

ADVANCES IN CARDIOVASCULAR ARRHYTHMIES & ADVANCEMENTS AND INNOVATIONS IN  
CARDIOLOGY

Torino: 20 - 22 October 2011

## Session IV

### Aortic Valve Implantation: Part I

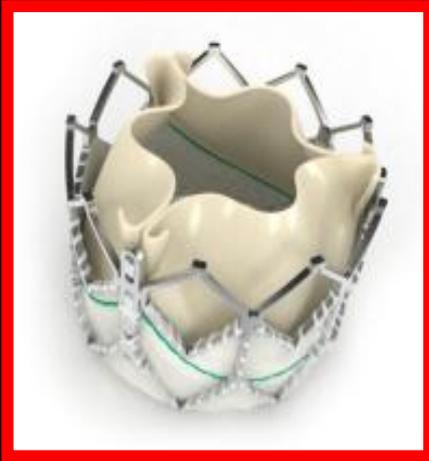
# Transcatheter Aortic Valve therapy: tips & trick

Speaker - 20'

**Antonio Colombo**

*Centro Cuore Columbus and  
S. Raffaele Scientific Institute, Milan, Italy*

# Percutaneous Aortic Valve



***Edwards SAPIEN XT***



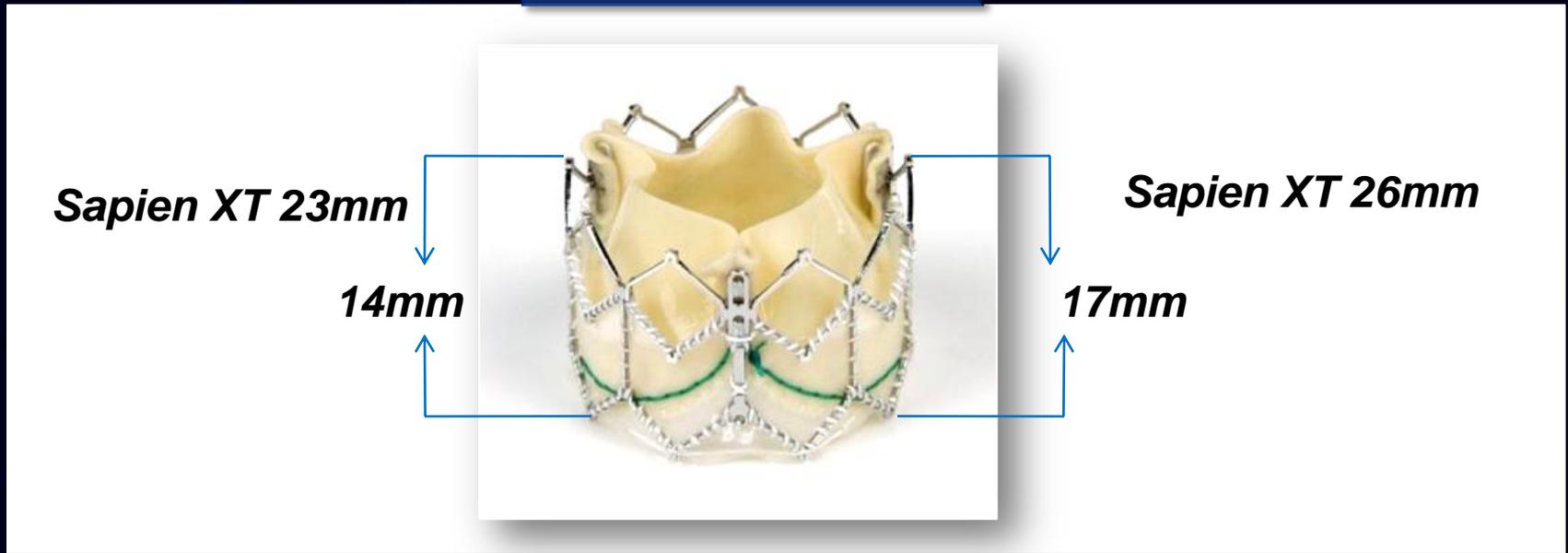
***CoreValve ReValving® System***

- ***Bovine valve on balloon-expandable stent frame***
- ***23 mm and 26 mm***
- ***18F and 19F (NovaFlex delivery system)***
- ***26F sheath (Ascendra Transapical delivery system)***

- ***Porcine valve in self-expandable nitinol stent***
- ***26 mm and 29 mm***
- ***18F sheath***
- ***Repositionable***

# SAPIEN XT

## SAPIEN XT Transcatheter Valve



- **High radial strength Cobalt Chromium Frame**
- **Bovine scallop leaflets, similar to those used in Carpentier PERIMOUNT™**
- **ThermaFix™ Anti-calcification Treatment**
- **20mm, 23mm, 26mm, 29mm**
- **Low profile NovaFlex™ Catheter (18F)**

# *Sapien XT + NovaFlex Delivery System*



**18 or 19 F profile: internal diameter**



# IMPLANTATION OF THE COREVALVE REVALVING SYSTEM



1: base  
2: mid segment  
3: outflow

5 cm

Central coaptation\*

Nadir leaflets

Skirt (12 mm high)

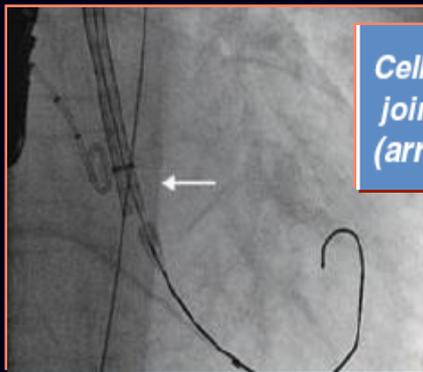
Cell (8 mm high)

**Current inflow sizes**  
26 mm and 29 mm

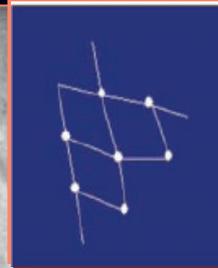
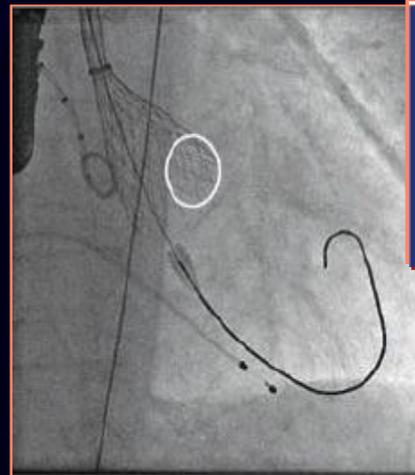
Each cell (diamond) has 3 joints (distance between joints is 4 mm)

**\*Diameter of frame at central coaptation**

26 mm:	22 mm
29 mm:	24 mm



Cells in collapsed state - joints seen as a row (arrow)



Cell = 3 joints:  
- at the base  
- at the mid segment  
- at the top

Joints are 4 mm apart  
Total height of cell: 8 mm

## Screening and decision making

Multislice CT with ecg-gating and contrast injection to evaluate: annulus, coronaries, aorta, iliacs and femorals arteries

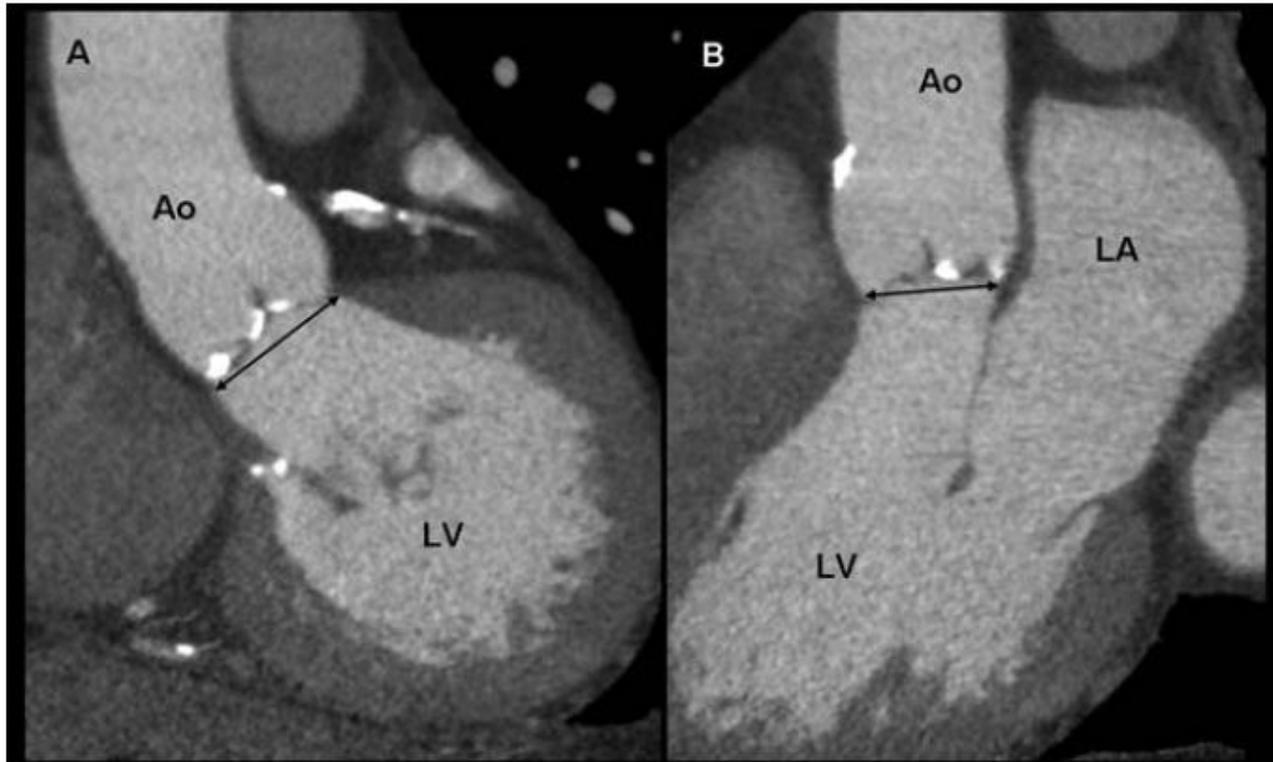
Transesophageal echo to evaluate: annulus, ventricular function

Coronary arteriography when needed

# Aortic valve sizing

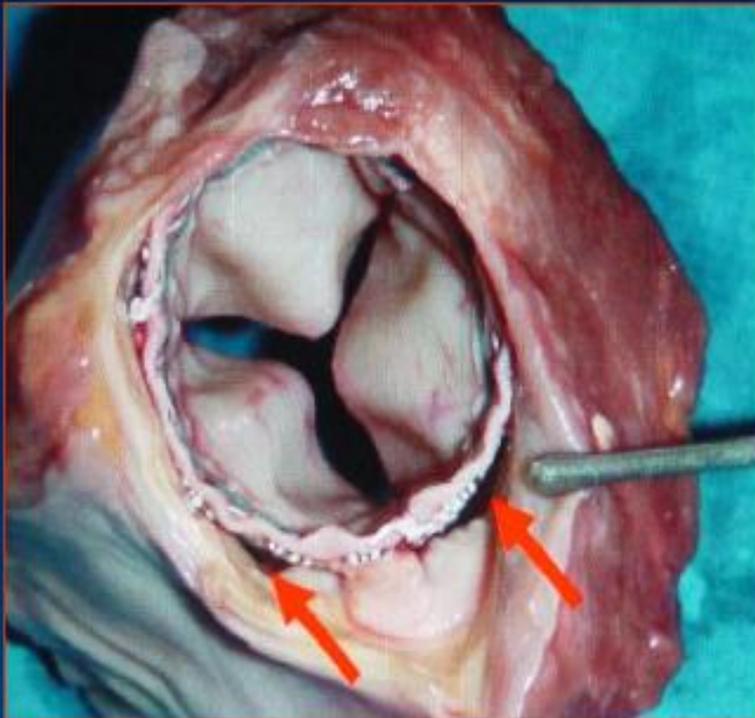
*Coronal: Right-Left*

*Sagittal: Anterior-Posterior*

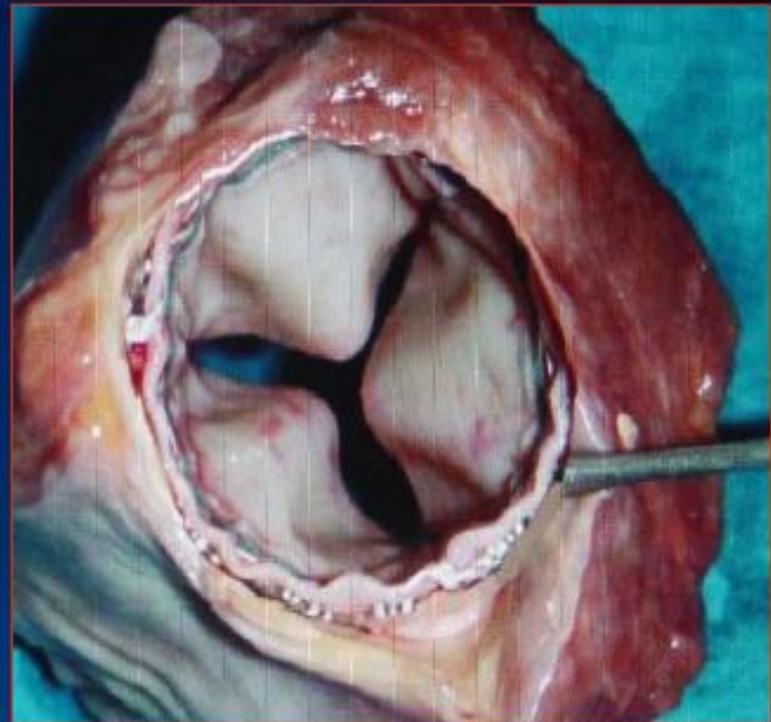


***By MDCT the aortic annulus is elipsoid with the coronal diameter larger than the sagittal diameter***

# Larger size valve: rationale

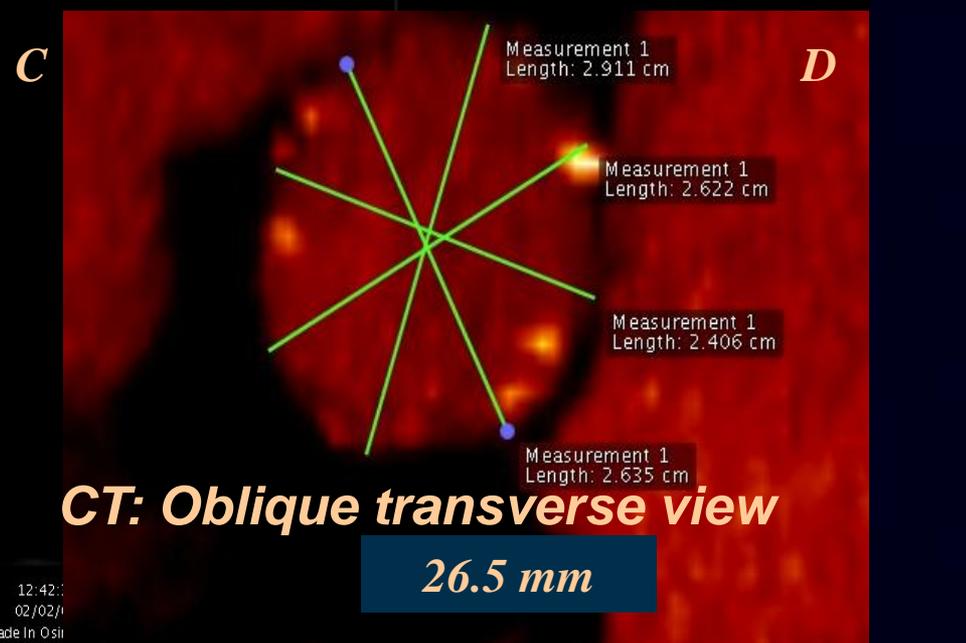
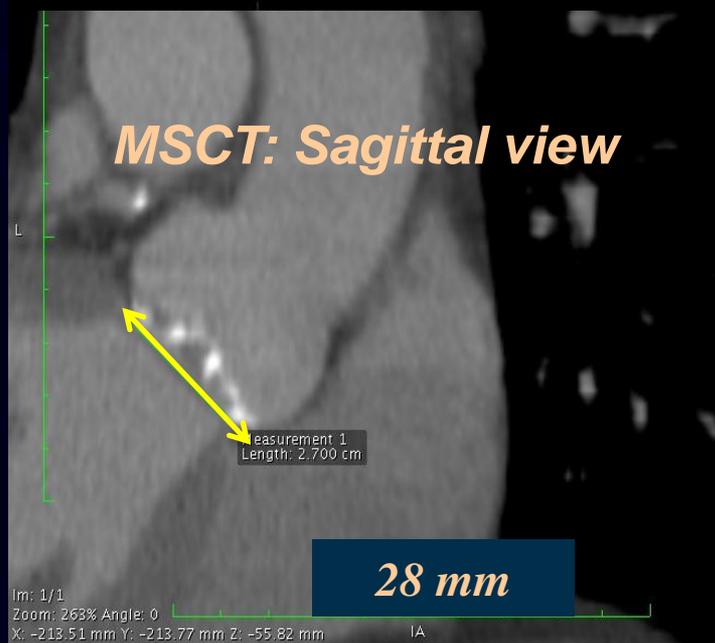
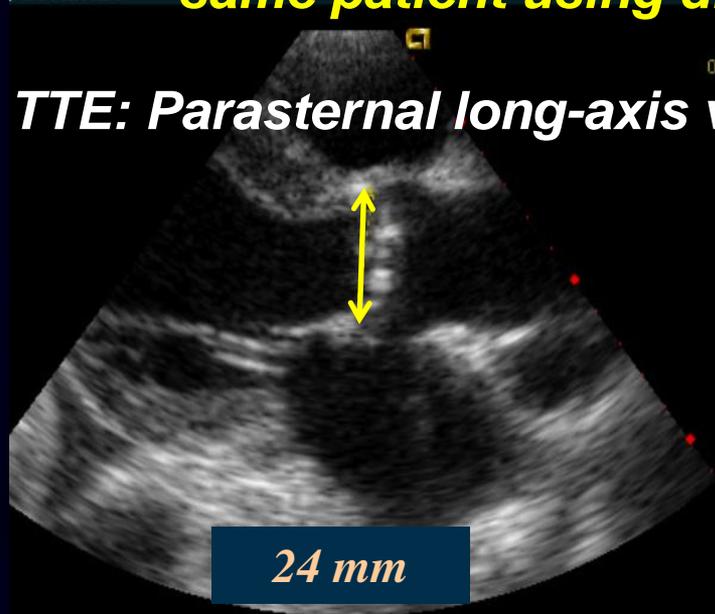


**PHV23MM**



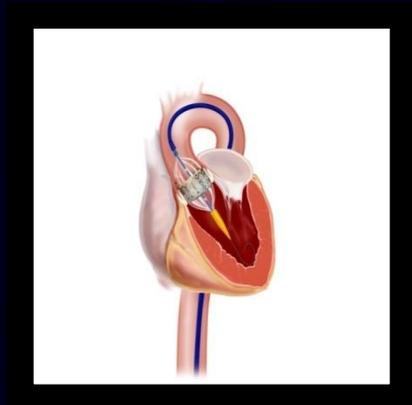
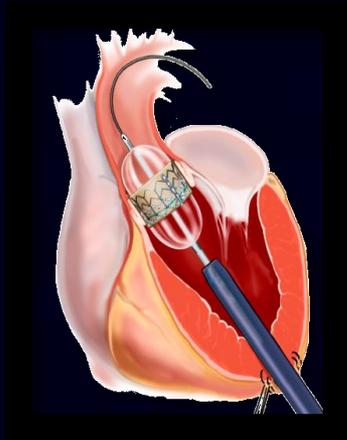
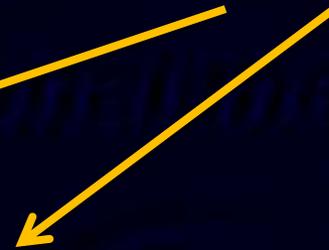
**PHV26MM**

# The variation in annulus size measurements made in the same patient using different investigative modalities.



# Edwards SAPIEN™/SAPIEN XT

# CoreValve ReValving®



**Trans-apical**

**Trans-femoral**

**Trans-aortic**

**Trans-axillary**

# Do we need Transesophageal Echo during the procedure ?

TE echo and TT Echo should be available in the room with an experienced operator

More monitoring and more on-line data means understanding unexpected complications, faster and appropriate interventions. We currently use TEE at the end of the implantation to evaluate the degree of residual AI and decide if postdilate. Echo distinguish perivalvular from central AI

M

# *Sapien or CoreValve*

## *CoreValve :*

*With tortuous vessels , borderline femoral or iliac size*

*Annulus between 25-27 mm*

*Bicuspid aortic valve*

*Very asymmetric aortic annulus*

*Uncertain annular size*

*Need for axillary implantation*

*In other cases Sapien*

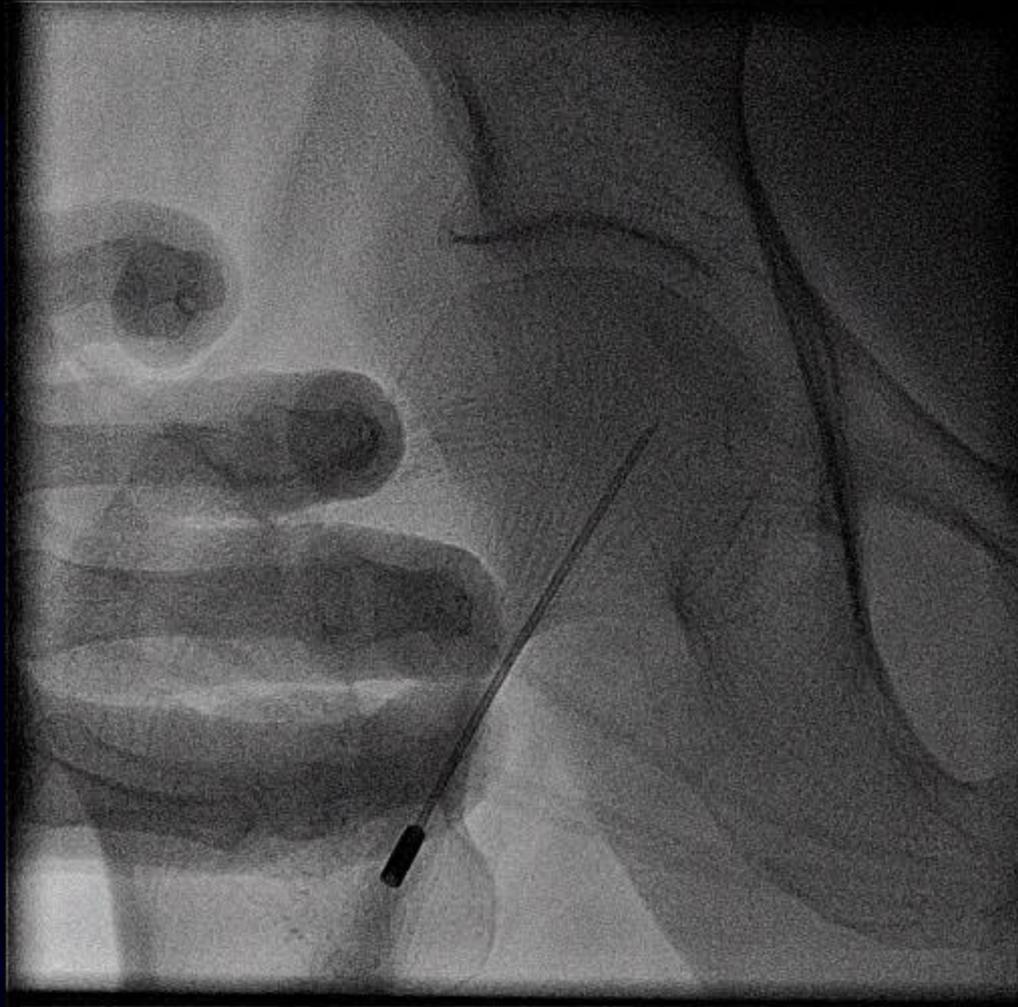
# Procedure - Screening



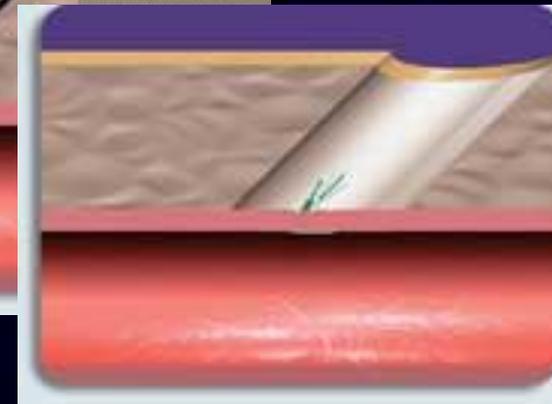
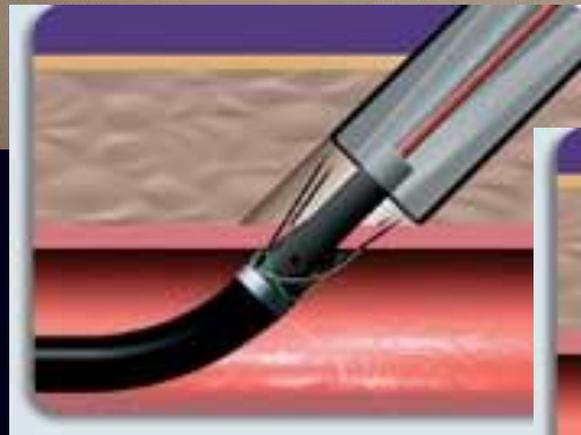
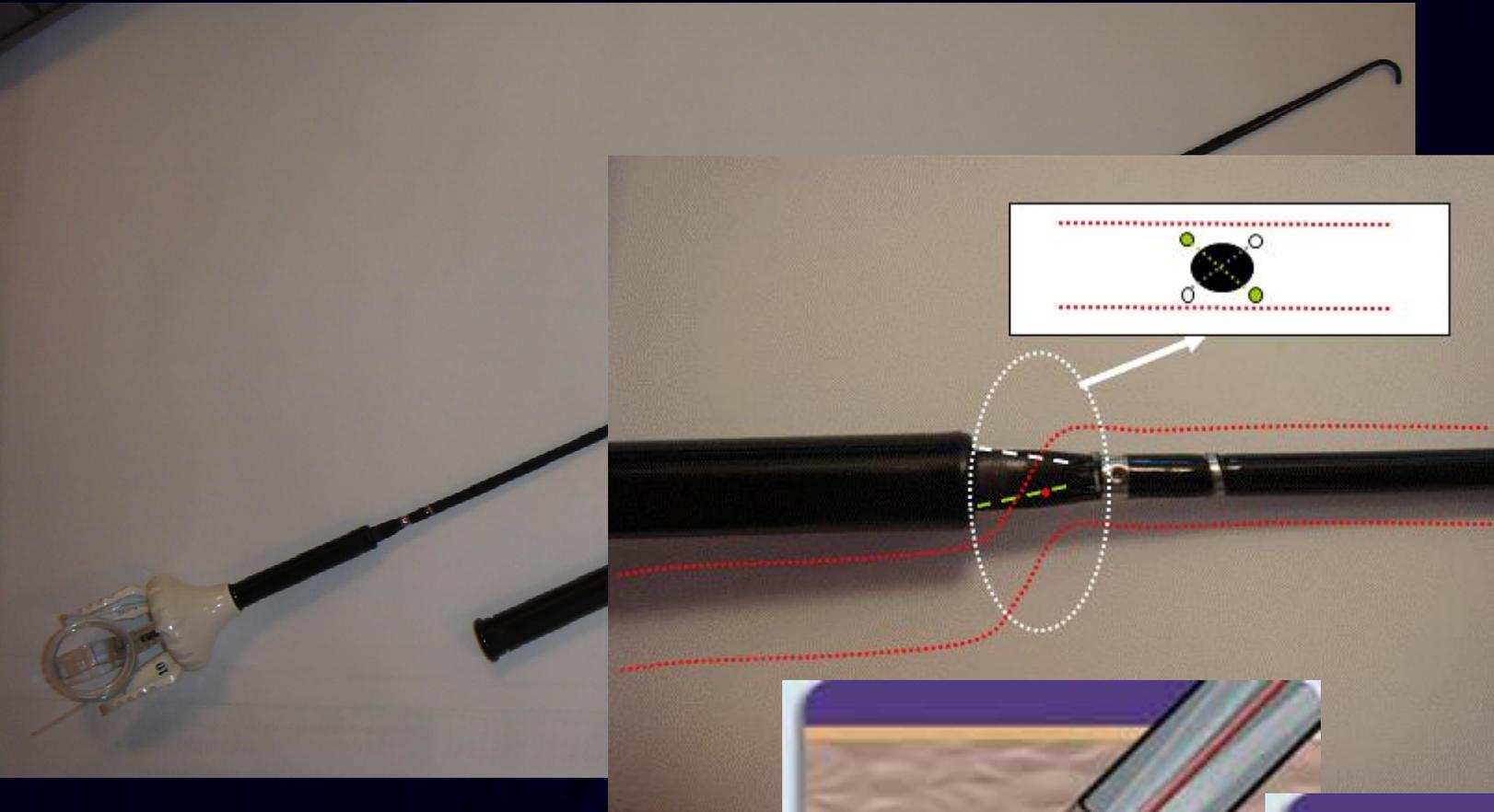
- Iliac-femoral access assessed by MSCT and by quantitative angiography
  - ; Femoral artery at the access size:
    - ; > 6 - 7mm for 18-19 F
    - ; Evaluate Calcium and possible elasticity of the vessels



# Correct puncture site



# Prostar XL 10 French





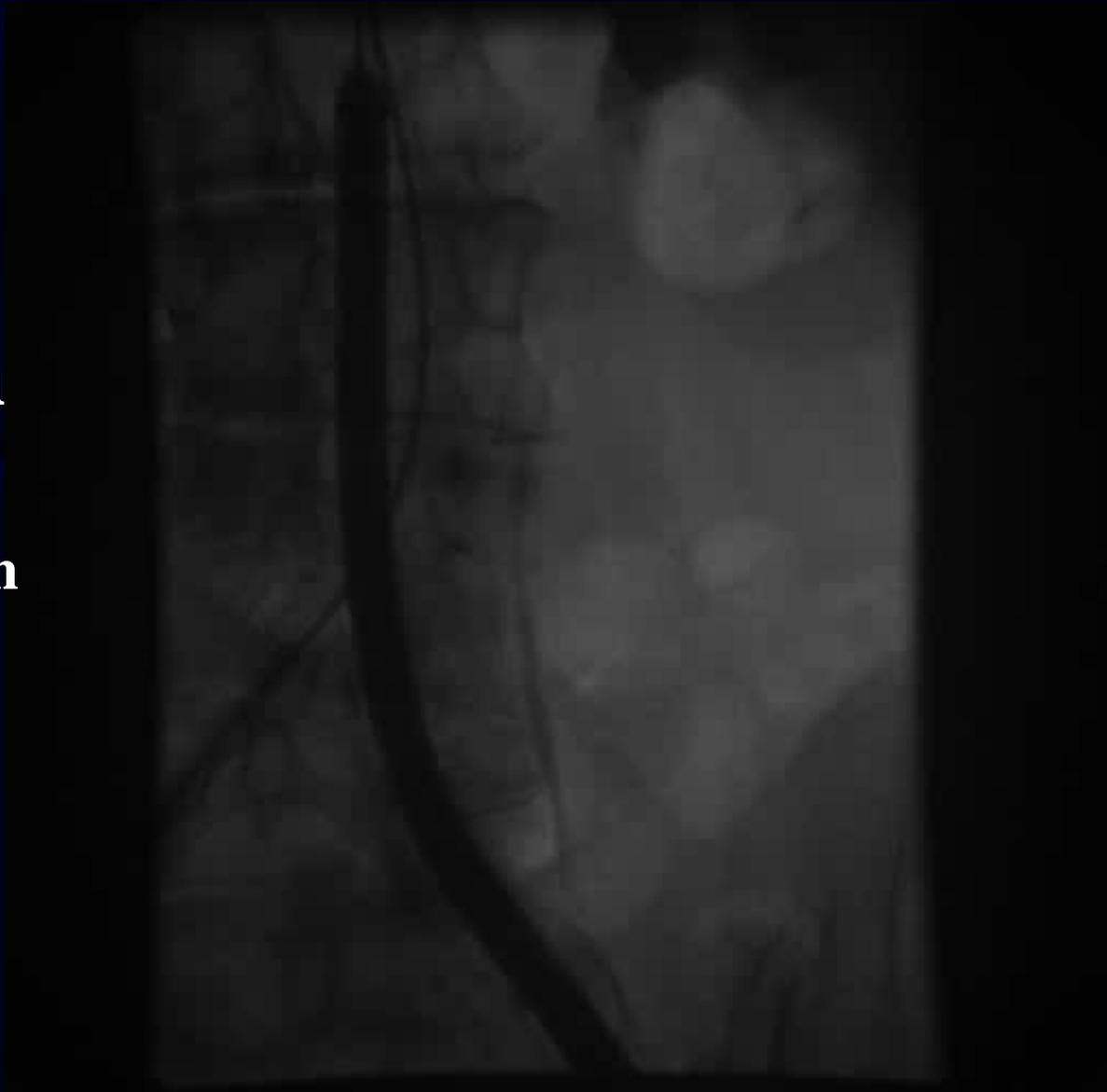
**Prostar 10XL  
after 9 F pre-  
dilatation**

# *One way to lower vascular complications*



***14-16 French becomes 18-19 French, the sheaths are  
available for CoreValve and for Sapien***

**Solo Path**  
**20 F. ID**  
**Inflated 20 atm**



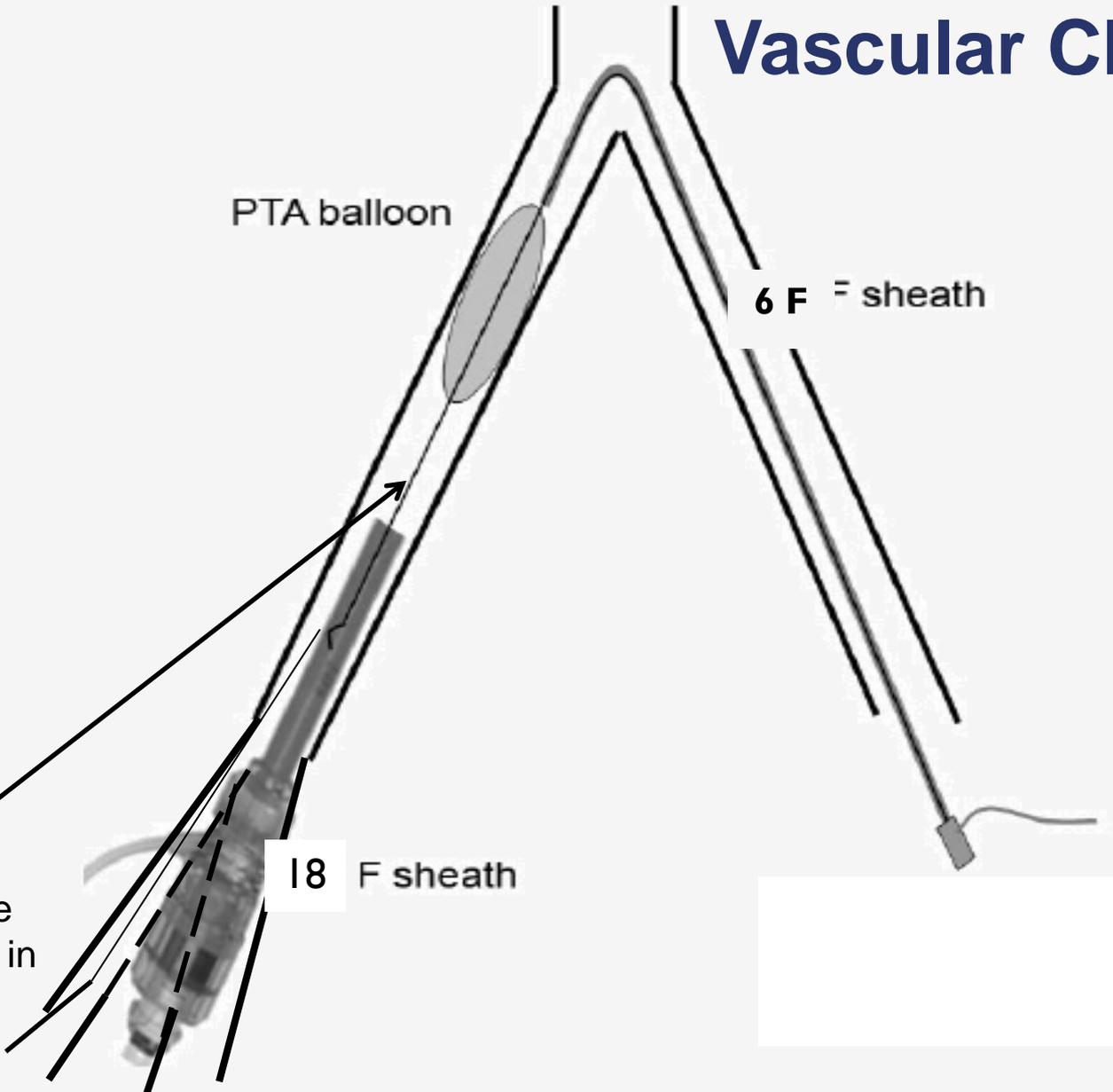
# Vascular Closure

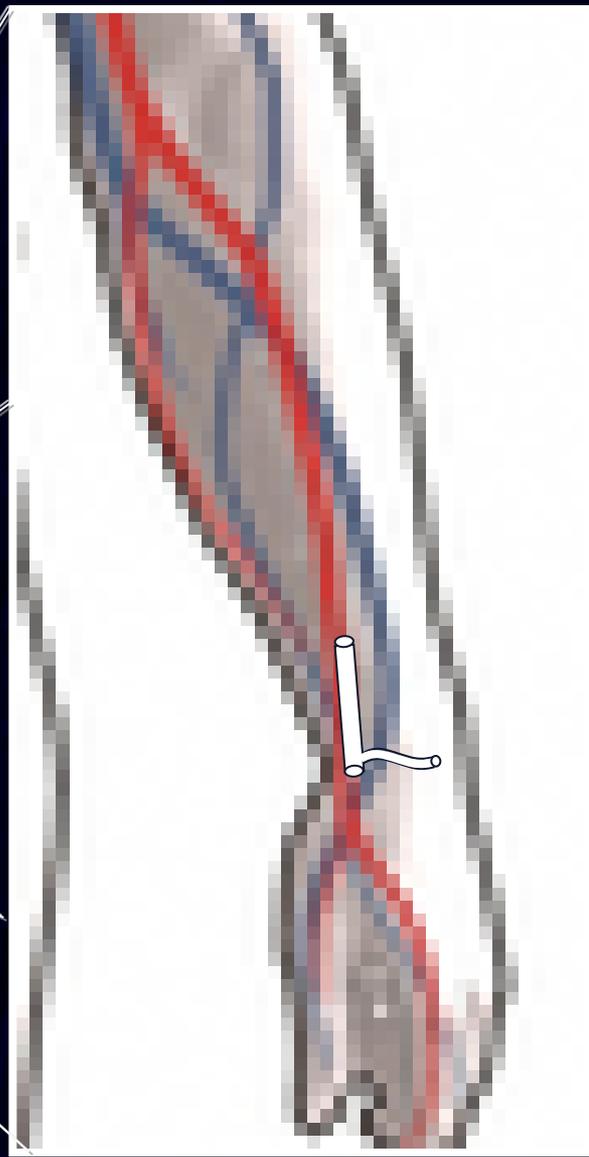
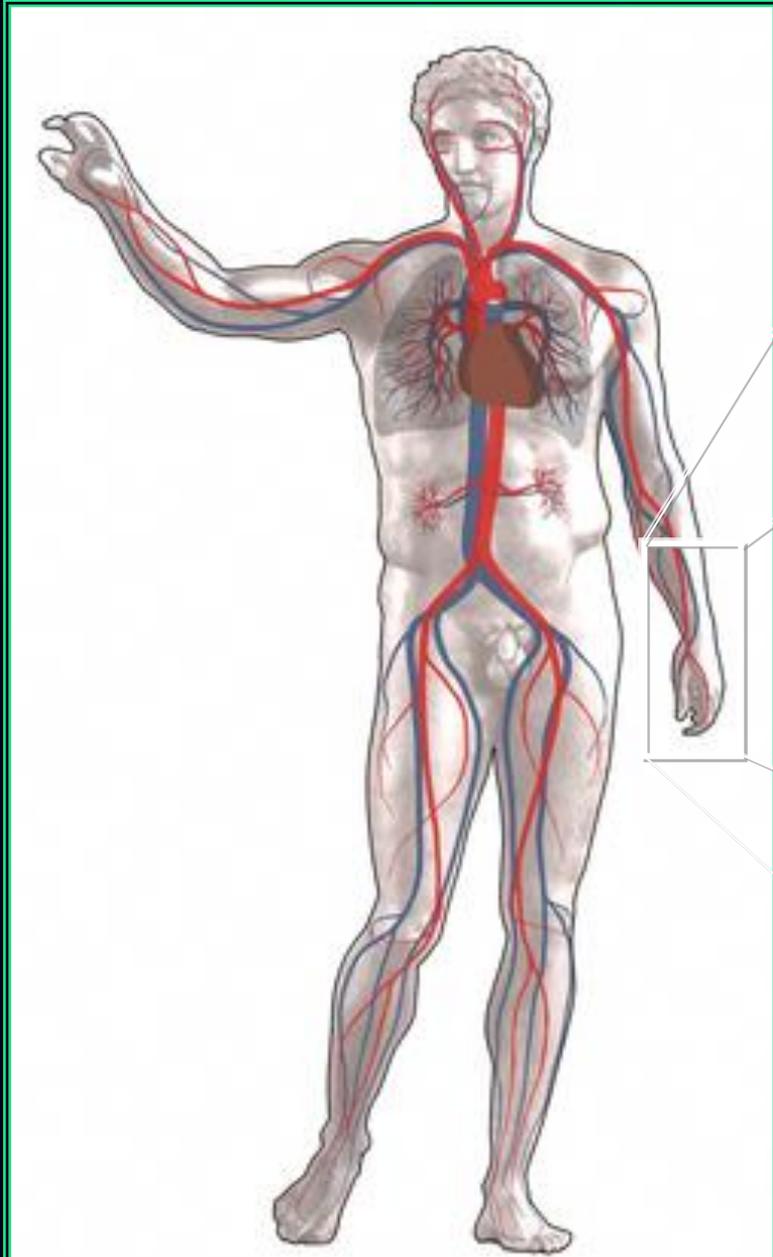
PTA balloon

6 F = sheath

18 F sheath

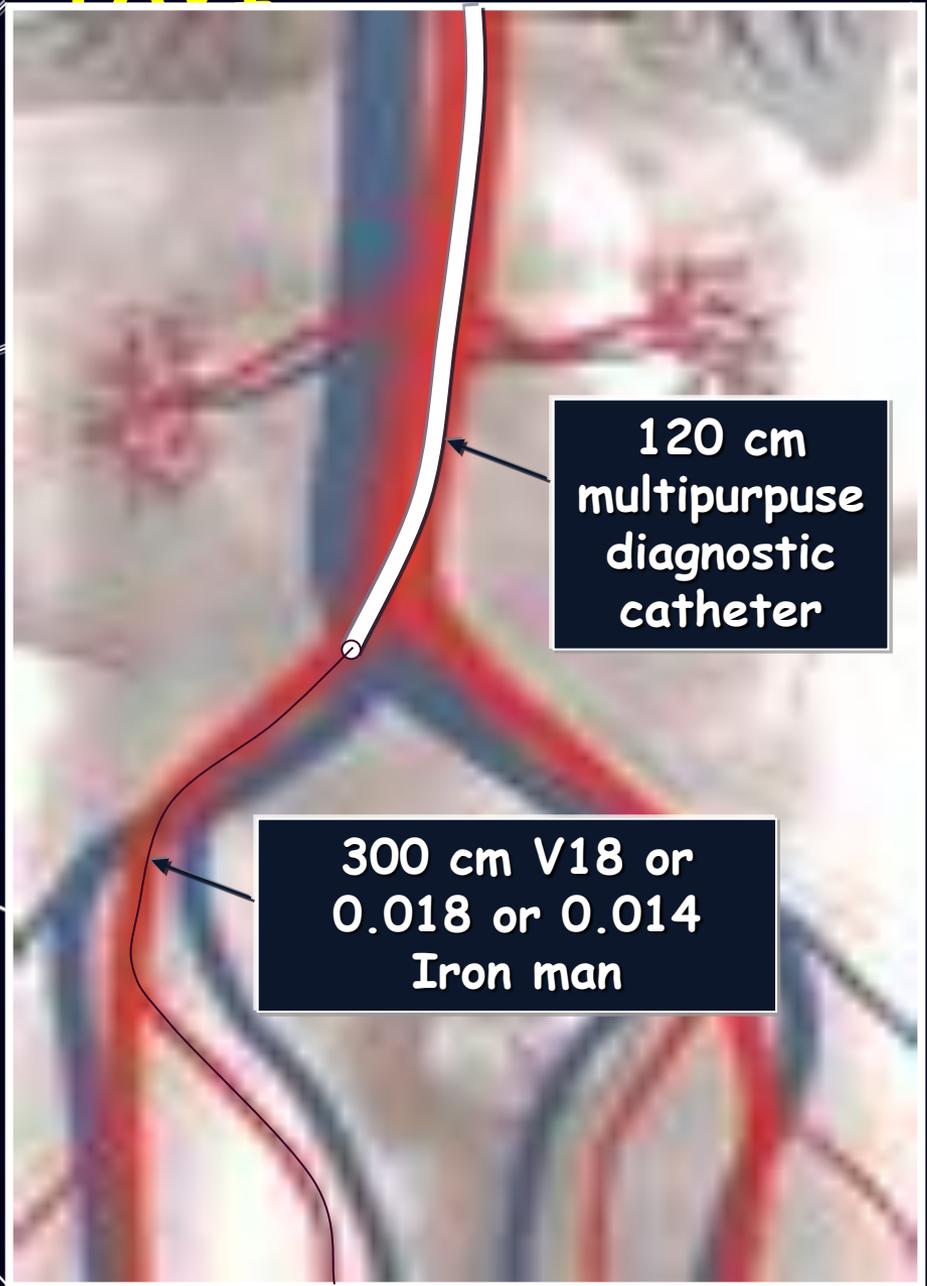
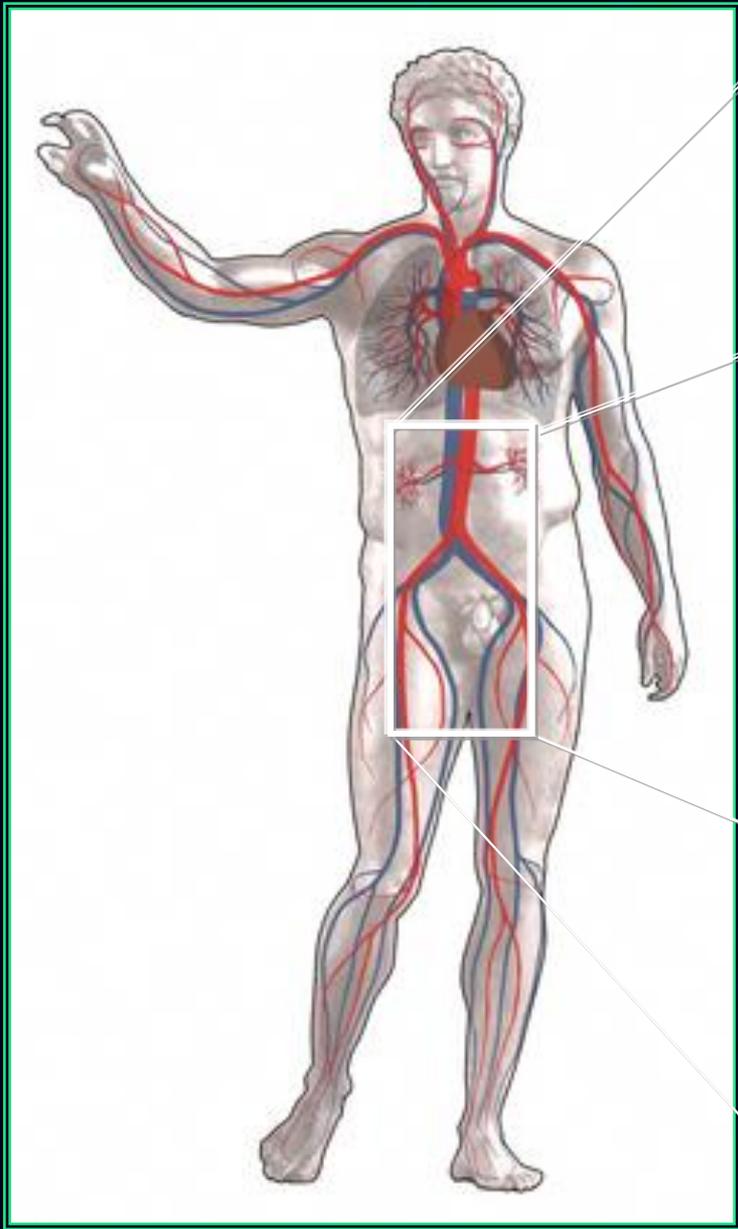
0,18" wire  
advanced in  
SFA



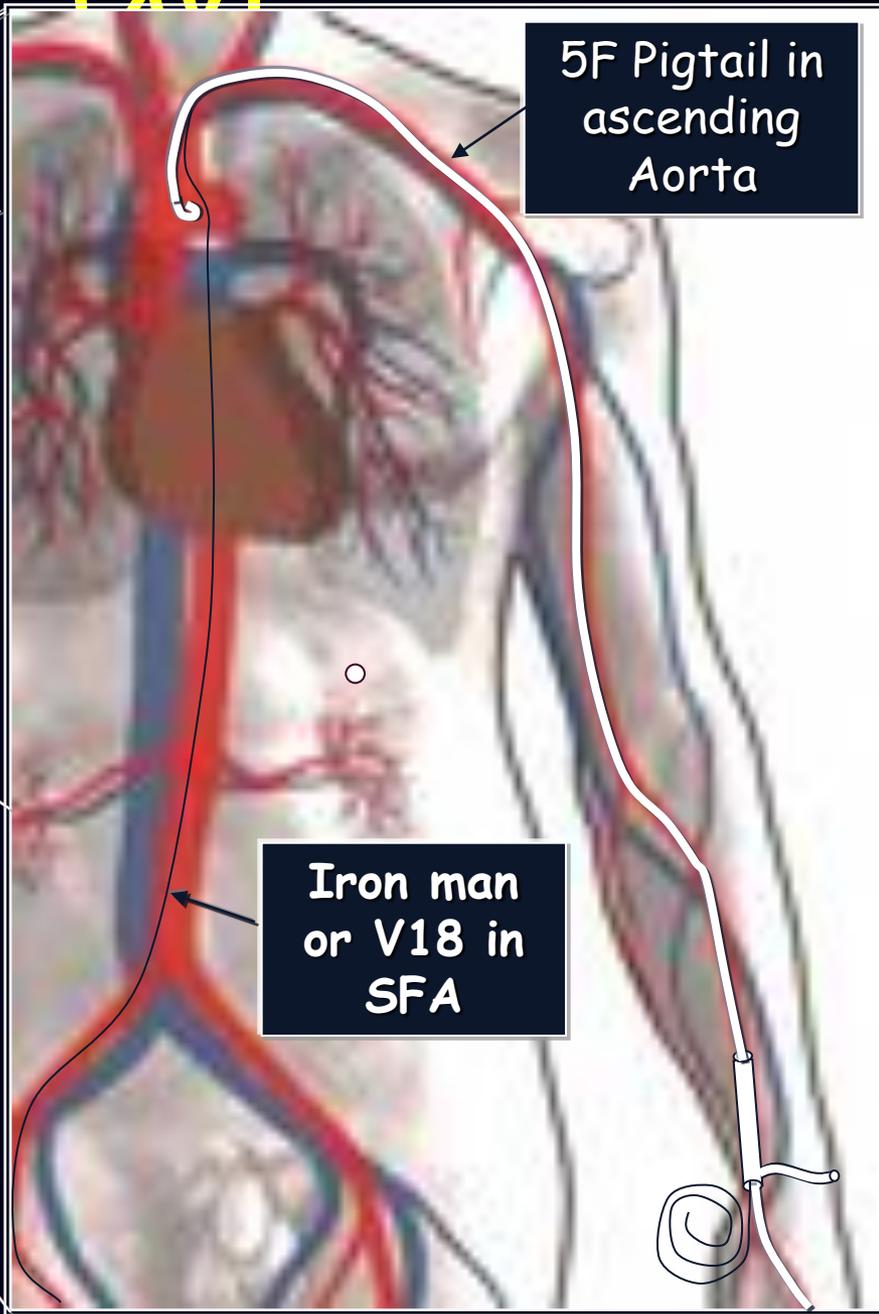
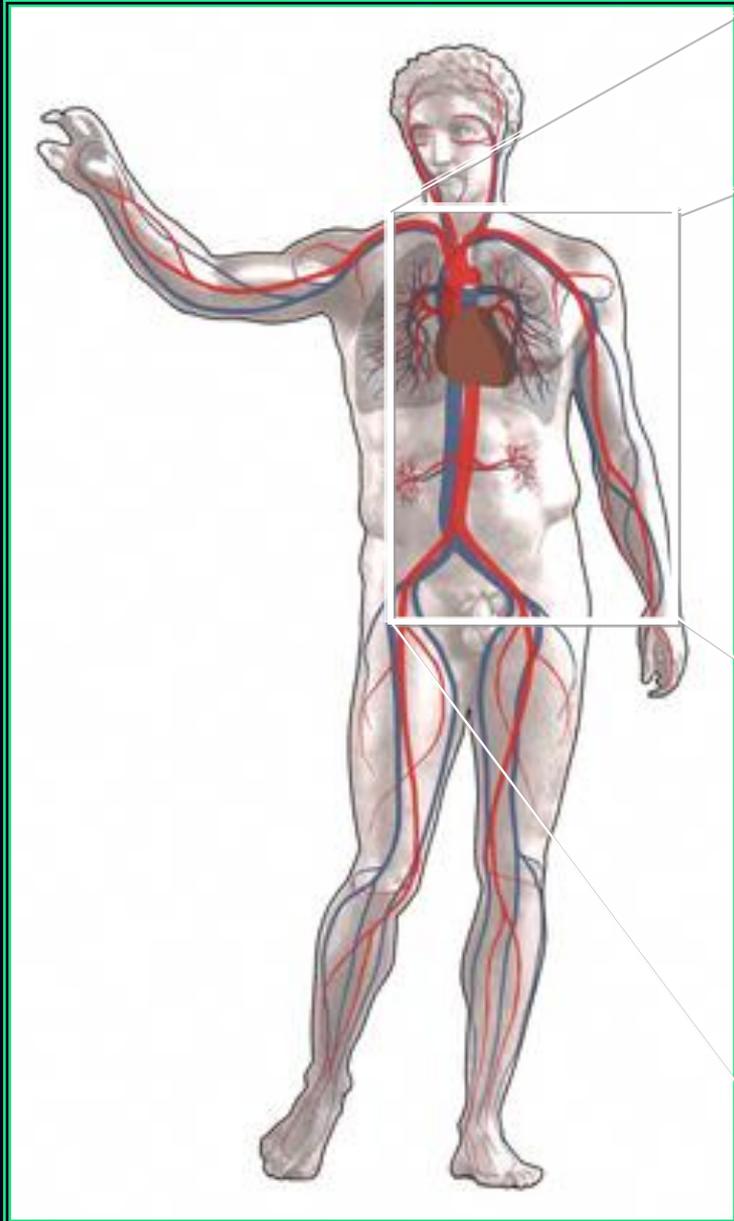


**6 F short**

# TAVI



# TAVI



5F Pigtail in ascending Aorta

Iron man or V18 in SFA

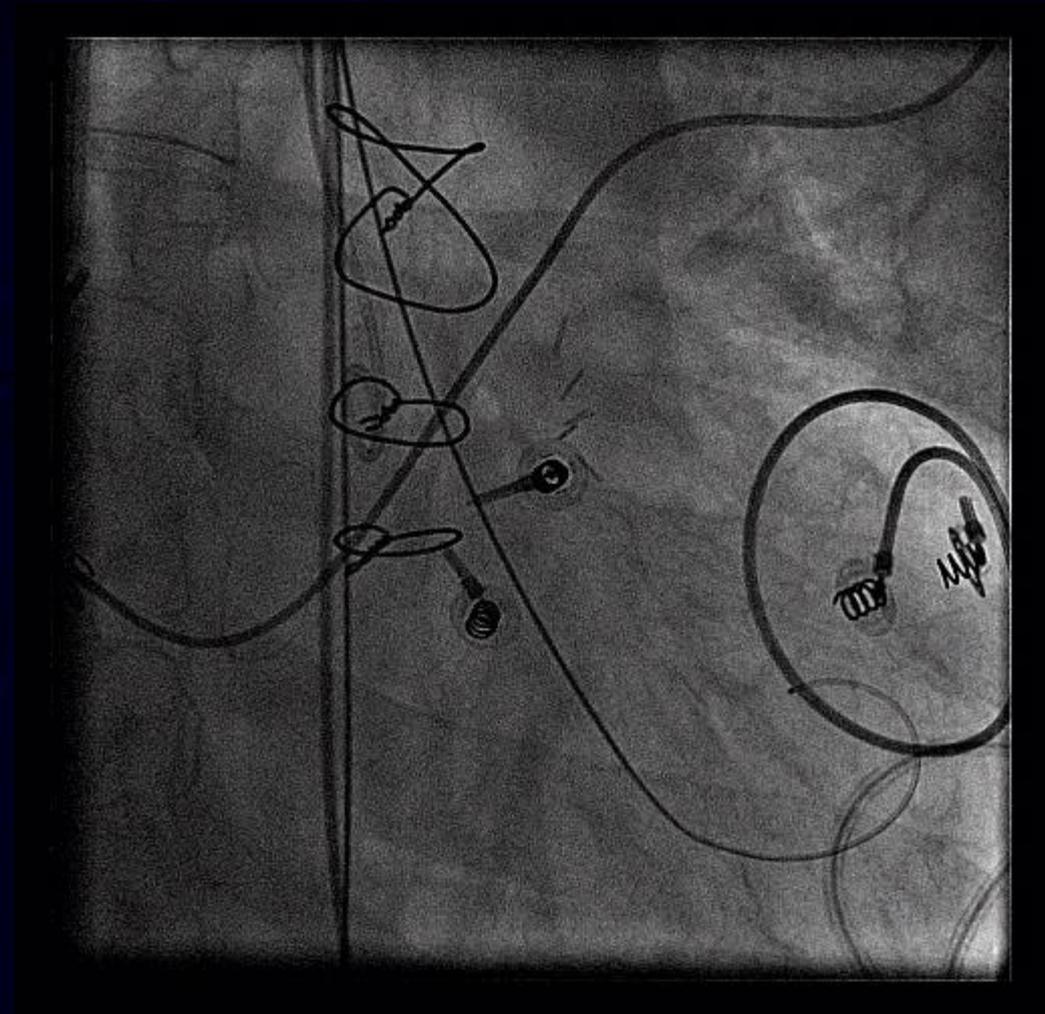
# TAVI

## Final Injection



# Placing the stiff wire

- Amplatz Superstiff ST1  
*(short floppy tip 1 cm)*
- Alternative stiff wires:  
long floppy tips
- → manually bending the  
stiff part into a pigtail  
shape
- Next, 18 French sheath  
(always over the stiff  
wire)



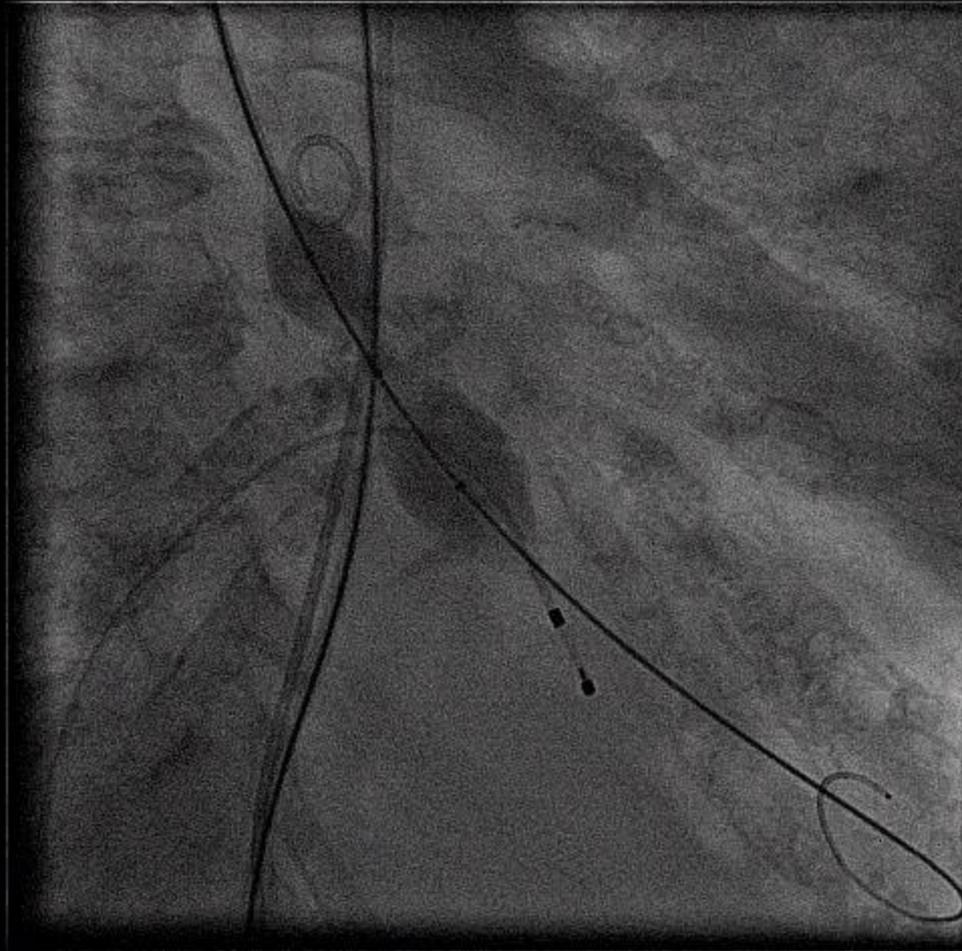
# Balloon valvuloplasty

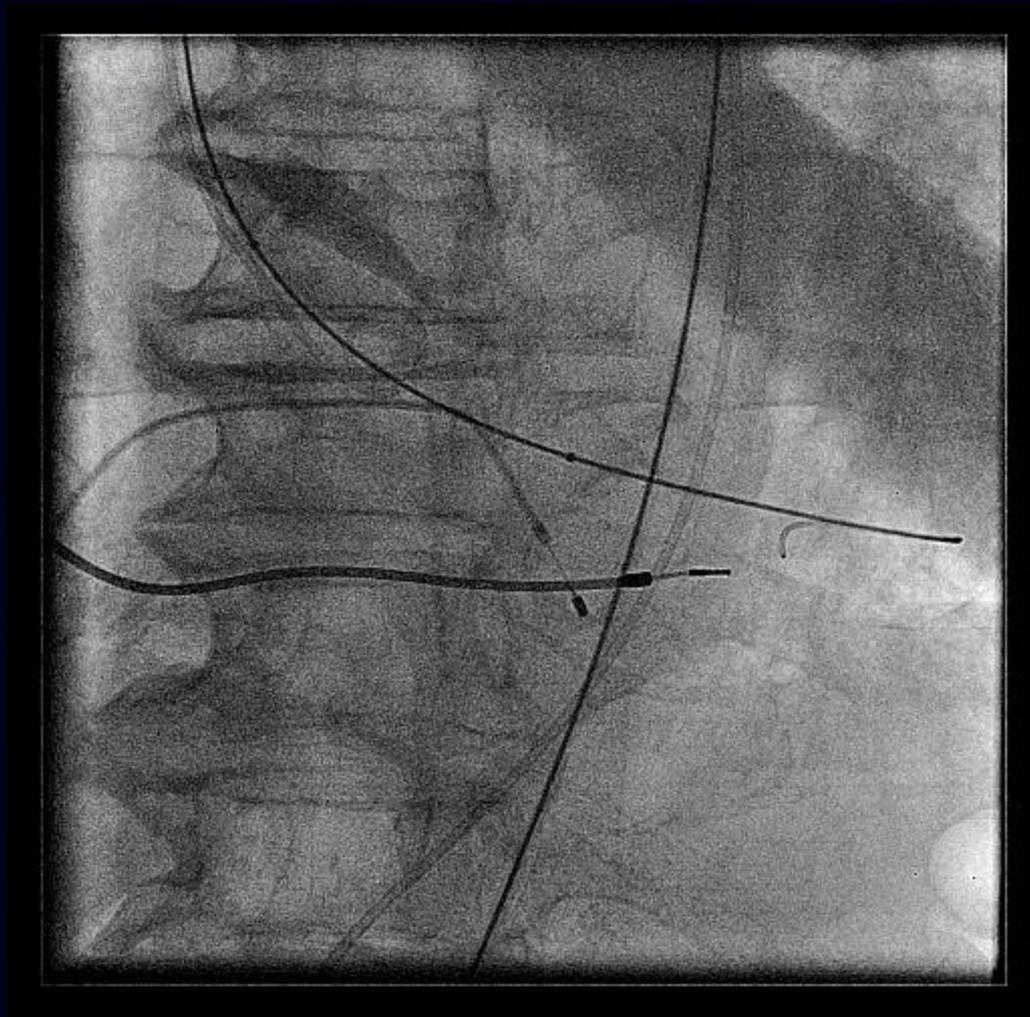
- **Balloon catheters:**
  - **Nucleus 12 F (Inoue like behavior)**  
→ **Stabilize position**
  - **Z-med X 12 F**
  - **Tyshak II (9 F to 25mm) but  
rated burst 1.0-1.5 atm**
  - **Or other valvuloplasty balloons possible**
  - **Ideal balloon length 40-60 mm**

**Rapid RV stimulation ~180 - 200 BPM**

**(systolic pressure <60 mmHg), use lead with tip  
balloon or lead with screw (be careful of  
perforations) → Stabilize position, less embolization?**

# Balloon valvuloplasty with Nucleus (balloon rupture !)





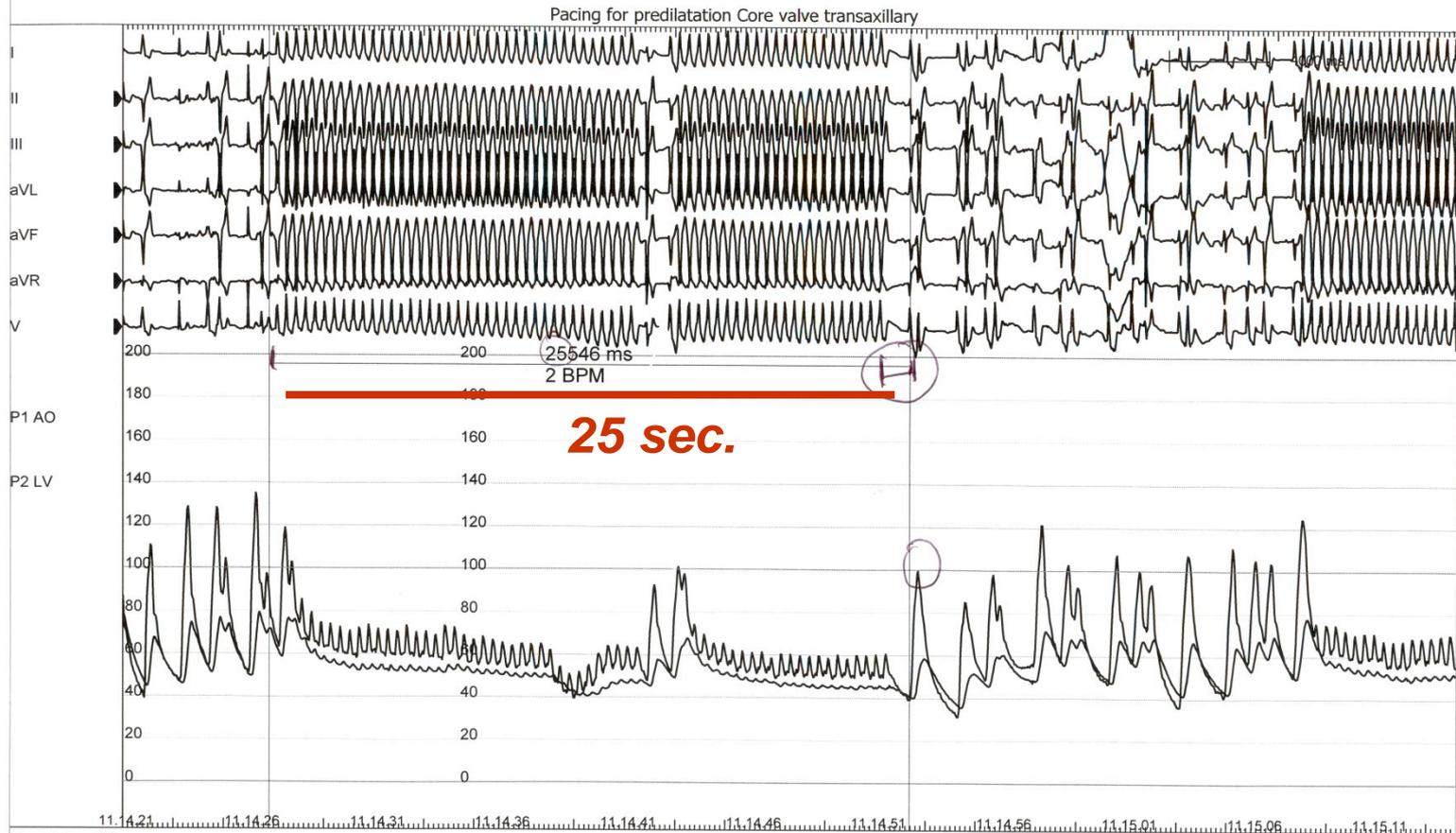
## **Balloon valvuloplasty**

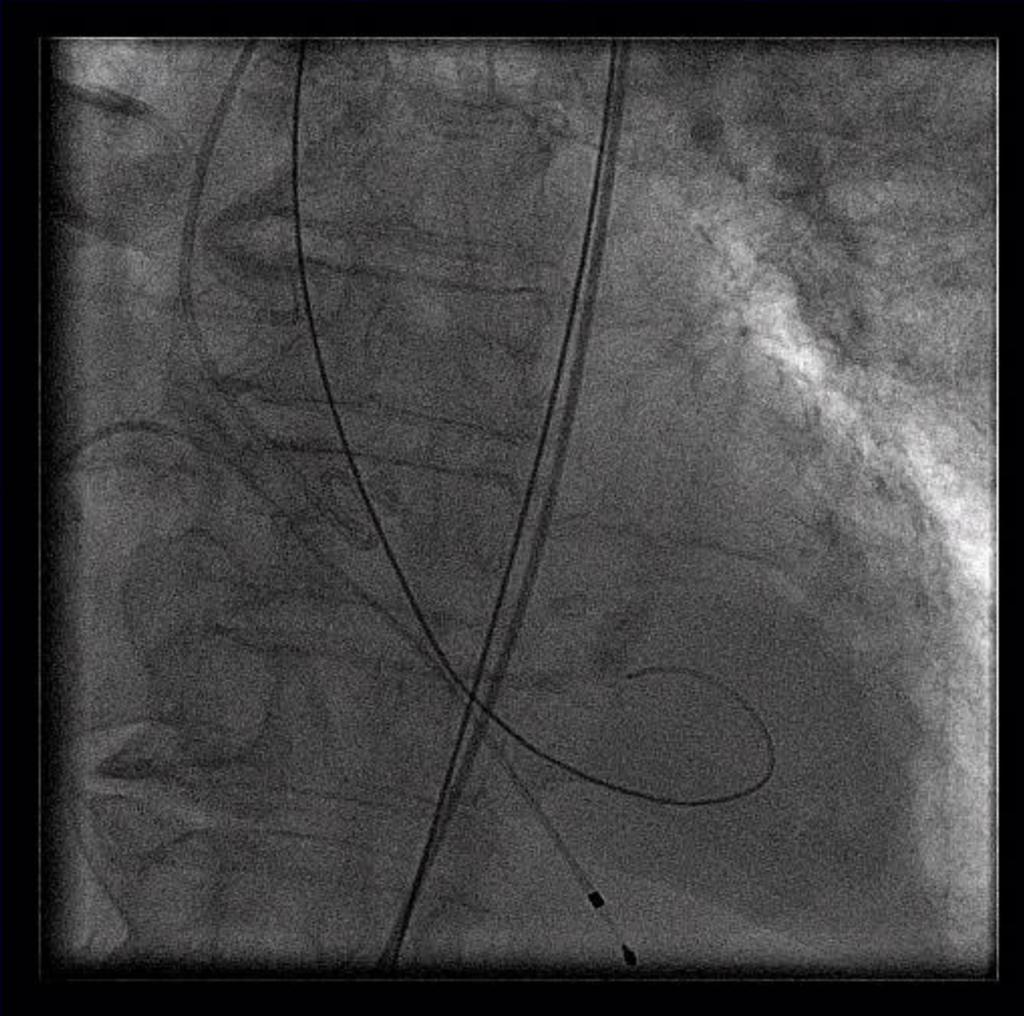
**using a 25 mm  
ZMed  
balloon and  
simultaneous dye  
injection  
in a 28 mm  
annulus  
(measured by CT)**

# Valvuloplasty: Rapid Pacing



B, I  
13/10/2010 11.14.21 (Velocità: 5 mm/s)  
2010  
**5 mm/sec**





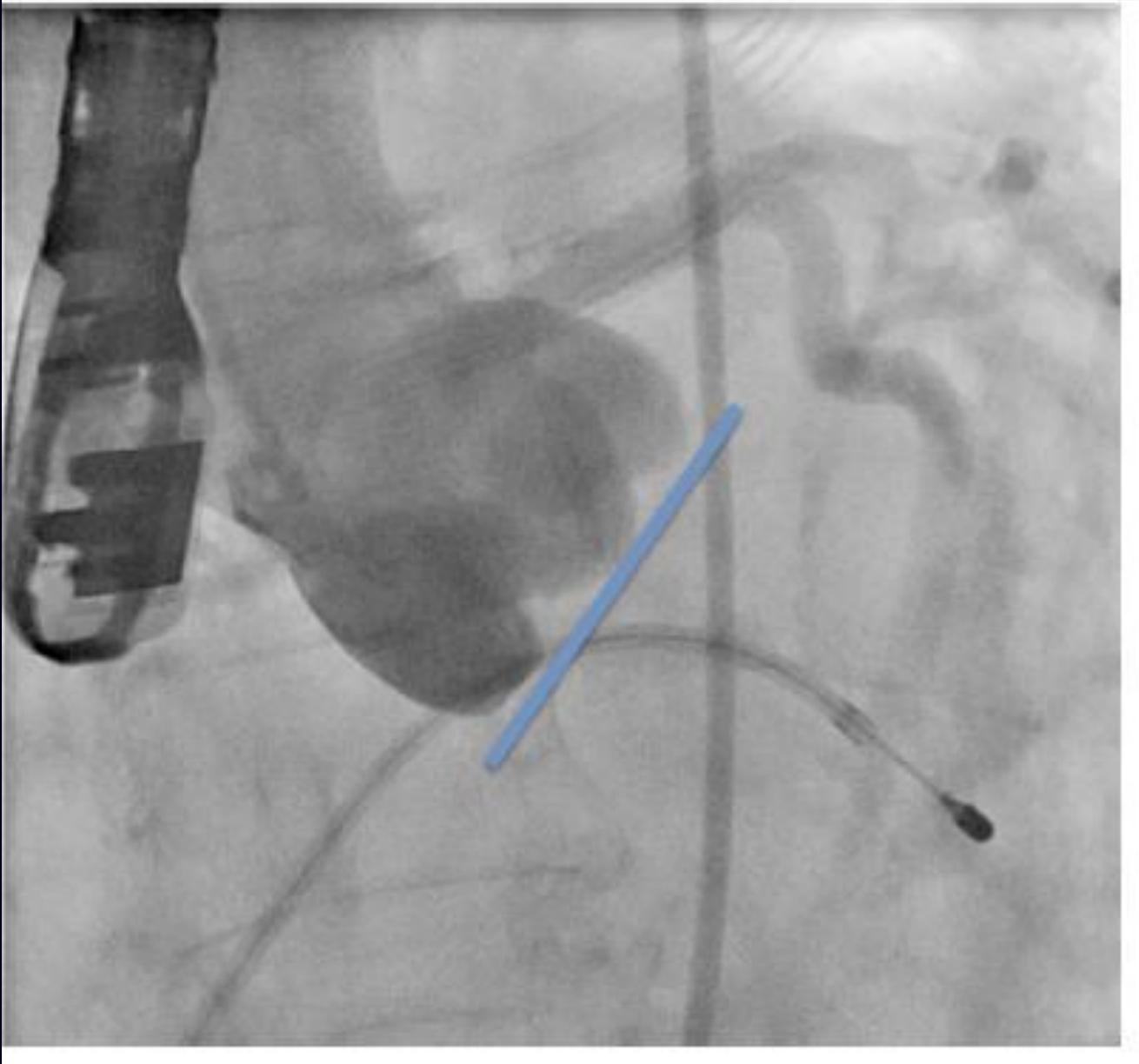
## Severe aortic regurgitation

after  
valvuloplasty  
(incidence 2-  
5%)

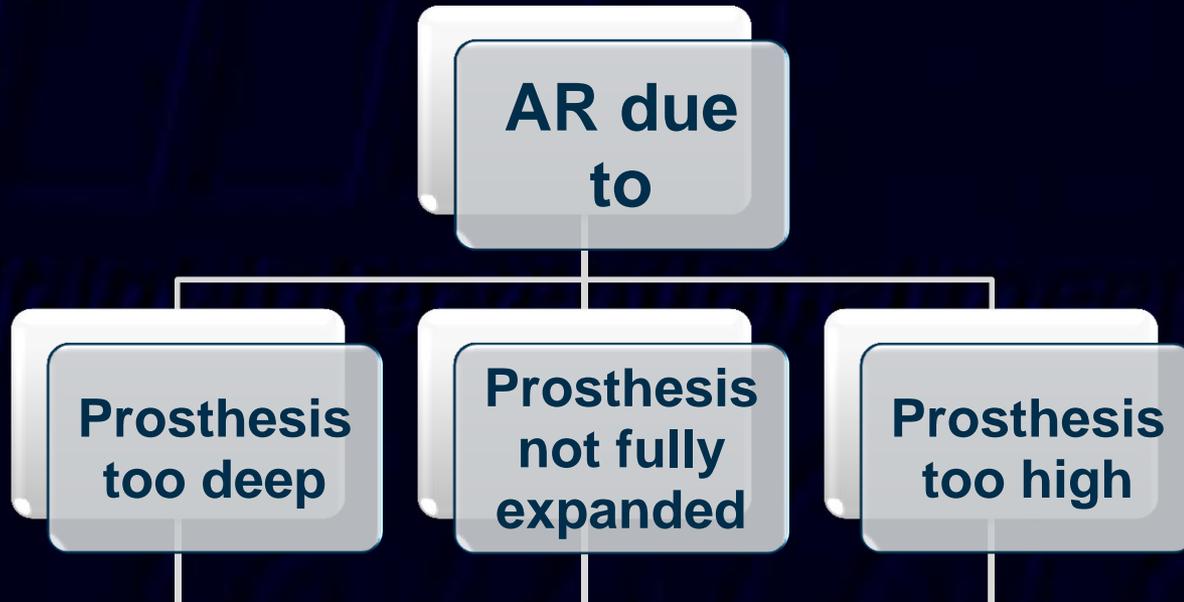
Acute aortic regurgitation  
resulting in  
acute LV overload



Acute LV failure / asystole  
or VF due to  
(Volume-loading of the LV)



# Aortic regurgitation after delivery of the prosthesis



*For CoreValve*

*For CoreValve*

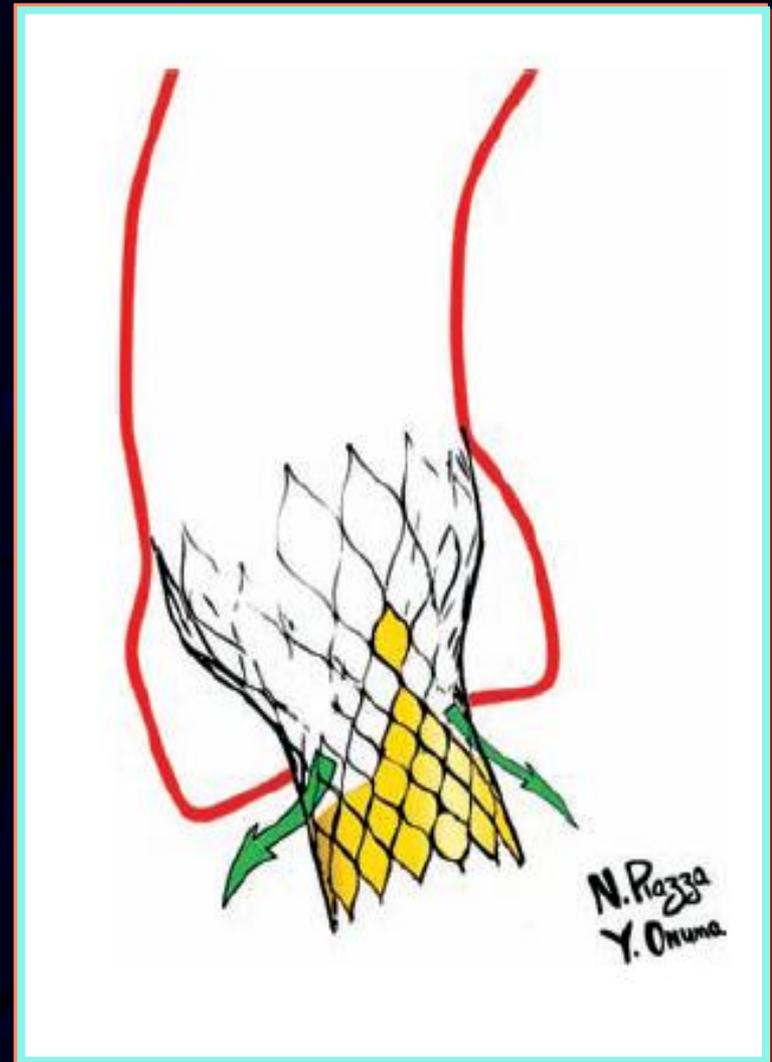
***Implantation of a second valve for malpositioning which cannot be corrected***

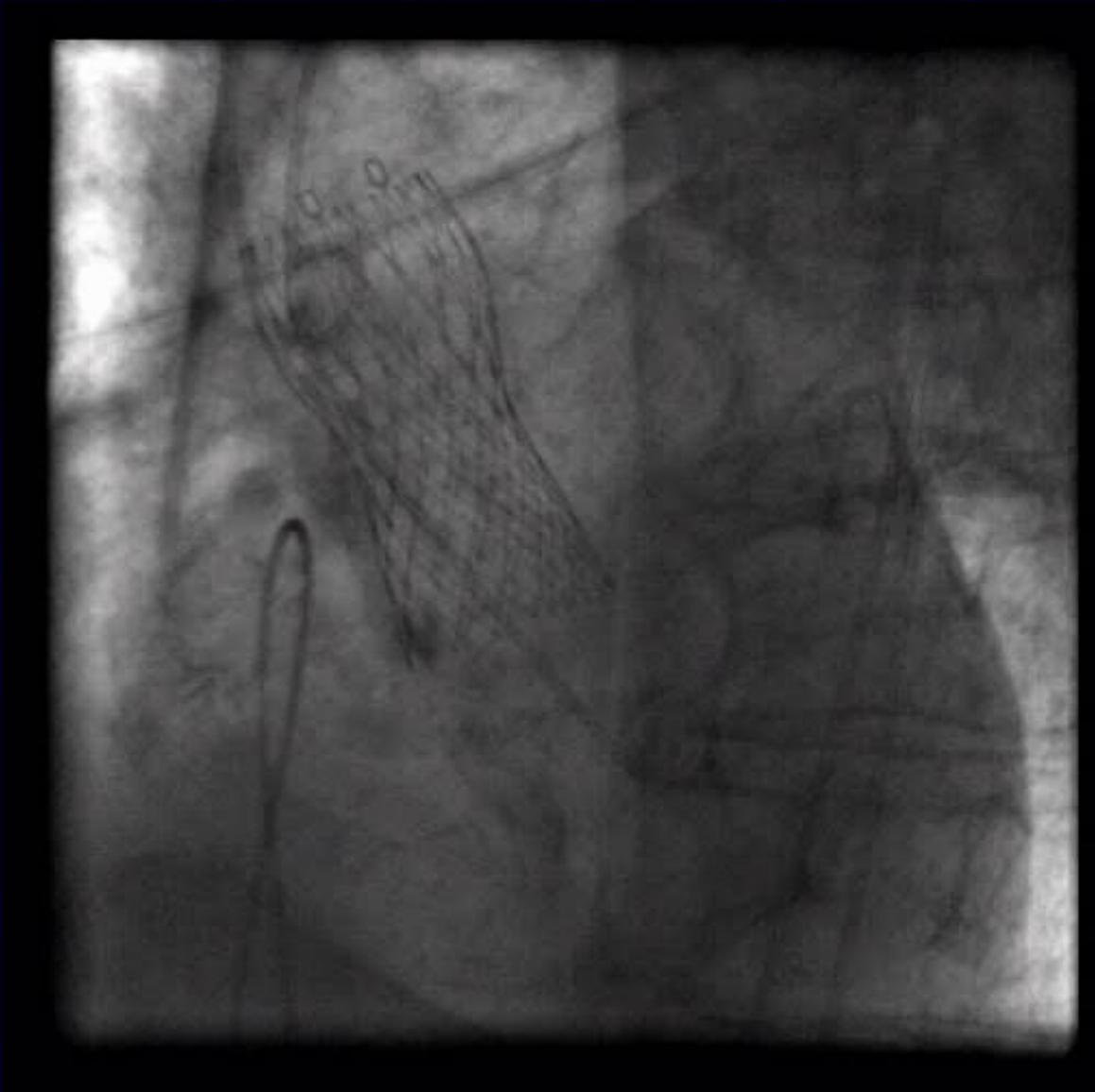
*For Sapien*

*Aortic regurgitation due to a  
incorrect (too deep)  
implantation.*

*The top pericardial skirt  
is below the base of the aortic  
root.*

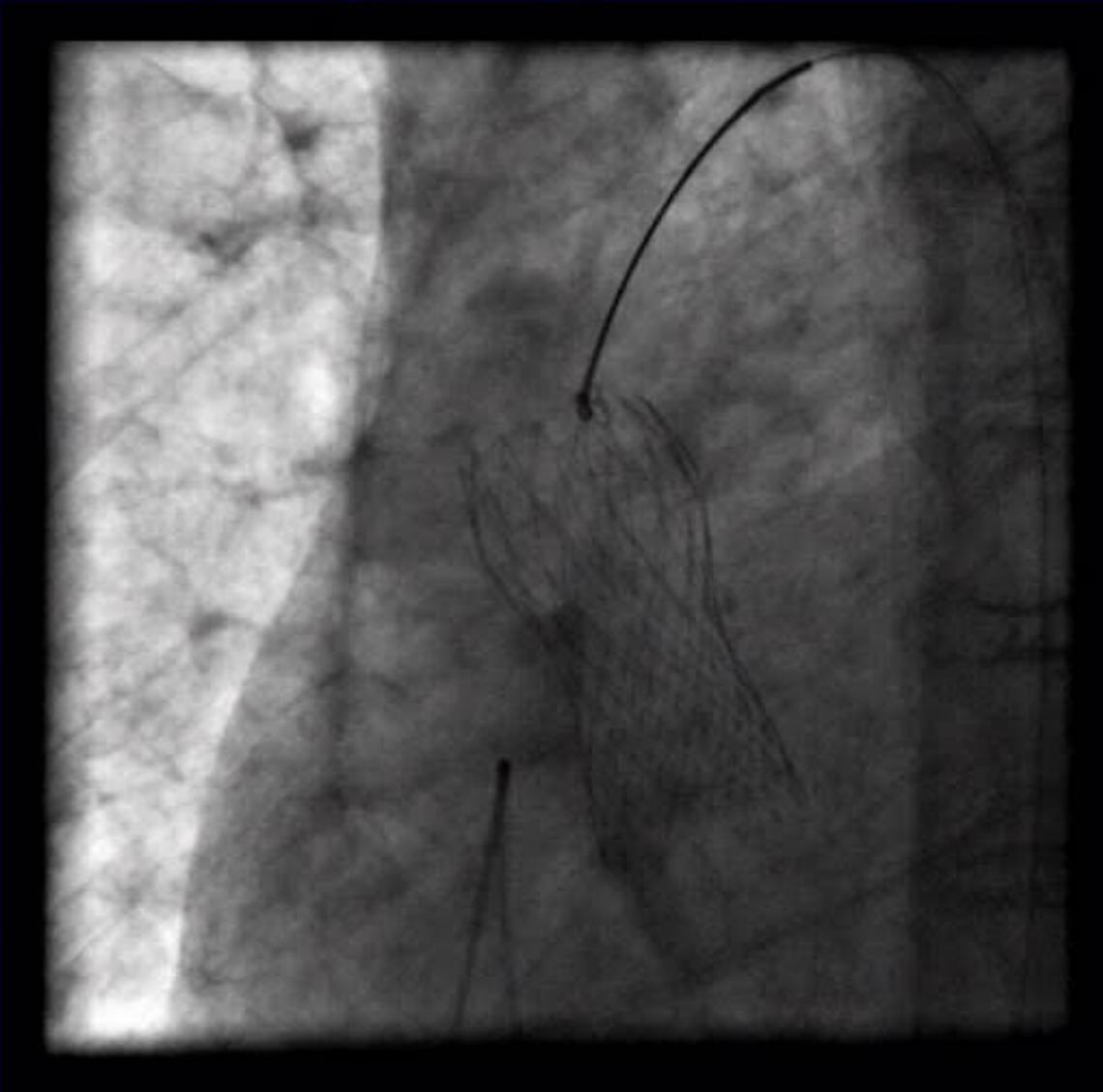
*As a result there is aortic  
regurgitation due to operator  
related misplacement of the  
valve.*





**AR due to  
too deep  
prosthesis**

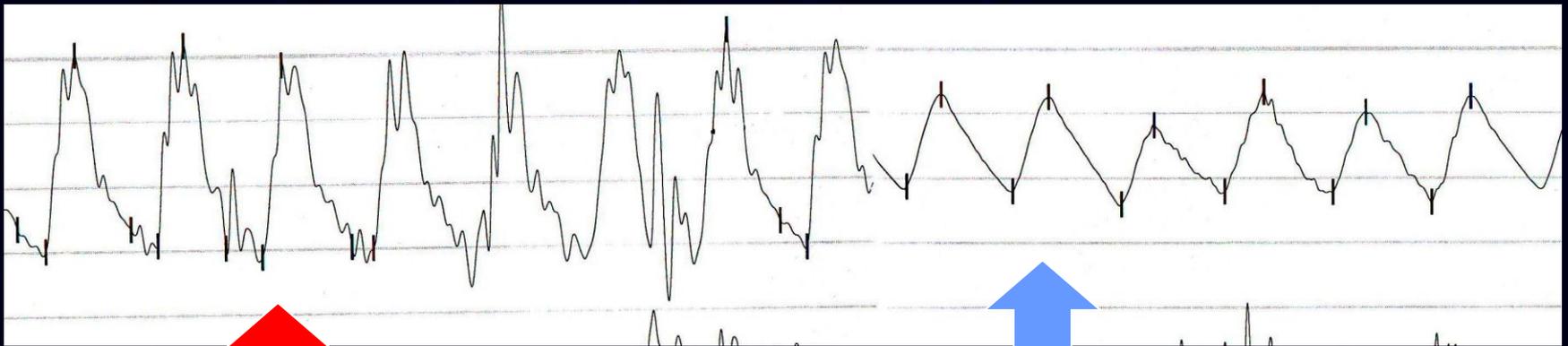
**(paravalvular  
leakage)**



## Re-positioning

using  
a Goose Neck ,snare'  
(15/20 mm)  
from femoral 6F

# Controlled during continuous pulling by monitoring of the diastolic blood pressure



# *Valve misplacement CoreValve*

## *Valve is too low:*

- 1) snare the valve to pull it up*
- 2) implant a second valve.*

## *Valve is too high:*

*Retrival the valve to proximal position, keep the coronary ostial clear and position a second valve.*

# *Valve misplacement Sapien*

***Valve is too low:***

***Implant a second valve***

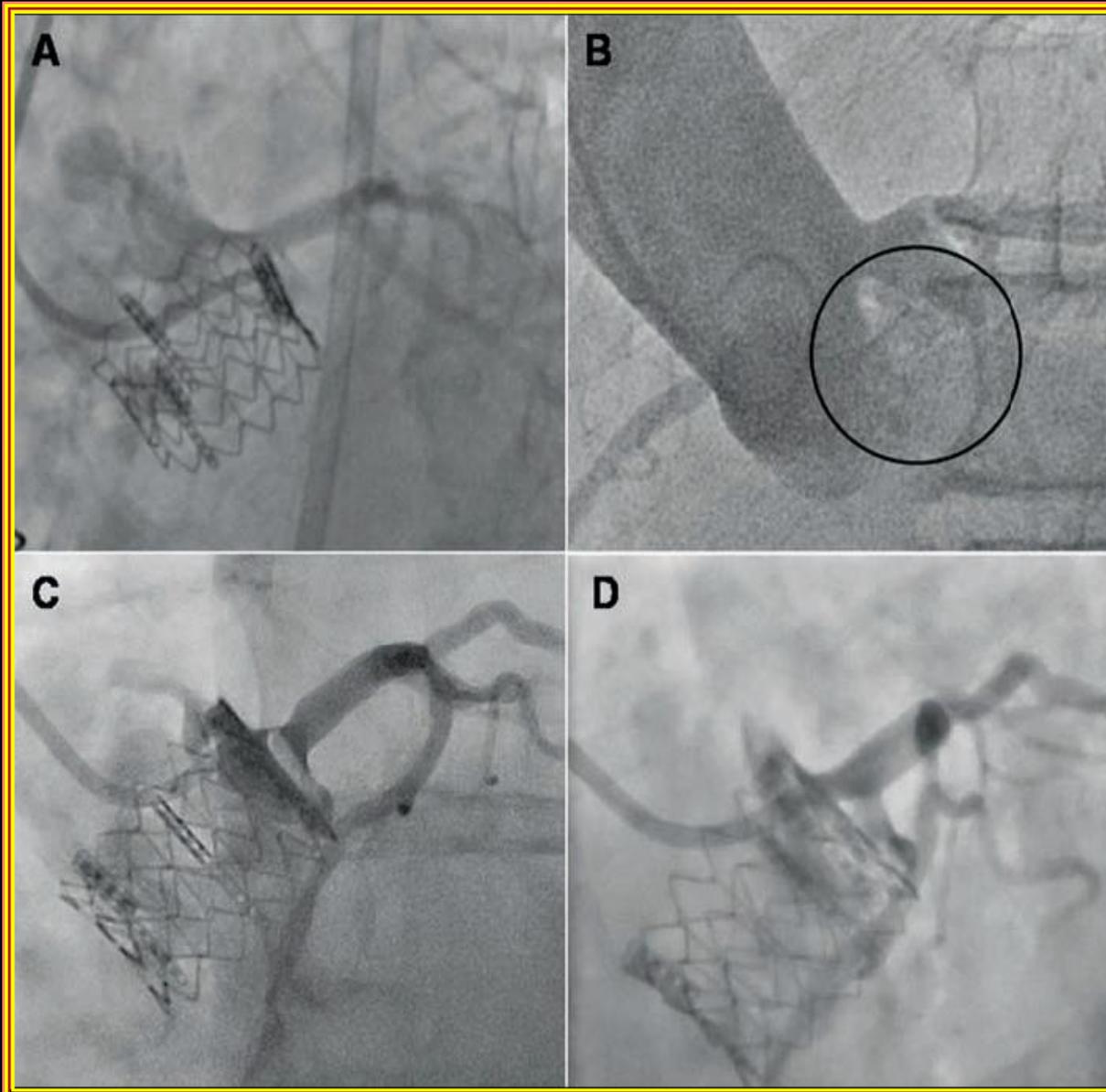
***Valve is too high:***

***Implant a second valve***

# Generic Cardiac Complications

- ✓ *LV perforation: pacemaker, nose of the delivery catheter, LV wire*
- ✓ *Dissection of the Aorta or of the anulus*
- ✓ *Injury to the mitral valve*
- ✓ *Obstruction of coronary ostia*
- ✓ *Arrhythmias*
- ✓ *AV block: 20% for CoreValve and 5% for Sapien*

# Coronary obstruction



*(A) The very uncommon situation of a coronary ostium being obstructed by a stent strut.*

*(B) Bulky coronary leaflets that warrants further evaluation.*

*(C) Left main obstruction by a bulky coronary leaflet.*

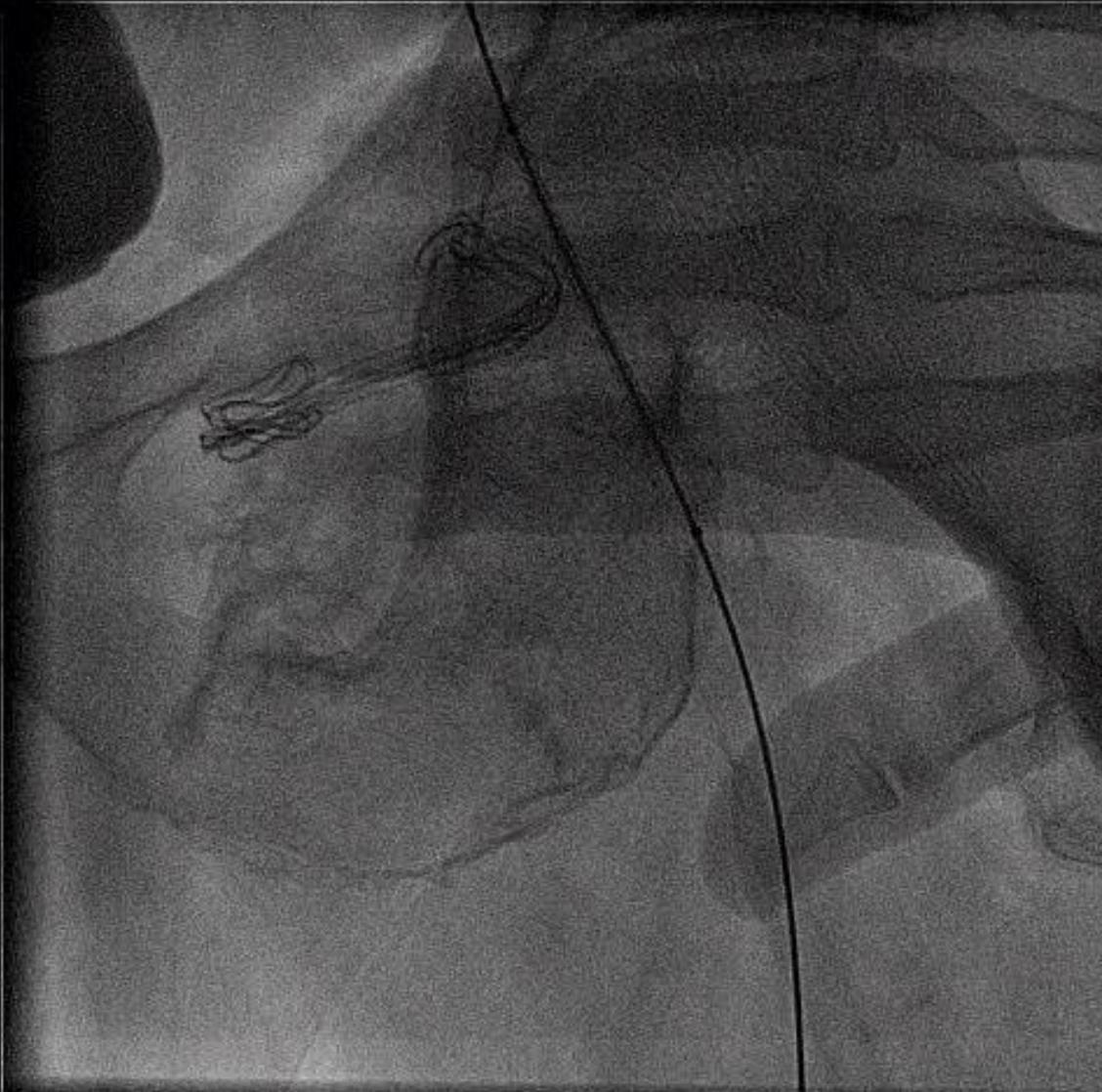
*(D) Successful stenting of the left main coronary through an open cell of the valved stent.*

# Obstruction of coronary ostia

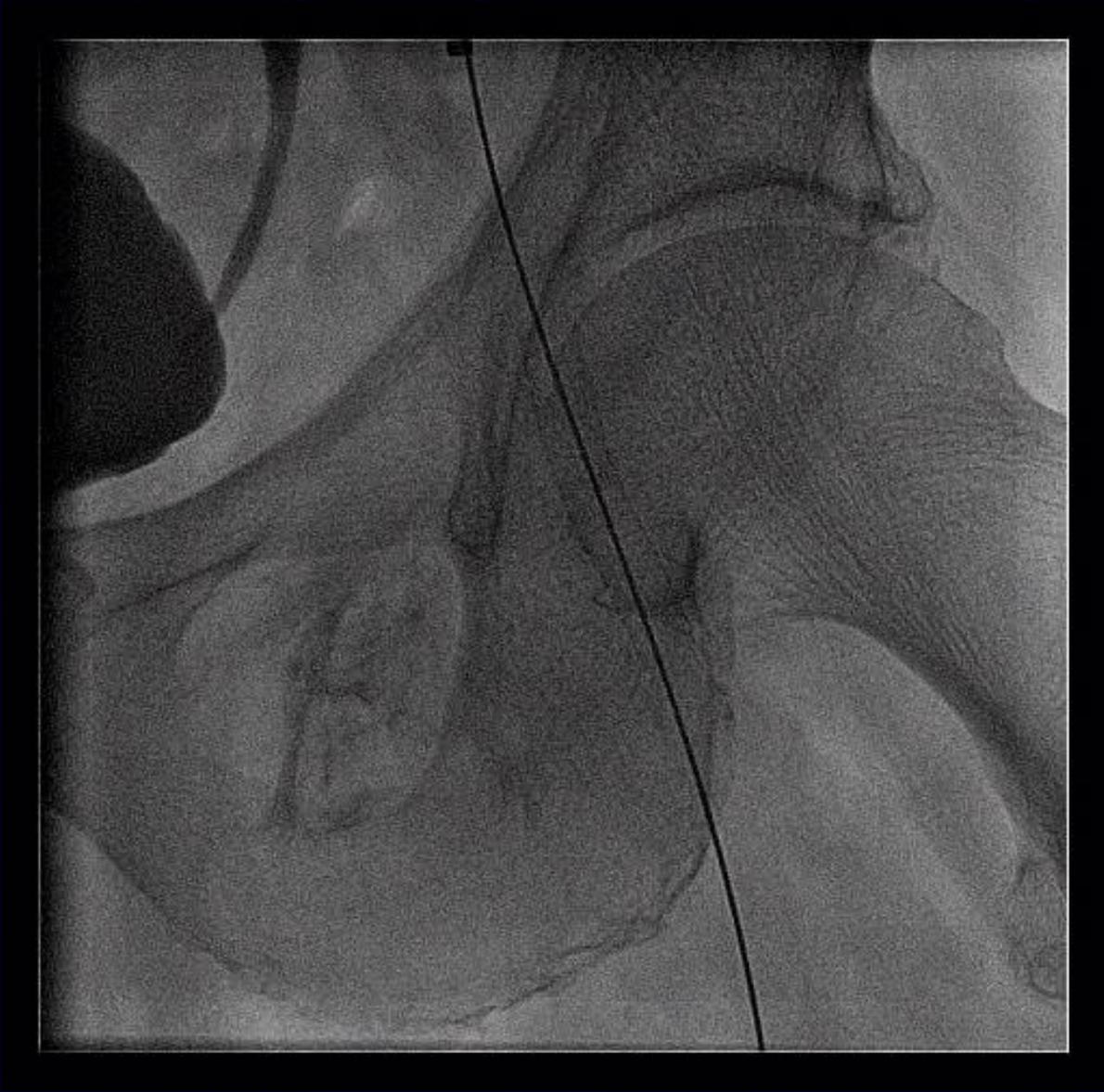
May occur at the time of valve  
implantation. Senior or during post-

Higher risk of occlusion in severely calcified valves and in low set coronary ostia, less than 12 mm above the annulus. In high risk conditions leave a guide catheter with wire in the left coronary

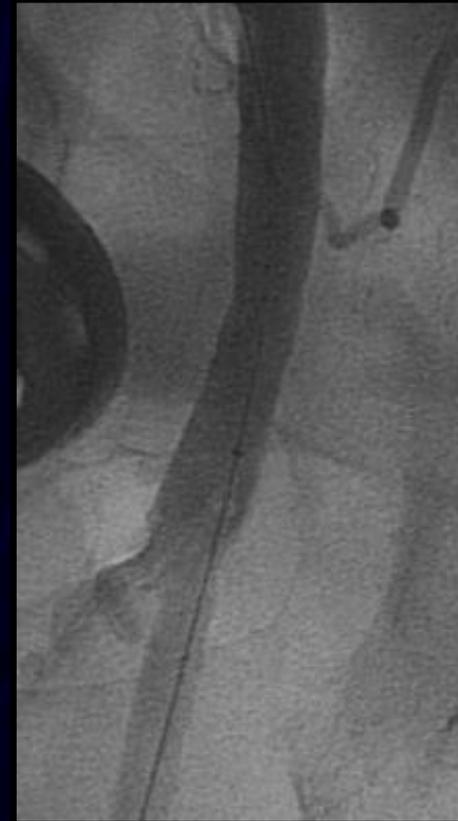
If the patient is sedated chest pain may be absent



**Implantation of a  
covered self-  
expandable  
Viabahn stent 8 /  
50 ( 8 F sheath)**



**Final result**



*In the left hand picture, a stenosis caused by excessive tension on the Prostar sutures is seen in the common femoral artery. Distal extravasation is also evident. Balloon inflation at two atmospheres for 5 minutes improved both issues significantly.*

# Neurological Events at 30 Days and 1 Year

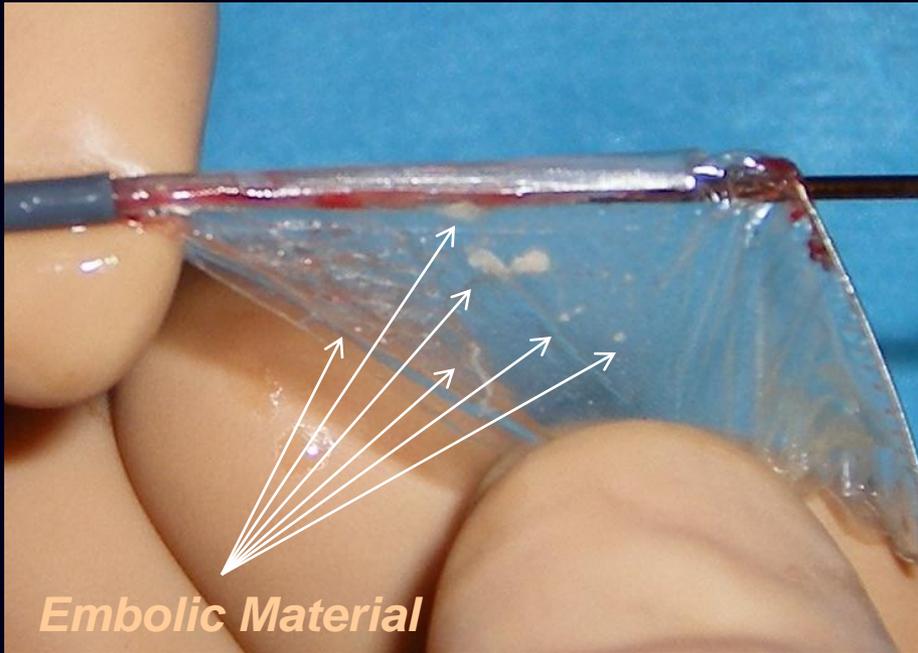
## All Patients (N=699)



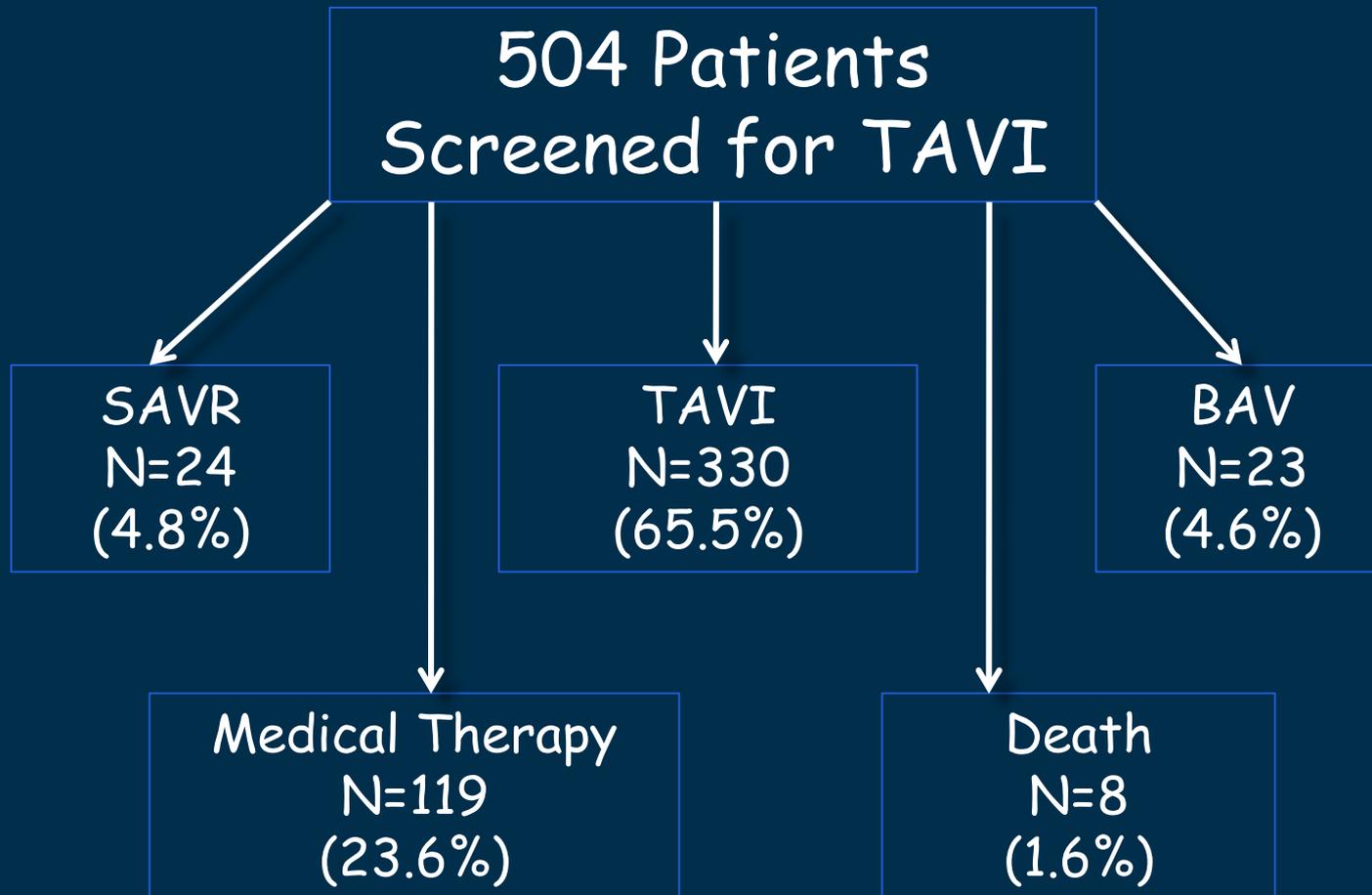
<b>Outcome</b>	<b>30 Days</b>			<b>1 Year</b>		
	<b>TAVI 348</b>	<b>SURG 351</b>	<b>p-value</b>	<b>TAVI</b>	<b>SURG</b>	<b>p-value</b>
All Stroke – no. (%)	16 (4.6)	8 (2.4)	0.12	20 (6.0)	10 (3.2)	0.08
Major Stroke – no. (%)	13 (3.8)	7 (2.1)	0.20	17 (5.1)	8 (2.4)	0.07

50% of neurological events occurred after 24 hrs from valve implantation and up to 1 yr.

# Embolic Material



# November 2007 - July 2011



Patients Undergoing TAVI  
Nov 2007 - July 2011  
N=330

Edwards SAPIEN™ \*  
N=199  
(60.3%)

CoreValve Revalving  
System®  
N=131 (39.7%)

Transfemoral  
N=169  
(84.9%)

Transaxillary  
N=4  
(2.0%)

Transfemoral  
N=99  
(75.6%)

Transaxillary  
N=30  
(22.9%)

Transapical  
N=25  
(12.6%)

Transaortic  
N=1  
(0.5%)

Transaortic  
N=2  
(1.5%)

\* Edwards SAPIEN™XT  
N=108

# Baseline Characteristics according to Valve Type

	All N=268	SAPIEN™ N=169	CoreValve® N=99	P value
Age; mean ± SD	79.7 ± 7.3	80.2 ± 7.8	78.9 ± 6.5	0.172
Male; n (%)	139 (51.9)	82 (48.5)	57 (57.6)	0.152
Hypertension; n (%)	192 (71.6)	117 (69.2)	75 (75.8)	0.253
Chronic Kidney Disease; n (%)	82 (30.7)	53 (31.4)	29 (29.6)	0.763
NYHA III/IV; n (%)	181 (68.0)	119 (71.3)	62 (62.6)	0.144
Ejection Fraction; mean ± SD	51.7 ± 13.2	53.0 ± 11.6	49.3 ± 15.3	0.023
Aortic Annulus; mean ± S D	23.6 ± 1.8	23.2 ± 1.6	24.3 ± 1.9	<0.001
Logistic EuroSCORE; mean ± SD	23.4 ± 16.5	22.9 ± 16.5	24.1 ± 16.5	0.583
STS-PROM Score; mean ± SD	8.0 ± 7.5	7.3 ± 5.9	9.3 ± 9.5	0.033

SAPIEN™XT 20.8±16.5%  
 SAPIEN™XT 7.3±6.5%

# VARC Outcomes According to the Valve Type: Safety & Efficacy

	All N=268	SAPIEN™ N=169	CoreValve® N=99	P value
Death; n (%)	10 (4.1)	4 (2.6)	6 (6.6)	0.127
Cardiovascular Death; n (%)	7 (2.9)	4 (2.6)	3 (3.3)	0.751
Stroke; n (%)	2 (0.7)	2 (1.2)	0	0.277
Myocardial Infarction; n (%)	2 (0.7)	0	2 (2.0)	0.064
Major Vascular Complication; n (%)	45 (16.8)	32 (18.9)	13 (13.1)	0.220
Life-Threatening Bleeding; n (%)	60 (22.4)	32 (18.9)	28 (28.3)	0.076
Major Bleeding; n (%)	88 (32.8)	57 (33.7)	31 (31.3)	0.685
Acute Kidney Injury Stage 3; n (%)	22 (8.2)	14 (8.3)	8 (8.1)	0.953

# VARC Outcomes According to Valve Type: Performance & Complications

	All	SAPIEN™	CoreValve®	P value
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## Transfemoral Only

AR Severity	SAPIEN™ N=63	SAPIEN™ XT N=105
0	10 (15.9)	41 (39.0)
1	36 (57.1)	41 (39.0)
2	13 (20.6)	22 (21.0)
3	4 (6.3)	1 (1.0)

Coronary Obstruction; n (%)	1 (0.4)	1 (0.6)	0	0.443
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# VARC Outcomes According to Valve Type: Composite Endpoints

	All N=268	SAPIEN™ N=169	CoreValve® N=99	P value
Device Success; n (%)	252 (94.0)	162 (95.9)	90 (90.9)	.099
Combined Safety Endpoint; n (%)	177 (66.0)	113 (66.9)	64 (64.6)	.711
Combined Efficacy Endpoint at 1 year; n (%)*	122 (77.2)	70 (77.8)	52 (76.5)	.846
All cause mortality at 1 year; n (%)*	17 (10.8)	8 (9.0)	9 (13.2)	.396



\* 158 Patients Eligible

# Conclusions

*Patients undergoing TAVI are very frail, most of the complications considered minor become major when they occur in these patients*

*There is the need for meticulous attention **to any detail even the minor ones***

*Be always ready to take action when there is a complication and acknowledge that an inappropriate solution to the first complication will not be forgiven*

# Problems still open

Degree of residual AI

Durability of the valves

Risk of stroke higher than surgery and potentially not fully resolved with cerebral protection during the procedure