

The background of the slide is a photograph of the Bichat Hospital building in Paris. The building is a modern, multi-story structure with a facade of light-colored panels and dark horizontal bands. A large, dark, cantilevered sign extends from the building, bearing the text 'CENTRE HOSPITALIER UNIVERSITAIRE BICHAT' in white capital letters. The sky is a clear, bright blue.

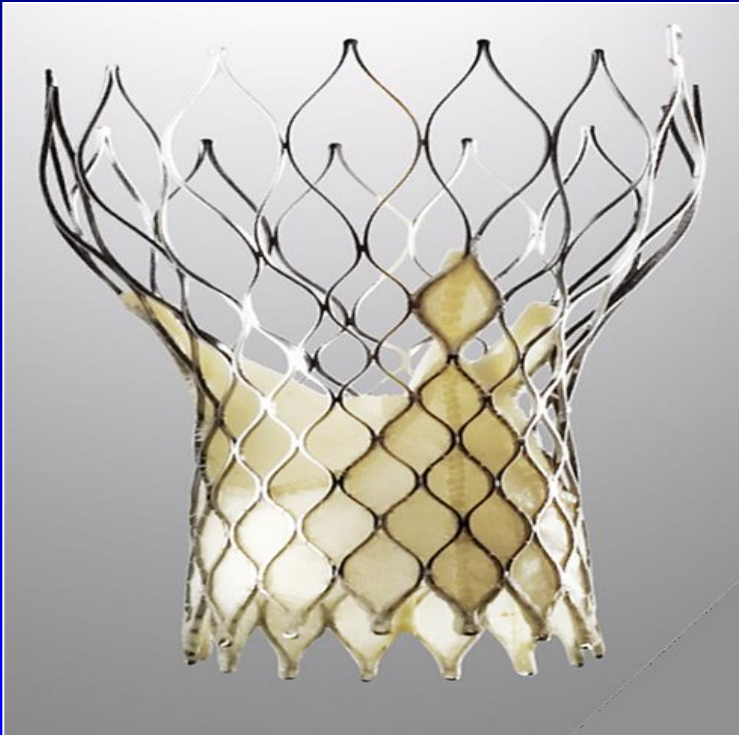
Transcatheter Aortic Valve Implantation:

Should we go to lower risk patients?

Alec Vahanian
Bichat Hospital, Paris

The Devices fo TAVI

Medtronic CoreValve® TAV



CE mark 2007

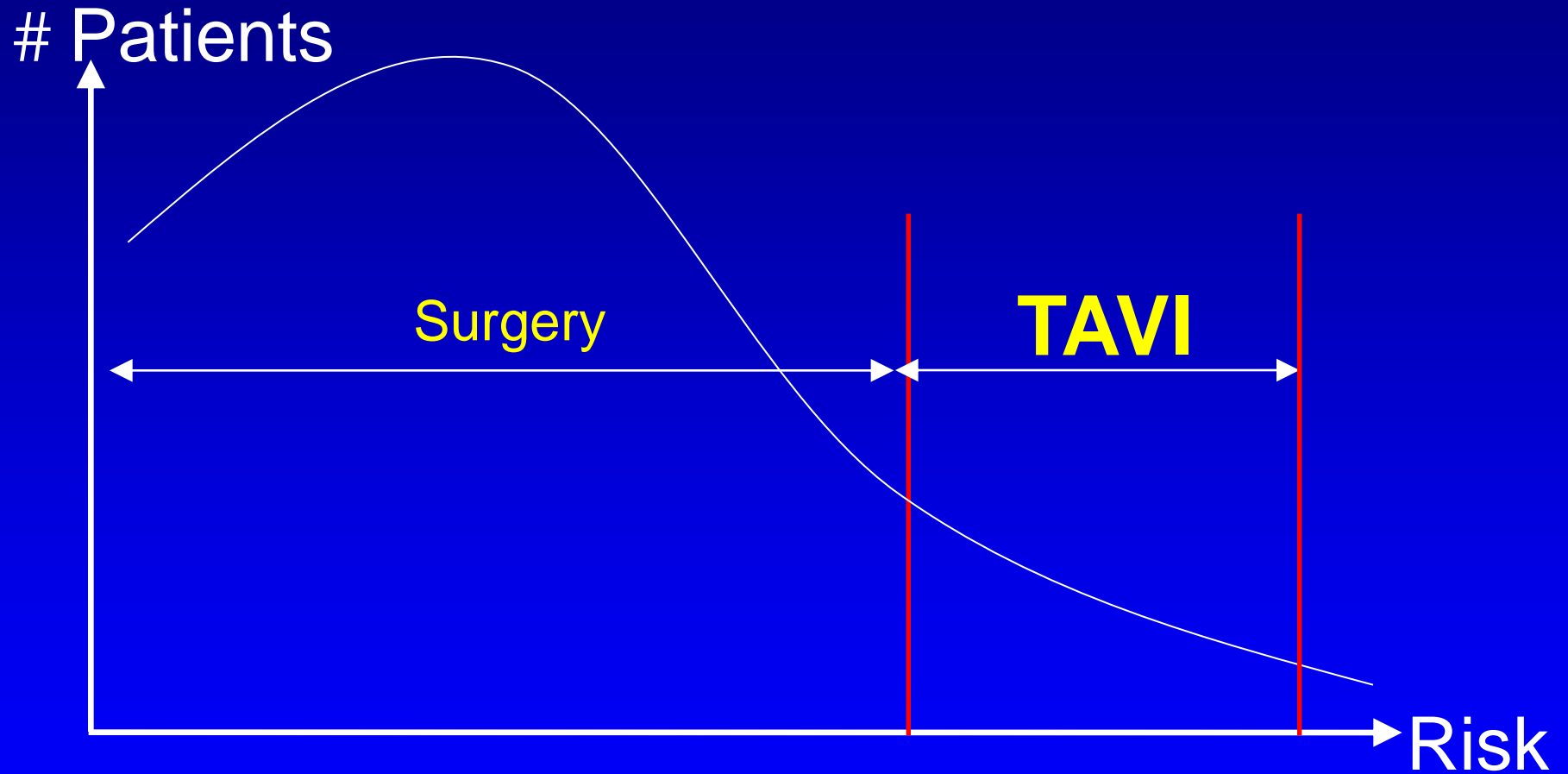
Edwards SAPIEN™ THV



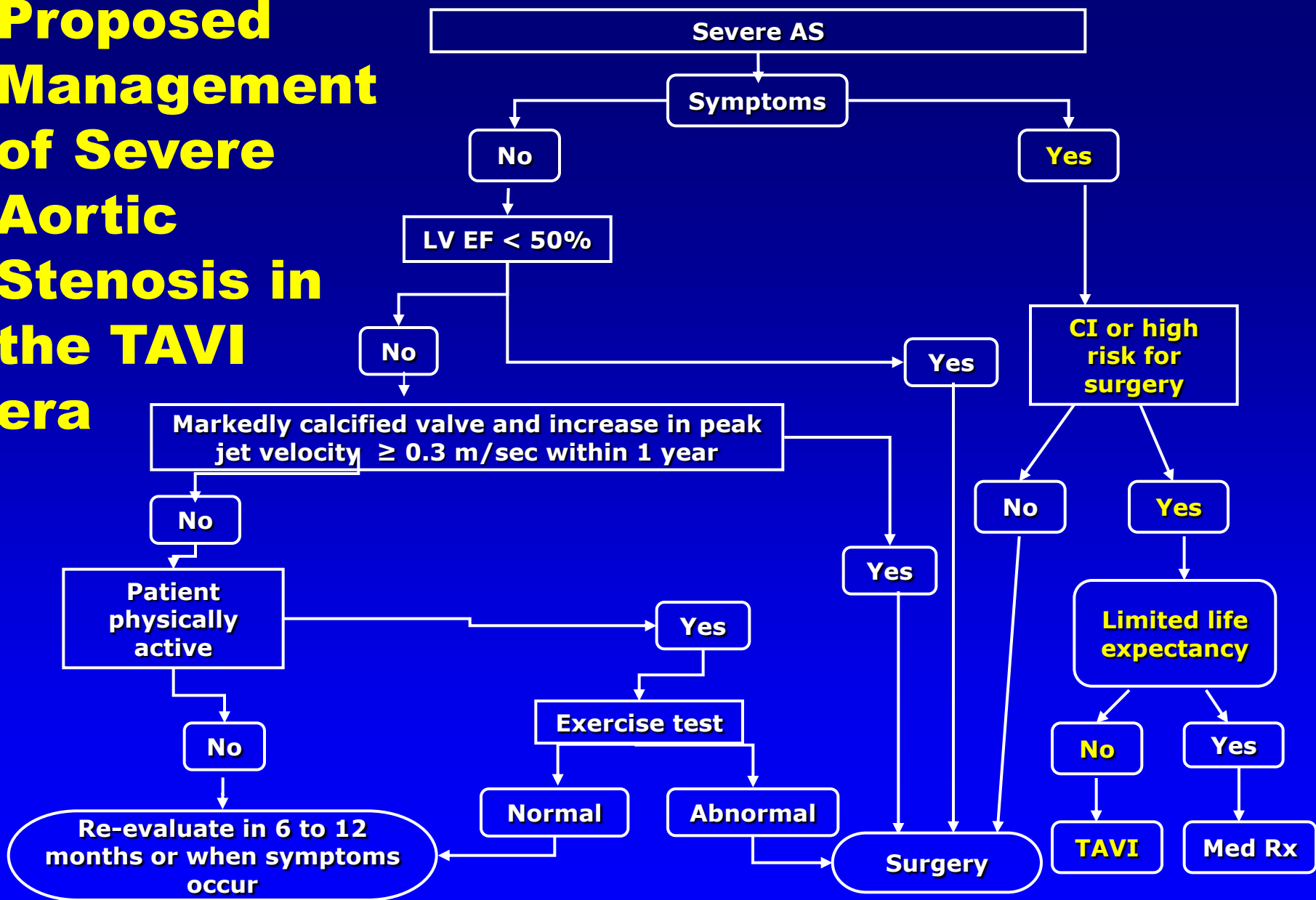
CE mark 2007

>25000 patients treated

Current Indications for TAVI



Proposed Management of Severe Aortic Stenosis in the TAVI era



Inclusion Criteria for TAVI

After assessment by the 'Team'

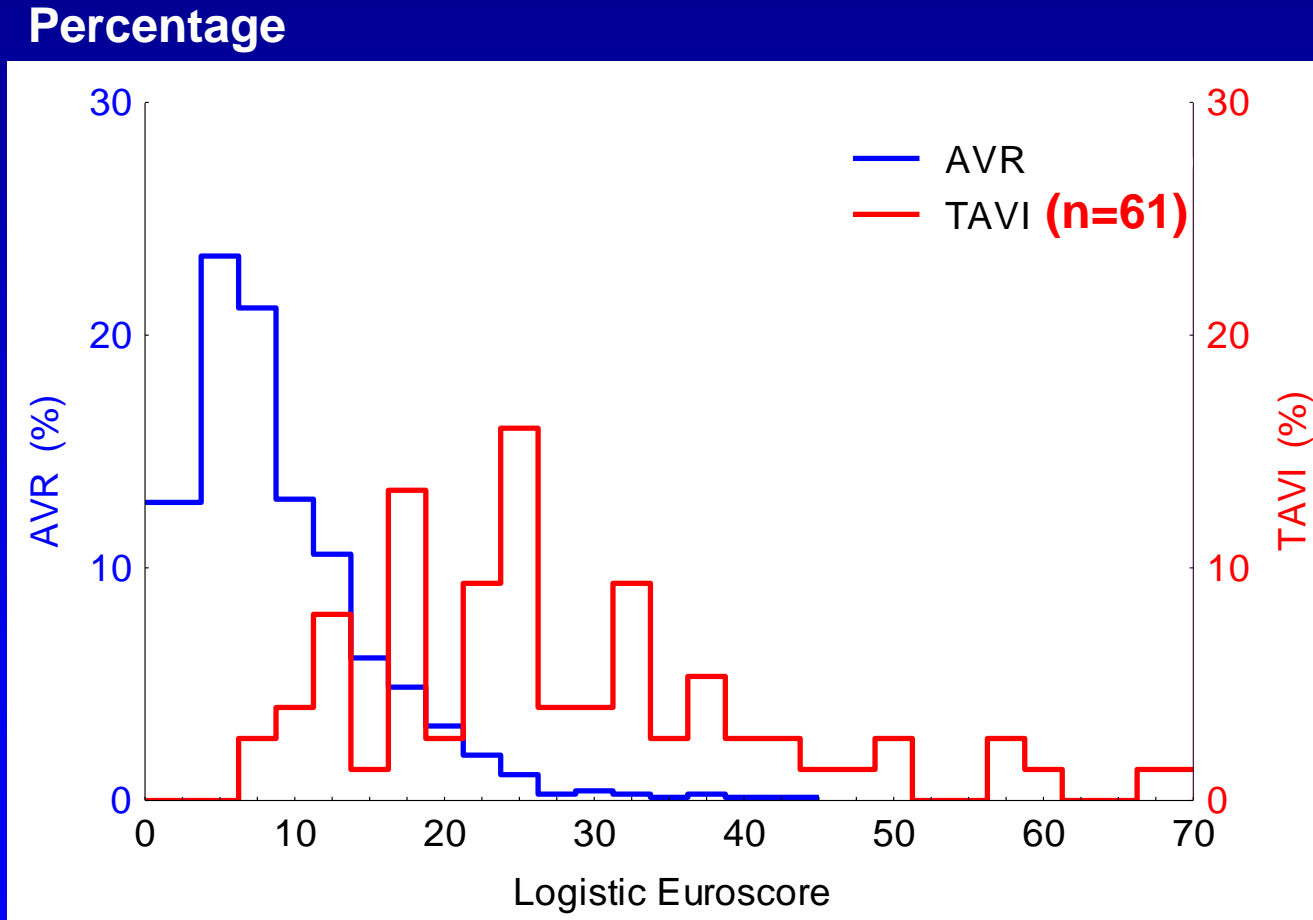
- Severe AS
- Symptomatic
- Life expectancy >1year
- Contra indications for surgery, or
High Risk for Surgery :
 - ✓ *Clinical judgement +*
 - EuroScore (logistic) > 20% ; STS Score>10%

AND/OR

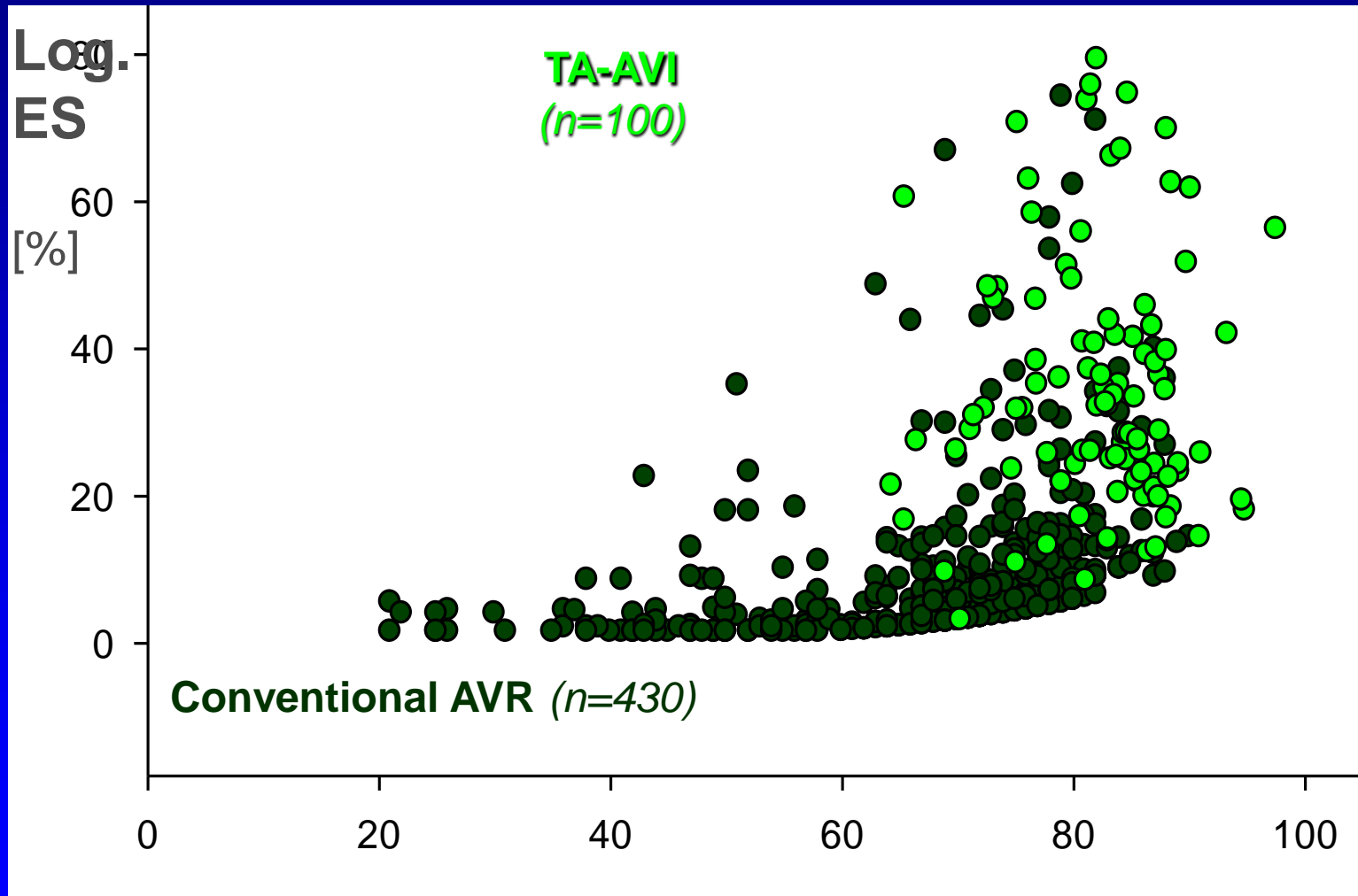
- ✓ Porcelain aorta
- ✓ History of thoracic irradiation
- ✓ Severe thoracic deformity
- ✓ Patent coronary by pass
- ✓

**(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)**

Logistical Euroscore distribution AVR vs. TAVI in Bichat Hospital (2008)



Logistical Euroscore distribution AVR vs. TAVI in Leipzig (2008)



Age

Results of TAVI

National TAVI Registries

%	Belgian (n= 279)	French (n=244)	Spanish (n=108)	UK (n=872)	Germany (n=833)	Italian (n=1248)
Devices	E/MCV	E/MCV	-	MCV/E	MCV/E	MCV
Procedural success	97	97	98.1	-	95.6	99
1 month survival	91	87.3	92.6	93.1	92.5 (in hosp)	94.6

Courtesy of J Bosmans (Belgian Registry); H Eltchaninoff (French Registry)
 A.S. Petronio (Italian Registry), Paul Avanzas (Spanish Registry) **(EuroPCR 2010)**

PARTNER: Inoperable patients

All Cause Mortality



Numbers at Risk					
	0	6	12	18	24
TAVI	179	138	122	67	26
Standard Rx	179	121	83	41	12

Transfemoral Aortic Valve Implantation

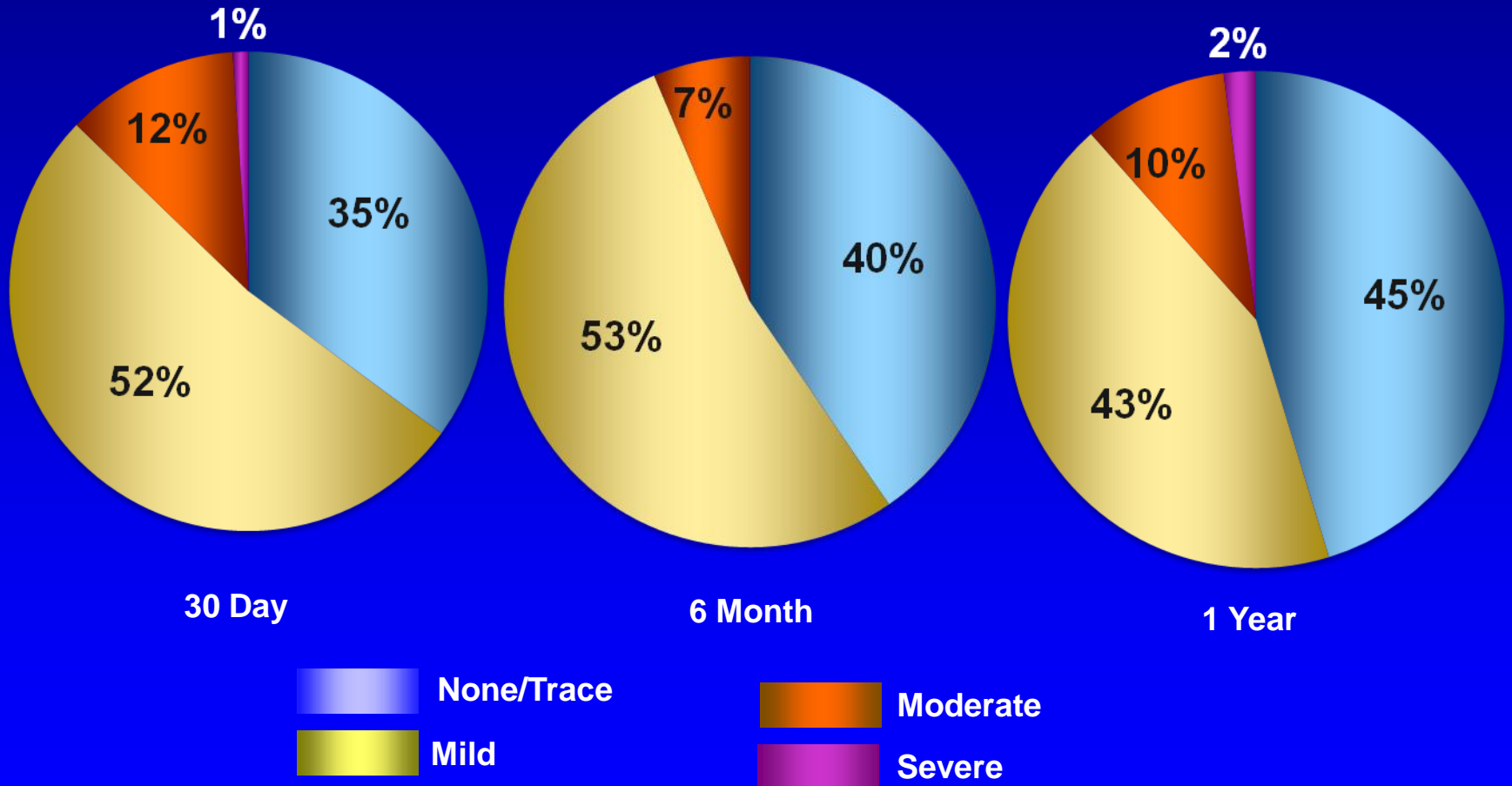
30-Day Complications

	Edwards Sapien			Medtronic CoreValve	
(%)	<i>Webb</i> (146)	<i>PARTNER</i> (179)	<i>Source</i> (946)	<i>Grube</i> (136)	<i>Tamburino</i> (663)
Death	8	5	7.5	12	5.4
Neurological complic.	5	6.7	3	4	1.2
Myocardial infarction	2	0	1	2	0
Permanent pacemaker	4	3.4	7	25	17
Vascular complications	8	16	11	NA	2
AR > 2/4	5	1*	6	2	6

*severe

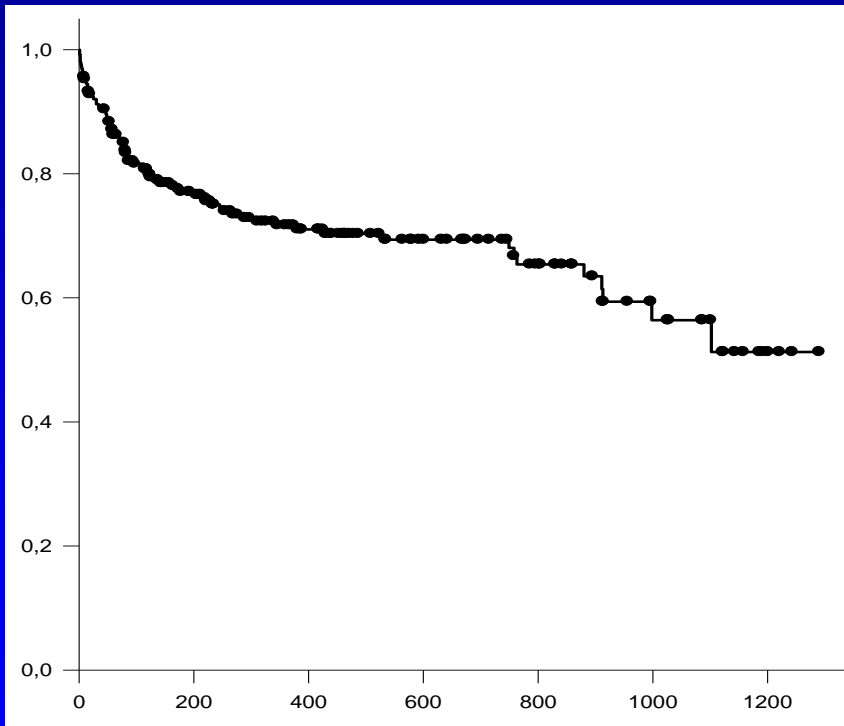
PARTNER

Paravalvular Regurgitation



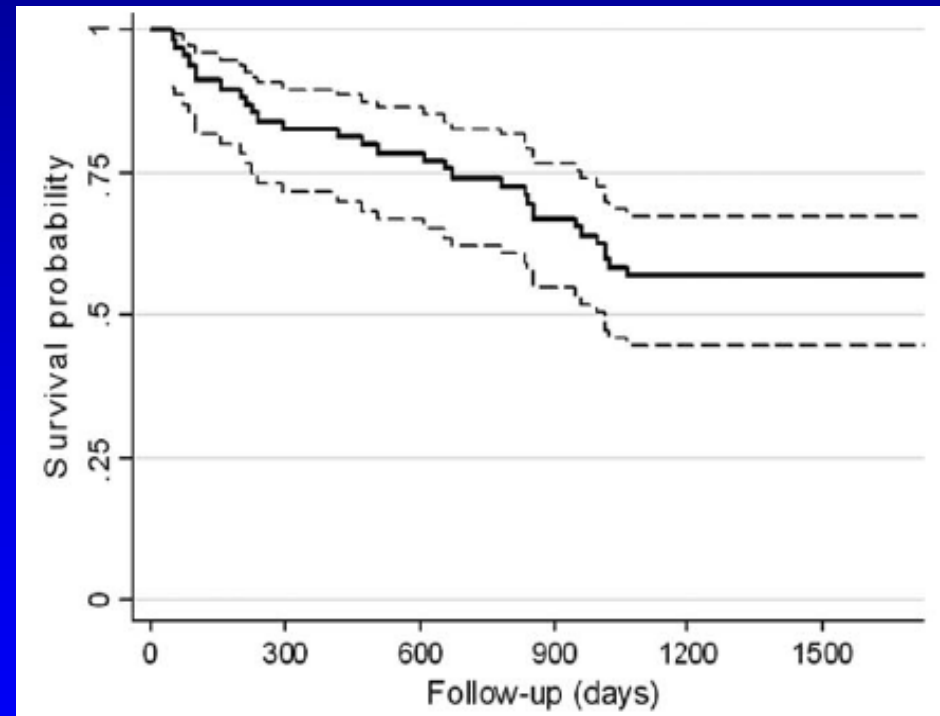
Follow-up After TAVI

TA



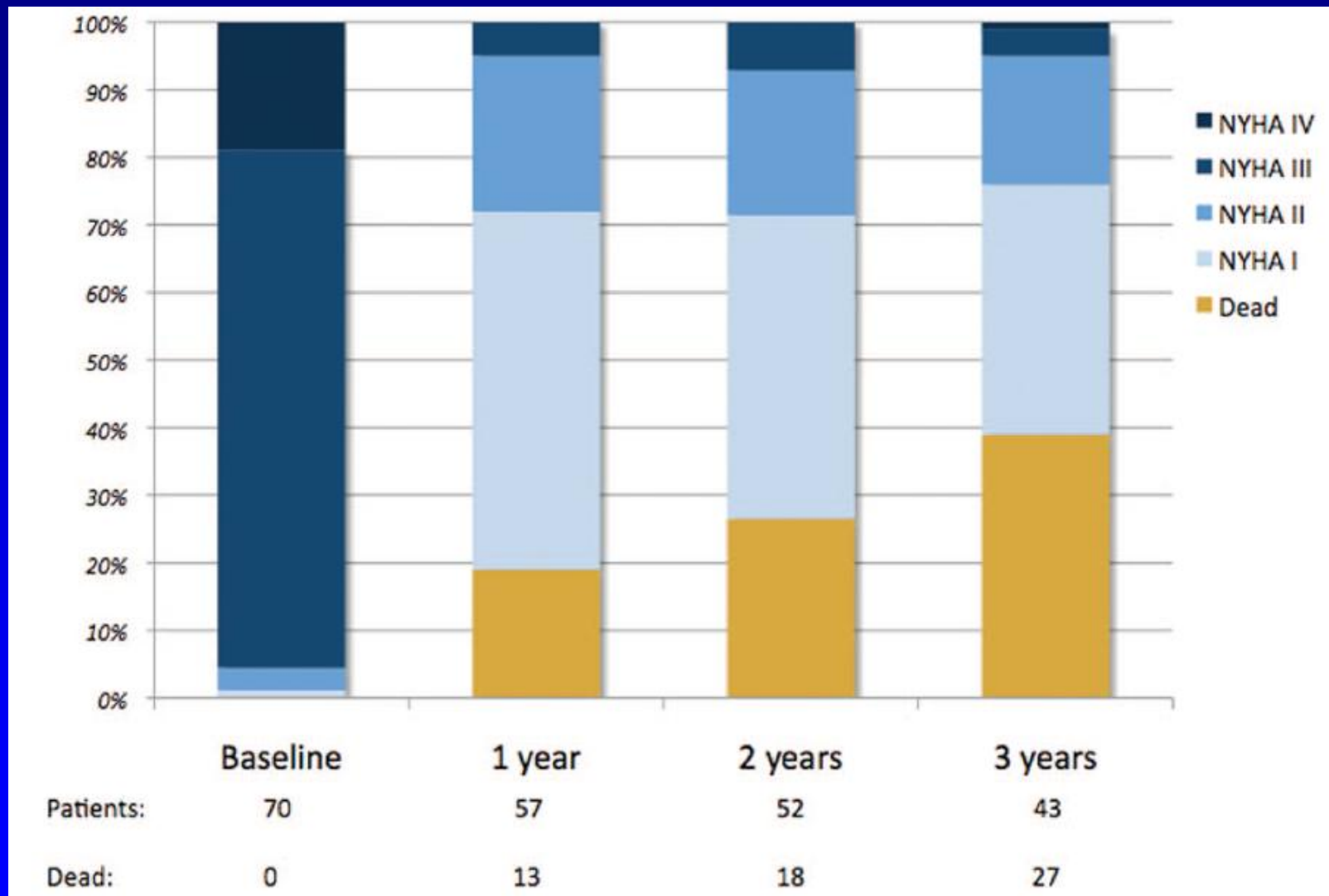
(Walther, Leipzig)

TF/TA



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

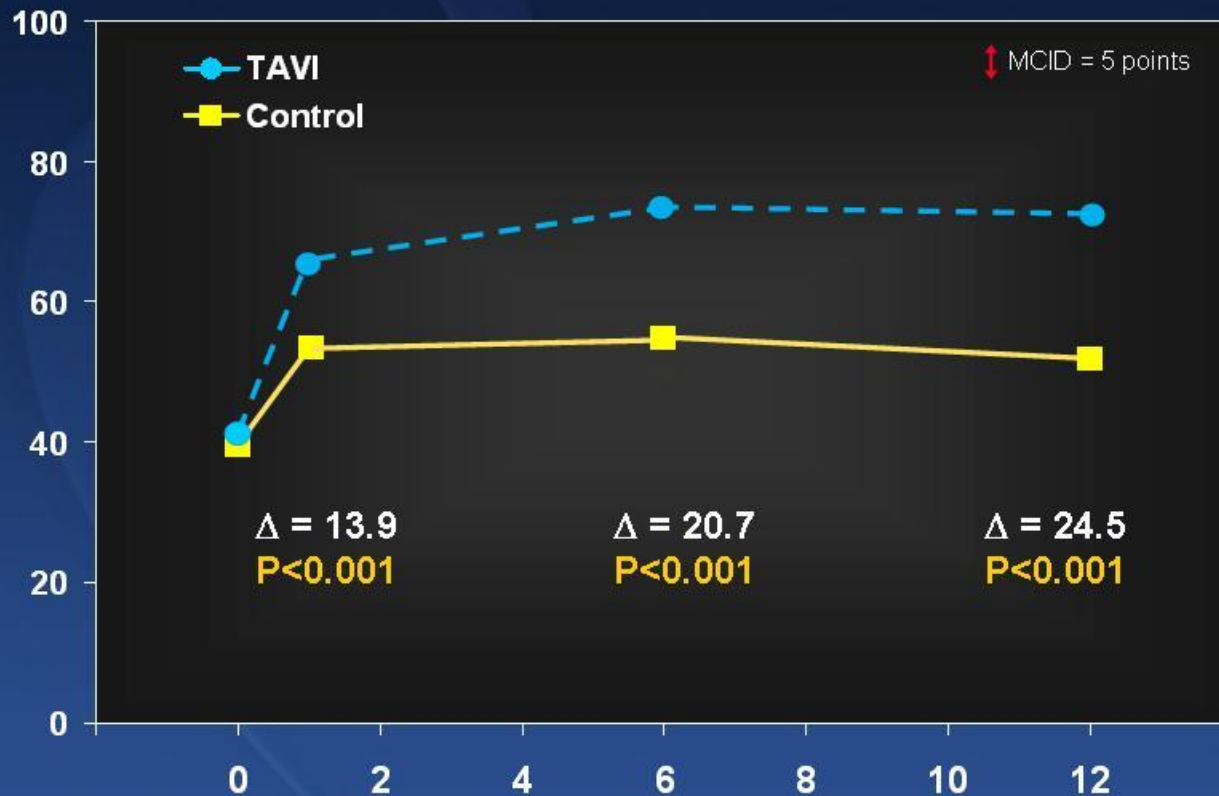
Functional Improvement 2 years after TF TAVI



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

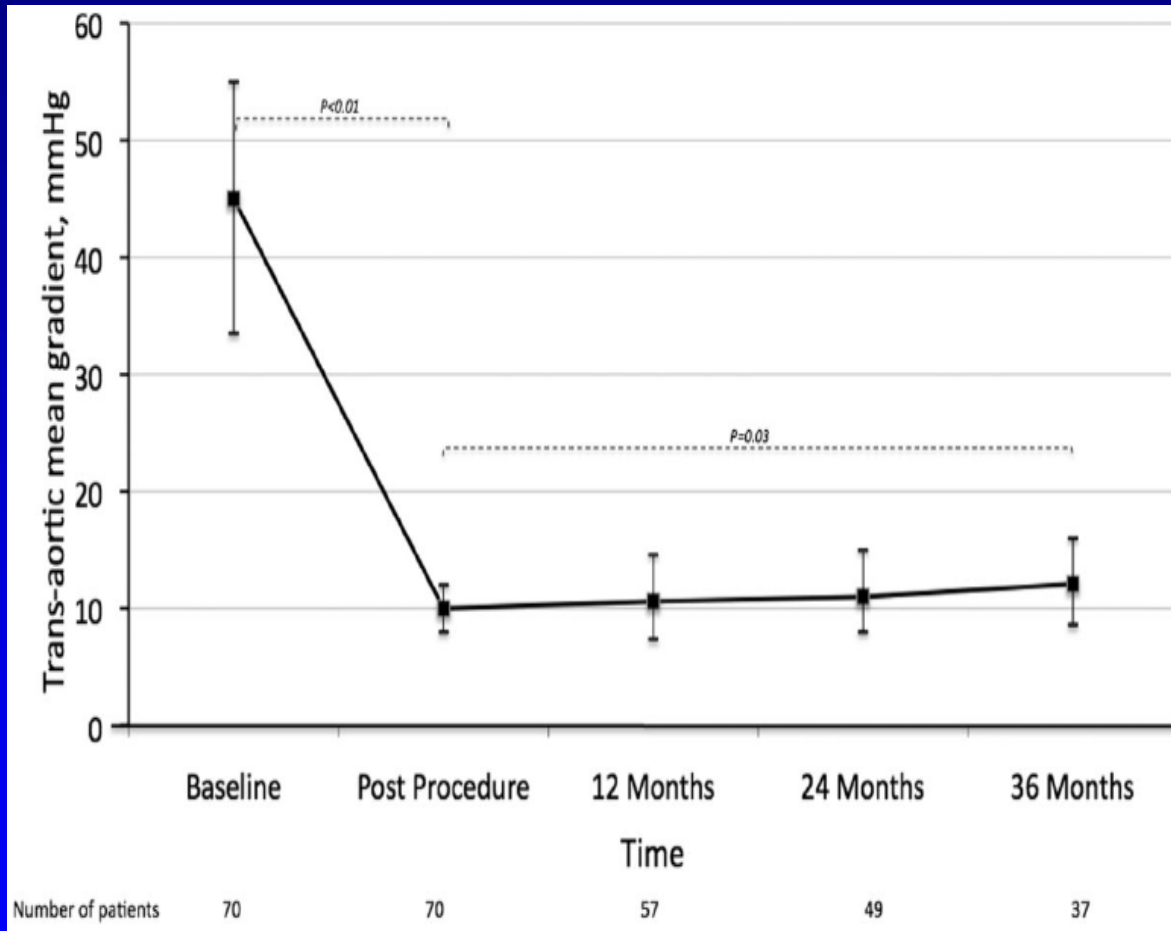
PARTNER: Quality of Life

Primary Endpoint: KCCQ Overall Summary



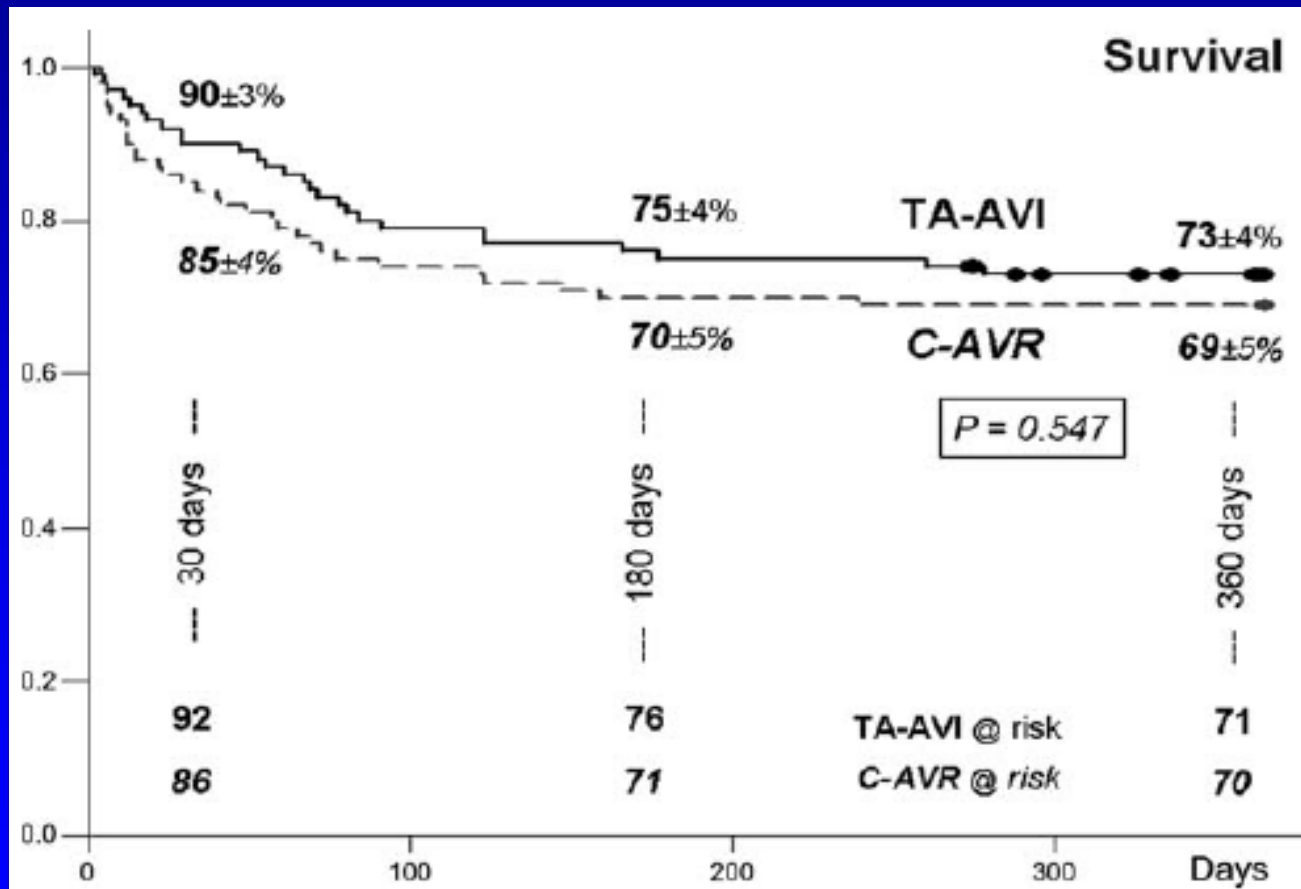
MCID = minimum clinically important difference

Valve Function after TAVI



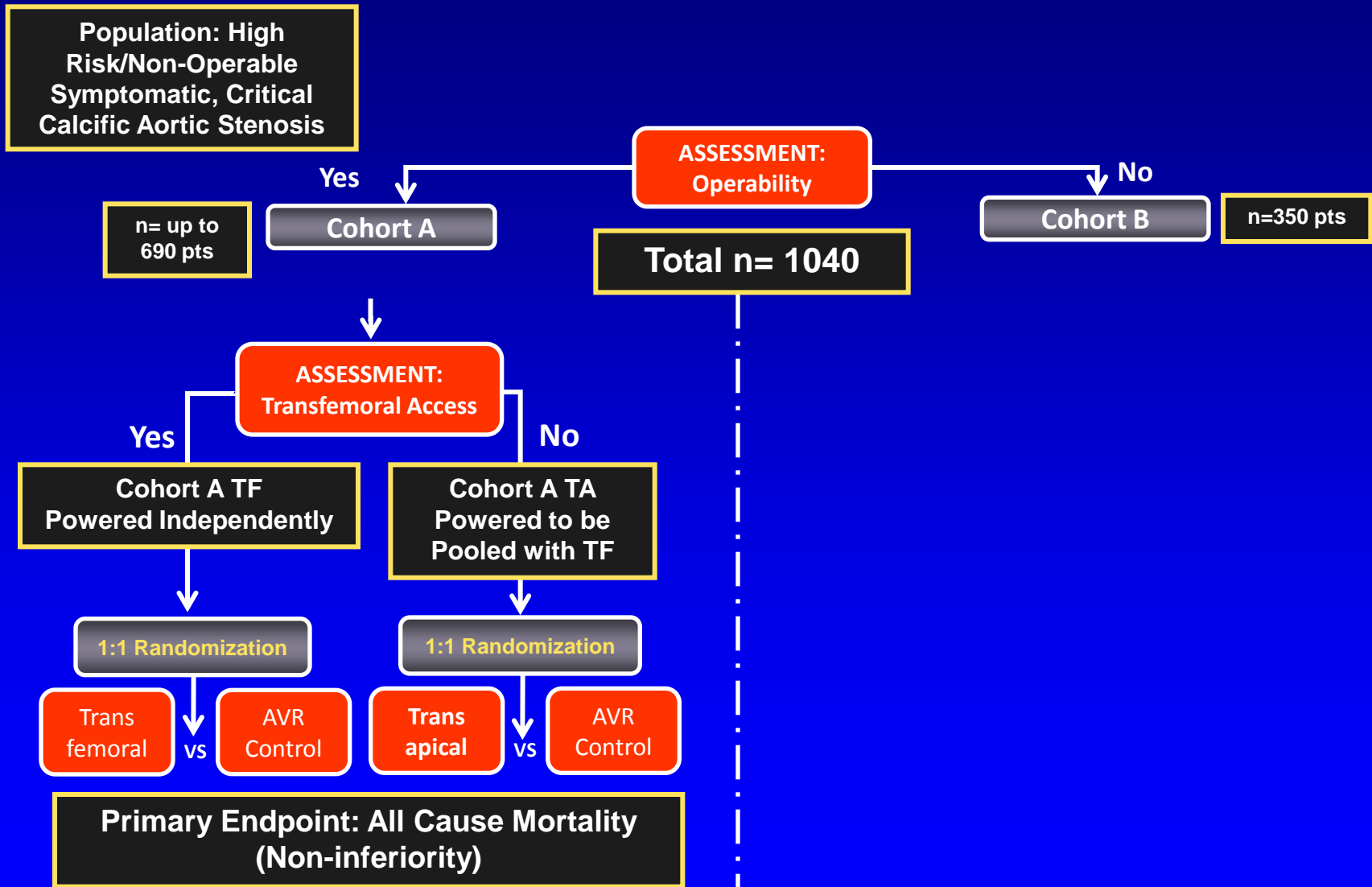
(Gurvitch R et al. Circulation 2010;122:1319-1327.)

Comparison of Outcomes for Transapical TAVI vs. Conventional Aortic Valve Replacement



(Walther et al. Euro Heart J 2010;31:1398-1403.)

The PARTNER US Trial



April 2011

The Situation Today

Growing TAVI Experience in Europe

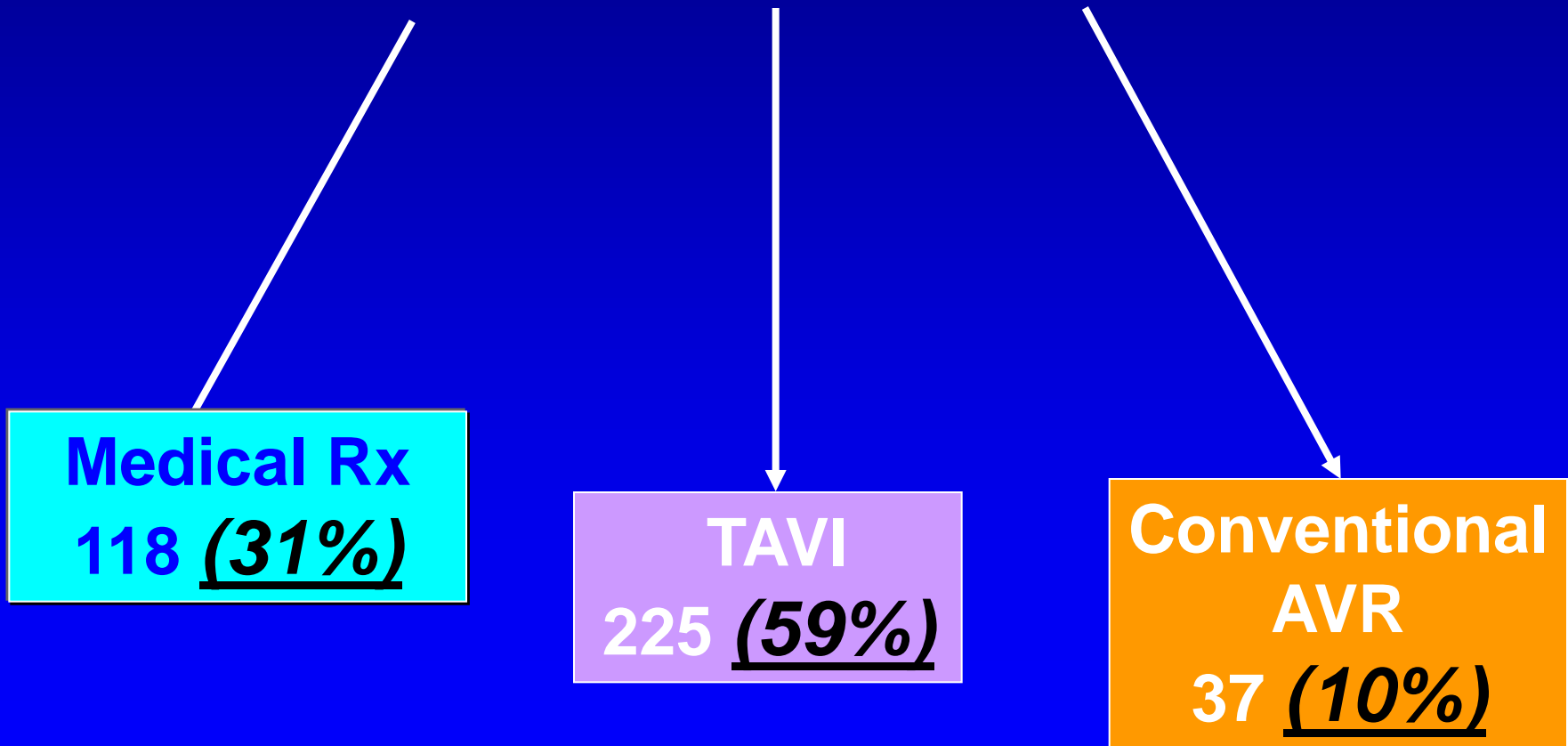


1.2% → **6.5%** → **13%** → **20%**



Screening in Bichat among 380 High-risk Patients Referred for TAVI

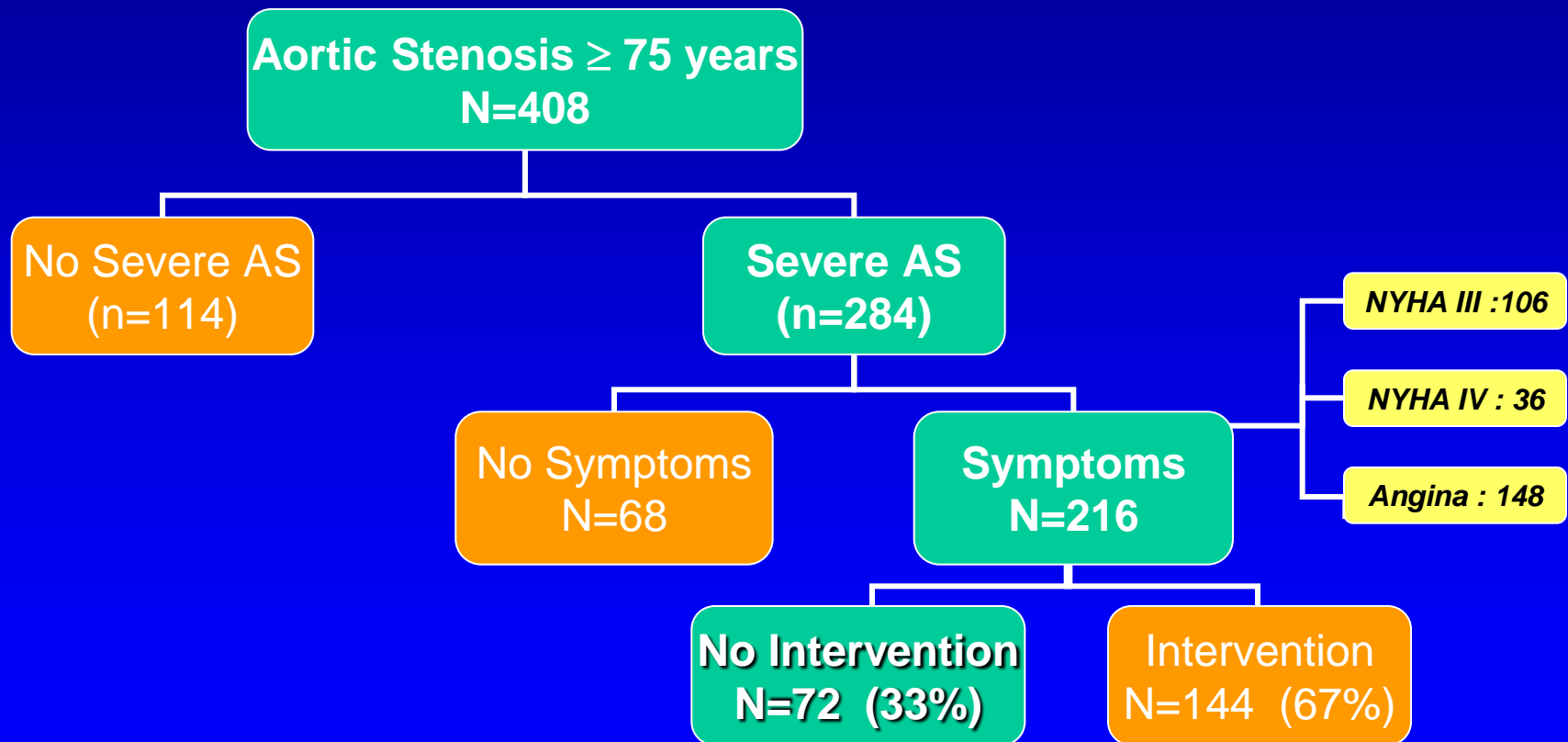
EuroSCORE $\geq 20\%$ - STS PROM $\geq 10\%$ / CI to AVR



Severe Symptomatic AS in the Elderly



Severe AS : Valve Area ≤ 0.6 cm²/m² BSA or Mean Gradient ≥ 50 mmHg
Symptomatic AS : NYHA Class III or IV or Angina



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

Management of High-Risk Patients with AS in the TAVI Era

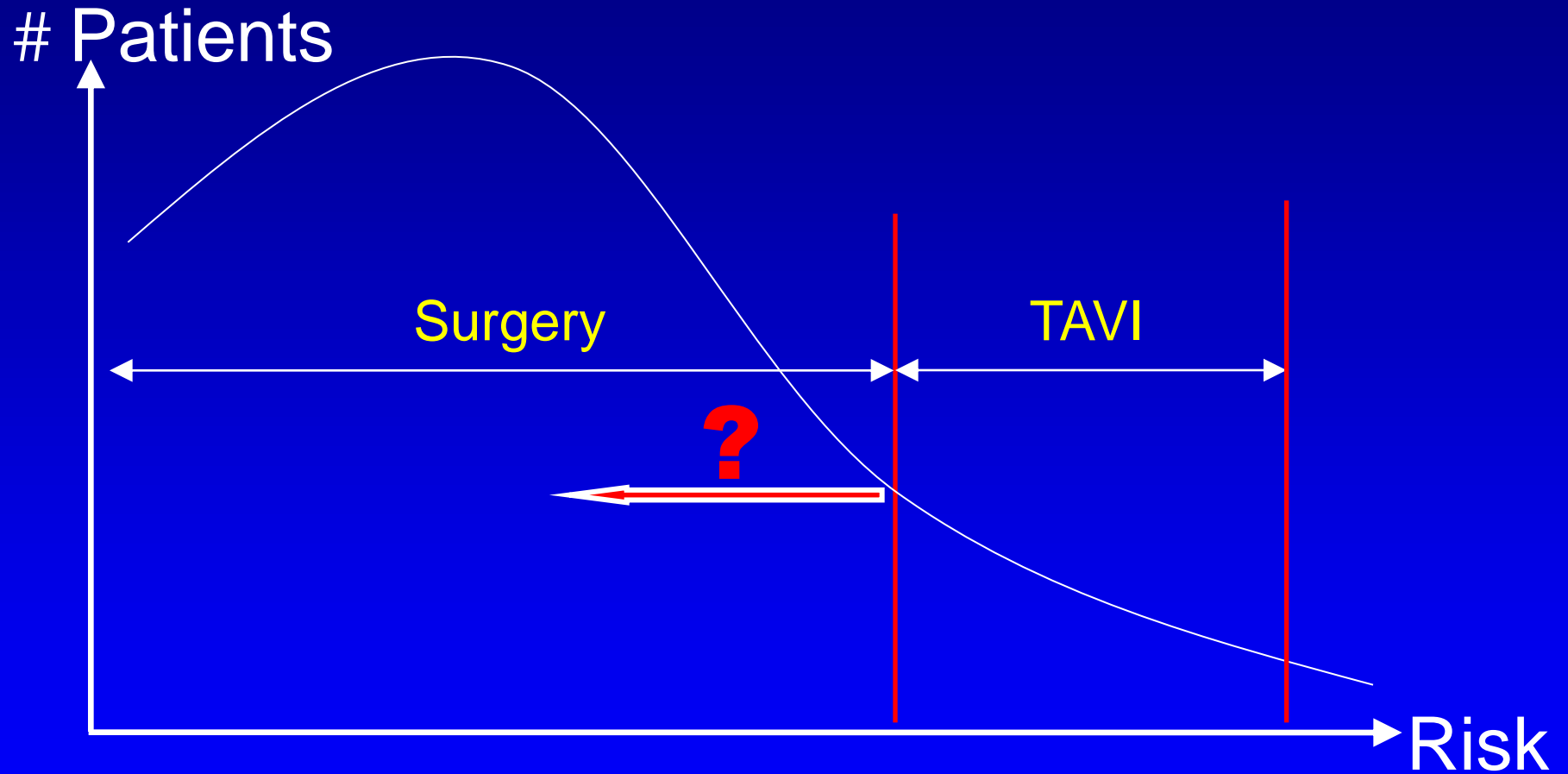
	N=	TAVI (%)	AVR (%)	Med. Therapy (%)
Dallas	71	21	14	65
Rotterdam	77	18	14	68
Cleveland	92	20	21	59
Vancouver	112	43	18	39
Milano *	220	45	14	41
Bichat *	273	54	12	34

* ESC 2009

BUT !!!!

- Systematic analysis of medical records in Rotterdam (2004-2007)
- 179 patients with severe AS and symptoms
 - 56% received medical treatment :
 - Perceived high operative risk 34% (LES=11%)
 - Symptoms perceived as mild 19%
 - AS perceived as non-severe 14%
 - Patient preference 9%

Indications for TAVI



Availability of Percutaneous Intervention is Attractive

- Less invasive:
 - ✓ Less painful
 - ✓ Shorter hospital stay
 - ✓ Faster recovery
 - ✓ Less influenced by patient's comorbidity

Food and Drug Administration modernization act of 1997

« nothing in the act shall be construed to limit or interfere with the authority of a health care practitioner to prescribe or administer any legally marketed device to a patient for any condition or disease within a legitimate health care practitioner-patient relationship »

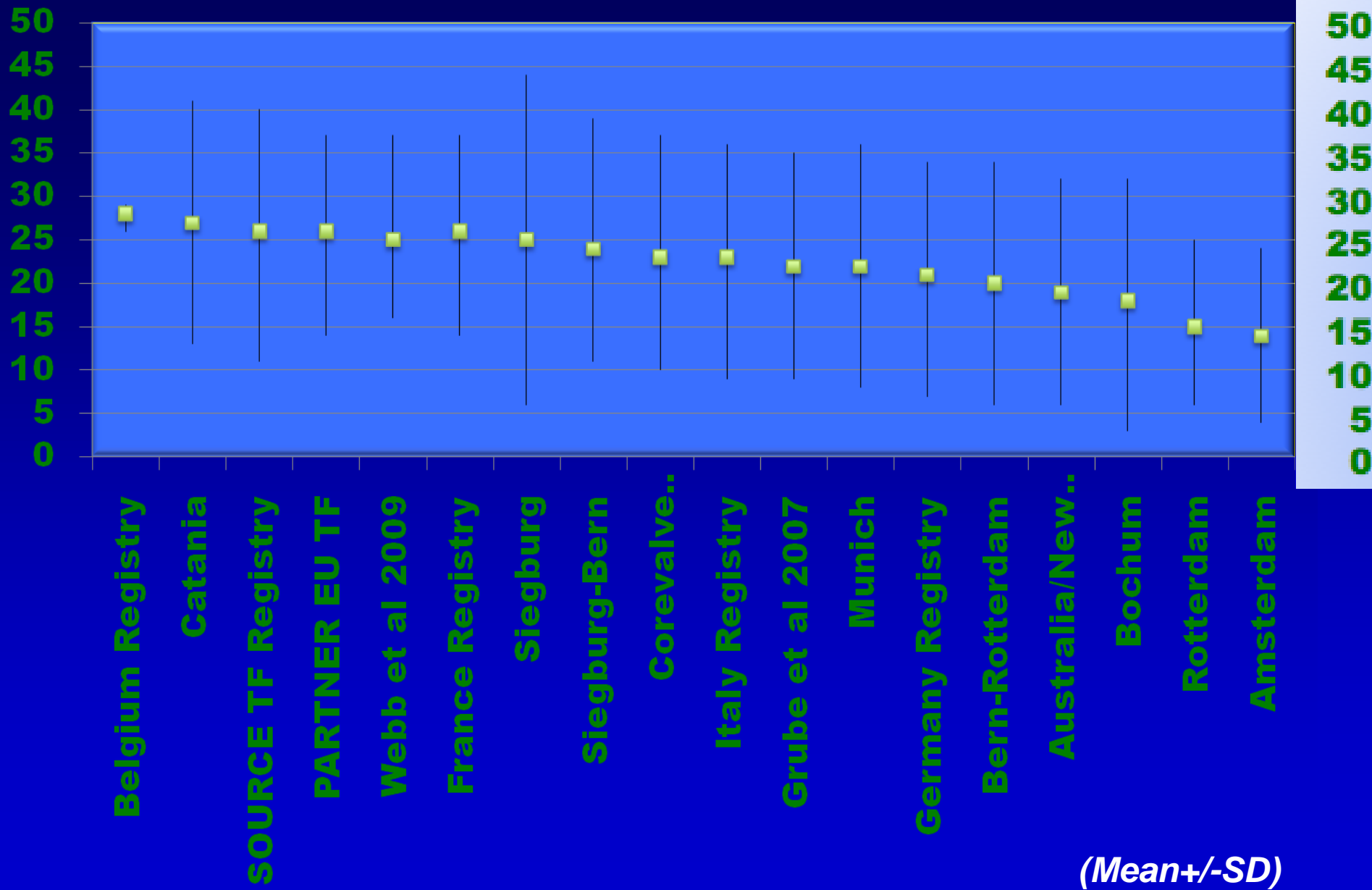
50 to 65% of DES are classified as off label but these implantations are now considered as standard care !!!

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)

Logistic EuroSCORE in TAVI Series



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

P Kappetein Eur Heart J ,Jan 2011

Inclusion Criteria for TAVI

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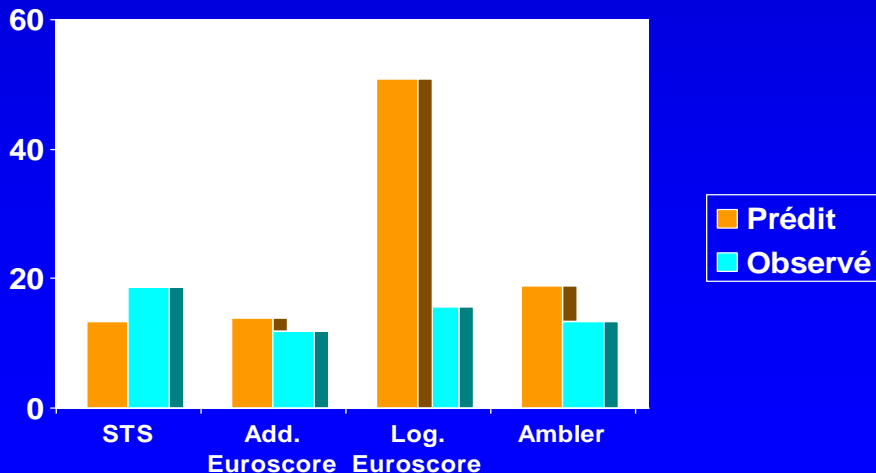
Risk Scores

➤ Good discrimination (low vs. high risk)

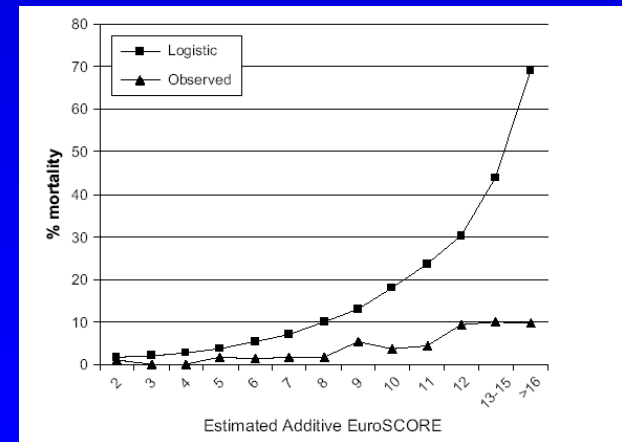
	N. of Patients	N. of Factors	Area under the ROC curve
STS score (Edwards et al.) (<i>J Am Coll Cardiol</i> 2001)	49073 val 43463 val+CABG	18 20	0.77 0.73
Ambler et al. (<i>Circulation</i> 2005)	32839	13	0.77
EuroSCORE (Roques et al.) (<i>J Heart Valve Dis</i> 2001)	5672	17	0.75
EuroSCORE tested in the Euro Heart Survey	1269	17	0.74

(lung
Heart 2008;94:519-24)

➤ But poor calibration (predicted vs. observed risk)



(Dewey et al. JTCS 2008;135:180-7)



(Brown et al. JTCS 2008;136:566-71)

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”

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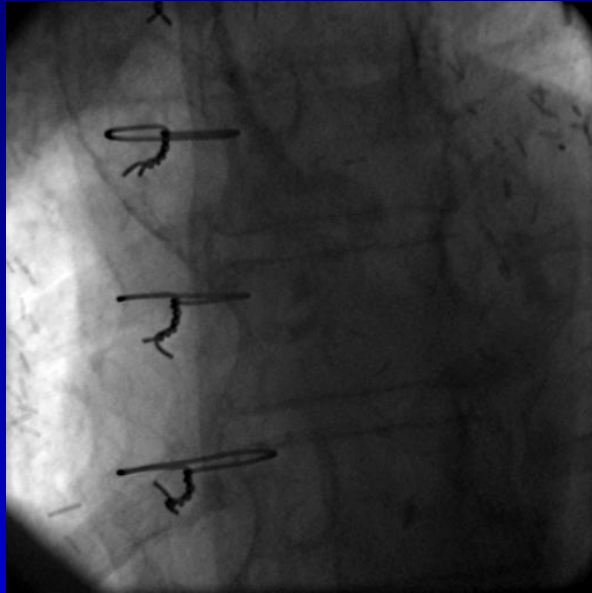
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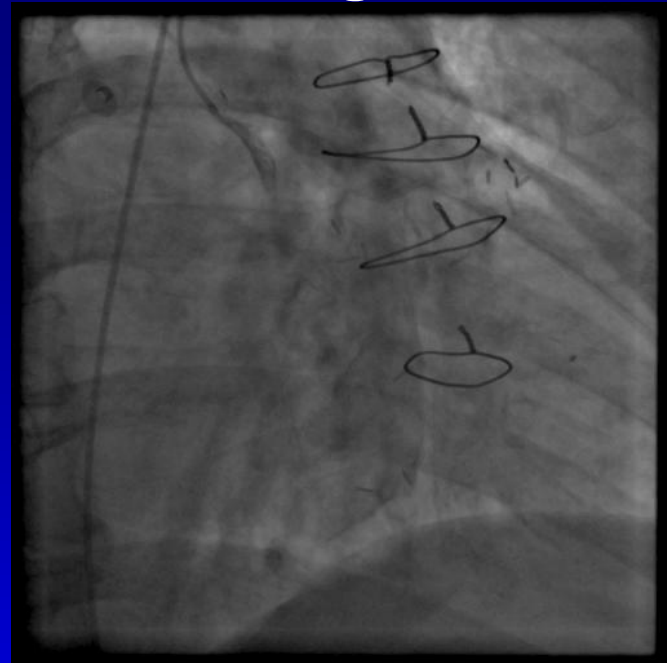
(EACTS/ESC/EAPCI Position Statement, *Eur Heart J*, 2008; 29:1463-1470,
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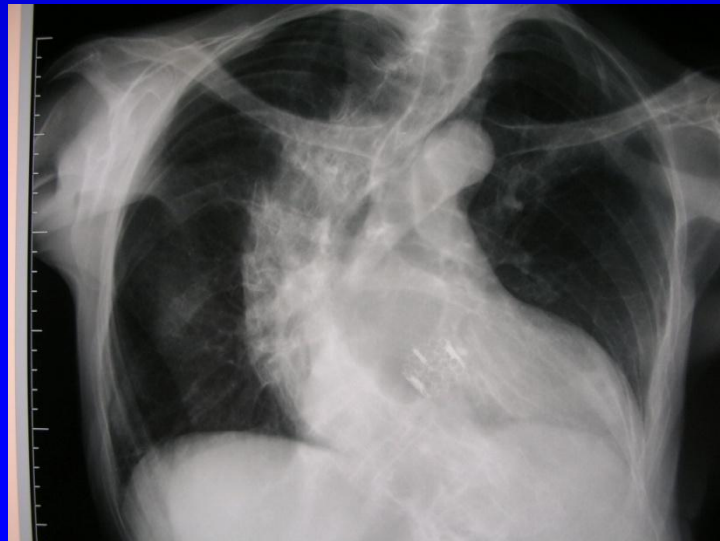
Porcelain Aorta



Patent grafts



Cyphoscoliosis



Chest radiation



SOURCE REGISTRY

Demographics and Risk Factors – Overall Group <20 & >20

Why TAVI for < LES 20?

Risk Factor	All Treatments < 20 (N=908)	All Treatments >= 20 (N=1429)	All Treatments p-value
NYHA Class IV	83 (9.14%)	244 (17.07%)	<.0001
Female	523 (57.60%)	815 (57.03%)	0.6345
Age >= 80 Years	526 (57.93%)	1016 (71.10%)	<.0001
Smoking	207 (22.80%)	263 (18.40%)	0.0110
Coronary Artery Disease	396 (43.61%)	838 (58.64%)	<.0001
Congestive Heart Failure	218 (24.01%)	499 (34.92%)	<.0001
Myocardial Infarction	99 (10.90%)	262 (18.33%)	<.0001
Carotid artery stenosis (over 50%)	63 (6.94%)	218 (15.26%)	<.0001
Porcelain Aorta	91 (10.02%)	95 (6.65%)	0.0037
Mitral valve disease	260 (28.63%)	448 (31.35%)	0.1803
Cancer	182 (20.04%)	186 (13.02%)	<.0001
Pulmonary disease	206 (22.69%)	389 (27.22%)	0.0149
Pulmonary disease: FEV1 less than 1.0	32 (3.52%)	29 (2.03%)	0.0327
Renal insufficiency / Failure	195 (21.48%)	476 (33.31%)	<.0001
Post thoracic radiation therapy	14 (1.54%)	6 (0.42%)	0.0396
Peripheral vascular disease (non carotid)	123 (13.55%)	346 (24.21%)	<.0001
PTCA / stent	203 (22.36%)	420 (29.39%)	0.0002
CABG	108 (11.89%)	392 (27.43%)	<.0001
Carotid endarterectomy / Carotid stent	20 (2.20%)	70 (4.90%)	0.0009
Prior surgical aortic bioprosthesis in place? (VIV)	6 (0.66%)	20 (1.40%)	0.0166

Risk-Benefit Assessment

“The key element to establish whether patients are high risk for surgery is clinical judgement, which should be used in association with a more quantitative assessment, based on the combination of several scores”

The Key role of the “Heart team”

*(EACTS/ESC/EAPCI Position Statement, Eur Heart J, 2008; 29: 1463-1470,
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Coronary Artery Disease



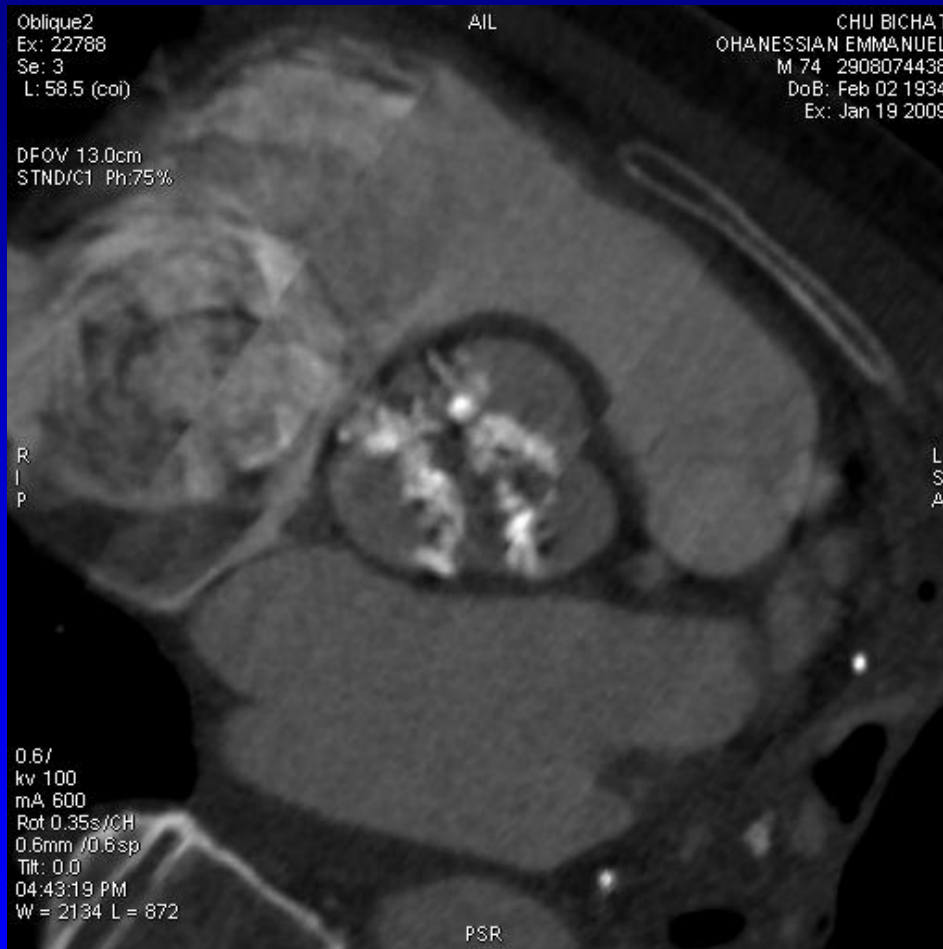
Decision based on

- 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 ?

Bicuspid valve



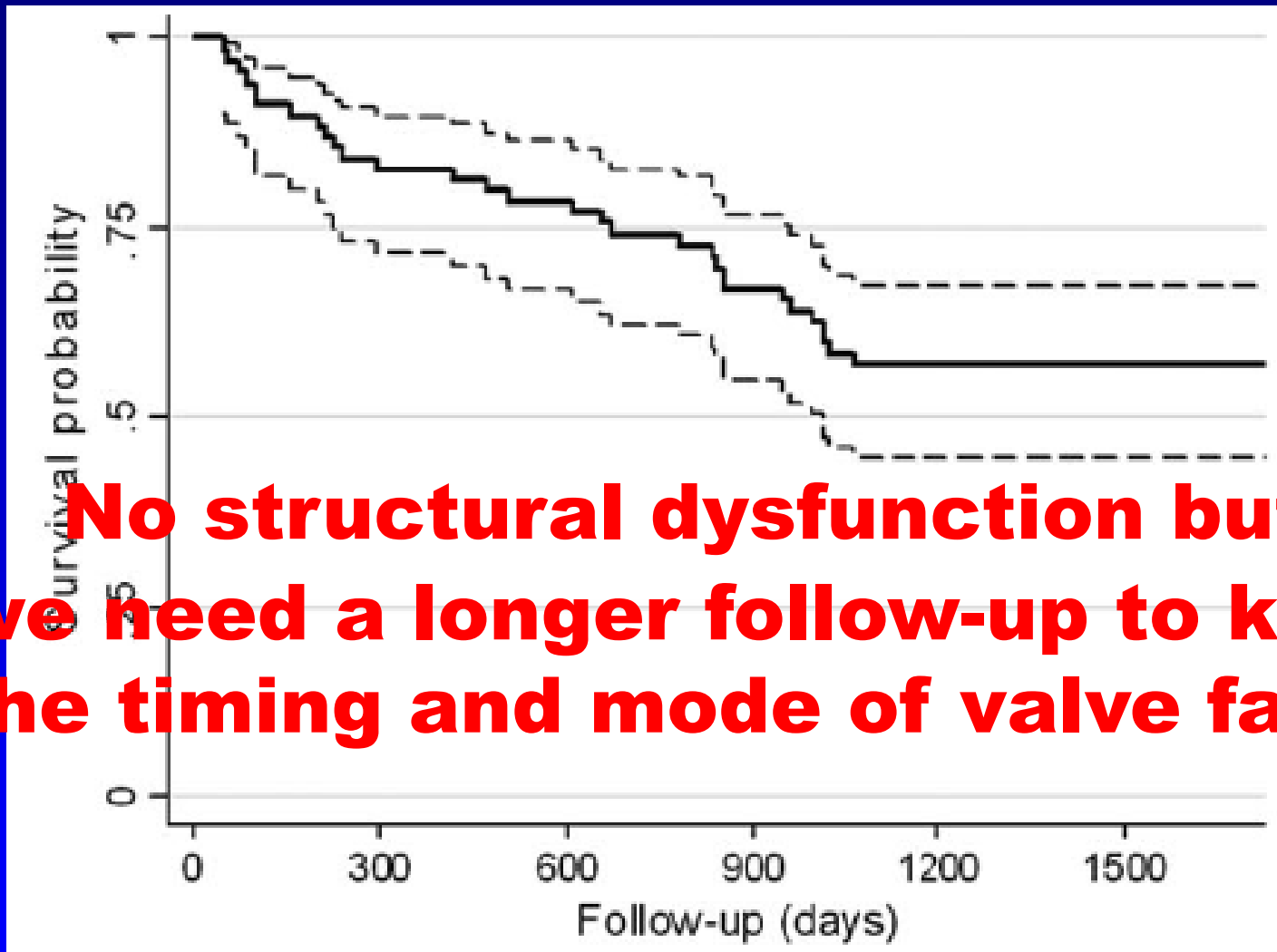
We need more data !

Case by case decision

- annulus: shape/diameter
- amount/distribution of Ca

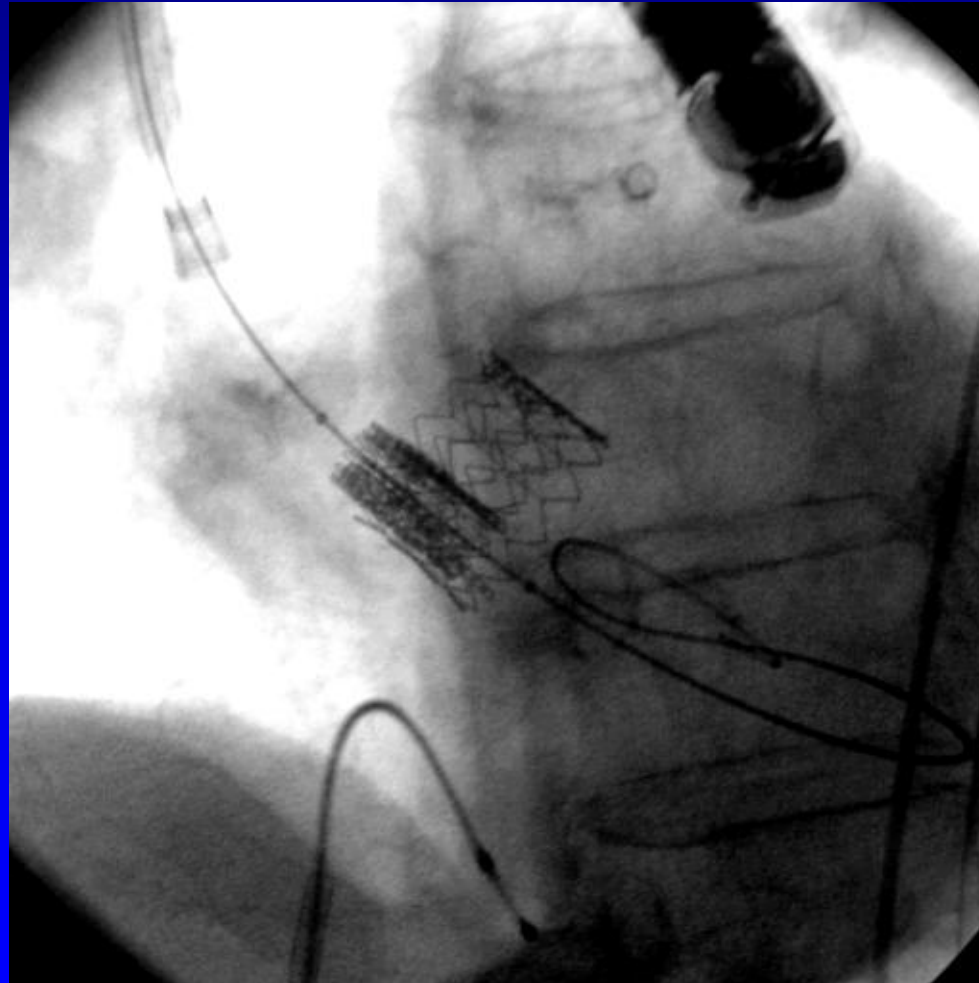
Dedicated devices?

Follow-up after TAVI



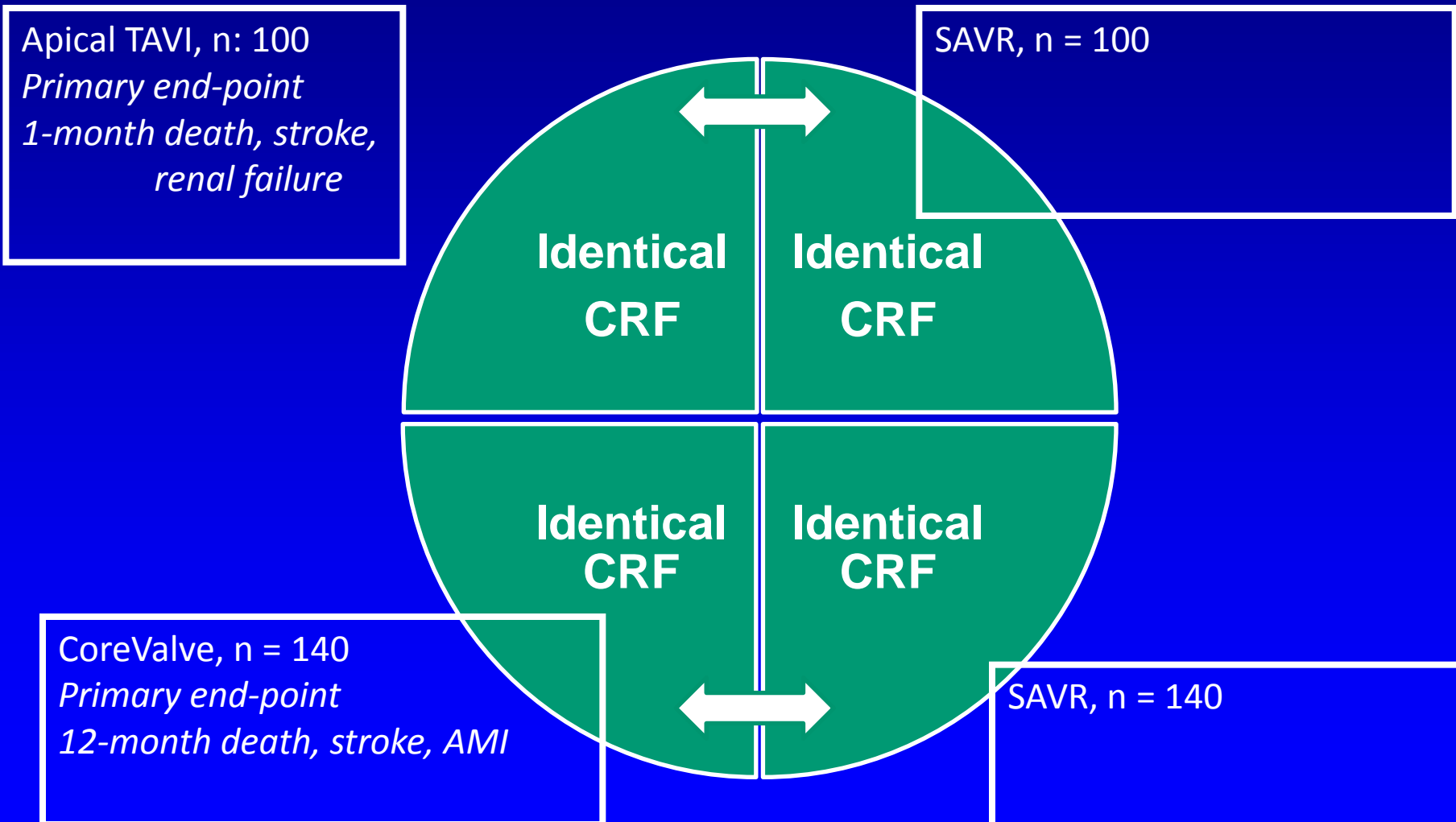
No structural dysfunction but we need a longer follow-up to know the timing and mode of valve failure

‘Valve-in-a-Valve’: The Solution if Valve Failure Occurs ?



Danish TAVI trials

Operable patients, age ≥ 75 yrs with aortic valve stenosis



(Courtesy of Leif Thuesen)

SURTAVI

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

'All-comers' trial

1. Documentation of risk scores
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

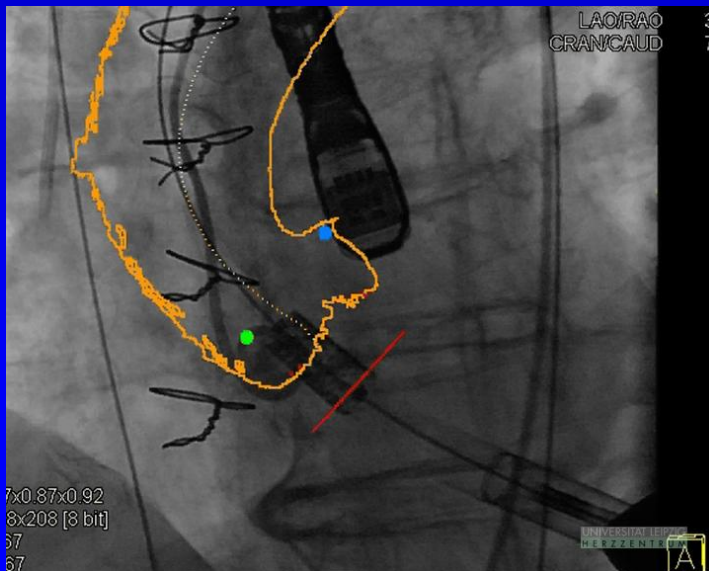
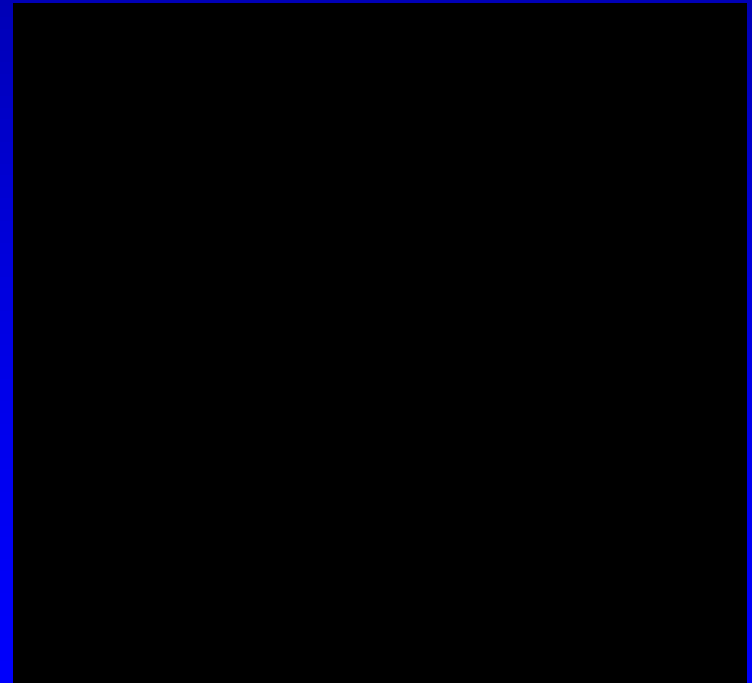
Inoperable

End Point : death or major stroke at 1 year (Courtesy of Patrick Serruys)

Trends towards Procedural Simplification

	2002	2010
Delivery Cath	25/24/22F	18F
Surgical cut-down	Yes	No
Cardiac Support	Yes	No
Anesthesia	Full	Local

Navigation and Positioning



Progress in Technology

- Stainless steel frame
- Untreated Equine Tissue



Cribier-Edwards™ THV

- Bovine Pericardial Tissue
- ThermaFix™ anti-calcification process
- Leaflets matched for both deflection and thickness



Edwards SAPIEN® THV
23mm, 26mm

- Cobalt-Chromium Frame
- Scalloped leaflet design
- Size extension



Edwards SAPIEN® XT THV
23mm, 26mm,

Conclusions

- Today, TAVI is only indicated in high risk patients with severe AS and severe symptoms
- Further research on:
 - ✓ Risk stratification models for AVR and TAVI and implementation of their use in conjunction with the other elements in decision-making
 - ✓ Evaluation of TAVI (safety, durability, feasibility of subsequent intervention) in single centre series, comprehensive registries, and randomised trials
 - ✓ Technology
- ***It is only then that indications could be expanded to lower risk patients***