

# STS/EACTS Latin America Cardiovascular Surgery Conference

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Hilton Cartagena | Cartagena, Colombia



The Society  
of Thoracic  
Surgeons



EACTS  
European Association for Cardio-Thoracic Surgery

## TRANSCATHETER VALVE IN MAC

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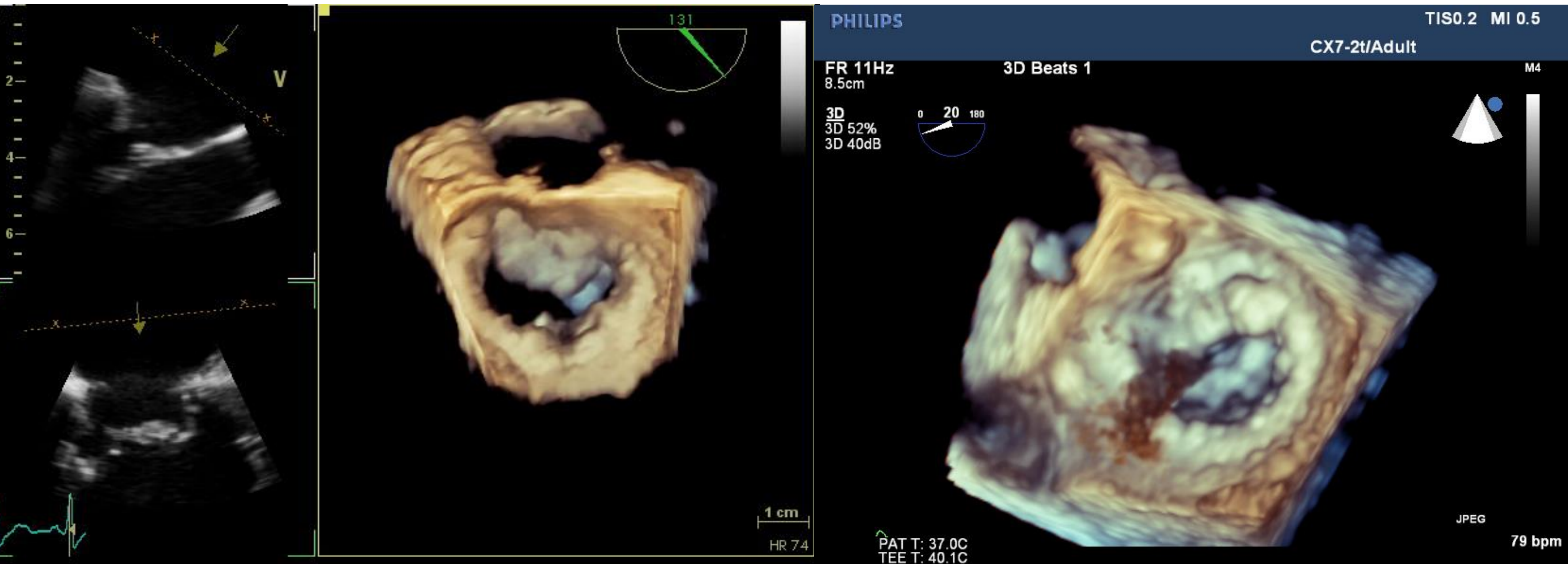
# Disclosure

- Consultant and proctor for Edwards Lifesciences
- Institutional grant/research support from Edwards Lifesciences
- Institutional grant/research support from Medtronic

# Transcatheter valve in severe MAC

- Low-profile aortic transcatheter valves (Sapien-3) (off-label use)
- Native mitral valve with severe Mitral Annular Calcifications (MAC)
- Old patients with high-risk profile and risk of **annular rupture**
- **Accesses:**
  - percutaneous (femoral vein and trans-septal)
  - Transapical (left mini-thoracotomy)
  - direct transatrial (surgical mini-thoracotomy, with CPB, fibrillating heart)

# Severe MAC



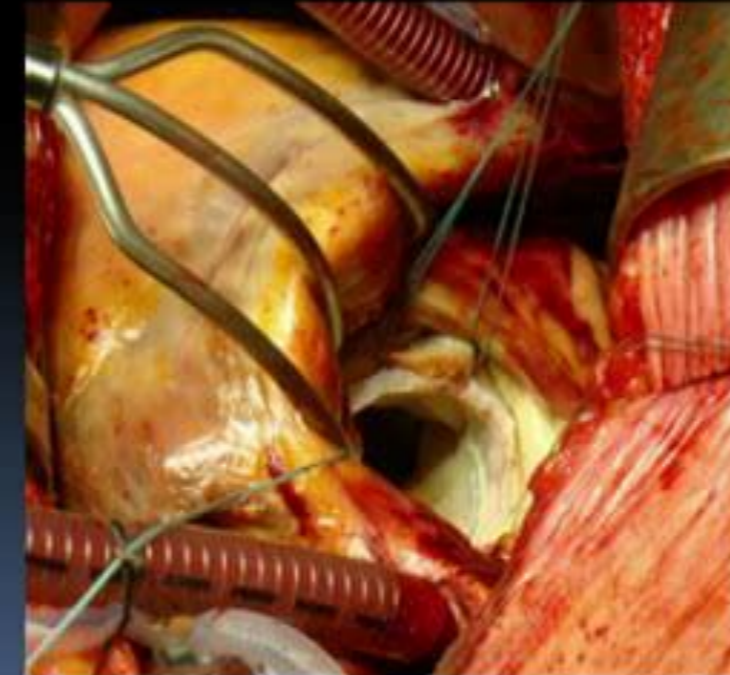
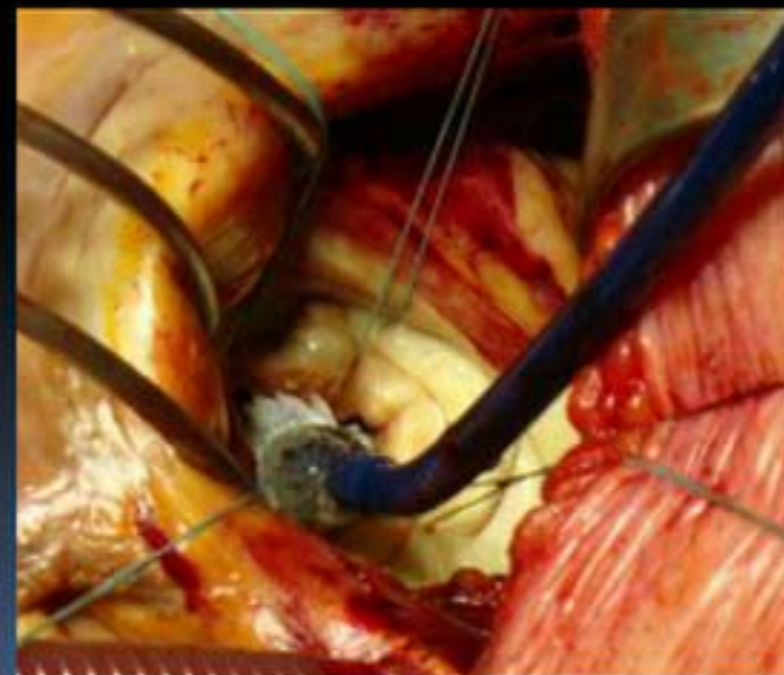
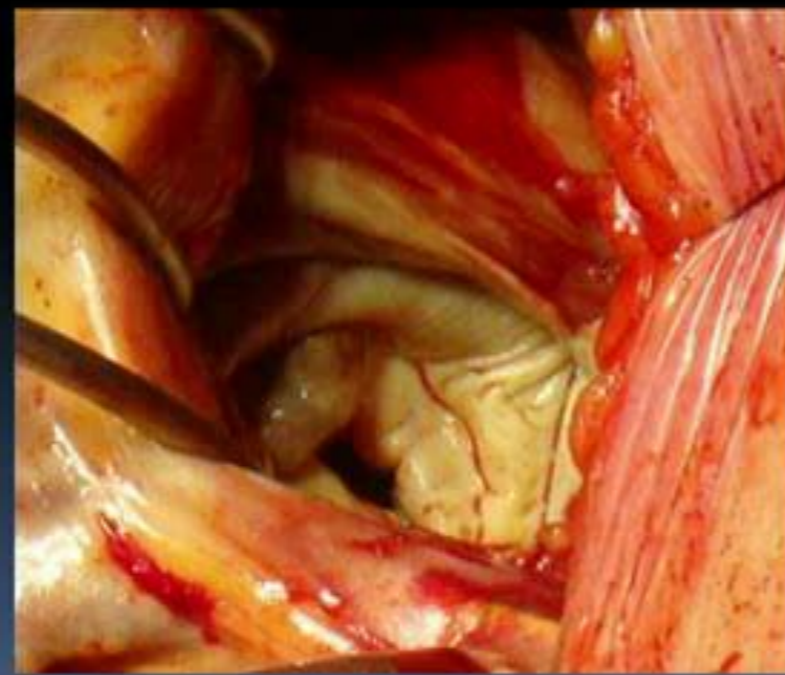
# Advantages of the surgical TAV in MAC

- Anterior leaflet ablation **to prevent LVOT** obstruction
- Direct annular measurement for valve sizing
- Direct visual implantation of the Sapien-3 valve (TA system)
- Valve fixation with surgical stitches **to prevent valve displacement**
- Use of “annular stabilisation technique” **to prevent PVL**
- Allows combined surgical procedures (TVR, CABG)

# Surgical TAV in MAC

**Transcatheter Heart Valve Implantation  
under Direct Vision  
in Rheumatic Calcified Mitral Valve**

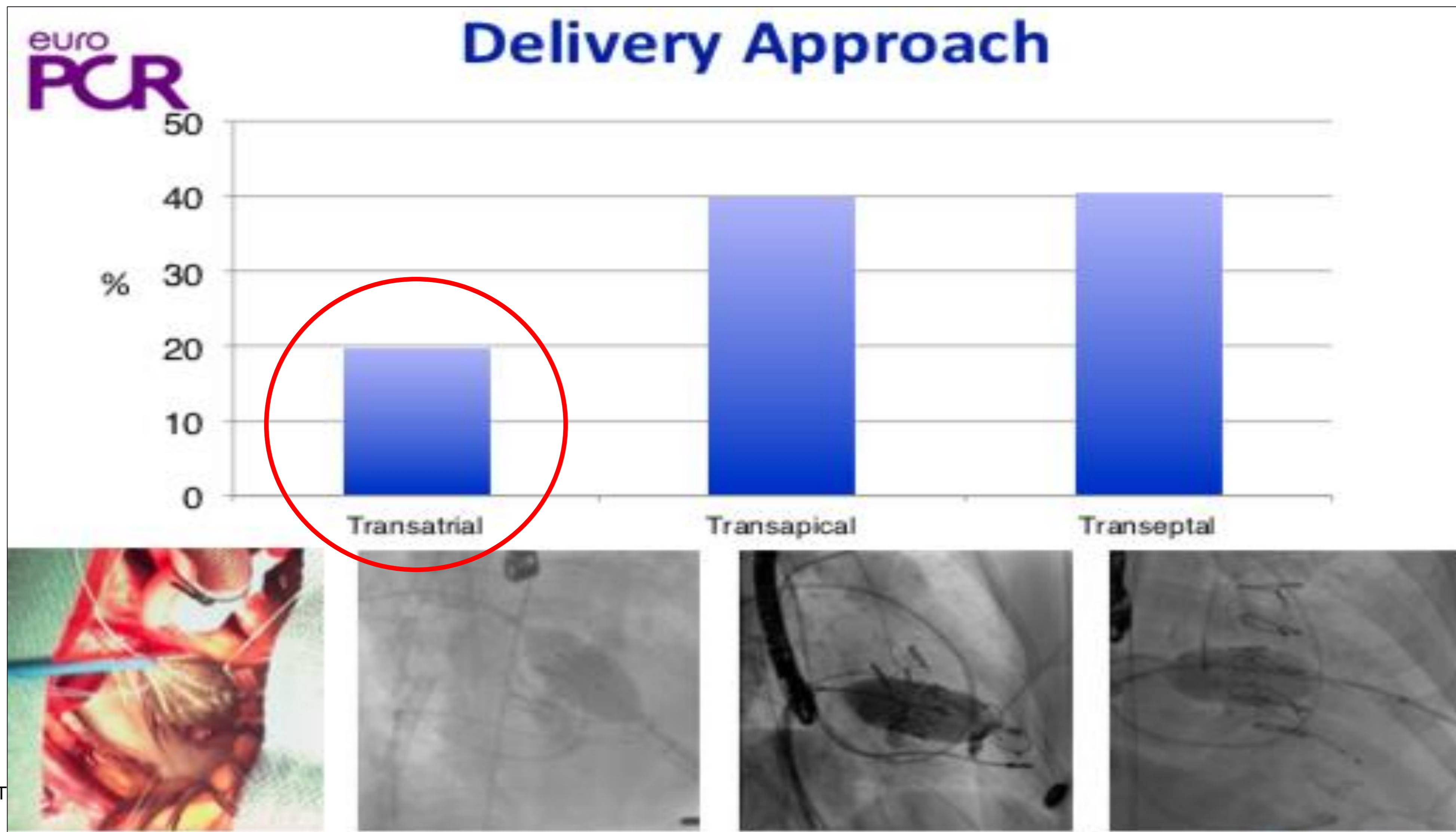
*Valve in Calcium*



# Results from the global registry

- 
- Multicentric global registry (51 centers, 11 countries)
  - Compassionate use of aortic transcatheter valves in MAC
  - 116 patients (up to end 2017)
  - Mean STS score:  $15 \pm 11$
  - Data presented at EuroPCR by Dr Mayra Guerrero

# Results from the global registry





# Results from the global registry



## Procedural Outcomes

n=116

	n (%)
Technical success by MVARC criteria	89 (76.7%)
LVOT obstruction with hemodynamic compromise	13 (11.2%)
Valve embolization	5 (4.3%)
Need for second valve (migration=6, MR=11)	17 (14.7%)
LV perforation	2 (1.7%)
Conversion to open surgery (embolization=2, LV perforation=1, LVOTO=1)	4 (3.4%)

# Results from the global registry

euro  
PCR

## Clinical Outcomes

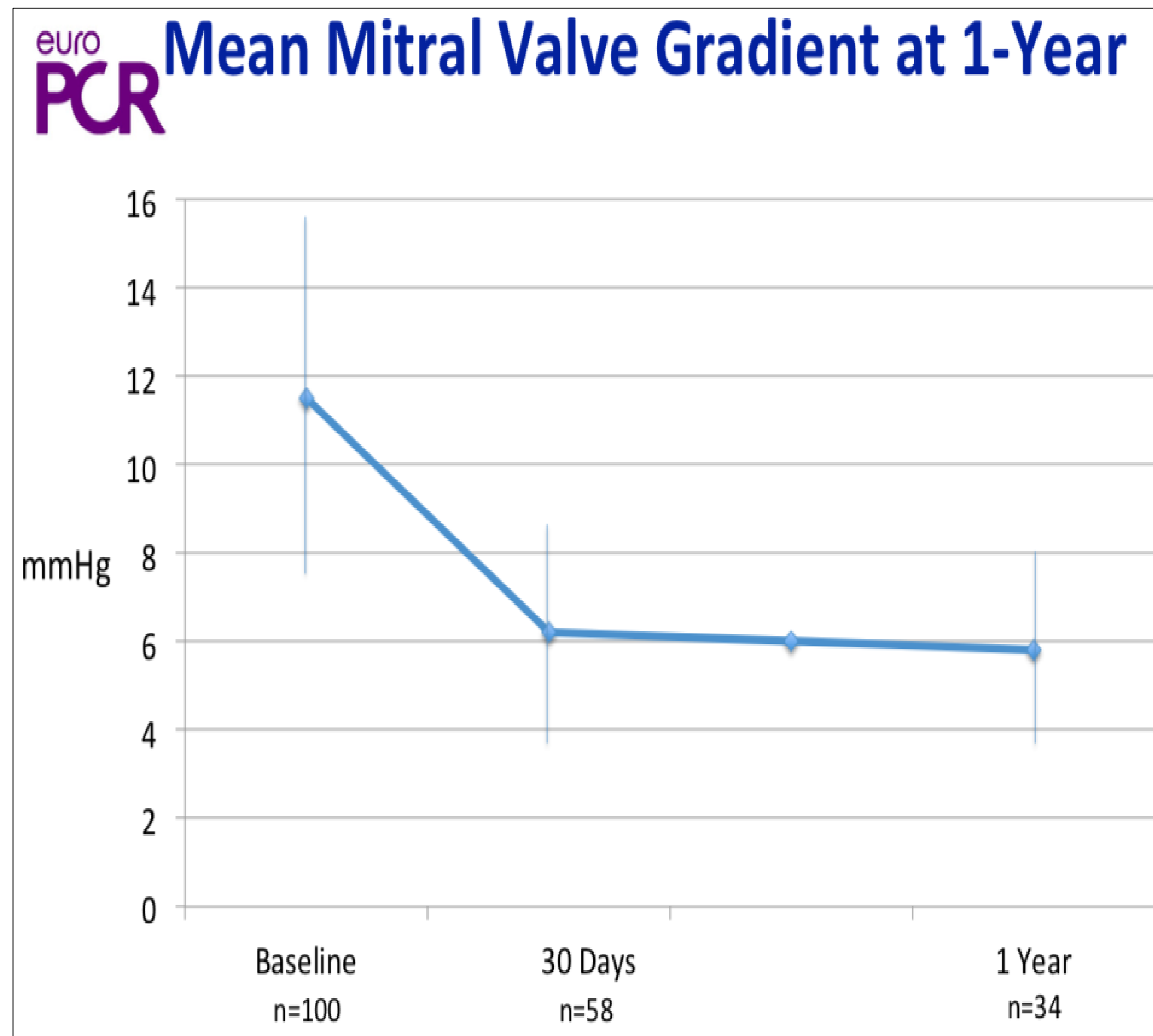
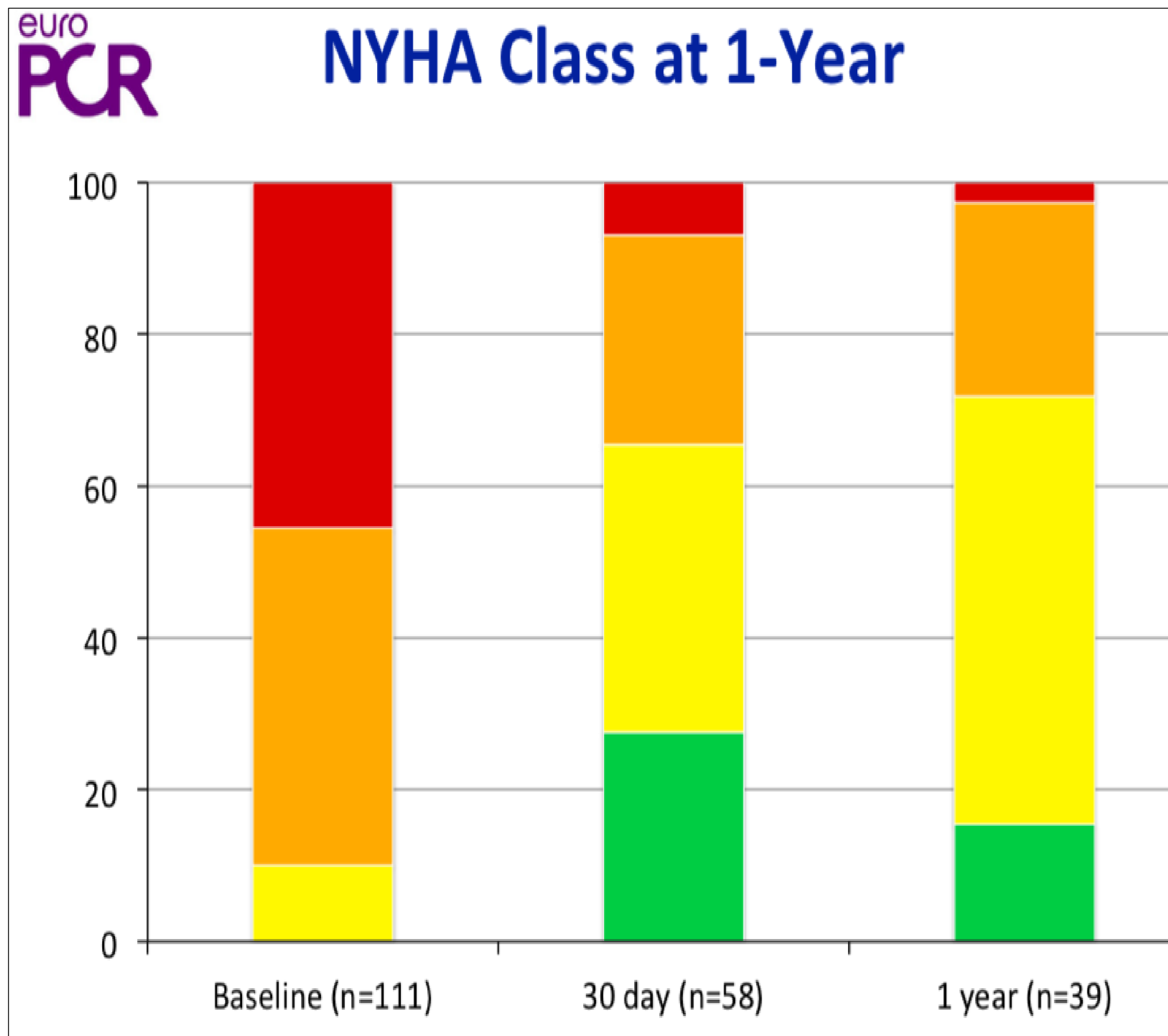
Outcomes	30 Days n=116	1 Year n=106
All-Cause Mortality	29 (25%)	58 (54.7%)
Cardiovascular death	15 (13%)	26 (24.5%)
Non-Cardiac death	14 (12%)	32 (30.2%)

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## Adverse Events

	30 Days n=116	1 Year n=106
Stroke	5 (4.3%)	7 (6.6%)
Myocardial Infarction	1 (0.8%)	2 (1.8%)
Mitral Valve Reintervention	9 (7.7%)	13 (12.3%)
Valve Embolization	5 (4.3%)	5 (4.7%)
Valve migration after procedure	2 (1.7%)	3 (2.8%)
Endocarditis	0 (0%)	3 (2.8%)
Hemolytic anemia	4/109 (3.7%)	4 (3.8%)
Valve Thrombosis	0 (0%)	2 (1.8%)

# Results from the global registry



# Results from the global registry

**euro PCR** **Univariate Cox Regression Analysis**  
Predictors of 1 year mortality

	HR	95% CI	p
Age (1 year increase)	1.03	1.00-1.06	<b>0.027</b>
Female gender	0.82	0.48-1.42	0.479
Chronic renal failure	1.51	0.88-2.57	0.131
Home oxygen	1.05	0.52-2.09	0.893
STS score (1 unit increase)	1.02	0.99-1.05	0.062
NYHA III-IV vs I-II	3.98	1.24-12.75	<b>0.019</b>
<b>Technical success (yes vs no)</b>	<b>0.23</b>	<b>0.12-0.44</b>	<b>&lt;0.0001</b>
<b>LVOT obstruction</b>	<b>3.56</b>	<b>1.81-7.01</b>	<b>0.0002</b>
<b>Valve embolization</b>	<b>2.93</b>	<b>1.16-7.42</b>	<b>0.023</b>
<b>Conversion to surgery</b>	<b>3.31</b>	<b>1.18-9.27</b>	<b>0.022</b>
Residual MR $\geq 3$ (+)	1.91	0.59-6.14	0.276
Need for second valve	1.34	0.68-2.66	0.393

Cite this article as: Ferrari E, Dvir D, Guerrero M. Transcatheter mitral valve replacement in degenerated calcified native mitral valves: is the currently available technology suitable? Eur J Cardiothorac Surg 2016;50:391–5.

## Transcatheter mitral valve replacement in degenerated calcified native mitral valves: is the currently available technology suitable?

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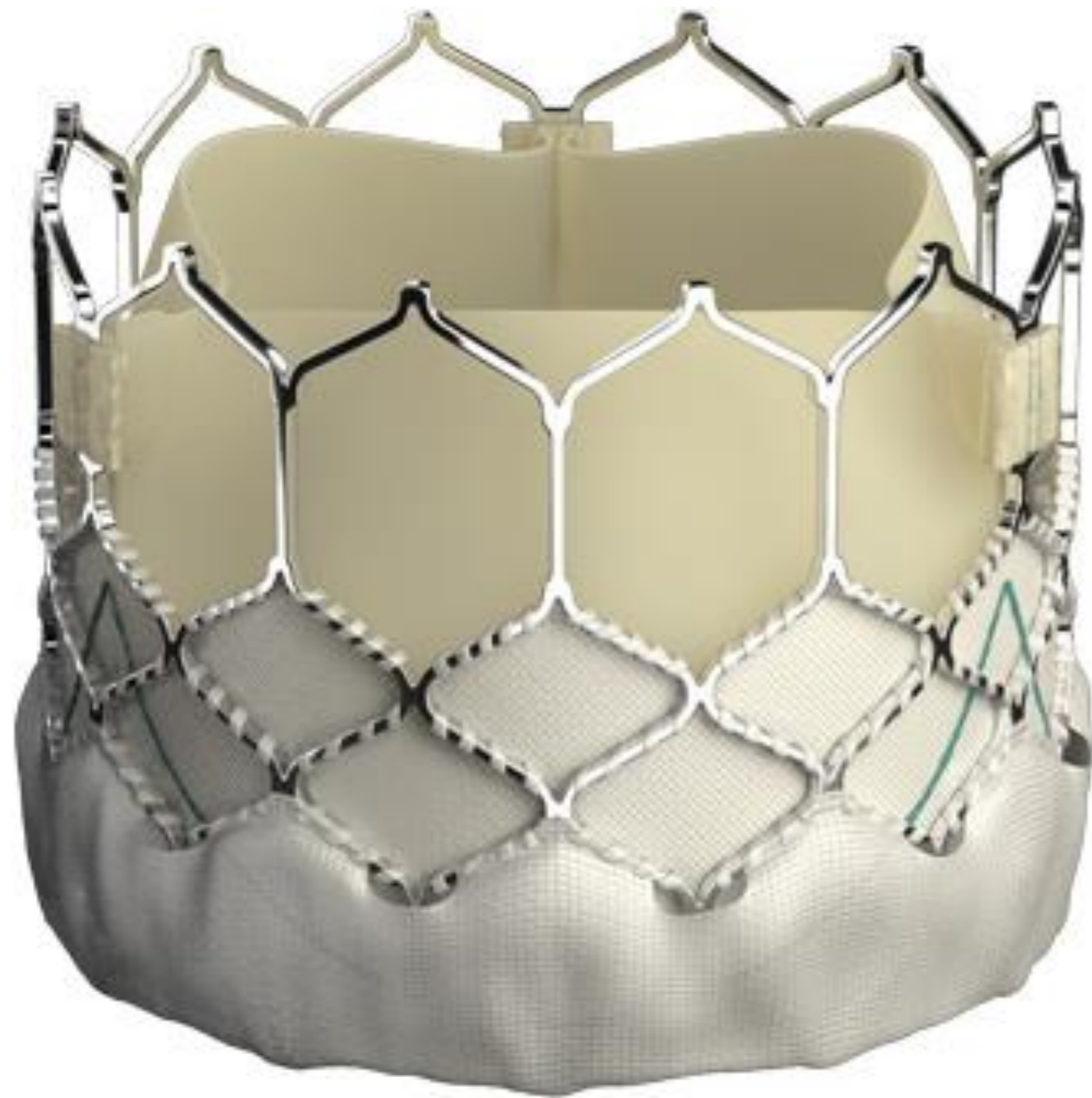
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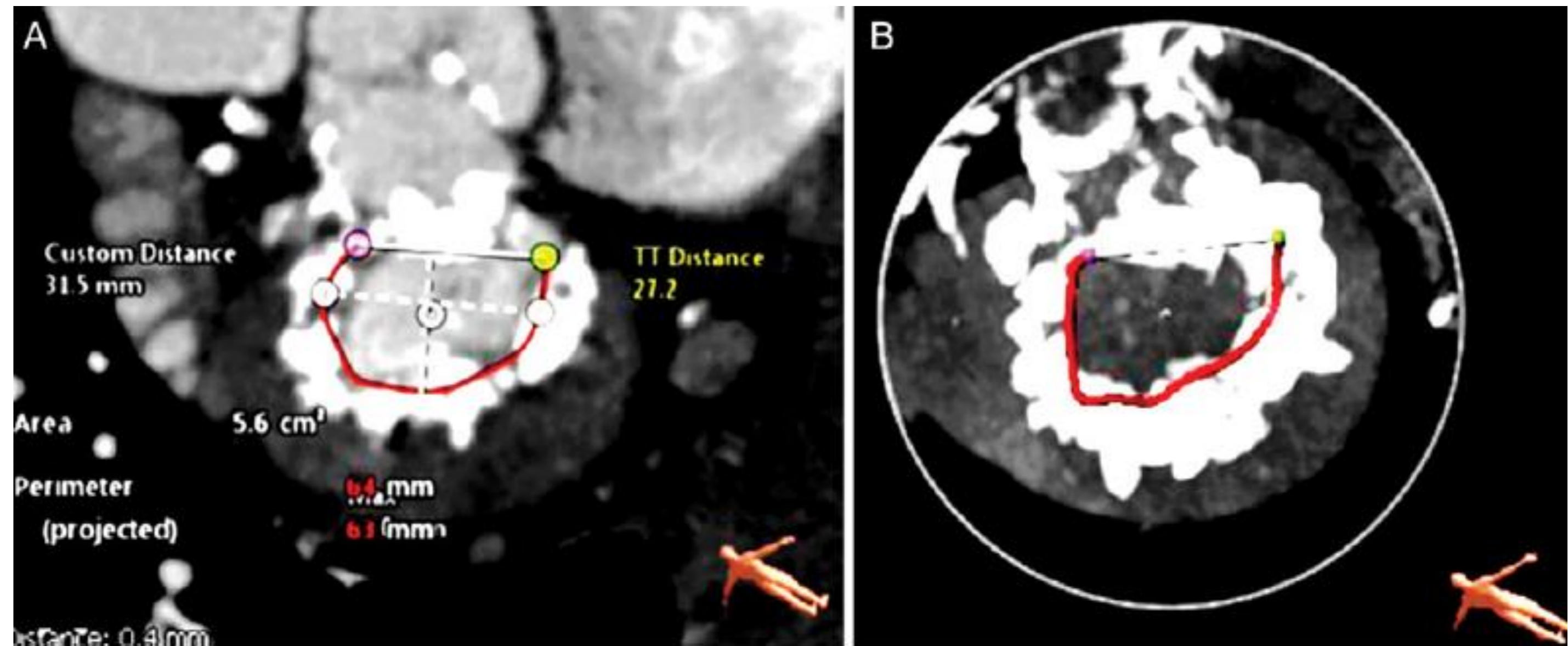
<sup>d</sup> Cardiology Division, Evanston Hospital, Evanston, IL, USA

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# Devices



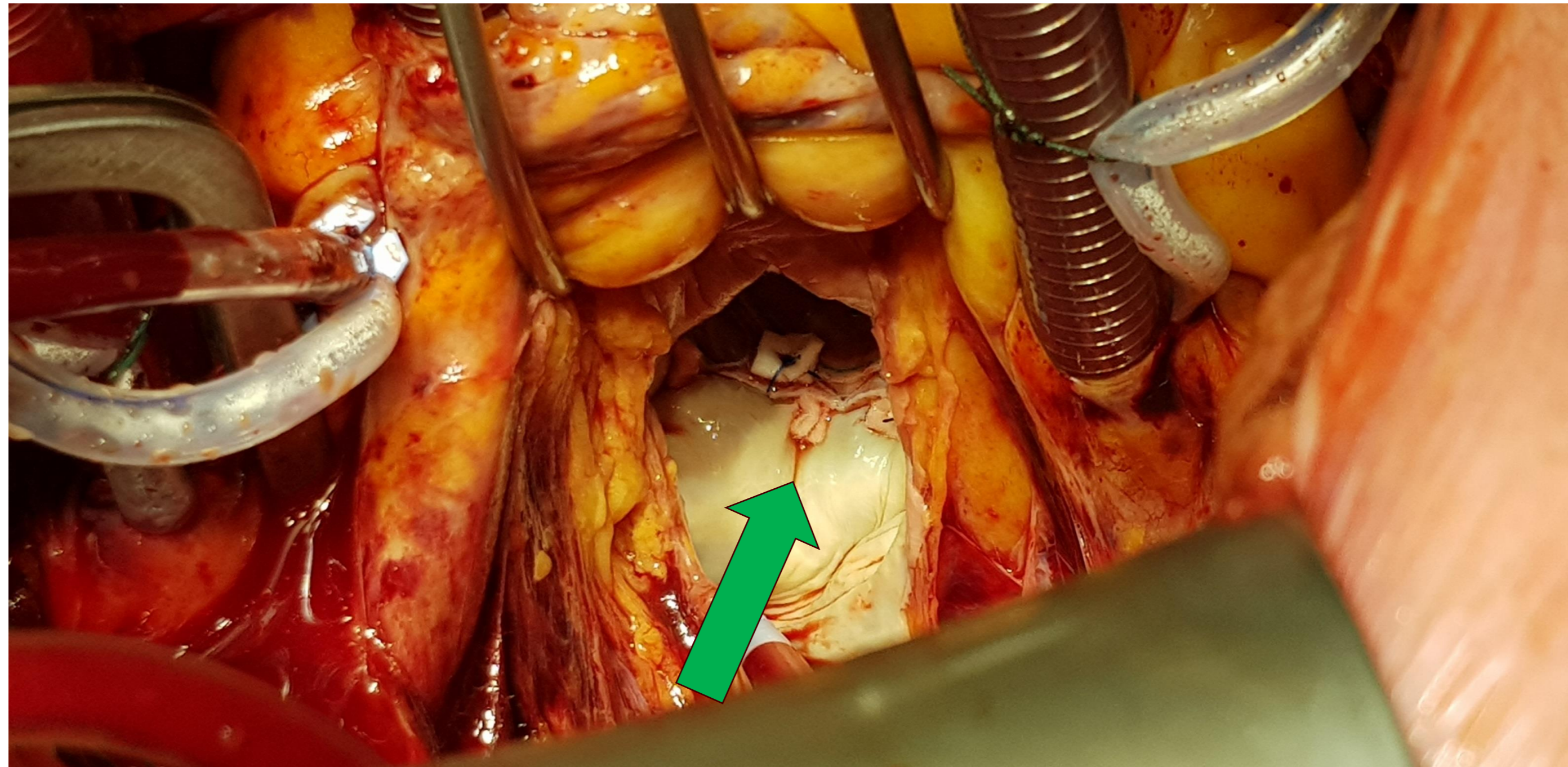
SAPIEN-3



PVL

## Aortic Annulus Stabilization Technique for Rapid Deployment Aortic Valve Replacement

*Enrico Ferrari, MD,\* Giuseppe Siniscalchi, MD,\* Piergiorgio Tozzi, MD,\* and Ludwig von Segesser, MD†*



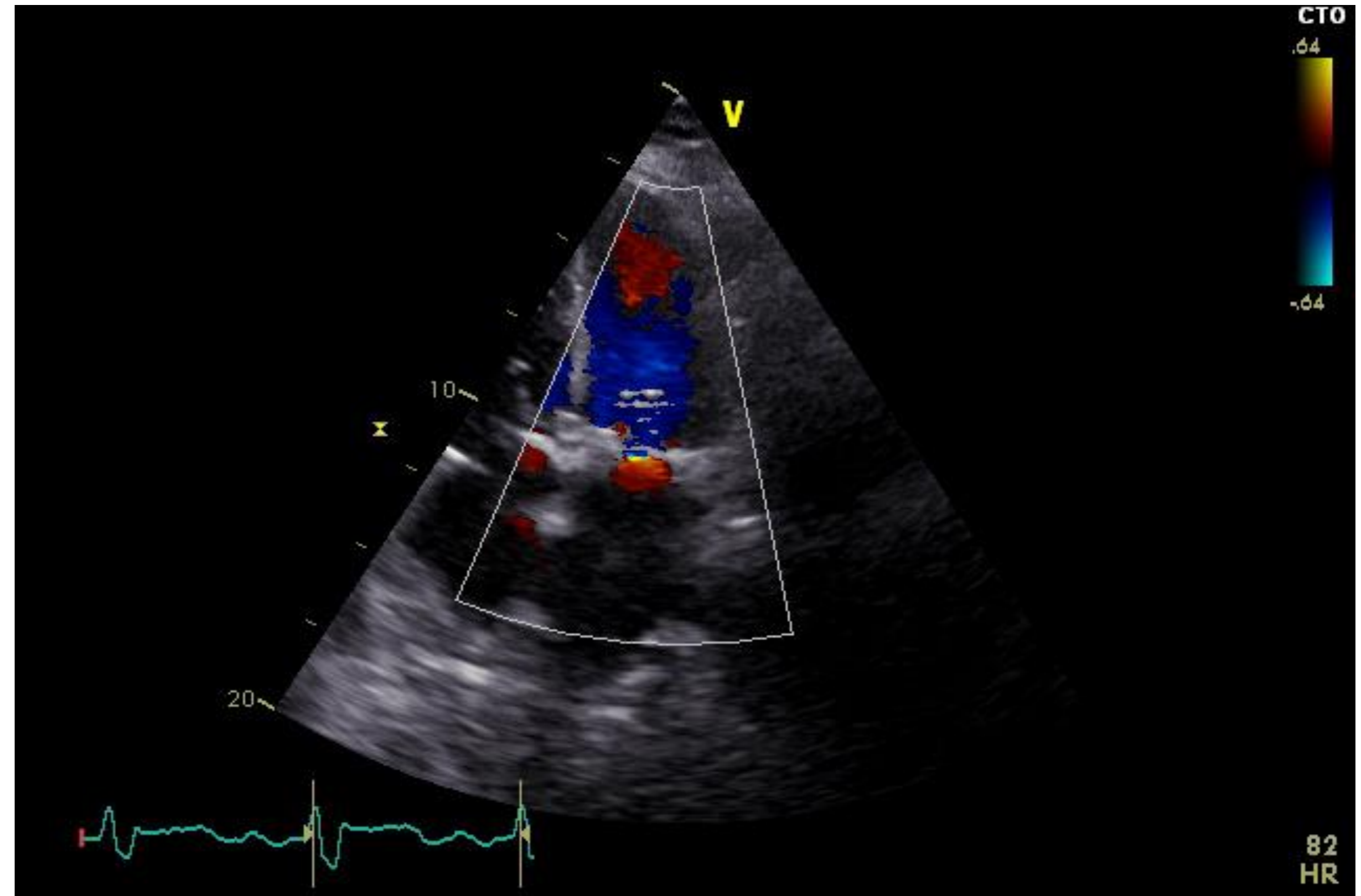
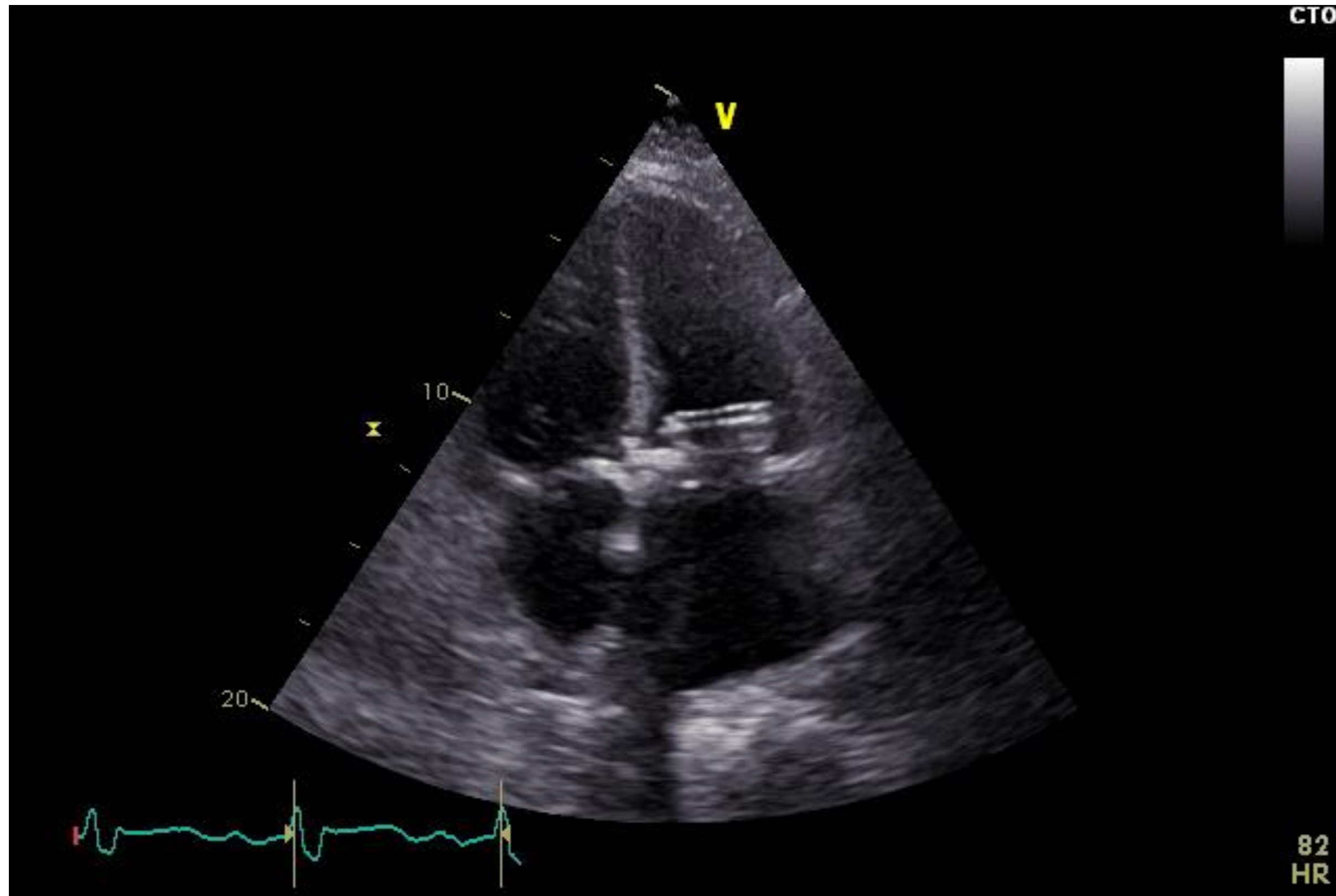
## New «annulus stabilization technique» prevents PVL

Ferrari E, et al. Aortic annulus stabilization technique for rapid deployment aortic valve replacement. *Innovations*. 2015;10:360-362

# PVL prevention

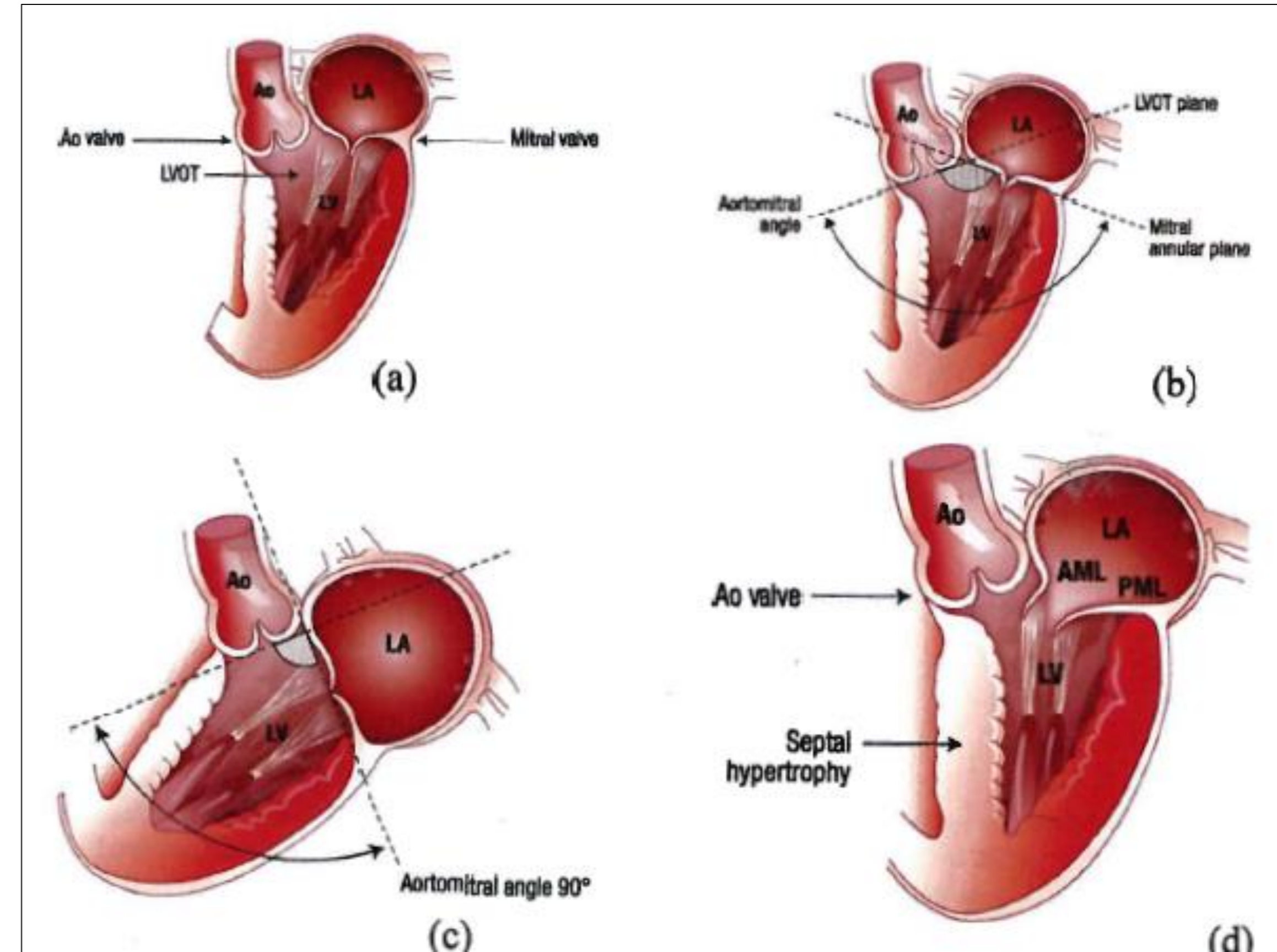
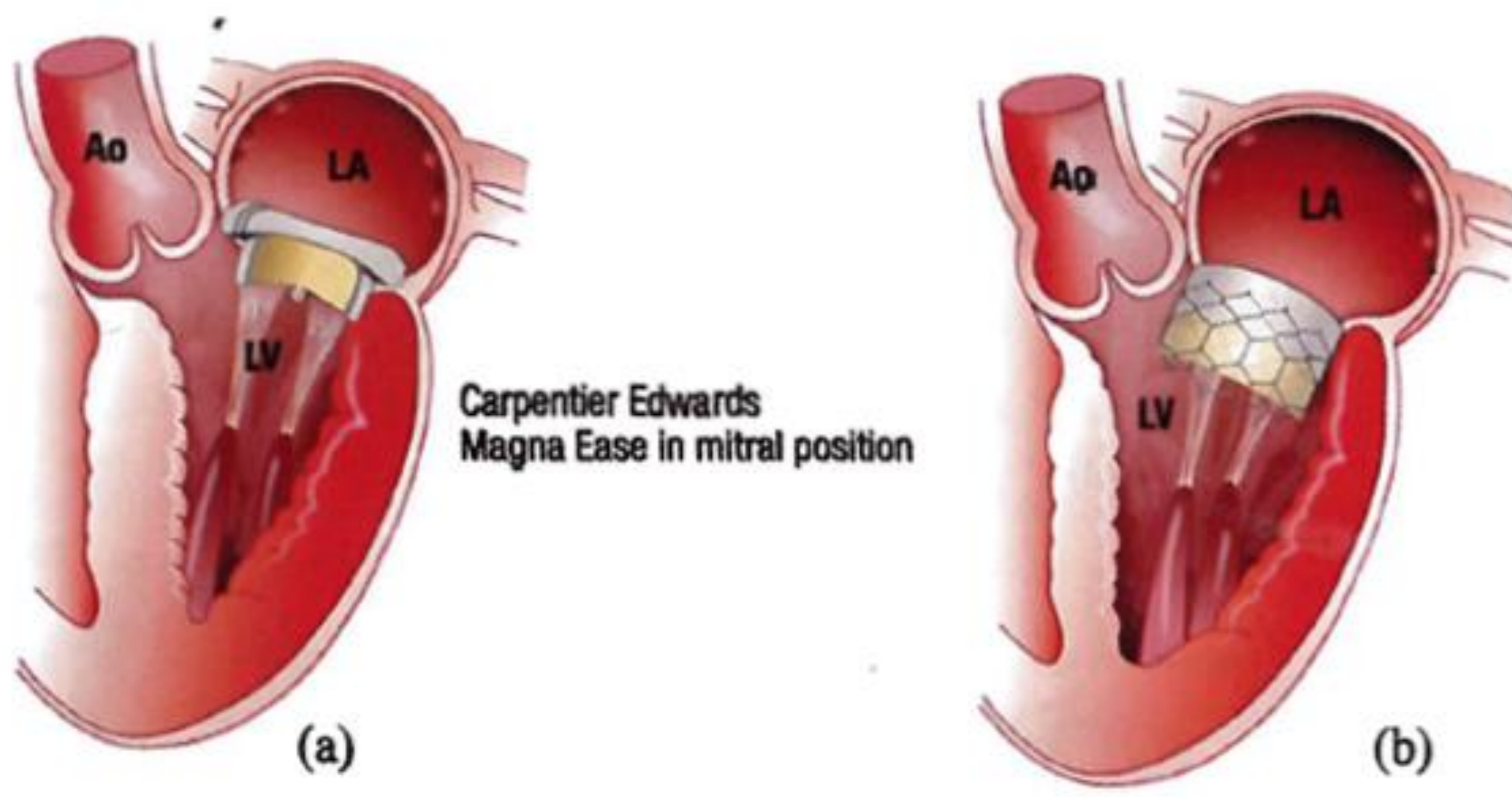
## Aortic Annulus Stabilization Technique for Rapid Deployment Aortic Valve Replacement

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# LVOT

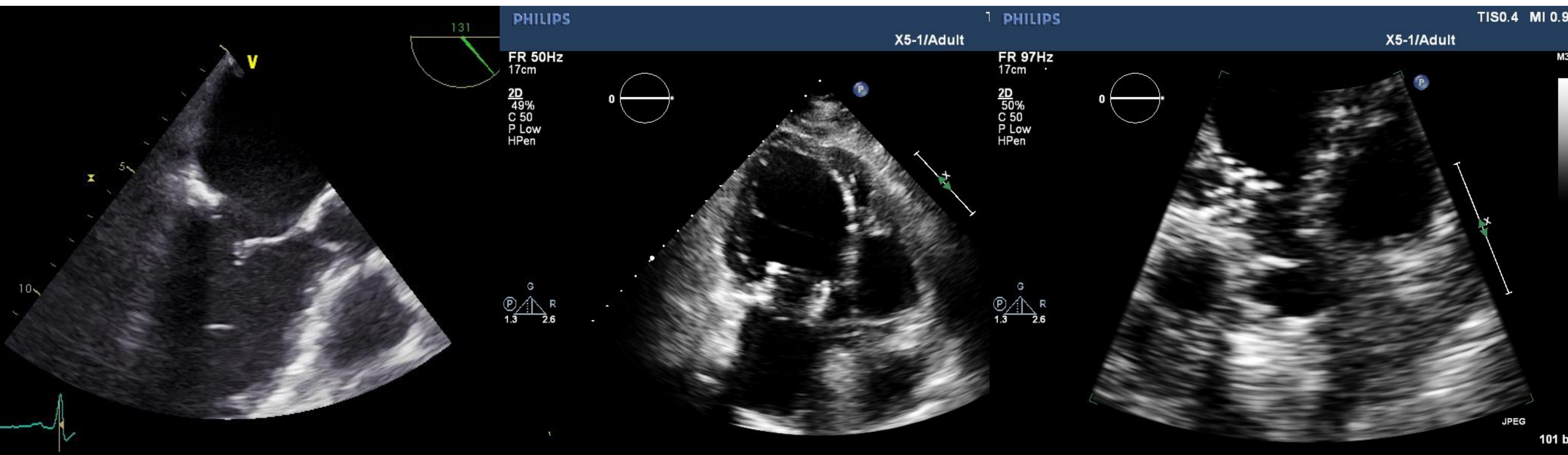


Surgical removal of the LAM prevents LVOT obstruction



# LVOT

Surgical removal of the LAM prevents LVOT obstruction



# Conclusions

- Transcatheter valve in MAC in high-risk patients is still associated with procedural complications and high mortality.
- Patients surviving 30-days have improved symptoms.
- The available technology was not developed for mitral valves.
- **Surgical TAV in MAC** guarantees AML removal, sizing, visual implantation (repositioning if required), valve fixation, no PVL.

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THANK YOU

