Tricuspid regurgitation .
Orthotopic - Heterotopic intervention.

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Marco Conceptual

- La IT aumenta con la edad, 4% de los pacientes con 75 años, mas fcte en mujeres
- Aumenta el riesgo de eventos CV y Muerte a largo plazo.
- La IT functional es la más frecuente – debido a remodelamienteo y disfunción de las camaras derechas – genera dilatación del anillo tricuspídeo y disfunción con o sin afectación de las valvas.

Marco Conceptual

- La mayoría de los casos de IT son de causa **secundaria** (estructura valvular normal)
  - alteraciones en la aurícula derecha
  - del anillo tricuspídeo
  - del ventrículo derecho,
- La IT **primaria** (5-10% de los casos): **enfermedad valvular:** anormalidades congénitas, endocarditis infecciosa, enfermedad reumática, síndrome carcinoide, tumores, trauma o degeneración mixomatosa

Marco Conceptual

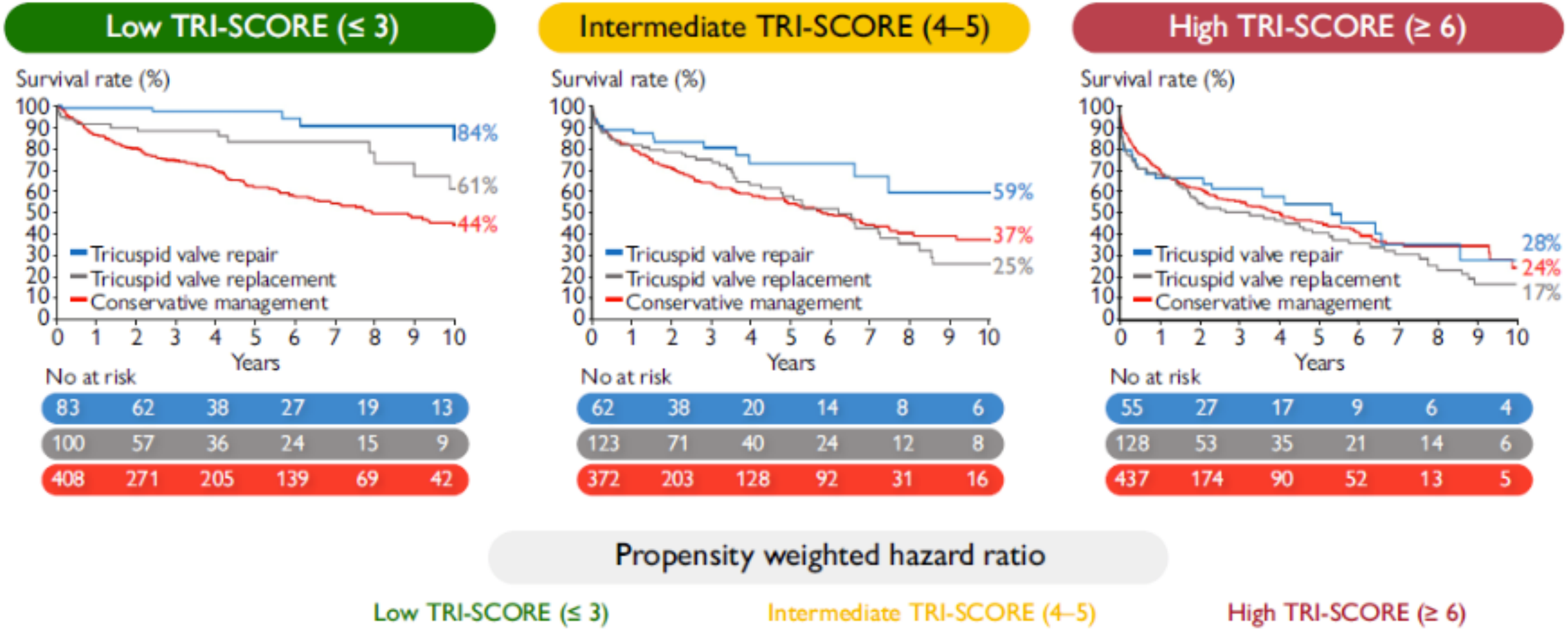
- **La *IT secundaria auricular***
  - Dilatación del anillo valvular y de la AD, con una estructura y función del VD conservada
  - Asociada a FA, FEY conservada y ausencia de valvulopatías izquierdas.
- **La *IT secundaria ventricular***
  - Dilatación del VD, tracción de las valvas y su falta de coaptación.
  - Asociada a hipertensión pulmonar, miocardiopatías del VD, infarto del VD.
  - Puede asociarse a disfunción del VI o valvulopatías izquierdas

Marco Conceptual

- Ecocardiograma: estudio diagnóstico de elección en el inico de la evaluación
  - Severidad de la regurgitación
  - Anatomia de la valvula
  - Función del VD
- TMS y cateterismo de ventriculo derecho se utilizan para planificación de tratamiento y seguimiento de la evolución

Marco Conceptual

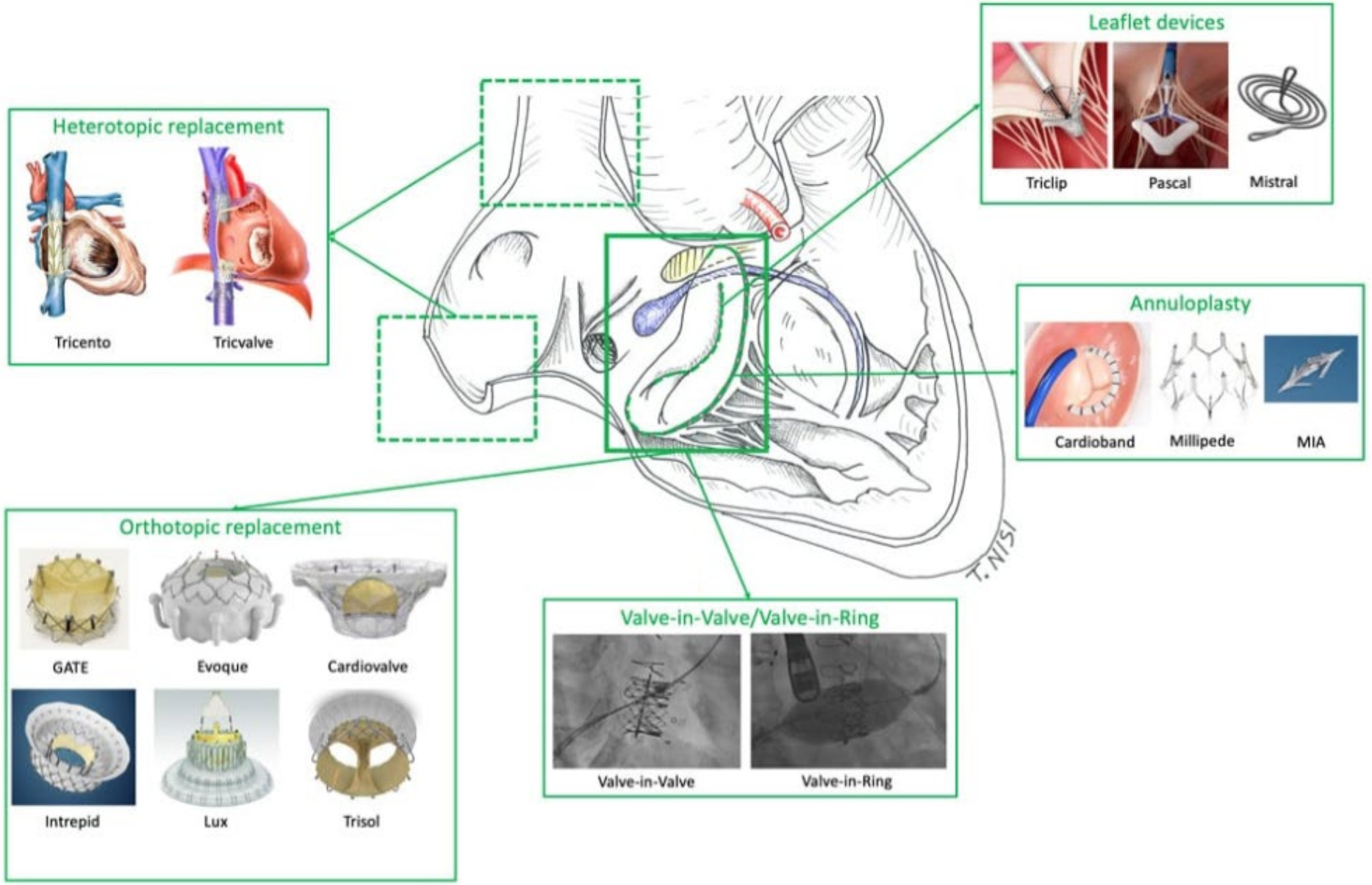
TRIGISTRY: 1768 pacientes, 1217 tto medico, 551 cirugía aislada de valv tricúspide.
Resultados de la reparación vs recambio vs tto medico de acuerdo a los tercilos de riesgo

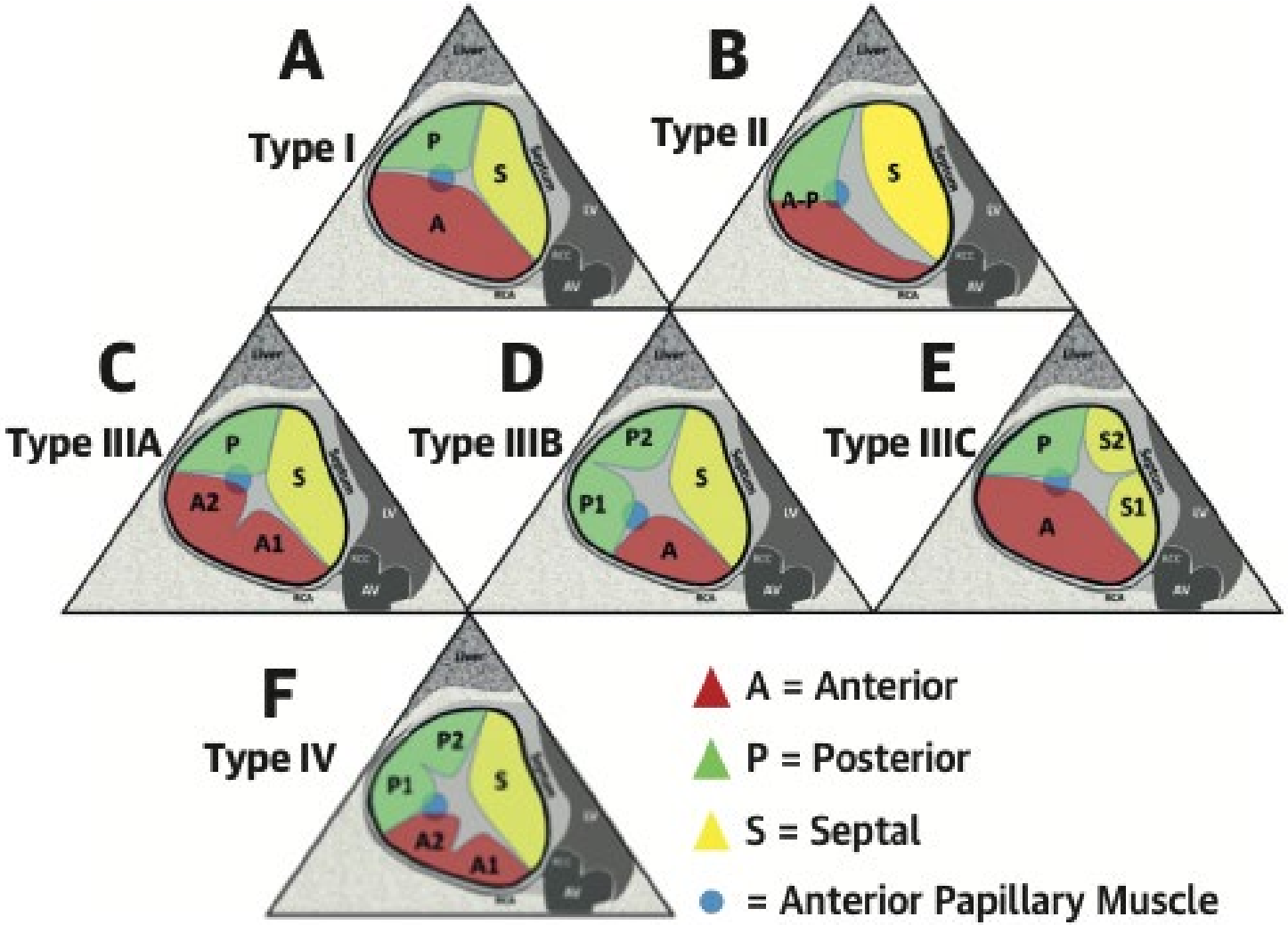


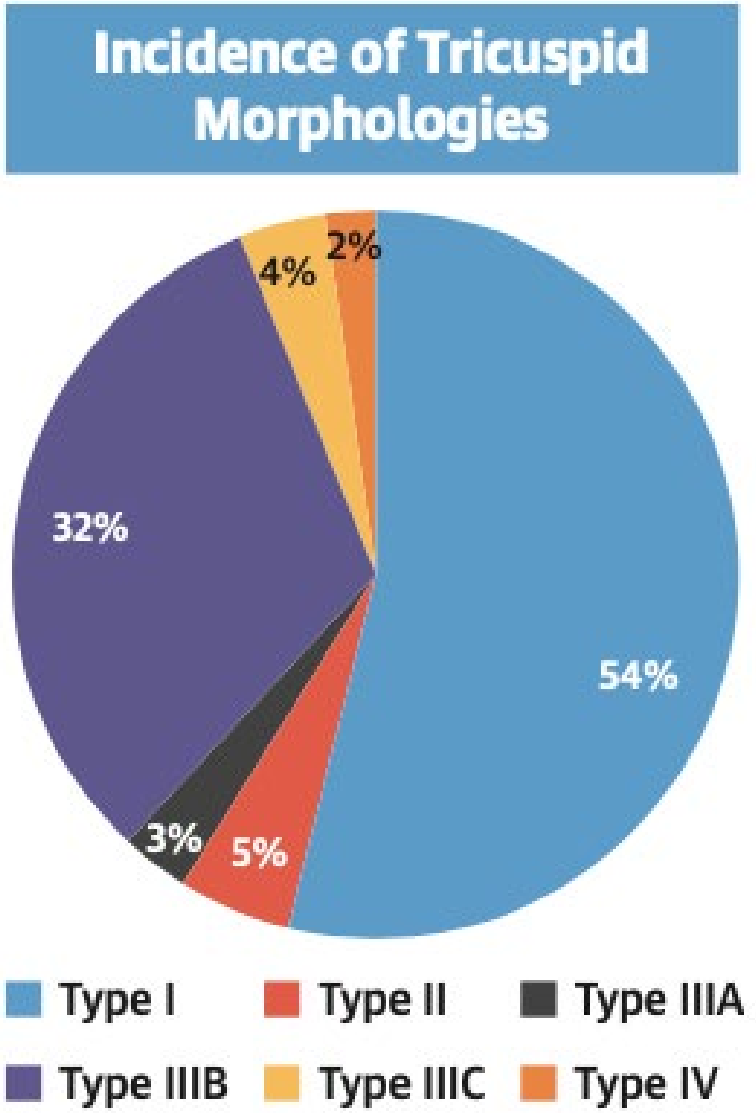
Marco Conceptual

- Numerosas y varias terapias endovasculares estan disponibles, teniendo diferentes objetivos
  - Aproximación de los Velos (Triclip – Pascal¡)
  - Anuloplastia (Cardioband . TriCinch)
  - Reemplazo valvular ortotopico y valve-in-valve (Evoque, Lux, Myvalve, Sapien)
  - Implante valvular heterotopico (TricValve)
- Aun en fase de Desarrollo, con resultados promisorios

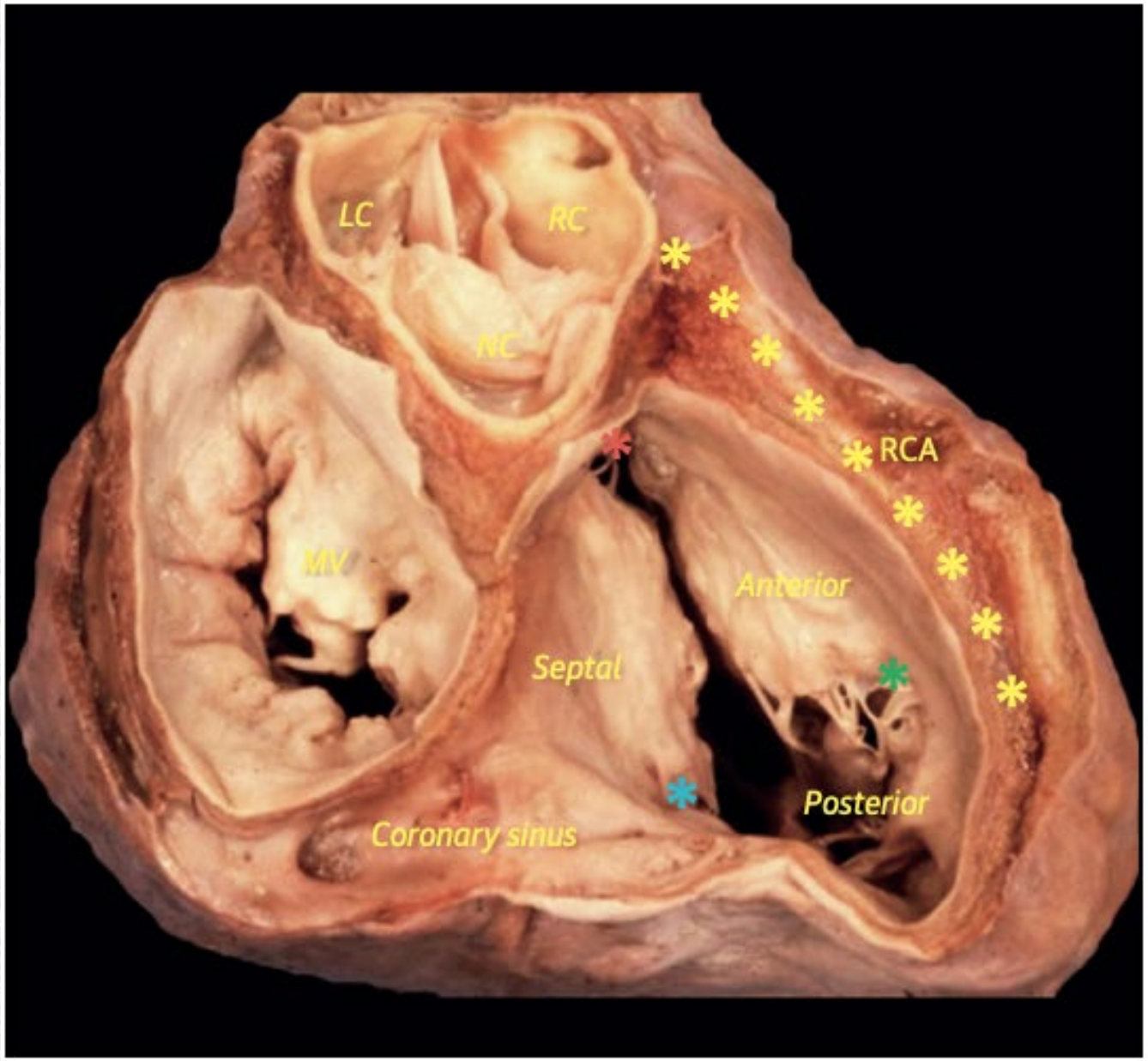
Terapia endovascular para IT

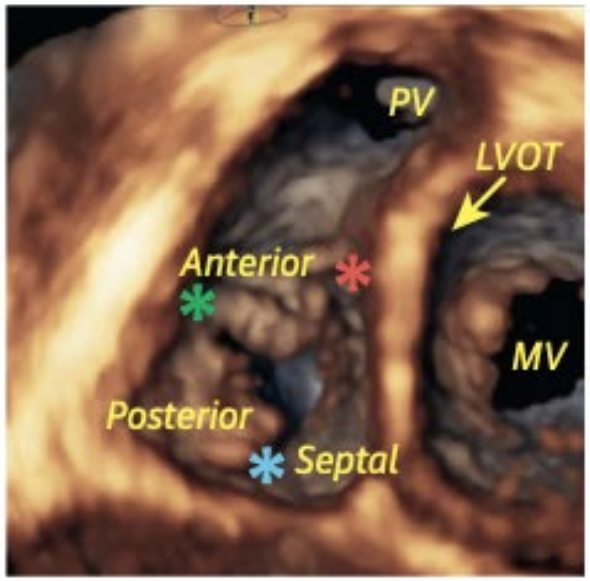




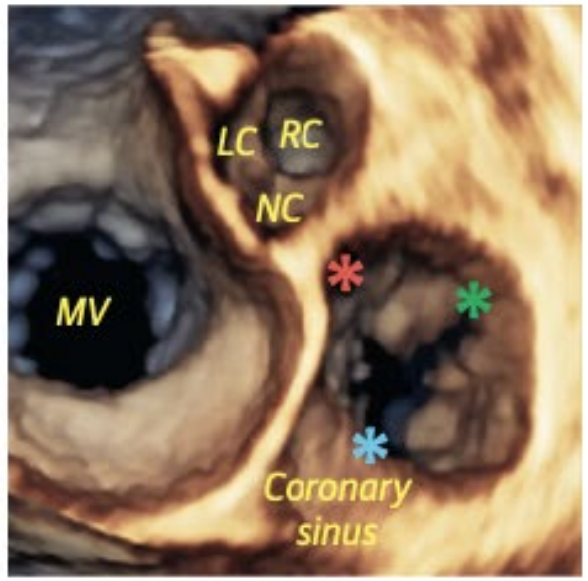


Hahn, R.T. et al. J Am Coll Cardiol Img. 2021;14(7):1299–305

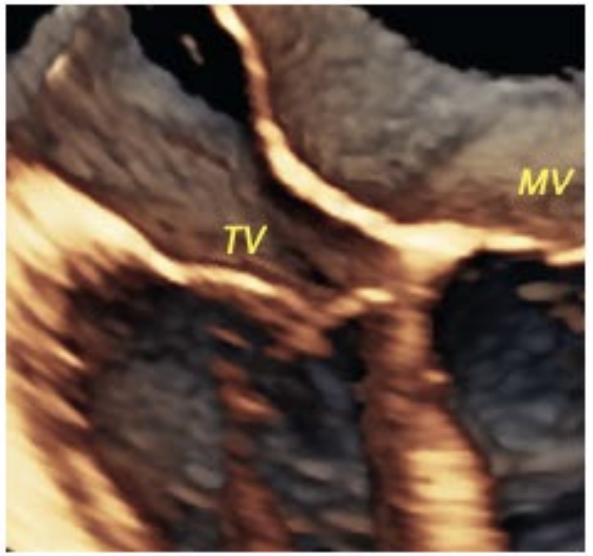

LC
RC
NC
RCA
MV
Anterior
Septal
Posterior
Coronary sinus

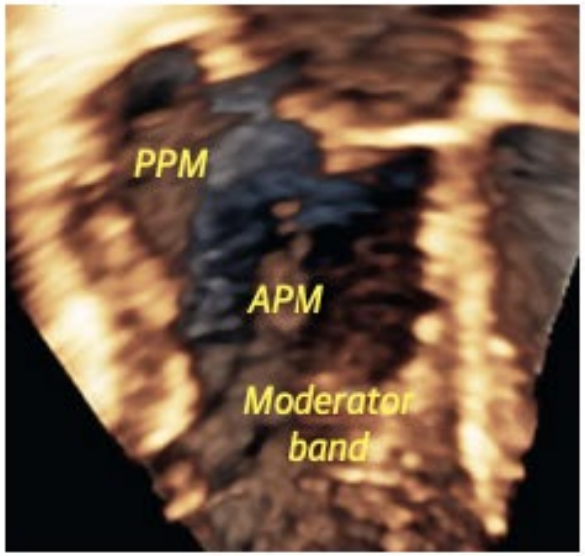

PV
LVOT
Anterior
MV
Posterior
Septal

D

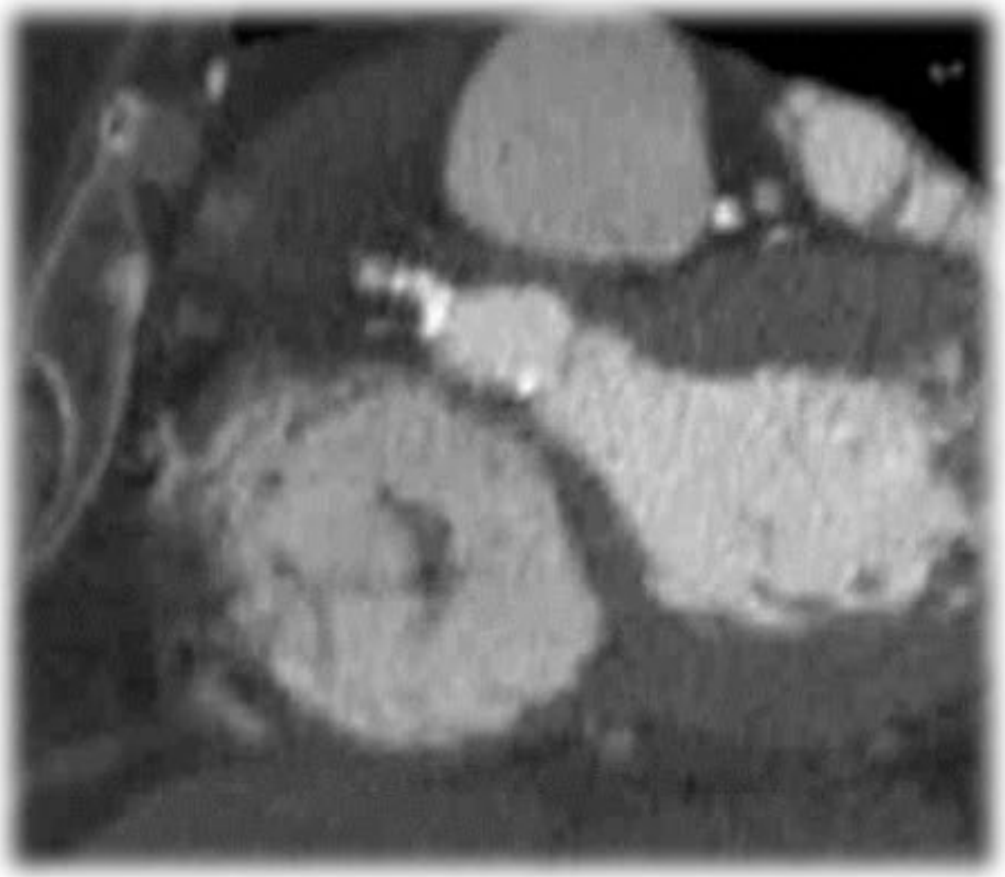

LC
RC
NC
MV
Coronary sinus

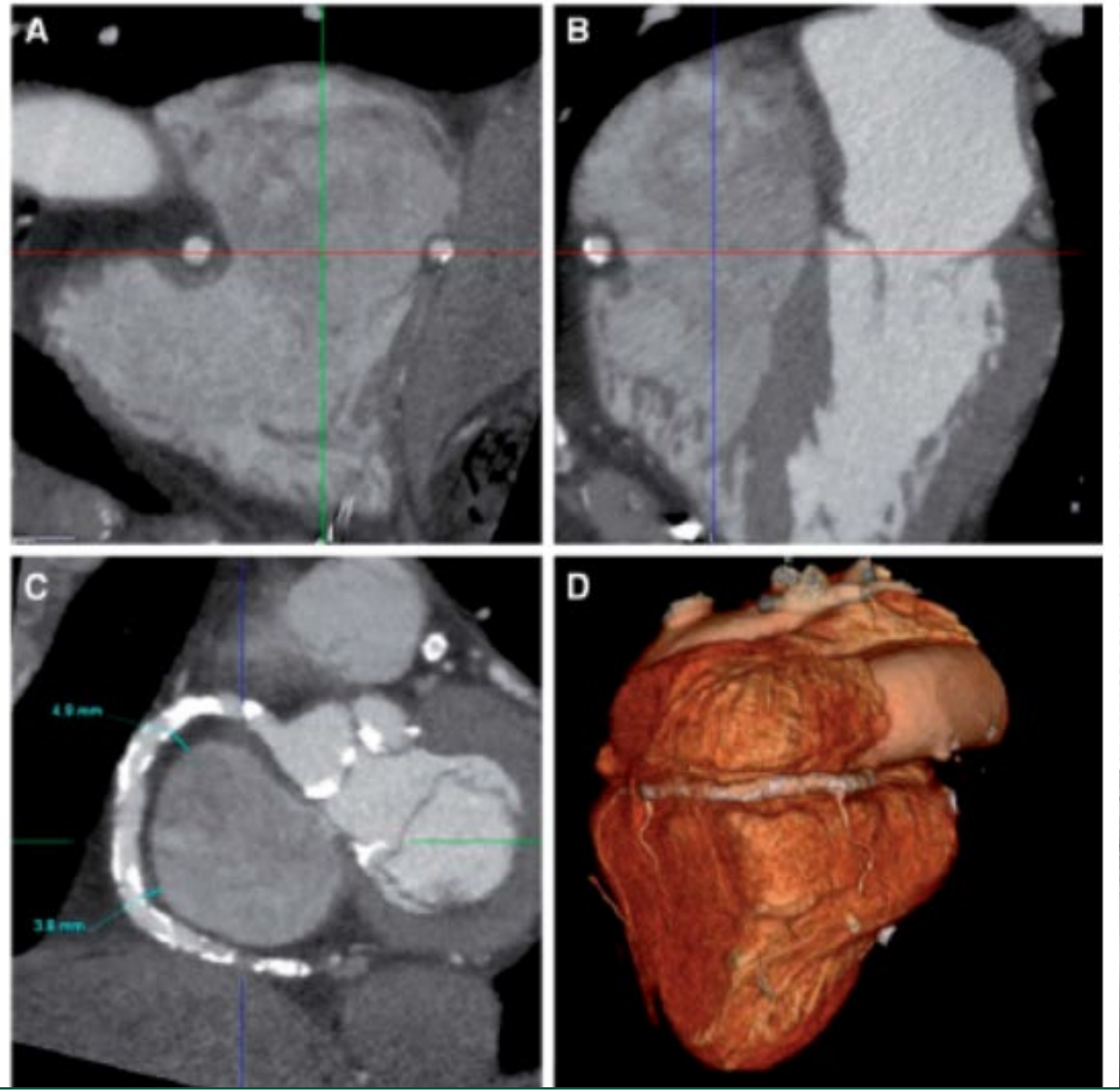
E


MV
TV

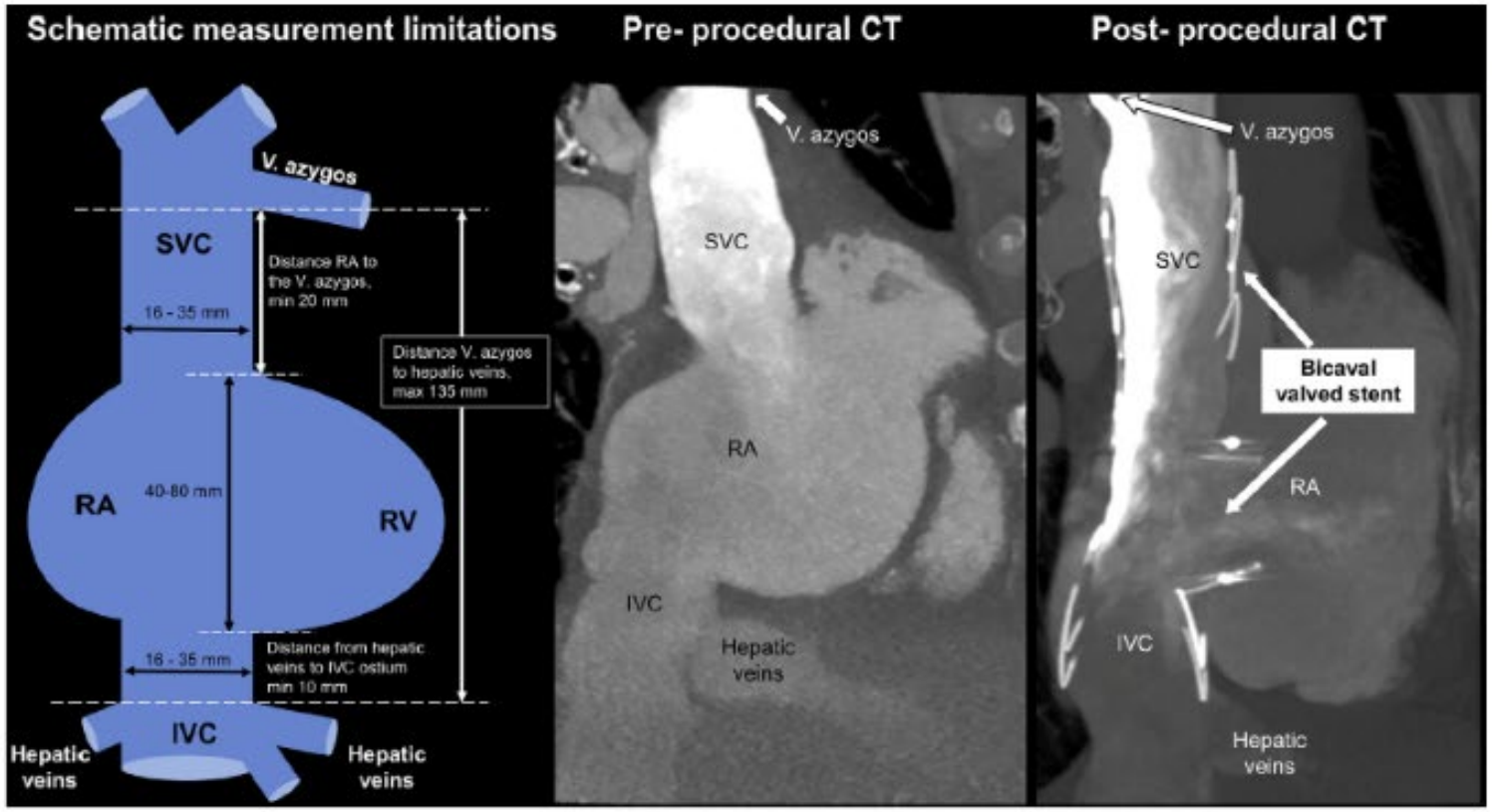

PPM
APM
Moderator band

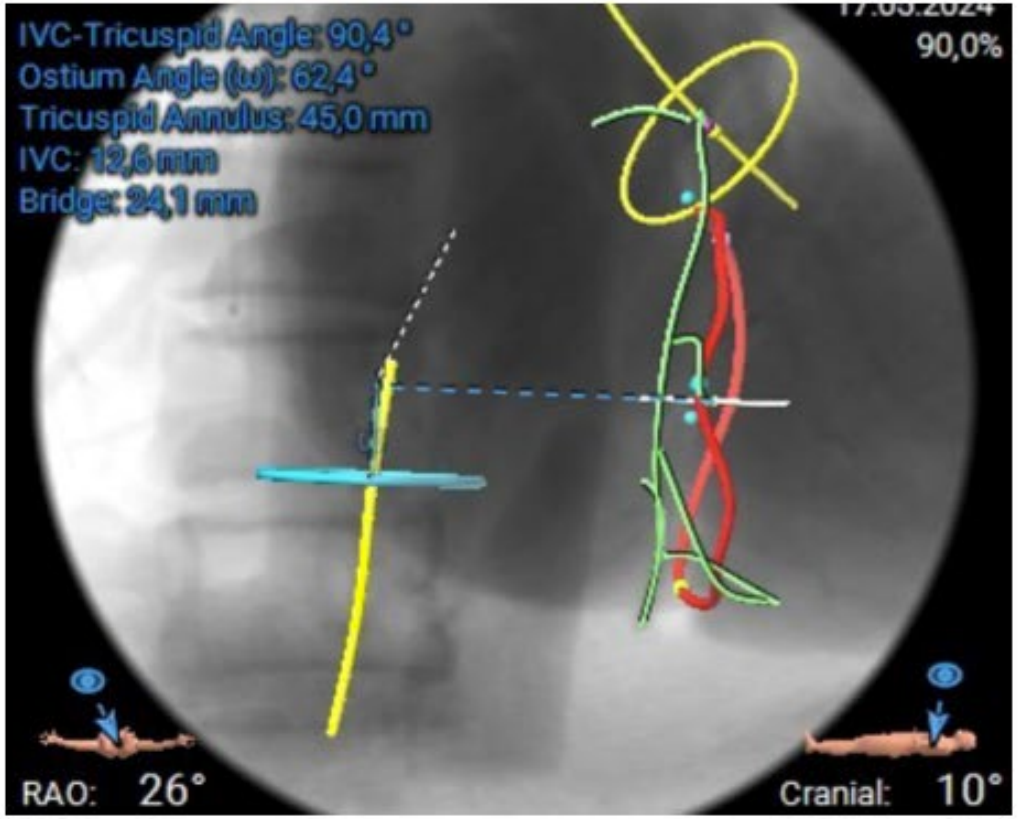
TMS: Evalaución anatomica





Anatomia de venas cavas





TRILUMINATE

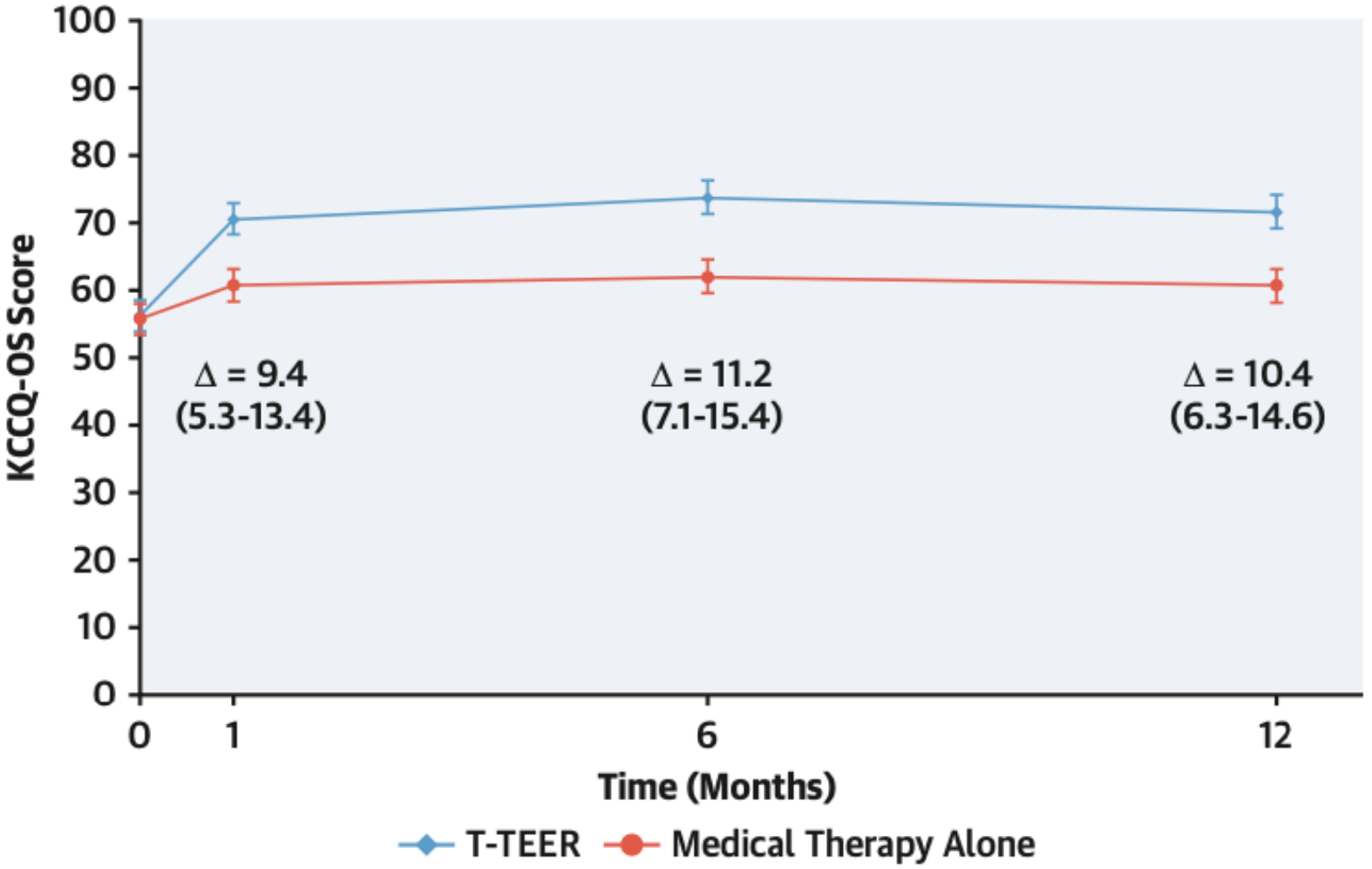
- Estudio Randomizado, multicentrico
- T-TEER vs tratamiento médico: Tri-clip (Abbott)
- 350 pacientes con IT sintomatica.
- PFP: compuesto de muerte/cirugía tricúspidea/internación por IC y mejoría de la calidad de vida evaluada por Kansas City Cardiomyopathy Questionnaire (KCCQ)
- Inclusión: pacientes con IT severa, masiva o torrencial
- NYHA II a IV
- PSAP <70 mm Hg

TRILUMINATE

End Point	TEER Group (N=175)	Control Group (N=175)	Difference (95% CI)	P Value
Primary				
Hierarchical composite of death from any cause or tricuspid-valve surgery; hospitalization for heart failure; and improvement of ≥15 points in KCCQ score at 1 yr — no. of wins†	11,348	7643	1.48 (1.06 to 2.13)	0.02
Secondary, listed in hierarchical order				
Kaplan–Meier estimate of percentage of patients with freedom from major adverse events through 30 days after the procedure (lower 95% confidence limit)‡	98.3 (96.3)	—	—	<0.001
Change in KCCQ score from baseline to 1 yr — points§	12.3±1.8	0.6±1.8	11.7 (6.8 to 16.6)	<0.001
Tricuspid regurgitation of no greater than moderate severity at 30-day follow-up — no. of patients/total no. (%)¶	140/161 (87.0)	7/146 (4.8)	—	<0.001
Change in 6-min walk distance from baseline to 1 yr — m‖	−8.1±10.5	−25.2±10.3	17.1 (−12.0 to 46.1)	0.25

Sorajja P **N Engl J Med 2023;388:1833-42**

Triluminate: FUP clínico a 1 año



Arnold SV, et al. J Am Coll Cardiol. 2024;83(1):1–13.

Tri.Fr TRIAL

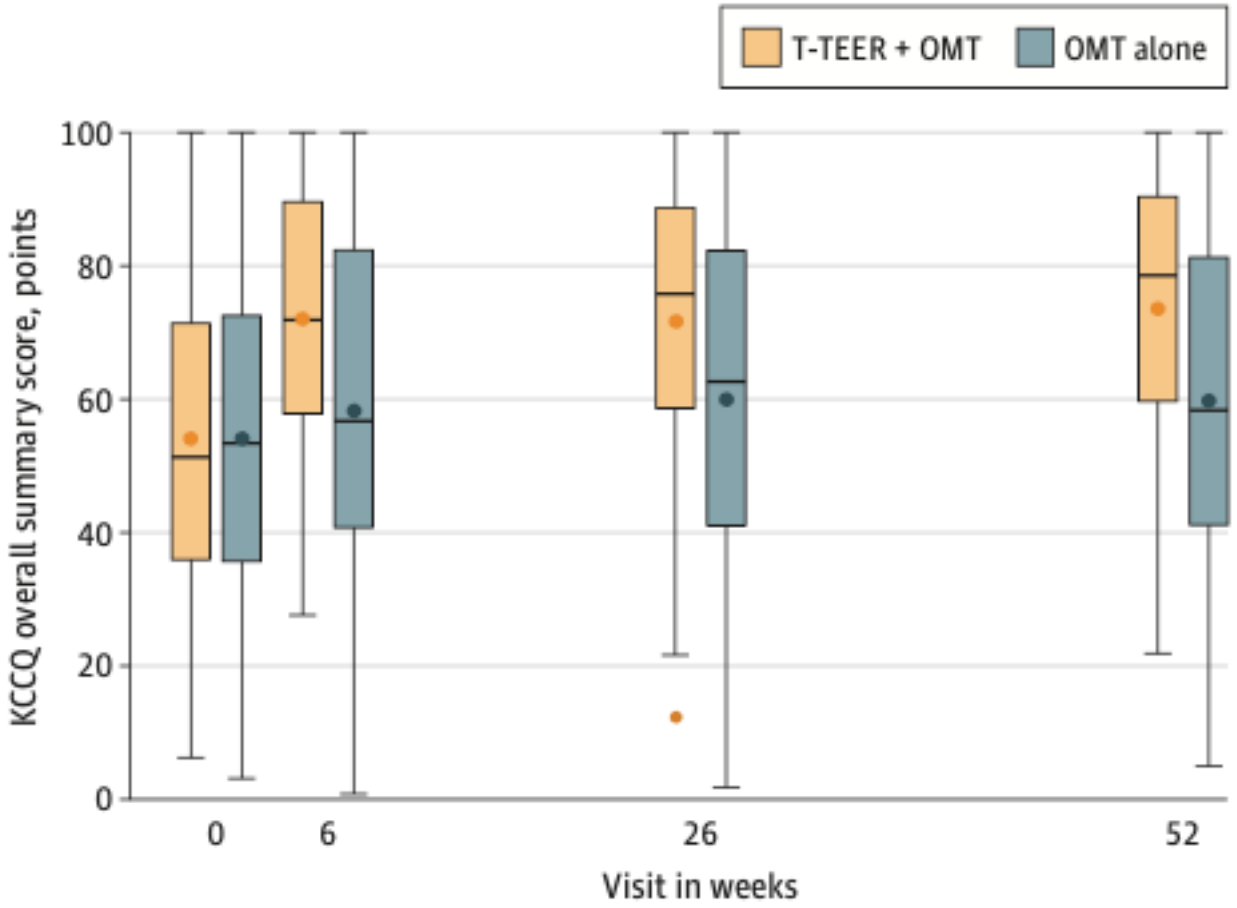
- Estudio Randomizado, multicentrico
- T-TEER vs tratamiento médico: Tri-clip (Abbott)
- 404 pacientes con IT sintomatica.
- Punto final clínico y ecocardiográfico
- 24 centros de Francia y belgica
- 84% implnate de 2 o más Clips

Tri.Fr TRIAL

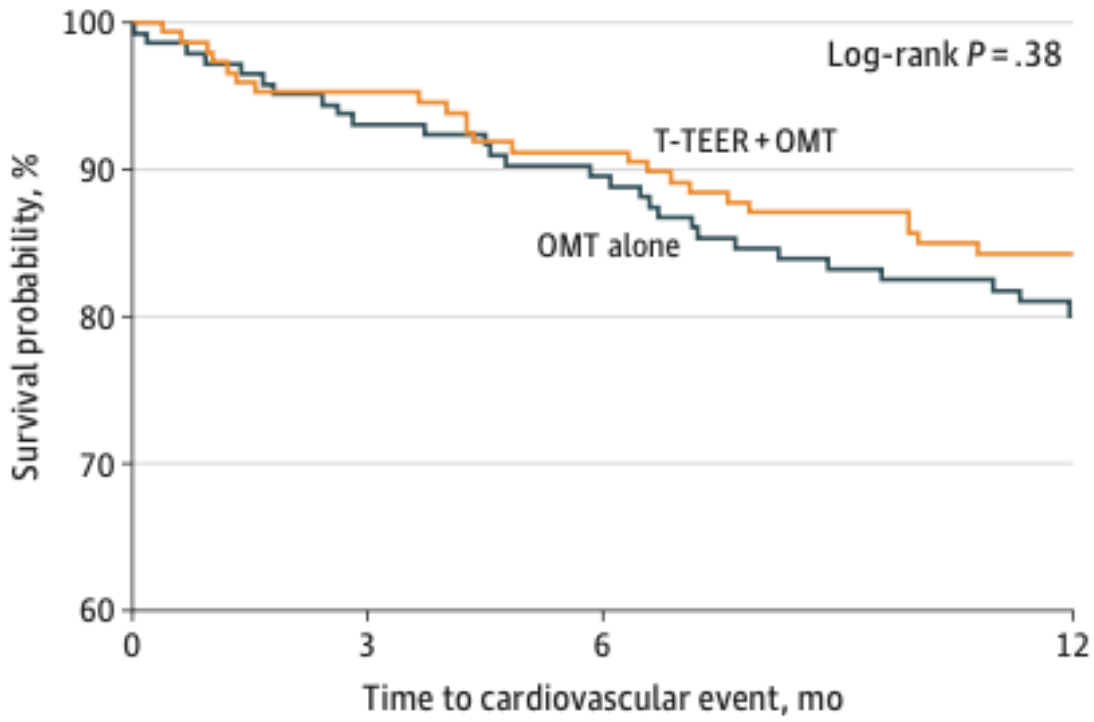
End point	T-TEER + OMT (n = 152)	OMT alone (n = 148)	Absolute difference (95% CI)	Effect estimate (95% CI)	*P* value
Primary					
Clinical Composite Score, No. (%)[a]					
Improved	109 (74.1)	58 (40.6)			
Unchanged	8 (5.44)	17 (11.9)	−0.34 (−0.44 to −0.23)[b]	0.67 (0.61 to 0.72)[c]	<.001
Worse	30 (20.4)	68 (47.6)	−0.27 (−0.38 to −0.17)[b]		
Missing, No.	5	5			
Secondary (listed in hierarchical order)					
TR grade at 1 y, No. (%)					
<2+	104 (78.3)	14 (11.0)			
3+	20 (15.0)	45 (35.4)			
4+	5 (3.76)	49 (38.6)		0.73 (0.68 to 0.78)[c]	<.001
5+	4 (3.01)	19 (15.0)			
Absolute change in KCCQ score from baseline to 1 y, mean (SD), points[d]	15.9 (30.1)	0.40 (25.7)	14.5 (27.2)		<.001
PGA at 1 y, No. (%)[e]					
Improved	100 (74.6)	51 (39.5)			
Unchanged	19 (14.2)	36 (27.9)	0.21 (0.12 to 0.31)[b]	0.68 (0.63 to 0.74)[c]	<.001
Worse	15 (11.2)	42 (32.6)	0.35 (0.24 to 0.46)[b]		

Tri.Fr TRIAL

Cambios en KCCQ en FUP



Curvas de sobrevida



No. at risk

T-TEER + OMT	152	134	108
OMT alone	147	128	85

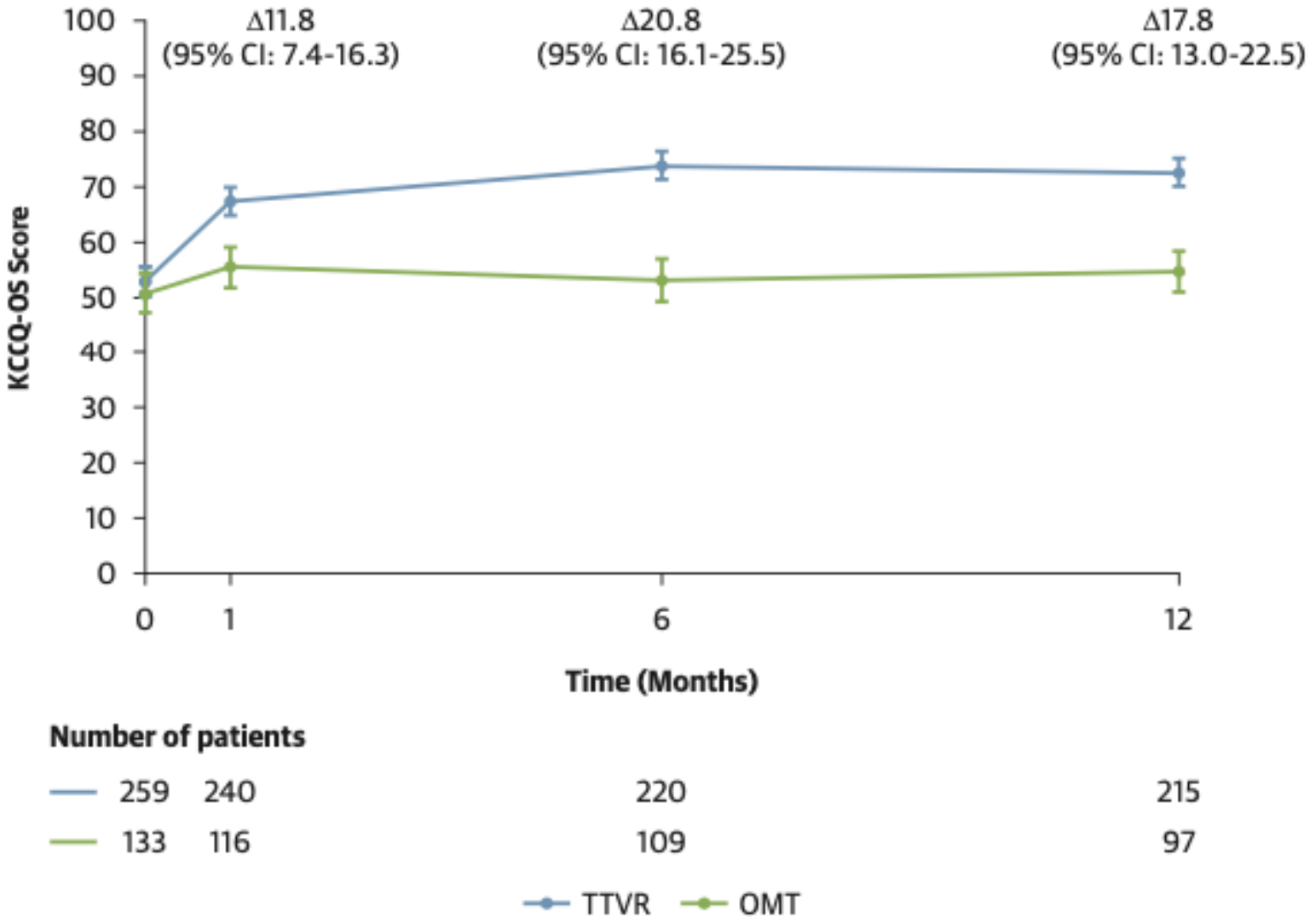
TRISCEND II Trial

- Estudio ramdomizado, prospectivo, mulicentrico
- TTVR con sistema EVOQUE (Edward) vs OMT (2:1)
- Pacientes con IT sintomática
- Entre Mayo 2021 y Abril 2023,
- 400 pacientes de 45 centros en USA y Alemania

Triscend : Resultados

	Predicted Mean (95% CI)			
	TTVR+OMT	OMT	Between-Group Difference (TTVR+OMT-OMT)	*P* Value
KCCQ Overall Summary Score				
30 d	67.3 (64.8-69.8)	55.5 (51.8-59.1)	11.8 (7.4-16.3)	<0.001
6 mo	73.8 (71.1-76.4)	53.0 (49.1-56.8)	20.8 (16.1-25.5)	<0.001
1 y	72.4 (69.8-75.1)	54.7 (50.8-58.6)	17.8 (13.0-22.5)	<0.001
KCCQ physical limitations				
30 d	66.9 (64.2-69.7)	58.9 (54.9-62.8)	8.1 (3.3-12.8)	0.001
6 mo	70.0 (67.1-73.0)	55.0 (50.8-59.2)	15.0 (9.9-20.1)	<0.001
1 y	66.9 (63.9-69.8)	56.1 (51.8-60.5)	10.7 (5.5-16.0)	<0.001
KCCQ total symptoms				
30 d	71.3 (68.6-74.1)	58.8 (54.9-62.8)	12.5 (7.7-17.3)	<0.001
6 mo	76.0 (73.2-78.8)	56.6 (52.6-60.7)	19.4 (14.4-24.3)	<0.001
1 y	75.5 (72.6-78.3)	58.7 (54.5-62.9)	16.8 (11.7-21.8)	<0.001
KCCQ quality of life				
30 d	64.9 (61.8-68.0)	48.3 (43.8-52.8)	16.6 (11.1-22.1)	<0.001
6 mo	73.5 (70.4-76.7)	50.0 (45.5-54.5)	23.6 (18.0-29.1)	<0.001
1 y	74.9 (71.8-77.9)	51.5 (47.0-56.0)	23.4 (18.0-28.8)	<0.001

Triscend : Resultados



Arnold SV, et al. JACC. 2025;85(3):206-216.

TRICUSP-EURO

Estudio prospectivo, multicéntrico (12 centros de España y Austria) y de rama única.
No randomizado, no ciego.
Para evaluar Seguridad y Eficacia del dispositivo TRIC VALVE

Inclusión: Pacientes con IT Severa, sintomática, CF II-IV, bajo tto médico óptimo
Onda v >25 mmhg - FEY >40% - TAPSE >14
Alto riesgo quirúrgico

PFP: cambio en el estilo de vida a los 6 meses, medido por KCCQ
PFS: 1- MACE (muerte, IAM, Cirugia de urgencia, ACV, sangrado mayor)
2- Evaluación functional (6MWT)
3- Parametros hemodinamicos, ECO y RHC

TRICUSP-EURO

Características del Procedimiento

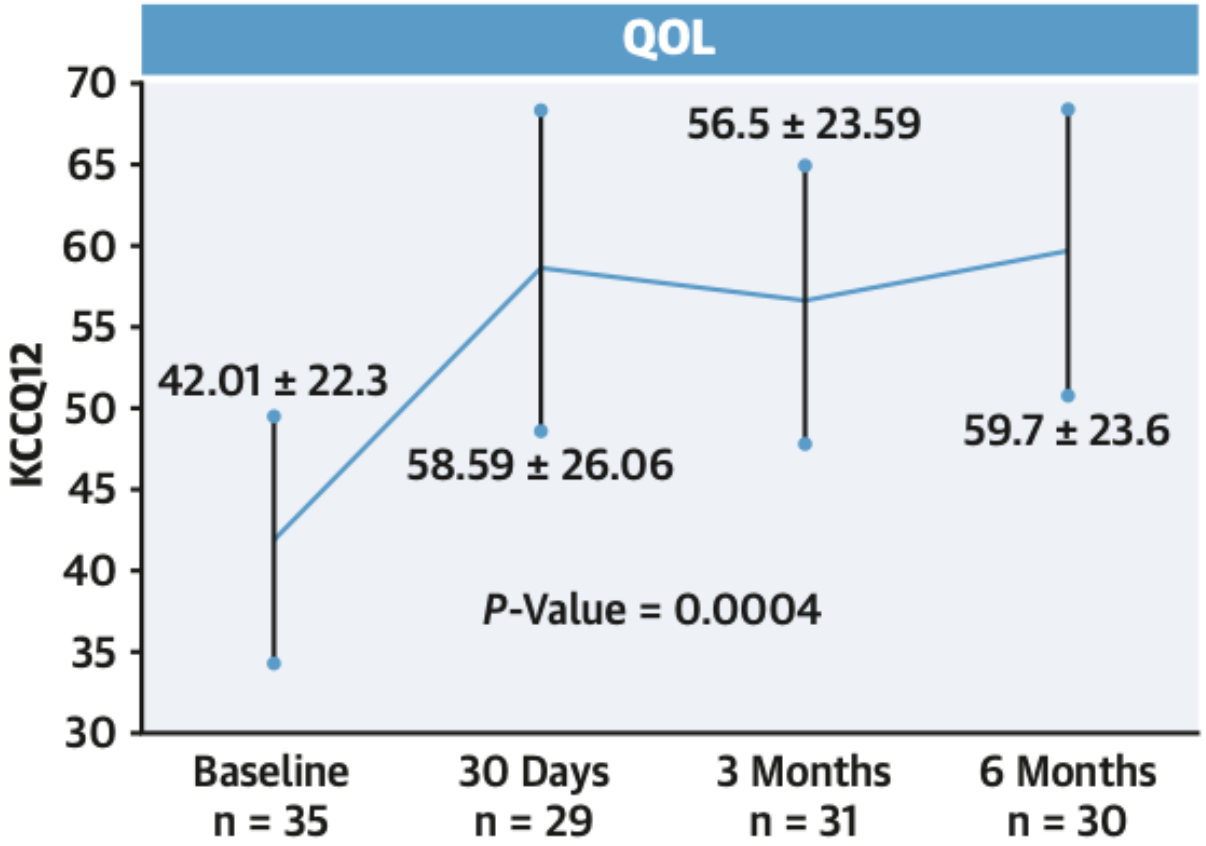
In-hospital mortality	1 (2.8)
Stroke/TIA	0
Number of valves implanted	70
Technical success	34 (97)
Procedural success	33 (94)
Device embolization/migration	1 (3)
Conversion to surgery	0 (0)
Cardiac tamponade	0 (0)
New pacemaker implantation	1 (3)
Length of hospital stay, d	7 (3.0-9.5)

Eventos Cardiovasculares

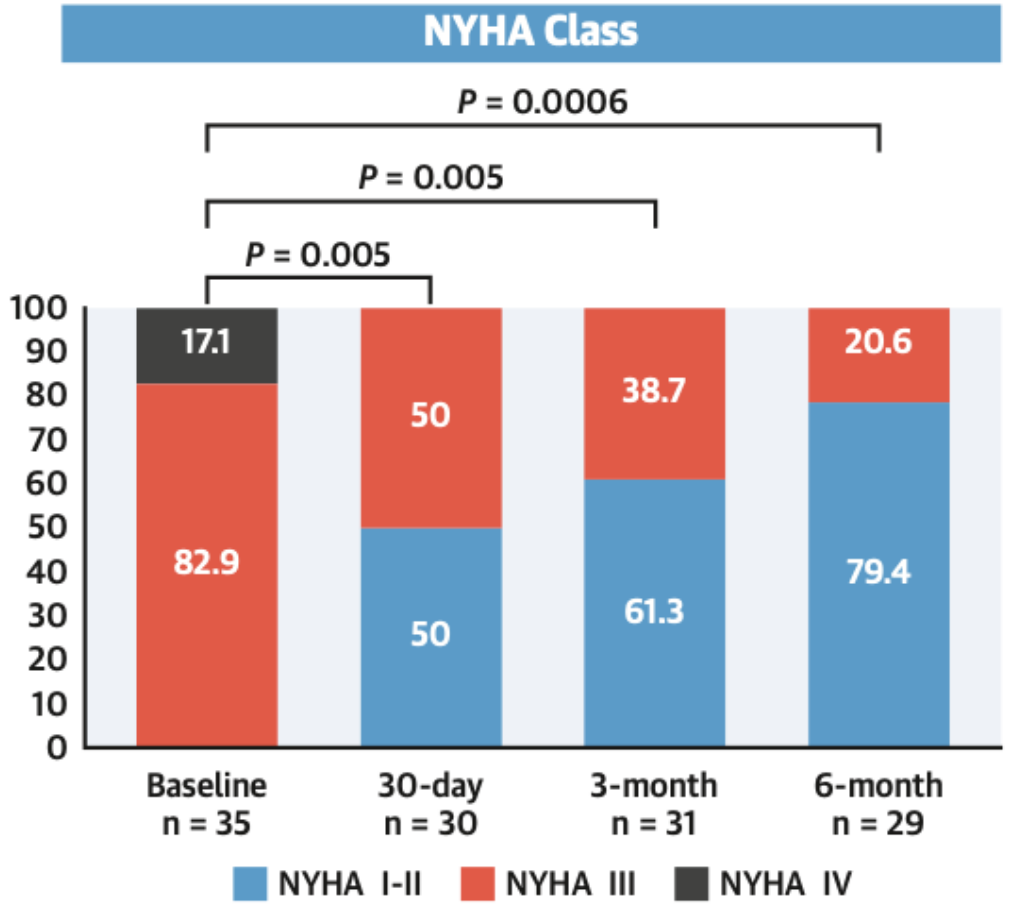
	Procedural	30 Days	3 Months	6 Months	Overall 6 Months
Death	0	2	1	0	8.5%
Myocardial infarction	0	0	0	0	0%
Cardiac tamponade	0	0	0	0	0%
Conversion surgery	0	0	0	0	0%
Stroke	0	0	1	1	5.7%
Major bleeding	1	3	2	0	17.1%
Transient shoulder pain	7	3	0	0	28.5%

TRICUSP-EURO

Seguimiento: Calidad de Vida (KCCQ12)



Seguimiento: Clase funcional NYHA



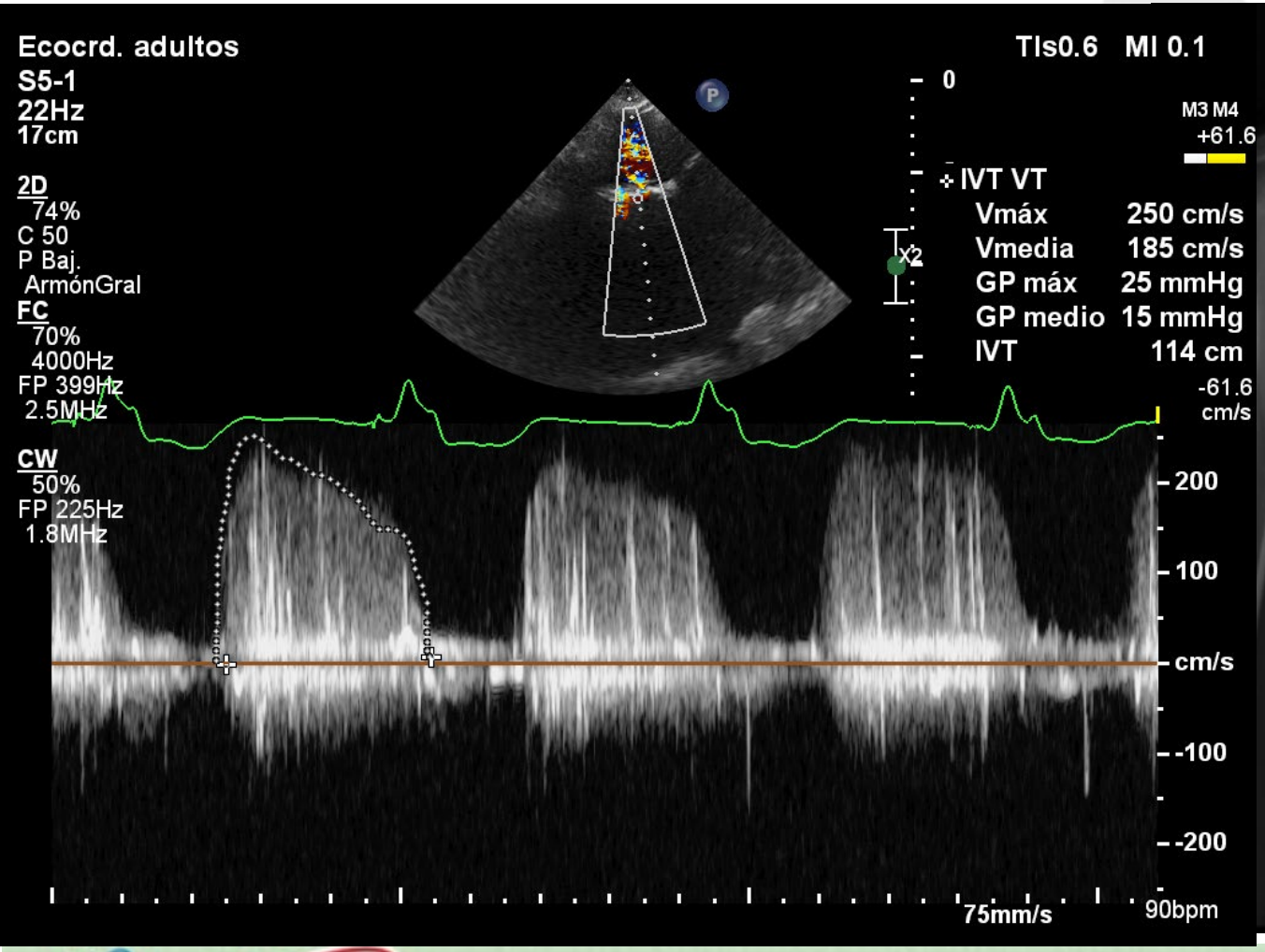
CASO CLINICO

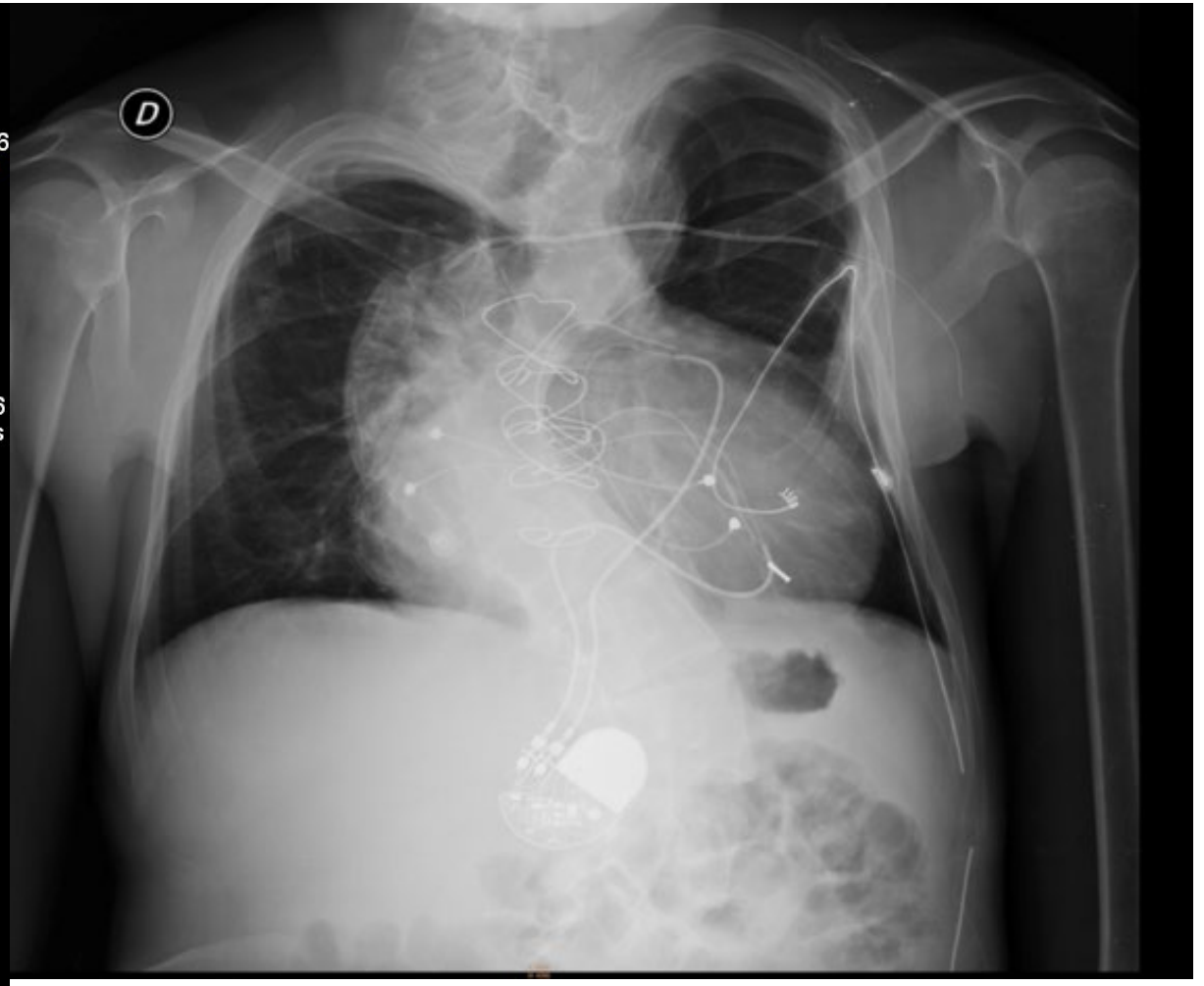
CASO CLINICO

- 39 años, varón con historia de enfermedad congenita compleja
- 1985: 1st CCV:
  - Correccion de drenaje venoso anómalo y corrección del defecto del SIV
  - MCPD.
- 2000: 2nd CCV:
  - Reemplazo de valvula tricuspide con bioprotesis num 29 mm
  - Corrección de defecto del SIA.
  - Marcapasos epicardico.

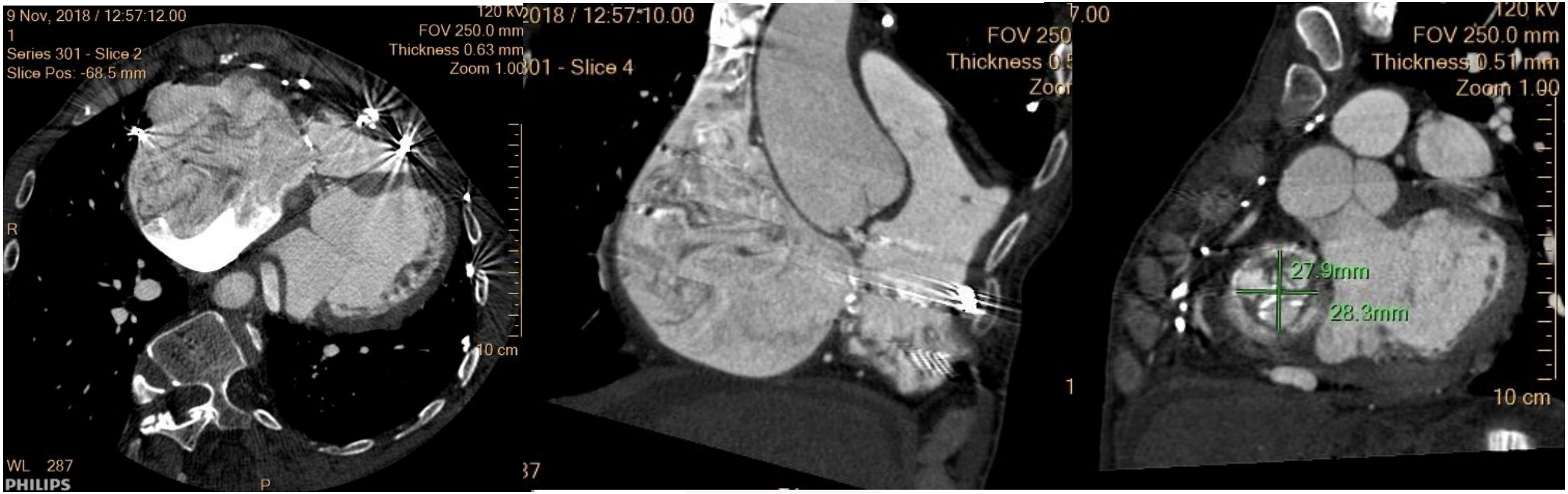
- Disnea NYHA II-III, edemas perifericos y distension abdominal por 2 años.
- FA permanente, bajo anticoagulation
- Internación por IC.
  - ECO TT: Degeneración de la bioprótesis, con estenosis severa (gradient pico 25mmHg, gradiente medio 18mmHg)
- Evaluación por Heart Team

ECO y RX Basal





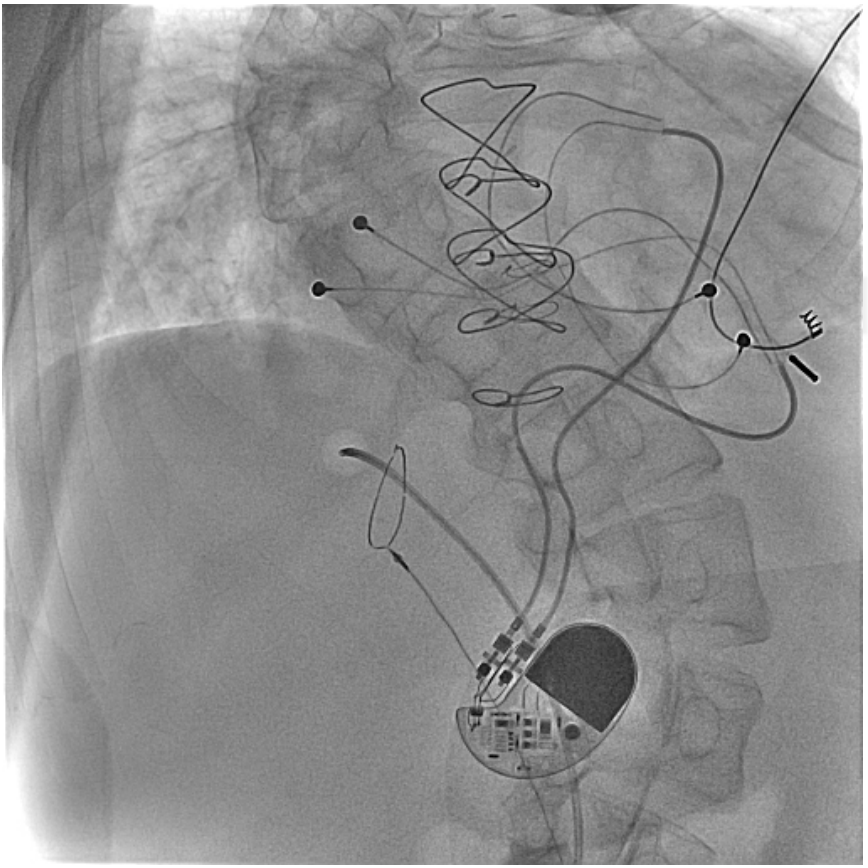
Agrandamiento severo de AD, VD hipoplásico, bioprótesis en posición tricuspídea

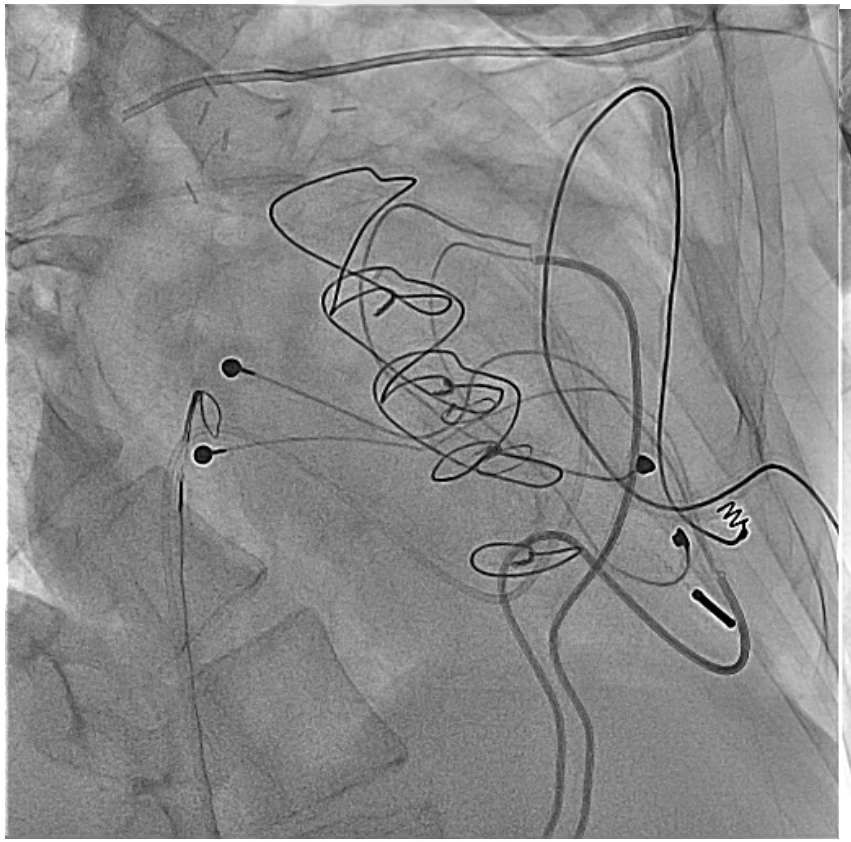


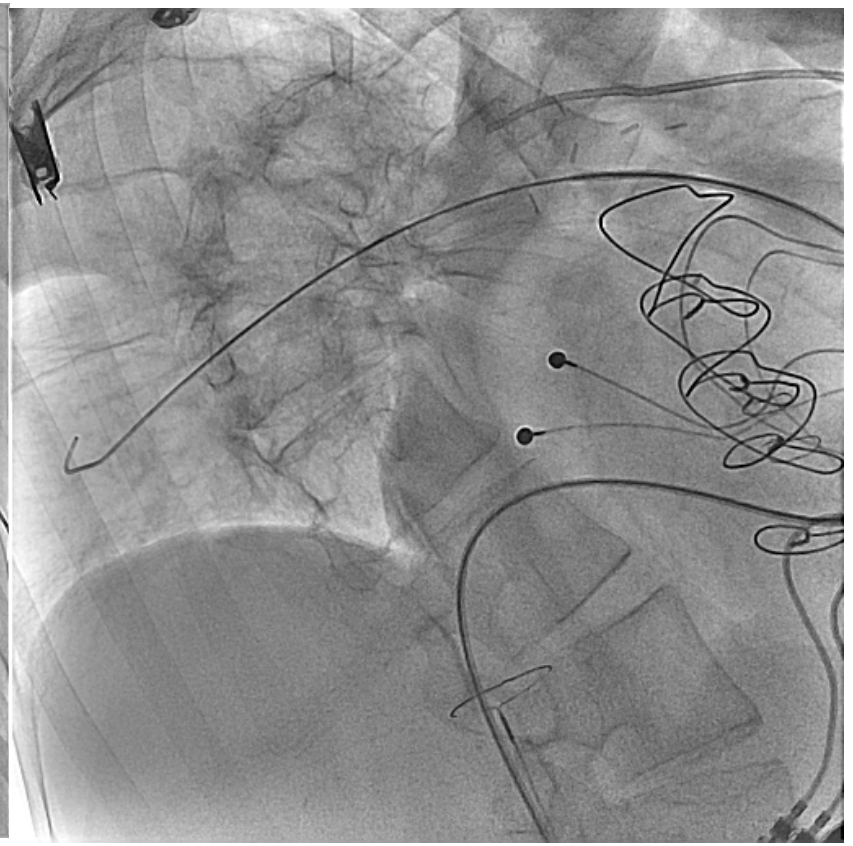
Plan de tratamiento

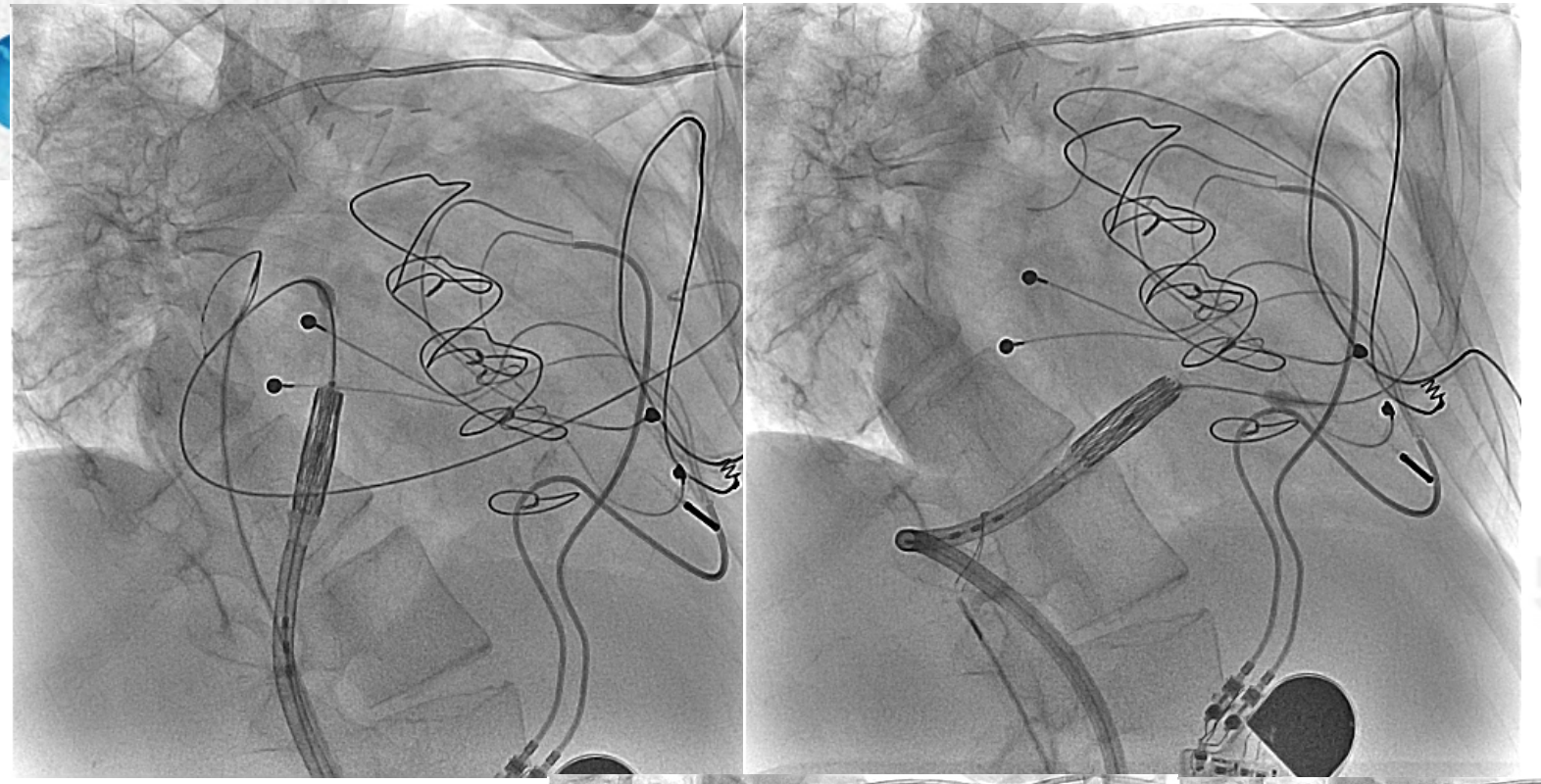
- Anestesia local y sedación consciente.
- Imagen : ECO TT y fluoroscopia
- Acceso:
  - Vena femoral derecha/ Edwards E-sheath 16F
  - Vena femoral izquierda 7F sheath.
  - Guías : Amplatz super stiff en Arteria Pulmonar/ Lunderquist
- VIV: SAPIEN S3 29mm (Edwards Lifescience)

Valve-in-valve tricuspidea

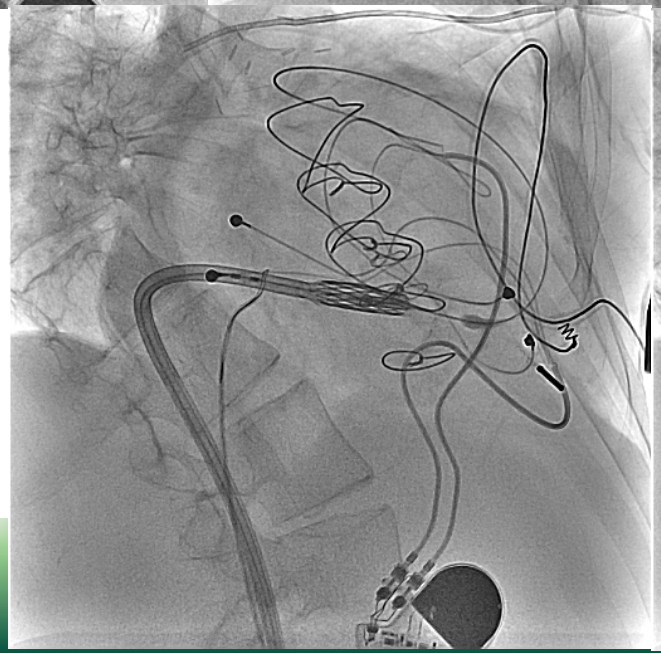


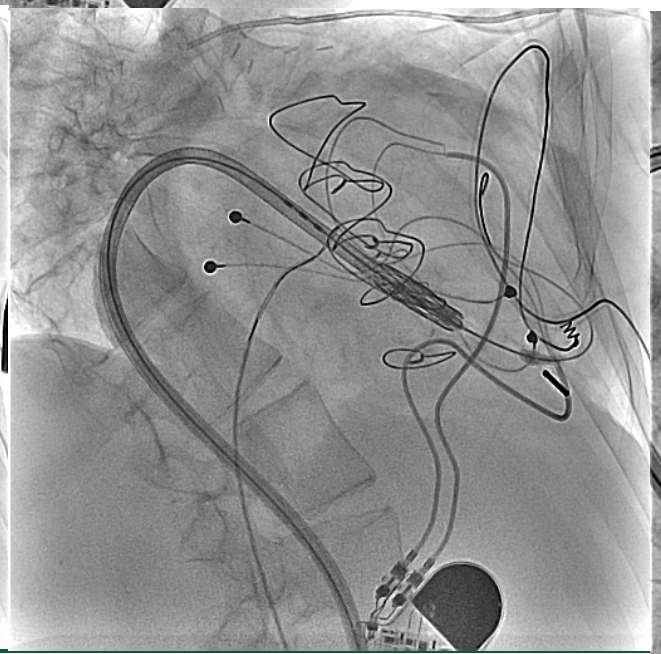


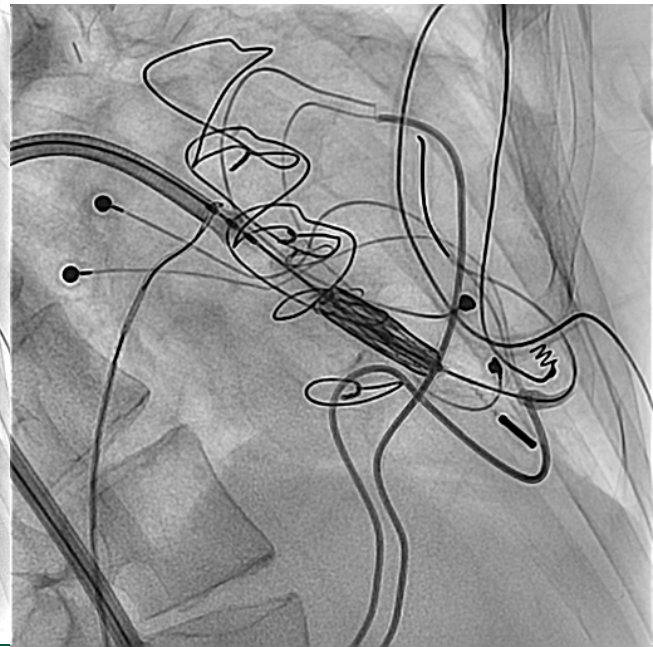


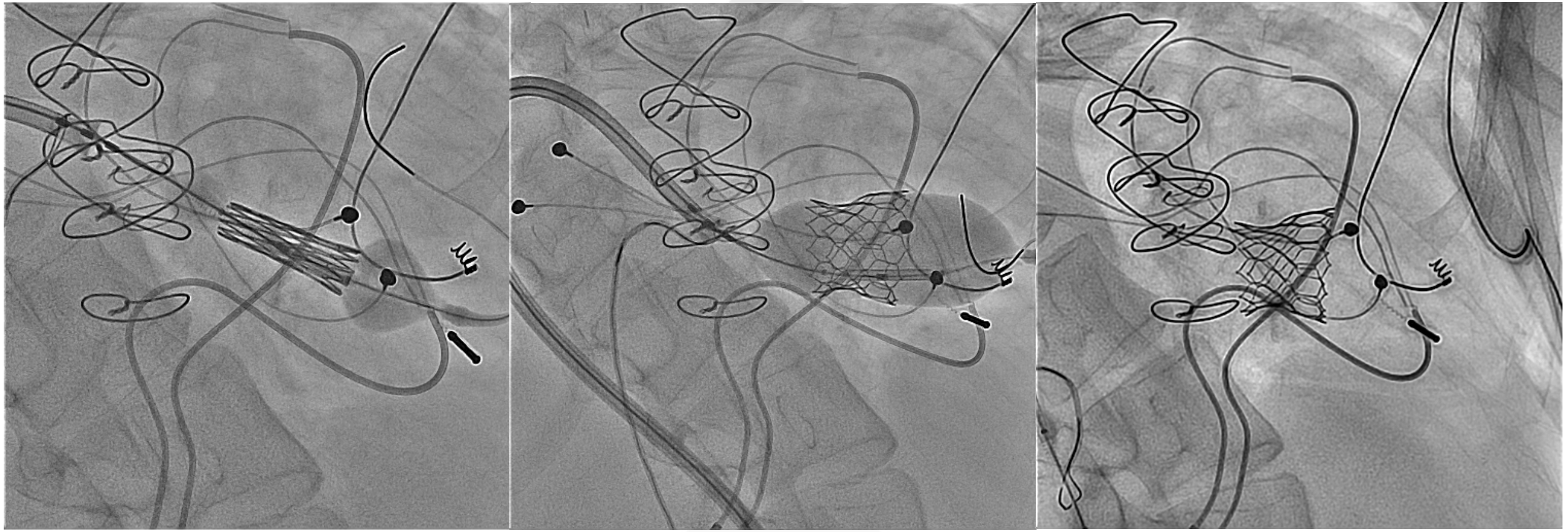


Uso de Lazo para ayudar a deflector la Valvula y alcanzar coaxialidad de la prótesis



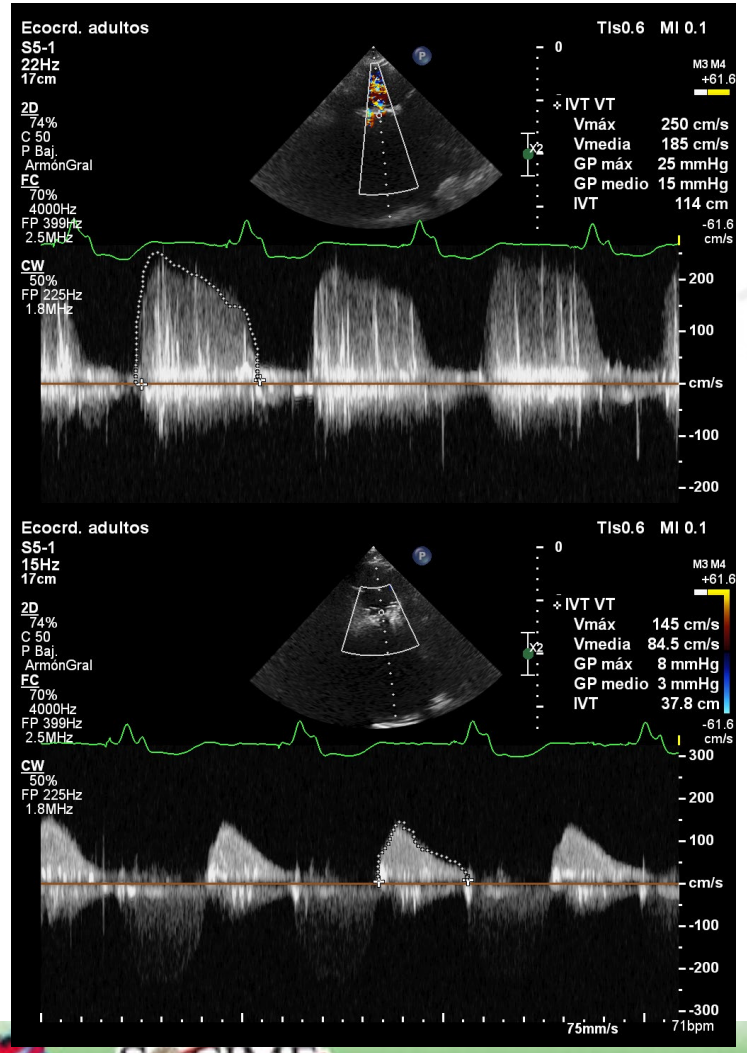






Resultado final

ECO TT pre y post procedimiento



- Alta 48 hs sin complicaciones.
- : Warfarina y furosemida
- Mejoria clínica significativa. NYHA I
- Sin nuevas internaciones.
- Ultimo ECO TT 2024 (5 years post procedure)
  Gradiente medio de la protesis gradiente 7 mm Hg;
  IT leve.

CASO CLÍNICO II

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- 39 años, varón con historia de enfermedad congenita compleja
- 1985: 1st CCV:
  - Correccion de drenaje venoso anómalo y corrección del defecto del SIV
  - MCPD.
- 2000: 2nd CCV:
  - Reemplazo de valvula tricuspide con bioprotesis num 29 mm
  - Corrección de defecto del SIA.
  - Marcapasos epicardico.

-***Ecocardiograma doppler:***

VI 42/29 AI 51 FEY 60%.

Septum aplanado y asincrónico.

Cavidades derechas dilatadas. TAPSE 19, área AD 44

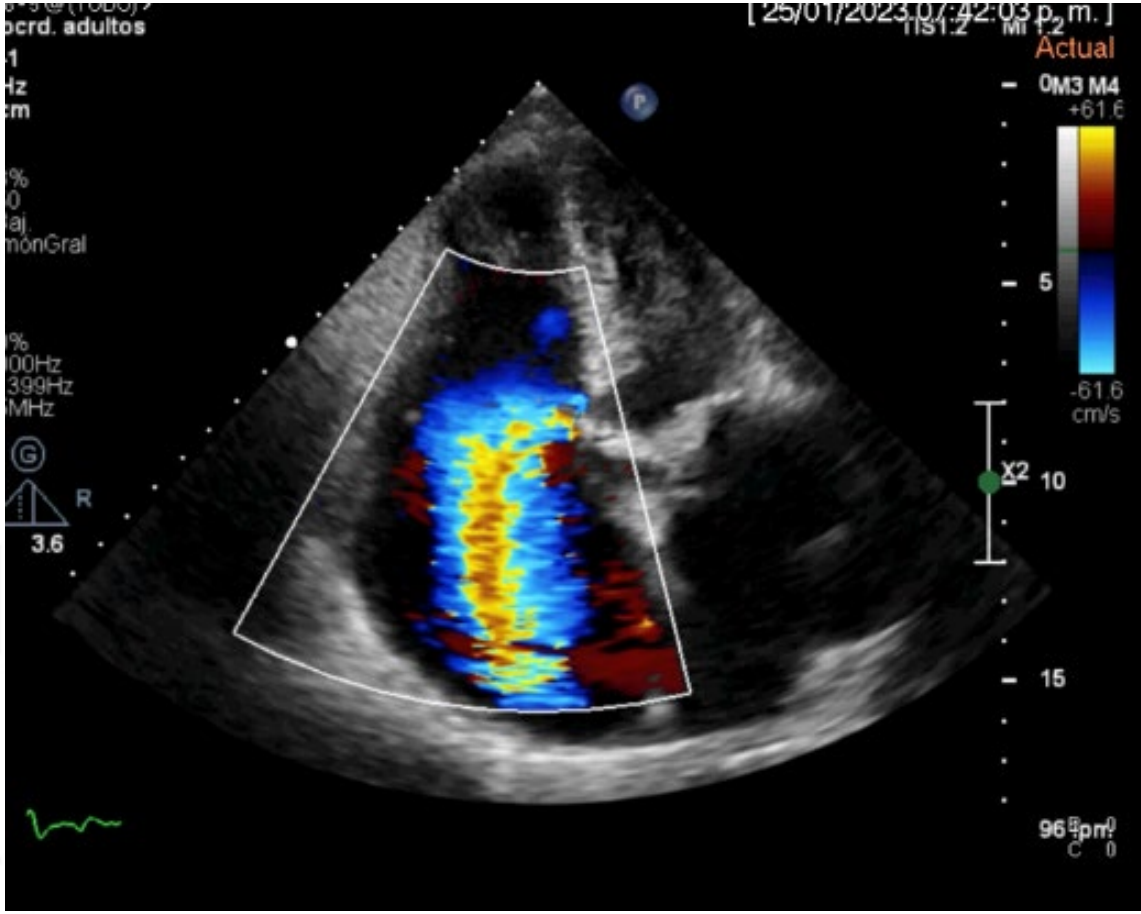
IAo, IM e IP leves.

IT masiva, jet central (ORE 2.08, Vol reg 111 ml), falta de coaptación entre valva anterior y septal, dilatación del anillo 56mm.

PSAP 38 mmHg. Strain de pared libre VD -15%

***-Cateterismo cardiaco derecho*:**

PAP 17 (27/13) VMC 3.3 lt/min IC 1.6. (Fick) PCP 12 mmhg.


crd. adultos
[25/01/2023 07:42:03 p. m.]
Actual
M3 M4
+61.6
5
-61.6
cm/s
10
15
3.6
R
96

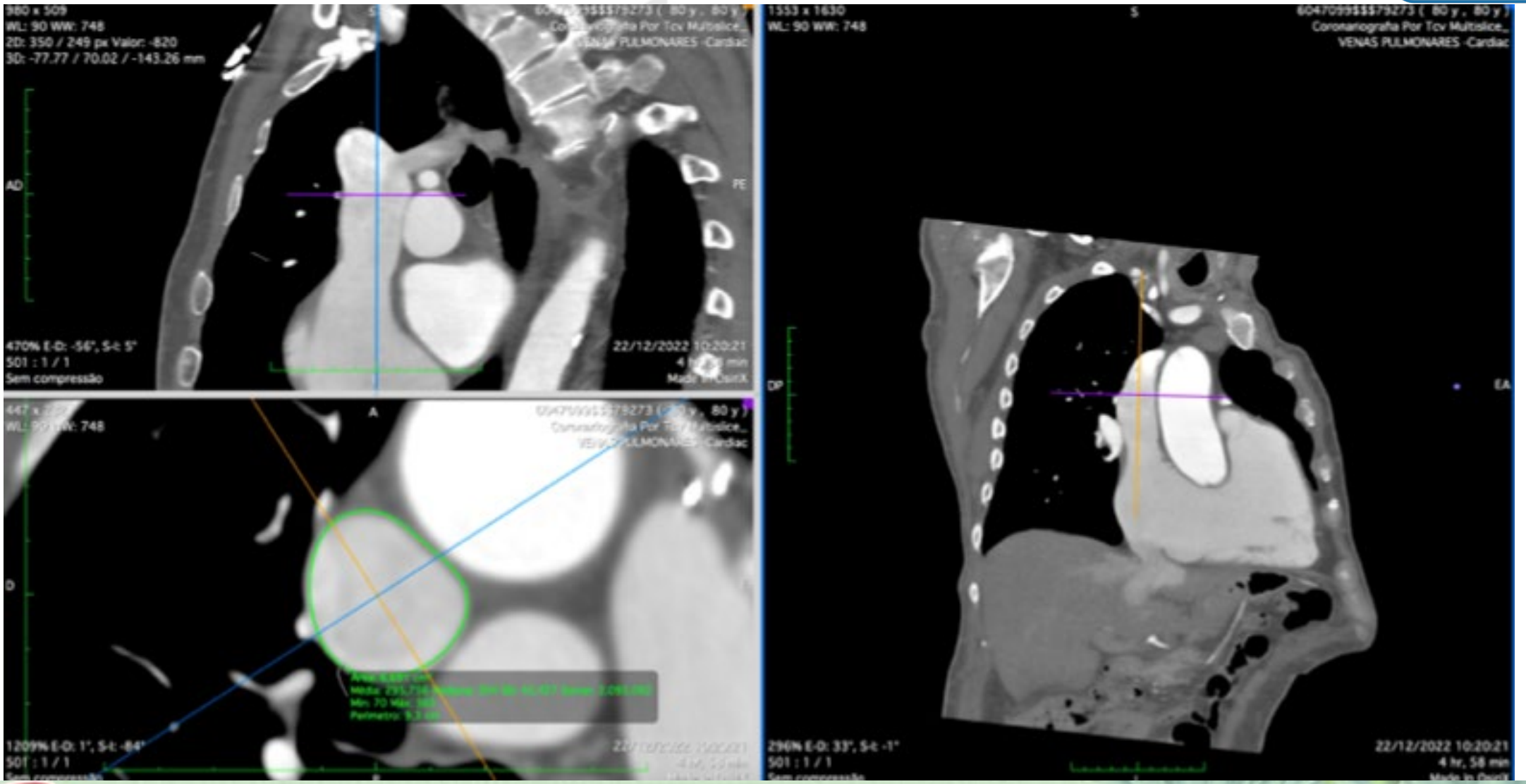
En reunion multidisciplinaria se decide por síntomas refractarios al tratamiento y alto riesgo quirúrgico, el tratamiento endovascular de la patología valvular tricuspídea.

Caso Clínico

- Estrategia
- Implante valvular bicaval
- Sedación consciente, accesos venosos percutáneos

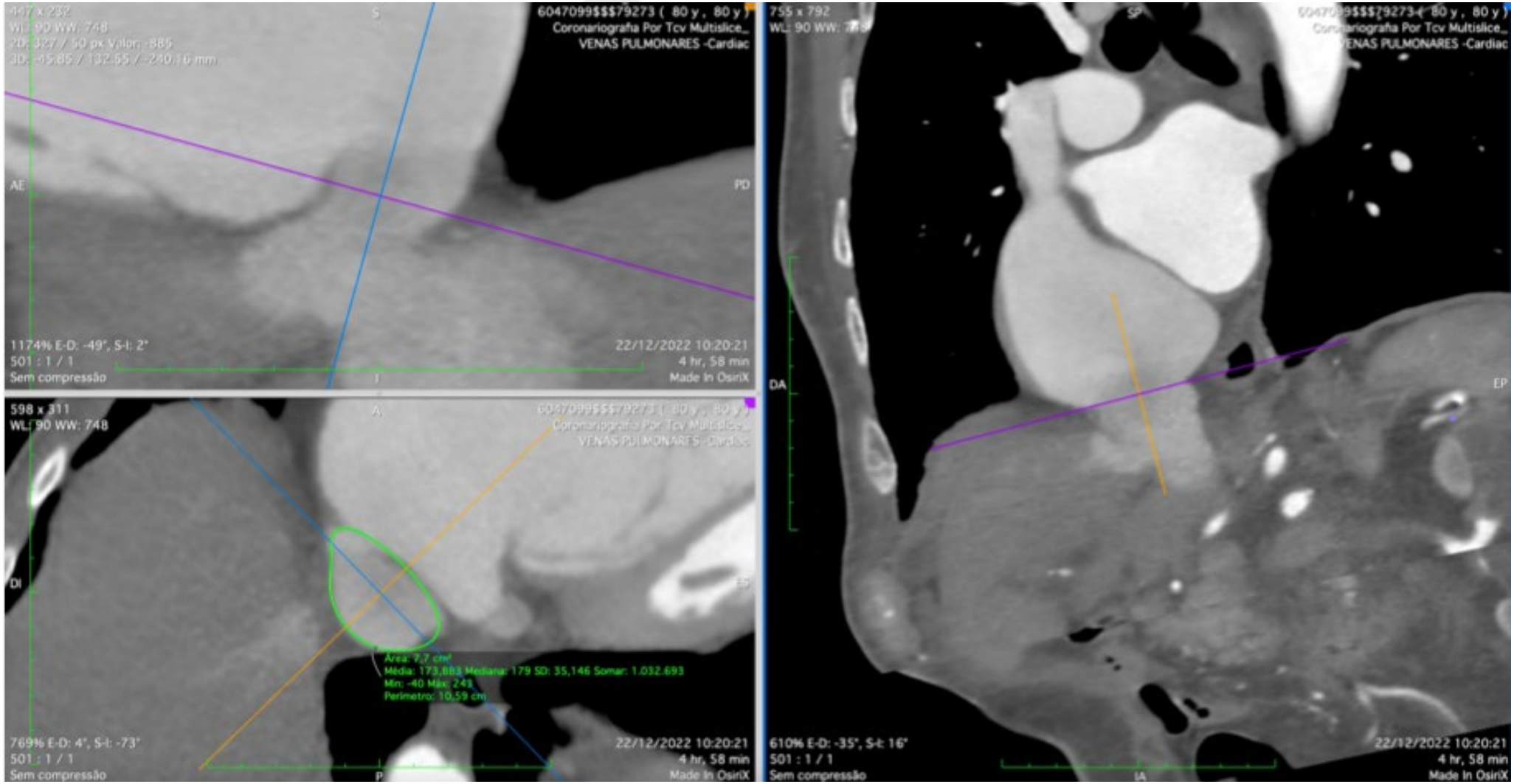
Tomografia Multislice

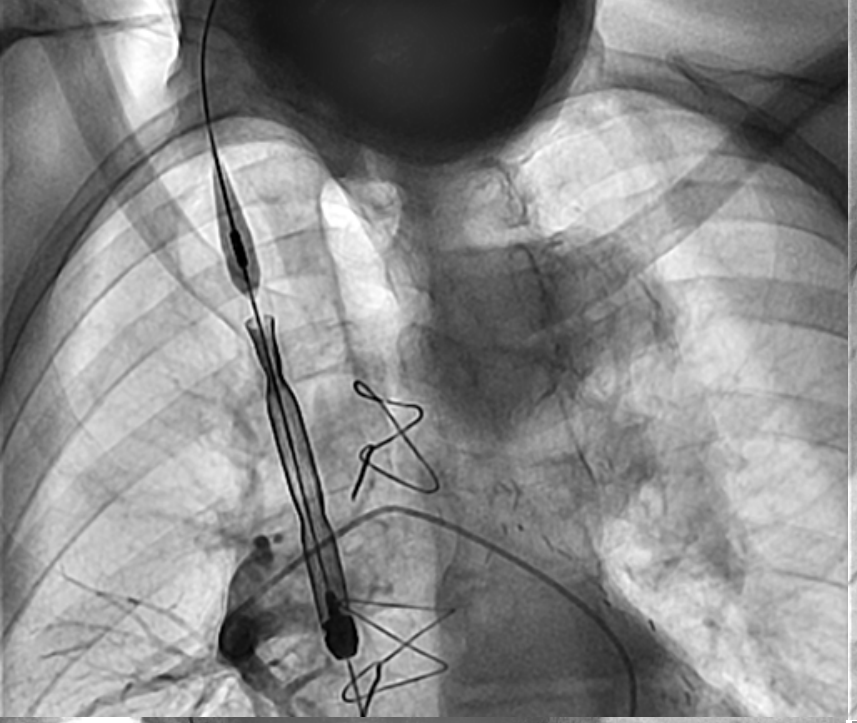
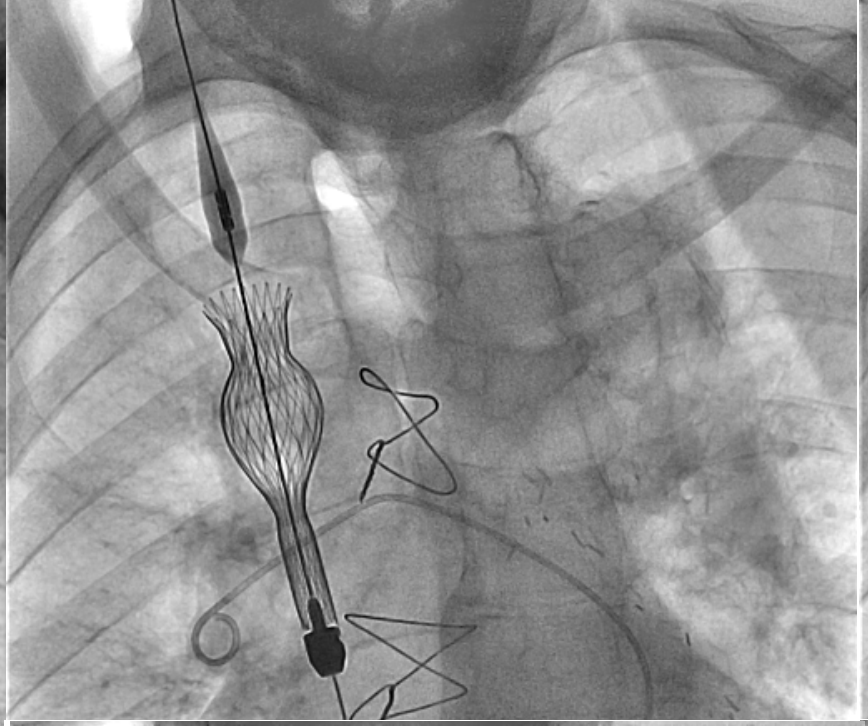
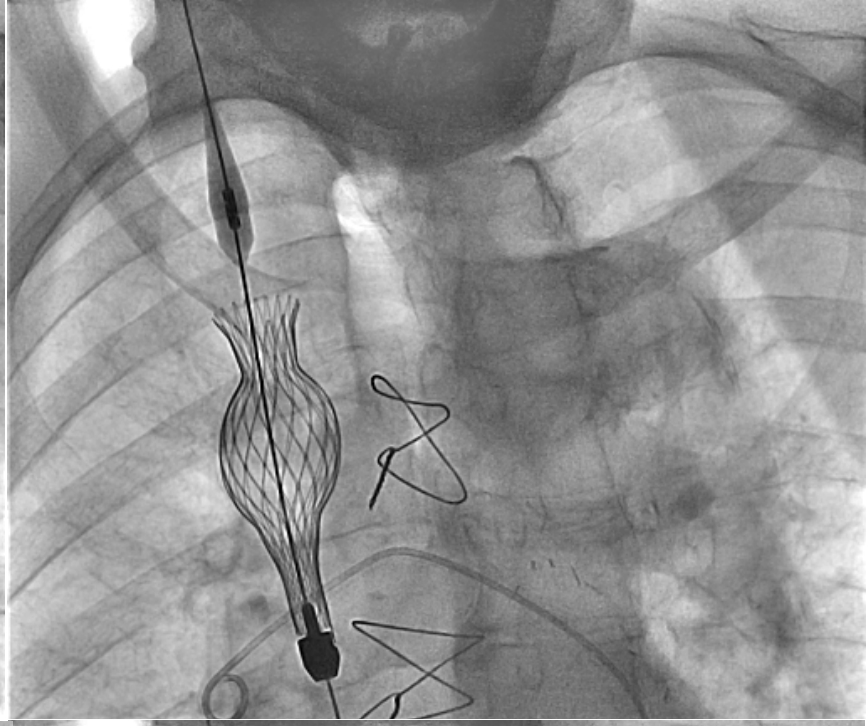
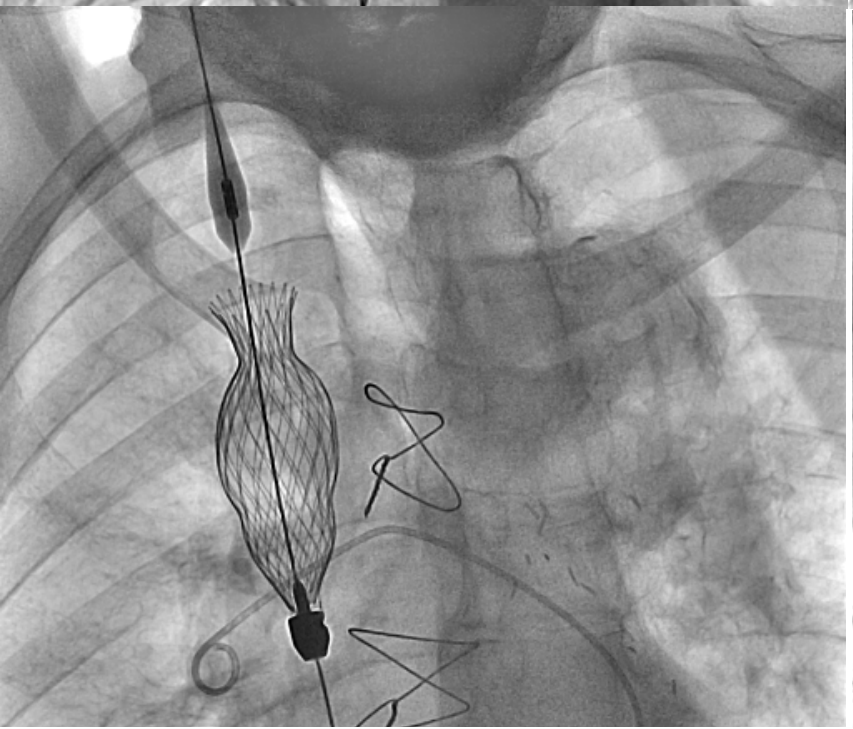
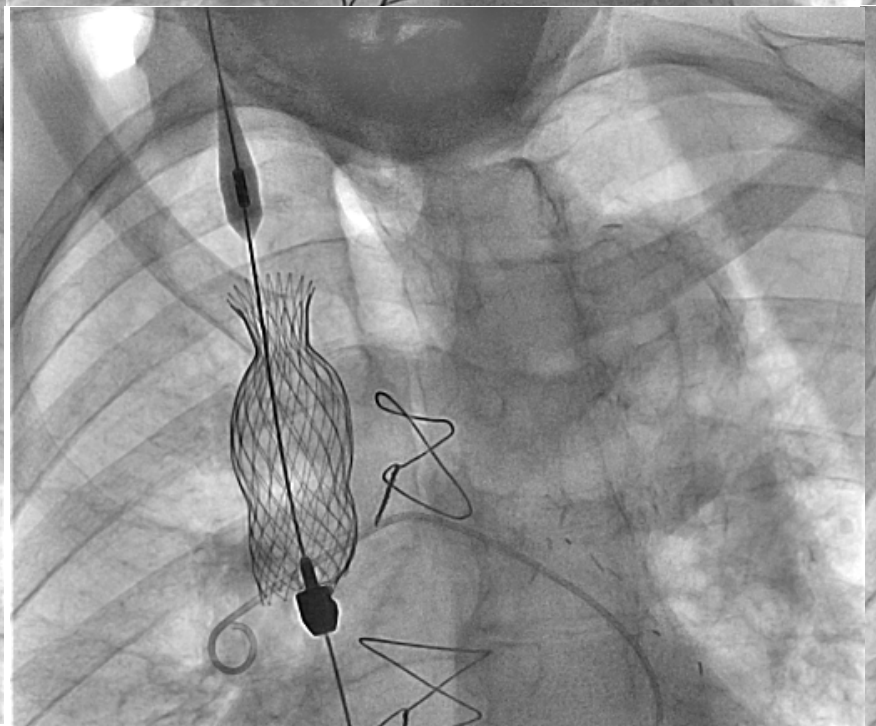
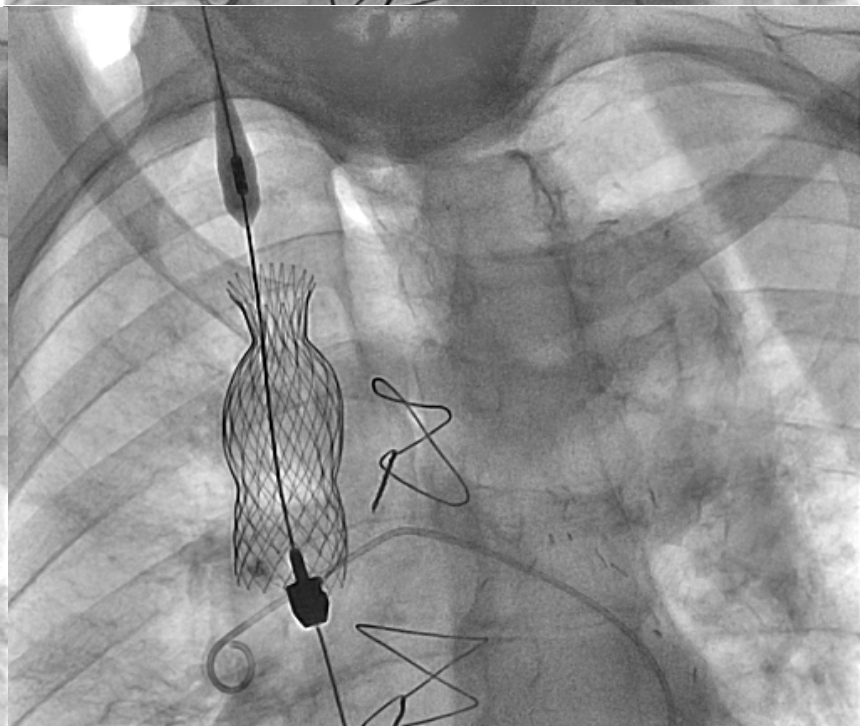
VCS
Size 29



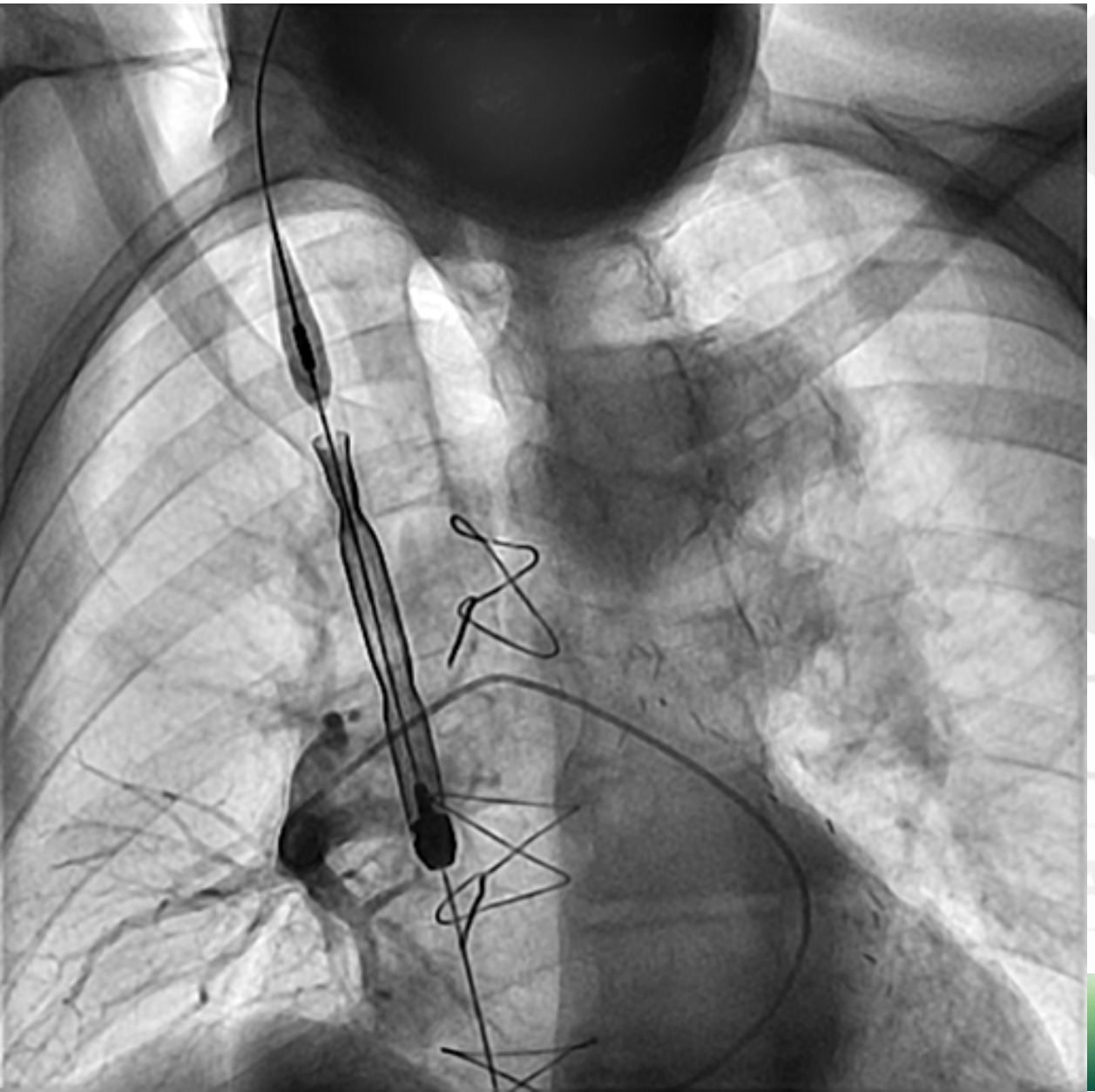
Tomografia Multislice

VCI
Size 35

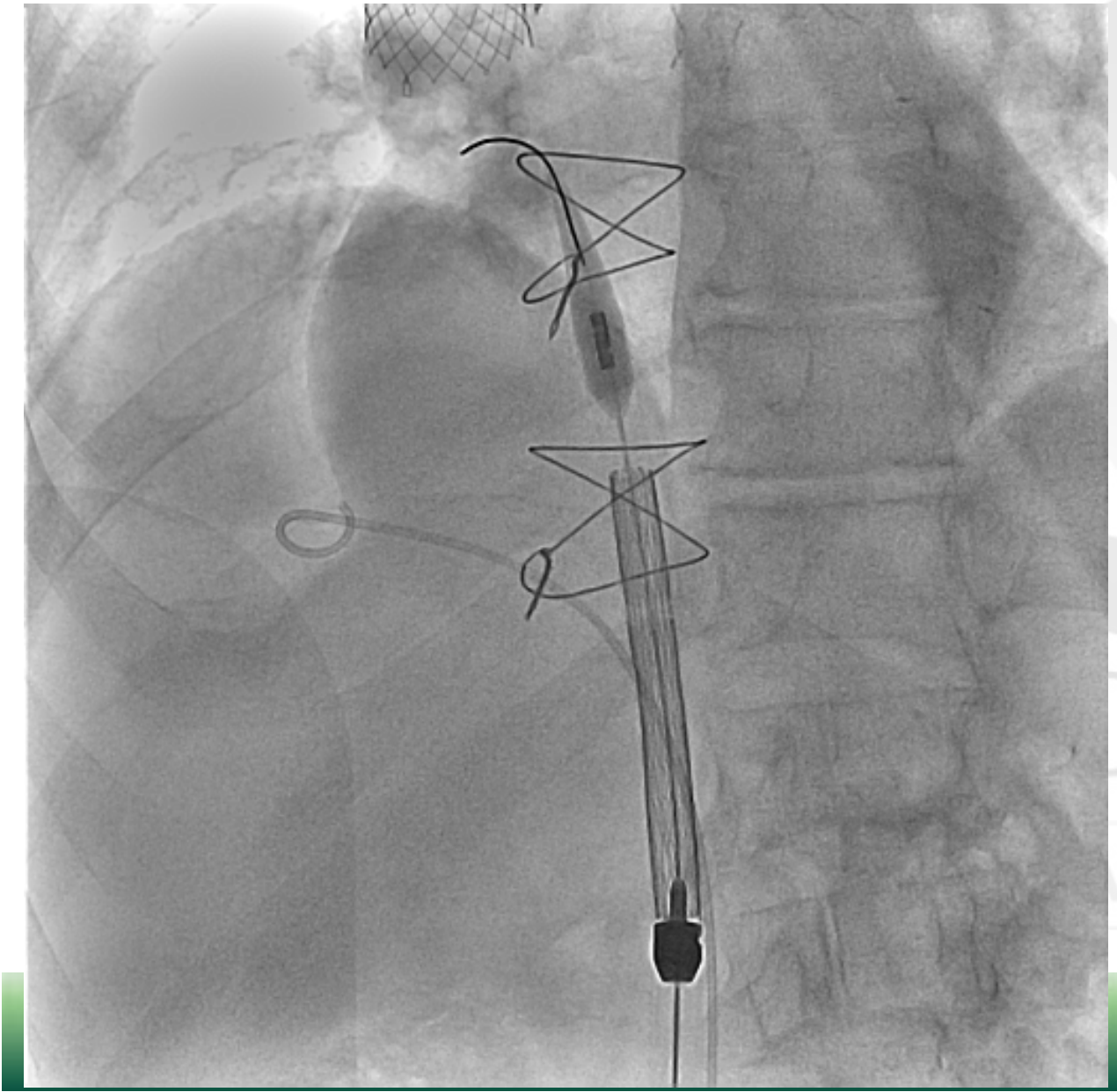


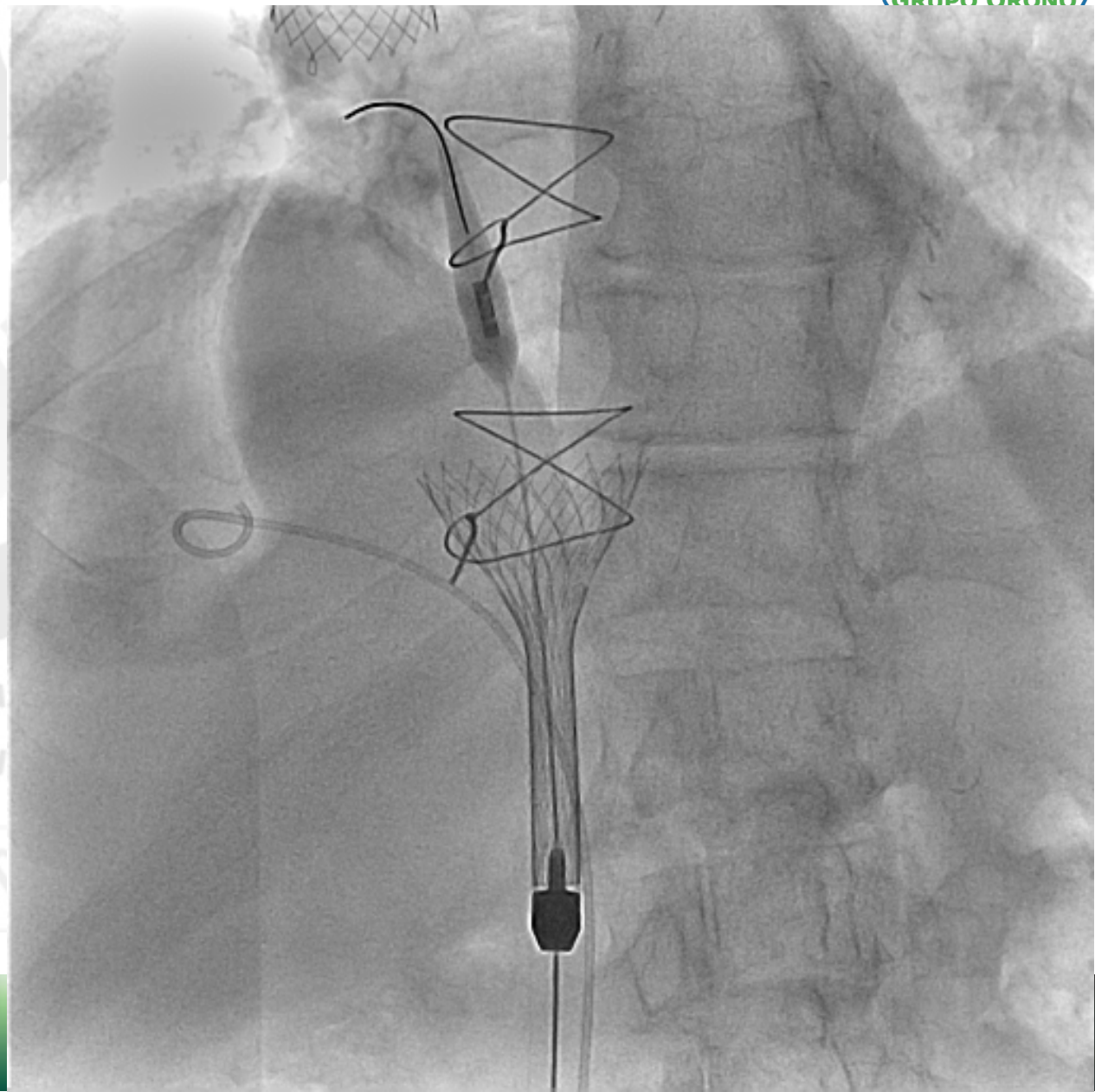







TRIC VALVE



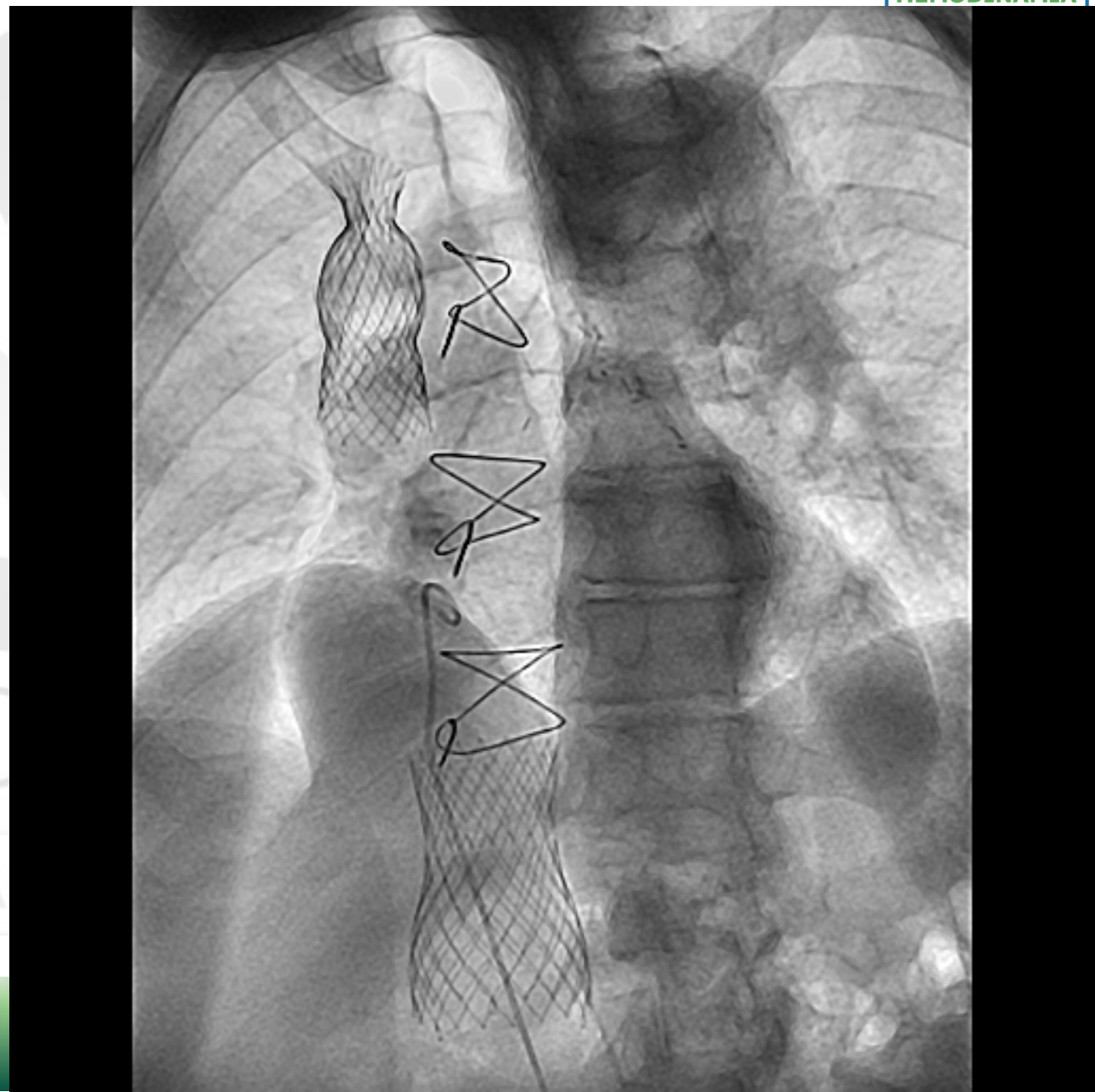
TRIC VALVE





TRIC VALVE

TRIC VALVE



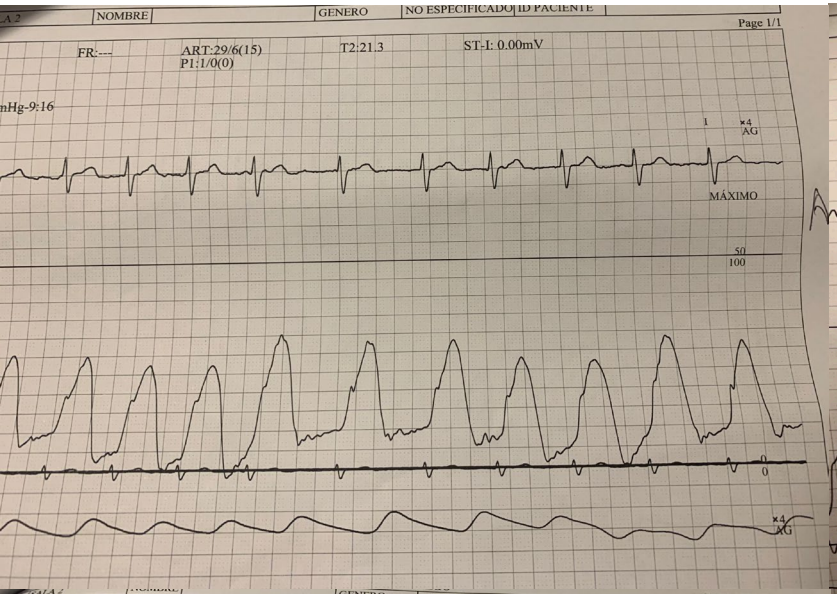
SOLACI SOCIME'25
MEXICO CITY

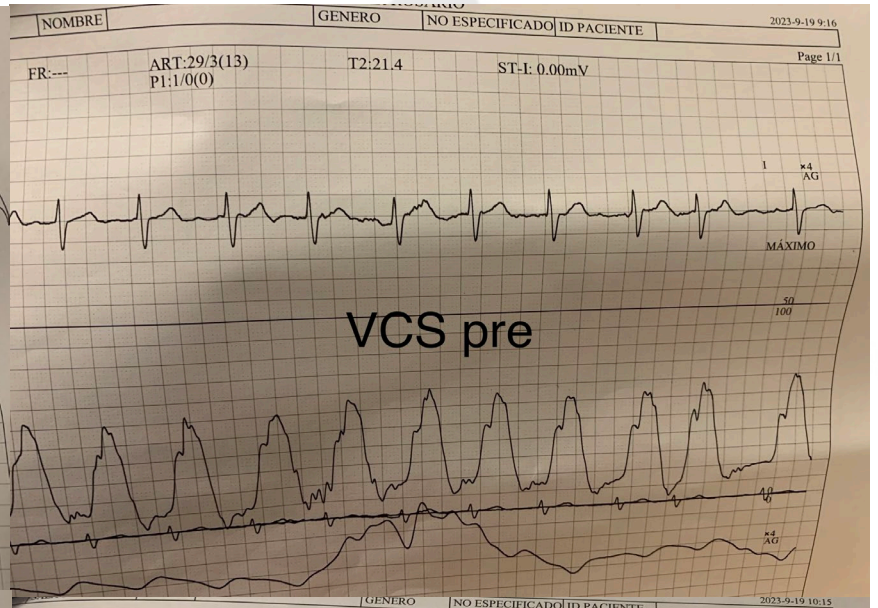
HEMODINAMIA GRUPO OROÑO

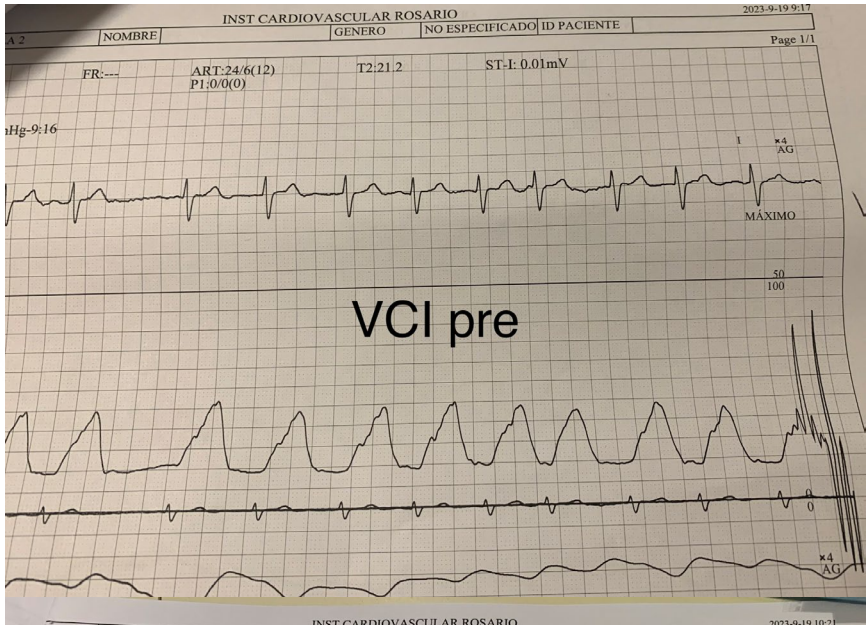
Auricula derecha

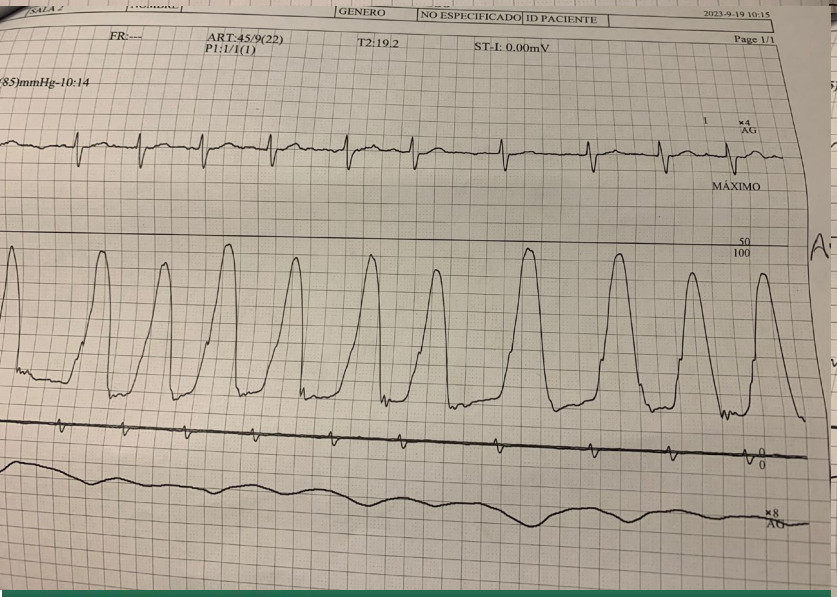
Vena Cava Superior

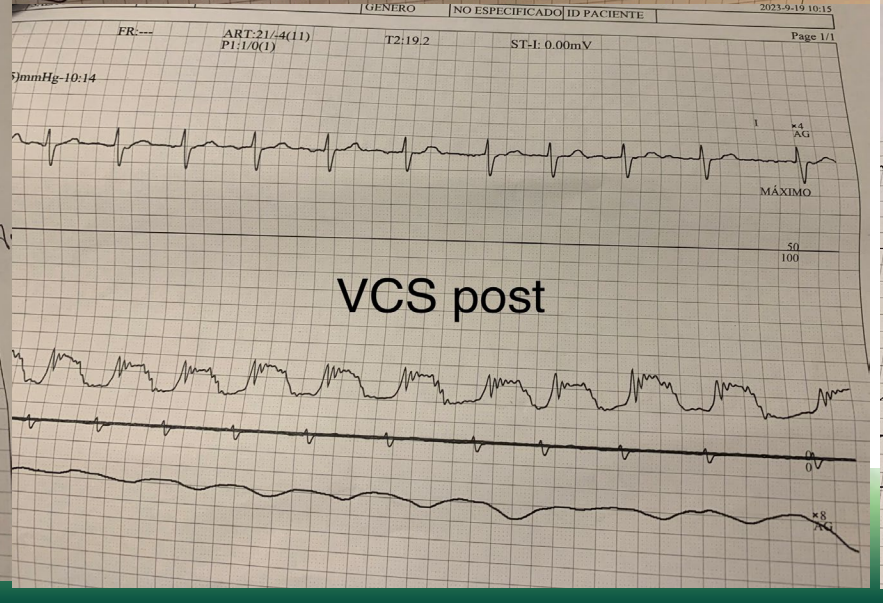
Vena Cava Inferior

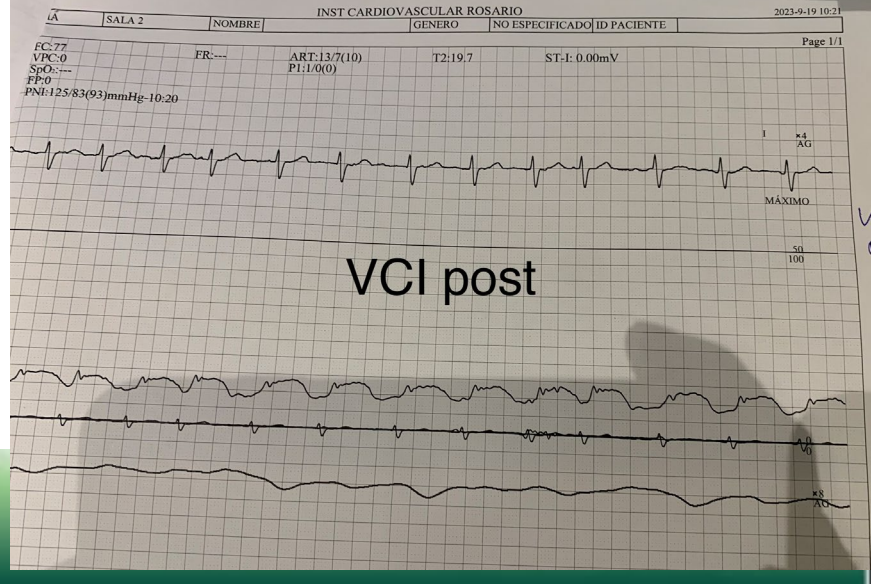










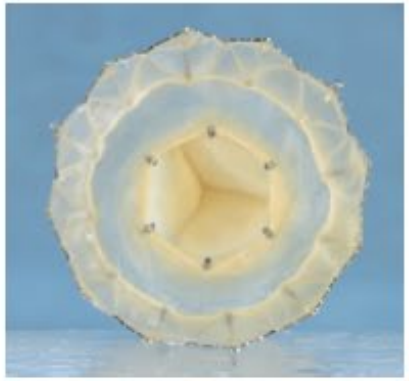


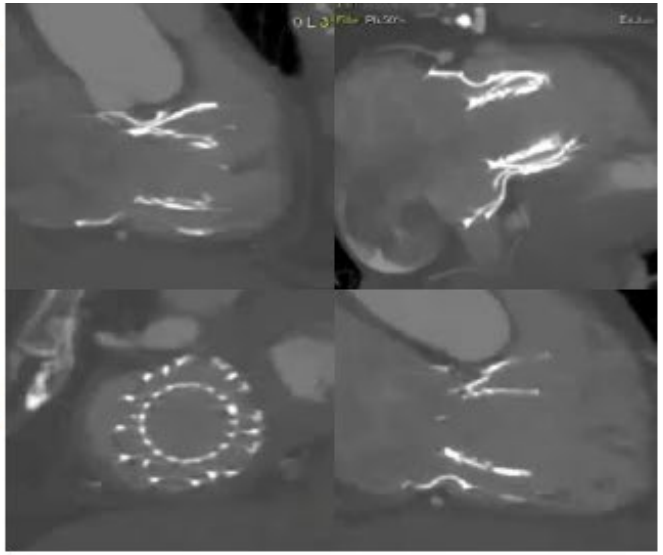
- Evoluciona con mejoria clinica lenta y progresiva
- FUP 9 meses, asintomatico

TTVR: Nuevos dispositivos

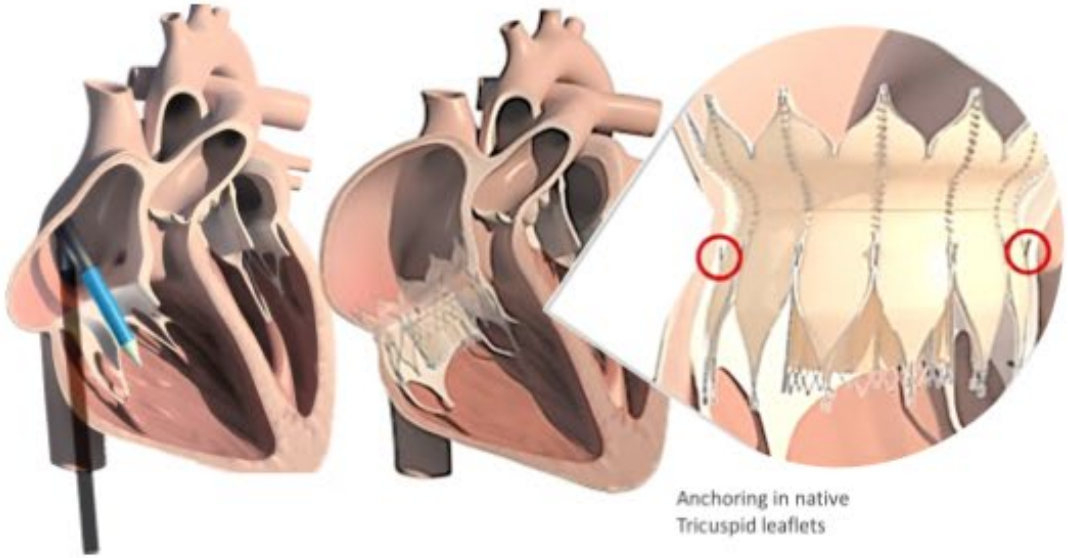
TOPAZ TTVR System

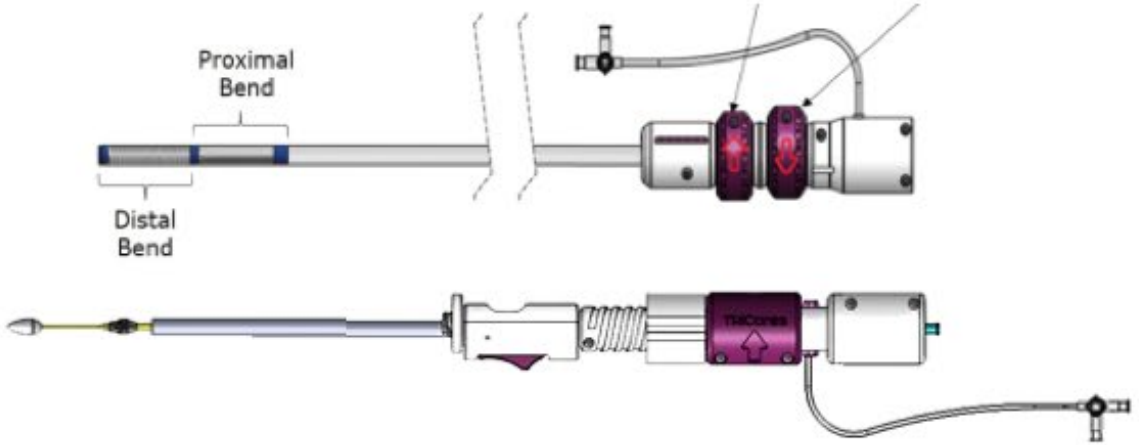
- **RIGID Inner Stent** → Reliable valve hemodynamics, round and competent
- **SOFT Outer Stent** → Conforms to patients' native tricuspid anatomy
  → Extremely low radial force prevents conduction disorders
- **ATRAUMATIC Anchors** → Secure and safe fixation to the native leaflets





A Tricuspid Valve that FLEXES WITH EVERY HEARTBEAT





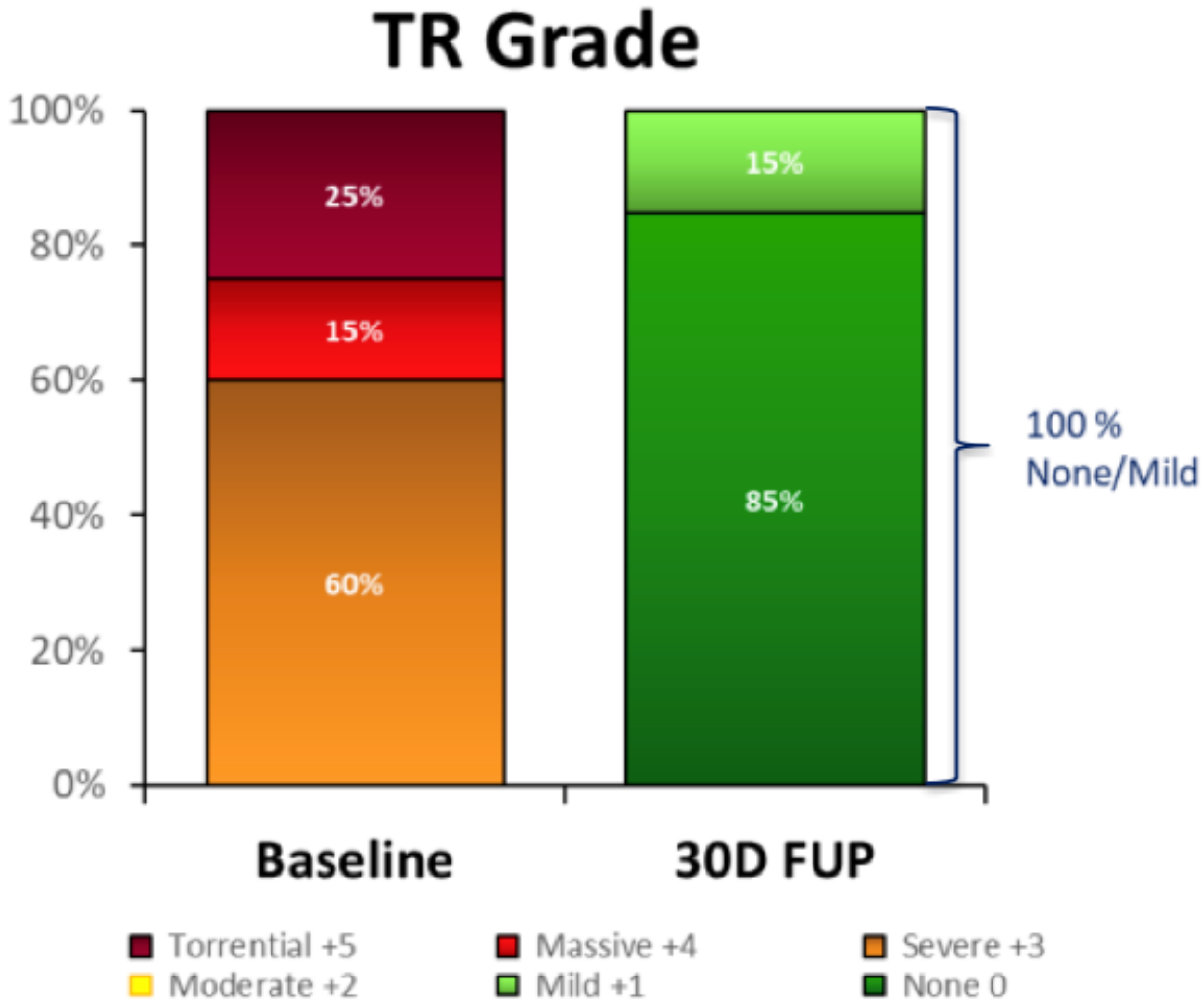
29 Fr Delivery Catheter and Steerable Sheath

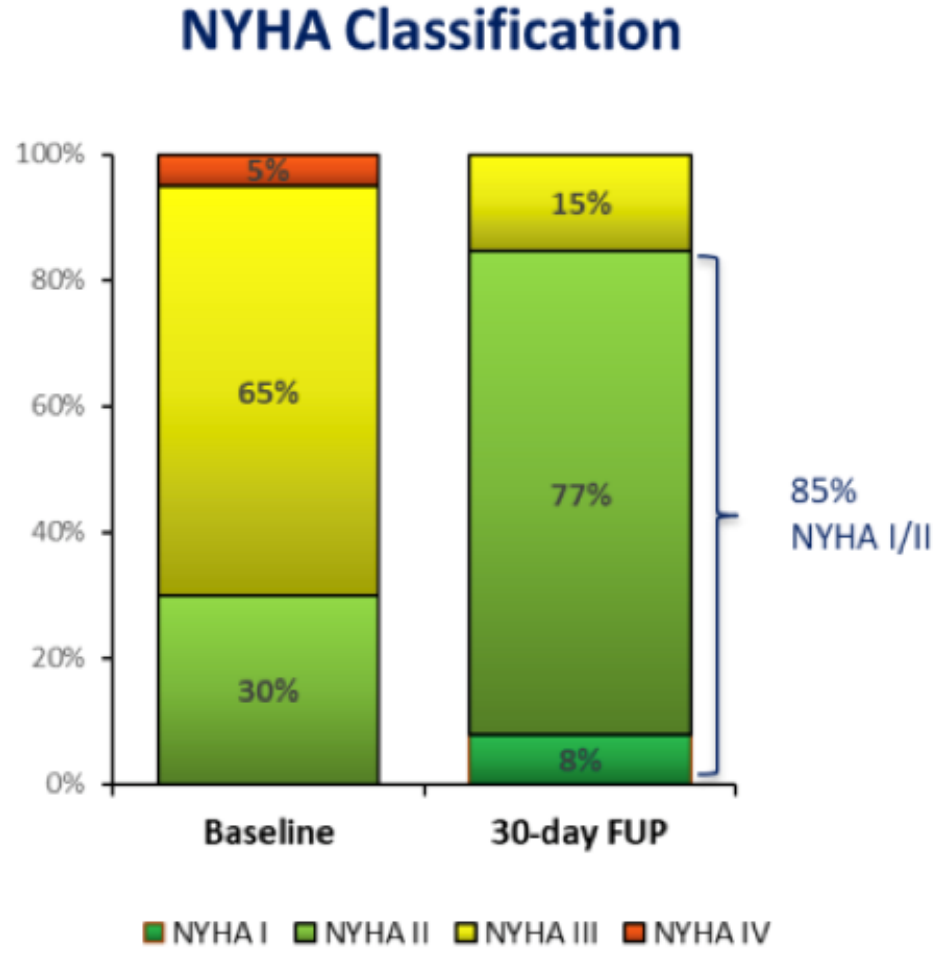
TRICURE FIH : Safety 30 days

Mean procedural time: 35 min

CEC adjudicated MAE	N (%)
All-cause mortality	3 (15%)
Cardiovascular mortality	2 (10%)
Non-cardiac mortality	1 (5%)
Re-intervention	3 (15%)
Elective (Topaz remained in situ)	2 (10%)
Non-elective	1 (5%)
HF hospitalization	1 (5%)
Composite MAE rate	**7 (35%)**
Myocardial infarction	0 (0%)
Stroke	0 (0%)
Renal complication	0 (0%)
Device-related PPM	0 (0%)
Device-related pulmonary embolism	0 (0%)
Thrombotic event	0 (0%)

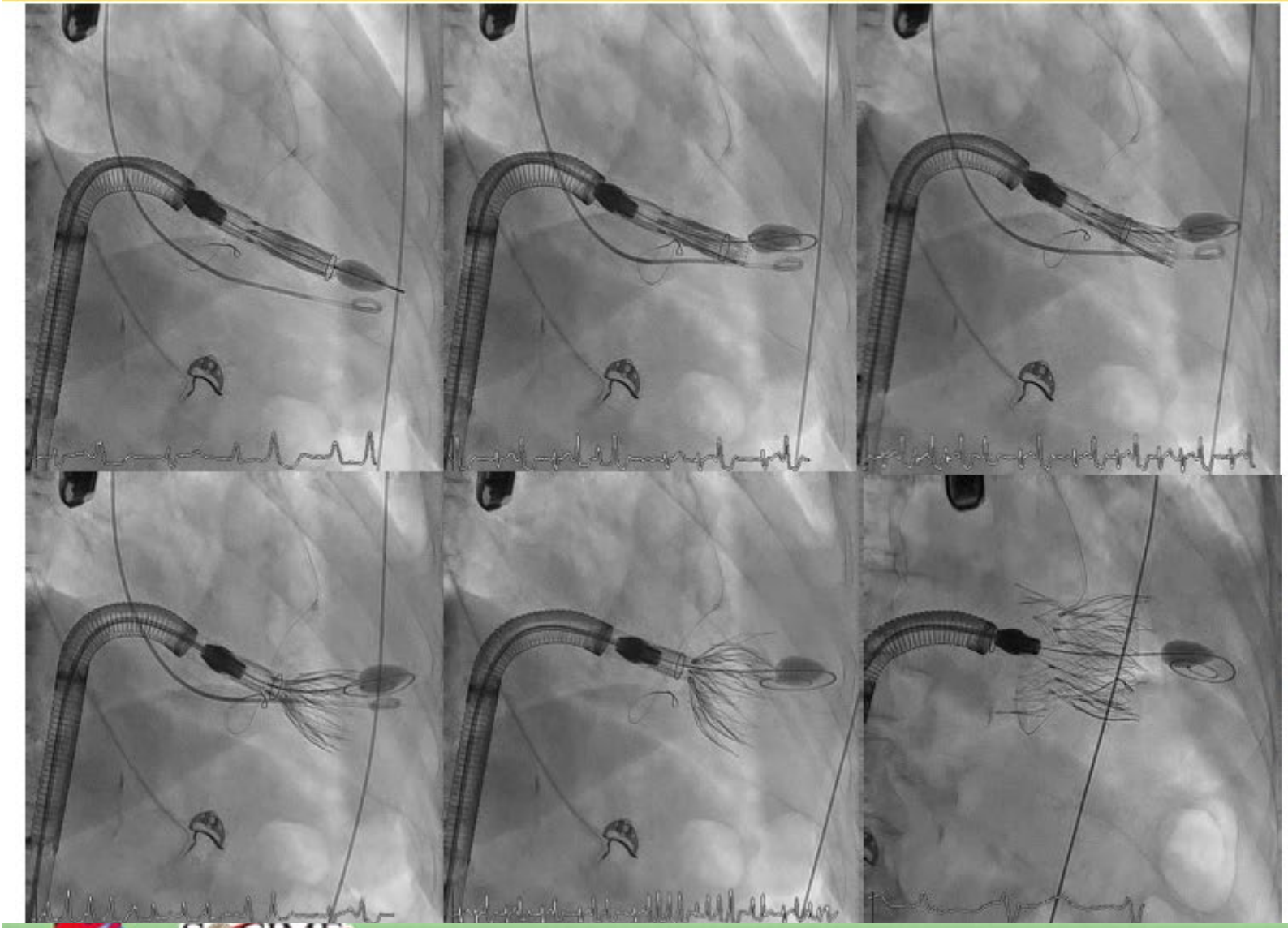
TRICURE FIH : Performance

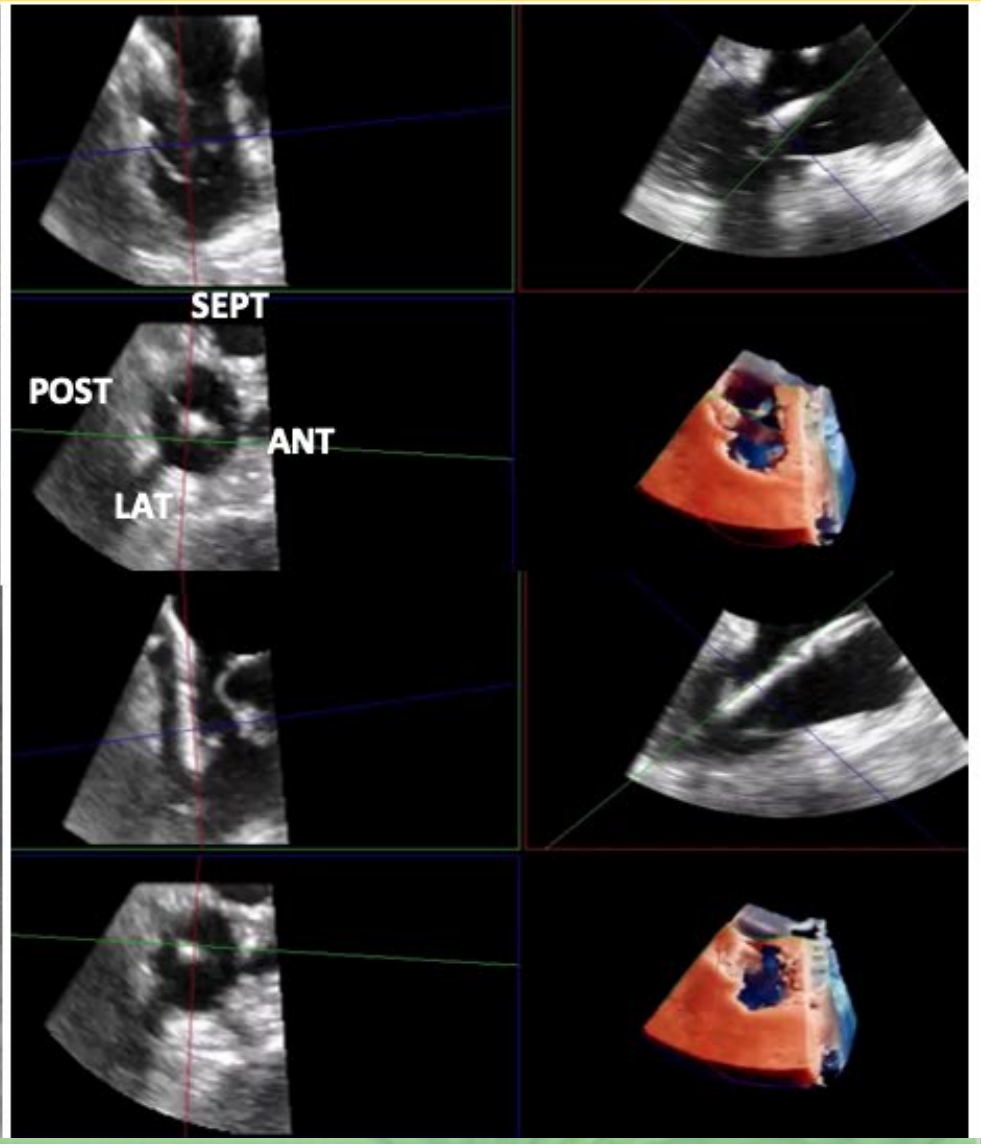




None/Mild = 100% of Topaz Implants*

TOPAZ Intervention



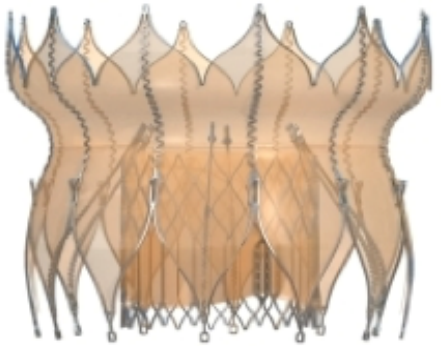


TRICURE FIH : Performance

- **Uniquely designed for the tricuspid valve anatomy**
- **Simple** and **fast** procedure
- The **early clinical experience** of the **TRICURE FIH study** showed **at 30 days**:
  - **10% Cardiovascular mortality**
  - **100% TR reduction to None/Mild**
  - **0% Topaz-related pacemaker implantation**
- Based on the **current learnings**,

the **ongoing TRICURE EU Study and TRICURE EFS** aim at :

  - confirming excellent **performance** results
  - showing significantly improved **safety** (currently >60 procedures with encouraging results)

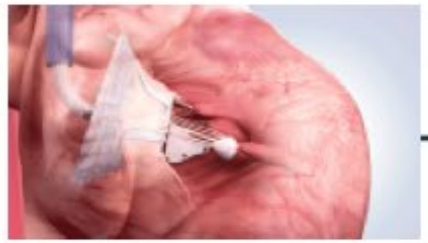


LUX VALVE PLUS TTVR

- Designated as the **"Breakthrough Device" by the FDA**
- Enrolled in the **Total Product Life Cycle Advisory Program ("TAP") by the FDA**
- Enrolled in the **Expert Panel Scientific Advice Pilot Program by the EMA**
- Admitted into the **Innovative Medical Device "Green Path" by the NMPA**

Non-radial Force Anchoring Design

- Interventricular septal anchoring free from radial force, complemented by a multi-dimensional fixation design using dual leaflet-grasping clips
- Facilitates postoperative right heart remodeling
- Reduces the risk of postoperative permanent pacemaker implantation



Innovative Self-adaptive Braided Ring

- Effectively reduces annular dilation
- Reduces postoperative PVL risk due to complex anatomical structures
- Braided ring sizes up to 70mm and inner annulus diameter sizes 30mm

Multi-dimensional Adjustable-Deflectable Delivery System

- Precise valve release positioning during the procedure
- Facilitates good coaxial alignment, reducing the risk of postoperative valve instability and PVL

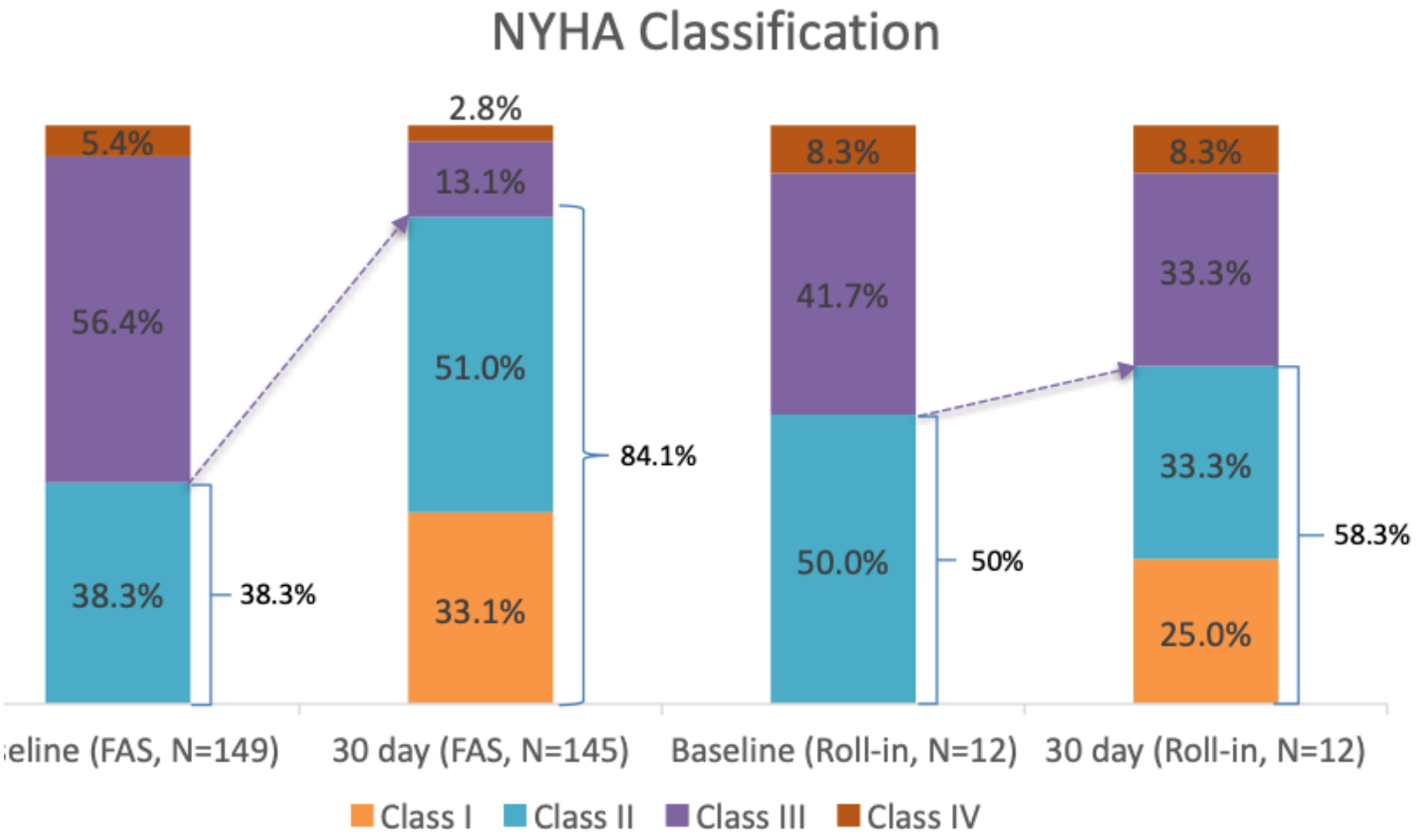
Composite adverse event at 30-day

■ **CEC-adjudicated Composite Adverse Events**

Composite Events at 30 day	FAS, N=149	Roll-in, N=12
Cardiovascular mortality	2/149 (1.3%)	0
Myocardial infarction	0	0
Strokes	1/149 (0.7%)	0
New onset renal failure	0	0
Severe bleeding (includes fatal, life-threatening and extensive bleeding as defined by MVARC)	6/149 (4.0%)	0
Non-selective tricuspid valve surgery/intervention post procedure	1/149 (0.7%)	1/12 (8.3%)
Major cardiac structural complications	3/149 (2.0%)	0
Major access site and vascular complications	0	0
Device-related pulmonary embolism	0	0
New pacemaker implantation due to AV block New pacemaker implantation due to AV block (Naive)	13/149 (8.7%) 13/109 (11.9%)	1/12 (8.3%) 1/9 (11.1%)

The overall CEC-adjudicated composite events rate at 30 day of FAS group is 14.8%.
The overall CEC-adjudicated composite events rate at 30 day of FAS + Roll-in group is 14.9%.

- *Device success rate is 96.64%, and procedural success rate is 91.95%.*
- *Average device time is 41.60±19.62 minutes, with the shortest device time being 11 minutes.*


NYHA Classification
5.4%
56.4%
38.3%
38.3%
2.8%
13.1%
51.0%
33.1%
84.1%
8.3%
41.7%
50.0%
50%
8.3%
33.3%
33.3%
25.0%
58.3%
eline (FAS, N=149)
30 day (FAS, N=145)
Baseline (Roll-in, N=12)
30 day (Roll-in, N=12)
Class I
Class II
Class III
Class IV

Resumen Final

- Insuficiencia tricuspidea es una enfermedad subtratada
- Progresa a IC con internaciones repetidas y aumenta el riesgo de eventos cardiovasculares
- Cirugia aislada de la valvula es de riesgo
- Multiples estrategias de intervenciones endovasculares en Desarrollo
- Futuro promisorio y necesidad de estudios randomizados

- **LuX-Valve Plus TTVR system is an innovative device indicated for high-surgical risk patients with severe TR, with the following advantages:**
  - ✓ Radial-force independent anchoring mechanism, which is designed particularly for TV
  - ✓ Low demands on imaging quality, which significantly reduce device time
  - ✓ Large size options enables wide applicability on large TV anatomies

- **The 30-day clinical outcomes of Trinity Trial demonstrated good safety and performances, with improvements in quality of life and low rate of composite adverse events.**

- **The wide application on large anatomy patients provides encouraging treatment options for severe TR patients, while current therapies are limited.**

- **Further follow-ups of Trinity Trial and clinical studies in the U.S. using LuX-Valve Plus system are underway.**