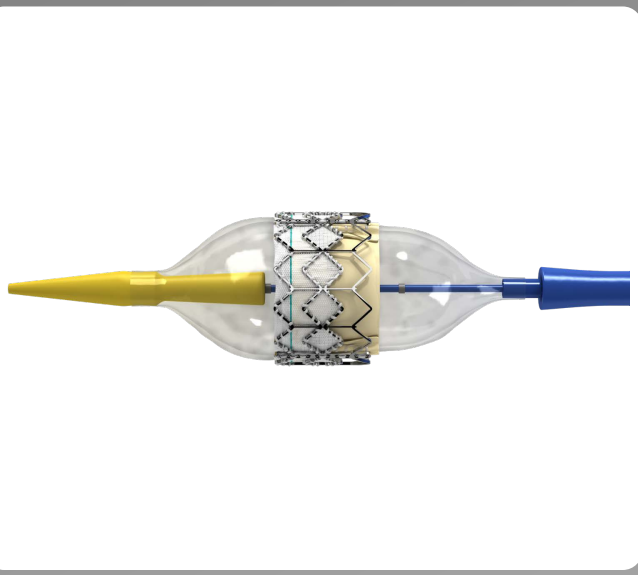
All patients with aortic stenosis requiring a bioprosthetic heart valve should have a TAVR

It has Already Happened and Is Justified!

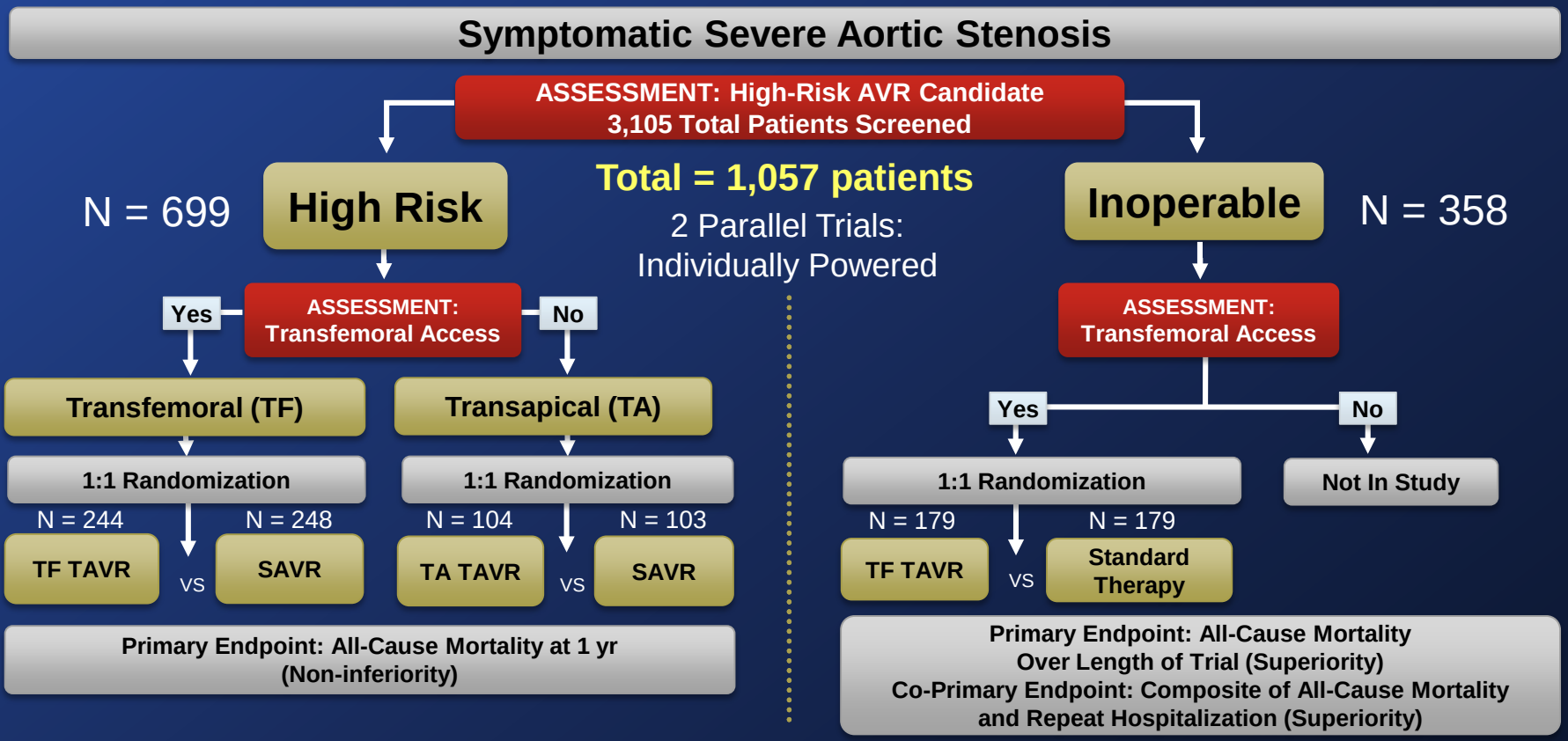
Pieter Kappetein, Erasmus MC, Rotterdam, The Netherlands

Study Devices

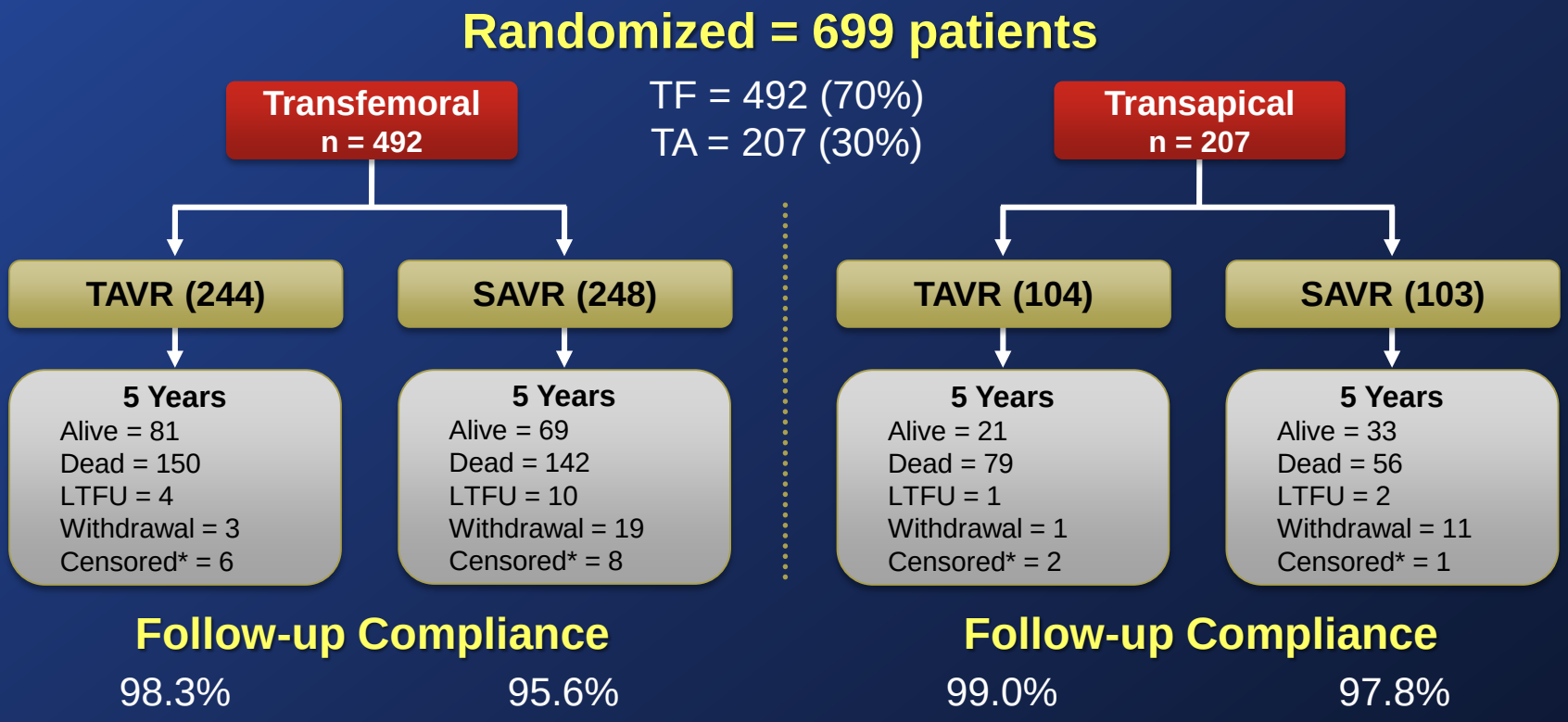
THE PARTNER TRIAL

	Transfemoral	Transapical
		
Edwards SAPIEN THV 23 and 26 mm valves	**RetroFlex 1** 22 and 24 F sheaths	**Ascendra** 24 and 26 F sheaths

PARTNER Study Design



Study Flow



** Censored = Patient alive at last contact but no information available within FU window*

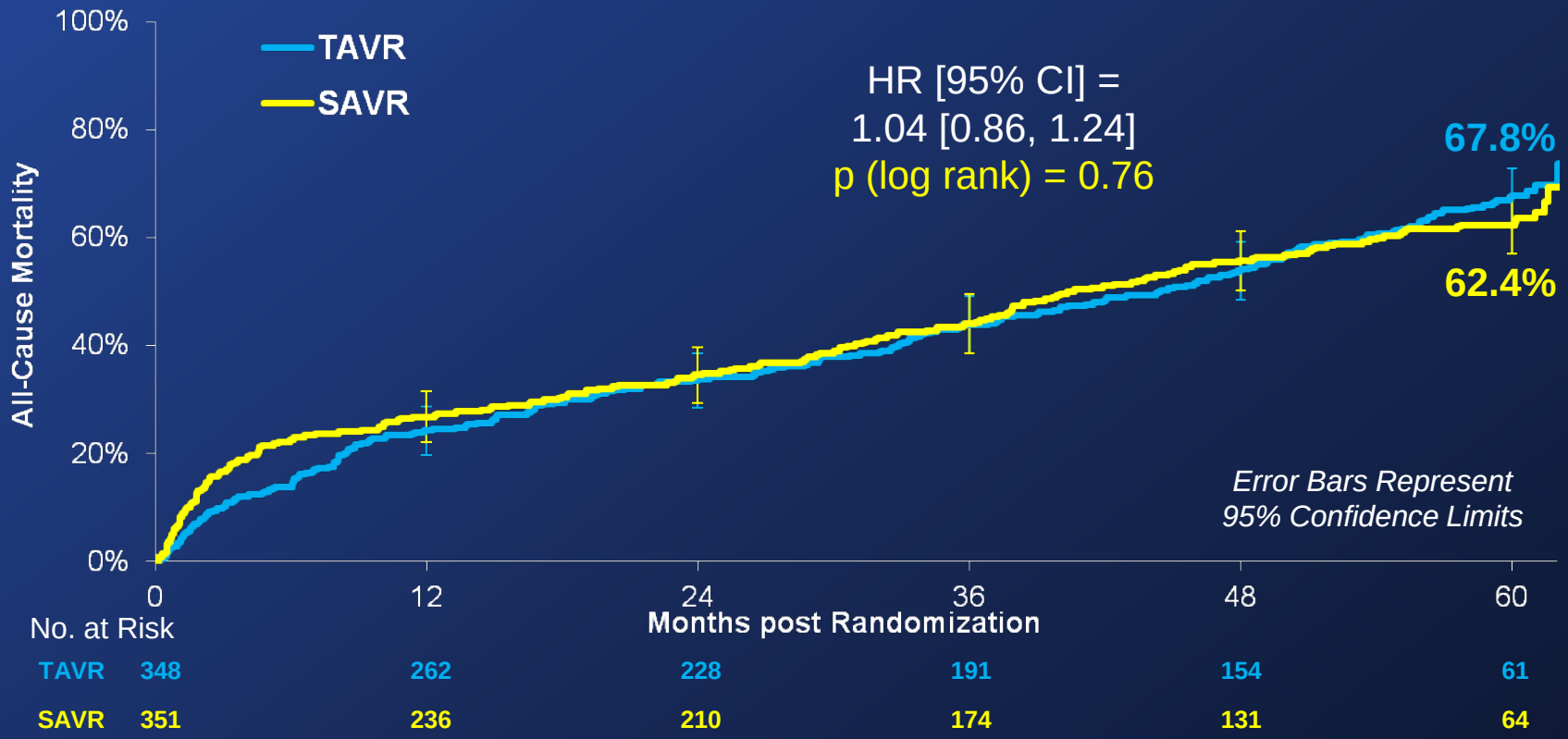
Baseline Patient Characteristics

Demographics

	TAVR (n=348)		SAVR (n=351)	
Characteristic	**n**		**n**	
Age – years (Mean ± SD)	348	83.6 ± 6.8	349	84.5 ± 6.4
Male	201	57.8%	198	56.7%
NYHA Class III or IV	328	94.3%	328	94.0%
Previous CABG	148	42.5%	152	43.6%
Cerebrovascular disease	96	29.4%	87	26.8%
Peripheral vascular disease	149	43.2%	142	41.6%
STS Score (Mean ± SD)	347	11.8 ± 3.3	349	11.7 ± 3.5

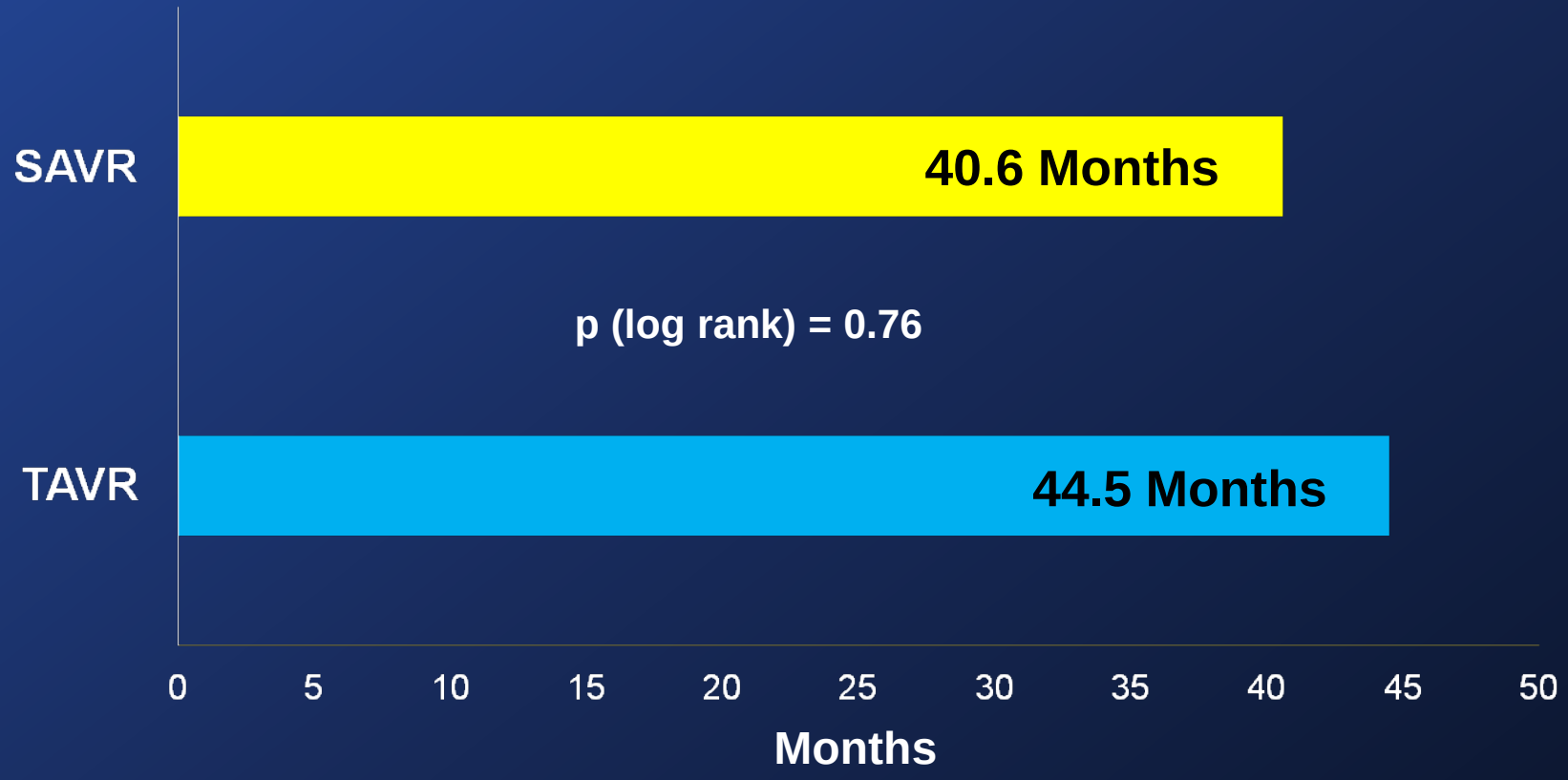
All-Cause Mortality (ITT)

All Patients



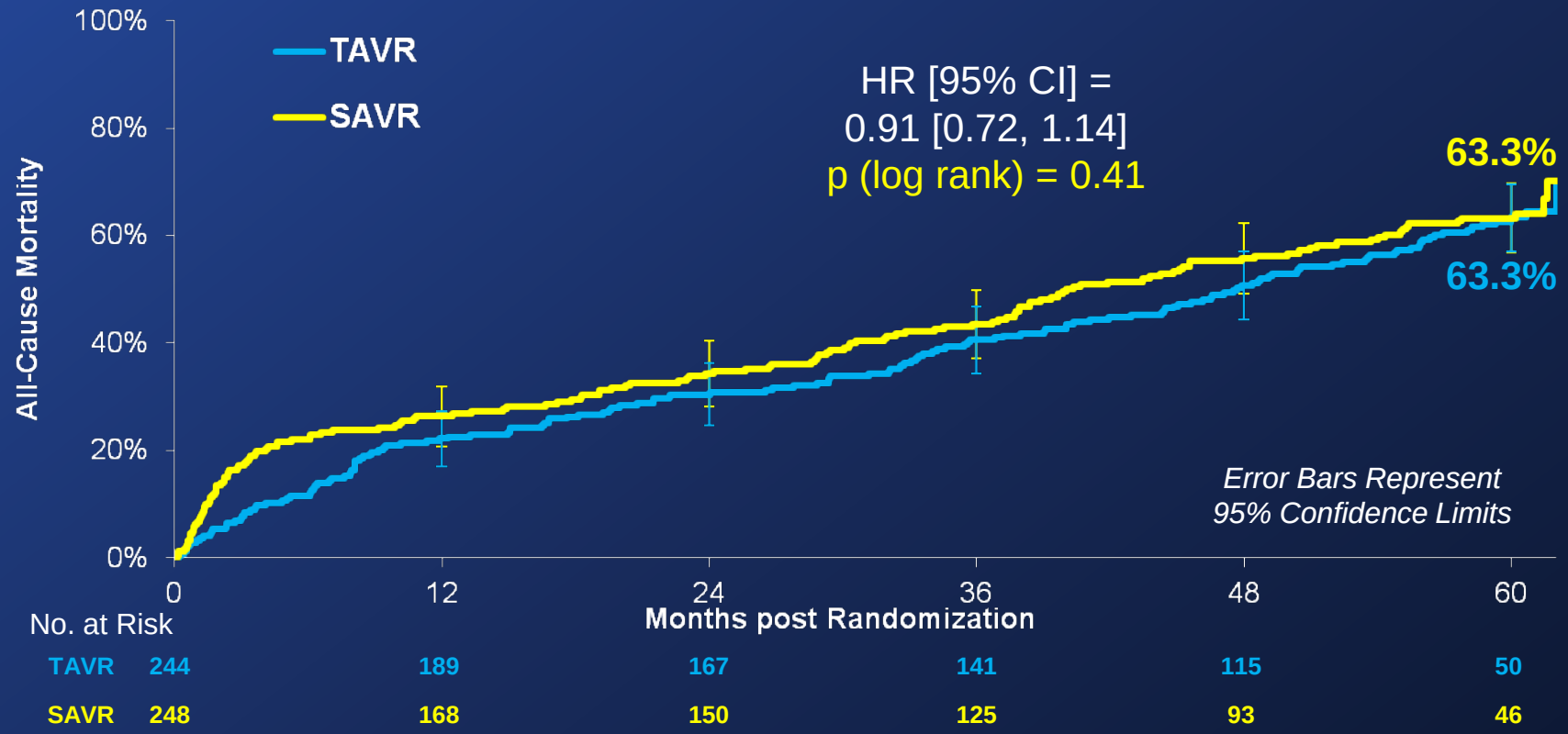
Median Survival

All Patients



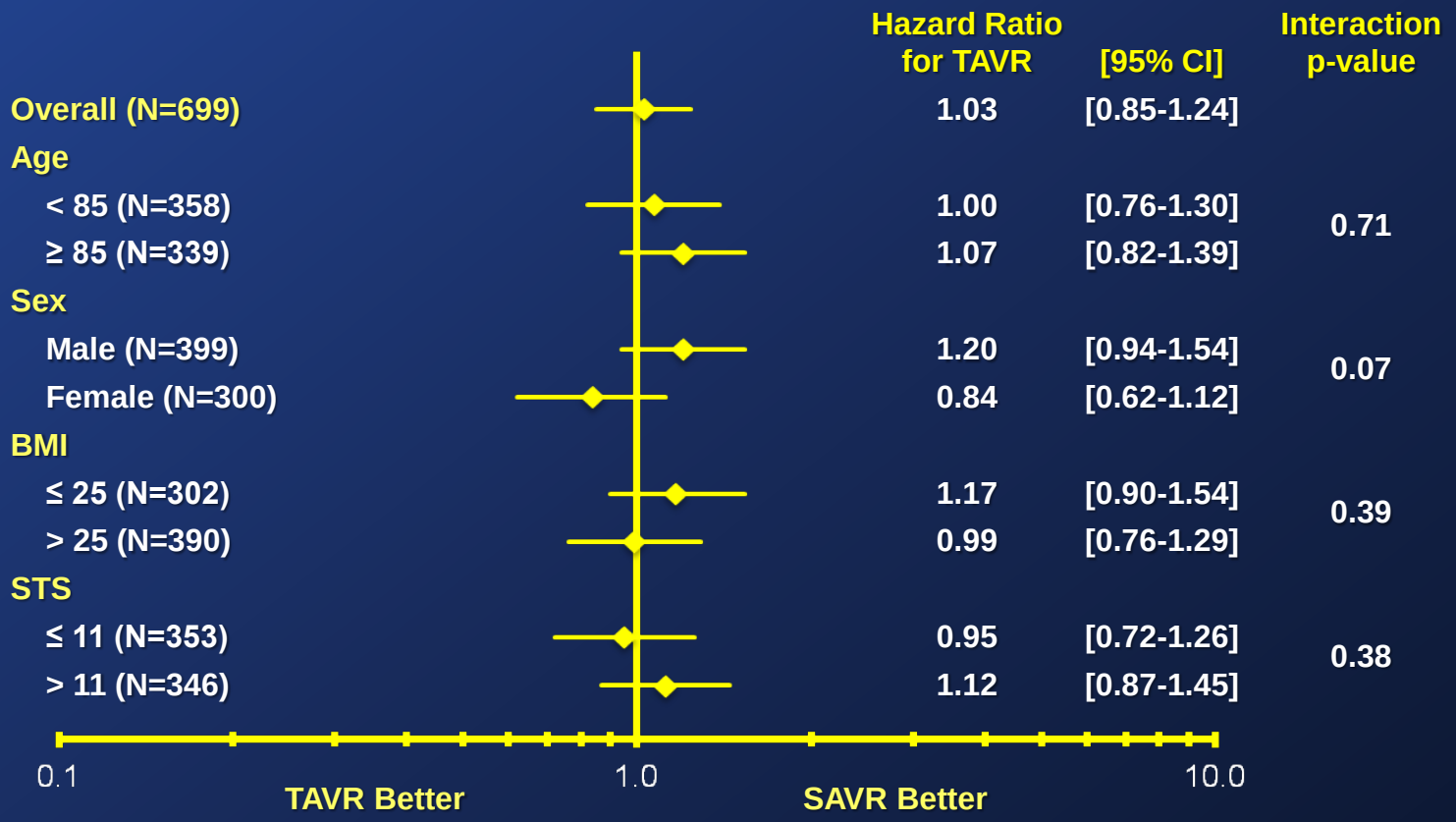
All-Cause Mortality (ITT)

Transfemoral Patients



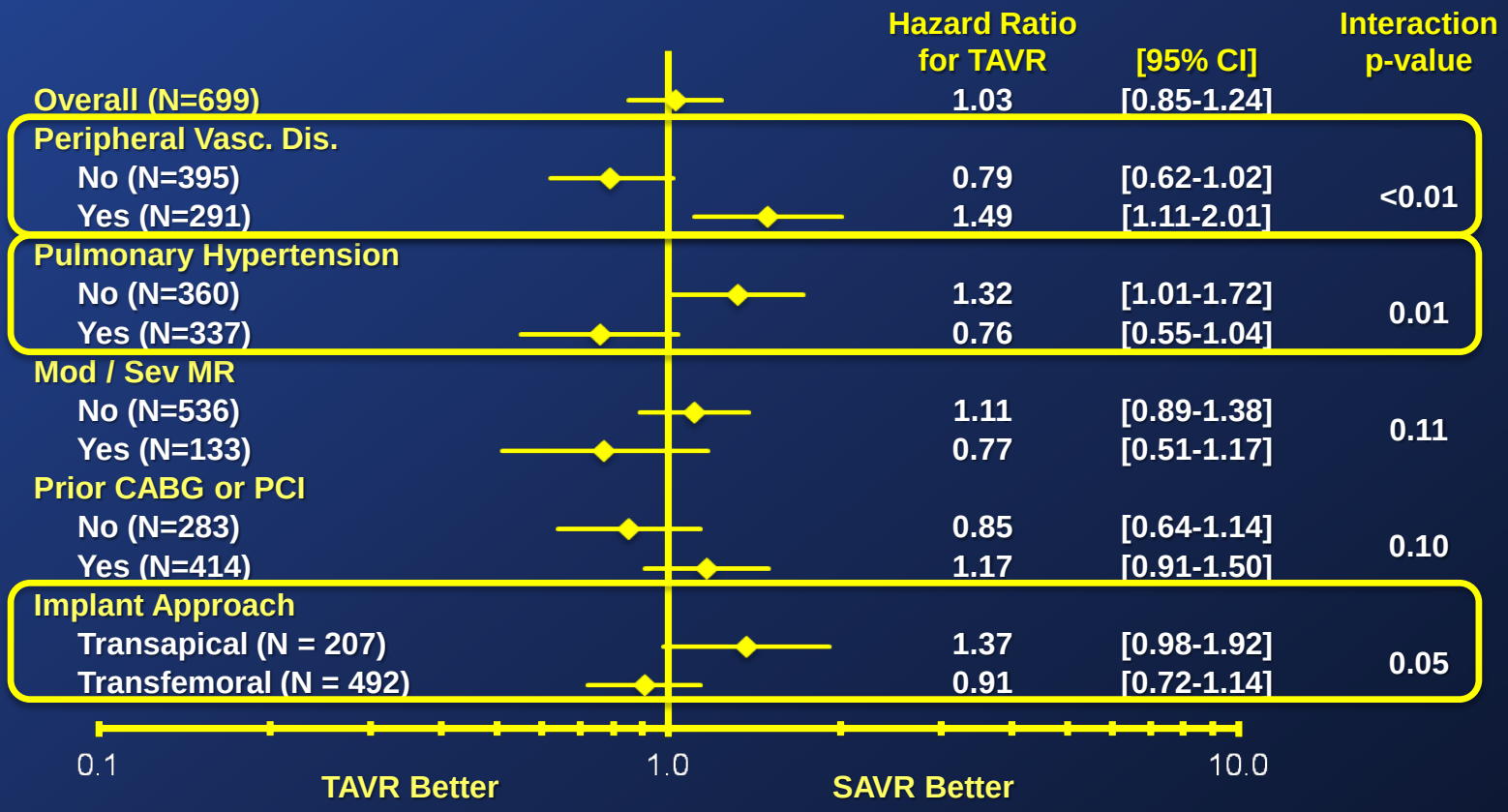
Subgroup Analysis

All-Cause Mortality



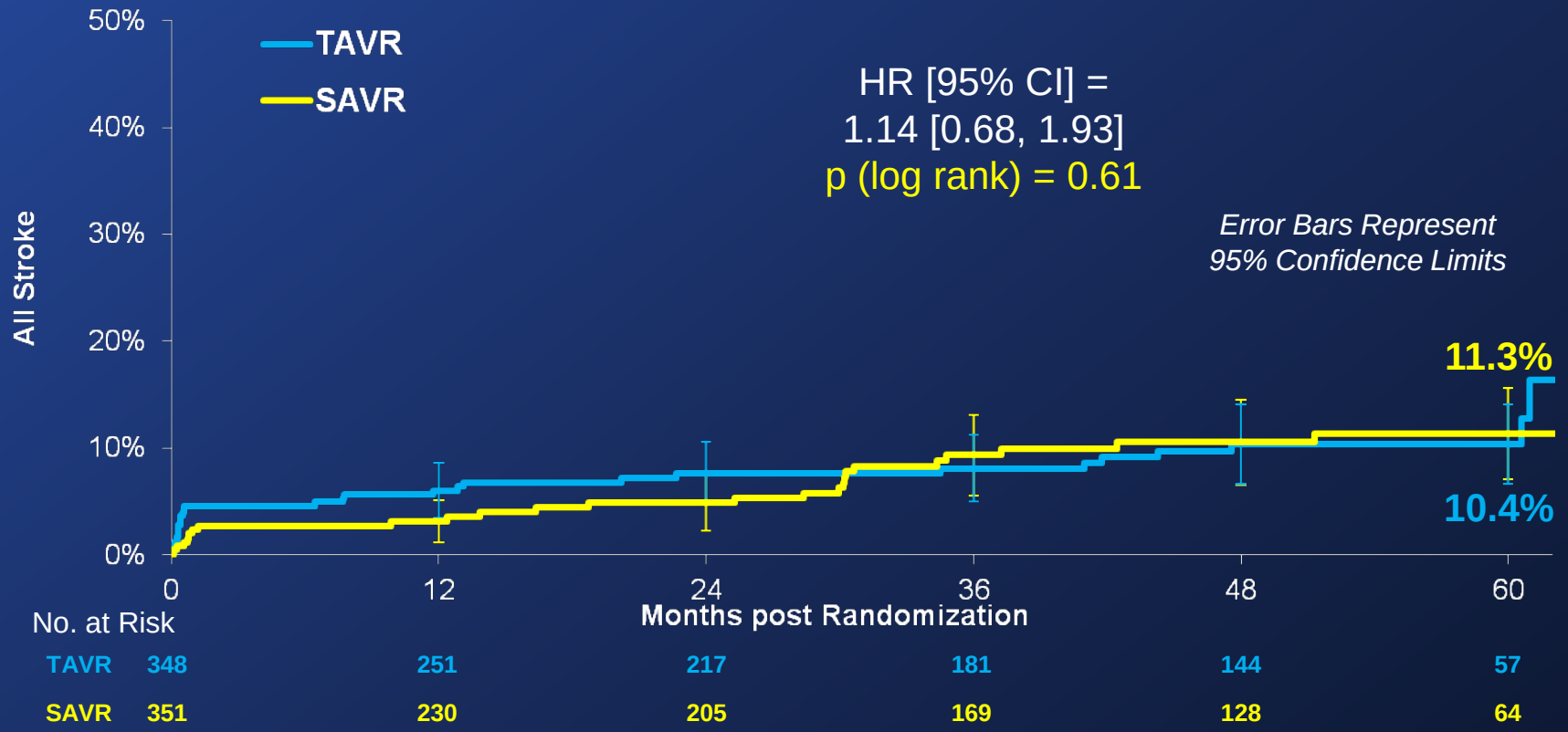
Subgroup Analysis

All-Cause Mortality



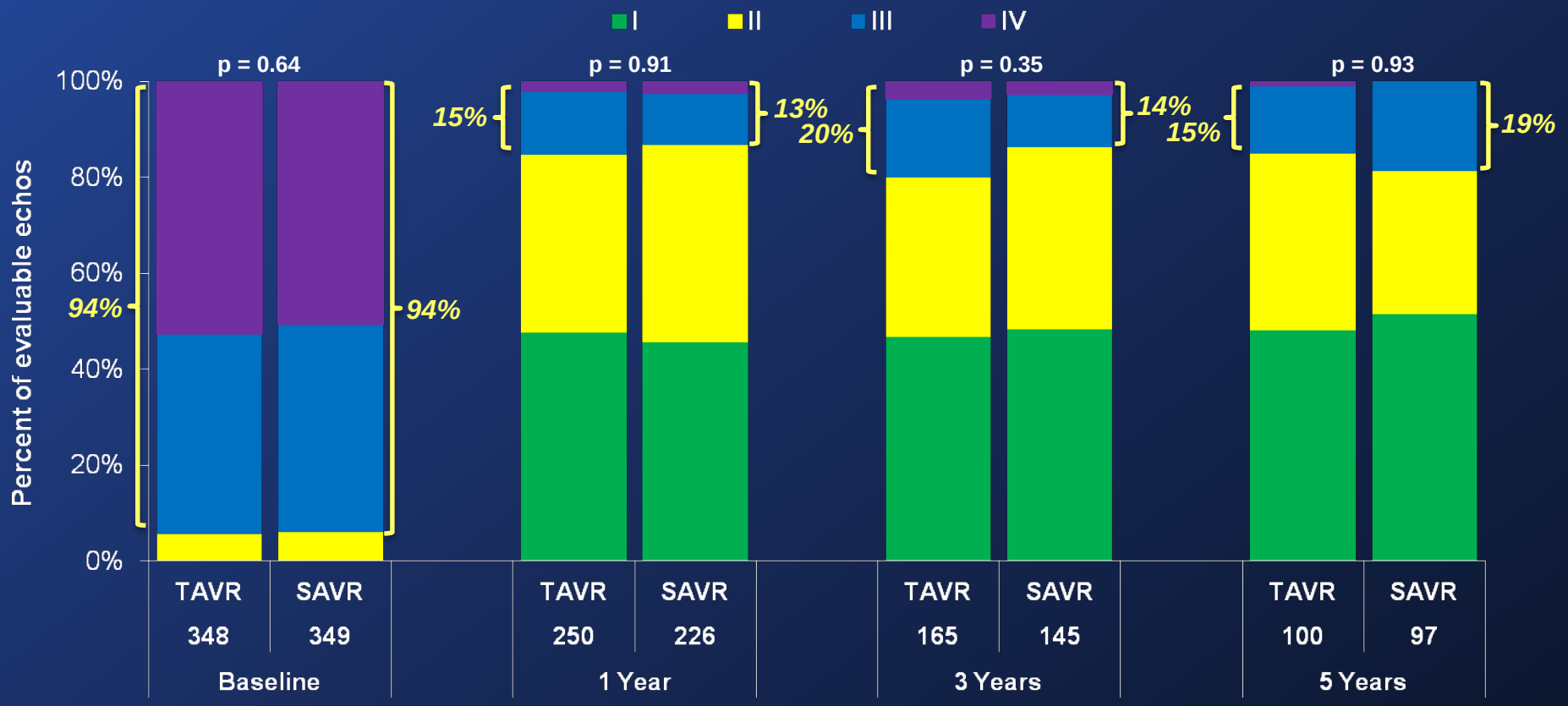
All Stroke (ITT)

All Patients



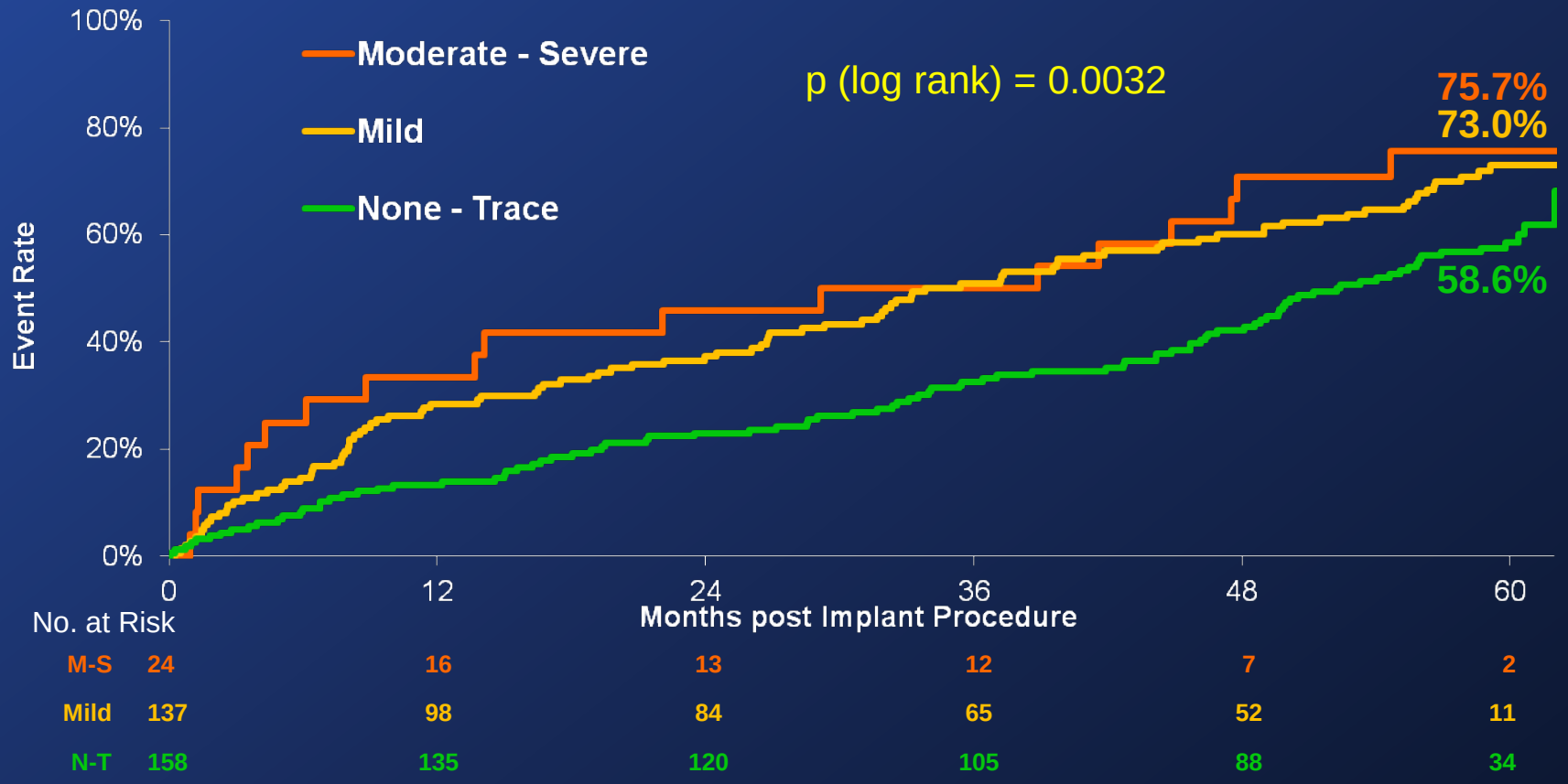
NYHA Over Time (ITT)

Survivors



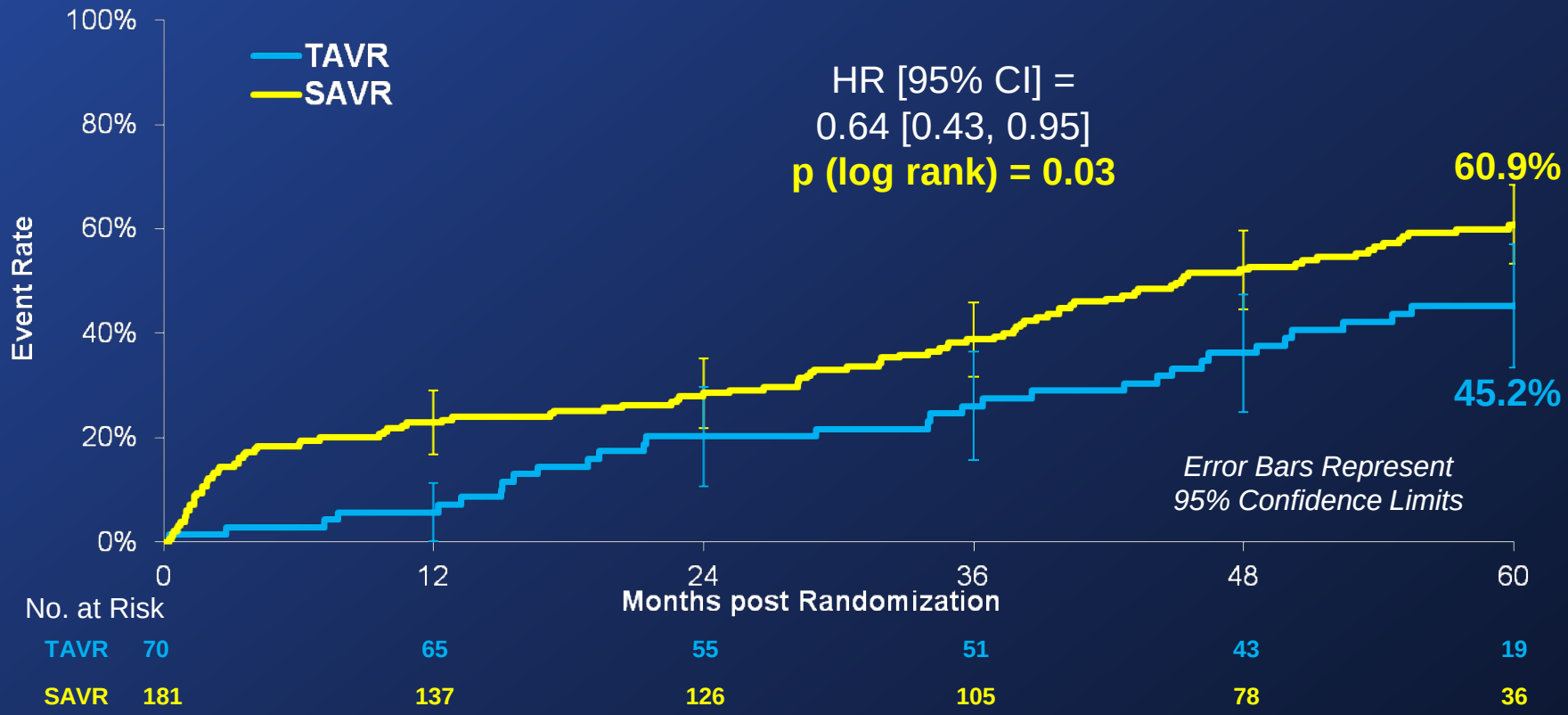
Mortality and Post Procedural PVL

TAVR Patients

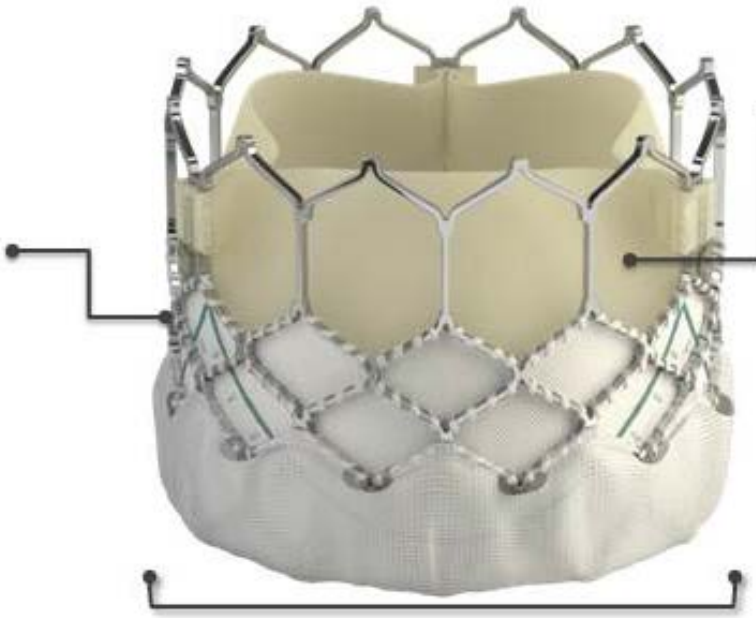


Mortality and None-Trace Total AR

Transfemoral Patients

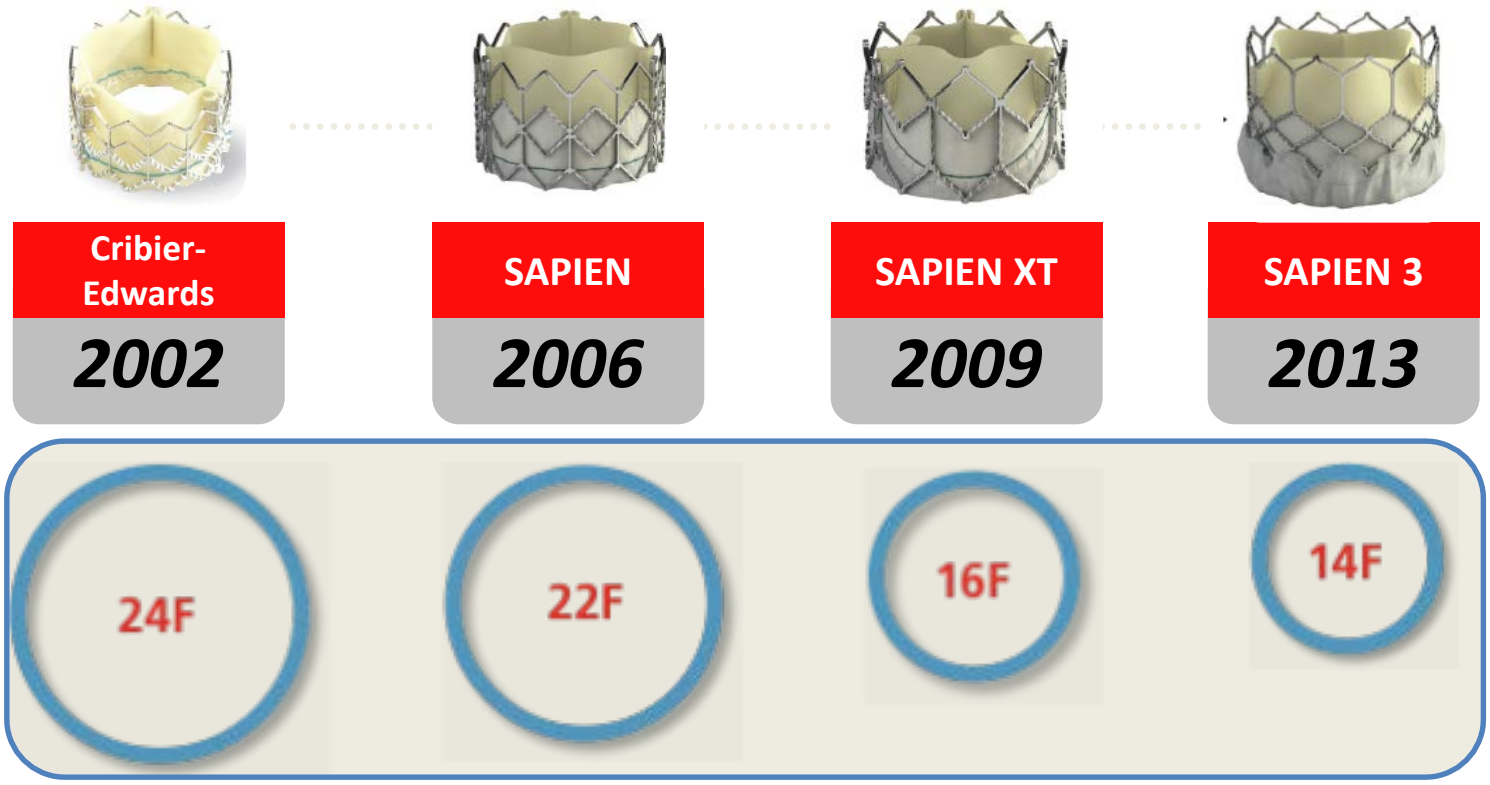


Edwards SAPIEN 3 Transcatheter Heart Valve



THE SAPIEN 3 TRIAL

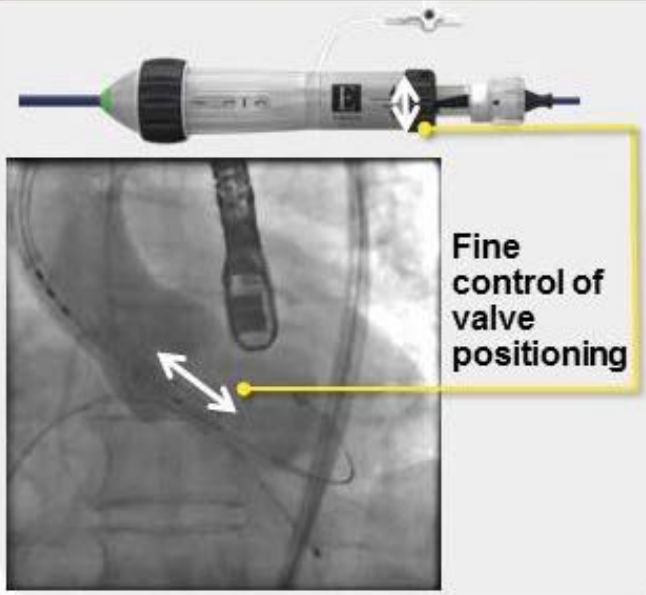
Evolution of the Edwards Balloon-Expandable Transcatheter Valves



Edwards Commander Delivery System

Improved coaxial alignment

Accurate positioning

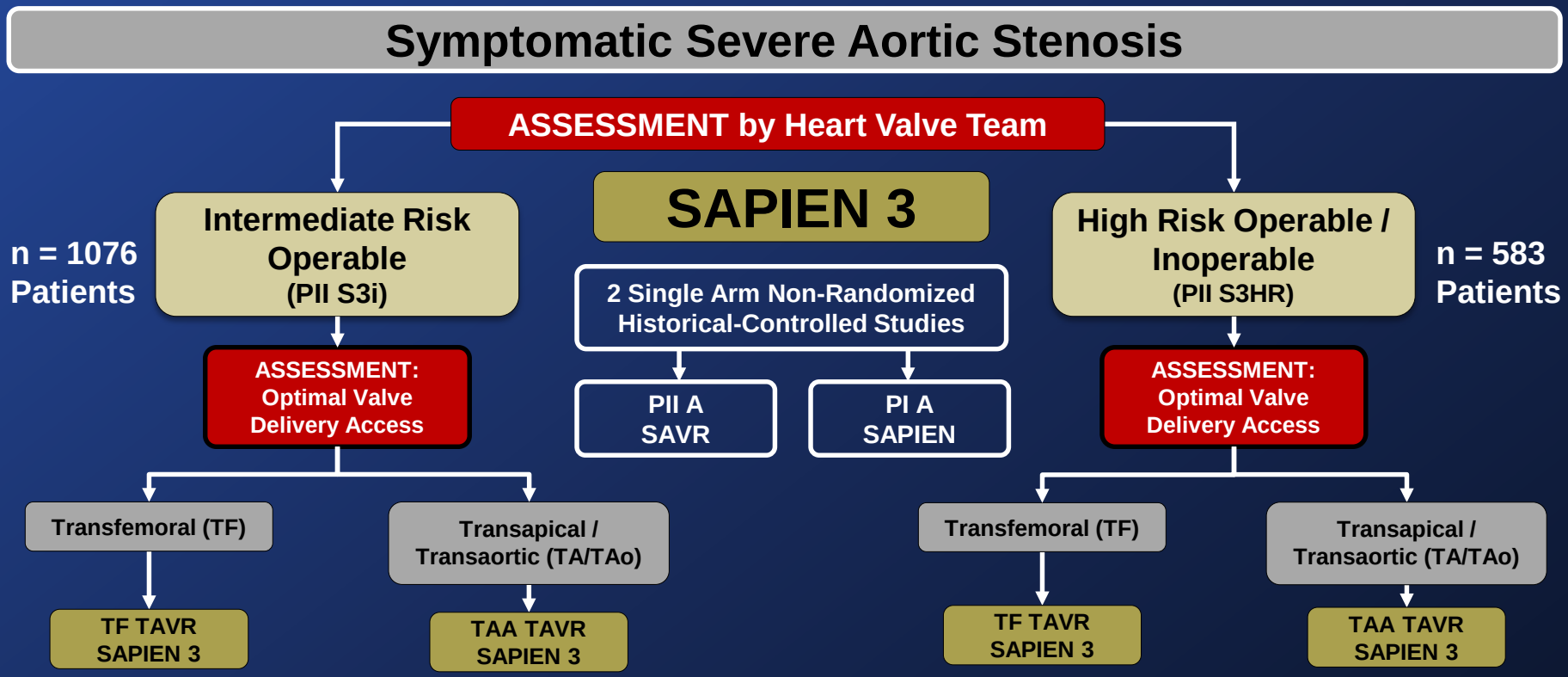


SAPIEN 3 Valve Size	23 mm	26 mm	29 mm
Edwards eSheath	14F	14F	16F
Minimum Access Vessel Diameter	5.5 mm	5.5 mm	6.0 mm

THE SAPIEN 3 TRIAL

The PARTNER II S3 Trial

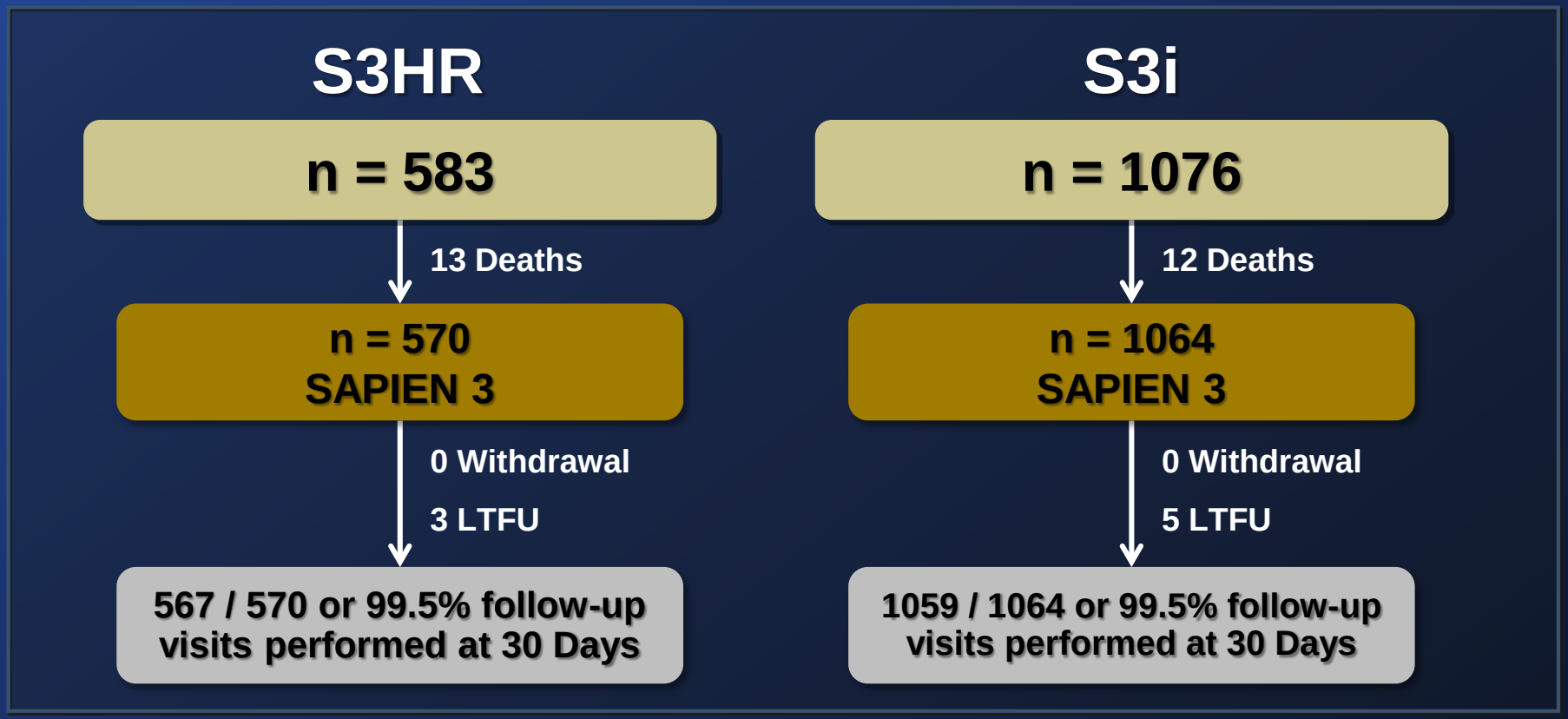
Study Design



Study Flow: S3HR & S3i

30 Day Patient Status

THE PARTNER II TRIAL



THE PARTNER II TRIAL

Baseline Patient Characteristics

S3HR Patients

Average STS =

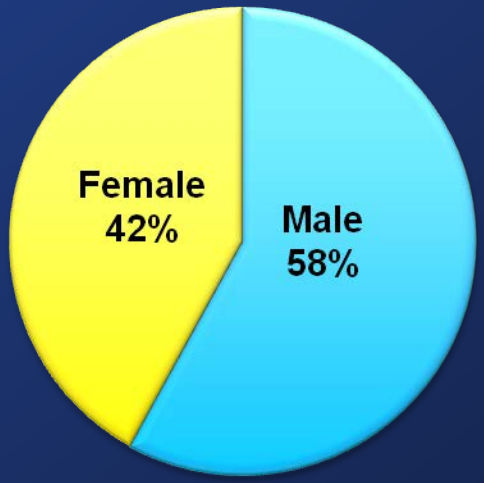
8.6%

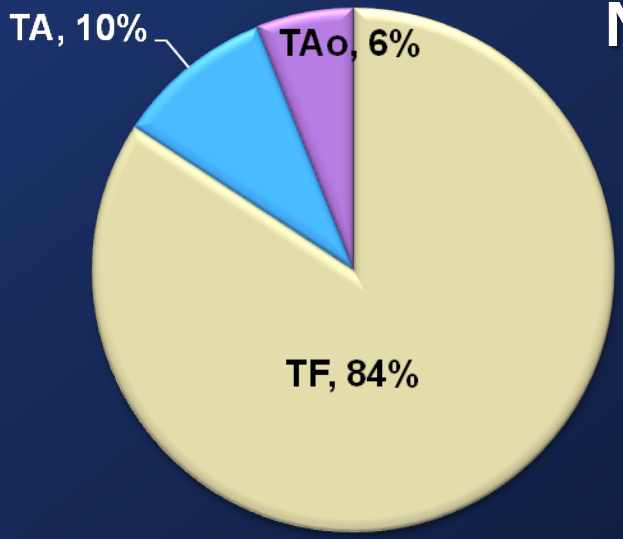
(Median 8.4%)

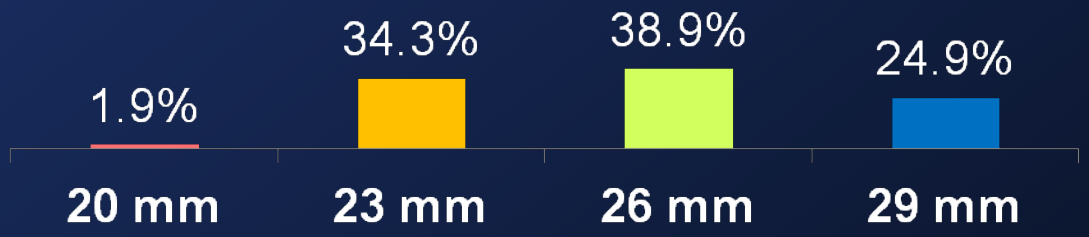
Average Age =

82.6yrs

N = 583



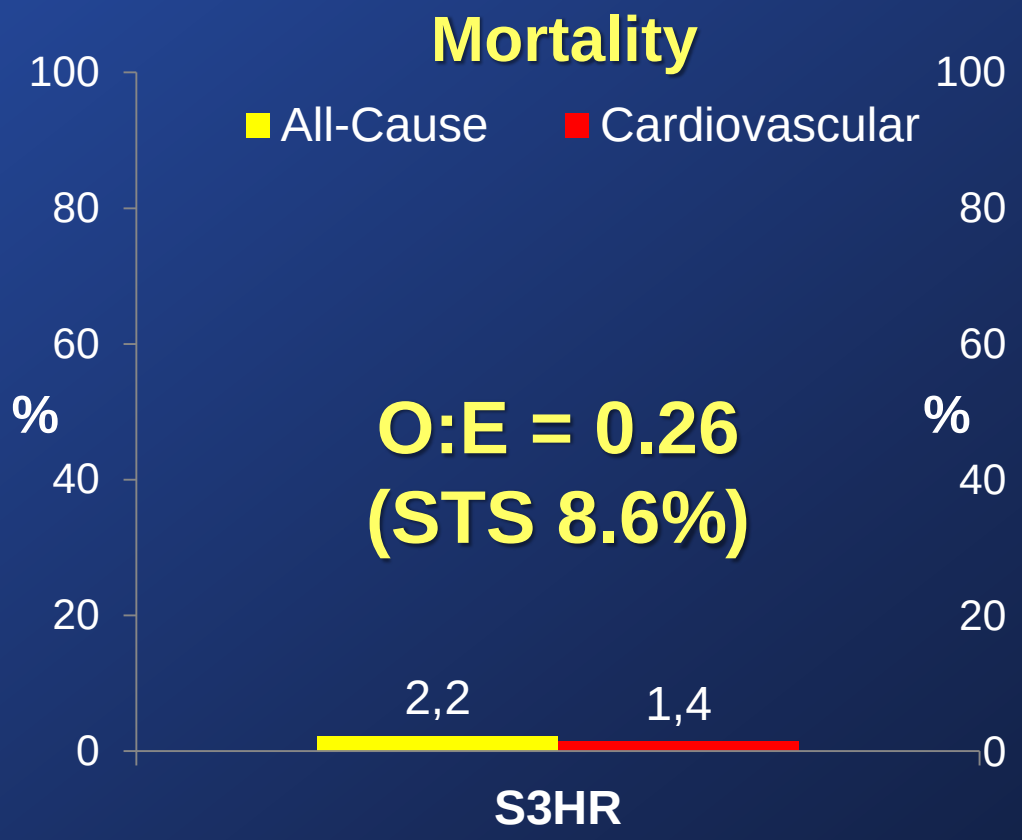


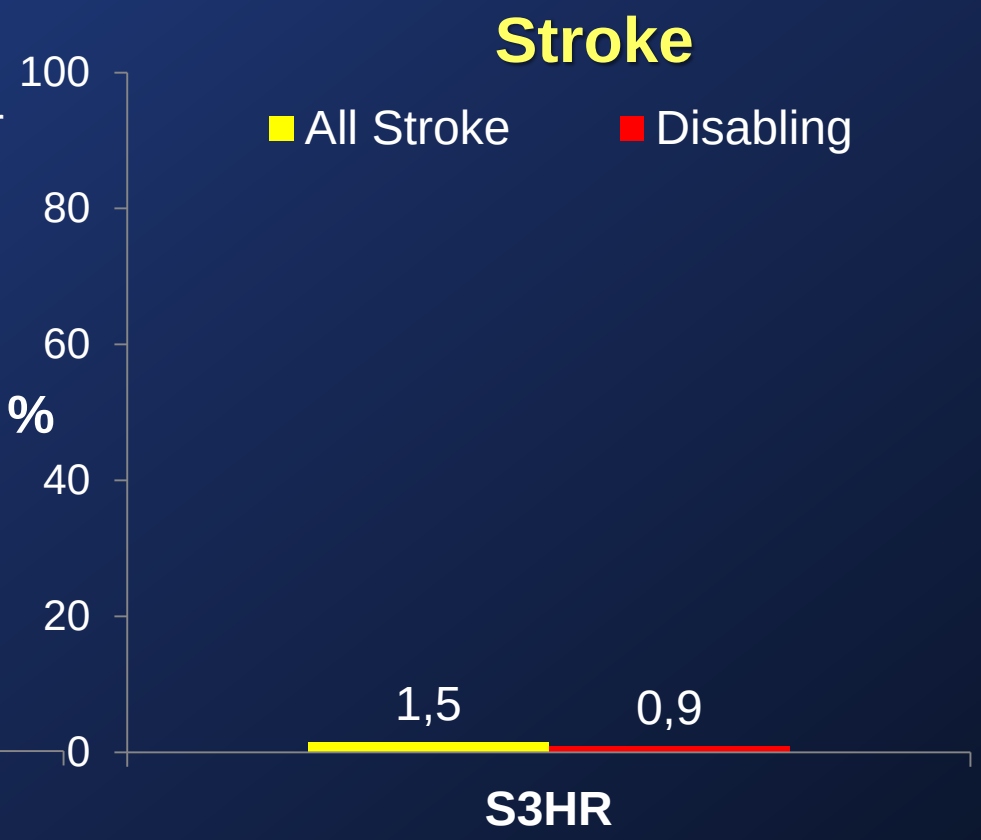


Mortality and Stroke: S3HR

At 30 Days (As Treated Patients)

THE PARTNER II TRIAL

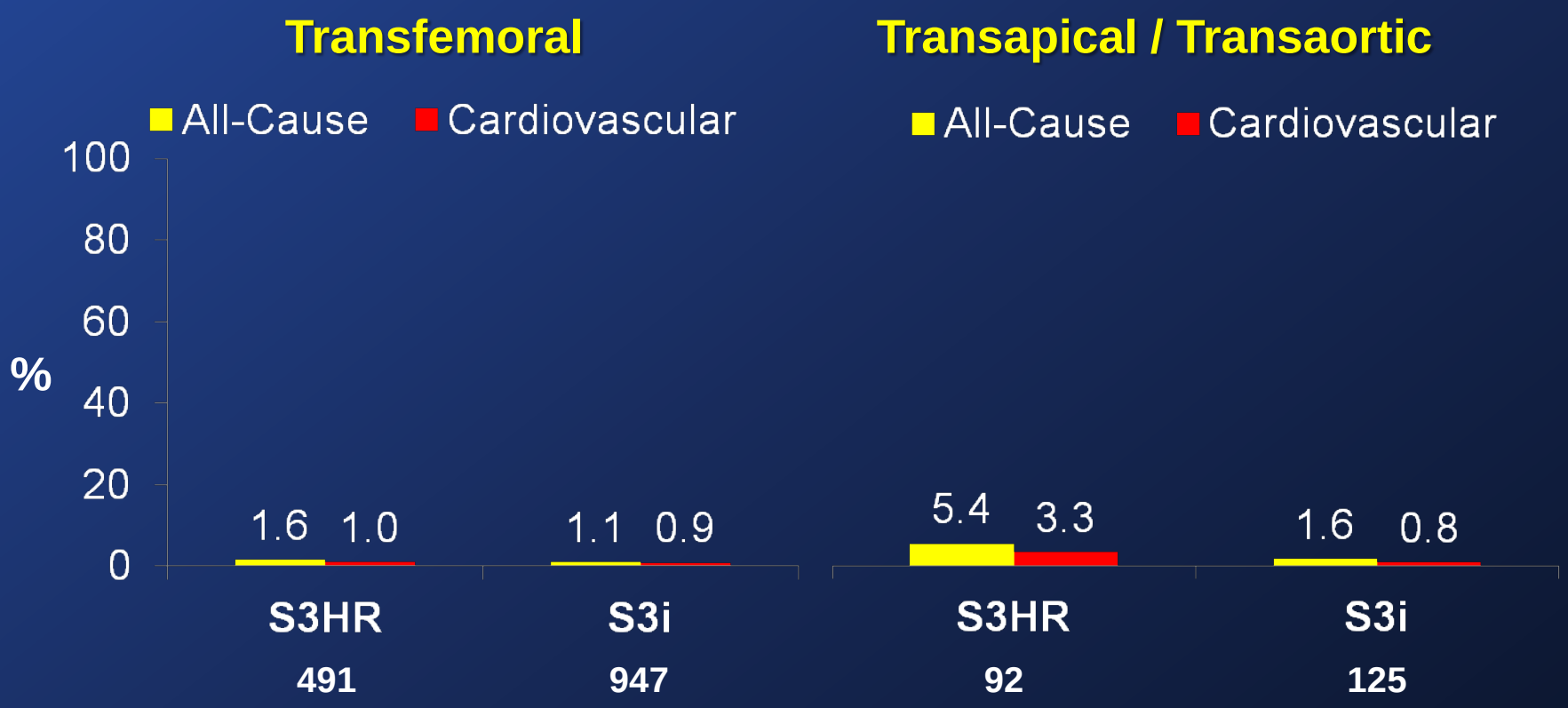




Mortality: S3HR & S3i

At 30 Days (As Treated Patients)

THE PARTNER II TRIAL



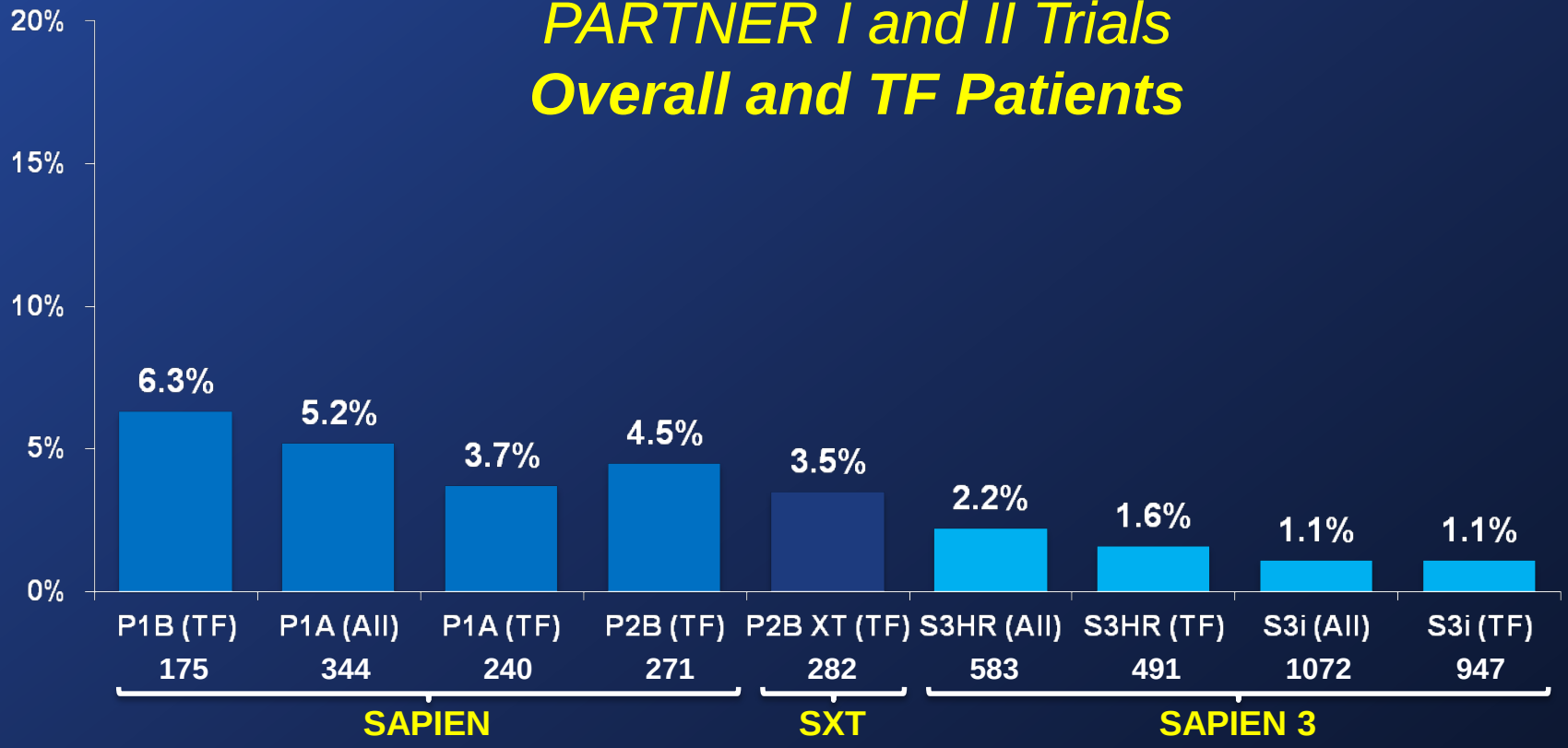
All-Cause Mortality at 30 Days

Edwards SAPIEN Valves (As Treated Patients)

THE PARTNER II TRIAL

PARTNER I and II Trials

Overall and TF Patients



CoreValve® Valve-in-Valve

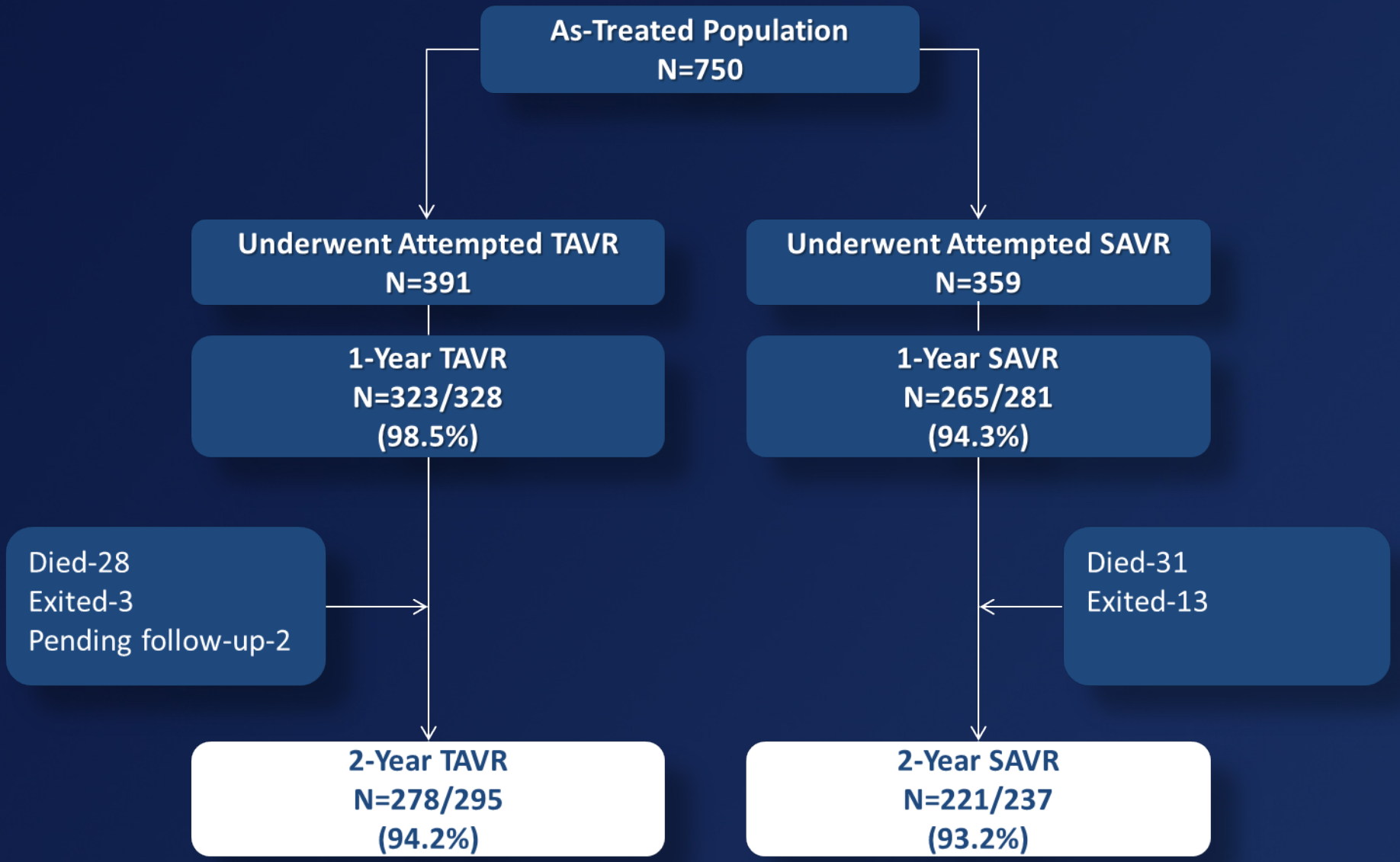
The following presentation outlines best practices and procedural considerations for the implantation for the CoreValve® System in failed stented aortic bioprostheses.

Academia
Medical Education

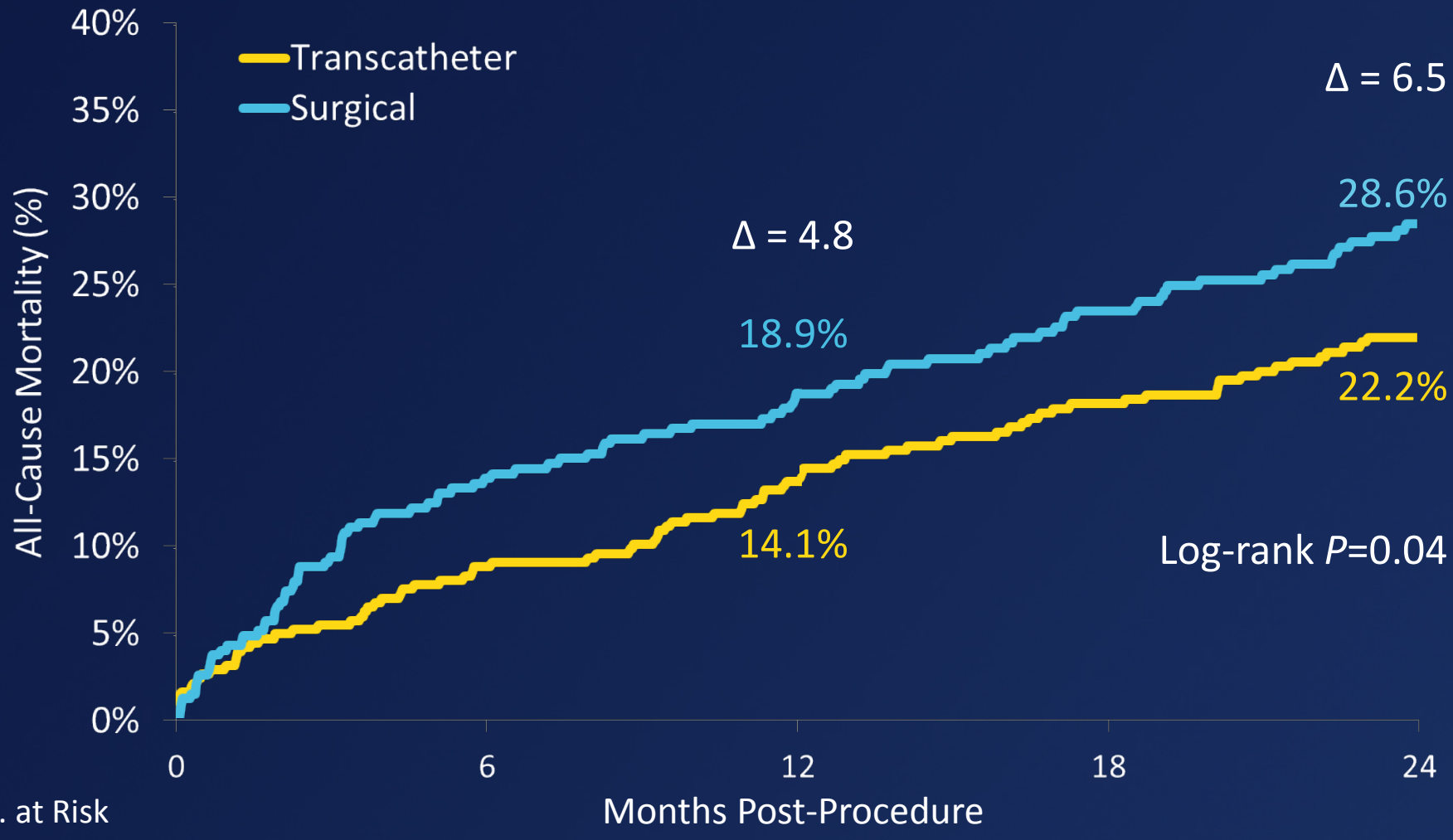
Medtronic

CoreValve US Pivotal Trial
High Risk 2-Year Results

Patient Flow

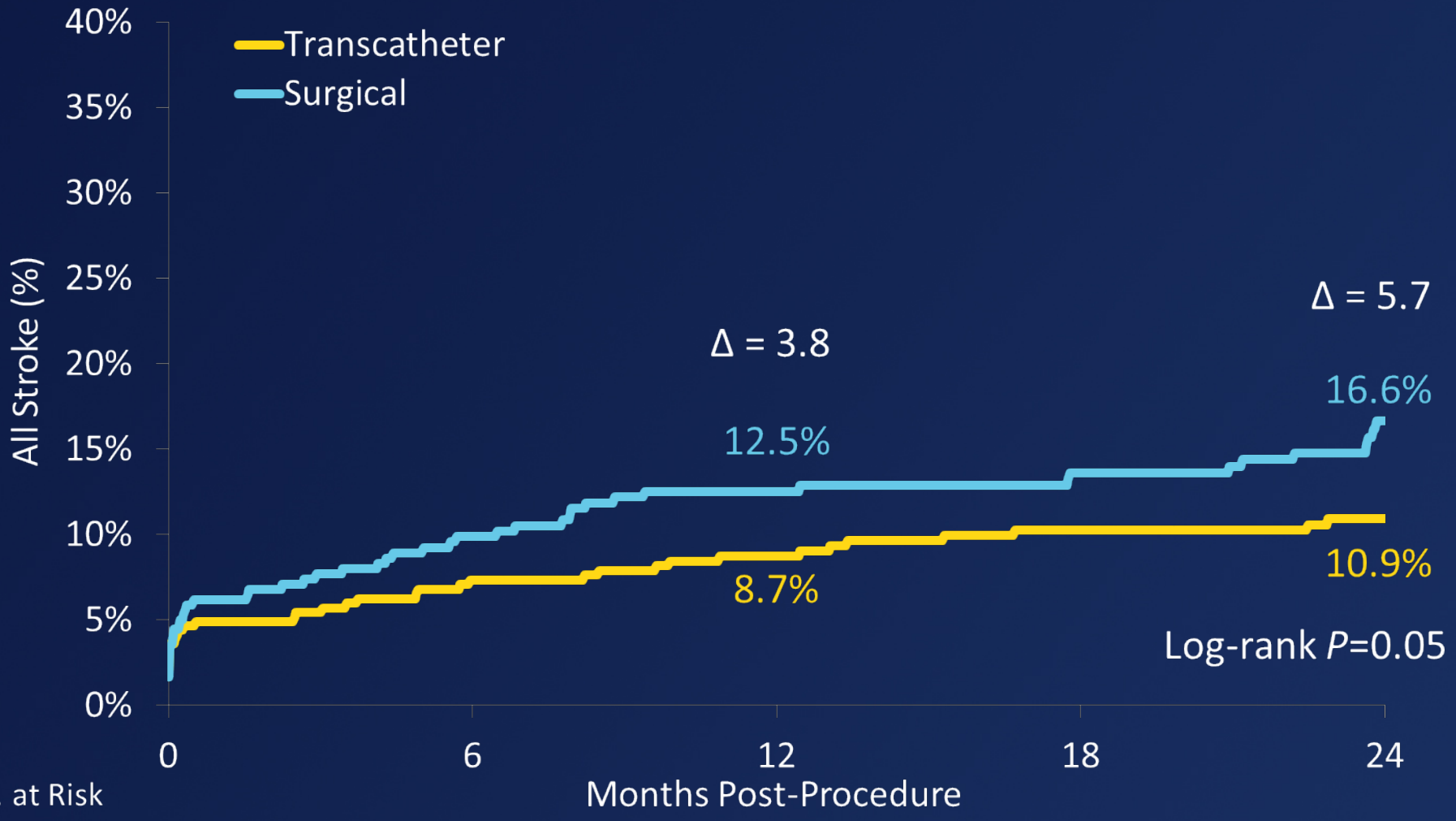


All-Cause Mortality



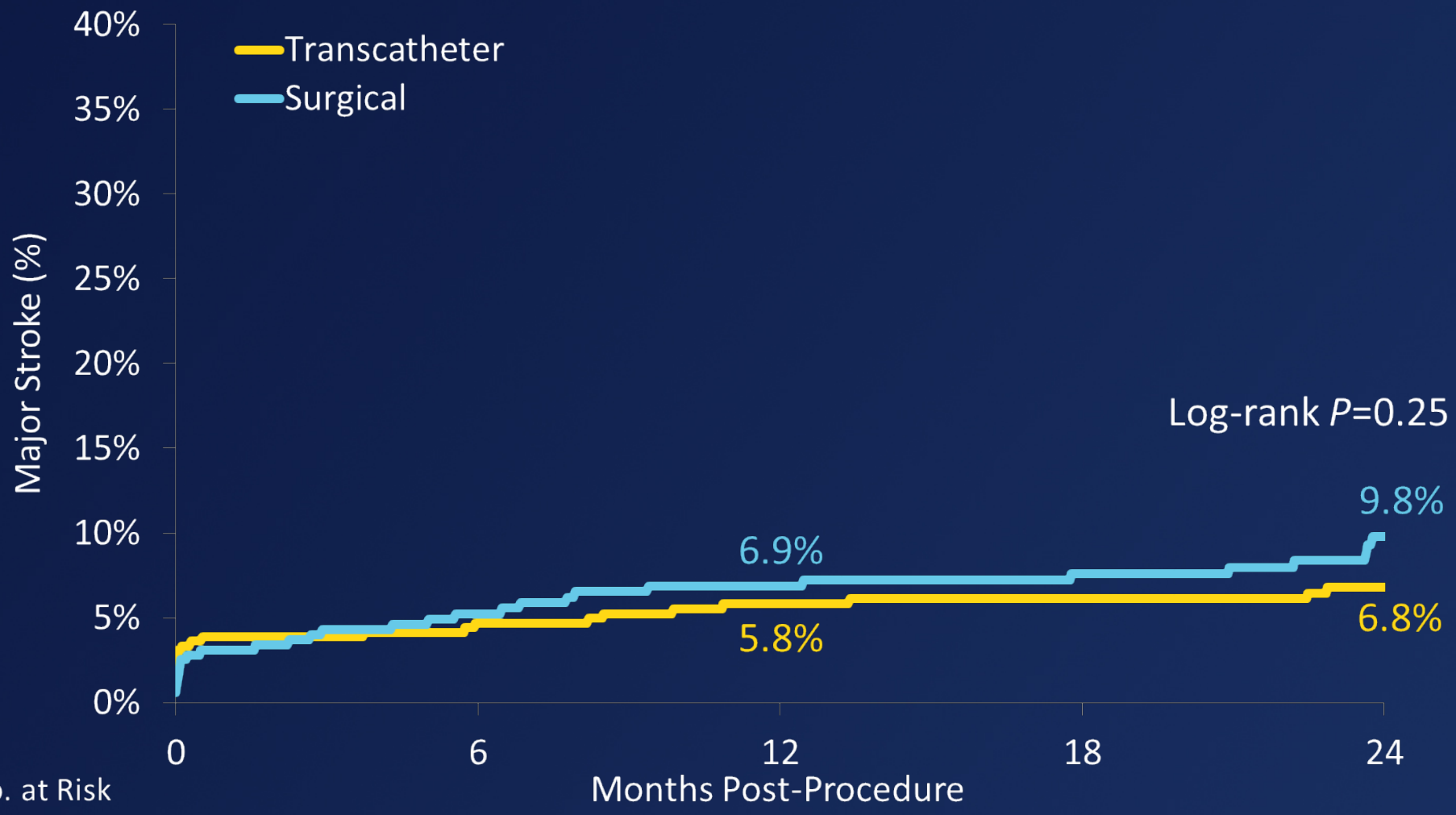
No. at Risk					
Transcatheter	391	378	354	334	219
Surgical	359	343	304	282	191

All Stroke



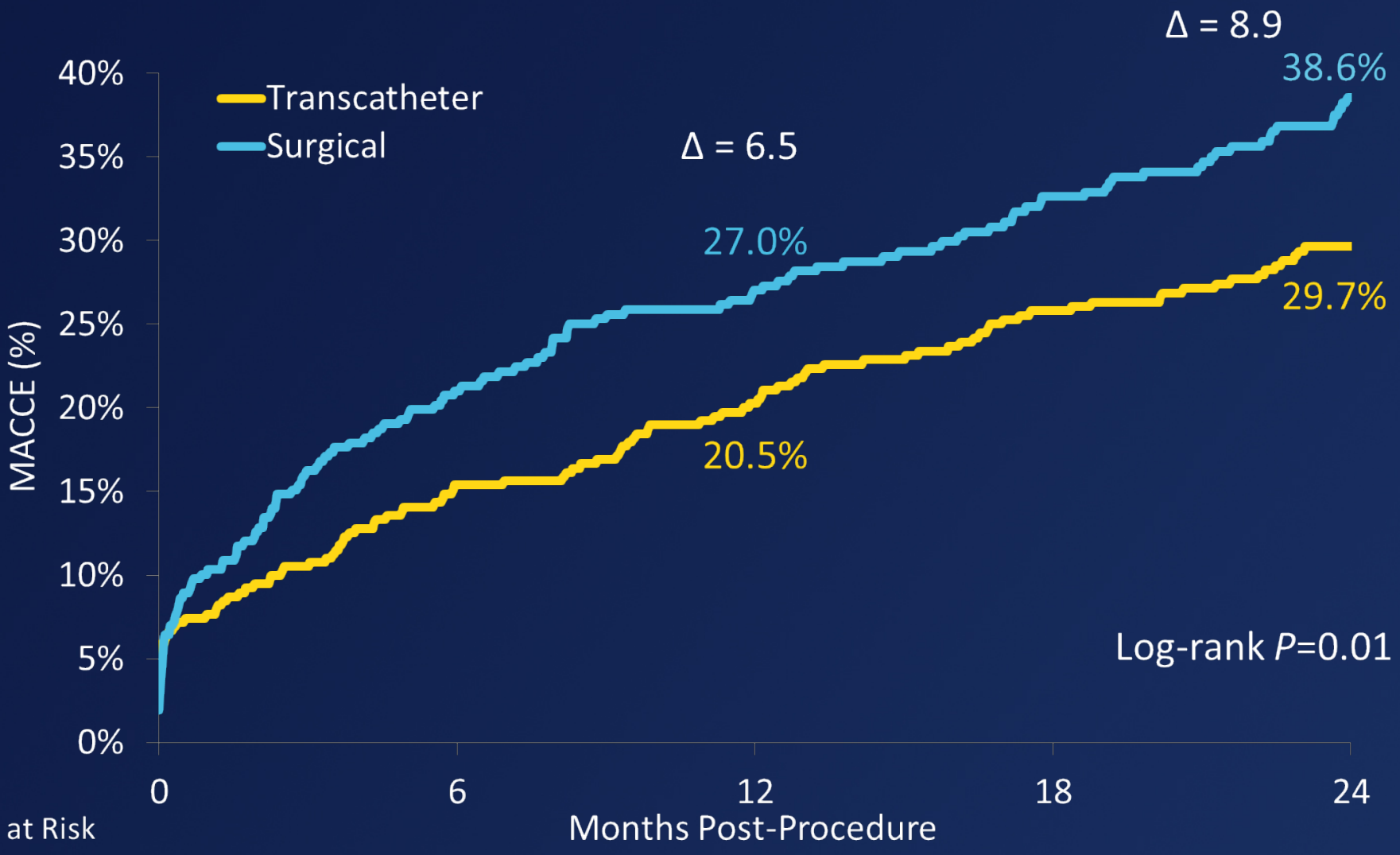
No. at Risk					
Transcatheter	391	364	335	318	205
Surgical	359	324	281	256	169

Major Stroke



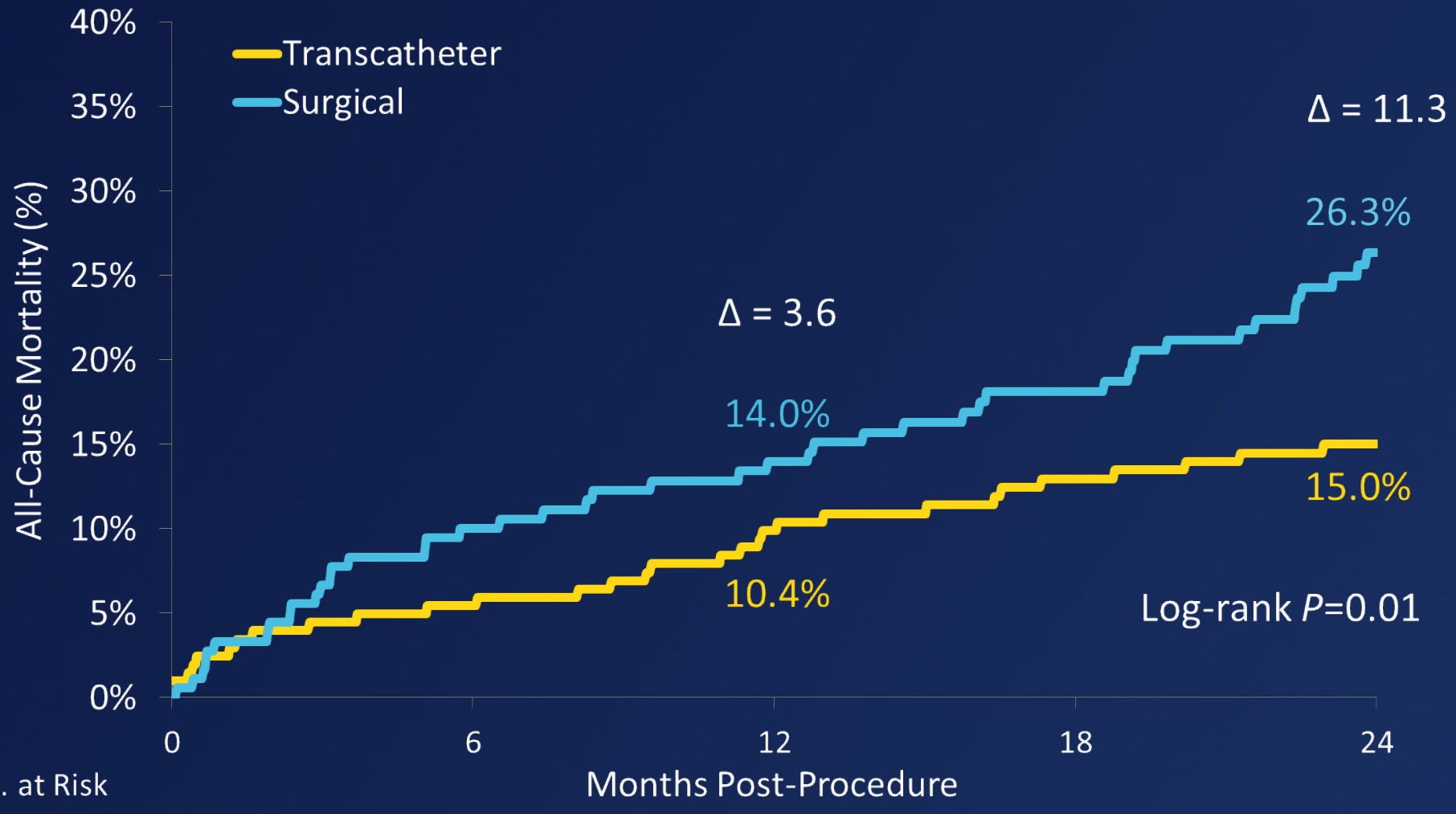
No. at Risk					
Transcatheter	391	368	345	326	214
Surgical	359	335	296	271	184

MACCE



No. at Risk					
Transcatheter	391	361	329	309	197
Surgical	359	322	280	254	166

All-Cause Mortality STS ≤7%



No. at Risk					
Transcatheter	202	197	191	182	128
Surgical	181	174	161	151	93

Conclusions

At 2 years for patients with symptomatic severe AS at increased risk of surgery;

- The superior survival seen at 1 year for TAVR over SAVR is maintained
- All stroke was less with TAVR over SAVR but major stroke showed no difference
- MACCE was significantly less with TAVR over SAVR
- Hemodynamics were superior for TAVR over SAVR at all time points without any structural valve failure
- Post-procedural AR showed a decrease in the TAVR group between 30 days and 1 year and this low level of moderate or severe PVL was maintained at 2 years
- TAVR was favored in every subgroup analysis

European Experience

TAVR in lower risk patients

It's already happened!

MINI-FOCUS ON TAVI

CLINICAL RESEARCH

A 3-Center Comparison of 1-Year Mortality Outcomes Between Transcatheter Aortic Valve Implantation and Surgical Aortic Valve Replacement on the Basis of Propensity Score Matching Among Intermediate-Risk Surgical Patients

Nicolo Piazza, MD, PHD,*† Bindu Kalesan, PHD,‡ Nicolas van Mieghem, MD,§ Stuart Head, MSC,‖ Peter Wenaweser, MD,¶ Thierry P. Carrel, MD,# Sabine Bleiziffer, MD,*† Peter P. de Jaegere, MD, PHD,§ Brigitta Gahl,# Robert H. Anderson, MD, PHD,** Arie-Pieter Kappetein, MD, PHD,‖ Ruediger Lange, MD, PHD,*† Patrick W. Serruys, MD, PHD,§ Stephan Windecker, MD,¶ Peter Jüni, MD‡

Munich, Germany; Bern, Switzerland; Rotterdam, the Netherlands; Montreal, Canada; and Newcastle-Upon-Tyne, United Kingdom

STRUCTURAL HEART DISEASE

Acute and Late Outcomes of Transcatheter Aortic Valve Implantation (TAVI) for the Treatment of Severe Symptomatic Aortic Stenosis in Patients at High- and Low-Surgical Risk

GERHARD SCHYMIK, M.D.,[1] HOLGER SCHRÖFEL, M.D.,[2] JAN S. SCHYMIK,[3] RAINER WONDRASCHEK,[1] TIM SÜSELBECK, M.D.,[4] RÜDIGER KIEFER,[2] VERONIKA BALTHASAR, M.D.,[2] ARMIN LUIK, M.D.,[1] HERBERT POSIVAL, M.D.,[2] and CLAUS SCHMITT, M.D.[1]

From the [1]Medical Clinic IV, Municipal Hospital Karlsruhe, Germany; [2]Clinic for Cardiac Surgery Karlsruhe, Germany; [3]University of Munich, Germany; and [4]Department of Medicine, University Medical Centre Mannheim, Germany

Improvements in Transcatheter Aortic Valve Implantation Outcomes in Lower Surgical Risk Patients

A Glimpse Into the Future

Ruediger Lange, MD, PHD, Sabine Bleiziffer, MD, Domenico Mazzitelli, MD, Yacine Elhmidi, MD, Anke Opitz, MD, Marcus Krane, MD, Marcus-Andre Deutsch, MD, Hendrik Ruge, MD, Gernot Brockmann, MD, Bernhard Voss, MD, Christian Schreiber, MD, Peter Tassani, MD, PHD, Nicolo Piazza, MD, PHD

Munich, Germany

Clinical outcomes of patients with estimated low or intermediate surgical risk undergoing transcatheter aortic valve implantation

Peter Wenaweser[1]†*, Stefan Stortecky[1]†, Sarah Schwander[1], Dik Heg[2], Christoph Huber[3], Thomas Pilgrim[1], Steffen Gloekler[1], Crochan J. O'Sullivan[1], Bernhard Meier[1], Peter Jüni[2], Thierry Carrel[3], and Stephan Windecker[1,2]

Transcatheter vs surgical aortic valve replacement in intermediate-surgical-risk patients with aortic stenosis: A propensity score–matched case-control study

Azeem Latib, MB ChB,[a,b,f] Francesco Maisano, MD,[c,f] Letizia Bertoldi, MD,[b] Andrea Giacomini, MD,[c] Joanne Shannon, MD,[a] Micaela Cioni, MD,[c] Alfonso Ielasi, MD,[b] Filippo Figini, MD,[a,b] Kensuke Tagaki, MD,[a] Annalisa Franco, MD,[d] Remo Daniel Covello, MD,[d] Antonio Grimaldi, MD,[d] Pietro Spagnolo, MD,[c] Gill Louise Buchannan, MD,[b] Mauro Carlino, MD,[b] Alaide Chieffo, MD,[b] Matteo Montorfano, MD,[b] Ottavio Alfieri, MD,[c] and Antonio Colombo, MD[a,b] *Milan, Italy*

Transcatheter aortic valve implantation versus surgical aortic valve replacement for severe aortic stenosis: Results from an intermediate risk propensity-matched population of the Italian OBSERVANT study

Paola D'Errigo [a], Marco Barbanti [b,c,*], Marco Ranucci [d], Francesco Onorati [e], Remo Daniel Covello [f], Stefano Rosato [a], Corrado Tamburino [b,c], Francesco Santini [c], Gennaro Santoro [g], Fulvia Seccareccia [a] and on behalf of the OBSERVANT Research Group

[1]Wenaweser, et al., *Eur Heart J* 2013; 34: 1894-905; [2]Lange, et al., *J Am Coll Cardiol* 2012; 59: 280-7; [3]Piazza, et al. , *J Am Coll Cardiol Intv* 2013; 6: 443-51; [4]D'Errigo, et al., *Int J Cardiol* 2013: 167: 1945-62; epub; [5]Latib, et al., *Am Heart J* 2012; 164: 910-7; Schymik, et al., *J Interv Cardiol* 2012; 25: 364-74

Retrospective Risk-Stratification

Lower risk patients have favorable outcomes

euro PCR 2012 YEAR OF THE TEXTBOOK

Procedural, 30-day, 6 month, 1 year, 2 years and 3 years outcome following CoreValve or Edwards Sapien TAV

results of the Belgian TAVI

Prof Dr Johan Bosmans
Interventional cardiologis
University Hospital Antwe
Belgium

Jacques Boschat, M.D., Herve Le Breton, M.D., Fr
Remi Houel, M.D., Stephane Delpine, M.D., Gerau
Xavier Favereau, M.D., Patrick Ohlmann, M.D., V
Gilles Grollier, M.D., Antoine Gommeaux, M.D., Jean-
Francois Bourlon, M.D., Bernard Bertrand, M.D., Eric
and Marc Laskar, M.D., for the FRANCE 2 I

results from 13 680 patients

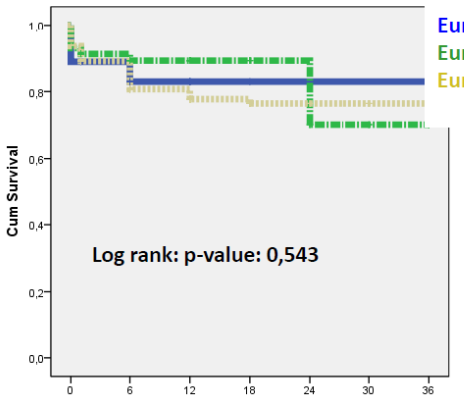
isease†

EuroSCORE 10 - < 20

euro PCR

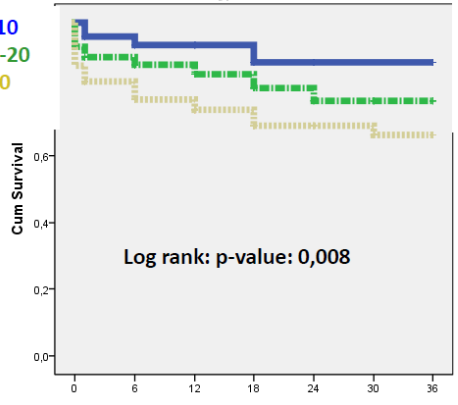
Medium outcome of transfemoral TAVI in relation to EuroScore:
Edwards Sapien vs CoreValve

Edwards Sapien



Edwards	Survival	1 m	6 m	12 m	18 m	24 m	30 m	36 m
EuroScore 0-10	no	2	2	3	3	3	3	3
	yes	16	15	11	15	4	1	1
EuroScore 10-20	no	4	5	6	6	6	9	9
	yes	53	46	34	19	14	7	4
EuroScore > 20	no	13	23	37	41	42	43	43
	yes	190	149	108	67	23	20	18

CoreValve



CoreValve	Survival	1 m	6 m	12 m	18 m	24 m	30 m	36 m
EuroScore 0-10	no	0	2	3	3	4	4	4
	yes	48	38	29	20	13	8	6
EuroScore 10-20	no	7	9	12	14	16	17	17
	yes	95	79	62	42	22	15	6
EuroScore > 20	no	19	27	34	37	40	40	41
	yes	132	107	77	47	32	27	20

Improvements in Transcatheter Aortic Valve Implantation Outcomes in Lower Surgical Risk Patients

A Glimpse Into the Future

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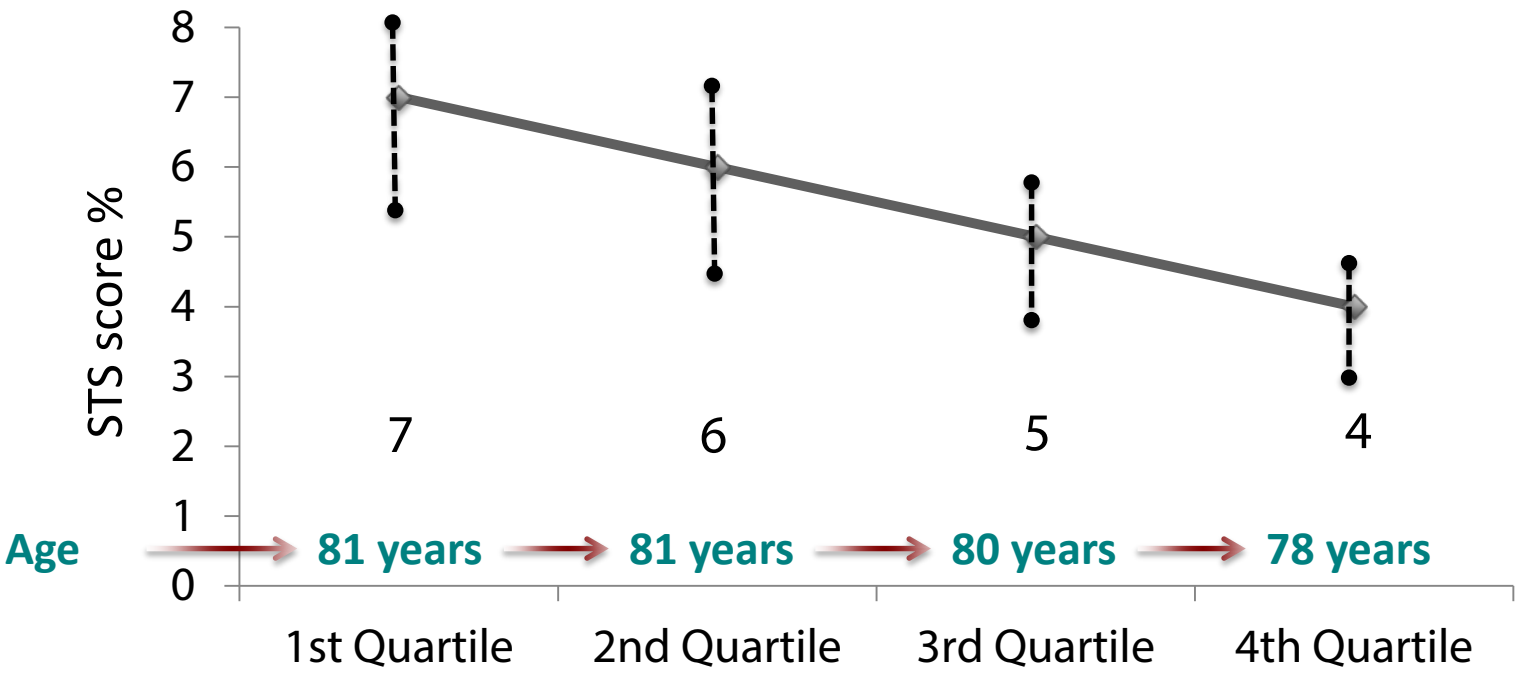
Munich, Germany



Lange et al. J Am Coll Cardiol 2012; 59:280-7

TAVR in lower risk patients

Outcomes are better

	Munich[1]	
	Higher Risk (n=105)	Lower Risk (n=105)
STS (%)	7.13 ± 5.4 →	4.8 ± 2.6
Log EuroSCORE (%)	25.44 ± 16.0	17.8 ± 12.0
30 Day Mortality (%)	11.4 →	3.8
Total Vascular Complications (%)	28.6	14.7
Stroke / TIA (%)	6.7	1

[1]Lange, et al., *J Am Coll Cardiol* 2012; 59: 280-7
[2]Wenaweser, et al., *Eur Heart J* 2013; 34: 1894-905;

CoreValve Advance Registry
STS < 7% vs. STS > 7%

Baseline Characteristics

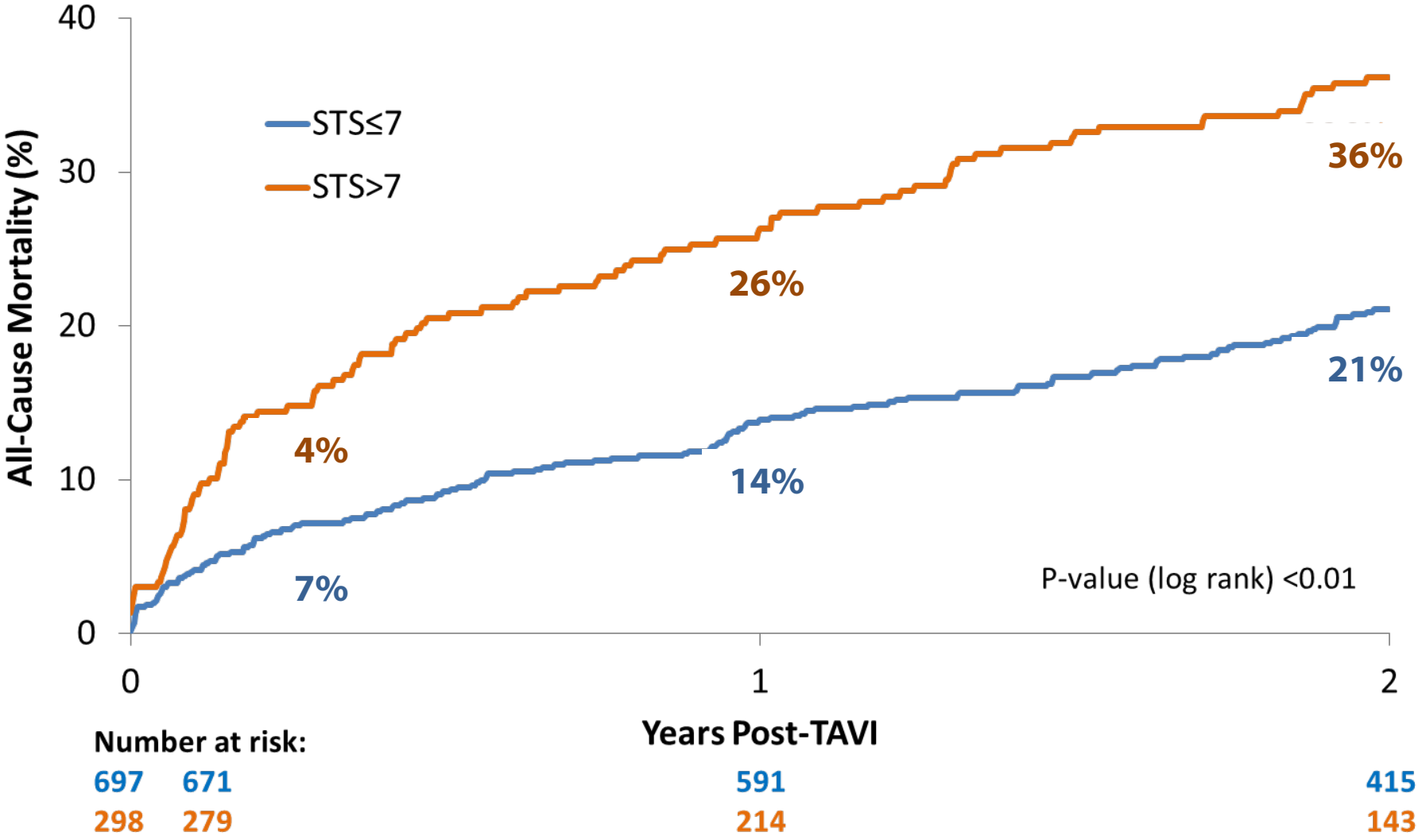
CoreValve ADVANCE Registry

Characteristic, % or mean ± SD	All Patients N=995	STS ≤7 N=697	STS >7 N=298	p*
Age (yrs)	81.1 ± 6.4	80.0 ± 6.4	83.5 ± 5.8	<0.001
Female	50.7	46.1	61.4	<0.001
Logistic EuroSCORE	19.3 ± 12.3	16.0 ± 9.6	27.1 ± 14.2	<0.001
STS	6.4 ± 4.4	4.3 ± 1.5	11.3 ± 5.0	<0.001
NYHA III or IV	80.0	76.3	88.5	<0.001
Diabetes	31.2	29.2	35.8	0.041
CAD	57.8	56.4	60.9	0.185
PVD	19.9	17.7	25.1	0.007
Cerebrovascular Disease	13.3	11.3	17.9	0.005
Pulmonary Hypertension	12.9	11.1	16.9	0.015
COPD	22.8	17.1	36.1	<0.001
Creatinine Clearance < 20ml/min	14.4	10.2	24.3	<0.001
Atrial Fibrillation	33.6	30.6	40.5	0.002

*p STS ≤7 vs. >7

2-Year All-Cause Mortality

CoreValve ADVANCE Registry



CoreValve ADVANCE Study

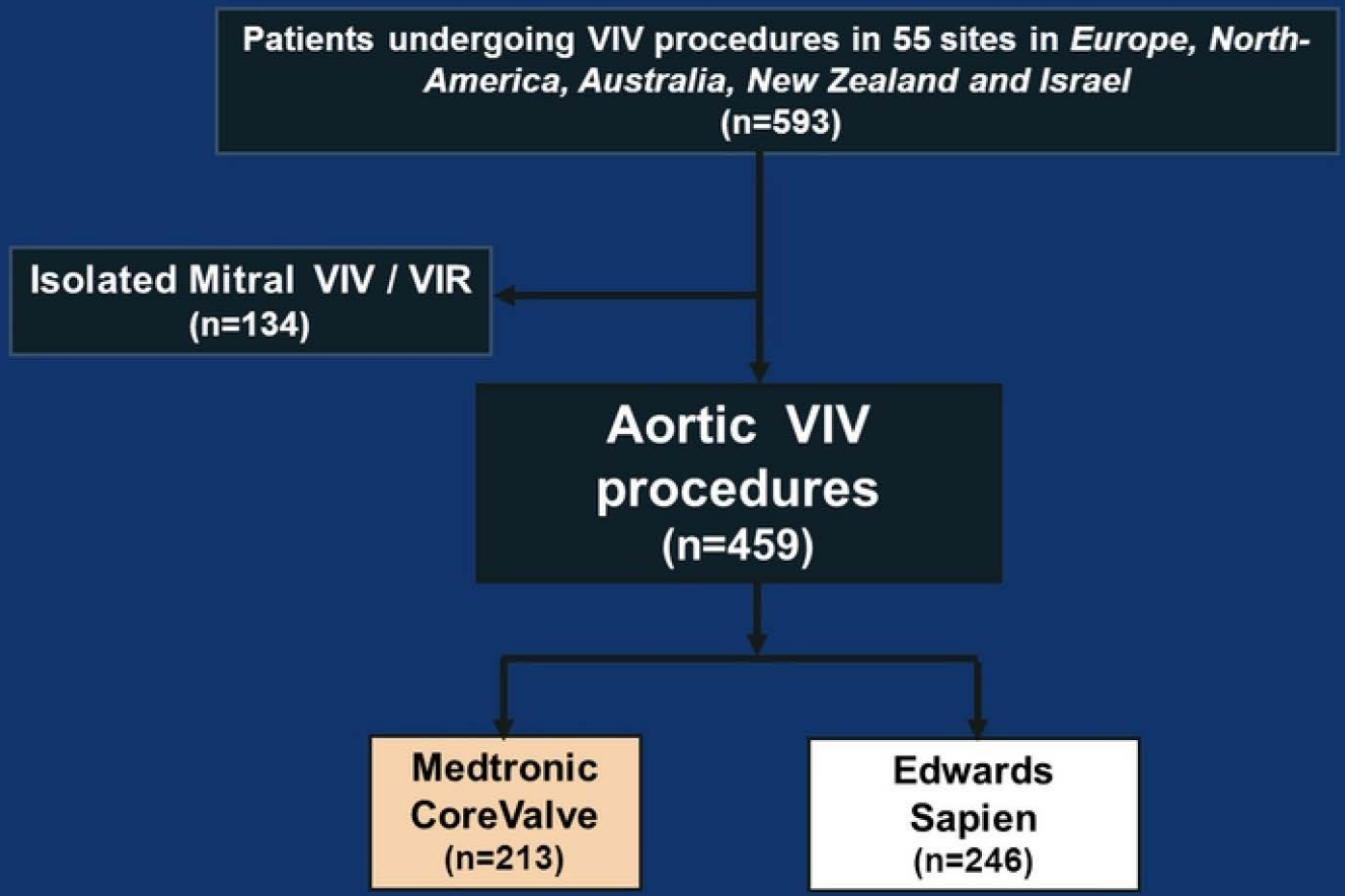
European Experience

Durability

Studies reporting no valve failures at 1,2 and 3 years

- Gurvitch et al. Circulation 2010;122:1319-27
- Thielmann et al. Ann Thorac Surg 2009;88:1468-1474
- Webb et al. Circulation 2007;116:755-763
- Buellesfeld et al. JACC 2011;57:1650-1657
- Ussia et al. Eur Heart J 2012;33:969-976
- Ussia et al. EuroIntervetion 2012;7:1285-1292
- Kodali et al. NEJM 2012;366:1686-1695
- Nietlispach et al. JACC Cardiovasc Interv 2012;5:582-590 (autopsy 20 pts)

Global Valve in Valve Registry



Kornowski, EuroPCR 2013

Baseline Demographics at Time of VIV

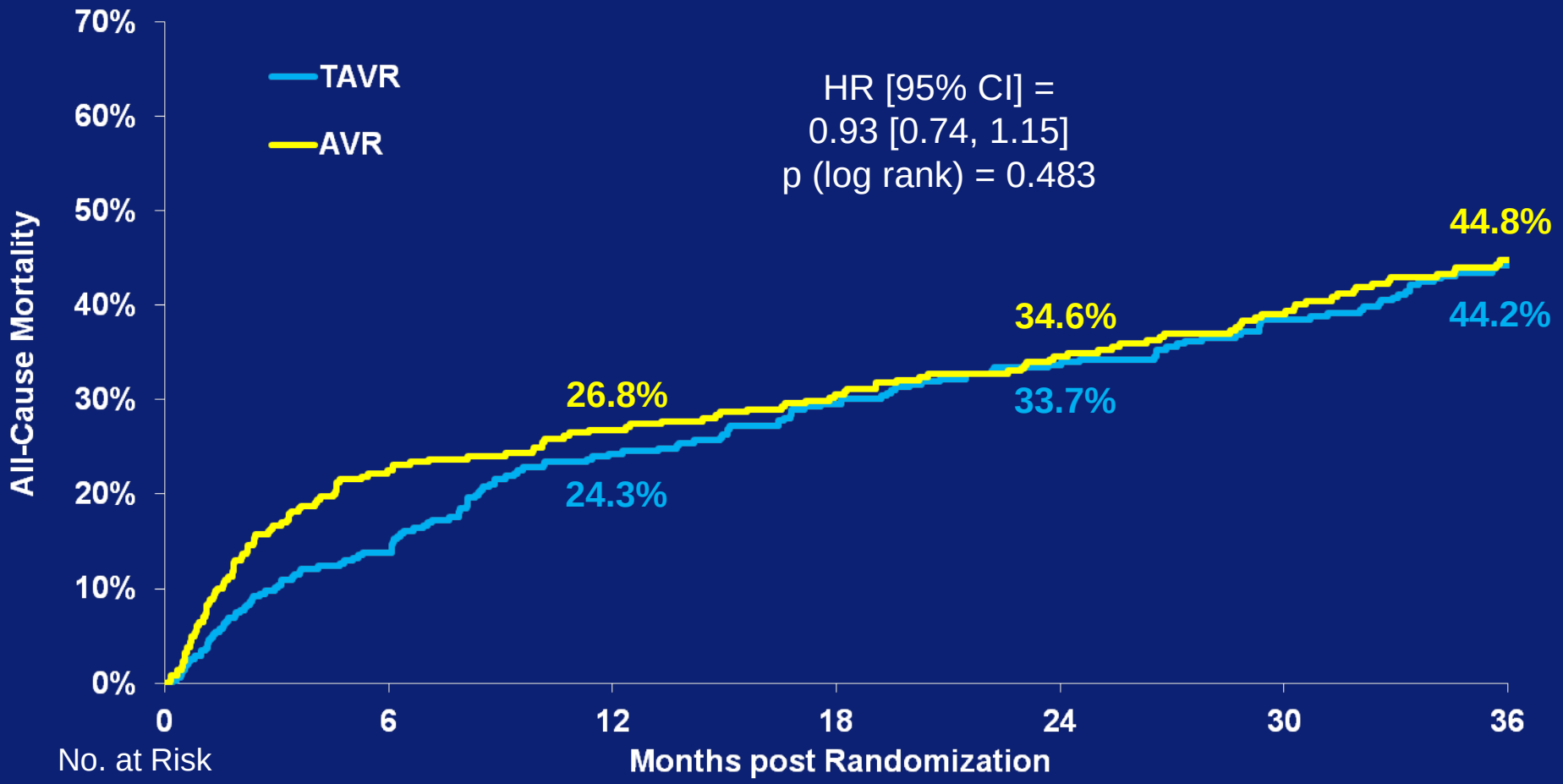
	CoreValve n=213	*SAPIEN n=246*
Age (yrs)	77.6 ± 10.0	77.6 ± 9.7
Gender (% male)	53.1%	59.0%
LogEuroSCORE	31.1 ± 16.8	33.0 ± 18.9
STS score (%)	12.8 ± 10.6	11.9 ± 9.2
Diabetes Mellitus	31.1%	26.5%
Peripheral Vascular Disease	17.9%	32.6%
Chronic Renal Failure	38.0%	57.3%
Previous CVA	12.2%	11.3%
NYHA III/IV	93.9%	91.5%

Median time from SAVR to VIV TAVI was 9 yrs (IQR 6-12)

Kornowski, EuroPCR 2013

Choice of the patient

PARTNER I A
Mortality Surgery versus TAVR

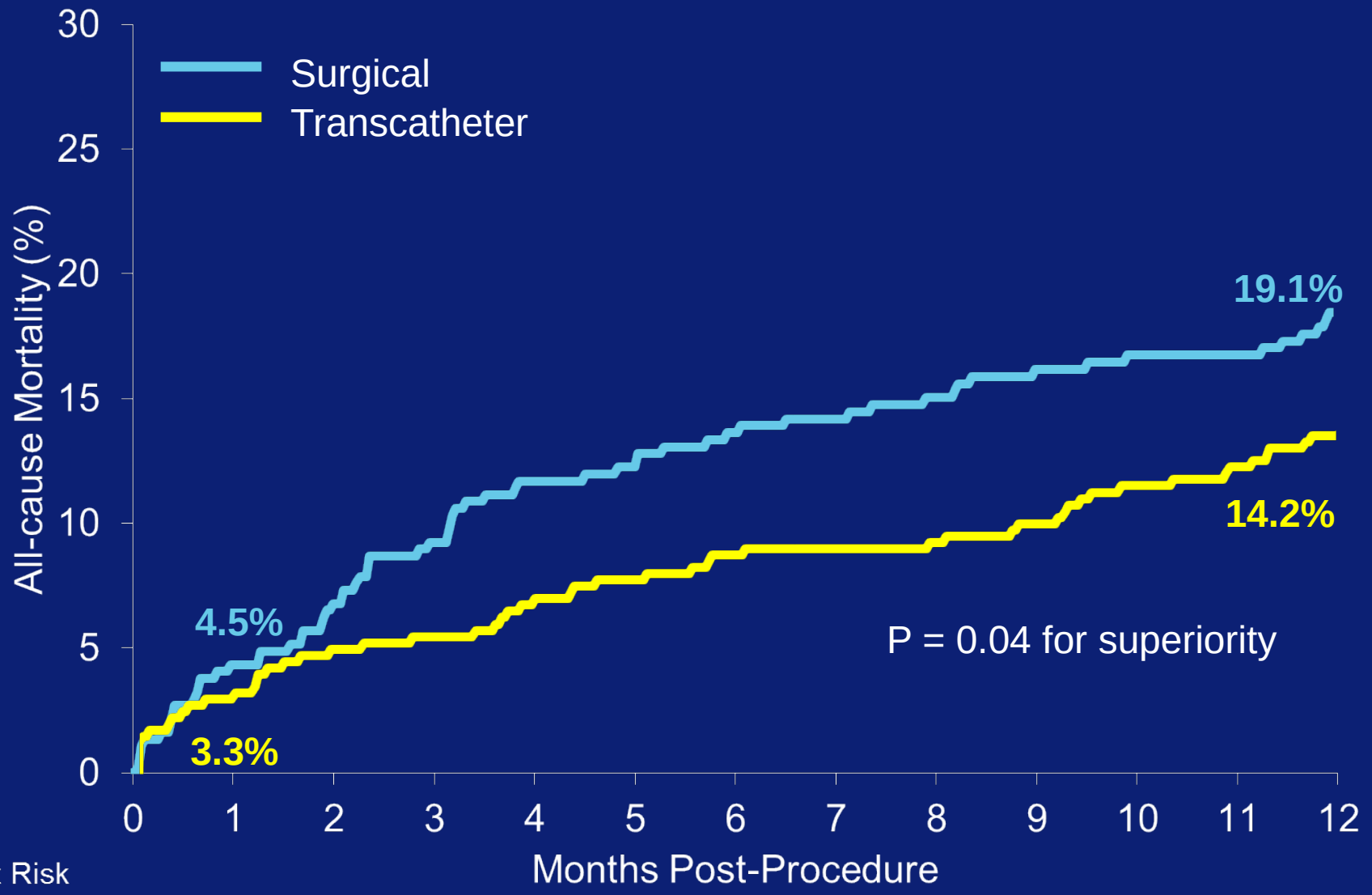


No. at Risk

TAVR	348	298	261	239	222	187	149
AVR	351	252	236	223	202	174	142

Primary Endpoint: 1 Year All-cause Mortality

ACC 2014



No. at Risk					
Surgical	357	341	297	274	
Transcatheter	390	377	353	329	

Conclusions-1

- A systematic fall in surgical risk scores is evident (Europe > US)
- “Lower” risk patients are currently being treated (Europe > US)
- Patients with lower risk scores may have other reasons not to undergo surgery

Conclusion-2

- Clinical outcomes in patients with lower surgical risk scores are excellent
- Offering TAVR to intermediate surgical risk patients is justified if performed within the confines of a Heart Team
- Appropriate surgical and TAVR risk scores are lacking and may provide physicians better guidance in the treatment of patients