Learning Clinical Case: TAVI with cerebral protection

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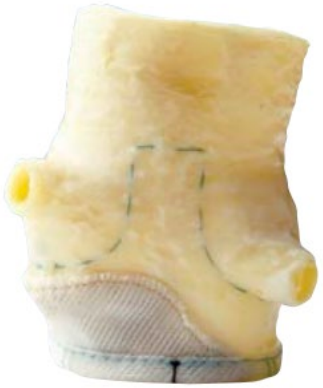
A 82 year-old Female

Past medical history: hypertension; dyslipidemia; stage 3 chronic kidney disease.

Past surgical history: aortic valve replacement for severe symptomatic aortic stenosis with a stentless bioprosthetic valve Prima Plus 23 mm (2003)

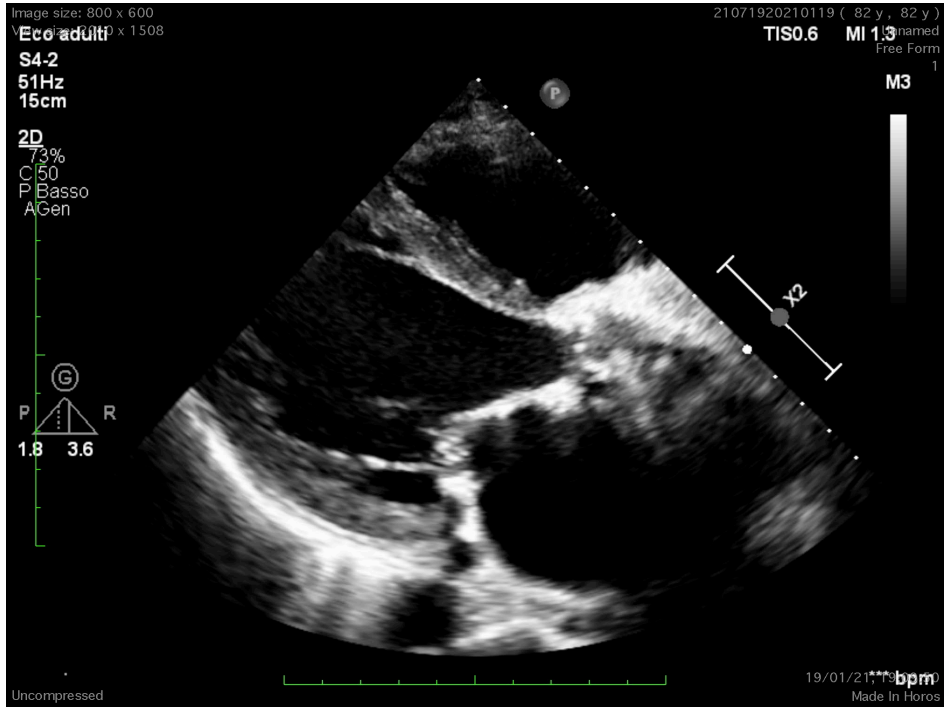


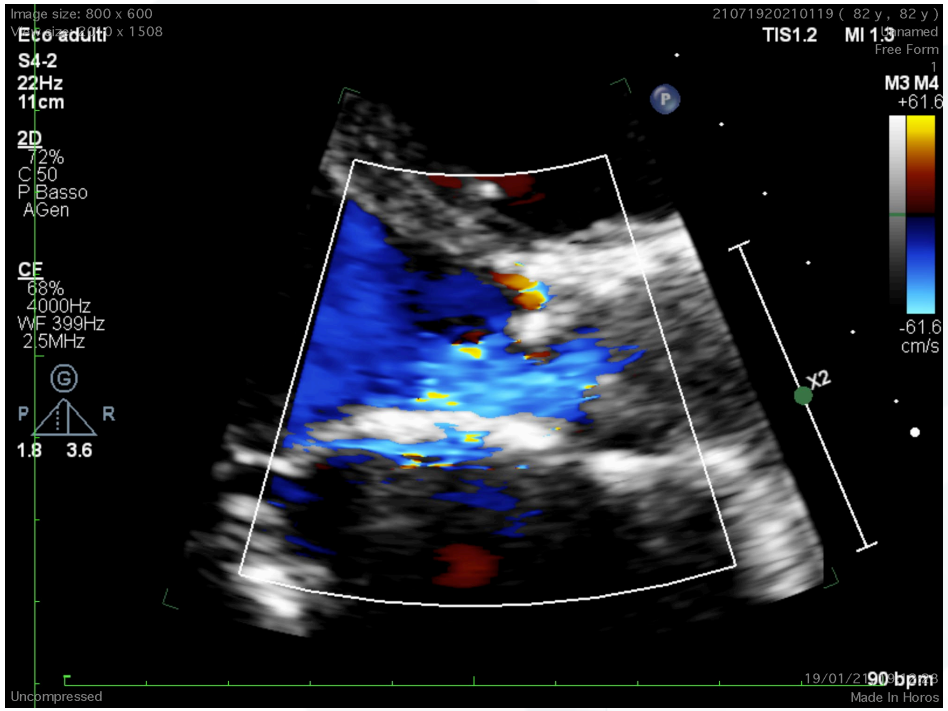
Edwards Prima Plus
Stentless Bioprosthesis

Clinical presentation: hospital admission for worsening dyspnea (NYHA III), ankles swelling, pleural effusion, worsen GFR (20ml/min/m2) and LVEF.

Echocardiographic assessment

- Severe left ventricular dilatation (VTD 103 mL/mq) with diffuse hypokinesis and sistolic moderate disfunction (LVEF 37%)
- Dilated right ventricle with mild disfunction
- Bioprosthesis degeneration: severe aortic regurgitation with diastolic flow reversal in the abdominal aorta
- Moderate mitral regurgitation
- Moderate tricuspid regurgitation with severe pulmonary hypertension (PAPs 60 mmHg)

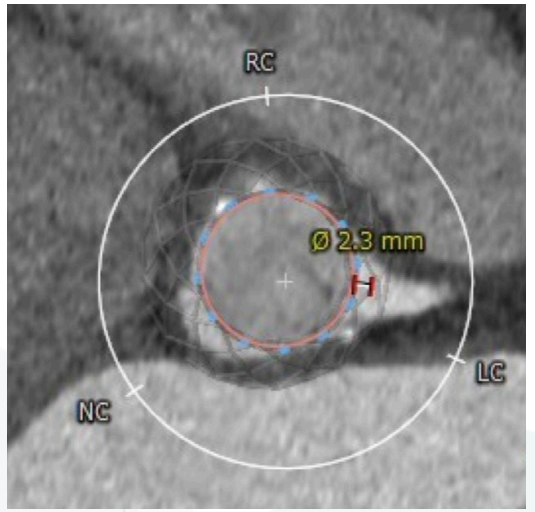




Pre-procedural assessment

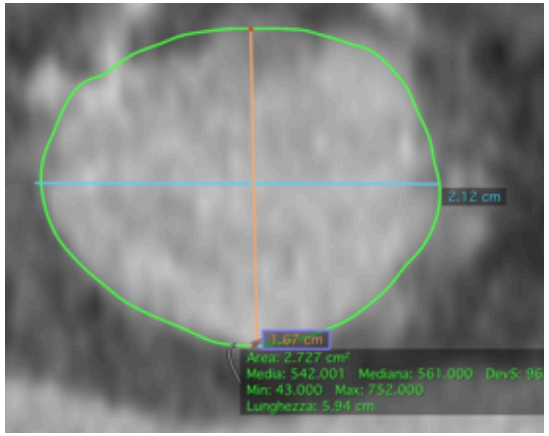
Pre-TAVI Computed Tomography (CT) assessment:

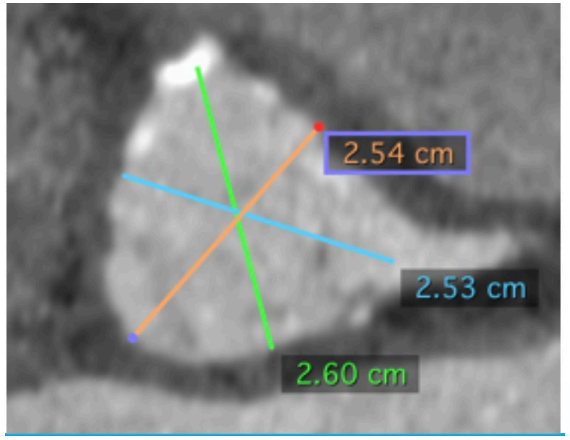
- Non-calcific degenerated bioprosthesis
- Very high risk of left main coronary occlusion
  - Left main coronary ostium height (<10 mm) –> 3.7 mm
  - Sinuses of Valsava width (< 30 mm) –> 25x24x24 mm
  - Left coronary artery virtual transcatheter heart valve to coronary distance (VTC< 4 mm) –> 2.3 mm



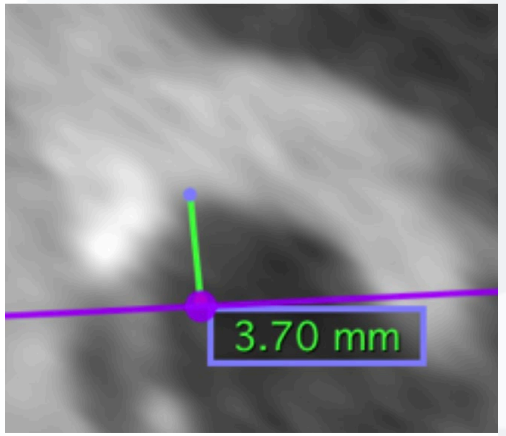
Left Coronary Artery (LCA) Virtual Transcatheter heart valve to Coronary distance (VTC)

Annulus: area 2.7 cm2; diameters 21x16 mm.

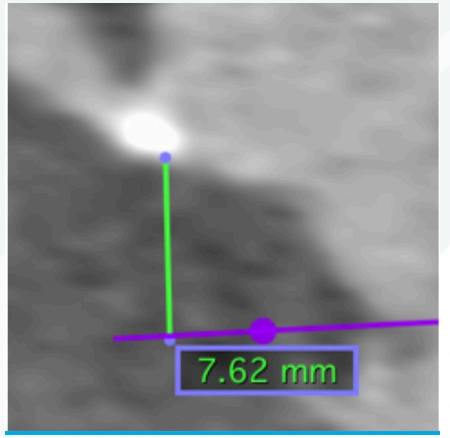




Sinuses width



Left ostium height

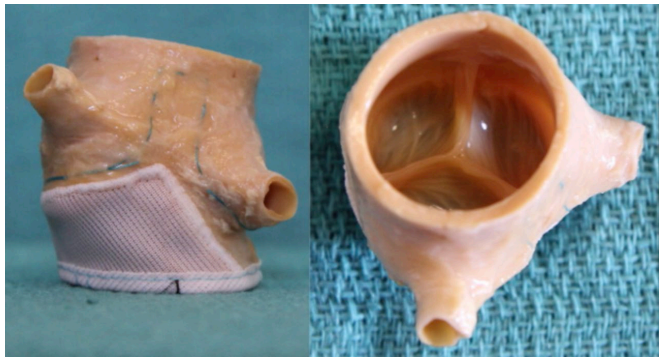


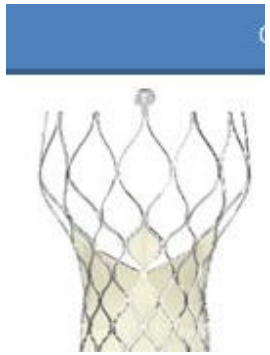
Right ostium height

TAVI planning

- **Need for left main coronary artery protection**
  - **BASILICA technique**
  - **Snorkel technique**
- **Bioprosthesis Valve**: Edwards Prima Plus 23 mm
  - Porcine aortic root
  - Sewing ring at the base
  - Used as root with coronary re-implantation
- **Selected valve for Valve-in-Valve TAVI:** CoreValve Evolut R 23 mm

TAVI Valve Choices For: Prima Root, 23	
S3 23	*Evolut R* 26
Accurate TA S	*Accurate NEO* S
Lotus 23	*Sapien XT* 23/26
Portico 25	*Allegra* 23
Jena 23	





TAVI procedural planning

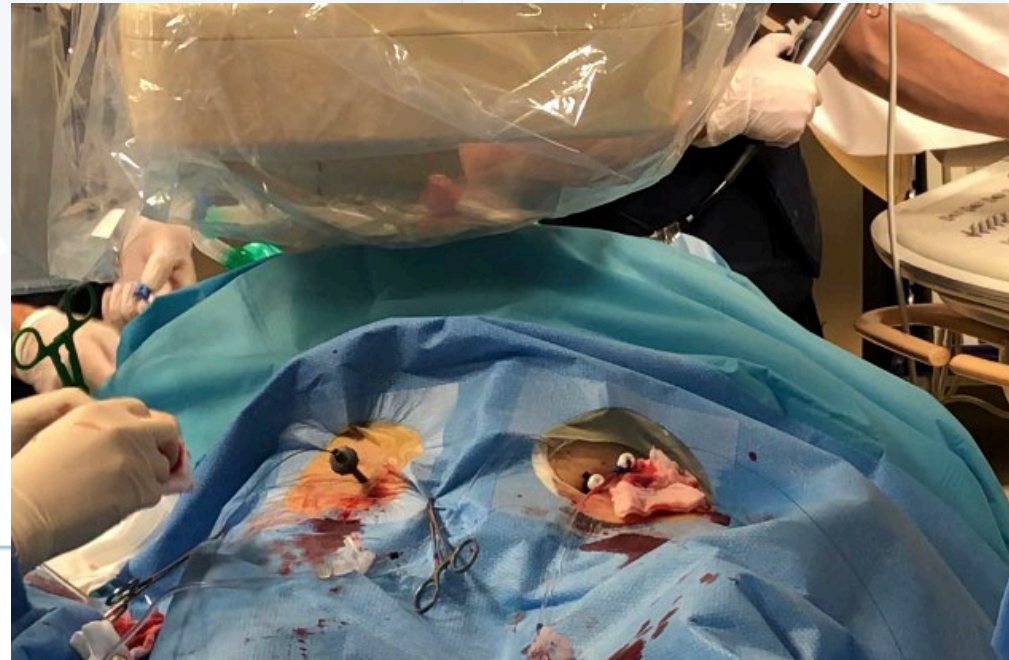
- General anesthesia
- TEE guidance for BASILICA procedure and intraprocedural assessment

Operative access (right femoral artery): 14 Fr Gore® DrySeal sheath
Traversal catheter: AL 3 8Fr + 5F multipurpose catheter (MP) 125cm + PiggyBack + Astato XS 20 300 cm

Non-operative access (left femoral artery): 8 Fr Introducer
Snare catheter: 6Fr MP guiding catheter + 20 mm Amplatz GooseNeck™ snare + V18 guidewire

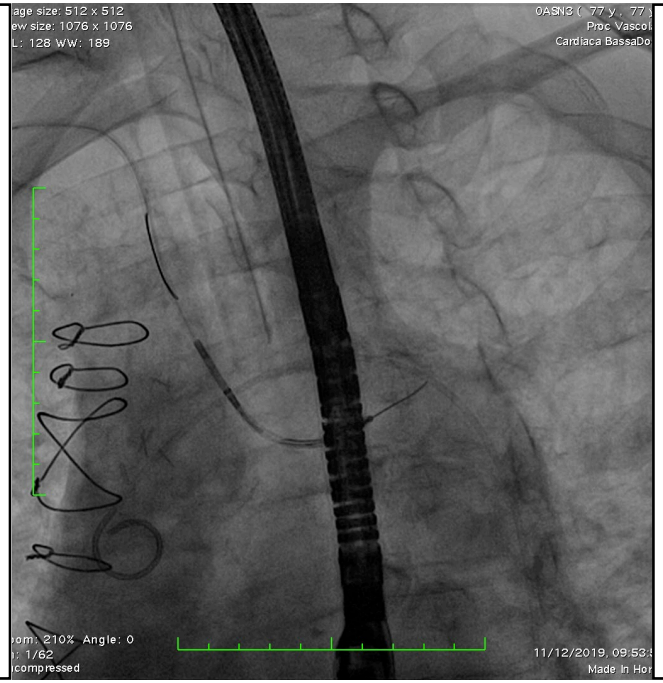
Right brachial access: 6 Fr Sentinel™ cerebral protection device

Left radial access: 6 Fr Pigtail



Step 1 – Cerebral protection

The cerebral protection SENTINEL system was positioned in both common carotid arteries from the right radial.



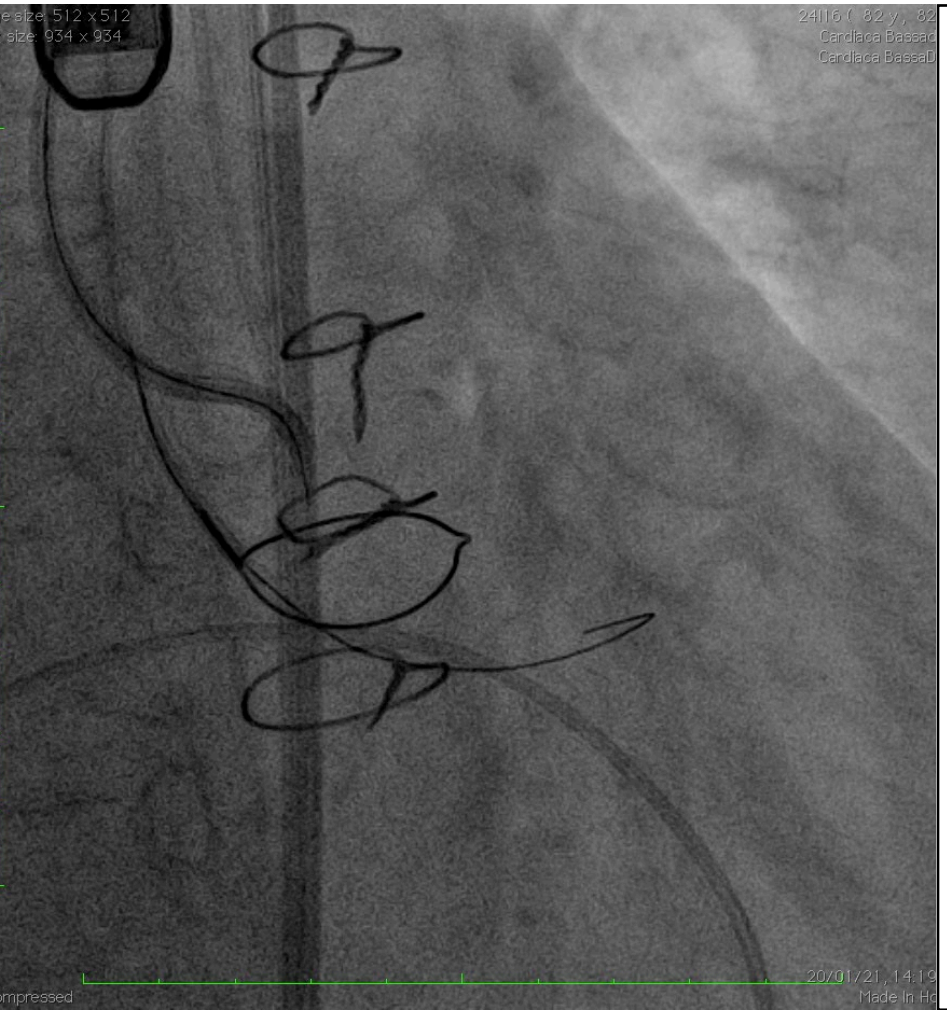
Step 2 – Snare and traversal systems

Snare System

A 6Fr multipurpose (MP) guide and an Amplatz GooseNeck™ snare with V18 guidewire were positioned in the LVOT.

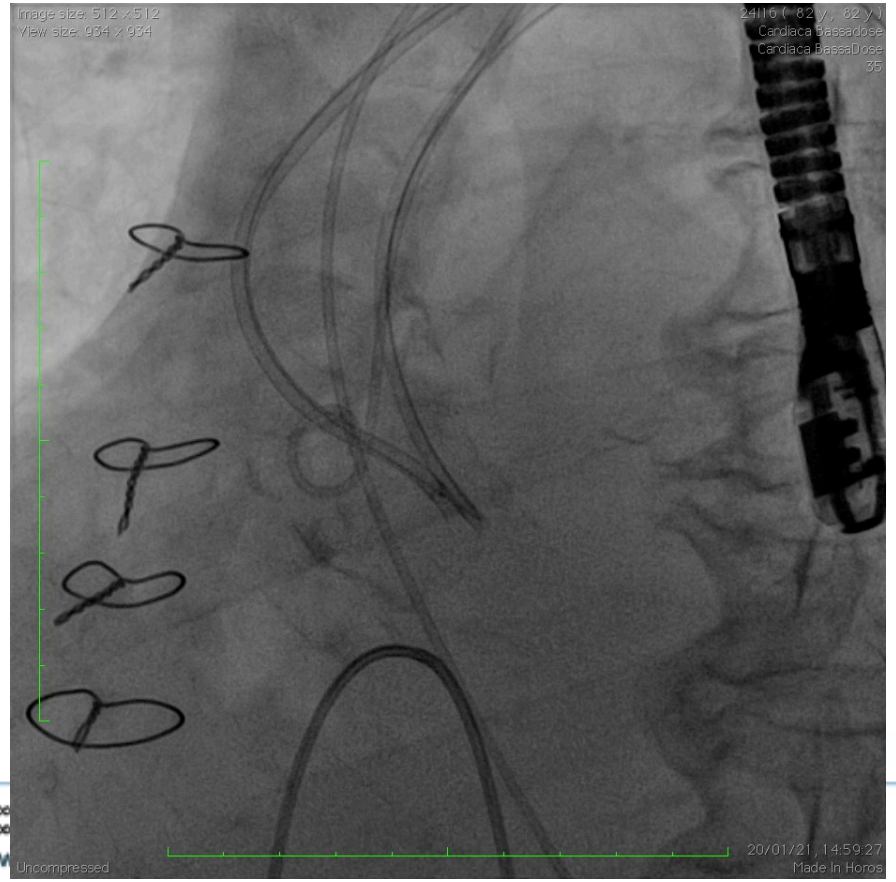
Traversal System

AL 3 8Fr + IM 5Fr catheter + PiggyBack + Astato XS 20 300cm

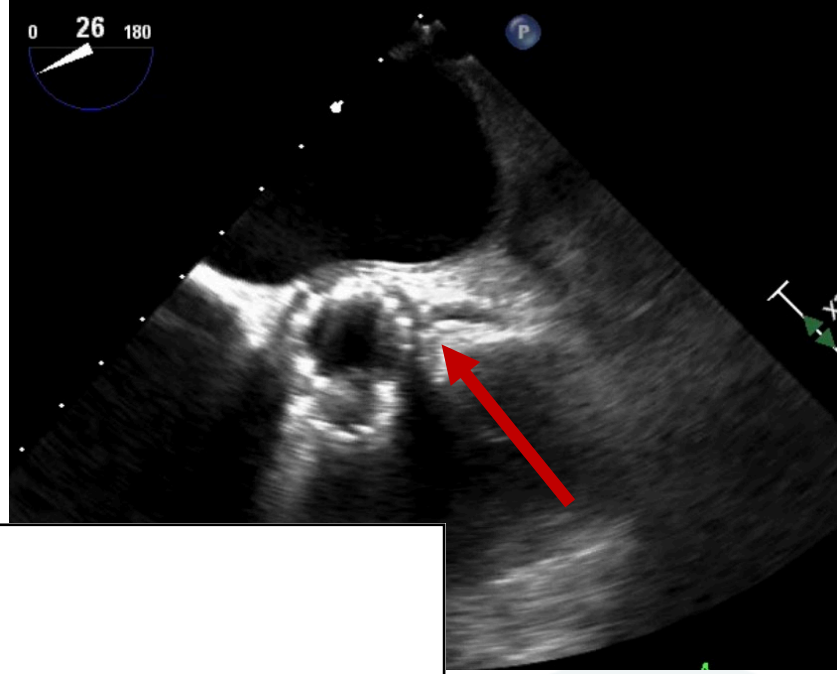


Step 3 – Leaflet laceration and TEE assessment

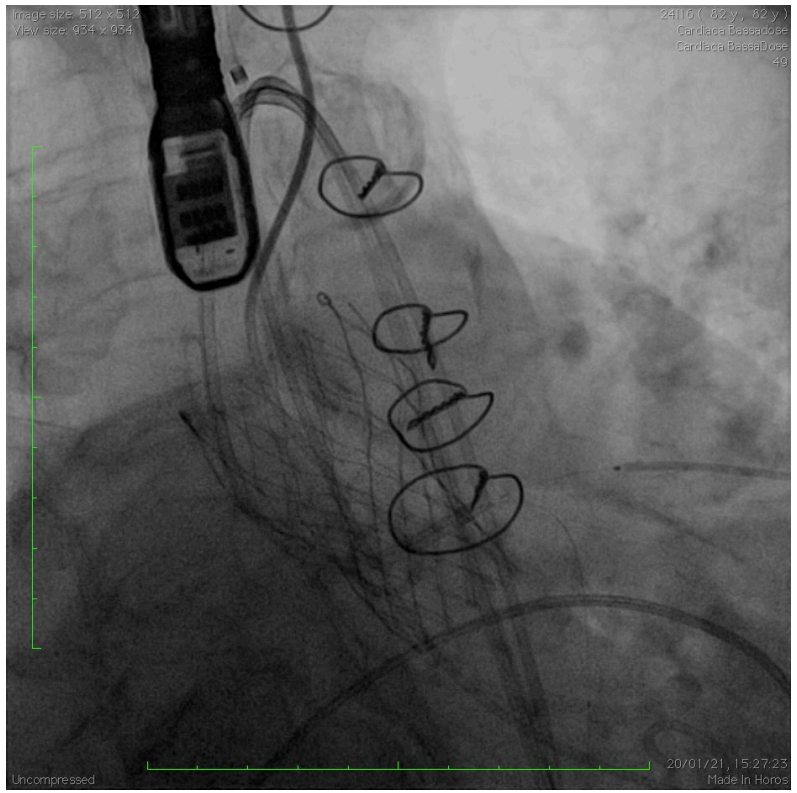
Cusp base perforation with Astato guide and high energy electrocautery (50 Watt) and then **wire snaring, Vshape and leaflet laceration.** TEE confirmed leaflet's laceration.



Step 4 – CoreValve Evolut R 23mm

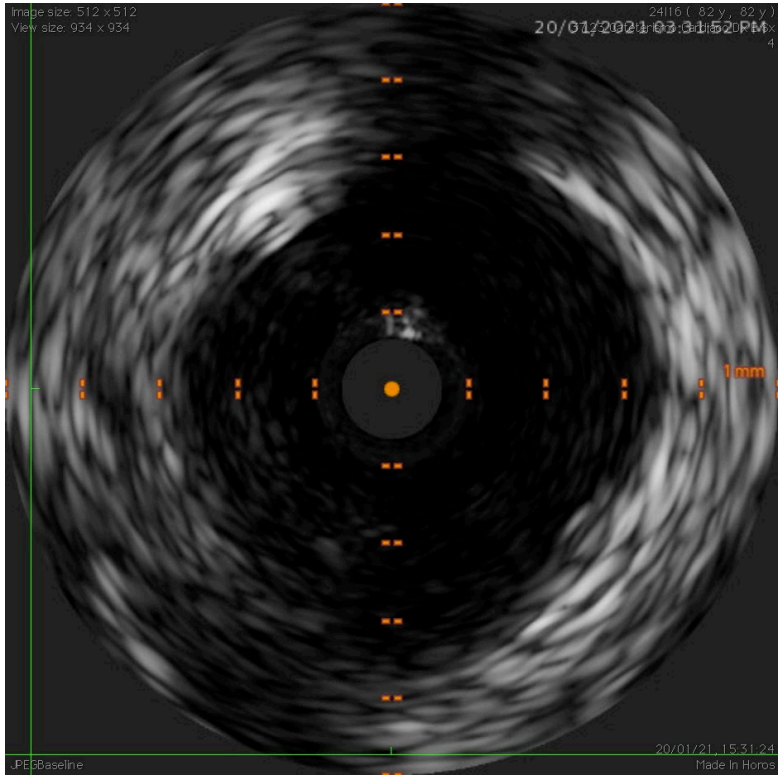


CoreValve Evolut R 23mm was positioned across the bioprosthetic valve and it was deployed during rapid ventricular pacing

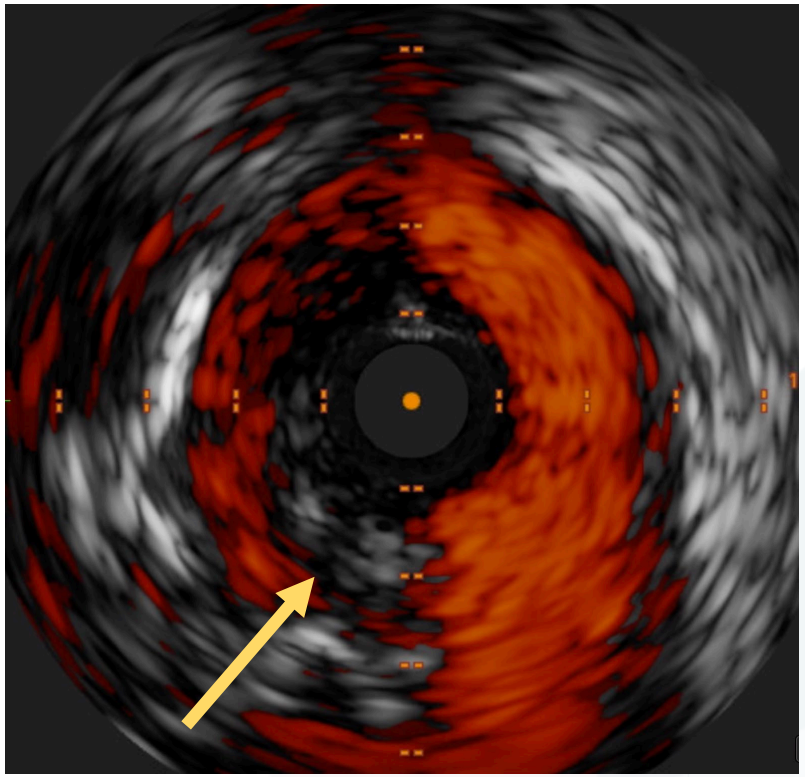


Step 5 – Angiographic/IVUS LM assessment

IVUS



ChromaFlo



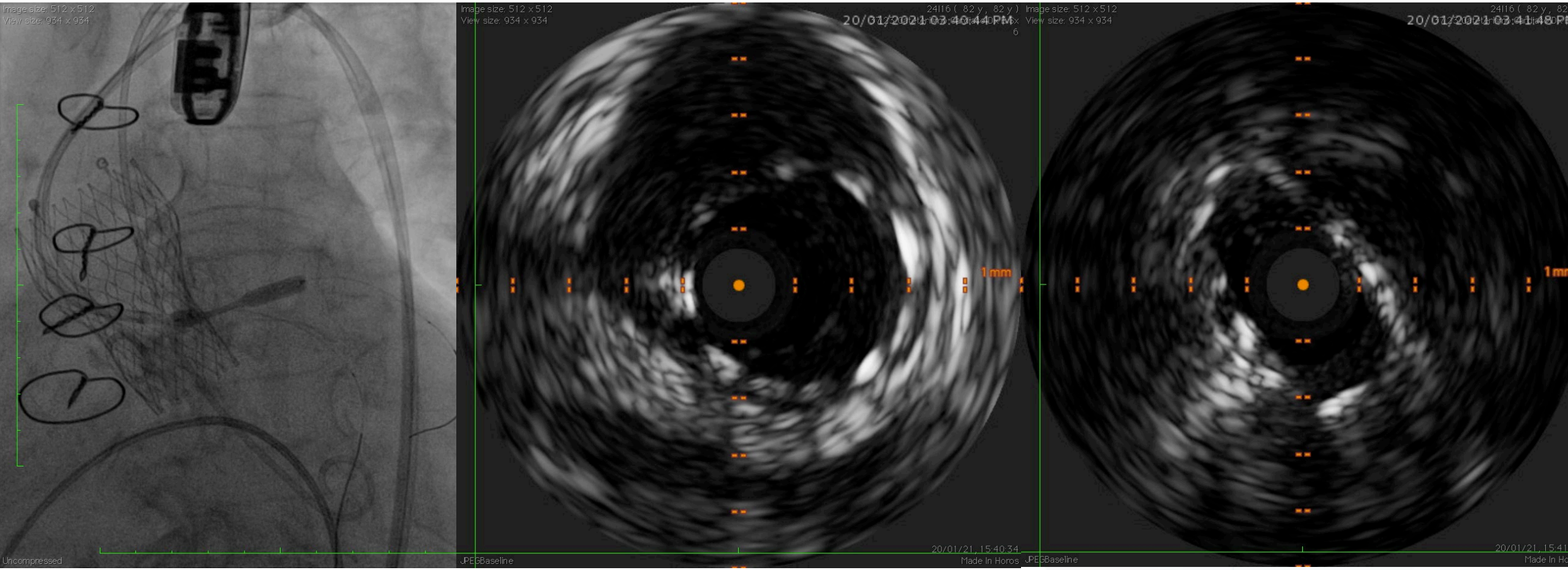
Partial obstruction of the left main ostium due to the lacerated leaflet

Step 6 – Left main stenting

Stent implantation

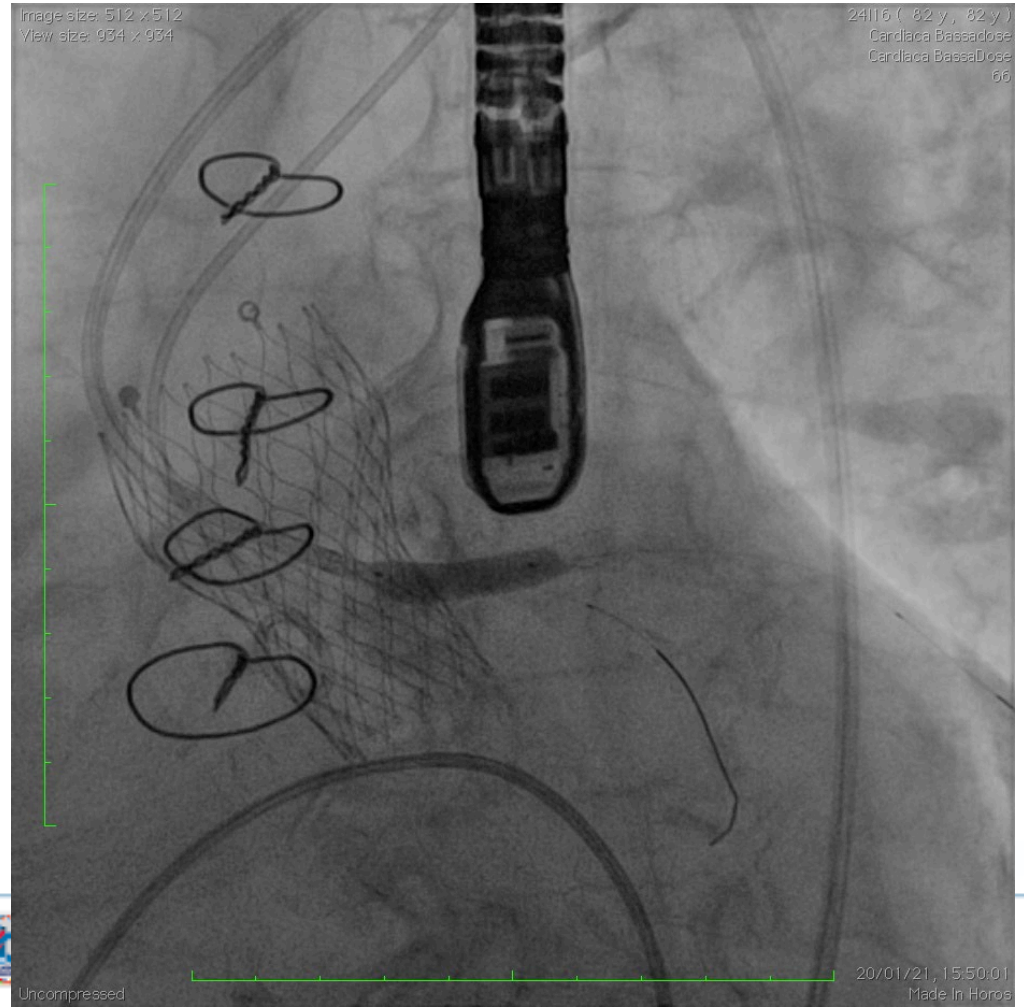
Stent under-expansion

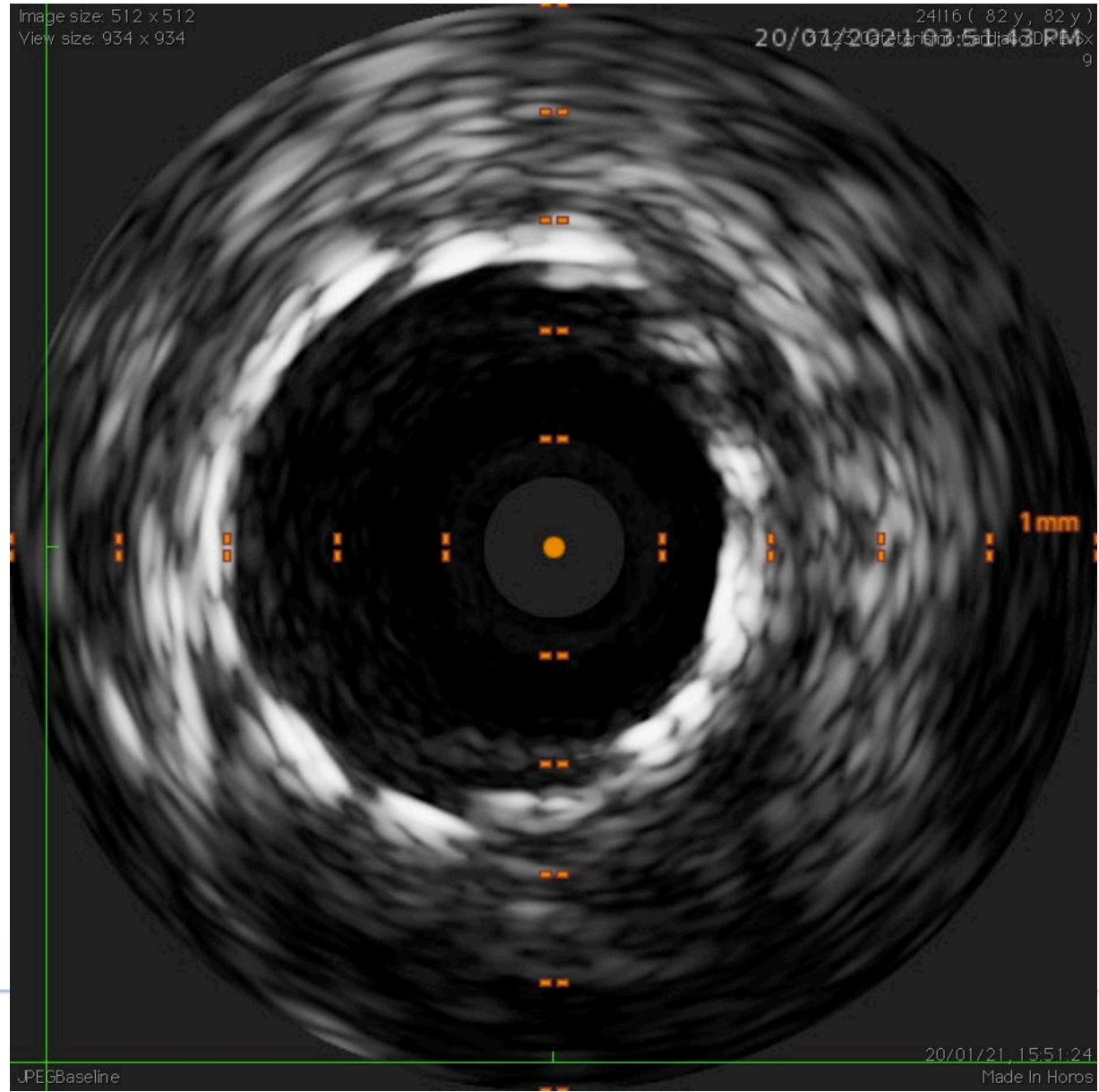
Stent deformation



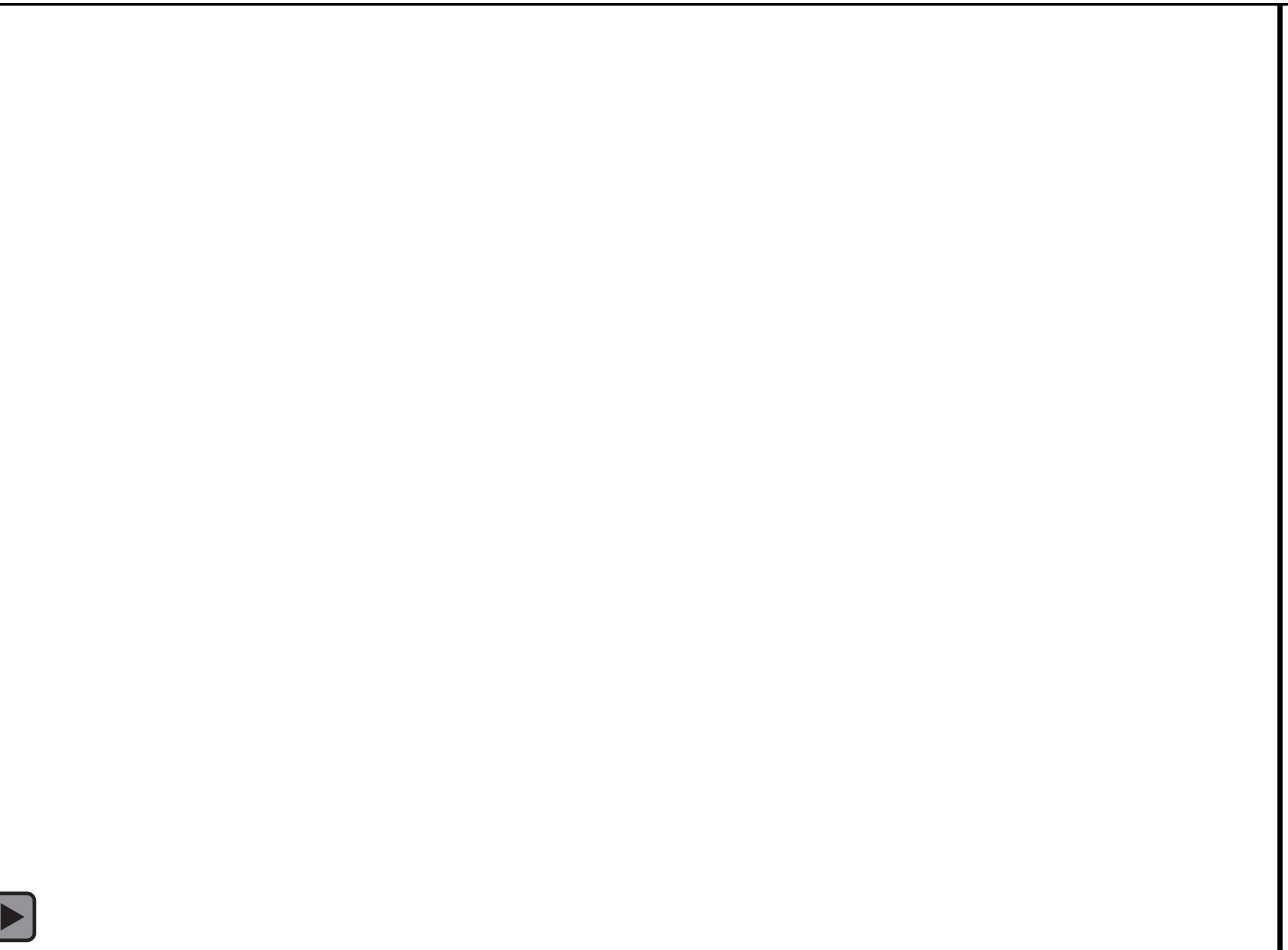
Step 6 – Left main stenting and final result

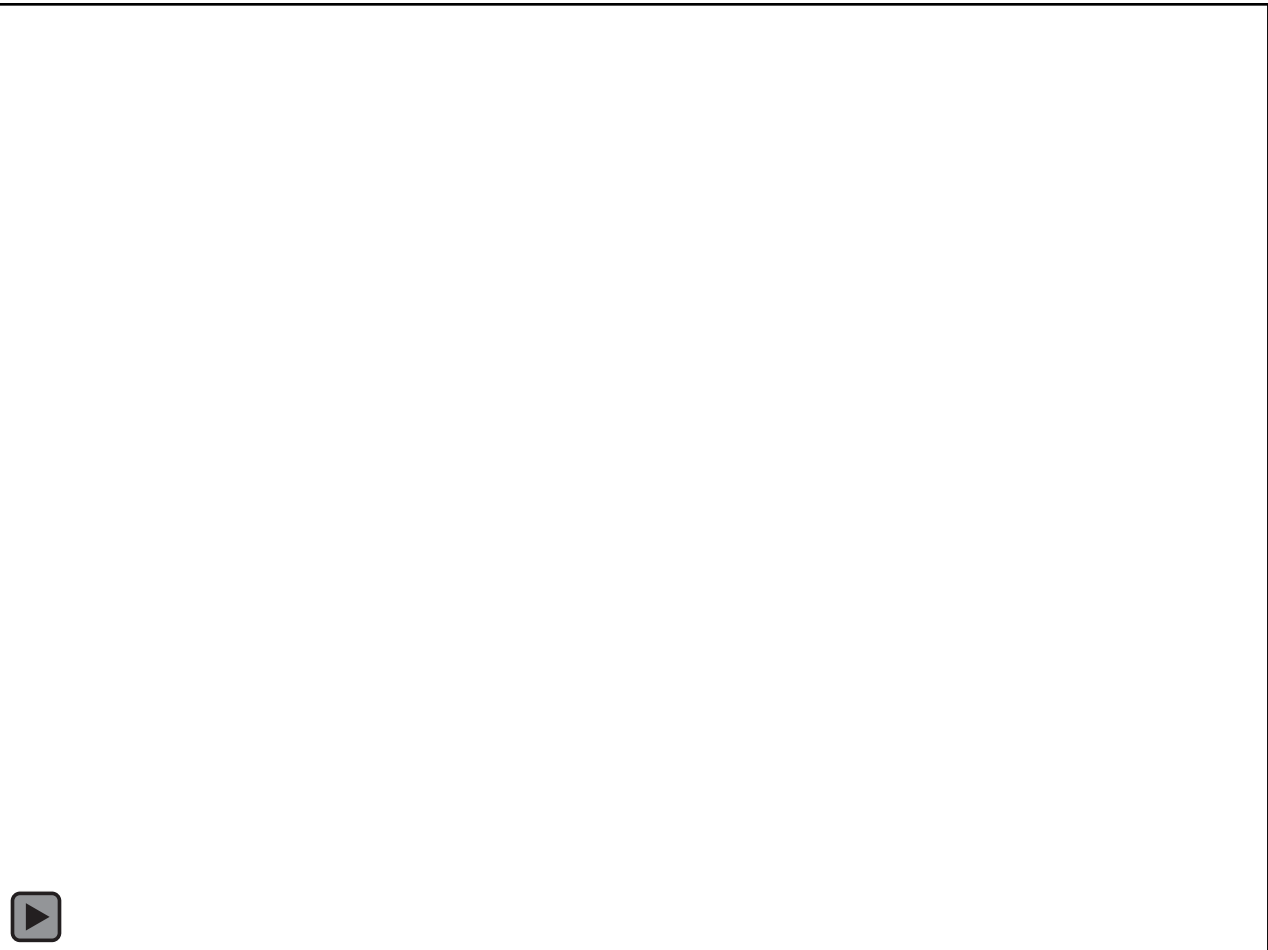
Implantation of a second Zotarolimus-eluting stent (4.0x15mm) to increase the radial force. Post-dilation with 5.0 mm NC balloon. Final IVUS and angiographic assessment.





Step 7 - TEE assessment post LM-stenting





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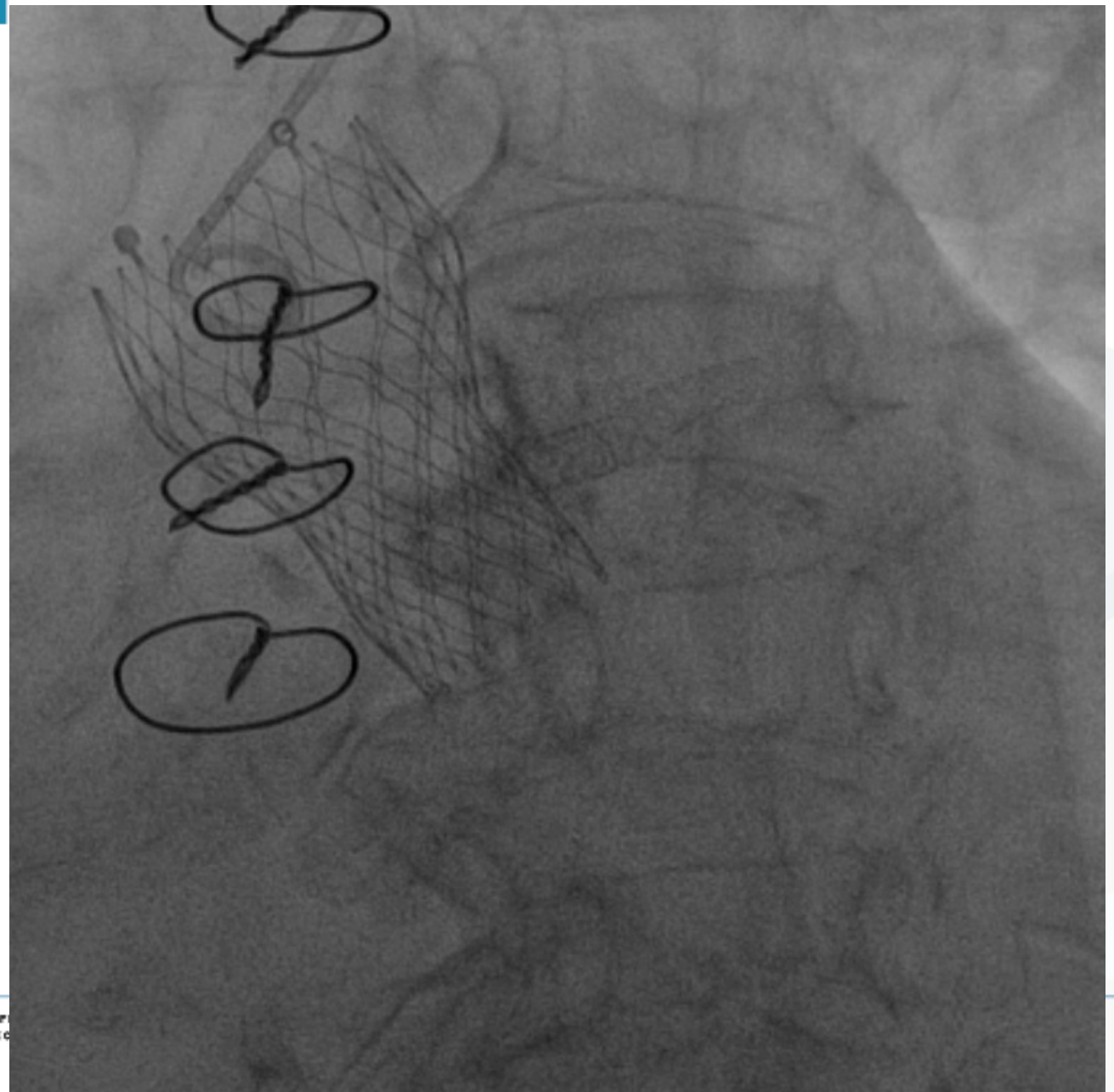
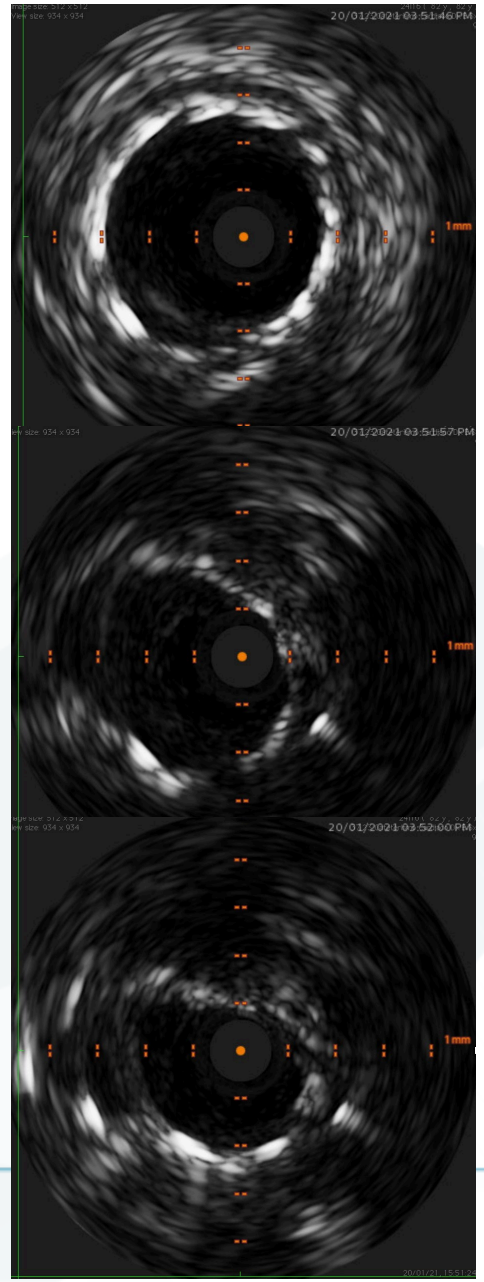
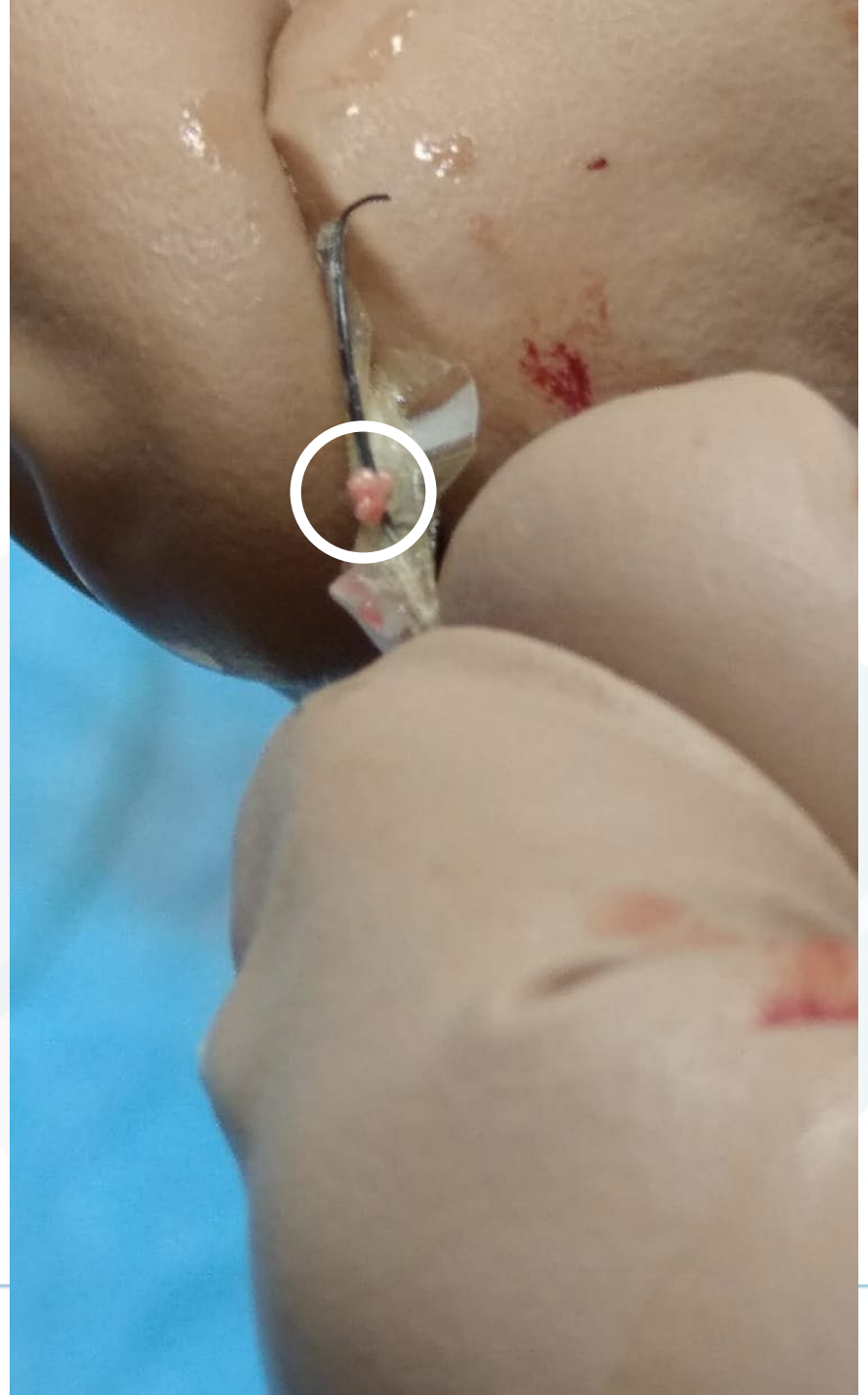


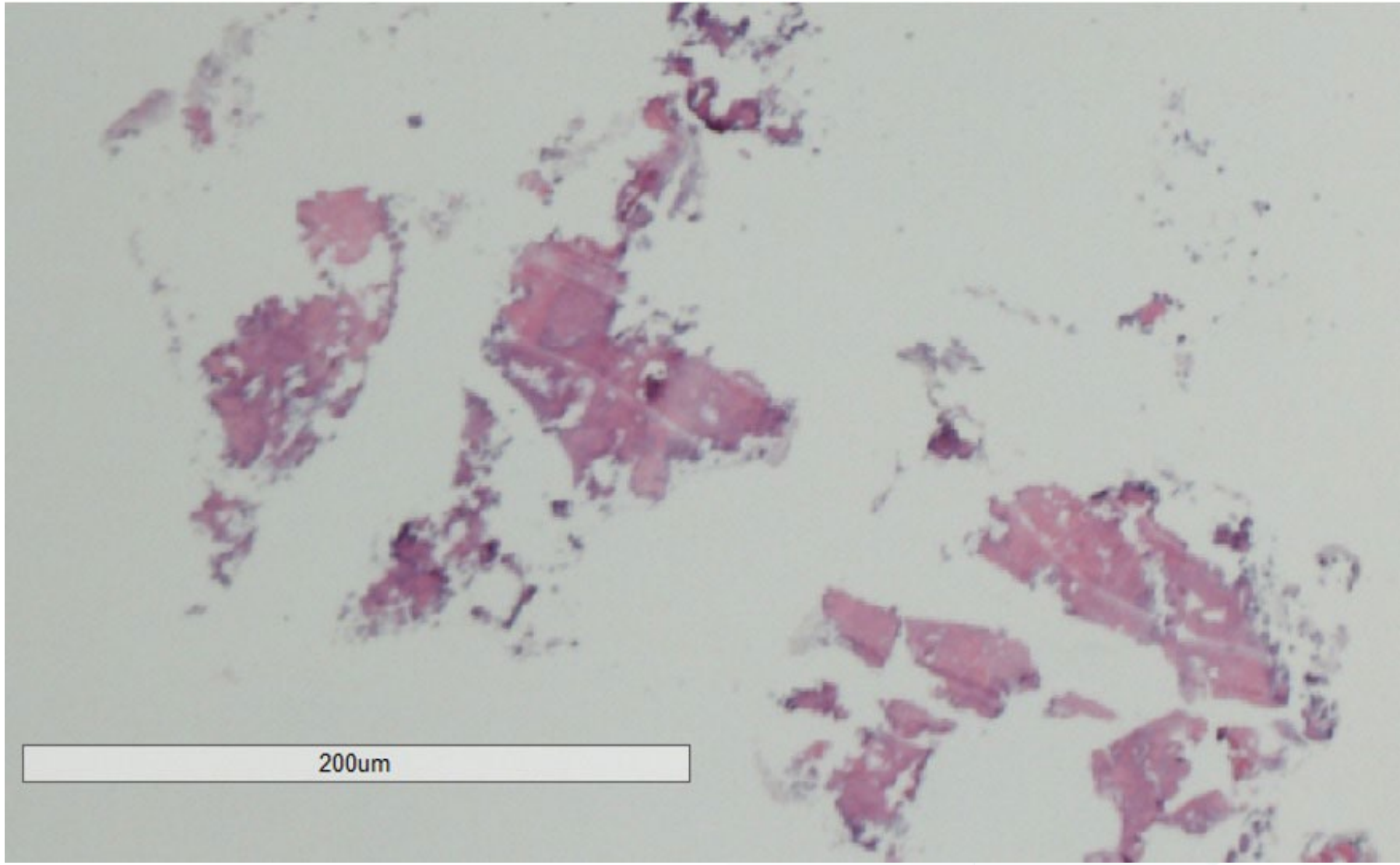


Embolization of lacerated bioprosthesis leaflet?



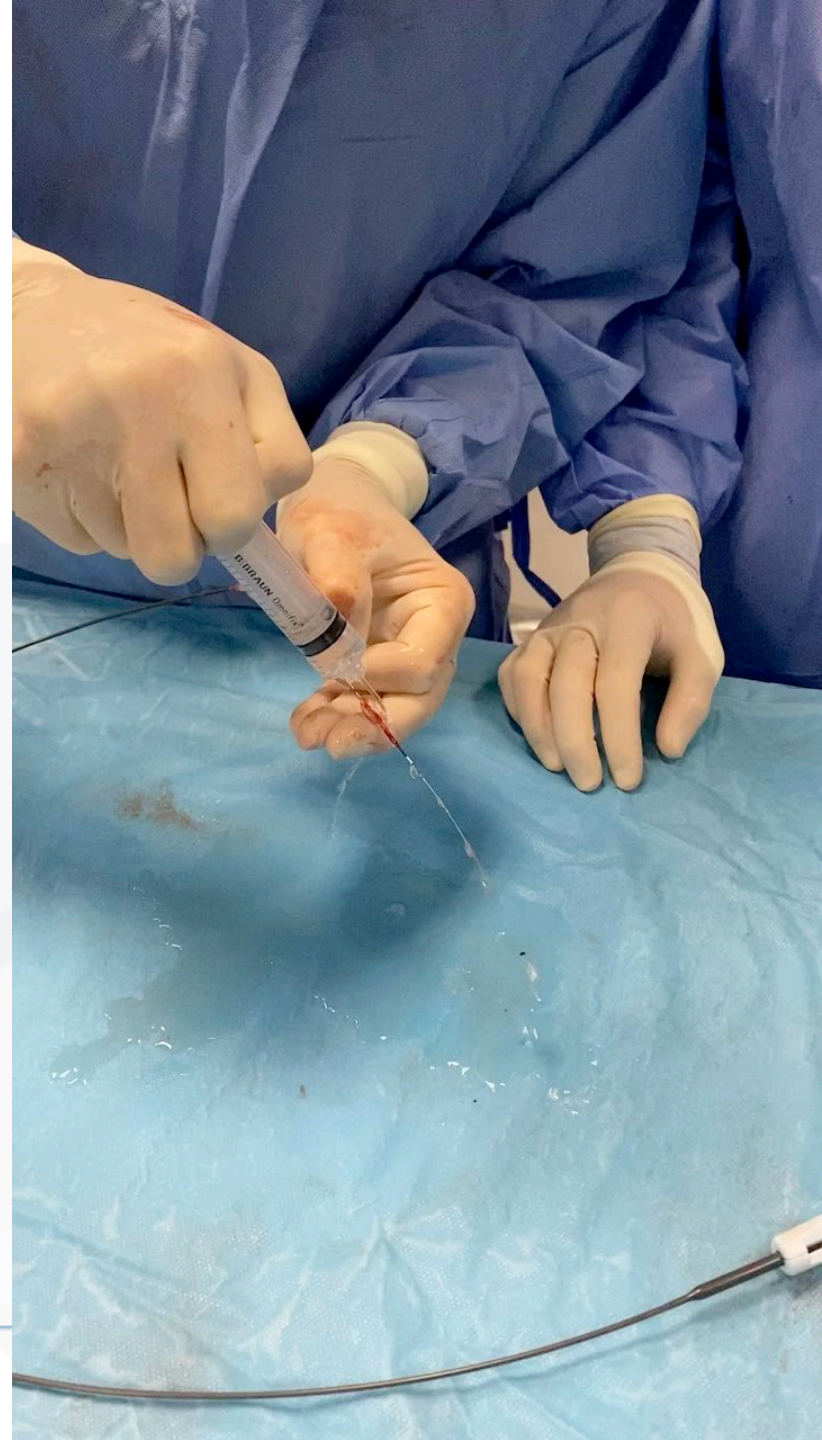
Histology:

acellular tissue confirms the origin from the pericardial surgical valve



Clean filter

Small thrombus



CLINICAL QUESTIONS

1. Is embolic stroke during TAVI a relevant clinical problem?

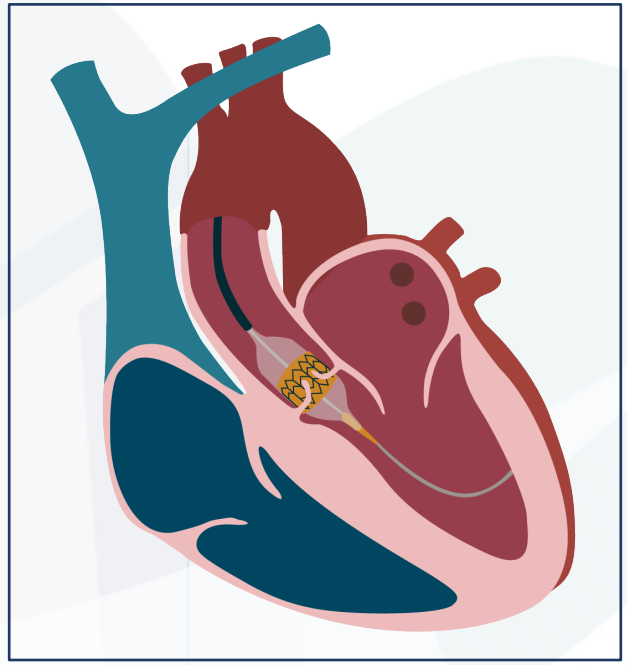
2. Does the detection of 'silent' microembolic events correlate with functional decline ?

3. Can we improve outcomes with embolic protection devices ?

BACKGROUND

Technological advancements, refinements in techniques and increased operator experience have reduce **periprocedural strokes** (within 30 days) to **approximately 2%** of patients undergoing TAVI.

- Huded CP. JAMA 2019: STS-ACC TVT Registry (101.430 2011-2017), 30-days stroke of any kind **(2.3%)**
- Vlastra W, Ribichini F et al. *Circ Cardiovasc Interv.* 2019 (10 982 patients) 30-days stroke **(2.4%).**
- Levi a., et al. The ASTRO-TAVI Study Group (*J Am Coll Cardiol Intv 2022*). 16.615 patients included between 2006 and 2021. 30-days stroke: 387 patients **(2.3%).**



RATIONALE

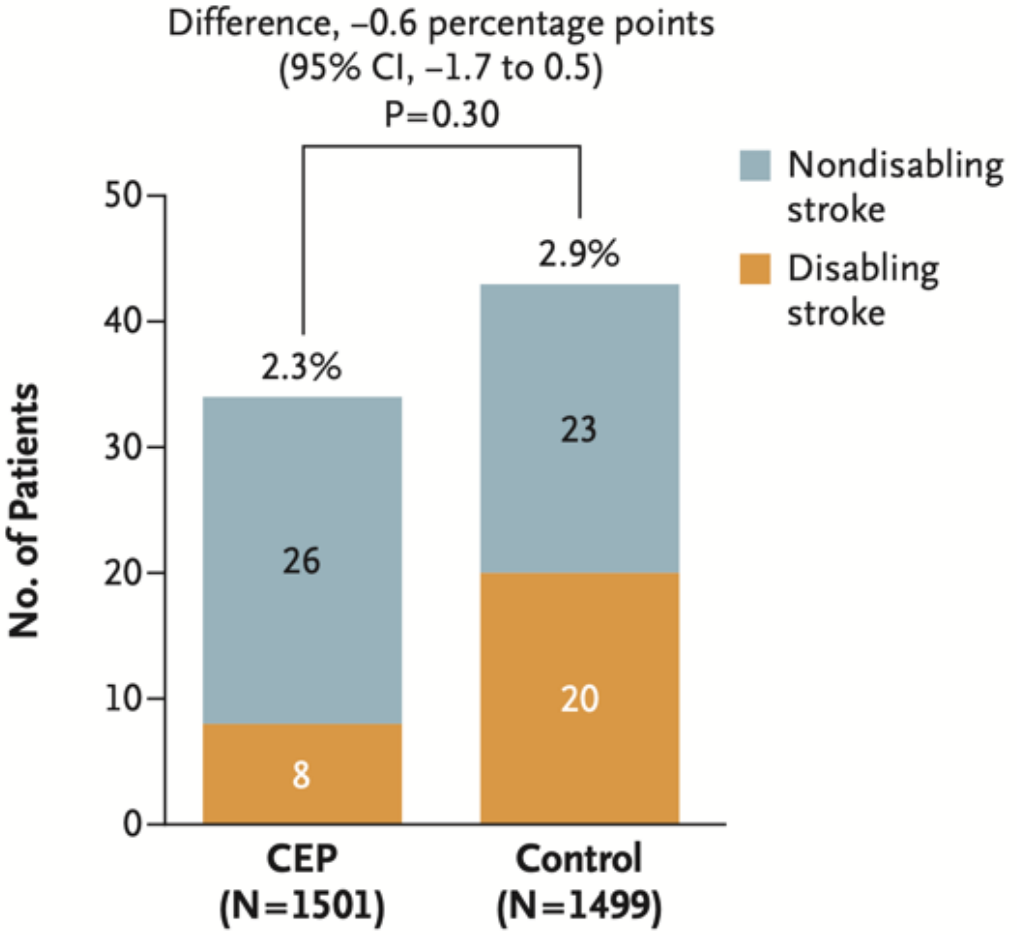
The **SENTINEL™ Cerebral Protection System (CPS)** (Boston Scientific) is the most widespread cerebral embolic protection (CEP) device used to mitigate the risk of embolization of vascular or heart debris during TAVI.

- Dual filter-based intra-luminal CEP device 6-Fr sheath compatible.
- Right radial or brachial artery access over a 0.014-inch guidewire.
- Proximal filter positioned in the brachiocephalic trunk, the second filter in the left common carotid artery.
- It covers all brain areas supplied by 3 out of 4 arteries (excluding left vertebral artery).

The PROTECTED TAVR trial

Kapadia S. R., et al. *N Engl J Med.* 2022

- 3.000 patients underwent TAVR: 1.501 in the CEP group vs. 1499 in the Control group.
- Primary endpoint (clinical stroke within 72 hours after TAVR): 2.3% vs. 2.9%, **p=0.30.**
- Additional prespecified endpoint (disabling stroke): 0.5% vs. 1.3%.
- The number needed to treat (NNT) to prevent one additional disabling stroke would be 125



Conclusion

- The rate of neurologic events in patients undergoing TAVI are nowadays very low.
- SENTINEL CPS is a safe and easy to use device, and it does not increase risk of major vascular complications.
- SENTINEL CPS does not decrease periprocedural neurologic events and mortality.
- The use of SENTINEL CPS dose not change periprocedural TAVI-related outcomes.
- CEP devices may be very useful in specific cases, not yet well identified

CLINICAL QUESTIONS

1. Is embolic stroke during TAVI a relevant clinical problem?

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3. Can we improve outcomes with embolic protection devices ?

no answers...