

# Patient selection in TAVI: A Heart Team Approach

Lars Søndergaard  
Consultant, MD, MDSc  
Department of Cardiology  
Rigshospitalet  
Denmark

# Guidelines on the management of valvular heart disease (version 2012)

## The Joint Task Force on the Management of Valvular Heart Disease of the European Society of Cardiology (ESC) and the European Association for Cardio-Thoracic Surgery (EACTS)

**Authors/Task Force Members:** Alec Vahanian (Chairperson) (France)\*, Ottavio Alfieri (Chairperson)\* (Italy), Felicita Andreotti (Italy), Manuel J. Antunes (Portugal), Gonzalo Barón-Esquivias (Spain), Helmut Baumgartner (Germany), Michael Andrew Borger (Germany), Thierry P. Carrel (Switzerland), Michele De Bonis (Italy), Arturo Evangelista (Spain), Volkmar Falk (Switzerland), Bernard Iung (France), Patrizio Lancellotti (Belgium), Luc Pierard (Belgium), Susanna Price (UK), Hans-Joachim Schäfers (Germany), Gerhard Schuler (Germany), Janina Stepinska (Poland), Karl Swedberg (Sweden), Johanna Takkenberg (The Netherlands), Ulrich Otto Von Oppell (UK), Stephan Windecker (Switzerland), Jose Luis Zamorano (Spain), Marian Zembala (Poland)

# Heart Team

Decision-making should ideally be made by a 'heart team' with a particular expertise in VHD, including cardiologists, cardiac surgeons, imaging specialists, anaesthetists and, if needed, general practitioners, geriatricians, or intensive care specialists. This 'heart team' approach is particularly advisable in the management of high-risk patients and is also important for other subsets, such as asymptomatic patients, where the evaluation of valve repairability is a key component in decision-making.

# Duties of the Heart Team

A 'heart team' that assesses individual patient's risks, as well as the technical suitability of TAVI and access issues, should be best able to make decisions in this patient population.

Patient's risk

# Classification of surgical risk

Extreme

High

STS score  $>8$

Intermediate

STS score 4-8

Low

STS score  $<4$

# Randomised Clinical Trials

Risk

Edwards

CoreValve

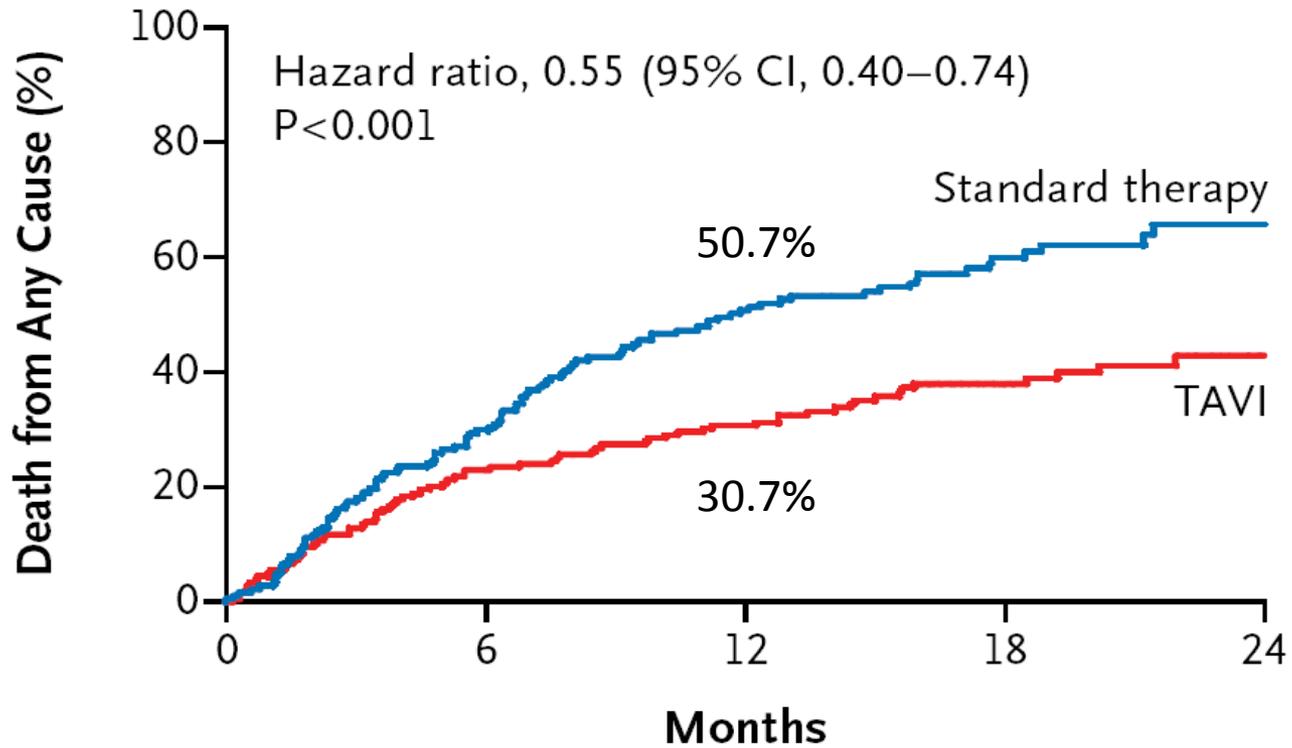
Extreme

Partner B

US pivotal trial

# Partner Cohort B

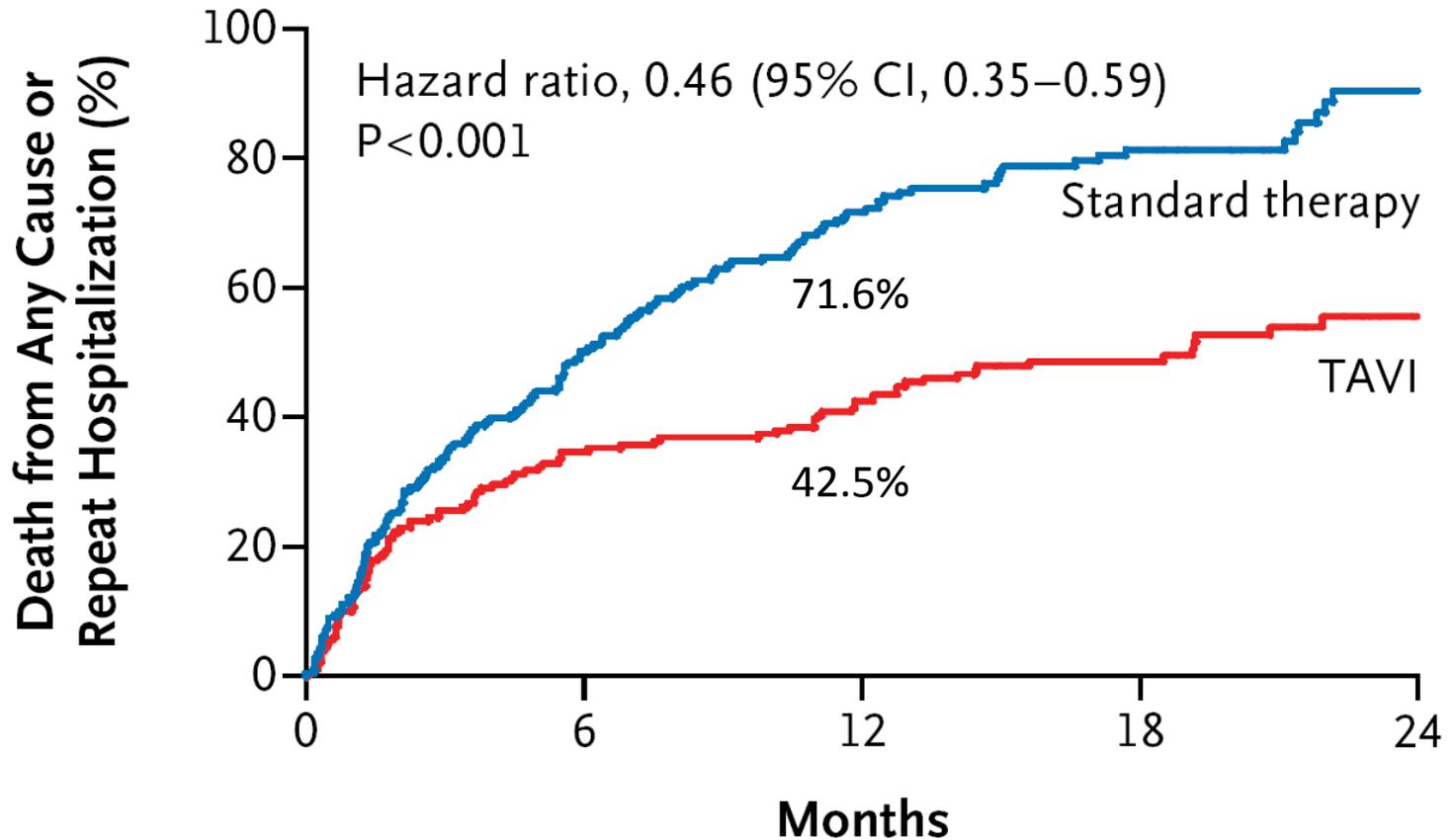
A



## No. at Risk

TAVI	179	138	122	67	26
Standard therapy	179	121	83	41	12

# Partner Cohort B



## No. at Risk

TAVI	179	117	102	56	22
Standard therapy	179	86	49	23	4

# Clinical Frailty Scale\*



**1 Very Fit** – People who are robust, active, energetic and motivated. These people commonly exercise regularly. They are among the fittest for their age.

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**2 Well** – People who have **no active disease symptoms** but are less fit than category 1. Often, they exercise or are very **active occasionally**, e.g. seasonally.

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**3 Managing Well** – People whose **medical problems are well controlled**, but are **not regularly active** beyond routine walking.

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**4 Vulnerable** – While **not dependent** on others for daily help, often **symptoms limit activities**. A common complaint is being “slowed up”, and/or being tired during the day.

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**5 Mildly Frail** – These people often have **more evident slowing**, and need help in **high order IADLs** (finances, transportation, heavy housework, medications). Typically, mild frailty progressively impairs shopping and walking outside alone, meal preparation and housework.

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**6 Moderately Frail** – People need help with **all outside activities** and with **keeping house**. Inside, they often have problems with stairs and need **help with bathing** and might need minimal assistance (cuing, standby) with dressing.

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**7 Severely Frail** – **Completely dependent for personal care**, from whatever cause (physical or cognitive). Even so, they seem stable and not at high risk of dying (within ~ 6 months).

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**8 Very Severely Frail** – Completely dependent, approaching the end of life. Typically, they could not recover even from a minor illness.

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**9. Terminally Ill** - Approaching the end of life. This category applies to people with a **life expectancy <6 months**, who are **not otherwise evidently frail**.

## Scoring frailty in people with dementia

The degree of frailty corresponds to the degree of dementia. Common **symptoms in mild dementia** include forgetting the details of a recent event, though still remembering the event itself, repeating the same question/story and social withdrawal.

In **moderate dementia**, recent memory is very impaired, even though they seemingly can remember their past life events well. They can do personal care with prompting.

In **severe dementia**, they cannot do personal care without help.

\* 1. Canadian Study on Health & Aging, Revised 2008.

2. K. Rockwood et al. A global clinical measure of fitness and frailty in elderly people. CMAJ 2005;173:489-495.

# Randomised Clinical Trials

Risk

Edwards

CoreValve

Extreme

Partner B

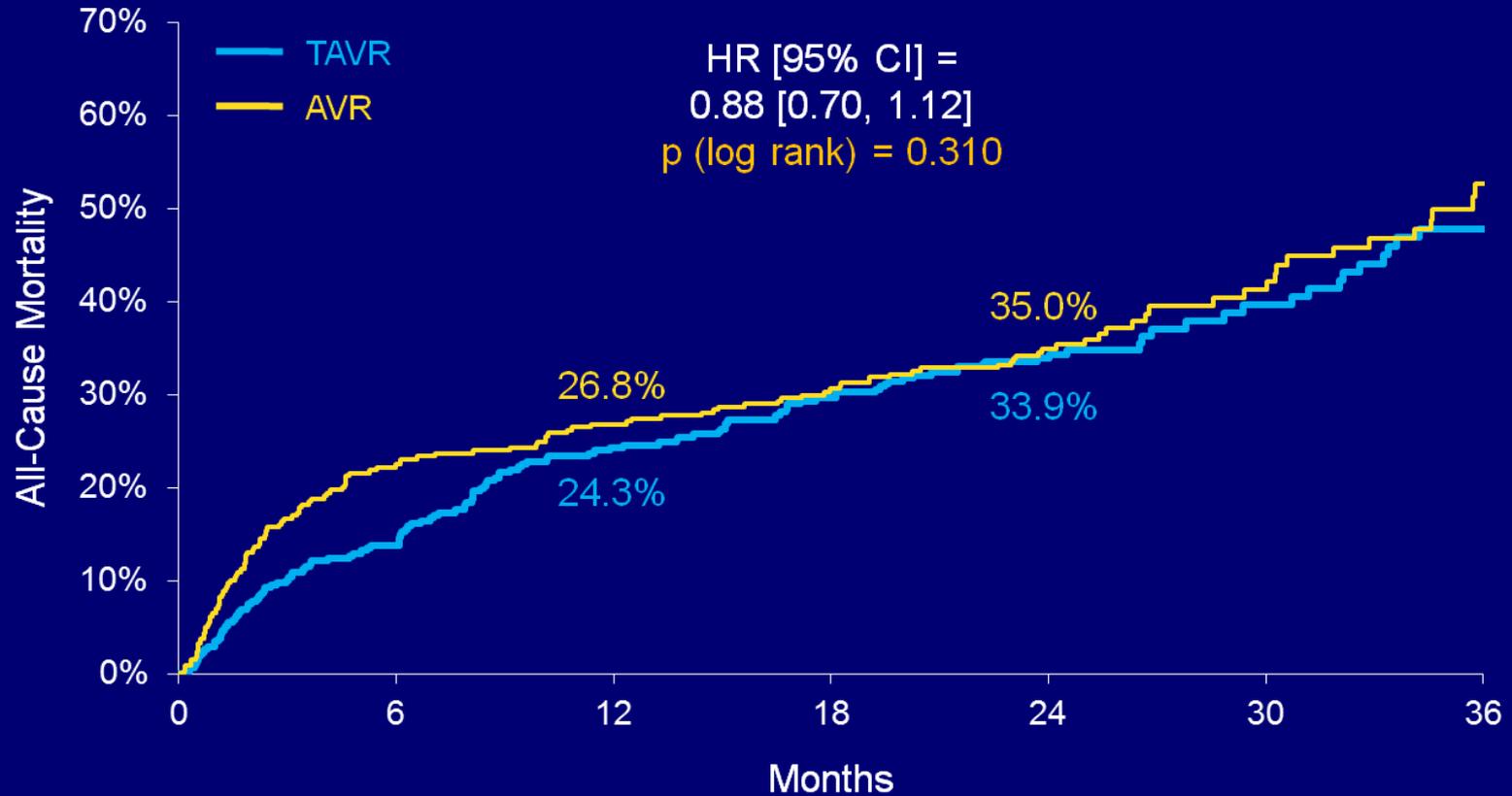
US pivotal trial

High

Partner A

US pivotal trial

# Partner Cohort A



## Numbers at Risk

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

# Randomised Clinical Trials

Risk

Edwards

CoreValve

Extreme

Partner B

US pivotal trial

High

Partner A

US pivotal trial

Intermediate

Partner II

SURTAVI

# SURTAVI

Evaluate in a prospective randomized fashion whether TAVI is non-inferior to SAVR with respect to the event free survival of the combined endpoint of all-cause mortality and major stroke at 24 months in patients with symptomatic severe aortic stenosis and at intermediate surgical risk.

# SURTAVI

## Study design

- **1200 patients**
  - 1:1 randomization
    - 600 MCS TAVI
    - 600 SAVR
- **Non-Inferiority**
  - Intent to treat
  - As treated
- **Up to 50 trial sites globally**

# SURTAVI

## Study design

- **1200 patients → 2,500 patients**
  - 1:1 randomization
    - 600 MCS TAVI
    - 600 SAVR
- **Non-Inferiority**
  - Intent to treat
  - As treated
- **Up to 50 trial sites globally**

# SURTAVI

## Study design

- **Patient population**
    - Symptomatic severe aortic stenosis
    - Intermediate surgical risk, defined by:
      - Society of Thoracic Surgeons (STS) mortality risk  $\geq 3\%$  and  $\leq 8\%$  (OUS)
      - STS mortality risk  $\geq 4\%$  and  $\leq 8\%$  (US)
  - **Long-term follow-up through 5 years**
    - Enrollment phase ~ 20 months
    - Trial duration ~ 7 years
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# Randomised Clinical Trials

Risk

Edwards

CoreValve

Extreme

Partner B

US pivotal trial

High

Partner A

US pivotal trial

Intermediate

Partner II

SURTAVI

Low

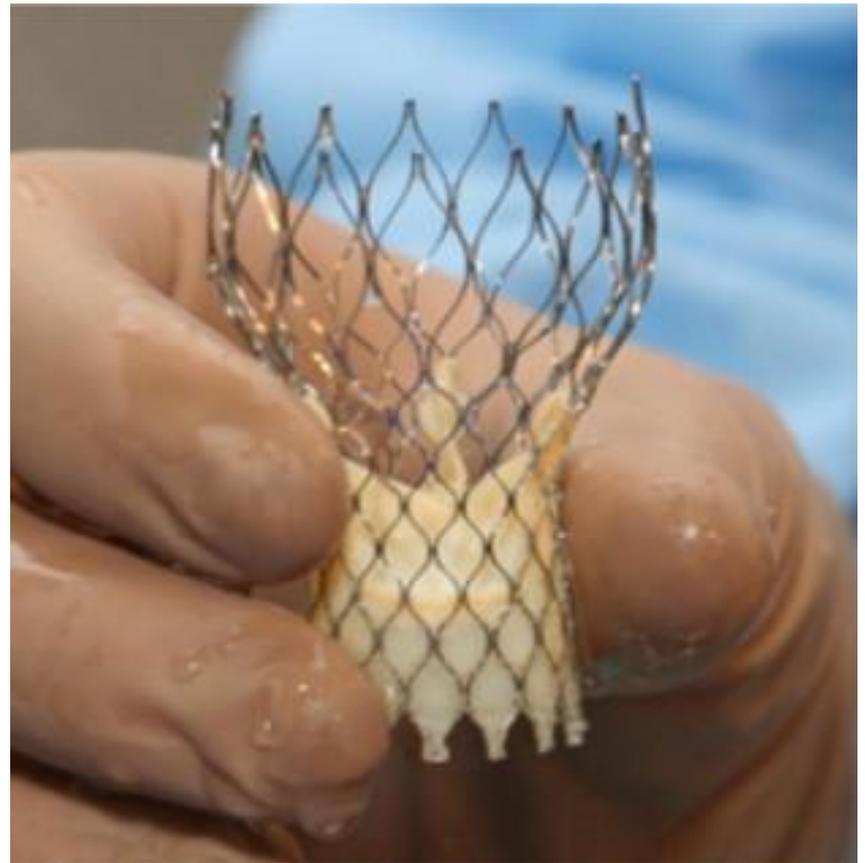
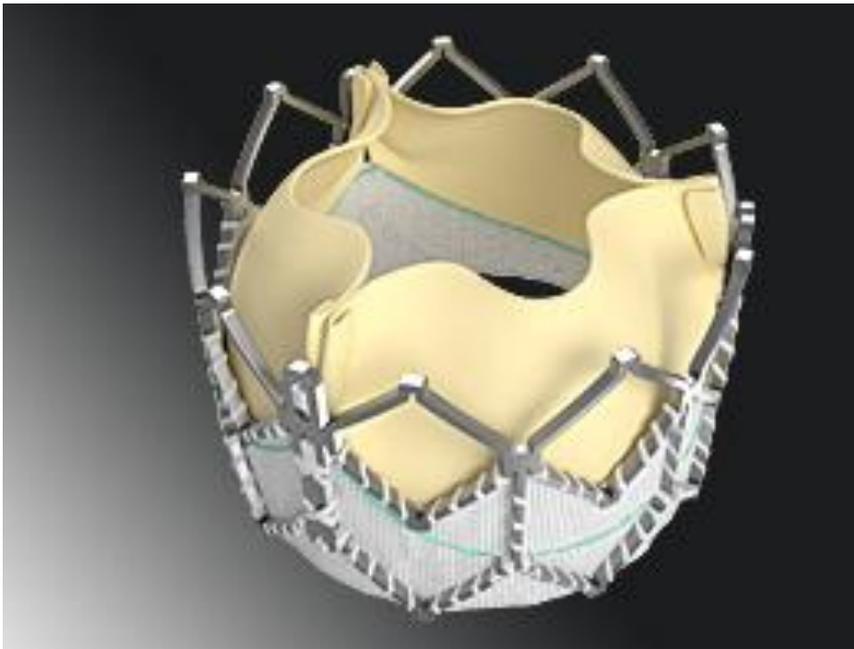
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Technical suitability

# TAVI systems

Edwards XT

Medtronic CoreValve



# Annulus size

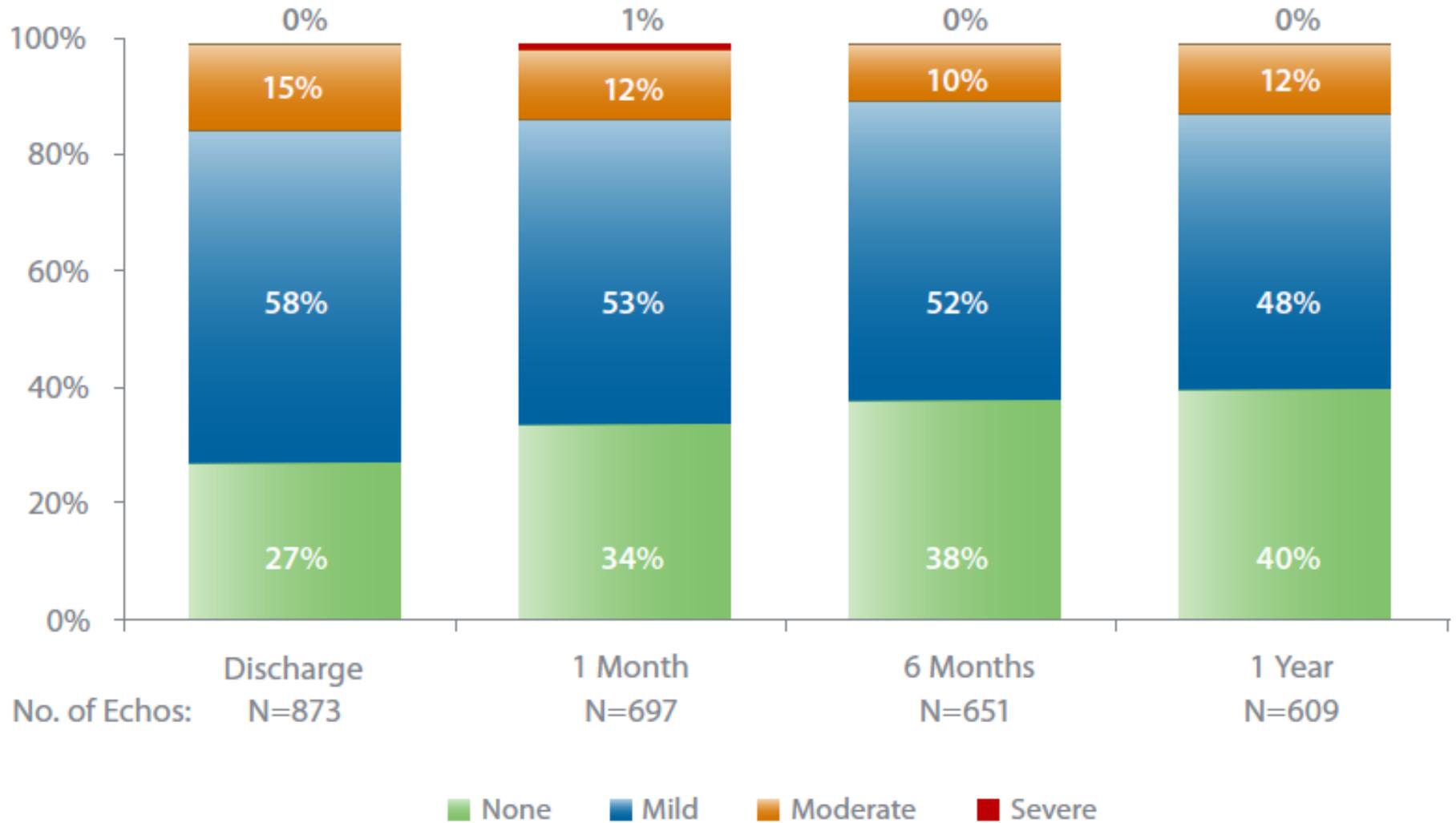
Range: 18- 29 mm

<i>Valve sizes</i>	<i>Edwards XT</i>	<i>CoreValve</i>
23 mm	18-22 mm	18-20 mm
26 mm	21-25 mm	20-23 mm
29 mm	24-27 mm (only TA)	23-27 mm
31 mm		26-29 mm

Paravalvular leakage

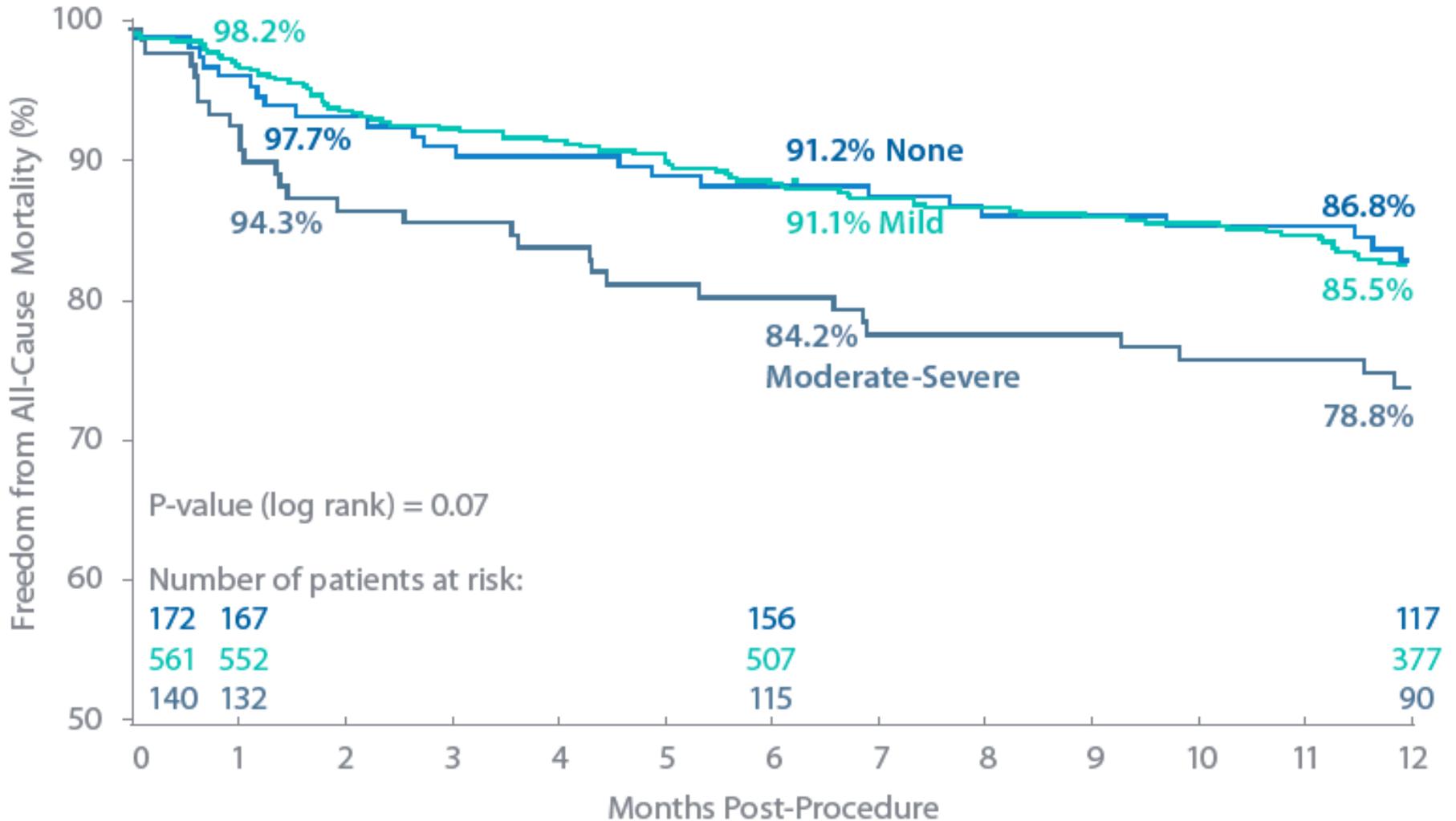
# PVL

## Advance study

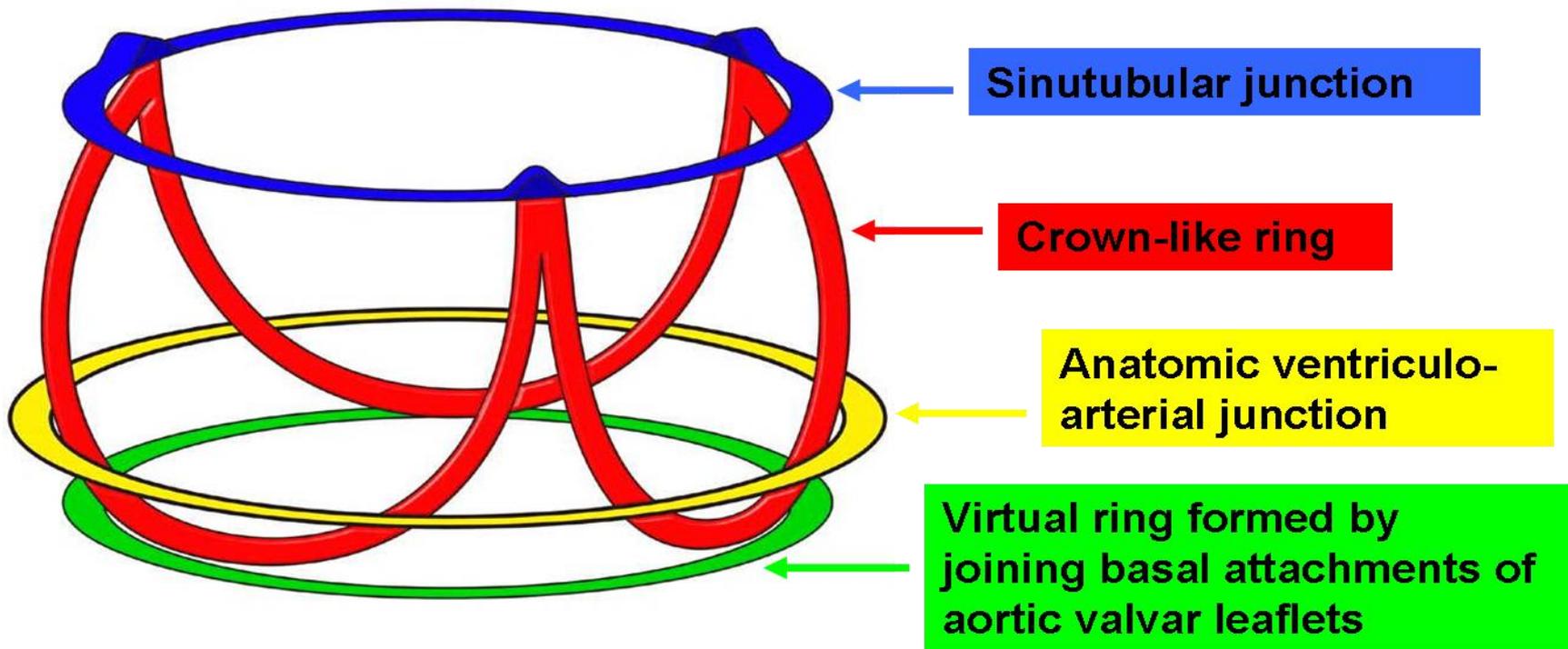


# PVL and Mortality

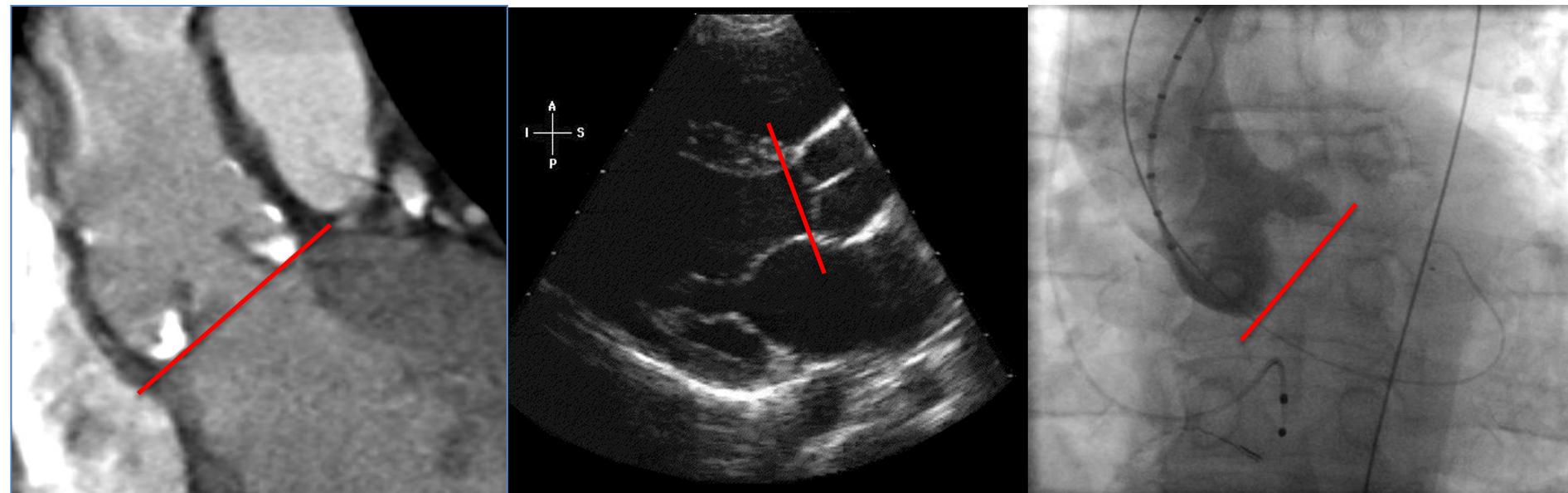
## Advance study



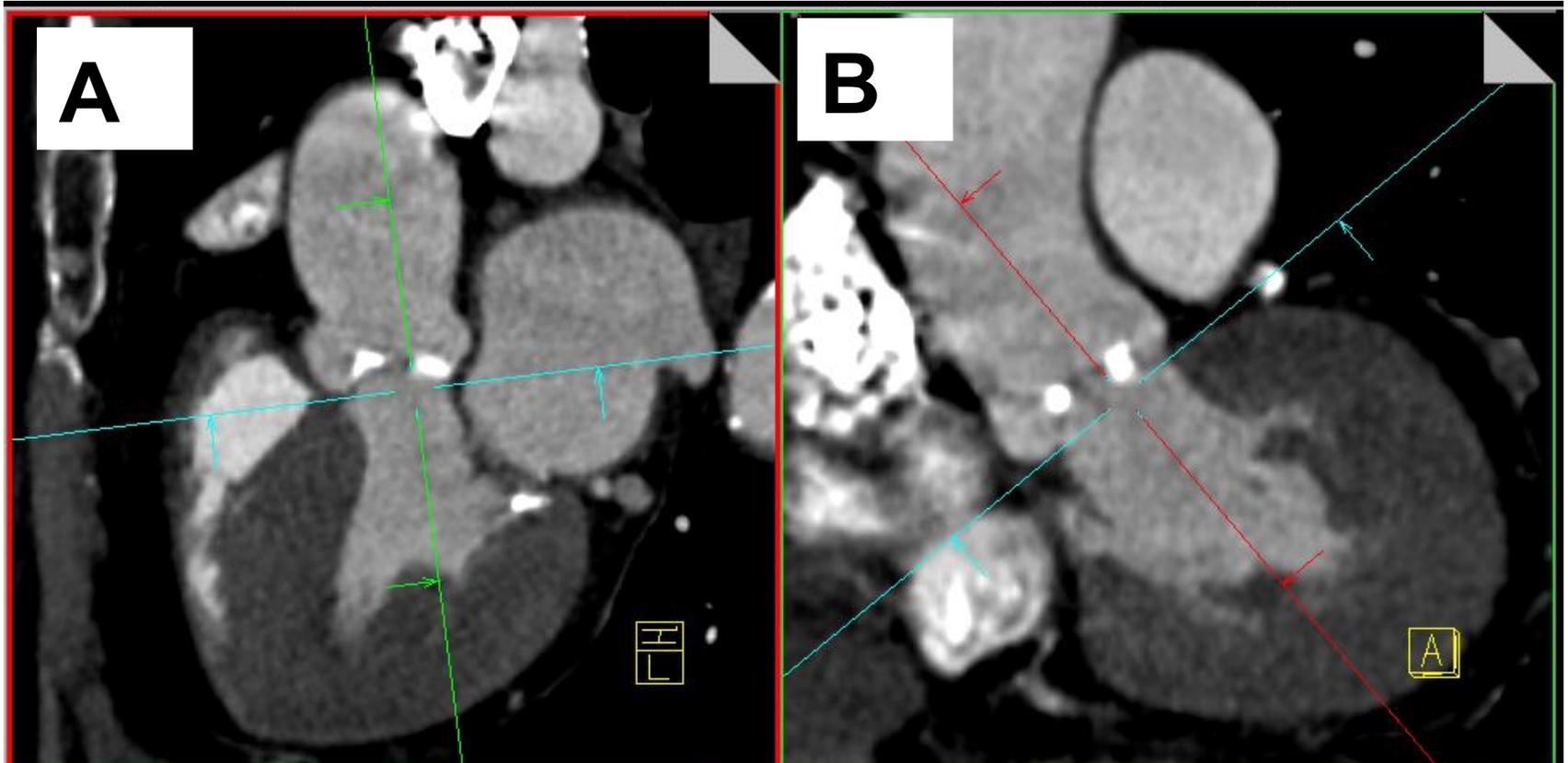
# Rings of the aortic root



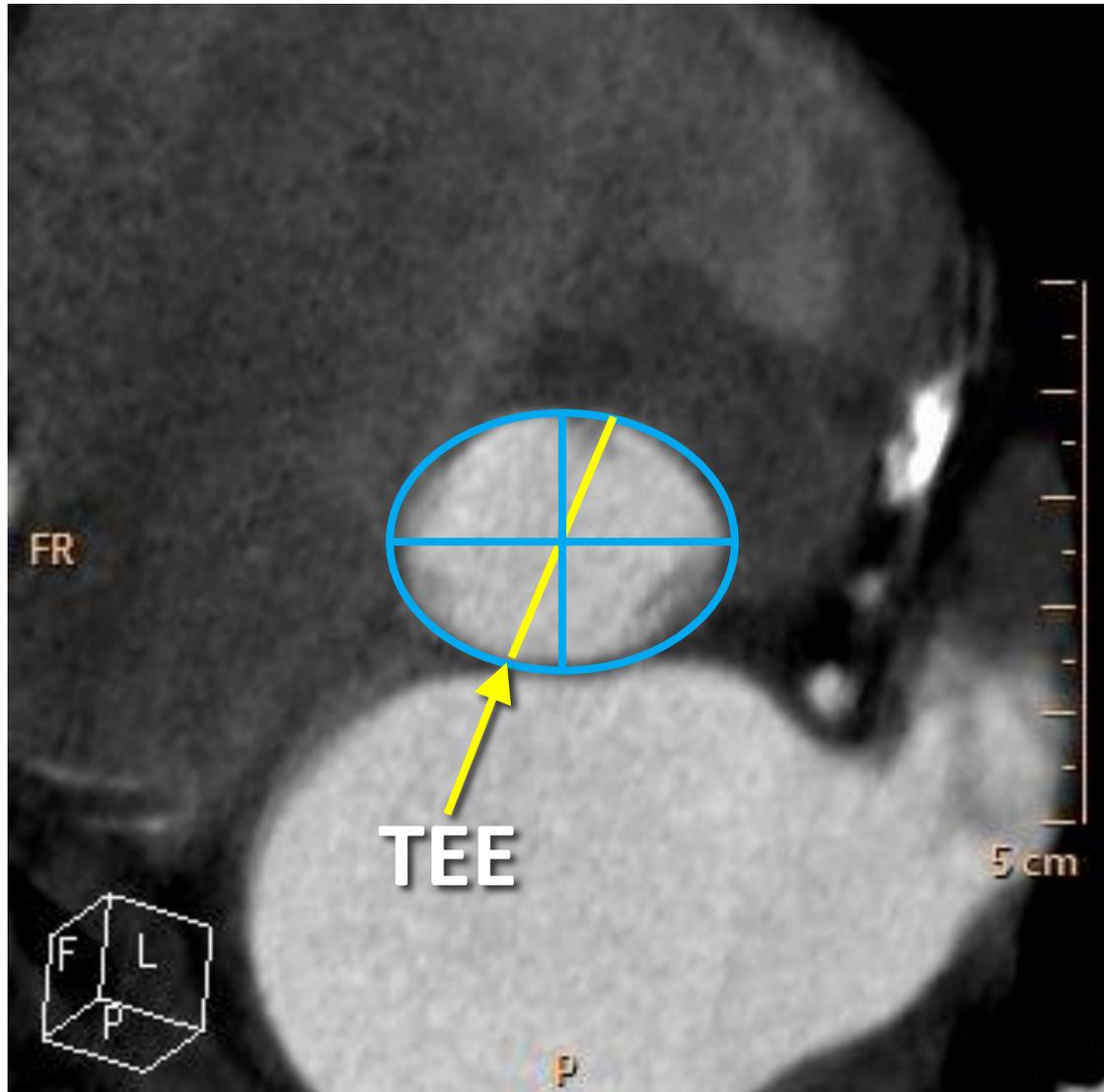
# Definition of aortic annulus



# CT scan of aortic annulus



# The aortic annulus is oval



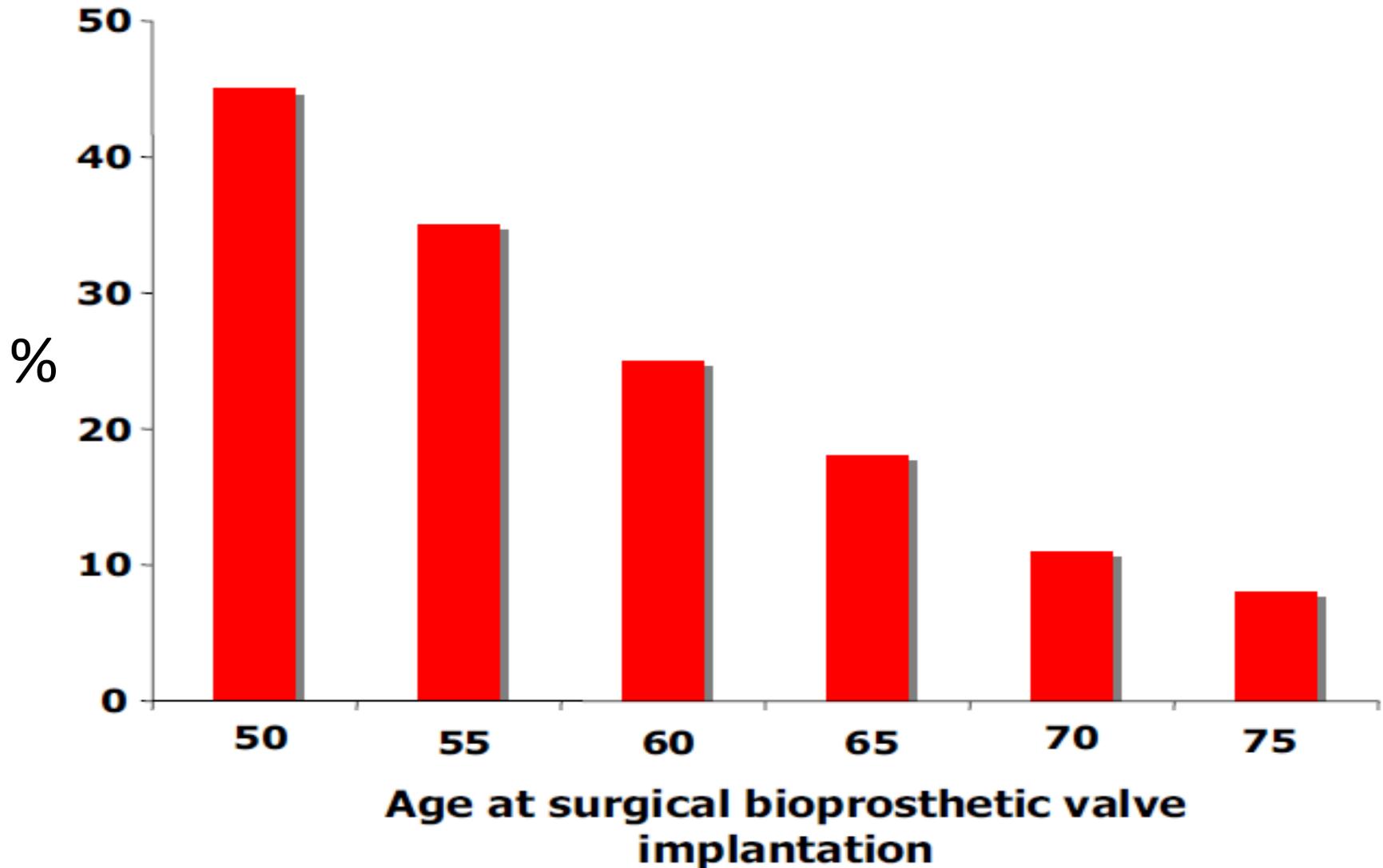
# Anatomical contraindications

- Thrombus in the left ventricle
- Active endocarditis
- Elevated risk of coronary ostium obstruction
  - Asymmetric valve calcification
  - Short distance between annulus and coronary ostium
  - Small aortic sinuses
- Plaque with mobile thrombi in asc aorta or arch

# Valve-in-valve



# Life-time incidence of re-operation

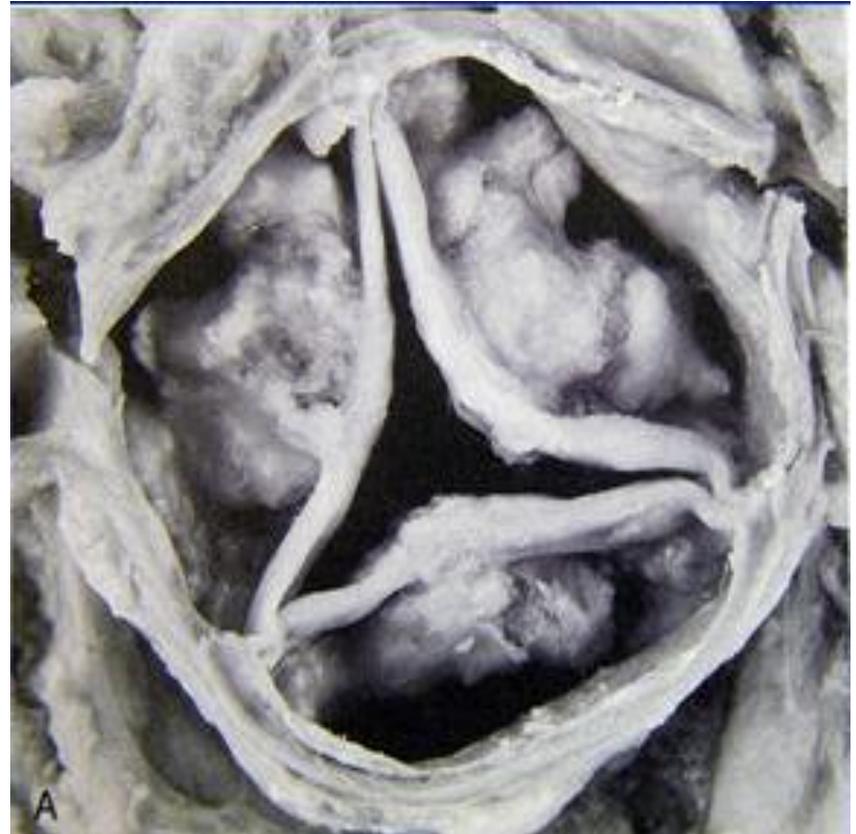


# Aortic stenosis

Tricuspid aortic valve



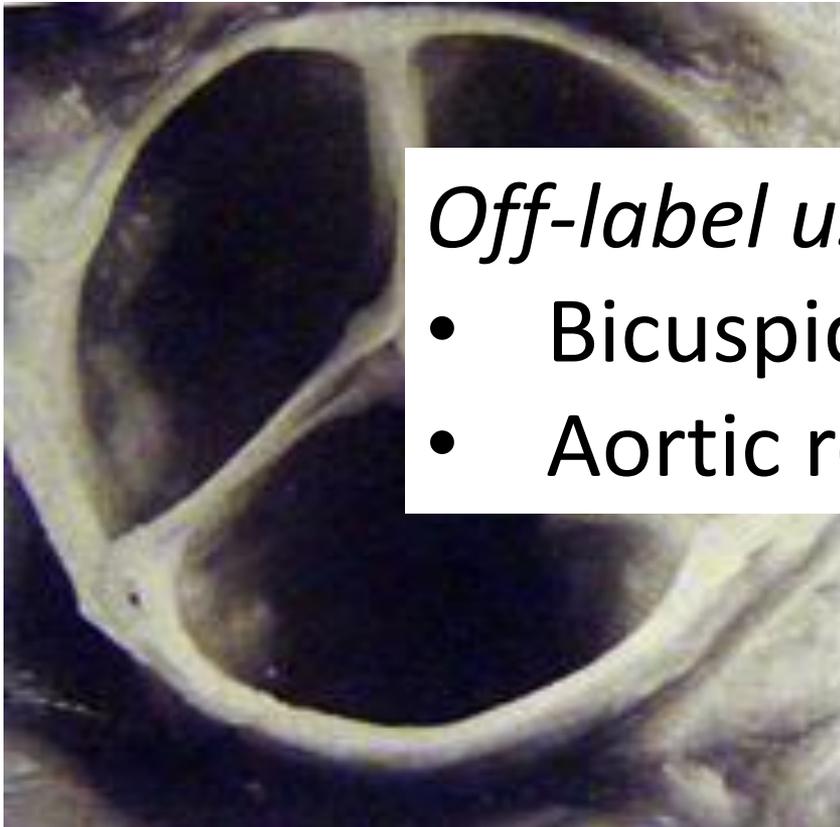
Stenotic aortic valve



# Aortic stenosis

Tricuspid aortic valve

Stenotic aortic valve



*Off-label use:*

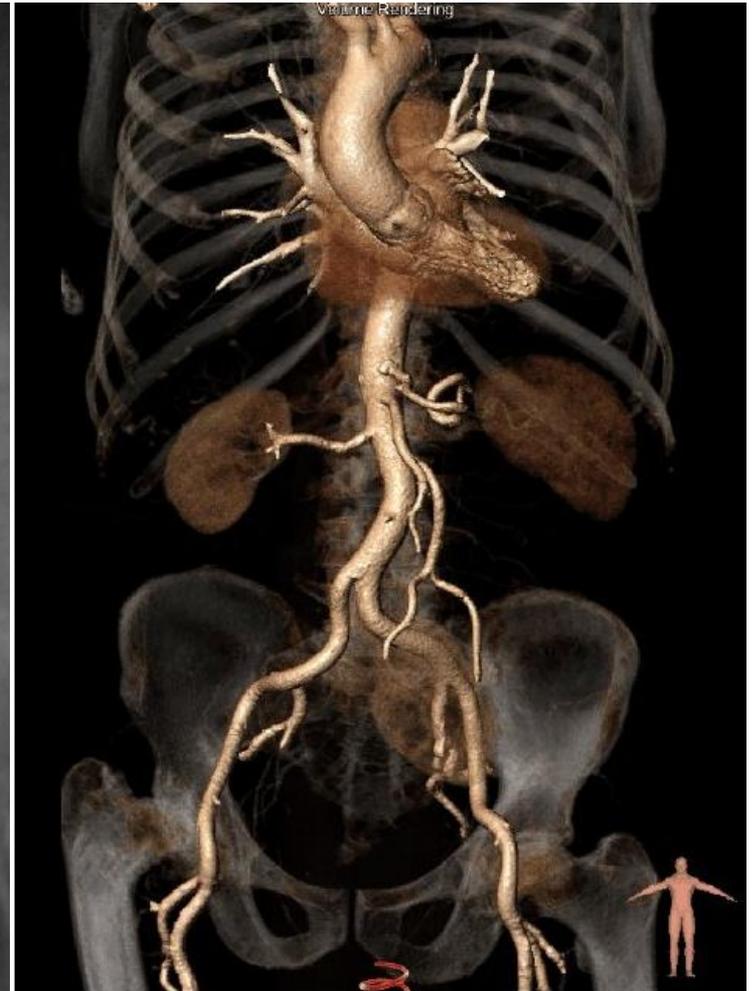
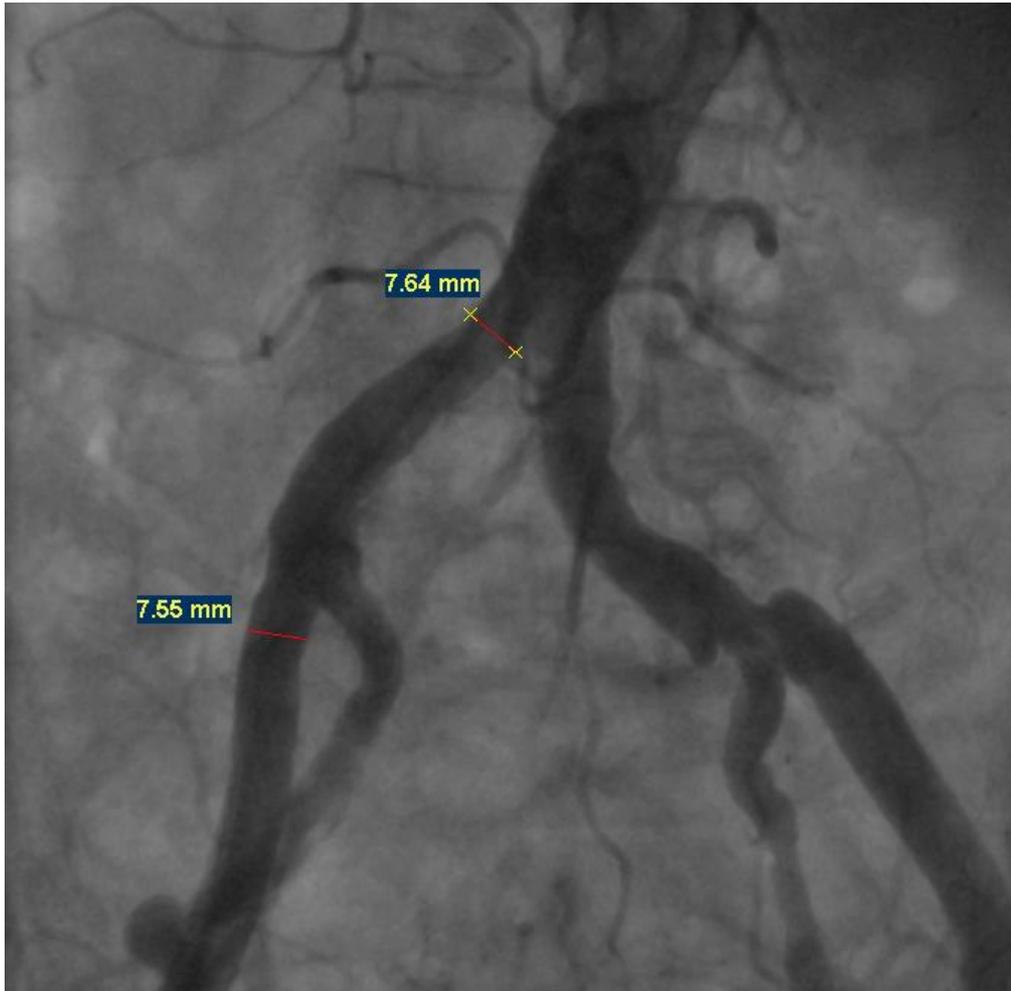
- Bicuspid valve
- Aortic regurgitation

# Relative contraindications

- Bicuspid and non-calcified valves
- Untreated coronary artery disease requiring revascularization
- Hemodynamic instability
- LVEF <20%

Access issues

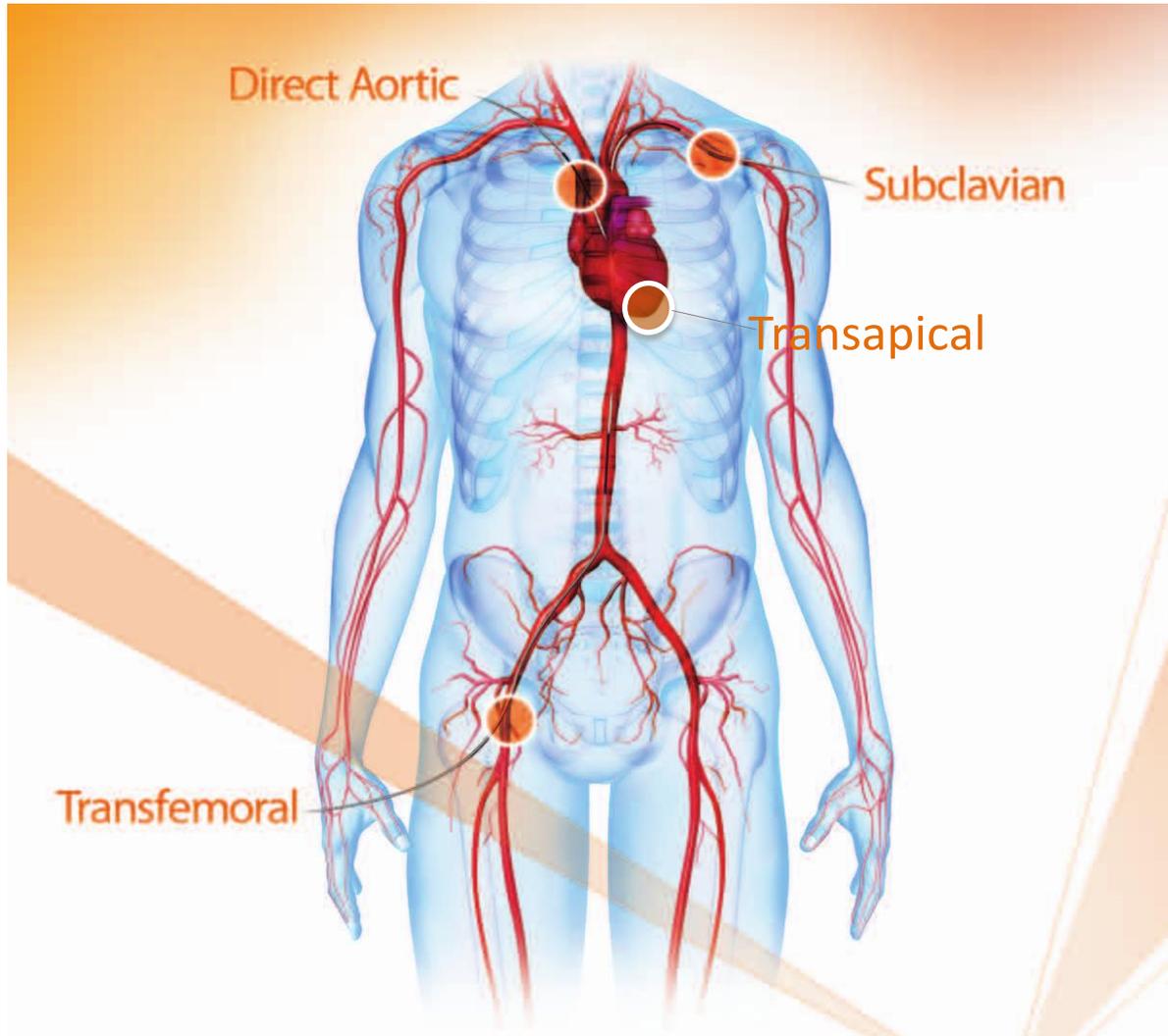
# Vascular access



# Self-expanding covered stents



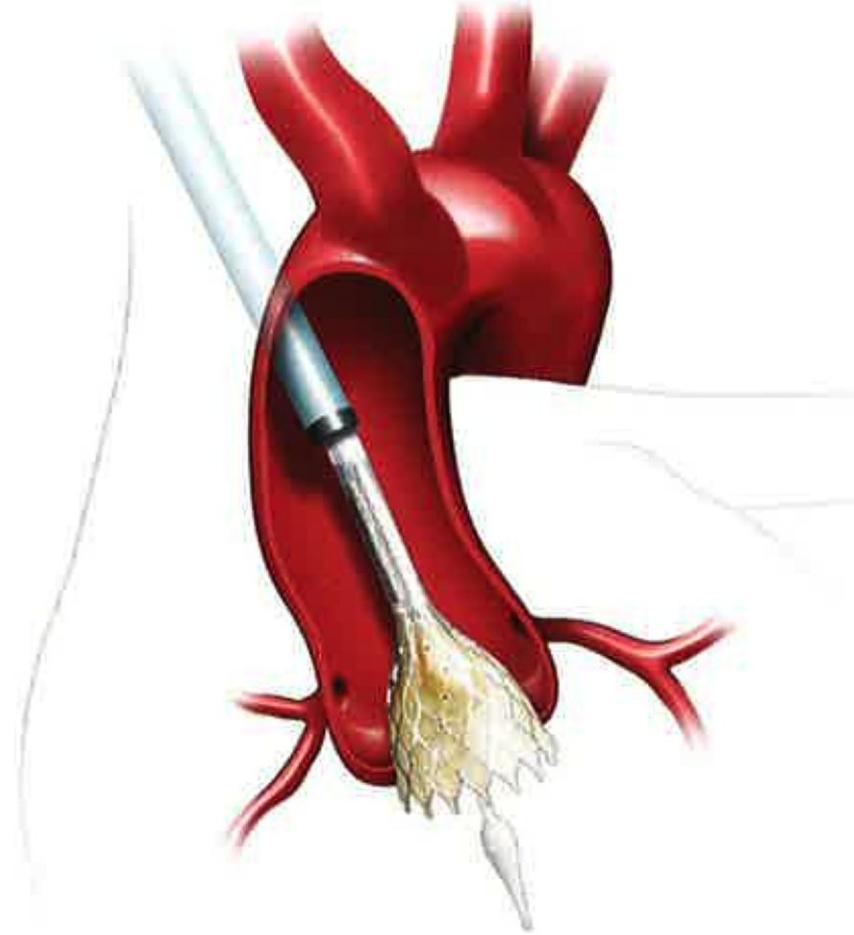
# Different access routes



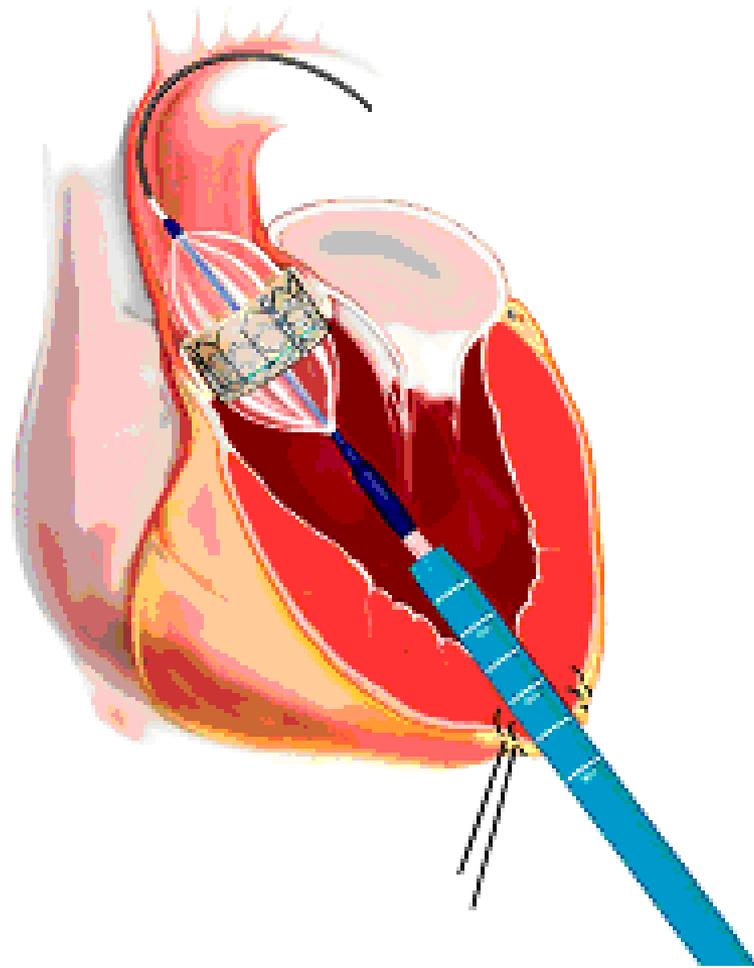
# Subclavian/axillary access



# Direct aortic access



# Transapical access



# Summary

- Patient selection is a *Heart Team* decision
- Anatomical and frailty related considerations
- TAVI is feasible in selected extreme and high risk patients
- Prognostic and symptomatic effects of TAVI
- On-going and future studies will show the role of TAVI in treatment of aortic stenosis