

**ADVANCES IN  
CARDIOVASCULAR  
ARRHYTHMIAS AND  
GREAT INNOVATIONS  
IN CARDIOLOGY**

XXIV GIORNATE CARDIOLOGICHE  
TORINESI

**II ANNOUNCEMENT**

DIRECTORS

Fiorenzo Gaita | Sebastiano Marra

Turin, October 20-22, 2011

Centro Congressi

Unione Industriale

**JM**  
JOINT MEETING  
OF CARDIOLOGY



From Caliper to Catheter



Cardiologie AOU  
San Giovanni Battista di Torino

## **Aortic valve implantation**

# **Aortic stenosis: an underestimated pathology in the elderly**

Antonio Marzocchi - Bologna

**TORINO, 21 OTTOBRE 2011**

Aortic sclerosis (aortic valve calcification without obstruction to blood flow, considered a precursor of calcific degenerative calcific aortic stenosis) increases in incidence with age and is present in 29% of individuals older than 65 years and in 37% of individuals older than 75 years. In elderly persons, the prevalence of aortic stenosis is between 2% and 9%.

Degenerative calcific aortic stenosis usually manifests in individuals older than 75 years and occurs most frequently in males.

# Aortic valve stenosis

## Prevalence

Approximately 2% of people over the age of 65,  
3% of people over age 75,  
and 4% percent of people over age 85  
have aortic valve stenosis.

The prevalence is increasing with the aging population  
in North America and Europe.

## **Incidence & Prevalence of Aortic Stenosis**

Aortic stenosis affects approximately 5 out of every 10,000 people in the United States. It is more likely to affect men than women; 80% of adults with symptomatic AS are male.

# Epidemiologia della stenosi aortica degenerativa

Prevalence of aortic valve abnormalities in the elderly:  
an echocardiographic study of a random population sample.  
(Helsinki - Finland)

age groups 75 to 76, 80 to 81 and 85 to 86 years (n = 501)  
Mild calcification in 222 (40%)  
Severe calcification in 72 (13%)  
critical aortic valve stenosis was **2.9%**  
( $\leq 0,8 \text{ cm}^2$ )

# Burden of valvular heart diseases: a population-based study



*Vuyisile T Nkomo, Julius M Gardin, Thomas N Skelton, John S Gottdiener, Christopher G Scott, Maurice Enriquez-Sarano*

Prevalenza delle valvulopatie  
USA  
3 studi dal 1985 al 1992

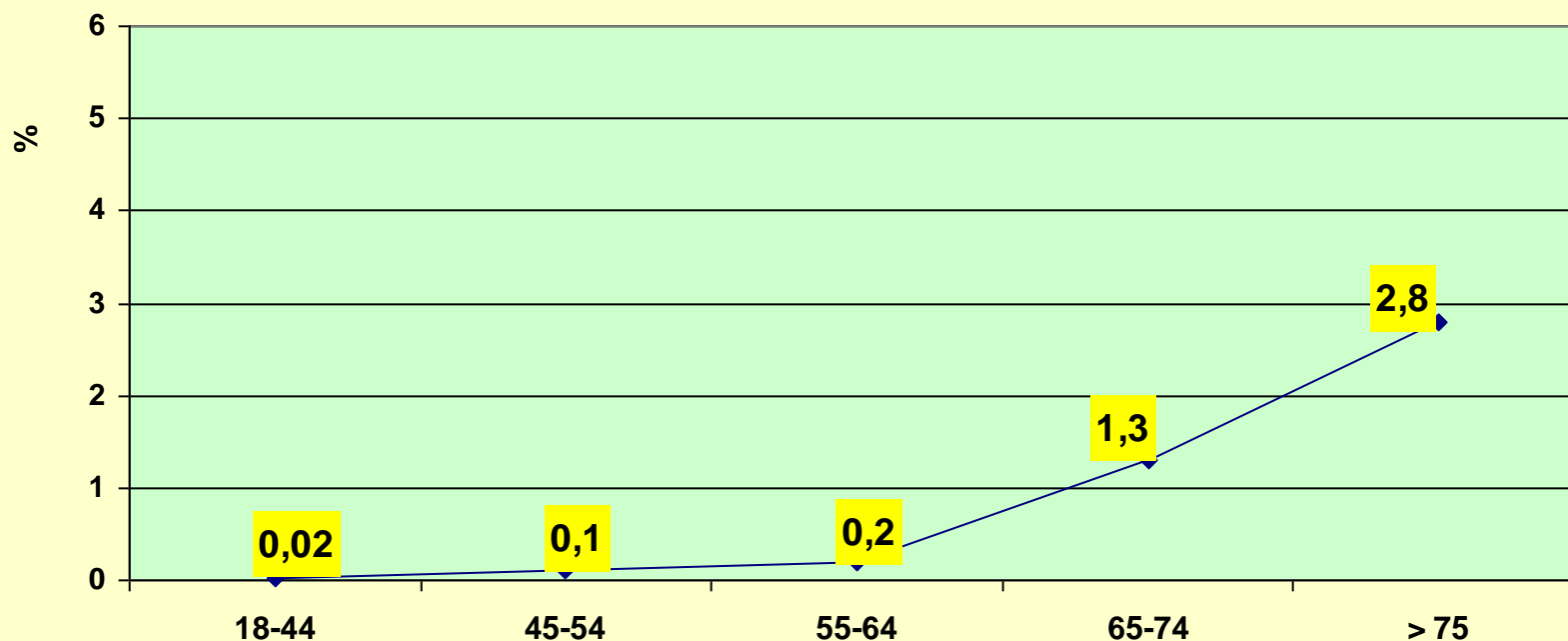
# Burden of valvular heart diseases: a population-based study



Vuyisile T Nkomo, Julius M Gardin, Thomas N Skelton, John S Gottdiener, Christopher G Scott, Maurice Enriquez-Sarano

## Prevalenza della stenosi aortica moderata o severa ( $\leq 1,5 \text{ cm}^2$ )

USA - 3 studi dal 1985 al 1992

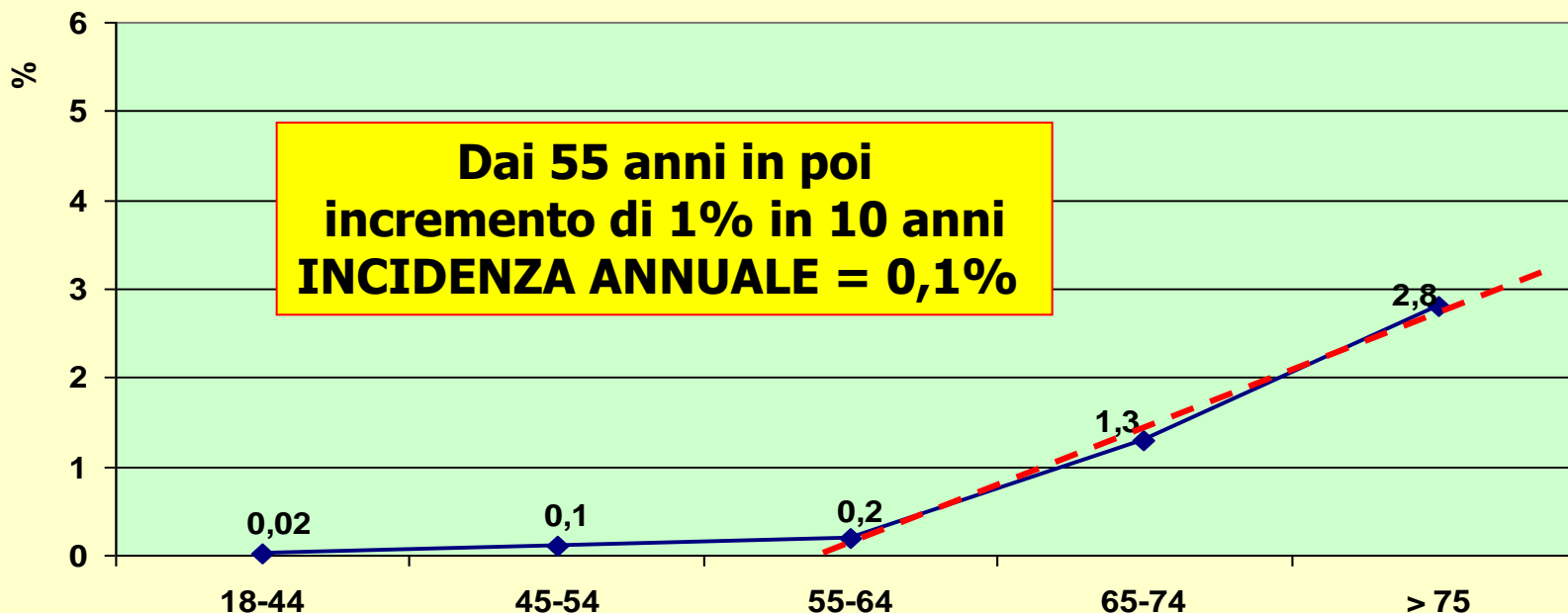


# Burden of valvular heart diseases: a population-based study



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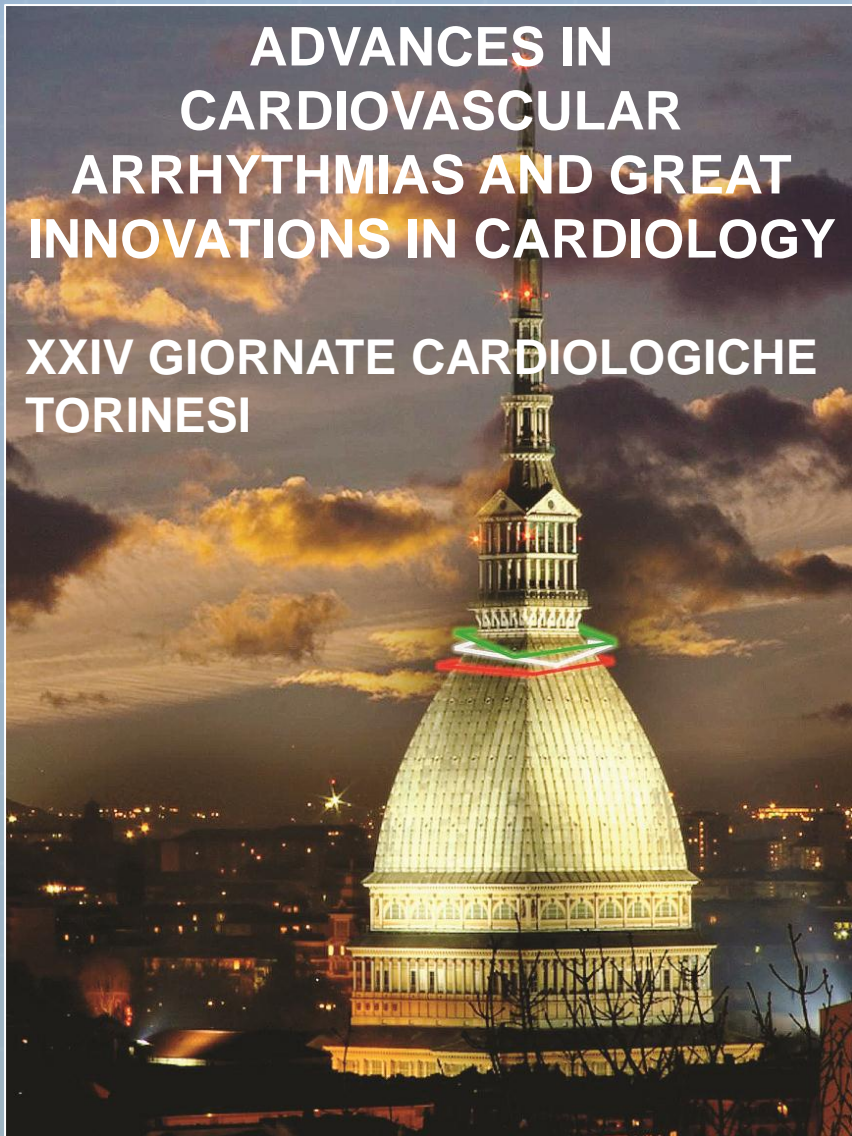
## Prevalenza della stenosi aortica moderata o severa ( $\leq 1,5 \text{ cm}^2$ ) USA - 3 studi dal 1985 al 1992





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OF CARDIOLOGY



From Caliper to Catheter



Turin, October 21,  
2011

**HEART TEAM  
AND  
PATIENT SELECTION**

**Maurizio D'Amico**

Struttura Complessa di Cardiologia Ospedaliera  
Azienda Ospedaliera S.G. Battista, Molinette di Torino

**Why TAVI?**

**Who thinks to TAVI first?**

**When TAVI?**

**Who does select the “TAVI patient”?**

**Clinical features**

**Imaging**

**Why TAVI?**

**When TAVI?**

**Who thinks to TAVI first?**

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# SURGICAL AORTIC VALVE REPLACEMENT (AVR)

Good results from AVR

↑ Survival

↓ Symptoms

Low operative mortality

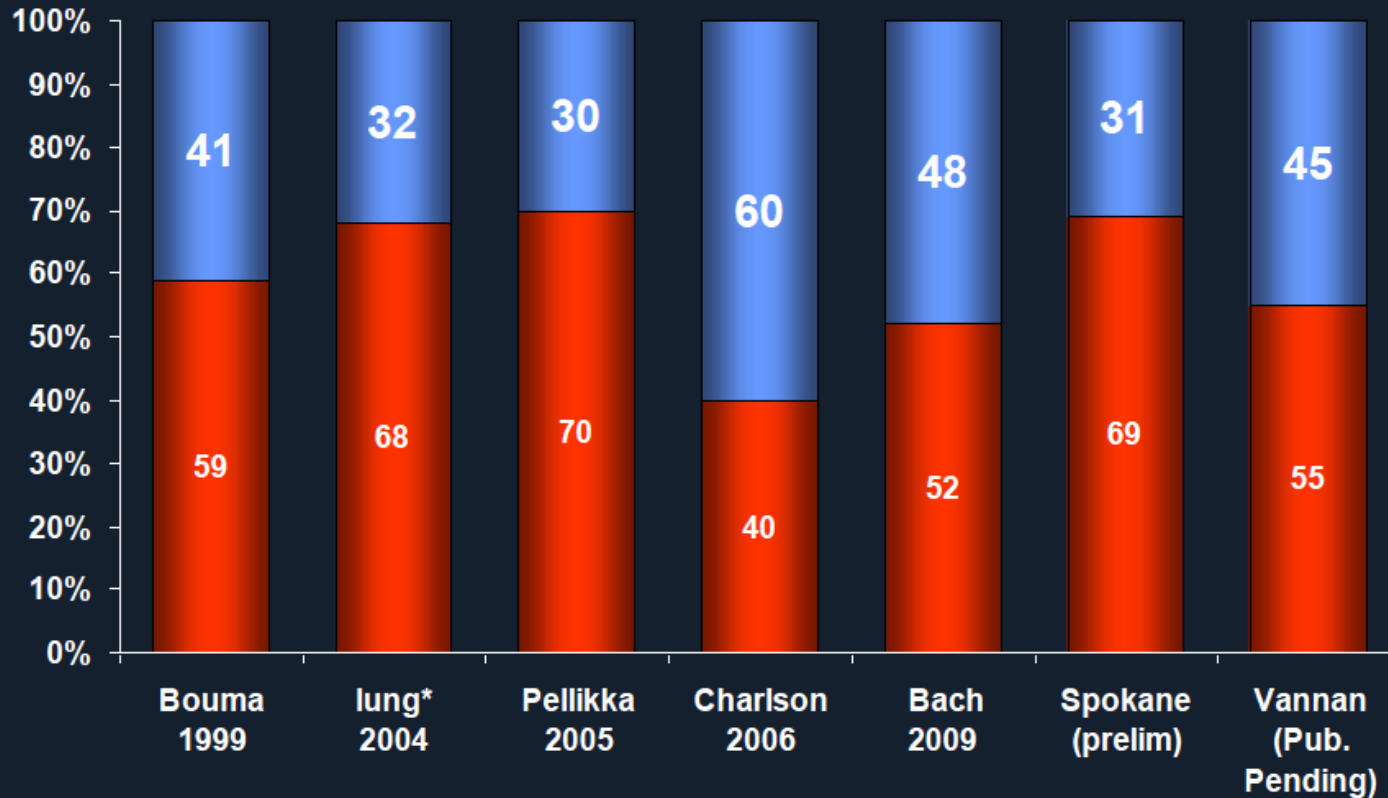
in low risk patients

# At Least 30% of Patients with Severe Symptomatic AS are “Untreated”!

## Severe Symptomatic Aortic Stenosis

Percent of Cardiology Patients Treated

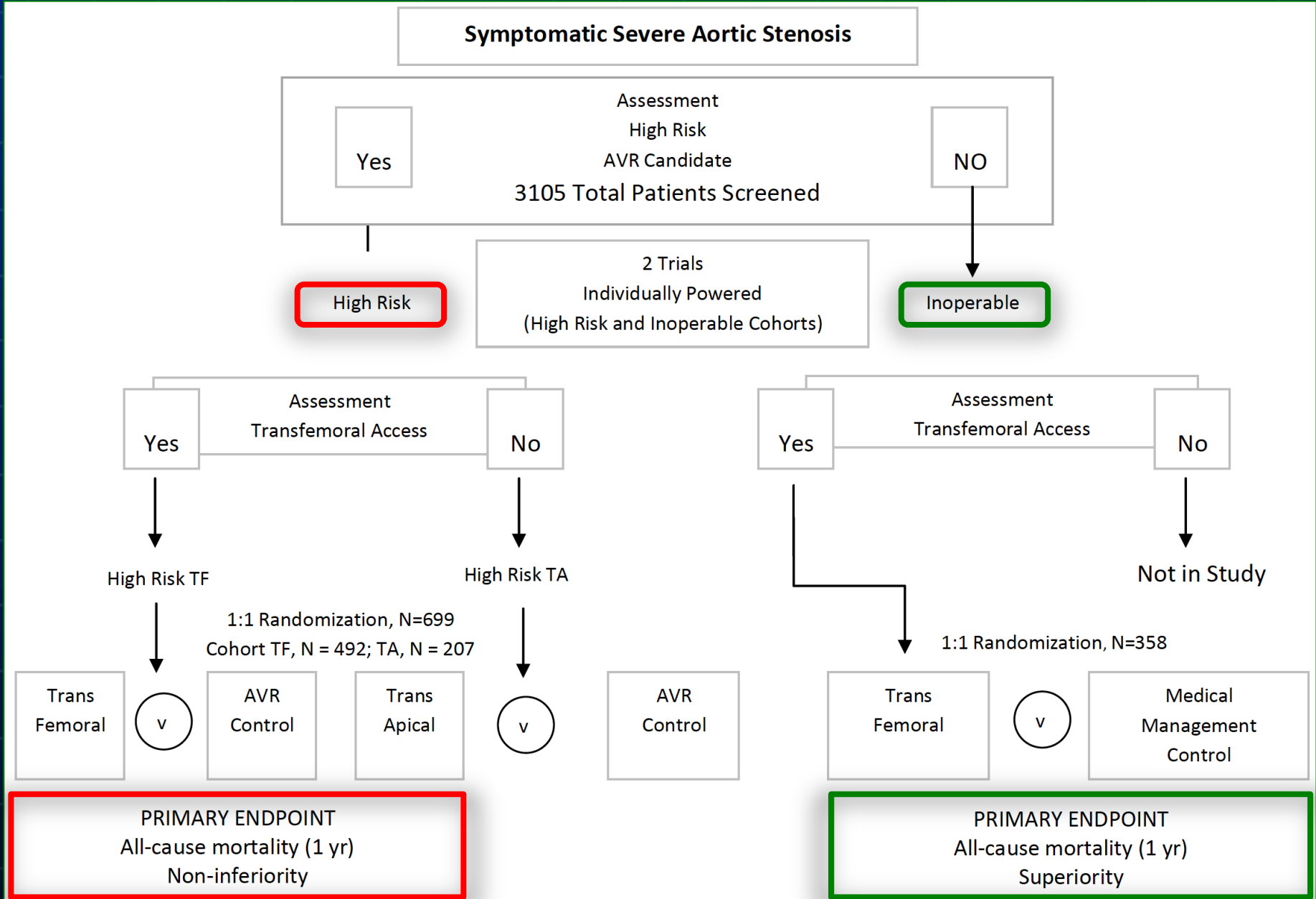
AVR  
No AVR

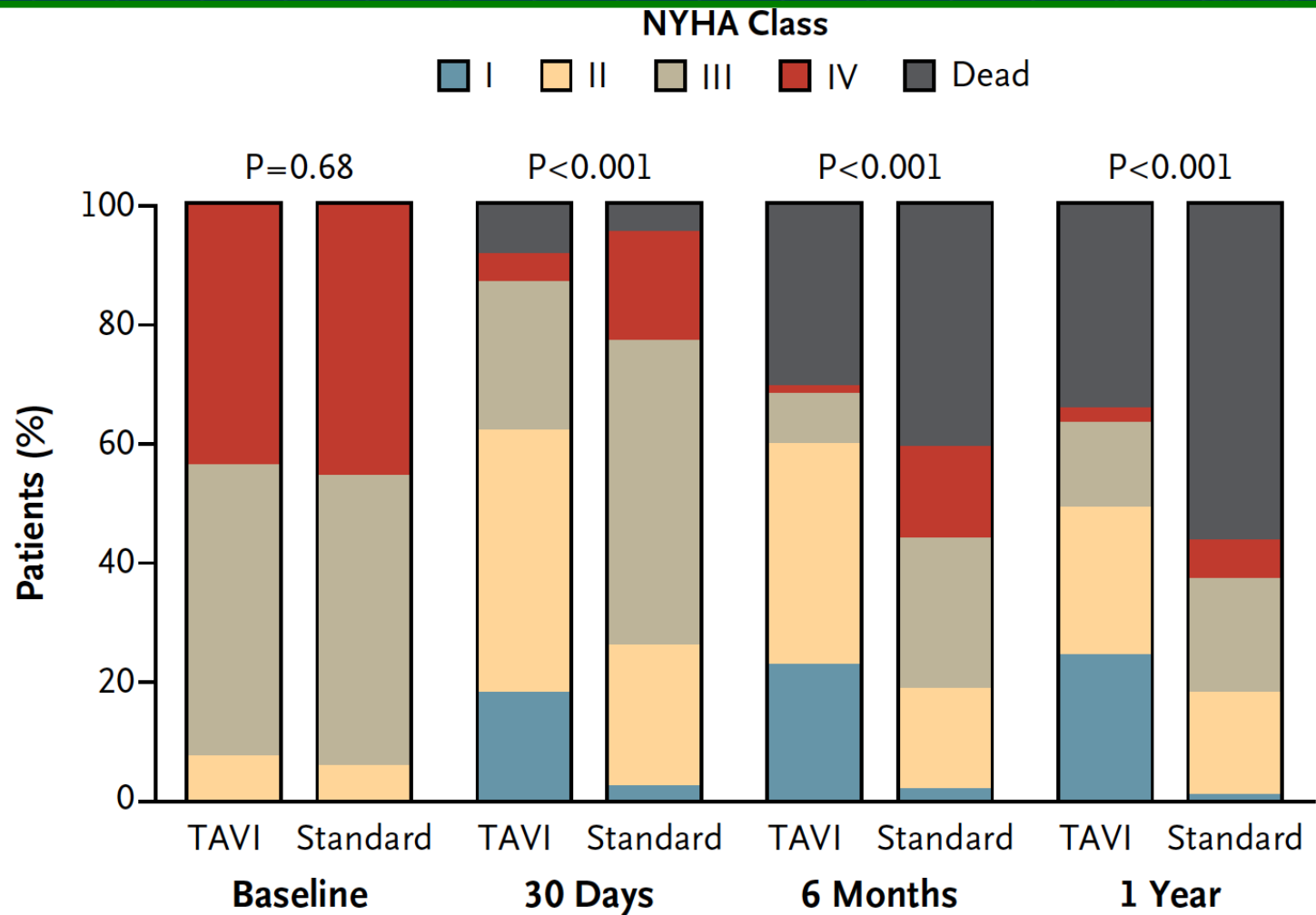


*Under-treatment especially prevalent among patients managed by Primary Care physicians*

1. Bouma B J et al. To operate or not on elderly patients with aortic stenosis: the decision and its consequences. *Heart* 1999;82:143-148
2. lung B et al. A prospective survey of patients with valvular heart disease in Europe: The Euro Heart Survey on Valvular Heart Disease. *European Heart Journal* 2003;24:1231-1243 (\*includes both Aortic Stenosis and Mitral Regurgitation patients)
3. Pellikka, Sarano et al. Outcome of 622 Adults with Asymptomatic, Hemodynamically Significant Aortic Stenosis During Prolonged Follow-Up. *Circulation* 2005
4. Charlson E et al. Decision-making and outcomes in severe symptomatic aortic stenosis. *J Heart Valve Dis* 2006;15:312-321

# Overall PARTNER Trial Design





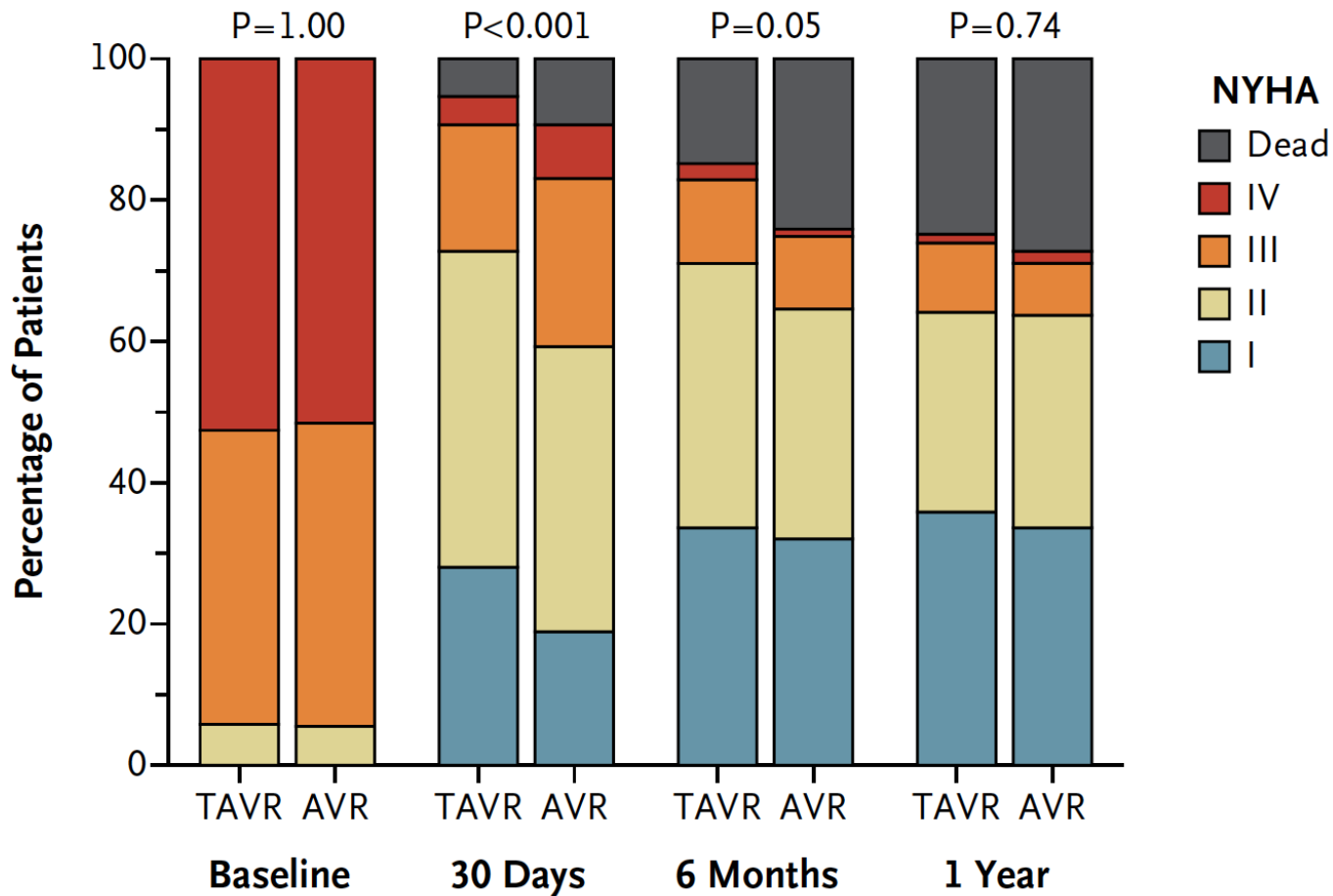
**Figure 3. Symptom Status over Time.**

NYHA Symptom status according to New York Heart Association (NYHA) class is shown at baseline and at 30 days, 6 months, and 1 year among patients randomly assigned to transcatheter aortic-valve implantation (TAVI) or standard therapy (Standard).

py  
VI  
24

26  
12

A D



**Figure 4. Symptom Status.**

No Tra Sur Shown is the New York Heart Association (NYHA) functional status (according to time point) for 697 of 699 patients who were randomly assigned to undergo either transcatheter aortic-valve replacement (TAVR) or surgical aortic-valve replacement (AVR).

24

67

65



# Why TAVI?

- ✓ **New option for inoperable and high risk patients**
- ✓ **Less invasive procedure**

**Why TAVI?**

**Who thinks to TAVI first?**

**When TAVI?**

**Who does select the “TAVI patient”?**

**Clinical features**

**Imaging**

# Who thinks to TAVI first?

- General Practitioner
- Outpatient Cardiologist
- Hospital Cardiologist
- Echocardiographer
- Heart Surgeon
- Other physicians



- ✓ **AVR indications**
- ✓ **Old patients and comorbidities**
- ✓ **Euroscore**

# EUROscore II EATCS Lisbon October 3 200



## Patient related factors

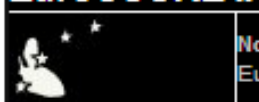
Age <sup>1</sup> (years)	<input type="text" value="0"/>	<input type="text" value="0"/>
Gender	<input type="text" value="select"/>	<input type="text" value="0"/>
Renal impairment <sup>2</sup> <small>See calculator below for creatinine clearance</small>	<input type="text" value="normal (CC &gt;85ml/min)"/>	<input type="text" value="0"/>
Extracardiac arteriopathy <sup>3</sup>	<input type="text" value="no"/>	<input type="text" value="0"/>
Poor mobility <sup>4</sup>	<input type="text" value=""/>	<input type="text" value=""/>

## Cardiac related factors

Previous cardiac surgery	NYHA	<input type="text" value="select"/>	<input type="text" value="0"/>
Chronic lung disease	CCS class 4 angina <sup>8</sup>	<input type="text" value="no"/>	<input type="text" value="0"/>
Active endocarditis <sup>6</sup>	LV function	<input type="text" value="select"/>	<input type="text" value="0"/>
Critical preoperative status	Recent MI <sup>9</sup>	<input type="text" value="no"/>	<input type="text" value="0"/>
Diabetes on insulin	Pulmonary hypertension <sup>10</sup>	<input type="text" value="no"/>	<input type="text" value="0"/>

EuroSCORE II

**EuroSCORE II**



Note: The EuroSCORE II calculator is a simplified version of the EuroSCORE II calculator.

## Operation related factors

Urgency <sup>11</sup>	<input type="text" value="elective"/>	<input type="text" value="0"/>
Weight of the intervention <sup>12</sup>	<input type="text" value="isolated CABG"/>	<input type="text" value="0"/>
Surgery on thoracic aorta	<input type="text" value="no"/>	<input type="text" value="0"/>

**Why TAVI?**

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# When TAVI?

Severe aortic stenosis  
Old patients  
Symptomatic aortic stenosis

Comorbidities

- COPD
- Renal impairment
- History of CABG or previous heart intervention
- History of chest irradiation
- Low EF
- Scores (Euroscore; Euroscore 2; STS score; LEE score)
- Frailty
- ...

**Why TAVI?**

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**Who does select the “TAVI patient”?**

**Clinical features**

**Imaging**

# Who does select the “TAVI patient”?

- General Practitioner
- Outpatient Cardiologist
- Hospital Cardiologist
- Echocardiographer
- Heart Surgeon
- Other physicians

Is TAVI a possible option for the patient?

**HEART TEAM**



# HEART TEAM



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

**SPECIAL ARTICLE**

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**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)**

# HEART TEAM

## Patient selection

Selection of candidates for TAVI, especially risk assessment, should involve multi-disciplinary consultation between cardiologists, surgeons, imaging specialists, anaesthesiologists, and possibly other specialists if necessary.



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

# HEART TEAM

Cardiologist

Radiologist

Heart Surgeon

Geriatrist

Anaesthesiologist

Pulmonologist

Imaging specialist

Vascular surgeon



# HEART TEAM

Is TAVI possible for the patient

If yes:

Wich Kind of valve?

Wich Kind of access?



# HEART TEAM

The following are the four steps of patient selection:

- confirmation the severity of AS;
- evaluation of symptoms;
- analysis of the risk of surgery and evaluation of life expectancy and quality of life;
- assessment of the feasibility and exclusion of contraindications for TAVI.



# 1) CONFIRMATION THE SEVERITY OF A

*“Echocardiography is the preferred tool to assess the severity of AS according to a combination of measurements of valve area and flow-dependent indices”*

- ✓ Aortic jet velocity  $> 4.0$  m/s
- ✓ Mean gradient  $> 40$  mmHg
- ✓ AVA  $< 1$  cm<sup>2</sup>
- ✓ Index AVA  $< 0.6$  cm<sup>2</sup>/m<sup>2</sup>

*“Low-dose dobutamine echocardiography is useful to differentiate between severe and the rare ‘pseudo severe’ AS in patients with low LV ejection fraction and low gradient”*

European Heart Journal (2008) 29, 1463–1470

# HEART TEAM

The following are the four steps of patient selection:

- confirmation the severity of AS;
- evaluation of symptoms;
- analysis of the risk of surgery and evaluation of life expectancy and quality of life;
- assessment of the feasibility and exclusion of contraindications for TAVI.



## 2) EVALUATION OF SYMPTOMS

*“At the present stage, TAVI should only be proposed in patients with **severe symptoms** that can definitely be attributed to valve disease because of pending questions on safety and valve durability”.*



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

Today TAVI should be considered in asymptomatic patients with initial signs of ventricular impairment



# “Heart Team”

The following are the four steps of patient selection:

- confirmation the severity of AS;
- evaluation of symptoms;
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- assessment of the feasibility and exclusion of contraindications for TAVI.



### 3) ANALYSIS OF THE RISK OF SURGERY AND EVALUATION OF LIFE EXPECTANCY AND QUALITY OF LIFE

**Risk scores:** { Logistic Euroscore > 20%  
STS score > 10%  
...

**Life expectancy:** TAVI should not be performed in patients whose life expectancy is < 1 year

***“For the Committee, the key element to establish whether patients are at high risk for surgery is **clinical judgement**”.***

### 3) ANALYSIS OF THE RISK OF SURGERY AND EVALUATION OF LIFE EXPECTANCY AND QUALITY

## OF LIFE RISK SCORES

- ✓ EUROSCORE Logistic
- ✓ EUROSCORE Standard  $\phi$  PROCEDURAL SUCCESS
- ✓ **EUROSCORE II**
- ✓ STS score

- LEE score
- ADL score
- 15 feet walking test
- Prension test

FRIALTY score

### 3) ANALYSIS OF THE RISK OF SURGERY AND EVALUATION OF LIFE EXPECTANCY AND QUALITY OF LIFE

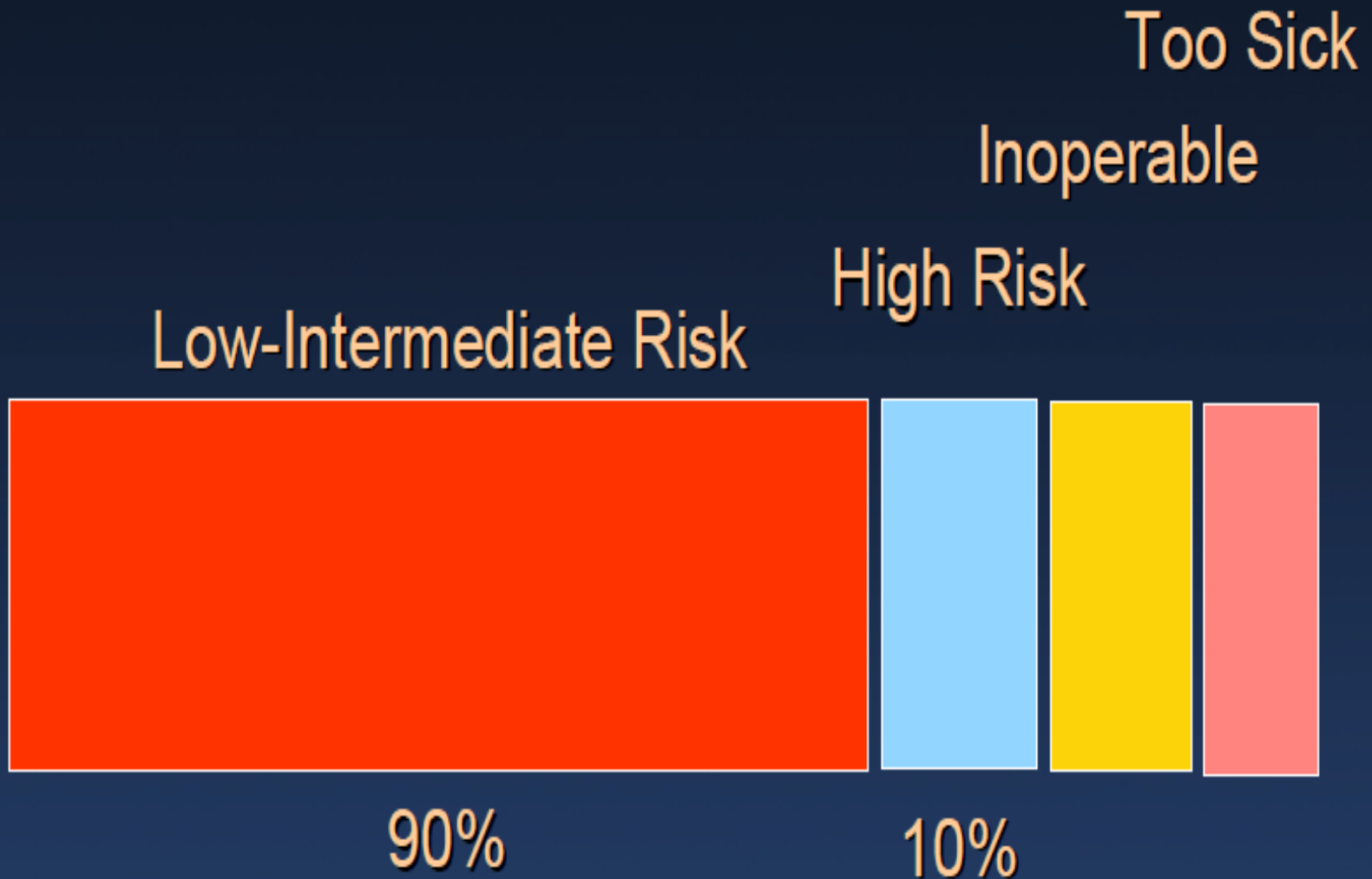
## FACTORS THAT ARE NOT COVERED IN SCORES

- ✓ Chest radiation
- ✓ Previous aorto-coronary bypass with patent grafts
- ✓ Porcelain aorta
- ✓ Liver cirrhosis
- ✓ Severe thoracic deformity
- ✓ Pulmonary hypertension
- ✓ Right ventricular failure
- ✓ Marked patient frailty
- ✓ ...



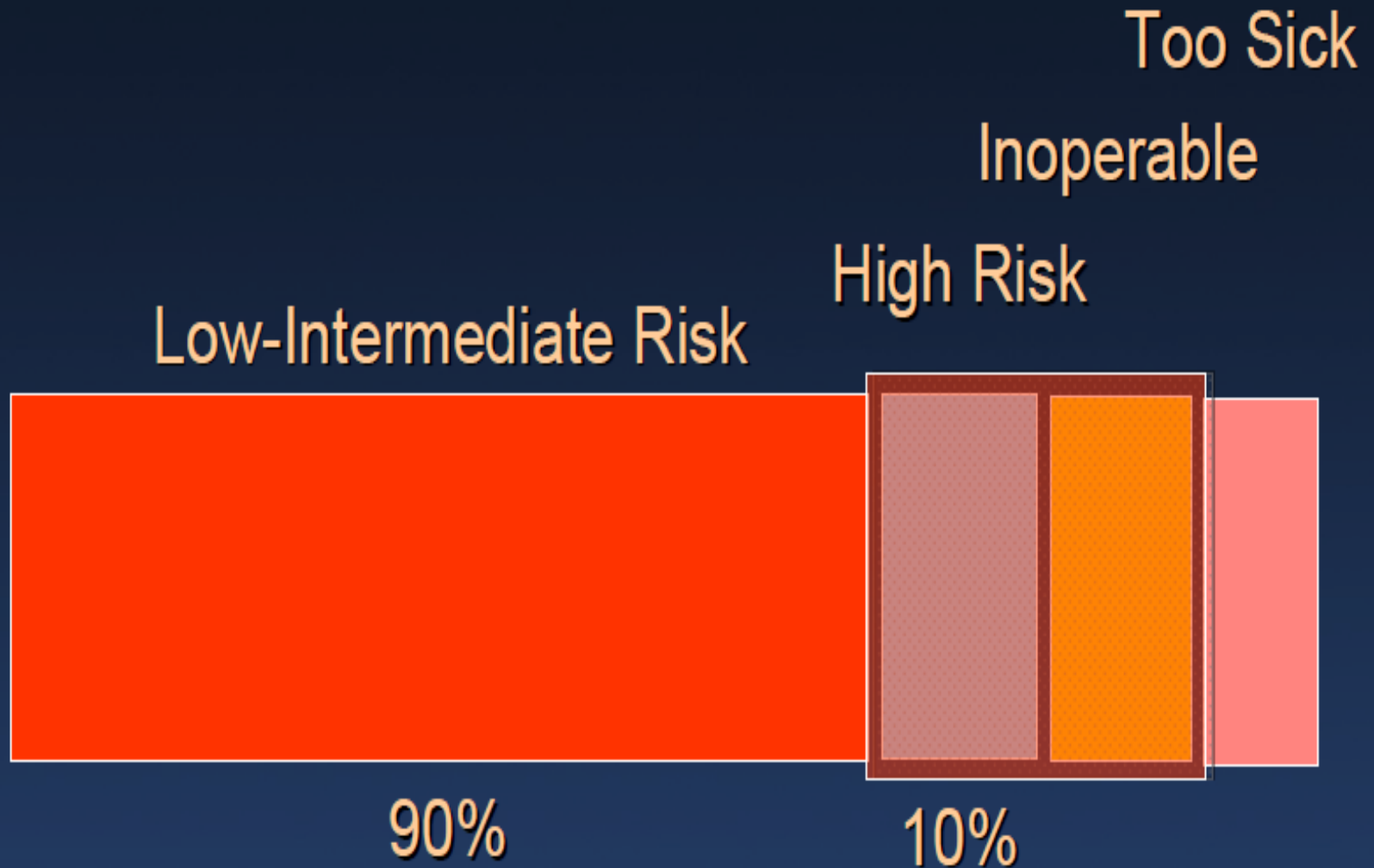
# Operable AS patients

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# Operable AS patients

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# Transfemoral: Predictors for 1-Year Mortality

(Multivariable analysis)

<b><i>Increased Mortality</i></b>	<b><i>p</i></b>	<b>Hazard Ratio</b>
Smoking	0.0001	1.94
Renal insufficiency / Failure	0.0003	1.77
Scaled LogEURO Score (/10)	0.004	1.15
Carotid endarterectomy / Carotid stent	0.01	2.81

<b><i>Decreased Mortality</i></b>	<b><i>p</i></b>	<b>Hazard Ratio</b>
Carotid artery stenosis (over 50%)	0.006	0.29
Hyperlipidemia / Hypercholesterolemia	0.006	0.65

# Transapical: Predictors for 1-Year Mortality

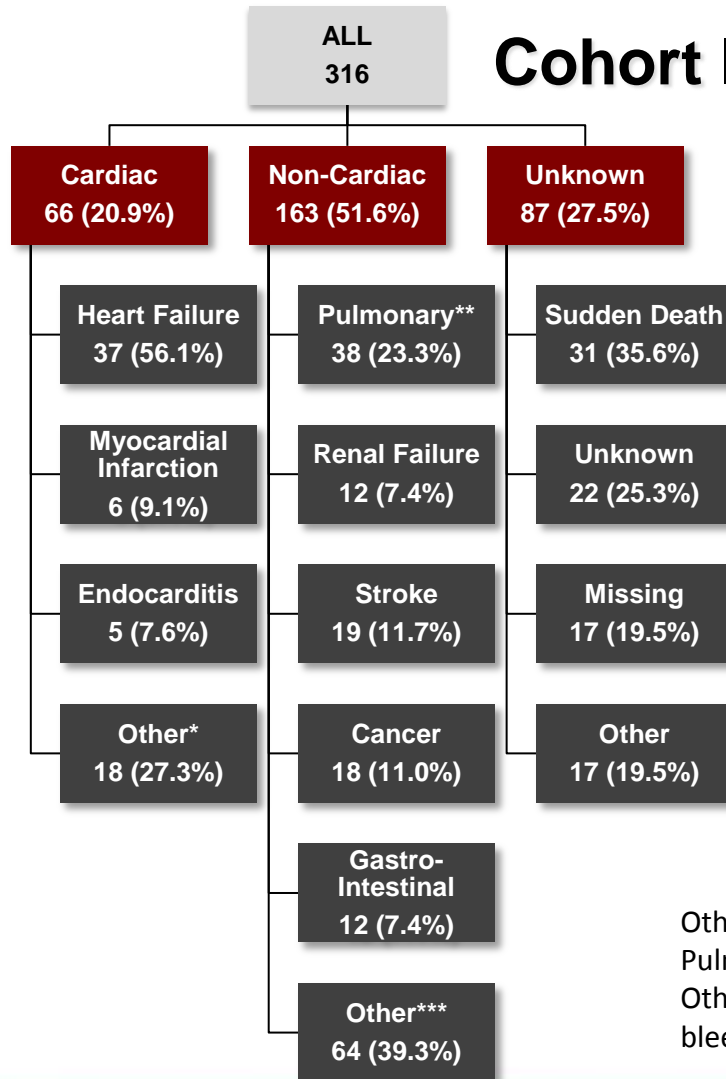
(Multivariable analysis)

<b><i>Increased Mortality</i></b>	<b><i>p</i></b>	<b>Hazard Ratio</b>
<b><i>Scaled LogEURO Score (/10)</i></b>	<b><i>&lt;0.000</i></b> <b><i>1</i></b>	<b>1.17</b>
<b><i>Renal insufficiency / Failure</i></b>	<b><i>0.0002</i></b>	<b>1.51</b>
<b><i>Decreased Mortality</i></b>	<b><i>p</i></b>	<b>Hazard Ratio</b>
<b><i>Female</i></b>	<b><i>0.00</i></b> <b><i>2</i></b>	<b>0.68</b>
<b><i>Hyperlipidemia / Hypercholesterolemia</i></b>	<b><i>0.00</i></b> <b><i>3</i></b>	<b>0.73</b>
<b><i>Product valve size 26</i></b>	<b><i>0.00</i></b> <b><i>2</i></b>	<b>0.68</b>

E2180/06-11/THV



# Causes of Death: 30 Days to 1-Year



Other\* = Arrhythmia, cardiac arrest, and other.

Pulmonary\*\*= Respiratory failure, pulmonary embolism and pneumonia.

Other\*\*\* = Multiple organ failure, sepsis, vascular access related, major bleeding, infection, hemorrhage, aneurysm, aortic dissection, and other.

# 3) ANALYSIS OF THE RISK OF SURGERY AND EVALUATION OF LIFE EXPECTANCY AND QUALITY OF LIFE

## **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**

Neil E. Moat, Peter Ludman, Mark A.de Belder, Ben Bridgewater, Andrew D. Cunningham, Christopher P. Young, Martyn Thomas, Jan Kovac, Tom Spyt, Philip A. MacCarthy, Olaf Wendler, David Hildick-Smith, Simon W. Davies, Uday Trivedi, Daniel J. Blackman, Richard D. Levy, Stephen J.D. Brecker, Andreas Baumbach, Tim Daniel, Huon Gray, and Michael J. Mullen

*J. Am. Coll. Cardiol.* published online Oct 19, 2011;  
doi:10.1016/j.jacc.2011.08.050

**This information is current as of October 20, 2011**

The online version of this article, along with updated information and services, is located on the World Wide Web at:

<http://content.onlinejacc.org/cgi/content/full/j.jacc.2011.08.050v1>

# 3) ANALYSIS OF THE RISK OF SURGERY AND EVALUATION OF LIFE EXPECTANCY AND QUALITY

OF LIFE

**Table 3** Predictors of Mortality at 1 Year

Variables	Alive (n = 684)	Dead (n = 186)	Univariate Model	p Value	Multivariate Model	p Value
Edwards SAPIEN	321/680 (47.2)	89/182 (48.9)	1.00			
Medtronic CoreValve	359/680 (52.8)	93/182 (51.1)	0.95 (0.70–1.29)	0.75		
Route, other	196/684 (28.7)	75/186 (40.3)	1.00			
<u>Route, transfemoral</u>	488/684 (71.3)	111/186 (59.7)	0.65 (0.48–0.88)	0.006	0.73 (0.52–1.04)	0.08
<u>AR moderate/severe</u>	83/674 (12.3)	32/175 (18.3)	1.49 (1.00–2.21)	0.048	1.66 (1.10–2.51)	0.016
Major vascular complication	39/684 (5.7)	16/185 (8.7)	1.42 (0.82–2.45)	0.21		
Permanent pacemaker	108/683 (15.8)	33/184 (17.9)	1.21(0.83–1.77)	0.32		
Male	355/684 (59.9)	101/186 (54.3)	1.19 (0.88–1.61)	0.25		
Age, yrs	81.8 ± 7.3	82.3 ± 6.4	1.01 (0.99–1.03)	0.52		
AV gradient	81.1 ± 27.1	79.9 ± 27.8	0.996 (0.990–1.002)	0.20		
LVEF ≥50%	459/680 (67.5)	94/185 (50.8)	1.00		1.00	
<u>LVEF 30%–49%</u>	169/680 (24.9)	69/185 (37.3)	1.93 (1.40–2.66)	<0.001	1.49 (1.03–2.16)	0.03
<u>LVEF &lt;30%</u>	52/680 (7.6)	22/185 (11.9)	1.89 (1.16–3.07)	0.01	1.65 (0.98–2.79)	0.06
NYHA functional class I/II	160/680 (23.5)	39/186 (21.0)	1.00			
NYHA functional class III/IV	520/680 (76.5)	147/186 (79.0)	1.14 (0.79–1.63)	0.50		
Coronary disease	301/653 (46.1)	93/175 (53.1)	1.38 (1.01–1.87)	0.04	1.23 (0.88–1.73)	0.23
Any previous cardiac surgery	202/667 (30.3)	57/186 (30.7)	1.04 (0.75–1.43)	0.83		
PVD	179/654 (27.4)	62/178 (34.8)	1.28 (0.91–1.75)	0.16		
Diabetes mellitus	146/675 (21.6)	50/136 (26.9)	1.36 (0.98–1.89)	0.07		
<u>COPD</u>	176/654 (26.9)	63/180 (35.0)	1.40 (1.02–1.93)	0.04	1.41(1.00–1.98)	0.05
Creatinine >200	38/668 (5.7)	19/185 (10.3)	1.84 (1.14–2.97)	0.012	1.55 (0.90–2.68)	0.11

# “Heart Team”

The following are the four steps of patient selection:

- confirmation the severity of AS;
- evaluation of symptoms;
- analysis of the risk of surgery and evaluation of life expectancy and quality of life;
- assessment of the feasibility and exclusion of contraindications for TAVI.



## 4) ASSESSMENT OF THE FEASIBILITY AND EXCLUSION OF CONTRAINDICATIONS FOR TAVI

- ✓ **Multidetector Computed Tomography**  
*64 slides cardiac gated*
- ✓ **Echocardiography** (*TTE and TEE*)
- ✓ **Angiography**

## 4) ASSESSMENT OF THE FEASIBILITY AND EXCLUSION OF CONTRAINDICATIONS FOR

### **Multidetector <sup>TAVI</sup> Computed Tomography**

**Anulus morphology and dimension (3D)**

**Aortic root morphology and dimension (3D)**

**Coronary ostia**

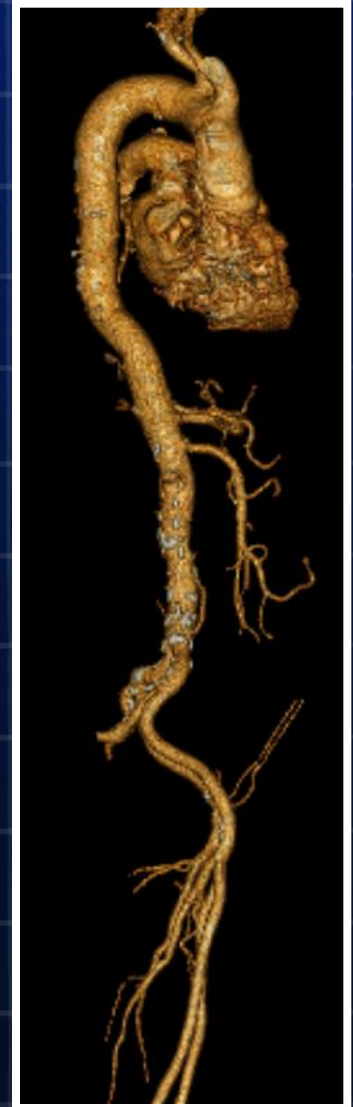
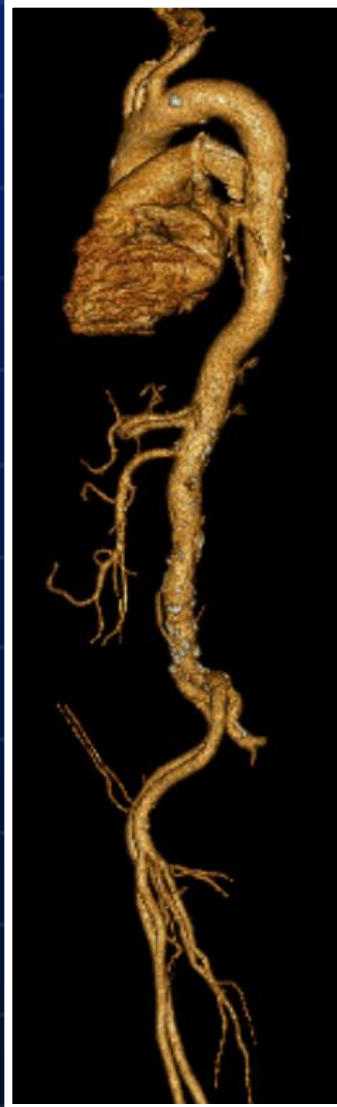
**Ascending Aorta and aortic arch)**

**Subclavian access**

**Abdominal and thoracic Aorta**

**Iliofemoral access**

# Multidetector Computed Tomography

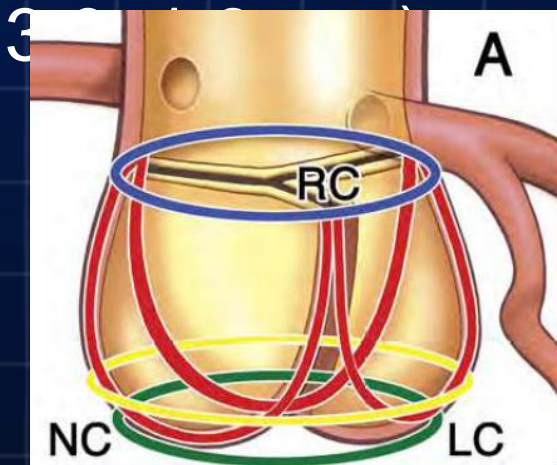


## 4) ASSESSMENT OF THE FEASIBILITY AND EXCLUSION OF CONTRAINDICATIONS FOR

### TAVI

#### Multidetector Computed Tomography Anulus

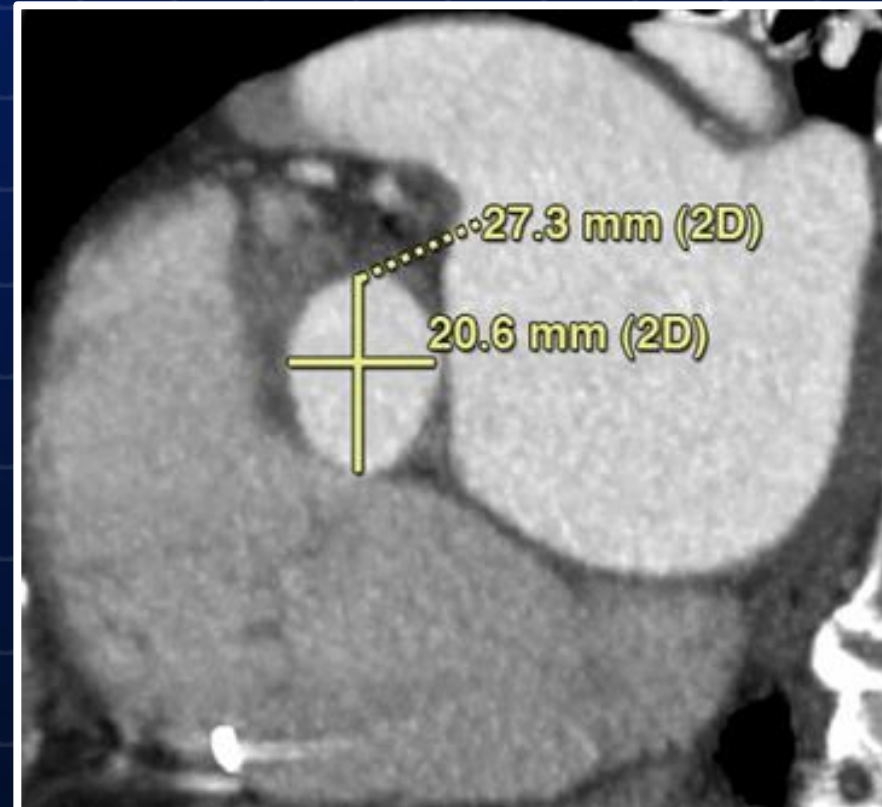
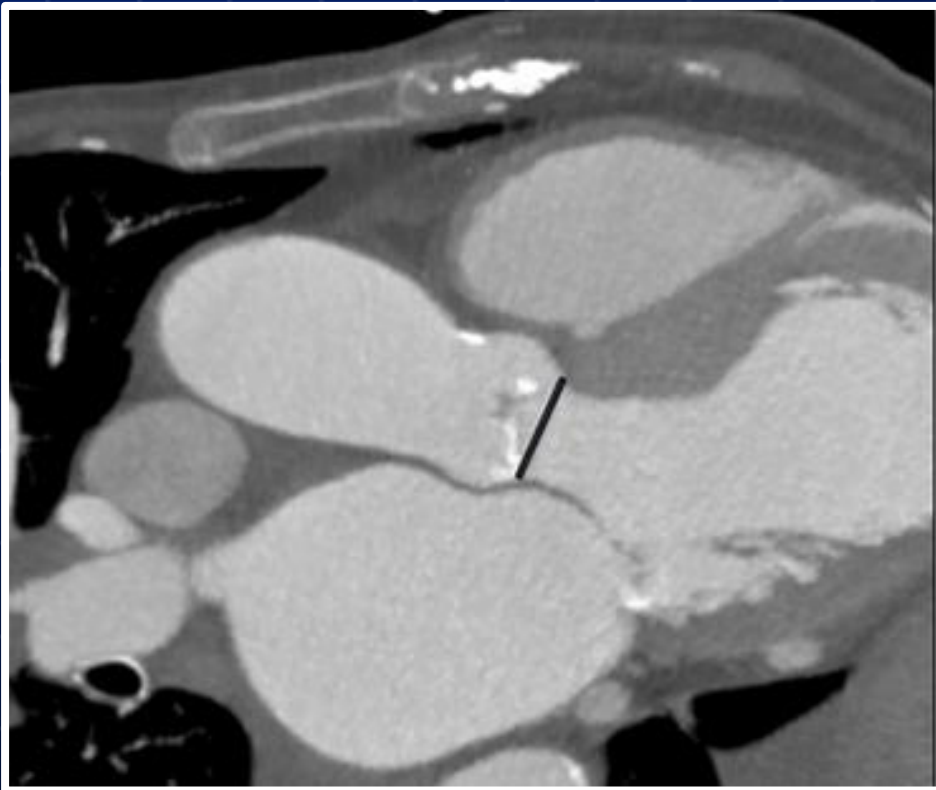
- complex 3D structure and it is NOT a RING
- **oval configuration** in approximately 50% of patients evaluated for TAVI ( mean difference between coronal and sagittal measurements of





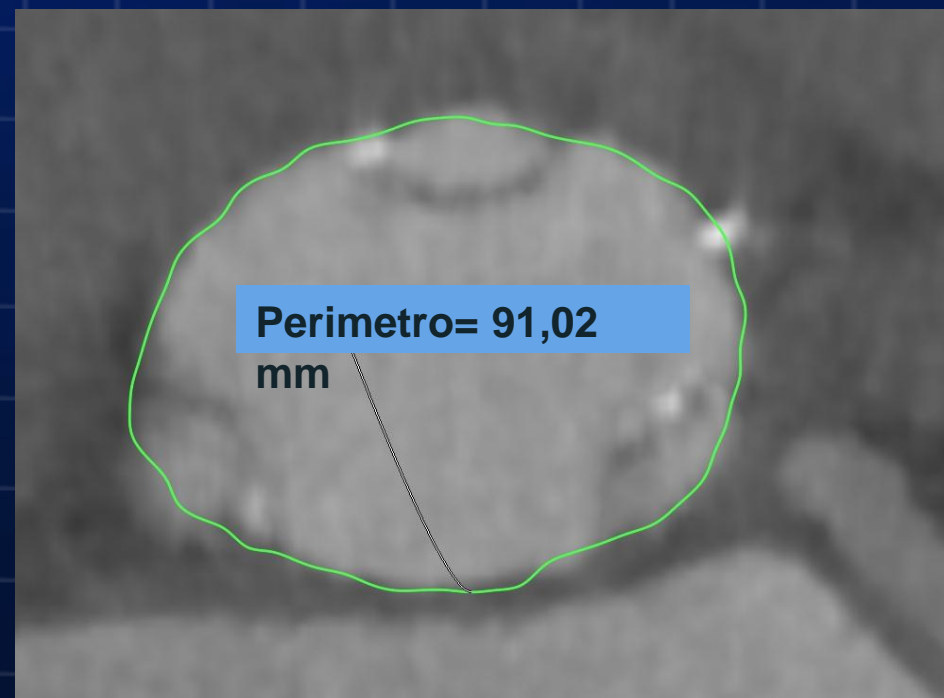
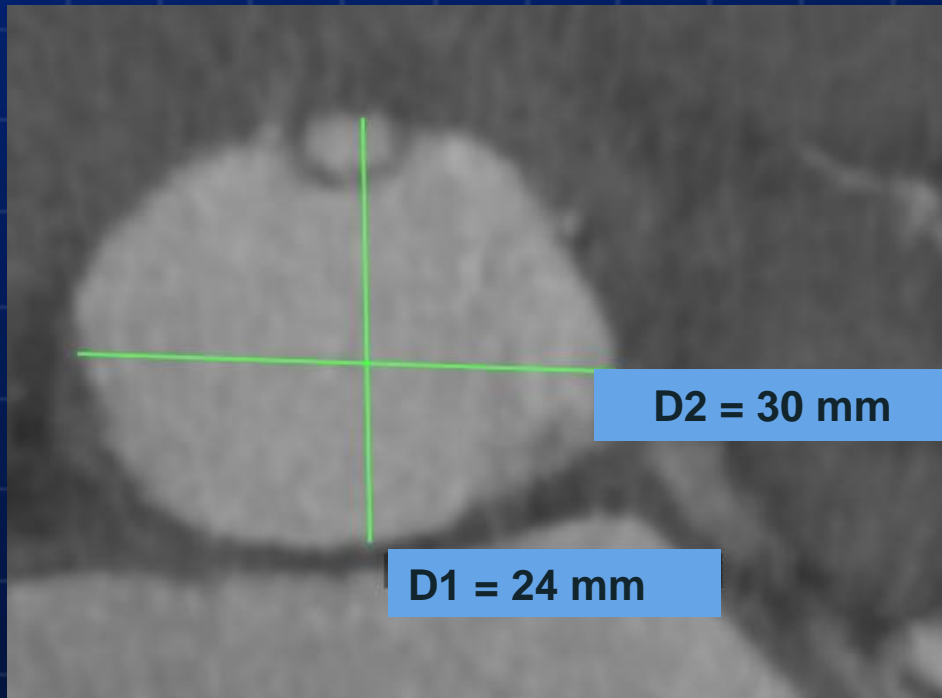
# 4) ASSESSMENT OF THE FEASIBILITY AND EXCLUSION OF CONTRAINDICATIONS FOR

## Multidetector Computed Tomography <sup>TAVI</sup> Annulus



# 4) ASSESSMENT OF THE FEASIBILITY AND EXCLUSION OF CONTRAINDICATIONS FOR

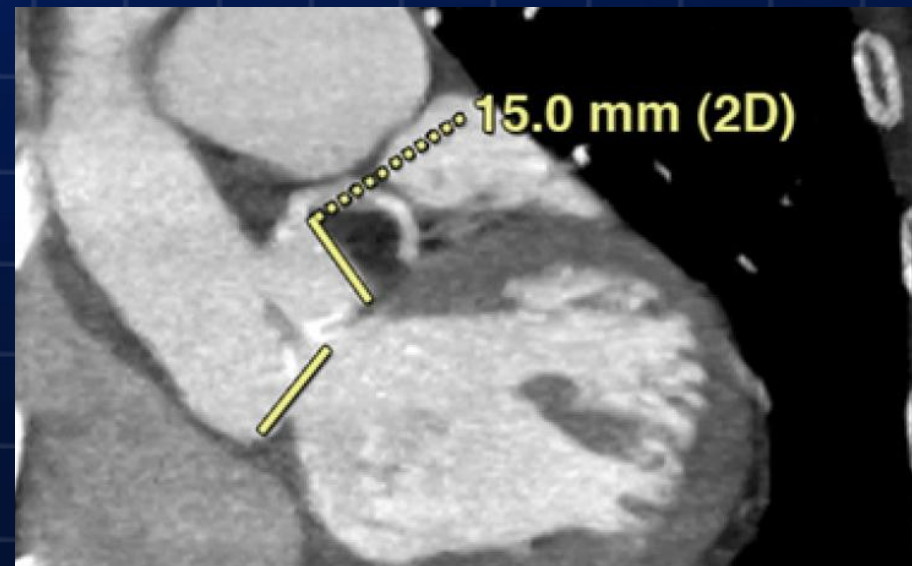
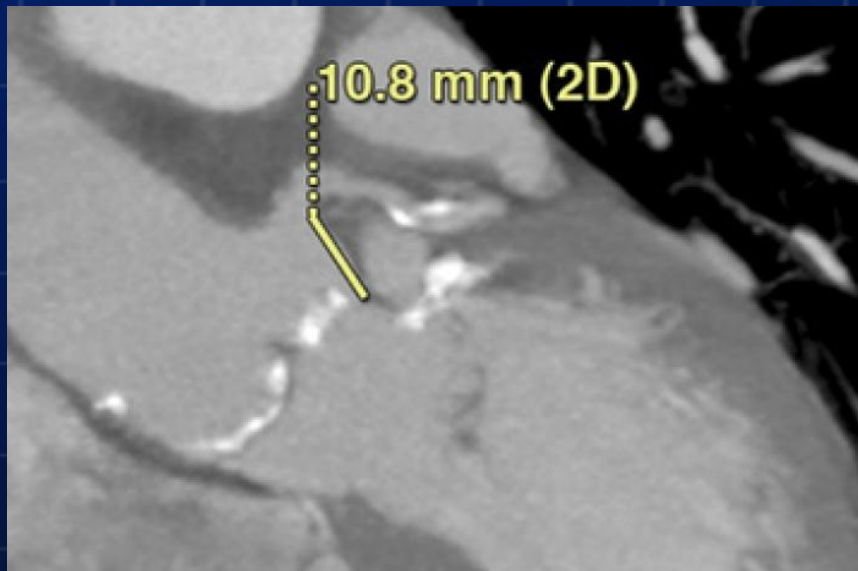
## TAVI! Anulus Multidetector Computed Tomography



# 4) ASSESSMENT OF THE FEASIBILITY AND EXCLUSION OF CONTRAINDICATIONS FOR

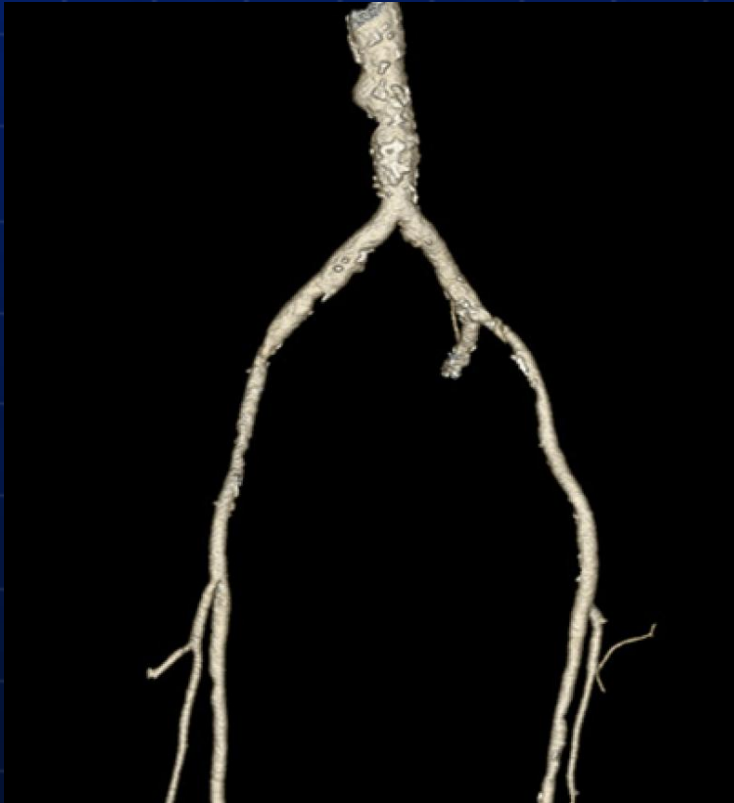
## TAVI Multidetector Computed Tomography

### Coronary Ostia



# 4) ASSESSMENT OF THE FEASIBILITY AND EXCLUSION OF CONTRAINDICATIONS FOR

## TAVI Multidetector Computed Tomography Iliofemoral access



# 4) ASSESSMENT OF THE FEASIBILITY AND EXCLUSION OF CONTRAINDICATIONS FOR

## TAVI Echocardiography

### EXPERT CONSENSUS STATEMENT

## EAE/ASE Recommendations for the Use of Echocardiography in New Transcatheter Interventions for Valvular Heart Disease

Jose L. Zamorano<sup>1\*†</sup>, Luigi P. Badano<sup>2</sup>, Charles Bruce<sup>3</sup>, Kwan-Leung Chan<sup>4</sup>, Alexandra Gonçalves<sup>5</sup>, Rebecca T. Hahn<sup>6</sup>, Martin G. Keane<sup>7</sup>, Giovanni La Canna<sup>8</sup>, Mark J. Monaghan<sup>9</sup>, Petros Nihoyannopoulos<sup>10</sup>, Frank E. Silvestry<sup>7</sup>, Jean-Louis Vanoverschelde<sup>11</sup>, and Linda D. Gillam<sup>12‡</sup>, *Rochester, Minnesota; Ottawa, Ontario, Canada; Porto, Portugal; New York, New York; Philadelphia, Pennsylvania; London, United Kingdom; Brussels, Belgium; Morristown, New Jersey*

## 4) ASSESSMENT OF THE FEASIBILITY AND EXCLUSION OF CONTRAINDICATIONS FOR

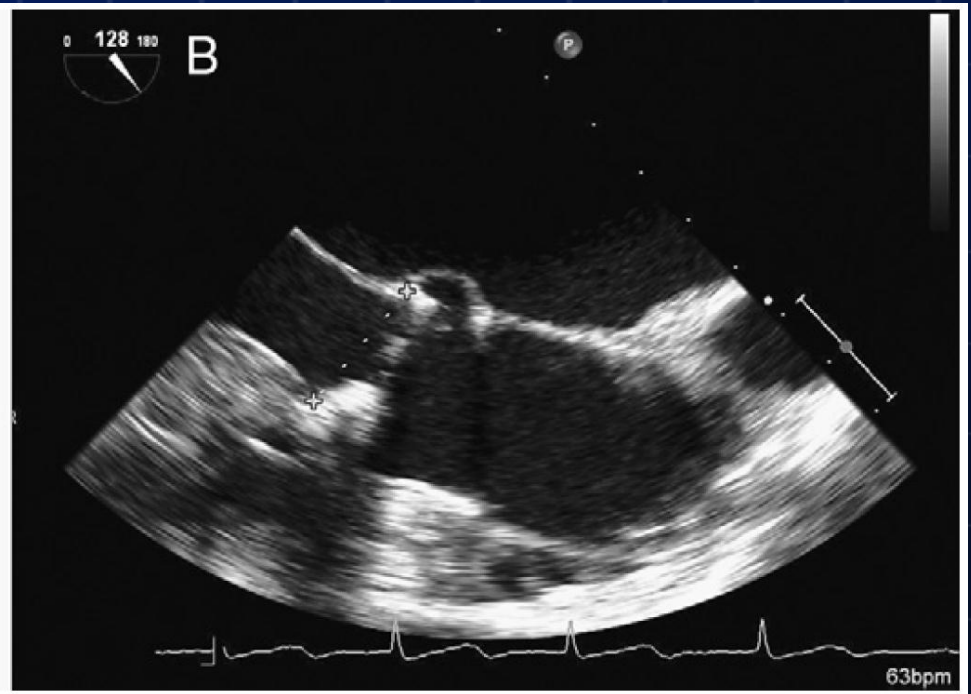
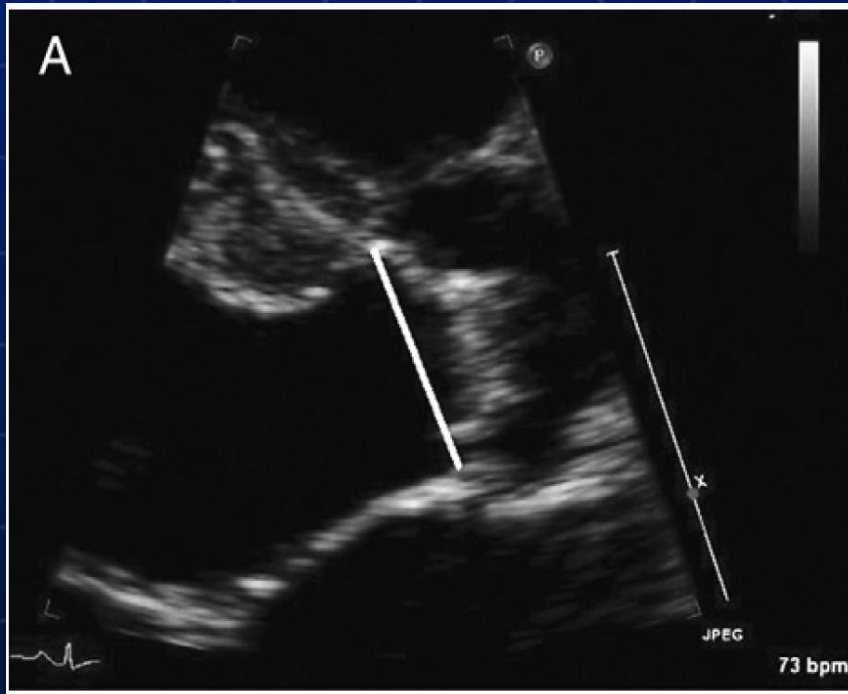
### TAVI Echocardiography

- Annular dimension
- Cusps (number, mobility, thickness)
- Calcifications
- Aortic regurgitation
- LV and RV dimension and function
- Basal septal hypertrophy
- ...

*“Currently, **bicuspid aortic valve** is an exclusion criterion for TAVI because an elliptical valvular orifice may predispose to an increased risk of incomplete and incorrect deployment of the aortic prosthesis”*

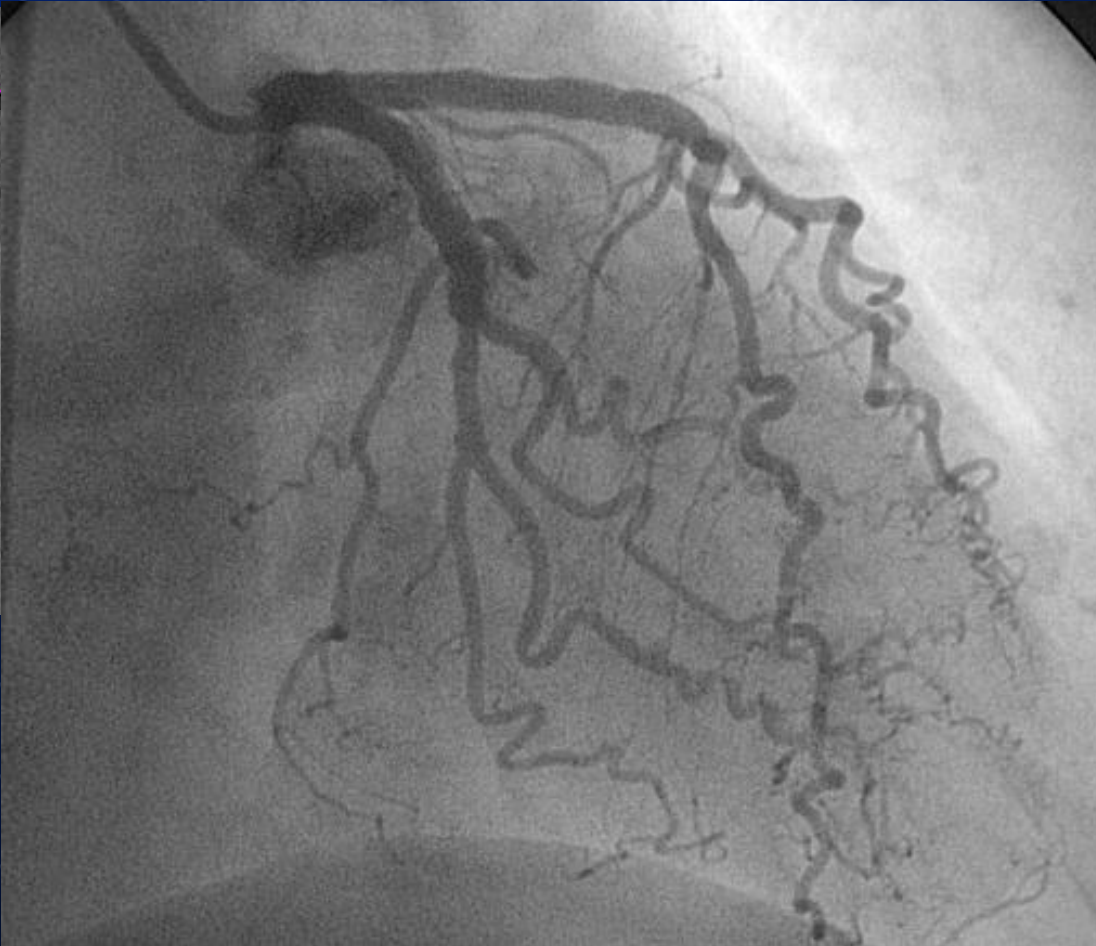
# 4) ASSESSMENT OF THE FEASIBILITY AND EXCLUSION OF CONTRAINDICATIONS FOR

## TAVI Echocardiography



# 4) ASSESSMENT OF THE FEASIBILITY AND EXCLUSION OF CONTRAINDICATIONS FOR

## TAVI Angiography



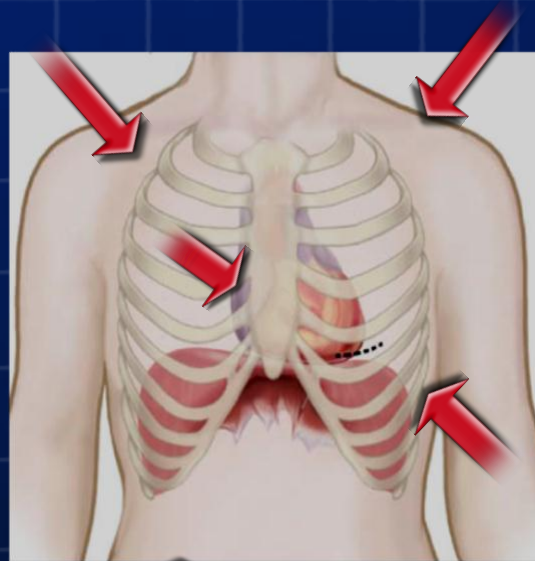


# WICH KIND OF ACCESS?

Right Subclavian

Left Subclavian

*Trans aorta*



*Transapical*

**Transfemoral**

# WICH KIND OF VALVE?

## Edwards Sapien Valve



- Transfemoral
- Transapical

## CoreValve – Medtronic



- Transfemoral
- Transaortic
- Transsubclavian

# NEW VALVES

**Edwards 29 mm** (annulus 24.5 mm-27 mm) TA only

## General

- ▶ Aortic annulus <20 mm (relative contraindication)
- ▶ Bicuspid valves (relative contraindication)
- ▶ Presence of asymmetric heavy valvular calcification
- ▶ Aortic root dimension >45 mm at the sino-tubular junction for self expandable prostheses
- ▶ Low position of coronary ostia (<8 mm from the aortic annulus)
- ▶ Dynamic subvalvular obstruction
- ▶ Severe organic mitral regurgitation
- ▶ Apical left ventricular thrombus

## **Specific contraindications for the transfemoral approach**

- ▶ Iliac arteries: severe calcification, tortuosity, small diameter (<6–9 mm depending on the device used), previous aorto-femoral bypass
- ▶ Aorta: severe angulation, severe atheroma of the arch, coarctation, aneurysm of the abdominal aorta with protruding mural thrombus
- ▶ The presence of bulky atherosclerosis of the ascending aorta and arch detected by transoesophageal echocardiography

## **Contraindications for the transapical approach**

- ▶ Severe respiratory insufficiency
- ▶ Major chest deformity
- ▶ Previous surgery of the left ventricle using a patch

THANK YOU

