Learning from the Cases of TAVI

IPS 2010

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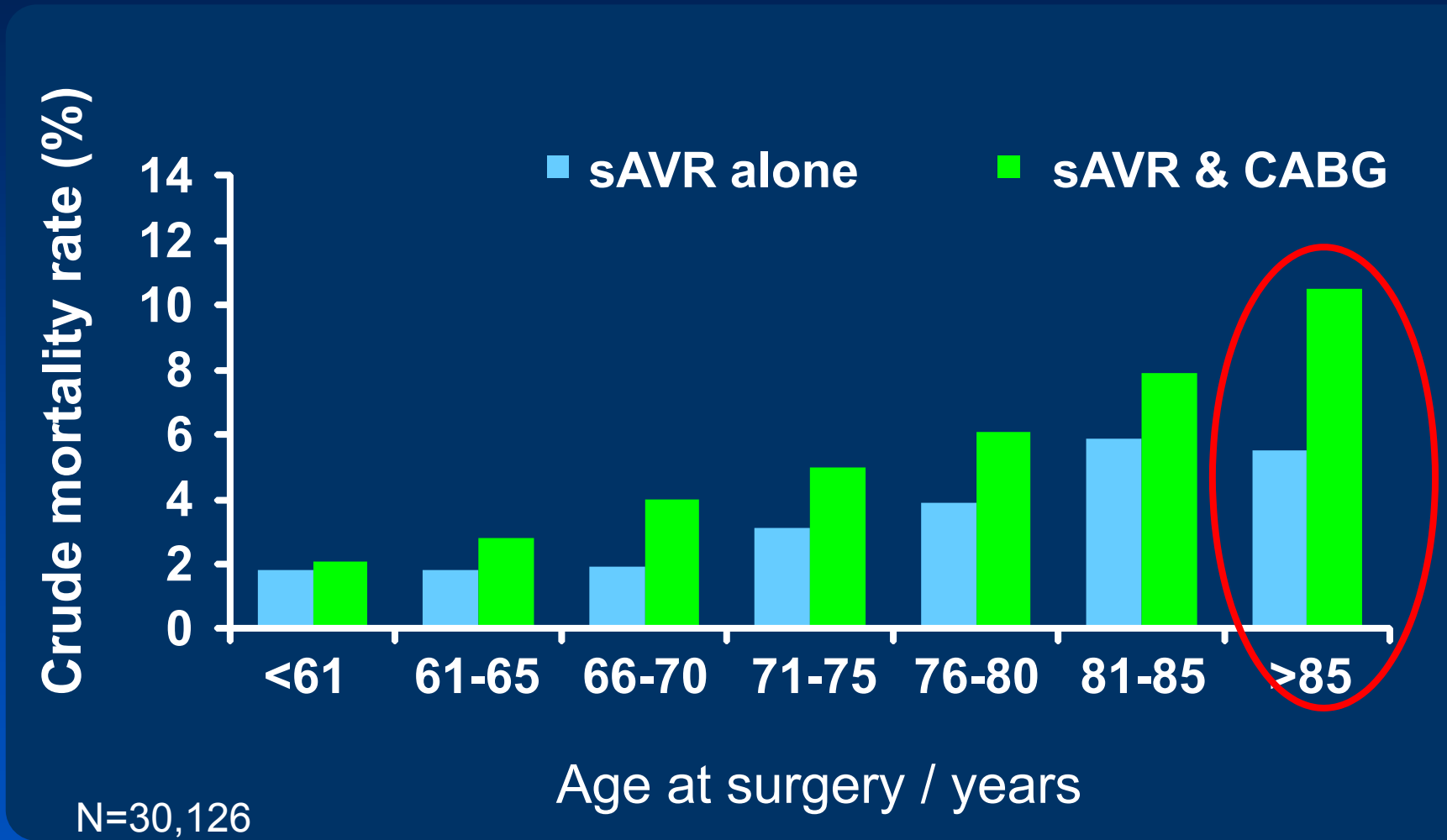
Disclosure Statement of Financial Interest

I, Won-Jang Kim DO NOT have a financial interest/arrangement or affiliation with one or more organizations that could be perceived as a real or apparent conflict of interest in the context of the subject of this presentation.

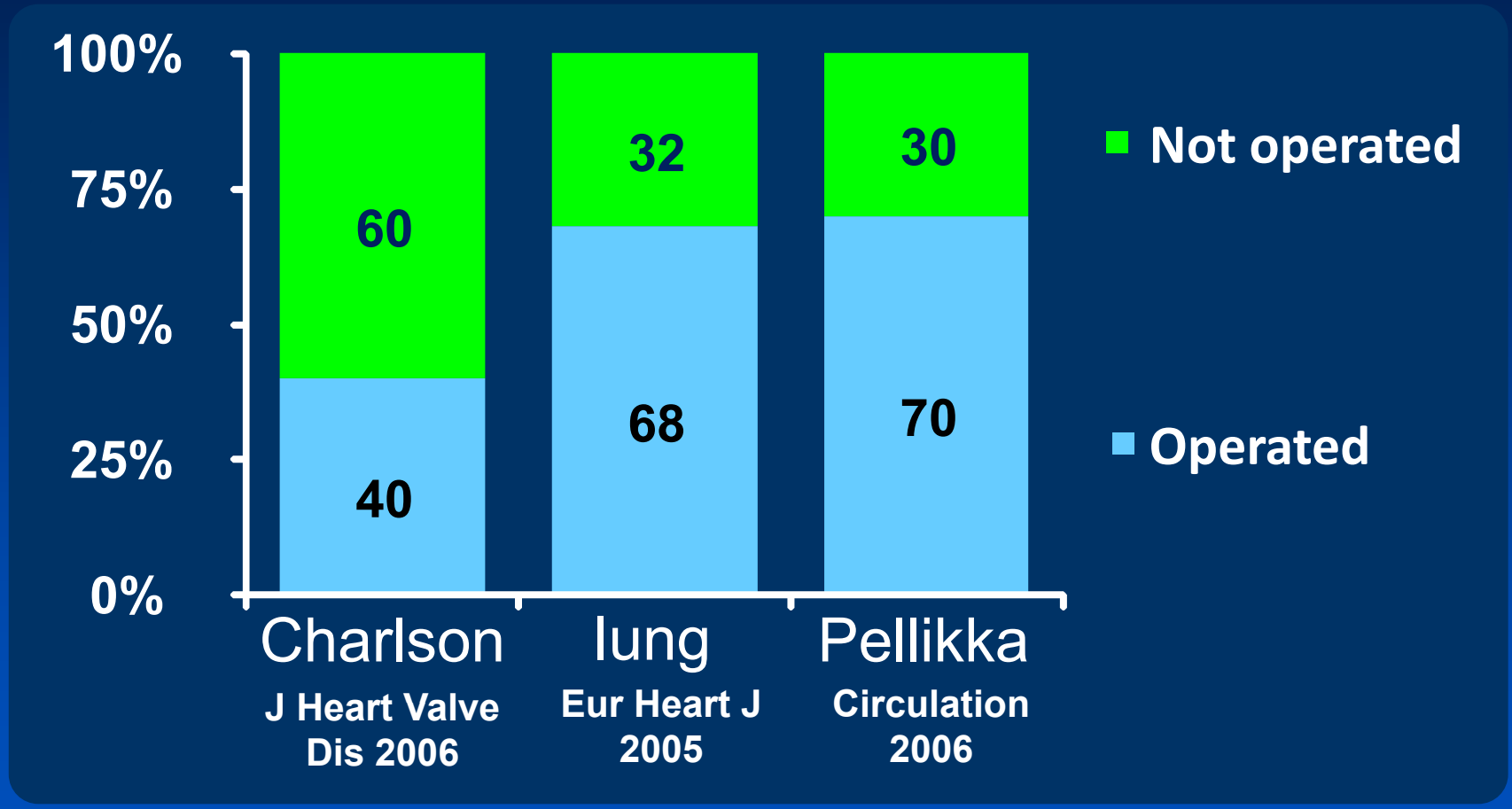
Surgical mortality increases with age



N=30,126

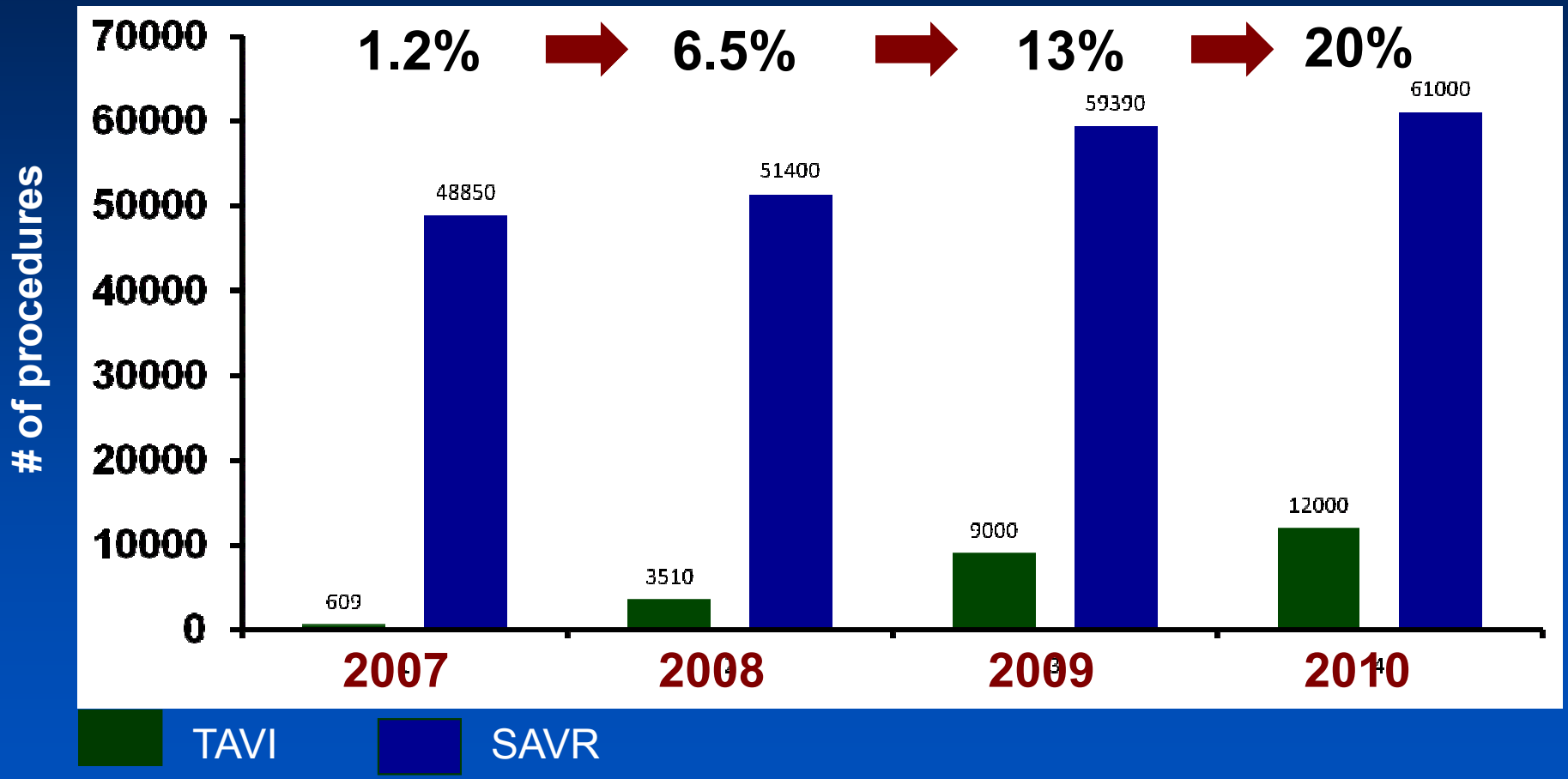
Society of Cardiothoracic Surgery GB&IR.

Many symptomatic patients are not treated

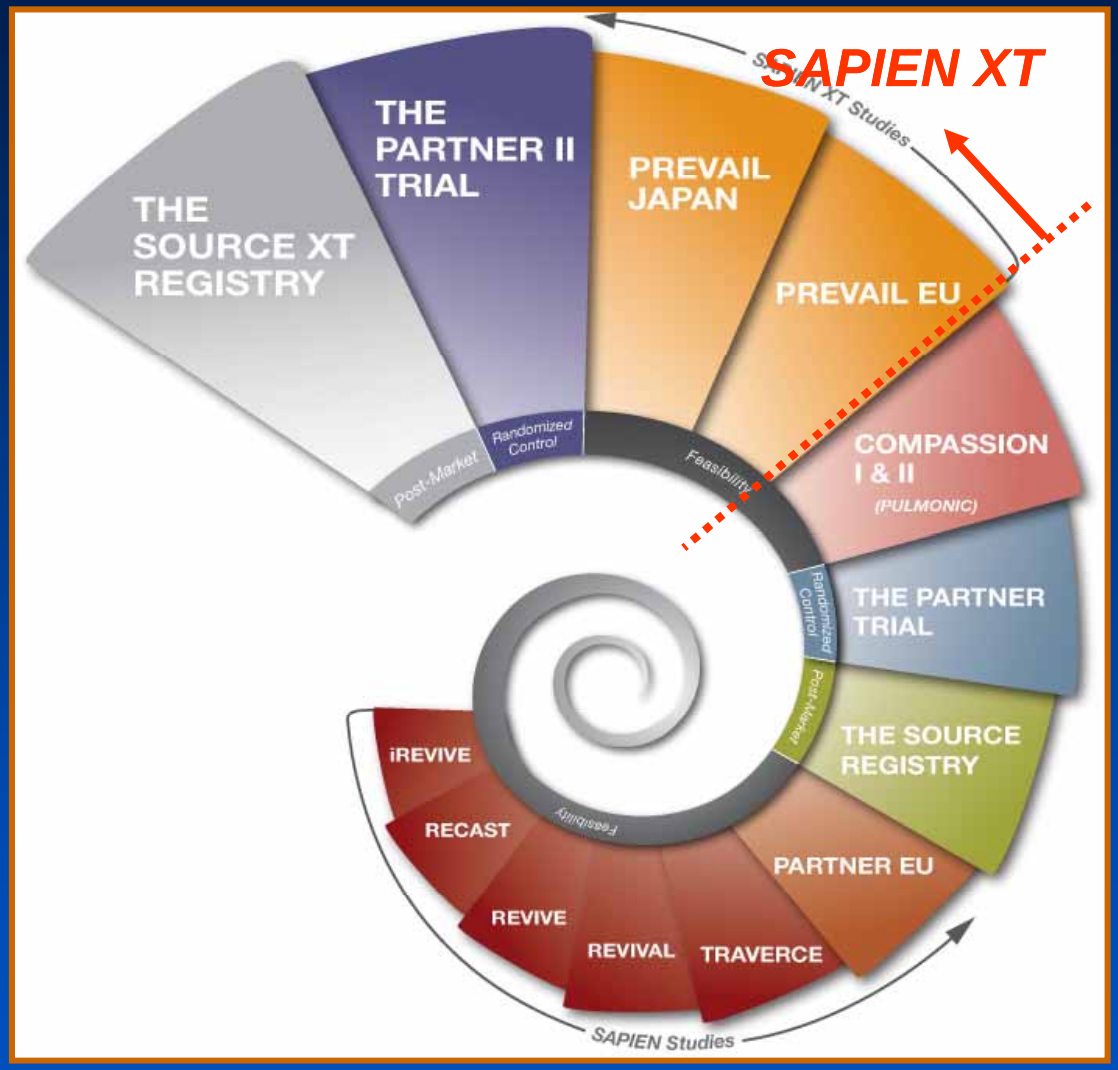


Contemporary rates of Surgical AVR in patients with Aortic Stenosis

Growing TAVI Experience in Europe



Edwards Sapien™ Studies



- *13 clinical programs complete/underway*
- *>4500 patients enrolled*

Current CoreValve Clinical Studies

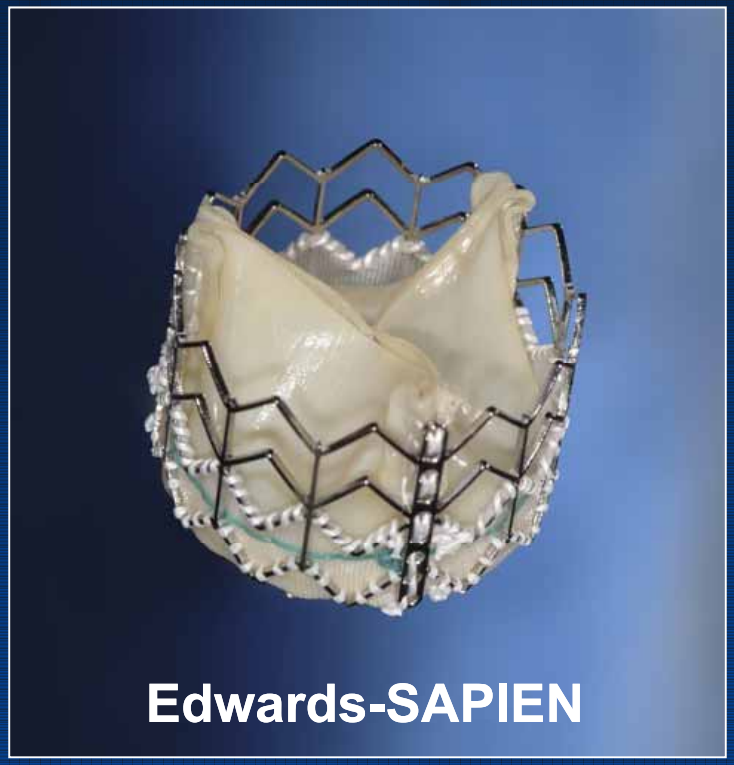
	Study	Site Reported Data	Monitored Data	CEC Adjudicated	Core Lab Analyzed
Medtronic-Sponsored Studies	18 Fr Safety and Efficacy Trial		√	√	√
	Australia-New Zealand Study		√	√	In progress
	Advance Study		√	√	√
Independent Studies	Italian Registry[1]	√	In progress	In progress	
	Belgian Registry[1]	√			
	Spanish Registry[2]	√			
	French Registry[1]	√			
	UK Registry[1]	√			
	German Registry[1]	√			

√ - Incorporated in trial

[1] TAVI Facts, Figures and National Registries. EuroPCR 2010
[2] Avanzas P, et al; *Rev Esp Cardiol*. 2010;63:141-148

According to this facts, the first case of TAVI in Korea was implanted at AMC

Available Devices in Korea



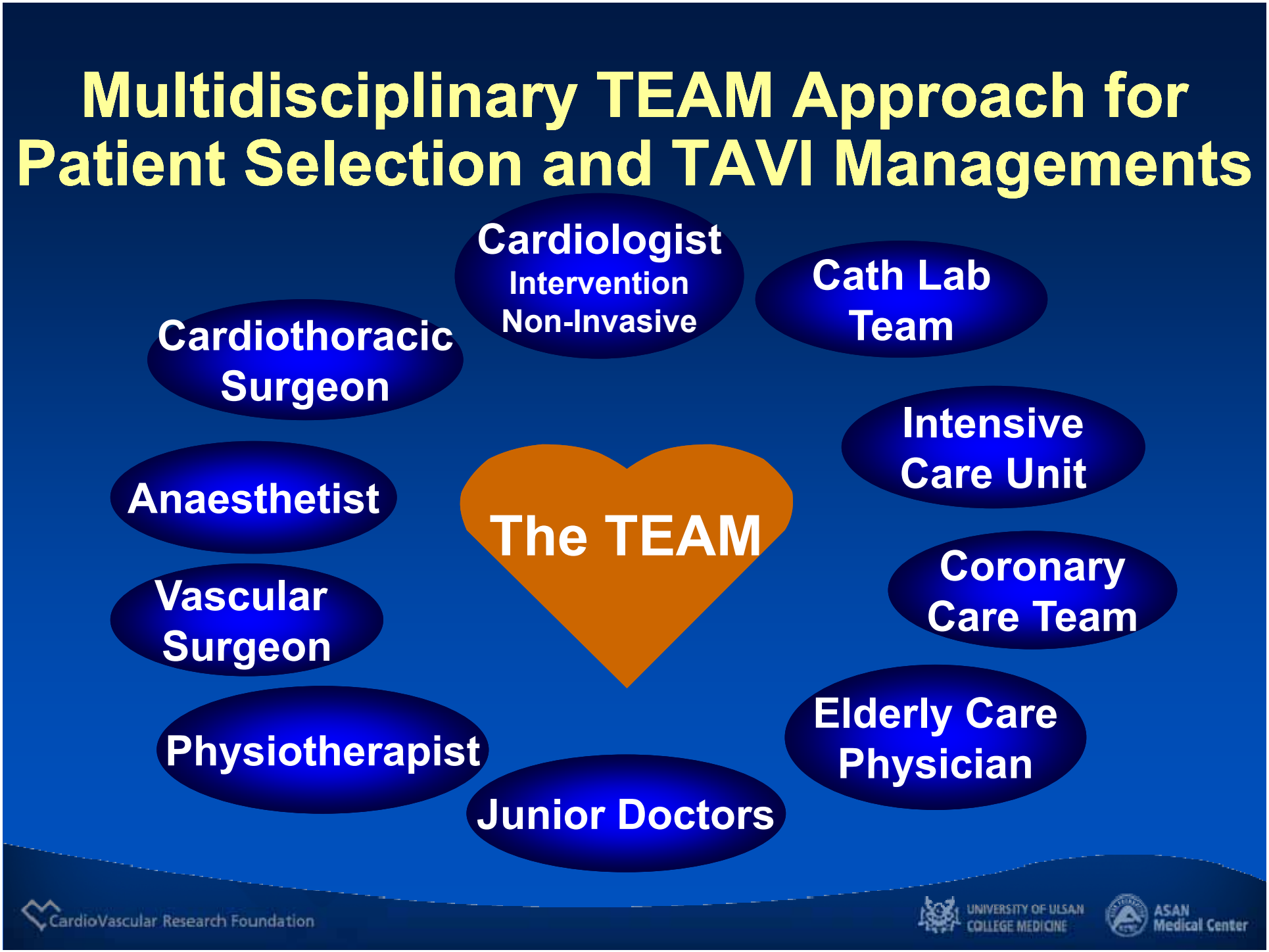
Edwards-SAPIEN

23mm and 26mm valve sizes

Retroflex 1

22F and 24F sheath sizes

Multidisciplinary TEAM Approach for Patient Selection and TAVI Managements



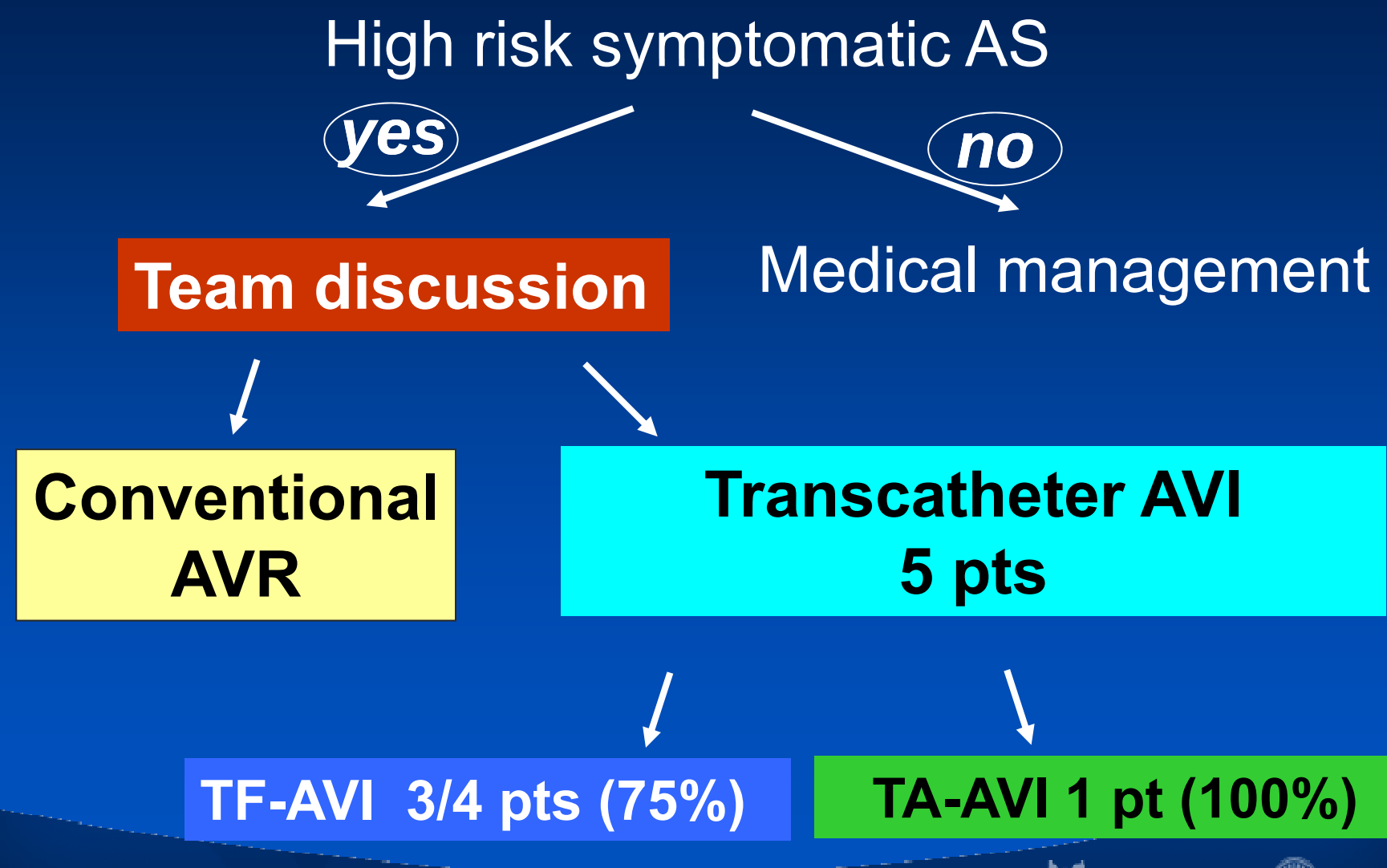
Key Components for a Successful TAVI Program

- The TEAM: multiple stockholders
- The patient : adequate clinical, anatomic indication
- The location / site
- The procedure (Pre, Peri and Post) management
- Follow-up

Current Accepted Indication for TAVI

- Symptomatic patient with severe AV disease:
  - Surgically not suitable
  - High risk for surgery
  - Elderly
  - Frail
  - Technically challenging for conventional AVR

High risk AV disease in AMC, *Mar 2010 -*



Etiology of Unsuccessful TAVI in AMC cases

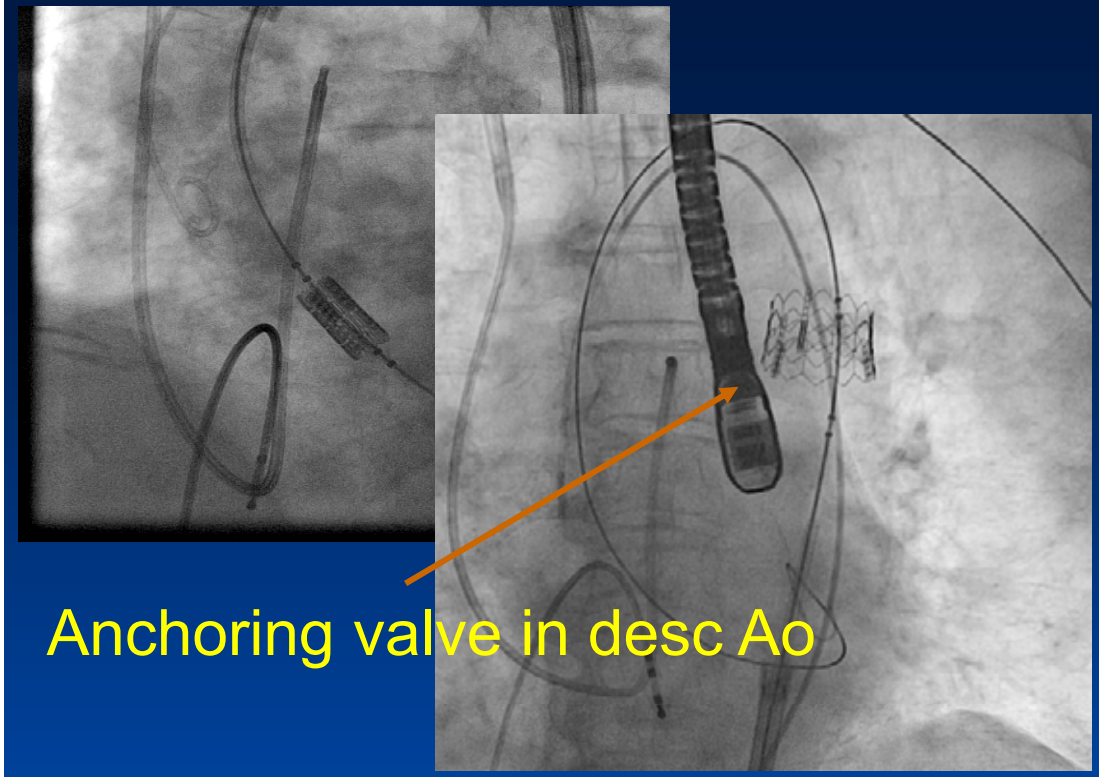
- Early termination of rapid pacing after balloon deflation
- Difficulty in crossing the valve with wire
- Difficulty in crossing the valve with TAVI
- Vascular complication after implantation

Lessions from the First Case

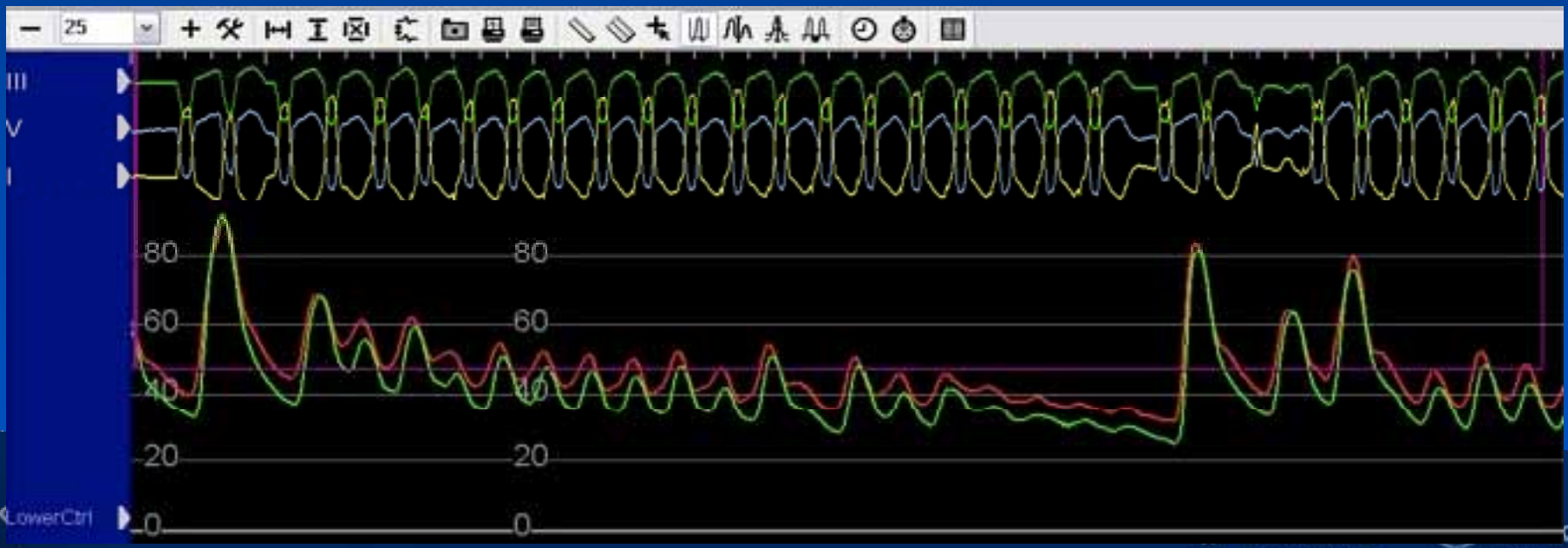
In the First Experience with TAVI

Valve Positioning Events

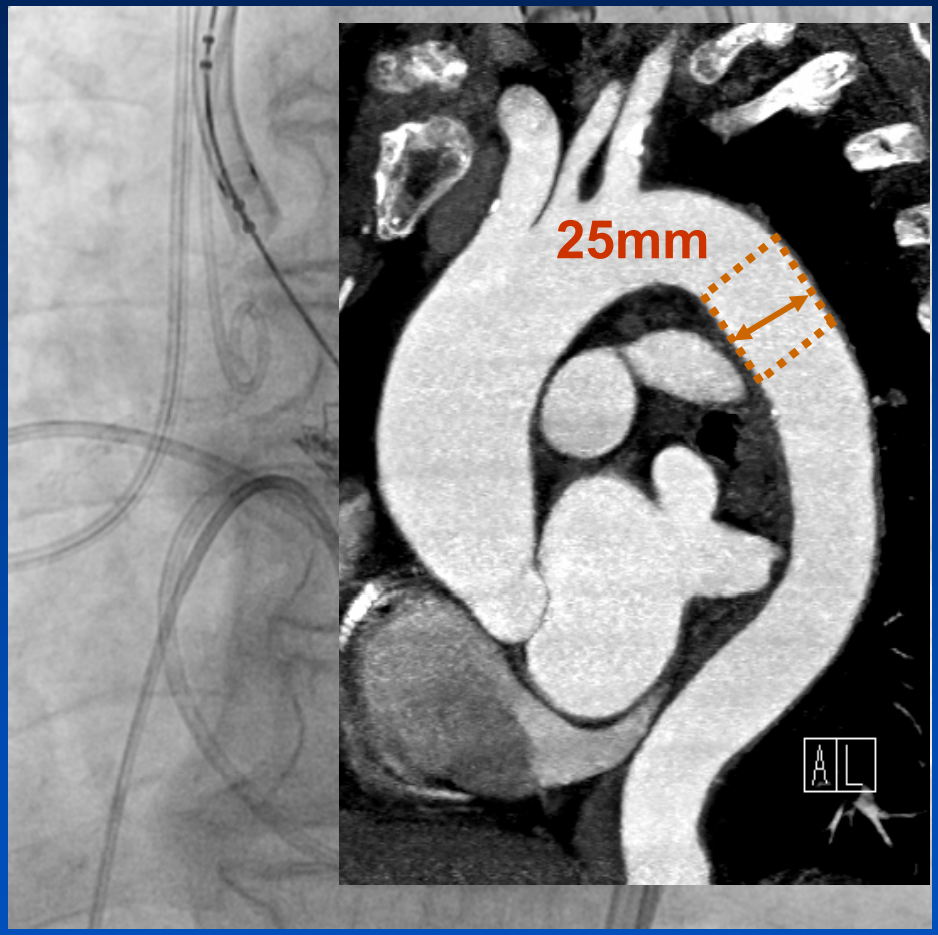
In the Early Experience with TAVI



- Valve migrated cranial during deployment
- During valve deployment there was loss of pacemaker capture
- This resulted in LV contraction ejecting the valve



Aortogram after Reimplanted TAVI



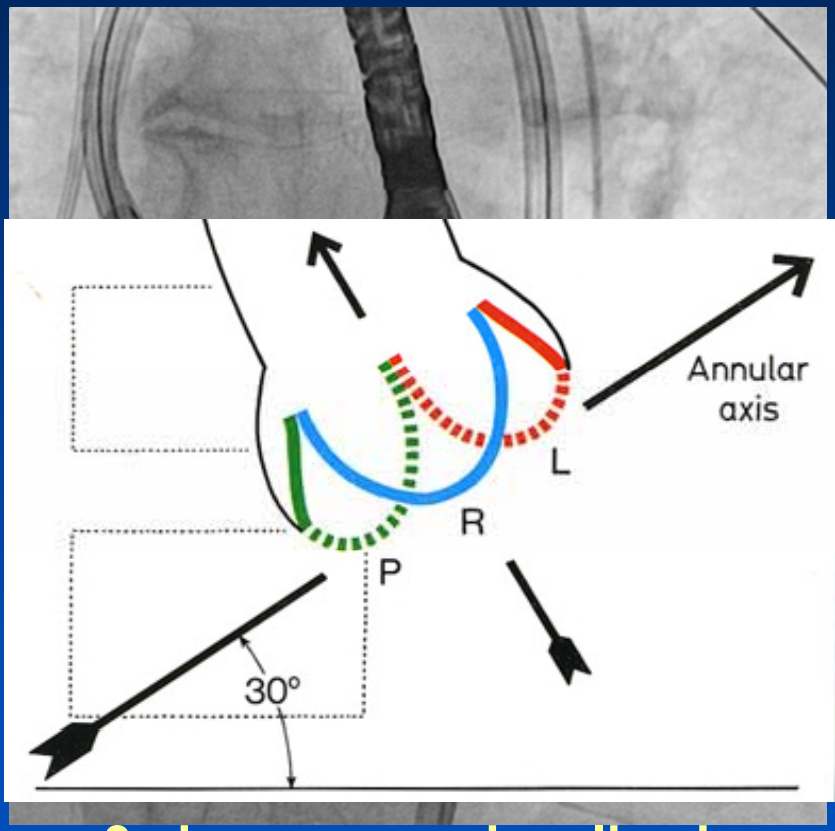
- The coaxial wire position was maintained to prevent the valve from flipping over to obstruct anterograde flow
- After valve was anchored in the desc Ao
- Additional TAVI could be successfully reimplanted

Valve Embolization

Possible Causes and Lessons

- Valve positioned too high
- Valve not inflated fully immediately : 3-5 seconds
- Pacing stopped prematurely : stop pacing after complete deflation
- Too aggressive pre-dilation & possible undersizing of valve (annulus too large)
- Valve positioned too ventricular
- Lack of significant calcification for TAVI anchoring
- If Balloon bursts or leaks during deployment before TAVI is fully expanded

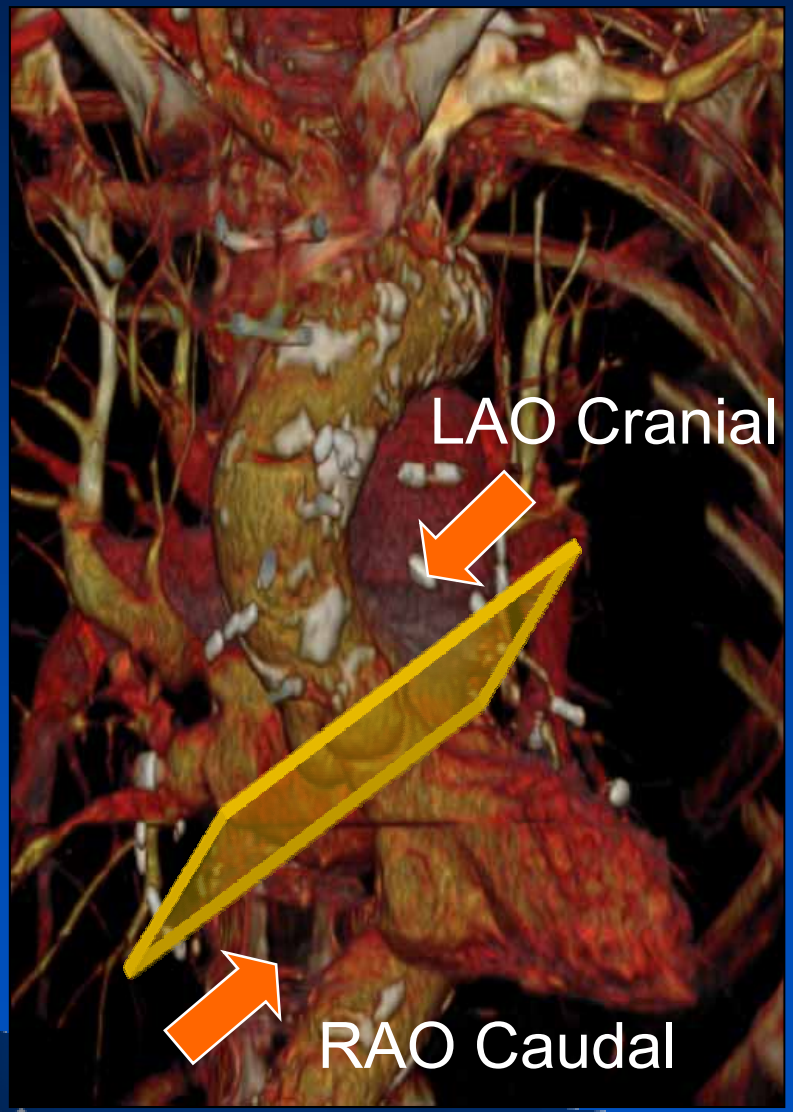
Positioning of the Valve

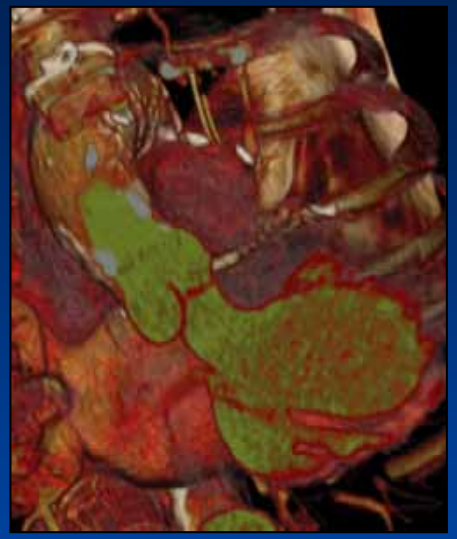


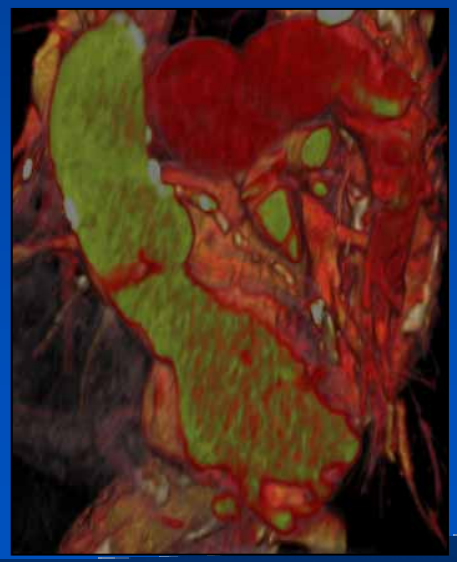
3 sinuses are visualized
on 1 single line - perpendicularity
Slightly LAO cranial or caudal

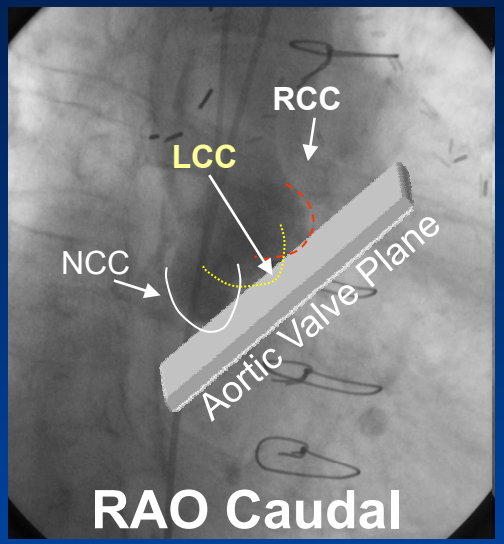
- Pull flexcath back
- Confirm x-ray angles are correct
- Use calcified landmarks
- Small injections via pigtail
- TAVI mid-portion at annulus (50%/50%)
- Confirm in predetermined views
- If needed, dry run w/ pacing
- TEE may help as adjunctive imaging
- Keep an eye on hemodynamics

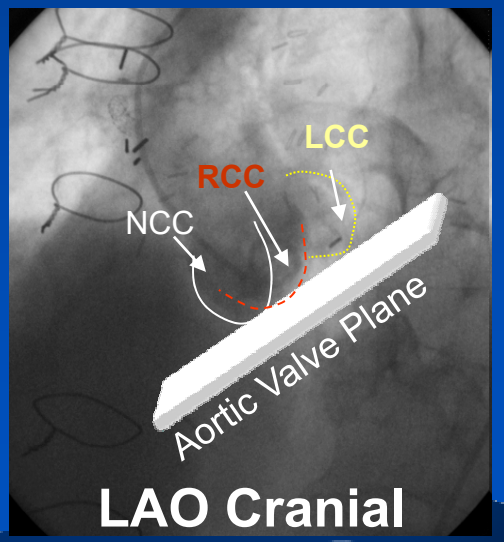
Aortic Valve Plane by CT Scan





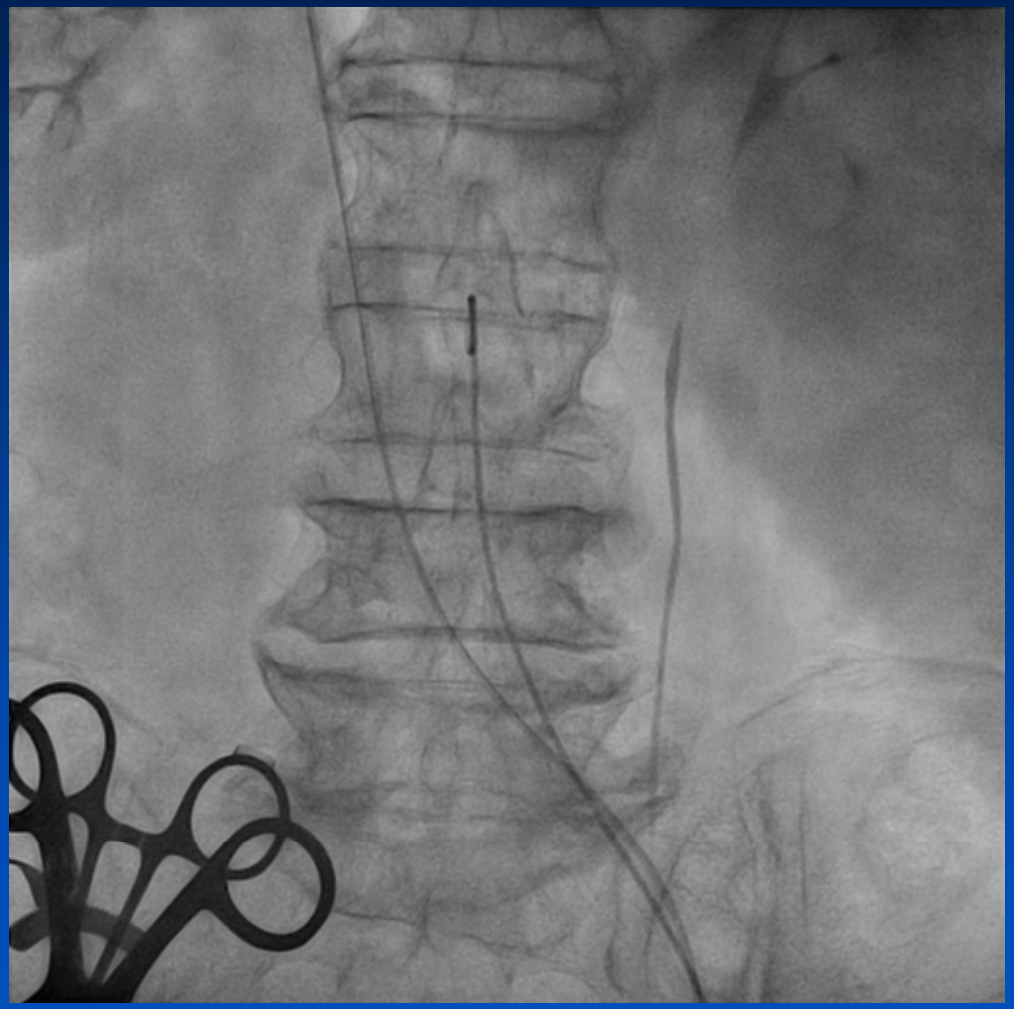






Vascular Complications

Iliac Perforation

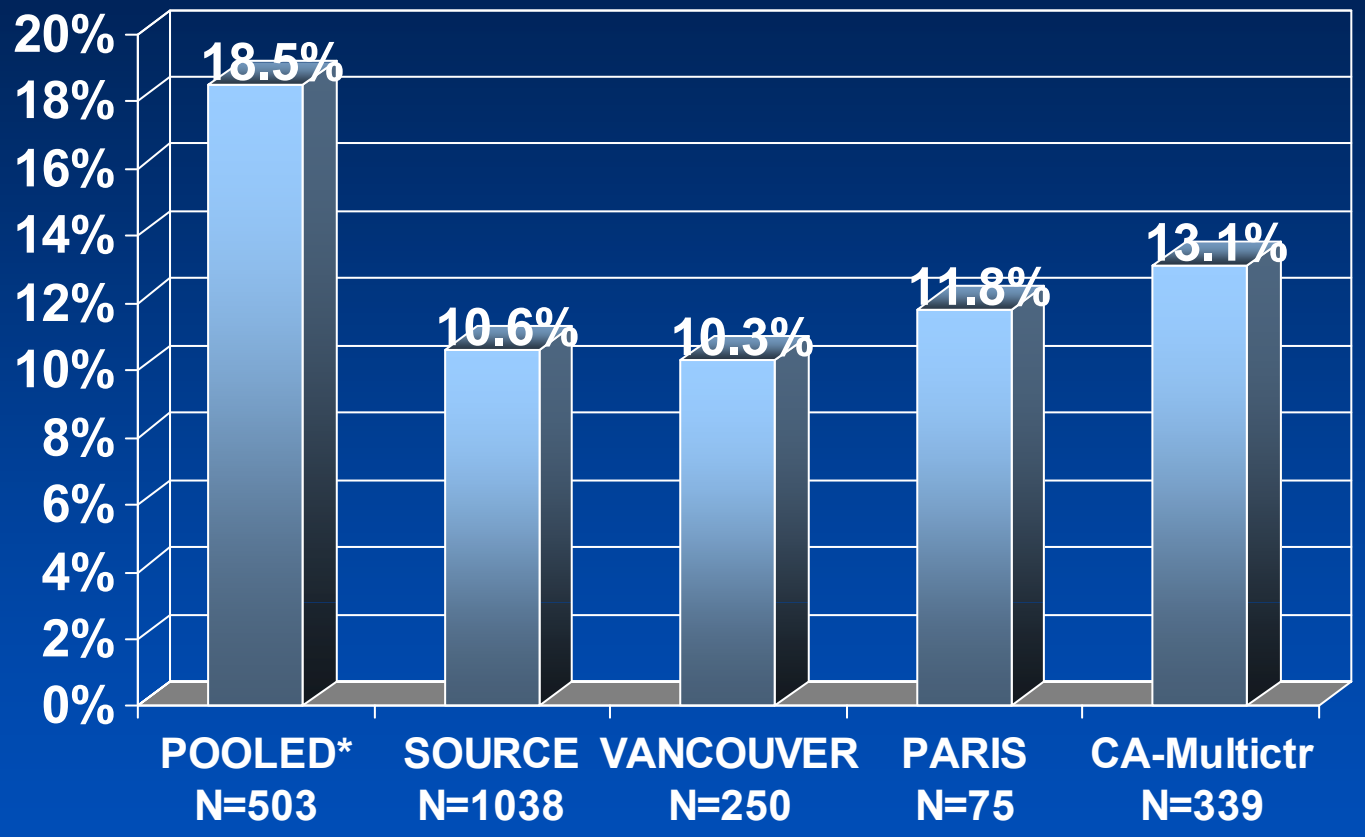


➡ ***Balloon occlusion, emergent surgical repair***

Vascular Complications
Potential risk factors

- Patient related
  - Calcification
  - Tortuosity
  - Vessel Calibre
  - Vessel stenosis
  - Plaque
- Device related
  - TAVI system
  - Sheath
  - Guide wires
  - Balloon
  - Closure device
- Technique/operator related
  - Aggressive manipulation
  - Inaccurate calibration and measurements
  - Poor control

Vascular Complications – Edward Sapien TF



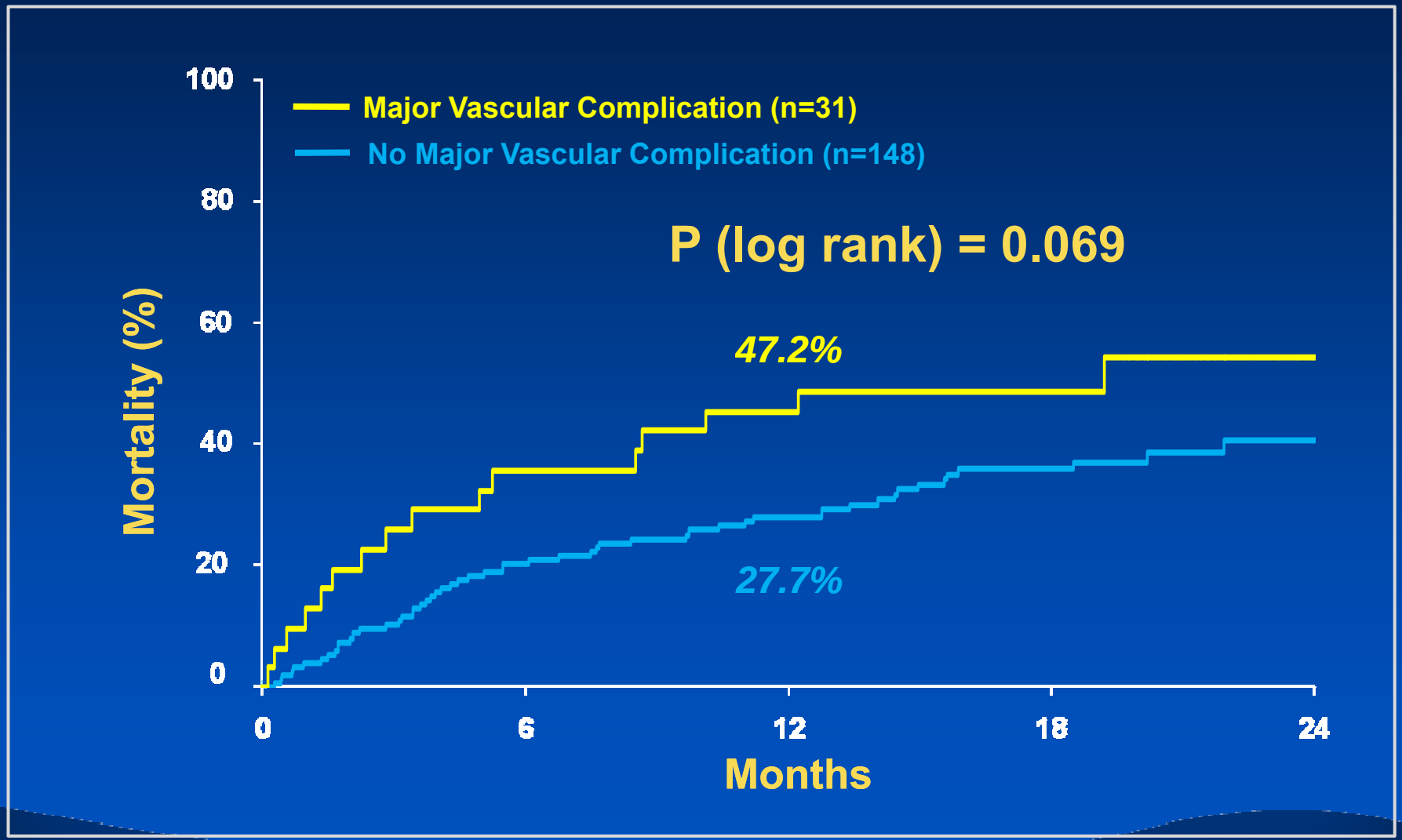
Major vascular complications only, TF only

* *REVIVE, REVIVAL, TRAVERCE, PARTNER EU*

Source: Marty Leon, Clinical Results from the Worldwide EDW Sapien Experience, TVT2010

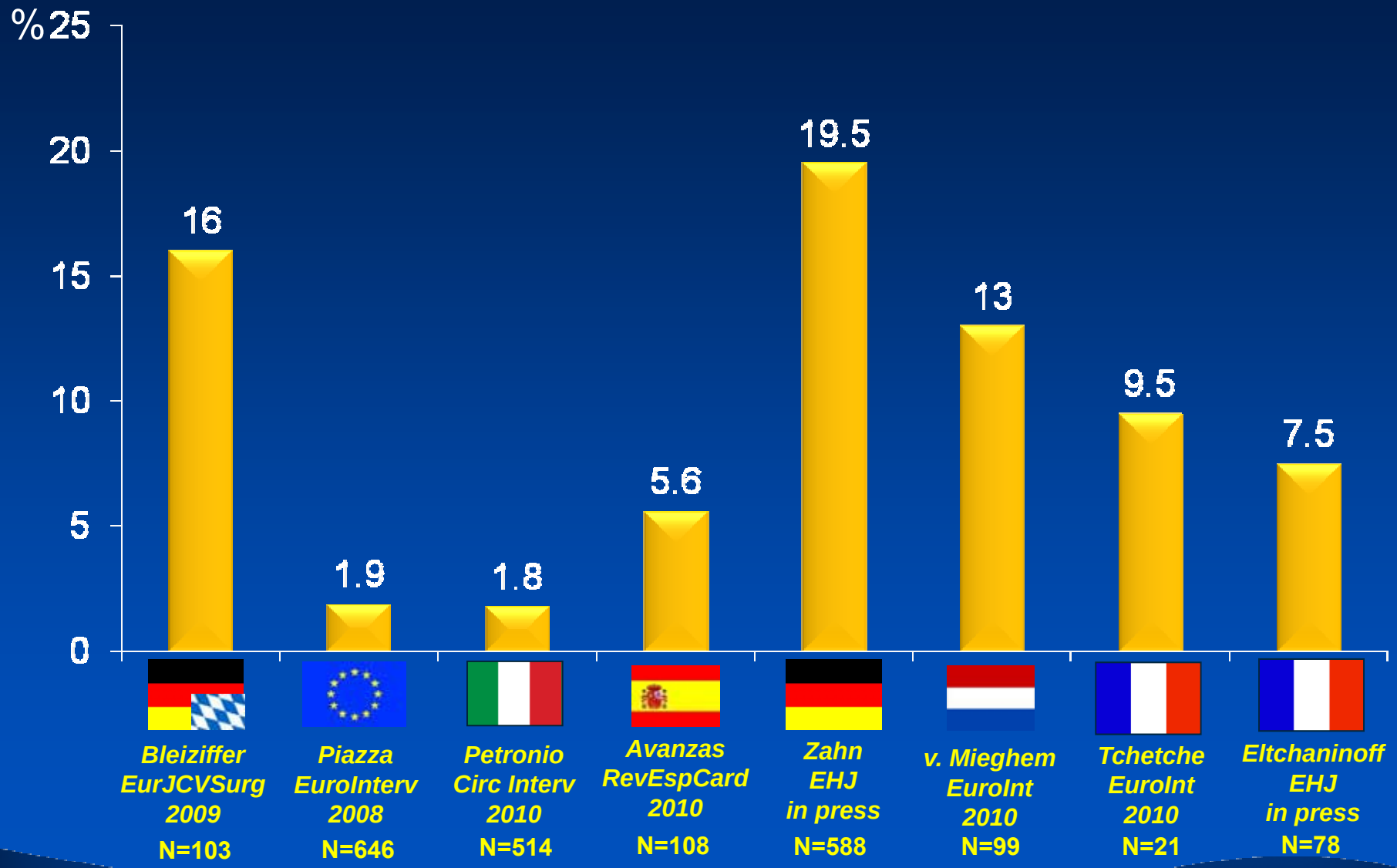
Mortality vs. Major Vasc Complications

TAVI patients- PARTNER trial



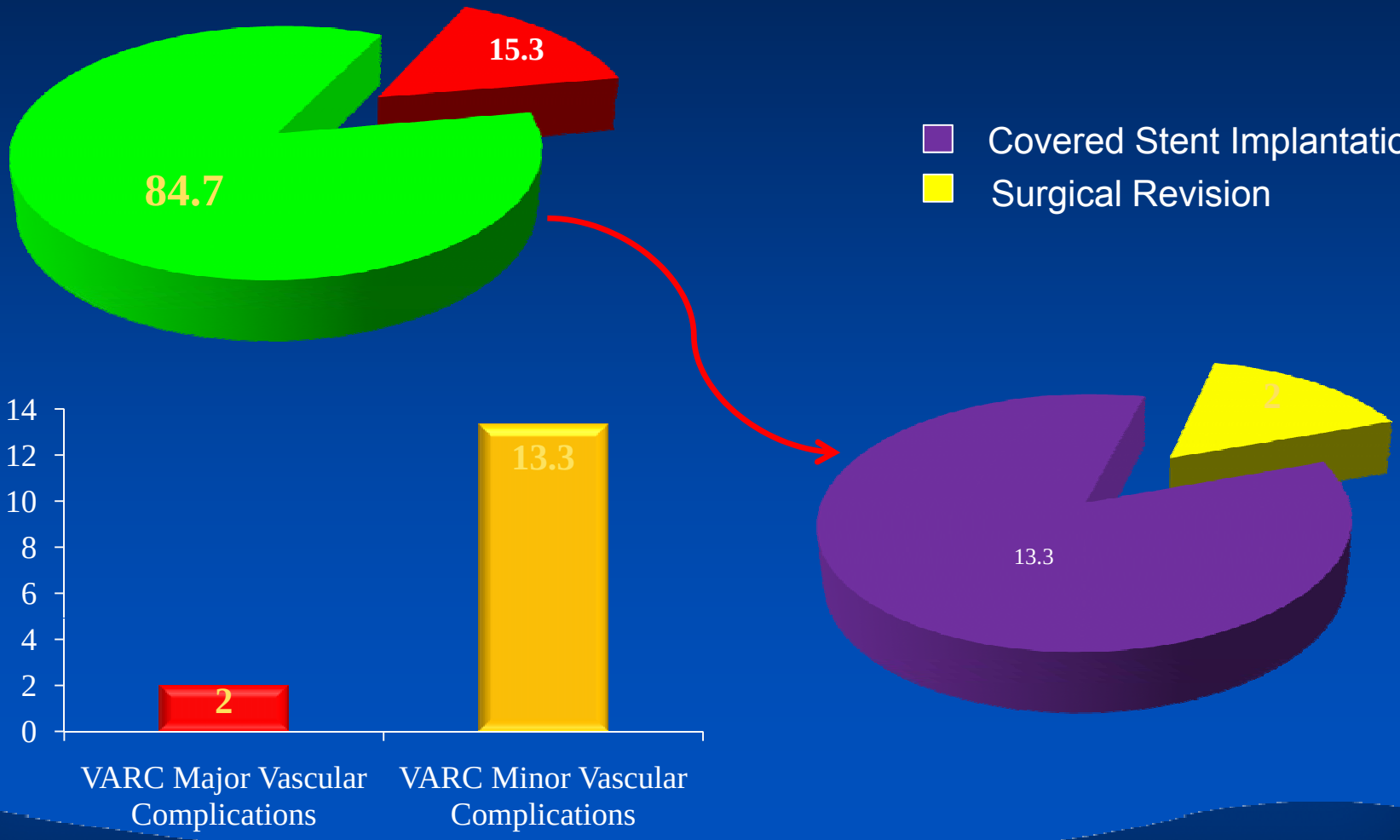
Leon MB et al. NEJM 2010;363:1597-1607

Vascular Complications - CoreValve



Vascular Complications - CoreValve

The Bern Experience (August 2007 – July 2010) – N=150



Vascular Complications

Lessons

- Vascular complications impacts on acute and late outcome during TAVI
  - attention to detail paramount
- Prompt recognition and diagnosis will save lives
- Ensure all back-up equipment is available in the room

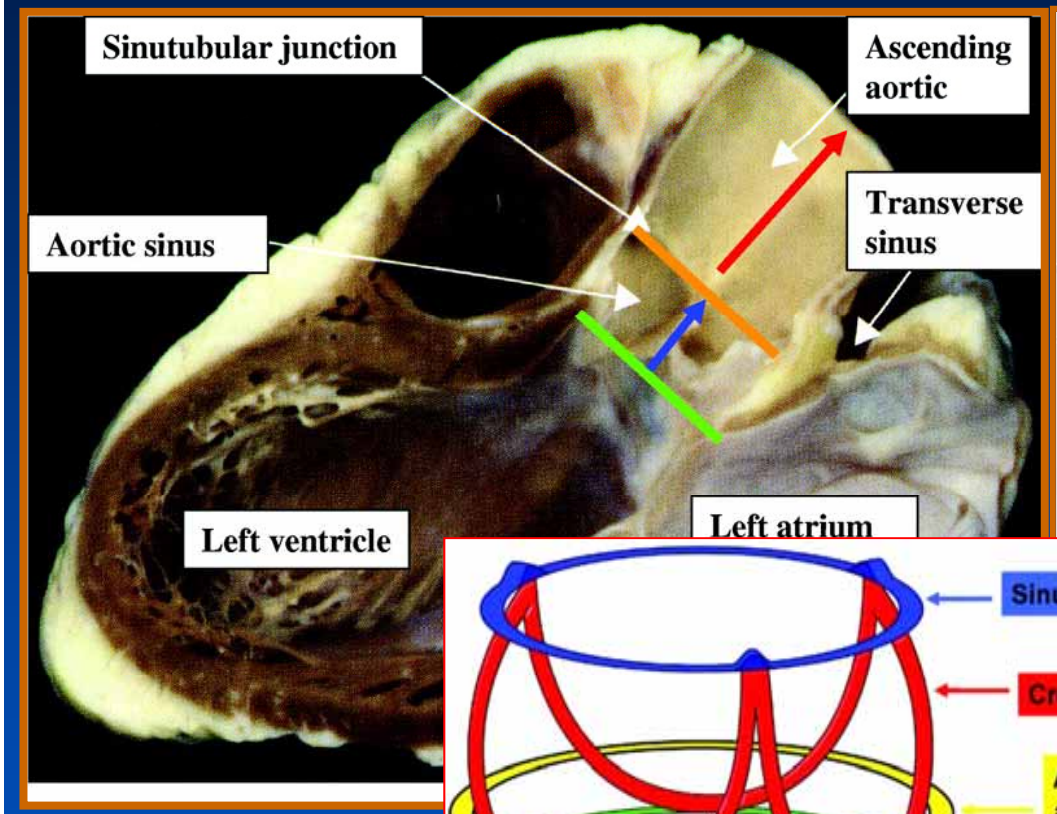
Lessions from the 5th Cases

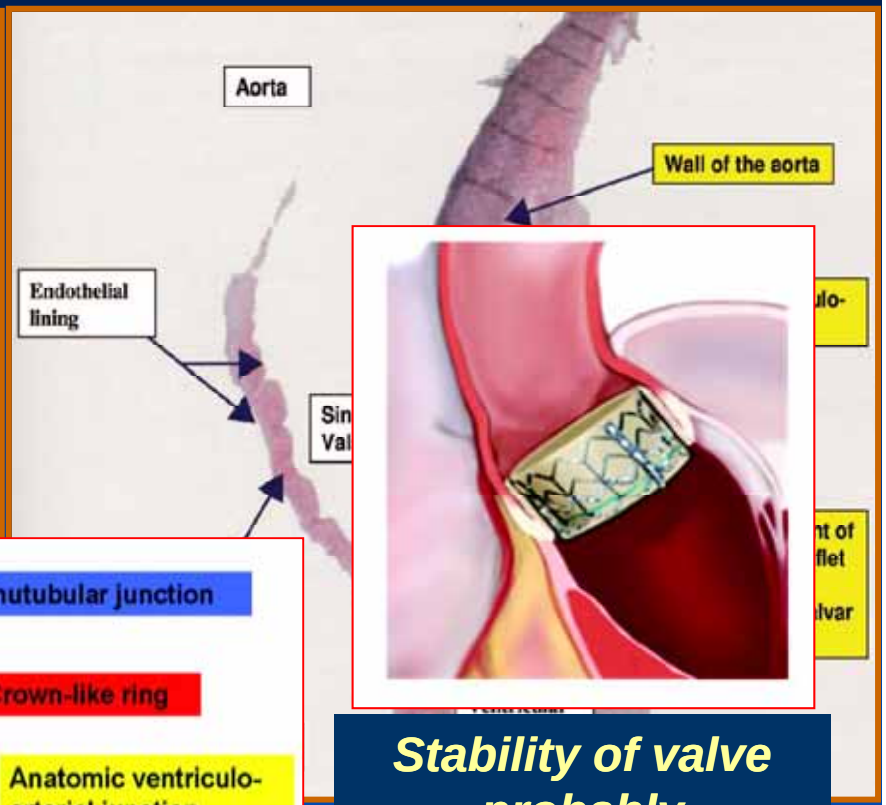
AV annulus sizing

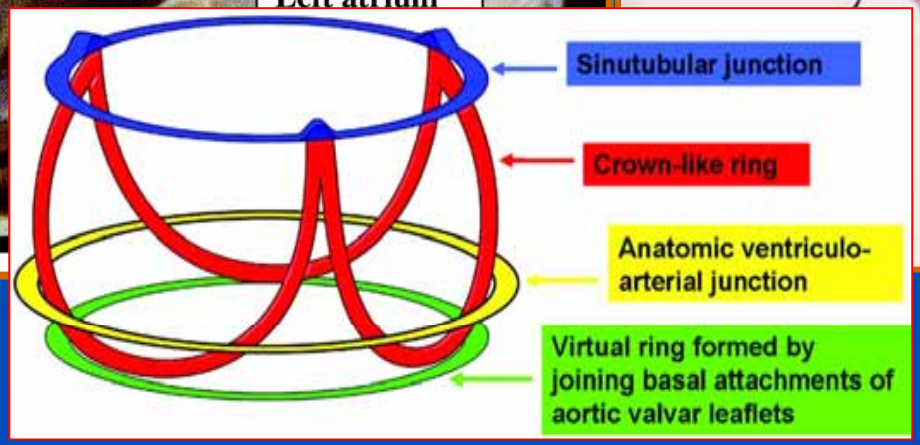
Aortic Annular Sizing

TTE vs TEE vs CT vs MRI

Anatomy of Aortic Valvar Complex







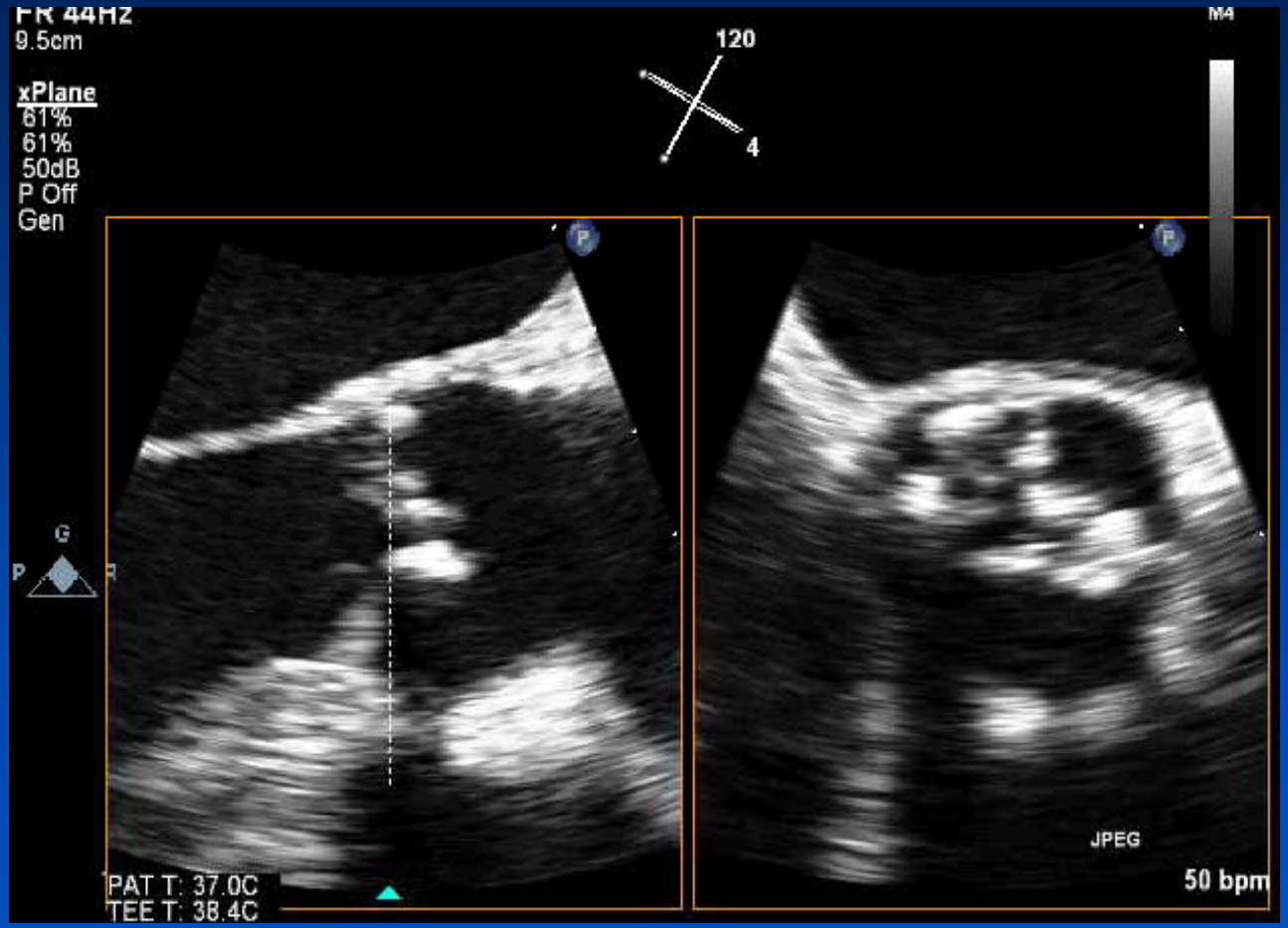
Stability of valve probably determined by the "virtual ring"

Aortic Root thus composed of 3 rings and one crown-like ring

Piazza, N. et al. Circ Cardiovasc Intervent 2008;1:74–81

Annular Dimensions: Biplane TEE

Use of biplane imaging to align the annulus



Parasternal long-axis view

Short-axis view at Valsalva

Aortic Valve Annular Dimensions: CT Measurement

Aortic Root Evaluated in 3 Planes or More

Coronal view

Sagittal view
= Parasternal long-axis view

Double oblique view at annular level

Oval shape : Sagittal < Coronal diameter

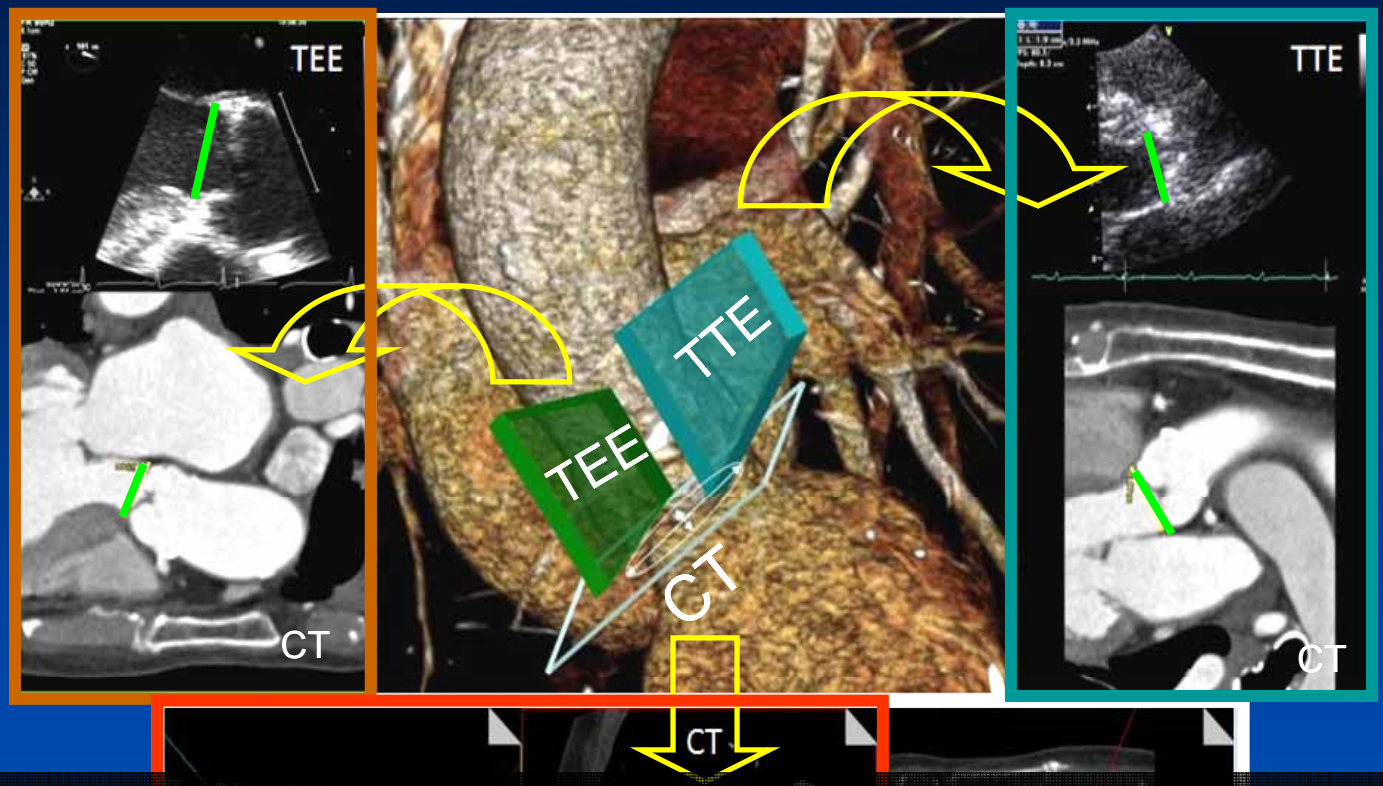
CardioVascular Research Foundation

COLLEGE MEDICINE

ASAN Medical Center

Multiple measures from multiple modes

Which one is “right”?

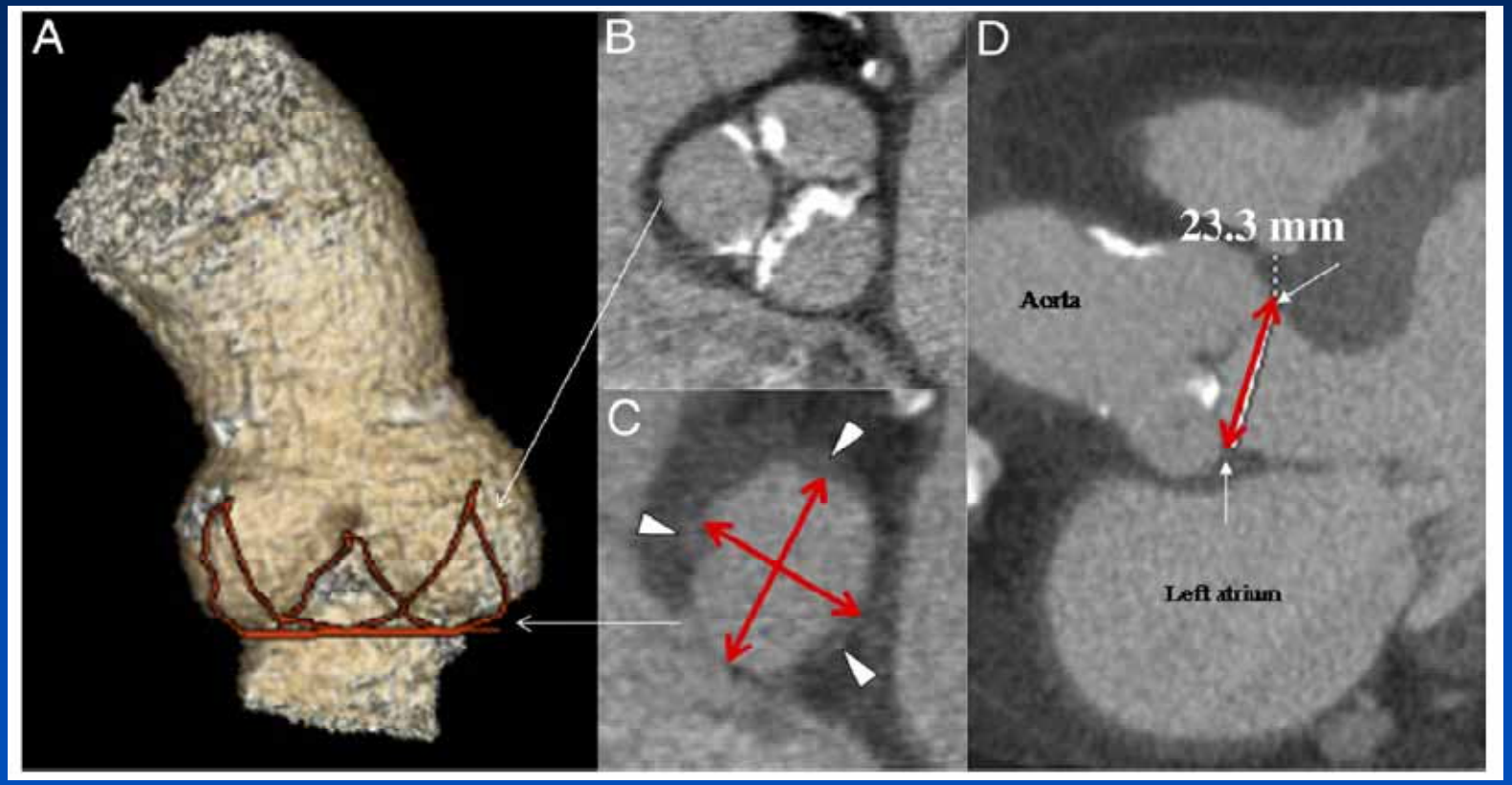


CT coronal & double oblique views cannot be assessed on echo

- Valve size should be based on the largest diameter of the AV annulus

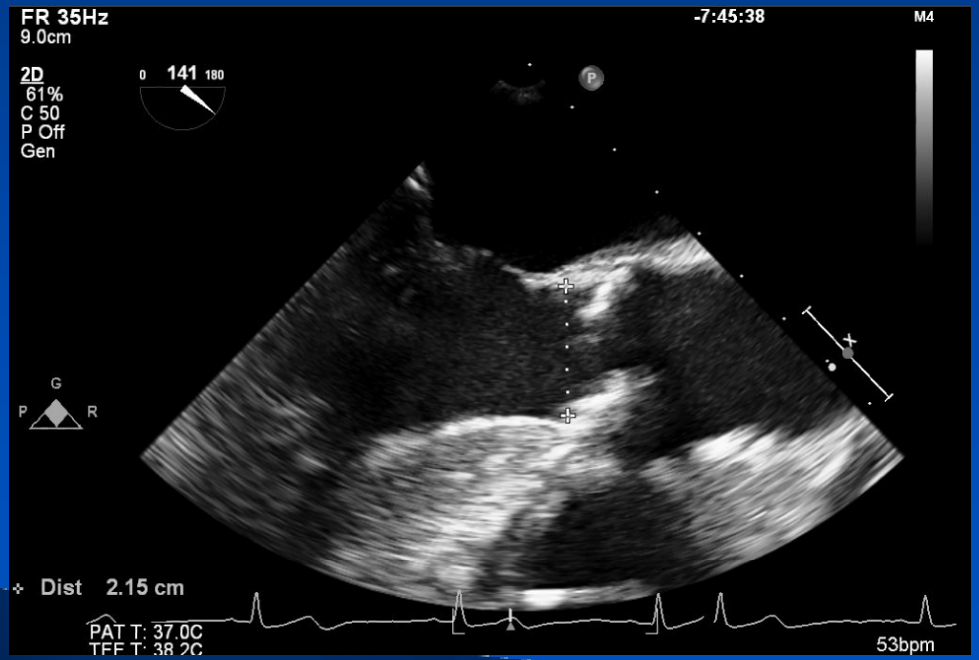
Tuzcu et al, JACC, *2010* Topol L, et al. JACC imaging. *2008* Doddamani S, et al. Int J Cardiovasc imaging. *2009*

Multimodality assessment of aortic annulus diameter



Messika-Zeitoun D et al. JACC 2010;55:186-94

Echocardiogram



Annulus: 22 mm

Vmax: 4.7 m/sec

Max gradient: 76 mmHg

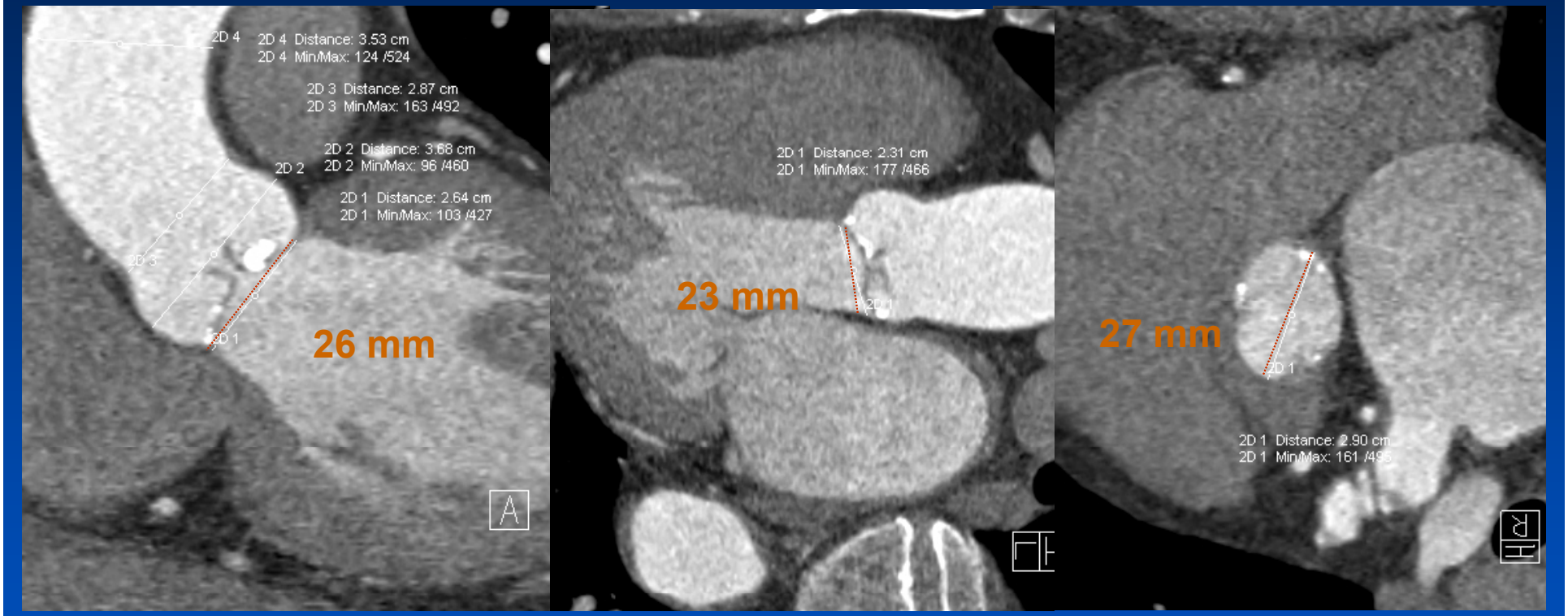
Mean gradient: 46 mmHg

Aortic valve area: 0.7 cm^2

EF: 55%

TR Vmax: 21 mmHg

AV Annular Size by CT

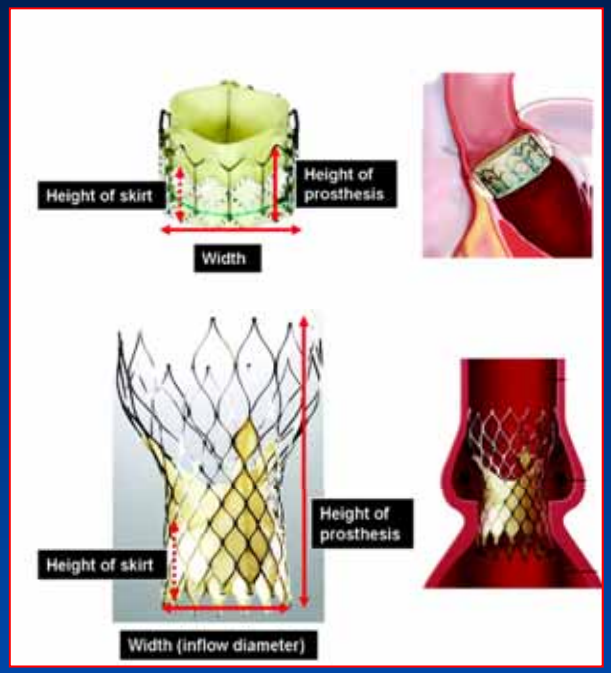


Coronal view

Sagittal view
= Parasternal long-axis view

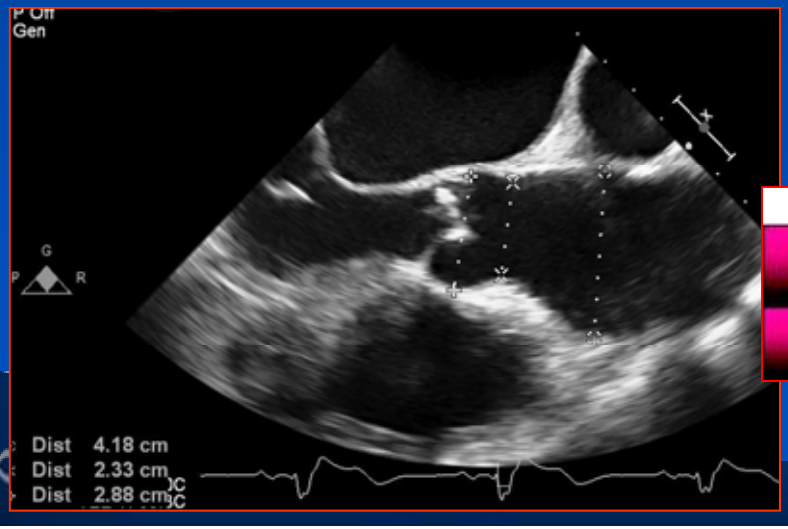
Double oblique view at annular level

Aortic Root Measurements



Important Aortic Root Measurements:

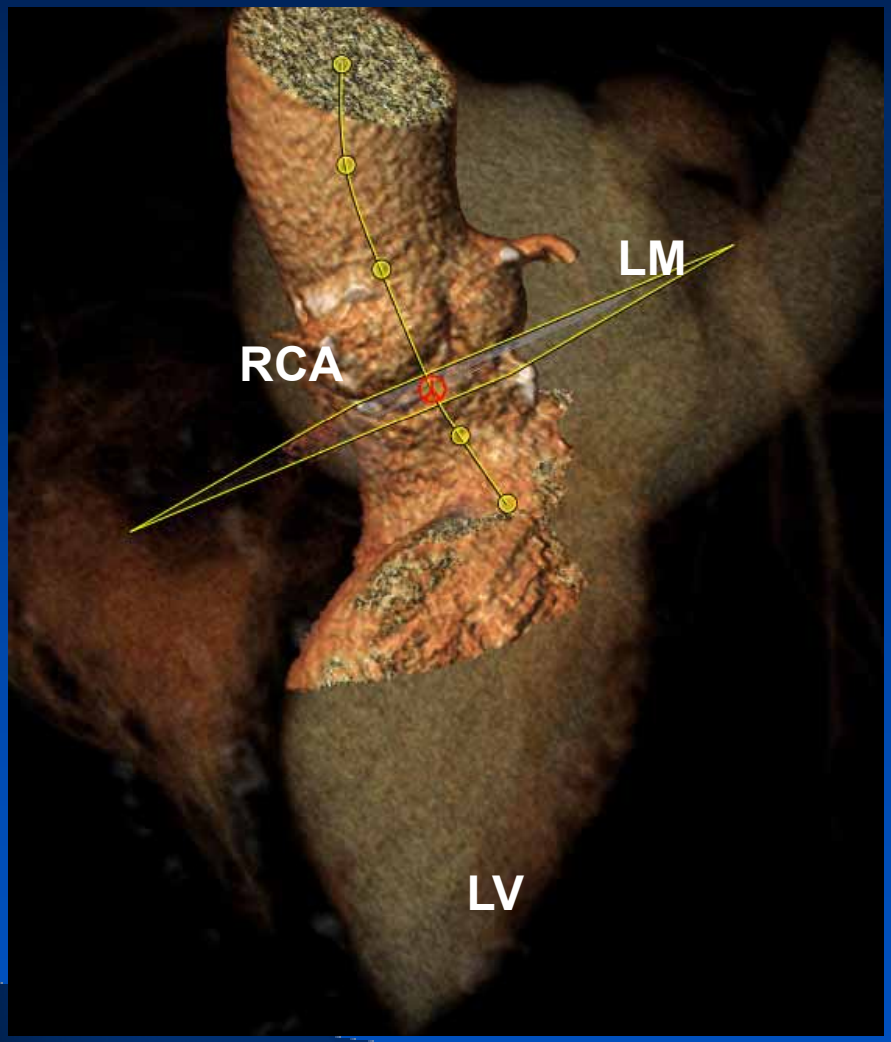
- Height of the Sinuses
  - Different valve sizes have different heights
- Diameter of the STJ
- Diameter of the ascending aorta
- Annulus → LM length
  - Length of the LCC



	Size (width x height)	For annulus diameter	Height of skirt
Edward SAPIEN™	23 x 14.5 mm	18-22 mm	10.1 and 7.74 mm
	26 x 16 mm	21-25 mm	11.4 and 8.67 mm
CoreValve Revalving™	26 x 53 mm	20-23 mm	12 mm
	29 x 55 mm	23-27 mm	12 mm

Piazza, N. et al. Circ Cardiovasc Intervent 2008;1:74–81

Aortic root dimension and spatial relationship with surrounding structures



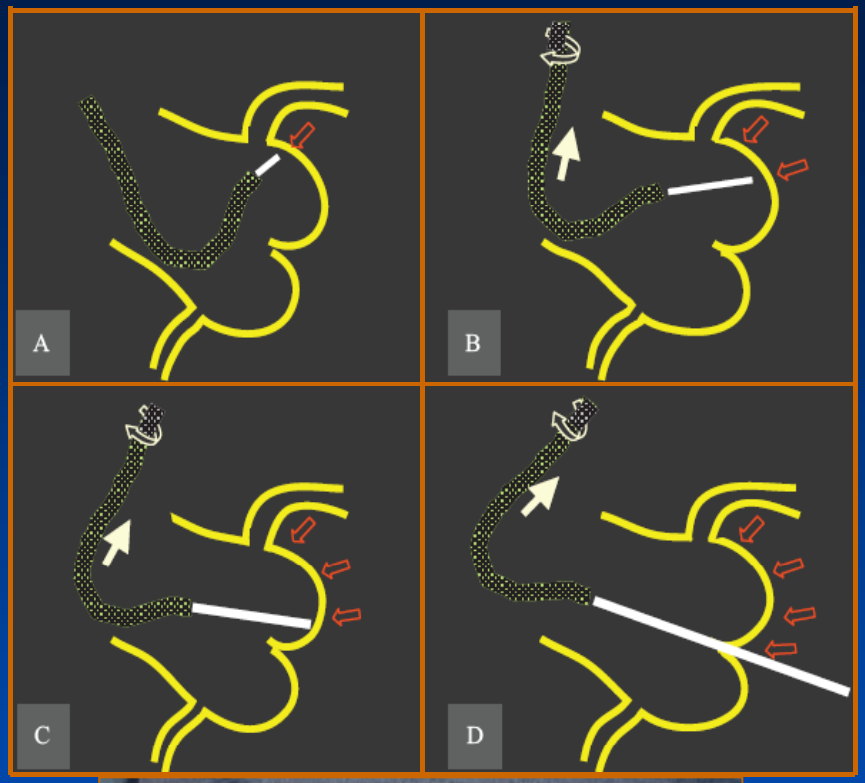
From annulus to LMCA

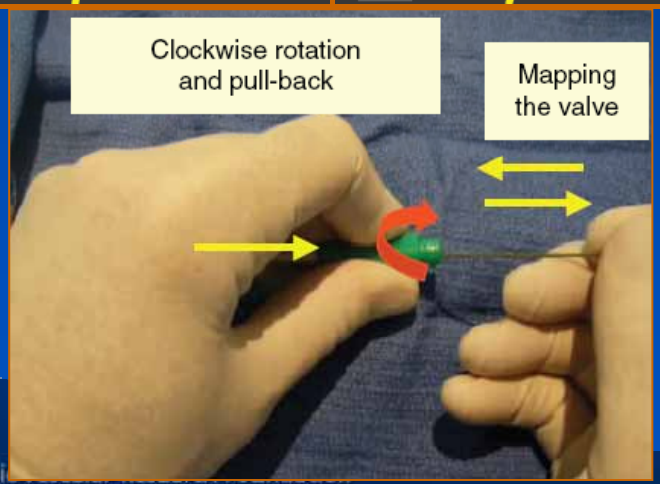
From annulus to RCA os

Lessions from the other Cases

Other technical problems

Crossing the Stenotic AV with Wire





- Left Amplatz catheter (5F AL)
- 0.35” extra-stiff straight wire
- Locate the aortic valve orifice
  - Calcified leaflet movement
  - Aortography
- Control movement
  - Catheter clockwise and counter
  - Wire protrusion
  - Catheter height
- Avoid coronaries and SVG
- Cross and advance wire into LV
- Advance catheter over the stiff part of the wire
  - May be difficult if very tight & Ca

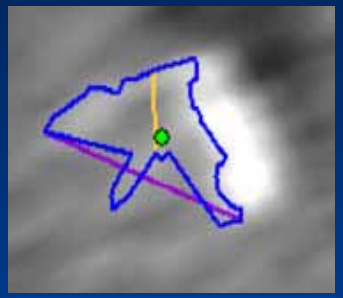
Vascular Evaluation

Access Site, Pass Route

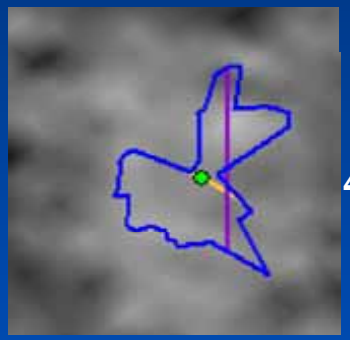
Iliofemoral Sizing & Plaque Burden

Right

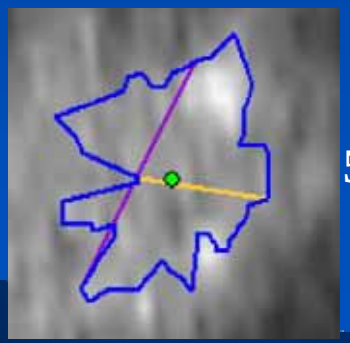
Left



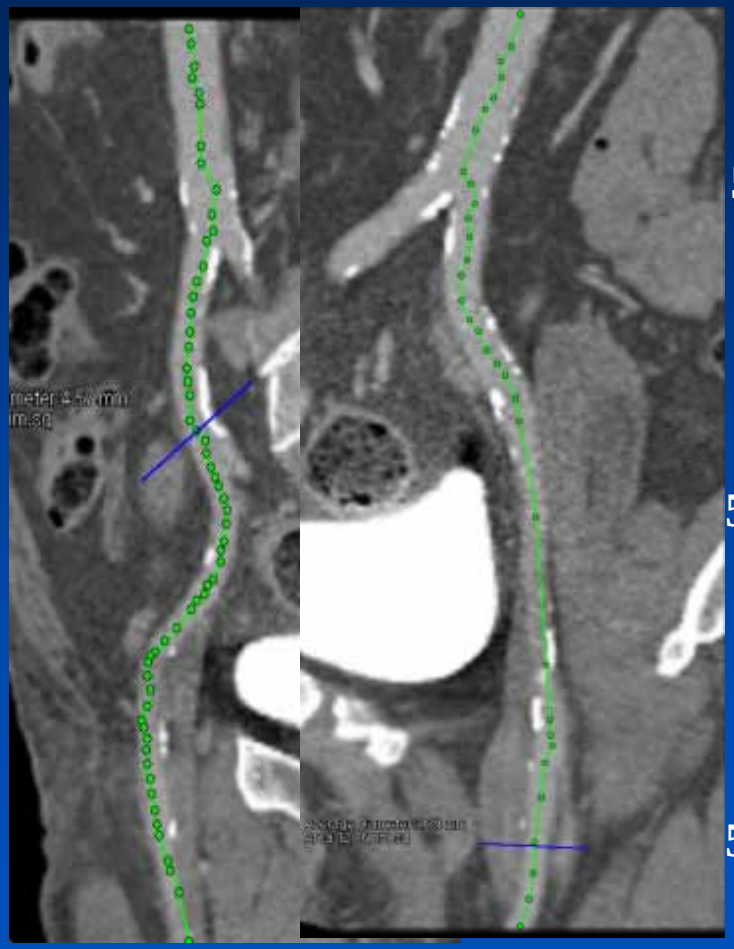
4.5 mm



4.4mm



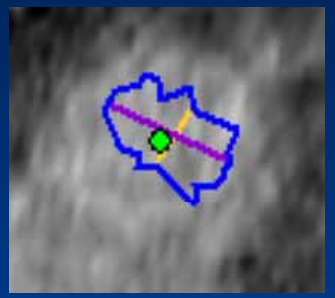
5.9 mm

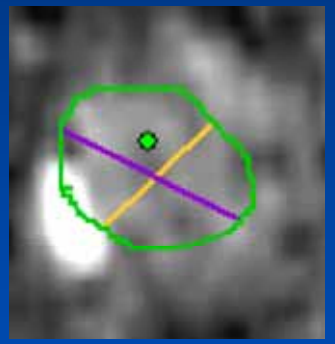


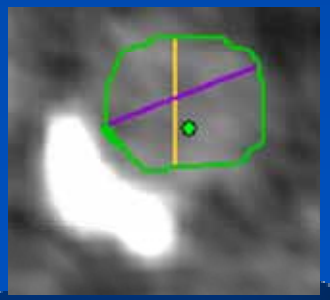
5.5 mm

5.6 mm

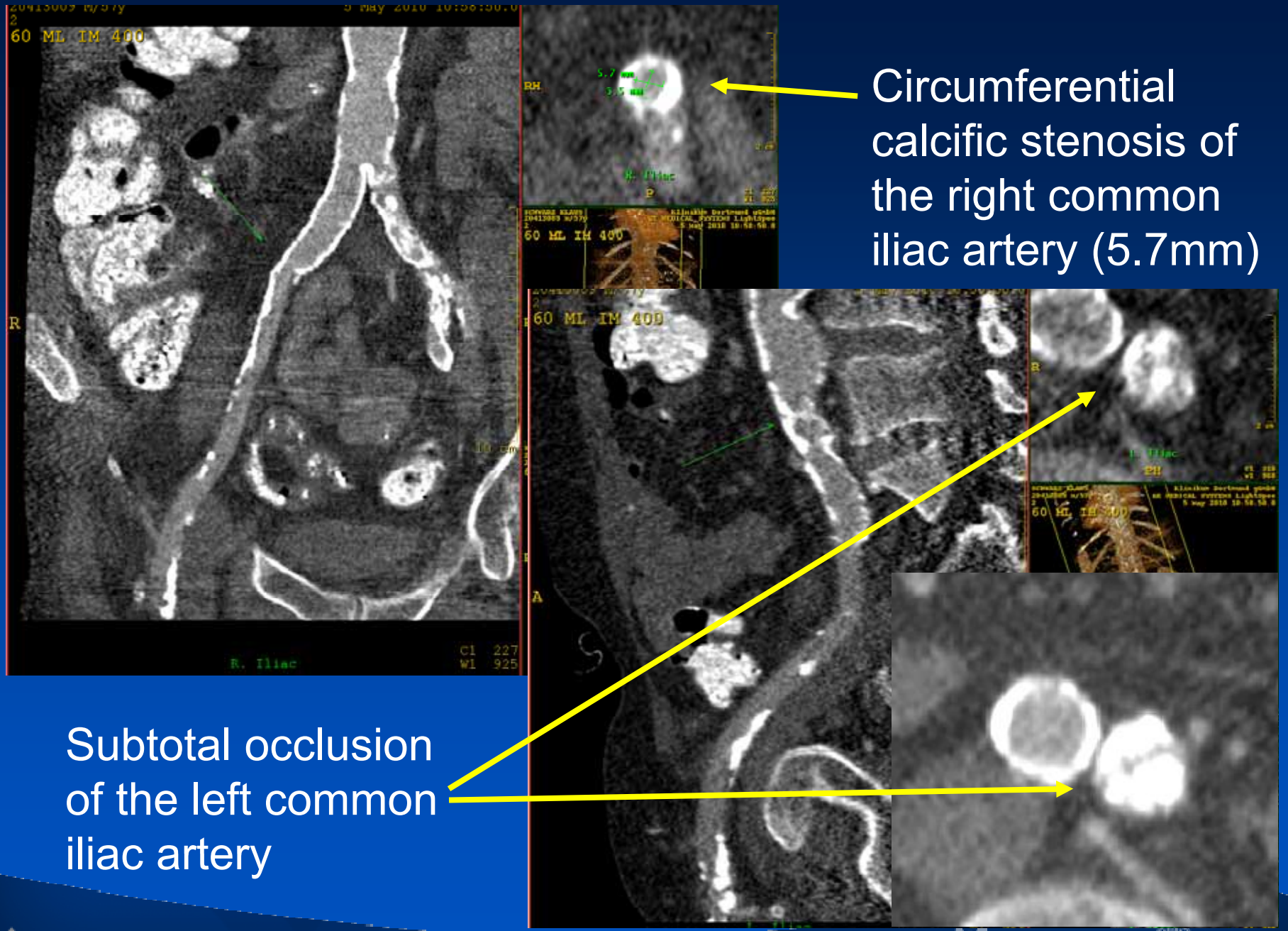
5.8 mm







Tortuousity - Minimal Plaque Burden


Circumferential calcific stenosis of the right common iliac artery (5.7mm)
Subtotal occlusion of the left common iliac artery
60 ML IM 400
R. Iliac
CardioVascular Research Foundation
UNIVERSITY OF ULSAN COLLEGE MEDICINE
ASAN Medical Center

Future Perspective

Development of Devices

Evolution of the Edwards Valve

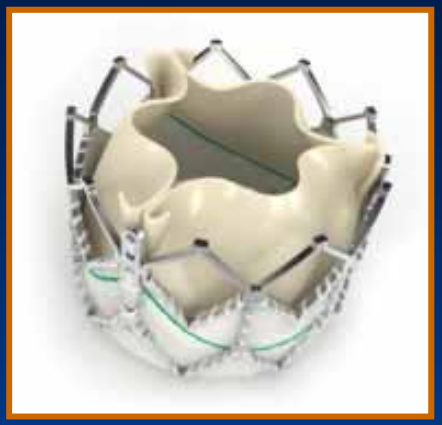
Cribier-Edwards

- 23 mm Valve
- Stainless Steel Frame

- Untreated Equine Tissue

Edwards SAPIEN

- 23 and 26 mm Valves
- Stainless Steel Frame
- Bovine Pericardial Tissue
- Carpentier-Edwards ThermaFix Process*
- Leaflet Matching Technology



Edwards SAPIEN XT

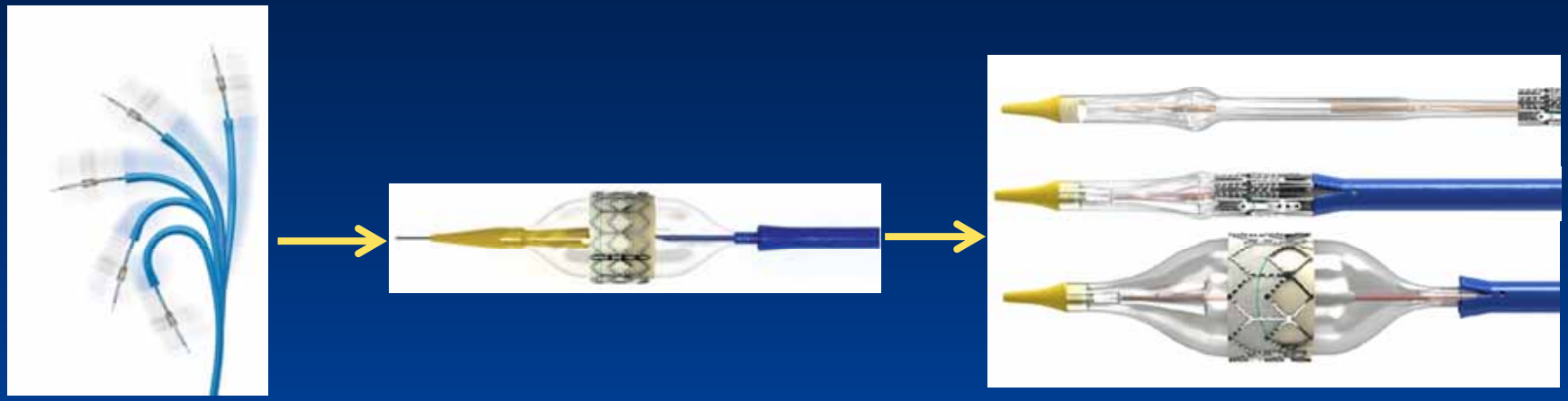
- 23 and 26 mm Valves
  - 20mm and 29mm Under Development
- Bovine Pericardial Tissue
- Carpentier-Edwards ThermaFix Process*
- Leaflet Matching Technology

Product Design Updates

- **New Frame Design**
  - **Lower Crimp Profile Geometry**
  - **Cobalt-chromium Material**
- **New Leaflet Design**
  - **Surgical Leaflet Design**

*No clinical data are available which evaluate the long-term impact of the Edwards Lifesciences tissue treatment in patients.

Evolution of the Edwards Transfemoral Delivery System



RetroFlex System

- Balloon-expandable transcatheter valve delivery
- Steerable catheter

RetroFlex 3 System

- Balloon-expandable transcatheter valve delivery
- Steerable catheter
- Tapered distal end
- Accurate valve deployment

RetroFlex 4 System

- low-profile SAPIEN XT

NovaFlex System

- Balloon-expandable transcatheter valve delivery
- Steerable catheter
- Tapered distal end
- Accurate valve deployment

Product Design Updates

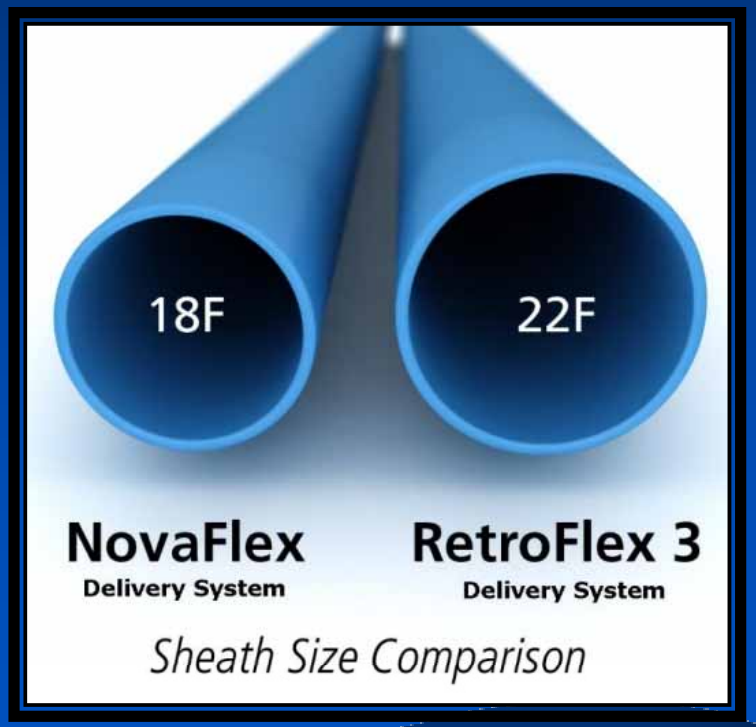
- **18F Profile**
- **Enhanced distal end**
- **Designed for Valve Alignment**

Innovative Catheter Tip Design

New shorter softer tip

New balloon Processing for Smooth transition To valve

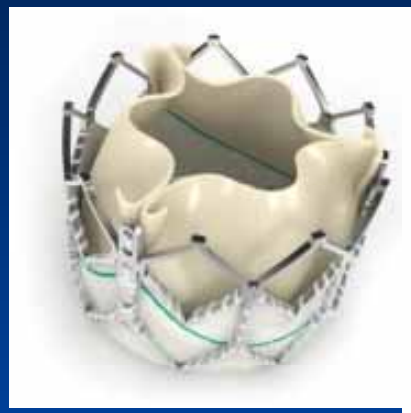
Edwards SAPIEN XT Valve Size	NovaFlex Sheath	Minimum Vessel Diameter
23 mm	18F	6.0 mm
26 mm	19F	6.5 mm

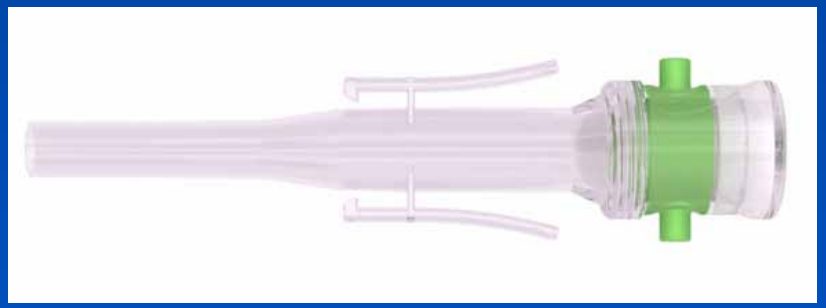


Transapical approach
Edwards SAPIEN XT

33F 26F 24F 22F

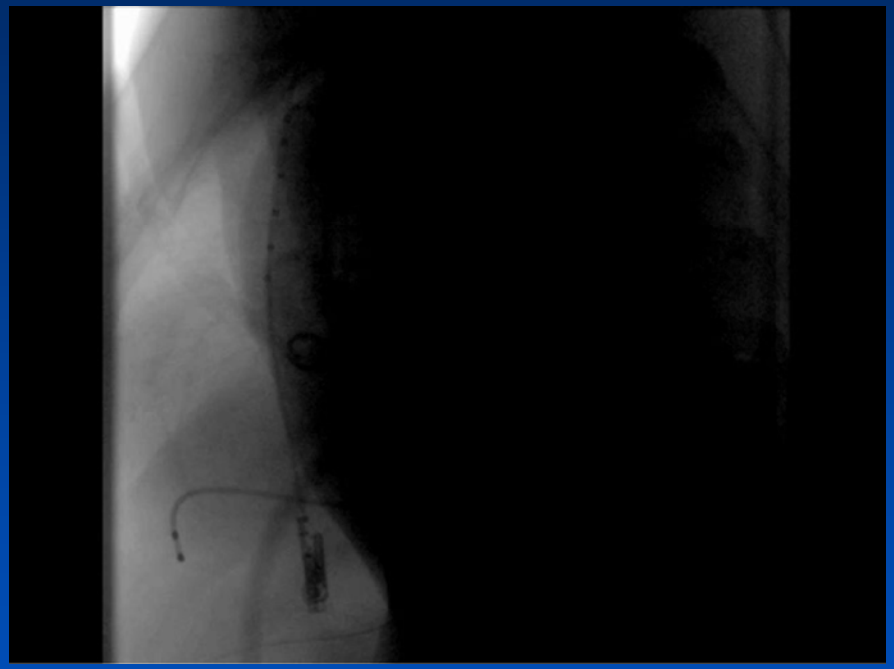
Ascendra 1 Ascendra 2





Delivery System

DynaCT Image Acquisition with rapid pacing



Courtesy Siemens Systems

Valve deployment under DynaCT

Edwards SAPIEN

CoreValve

Courtesy by Alois Nöttling Siemens

Courtesy by Brockmann German Heart Center Munich

Conclusions

- Team Approach is most important
- Appropriate patient selection effects outcome
- Both clinical and technical criteria equally important for success
- Be prepared to stop; defer; ask for help for complex cases
- With development of device technology and accumulated experience, current contraindication may be changed to appropriate in the near future

Thanks for your attention !