

# Revisión a propósito de un caso:

## Cierre percutáneo de fuga perivalvular en prótesis aórtica transcatéter

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## Introducción a las fugas perivalvulares:

- Incidencia entre 3-12.5% según las series.
- La mayoría se detectan durante el primer año y no evolucionan (a no ser que hagan endocarditis). Solo entre el 2–5% dan clínica
- Son más frecuentes las fugas mitrales que aórticas (60/30).

- **Factores de riesgo:**
  - ◆ Calcificación severa del anillo
  - ◆ Válvulas mecánicas
  - ◆ Sutura continua o sin “pledgeds”
  - ◆ Endocarditis infecciosa
  - ◆ Aurículas muy grandes
  - ◆ Insuficiencia renal.



Figura 1. Anatomía de una prótesis biológica en posición mitral con múltiples fugas paravalvulares (marcadores blancos)

## Tipos de fugas

Leak Perivalvular

Leak Valvuloplastia

Leak PeriTAVI

## Tipos de abordajes

Anterógrado

Retrógrado

Apical

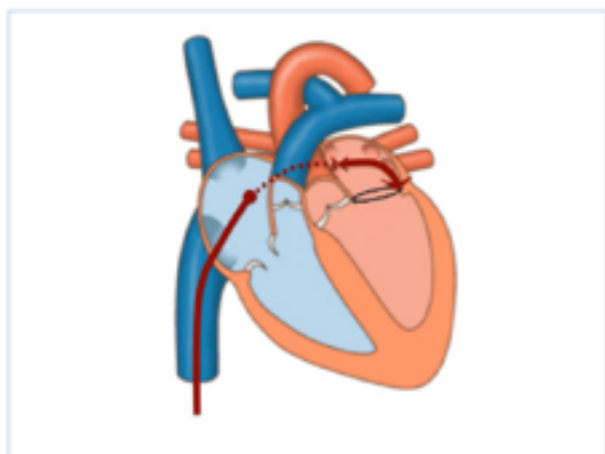


Figura 3A. Acceso anterógrado transeptal para el tratamiento de fugas paravalvulares mitrales

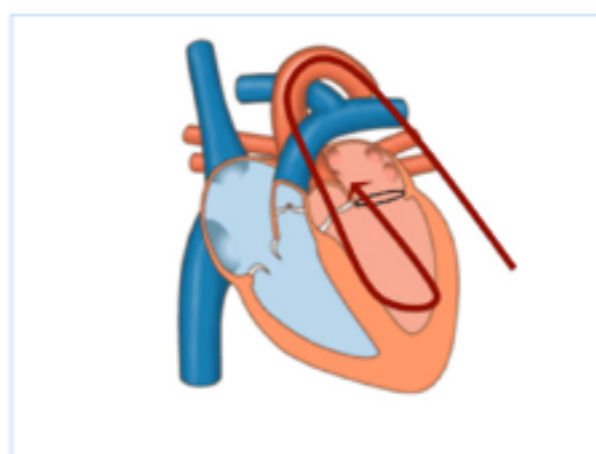


Figura 4. Acceso retrógrado transaórtico para el tratamiento de fugas paravalvulares mitrales

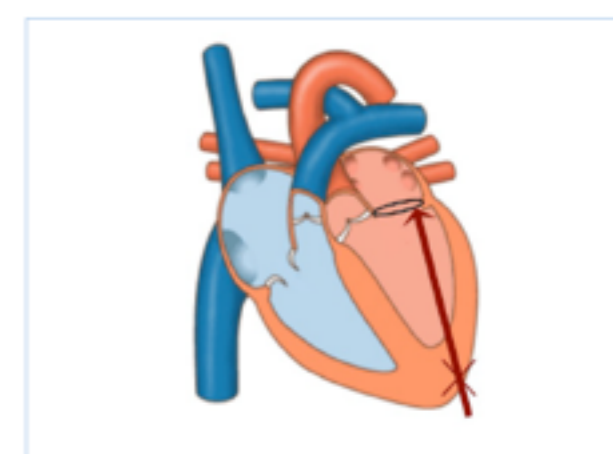


Figura 5. Acceso transapical para el tratamiento de fugas paravalvulares mitrales

# Cierre de “leak” en TAVI

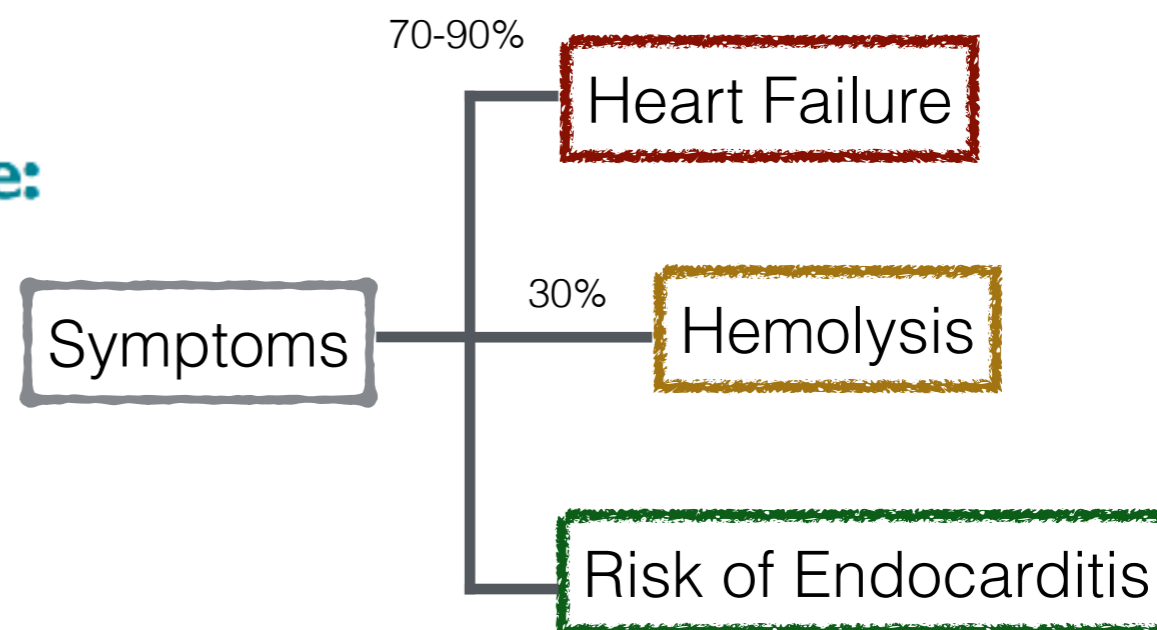
## Clinical update

## Percutaneous paravalvular leak closure: chasing the chameleon

## Clinical Trial Principles and Endpoint Definitions for Paravalvular Leaks in Surgical Prosthesis

## An Expert Statement

- **Technical success:** en CathLab liberar con éxito sin Mx ni AVC.
- **Procedural success:** bajar >1 grado la IM a 30 días
- **Clinical success:** Mejoría de la CF o Hemolisi >30 días.



**Table I** Absolute and relative indications for paravalvular leak closure

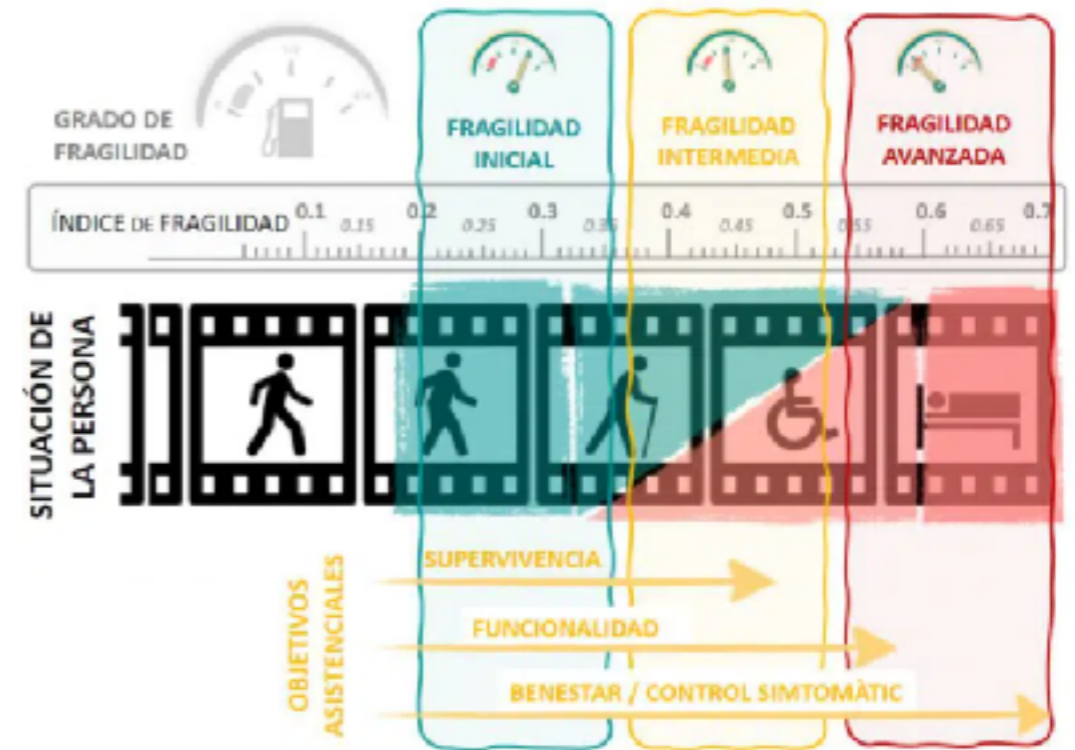
	Absolute indications	Relative indications
Haemolysis d/t PVL	x	
Symptoms of heart failure d/t PVL	x	
Risk of endocarditis		x
Asymptomatic mild/moderate PVL		x
Mild/moderate PVL with declining LVEF	x	
Mild/moderate PVL with progressive LV enlargement	x	
Mild/moderate PVL after TAVI		x

d/t, due to.

# Cierre de “leak” en TAVI

La primera opción terapéutica en las guías ESC y AHA es la Cirugía pero con un nivel de evidencia C

Surgical repair was historically the first-line therapy for treatment of symptomatic PVL; however, rapid development of safe, minimally invasive transcatheter techniques has obviated the need for open surgical repair in most patients in the contemporary era. Repeat surgery is associated with a significant increase in risk of morbidity and mortality, and the same anatomic factors may still prevent appropriate repair. Therefore, surgical management of PVL is reserved for the following situations: (1) patient undergoing CABG or another valve surgery, (2) active endocarditis, (3) large prosthesis dehiscence involving  $> 1/3$  of the annular circumference, or (4) unsuccessful percutaneous closure.

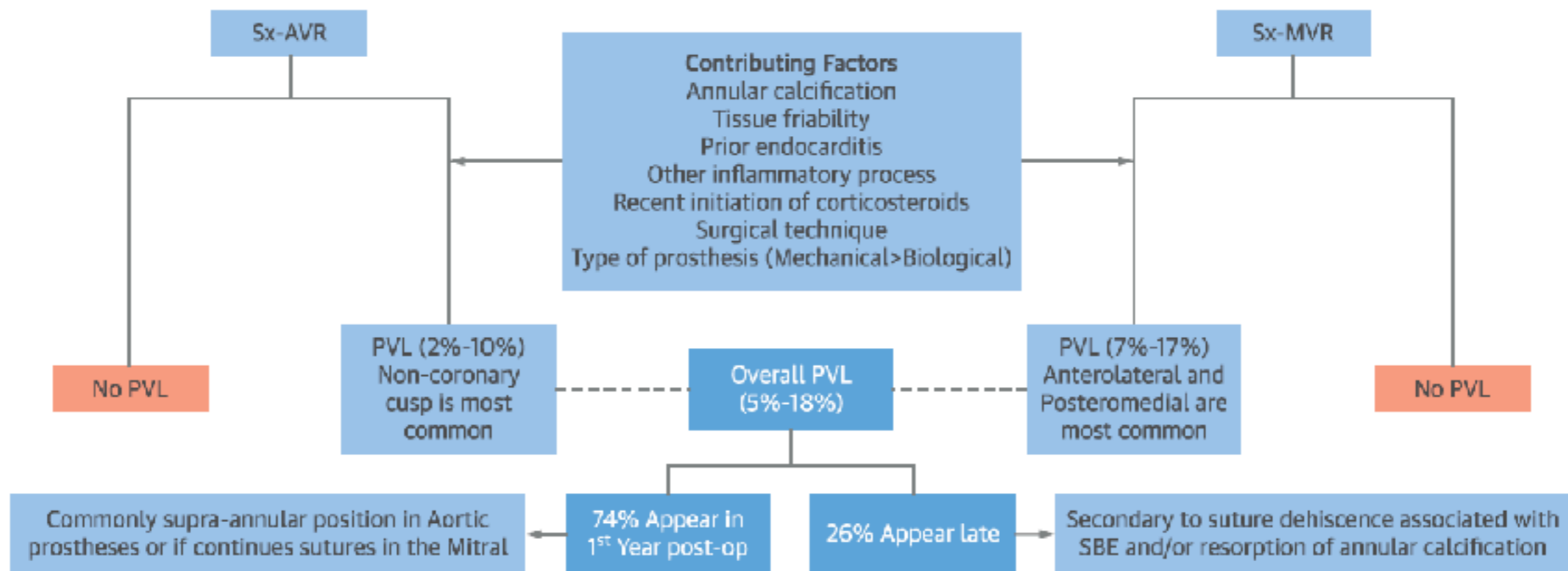


# Estudios comparativos Percutaneo vs Cirugia

Study	Country and Period	Type of Study	N Percutaneous vs. Surgical Closure	Endpoint	Results
Tamarasso et al., 2014	Italy 2000–2013	Single-centre, retrospective analysis	17 vs. 122	In-hospital death	Risk of death increased with surgical treatment (OR 8.0, 95% CI 1.8–13; $p = 0.05$ )
Angulo-Llanos et al., 2016	Spain 2008–2014	Single-centre, retrospective, propensity-score matched analysis	51 vs. 36	Composite of death or readmission. (mean follow-up 784 days)	- Non-significant difference in composite end point. - Reduced in-hospital mortality with percutaneous approach.
Pinheiro et al., 2016	Brazil 2011–2013	Single-centre, retrospective analysis	10 vs. 25	Reintervention or death at 1 year	Non-significant difference between groups for either end point
Milan et al., 2017	Canada 1994–2014	Single-centre, retrospective, propensity-score matched analysis	80 vs. 151	Composite of all-cause death and hospitalization for heart failure. Median follow-up 3.5 years	Reduced risk of end point with surgical treatment (HR 0.28; 95% CI 0.18–0.44; $p < 0.001$ )
Alkhouli et al., 2017	USA 1995–2015	Single-centre, retrospective analysis	195 vs. 186	Technical success and long-term survival (mean follow-up 4 years)	- Technical success greater in the surgical group - Non-significant difference in long-term survival between groups.
Wells et al., 2017	USA 2007–2016	Single-centre, retrospective analysis	56 vs. 58	Composite of death, reintervention or heart failure admission at 1 year	No difference in primary end point or 1-year survival between groups
Zhang et al., 2017	China 2009–2015	Single-centre, retrospective analysis	46 vs. 41	Survival Mean follow-up 49 months	- Non-significant difference in survival - Fewer in-hospital major adverse events and more cost-effective with percutaneous treatment

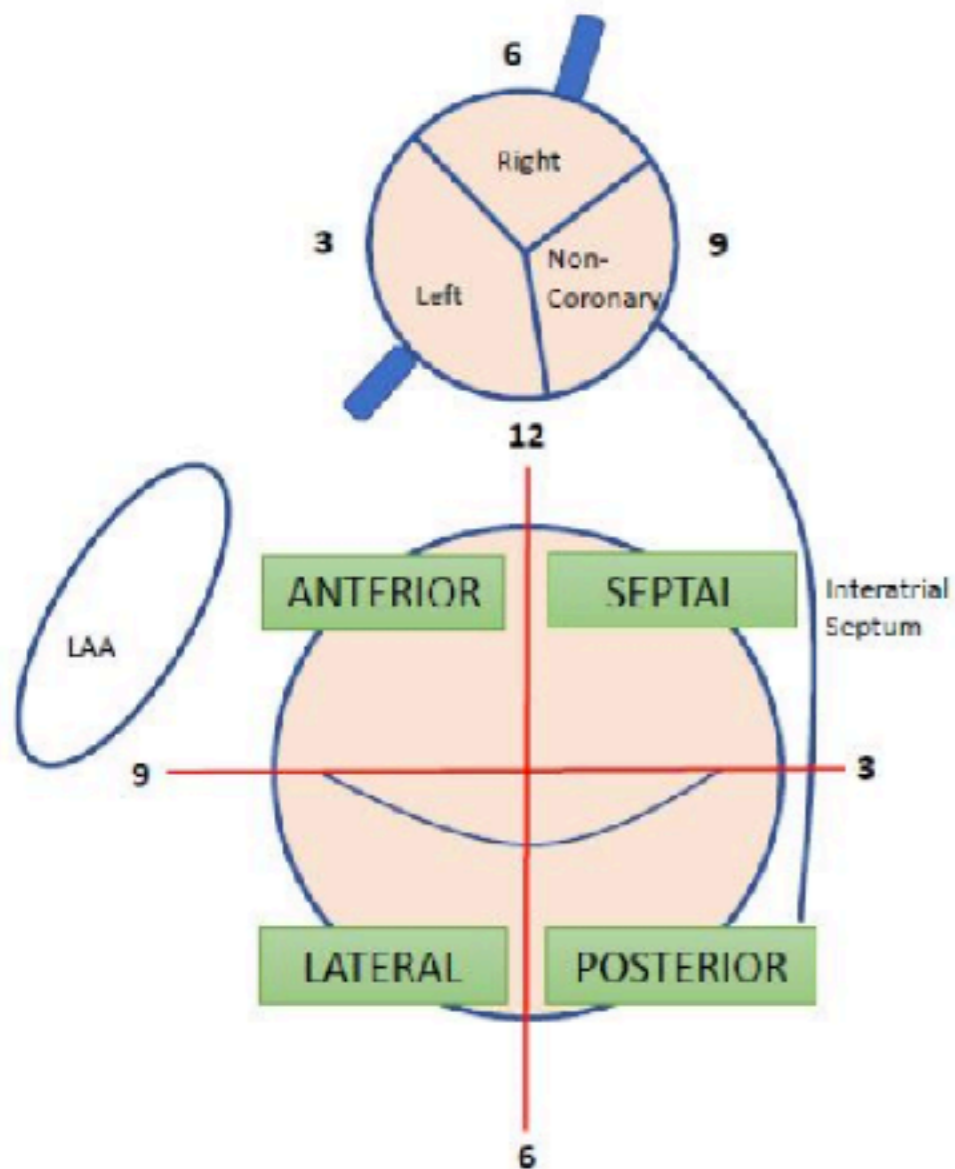
Summarize of studies comparing percutaneous vs. surgical closure of mitral PVL.

# Cierre de "leak" en TAVI



**Figure 1** Prevalence and Etiology. The prevalence and etiology of PVL are summarized in this chart. AVR, aortic valve replacement; MVR, mitral valve replacement; PVL, paravalvular leak; SBE, subacute bacterial endocarditis; Sx, surgical.

# Cierre de "leak" en TAVI



**Figure 7.** PVL closure devices. (a): Amplatzer Muscular VSD Occluder. (b): Amplatzer Duct Occluder. (c): Amplatzer Vascular Plug III. (d): Occlutech PLD (square-shaped design). (e): Amplatzer Septal Occluder. (f): Amplatzer Vascular Plug II. (g): Amplatzer Vascular Plug IV. (h): Occlutech PLD (rectangular-shaped design).



# Cierre de "leak" en TAVI

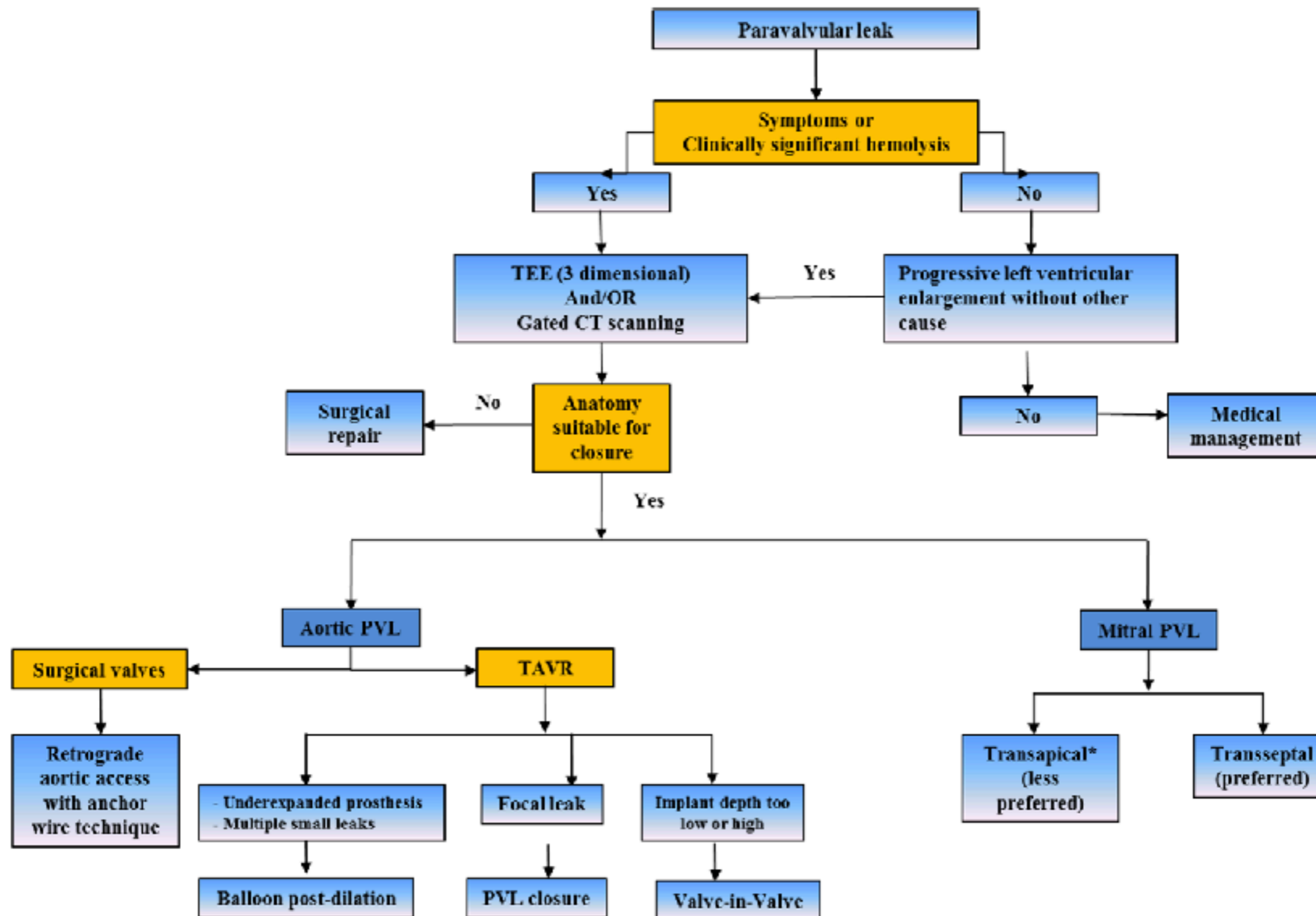


Fig. 1 Algorithm for management of paravalvular leak in structural heart disease. Parentheses, for unfavorable atrial septum or AV rail in a patient with aortic mechanical prosthesis. Abbreviations: CT, computed

tomography; PVL, paravalvular leak; TAVR, transcatheter aortic valve replacement; TEE, transesophageal echocardiography

## Outcomes and predictors of success and complications for paravalvular leak closure: an analysis of the Spanish real-world paravalvular LEaks closure (HOLE) registry

Table 2. Procedural characteristics.

Characteristic	Mitral	Aortic
<b>Imaging during procedure</b>		
Intracardiac echocardiography	1.7%	0%
Transthoracic echocardiography	1.4%	5.2%
2D transoesophageal echocardiography	31.2%	38.6%
3D transoesophageal echocardiography	65.2%	43.1%
Fluoroscopy alone	0.6%	13.1%
<b>Access</b>		
Transfemoral	94.5%	93.5%
Brachial	0.3%	6.5%
Transapical	5.0%	0%
Jugular	0.1%	0%
<b>Technique</b>		
Antegrade	53.1%	
Retrograde (transfemoral and transapical)	46.5%	
Both	0.3%	
<b>Device used</b>		
AVP III	85.3%	81.4%
AVP III+ductal occluder	0.6%	0.7%
AVP III+other	0.3%	1.4%
Ductal occluder	11.6%	12.4%
Ventricular septal occluder	0.6%	2.8%
Other	1.6%	1.4%
<b>Number of devices implanted</b>		
1	83.7%	87.6%
2	15.9%	11%
3	0.3%	1.4%

Registro español de 19 hospitales durante 12 años.  
514 PVL closure en 469 pacientes

Table 3. Periprocedural and adverse events at 30 days.

Event	%
No complications	80.2%
Vascular complications and bleeding	8.6%
Pseudoaneurysm	2.9%
Haematoma	1.2%
Cardiac (complete AV block, air embolism, ventricular fibrillation)	0.8%
Pericardial effusion	0.8%
Device embolisation	1.2%
Emergency cardiac surgery	1.2%
Prosthetic impingement	3.1%
All-cause death	4.5%
All-cause death, stroke or emergency surgery	5.6%

## Caso clínico:

# Leak Perivalvular en pacient amb TAVI autoexpandible



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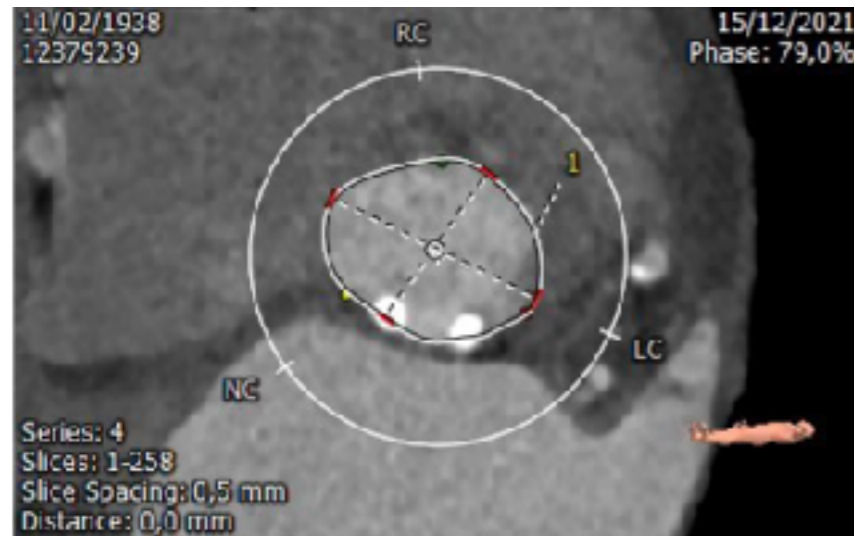
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## Discusión del caso

- Paciente varón de 83 años, independiente para ABVD.
- **Factores de riesgo:**
  - HTA en tratamiento. DLP con estatinas.
  - Insuficiencia renal crónica con Creatinina de 1.53mg/dl (FG 43)
  - Psoriasis de 30 años, afectación únicamente cutánea.
- **Estenosis aórtica degenerativa** grave y sintomática en forma de disnea.
  - ETT: VI con HVI moderada, FEVI normal. AD moderadamente dilatada. Válvula aórtica degenerada trivalva con estenosis crítica (Grad 118/77mmHg, V máx 5.43m/s). IAo ++ IM +. VD normal. Coronariografía ok y ejes aptos para TAVI TF.
- **STS score 2.31%**

**Discutido en Heart Team  
aceptado para TAVI**

## Planificación del caso



IDType	Label	Value
1	Polygon Annulus Dimensions - Min. Ø	23,7 mm
	Annulus Dimensions - Max. Ø	30,3 mm
	Annulus Dimensions - Avg. Ø	27,0 mm
	Annulus Dimensions - Area derived Ø	26,3 mm
	Annulus Dimensions - Perimeter derived Ø	26,8 mm
	Annulus Dimensions - Area	543,5 mm <sup>2</sup>
	Annulus Dimensions - Perimeter	84,1 mm

### Aortic Valve

Aortic Annulus	
Perimeter:	84,1 mm
Perimeter Derived Ø:	26,8 mm
Area:	543,5 mm <sup>2</sup>
Area Derived Ø:	26,3 mm

LVOT Ø:	25,4 mm
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RCA Height: 18,4 mm

Asc. Aorta Ø: \_\_\_\_\_

STJ Ø: 29,3 mm

LCA Height: 11,3 mm

Aortic Valve Calcification: Severe



#### Sinus Of Valsalva Diameters:

Left: 35,1 mm

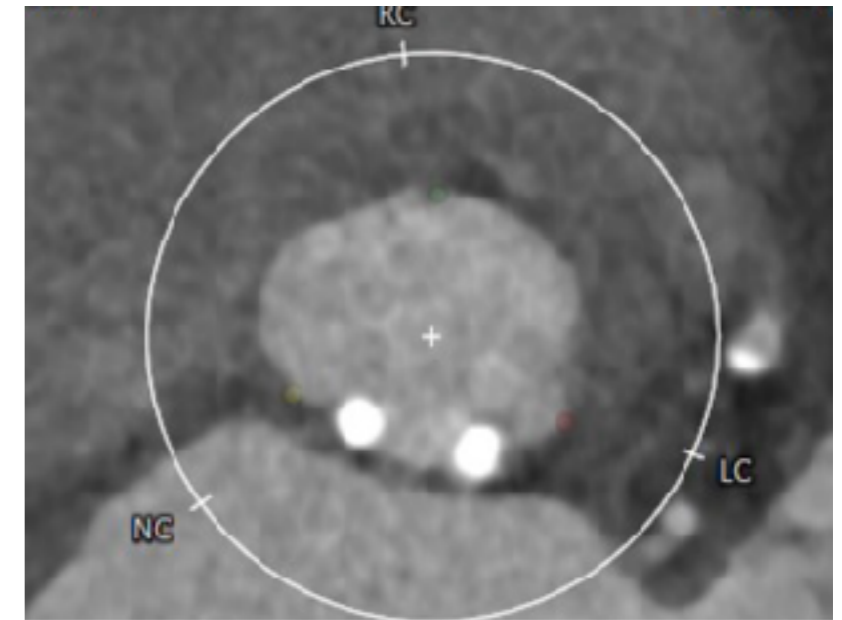
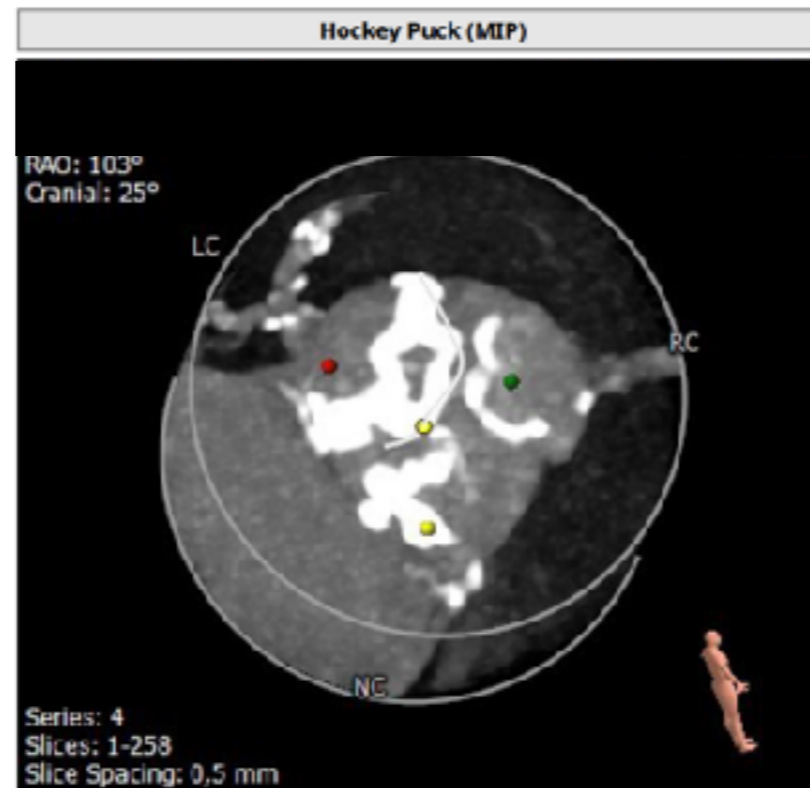
Right: 31,6 mm

Non: 35,3 mm

#### Measurements:

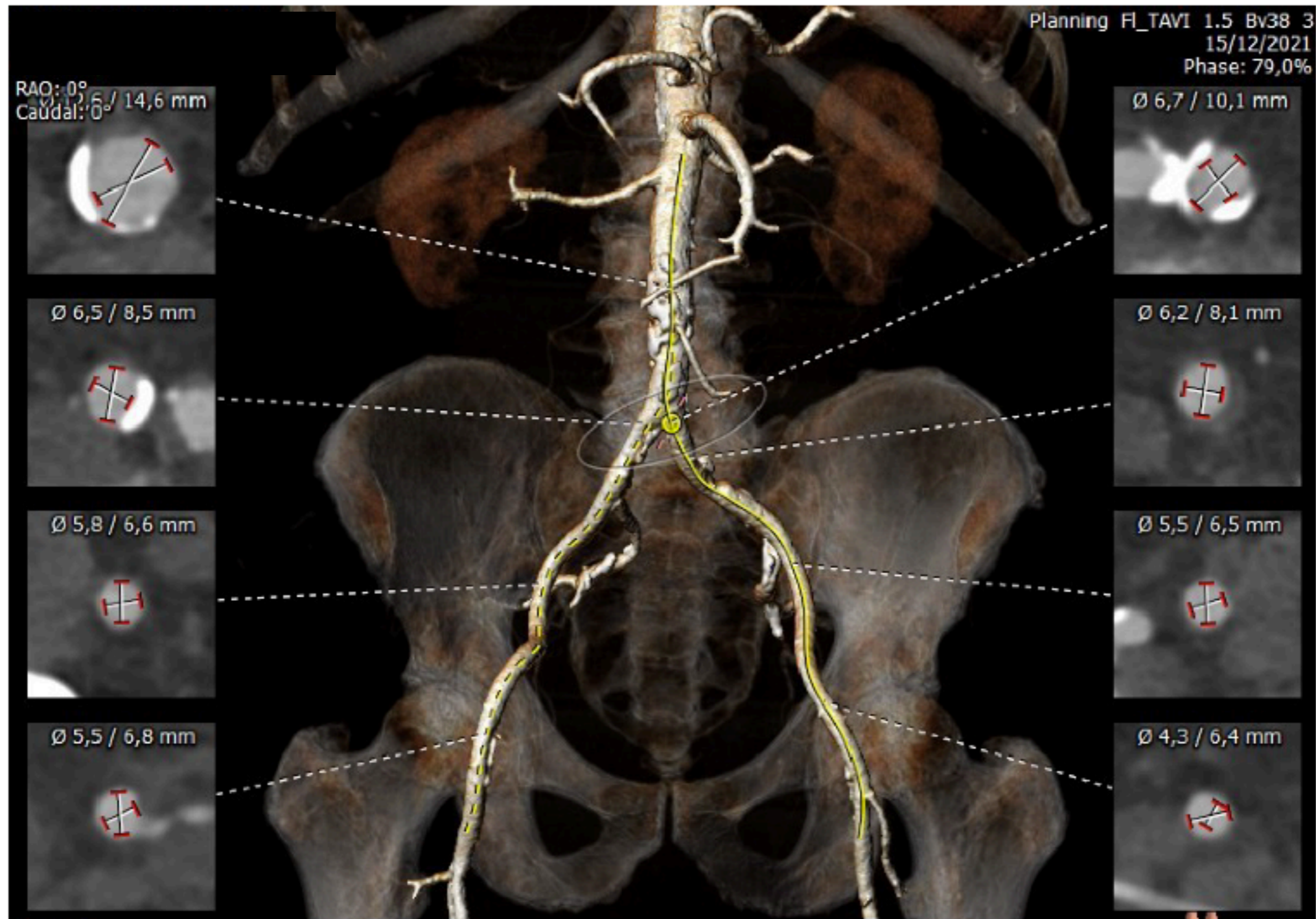
Ascending Aorta Ø	
Stenotubular Junction Ø	Min: 27,5 mm Max: 31,0 mm Average: 29,3 mm
Aortic Annulus	Min Ø: 23,7 mm Max Ø: 30,3 mm Average Ø: 27,0 mm Eccentricity: 0,22
LVOT Ø	Min: 21,0 mm Max: 29,8 mm Average: 25,4 mm

## Planificación del caso



Dos espículas de calcio que bajan por el TSVI.  
Se considera elevado el riesgo de rotura y se decide  
implantar válvula autoexpandible Evolute PRO de 34mm

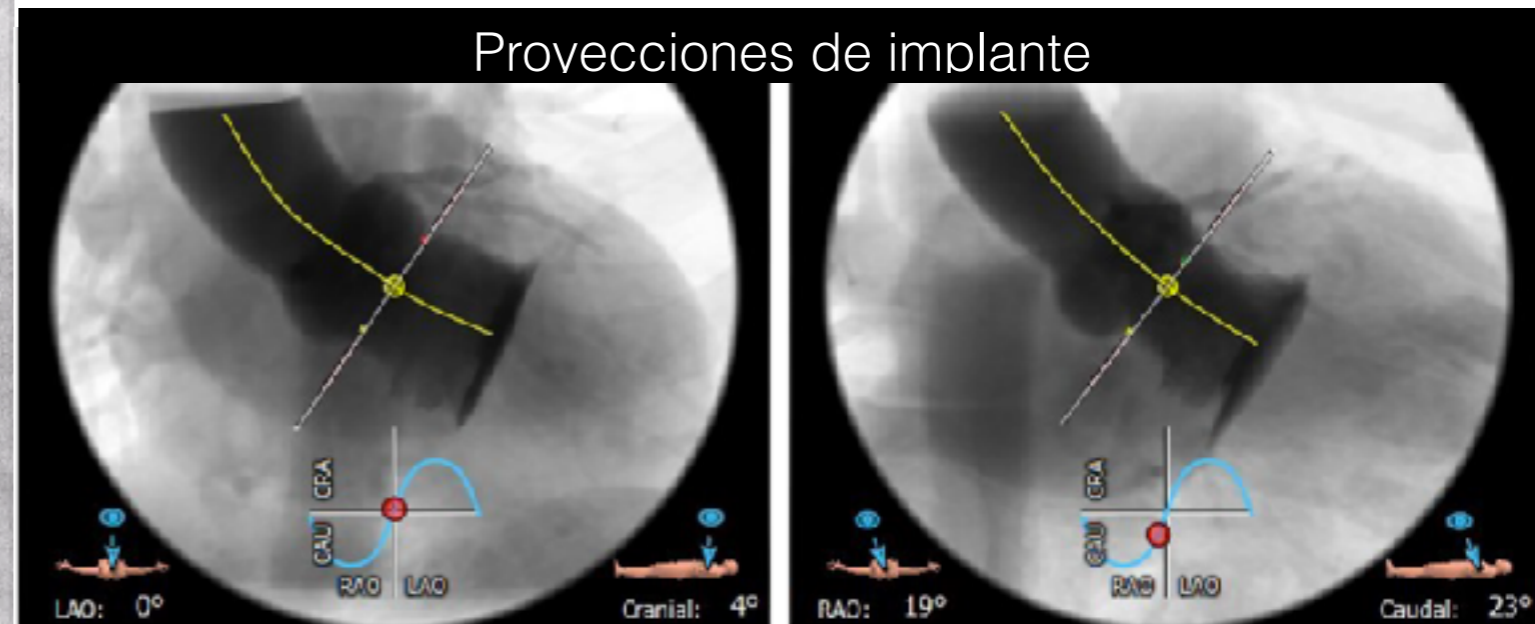
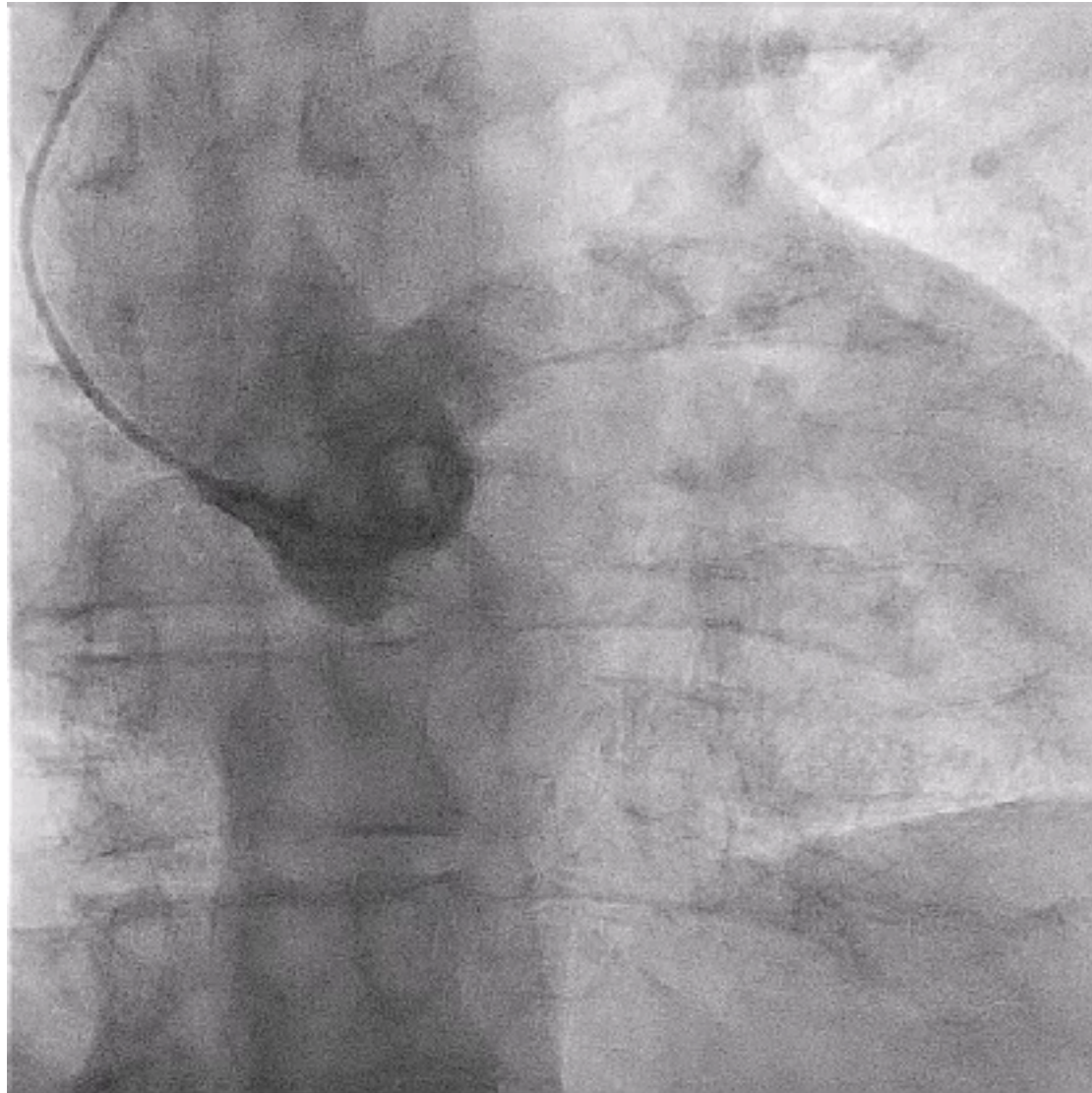
## Planificación del caso



TAVI por acceso Transfemoral derecha

## Implant de TAVI

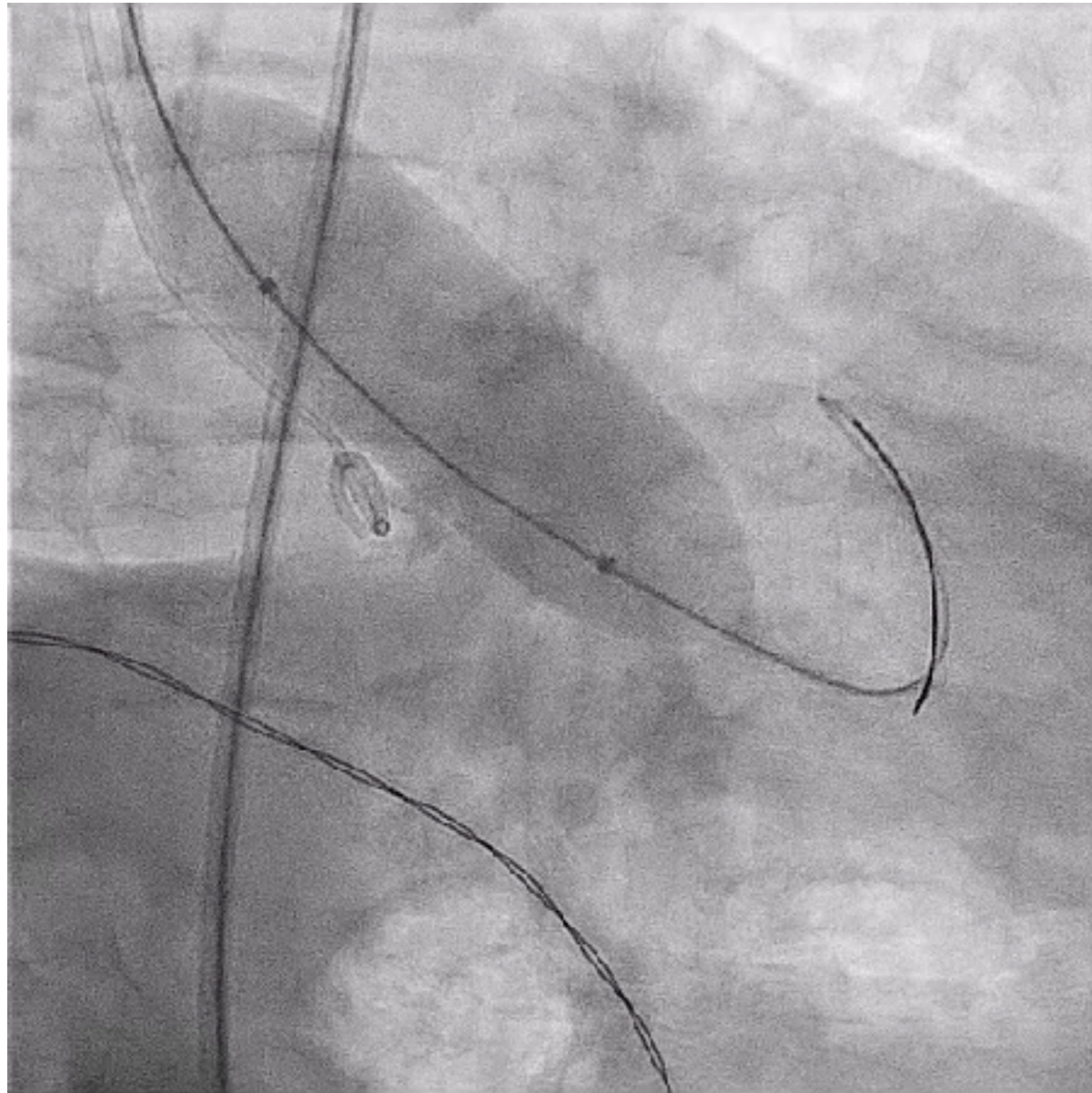
Aortograma basal.



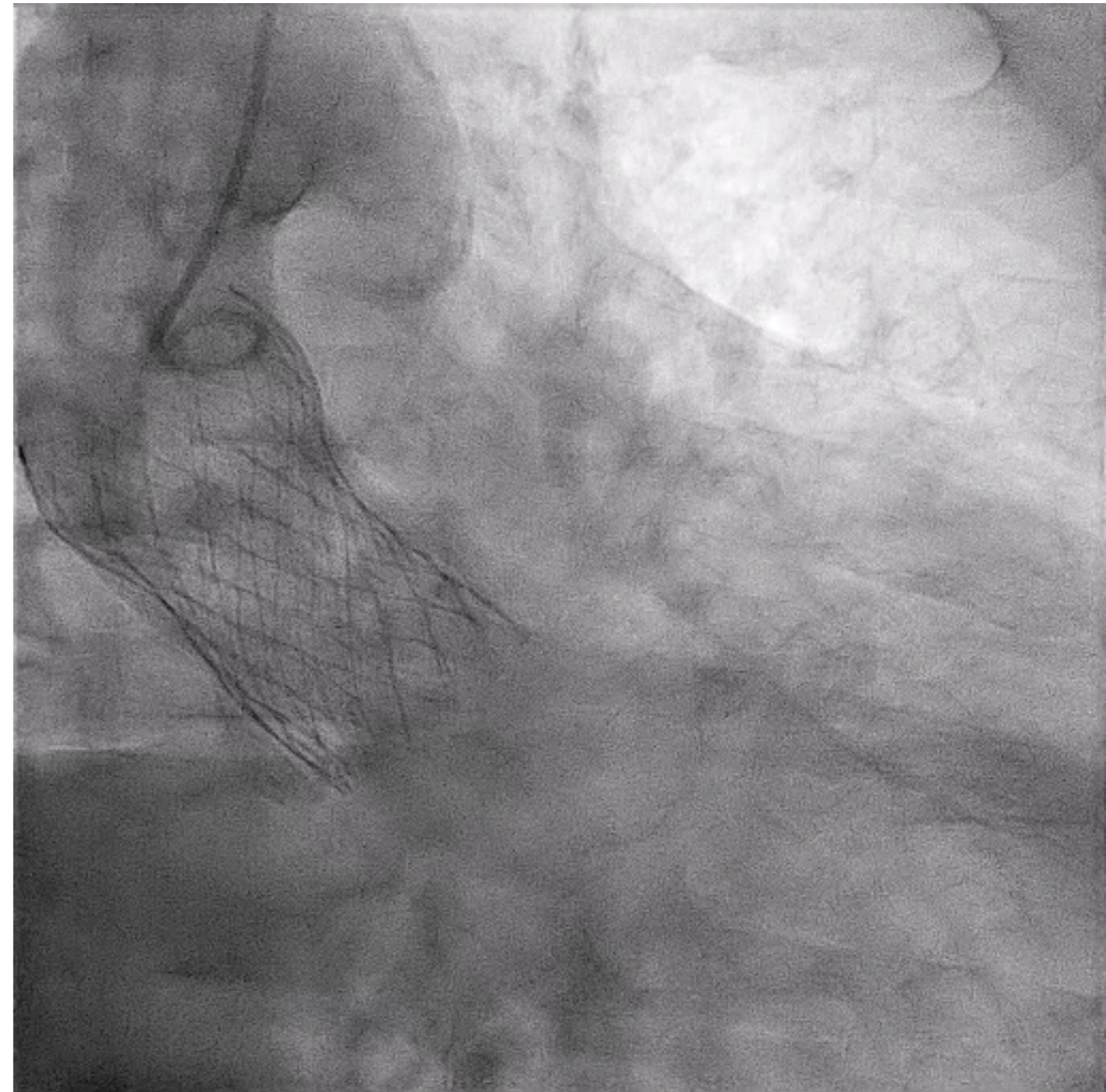


## Implant de TAVI

Implantación con estimulación a 120x' de  
EVOLUTE PRO de 34mm



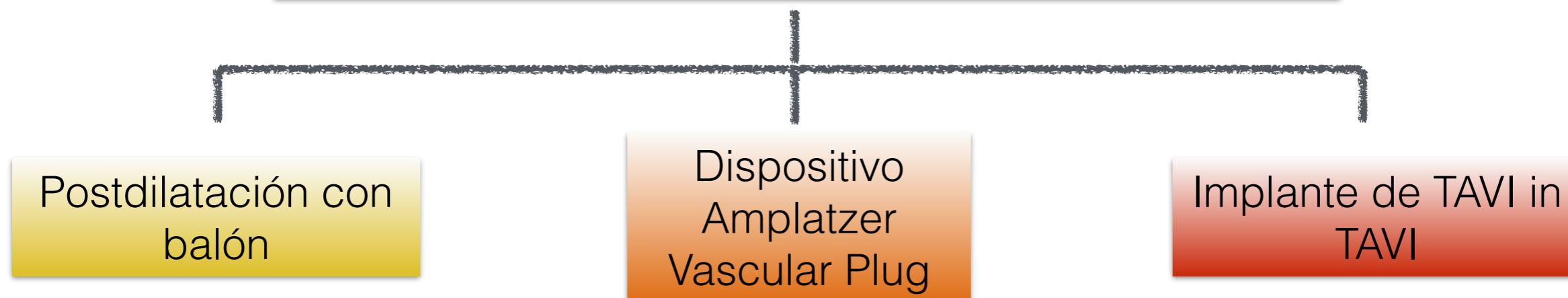
Guia Lunderquist para mayor soporte  
Predilatación con balón de 26mm



# Cierre de “leak” en TAVI

- Postoperatorio tórpido en **semicríticos**:
- Derrame pericardico moderado per possible perforación con la guía, se contiene espontáneamente sin compromiso por eco sin necesidad de pericardiocentesis.
- Insuficiencia renal por contraste amb oligoanúria (Furo y DPM) hasta a creatininas de 3.1mg/dl.
- Fibrilación auricular con múltiples episodios revertidos con amiodarona.
- En **planta** presenta episodi de EAP que requiere VMNI e traslado a coronarias. Per ETT IAO lleu-mod però per ETE IAo moderada +++. Se orienta la fuga como el causante del EAP.

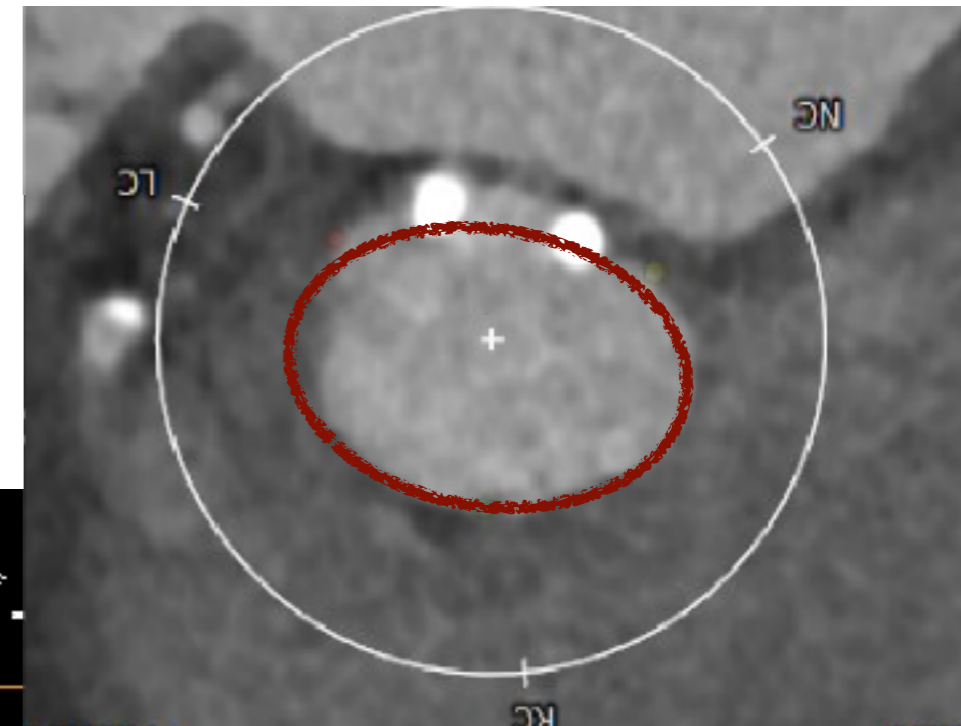
## OPCIONES PARA CERRAR LA FUGA PERIVALVULAR



# Cierre de "leak" en TAVI

15 días post TAVI

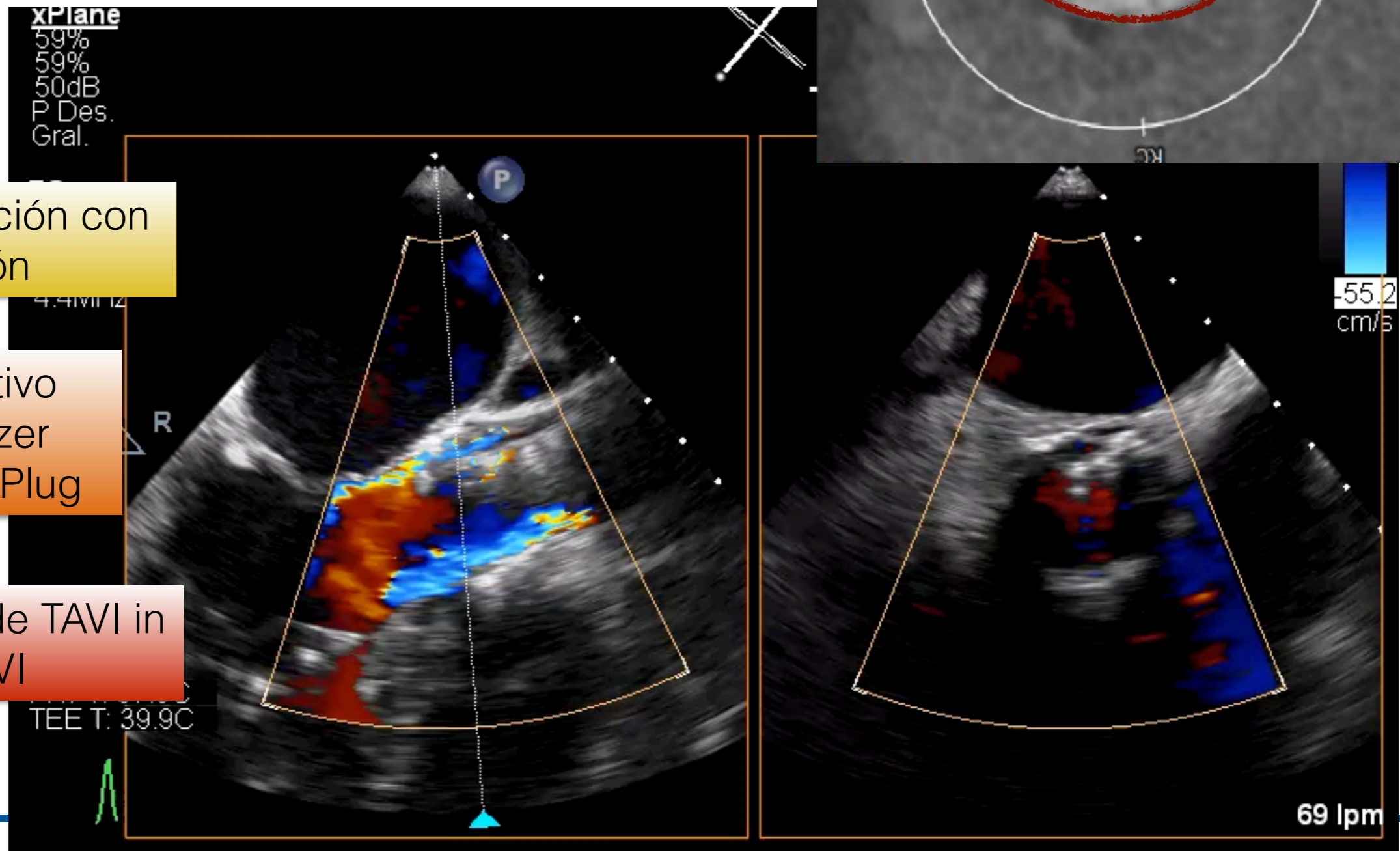
- Anestesia general y valoración por ETE
- Leak perivalvular entre el NC y LC.
- Acceso femoral bilateral 12Fr y 6 Fr



Postdilatación con balón

Dispositivo Amplatzer Vascular Plug

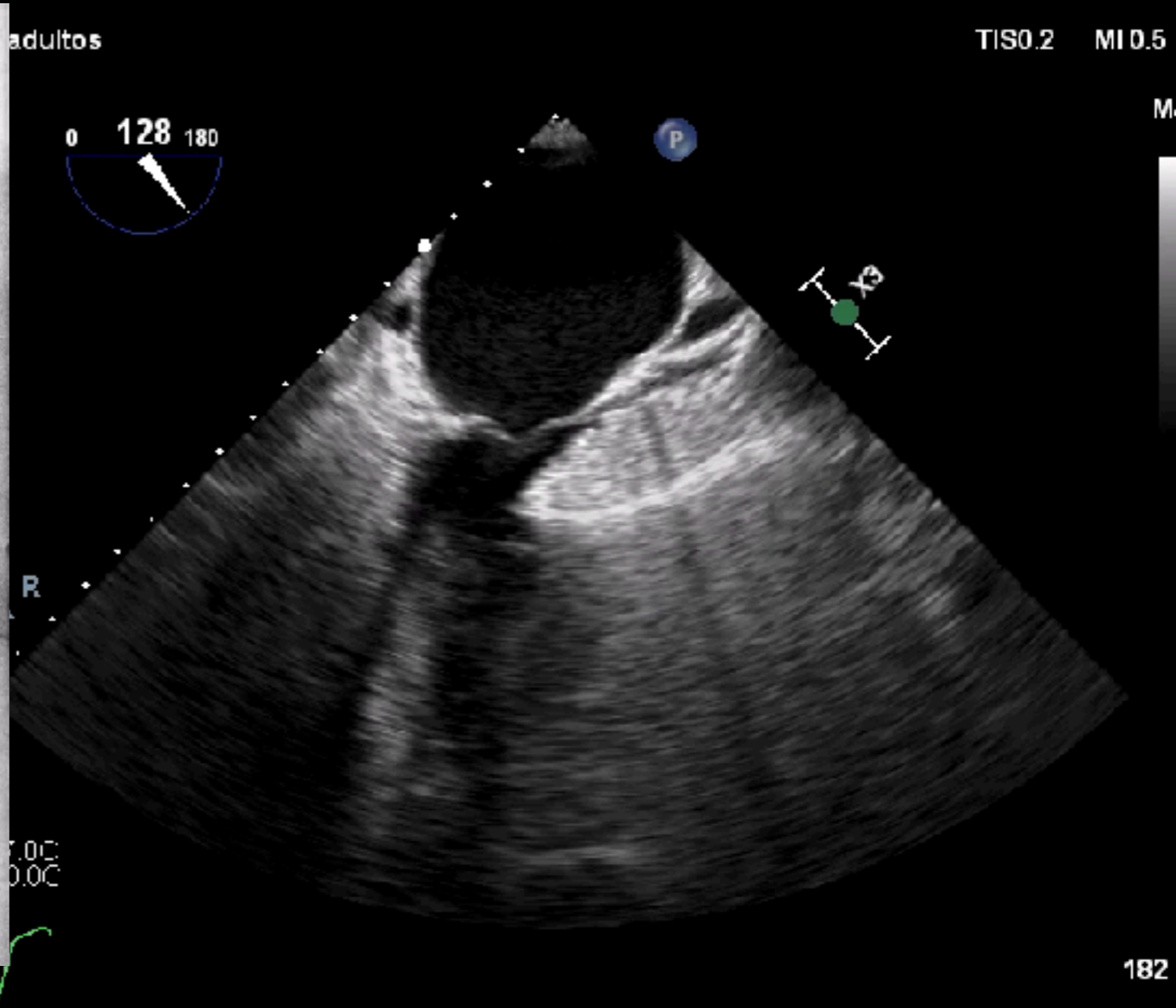
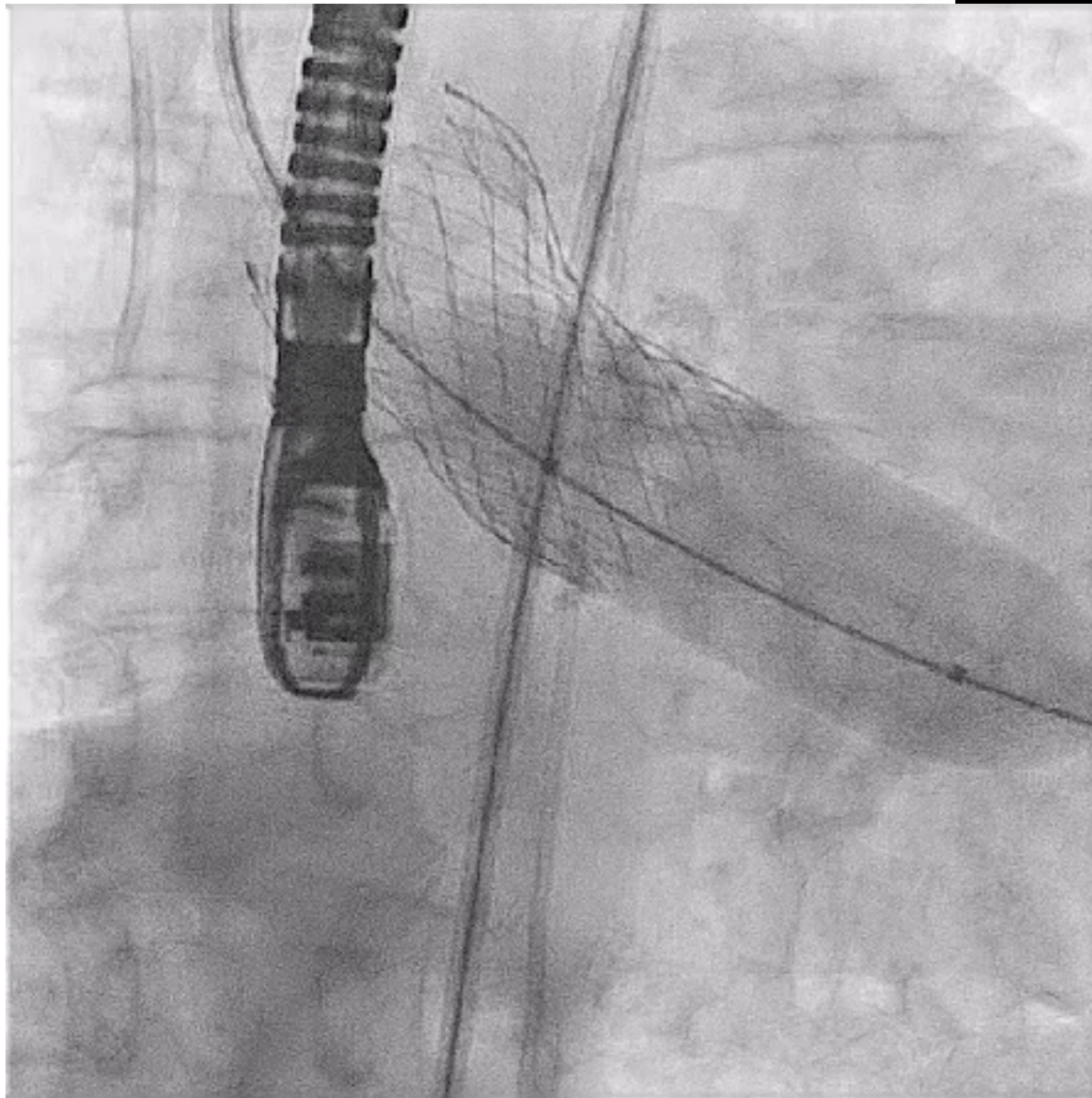
Implante de TAVI in TAVI



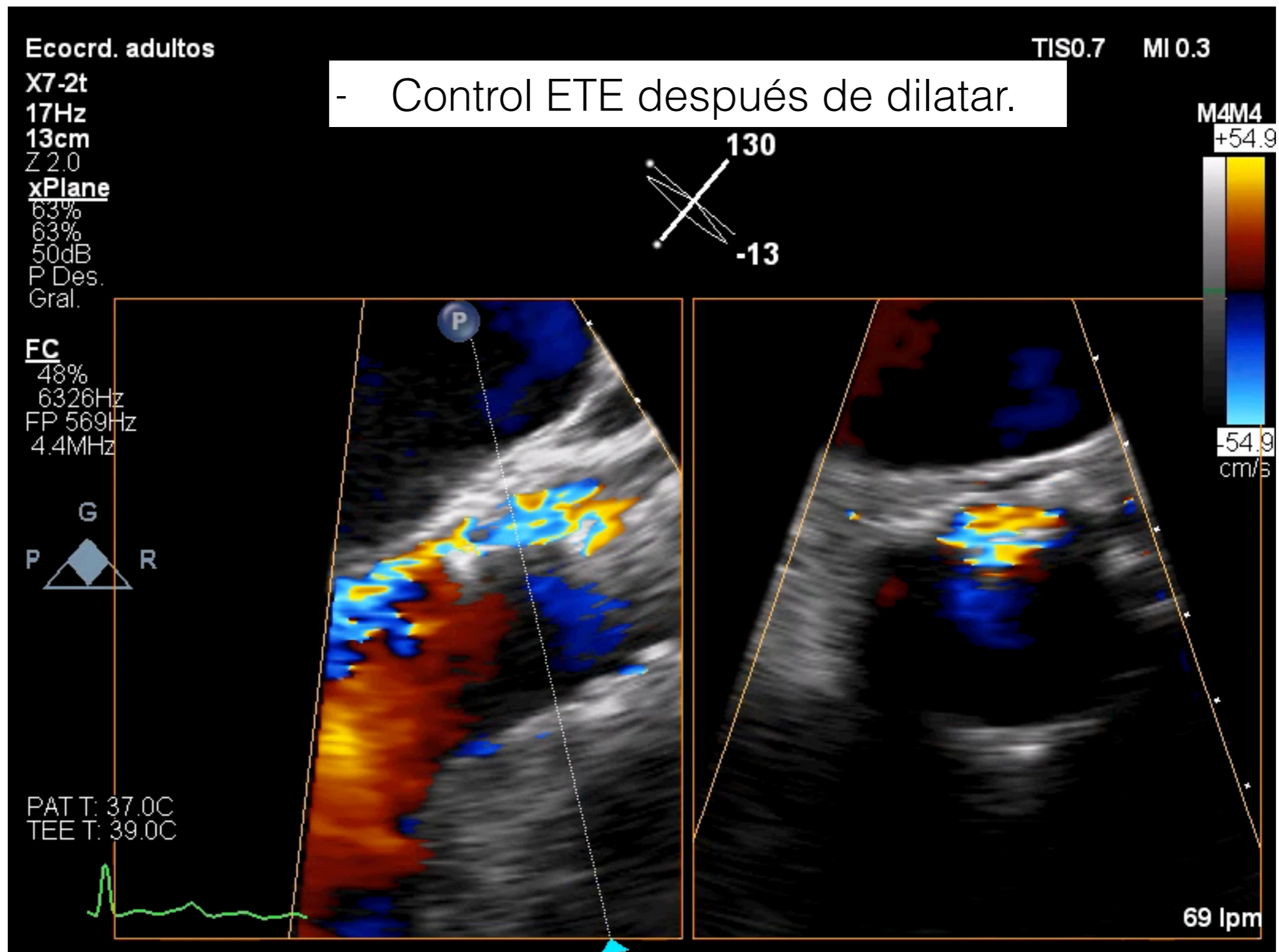
# Cierre de "leak" en TAVI

Postdilatación con balón

- Cristal Ballon 26mm (BALD)
- 3 hinchadas con mayor volumen del recomendado.

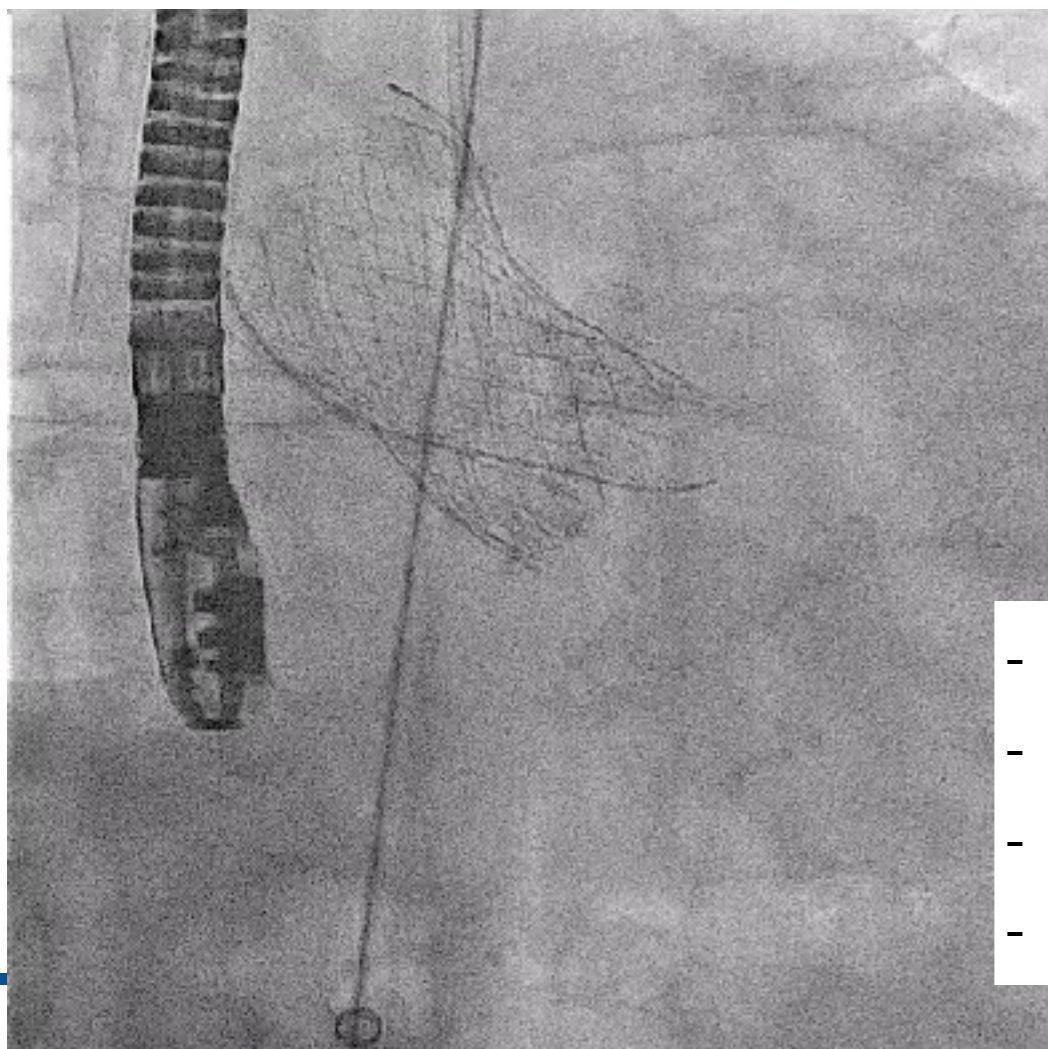
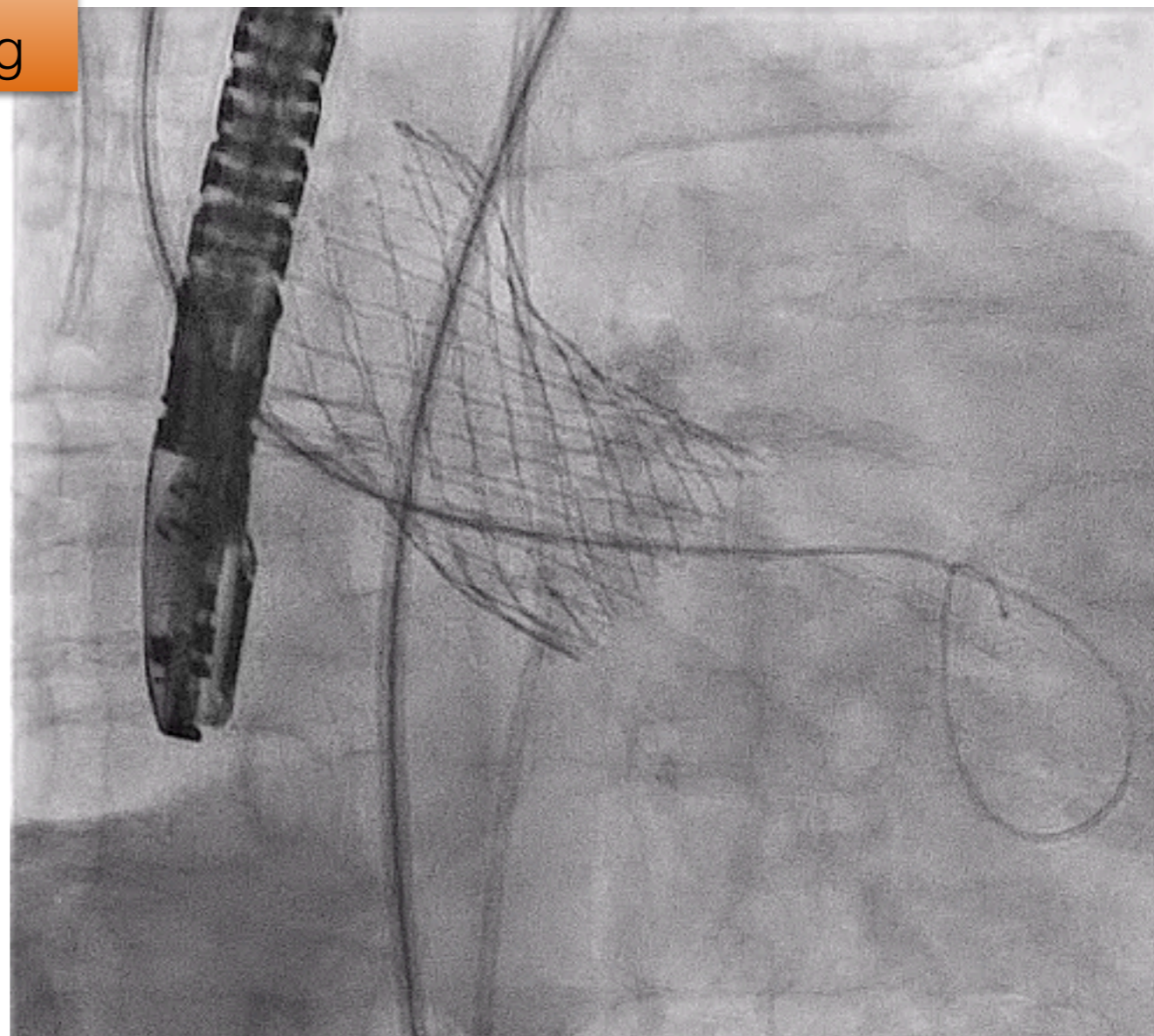
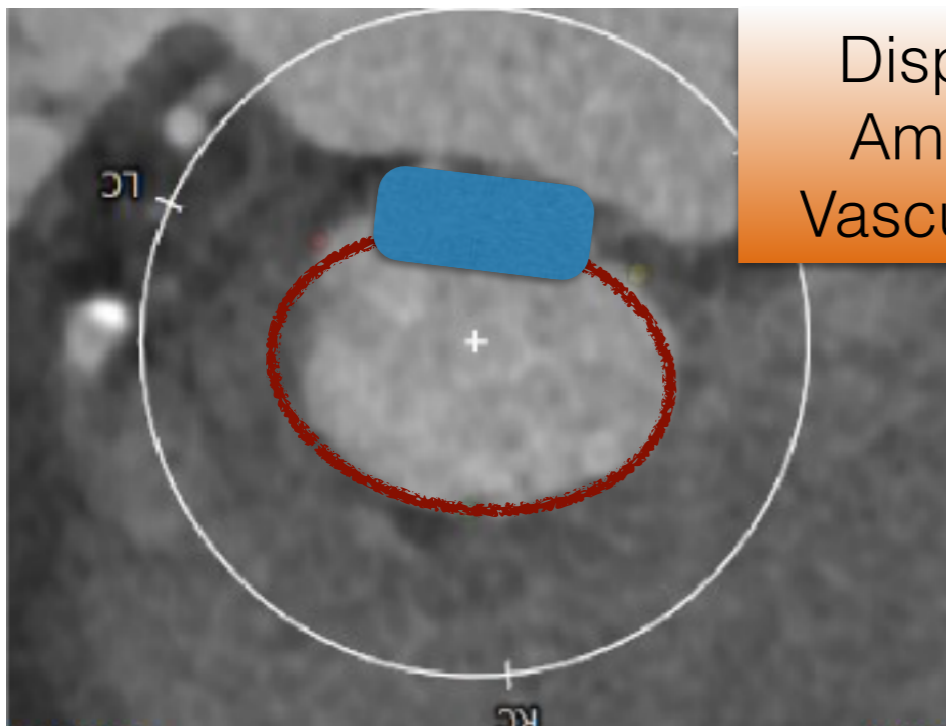


# Cierre de "leak" en TAVI



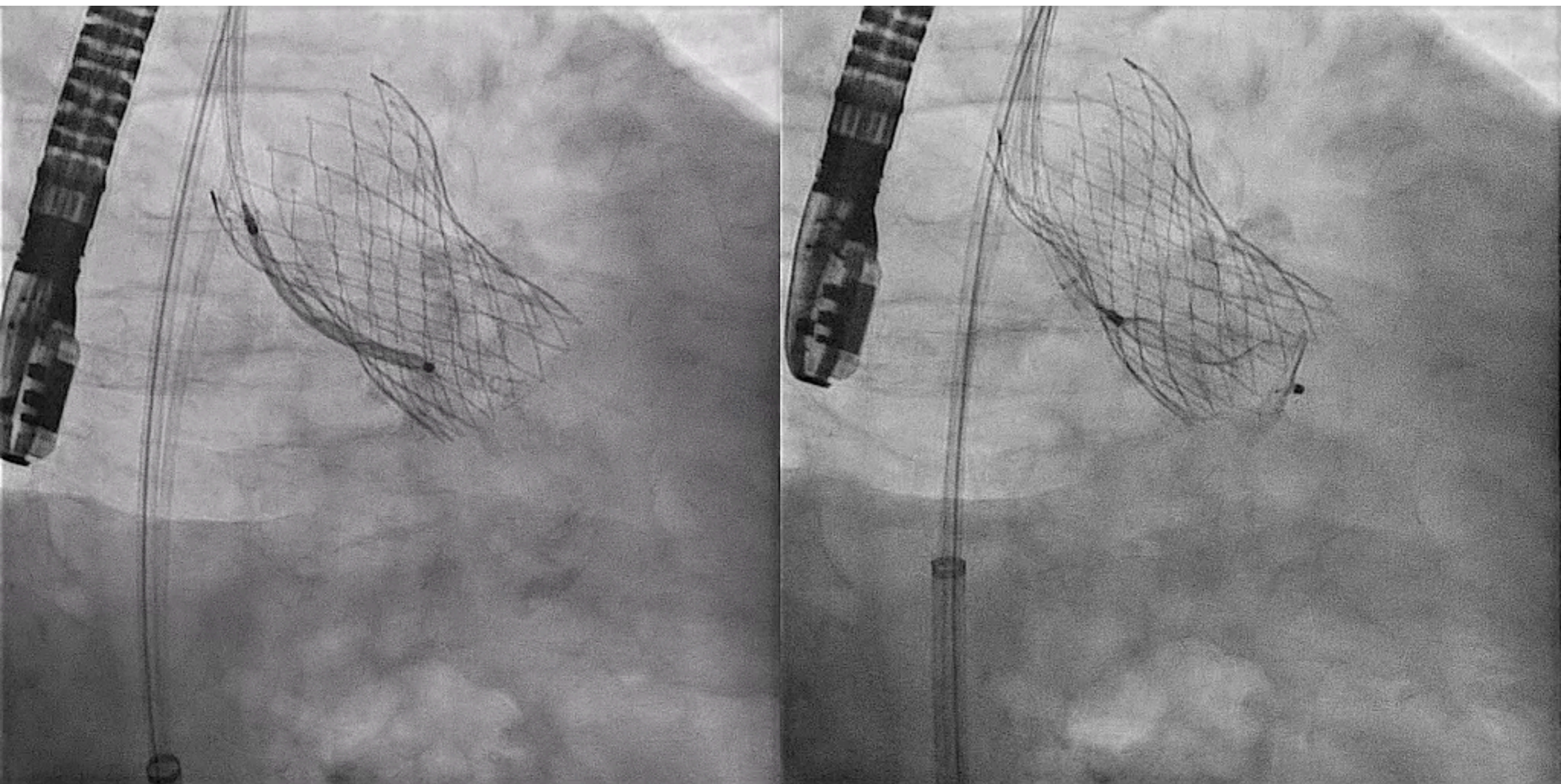
# Cierre de "leak" en TAVI

Dispositivo  
Amplatzer  
Vascular Plug



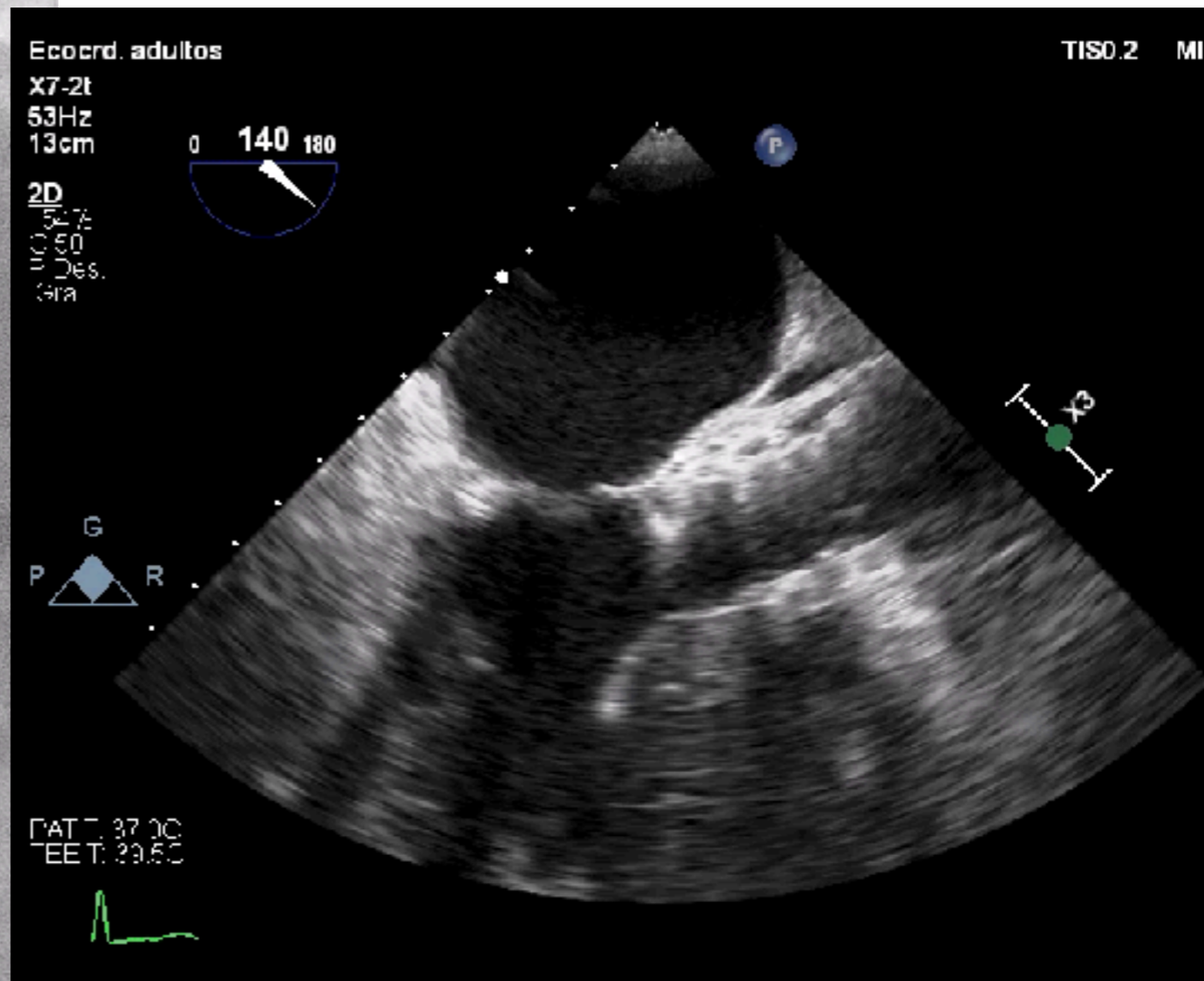
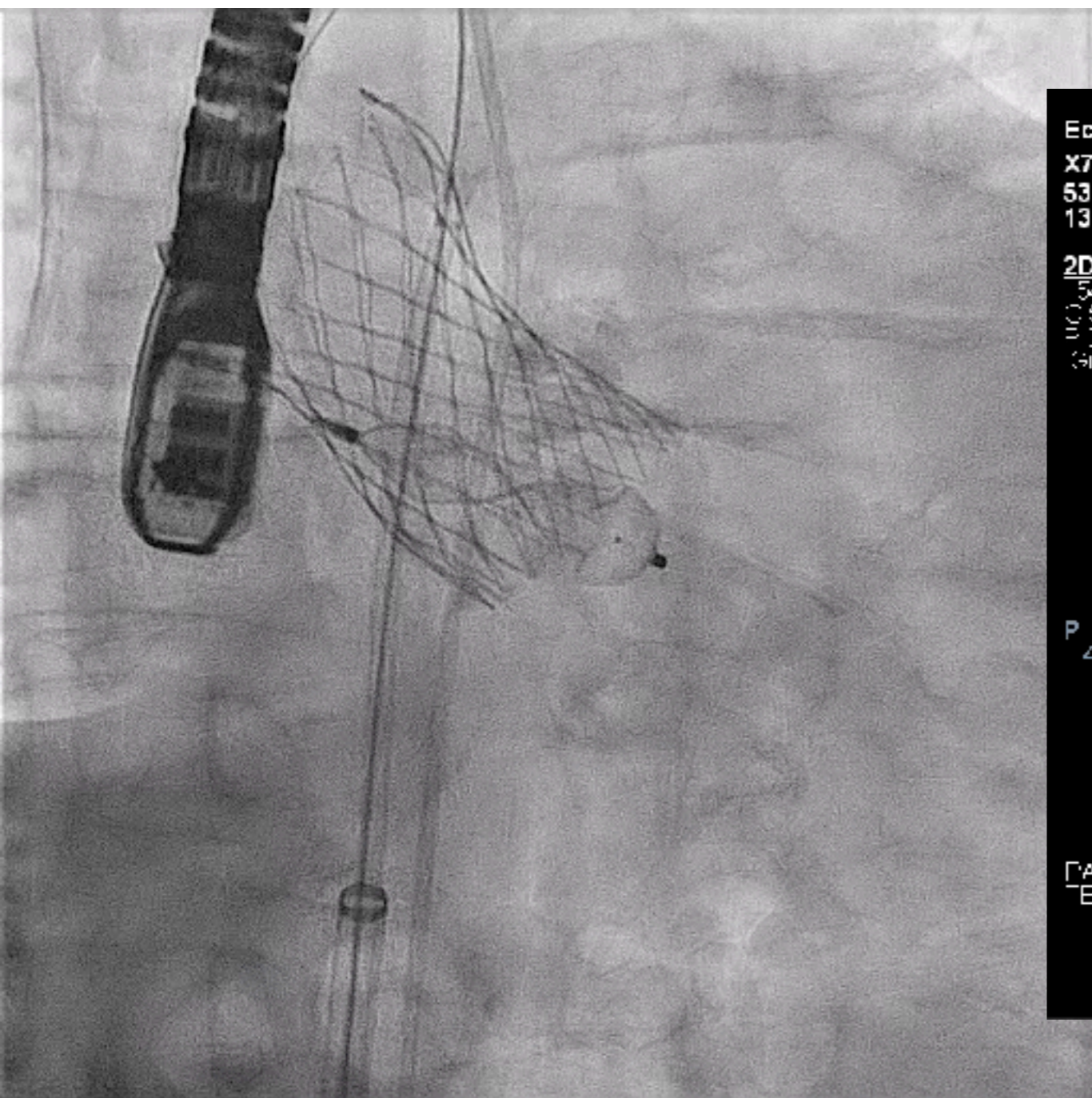
- Catéter diagnostico MP y guía Terumo.
- Se cruza por fuera de la TAVI por el Leak.
- Intercambio por guia Amplatzer ES.
- Introductor Destination 6Fr 90cm

# Cierre de “leak” en TAVI



- Implantación de dispositivo Amplatzer Vascular Plug III de 14x8mm a través del Destination 6Fr.

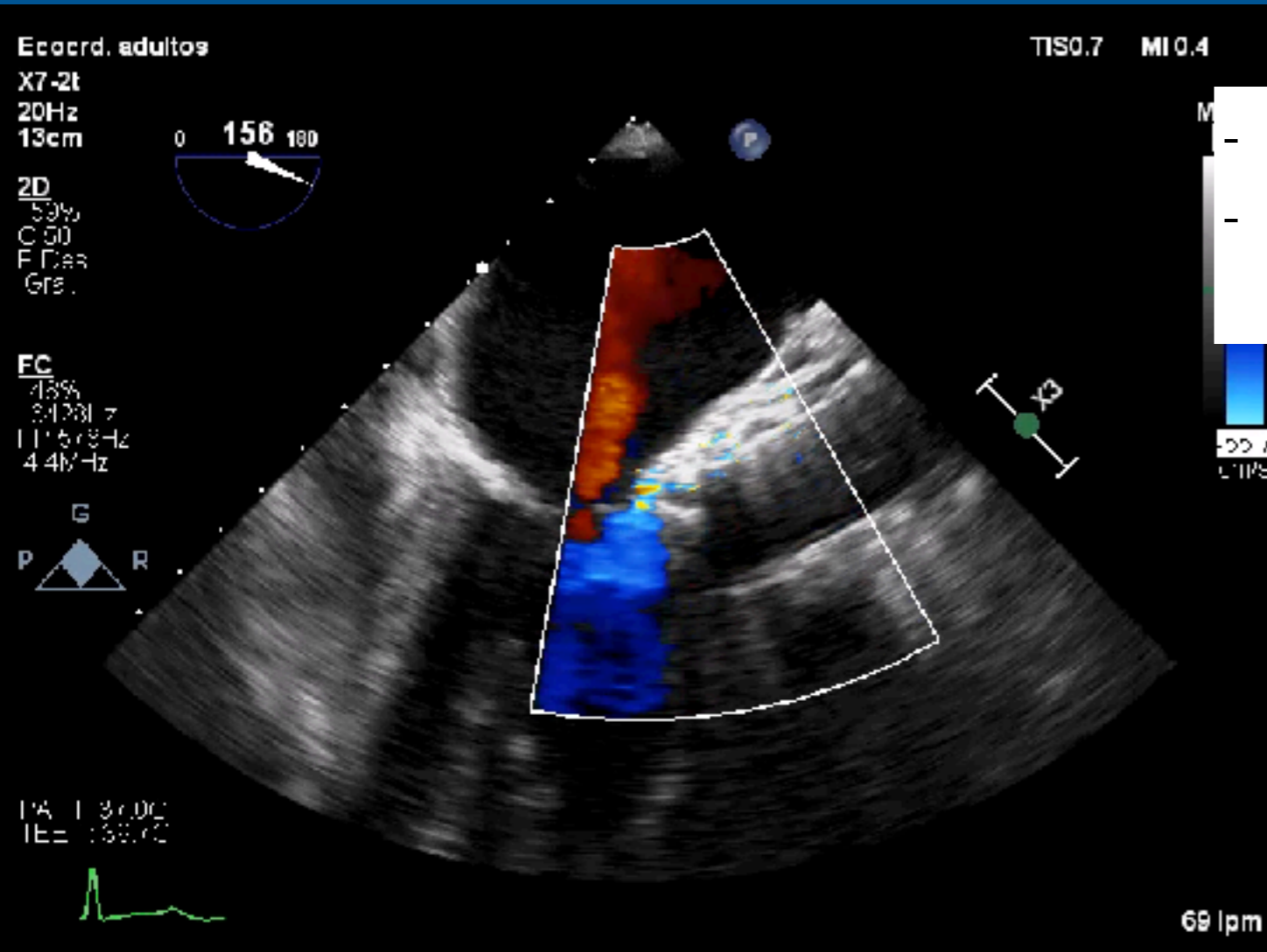
# Cierre de "leak" en TAVI



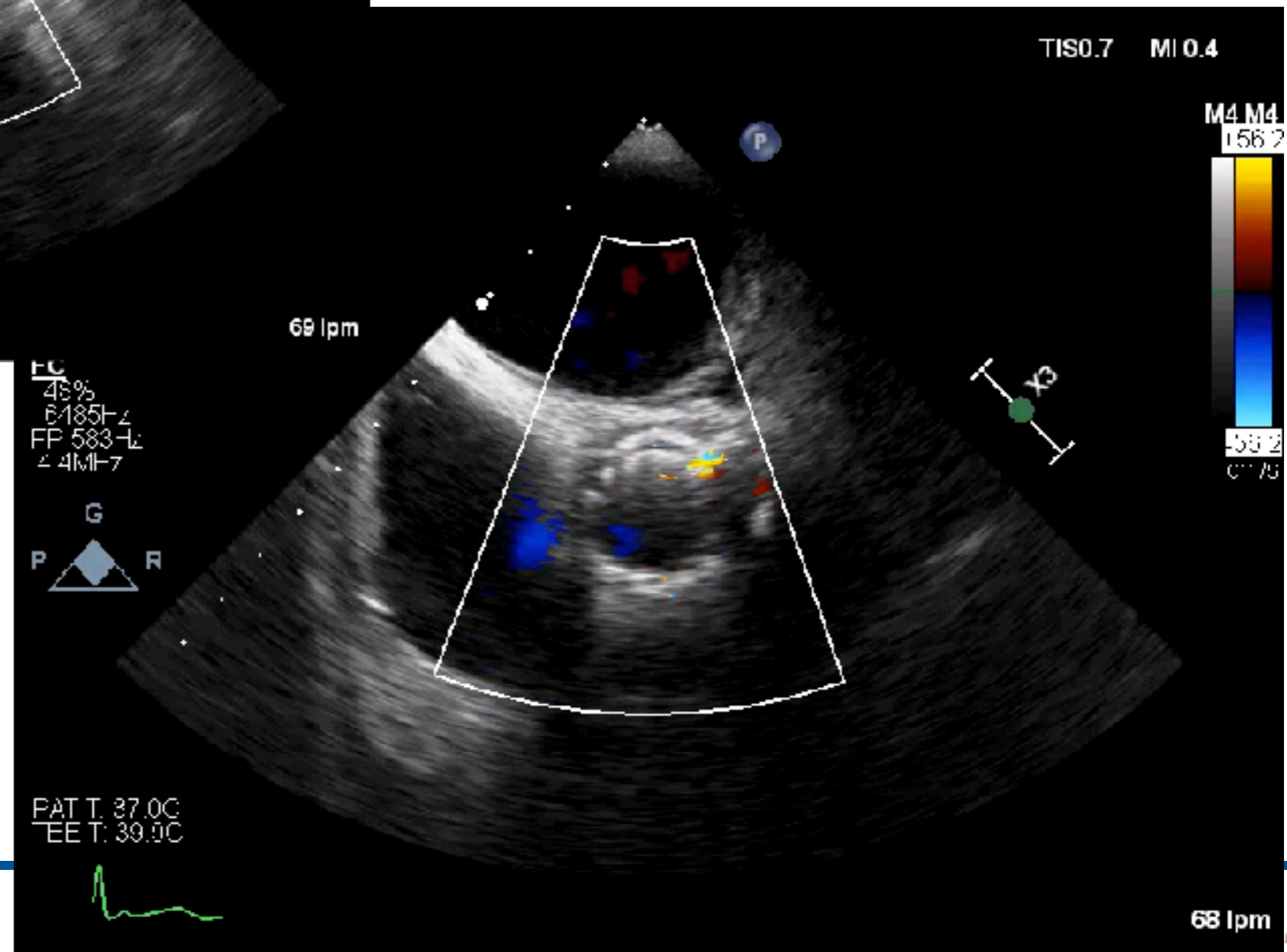
- Primer "deployment" demasiado en el TSVI, segundo más incrustado en la válvula cubriendo todo el trayecto del "leak".



# Cierre de "leak" en TAVI

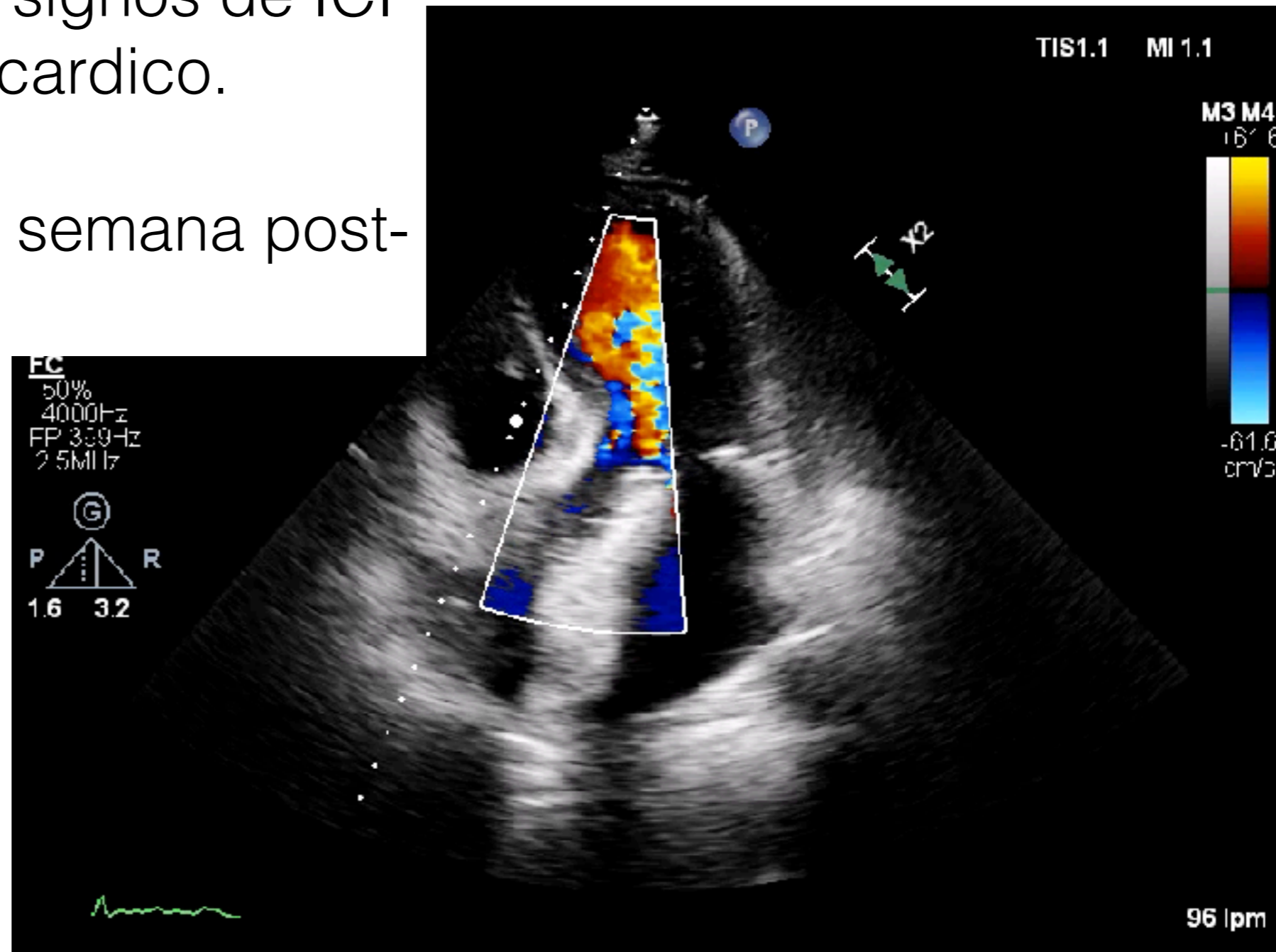


- Mejoría muy evidente de la fuga.
- Desaparición del leak central, solo leak residual en el lado del NC.



## Evolución

- Buena evolución posterior con resolución de los signos de ICI y el derrame pericardico.
- Alta a domicilio 1 semana post-procedimiento.



# Conclusiones

- El cierre percutáneo de “leaks” paravalvulars es un procedimiento seguro con una alta tasa de éxito.
- El cierre percutáneo debería ser el tratamiento de primera elección en los pacientes anatómicamente favorables.
- Los “leaks” asociados a TAVI son “diferentes”, con diversas técnicas para cerrarlos en función del mecanismo causal.



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