Recent Advances in Transcatheter Tricuspid & Mitral Valve Replacement

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Cedars-Sinai Medical Center, Los Angeles
Tricuspid Regurgitation Is Associated With Poor Outcomes

Mortality Increases with TR Severity

Benfari et al. 2019 Circulation; 140: 196-206.
Patients are largely undertreated with surgery

- 1,600,000 moderate to severe TR cases
- 250,000 new TR cases annually
- <8,000 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


J Am Coll Cardiol, 70 (2017), pp. 2953-2960
Highly Prevalent

Poor Prognosis

Limited Therapies

~ 1.6 million Americans with > moderate TR

>50% three-year mortality with > moderate TR

Operative mortality ~ 9%
There is a significant unmet clinical need to find novel therapies for patients with tricuspid regurgitation.
Off-label MitraClip in Tricuspid Valve

- 22-year-old female transferred from OSH with cardiogenic shock
- History of HOCM treated with OHT in 2003
  - Complicated by rejection in 2013
- Severe TR of the transplanted heart due to flail of the tricuspid valve secondary to RV biopsy
- Transferred for consideration of transcatheter therapies
Patient underwent tricuspid valve repair with MitraClip x 2

MitraClip x 2 to the tricuspid valve

Patient successfully weaned from dobutamine and discharged home in 4 days

Final result: Mild-moderate TR
TRILUMINATE Single arm Registry

Essential Results:

- **Mean Age:** 77.8 ± 7.9 years
- **65.9% Female**
- **Implant success rate:** 100%
- **Acute Procedural Success rate:** 90.5%
- **TR reduction of at least 1 grade at 1 Year:** 87%
- **Mean Improvement in KCCQ-OS score of 20 points from baseline to 1 Year:**

- **2.2**
  - On average number of clips used
- **152 min**
  - Average procedure time

At 1 Year, a significantly greater proportion (83%) of subjects were categorized as NYHA class I or II compared to 31% of subjects at baseline.

1. Lurz, Philip MD, PhD as presented at PCR eCourse 2020

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TRILUMINATE Pivotal Study - Trial Overview

Subject has Symptomatic Severe TR and is at intermediate or greater risk of mortality and morbidity with TV Surgery

TR Severity Confirmed by the Echo Core Laboratory

Subject Meets all Inclusion/Exclusion Criteria and the Eligibility Committee Confirms that the Tricuspid Valve Anatomy is Suitable for TR Reduction by TriClip™

Eligibility Committee Determines that TR can be Reduced to Moderate or Less

Randomization (1:1) (N=450)

TriClip Device (Device)  Medical Therapy (Control)

NO  YES

Exclude Subject  YES

Single Arm (N=100)

TriClip Device (Device)

NO

Exclude Subject

YES

Principal Investigators:
Dr. David Adams (Mt.Sinai)
Dr. Paul Sorajja (Abbott Northwestern)
Transcatheter Tricuspid Valve Replacement

Devices with FIM experience

Navigate  Lux  Intrepid  Evoque
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

90% Diastole

30% Systole
Enrolled in Early Feasibility TTVR study

Single Access: Femoral Vein

Device orientated in RV across tricuspid valve
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
91 year old female with severe functional tricuspid regurgitation
- treated with 44mm EVOQUE TTVR
- NYHA Class III to NYHA Class I
• 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
TRISCEND Study – Early Feasibility Results

<table>
<thead>
<tr>
<th>Baseline characteristics</th>
<th>N=132</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N (%) or Mean ± SD</td>
</tr>
<tr>
<td>Age, years</td>
<td>79.2 ± 7.39</td>
</tr>
<tr>
<td>Female</td>
<td>97 (74%)</td>
</tr>
<tr>
<td>EuroSCORE II (%)</td>
<td>5.3 ± 4.3</td>
</tr>
<tr>
<td>STS score (MV repair)²</td>
<td>7.4 ± 5.39</td>
</tr>
<tr>
<td>NYHA functional class III or IV</td>
<td>76%</td>
</tr>
<tr>
<td>TR grade ≥severe²</td>
<td>113 (88%)</td>
</tr>
<tr>
<td>Atrial fibrillation</td>
<td>119 (90%)</td>
</tr>
<tr>
<td>Pulmonary hypertension (sPAP ≥30 mmHg)</td>
<td>104 (79%)</td>
</tr>
<tr>
<td>Diabetes</td>
<td>25 (19%)</td>
</tr>
<tr>
<td>Chronic kidney disease</td>
<td>73 (55%)</td>
</tr>
<tr>
<td>History of ascites</td>
<td>26 (20%)</td>
</tr>
<tr>
<td>Prior stroke</td>
<td>16 (12%)</td>
</tr>
<tr>
<td>CABG surgery</td>
<td>26 (20%)</td>
</tr>
<tr>
<td>Prior valve surgery/intervention</td>
<td>50 (38%)</td>
</tr>
<tr>
<td>Pacemaker or ICD</td>
<td>46 (35%)</td>
</tr>
<tr>
<td>TR etiology</td>
<td></td>
</tr>
<tr>
<td>Functional</td>
<td>93 (70.5%)</td>
</tr>
<tr>
<td>Degenerative</td>
<td>9 (6.8%)</td>
</tr>
<tr>
<td>Mixed/other</td>
<td>30 (22.7%)</td>
</tr>
</tbody>
</table>

Enrolled patients N=132

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

Follow up n=56

1²n=130³Core 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
## Procedural Characteristics

<table>
<thead>
<tr>
<th></th>
<th>n/N (%) or Mean ± SD (N)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Percutaneous</td>
<td></td>
</tr>
<tr>
<td>• Right femoral vein access</td>
<td>132/132 (100%)</td>
</tr>
<tr>
<td>• Left femoral vein access</td>
<td>125/132 (94.7%)</td>
</tr>
<tr>
<td>Device success (per device)*</td>
<td>7/132 (5.3%)</td>
</tr>
<tr>
<td></td>
<td>128/133 (96.2%)</td>
</tr>
<tr>
<td>Device time (implant insertion to release), mins</td>
<td>72.8 ± 28.15 (130)</td>
</tr>
</tbody>
</table>

## Hospital Disposition

<table>
<thead>
<tr>
<th></th>
<th>n/N (%) or Median (Min,Max)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Length of Stay (days)</td>
<td>3 (0,35)</td>
</tr>
<tr>
<td>Discharge Location</td>
<td></td>
</tr>
<tr>
<td>Home</td>
<td>114/129 (88.4%)</td>
</tr>
<tr>
<td>Home with Services</td>
<td>6/129 (4.7%)</td>
</tr>
<tr>
<td>Skilled Nursing Facility</td>
<td>6/129 (4.7%)</td>
</tr>
<tr>
<td>Other</td>
<td>3/129 (2.4%)</td>
</tr>
</tbody>
</table>
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**

- 97 ± 2%
- 96 ± 2%

**At Risk**

<table>
<thead>
<tr>
<th>Months</th>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
</tr>
</thead>
<tbody>
<tr>
<td>N=120</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Freedom from Heart Failure Hospitalization**

- 95 ± 2%
- 94 ± 2%

**At Risk**

<table>
<thead>
<tr>
<th>Months</th>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
</tr>
</thead>
<tbody>
<tr>
<td>N=114</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Major Adverse Clinical Events**

<table>
<thead>
<tr>
<th>Event</th>
<th>N=124a N (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cardiovascular mortality</td>
<td>3 (2.4%)</td>
</tr>
<tr>
<td>Myocardial infarction</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>Stroke</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>Renal complications requiring unplanned dialysis or renal replacement therapy</td>
<td>1 (0.8%)</td>
</tr>
<tr>
<td>Severe bleeding b</td>
<td>22 (17.7%)</td>
</tr>
<tr>
<td>Major access site and vascular complications</td>
<td>2 (1.6%)</td>
</tr>
<tr>
<td>Non-elective tricuspid valve re-intervention, percutaneous or surgical</td>
<td>2 (1.6%)</td>
</tr>
<tr>
<td>Major cardiac structural complications</td>
<td>1 (0.8%)</td>
</tr>
<tr>
<td>Device-related pulmonary embolism</td>
<td>0 (0%)</td>
</tr>
<tr>
<td><strong>Composite MAE Rate</strong></td>
<td>23 (18.5%)</td>
</tr>
</tbody>
</table>

81.5% of patients had no MAEs at 30 days
TRISCEND Study – Early Feasibility Results

Significantly Improved Functional and Quality of Life Outcomes at 6 Months

NYHA Class

<table>
<thead>
<tr>
<th>NYHA Class</th>
<th>Baseline n=53</th>
<th>6 Months</th>
<th>Patients (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>8%</td>
<td>17%</td>
<td>25%</td>
</tr>
<tr>
<td>II</td>
<td>46%</td>
<td>56%</td>
<td>19%</td>
</tr>
<tr>
<td>III</td>
<td>37%</td>
<td>28%</td>
<td>2%</td>
</tr>
</tbody>
</table>

p < 0.001a

6MWD

<table>
<thead>
<tr>
<th>6MWD - Distance Walked (m)</th>
<th>Baseline n=53</th>
<th>6 Months</th>
<th>Δ=56 m</th>
</tr>
</thead>
<tbody>
<tr>
<td>199.5 ± 123.4</td>
<td>255.8 ± 109.9</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

p < 0.001b

KCCQ Score

<table>
<thead>
<tr>
<th>KCCQ - Overall Score</th>
<th>Baseline n=53</th>
<th>6 Months</th>
<th>Δ=27 points</th>
</tr>
</thead>
<tbody>
<tr>
<td>48.6 ± 22.8</td>
<td>75.6 ± 20.8</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Data are presented as Mean ± SD, 95% CI by normal approximation. *Wilcoxon signed-rank test; bPaired t-test.
NYHA Class, New York Heart Association functional classification; 6MWD, 6-minute walk distance;
KCCQ, Kansas City Cardiomyopathy Questionnaire
On-going: TRISCEND Pivotal Study

Edwards EVOQUE Transcatheter Tricuspid Valve Replacement: Pivotal Clinical Investigation of Safety and Clinical Efficacy Using a Novel Device

Prospective, multicenter, randomized, controlled pivotal trial

Inclusion Criteria:
- Age ≥ 18 years
- Symptomatic TR despite optimal medical therapy
- TR graded as ≥ severe
- Patient appropriate for transcatheter tricuspid valve replacement per the local heart team

Primary Endpoints:
- MAE rate at 30 days
- TR grade reduction to ≤ moderate along with hierarchical composite endpoint including KCCQ, NYHA, and 6MWD improvement at 6 months
- Hierarchical composite endpoint including all-cause mortality, RVAD implantation or heart transplant, tricuspid valve intervention, heart failure hospitalizations, and improvements in KCCQ, NYHA, and 6MWD at 1 year

Follow-up: discharge, 30 days, 3 months, 6 months, 1 year, and annually through 5 years

Clinicaltrials.gov NCT04482062
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
CHOICE-MI

The CHOICE of Optimal transCatheter trEatment for Mitral Insufficiency Registry
- investigator-initiated
- multicentre
- international
- retrospective
- device-independent
- 05/2014 – 03/2021

Baseline characteristics (clinical, echo, CT)
- PMR
- SMR
- Mixed PMR/SMR
- MAC

MVARC criteria
Clinical / echo outcome at 30-days and 1-year

Primary composite outcome: 1-year all-cause mortality or heart failure hospitalisation

CHOICE-MI inclusion criteria:
- significant MR
- unsuitable for standard therapy
  - high risk for surgery
  - suboptimal TEER anatomy
- screening for TMVI
TA-TMVI 89.2%, TS-TMVI 10.8%

**MVARC 30-day outcomes**

Technical success 95.2%
Procedural mortality 1.8%
30-day mortality 9.9%

LVOT obstruction 3.2%
Valve malposition 3.7%
Conversion to surgery 2.8%
Access site complications 9.6%
Reintervention for bleeding 7.5%
Disabling stroke 3.1%
AKI 15.4%

Median follow-up time 1.94 (1.53-2.11) years

Primary composite endpoint of **1-year** all-cause mortality or HF hospitalization 39.2%
[no difference primary MR (44.1%), secondary MR (39.1%), mixed MR (20.0%) (p=0.68)]
CHOICE-MI

Echocardiographic outcome

At discharge, MR eliminated (residual MR <1+) in 83.9% patients treated with TMVI

At 1-year, MR eliminated (residual MR <1+) in 72.2% patients treated with TMVI
CHOICE-MI

• Global Multicentre Registry of patients at high surgical risk with severe mitral valve disease
• 229 patients treated with 10 devices
  • 90% transapical access
• High technical success and low procedural mortality
  • But higher 30 day mortality
• Excellent sustained reduction in mitral regurgitation
• Transcatheter mitral valve implantation is a reasonable alternative for patients unsuitable for standard therapies.
Sapien M3 System

Dock Delivery
SAPIEN M3 Dock Delivery System

Valve Delivery
SAPIEN M3 Valve

Final Implant
Commander Delivery System
Sapien M3 System Deployment
60-year-old male referred for percutaneous treatment of mitral regurgitation

Severe Mitral regurgitation
EF 30%

Severe restriction of posterior mitral leaflet

Severe central MR
Sapien M3 System

60-year-old male referred for percutaneous treatment of mitral regurgitation

Dock deployed, under TEE guidance

Dock deployment

Positioning of the Dock outside the mitral chords confirmed with TEE

Turn # 1

Turn # 2

Turn # 3
Sapien M3 System

60-year-old male referred for percutaneous treatment of mitral regurgitation treated with a SAPIEN M3 system
### Sapien M3 System

<table>
<thead>
<tr>
<th>Primary Endpoint</th>
<th>CU (N=10) % (n/N)</th>
<th>EFS (N=35) % (n/N)</th>
<th>Total (N=45) % (n/N)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Technical Success</strong></td>
<td>90 (9/10)</td>
<td>88.6 (31/35)</td>
<td>88.9 (40/45)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Adverse Events</th>
<th>CU (N=10) n (%)</th>
<th>EFS (N=35) n (%)</th>
<th>Total (N=45) n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>All-cause mortality</td>
<td>0 (0)</td>
<td>1 (2.9)</td>
<td>1 (2.2)</td>
</tr>
<tr>
<td>All stroke</td>
<td>0 (0)</td>
<td>3 (8.6)</td>
<td>3 (6.7)</td>
</tr>
<tr>
<td>MI</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>LVOT obstruction</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Device migration, embolization, or fracture</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Mitral valve surgery</td>
<td>0 (0)</td>
<td>1 (2.9)</td>
<td>1 (2.2)</td>
</tr>
</tbody>
</table>
## Sapien M3: ENCIRCLE High-Risk Trial Design

<table>
<thead>
<tr>
<th><strong>Objective</strong></th>
<th>To establish the safety and effectiveness of the SAPIEN M3 System in patients with mitral regurgitation who are at high surgical risk</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Study Device</strong></td>
<td>Edwards SAPIEN M3 System</td>
</tr>
<tr>
<td><strong>Study Design</strong></td>
<td>Prospective, single-arm, multicenter study in 250 patients Up to 100 additional subjects who had an attempted but failed MitraClip procedure will be enrolled in a separate registry</td>
</tr>
<tr>
<td><strong>Primary Endpoint</strong></td>
<td>Non-hierarchical composite of death and heart failure rehospitalization at 1 Year</td>
</tr>
</tbody>
</table>
EVOQUE Mitral Valve Replacement System

• 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

<table>
<thead>
<tr>
<th></th>
<th>N=14</th>
<th>% or Mean ± SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Procedure Success¹</td>
<td></td>
<td>93% (13/14)</td>
</tr>
<tr>
<td>Procedure Time, mins</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Skin-to-Skin</td>
<td></td>
<td>187 ± 51</td>
</tr>
<tr>
<td>Device Insertion-To-Deployment</td>
<td></td>
<td>59 ± 27</td>
</tr>
<tr>
<td>Device Embolization</td>
<td></td>
<td>0%</td>
</tr>
<tr>
<td>Post-implant MR Severity ≤ 1+</td>
<td></td>
<td>100%</td>
</tr>
</tbody>
</table>

Webb et al, JACC CV Intv 2020;13:2418
EVOQUE Mitral Valve Replacement System

- 30 day clinical and echocardiographic outcomes:

**NYHA class**

- Baseline: 83% in NYHA class III, 17% in NYHA class II, 0% in NYHA class I
- 30 Days: 100% in NYHA class II, 0% in NYHA class III, 0% in NYHA class I

**MR severity**

- Baseline: 92% in Severe (4+), 8% in Moderate-Severe (3+)
- 30 Days: 15% in Severe (4+), 85% in None/Trace (0+)

**LVEF**

- Baseline: 50±10%
- 30 Days: 44±12%

MISCEND Trial with EVOQUE EoS (NCT 02718001) enrolling
Next Generation: EVOQUE Eos Mitral Valve

Goal: Achieve secure placement and reduce risk of LVOT obstruction

Atrial Shoulders
Enable valve positioning

Nitinol Frame
Conforms to mitral annulus

Anchors
Engage leaflets and native anatomy

Made with RESILIA Tissue
Edwards latest tissue technology

Available in 44, 48mm sizes
Allows treatment of a wide range of annulus sizes

CAUTION: Investigational device. Limited by Federal (or United States) law to investigational use.
Transcatheter Mitral Valve Replacement - Eos

Recorded Case Available on TCT 2021

Structural Heart Disease #11
Cedars-Sinai Medical Center, Los Angeles, CA
https://tct2021.crfconnect.com/channels
Tendyne: Transapical TMVR

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: Case Example

76-year-old female with severe MR with a history of chest wall radiation. She referred for percutaneous treatment of mitral regurgitation

Moderate MAC -- Mild mitral stenosis – PG 17.4mmHg / MG 7mmHg -- Severe mitral regurgitation

CT Suitable for TMVR with the Tendyne System
Tendyne: Case Example

76-year-old female with severe MR with a history of chest wall radiation. She referred for percutaneous treatment of mitral regurgitation.

Transapical access / TEE Guidance
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

• **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 – Transapical Delivery

50 patients undergoing TMVR with Medtronic Intrepid valve

Device implant success = 98%
No device malfunction or thrombosis
30-day mortality = 14%
Mild or no residual MR in all patients
Symptom improvement in follow-up = 79%

Intrepid™ TMVR Transeptal System

Intrepid™ TMVR Delivery System

- Transfemoral access with dilator and 35-Fr sheath
- Cradle and delivery catheter with familiar transeptal MV maneuvers
### Intrepid™ TMVR Early Feasibility Study Results

#### 30 Day Echocardiographic Outcomes (n = 15)

<table>
<thead>
<tr>
<th>Condition</th>
<th>Baseline</th>
<th>Discharge</th>
<th>30 Days</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Mitral Regurgitation</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>None/Trace</td>
<td>64%</td>
<td>36%</td>
<td>0%</td>
</tr>
<tr>
<td>Mild</td>
<td>21%</td>
<td>79%</td>
<td>100%</td>
</tr>
<tr>
<td>Moderate</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Moderate-Severe</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Severe</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

| **Paravalvular Leak**      |          |           |         |
| None/Trace                 | 7%       | 0%        | 100%    |
| Mild                       | 93%      | 60%       | 40%     |
| Moderate                   |          |           |         |
| Moderate-Severe            |          |           |         |
| Severe                     |          |           |         |

Core lab adjudicated. Data reported on implanted cohort.
Intrepid™ TMVR Early Feasibility Study Results
Functional Outcomes – NYHA Class (n = 15)

- Baseline:
  - NYHA IV: 7%
  - NYHA III: 60%
  - NYHA II: 33%
  - NYHA I: 0%

- 30 Days:
  - NYHA IV: 14%
  - NYHA III: 57%
  - NYHA II: 29%
  - NYHA I: 0%
Putting it all together

60-year-old female with severe mitral regurgitation
- Deemed not a surgical candidate
- Considered for TMVR

NYHA Class III,
Congestive Heart Failure
Atrial Fibrillation
Obesity (previously 400lbs)
Severe PAH
M-Dock Procedure for Mitral Regurgitation

Pre-procedure

Post-Procedure
Excellent symptomatic response 1 year later returns with peripheral oedema
- No MR but severe functional TR

NYHA Class III,
Severe MR s/p MVR with SM3 device
Congestive Heart Failure
A-fib on Eliquis
Severe PAH
61-year-old female with severe functional TR - Treated with 48mm EVOQUE TTVR
Thank You