

2013 TCTAP

Wrap-Up Interview

TransAortic Valve Implantation

Moderator

Eberhard Grube

Interviewees

Alain G. Cribier, Thierry Lefevre, Raj Makkar

Issues Briefs

Indication of TAVI

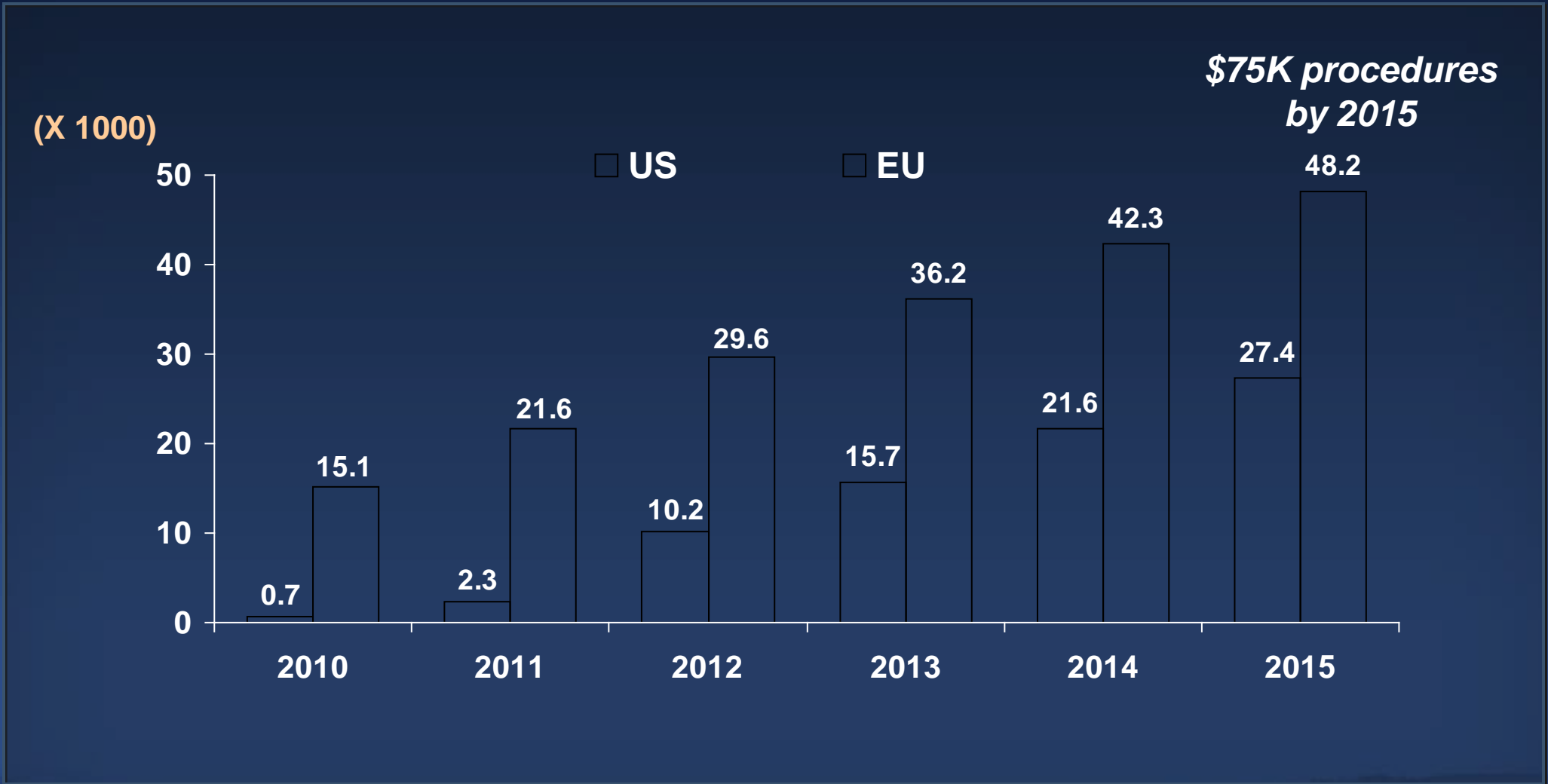
- Current indication and contraindication
- Heart team approach
- Clinical studies: PARTNER B and A, PARTNER 2, SURTAVI
- Future perspectives

TAVI Outcomes

- Outcomes of FDA-approved devices
- Cost-effectiveness
- New technologies

TAVR Procedures

Growth from 2010 - 2015



Courtesy of Mike Weinstein; J.P. Morgan

EXPERT CONSENSUS DOCUMENT

2012 ACCF/AATS/SCAI/STS Expert Consensus Document on Transcatheter Aortic Valve Replacement

Developed in collaboration with the American Heart Association, American Society of Echocardiography, European Association for Cardio-Thoracic Surgery, Heart Failure Society of America, Mended Hearts, Society of Cardiovascular Anesthesiologists, Society of Cardiovascular Computed Tomography, and Society for Cardiovascular Magnetic Resonance

**Writing
Committee
Members**

David R. Holmes, Jr., MD, FACC, *Chair**
Michael J. Mack, MD, FACC, *Vice Chair†*
Sanjay Kaul, MBBS, FACC, *Vice Chair**

Arvind Agnihotri, MD‡
Karen P. Alexander, MD, FACC*
Steven R. Bailey, MD, FACC, FSCAI§
John H. Calhoon, MD‡
Blase A. Carabello, MD, FACC*
Milind Y. Desai, MBBS, FACC¶¶
Fred H. Edwards, MD, FACC†
Gary S. Francis, MD, FACC#
Timothy J. Gardner, MD, FACC†
A. Pieter Kappetein, MD, PhD**
Jane A. Linderbaum, MS, CNP, AACCF*
Chirojit Mukherjee, MD††

Debabrata Mukherjee, MD, FACC*
Catherine M. Otto, MD, FACC*
Carlos E. Ruiz, MD, PhD, FACC, FSCAI§
Ralph L. Sacco, MD, MS, FAHA‡‡
Donnette Smith§§
James D. Thomas, MD, FACC|||

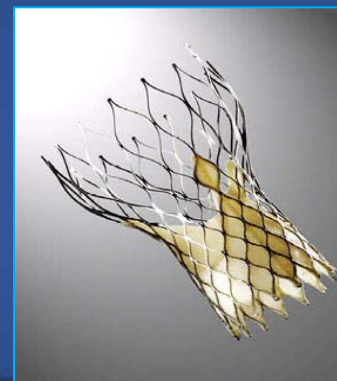
*American College of Cardiology Foundation Representative; †Society of Thoracic Surgeons Representative; ‡American Association for Thoracic Surgery Representative; §The Society for Cardiovascular Angiography and Interventions Representative; ¶Society of Cardiovascular Computed Tomography Representative; †Society for Cardiovascular Magnetic Resonance Representative; #Heart Failure Society of America Representative; **European Association for Cardio-Thoracic Surgery Representative; ††Society of Cardiovascular Anesthesiologists Representative; ‡‡American Heart Association Representative; §§Mended Hearts Consumer Advocate, Patient Representative; |||American Society of Echocardiography Representative.



Guidelines on the management of valvular heart disease (version 2012)

The Joint Task Force on the Management of Valvular Heart Disease of the European Society of Cardiology (ESC) and the European Association for Cardio-Thoracic Surgery (EACTS)

Authors/Task Force Members: Alec Vahanian (Chairperson) (France)*, Ottavio Alfieri (Chairperson)* (Italy), Felicita Andreotti (Italy), Manuel J. Antunes (Portugal), Gonzalo Barón-Esquivias (Spain), Helmut Baumgartner (Germany), Michael Andrew Borger (Germany), Thierry P. Carrel (Switzerland), Michele De Bonis (Italy), Arturo Evangelista (Spain), Volkmar Falk (Switzerland), Bernard Iung (France), Patrizio Lancellotti (Belgium), Luc Pierard (Belgium), Susanna Price (UK), Hans-Joachim Schäfers (Germany), Gerhard Schuler (Germany), Janina Stepinska (Poland), Karl Swedberg (Sweden), Johanna Takkenberg (The Netherlands), Ulrich Otto Von Oppell (UK), Stephan Windecker (Switzerland), Jose Luis Zamorano (Spain), Marian Zembala (Poland)



2012 Consensus of TAVI Indication

Class I:

- Heart Team required
- On-site cardiac surgery
- **Inoperable Patients**

Class IIa:

- **High-risk operable** as an alternative to surgery; determined by heart team and case-based decisions

Contraindication in ESC

Absolute

- Estimated life expectancy <1 year
- Severe primary disease that can be treated only by surgery
- Absence of a 'heart team' and no cardiac surgery on the site
- Inadequate annulus size (<18 mm, >29 mm)
- Thrombus in the left ventricle
- Active endocarditis
- Elevated risk of coronary ostium obstruction
- Plaques with mobile thrombi in the ascending aorta, or arch
- For transfemoral/subclavian: inadequate vascular access

Relative

- Bicuspid or non-calcified valves
- Untreated coronary artery disease requiring revascularization
- Haemodynamic instability
- LVEF <20%
- For transapical : severe pulmonary disease, LV apex not accessible

Edward Valve: PARTNER

1st RCT for Edwards Valve

Symptomatic Severe Aortic Stenosis

ASSESSMENT: High Risk AVR Candidate
3105 Total Patients Screened

Total = 1057 patients

**2 Parallel Trials:
Individually Powered**

n= 699

A: High Risk

**ASSESSMENT:
Transfemoral Access**

High Risk TF

High Risk TA

1:1 Randomization

1:1 Randomization

N = 244

N = 248

TAVI
Trans
femoral

vs

Surgical
AVR

N = 104

N = 103

TAVI
Trans
femoral

vs

Surgical
AVR

Primary Endpoint: All Cause Mortality (1 yr)
(Non-inferiority)

n=358

B: Inoperable

**ASSESSMENT:
Transfemoral Access**

1:1 Randomization

Not In Study

N = 179

N = 179

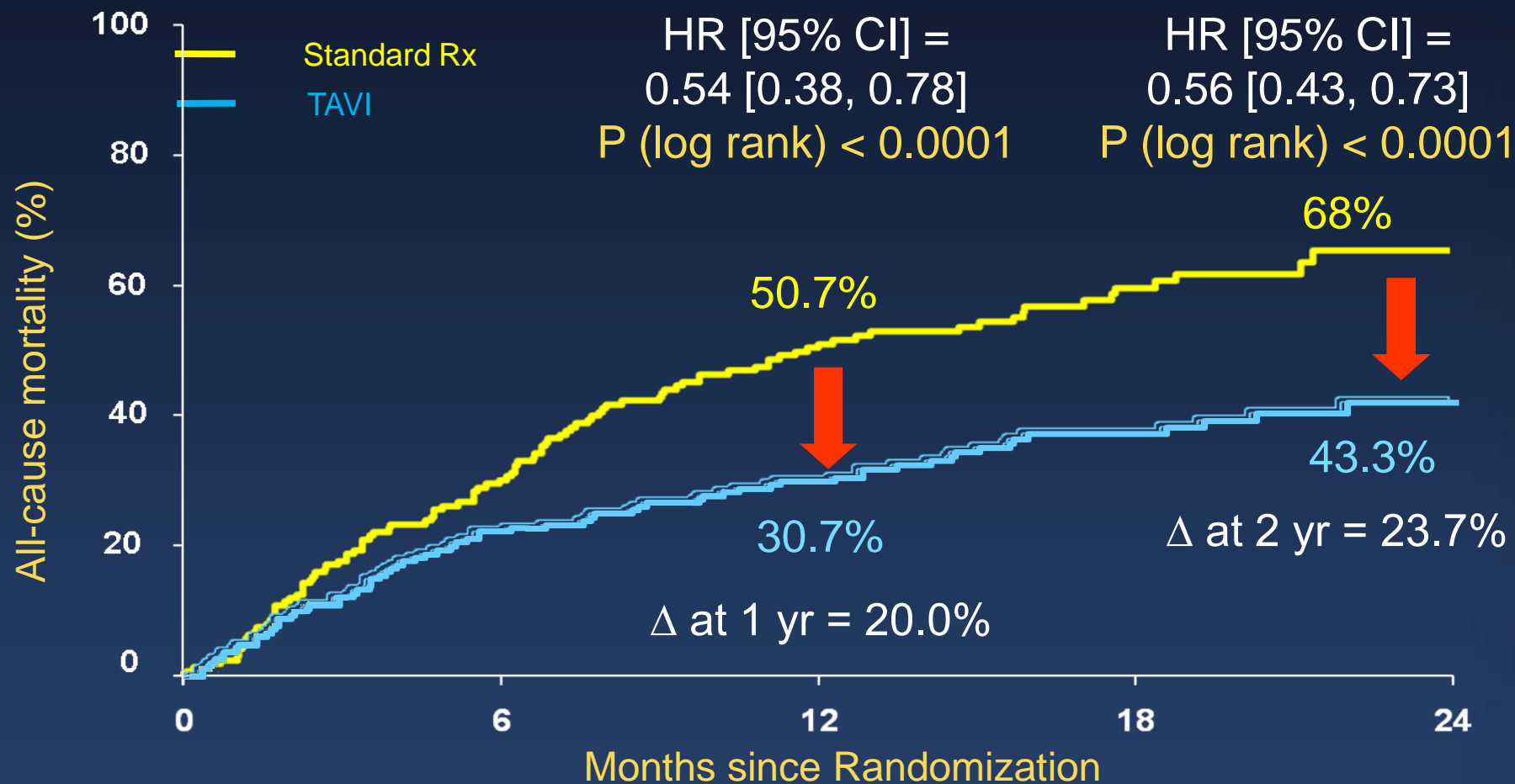
TAVI
Trans
femoral

vs

Standard
Therapy
(usually BAV)

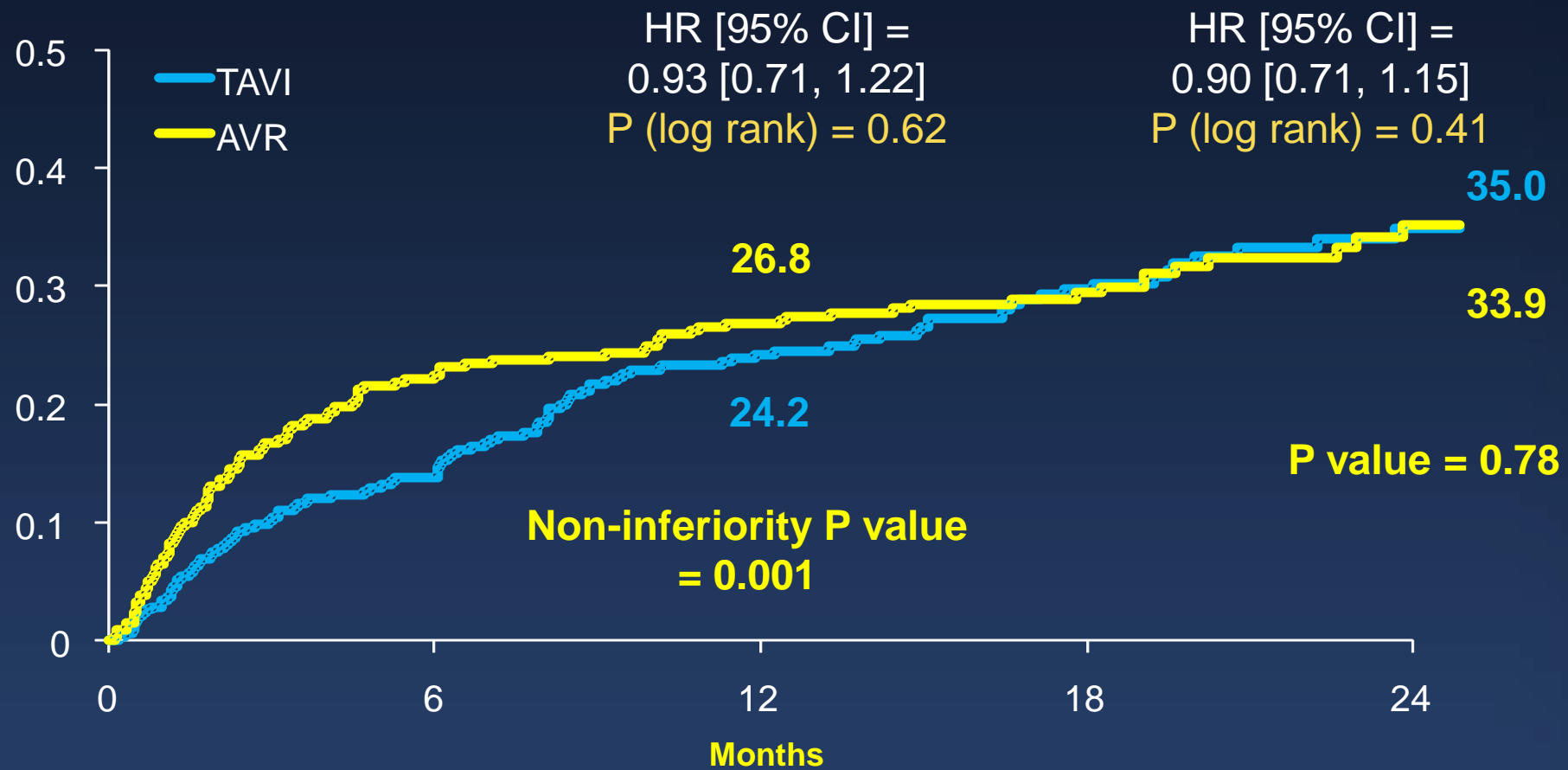
Primary Endpoint: All Cause Mortality over length
of trial (Superiority)

All Mortality at 1,2 Year: Inoperable



Numbers at Risk						
TAVI	179	138	124	110	88	83
Standard Rx	179	121	85	62	42	42

All Mortality at 1,2 Year: High Risk



Number at Risk

TAVR	348	298	260	147	67
AVR	351	252	236	139	65

Edward-Sapien Registries

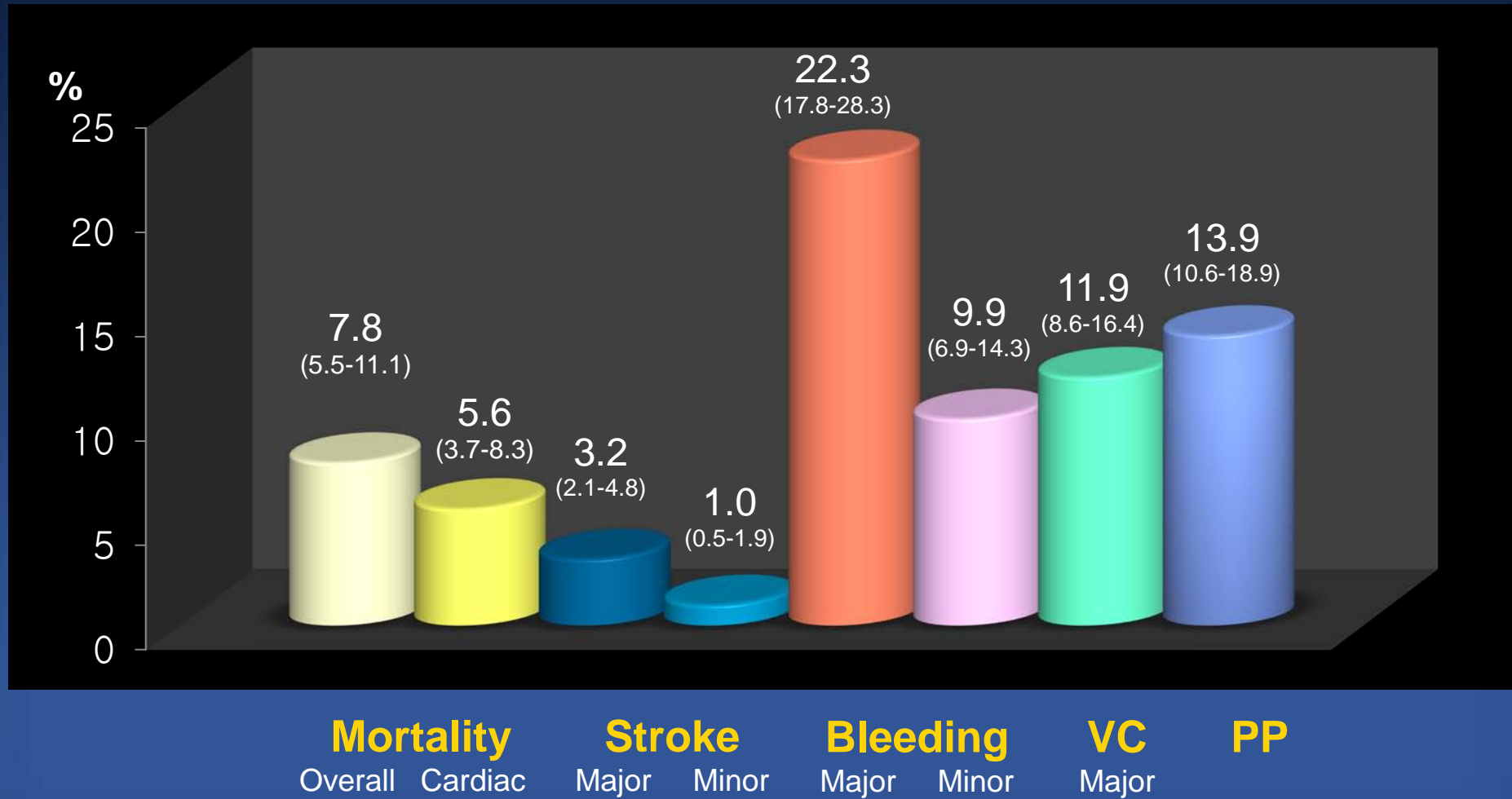
Characteristic	REVIVE, REVIVAL, PARTNER EU (N=222)	SOURCE Registry (TF) (N=920)	France Registry (N=1,137)	Belgium Registry (N=303)	Canada Registry (TF) (N=162)
Demographics					
Age (y)	83	82	83	83	83
Female (%)	55	56	49	46	44
EuroSCORE (mean, %)	26	24	23	29	26
NYHA class III/IV (%)	89	76	75	80	93
Mean gradient (mm Hg)	45	49	48	47	48
Prior CABG (%)	26	15	19	20	30
Ejection fraction (%)	51	52	53	50	55
Outcomes					
30-day mortality (%)	10.4	7.5	7.8	8	9.5
1-y mortality (%)	24	18.9	-	-	-
Stroke (%)	3.3	3.5	3.5	5.0	3.0
Permanent pacemaker (%)	1.8	6.7	8.5	4.0	3.6

Medtronic CoreValve Registries

characteristic	Tamburino (N=663)	Milan (N=61)	French (N=66)	Spanish (N=108)	UK/Ireland (N=288)	UK (N=452)	German (N=588)	Buellesfeld (N=126)
Demographics								
Age (y)	82	79	82.5	78.6	81	81.3	81.4	81.9
Female (%)	56	47	51.5	54.6	-	48	55.8	57.1
EuroSCORE (mean, %)	23	26.6	24.7	16	22	18.1	20.8	23.4
NYHA class III/IV (%)	71.5	69	74.6	58.4	74	73.9	88.2	74.6
Mean gradient (mm Hg)	52	54	46	55	-	-	48.7	46.8
Outcomes								
30-day mortality (%)	5.9	2.2	15.1	7.4	4.7	5.8	12.4	15.2
1-y mortality (%)	15	18.4	-	17.7	-	21.7	-	38.1
Stroke (%)	2.5	2.2	4.5	0.0	4.2	4.0	2.8	-
Major vascular complications (%)	2.0	21.3	7.5	5.6	9.0	6.2	4.0	-
Permanent pacemaker (%)	19.1	26.1	25.7	35.2	26	24.4	42.5	26.2

TAVI Outcomes at 30 Days - VARC Meta-Analysis

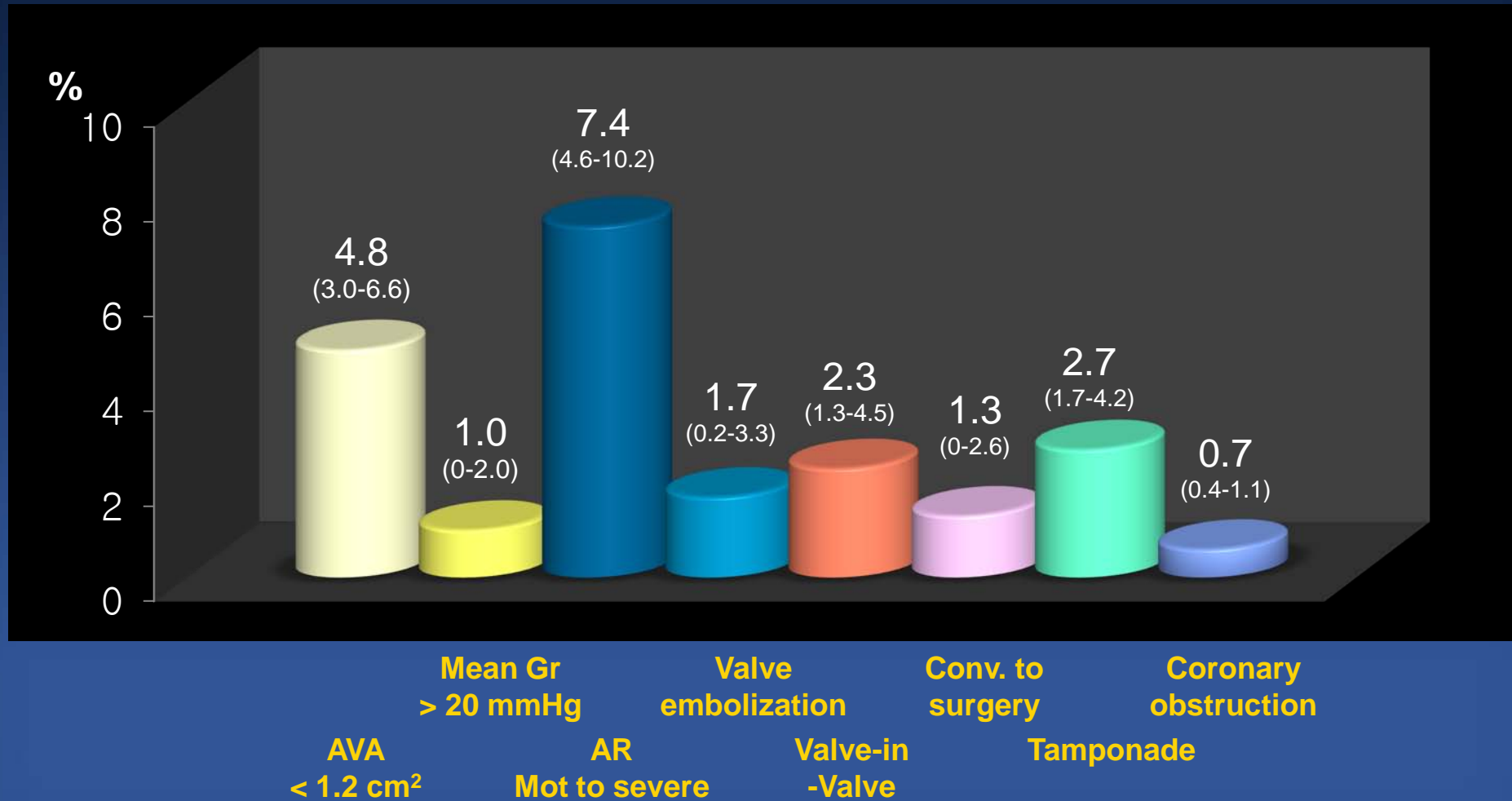
(16 studies; 3,519 patients)



VC = vascular complication, PP = permanent pacemaker

TAVI Outcomes at 30 Days - VARC Meta-Analysis

(16 studies; 3,519 patients)



PARTNER II: Intermediate, Edwards

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

VS

AVR

TA TAVR
Ascendra 2

VS

AVR

Primary Endpoint: All-Cause Mortality +
Major Stroke at Two Years
(Non-inferiority)

ASSESSMENT:
Transfemoral
Access

Yes

No

1:1 Randomization

Not In Study

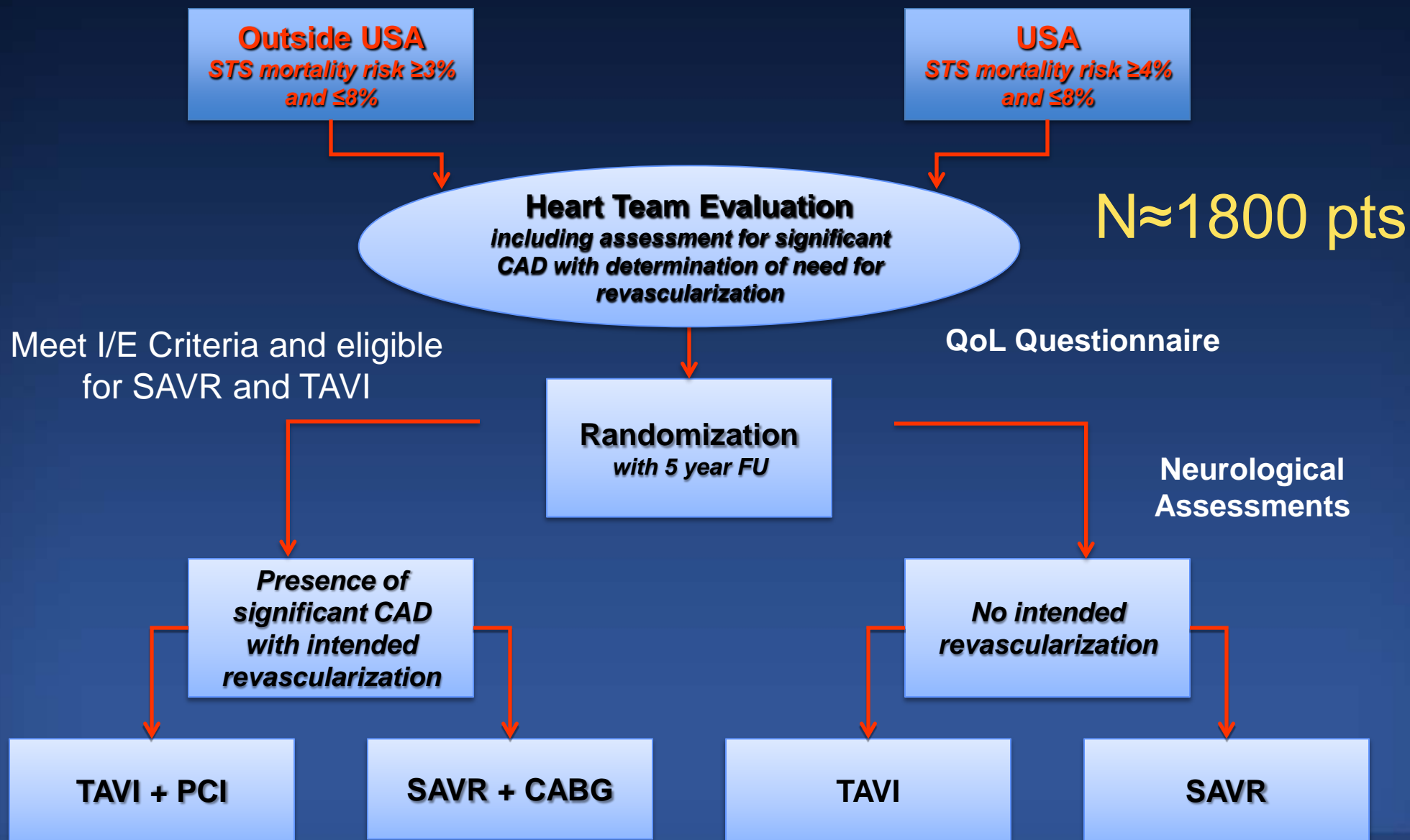
TF TAVR
Sapien XT

VS

TF TAVR
Sapien

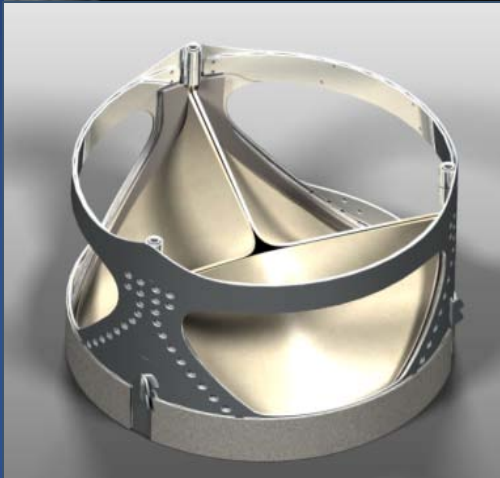
Primary Endpoint: All-Cause Mortality +
Major Stroke + Repeat Hospitalization at One Year
(Non-inferiority)

SURTAVI – Intermediate, CoreValve



Primary Endpoint: Death+Stroke at 2 Yrs

New Devices



Discussion

- Increasing penetration rate
- Rationale of the current indications of TAVI
- Management of heart team
- Outcomes and complications of Sapien vs. Core Valves
- Utilization for intermediate-risk patients
- New TAVI devices
- Best image guidance
- Durability of devices