TAVI, Can It Replace on Open Heart Surgery ?

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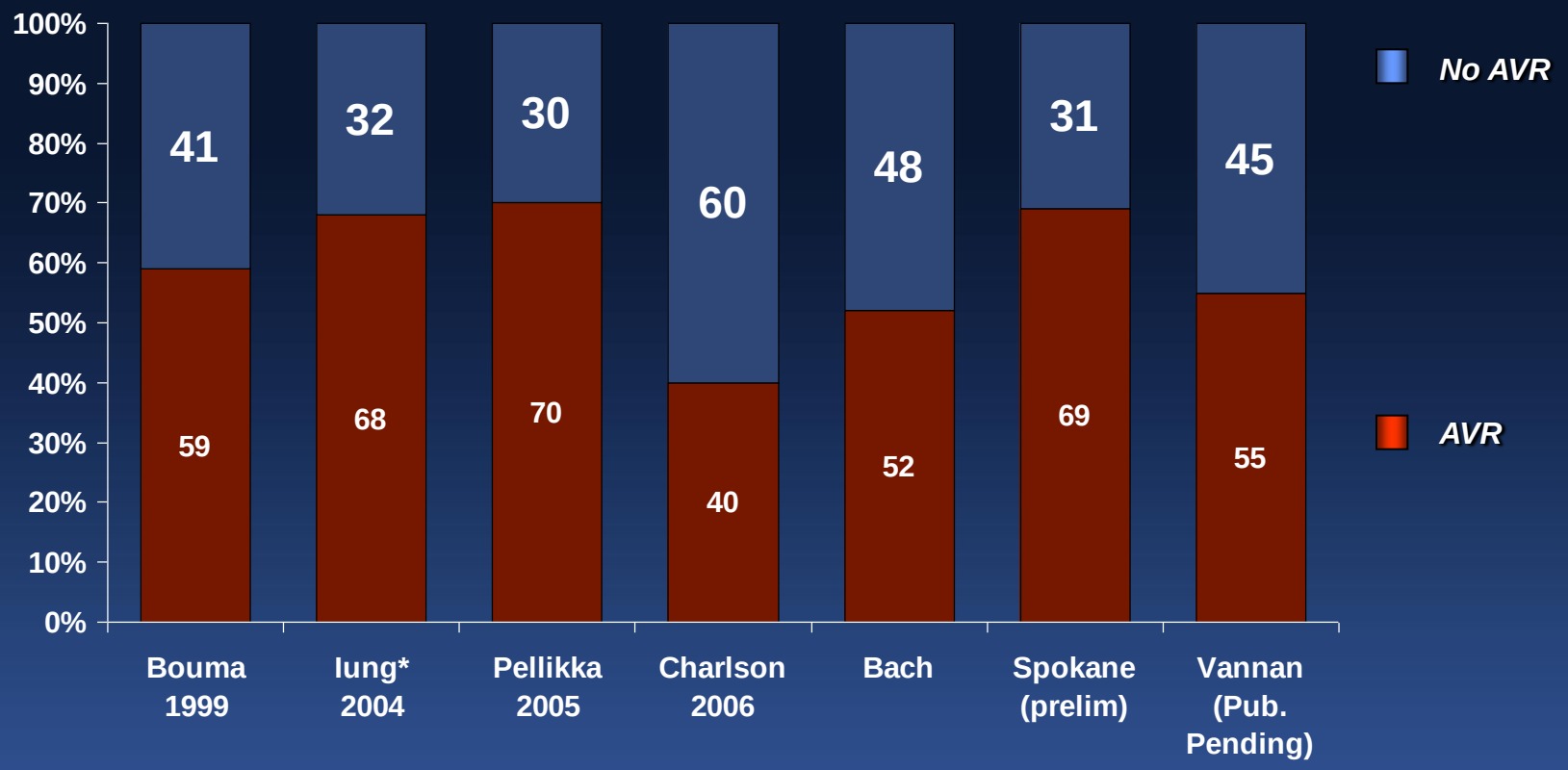
Surgical Aortic Valve Replacement (SAVR)
for Symptomatic Severe Aortic Stenosis

Improves Survival,
Symptoms,
and Quality of life.

However, at least 30% of Patients with Severe Symptomatic AS are "Untreated" !



Due to increased surgical risk with advanced age, and baseline comorbidities.

As a less invasive solution

for those high risk and inoperable patients,

Transcatheter Aortic Valve Implantation (TAVI) was pioneered in the last decade as a treatment alternative to SAVR.

History of TAVI

1985 **1987** 1999 2000 **2002** 2005~7 2007 **2010** 2011

It takes 20 years from Concept to Real World !

First In Man, TAVI

International Feasibility Studies

CE mark

1st RCT, PARTNER trials

FDA approval in US

For the TAVI,

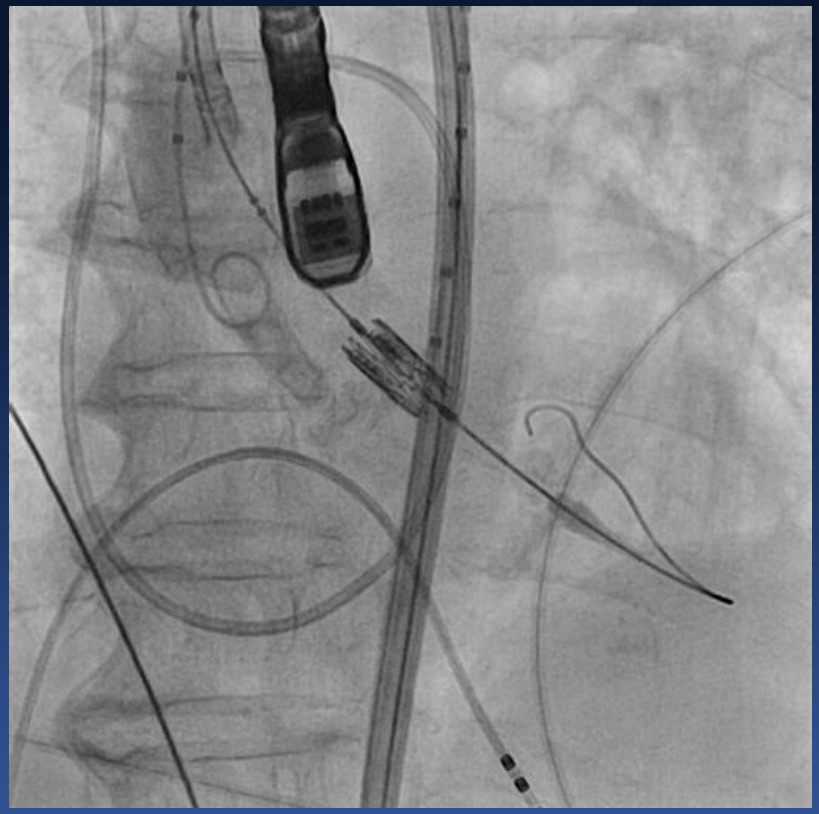
A unique collaborative experience !

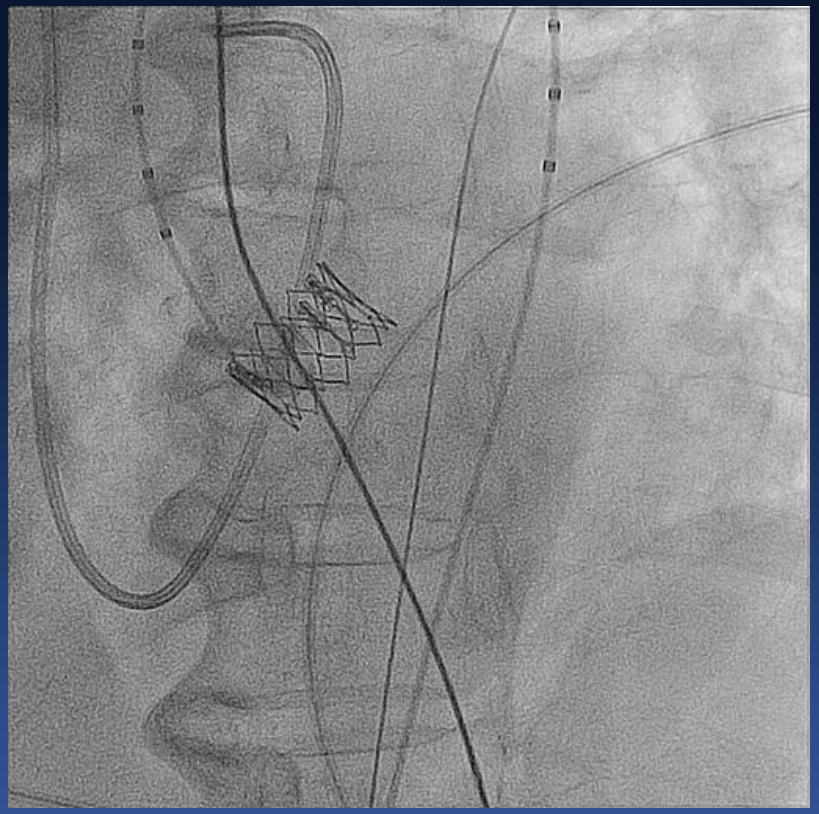
Current Active Devices

Edwards Sapien
Balloon Expandable
System, 22-24F

Medtronic CoreValve
Self Expanding
18F

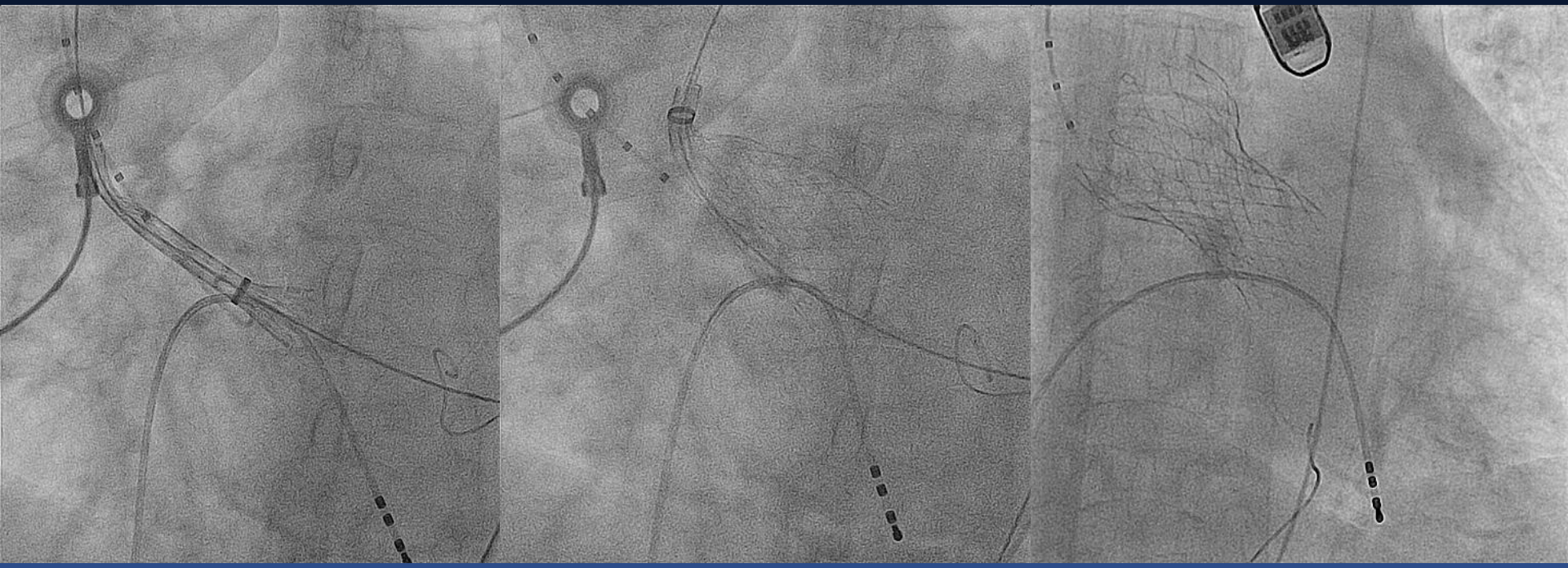
Edwards Sapien, Balloon Expandable (TF)





23mm Valve

Core Valve, Self Expanding (TF)



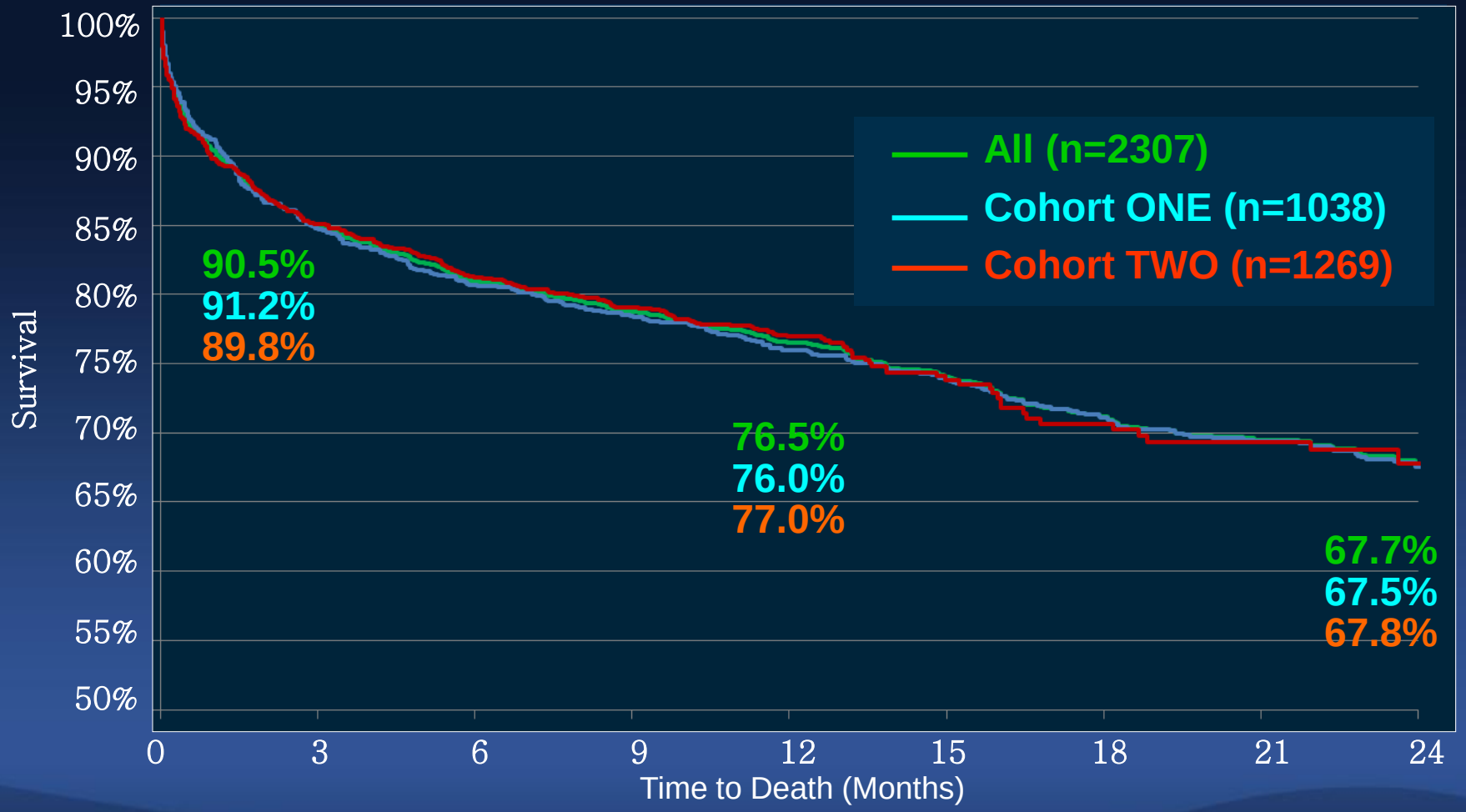
26 mm Valve

Data
From Registry

Edward Sapien (n=2,317 pts, age 81 yrs)

1-Yr Survival

European SOURCE Registry

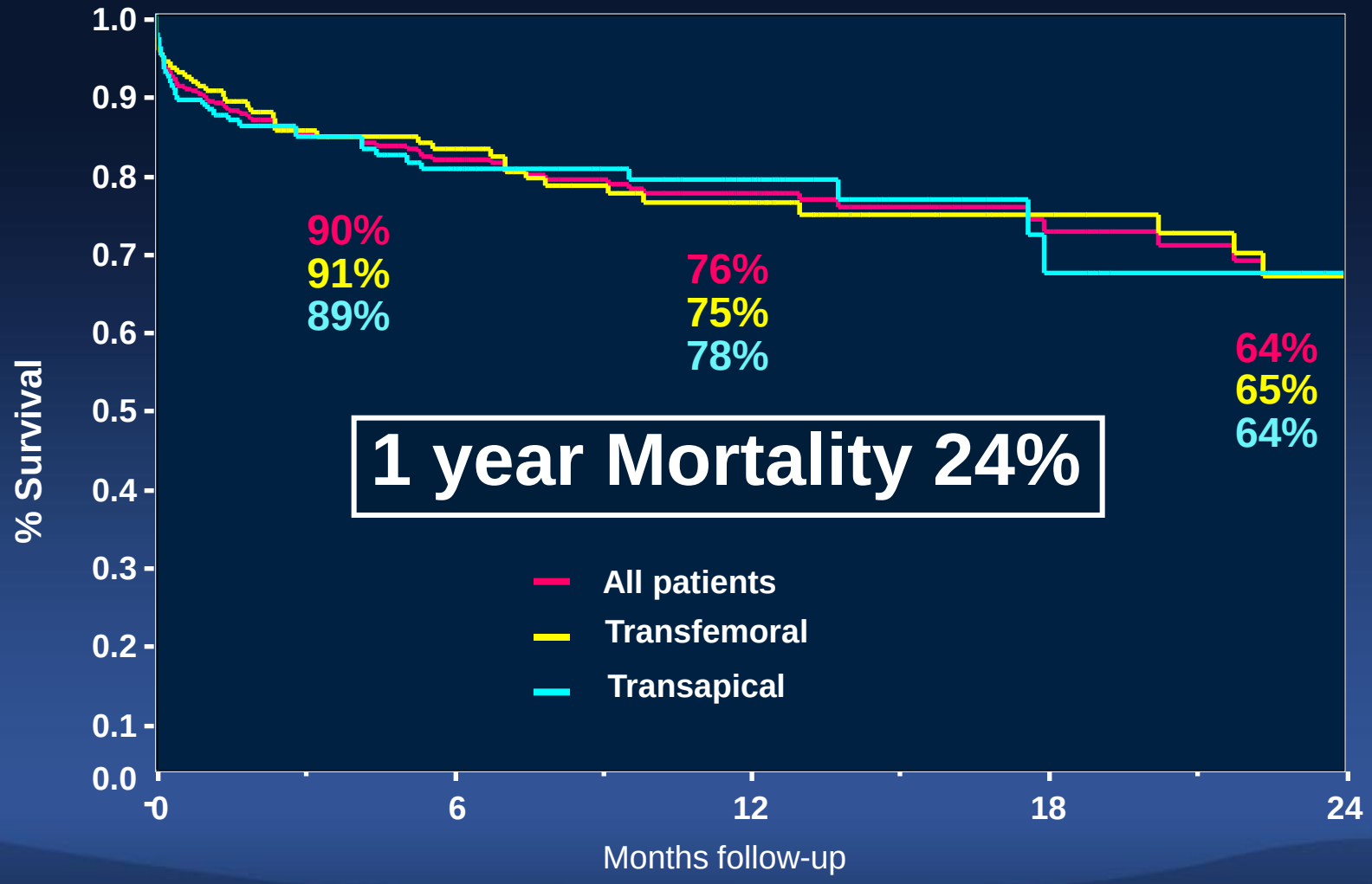


N @ Risk	30 Days	1 Year	2 Years
All (N=2307)	2080	1506	487

Edward Sapien (n=345 pts, age 82 yrs)

1-Yr Survival

Canadian Multicenter Registry



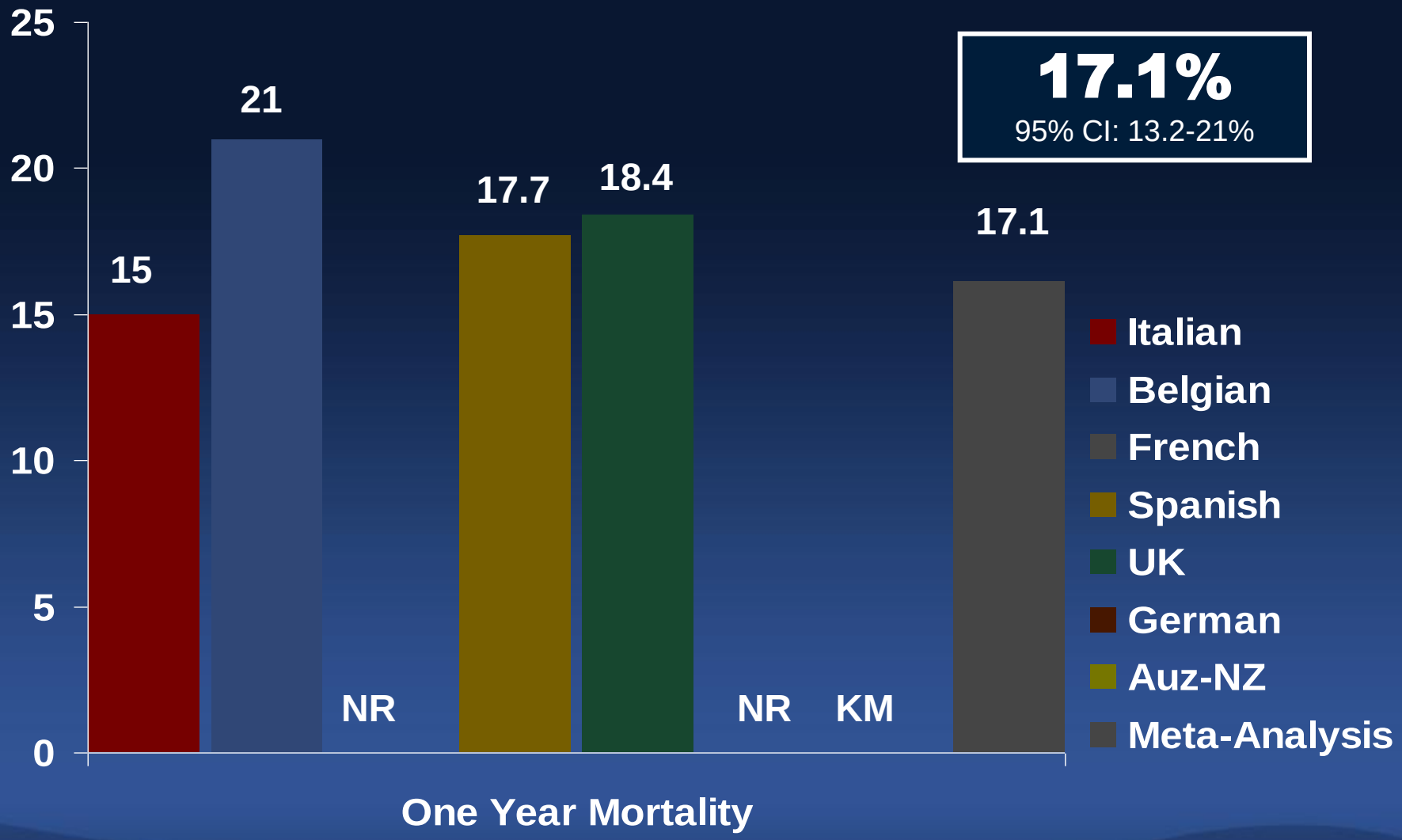
Rodes-Cabau et al. JACC 2010;55;1080-1090

Meta-Analysis Results, *CoreValve*

Registry	Pts	Age, yrs	Males, %	Logistic EuroScore	NYHA Class III-IV, %	Mean Gradient, mmHg
Italian[1]	663	82	44	22.9+13.5	70.6	52+17
Belgian[2]	141	82	44	25+15	78	49_16
French[3]	66	82.5	48.5	24.7+11.2	NR	55+15
Spanish[4]	108	78.6	45.4	16+13.9	58.4	55+14.3
UK[5]	460	83	52	20.3	74	NR
German[6]	588	81.4	44.2	20.8+13.3	88.2	48.7+17
Australia-NZ[7]	118	82.7	59.3	18+12	84	51+16
Average	**2,156**	**81.6**	**47**	**21.3**	**77**	**49.7**

[1] Tamburino Circulation 2011;123;299-308; [2]Bosmans EuroPCR 2010; [3]Eltchaninoff Eur Heart J 2010; Sept 15, 2010 epub; [4]Avanzas Rev Esp Cardiol 2010;63(2):141-8 [5]Moat EuroPCR 2010; [6]Zahn EuroPCR 2010; [7]Meredith TCT2010

Meta-Analysis, CoreValve
1-year Mortality



Meta-Analysis Results, *CoreValve*

Registry	Procedural Success, %	Vascular Compls, %	Stroke, %	PPM, %
Italian[1]	98.0	2.0	1.2	16.6
Belgian[2]	98.0	---	5	23.0
French[3]	92.6[§]	7.5	4.5	25.7
Spanish[4]	98.1	5.6	0	35.2
UK[5]	---	4.0	4.3	26.0
German[6]	---	4.0	---	42.5
Australia-NZ[7]	95.8	6.5	1.9	40.0
Average	97.8	4.2	2.8	28.7
95% CI	96.4-99.2	1.6-6.8	0.6-5.0	20.6-36.8

[1] Tamburino Circulation 2011;123;299-308; [2]Bosmans EuroPCR 2010; [3]Eltchaninoff Eur Heart J 2010; Sept 15, 2010 epub; [4]Avanzas Rev Esp Cardiol 2010;63(2):141-8 [5]Moat EuroPCR 2010; [6]Zahn EuroPCR 2010; [7]Meredith TCT2010

[§] Mixed with balloon-expandable TAVR

VARC Observations

Valve **A**cademic **R**esearch **C**onsortium

- Non-uniformity in endpoint definitions precludes more in-depth data analysis of different TAVR clinical studies. Standardization of clinical endpoint.
- VARC definition was meant to be an early "best approximation" for identifying the most relevant clinical endpoints.

VARC-Meta-Analysis included (Edward Sapien + CoreValve)

Organized by P Généreux and S.J.Head, September, 2011

TAVR Outcomes - VARC Meta-Analysis
(17 studies; 3,519 patients)

Endpoint	*Pooled Estimate (%)*	*[95% CI]*
Mortality		
All @ 30 days	7.8	[5.5, 11.1]
CV @ 30 days	5.6	[3.7, 8.3]
All @ 1 year	22.1	[17.9, 26.9]
CV @ 1 year	14.4	10.6, 19.5
Strokes @ 30 days		
Major	3.2	[2.1, 4.8]
Major + minor	4.0	[2.4, 6.3]
TIA	1.2	[0.0, 2.3]
All	5.7	[3.7, 8.9]

P Généreux and S.J.Head
Unpublished data/Submitted JACC

TAVR Outcomes - VARC Meta-Analysis
(17 studies; 3,519 patients)

Endpoint	*Pooled Estimate (%)*	*[95% CI]*
Vascular events @ 30 days		
Major	11.9	[8.6, 16.4]
Minor	9.7	[6.7, 14.0]
All	18.8	[14.5, 24.3]
Bleeding @ 30 days		
Life threatening	15.6	[11.7, 20.7]
Major	22.3	[17.8, 28.3]
Minor	9.9	[6.9, 14.3]
All	41.4	[35.5, 47.6]
Transfusion ≥ 1 unit	42.6	[19.8, 62.4]

P Généreux and S.J.Head
Unpublished data/Submitted JACC

TAVR Outcomes - VARC Meta-Analysis
(17 studies; 3,519 patients)

Endpoint	*Pooled Estimate (%)*	*[95% CI]*
MI (peri-procedural)	1.1	[0.2, 2.0]
Valve performance @ 30 days		
AVA ≤ 1.2 cm^2	4.8	[3.0, 6.6]
Mean gradient ≥ 20 mmHg	1.0	[0.0, 2.1]
AR ≥ moderate (PVL)	7.4	[4.6, 10.2]
Valve-in-valve	2.3	[1.3, 4.5]
Valve embolization	1.7	[0.2, 3.3]
Perm Pacemaker @ 30 days		
Edwards	4.9	[3.9, 6.2]
MDT-Corevalve	28.9	[23.0, 36.0]

P Généreux and S.J.Head
Unpublished data/Submitted JACC

Edward Sapien vs. CoreValve

Major Complications at 30 Days

870 pts from UK registry

Implanted with Edwards or CoreValve devices: Jan. 2007 to Dec. 2009

	CoreValve	Edwards Sapien	*P* Value
Mortality	5.8%	8.5%	0.11
Stroke	4.0%	4.2%	0.91
MI	1.1%	1.5%	0.65
Moderate/Severe Aortic Regurgitation	17.3%	9.6%	0.001
Major Vascular Complications	6.2%	6.3%	0.94
Pacemaker Implantation	24.4%	7.4%	< 0.001

Survival was 78.6% at 1 year and 73.7% at 2 years.

Moat NE, et al, JACC 2011;58:1-8

Prospective Single Center Registry

FOCUS ISSUE: STRUCTURAL HEART DISEASE

Clinical Research

Clinical Outcomes of Patients With Severe Aortic Stenosis at Increased Surgical Risk According to Treatment Modality

Wenawesere P, Windekcer S, et al. J Am Coll Cardiol. 2011;58:2151-2162.

Comparison Data for Medical Therapy vs. SAVR vs. TAVI

Baseline Characteristics

	Overall (n = 442)	MT (n = 78)	SAVR (n = 107)	TAVI (n = 257)	p Value*
Age (yrs)	81.7 ± 6.0	83.2 ± 5.7	79.7 ± 5.5	82.1 ± 6.2	<0.001
Women	230 (52.0%)	33 (42.3%)	53 (49.5%)	144 (56.0%)	0.09
BMI (kg/m^2)	25.6 ± 4.6	24.4 ± 3.5	26.0 ± 4.7	25.8 ± 4.9	0.03
Cardiac risk factors					
Hypertension	338 (76.5%)	52 (66.7%)	85 (79.4%)	201 (78.2%)	0.08
Current smoker	65 (14.7%)	7 (9.0%)	16 (15.0%)	42 (16.3%)	0.27
Diabetes mellitus	101 (22.9%)	18 (23.1%)	21 (19.6%)	62 (24.1%)	0.65
Positive family history for coronary artery disease	78 (17.6%)	12 (15.4%)	17 (15.9%)	49 (19.1%)	0.65
Hypercholesterolemia	233 (52.7%)	32 (41.0%)	46 (43.0%)	155 (60.3%)	0.001
Past medical history					
Prior MI	79 (17.9%)	23 (29.5%)	9 (8.4%)	47 (18.3%)	0.001
Prior PCI	77 (17.4%)	10 (12.8%)	9 (8.4%)	58 (22.6%)	0.003
CABG	76 (17.2%)	18 (23.1%)	4 (3.7%)	54 (21.0%)	<0.001
Previous stroke	44 (10.0%)	13 (16.7%)	8 (7.5%)	23 (8.9%)	0.08
Peripheral vascular disease	93 (21.0%)	16 (20.5%)	13 (12.1%)	64 (24.9%)	0.03
Cardiac rhythm					
Atrial fibrillation	105 (23.8%)	20 (25.6%)	19 (17.8%)	66 (25.7%)	0.25
Prior pacemaker	39 (8.8%)	4 (5.1%)	9 (8.4%)	26 (10.1%)	0.39
Risk Assessment (%)					
Log. EuroSCORE	22.3 ± 14.6	27.9 ± 14.5	12.5 ± 8.2	24.7 ± 24.9	<0.001
Lin. EuroSCORE	10.2 ± 2.5	11.2 ± 2.2	8.3 ± 2.0	10.7 ± 2.5	<0.001
STS score	6.0 ± 5.0	6.5 ± 4.1	4.8 ± 5.3	6.4 ± 5.0	0.009

TAVI group included

More Complicated High Risk Patients

Thirty-Month Outcomes

	Medical (n = 78)	TAVR (n = 257)	Surgical (n = 107)	*P* Value[a]
Death	61.5%	22.6%	22.4%	< 0.001
CV Death	59.0%	15.6%	11.2%	< 0.001
MI	2.6%	1.6%	0	0.25
Major Stroke	3.9%	4.3%	4.7%	0.89
TIA	0	0.8%	2.8%	0.42
Death, Major Stroke, or MI	64.1%	25.7%	24.3%	< 0.001

[a] *P* for differences between TAVR and medical therapy, and surgical and medical therapy.

Wenaweser P, et al. J Am Coll Cardiol. 2011;58:2151-2162.

AMC Registry

Procedure

(RF1=5, RF3=5, NovaFlex=15, CoreValve=2)	N=27
Age, years	75.9±5.4
Logistic EuroSCORE, %	25.6±5.1
Implanted valve size, mm	
23 mm	16
26 mm	9
29 mm, (CoreValve)	2
Transfemoral approach	24
Surgical closure	4
Percutaneous closure	20
Transapical approach	3

In-Hospital, 30 days

	N=27
Procedural Success	26/27 (96%)
Mortality	0
Major or minor Stoke	0
Permanent Pacemaker	0
Moderate to severe AR (CoreValve)	1 (4%)
Vascular complication (RF1, Edward Sapien)	2 (8%)
Access site	1
Iliac artery perforation	1

Lessons from Registry

1. TAVI is feasible and provide at least favorable short- and medium-term procedural, clinical, and hemodynamic results.

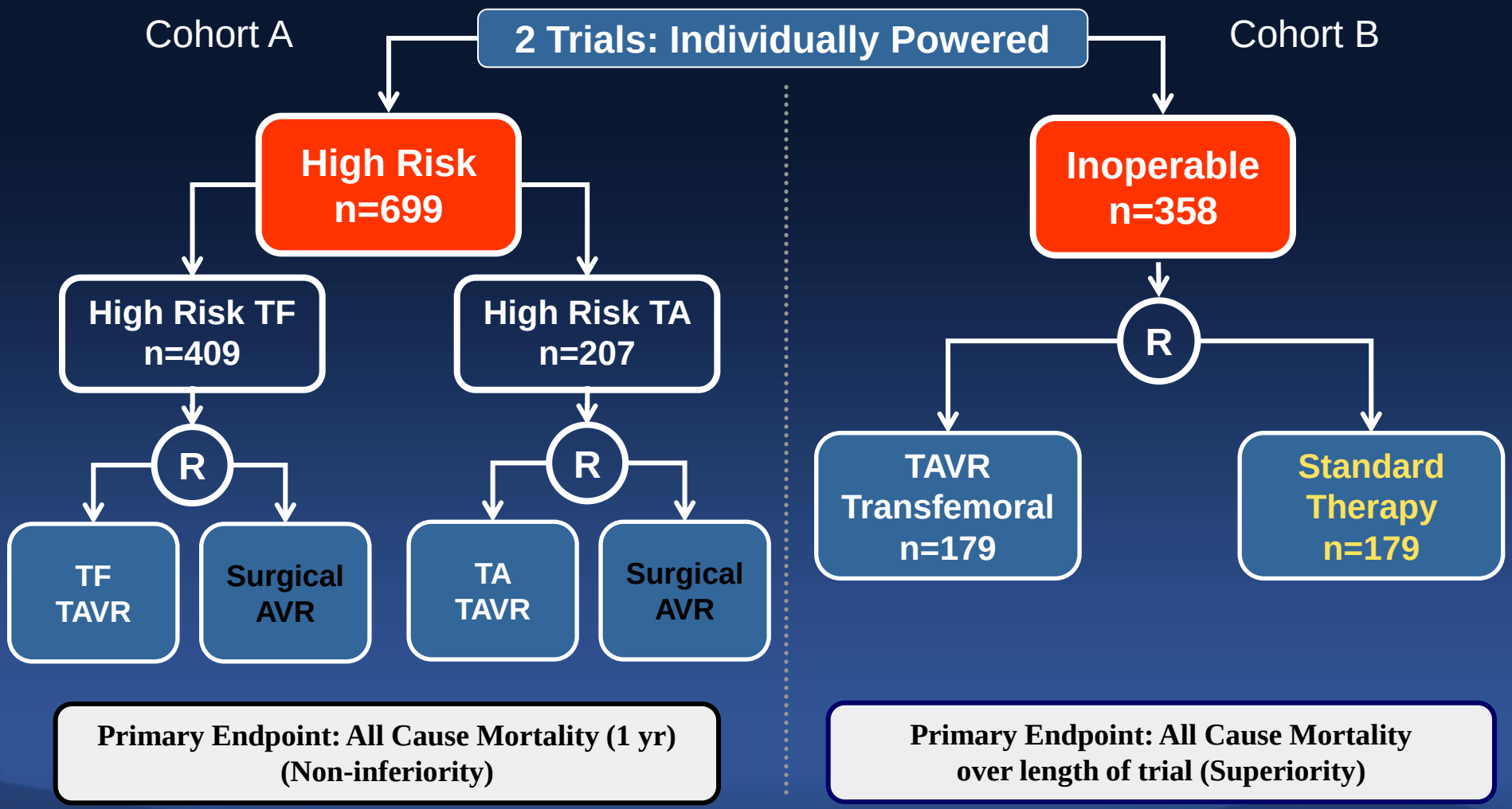
2. SAVR and TAVI improve survival and symptoms, compared with medical therapy. Clinical outcomes of TAVI and SAVR seem similar among carefully selected high-risk patients with severe aortic stenosis.

PARTNER trial

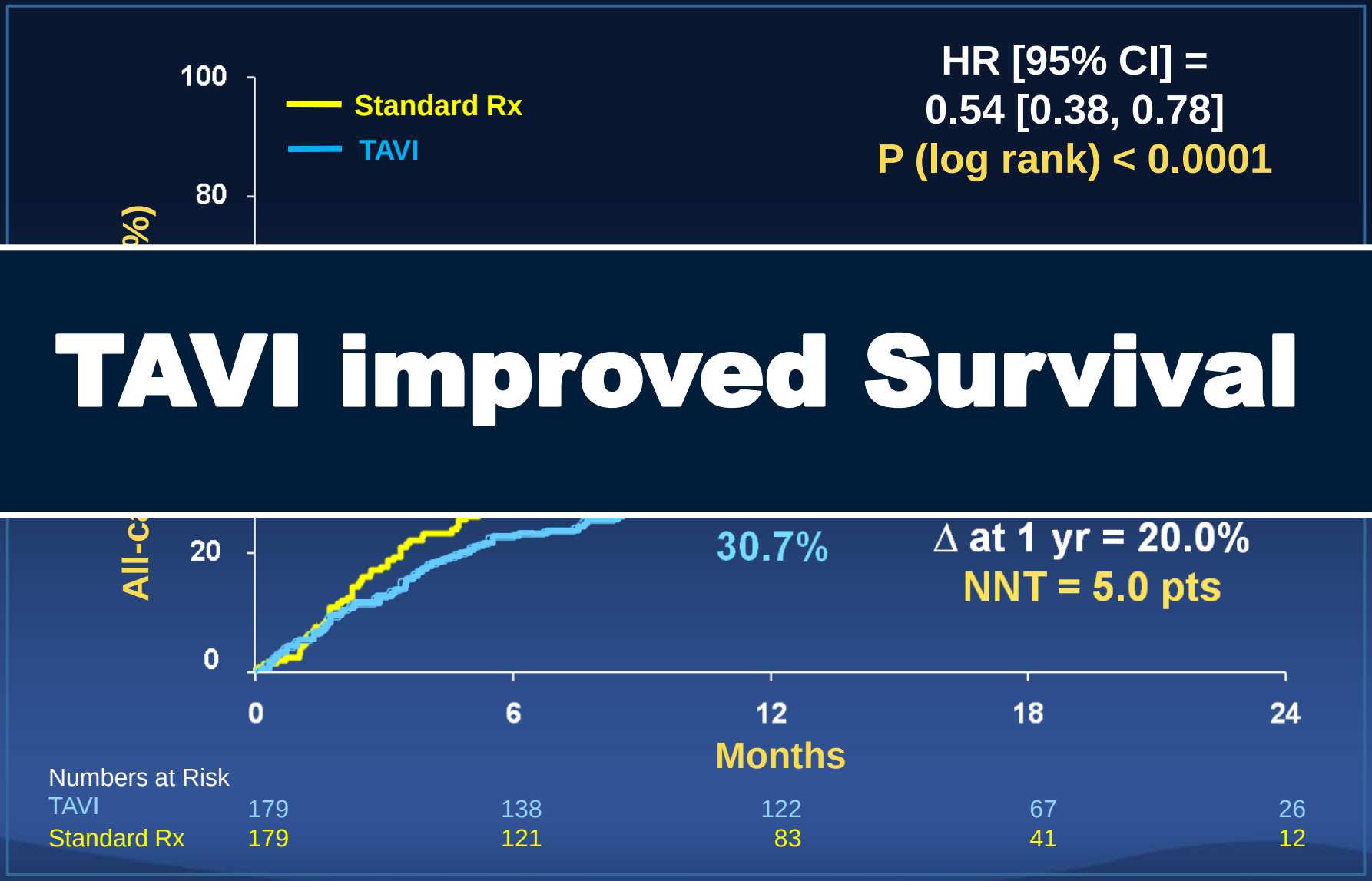
First Randomized Study

PARTNER Trial Design

Symptomatic Severe Aortic Stenosis



All Cause Mortality, Inoperable

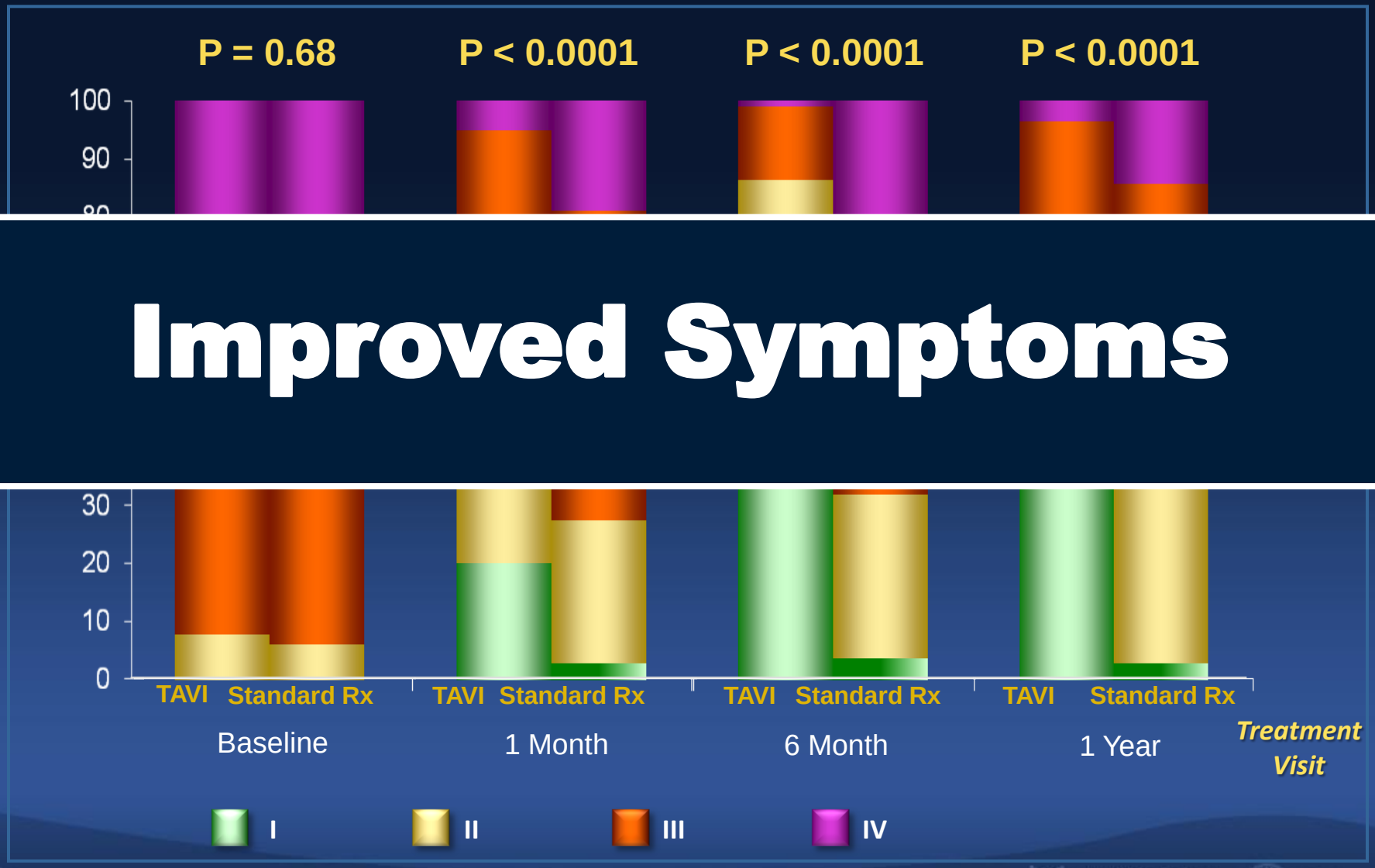


TAVI improved Survival

Leon MB et al. NEJM 2010;363:1597-607.

NYHA Class Over Time

Survivors



Improved Symptoms

Improved
Health-related Quality of Life

KCCQ* Overall Score at 30 Days and 1 Year

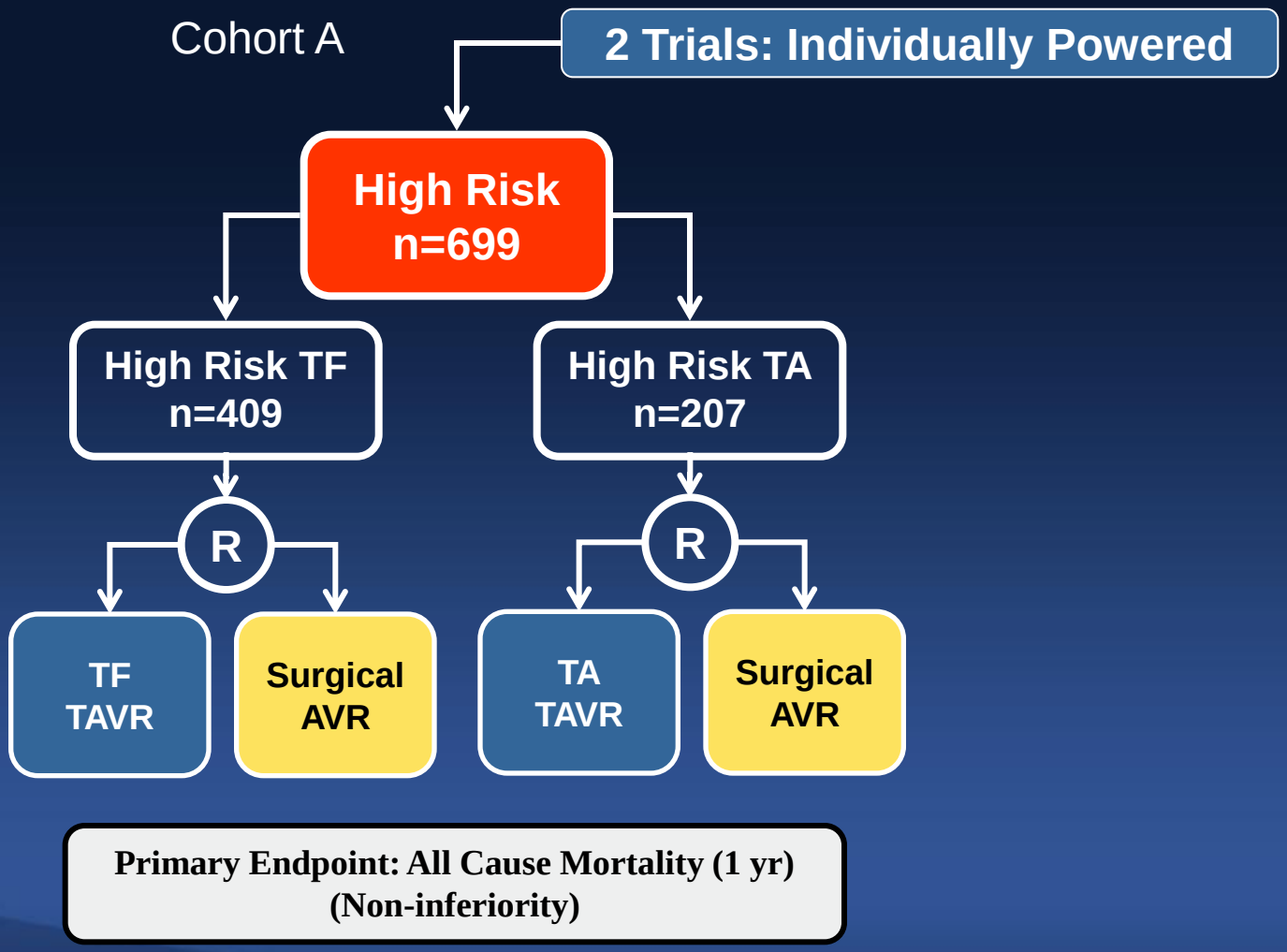
Improved Quality of Life

*KCCQ ; Kansas City Cardiomyopathy Questionaire

Reynolds MR, Magnuson E, Lei Y et al. Circulation 2011;124:1-9

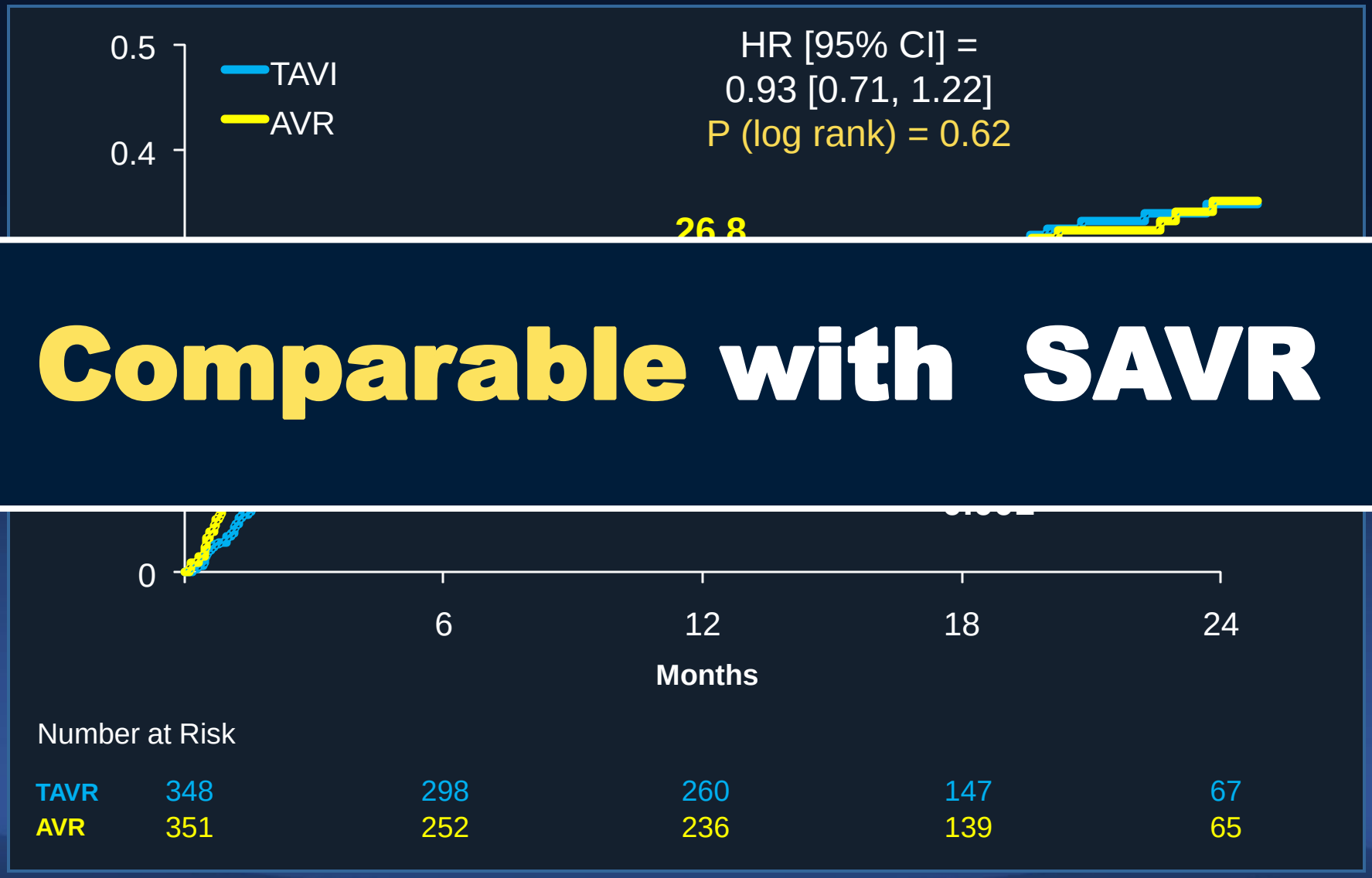
PARTNER Trial Design

Symptomatic Severe Aortic Stenosis



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

All Cause Mortality, High Risk

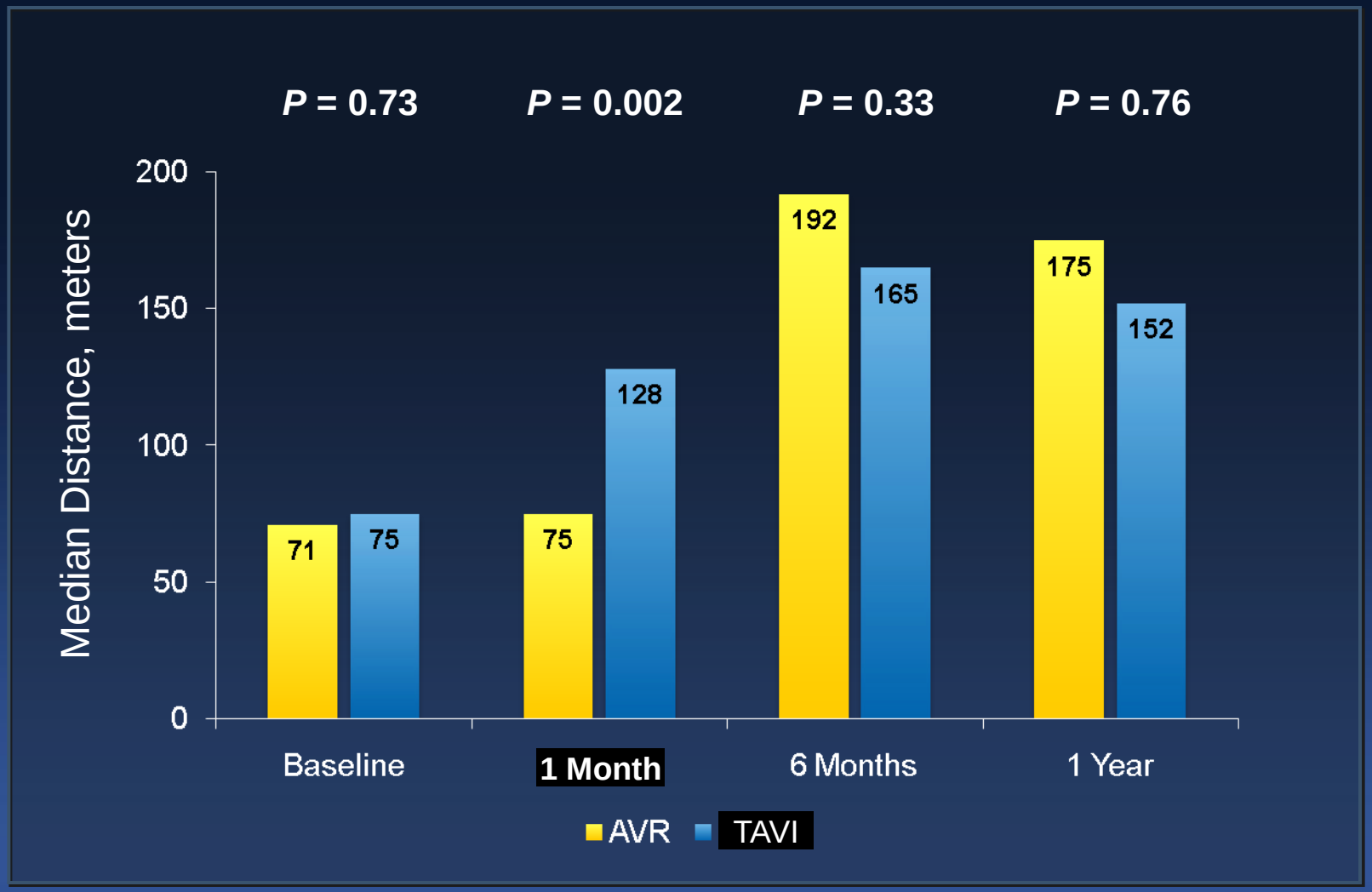


Comparable with SAVR

Smith CR et al. NEJM 2011;364:2187-98.

NYHA Functional Class

Six-Minute Walk Test



PARTNER trial
Cohort A and B

TAVI was superior to standard medical therapy in terms of 1-year mortality in an inoperable patients group with severe AS. It should be new standard of care for patients who are not suitable candidates for surgery.

Leon MB et al. NEJM 2010;363:1597-607.

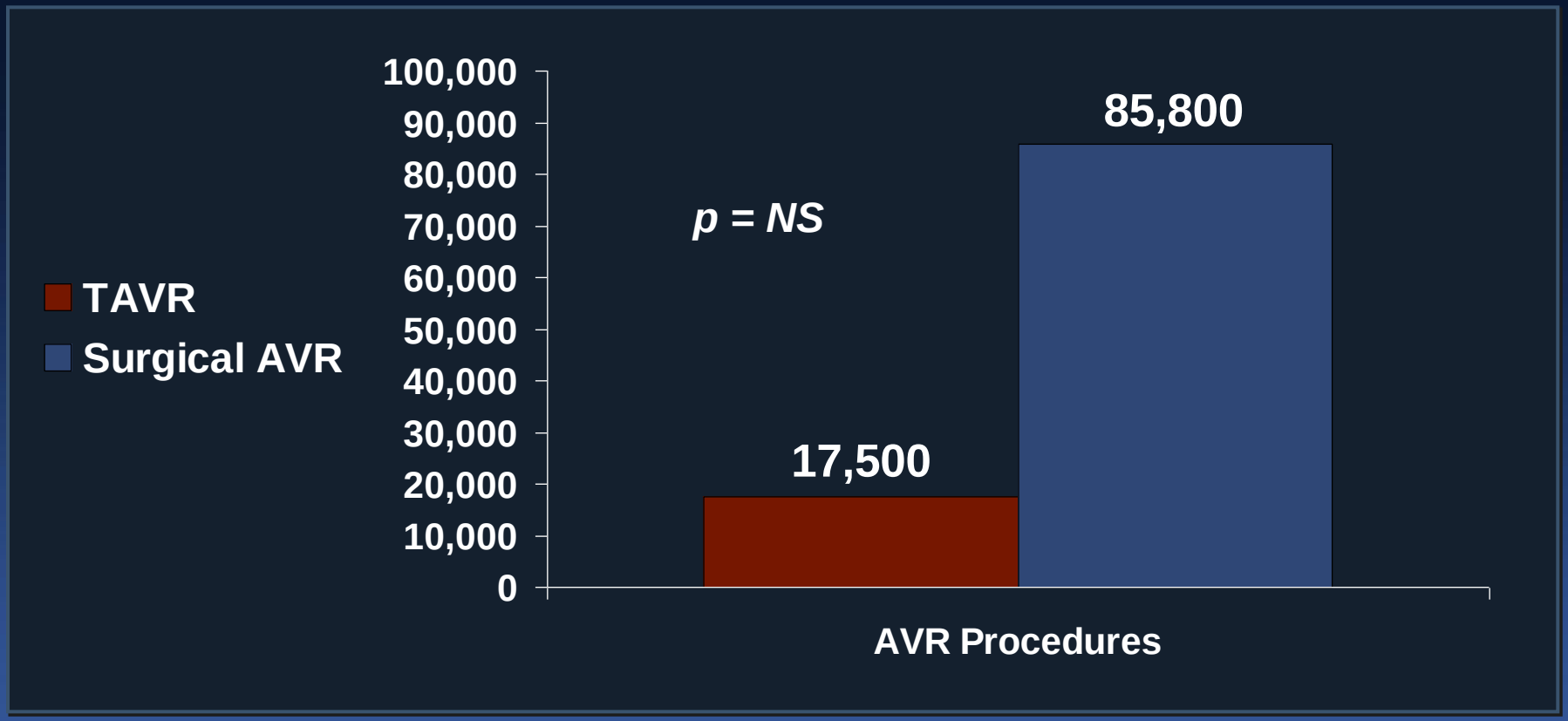
TAVI was non-inferior to SAVR in terms of 1-year mortality in a high-risk group of patients with severe AS. It should be an alterative to surgery.

Smith CR et al. NEJM 2011;364:2187-98.

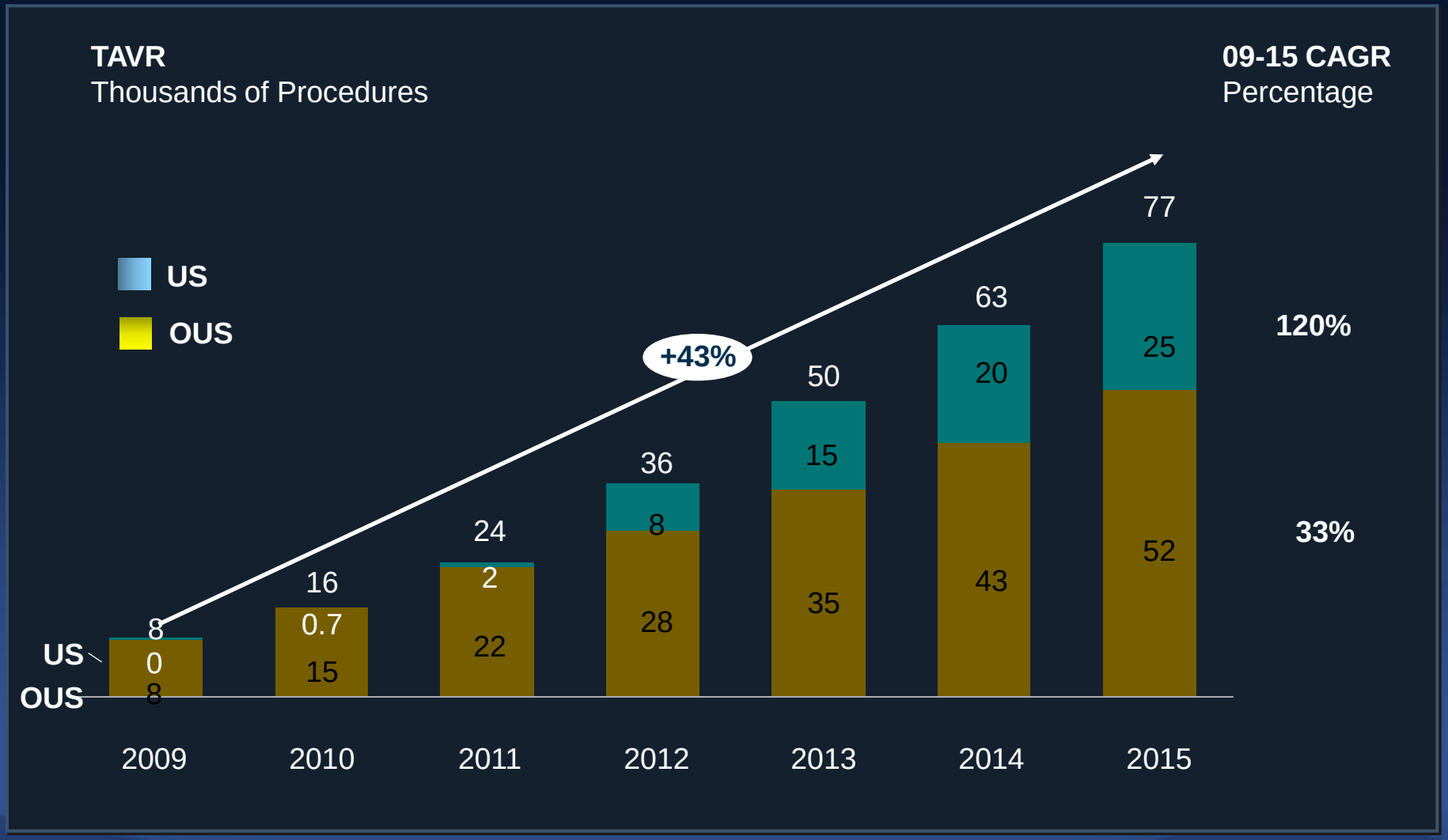
Real Practice of TAVI

TAVR vs. AVR in EU, 2011

TAVR 16.9% of all AVR procedures



TAVR Procedures



Source: JP Morgan

TAVI 2011

Complications

- Vascular complications
- Paravalvular AR
- Permanent Pacemaker
- Increased risk of Stroke

Vascular Complications

VARC Meta-Analysis

(17 studies; 3,519 patients, Edward Sapien + CoreValve)

Endpoint	*Pooled Estimate (%)*	*[95% CI]*
Vascular events @ 30 days		
Major	11.9	[8.6, 16.4]
Minor	9.7	[6.7, 14.0]
All	18.8	[14.5, 24.3]

P Généreux and S.J.Head, Unpublished data/Submitted JACC

Vascular Complications of *CoreValve* (18F)

Registry	Vascular Compls, %
Italian[1]	2.0
Belgian[2]	---
French[3]	7.5
Spanish[4]	5.6
UK[5]	4.0
German[6]	4.0
Australia-NZ[7]	6.5
Average	**4.2**
95% CI	1.6-6.8

[1] Tamburino Circulation 2011;123;299-308; [2]Bosmans EuroPCR 2010; [3]Eltchaninoff Eur Heart J 2010; Sept 15, 2010 epub; [4]Avanzas Rev Esp Cardiol 2010;63(2):141-8 [5]Moat EuroPCR 2010; [6]Zahn EuroPCR 2010; [7]Meredith TCT2010 [§] Mixed with balloon-expandable TAVR

Multivariate Predictors of Major Vascular Complications

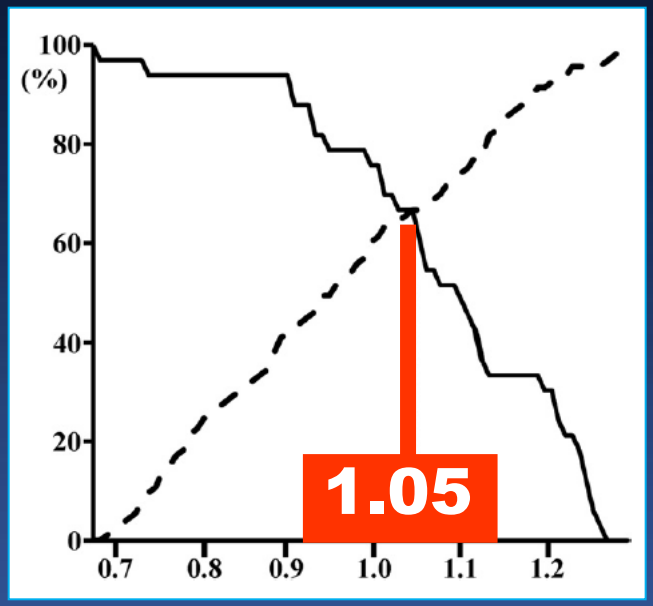
- Sheath to femoral artery ratio (SFAR)* HR: 186.20
- Center experiences, HR: 3.66
- Femoral calcification, HR: 3.44

*SFAR ; the ratio of sheath OD (mm) and minimal femoral artery diameter (mm), measured usually by CTA

SFAR threshold

Predicting Major Vascular Complications

SFAR threshold of 1.05 (AUC 0.723)



Variables	SFAR ≥1.05	SFAR <1.05	P Value
VARC Major	30.9	6.9	0.001
Iliac artery complication	20.0	2.8	0.002
Femoral artery complication	27.3	12.5	0.035
30-day mortality	18.2	4.2	0.016

Hayashida K, Lefevre T, Chevalier B et al.JACC Intv 2011;4;851-58

System is Evolving…

RF1,RF3

MLA, mm	Caucasian	AMC data
Femoral artery	8.17+1.14	8.2+1.6
External iliac artery	8.73+1.60	9.30+1.8
Common iliac artery	10.3+2.42	10.2+2.1

SFAR: 1.12 **SFAR: 0.9**

"18-19F is Safe"

22, 24F
(OD : 8.4-9.2 mm)

18, 19F
(OD : 7.2-7.5 mm)

Vascular Complications

Not too much Concerns Anymore !

Paravalvular Regurgitation

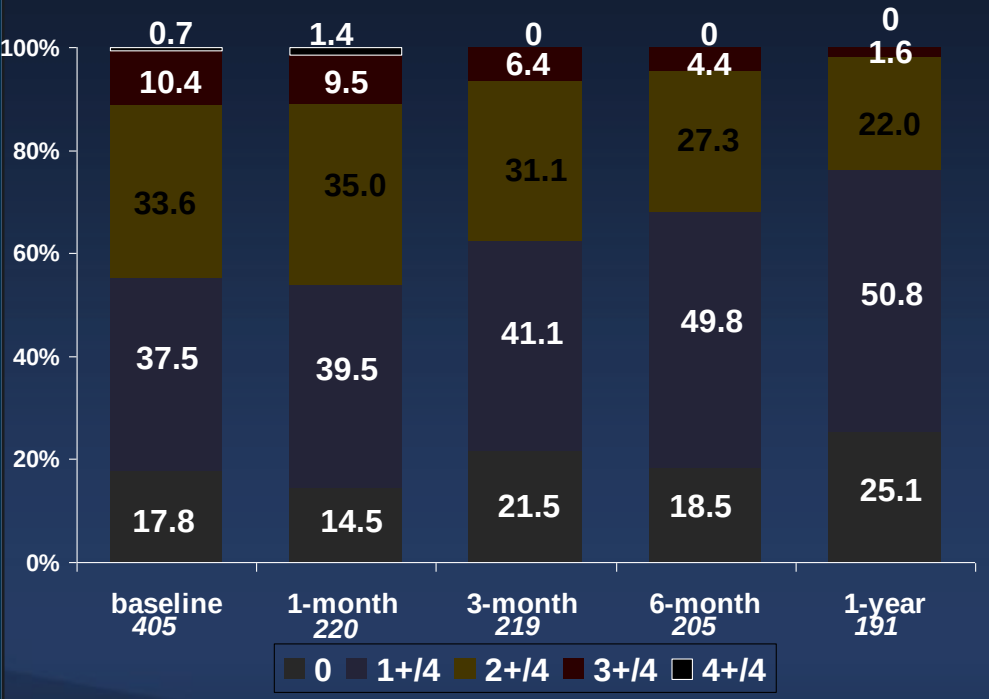
VARC Meta-Analysis (17 studies; 3,519 patients)

Endpoint	*Pooled Estimate (%)*	*[95% CI]*
Valve performance @ 30 days		
AVA ≤ 1.2 cm^2	4.8	[3.0, 6.6]
Mean gradient ≥ 20 mmHg	1.0	[0.0, 2.1]
AR ≥ moderate (PVL)	7.4	[4.6, 10.2]
Valve-in-valve	2.3	[1.3, 4.5]
Valve embolization	1.7	[0.2, 3.3]

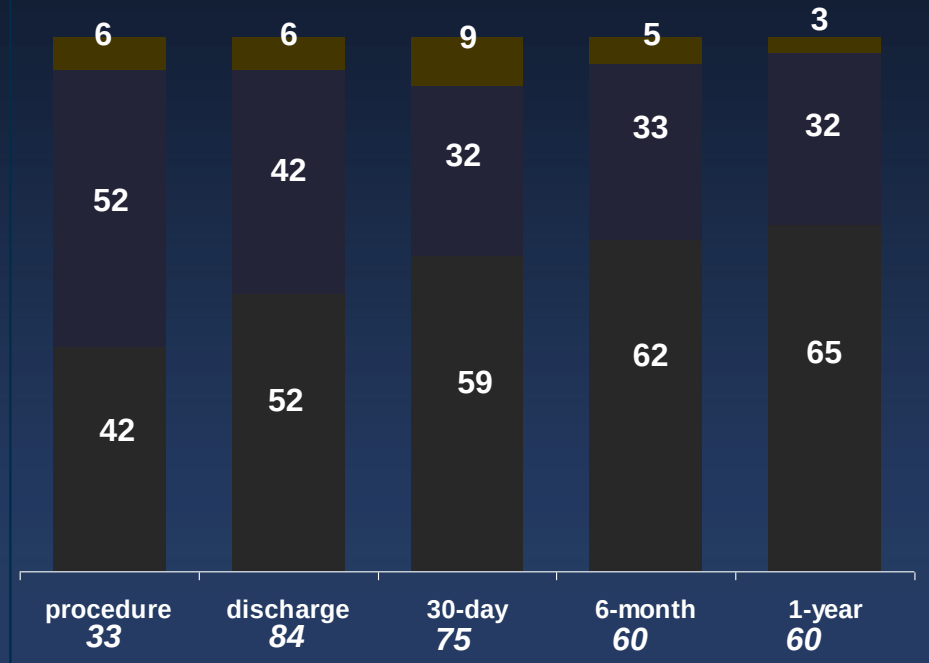
P Généreux and S.J.Head, Unpublished data/Submitted JACC

PVR

Edward SAPIEN
REVIE/ REVIVAL
TRAVERCE/ PARTNER EU



Medtronic CoreValve
SOURCE and European Registry



Multivariate Predictors of PVL (Edward Sapien)

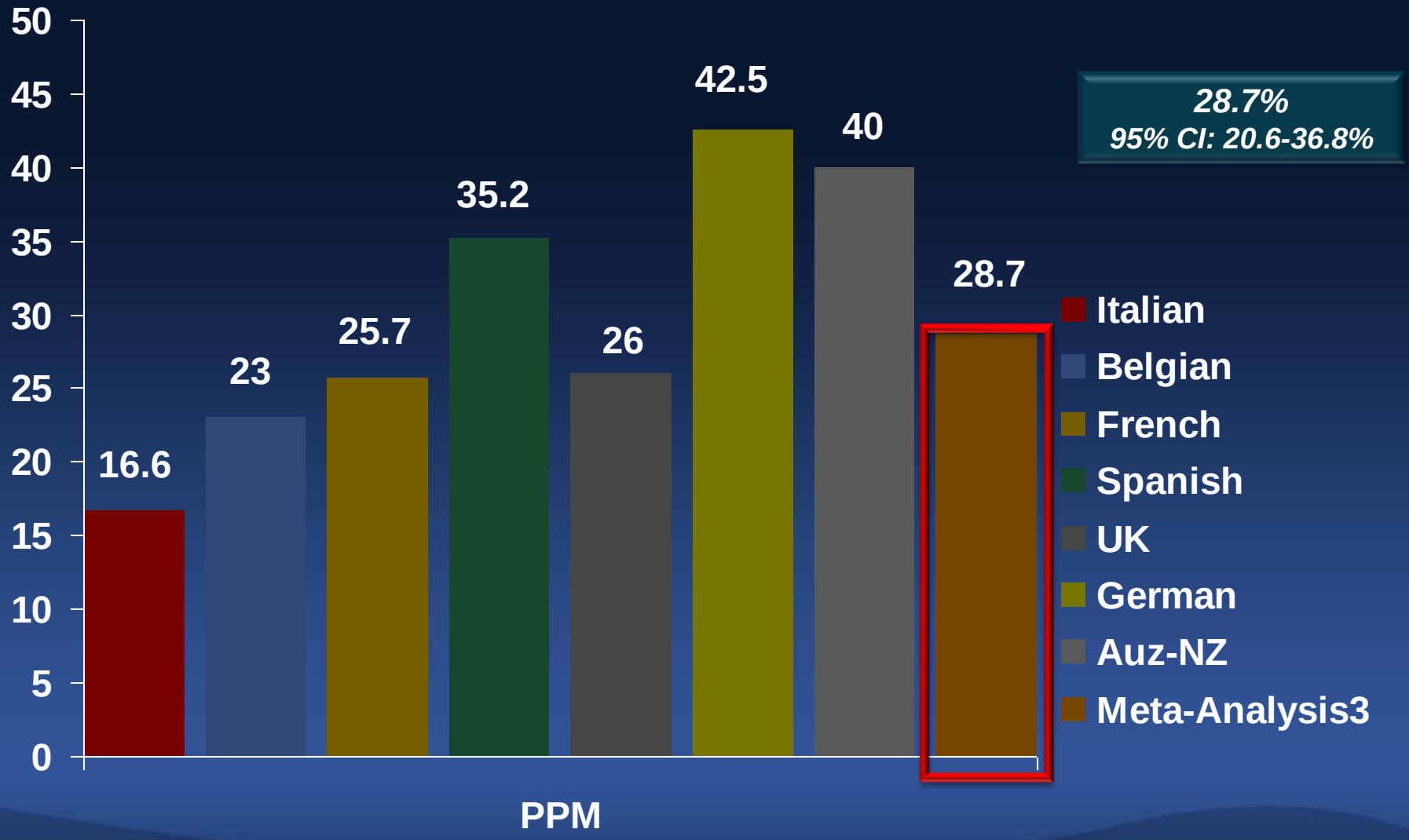
"Size and Calcium" Measurable, Manageable,

HR : 8.47 (95% CI 1.22 to 58.92)

- Asymmetry of valve calcification (TEE)
  HR : 13.70 (95% CI 1.52 to 122.40)
- Annulus size (MSCT)
  (28.2±1.8 mm vs. 24.8±2.3 mm, p=0.003)

Detaint et al. JACC Interv 2009;2:82107, Coli et al. Circulation 2009;120:S982
Delgado et al.Circulation 2009;120;S957

Permanent Pacemaker Meta-Analysis - *CoreValve*



Predictors for PPM
CoreValve

Pre-existing RBBB	✓	✓	✓	✓	✓	✓	✓	✓
Depth of implantation	✓	✓	✓	✓	✓	✓	✓	
Small LVOT/annulus	✓	✓						
Septal wall thickness	✓	✓						
Calcification	✓							

Permanent Pacemaker

VARC Meta-Analysis (17 studies; 3,519 patients)

"Achilles' Heel" of *CoreValve*

P Généreux and S.J.Head, Unpublished data/Submitted JACC

Is Risk of Stroke really Serious ?

Stroke

VARC Meta-Analysis (17 studies; 3,519 patients)

Endpoint	*Pooled Estimate (%)*	*[95% CI]*
Strokes @ 30 days		
Major	3.2	[2.1, 4.8]
Major + minor	4.0	[2.4, 6.3]
TIA	1.2	[0.0, 2.3]
All	5.7	[3.7, 8.9]

The increased risk of stroke associated with TAVI is special concern.

Schaff HV. Editorials NEJM 2011:364;23 :2256-2258

Meta-Analysis Results, *CoreValve*

Registry	Stroke, %
Italian[1]	1.2
Belgian[2]	5
French[3]	4.5
Spanish[4]	0
UK[5]	4.3
German[6]	---
Australia-NZ[7]	1.9
Average	2.8
95% CI	0.6-5.0

[1] Tamburino Circulation 2011;123;299-308; [2]Bosmans EuroPCR 2010; [3]Eltchaninoff Eur Heart J 2010; Sept 15, 2010 epub; [4]Avanzas Rev Esp Cardiol 2010;63(2):141-8 [5]Moat EuroPCR 2010; [6]Zahn EuroPCR 2010; [7]Meredith TCT2010

§ Mixed with balloon-expandable TAVR

Stroke after Isolated AVR in Moderate and High Risk Patients

First Author (Ref. #)	Type of Study	n	STS	Mean EuroSCORE	In-Hospital Death	In-Hospital Stroke
High-risk feature: >80 yrs of age						
Thourani et al. (8)	Retrospective, single-center	88	—	—	5.7%	3.4%
Leontyev et al. (9)	Retrospective, single-center	282	—	16.2%	10.6%	1.4%
Culliford et al. (10)	Retrospective, single-center	35	—	—	5.7%	0%
Akins et al. (11)	Retrospective, single-center	105	—	—	8.0%	1.0%
Kolh et al. (12)	Retrospective, single-center	70	—	—	8.5%	2.0%*
Ennker et al. (13)	Retrospective, single-center	62	—	—	4.8%	0%
Ferrari et al. (14)	Retrospective, single-center	124	—	12.6%	6.0%	2.0%
Elbardissi et al. (15)†	Retrospective, single-center	249	10.5%	11.0%	3%	4.0%
High-risk feature: STS >10%						
Thourani et al. (17)	Retrospective, multicenter	159	16.3%	—	16.4%	4.4%

*2 of 100 cases (70 isolated aortic valve regurgitation [AVR] and 30 AVR/coronary artery bypass graft); †Mini AVR.
EuroSCORE = European System for Cardiac Operative Risk Evaluation; STA = Society of Thoracic Surgeons; STS = Society of Thoracic Surgeons.

The risk of stroke after AVR in the general population is approximately 1.5% and the risk is increased (to approximately 2% to 4%) in older and higher risk patients.

Multivariate Predictors

Mainly Clinical Variables !

- Diabetes
- Bypass procedure time >120 min
- Calcification of ascending aorta

- Diabetes
- Atrial fibrillation
- A history of or current smoking
- Previous stoke

Filsoufi F, et al. AJC 2008;101:1472-8
De Arenaza DP, et al. Heart 2010;96:113-7
Gulbins H, et al. Ann Thorac Surg 2008;86:769-73

Stroke after TAVI

You have to realize that,
No surgical data to date have included *such an extremely high risk group of patients* as those treated by TAVI.

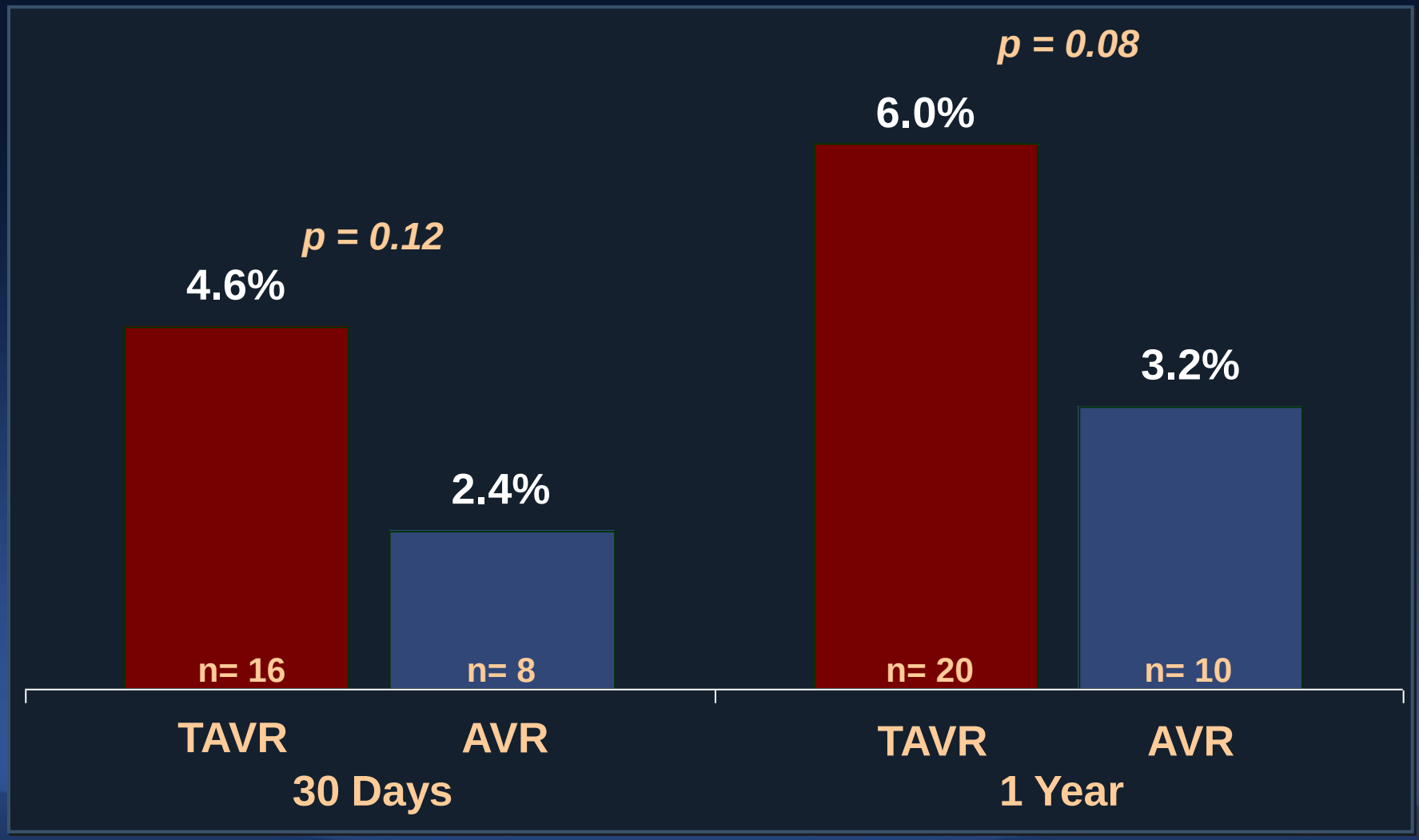
Rodes-Cabau et al. (22)	Registry	177	10.5%	—	1	11.3%	22.0%	1.7%	—
Thomas et al. (23)	Registry	575	—	16.3%	1	10.3%	27.9%‡	2.6%	—
Medtronic CoreValve: TF									
Grube et al. (29)	Registry	136	—	23.1%	12	12.5%	29.8%	4.4%	7.1%‡
Piazza et al. (31)	Registry	646	—	23.1%	1	8.0%	—	1.9%	—
Eltchaninoff et al. (21)	Registry	66	21.3%	24.7%	1	15.1%	—	4.5%	—
Petronio et al. (30)	Registry	460	—	19.4%	6	6.1%	11.4%	1.7%	—
Medtronic CoreValve: SC									
Eltchaninoff et al. (21)	Registry	12	21.0%	24.6%	1	8.3%	—	0%	—
Petronio et al. (30)	Registry	54	—	25.3%	6	0%	6.7%	1.9%	—
Zahn et al. (32)	Registry	697	—	20.5%	1	12.4%	—	2.8%*	—

The risk of stroke after TAVI were in 1.5% to 6%.

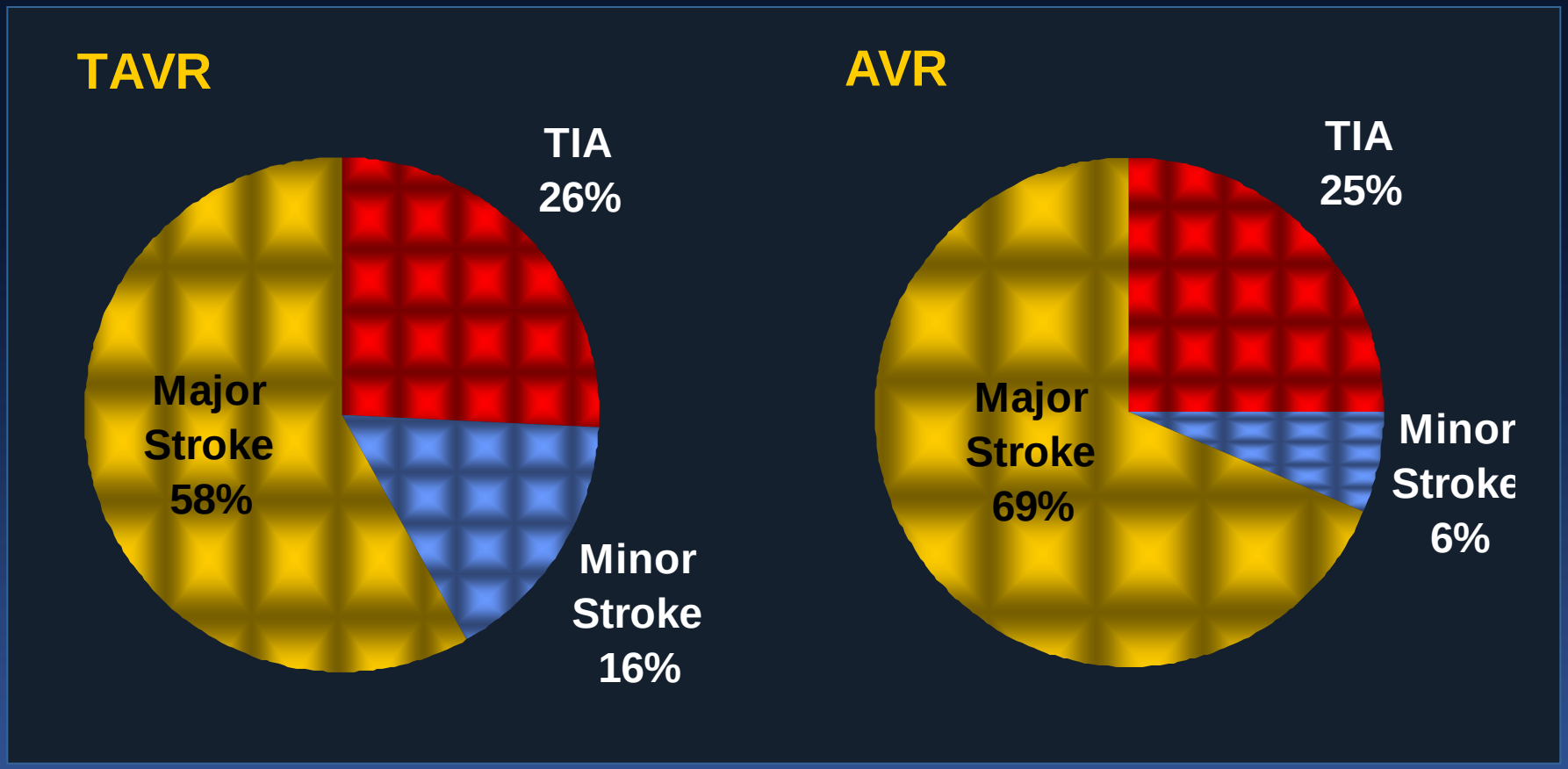
Daneault B et al, JACC 2011;58:2143-50

All Strokes (major and minor) at 30 Days & 1 Year

The only RCT Data, TAVI vs. SAVR (PARTNER, Cohort A)



Distribution of Types of Neurological Events



47 patients, 49 neuro events ; Ischemic-72%, hemorrhagic-0%, ischemic evolving to hemorrhagic-4%, unknown-24%

Multivariate Predictors

Early Stroke after TAVI

- TAVI
- Smaller aortic valve area

Late Stroke after TAVI

- History of stoke 6-12 months before TAVI
- Non-TF candidate, higher burden of atherosclerosis and more frequent vasculopathy
- Higher NYHA functional class

Miller CD. Paper presented at AATS 91st Annual Meeting; May 7-11, 2011, Philadelphia, PA.

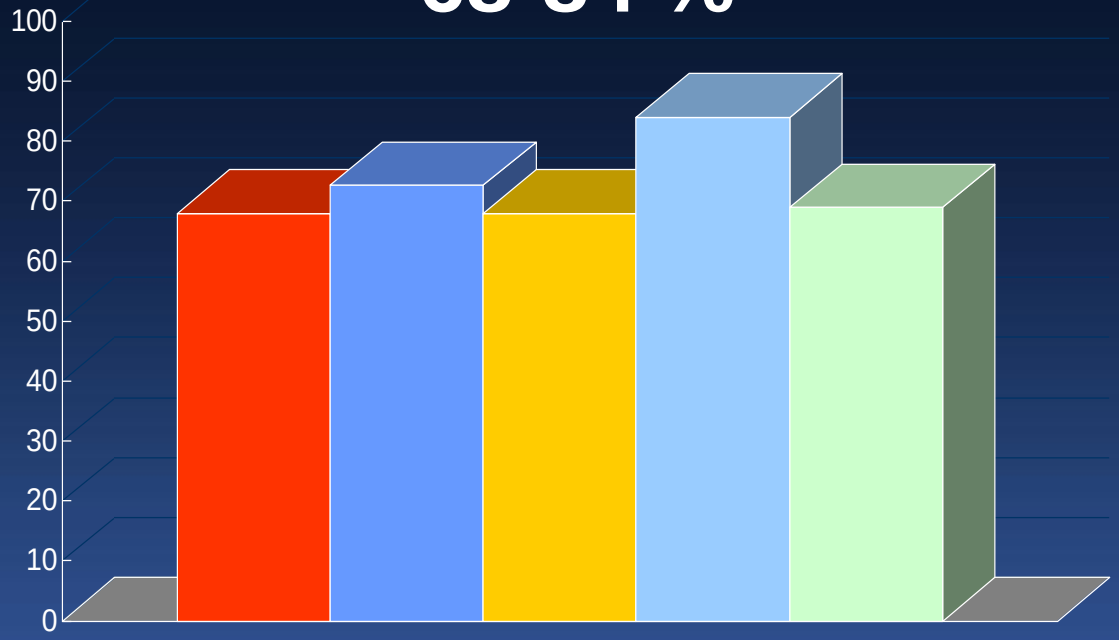
Concerns about the Early Procedure related Embolic Stroke,

In Fact,

Diffusion Weighted-MRI after TAVR

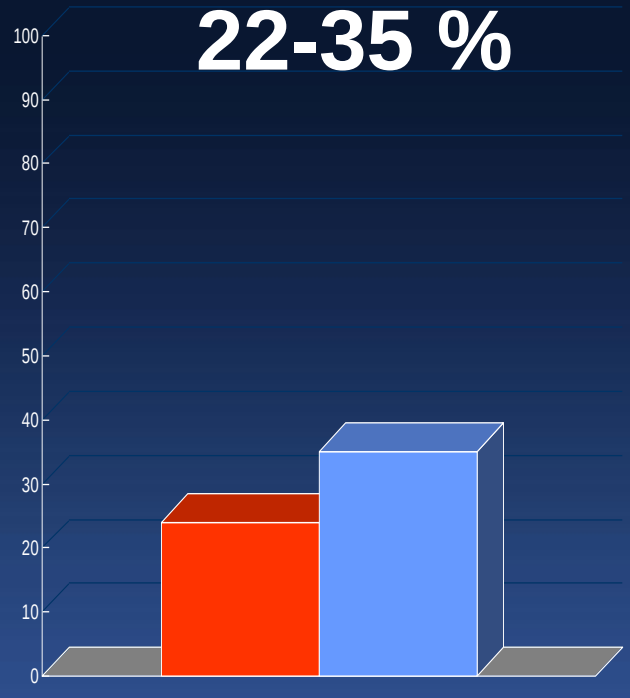
% of Patients with New Ischemic Lesions

68-84 %



TAVI

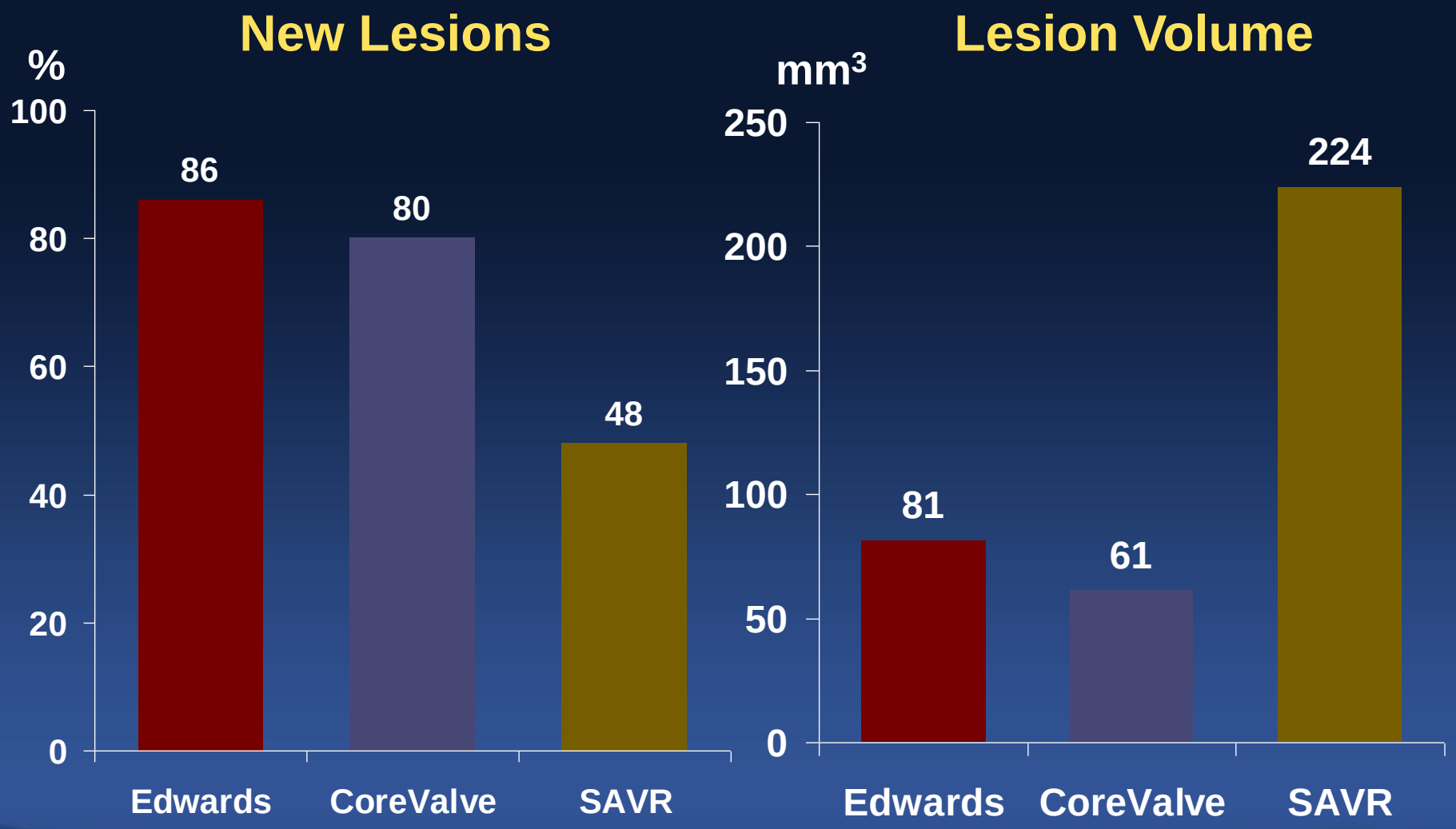
22-35 %



Only
Left Heart
Diagnostic
Catheterization

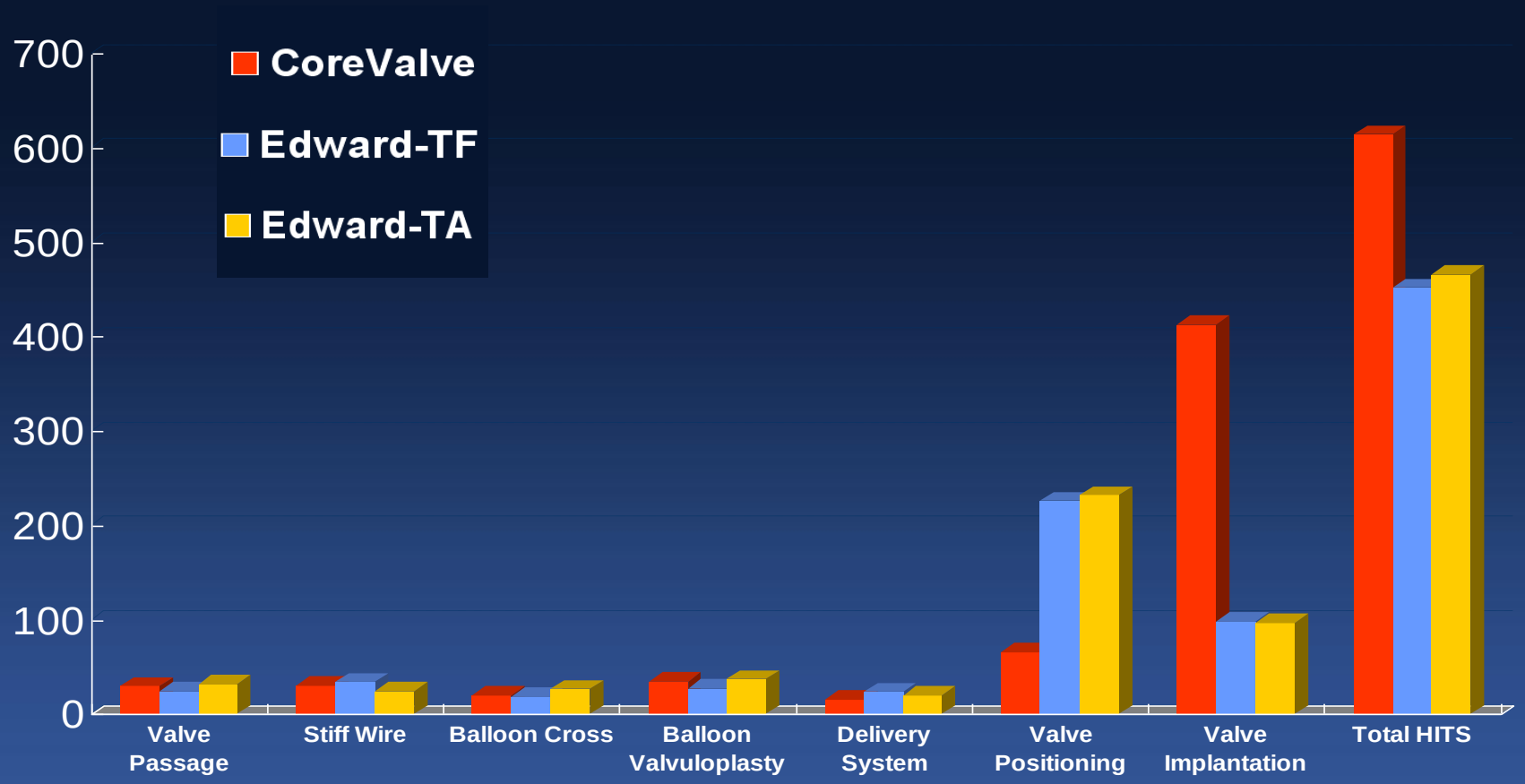
Kahlert PK Circulation 2010, Rodes-Cabau JACC 2011, Astarci EJCTS 2011,Ghanem JACC 2010, Arnold JACC interv 2011

Cerebral Ischemia After TAVI



Kahlert PK et al. *Circulation* 2010;121:870-878

Transcranial Doppler detected HITS (Microemboli)



Kahlert PK et al. *AHA* 2010

But,
Majorities are silent.

Insight from
Diffusion Weighted-MRI and Doppler Studies

1. New foci of restricted perfusion in 60-84%.
2. Cerebral microemboli were detected by TCD in all pts
3. No association between the occurrence of new ischemic lesions and neurocognitive function. 80% of MRI defects resolved at 3 months imaging study
4. No difference in the number of cerebral perfusion defects among TF-TAVI and TA-TAVI.

Kahlert PK et al. *Circulation* 2010;121:870-878, Rodes-Cabau JACC 2011, Astarci EJCTS 2011,Ghanem JACC 2010

Possible Mechanisms of Early Cerebral Embolism ?

- **Air embolism**
- **Procedure induced severe hypotension**
- **Mechanical causes**
  - Direct manuplation of the calcified aortic valve
  - Guiding of large-bore catheters
  - Passage of stiff aorta and aortic arch
  - Prior balloon valvuloplasty
  - Device induced crushing of calcified leaflets

Is it Manageable ?

- Device system is evolving. All the presented data were *already past*. They all used old system (RF1,RF3, 22-24F). New version of system (16-18F) is *totally different system*, we need new data (RCTs).
- Accumulation of experience. We definitely need leaning curve just like a surgery.
- Regarding protection device for embolic stroke, we need more data (RCTs).

Reasonable
Future Perspective

"Good Patient" can make a Good Clinical Outcomes

If TAVI use is expanded to a younger age and healthier population the outcomes will also be expected to be very good.

TAVI 2011

Now,

TAVI is an alternative to surgical AVR in a well chosen, high risk subgroup of patients with AS.


Surgical AVR
흉부
외과
TAVI

TAVI 2011

Where We Are Going...

- Lower risk AS patients "Good Patients"
- Valve-in-Valve for bio-prosthetic aortic and mitral valve failure
- Mixed AS and CAD patients
- Asymptomatic severe AS
- Aortic regurgitation
- Embolic protection ?

TAVI,
Can It Replace on Open Heart Surgery ?

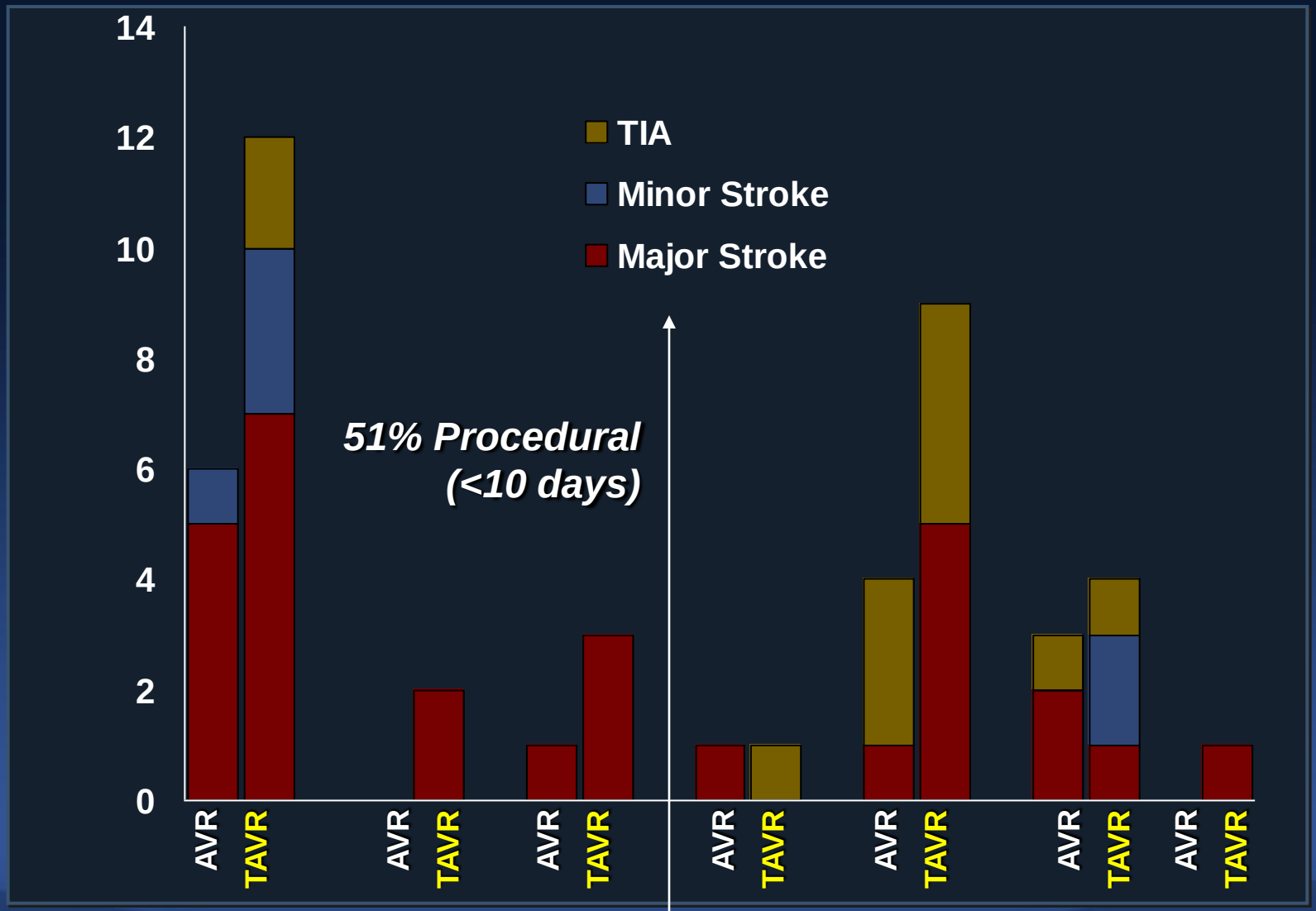
Yes, we are ready !

Most patients with severe AS requiring AVR will be treated using TAVI in the next 5-10 years !

Thank You !!

summitMD.com

Timing and Types of Neurologic Events (Strokes and TIAs)



UK registry

Predictors of 1 year Mortality

In multivariate analysis

- **LVEF less than 30%**
- **COPD**
- **Moderate or severe aortic regurgitation**

Newly Developing TAVI Devices

just like various coronary stents

~ 2011

Six-Minute Walk Tests