Recent Advances in Transcatheter Tricuspid & Mitral Valve Replacement

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Formación Biotronik

Patients are largely undertreated with surgery

1,600,000
Number of
moderate to severe TR cases

250,000
Number of
new TR cases annually

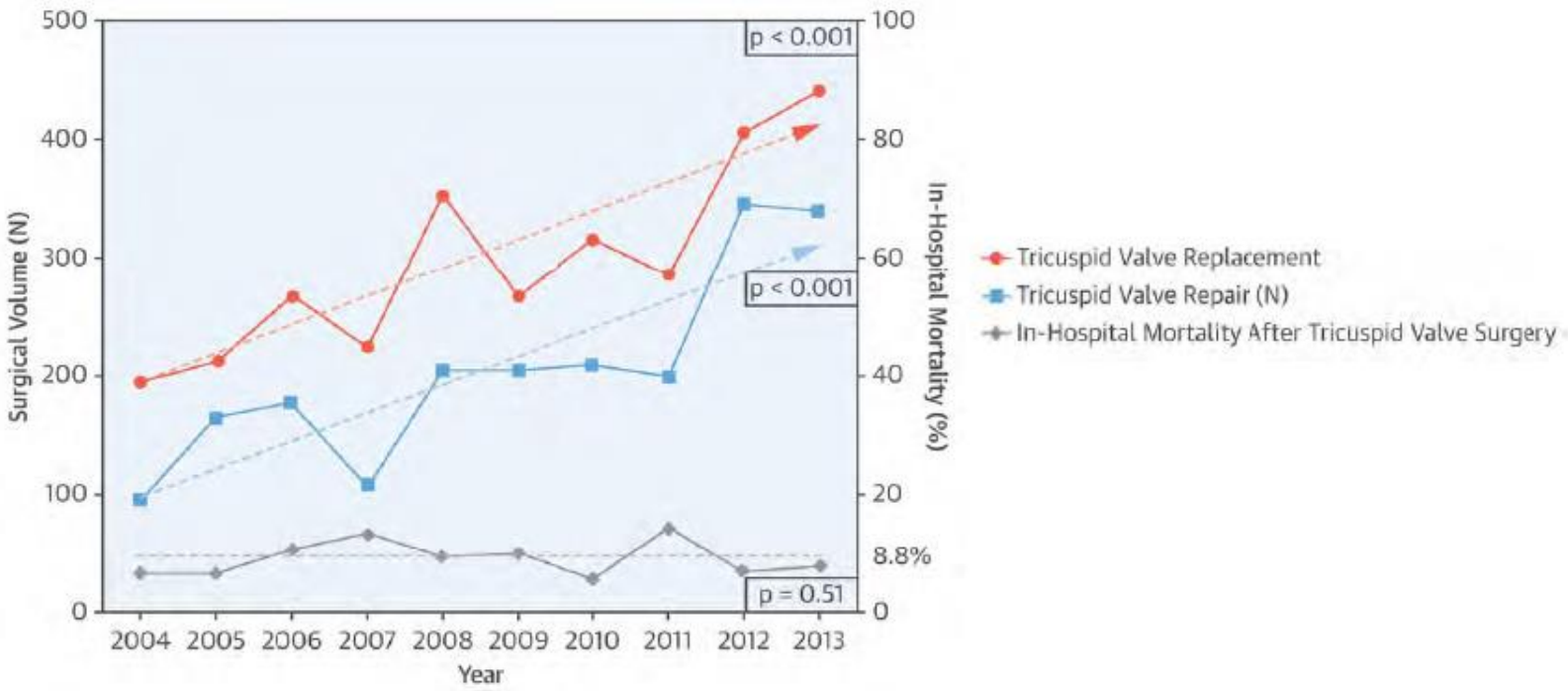
<8,000
Number of
TR surgeries

<0.5%
of TR cases treated surgically

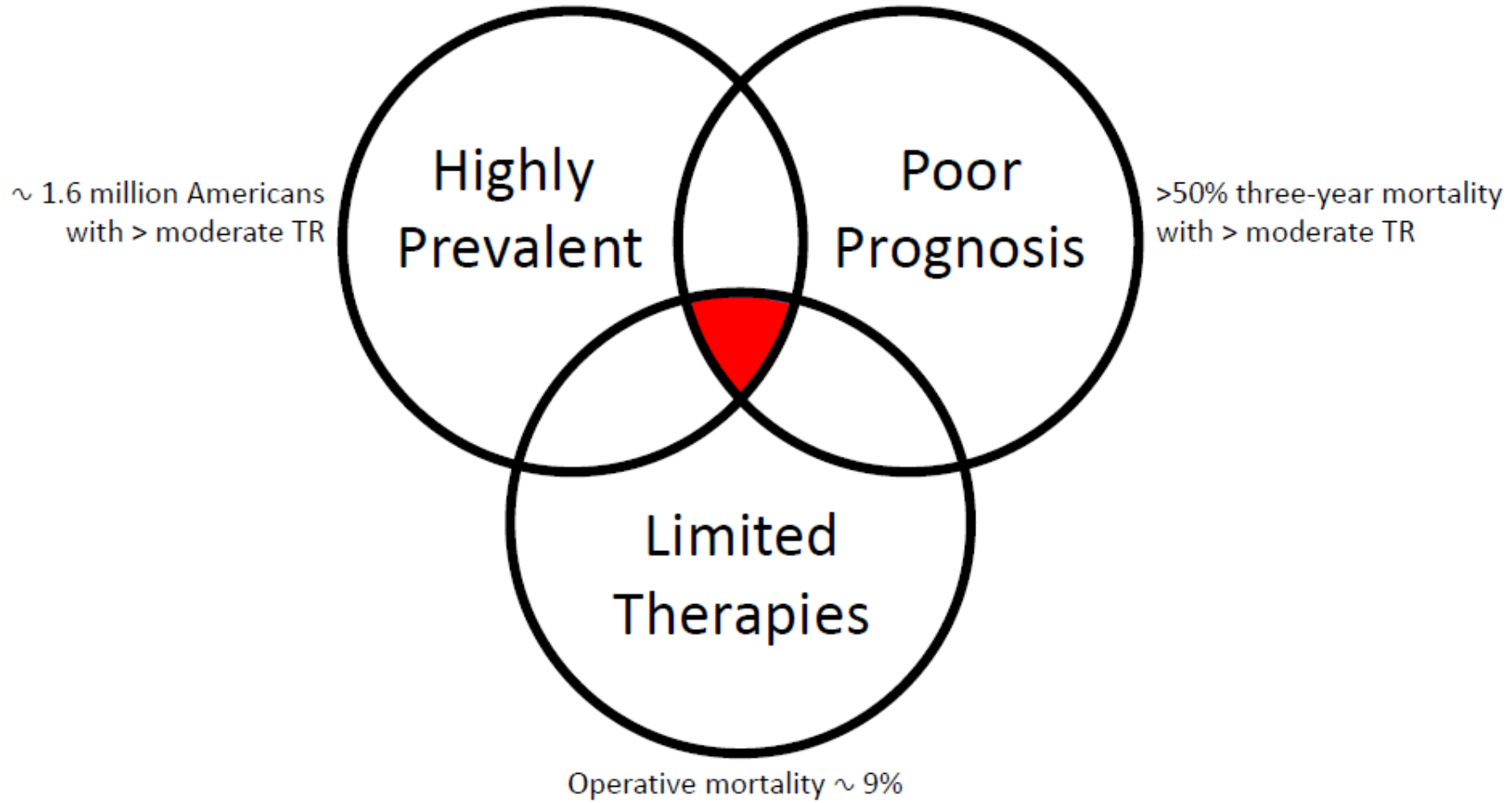
90%
are repair

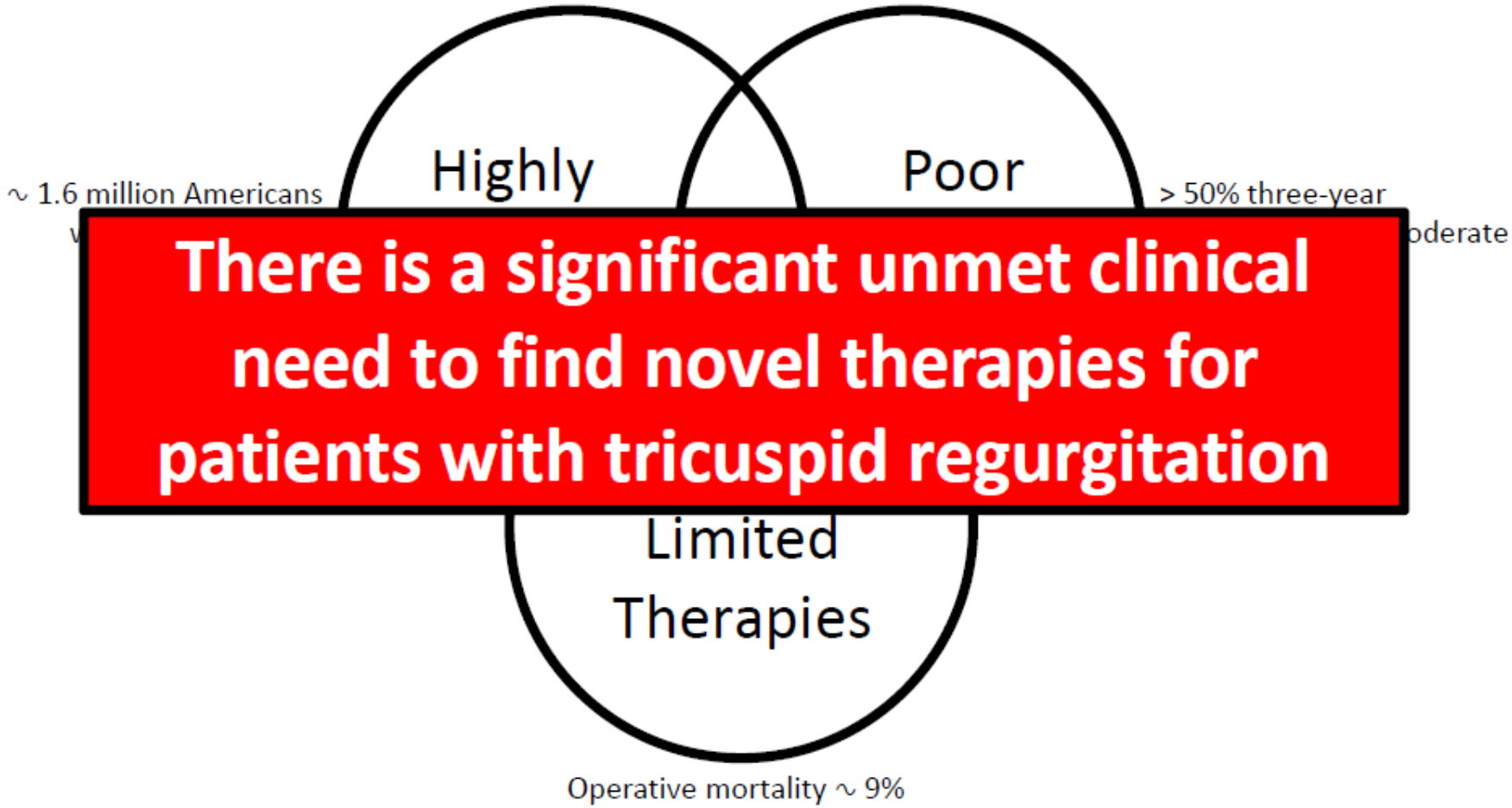
Agarwal et al. Interventional Cardiology Perspective on fTR
Circ Cardiovascular Intervention 2009; 565-573

Operative Mortality for TR remains high



C.J. Zack, E.A. Fender, P. Chandrashekar, et al. National trends and outcomes in isolated tricuspid valve surgery
J Am Coll Cardiol, 70 (2017), pp. 2953-2960


∼ 1.6 million Americans
with > moderate TR
Highly
Prevalent
Poor
Prognosis
>50% three-year mortality
with > moderate TR
Limited
Therapies
Operative mortality ∼ 9%

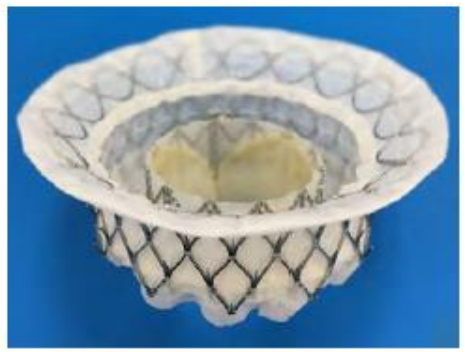

∼ 1.6 million Americans
Highly
Poor
> 50% three-year
oderate
There is a significant unmet clinical need to find novel therapies for patients with tricuspid regurgitation
Limited
Therapies
Operative mortality ∼ 9%

Transcatheter Tricuspid Valve Replacement

Devices with FIM experience

Navigate

Lux

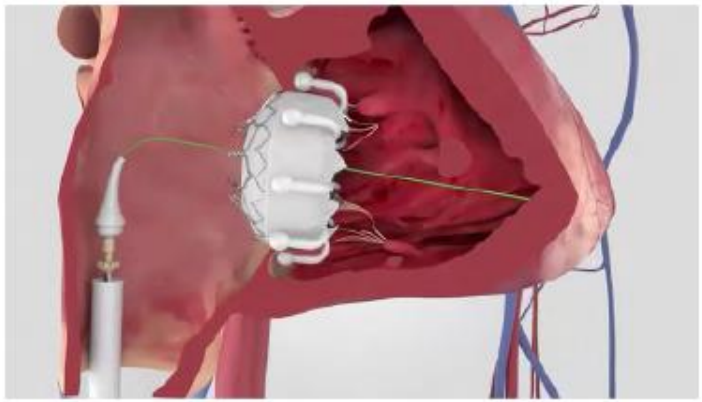


Intrepid

Evoque

EVOQUE Tricuspid Valve Replacement

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



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

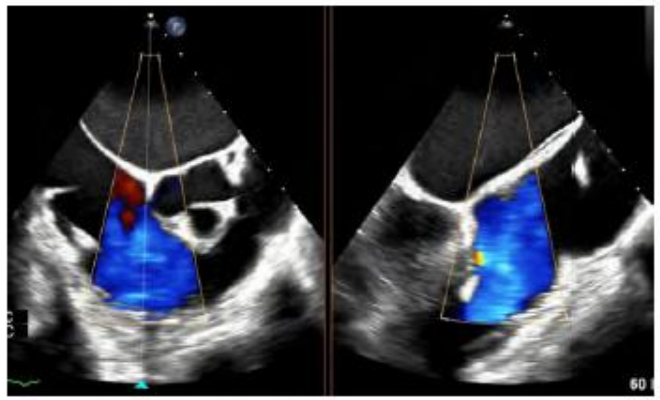
Conforming frame designed to achieve optimal retention force

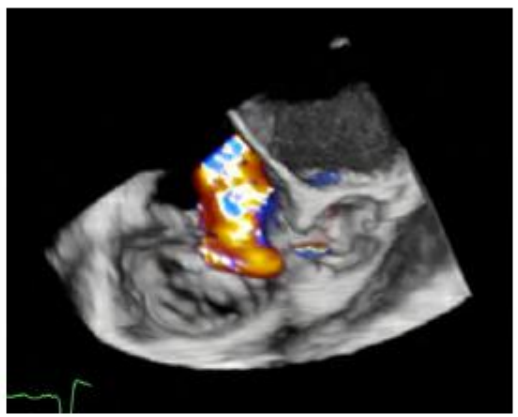
Multiple sizes offer treatment for a broad range of tricuspid pathologies and anatomies **(44, 48, 52 mm)**

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

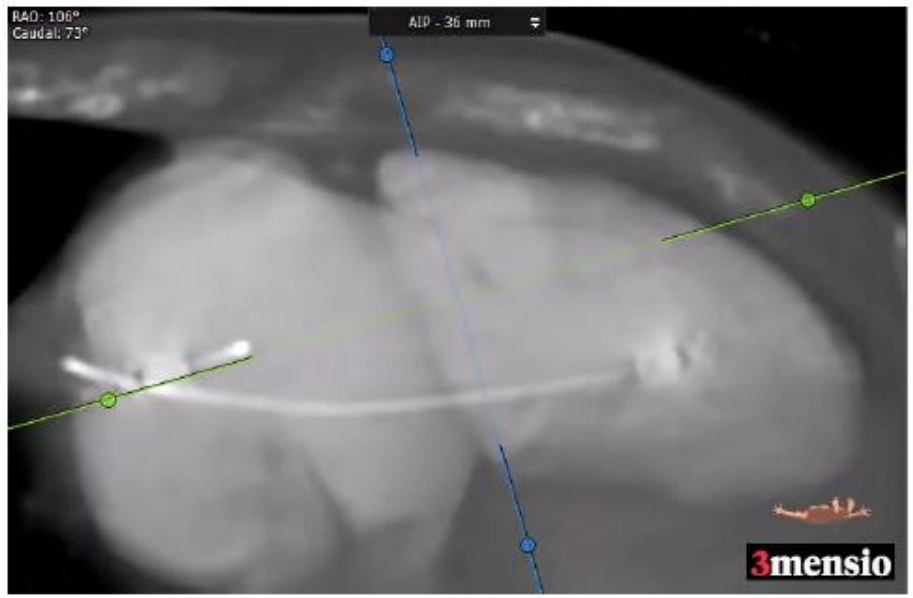
Transcatheter Tricuspid Valve Replacement

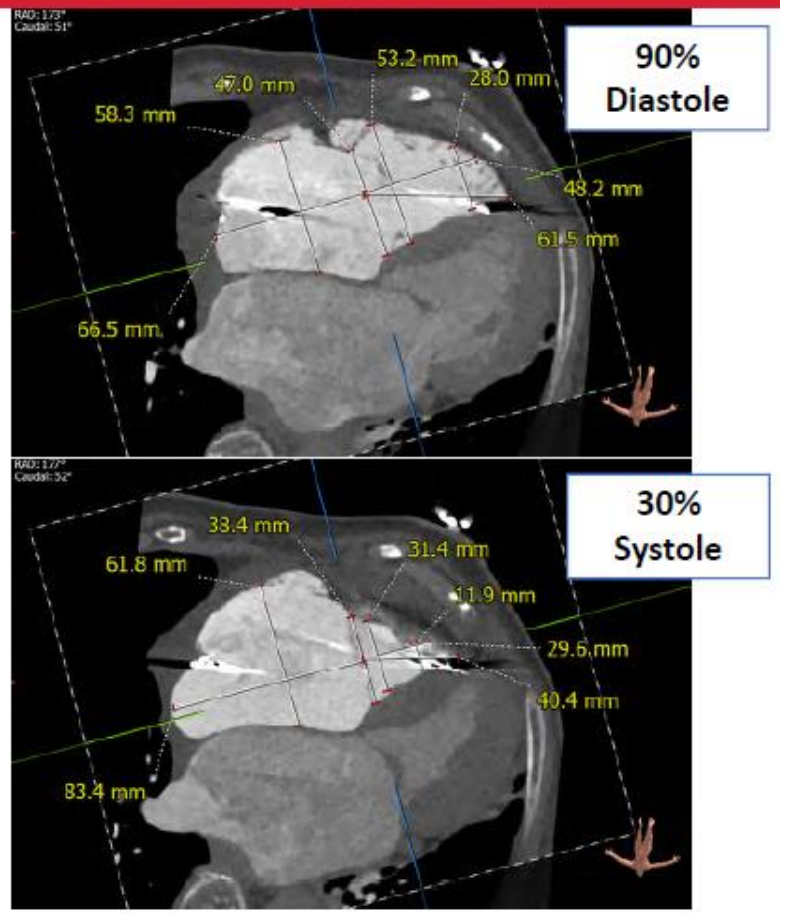
- 74-year-old female with worsening peripheral oedema and shortness of breath.
- History of atrial fibrillation, permanent pacemaker insertion, and previous TIA.
- Two hospital admissions with right sided heart failure
  - Echo demonstrated severe TR
  - Referred for consideration of transcatheter therapy



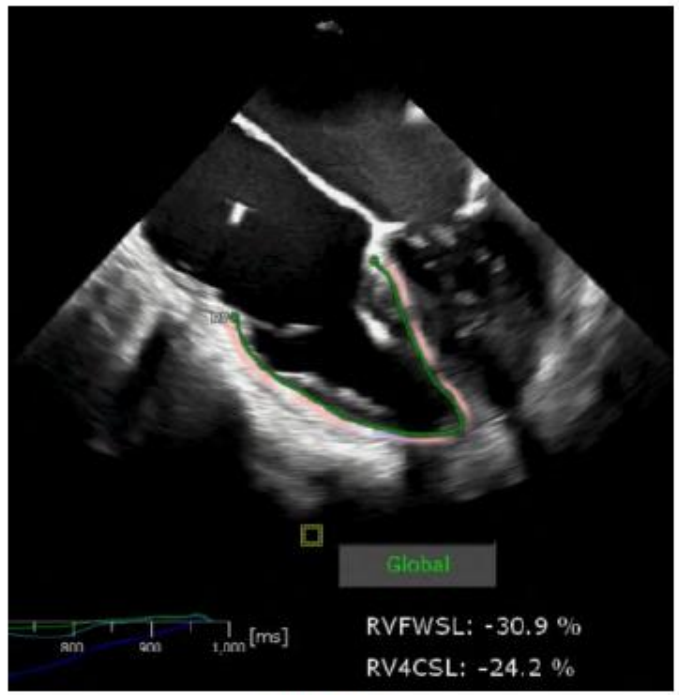


CT Screening to assess RV & TV anatomy



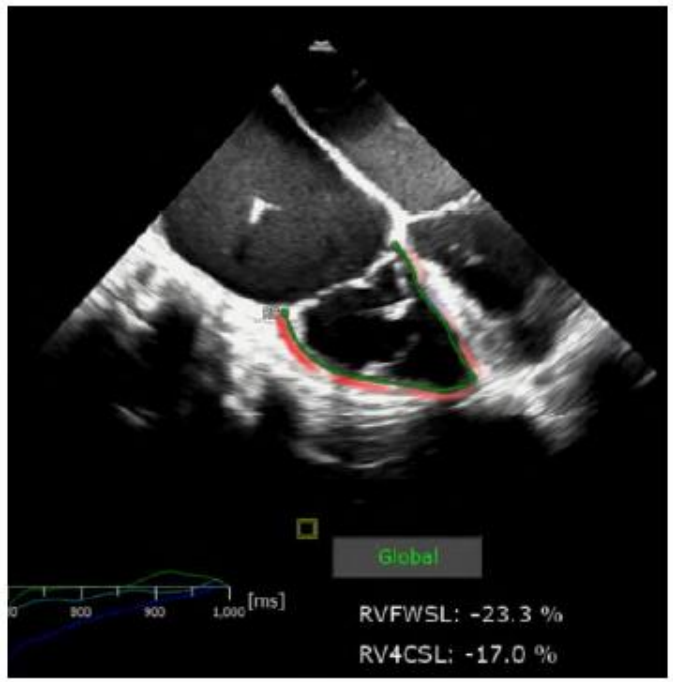


Challenge: Hyperdynamic RV function



Baseline

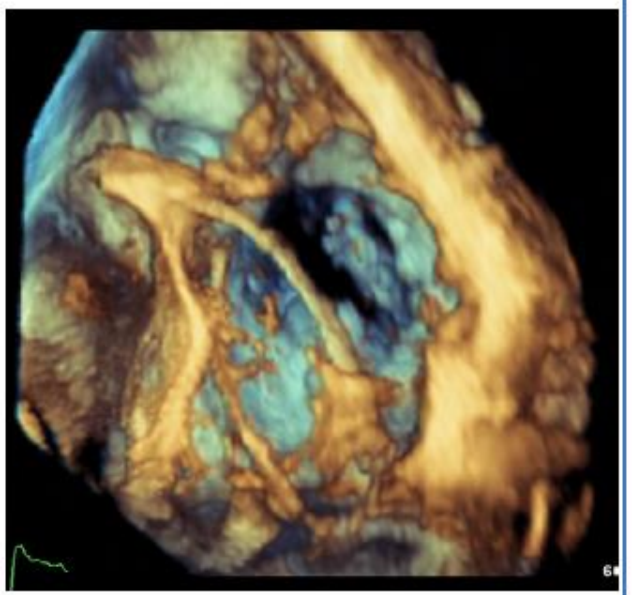
RVFW Longitudinal Strain -30.9%



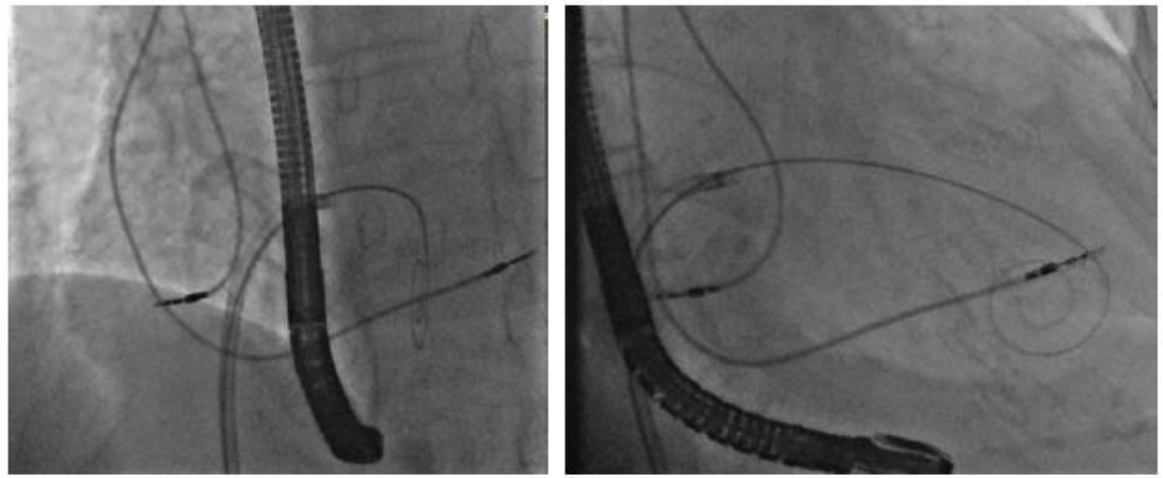
After Beta-blockers

RVFW Longitudinal Strain -23.3%

Procedure: Safari Wire Placement

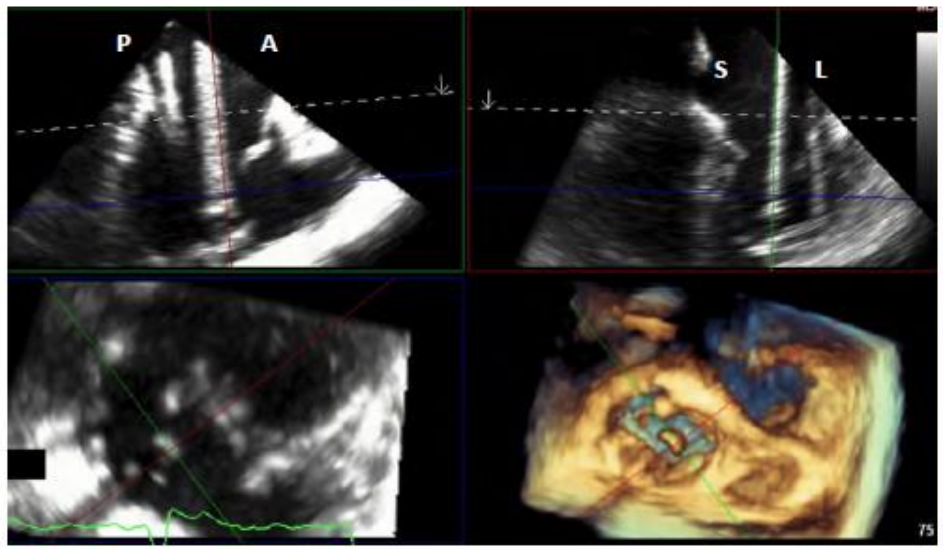


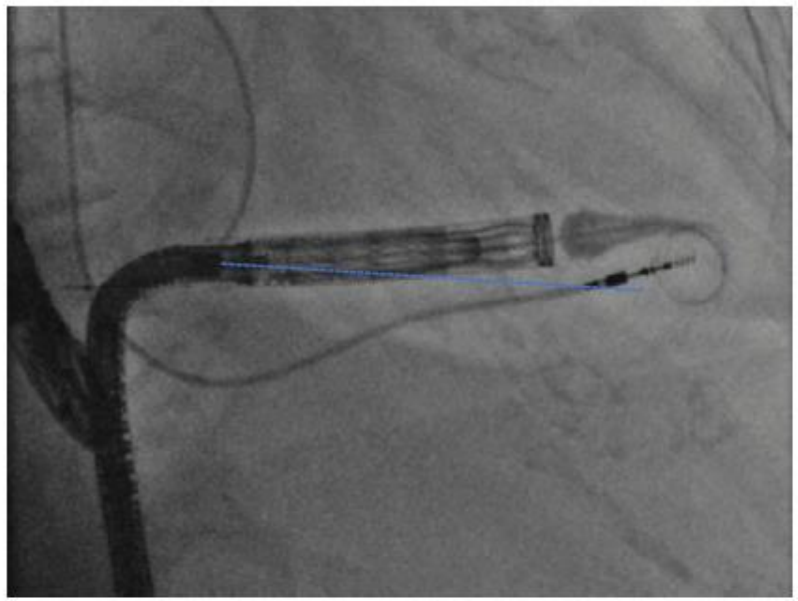
Safari wire advanced on septal side of both RA and RV leads



A combination of LAO and RAO fluoro projections were used to confirm wire positioning in relation to pacing leads

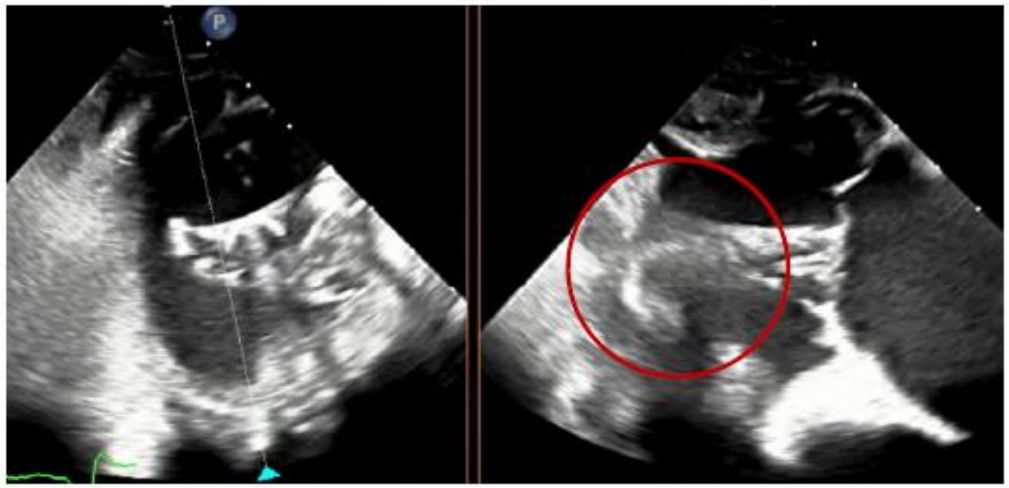
Procedure: Establish depth, position & trajectory



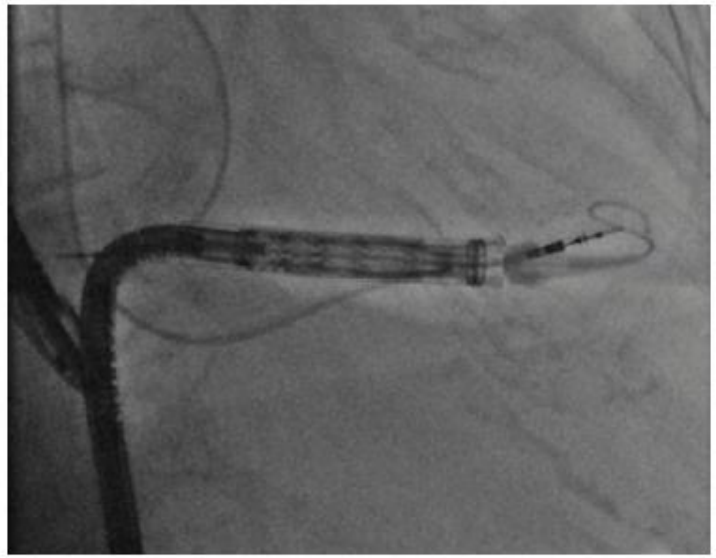


Interaction of the tapered tip with the RV was preventing the capsule from getting coaxial to the TV in A-P.

Procedure: Nose Cone Interaction

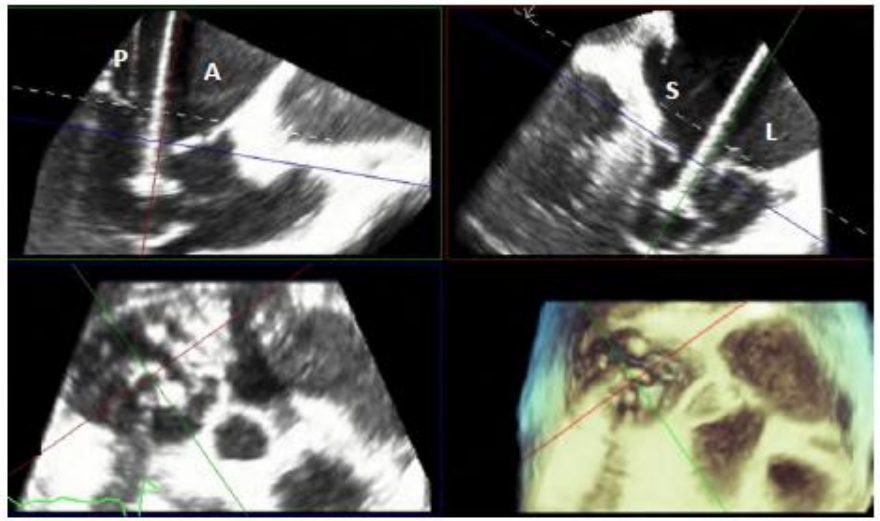


Transgastric views illustrate the interaction of the delivery system with the highly trabeculated RV.

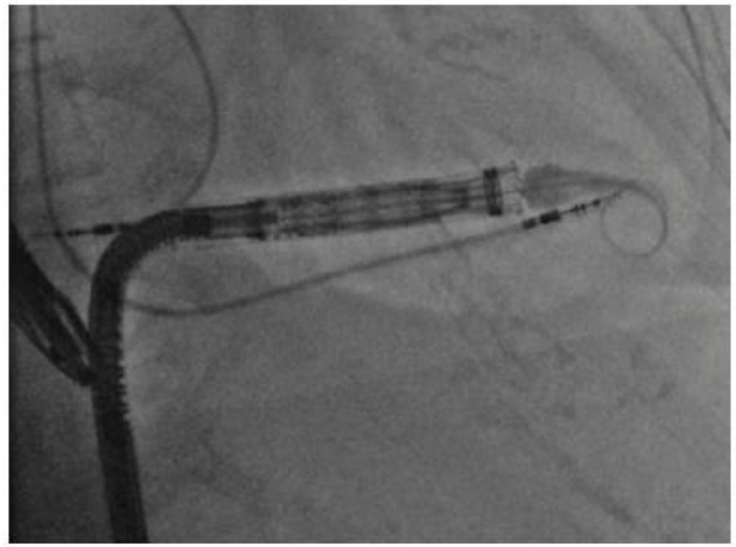


Retraction of the nose cone and slight rotation of the delivery system released the tip of the nose cone from the sub-valvular anatomy.

Enrolled in Early Feasibilty TTVR study

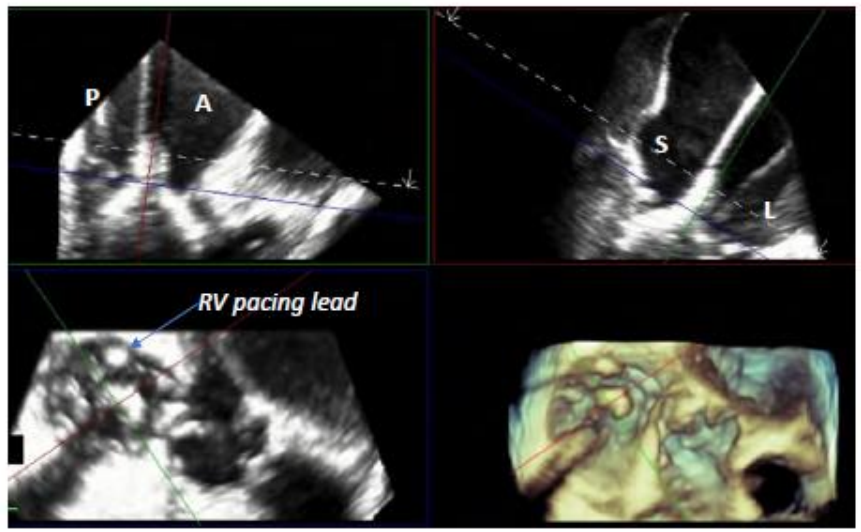


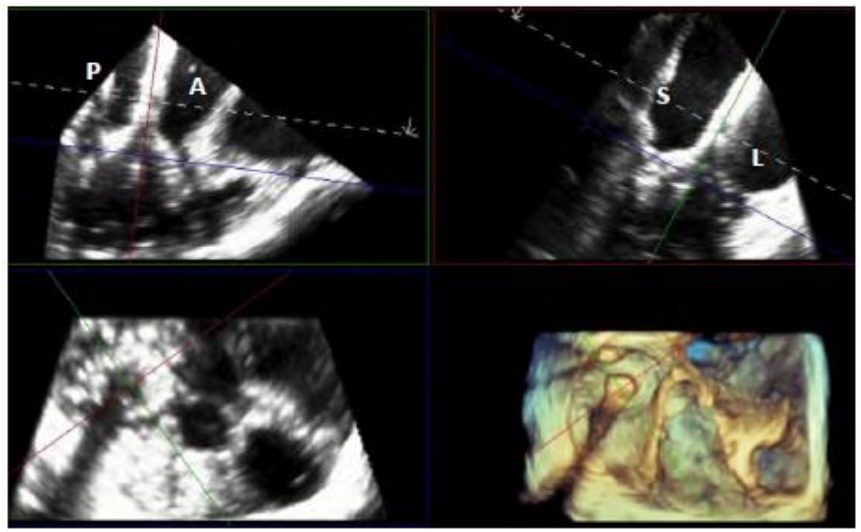
Single Access: Femoral Vein



Device orientated in RV across tricuspid valve

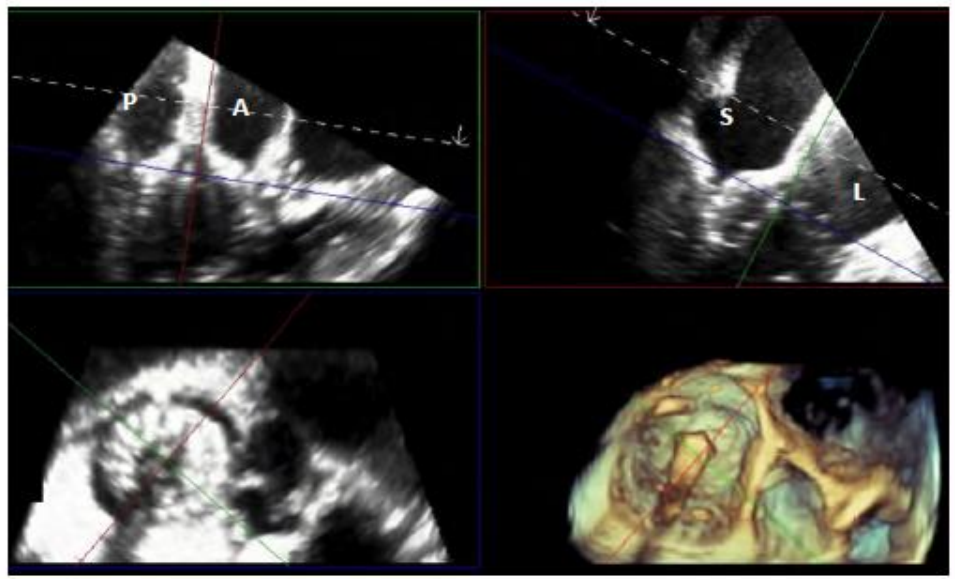
Procedure: Valve Expansion



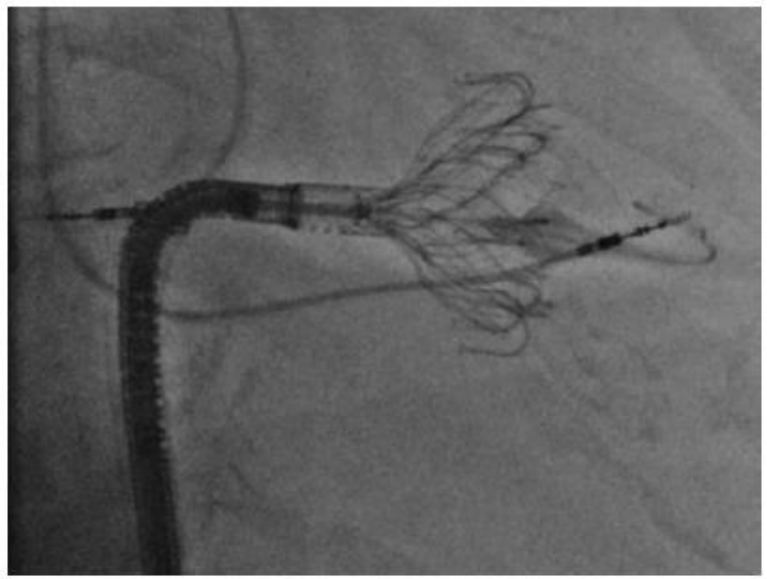


Complete capture of all leaflets/ scallops.
Confirmed RV pacing lead position in posteroseptal commissure, as planned.

Procedure: Valve Release

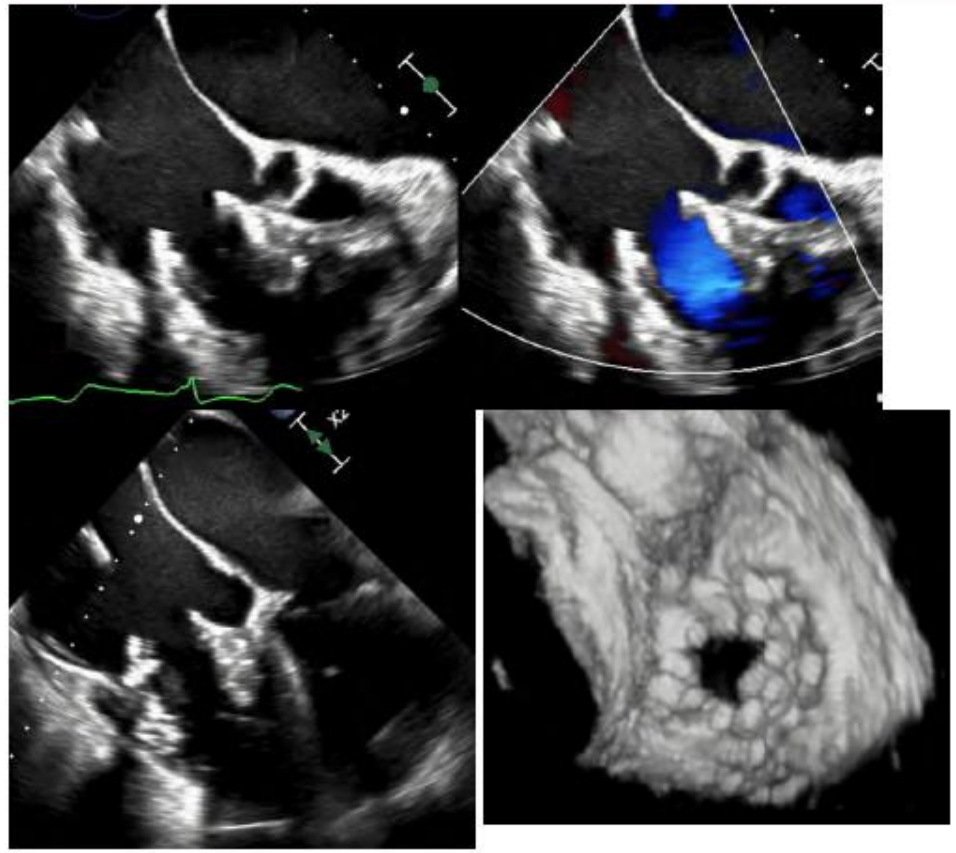


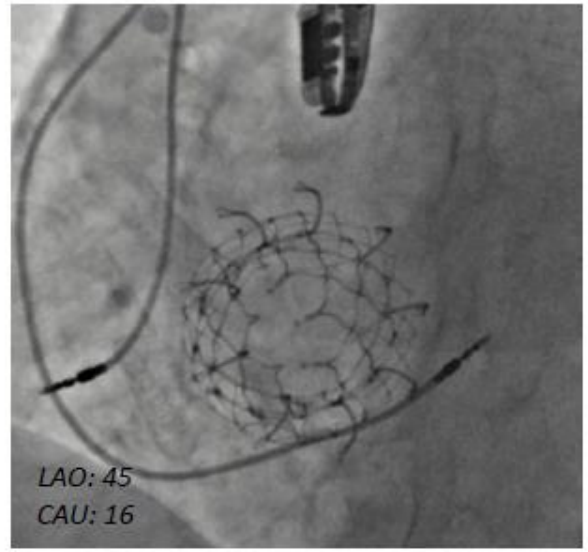
TEE guidance for leaflet capture



Haemodynamic Stability throughout

Procedure: Final Result





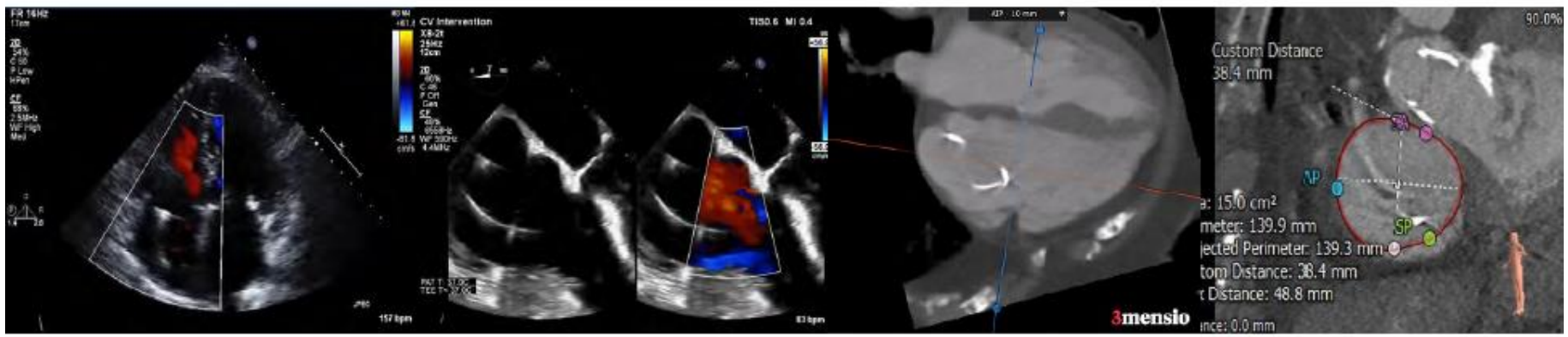
***TR reduction**: Severe to None*

Mean PG 1mmHg

Another Example

91-year-old female with severe functional tricuspid regurgitation

NYHA III Heart Failure Symptoms,
Hx SAVR,
Dual chamber pacemaker,
Hx of DVT s/p IVC filter,
Hypertension

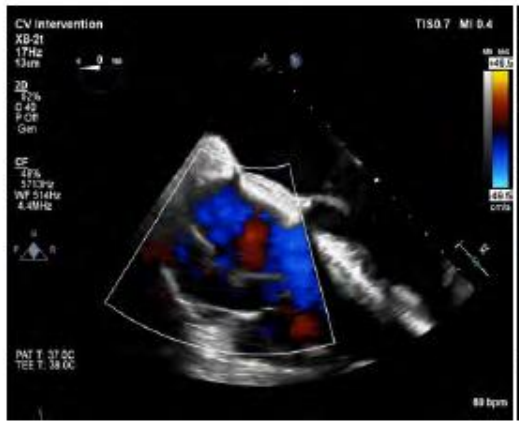


EVOQUE Example 2

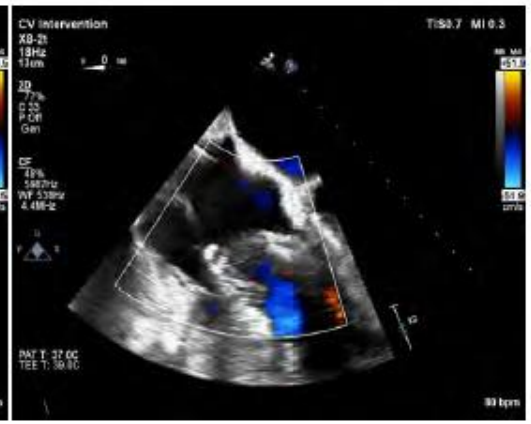
91 year old female with severe functional tricuspid regurgitation

- **treated with 44mm EVOQUE TTVR**
- **NYHA Class III to NYHA Class I**

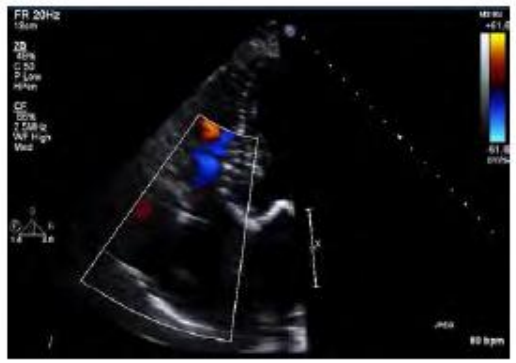
TEE Pre-Procedure

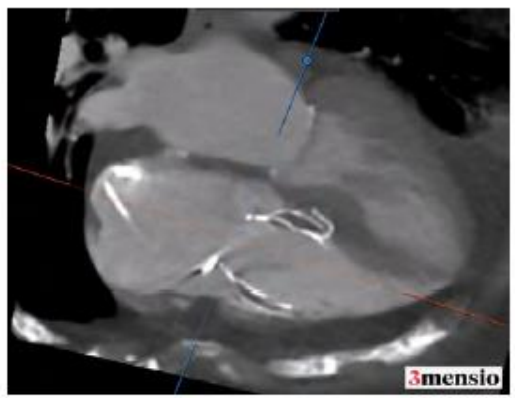


TEE Post-Procedure



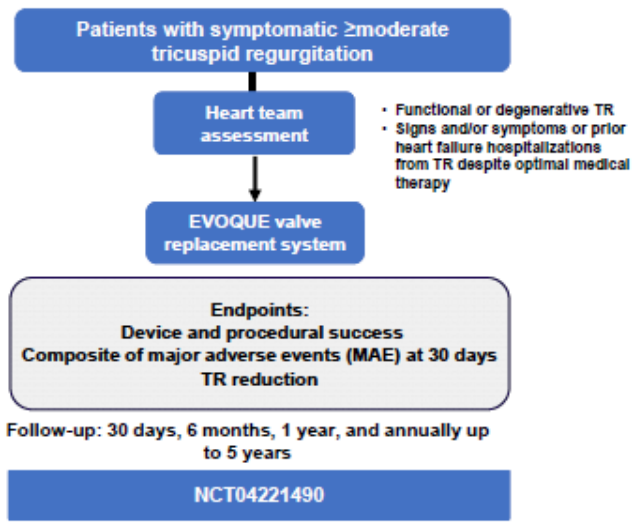
Day 30 Follow-up



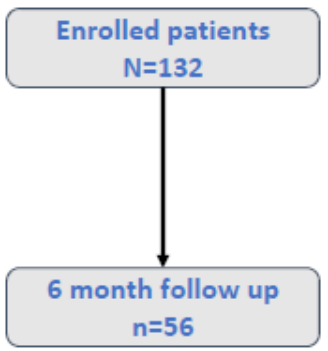


TRISCEND Study – Early Feasibility Results

- Prospective, single-arm, multicenter study
- Purpose: Evaluate the safety and performance of the transfemoral EVOQUE tricuspid valve replacement system in tricuspid regurgitation
- Trial oversight
  - Central screening committee
  - Echocardiographic core laboratory
  - Clinical events committee
  - Data safety monitoring board



TRISCEND Study – Early Feasibility Results



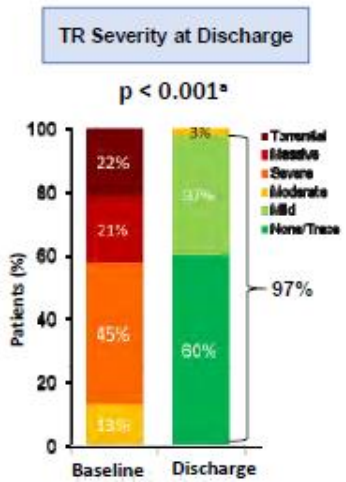
Follow up not due n=29
Pending visit n=27
Missed visit n=10
All-cause mortality n=5
Exited for other reasons n=5

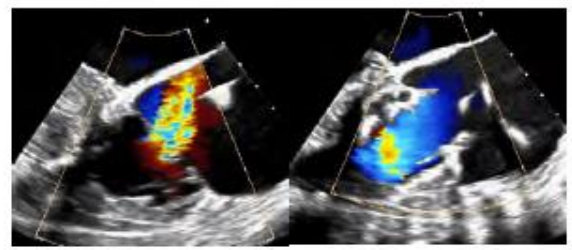
Baseline characteristics	N=132 N (%) or Mean ± SD
Age, years	79.2 ± 7.39
Female	97 (74%)
EuroSCORE II (%)	5.3 ± 4.3
STS score (MV repair)[1]	7.4 ± 5.39
NYHA functional class III or IV	76%
TR grade ≥severe[2]	113 (88%)
Atrial fibrillation	119 (90%)
Pulmonary hypertension (sPAP ≥30 mmHg)	104 (79%)
Diabetes	25 (19%)
Chronic kidney disease	73 (55%)
History of ascites	26 (20%)
Prior stroke	16 (12%)
CABG surgery	26 (20%)
Prior valve surgery/intervention	50 (38%)
Pacemaker or ICD	46 (35%)
TR etiology	
Functional	93 (70.5%)
Degenerative	9 (6.8%)
Mixed/other	30 (22.7%)

[1]n=130 [2]Core lab: Baylor, Scott and White Research Institute; TR regurgitation at baseline available in 129 patients.
CABG, coronary artery bypass graft; ICD, implantable cardioverter defibrillator; NYHA, New York Heart Association; sPAP, systolic pulmonary artery pressure; STS, Society of Thoracic Surgeons; TR, tricuspid regurgitation

TRISCEND Study – Early Feasibility Results

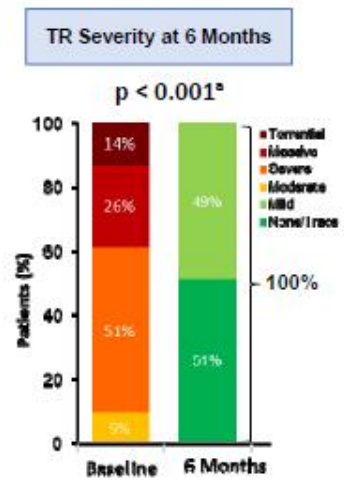
Significant Reduction in TR Severity by Core Lab[1] at 6 Months





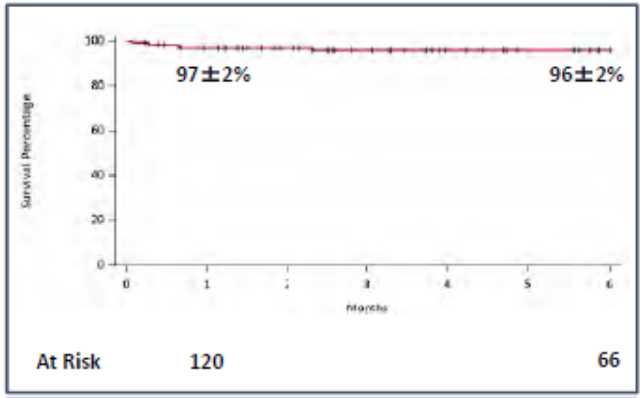
≥1 grade reduction in 100% at discharge and 6 months

≥2 grade reduction in 95% at discharge and 98% at 6 months

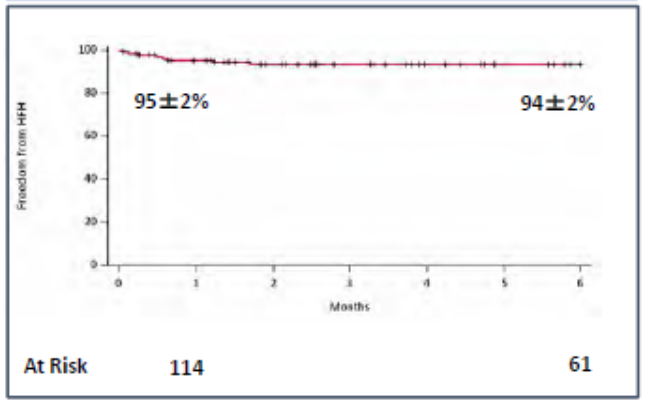


TRISCEND Study – Early Feasibility Results

Survival



Freedom from Heart Failure Hospitalization



Major Adverse Clinical Events

CEC Adjudicated Events	N=124[a] N (%)
Cardiovascular mortality	3 (2.4%)
Myocardial infarction	0 (0%)
Stroke	0 (0%)
Renal complications requiring unplanned dialysis or renal replacement therapy	1 (0.8%)
Severe bleeding[b]	22 (17.7%)
Major access site and vascular complications	2 (1.6%)
Non-elective tricuspid valve re-intervention, percutaneous or surgical	2 (1.6%)
Major cardiac structural complications	1 (0.8%)
Device-related pulmonary embolism	0 (0%)
Composite MAE Rate	23 (18.5%)

81.5% of patients had no MAEs at 30 days

Transcatheter Tricuspid Valve Therapy

- There is renewed interest and focus on the tricuspid valve in the era of transcatheter valve technologies
- There are a number of concepts that have been shown to be feasible with early acceptable safety and efficacy results
- Early experience with dedicated devices to treat TR with valve replacement have encouraging results.
- On-going pivotal studies randomizing against medical therapy are essential to determining efficacy and safety.

Key question: TR is associated with adverse outcomes but does transcatheter correction of TR result in improved clinical outcomes

Transcatheter mitral replacement vs repair?

- **More durable reduction in MR**
  - Residual MR following therapy affects survival
  - Residual MR in MitraFR: 17% had ≥3+ MR at 12 mos
  - Residual MR in COAPT: 31% had ≥2+ MR at 12 mos
- **Fewer anatomic and clinical exclusions**
  - Able to treat small valves, MAC, multiple jets and perforations
  - Some devices able to treat mitral stenosis
  - Exclusions of those considered for COAPT = 58%
- **Reproducible procedural success**
  - Encouraging data with regards to feasibility and safety with a variety of devices

TMVR Devices

Tendyne (Abbott)

M3 (Edwards)

Intrepid (Medtronic)

Tiara (Neovasc)

Cephea (Abbott)

EVOQUE (Edwards)

Highlife

AltaValve

Sapien M3 System

Cedars Sinai
Smidt Heart Institute

Dock Delivery	Valve Delivery	Final Implant
SAPIEN M3 Dock	SAPIEN M3 Valve	
		
SAPIEN M3 Dock Delivery System	Commander Delivery System	
		

Sapien M3 System Deployment

Cedars Sinai
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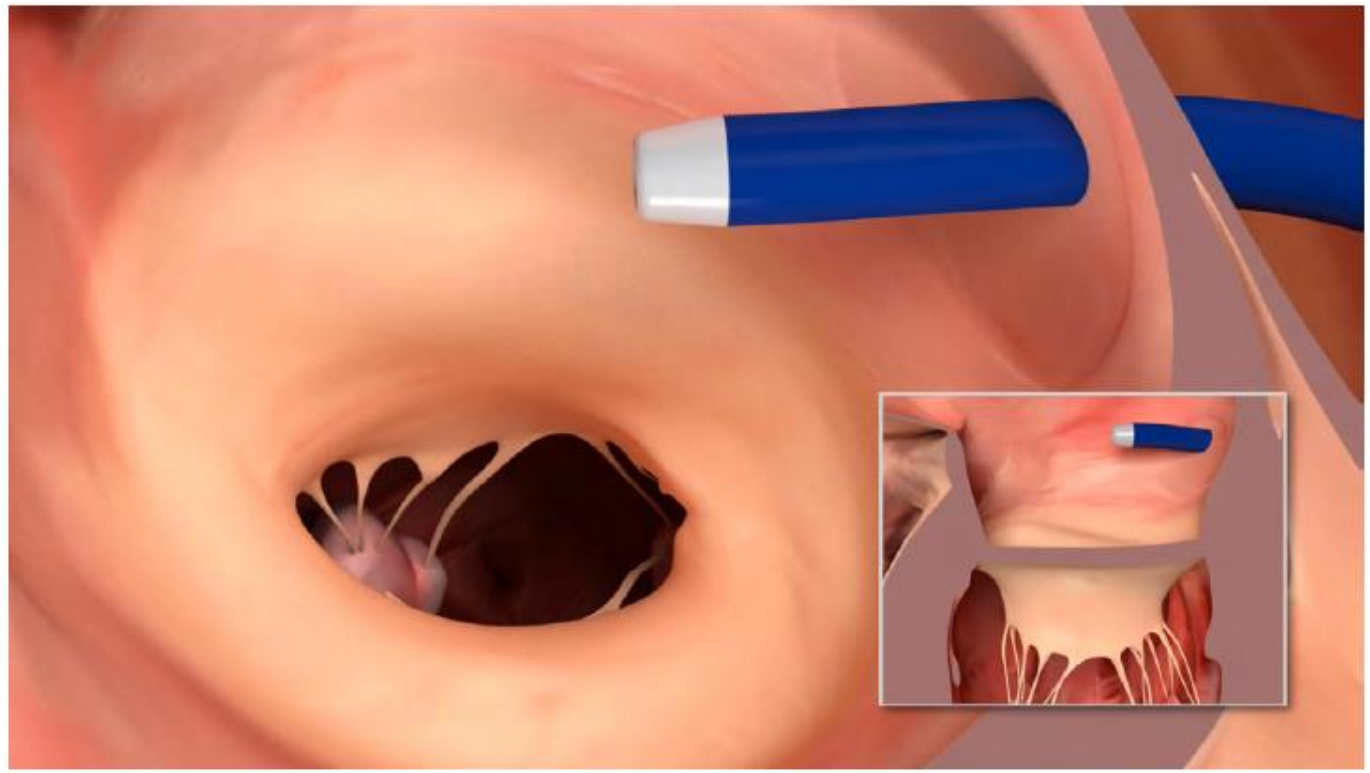


EVOQUE Mitral Valve Replacement System

Cedars Sinai
Smidt Heart Institute

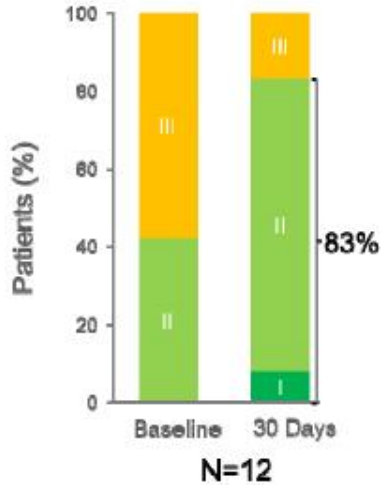
- Unique anchoring mechanism utilizes annulus, leaflets, and chords, respecting the native mitral anatomy
- Intra-annular sealing skirt and frame to minimize PV leak
- Low atrial and ventricular profile to reduce procedural complications
- Integrates Edwards bovine pericardial leaflet design and tissue treatment
- 44 and 48 mm devices compatible with one size delivery system

EVOQUE Mitral Valve Replacement System

Cedars Sinai
Smidt Heart Institute

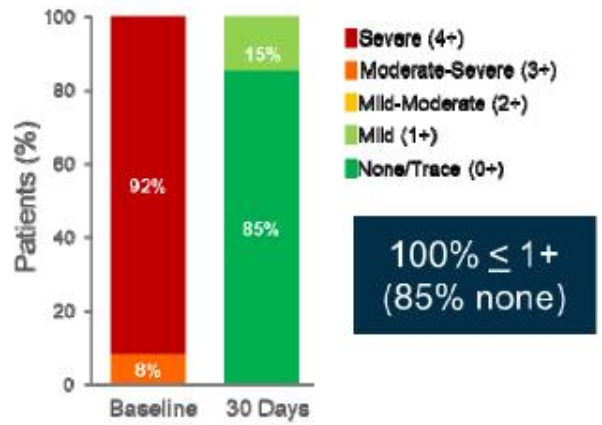
- **30 day clinical and echocardiographic outcomes:**

NYHA class



N=12

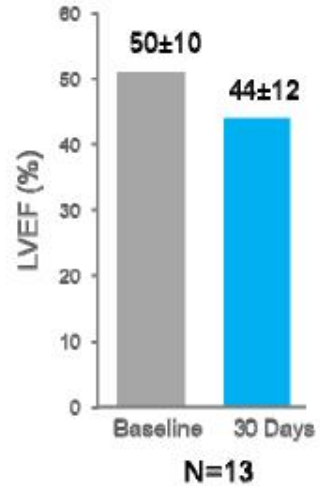
MR severity



100% ≤ 1+
(85% none)

N=13

LVEF

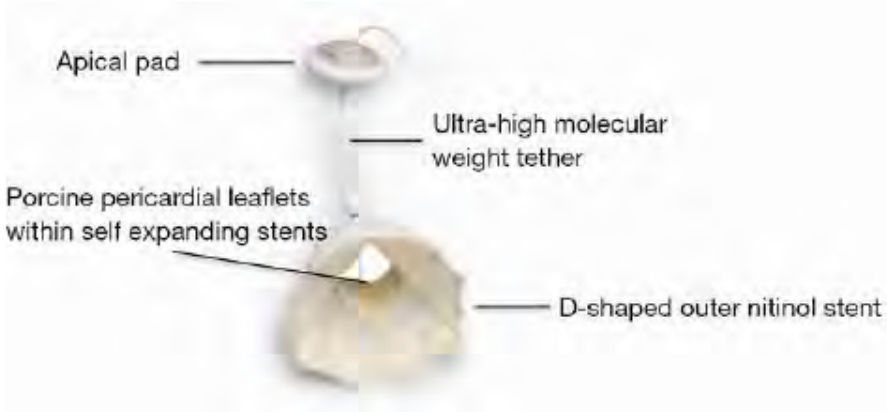


N=13

MISCEND Trial with EVOQUE EoS (NCT 02718001) enrolling

Tendyne: Transapical TMVR

Cedars Sinai
Smidt Heart Institute



Key results of global feasibility trial

- Successful implantation in 93.3% of patients
- Residual MR grade 0 in 27/28 patients
- No LVOT obstruction (gradient <5 mmHg) in any patient
- Mean device placement time 33.2 minutes
- Significant reduction in left ventricular end diastolic volume index at 30 days
- 75% NYHA class I or II symptoms at 30 days

MR, mitral regurgitation; LVOT, left ventricular outflow tract; NYHA, New York Heart Association.

Tendyne: Recent Data

Cedars Sinai
Smidt Heart Institute

The first **100 patients** enrolled:

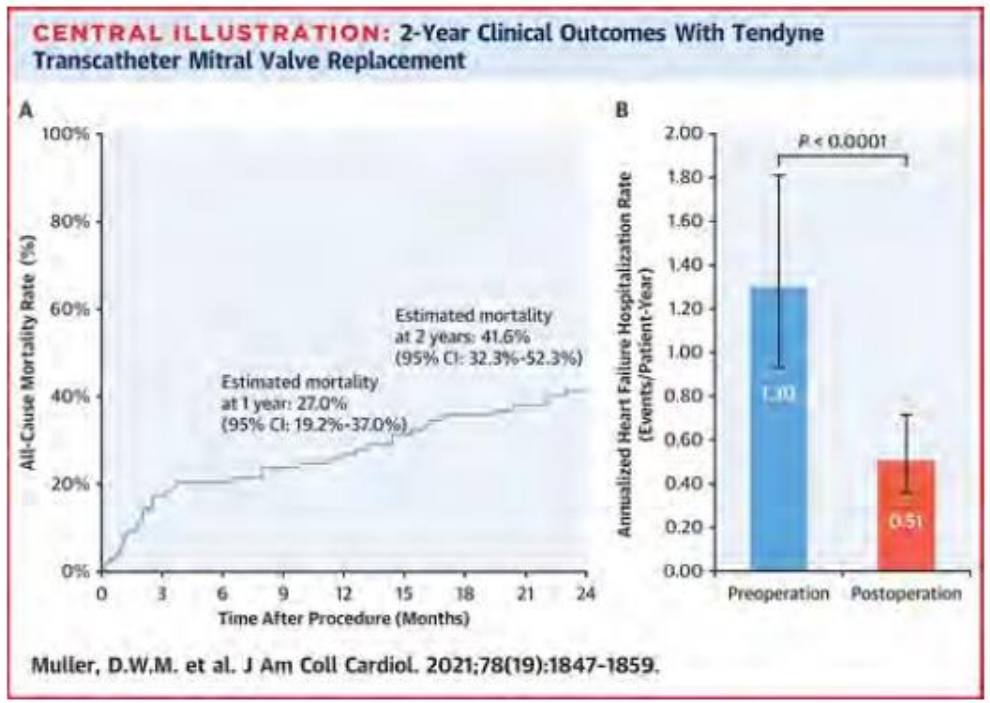
- an open-label
- Nonrandomized study of T-A TMVR,
- 2 year follow-up data

In this study, TMVR achieved:

- Reduction in severity of MR
- reduction in HFH rate
- improvement in symptoms

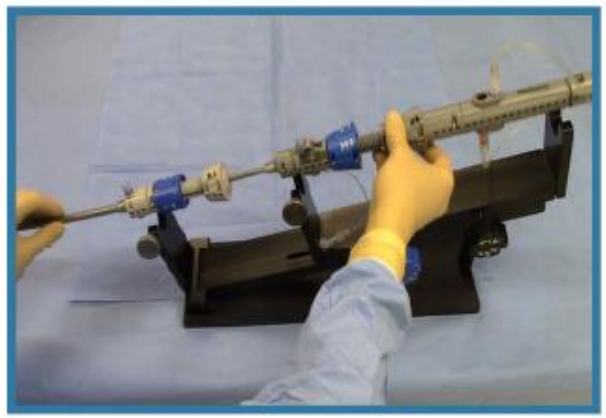
And these results were sustained through 2 years.

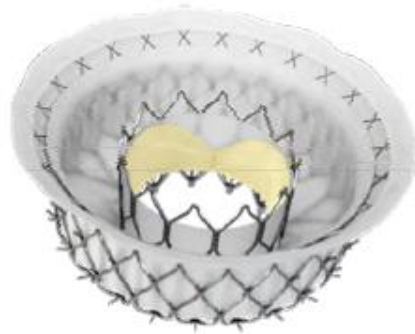
However, all-cause mortality and the need for HFH was highest in the first 3 months postprocedure.



Intrepid TMVR

Cedars Sinai
Smidt Heart Institute





- Conformable Outer Stent engages the annulus and leaflets providing fixation & sealing while isolating the inner stent from the dynamic anatomy
- Circular Inner Stent houses a 27mm tricuspid bovine pericardium valve
- Flexible Brim aids imaging during implantation & subsequent tissue in-growth

Intrepid™ TMVR Early Feasibility Study Results
Functional Outcomes – NYHA Class (n = 15)