Hospital Universitario Ramón y Cajal
SaludMadrid
Comunidad de Madrid

Tratamiento percutáneo de la válvula tricúspide

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Hospital Universitario Ramón y Cajal

Clinical history

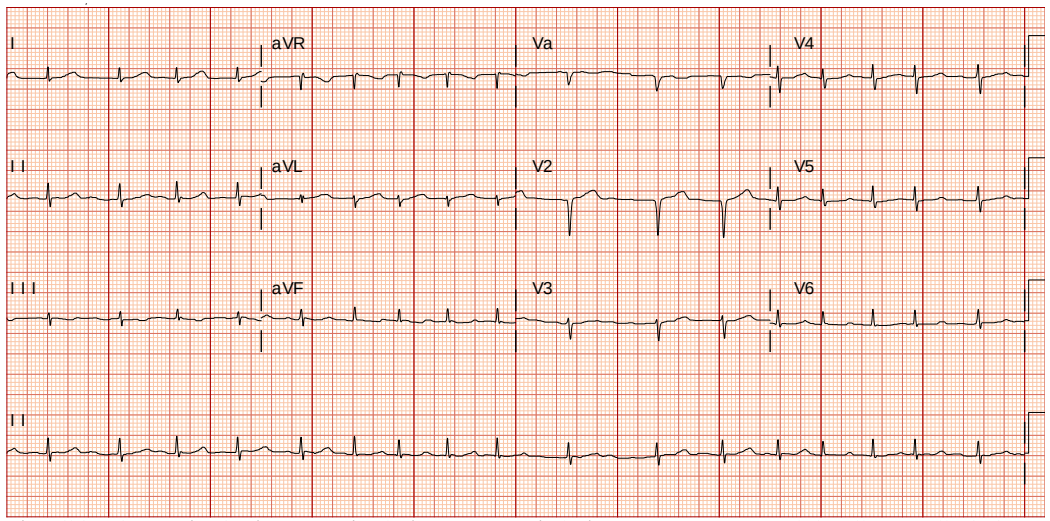
85 yo

HYPERTENSION. DIABETES MELLITUS. DYSLIPIDAEMIA

ATRIAL FIBRILLATION

SEVERAL ADMISSIONS FOR RHF. PERIPHERAL EDEMA & ASCITES

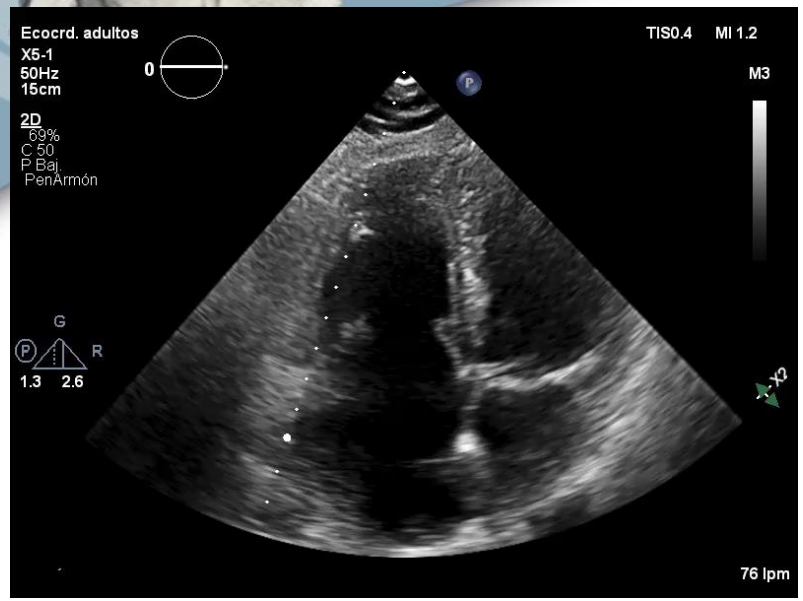
NYHA III

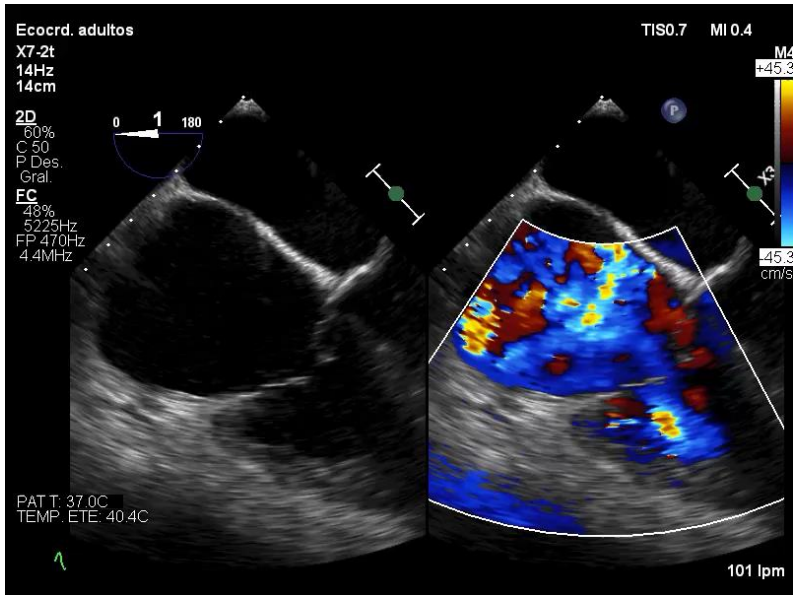


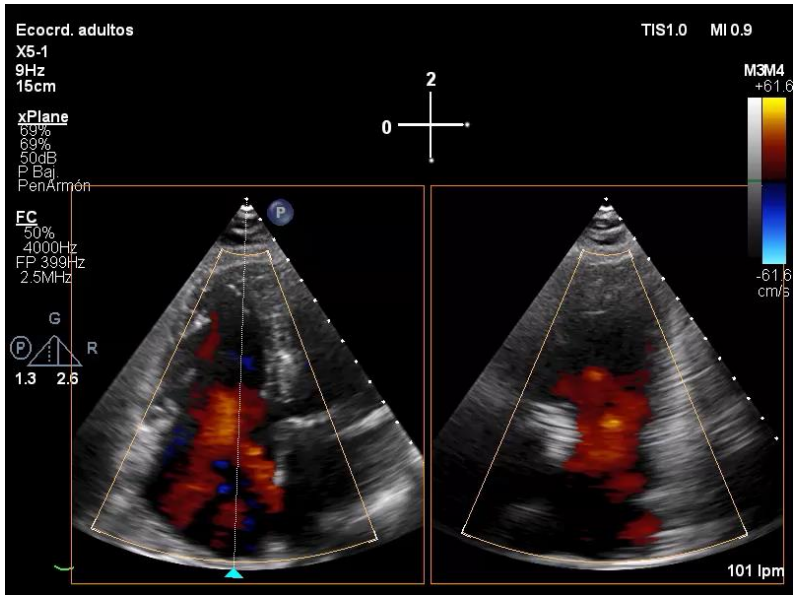
TREATMENT

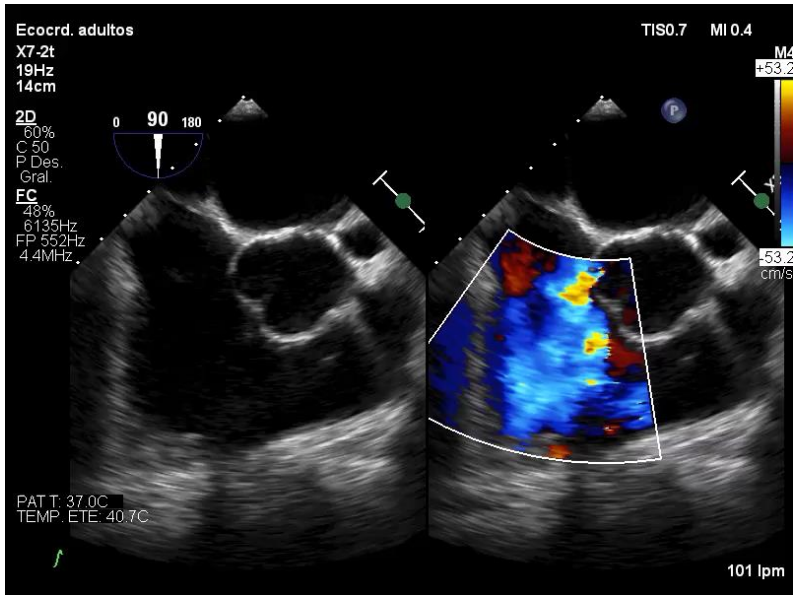
Furosemide 120 mgr/day + Digoxin + Losartan + Edoxaban

Echo









LVEF 55%
MR grade I
PP 45 mmHg
TAPSE 20
TA 50 mm
Tenting: 9mm
Gap: 5 mm
VC 16 mm

Functional massive TR 2º to anulus dilatation

TR. What To Do

Surgery ?

ESC European Society of Cardiology
European Heart Journal (2017) 38, 2739–2791
doi:10.1093/eurheartj/ehx391
ESC/EACTS GUIDELINES

Guías Clínicas

2017 ESC/EACTS Guidelines for the management of valvular heart disease

Cirugía IT - evidencia limitada

Cirugía IT aislada - controvertida

Cirugía IT – alta mortalidad

Recommendations on primary tricuspid regurgitation		
Surgery is indicated in patients with severe primary tricuspid regurgitation undergoing left-sided valve surgery.	I	C
Surgery is indicated in symptomatic patients with severe isolated primary tricuspid regurgitation without severe RV dysfunction.	I	C
Surgery should be considered in patients with moderate primary tricuspid regurgitation undergoing left-sided valve surgery.	IIa	C
Surgery should be considered in asymptomatic or mildly symptomatic patients with severe isolated primary tricuspid regurgitation and progressive RV dilatation or deterioration of RV function.	IIa	C

Percutaneous repair techniques are in their infancy and must be further evaluated before any recommendations can be made.

Recommendations on secondary tricuspid regurgitation		
Surgery is indicated in patients with severe secondary tricuspid regurgitation undergoing left-sided valve surgery.	I	C
Surgery should be considered in patients with mild or moderate secondary tricuspid regurgitation with a dilated annulus (≥40 mm or > 21 mm/m^2 by 2D echocardiography) undergoing left-sided valve surgery.	IIa	C
Surgery may be considered in patients undergoing left-sided valve surgery with mild or moderate secondary tricuspid regurgitation even in the absence of annular dilatation when previous recent right-heart failure has been documented.	IIb	C
After previous left-sided surgery and in absence of recurrent left-sided valve dysfunction, surgery should be considered in patients with severe tricuspid regurgitation who are symptomatic or have progressive RV dilatation/dysfunction, in the absence of severe RV or LV dysfunction and severe pulmonary vascular disease/hypertension.	IIa	C

?

Cirugía tricúspide

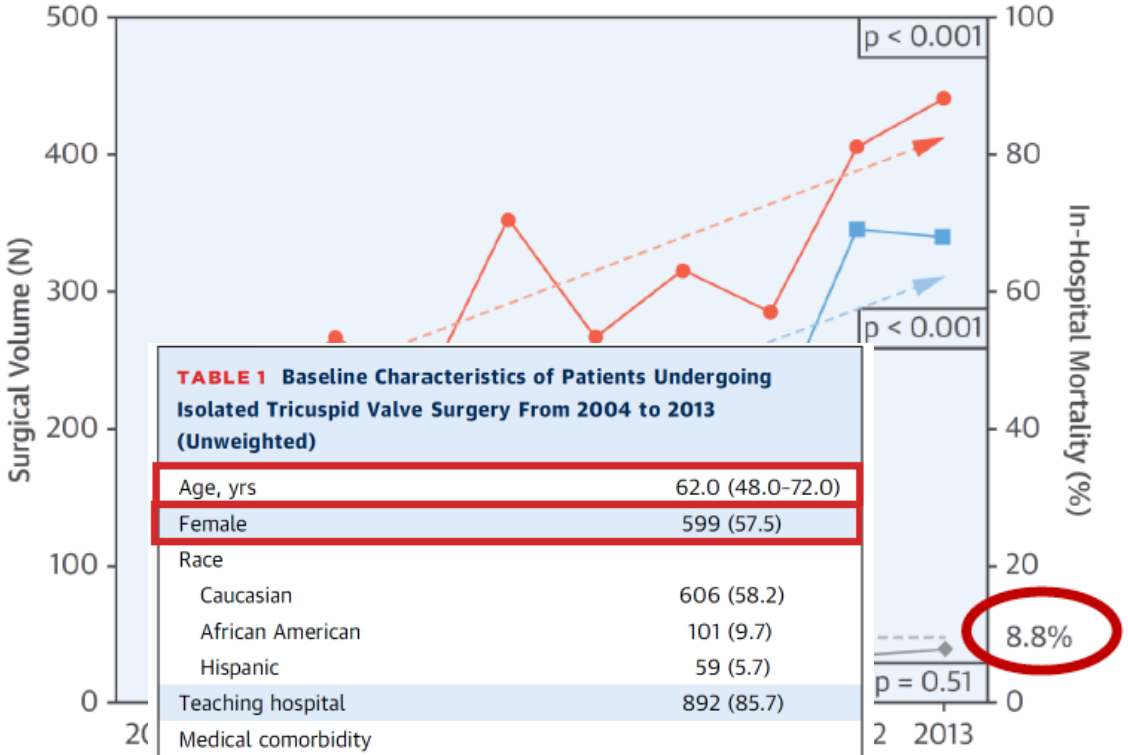


TABLE 1 Baseline Characteristics of Patients Undergoing Isolated Tricuspid Valve Surgery From 2004 to 2013 (Unweighted)

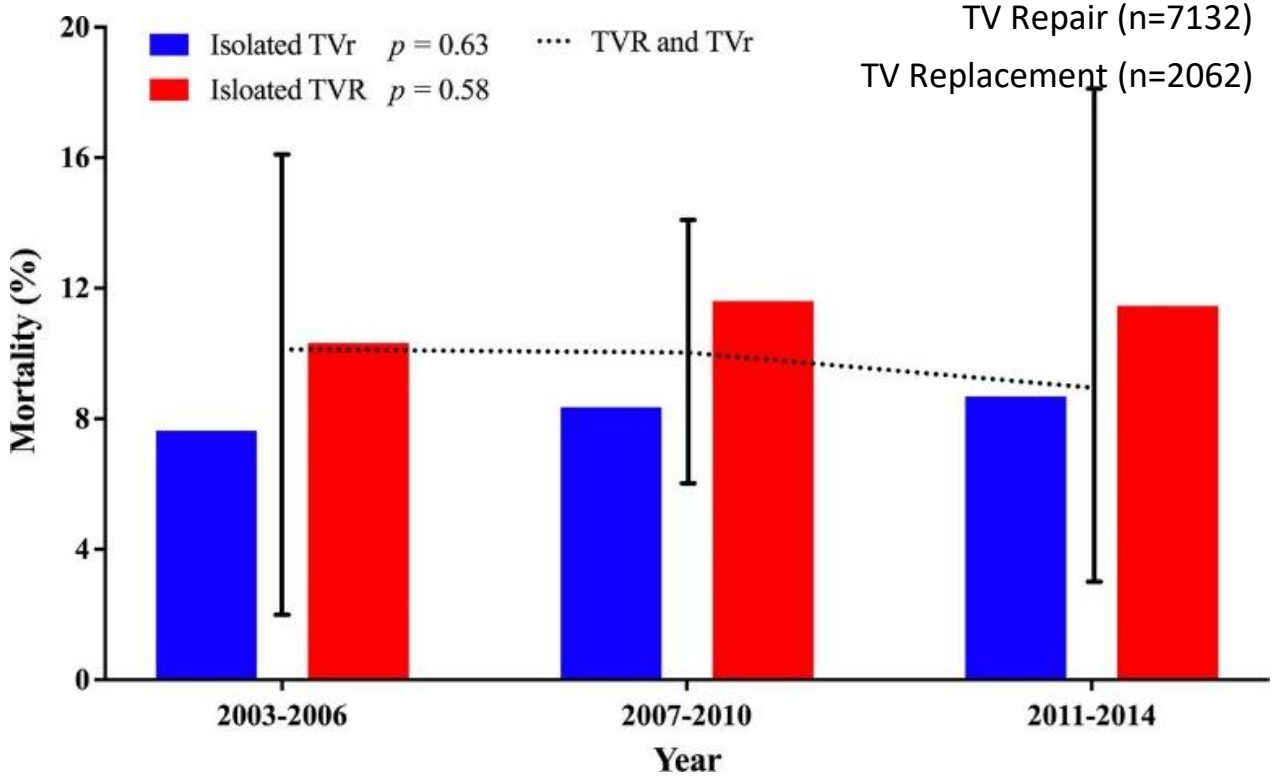
Age, yrs	62.0 (48.0-72.0)
Female	599 (57.5)
Race	
Caucasian	606 (58.2)
African American	101 (9.7)
Hispanic	59 (5.7)
Teaching hospital	892 (85.7)
Medical comorbidity	
Hypertension	512 (49.2)
Diabetes	208 (20.0)
Coronary artery disease	350 (33.6)
Pacemaker/intracardiac defibrillator	116 (11.1)
Atrial fibrillation/flutter	517 (49.7)
Pulmonary hypertension	238 (22.9)
Chronic kidney disease	197 (18.9)
End-stage renal disease	59 (5.7)
Liver disease	80 (7.7)
Cirrhosis	41 (3.9)
Charlson comorbidity index ≥2	597 (57.3)
Prior sternotomy	130 (12.5)

Zack. JACC 2017;70:2953-60

12.567 pacientes sometidos reparación TV & reemplazo 2003-2014

No de pacientes sometidos a cirugía VT por IT se incrementó un 48% (3100 en 2003 a 4600 en 2014)

Mortalidad hospitalaria

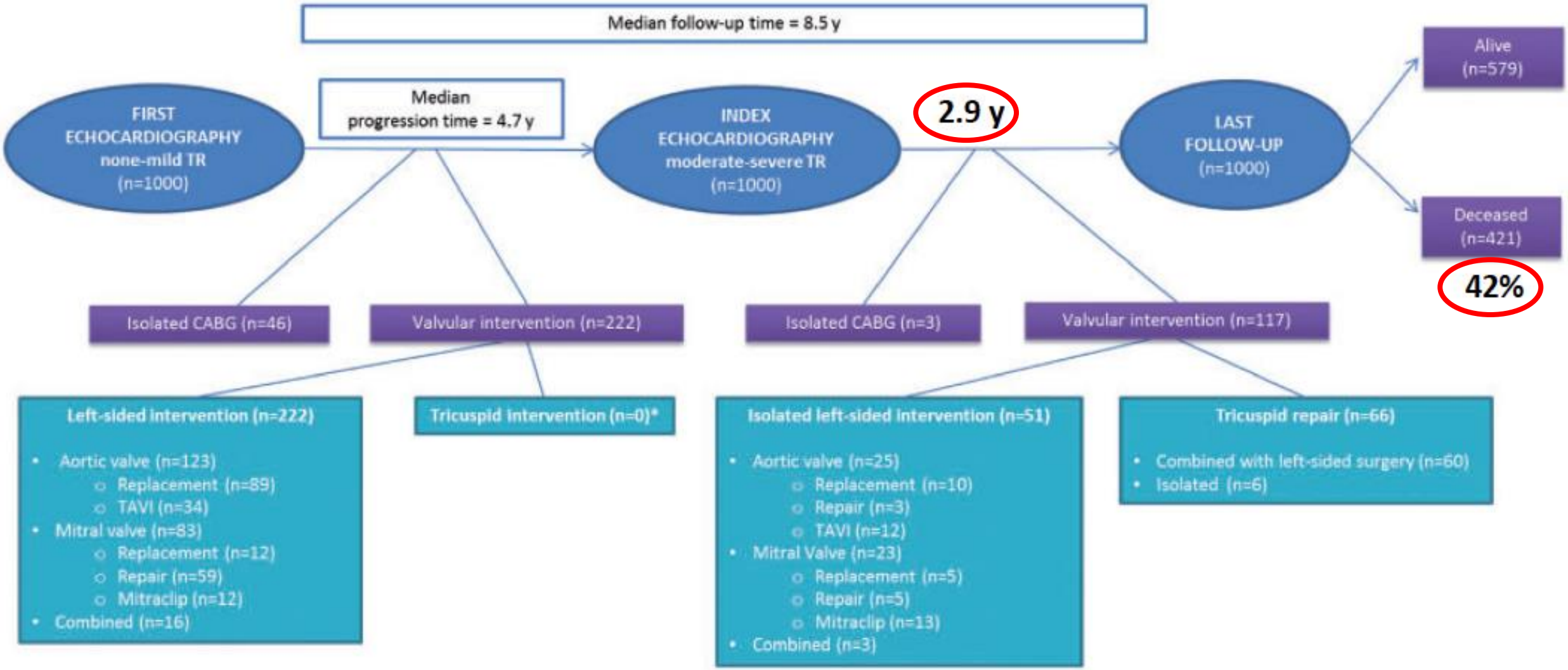


Fahad Alqahtani et al. J Am Heart Assoc 2017;6:e007597

TR. What To Do

Conservative? Diuretics?

TR. What To Do



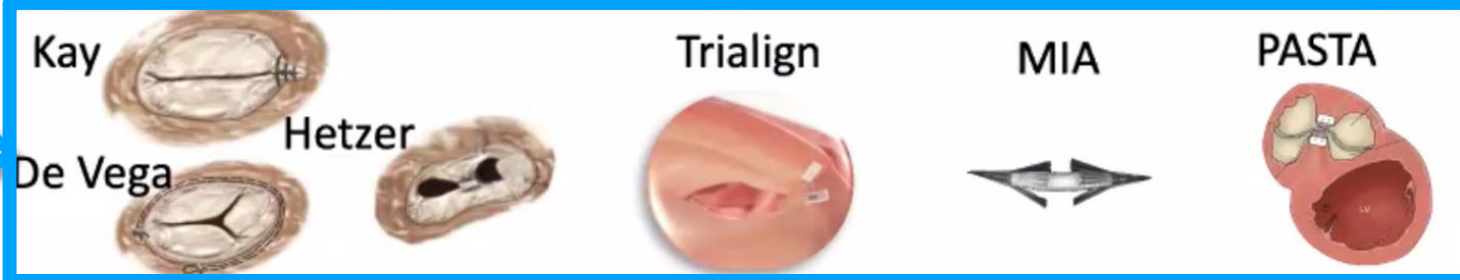
Prihadi. EHJ 2018;39:3574-81

TR. What To Do

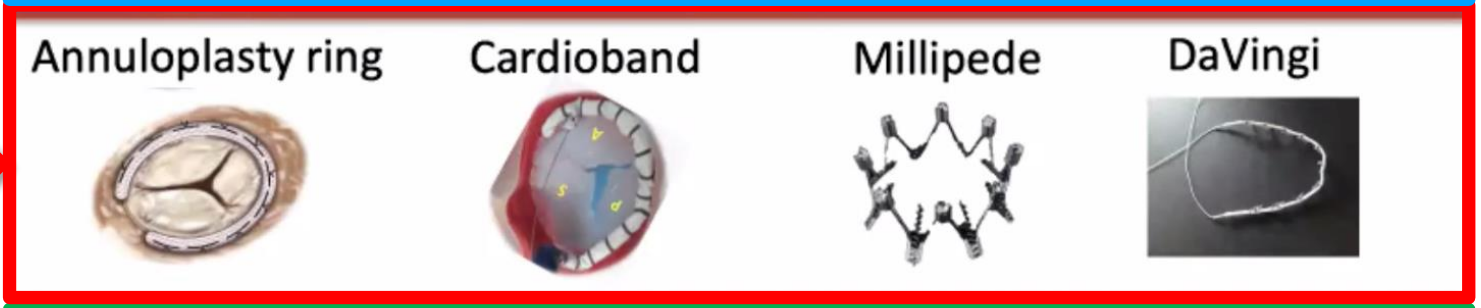
Interventional ?

Tratamiento percutáneo

ANULOPLASTIA SUTURA DIRECTA

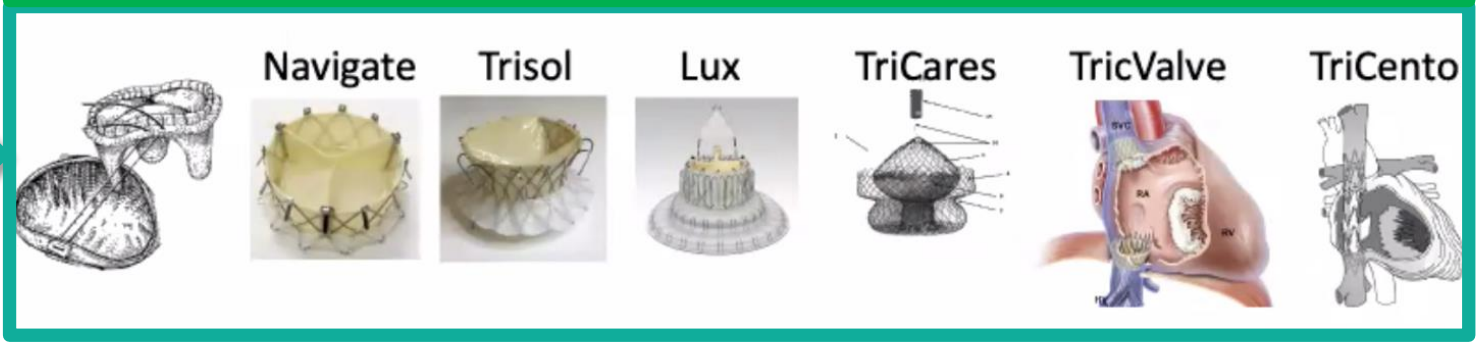


ANULOPLASTIA IMPLANTE ANILLO



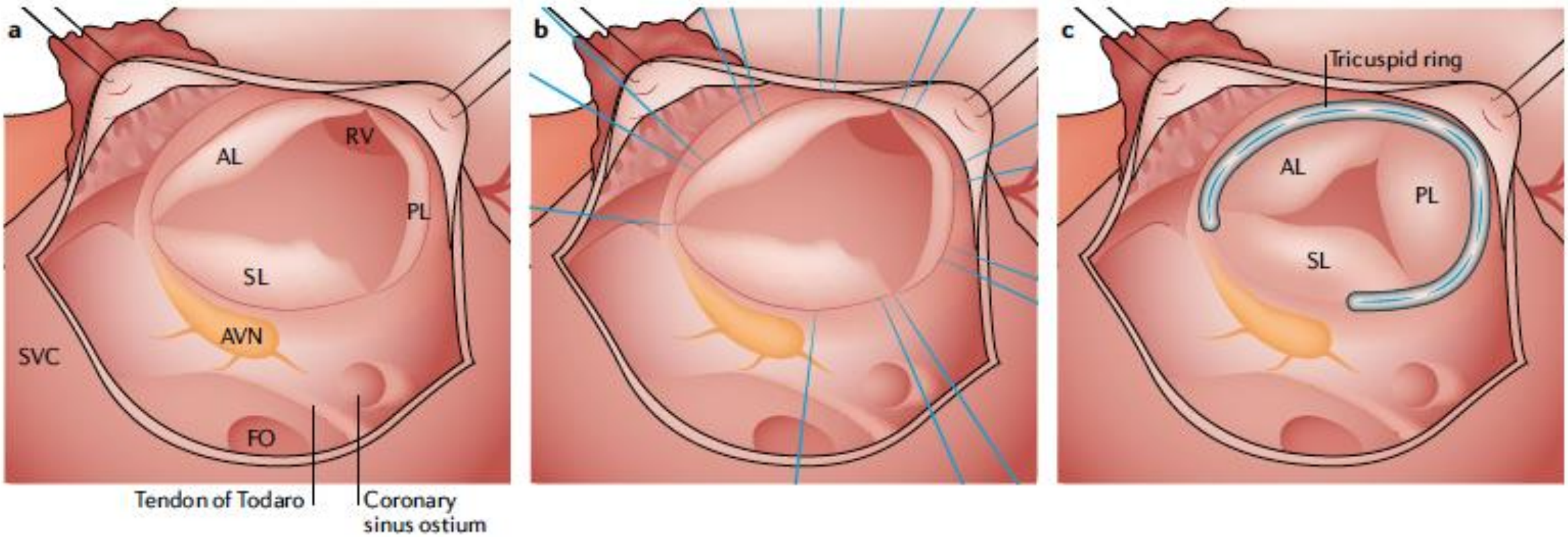
COAPTACIÓN VELOS

REEMPLAZO ORTO/HETEROTÓPICO



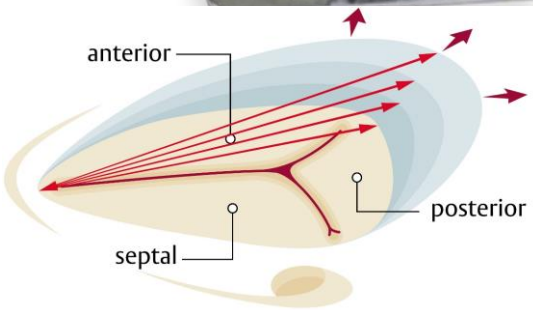
Gold-standard treatment

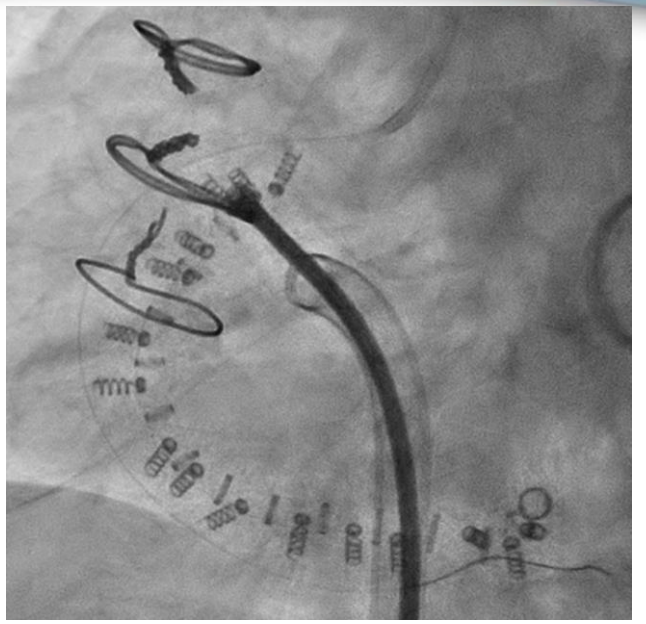
Surgical tricuspid valve annuloplasty incomplete semi-rigid prosthetic ring

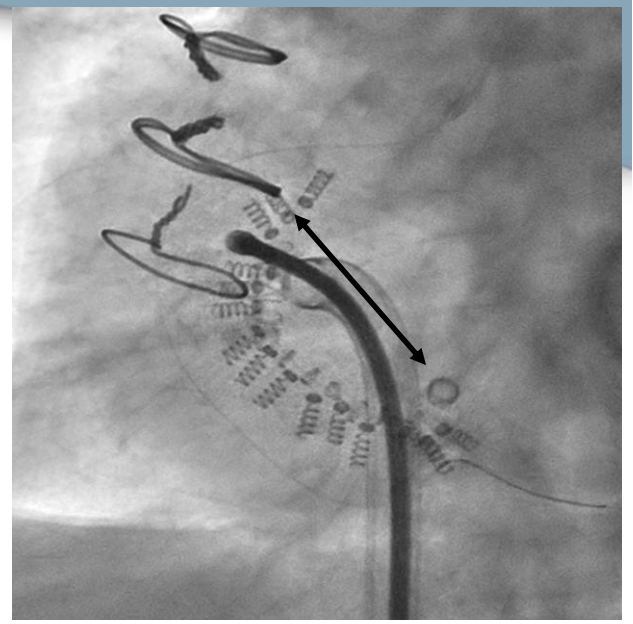


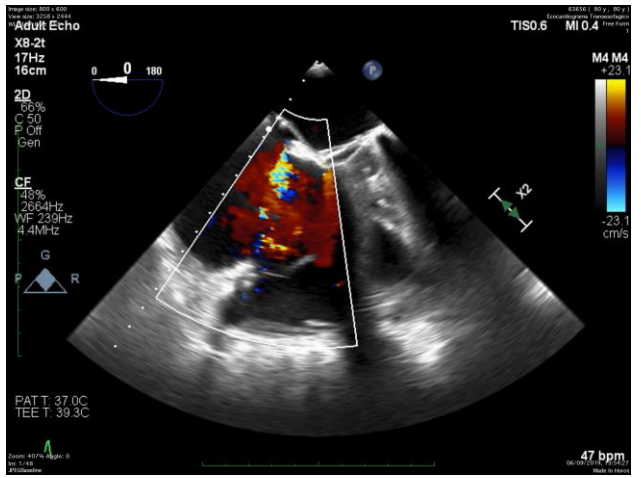
Reducción anular: *Cardioband*

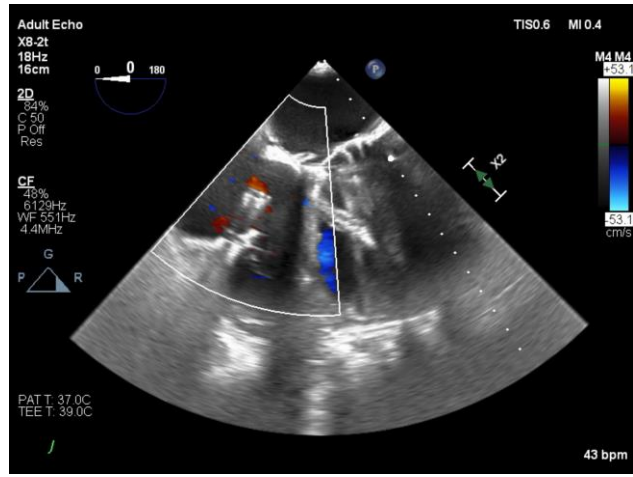
Marcado CE (abril 2018) para tto IT
Vía venosa transfemoral
Anillo incompleto y ajustable







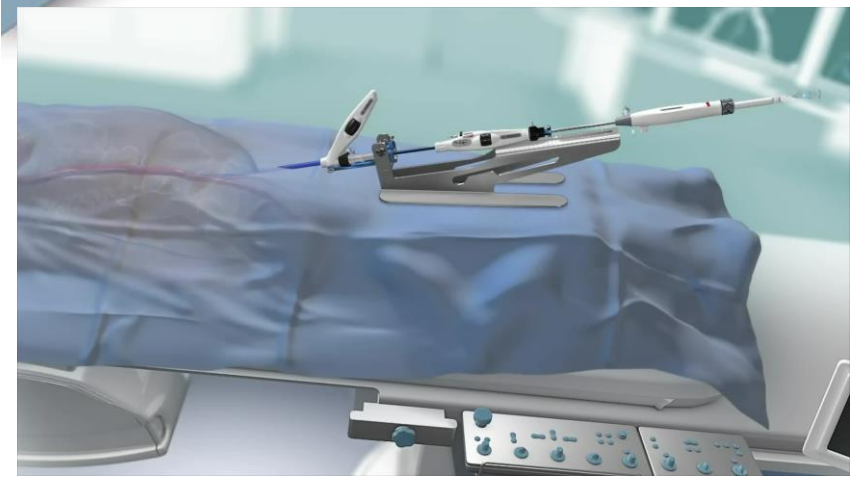


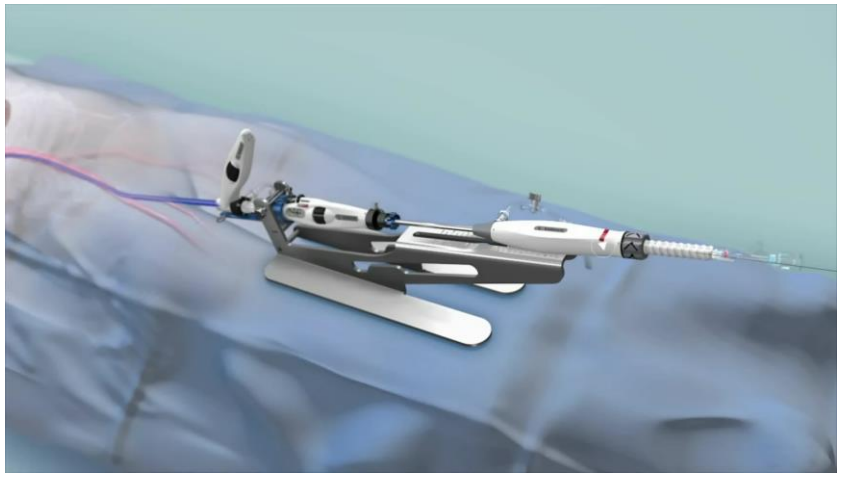


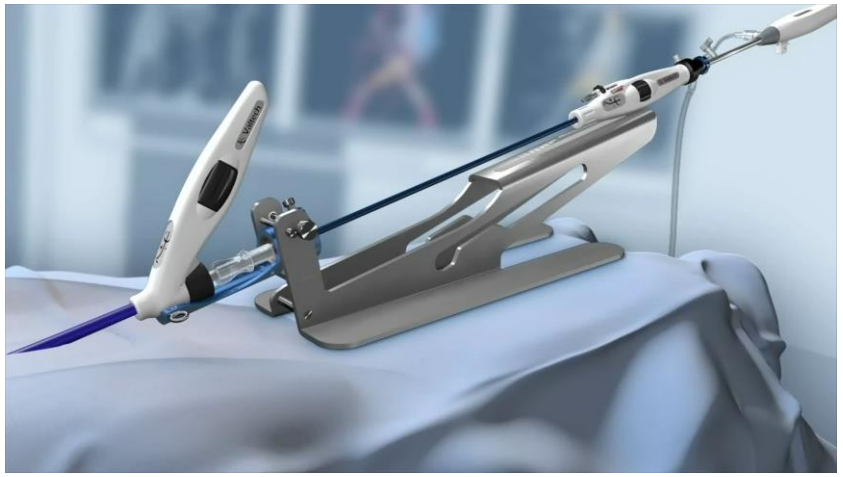
TA 50 mm —(-28%)→ **TA 36 mm**
Torrential TR → **Moderate TR**

Sanchez-Recalde et al. Rev Esp Cardiol 2020; 73: 507-8

Reducción anular: *Cardioband*





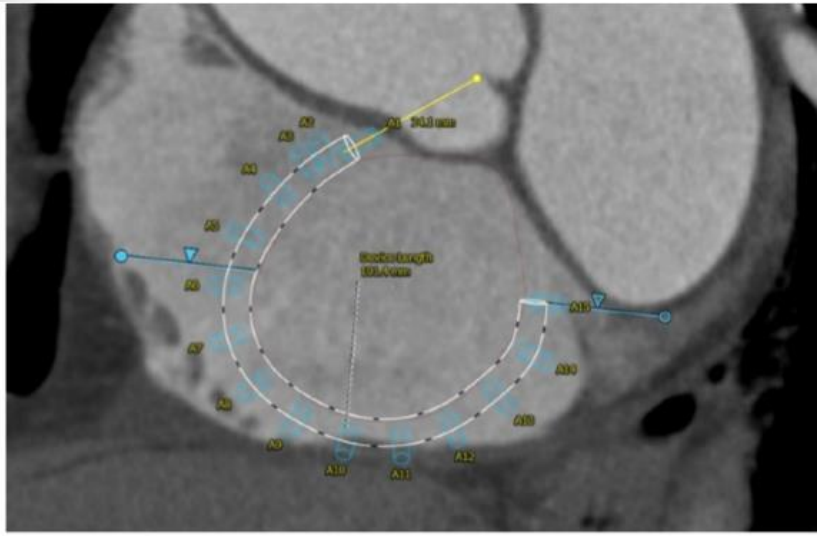


1 Venous femoral access
Delivery system insertion

2 Navigation
Deployment

3 Adjustment
Contraction

TAC



Device Size D (101.4 mm)

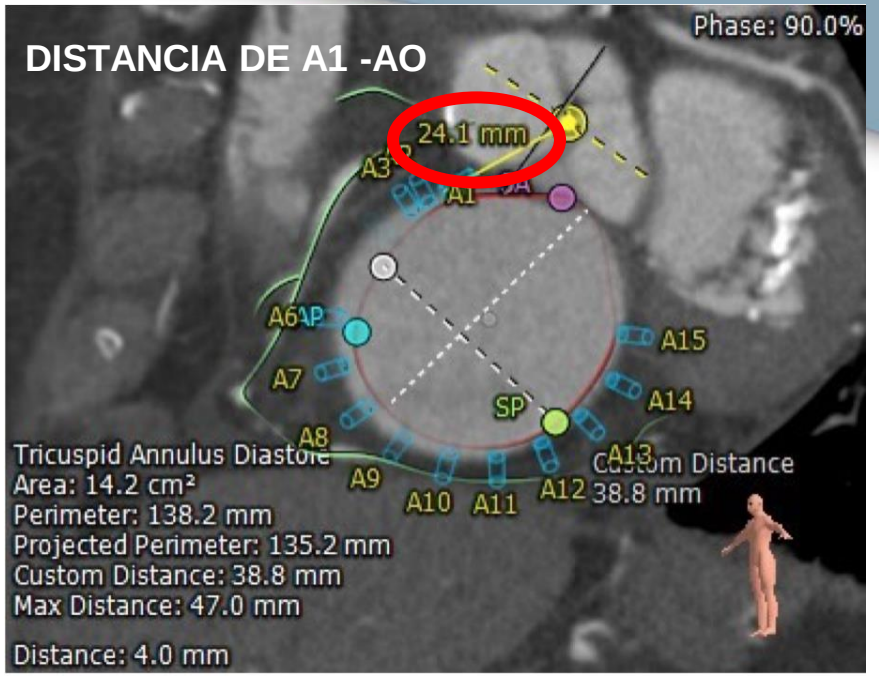
TV Perimeter (mm) 138.2

1st to Final Anchor Distance

=

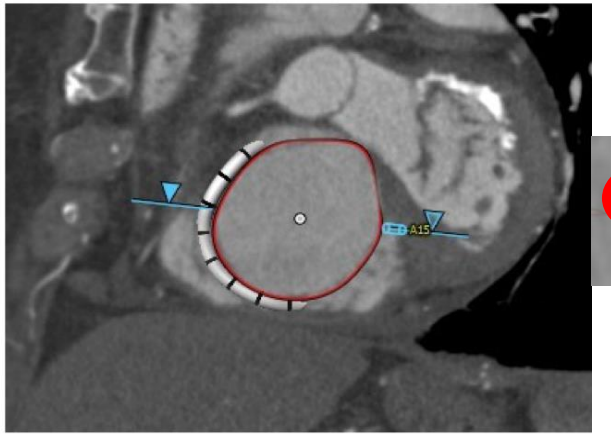
73% Device Annular Coverage

	Band length	Implant size	Nr of anchors	Max SAT cinching
☐	73-80 mm	A	12	3.5
☐	81-88 mm	B	13	4
☐	89-96 mm	C	14	4.5
X	97-104 mm	D	15	5
☐	105-112 mm	E	16	5.5
☐	113-120 mm	F	17	5.5

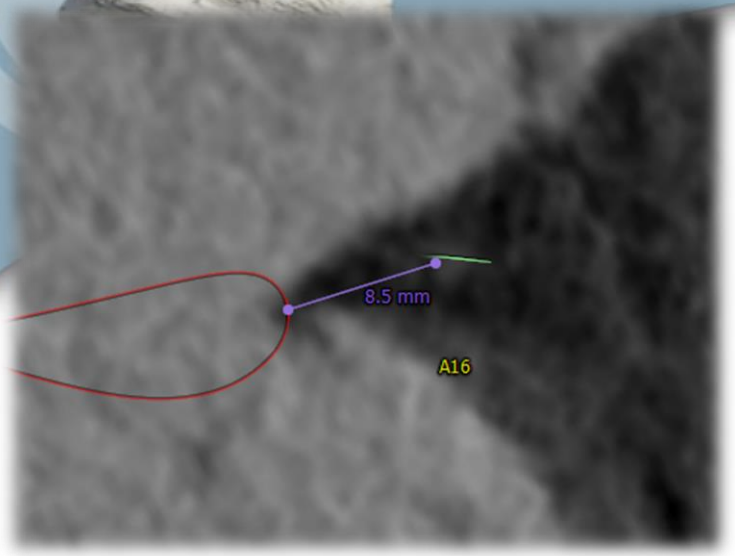


DISTANCIA DE A15 -SC

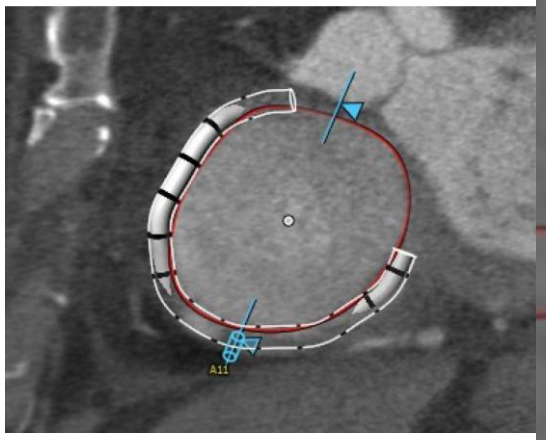
Anchor A15 last one @ distal CS ostiur

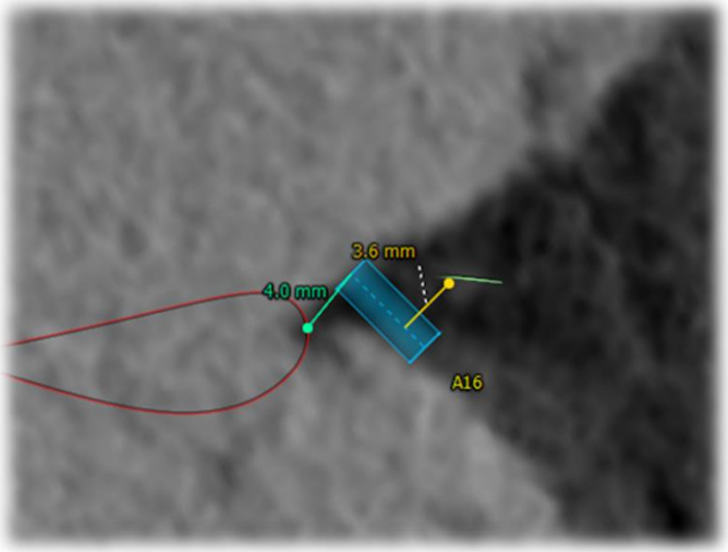


TAC

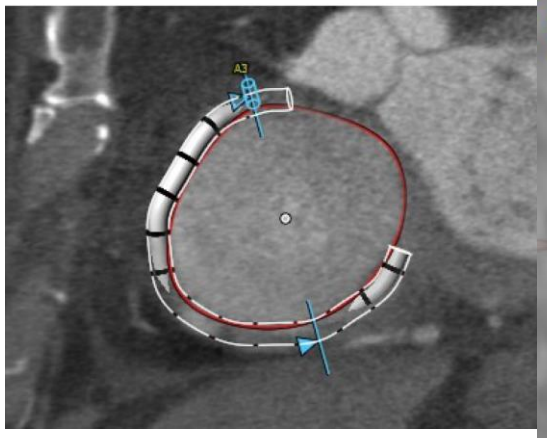


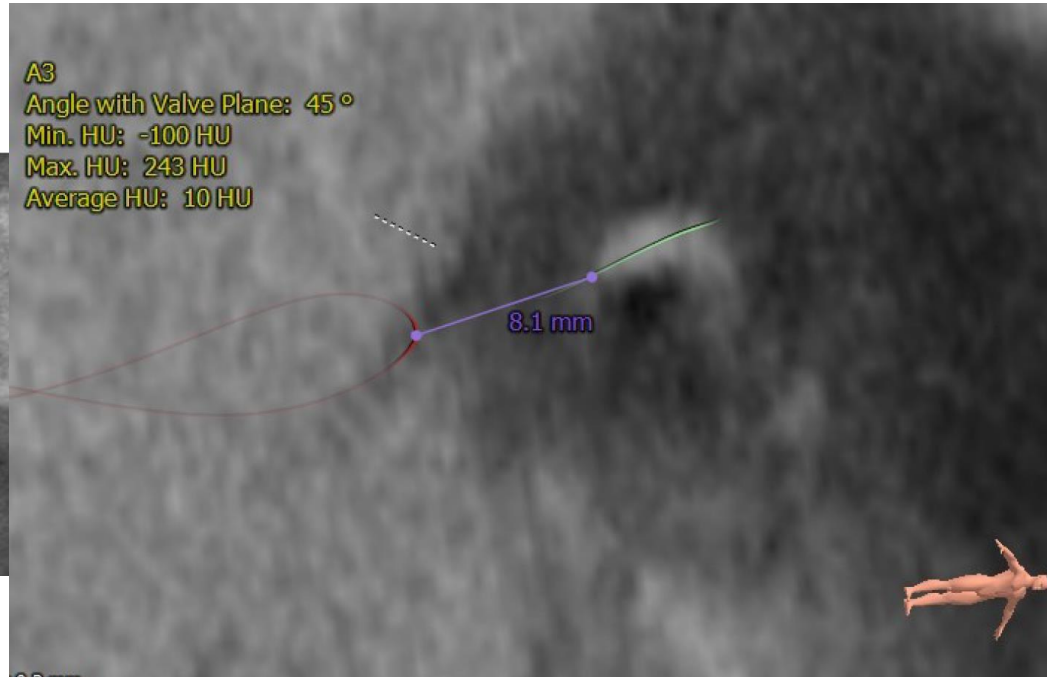
Anchor A11





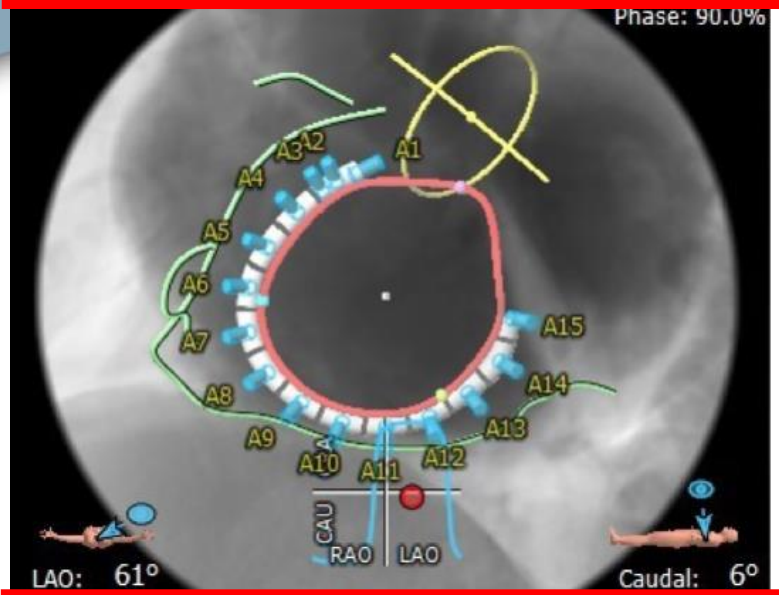
Anchor A3



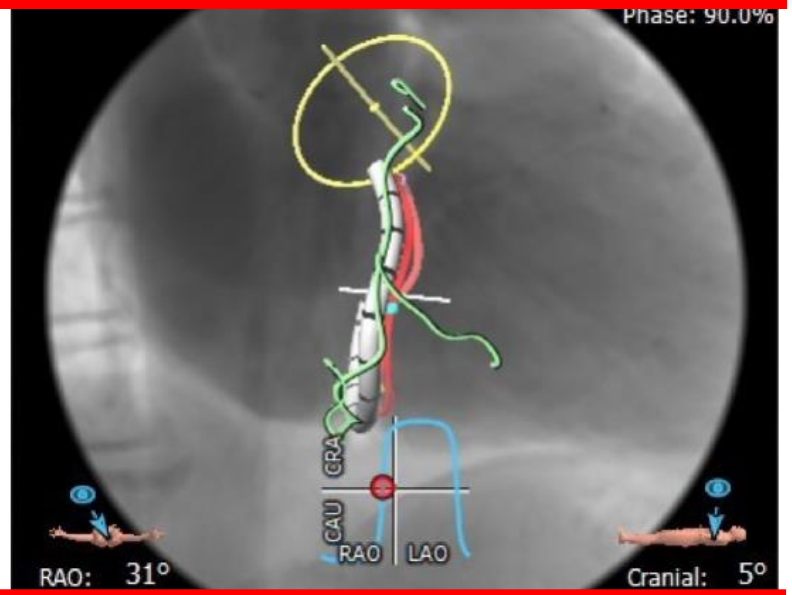


TAC

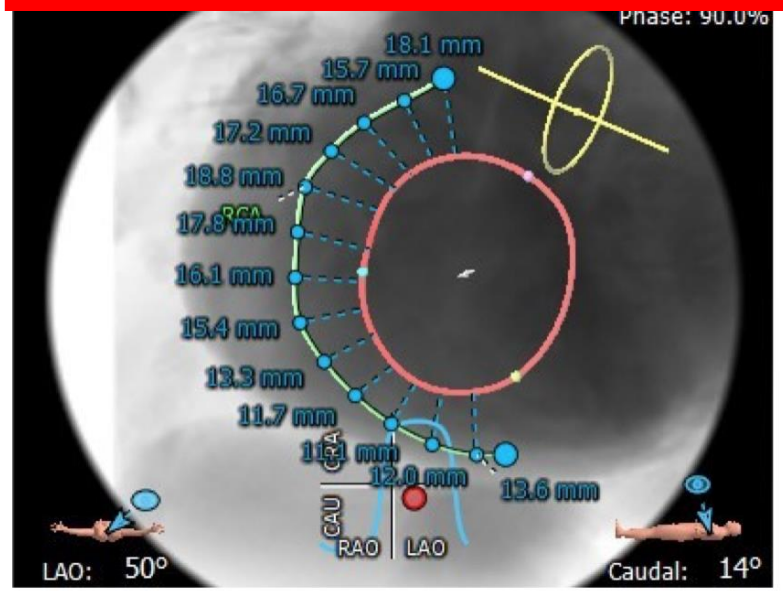
Angio - En Face



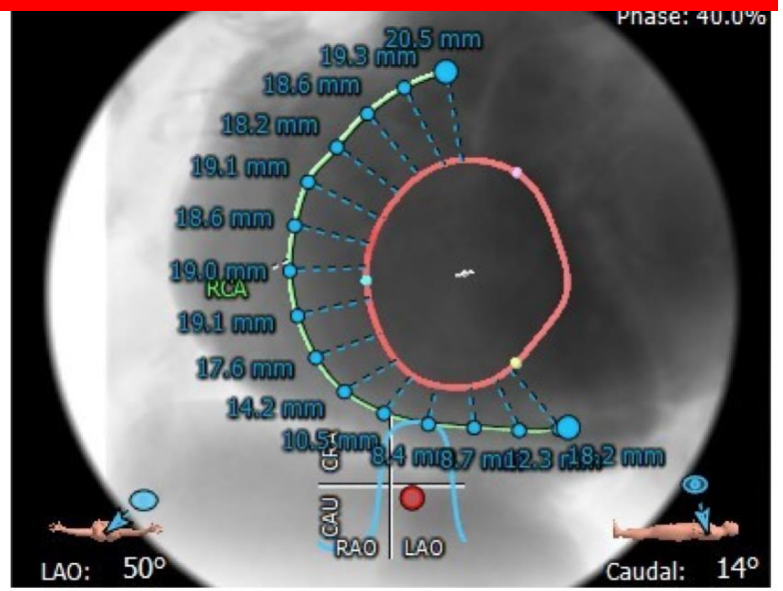
Angio - RAO

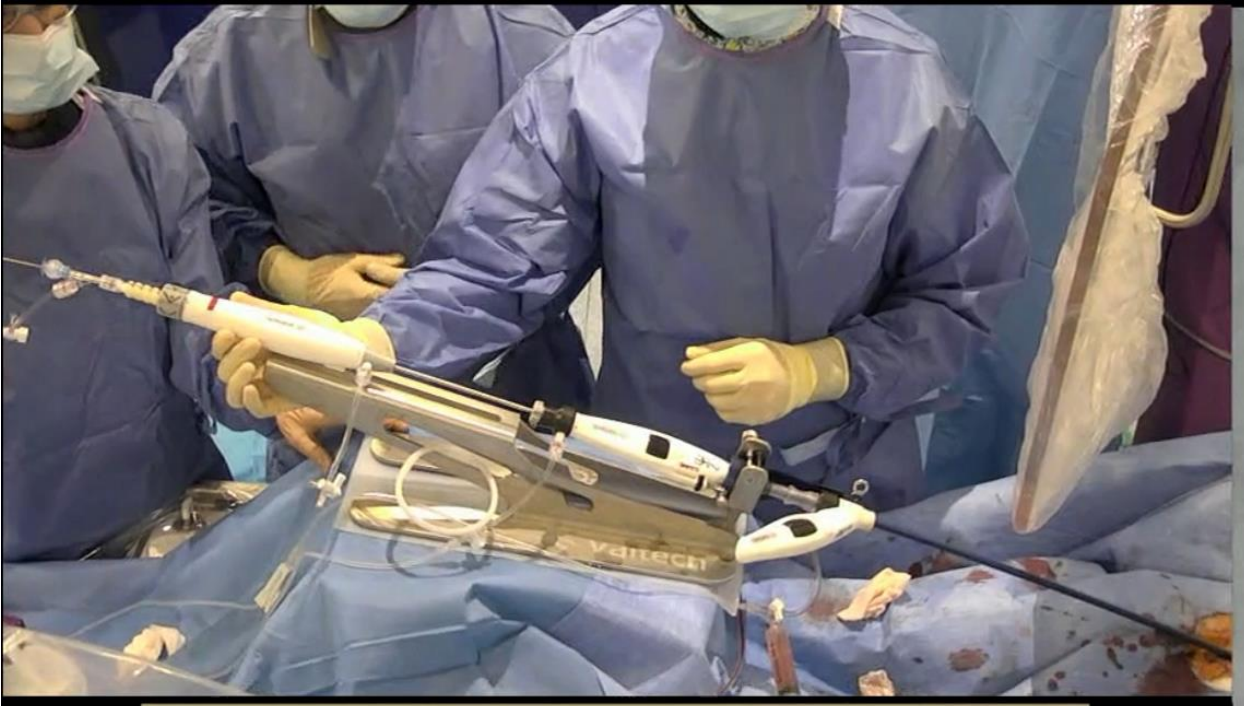


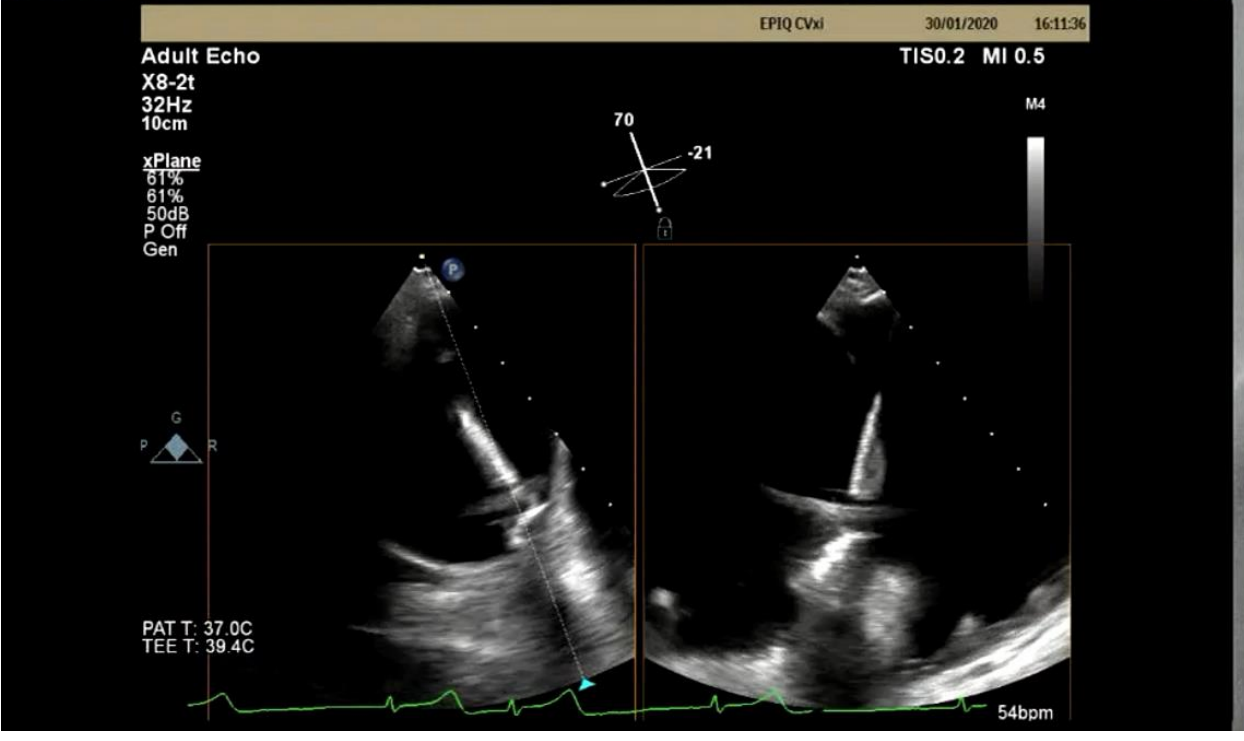
RCA to Annulus Distances - Diastole



RCA to Annulus Distances - Systole



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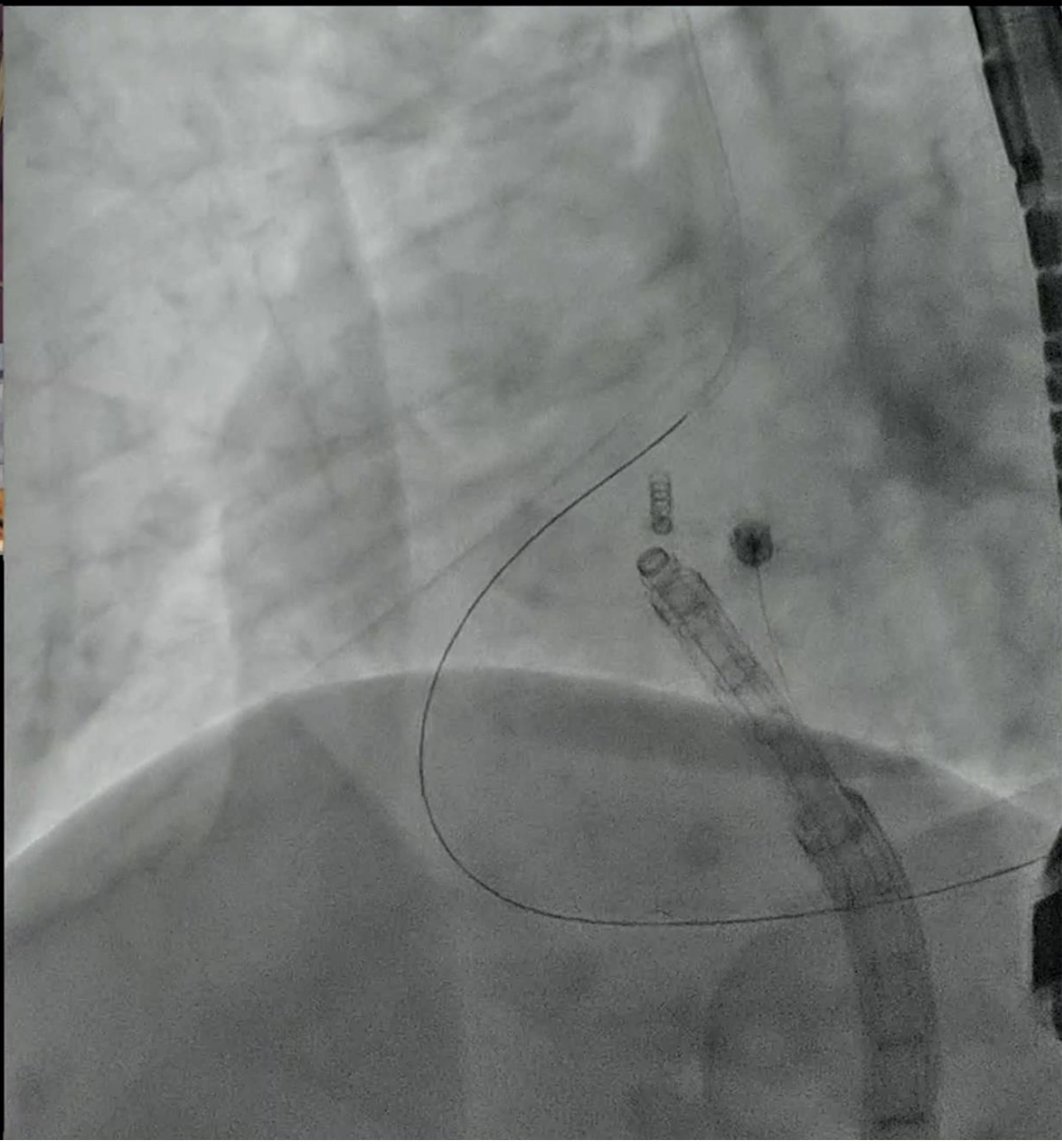
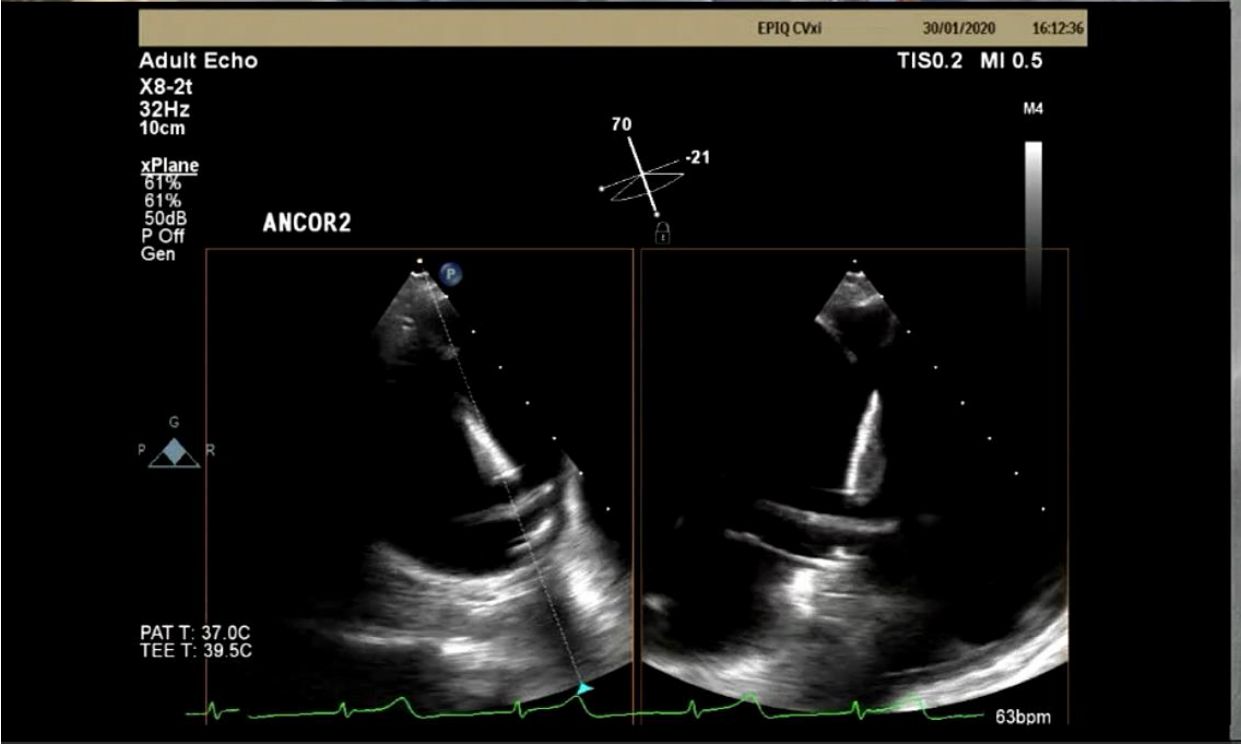
30/01/2020
16:11:36
Adult Echo
X8-2t
32Hz
10cm
xPlane
61%
61%
50dB
P Off
Gen
TIS0.2 MI 0.5
M4
70
-21
PAT T: 37.0C
TEE T: 39.4C
54bpm

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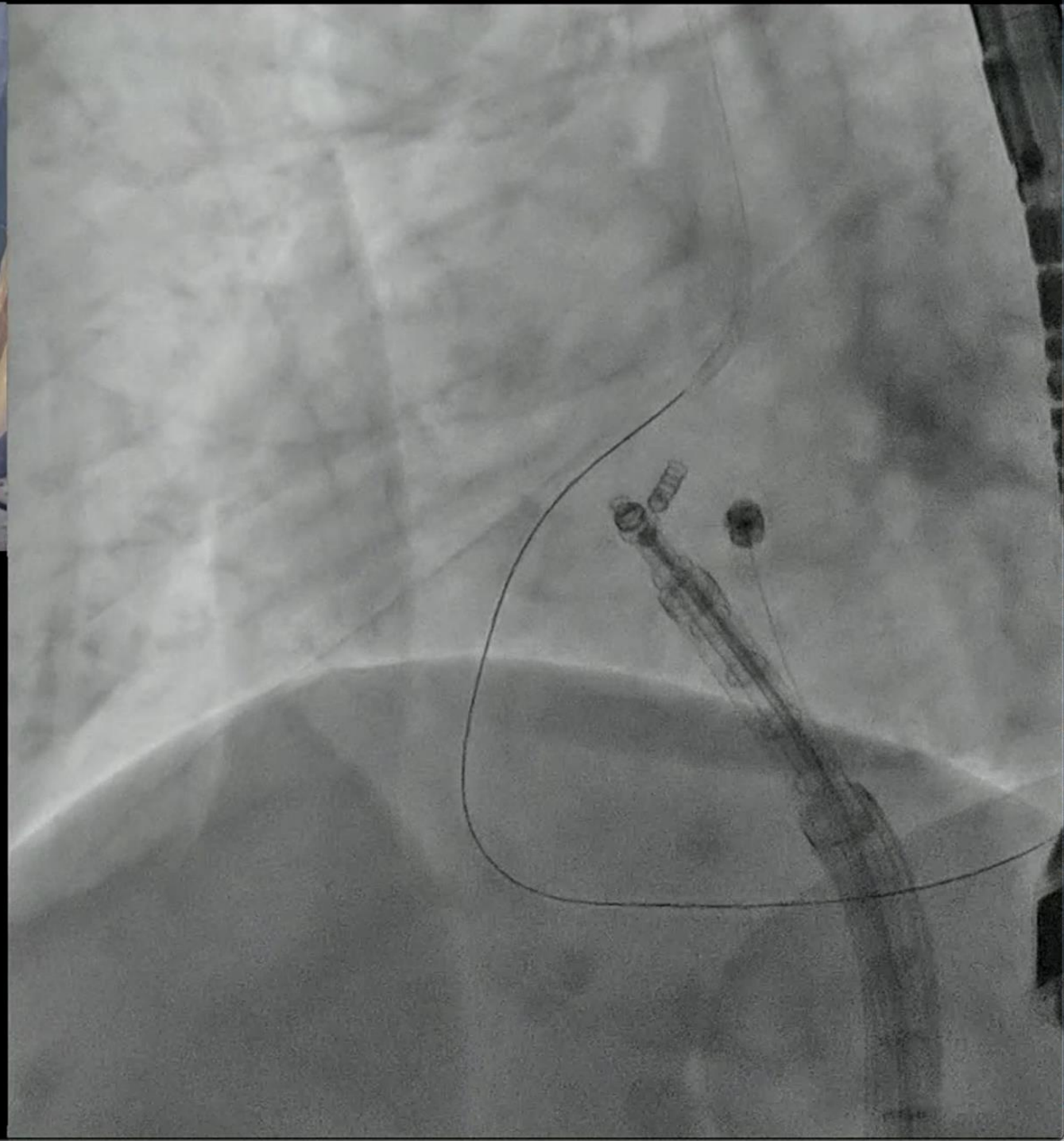
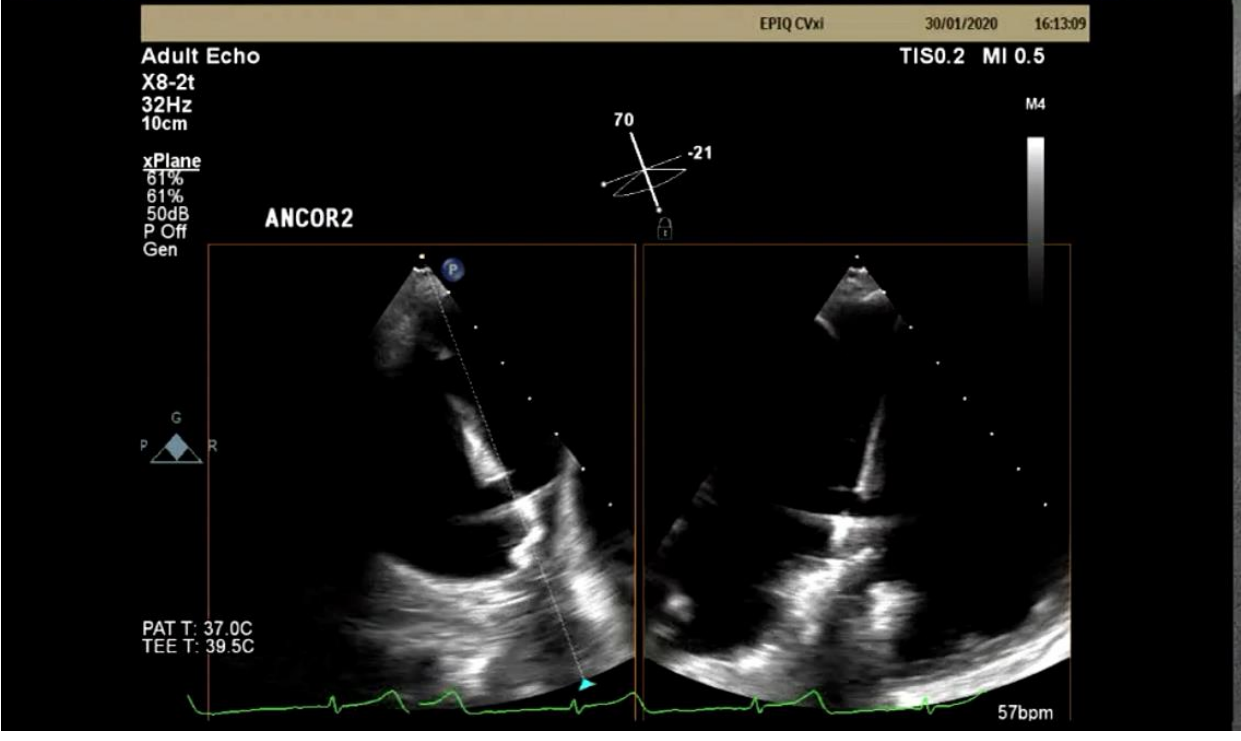
xPlane
61%
61%
50dB
P Off
Gen
TIS0.2 MI 0.5
M4
70
-21
ANCOR2
PAT T: 37.0C
TEE T: 39.5C
63bpm

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30/01/2020
16:13:09
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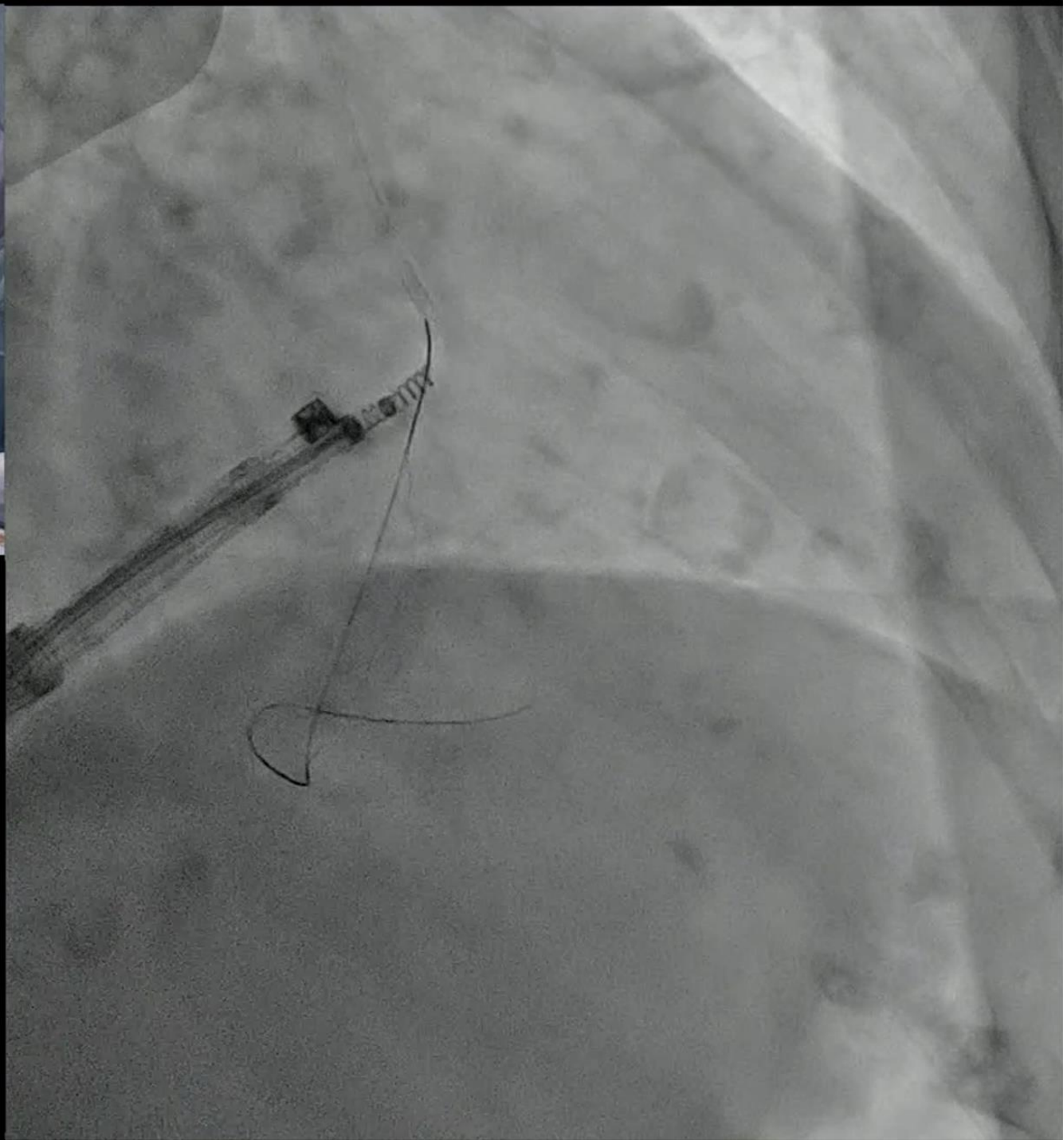
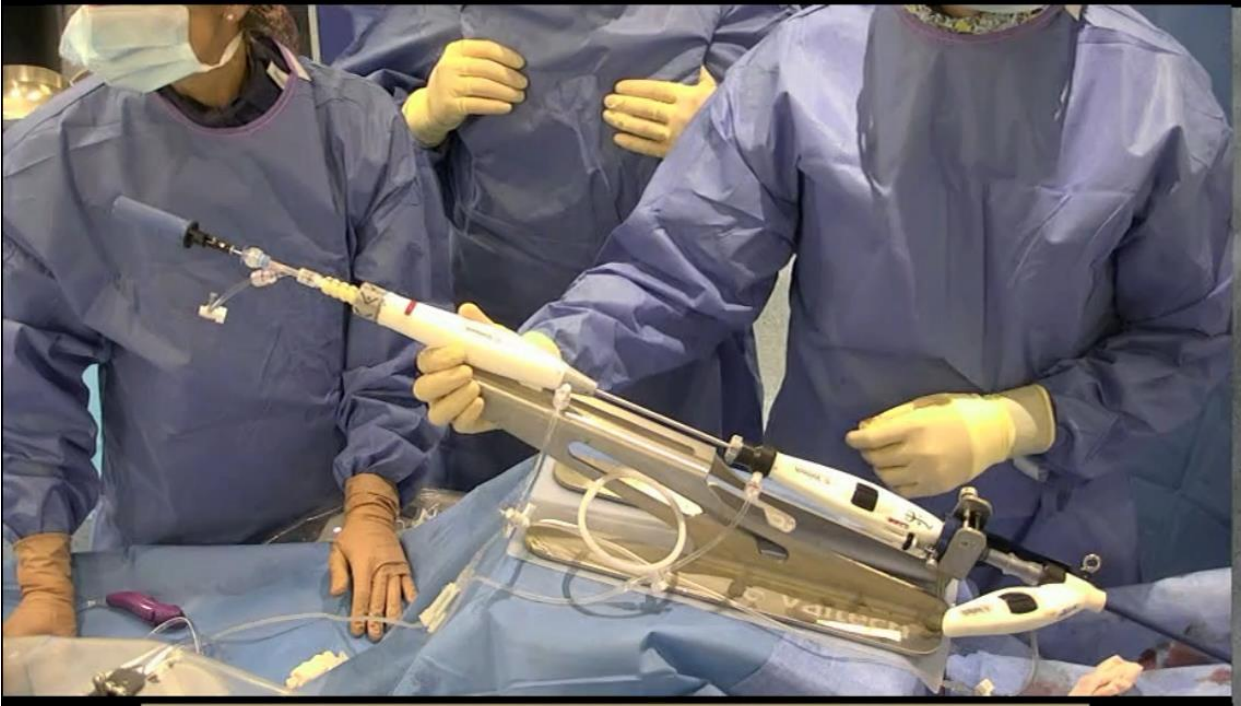
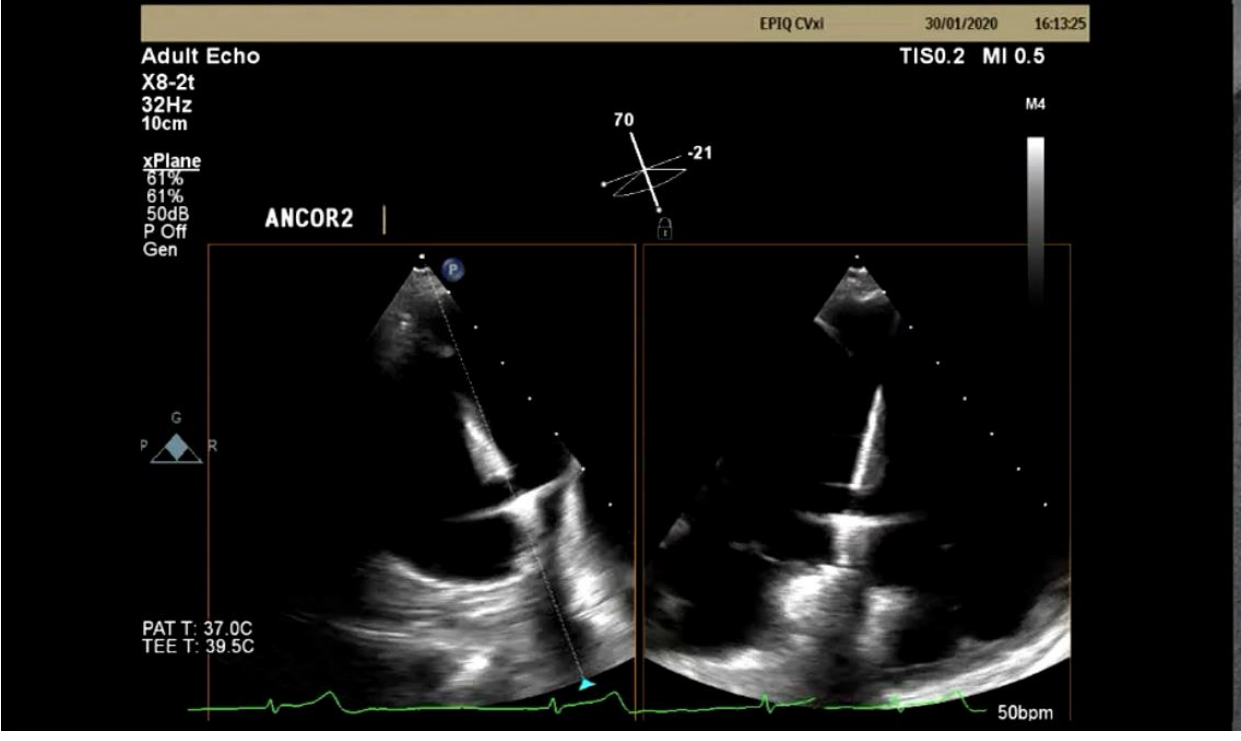
X8-2t
32Hz
10cm
xPlane
61%
61%
50dB
P Off
Gen
TIS0.2 MI 0.5
M4
70
-21
ANCOR2
PAT T: 37.0C
TEE T: 39.5C
57bpm



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16:13:25
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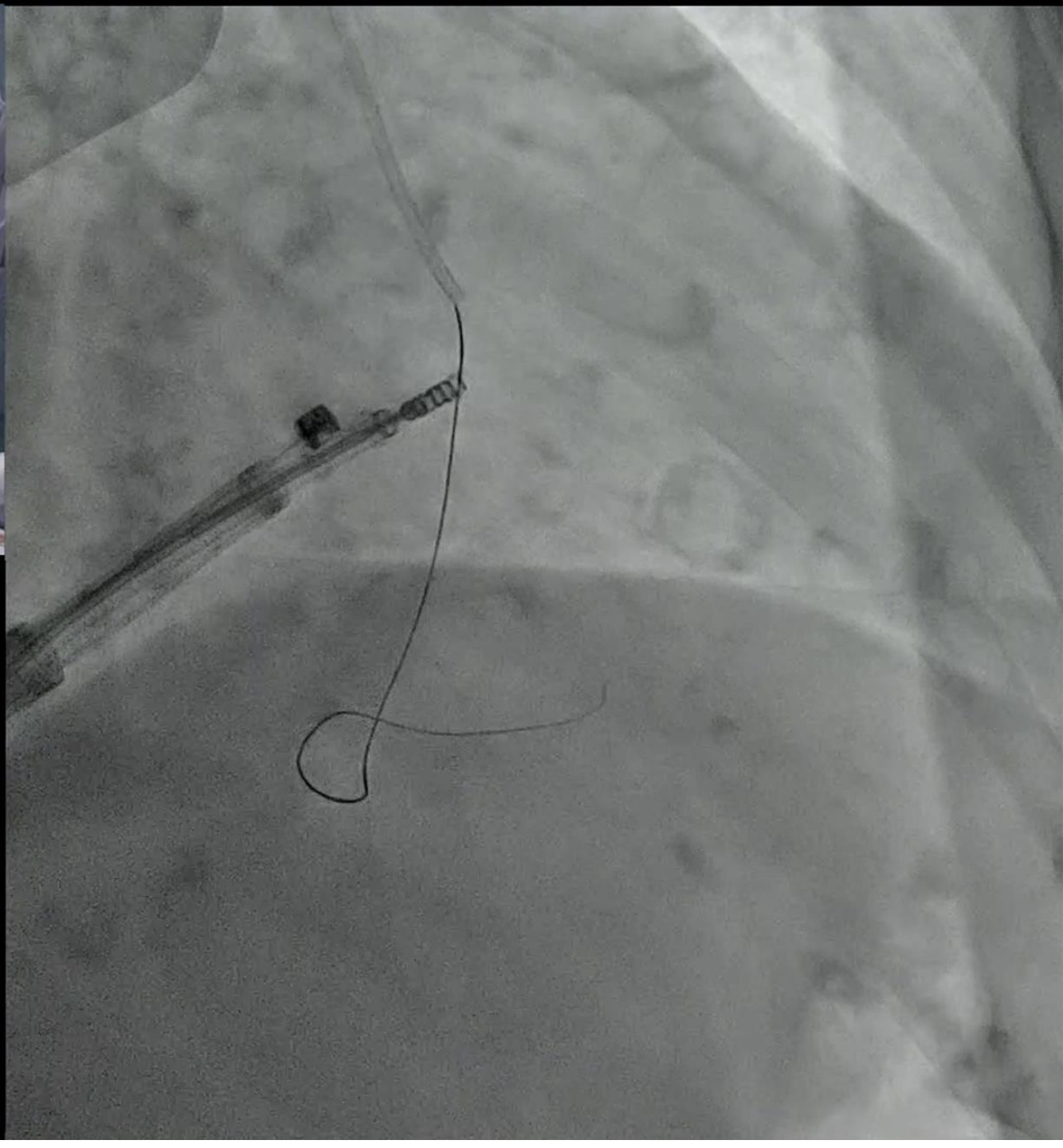
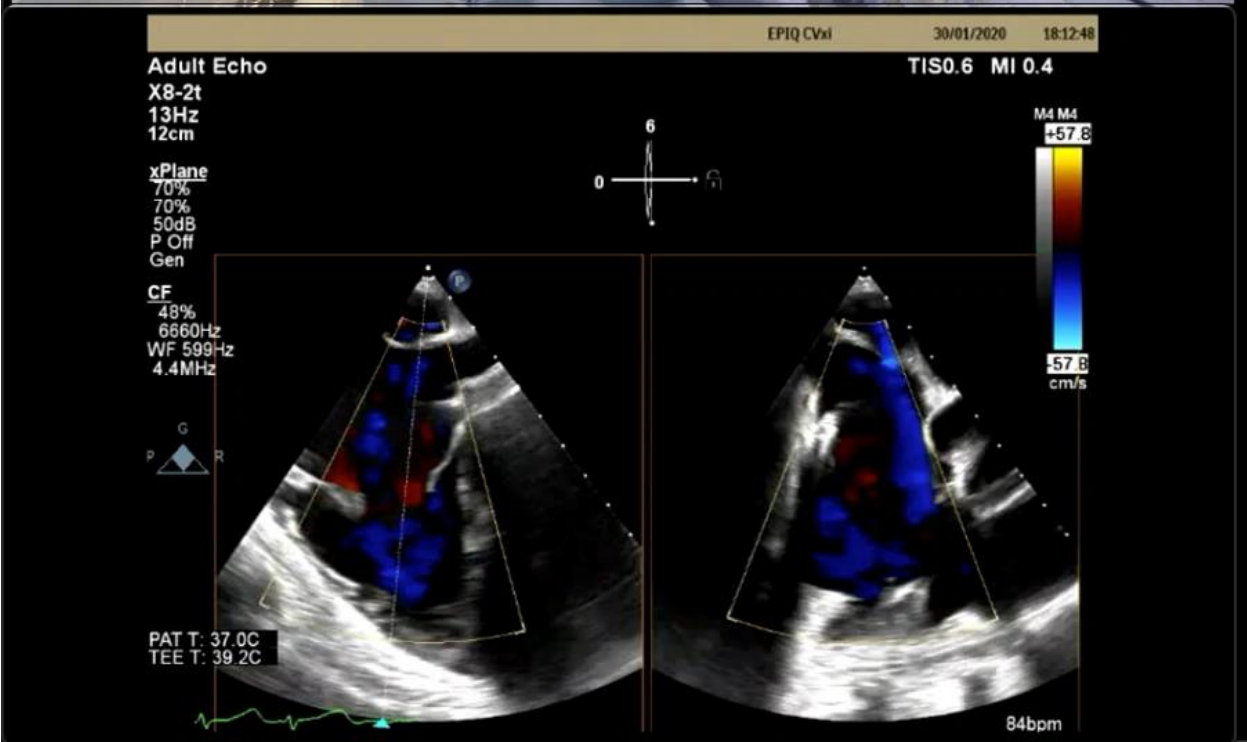
X8-2t
32Hz
10cm
xPlane
61%
61%
50dB
P Off
Gen
TIS0.2 MI 0.5
M4
70
-21
ANCOR2
G
P
R
PAT T: 37.0C
TEE T: 39.5C
50bpm

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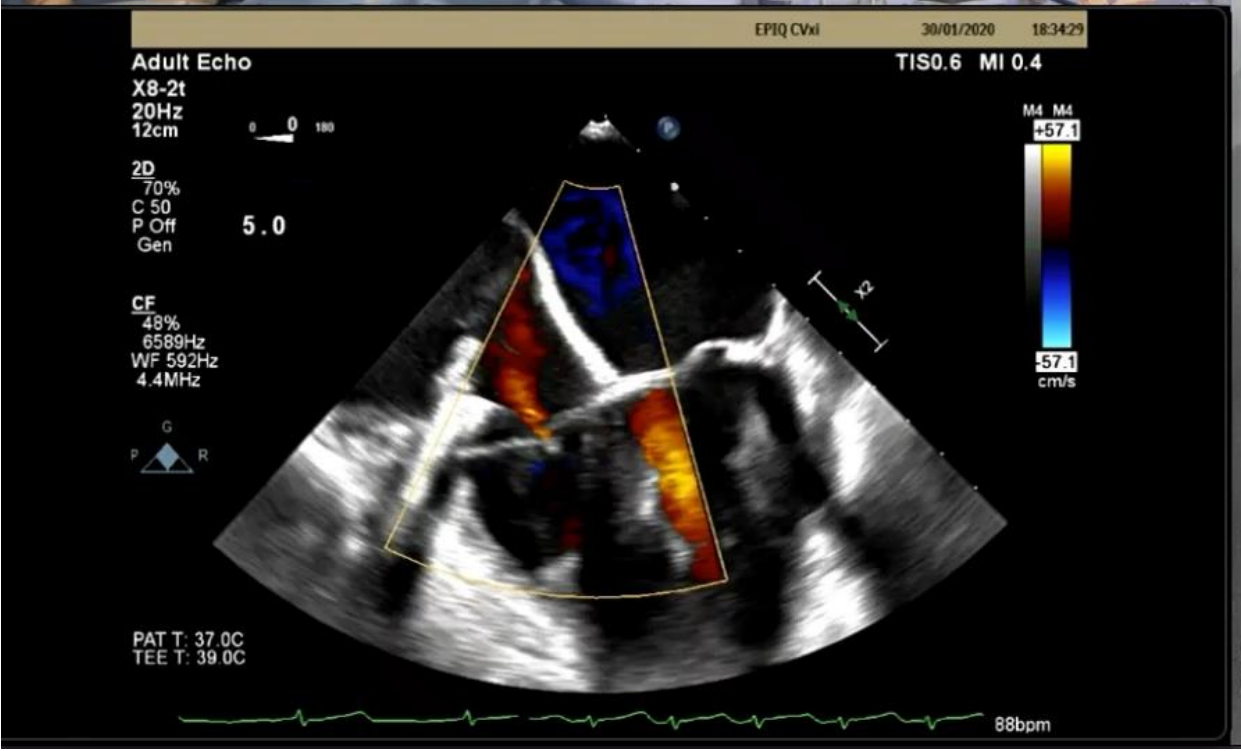
X8-2t
13Hz
12cm
xPlane
70%
70%
50dB
P Off
Gen
CF
48%
6660Hz
WF 599Hz
4.4MHz
M4 M4
+57.8
-57.8
cm/s
PAT T: 37.0C
TEE T: 39.2C
84bpm


EPIQ CVxi
30/01/2020
18:34:29
Adult Echo
TIS0.6 MI 0.4
X8-2t
20Hz
12cm
2D
70%
C 50
P Off
Gen
5.0
CF
48%
6589Hz
WF 592Hz
4.4MHz
M4 M4
+57.1
-57.1
cm/s
PAT T: 37.0C
TEE T: 39.0C
88bpm

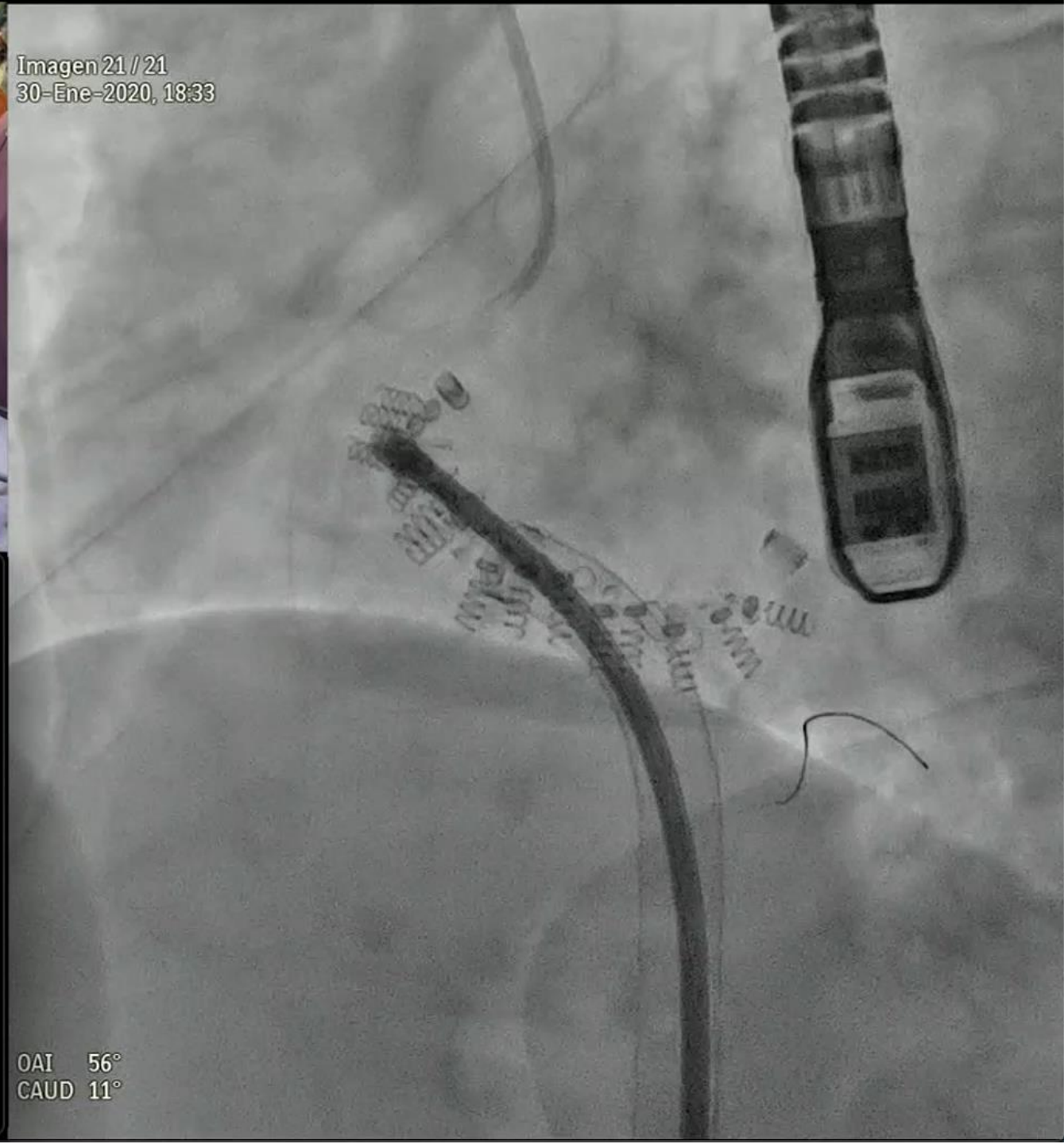
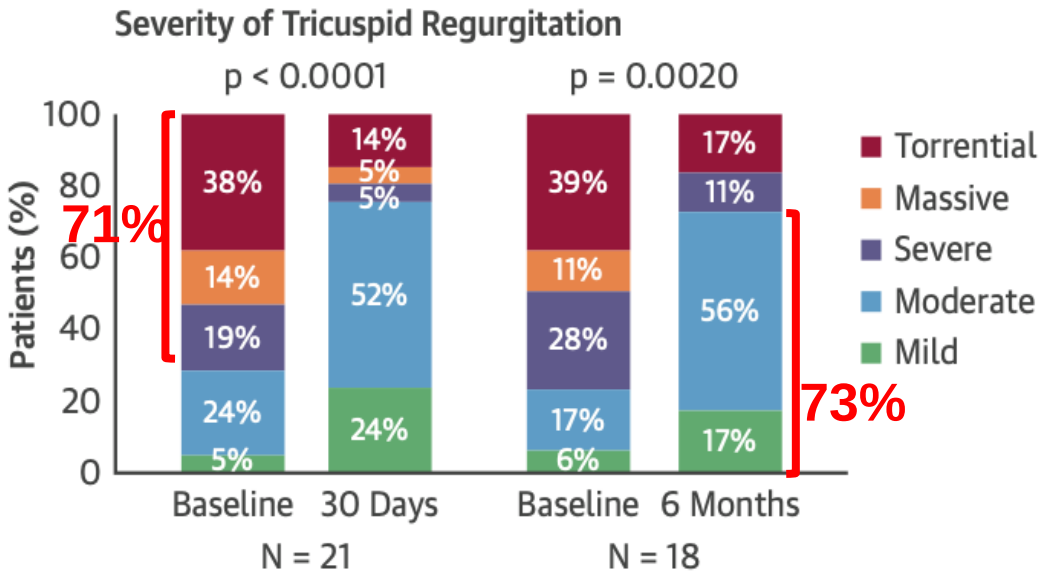


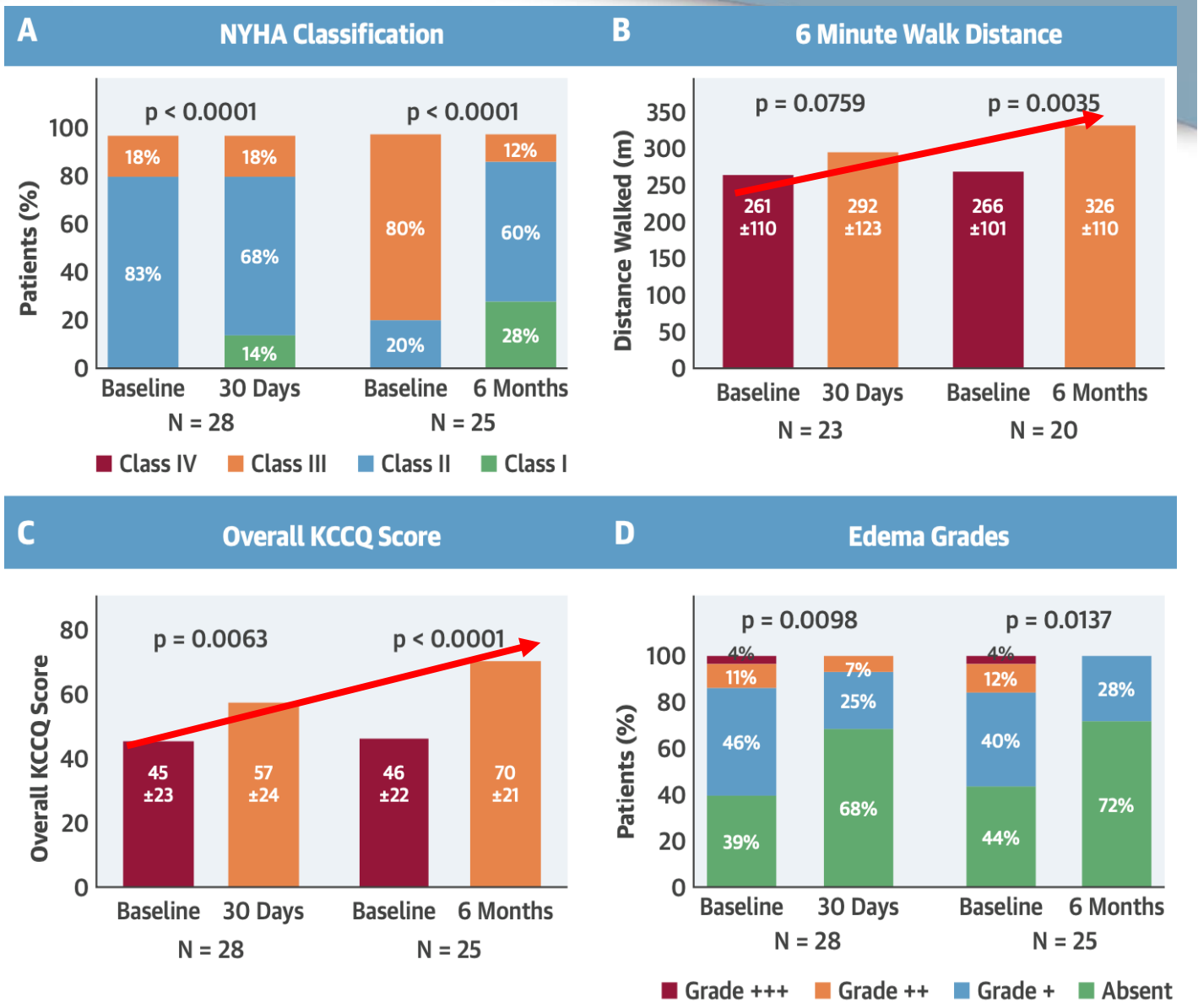
Imagen 21 / 21
30-Ene-2020, 18:33
OAI 56°
CAUD 11°

Tri-Repair

6-Month Outcomes of Tricuspid Valve Reconstruction for Patients With Severe Tricuspid Regurgitation

Georg Nickenig, MD,[a] Marcel Weber, MD,[a] Robert Schueler, MD,[a] Jörg Hausleiter, MD,[b] Michael Näbauer, MD,[b] Ralph S. von Bardeleben, MD,[c] Efthymios Sotiriou, MD,[c] Ulrich Schäfer, MD,[d] Florian Deuschl, MD,[d] Karl-Heinz Kuck, MD,[e] Felix Kreidel, MD,[e] Jean-Michel Juliard, MD,[f,g,h] Eric Brochet, MD,[f,g,h] Azeem Latib, MD,[i] Eustachio Agricola, MD,[i] Stephan Baldus, MD,[j] Kai Friedrichs, MD,[j] Prashanthi Vandrangi, PhD,[k] Patrick Verta, MS Stat, DVM, MD,[k] Rebecca T. Hahn, MD,[l] Francesco Maisano, MD[m]



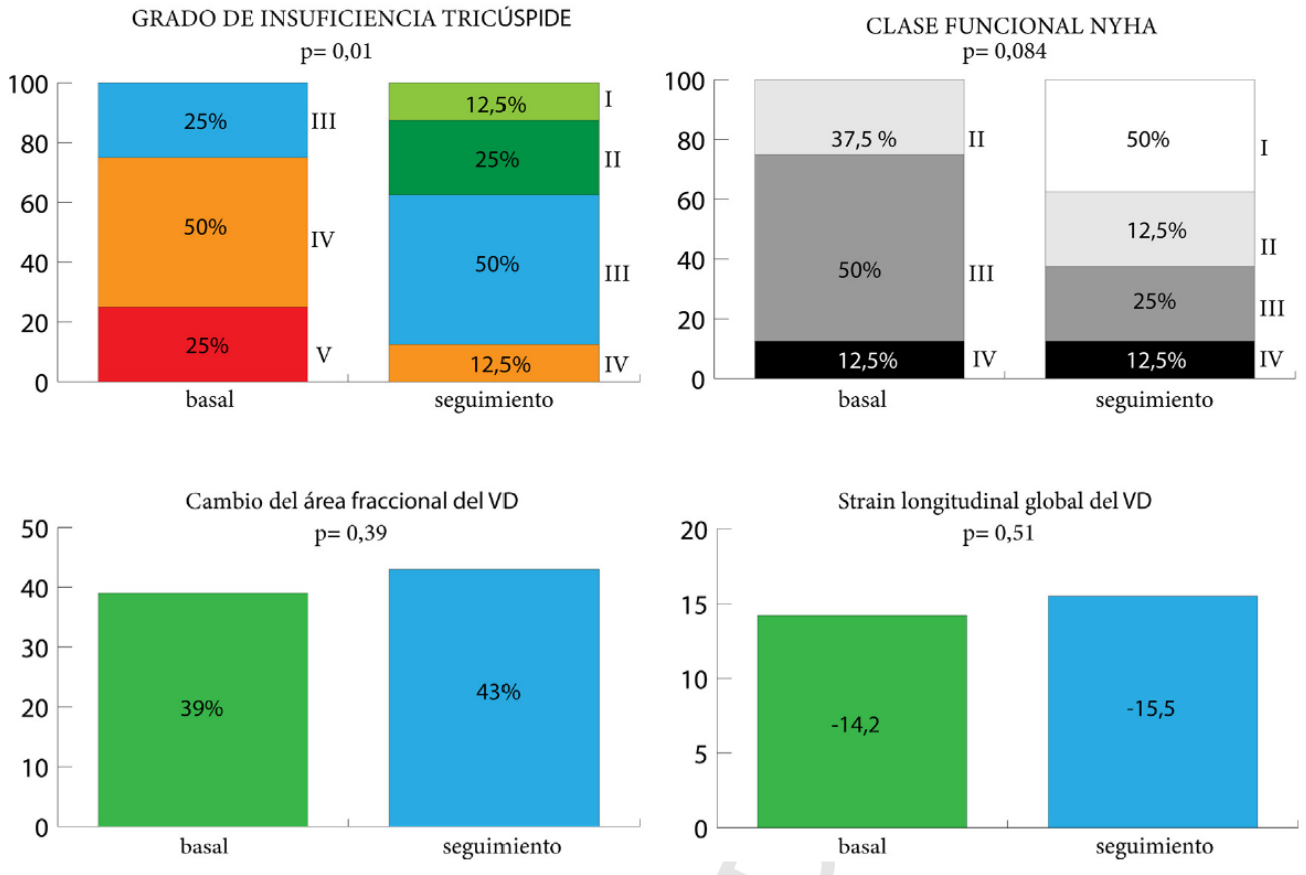


Nickening G et al. J Am Coll Cardiol 2019; 73: 1905-15

Resultados a medio plazo de la anuloplastia tricuspídea percutánea con dispositivo Cardioband

Mid-term outcomes of percutaneous tricuspid annuloplasty with the Cardioband device

Carta científica / Rev Esp Cardiol. 2021;xx(x):xxx–xxx

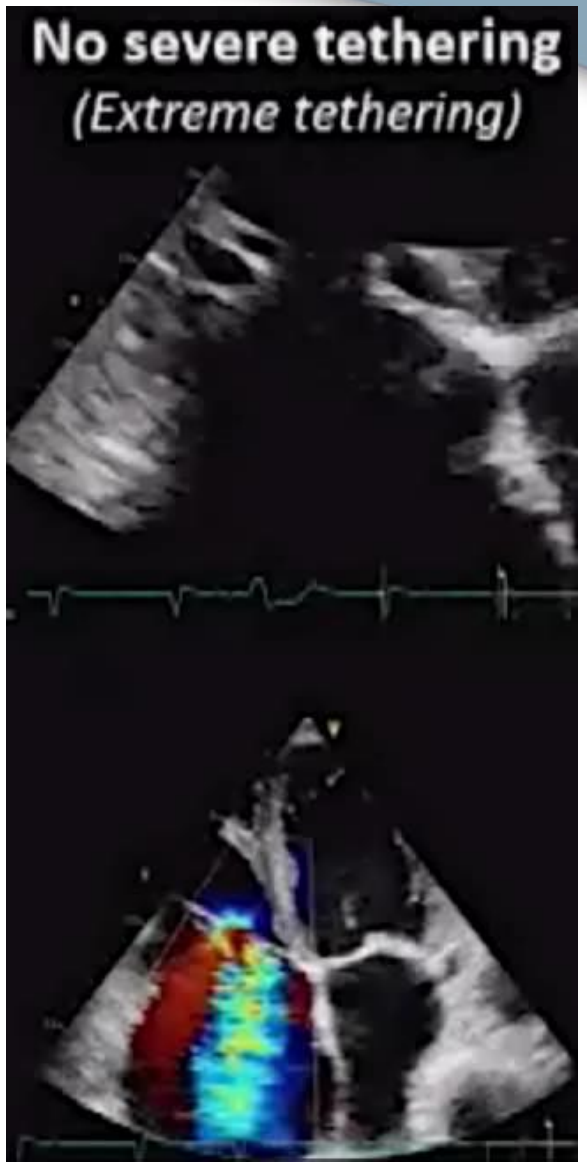


Solano J…..Sanchez-Recalde A. Rev Esp Cardiol 2021

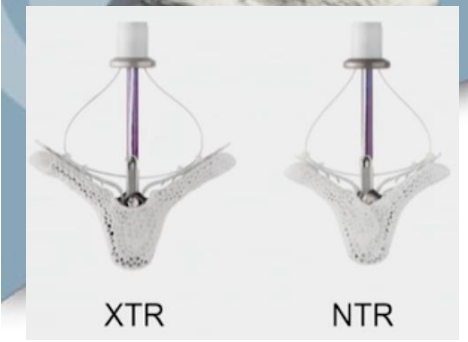
Candidato ideal: *Cardioband*

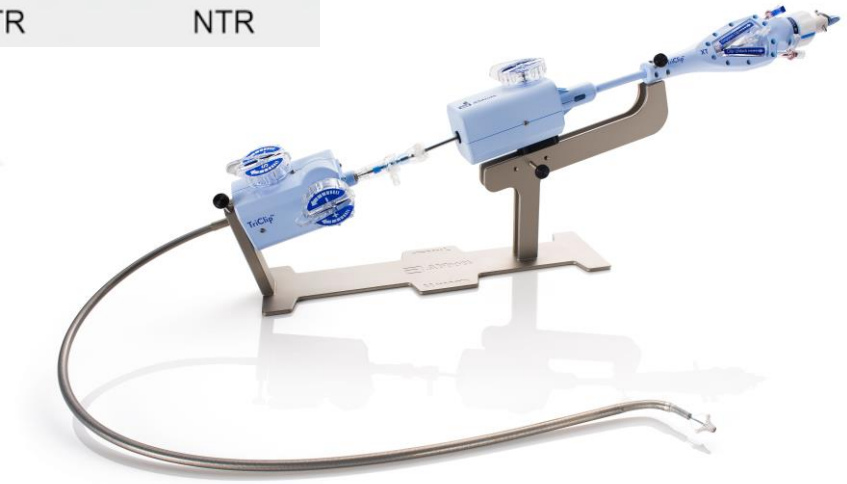
- TR etiology
- Tethering
- Coaptation gap
- Jet orientation
- LV / RV function
- Pulmonary hypertension
- RV geometry

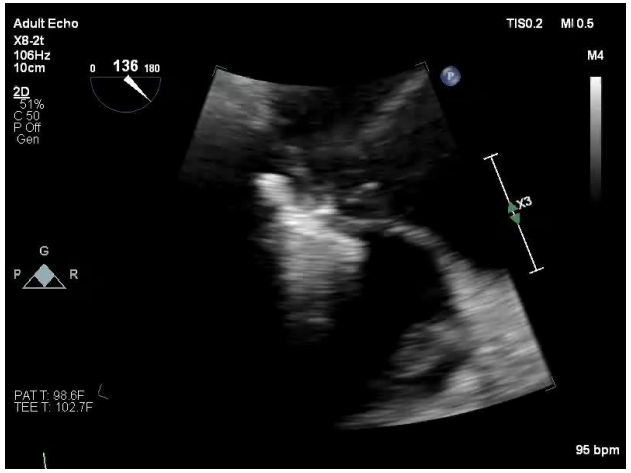
IT predominantemente funcional – dilatación anular
&
No tenting extremo (<10 mm)
&
FEVD normal
&
LVEF >30%
&
No HP

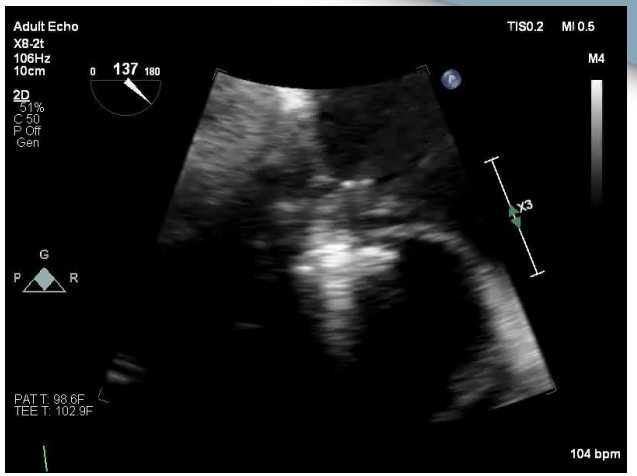


Reparación velos: *Triclip*



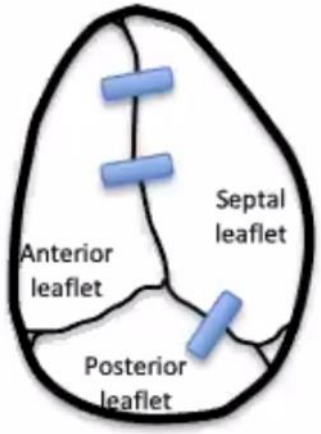


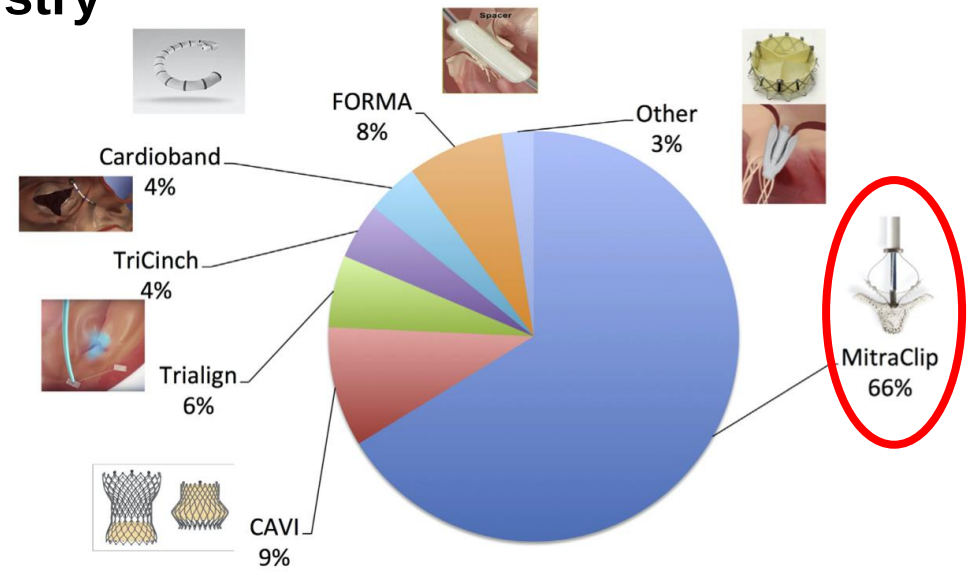


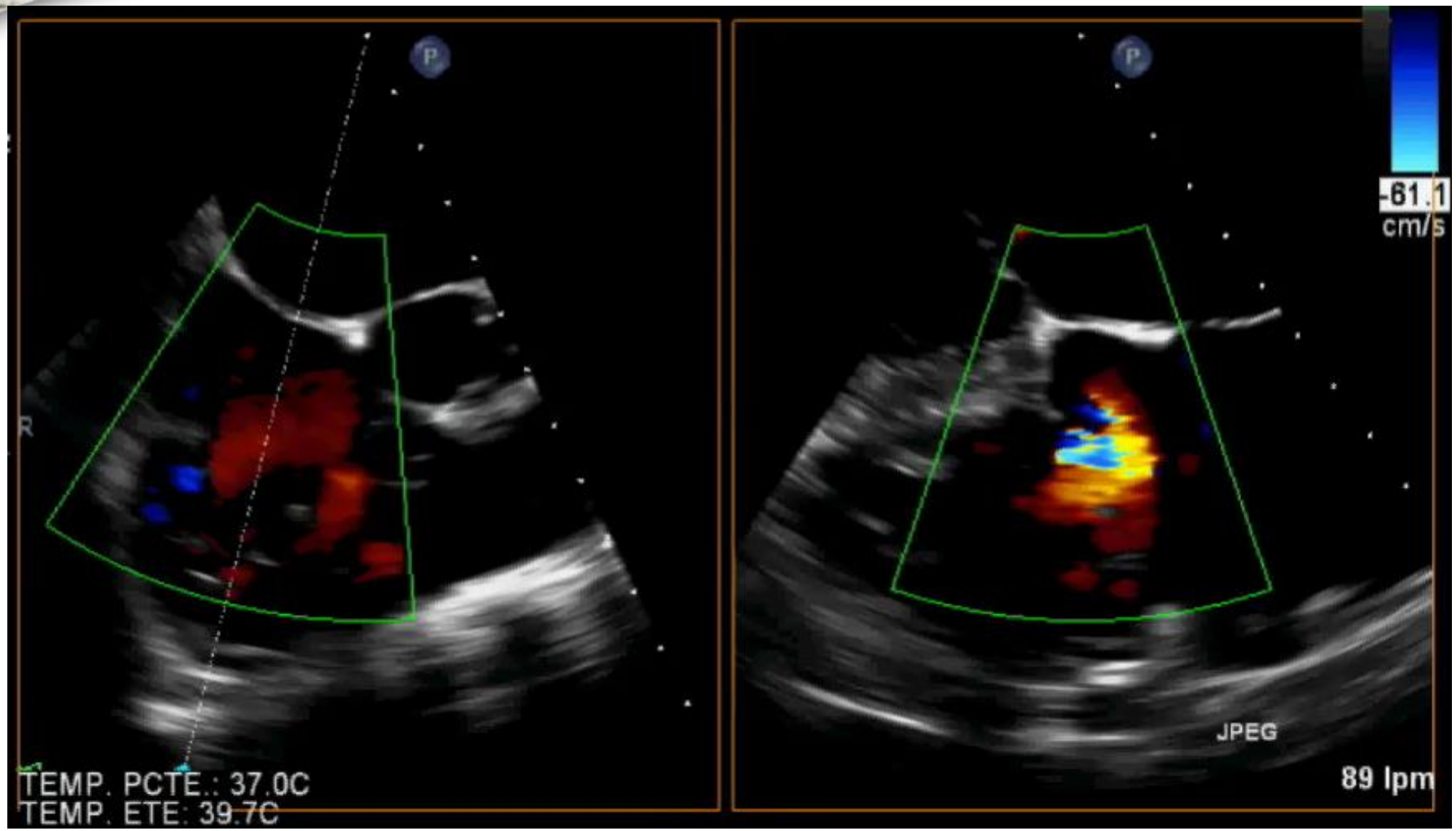


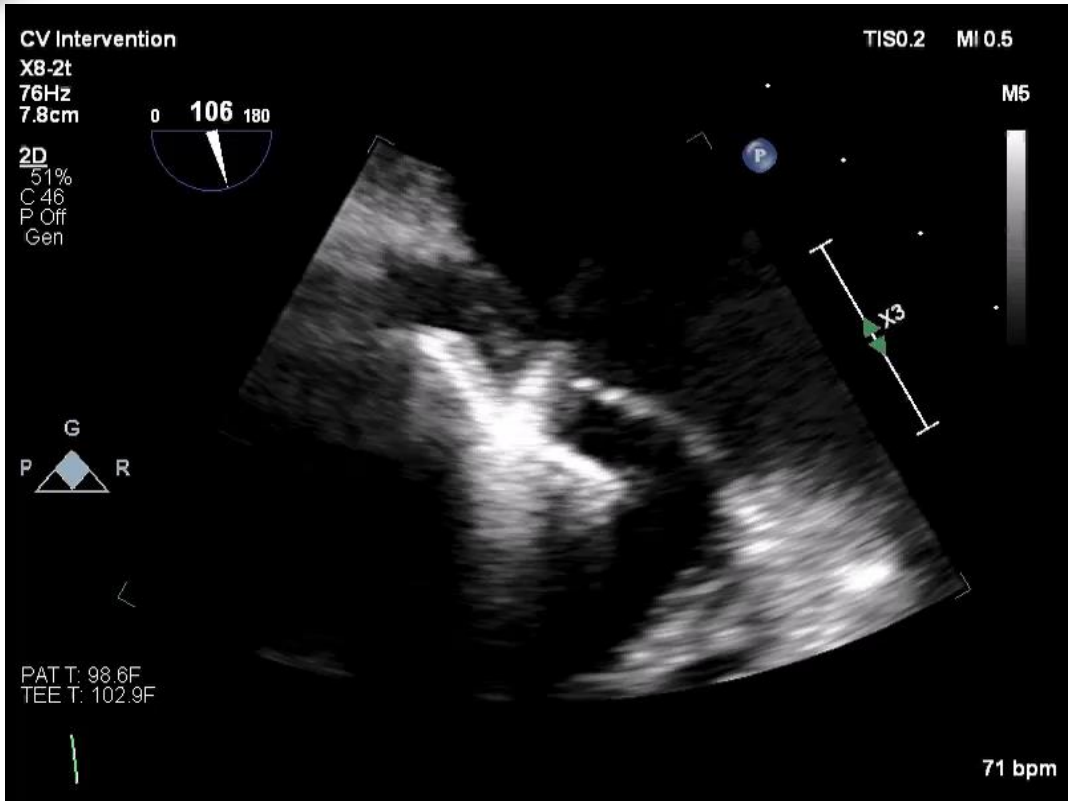
-Inicialmente muchos casos ”off label” Mitraclip en tricúspide
-Marcado CE (abril 2020) para tto IT
-Vía venosa transfemoral

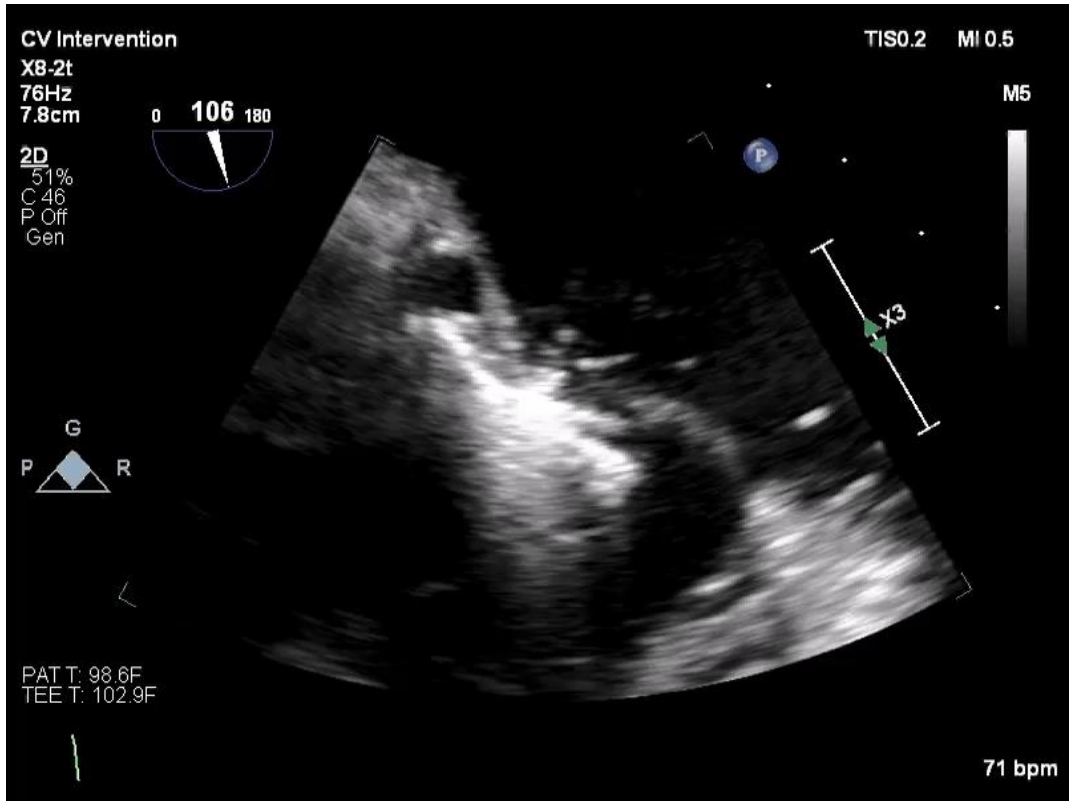
TriValve Registry

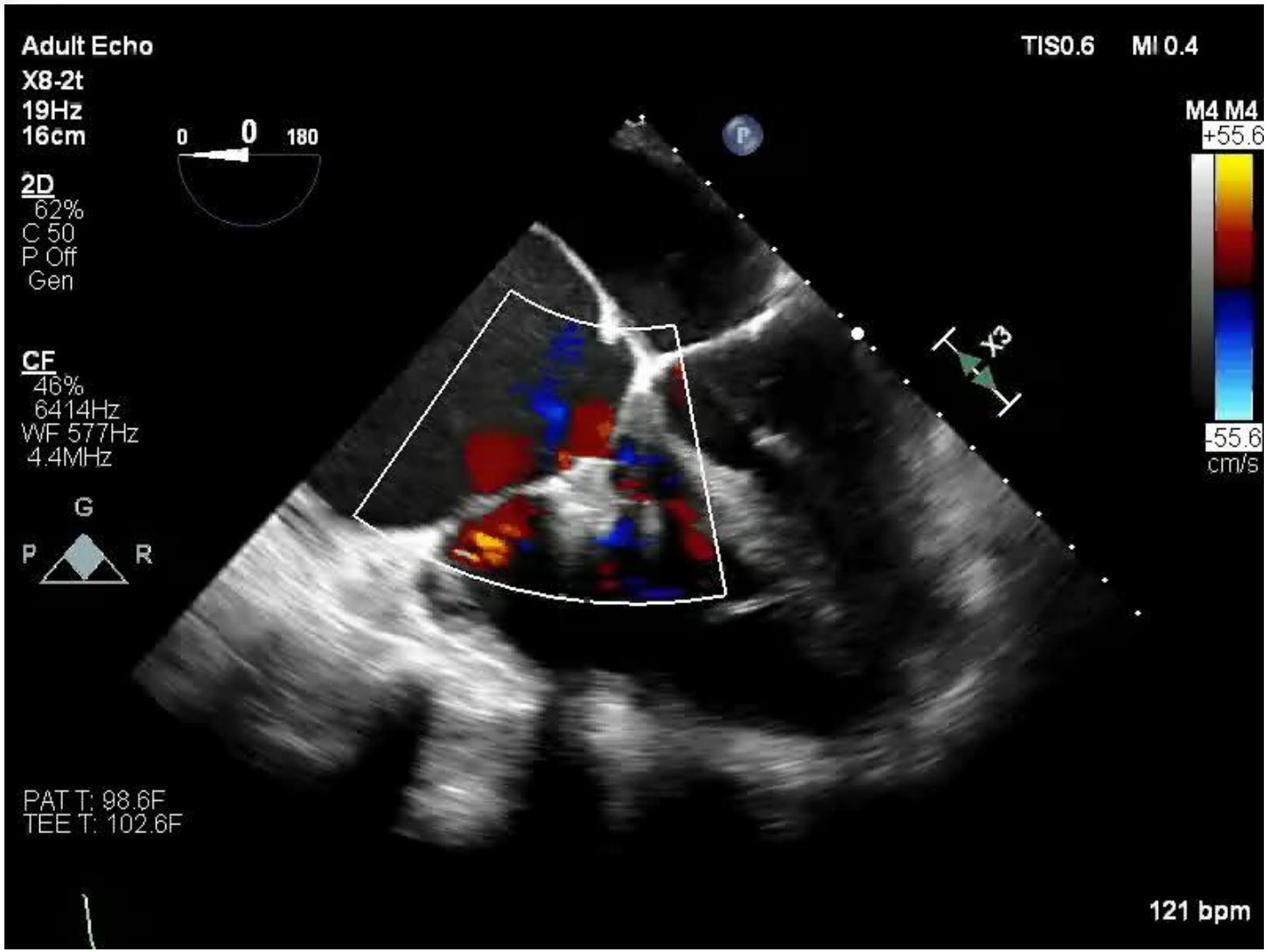





-61.1
cm/s
JPEG
89 lpm
TEMP. PCTE.: 37.0C
TEMP. ETE: 39.7C


CV Intervention
X8-2t
76Hz
7.8cm
2D
51%
C 46
P Off
Gen
0
106
180
TIS0.2
MI 0.5
M5
X3
G
P
R
PAT T: 98.6F
TEE T: 102.9F
71 bpm


CV Intervention
X8-2t
76Hz
7.8cm
2D
51%
C 46
P Off
Gen
0
106
180
TIS0.2
MI 0.5
M5
X3
G
P
R
PAT T: 98.6F
TEE T: 102.9F
71 bpm

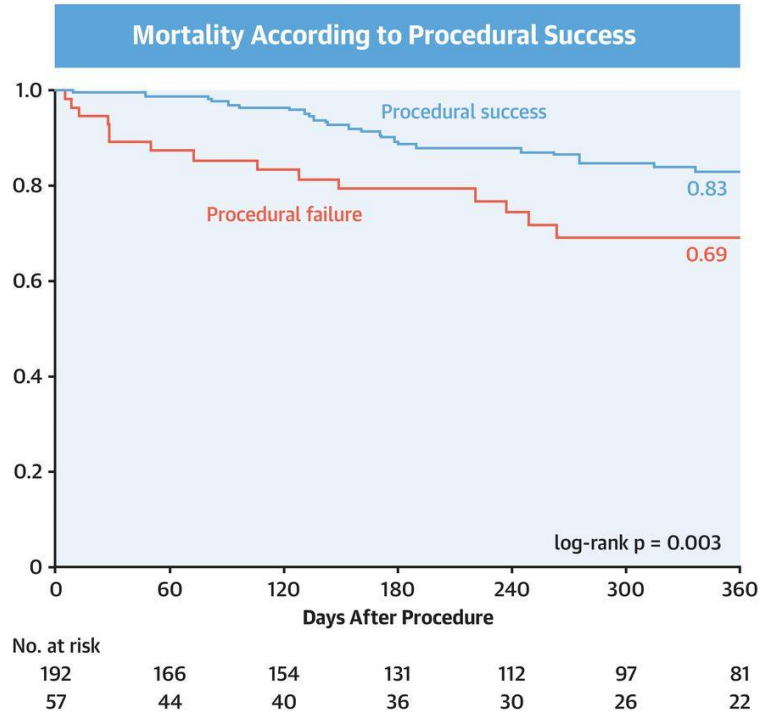

Adult Echo
X8-2t
19Hz
16cm
TIS0.6 MI 0.4
0 0 180
2D
62%
C 50
P Off
Gen
CF
46%
6414Hz
WF 577Hz
4.4MHz
G
P R
M4 M4
+55.6
-55.6
cm/s
X3
PAT T: 98.6F
TEE T: 102.6F
121 bpm

Reparación velos: *Mitraclip "off-label"*

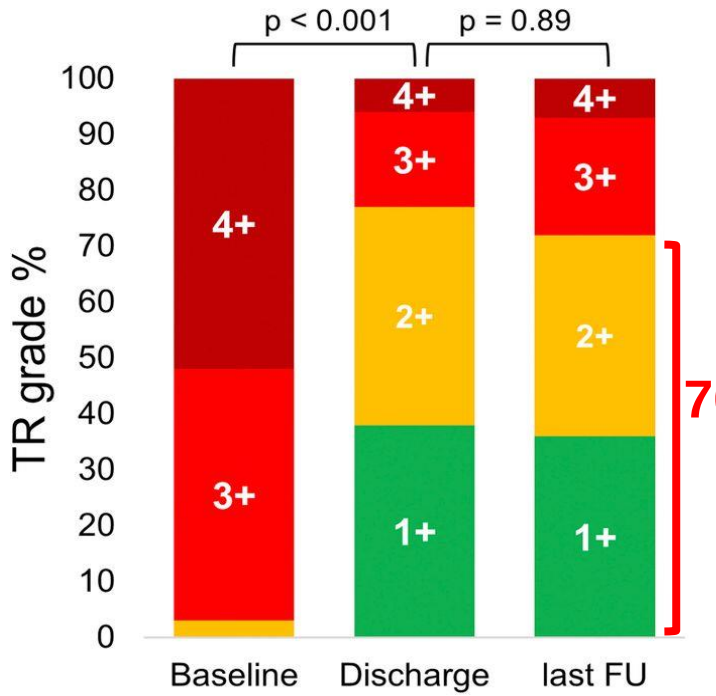
TriValve Registry: 249 pacientes – clip +/2 clips/paciente (AS 65% y AS & PS 20%)

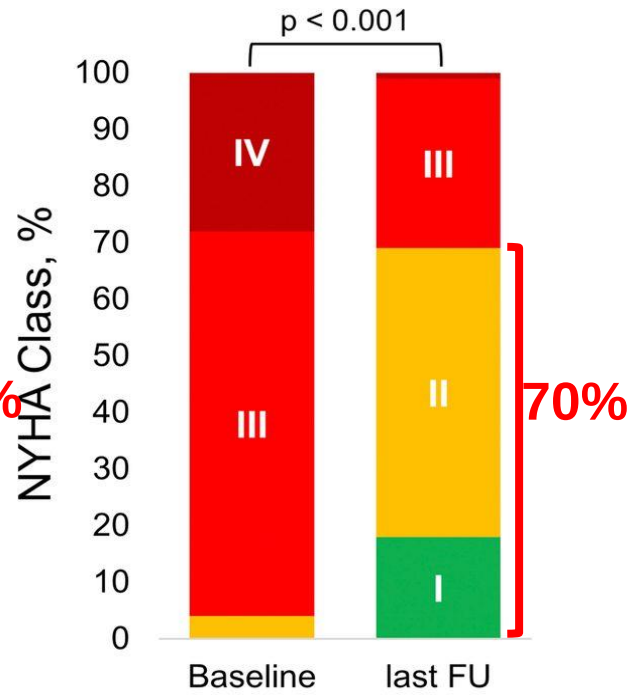
Éxito del procedimiento: implante de clip con IT residual ≤2

CENTRAL ILLUSTRATION: Kaplan-Meier Estimates of 1-Year Mortality According to Procedural Failure After Edge-to-Edge Tricuspid Valve Repair



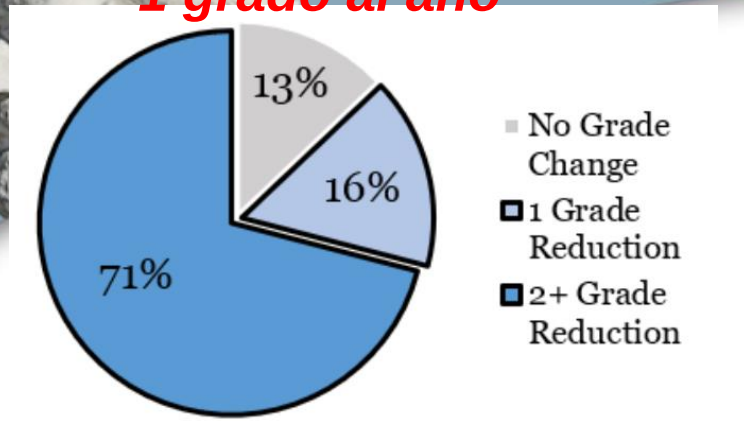
Mehr, M. et al. J Am Coll Cardiol Intv. 2019;12(15):1451-61.



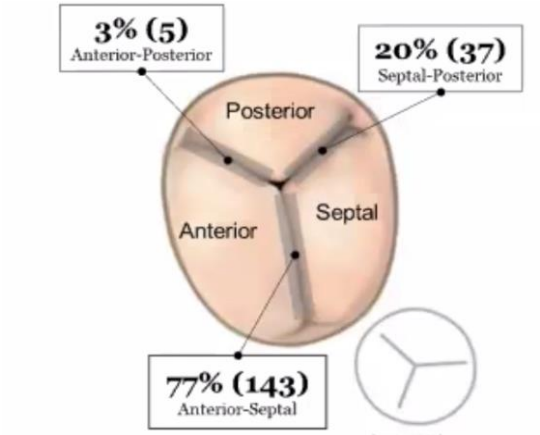


Triluminate CE (*Triclip*)

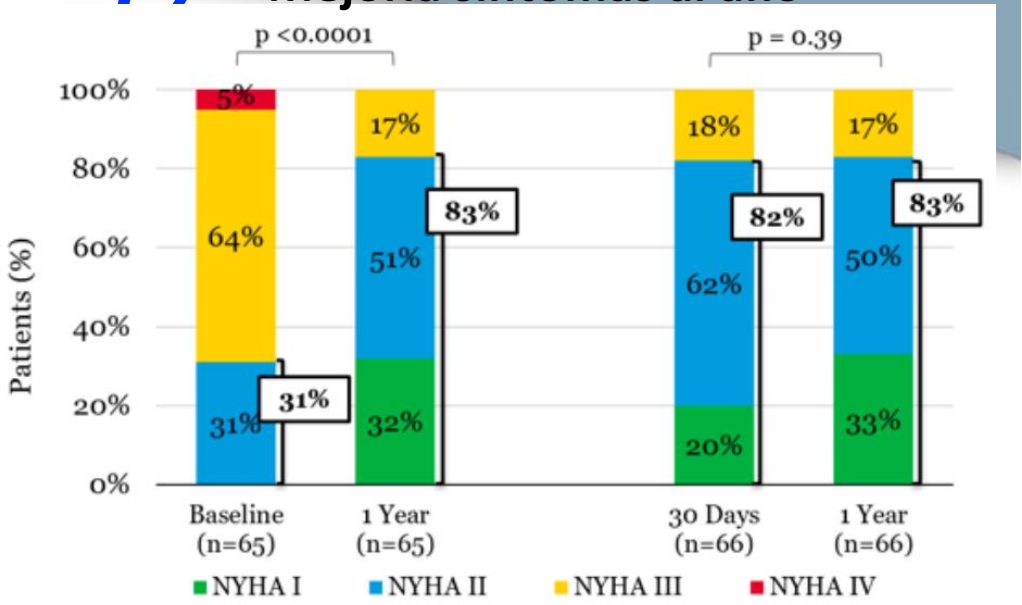
87% reducción al menos 1 grado al año



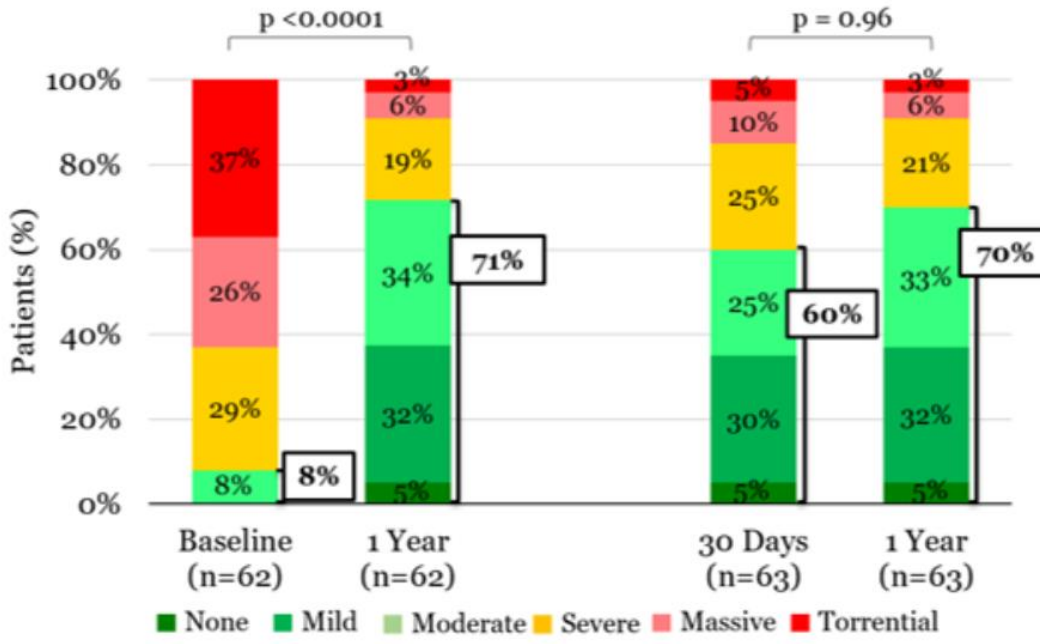
85 pacientes en 21



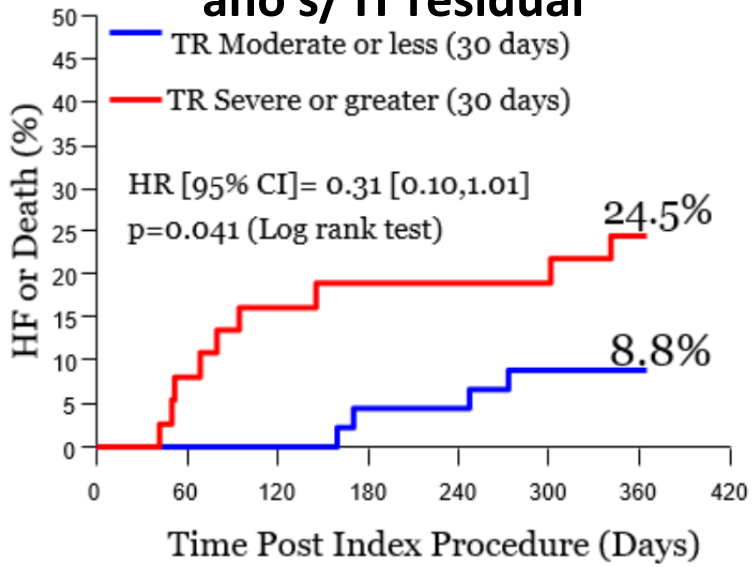
Mejoría síntomas al año



70% IT leve-mod al año



Mortalidad y hospitalizaciones ICC al año s/ IT residual

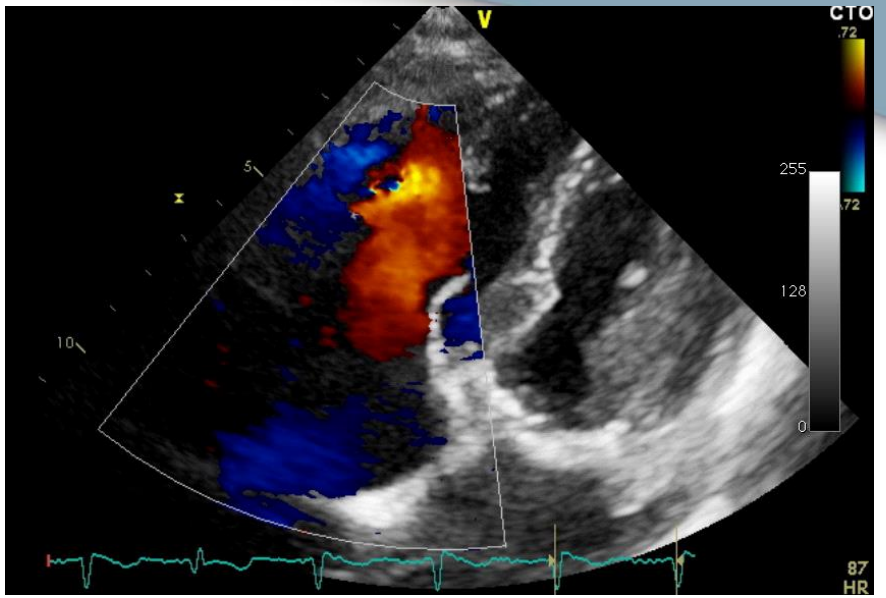


Lurz et al. PCR 2020

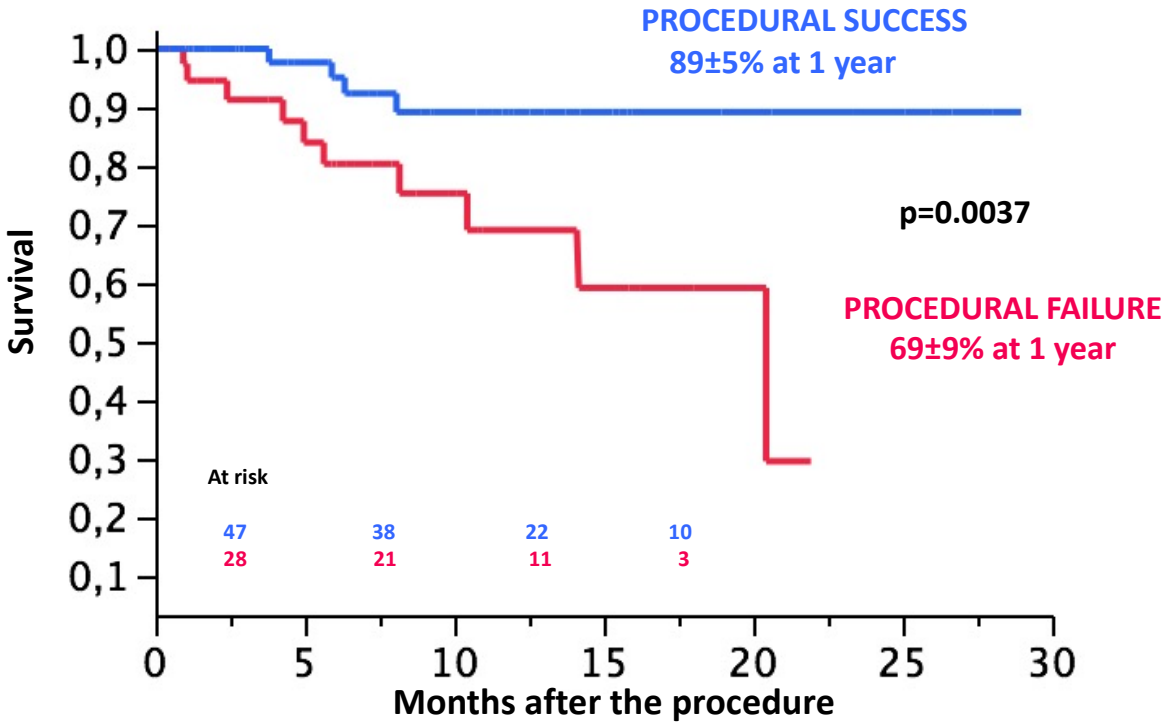
Trivalve Registry

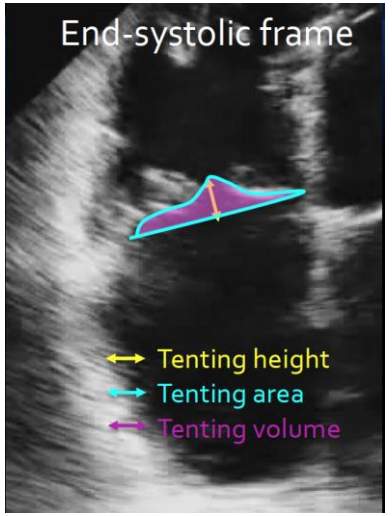
Predictores fracaso técnica

- Altura tenting (>1 cm)
- Tamaño del gap (> 7mm)



Mortalidad

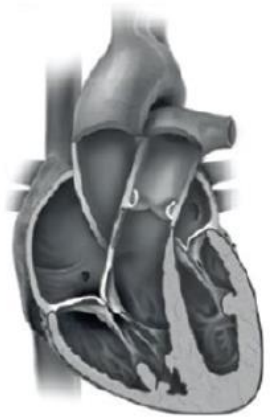
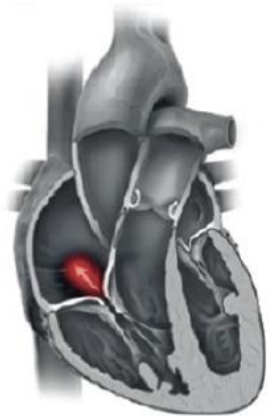
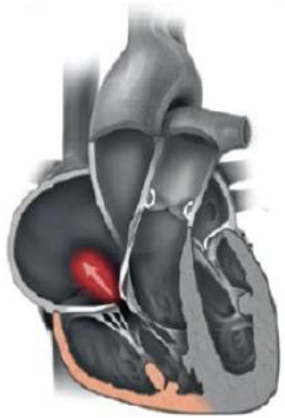
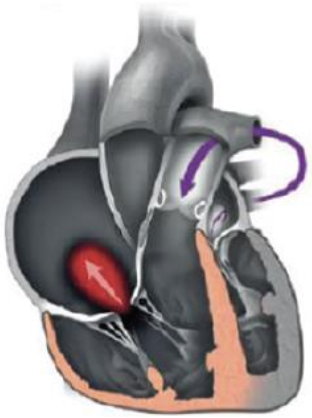
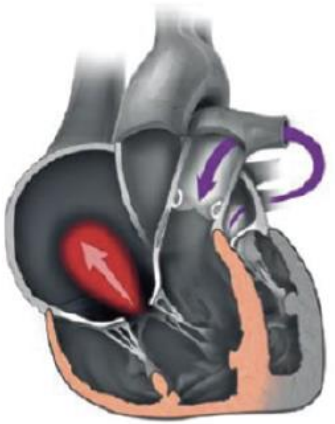




Taramasso et al. JACC Cardiol Intv 2019; 12: 155-65
Mehr et al. JACC Cardiol Intv 2019; 12:1451-61

Heterogeneity of TR Population

Proposed classification of TR stages and potential treatment options

	Stage 1	Stage 2	Stage 3	Stage 4	Stage 5
					
Percutaneous treatment	No	Potential future target for percutaneous options as minimally invasive option could change natural history with minimal risk	Potential candidates for isolated TR surgery who could be enrolled in upcoming IDE RCTs	Current group of patients being treated in EFS if high-risk for surgery. May reguire combination of annuloplasty and leaflet device or TVR	Prohibitive risk and potentially futile. (Palliative procedures can be considered in highly selected patients)

Early

RV: Initial dilatation
TA: Subsequent initial dilatation

Annuloplasty
Leaflet Approximation
Replacement (orthotopic)

Progressive

RV: Progressive dilatation
TA: Progressive dilatation → lack of leaflet coaptation

± Annuloplasty
Leaflet Approximation
Replacement (orthotopic)

Late

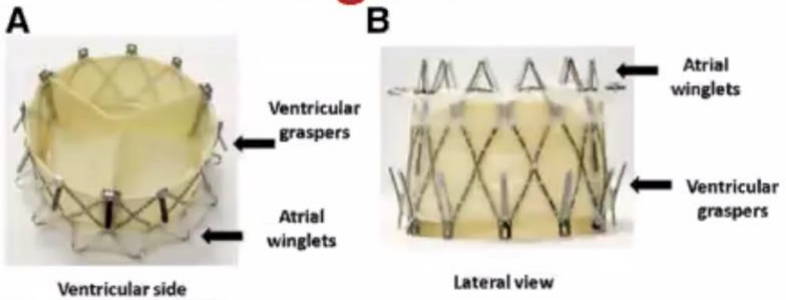
RV/TA: Progressive distortion and subsequent further leaflet tethering

± Leaflet Approximation
Replacement (heterotopic)
Replacement (orthotopic; depending on RV function)

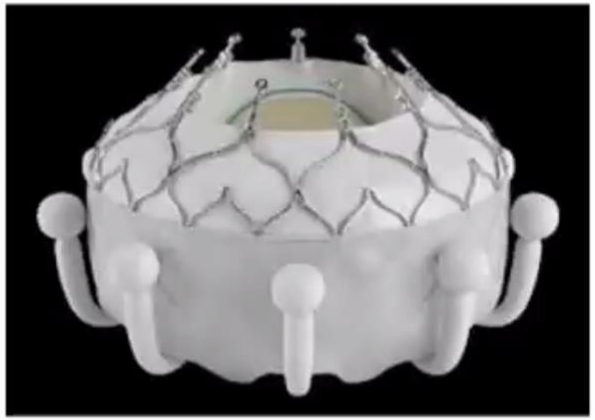
RV = right ventricle; TA = tricuspid annulus; TR = tricuspid regurgitation. Adapted from: Hahn 2018[88] and Latib et al. 2018.[13] Used with permission from Europa Digital & Publishing.

Reemplazo valvular ortotópico

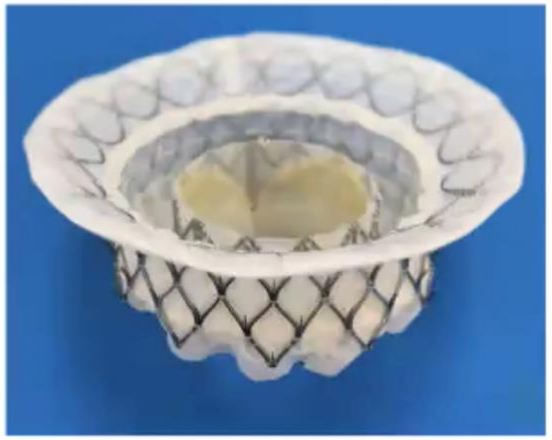
Navigate



Evoque

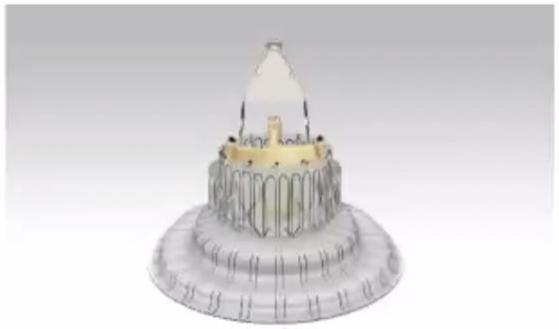


Intrepid

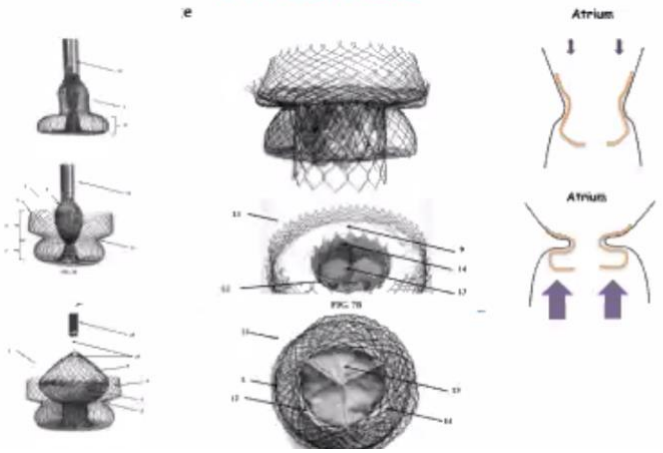


Trisol

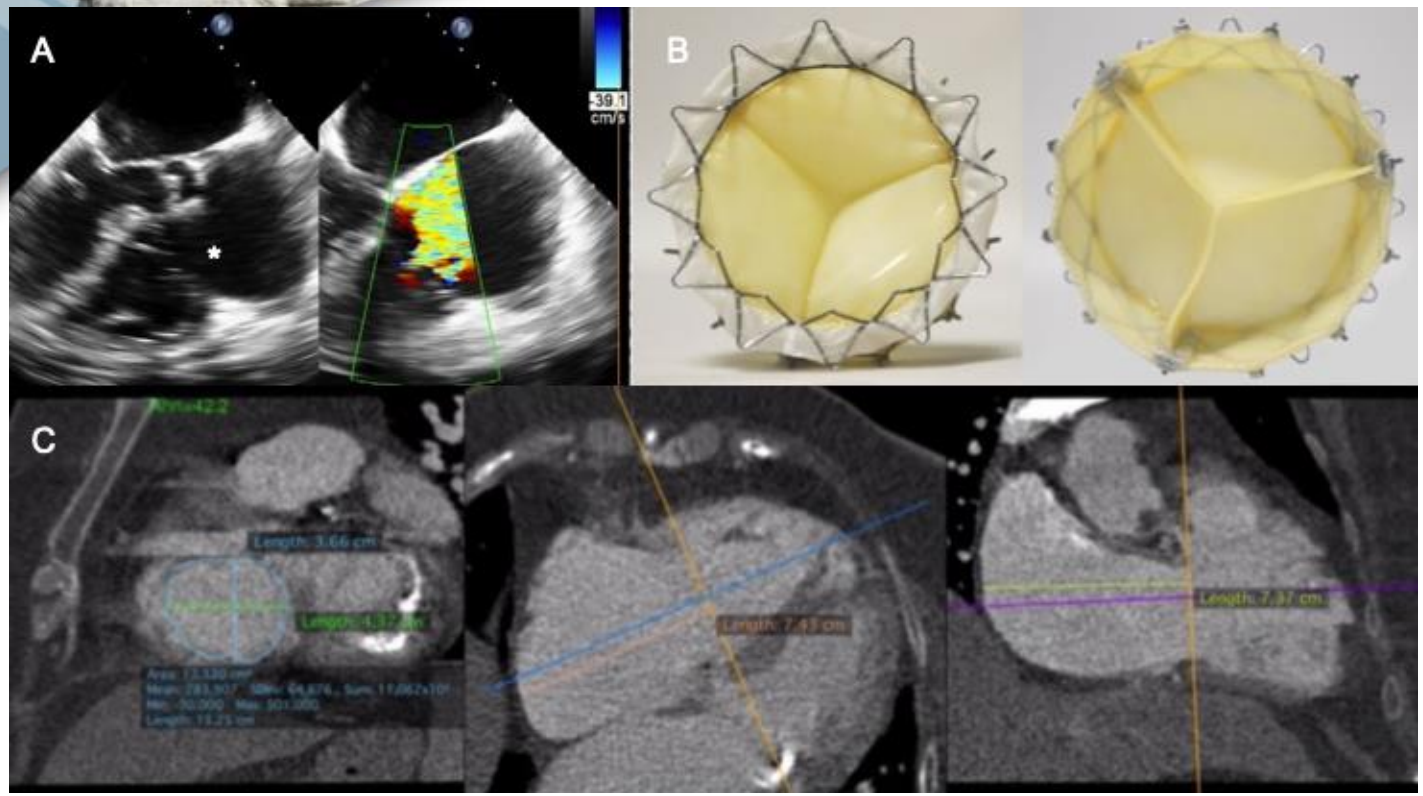
Lux

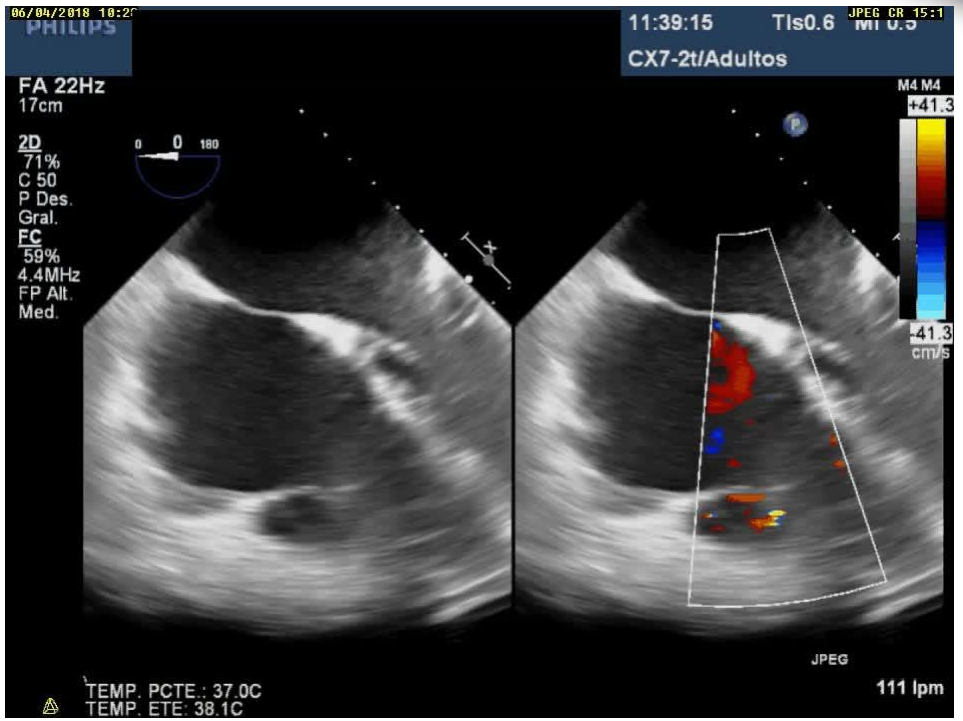


Tricares



NAVIGATE

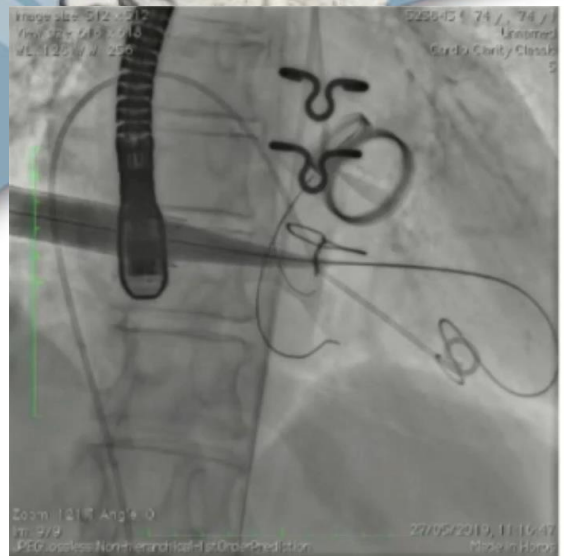


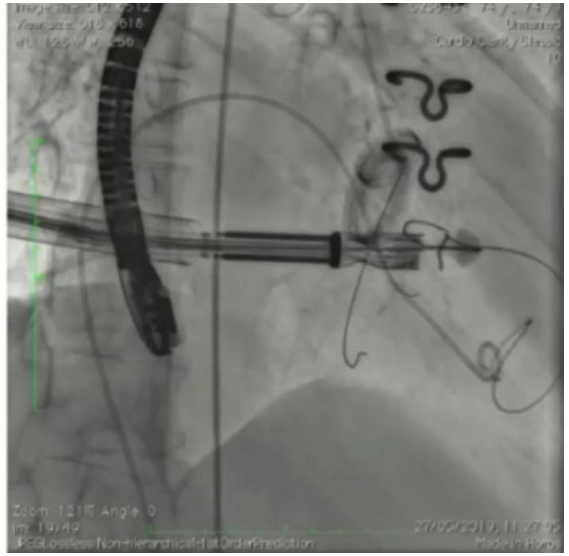


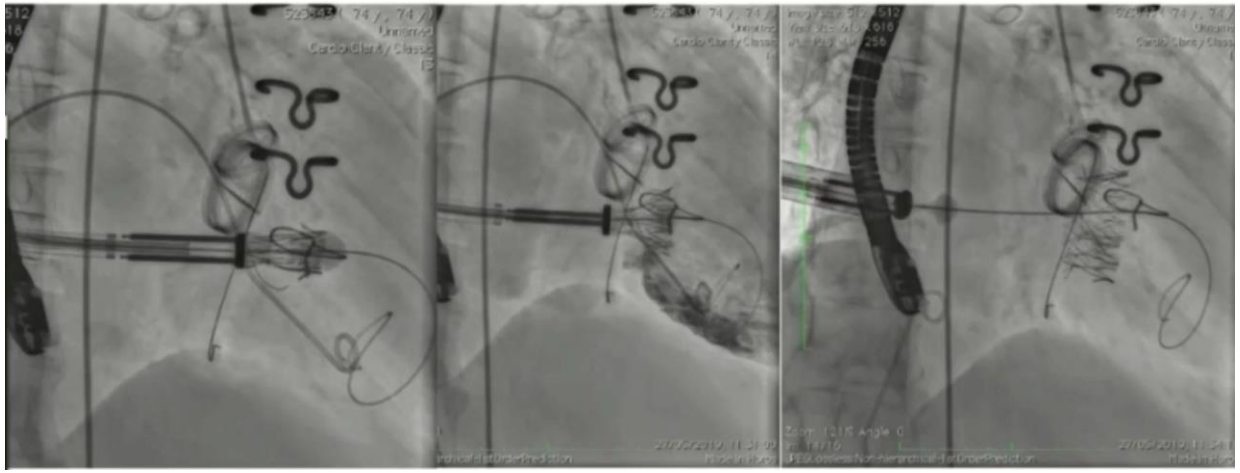
- **35 Fr distal capsule**
- **Transyugular 42Fr**
- **Requires a 14-15mm IVY**
- **70 deg articulación**
- **Pericardio equino**
- **36mm,40mm,44mm,48mm,52mm**

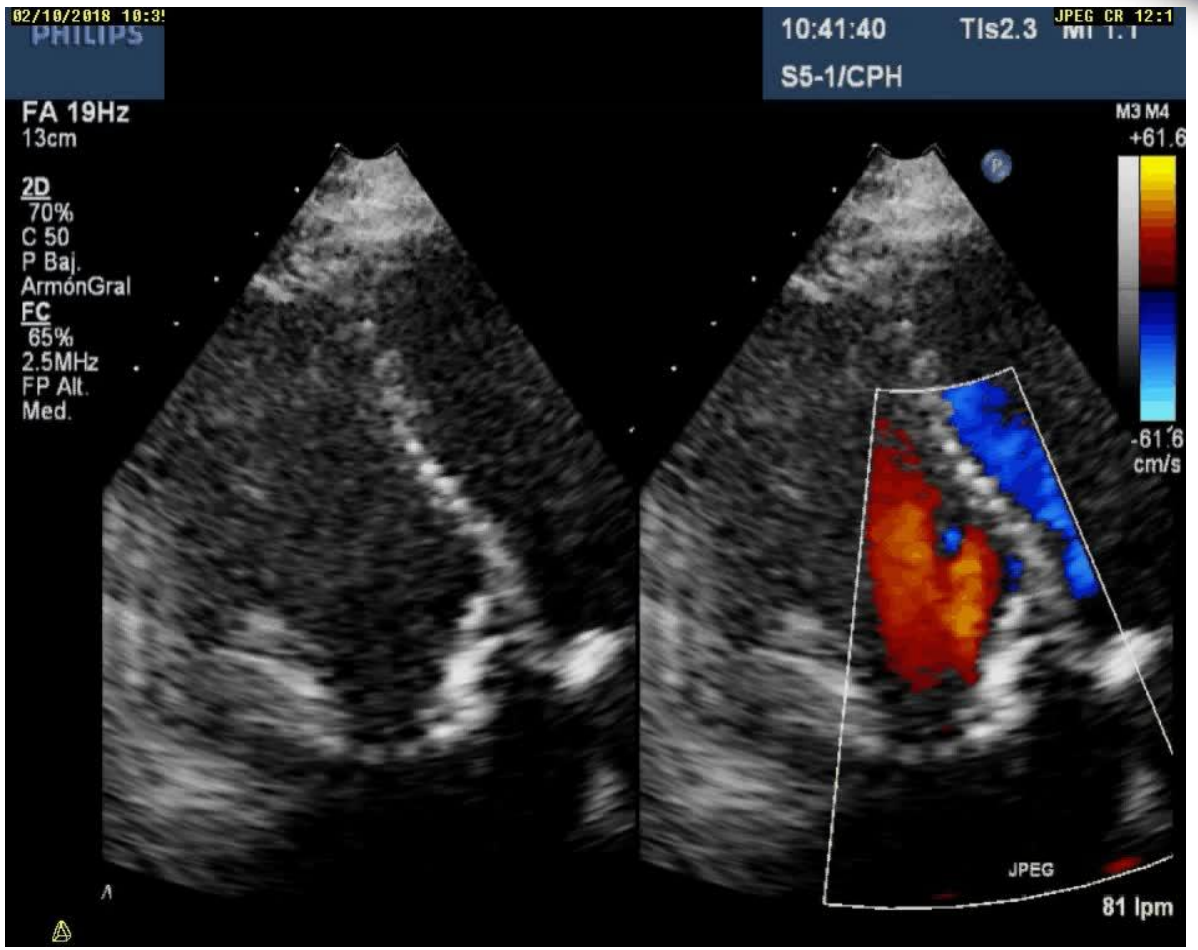
Estevez-Loureiro et al. Rev Esp Cardiol 2019

NAVIGATE









Estevez-Loureiro et al. Rev Esp Cardiol 2019

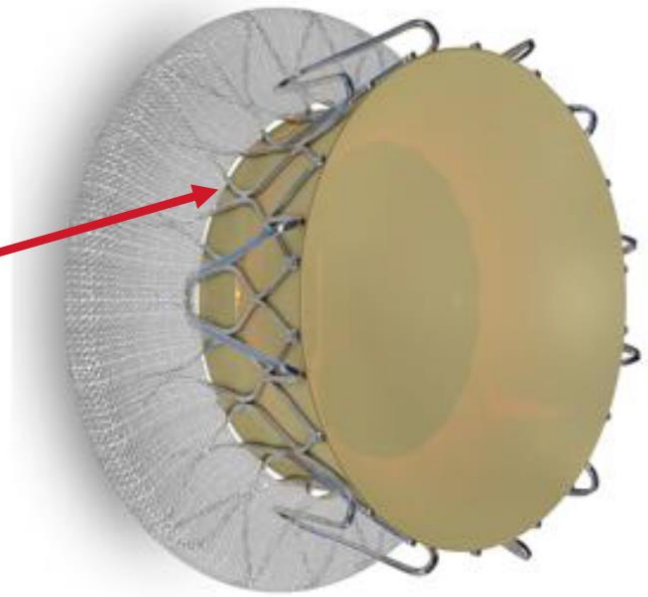
Trisol Valve – Unique Design

Addresses the Special Anatomy of the Tricuspid Annulus

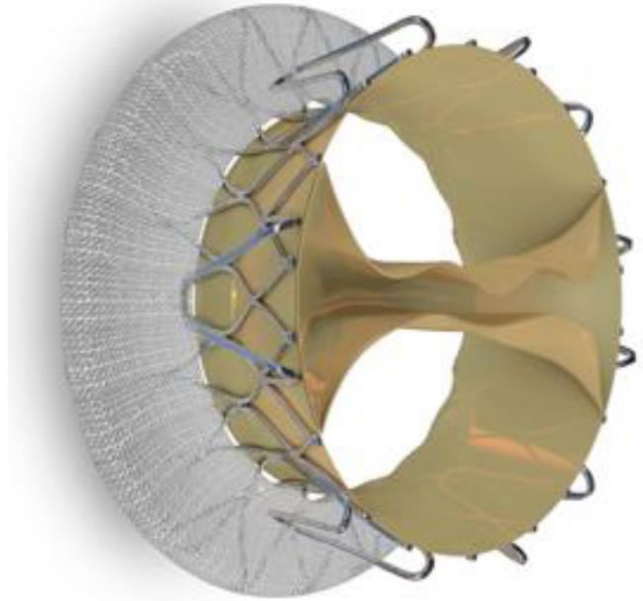
- Axial anchoring
- Large diameter
- Low profile

Dome-shaped Leaflet allows large diameter/low profile valve with augmented RV closing volume

Systole



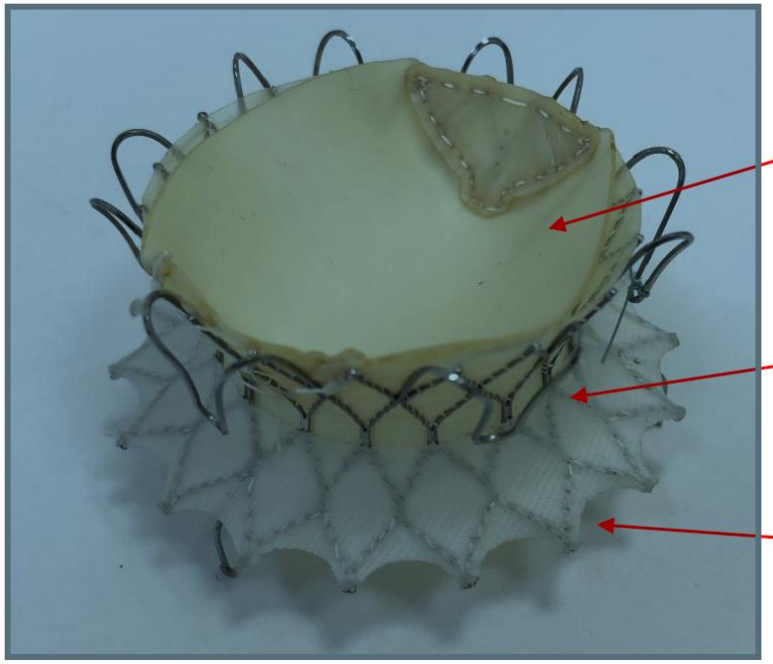
Diastole



TRISOLMEDICAL

Trisol Valve – Unique Design

- Conical shape for max leaflet coaptation
- Mono leaflet (higher closing volume)
- Support arms sandwich effect
- Frame conforming to native anatomy



Leaflet:
Bovine
pericardium

Ventricular skirt:
Porcine pericardium

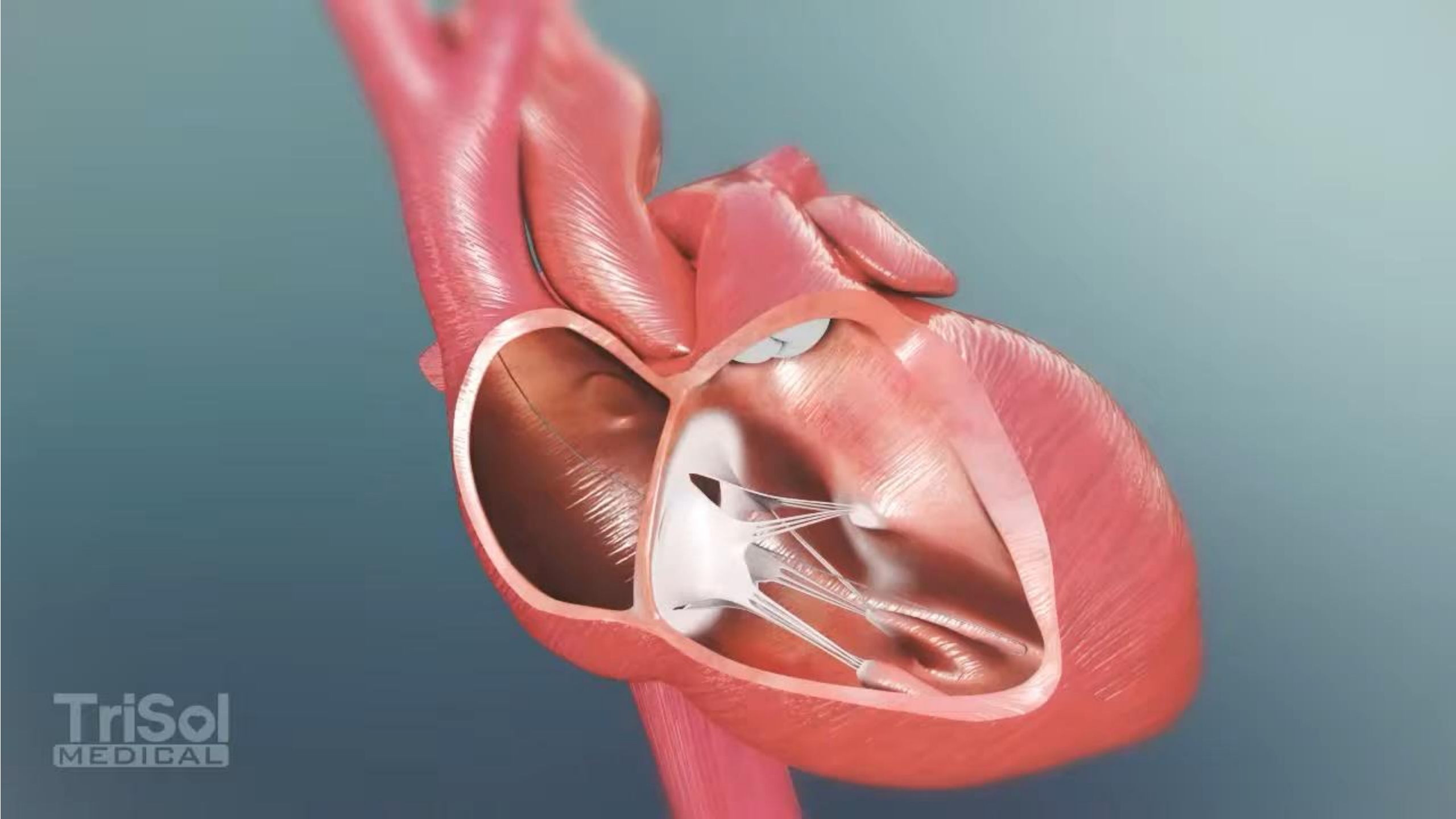
Atrial skirt:
Polyester

Frame

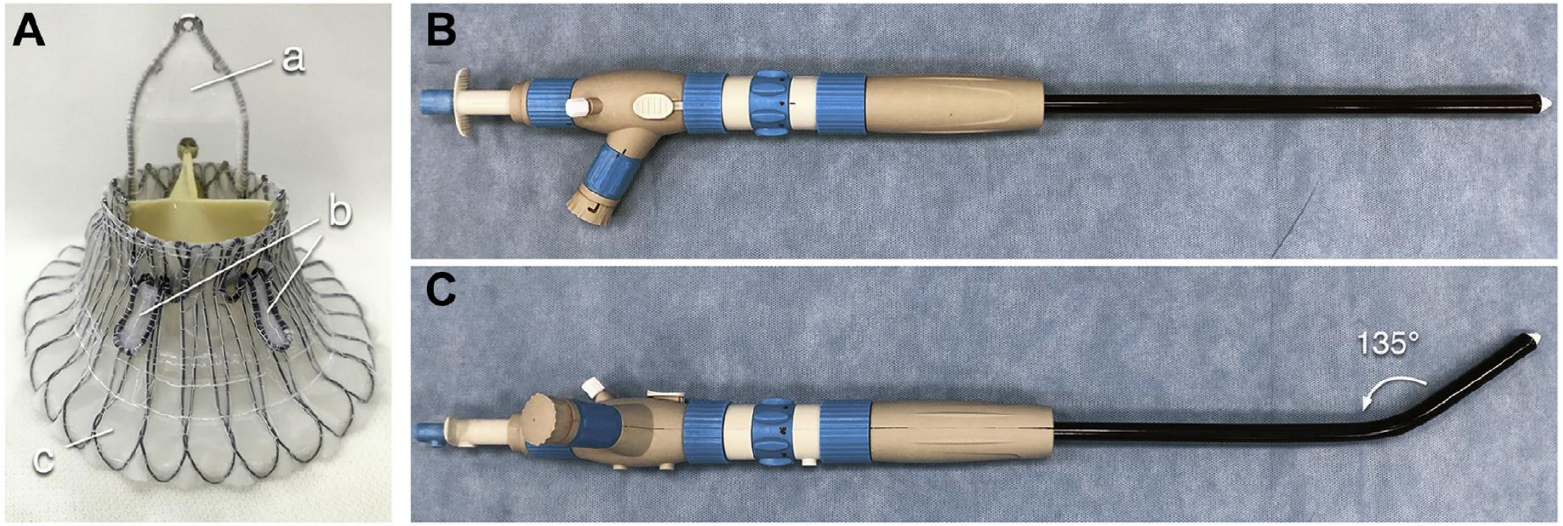
- Nitinol self-expanding stent
- Conforms to native anatomy
- Conical shape for max leaflet coaptation
- Anchor arms with sandwich effect

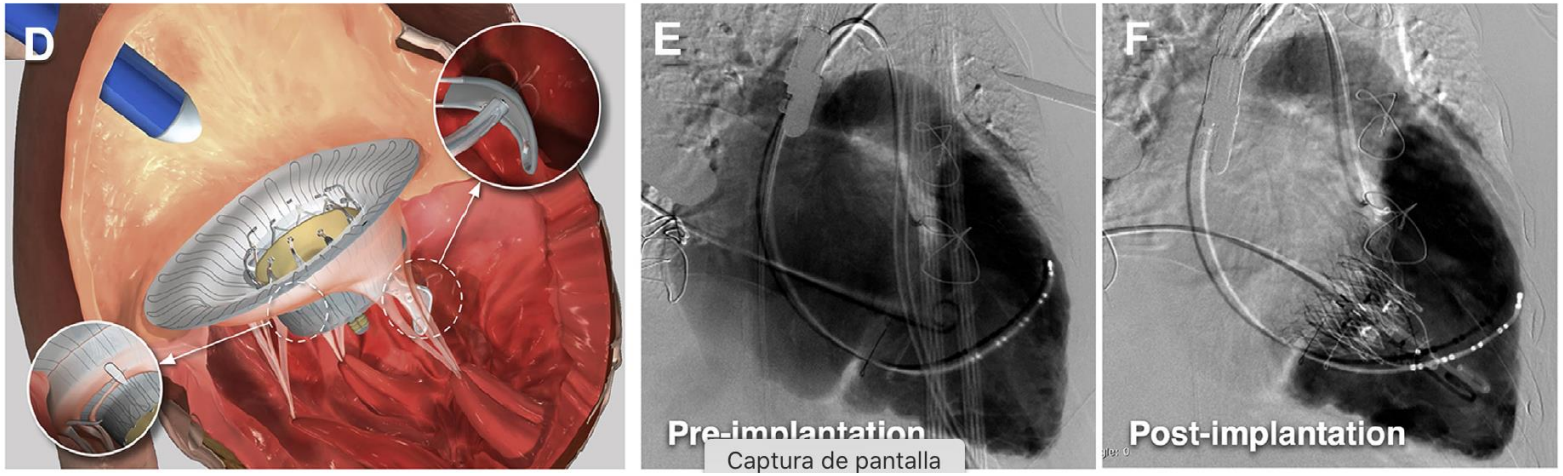
Delivery system

- Trans Jugular vein
- 30 Fr
- Steerable
- Retrievable, repositionable


TriSol
MEDICAL

LUX

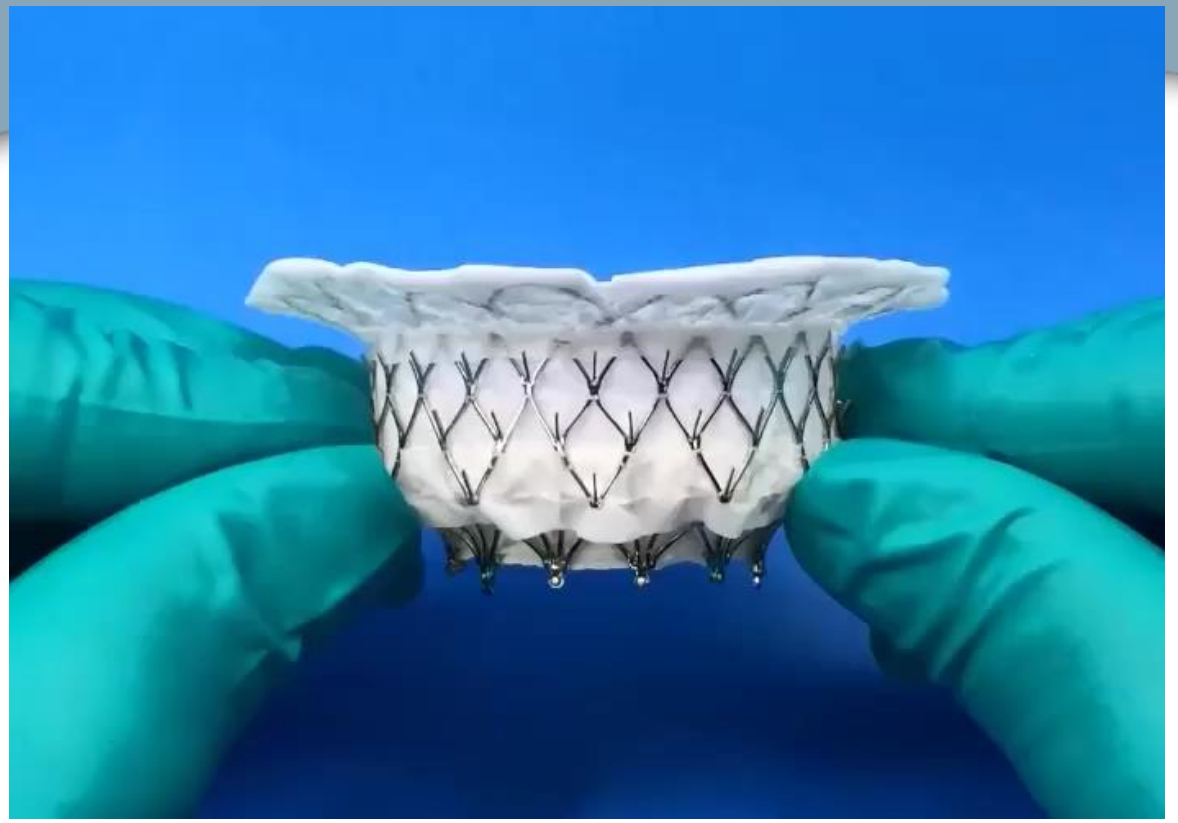


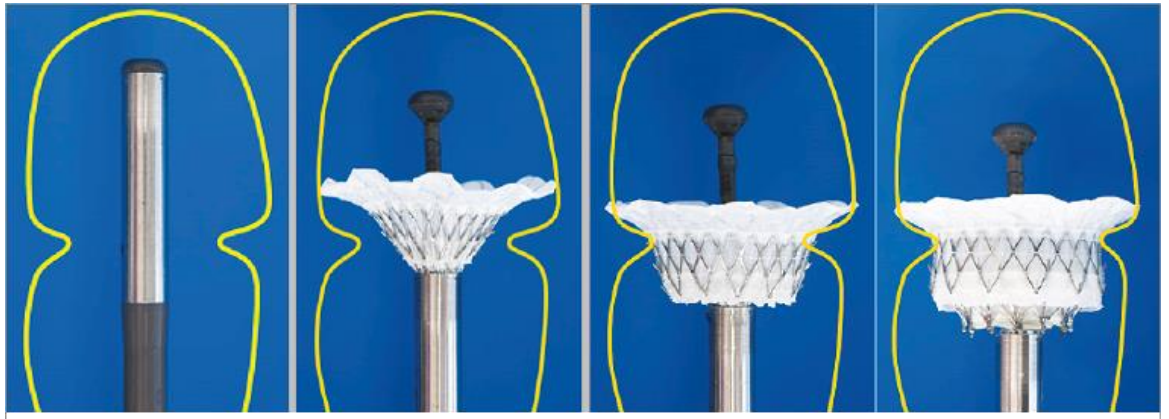


Captura de pantalla

-Trileaflet prosthetic valve bovine pericardium
-Self-expandable nitinol valve stent consisting of an atrial disc
-1 interventricular septal anchor “tongue”
-2 expanded polytetrafluoroethylene-covered graspers
32-F catheter through a minimally invasive right thoracotomy and transatrial approach

INTREPID



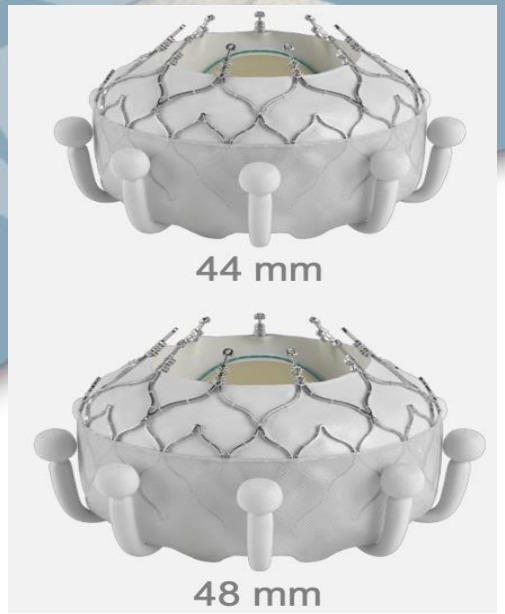


Step 1. Advance into left atrium.

Step 2. Expand brim and align with annulus target.

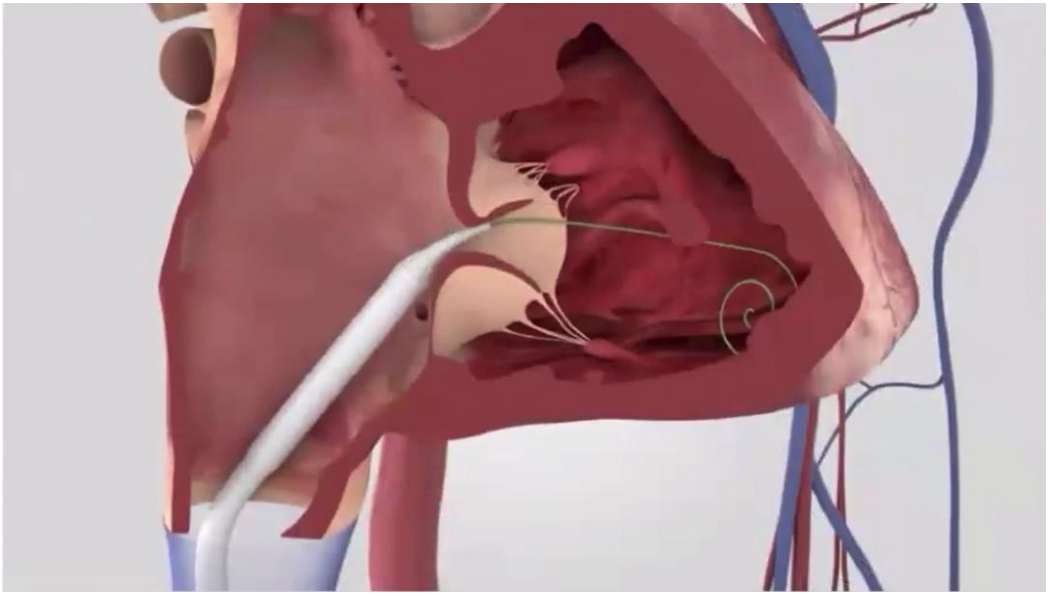
Step 3. Retract to annulus target and deploy the valve.

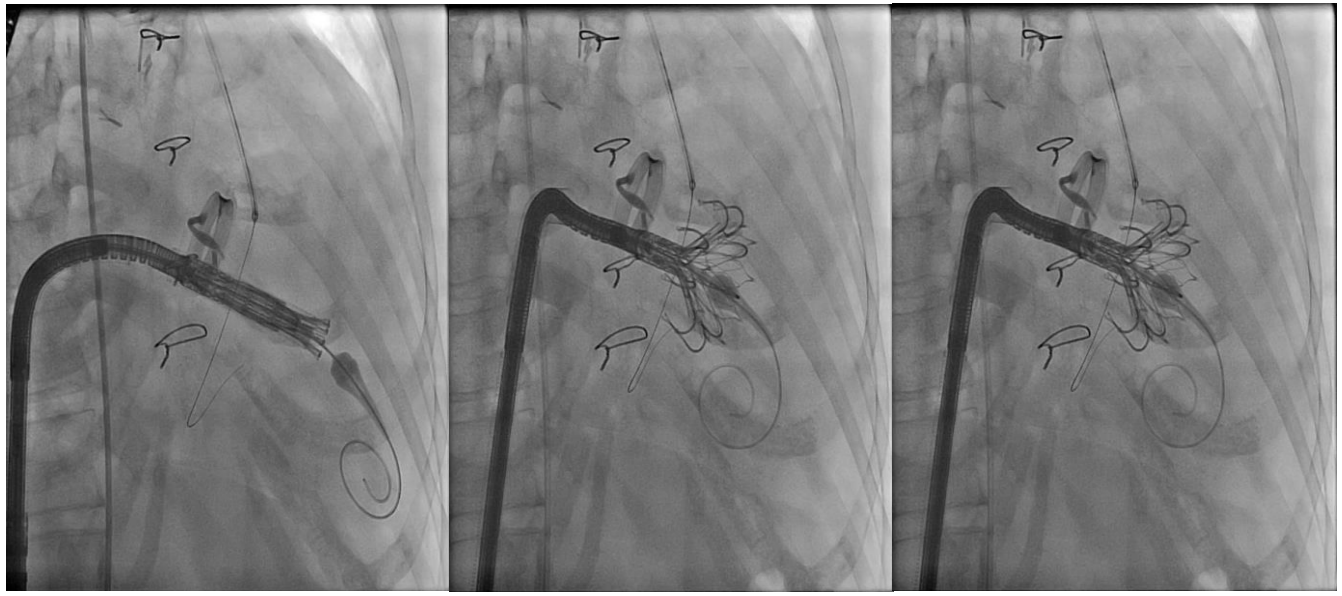
EVOQUE



The EVOQUE valve

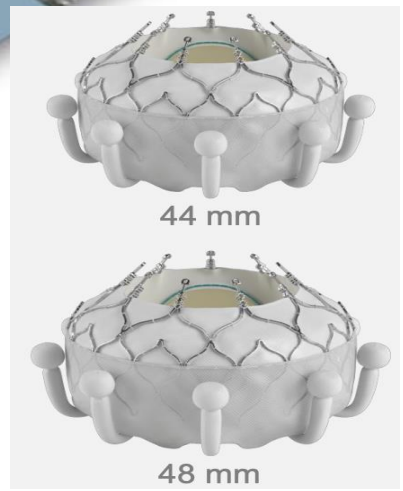
28F EVOQUE transfemoral system





EVOQUE

25 pacientes sintomáticos con IT sev en 6 hospitales



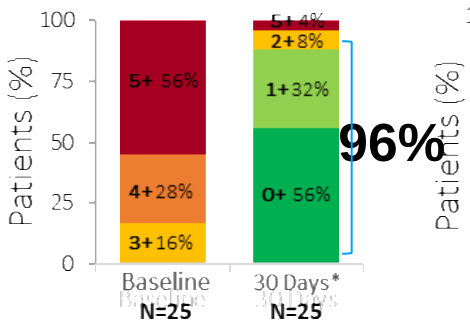
Institution
St. Michael's Hospital, Toronto, Canada
St. Paul's Hospital, Vancouver, Canada
Columbia University Medical Center, New York
Universitaetsklinikum Mainz, Germany
Ludwig-Maximilians-Universität München, Munich, Germany
The Heart Hospital Plano, Plano, Texas

Procedural results	N=25
Technical success - 1 unsuccessful procedure due to non-coaxial approach - 1 low placement requiring valve-in-valve (SAPIEN 3, Edwards Lifesciences)	92%
Delivery system insertion to removal, minutes; mean (min, max)	68 (37, 101)

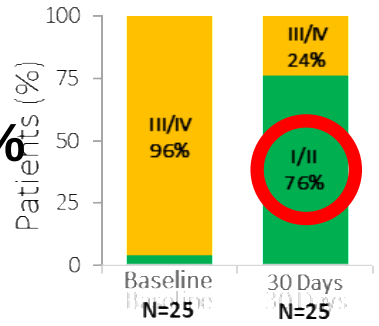
30 day results

Safety profile	N=25
Mortality	0%
Myocardial infarction	0%
Stroke	0%
Reintervention	0%
HF hospitalization	0%
Renal failure requiring dialysis	4%
Device embolization	0%
Conduction system disturbance requiring PPM	8%

TR severity



NYHA functional class

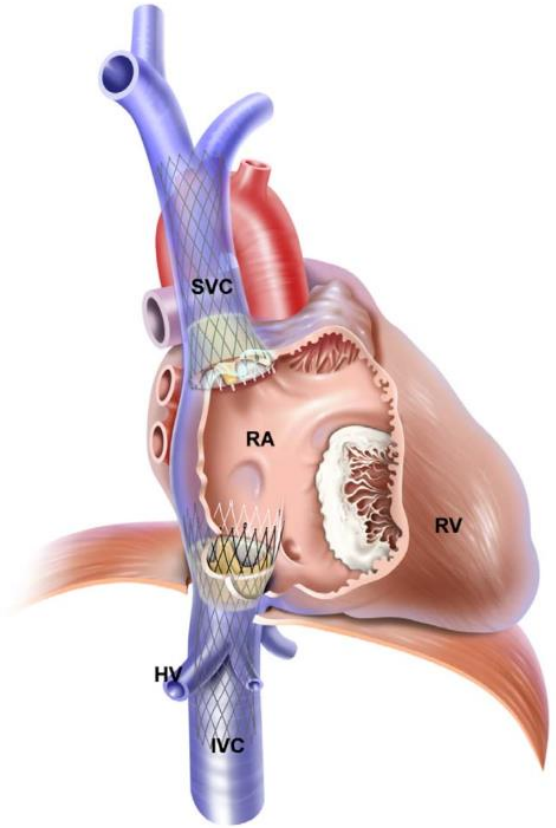


*Mean TV gradient: 3.2 ± 0.6 mmHg

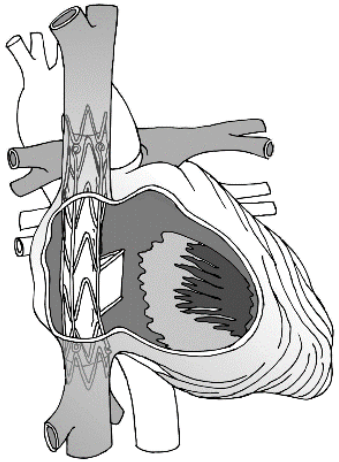
Fam et al. JACC Cardiovasc Interv 2021;14:501-511

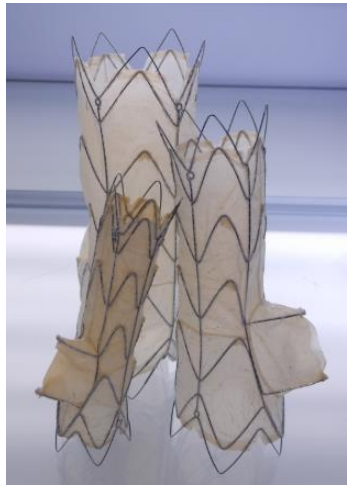
Reemplazo valvular heterotópico

TricValve

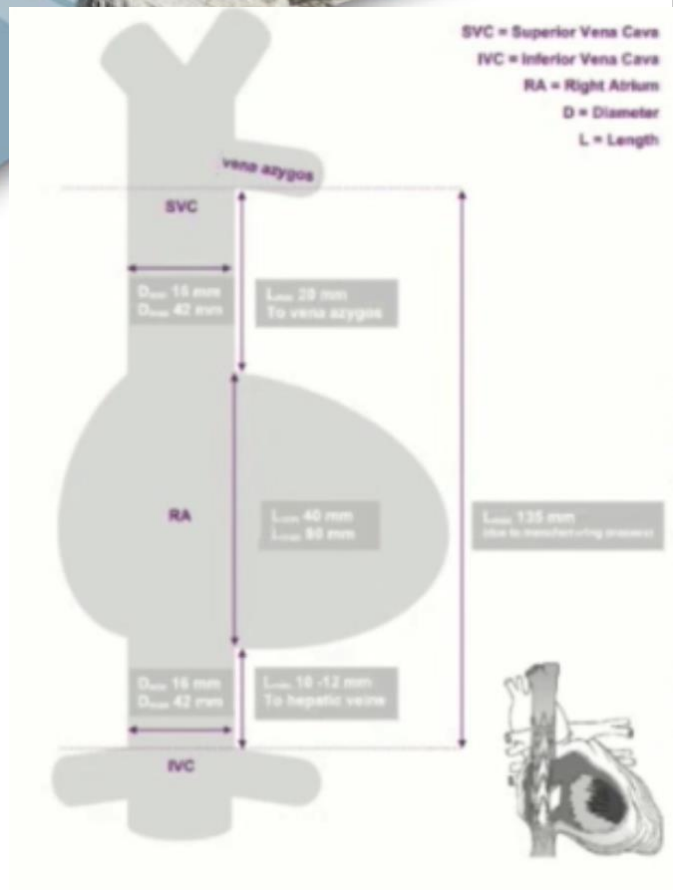


NVT TriCento

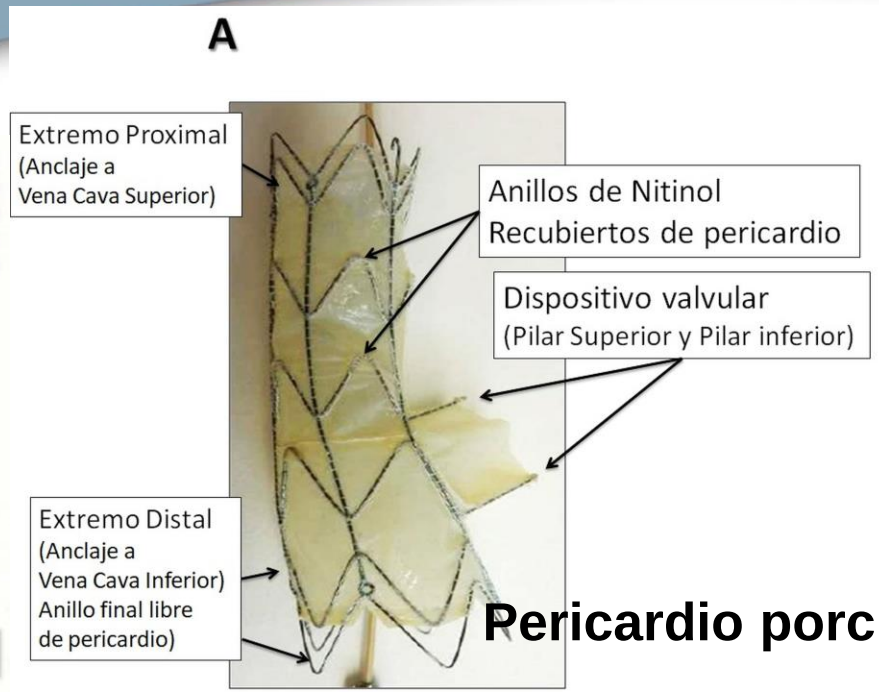




Tricento



A



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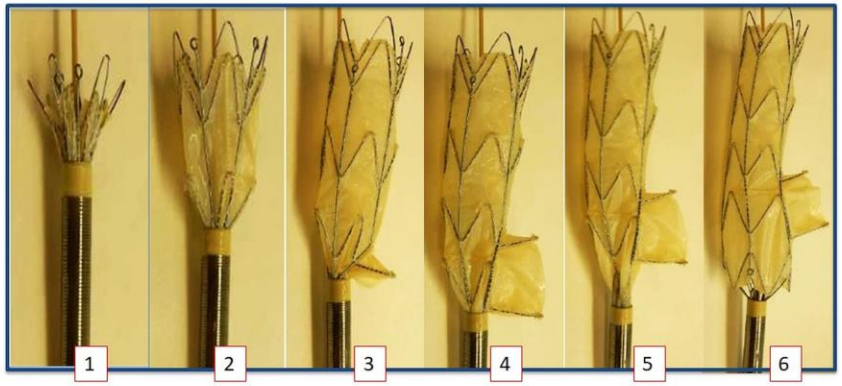
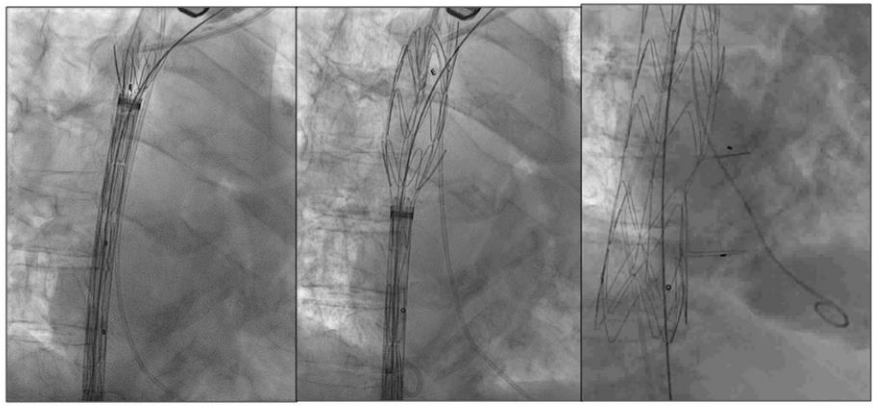
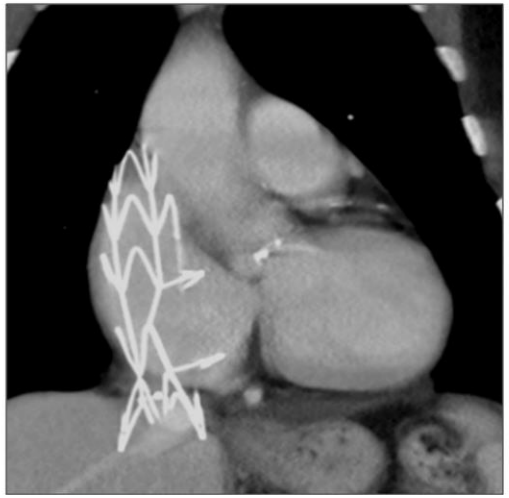


Pericardio porcino

C



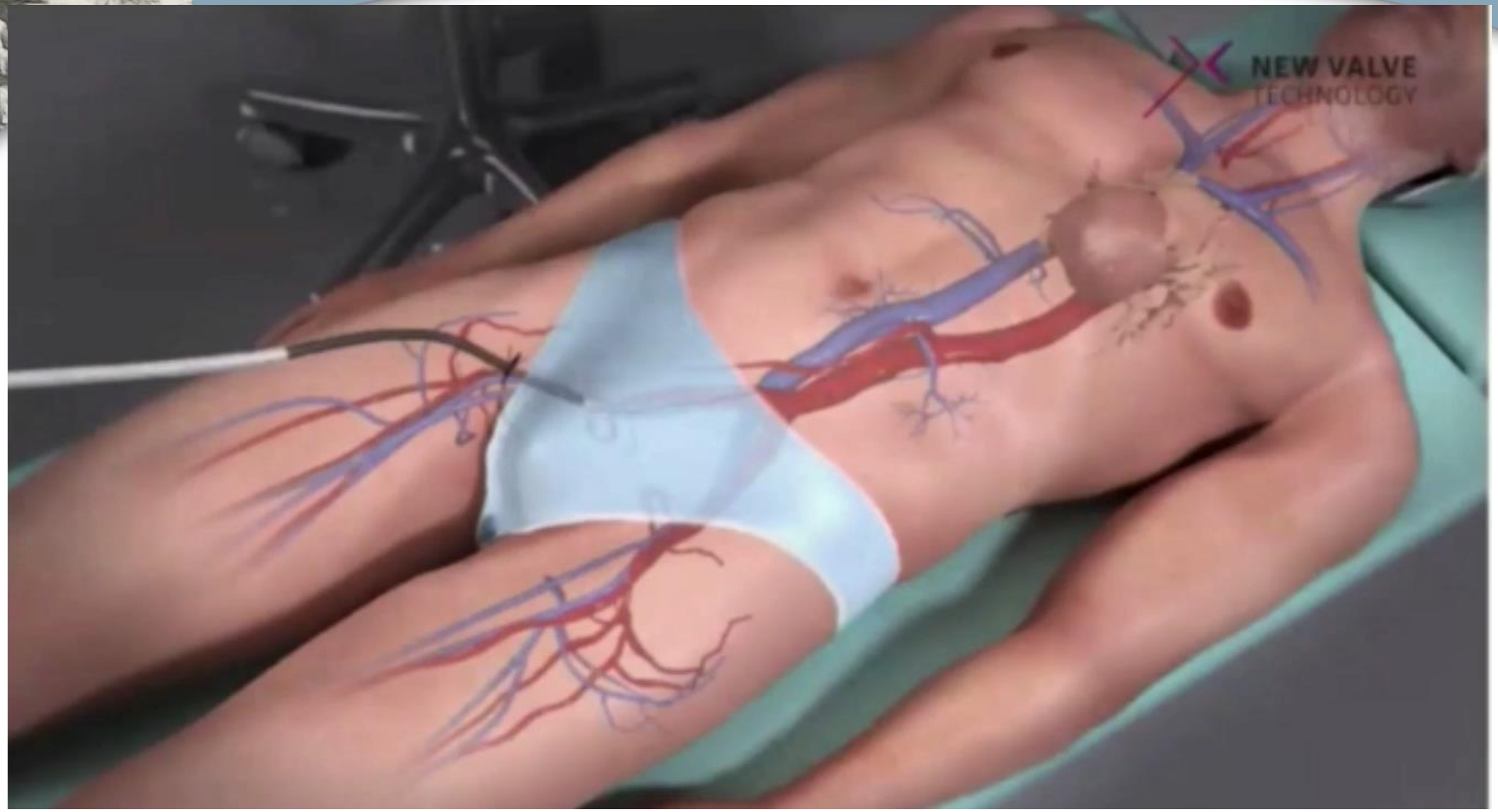
D



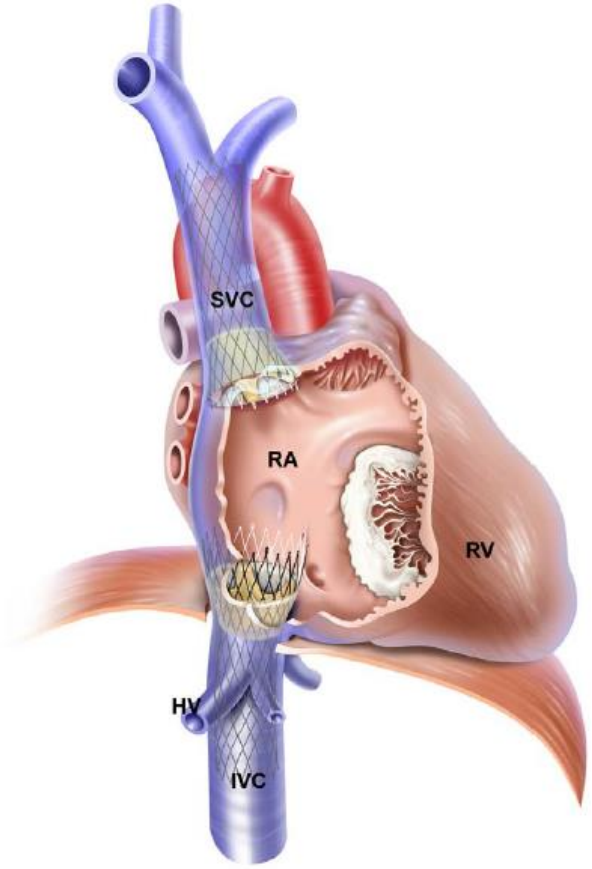
Iñiguez et al. REC 2019

4Doctors

AsociaciónEpic

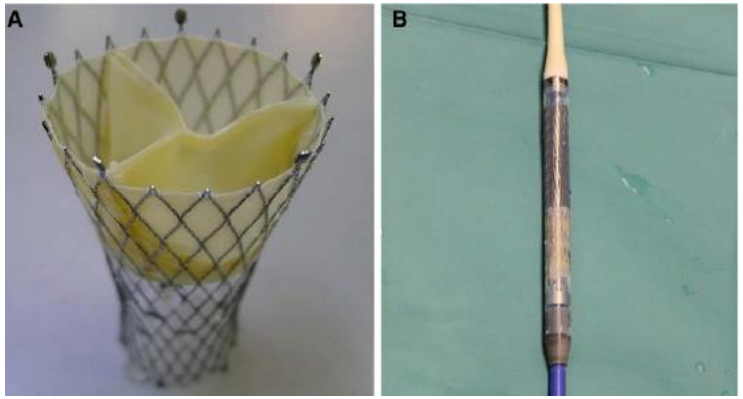

NEW VALVE
TECHNOLOGY

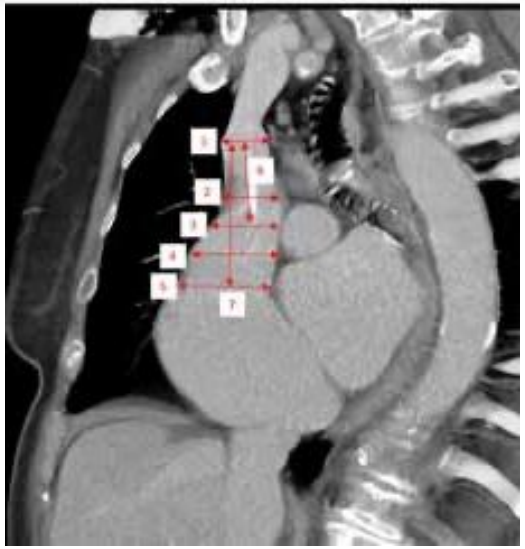
TricValve

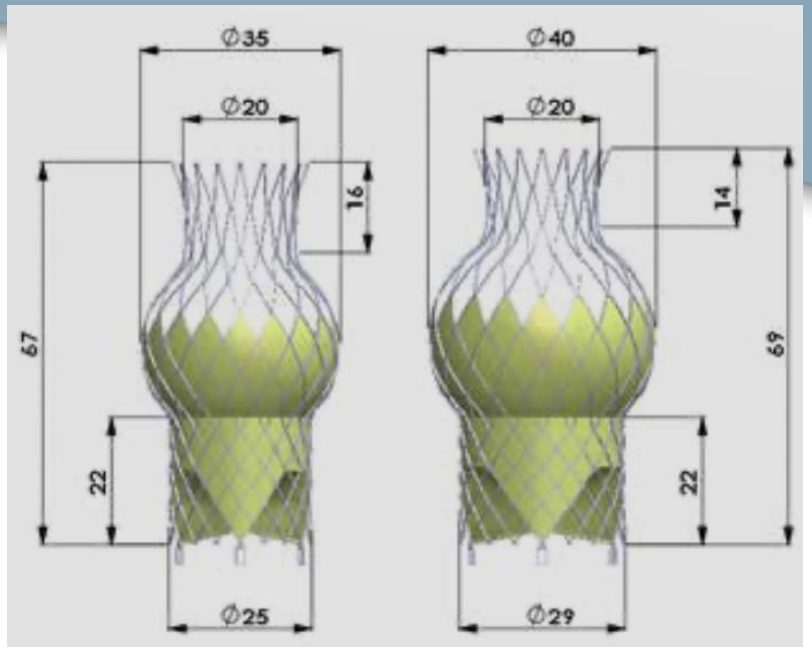


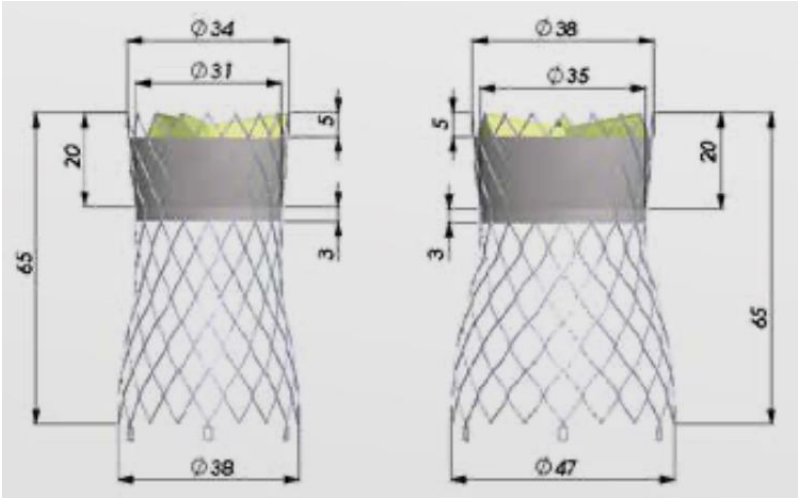
Valvula pericardio bovino

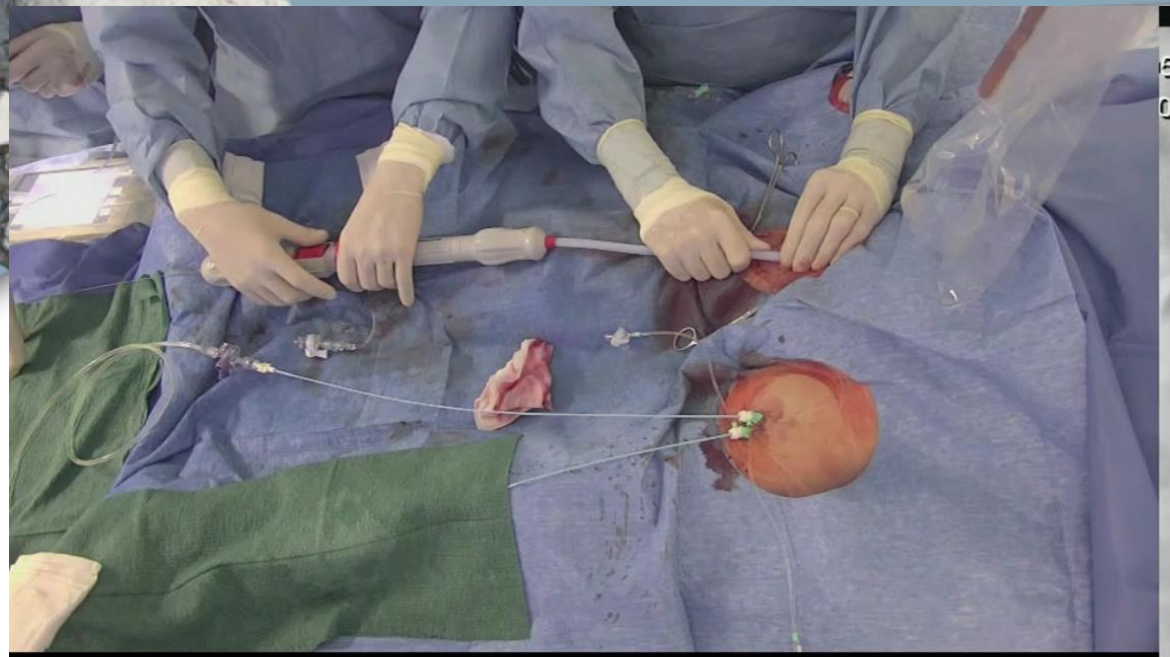
Vaina liberación 27 F

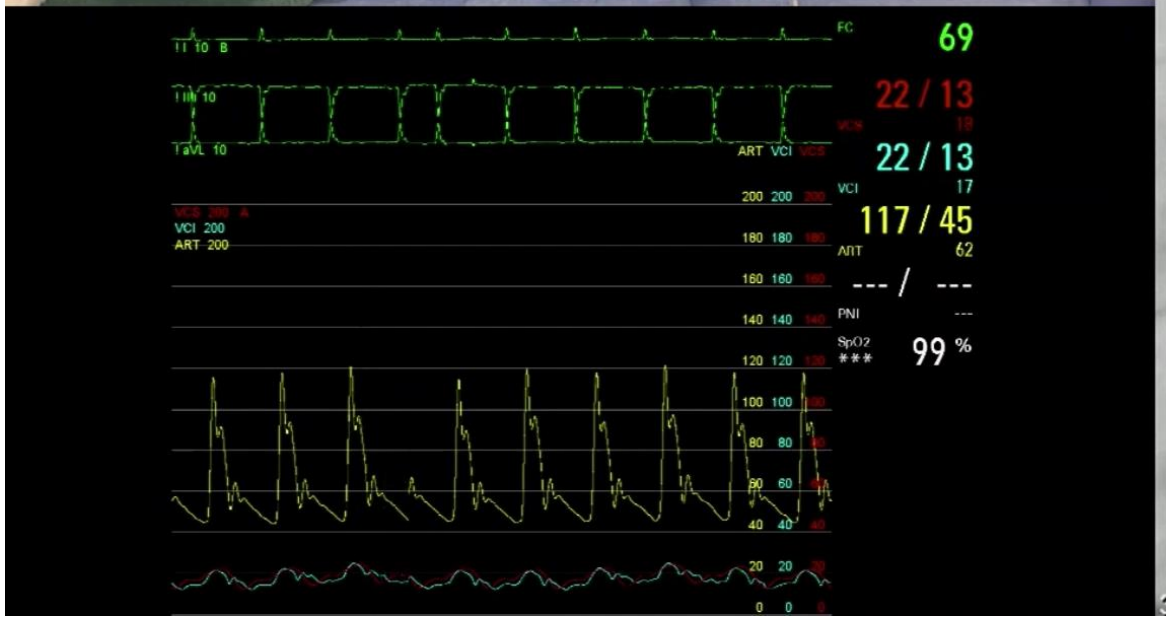




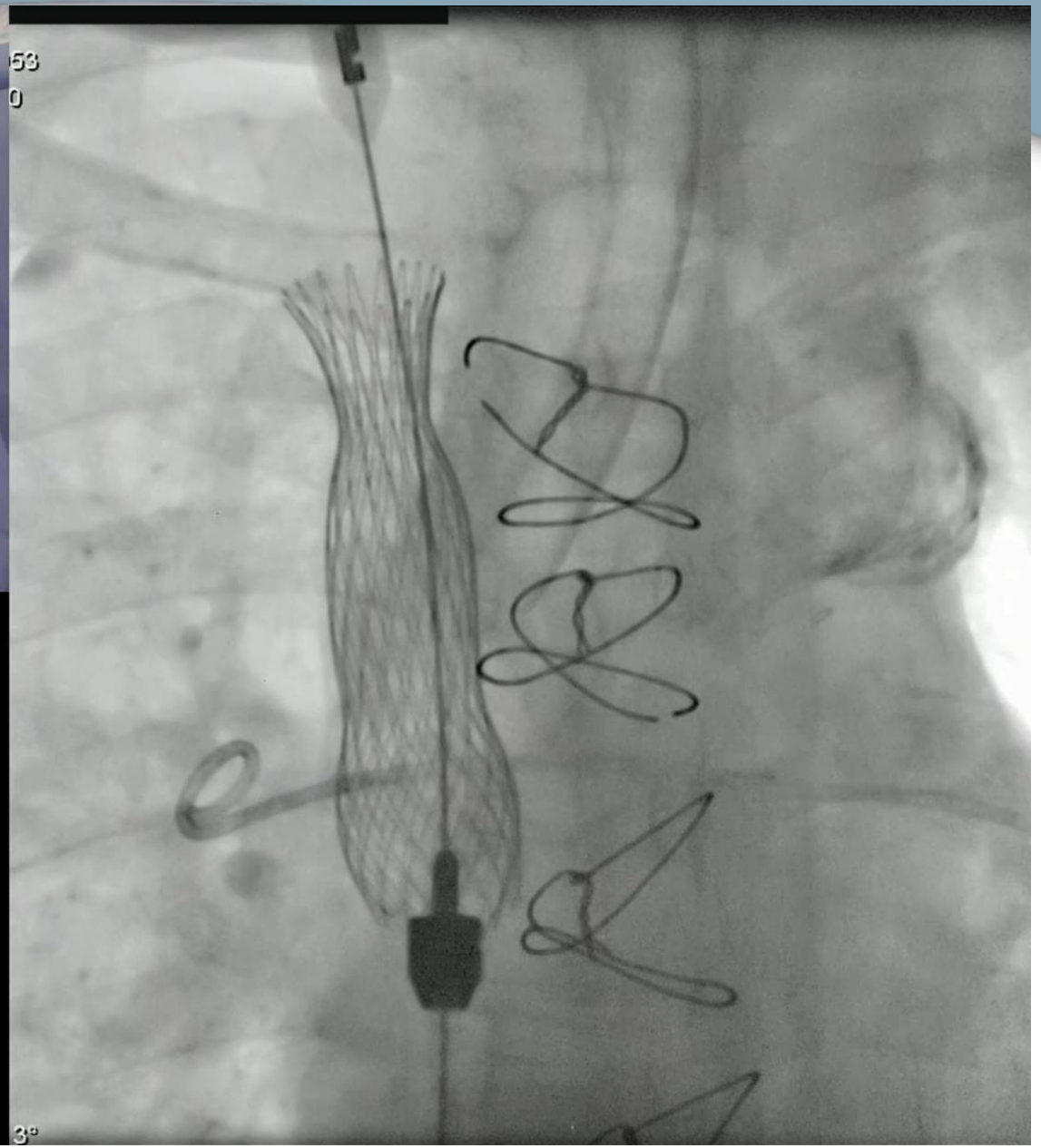


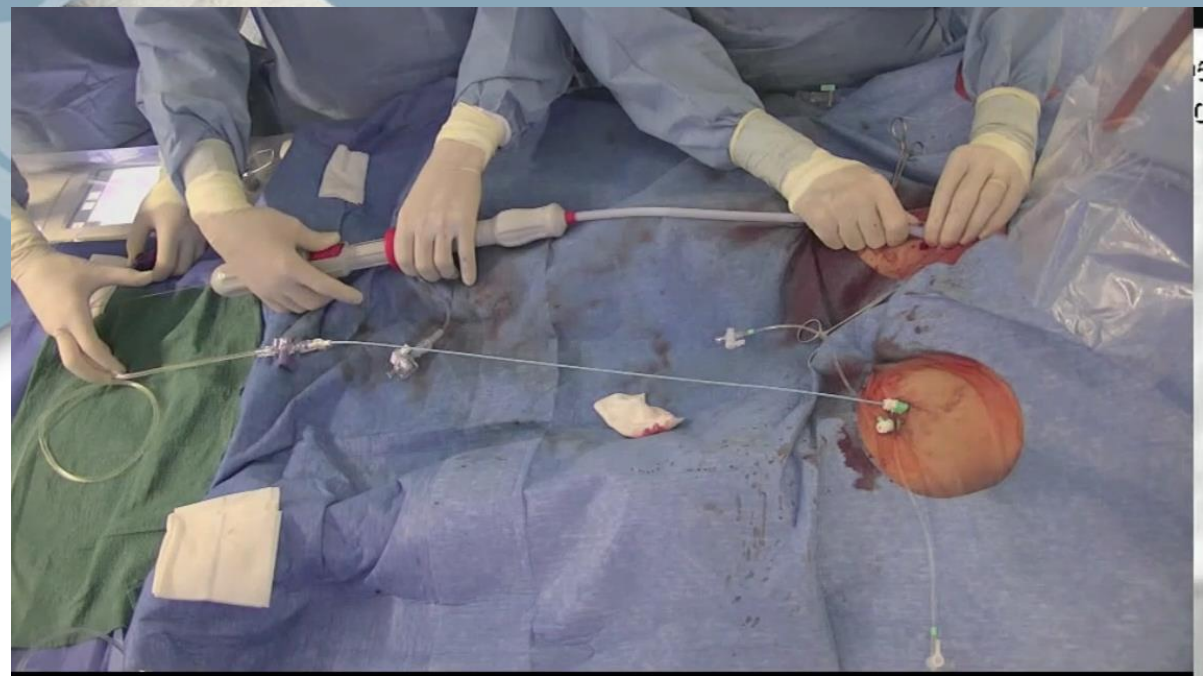




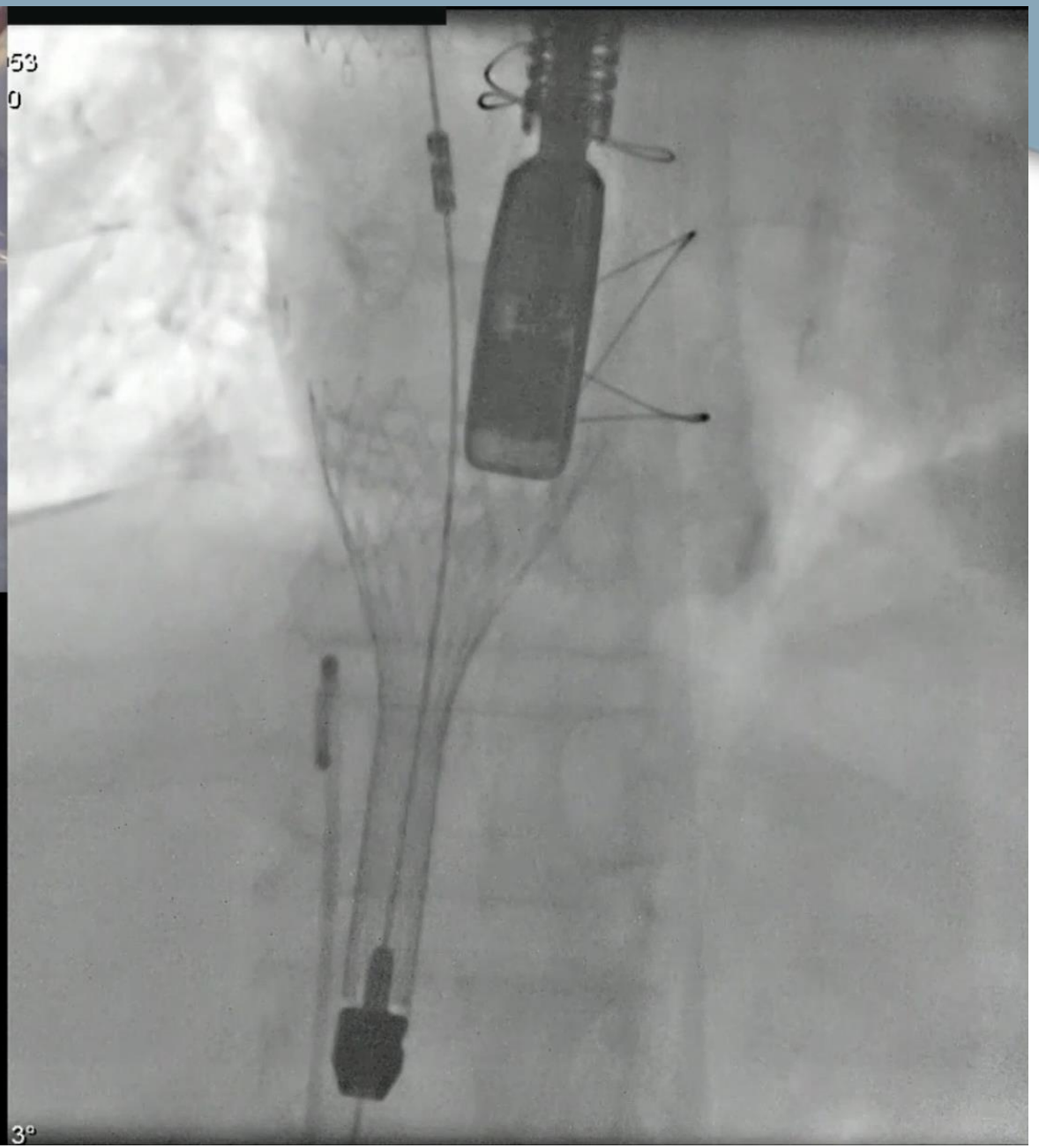

II 10 B
III 10
aVL 10
ART VCI
VCS 200
VCI 200
ART 200
FC
69
22 / 13
VCS
18
22 / 13
VCI
17
117 / 45
ART
62
--- / ---
PNI

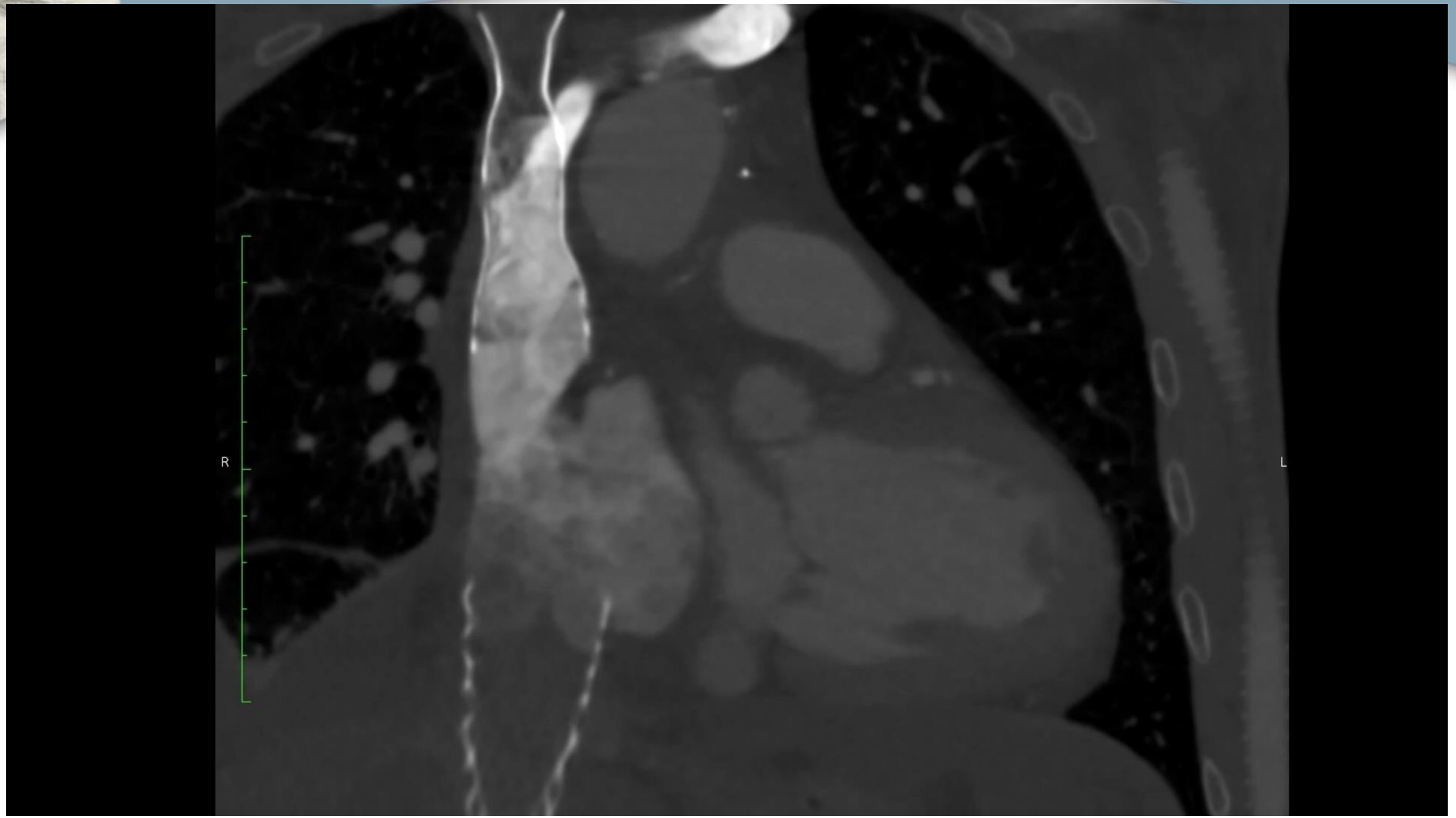
SpO2
***
99 %

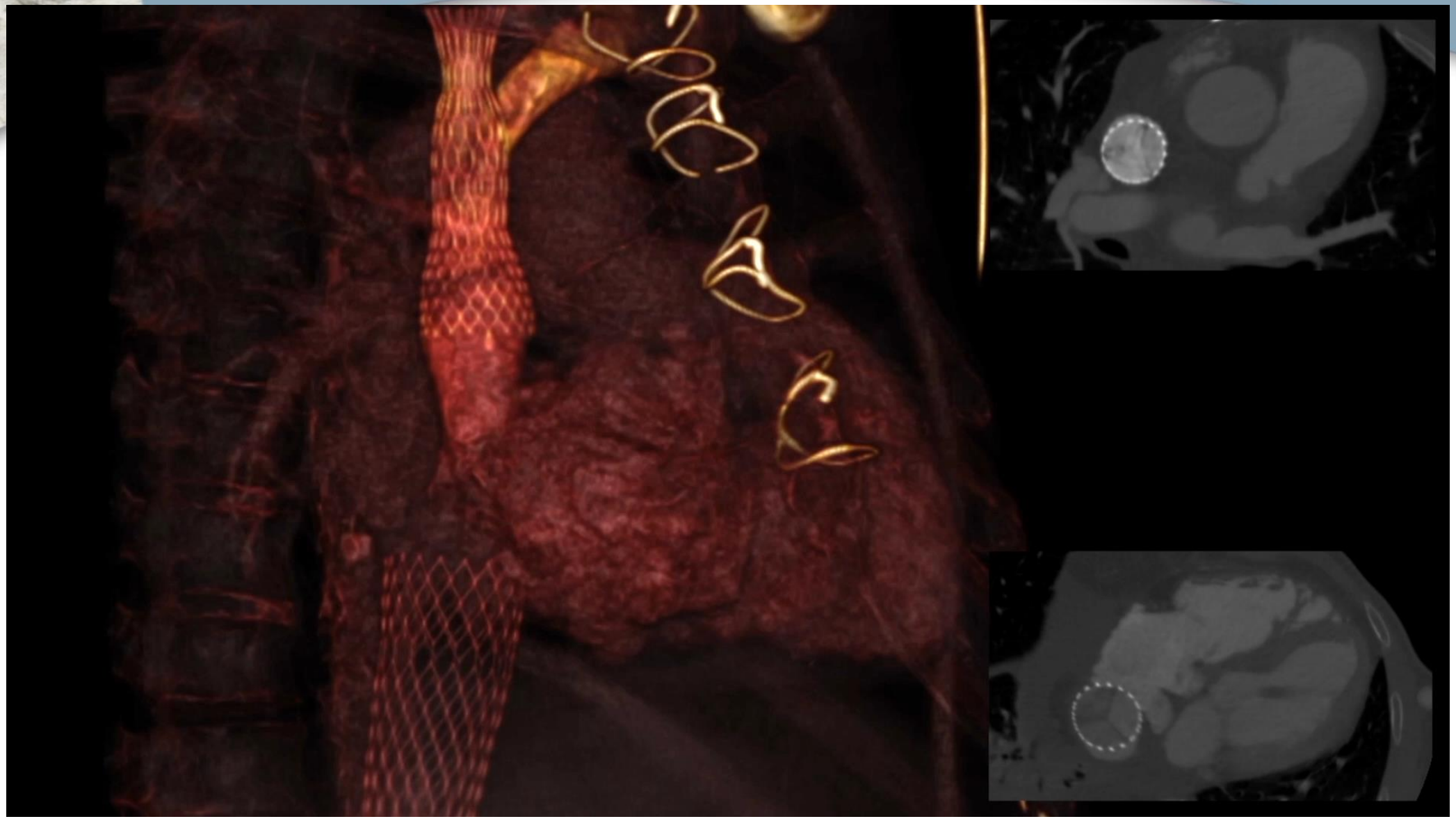

53
0
3°




H.U.BELLVITGE
17/12/2020 11:14:18
6VT
Cardiaco_U
MI 0.6
TIs 0.5
HR 65
38.2°


3ª


R
L



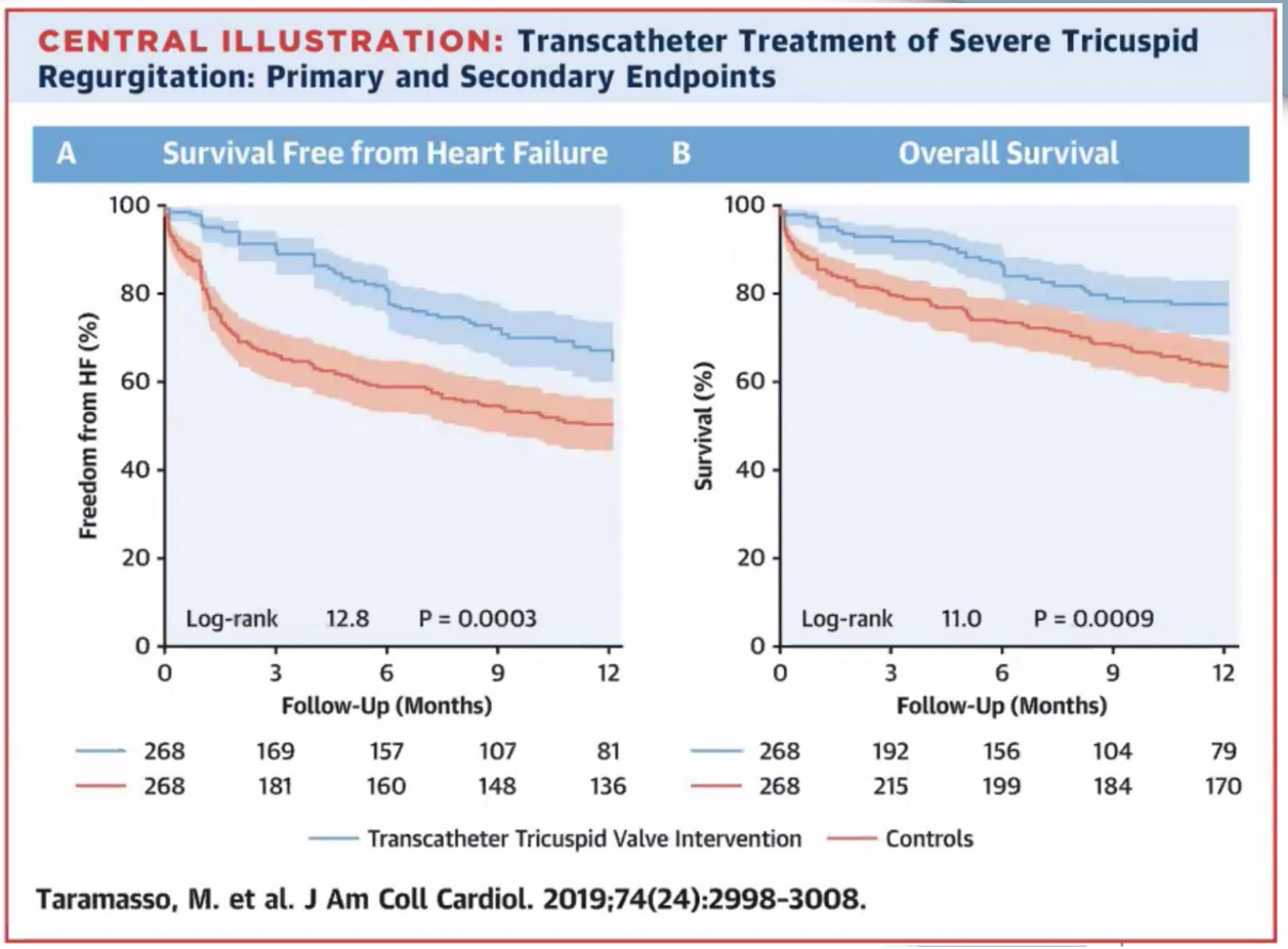
TTVT vs Tto médico

No RCT Cirugía vs Tto médico

No RCT Tto percutáneo vs médico

Estudio *"propensity matched case control"*
472 pac TTVT
1179 pac Tto medico

En 268- pareados
Menor mortalidad (23% vs 36%)
Menor re-hospitalización
(26% vs 47%)



Conclusiones

Registros - dispositivos percutáneos reparación/reemplazo VT excelente seguridad y eficacia

Heart team: selección de pacientes y ”timing” para intervención – fundamental IT

Mecanismo de la IT y estadío de la enfermedad – selección de la terapia

Mismatch entre reducción de la IT y beneficio sintomático

Grado IT residual se relaciona con la mortalidad

Estudios aleatorizados actualmente en marcha - posible superioridad sobre tto médico

recalde@secardiologia.es