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

CRF®
TCT® TRANSCATHETER CARDIOVASCULAR THERAPEUTICS®

RV Leads and Tricuspid Valve Interventions

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

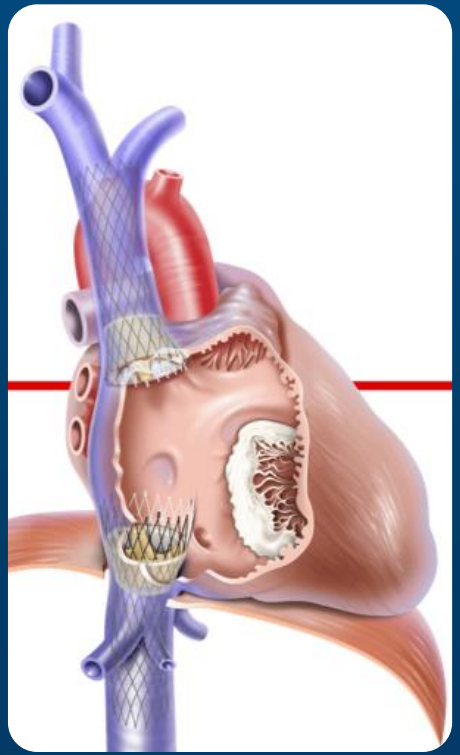
Leads may cause tricuspid regurgitation (TR) by interfering with leaflet coaptation, causing chordal entanglement, fibrosis, or leaflet impingement.

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 trancatheter 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.

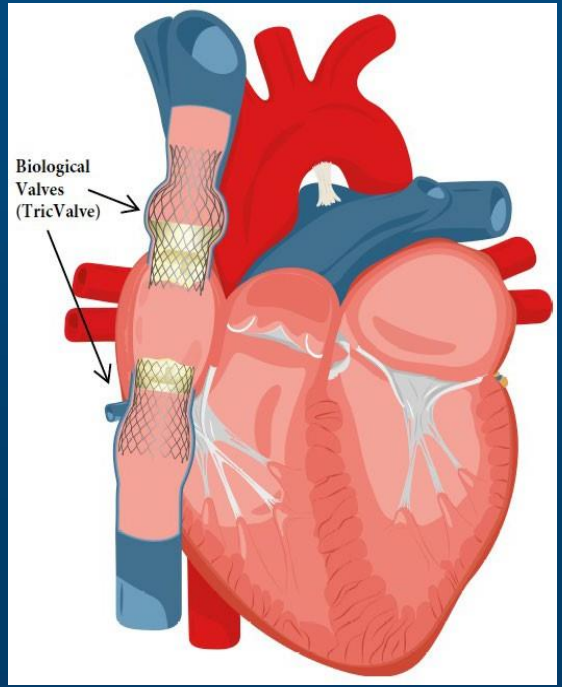
TRICAV I EFS (NCT06137807)

Trial Overview

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

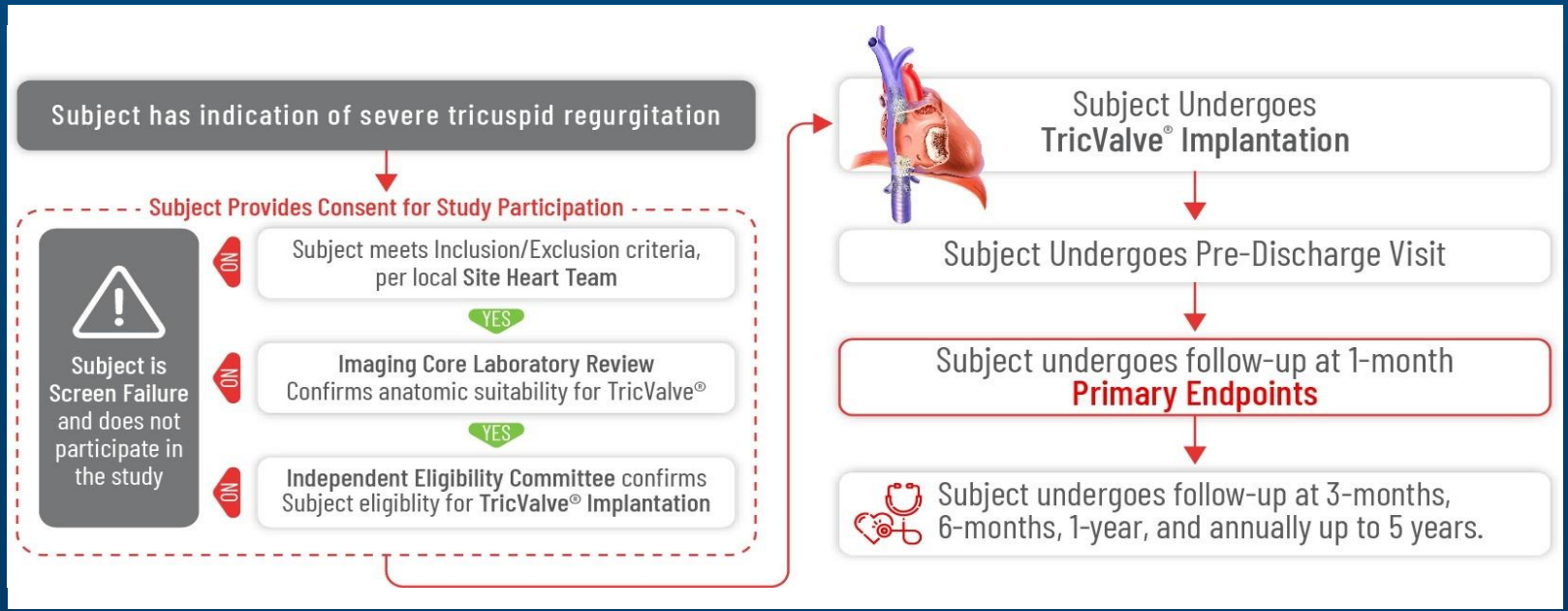
Bi-Caval Procedure Highlights

- 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

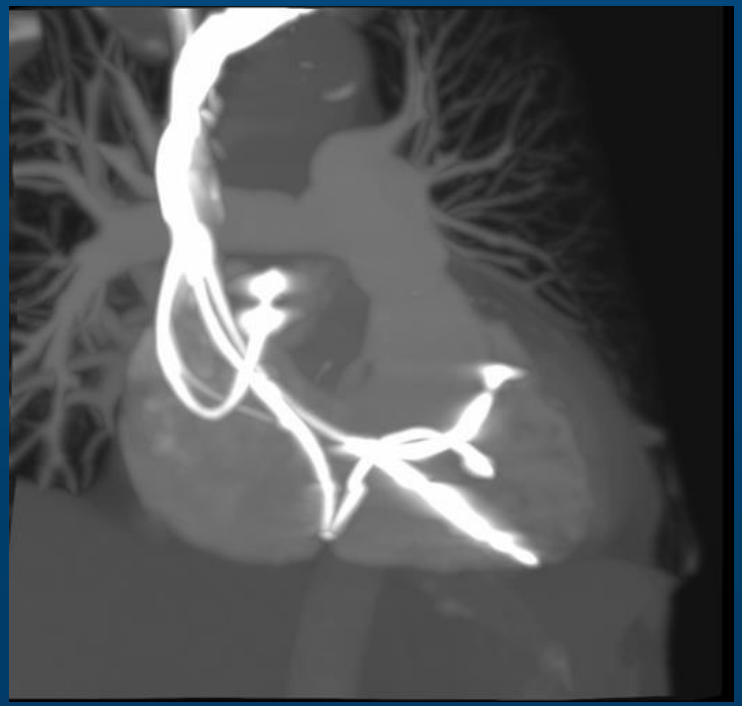
- **78-year-old male**
- 20-year history of non-ischemic cardiomyopathy
  - LVEF 30%
- CKD Stage III
- STS-PROM: 6.77%
- TRI-SCORE: 3

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:	NYHA	KCCQ:
359m	Class III	52.9

Baseline CT Imaging Data



Leads through SVC crossing the TV

3D Reconstruction

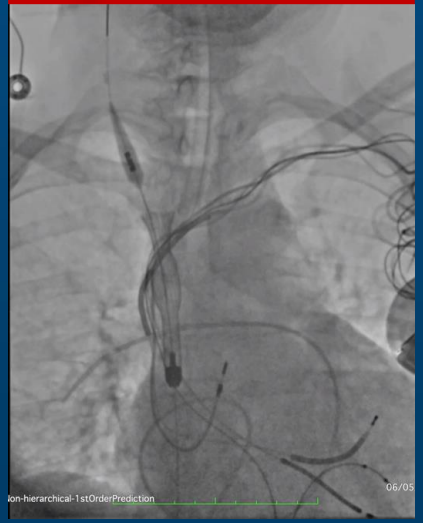
Baseline TTE Data

- 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

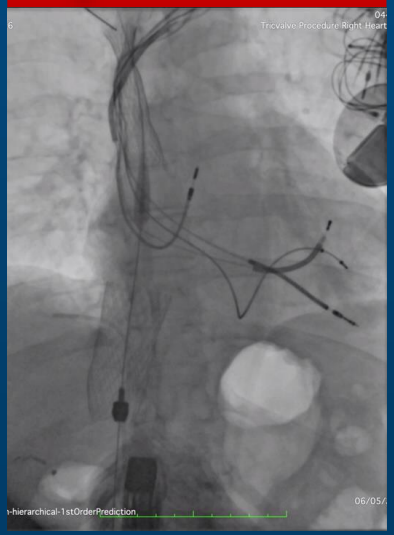
TricValve Deployment

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.

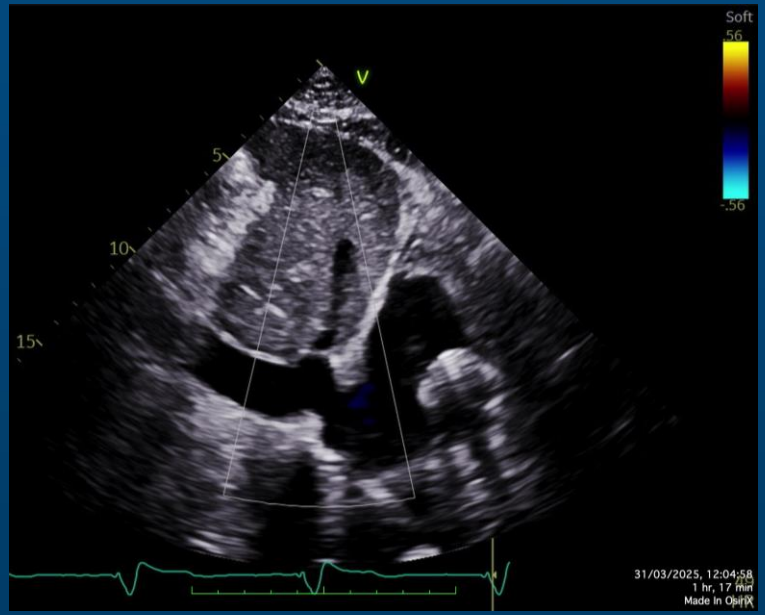
No dislodgment, entrapment, or loss of function were detected at 1 month follow-up.

Intraprocedural Hemodynamics and 30-day Clinical Outcomes

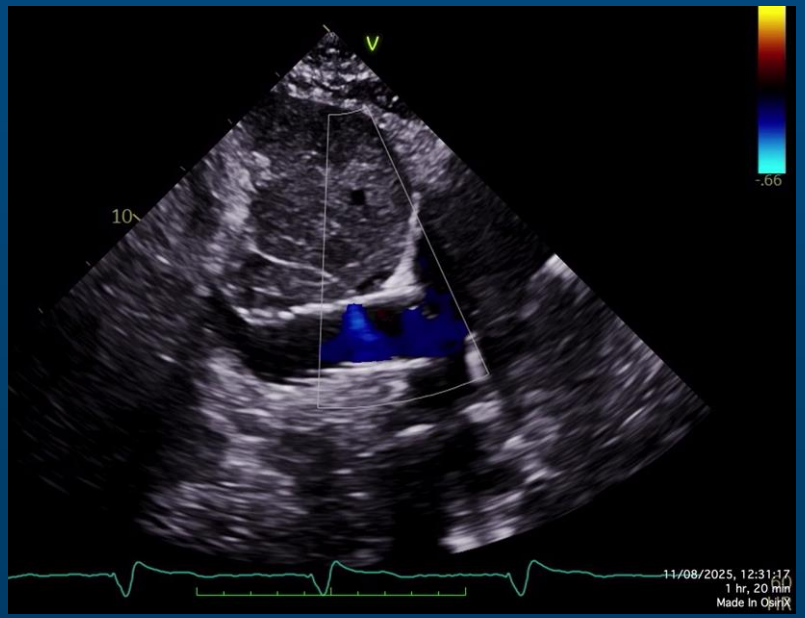
- Stable RV and pulmonary pressures suggest no acute right-sided overload post-implant.
- Improved CO indicates enhanced forward flow, likely due to **relief of caval reflux**.
- Results at 30 Days:
  - NYHA from class III → class II
  - KCCQ score from 52.9 → 68.8
  - 6MWT from 359 mt → 364 mt

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.