Critical factors in patient selection before transcatheter aortic valve implantation

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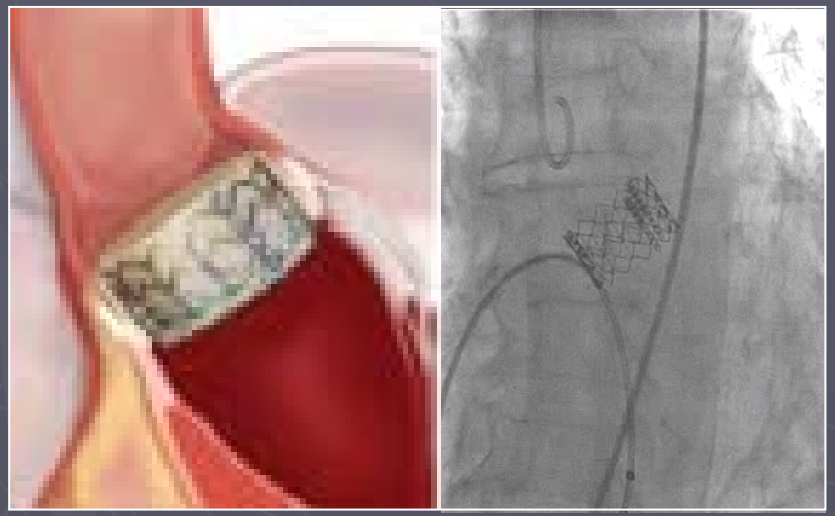
EDWARDS Sapien

COREVALVE

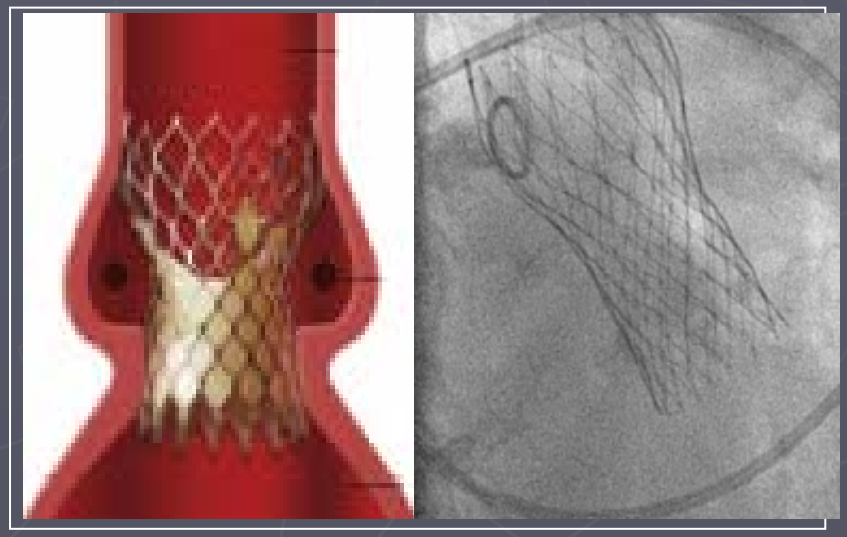
CE mark in 2007

> 10 000 Pts

	Stent Ø	Height	Annulus Ø
Edwards-Sapien ™	23 mm	14.5mm	18-21 mm
	26 mm	16 mm	21-25 mm
CoreValve Revalving ™	26 mm	53 mm	20-23 mm
	29 mm	55 mm	23-27 mm



Edwards-Sapien

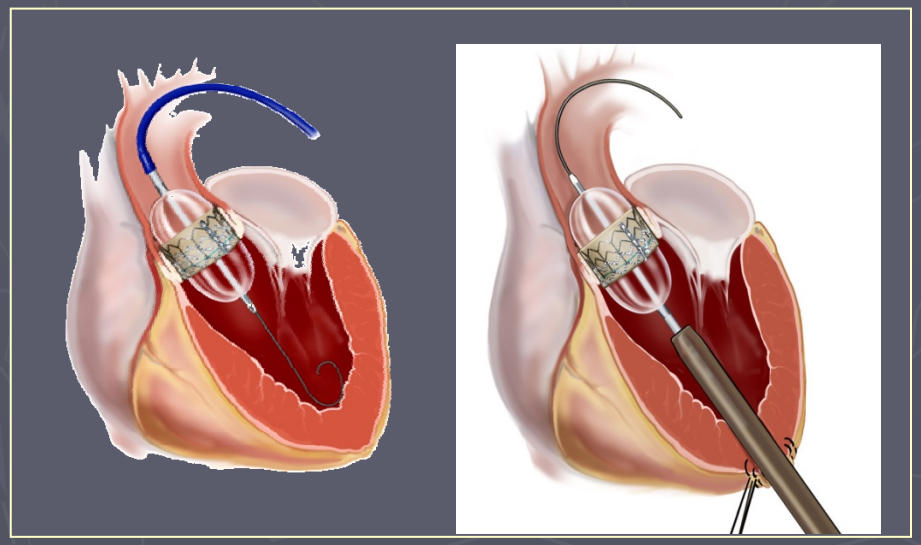


CoreValve Revalving

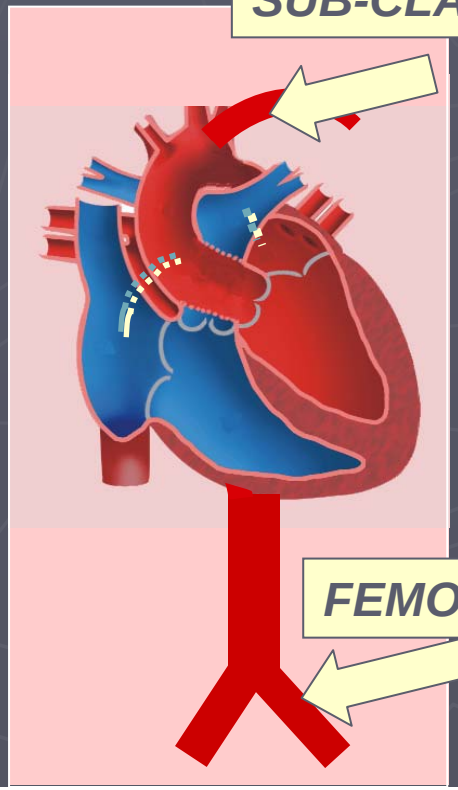
Arterial access

FEMORAL
22 / 24 F

APICAL



SUB-CLAVIAN



FEMORAL
18 F

European statement - 2008

European Heart Journal (2008) **29**, 1463–1470
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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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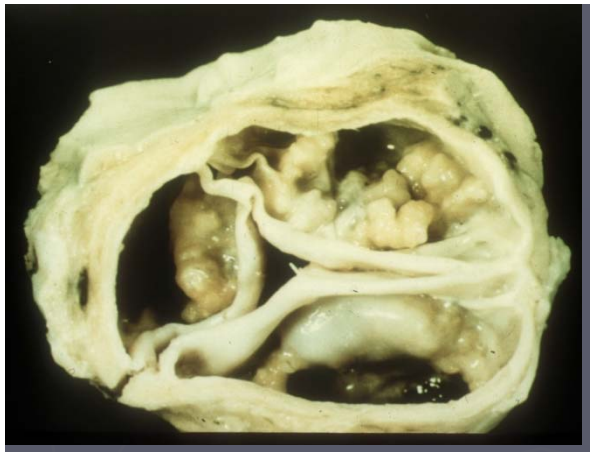
Patient selection for TAVI

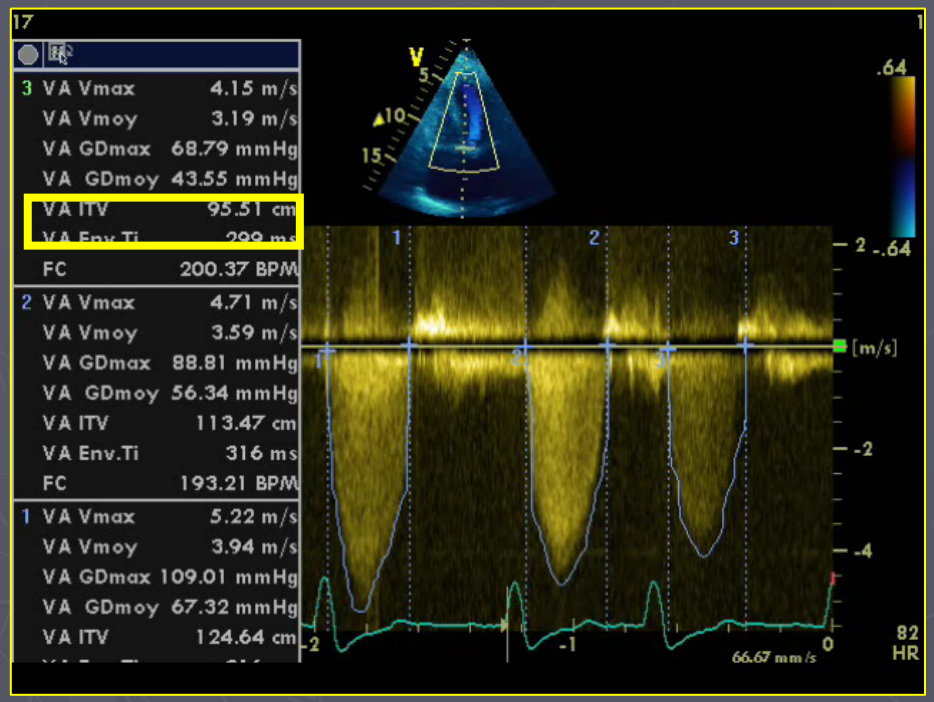
Two questions:

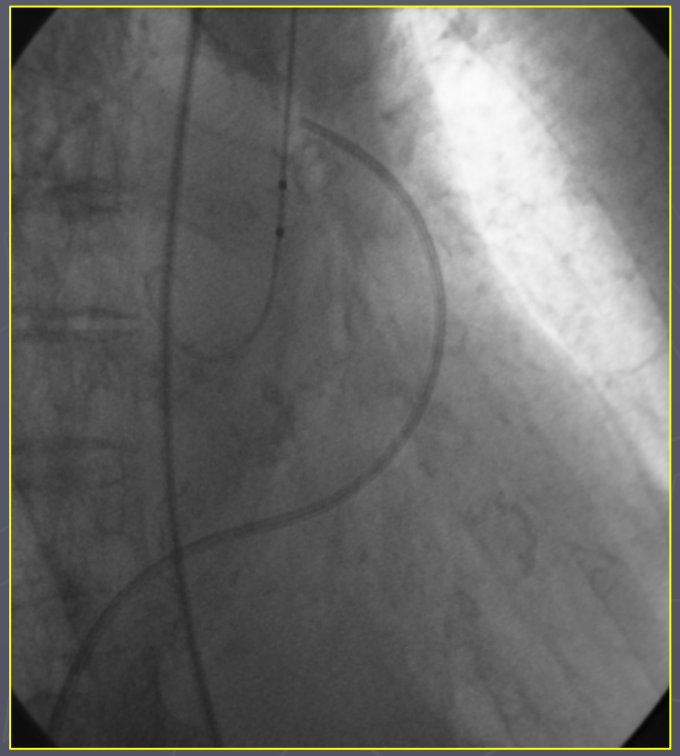
1) *Is the patient a good candidate?*

2) *Route selection*



1. Severe symptomatic AS





AVA < 1 cm² (< 0.6 cm²/m²)
NYHA ≥ 2

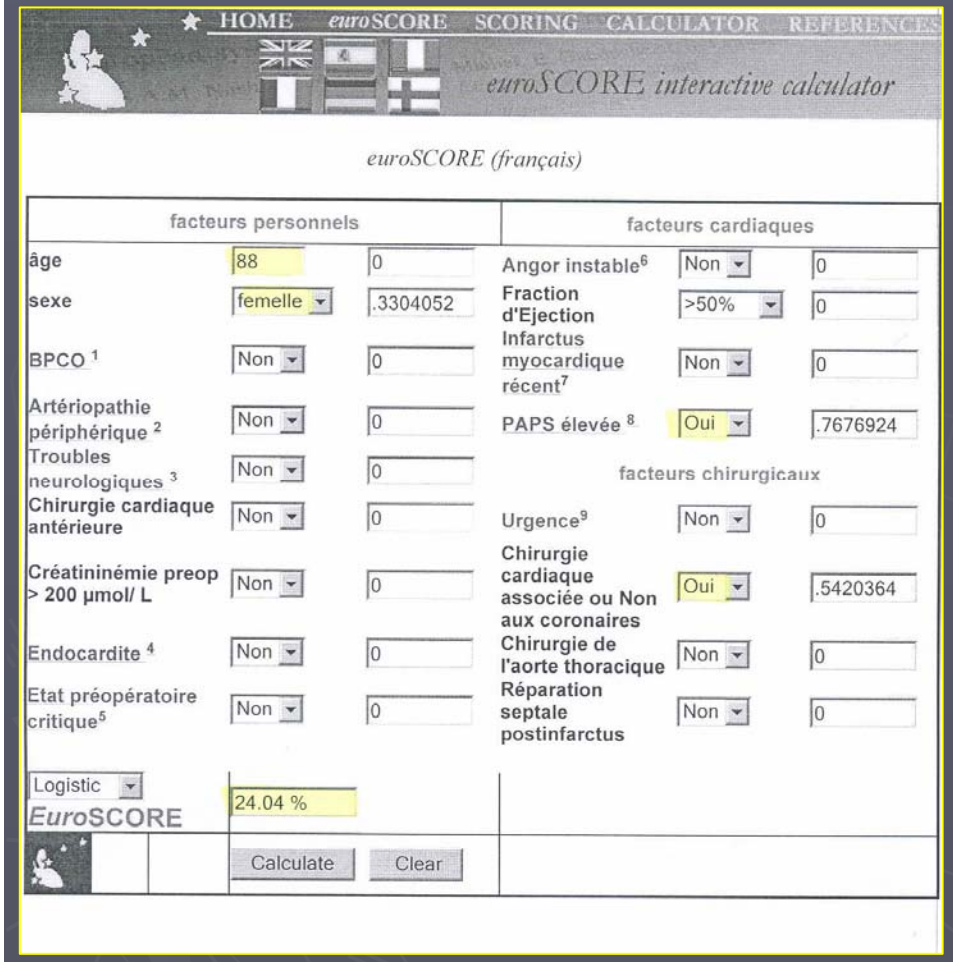
2) Is the patient a surgical candidate ?

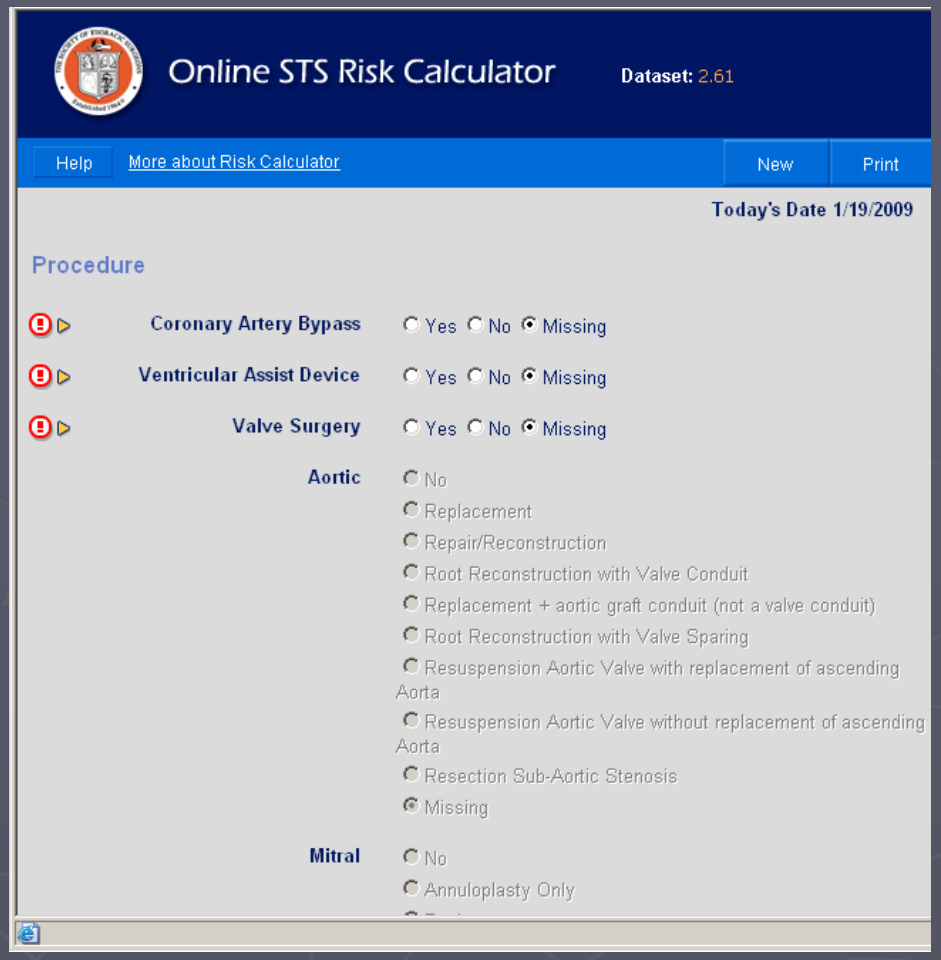
Nowadays, age per se and patient refusal are not sufficient conditions to undergo TAVI

Criteria for TAVI:

- CI to surgical AVR
- High surgical risk (STS, Euroscore)

Score calculation





EuroSCORE

http://www.euroscore.org/calcfr.html

STS Score

http://66.89.112.110/STSWebRiskCalc261/de.aspx

Score calculation

Criteria for TAVI:

- Logistic Euroscore > 20%
- STS score > 10%

Importance of clinical judgement to assess:

- Cardiac and extra-cardiac comorbidities
- Life expectancy
- Quality of life
- Patient's decision

3) Is TAVI anatomically feasible ?

- Are the native valve and LV suitable for THV?

  - Echocardiography: TTE ± TEE

- How are: 1- the coronary arteries:

  coronary angiography

  2- the aortic root:

  aortogram

  3- the femoro-iliac access:

  abdominal aortogram
  CT-Scan

CT-Scan / MR
3D-Echo
Intra Card. U.S.

CT-Scan

CT-Scan
CardiOp System

MRI
IVUS

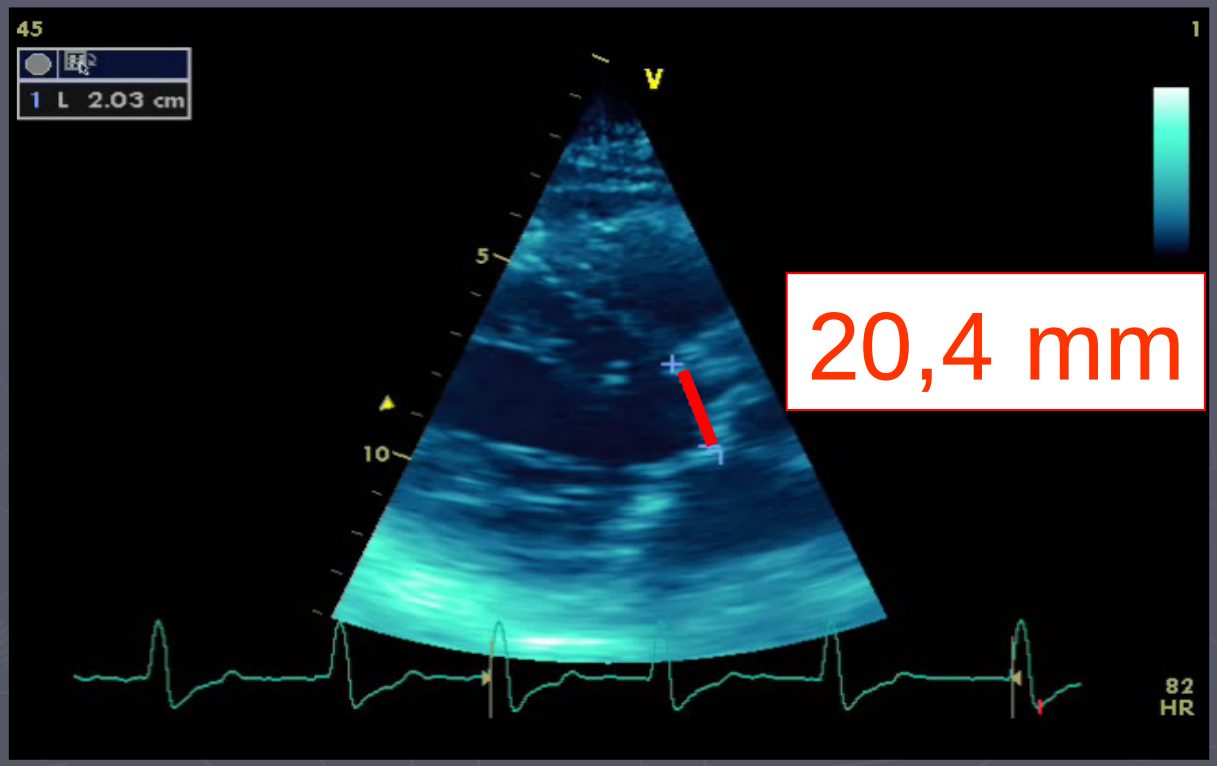
ECHOCARDIOGRAPHY

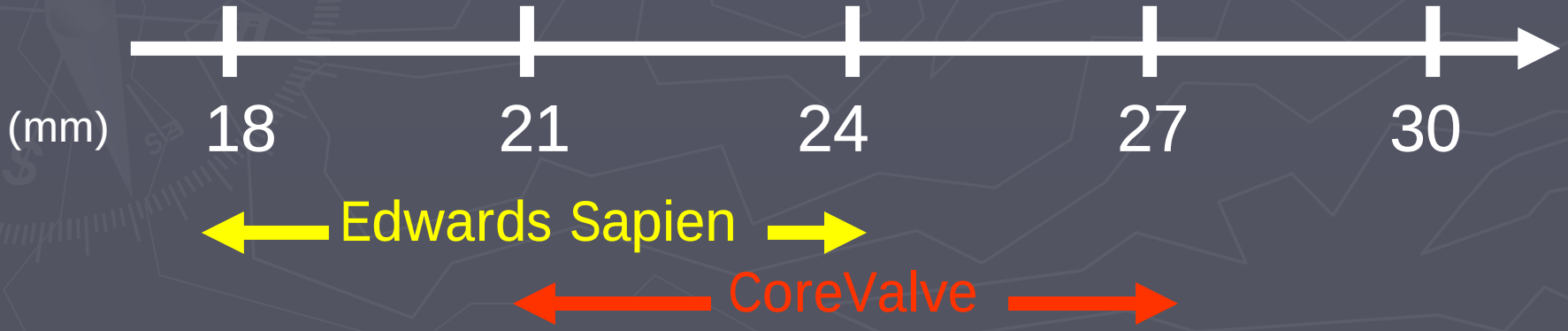
1- Severity of aortic stenosis and associated AR

2- Aortic annulus dimensions

Critical component to evaluate THV sizing

Echocardiography: Annulus diameter





ECHOCARDIOGRAPHY

1- Severity of aortic stenosis and associated AR

2- Aortic annulus dimensions

3- LV hypertrophy and function

LVEF, LVEDV, Hypertrophic or obstructive cardiomyopathy

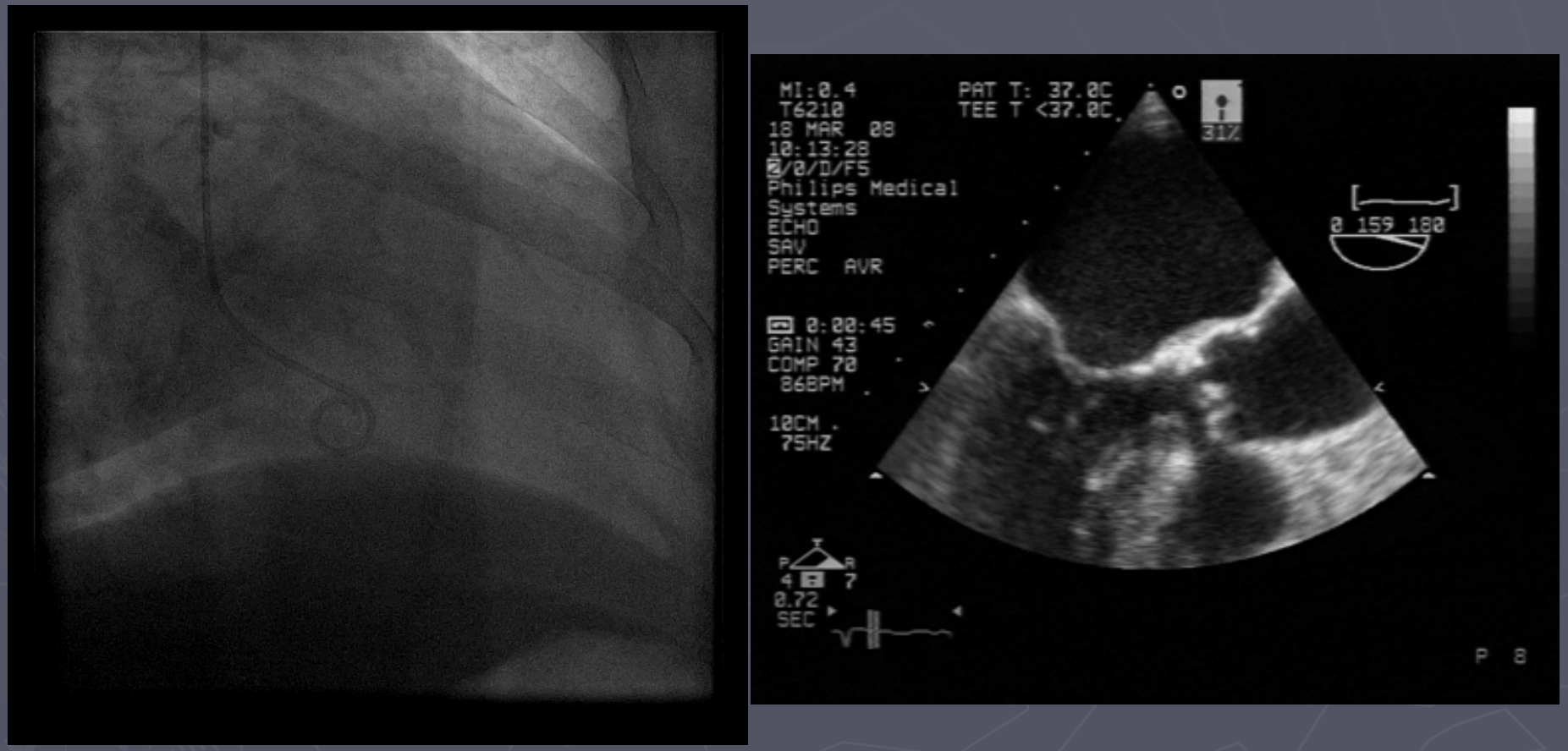
LV function

LVEF < 30% :

- **Increases the risk of the procedure**
- **Myocardial contractility reserve should be assessed**
  (stress ECHO or BAV as a bridge to THV)
- **Relative contra-indication of trans-apical approach**

Severe LV hypertrophy may impair the accuracy of THV positioning

and may be a contra-indication of THV implantation



Severe LV Hypertrophy

ECHOCARDIOGRAPHY

1- Severity of aortic stenosis and associated AR

2- Aortic annulus dimensions

3- LV hypertrophy and function

4- Exclude patients with bulky calcified leaflets

Risk of coronary obtruction post-THV deployment

Trans Esophageal Echo

-TEE not required in all patients

If annulus appears too small, large or can not be visualized by TTE, TEE is recommended for assessment of annulus size.

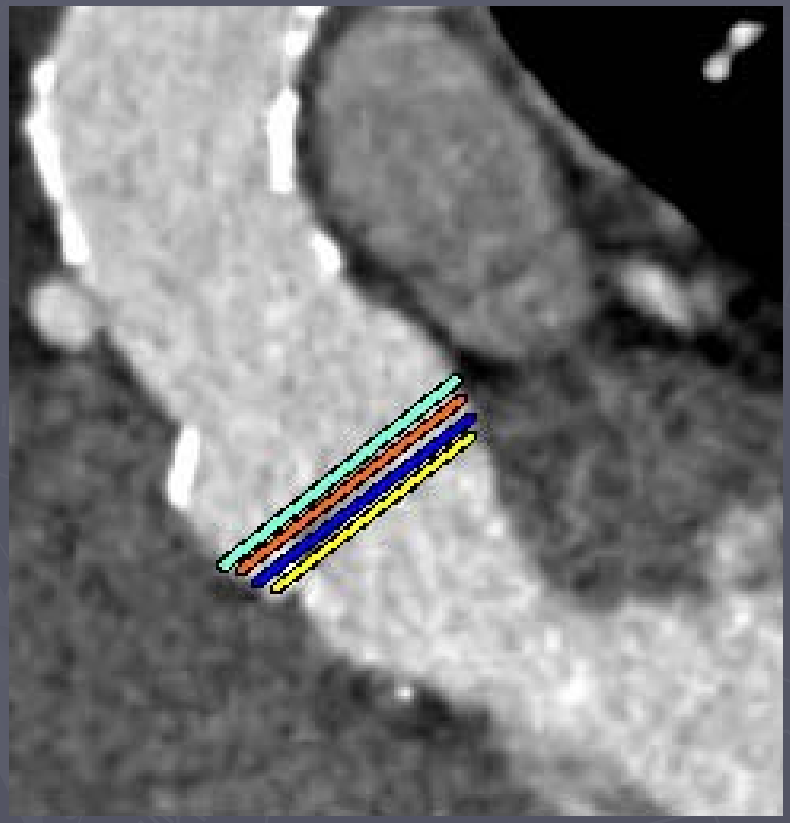
TEE aortic annulus sizing typically measures > than TTE by 1 mm

- Can be used at time of implantation for final determination of THV size

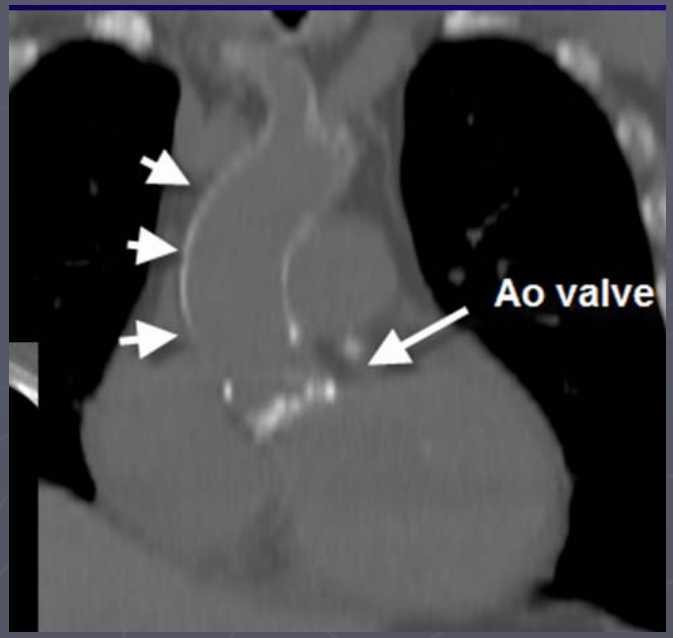
Ascending Aorta evaluation: *Angiography*

- Valve calcifications
- Ascending aorta orientation
- Selection of the optimal projection for valve delivery

Ascending Aorta evaluation: CT-scan



Measure of annulus diameters



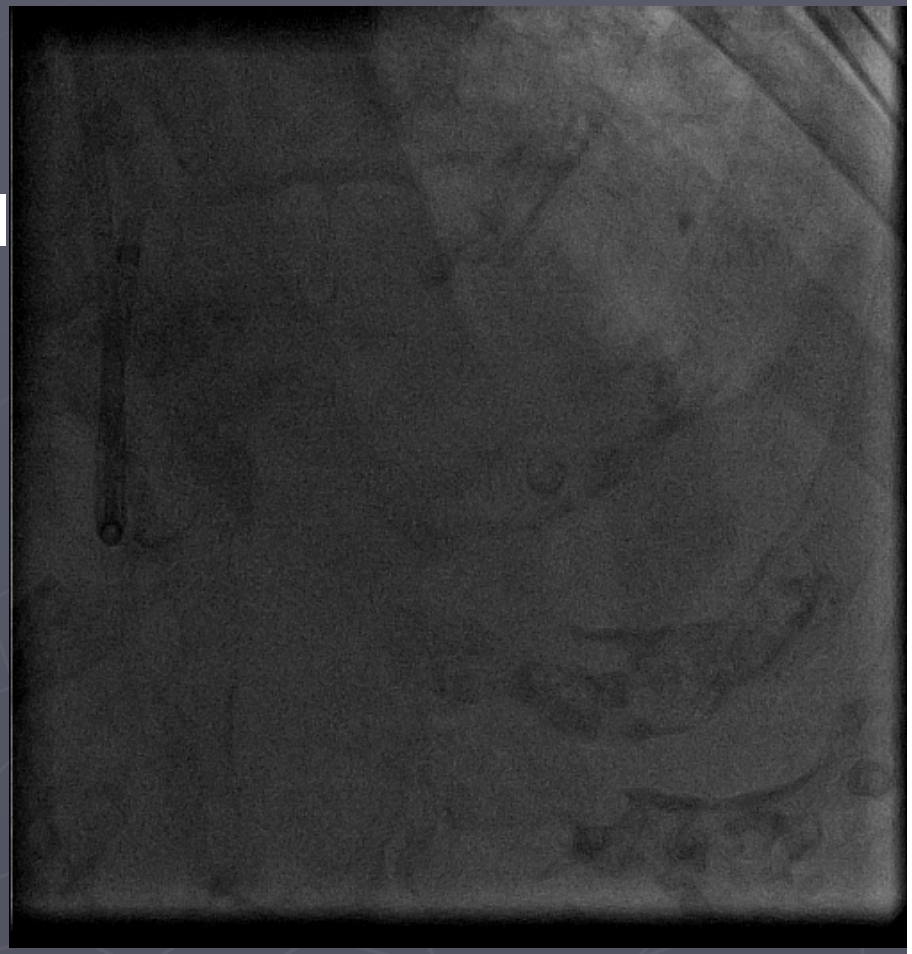
Porcelain Aorta

Selecting the view from CT-Scan

LAO 16° / Cranial 20°

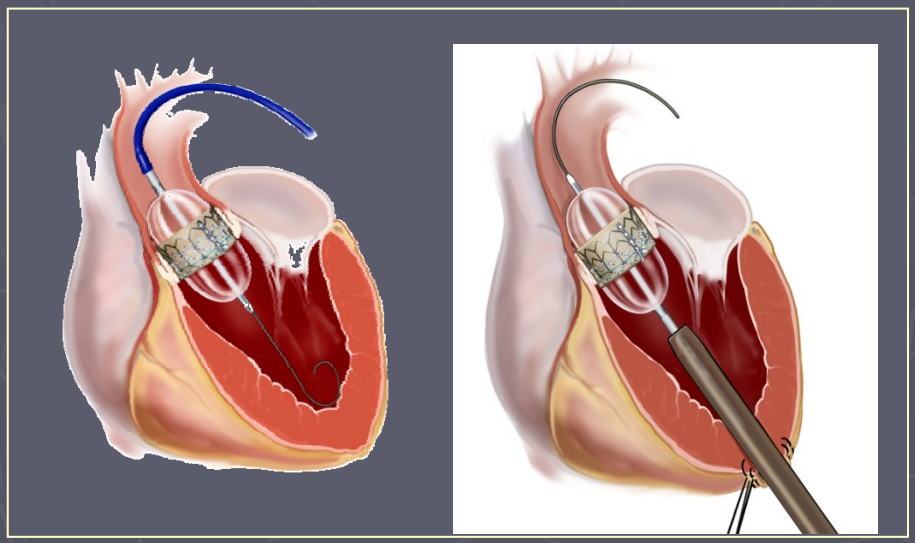
Coronary arteries evaluation

- Presence of CAD
- Consider PCI prior to TAVI
- Coronary stenting limited to severe lesions of main branches
- Recommend bare metal stent then wait 1-3 weeks



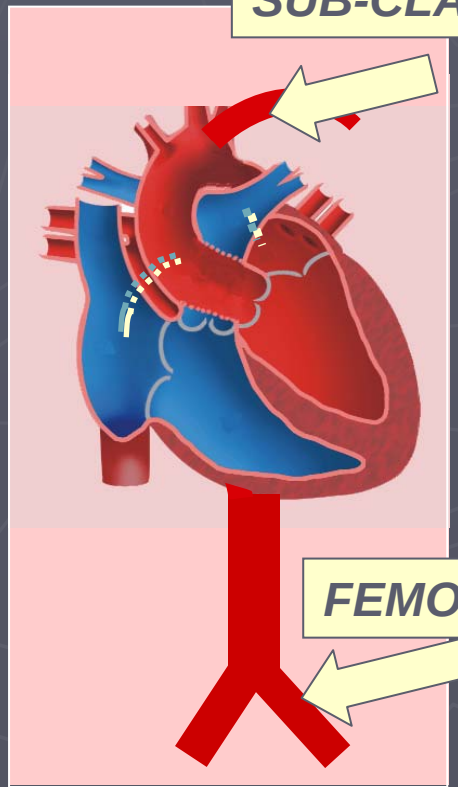
Selection of approach

FEMORAL
22 / 24 F



APICAL

SUB-CLAVIAN



FEMORAL

18 F

TF approach is feasible if:

- Minimal ilio-femoral diameter:
  - > 6 mm for Corevalve
  - > 7 mm for Edwards Sapien 23-mm
  - > 8 mm for Edwards Sapien 26-mm

\+ No excessive calcifications

\+ No excessive tortuosities

Ilio-femoral access evaluation:
Angiography and CT-scan

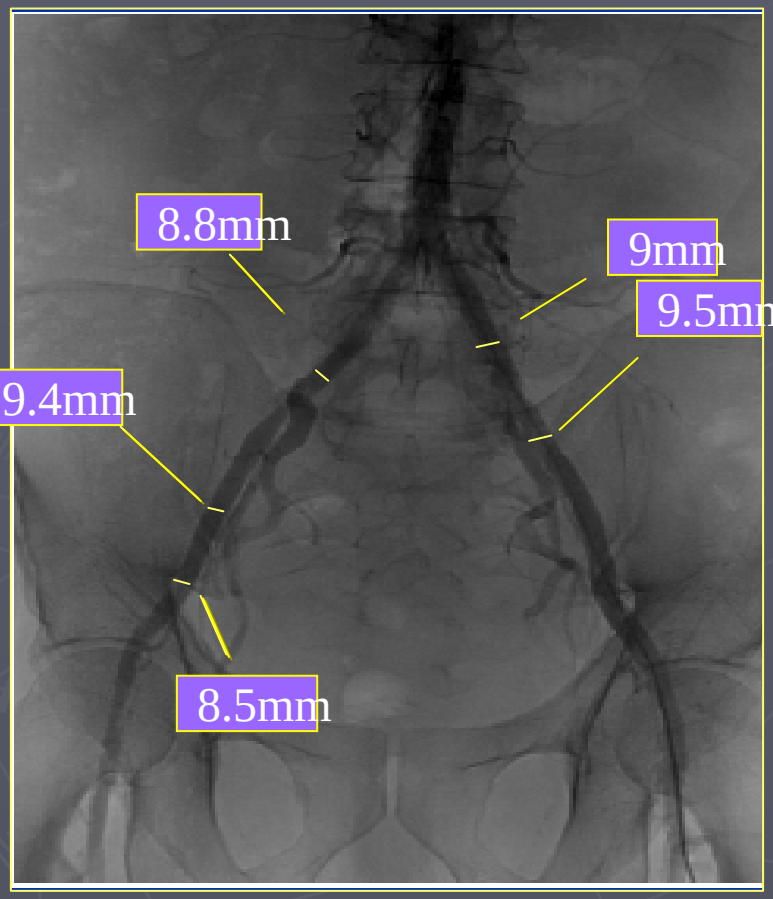
- Adequacy for ilio-femoral access

- Diameters

-Vascular tortuosity

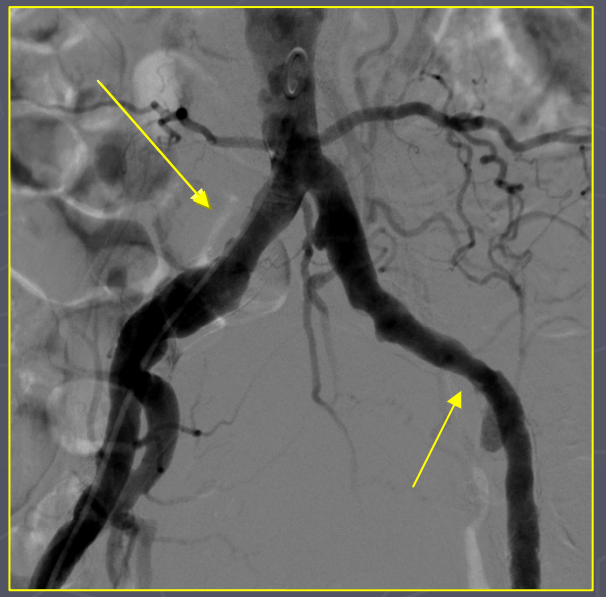
- Calcification

AORTO-ILIAC ANGIOGRAM



Diameters

Tortuosities



Focal stenosis

CT- SCAN of the ilio-femoral arteries and aorta

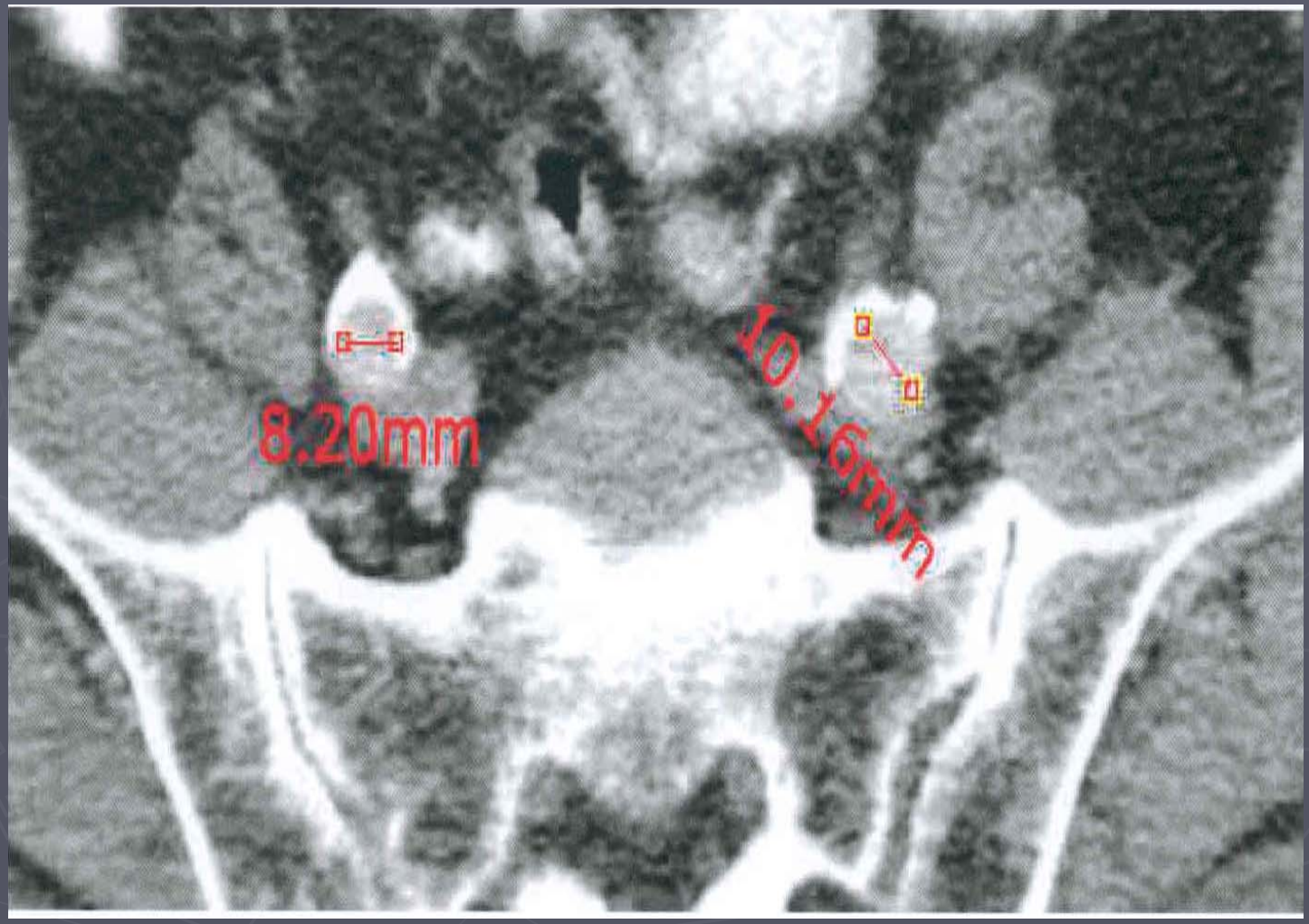
- CT-Scan is highly recommended in all cases in addition to aortic angiogram

- Critical to confirm the indication of the transfemoral approach!

CT- SCAN of the ilio-femoral arteries and aorta

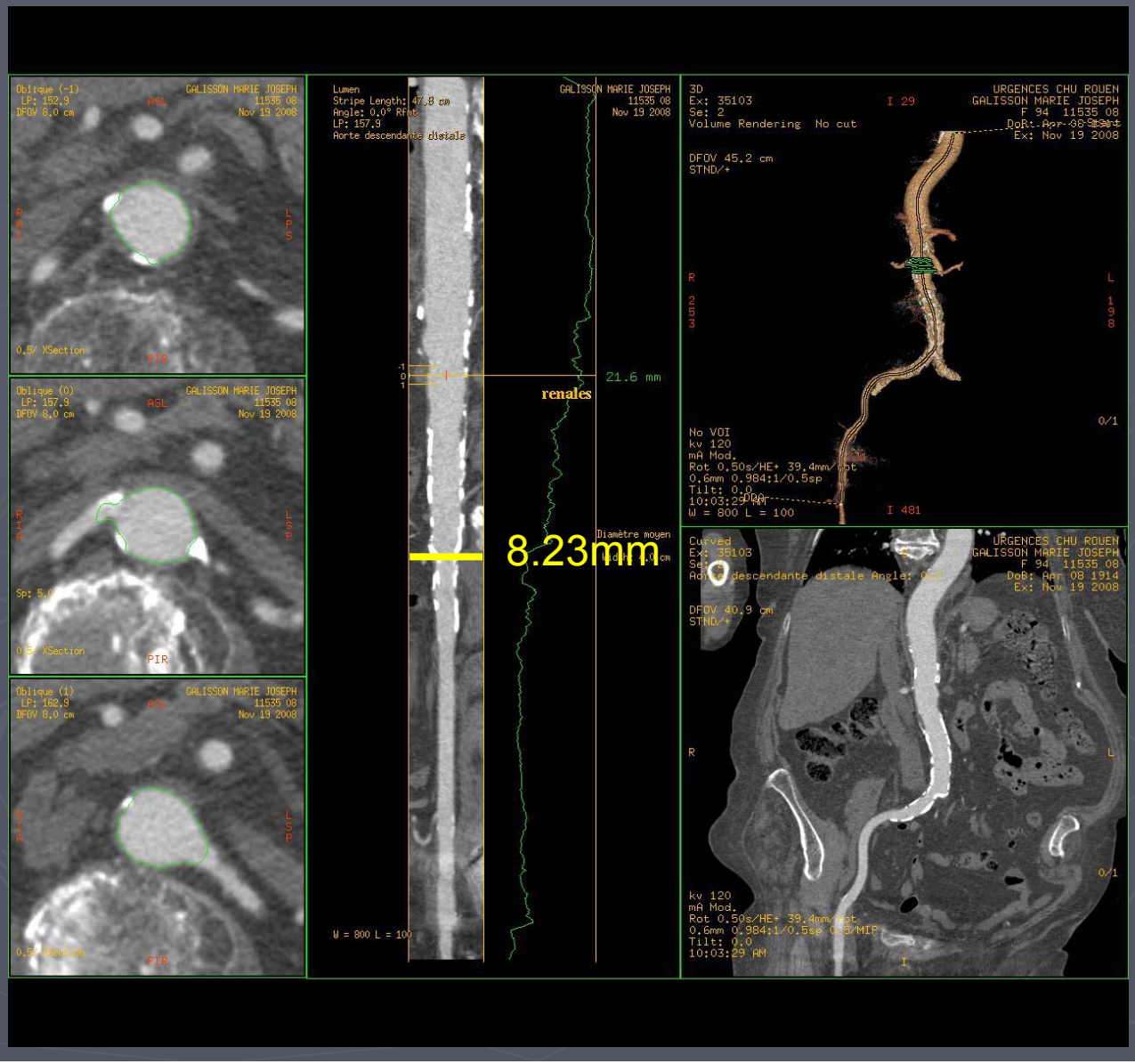
CT-Scan: cross section assessment is crucial

Diameters measured from internal border of calcification



CT-Scan

Search for critical zone on « lumen » view



Minimal information before submitting a patient for evaluation

(1- Clinical indication)
Euroscore or patient declined for surgery

2- Aortic annulus diameter (TTE)

3- Supra-aortic angiogram

4- Angiography of arterial access

5- CT-Scan of arterial access

Type of valve

- Personal choice of the operators
- Anatomical requirements:
  - Annulus diameter
  - Ascending aorta
  - Ilio-femoral diameters

Technologic improvements

EDWARDS

Treated bovine pericardium
Cobalt Chrome frame
23 and 26mm
Next generation

18F, 19F

COREVALVE

Decreased size to 16 F ?

Ongoing PREVAIL Study

Optimal candidate for TAVI

- Patient with severe and symptomatic AS
- CI for AVR or at high risk (scores)

+

- Favorable anatomy of the aortic valve (annulus diameter and ascending aorta)

↓

- Selection of best approach

Conclusions

- **Even though results of TAVI are good in experienced teams, there is a learning curve and careful patient selection is crucial.**

- **Training and personal preparation of the operators and their team, and cooperative work are crucial for the success and the future of this procedure.**

Balloon Expandable Valve

Percutaneous Heart Valve	Cribier Edwards	Edwards Sapien	Edwards Sapien XT
			
Bovine pericardium Nnl. steel frame 23mm	Equine pericardium Stainl. steel frame 23mm	Treated bovine peric Stainl. steel frame 23 and 26mm	
Exp. and F.I.M.	2003-2006	From 2006	
24F	22F	22F, 24F	

Transfemoral sheath sizes

Aortogram during 23mm balloon inflation:

1) Confirmation of THV size in border line cases: *annulus 20-22mm = 23 or 26mm THV?*

2) Detection of bulky calcific leaflet that could move up and occlude the LM after THV placement (can lead to decline the procedure)

AORTOGRAM during 23mm balloon dilatation

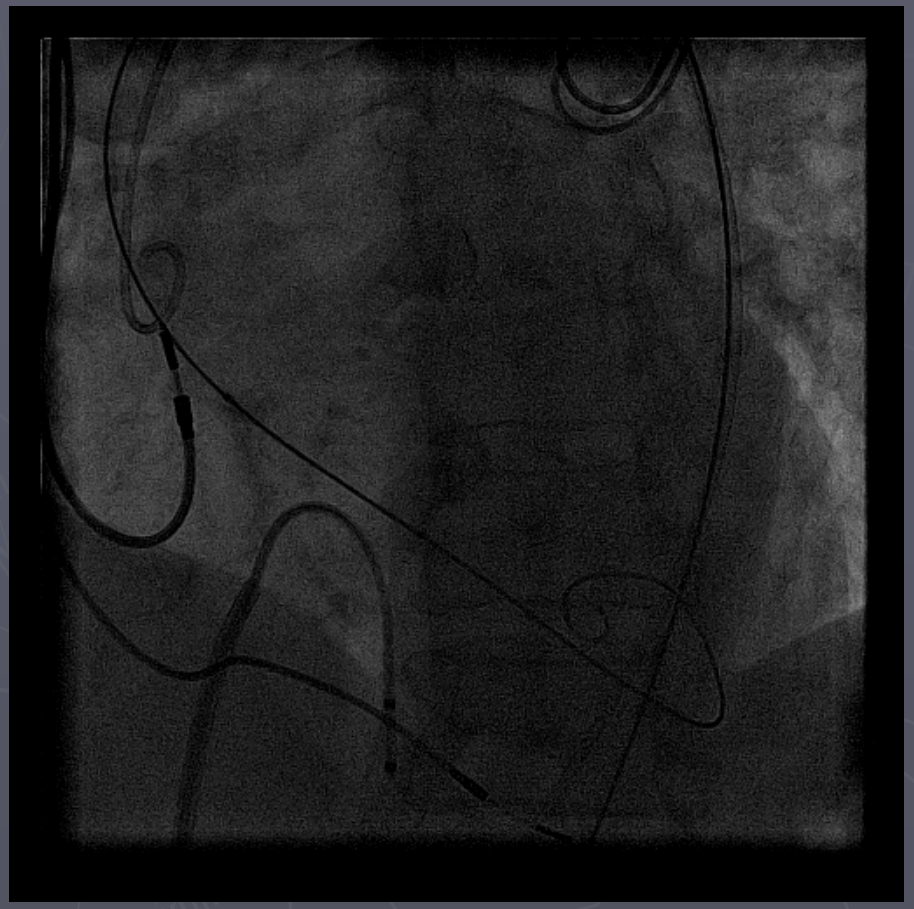
- In regular cases, balloon pre-dilatation of the aortic valve is performed with a 20mm balloon *(for the 23mm THV)* or a 23mm balloon *(for the 26mm THV)*

- In borderline cases (annulus 20 to 22mm) BAV should be performed with a 23mm balloon and aortogram obtained at full balloon inflation

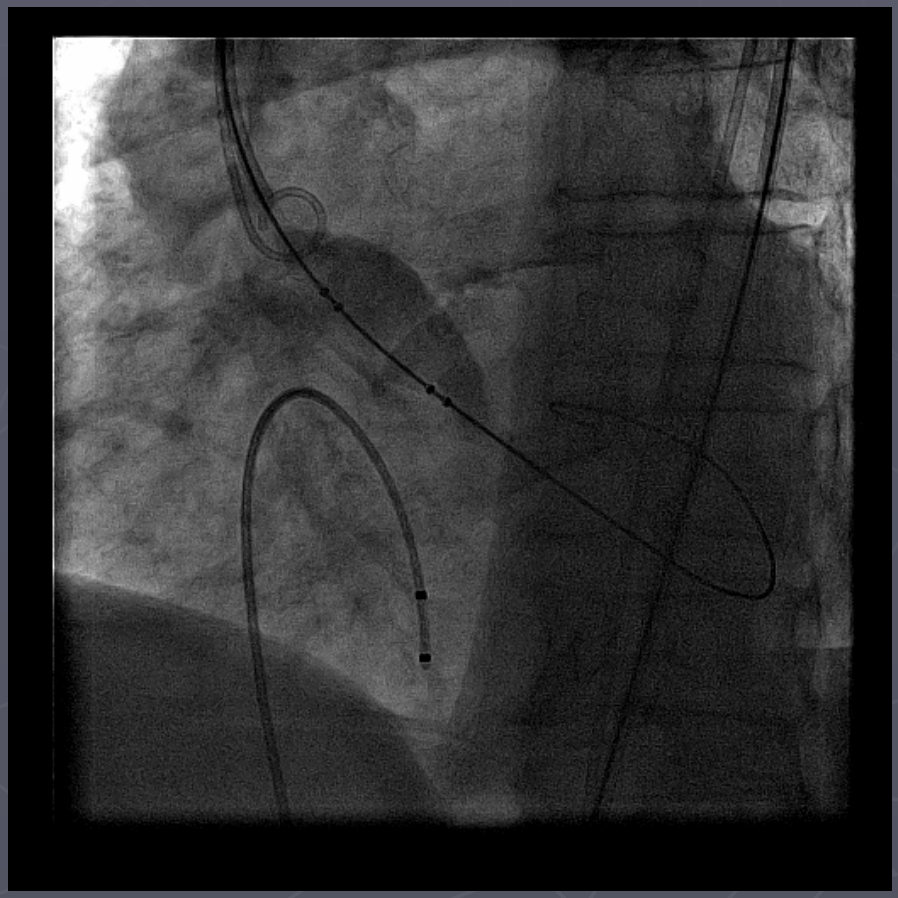
-The free space between balloon edges / aortic wall, and the degree of paravalvular leak will confirm the optimal THV size

Aortogram during 23mm balloon inflation

Aortic annulus measured 21mm

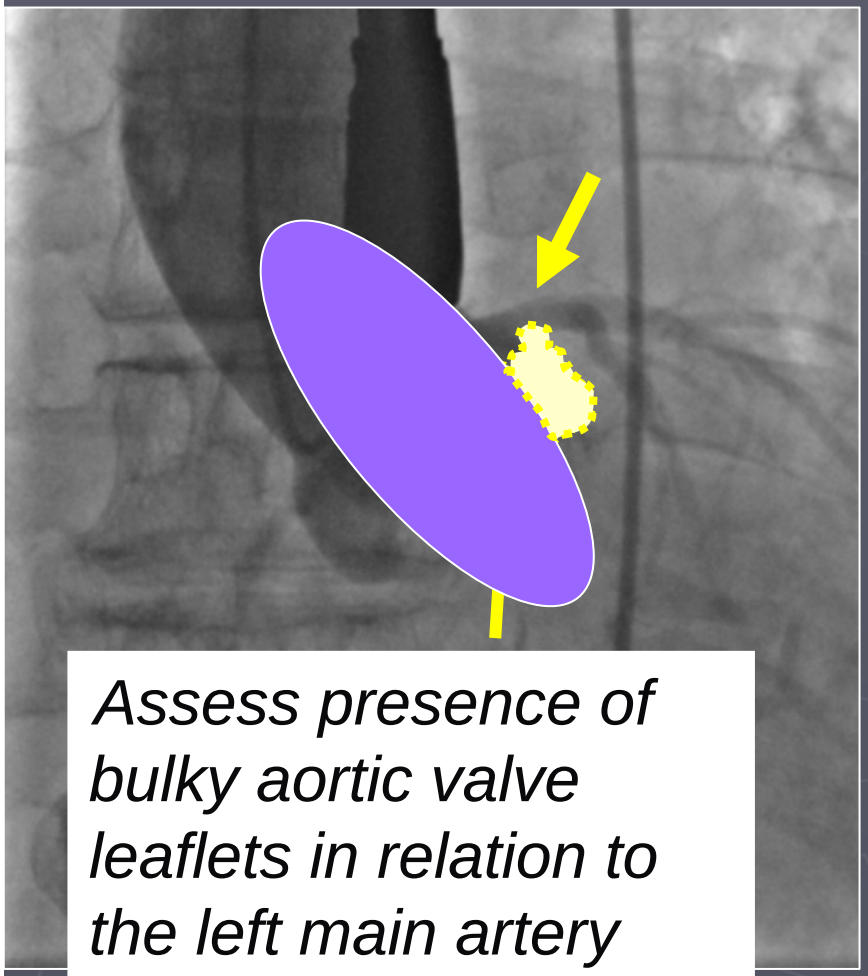


23mm THV OK



26mm THV OK

Aortogram during 23mm balloon inflation



Assess presence of bulky aortic valve leaflets in relation to the left main artery

Will bulky calcific leaflets compromise left main artery?

Stenting a bulky aortic valve can result in displacing a calcific nodule and a possible occlusion of the coronary ostium

This patient should be excuded