

Session V - New frontiers in structural heart
disease interventions

**Learning from mistakes: common and
avoidable complications during
structural heart disease interventions**

Speaker - 20'

Antonio Colombo

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

PROCEDURAL COMPLICATIONS WITHIN 48 HOURS

SOURCE XT REGISTRY

2688 patients
93 centers in 17
countries
Enrolled from July
2010 to October
2011

Access

Transfemoral
 Transapical
 Transaortic
 Transsubclavian

EVENTS (%)	RESULTS (N = 2688)
PROCEDURE RELATED DEATH	2.3
PROCEDURE RELATED STROKE	2.2
ANNULUS RUPTURE OR DISSECTION	0.4
CARDIAC TAMPONADE	0.9
PERICARDIAL EFFUSION	1.2
CORONARY OCCLUSION	0.4
NEW ONSET ATRIAL FIBRILLATION	3.8
PERMANENT PACEMAKER IMPLANT	5.7
MAJOR/LIFE-THREATENING BLEEDING	10.8
VASCULAR ACCESS RELATED COMPLICATION	11.0

Valvular Heart Disease

Anatomical and Procedural Features Associated With Aortic Root Rupture During Balloon-Expandable Transcatheter Aortic Valve Replacement

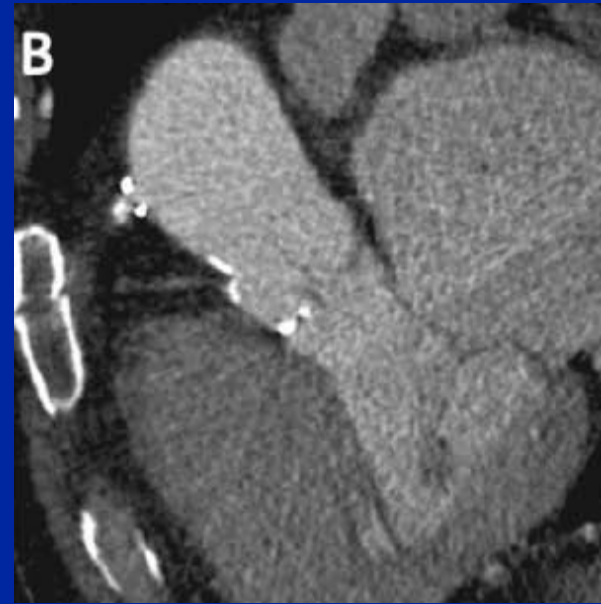
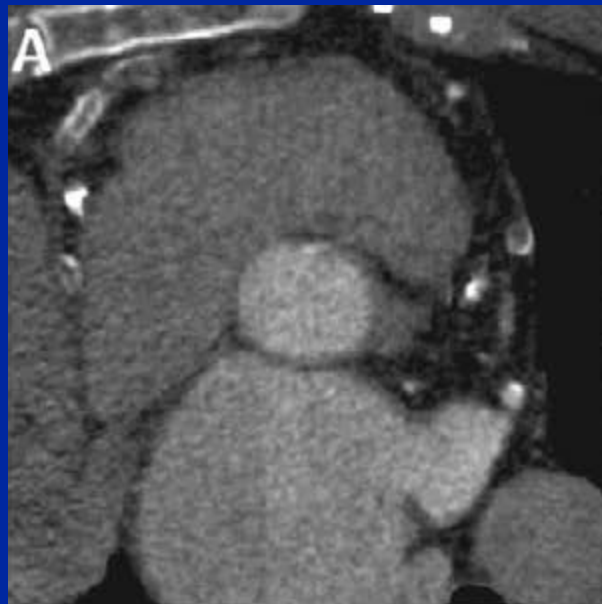
Marco Barbanti, MD; Tae-Hyun Yang, MD; Josep Rodès Cabau, MD; Corrado Tamburino, MD;
David A. Wood, MD; Hasan Jilaihawi, MD; Phillip Blanke, MD; Raj R. Makkar, MD; Azeem Latib, MD;
Antonio Colombo, MD; Giuseppe Tarantini, MD; Rekha Raju, MD; Ronald K. Binder, MD;
Giang Nguyen, MD; Melanie Freeman, MD; Henrique B. Ribeiro, MD; Samir Kapadia, MD;
James Min, MD; Gudrun Feuchtner, MD; Ronen Gurtvich, MD; Faisal Alqoofi, MD; Marc Pelletier, MD;
Gian Paolo Ussia, MD; Massimo Napodano, MD; Fabio Sandoli de Brito, Jr, MD; Susheel Kodali, MD;
Bjarne L. Norgaard, MD; Nicolaj C. Hansson, MD; Gregor Pache, MD; Sergio J. Canovas, MD;
Hongbin Zhang, PhD; Martin B. Leon, MD; John G. Webb, MD; Jonathon Leipsic, MD

Barbanti et al Circulation. 2013;128:244-253

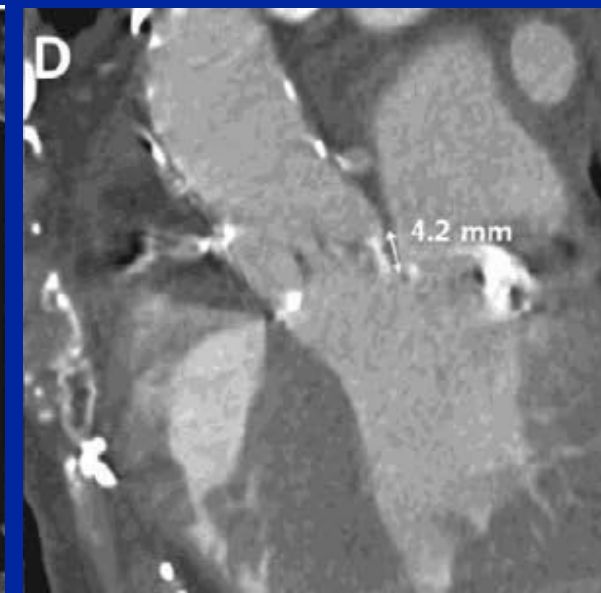
Rome, Italy

International meeting

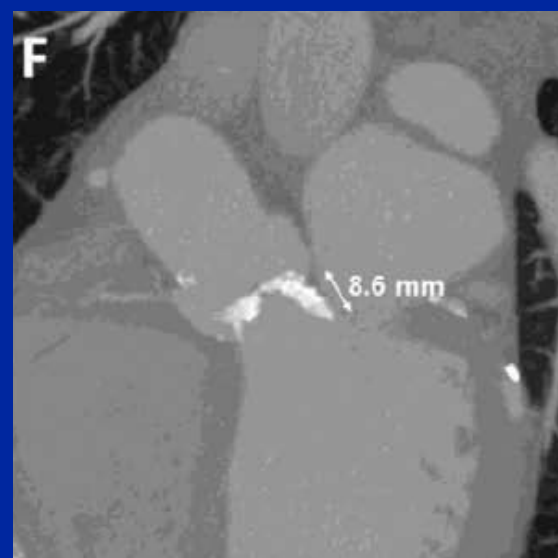
No
Calcification



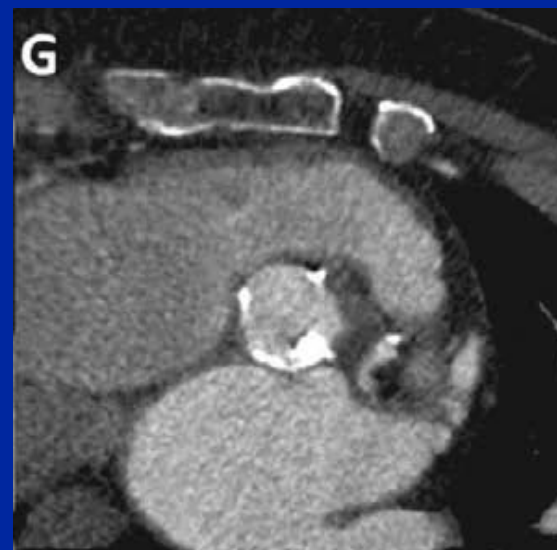
Mild
Calcification



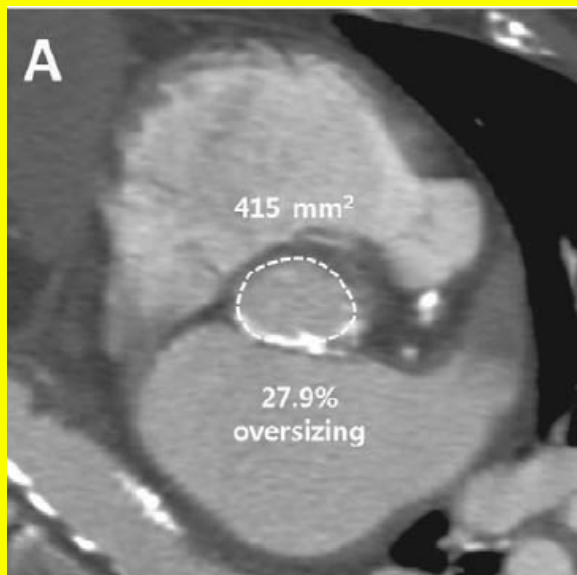
Moderate Calcification



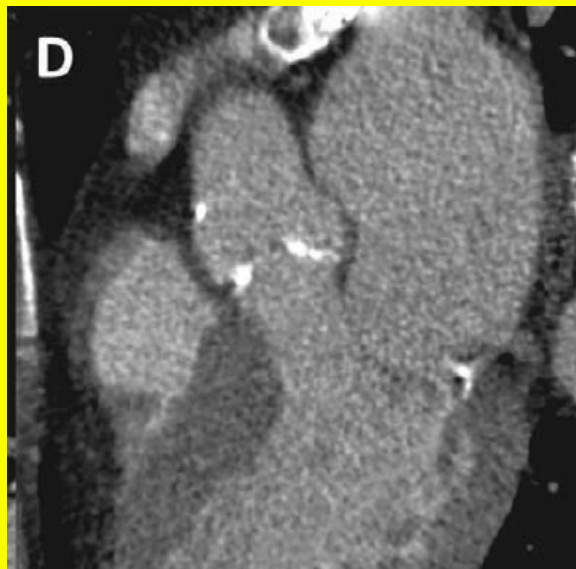
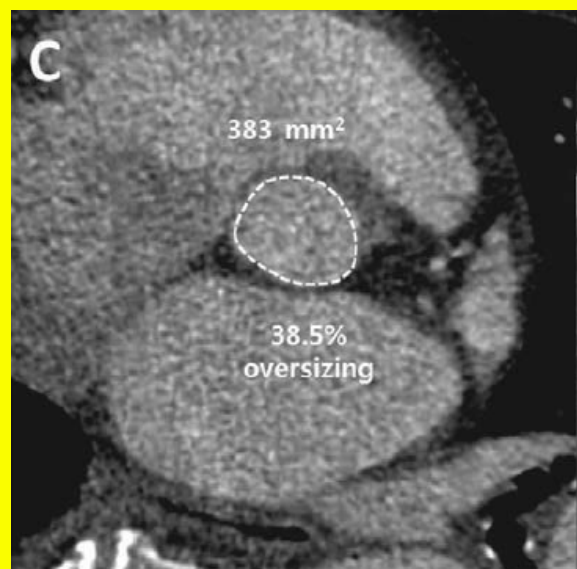
Severe Calcification



Implanted a 26 mm
Sapien XT valve= 530
mm² with 27.9%
oversizing
leading to RUPTURE



Implanted with 23 mm
Sapien XT valve=415
mm² with 38.5%
oversizing
WITHOUT RUPTURE

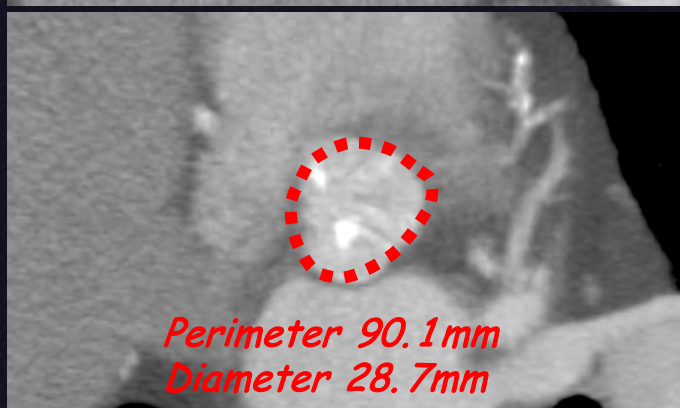


2. Asymmetric calcification or extension into the LVOT

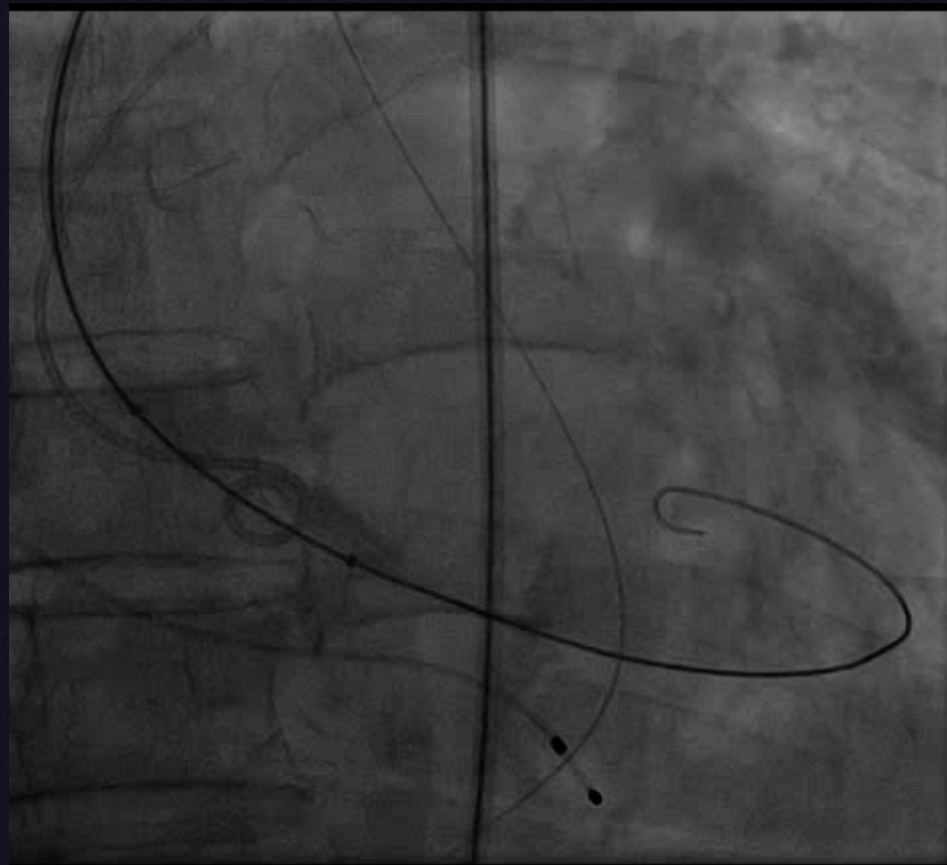


Extensive calcification between NCC and LCC

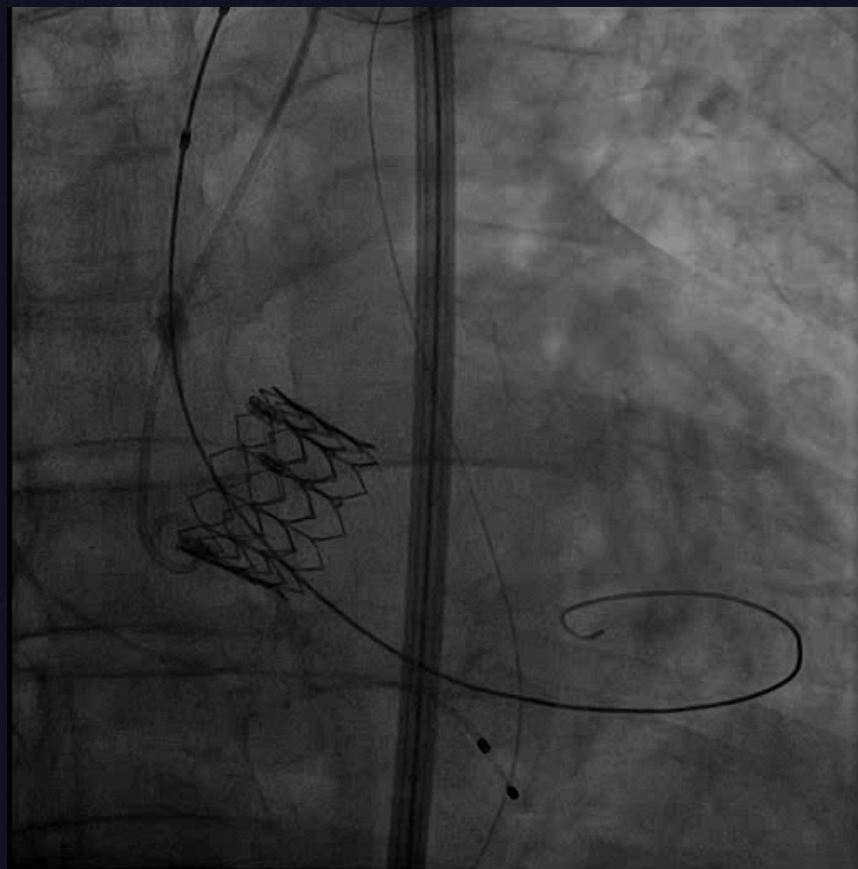
2. Asymmetric calcification or extension into the LVOT



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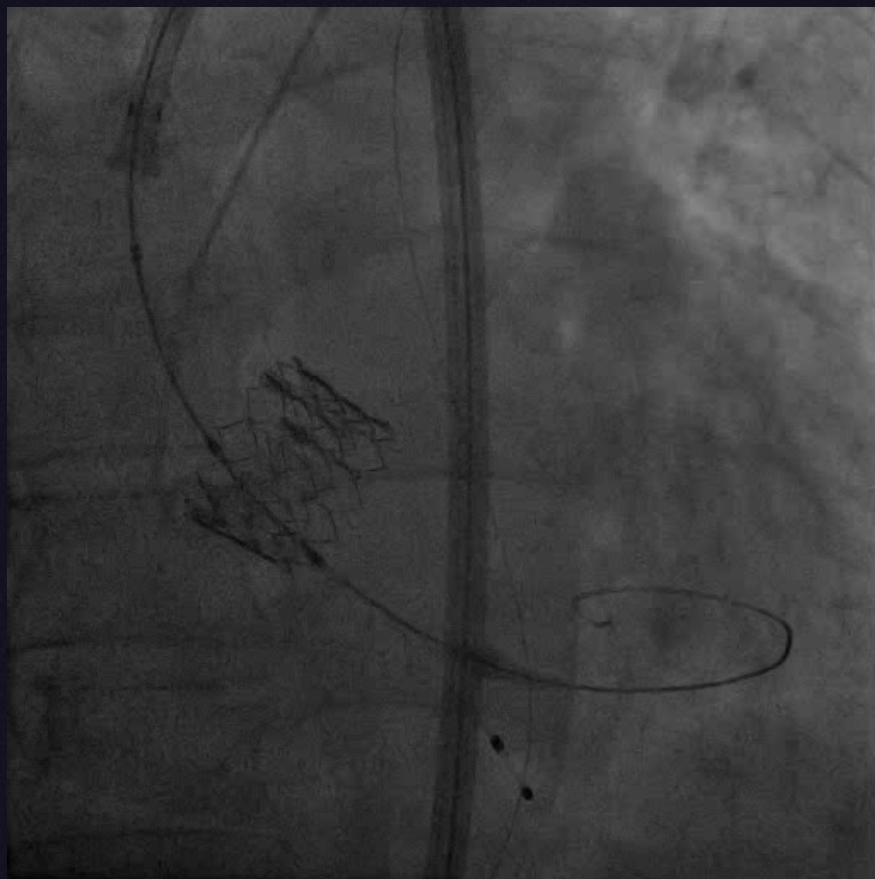


Pre-dilatation 25mm balloon

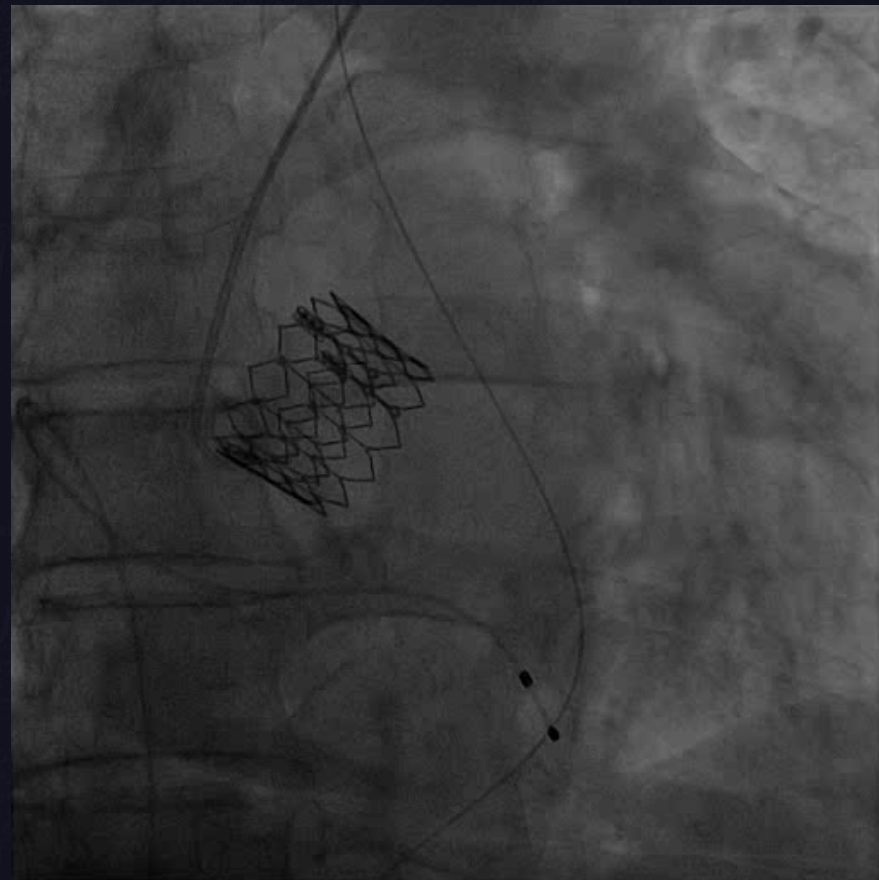


*Moderate AR after SAPIEN XT
29mm implantation*

2. Asymmetric calcification or extension into the LVOT



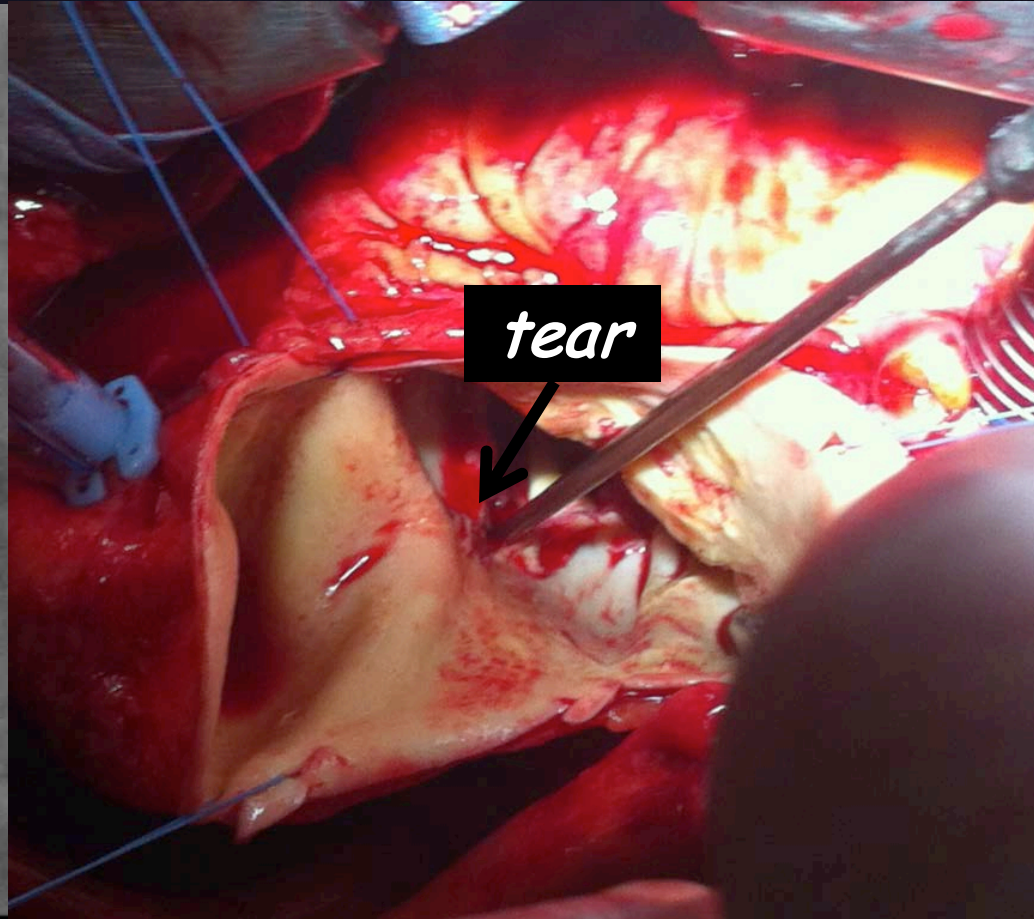
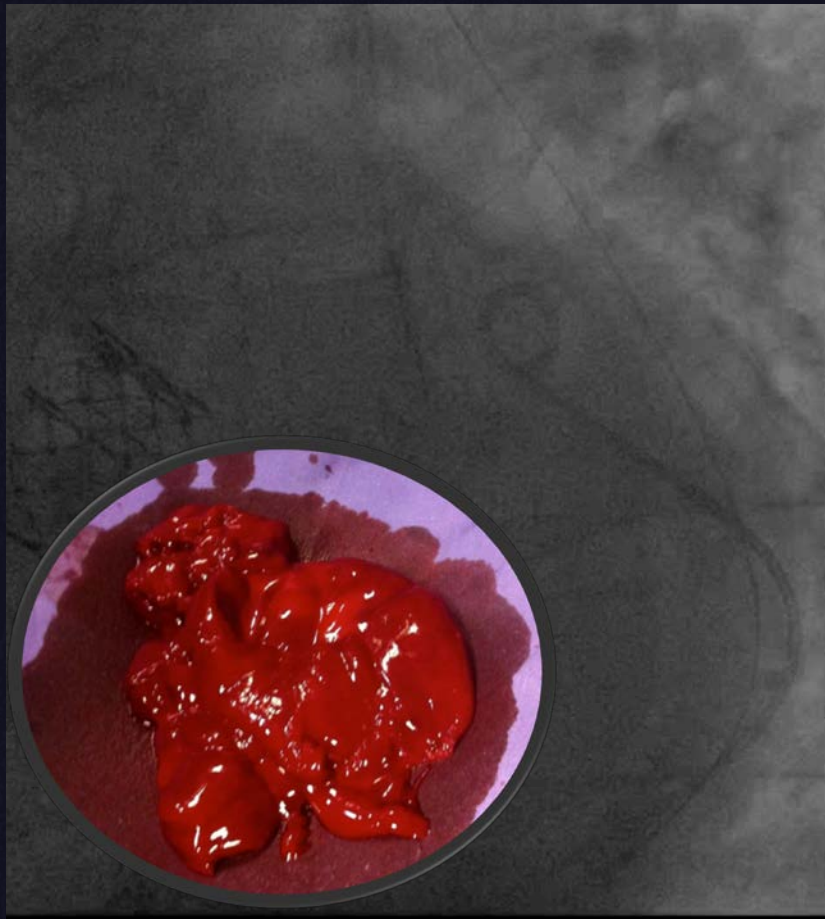
Post-dilatation 25mm balloon



Still moderate AR...

Severe hypotension!!

2. Asymmetric calcification or extension into the LVOT



Annulus rupture → pericardiocentesis

Uncertainty regarding annular size



→ Medtronic CoreValve is better

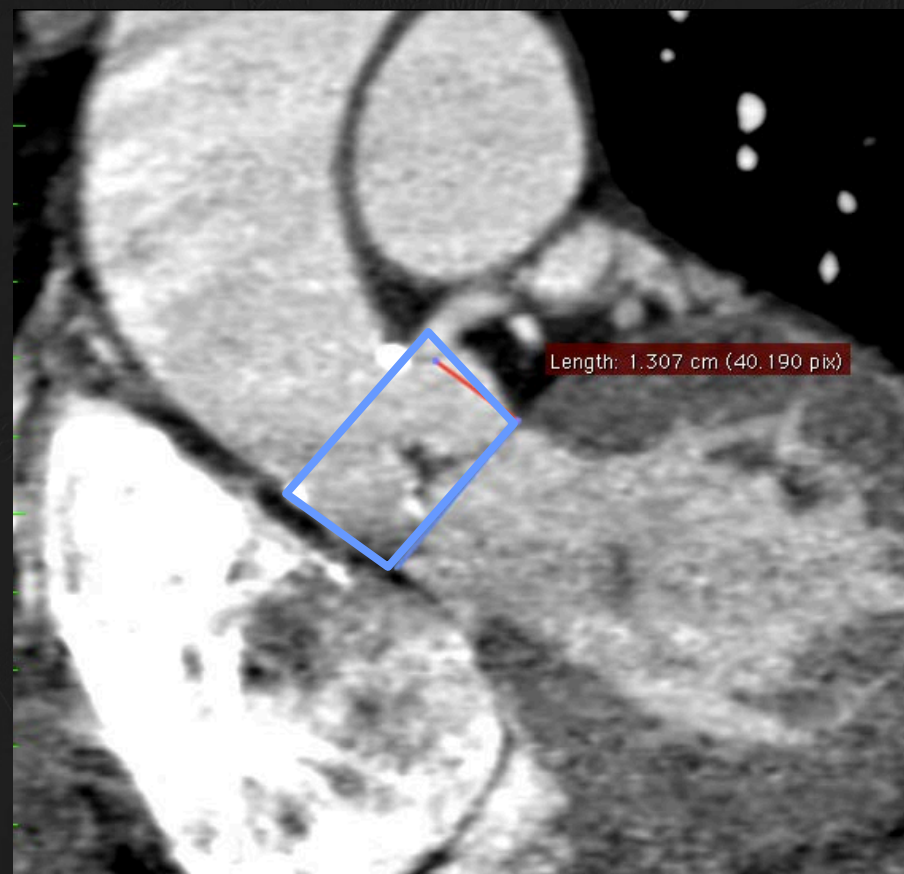
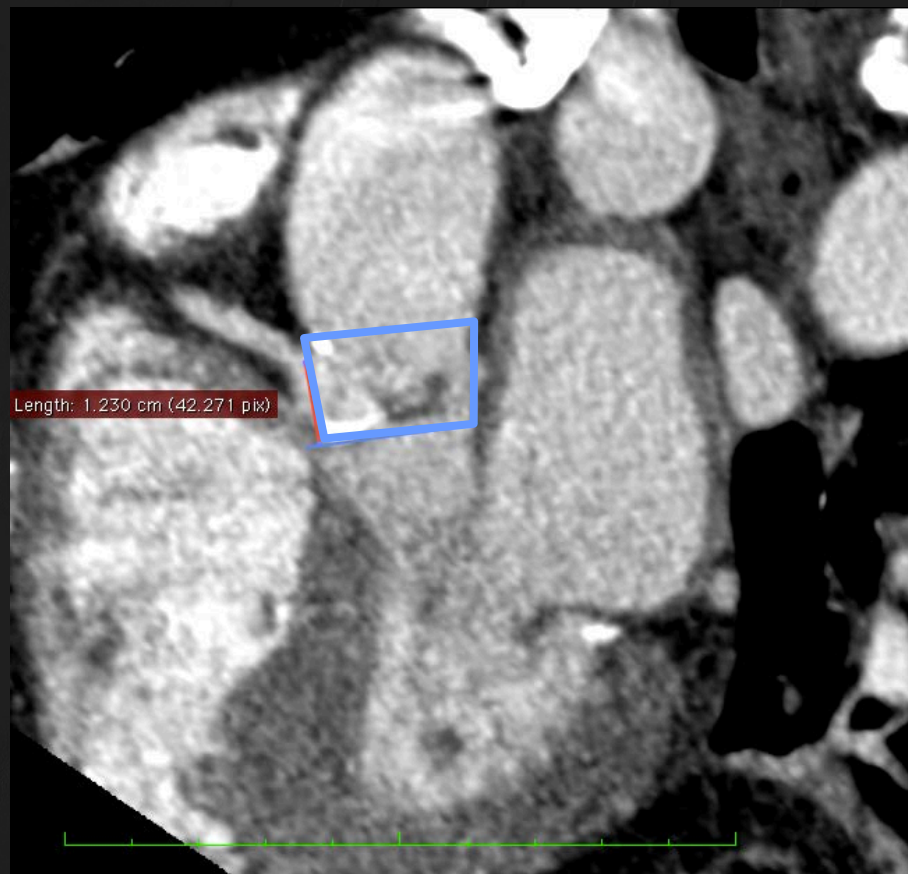
We need precise measurements for the balloon-expandable Edwards Sapien valve to prevent complications such as valve dislocation or annulus rupture. Also precise measurements required for DFM - CT is mandatory!!!

Repositioning to prevent coronary obstruction

February 10-12, 2011
Rome, Italy

international meeting

Risk of coronary obstruction predicted by CT



February 10-12, 2011
Rome, Italy

International meeting

Coronary Obstruction



Sluggish LCA flow & occluded RCA



Post-repositioning

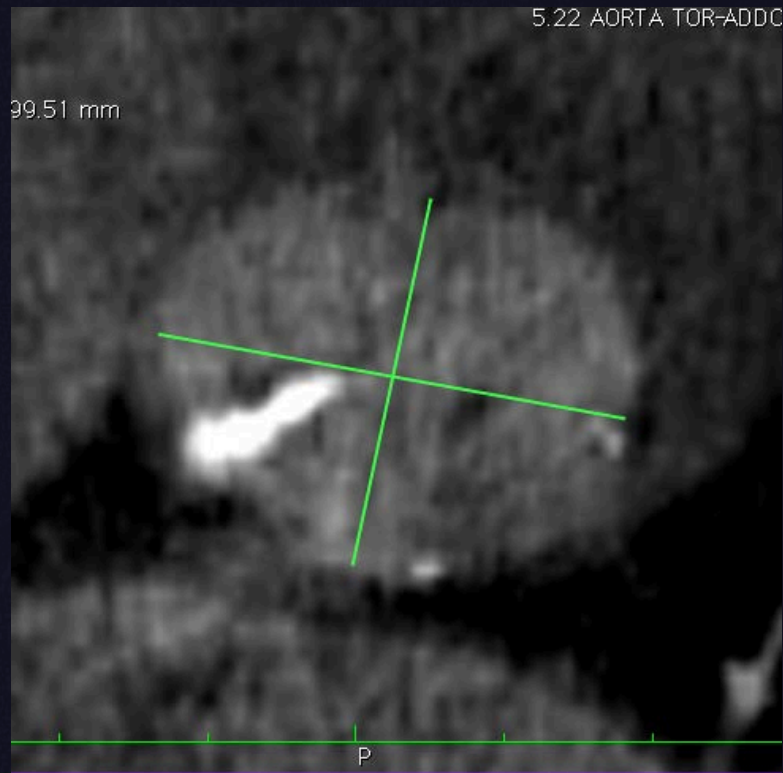
Large annulus

Joint interventional meeting

February 10-12, 2011
Rome, Italy

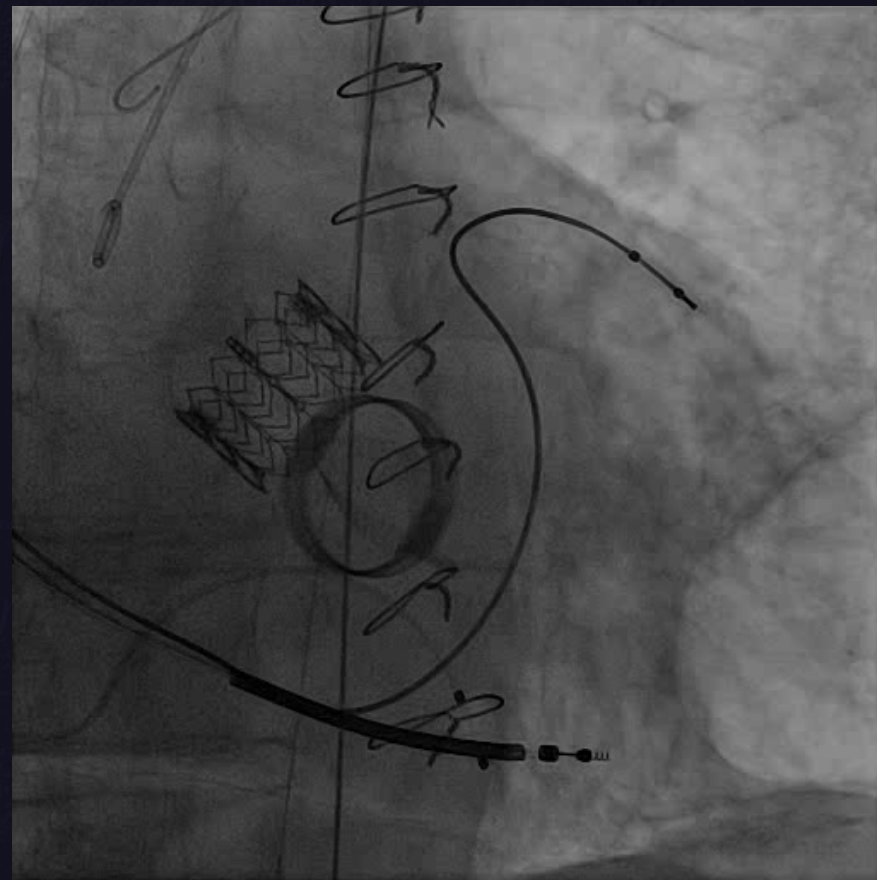
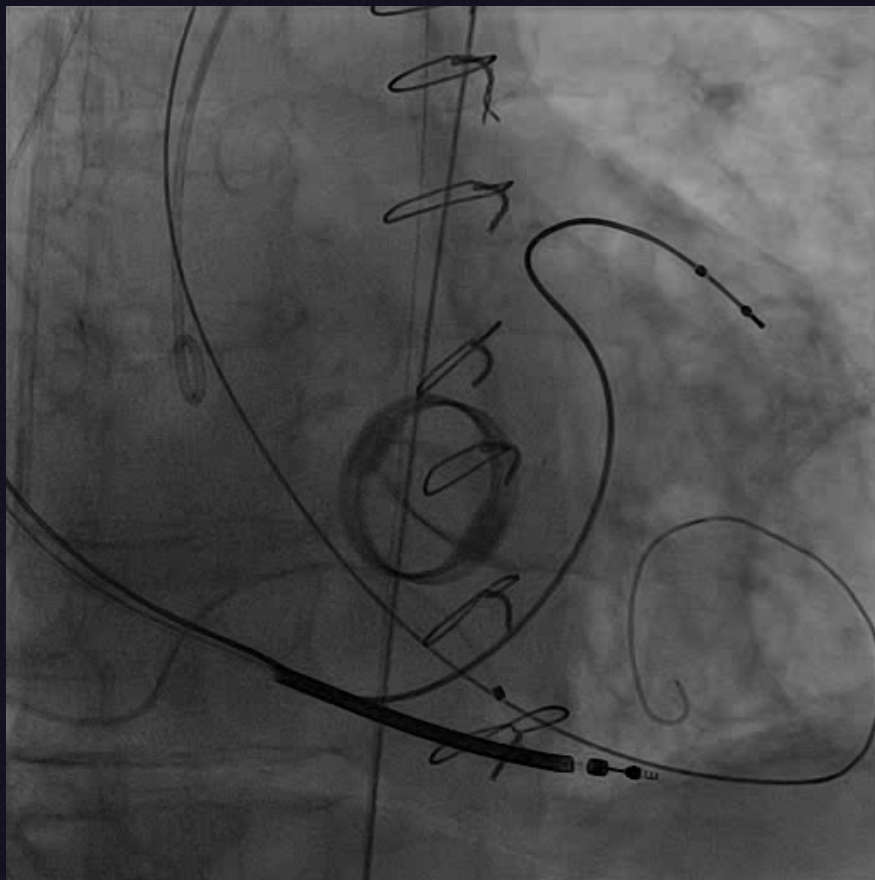
international meeting

Large annulus: more than 27mm



Diameter 2.5×3.2 mm
Perimeter 91.0 mm

Large annulus: more than 27mm

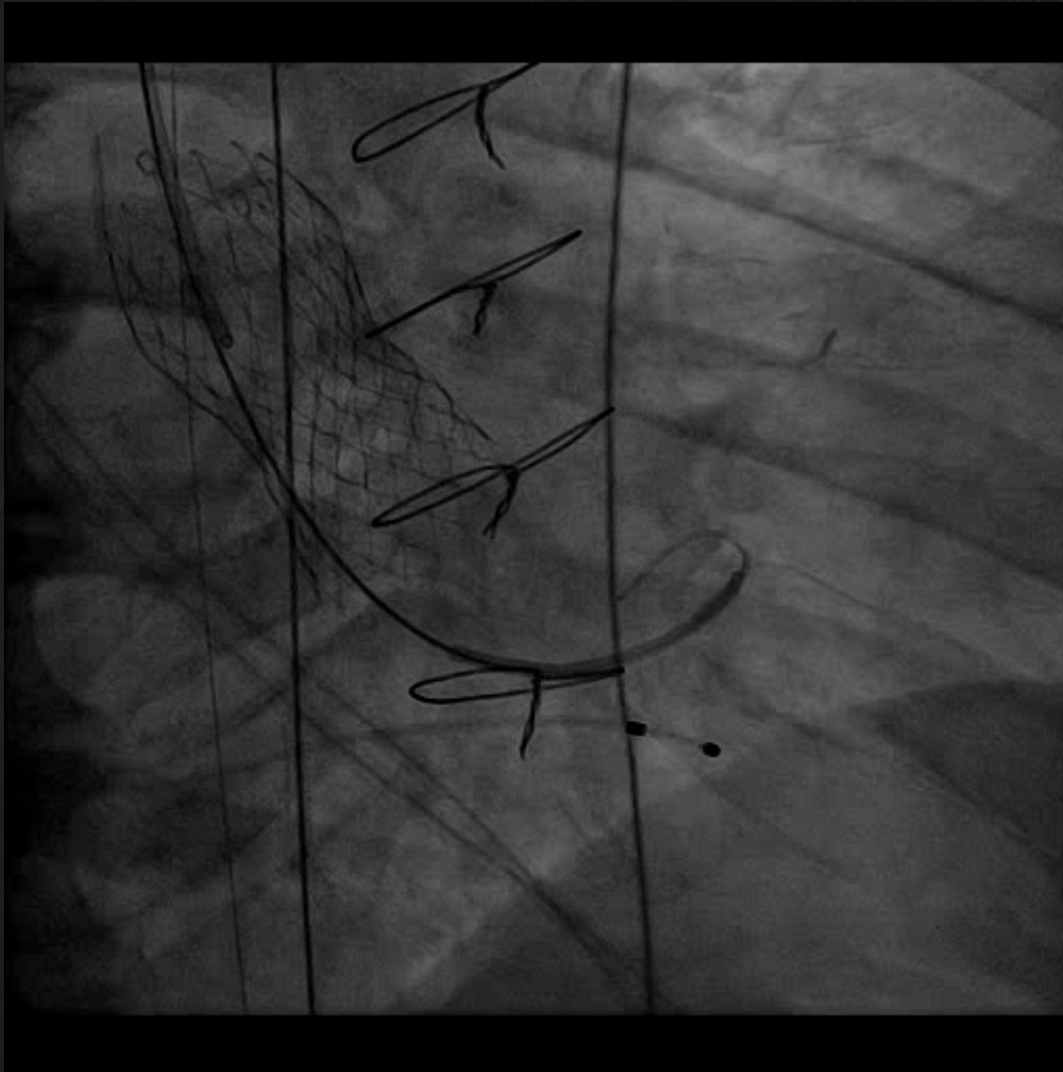


→ Edwards Sapien valve 29mm is better
than 31mm CoreValve

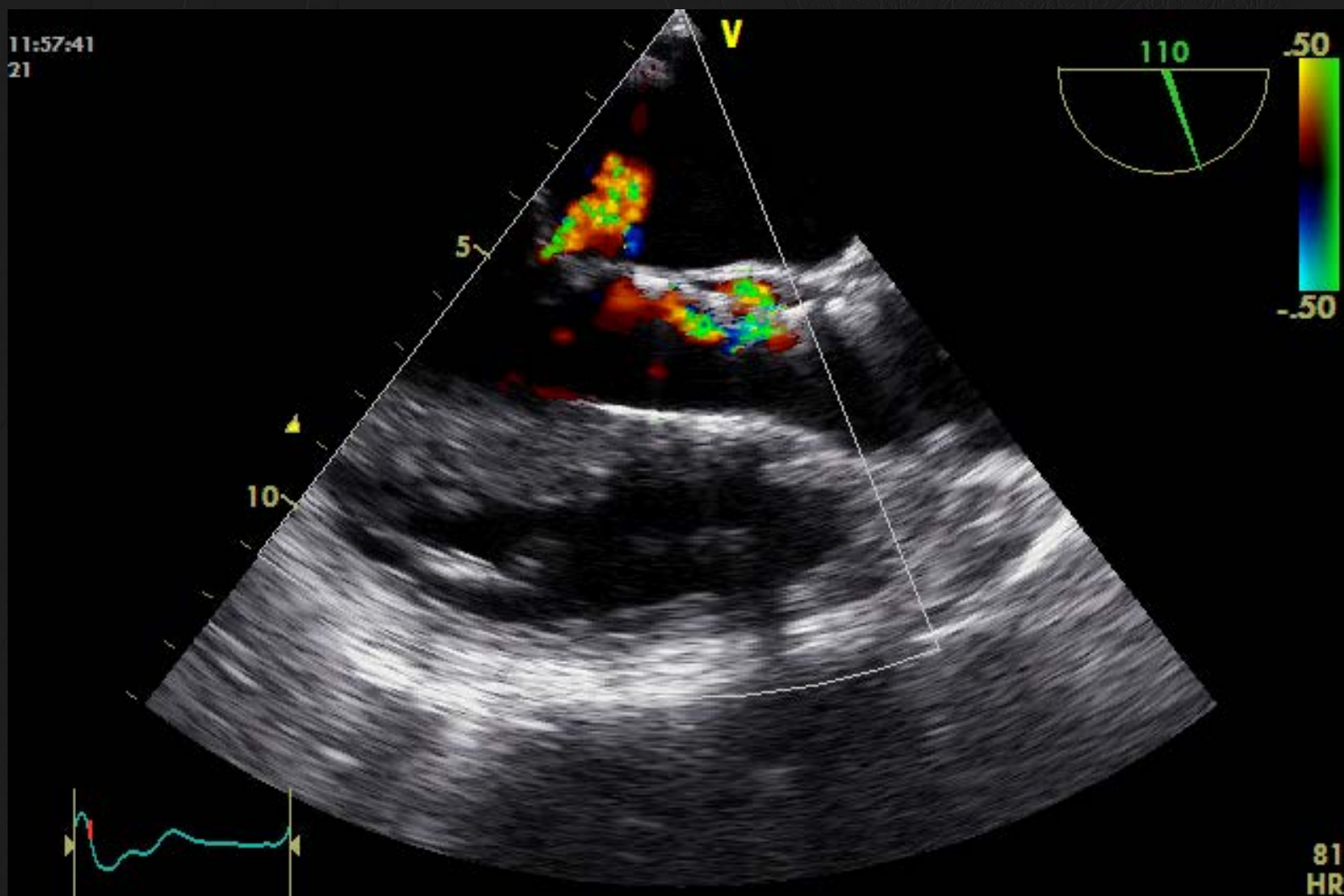
- 80-year old gentleman underwent TAVI for symptomatic severe AS due to high risk for conventional surgical AVR
- Annular diameter on the CT-26 mm
- Procedure from trans-femoral route
- 19-French Solopath

February 10-12, 2011
Rome, Italy

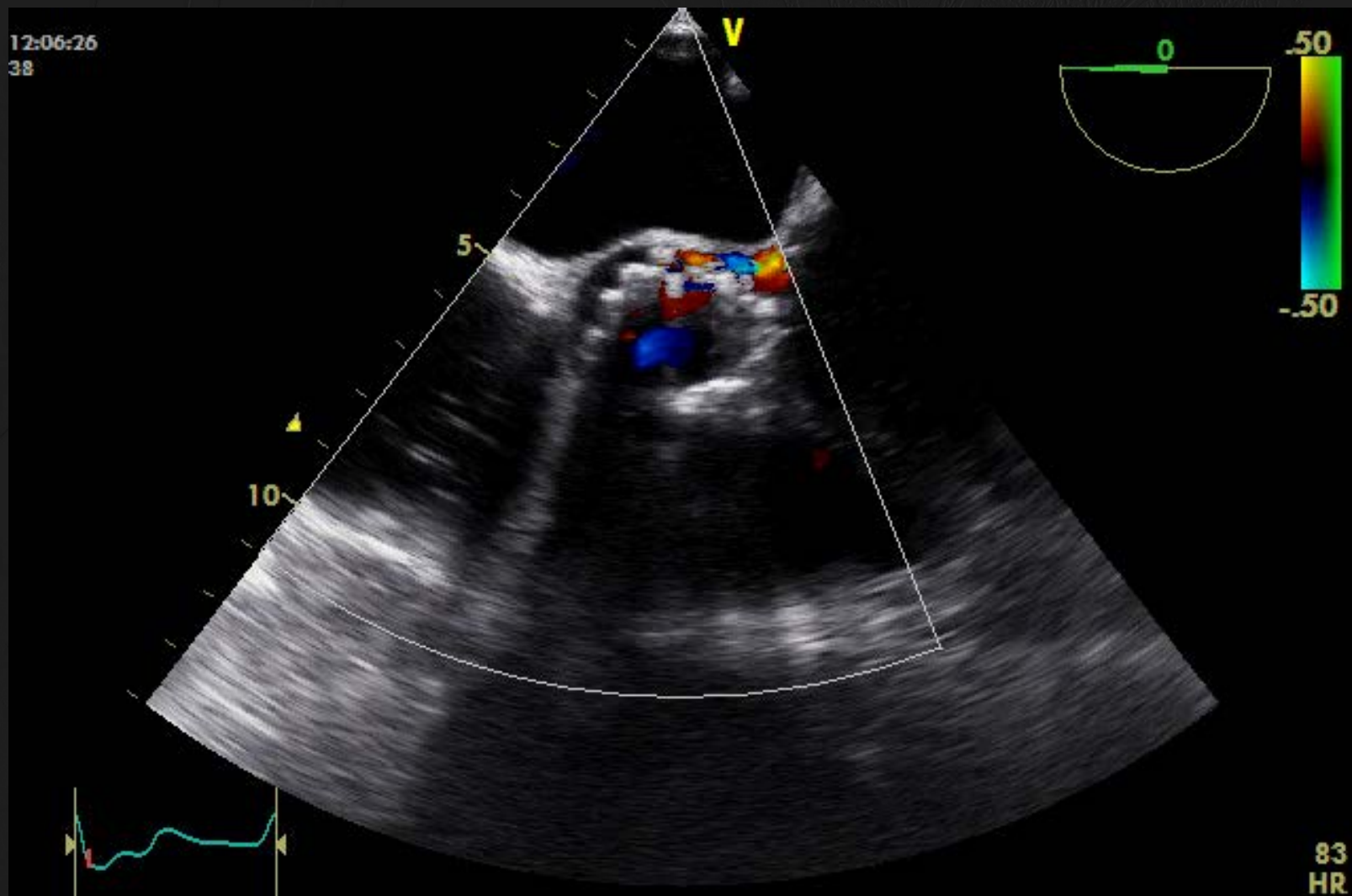
International meeting



CoreValve AR – What is the cause?

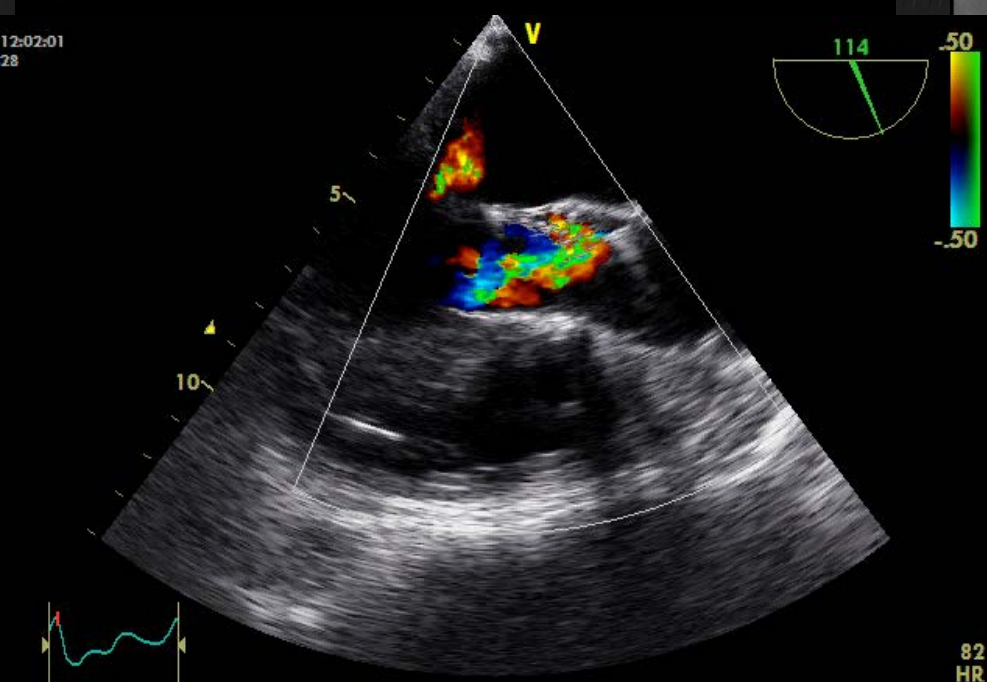
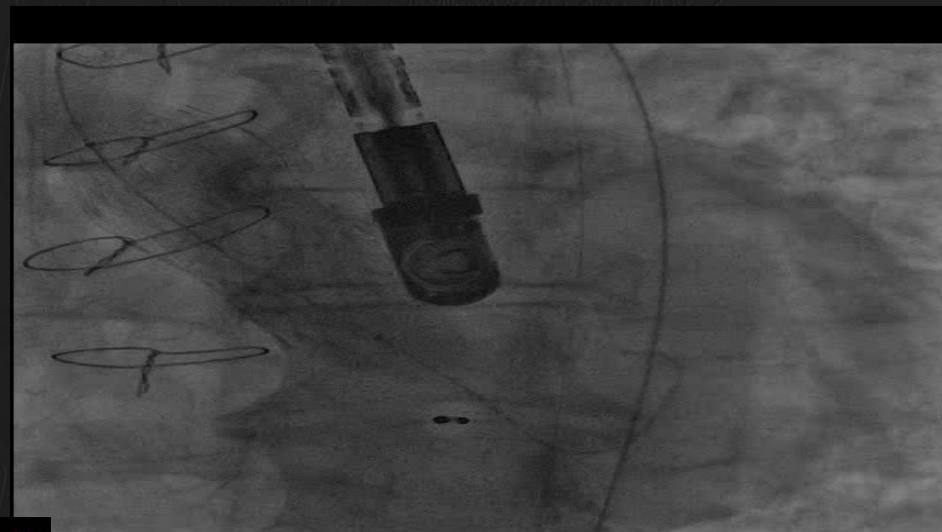
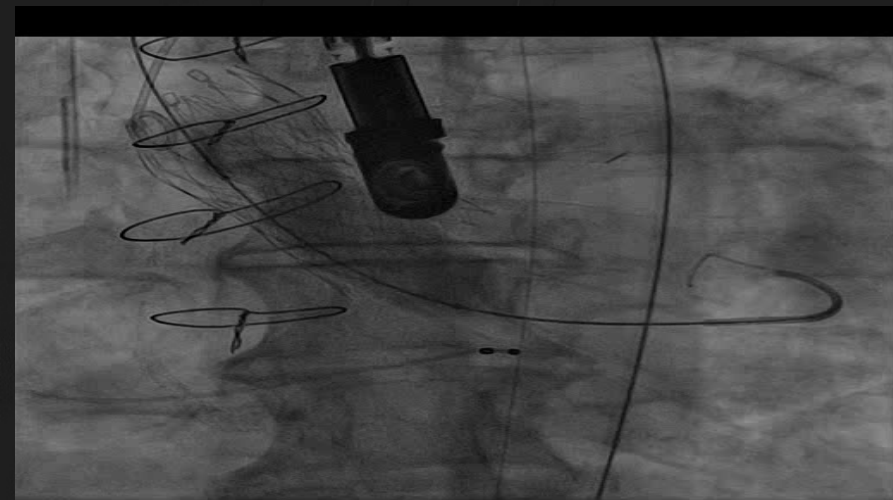


Grade 3 - Para-prosthetic and Intra-prosthetic AR



Grade 3 - Para-prosthetic and Intra-prosthetic AR

Serial Post-dilatation with 22 and 23 mm Balloon



No improvement

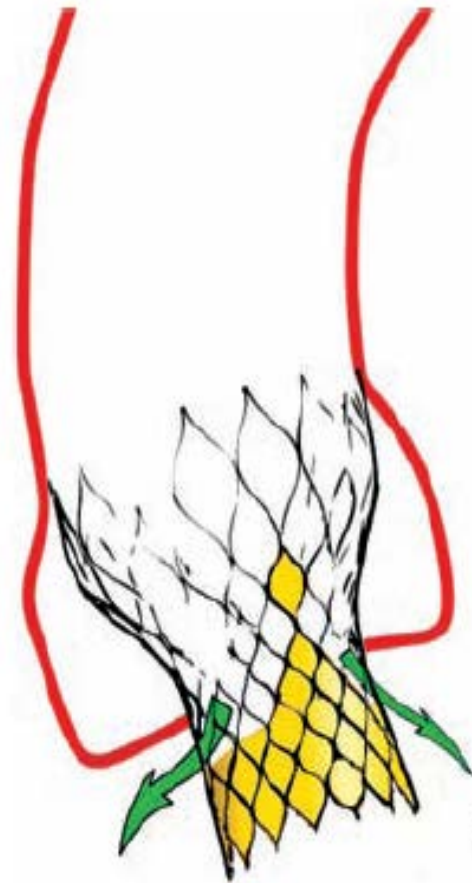
Persistence of grade 3 -AR

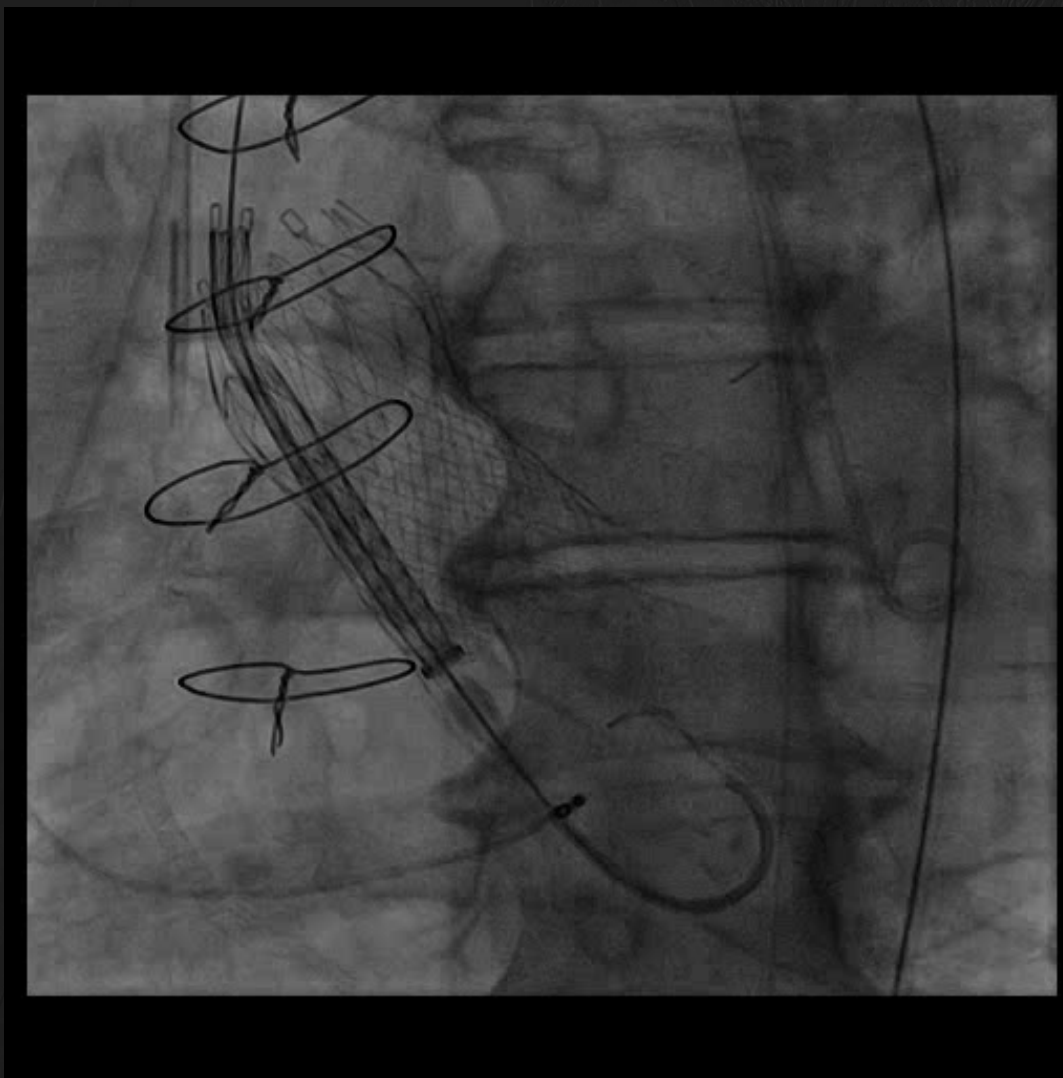
Why?

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

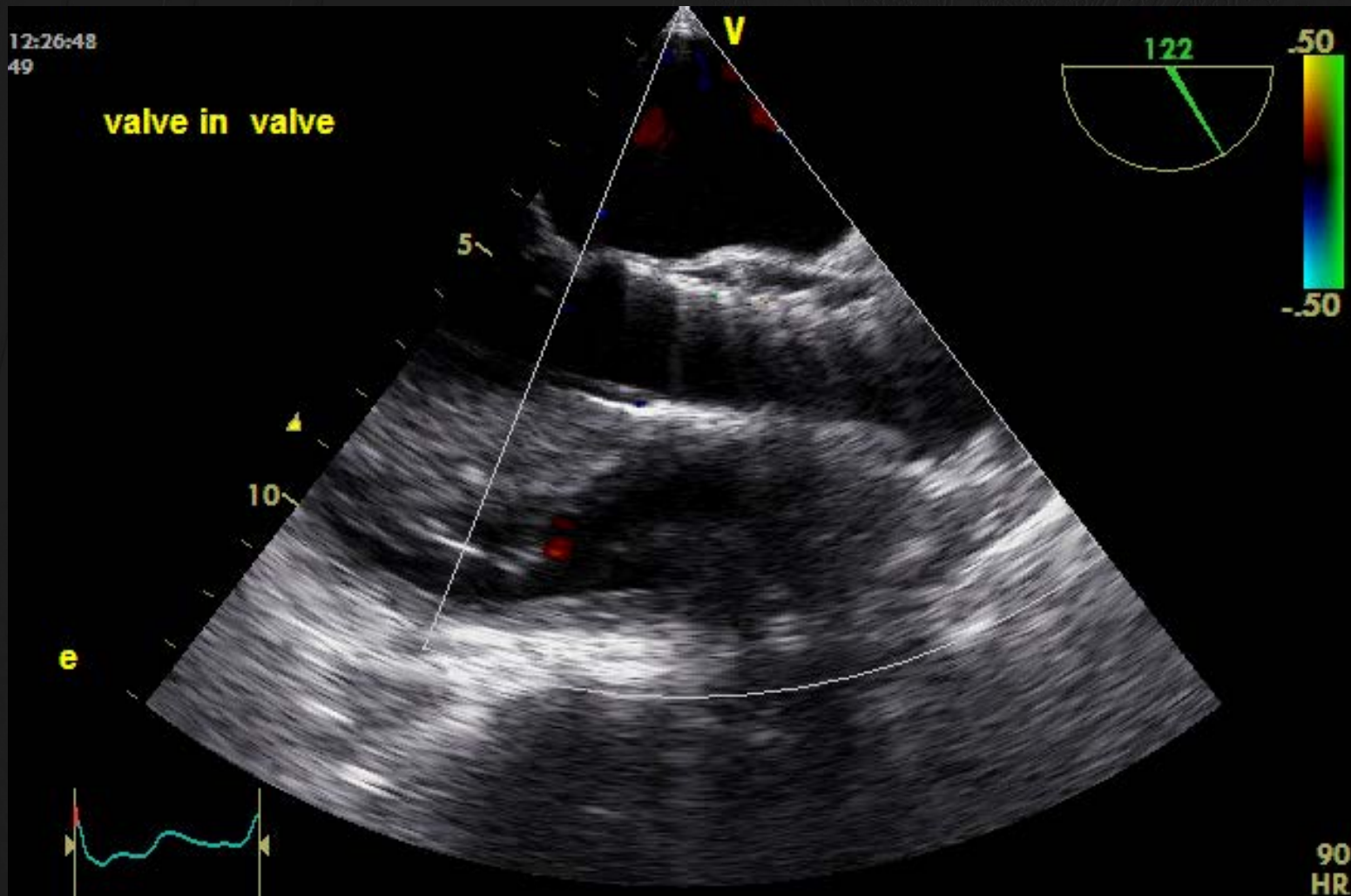
*The top pericardial skirt is
below the base of the aortic
root.*

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





Valve-in-Valve with 2nd CoreValve 26mm

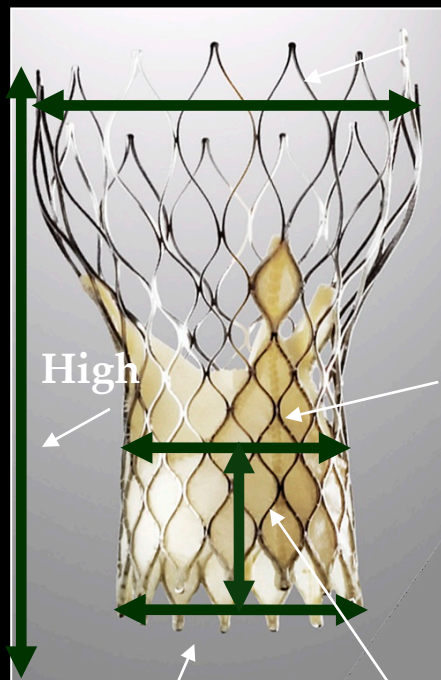


Final ECHO after 2nd CoreValve 26mm

Lessons

- Low position of the CoreValve leads to para-prosthetic AR
- It leaks through the normal gap in the valve above the skirt
- ** On the 2D-echo may appear as intra-prosthetic AR **
- Post-dilatation will not have effect on the AR

Measurements



Outflow Part

Constrained Part

Skirt (Height = 12 mm)

Inflow Part

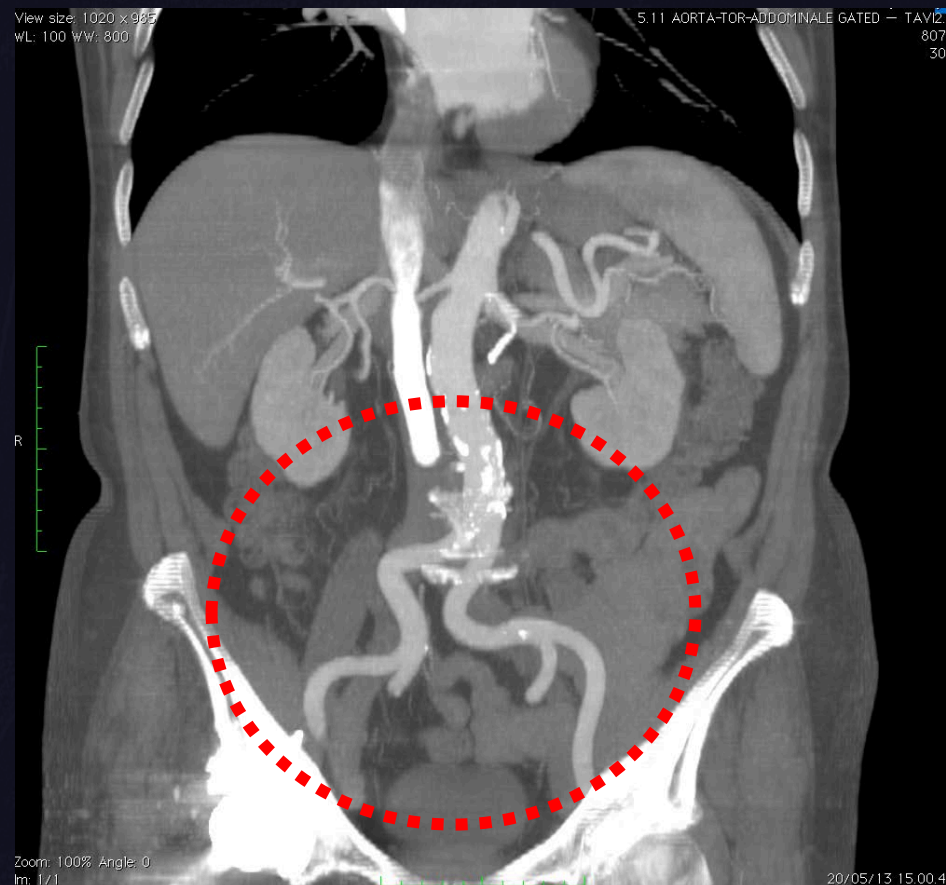
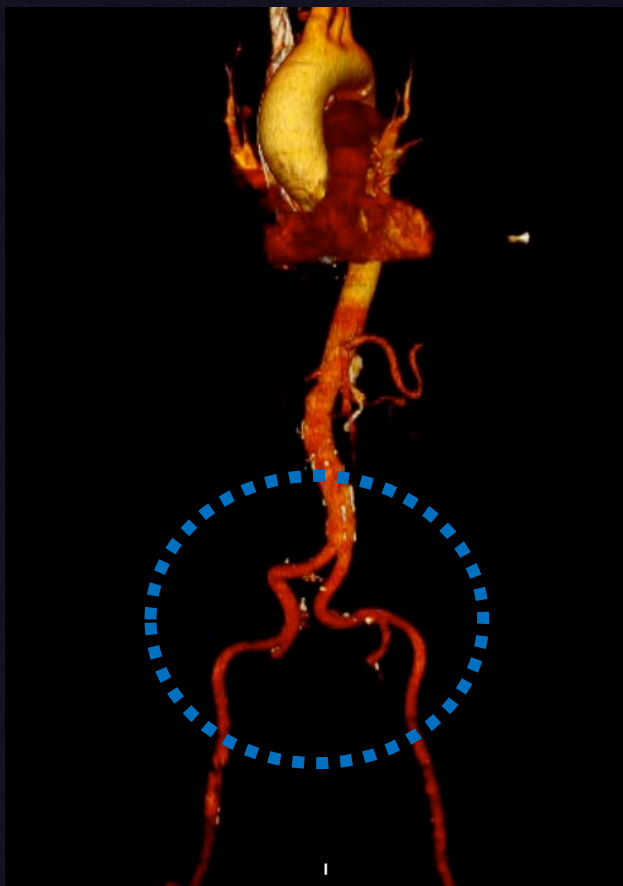
	26mm	29mm	31mm
Constrained Part Diameter [mm]	22	24	24
Inflow Part Diameter [mm]	26	29	31
Outflow part [mm]	40	43	43
High [mm]	55	53	53

Tortuosity

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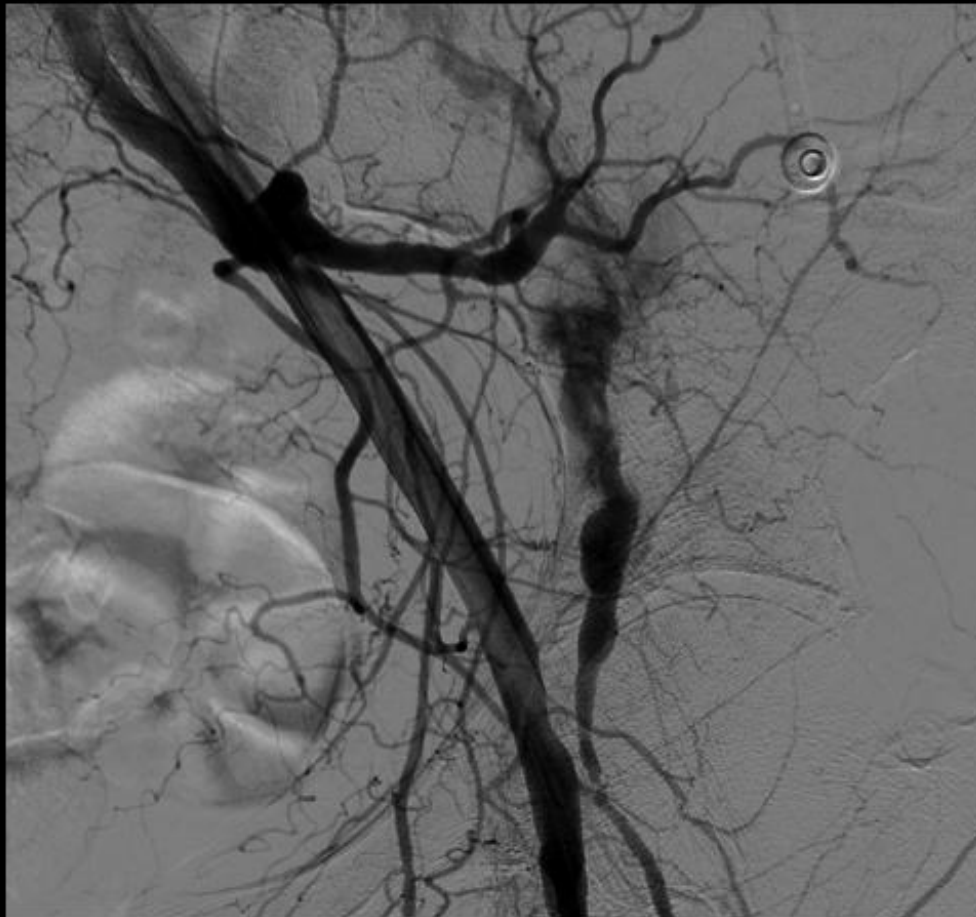
international meeting

4. Severe tortuosity in the access route



→ CoreValve is better?
→ Direct Flow is just as good!

Vessel rupture



Puncture and perforation of the left superficial epigastric artery



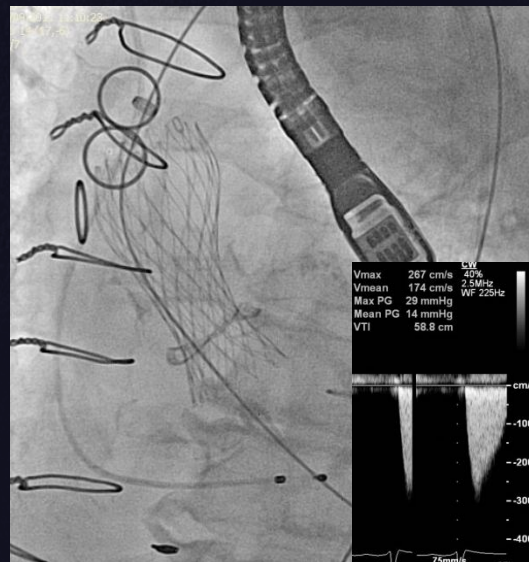
Implantation of covered stent (Aneugraft
3.5x18mm)

Valve-in-valve

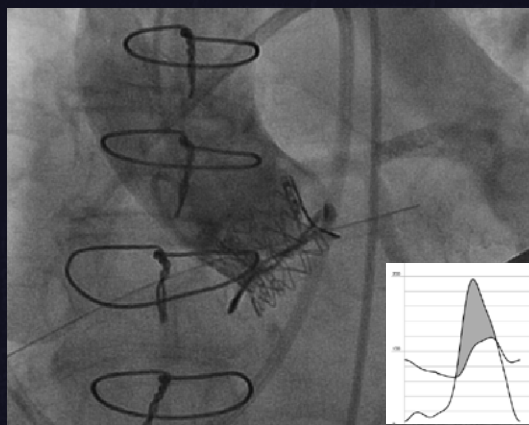
→ Medtronic CoreValve

We can obtain less pressure gradient as compared to Edwards Sapien valve.

Case examples of VIV in small Surgical bioprosthetic valves



Center #22, case#5
Mitroflow 19mm (ID 15.4mm)
Transfemoral CoreValve 26mm
Post TAVR gradients: 29/14mmHg

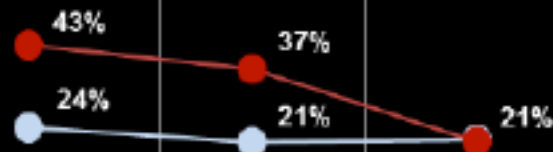


Center #33, case#1
Mitroflow 21mm (ID 17mm)
Transapical Edwards-SAPIEN 23mm
Post TAVR gradients: 88/58mmHg

Current Edwards-Sapien devices result-in very high gradients when used in small bioprosthetic valves

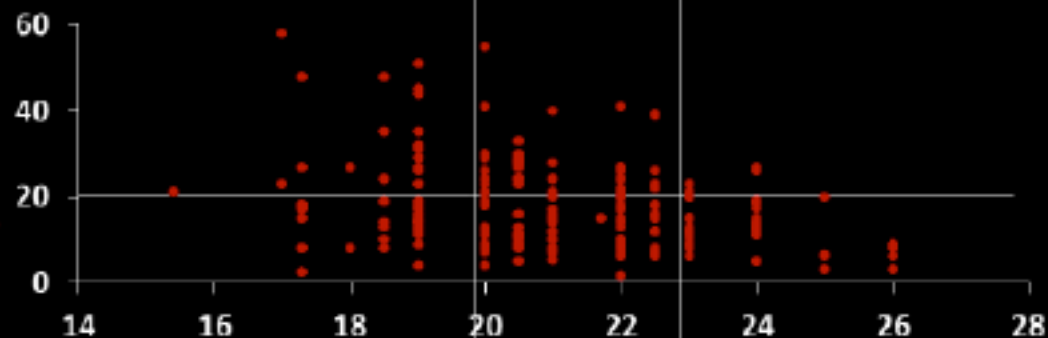
Valve in Valve International Registry

**Rate of Post-procedural
mean gradients ≥ 20 mmHg (%)**



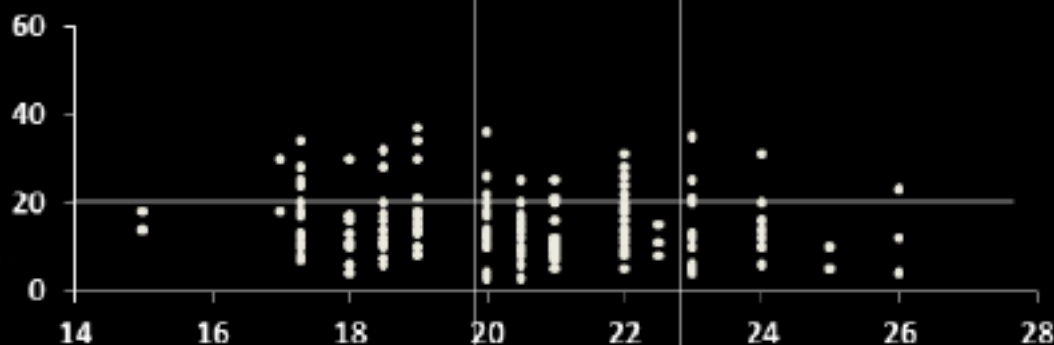
Edwards SAPIEN

**Post procedural mean
aortic-valve gradients (mmHg)**



CoreValve

**Post procedural mean
aortic-valve gradients (mmHg)**



**Small
< 20**

**Intermediate
≥ 20 & < 23**

**Large
≥ 23**

Surgical valve internal diameter (mm)

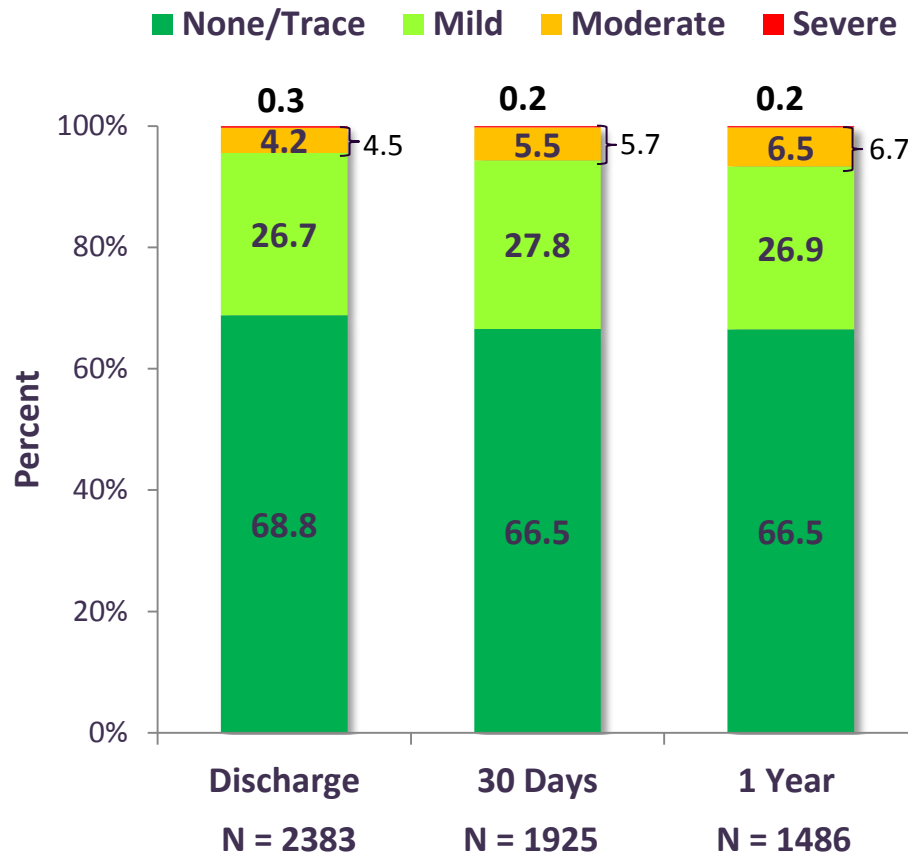
Residual aortic regurgitation

joint interventional meeting

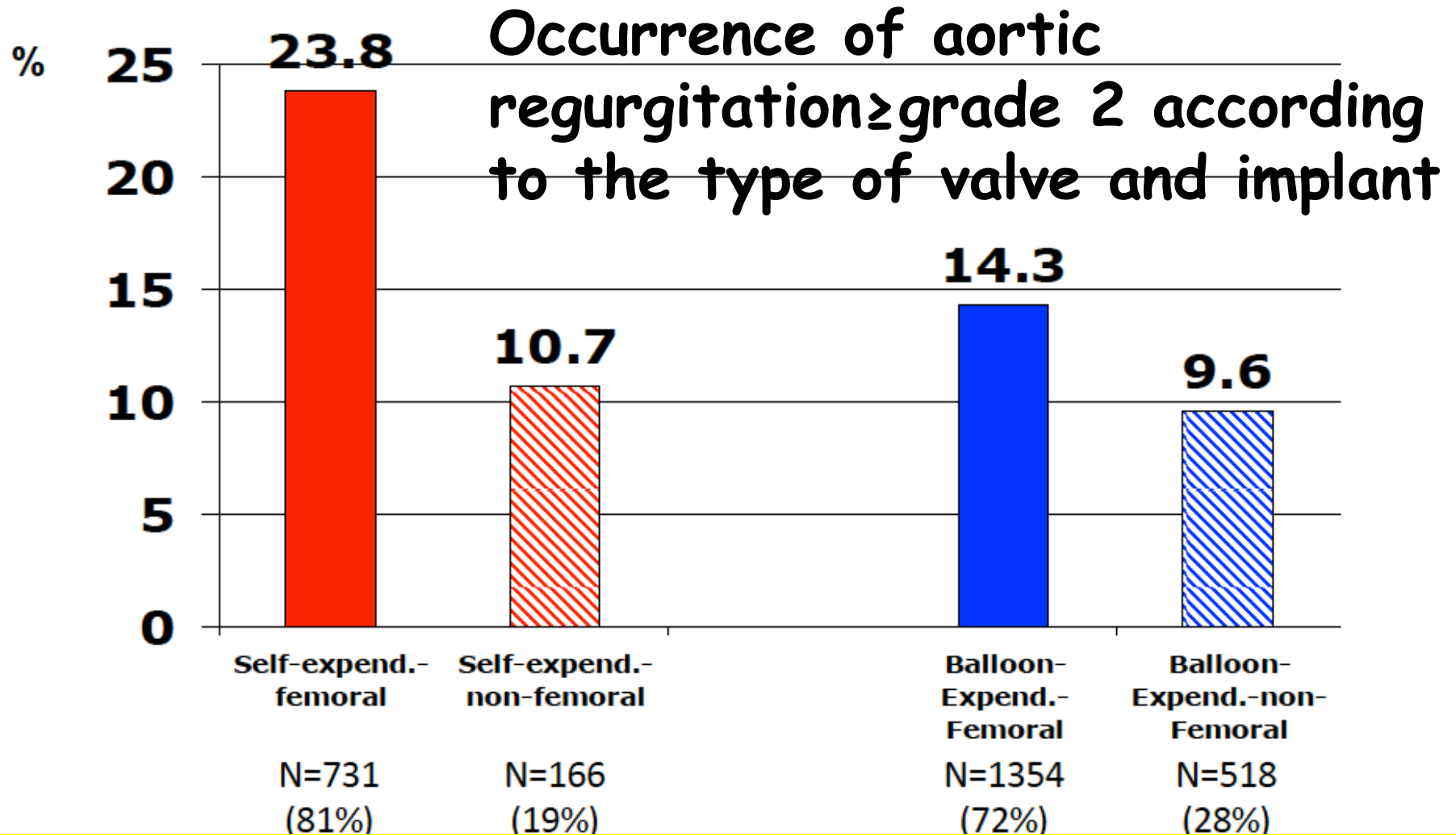
2019

AORTIC REGURGITATION SOURCE XT REGISTRY

TOTAL AR

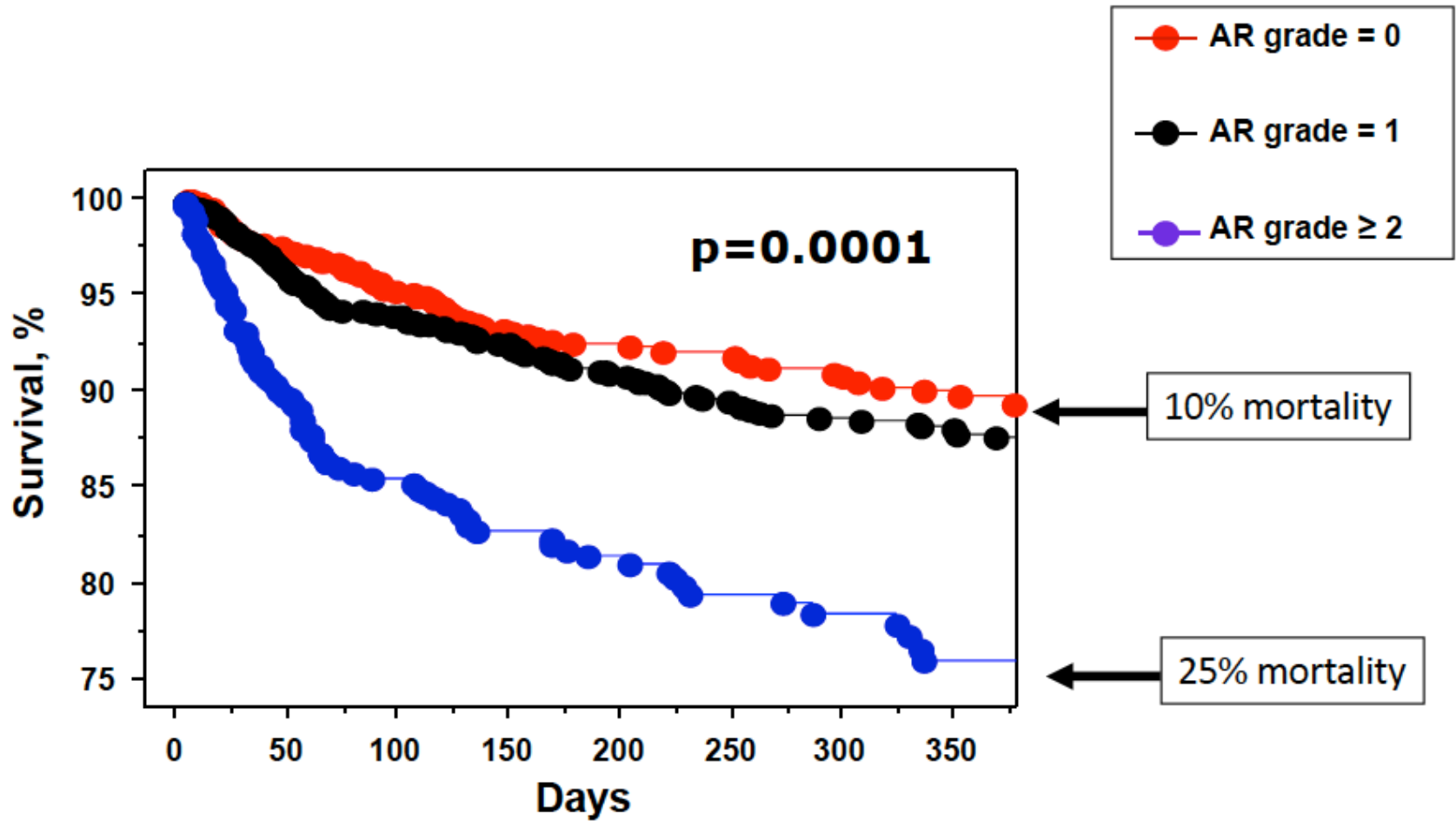


FRANCE 2 Registry 3195 pts., TTE in 2769 pts. at 2 days

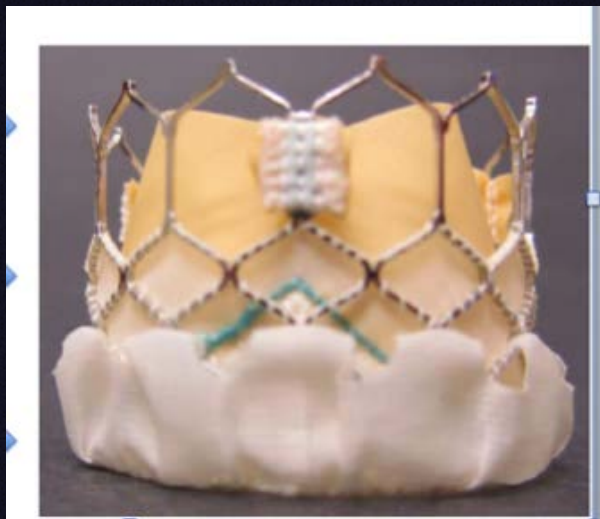


none or trivial (=0), mild (=1), moderate (=2), moderate-to-severe (=3), severe (=4)

1 yr. mortality according to the degree of residual AR



New valves are coming



Sapien 3

Lotus by BS



Lotus



Direct Flow

Direct
Flow
CE Mark

IMAGES IN CARDIOLOGY

Treating Aortic Stenosis and Mitral Regurgitation With 1 Transcatheter Heart Valve

2 Birds With 1 Stone

William M. Suh, MD,* Gabriel Vorobiof, MD,* Richard J. Shemin, MD,†
Murray H. Kwon, MD,† Melissa Fusari, MD,‡ Jonathan M. Tobis, MD*

Los Angeles and Irvine, California

An 82-year-old woman with severe aortic stenosis and left ventricular ejection fraction (LVEF) of 20% was referred for transcatheter aortic valve replacement (TAVR). Aortic regurgitation was moderate, mean gradient was 38 mm Hg (B), mitral regurgitation (MR) was severe (I), and the LV was markedly dilated to 251 ml (D). TAVR with a 23-mm Edwards Sapien valve was performed with cardiopulmonary bypass for hemodynamic stability during valve implantation. After TAVR, there was trace central aortic regurgitation (E), mean gradient was reduced to 9 mm Hg (F), MR disappeared completely, and LV volume was reduced to 168 ml (H) with an LVEF of 30%

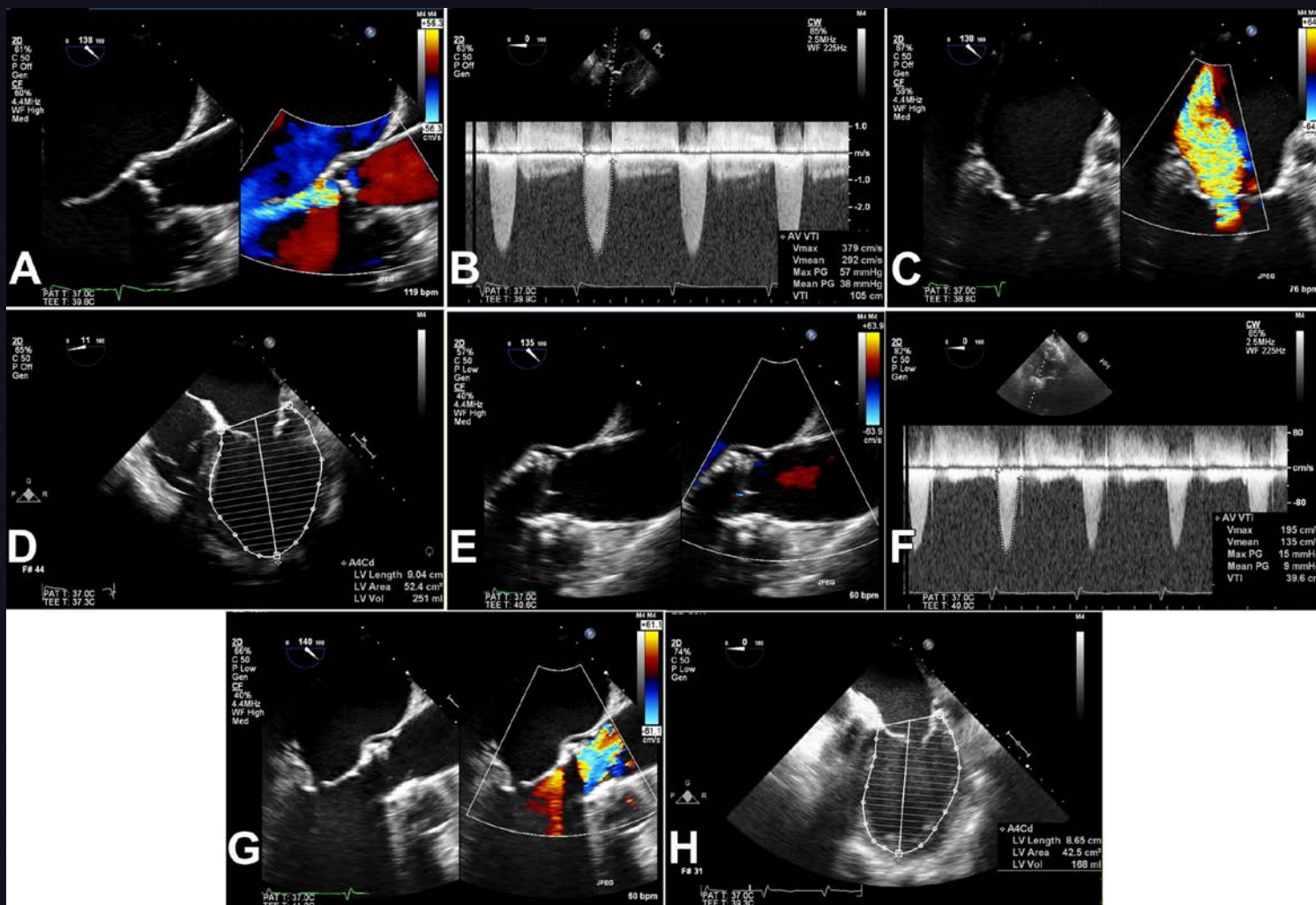
SOURCE XT Registry Moderate MR: 462 Severe MR: 57

• euro
PCR
2013

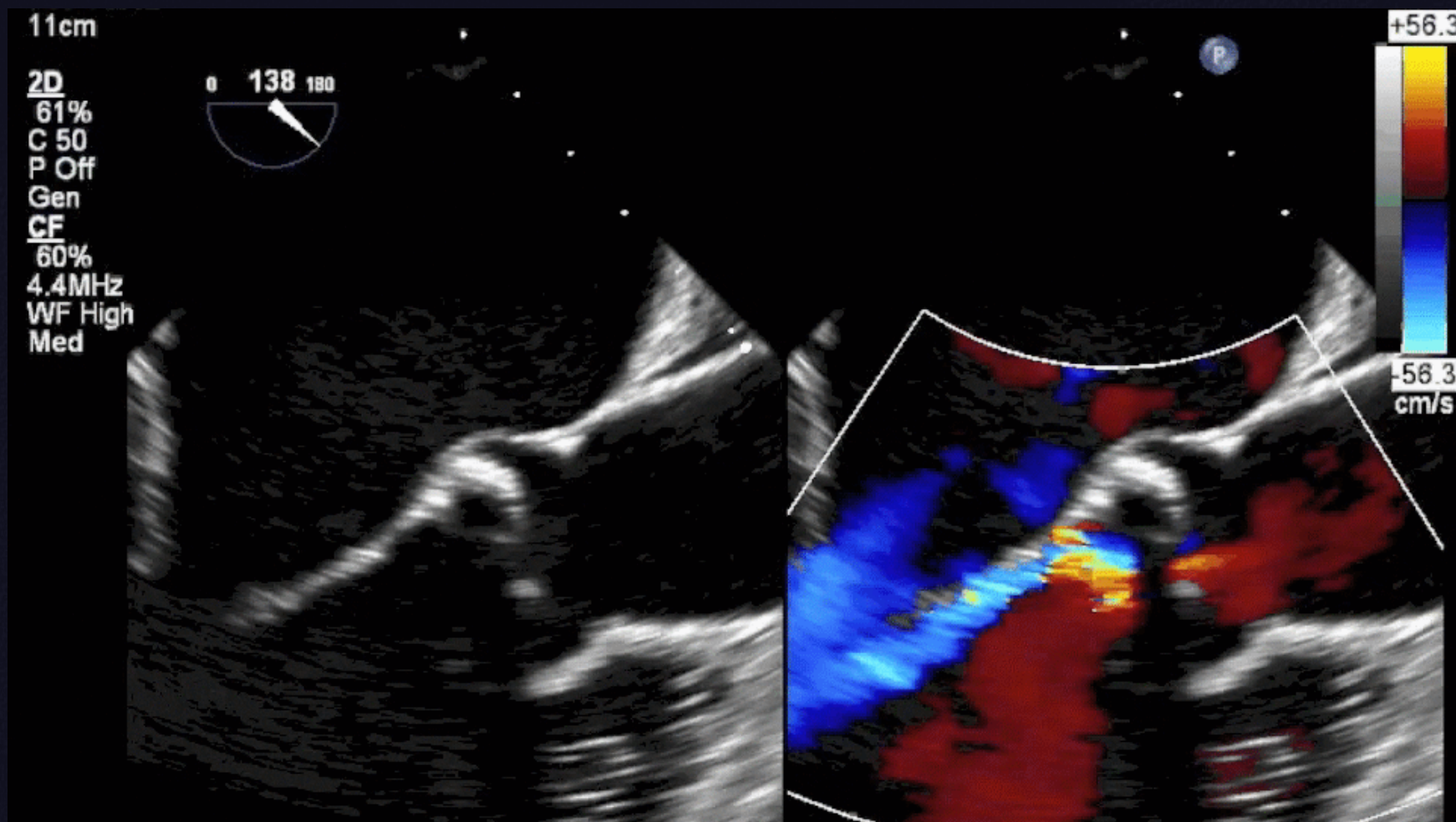
Conclusions

- Appr. 20% of patients currently undergoing TAVI with the SAPIEN XT valve have moderate or severe MR.
- Patients with MR have a significantly worse risk profile and increased 1-year mortality.
- Moderate or severe MR improves in more than 2/3 of patients following TAVI with the SAPIEN XT valve.
- The significant improvement in functional class does not differ from patients without moderate or severe MR.
- Residual moderate/severe MR is associated with higher mortality and predicted by more advanced disease and co-morbidities.
- Given the clinical benefit patients with concomitant moderate or severe MR should be considered suitable for TAVI.

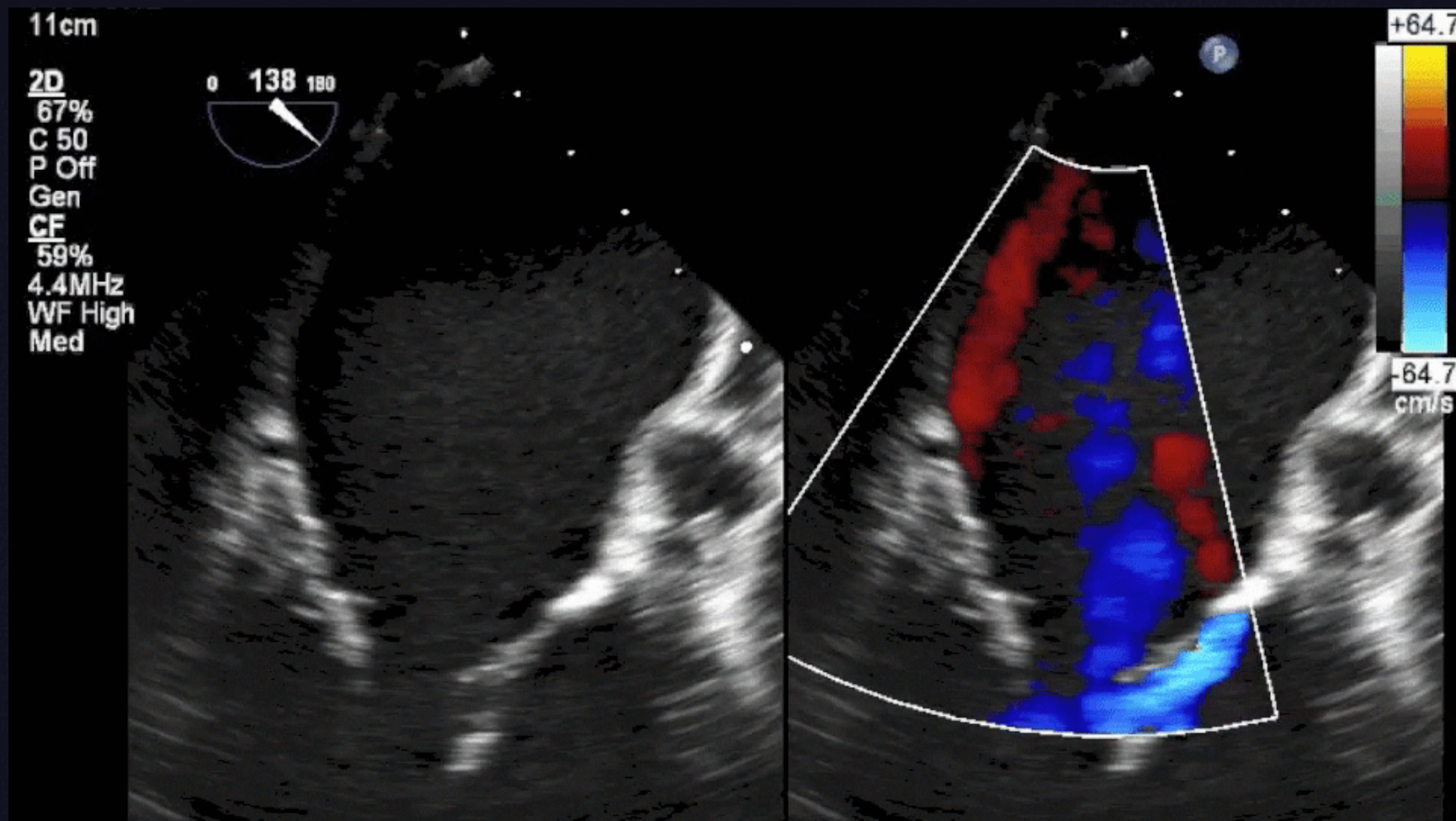
Thank you for your attention



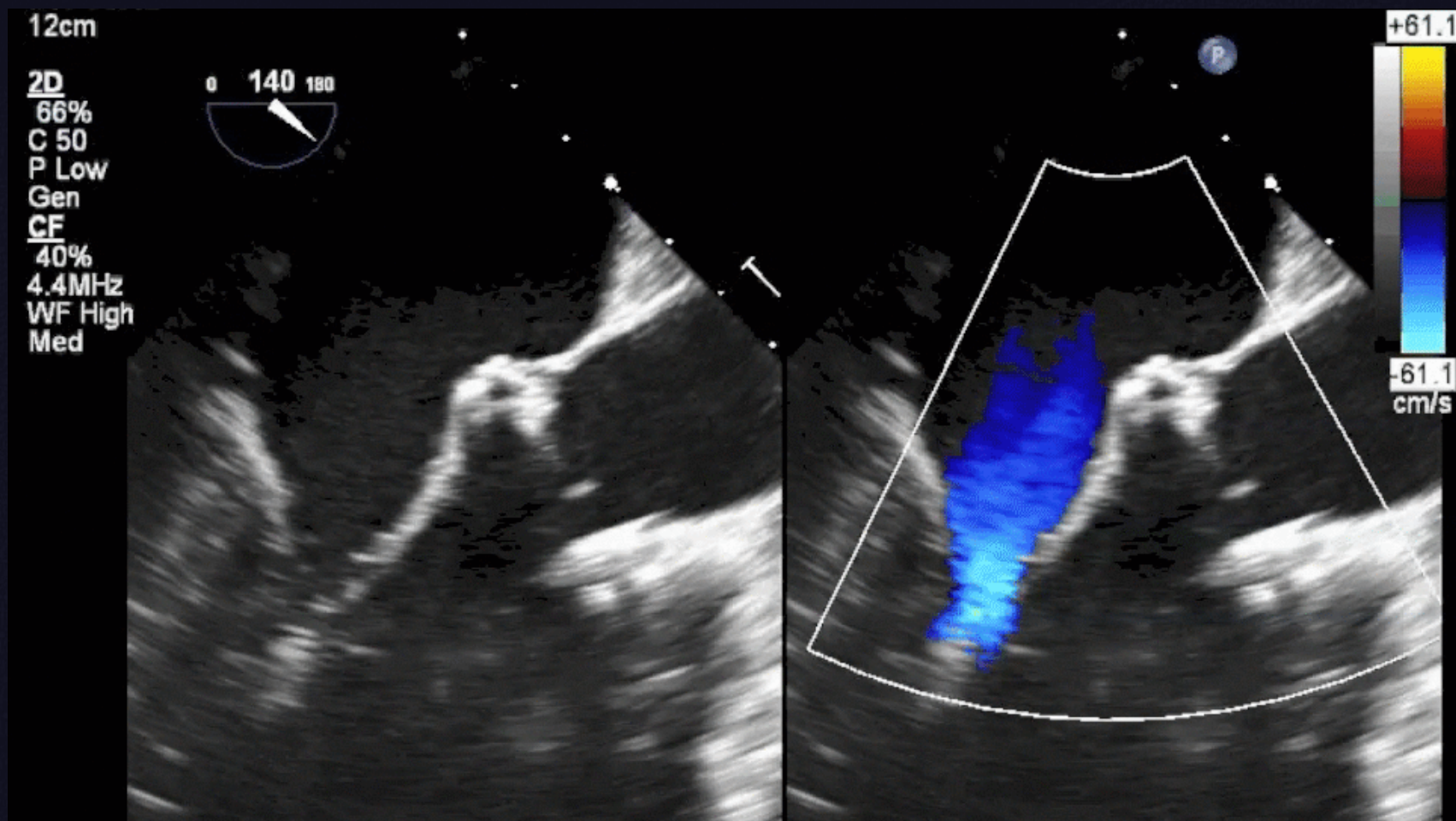
Aortic regurgitation was moderate (A), mean gradient was 38 mm Hg (B), mitral regurgitation (MR) was severe (C), and the LV was markedly dilated to 251 ml (D). TAVR with a 23-mm Edwards Sapien valve was performed with cardiopulmonary bypass for hemodynamic stability during valve implantation. After TAVR, there was trace central aortic regurgitation (E), mean gradient was reduced to 9 mm Hg (F), MR disappeared completely (G), and LV volume was reduced to 168 ml (H) with an LVEF of 30%



Aortic regurgitation was moderate



Mitral regurgitation (MR) was severe



MR disappeared completely

Transfemoral TAVI without contrast

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Rome, Italy

international meeting

Case Summary

Patient demographics

- Age: 76
- Male
- 160 cm, 60 Kg, BMI 23.4

Past medical history

- Ischemic dilated cardiomyopathy, previous open CABG
- Bladder Ca
- Chronic Renal Failure
creatinine 2.6 mg/dl
CrCl 26 mL/min/1.73 m²

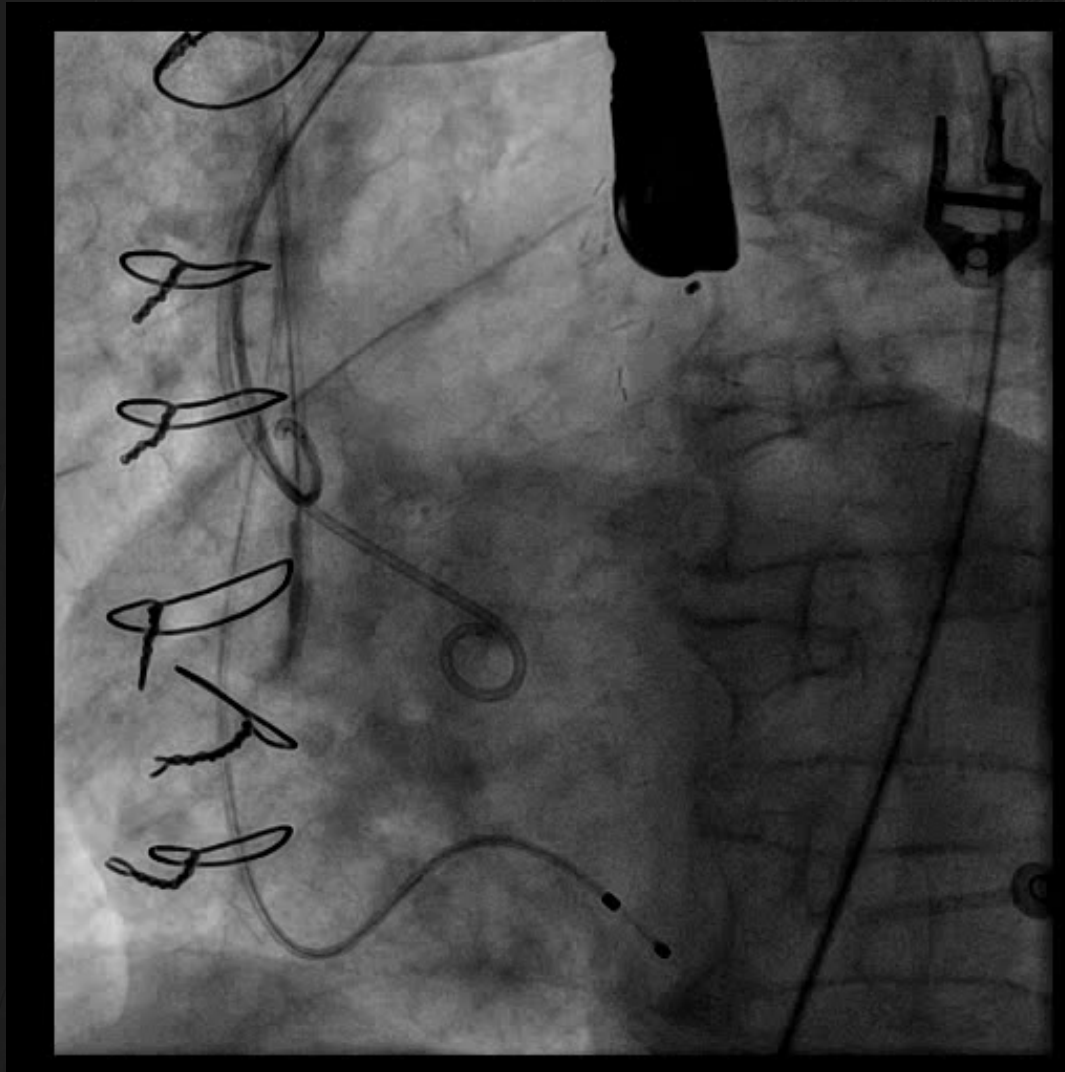
Clinical presentation

- Progressively worsening dyspnea NYHA III associated with episodes of chest pain

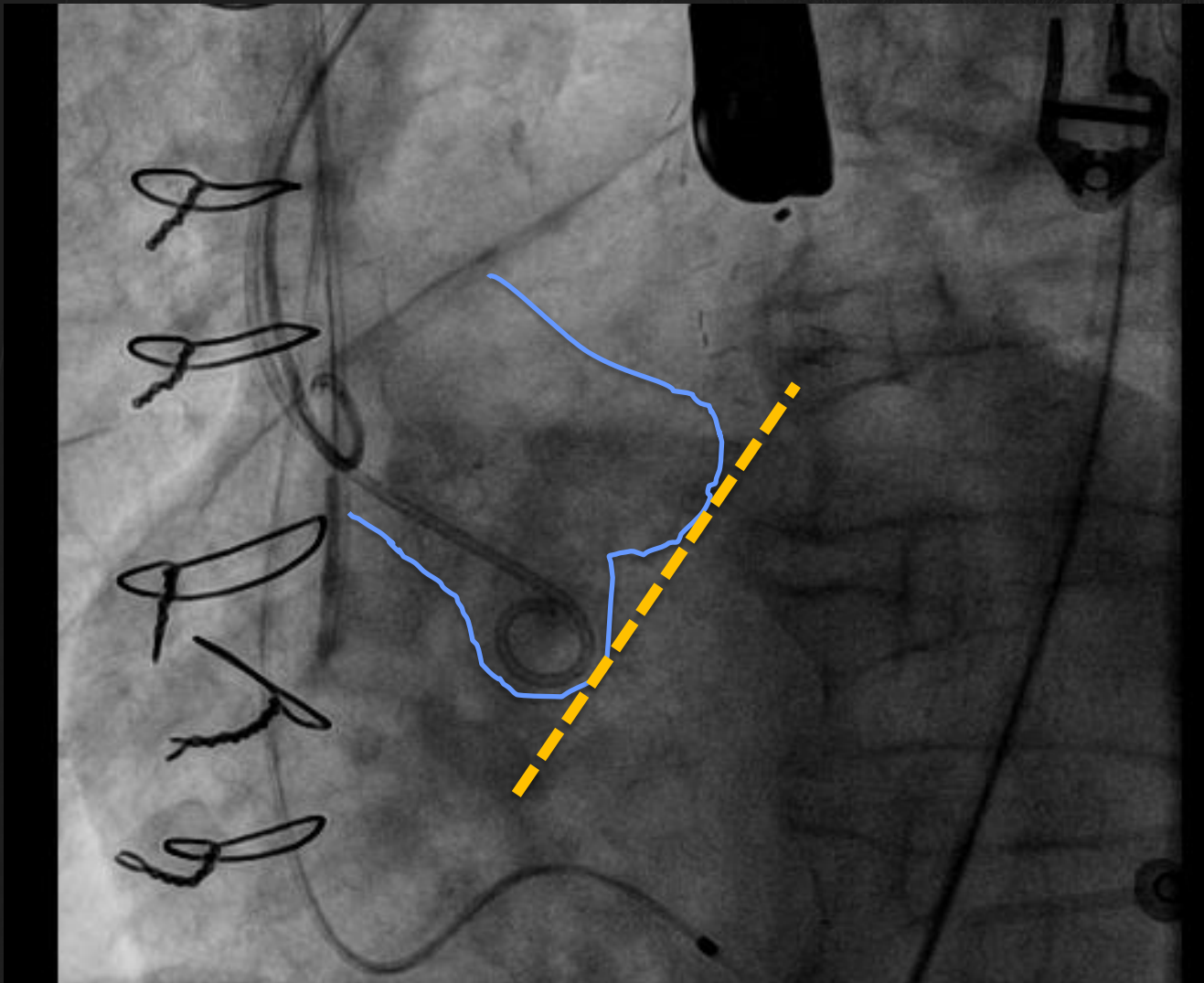
Diagnosis

- Severe symptomatic low-flow low-gradient aortic stenosis, LVEF 20-25%, Gmean 20mmHg, AVA 0.9cm², PAPs 67 mmHg, AoI g 2-3/4, MR 3/4

Fluoroscopy to Identify Valve Plane



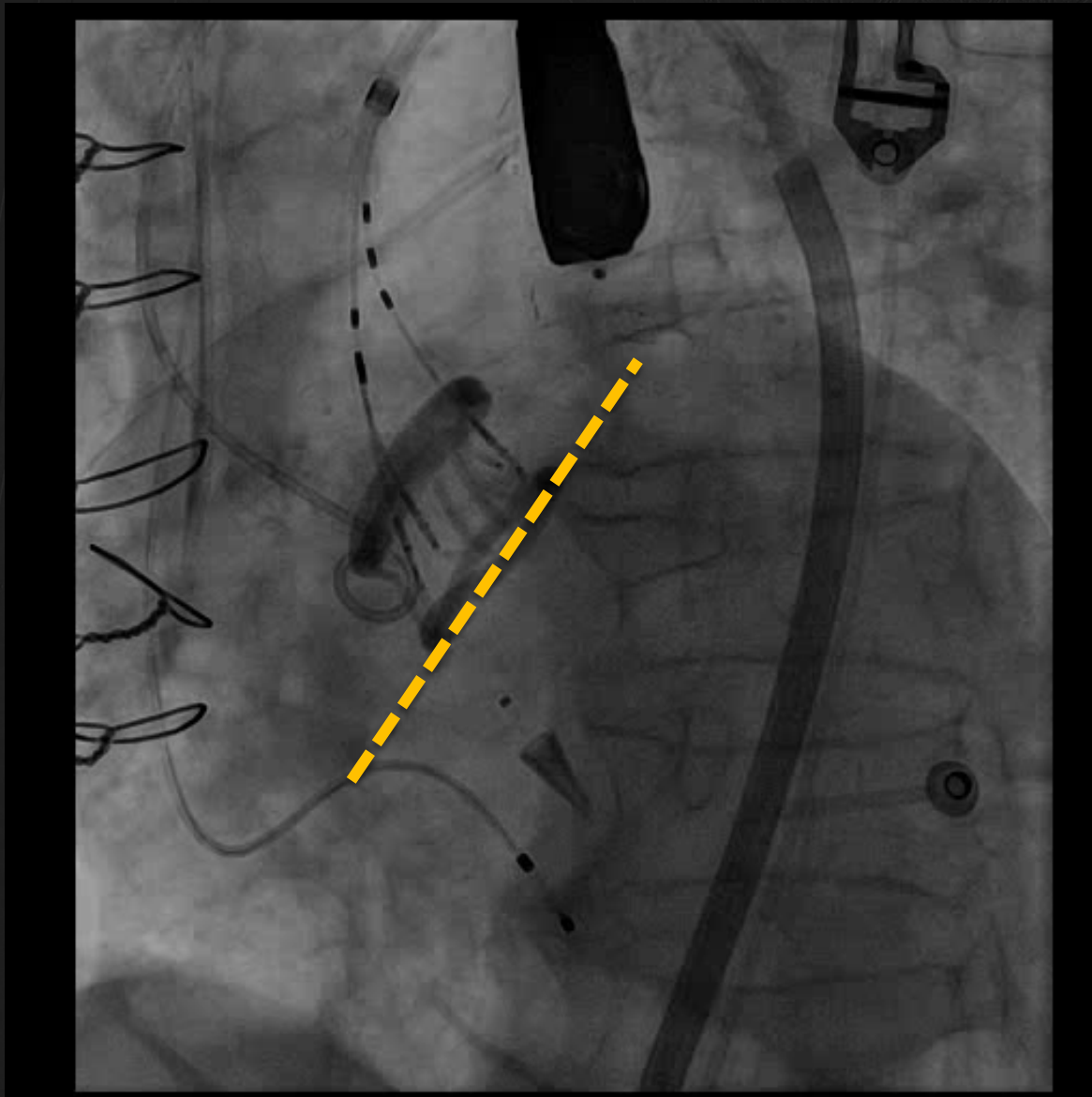
Valve Plane



12, 2011

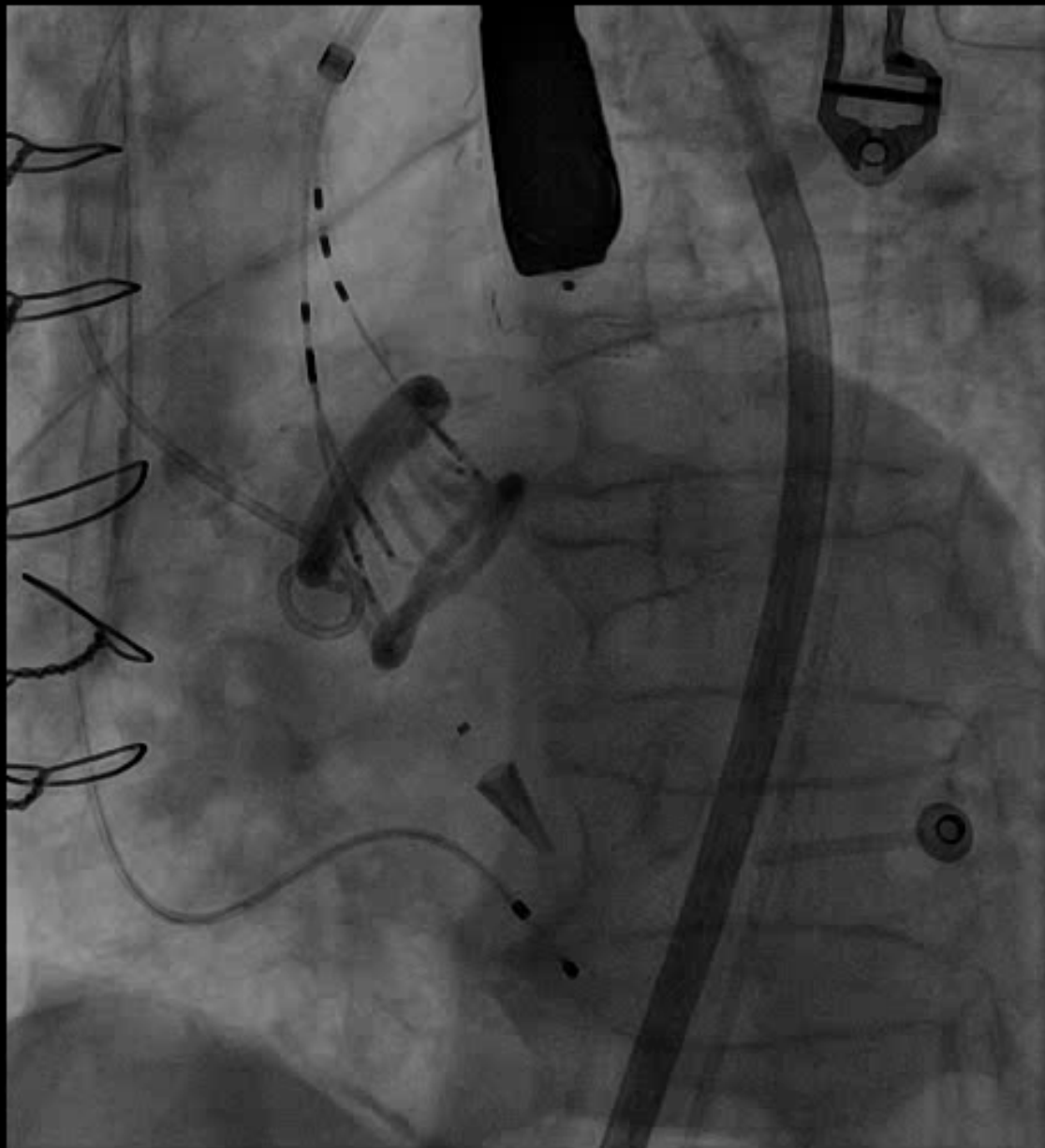
International meeting

Valve position

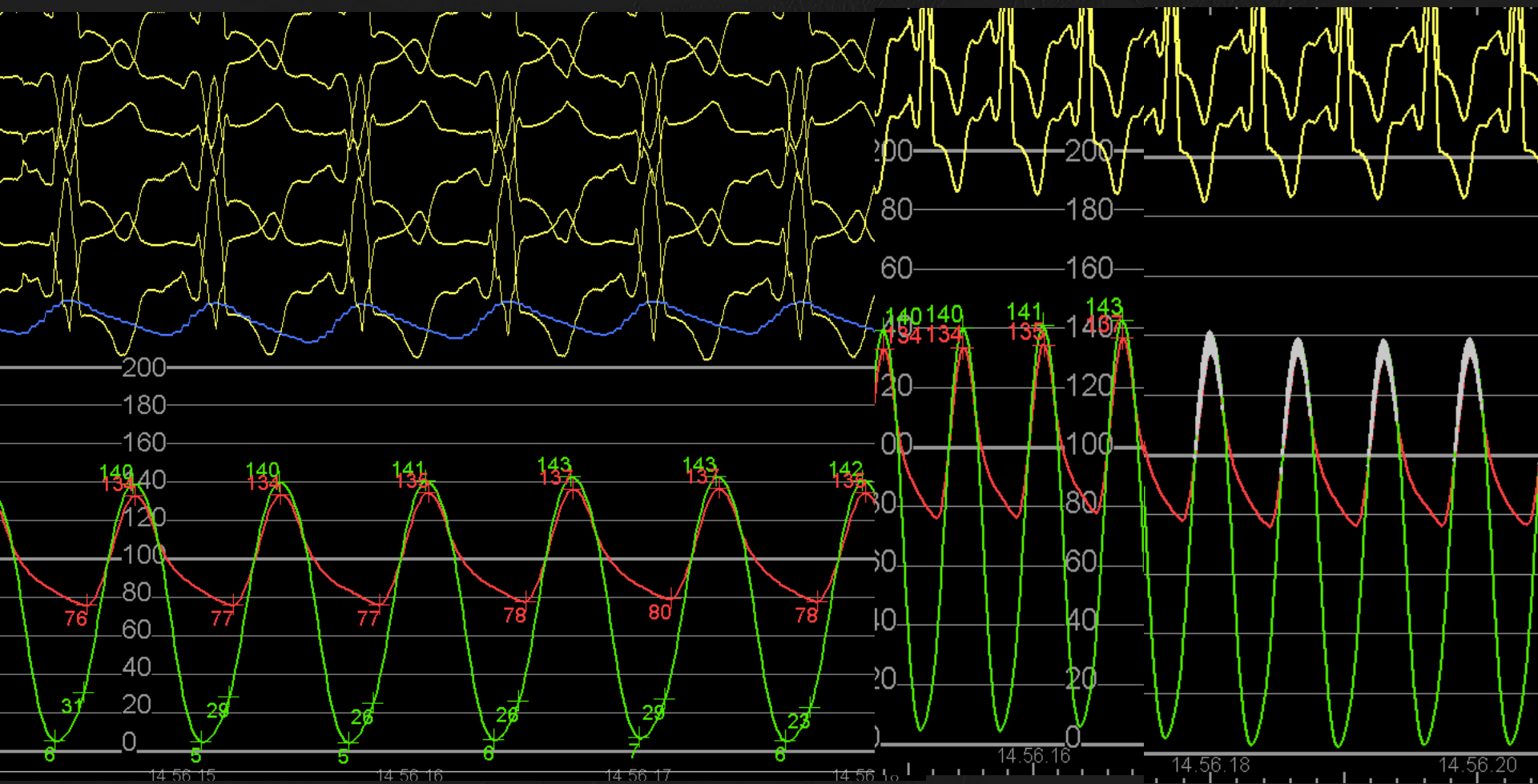


10-12, 2011

Rotational view confirm correct valve position



12, 2011



Peak to Peak LV-Ao Gradient = 4mmHg
Mean LV-Ao Gradient = 5mmHg
LVEDP = 27mmHg

the final ultrasound TEE



CO₂ angiography to evaluate access site after percutaneous closure

LAO 22°
CRAN 1°
200

0:00
5:00
15:06:18

42
38-28

ary 10-12, 2011
Italy

CO₂ angiography to evaluate access site after percutaneous closure

LAO 22°
CRAN 1°
FD 25 cm

0:00
5:00
15:10:15

43
39-28

February 10-12, 2011
Rome, Italy