INTERVENCIONISMO SOBRE LA VÁLVULA TRICÚSPIDE. ESTADO ACTUAL

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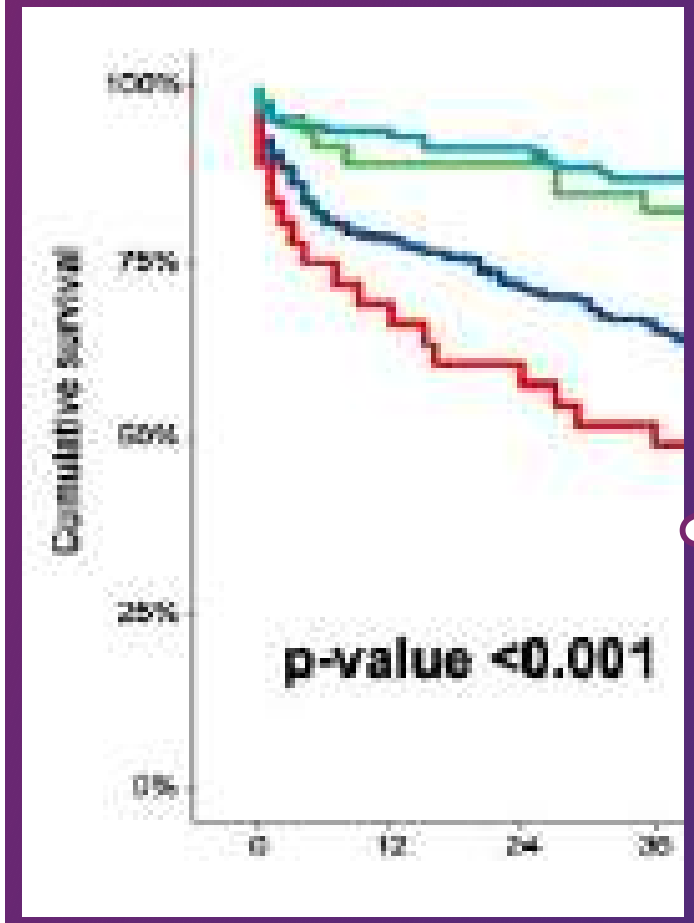
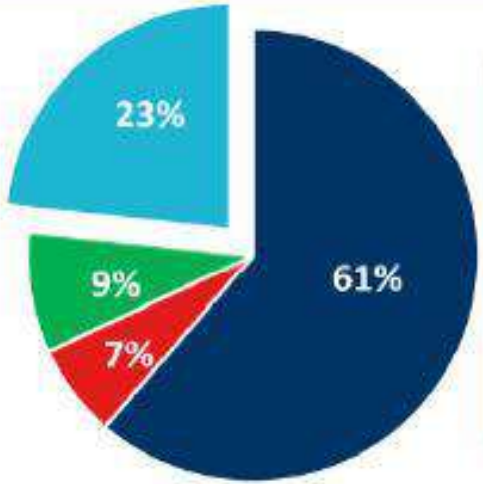
IMPLICACIONES PRONÓSTICAS DE LA ETIOLOGÍA DE LA INSUFICIENCIA TRICUSPÍDEA



Distribution of severe functional TR

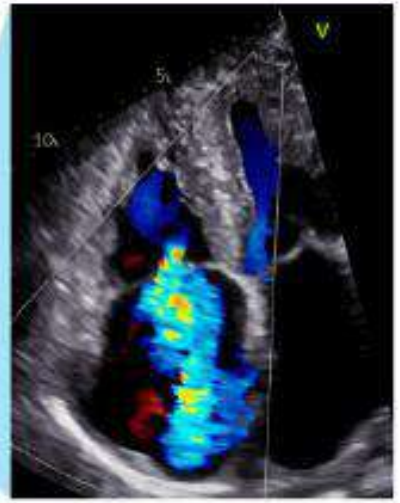


- Left-sided cardiac disease
- Pulmonary hypertension
- RV dysfunction

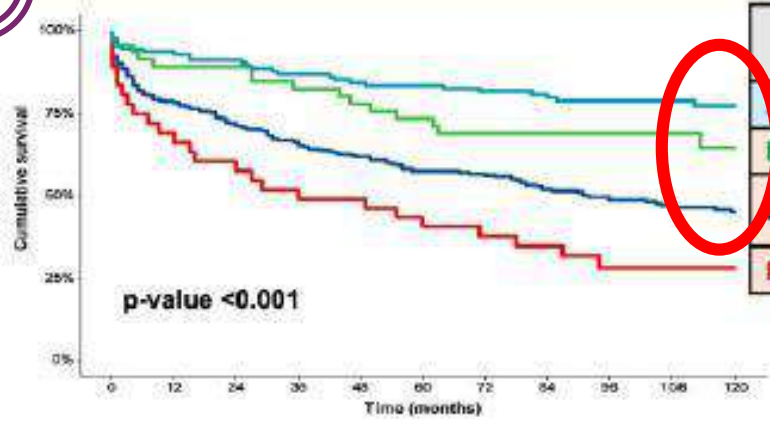
VFTR

- Atrial FTR

AFTR



Overall survival of severe functional TR



	1-year survival	5-year survival	10-year survival
Atrial FTR	94%	84%	78%
RV dysfunction	89%	74%	65%
Left-sided cardiac disease	79%	58%	45%
Pulmonary hypertension	69%	43%	28%

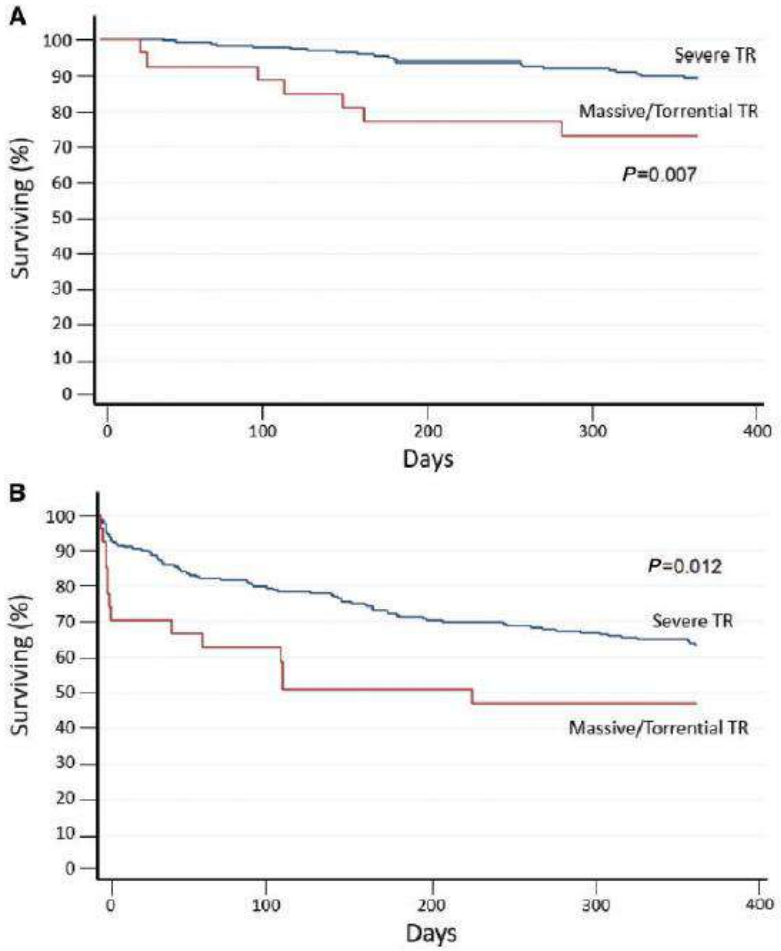
Galloo et al. European Heart Journal - Cardiovascular Imaging (2023) 00, 1–9

There is a Difference Between Severe, Massive & Torrential TR[1]

- 13,071 consecutive patients underwent complete TTE with TR evaluation based on qualitative and semi-quantitative parameters performed according to recent guidelines

- 249 patients identified with >moderate TR (1.9%)
- 1 Year F/U
- TR was re-classified into Severe, Massive & Torrential by quantitative echo evaluation

- Differences shown at 1 Year:
  - Cardiovascular mortality in the Massive/Torrential TR (A)
  - Combined endpoint for cardiovascular mortality and re-hospitalization (B)



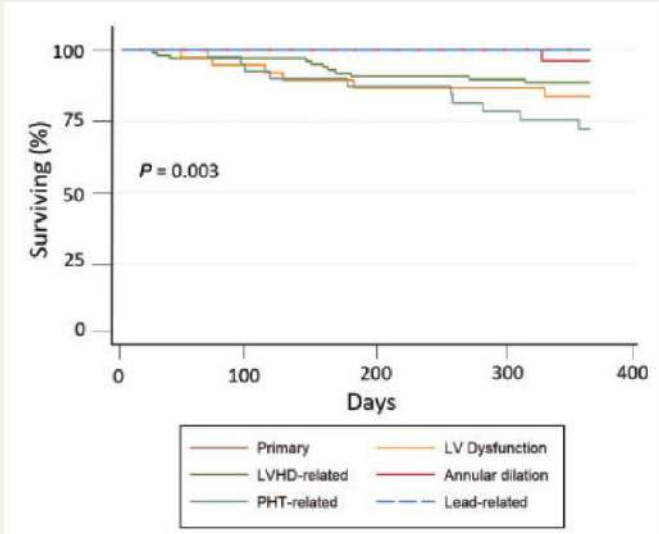


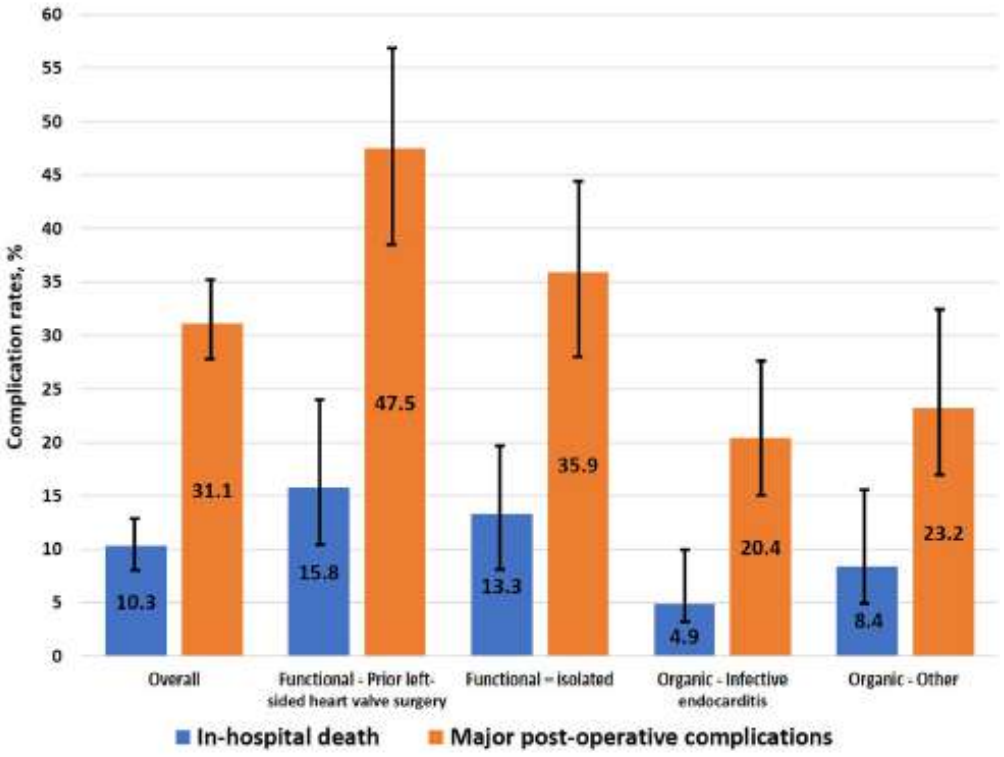
Figure 3 Cardiovascular mortality risk at 1-year follow-up according to TR aetiology. Kaplan–Meier survival curves for cardiovascular mortality according to TR aetiology group.

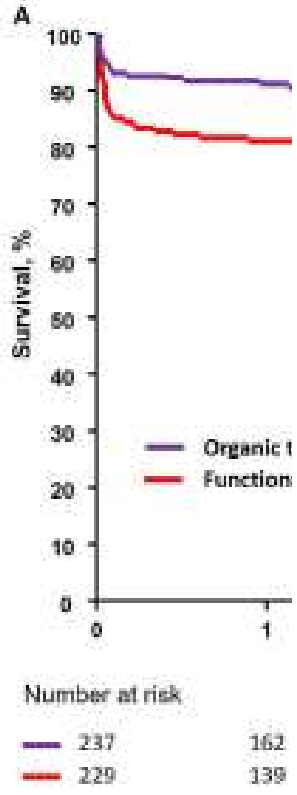
Patients with pulmonary hypertension had the worst prognosis

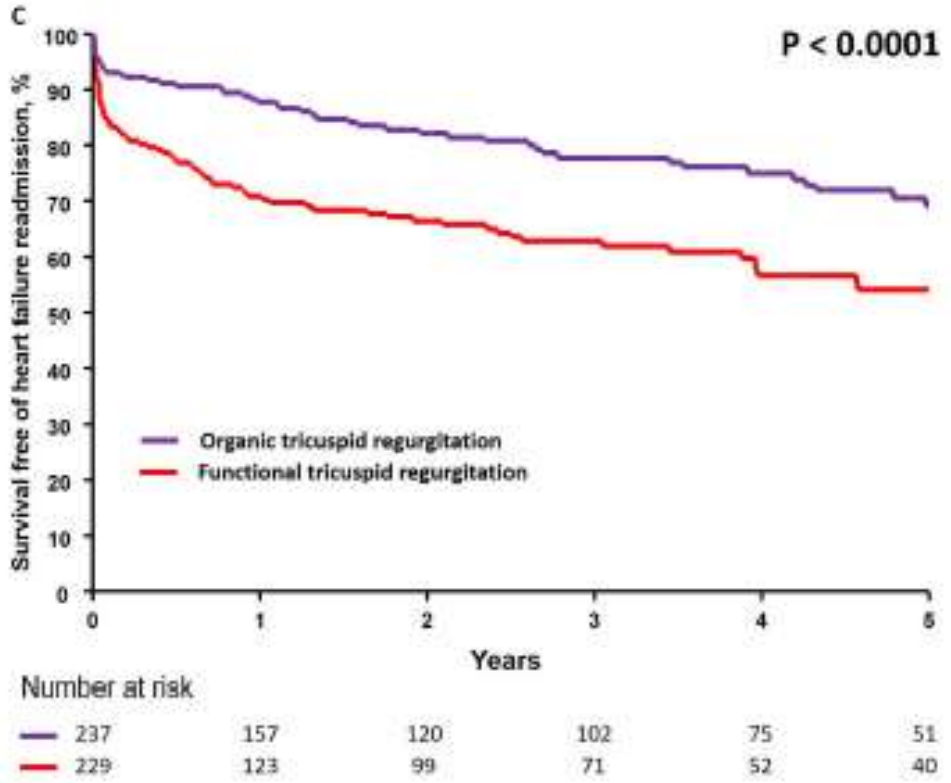
1. Santoro et al EHJ CV Imaging 2019

Surgery for isolated TR

- 5661 pts 12 French high-volumen centers 10 year period
- 8% (441) isolated valve surgery; ≈ 3.6 cases/center/year
- FTR 49%







Overall mortality 10%
FTR 13.3%-15.8%

Dreyfus J, Eur Heart J 2020

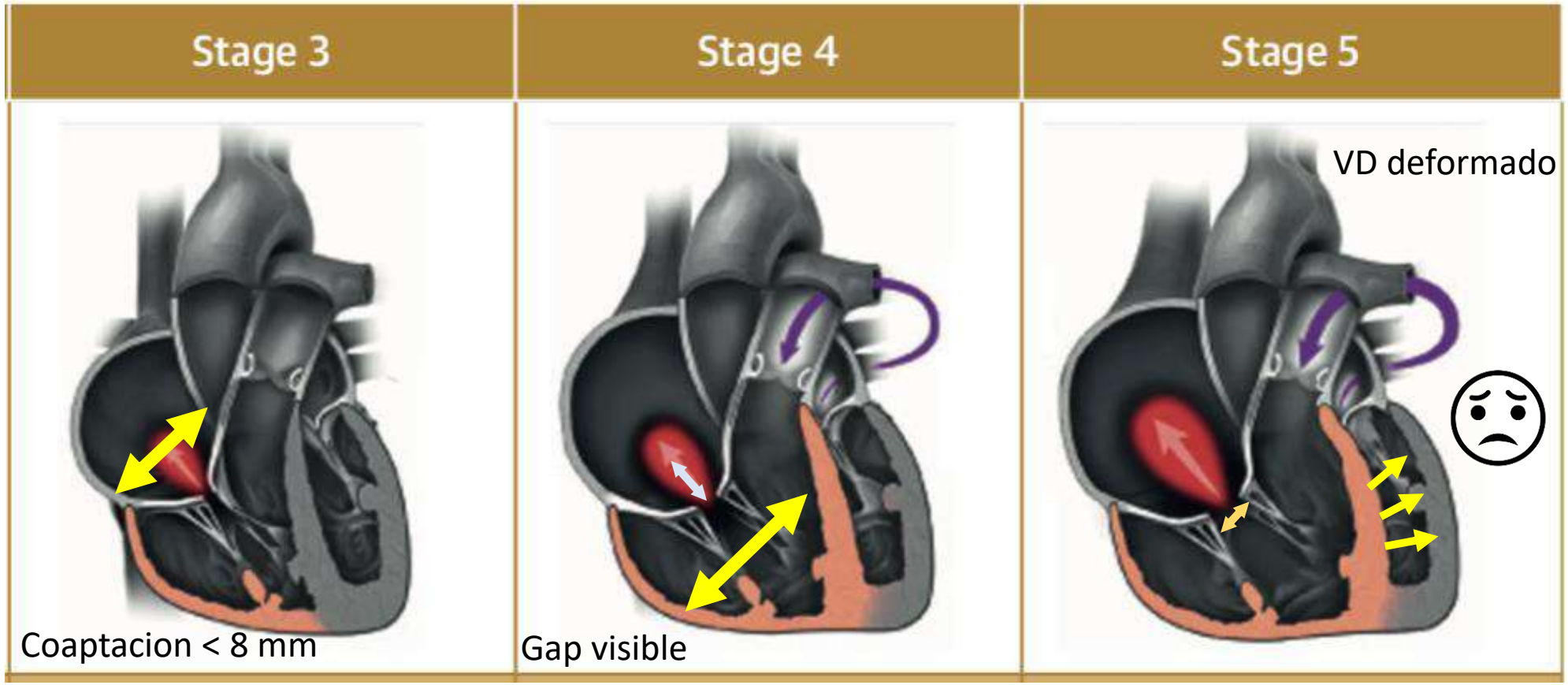
INSUFICIENCIA TRICUSPÍDEA. CLASIFICACIÓN

	Secondary		CIED (A)	Primary	
2D TTE					
3D TTE					
Parameter	**Ventricular**	**Atrial**	**CIED Type A**	**Primary TR**	
Carpentier Class	*IIIb*	*I*	*I, IIIa, IIIb*	*Prolapse II*	*RHD IIIa*
TV Tethering	++++	+/−	++	−	−
Leaflet Restriction	Systole	−	Systole/Diastole	−	Diastole
RA/TA Dilatation	++	++++	+/−	++	+++
RV Dilatation	+++	+/−	+/−	+/−	+/−
RV Dysfunction	+++	+/−	+/−	+/−	+/−

Rebecca T Hahn Eur Heart J octubre 2023

FUNCIÓN VD

PRESIÓN PULMONAR



ANILLO

VALVAS

PROTESIS HETEROTÓPICA

PROTESIS ORTOTÓPICA

Taramasso et al. J Am Coll Cardiol Img 2019;12:605–21

DISPOSITIVOS PARA TRATAMIENTO DE INSUFICIENCIA TRICUSPÍDEA

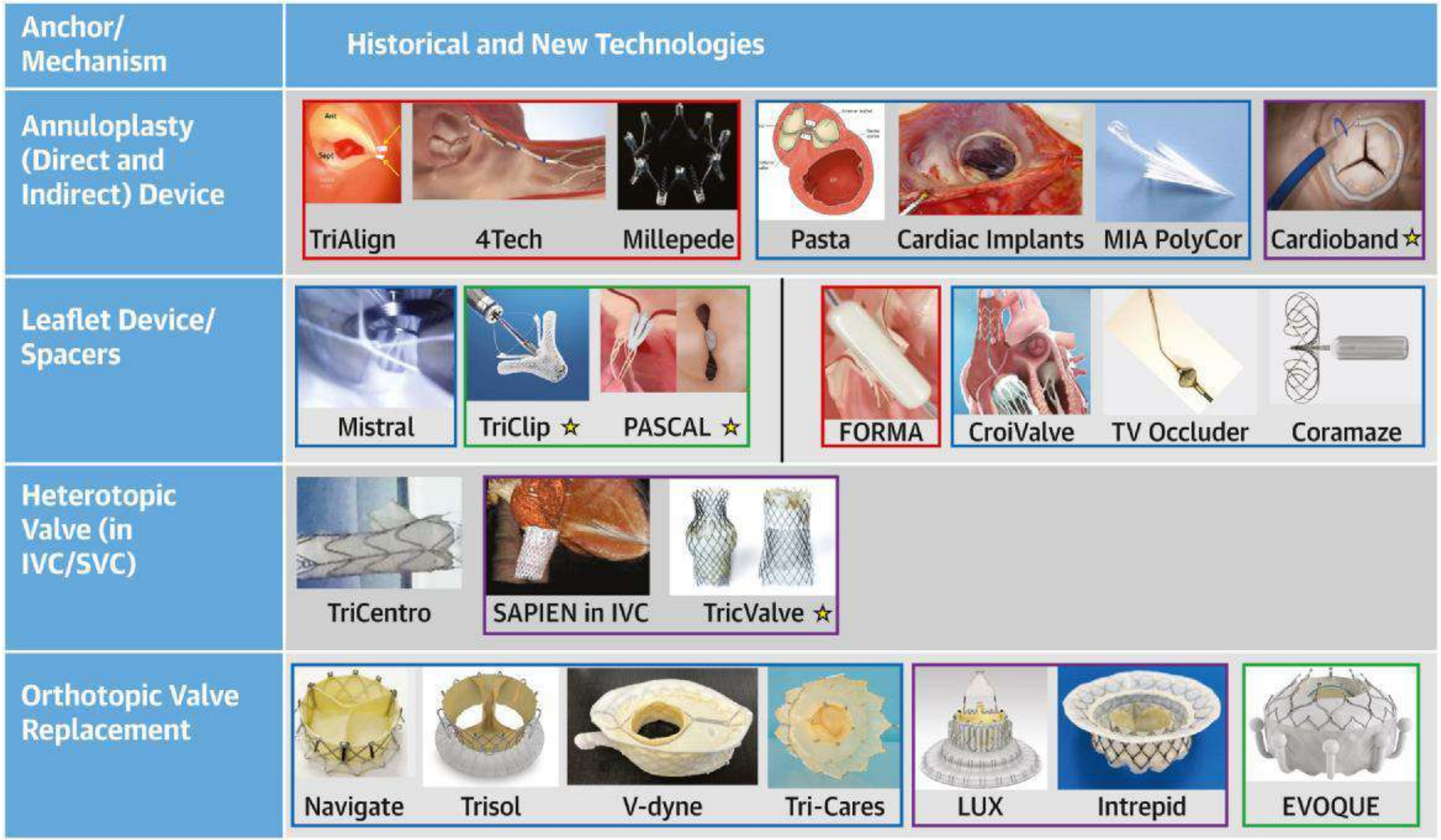


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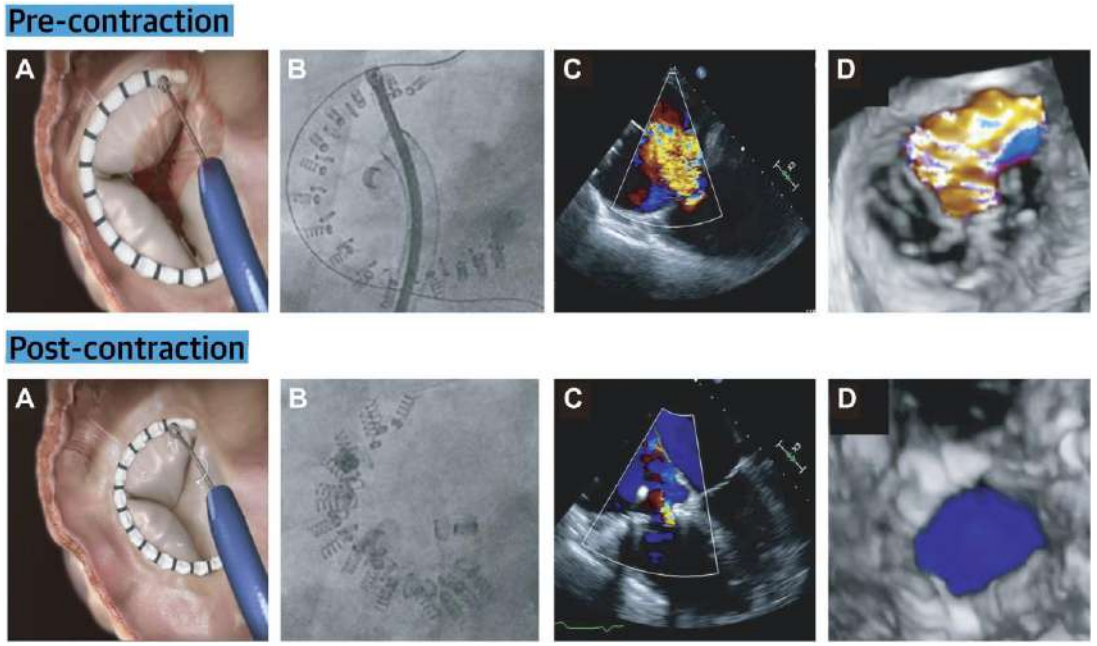
Table 3. Anatomical criteria for device selection.

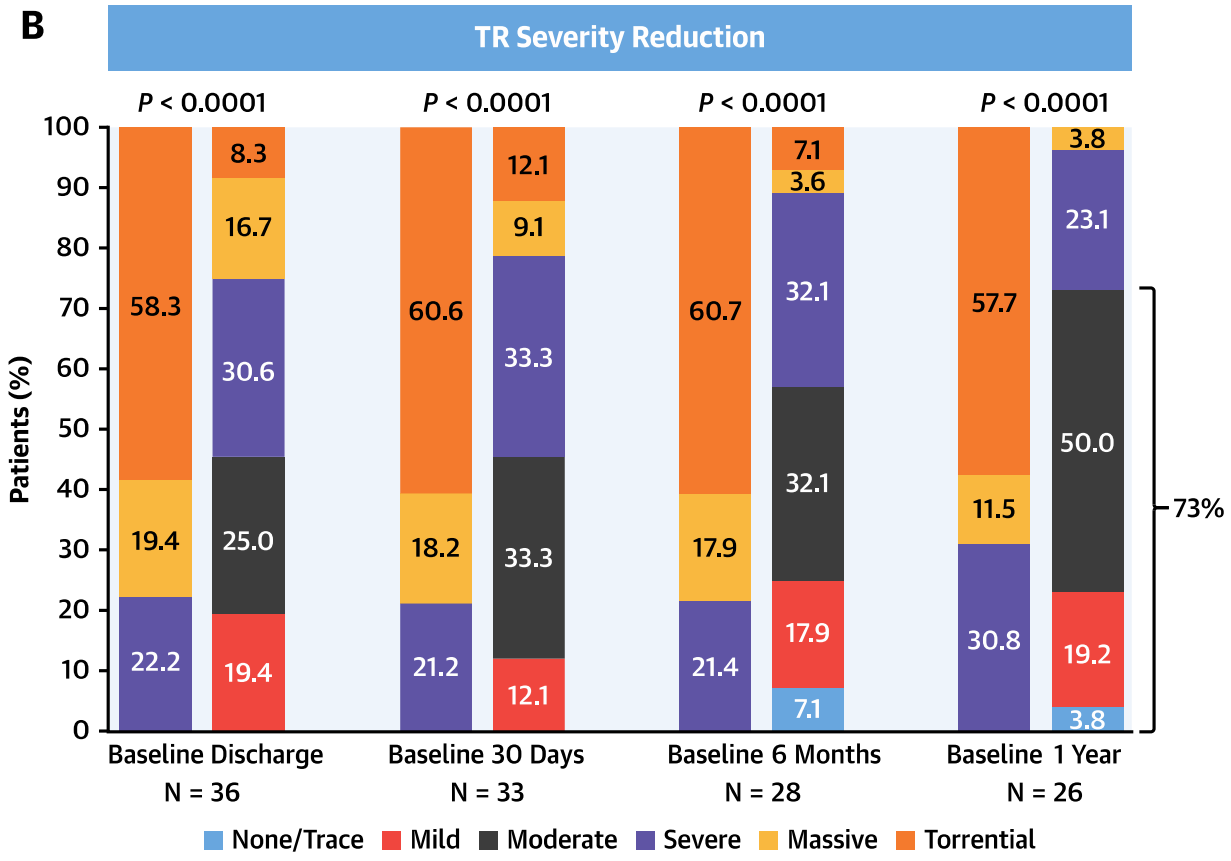
Strategy	Favourable anatomy	Feasible anatomy	Unfavourable anatomy
Leaflet approximation	Small septolateral gap ≤7 mm[10] Anteroseptal jet location Confined prolapse or flail Trileaflet morphology	Septolateral coaptation gap >7 but ≤8.5 mm[65] Posteroseptal jet location Non-trileaflet morphology Incidental CIED RV lead (i.e., without leaflet impingement)	Large septolateral coaptation gap >8.5 mm[65] Leaflet thickening/shortening (rheumatic, carcinoid)/perforation Dense chordae with marked leaflet tethering Anteroposterior jet location Poor echocardiographic leaflet visualisation CIED RV lead leaflet impingement Unfavourable device angle of approach
Annuloplasty	Annular dilatation as primary mechanism of TR Mild tethering (tenting height <0.76 cm, tenting area<1.63 cm², tenting volume [3D] <2.3 mL)[110,111] Central jet location Sufficient landing zone for anchoring	Moderate tethering (tethering height ≥0.76 cm but <1.0 cm, tenting area >1.63 but <2.5 cm², tenting volume [3D] ≥2.3 mL but ≤3.5 mL)[110,111] Incidental CIED RV lead (i.e., without leaflet impingement)	Excessive annular dilatation (exceeding device size) Severe tethering (tethering height >1.0 cm, tenting volume >3.5 mL). Poor echocardiographic annular visualisation[110,111] Annular proximity of RCA CIED RV lead leaflet impingement
Orthotopic valve implantation	Previous surgical repair or bioprosthetic valve replacement Leaflet thickening/shortening (rheumatic, carcinoid) Incidental CIED RV lead (i.e., without leaflet impingement) Any leaflet morphology	Large coaptation gap CIED RV lead leaflet impingement	Excessive annular dilatation (exceeding device size) Unfavourable device angle of approach Severe right ventricular dysfunction
Heterotopic valve implantation	Appropriate caval diameters (and intercaval distance) No option for direct valve treatment		Proximity of the RA to the orifice of the liver veins (<10-12 mm) Severely increased pulmonary artery and RA pressures due to the risk of fracture of bicaval valved stents

3D: three-dimensional; CIED: cardiac implantable electronic device; RA: right atrium; RCA: right coronary artery; RV: right ventricular; TR: tricuspid regurgitation

Annuloplasty Devices

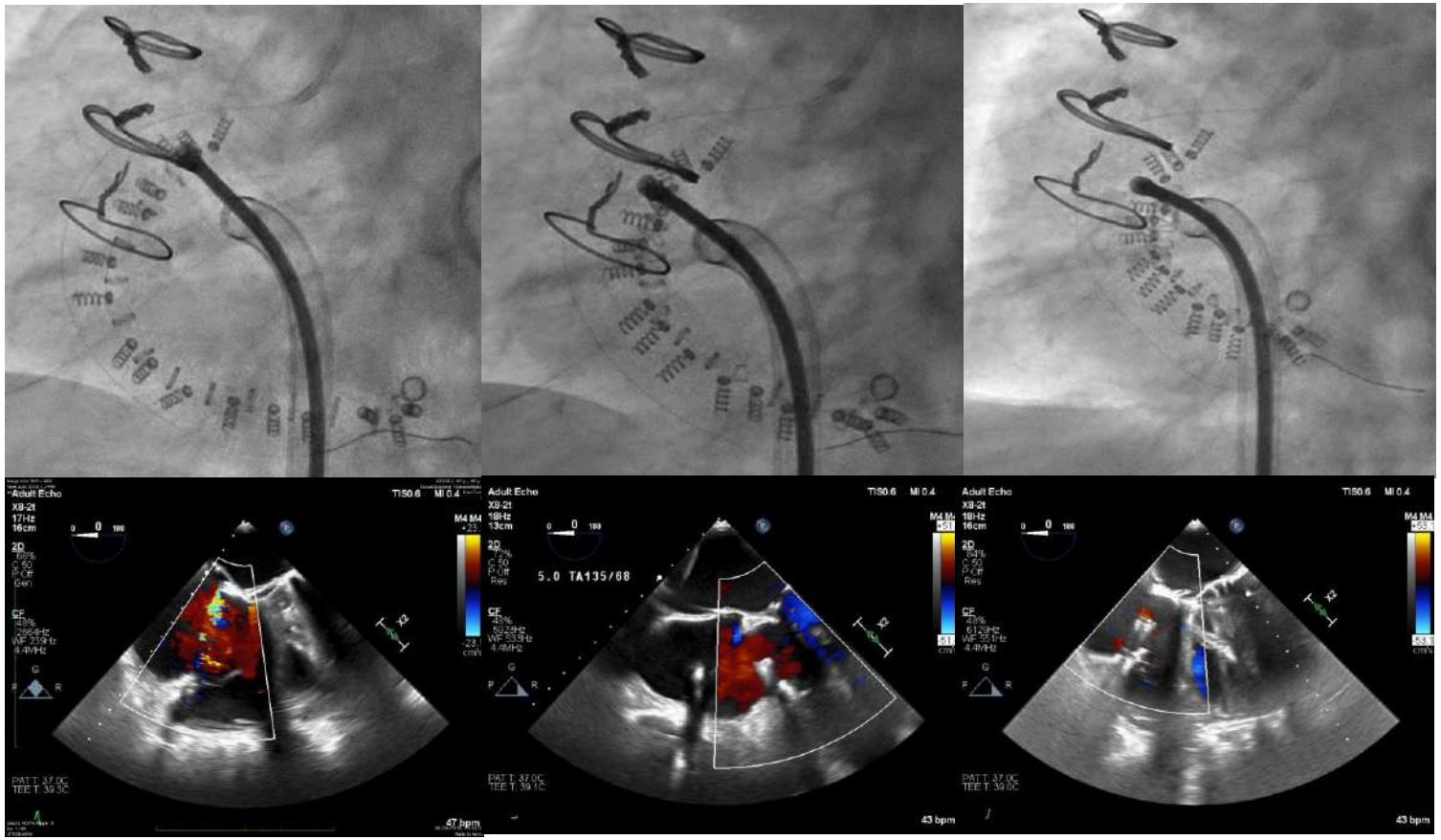
1-Year Outcomes of Cardioband Tricuspid Valve Reconstruction System Early Feasibility Study





Gray WA, et al. J Am Coll Cardiol Intv. 2022;15(19):1921-1932.

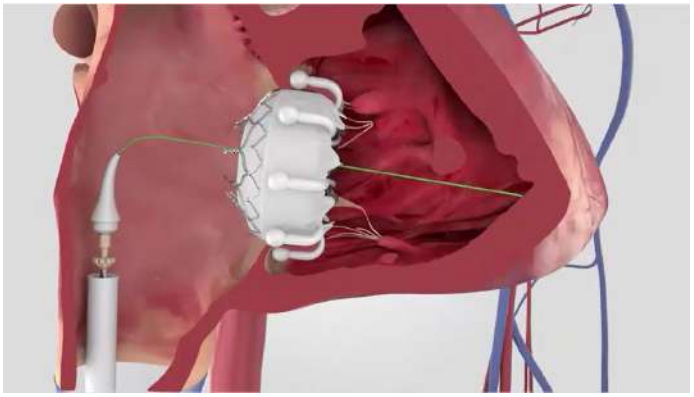
Cardioband

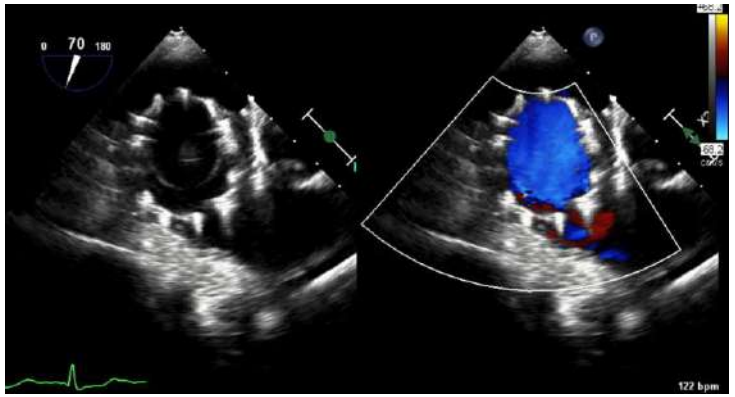


Courtesy of Dr. Sánchez-Recalde &
Ramon y Cajal Hospital

EVOQUE Tricuspid Valve Replacement System

***Unique valve design** engages leaflets, chords, and annulus to achieve secure placement*





Atraumatic anchors compatible with pre-existing leads and respect the native anatomy

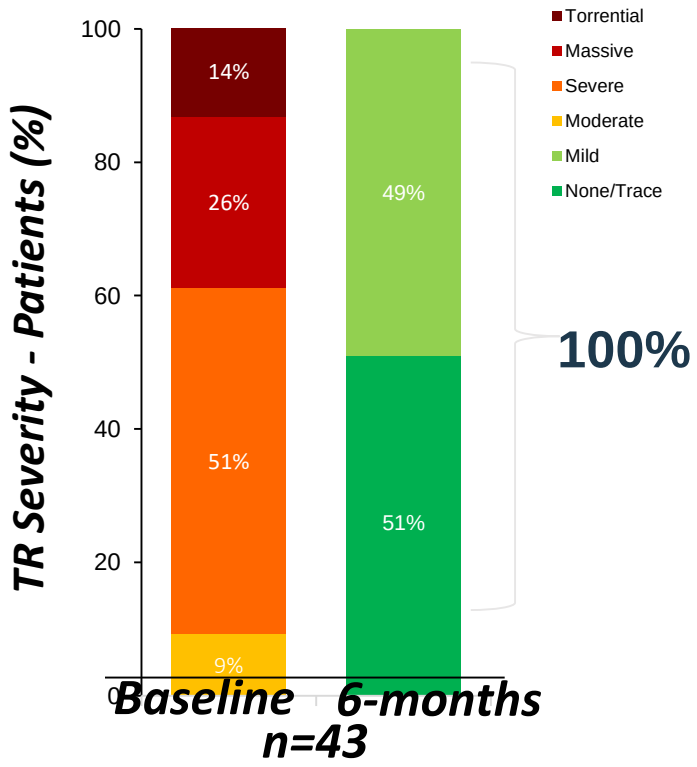
Conforming frame designed to achieve optimal retention force

Multiple sizes offer treatment for a broad range of tricuspid pathologies and anatomies ***(44, 48, 52 mm)***

***28F transfemoral delivery system** compatible with all valve sizes*

TR Severity / 6-Months

p < 0.001[a]



THE TRISCEND STUDY

EVOQUE Transcatheter Tricuspid Valve Replacement System

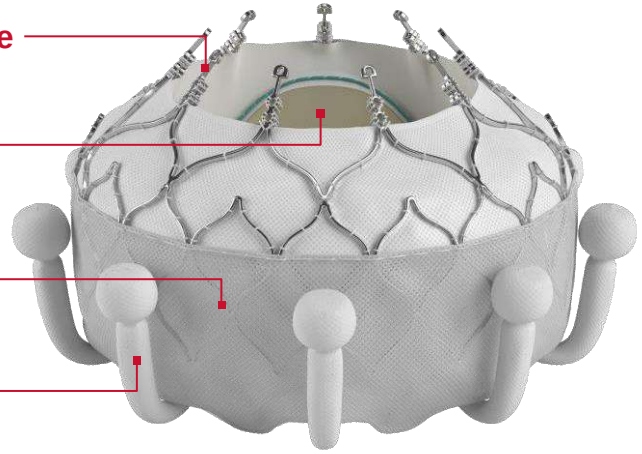
EVOQUE Valve

Nitinol self-expanding frame

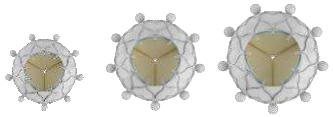
Bovine pericardial tissue

Intra-annular sealing skirt

9 ventricular anchors



Available in three sizes



44 mm 48 mm 52 mm

EVOQUE Delivery System

Transfemoral

28 Fr outer diameter

3 planes of movement

TRISCEND II: Two-Part Study Design Based on the Breakthrough Designation

THE TRISCEND II PIVOTAL TRIAL

‘First 150’
First 150 patients randomized and treated

Total Cohort
N = 400
All-randomized patients

Enrolled, follow-up ongoing

Primary Endpoints	First 150	Total Cohort
Safety (30 Days) • Composite MAE rate	✓	✓
Effectiveness (6 Months) • TR grade reduction • Hierarchical composite of KCCQ, NYHA and 6MWD	✓	✓
Hierarchical Composite (1 Year) 1. All-cause mortality 2. RVAD implant or heart transplant 3. TV surgery or intervention 4. Annualized heart failure hospitalization 5. KCCQ, NYHA, 6MWD		✓

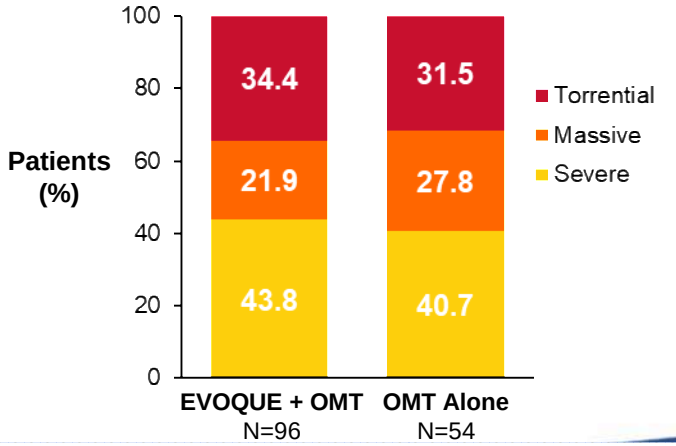
Susheel Kodali TCT 2023

Baseline Characteristics

	EVOQUE + OMT N=96	OMT Alone N=54
Age, years	79.4 ± 7.7	78.2 ± 8.3
Female, %	82.3	75.9
NYHA class III-IV, %	79.2	70.4
KCCQ overall score, points	49.1 ± 21.5	49.7 ± 22.3
STS score, mitral valve replacement, %	10.2 ± 5.7	9.4 ± 4.5
Left ventricular ejection fraction, %	55.1 ± 8.6	52.4 ± 11.6
Atrial fibrillation, %	97.9	96.3
Hypertension,%	91.7	87.0
COPD, %	19.8	16.7
Stroke, %[a]	19.8	5.6
Renal disease, ≥ stage II, %	50.0	57.4
Ascites, %	15.6	20.4
HF hospitalization in past 12 months, %	31.3	31.5
Pacemaker/ICD, %	36.5	42.6
Prior valve surgery/intervention, %	31.3	31.5
Coronary artery bypass graft, %	10.4	24.1

TR Etiology by Core Lab[b]	EVOQUE + OMT N=96	OMT Alone N=54
Primary, %[c]	14.6	13.0
Secondary, %[d]	77.1	70.4
Mixed, %	7.3	14.8
Indeterminate, %	1.0	1.9

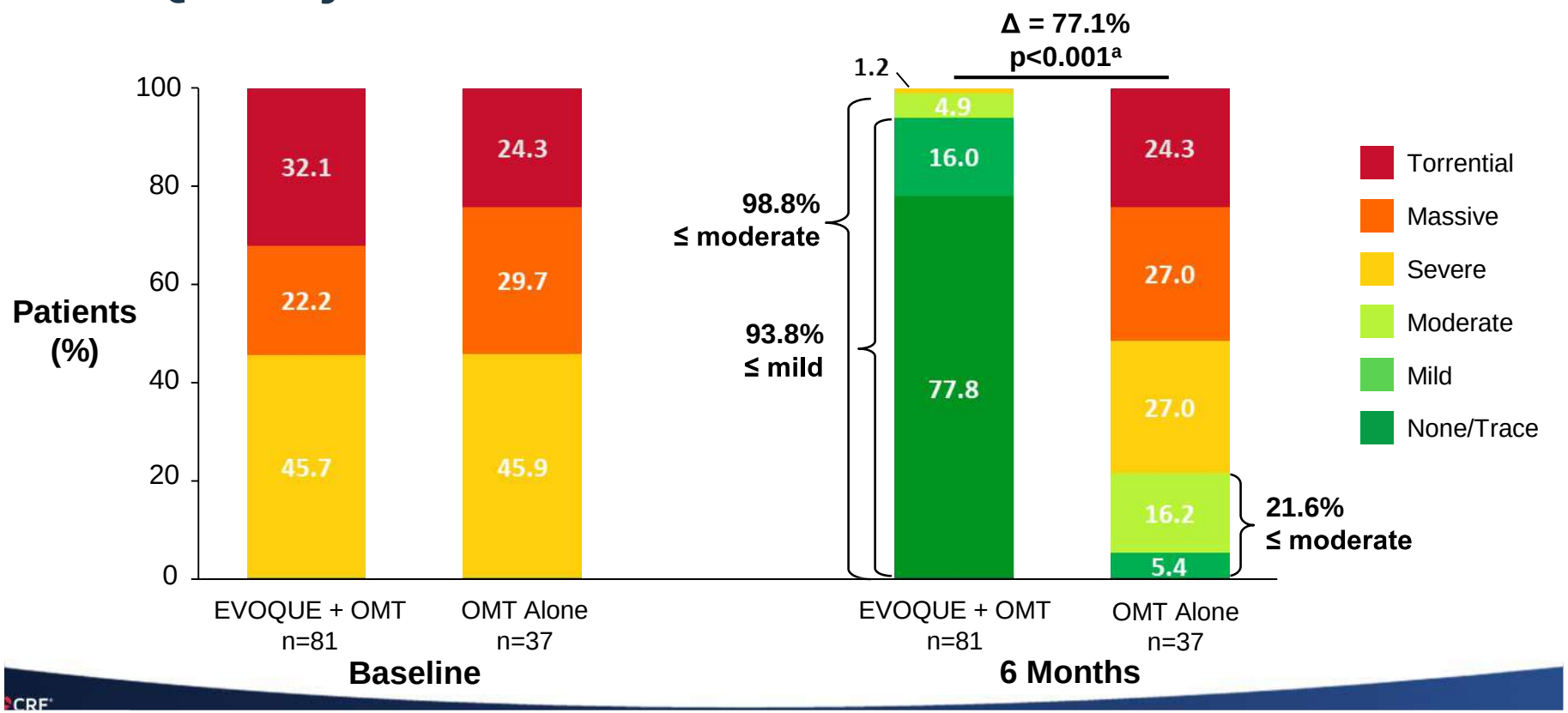
TR Severity by Core Lab[b]



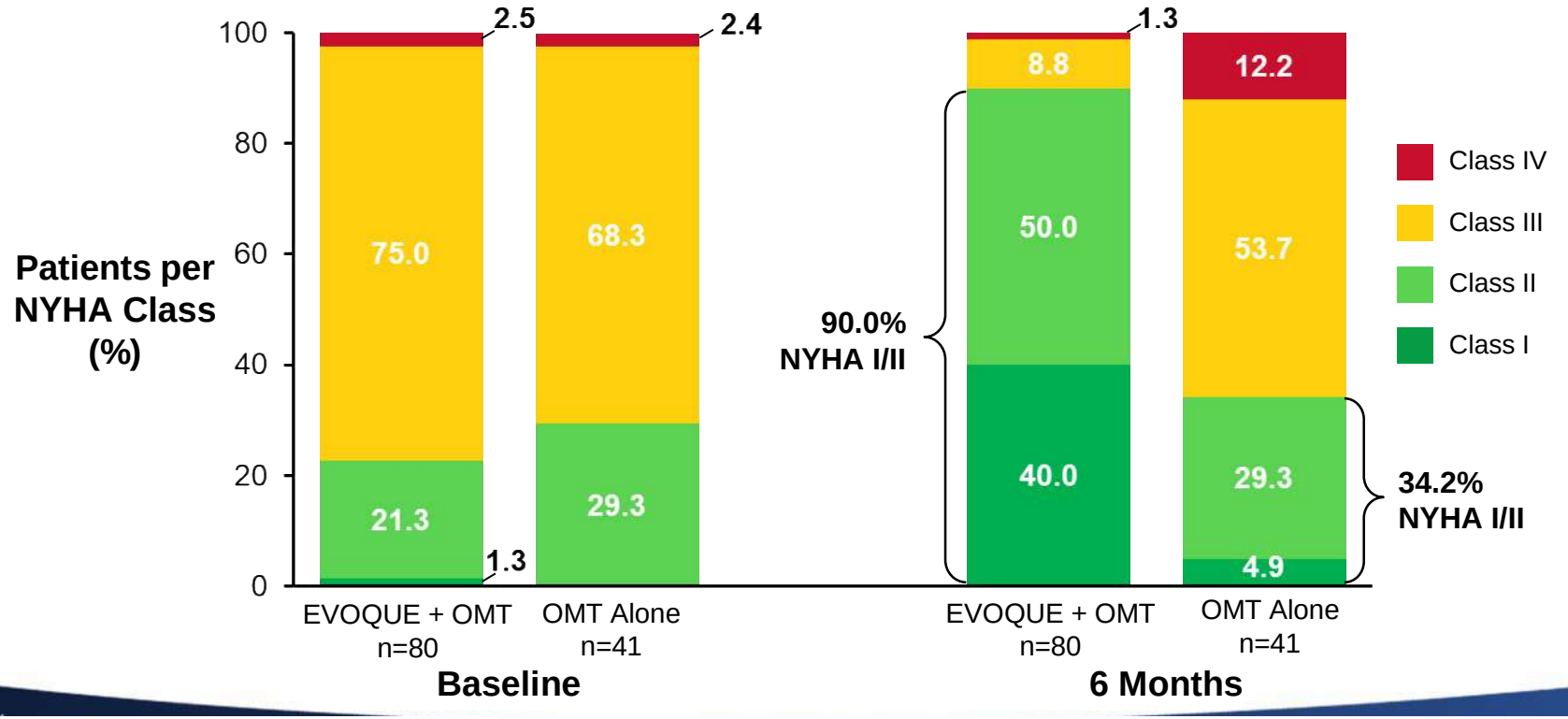
Primary Safety Endpoint at 30 Days

CEC-Adjudicated Major Adverse Events	EVOQUE + OMT N=95 % (n)
Cardiovascular mortality	3.2 (3)
Myocardial infarction	1.1 (1)
Stroke	0.0 (0)
New need for renal replacement therapy	1.1 (1)
Severe bleeding[a]	10.5 (10)
Non-elective TV re-intervention	0.0 (0)
Major access site and vascular complication	3.2 (3)
Major cardiac structural complication	2.1 (2)
Device-related pulmonary embolism	1.1 (1)
Arrhythmia and conduction disorder requiring permanent pacing	14.7 (14)
Composite MAE Rate[b]	**27.4 (26)**

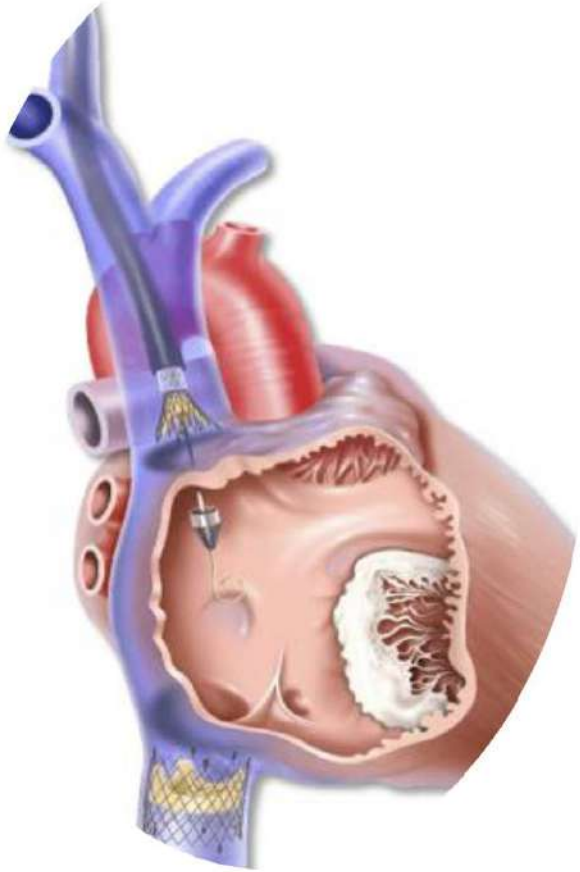
Significant Reductions in TR Grade with EVOQUE System at 6 Months

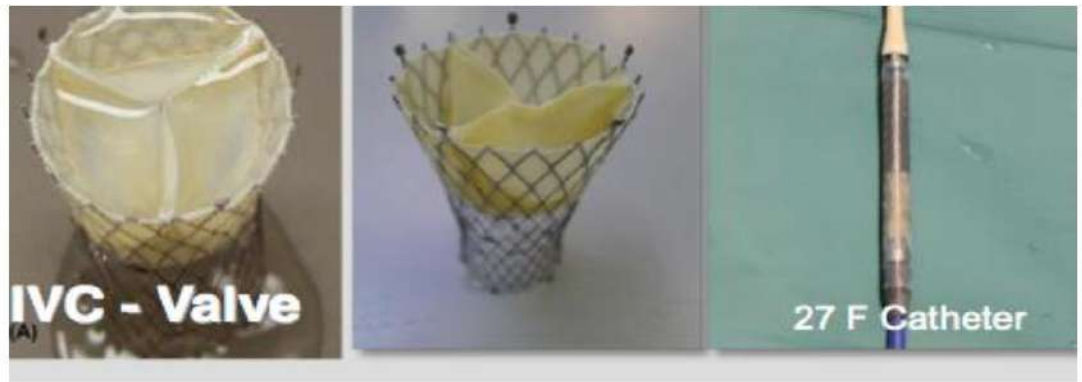


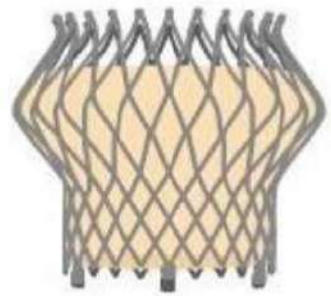
Changes in NYHA Class at 6 months between EVOQUE and OMT Groups



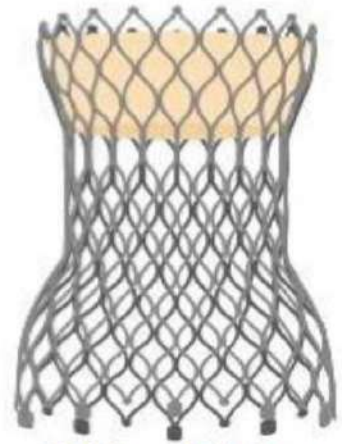
IMPLANTE HETEROTÓPICO. EL CONCEPTO “CAVI”





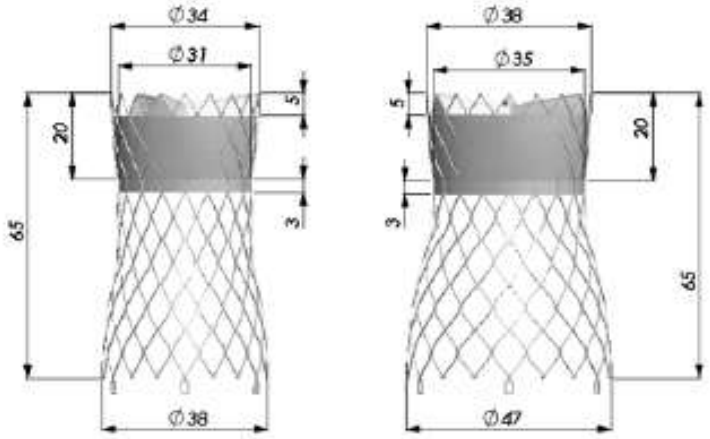


SVC - Valve

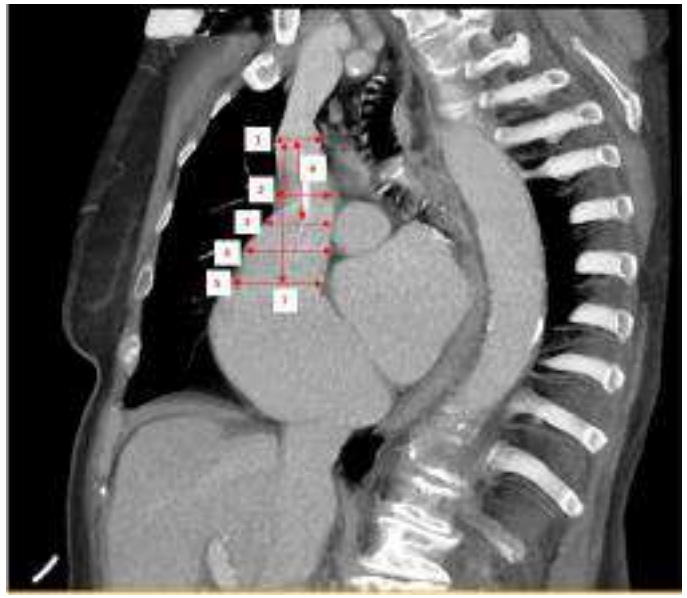


IVC - Valve

CT. IVC



CT. SVC



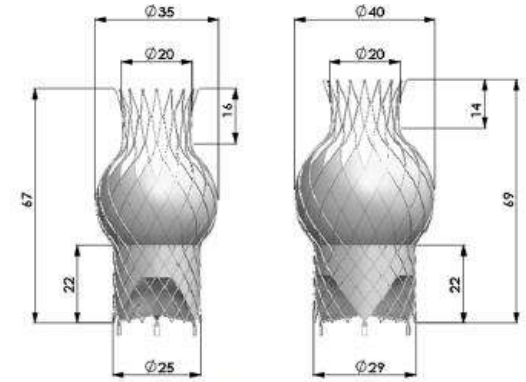
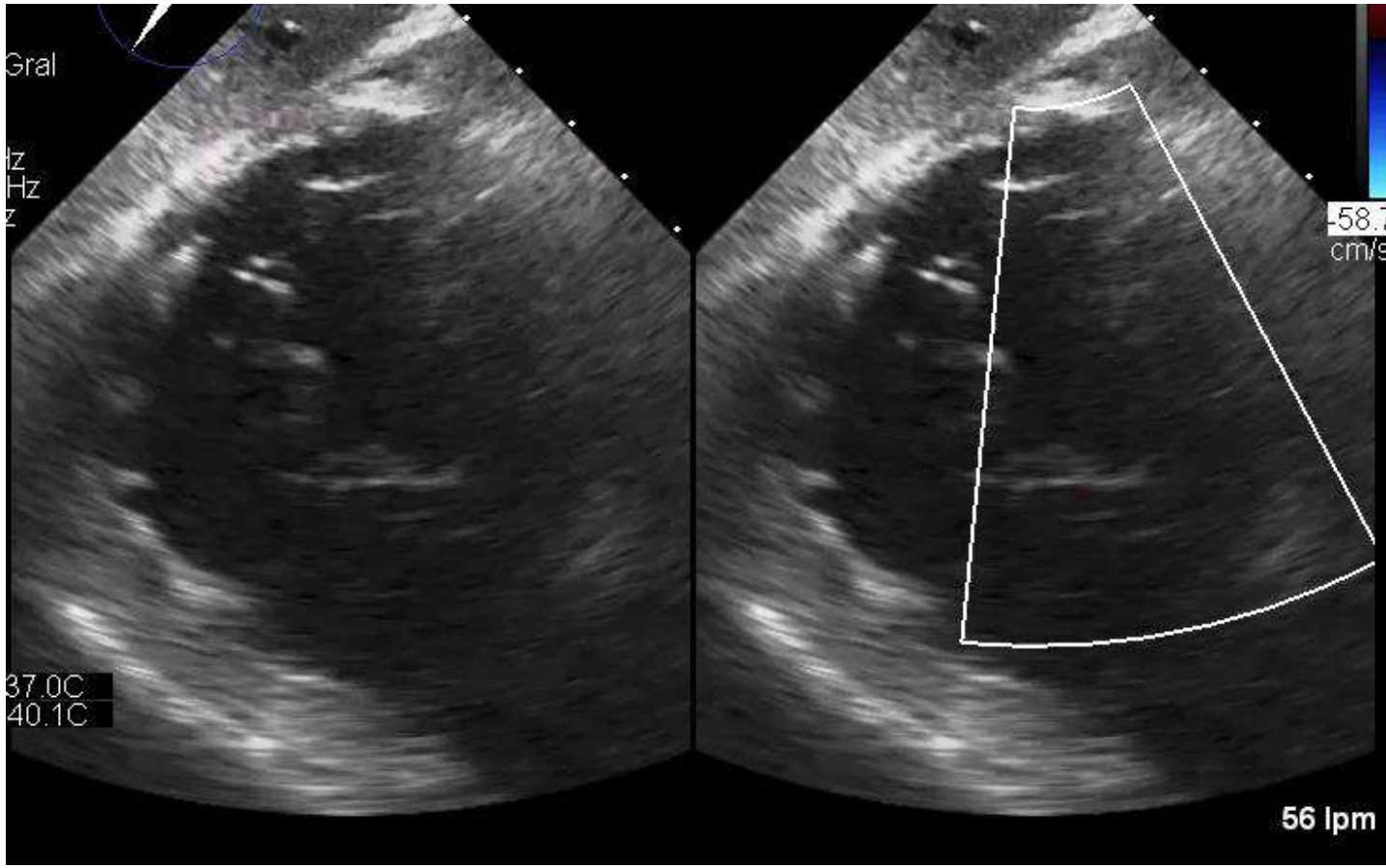


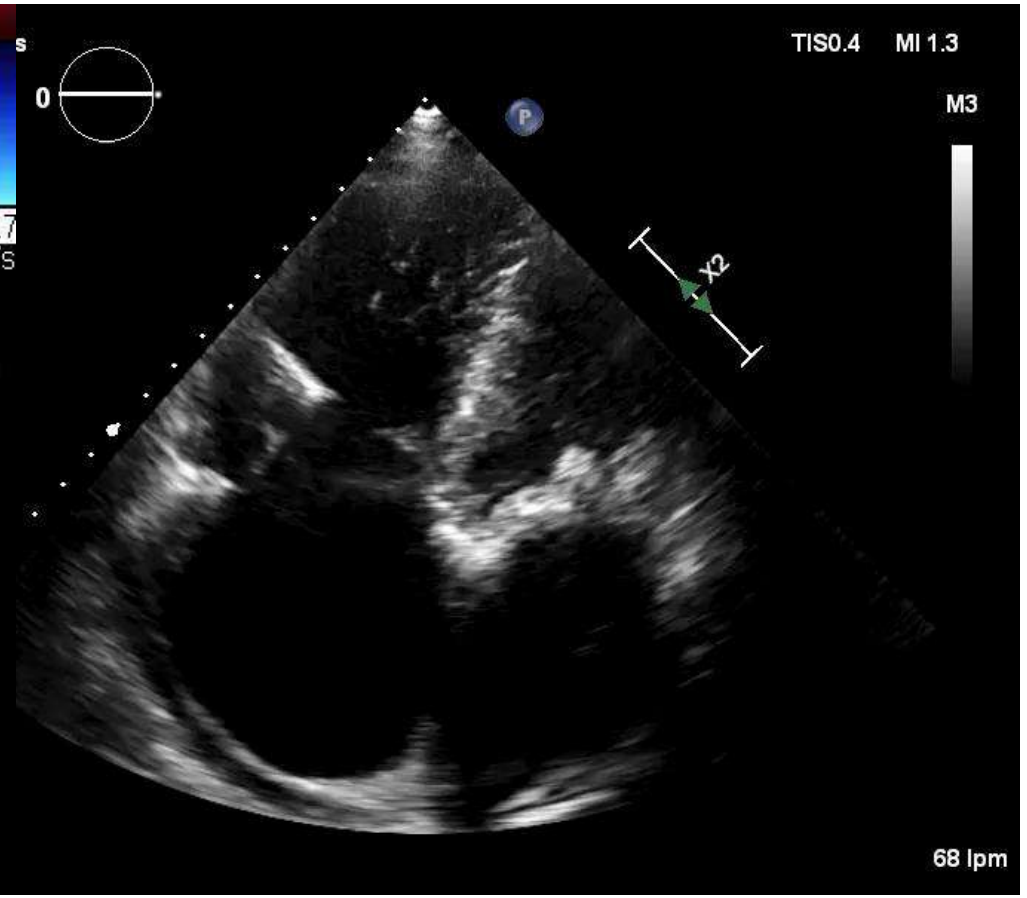
Figura 7: TricValve® para la VCS - medidas

Implante sencillo. Solo con RX. ETE es aconsejable para la válvula de cava inferior

Cases more suitable for TricValve



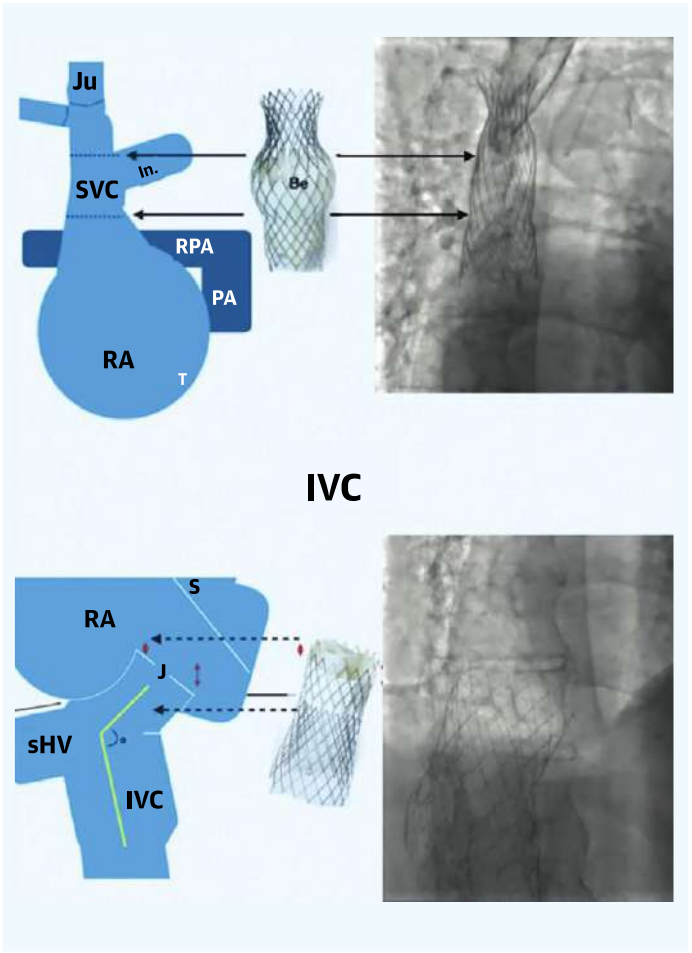
Severe gap+severe anular dilation

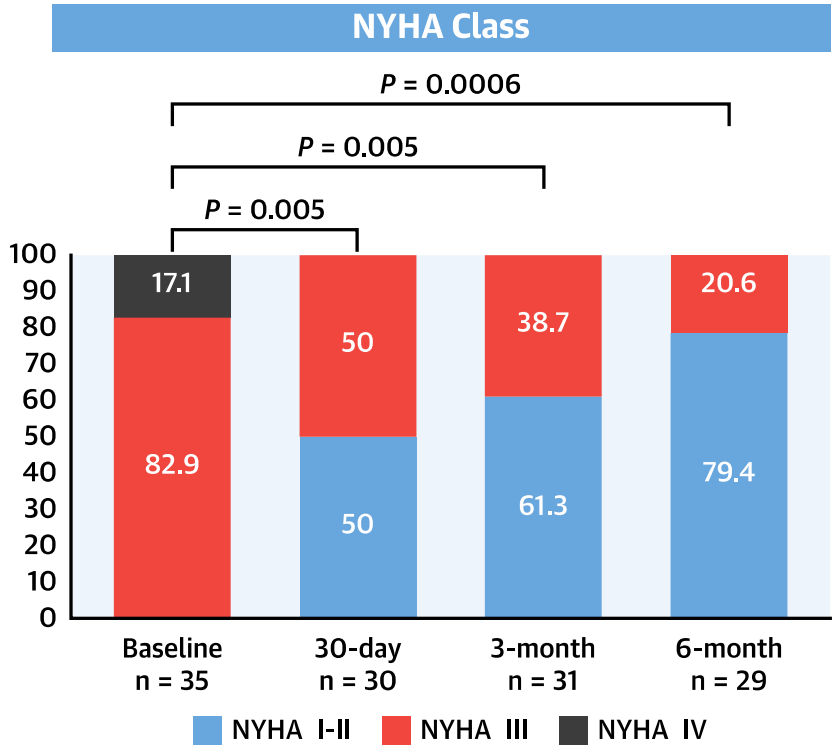


Severe gap + PM lead

6-Month Outcomes of the TricValve System in Patients With Tricuspid Regurgitation

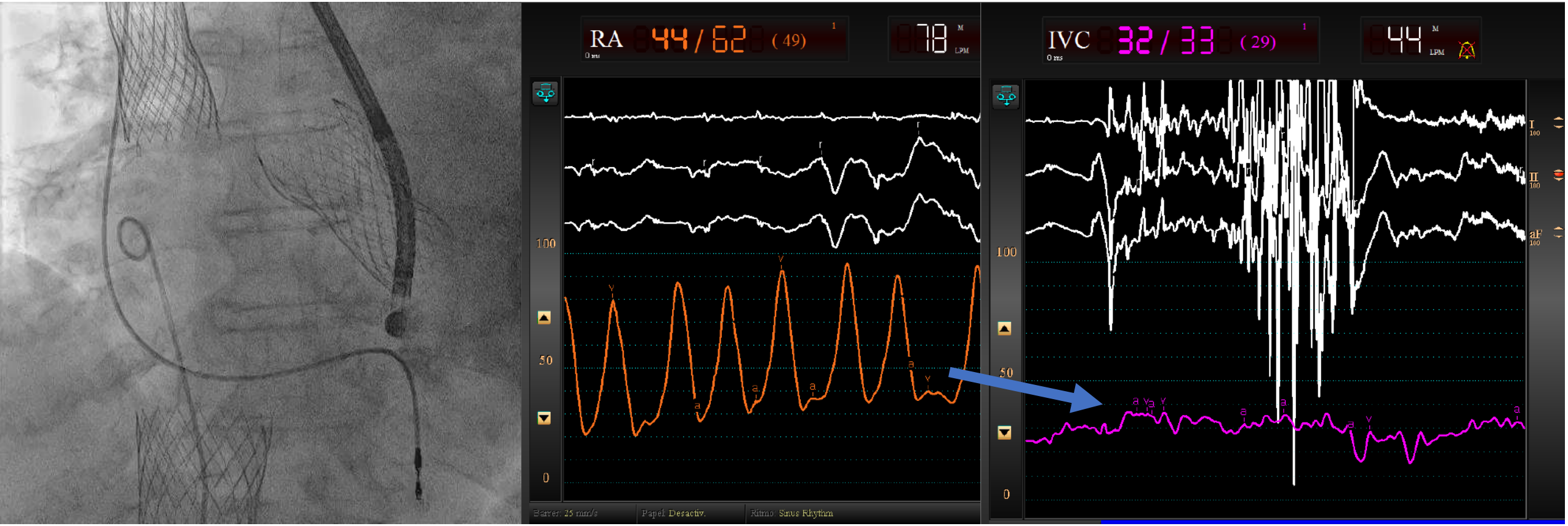
The TRICUS EURO Study





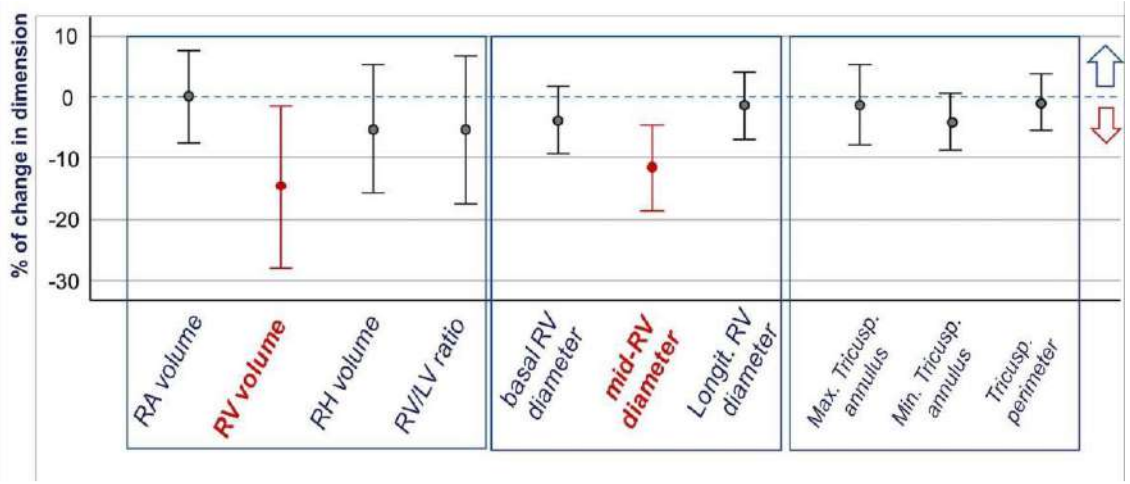
Estévez-Loureiro R, et al. J Am Coll Cardiol Intv. 2022;15(13):1366-1377.

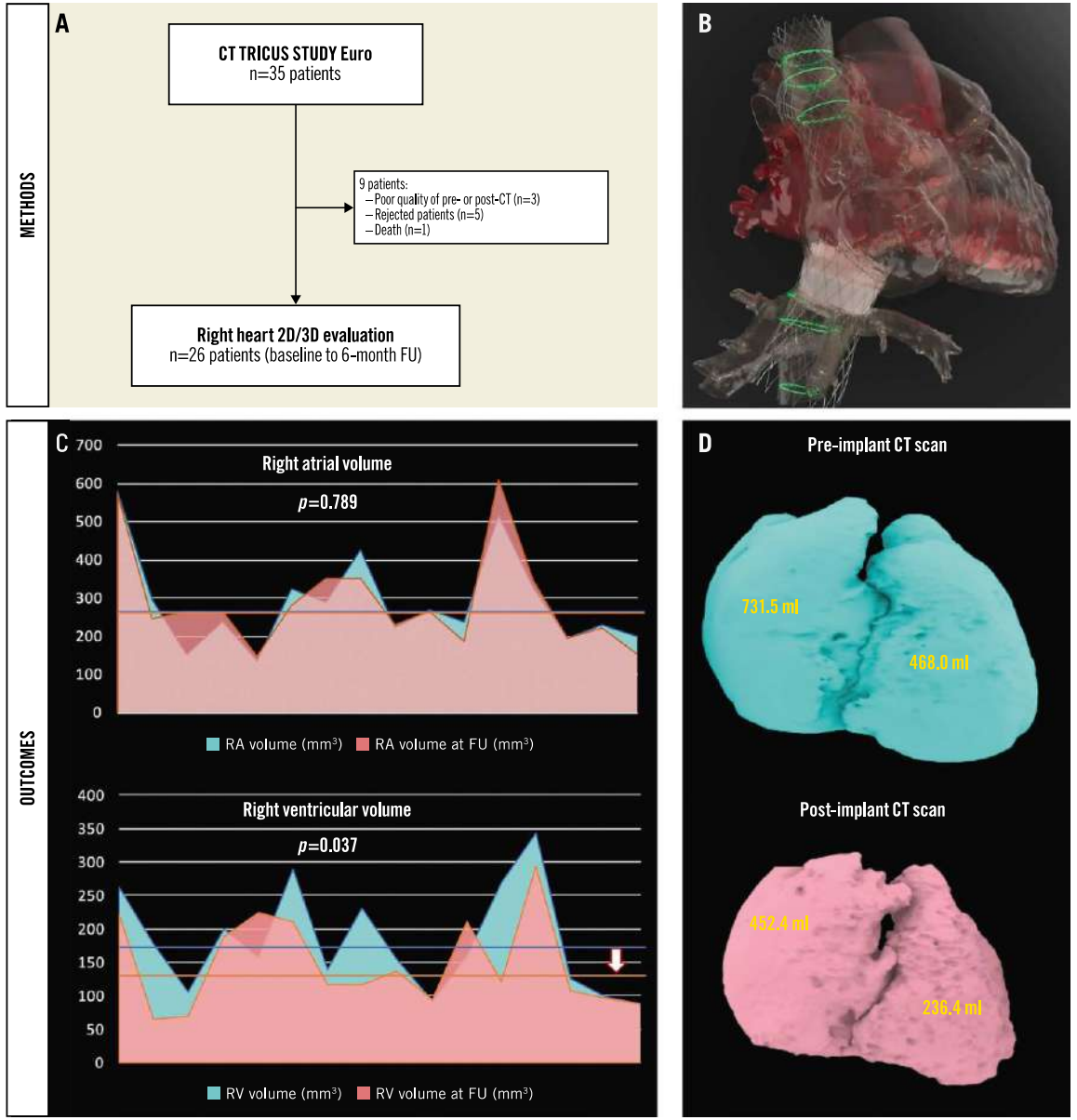
TRICVALVE SYSTEM Hemodynamics



Massive decrease in IVC pressure

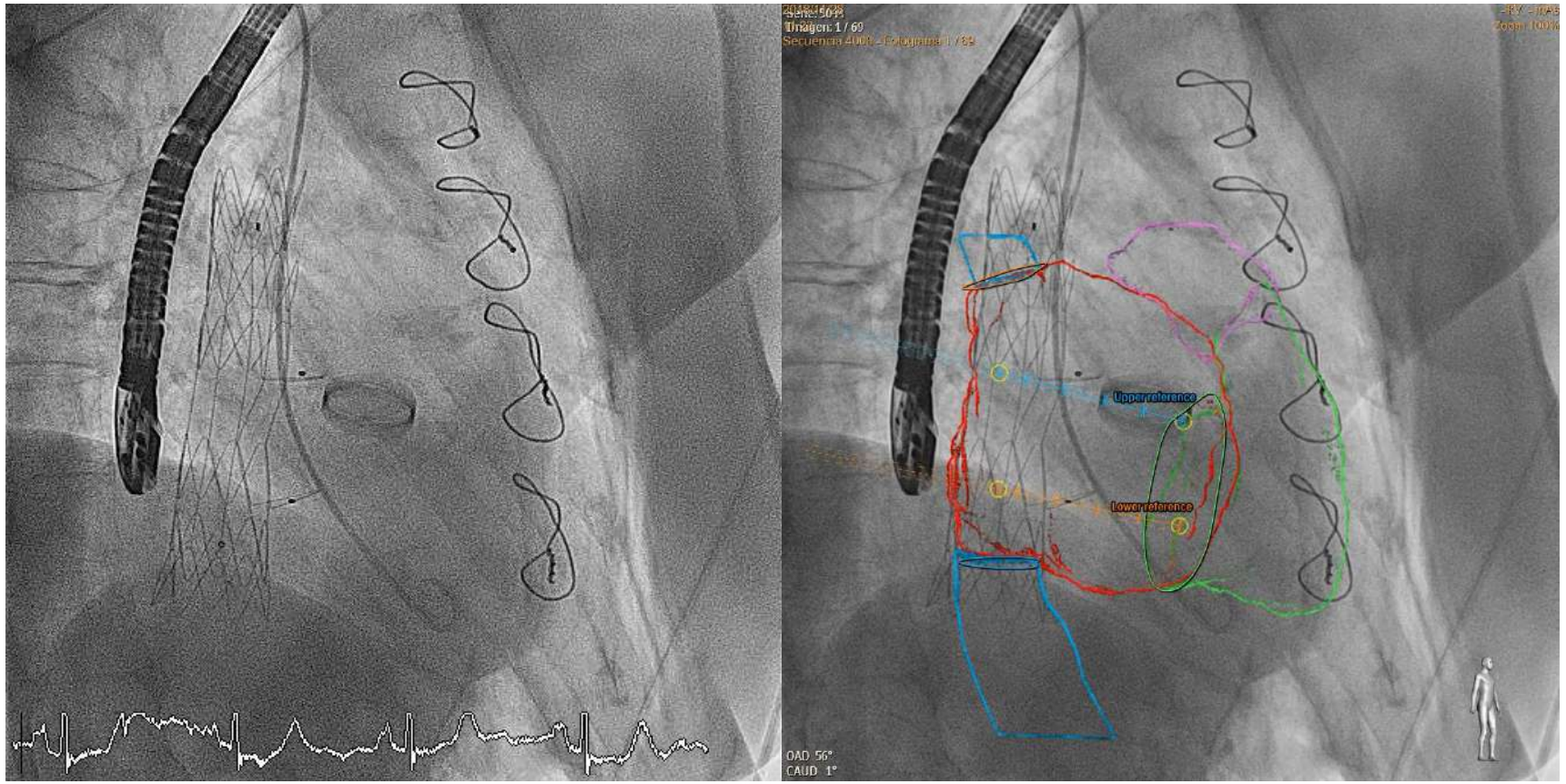
Right heart remodelling after bicaval TricValve implantation in patients with severe tricuspid regurgitation





AMAT SANTOS I, Eurointervention 2023, april

TRICENTO



Courtesy of Dr. Cruz González

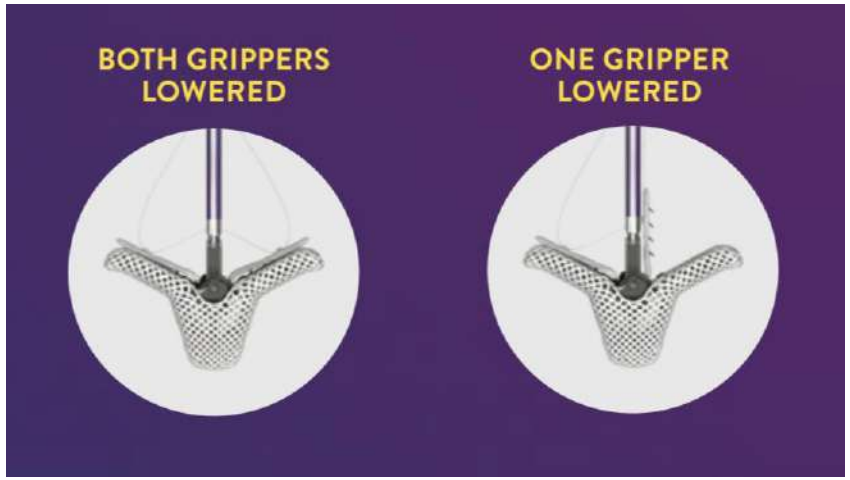
TEER: Transcatheter edge to edge repair

$ PBQUBUPO
&OI BODFN FOU

&EHF UP &EHF

5 SJ$ NQ

1 BIDBM



TRICLIP

4 tamaños

Dispositivo específico para tricúspide

PASCAL

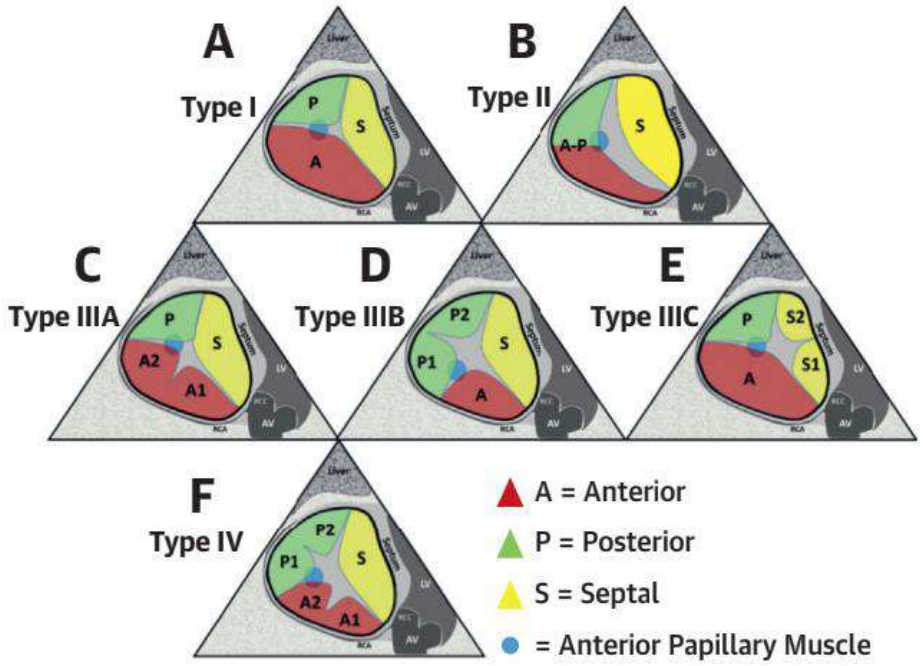
2 tamaños

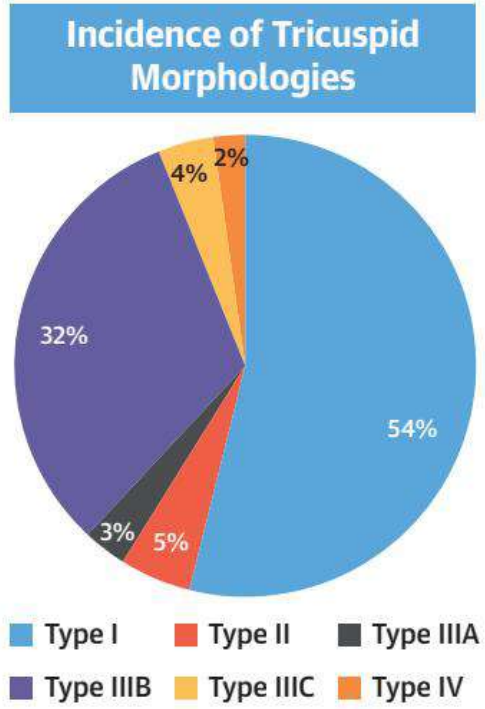
Mismo dispositivo que para mitral

Posibilidad de “grasping” separado

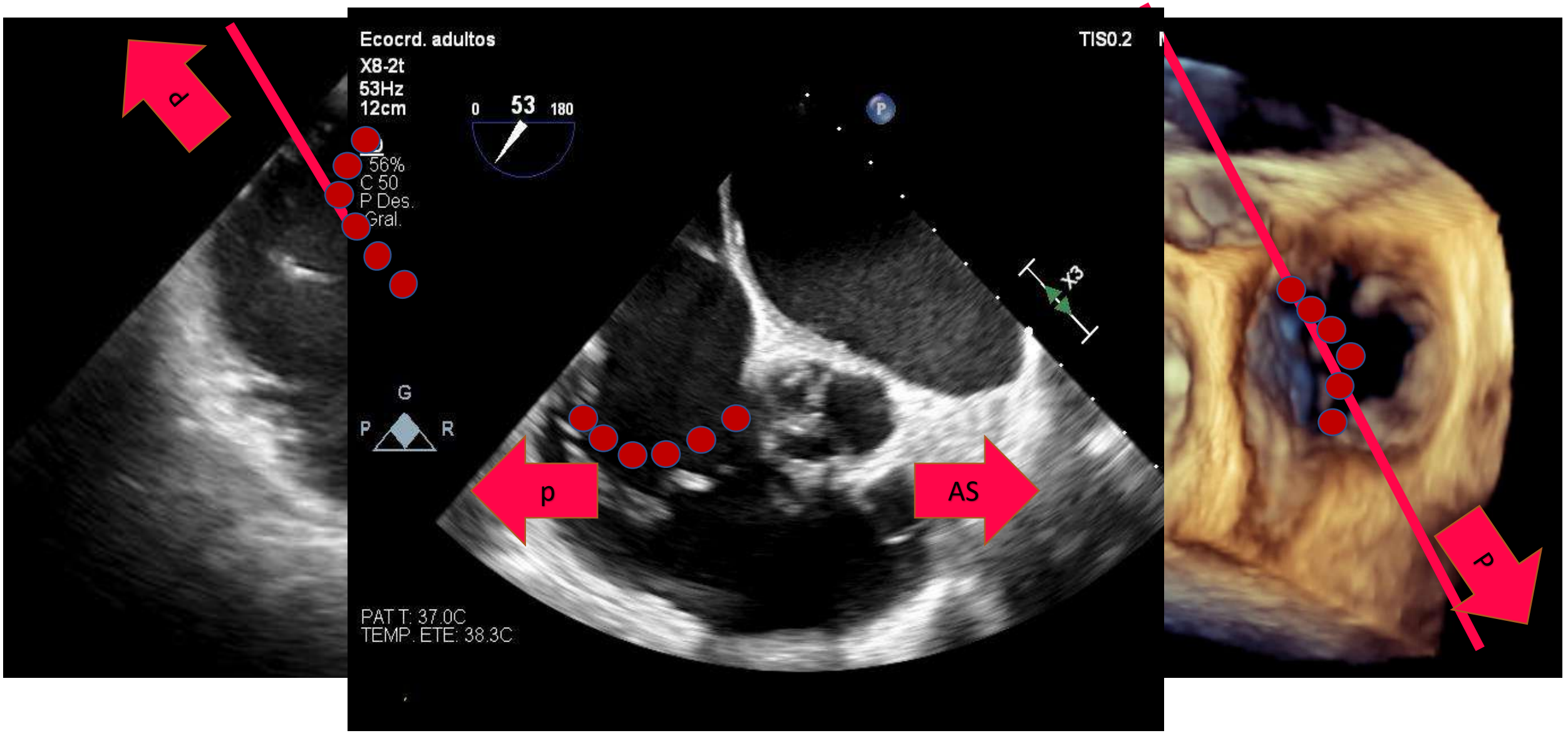
TEER. Entender la válvula tricúspide

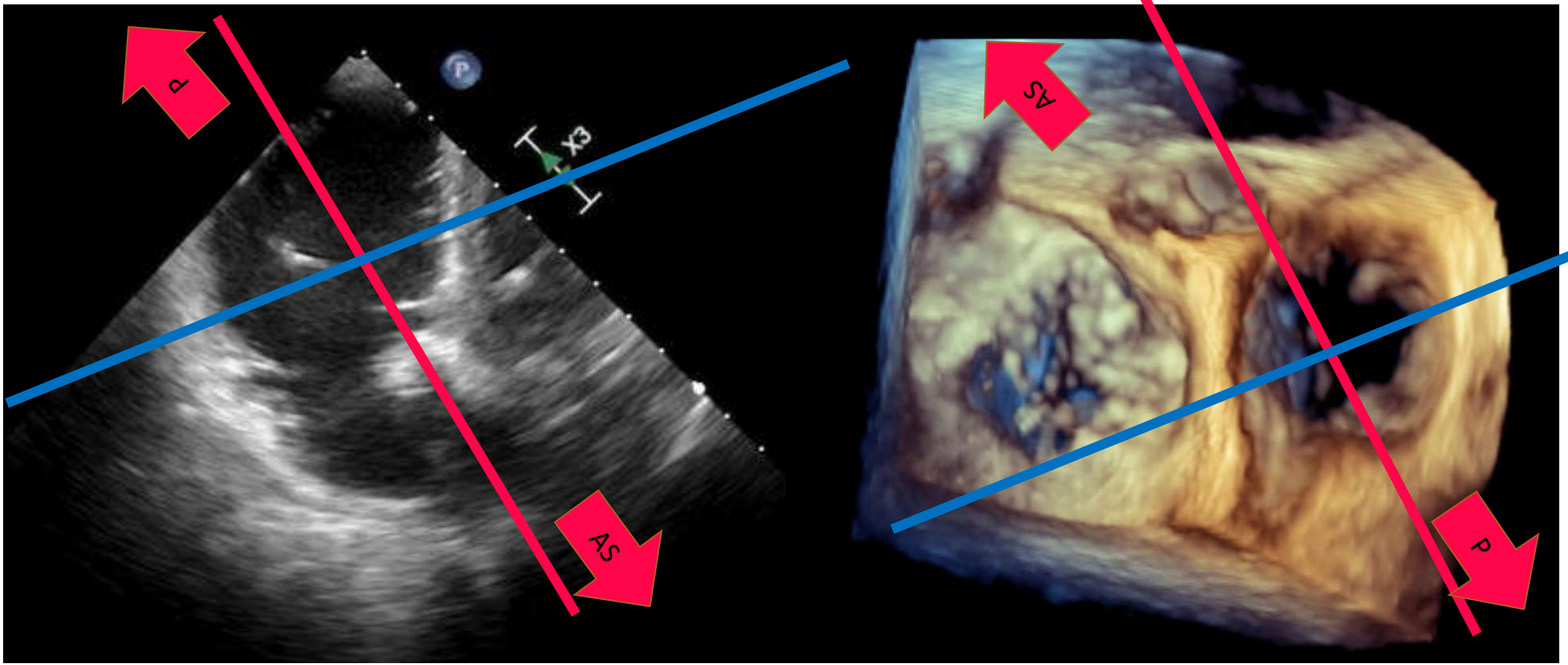
CENTRAL ILLUSTRATION Tricuspid Valve Nomenclature Classification Scheme





Hahn, R.T. et al. J Am Coll Cardiol Img. 2021;■(■):■-■.


Ecocrd. adultos
X8-2t
53Hz
12cm
0
53
180
56%
C 50
P Des.
Gral.
TIS0.2
X3
G
P
R
PAT T: 37.0C
TEMP. ETE: 38.3C
a
p
AS
P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AS
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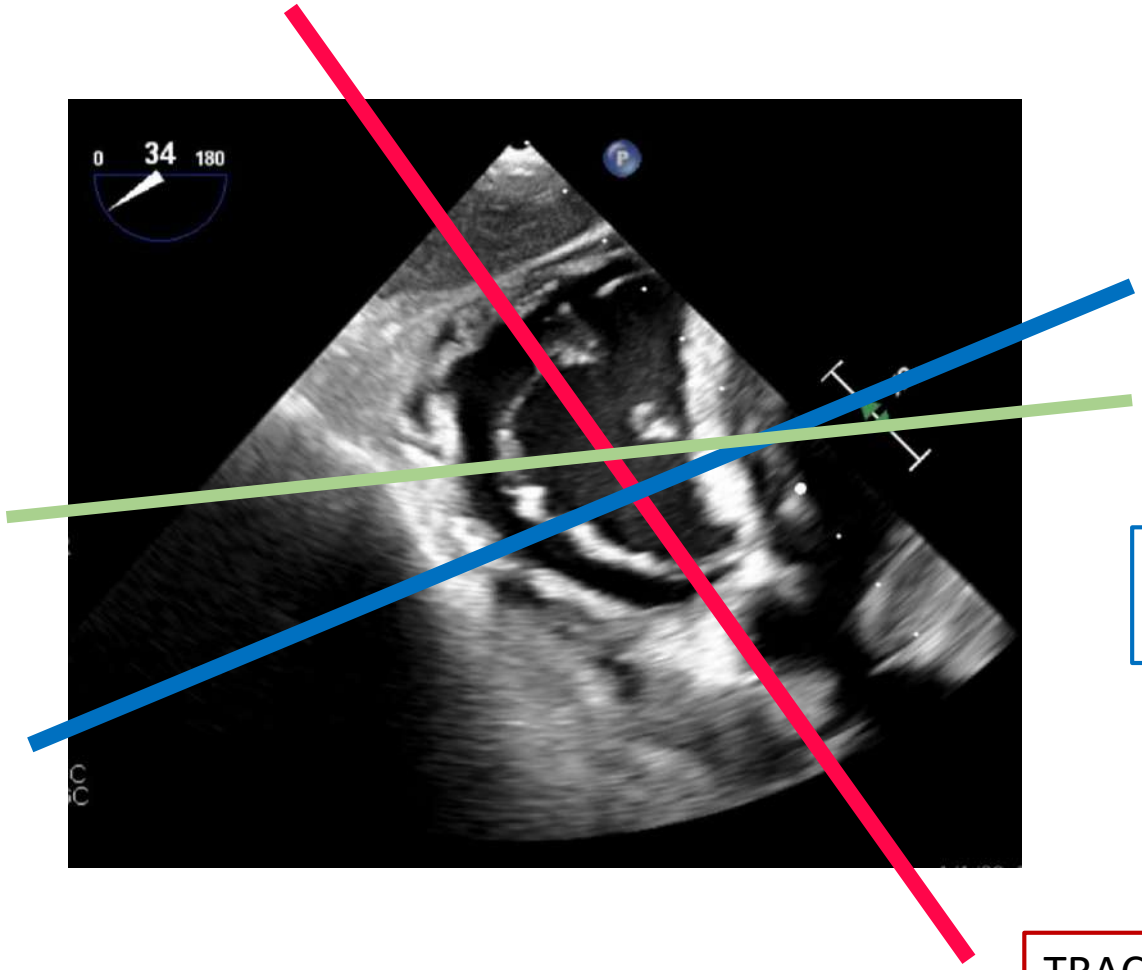
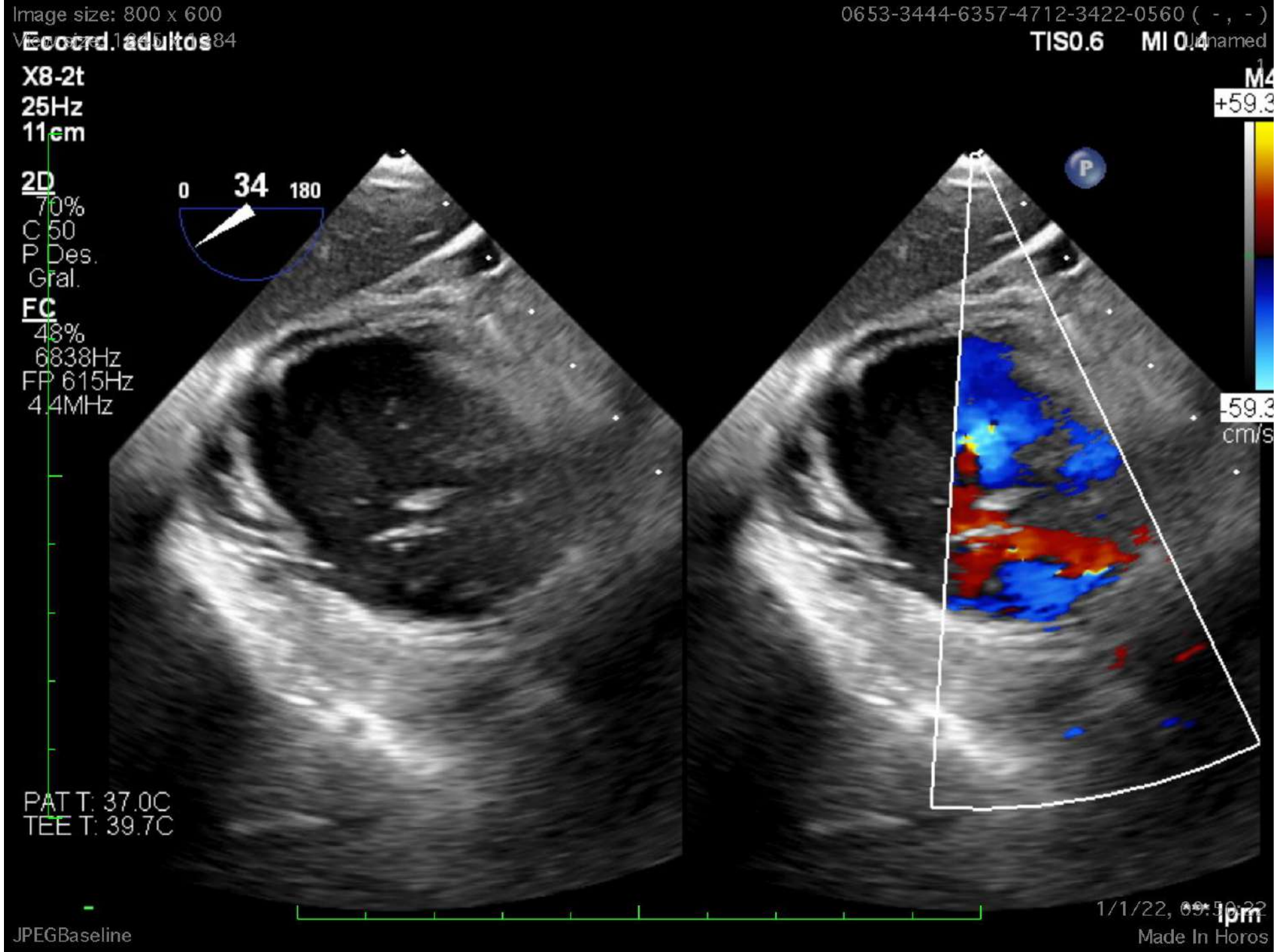


4 CÁMARAS A VARIAS NIVELES
Estudiar las valvas, su movilidad y el gap

ORTOGONAL AL TRACTO DE ENTRADA VD
Estudiar las valvas, su movilidad y el gap

TRACTO DE ENTRADA VD: situar el jet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Ecocrd. adultos
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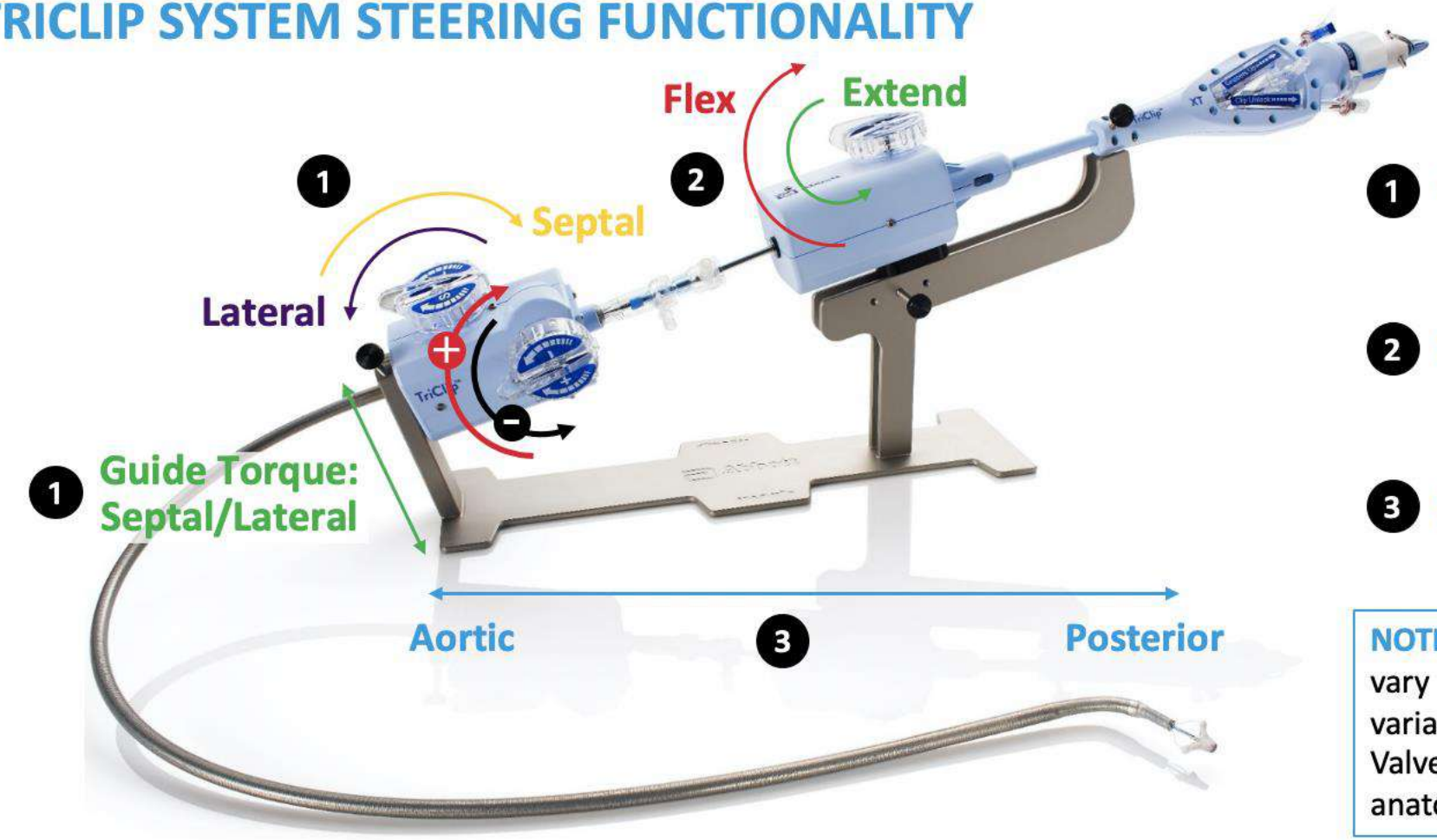
Unnamed
X8-2t
25Hz
11cm
2D
70%
C 50
P Des.
Gral.
FC
48%
6838Hz
FP 615Hz
4.4MHz
0 34 180
+59.3
-59.3
cm/s
PAT T: 37.0C
TEE T: 39.7C
1/1/22, 09:50:22
1pm
JPEGBaseline
Made In Horos

Table 3. Anatomical criteria for device selection.

Strategy	Favourable anatomy	Feasible anatomy	Unfavourable anatomy
Leaflet approximation	Small septolateral gap ≤7 mm[10] Anteroseptal jet location Confined prolapse or flail Trileaflet morphology	Septolateral coaptation gap >7 but ≤8.5 mm[65] Posteroseptal jet location Non-trileaflet morphology Incidental CIED RV lead (i.e., without leaflet impingement)	Large septolateral coaptation gap >8.5 mm[65] Leaflet thickening/shortening (rheumatic, carcinoid)/perforation Dense chordae with marked leaflet tethering Anteroposterior jet location Poor echocardiographic leaflet visualisation CIED RV lead leaflet impingement Unfavourable device angle of approach

Praz F et al. Eurointervention 2021

TRICLIP SYSTEM STEERING FUNCTIONALITY

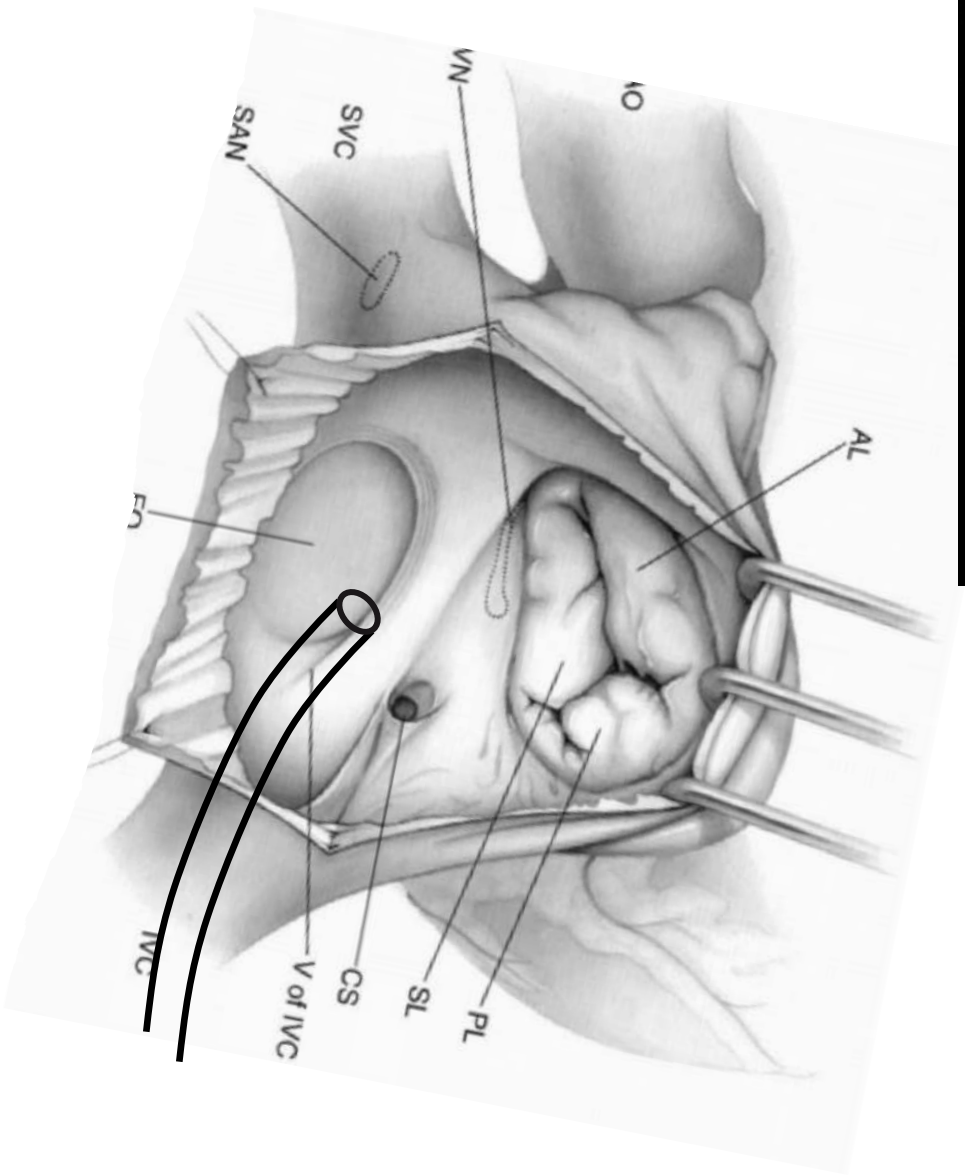


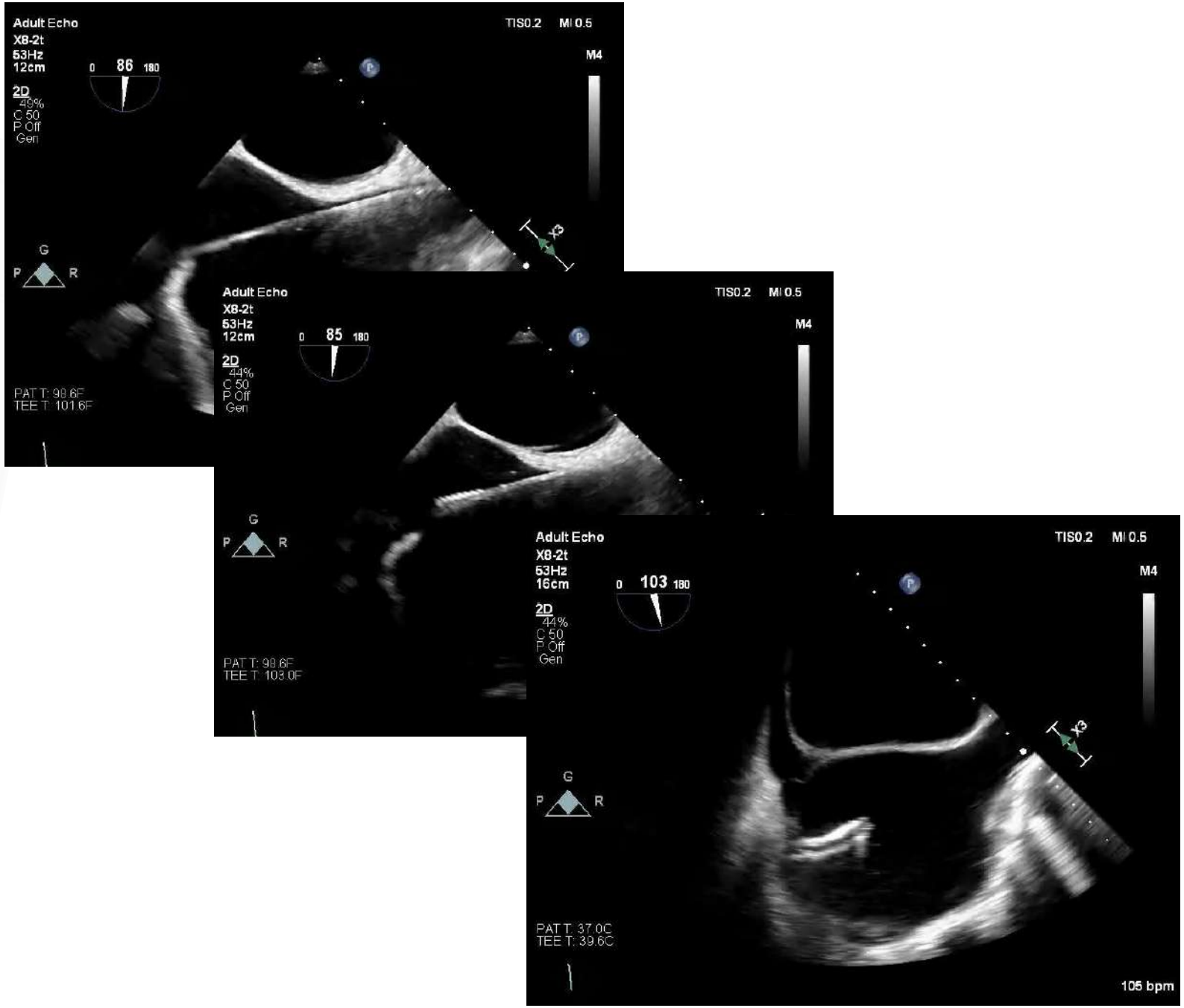
1 **GUIDE HANDLE:**
Septal/Lateral movement;
Height above valve

2 **STEERABLE SLEEVE:**
Flex/Extend to steer down to or up from valve

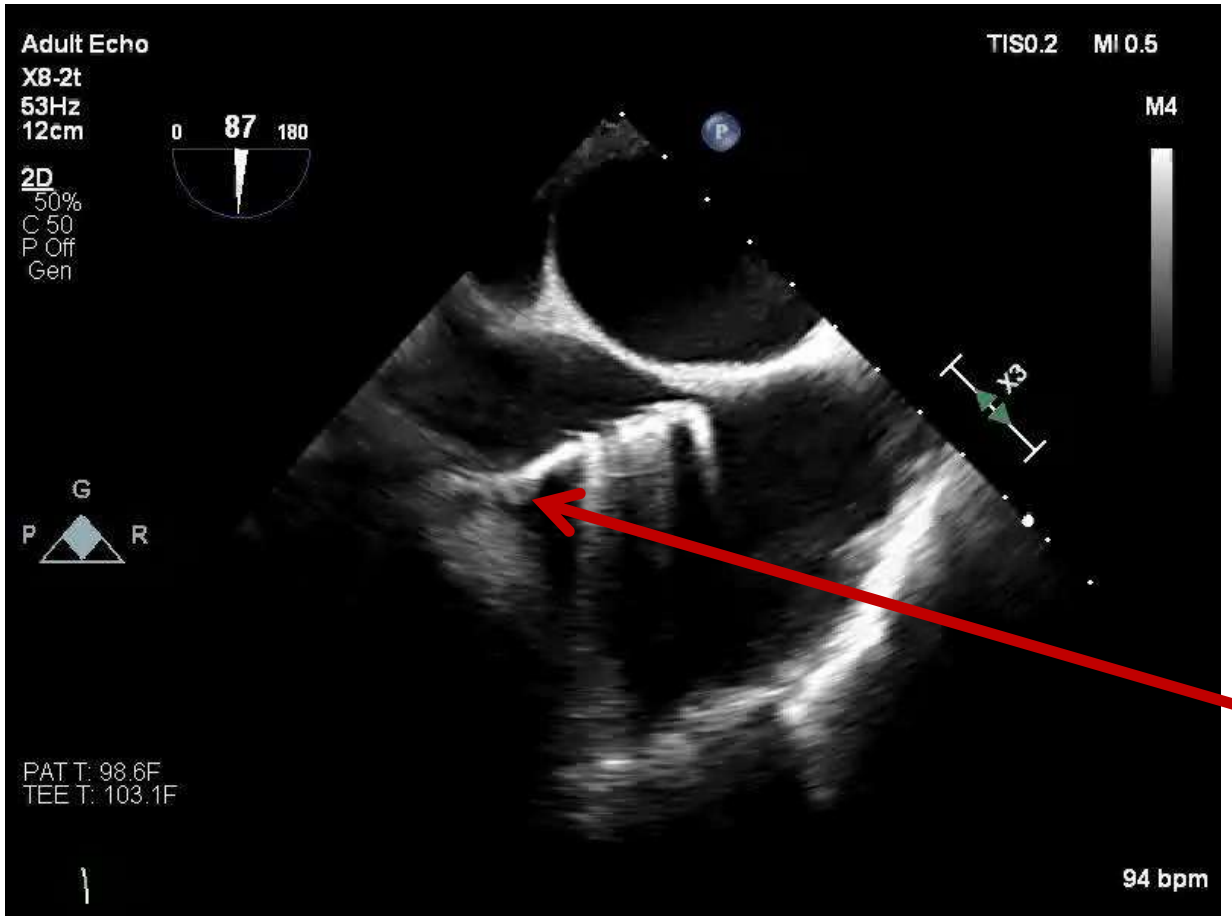
3 **STABILIZER:**
Aortic/Posterior movement

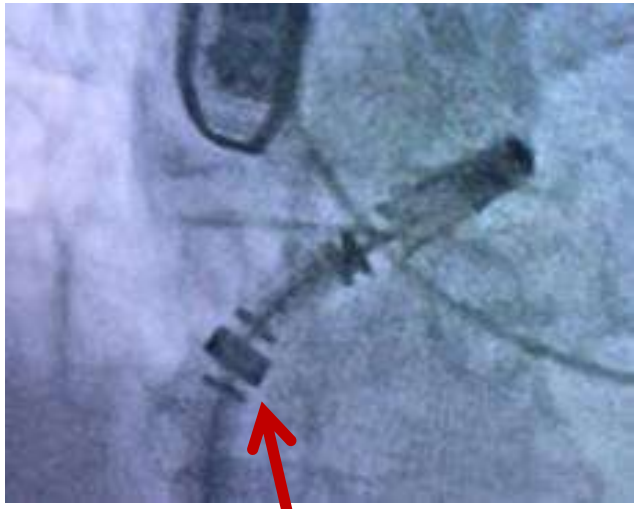
NOTE: TriClip System movements may vary based on patient anatomy, due to variations in the non-planar Tricuspid Valve annulus and varying leaflet anatomy/orientation.





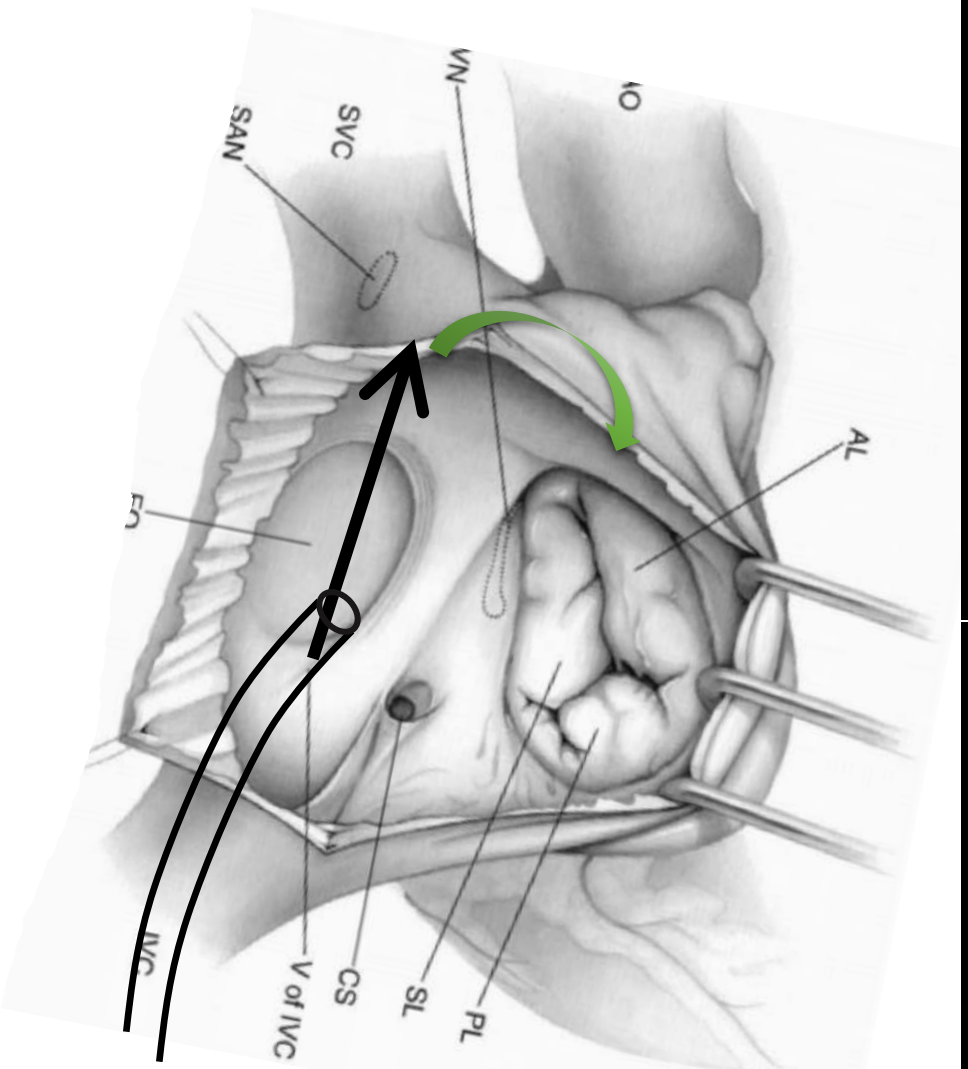
1. Posicionar CG en AD

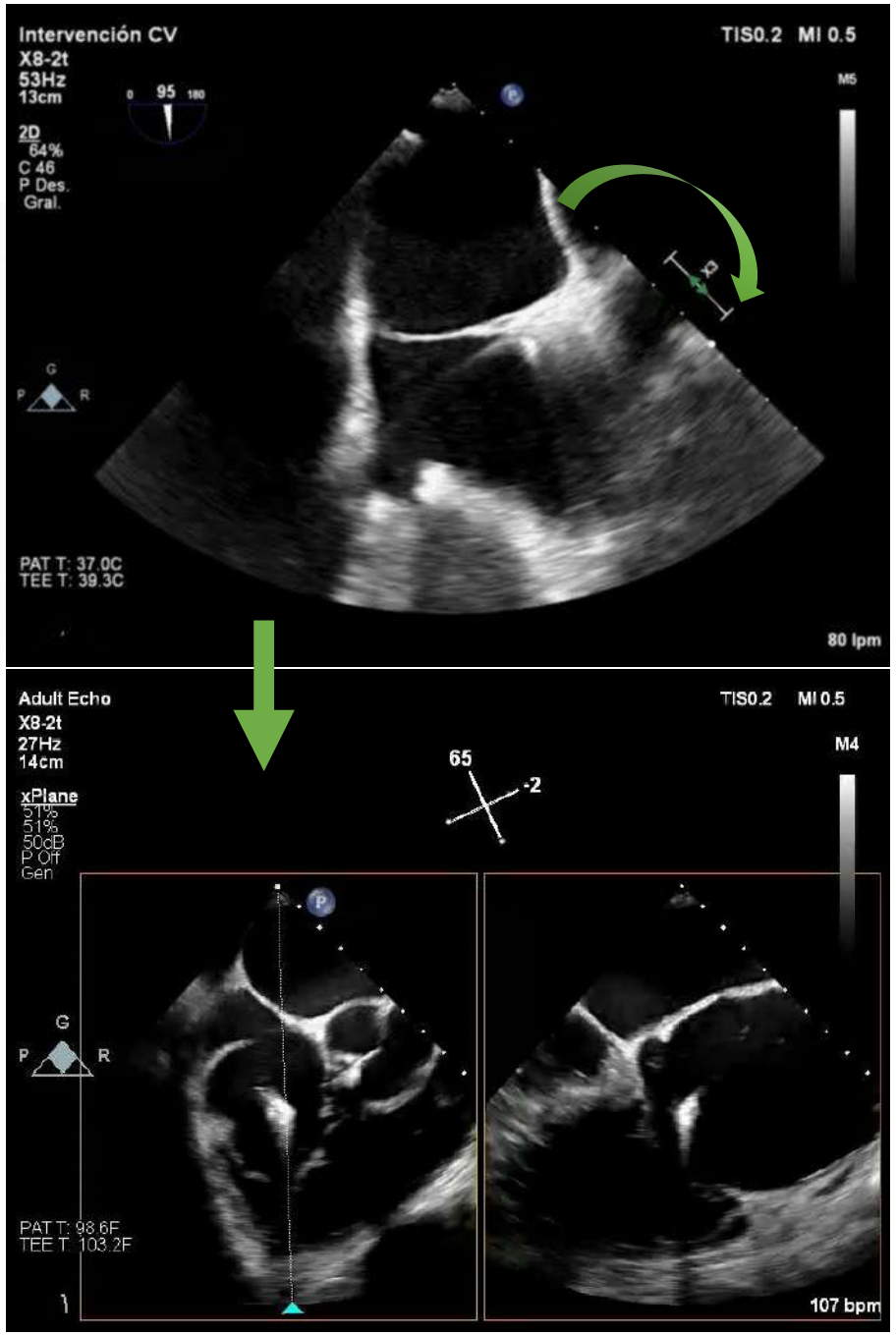




STRADDLING

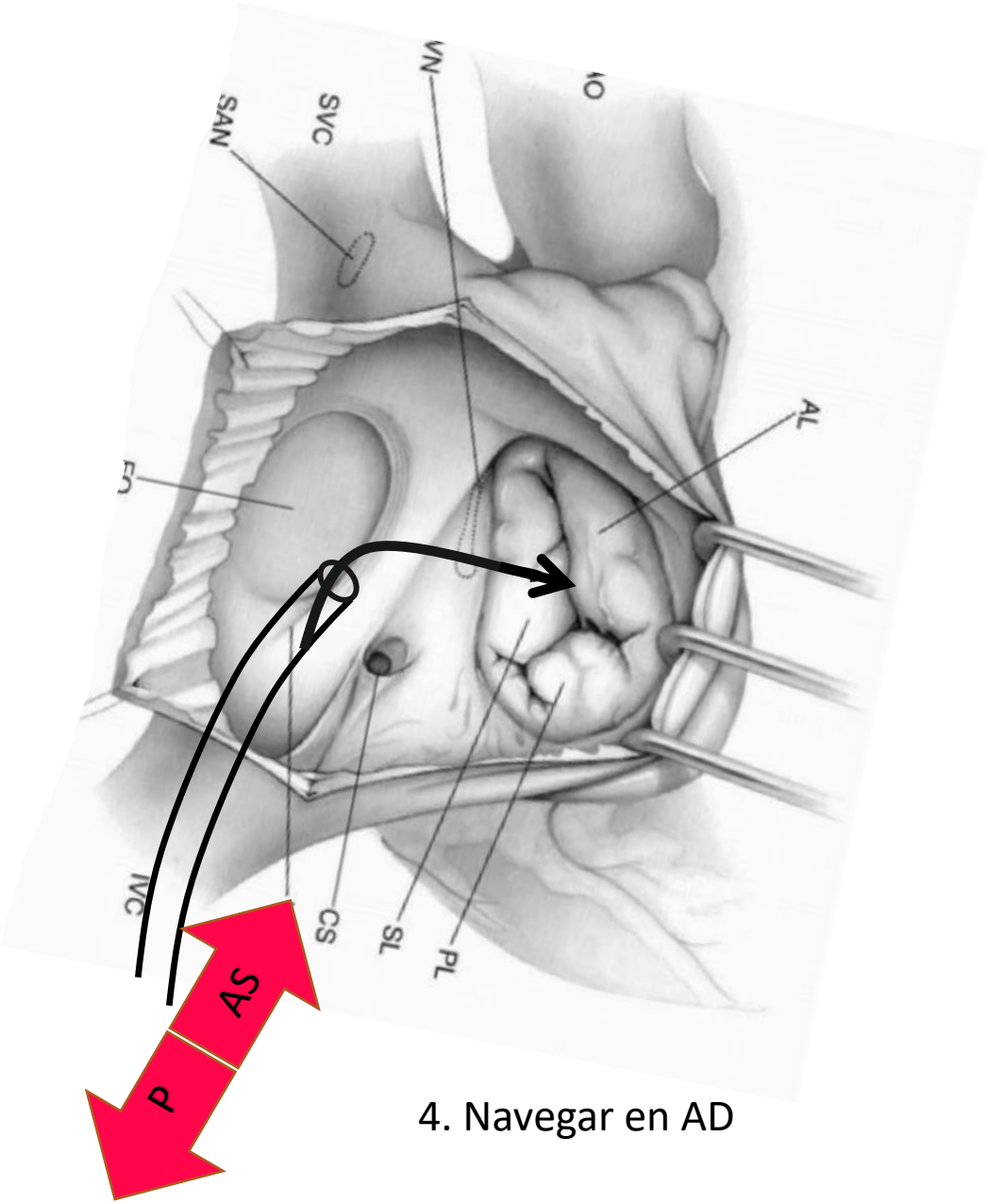
2. Avancar CDS hasta posición de straddling





RUEDA F/L

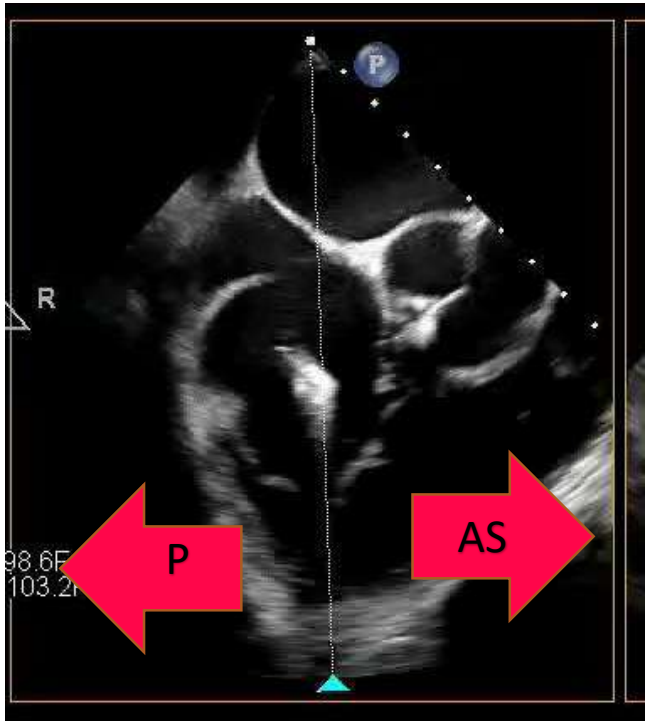
3. Deflectar para apuntar a la válvula tricúspide

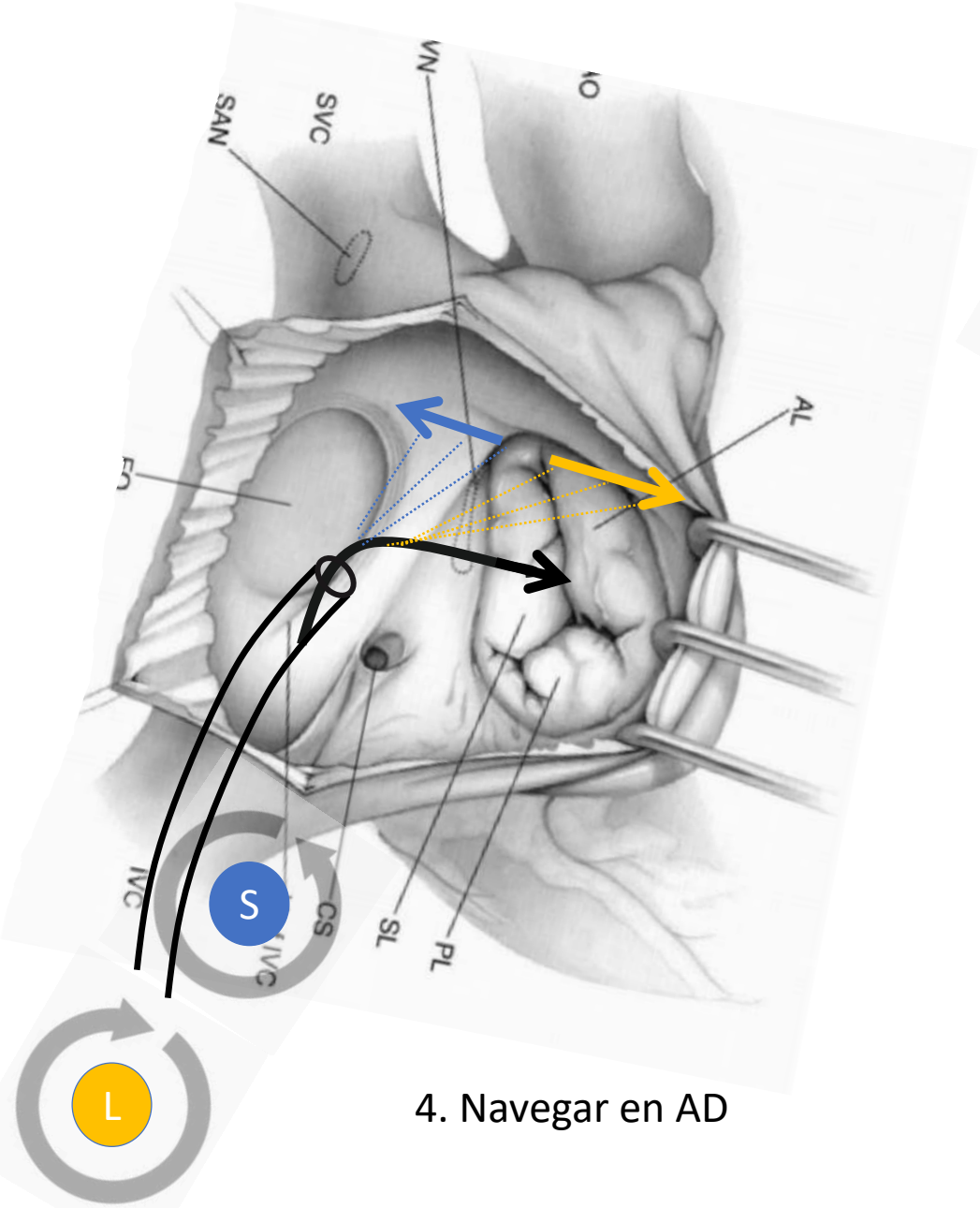


4. Navegar en AD

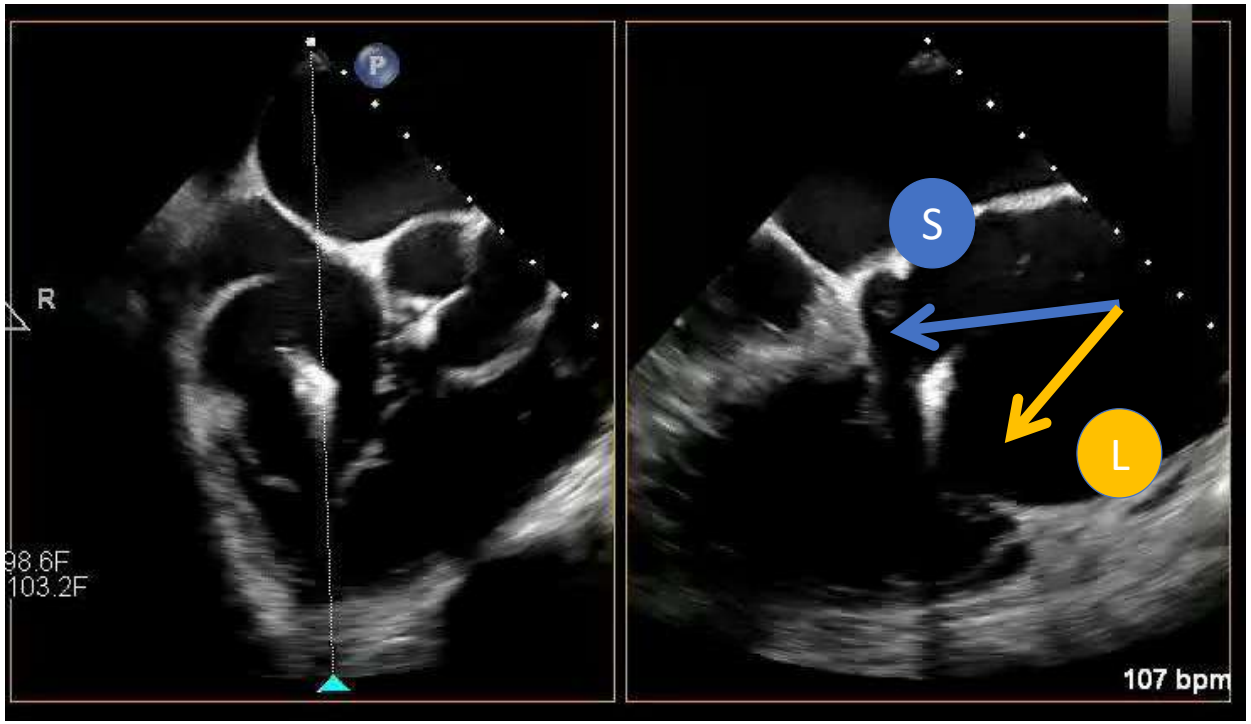
AS

PL





TORQUE
Septal/Lateral



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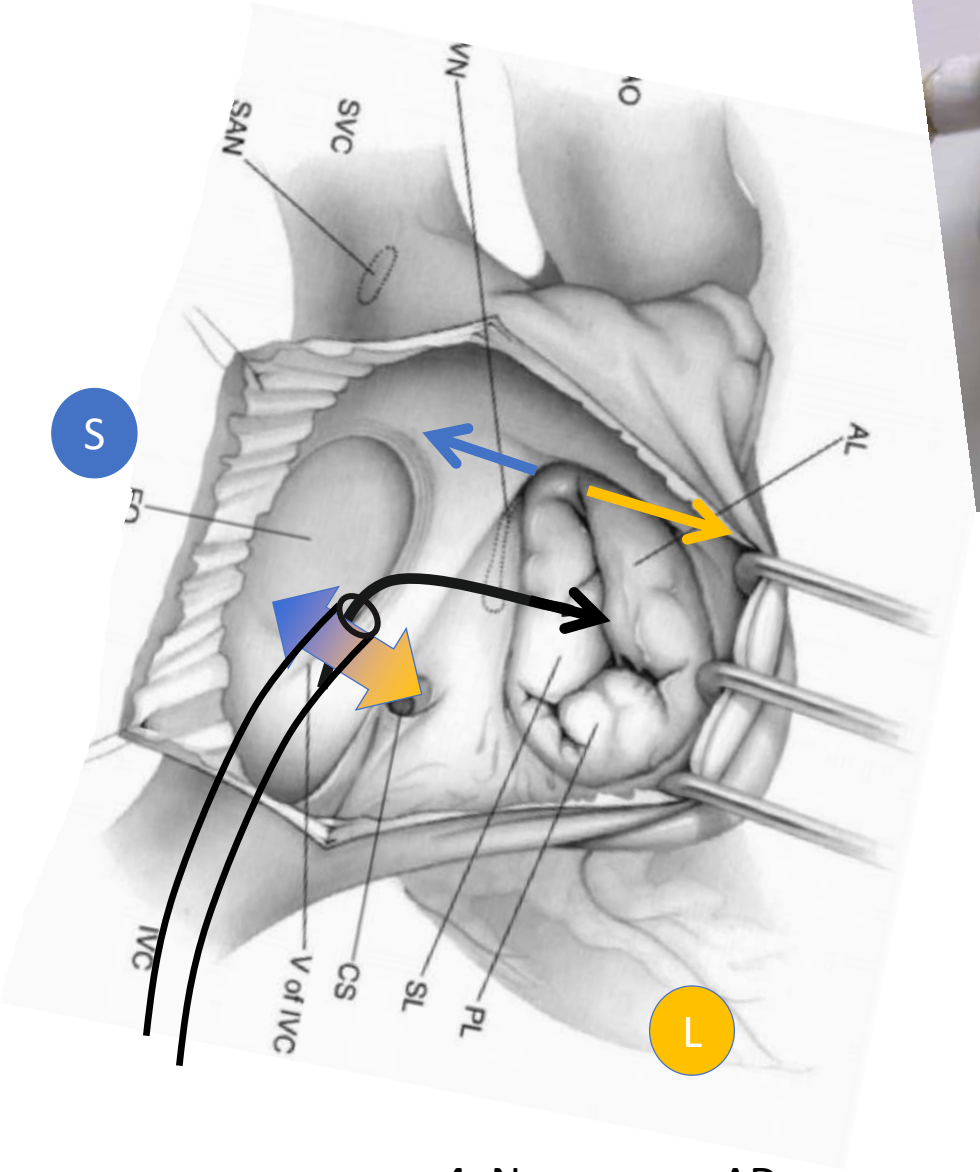
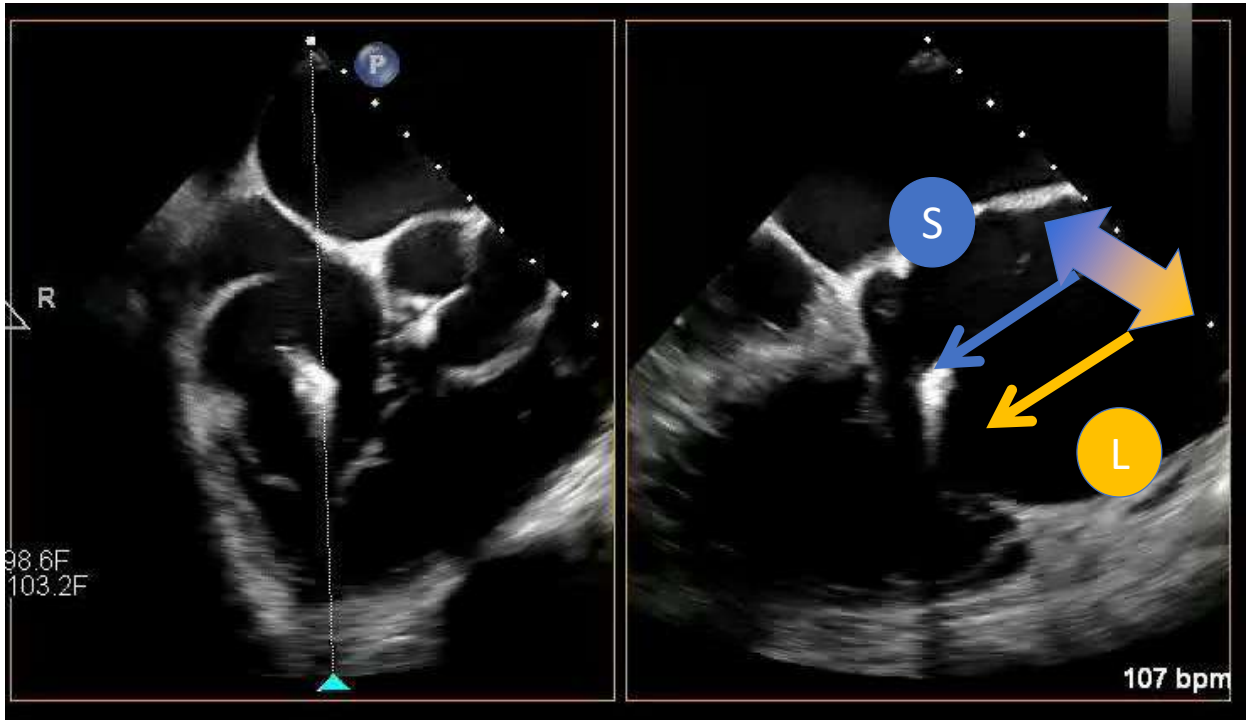


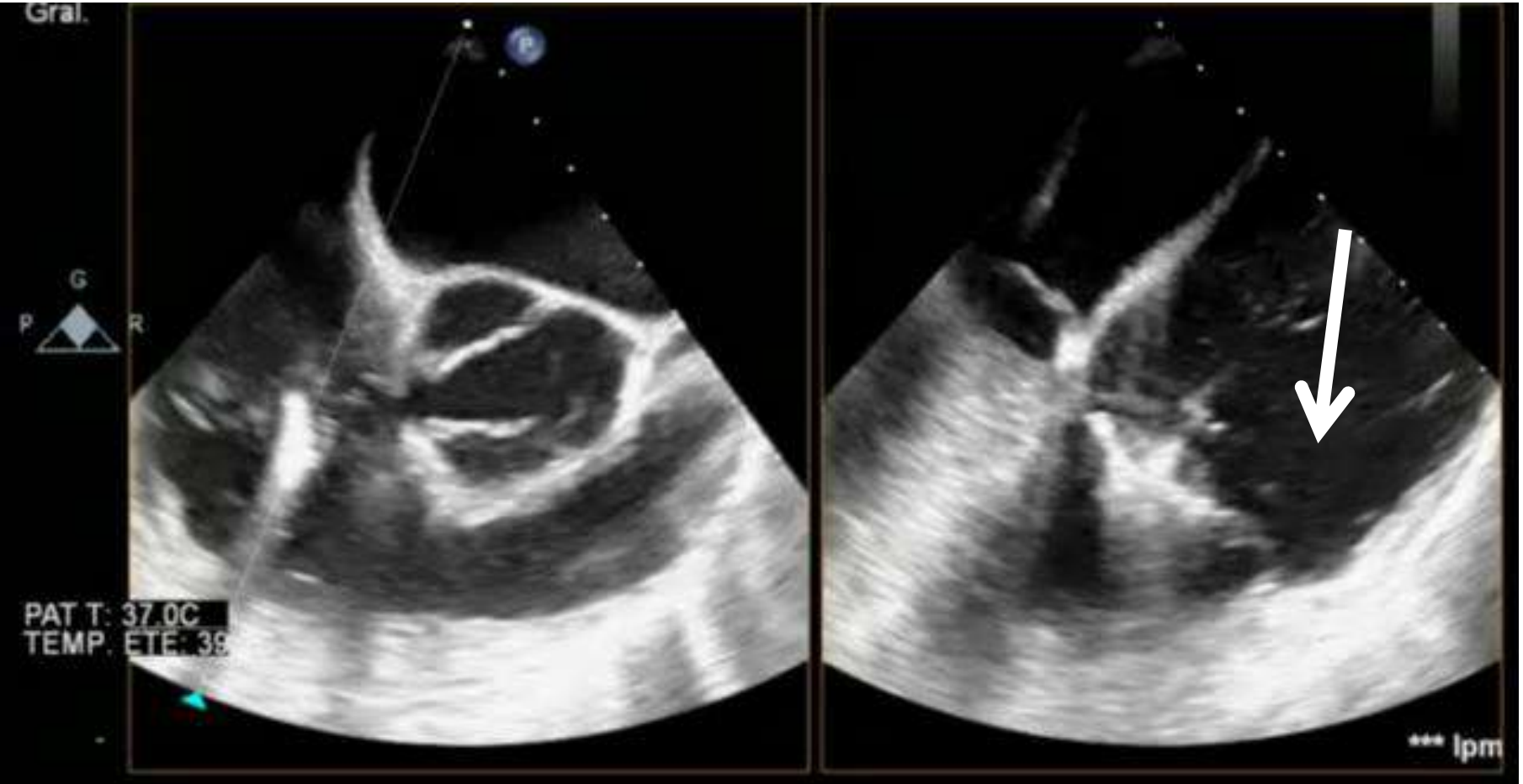
RUEDA
Septal/Lateral



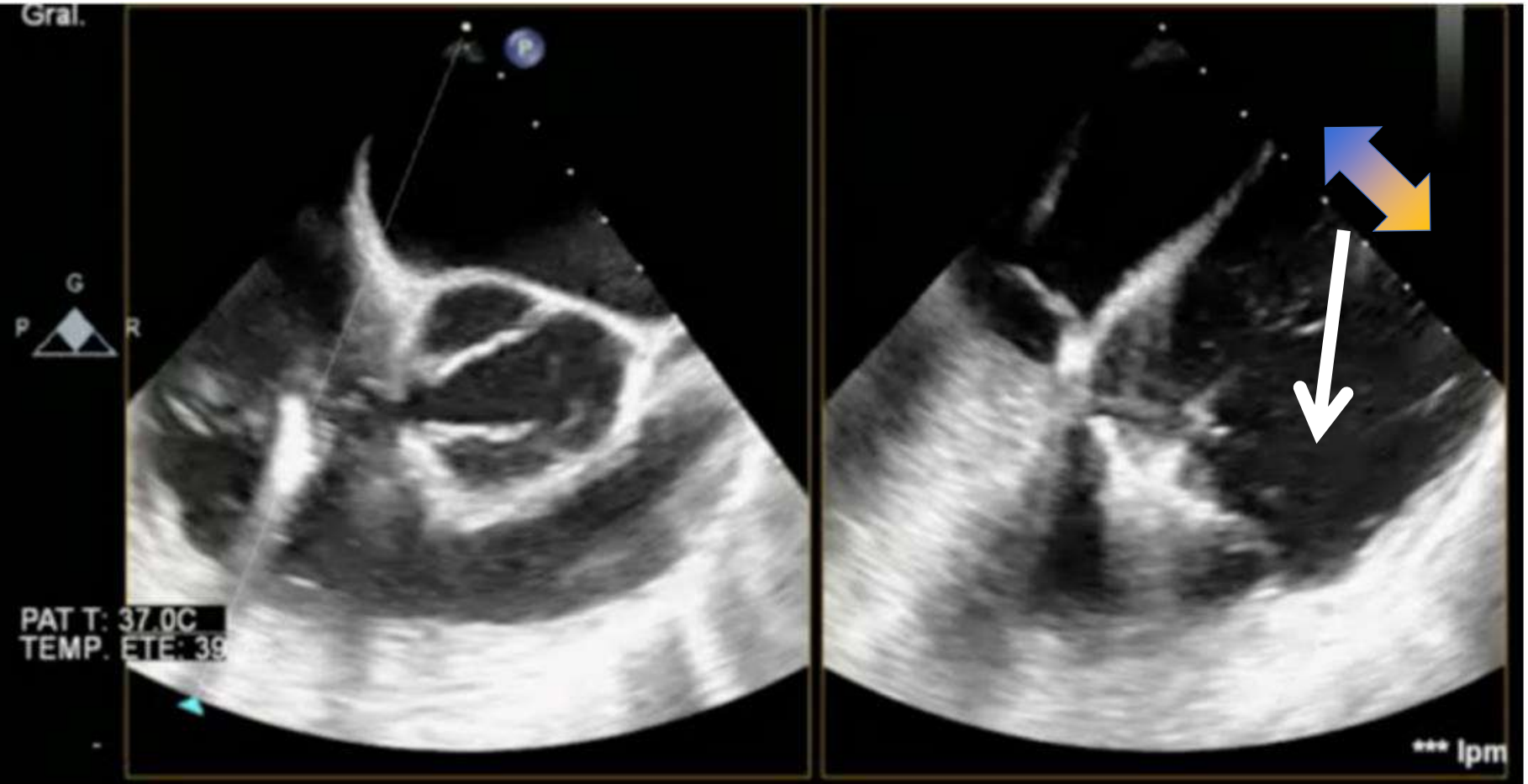
4. Navegar en AD

RUEDA
Septal/Lateral

TORQUE
Septal/Lateral



RUEDA
Septal/Lateral



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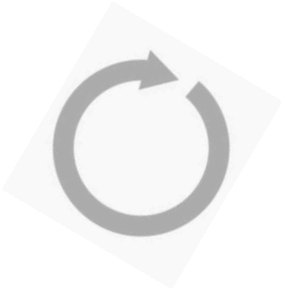
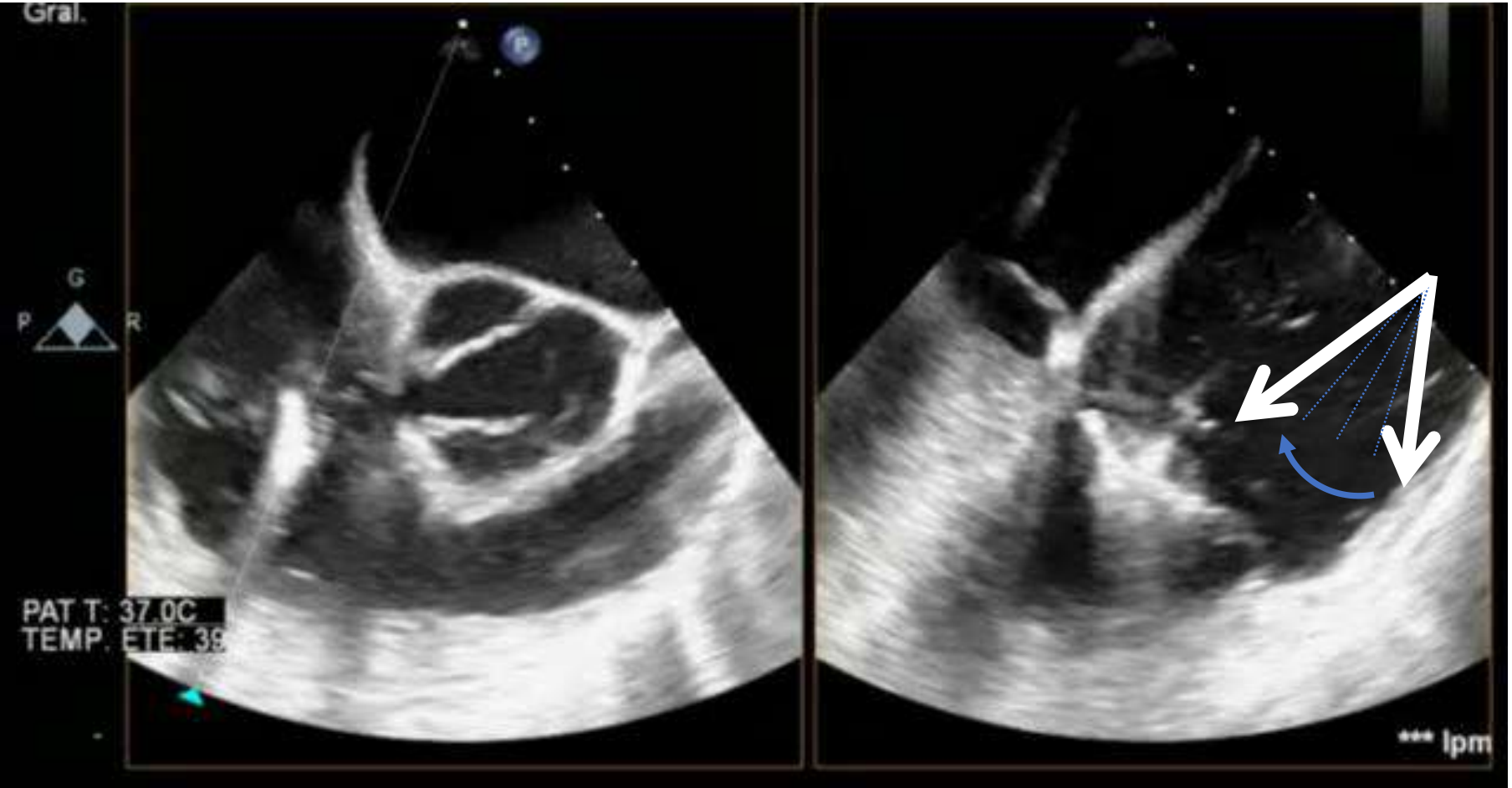
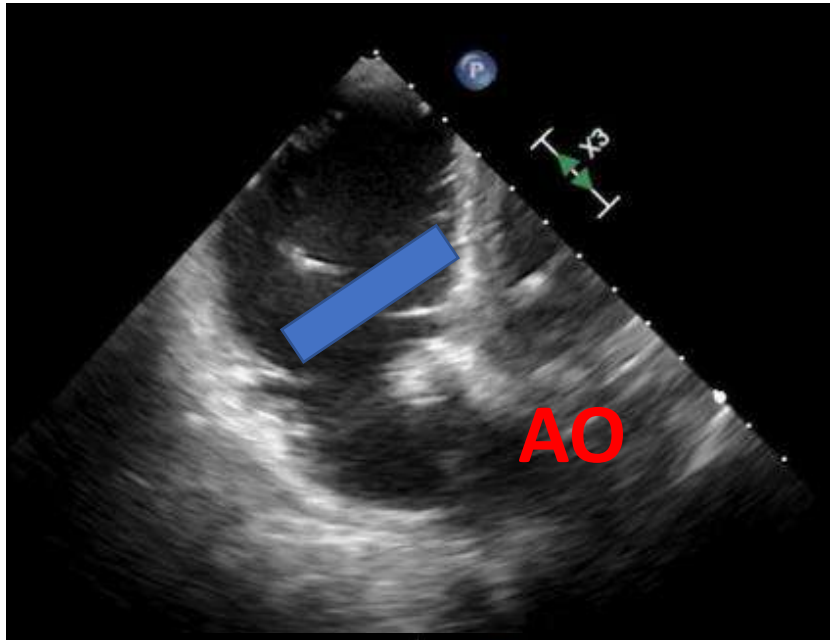


TORQUE
Septal/Lateral



1. RUEDA L
2. TORQUE A S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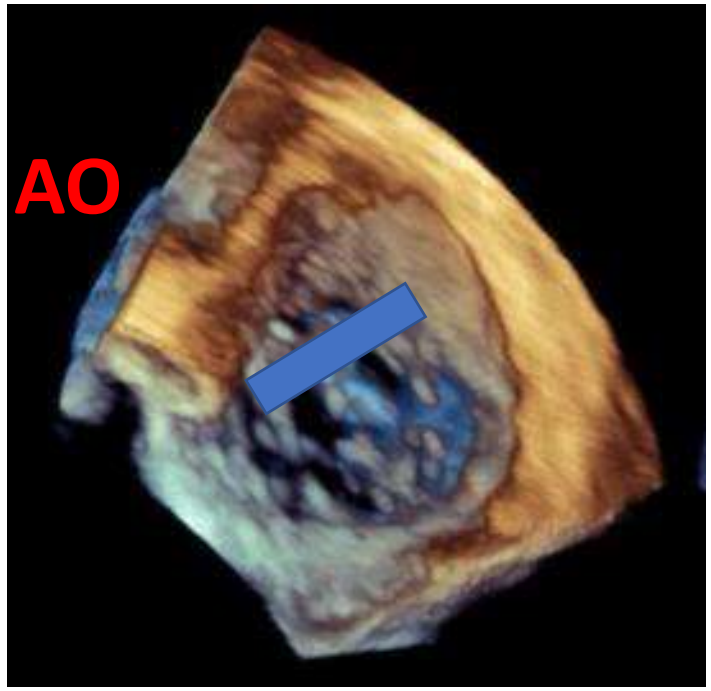
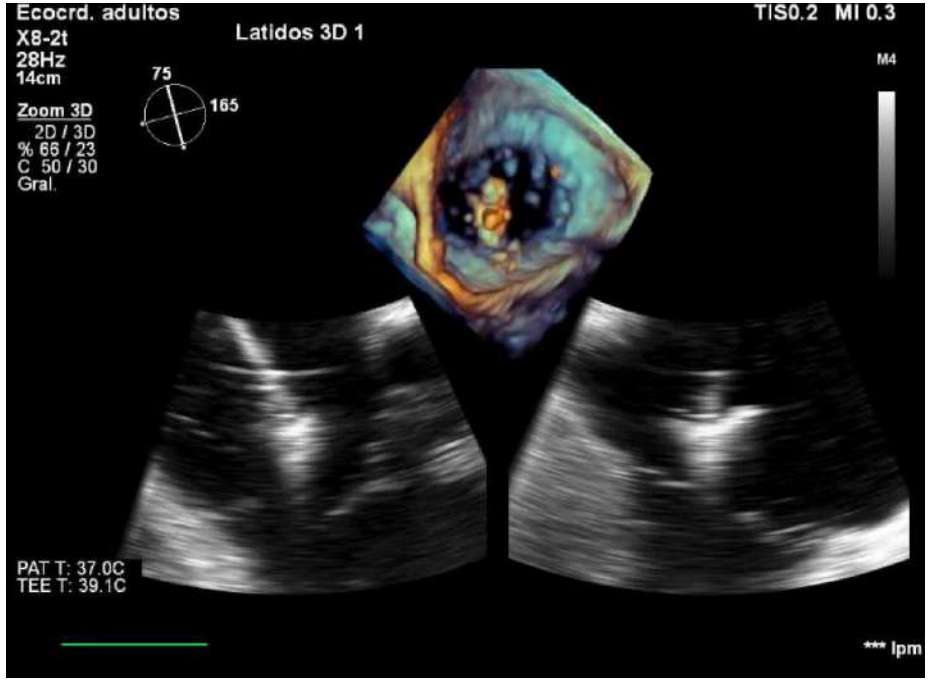
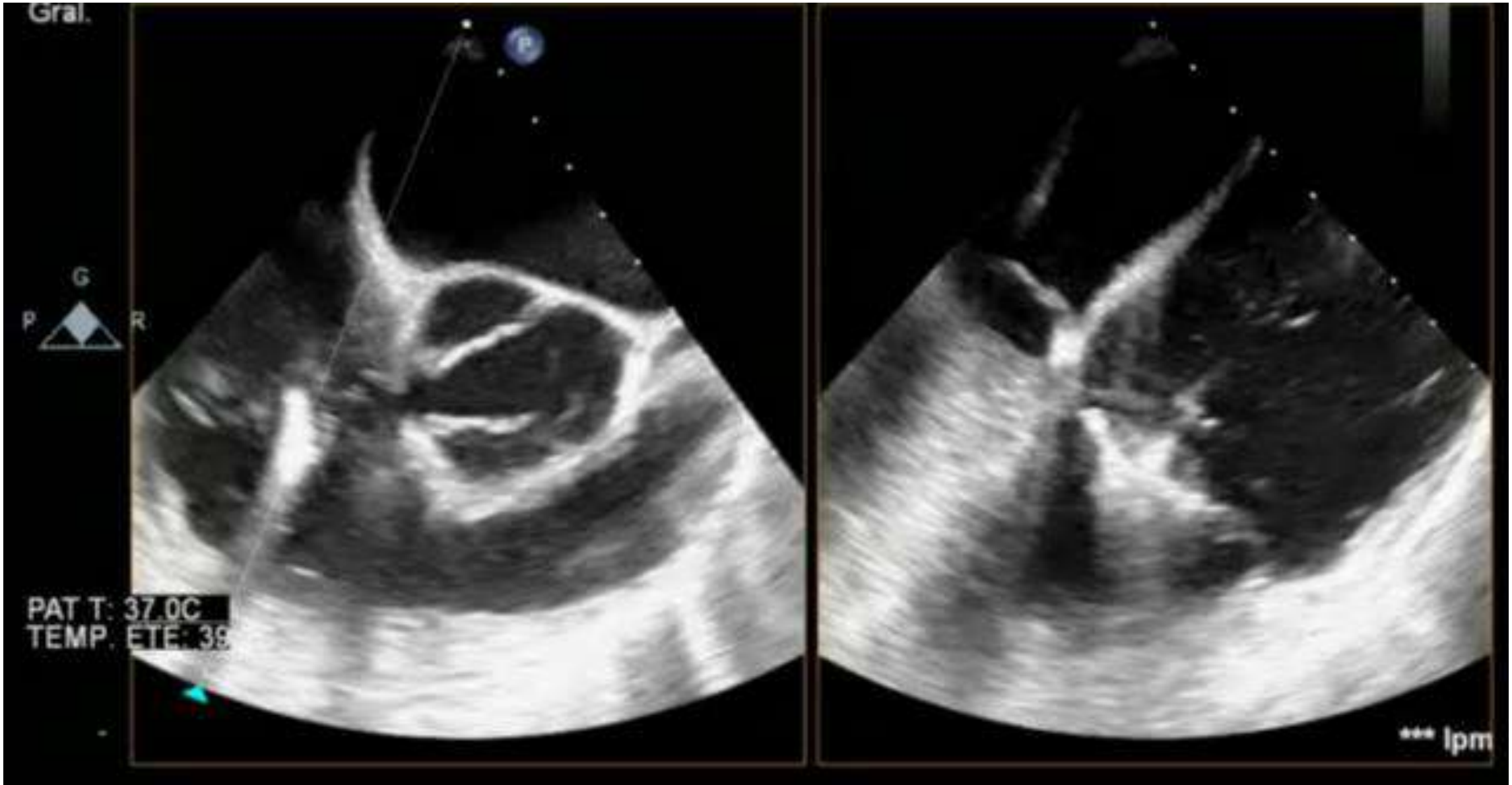
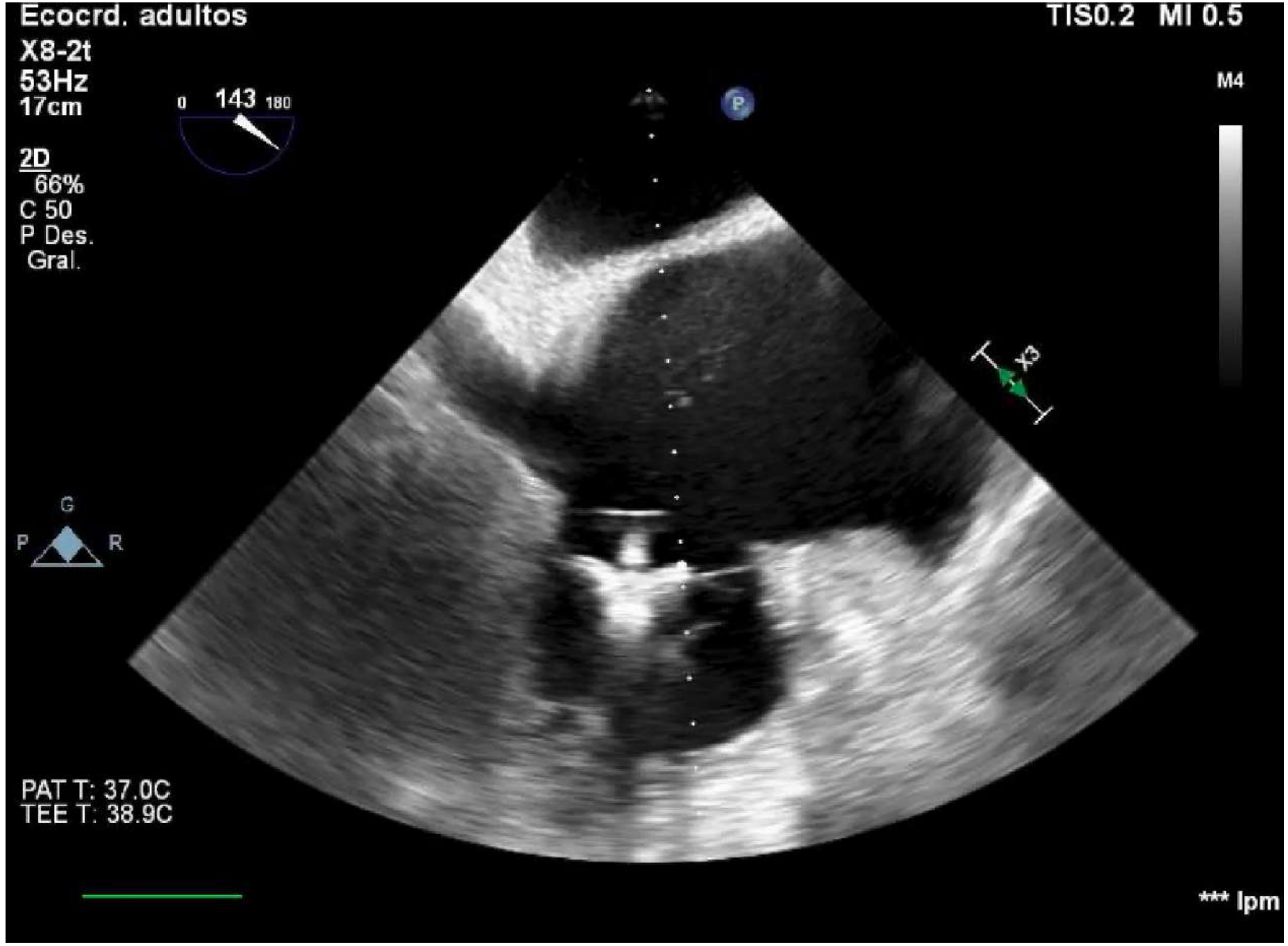

AO


0
42
180
6F
2.7F


Ecocrd. adultos
X8-2t
28Hz
14cm
Zoom 3D
2D / 3D
% 66 / 23
C 50 / 30
Gral.
Latidos 3D 1
TIS0.2 MI 0.3
M4
75
165
PAT T: 37.0C
TEE T: 39.1C
*** Ipm

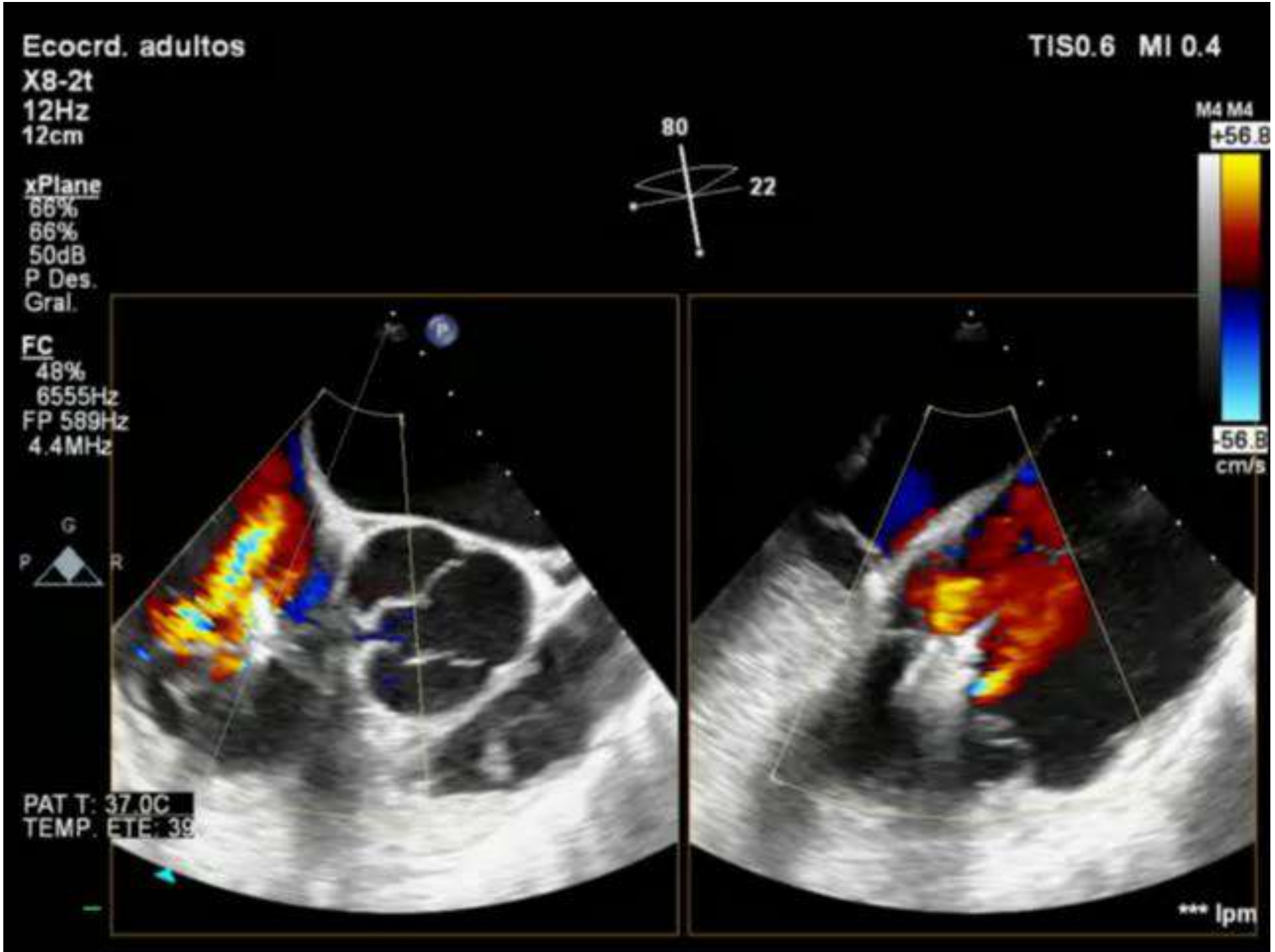

Gral.
G
P
R
PAT T: 37.0C
TEMP. ETE: 38
*** lpm

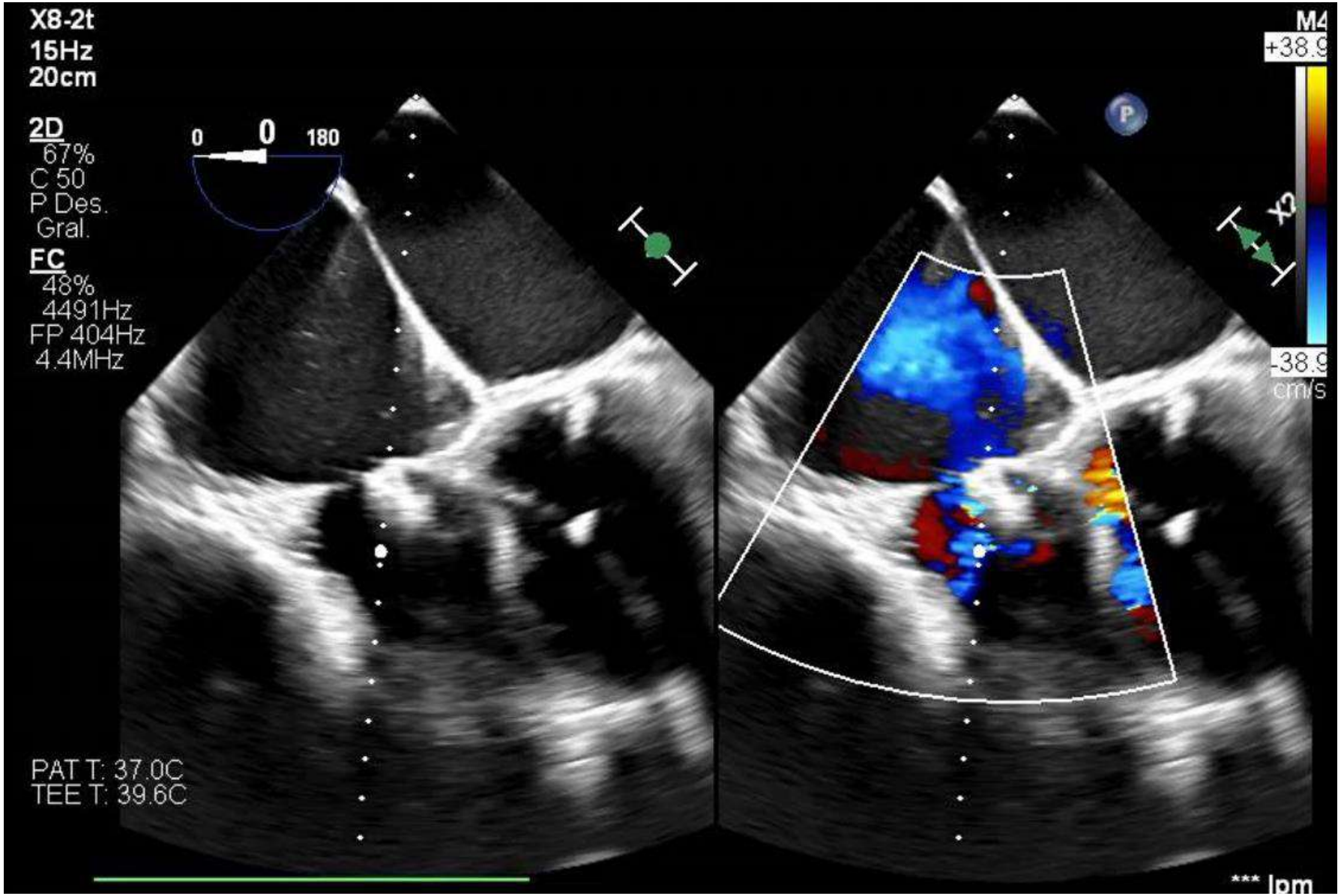

Ecocrd. adultos
X8-2t
53Hz
17cm
2D
66%
C 50
P Des.
Gral.
0
143
180
TIS0.2 MI 0.5
M4
G
P
R
PAT T: 37.0C
TEE T: 38.9C
*** Ipm


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


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

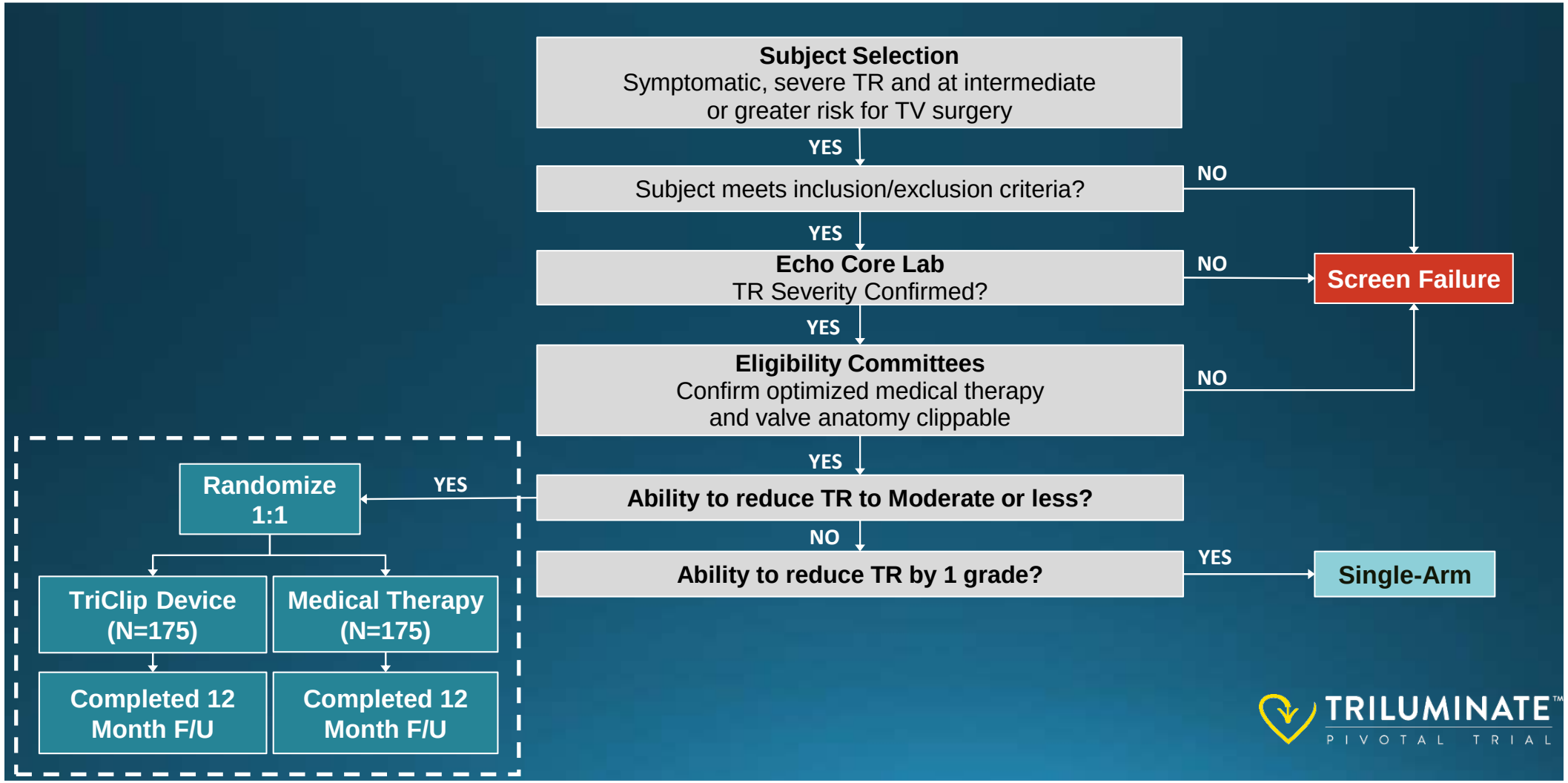

CV Intervention
X8-2t
76Hz
7.8cm
TIS0.2 MI 0.5
M5
0 106 180
2D
51%
C 46
P Off
Gen
X3
G
P R
PAT T: 98.6F
TEE T: 102.9F
70 bpm


Ecocrd. adultos
X8-2t
12Hz
12cm
xPlane
66%
66%
50dB
P Des.
Gral.
FC
48%
6555Hz
FP 589Hz
4.4MHz
TIS0.6 MI 0.4
80
22
M4 M4
+56.8
-56.8
cm/s
G
P
R
PAT T: 37.0C
TEMP. ETE: 39
*** lpm


X8-2t
15Hz
20cm
2D
67%
C 50
P Des.
Gral.
FC
48%
4491Hz
FP 404Hz
4.4MHz
0
0
180
M4
+38.9
-38.9
cm/s
PAT T: 37.0C
TEE T: 39.6C
*** bpm

Transcatheter Repair for Patients with Tricuspid Regurgitation

TRILUMINATE Trial



Paul Sorajja N Eng J Med May 2023

TRILUMINATE

Primary Endpoint	**To be assessed after the first 350 randomized subjects complete 12-month follow-up** A composite of mortality or tricuspid valve surgery, heart failure hospitalizations, and quality of life improvement ≥15 points assessed using the Kansas City Cardiomyopathy Questionnaire (KCCQ), evaluated at 12 months in a hierarchical fashion using the Finkelstein-Schoenfeld methodology
Secondary Endpoint	**Assessed hierarchically in the following order:** • Freedom from major adverse events (MAE) after procedure attempt (femoral vein puncture) at 30 days (Device group only) • Change in KCCQ at 12 months (superiority of Device vs. Control) • TR Reduction to moderate or less at 30-day post procedure (superiority of Device vs. Control) • Change in 6MWD at 12 months (superiority of Device vs. Control)

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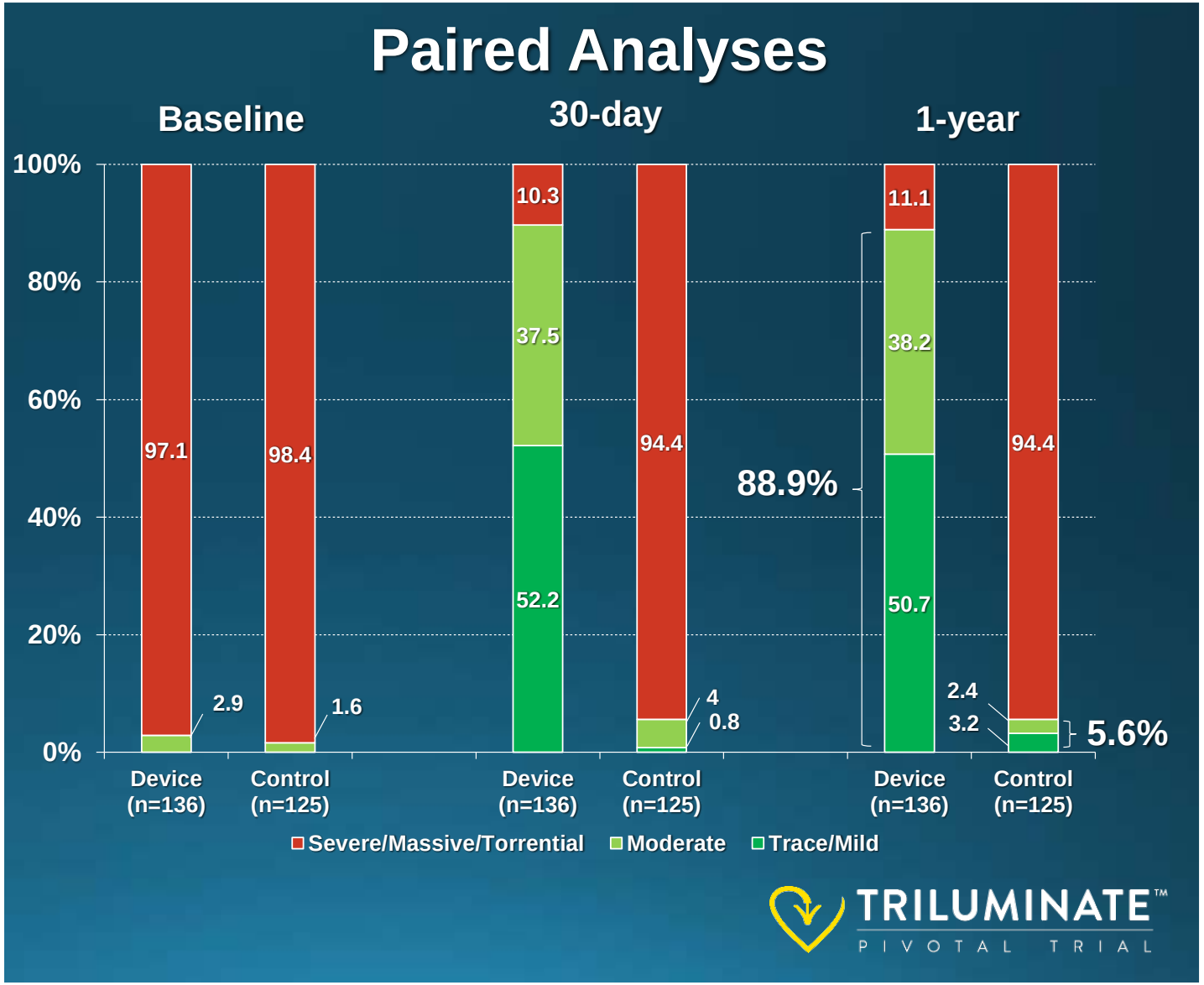
TRILUMINATE

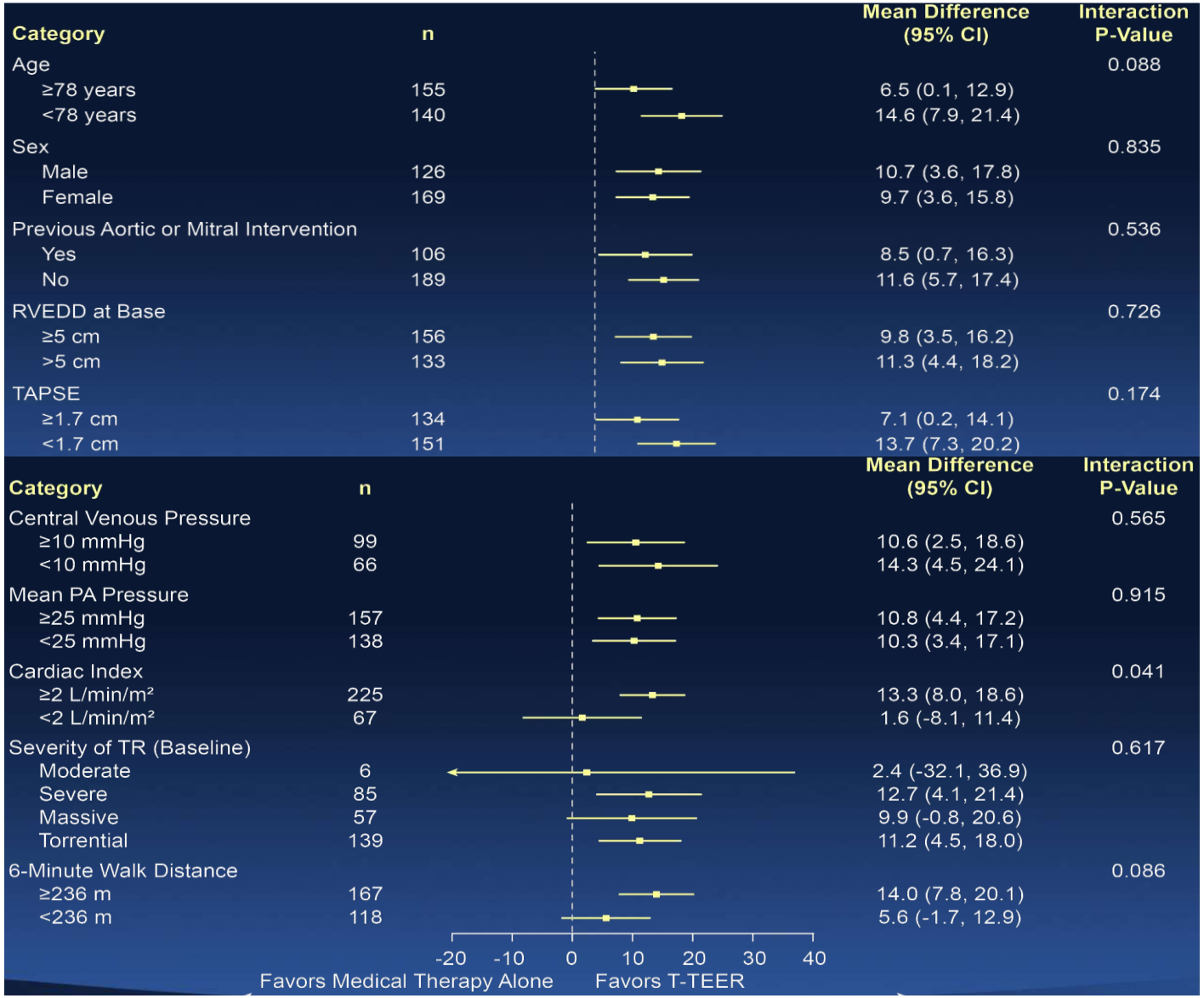
	Device N=175 # (%)	Control N=175 # (%)
Age, Mean (years)	78.0 ± 7.4	77.8 ± 7.2
Sex (Female)	98 (56.0)	94 (53.7)
NYHA class III or IV	104 (59.4)	97 (55.4)

	Device N=175 # (%)	Control N=175 # (%)
TR Severity		
Moderate	4 (2.3)	2 (1.2)
Severe	44 (25.4)	49 (29.7)
Massive	37 (21.4)	30 (18.2)
Torrential	88 (50.9)	84 (50.9)
Etiology (functional)	165 (94.8)	158 (92.9)
Coaptation Gap, Mean (mm)	5.5 ± 1.8	5.2 ± 1.7

TRILUMINATE. REDUCCIÓN DE LA INSUFICIENCIA TRICUSPÍDEA



CALIDAD DE VIDA. TRILUMINATE. 1 AÑO: ANÁLISIS POR SUBGRUPOS



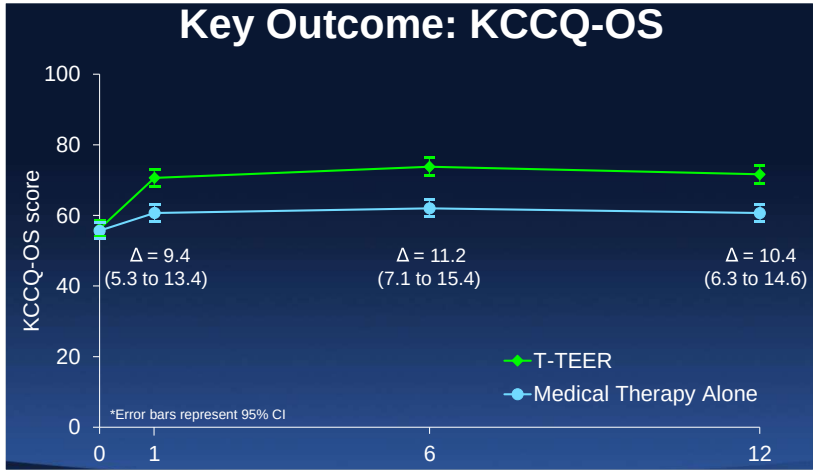
S Arnold TCT 2023 y JACC Oct 2023

CALIDAD DE VIDA. TRILUMINATE. 1 AÑO

Test Kansas City para cardiomiopatias (KCCQ) 1 mes y 1 año

Relación de la mejoría del test KCCQ-OS con la reducción de la IT

Relación de la mejoría del KCCQ-Os con mortalidad y hospitalizaciones



Association of change in KCCQ-OS with change in TR grade (baseline to 1 year)

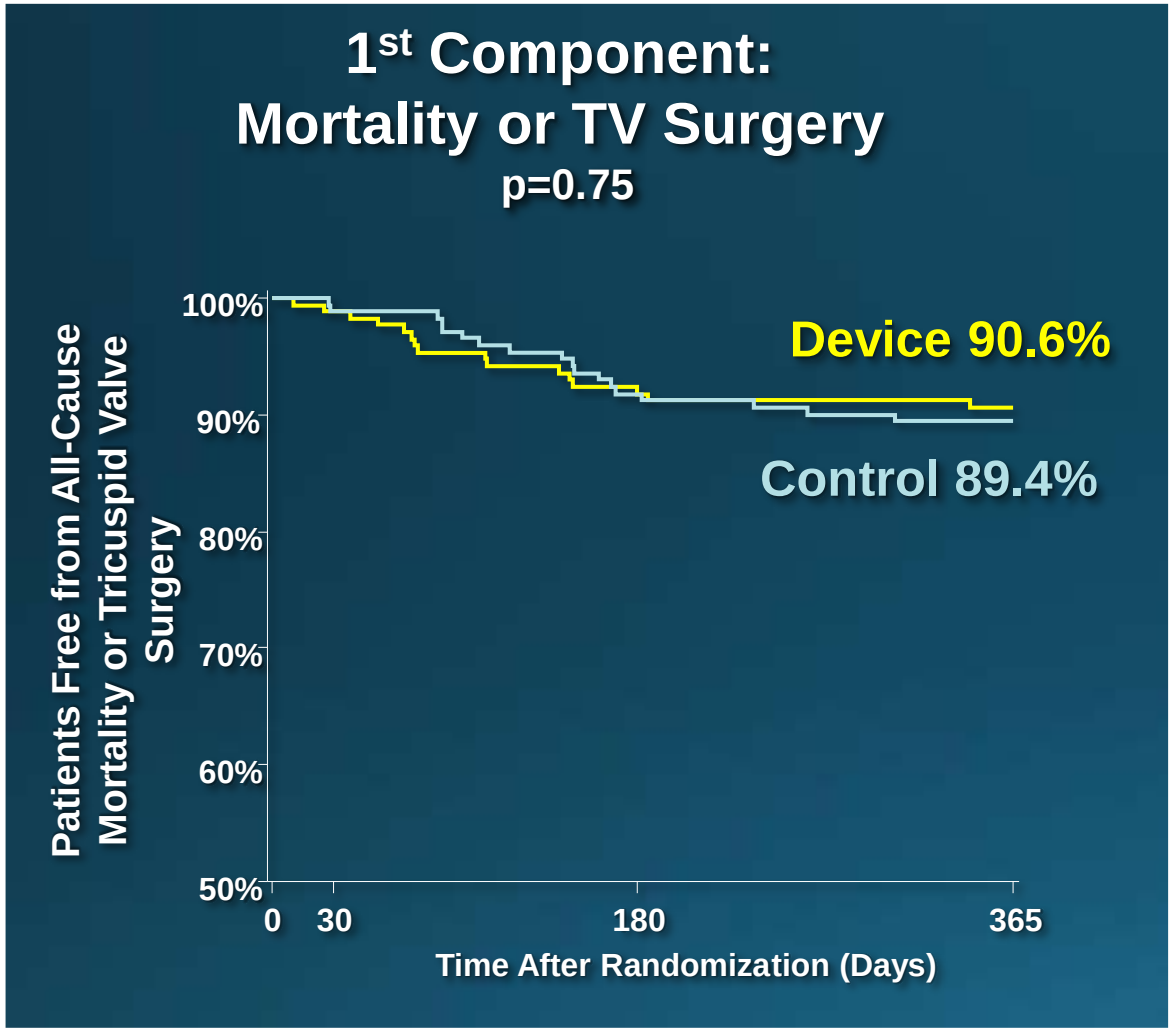
	Estimate (95% CI)	P-value
Change in KCCQ-OS per 1 grade improvement in TR severity	4.1 (1.8 to 6.5)	0.001

Association of change in KCCQ-OS at 1 month with subsequent events

	Hazard Ratio (95% CI) per 10-point increase in KCCQ-OS	P-value
Death	0.77 (0.64-0.93)	0.007
Heart failure hospitalization	0.70 (0.58-0.84)	<0.001
Death or heart failure hospitalization	0.74 (0.65-0.84)	<0.001

Suzanne W Arnold TCT 2023 y JACC Oct 2023

TRILUMINATE



Other Clinical Safety Endpoints Through 30 Days Post-Procedure– no.(%)	Device N=172†
Any-cause mortality	1 (0.6%)
Tricuspid valve surgery	1 (0.6%)
Tricuspid valve re-intervention	3 (1.7%)
Major bleeding#	8 (4.7%)
Tricuspid mean gradient ≥ 5mmHg	8 (4.7%)
Single leaflet device attachment (SLDA)*	12 (7.0%)
Stroke	1 (0.6%)
Myocardial Infarction	0 (0%)
Embolization*	0 (0%)
Thrombosis	0 (0%)
New CRT/CRT-D/ICD/perm. pacemaker^	1 (0.6%)

TRILUMINATE. ¿QUÉ CONCLUSIONES SACAR?

Es el primer estudio aleatorizado de una población hasta ahora infratratada

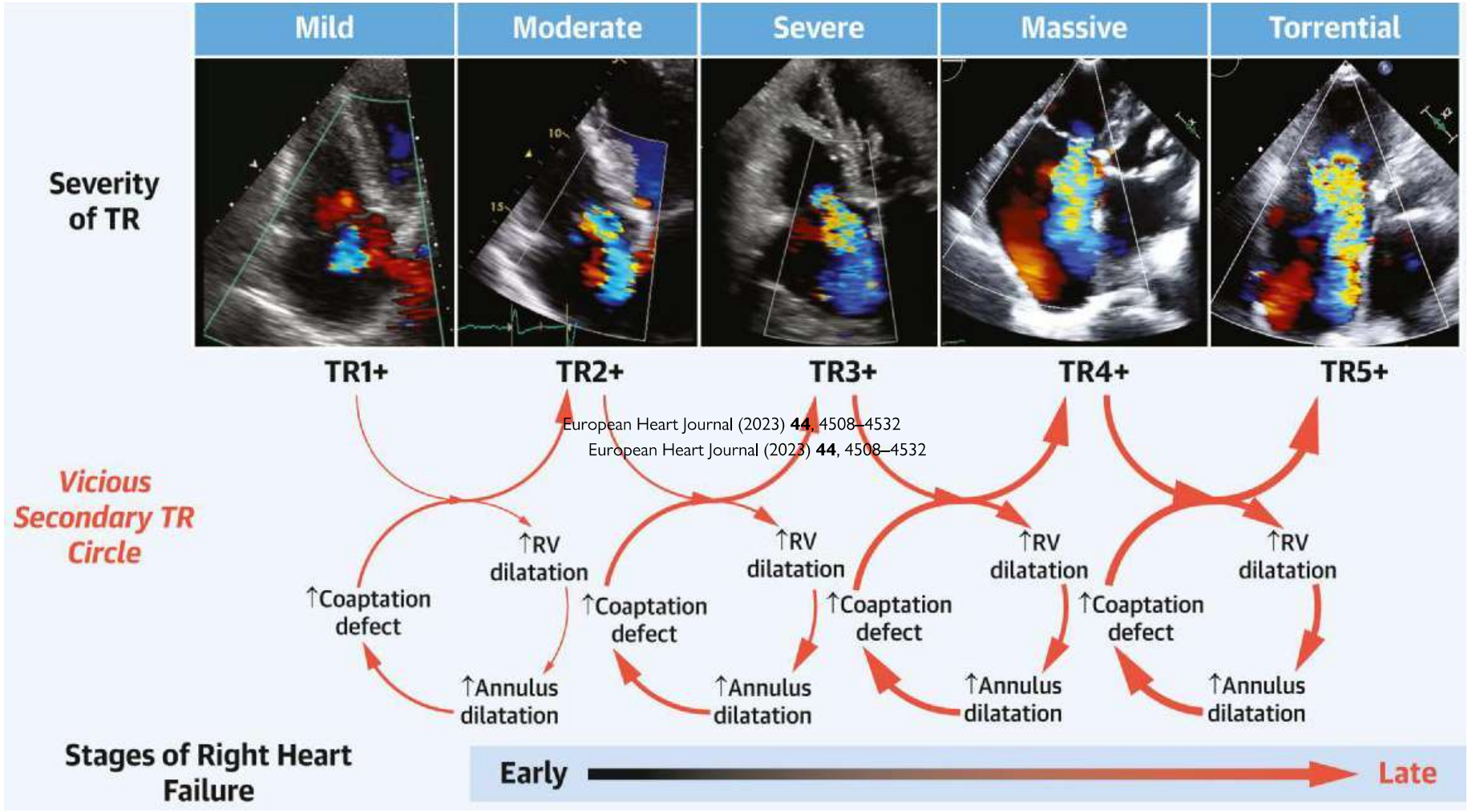
El perfil de seguridad (mortalidad) y la reducción de la IT son elevados

La mortalidad de la terapia alternativa es muy alta

Probablemente el seguimiento debería ser a mas largo plazo para demostrar reducciones en mortalidad (evitando la progresión de la enfermedad)

¿QUÉ TRATAMIENTO ELEGIR?

PROGRESIÓN DE LA INSUFICIENCIA TRICUSPÍDEA



¿CUÁNDO ME ADELANTO? ¿CUÁNDO ES DEMASIADO TARDE?

Rebecca T Hahn Eur Heart J octubre 2023

CONCLUSIONES

- **Los resultados iniciales sugieren que el tratamiento transcatéter de la válvula tricúspide es seguro y efectivo con diferentes técnicas, con disminución de la insuficiencia tricuspídea, mejoría clínica y mortalidad muy baja.**

- **La selección clínica, buscando el momento adecuado para la terapia y la anatómica son claves, y estyán aún por determinar**

- **TRICLIP/PASCAL es hoy día el primer tratamiento a considerar**

- **La válvula ortotópica tiene resultados preliminaries muy esperanzadores, y ya está comercializada la primera válvula (Evoque)**

- **Los dispositivos en venas cavas deberían utilizarse cuando otras opciones no sean posibles o hayan fallado**

- **La mortalidad del tratamiento alternativo de “intervención” es muy elevada**

¡ MUCHAS GRACIAS !