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

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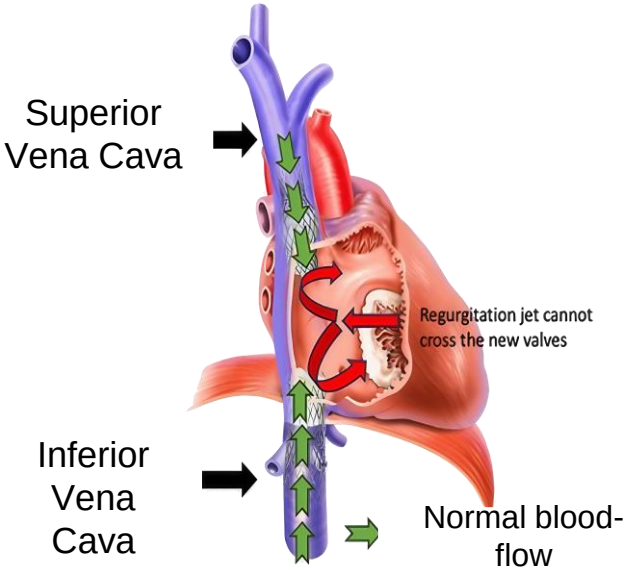
Disclosure of Relevant Financial Relationships

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	Ineligible Company
Consultant	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

All relevant financial relationships have been mitigated.
Faculty disclosure information can be found on the app

TricValve CAVI: A physiological approach to severe TR

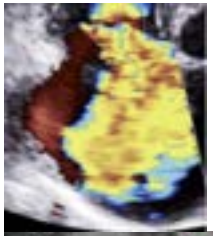


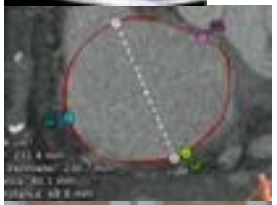
TricValve Model	Valve size (mm)
SVC 25	25
SVC 29	29
IVC 31	31
IVC 35	35

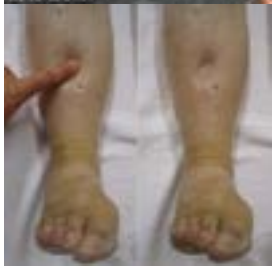
☑	Prior tricuspid interventions or surgery
☑	Existing pacemakers or defibrillator leads (and future ones)
☑	TTE guidance for IVC (Fluoro for SVC deployment)
☑	100% agnostic to tricuspid anatomy, all future TV options open
☑	Conscious sedation
☑	Easier imaging requirements
☑	• Minimal to zero HALT in global experience, under standard OAC conditions) • Low rate of thrombosis

TricValve Enables Systemic & Clinical Improvement While Maintaining All Future Options

Severe TR + RHF

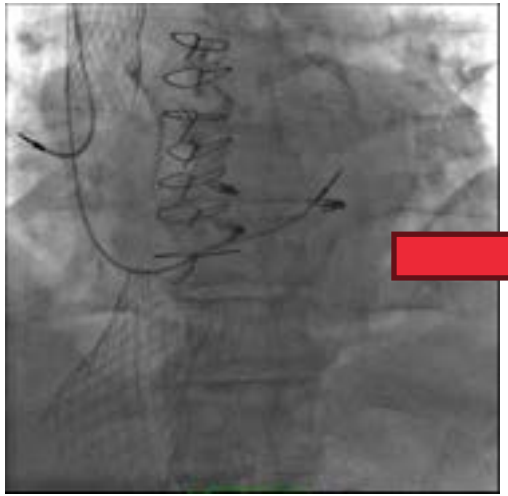






TricValve

↑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)

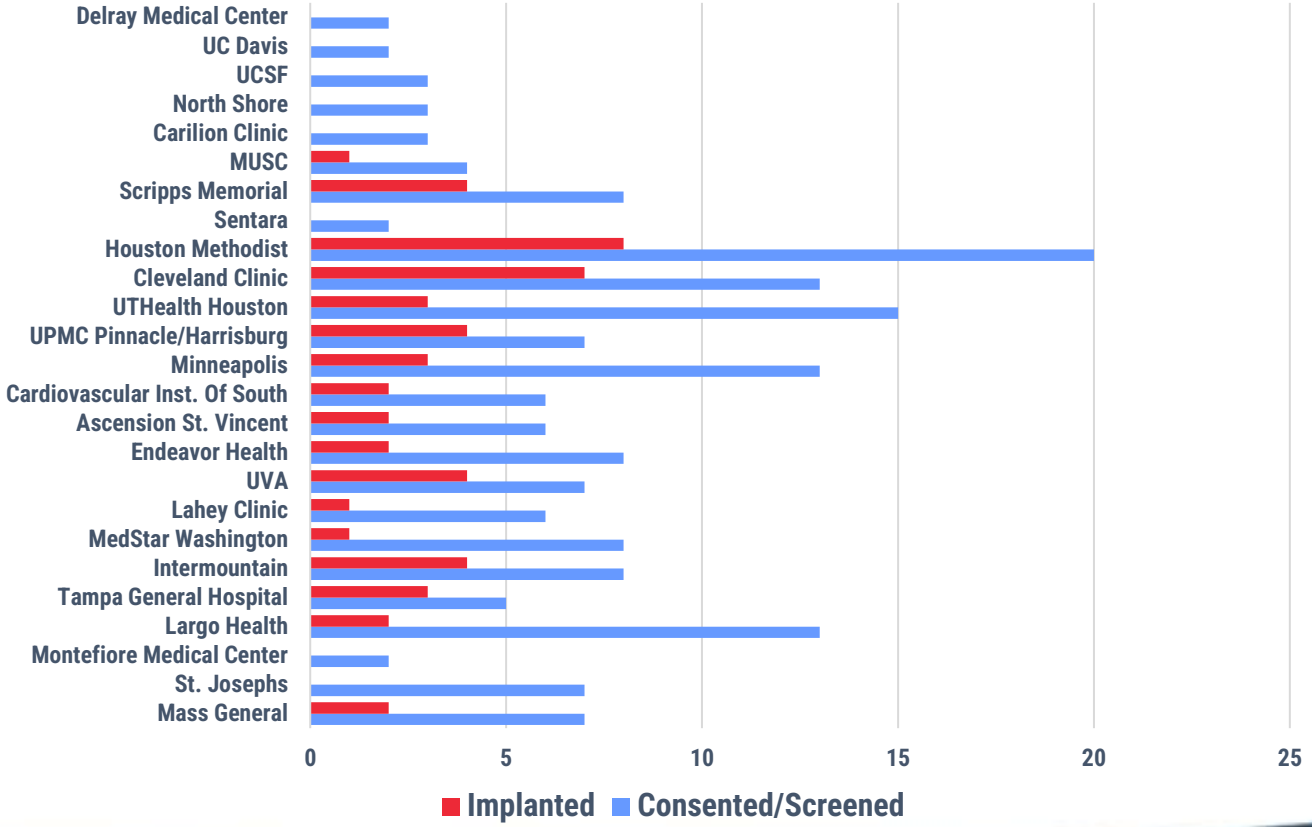
Enrolling(26) Upcoming (24)

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

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

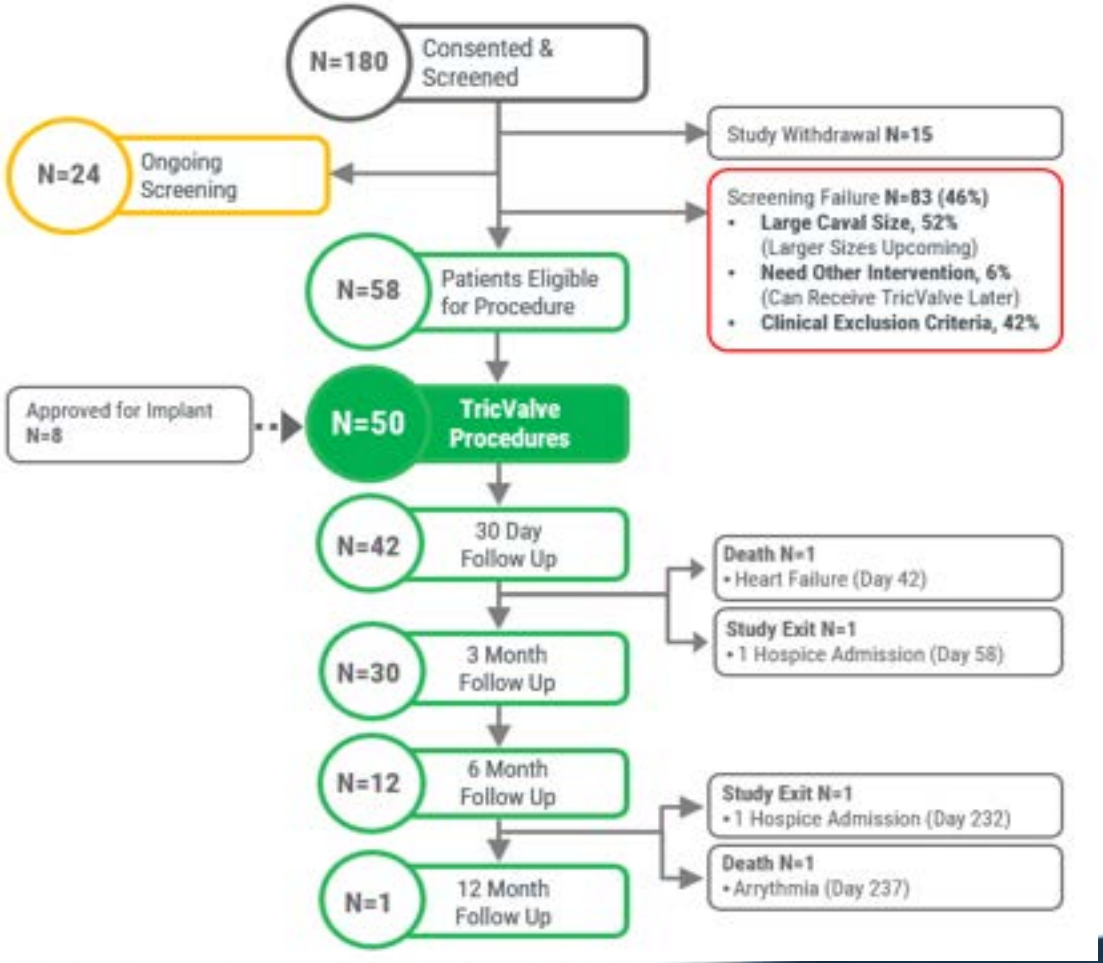
Safety (at 12 months): The percentage of subjects with Device- and/or Procedure-related MAEs through 1 year, as classified by the CEC.

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 ≥30m).

TRICAV-1
Study Progress

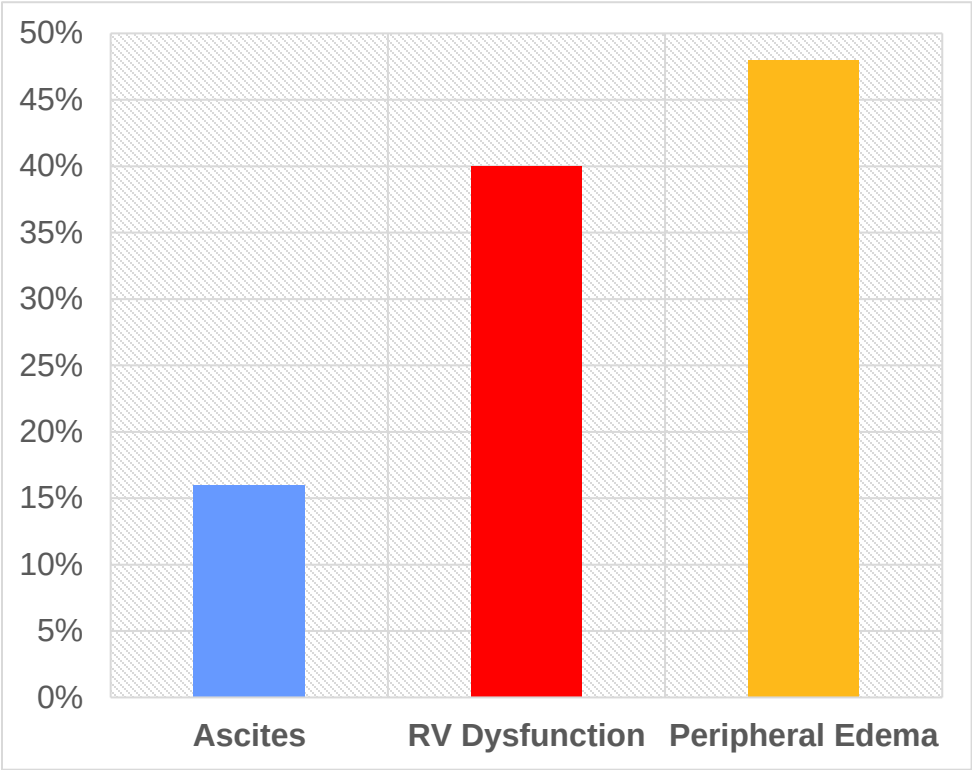
Screen failure rate is driven by lack of a larger IVC size and clinical exclusion criteria



TRICAV-1: Baseline Data

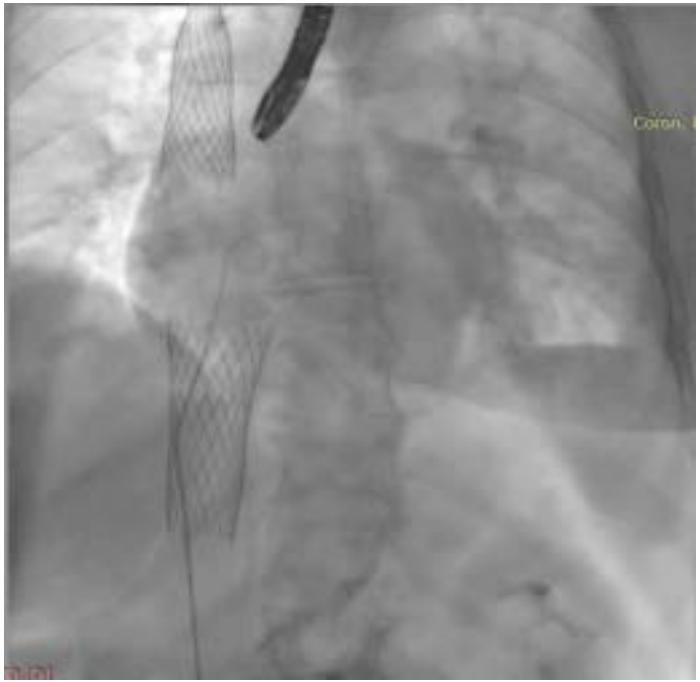
Baseline characteristics	
Age (years)	79.6 ± 8.0
Female	38%
Male	62%
NYHA (%)	IV (2%); III (98%)
Euro Score II	6.00 ± 4.56
TRI-Score	4.6 ± 1.6
TR etiology (%)	FTR (80%); DTR (20%)
Atrial Fibrillation	92%
Cancer History	36%
Coronary Artery Disease	48%
Pacemaker/ICD	40%
Prior Tricuspid Intervention	14%
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%**



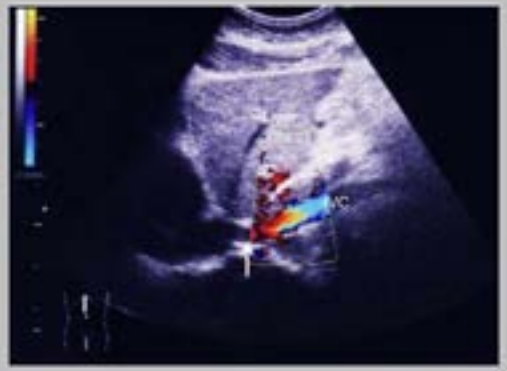
**1 Valve in Valve for PVL; 1 Tortuosity preventing IVC deployment*

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%)

IVC Caval Reflux by color Doppler Ultrasonography

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



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

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

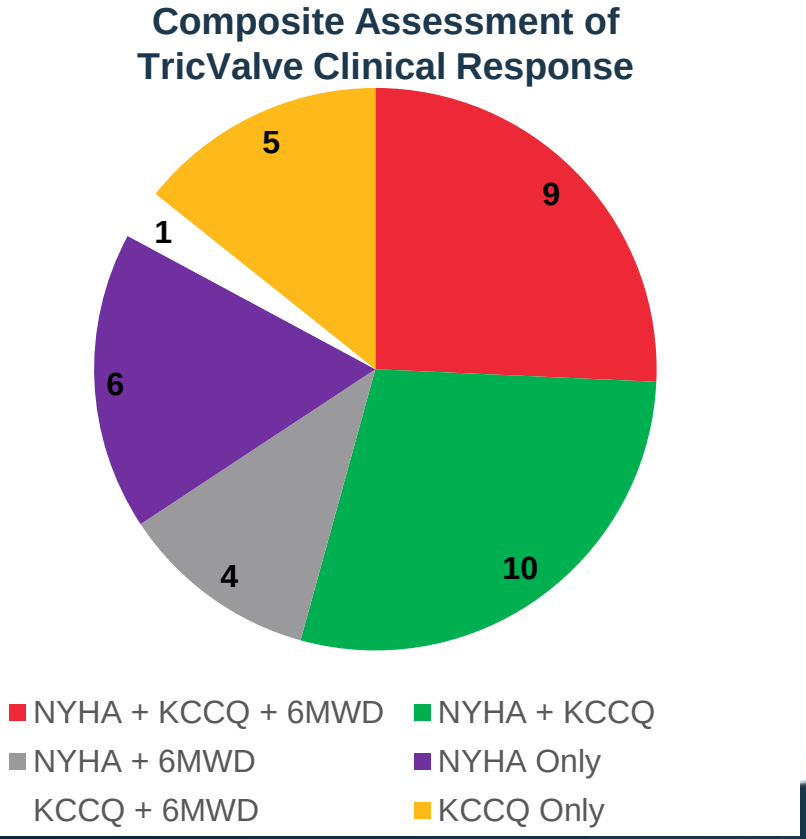
TRICAV-1: Clinical Functional Outcomes

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)

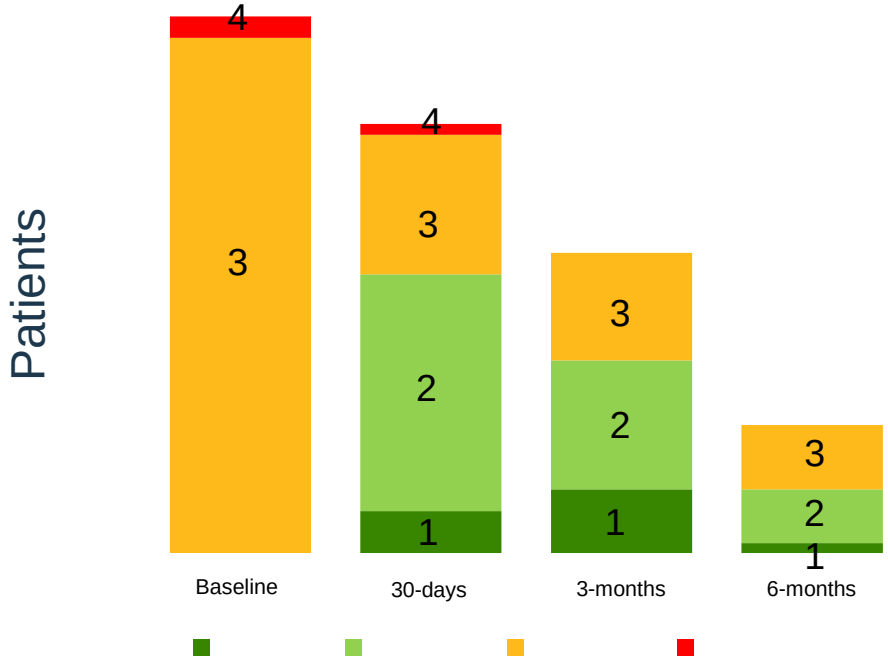
6MWT
Distance Improvement
(≥ 30 meters)



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

TRICAV-1: 30-Day Functional Status

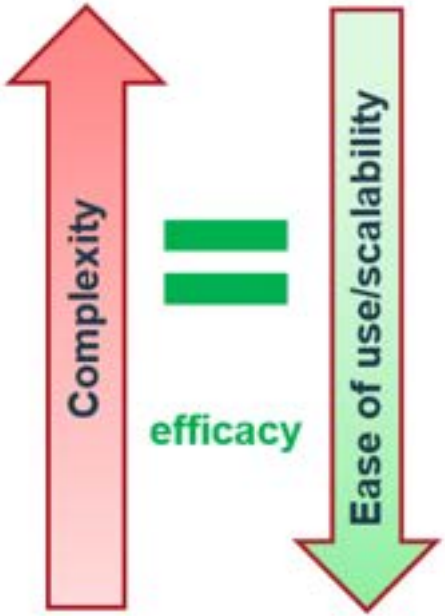
NYHA



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