Extended Indications for Catheter Interventions in Patients with Congenital Heart Disease

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Self Expanding Valves for „native“ RVOT Dysfunction

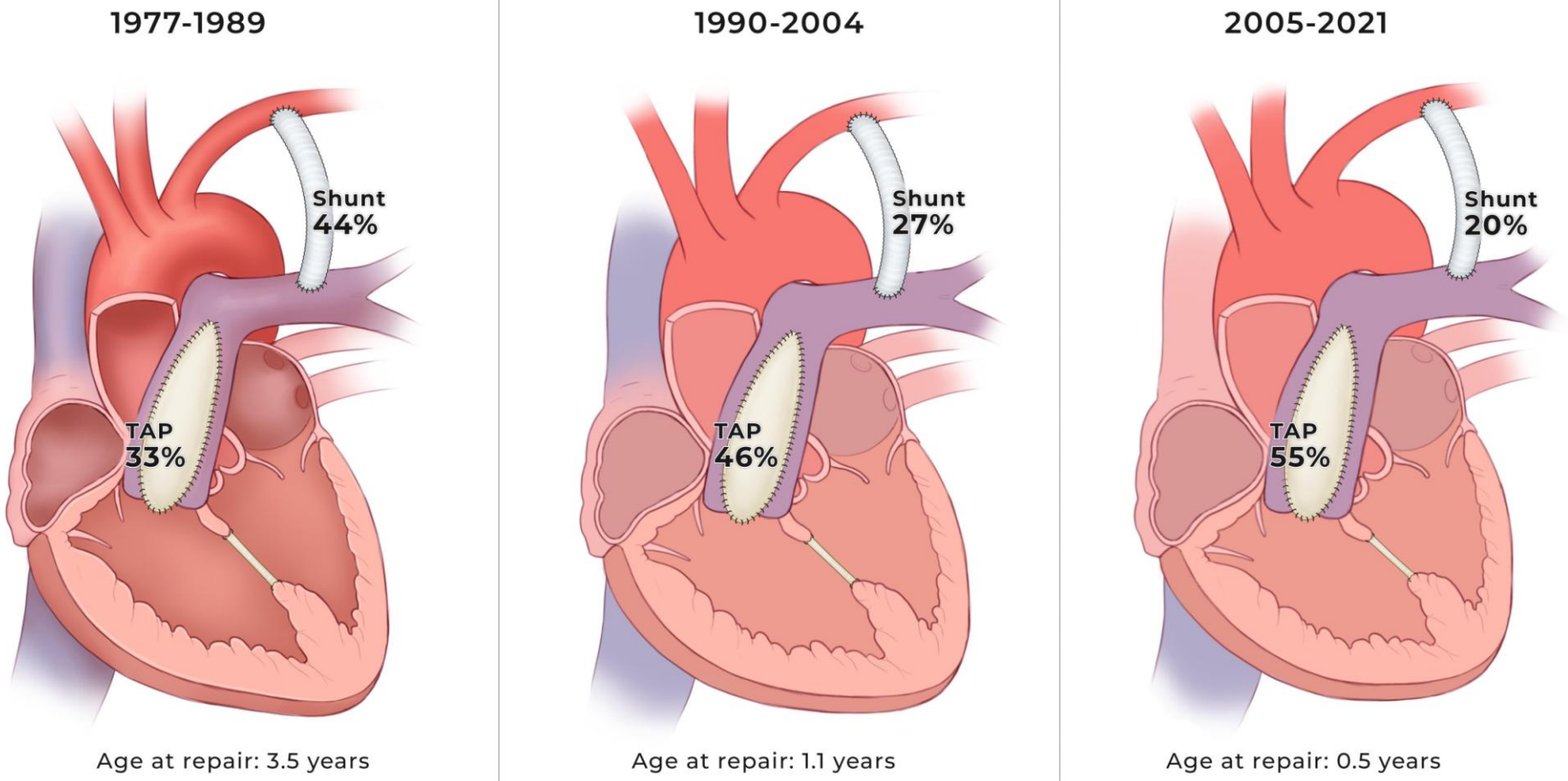
Catheter Interventional Treatment of Sinus Venosus Defect

Closure of open Ductus in VLBW Preterm Infants under Echo

Stenting of non compliant Biological Valves – The Materna approach

Self expanding valves in RVOT

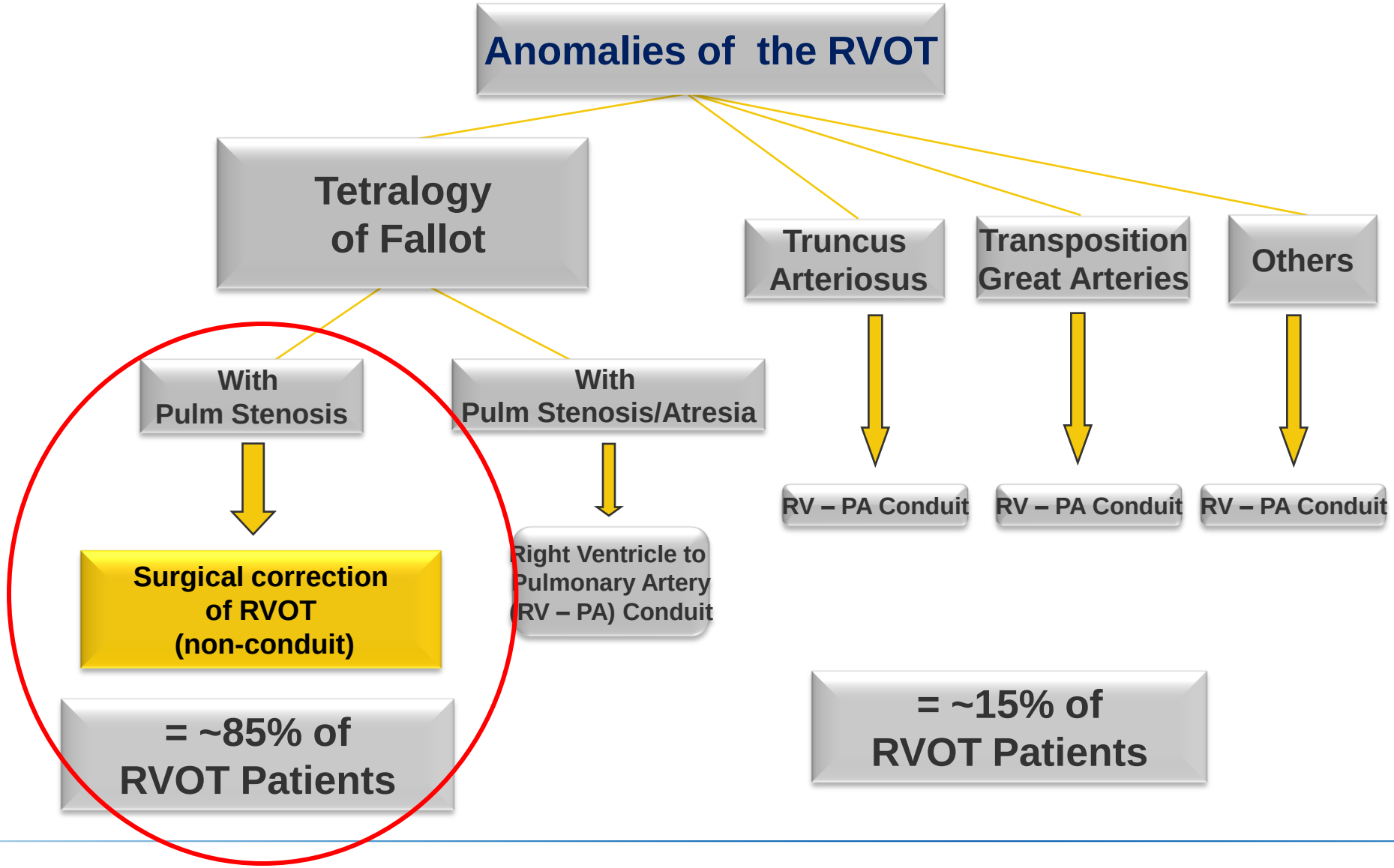
Surgical repair of Tetralogy of Fallot



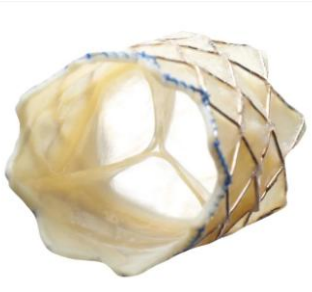
Gröning et al. Work in progress

courtesy Lars Sondergaard

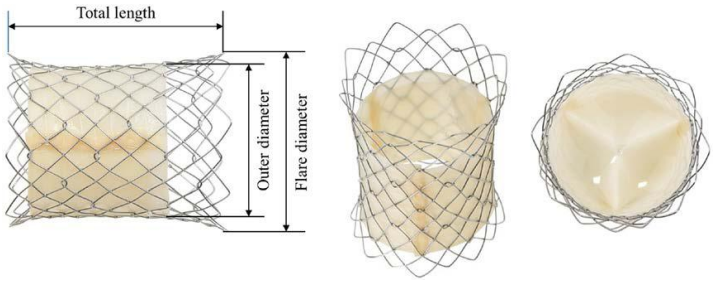
Self expanding valves in RVOT



PPVI – Size Matters

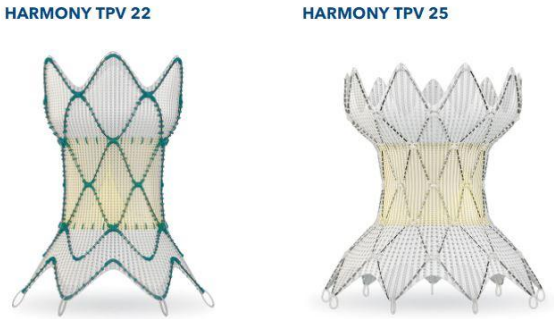


Melody – 25 mm



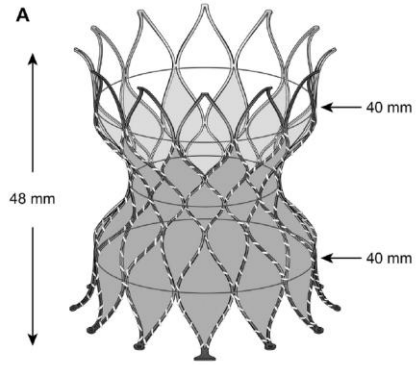
Pusta – 32 mm

Sapien 3 – 31 mm



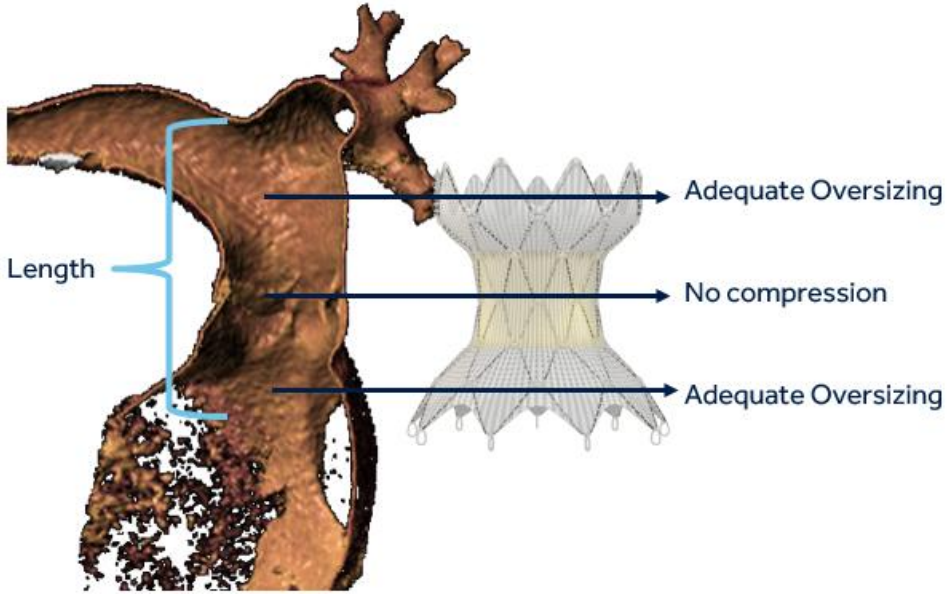
Harmony

Venous P – 34 mm

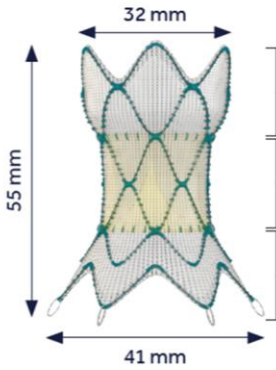


Alterra

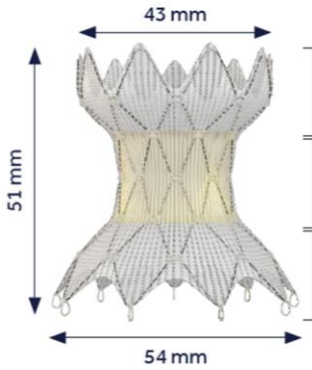
Harmony™ TPV Device Sizing



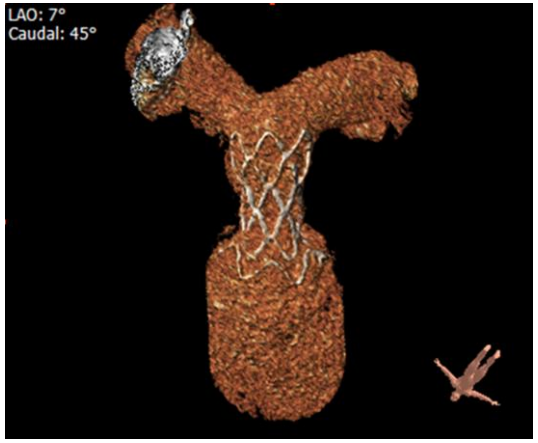
Anatomical size ranges appropriate for gated end- diastolic CT scan measurements



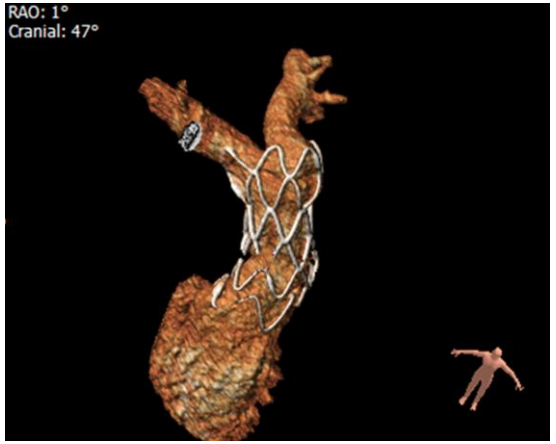
Harmony TPV 22 PA section	Anatomical Size (perimeter-derived diameter)
Outflow — Distal PA/Bifurcation	22–28 mm
Valve Housing	> 22 mm
Inflow — Proximal PA/RVOT	23–39 mm



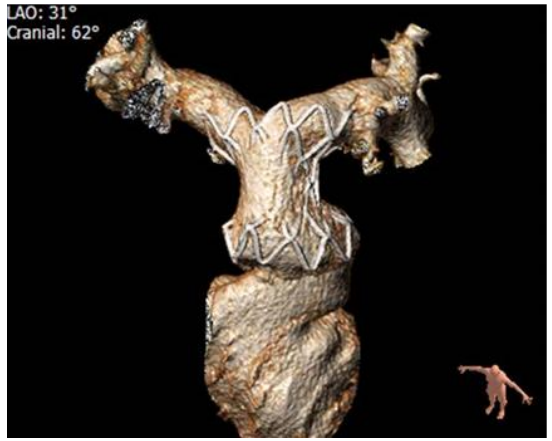
Harmony TPV 25 PA section	Anatomical Size (perimeter-derived diameter)
Outflow — Distal PA/Bifurcation	25–38 mm
Valve Housing	> 25 mm
Inflow — Proximal PA/RVOT	32–48 mm



TPV22, with the distal outflow crown sitting in the pre-bifurcation area



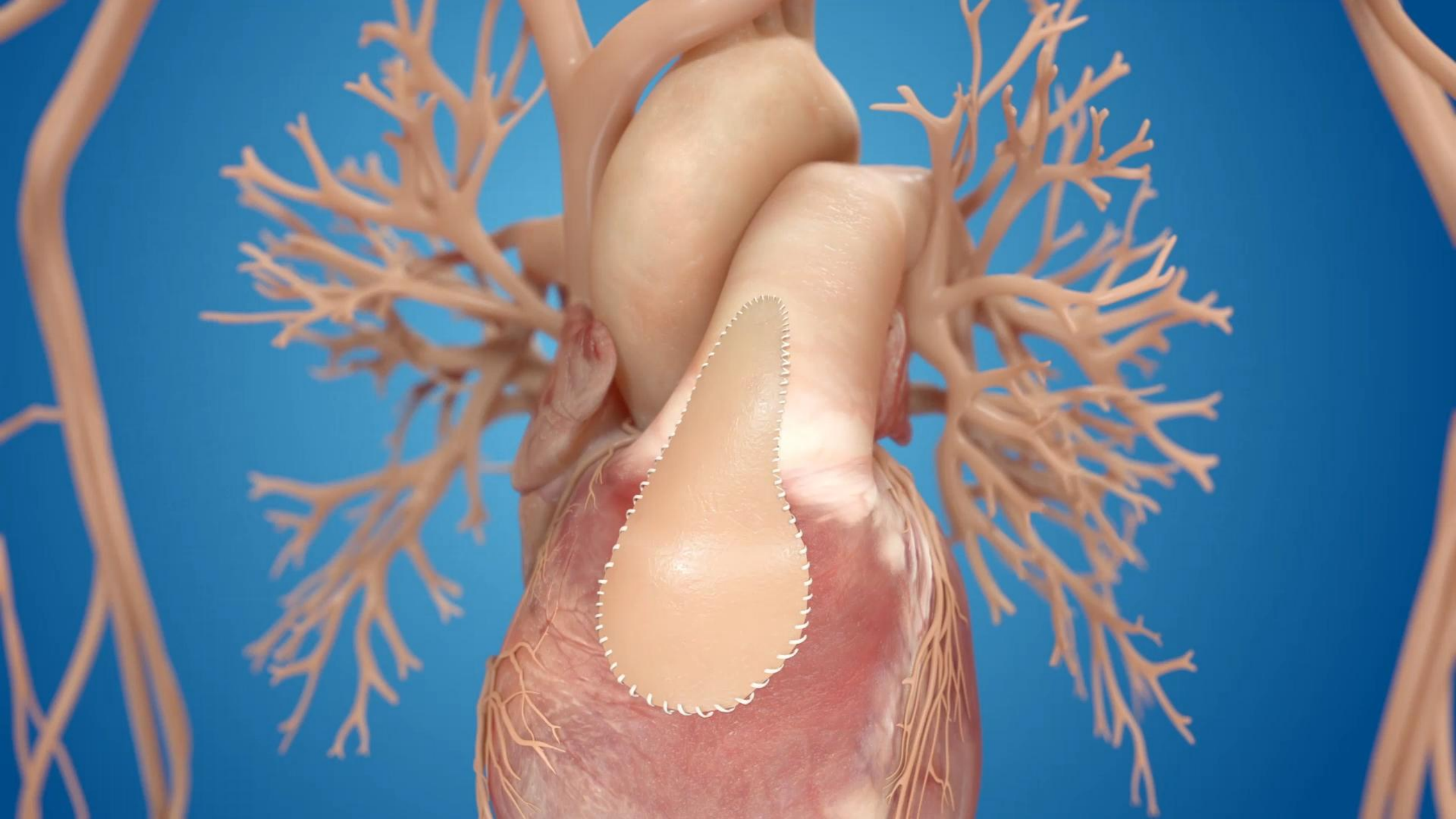
TPV 22



TPV 25

The devices are higher, at the bifurcation

courtesy Lee Benson

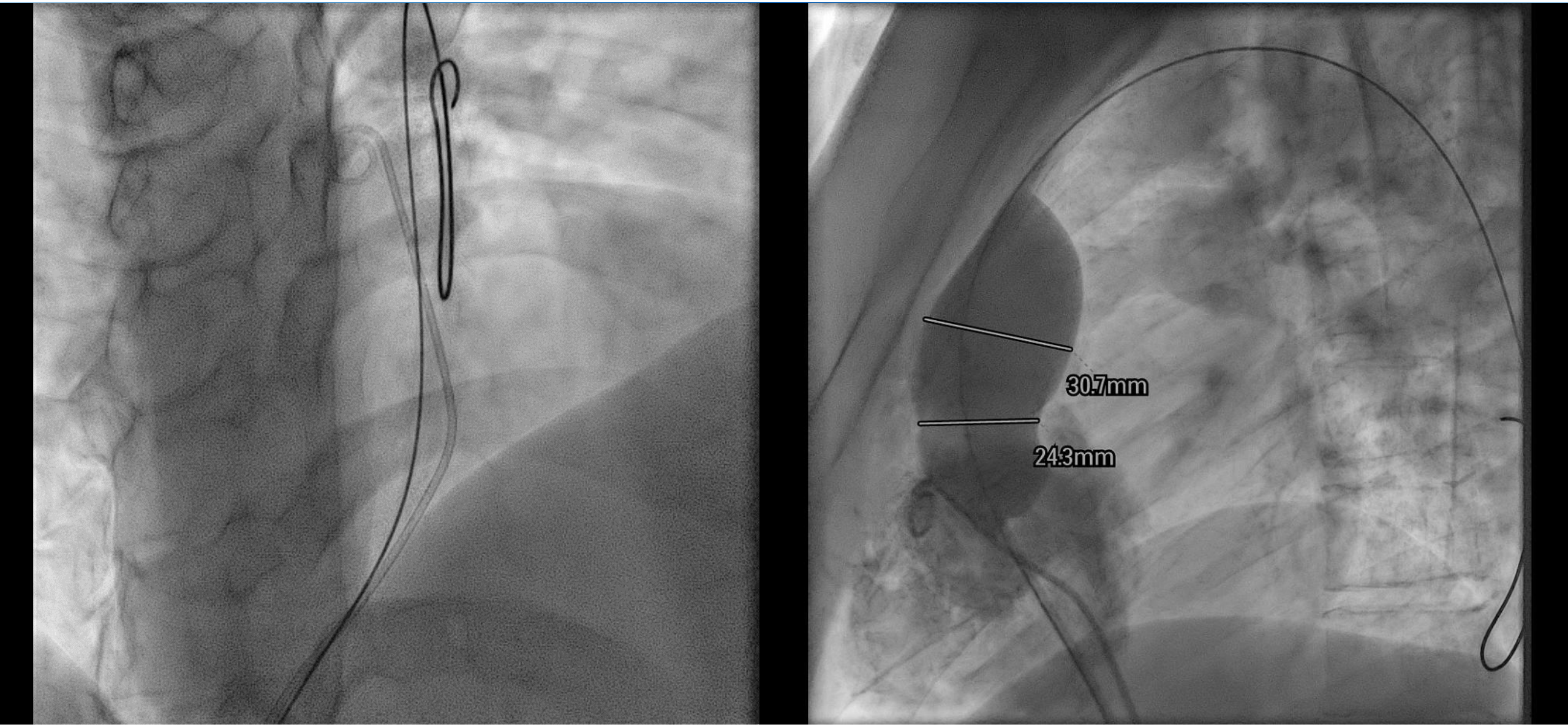


PPVI – DHM Experience

12/2006 - 09/2022 n = 423 patients

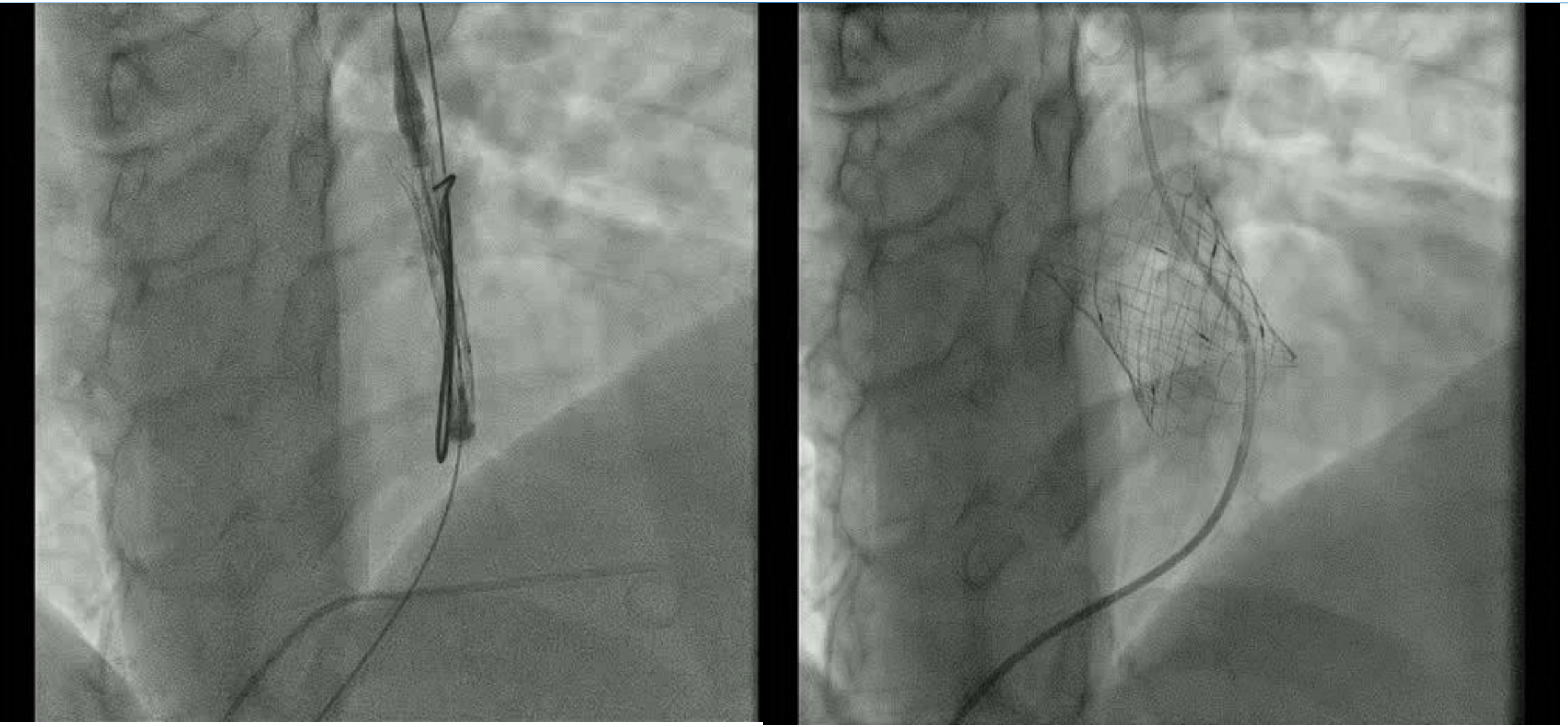
age median (y)	19.9 (4.1-78.9)
weight (kg)	60.0 (17 -176)
gender	f = 164, m = 259
OP	2 (1-6)
diagnosis	TOF/PA 201, TAC 59, TGA 28, AoVS 39, other 96
conduit	Homograft 221, none 71, Heterograft 131
Valve position	PaV 382, (TrV 38, TCPC 1, other 1, MiV 1)
valve	Melody 345, Sapien 71, Pulsta 7 Sapien 23 n = 8, Sapien 26 n = 34; Sapien 29 n = 29,

Pulsta Case



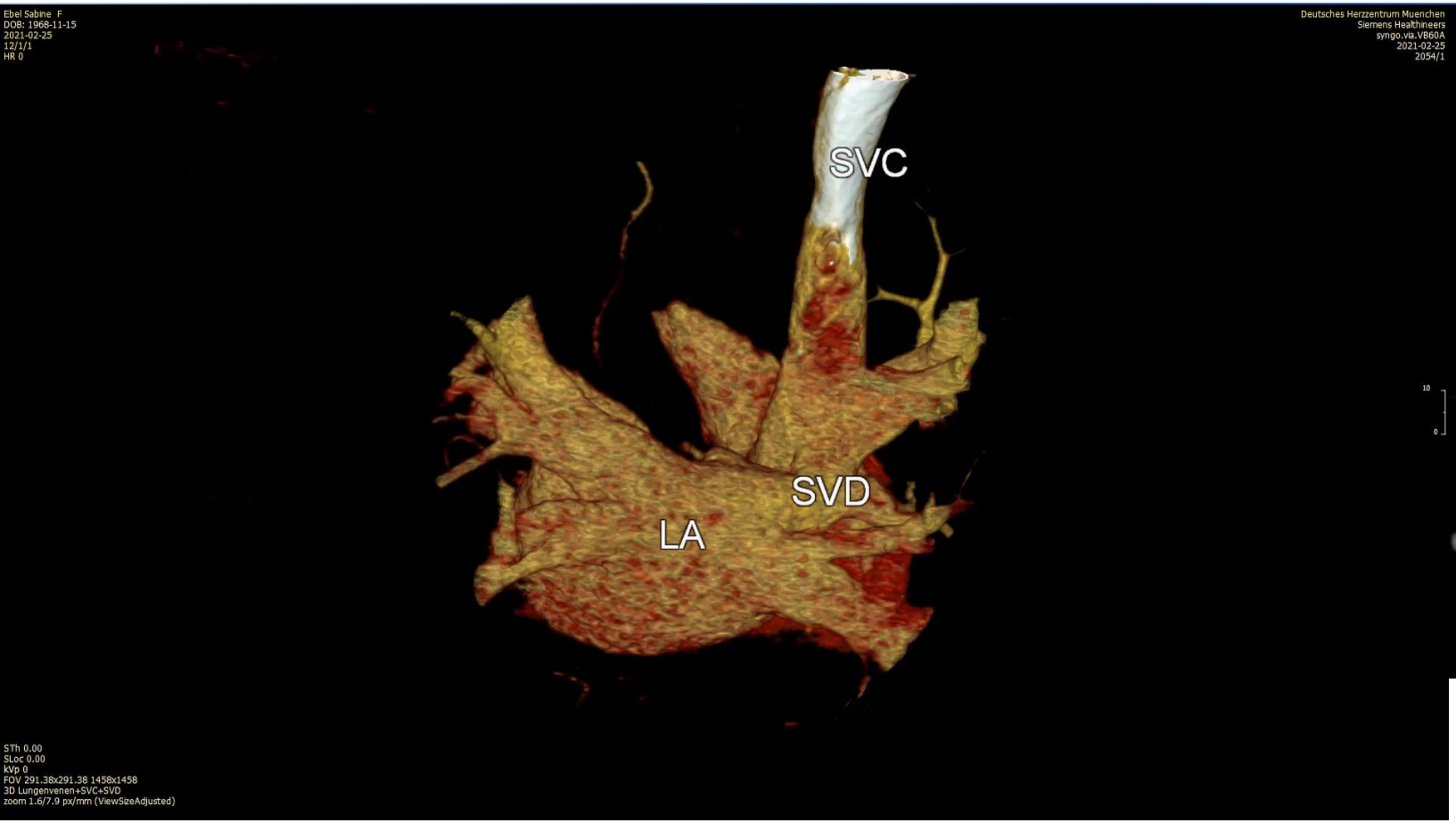
25 y, 82kg, ToF, severe PR, RVEDvolIndex 129ml/m2, reduced exercise tolerance

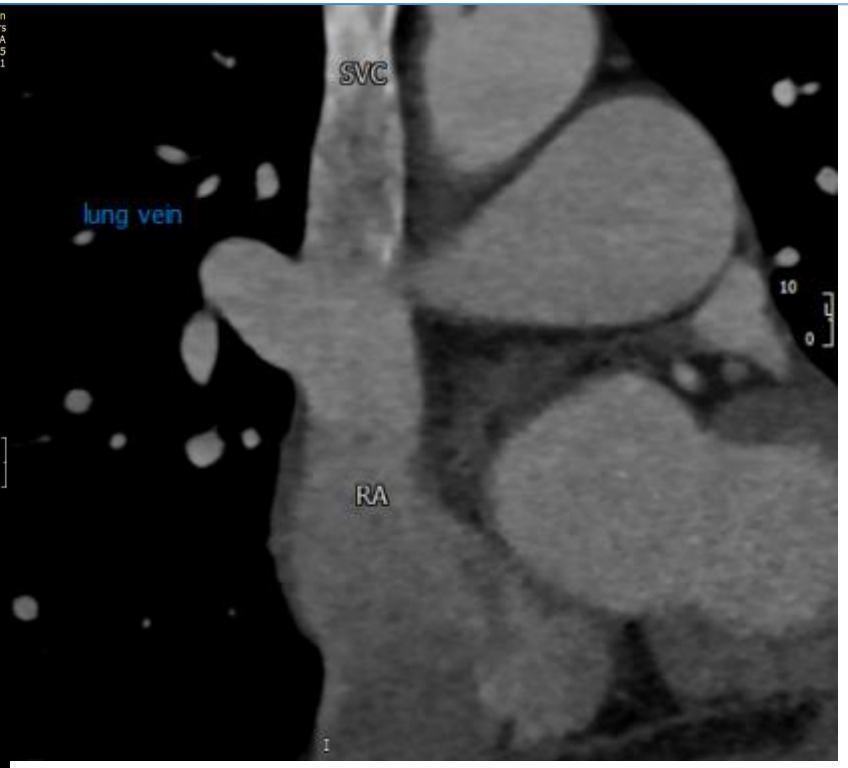
Pulsta Case



25 y, 82kg, ToF, severe PR, RVEDvolIndex 129ml/m2, reduced exercise tolerance

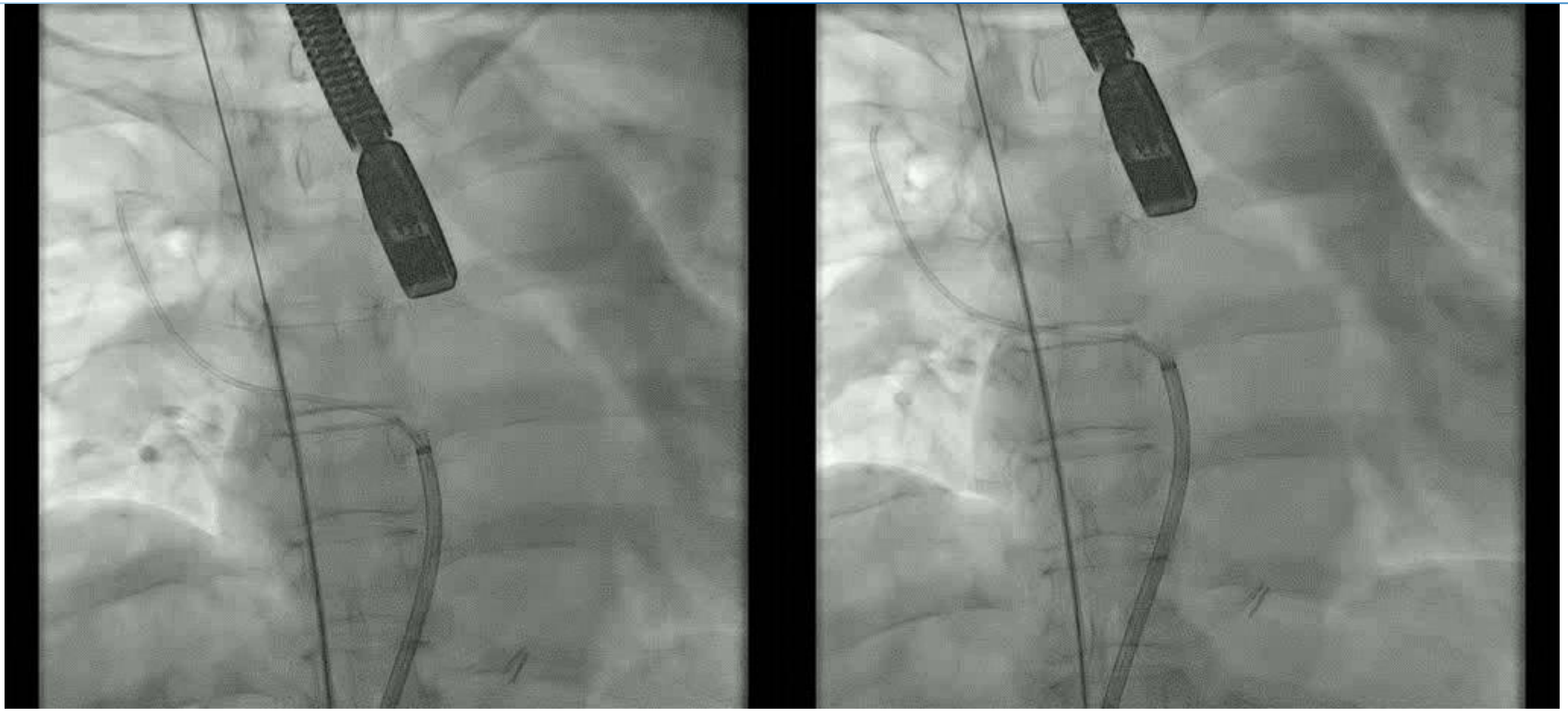
Sinus Venosus Defect





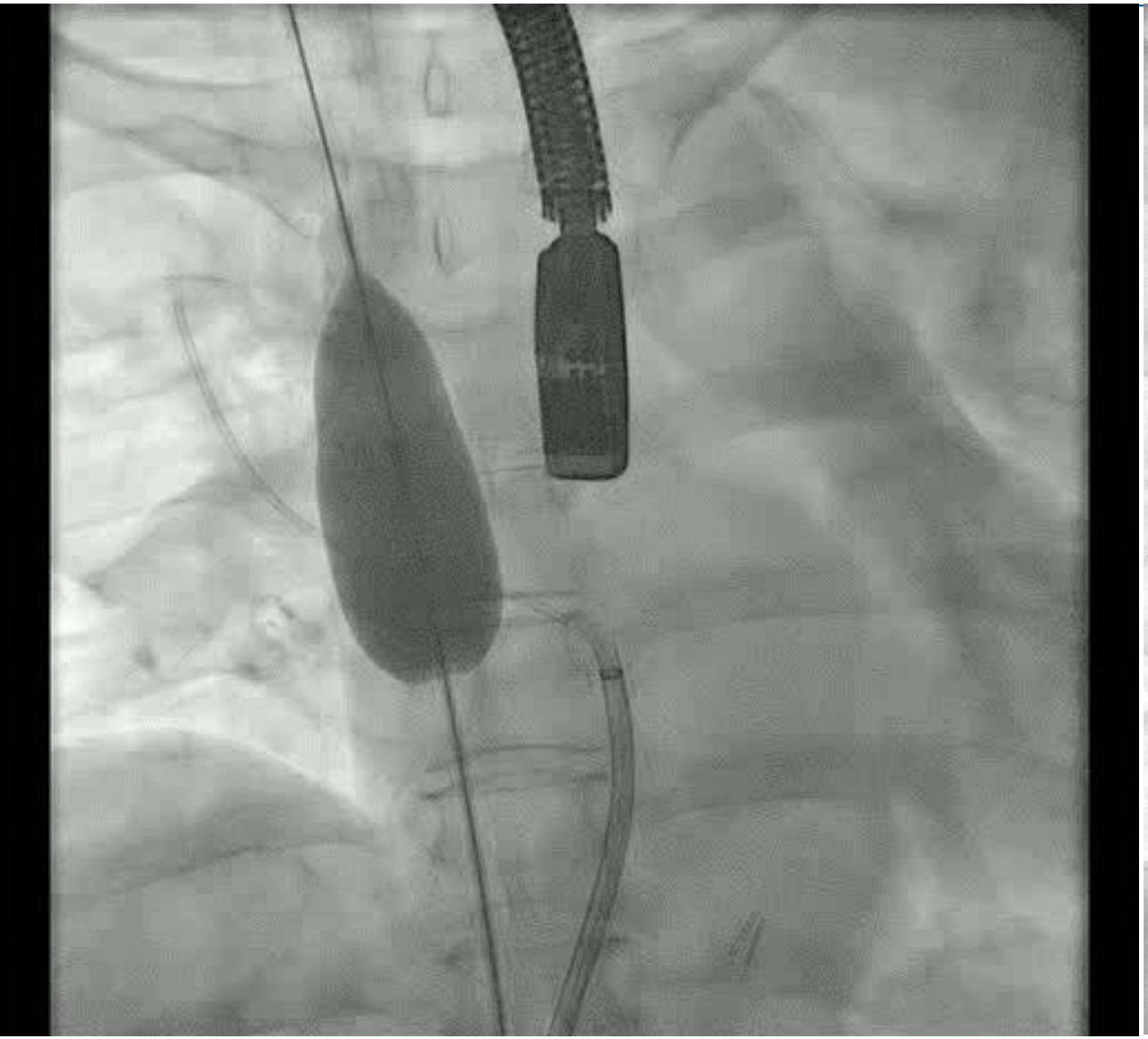
54 y, 96kg, SVD, severe RV- enlargement, reduced exercise tolerance

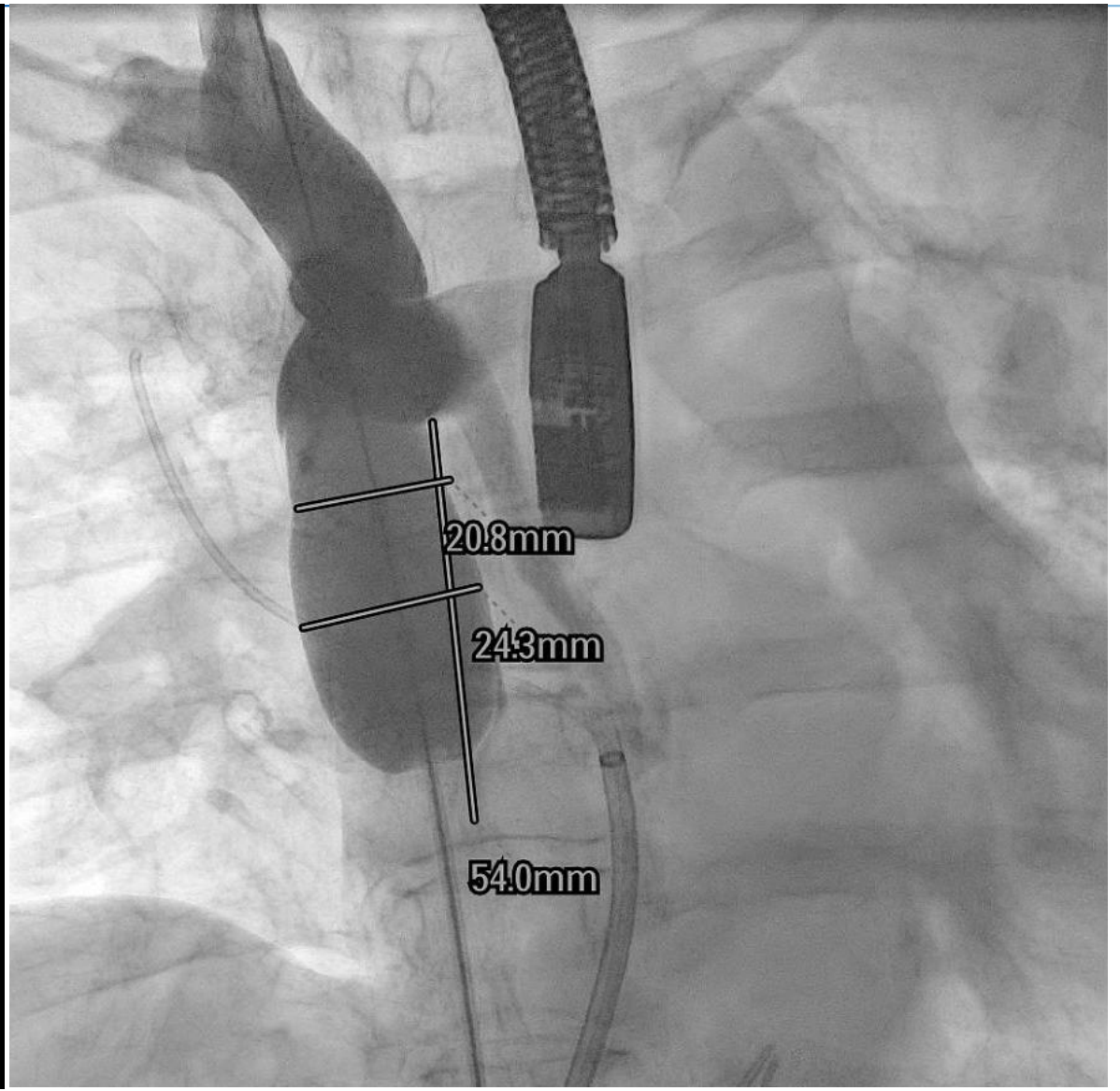
Sinus Venosus Defect



54 y, 96kg, SVD, severe RV- enlargement, reduced exercise tolerance

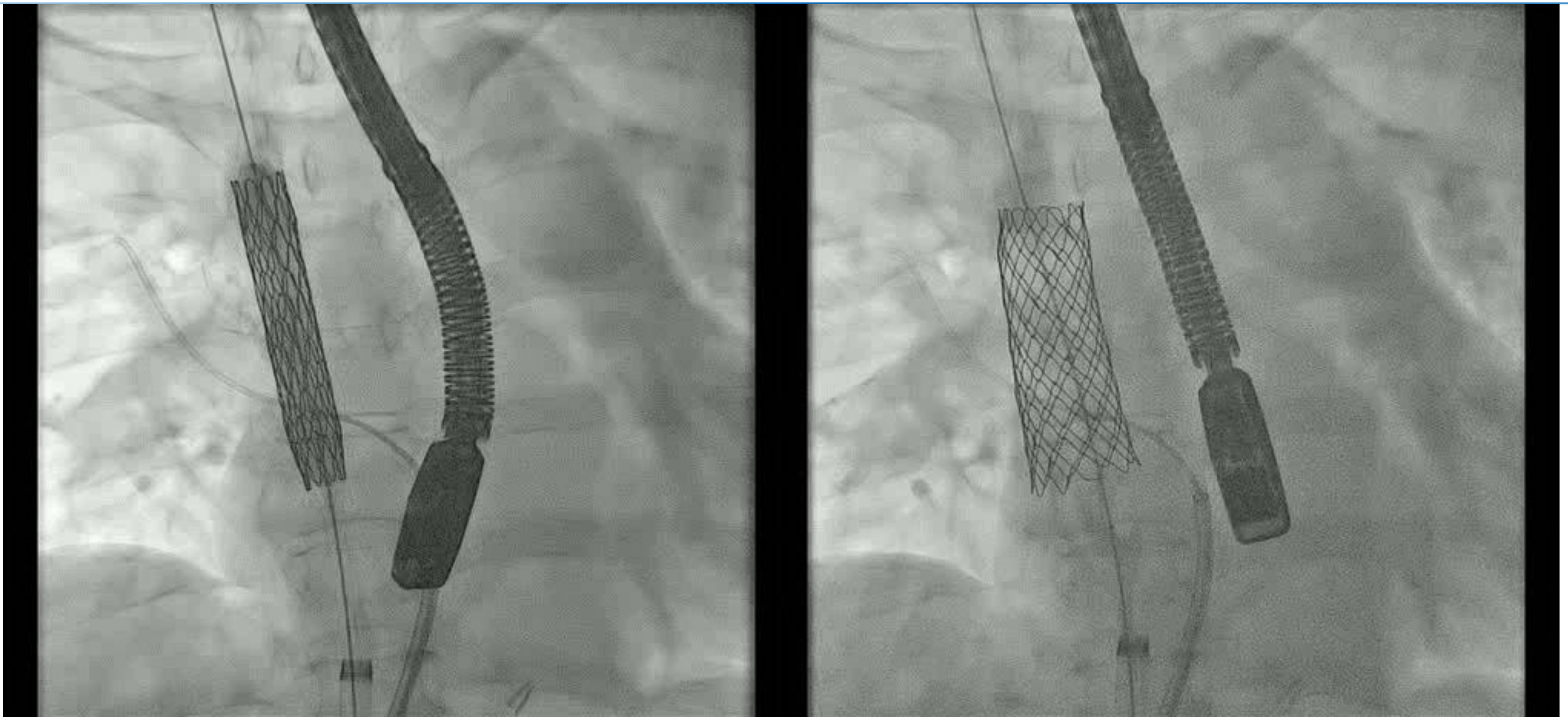
Sinus Venosus Defect





balloon test

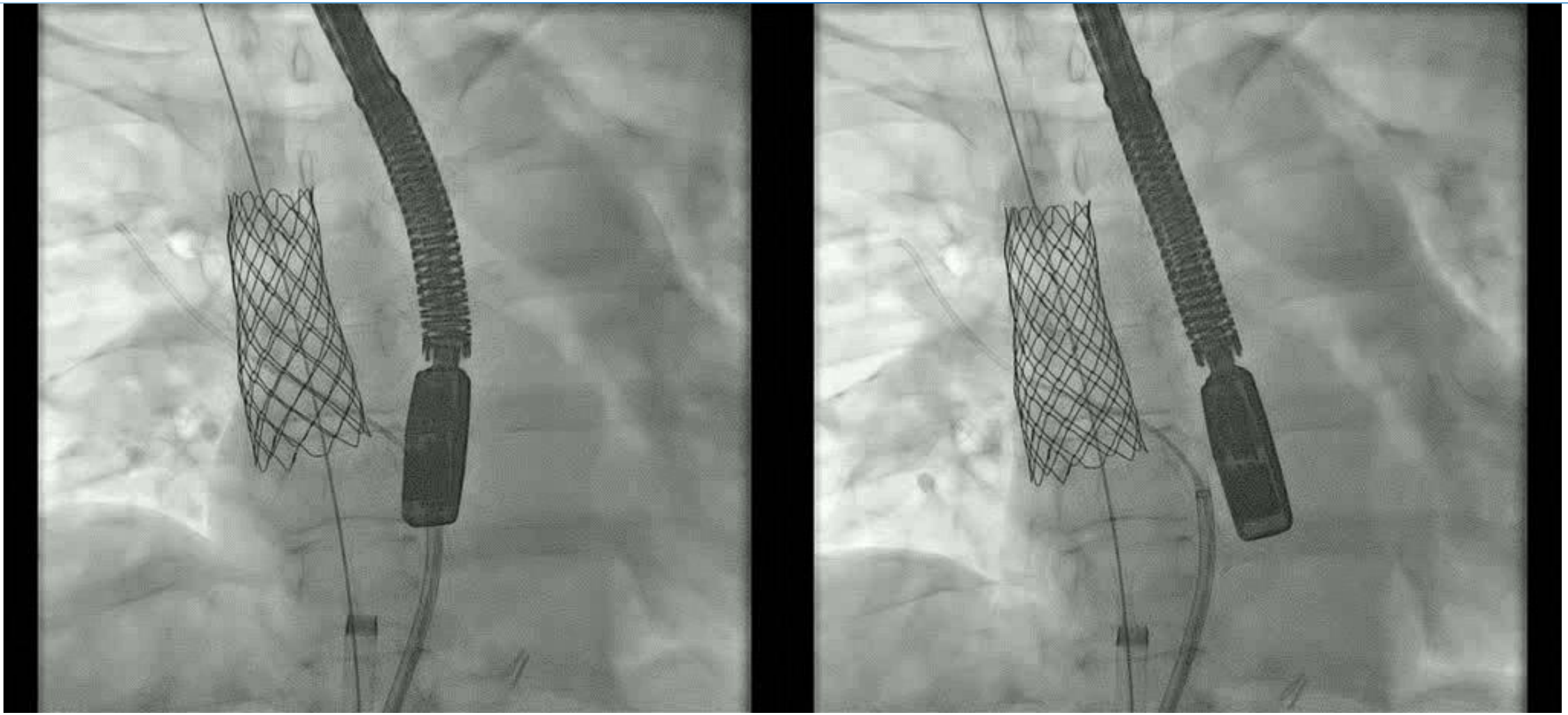
Sinus Venosus Defect



inner balloon inflation (28x80mm)
cCP 10z 70mm

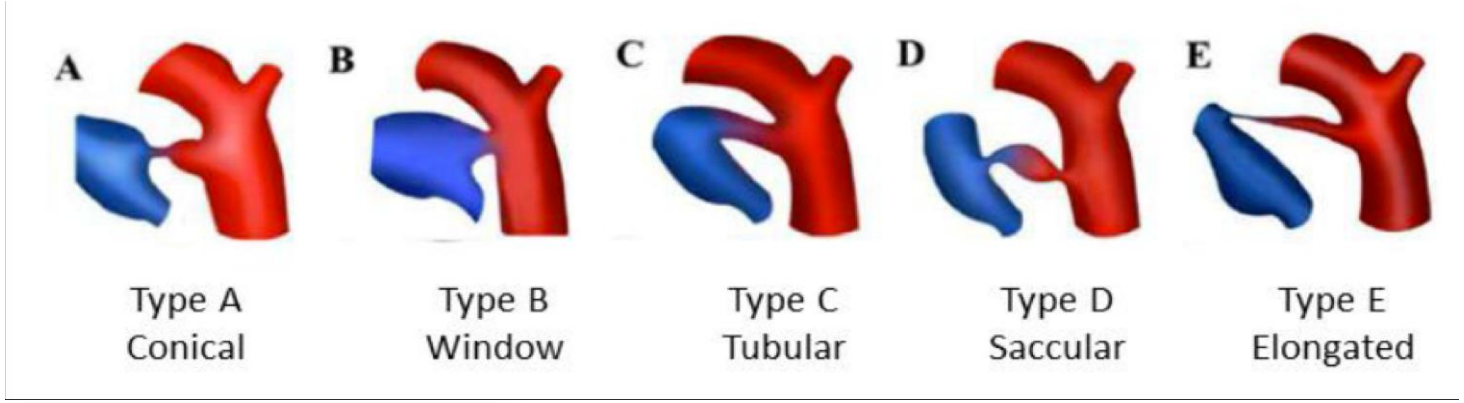
distal stent flaring VACS balloon 30x40mm

Sinus Venosus Defect

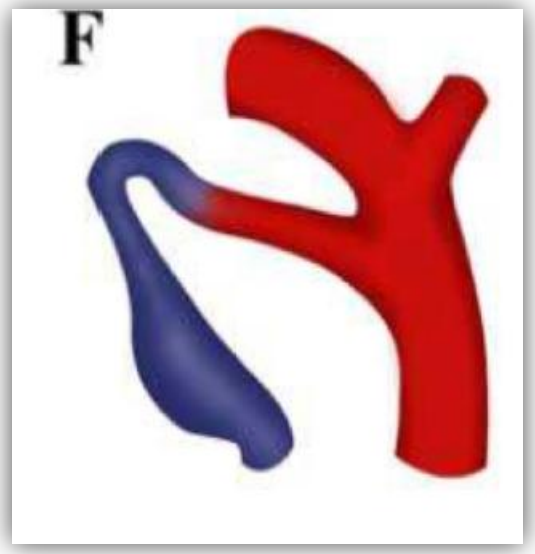


final

Duct Occlusion in VLBW



Krichenko et al. AJC 1989



„fetal“ PDA

Catheterization and Cardiovascular Interventions 87:310–317 (2016)

Morphologic Characterization of the Patent Ductus Arteriosus in the Premature Infant and the Choice of Transcatheter Occlusion Device

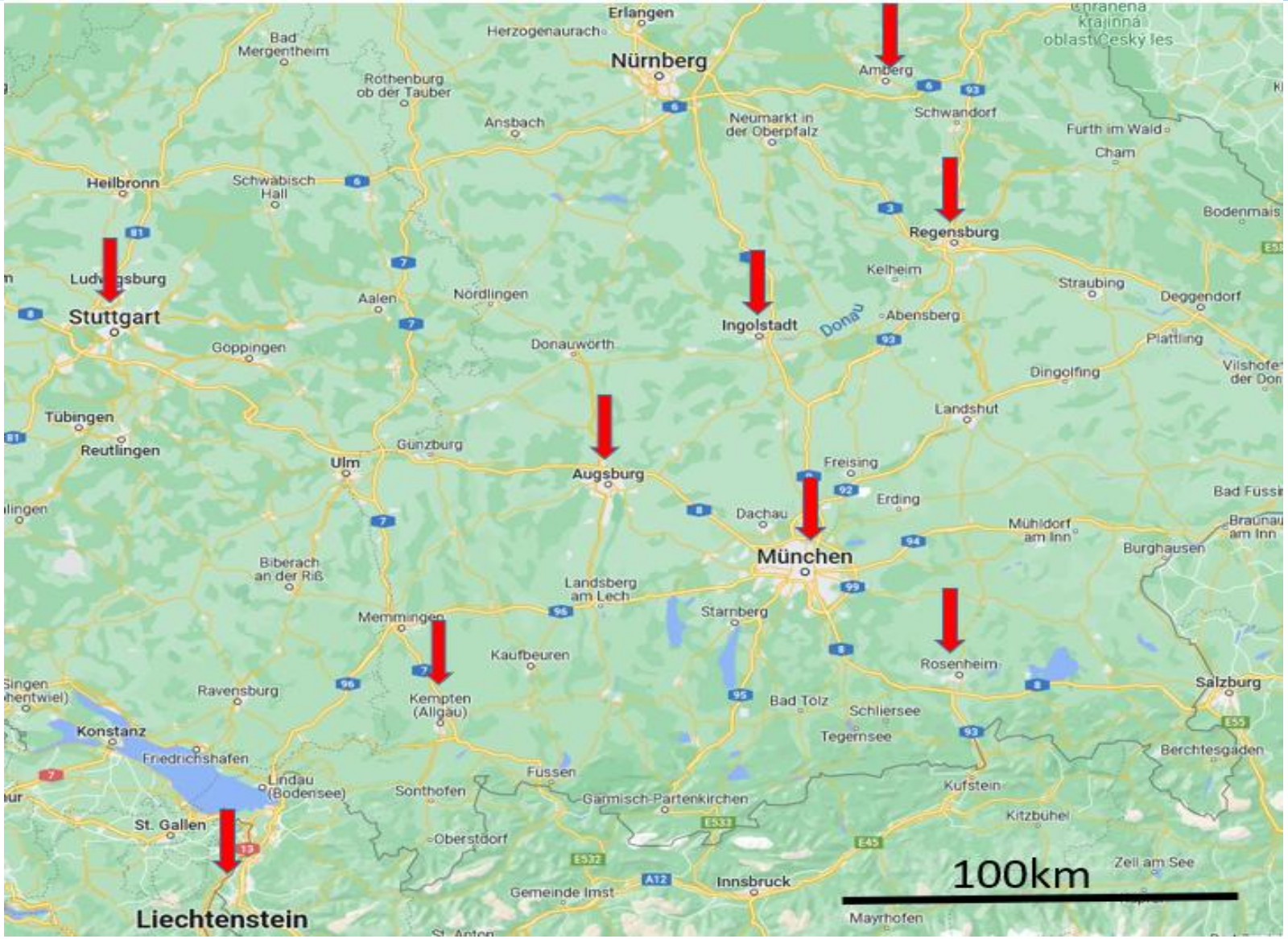
Ranjit Philip,[1,2*] MD, B. Rush Waller III,[1,2] MD, Vijaykumar Agrawal,[3] MD, Dena Wright,[1,2] RN, Alejandro Arevalo,[1,2] MD, David Zurakowski,[4] PhD, and Shyam Sathanandam,[1,2] MD

PDO under Echo only

Georgiev S. et al. JACC Cardiovasc Interv. 2021;14(7):814-16: Transvenous, echocardiographically guided Closure of PDA in 11 premature Infants: A Pilot Study

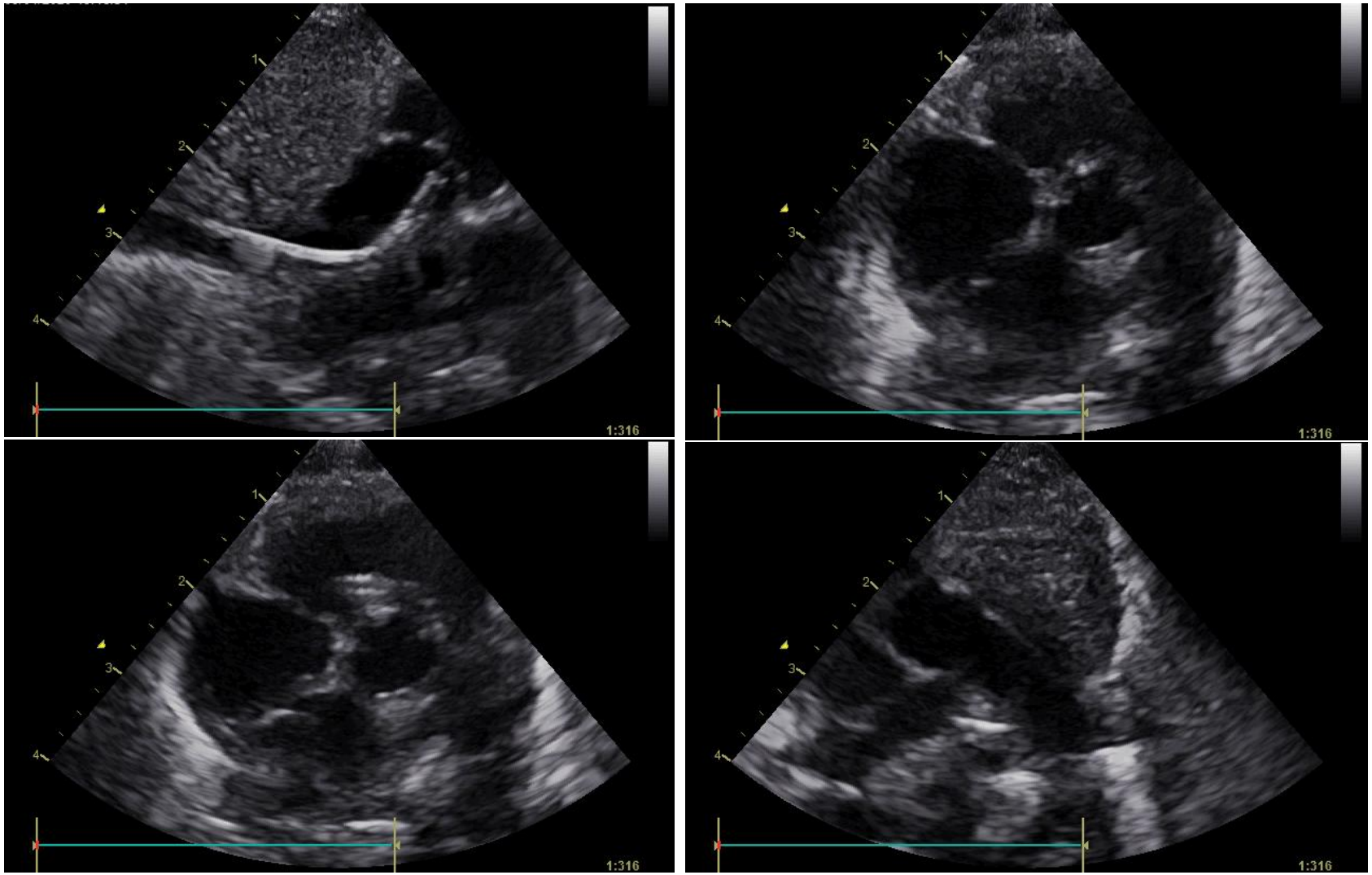
Duct Occlusion in VLBW

Duct Occlusion in VLBW

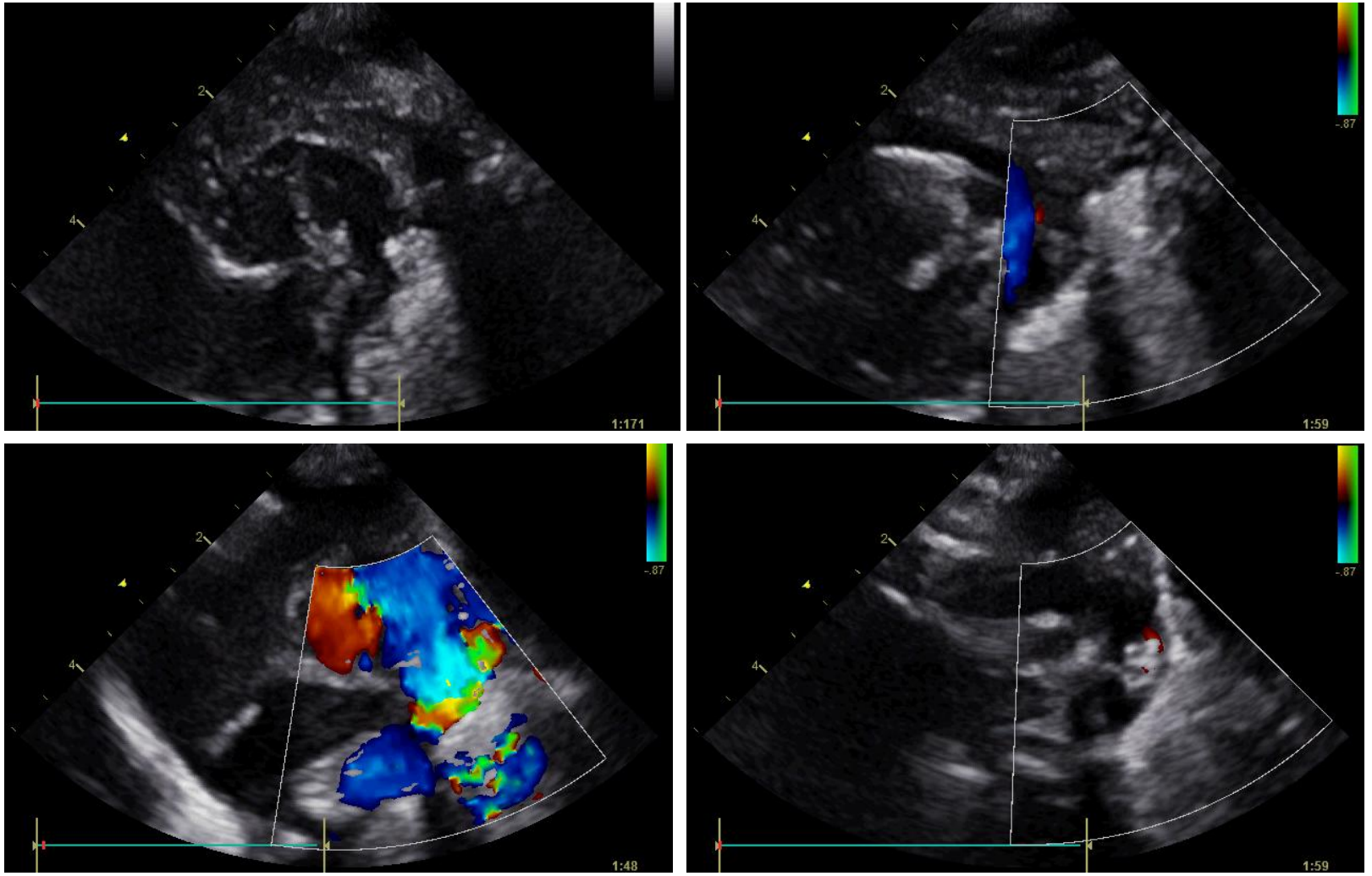


14 neonatology units
9 towns

PDO under Echo only



PDO under Echo only



Piccolo 4/2

Duct Occlusion in VLBW

Weight at birth (g)	755 (340-2560)
Weight at intervention (g)	1115 (730-2800)
Age at intervention (days)	26(9-95)
History of infection N,(%)	20 (47%)
History of NEC	4 (9%)
Trial of NSAIDs	42 (98%)
Respiratory support during intervention	
high flow cannula	2 (5%)
CPAP	6 (14%)
Ventilation	29 (67%)
HFOV	6 (14%)

43 patients
submitted
JACC interv.

Duct Occlusion in VLBW

Technische Universität München

Prague – Munich Meeting 2021

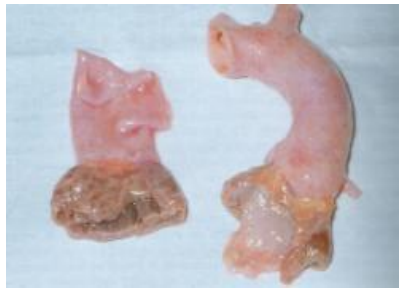
Nove Hrady

Ondrej Materna:
Do you have experience stenting a stenotic Hancock conduit to prolong its life span?

Andreas Eicken:
No, but it sounds like a reasonable idea

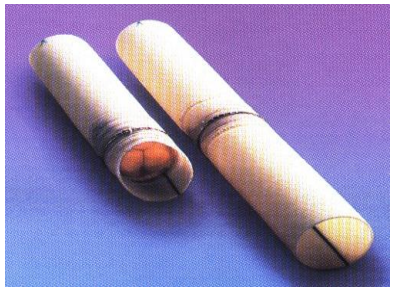
Biological valves for the RVOT

distensible non distensible „crackable“



Homograft

Contegra



Hancock

CE valve

# Patients 2016 – 2022
n = 10

Diagnosis	PA/ToF:7, TGA:1, other:2
Hancock Size (mm)	12:2; 14:4, 16:2; 18:1; 22:1
Treatment after stent	correction 2, Melody 1; waiting 7
Patient Ys without treatment	22.7 years

Since 2016 initial trial for stenotic Hancock conduits is stenting with a bare metal stent

Clinical, echocardiographic and MRI evaluation to monitor RV-function

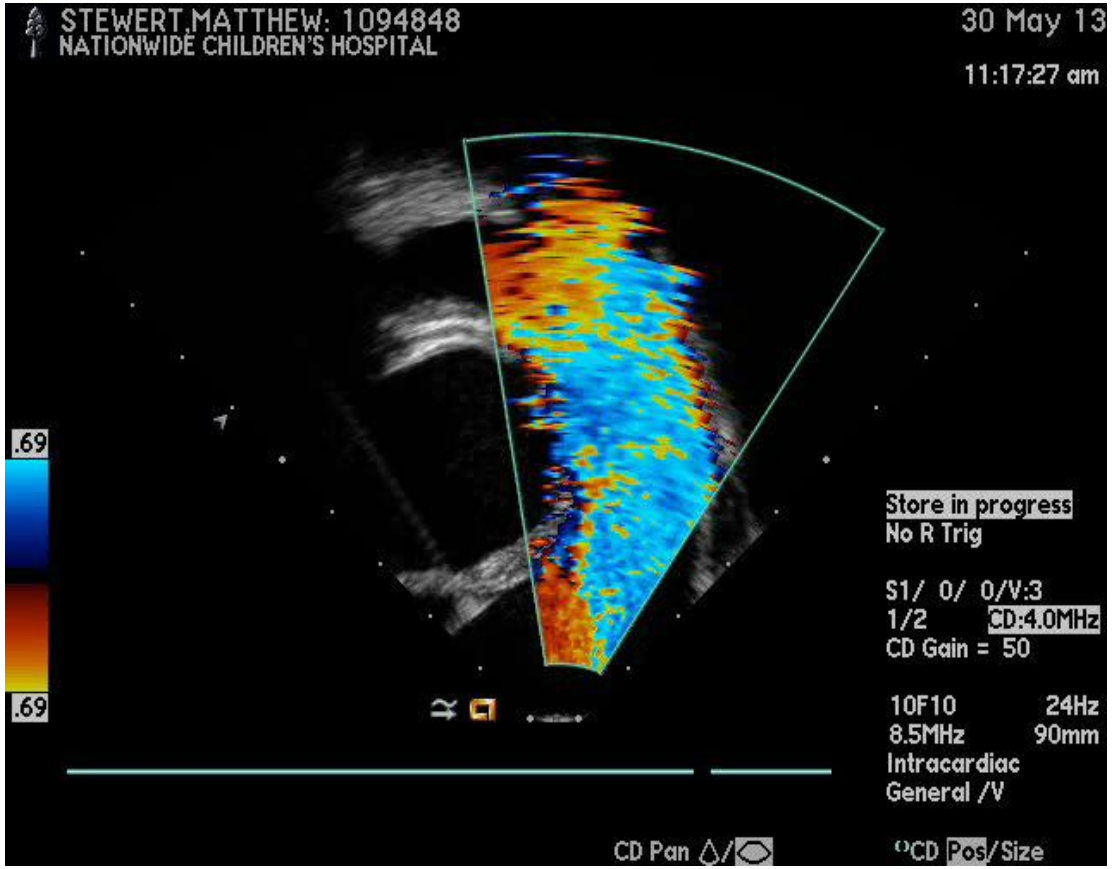

Thank you!

Clinical Outcomes Through 1 Year

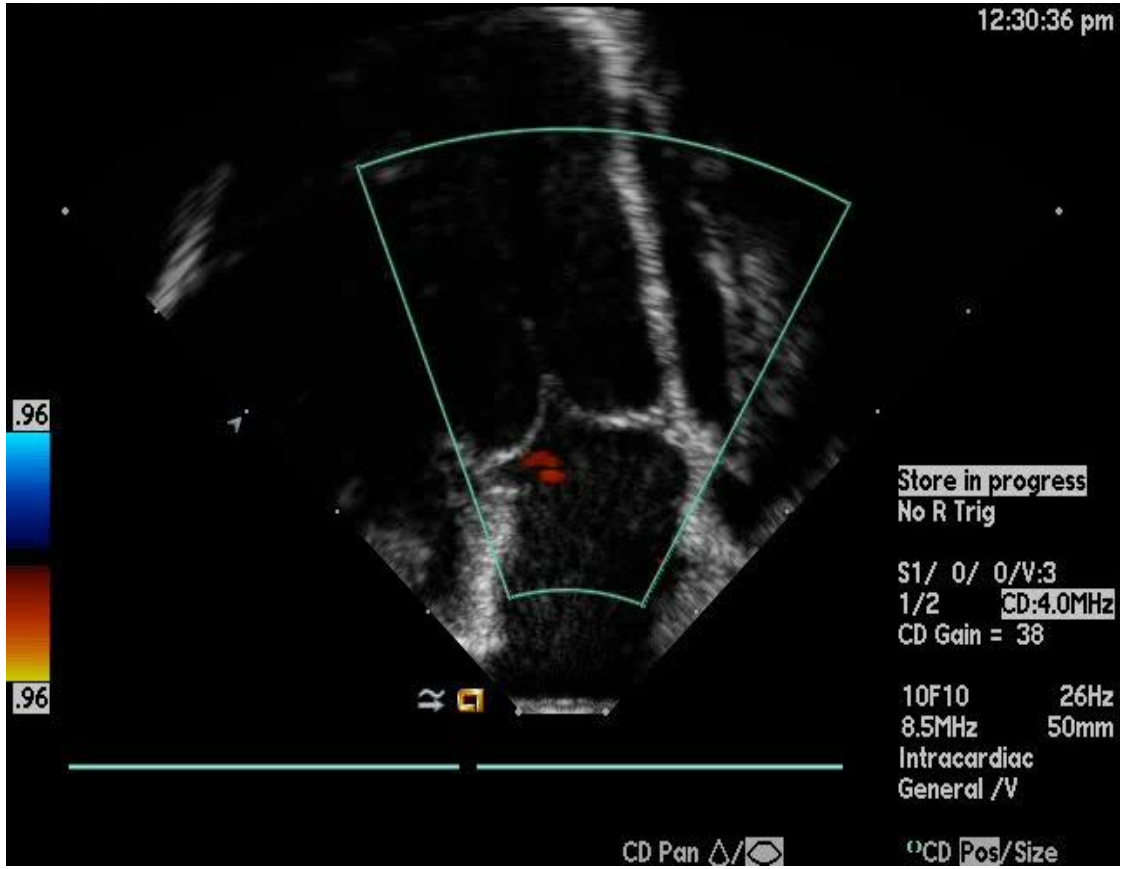
n (%)	TPV22 (N = 44)	mTPV25 (N = 45)	cTPV25 (N = 19)	All Patients (N = 108)
All-cause mortality	**0 (0.0%)**	**0 (0.0%)**	**0 (0.0%)**	**0 (0.0%)**
Embolization of the TPV	0 (0.0%)	0 (0.0%)	2 (10.5%)	2 (1.9%)
Endocarditis	**0 (0.0%)**	**0 (0.0%)**	**0 (0.0%)**	**0 (0.0%)**
Major stent fracture	1 (2.3%)	0 (0.0%)	0 (0.0%)	1 (0.9%)
Thrombosis of the TPV	0 (0.0%)	1 (2.2%)	0 (0.0%)	1 (0.9%)
Myocardial infarction	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Pulmonary thromboembolism	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Brachial plexus injury	1 (2.3%)	0 (0.0%)	0 (0.0%)	1 (0.9%)
Arrythmias	7 (15.9%)	16 (35.6%)	8 (42.1%)	31 (28.7%)
Ventricular premature beats	2 (4.5%)	5 (11.1%)	2 (10.5%)	9 (8.3%)
Ventricular tachycardia	**3 (6.8%)**	**11 (24.4%)**	**5 (26.3%)**	**19 (17.6%)**
Sustained	**0**	**0**	**0**	**0**
Nonsustained	**3 (6.8%)**	**11 (24.4%)**	**5 (26.3%)**	**19 (17.6%)**
Using beta blockers	1 (2.3%)	1 (2.2%)	0 (0%)	2 (1.9%)

Harmony TPV CASE - Intracardiac echo

PRE



POST



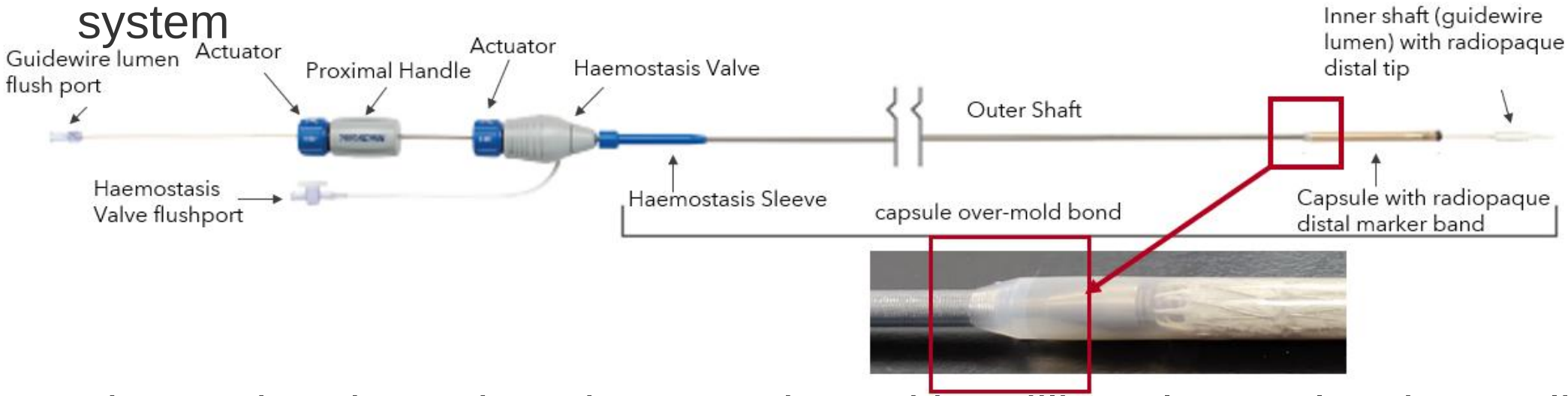
Summary

Harmony TPV recipients in this expanded analysis cohort had favorable clinical and hemodynamic outcomes at 1 year, confirming earlier results and demonstrating continued device success across studies and valve types

- All patients were alive
- 95.1% TPV22 and 89.7% mTPV25 were free from PR, PS, and interventions at 1Y
- ≥ 85% had none/trace PR and ≥ 90% had none/trace PVL at all follow-up visits
- Major stent fracture occurred in 1 EFS patient at 1 month follow-up
- 4 explants: 2 with the discontinued cTPV25 and 2 with the TPV22 in the EFS
- 4 reinterventions: 2 with the discontinued cTPV25 and 2 valve-in-valve procedures (1 with RVOT stent placement) with the mTPV25 in the CAS
- Follow-up will continue through 10 years

Harmony Delivery Catheter Issue

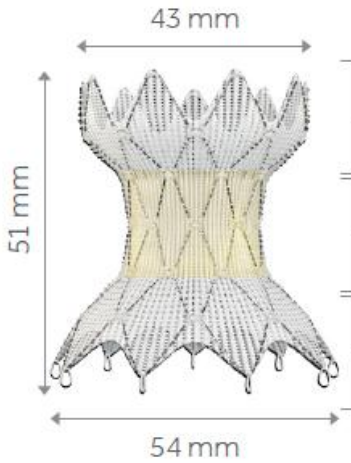
- Medtronic has initiated a voluntary recall of all the Harmony delivery systems following recent occurrences of six capsule separations
- All 6 patients went on to receive a Harmony valve via a new delivery system



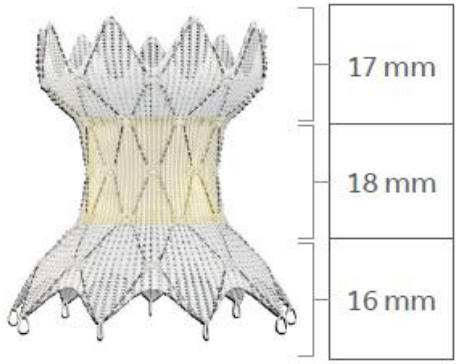
- The Medtronic engineering team is working diligently to solve the quality issue on the delivery system

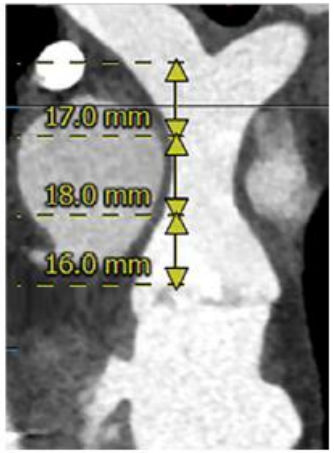
Screening Process

Compare the anatomical size range on the sizing matrix to the patient's anatomy (in relation to each device segment).

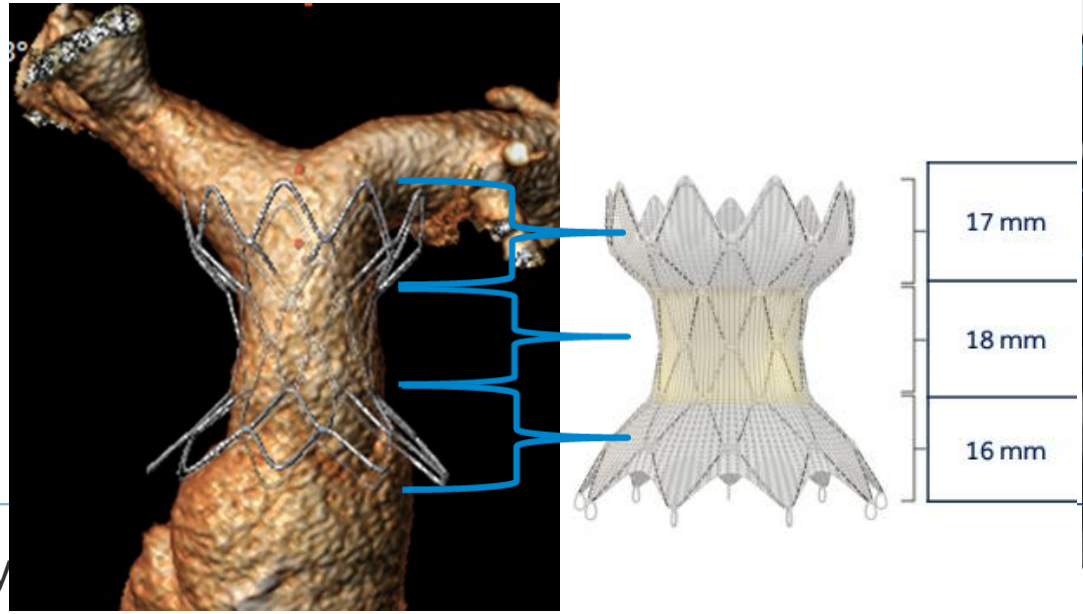


Harmony TPV25 PA Section	Anatomic Size (perimeter-derived diameter)
Outflow — Distal PA/Bifurcation	25–38 mm
Valve Housing	> 25 mm
Inflow — Proximal PA/RVOT	32–48 mm



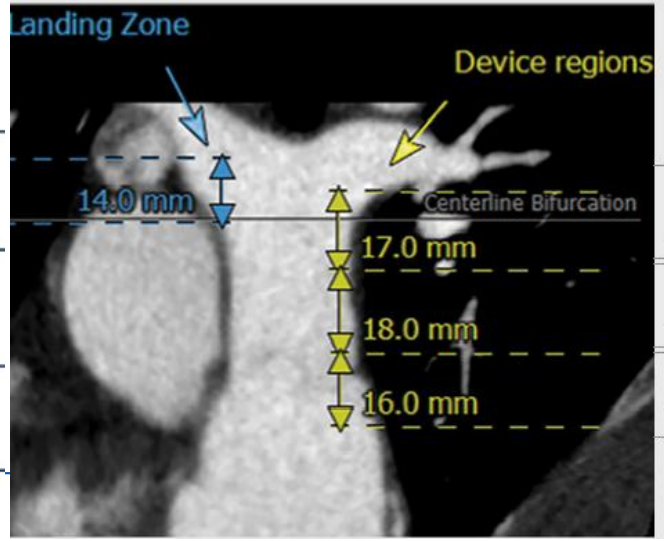


Implant scenarios should be considered starting at the roof of the bifurcation.



courtesy

Confirmation measurements: Regions of the anatomy are identified in relation to the device and compared to the sizing matrix.



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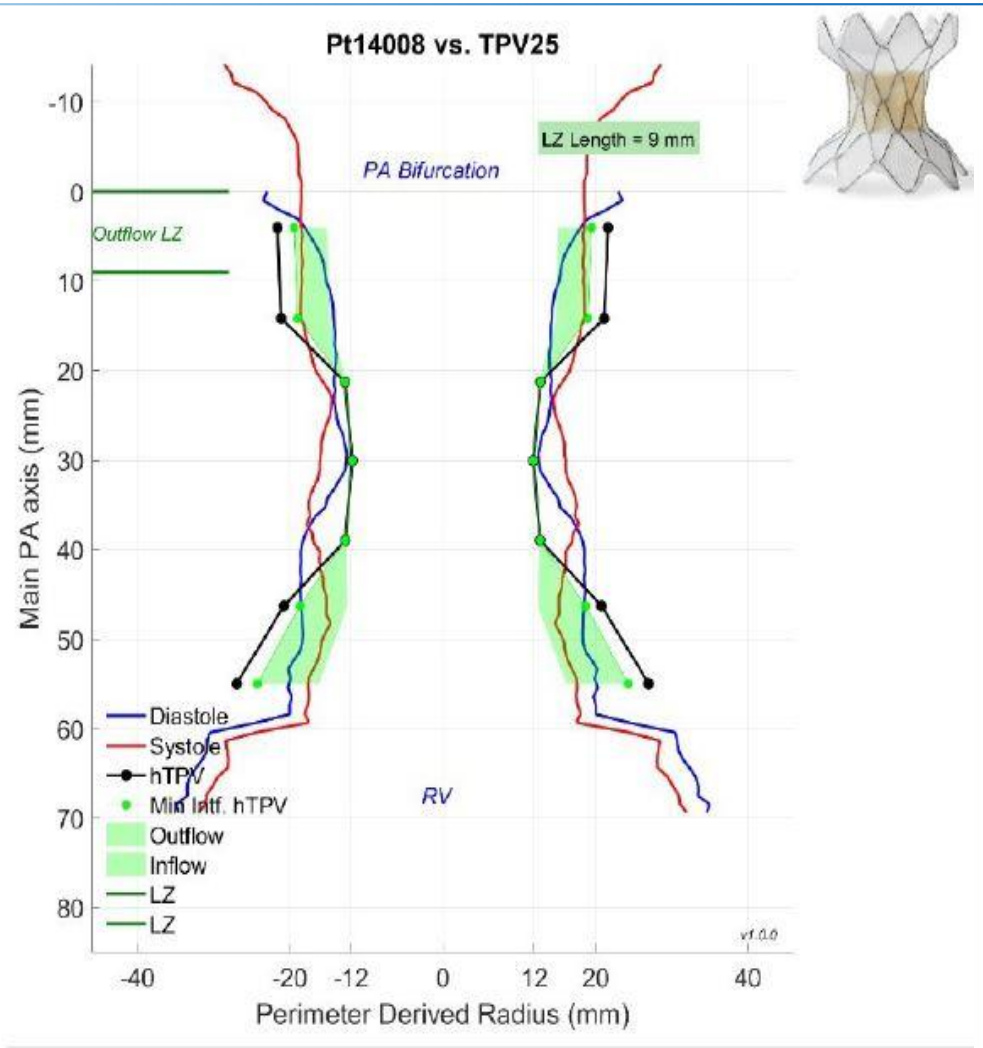
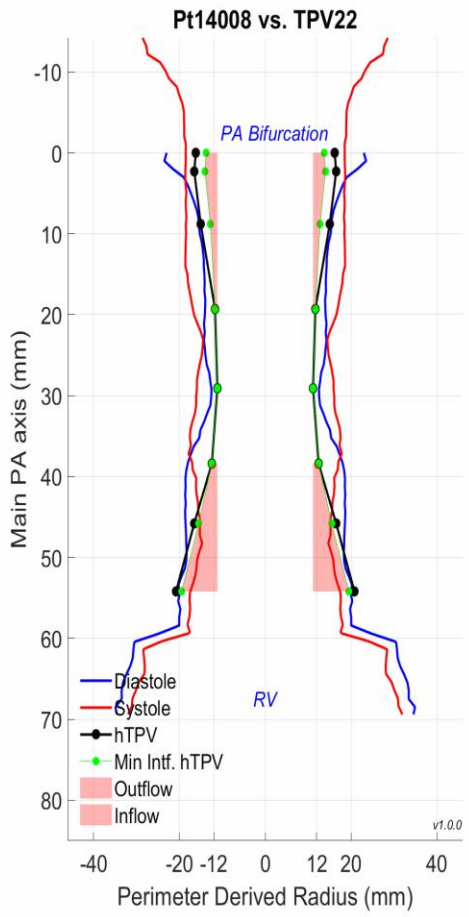
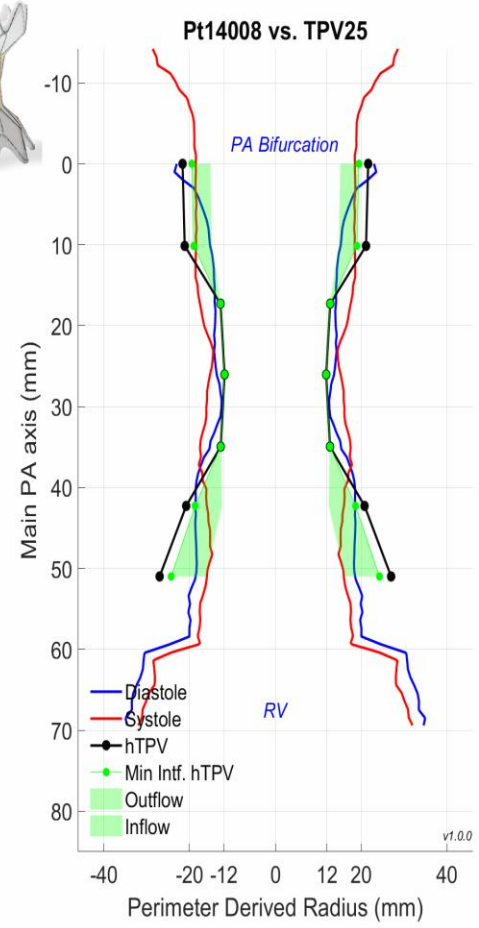
Screening Process



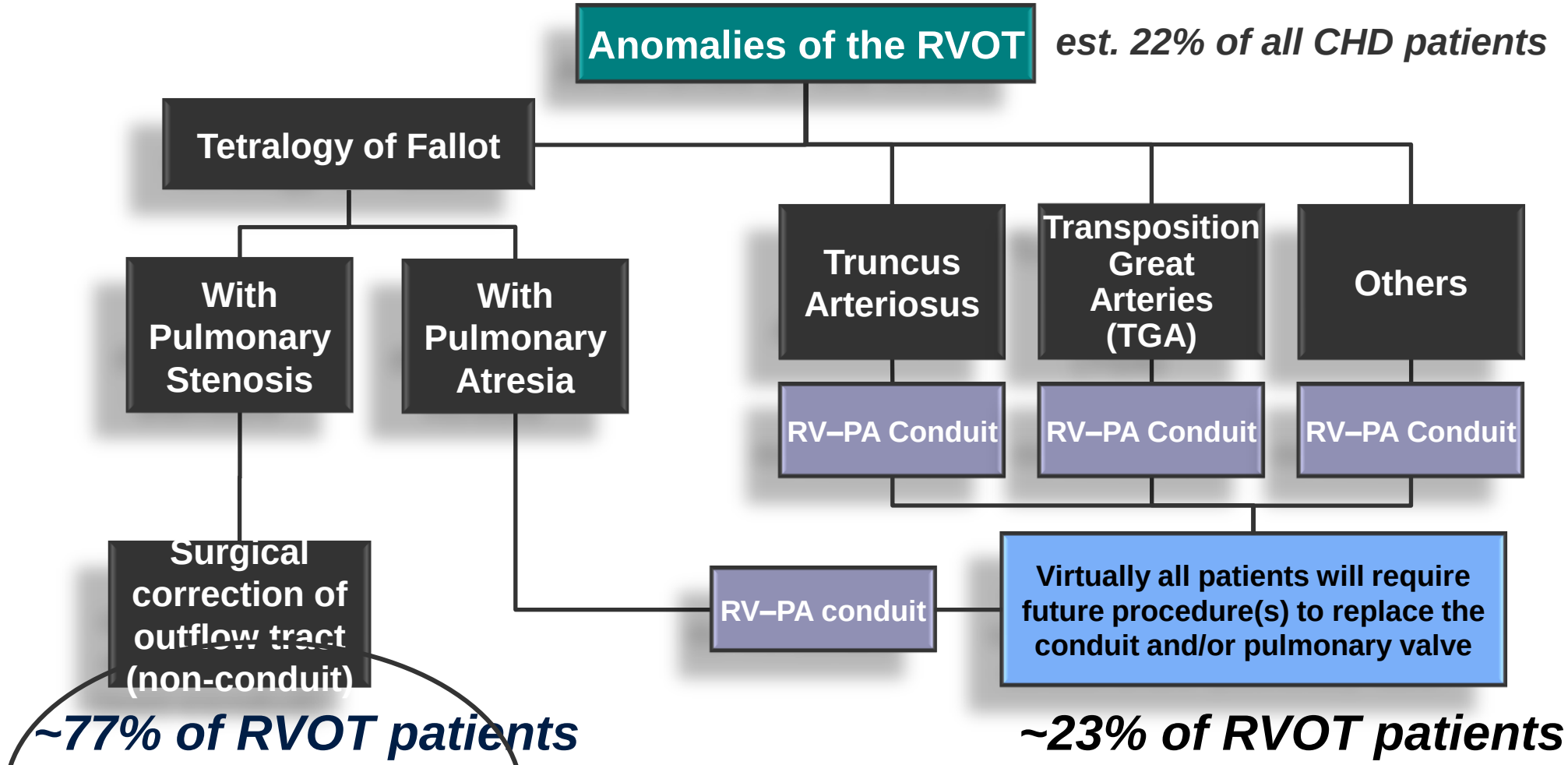




courtesy Lee Benson

Conclusion

- PPVI is one of the most significant advances in the treatment of patients with CHD in the past two decades
- The intervention is safe and effective – coronary compression and conduit rupture need to be avoided
- Both approved percutaneous valves (Melody and Sapien) have excellent immediate results
- Melody is limited to RVOT Diameter < 25mm, Sapien < 31mm
- So far longer follow-up data (patient years) are available for the Melody valve
- Compared to surgical PVR – similar long term results can be expected after PPVI with less morbidity for the patients
- The approval of large self expanding valves enables the treatment of patients with larger RVOT’s


Anomalies of the RVOT
est. 22% of all CHD patients
Tetralogy of Fallot
With Pulmonary Stenosis
With Pulmonary Atresia
Truncus Arteriosus
Transposition Great Arteries (TGA)
Others
RV–PA Conduit
RV–PA Conduit
RV–PA Conduit
Surgical correction of outflow tract (non-conduit)
RV–PA conduit
Virtually all patients will require future procedure(s) to replace the conduit and/or pulmonary valve
~77% of RVOT patients
~23% of RVOT patients

Prospective, non-randomized, multicenter study

12 participating sites in the US, Canada and Japan (Pivotal Trial)
9 US sites for (Continued Access - CAS)

- Primary safety endpoint:
  - freedom from procedure- or device-related mortality at 30 days
- Primary efficacy endpoint
  - percent of subjects at 6 months with composite of mean RVOT gradient ≤40 mm Hg AND PR fraction <20% by CMR or PR <moderate by echo, and no prior Harmony valve interventions

Recommendations for intervention after repair of tetralogy of Fallot

Recommendations	Class[a]	Level[b]
PVRep is recommended in symptomatic patients with severe PR[c] and/or at least moderate RVOTO.[d]	I	C
In patients with no native outflow tract,[e] catheter intervention (TPVI) should be preferred if anatomically feasible.	I	C
PVRep should be considered in asymptomatic patients with severe PR and/or RVOTO when one of the following criteria is present. • Decrease in objective exercise capacity. • Progressive RV dilation to RVESVi ≥80 mL/m^2, and/or RVEDVi ≥160 mL/m^2 [f], and/or progression of TR to at least moderate. • Progressive RV systolic dysfunction. • RVOTO with RVSP >80 mmHg.	IIa	C
VSD closure should be considered in patients with residual VSD and significant LV volume overload or if the patient is undergoing pulmonary valve surgery.	IIa	C
In patients with sustained VT who are undergoing surgical PVRep or transcutaneous valve insertion, pre-operative catheter mapping and transsection of VT-related anatomical isthmuses before or during the intervention should be considered.	IIa	C
Electrophysiologic evaluation, including programmed electrical stimulation, should be considered for risk stratification for SCD in patients with additional risk factors (LV/RV dysfunction; non-sustained, symptomatic VT; QRS duration ≥180 ms, extensive RV scarring on CMR).	IIa	C
ICD implantation should be considered in selected TOF patients with multiple risk factors for SCD, including LV dysfunction, non-sustained, symptomatic VT, QRS duration ≥180 ms, extensive RV scarring on CMR, or inducible VT at programmed electrical stimulation.	IIa	C
Catheter ablation or concomitant surgical ablation for symptomatic monomorphic sustained VT may be considered in those with a preserved biventricular function as an alternative to ICD therapy, provided that the procedure is performed in highly experienced centres and that established ablation endpoints have been reached (e.g. non-inducibility, conduction block across ablation lines).	IIb	C

ESC guidelines ACHD 2020

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