Catheter-Based Strategies to Creating Valve Competence on the Right Side of the Heart

Bryan H. Goldstein, MD
Professor of Pediatrics
Director, Cardiac Catheterization Laboratory
Heart Institute
UPMC Children's Hospital of Pittsburgh

University of Pittsburgh

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Disclosures

- W.L. Gore & Associates: Consultant and Proctor
- Medtronic, Inc: Consultant and Proctor
- Mezzion Pharma: Consultant and Scientific Advisory Board Member
- PECA Labs: Consultant

We will focus on patients with congenital heart disease

Outline

- Origins of transcatheter valve replacement
- TPVR in conduits and BPV
- TPVR in native/TAP RVOT
- TTVR in BPV and rings
- What don’t we know and where are we headed?

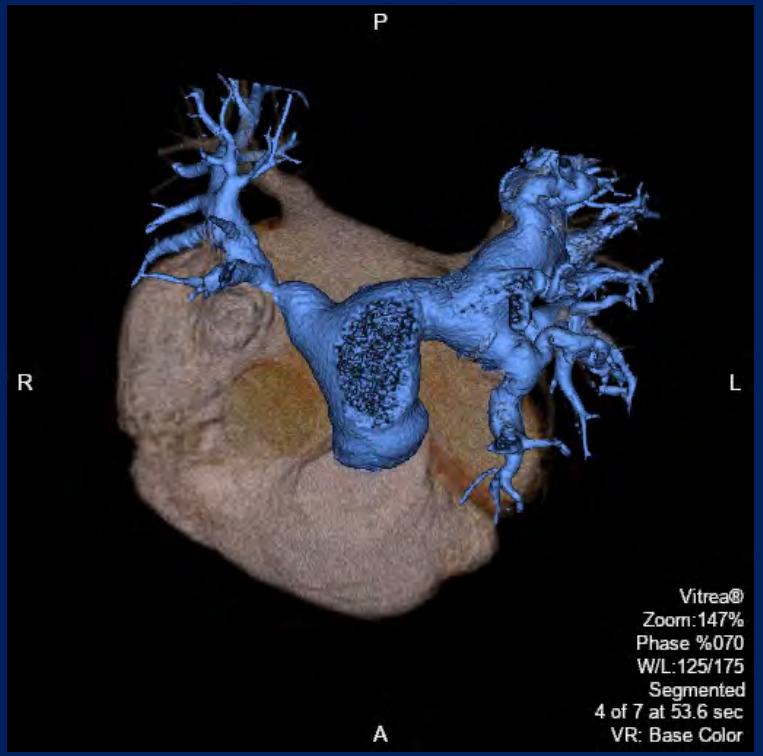
TPVR & TAVR

2000

2002

The first TPV (Melody) was FDA cleared in 2010

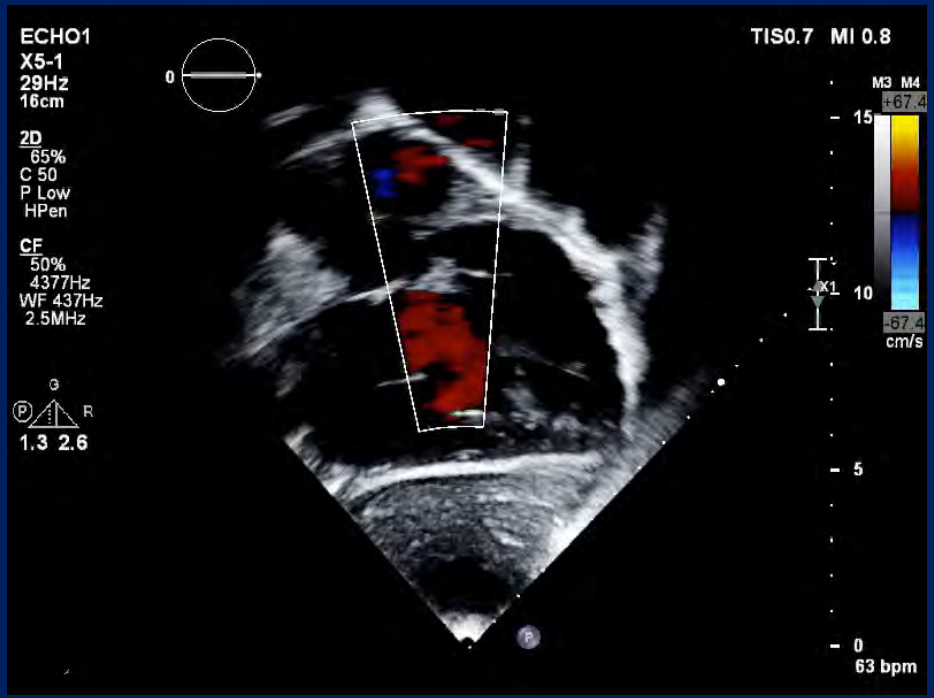
We can now treat most anatomic variants

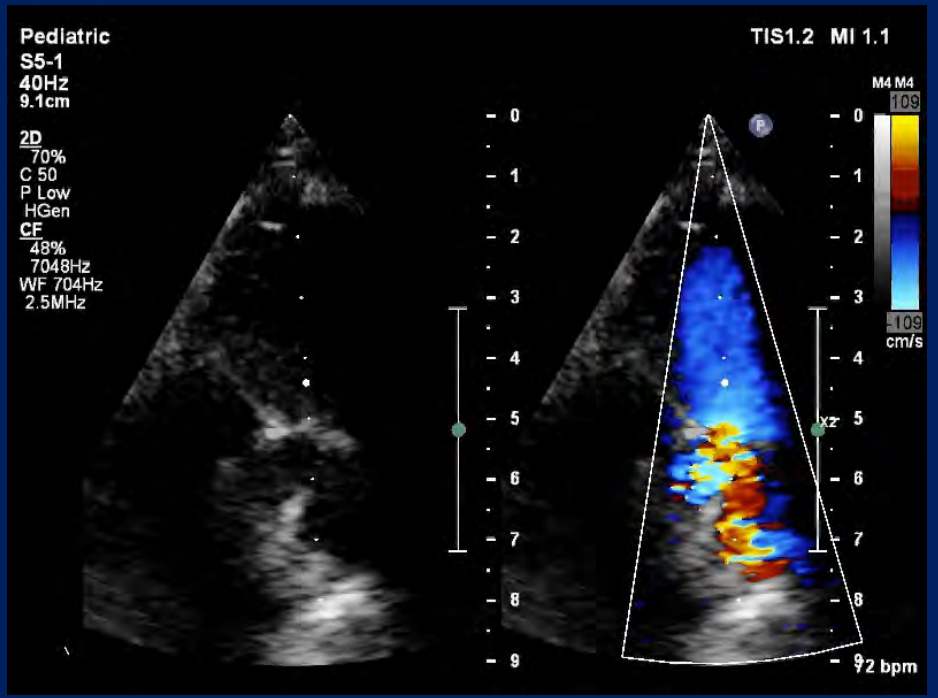


Case Example – Melody TPV

- 10 yo M with truncus arteriosus and right aortic arch
- S/p neonatal repair with 9 mm pulmonary homograft RV-PA conduit
- S/p “kissing” stent placement in branch PAs
- S/p conduit replacement with 13 mm homograft and branch PA reconstruction
- S/p conduit stent placement
- S/p conduit replacement with 20 mm Contegra conduit and RPA repair
- S/p branch PA angioplasty
- Now with symptomatic severe RV-PA conduit stenosis and insufficiency, branch PA stenosis and moderate RV dilation

Case Example – Melody TPV





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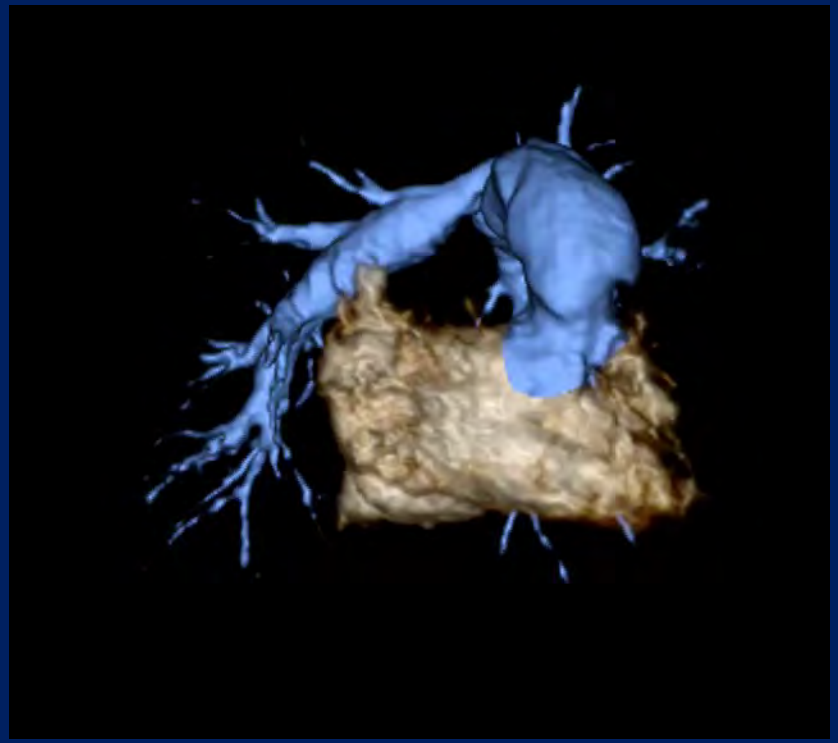
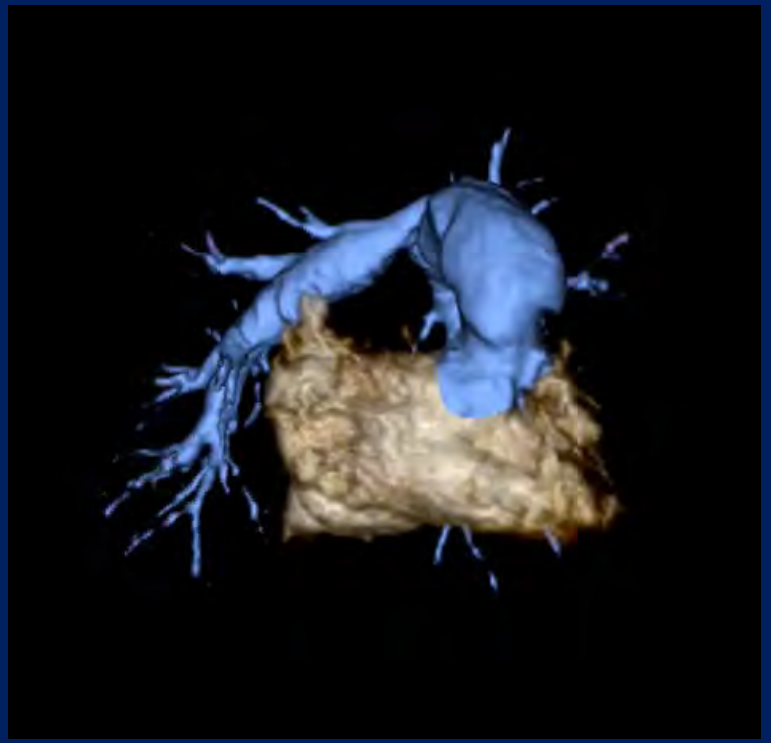
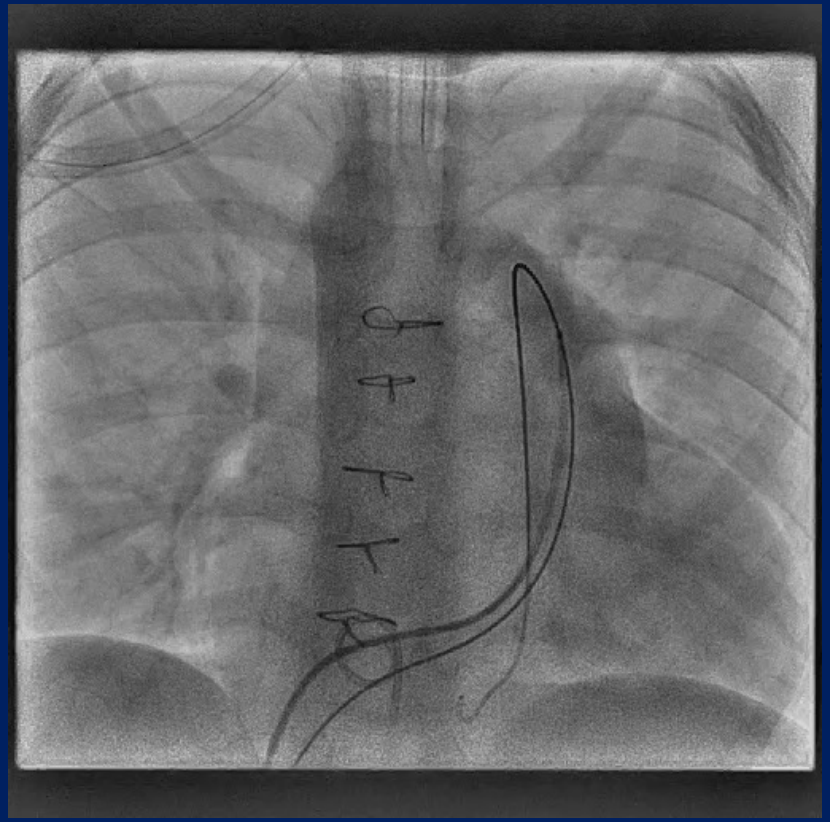
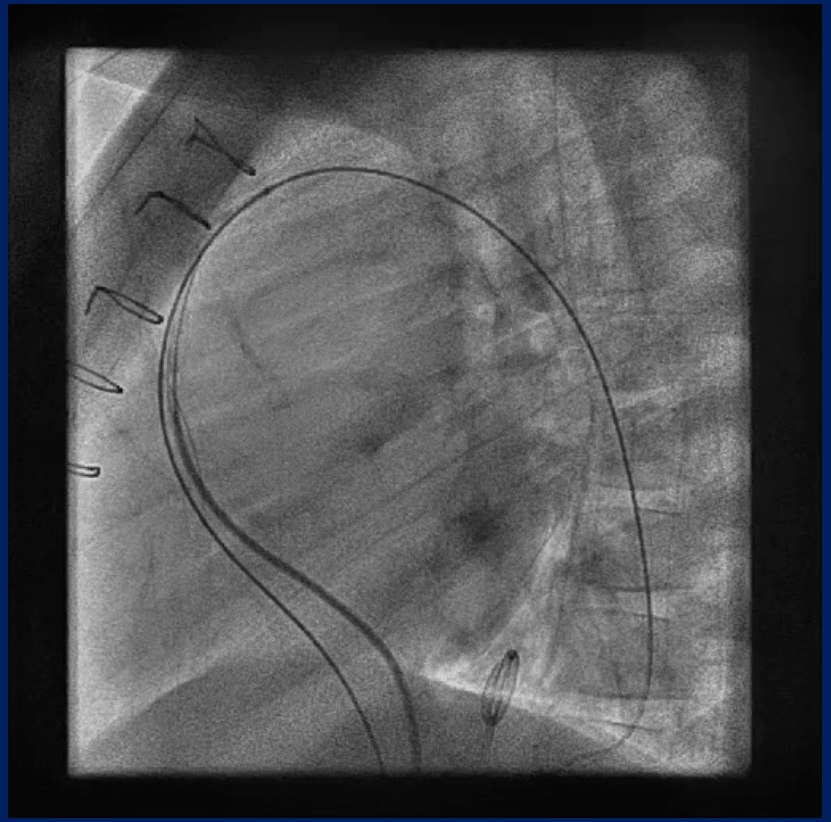
Case Example – Melody TPV





Case Example – Melody TPV





Case Example – Melody TPV

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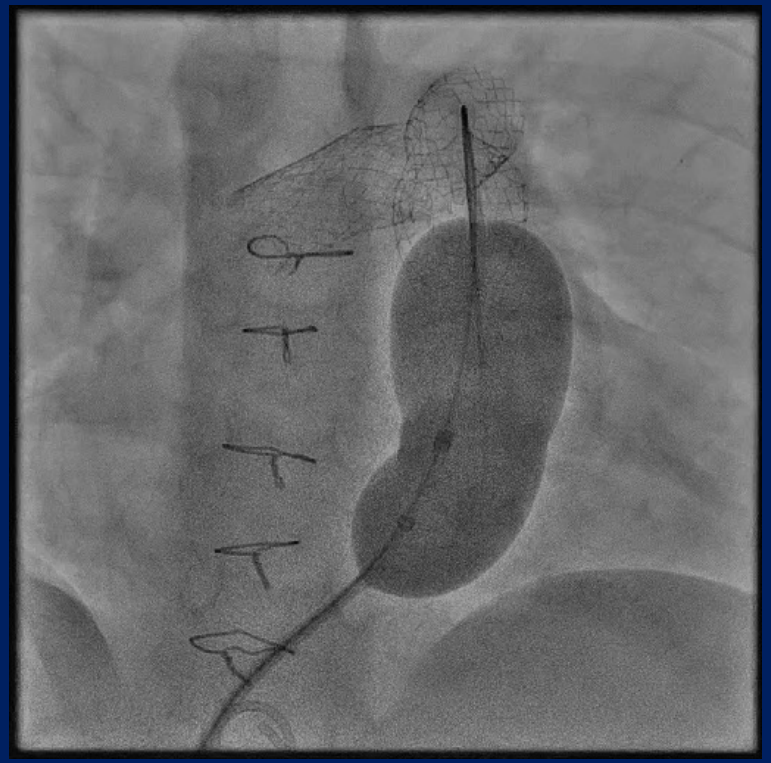

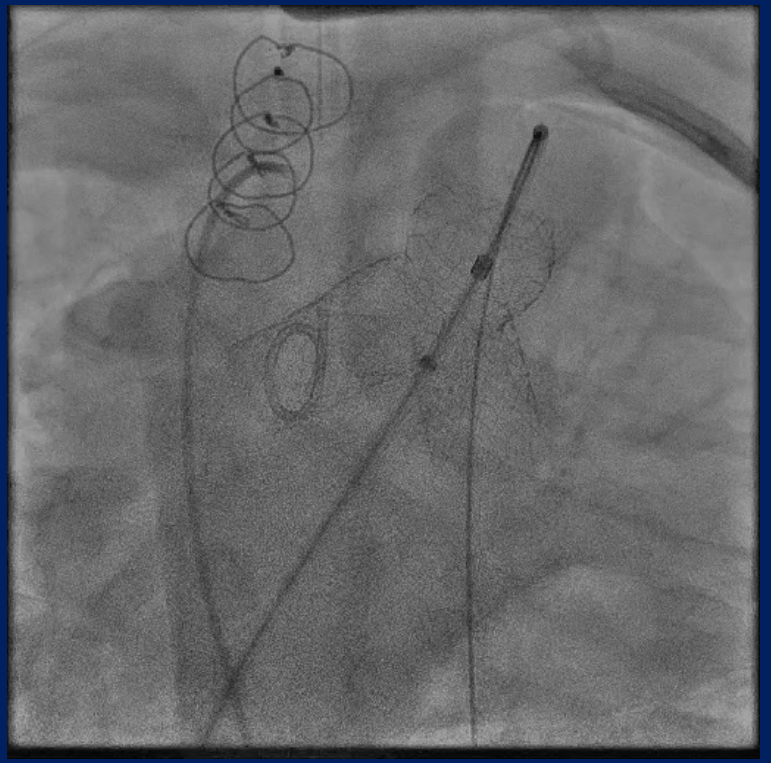

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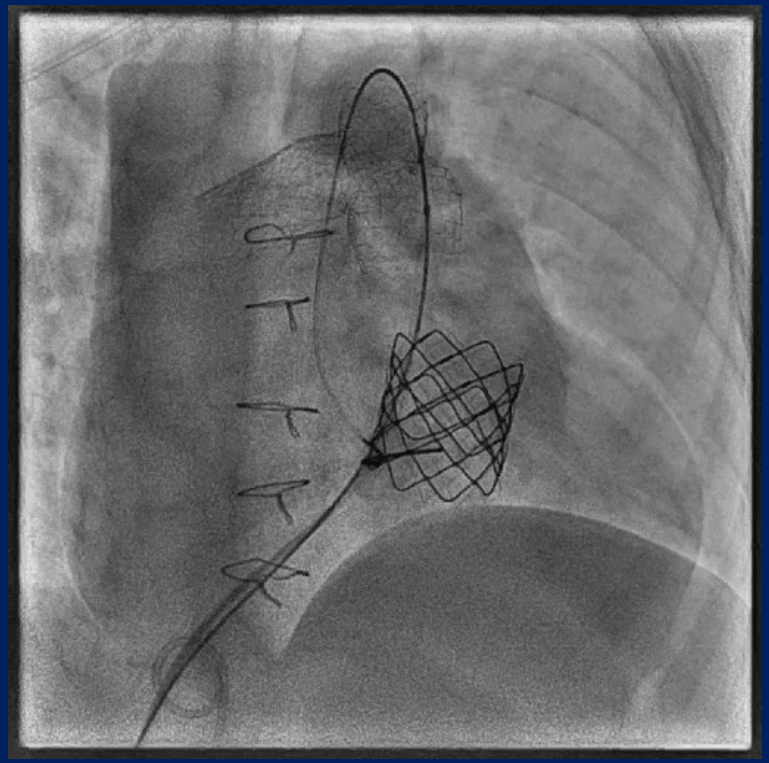
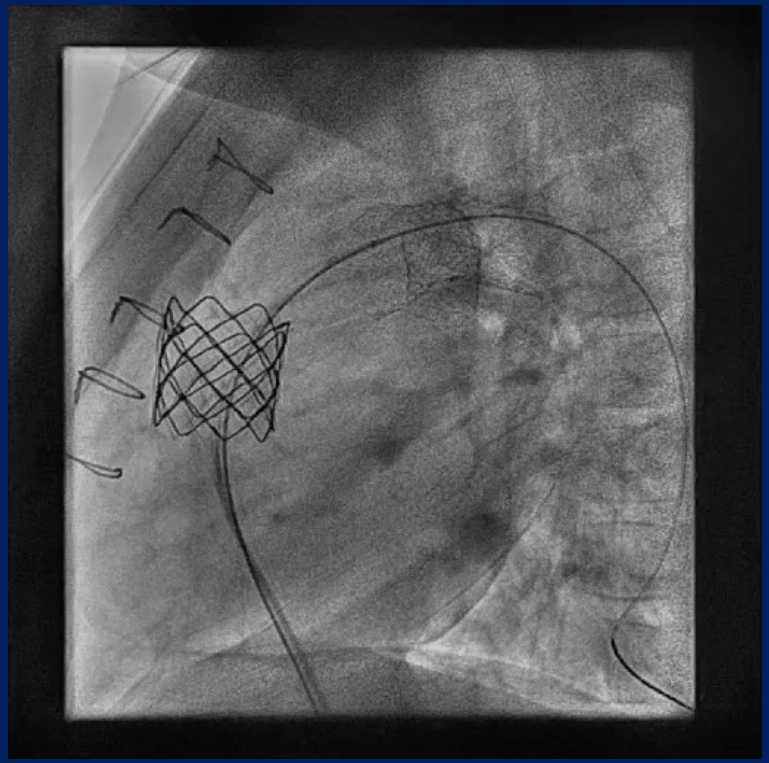
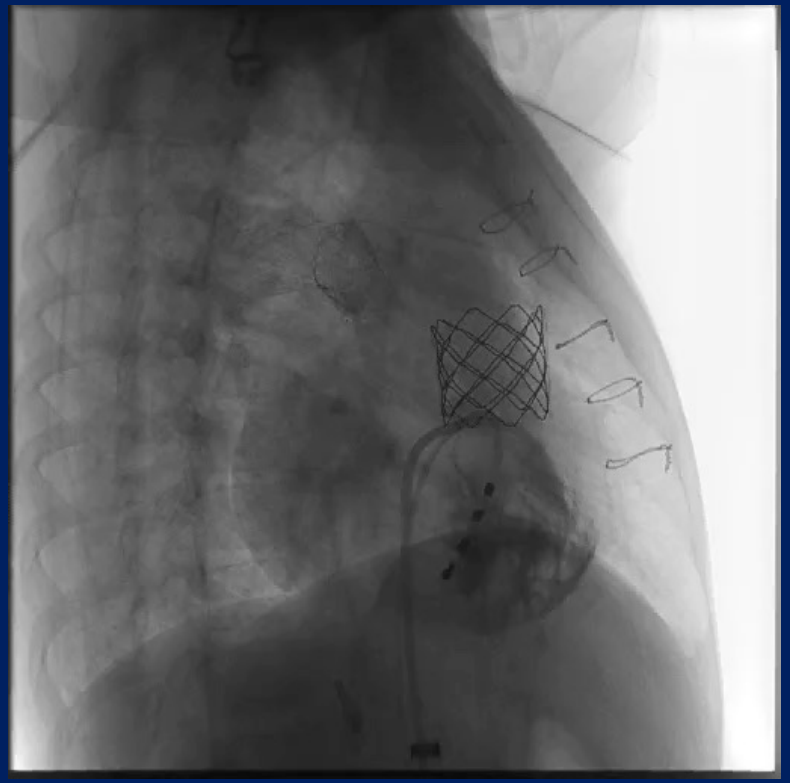
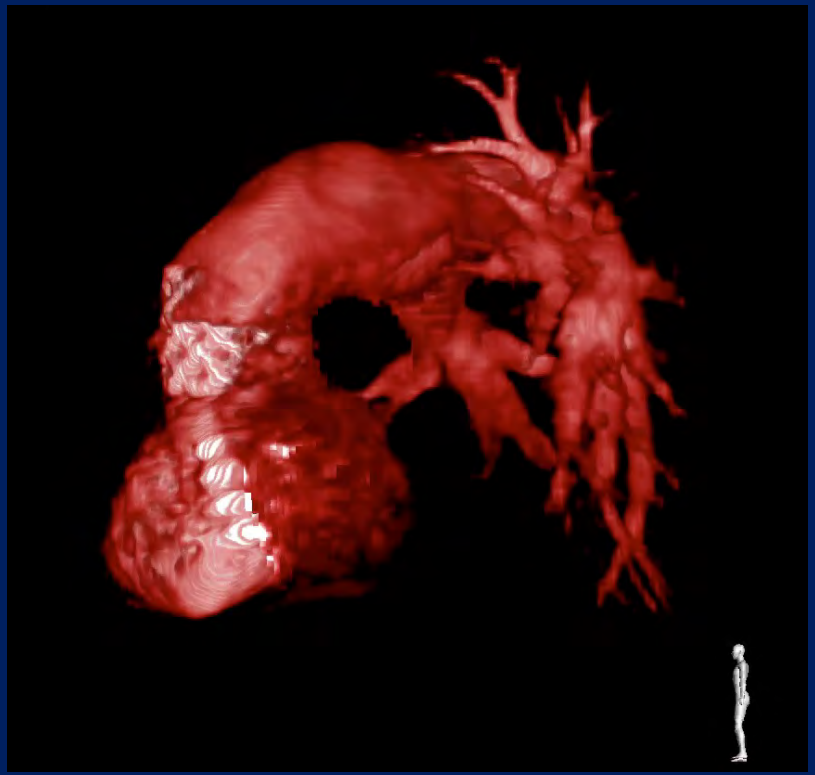


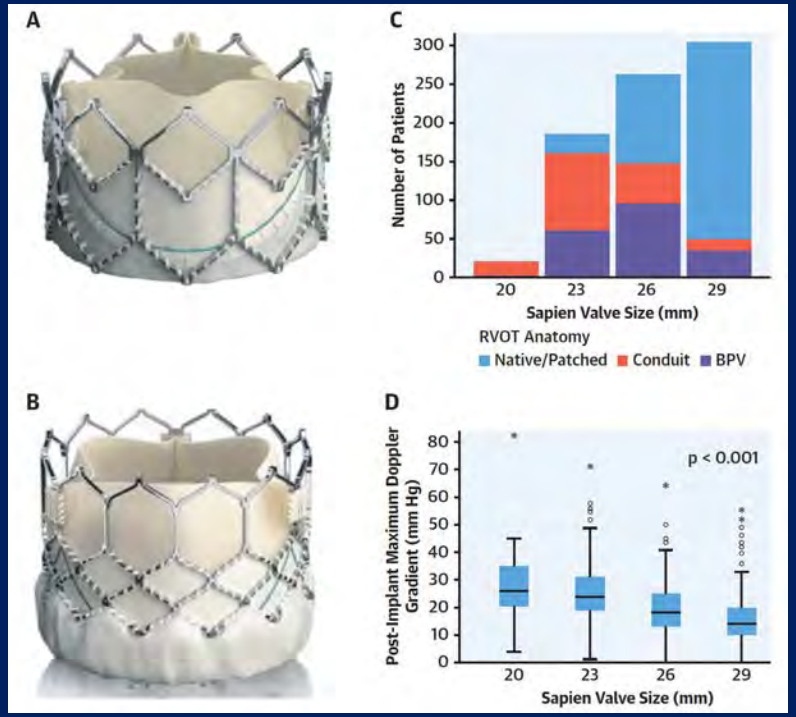


Case Example – Melody TPV



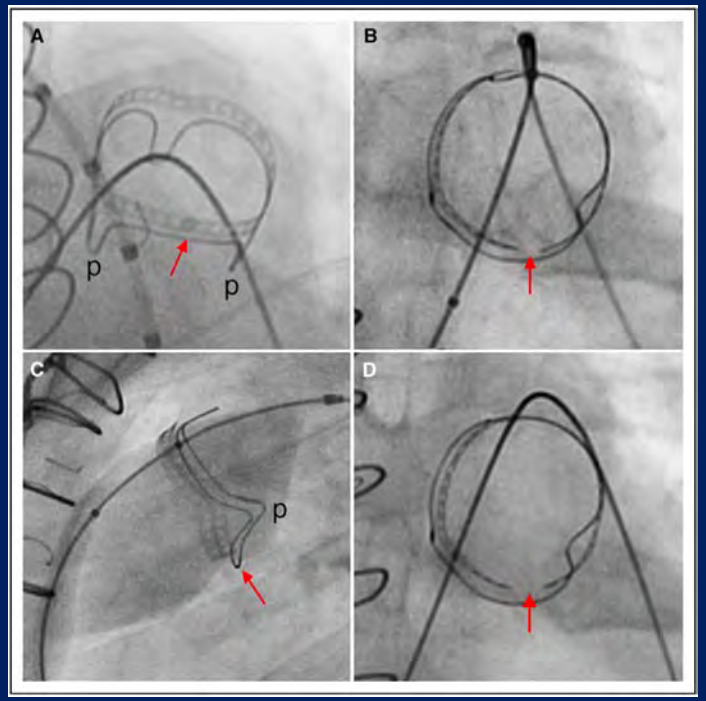


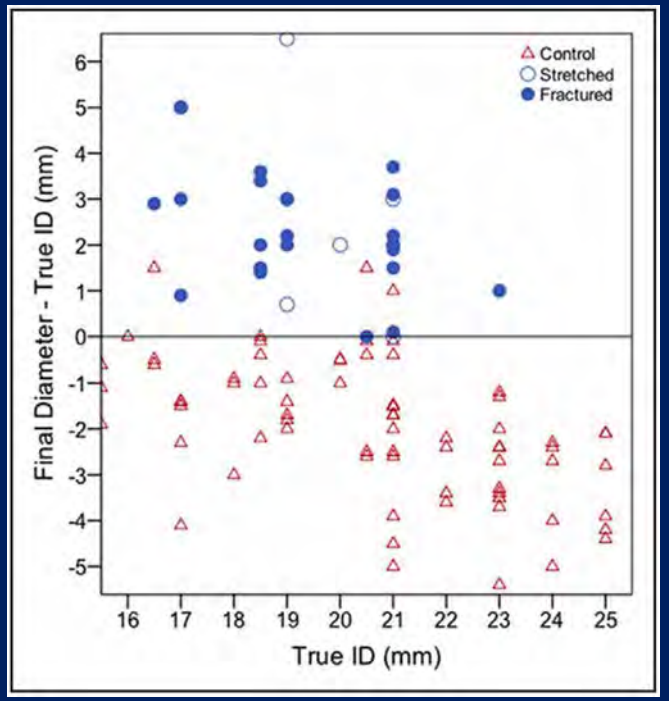
TPVR with Sapien 3



Shahanavaz et al. *J Am Coll Cardiol*. 2020.

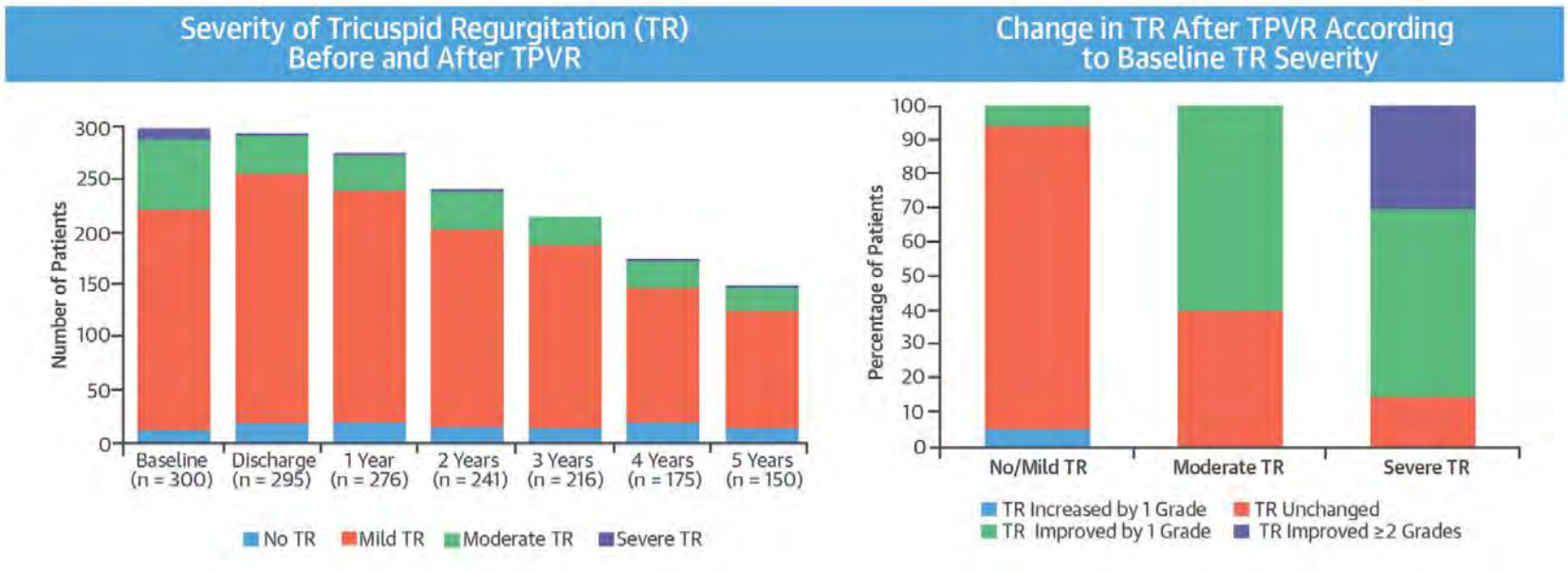
Intentional Fracture of BPV Frames





Shahanavaz et al. *Circ Cardiovasc Interv*. 2018.

Impact of TPVR on TR (without TV intervention)

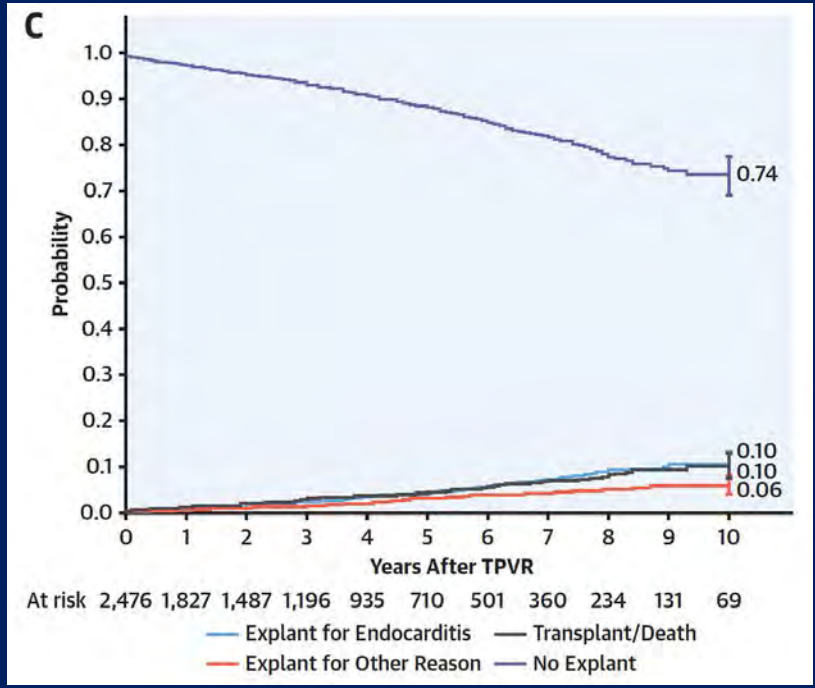


Jones et al. *J Am Coll Cardiol*. 2016.

Endocarditis After TPVR

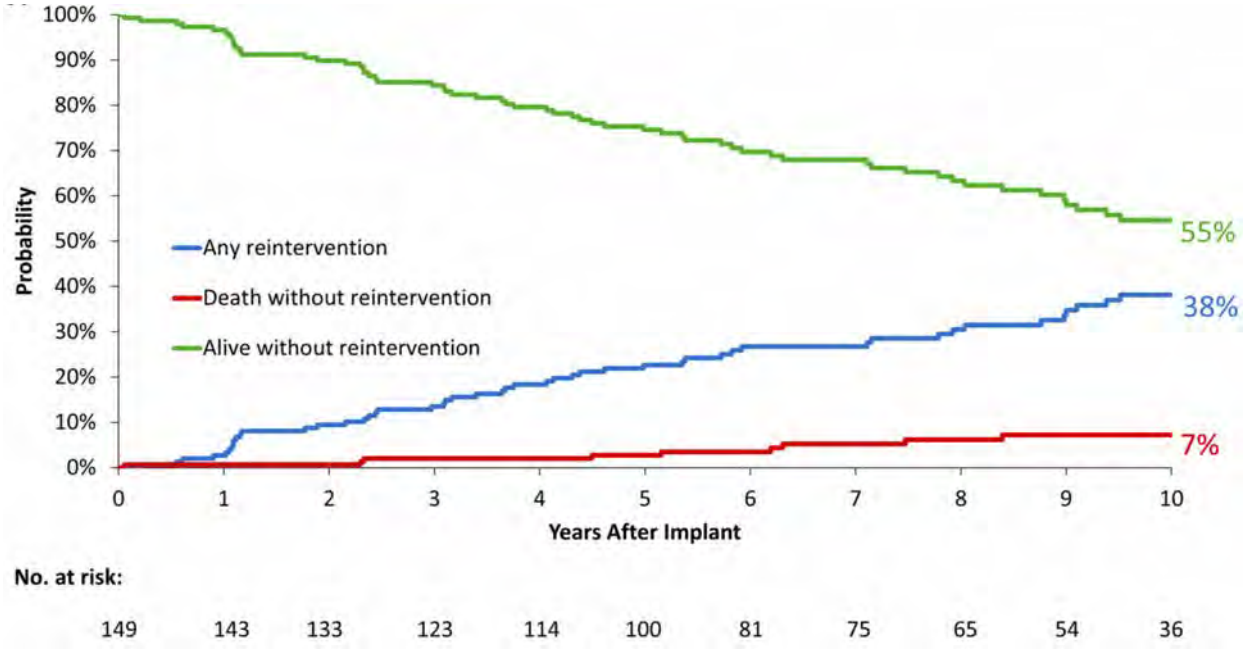
Risk factors

- Younger age
- Prior IE
- Higher gradient pre-TPVR
- Higher gradient post-TPVR



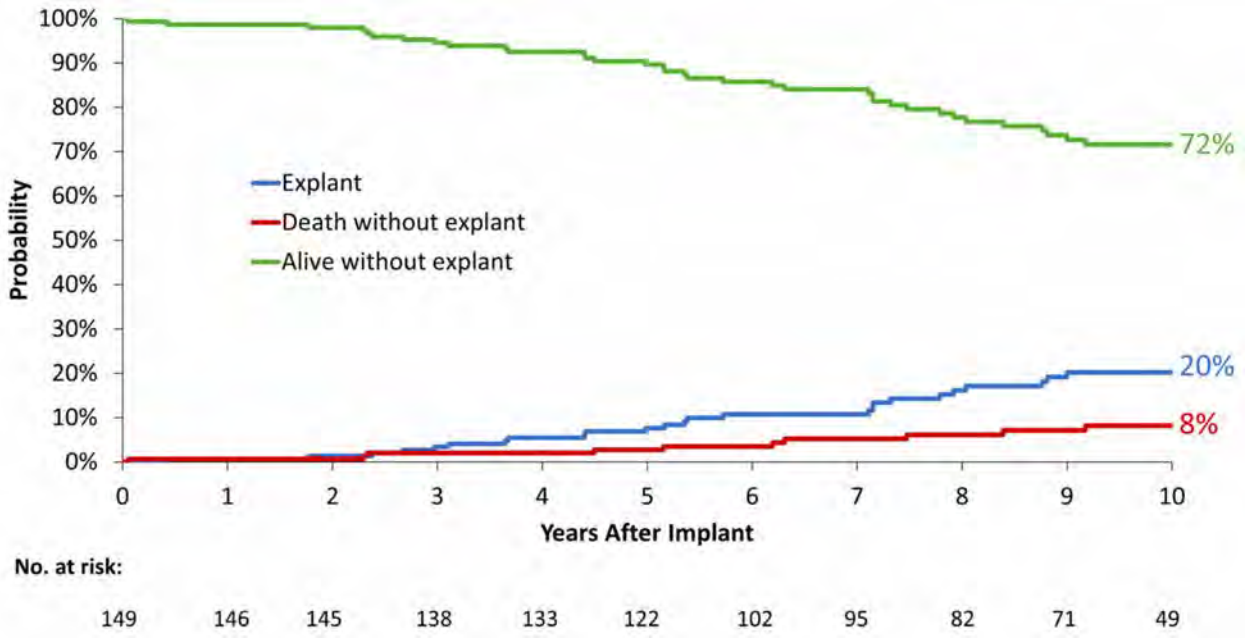
McElhinney et al. *J Am Coll Cardiol*. 2021.

Late Outcomes of Melody TPVR



Jones et al. *Circ Cardiovasc Interv*. 2022.

Late Outcomes of Melody TPVR



Jones et al. *Circ Cardiovasc Interv*. 2022.

Current State of TPVR

Tetralogy of Fallot

With Pulmonary Stenosis

With Pulmonary Atresia

Transannular patch (TAP):
= CHRONIC REGURGITATION

~85% of RVOT Patients

Anomalies of the RVOT

est. 22% of all CHD patients

...reat ...es (TGA)

RV–...uit

RV-PA Conduit Dysfunction:
- **STENOSIS**
- regurgitation

RV–PA Conduit

Virtually all patients will require future procedure(s) to replace the conduit and/or pulmonary valve

~15% of RVOT Patients

Virtually all patients with surgically corrected outflow tracts will require future valve replacement to address RV dysfunction

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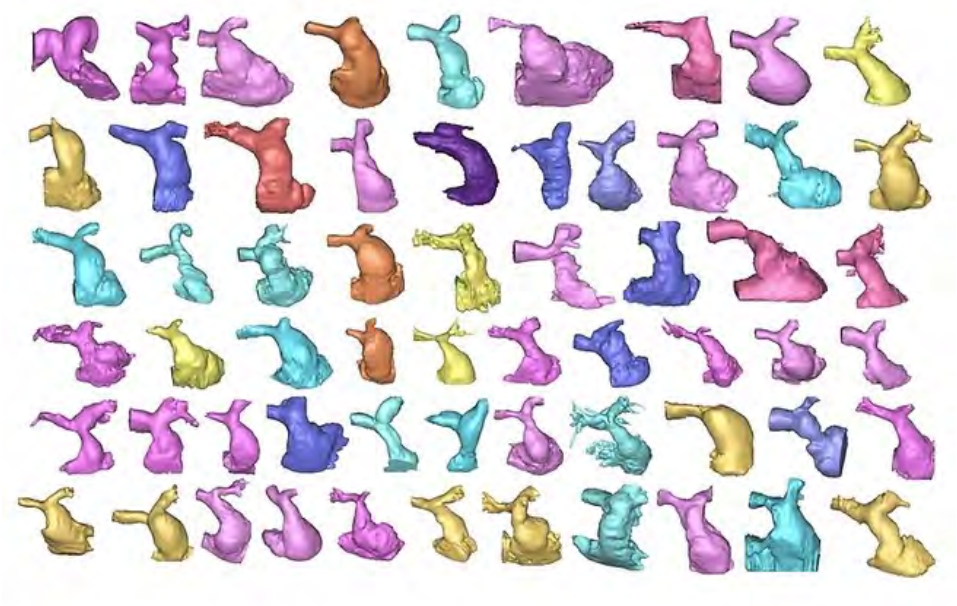
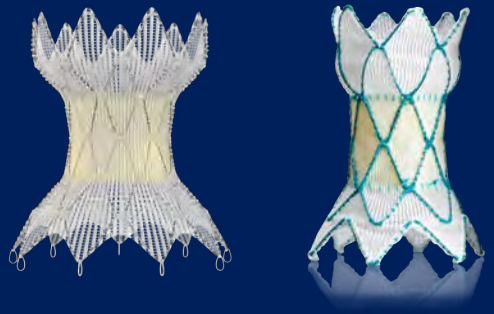
The Challenge with TPVR in Repaired TOF



TPVR in Native RVOT

Medtronic Harmony TPV



FDA cleared in Mar 2021

Edwards Alterra Adaptive Pre-stent + Sapien 3

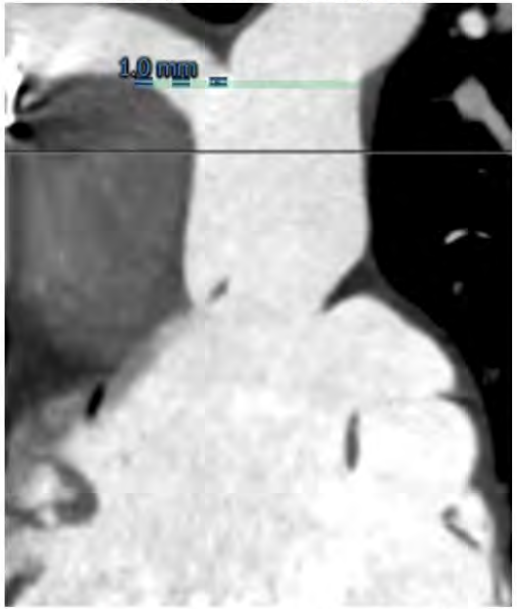
FDA cleared in Dec 2021

Case Example – Harmony TPV

- 24 yo F with TOF
- S/p TAP repair with monocusp PV
- Moderate-severe PI (RF 34%)
- Severe RV dilation (RVEDVi 163 ml/m^2)
- Progressive exertional symptoms

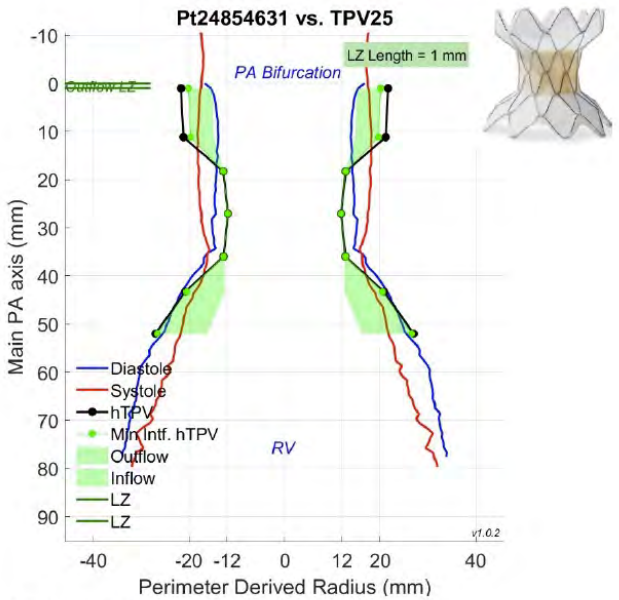
Case Example – Harmony TPV

TPV Target Outflow Landing Zone



Borderline **1 mm** landing zone begins at the roof of the bifurcation

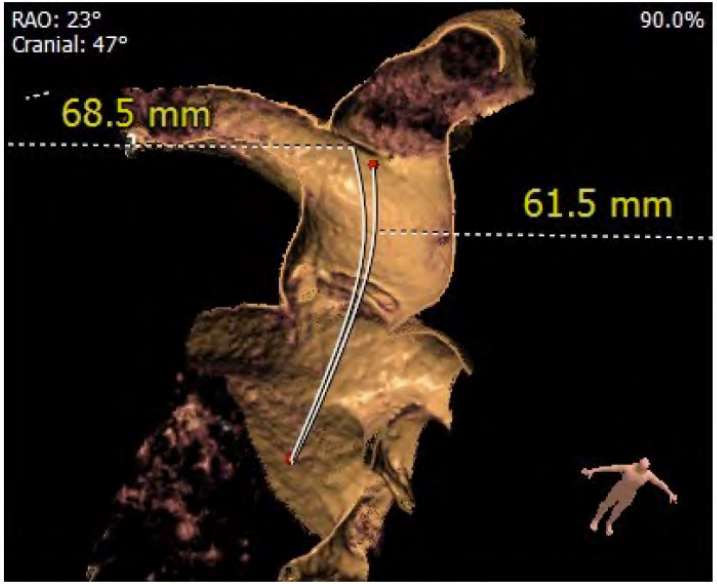
Harmony™ TPV Fit Analysis



Perimeter plot aligned at annulus

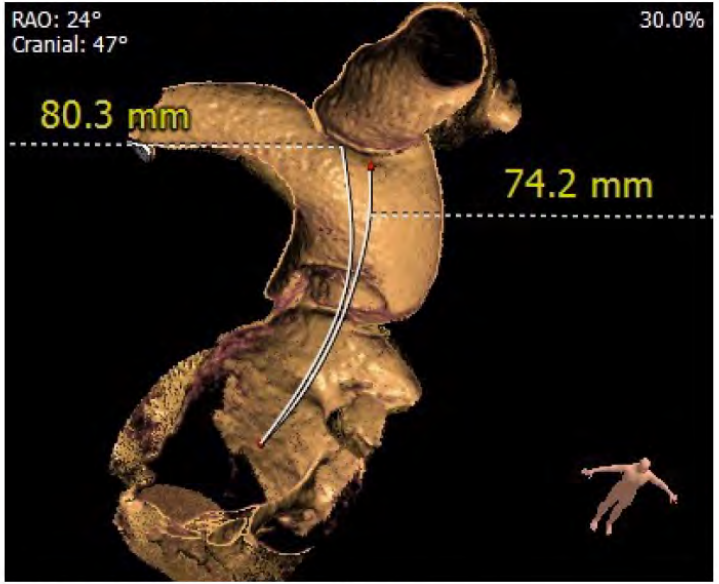
Case Example – Harmony TPV

Diastole pulmonary artery length



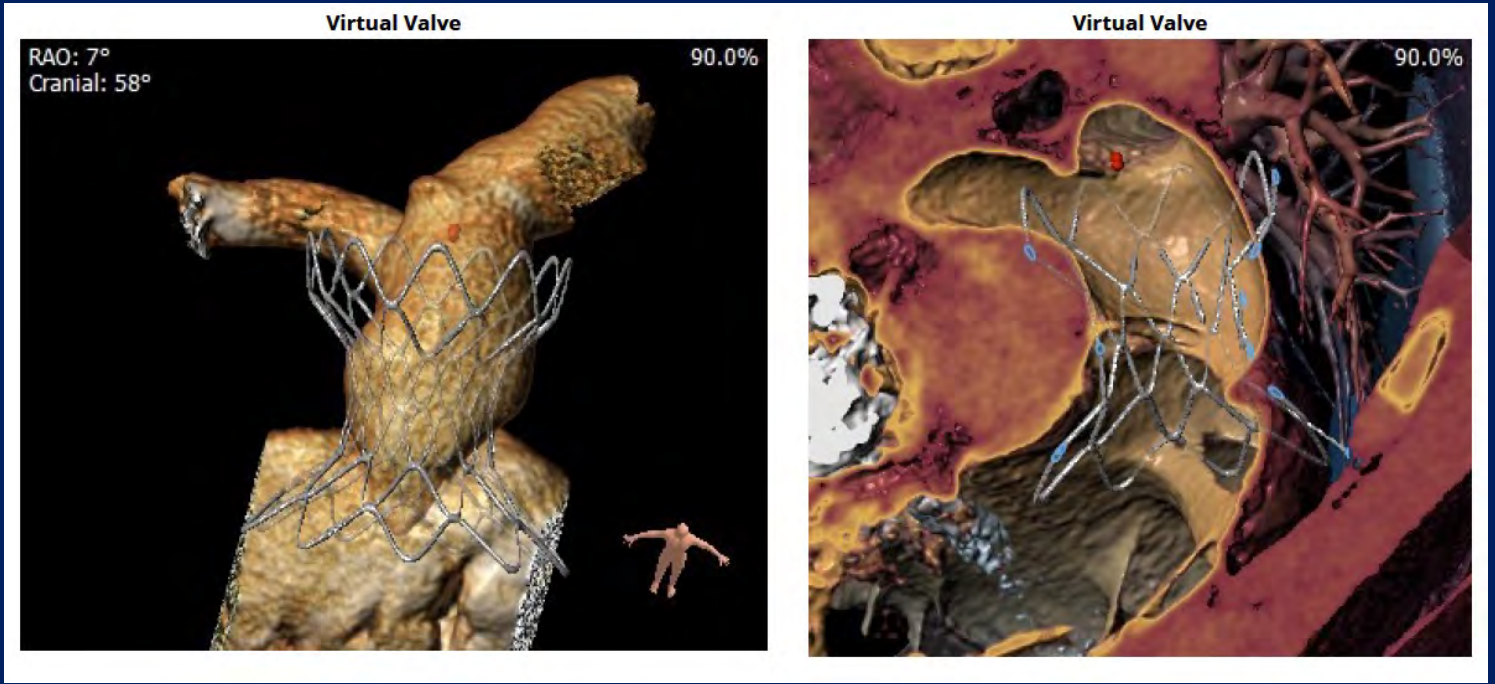
RVOT to Pre-Bifurcation length: 61.5 mm
RVOT to Bifurcation Roof length: 68.5 mm

Systole pulmonary artery length

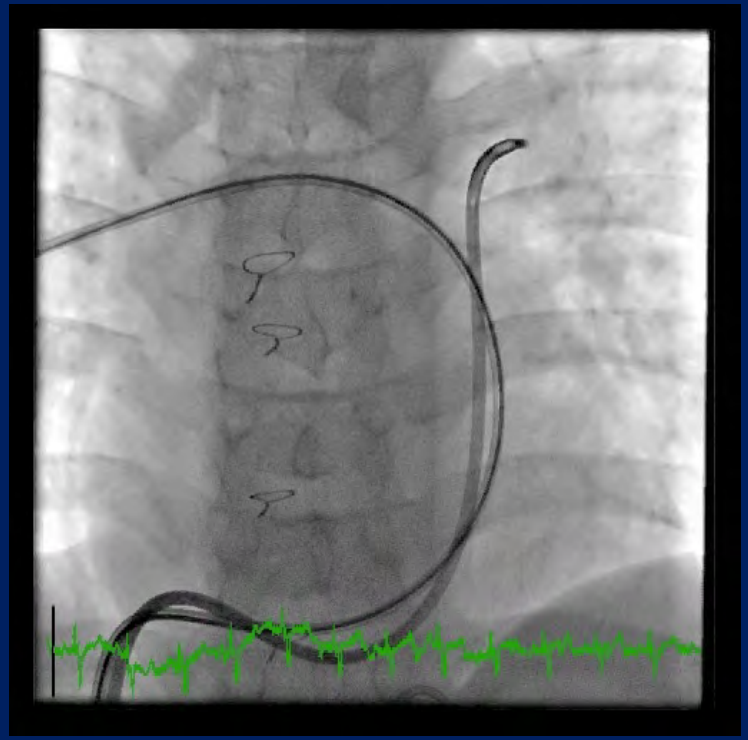


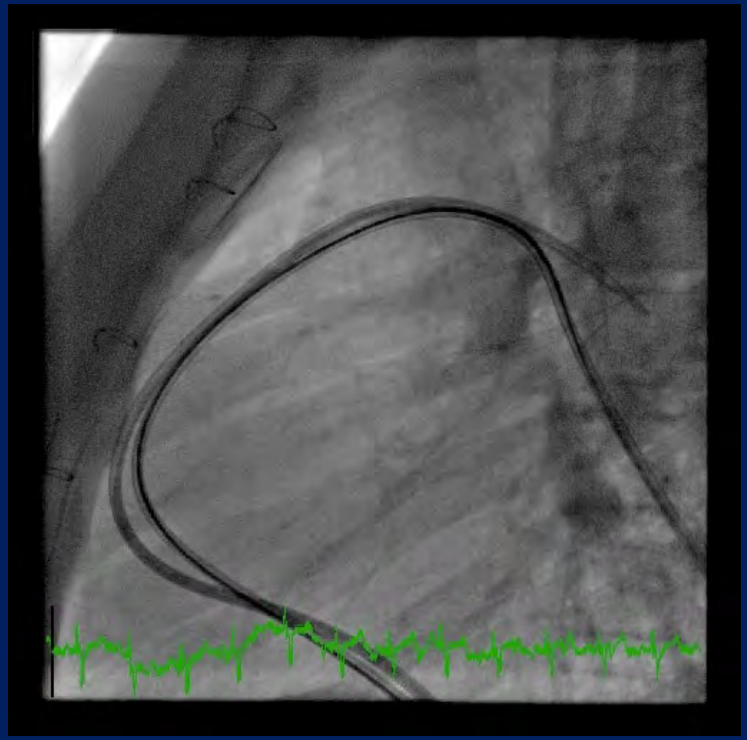
RVOT to Pre-Bifurcation length: 74.2 mm
RVOT to Bifurcation Roof length: 80.3 mm

Case Example – Harmony TPV

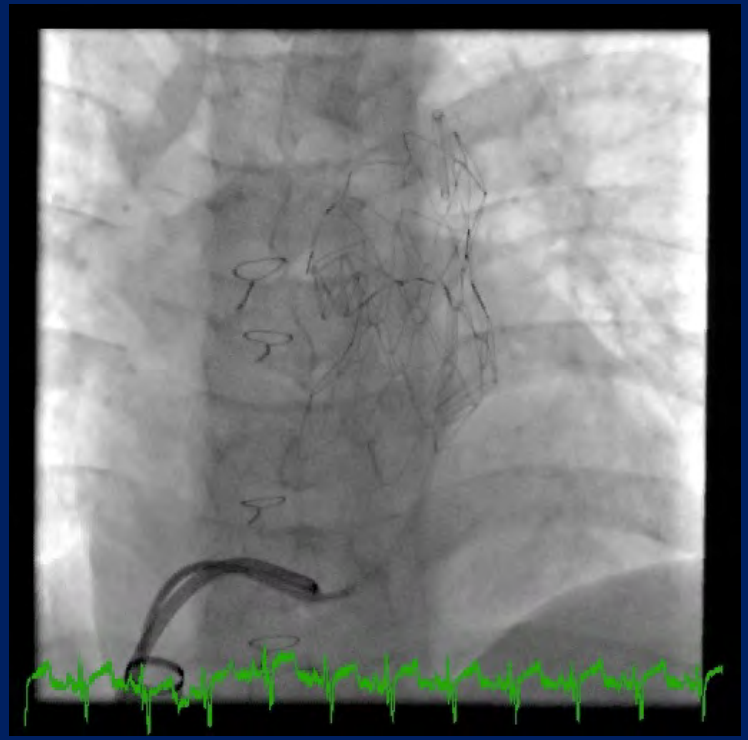


Baseline Pulmonary Angiogram

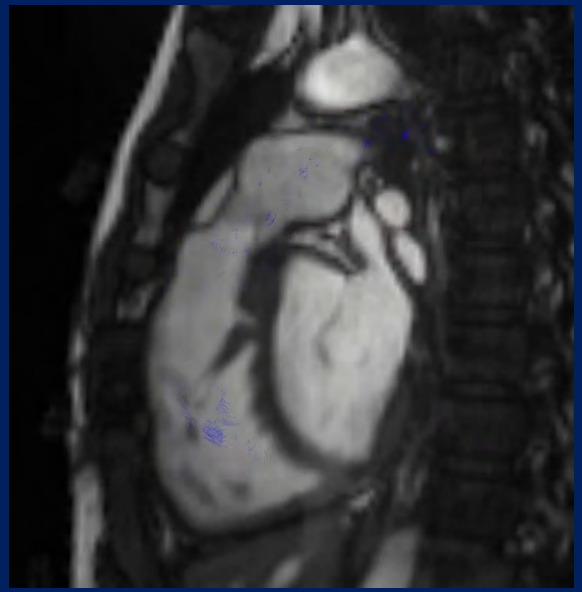




Post-Harmony TPVR



CMR post-Harmony TPVR

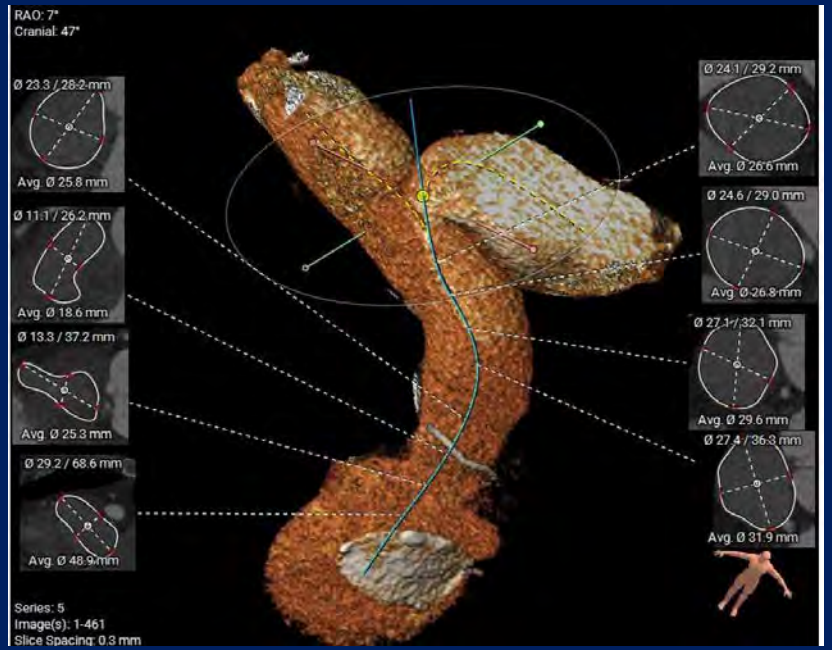


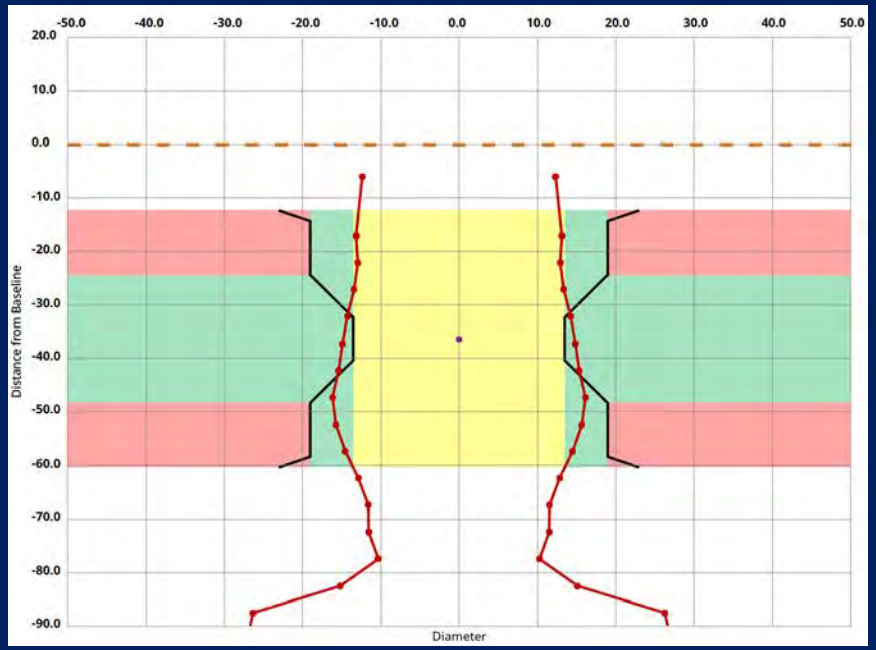
Courtesy of Drs. Laura Olivieri, Adam Christopher and the imaging team at UPMC Children's

Case Example – Alterra + S3

- 56 yo M with TOF
- S/p staged repair with left classic BTTS (2 years) and TAP repair (4 years)
- Severe PI
- Moderate RV dilation
- RV systolic dysfunction (RVEF 36%); preserved LV function (LVEF 54%)
- Progressive exertional symptoms

Case Example – Alterra + S3





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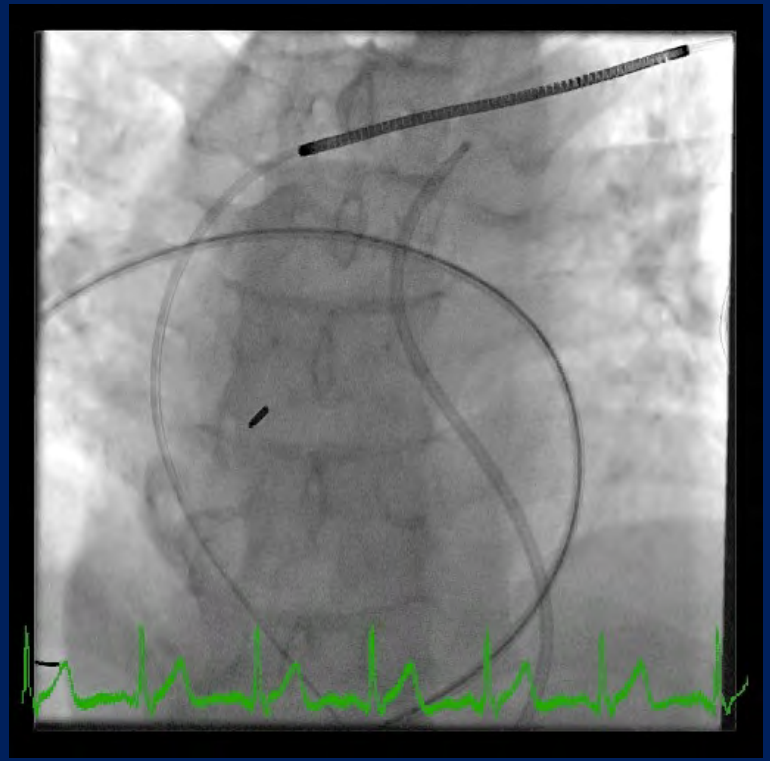
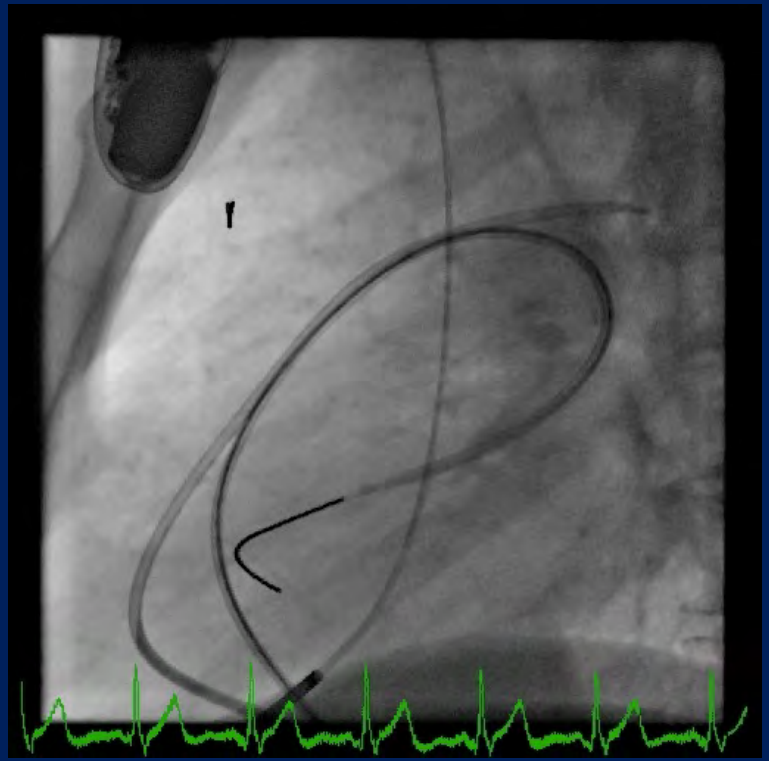
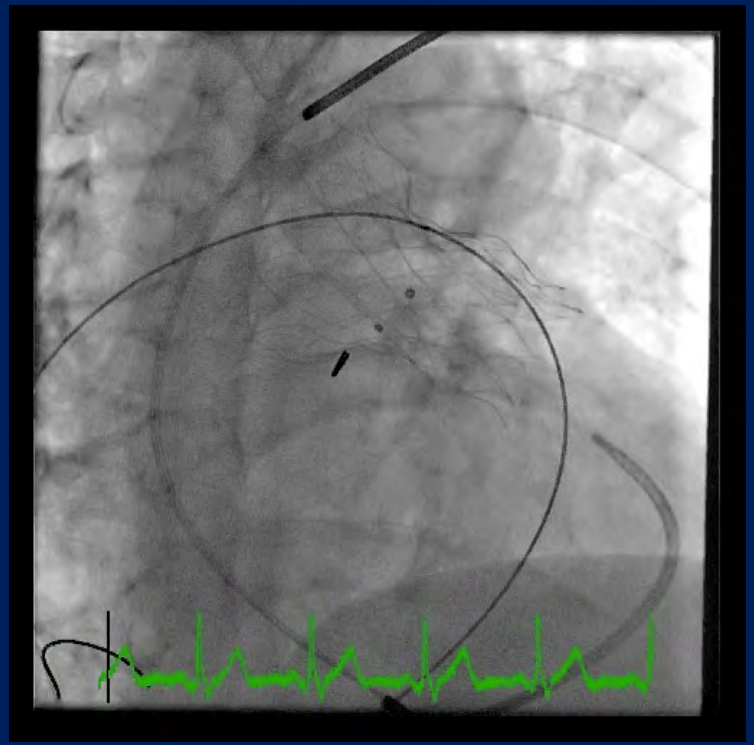
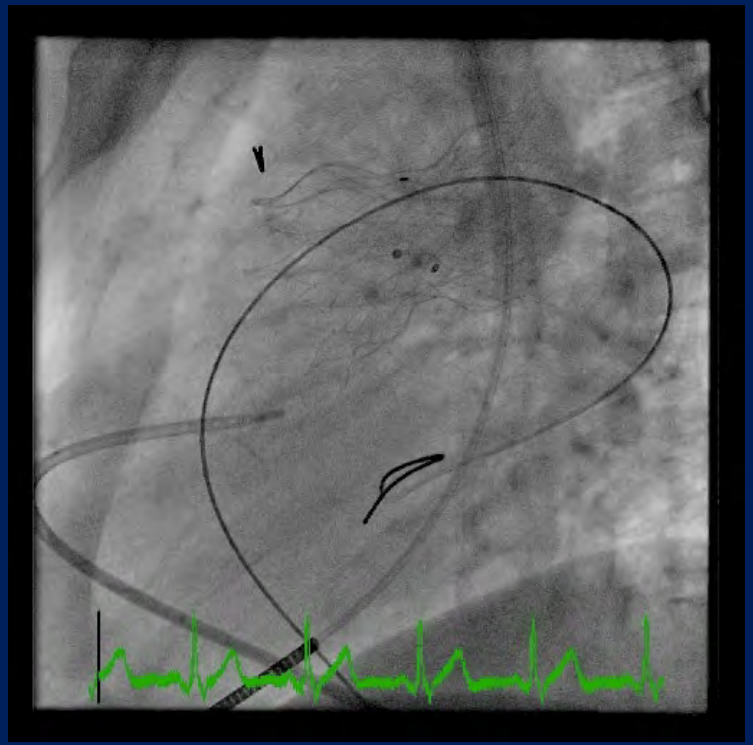
Baseline Pulmonary Angiogram





After Deployment of Alterra Adaptive Prestent





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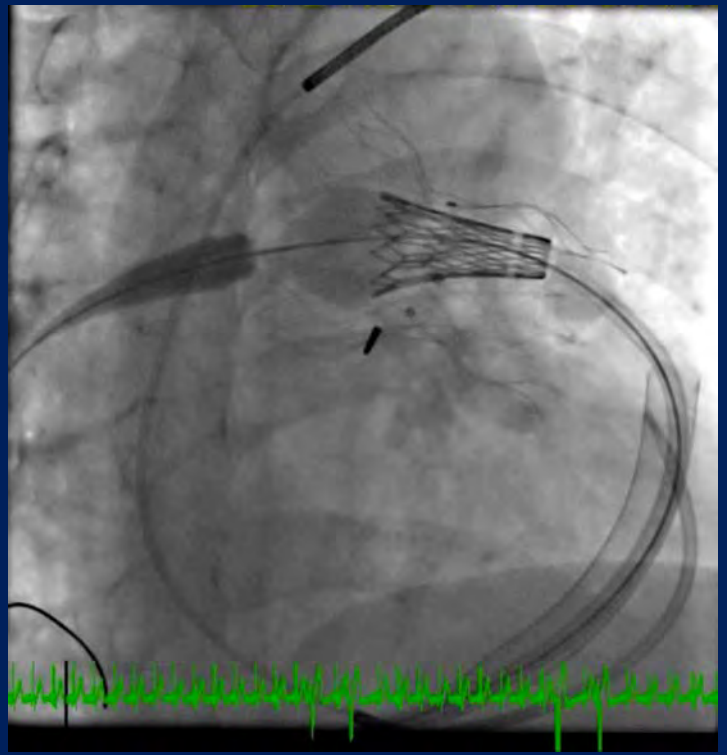

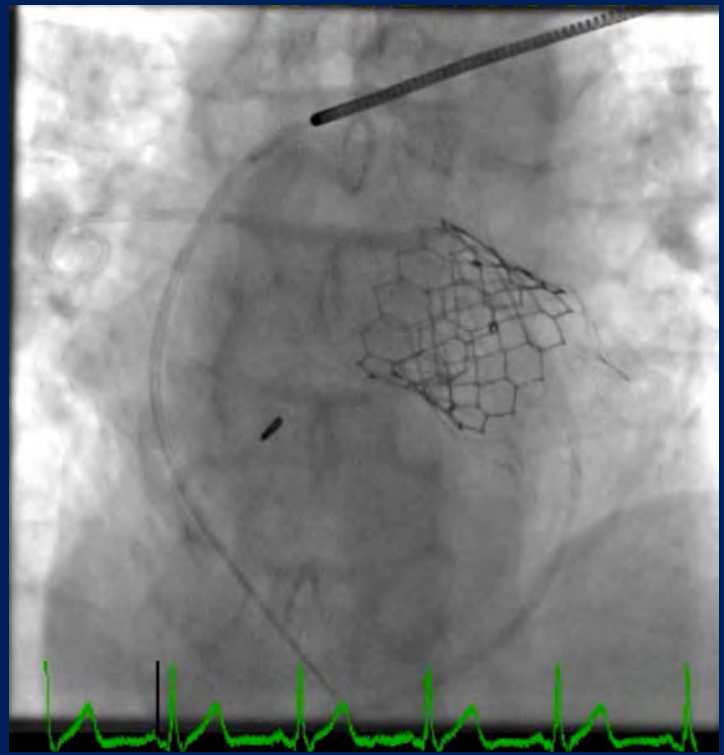

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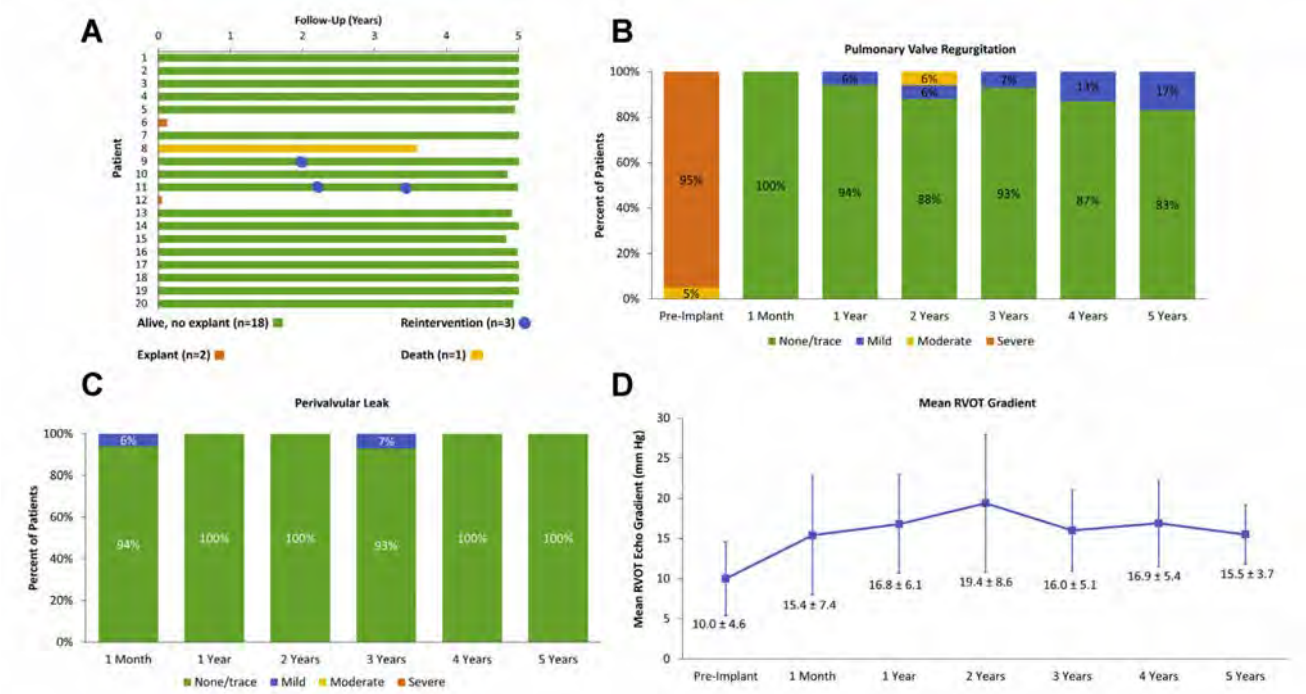
In both Harmony and Alterra, the native RVOT is internally “converted” to a conduit

Mid-Term Outcomes after Harmony TPV

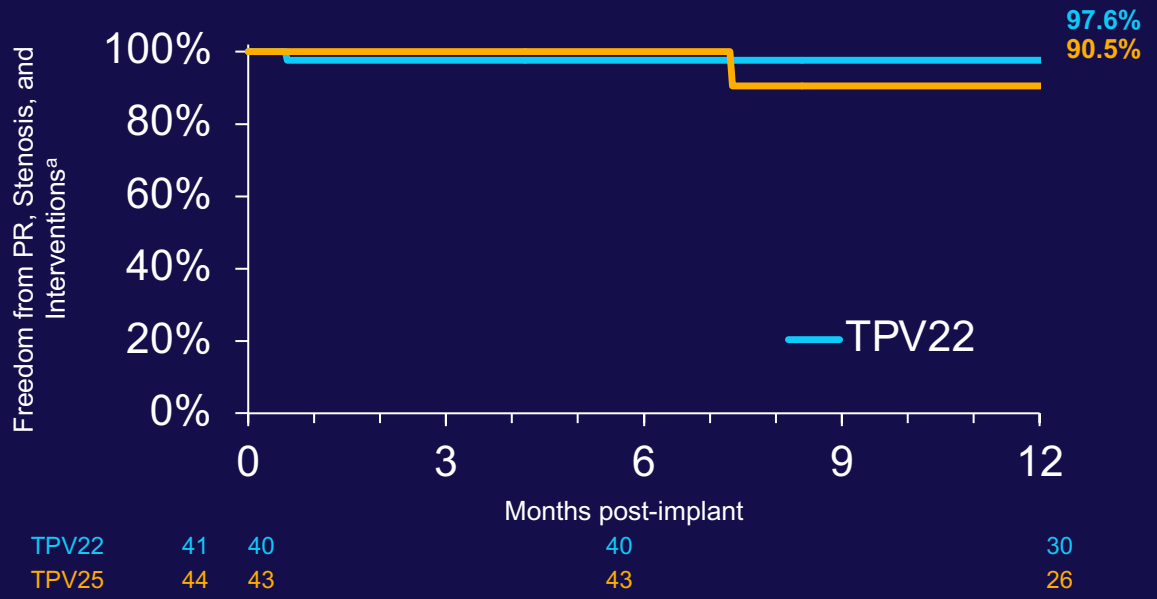


Gillespie et al. *JACC Cardiovasc Interv*. 2021.

Freedom from PR, stenosis, and interventions

Interval censoring analysis landmarked at 30 days in patients implanted > 24 hr

Harmony™ TPV Clinical Study

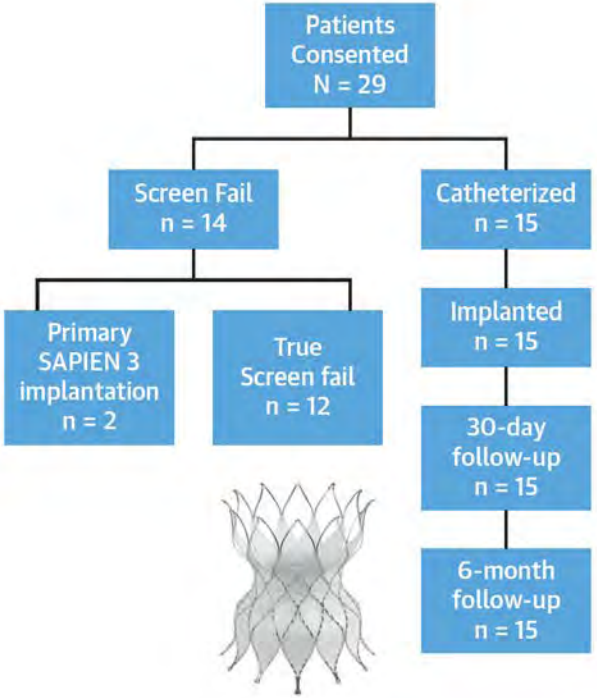


Composite endpoint: PR, stenosis, and interventions

- ≥ Moderate PR
- Mean RVOT gradient > 40 mmHg
- RVOT reoperation for device-related reasons
- Catheter reintervention of the TPV
  - Excludes intraprocedural wire repositioning and balloon angioplasty

[a]Analysis is landmarked at 30 days. Any patients with death or dysfunction events prior to 30 days are not included.

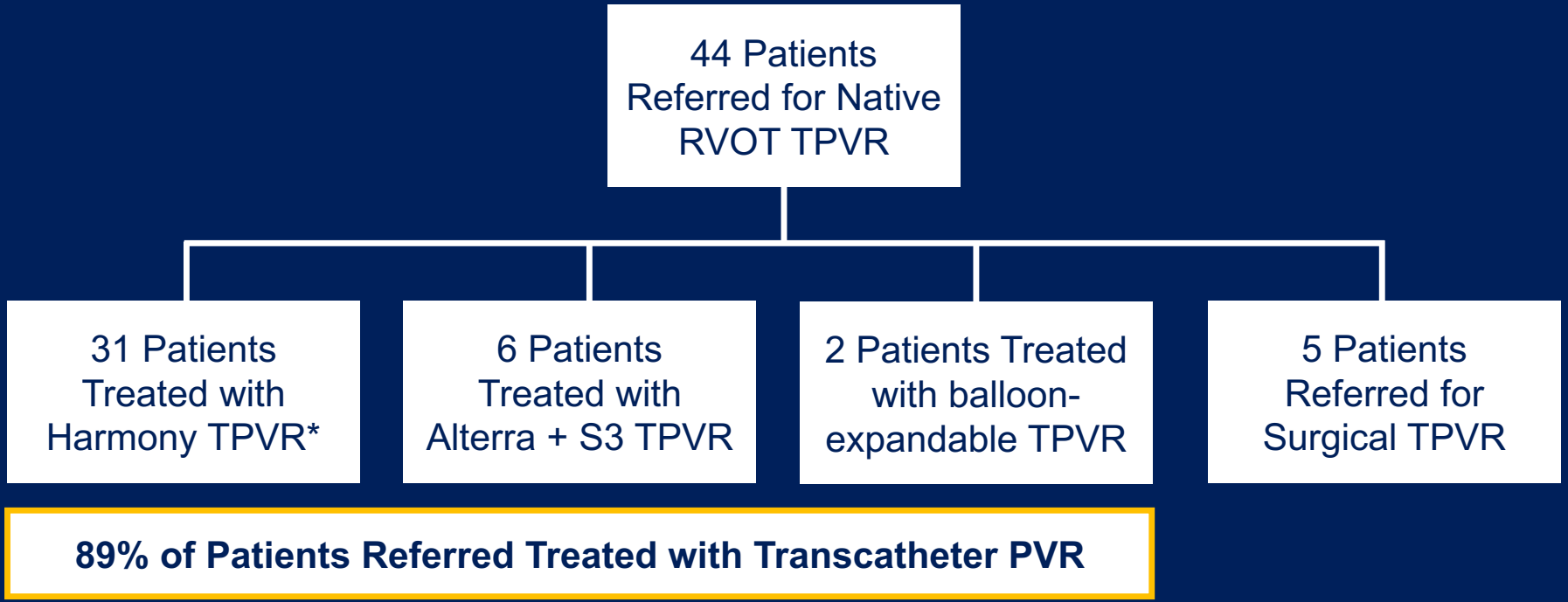
Early Outcomes after Alterra / Sapien 3 TPVR



Variable	6 Months N = 15
Mean right ventricular outflow tract gradient (mm Hg) Median (quartile 1, quartile 3)	9.0 (6.8, 14.3)
Total pulmonic regurgitation, n (%)	
None	8 (53.3)
Trace	7 (46.7)
Tricuspid regurgitation, n (%)	
None	0
Trace	2 (13.3)
Mild	11 (73.3)
Moderate	2 (13.3)
Severe	0

Shahanavaz et al. *JACC Cardiovasc Interv*. 2020.

UPMC Children's Hospital of Pittsburgh Clinical Experience



*Includes 7 patients currently awaiting implant procedure

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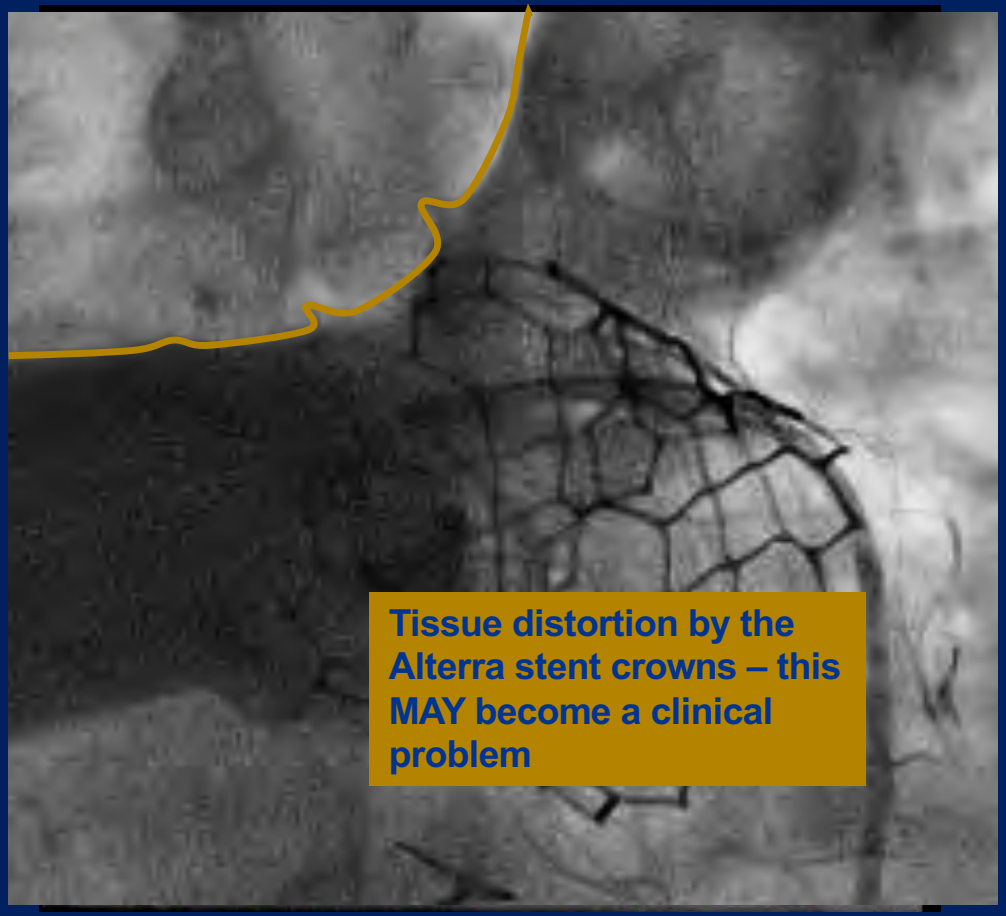
Early Challenges in Native/TAP TPVR

- Early chest pain is common (benign)
- Valves aren’t recapturable / repositionable
- Proximal embolization requires surgery
- PVCs / NSVT / VT in some patients
- Small burden of early leaflet thrombosis

Device-related vascular injury (erosion or laceration)



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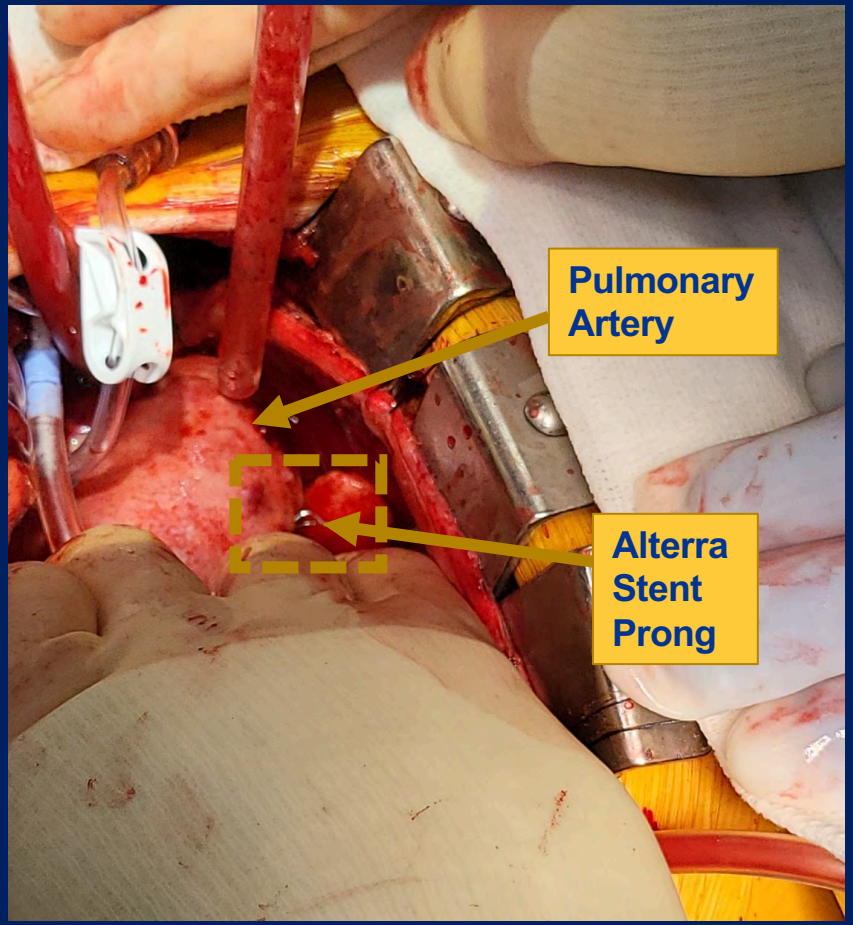

Courtesy of Brent Gordon, MD and the team at Loma Linda

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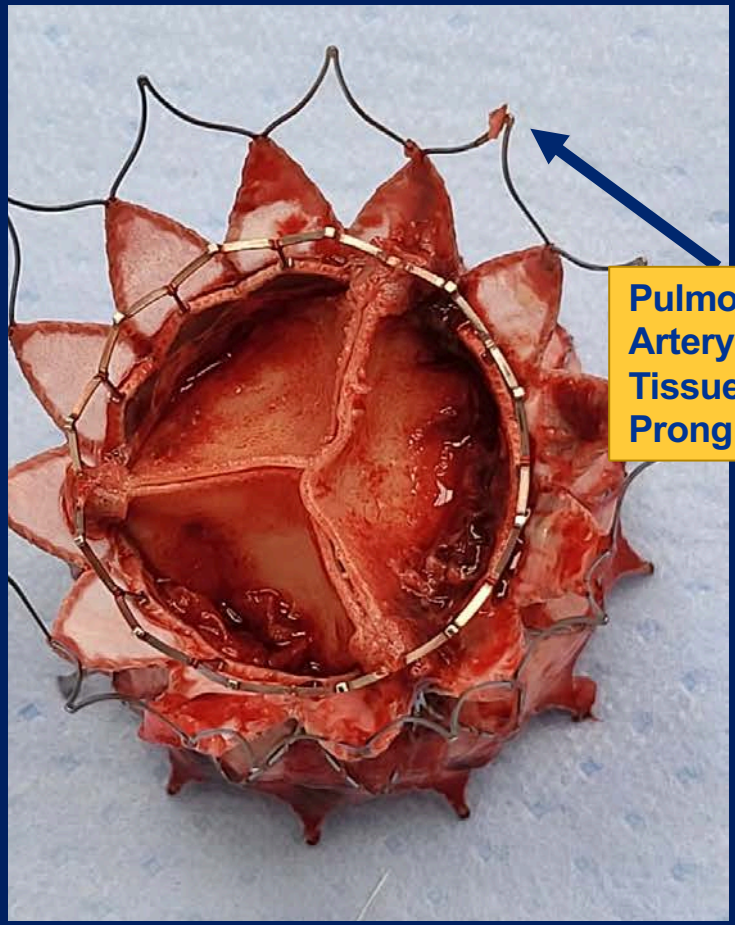

Courtesy of Brent Gordon, MD and the team at Loma Linda

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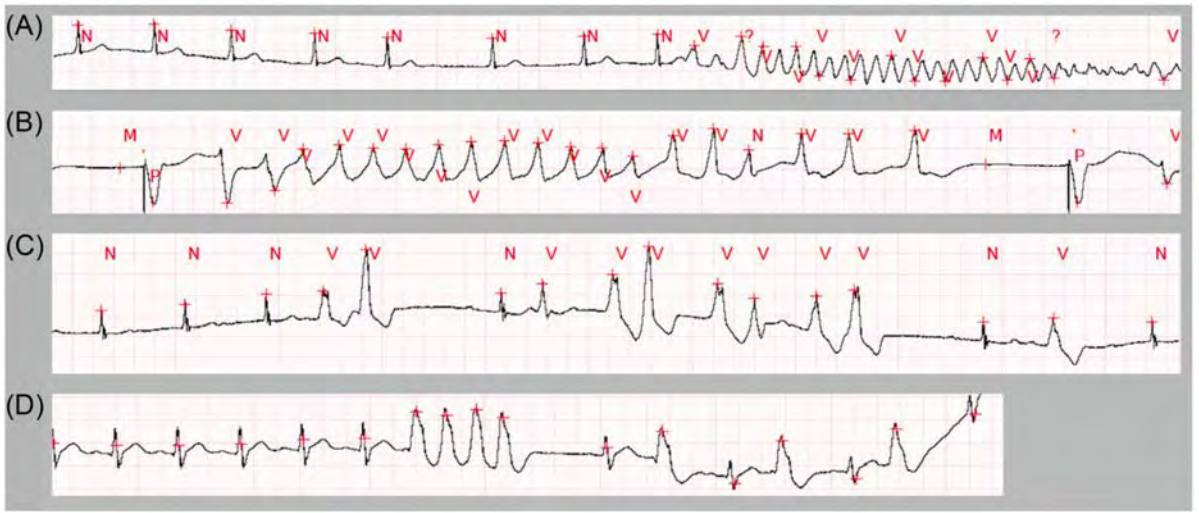
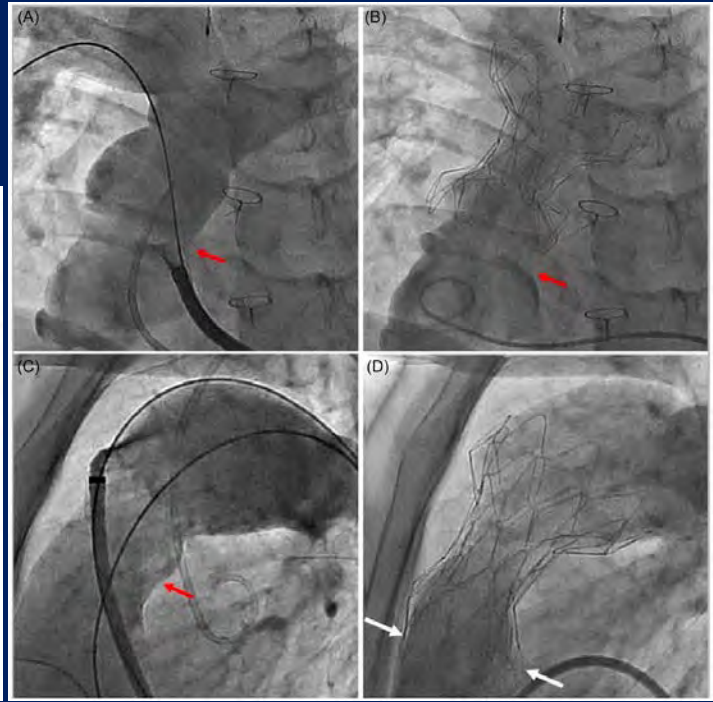
Commotio Cordis

Ventricular arrhythmias following transcatheter pulmonary valve replacement with the harmony TPV25 device

Anne C. Taylor MD | Jeffrey Yang MD | Anne M. Dubin MD |
Mark Henry Chubb MBBS, PhD | Kara S. Motonaga MD | Will R. Goodyer MD, PhD |
Heather Giacone MD | Lynn F. Peng MD | Anitra W. Romfh MD |
Doff B. McElhinney MD | Scott R. Ceresnak MD





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Taylor et al. *Catheter Cardiovasc Interv*. 2022.

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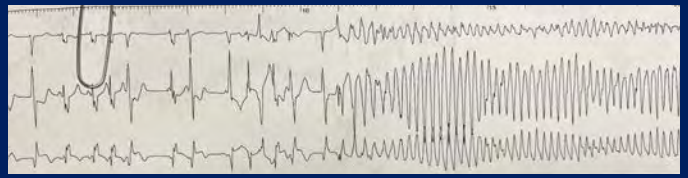
R on T after TPVR in PS Substrate (Internal Commotio Cordis)

+

=

??? Risk TBD

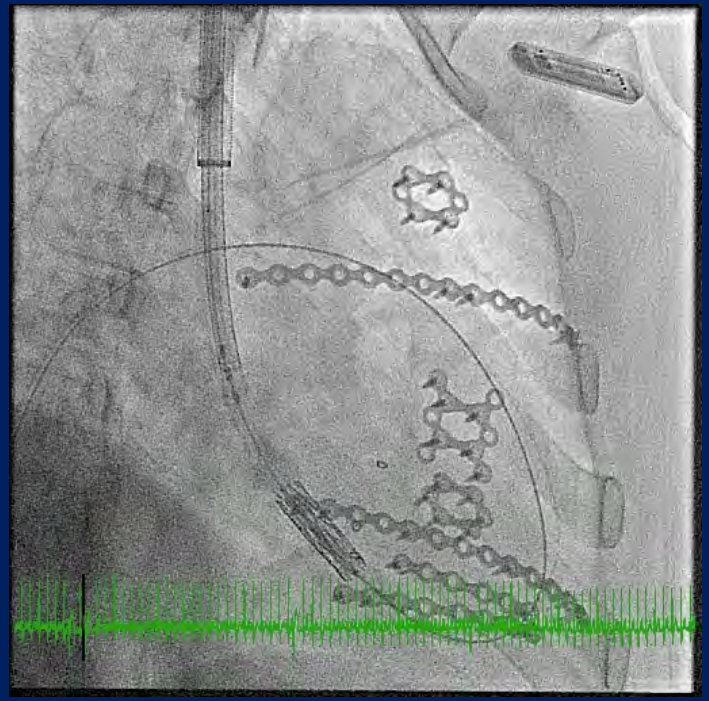


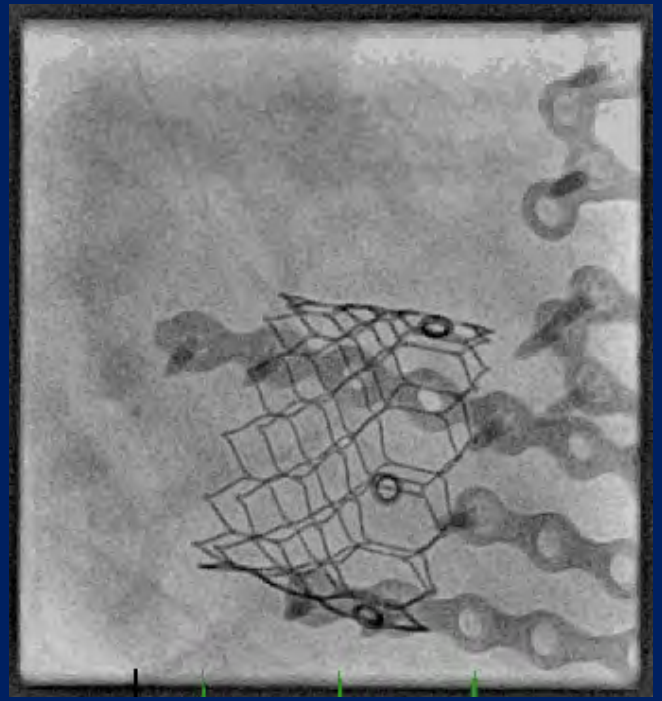
Nearly 1000 native RVOT TPV implants in ~2 years

In absence of a mandated registry, we await large scale outcomes data

Indications for PVR need to “catch up” with clinical practice

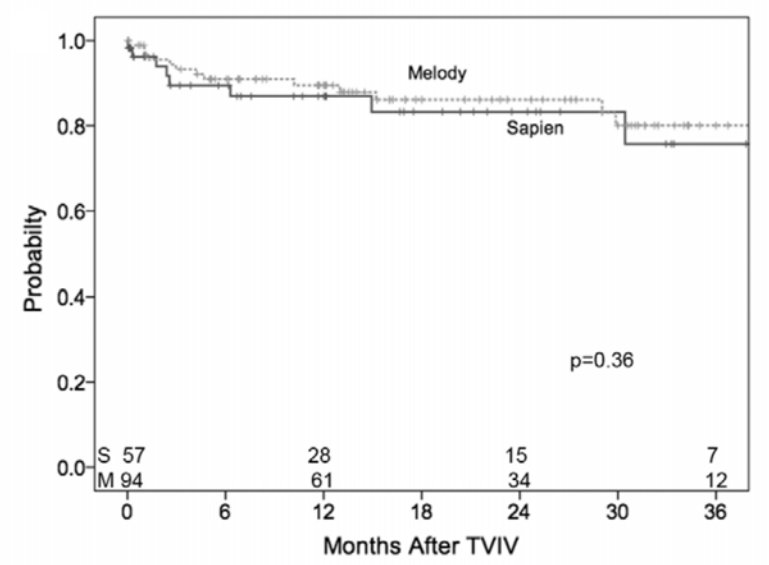
Transcatheter TVIVR



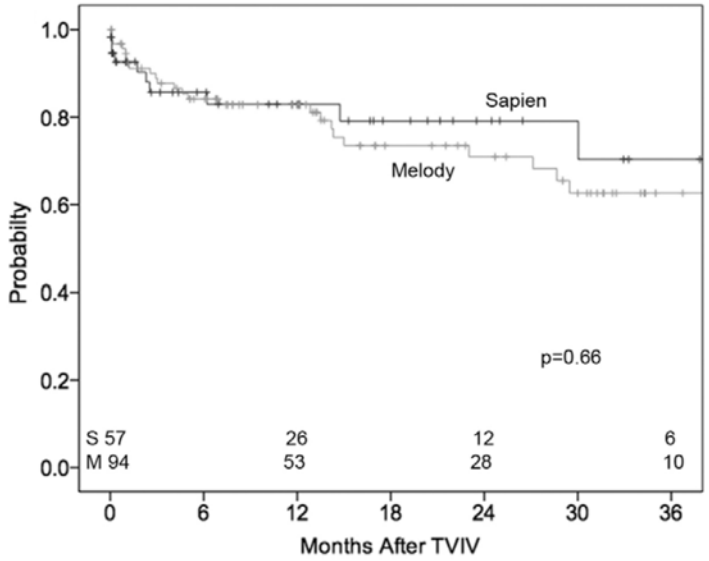


Transcatheter TVIVR

Overall Survival

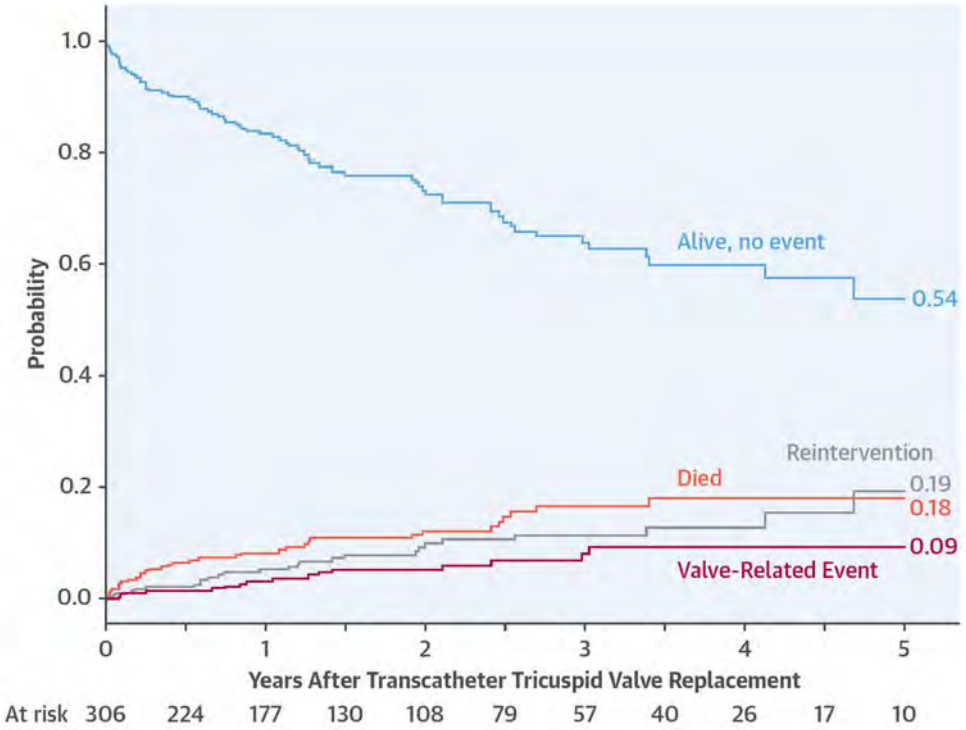


Reintervention and TVIV Dysfunction Free Survival



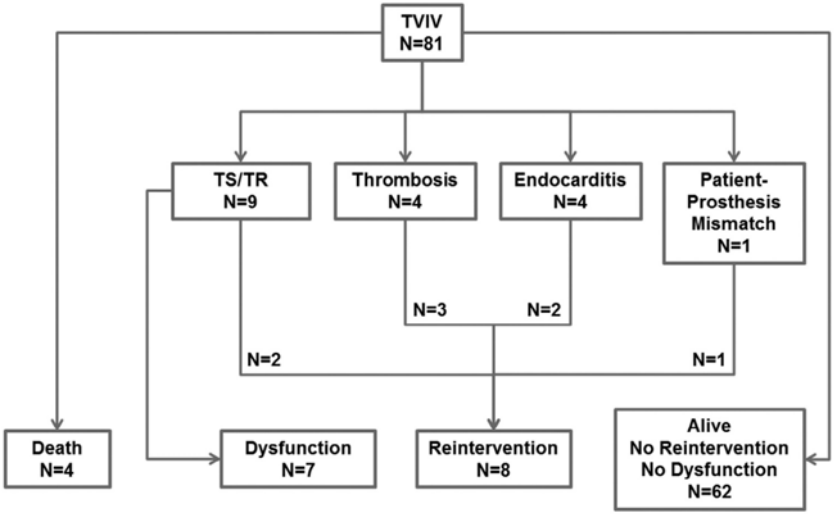
McElhinney et al. *Circulation*. 2016.

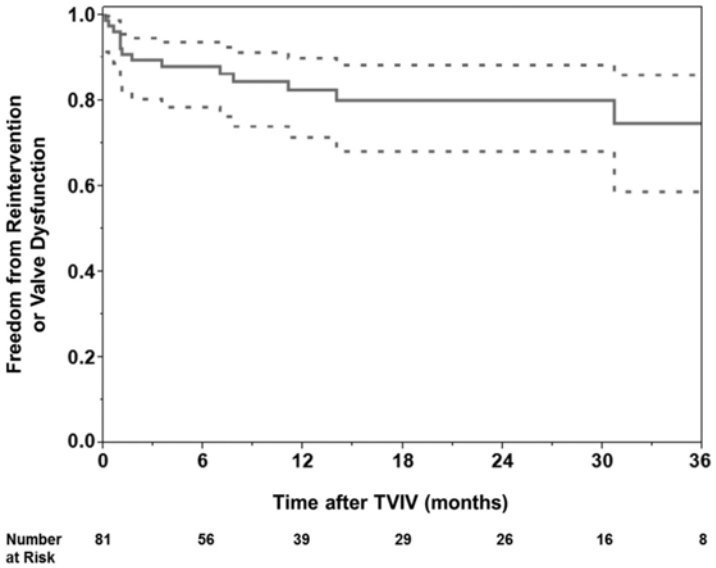
Mid-Term Outcomes after TTVR



McElhinney et al. *J Am Coll Cardiol*. 2019.

Transcatheter TVIV in Ebstein Anomaly





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Taggart et al. *Am J Cardiol*. 2018.

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	Repair	Replace
Pulmonic	Inadequate leaflet tissue	
Tricuspid		

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Pulmonic	Inadequate leaflet tissue	
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Is There a Role for AVV Repair in SVHD?

Courtesy of Drs. Matthew Gillespie, Matthew Jolley and the team at CHOP

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Conclusions

- Balloon-expandable TPVR is now well-established
- Native RVOT TPVR has had rapid uptake
- Outcomes data are needed (native RVOT)
  - Malignant arrhythmia risk
  - Implications to later surgery
- TTVR is feasible but long-term outcomes remain challenging
- Anticipate improvements with Gen 2 systems
- Early days for transcatheter native AVV repair (and replacement) in CHD

Thank You

bryan.goldstein@chp.edu