



Presentación de Biosud S.A. Nuevas tecnologías para las válvulas Mitral y Tricúspide

Dr. Marcelo Agüero
Instituto de Cardiología de Corrientes


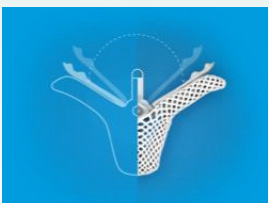
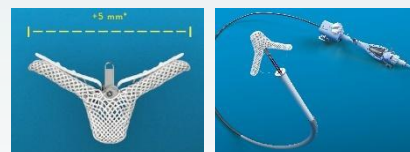



JORNADAS CIENTÍFICAS Y GREMIALES CACI 2021
4 Y 5 DE DICIEMBRE 2021 . HOTEL HILTON - PRESENCIAL



4 Generaciones de MITRACLIP

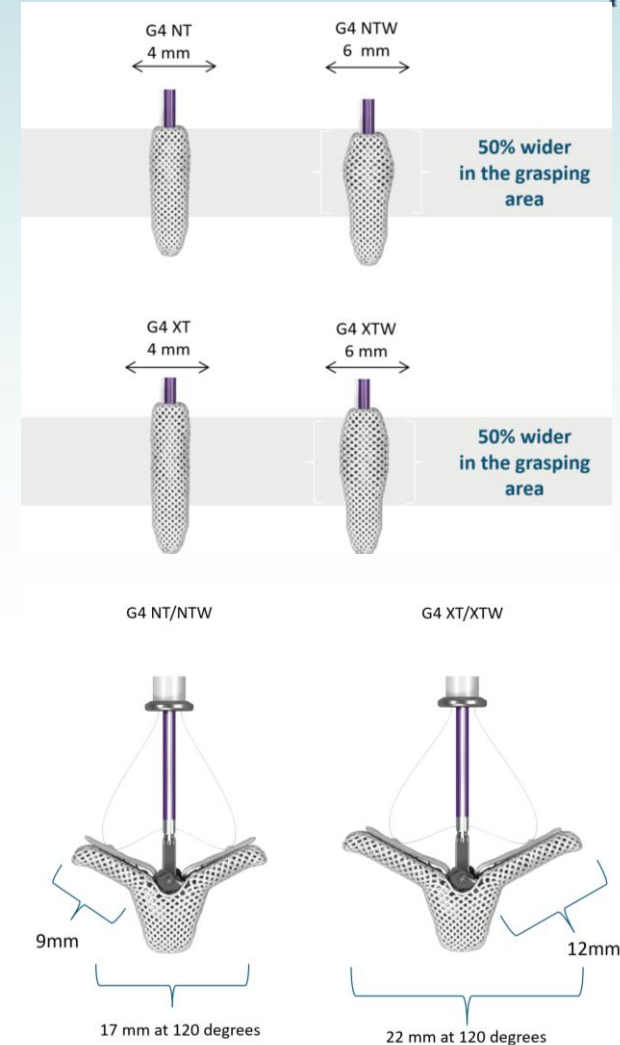


MitraClip Pipeline			
GEN 1	GEN 2	GEN 3	GEN 4
<p>MitraClip</p>  <p>Breakthrough Technology to restore leaflet coaptation with a delivery system specifically designed for the MV</p>	<p>MitraClip NT</p>  <p>Leaflet grasping and steering enhancements</p>	<p>MitraClip NTR & MitraClip XTR</p>  <ul style="list-style-type: none"> • Improved grasping, Increased coaptation surface area • Customized repair with 2 Clip sizes¹ • Enhanced steering accuracy and ease-of-use¹ 	<p>MitraClip G4</p>  <ul style="list-style-type: none"> • Enable ability to choose Clip size based on MV anatomy with 4 sizes • Ability to grasp leaflets simultaneously or independently with Controlled Gripper Actuation (CGA) • Streamlined procedure with simplified system deployment & reduced number of steps*

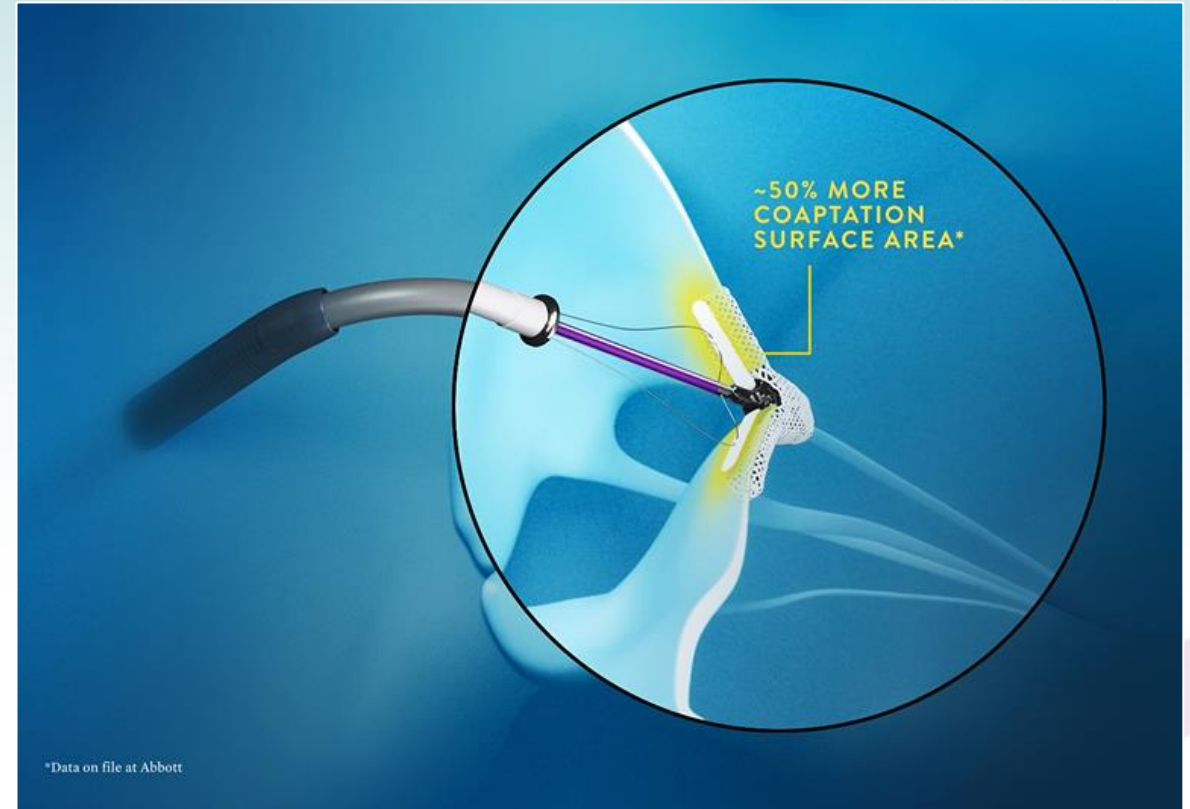
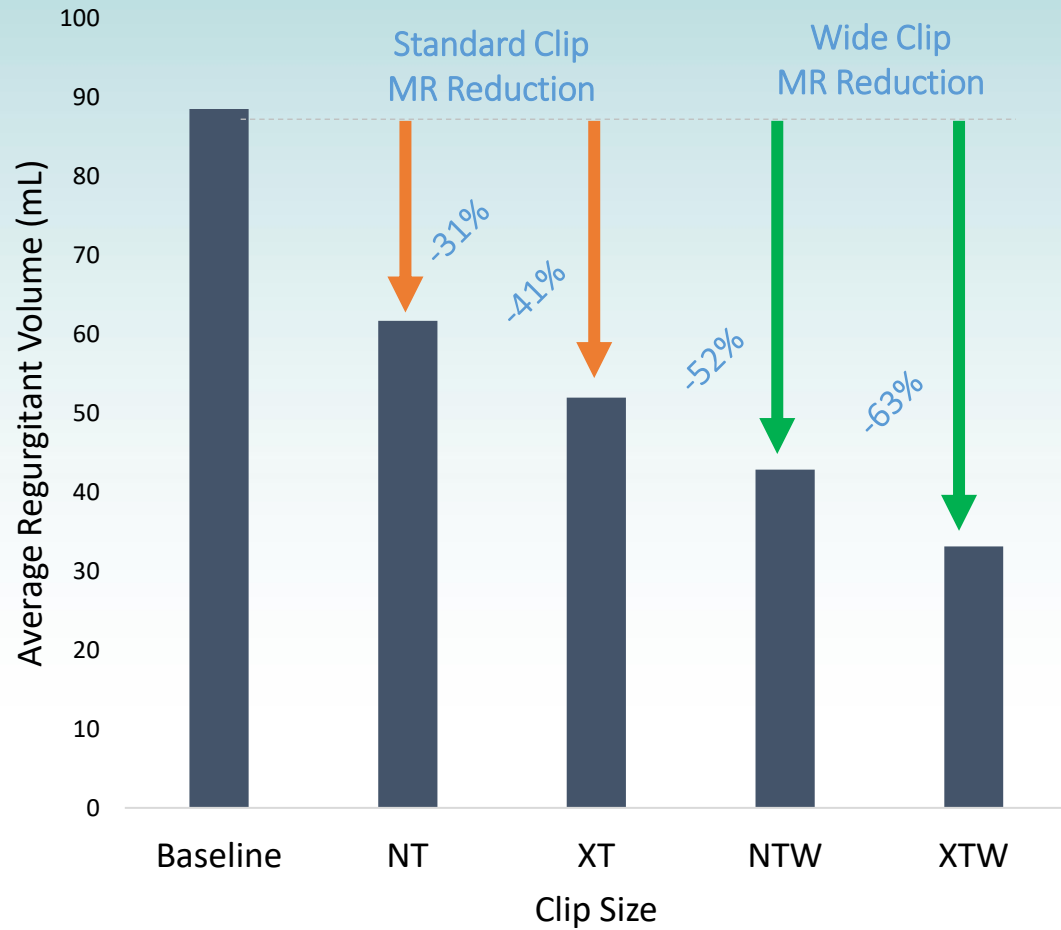


MITRACLIP G4: revisión

- 4 medidas de clips: NT, XT, NTW, XTW
Selección del clip basada en la anatomía
- Procedimiento simplificado:
40% reducción pasos de preparación
Secuencia de deployment simplificada
- Actuación controlada de grippers
Grasping simultáneo o independiente
- Mejoras en el delivery system:
estabilidad y precisión
- Monitoreo de presión de AI
Mejor evaluación de la reducción de la IM



Regurgitant Volume vs Clip Size at LV Systolic Pressure of 100 mmHg



MITRACLIP G4:

Actuación controlada de grippers



New Gripper Levers



JORNADAS CIENTÍFICAS Y GREMIALES CACI 2021
4 Y 5 DE DICIEMBRE 2021 . HOTEL HILTON - PRESENCIAL

MITRACLIP G4:

Modificaciones en el sistema de liberación

- Trayectoria recta al cruzar al VI
- Mayor precisión al seleccionar sitio de clipado
- Orientación estable del clip al cruzar al VI



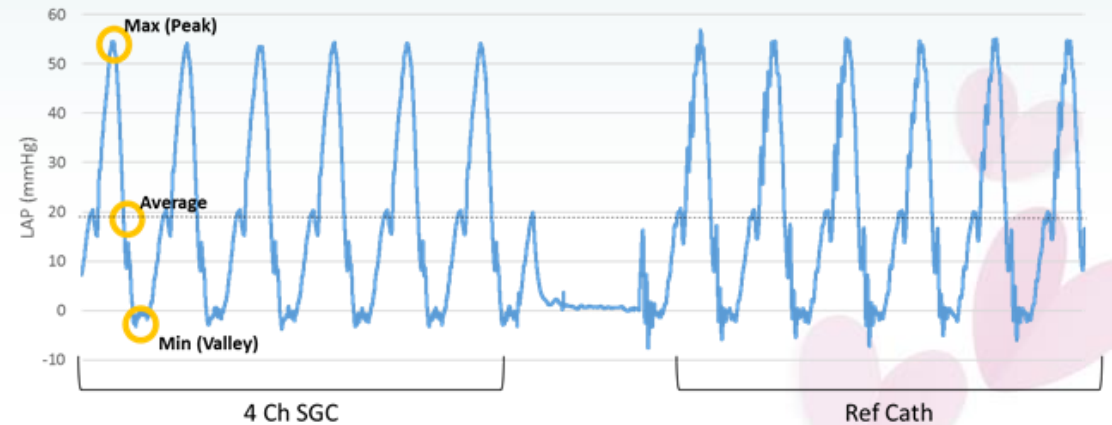
MITRACLIP G4:

Monitoreo de presión de AI

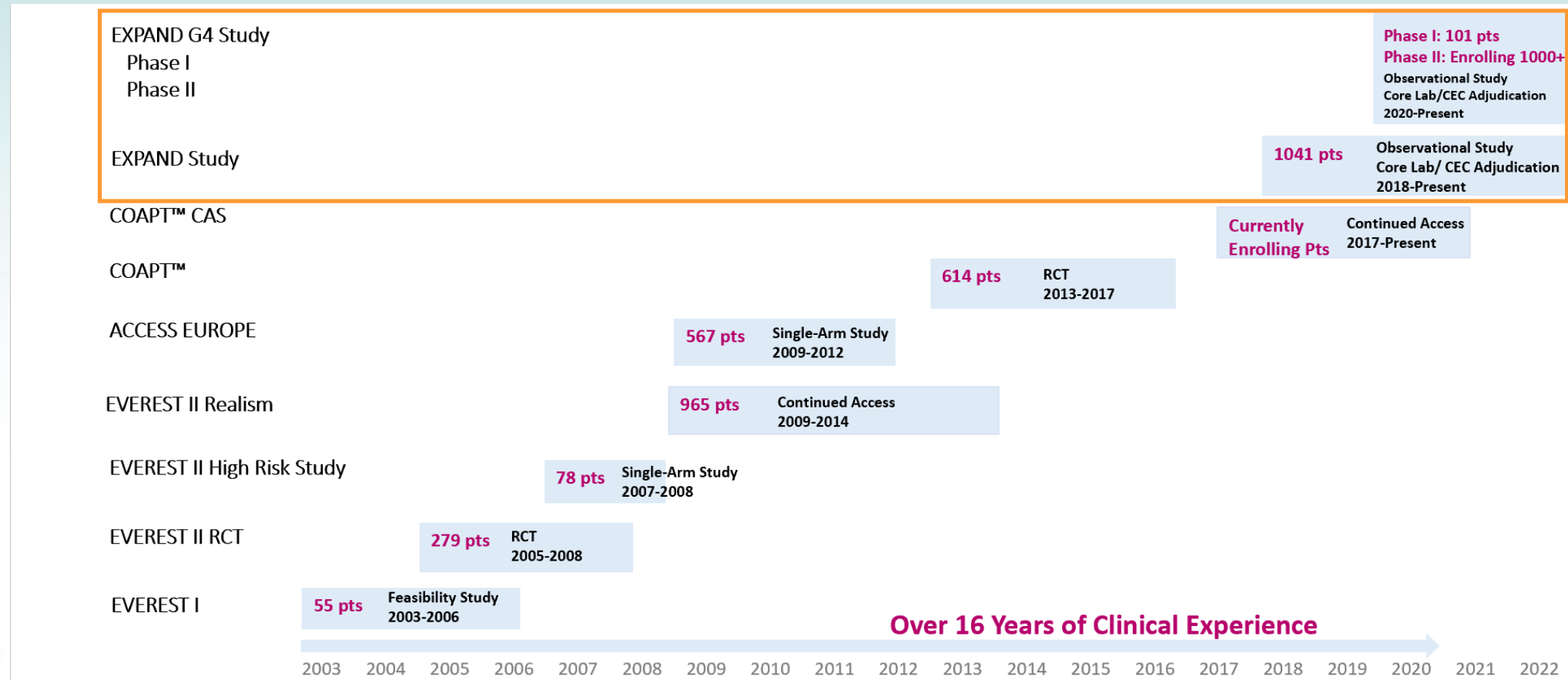
- La elevación de presión de AI es proporcional a la severidad de la IM.
- La reducción de la presión de AI caracteriza a una reparación exitosa.

Información hemodinámica relevante para optimizar la reducción de la IM

MitraClip G4 LAP signal



Evolución de la experiencia clínica con Mitraclip

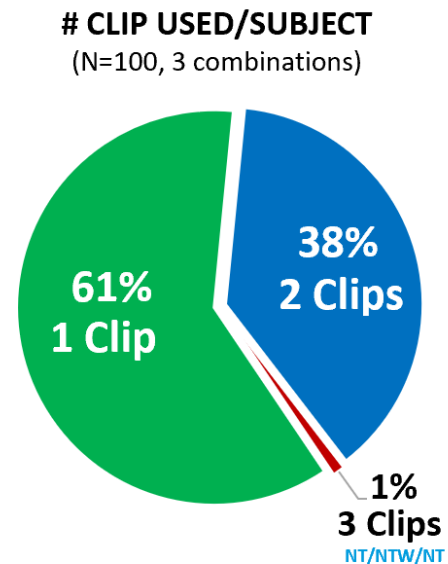
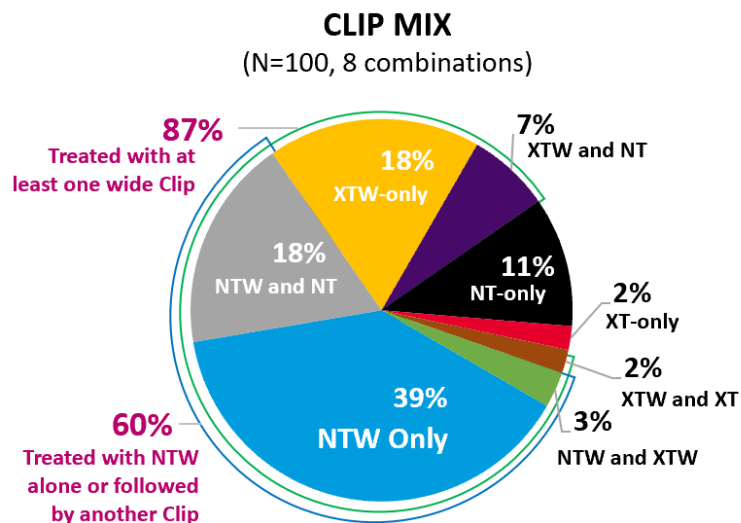


JORNADAS CIENTÍFICAS Y GREMIALES CACI 2021
 4 Y 5 DE DICIEMBRE 2021 . HOTEL HILTON - PRESENCIAL

EXPAND G4: distribución de clips usados



WIDER CLIPS USED IN MAJORITY OF CASES



More subjects treated with 1 Clip than in the EXPAND study (55%)*



EXPAND G4: eficacia del procedimiento



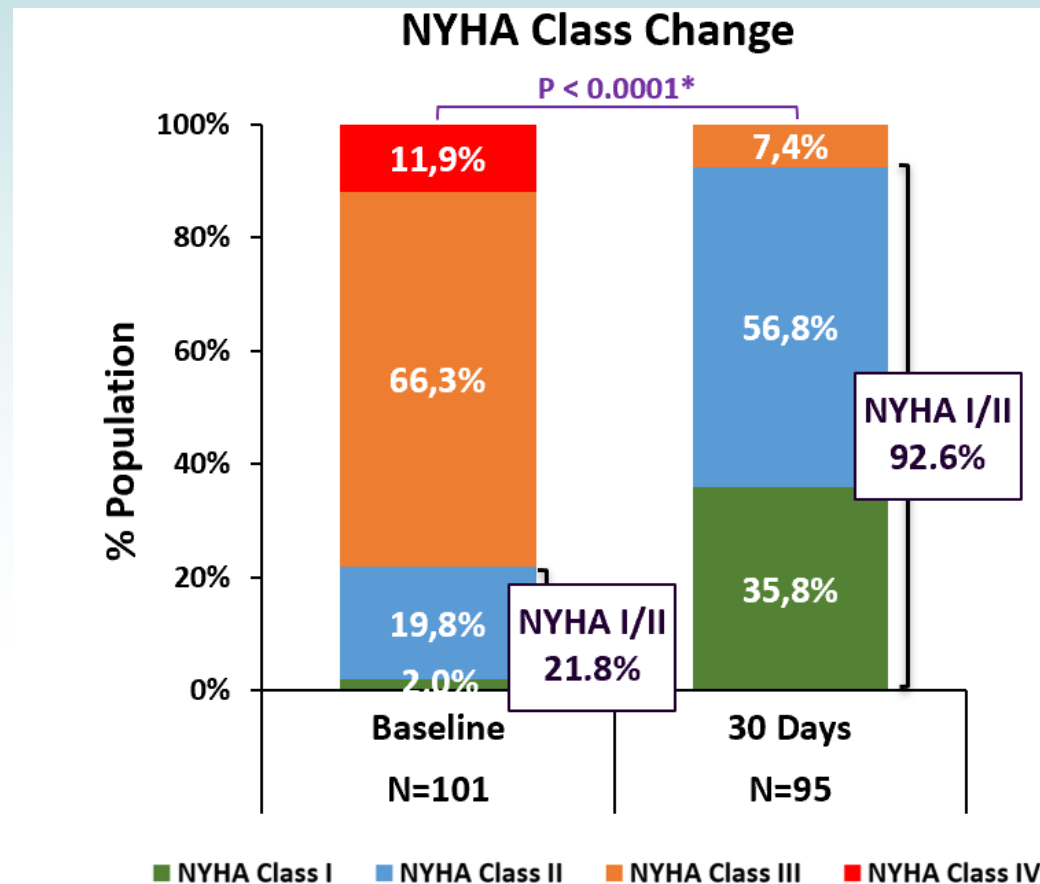
	EXPAND G4 (N=101)	EXPAND¹ (N=1040)	TVT Registry² (N=2,952)	ACCESS-EU³ (N=567)
Implant Rate % (n/N) [95% Confidence Interval]	99.0% (100/101) [94.6%, 100.0%]	98.9% (1030/1041) [98.12%, 99.5%]	NA	99.6%
Acute Procedural Success (APS)* % (n/N) [95% Confidence Interval]	99.0% (99/100) [94.6%, 100.0%] (ECL)	95.9% (983/1026) [94.4%, 97.0%] (ECL)	91.8% (2,709/2,952) Site-Reported	91% [514/565] Site-Reported
Device Time (min) Median [Inter-Quartile Range]	39.0 [24.0-63.0]	46.0 [30.0-71.0]	NA	NA
Fluoroscopy Time (min) Median [Inter-Quartile Range]	16.2 [11.1 – 22.1]	17.2 [11.1 – 27.0]	NA	25.0 (0.0, 152)
Procedure Time (min) Median [Inter-Quartile Range]	80.0 [57.0-109.0]	80.0 [54.0-115.0]	NA	100.0 (15, 390)
Length of Stay in Hospital for Index Procedure, Mean±SD	3.3±4.2	3.2±4.2 (US only)	NA	7.7±8.2



JORNADAS CIENTÍFICAS Y GREMIALES CACI 2021
4 Y 5 DE DICIEMBRE 2021 . HOTEL HILTON - PRESENCIAL



EXPAND G4: eficacia clínica





Mitraclip G4:

Mayor tasa de éxito técnico que generaciones anteriores
Mantenimiento de la seguridad
Eficacia clínica
Disponible en Argentina a inicios de 2022



JORNADAS CIENTÍFICAS Y GREMIALES CACI 2021
4 Y 5 DE DICIEMBRE 2021 . HOTEL HILTON - PRESENCIAL





Reparación Percutánea de la Válvula Tricúspide

TRICLIP

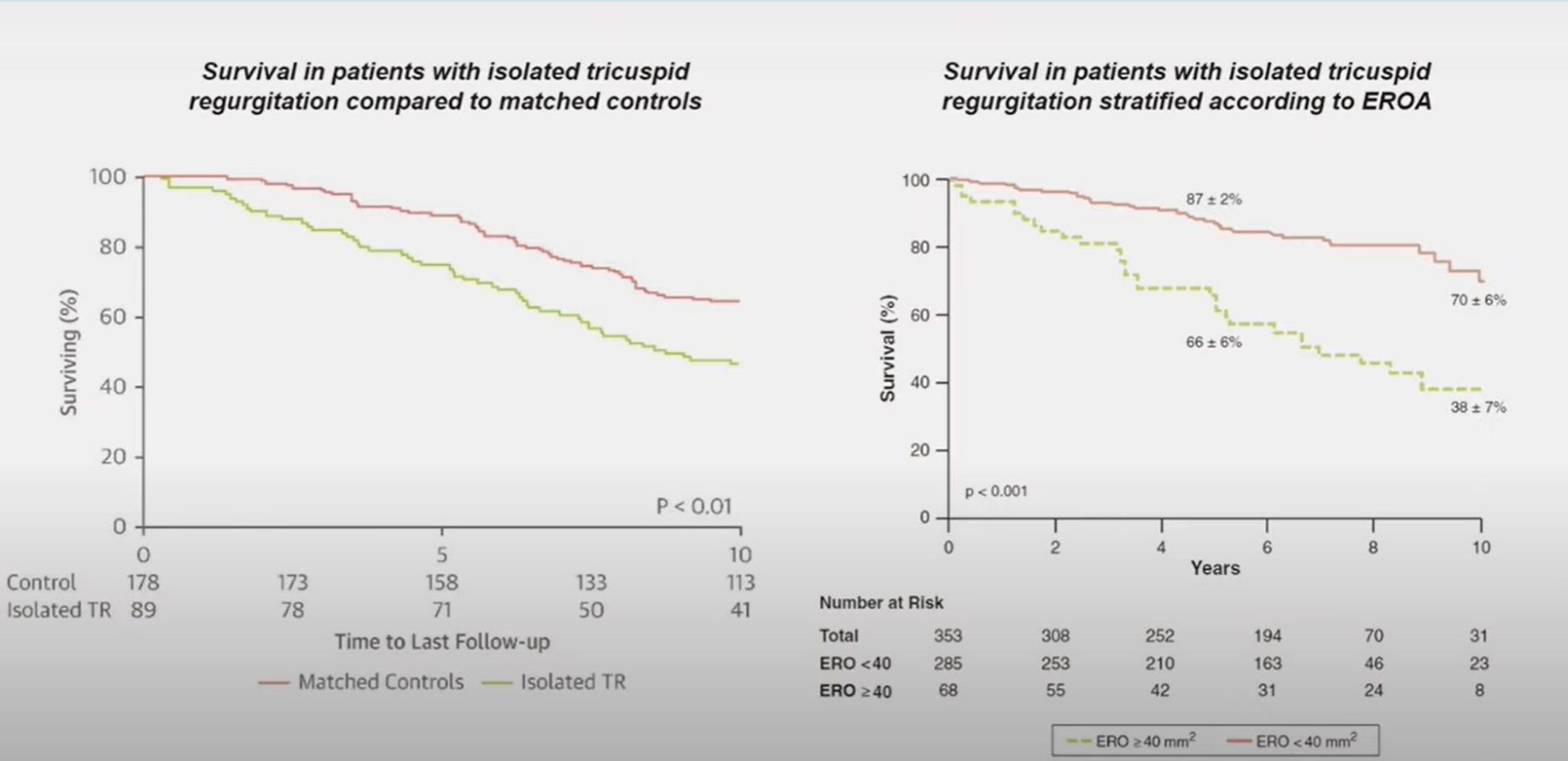
Dr. Marcelo Agüero
Instituto de Cardiología de Corrientes



JORNADAS CIENTÍFICAS Y GREMIALES CACI 2021
4 Y 5 DE DICIEMBRE 2021 . HOTEL HILTON - PRESENCIAL



Historia natural de la Ins. Tricuspídea



JORNADAS CIENTÍFICAS Y GREMIALES CACI 2021
 4 Y 5 DE DICIEMBRE 2021 . HOTEL HILTON - PRESENCIAL



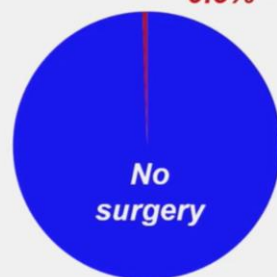
Baja accesibilidad al tratamiento correctivo



Patients with severe tricuspid regurgitation

Stuge O et al. *J Thorac Cardio Surg* 2006

N=1,600,000



Tricuspid surgery

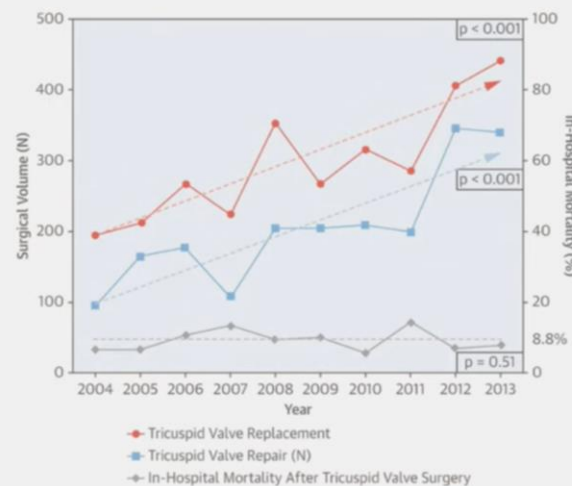
Patients referred for heart valve surgery

Scully et al. *J Thorac Cardiovasc Surg* 1995

N=4,741



Resultados de la cirugía



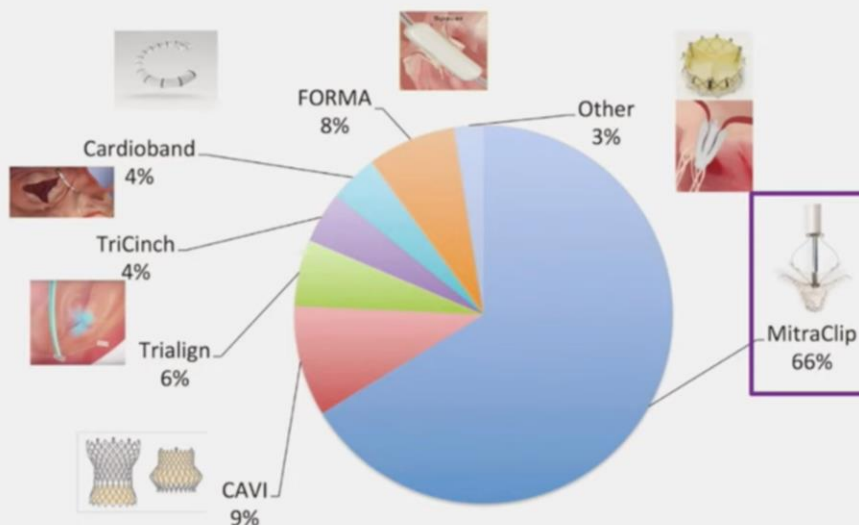
JORNADAS CIENTÍFICAS Y GREMIALES CACI 2021
4 Y 5 DE DICIEMBRE 2021 . HOTEL HILTON - PRESENCIAL

Tratamiento endovascular de la IT

THE INTERNATIONAL MULTICENTER TRIVALVE REGISTRY

Taramasso et al JACC Cardiovasc Interv 2019;12(2):155-165

- **312 high-risk patients:**
 - 76 ± 8.6 years of age
 - 55% women
 - EuroSCORE II: $9 \pm 8\%$
- 95% NYHA class III to IV
- Functional TR in 93%
- Mean tricuspid annulus: 46.9 ± 9 mm



JORNADAS CIENTÍFICAS Y GREMIALES CACI 2021

4 Y 5 DE DICIEMBRE 2021 . HOTEL HILTON - PRESENCIAL



TRICLIP: UNIQUELY DESIGNED FOR THE RIGHT HEART

Multi-axis steering enables movement across all lines of coaptation

F/E Knob

S/L Knob

Knob configuration allows height above valve

High support delivery system

+/- Knob

Delivery system curves anatomically designed for direct access to the tricuspid valve

Two Sizes for Patient Specific Therapy Options

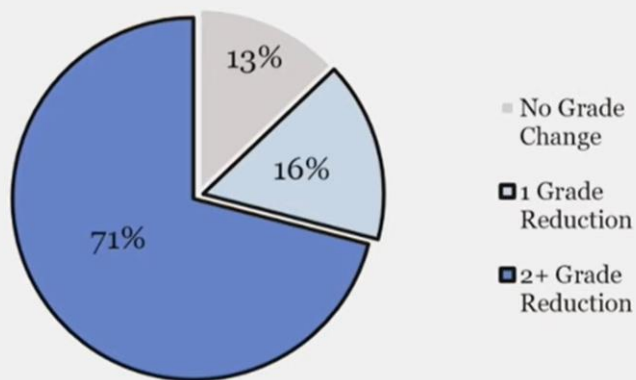


JORNADAS CIENTÍFICAS Y GREMIALES CACI 2021
4 Y 5 DE DICIEMBRE 2021 . HOTEL HILTON - PRESENCIAL



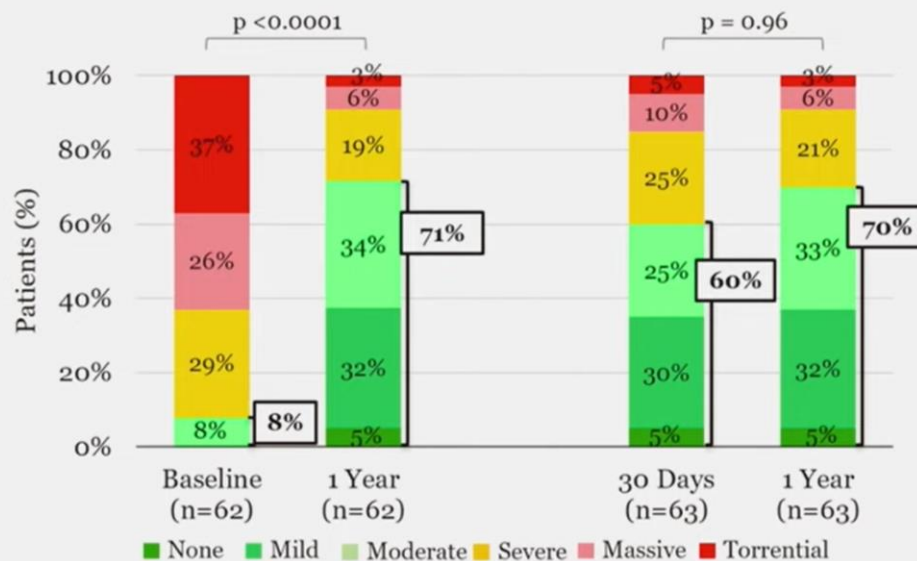
TRILUMINATE. SUSTAINED TR REDUCTION

TR Reduction Sustained
at 1 Year (n=62)



87.1% showed at least 1 grade improvement at 1 Year

70% Moderate or Less at 1Y



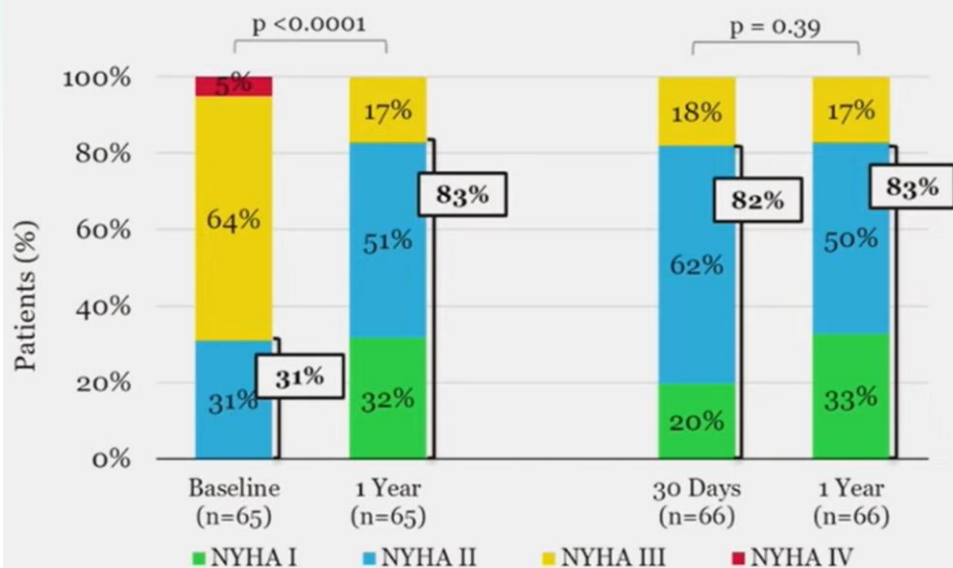
JORNADAS CIENTÍFICAS Y GREMIALES CACI 2021

4 Y 5 DE DICIEMBRE 2021 . HOTEL HILTON - PRESENCIAL

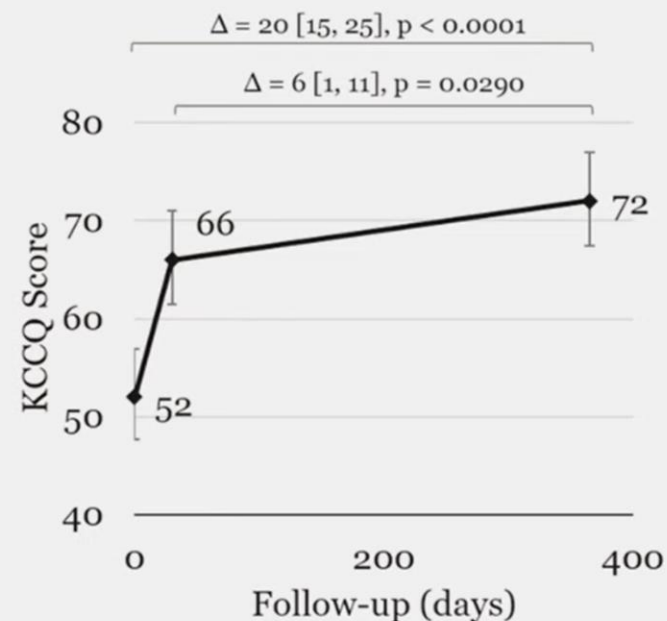


TRILUMINATE. CONTINUED CLINICAL IMPROVEMENTS

Sustained Symptomatic Improvement



Continued KCCQ Improvement



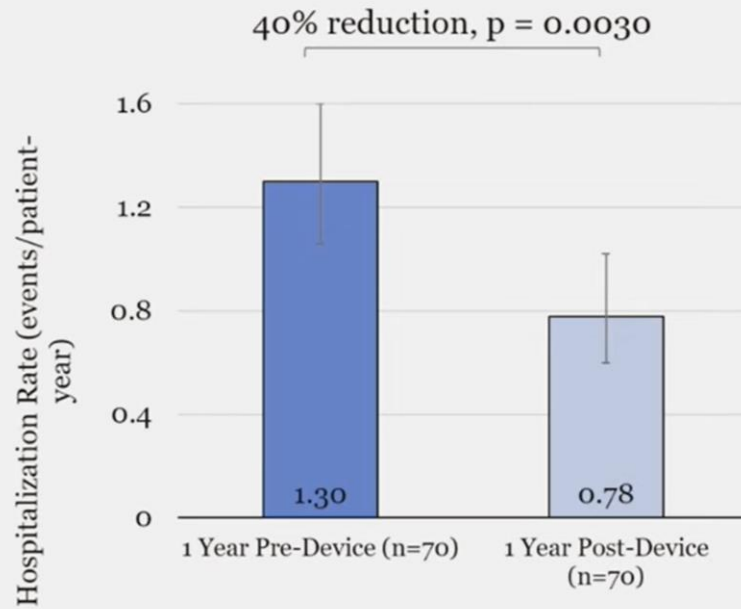
JORNADAS CIENTÍFICAS Y GREMIALES CACI 2021

4 Y 5 DE DICIEMBRE 2021 . HOTEL HILTON - PRESENCIAL

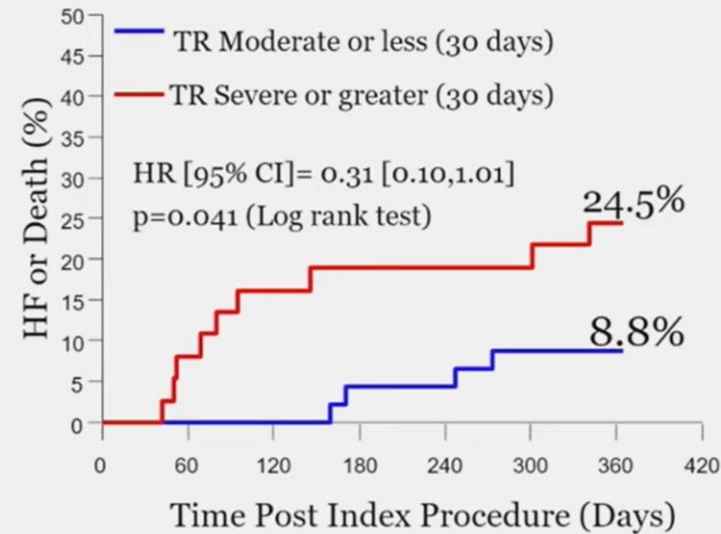


TRILUMINATE. REDUCED HOSPITALIZATIONS

Reduced Hospitalization Rate



Procedural Success Predictive of Mortality and Heart Failure Hospitalizations at 1Y



JORNADAS CIENTÍFICAS Y GREMIALES CACI 2021

4 Y 5 DE DICIEMBRE 2021 . HOTEL HILTON - PRESENCIAL



SELECTION ASSISTANCE FOR TRICLIP

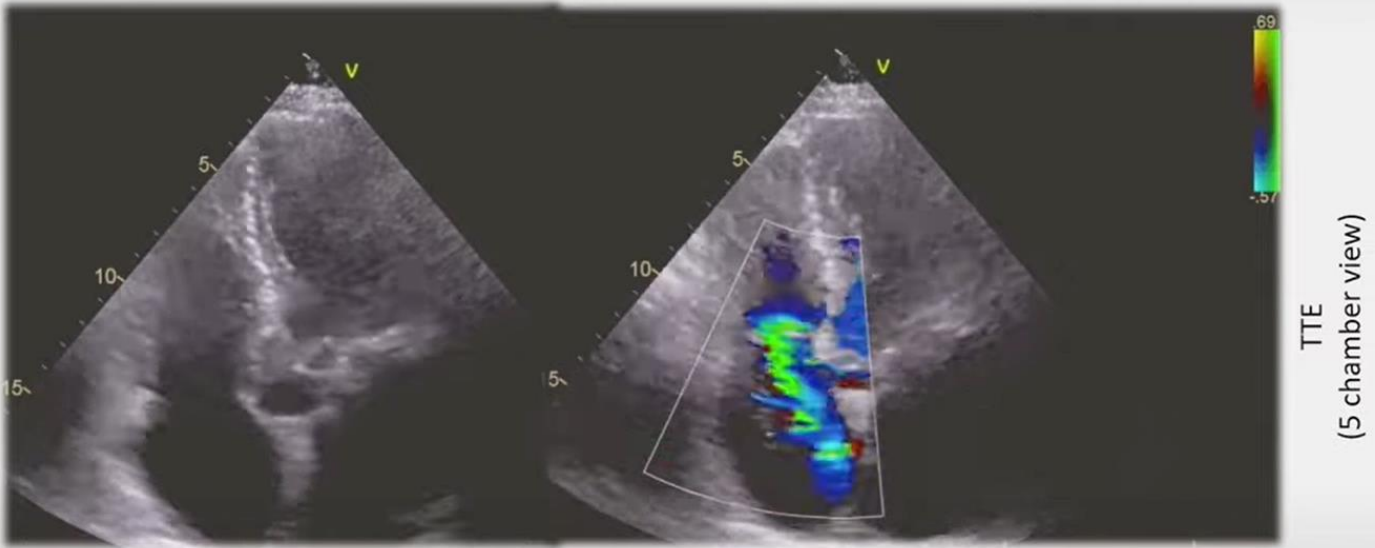
Ideal for edge-to-edge repair	Edge-to-edge repair to be considered	Edge-to-edge repair not recommended or only in exceptional cases
Secondary TR with structurally normal leaflets	Secondary TR with normal leaflets or primary TR with leaflet prolapse	Severe leaflet (rheumatic) thickening or shortening or destruction or very large leaflet prolapse
Severe TR based on the 5 grade scale	Massive TR based on the 5 grade scale	Torrential TR based on the 5 grade scale
Good transesophageal & transgastric echocardiographic windows	Sufficient transesophageal & transgastric echocardiographic windows	Insufficient echocardiographic windows
Coaptation defect < 3 – 4 mm measured at the location of planned Clip placement and good leaflet mobility	Coaptation defect 4 – 7 mm measured at the location of planned Clip placement, reduced leaflet mobility	Coaptation defect 7 mm measured at the location of planned Clip placement or/and severe leaflet tethering
Central TR jet extending in the antero-septal commissure	Central TR jet extending in the postero-septal or antero-posterior commissure	Non-central or very eccentric jets or jets originating from antero-posterior commissure
No PM/ICD lead	Presence of PM/ICD lead, no significant leaflet interaction and no potential interaction with clip	PM/ICD lead-induced TR
Normal to moderately reduced RV function, normal to moderate RV/annular dimension	Moderately reduced RV function, moderate RV/annular dilatation	Severely reduced RV function or severe RV/annular dilatation
No pulmonary hypertension	Post-capillary pulmonary hypertension	Pre-capillary pulmonary hypertension



technology you know and trust, designed for the tricuspid valve - PCR e-...

FAVORABLE CANDIDATE

Ver más tarde Compart



sPAP: 35mmHg
mPAP: 22mmHg
PCWP: 15mmHg
TAPSE: 25 mm
Vena cava inferior: 2,6 cm

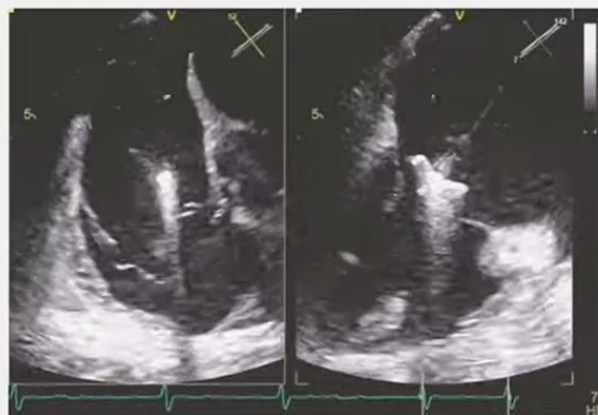
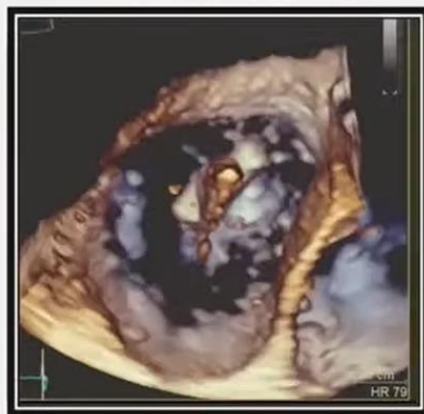
RA area: 40cm²
PISA: 11 mm
Vena contracta: 10 mm
EROA: 0.61cm²
Regurgitation volume: 55ml/beat
sPAP 42 mmHg



JORNADAS CIENTÍFICAS Y GREMIALES CACI 2021
4 Y 5 DE DICIEMBRE 2021 . HOTEL HILTON - PRESENCIAL



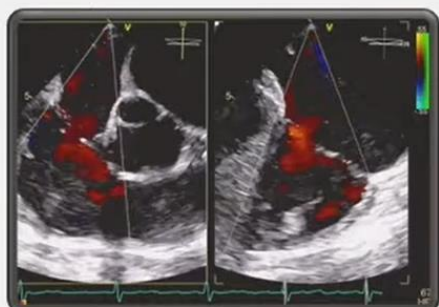
CLIP POSITIONING



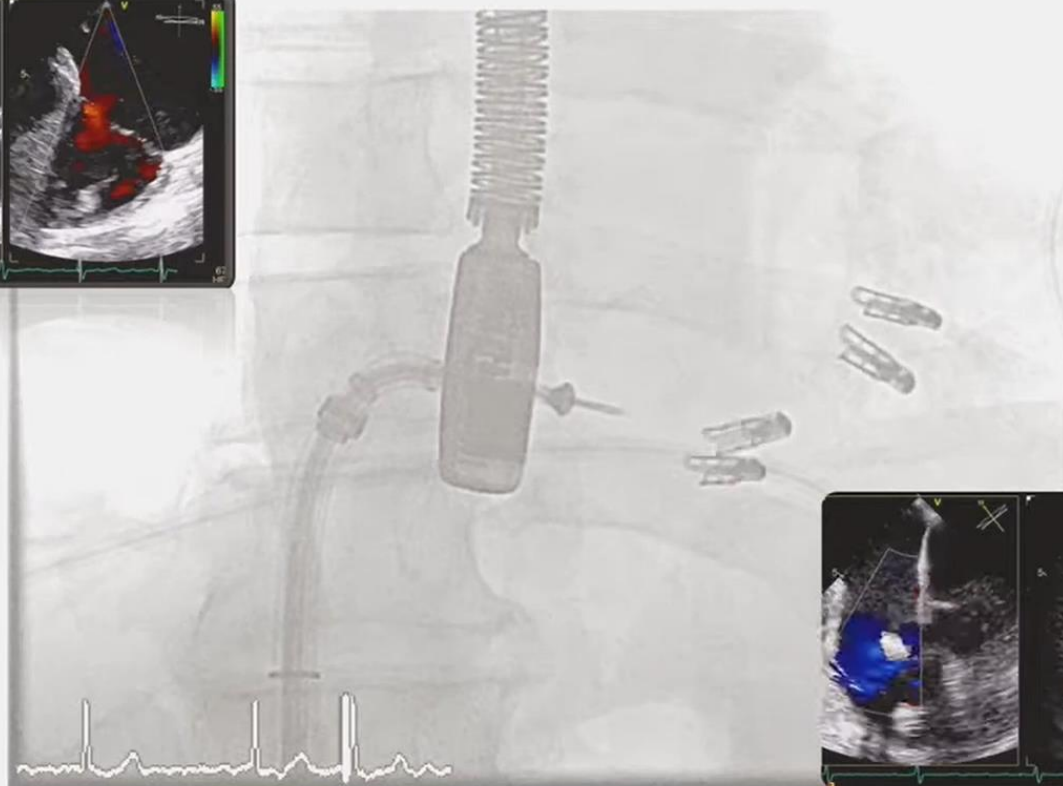
JORNADAS CIENTÍFICAS Y GREMIALES CACI 2021
4 Y 5 DE DICIEMBRE 2021 . HOTEL HILTON - PRESENCIAL



FINAL RESULT



Pre



Post

