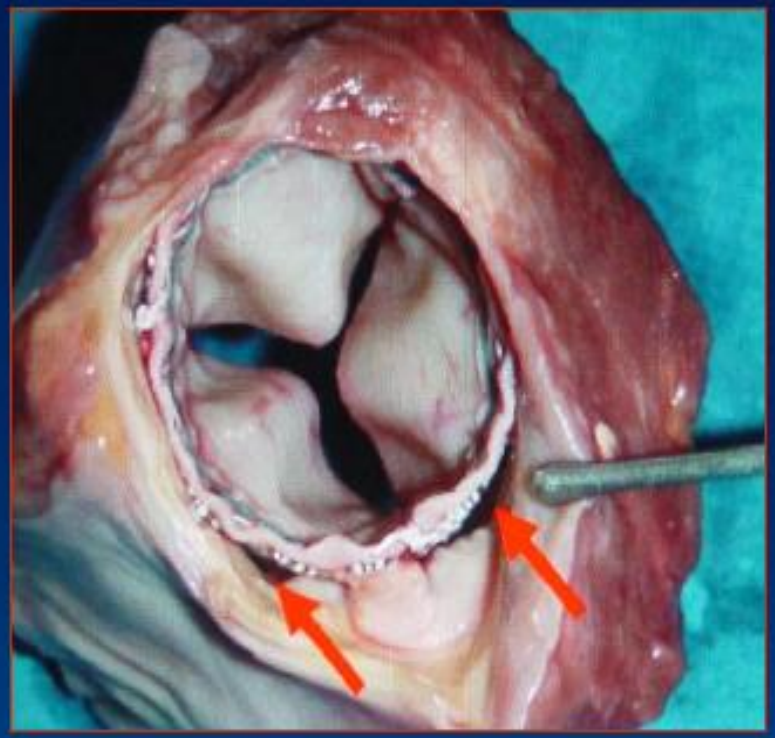
28 mm

D

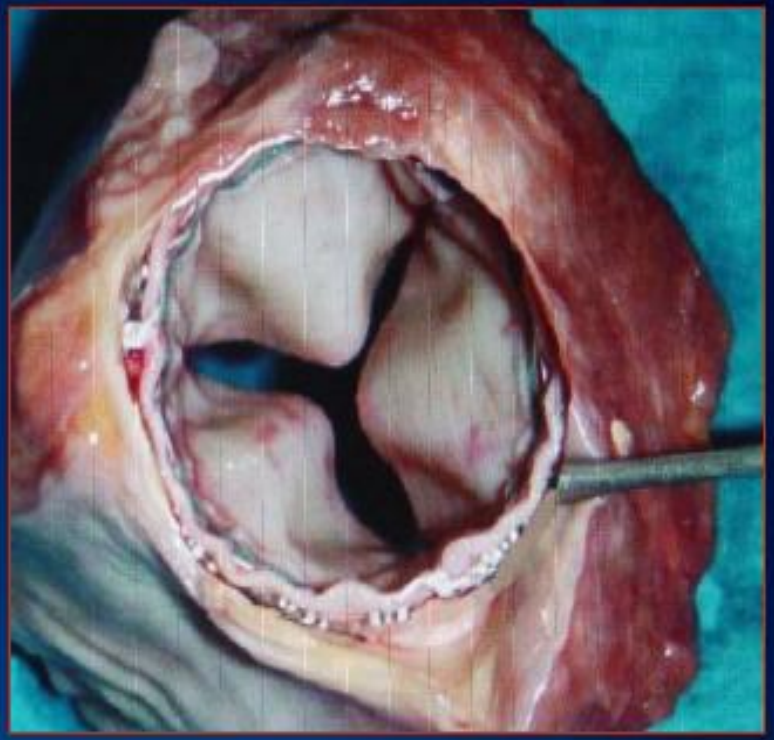
CT: Oblique transverse view

26.5 mm

Larger size valve: rationale

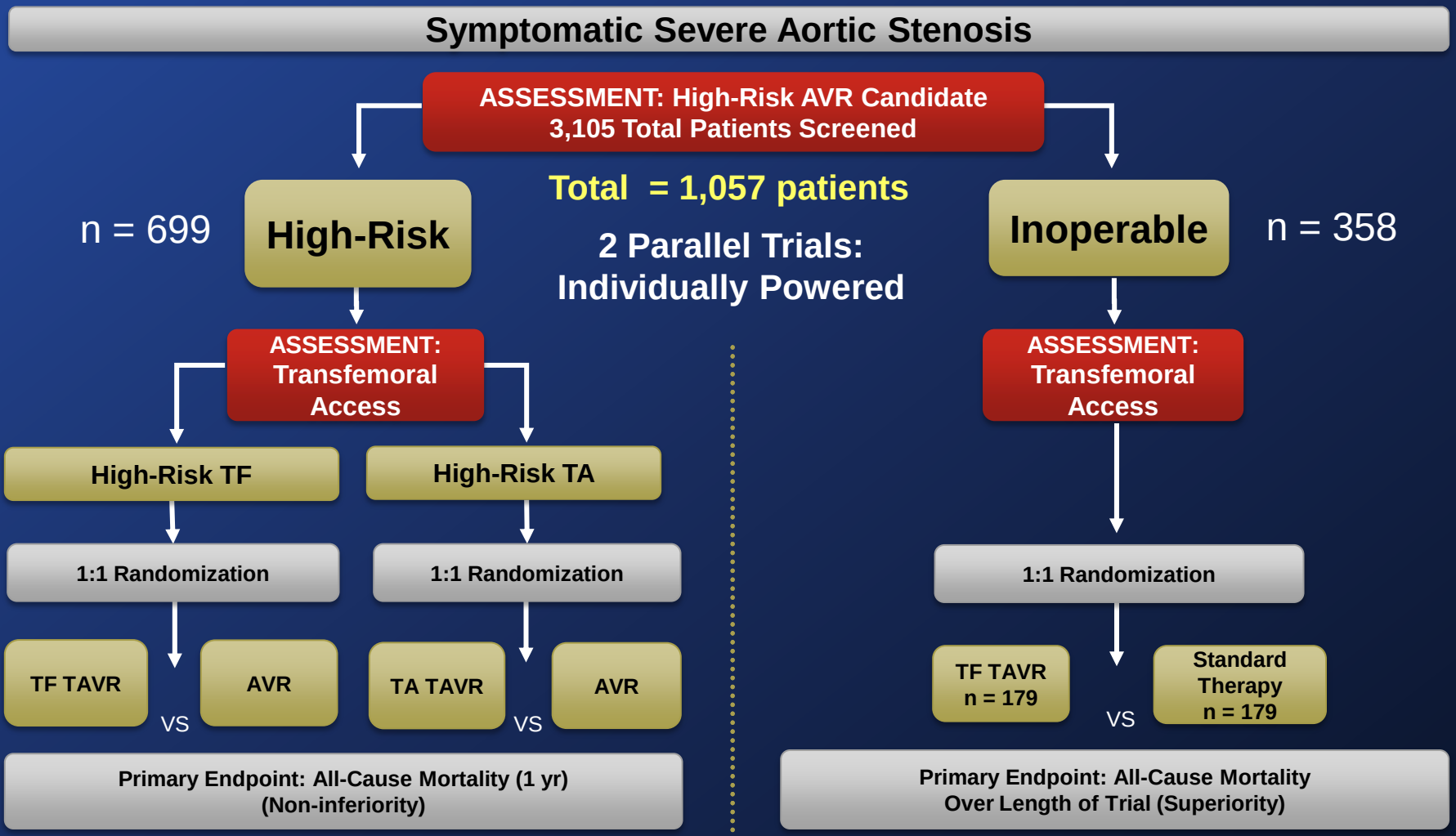


PHV23MM



PHV26MM

PARTNER Study Design



Impact of paravalvular leak on 2-year all-cause mortality. Adopted from Kodali and colleagues

Inoperable pts

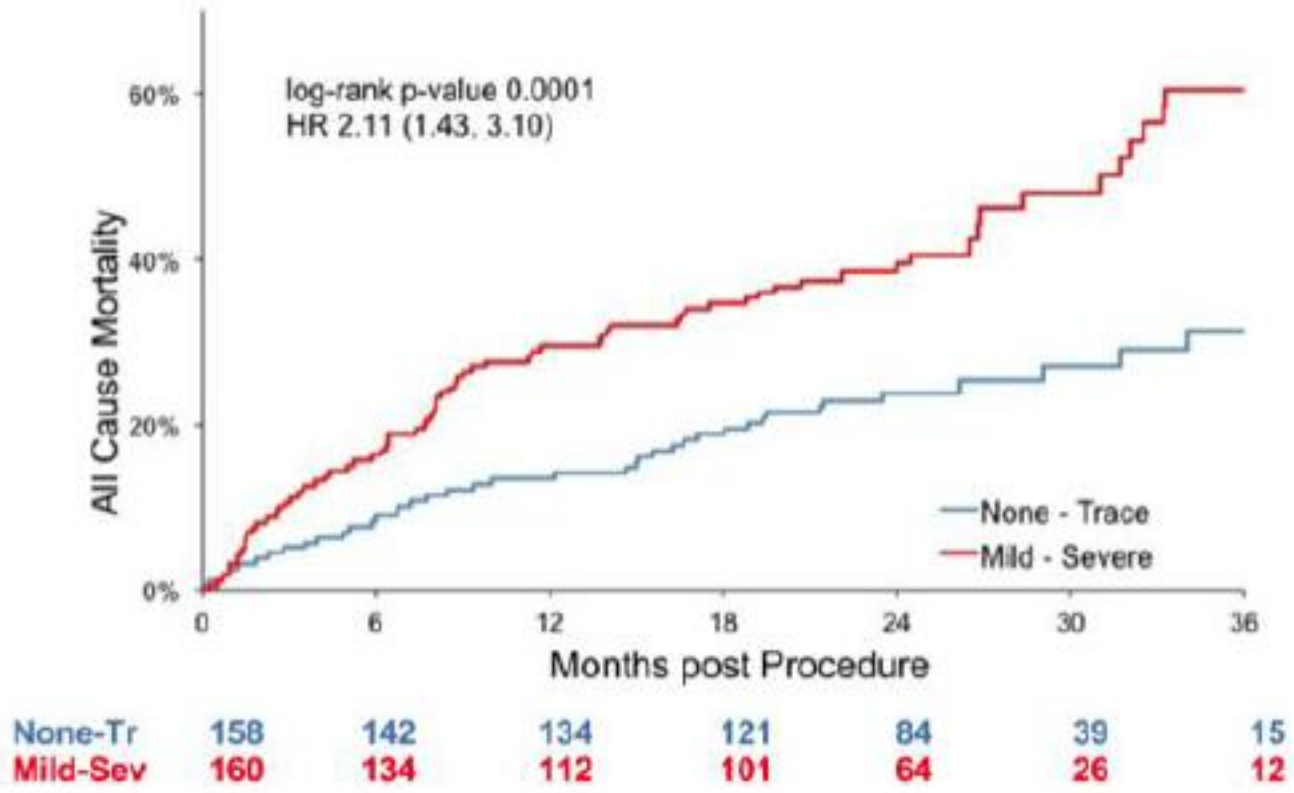
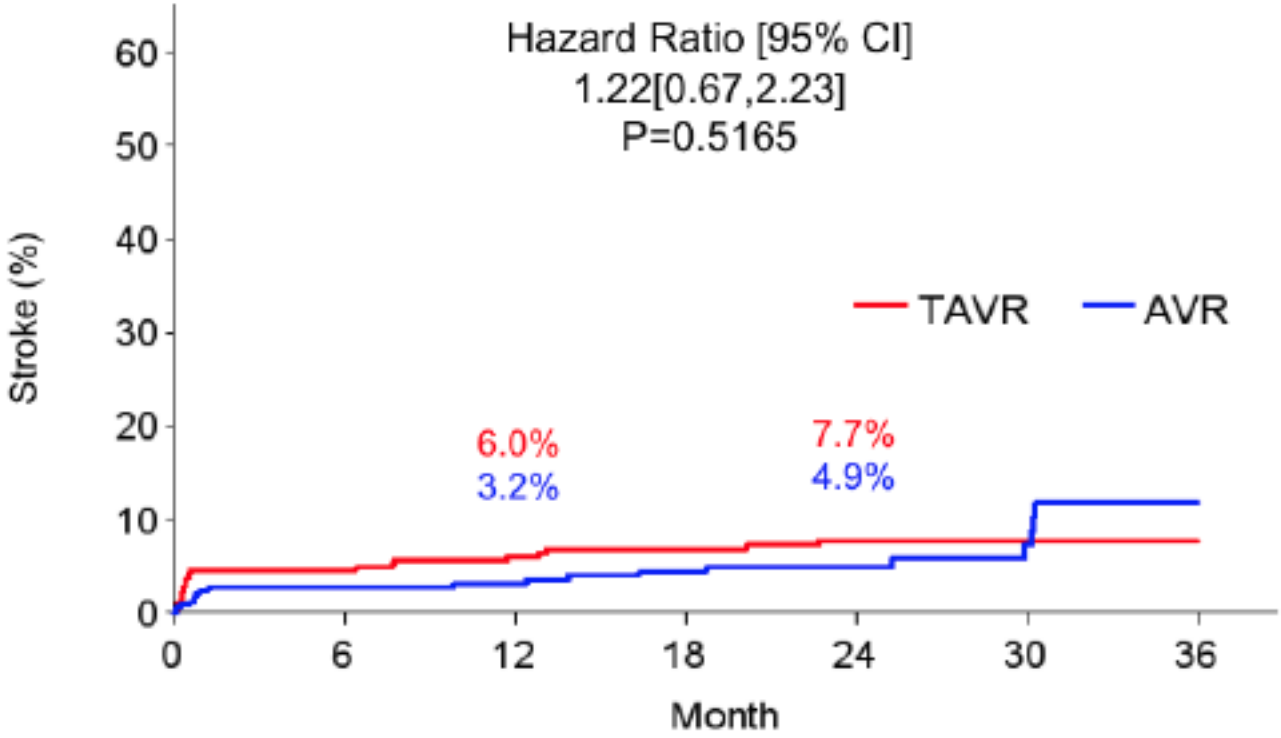


Figure 3c. Two-year stroke Kaplan-Meier curve in PARTNER trial cohort 1A. Adapted from Kodali and colleagues [34].



In PARTNER Trial Cohort A

Core lab evaluation of aortic regurgitation:

10% of patients had moderate to severe AR
40% of patients had mild AR

Moderate, severe and mild AR were associated with higher mortality at FU

Cohort A

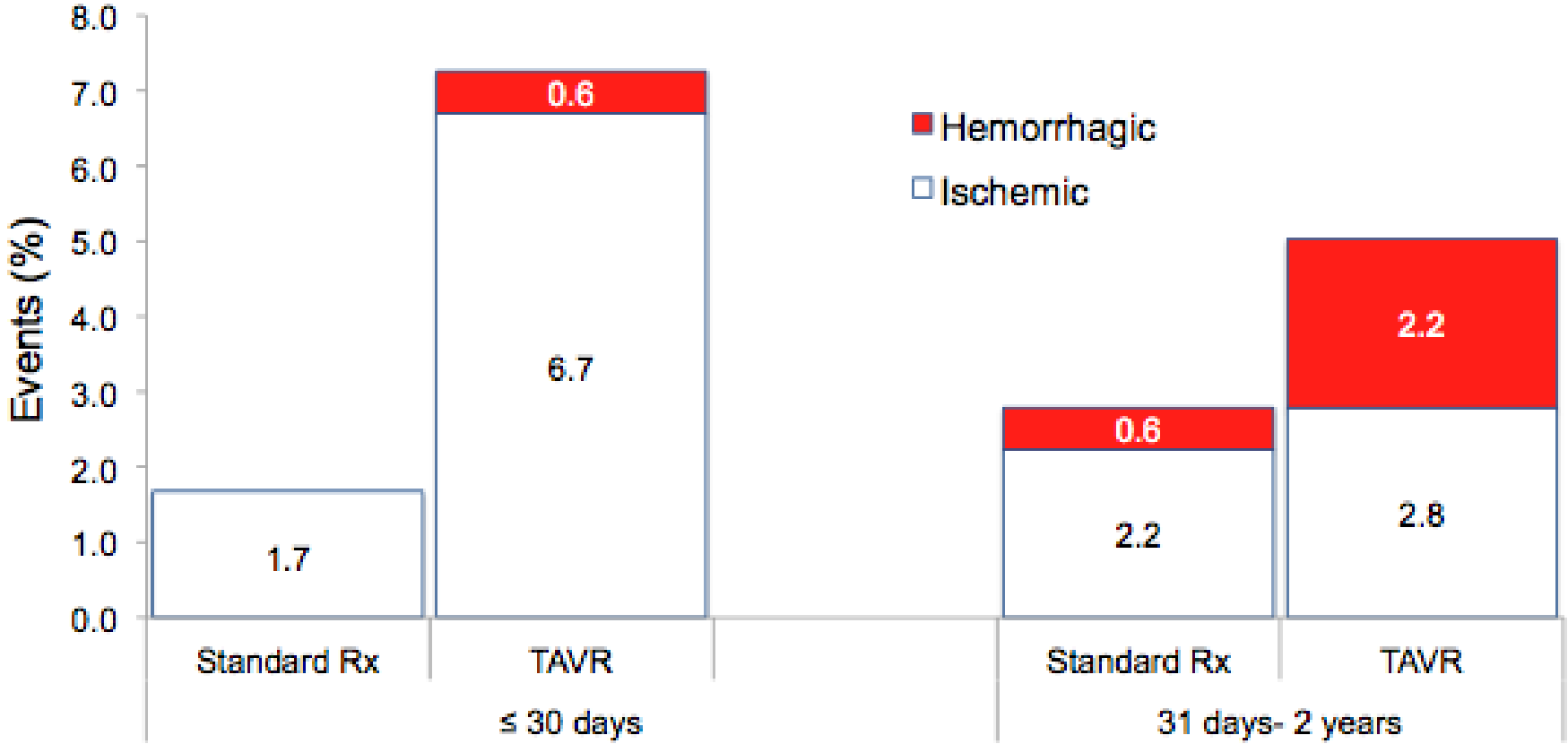
Mortality According to Presence/Severity of Aortic Regurgitation

Aortic regurgitation	None/trace	Mild	Moderate/severe	P (log rank)
1-y mortality (%)	14.5	29.2	29.5	<0.001
2-y mortality (%)	24.8	39.2	41.1	<0.001

Bulky Calcium..

When calcifications are massive we should expect more residual aortic insufficiency

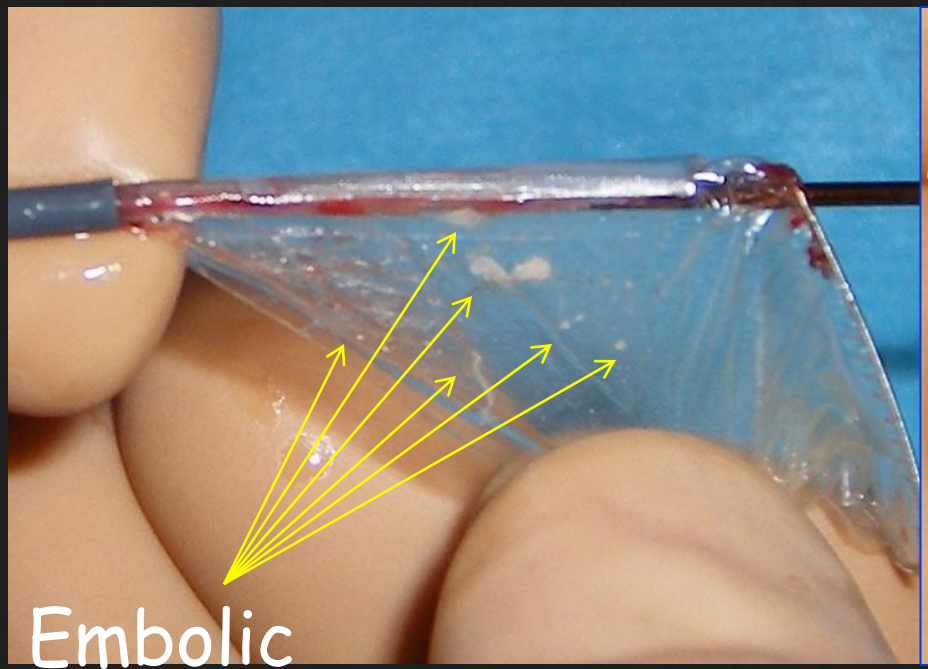
Strokes in PARTNER trial (B, inoperable pts.)

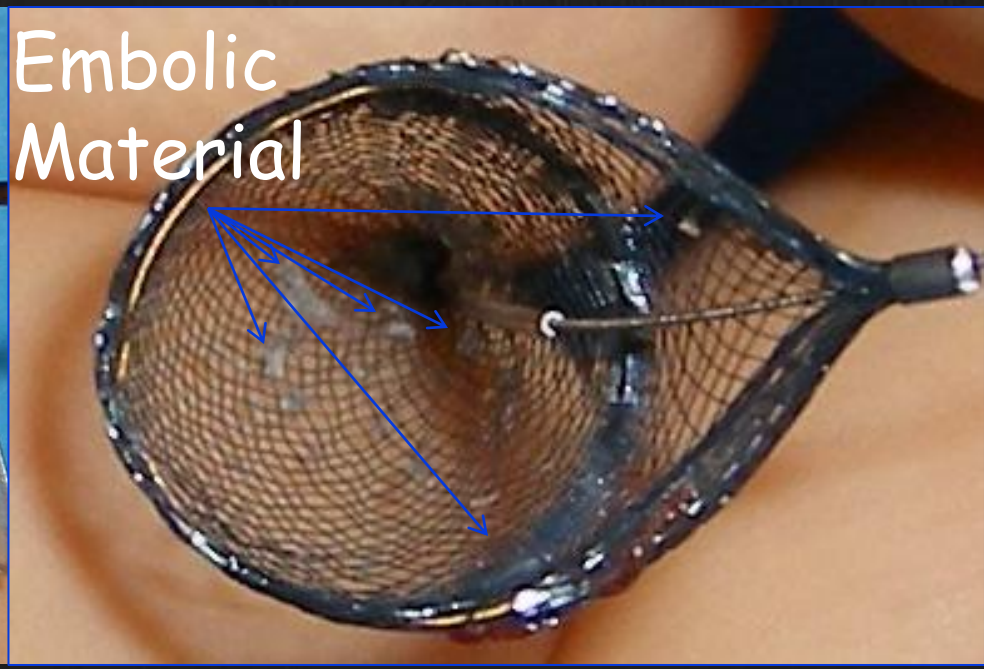


At 1 yr. in PARTNER IA any neurological event occurred in 4.3% of patients treated with surgery versus 8.3% of patients treated with TAVI.

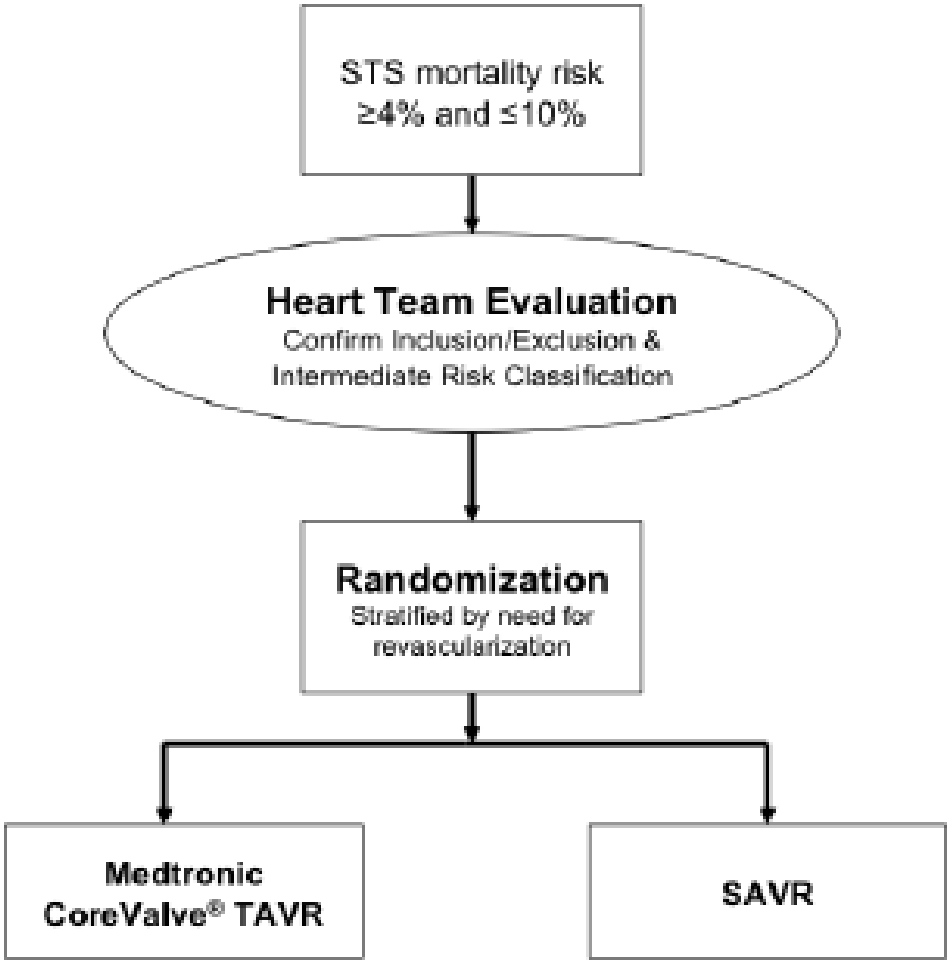
Transapical access was a predictor of stroke in TAVI

Embolic Material

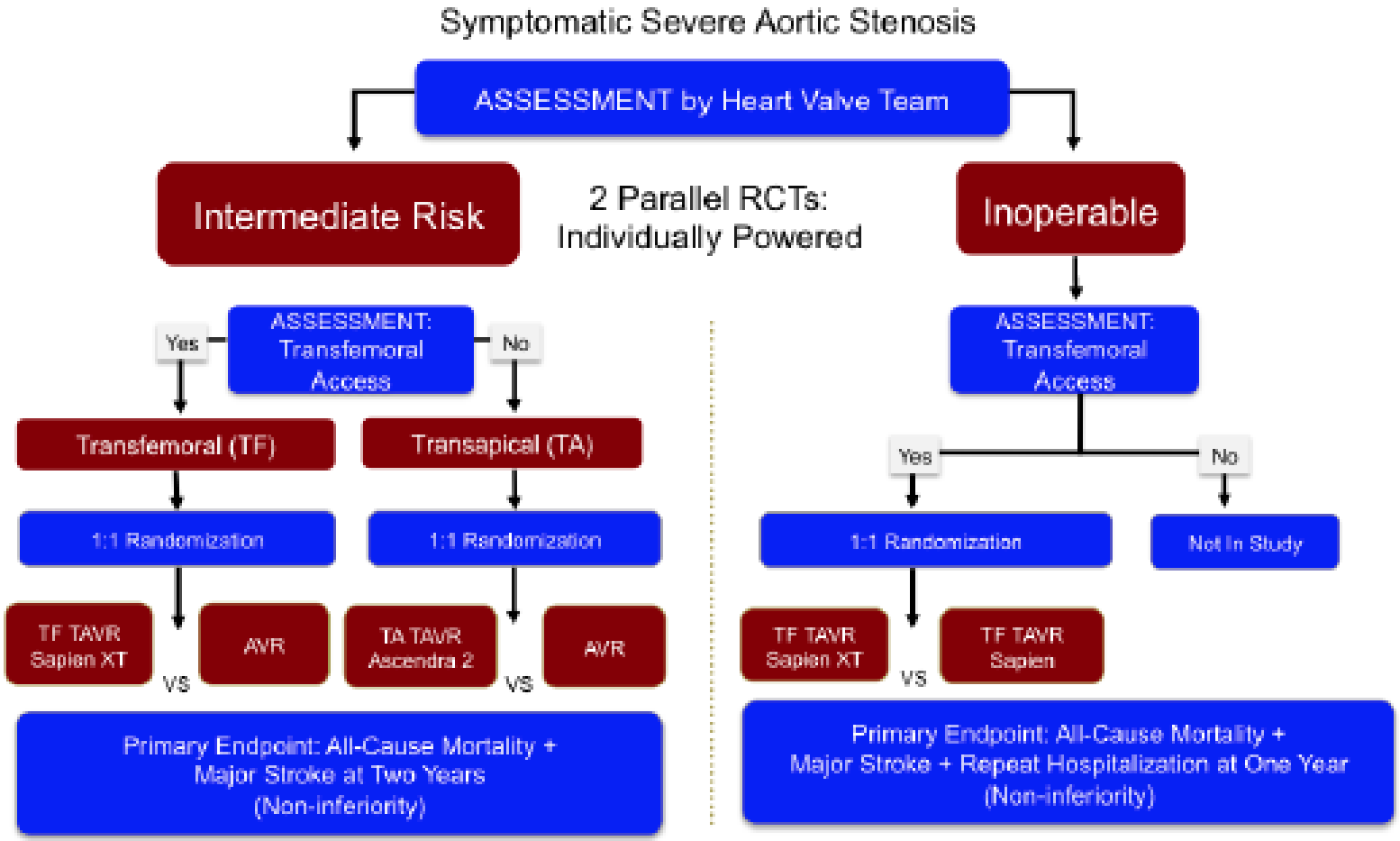




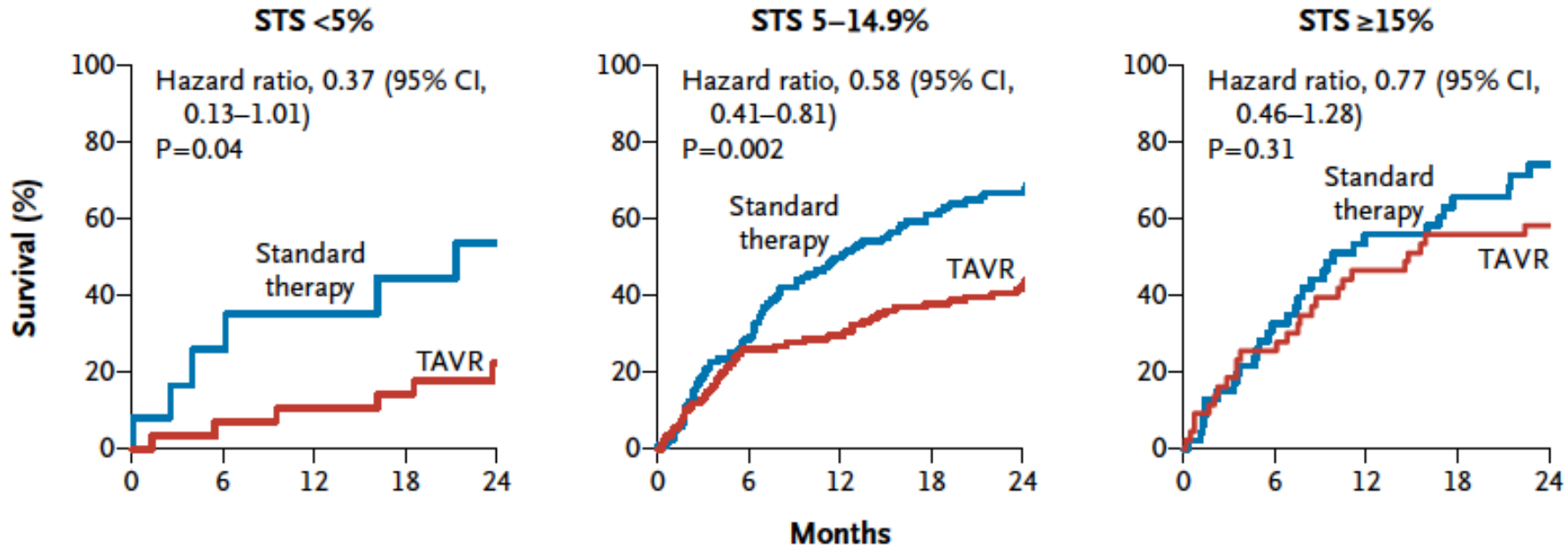
SURTAVI


STS mortality risk
≥4% and ≤10%
Heart Team Evaluation
Confirm Inclusion/Exclusion &
Intermediate Risk Classification
Randomization
Stratified by need for
revascularization
Medtronic
CoreValve® TAVR
SAVR

PARTNER II


Symptomatic Severe Aortic Stenosis
ASSESSMENT by Heart Valve Team
Intermediate Risk
2 Parallel RCTs:
Individually Powered
Inoperable
ASSESSMENT:
Transfemoral
Access
Yes
No
Transfemoral (TF)
Transapical (TA)
1:1 Randomization
1:1 Randomization
TF TAVR
Sapien XT
AVR
VS
TA TAVR
Ascendra 2
AVR
VS
Primary Endpoint: All-Cause Mortality +
Major Stroke at Two Years
(Non-inferiority)
ASSESSMENT:
Transfemoral
Access
Yes
No
1:1 Randomization
Not In Study
TF TAVR
Sapien XT
TF TAVR
Sapien
VS
Primary Endpoint: All-Cause Mortality +
Major Stroke + Repeat Hospitalization at One Year
(Non-inferiority)

2 years mortality in inoperable patients (PARTNER B)

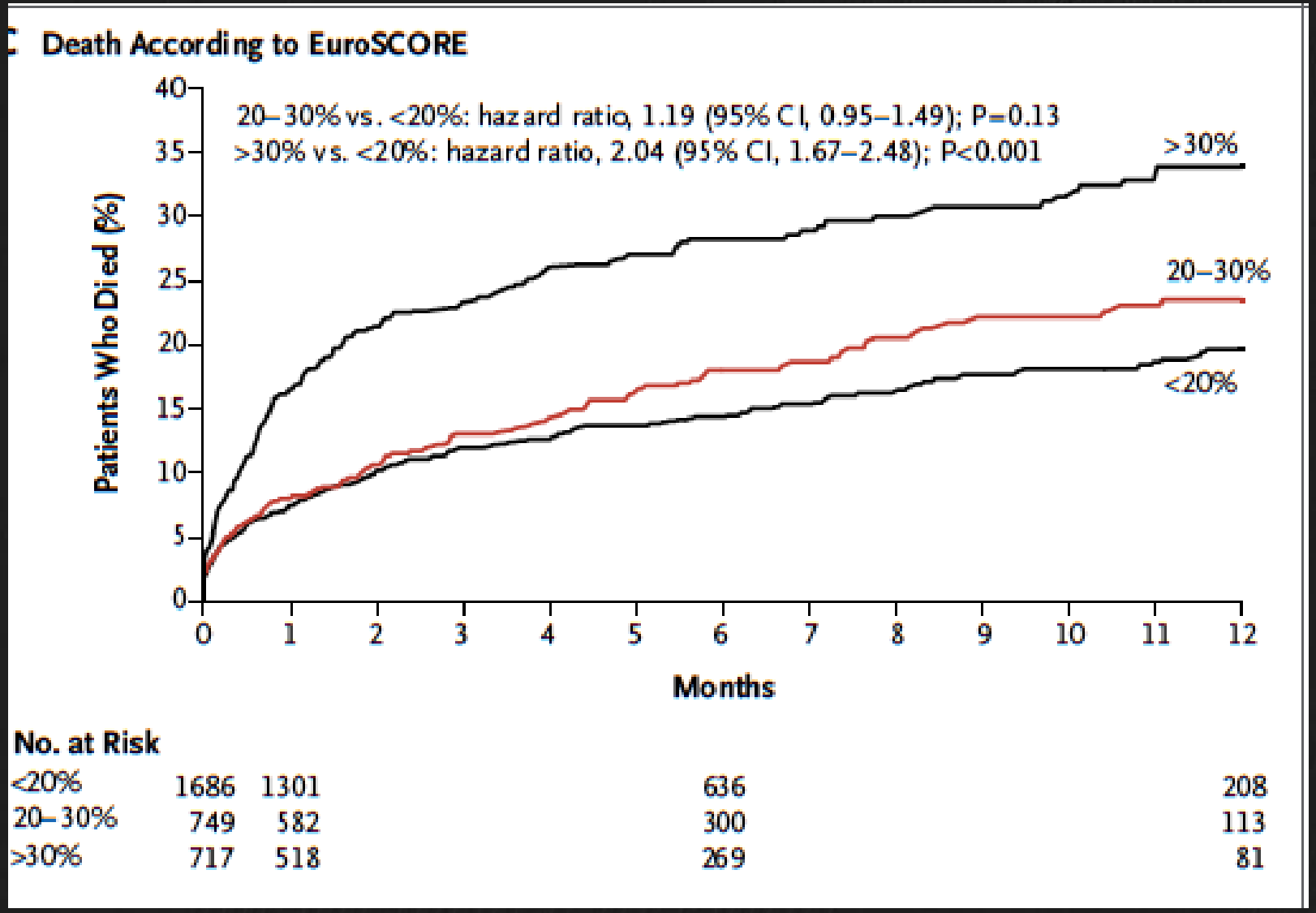


No. at Risk														
TAVR	28	26	25	24	16	108	80	76	67	52	43	32	23	19	15
Standard therapy	12	8	7	6	5	119	84	59	42	29	47	29	19	14	8

In very high risk pts. TAVI may be futile

FRANCE 2 TAVI Registry 3195 pts.

Gilard et al. NEJM 2012



Two important studies in intermediate risk populations have benn launched:
SURTAVI with CoreValve and PARTENER II with Sapien XT