# Transcatheter Mitral Valve Replacement
## *Devices and Data*

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# Disclosure

**Consultant:** **Edwards Lifesciences**

**JC Medical Inc.**

# Transcatheter Mitral Valves in Humans

**Edwards CardiAQ**
**FIH June 12, 2012**

**Abbott Tendyne**
**FIH February 2013**

**Neovasc Tiara**
**FIH January 2014**

**Edwards Fortis**
**FIH March 2014**

**Medtronic Intrepid**
**FIM September 2014**

**NaviGate**
**FIM October 2015**

**HighLife**
**FIH 2016**

**Caisson**
**FIM 2016**

# TMVR Technologies

**TABLE 2** TMVR Technologies Under Clinical Evaluation

| | CardiAQ-Edwards | Neovasc Tiara | Tendyne | Intrepid TMVR |
|---|---|---|---|---|
| Valve shape | Circular | D-shaped | D-shaped (outer stent)<br>Circular (inner frame) | Circular |
| Frame | Nitinol, self-expandable | Nitinol, self-expandable | Nitinol, double frame;<br>Self-expandable | Nitinol, double stent;<br>Self-expandable |
| Anchoring mechanism | Mitral annulus capture with native leaflet engagement | Fibrous trigone capture with native leaflet engagement | Apical tether | Radial force and subannular cleats |
| Leaflets | Trileaflet<br>Bovine pericardium | Trileaflet<br>Bovine pericardium | Trileaflet<br>Porcine pericardium | Trileaflet<br>Bovine pericardium |
| Valve position | Supra-annular | Intra-annular | Intra-annular | Intra-annular |
| Access | Transapical<br>Transseptal | Transapical | Transapical | Transapical |
| Delivery system size | 33-F | 32-F | 36-F | 35-F |
| Recapture | No | No | Fully recapturable system after complete deployment | No |
| Valve size(s) | 30 mm | 35 mm and 40 mm | Outer frame ranges from 30–43 mm in the SL dimension and 34-50 mm in the IC dimension | 27 mm with 3 outer stent sizes (43, 46, and 50 mm) |
| Additional features | Supra-annular position<br>Intra-annular sealing skirt<br>Tapered outflow | 2 anterior and 1 posterior anchoring structures | Single inner valve size; Multiple outer frame sizes | Dual stent design; Outer frame provides fixation and isolates the inner stent |

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# TMVR Technologies

**TABLE 2 Continued**

| | Caisson | HighLife TMVR | MValve system | NCSI NaviGate Mitral |
|---|---|---|---|---|
| Valve shape | D-shape | Circular | - | Circular |
| Frame | 2 components (anchor and valve); Nitinol, self-expandable. | 2 components (ring and valve); Nitinol, self-expandable | Dock system to be used with commercially available valves | Nitinol, self-expandable; Xenogeneic pericardium |
| Anchoring mechanism | External anchor; Mitral annulus capture with engagement at subannular fibrous groove | External anchor; Valve in subannular mitral ring | External anchor; Mitral annulus capture | Annular winglets |
| Leaflets | Trileaflet Porcine pericardium | Trileaflet Bovine pericardium | - | Trileaflet |
| Valve position | Supra-annular | | - | |
| Access | Transseptal | Transapical (Transfemoral artery for loop placement) | Transapical | Transapical, transatrial or transfemoral |
| Delivery system size | 31-F | NA | 32-F | 30-F |
| Recapture | Fully recapturable and retrievable | No | Fully retrievable | NA |
| Valve size(s) | 35-40 mm | 31 mm | NA | Inflow/outflow: 30 mm/36 mm; 30 mm/40 mm; 33 mm/44 mm |
| Additional features | SAM Management feature 1 delivery catheter for each system (anchor and valve) | NA | Universal dock system | NA |

IC = intercommissural; NA = not available; SAM = systolic anterior motion of the mitral valve; SL = septal-lateral; TMVR = transcatheter mitral valve replacement.

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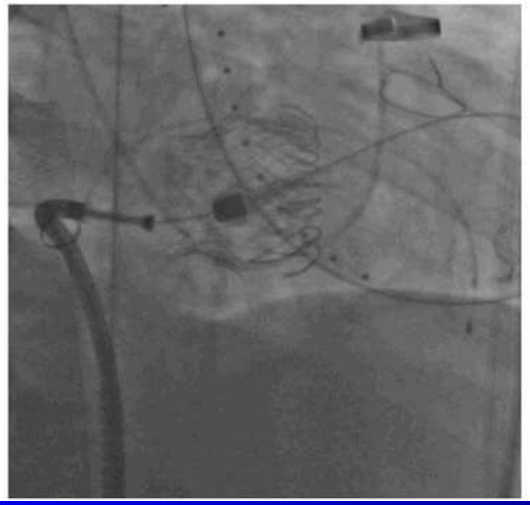
# MR Target and Approach

| Valve | MR Target | Approach | Current Status |
|---|---|---|---|
| Tendyne | Secondary | TA | CE Trial, US EFS |
| Tiara | Primary/Secondary | TA | CE Trial, US EFS |
| CardiaQ | Primary/Secondary | TA, TF | CE Trial, US EFS |
| Twelve | Secondary | TA | OUS EFS |
| Fortis | Secondary | TA | OUS EFS halted |
| MValve | Primary/Secondary | TA | OUS EFS |
| Cephea | Secondary | TF | In Development |
| Cardiovalve | Secondary | TF | In Development |
| MitrAssist | Primary/Secondary | TA | In Development |
| HghLife MVR | Secondary | TA, TF | In Development |
| MitraCath | Secondary | TA | In Development |
| EndoValve | Secondary | TF | In Development |
| Navigate TMVR | Secondary | TA, TF | In Development |

# CardiAQ-Edwards Valve

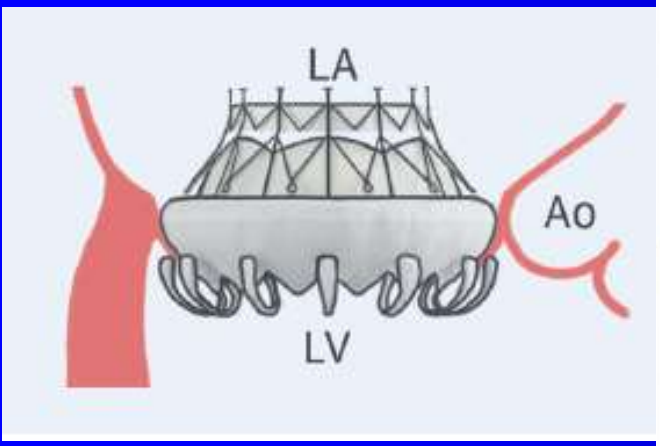


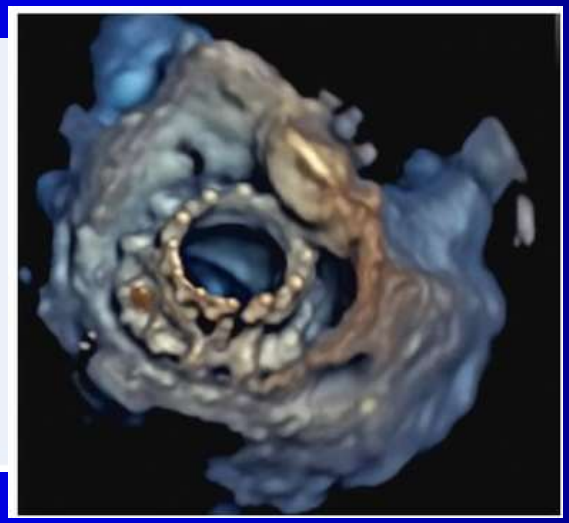
**Transseptal & transapical**

**FIM in 2012**

**N=13**

| Procedural and 30-day data | |
|---|---|
| Technical success | 12/13 (92.3) |
| Valve dislocation/embolization | NA |
| Conversion to open-heart surgery | NA |
| Post-procedural ≥ moderate MR | NA |
| LVOT obstruction | NA |
| Procedural mortality | 2/13 (15.4) |
| 30-day moderate or severe MR | NA |
| All-cause 30-day mortality | 7/13 (53.8) |
| **Follow-up** | |
| Follow-up, months | NA |
| MR ≥ moderate | NA |
| NYHA functional class ≥III | NA |
| Mortality | 7/13 (53.8) |



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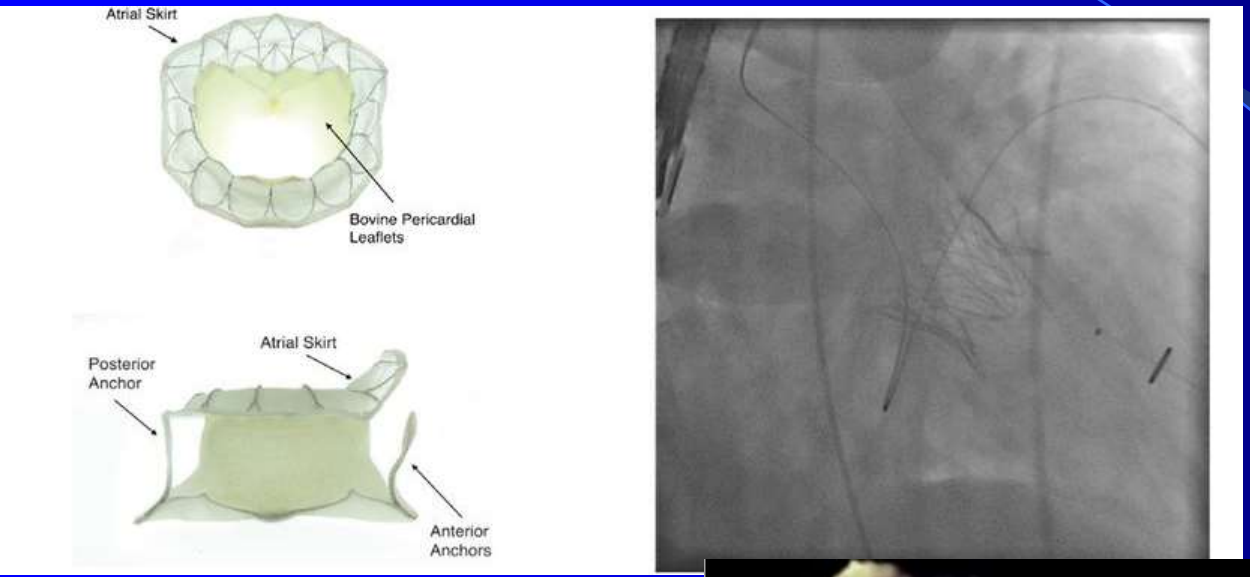
# Neovasc Tiara valve

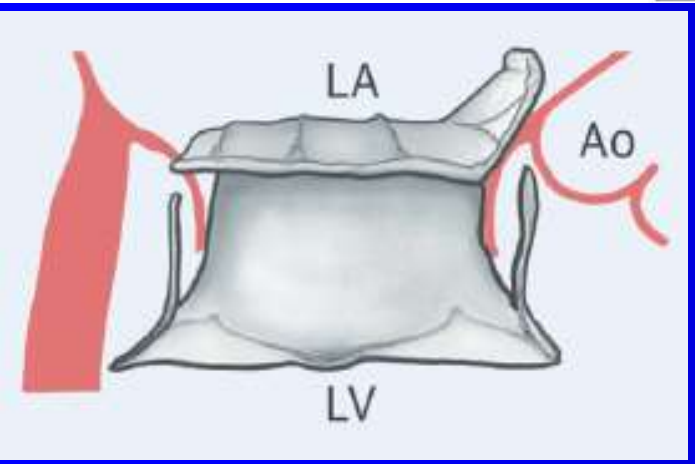
**Transapical**
**FIM in January 2014**

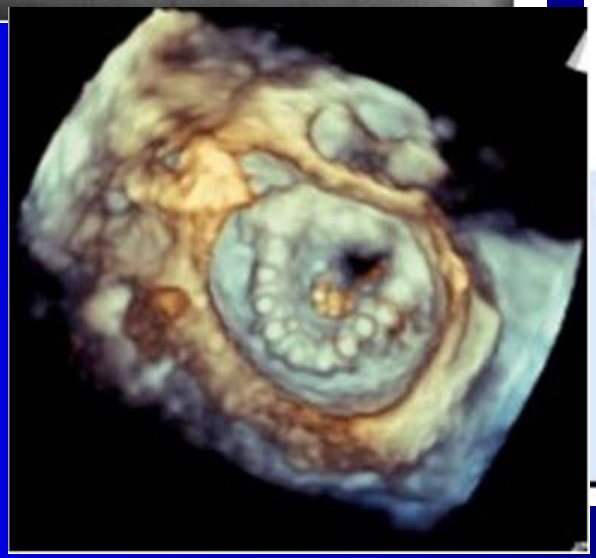
**N=19**






| Procedural and 30-day data | |
|---|---|
| Technical success | 16/19 (84.2) |
| Valve dislocation/embolization | 3/19 (15.8) |
| Conversion to open-heart surgery | 3/19 (15.8) |
| Post-procedural ≥ moderate MR | NA |
| LVOT obstruction | 0/19 (0.0) |
| Procedural mortality | 0/19 (0.0) |
| 30-day moderate or severe MR | NA |
| All-cause 30-day mortality | 3/19 (15.8) |
| **Follow-up** | |
| Follow-up, months | NA |
| MR ≥ moderate | 0/14 (0.0) |
| NYHA functional class ≥III | NA |
| Mortality | 3/19 (15.8) |



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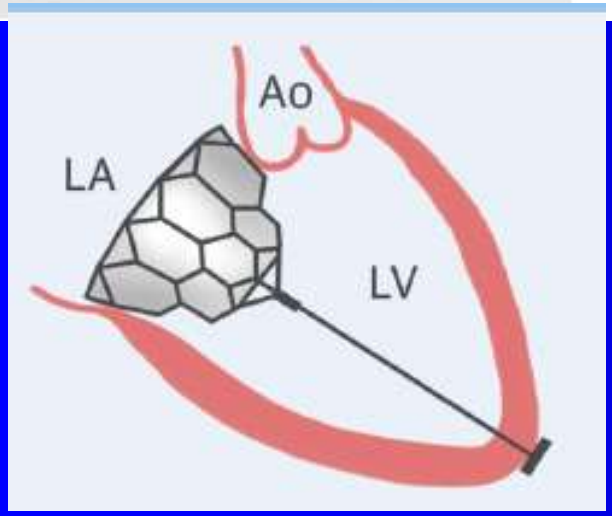
# Tendyne Mitral Valve System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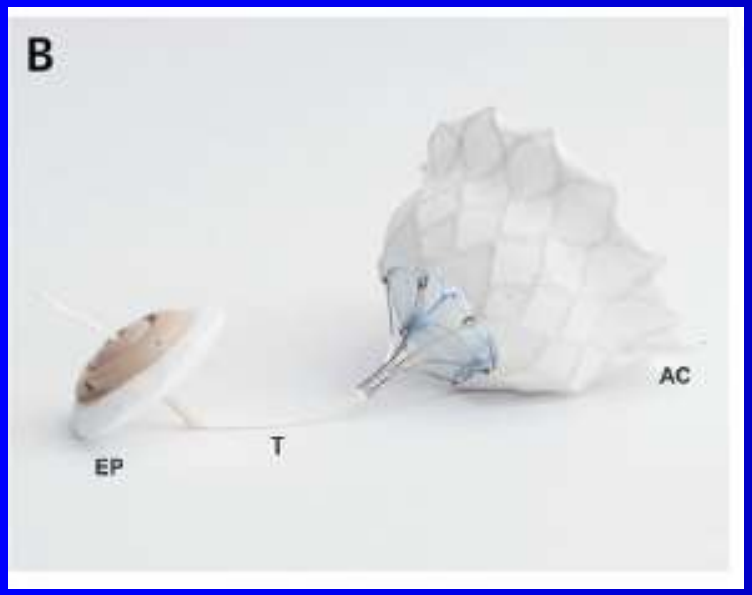
**Transapical**
**FIM in October 2014**
**N=30**

| | |
|---|---|
| Procedural and 30-day data | |
| Technical success | 28/30 (93.3) |
| Valve dislocation/embolization | 0/30 (0.0) |
| Conversion to open-heart surgery | 0/30 (0.0) |
| Post-procedural ≥ moderate MR | 1/30 (3.3) |
| LVOT obstruction | 1/30 (3.3) |
| Procedural mortality | 0/30 (0.0) |
| 30-day moderate or severe MR | 0/26 (0.0) |
| All-cause 30-day mortality | 1/30 (3.3) |
| Follow-up | |
| Follow-up, months | NA¶ |
| MR ≥ moderate | 0/5 (0.0) |
| NYHA functional class ≥III | NA |
| Mortality | 0/5 (0.0) |

# Transcatheter Mitral Valve Replacement for Patients With Symptomatic Mitral Regurgitation

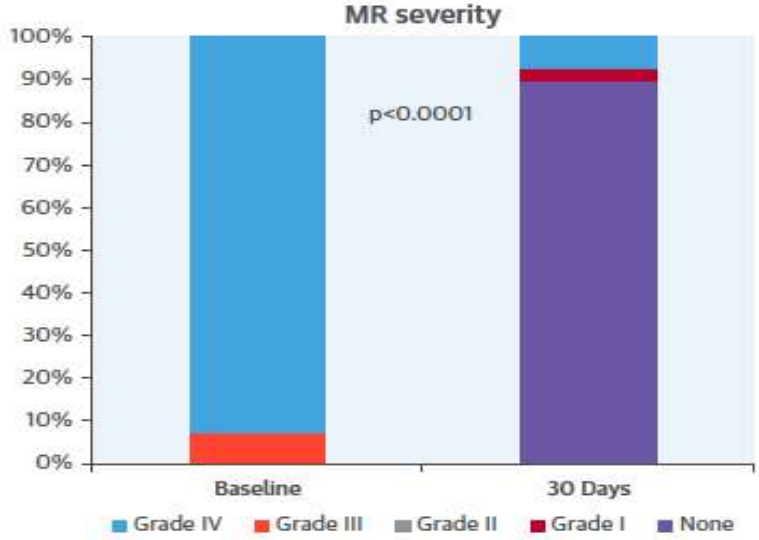
## A Global Feasibility Trial

David W.M. Muller, MBBS, MD,[a] Robert Saeid Farivar, MD,[b] Paul Jansz, MBBS, PhD,[a] Richard Bae, MD,[b] Darren Walters, MBBS, MPhil,[c] Andrew Clarke, MBBS,[c] Paul A. Grayburn, MD,[d] Robert C. Stoler, MD,[d] Gry Dahle, MD,[e] Kjell A. Rein, MD,[e] Marty Shaw, MBBS,[a] Gregory M. Scalia, MBBS,[c] Mayra Guerrero, MD,[f] Paul Pearson, MD,[f] Samir Kapadia, MD,[g] Marc Gillinov, MD,[g] Augusto Pichard, MD,[h] Paul Corso, MD,[h] Jeffrey Popma, MD,[i] Michael Chuang, MD,[i] Philipp Blanke, MD,[j] Jonathon Leipsic, MD,[j] Paul Sorajja, MD,[b] on behalf of the Tendyne Global Feasibility Trial Investigators

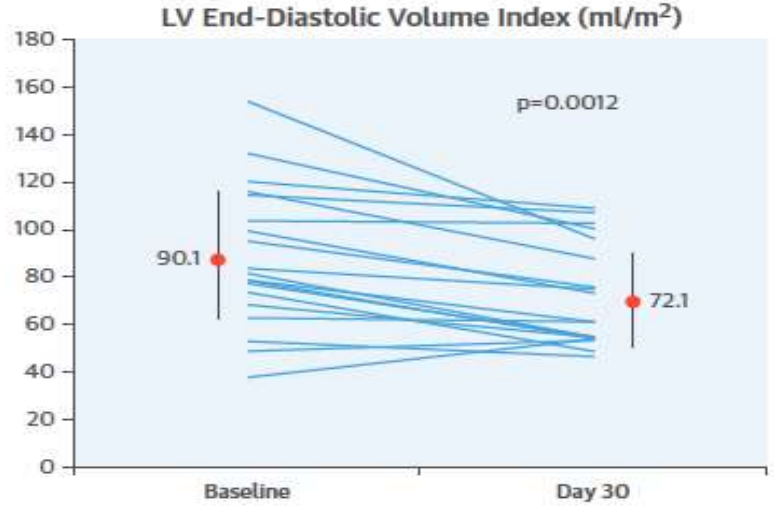



**CENTRAL ILLUSTRATION** Change in Mitral Regurgitation and LV Volumes After TMVR

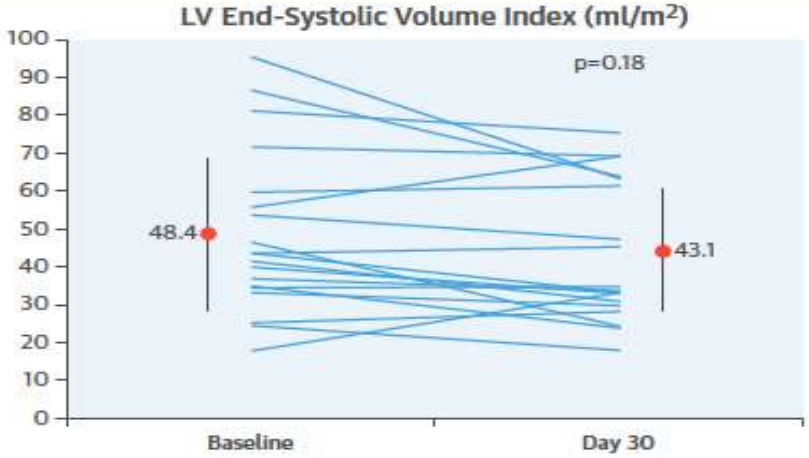
## A. Change in mitral regurgitation (MR) with TMVR




## B. Left ventricular end-diastolic volume index at baseline and after TMVR




## C. Left ventricular end-systolic volume index at baseline and after TMVR




Muller, D.W.M. et al. J Am Coll Cardiol. 2017;69(4):381-91.

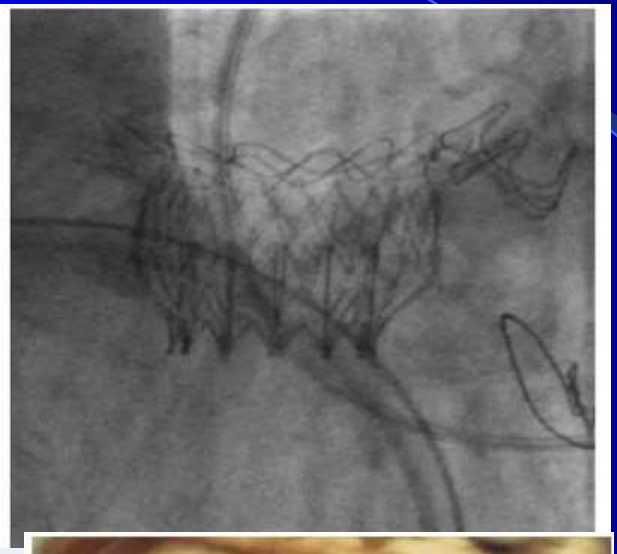
# 30-day Outcomes

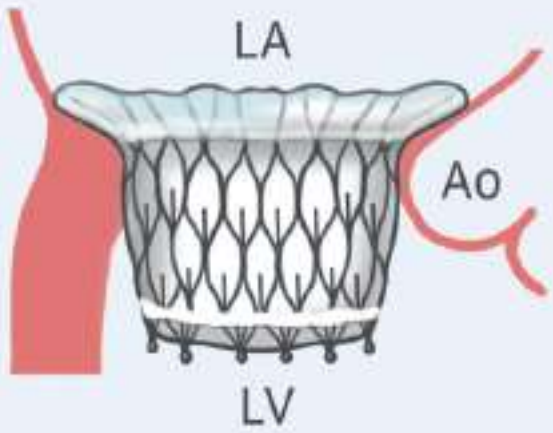
| | |
|---|---|
| Mitral regurgitation severity | |
| None | 96.2 (25/26) |
| 1+ | 3.8 (1/26) |
| 2+ | 0.0 (0/26) |
| 3+ | 0.0 (0/26) |
| 4+ | 0.0 (0/26) |
| Mitral valve gradient, mm Hg | 3.4 ± 1.7 (25) |
| LVOT gradient, mm Hg | 1.9 ± 0.7 (24) |

**TABLE 3 30-Day Clinical Outcomes**

| | |
|---|---|
| Death | |
| Cardiovascular | 0.0 (0/30) |
| Noncardiovascular | 3.3 (1/30) |
| Stroke | |
| Disabling | 0.0 (0/30) |
| Nondisabling | 0.0 (0/30) |
| Myocardial infarction | 0.0 (0/30) |
| Bleeding (BARC classification) | |
| Type 2 | 6.7 (2/30) |
| Type 3 | 0.0 (0/30) |
| Type 4 | 3.3 (1/30) |
| Type 5 | 0.0 (0/30) |
| Acute renal insufficiency | |
| Not requiring dialysis | 13.3 (4/30) |
| Requiring dialysis | 3.3 (1/30) |
| Sepsis | |
| Cardiac | 0.0 (0/30) |
| Noncardiac | 10.0 (3/30) |
| Arrhythmia | |
| New-onset atrial fibrillation | 3.3 (1/30) |
| New LBBB | 10.0 (3/30) |
| Ventricular arrhythmia | 0.0 (0/30) |
| Prosthesis dysfunction | |
| Thrombosis | 3.3 (1/30) |
| Embolism or migration | 0.0 (0/30) |
| Hemolysis | 3.3 (1/30) |
| Mitral valve surgery | 0.0 (0/30) |
| Rehospitalization for heart failure | 13.8 (4/29) |

# Medtronic Intrepid TMVR



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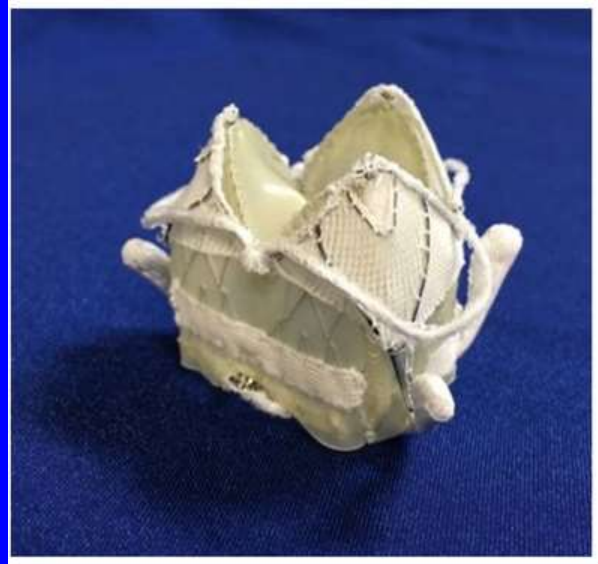
**Transapical**

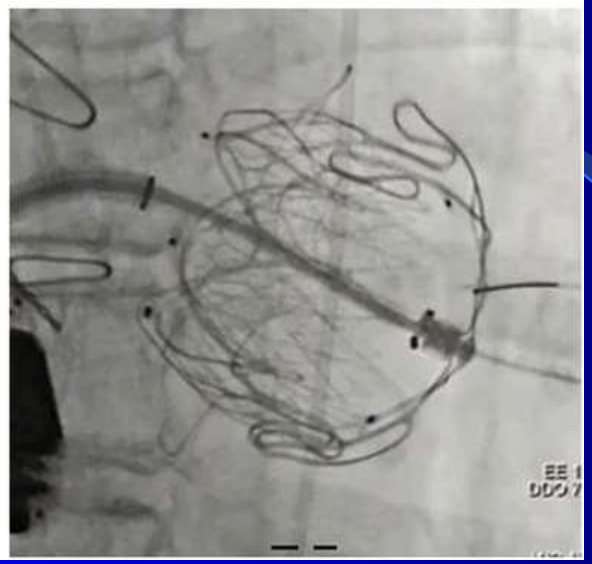
**FIM in September 2014**

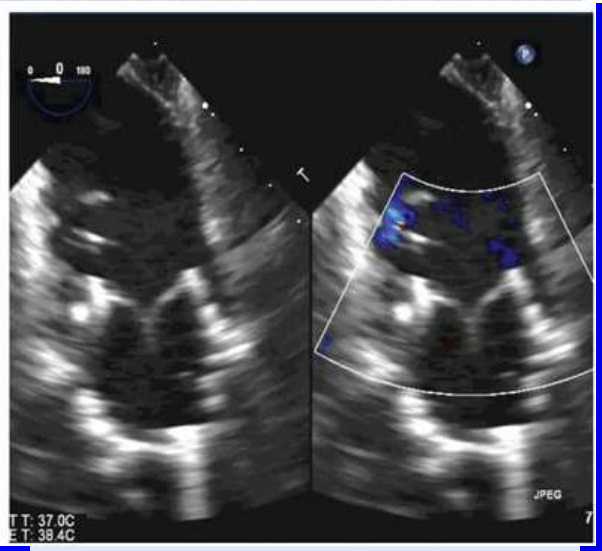
**N=27**

| | |
|---|---|
| Procedural and 30-day data | |
| Technical success | 24/26 (92.3)‡ |
| Valve dislocation/embolization | NA |
| Conversion to open-heart surgery | NA |
| Post-procedural ≥ moderate MR | 0/26 (0.0) |
| LVOT obstruction | 0/26 (0.0) |
| Procedural mortality | 4/27 (14.8) |
| 30-day moderate or severe MR | NA |
| All-cause 30-day mortality | 6/25 (24.0) |
| Follow-up | |
| Follow-up, months | 8.1 (0-20.7) |
| MR ≥ moderate | 0/24 (0.0) |
| NYHA functional class ≥III | 2/18 (11.1) |
| Mortality | 7/27 (25.9) |

# Caisson TMVR System







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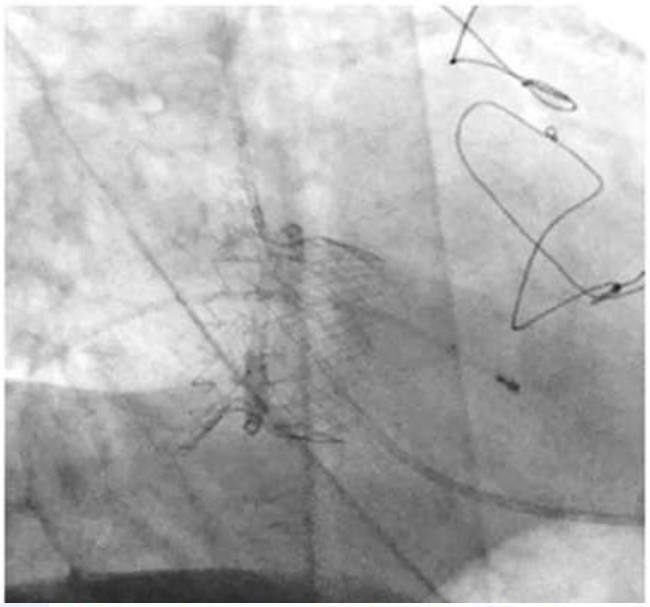
**Transseptal**

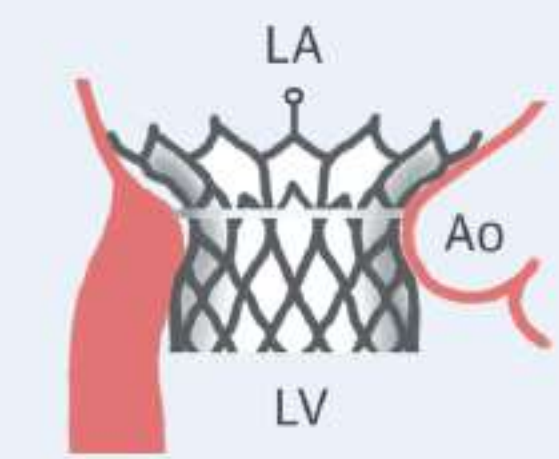
**FIM in October 2016**

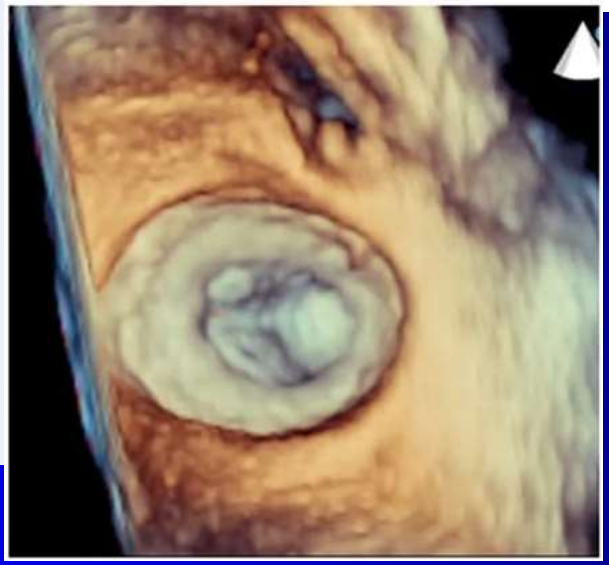
**N=5**

| Procedural and 30-day data | |
|---|---|
| Technical success | 4/5 (80.0) |
| Valve dislocation/embolization | 0/5 (0.0) |
| Conversion to open-heart surgery | 0/5 (0.0) |
| Post-procedural ≥ moderate MR | 0/4 (0.0) |
| LVOT obstruction | 0/4 (0.0) |
| Procedural mortality | 0/5 (0.0) |
| 30-day moderate or severe MR | 0/3 (0.0) |
| All-cause 30-day mortality | 1/4 (25.0) |
| **Follow-up** | |
| Follow-up, months | 3.4 (3-4) |
| MR ≥ moderate | 0/4 (0.0) |
| NYHA functional class ≥III | 0/3 (0.0) |
| Mortality | 1/4 (25.0) |

# HighLife Valve





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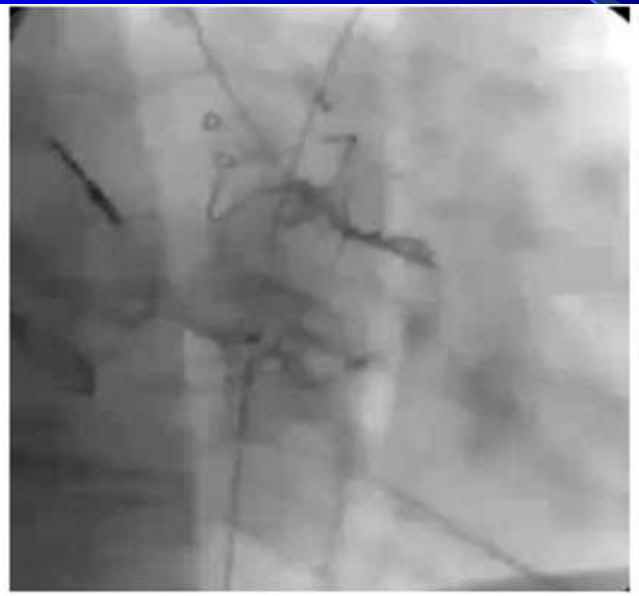
**Transapical**

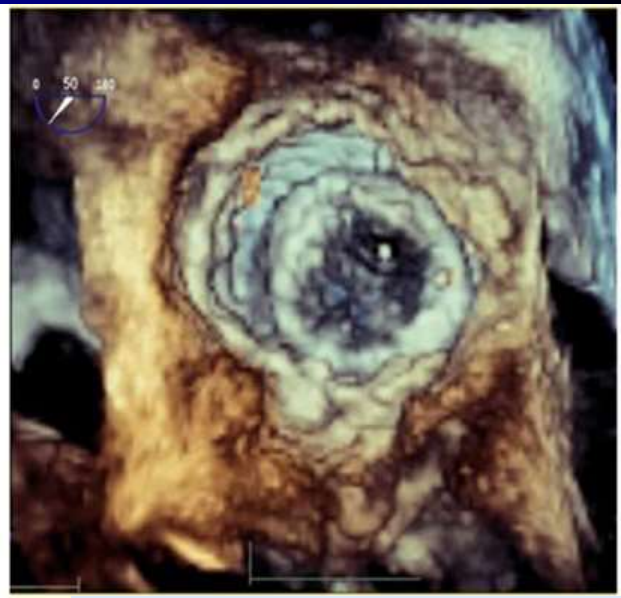
**FIM 2016**

**N=6**

| | |
|---|---|
| Procedural and 30-day data | |
| Technical success | 5/6 (83.3) |
| Valve dislocation/embolization | 0/5 (0.0) |
| Conversion to open-heart surgery | 1/6 (16.7) |
| Post-procedural ≥ moderate MR | 0/6 (0.0) |
| LVOT obstruction | 0/6 (0.0) |
| Procedural mortality | 1/6 (16.7) |
| 30-day moderate or severe MR | 0/4 (0.0) |
| All-cause 30-day mortality | 2/6 (33.3) |
| Follow-up | |
| Follow-up, months | 4.1 (3-6) |
| MR ≥ moderate | 0/4 (0.0) |
| NYHA functional class ≥III | 0/4 (0.0) |
| Mortality | 2/6 (33.3) |

# Mvalve System
## (Docking system for other THVs)





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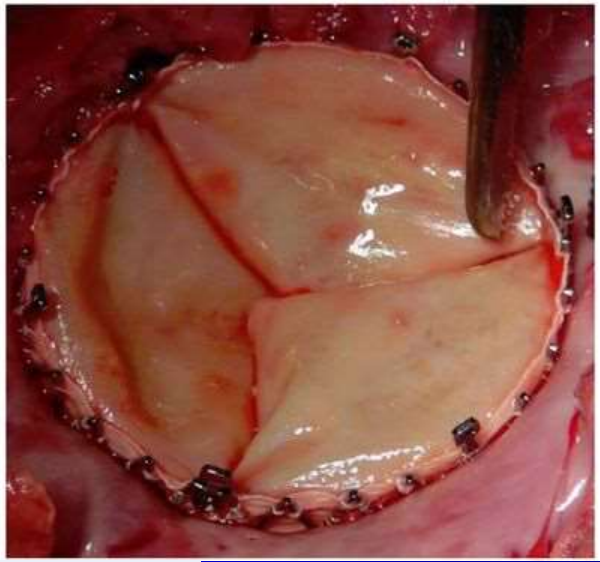
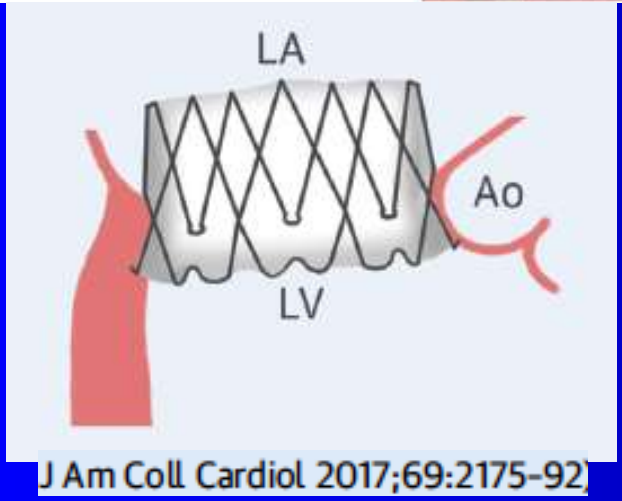
**Transapical**

**Recaptured and retrieved after full deployment**

**FIM in September 2015**

# NCSI NaviGate Valve



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**Transseptal, transapical**

**FIM October 2015**

# Global Experience

N=115
TA approach 94%
Technical success 88.4%
Procedural mortality 8.8%
30-day mortality 23.2%

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**TABLE 5** Early Clinical Experience With TMVR in Native Severe MR (N = 115)*

| | |
|---|---|
| Patient characteristics | |
| Age, yrs | 73.8 (39–91) |
| Female | 30/115 (26.1) |
| STS score | 7.5 (1.0–47.7) |
| NYHA functional class ≥III | 83/101 (82.2) |
| Ischemic/functional MR | 85/114 (74.6) |
| LVEF <50% | 65/86 (75.6) |
| Valve type and approach | |
| Devices | |
| Tendyne | 30/115 (26.1) |
| Intrepid | 27/115 (23.5) |
| Neovasc Tiara | 19/115 (16.2) |
| CardiAQ-Edwards | 13/115 (11.3) |
| FORTIS† | 13/115 (11.3) |
| HighLife | 6/115 (5.2) |
| Caisson | 5/115 (4.3) |
| MValve | 1/115 (1.0) |
| NCS NaviGate | 1/115 (1.0) |
| Transfemoral approach | 7/115 (6.1) |
| Procedural and 30-day outcomes | |
| Technical success | 100/113 (88.4) |
| Procedural mortality | 10/114 (8.8) |
| LVOT obstruction | 1/96 (1.0) |
| Post-procedural ≥ moderate MR | 1/77 (1.3) |
| 30-day mortality | 26/112 (23.2) |

# Preclinical Evaluation

AccuFit

Cardiovalve

Cephea

Saturn

Abbott TMVR

# Summary

- TMVR is still in the very early phase of the development.
- Multiple TMVR systems have being evaluated in a very small number of highly selected patients.
- Feasibility of TMVR has been demonstrated. But the success rate is low with relatively high mortality and complications.
- Safety and efficacy needs to be further evaluated.
- At this point, TMVR should be considered only in patients with symptomatic severe MR and very high-risk or prohibitive surgical risk.


THANKS!