HealthCare
GILL HEART & VASCULAR INSTITUTE
Network

NEW DEVELOPMENTS IN TRANSCATHETER PULMONARY VALVE THERAPY

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University of Kentucky

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FACULTY DISCLOSURE

- I have the following relevant financial relationships to disclose:

  Medtronic: Consultant

  Edwards: Consultant

- I will discuss non-FDA-approved uses for devices.

- All relevant financial relationships have been mitigated.

EXPECTED OUTCOME & EDUCATIONAL NEED/ PRACTICE GAP

- **Expected outcome:** After attending this presentation, providers should be able to better recognize patients with adult congenital heart disease (particularly pulmonary valve disorders) and refer early to adult congenital heart centers with expertise in catheter-based pulmonary valve therapy.

- **Educational Need:** Most adult cardiology providers have limited experience with adult congenital heart disease which can lead to misdiagnosis, late diagnosis, and late referrals.

- **Practice Gap:** After this presentation, I anticipate that the Gill Network will move towards more optimal care with early referral of adult congenital heart patient to our nationally-recognized ACHD center at the University of Kentucky.

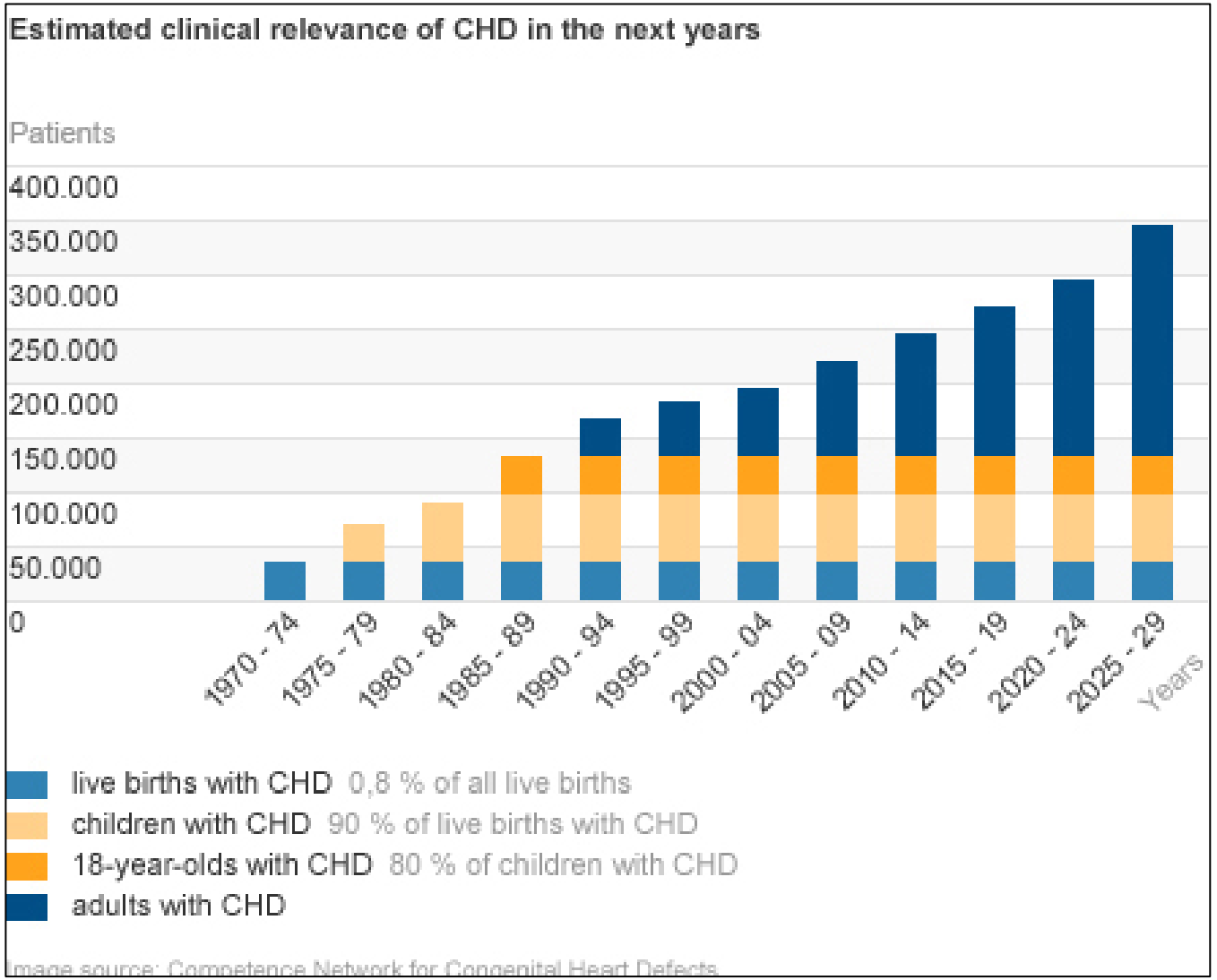
OBJECTIVES

After this educational activity, participants will be able to:

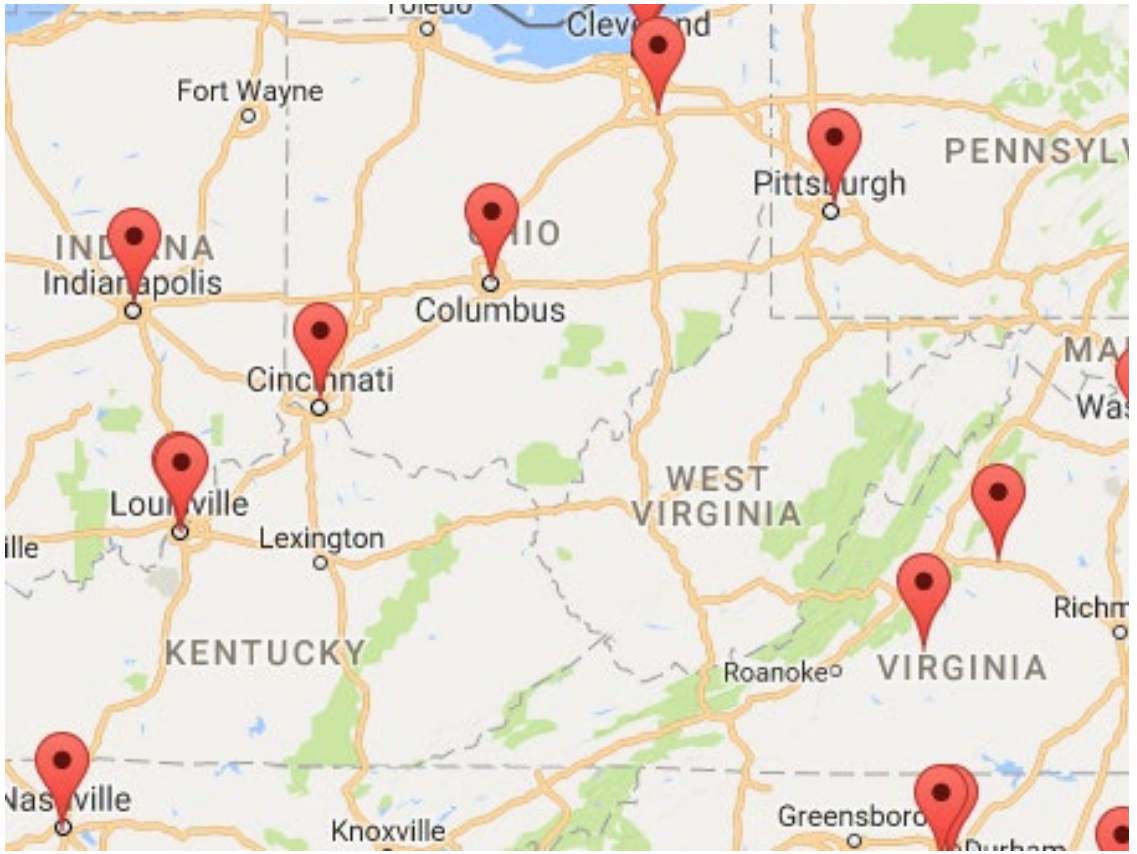
1) List diagnoses in adult congenital heart disease (ACHD) clinic

2) Describe transcatheter pulmonary valves and indications

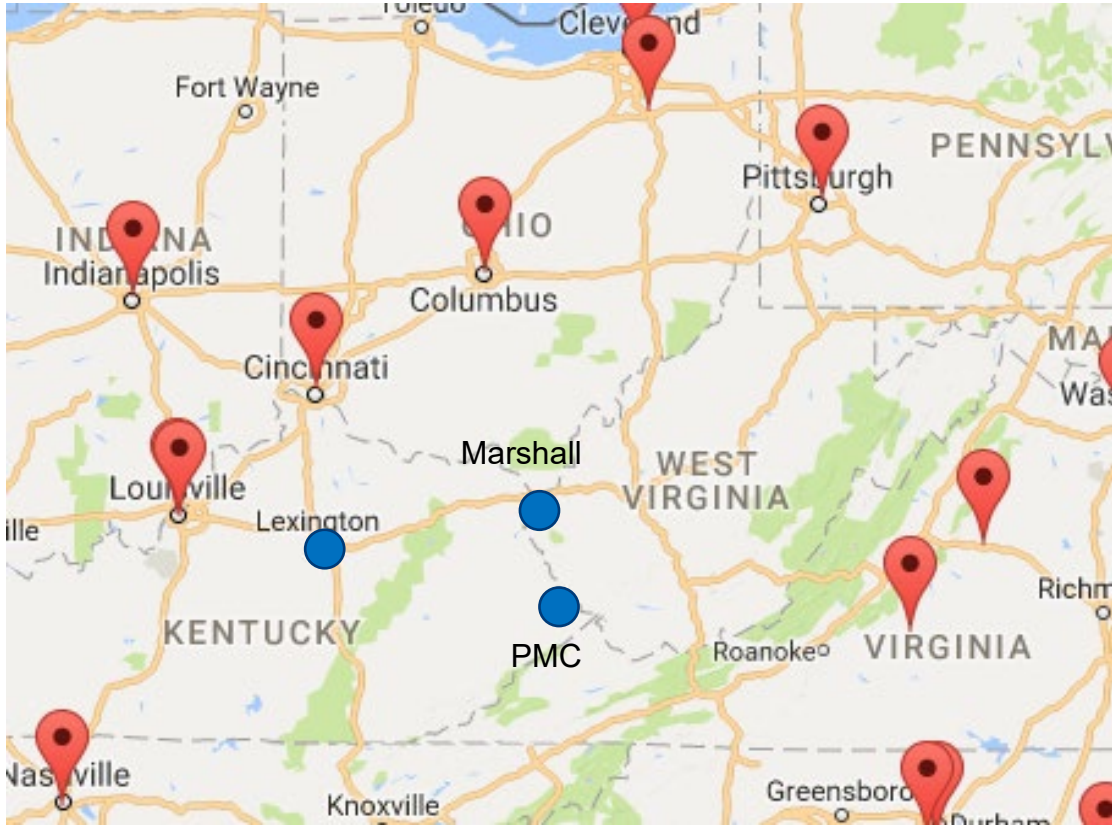
ACHD: A GROWING POPULATION



ACHD CLINICS 2016



ACHD CLINICS 2025



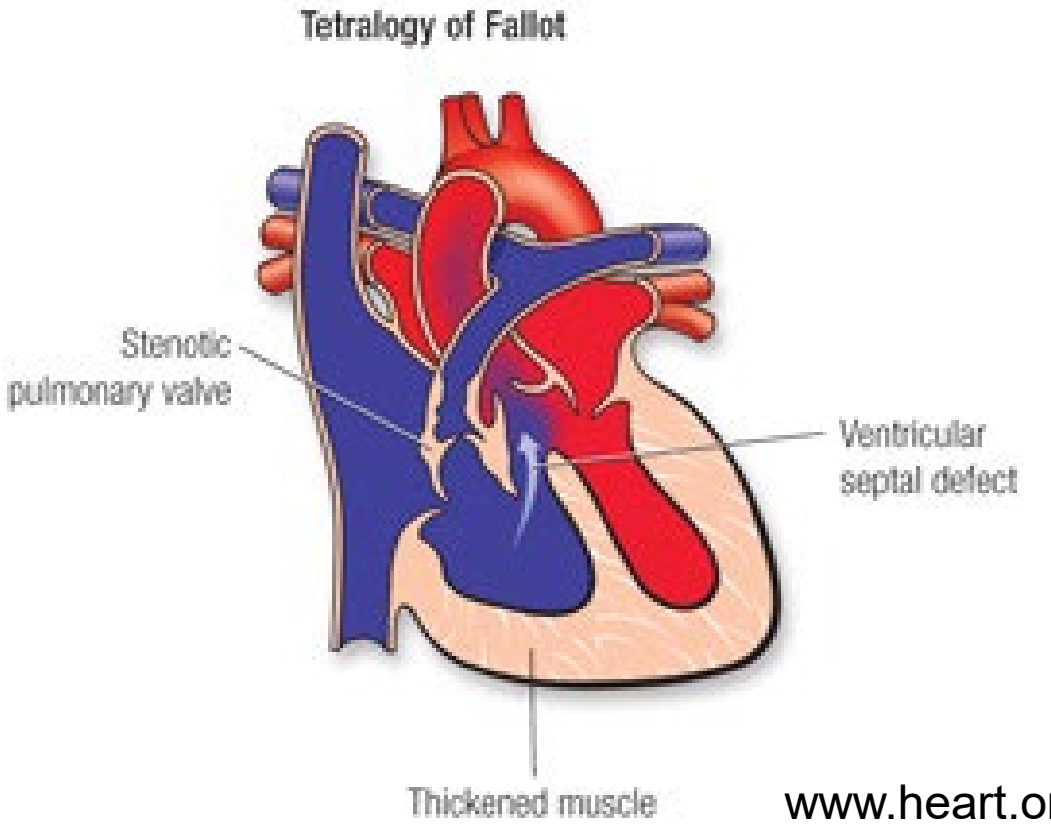
COMMON ACHD DIAGNOSES

- Sinus Venosus Defects
- Primum ASD
- Ebstein Anomaly
- Pulmonary Valve Disorders
- Tetralogy of Fallot (TOF)
- Ross procedure
- Truncus Arteriosus
- Patent Ductus Arteriosus (“PDA”)
- Pulmonary or Coronary AVMs
- Bicuspid aortic valve
- Coarctation of the Aorta
- D-Transposition (Mustard, Senning, Rastelli, Arterial Switch)
- L-Transposition
- Fontan (“single ventricle”) patients

TETRALOGY OF FALLOT (TOF)

- Described by Steno in 1672
- Fallot described it as a single pathologic process in 1888
- 4 components:

  VSD
  Overriding aorta
  RVOT obstruction
  RVH



www.heart.org

TOF SURGICAL ADVANCES

- 1945

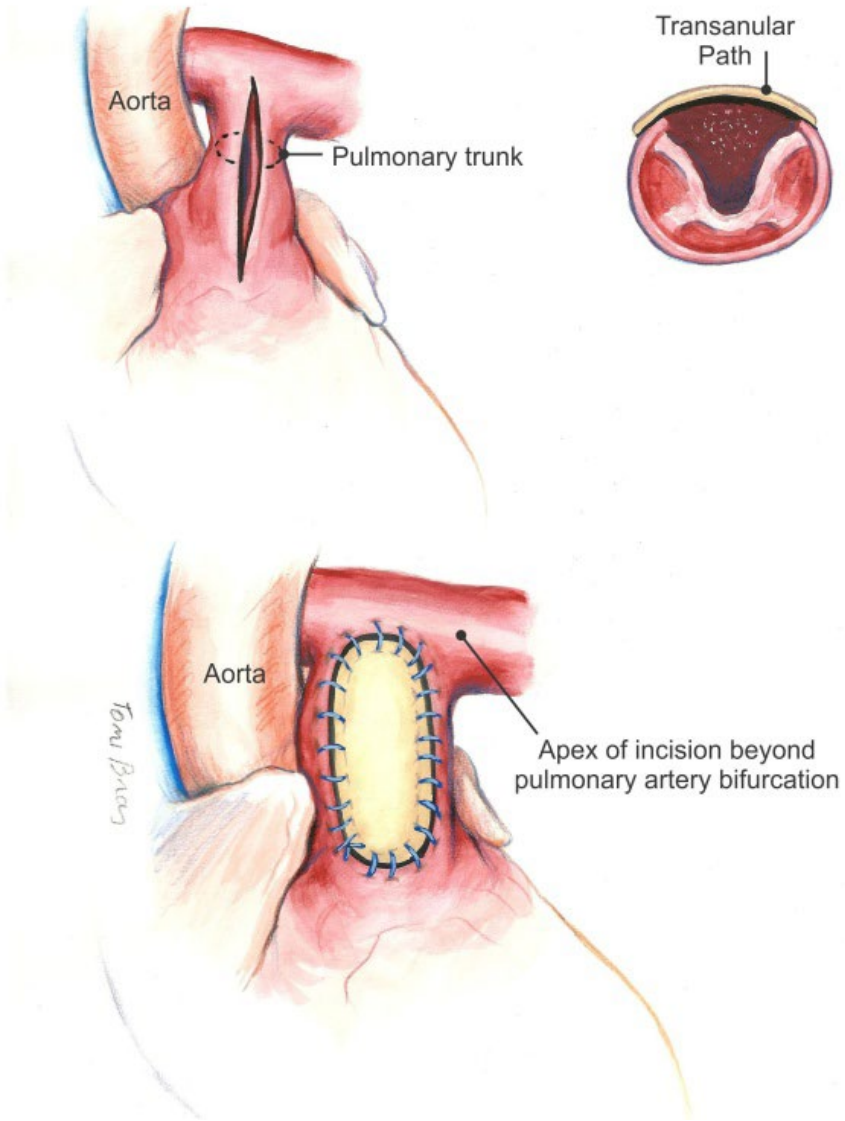
Blalock-Taussig Shunt (Johns Hopkins)

- 1954

Complete TOF repair Lillehei (U Minn)

- 1970s-80s: Infant repair

- 1990s: Neonatal repair



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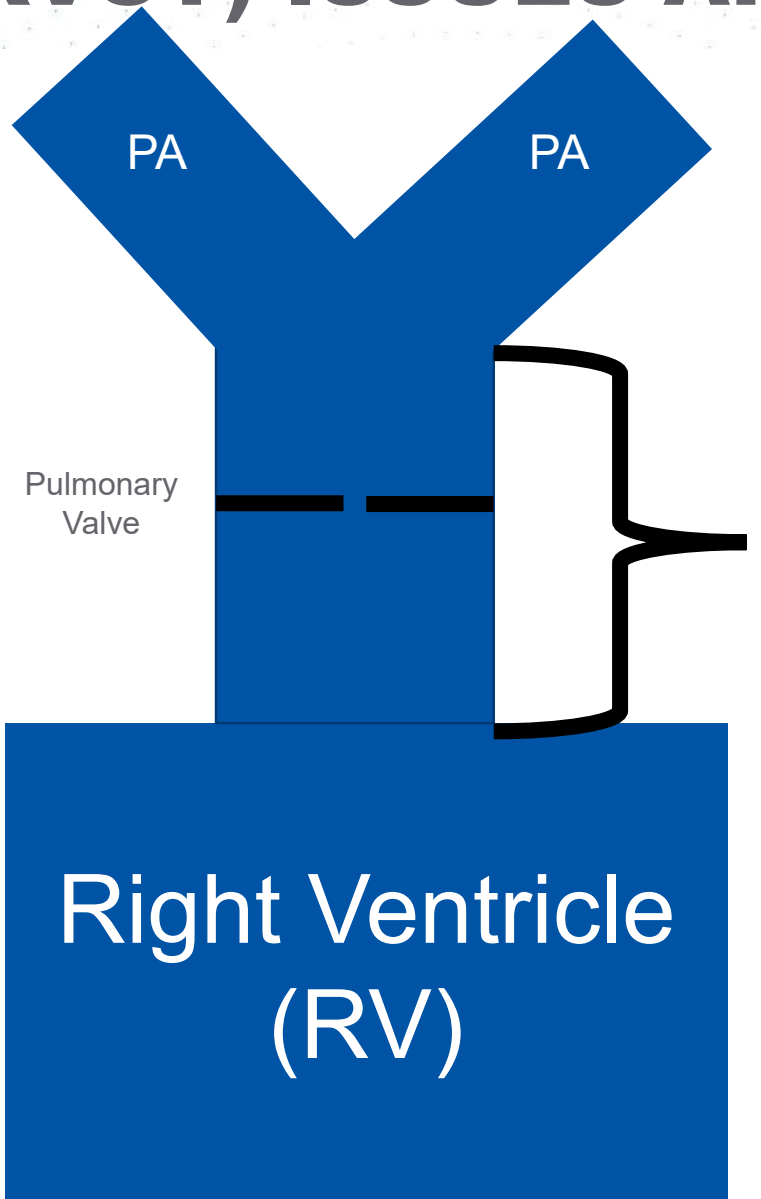
Nina, “Cardiac Surgery-A Commitment to Science, Technology, and Creativity, Ch 9.

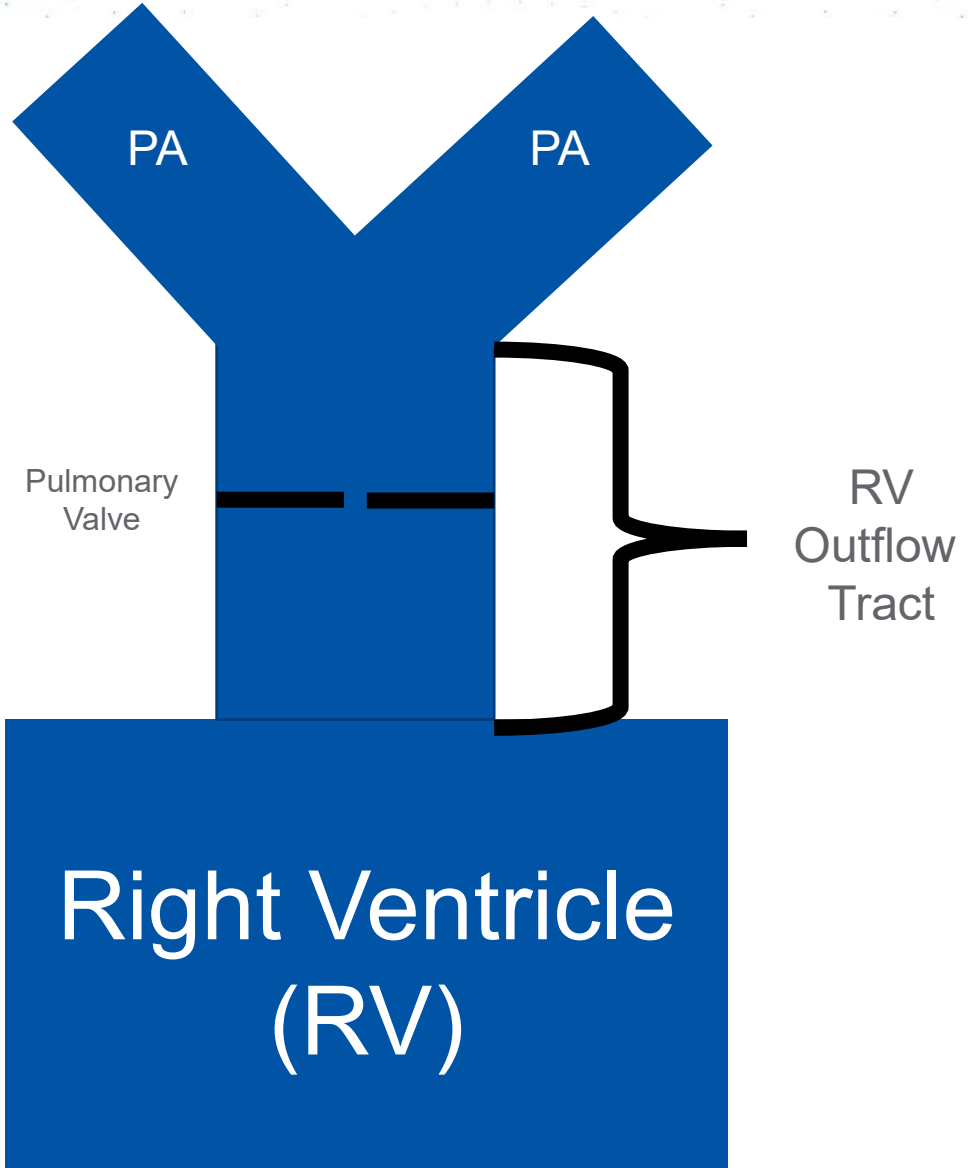
RIGHT VENTRICULAR OUTFLOW TRACT (RVOT) ISSUES ARE COMMON IN ACHD



Diagnoses

1) Tetralogy of Fallot
2) Ross Procedure
3) Pulmonary Stenosis
4) Truncus Arteriosus
5) Pulmonary Atresia
6) Rastelli Operation
7) Double Outlet RV (DORV)

RIGHT VENTRICULAR OUTFLOW TRACT (RVOT) ISSUES ARE COMMON IN ACHD



1) Conduit
   - Homograft
   - Synthetic
   - 2 FDA-Approved Transcatheter Valves

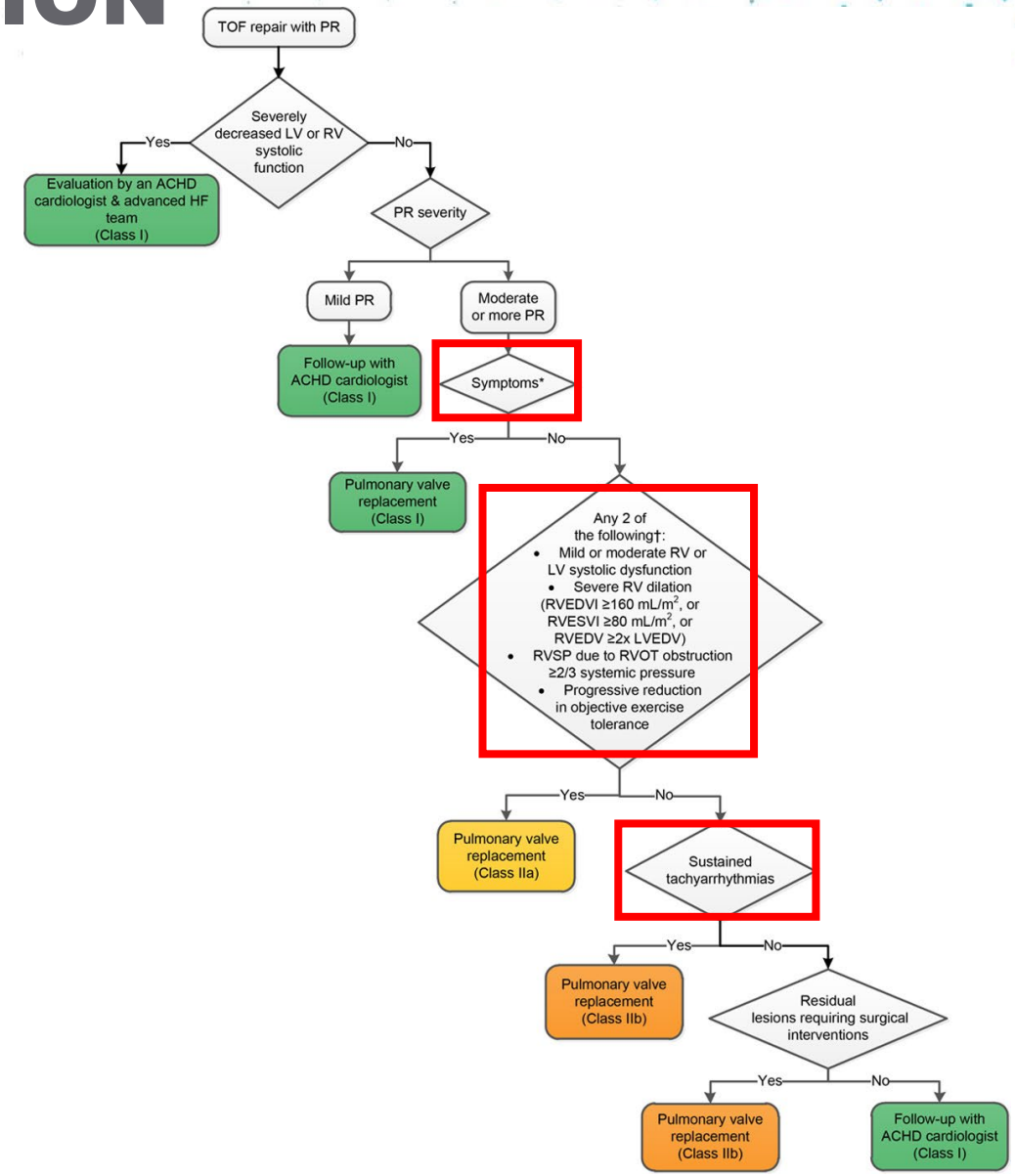
2) Bioprosthetic Pulmonary Valve (BPV)
   - 2 FDA-Approved Transcatheter Valves

3) Native RVOT
   - Distensible
   - Only option was surgery
   - 2 FDA-Approved Transcatheter Valves in 2021

CHRONIC PULMONARY REGURGITATION

- RV dilation/failure (edema/dyspnea)
- Arrhythmia
- Early mortality
- LV dysfunction
  - ~21% of all adults with repaired TOF have LV dysfunction (Broberg et al, AJC, 2011)

ACC/AHA GUIDELINES FOR PV INTERVENTION



ACC/AHD ACHD Guidelines 2018

THE TRANSCATHETER VALVE ERA BEGINS!!

Early report

Percutaneous replacement of pulmonary valve in a right-ventricle to pulmonary-artery prosthetic conduit with valve dysfunction

Philipp Bonhoeffer, Younes Boudjemline, Zakhia Saliba, Jacques Merckx, Yacine Aggoun, Damien Bonnet, Philippe Acar, Jérôme Le Bidois, Daniel Sidi, Jean Kachaner

- 12-year-old boy
- PA + VSD

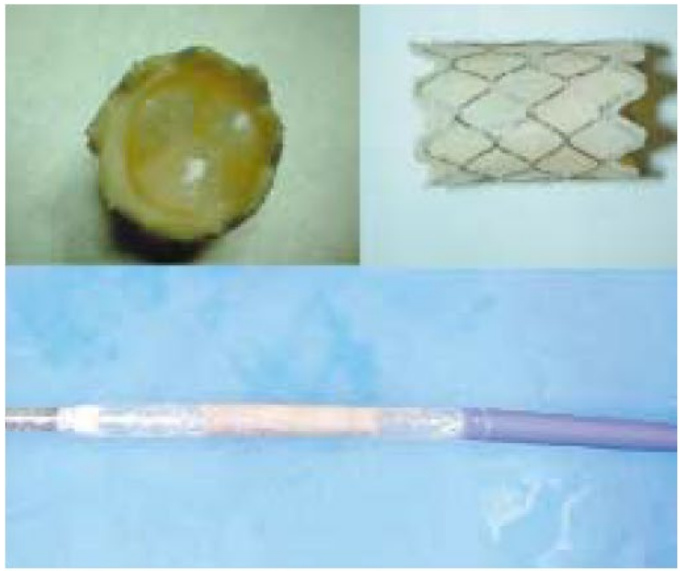


Figure 1: **Valved stent**
Upper left: closed valve mounted in the stent. Upper right: profile of the valved stent before compression. Below: valved stent in the delivery system.

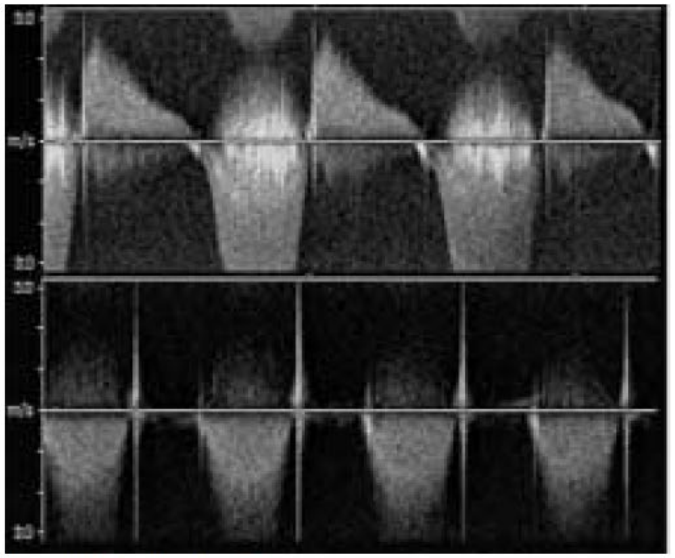


Figure 3: **Doppler imaging**
Upper panel: pulmonary regurgitation before implantation of the valve. Lower panel: perfect competence of the implanted valve.

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Lancet 2000; **356:** 1403–05

TRANSCATHETER PULMONARY VALVES FOR CONDUITS/BPVS

Melody® (Medtronic)

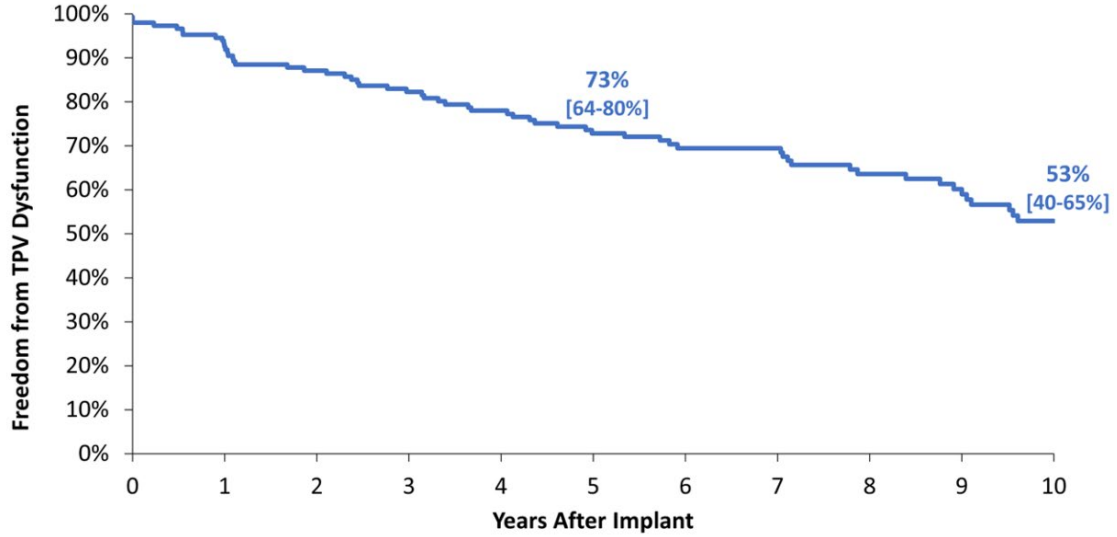
- 18 mm segment of bovine jugular valve in a covered stent
- **18-24 mm in diameter**

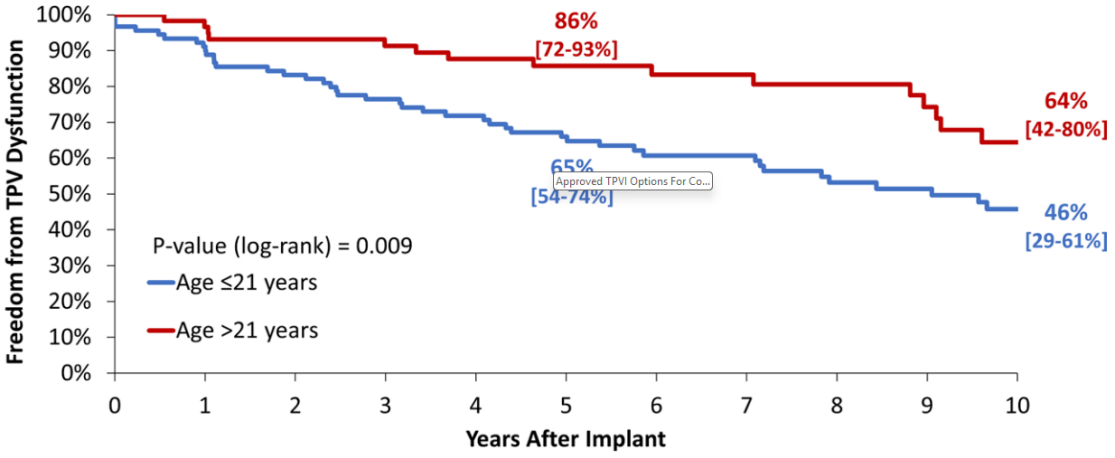
Sapien 3 (Edwards)

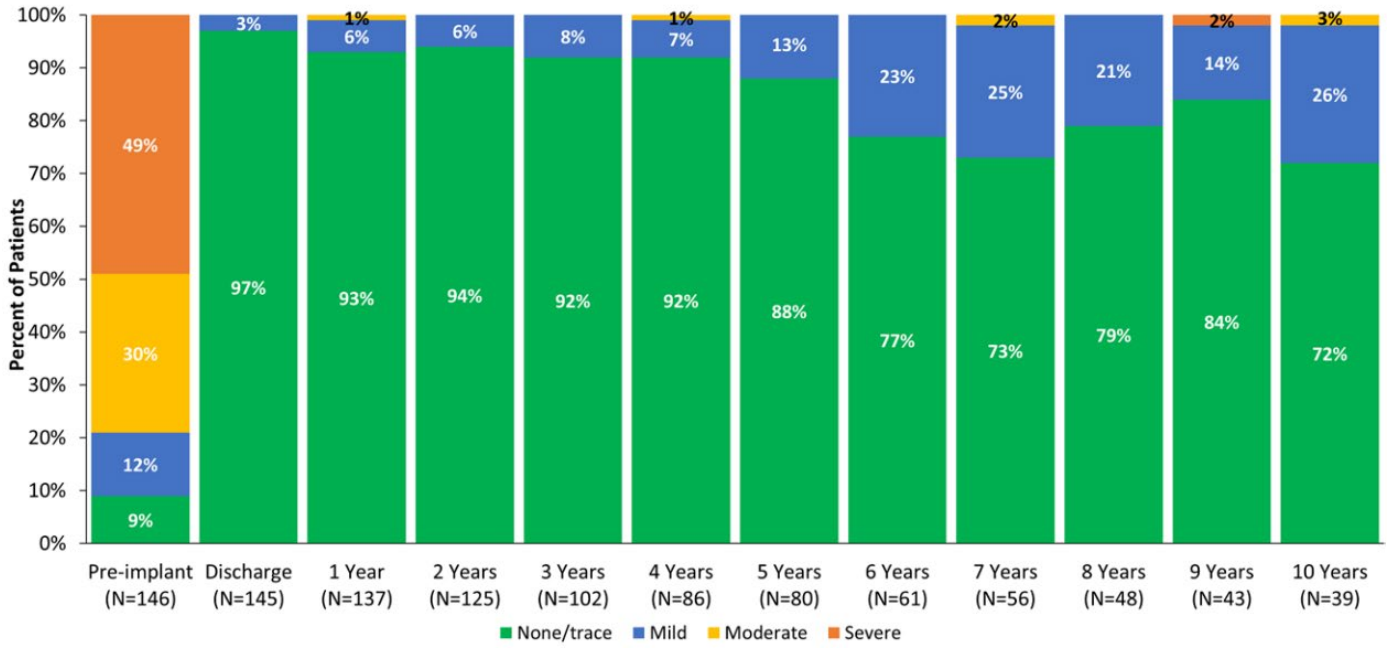
- Bovine pericardium in a cobalt-chromium stent
- **Diameters up to 30**

MELODY LONG-TERM OUTCOMES

10-YEAR FOLLOW-UP FROM 171 IDE TRIAL PATIENTS







Jones *et al*, CCI, 2022

SAPIEN S3 LONG-TERM OUTCOMES
5-YEAR FOLLOW-UP FROM 58 COMPASSION S3 TRIAL PATIENTS

	1 Year VI population, % (n/N at risk)	5 Years VI population, % (n/N at risk)
THV dysfunction	**4.3%** (2/47)	**10.0%** (4/40)
RVOT re-intervention	**0%** (0/56)	**2.1%** (1/49)
Moderate or greater PR	**2.1%** (1/47)	**5.0%** (2/40)
Mean RVOT gradient >40 mmHg	**2.1%** (1/48)	**2.5%** (1/40)

Event, KM estimates % (n, N events)	30 Days	1 year	5 years
Death	0%	0%	0%
Reintervention	0%	0%	1.9% (1,1)
Arrhythmia, including conduction abnormalities†	5.2% (3,3)	8.7% (6,5)	16.2% (11,9)
Permanent Pacemaker	0%	1.8% (1,1)	1.8% (1,1)
Endocarditis	0%	0%	3.8% (2,1)
Valve Thrombosis*	0%	0%	4.3% (2,2)
Myocardial Infarction#	0%	0%	1.9% (1,1)
Pulmonary Embolism	0%	0%	-
Stroke / Transient Ischemic Attack	0%	0%	-

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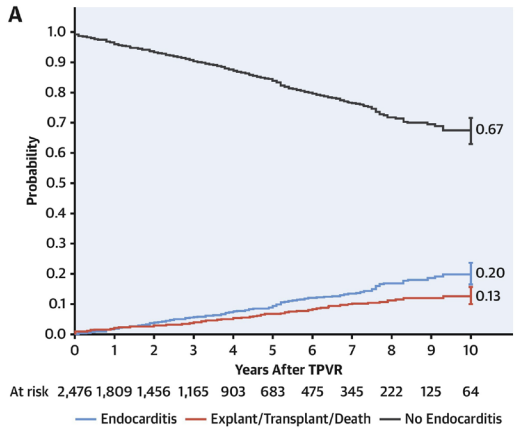
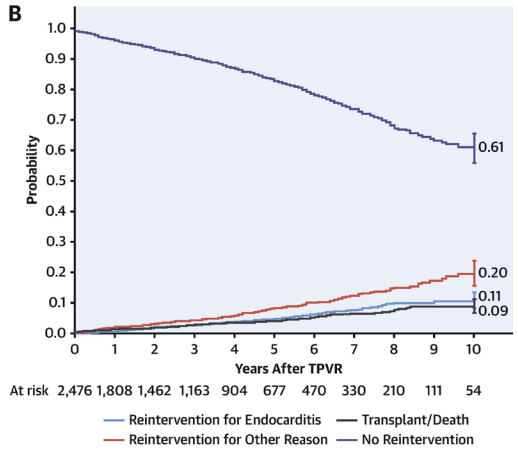
Presented at PICS 2024

INFECTIVE ENDOCARDITIS

CENTRAL ILLUSTRATION: Cumulative Incidence Curves Depicting Outcomes Related and Unrelated to Endocarditis

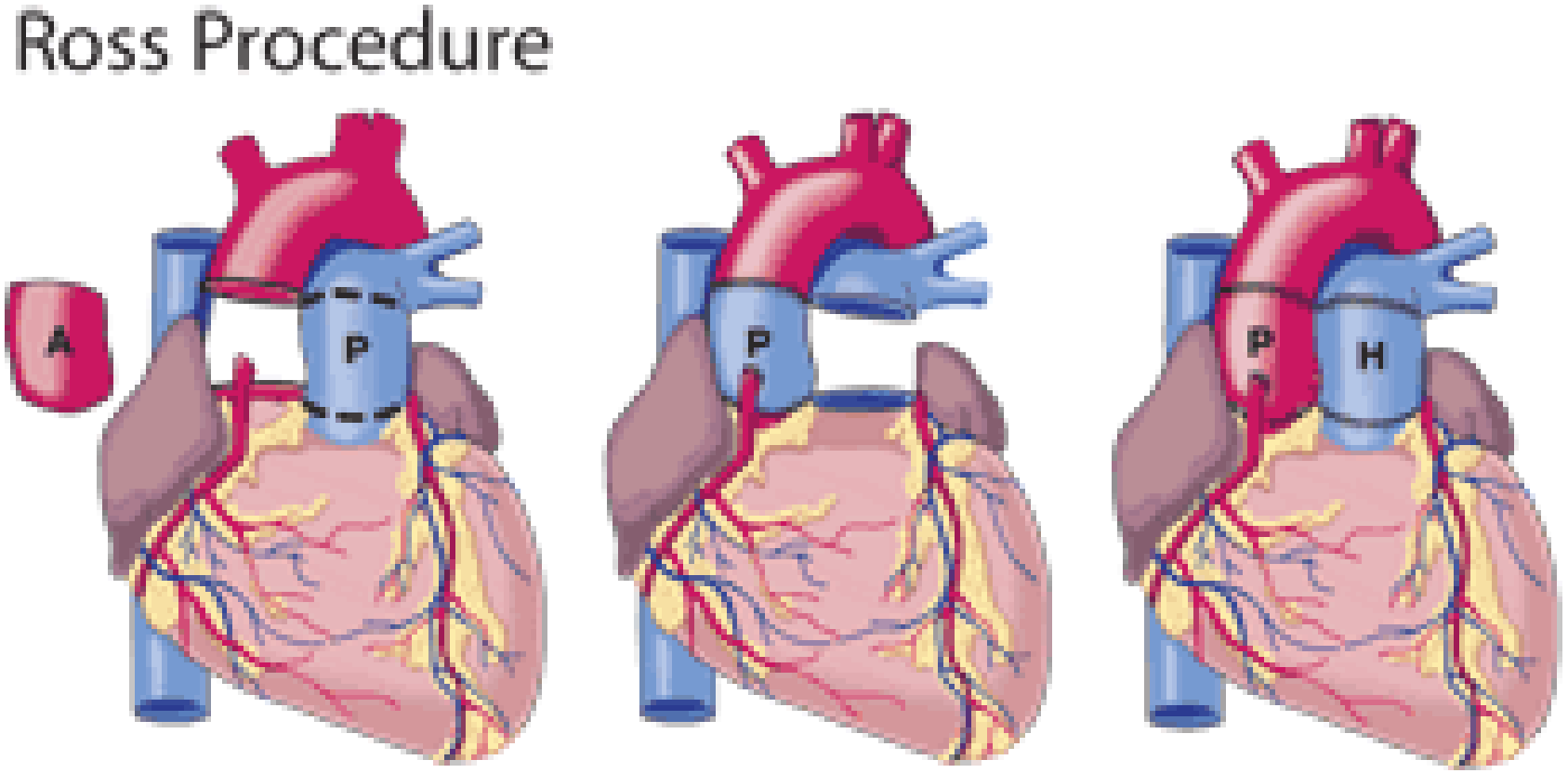




McElhinney, D.B. et al. J Am Coll Cardiol. 2021;78(6):575-589.

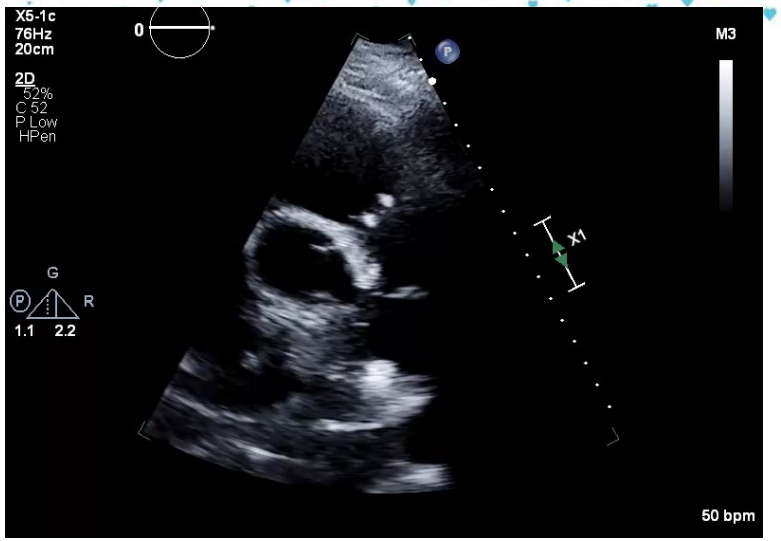
- 2,476 patients
- 9.5% IE at 5 years
- 16.9% IE at 8 years
- 2%/year in IDE
- *S. aureus is bad!*
- Risk factors:
  - Younger
  - Previous IE
  - **Higher residual gradient**
  - NOT TPV type

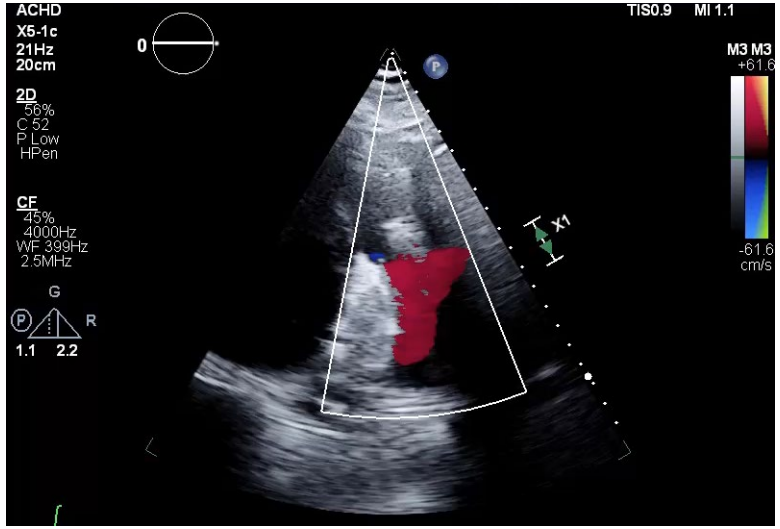
ROSS PROCEDURE



TRANSCATHETER PULMONARY VALVE IMPLANTATION (TPVI) EDWARDS SAPIEN

- 66-year-old man
- Ross 20 years prior
- PV IE with *S. mitis*
- Eradicated with PCN
- Symptomatic PI with veg





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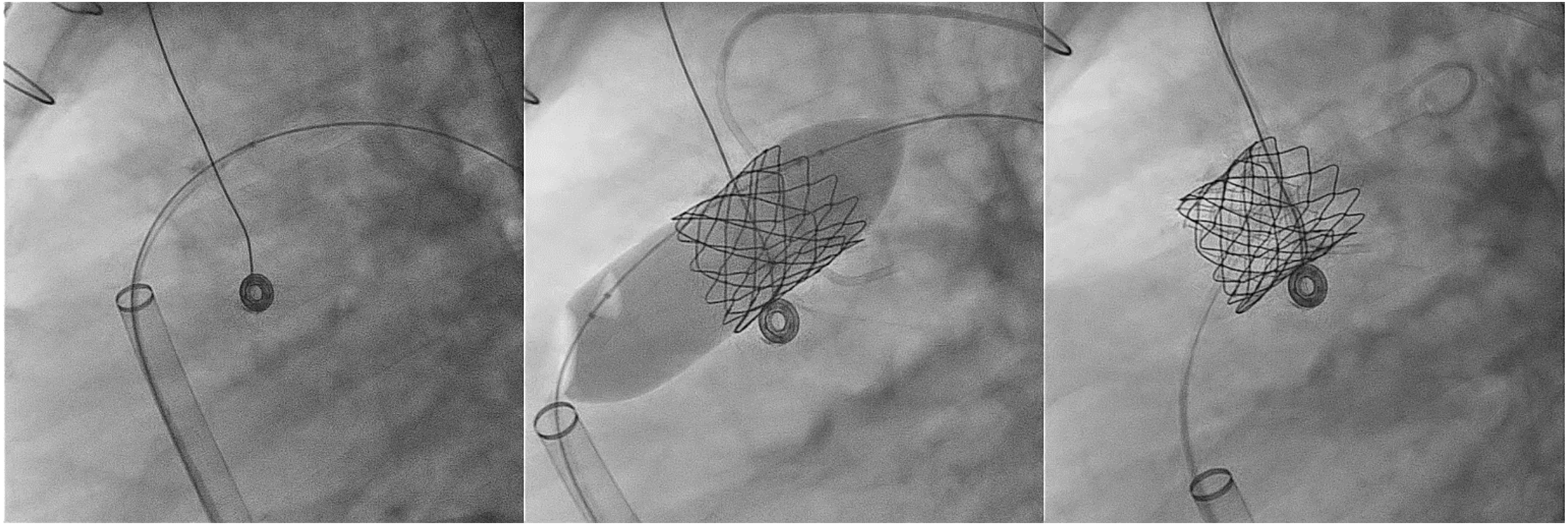
TRANSCATHETER PULMONARY VALVE IMPLANTATION (TPVI) EDWARDS SAPIEN



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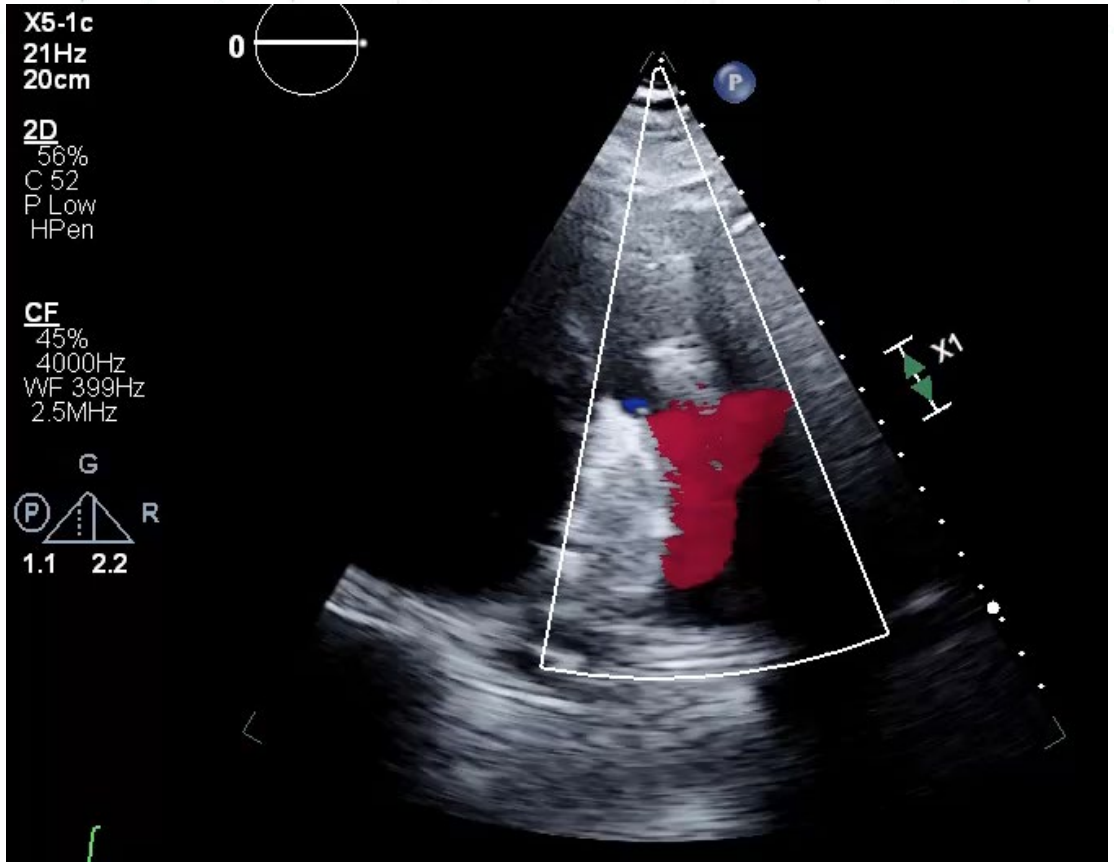

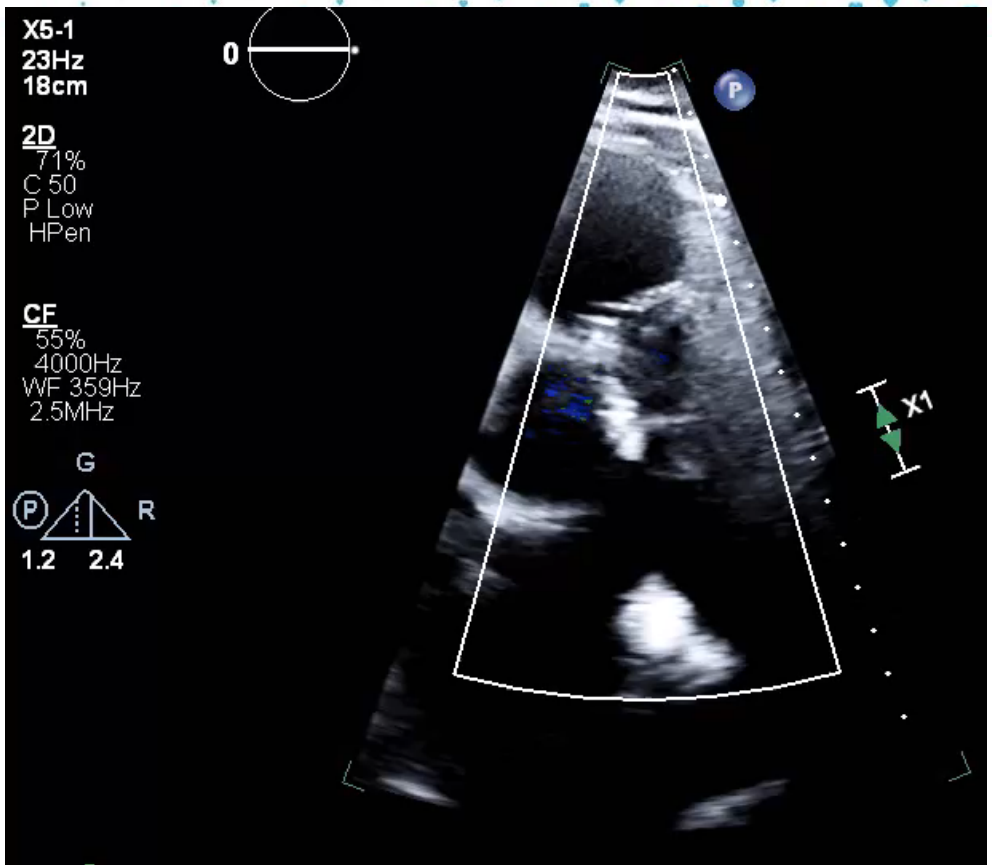

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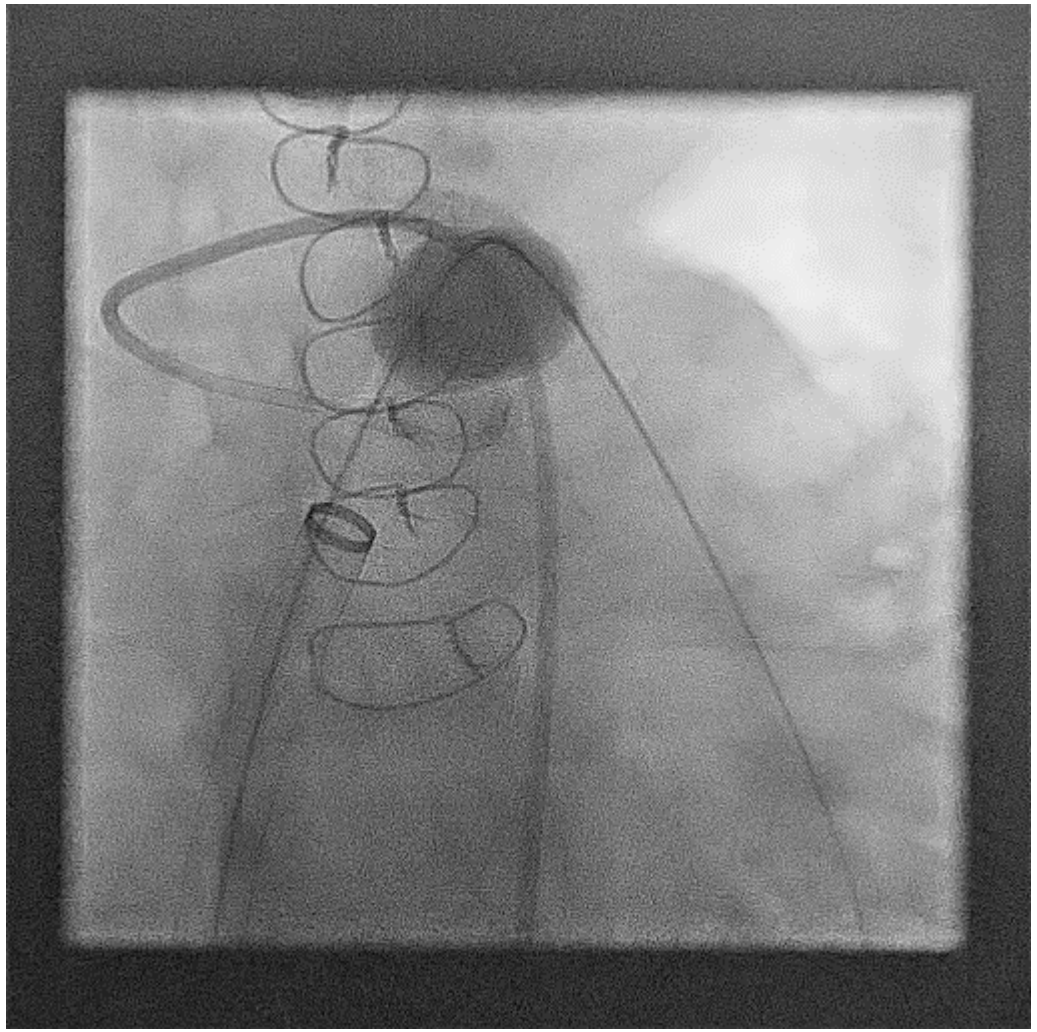
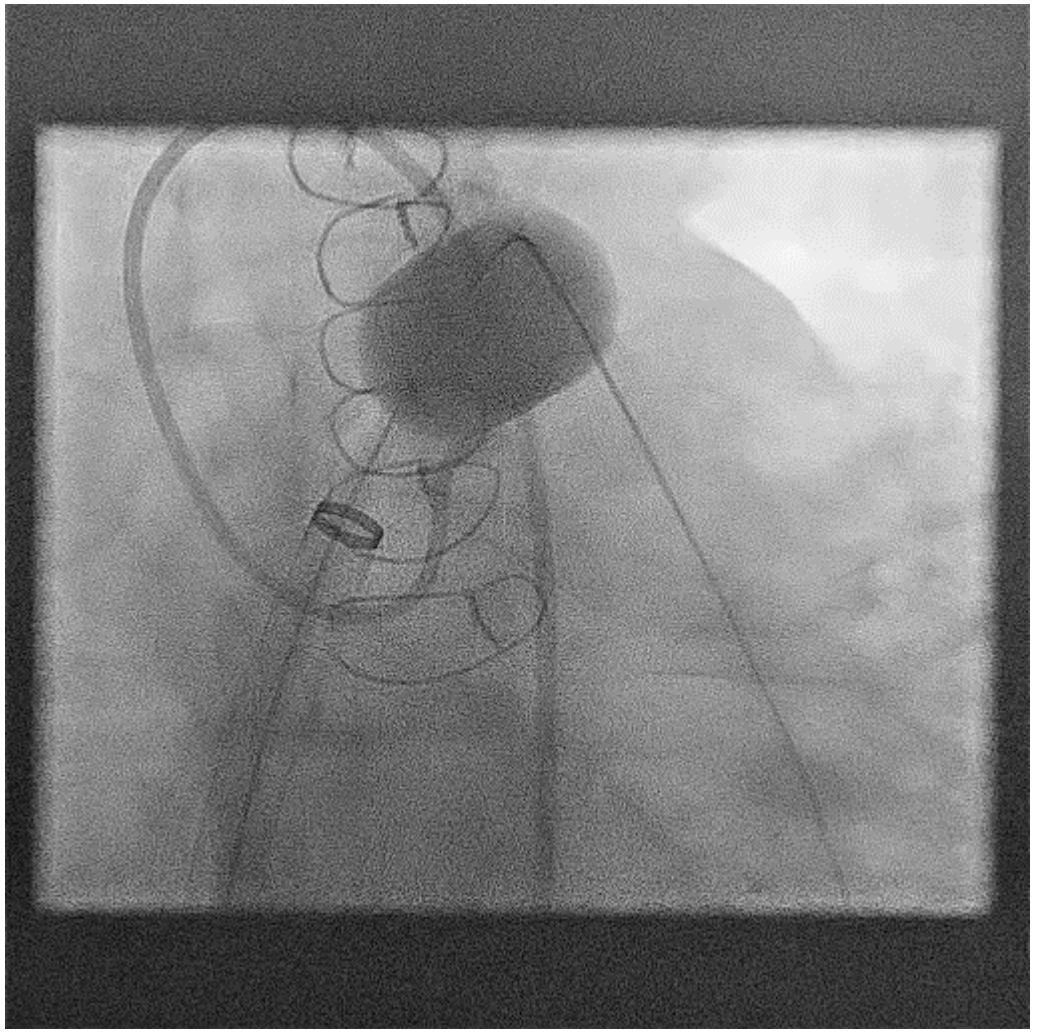
COMPLICATIONS

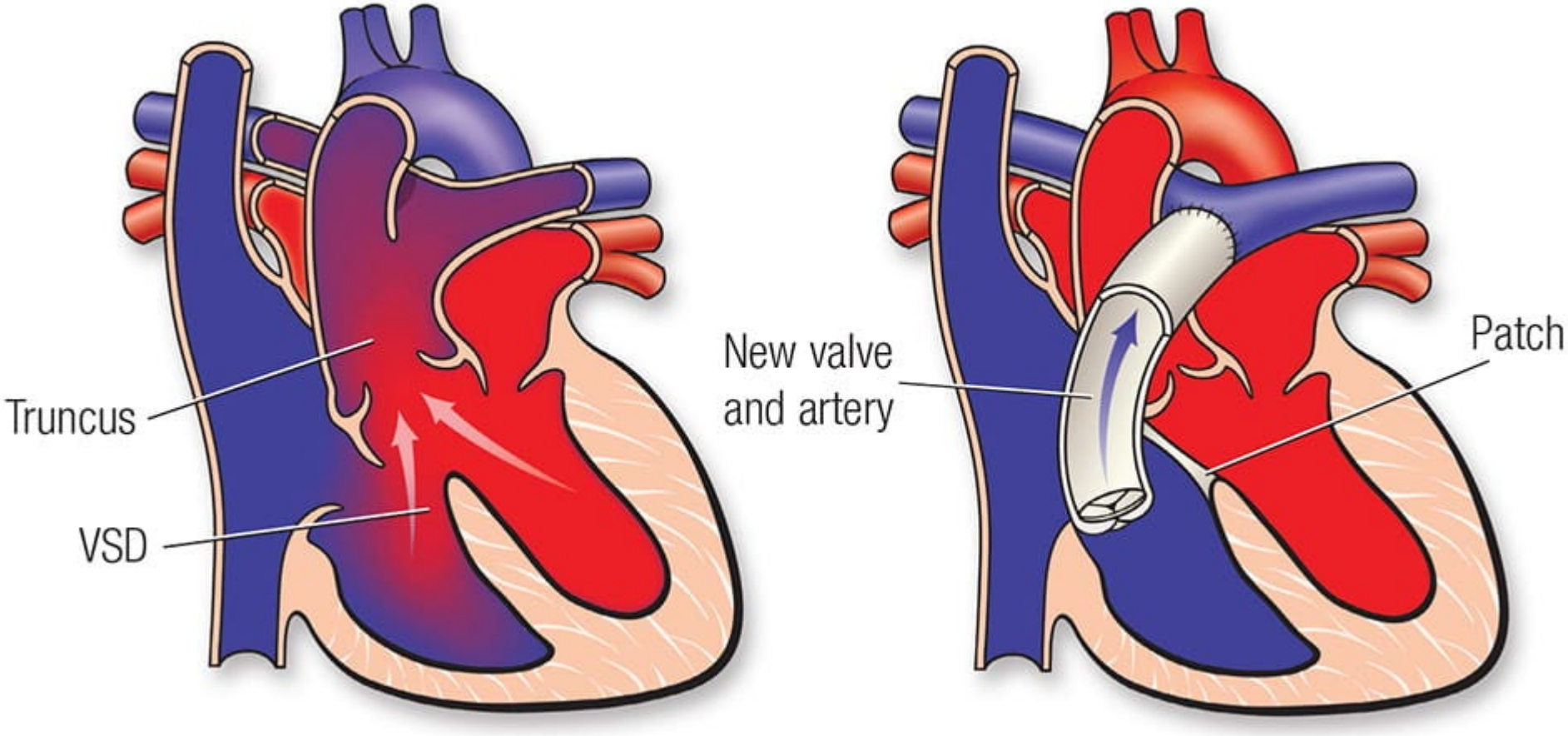
- Stent fracture
  - This can lead to embolization or restenosis.
  - The Melody valve must be pre-stented.
- Conduit rupture (<1%)
- Coronary compression (~1%)
- Tricuspid valve damage

CORONARY COMPRESSION

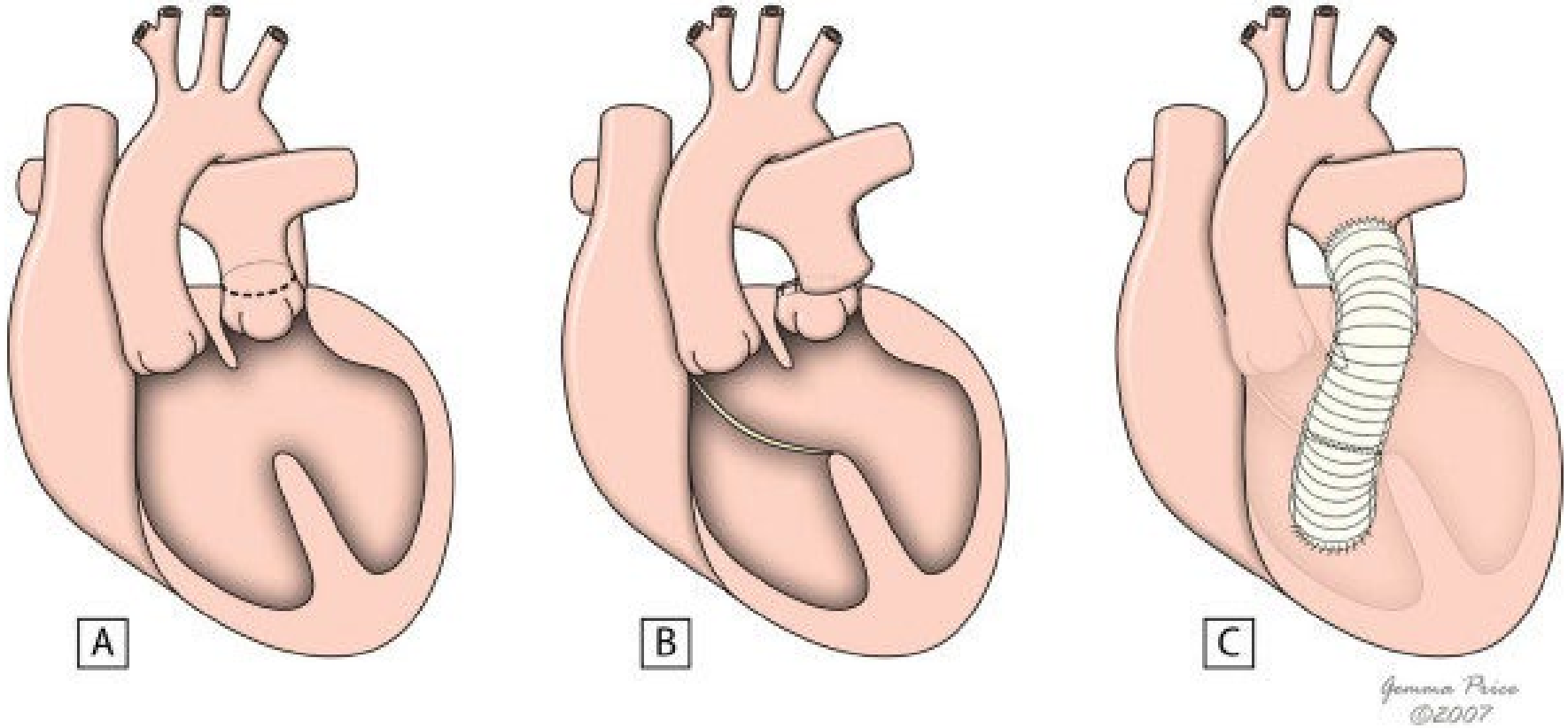




TRUNCUS ARTERIOSUS



“RASTELLI” OPERATION FOR D-TGA + PS + VSD



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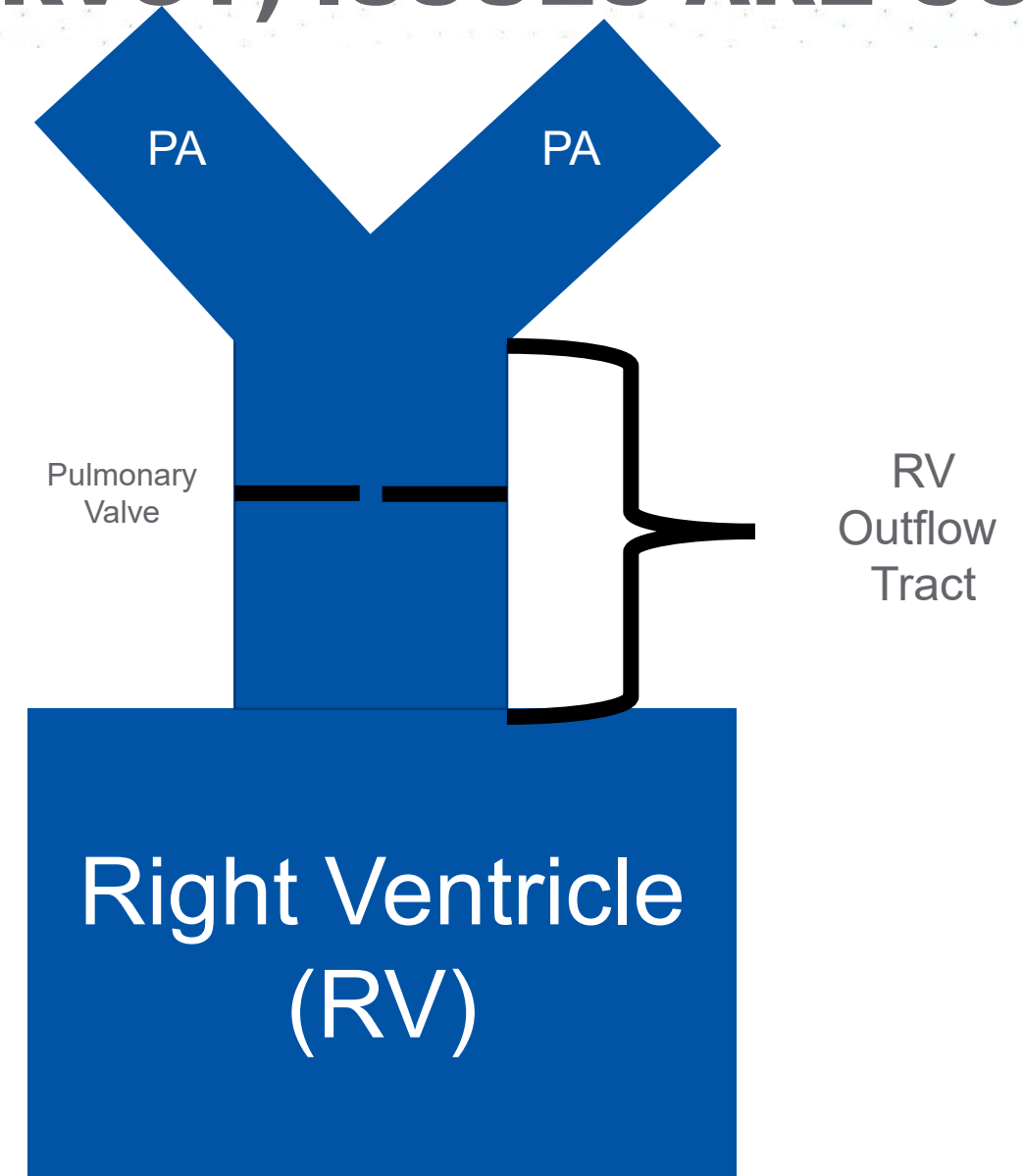

1) Conduit
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2) Bioprosthetic pulmonary valve
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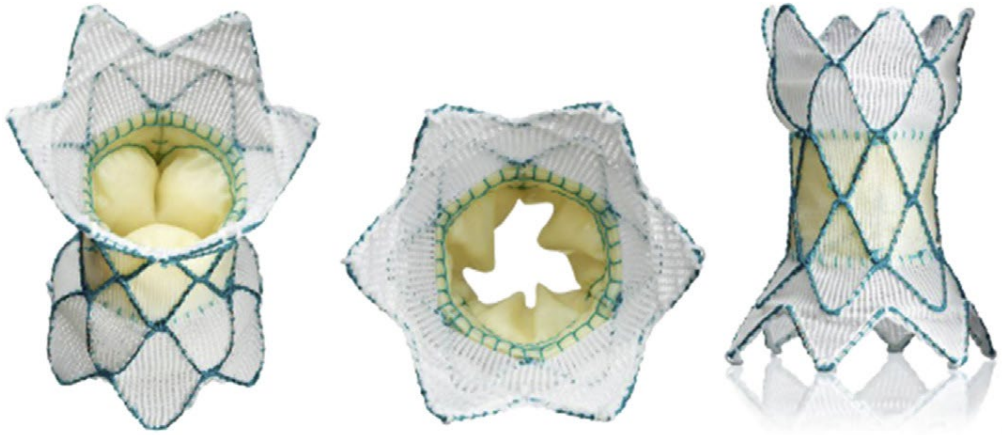
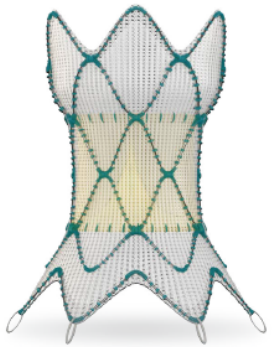
3) Native RVOT
   - Distensible
   - Only option was surgery
   - Harmony approved in 2021

HARMONY TRANSCATHETER VALVE

A



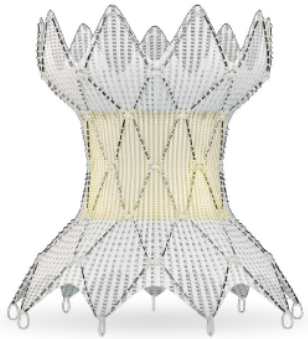
TRANSCATHETER PULMONARY VALVE
Harmony™ TPV



Harmony TPV 22
22 mm Valve

Model Number:
HARMONY-22

(240)Harmony-22



Harmony TPV 25
25 mm Valve

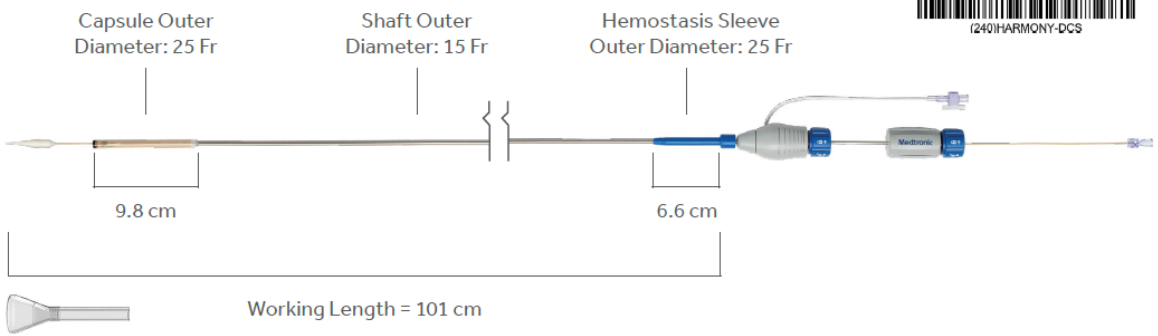
Model Number:
HARMONY-25

(240)Harmony-25

DELIVERY CATHETER SYSTEM
Harmony DCS

Model Number:
HARMONY-DCS

(240)HARMONY-DCS



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THE HARMONY WORK-UP

Harmony TPV patient identification to implant

Process

- CT is required for Harmony transcatheter pulmonary valve (TPV) patient screening.
- CT is the "gold standard" for structural procedural planning and is vital for patient selection, sizing, and risk assessment.

CTA

CT provides superior image quality for detailed measurements.

- Gated CT scan to isolate key cardiac phases (90% end-diastole & 30% systole)
- Slice thickness of < 1 mm
- Field of view mid-aortic arch to mid-RV cavity (covering main & branch PA's)
- Peak contrast concentration in the MPA.

Patient Screening

Medtronic

Engineering the extraordinary

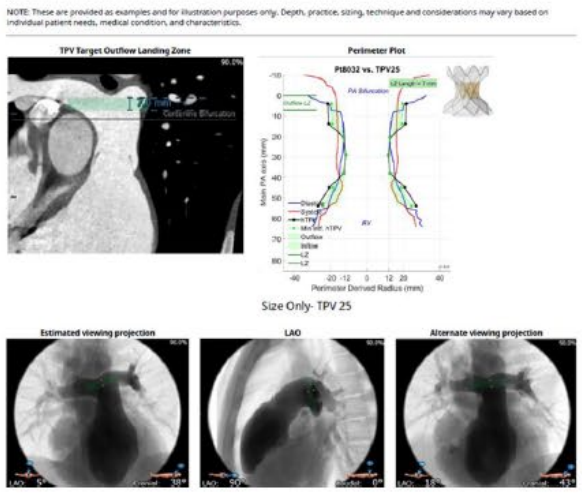
24-72 Hours

Medtronic provides screening evaluation for patients being considered for Harmony TPV within 24-72 hours.

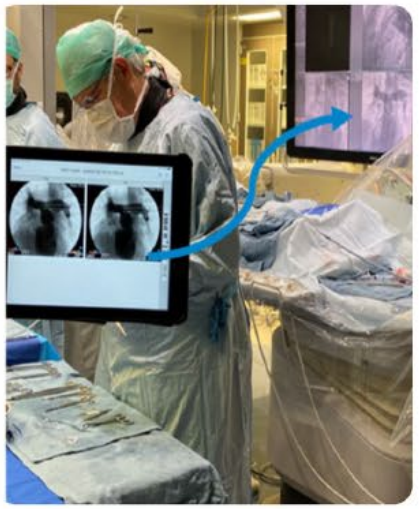
Pre-Case Planning

Patient screening report assists with

- Patient selection
- Device selection
- Device placement

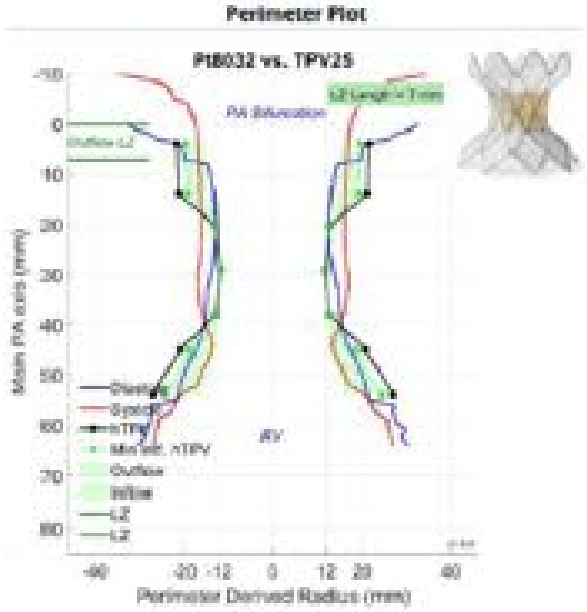


Implantation

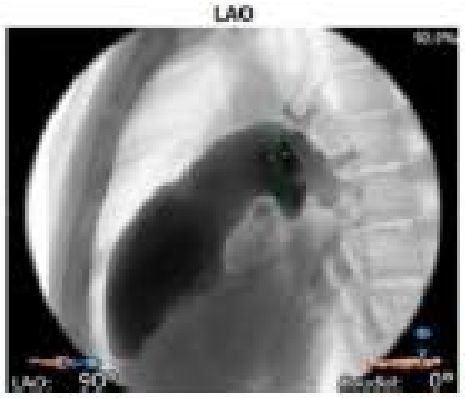


Medtronic

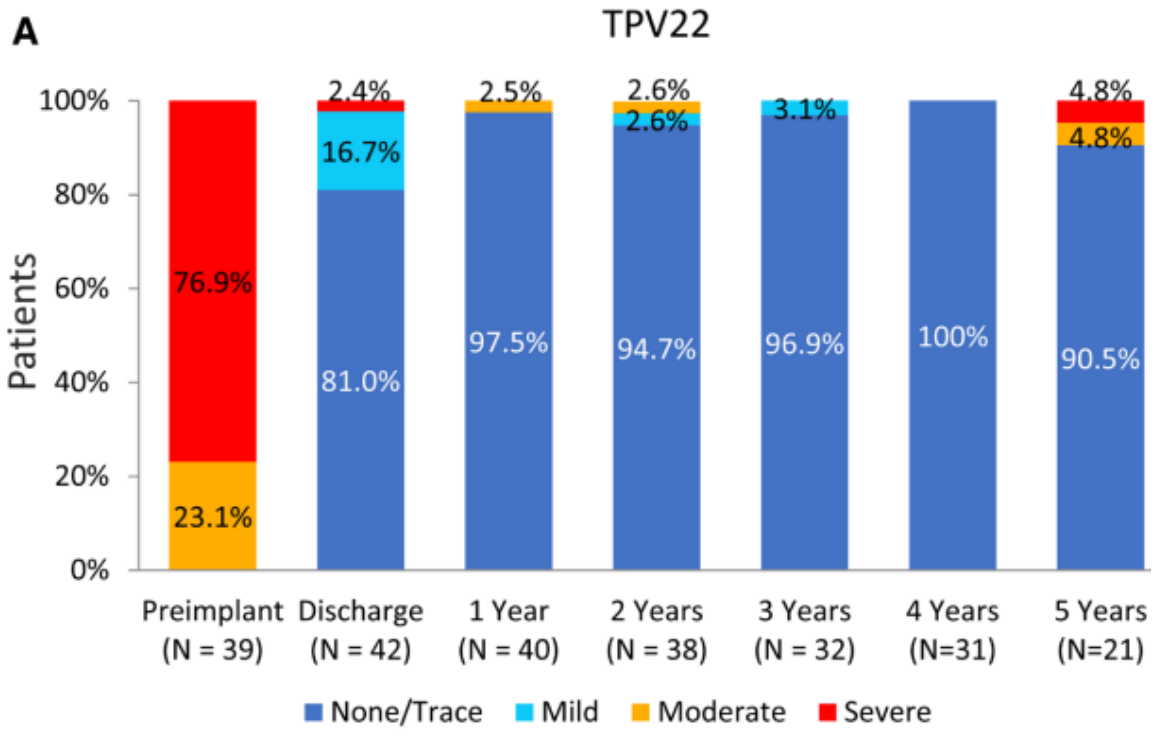
THE HARMONY CT

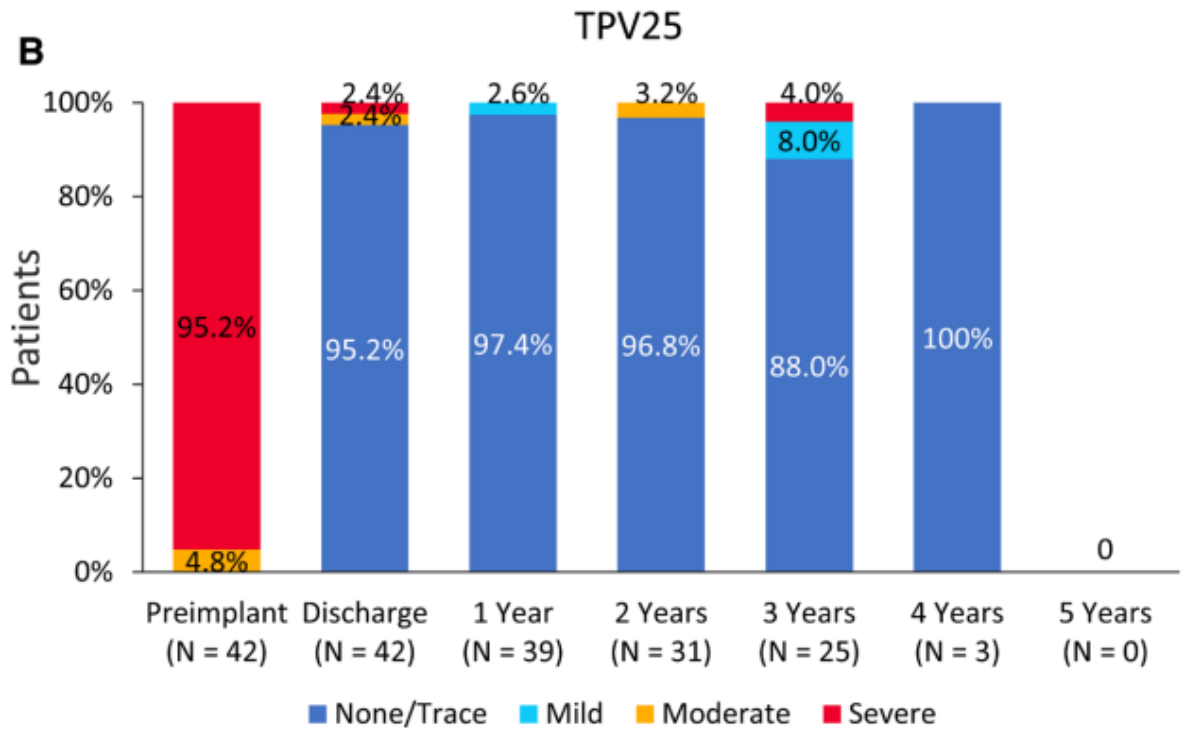


Size Only- TPV 25



86 HARMONY PATIENTS FROM EF-PIVOTAL-CAS





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Morray et al, CCI, 2025

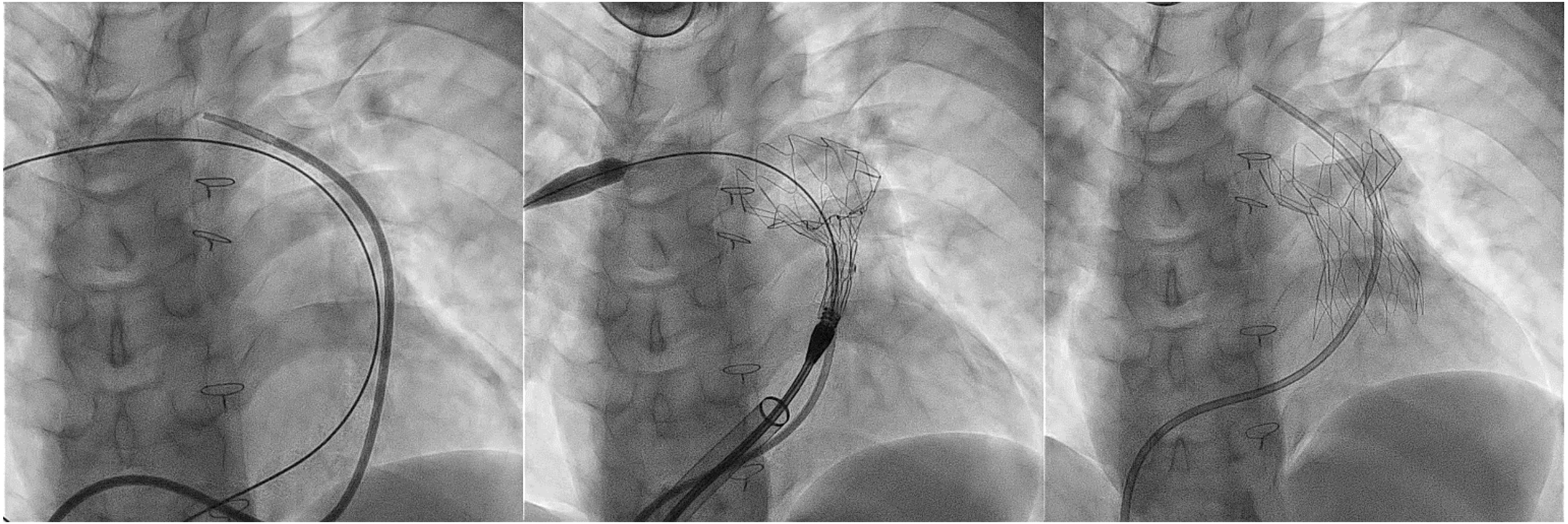
HARMONY NATIVE OUTFLOW TRACT – EARLY FEASIBILITY STUDY (5-YEAR OUTCOMES)

Table 2. Surgical Reoperation and Catheter Reintervention After Hospital Discharge

Patient	Valve	Days postprocedure	Reintervention	Indication and related AEs	Last site-reported mean RVOT gradient before intervention
TPV22					
1	TPV22 (EFS)	39	Surgical explant	Major stent fracture*	31 mm Hg
2	TPV22 (EFS)	881	ViV (Melody)	In-stent stenosis	32 mm Hg
3	TPV22 (EFS)	899	ViV (Melody)	In-stent stenosis	40 mm Hg
4	TPV22	1264	Mechanical thrombectomy	Stenosis related to vegetation on the TPV	47 mm Hg
TPV25					
5	TPV25	303	ViV (Melody)	In-stent stenosis†	46 mm Hg
6	TPV25	444	ViV (Sapien)	Stenosis/valve thrombosis†	46 mm Hg
7	TPV25	610	ViV (Sapien)	Stenosis/valve thrombosis†	40 mm Hg
8	TPV25	840	ViV (Sapien)	Valve-frame distortion†	27 mm Hg

Morray et al, CCI, 2025

HARMONY TRANSCATHETER PULMONARY VALVE



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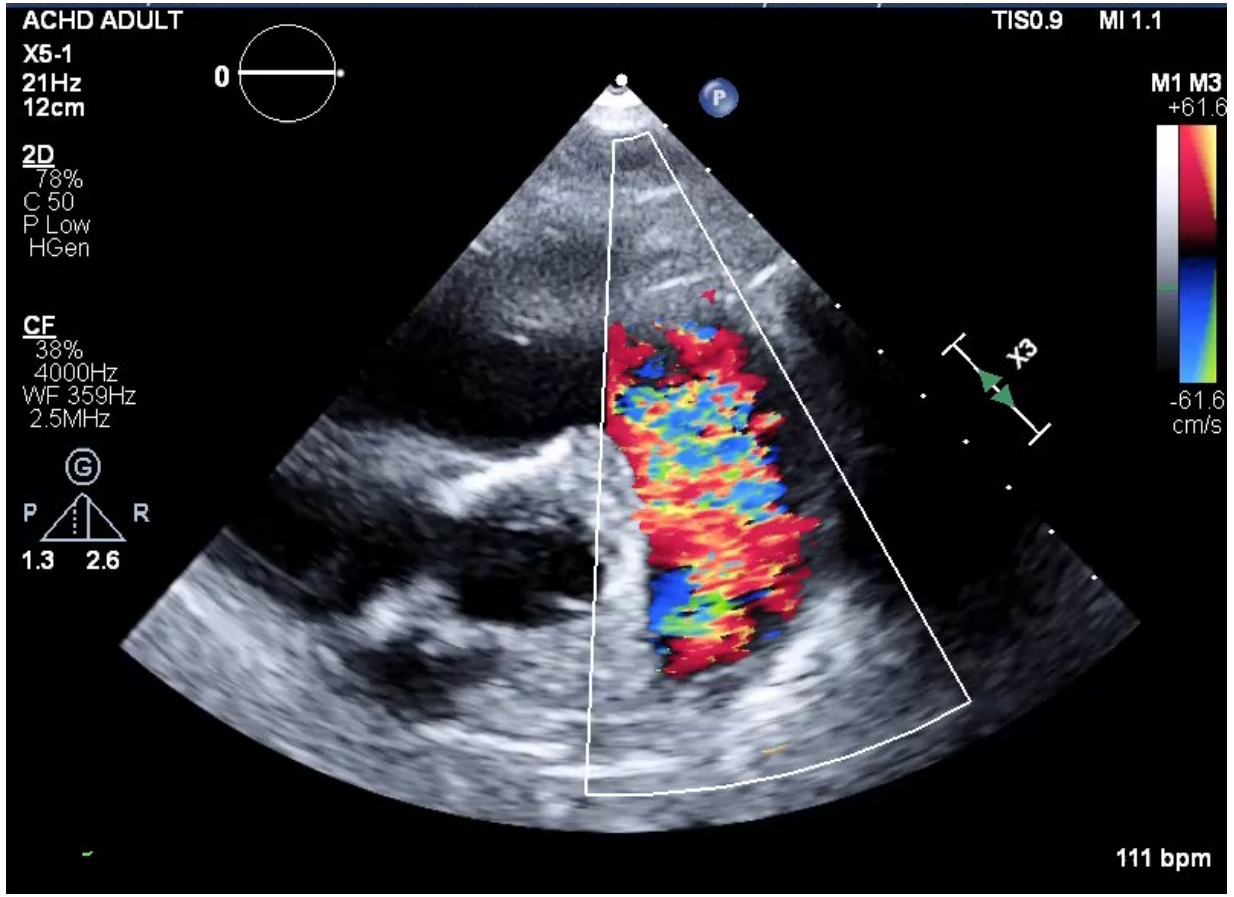
HARMONY TRANSCATHETER PULMONARY

PRE



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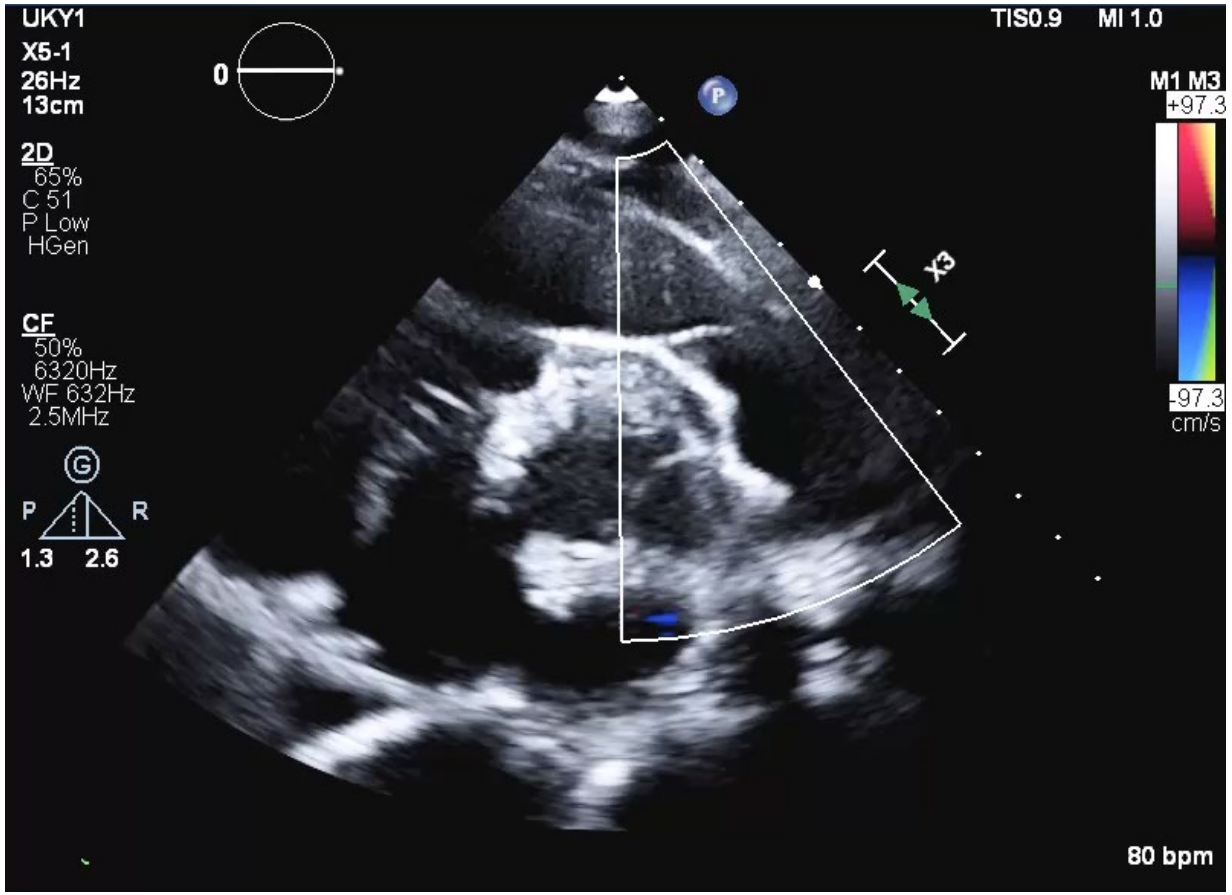
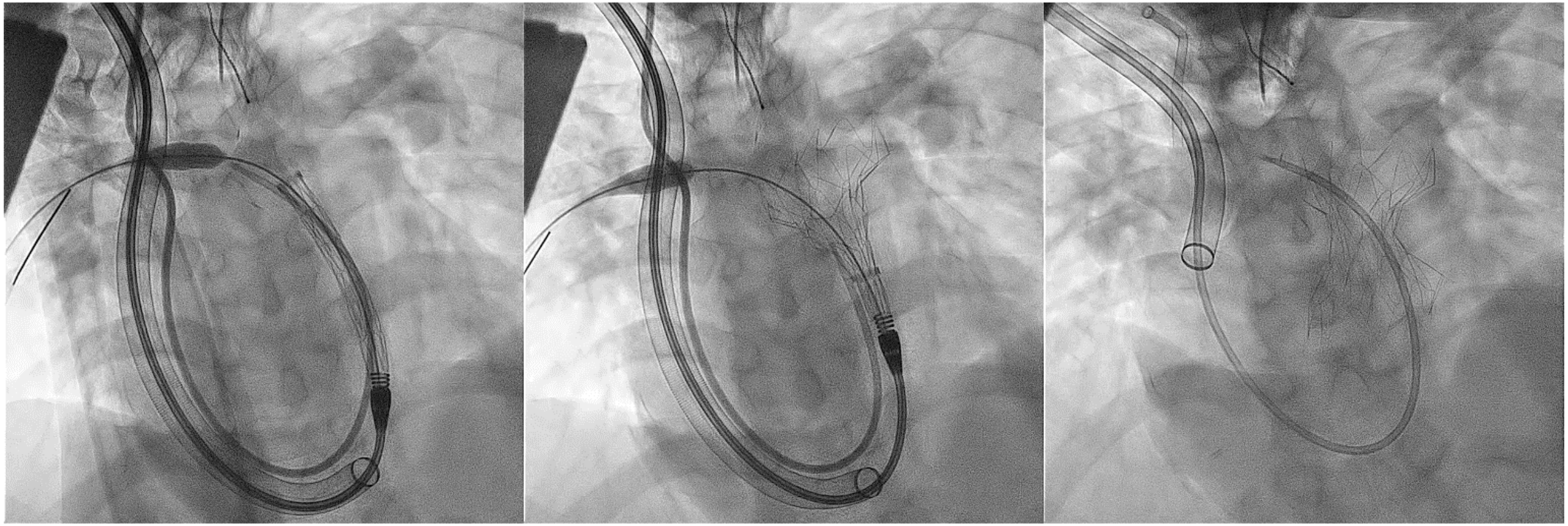


HARMONY TRANSCATHETER PULMONARY VALVE



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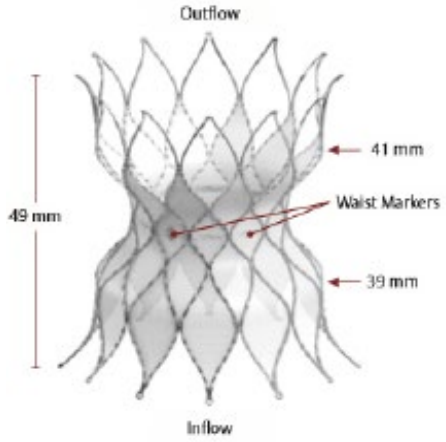
ALTERRA TRANSCATHETER PRE-STENT

Edwards Alterra Adaptive Prestent

Designed to provide an RVOT area for 29 mm SAPIEN 3 valve



Edwards Alterra adaptive prestent dimensions

Inflow Sealing OD	39 mm
Outflow Sealing OD	41 mm
Height	49 mm

Prestent Sizing in RVOT landing zone

Perimeter	84.9 mm – 119.3 mm
Perimeter Derived Diameter*	27 mm – 38 mm
Prestent Size	40 mm** x 49 mm
THV Size	29 mm

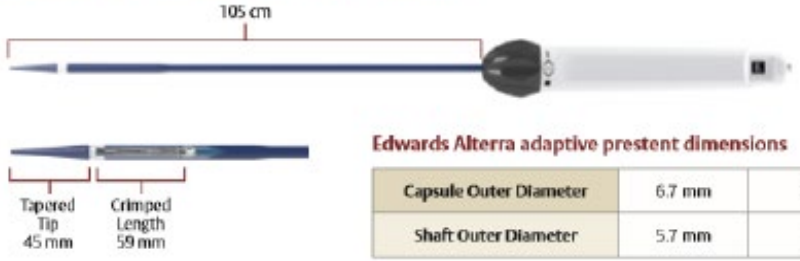
* *Diameter range throughout cardiac cycle*
** *Diameter is average of inflow and outflow diameters*

Edwards SAPIEN 3 valve with the pulmonic delivery system

Edwards SAPIEN 3 29mm valve sizing

Inflation Volume	33 mL
Crimped Height*	31 mm
Expanded Height	22.8 mm
Foreshortening	8.2 mm
Inner Skirt Height†	11.6 mm
Outer Skirt Height	8.1 mm

Edwards Alterra Delivery System

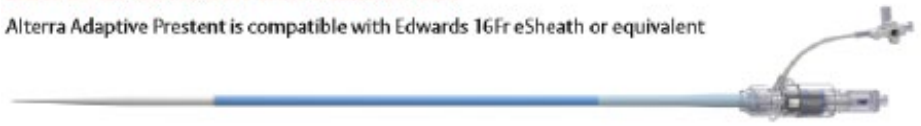


Edwards Alterra adaptive prestent dimensions

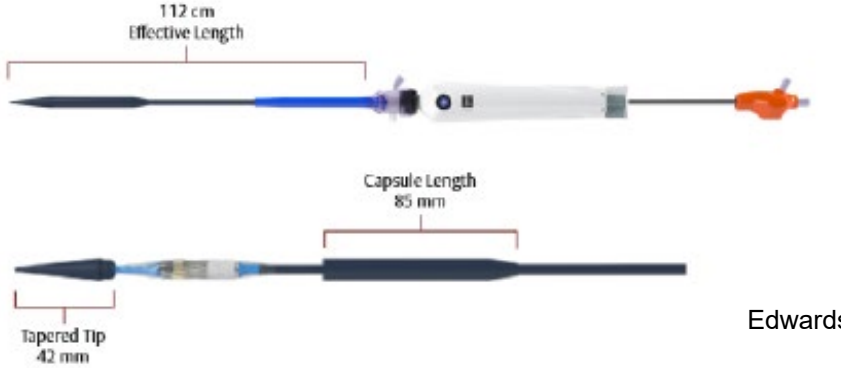
Capsule Outer Diameter	6.7 mm	20F
Shaft Outer Diameter	5.7 mm	17F

Edwards eSheath introducer set

Alterra Adaptive Prestent is compatible with Edwards 16Fr eSheath or equivalent



Edwards SAPIEN 3 Pulmonic Delivery System



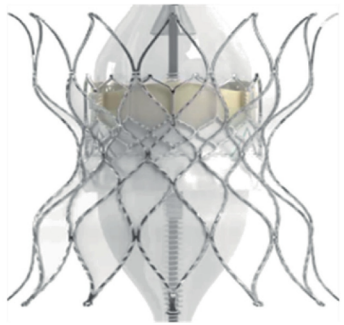
Edwards.com

ALTERRA 2- & 3-YEAR OUTCOMES

CENTRAL ILLUSTRATION: Key 2-Year Outcomes of the ALTERRA Pivotal Trial

Prospective, Single-Arm, Multicenter Study of Patients With a Dysfunctional Native or Patched RVOT and ≥Moderate PR by TTE

Trial Devices: Alterra Adaptive Prestent and 29-mm SAPIEN 3 THV



Screen-Fail Rate for Patient Population: 37.1% (36/97)
N = 60 patients implanted

Both devices implanted in a single procedure	98.3%
Free of explant within 24 h	100%

Primary Endpoint

THV dysfunction at 6 months	0% (0/59)
RVOT reintervention	0
Moderate or greater PR	0
Mean gradient ≥35 mm Hg	0

2-Year Follow-Up: 96.7% (58/60)

Key Outcomes at 2 Years

All-cause mortality	0%
Fracture requiring intervention	0%
Coronary artery compression	0%
Endocarditis	0%
Sustained VT	0%
RVOT/PV reintervention	1.7%
≥Moderate PR	7.5%

- At 2 years, 92.5% of patients treated in the ALTERRA Pivotal Trial had ≤mild PR
- No deaths, endocarditis, device embolization, or explants

Dimas VV, et al. JACC Cardiovasc Interv. 2024;17(19):2287-2297.

Incidence Rate, % (N patients) Valve Implanted Population	0 - 3 Years (N=118)
All-cause mortality	3.3% (4)
Cardiovascular deaths	1.7% (2)
RVOT reintervention	2.5% (3)
Major CV bleed (transient pericardial effusion)*	0.8% (1)
Coronary artery compression†	0%
Endocarditis	0%
Prestent thrombus‡	4.1% (5)
SAPIEN 3 valve thrombus‡§	5.0% (6)

Presented at PICS 2025

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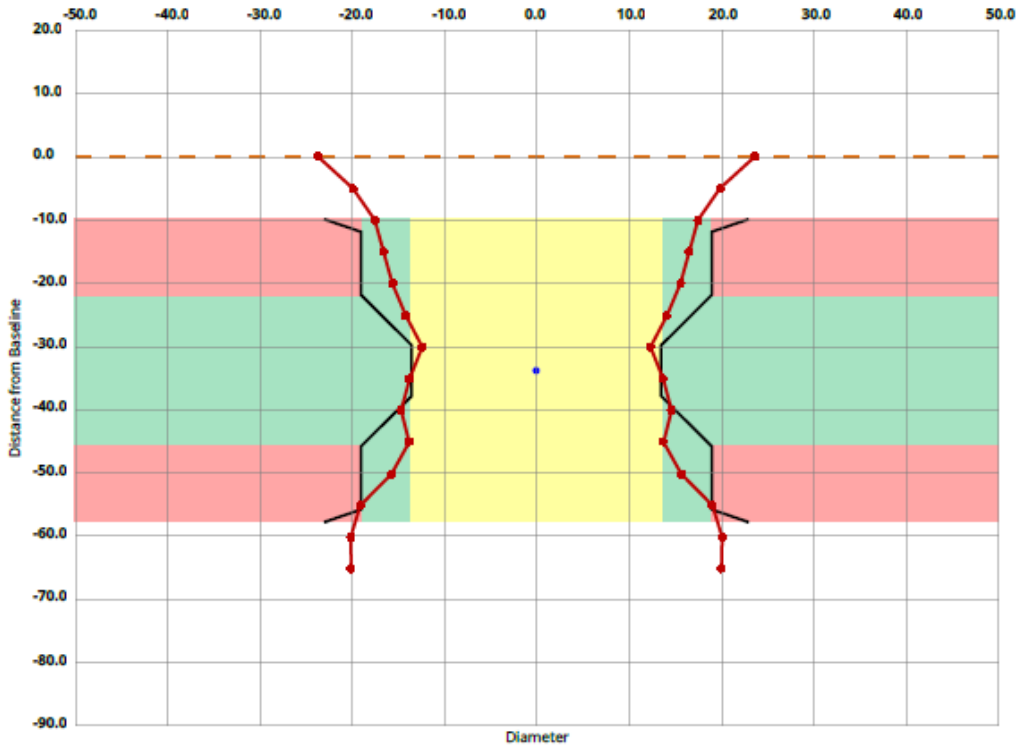
CASE

- 20-year-old woman
- TOF status post surgical repair with free PI
- CT scan revealed a dilated and dysfunctional RV

CASE

Systole 30.0%

Distance (mm)	Prestent allowable Minimum Perimeter (mm)	Anatomy Perimeter (mm)	Prestent allowable Maximum Perimeter (mm)
0.0		148.5	
-5.0		124.8	
-10.0	84.8	110.0	119.3
-15.1	84.8	104.0	119.3
-20.1	84.8	98.0	119.3
-25.1	84.8	89.0	
-30.1	84.8	77.7	
-35.2	84.8	86.3	
-40.2	84.8	92.0	
-45.2	84.8	86.6	
-50.2	84.8	98.6	119.3
-55.3	84.8	119.9	119.3
-60.3		126.5	
-65.3		126.0	



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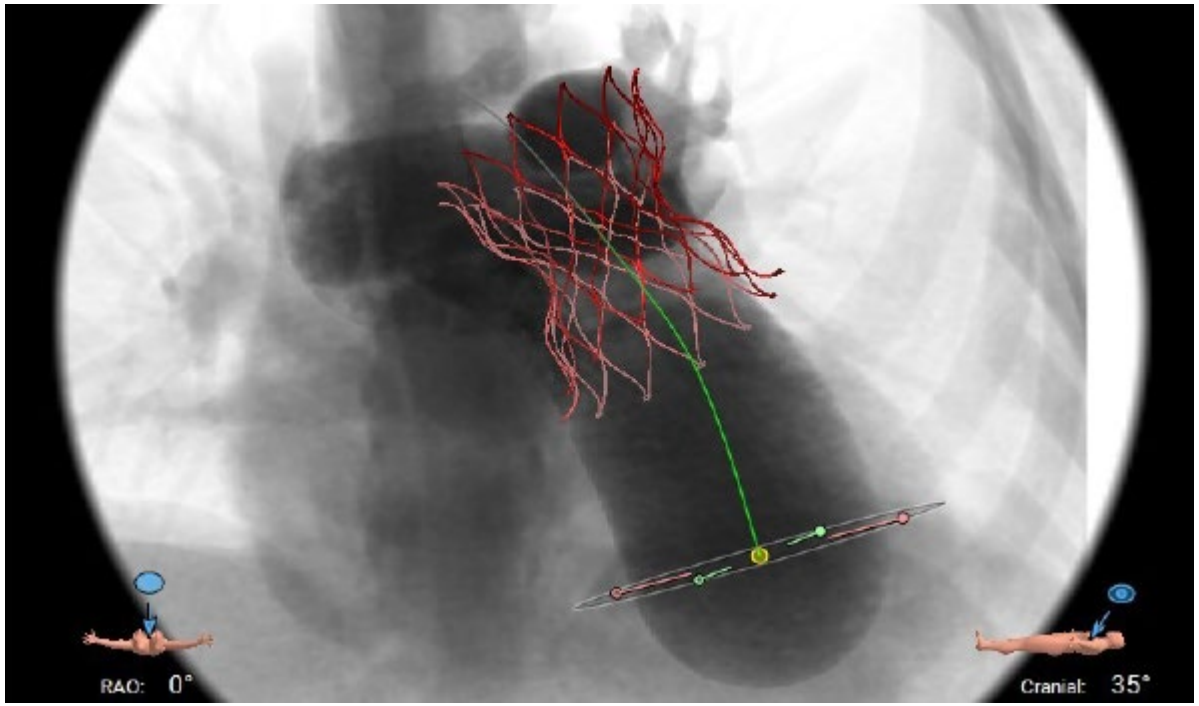
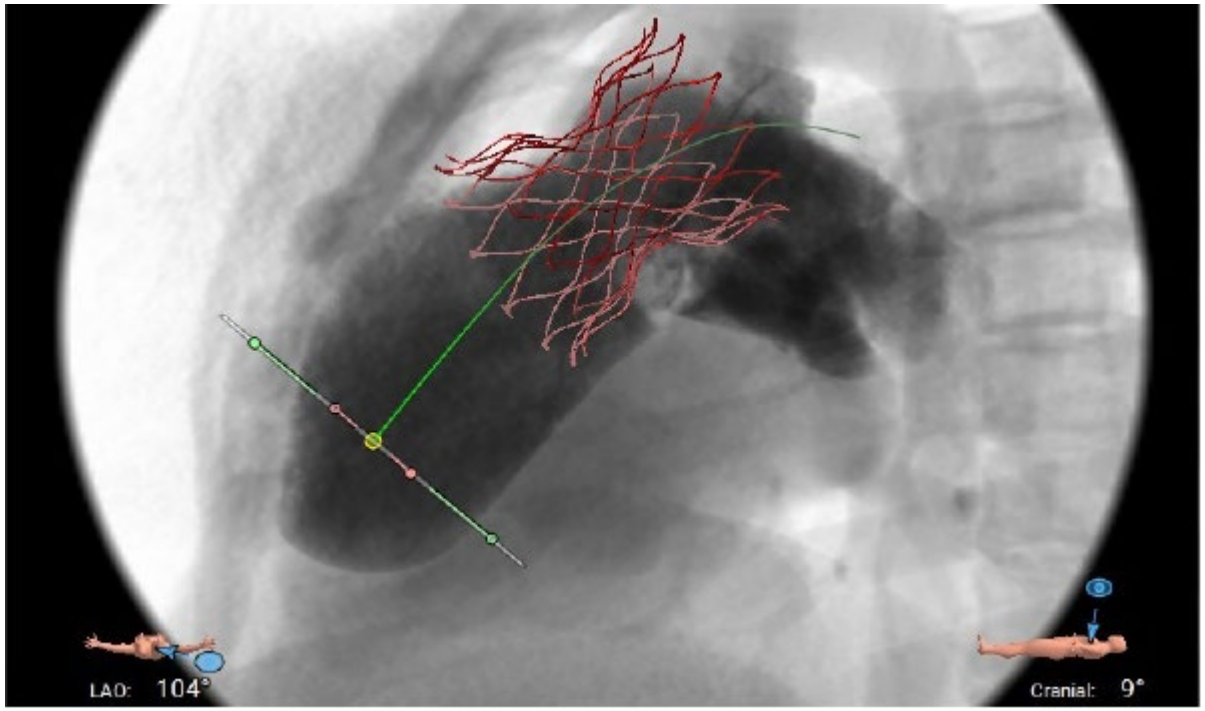
CASE





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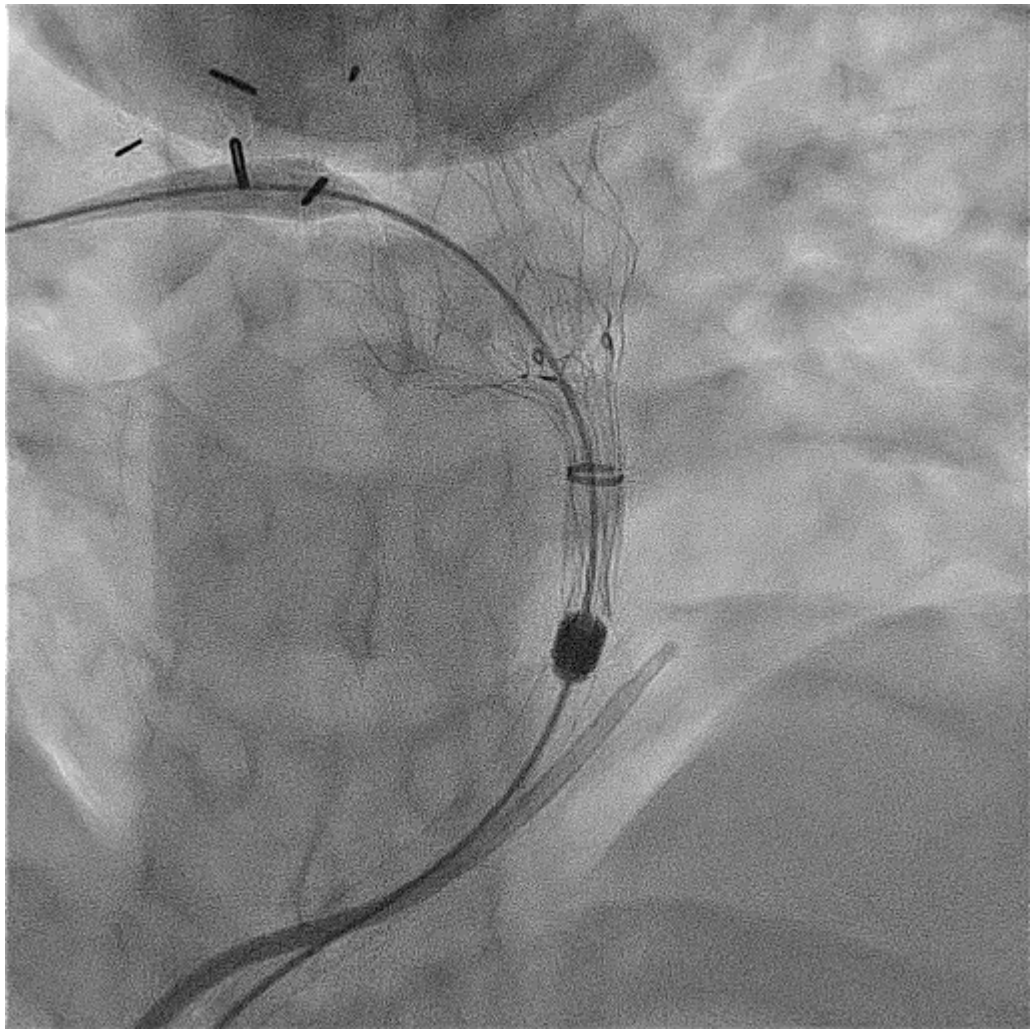

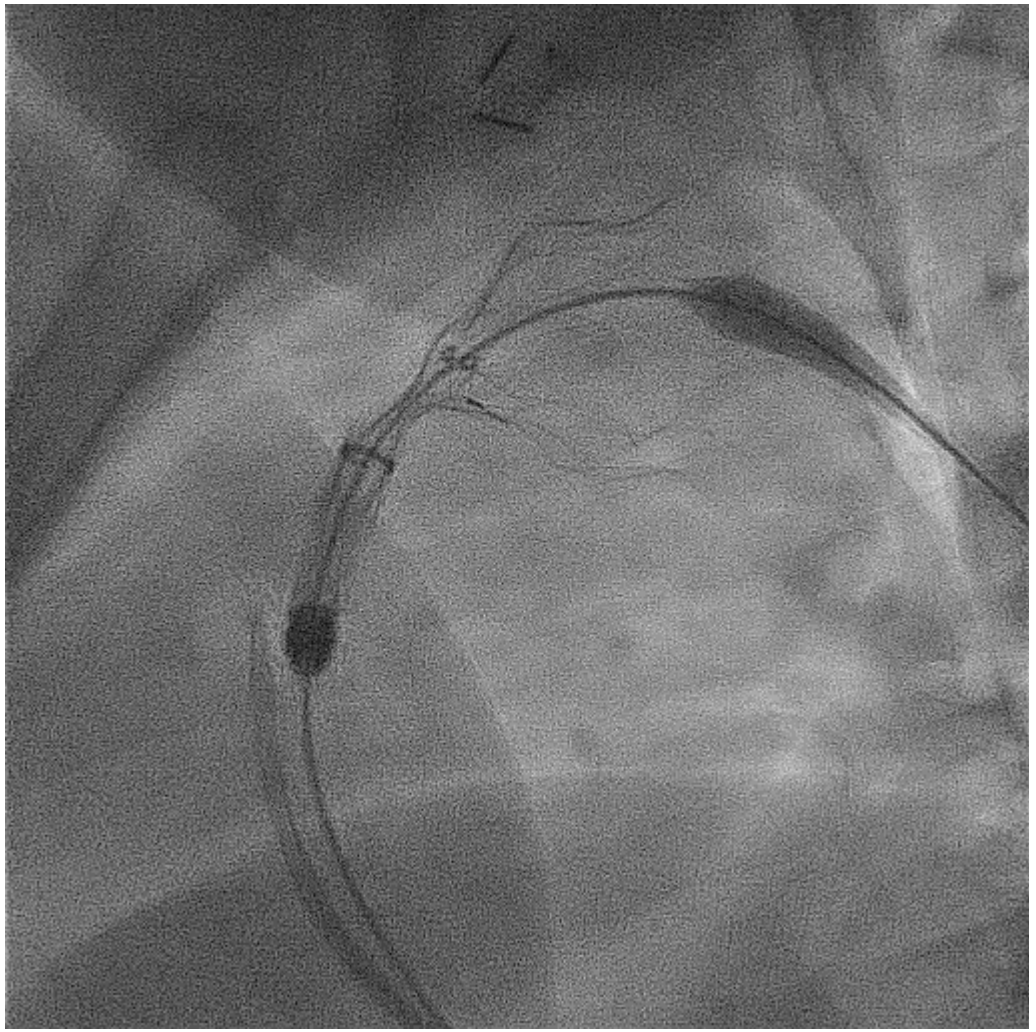

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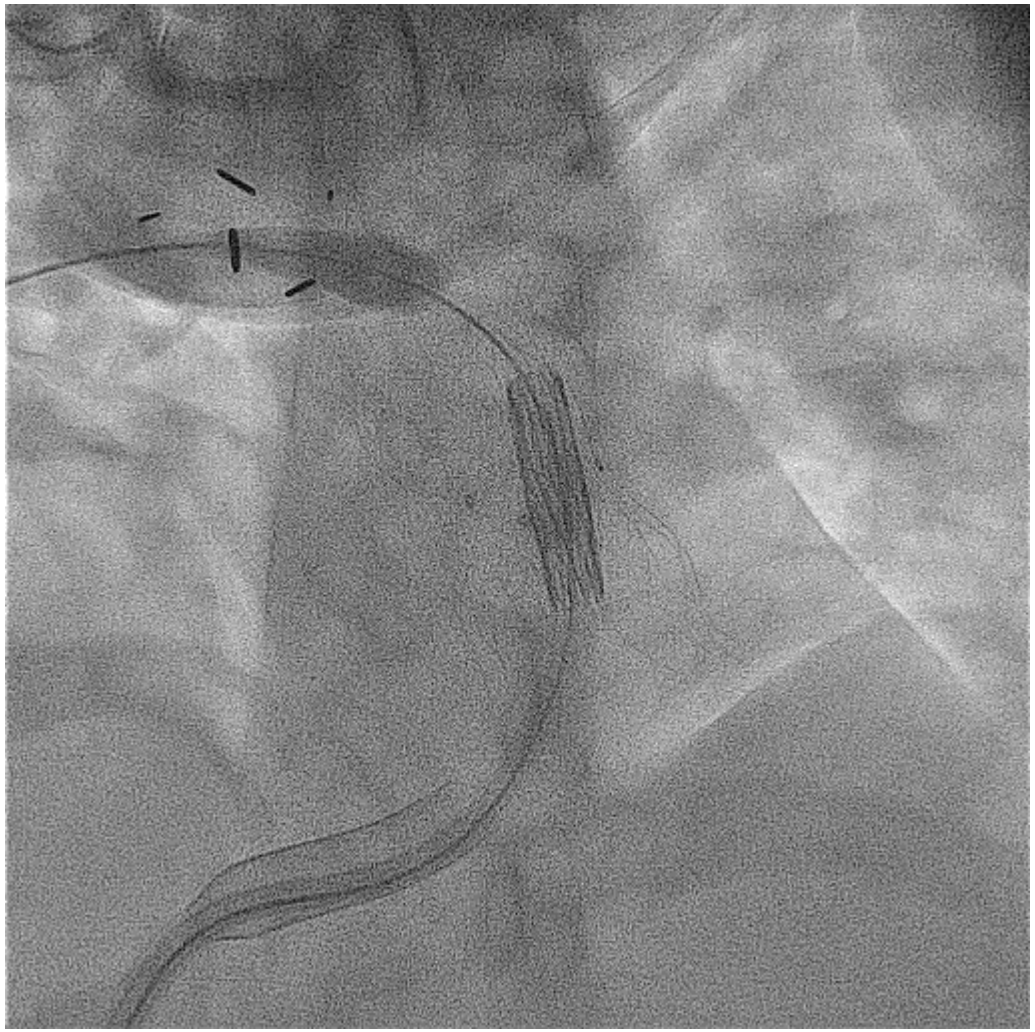

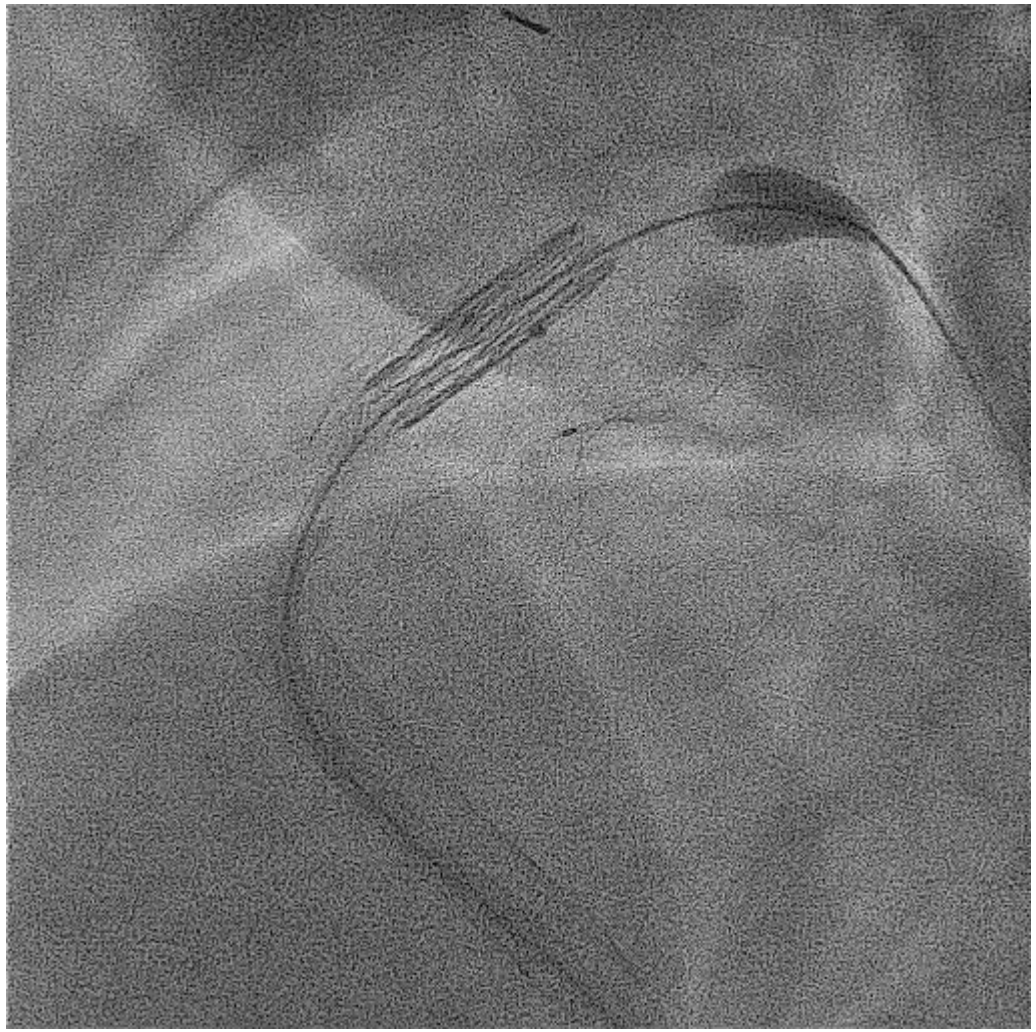

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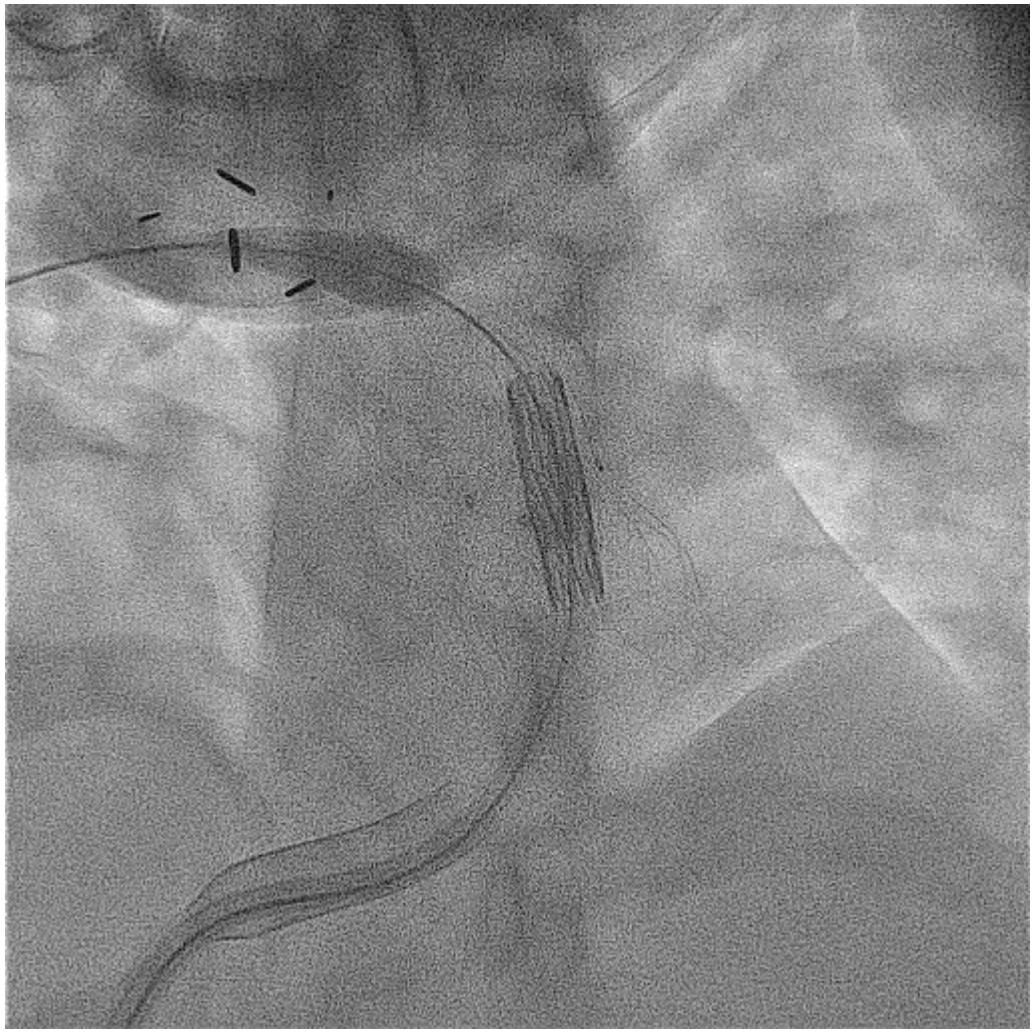

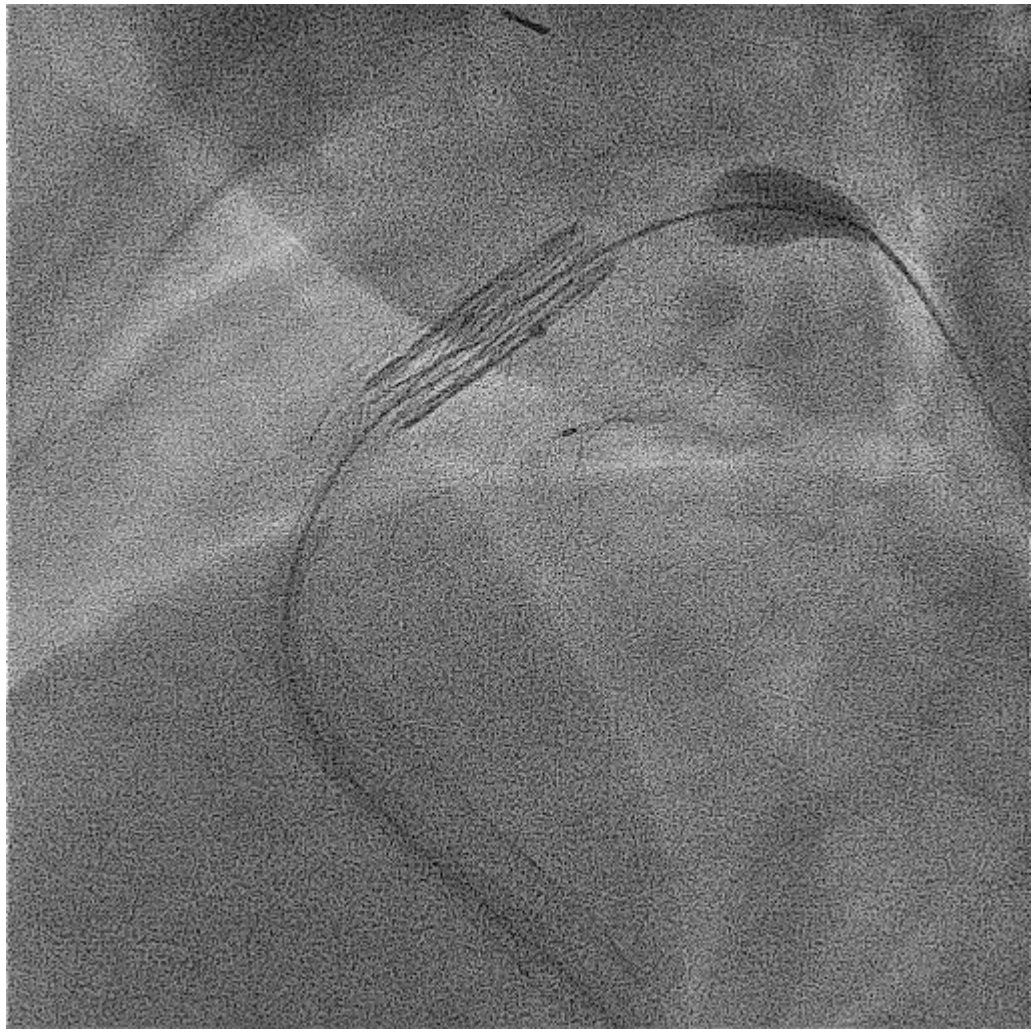

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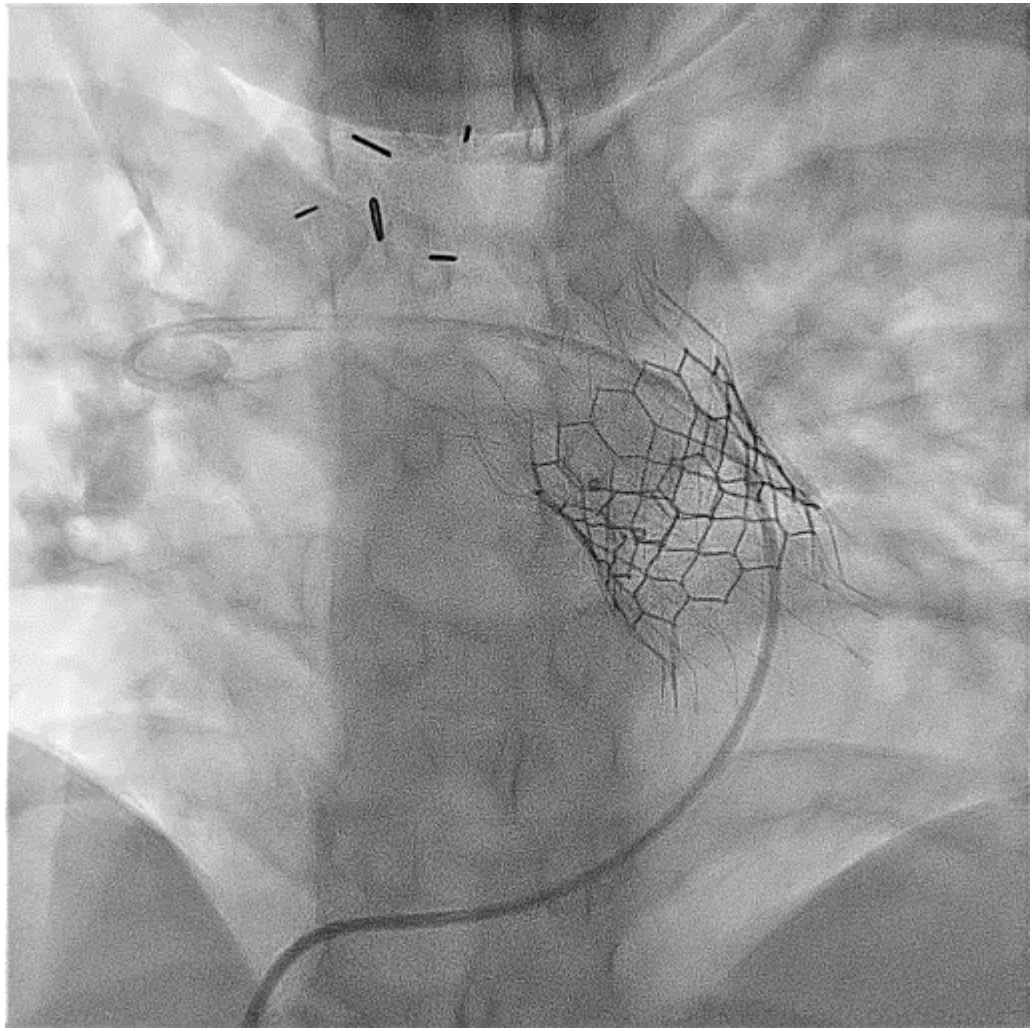
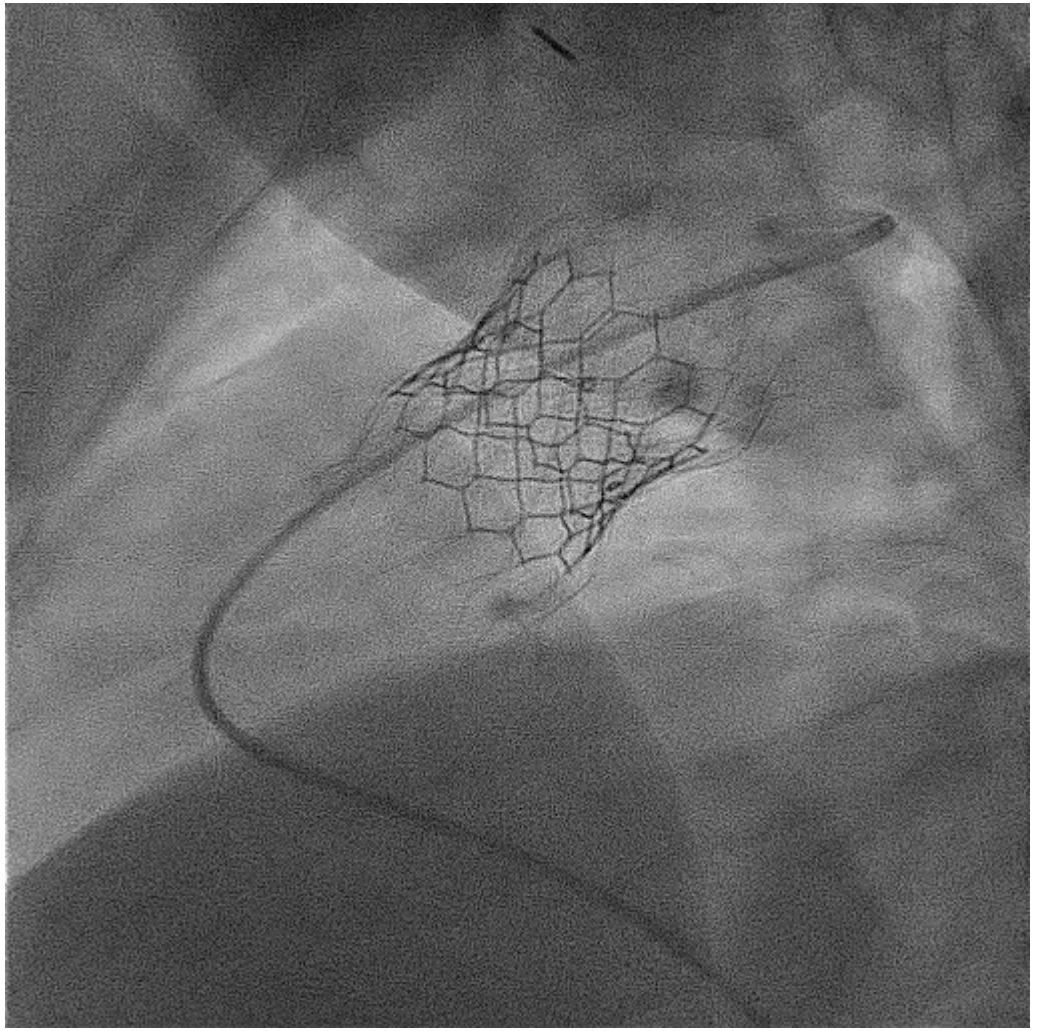
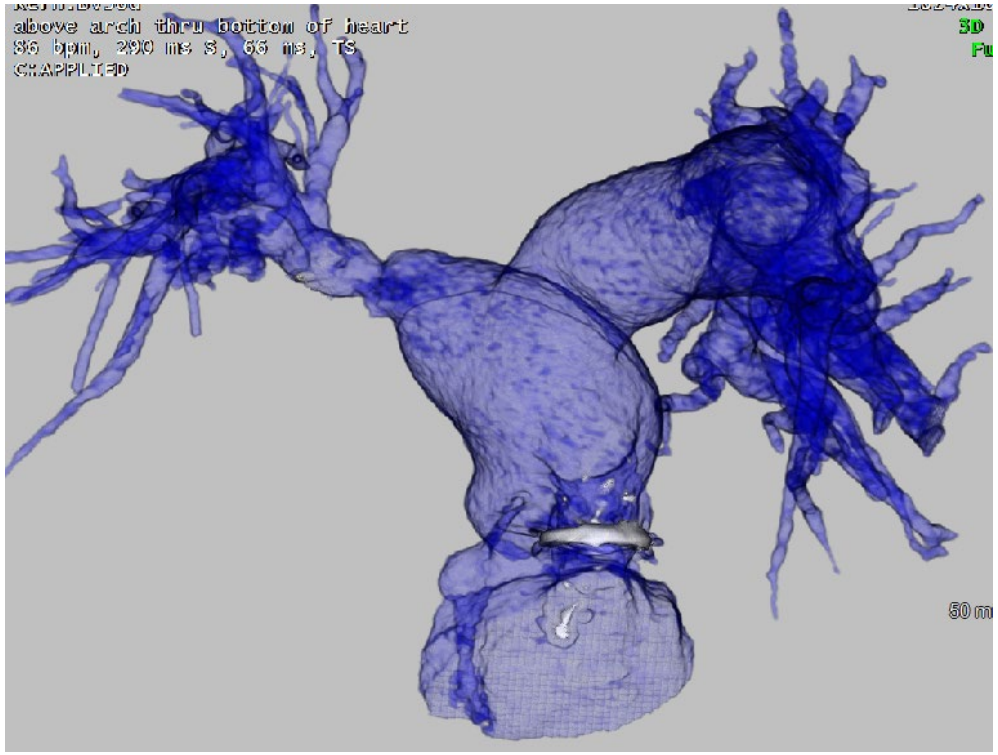


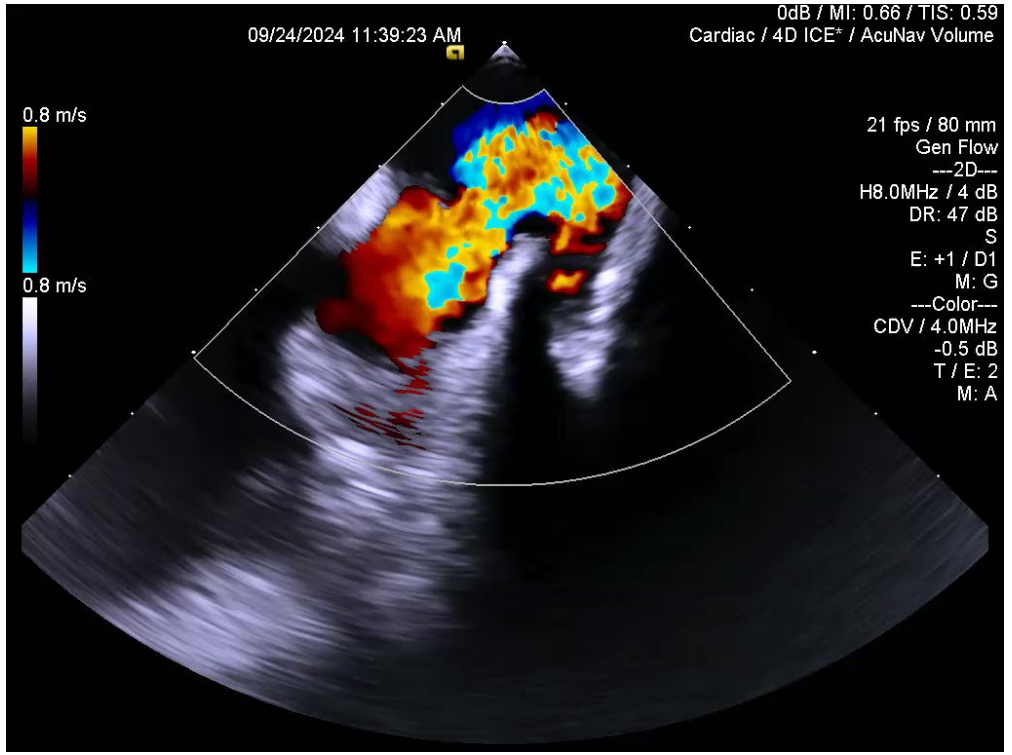


CASE – “A TRUE DOUBLE-OUTLET RV”

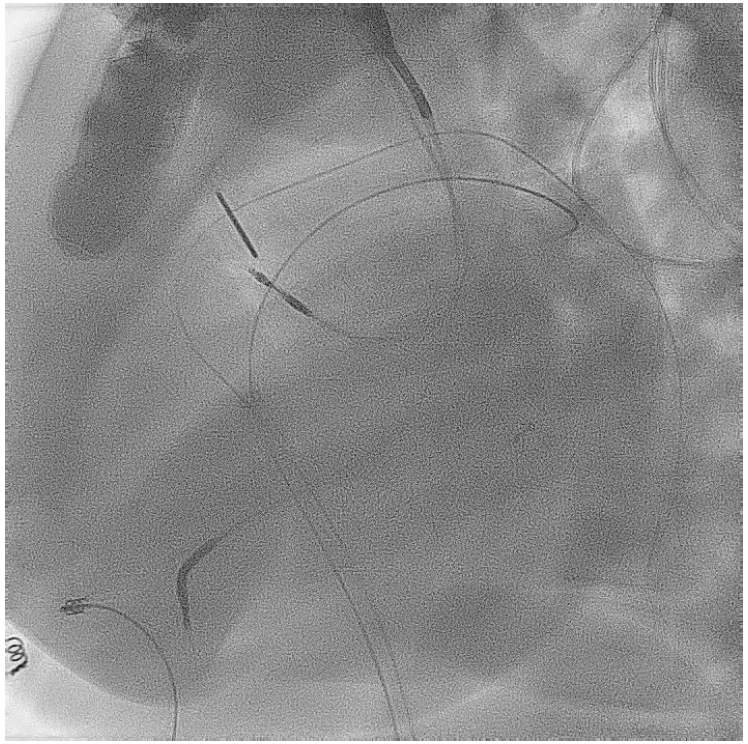
- 47-year-old woman with TOF
- Repaired with 14 mm Hancock conduit
- Biventricular failure (RVEF 20%, LVEF 30%)
- CRT-D
- Free PI

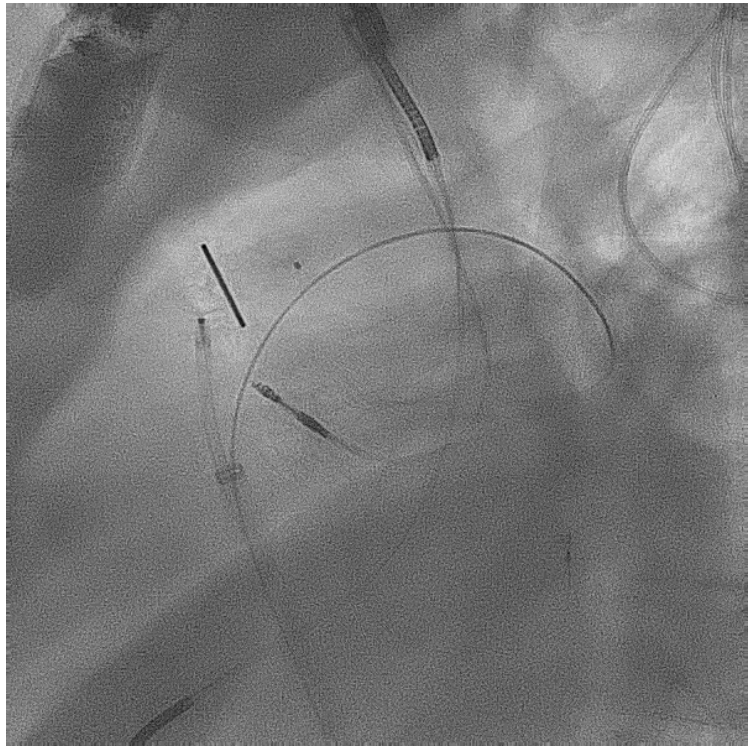
CASE – “A TRUE DOUBLE-OUTLET RV”

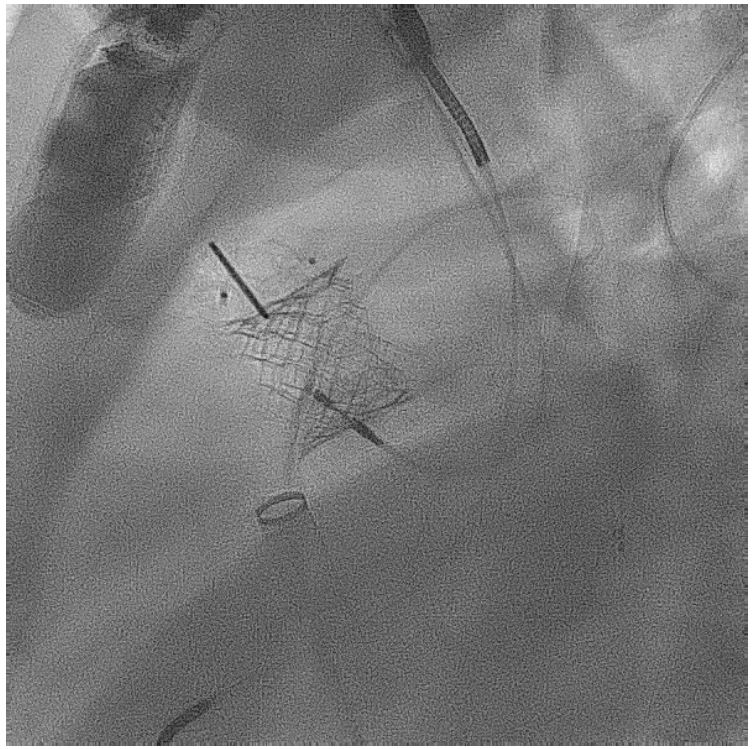




CASE – “A TRUE DOUBLE-OUTLET RV”







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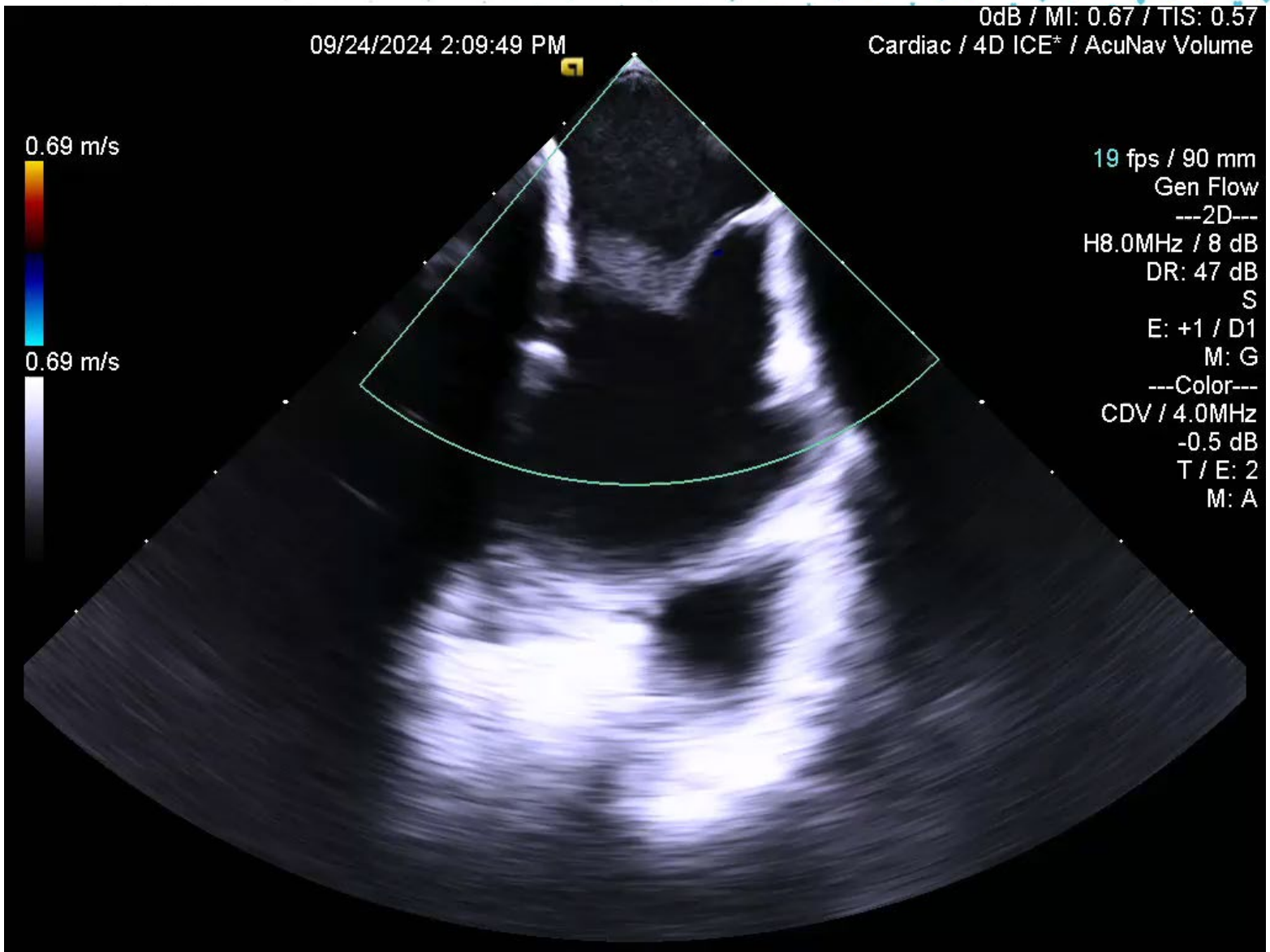

SUMMARY

- ACHD is a growing field. The patients require multi-disciplinary congenital care at sub-specialty centers.

- Many ACHD patients previously treated with surgery can now be offered transcatheter solutions.

- No patient should have pulmonary valve surgery without being evaluated for transcatheter therapy.

PV DISORDERS

1) Tetralogy of Fallot
2) Aortic valve disease who have had the Ross procedure
3) Pulmonary stenosis with surgical repair or balloon valvuloplasty
4) Truncus arteriosus
5) Pulmonary atresia
6) Rastelli
7) Double Outlet Right Ventricle (DORV)

HealthCare
GILL HEART & VASCULAR INSTITUTE
Network

THANK YOU!

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Medical Director, Kentucky Adult Congenital Heart (KACH)
University of Kentucky

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