Transcatheter Mitral Valve Replacement Current Evidence and Experience

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Disclosure

Consultant:

Edwards Lifesciences
JC Medical Inc.

First in Human TMVR



Edwards CardiAQ June 2012



Neovasc Tiara Jan 2014



Medtronic Intrepid Nov 2014



Highlife Feb 2016



Edwards M3 Aug 2017



AltaValve
2018

Feb 2013 Abbott Tendyne



Feb 2014 Edwards Fortis



Oct 2015
NaviGate



June 2016

Caisson



2018

Cardiovalve



Transsepatal TMVR

Edwards SAPIEN M3 System







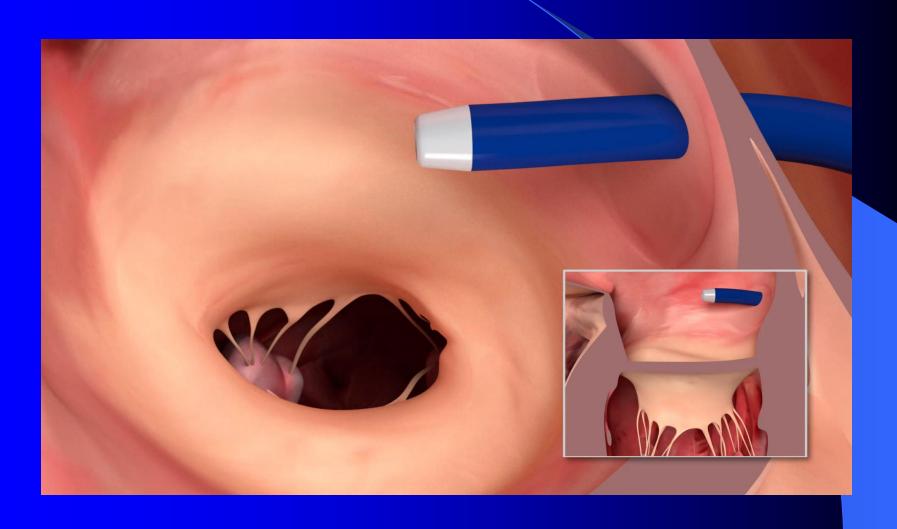




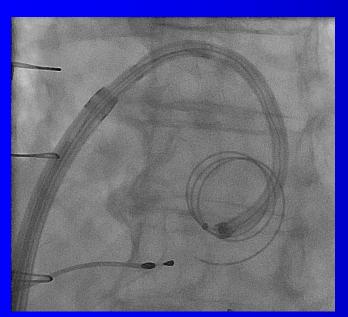
Final Implant

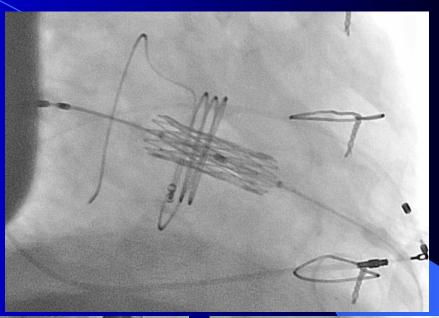


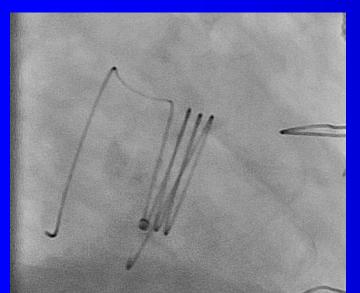
SAPIEN M3 System

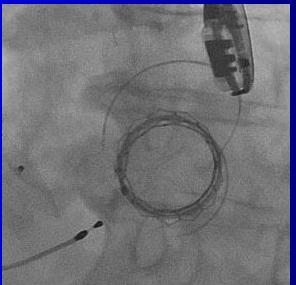


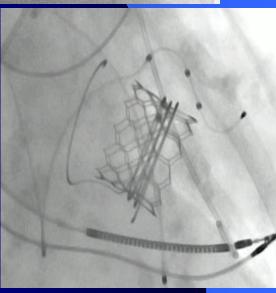
M3 TMVR System











Reported Early Clinical Outcomes

	Cases	30-day mortality	Residual MR≥ Moderate	Technical success	30-day stroke	1-year survival
Tendyne	100	6%	1.1%	97%	2%	72.4%
Tiara	58	10.3%	2%	95%	3%	
Intrepid	50	14%		92.6%	4%	76.5%
SAPIEN M3	10	0%	10%	90%	10%	
TS CardiAQ	12	16%		75%		
Caisson	21			81%		
Cardiovalve	5		0%	100%		
HighLife	15					

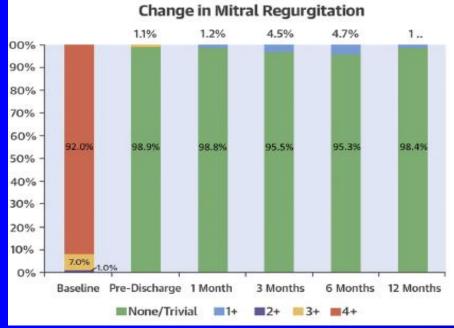
Initial Feasibility Study of a New Transcatheter Mitral Prosthesis

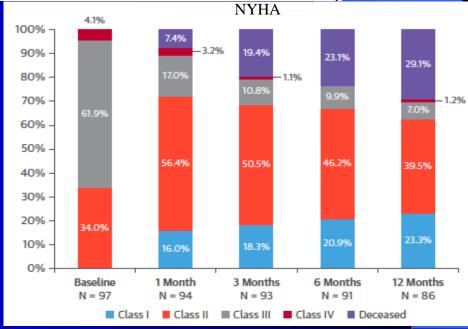


The First 100 Patients

J Am Coll Cardiol 2019;73:1250-60)

	n	Baseline	1 Year	Change	p Value
LV ejection fraction, %	49	45.4 ± 9.1	$\textbf{39.2} \pm \textbf{10.3}$	-6.2 ± 10.1	0.0001
LVEDV, ml	41	$\textbf{174.0} \pm \textbf{60.4}$	$\textbf{159.0} \pm \textbf{41.4}$	$\textbf{-15.0} \pm \textbf{39.3}$	0.019
LVESV, ml	41	$\textbf{97.6} \pm \textbf{40.2}$	$\textbf{98.4} \pm \textbf{35.5}$	$\textbf{0.9} \pm \textbf{29.1}$	0.852
Forward stroke volume, ml	39	$\textbf{54.0} \pm \textbf{16.3}$	$\textbf{56.4} \pm \textbf{16.7}$	$\textbf{2.3} \pm \textbf{17.6}$	0.411
Cardiac output, l/min	37	3.9 ± 1.1	4.0 ± 1.1	0.1 ± 1.3	0.563
RVSP, mm Hg	20	43.5 ±11.3	$\textbf{35.5} \pm \textbf{12.4}$	-8.0 ± 15.6	0.034
LVOT gradient, mm Hg	43	1.4 ± 0.6	1.7 ± 1.0	0.3 ± 1.0	0.073
Mean mitral gradient, mm Hg	38	2.9 ± 1.3	3.0 ± 1.1	0.1 ± 1.6	0.627





Randomized Controlled Clinical Trials

APOLLO Trial Medtronic Intrepid TMVR

Intrepid TMVR
vs
Surgical MVR
1:1 randomization

SUMMIT Trial Tendyne TMVR

Tendyne TMVR
vs
Surgical MVR/r
2:1 randomization

Challenges

Targeting different disease and etiology

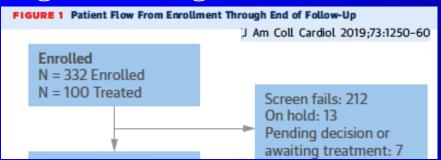
Delivery (transapical, transseptal)

Complexity of implantation (transseptal)

Anchoring (instability, migration, embolization)

Sealing (PVL)

High screening failure rate



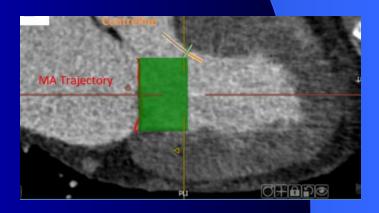
Durability

Valve thrombosis

Valve performance

Stent fatigue/fracture

LVOT obstruction



CT Assessment

LA

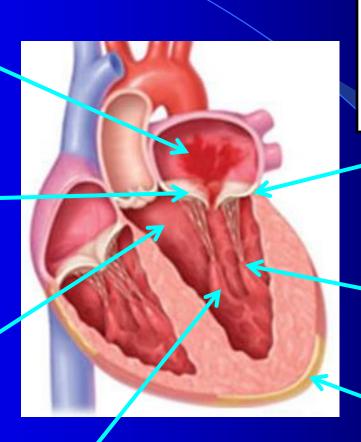
height size near annulus

Leaflets

height calcification commissure

LVOT

aorto-mitral angle septum thickness Neo-LVOT



Annulus

size (area, perimeter) a-p, c-c or t-t distance calcification

Papillary

distance to annulus p-p distance

LV

size (short and long axis)

TA approach

apico-mitral distance implanting angle

Interdisciplinary Rounds

- Interventional cardiologists
- Cardiac surgeons (Valve repair surgeon)
- Heart failure specialist
- Echocardiologist
- Radiologist
- Anesthetist
- THV nurses
- Other specialists





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