Surgical or Percutaneous Treatment of Aortic Valve Disease

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Disclosures

- Relationship with companies who manufacture products used in the treatment of the subjects under discussion

Relationship	Manufacturer(s)
Speaker's Honoraria	Edwards Lifesciences
Consultant (Advisory Board)	Medtronic, Saint Jude Medical

Background

- Aortic stenosis is frequent and carries a poor prognosis in symptomatic patients with severe AS
- Patients are mostly elderly with several comorbidities
- Surgery may be high risk or even contraindicated
- In practice, many patients are denied surgery

- ***Current results and indications of TAVI***
- What is next ?
- The «essentials »

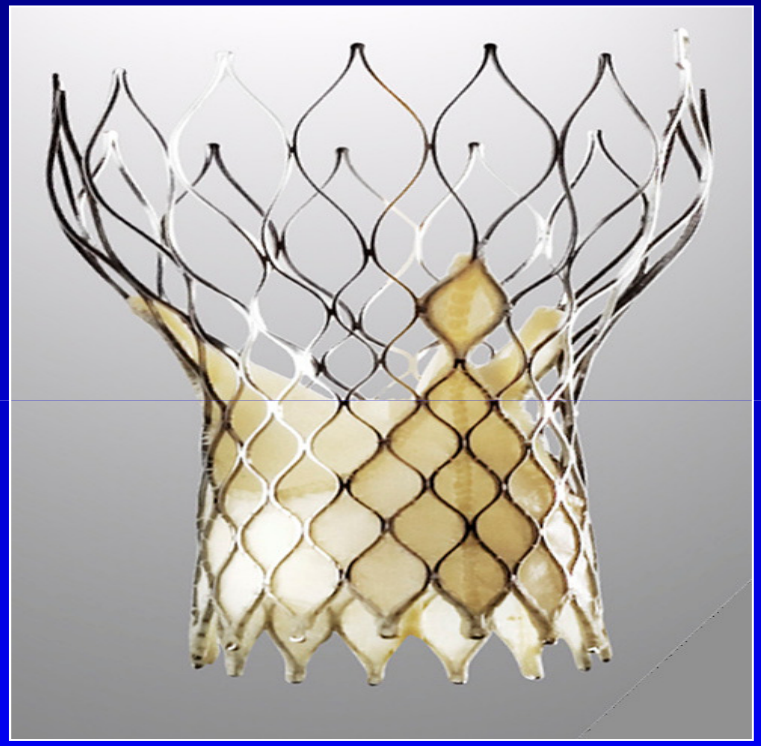
First in man

Alain Cribier -16 April 2002

Cardiogenic shock, patient not amenable to surgical treatment

The Devices for TAVI

Medtronic CoreValve® TAV



CE mark 2007

Edwards SAPIEN™ THV

CE mark 2007

> 50000 patients treated in > 500 centers

Demographics of TAVI patients

	ADVANCE	SOURCE	
	(n=1015)	TF (n=2706)	TA
Age	81	82	81
Log Euroscore	19.2	23.9	27.6
CAD	57.6	48.4	55.8
PVD	19.5	10.2	26.4
Prior MI	16	12.7	17.5
Prior PCI	31.1	24.5	28.5
Prior CABG	21.4	15.4	25.5
COPD	22.6	18.2	20
Renal insuffiency	14.6	24.9	31.1

(Thomas EuroPCR 2012)

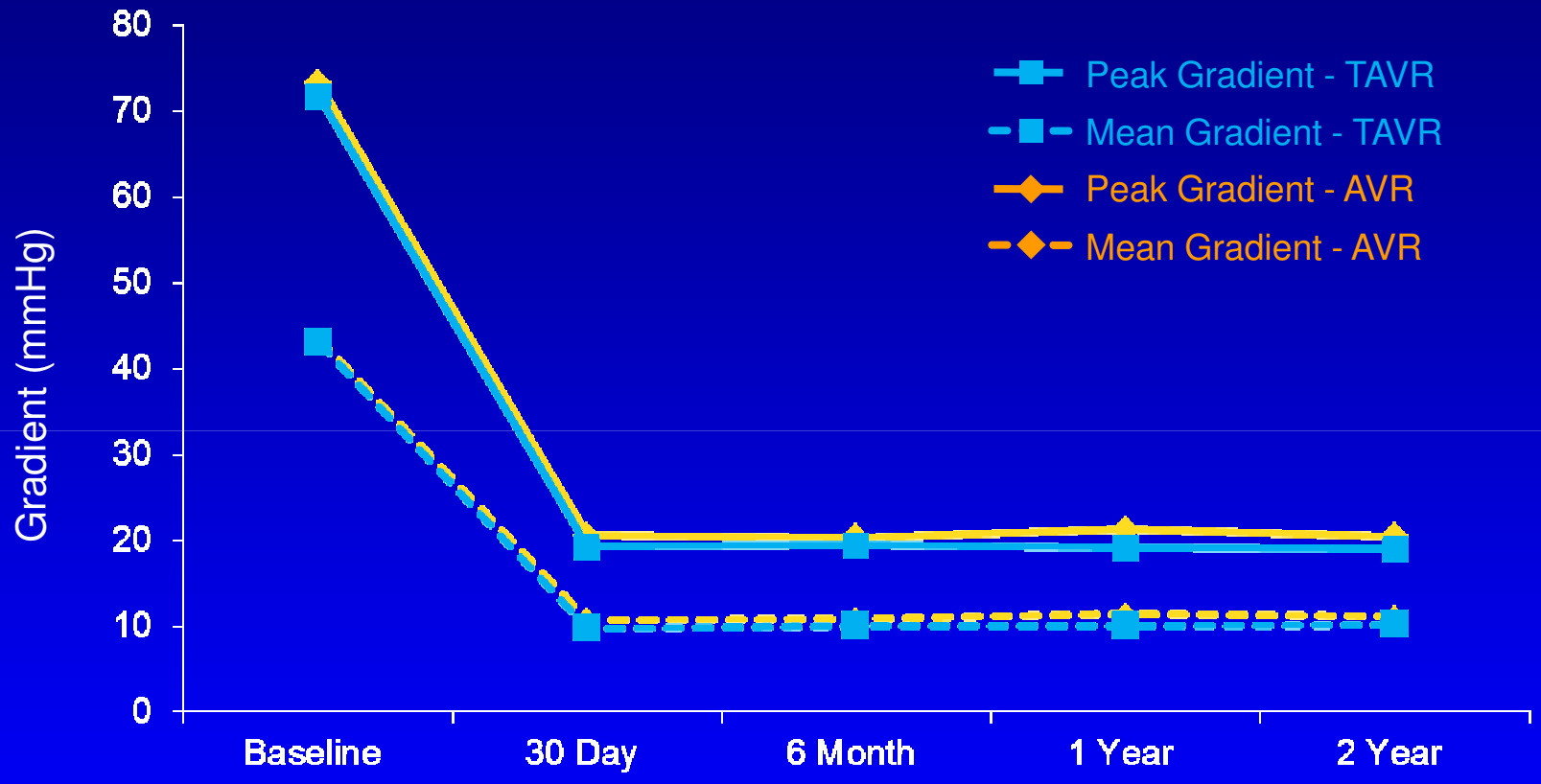
Procedural Success in European TAVI Registries

	French	UK	Belgian	German	Italian
n	3195	870	800	697	633
Procedural success (%)	97	99	98	98.7	98

Gilard NEJM 2012;366:1705-11
Moat J Am Coll Cardiol 2011;58:2130-8
Bosmans Inter Cardiovasc Thoracic Surgery 2011;12:762-67
Zahn Eur Heart J 2011;32:198-204
Tamborino C Circulation 2011;123:299-308

Efficacy of TAVI

Echocardiographic Findings in PARTNER A



Numbers at Risk					
TAVR	*307*	*275*	*233*	*218*	*144*
AVR	*295*	*228*	*168*	*155*	*112*

(Kodali ,NEJM ,2012;366:1686-95)

Procedural Complications in SOURCE XT

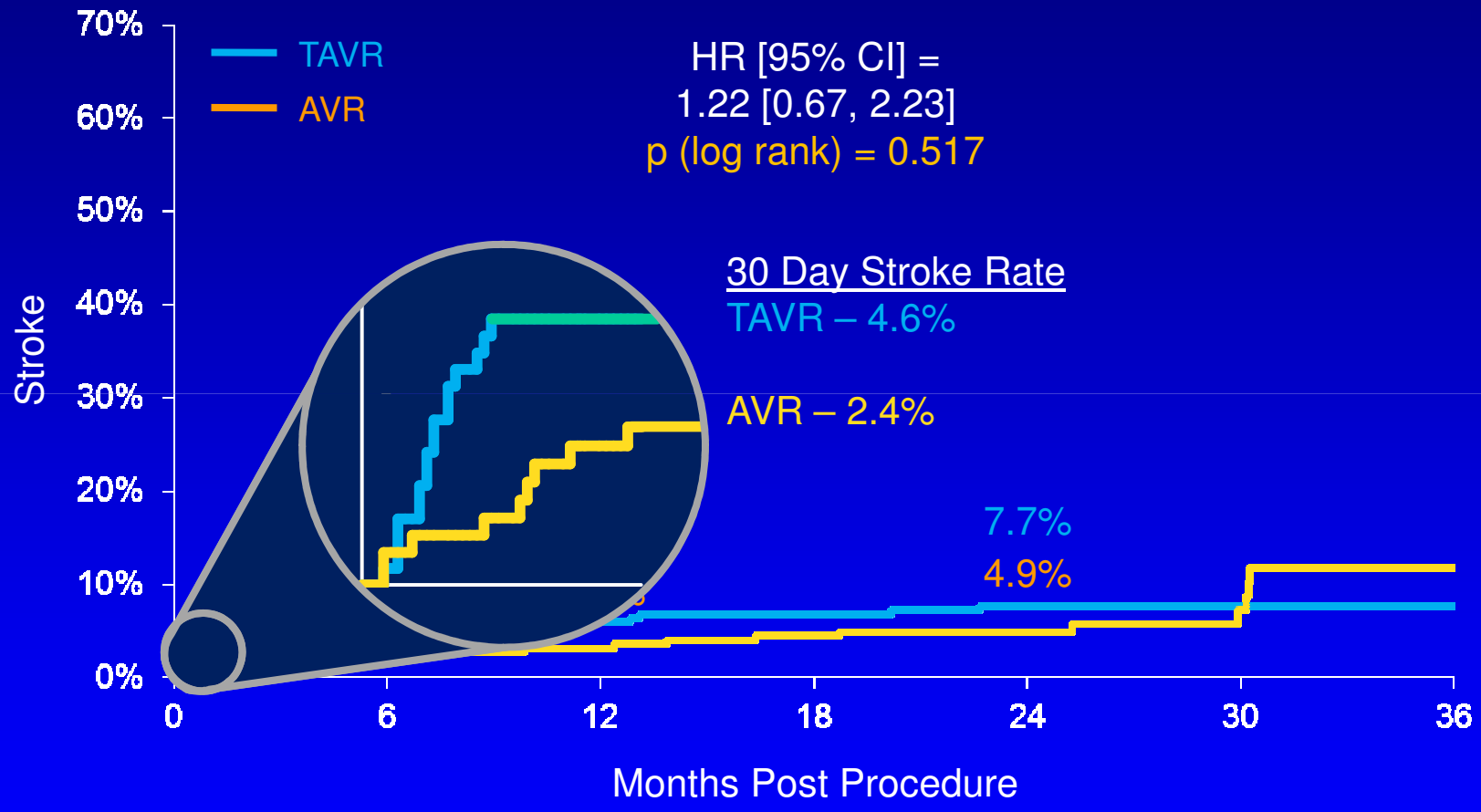
Events	Results (N = 2706)
Aborted Procedures - %	0.6
Unable to Cross Native Valve - %	0.04
Conversion to Surgery - %	0.4
Annular Dissection - %	0.4
Coronary Occlusion - %	0.4
SAPIEN-in-SAPIEN (Bailout) - %	1.1
Valve Embolization - %	0.7
Cardiac Tamponade - %	0.5

Clinical Outcome at 30 Days

	ADVANCE Transfemoral N=1015	SOURCE Transfemoral N = 1694	SOURCE Transapical N = 906
All-cause Mortality (%)	4.5	4.3	9.9
Any Stroke (%)	2.9	2.3	2.1
Myocardial Infarction (%)	0.2	0.5	0.7
New Pacemaker (%)	26.3	8.0	10.9
Vascular Complication – Major (%)	10.7	7.3	3.6
Renal Failure with Temporary Dialysis) (%)	5.7	1.2	4.0
Major Bleeding (%)	9.7	5.0	11.4

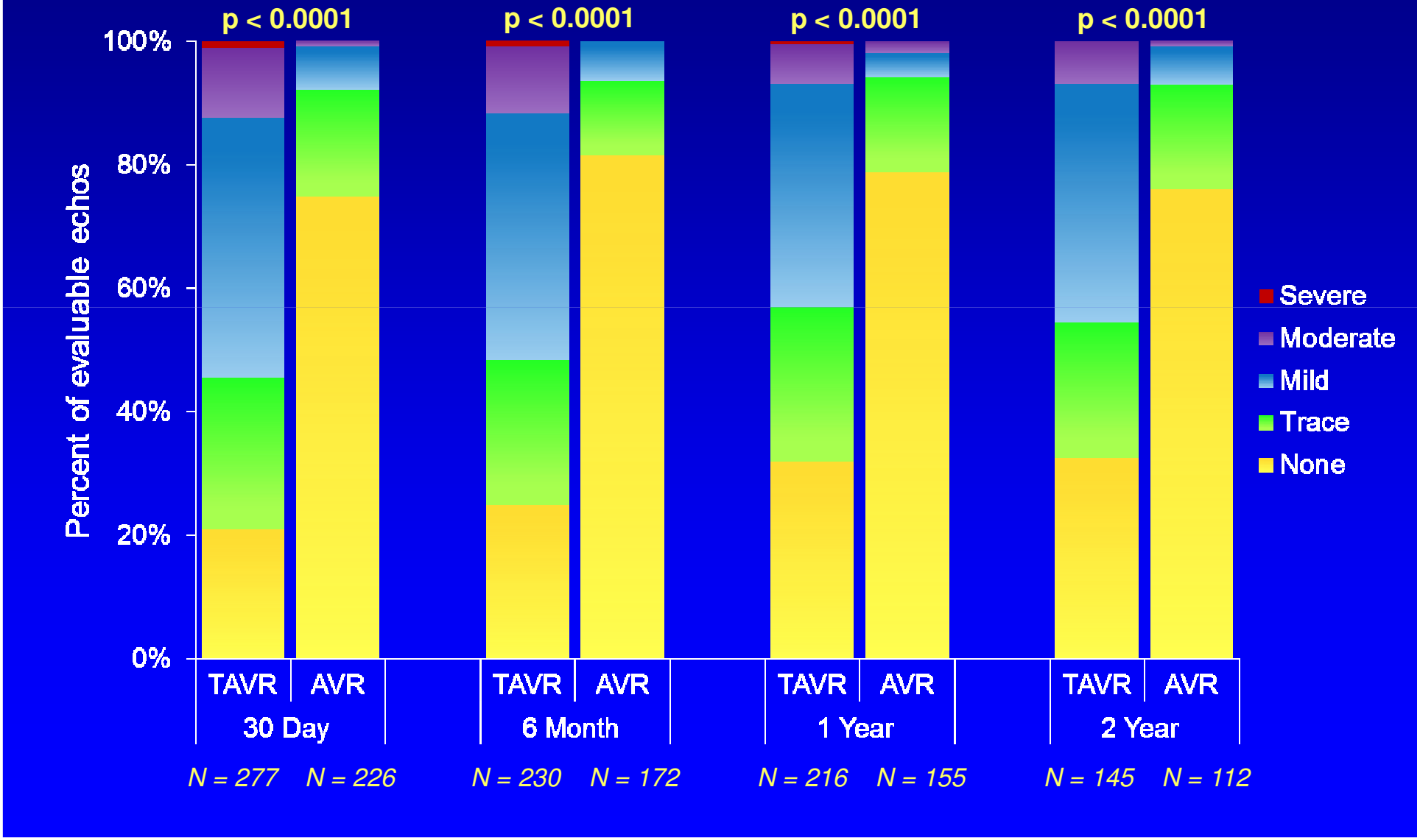
(Bauernschmidt ; Wendler EuroPCR 2012)

Strokes in PARTNER A

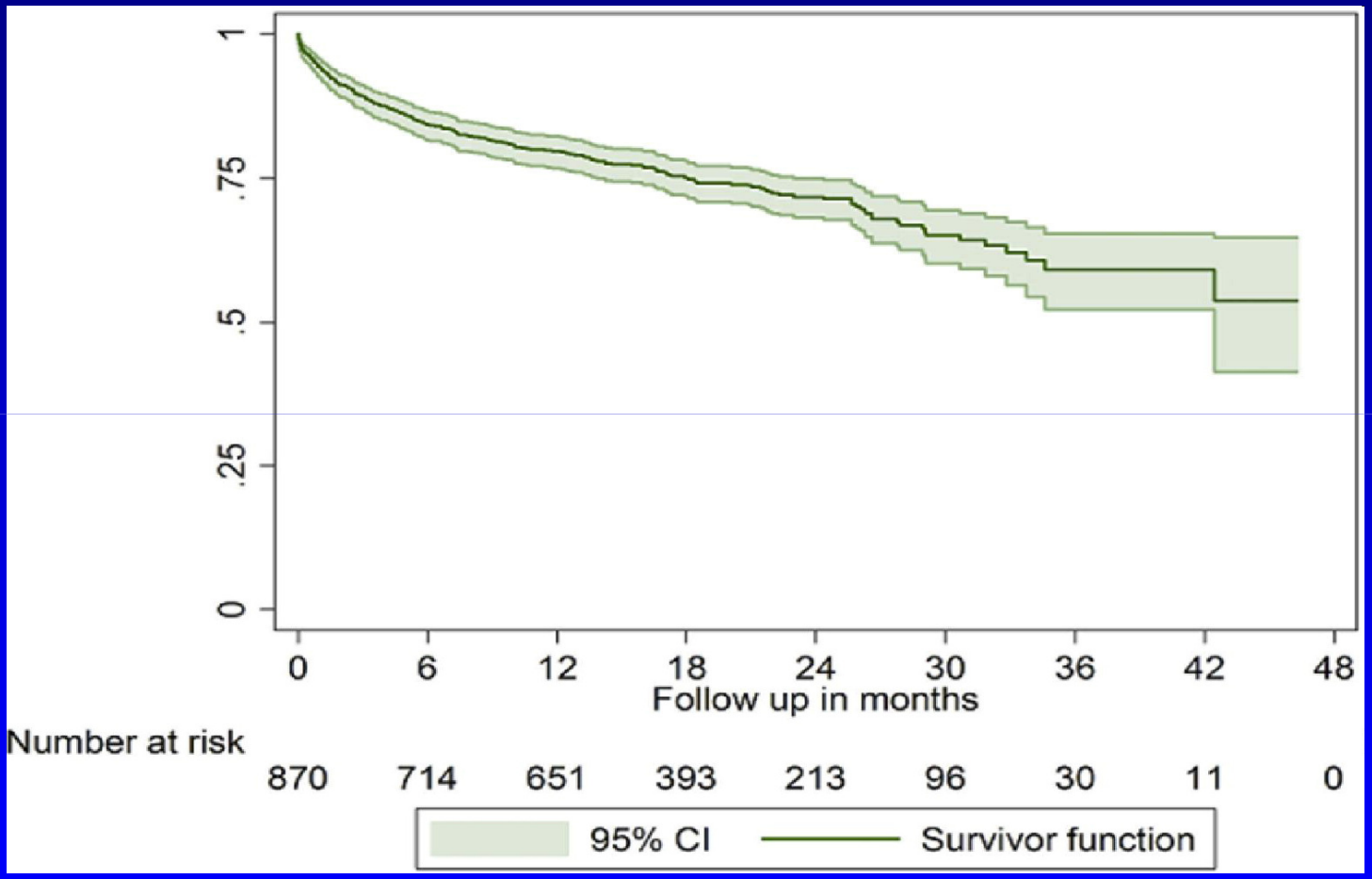


Paravalvular Aortic Regurgitation in PARTNER A

TAVI vs AVR



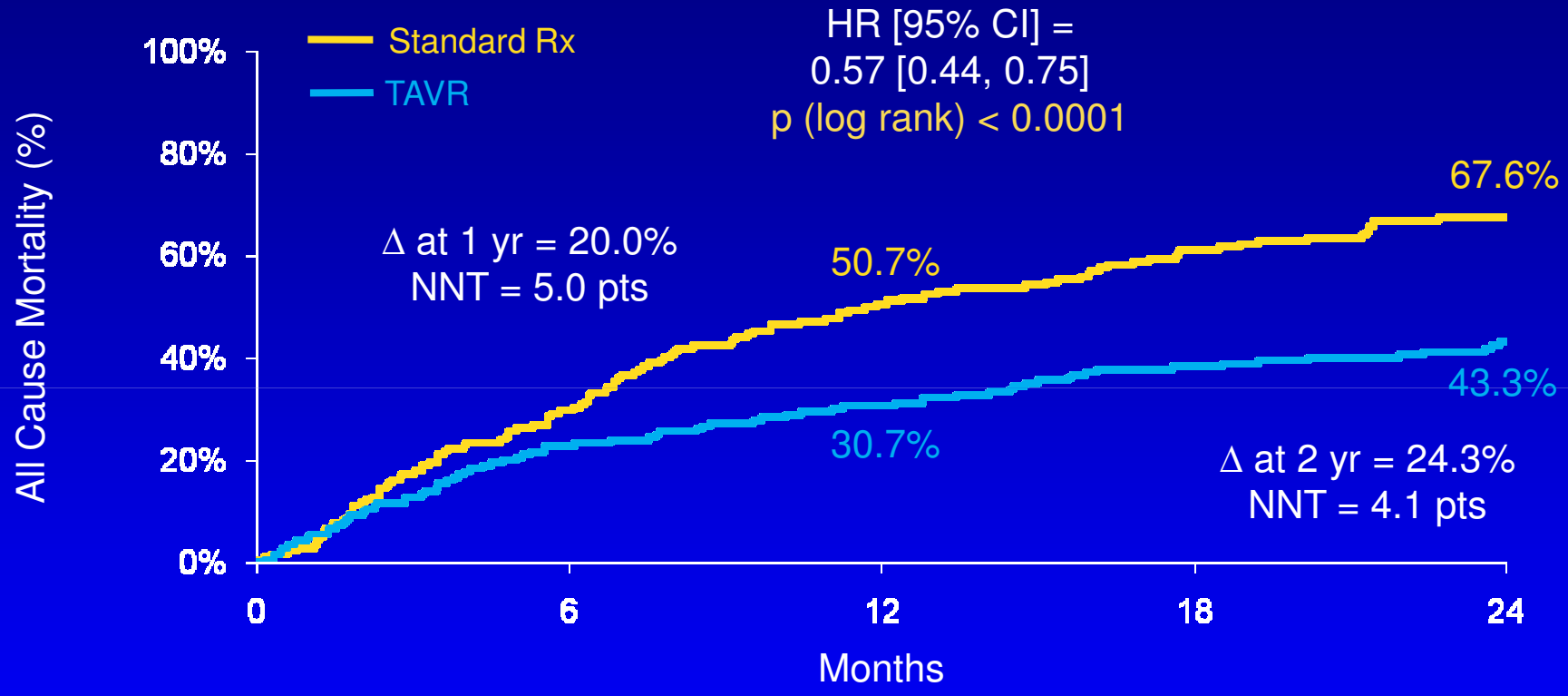
Follow-up after TAVI in the UK Registry



(Moat J Am Coll Cardiol2011;58:2130-8)

All Cause Mortality in PARTNER B

TAVI vs Medical Treatment



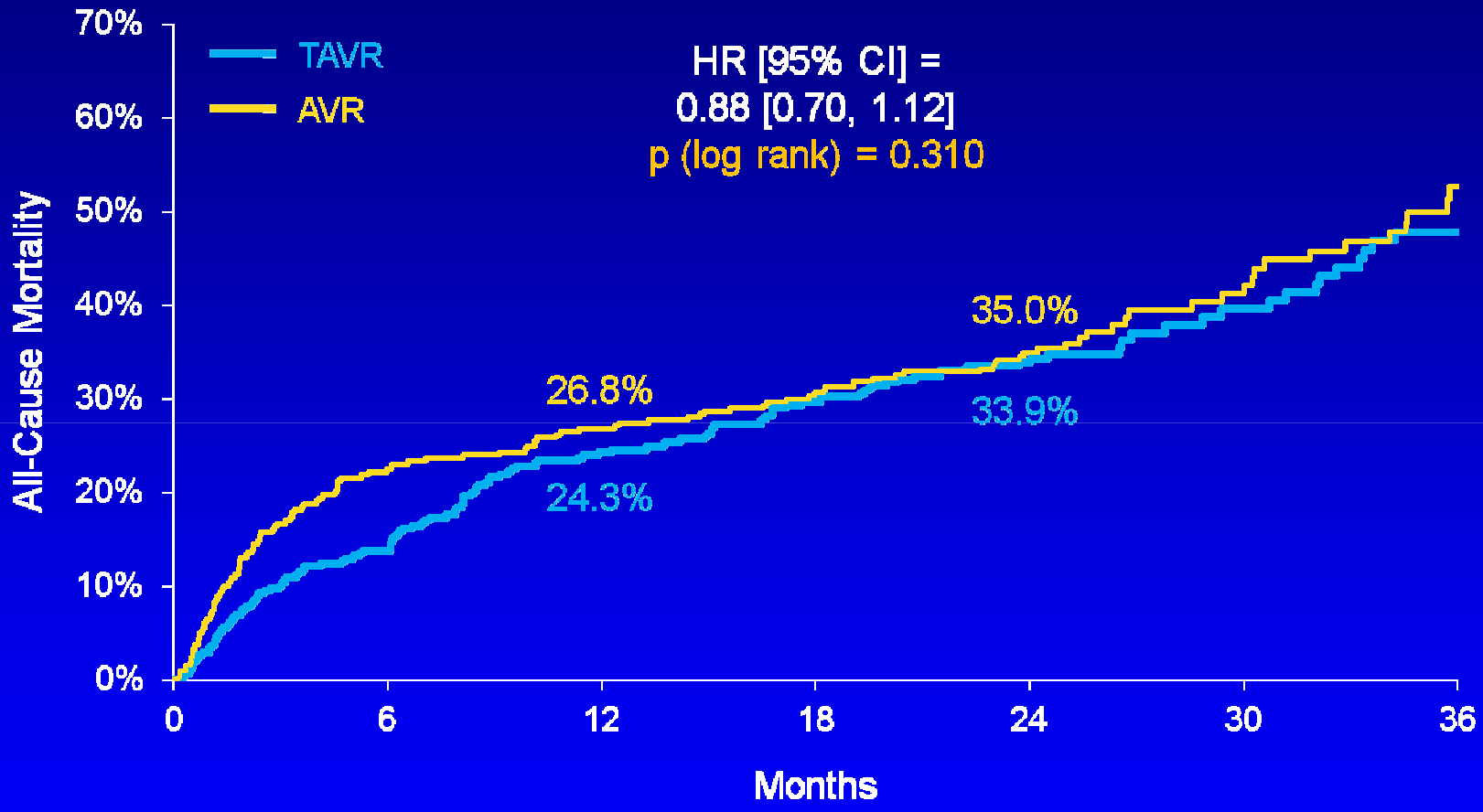
Numbers at Risk

TAVR	*179*	*138*	*124*	*110*	*83*
Standard Rx	*179*	*121*	*85*	*67*	*51*

(Makkar,NEJM 2012;366:1696-704)

All Cause Mortality in PARTNER A

TAVI vs AVR



Numbers at Risk

TAVR	348	298	260	234	172	70	31
AVR	351	252	236	217	165	65	32

(Kodali,NEJM 2012 ;366:1686-95)

Predictors of 1-year Death after TAVI

Non–cardiac

- Age
- Logistic Euroscore
- STS Score
- COPD
- Chronic Kydney D.
- Diabetes
- Prior stroke
- Carotid stenosis
- Dyslipidemia
- HTN

Cardiac

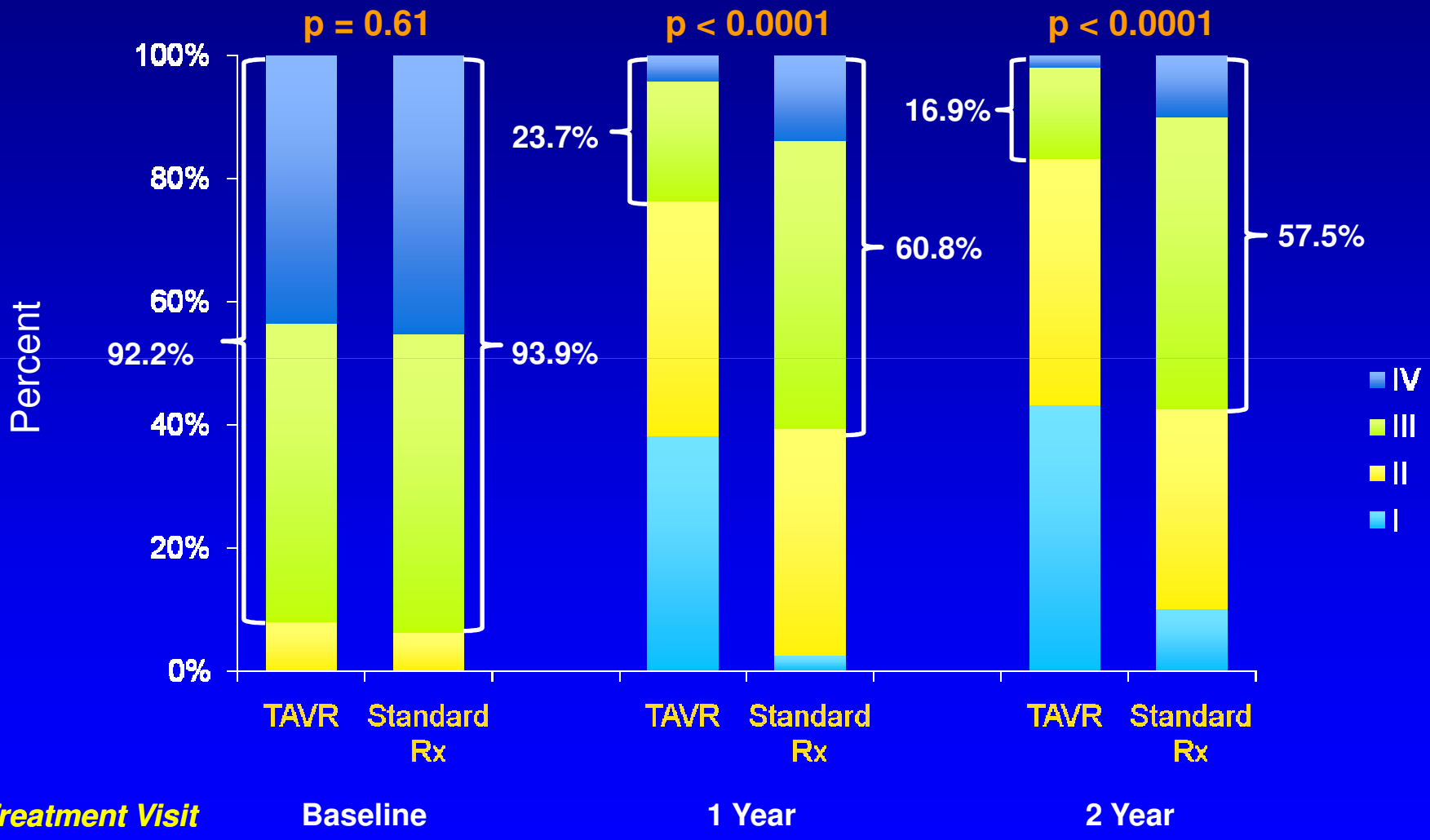
- PHT
- NYHA Class IV
- Acute pulm.oedema
- CAD
- Severe MR
- M Valvuloplasty

Procedural

- Moderate/ severe AR
- Major vascular compl
- Stroke
- Kidney injury
- Experience
- Transapical

Functional Results in PARTNER B

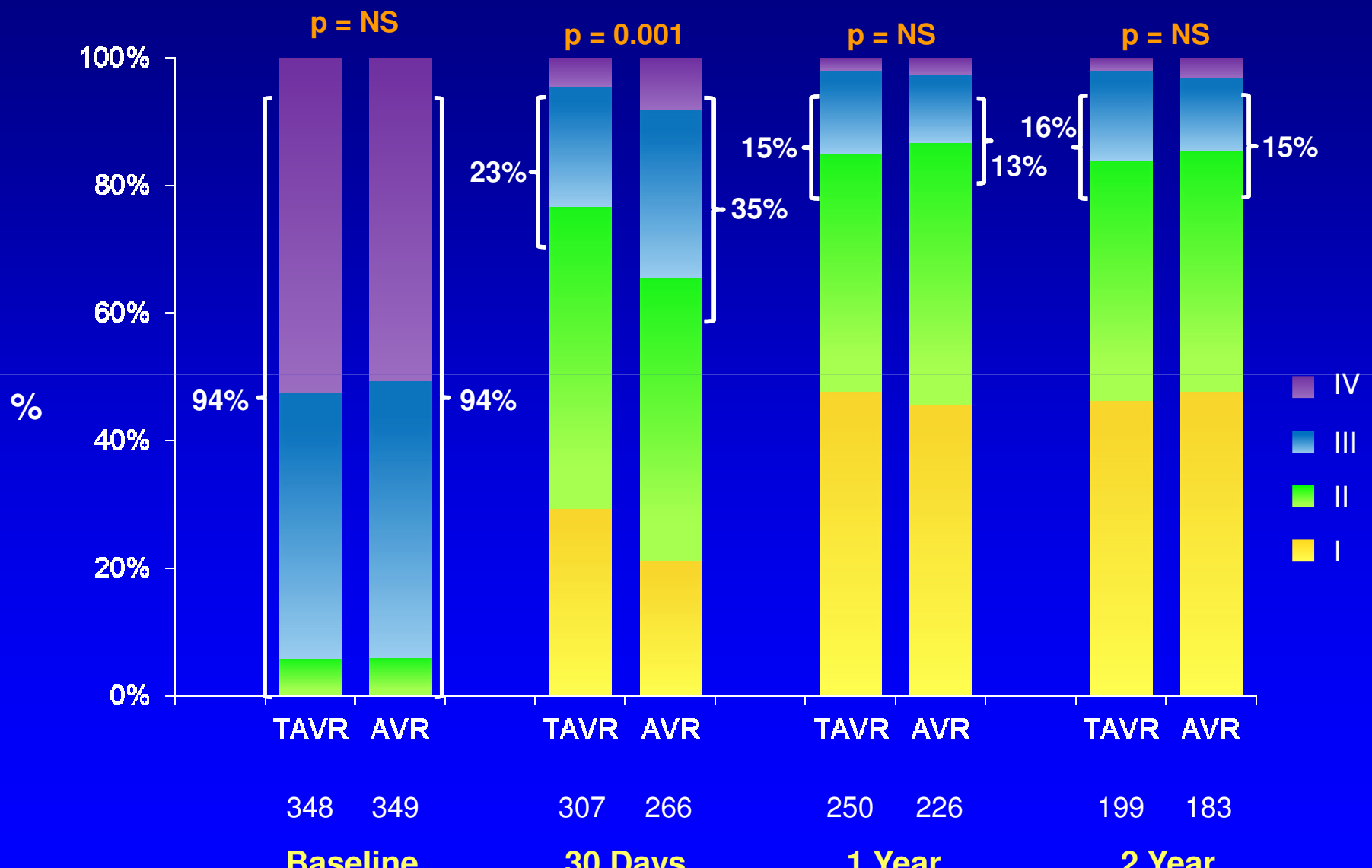
TAVI vs Medical Treatment



(Makkar,NEJM 2012;366:1696-704)

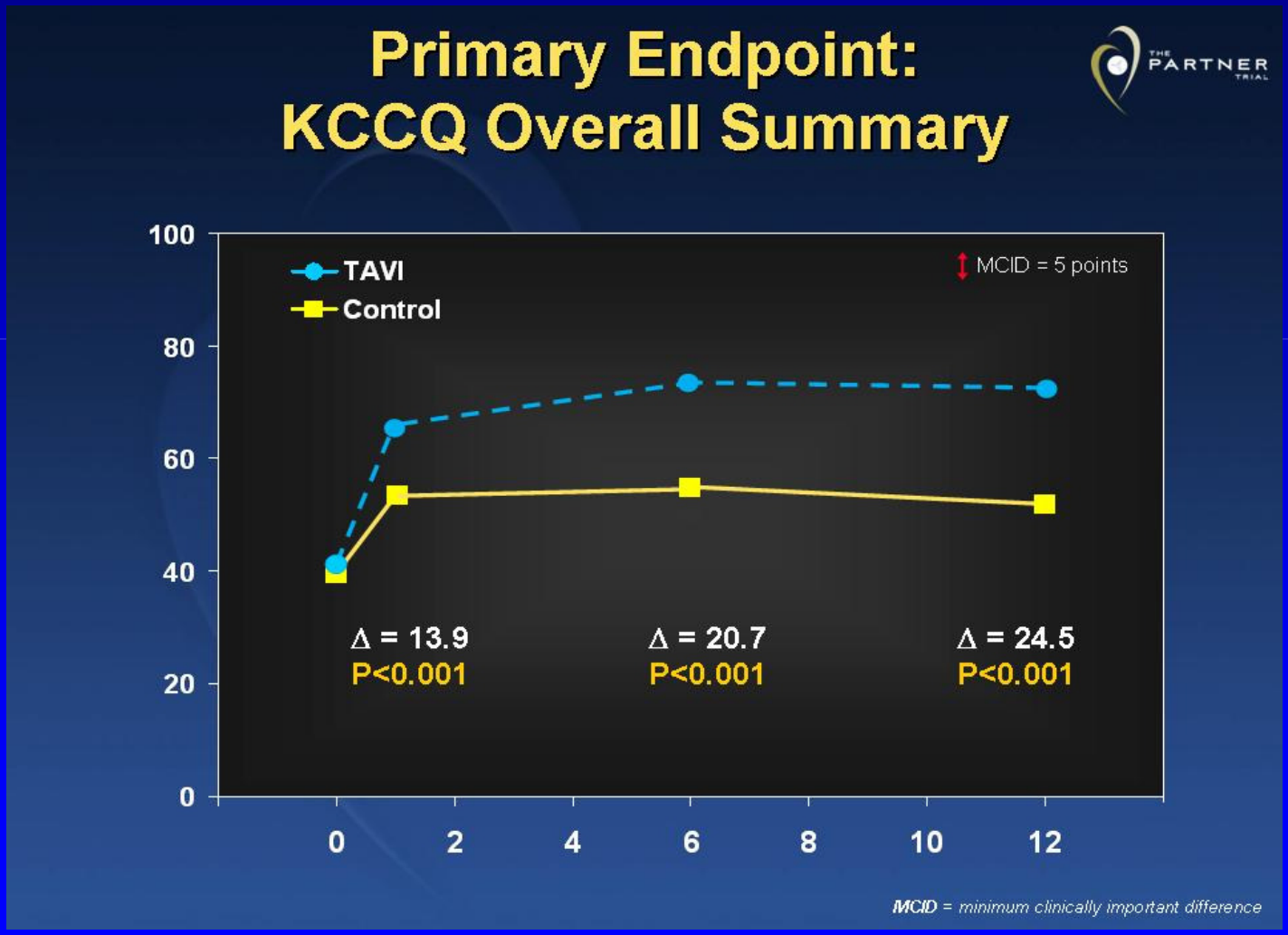
Functional Results in PARTNER A

TAVI vs AVR



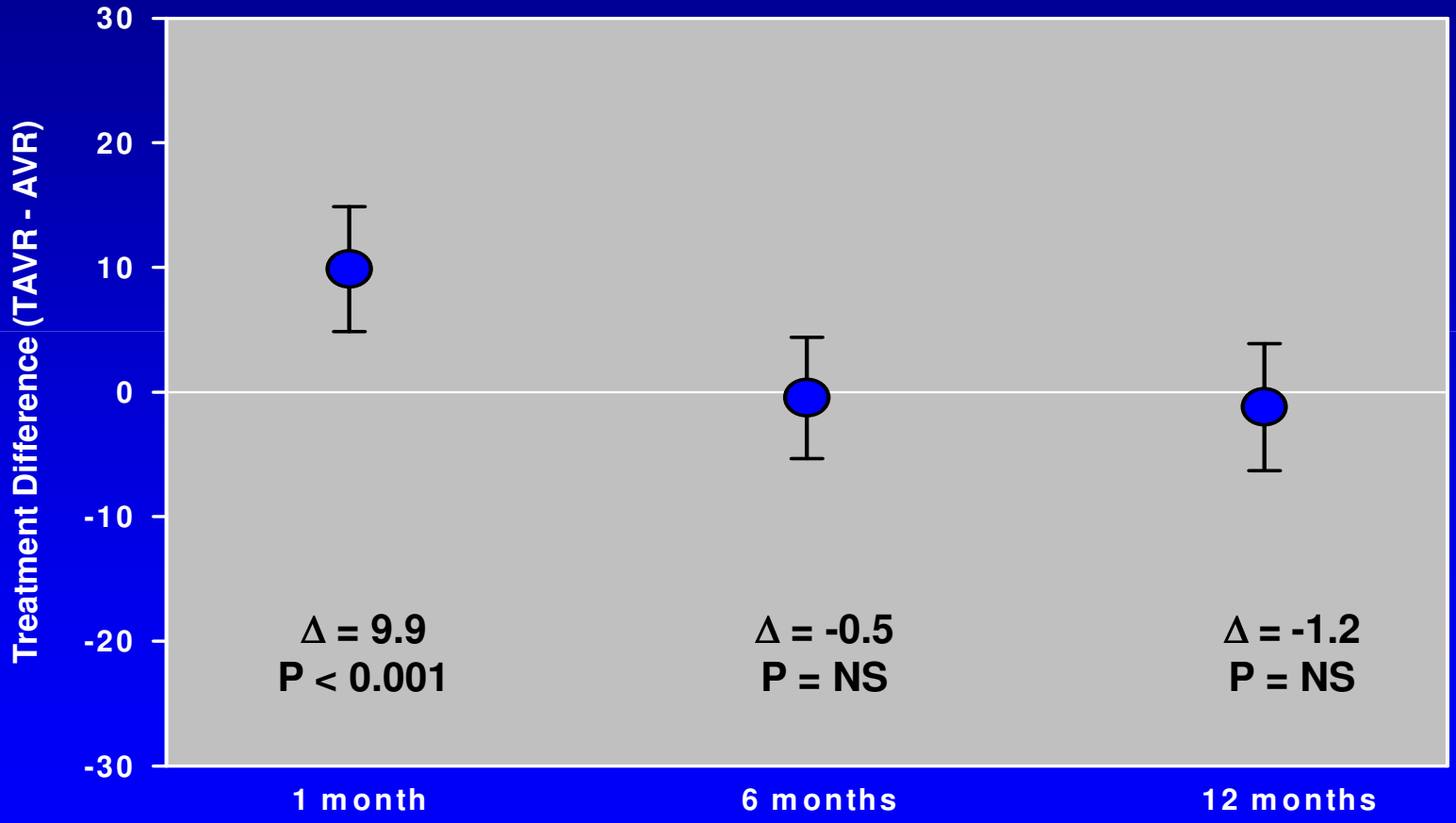
(Kodali,NEJM 2012 ;366:1686-95)

Quality of Life after TAVI in Inoperable Patients



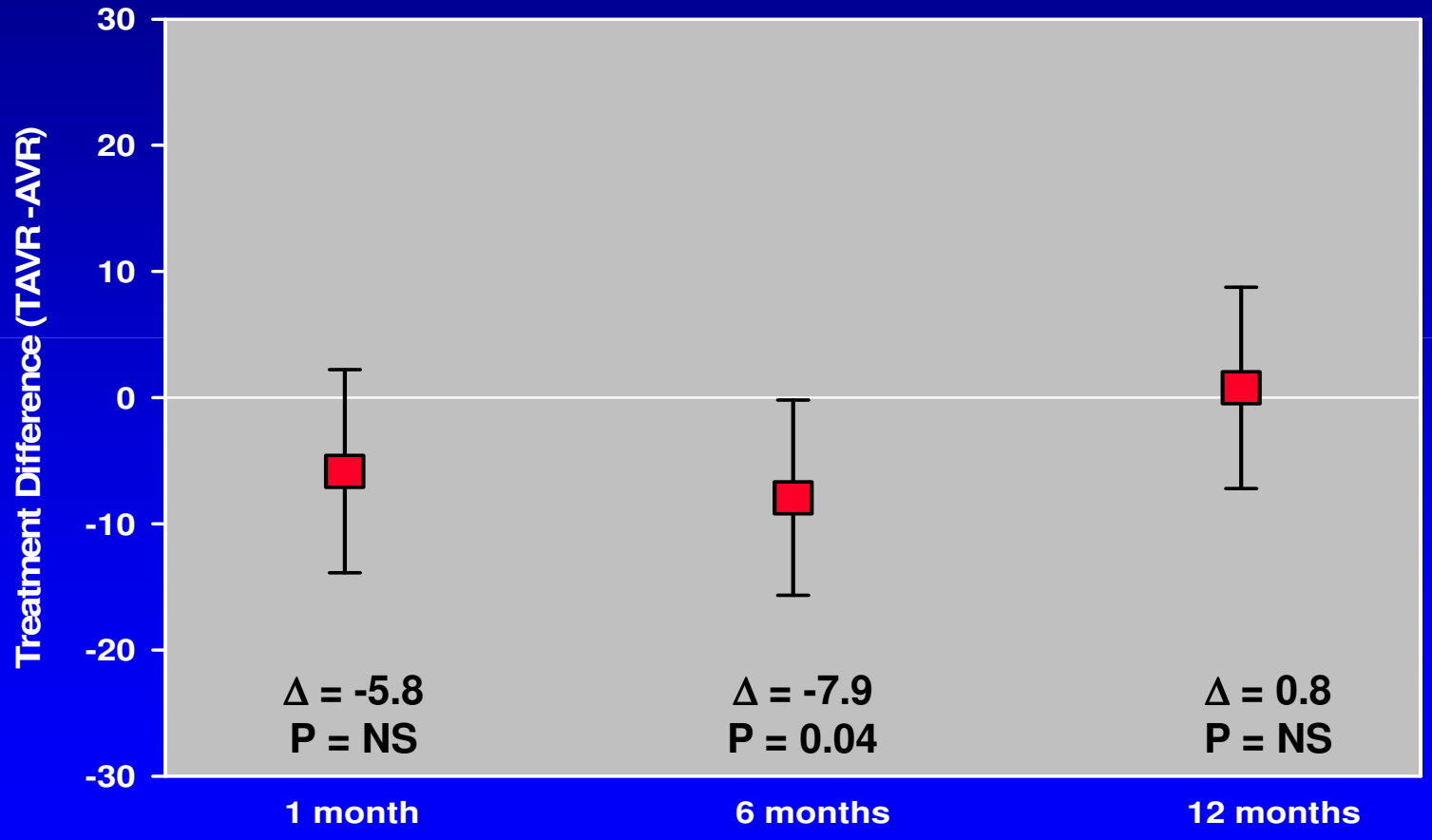
PARTNER :Quality of Life in Operable Patients

TF Subgroup / AVR

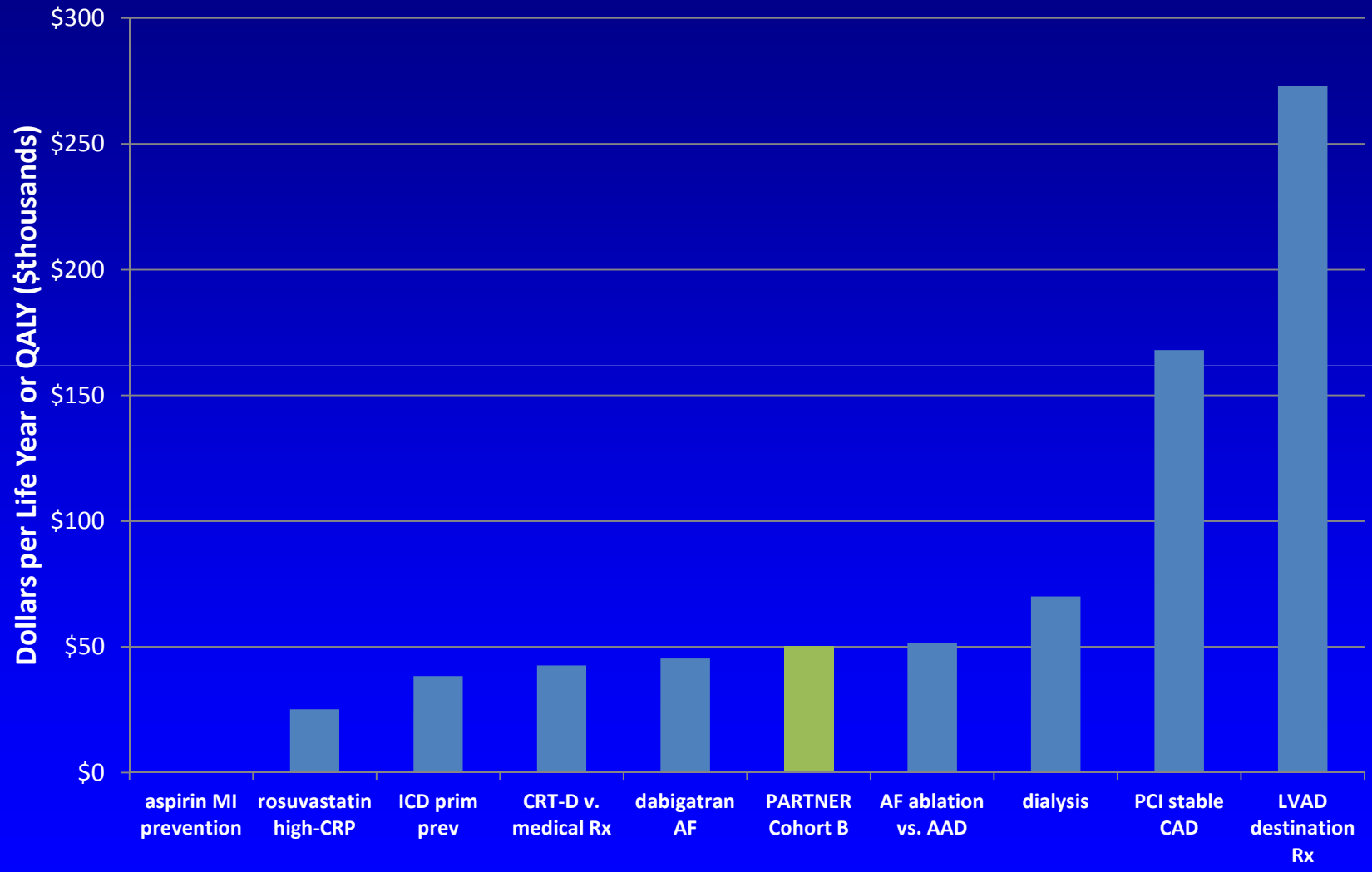


PARTNER :Quality of Life in Operable Patients

TA Subgroup / AVR



Cost-Effectiveness Estimates from PARTNER B (Inoperable patients)



(Reynolds. Circulation 2012;125:1102-9)

Cost-Effectivness of TAVI/SAVR in High Risk Patients in PARTNER A

- ***In TF TAVR /SAVR***:

  Comparable Costs

  Minor number of life-years and QALYs gained

  Cost < 50.000 USD per QALY in 74.7% of times

(Reynolds , ACC 2012)

Current Indications for TAVI

European Heart Journal (2008) **29**, 1463–1470
doi:10.1093/eurheartj/ehn183

SPECIAL ARTICLE

Transcatheter valve implantation for patients with aortic stenosis: a position statement from the European Association of Cardio-Thoracic Surgery (EACTS) and the European Society of Cardiology (ESC), in collaboration with the European Association of Percutaneous Cardiovascular Interventions (EAPCI)

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Aims To critically review the available transcatheter aortic valve implantation techniques and their results, as well as propose recommendations for their use and development.

Current Indications for TAVI

After assessment by the 'Team'

- Severe AS
- Symptomatic
- Life expectancy >1 year
- Contra indication for surgery, or
  High Risk for Surgery :
  - ✓ *Clinical judgment* +
    - – EuroScore (logistic) > 20%; STS Score>10%

  AND/OR
  - ✓ Porcelain aorta
  - ✓ History of thoracic irradiation
  - ✓ Severe thoracic deformity
  - ✓ Patent coronary by pass
  - ✓ ……

Conclusions from PARTNER :

- **"TAVI is already the standard-of-care for inoperable patients with severe aortic stenosis."**
- **"TAVI is an acceptable alternative to AVR in selected high-risk operable patients."**

(EACTS/ESC/EAPCI Position Statement, Eur Heart J, 2008; 29: 1463-1470, Eur J Cardiothorac Surg 34 (2008) 1-8, Eurointerv. 2008; 4:193-199)

TAVI Reimbursement in Europe

United Kingdom
Local negotiation

Denmark
DRG covers all costs

Germany
DRG covers all costs

Poland
Special Funds for 230 implants in 2012

France
DRG covers all costs
Restricted to 33 centers

The Netherlands
DRG covers all costs

Austria
DRG covers all costs

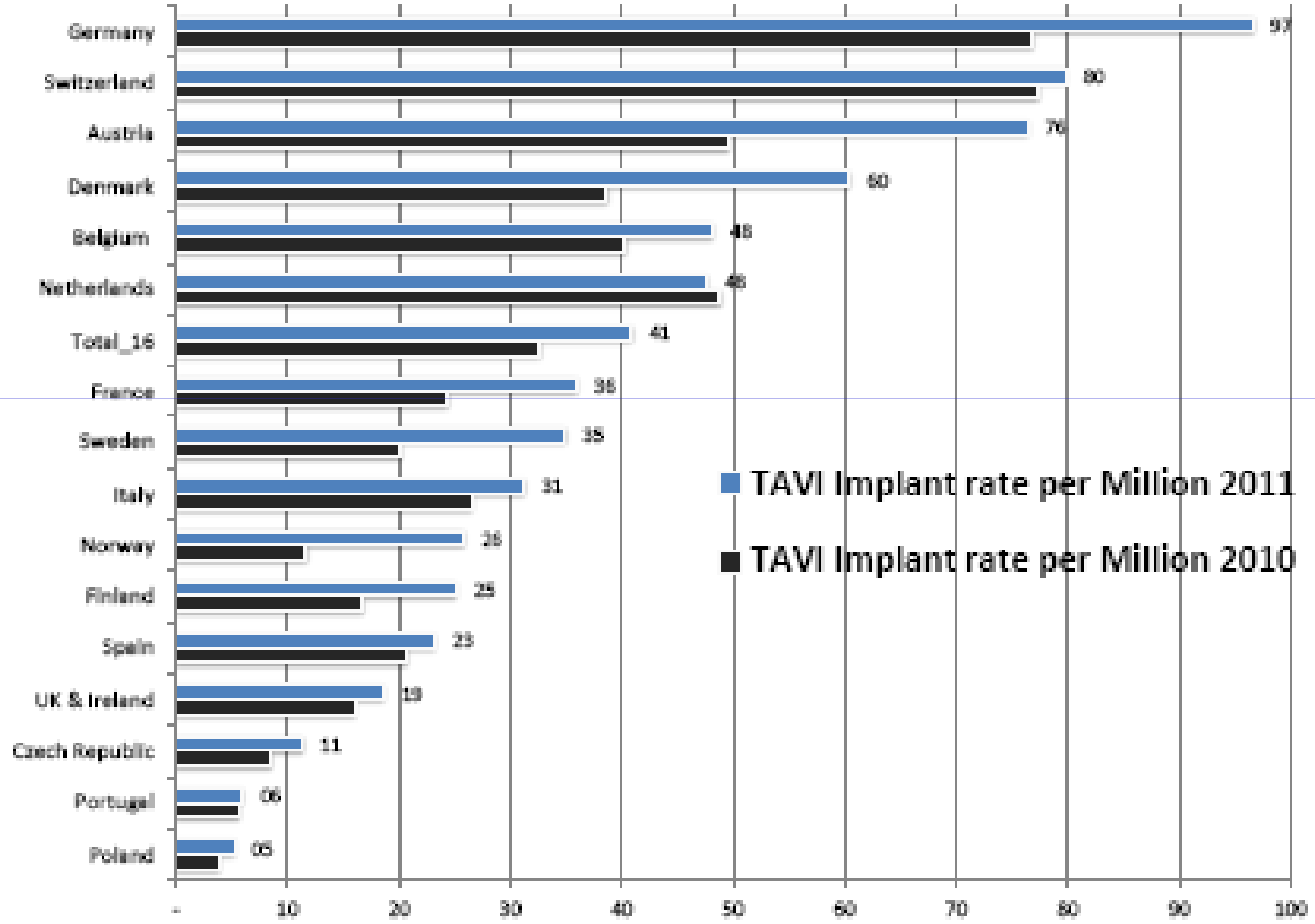
Spain
Hospital budget

Switzerland
DRG covers all costs

Italy
Lombardia, Veneto, Sicily, : DRG covers all costs
Emilia Romangna: Special Funds for 120 implants in 2012

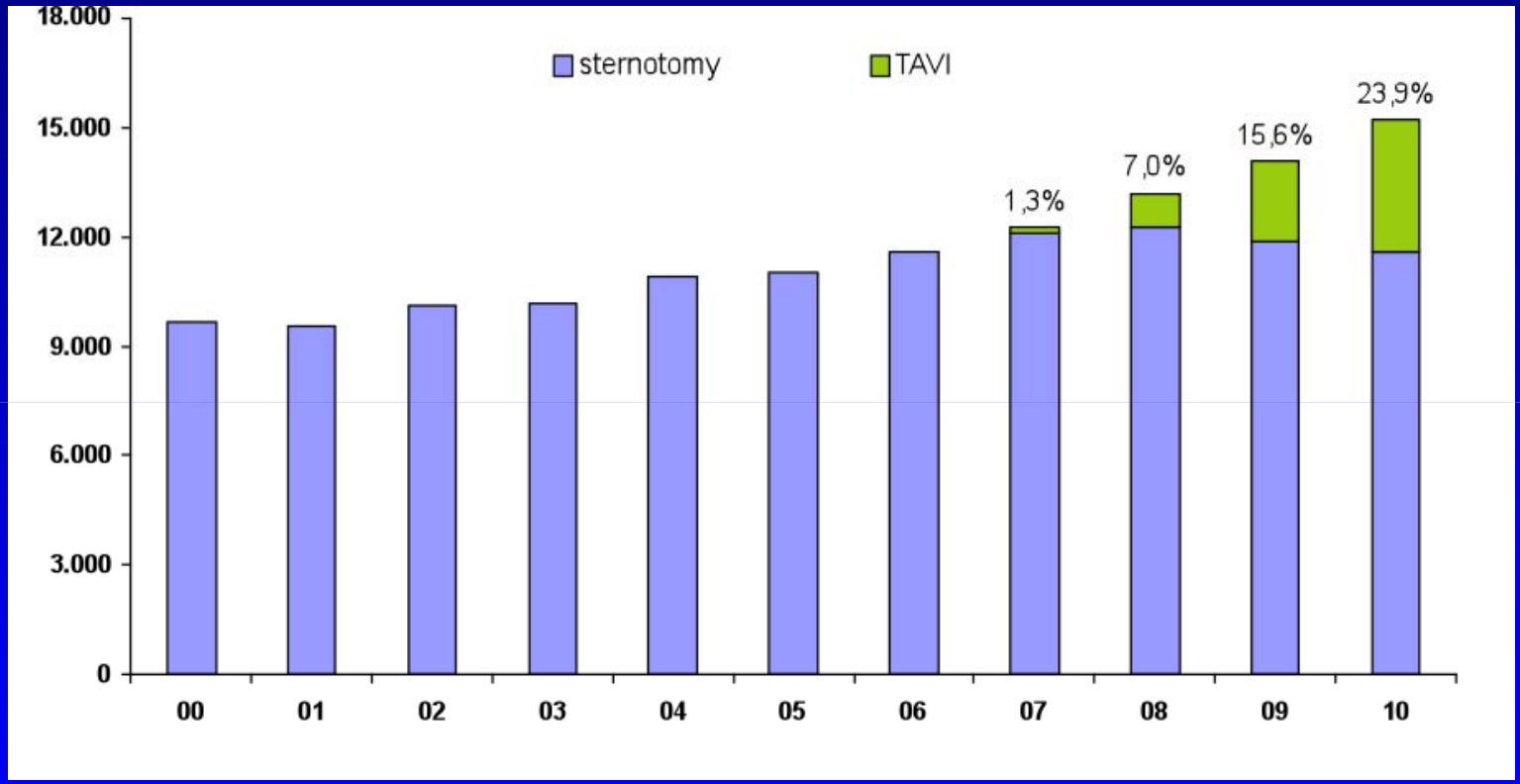
(Piazza EuroPCR 2012)

TAVI implants per million inhabitants 2010 vs. 2011



(Piazza EuroPCR 2012)

TAVI and AVR in Germany



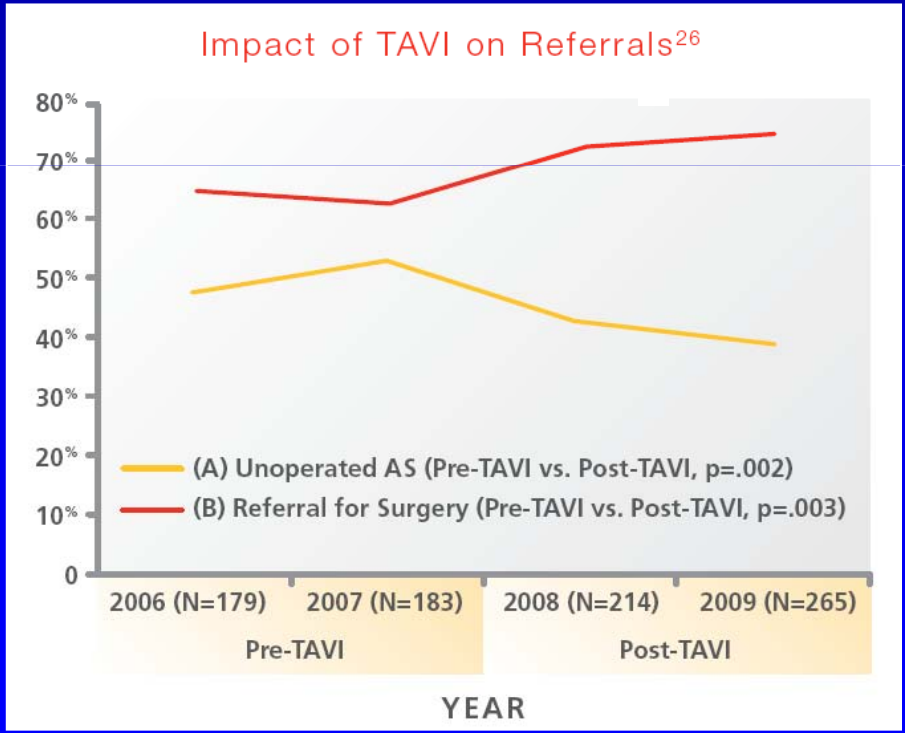
29% in 2011

(Quelle: DGTHG Statistik 2010)

Impact of TAVI on Patient Referral

Patients referred for severe and symptomatic aortic stenosis

- 362 between 2005 and 2007, 479 between 2008 and 2009
- Median age 78 years
- ***10% increase in surgical referral and interventions***

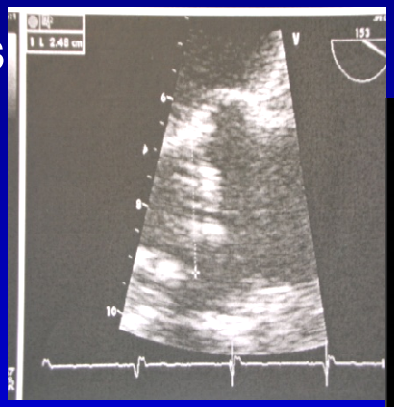


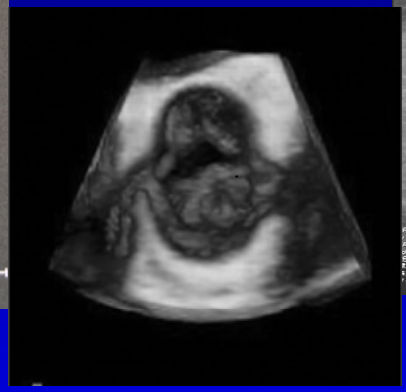
(Malaisrie et al. Eur J Cardiothorac Surg 2011;40:43-8)

- Current results and indications of TAVI
- ***What is next ?***
- The «essentials »

Multi Modality Screening before Transcatheter Aortic Valve Implantation

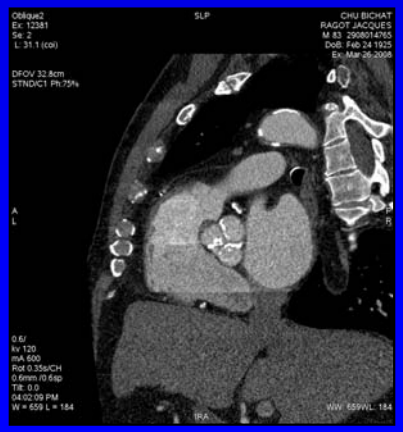
Measurement of aortic annulus



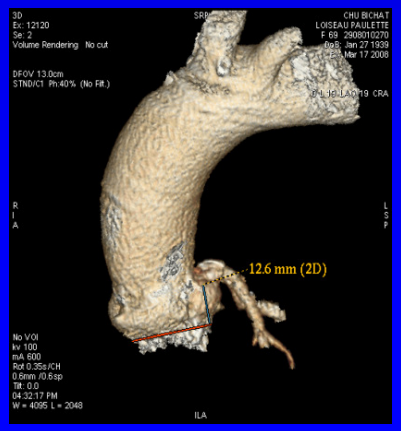


Echo/CT/MRI?

Evaluation of calcium distribution



Distance coronary – aortic valve



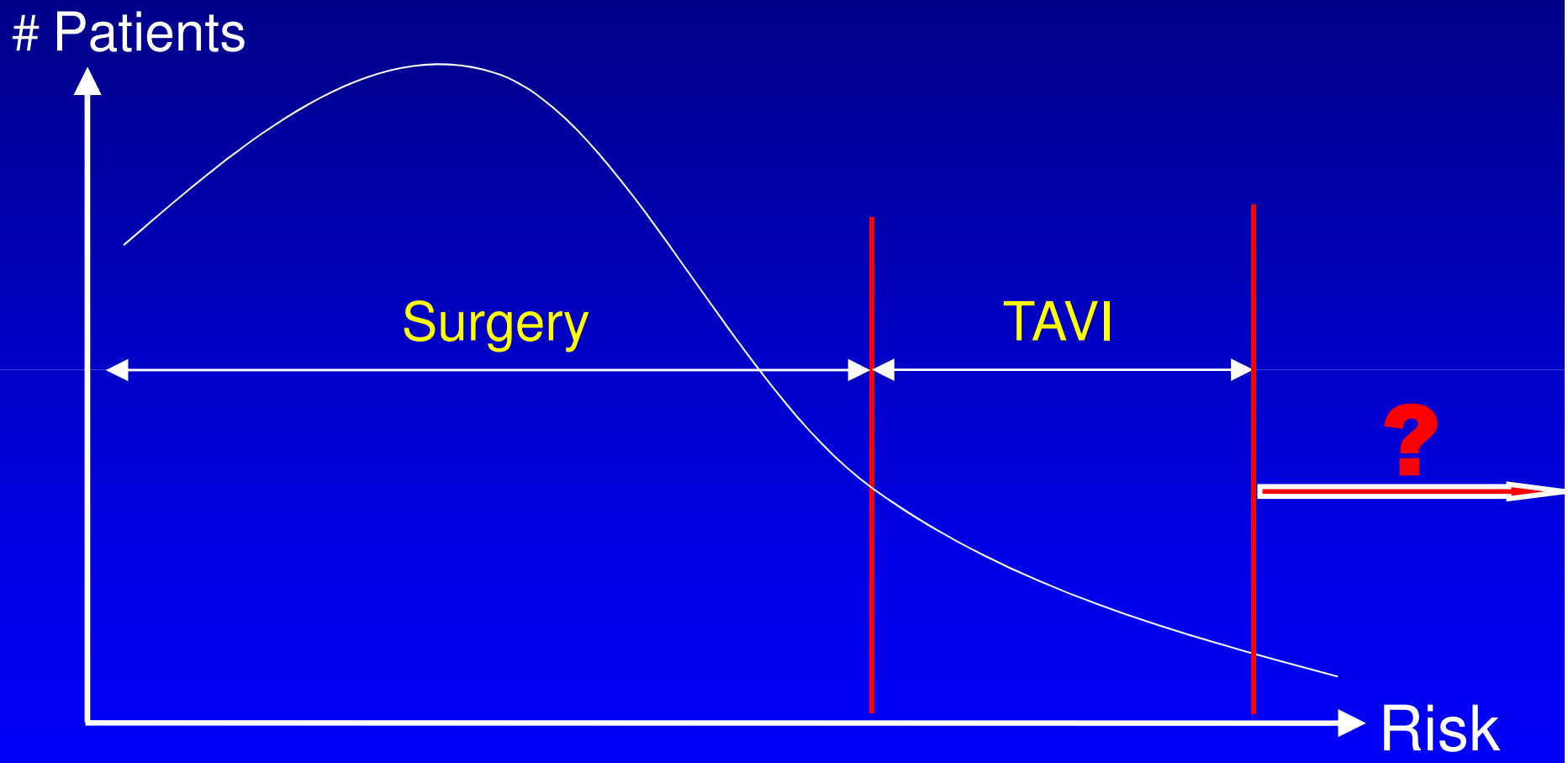
Peripheral arterial disease

"The Model" for the Prediction of the Risk of AVR @ TAVI

- Simple score based on a limited number of variables
- Specific evaluation in valve patients
- Elaborated from a broad spectrum of operative risks
- External validation in high- and low-volume centers
- Updated on a regular basis
- *Inclusion of indices of functional and/or cognitive capacities*
- Consider specific model for high-risk patients?

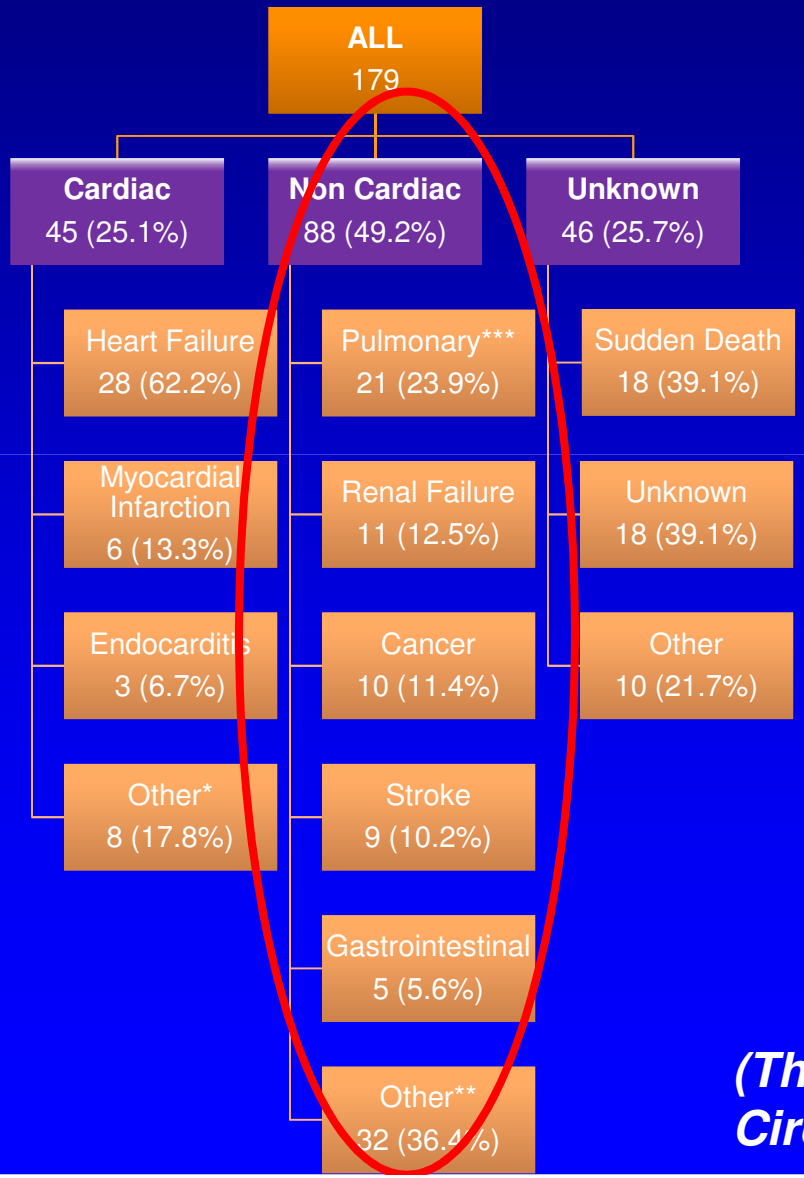
(Rosenhek et al. Eur Heart J 2011, e-pub March 15 2011)

Future Indications for TAVI



Causes of Death 30 Days to 1 Year

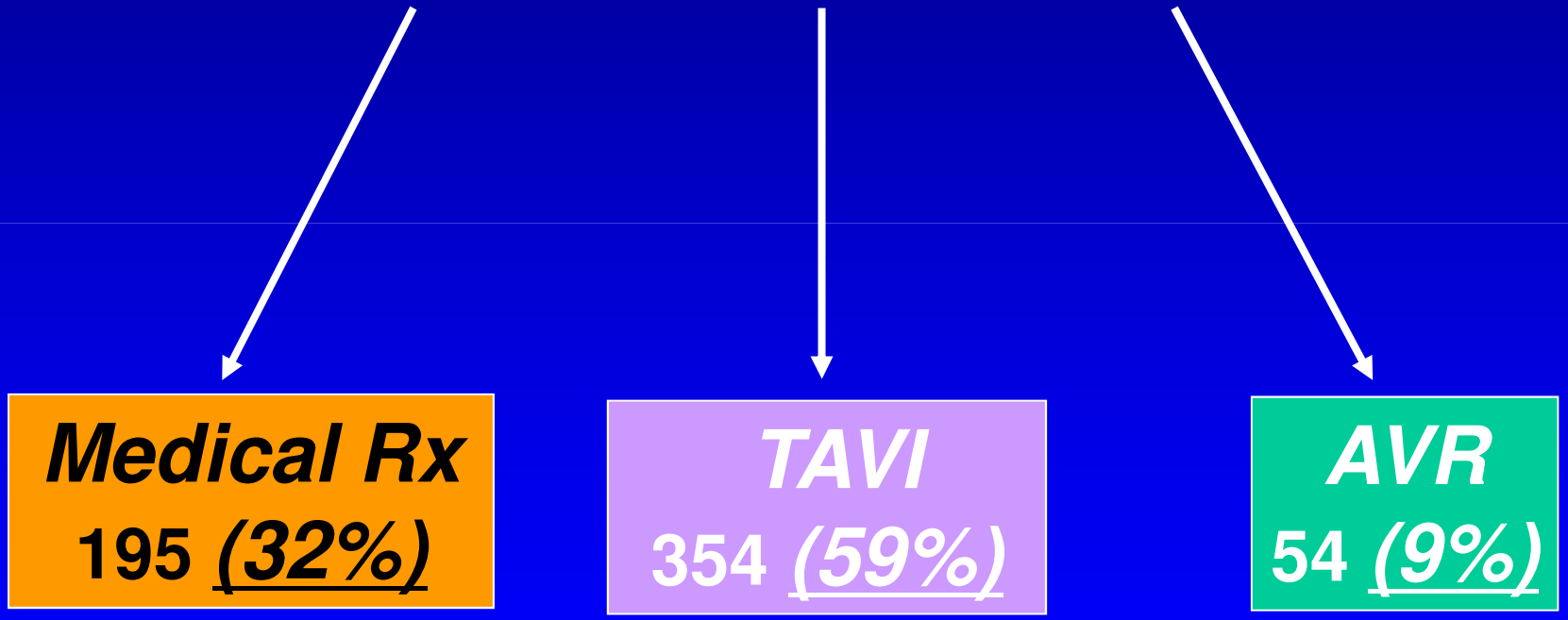
SOURCE Registry



(Thomas et al. Circulation 2011;124:425-33)

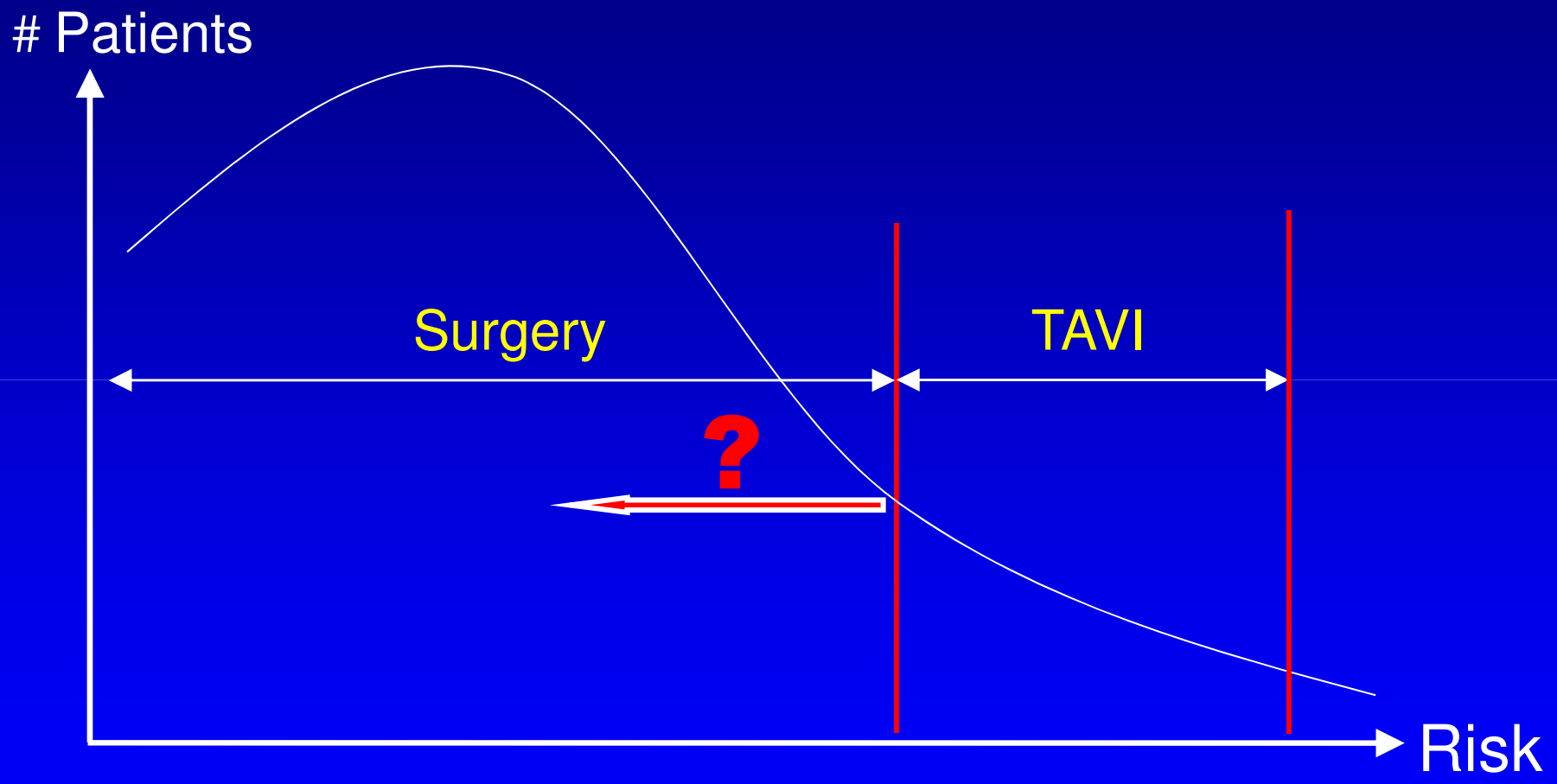
Screening in Bichat among 603 High-risk Patients Referred for TAVI

EuroSCORE ≥ 20% - STS PROM ≥ 10% / CI to AVR



« Futility >Utility »

Future Indications for TAVI



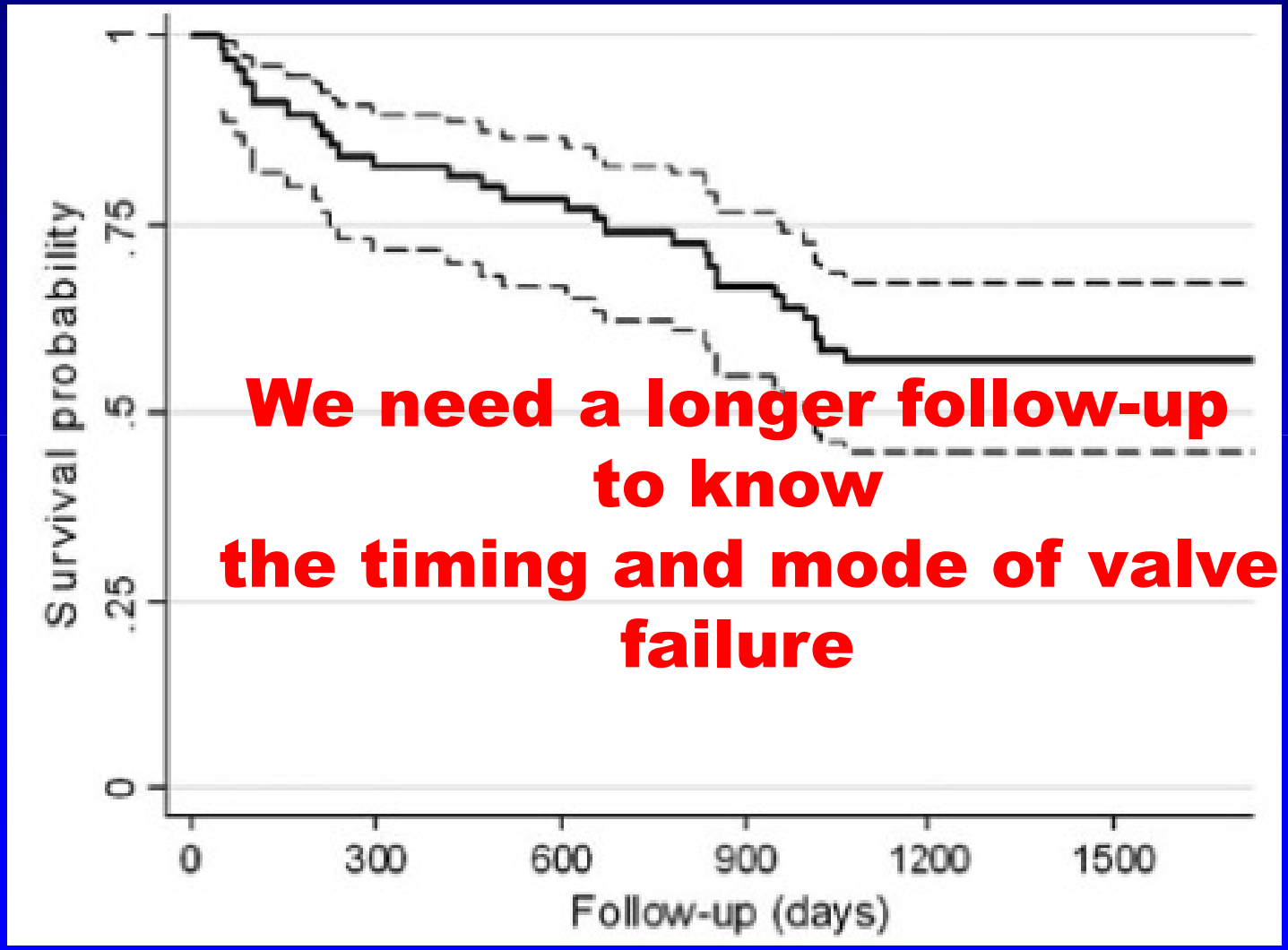
« German TAVI Registry : The 13% patient decision rate as a reason to perform TAVI is alarming »

Zahn et al. Eur Heart J 2011,32;198-204

« If you don't come up with good evidence people will still continue to expand the indication »

P Kappetein Eur Heart J ,Jan 2011

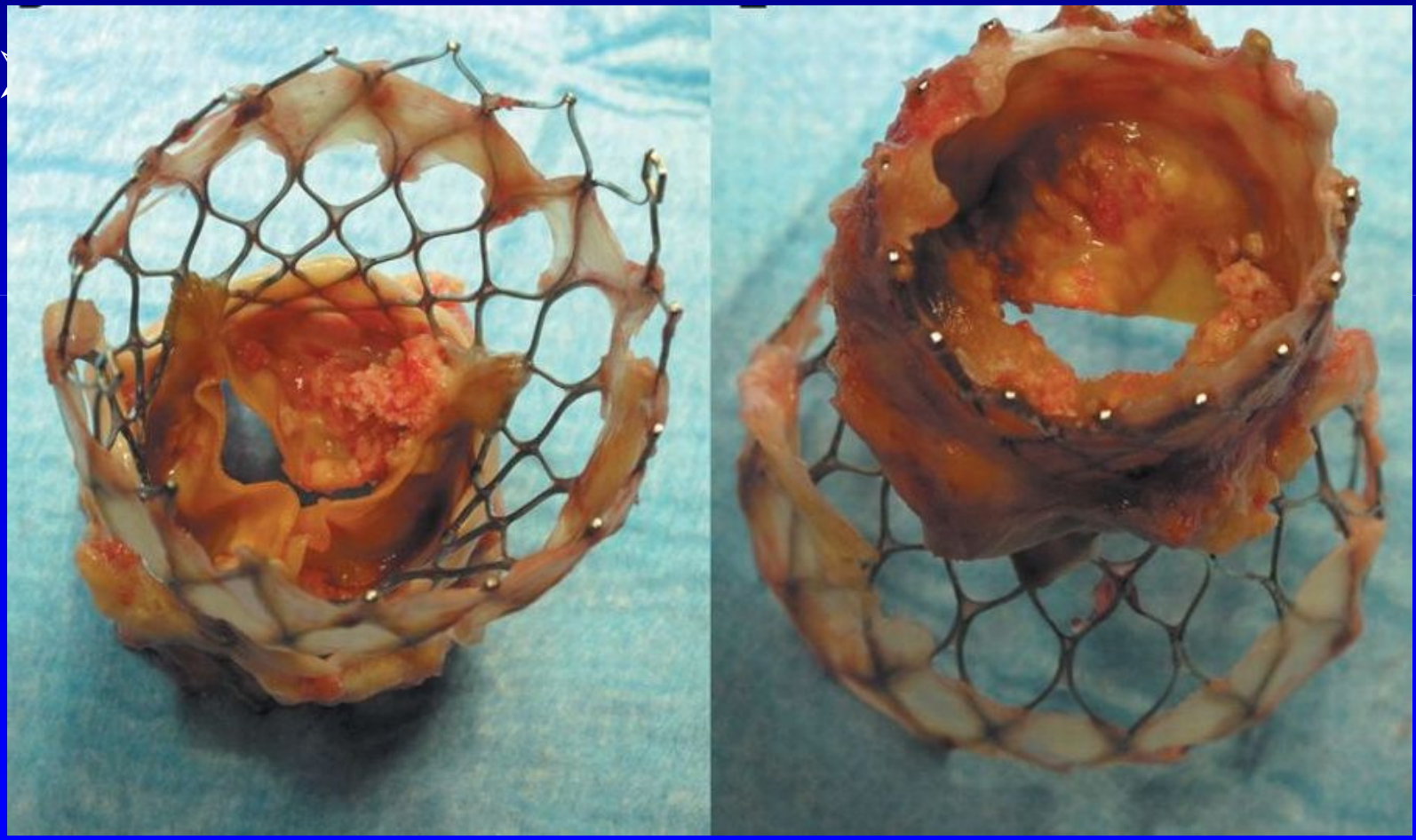
Follow-up after TAVI



We need a longer follow-up to know the timing and mode of valve failure

(Gurvitch R et al. Circulation 2010;122:1319-1327)

Early Calcific Degeneration of a CoreValve Bioprosthesis (5years)



(Ong Eur Heart J Online August 2011)

SURTAVI

Patient referred for severe aortic stenosis
with indication for aortic valve replacement

'All-comers' trial

1. Documentation of risk scores (STS 4 to 8)
2. ***Clinical judgment based on 'State of the Art' by the Heart Team***

Surgical AVR registry

Low risk

Moderate-High risk

Randomise (1100pts)

TAVI (transfemoral, subclavian, retroperitoneal, transapical) vs. SAVR

TAVI registry

Inoperable

Primary end-point :All cause death and major stroke at 24months

« Revisiting Exclusion Criteria »

Coronary Artery Disease

Decision based on

- Symptoms, clinical presentation
- Location of lesions
- Myocardium at risk
- Suitability for PCI

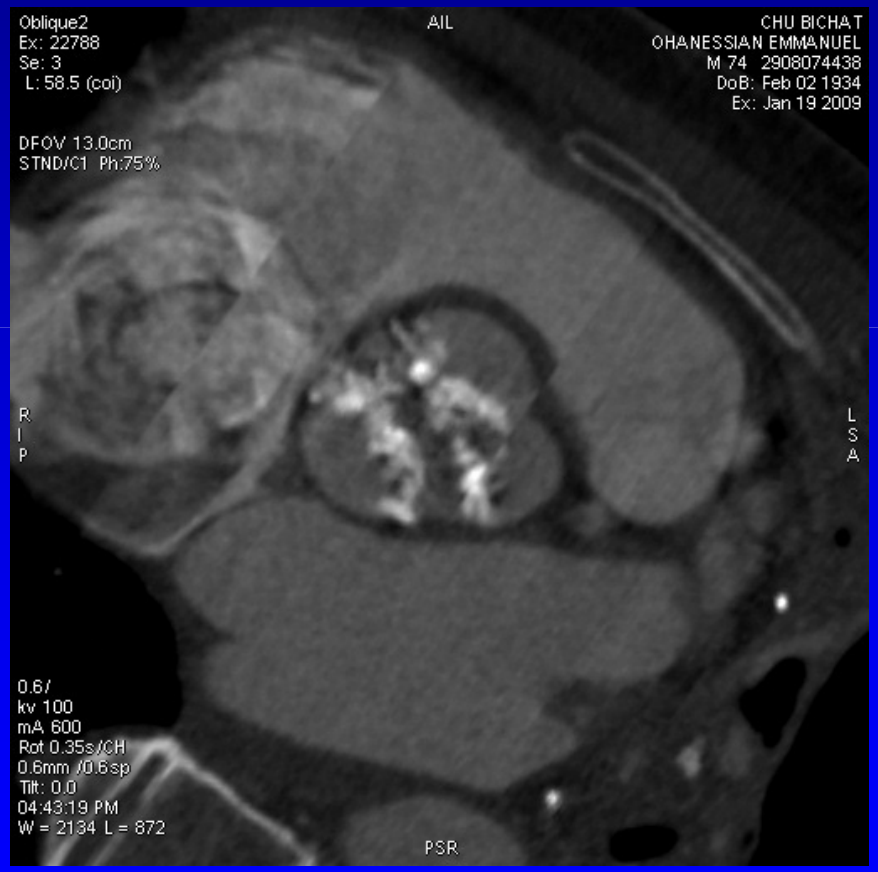
Options

- TAVI + medical Rx
- PCI pre > per TAVI
- Reconsideration of surgery
- Give up any intervention

ACTIVATION Trial will start soon

« Revisiting Exclusion Criteria »

Bicuspid valve

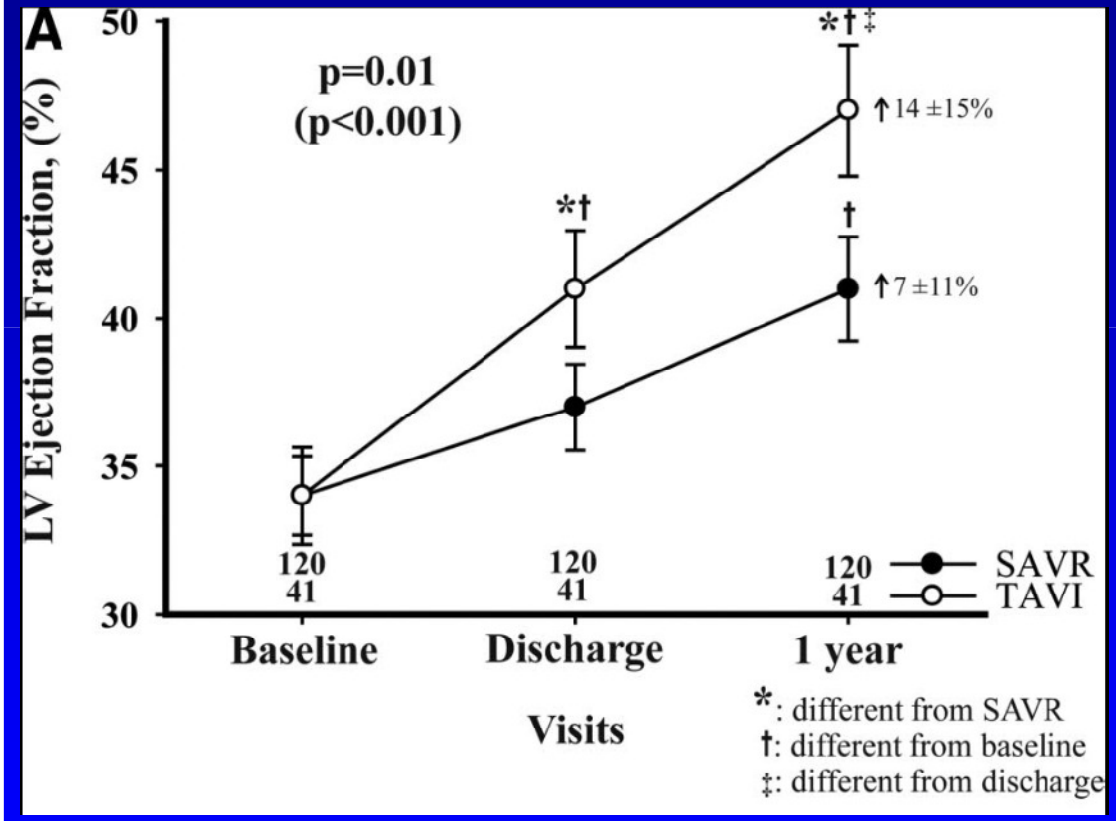


Case by case decision

- annulus: shape/diameter
- amount/distribution of Ca
- specific valve design?

« Revisiting Exclusion Criteria »

Left Ventricular Dysfunction



- BAV as a Bridge ?
- TAVI ?
- Cardiac assist for pts in Shock ?

(Clavel. Circulation 2010;122:1928-36.)

Trends towards Procedural Simplification

	2002	2012	In the Future
Delivery Cath	25/24/22F	16F	Down
Surgical cut-down	Yes	No	Full percutaneous
Balloon dilatation	yes	yes	No with MCV?
Cardiac Support	Yes	No	But available
Anesthesia	Full	Local	But present

Improvement in Safety

- ***Stroke*** :

  Protection devices; antithrombotic/antiarrhytmic therapy

- ***Aortic Regurgitation*** :

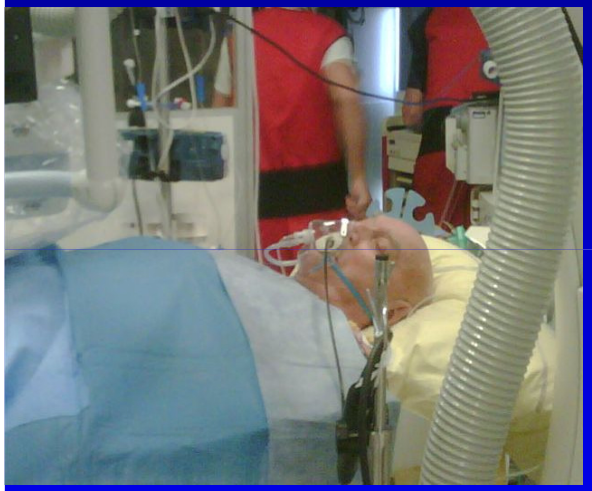
  Valve sizing and positionning; quantification;

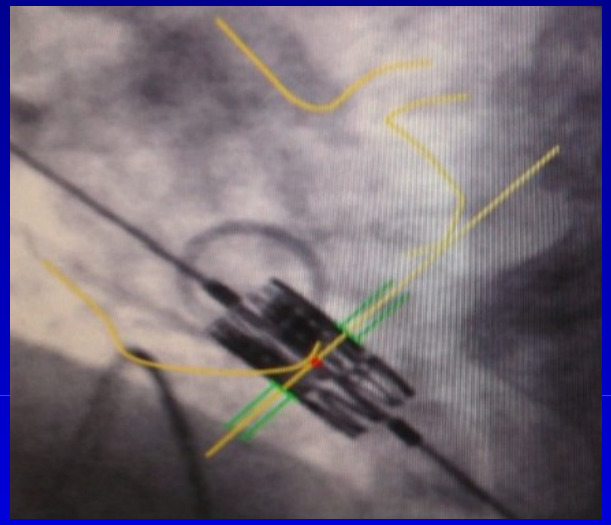
  valve design

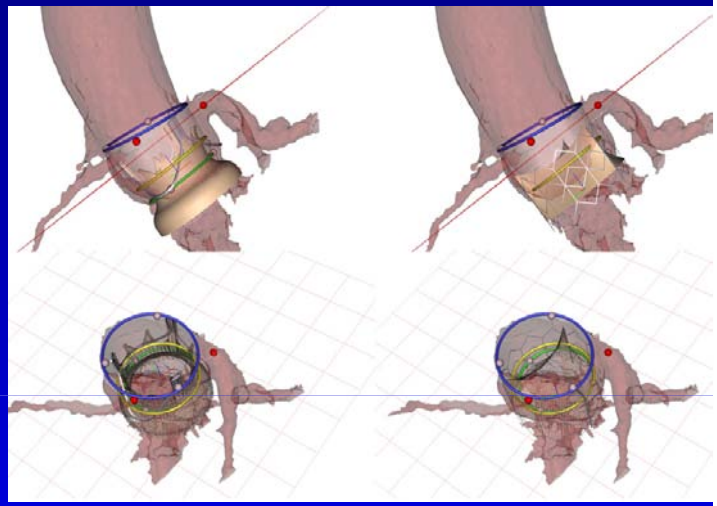
- ***Vascular complications*** :

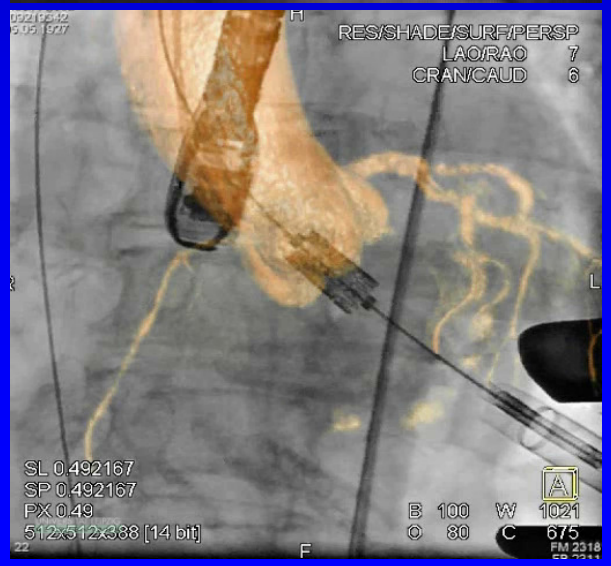
  Assesment of peripheral vasculature ; tailoring the approach;
  devices profile

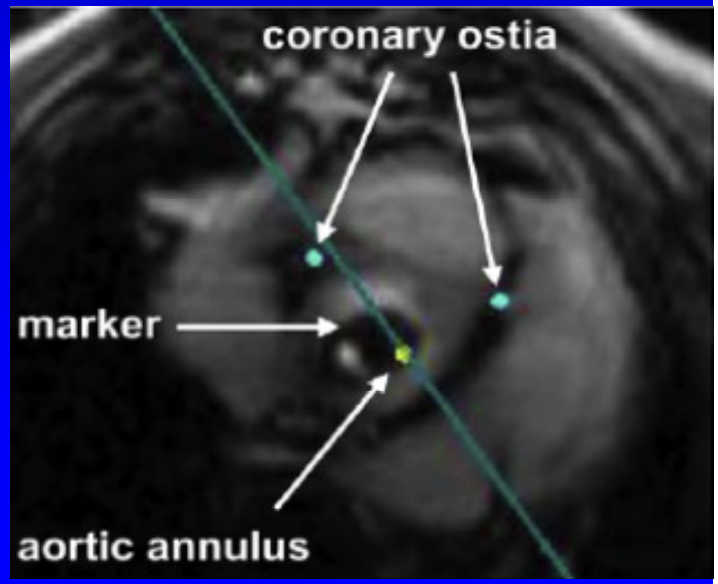
New Systems for Navigation and Positioning during TAVI





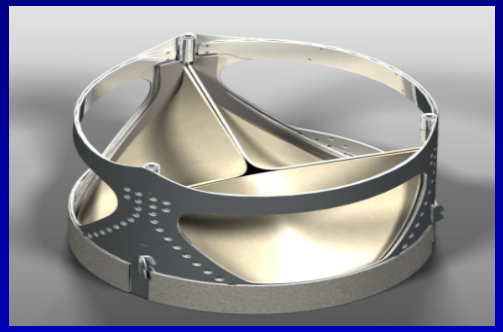






New Prosthesis Design





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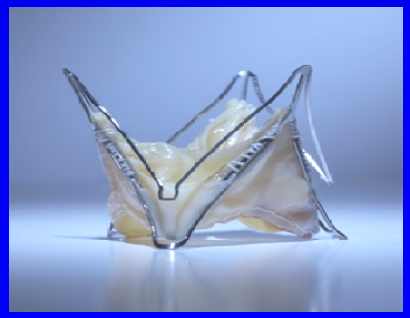
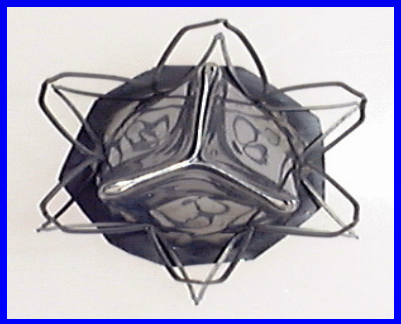
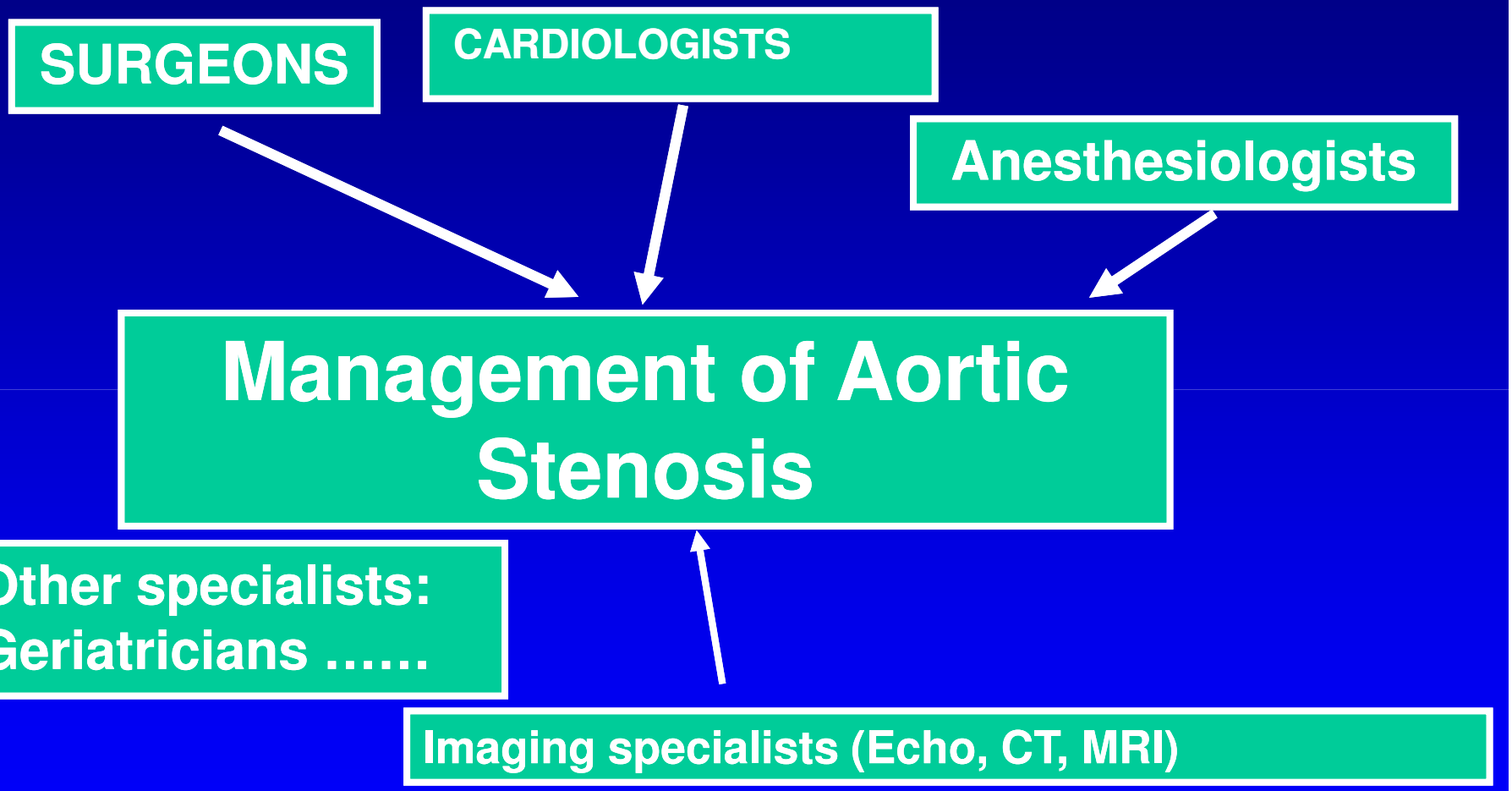




- Current results and indications of TAVI
- What is next ?
- ***The « essentials »***

The « Heart Team »



With expertise in the treatment of valve disease

EACTS/ESC/EAPCI Position Statement, Eur Heart J, 2008; 29: 1463-1470,
Eur J Cardiothorac Surg 34 (2008) 1-8

“ When surgery and medicine collaborate rather than compete, patients are the ultimate winners”

S.E. Nissen. J Am Coll Cardiol 2006

Careful Training for Percutaneous Interventions

- Procedural success in registries: TAVI > 95%
- Training for individuals and teams
- Firstly disease - then technique - finally device-oriented
- Simulators - proctoring - post graduate courses
- By companies – scientific societies

Evaluation is Key

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EXPEDITED PUBLICATIONS

Long-Term Outcomes After Transcatheter Aortic Valve Implantation in High-Risk Patients With Severe Aortic Stenosis

The U.K. TAVI (United Kingdom Transcatheter Aortic Valve Implantation) Registry

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London, Birmingham, Bristol, Middlesbrough, Manchester, Leicester, Brighton, Leeds, and Southampton, United Kingdom

Objectives The objective was to define the characteristics of a real-world patient population treated with transcatheter aortic valve implantation (TAVI), regardless of technology or access route, and to evaluate their clinical outcome over the mid to long term.

Background Although a substantial body of data exists in relation to early clinical outcomes after TAVI, there are few data on outcomes beyond 1 year in any notable number of patients.

Methods The U.K. TAVI (United Kingdom Transcatheter Aortic Valve Implantation) Registry was established to report outcomes of all TAVI procedures performed within the United Kingdom. Data were collected prospectively on 870 patients undergoing 877 TAVI procedures up until December 31, 2009. Mortality tracking was achieved in 100% of patients with mortality status reported as of December 2010.

Results Survival at 30 days was 92.9%, and it was 78.6% and 73.7% at 1 year and 2 years, respectively. There was a marked attrition in survival between 30 days and 1 year. In a univariate model, survival was significantly adversely affected by renal dysfunction, the presence of coronary artery disease, and a nontransfemoral approach; whereas left ventricular function (ejection fraction <30%), the presence of moderate/severe aortic regurgitation, and chronic obstructive pulmonary disease remained the only independent predictors of mortality in the multivariate model.

Conclusions Midterm to long-term survival after TAVI was encouraging in this high-risk patient population, although a substantial proportion of patients died within the first year. (J Am Coll Cardiol 2011;58:2130–8) © 2011 by the American College of Cardiology Foundation

From the *Royal Brompton and Harefield National Health Service (NHS) Foundation Trust, London, United Kingdom; †University Hospitals Birmingham NHS Foundation Trust, Birmingham, United Kingdom; ‡James Cook University Hospital, Middlesbrough, United Kingdom; §University Hospital of South Manchester NHS Foundation Trust, Manchester, United Kingdom; ‖Bristol Heart Institute, Bristol, United Kingdom; ¶Guy's and St. Thomas' NHS Foundation Trust, London, United Kingdom; #University Hospitals Leicester NHS Trust, Leicester, United Kingdom; **King's College Hospital (King's Health Partners), London, United Kingdom; ††Sussex Cardiac Centre, Brighton and Sussex University Hospitals, Brighton, United Kingdom; ‡‡Leeds General Infirmary, Leeds, United Kingdom; §§St. Georges Hospital London, London, United Kingdom; ‖‖Central Cardiac Audit Database, London, United Kingdom; ¶¶East Midlands Specialised Commissioning Group, Leicester, United Kingdom; ##Southampton University Hospitals NHS Trust, Southampton, United Kingdom; and the ***University College Hospital London NHS Foundation Trust, London, United Kingdom. Dr. Moat is a consultant to Medtronic; and has received honoraria from Edwards LifeSciences and Abbott. Dr. Young is a proctor for Edwards. Dr. Thomas is a consultant and proctor for Edwards. Dr. Kovac is a consultant to and proctor for Medtronic; and a proctor for Edwards

Augusto D. Pichard, M.D., Joseph E. Bavaria, M.D., Howa
John L. Petersen, M.D., Jodi J. Akin, M.S., William N
and Stuart Pocock, Ph.D., for the PAR[illegible] Trial Investigators

Circulation
JOURNAL OF THE AMERICAN HEART ASSOCIATION

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Percutaneous Transarterial Aortic Valve Replacement in Selected High-Risk Patients With Aortic Stenosis

John G. Webb, Sanjeevan Pasupati, Karin Humphries, Christopher Thompson, Lukas Altwegg, Robert Moss, Ajay Sinhal, Ronald G. Carere, Brad Munt, Donald Ricci, Jian Ye, Anson Cheung and Sam V. Lichtenstein

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The online version of this article, along with updated information and services, is located on the World Wide Web at:
http://circ.ahajournals.org/content/116/7/755

Conclusions

- Expert centers in VHD, team approach, careful training, good imaging, and careful evaluation, are, and will remain, essential

- Today, TAVI is only indicated in inoperable or high risk patients with severe AS and severe symptoms

Further research is needed on risk stratification models for AVR and TAVI - improvement of safety and ease of the procedure- technology- evaluation in comparison with surgery

Then indications will be expanded to lower risk patients

“We are still learning a lot, but I can see a great potential”

adapted from Andreas Gruntzig

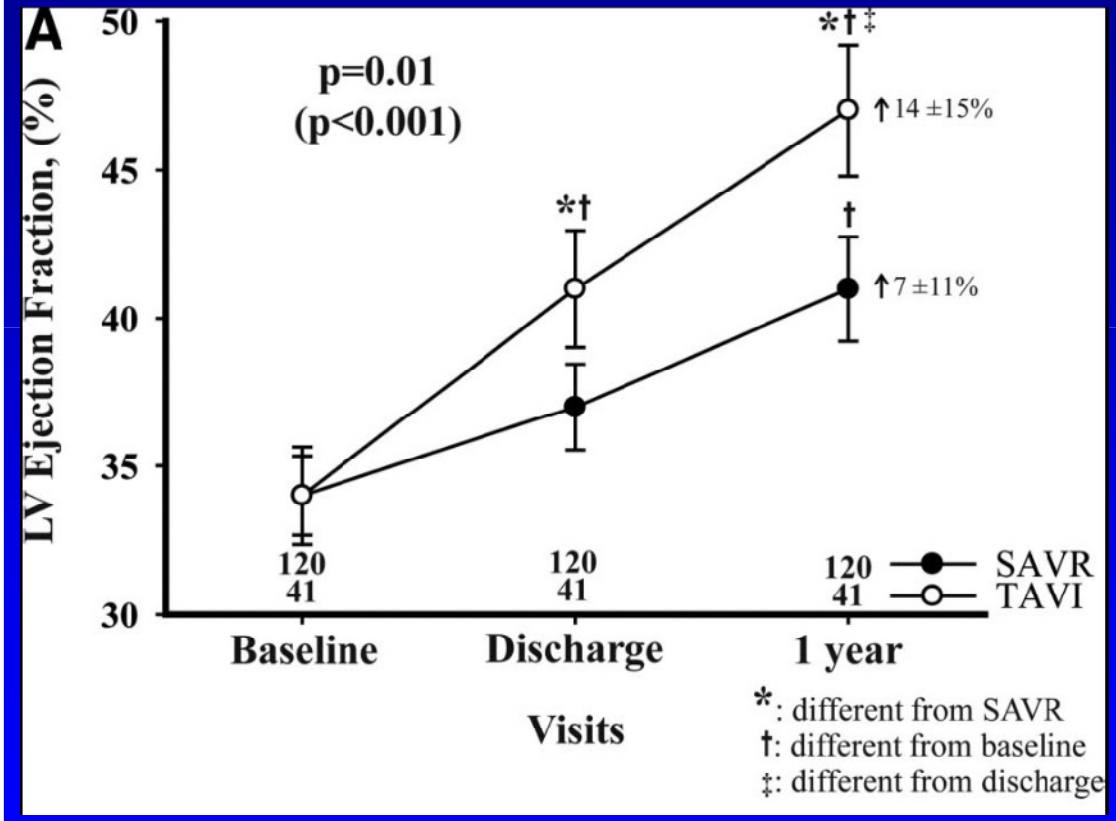
“ Transcatheter valve interventions are the natural evolution of surgery”

Michael Mack

- STOP

« Revisiting Exclusion Criteria »

Left Ventricular Dysfunction



- BAV as a Bridge ?
- TAVI ?
- Cardiac assist for pts in Shock ?

(Clavel. Circulation 2010;122:1928-36.)

« Revisiting Exclusion Criteria »

Aortic Regurgitation

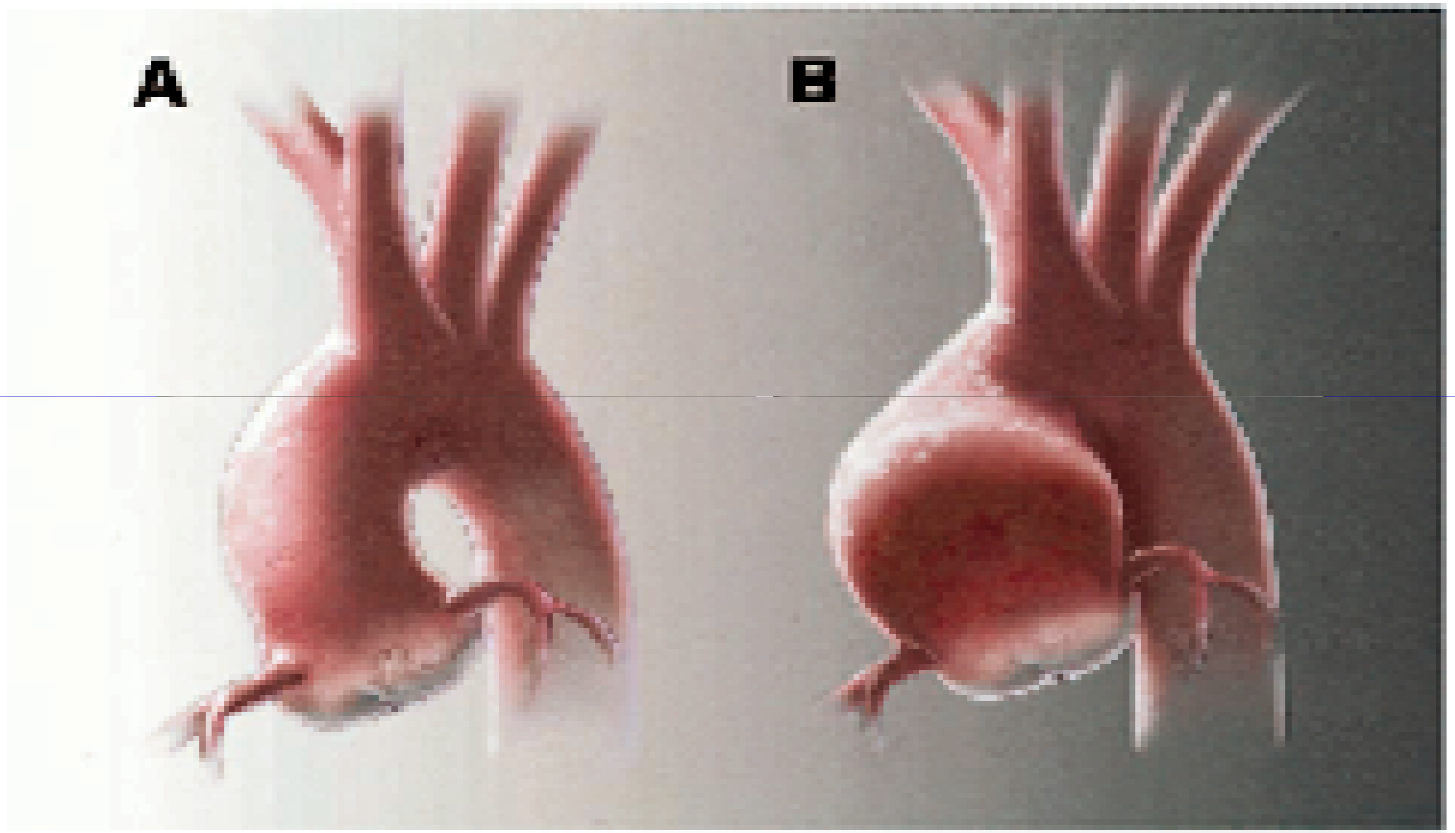


Figure 2. Normal aortic root (A) and dilated aortic root (B) characteristic of patients with BAV.

(Ducrocq. J Thorac Cardiovasc Surg 2010)

Conclusion

- ***Percutaneous mitral commissurotomy*** is here to stay for as long as MS and rheumatic valve disease.
- The current results of ***the Edge to Edge technique*** suggest that it may be useful in selected high risk patients. Long- term FU and RCT in secondary MR are needed.
- The results with ***coronary sinus annuloplasty*** are disappointing
- In the future a combination of techniques for percutaneous mitral valve repair ,and evaluation of new devices aimed at reproducing surgical techniques is expected.
- Preliminary data on ***transcatheter treatment after surgical failure*** show that it is feasible. This new option may have important clinical implications.

« We need to be sure that we do not sacrifice proven long-term effectiveness for short-term issues, such as convenience, invasiveness, or irreversible procedural complications »

Catherine Otto NEJM 2011

Evaluation of Percutaneous Valve Intervention

- In centres performing TAVI, multidisciplinary meetings should be held to discuss indications, procedural techniques, and case outcomes. Hospitals should keep proof of close medico-surgical collaboration and maintain a log of all patients referred to TAVI for continuous evaluation of the programme

(EACTS/ESC/EAPCI Position Statement, Eur Heart J, 2008; 29: 1463-1470, Eur J Cardiothorac Surg 34 (2008) 1-8, Eurointerv. 2008; 4:193-199)

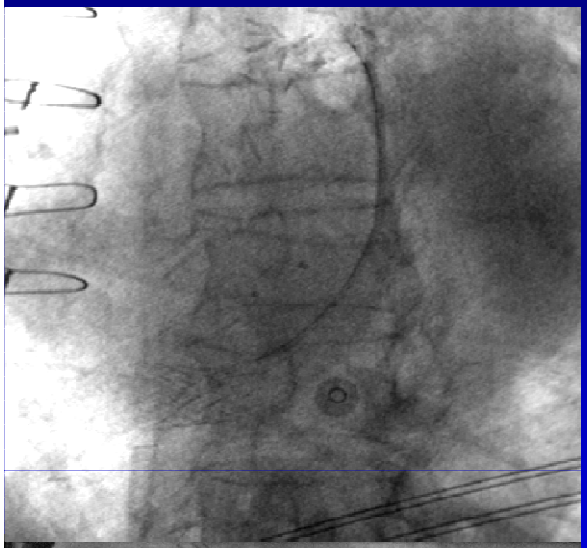
Surgery and Interventional Cardiology are Complementary

A patient's story...

- C….47 years old
- 1986 Percutaneous Mitral Commissurotomy
- 1998 re –PMC
- 2001 AVR (Stentless valve) for AS
- 2010 Severe AR; MVA= 1.8cm²
  cerebral tumor requiring surgery :
  « Valve in a Valve «

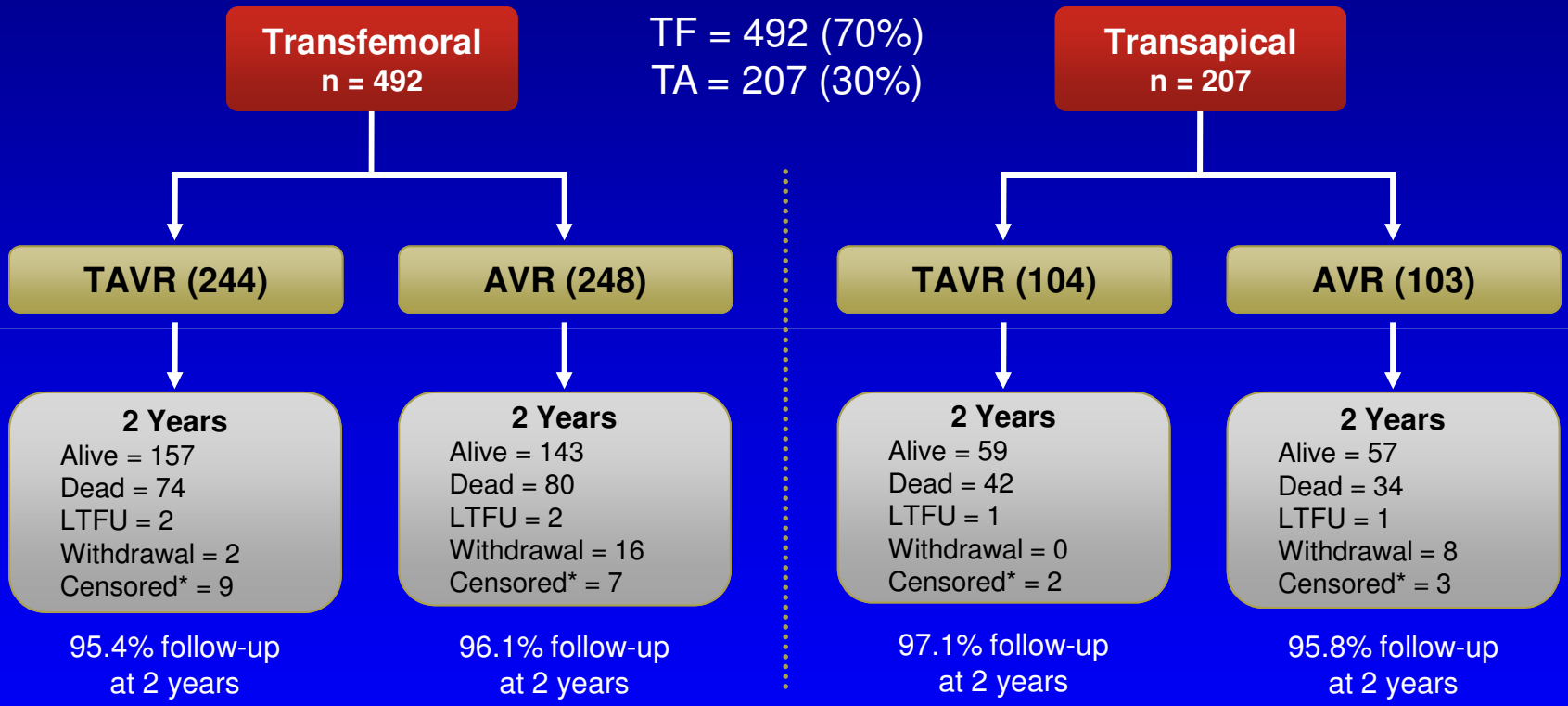
During 25 years she had 3 pregnancies and never took Coumadin ….

Combining Interventions



Study Flow

Randomized = 699 patients



*Censored = Patient is alive at last contact but no information available within follow-up window

Baseline Patient Characteristics

Demographics (ITT)

Characteristic	TAVR (n = 348)		AVR (n = 351)		
	n		n		p-value
Age – years (Mean ± SD)	***348***	***83.6 ± 6.8***	***349***	***84.5 ± 6.4***	***0.07***
Male	***201***	***57.8%***	***198***	***56.7%***	***0.82***
STS Score (Mean ± SD)	***347***	***11.8 ± 3.3***	***349***	***11.7 ± 3.5***	***0.61***
NYHA Class III or IV	***328***	***94.3%***	***328***	***94.0%***	***0.79***

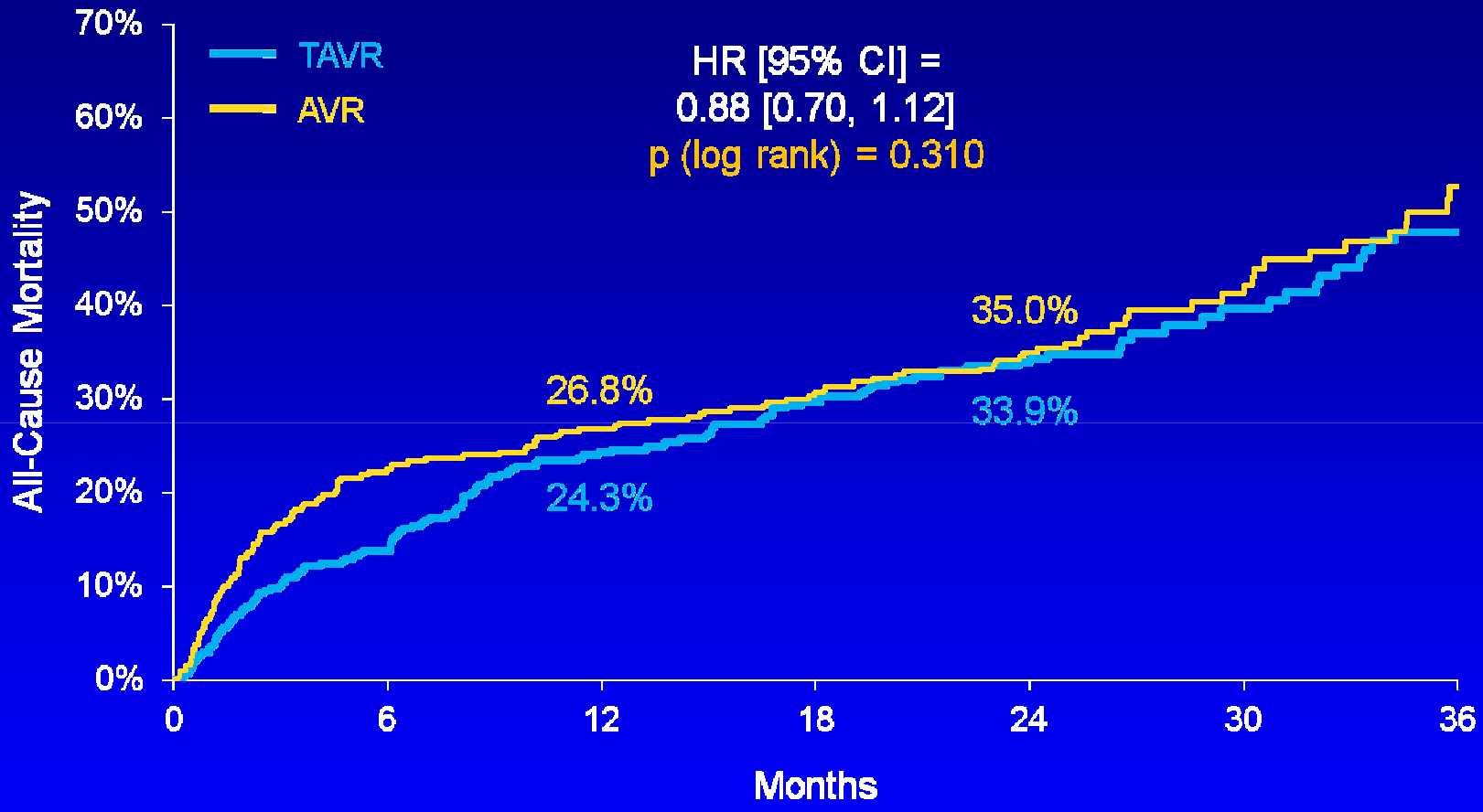
Baseline Patient Characteristics
Vasculopathy (ITT)

Characteristic	TAVR (n = 348)		AVR (n = 351)		
	n	%	n	%	p-value
CAD	***260***	***74.7***	***266***	***76.2***	***0.66***
Previous MI	***92***	***26.5***	***103***	***29.8***	***0.35***
Previous CABG	***148***	***42.5***	***152***	***43.6***	***0.82***
Previous PCI	***116***	***33.5***	***110***	***31.6***	***0.63***
Cerebrovascular disease	***96***	***29.4***	***87***	***26.8***	***0.49***
Peripheral vascular disease	***149***	***43.2***	***142***	***41.6***	***0.70***

Baseline Patient Characteristics
Other Co-morbidities (ITT)

Characteristic	TAVR (n = 348)		AVR (n = 351)		
	n	%	n	%	p-value
COPD – Any	***152***	***43.7***	***151***	***43.0***	***0.88***
COPD – O_2 dependent	***38***	***17.3***	***38***	***16.6***	***0.90***
Creatinine >2mg/dL	***37***	***10.8***	***22***	***6.4***	***0.04***
Atrial fibrillation	***81***	***40.7***	***75***	***43.6***	***0.60***
Pacemaker implant	***69***	***19.8***	***76***	***21.8***	***0.58***
Pulmonary hypertension	***126***	***42.7***	***111***	***36.8***	***0.15***

All-Cause Mortality (ITT)

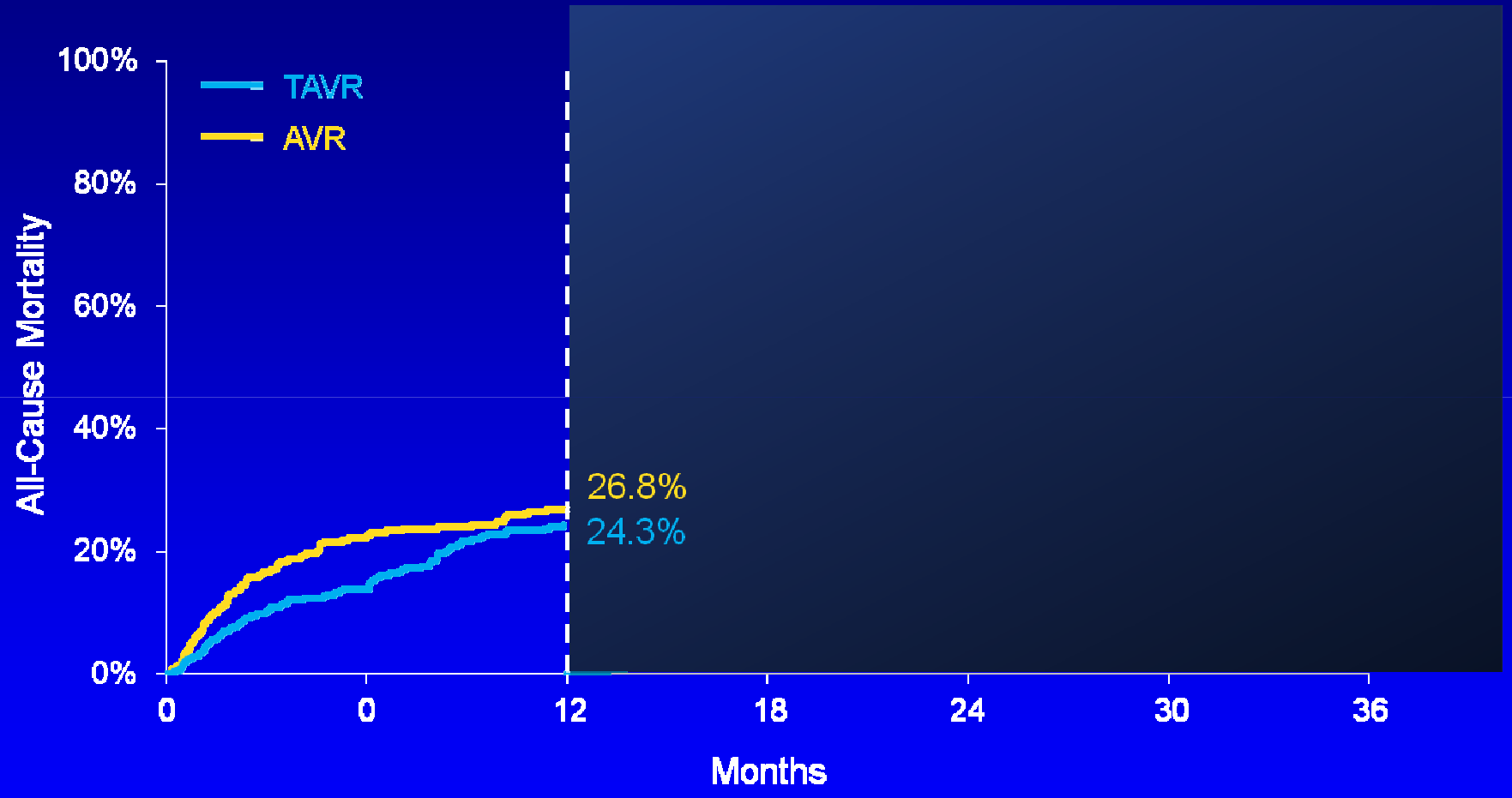


Numbers at Risk

TAVR	348	298	260	234	172	70	31
AVR	351	252	236	217	165	65	32

All-Cause Mortality (ITT)

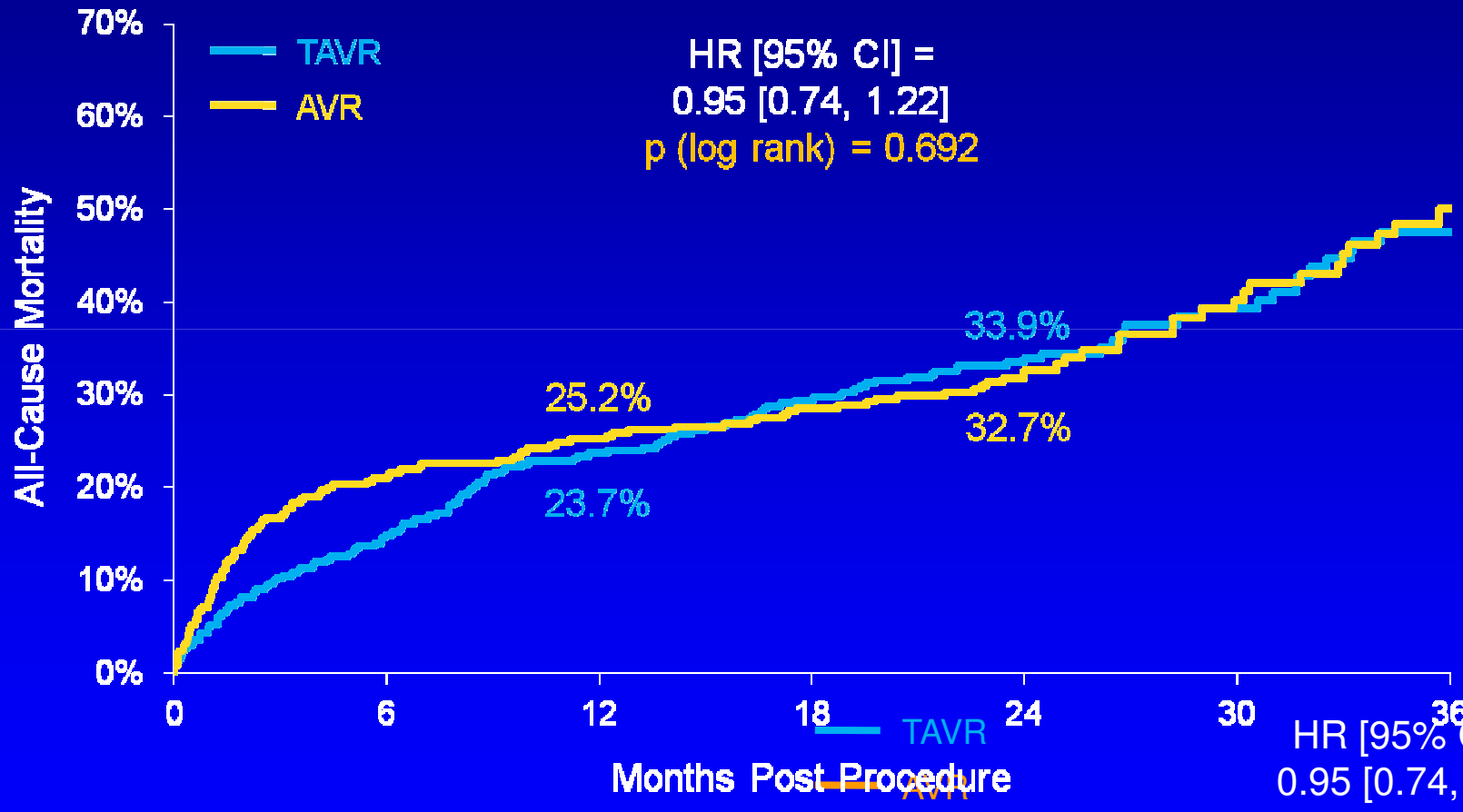
Landmark Analysis



Numbers at Risk

TAVR	348	298	260	234	172	70	31
AVR	351	252	236	217	165	65	32

All-Cause Mortality (AT)



HR [95% CI] =
0.95 [0.74, 1.22]
p (log rank) = 0.692

Numbers at Risk

TAVR	344	291	259	232	155	70	29
AVR	313	243	229	211	143	63	28

All-Cause Mortality at 1 and 2 Years Patient Subgroups

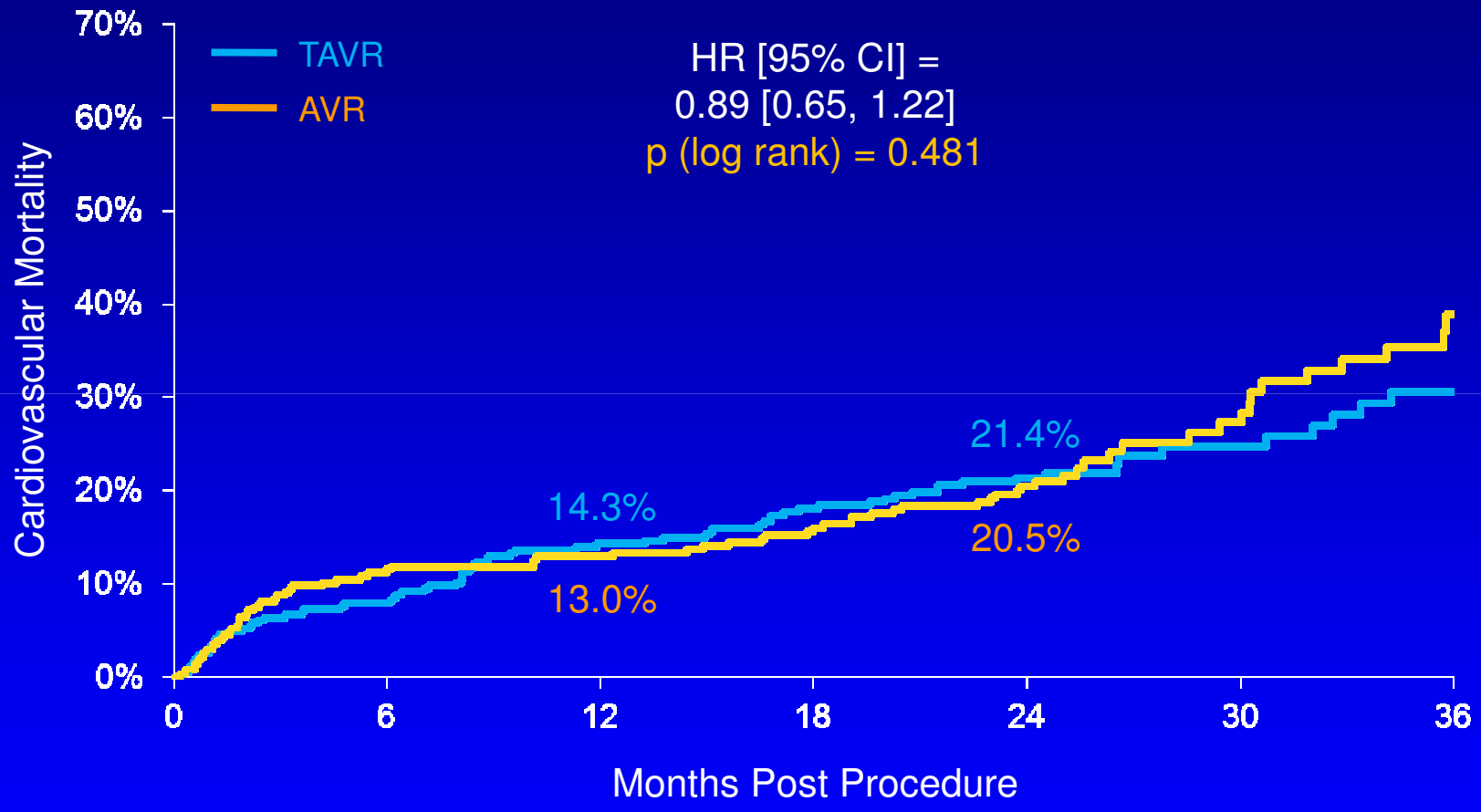
All-Cause Mortality at 1 Year

	All Patients no. of patients (%)			TF Patients no. of patients (%)			TA Patients no. of patients (%)		
	TAVR	AVR	p-value	TAVR	AVR	p-value	TAVR	AVR	p-value
ITT	84 (24.3)	89 (26.8)	0.45	54 (22.2)	62 (26.4)	0.29	30 (29.0)	27 (27.9)	0.85
AT	81 (23.7)	78 (25.2)	0.65	51 (21.4)	55 (25.2)	0.33	30 (29.1)	23 (25.3)	0.55

All-Cause Mortality at 2 Years

	All Patients no. of patients (%)			TF Patients no. of patients (%)			TA Patients no. of patients (%)		
	TAVR	AVR	p-value	TAVR	AVR	p-value	TAVR	AVR	p-value
ITT	116 (33.9)	114 (35.0)	0.78	74 (30.9)	80 (34.6)	0.38	42 (41.1)	34 (35.8)	0.44
AT	114 (33.9)	99 (32.7)	0.75	72 (30.7)	68 (31.6)	0.83	42 (41.3)	31 (35.5)	0.42

Cardiovascular Mortality (ITT)



Numbers at Risk

TAVR	*348*	*298*	*260*	*234*	*172*	*70*	*31*
AVR	*351*	*252*	*236*	*217*	*165*	*65*	*32*

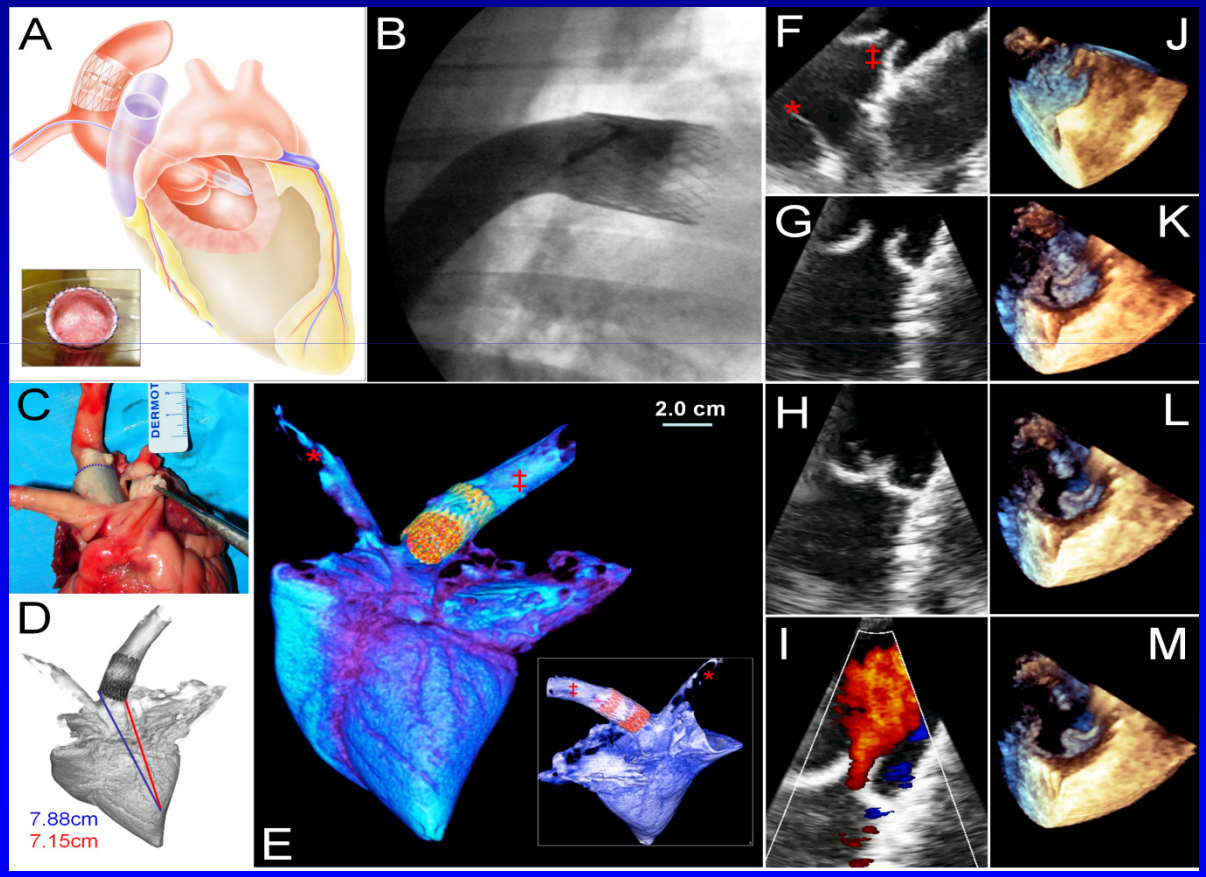
Multivariate Baseline Predictors of Mortality - Pooled Cohort

	Hazard Ratio [95% CI]	p-value
TAVR Arm	***0.89 [0.70-1.13]***	***0.34***
Body Mass Index (kg/m^2)	***0.96 [0.94-0.98]***	***<0.001***
Liver Disease	***2.24 [1.30-4.00]***	***0.006***
Mean Gradient (mmHg/10)	***0.89 [0.81-0.98]***	***0.020***
STS Risk Score	***1.04 [1.01-1.08]***	***0.018***
Moderate/Severe MR	***1.36 [1.02-1.82]***	***0.036***

Multivariate Baseline Predictors of Mortality - By Treatment Arm

TAVR	Hazard Ratio [95% CI]	p-value
Body Mass Index (kg/m^2)	***0.93 [0.90-0.97]***	***<0.001***
Mean Gradient (mmHg/10)	***0.82 [0.72-0.94]***	***0.003***
Baseline Creatinine	***1.06 [1.00-1.13]***	***0.044***
Prior Vascular Surgery or Stent	***1.85 [1.01-3.39]***	***0.045***
AVR		
Prior CABG	***0.57 [0.40-0.82]***	***0.002***
STS Risk Score	***1.07 [1.02-1.12]***	***0.004***
Liver Disease	***2.59 [1.16-5.43]***	***0.020***
Moderate/Severe MR	***1.77 [1.17-2.68]***	***0.006***

Feasibility of BMC Derived Autologous Heart Valve Implantation



Study Design:

Adult Sheep (n = 4)

acute Study (24hrs)

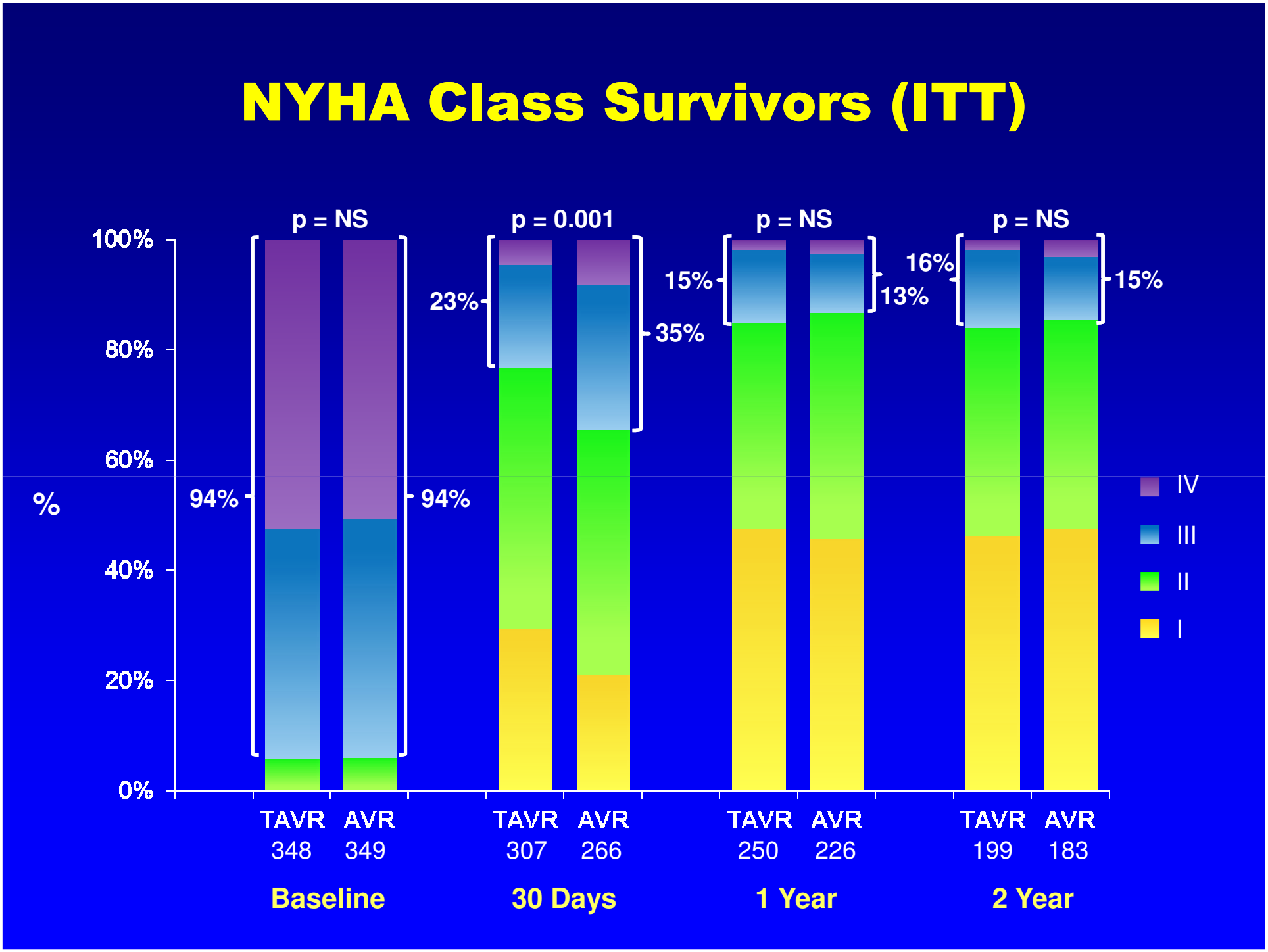
Hufnagel Procedure

Results:

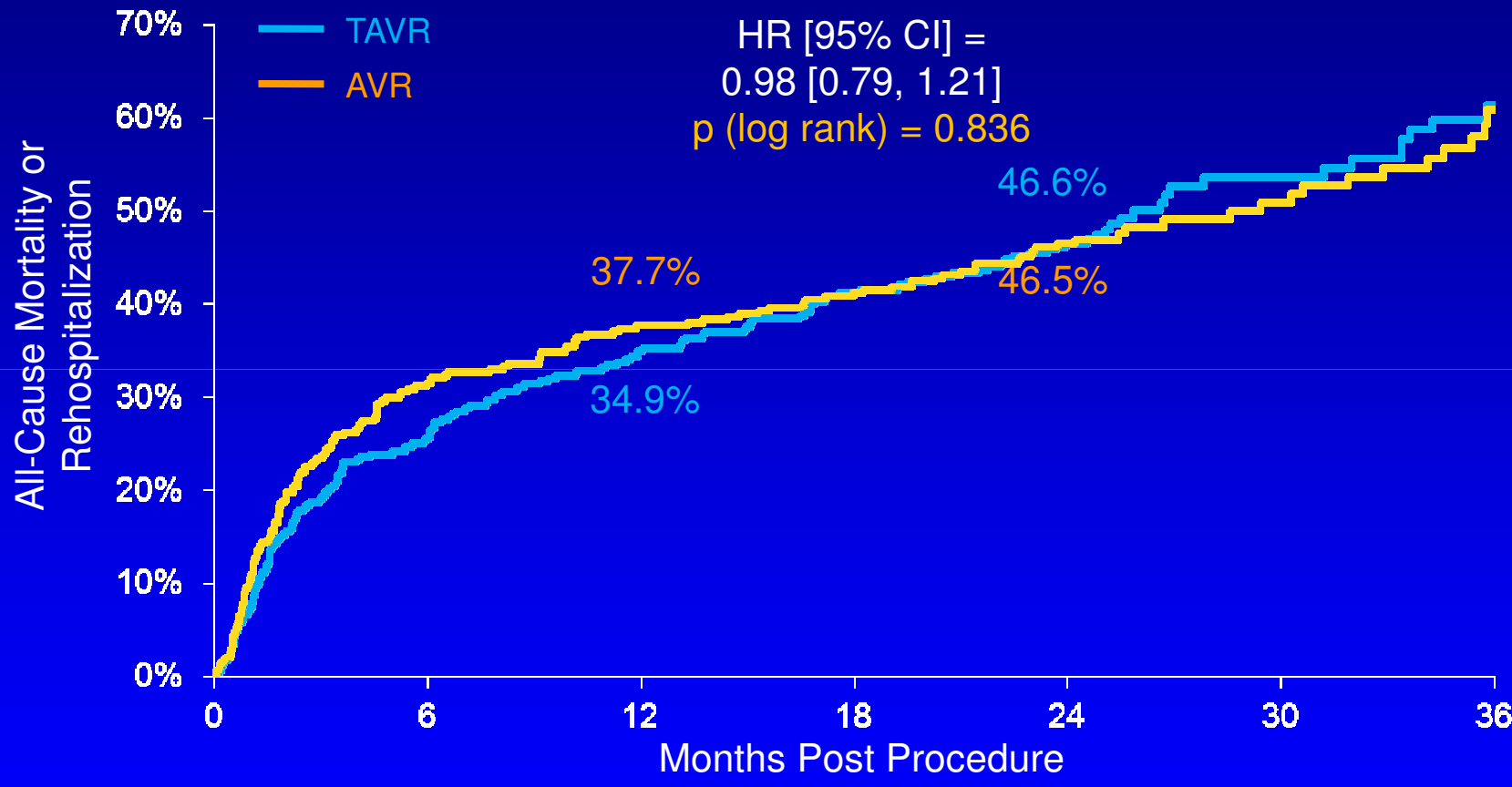
- ✓ Systemic pressure accepted
- ✓ Good motion and co-aptation
- ✓ dp mean: 12 mmHg
- ✓ No regurgitation

(Emmert et al, JACC Cardiovasc Interv. 2011,7;822)

NYHA Class Survivors (ITT)



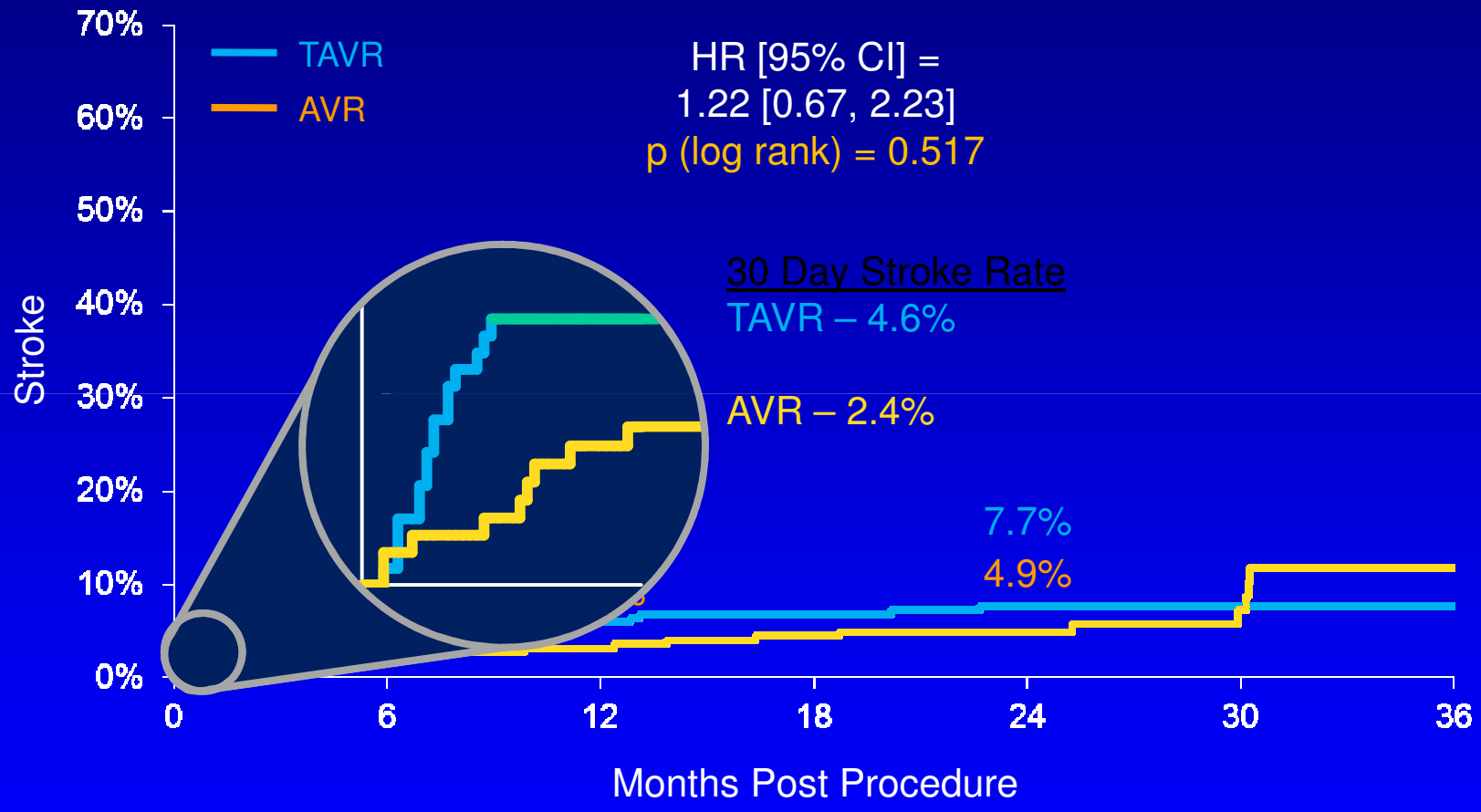
All-Cause Mortality or Rehospitalization (ITT)



Numbers at Risk

TAVR	*348*	*257*	*223*	*194*	*139*	*48*	*18*
AVR	*351*	*222*	*200*	*183*	*130*	*53*	*26*

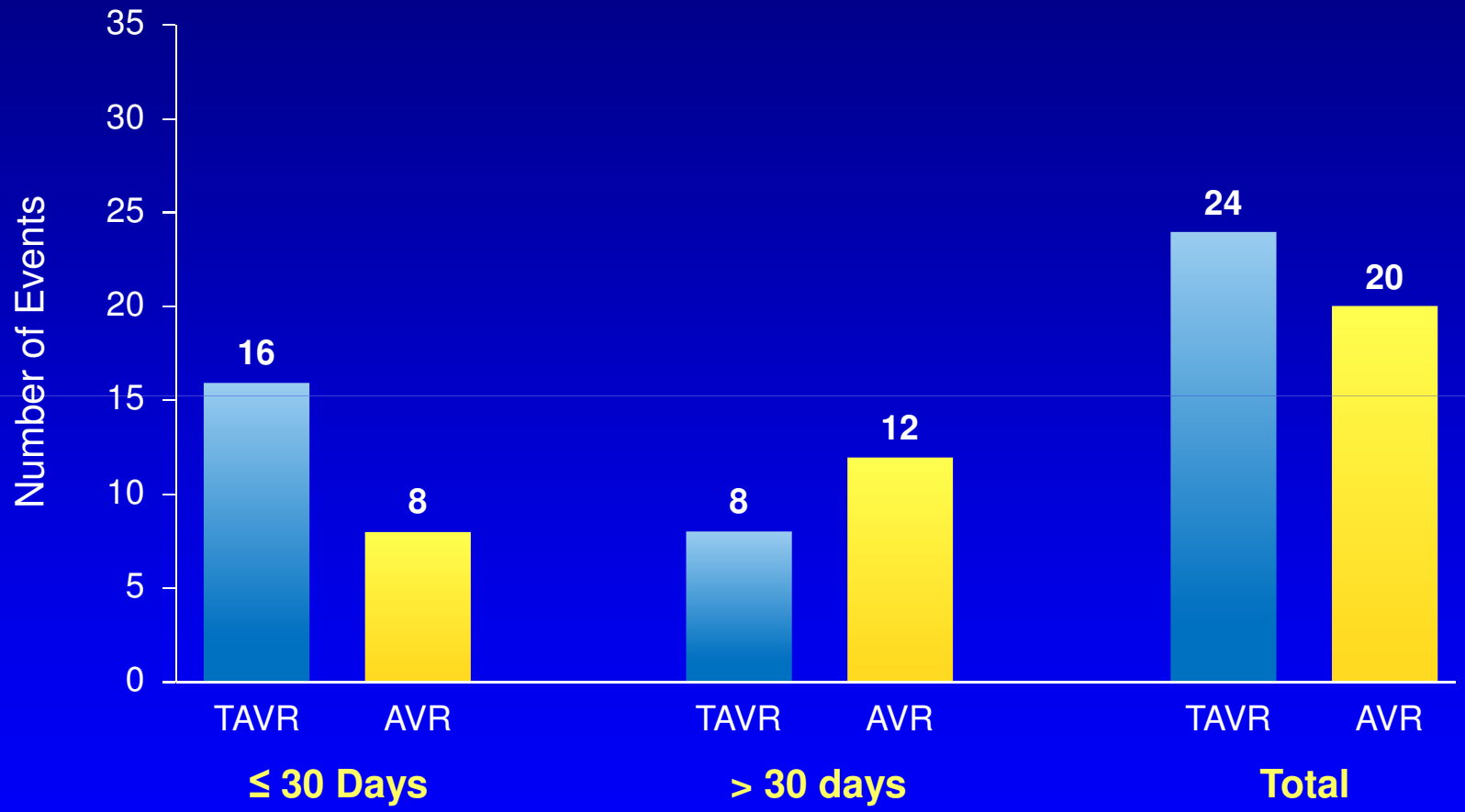
Strokes (ITT)



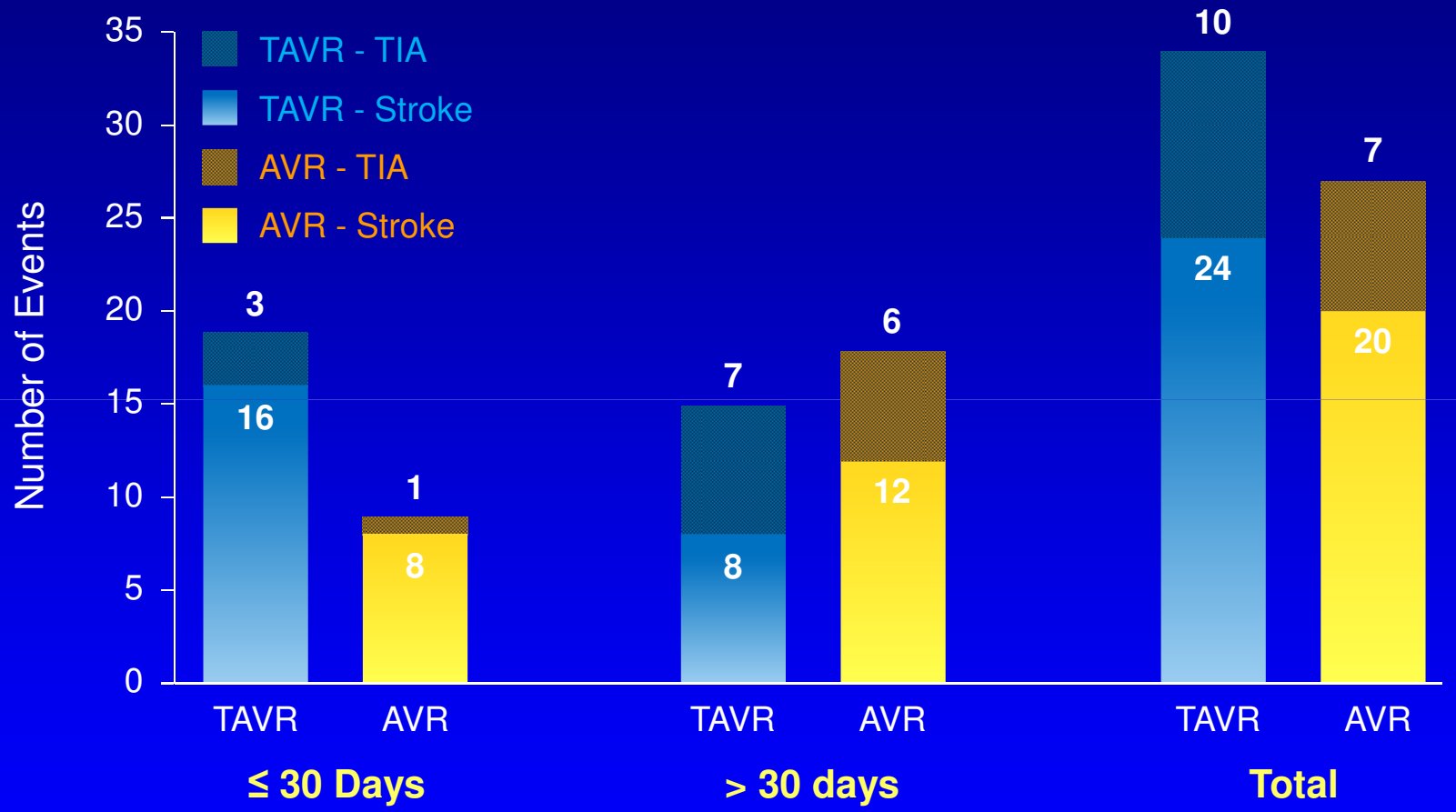
Numbers at Risk

TAVR	*348*	*287*	*249*	*224*	*162*	*65*	*28*
AVR	*351*	*246*	*230*	*211*	*160*	*62*	*31*

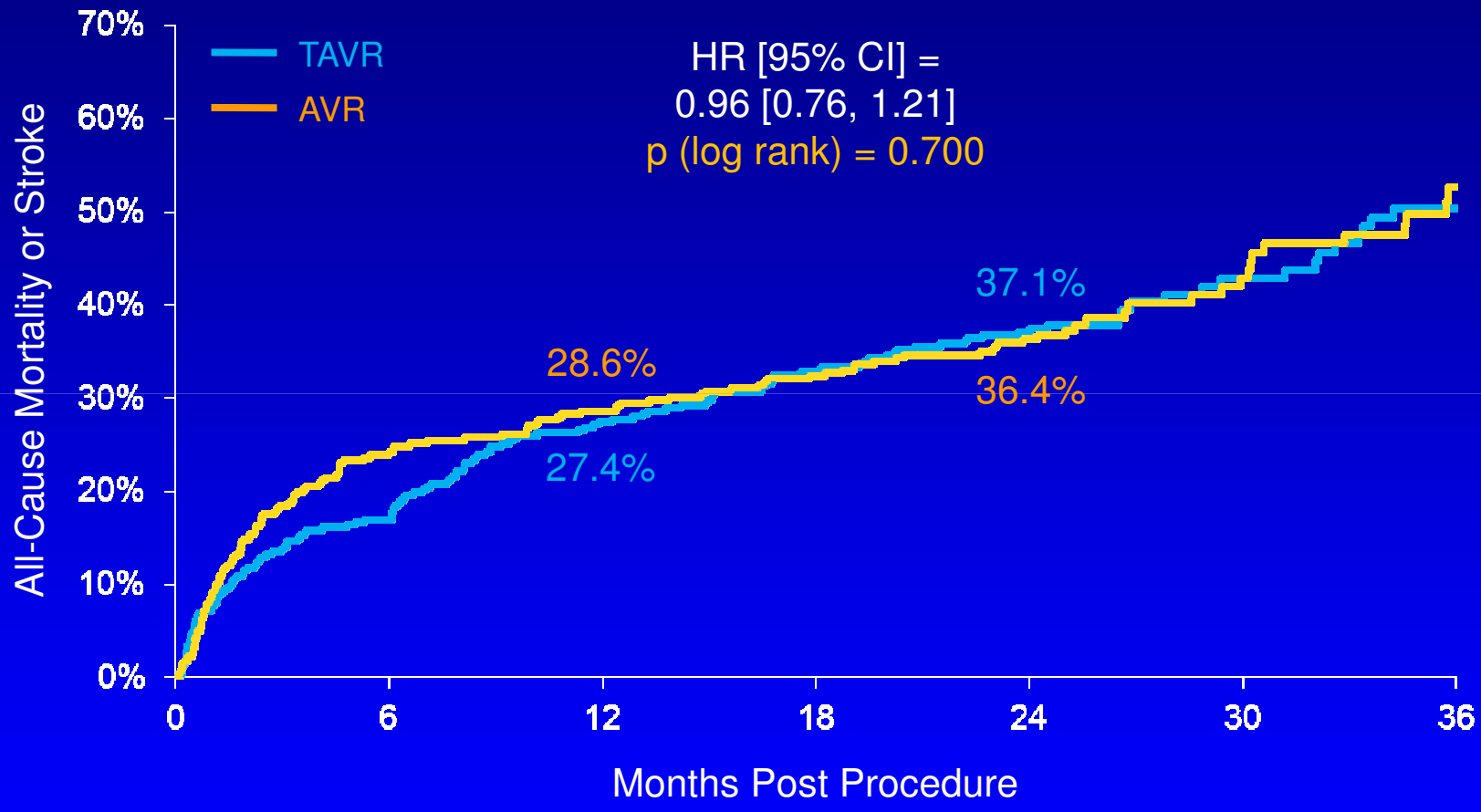
Strokes (ITT Population)



All Neurologic Events (ITT)



All-Cause Mortality or Strokes (ITT)



Numbers at Risk

TAVR	*348*	*287*	*249*	*224*	*162*	*65*	*28*
AVR	*351*	*246*	*230*	*211*	*160*	*62*	*31*

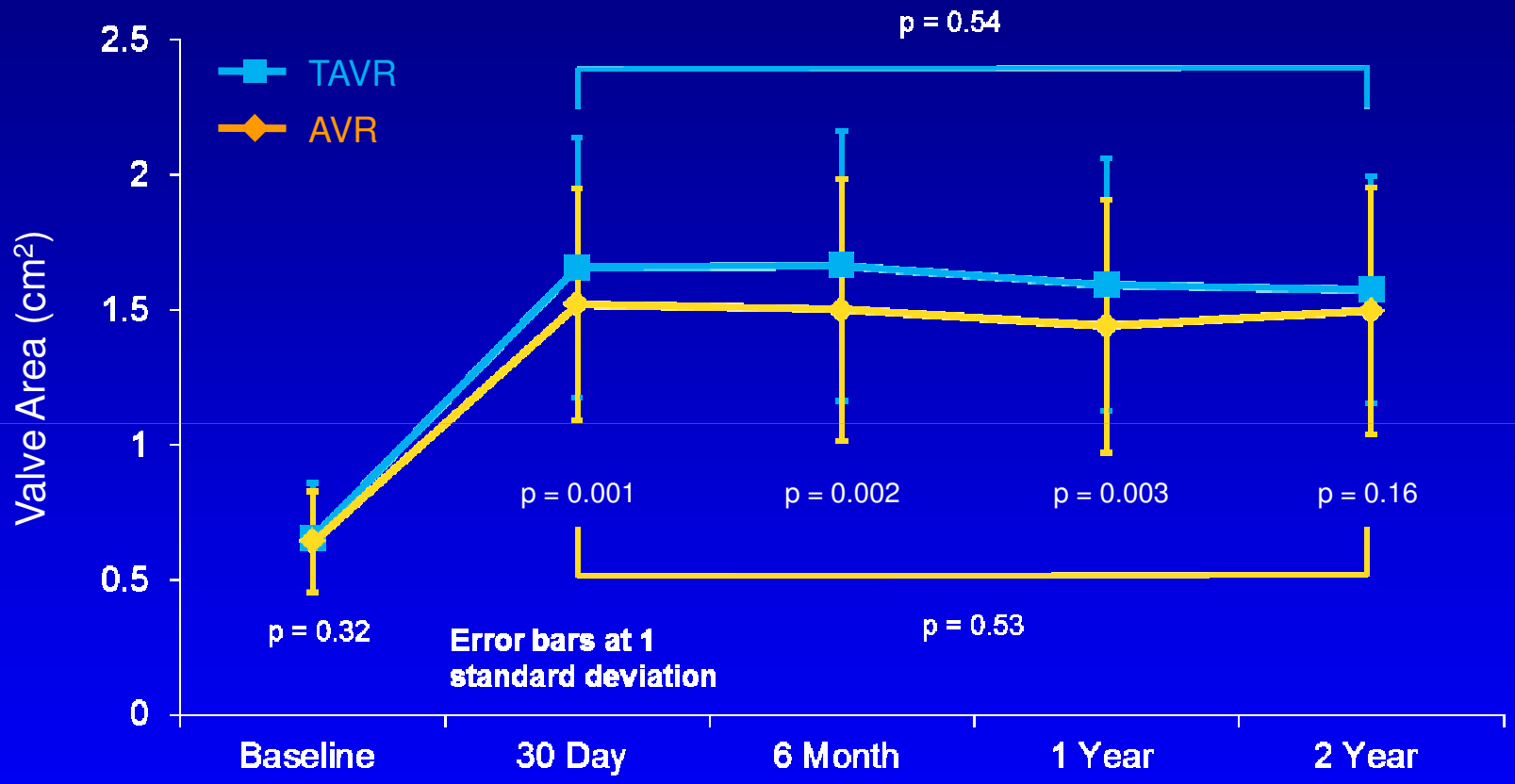
Clinical Outcomes at 1 and 2 Years
All Patients (N = 699)

Outcome	1 Year			2 Years		
	AVR (N = 351)	TAVR (N = 348)	p-value	AVR (N = 351)	TAVR (N = 348)	p-value
Major Vascular complications	13 (3.8)	39 (11.3)	<0.001	13 (3.8)	40 (11.6)	<0.001
Major bleeding – no. (%)	88 (26.7)	52 (15.7)	<0.001	95 (29.5)	60 (19.0)	0.002
New PM – no. (%)	16 (5.0)	21 (6.4)	0.44	19 (6.4)	23 (7.2)	0.69
Endocarditis – no. (%)	3 (1.0)	2 (0.6)	0.63	3 (1.0)	4 (1.5)	0.61
SVD§ requiring AVR	0	0		0	0	
MI – no. (%)	2 (0.6)	0	0.16	4 (1.5)	0	0.05
Acute kidney inj* – no. (%)	20 (6.5)	18 (5.4)	0.57	21 (6.9)	20 (6.2)	0.75

§SVD = Structural Valve Deterioration
*Renal replacement therapy

Echocardiographic Findings

AVA (AT)

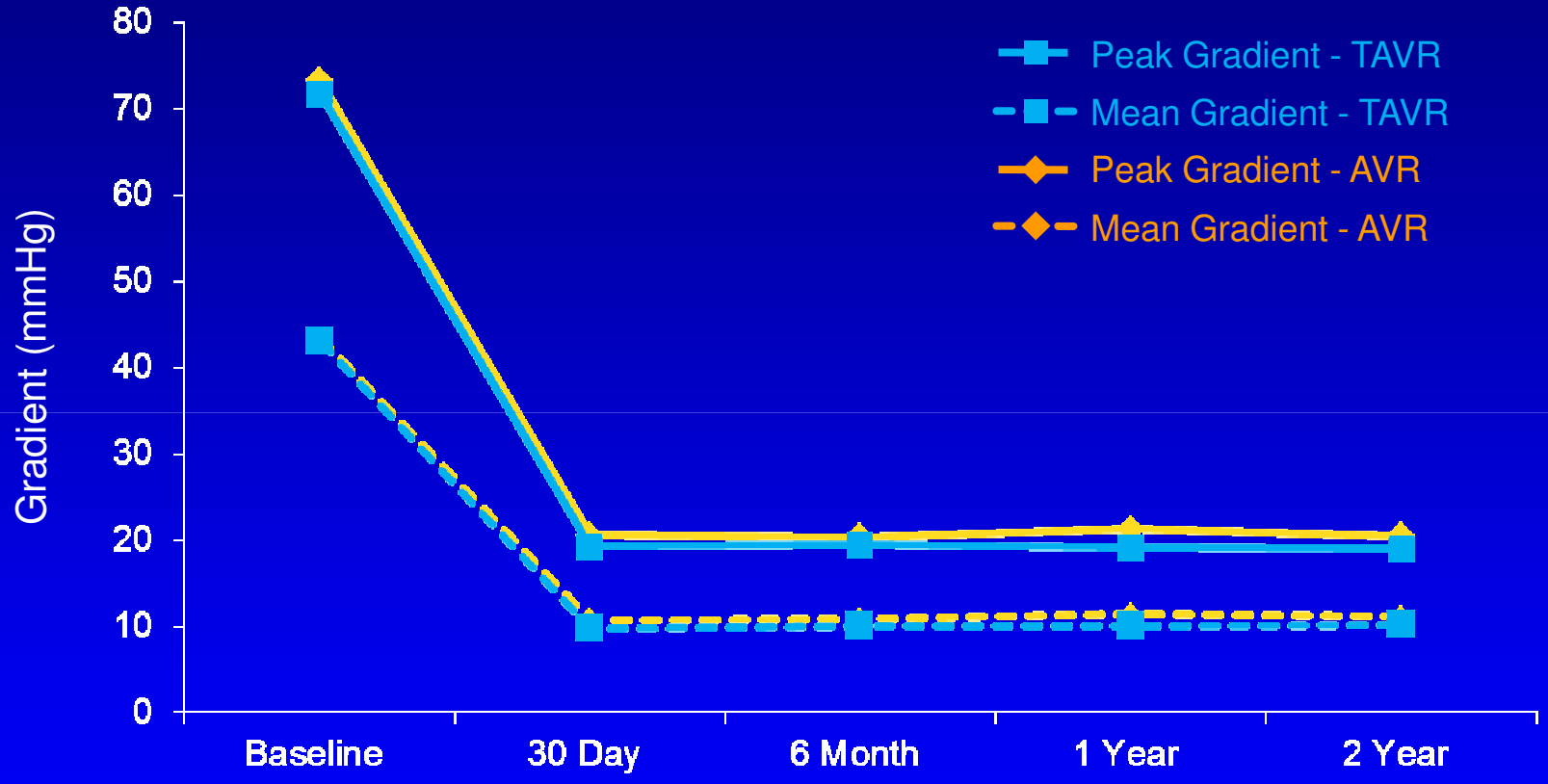


Numbers at Risk

TAVR	*301*	*269*	*223*	*210*	*139*
AVR	*290*	*224*	*162*	*151*	*110*

Echocardiographic Findings

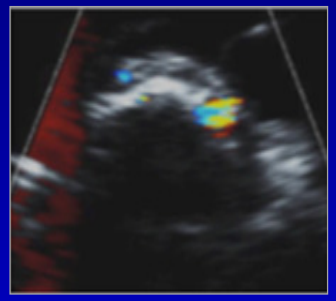
Mean and Peak Gradients (AT)

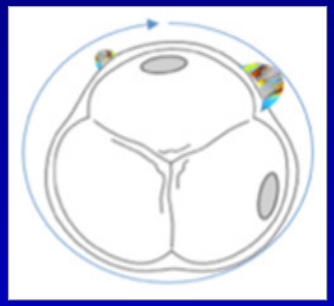


Numbers at Risk

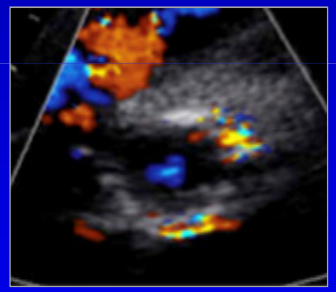
TAVR	*307*	*275*	*233*	*218*	*144*
AVR	*295*	*228*	*168*	*155*	*112*

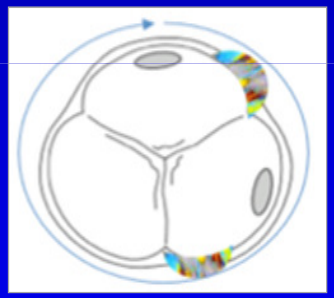
PARTNER Grading Criteria for Paravalvular AR



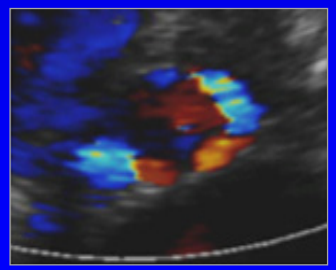


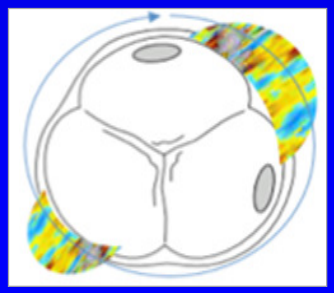
Circumference = 6″
AR = 0.1+0.35 = 0.45″
Ratio = 8%
Severity = Mild (< 10%)





Circumference = 6″
AR = 0.5+0.5 = 1.0″
Ratio = 17%
Severity = Moderate (10 – 20%)
(Trans AR also present)

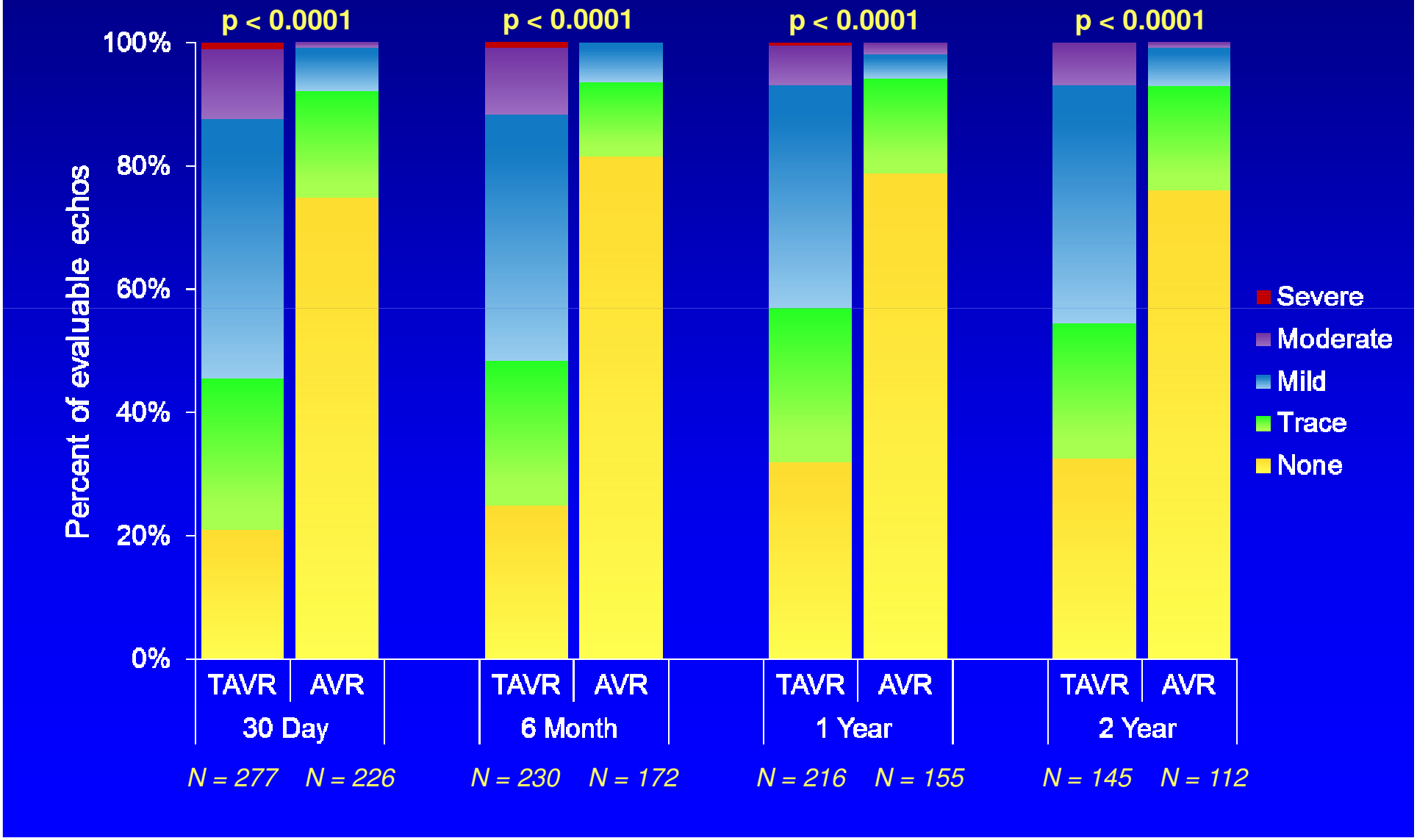




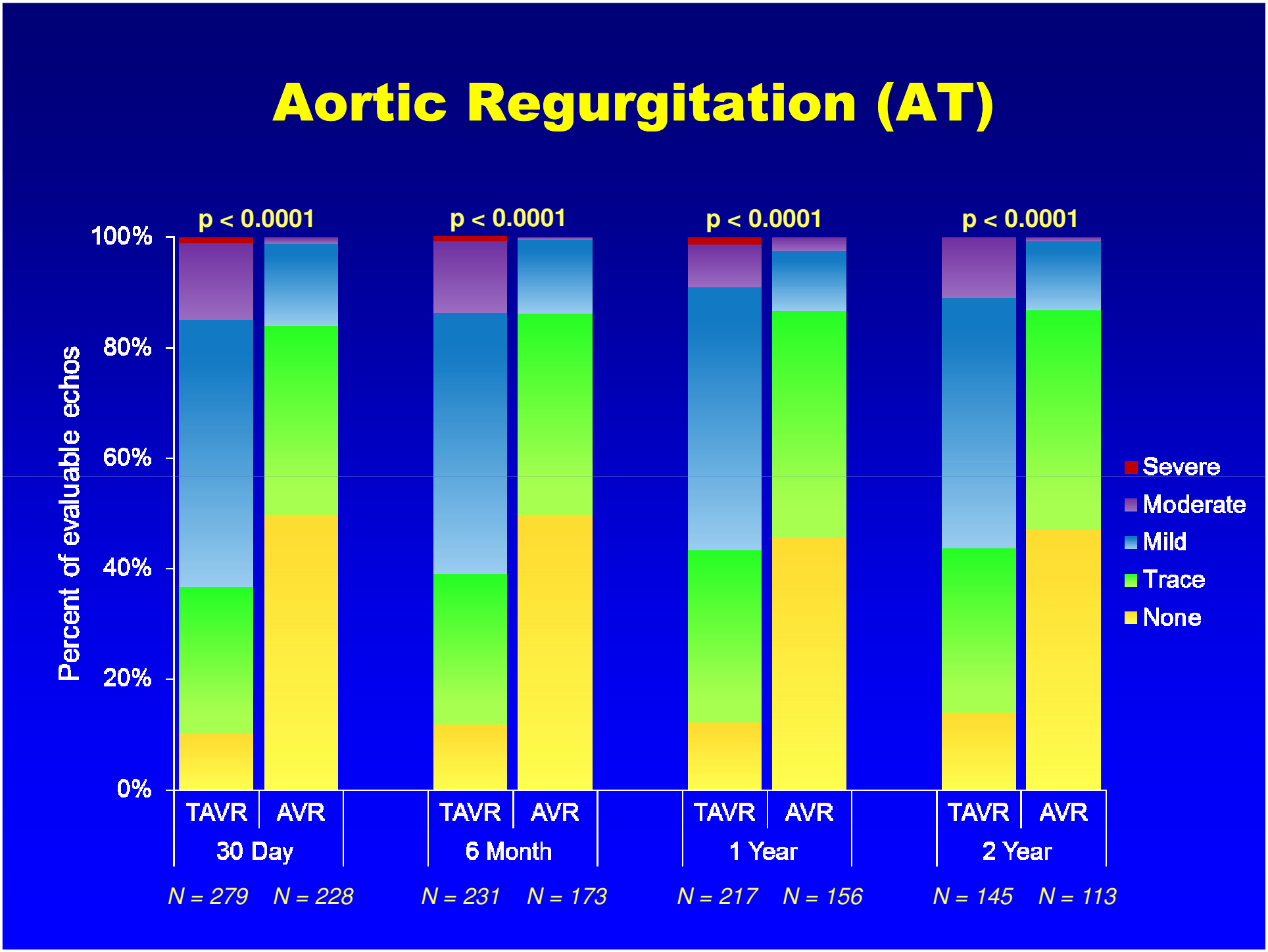
Circumference = 6″
AR = 0.6+1.1 = 1.7″
Ratio = 28%
Severity = Severe (> 20%)

Images courtesy of Pamela Douglas, MD, FASE

Paravalvular Aortic Regurgitation (AT)

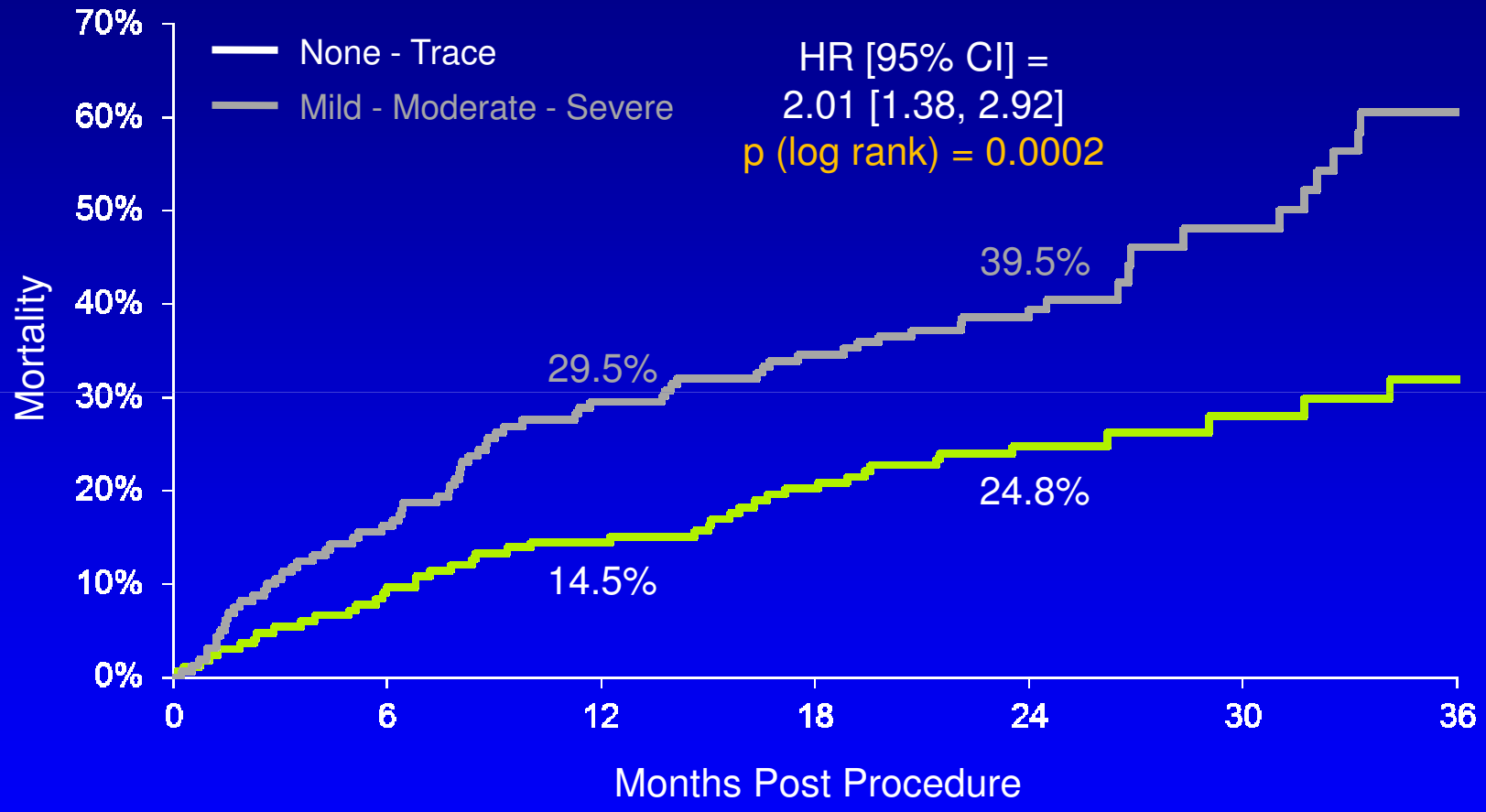


Aortic Regurgitation (AT)



Paravalvular AR and Mortality

TAVR Patients (AT)

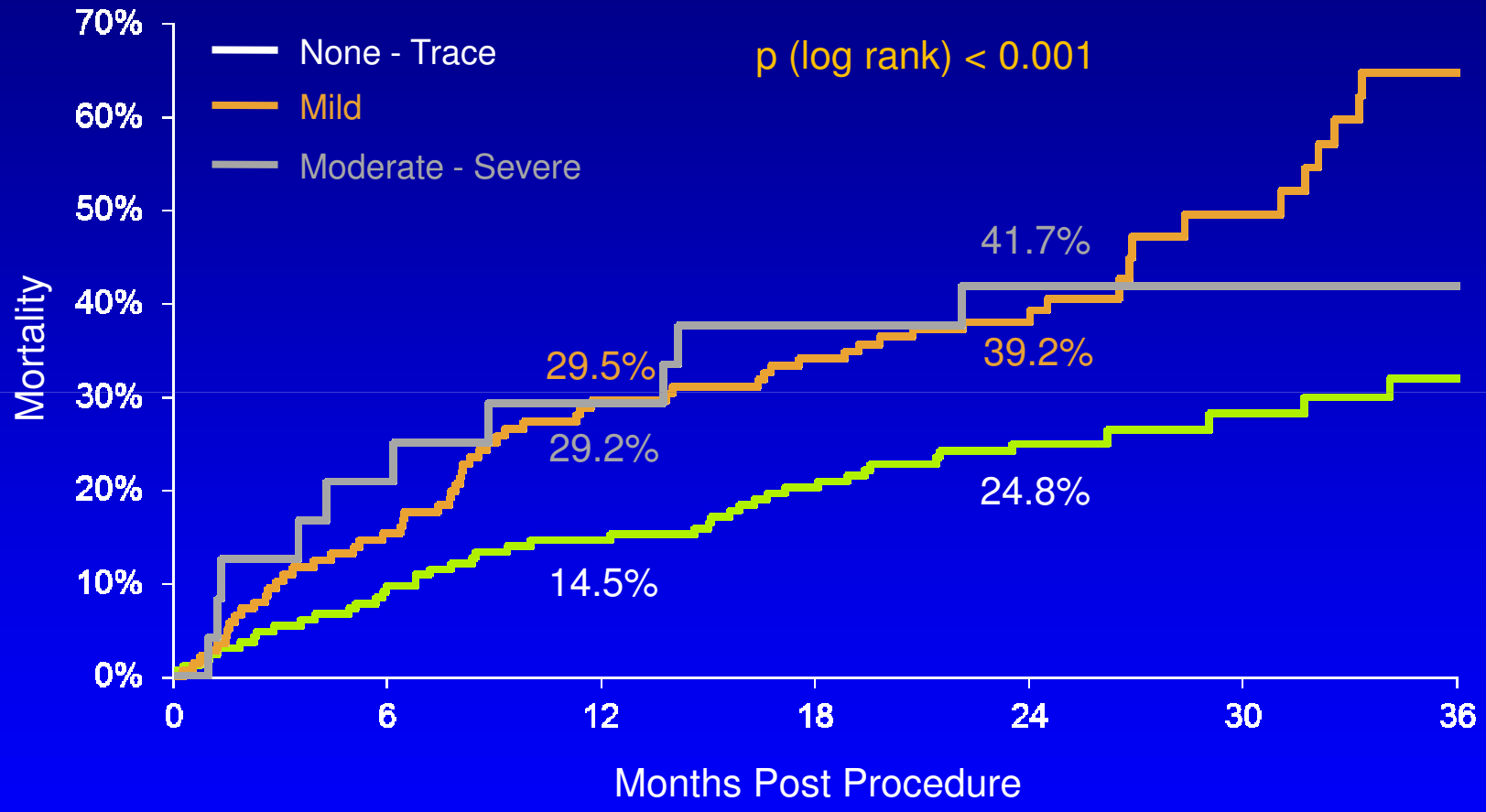


Numbers at Risk

None-Tr	*167*	*149*	*140*	*126*	*87*	*41*	*16*
Mild-Mod-Sev	*160*	*134*	*112*	*101*	*64*	*26*	*12*

Paravalvular AR and Mortality

TAVR Patients (AT)

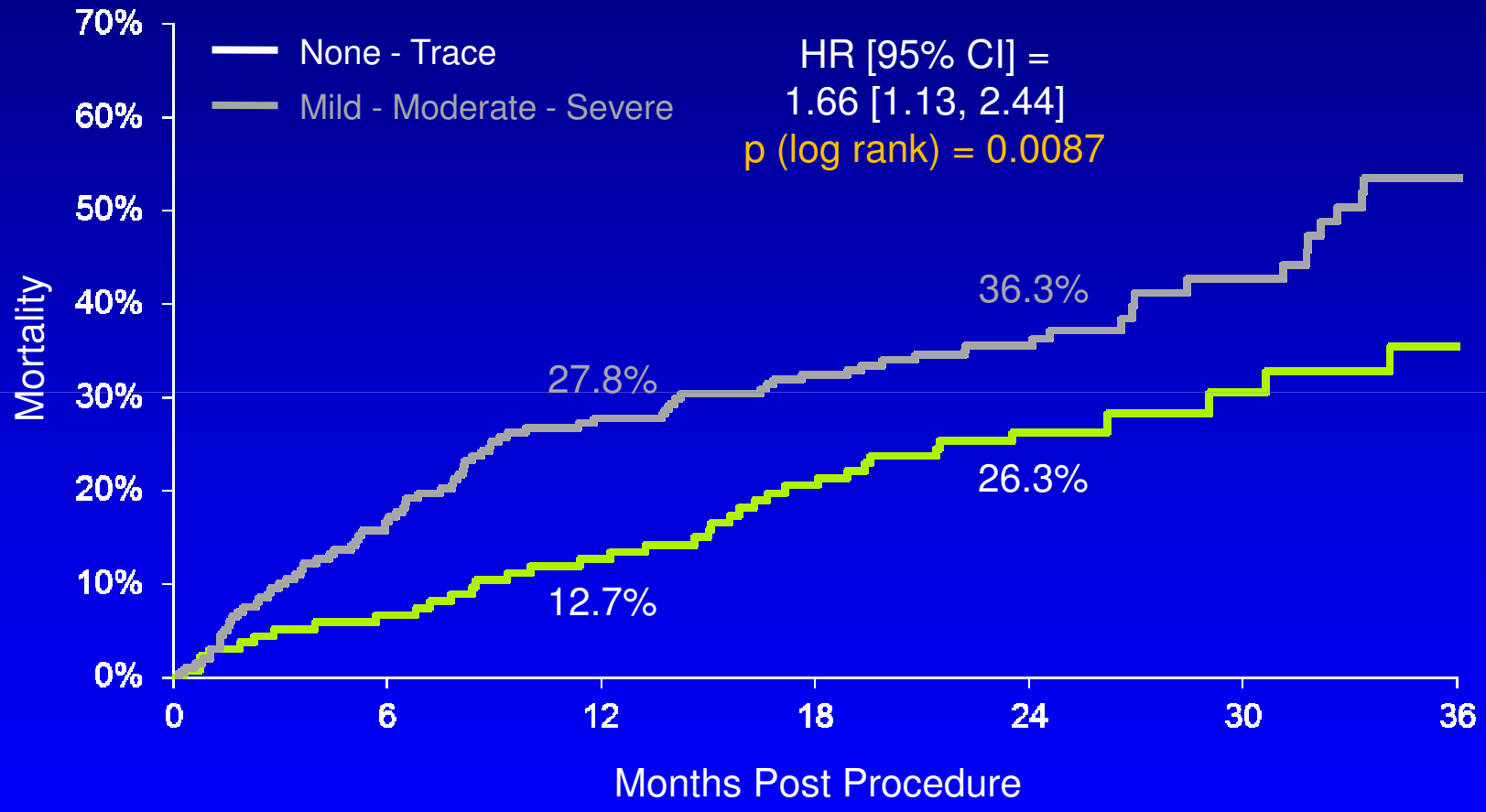


Numbers at Risk

None-Tr	*167*	*149*	*140*	*126*	*87*	*41*	*16*
Mild	*136*	*115*	*95*	*86*	*51*	*21*	*10*
Mod-Sev	*24*	*19*	*17*	*15*	*13*	*5*	*2*

Total AR and Mortality

TAVR Patients (AT)

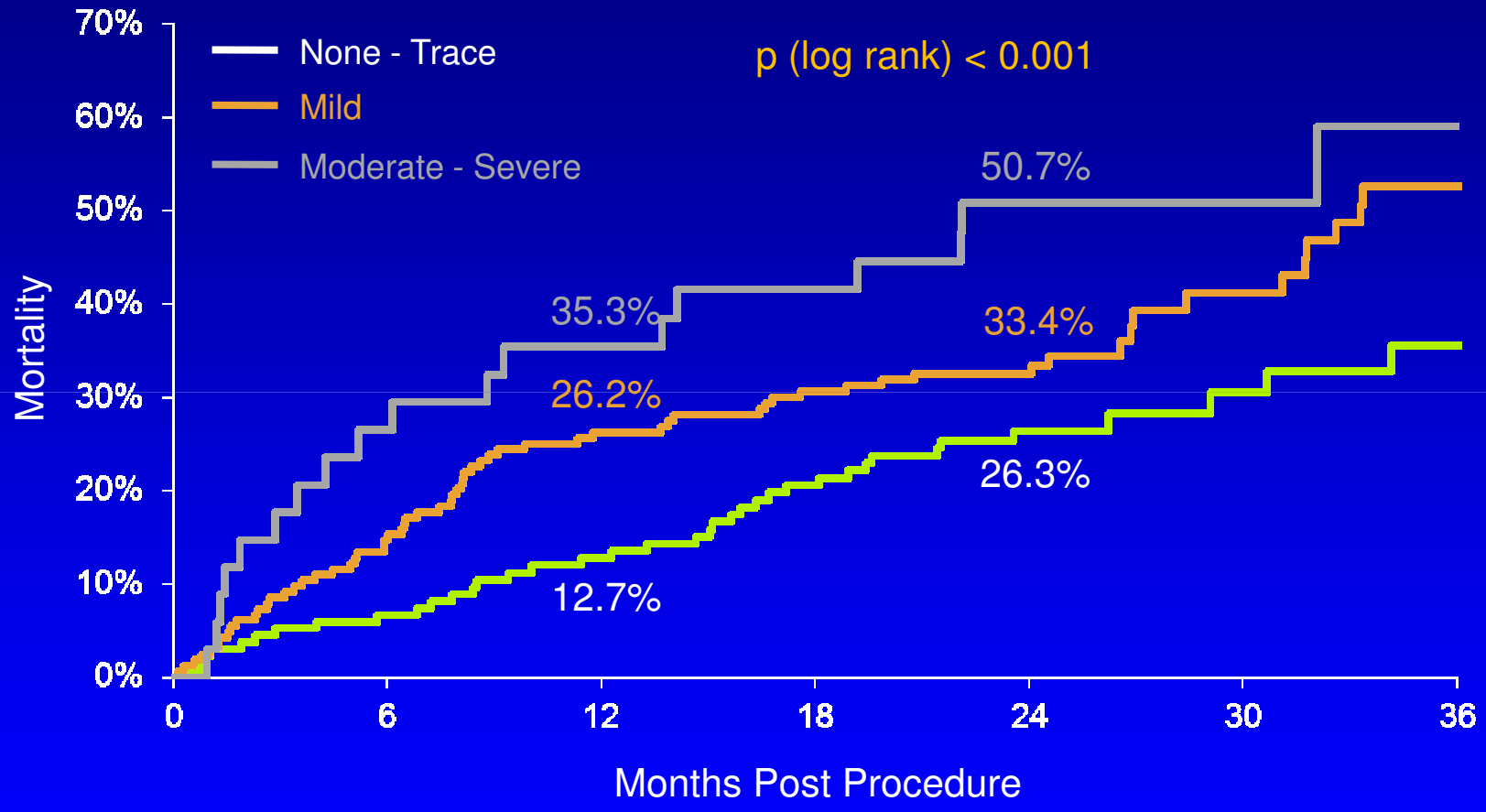


Numbers at Risk

None-Tr	*135*	*125*	*115*	*101*	*68*	*31*	*11*
Mild-Mod-Sev	*199*	*164*	*143*	*130*	*86*	*39*	*18*

Total AR and Mortality

TAVR Patients (AT)

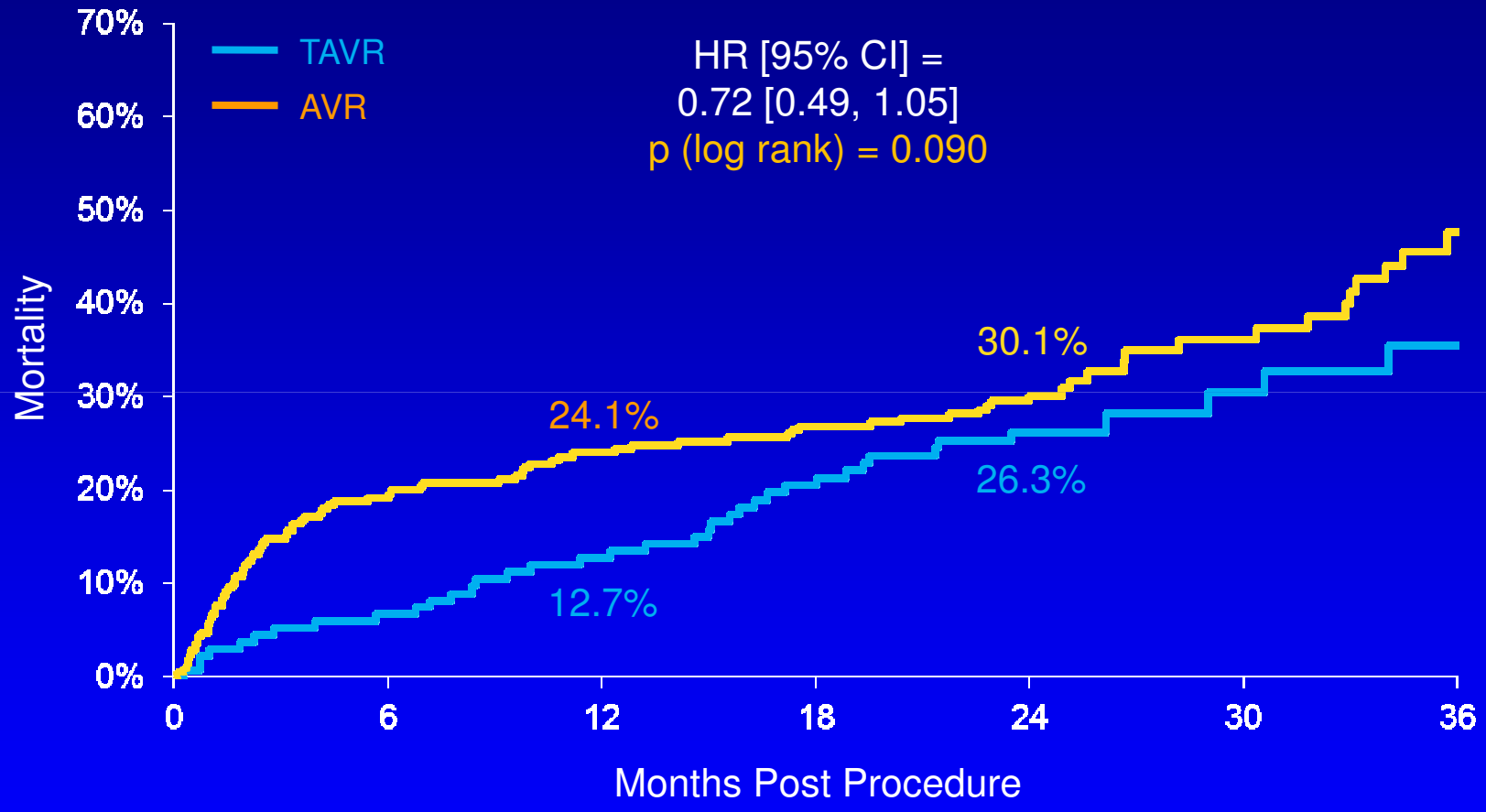


Numbers at Risk

None-Tr	*135*	*125*	*115*	*101*	*68*	*31*	*11*
Mild	*165*	*139*	*121*	*111*	*71*	*33*	*16*
Mod-Sev	*34*	*25*	*22*	*19*	*15*	*6*	*2*

Mortality in Patients with None-Trace AR

TAVR vs AVR



Numbers at Risk

TAVR	*135*	*125*	*115*	*101*	*68*	*31*	*11*
AVR	*252*	*201*	*189*	*176*	*118*	*52*	*22*

Conclusions (1)

- *At 2 years, in patients with symptomatic severe AS who were high-risk candidates for surgical AVR…*
- ***TAVR remained equivalent to surgical AVR with similar rates of all-cause and cardiovascular mortality***
- ***Symptom improvement was similar in both groups and maintained thru two years***
- ***TAVR hemodynamic performance was maintained with similar valve gradients and areas compared with surgery; there was no***

Conclusions (2)

- *Baseline predictors of mortality were different for TAVR (e.g. BMI, PVD) and surgery (e.g. STS score, mod/severe MR)*
- *Adverse procedural events had a significant impact on subsequent mortality, including stroke and major bleeding (for TAVR and AVR) and major vascular complications (for TAVR)*
- *Strokes were similar in TAVR and surgery patients, despite increased peri-procedural events after TAVR; there was no late (after 30 days) stroke hazard in TAVR patients*

Conclusions (3)

- ***Post-procedural AR, was more common after TAVR (mild-mod-severe ~50%) and did not change significantly during follow-up***
- ***Even mild post-procedural AR (paravalvular and total AR) was associated with increased subsequent mortality***

Implications

- *2-year results from the high-risk operable PARTNER cohort indicate…*
  - **TAVR should be considered an option for patients with severe symptomatic aortic stenosis who are high risk for AVR**
  - **Peri-procedural stroke concerns after TAVR have diminished with longer follow-up**
  - **TAVR valve hemodynamics have remained stable, although peri-procedural AR (even mild) has emerged as a predictor of**

March 26, 2012 on NEJM.org

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Two-Year Outcomes after Transcatheter or Surgical Aortic-Valve Replacement

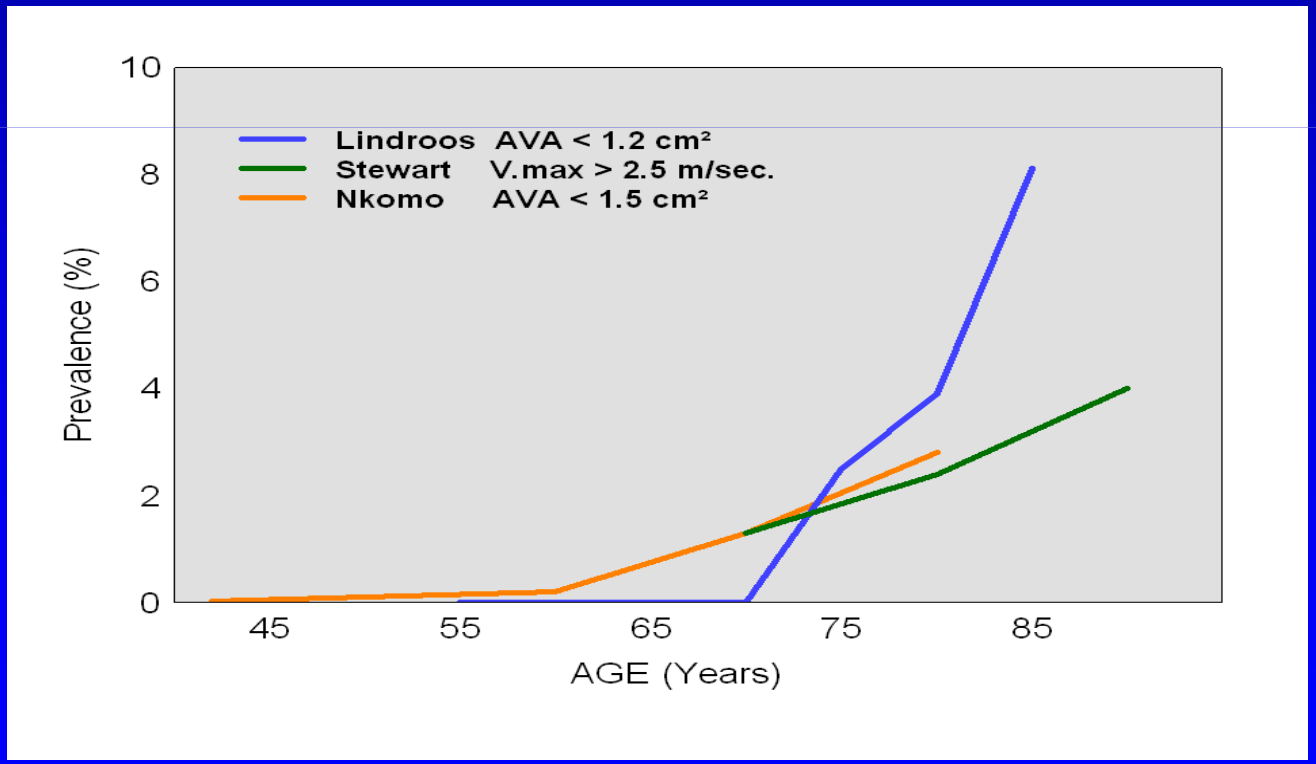
Susheel K. Kodali, M.D., Mathew R. Williams, M.D., Craig R. Smith, M.D., Lars G. Svensson, M.D., Ph.D., John G. Webb, M.D., Raj R. Makkar, M.D., Gregory P. Fontana, M.D., Todd M. Dewey, M.D., Vinod H. Thourani, M.D., Augusto D. Pichard, M.D., Michael Fischbein, M.D., Wilson Y. Szeto, M.D., Scott Lim, M.D., Kevin L. Greason, M.D., Paul S. Teirstein, M.D., S. Chris Malaisrie, M.D., Pamela S. Douglas, M.D., Rebecca T. Hahn, M.D., Brian Whisenant, M.D., Alan Zajarias, M.D., Duolao Wang, Ph.D., Jodi J. Akin, M.S., William N. Anderson, Ph.D., and Martin B. Leon, M.D., for the PARTNER Trial Investigators*

Thank you to the dedicated study teams at all the PARTNER Sites!

- ***General comments***
- Natural history
- Medical treatment / Surgery/ TAVI
- Guidelines
- Real life
- What is next?

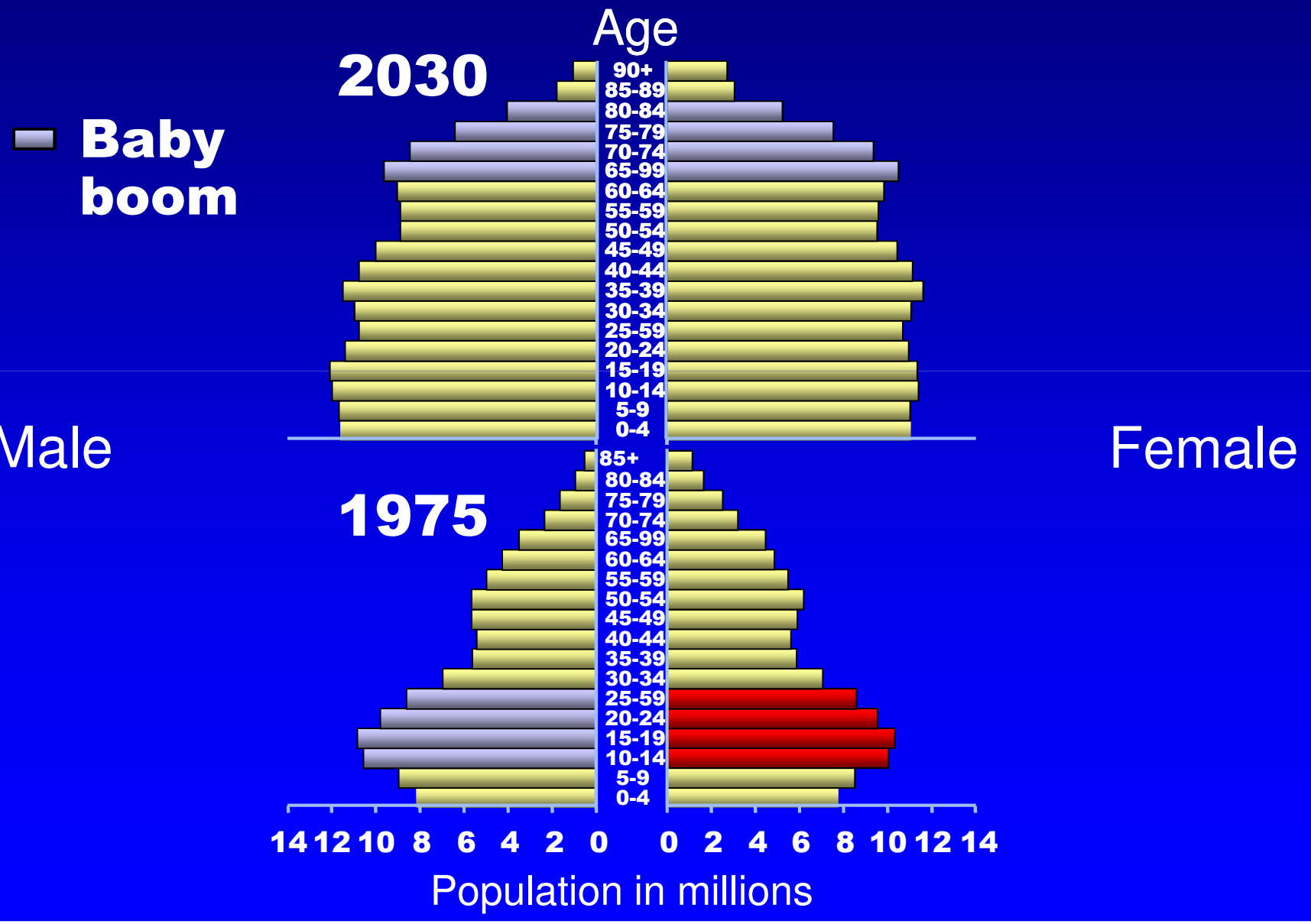
Prevalence of Aortic Stenosis

- 11 911 patients *(Nkomo et al. Lancet 2006;368:1005-11)*
- 5 201 patients ≥ 65 years
  (Stewart et al. J Am Coll Cardiol 1997;29:630-4)
- 577 patients ≥ 55 years
  (Lindroos et al. J Am Coll Cardiol 1993;21:1220-5)



(Iung,Nat Rev Cardiol 2011;8:162-72)

The Graying of the World
Population by Age, Sex

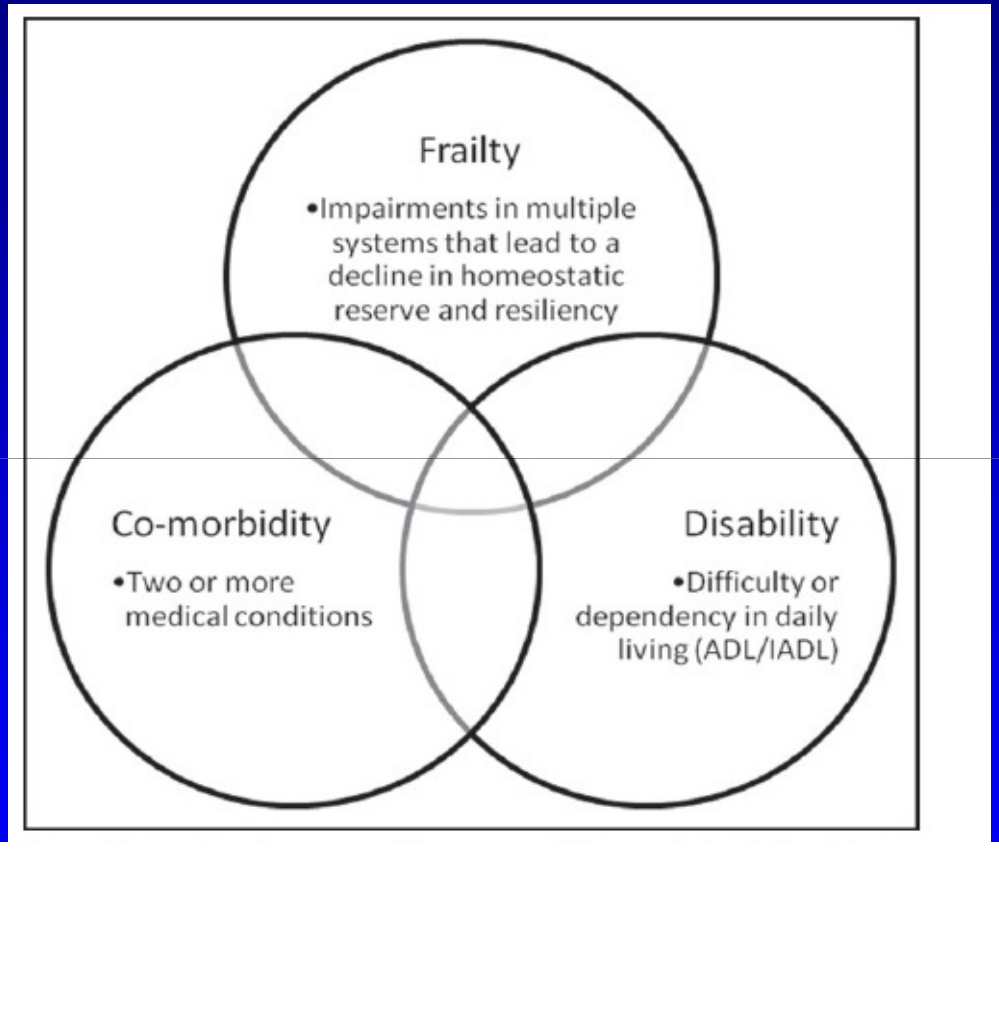


Patient Characteristics in the Euro Heart Survey

	Age (years)	*≥ 70 years (%)*	*≥ 1 comorbidity (%)*
AS	***69±12***	***56***	***36***
AR	58±16	25	26
MS	58±13	18	22
MR	65±14	44	42

(Iung. Eur Heart J 2003;24:1244-53)

Frailty, Co-morbitity, and Disability



(Fried LP et al, J Gerontology 2001;56A:M146-56)

- General comments
- ***Natural history***
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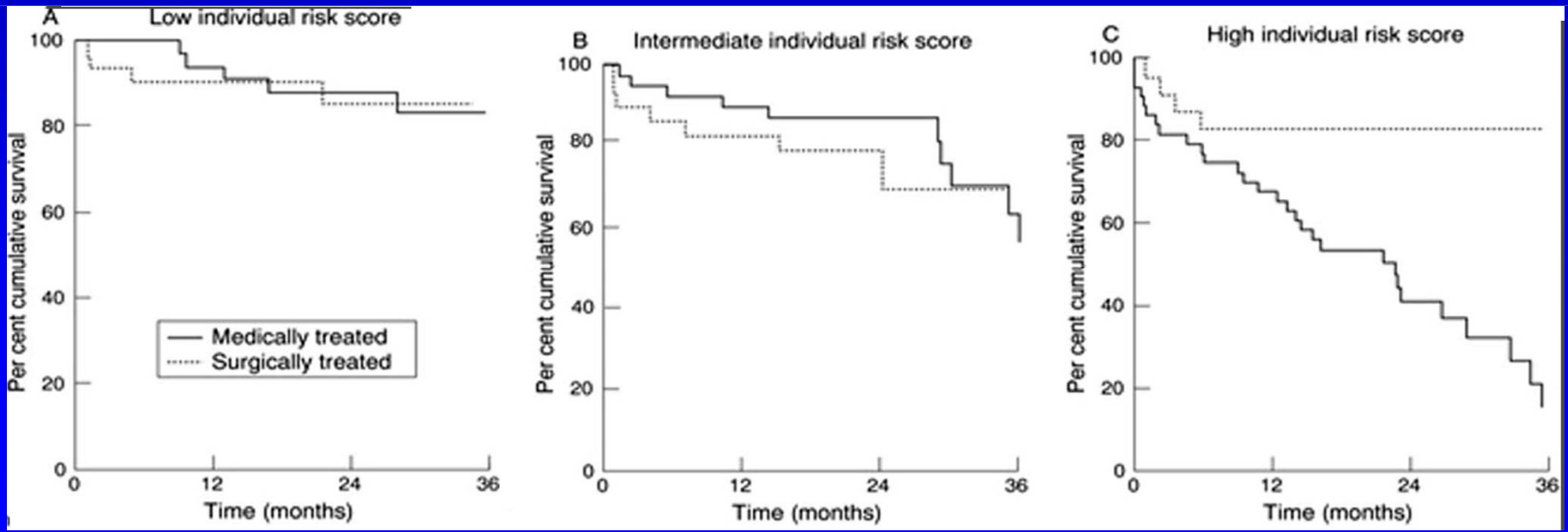
Natural History of AS

- Patients aged ≥ 70 yrs (median 78)
- Stratification of spontaneous prognosis
  - LV dysfunction (RR=4.8)
  - Mitral regurgitation (RR=2.0)
  - Class III or IV (RR=1.6)

3 risks groups

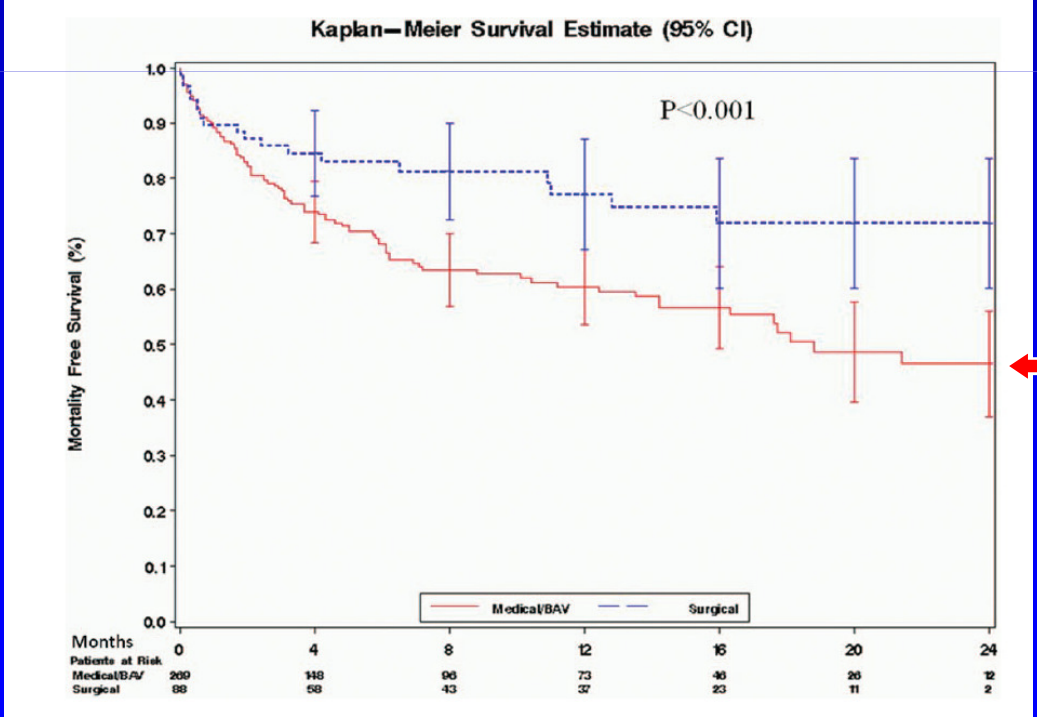


(Bouma et al. Heart 1999;82:143-8)

Natural History of AS in High-Risk Patients

274 patients screened for TAVI but non-eligible, treated medically ± BAV

- Age 81 ± 9 years
- Mean Euroscore 42%
- Mean STS score 13%



1-year mortality: 40%

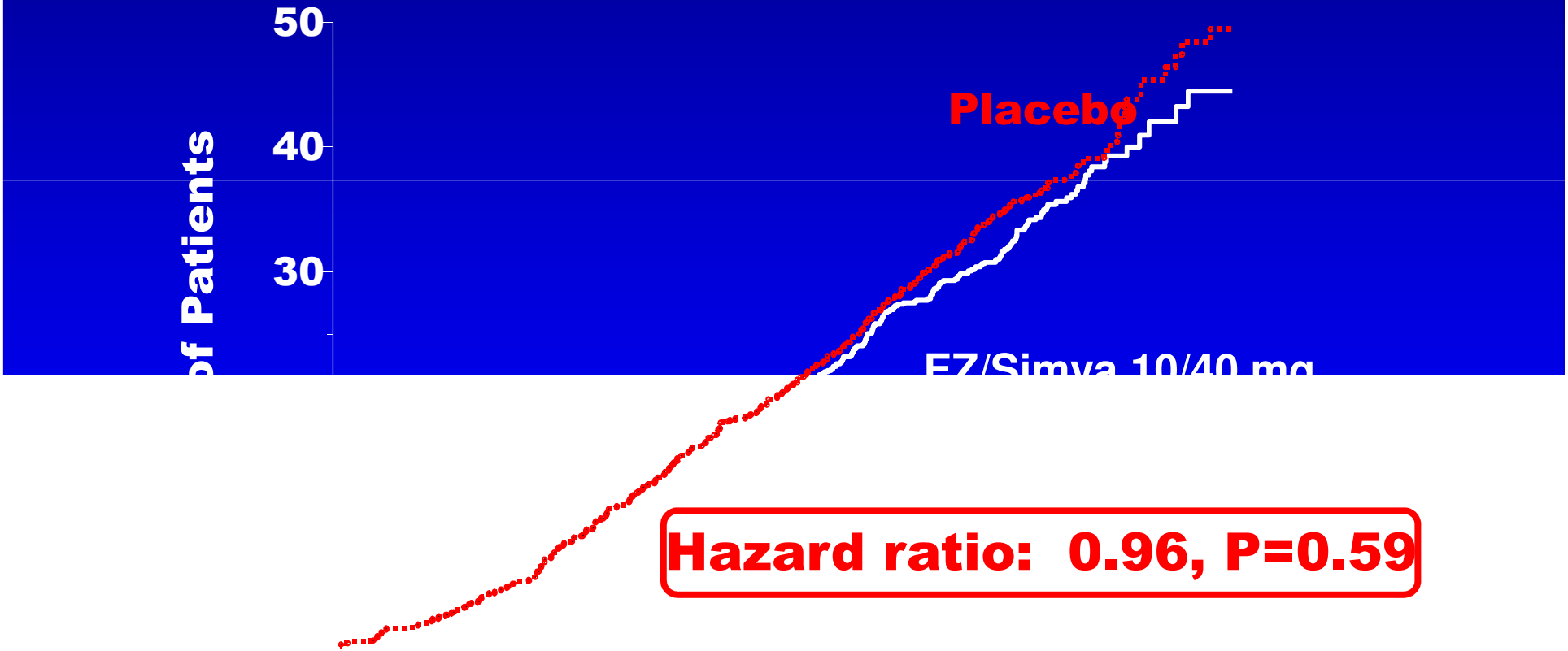
(Ben-Dor et al. Circulation 2010;122(suppl.1):S37-S42)

- General comments.
- Natural history
- ***Medical treatment / Surgery/ TAVI***
- Guidelines
- Real Life
- What is next?

Medical Therapy

SEAS Trial

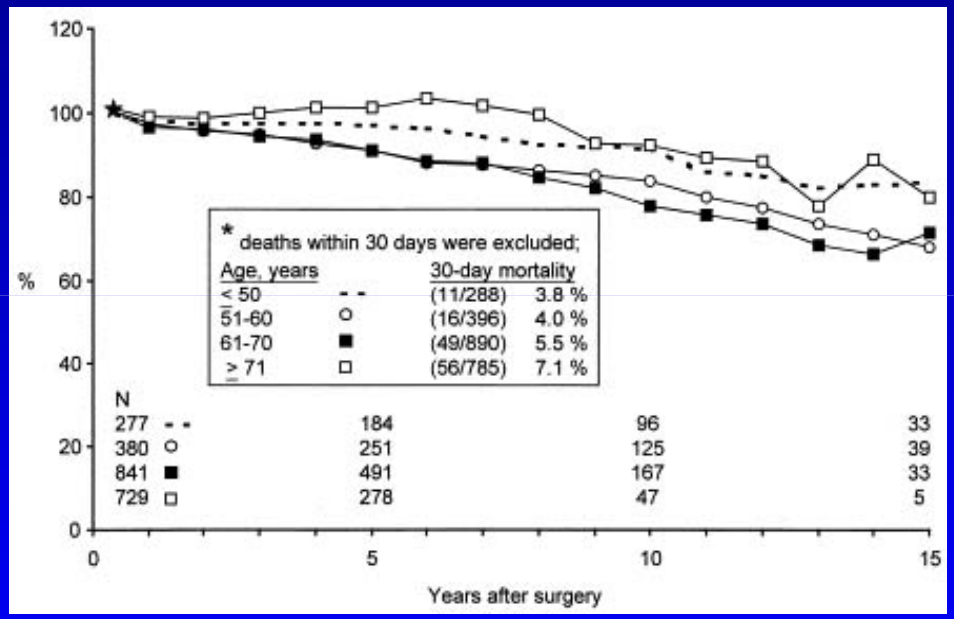
355 Placebo / 333 Simvastatine + Ezetimibe



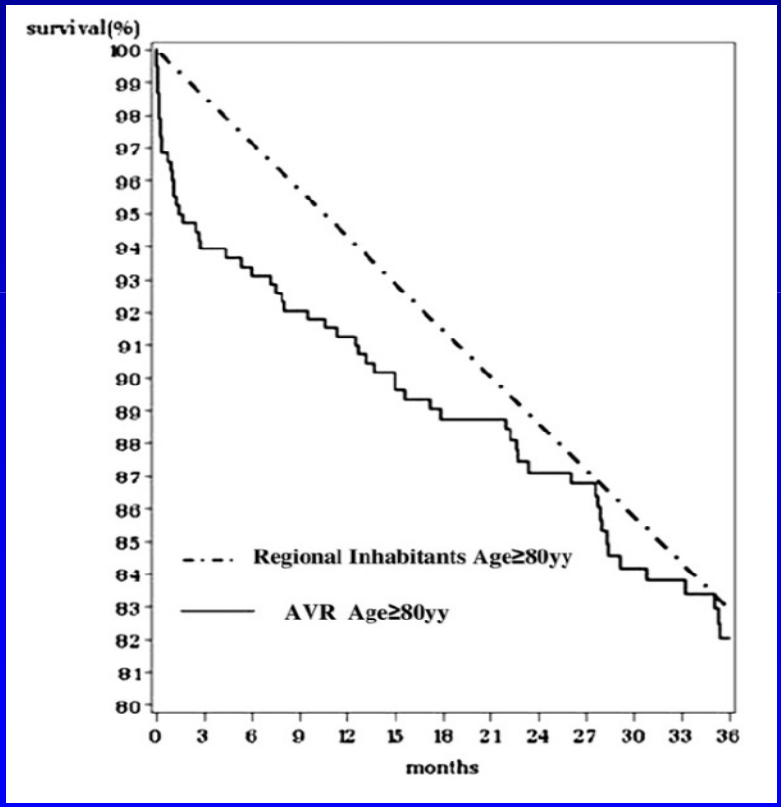
Hazard ratio: 0.96, P=0.59

Survival after Surgical AVR

Relative survival



Observed survival



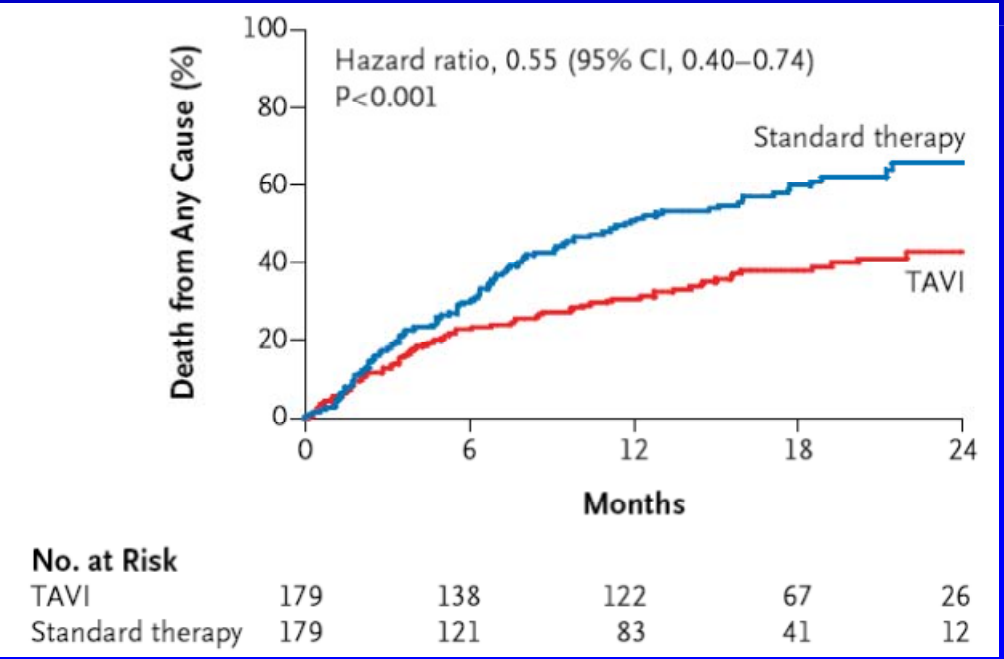
(Kvidal et al.
J Am Coll Cardiol 2000;35:747-56)

(Di Eusanio et al.
J Thorac Cardiovasc Surg 2011;141:940-7)

Survival after TAVI in Inoperable Patients

The PARTNER US trial: B cohort

- 358 patients randomnised to TAVI or standard therapy
- Age 83 ± 8 years
- Mean Euroscore 28%
- Mean STS score 12%

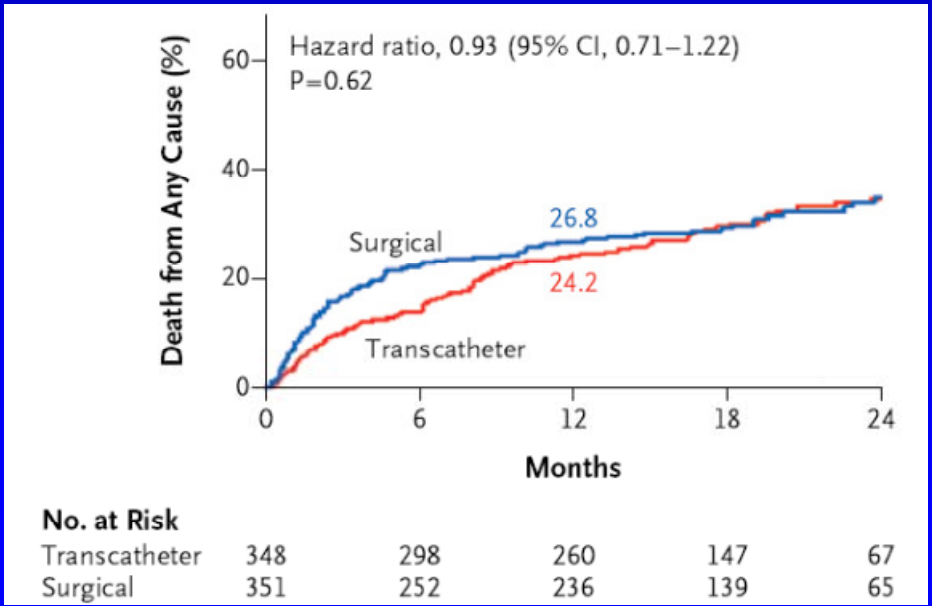


(Leon et al. N Engl J Med 2010;363:1597-607)

Survival after TAVI in High-Risk Patients

The PARTNER US trial: A cohort

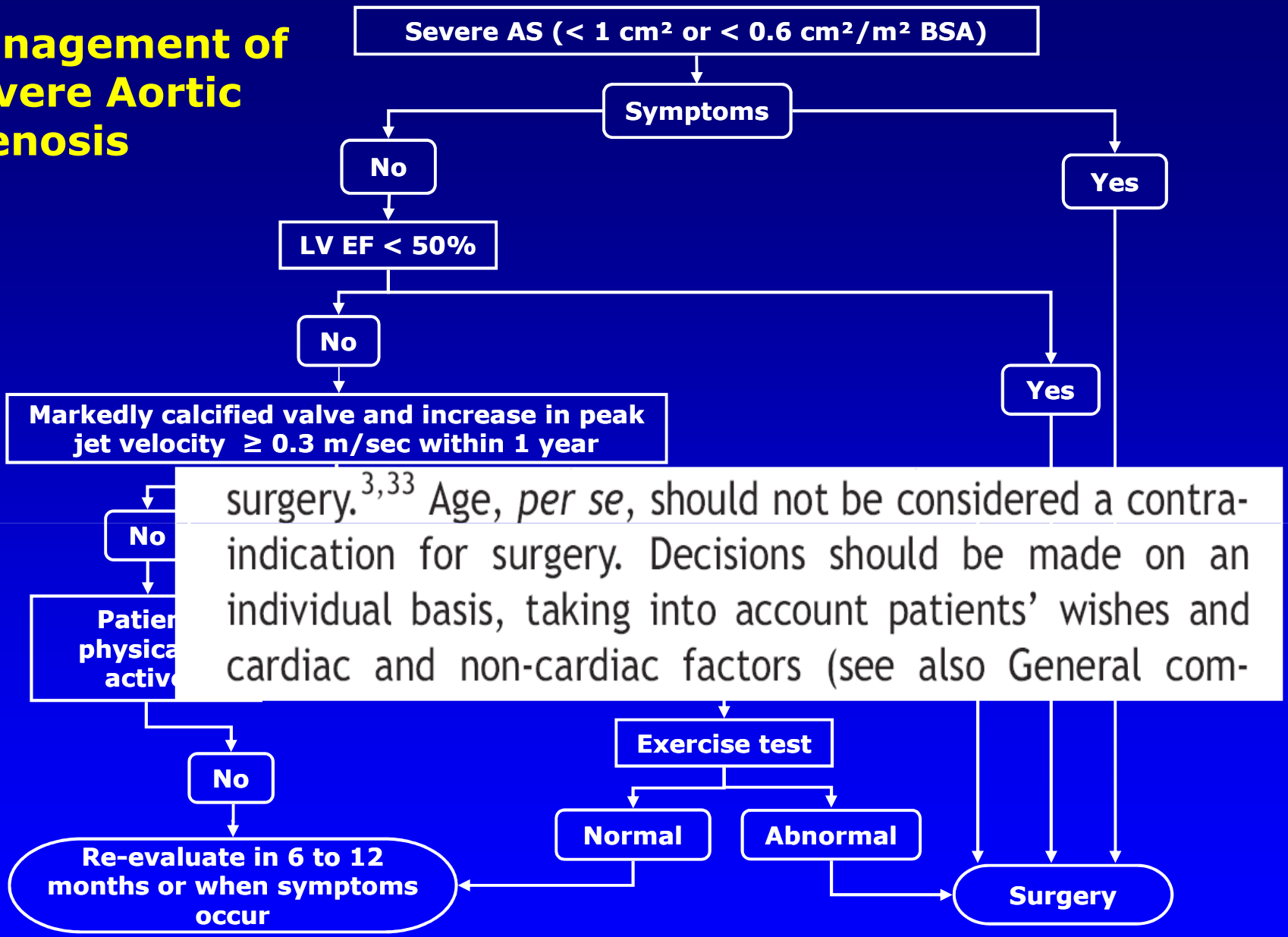
- 699 patients randomnised to surgical AVR (n=351) or TAVI (transfemoral: n=244,transapical: n=104)
- Age 84 ± 7 years
- Mean Euroscore 29%
- Mean STS score 12%



(Smith et al. N Engl J Med 2011;364:2187-98)

- General comments.
- Natural history
- Medical treatment / Surgery / TAVI
- ***Guidelines***
- Real life
- What is next ?

Management of Severe Aortic Stenosis



Modalities of Follow up

- In cases of moderate to severe calcification of the valve and peak aortic jet velocity > 4 m/s at initial evaluation patients ***should be re-evaluated every 6 months*** for the occurrence of symptoms, change in exercise tolerance or in echo-parameters:

If peak aortic jet velocity has increased since the last visit

(> 0.3 m/sec. per year) or if other evidence of haemodynamic progression is present, surgery should be considered.

If no change has occurred and the patient remains

(ESC Guidelines on VHD, Eur Heart J 2007; 28; 230-268)

European Heart Journal Advance Access published May 12, 2008

European Heart Journal
doi:10.1093/eurheartj/ehn183

SPECIAL ARTICLE

Transcatheter valve implantation for patients with aortic stenosis: a position statement from the European Association of Cardio-Thoracic Surgery (EACTS) and the European Society of Cardiology (ESC), in collaboration with the European Association of Percutaneous Cardiovascular Interventions (EAPCI)

Alec Vahanian[1*], Ottavio Alfieri[2*], Nawwar Al-Attar[1], Manuel Antunes[3], Jeroen Bax[4], Bertrand Cormier[5], Alain Cribier[6], Peter De Jaegere[7], Gerard Fournial[8], Arie Pieter Kappetein[7], Jan Kovac[9], Susanne Ludgate[10], Francesco Maisano[2], Neil Moat[11], Friedrich Mohr[12], Patrick Nataf[1], Luc Piérard[13], José Luis Pomar[14], Joachim Schofer[15], Pilar Tornos[16], Murat Tuzcu[17], Ben van Hout[18], Ludwig K. Von Segesser[19], and Thomas Walther[12]

(EACTS/ESC/EAPCI Position Statement, Eur Heart J, 2008; 29: 1463-1470, Eur J Cardiothorac Surg 34 (2008) 1-8, Eurointerv. 2008; 4:193-199)

Inclusion Criteria for TAVI

After assessment by the 'Team'

- Severe AS
- Symptomatic
- Life expectancy >1year
- Contra indication for surgery, or
  High Risk for Surgery :
  - ✓ *Clinical judgment* +
    - – EuroScore (logistic) > 20%;STS Score>10%

AND/OR

- ✓ Porcelain aorta
- ✓ History of thoracic irradiation
- ✓ Severe thoracic deformity
- ✓ Patent coronary by pass
- ✓ .....

Conclusions from PARTNER :

- **"TAVI is already the standard-of-care for inoperable patients with severe aortic stenosis."**
- **"TAVI is an acceptable alternative to AVR in selected high-risk operable patients."**

(EACTS/ESC/EAPCI Position Statement, Eur Heart J, 2008; 29: 1463-1470, Eur J Cardiothorac Surg 34 (2008) 1-8, Eurointerv. 2008; 4:193-199)

- General comments.
- Natural history
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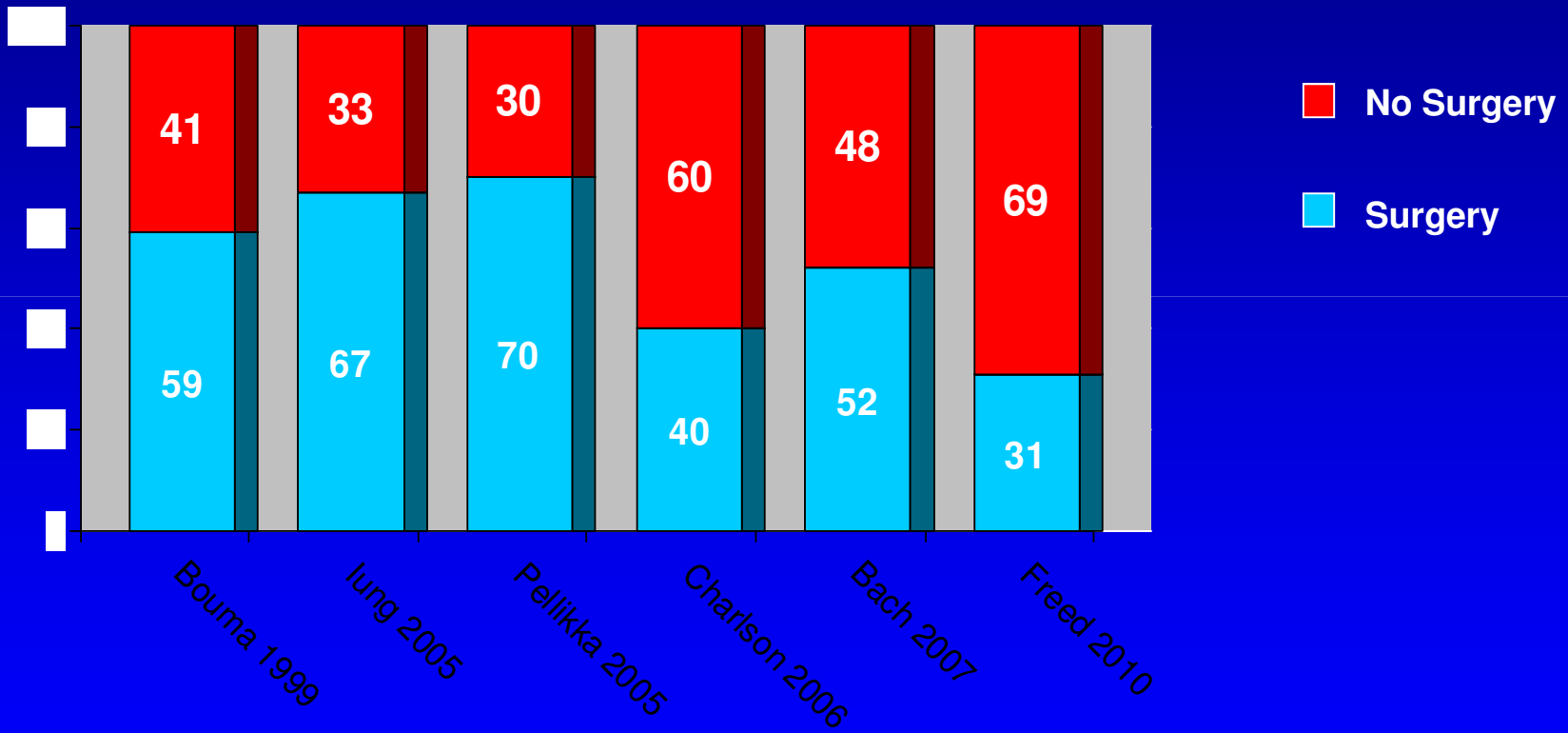
- Guidelines
- ***Real life***
- What is next?

Actual Practices (Pre-TAVI Era)

> 30% of patients are not referred for surgery



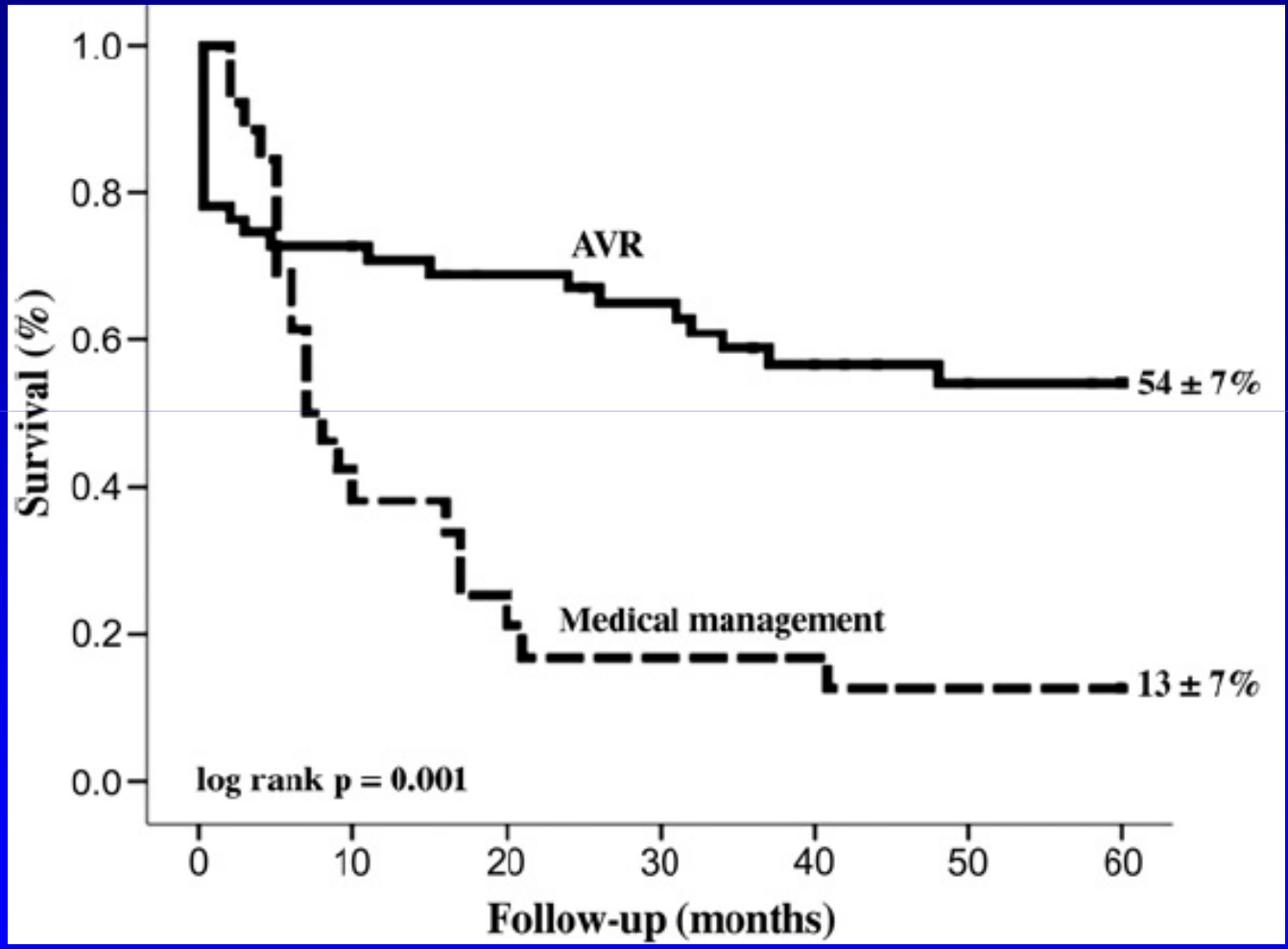
(Bouma et al. Heart 1999;82:143-8
Iung et al. Eur Heart J 2005;26:2414-20
Pellikka et al. Circulation 2005;111:3290-5
Charlson et al. J Heart Valve Dis 2006;15:312-21
Bach et al. J Am Coll Cardiol 2007;50:2018-9)

Factors Associated with a Decision not to Operate in the Elderly with AS

	X_2	p	OR [95% CI]
LV dysfunction (EF < 50%)	12	0.0005	3.78 [1.79-8.12]
Age (1-year increase)	10.7	0.001	1.15 [1.06-1.25]
Charlson comorbidity index	2.65	0.75	1.72 [0.83-3.50]

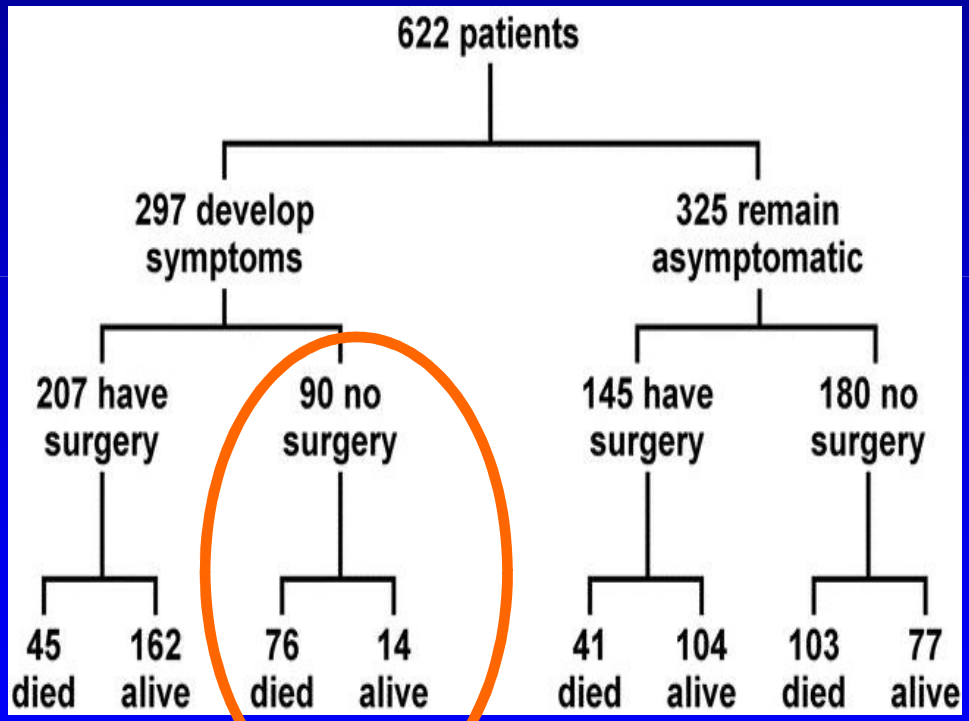
(Iung et al. Eur Heart J 2005;26:2714-20)

AS with LV Dysfunction and No Contractile Reserve on Dobutamine Echo

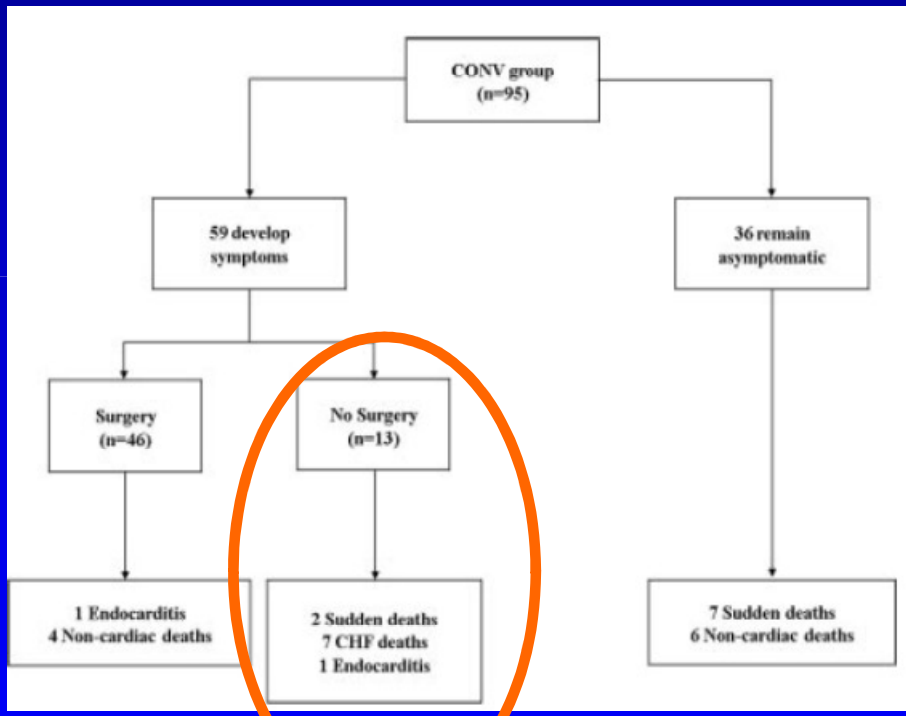


(Tribouilloy et al. JACC 2009;53:1865-73.)

Many Asymptomatic Patients will not be Operated when they become Symptomatic.....



(Pellikka et al. Circulation 2005;111:3290-5)

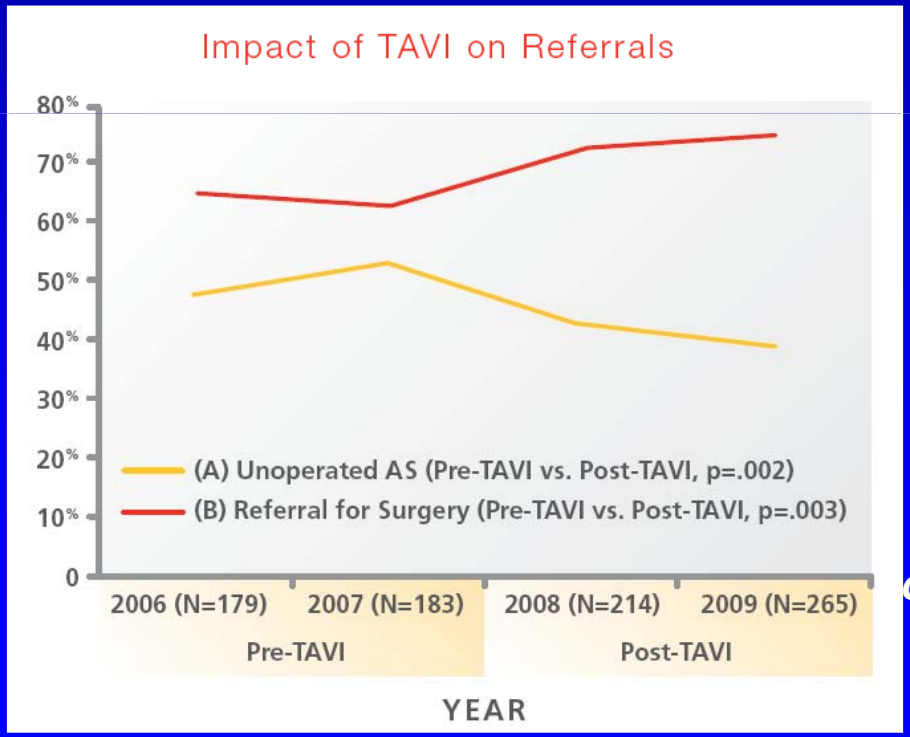


(Kang et al. Circulation. 2010;doi: 10.1161/CIRCULATIONAHA.109.909903)

Impact of TAVI on Patient Referral

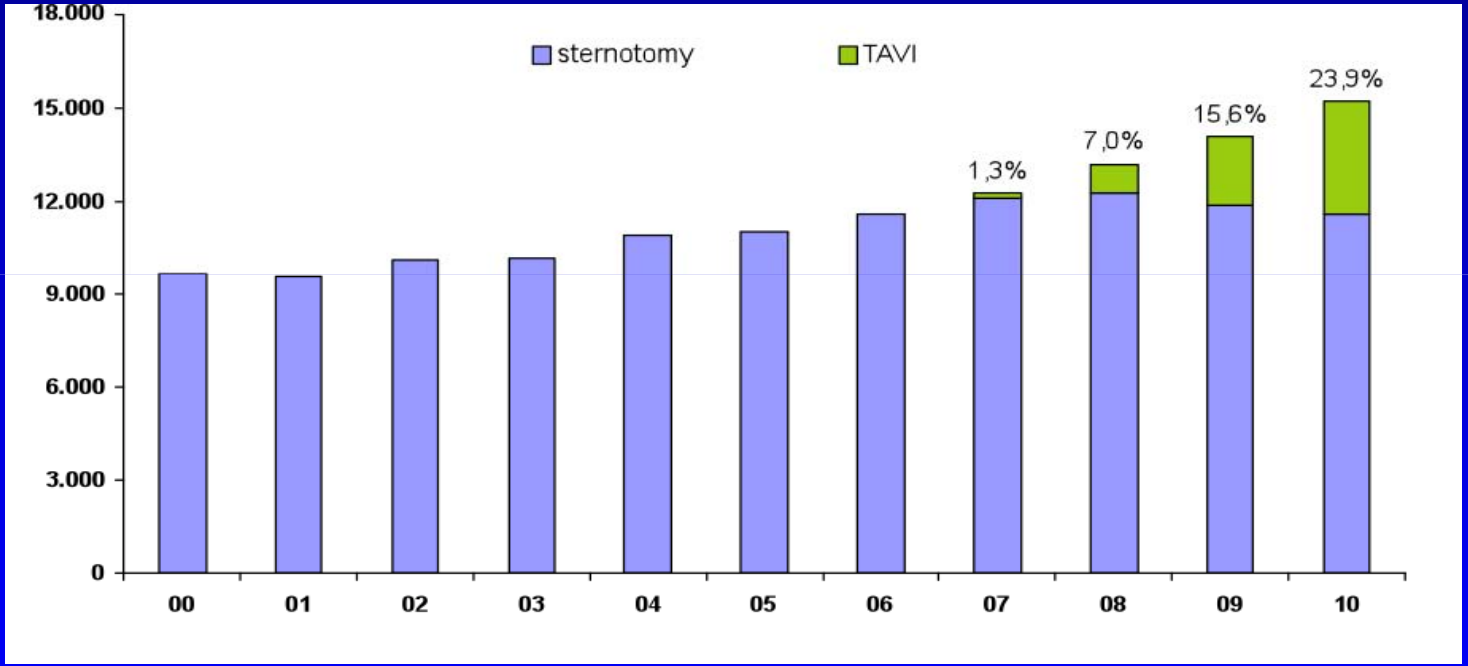
Patients referred for severe and symptomatic aortic stenosis

- 362 between 2005 and 2007, 479 between 2008 and 2009
- Median age 78 years
- 10% increase in surgical referral and interventions



orac Surg 2011;40:43-8)

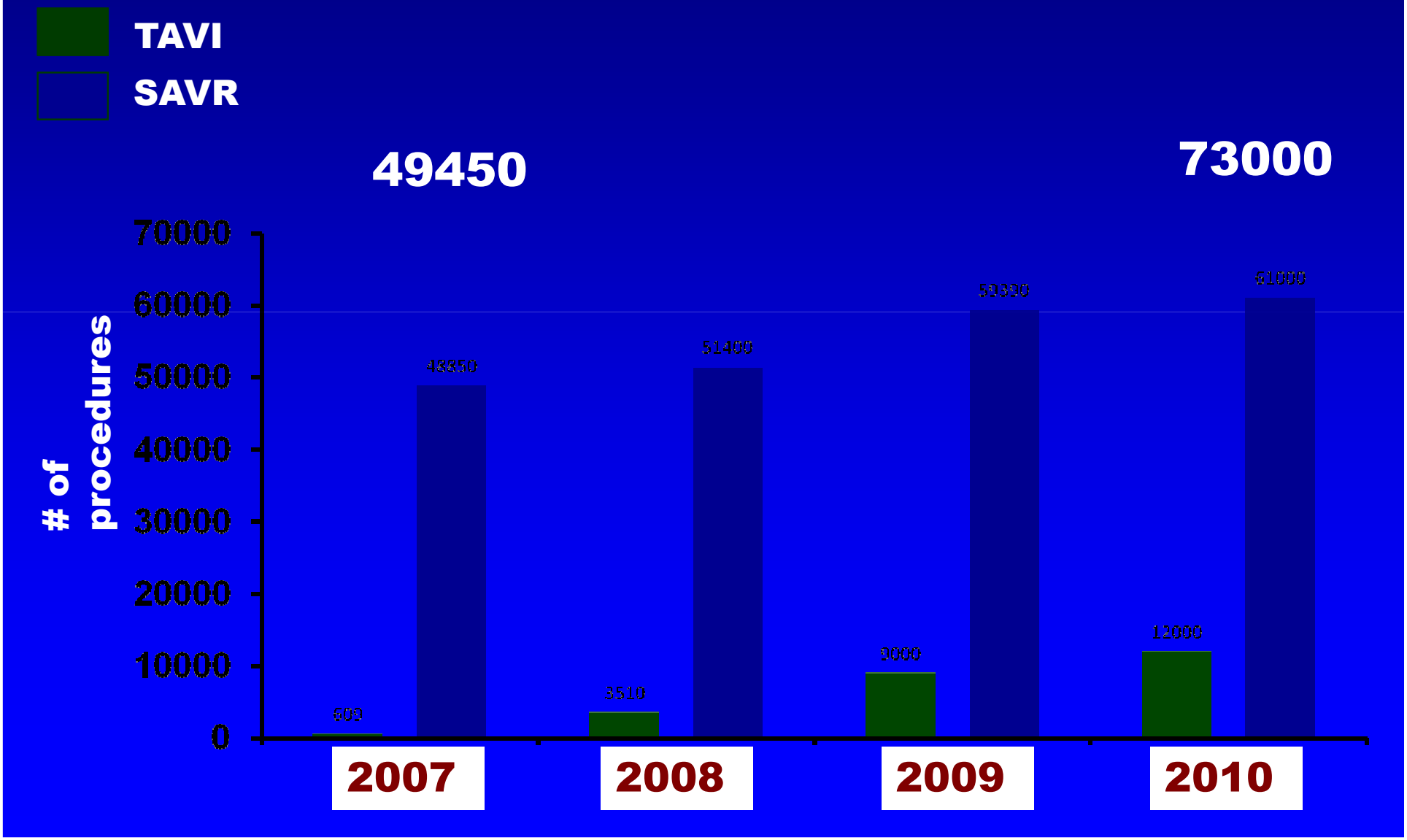
Germany
TAVI a Game Changer in AVR



% Patients undergoing conventional AVR vs TAVI

(Quelle: DGTHG Statistik 2010)

Growing TAVI Experience in Europe



- General comments.
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- Real life
- ***What is next ?***

The « Heart Team »

SURGEONS

CARDIOLOGISTS

Anesthesiologists

Treatment of Aortic Stenosis

Other specialists: Geriatricians ……

Imaging specialists (Echo, CT, MRI)

With expertise in the treatment of valve disease

EACTS/ESC/EAPCI Position Statement, Eur Heart J, 2008; 29: 1463-1470,
Eur J Cardiothorac Surg 34 (2008) 1-8

Risk-Benefit Assessment

- Decision-making for intervention is multifactorial:
  - ✓ Prognosis according to severity and consequences of valvular disease
  - ✓ Risks and late consequences of intervention
  - ✓ Patient life expectancy and quality of life
  - ✓ Patient wishes after information
  - ✓ Local resources, in particular results of surgery

The “Ideal" Model for the Prediction of the Risk of AVR @ TAVI

- Specific evaluation in valve patients
- Tested in a subset representative of the global patient population and practices
- Prospective and external validation
- Easy to use
- Prediction of long-term outcome, morbidity, costs
- “Use-by-date”

European Heart Journal
doi:10.1093/eurheartj/ehr061

ESC REPORT

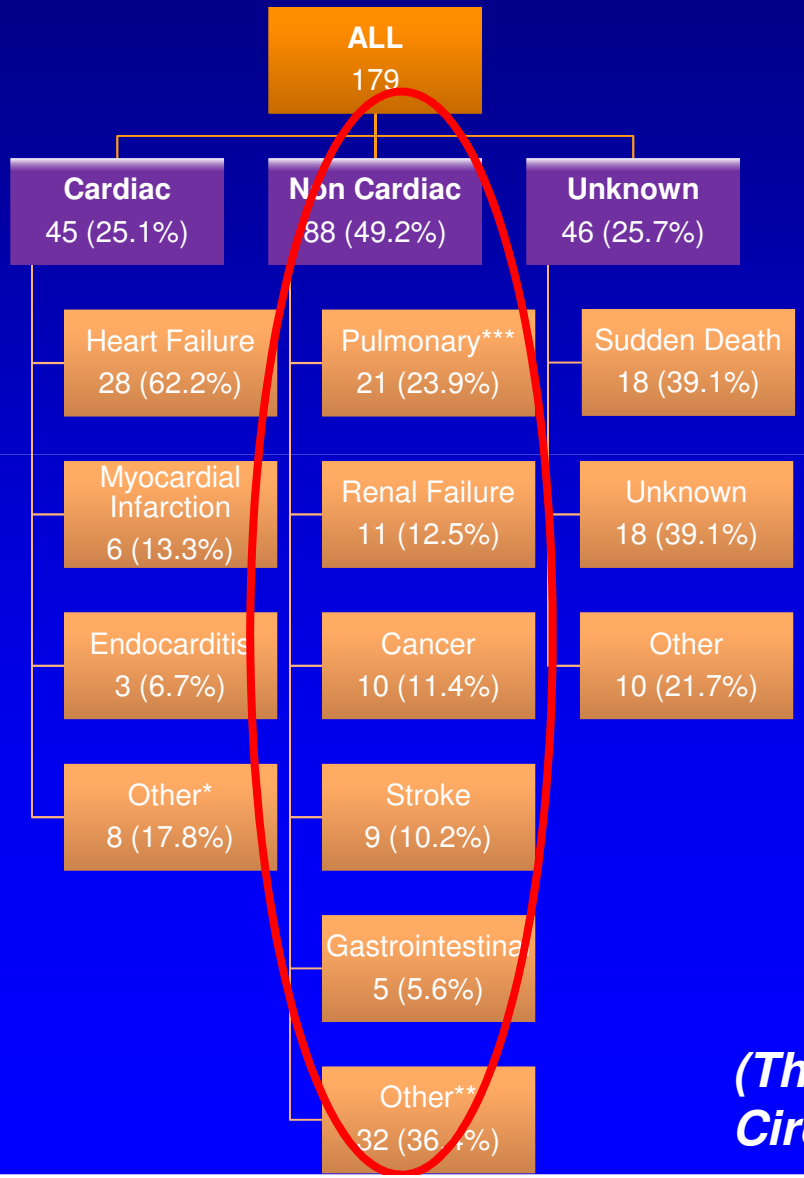
ESC Working Group on Valvular Heart Disease Position Paper: assessing the risk of interventions in patients with valvular heart disease

Raphael Rosenhek[1]*, Bernard Iung[2], Pilar Tornos[3], Manuel J. Antunes[4], Bernard D. Prendergast[5], Catherine M. Otto[6], Arie Pieter Kappetein[7], Janina Stepinska[8], Jens J. Kaden[9], Christoph K. Naber[10], Esmeray Acartürk[11], and Christa Gohlke-Bärwolf[12]

Heart team

Causes of Death 30 Days to 1 Year

SOURCE Registry

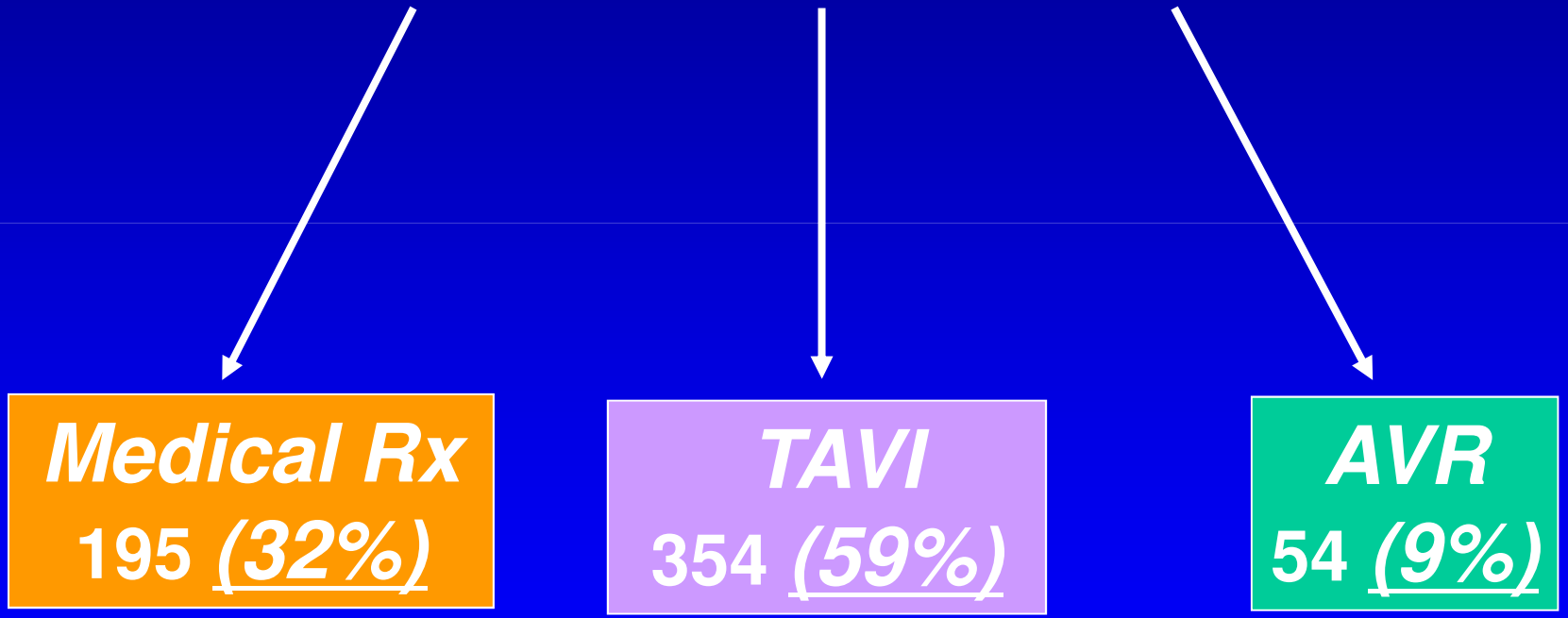


Avoid Cohort C !

(Thomas et al. Circulation 2011;124:425-33)

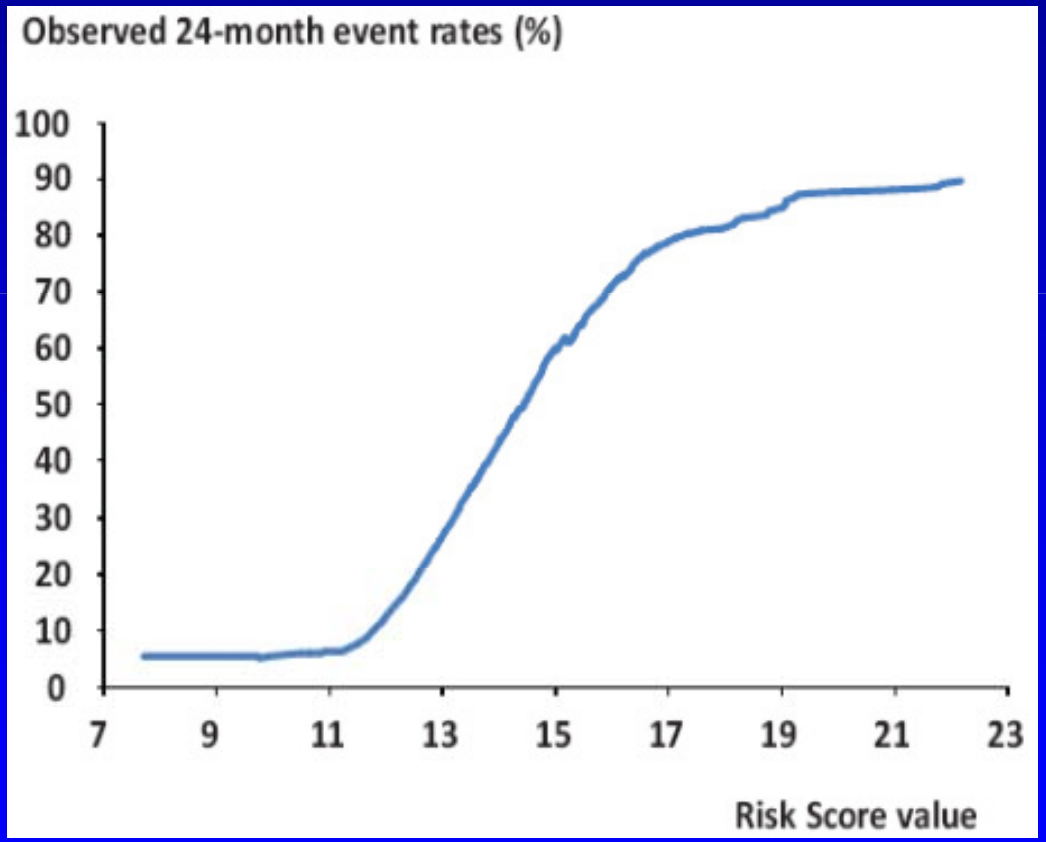
Screening in Bichat among 603 High-risk Patients Referred for TAVI

EuroSCORE ≥ 20% - STS PROM ≥ 10% / CI to AVR



Risk Score for Predicting Outcome in Asymptomatic AS

Score = (peak velocity (m/s) x 2)+ (logarithm of BNPx1.5) +1.5 (if female)



(Monin,Circulation ,2009;120;69-75)

Good Evaluation

Journal of the American College of Cardiology

Circulation

JOURNAL OF THE AMERICAN HEART ASSOCIATION

American Heart Association. Learn and Live℠

Percutaneous Transarterial Aortic Valve Replacement in Selected High-Risk Patients With Aortic Stenosis

John G. Webb, Sanjeevan Pasupati, Karin Humphries, Christopher Thompson, Lukas Altwegg, Robert Moss, Ajay Sinhal, Ronald G. Carere, Brad Munt, Donald Ricci, Jian Ye, Anson Cheung and Sam V. Lichtenstein

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Circulation

JOURNAL OF THE AMERICAN HEART ASSOCIATION

American Heart Association. Learn and Live℠

One-Year Outcomes of Cohort 1 in the Edwards SAPIEN Aortic Bioprosthesis European Outcome (SOURCE) Registry : The European Registry of Transcatheter Aortic Valve Implantation Using the Edwards SAPIEN Valve

Martyn Thomas, Gerhard Schymik, Thomas Walther, Dominique Himbert, Thierry Lefèvre, Hendrik Treede, Holger Eggebrecht, Paolo Rubino, Antonio Colombo, Rüdiger Lange, Rebecca R. Schwarz; and Olaf Wendler

Circulation 2011, 124:425-433: originally published online July 11, 2011
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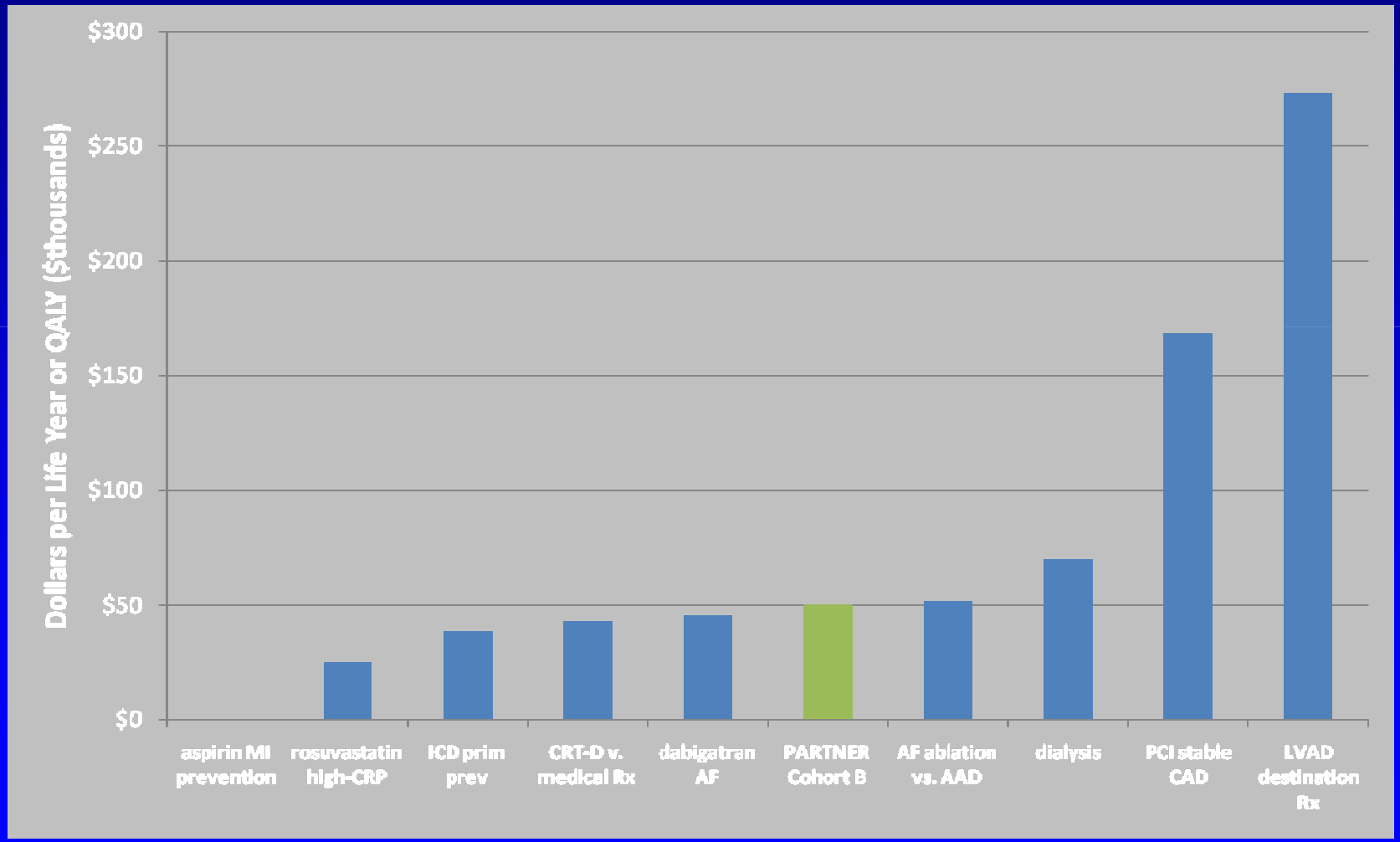
N. Anderson, Ph.D., Duolao Wang, Ph.D.,
RTNER Trial Investigators*

Cost -Effectiveness Assessment

TAVI: Estimates from PARTNER B



(Reynolds. ACC 2011)

Conclusions (I)

- The prevalence of AS increases sharply with age and represents an important burden, which is expected to increase in the near future.
- AS carries a poor prognosis when severe and symptomatic.
- The benefit of surgery has been largely demonstrated.
- Guidelines do not provide explicit age limitations to aortic valve replacement in severe symptomatic AS.

Conclusions (II)

- However, current experience shows that a high percentage of patients are denied surgery.
- The reasons for denying surgery are not always consistent with risk-benefit analysis.
- TAVI enables a higher number of patients to be effectively treated.
- Initial experience suggests that the availability of TAVI increases patient referral, not only for less invasive procedures, but also for conventional surgery.

Conclusions (III)

Further research is needed on :

- Impact of medical therapy on aortic valve sclerosis and new therapeutic pathways
- Early detection of LV dysfunction in asymptomatic patients
- Risk stratification models and implementation of their use in conjunction with the other elements in decision-making
- Evaluation of the role of TAVI in randomized trials and comprehensive registries
- Newer trials for better evidence……

“We may have all come in different ships, but we’re in the same boat now”

Martin Luther King, Jr.

stop

European TAVI Registries

	French	UK	Belgian	German	Italian
Age (yr)	82±6	83±7	83±6	81±6	81±7
LogEuroscore (%)	22±14	21±6	26±16	21±13	23±14
Procedural success (%)	97	99	98	98.7	98
1-month Survival (%)	90	93	92	88	94

Zahn et al Eur Heart J 2011;32:198-204
Moat In Press J Am Coll Cardiol 2011
Tamburino C et al Circulation 2011;123:299-308
Bosmans et al Inter Cardiovasc Thoracic Surgery 2011;12:762-67

European TAVI Registries

French registry
- 33 centers,
- 4042 consecutive pts

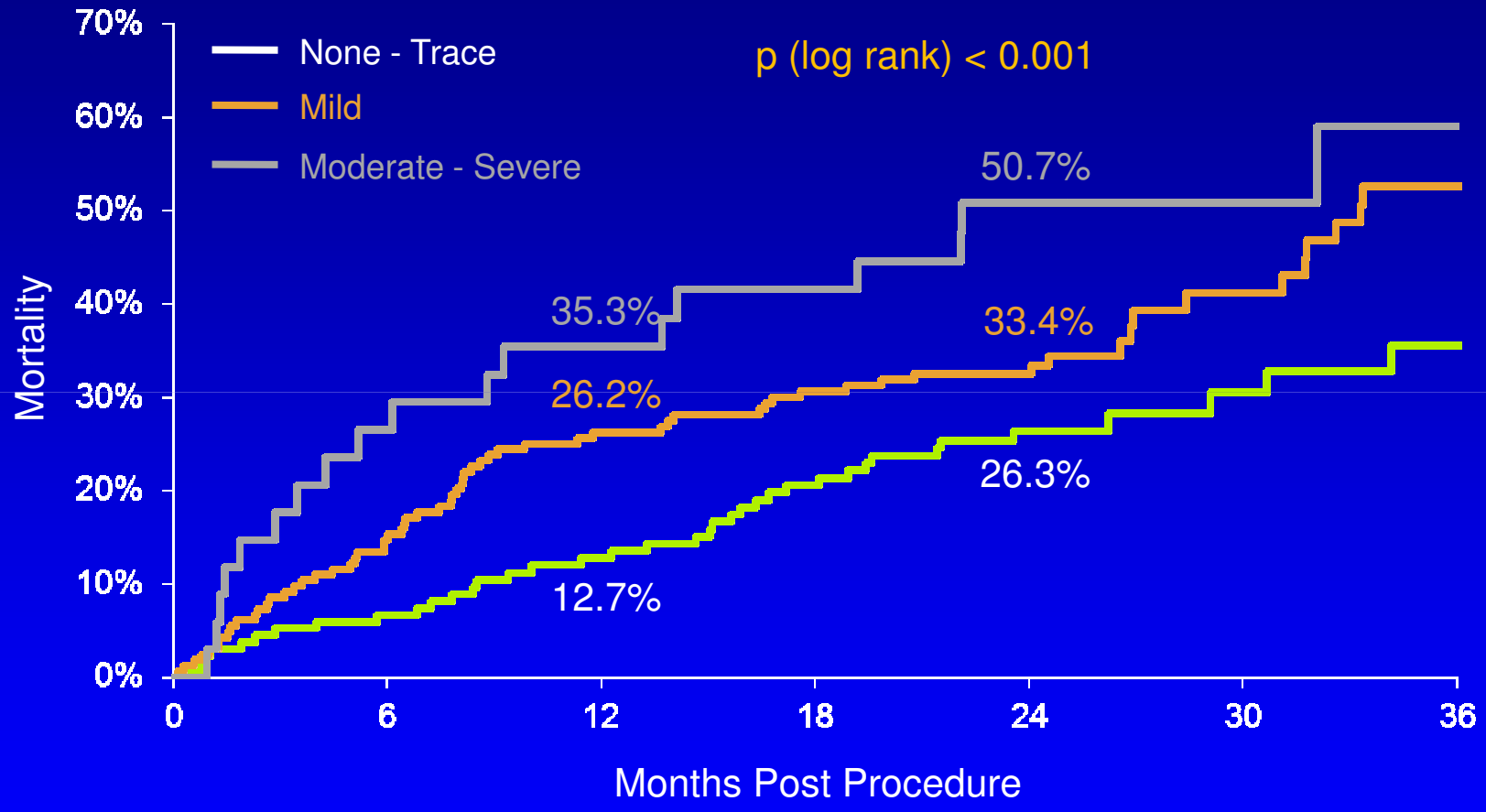
Belgian registry
- 18 centers,
- 600 consecutive pts

United Kingdom registry
- 26 centers
- 872 consecutive pts

German registry
- 22 centers
- 833 consecutive pts

Italian registry
- 14 centres
- 663 pts CoreValve

AR after TAVI and Mortality in PARTNER A



Numbers at Risk

None-Tr	*135*	*125*	*115*	*101*	*68*	*31*	*11*
Mild	*165*	*139*	*121*	*111*	*71*	*33*	*16*
Mod-Sev	*34*	*25*	*22*	*19*	*15*	*6*	*2*

Current Indications for TAVI

European Heart Journal (2008) **29**, 1463–1470
doi:10.1093/eurheartj/ehn183

SPECIAL ARTICLE

Transcatheter valve implantation for patients with aortic stenosis: a position statement from the European Association of Cardio-Thoracic Surgery (EACTS) and the European Society of Cardiology (ESC), in collaboration with the European Association of Percutaneous Cardiovascular Interventions (EAPCI)

Alec Vahanian[1]*, Ottavio Alfieri[2]*, Nawwar Al-Attar[1], Manuel Antunes[3], Jeroen Bax[4], Bertrand Cormier[5], Alain Cribier[6], Peter De Jaegere[7], Gerard Fournial[8], Arie Pieter Kappetein[7], Jan Kovac[9], Susanne Ludgate[10], Francesco Maisano[2], Neil Moat[11], Friedrich Mohr[12], Patrick Nataf[1], Luc Piérard[13], José Luis Pomar[14], Joachim Schofer[15], Pilar Tornos[16], Murat Tuzcu[17], Ben van Hout[18], Ludwig K. Von Segesser[19], and Thomas Walther[12]

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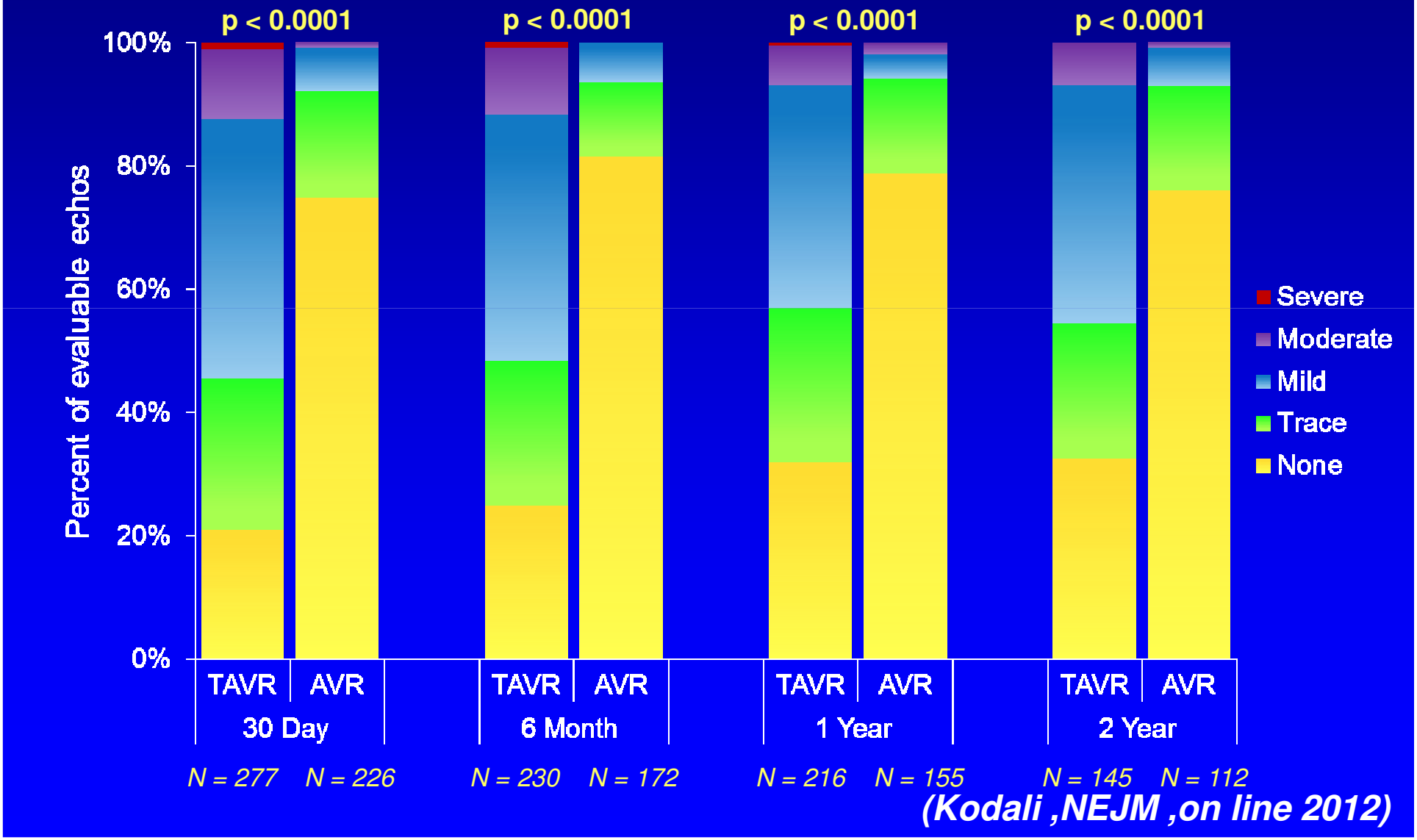
Aims To critically review the available transcatheter aortic valve implantation techniques and their results, as well as propose recommendations for their use and development.

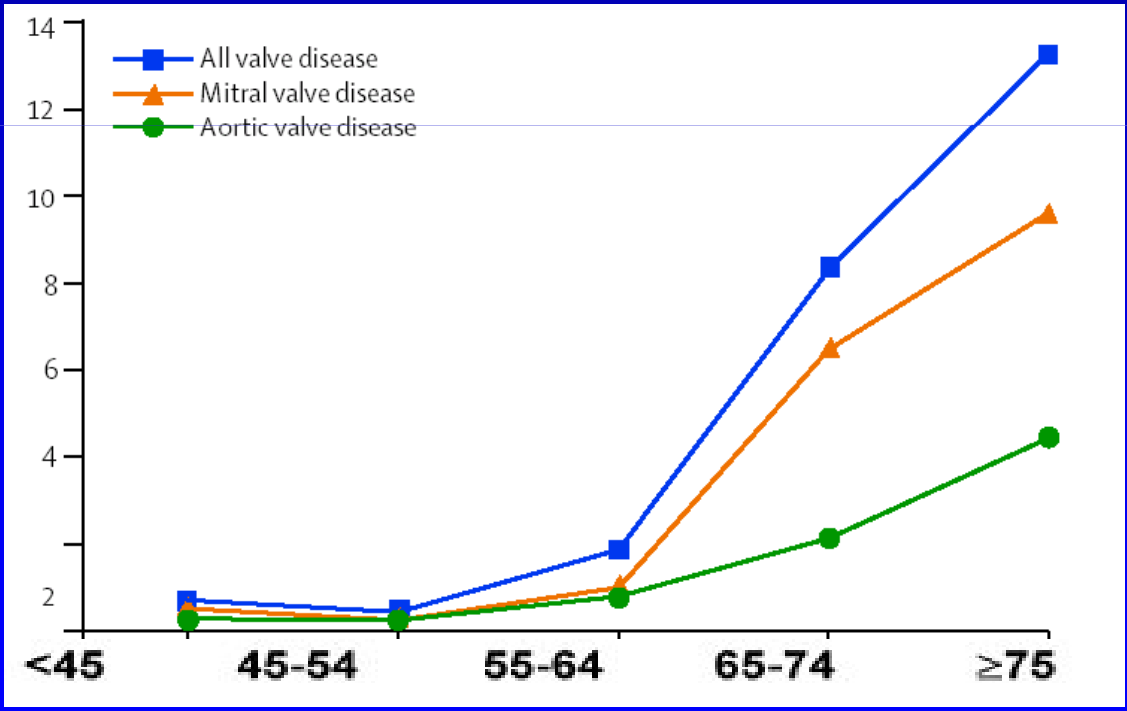
Paravalvular Aortic Regurgitation



(Kodali ,NEJM ,on line 2012)

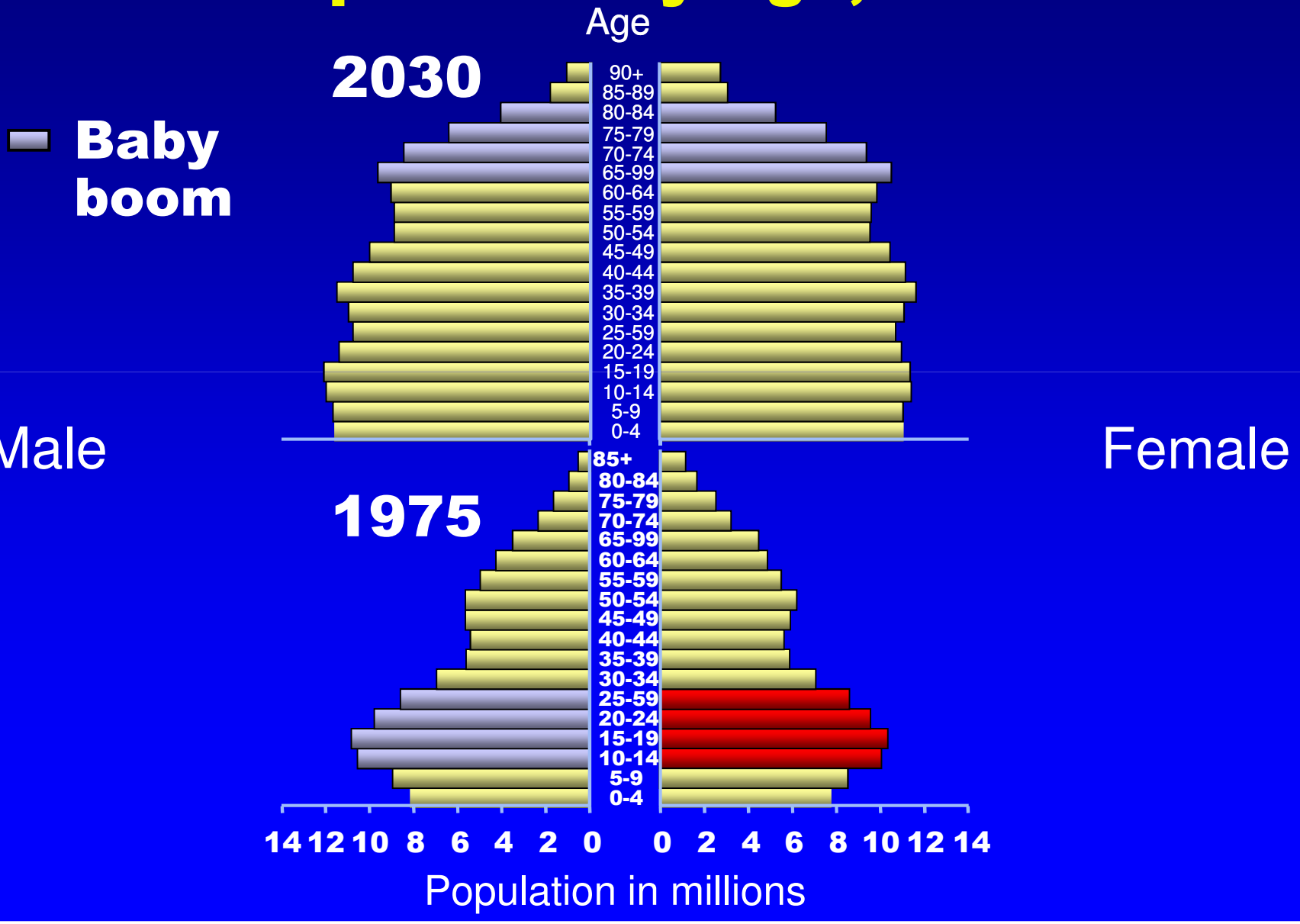
Prevalence of Valvular Heart Disease in US

- 11 911 randomly selected patients with echo
  Age-adjusted prevalence of valvular disease: ***2.5%***
- Prevalence :***1.8%*** in a community-based study



(Nkomo et al. Lancet 2006;368:1005-11)

The Graying of the World
Population by Age, Sex

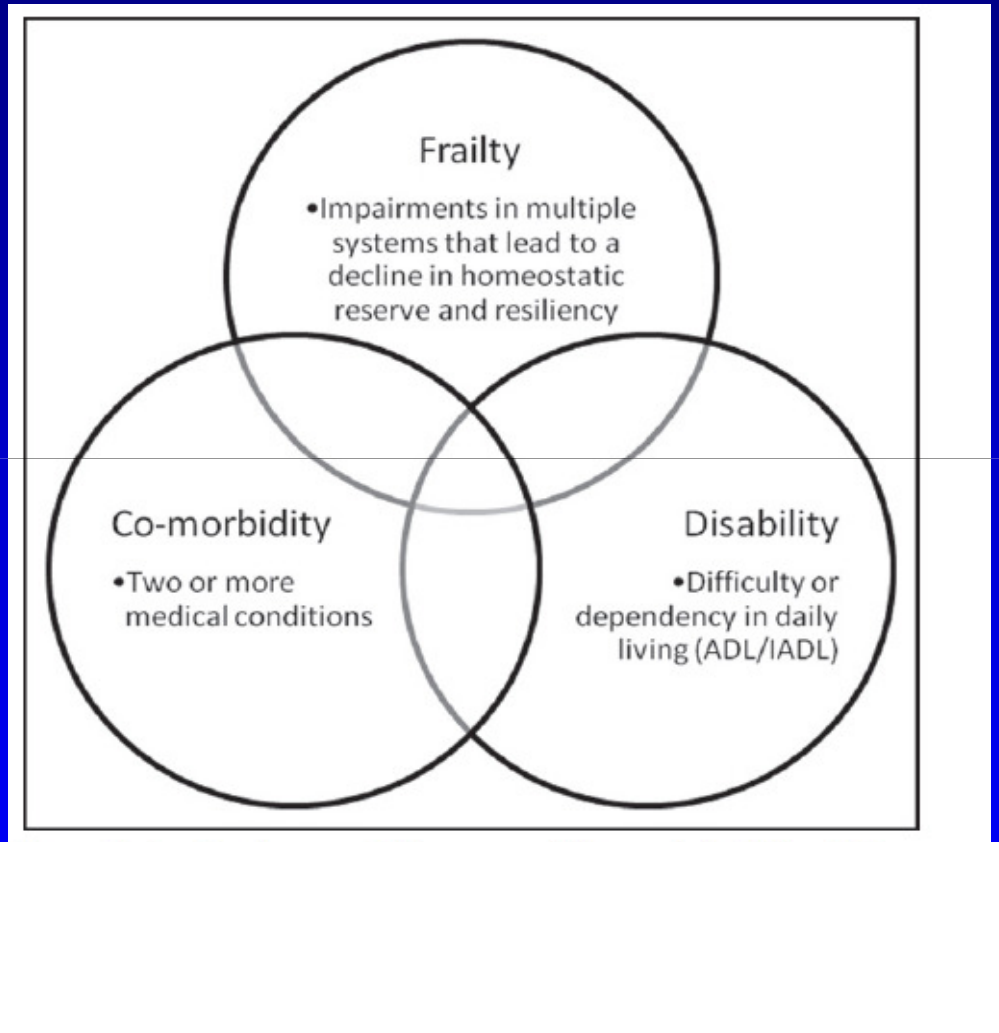


Patient Characteristics in the Euro Heart Survey

	Age (years)	***≥ 70 years (%)***	***≥ 1 comorbidity (%)***
AS	***69±12***	***56***	***36***
AR	58±16	25	26
MS	58±13	18	22
MR	65±14	44	42

(Iung. Eur Heart J 2003;24:1244-53)

Frailty, Co-morbitity, and Disability



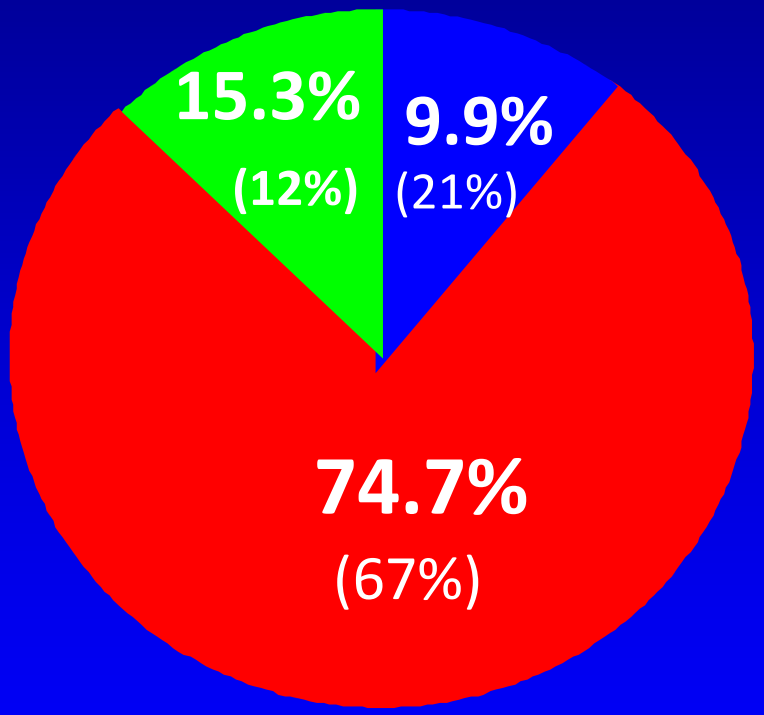
(Fried LP et al, J Gerontology 2001;56A:M146-56)

Where Shall we Perform?

In cardiology and cardiac surgery centers

FRANCE 2 (n=3195)

Procedural characteristics



The “Heart Team”

- ***A group of valve specialists who collaborate*** to:

  - ✓Select the most appropriate procedure
  - ✓ Perform the procedures
  - ✓ Evaluate the results

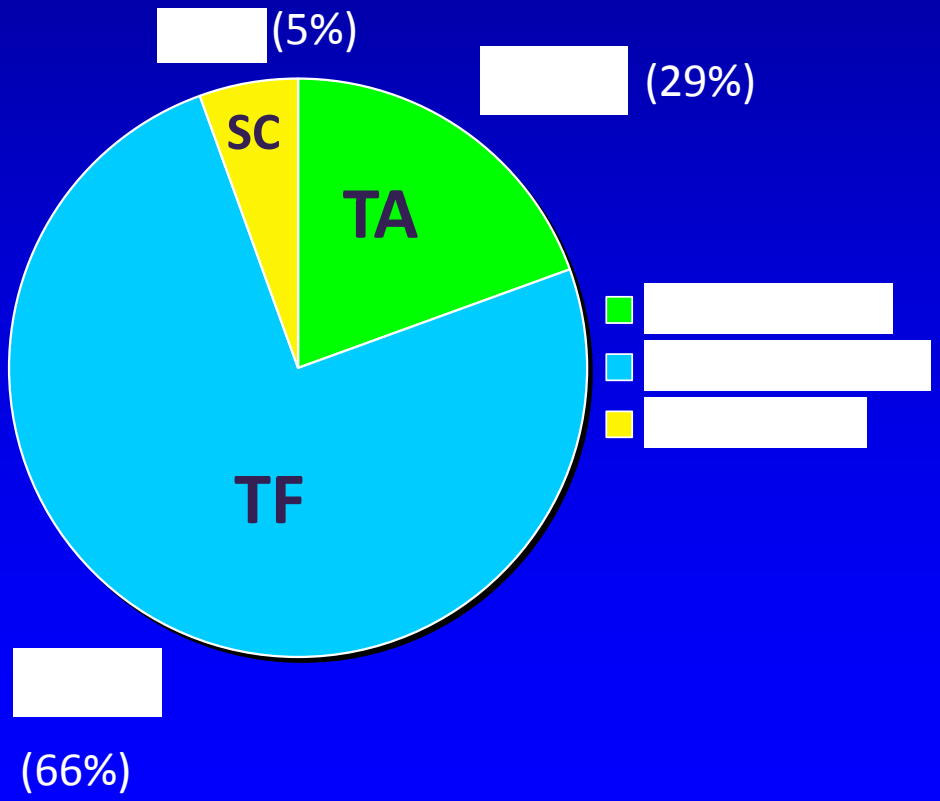
(EACTS/ESC/EAPCI Position Statement, Eur Heart J, 2008; 29: 1463-1470, Eur J Cardiothorac Surg 34 (2008) 1-8, Eurointerv. 2008; 4:193-199)

Decision-making for intervention

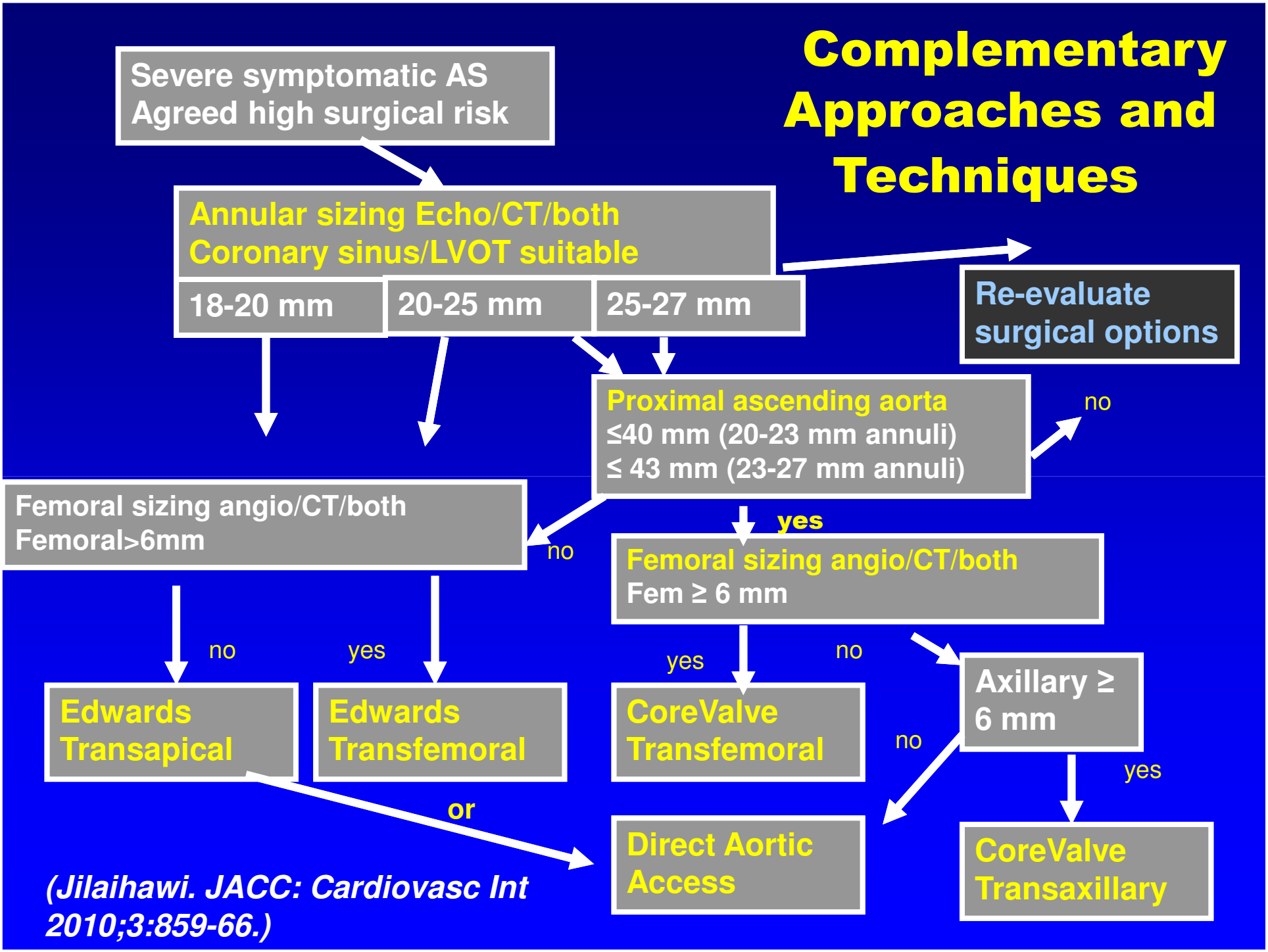
- ✓ Prognosis according to severity and consequences of valvular disease
- ✓ Risks and late consequences of intervention
- ✓ Patient life expectancy and quality of life
- ✓ Patient wishes after information
- ✓ Local resources, in particular results of surgery

FRANCE 2 (n=3195)

Approaches used

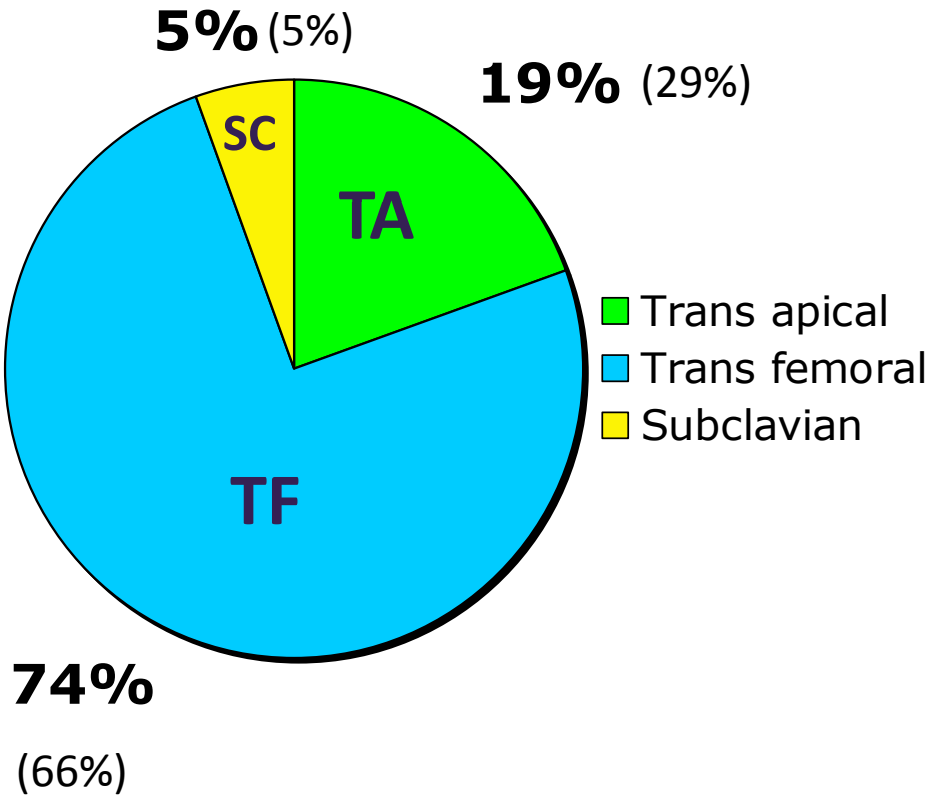


Complementary Approaches and Techniques

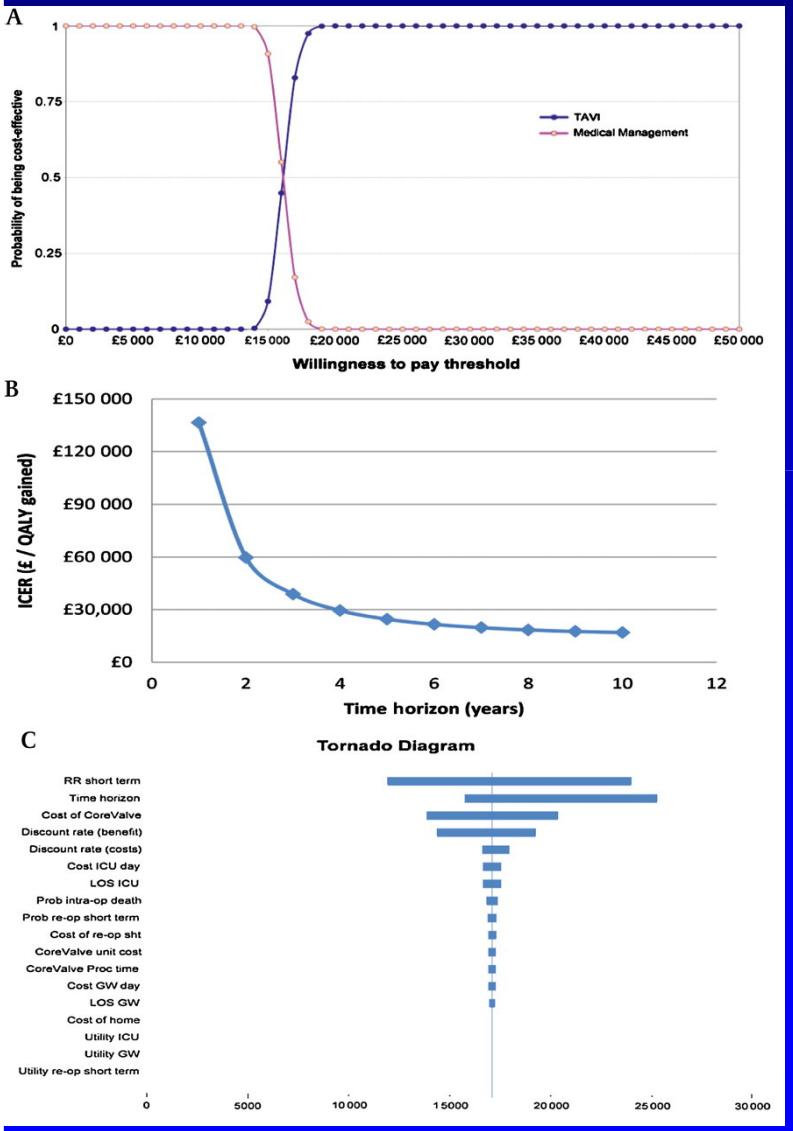


(Jilaihawi. JACC: Cardiovasc Int 2010;3:859-66.)

FRANCE 2 (n=3195)
Approaches used



Cost – effectivness acceptability curves for Medical Management and TAVI

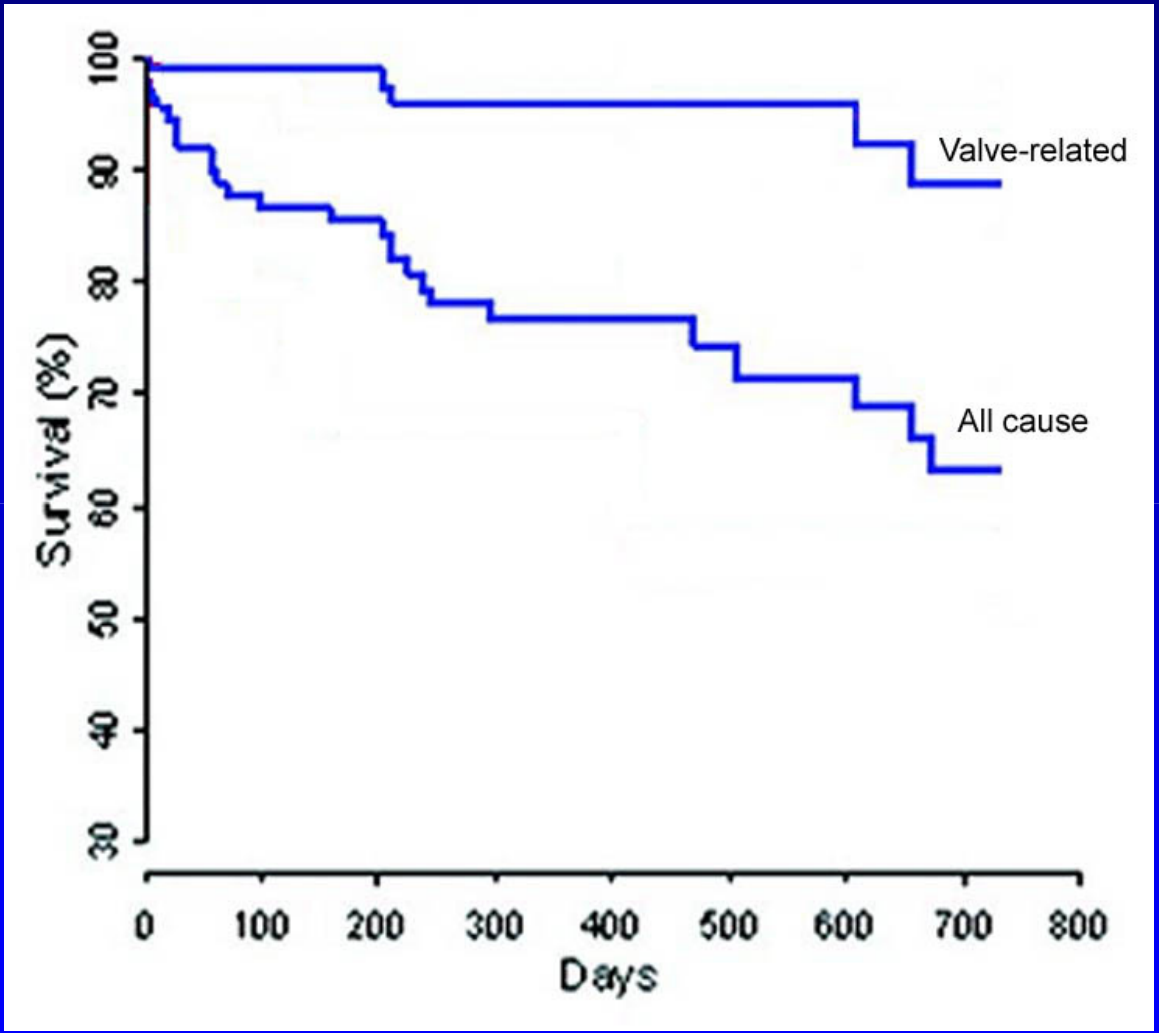


« Assuming a cost –effectiveness threshold of L12000 per QALY gained ,the probability that TAVI is a cost effective intervention in inoperable patients is 1 »

« TAVI is higly likely to be a cost effective treatment for patients with severe AS who are currently ineligible for SAVR »

(Watt M et al. Heart 2012;98:370-376)

Follow-up after TAVI

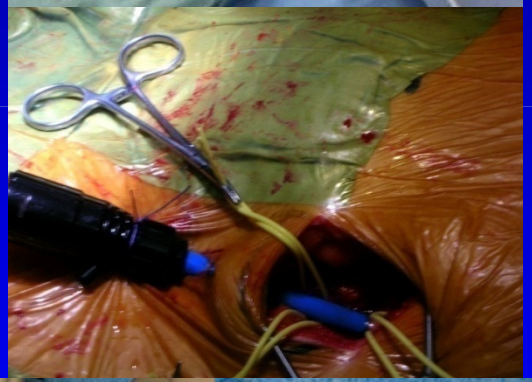


(Webb. Circulation 2009;119;3009-3016)

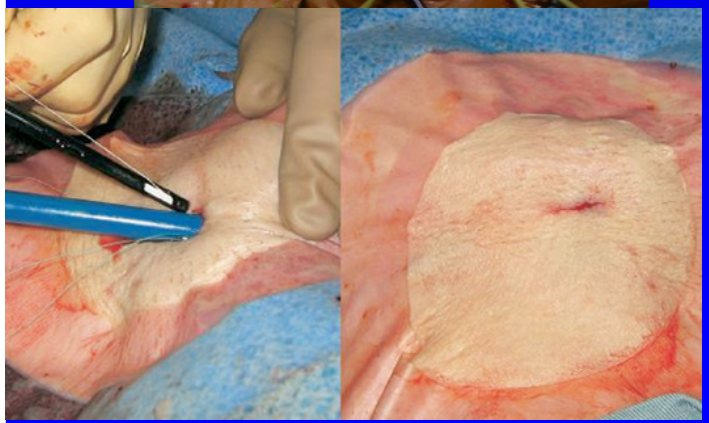
Transfemoral Approach

(74%in France 2)

Percutaneous access + surgical closure

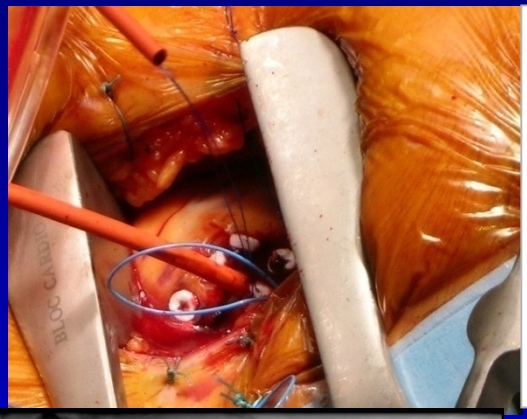


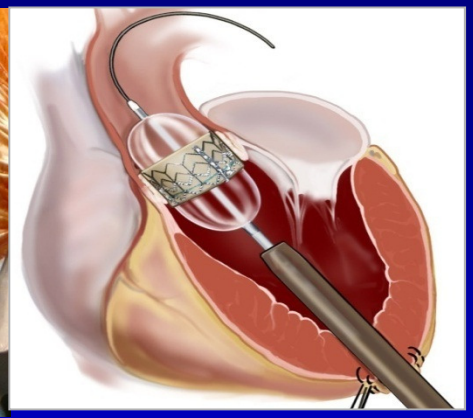
Surgical access and closure



Percutaneous access and closure
(closure device)

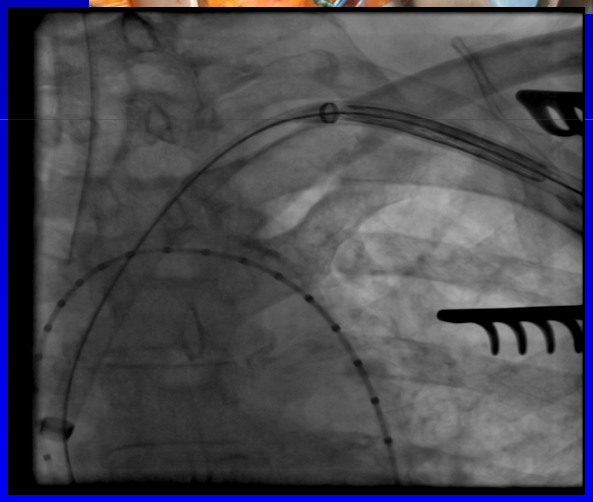
Alternatives to the TF approach





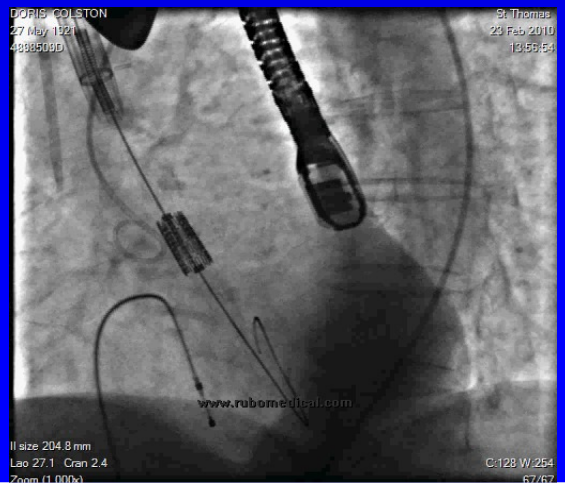
Transapical (Edwards Sapien)

(17% in France 2)



Subclavian (Medtronic CoreValve)

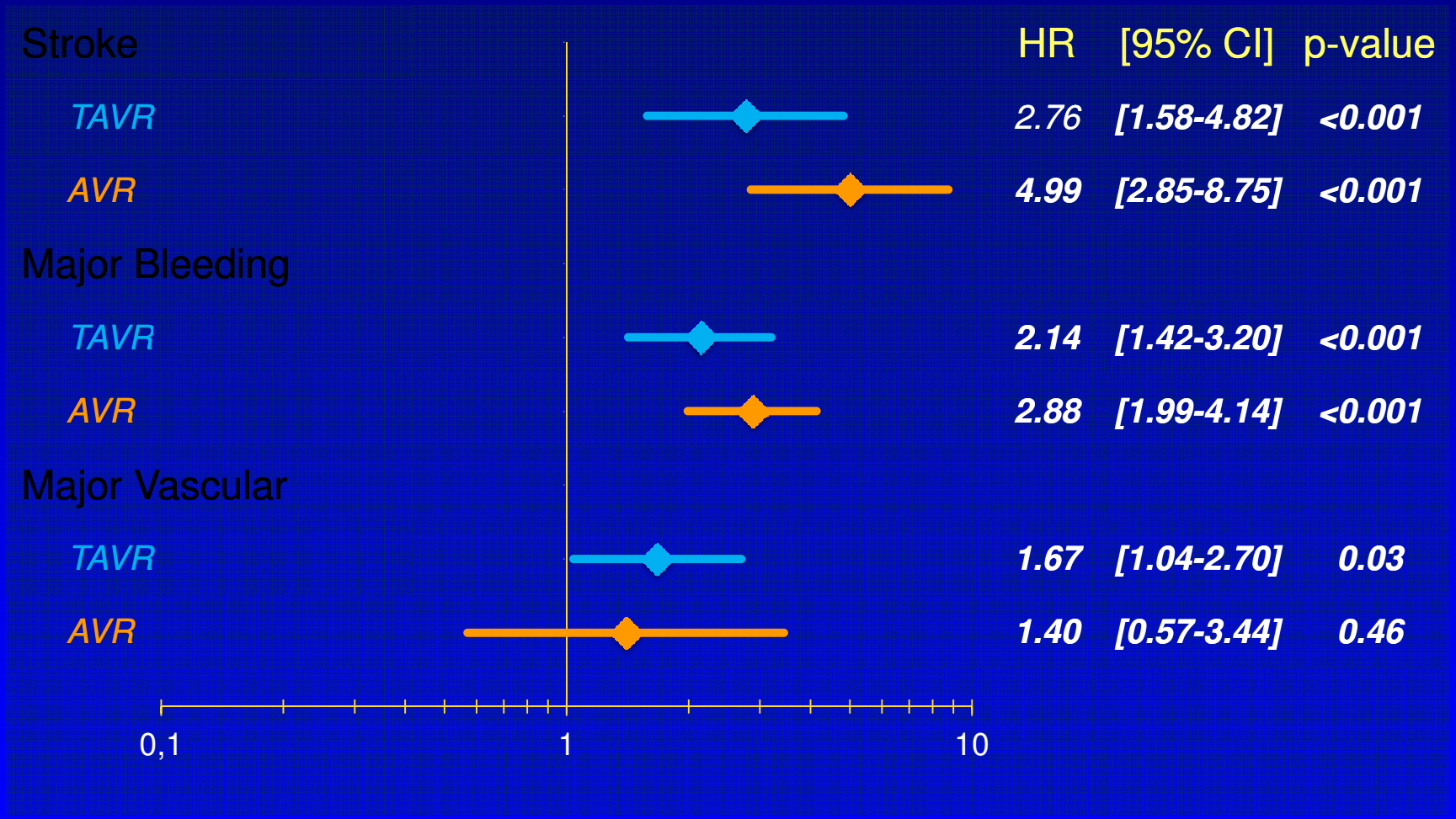
(5% in France 2)



Transaortic (Both)

(2% in France 2)

Procedural Predictors of Mortality in PARTNER



Decision-making for intervention

- ✓ Prognosis according to the severity and consequences of valvular disease
- ✓ Risks and late consequences of intervention
- ✓ Patient life expectancy and quality of life
- ✓ Patient wishes after information:

Self referral !

- ✓ Local resources, in particular results of surgery

(ESC Guidelines, Eur Heart J 2007;28:230-68)