

Transcatheter aortic valve implantation with the Edwards balloon-expandable bioprosthesis

Selection of patients

*Alain Cribier, MD
University of Rouen, France*

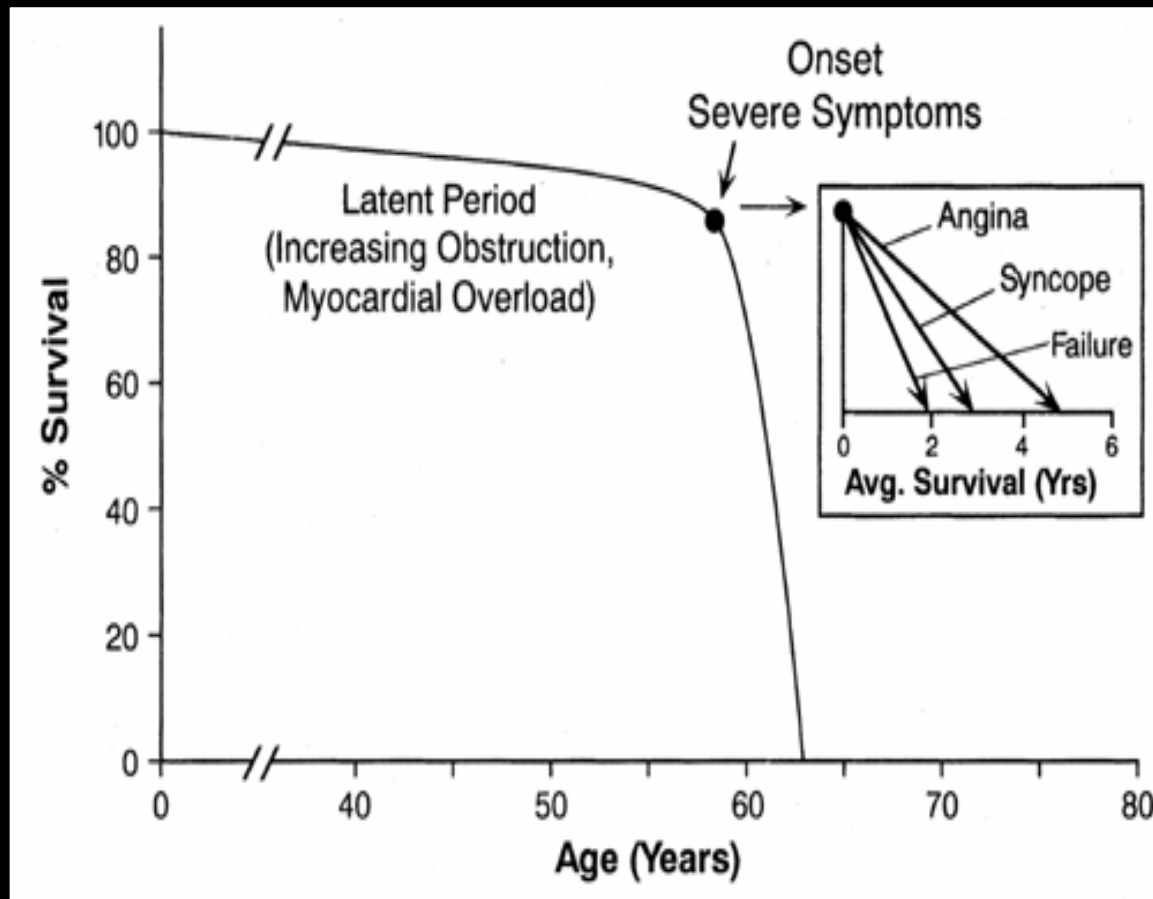
Prevalence of Aortic Stenosis

- Aortic stenosis is the most common acquired valvular disorder in developed countries
- The prevalence of calcific aortic stenosis increases with age
- Mild to severe AS is present in 2% to 4% of adults > 65 years

Aortic Stenosis / Treatment

- AVR improves the survival of elderly patients with severe AS, and patients aged > 80 years experience benefits similar to younger patients.
- Surgery is not always offered to elderly patients who might benefit from it.

Valvular Aortic Stenosis In Adults (Average Course)



“Surgical intervention should be performed promptly once even...minor symptoms occur”¹

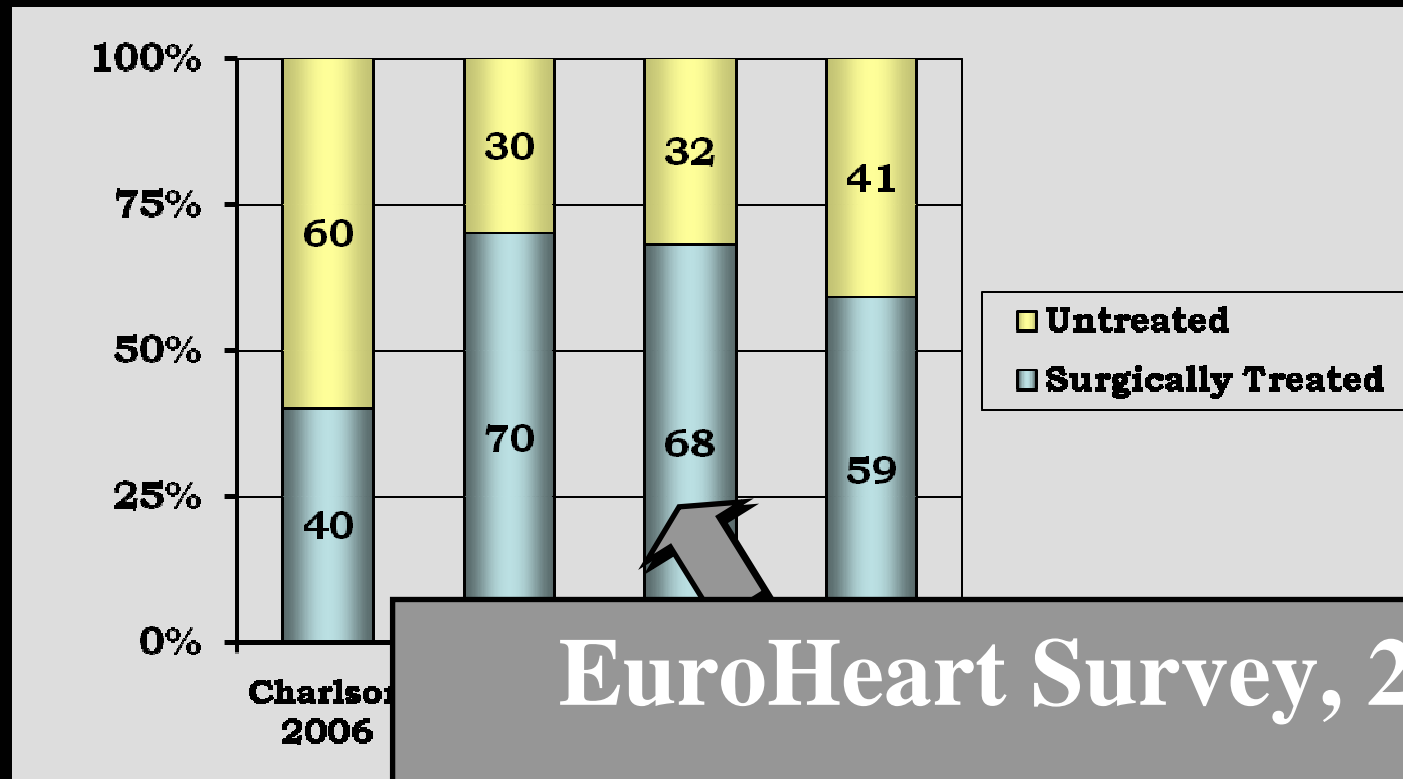
Chart: Ross J Jr, Braunwald E. Aortic stenosis. *Circulation* 1968;38 (Suppl 1)

1 C.M. Otto. Valve Disease: Timing of Aortic Valve Surgery. *Heart* 2000

Chart:: Ross J Jr, Braunwald E. Aortic stenosis. *Circulation*. 1968;38 (Suppl 1):61-7.

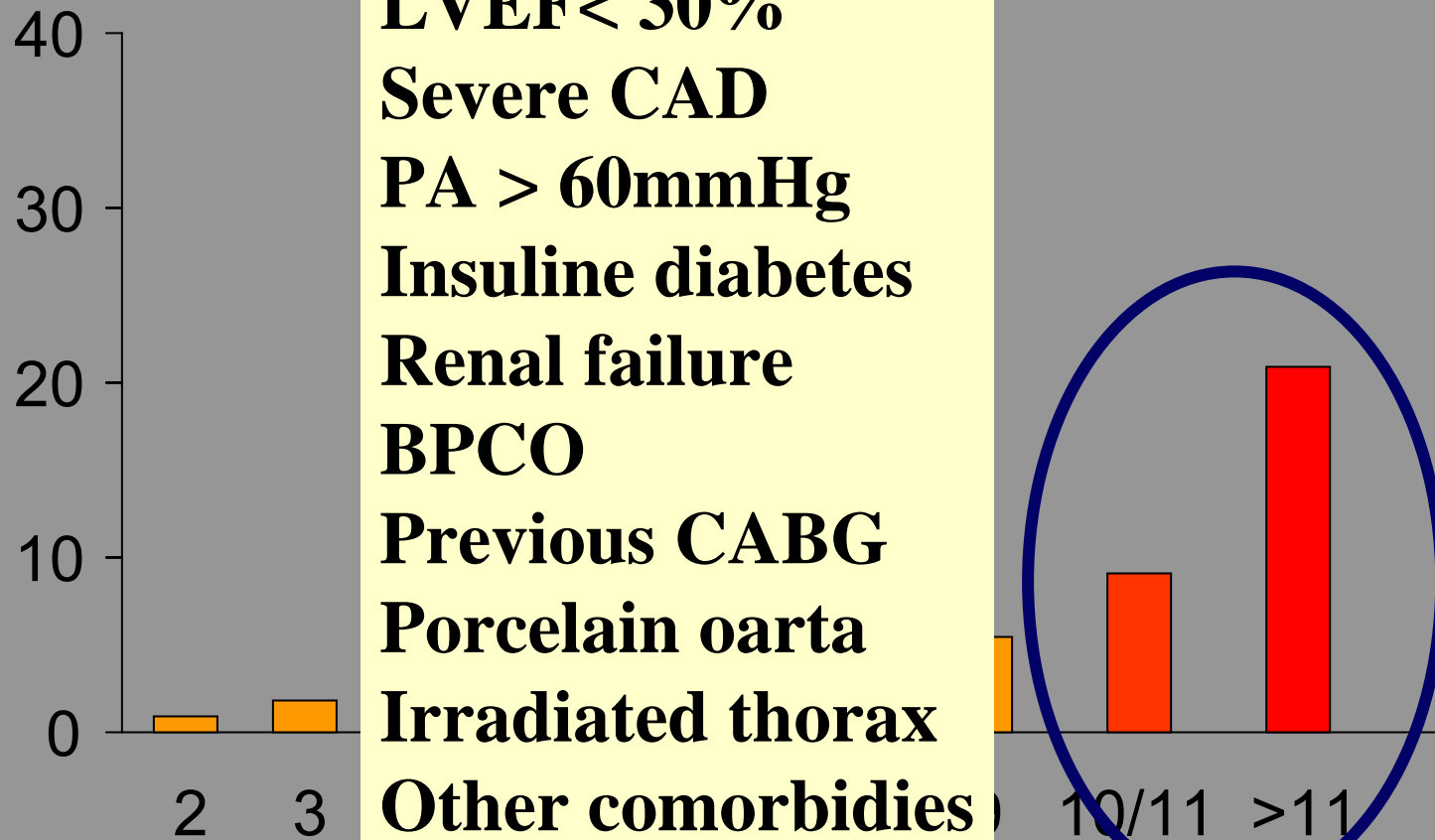
Many Patients Are Not Surgically Treated!

Severe AS* - Percent of Patients Treated



EuroHeart Survey, 2004
5001 Patients in 92 centres from 25 countries
31.8% did not undergo intervention,
most frequently because of comorbidities

Mortality %



Risk-Classification: Euroscore

GOAL OF TRASCUTANEOUS AORTIC VALVE IMPLANTATION

« To offer a therapeutic option to patients with degenerative AS who are at very high risk for surgical valve replacement or non operable »

The CRIBIER-EDWARDS/EDWARDS-SAPIEN™ TRANSCATHETER BIOPROSTHESIS

**Cribier-Edwards™
23mm**



Untreated
Equine Tissue

**Edwards SAPIEN™
23mm, 26mm**



Treated
Bovine Tissue

The Edwards SAPIEN™ valve incorporates TFX™ treatment

Retrograde Approach

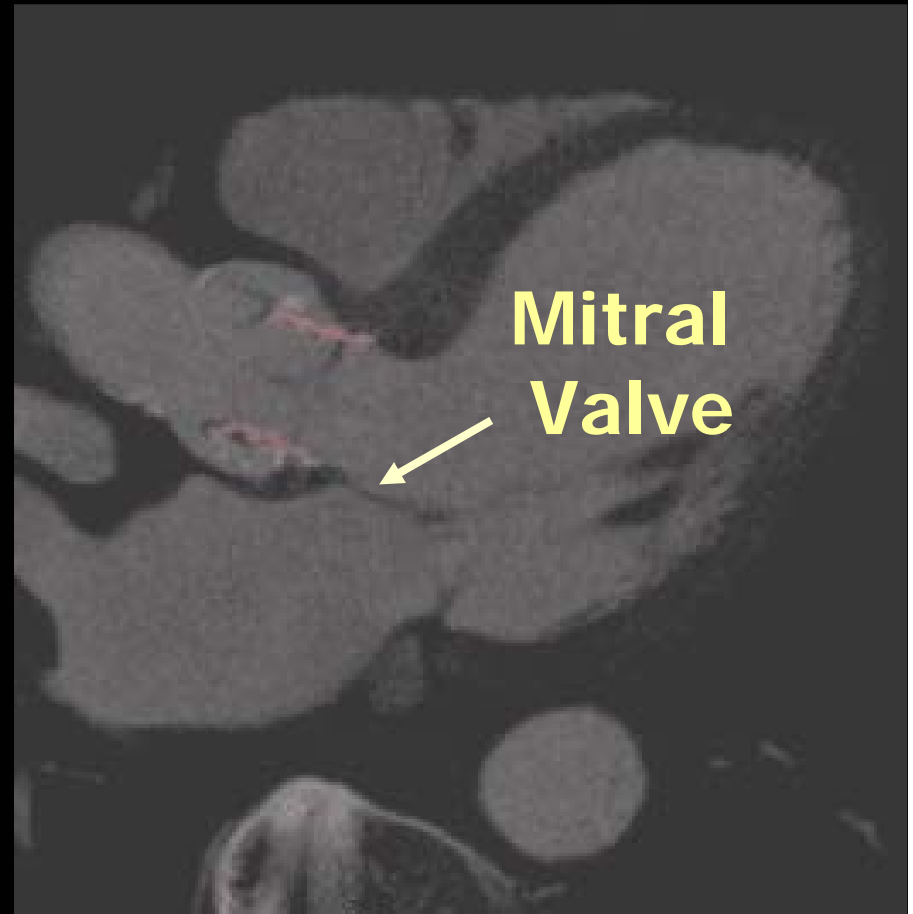
Sheath size:
22F for the 23mm valve
24F for the 26mm valve

Introducer / Loader



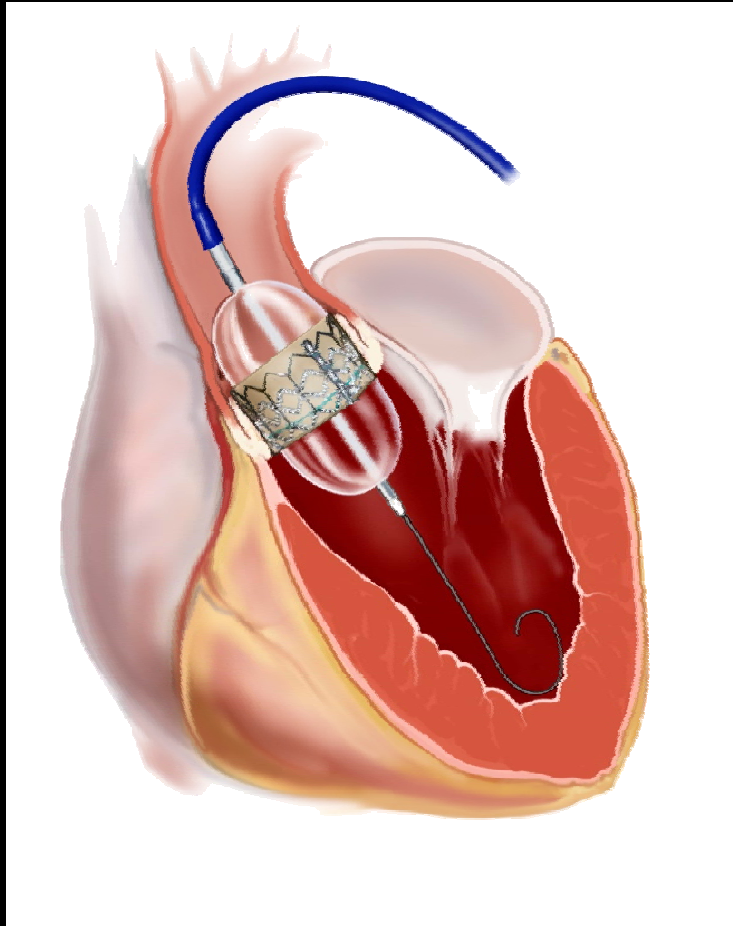
RetroFlex catheter

Scanner post-THV implantation



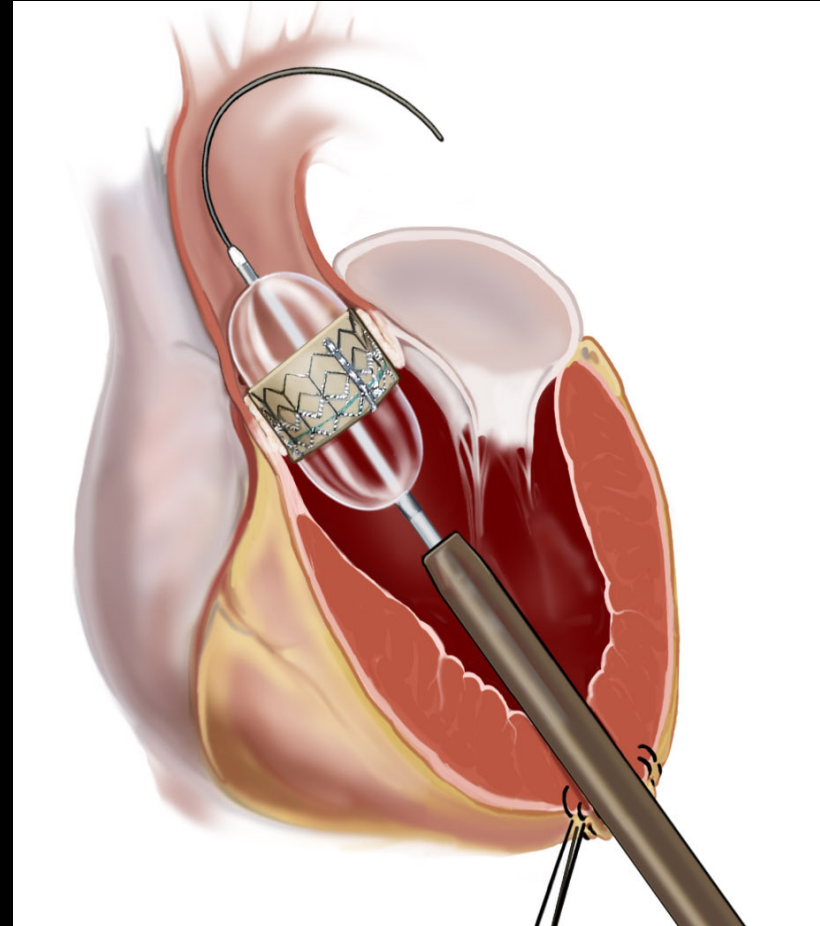
Current approaches to the aortic valve

Retrograde (since 2005)



Use of the RetroFlex catheter

Transapical (since 2005)



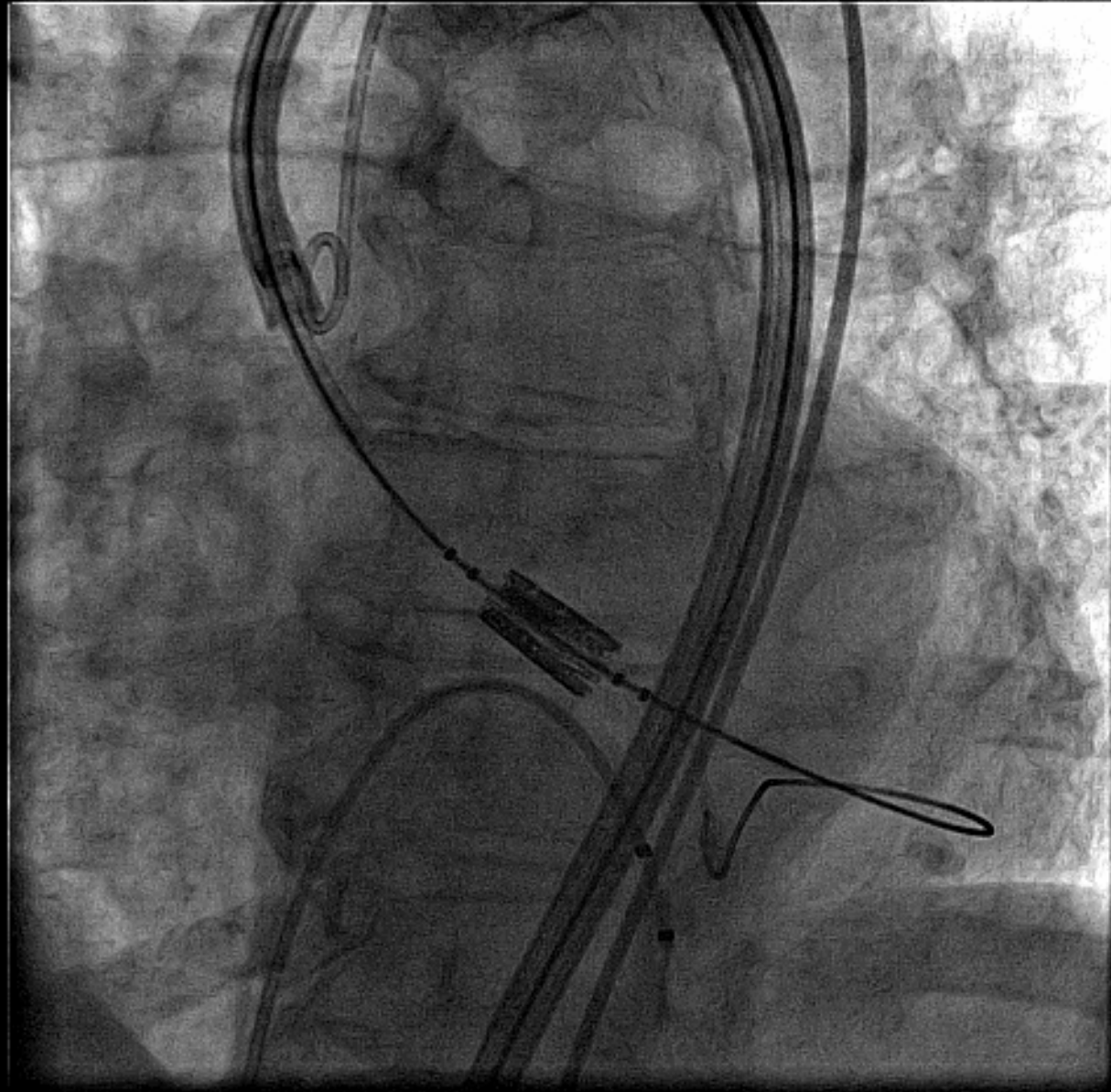
Mini-invasive surgery

Transfemoral Approach: Advancing the 22F Sheath

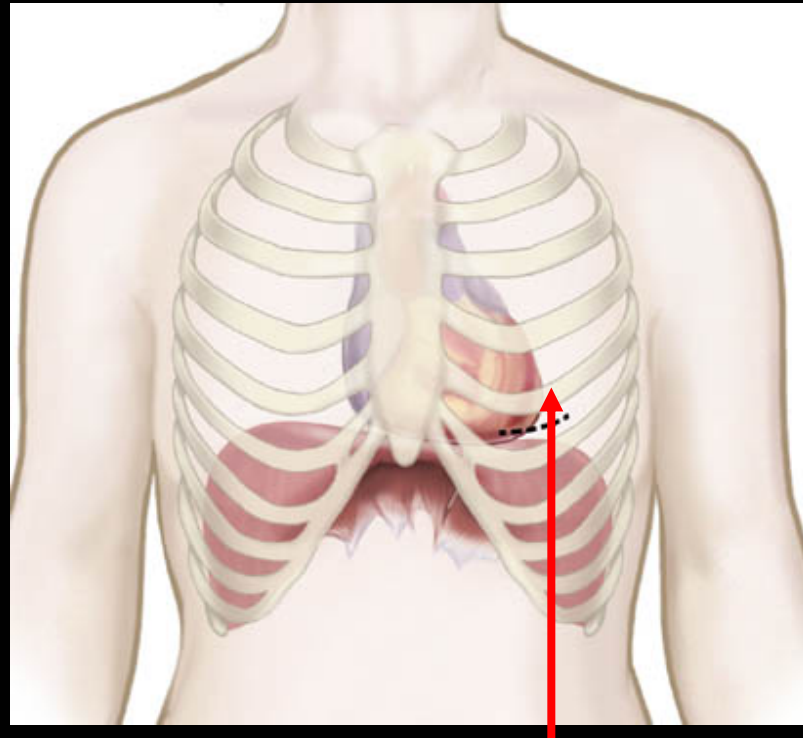


THV delivery (RVP 200/min)

LAO 15°
Cranial 10



Transapical Aortic Valve Implantation



Anterior Thoracotomy

Patient selection for THV

Two questions:

- 1) *Is the patient a good candidate?:*
Inclusion / exclusion criteria
- 2) *Route selection:*
Transfemoral or Transapical?

Inclusion criteria

Degenerative symptomatic SAS

- Area: $\leq 0.8 \text{ cm}^2$ / $\leq 0.6 \text{ cm}^2/\text{m}^2$
- **Patients with high surgical risk :**
 - Logistic Euroscore* $> 20\%$
 - STS* $> 10\%$
 - or formal surgical contraindication
- Aortic annulus (TTE or TEE) at valvular insertion site $> 16 \text{ mm}$ or $< 25 \text{ mm}$

PRE-PROCEDURAL PATIENT ASSESMENT

1) Is the patient a good candidate for THV implantation?

- Risk factors: *Calculation of STS or Euroscore*
Formal CI to thoracic/aortic surgery
- *Life expectancy > 1 year in spite of comorbidities*

2) Are Ao valve and LV suitable for THV implantation?

- *Echocardiography: TTE ± TEE*

3) How are:

- The coronary arteries: *coronary angiography*
- The aortic root: *aortogram*
- The femoro-iliac access: *abdominal aortogram*
CT -Scan

ECHOCARDIOGRAPHY: TTE and TEE ASSESSMENTS

1) Severity of aortic stenosis and AR severity

2) LV hypertrophy and function

LVEF, LVEDV, Hypertrophic or Obstructive Cardiomyopathy

1) Aortic annulus dimensions (NOT LVOT)

Critical component to evaluate THV sizing

4) Exclude patients with bulky calcified leaflets

Risk of coronary obstruction post-THV deployment

Assessment of the aortic annulus dimension

TTE

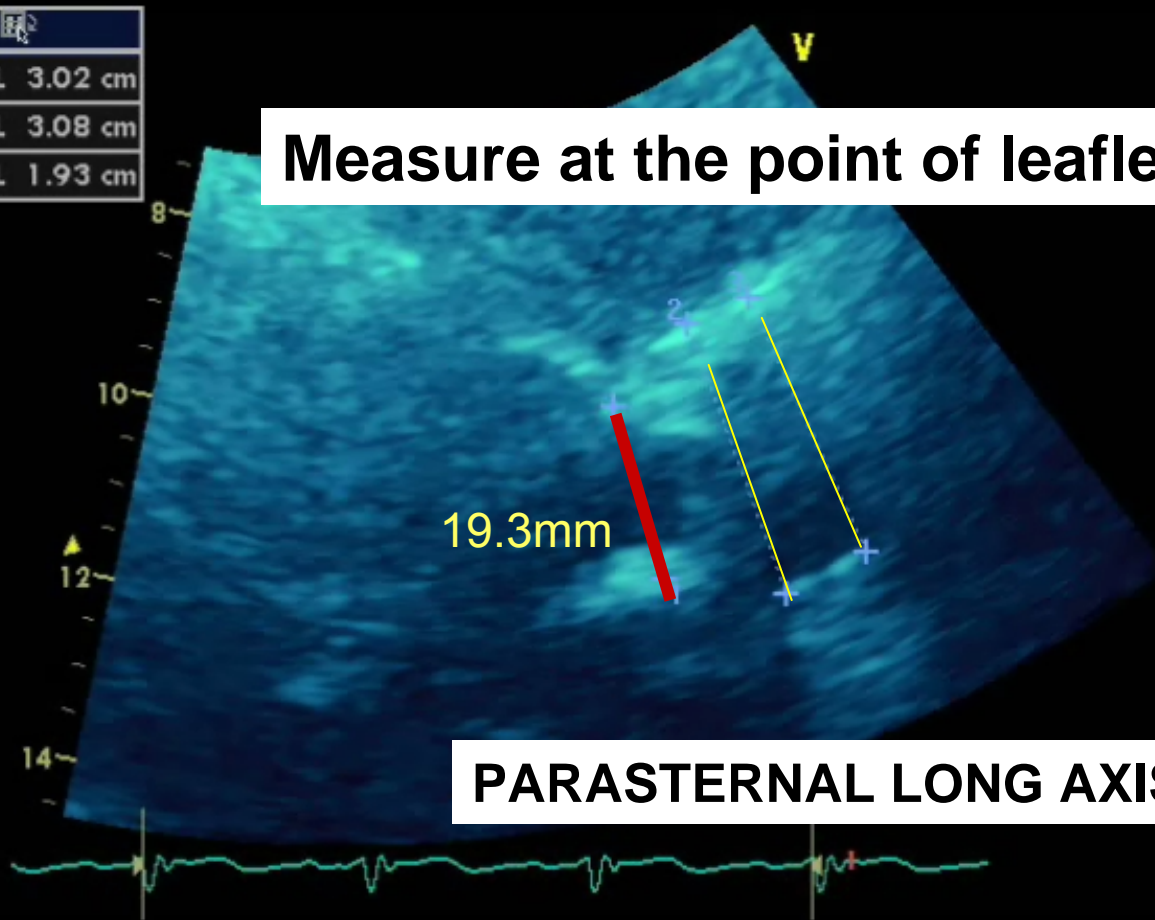
7	
3 L	3.02 cm
2 L	3.08 cm
1 L	1.93 cm

Measure at the point of leaflets insertion

19.3mm

PARASTERNAL LONG AXIS VIEW

76
HR



Assesment of the aortic annulus dimension

TEE

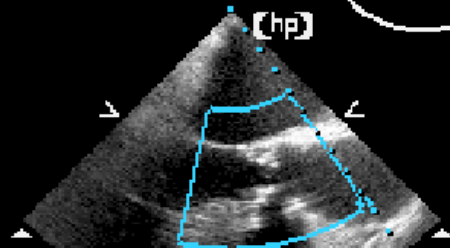
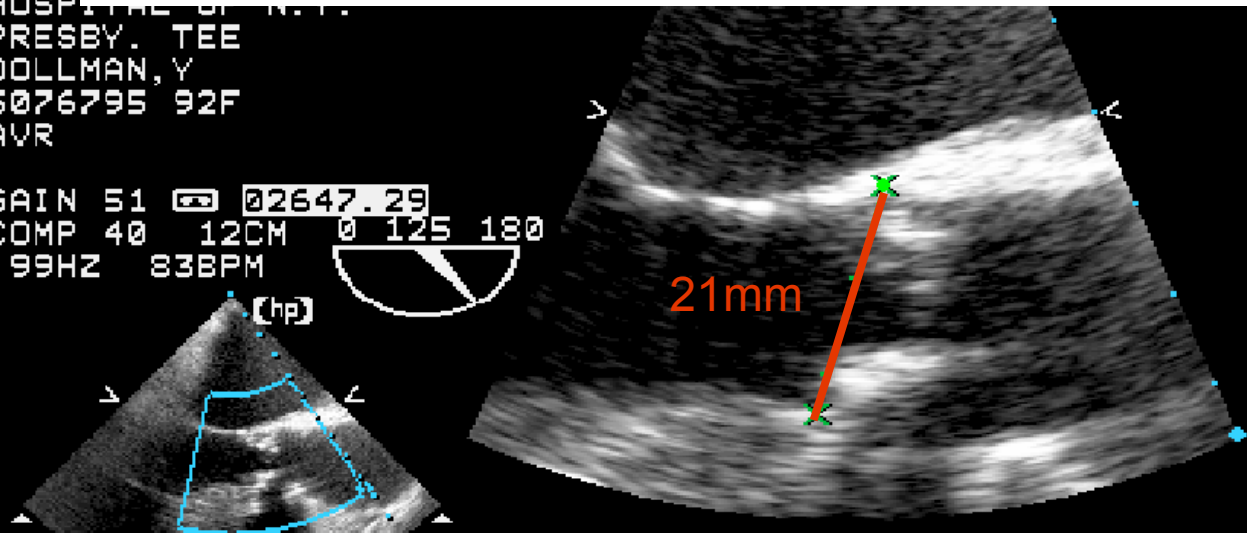
MI: 1.4 PAT T: 98.6F
T6210 TEE T: 98.8F
17 APR 06
A X DIST 2.41 cm

Length = 2.4 cm

Measure at the point of leaflets insertion

PROC
PRES
HOSP
PRESBY. TEE
DOLLMAN, Y
5076795 92F
AVR

GAIN 51 02647.29
COMP 40 12CM 0 125 180
99HZ 83BPM



TEE LONG AXIS VIEW



THV SIZING RECOMMENDATIONS

18-21mm annulus

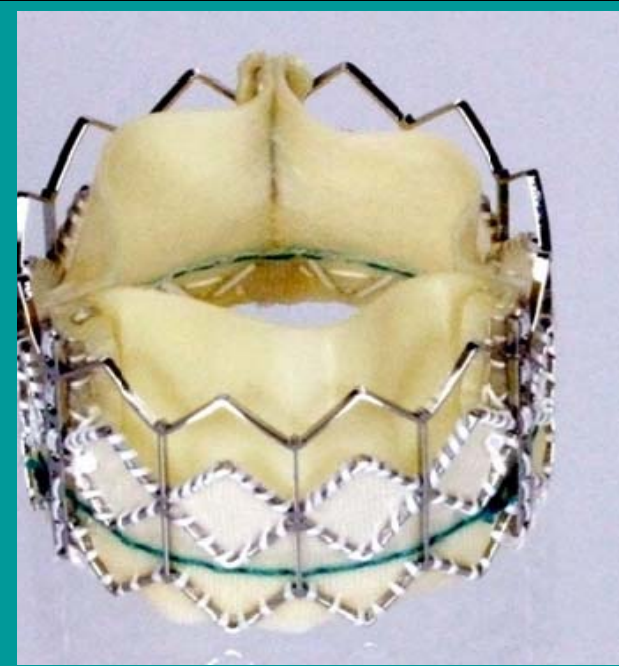
23mm size

21-25mm annulus

26mm size



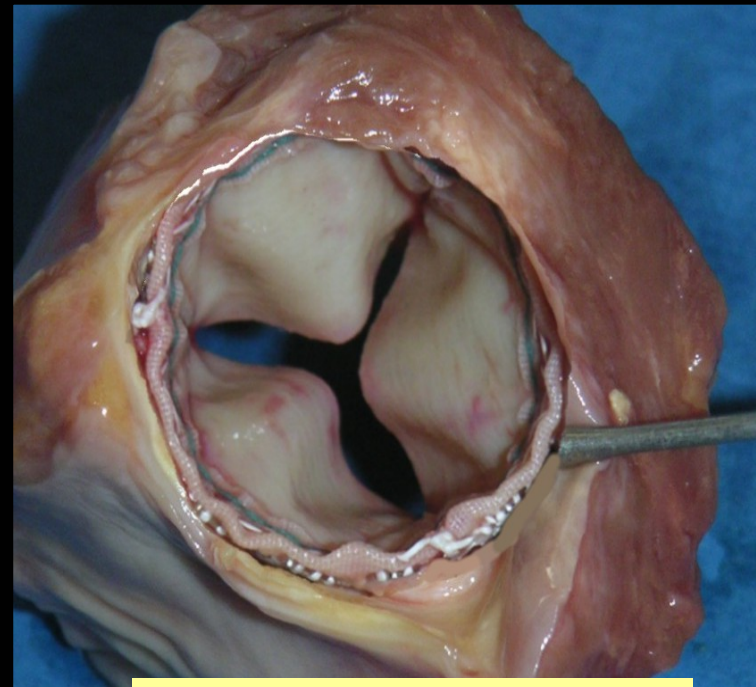
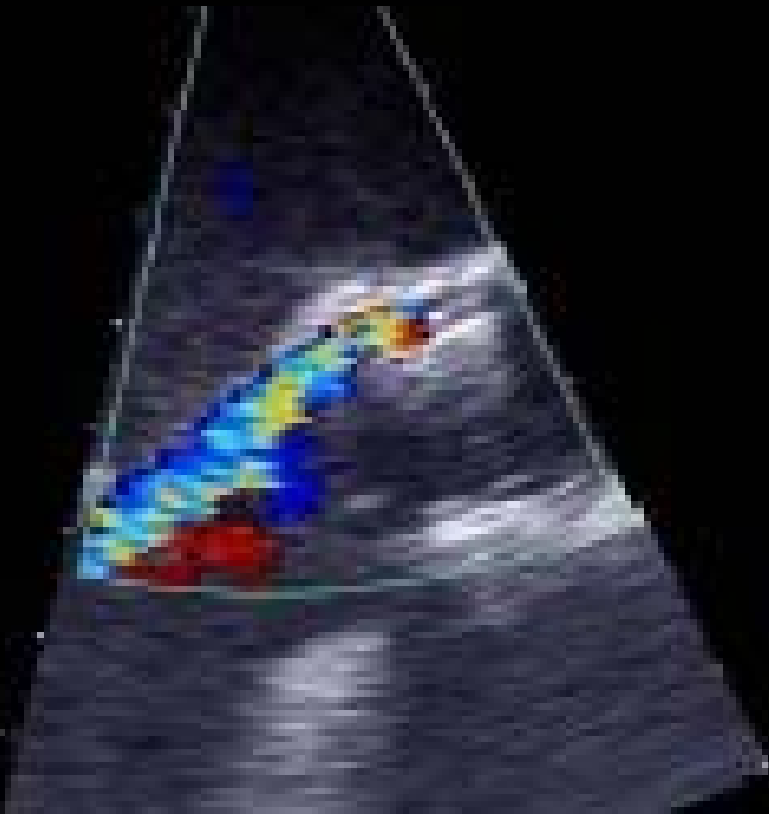
23 mm



26 mm

Accurate selection of THV size (23 or 26mm)

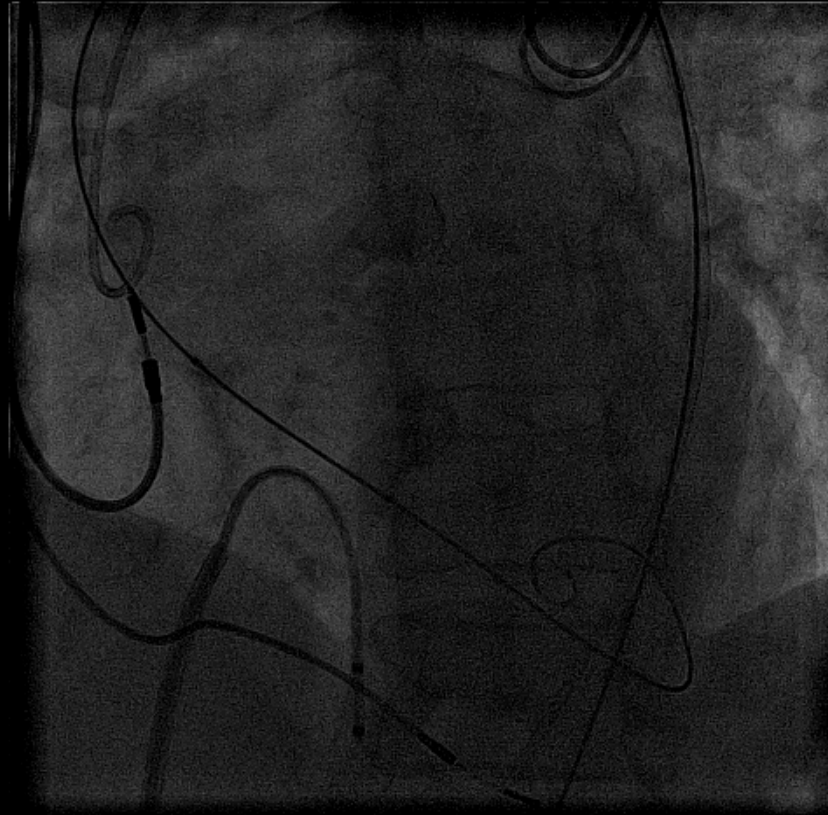
Prevention of paravalvular leaks



PHV 26mm

Borderline cases (21mm): choice of the adapted size

Aortogram during 23mm Balloon inflation



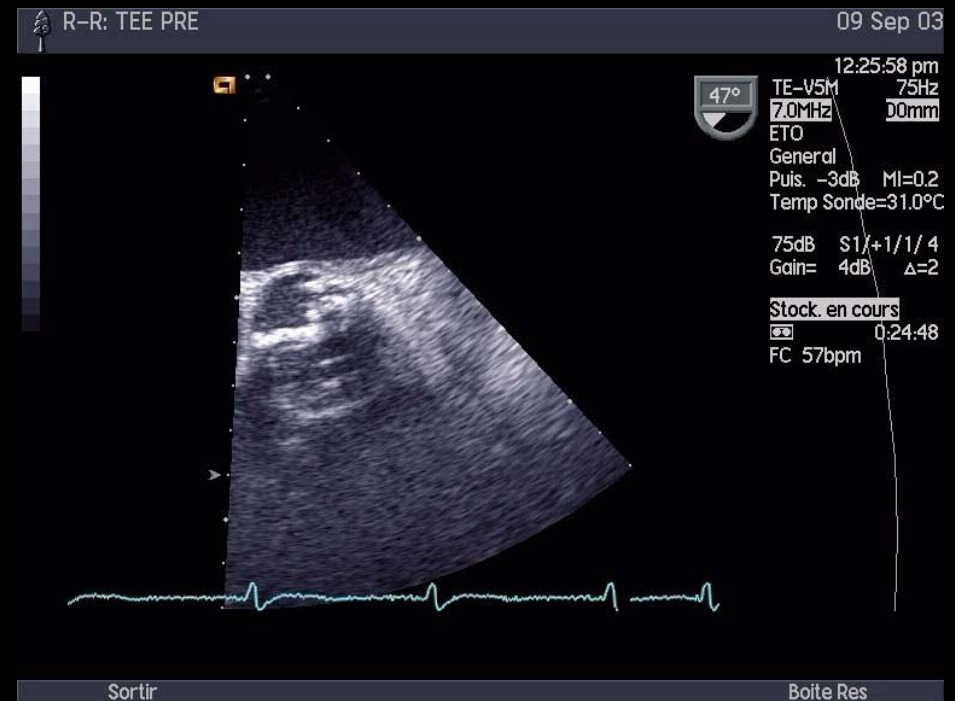
23mm THV OK



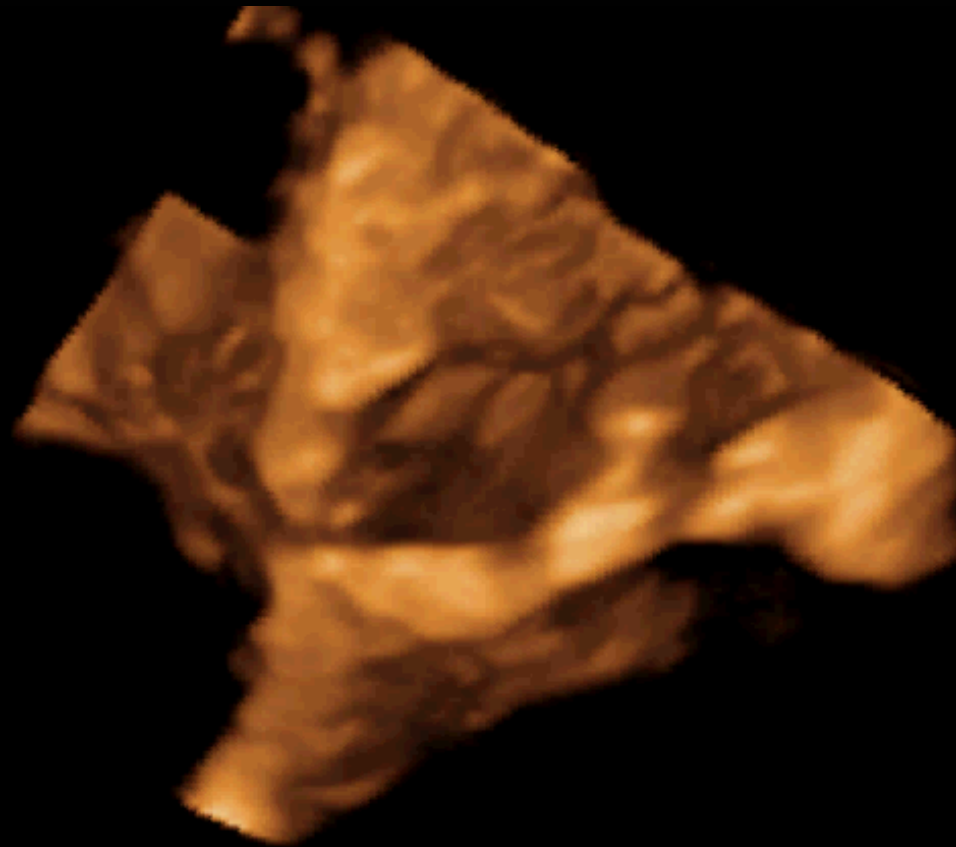
26mm THV OK

Trans Esophageal Echo

Assessment of calcium distribution over the valve



3D- ECHO

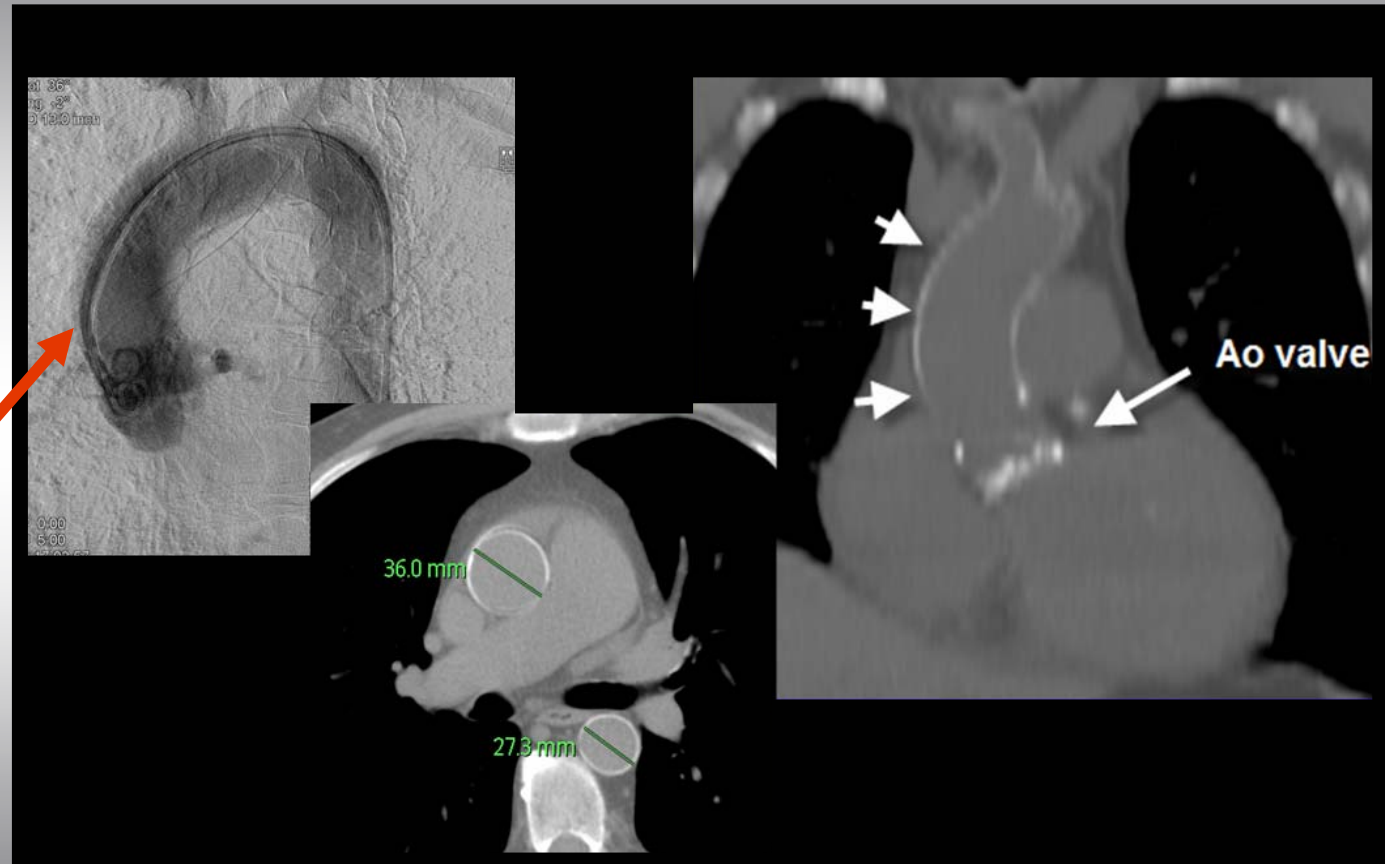


CT-SCAN

ADDITIONAL ASSESSMENTS

CT Scan

**Porcelain
Aorta**



Trans-apical approach is the best indication

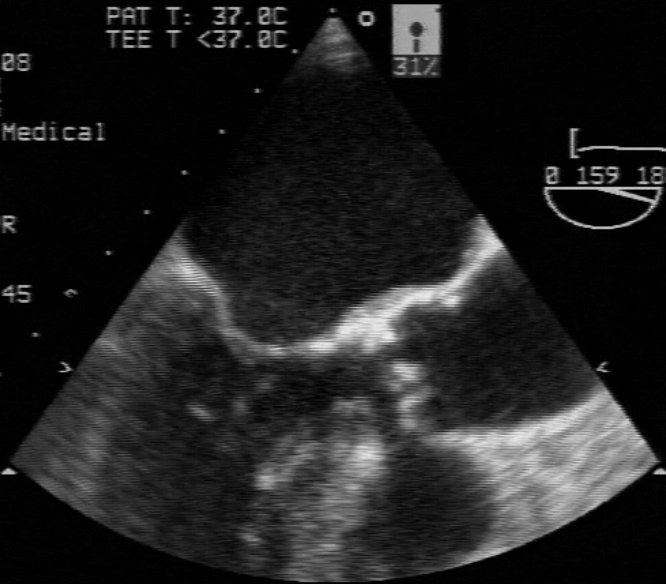
Detection of subvalvular muscular hypertrophy

MI:0.4 PAT T: 37.0C
T6210 TEE T <37.0C
18 MAR 08 31%

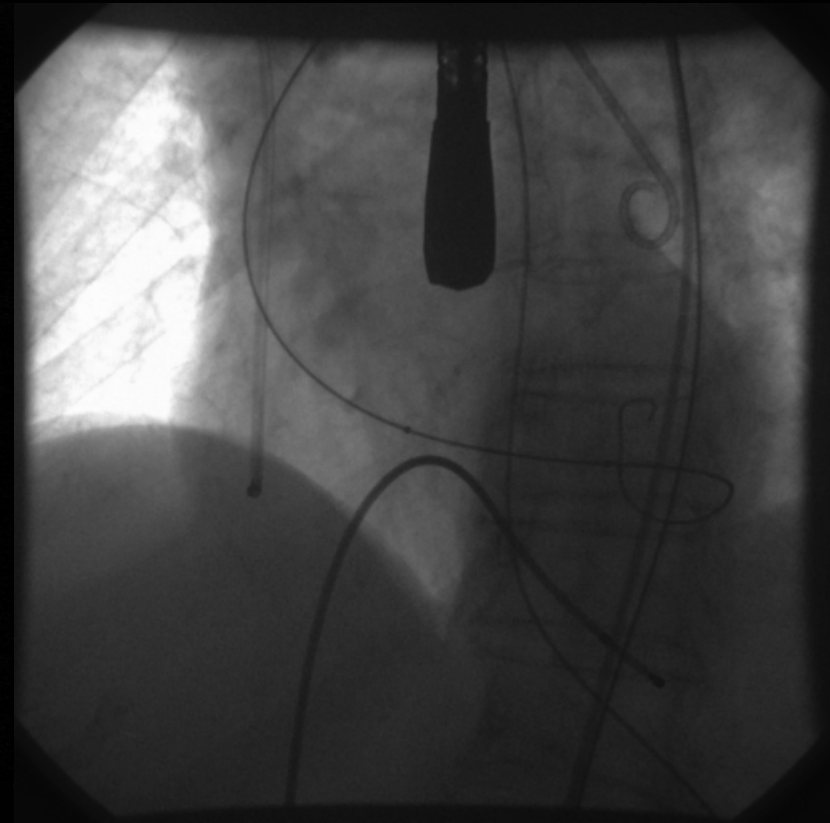
10:13:28
2/8/D/F5
Philips Medical
Systems
ECHO
SAV
PERC AVR

0:00:45
GAIN 43
COMP 70
86BPM
10CM
75HZ

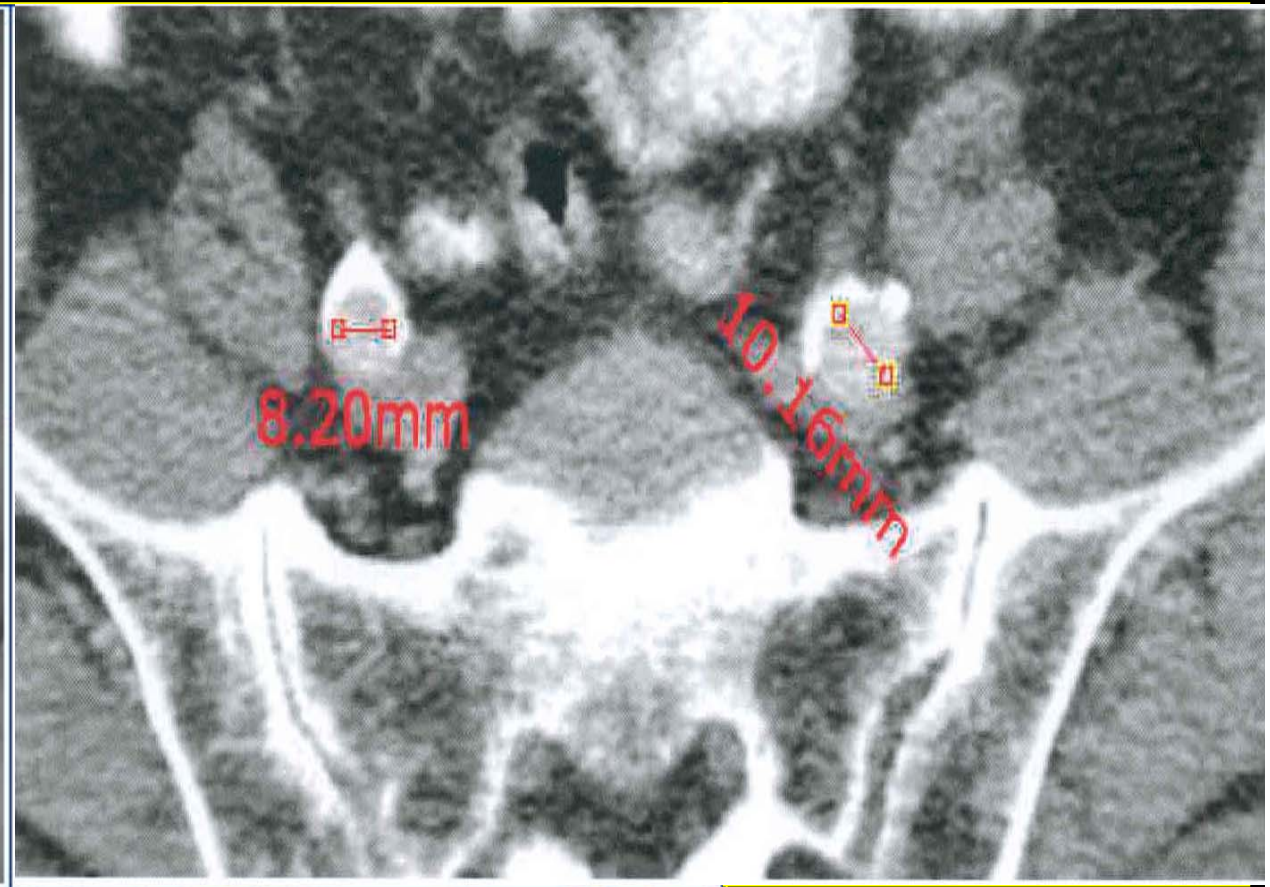
P R
4 7
0.72
SEC



P 8



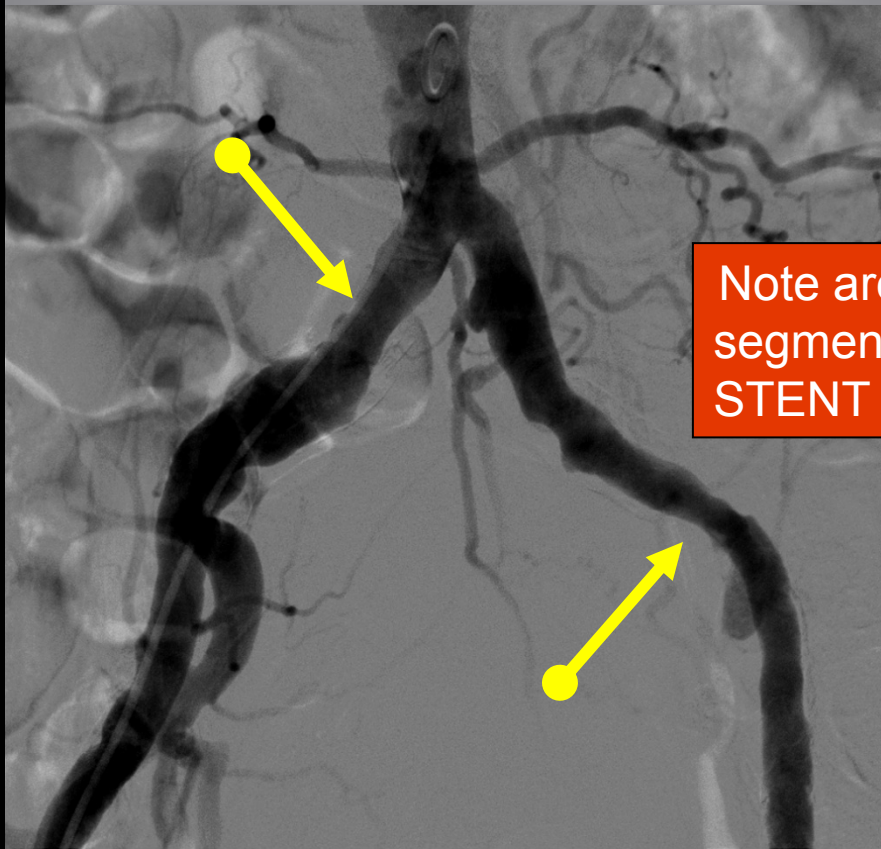
Angiography and CT-scan for evaluation of the ilio-femoral axis



AORTO-ILIAC ANGIOGRAM

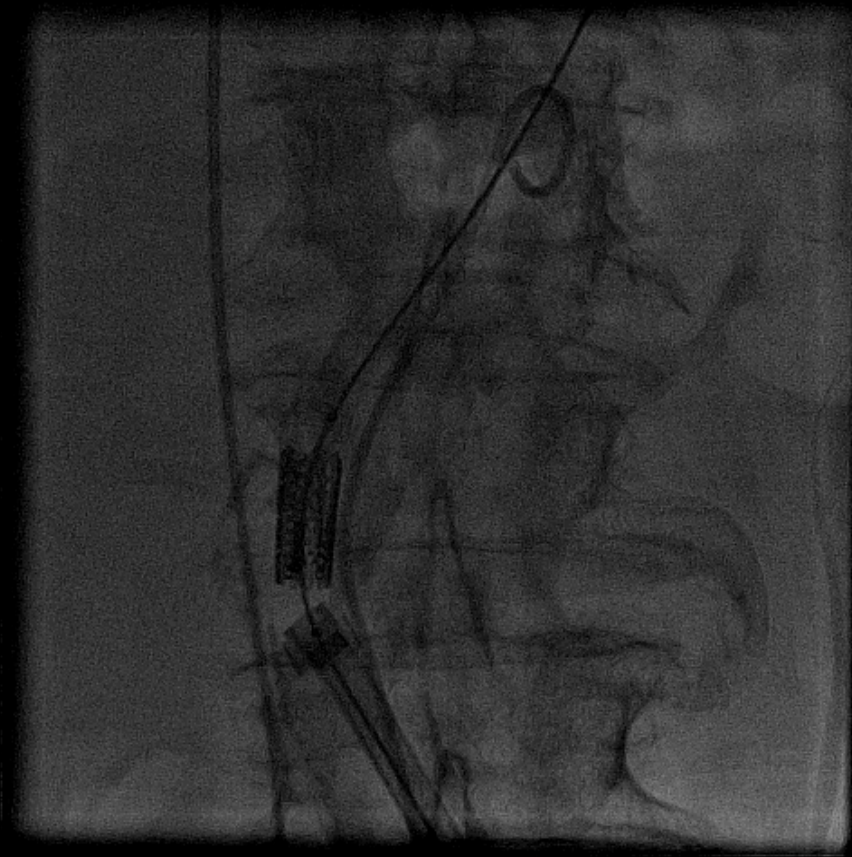
Focal lesions

CASE STUDY : MINOR LUMINAL LESIONS



Note areas of narrowing, however, short vessel segments with lesser diameter may be acceptable
STENT IMPLANTATION CAN BE INDICATED

Femoro-iliac complications



CONCLUSIONS

- Successful placement of T.H.V. depends on patient selection, procedural performance, and total cooperation of cardiologists, surgeons, echocardiographers, radiologists, anesthesiologists, nurses and technicians involved, *for the selection of patient as well as for the procedure itself*
- ▶ T.H.V. should be performed in carefully selected centers that have been well trained and have an active cardiac surgery program