

Global Insights from the TRICUS Registry

*Real-World Outcomes with TricValve
Bi-Caval Valve Therapy for Tricuspid
Regurgitation*

Philipp Nikolai , MD



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Disclosure of Relevant Financial Relationships

Within the prior 24 months, I have had a financial relationship with a company producing, marketing, selling, re-selling, or distributing healthcare products used by or on patients:

Nature of Financial Relationship

Consultant

Research Contract

Ineligible Company

Abbott, Bristol-Myers Squibb, Edwards
Lifesciences, P&F Products & Features GmbH,
Philips

Abbott

Unmet Clinical Need



P&F PRODUCTS & FEATURES

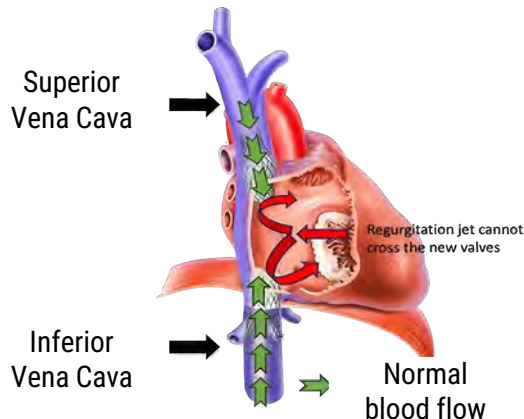
Intended Use

The TricValve® Transcatheter Bicaval Valve System is indicated for patients with symptomatic severe tricuspid regurgitation (hemodynamically relevant) and caval reflux, at high risk for open surgical therapy.

CE Marked since 2021 and commercially available outside the US

Breakthrough device designation

As the device enters pivotal U.S. trials, long-term clinical data are critical to guide its future role in treatment algorithms



TricValve Model	Valve size (mm)
SVC 25	25
SVC 29	29
IVC 31	31
IVC 35	35

✓	Prior tricuspid interventions or surgery
✓	Existing pacemakers or defibrillator leads
✓	TTE guidance for IVC (Fluoro for SVC deployment)
✓	100% agnostic to tricuspid anatomy
✓	TricValve can be done under conscious sedation
✓	Easier imaging requirements
✓	Minimal to zero HALT in global experience, under standard OAC conditions) Low rate of thrombosis

TRICUS Registry: European post market study



P&F PRODUCTS & FEATURES

Objective

The objective of this study is to monitor the mid- and long-term safety of the TricValve® in a real-world setting

Patients and sites

Target # of patients: 450 patients

Target # of sites: 100 sites

Data shown: **107 patients at 36 sites** in Europe

Endpoints

Primary endpoint

- First unplanned heart failure hospitalization (HFH) at 12 months

Secondary endpoints

- All-cause mortality,
- Serious adverse events (SAEs),
- NYHA class, functional capacity
- Device-related complications up to 5 years

	Procedure N =107	30 days N=102	3M N=96	6M N=89	1Y N=80	2Y N=58	3Y N=41	4Y N=33	5Y N=12
N. of pts with completed visit	107 (100%)	76 (75%)	71 (74%)	64 (72%)	72 (90%)	34 (59%)	16 (39%)	10 (30%)	3 (25%)
N. of pts with missed visit	26 (25%)	25 (26%)	25 (28%)	8 (10%)	24 (75%)	25 (41%)	61 (75%)	23 (70%)	9 (75%)

Medical History



P&F PRODUCTS & FEATURES

Baseline Medical History	N. Patients	% Patients
Medical Condition		
Tricuspid regurgitation	107	100.0%
Tricuspid regurgitation (primary/organic)	16	15.0%
Tricuspid regurgitation (secondary/functional)	91	85.0%
Comorbidities		
Atrial Fibrillation	96	89.7%
Arterial Hypertension	77	72.0%
Chronic Renal Failure	39	36.4%
Diabetes Mellitus	18	16.8%
Significant coronary heart disease (>75% stenosis)	14	13.1%
Chronic Obstructive Lung Disease	13	12.1%
Prior Stroke	10	9.3%
Prior Myocardial Infarction	7	6.5%
Peripheral Vascular Disease	4	3.7%
Other	67	62.6%
Surgeries / Medical Procedures		
Pacemaker implantation	23	21.5%

TRICUS Registry - Baseline Characteristics



P&F PRODUCTS & FEATURES

Parameter (N = 107 patients)	Mean $\pm$ SD or n (%)
Age	77.9 $\pm$ 6.0
Female	72%
Male	28%
Height (cm)	162.1 $\pm$ 8.9
Weight (kg)	68.6 $\pm$ 14.4
BMI (kg/m ²)	26.1 $\pm$ 5.2
EuroScore II	5.4 $\pm$ 4.1
NYHA Class I	0 (0%)
NYHA Class II	20 (20%)
NYHA Class III	69 (70%)
NYHA Class IV	9 (9%)
KCCQ-12	40.5 $\pm$ 21.1
6MWT (m)	230.9 $\pm$ 95.5

Major Adverse Events (MAE)



P&F PRODUCTS & FEATURES

MAEs in TRICUS registry, cumulative over time (N=107)

MAE	Causality	N (%)							
		30 D	3 M	6 M	1 Y	2 Y	3 Y	4 Y	5 Y
Death	Related	2 (2%)	3 (3%)	3 (3%)	3 (3%)**	4 (4%)	4 (4%)	4 (4%)	4 (4%)
	Unrelated	3 (3%)	5 (5%)	6 (6%)	9 (8%)*	12 (11%)	13 (12%)	15 (14%)	16 (15%)
	All-cause	5 (5%)	8 (7%)	9 (8%)	12 (11%)	16 (15%)	20*** (19%)	22*** (21%)	25*** (23%)
Stroke	Related	1 (1%)	1 (1%)	1 (1%)	1 (1%)	1 (1%)	1 (1%)	1 (1%)	1 (1%)
	Unrelated	0 (0%)	1 (1%)	2 (2%)	3 (3%)	3 (3%)	3 (3%)	3 (3%)	3 (3%)
	All-cause	1 (1%)	2 (2%)	3 (3%)	4 (4%)	4 (4%)	4 (4%)	4 (4%)	4 (4%)
Major Bleeding	Related	3 (3%)	3 (3%)	3 (3%)	3 (3%)**	3 (3%)	3 (3%)	3 (3%)	3 (3%)
	Unrelated	0 (0%)	1 (1%)	3 (3%)	3 (3%)*	4 (4%)	5 (5%)	5 (5%)	5 (5%)
	All-cause	3 (3%)	4 (4%)	6 (6%)	6 (6%)	7 (7%)	8 (7%)	8 (7%)	8 (7%)
Cardiac Surgery	Related	0	0	0	0	0	0	0	0
Cardiac Tamponade	All-cause	0	0	0	0	0	0	0	0
Myocardial Infarction	All-cause	0	0	0	0	0	0	0	0
Total (related)		6 (6%)	7 (7%)	7 (7%)	7 (7%)**	8 (7%)	8 (7%)	8 (7%)	8 (7%)
Total (unrelated)		3 (3%)	7 (7%)	11 (10%)	15 (14%)*	19 (18%)	21 (20%)	23 (21%)	24 (22%)
Total (All-cause)		9 (8%)	14 (13%)	18 (17%)	22 (21%)	27 (25%)	32* (30%)	34* (32%)	37* (35%)

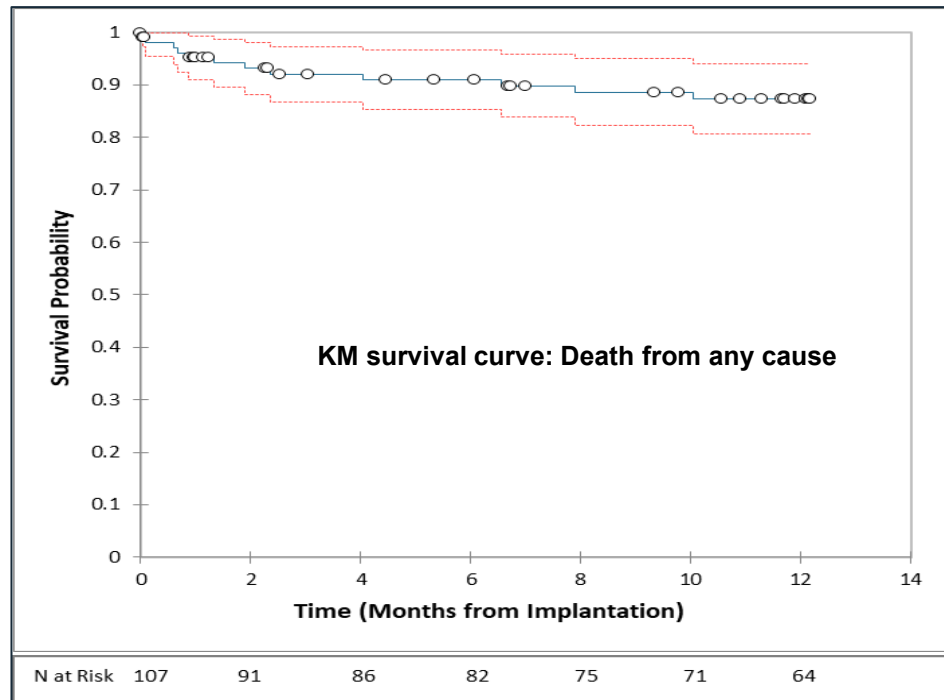
MAE profile of TricValve® supports the clinical acceptability of the safety risk in this surgically inoperable population.

Extremely low (< 1%) onset of new pacemaker due to TricValve® Implantation

All-Cause Mortality



P&F PRODUCTS & FEATURES



All cause
mortality at 1
year,
N = 107

11.2%

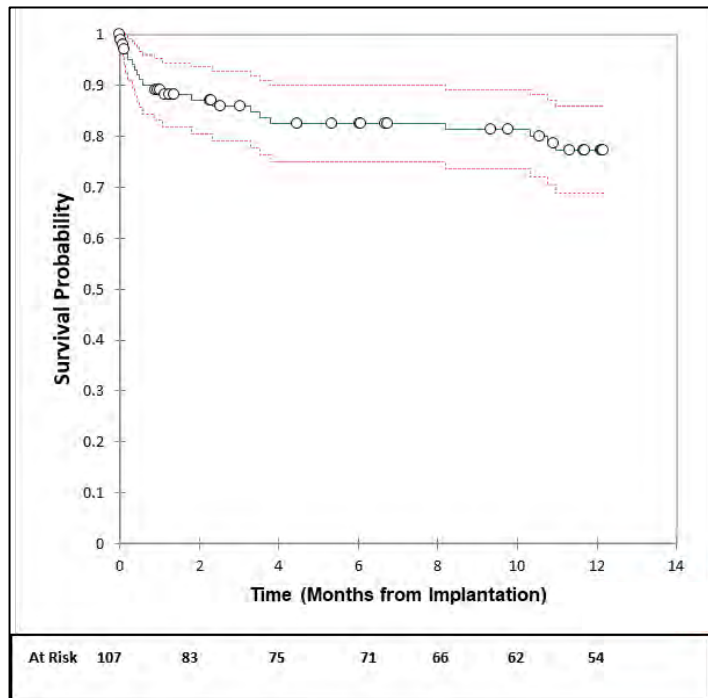
1-year survival rate is particularly notable when considering the high baseline mortality risk typically associated with this patient population

Heart Failure Hospitalizations



P&F PRODUCTS & FEATURES

Kaplan–Meier survival curve – First Heart Failure Hospitalization



Freedom from
HFH
at 1 year
80%

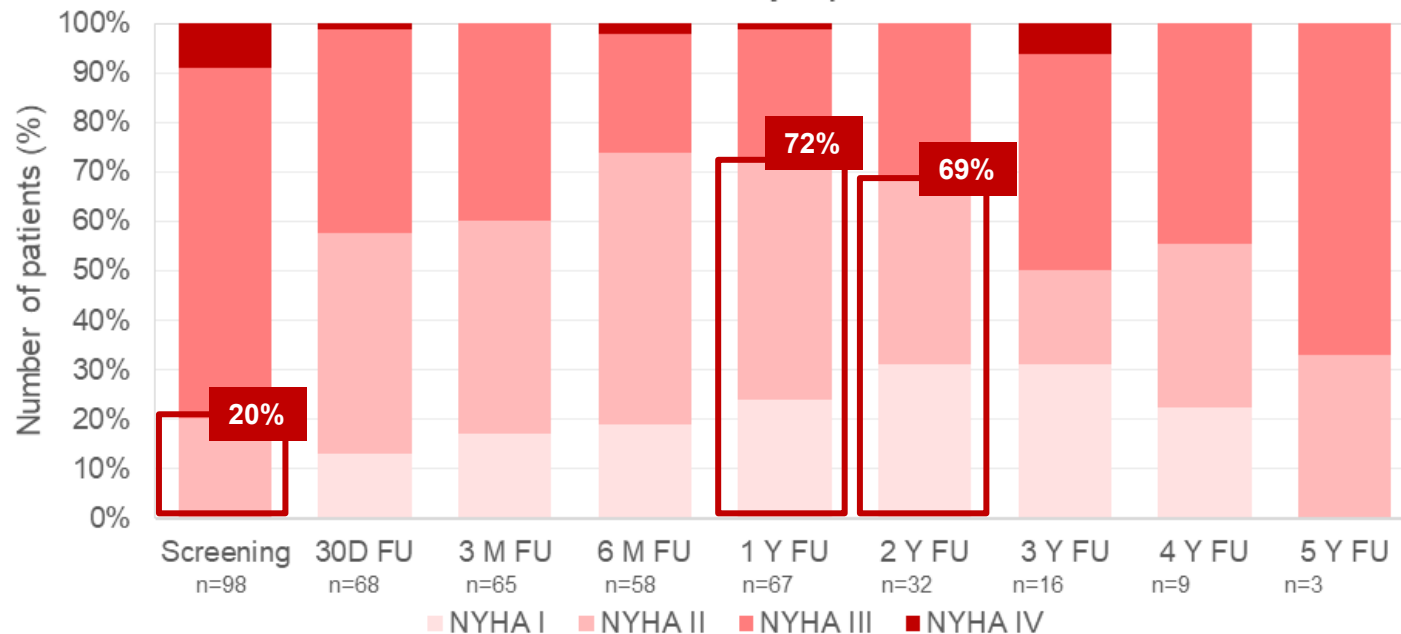
First Heart Failure Hospitalization during follow up

	30 days N (%)	3 months N (%)	6 months N (%)	1 year N (%)	2 years N (%)	3 years N (%)	4 years N (%)	5 years N (%)
N. of patients	102	96	89	80	58	41	33	12
N. of first HFH	11 (11%)	3 (3%)	3 (3%)	4 (5%)	2 (3.5%)	1 (2%)	0	1 (8%)
Related	1 (1%)	0	0	0	0	0	0	0
Unrelated	10 (10%)	3 (3%)	3 (3%)	4 (5%)	2 (3.5%)	1 (2%)	0	1 (8%)



P&F PRODUCTS & FEATURES

NYHA Class



72%

NYHA Class I
or II at 12
Months

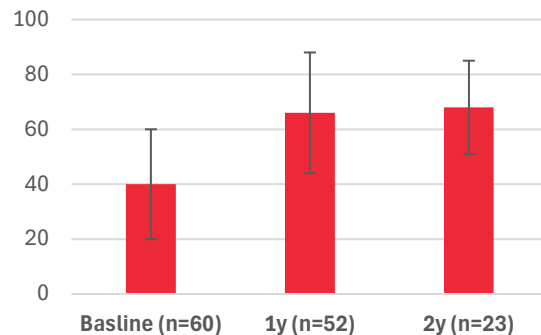
69%

NYHA Class I
or II at 24
Months



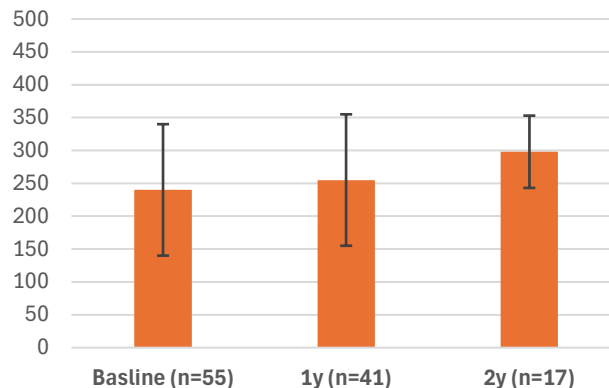
Quality of life improvements

KCCQ Score



54%
KCCQ Score
increase at
12 Months

6MW Distance



15%
6MW
Distance
increase at
12 Months



Conclusions

- TRICUS Registry represents the **post market dataset** to date for the TricValve® system
- The interim results confirm the **safety and durable clinical benefit** in a high-risk, comorbid patient population
- This global, real-world experience offers essential insights into patient selection and long-term performance, especially for US pivotal trials

A Novel Strategy Targeting Caval Reflux to Alleviate Right Heart Failure in Severe Tricuspid Regurgitation

*Early Outcomes from TRICAV-1:
A Multicenter US Feasibility Study*

Rishi Puri MD, PhD, FRACP



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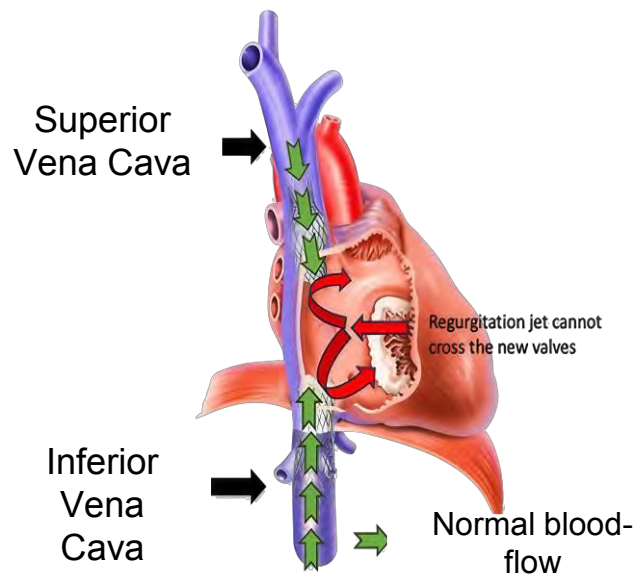
Ineligible Company

Centerline Biomedical, Medtronic, Abbott, P&F, VDYne, VahatiCor, AdvNanoT, NuevoSono, Alleviant Medical, Protembis, GE Healthcare, Pi-Cardia, AngioWave, T45 Labs, HRT, Anteris, Nyra Medical, Synkopi

Equity

Centerline Biomedical, VahatiCor, NuevoSono, Synkopi, T45 Labs

TricValve CAVI: A physiological approach to severe TR



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SVC 25	25
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✓	TTE guidance for IVC (Fluoro for SVC deployment)
✓	100% agnostic to tricuspid anatomy, all future TV options open
✓	Conscious sedation
✓	Easier imaging requirements
✓	- Minimal to zero HALT in global experience, under standard OAC conditions) - Low rate of thrombosis

TricValve Enables Systemic & Clinical Improvement While Maintaining All Future Options

Severe TR + RHF



TricValve
→

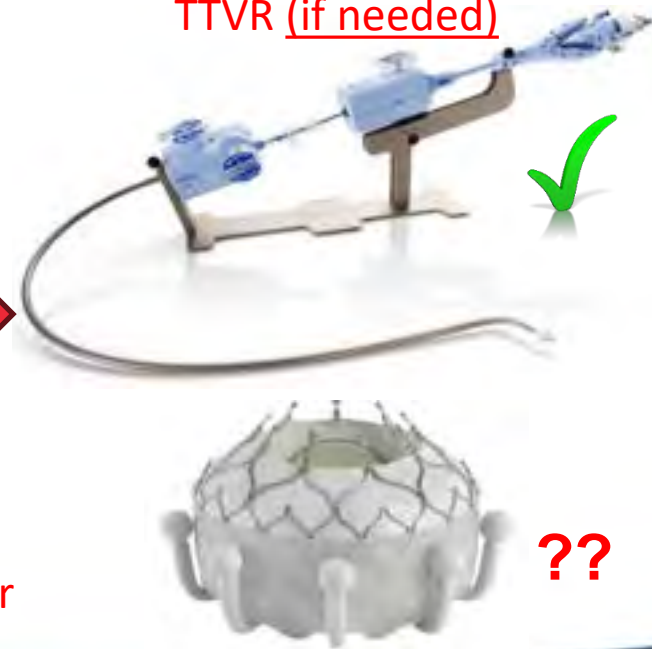
↑KCCQ,
↓decongestion, ↑CO



Reverse RV remodeling, ↓ TV annular size, reduced coaptation gap

→

Optimized T-TEER or
TTVR (if needed)



TRICAV-1: Alleviating Caval Reflux in RHF

Indication for Use

Patients with hemodynamically relevant tricuspid insufficiency and caval reflux, who are at extreme risk or inoperable for open surgical therapy.



TRICAV-I



TRICAV-II

Compassionate Use

- © 31 patients treated in the US
- © Not eligible for clip or replacement or surgery

TRICAV-I EFS

- © Largest Heterotopic Replacement trial for TR to date
- © Up to 80 patients
- © 50 US sites
- © Treated 53 patients

© This Presentation

TRICAV-II

- © Randomized vs OMT (2:1)
- © 430 randomized pts
- © 60 US sites
- © Includes 200 pts Registry
- © Crossover at 12 months

© In Discussion with FDA

TRICAV-1 US SITES (N=50)

■ Enrolling(26) ■ Upcoming (24)

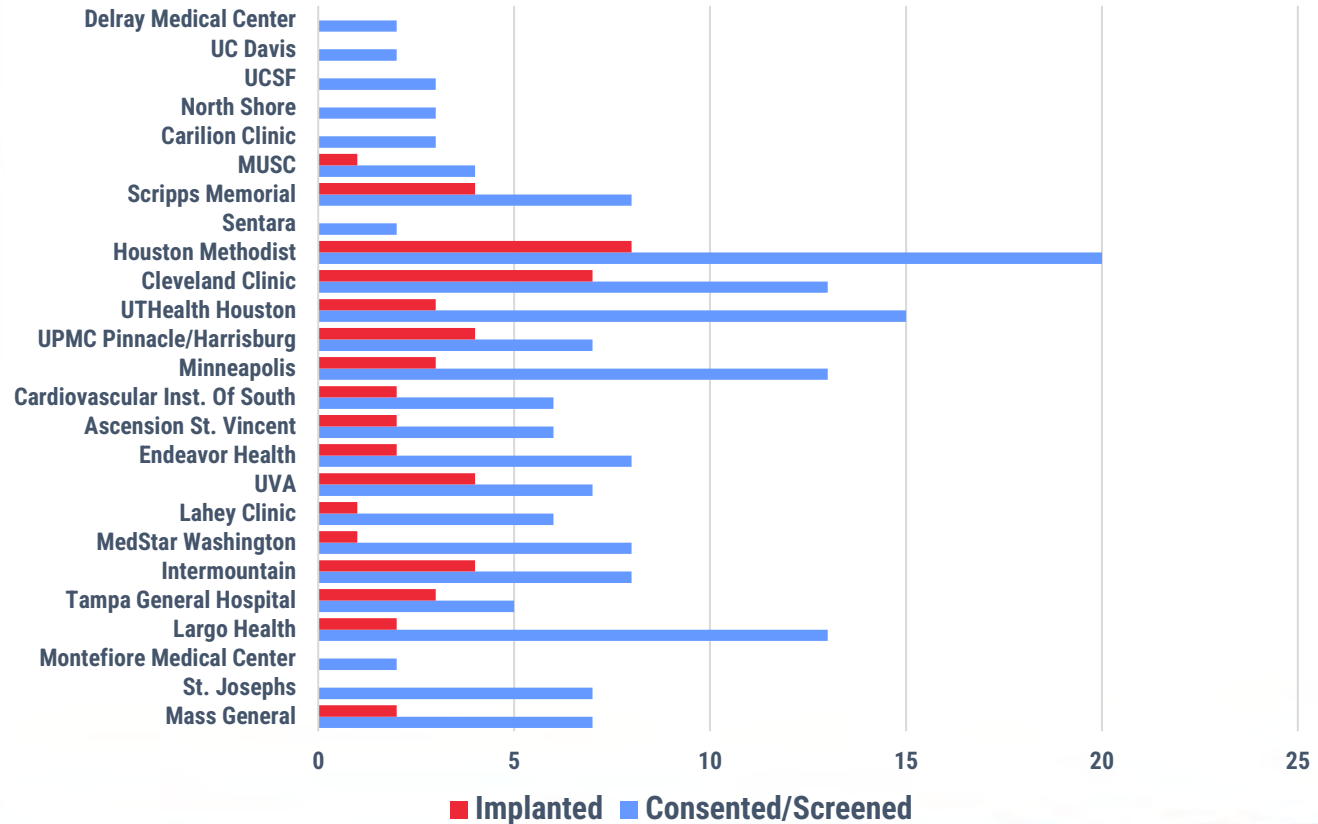


TRICAV-1 Site Enrollment

**53 Patients
Implanted with
TricValve**

Top Implanting Sites

Houston Methodist:	8
Cleveland Clinic:	7
Scripps Memorial:	4
UVA Health:	4
Intermountain:	4
UMPC Pinnacle:	4



TRICAV-1: Endpoints

Primary Endpoints



Safety at 30 Days:

Major Adverse Events (MAEs) related to Device- and/or Procedure as adjudicated by the Clinical Event Committee (CEC).

MAEs include:

- Cardiovascular Death
- Q-wave myocardial infarction (MI)
- Disabling stroke
- Life threatening bleeding
- Pulmonary embolism
- Renal failure requiring dialysis
- Major access-site and vascular complications
- Major cardiac structural complications
- Permanent pacemaker implantation
- Any valve-related dysfunction, migration, thrombosis
- Unplanned intervention performed to correct device/valve dysfunction/failure

Note: All definitions are based on TVARC guidelines (JACC 2023)



Clinical Efficacy at 30 Days:

- Adequate TricValve function assessed by Imaging Core Laboratory
- Improvement in quality-of-life Kansas City Cardiomyopathy Questionnaire
- Improvement in New York Heart Association (NYHA) functional class
- Improvement in six-minute walk test (6MWT)

Secondary Endpoints



Safety (at 12 months): The percentage of subjects with Device- and/or Procedure-related MAEs through 1 year, as classified by the CEC.



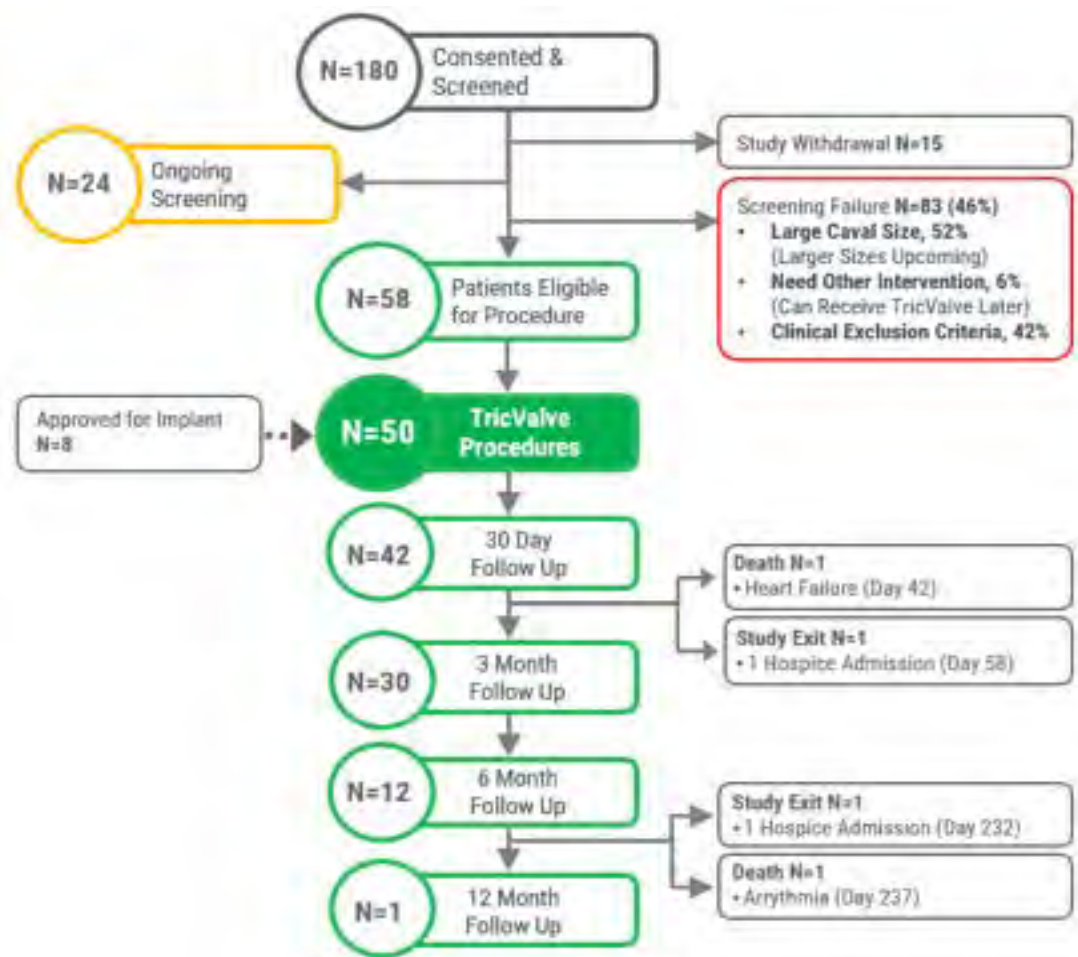
Clinical Efficacy (measured at 3 months, 6 months and 1 year):

- All-Cause mortality and Cardiovascular Mortality
- Changes in RV dimensions, volumes and indexes of RV dysfunction
- Heart failure hospitalization (HFH)
- RVAD implantation or heart transplant
- Changes in QoL (≥ 10 points by KCCQ overall summary score).
- Changes in symptom status (Reduction of at least 1 NYHA class).
- Changes in functional capacity (6MWT, with distance ≥ 30 m).

TRICAV-1

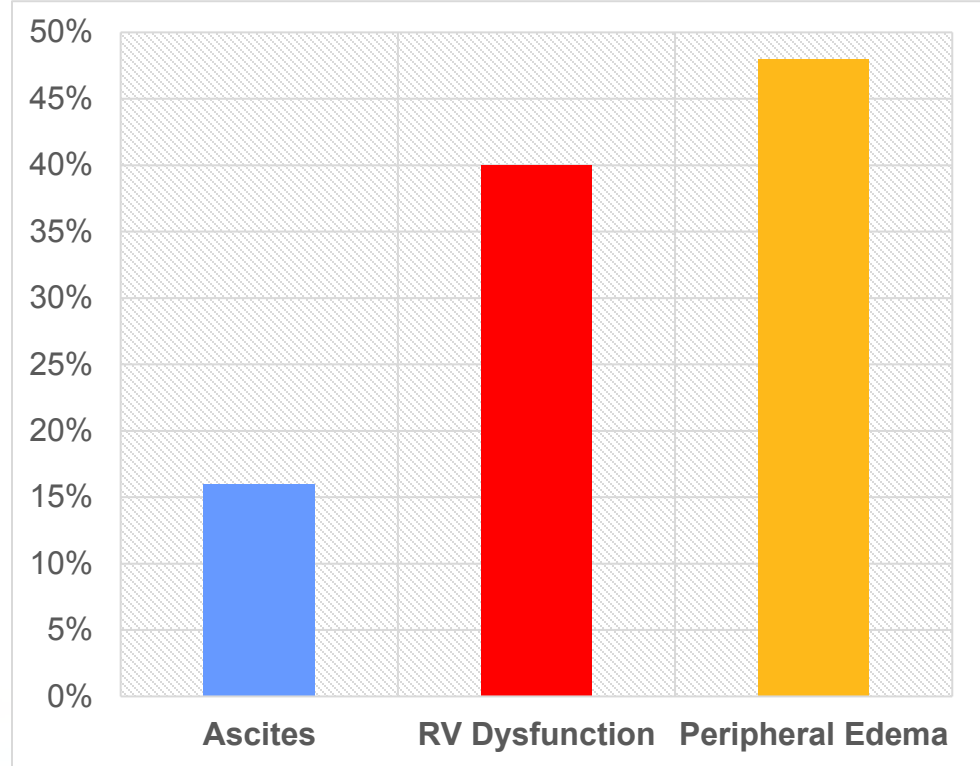
Study Progress

Screen failure rate is driven by lack of a larger IVC size and clinical exclusion criteria



TRICAV-1: Baseline Data

Baseline characteristics	
Age (years)	79.6 ± 8.0
Female	38%
Male	62%
NYHA (%)	IV (2%); III (98%)
Euro Score II	6.00 ± 4.56
TRI-Score	4.6 ± 1.6
TR etiology (%)	FTR (80%); DTR (20%)
Atrial Fibrillation	92%
Cancer History	36%
Coronary Artery Disease	48%
Pacemaker/ICD	40%
Prior Tricuspid Intervention	14%
Renal Dysfunction	38%
Laboratory values	
NTproBNP (pg/mL)	2185.9 +/- 2677.2
Creatinine (mg/dL)	1.28 +/- 0.37



TRICAV-1: Procedural Results in 50 Patients

Variables	TricValve Procedural Outcomes
Procedures Time Skin-to-Skin (min)	87.8 +/-34.0
Successful deployment and correct positioning of TricValve valves	96%*
Successful access, delivery, and retrieval of TricValve delivery system	98.0%
No emergency surgery or reintervention	0%
No procedural mortality	0%



**1 Valve in Valve for PVL; 1 Tortuosity preventing IVC deployment*

TRICAV-1: 30-Day Echo data

Echo Parameters	Baseline [Mean±SD]	30-Days [Mean±SD]
LVEF (%)	55.9 ± 8.6	57.0 ± 8.4
PASP (mmHg)	33.1 ± 12.2	31.4 ± 10.6
RV TAPSE (mm)	18.2 ± 4.4	16.9 ± 4.3
RV Free Wall Strain (%)	-22.7 ± 5.2	-21.1 ± 6.4
RV Fractional Area Change (%)	35.0 ± 8.0	34.6 ± 8.7
Caval Reflux Severity	Grade 2 (2%) (n=1) Grade 3 (90%) (n=45)	Grade 1 (57%)* Grade 2 (22%)* Grade 3 (2%)

**Echo data being collected & analyzed: some data is not available yet.*

IVC Caval Reflux by color Doppler Ultrasonography

- Grade 1: no-reflux or <1 cm
- Grade 2: <3 cm
- Grade 3: >3cm



TRICAV-1: MAEs at 30 Days

	N (%)
Life Threatening Bleeding	1 (2.1%)
Major Access-site and Vascular Complications	2 (4.2%)
Valve-in-Valve	2 (4.2%)

NO OCCURENCE OF:

- Cardiovascular Death
- Q-Wave Myocardial Infarction
- Disabling Stroke
- Pulmonary Embolism
- Renal Failure Requiring Dialysis
- Major Cardiac Structural Complications
- Need for Pacemaker Implantation
- Any Valve-related Dysfunction, Migration, Thrombosis

Favorable Safety
Profile At 30 Days
in High-Risk Elderly
Population with
Multiple
Comorbidities

TRICAV-1: Clinical Functional Outcomes

Improvement at Any Follow-Up (30 Days to 6 Months)	Frequency	
	n	%
Improvement of 1 or More Endpoints	35	83.3%
NYHA + KCCQ + 6MWD	9	21.4%
NYHA + KCCQ	10	23.8%
NYHA + 6MWD	4	9.5%
NYHA Only	6	14.3%
KCCQ + 6MWD	1	2.4%
KCCQ Only	5	11.9%

NYHA

Improvement
(≥ 1 Class)

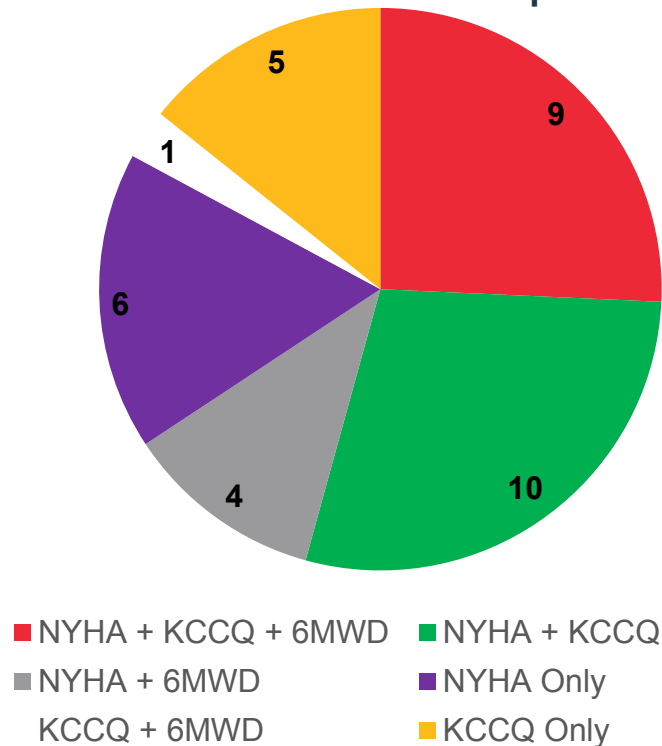
KCCQ

Improvement
(Score ≥ 10 Points)

6MWT

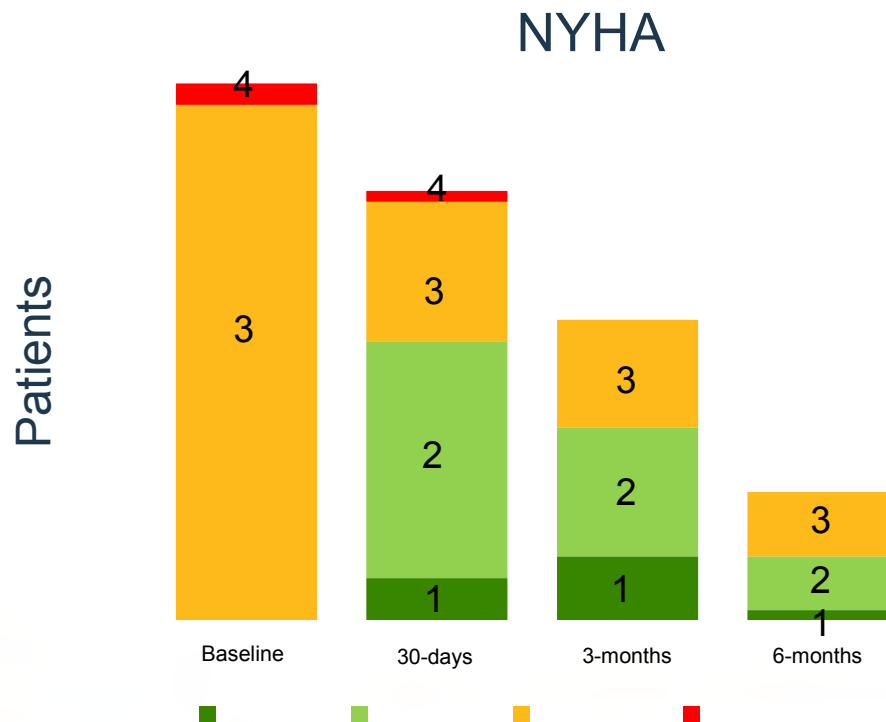
Distance Improvement
(≥ 30 meters)

Composite Assessment of
TricValve Clinical Response



Based on Limited Available Data. Study Follow-Up is Ongoing.

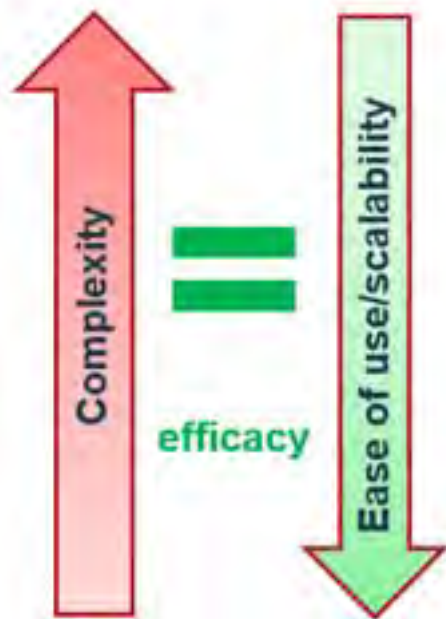
TRICAV-1: 30-Day Functional Status



KCCQ

	Baseline	30 Days	3 Months	6 Months
KCCQ	50.6 ± 19.3 (n=50)	54.4 ± 24.5 (n=44)	60.4 ± 21.6 (n=29)	65.5 ± 22.3 (n=15)
6MWT (mt)	258.1 ± 125.6 (n=50)	244.5 ± 101.5 (n=36)	256.4 ± 97.4 (n=24)	265.8 ± 105.7 (n=14)

TricValve: Bringing CAVI to our suffering 'forgotten majority' US TR patients



T-TEER

- Commercially optimal for **≈40-50% of the severe TR population**
- Anatomical constraints (leaflets, coaptation gaps, leads)
- Imaging constraints
- **Future options ???**

TTVR

- Commercially optimal for **≈40-50% of severe TR population**
- Anatomical constraints (annulus, pacing leads, RV size, IVC angles)
- RV function/PA coupling/RV shock
- Imaging constraints
- Thrombosis/durability, safety, **future options ?????**

CAVI - PRESERVES ALL FUTURE TV OPTIONS (NO RANDOMIZED DATA)

- Commercially applicable to **≈80% at least of severe TR population**
- RV function/PA coupling/RV shock (less than TTVR)

ALL of these therapies cause reverse RV remodeling and improved QoL

Percutaneous treatment for severe tricuspid regurgitation with Tricvalve device

Chilean National Registry (TRV-CHILE)

Alberto Barria , Cardiologist



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Disclosure of Relevant Financial Relationships

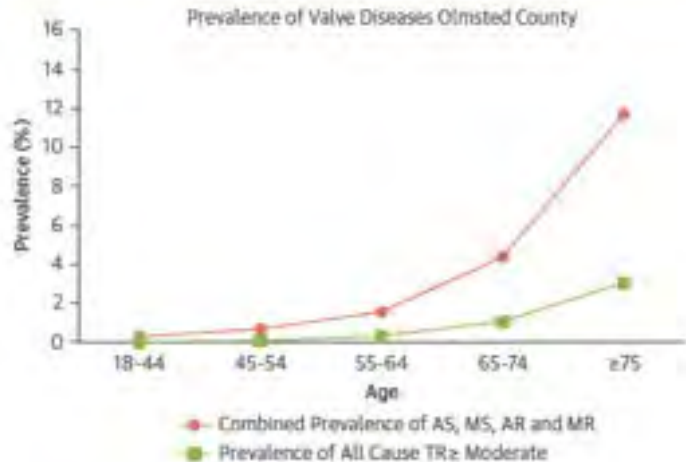
Within the prior 24 months, I have had a financial relationship with a company producing, marketing, selling, re-selling, or distributing healthcare products used by or on patients:

<u>Nature of Financial Relationship</u>	<u>Ineligible Company</u>
Grant/Research Support	CMS Chile
Consultant Fees/Honoraria	-
Individual Stock(s)/Stock Options	-
Royalties/Patent Beneficiary	-
Executive Role/Ownership Interest	-
Other Financial Benefit	-

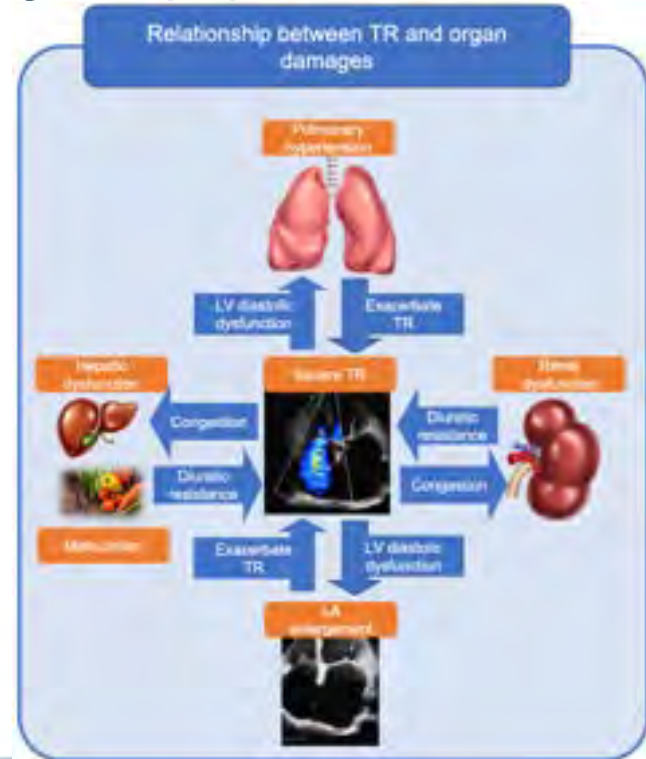
Tricuspid regurgitation: what we know?

- Prevalence depends on the aging of a given population
- Most relevant clinical manifestations

FIGURE 2 Prevalence of TR and Combined Prevalence of All Left Valvular Heart by Age



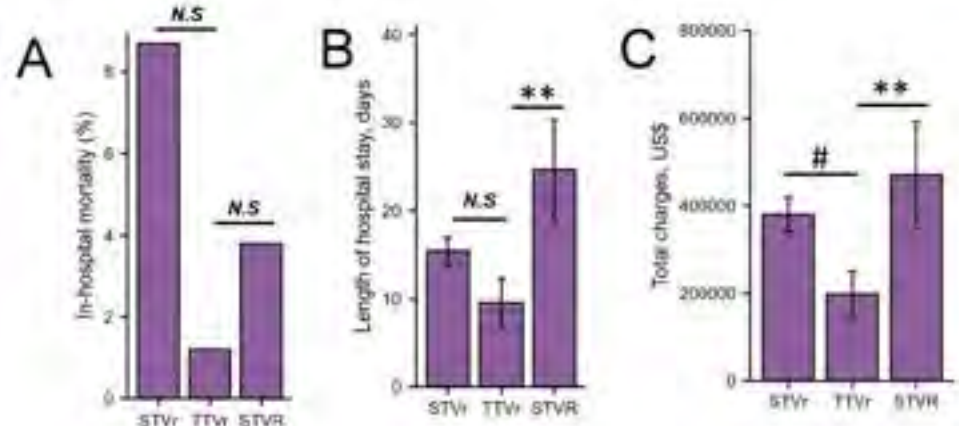
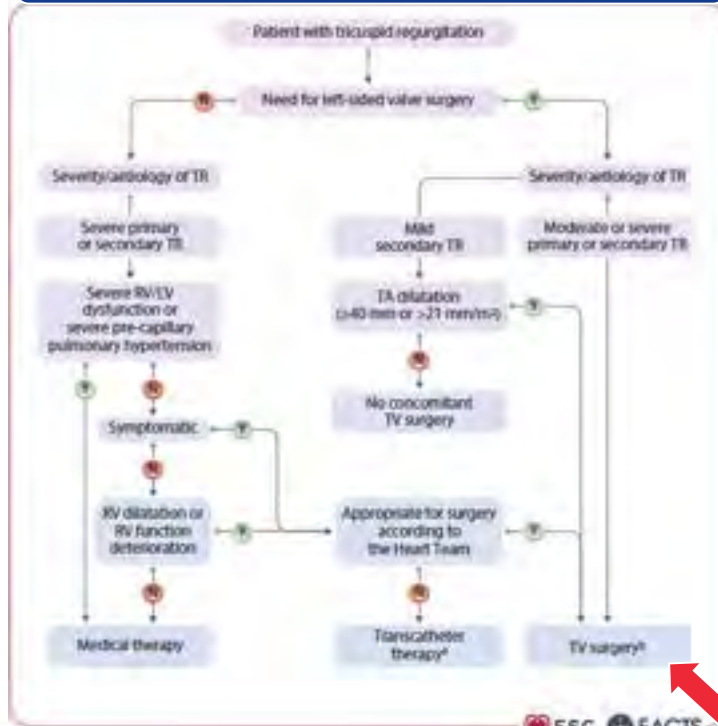
Topilsky Y et al. *J Am Coll Cardiol Img* 2019;12:433–42



Nishiura et al. *J Am Heart Assoc* 2023;12: e025751

Tricuspid regurgitation: what we know?

European Guidelines 2025



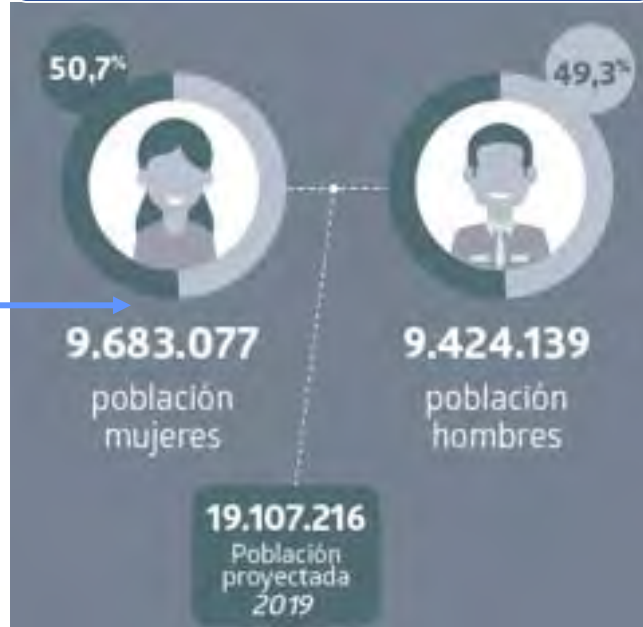
Wang et al. Journal of Cardiothoracic Surgery

(2023) 18:170

Praz et al: European Heart Journal(2025) 00, 1-102

Our population and demographic projections

Chilean demographics measured at 2019



Chilean population pyramid



Chile

*From: Instituto Nacional de Estadísticas de Chile
website*

<https://www.ine.gob.cl/estadisticas/sociales/demografia>

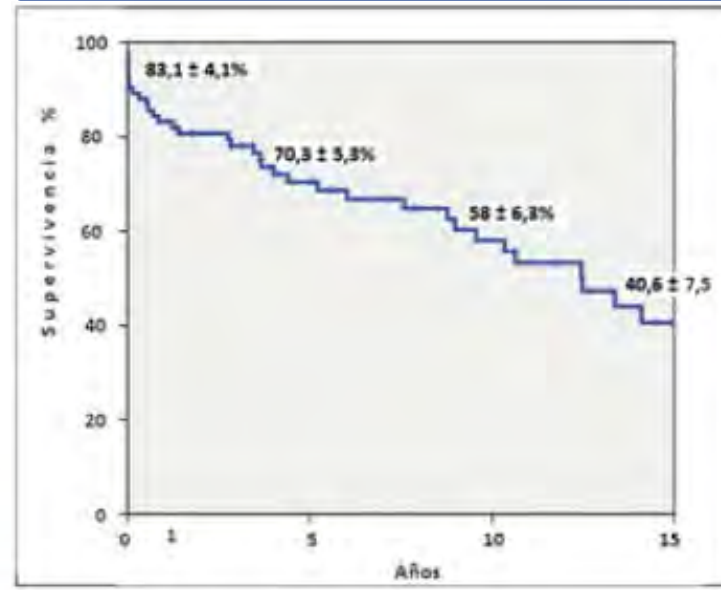
Severe tricuspid regurgitation therapy and local outcomes

- 83 patients
- Tricuspid valve replacement 1991 to 2017

Etiology

Etiología	n	%
Reumática	20	24
Dilatación anillo 2ª patología izquierda	16	19
Malformación de Ebstein	14	17
Endocarditis Infecciosa	8	9,6
Congénita no Ebstein	6	7,2
Carcinóide	5	6
Disfunción prótesis tricúspide	4	4,8
Otras	10	12
Total	83	100

Short & Long term outcomes

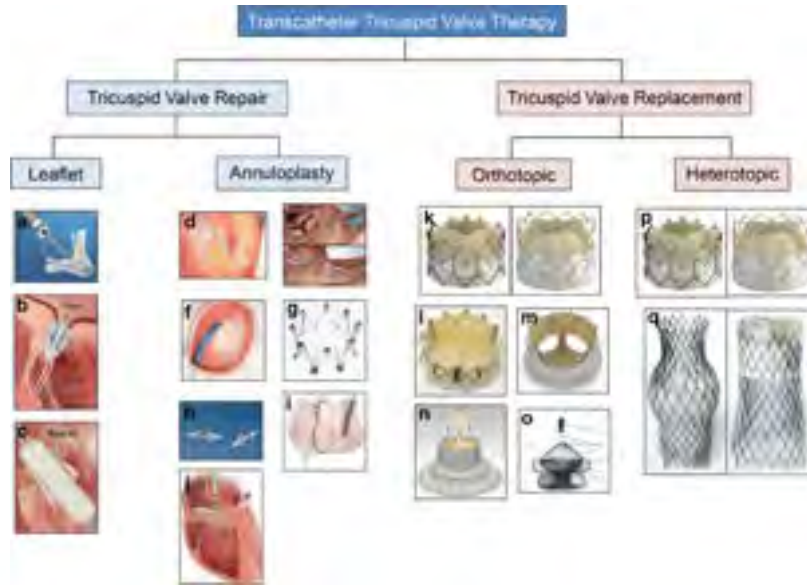


**9.6%
Operative
Mortality**

Percutaneous therapeutics options worldwide and local

Tricuspid valve replacement
heterotopic (local)

- Quickly available
- Accepted by public/private insurance
- Learning curve
- Not demanding anatomical requirements



Elmariah et al .Current treatment Options in Cardiovascular Medicine (2019) 21:26

Local registry TR treatment / heterotopic valve replacement

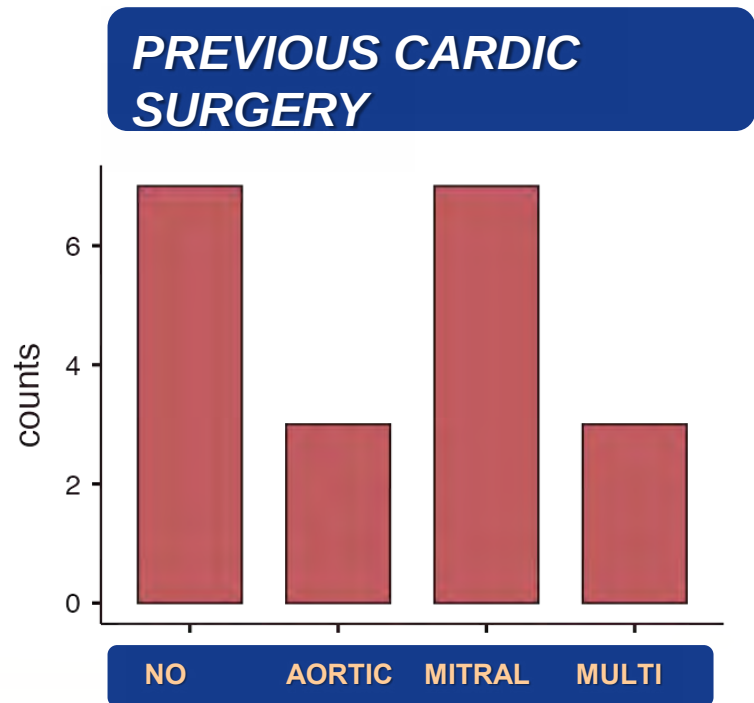
- Santiago de Chile
- Prospective registry
- 5 Hospitals (public/ private)
- Severe & symptomatic TR
- No candidates for cardiac surgery
- Surface Echocardiogram
- Angio CT scan
- Right heart catheterization

Elegibility

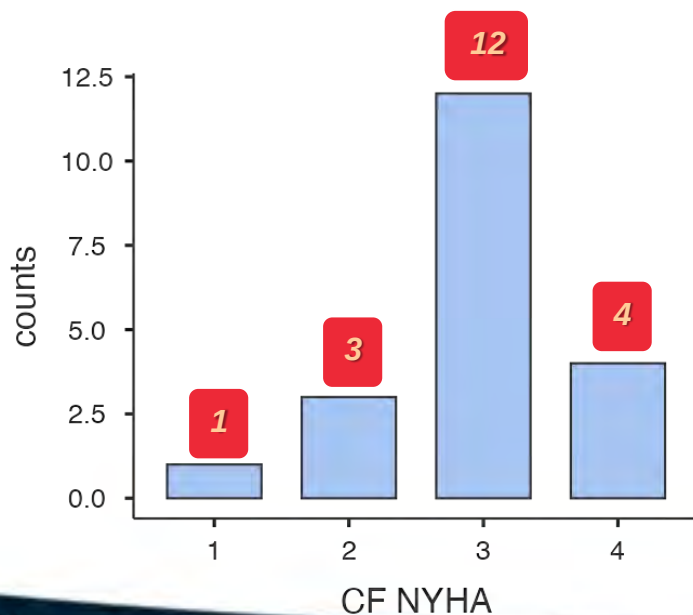
- No severe pulmonary hypertension
- No severe right failure by echocardiography
- Adequate landing zone by CT scan
- No previous caval device
- Written informed consent
- No tricuspid bioprosthesis

Population Characteristics

Population	Total 20 cases
Age (years)	71.4± 9.4
Female	13(65%)
Diabetic	6 (30%)
Peripheral vascular dis.	2(10%)
Liver disease	3(15%)
Atrial fibrillation	17(85%)
Pulmonary disease	1 (5%)
Coronary disease	2 (10%)
Previous surgery	13(65%)



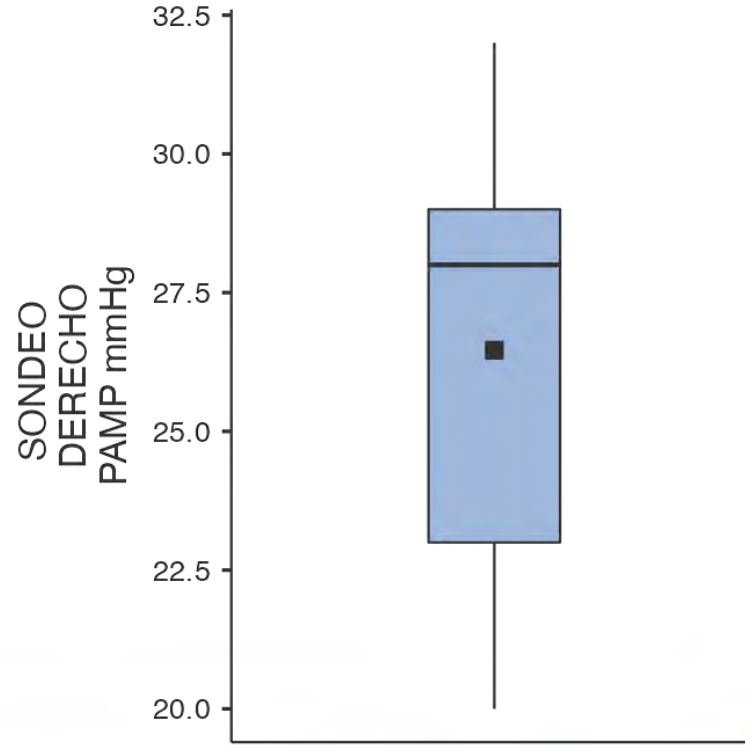
Clinical & general lab findings



- Dyspnea
- Leg vein edema
- Loop diuretics
- proBNP 3236 ± 3384
- INR 2.1 ± 1.4
- GOT 47.3 ± 38.4
- GPT 38.4 ± 45.0

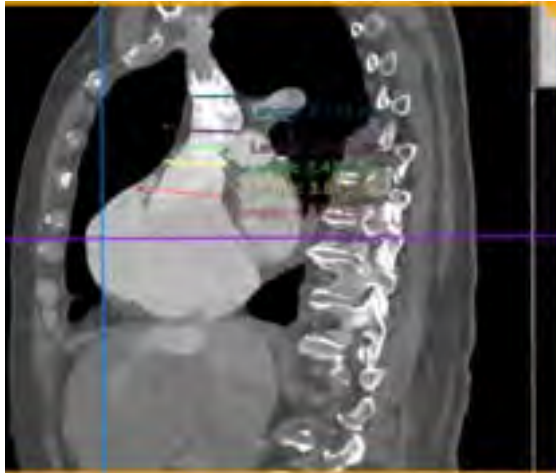
Hemodynamic assesment

- Median pulmonary pressure
 - 26.5 ± 4.1 mmHg
- Pulmonary vascular resistance
 - 2.0 ± 1.1 wood U
- Wedge pressure
 - 16.4 ± 5.3



Pre- procedure evaluation

EUROSCORE
4.6 (1.0- 18)



Echocardiogram	Total 20 cases
Ejection fraction %	54±11
Tricuspid reflux	
Severe	5 (25%)
Massive	9 (45%)
Torrential	6 (30%)
TAPSE (mm)	14.1±6.8
Right Ventricle diameter (mm)	47.1±8.4
Right atrial volume (mm3)	70±73.2
Hepatic reflux	5/11 cases

Heterotopic Tricuspid valve implantation

- Sedation & local anesthesia
 - General anesthesia
- Double femoral venous access
 - Pigtail (marker)
 - Tricvalve device
- Surface echo
- Vascular dilator 14 – 16F
- 27.5F venous sheath
- Vascular closure device or *figure of 8 suture*



Immediate Results

Peri procedure	Total 20 cases
Success	20 (100%)
Death	0
Stroke	0
Myocardial infarction	0
Tamponade	0
Device embolization	1
Open heart surgery	0
New pacemaker	1(5%)
Hospitalization (days)	4(2-91)

*5 cases prolonged
index admission*

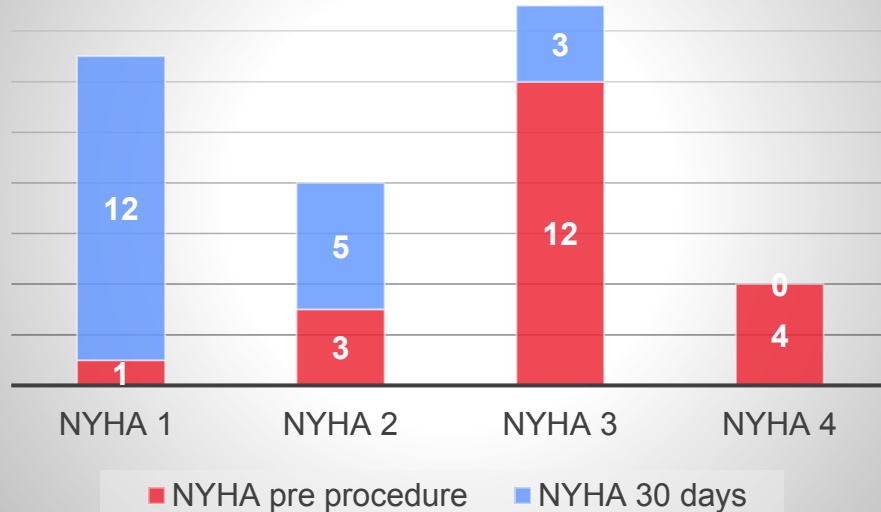
*3 due to insurance
issues*

*2 due to right heart
failure peri-
procedure*

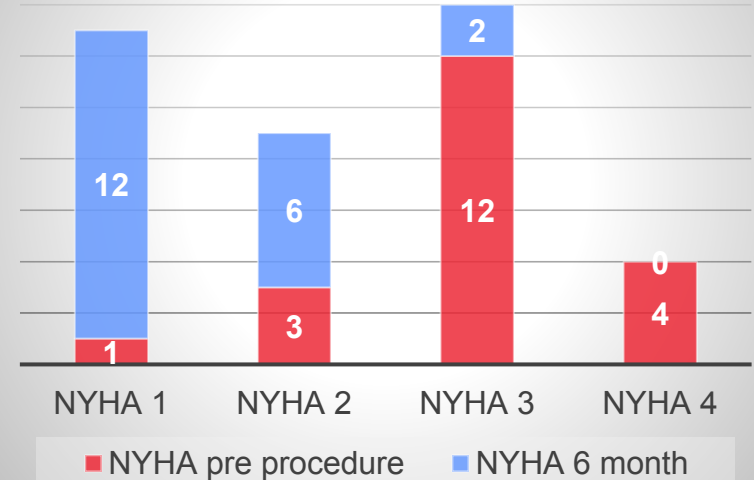


Clinical follow up

NYHA pre procedure -3 month



NYHA pre procedure- 6 months



Follow up

TOTAL 20 CASES	BASELINE	30 DAYS	6 MONTHS	12 MONTHS
DEATH	-	0	1(5%)	1 (5%)?
RE ADMISSION	-	4 (20%)	7 (35%)	7 (35%)
CARDIAC DEATH	-	0	0	0?

Conclusions

- Heterotopic tricuspid valvular replacement if a safe option for severe tricuspid reflux in selected population
- This procedure relieved symptoms in the most of our population
- High success rate
- Does not require TE echo or general anesthesia
- Better results in terms of success or adverse events in comparison to surgery (local data)
- 1 year Follow up 1 is pending

Acknowledgements

Hospital	
Dr Bastián Abarca	Sotero del Rio Hospital
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Dr Jorge Sandoval	Instituto Nacional del Tórax Hospital
Dr Martín Valdebenito	Sotero del Rio Hospital
Dr Nicolas Veas	BUPA Hospital

Jailed, But Unharmed: Navigating Bi-Caval TricValve Implantation in Tricuspid Regurgitation with Multiple Pre-Existing Leads.

A Complex Case from the TRICAV I US EFS

Brian Whisenant MD
For John Saxon MD



TCT®

TRANSCATHETER
CARDIOVASCULAR
THERAPEUTICS®

RV Leads and Tricuspid Valve Interventions

Transvenous RV pacing and defibrillator leads traverse the tricuspid valve (TV).

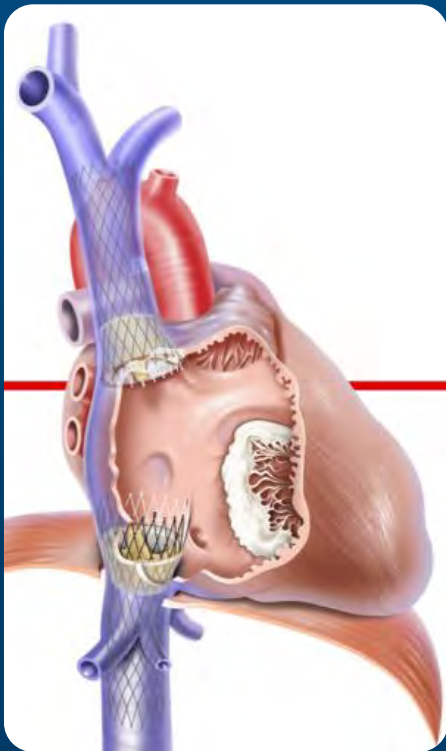
Leads may cause tricuspid regurgitation (TR) by interfering with leaflet coaptation, causing chordal entanglement, fibrosis, or leaflet impingement.

Pinned leads with large coaptation gaps may not be suitable to tricuspid edge to edge repair.

Transcatheter tricuspid valve replacement may harm leads pinned between the annulus and transcatheter valve.

Pre-existing RV leads present unique challenges in the management of Tricuspid Regurgitation.

Challenging Case Summary



- We present a case from the **TRICAV I study** of successful TricValve implantation in a TR patient with multiple transvenous pacing/ICD leads.
 - without compromising lead function or structural valve performance.
- Approximately **50% of patients in TRICAV I** had pre-existing leads, suggesting this a critical scenario in real-world practice.

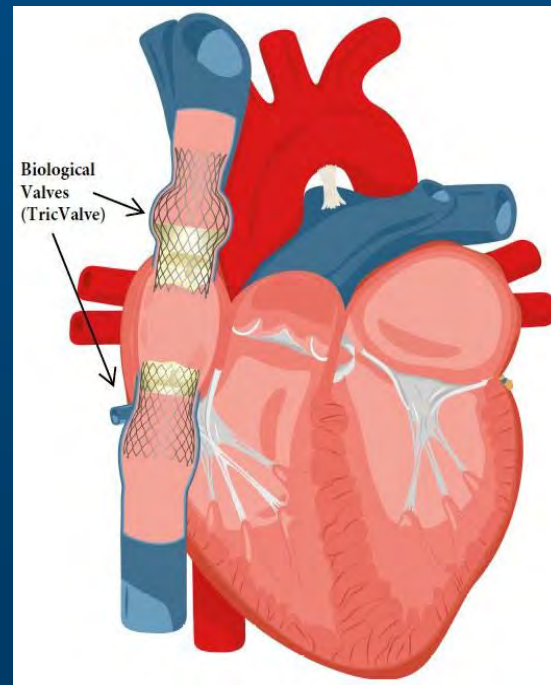
TRICAV I EFS (NCT06137807)

Trial Overview

- 50 Patients implanted (approved for up to 80 patients)
- 50 US Sites
- 5 Year Follow-Up

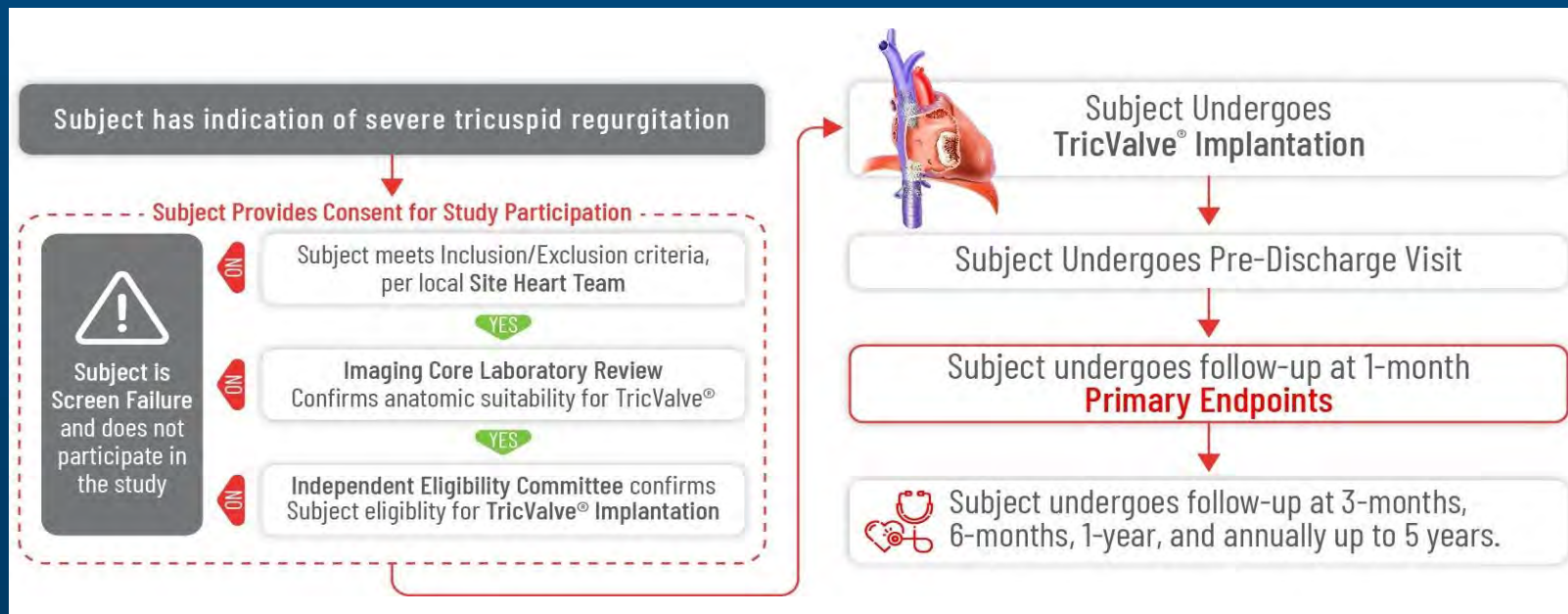
Bi-Caval Procedure Highlights

- Minimally invasive, **No TEE required**
- Reduced duration of the implantation (< 60 min)
- Procedure can be performed without general anesthesia
- TricValve does not interfere with the native tricuspid valve anatomy
- **Compatible with pre-existing pacemaker leads**
- Allows for future treatment options



TRICAV I Study Design

CoreLab Adjudicated NonRandomized Feasibility Trial



CAUTION: Investigational study device. Limited by Federal law to investigational use.

Clinical History

- **78-year-old male**
- 20-year history of non-ischemic cardiomyopathy
 - LVEF 30%
- CKD Stage III
- STS-PROM: 6.77%
- TRI-SCORE: 3

Arrhythmia History

- VT ablation in 2006
- Permanent AF
- AVN ablation in 2009
- ICD later upgraded to BiV-D
- New RV lead placed in 2011

FUNCTIONAL STATUS:

6-Minute Walk:
359m

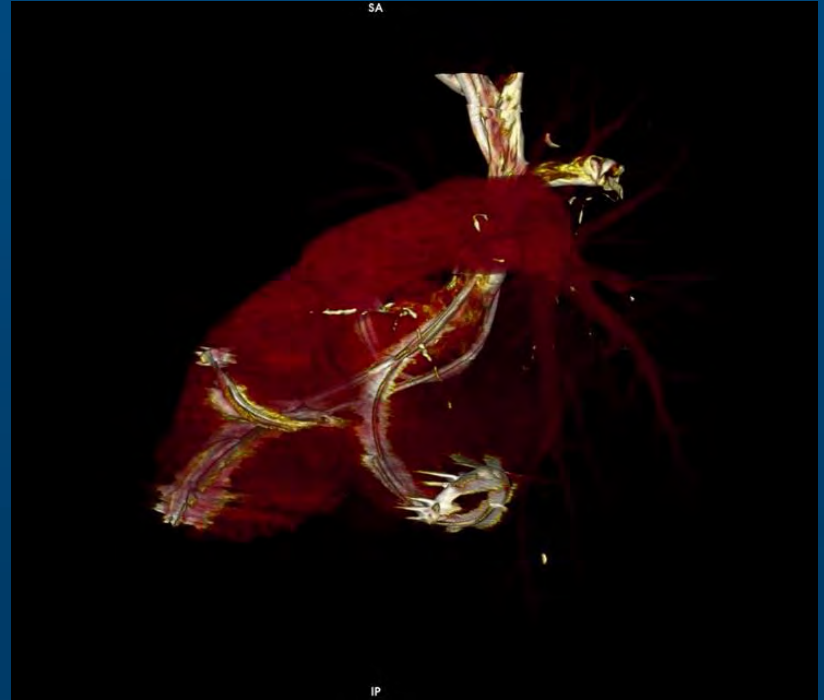
NYHA
Class III

KCCQ:
52.9

Baseline CT Imaging Data



Leads through SVC crossing the TV



3D Reconstruction

Baseline TTE Data

- TTE confirmed
 - Severe TR
 - Severely dilated right atrium
 - Mild RV dysfunction
- TricValve aims to reduce systemic venous pressure while preserving RV output.

ECHOCARDIOGRAPHY ASSESSMENT BY CORE LAB	
LVEF (%)	38.8
RA Volume (mL)	194.9
IVC Diameter (cm)	2
TV annulus mid diastolic dimension, Inflow (cm)	4.4
RIGHT VENTRICULAR FUNCTION	
TAPSE (mm)	17
RV FAC (%)	44.2
RV Free Wall Strain (%)	-26.9
RV Lateral S' (cm/s)	10.33
TRICUSPID REGURGITATION	
TR PISA EROA (cm ²)	0.43
TR PISA Regurgitant Volume (mL)	37.33

TricValve Deployment

1 Initiation of SVC Valve deployment



4 leads are jailed between the stent frame and the compliant venous wall.

2 Complete BiCaval valve deployment



IVC valve is deployed without lead interference.

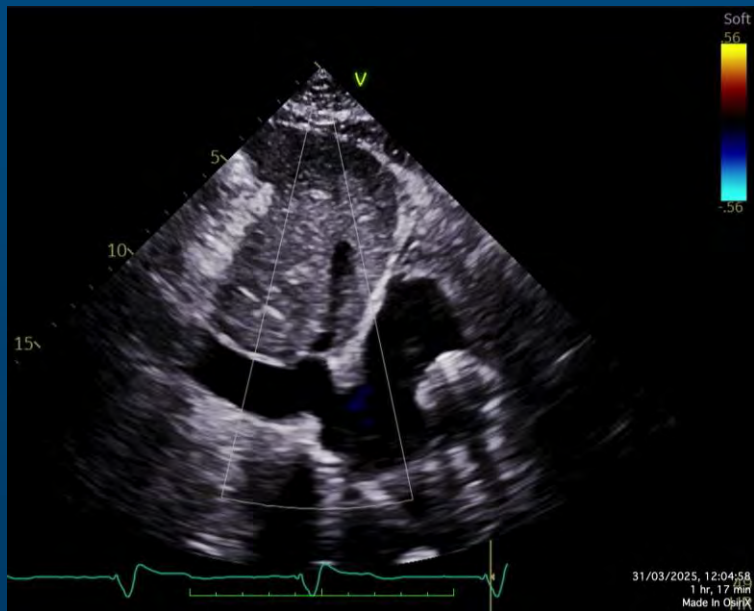
No dislodgment, entrapment, or loss of function were detected at 1 month follow-up.

Intraprocedural Hemodynamics and 30-day Clinical Outcomes

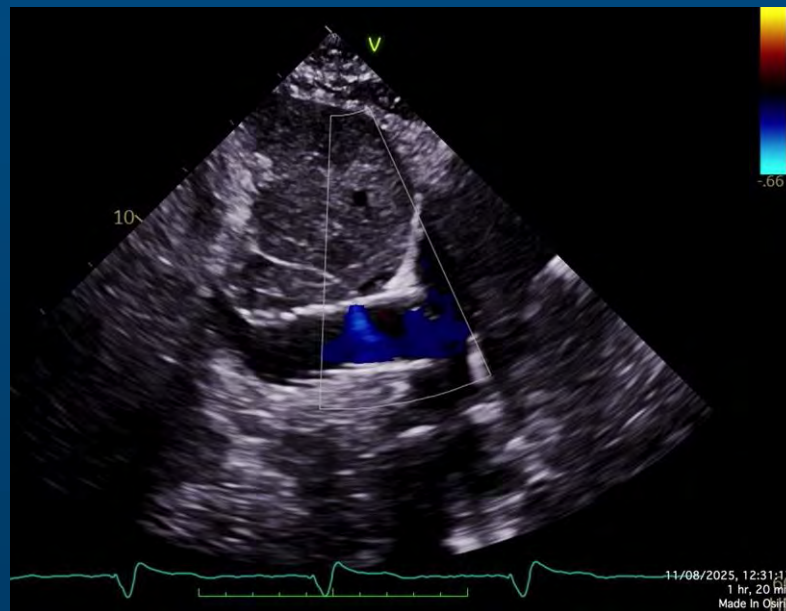
- Stable RV and pulmonary pressures suggest no acute right-sided overload post-implant.
- Improved CO indicates enhanced forward flow, likely due to **relief of caval reflux**.
- Results at 30 Days:
 - NYHA from class III → class II
 - KCCQ score from 52.9 → 68.8
 - 6MWT from 359 mt → 364 mt

RHC	Pre	Post
RV Systolic Pressure	32	32
Pulmonary Artery Systolic Pressure	37	37
Pulmonary Capillary Wedge Pressure	16	16
Cardiac Output	3.06	3.51

TTE Pre & Post Implant (90D FU)



ECHO AT BASELINE



ECHO AT 90 DAYS FOLLOW-UP

Conclusions

- TricValve is **safe for patients** with transvenous leads **without limiting future tricuspid or lead procedures**
- The low-pressure, compliant environment of the venous system allows for **safe jailing without lead damage**.
- Careful procedural technique and real-time imaging allow **successful navigation and deployment** even in complex anatomies.
- These insights will be key to **expanding treatment options** for high-risk patients with severe TR.