MHIF FEATURED STUDY:

SOLVE-CRT

Stimulation **O**f the **L**eft **V**entricular **E**ndocardium for **C**ardiac **R**esynchronization **T**herapy in Non-Responders, Previously Untreatable and High-risk Upgrade Patients

Coming soon (~Feb. 16)!
EPIC message: *Research MHIF Patient Referral*

CONDITION:
Heart Failure with previously untreatable CRT or High-Risk Upgrades (HRU)*

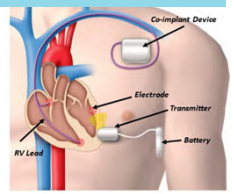
PI:
Jay Sengupta, MD

RESEARCH CONTACT:
Jessie Whelan
Jessica.Whelan@allina.com | 612-863-1661

SPONSOR:
EBR Systems

DESCRIPTION:

Three-part study that will work to demonstrate the safety and effectiveness of the WiSE CRT System. Two-part procedure (first implanting transmitter and battery and then implanting electrode in LV) followed by 5-year follow-up.



CRITERIA LIST/ QUALIFICATIONS:

Inclusion:

- Patient with a class I or IIa indication for implantation of a CRT device and one of the following:
  - CRT non-responder
    - EF remained unchanged or worsened since implant **AND**
    - Patient's clinical status has remained unchanged or worsened
  - Previously untreatable patient because CRT failed or programmed off
  - High-Risk Upgrade
- Patient is on stable Guideline Directed Medical Therapy
- Patient has suitable anatomy for implant
  - Adequate acoustic window, LV wall thickness in implant area >5mm, and absence of LV wall structural abnormalities)

Exclusion: (partial list)

- Pure RBBB
- LVEDD > 8 cm
- Non-ambulatory or unstable NYHA class IV
- Contraindications to heparin, chronic anticoagulants, or antiplatelet agents
- AF patients with RV pacing < 95% and/or have documented AF episode > 30 minutes or cardioversion within last 30 days
- Patients with prosthetic AV and non-viable transeptal approach, or patients with prosthetic MV and non-viable aortic approach for implant

**About 30% of patients have been found to not respond clinically to CRT.*

HOPE DISCOVERED HERE™

Minneapolis Heart Institute Foundation®
Creating a world without heart and vascular disease

Overview of Pulmonary Valve Dysfunction and Indications for Intervention AHCD

B. Kelly Han, MD
Santiago Garcia, MD
Karol Mudy, MD

1

Disclosures

- Grant funding
  - Siemens Healthineers
  - The Jon DeHaan Foundation

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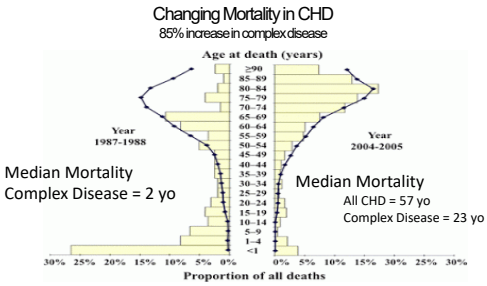
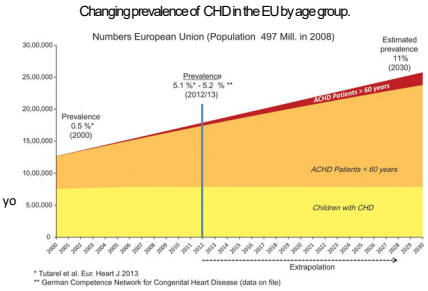
CHD is an Adult Disease





MIDWEST Adult Congenital Cardiac Center

Marelli, et all. Progress in CV diseases 53 (2011) 239-246
Marelli et al. Circulation. 2007;115:163-172
Helmut Baumgartner Eur Heart J 2014;35:683-685
Khairy et al. JACC 2010; 56:1149-1157
Agarwal et al. J Am Heart Assoc 2016;5:e002330

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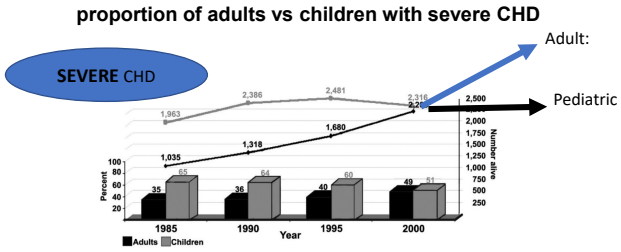
The Changing Prevalence of Complex ACHD



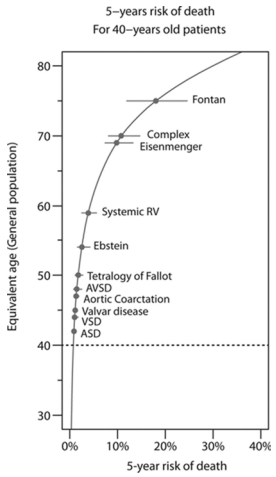
- Greatest survival trend is in severe/complex CHD
- There are now more adults than children with complex CHD
- Complex disease in adulthood increased 85% - 1985-2000
  complex=conduits, TGA (atrial or arterial switch), single V, PA, Truncus, any cyanotic lesion
- Median age of patient with complex disease 2000: 29 yo in

American Heart Association.

Marelli, et all. From Numbers to Guidelines. Progress in CV diseases 53 (2011) 239-246
Marelli et al. Circulation. 2007;115:163-172

4

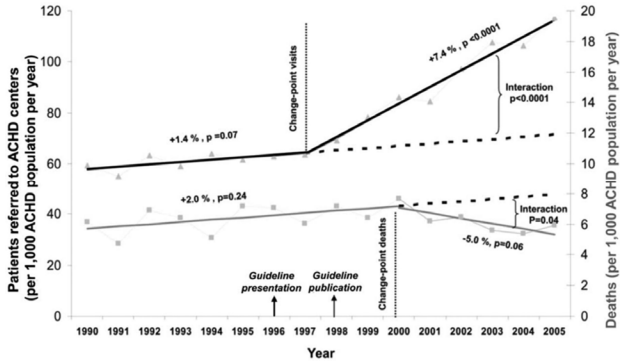
ACHD Mortality by Lesion



Newberger. Trends in CHD Circulation 2016

5

Referral to Specialized ACHD Centers and Mortality.



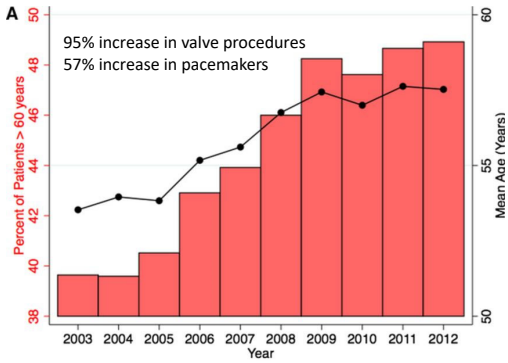
American Heart Association.

Darren Mylotte et al. Circulation. 2014;129:1804-1812

6

Changing ACHD Admission Demographics

% > 60 years of age 2003-2012:



National Inpatient Sample Database (195,306 admissions)

- 100% increase in simple lesion admissions
- 53% increase in complex lesion admissions
- 50% of admissions were Emergency
- Most common admission diagnosis
  - CHF, Valve disease, Stroke
- High percentage of diabetes, PVD, CAD, HTN, smoking, obesity

Shikhar Agarwal et al. J Am Heart Assoc 2016;5:e002330

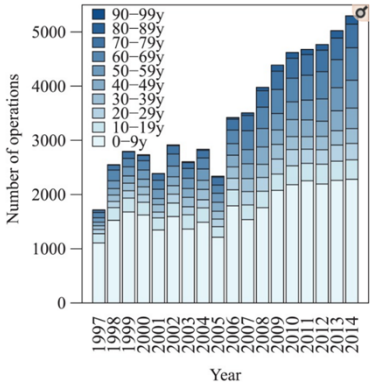
7

Intervention in ACHD

PLoS One. 2017; 12(6): e0178963.
Published online 2017 Jun 19. doi: 10.1371/journal.pone.0178963
PMCID: PMC5476245
PMID: 28628610

Outcome of cardiac surgery in patients with congenital heart disease in England between 1997 and 2015

Aleksander Kempny,[1,*] Konstantinos Dimopoulos,[1] Anselm Uebing,[1] Gerhard-Paul Diller,[1,2] Ulrich Rosendahl,[3] George Bellsitis,[3,4] Michael A. Gatzoulis,[#1] and Stephen J. Wort[#1]



- NHS data England 1997-2014
- 57,293 patients with CHD
- 3X increase in CHD procedures
- Largest increase in ACHD
  - 2x increase in patients < 10 yo
  - 6x increase in patients > 60 yo
- 75% of ACHD intervention is valve related
  - PVR most common

Holst & Dearani et al. ATS 2011 Vol 92 (1)122-130. Risk factors and early outcomes of multiple reoperations in adults with CHD
Kogon et al. ATS. 2013. vol 95(4). 1377-1382. Surgery in adults with CHD, risk factors for morbidity and mortality

8

Pulmonary Valve Dysfunction in CHD

- Surgical PVR as part of initial repair
  - TOF with pulmonary atresia
  - TOF with absent pulmonary valve
  - Rastelli
  - Nikaidoh
  - Truncus arteriosus
  - Ross procedure for AS (more common in children)
- Pulmonary valve dysfunction after initial repair
  - TOF with valvotomy or transannular patch
  - TGA after arterial switch
  - DORV (TOF type or TGA type)
  - L-TGA
  - Pulmonary valvuloplasty for PS
- Risk factors for repeat intervention
  - Young age at initial conduit
  - # previous conduits
  - High PA pressures or distal obstruction

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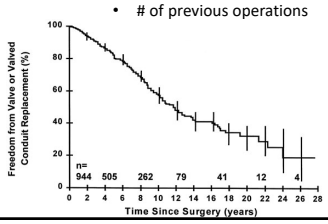
Outcomes for Surgical PVR

- <u>137 Surgical PVR – median age 13</u>
  - Freedom from re-intervention after surgical PVR in children < 20 years of age
    - 89% at 5 years
    - 55% at 10 years
  - Freedom from dysfunction (PI, gradient > 50, endocarditis)
    - 74% at 5 years
    - 32% at 10 years
- <u>945 Survical PVR (Toronto) – median age 6</u>
  - 25 % underwent 2 or more
  - Freedom from repeat PVR
    - 82% at 5 years
    - 58% at 10 years
  - Risk Factors for reintervention
    - Younger age at initial valve placement
    - Smaller valve size
    - Need for endovascular stents
    - # of previous operations

Question is When and How Many



The Midterm Outcomes of Bioprosthetic Pulmonary Valve Replacement in Children. Shinkawa et all, 2015 Seminars in thoracic and cardiac surgery

Outcome of Right Ventricle to Pulmonary Artery Conduit for Biventricular Repair

Takeshi Shinkawa, MD, Carl Chipman, RN, Tom Bozzay, PA, Xinyu Tang, PhD, Jeffrey M. Gossett, MS, and Michiaki Imamura, MD, PhD

Ann Thorac Surg 2015;99:1357–66)

Caldarone et al. JTCVS 2000.Volume 120 (6) 1022–1031.

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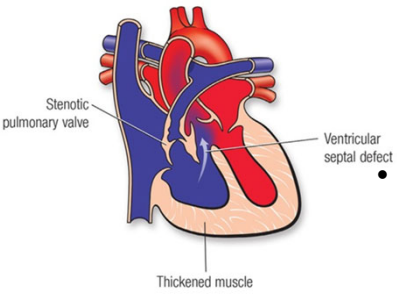
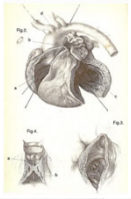
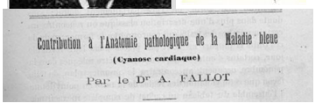
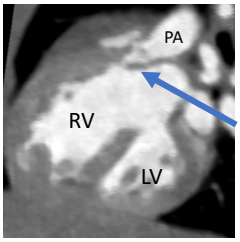
Tetralogy of Fallot









- First description
  - 1671 *Dissection of a monstrous foetus in Paris* 1671. Dr. Niels Stensen
  - 1777 "*The blue boy*" – autopsy of a 16 month old, Dr Eduard Sandiford
  - 1888 Etienne Louis Arthur Fallot: "*La maladie bleue*"
    - Described TOF as primarily an anomaly of the subpulmonary infindibulim/conus
  - 1924: Maude Abbott labeled "tetralogy of Fallot"
- VSD + variable RVOT Obstruction
- One of the most common CHD lesions
  - 3-6/1000 births
  - 8-10% of CHD
  - Most common cyanotic CHD lesion
- 95% mortality by age 40 untreated
- PS determines presentation and clinical course

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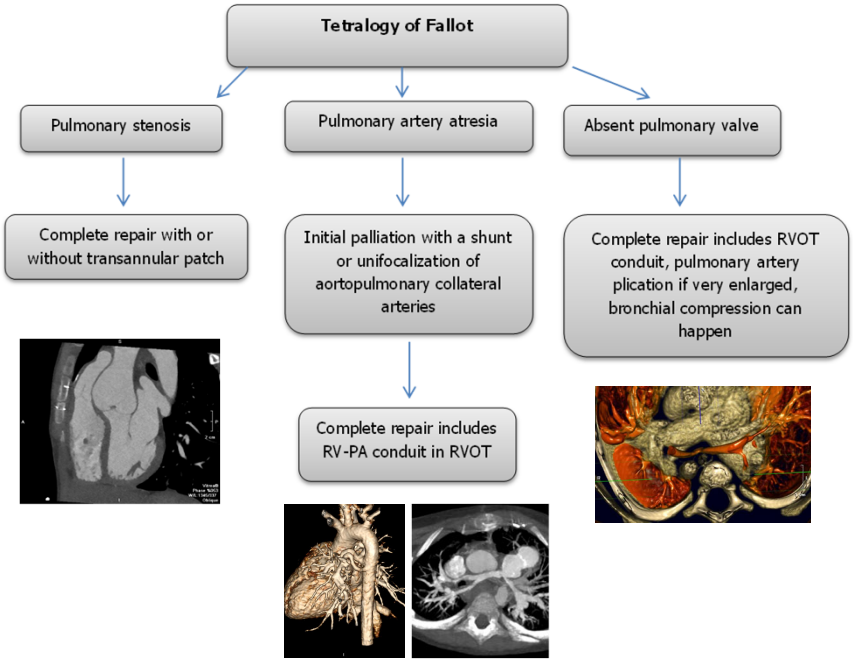

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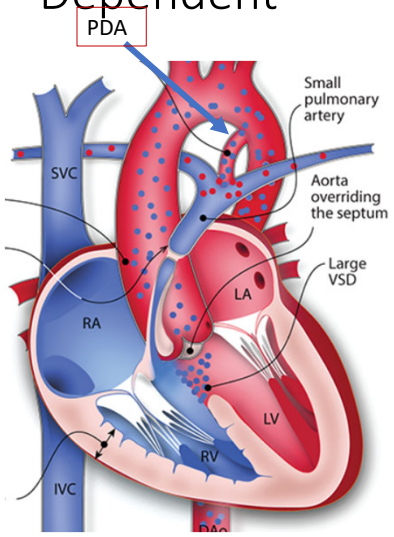
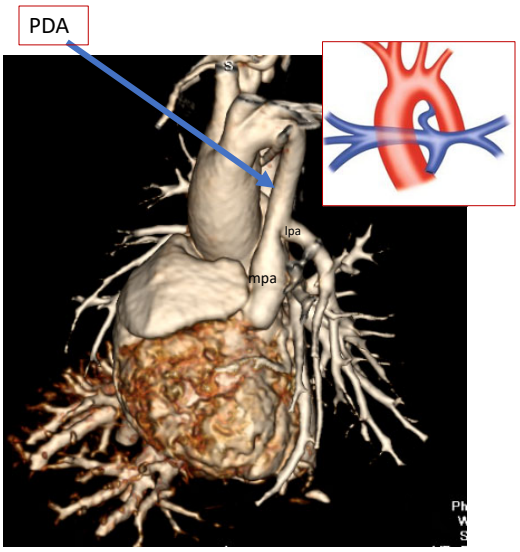
TOF with Severe PS/PA – Ductal Dependent





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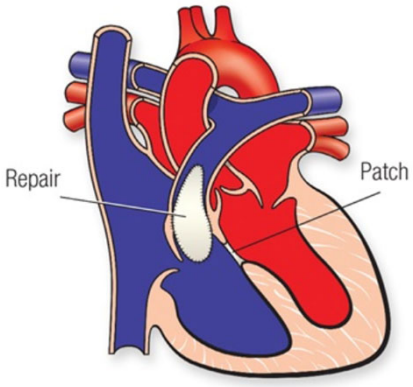
Tetralogy of Fallot Repair



Direct Vision Intracardiac Surgical Correction of the Tetralogy of Fallot, Pentalogy of Fallot, and Pulmonary Atresia Defects
Report of First Ten Cases*

C. Walton Lillehei, M.D., Morley Cohen, M.D., Herbert E. Warden, M.D., Raymond C. Read, M.D., Joseph B. Aust, M.D., Richard A. DeWall, M.D., and Richard L. Varco, M.D.

Minneapolis, Minn.

From the Department of Surgery, University of Minnesota Medical School, Minneapolis

Ann Surg. 1955 Sep; 142(3): 418–442.

- Close the VSD
- Relieve RVOT obstruction
  - Pulmonary valvotomy/commisurotomy
  - RV muscle bundle resection
  - Valve sparing patch
  - Transannular patch
  - RV-PA conduit
- Most severe forms
  - Palliative procedure before repair
    - Unifocalization of collaterals
    - Aortopulmonary shunt

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Tetralogy of Fallot: Residual Hemodynamic Lesions

TOF with Pulmonary stenosis	pulmonary stenosis, pulmonary insufficiency, RV dilation and dysfunction, aortic root dilation
TOF with Pulmonary artery atresia	RV-PA conduit, branch pulmonary artery or distal pulmonary artery stenosis, conduit insufficiency, RV dilation and dysfunction, aortic root dilation
TOF with Absent pulmonary valve	RV-PA conduit stenosis or insufficiency, airway abnormalities, pulmonary artery dilation

PVR most common re-intervention
- Pediatric patients – primarily have homograft placed
- Adults – primarily have stented bioprosthetic valve placed

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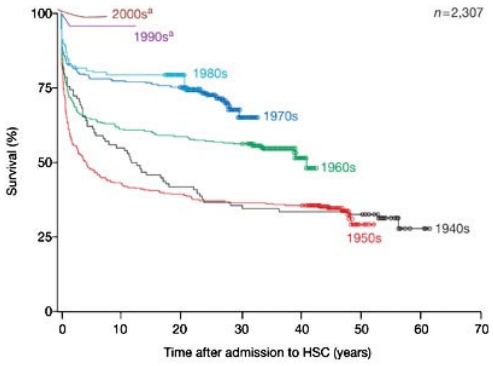
TOF Surgical Survival by Decade

98 % surgical survival in the current era
Size of pulmonary arteries correlates to morbidity and rate of intervention



Surgery Insight: late complications following repair of tetralogy of Fallot and related surgical strategies for management
Tara Karamlou, Brian W McCrindle and William G Williams* doi:10.1038/ncpcardio0682

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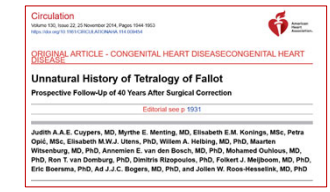
Circulation

ORIGINAL ARTICLE - CONGENITAL HEART DISEASECONGENITAL HEART DISEASE

Unnatural History of Tetralogy of Fallot

Prospective Follow-Up of 40 Years After Surgical Correction

Editorial see p 1931

Judith A.A.E. Cuypers, MD, Myrthe E. Menting, MD, Elisabeth E.M. Konings, MSc, Petra Opić, MSc, Elisabeth M.W.J. Utens, PhD, Willem A. Helbing, MD, PhD, Maarten Witsenburg, MD, PhD, Annemien E. van den Bosch, MD, PhD, Mohamed Ouhlous, MD, PhD, Ron T. van Domburg, PhD, Dimitris Rizopoulos, PhD, Folkert J. Meijboom, MD, PhD, Eric Boersma, PhD, Ad J.J.C. Bogers, MD, PhD, and Jolien W. Roos-Hesselink, MD, PhD

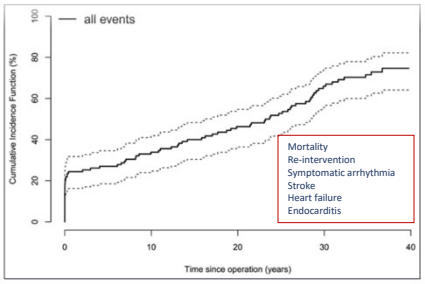

Figure 2. Cumulative incidence of all events.

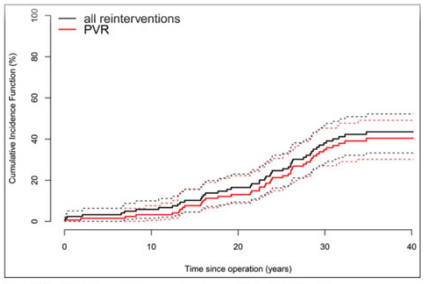

Figure 3. Cumulative incidences of pulmonary valve replacement (PVR) and all reinterventions.

- For hospital survivors, 85% survival after 40 years of followup
- Event free survival 25% 40 years post repair
- RV function abnormal in 75%, LV function abnormal in 50%

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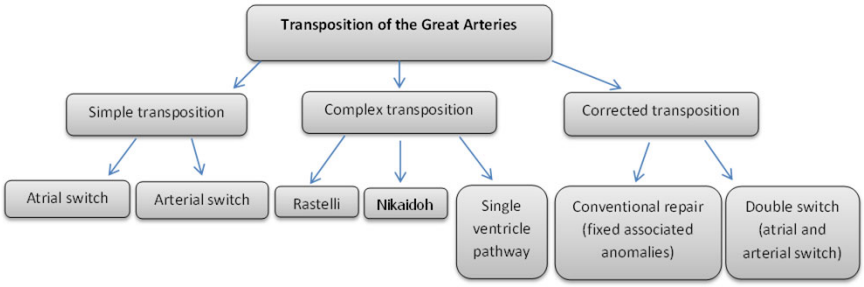

Procedure	Residual Hemodynamic Abnormalities
Atrial switch	Systemic or pulmonary venous baffle narrowing or occlusion
	RV failure (systemic ventricle)
	Tricuspid regurgitation (quantify by stroke volume differences)
Arterial switch	Neo-pulmonary root or branch pulmonary artery stenosis, pulmonary insufficiency
	Neo-aortic root dilation, stenosis or insufficiency
	Compromise of re-implanted coronary arteries
Rastelli	Obstruction of the RV-PA conduit or branch pulmonary arteries, pulmonary insufficiency
	Obstruction of LV-Aortic pathway in the area of VSD patch
Nikaidoh	Native RVOT or RVOT conduit stenosis or insufficiency
	Right coronary artery compromise due to translocation of the aorta leftward

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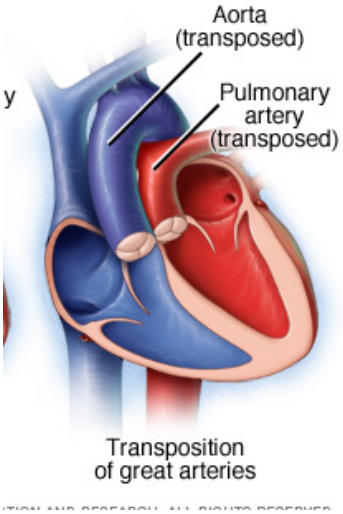
Simple Transposition (VA discordance)

Usually presents at birth: cyanosis



American Heart Association/Heart.org
CHD.gov

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d-TGA

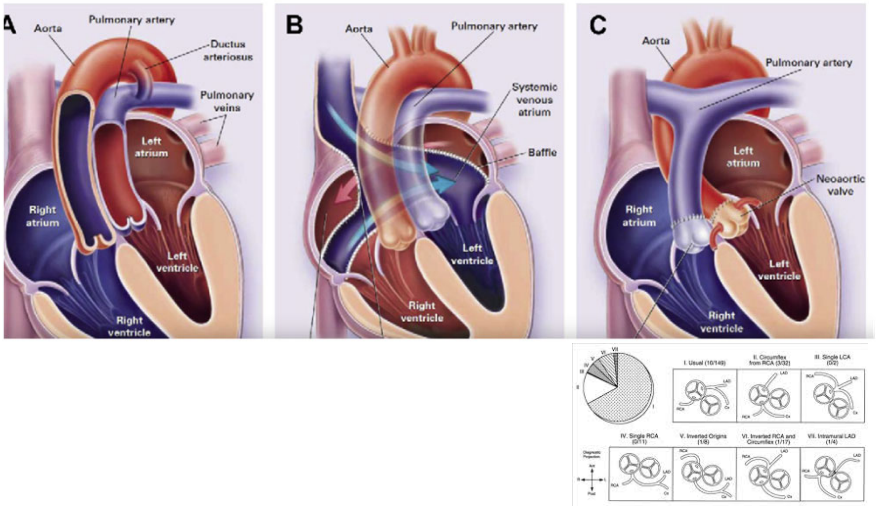
Atrial ventricular concordance
Ventricular-Arterial discordance

Atrial Switch

Atrial ventricular discordance
Ventricular-Arterial discordance

Arterial Switch

Atrial ventricular Concordance
Ventricular-Arterial concordance



Cardiology Clinics 2015 DOI:10.1016/j.ccl.2015.07.012

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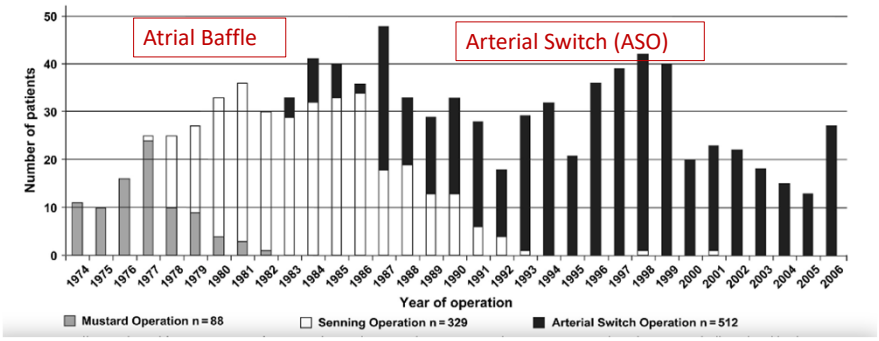
Operation for d-TGA by year



Emergence of the arterial switch procedure for transposition of the great arteries and the potential cost of surgical innovation

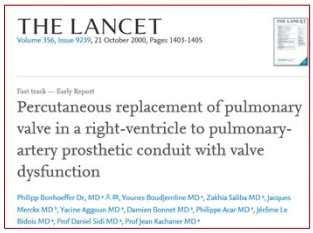
J Thorac Cardiovasc Surg 2017;154:1047-51
0022

Craig S. Broberg, MD, MCR,[a] Irving Shen, MD,[b] Victor Menashe, MD,[c] and Albert Starr, MD[a]

21

Pulmonary Valve Replacement
Most common Adult CHD procedure

- Surgical
- Percutaneous PVR
  - Melody since 2000
    - 20, 22 mm most commonly used
    - Bovine jugular valve
    - In previously placed conduits
    - In native RVOT (pre-stent)
  - Sapien since 2005
    - 23 and 26 mm valves most commonly used
    - Bovine pericardial valve
    - Compassion trial
    - Initial reports of tricuspid valve injury
    - Newer delivery system has been developed
    - Native RVOT (pre-stent)
- Current State:
  - 2/3 PVR surgical
  - 1/3 percutaneous
- Limitations
  - Need for other CHD surgery
  - Large RVOT (Alterra/Harmony)
  - Coronary Compression Concerns


THE LANCET
Volume 356, Issue 9239, 21 October 2000, Pages 1403-1405

Fast track — Early Report

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

Philipp Bonhoeffer Dr, MD [a, B, ¶], Younes Boudjemline MD [c], Zakhia Saliba MD [c], Jacques Mercke MD [c], Yacine Aggoun MD [c], Damien Bonnet MD [c], Philippe Acar MD [a], Jérôme Le Bidois MD [c], Prof Daniel Sidi MD [c], Prof Jean Kachaner MD [a]

J Cardiol. 2019 Sep;74(3):217-222. doi: 10.1016/j.jjcc.2019.03.021. Epub 2019 Jun 21.
The standing of percutaneous pulmonary valve implantation compared to surgery in a non-preselected cohort with dysfunctional right ventricular outflow tract - Reasons for failure and contraindications.

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Indications for PVR in ACHD TOF

	ESC 2010	CCS 2010	Circ 2013 (128:1855-7)	AHA/ACC 2018
RVEDV (ml/m2)	> 160	> 170	> 140-150	> 160
RVESV (ml/m2)			> 80	> 80
RV dysfunction	Progressive	> moderate	RV EF < 47%	> Mild RV dysfunction
PS	PG > 80 mmHg	RVp/systemic > 2/3	RVp/systemic > 2/3	RVp/systemic > 2/3
PI	severe	free	> Moderate (> 25%)	> Moderate
QRS duration	> 180 msec		> 140 msec	
Arrhythmia	Sustained AT/VT	AT or VT	Sustained arrhythmia	Sustained arrhythmia
CPET	Decreased		< 60% predicted	Progressive reduction

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Inclusion criteria for clinical trials with both the Melody® and SAPIEN™ valves.

Melody® [16]	SAPIEN™ [14]
Age ≥ 5 years/weight ≥ 30 kg	Weight > 35 kg
Original Conduit diameter ≥ 16 mm	In situ conduit ≥ 16 mm and ≤ 24 mm
Echocardiographic RVOT conduit dysfunction	≥ +3 PR (TTE) or PRF > 40% (MRI)
• Patints classified as NYHA class II, III, or IV: Doppler mean gradient ≥ 35 mmHg or ≥ moderate PR	With or without stenosis
• Patients classified as NYHA class I: Doppler mean gradient ≥ 40 mmHg or severe PR associated with TV annulus z-score ≥ 2 or RVEF ≤ 40%	

Hijazi PPVI 2015

Box 1. Indications for surgical valve replacement in the right ventricular outflow tract.

- The following situations may warrant intervention following repair [4]:
  - Free PR associated with:
    - Progressive or moderate to severe RV enlargement (RV end diastolic volume of greater than 170 ml/m²)
    - Moderate to severe RV dysfunction
    - Important tricuspid regurgitation
    - Atrial or ventricular arrhythmias
    - Symptoms such as deteriorating exercise performance
- European Society of Cardiology guidelines [13]:
  - PVR should be performed in symptomatic patients with severe PR and/or stenosis (RV systolic pressure >60 mmHg, TR velocity >3.5 m/s)
  - PVR should be considered in asymptomatic patients with severe PR and/or PS when at least one of the following criteria is present:
    - Decrease in objective exercise capacity
    - Progressive RV dilation
    - Progressive RV systolic dysfunction
    - Progressive TR (at least moderate)
    - RVOT with RV systolic pressure >80 mmHg (TR velocity >4.3 m/s)
    - Sustained atrial/ventricular arrhythmias

PR: Pulmonary regurgitation; PS: Pulmonary stenosis; PVR: Pulmonary valve replacement; RV: Right ventricular; RVOT: Right ventricular outflow tract; TR: Tricuspid regurgitation

Percutaneous pulmonary valve implantation: the Munich experience

Interv. Cardiol. (2012) **4**(2), 193–201

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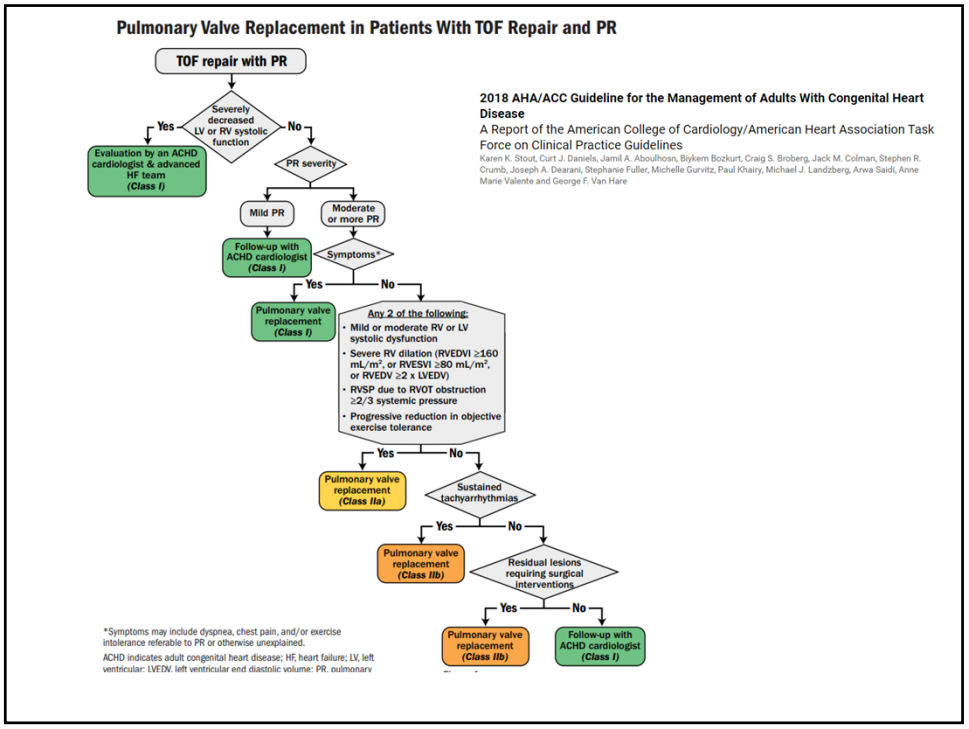

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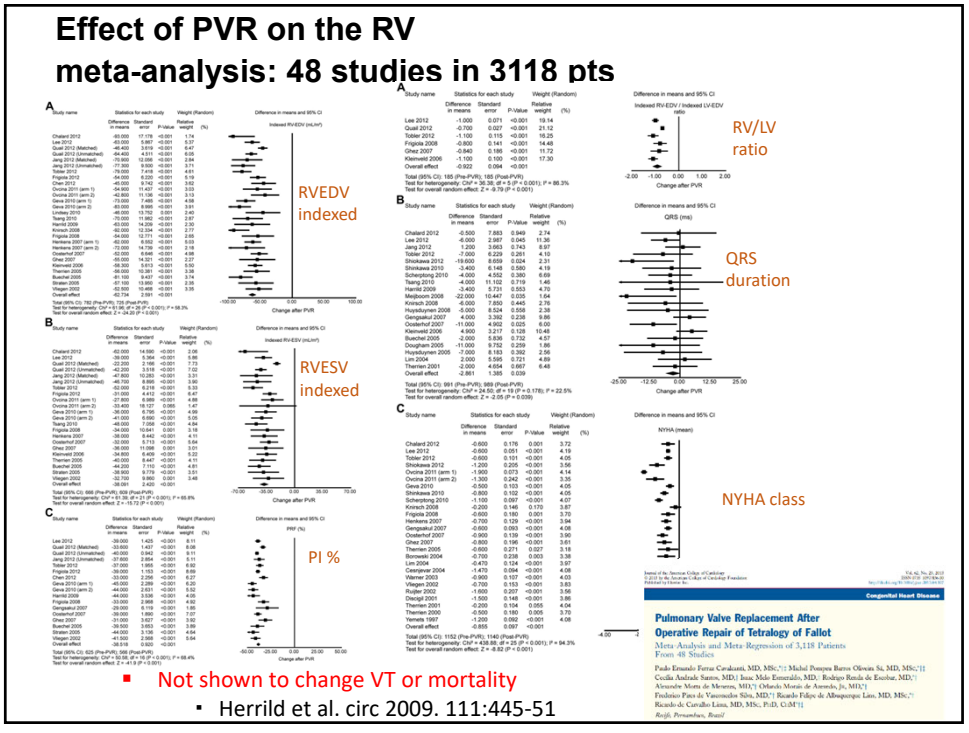


- Not shown to change VT or mortality
  - Herrild et al. circ 2009. 111:445-51

26

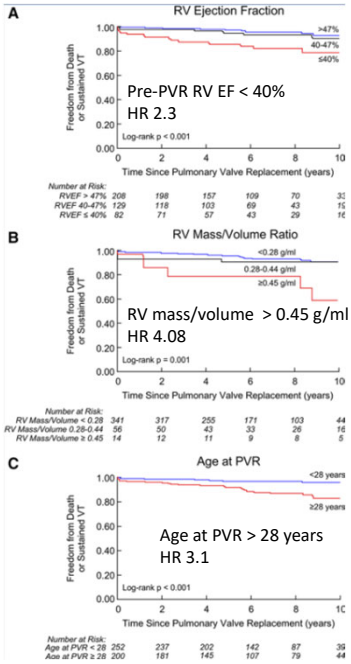
Circulation *Valente* 2018;138:2106–2115.

Indicator database of 1418 patients, 788 had PVR

ORIGINAL RESEARCH ARTICLE

Preoperative Predictors of Death and Sustained Ventricular Tachycardia After Pulmonary Valve Replacement in Patients With Repaired Tetralogy of Fallot Enrolled in the INDICATOR Cohort

- 452 patients: median age at PVR 25 yrs
  - Surgical bioprosthetic valve 66%
  - Surgical homograft 19%
  - Percutaneous PVR 15%
- Median followup 6.5 years
  - Primary outcome 8%: death/resuscitated SD/sustained VT
    - pre RV EF, RV mass or mass/volume ratio, age
    - echo TR> 40 mmHg
  - Secondary Outcome 9%: Atrial arrhythmias and heart failure
    - Older age at PVR, pre-PVR atrial arrhythmias and higher LVESVi
- Pre-PVR atrial arrhythmia: RR 2.6
- BMI > 30: RR 2.3
- Chromosomal Abnormality: RR 2.5
- TOF/PA: RR 1.7
- Imaging:
  - MRI: RVEDV and PI NOT ASSOCIATED WITH OUTCOME
  - Echo: RVp > 40 mmHg 4.4
  - Moderate or severe TR 2.39



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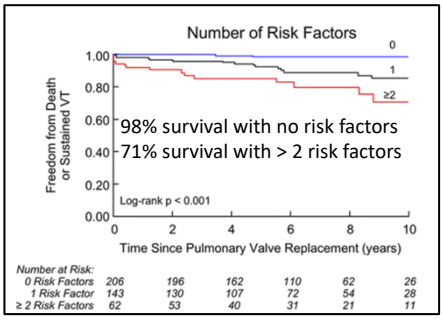
Combined outcomes

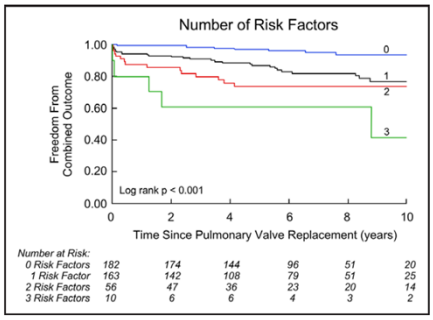
Primary Outcome (death/RSD/VT)

Age at PVR > 28 years
RV EF < 40
RV mass/volume ratio > 45 g/ml

Primary/Secondary Outcome (arrhythmia/CHF)

Age at PVR > 28 years
RV mass/Volume ratio > 28 g/ml
LVESVi > 48 ml/m2
Pre -PVR atrial flutter or fibrillation





28

Imaging for Percutaneous PVR

- Recommendations are for PI and PS, many have mixed PVR dysfunction
- Multi-modality assessment is essential for complete evaluation
  - PS gradient
  - PI
  - TR degree and estimate of RV pressure
  - RV size (high BMI – index to height)
  - RV systolic function
  - LV systolic function
  - RVOT anatomy including pulmonary valve/conduit and branch PA
  - Coronary assessment: relationship to sternum, RVOT, CAD
  - For PA/IVS: RA/IVC size
- Both MRI and CT can quantify RV volumes
  - Stroke volume differences for PI
  - MRI and CT have been shown to be equivalent for EF

29

CT Quantification of Shunts

- Only can measure stroke volume difference
  - Need correlation with echo to determine if concomitant valve regurgitation
- Functional datasets
  - Effect of shunt: Functional analysis for ventricular volumes and function
  - Quantification of shunt: Stroke volume differences can estimate shunt

Correlation: RV SV and MPA flow: overestimate 0.26 l/min - median 8.5 l/min
Correlation: LV SV and AO flow: underestimate 0.16 l/min - median 4.9 l/min

Evaluation of atrial septal defects with 4D flow MRI—multilevel and inter-reader reproducibility for quantification of shunt severity

Raluca G. Chelu[1,2] · Michael Horowitz[3] · Dominica Sucha[4] · Isabella Kardys[5] · Delphine Ingremeau[6] · Shreyas Vasanawala[7] · Koen Nieman[1,2,7,8] · Jean-Francois Paul[6] · Albert Hsiao[9]

Received: 7 March 2018 / Revised: 10 August 2018 / Accepted: 16 August 2018

Level of measurement	Flow (l/min) median (min–max)	Spearman's rho[R]	Bland–Altman	
			Bias	± 1.96 SD
Pulmonic flow				
Pulmonary valve	8.6 (3.2–20.3)	0.886	0.148	− 0.86 to 1.16
Main pulmonary artery	8.5 (4.4–20.2)	–	–	–
Right + left pulmonary arteries	8.7 (4.4–19.9)	0.885	0.266	− 1.12 to 1.65
Right ventricular stroke volume[b]	9.0 (4.6–20.0)	0.972	− 0.257	− 2.01 to 1.49
Systemic flow				
Aortic valve	5.2 (2.9–10.0)	0.991	0.135	− 1.23 to 1.5
Ascending aorta	4.9 (2.7–10.7)	–	–	–
SVC[c] + descending aorta	4.7 (2.9–10.5)	0.974	0.169	− 1.6 to 1.94
Left ventricular stroke volume[b]	4.8 (3.0–8.2)	0.906	0.157	− 2.45 to 2.1

30

CT and MRI Equivalent for EF Estimation

- Usefulness of multidetector row computed tomography to quantify right ventricular size and function in adults with either tetralogy of Fallot or transposition of the great arteries.
  - Raman, AJC 2005. Vol 95 (5) 683-6
- Multi-detector row cardiac computed tomography accurately quantifies right and left ventricular size and function compared with cardiac magnetic resonance.
  - Am Heart J . 2006. 151(3) 736-44
- Meta-analysis of global left ventricular function comparing multidetector computed tomography with cardiac magnetic resonance imaging.
  - Sharma et al, 2014. AJC. 113 (4). 731-8.
- Quantification of left and right ventricular function and myocardial mass: comparison of low-radiation dose 2nd generation dual-source CT and cardiac MRI.
  - Takx et al. Eur J Radiol. 2012 (4) 598-
- Assessment of right ventricular function with 320-slice volume cardiac CT: comparison with cardiac magnetic resonance imaging.
  - Huang et al. Int J Cardiovasc Imaging 2012. 28 supp 2. 87-92

31

Coronary Anatomy and Percutaneous Valve

- 404 pts (2007-2012)
- 85% had valve implantation
- 5% had evidence of CA compression on test balloon angioplasty
- 17% had abnormal coronary artery anatomy
- 71% with CA compression had abnormal CA anatomy

Circulation: Cardiovascular Interventions
Volume 6, Issue 5, October 2013, Pages 535-542
https://doi.org/10.1161/CIRCINTERVENTIONS.113.000202

ORIGINAL ARTICLE - TRANSCATHETER AORTIC VALVE REPLACEMENTTRANSCATHETER AORTIC VALVE REPLACEMENT

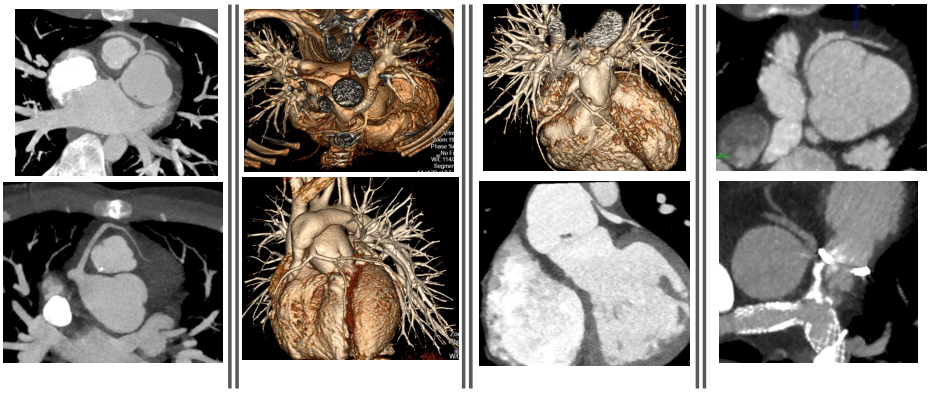
Risk of Coronary Artery Compression Among Patients Referred for Transcatheter Pulmonary Valve Implantation

A Multicenter Experience

Brian H. Morray, MD, Doff B. McElhinney, MD, John P. Cheatham, MD, Evan M. Zahn, MD, Darren P. Berman, MD, Patrick M. Sullivan, MD, James E. Lock, MD, and Thomas K. Jones, MD

Age at catheterization, y	18 (3–73)
Diagnosis	
Tetralogy of Fallot	226 (56%)
Pulmonary stenosis	130 (32%)
Pulmonary atresia	84 (21%)
Atrioventricular canal defect	3 (1%)
Absent pulmonary valve	9 (2%)
Transposition of the great arteries	37 (9%)
Truncus arteriosus	46 (11%)
Double-outlet right ventricle	22 (6%)
Aortic valve disease, before Ross procedure	51 (13%)
Pulmonary atresia with intact ventricular septum	7 (2%)
Valvar pulmonary stenosis	7 (2%)
Other	7 (2%)
Type of conduit	
Homograft	262 (65%)
Bioprosthetic valve or conduit	93 (23%)
Native right ventricular outflow tract	28 (7%)
Synthetic	14 (3%)
Unknown	7 (2%)
Conduit diameter at the time of surgical implantation, mm	20 (9–29)

32



Coronary Assessment Prior to PVR
Relationship to RVOT/AO/Sternum/Branch PA

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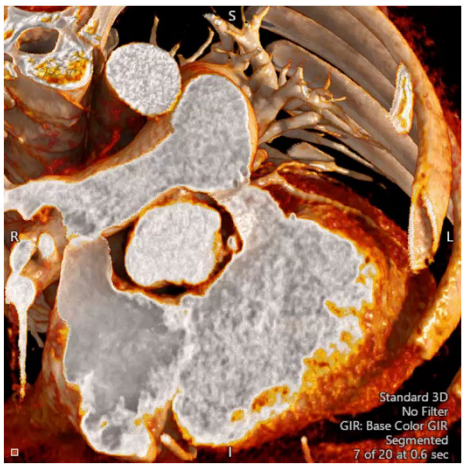
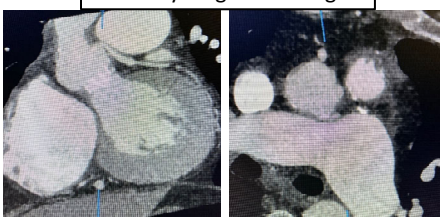
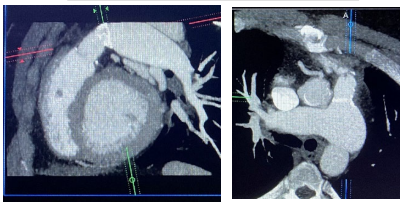
Previous Conduit



Coronary Origin and Height



Calcification and Branch PA



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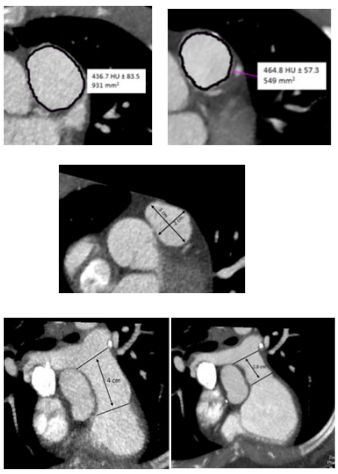
The need for 4D imaging
Dynamism of the Native RVOT

	n = 19
Circumferential Pulsatility	
Maximum area (mm2)	636 (530, 791)
Minimal area (mm2)	462 (410, 622)
Max phase % difference*	26% (20%, 32%)
Eccentricity of Annulus	
Minor axis (cm)	2.38 (2.05, 2.56)
Major Axis (cm)	2.81 (2.55, 3.58)
Major/Minor Axis Ratio	1.23 (1.09, 1.46)
Longitudinal Shortening of MPA	
Max phase MPA length (annulus to PA) (cm)	3.78 (3.20, 4.45)
Min phase MPA length (annulus to PA)(cm)	3.10 (2.20, 3.50)
MPA minimal Phase	45 (40, 80)
Major Axis (cm)	3.10 (2.44, 3.70)
Minor Axis (cm)	2.27 (1.80, 2.90)
MPA Variability†	28.1% (6.2%, 41.7%)



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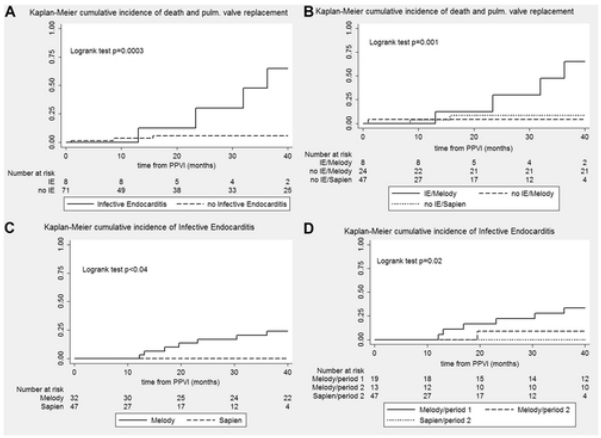
Infective Endocarditis Risk After Percutaneous Pulmonary Valve Implantation With the Melody and Sapien Valves

JACC 2017

Sebastien Hascoet, MD,* Lucia Mauri, MD,* Caroline Claude, MD,* Emmanuelle Fournier, MD,* Julie Lourtet, MD,† Jean-Yves Riou, MD,‡ Philippe Brenot, MD,‡ Jérôme Petit, MD*



Diagnostic Value of Contrast-Enhanced Multiphase Computed Tomography for Assessment of Percutaneous Pulmonary Valve Obstruction

B. Kelly Han, MD, Francis X. Moga, MD, David Overman, MD, Christopher Carter, MD, and John R. Lesser, MD

(Ann Thorac Surg 2016;101:e115–6)

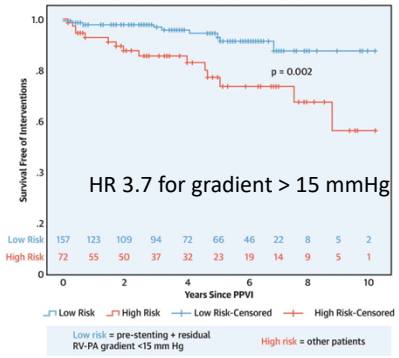
Sebastien Hascoet et al. *J Am Coll Cardiol Cardiovasc Interv* 2017; 10:510-517.

36

A Low Residual Pressure Gradient Yields Excellent Long-Term Outcome After Percutaneous Pulmonary Valve Implantation

Stanimir Georgiev, MD,[a] Peter Ewert, PhD,[a] Daniel Tanase, MD,[a] John Hess, PhD,[a] Alfred Hager, PhD,[a] Julie Cleuziou, PhD,[b] Christian Meierhofer, MD,[a] Andreas Eicken, PhD[a]

CENTRAL ILLUSTRATION: Better Survival After Percutaneous Pulmonary Valve Implantation With Pre-Stenting and Residual Right Ventricular-Pulmonary Artery Gradient <15 mm Hg



Georgiev, S. et al. J Am Coll Cardiol Intv. 2019;12(16):1594-603.

236 patients

Median age 18 (4-78)

Diagnosis:

- TOF 50%
- Truncus 17%
- TGA/Rastelli 11%
- Ross operation 8.1 %

Indication

- PS 42%
- PI 16%
- Mixed 42%

Valves

- Melody 93%
- Sapien 7%

Followup

- Median 3.9 years
- Range 2 months to 11 years

10 years post intervention:

- Survival 93%
- Surgery free survival 83%
- Intervention free survival 73%

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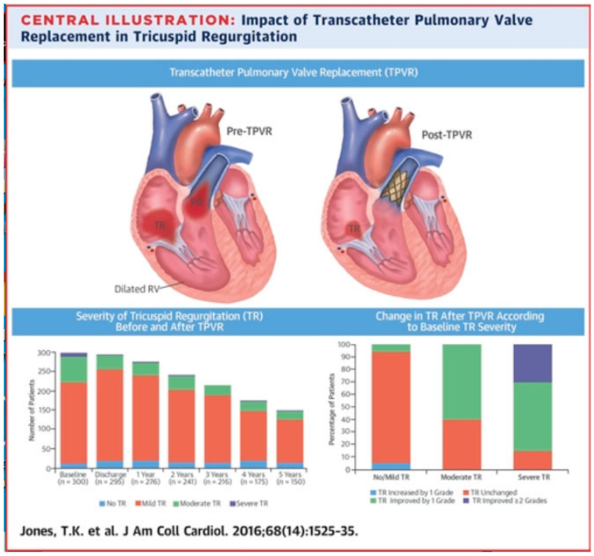
Transcatheter Pulmonary Valve Replacement Reduces Tricuspid Regurgitation in Patients With Right Ventricular Volume/Pressure Overload

Thomas K. Jones, MD,[a] Jonathan J. Rome, MD,[b] Aimee K. Armstrong, MD,[a] Felix Berger, MD,[a] William E. Hellenbrand, MD,[a] Allison K. Cabalka, MD,[c] Lee N. Benson, MD,[b] David T. Balzer, MD,[b] John P. Cheatham, MD,[a] Andreas Eicken, MD,[d] Doff B. McElhinney, MD[a]

CENTRAL ILLUSTRATION: Impact of Transcatheter Pulmonary Valve Replacement in Tricuspid Regurgitation



Jones, T.K. et al. J Am Coll Cardiol. 2016;68(14):1525-35.

38

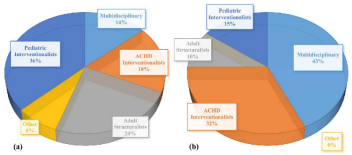
Imaging and indications for PVR

- Current criteria predict RV recovery
- Current criteria do not predict VT, death, CHF
- Many patients have mixed valve dysfunction
  - May not meet "strict" criteria for PI/PS
- With high BMI, index to height
- Heart team concept applies to PVR intervention
  - Interventionalist
  - Imager
  - ACHD cardiologist
  - Surgeon
- We have a lot to learn about planning PVR intervention

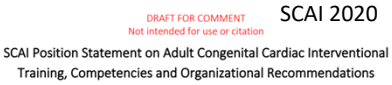
39

Intervention in ACHD

- Procedural Mix and Volumes
  - Congenital cases
  - TAVR
  - Mitraclip
  - Perivalvular leak closure
  - Radial artery access
  - Coronary angiography (40 cases)
  - Post infarct VSD closure
- Achievable with a co-team
  - Pediatric interventionalist
  - Adult structural interventionalist



SCAI, WADIA 2017 et all


DRAFT FOR COMMENT
Not intended for use or citation

SCAI 2020

SCAI Position Statement on Adult Congenital Cardiac Interventional Training, Competencies and Organizational Recommendations


TRAINING STATEMENT

COCATS 4 Task Force 14: Training in the Care of Adult Patients With Congenital Heart Disease

JACC 2015


SCAI EXPERT CONSENSUS STATEMENT

Interventional Fellowship in Structural and Congenital Heart Disease for Adults

JACC 2010

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MHI ACHD Intervention Volumes

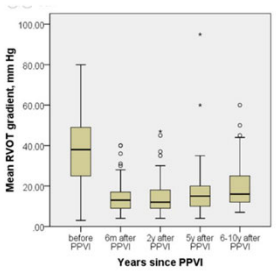
- 2019: Dr. Garcia/Dr. Vezmar
  - 31 total cath (11 Children's, 20 MHI)
  - 7 interventional
  - 20 surgeries
- 2020: Dr. Garcia/Dr. Baker – August 2020
  - 55 total caths (all MHI)
  - Hemodynamic
  - Interventional 17
  - 24 surgeries
- 2 days monthly/ 3 cases daily

41

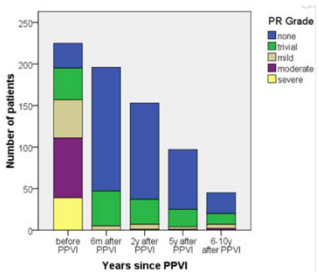
Long Term followup after PVR

- 226 patients with followup in 96%
  - 2 procedural related deaths
    - Conduit rupture
    - Left main compression
  - 17 patients needed valve replacement
    - 7 valve degeneration
    - 10 endocarditis

Pulmonary Stenosis



Pulmonary Insufficiency



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Percutaneous PVR

- Pulmonary valve and conduit dysfunction is common in ACHD patients
- Patients will need multiple interventions in adulthood
- Percutaneous PVR is non inferior to surgical PVR
- Long term complications have been related to endocarditis and stent fracture, may be less with Sapien based on early results
- Technology is advancing to treat native RVOT in addition to conduits
- The “heart team” concept is essential to ACHD intervention

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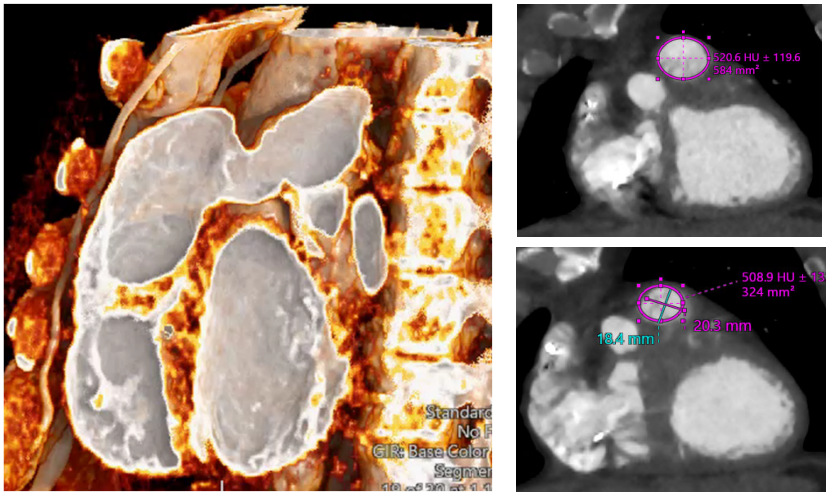
Dynamism of the Native RVOT



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RVOT Open Intervention

Karol Mudy, MD
Cardiac Surgery

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Conflict of Interest

- None

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28 year-old Female- PMH:

- DORV with malposition of great vessels
- 1993- baffling of VSD to aorta
  - Unclear intervention on RVOT
- 2016- slowly increasing LVOT/ RVOT gradients with normal LV/RV function
- August 2020- mean RVOT gradient of 52 mm Hg
  mean LVOT gradient of 35 mm Hg
  moderate PI

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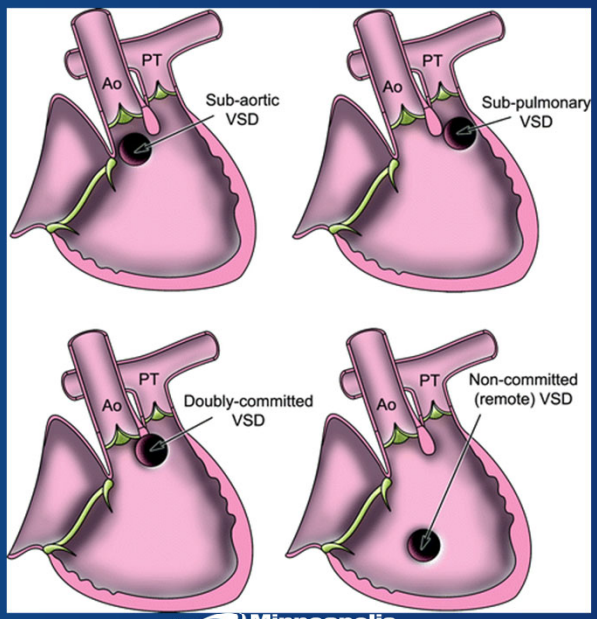
DORV



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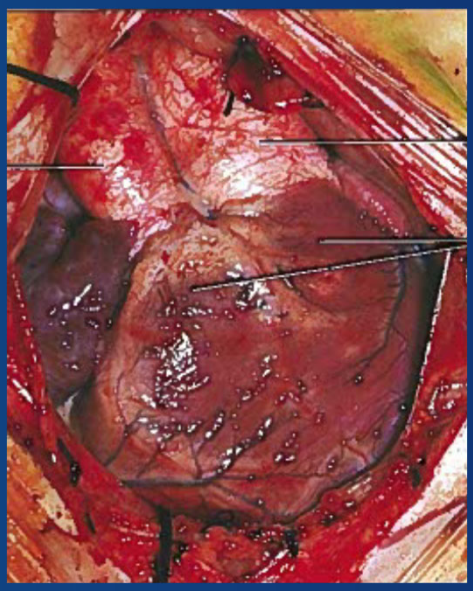
DORV



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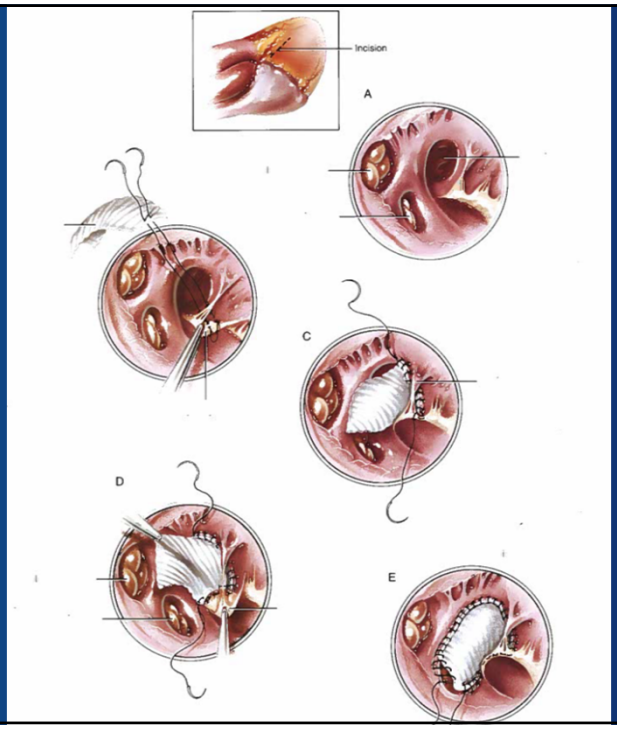
DORV



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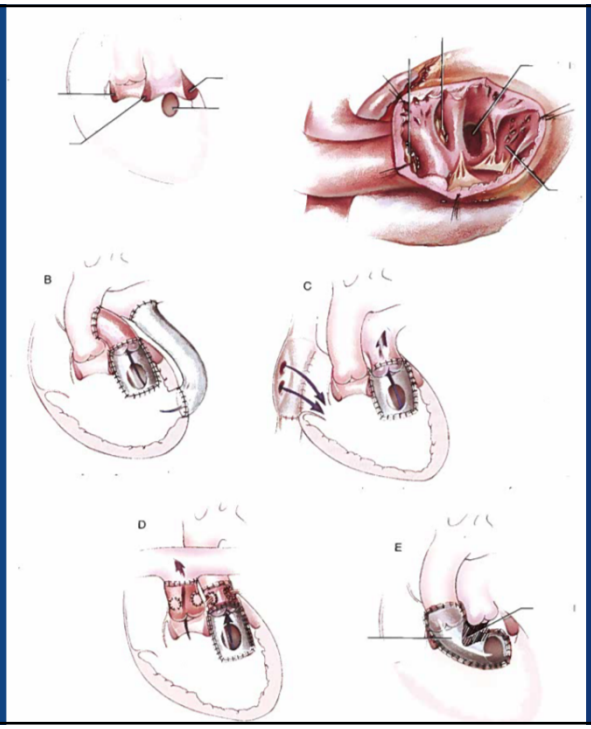
DORV



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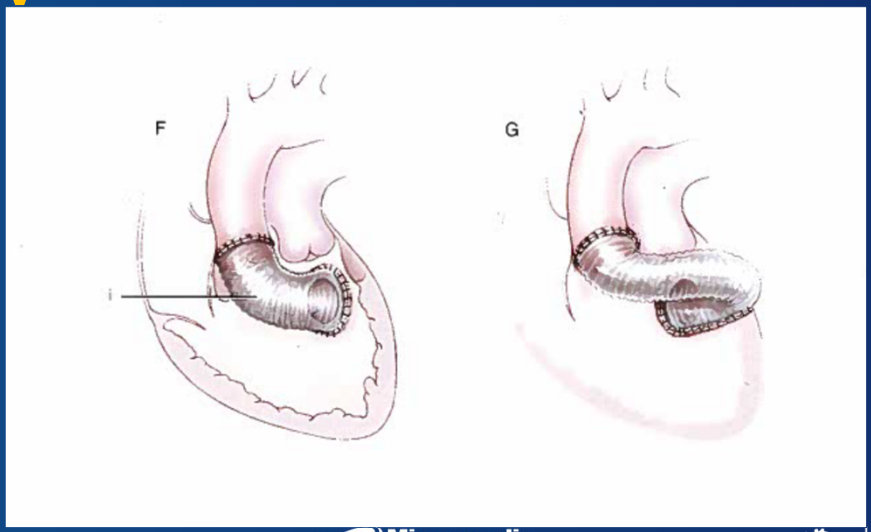
DORV



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CT cardiac:

1. Double outlet right ventricle, malposed great arteries.
2. S/P VSD baffling to the aorta, RVOT conduit.
3. Normal systemic venous return to the right atrium.
4. Right ventricle- Decreased right ventricular systolic function ejection fraction is 49%.
   Increased right ventricular end-diastolic end-systolic dimensions.
5. Left ventricle- Normal systolic function, ejection fraction 60%.
6. Left ventricular outflow tract- Tortuous left ventricular outflow tract from left ventricle to the malposed aorta. There is a subaortic membrane approximately 1 cm inferior to the aortic valve annulus. This is primarily in the posterior LVOT.
7. Trileaflet aortic valve. Aortic root dilation.
8. Single coronary artery arising from the right facing aortic sinus immediately adjacent to the dilated main pulmonary artery.

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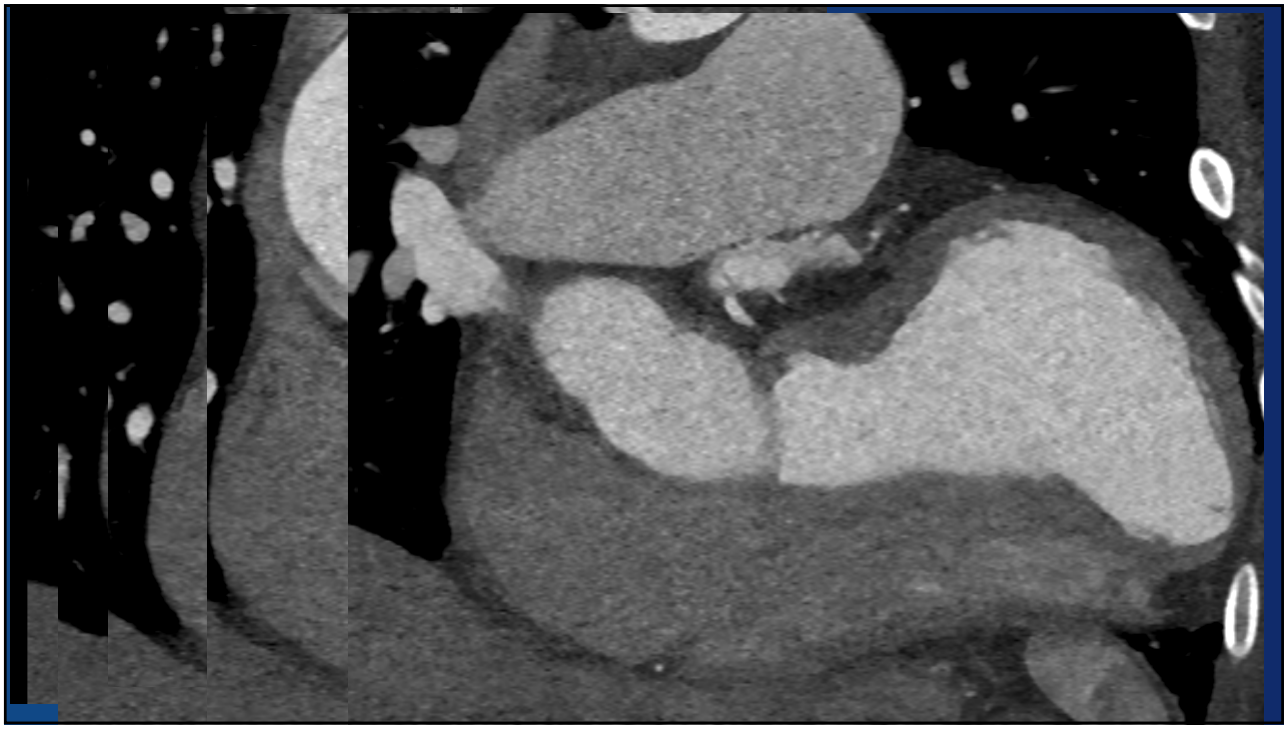

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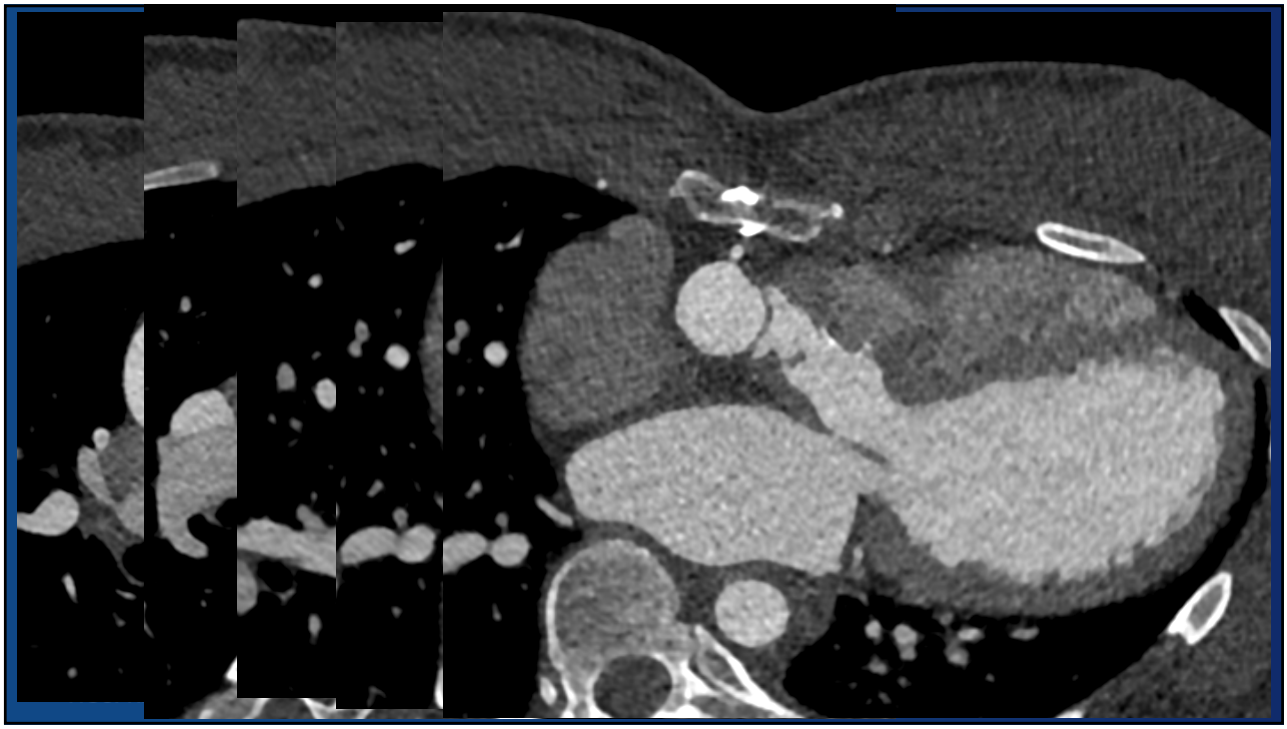

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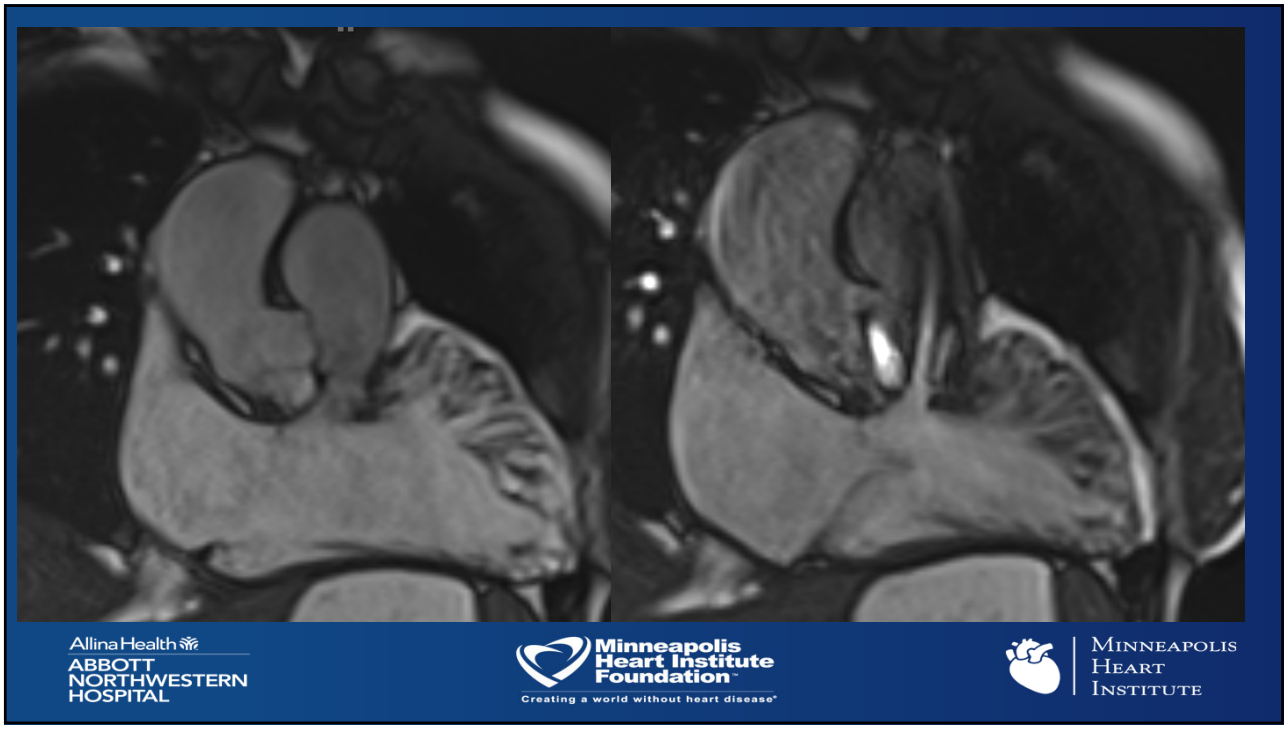
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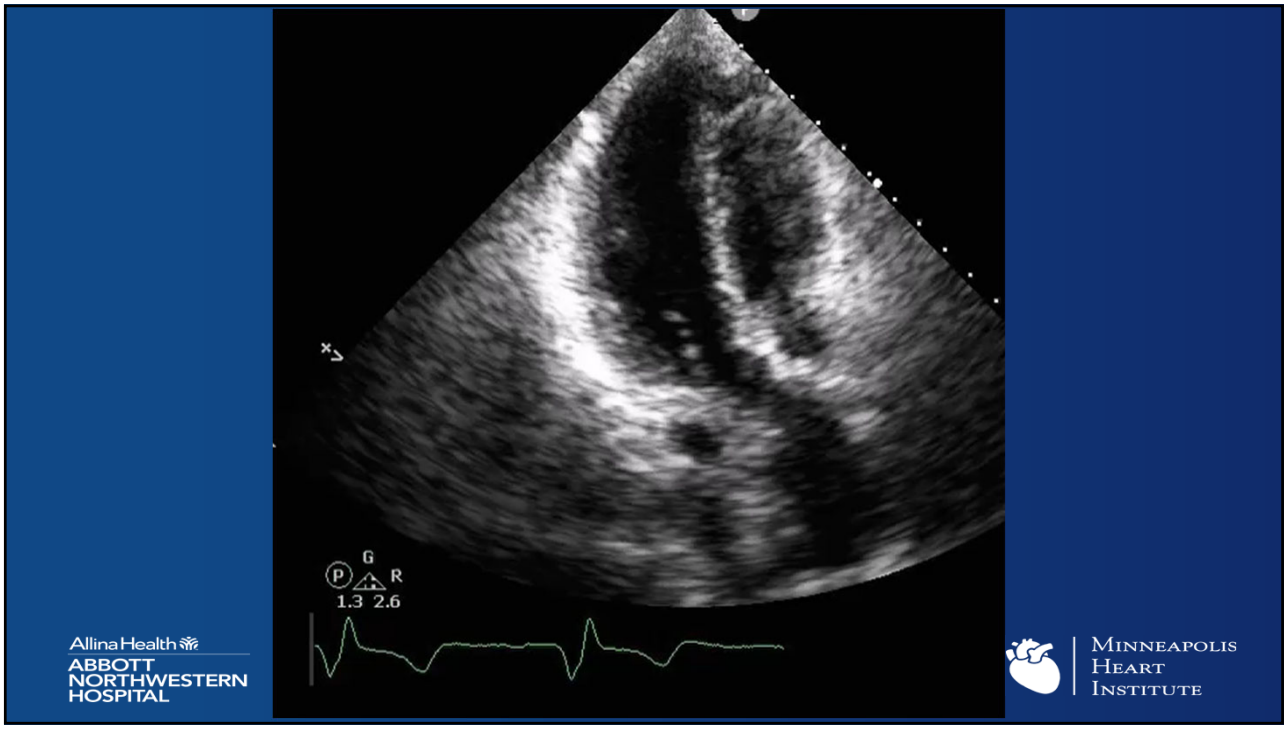
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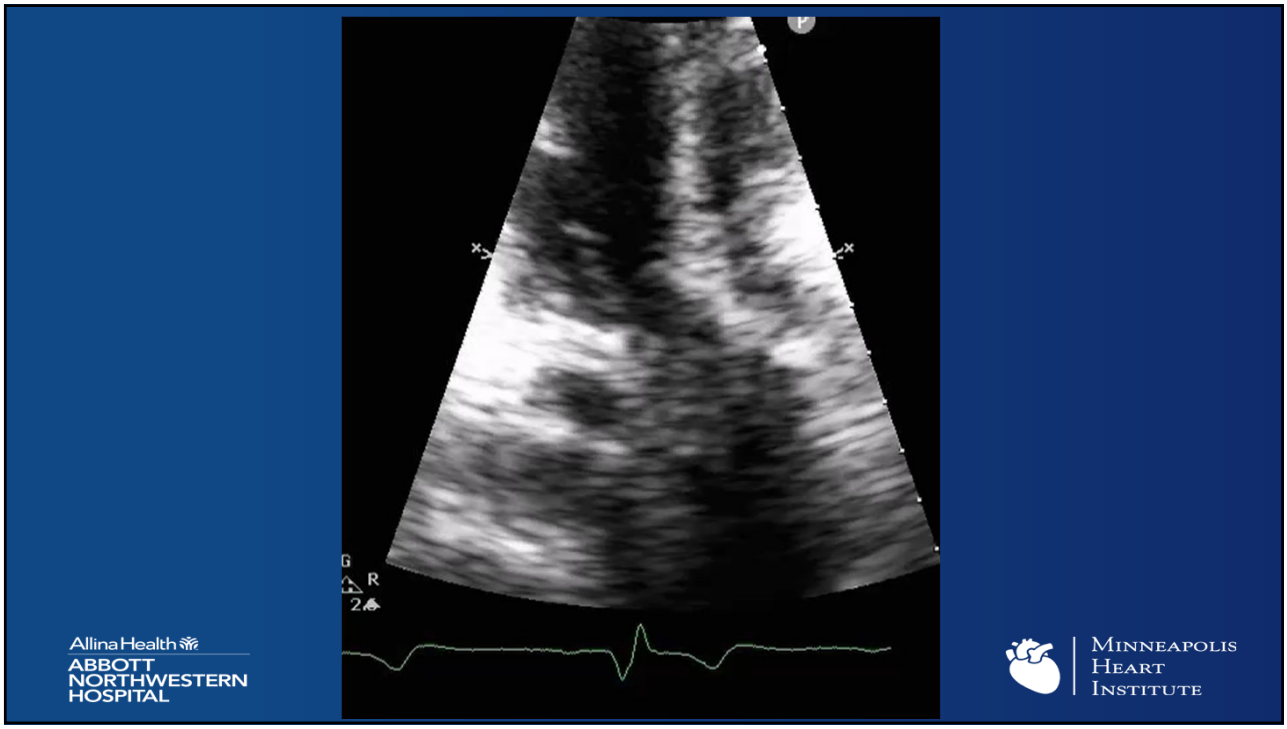
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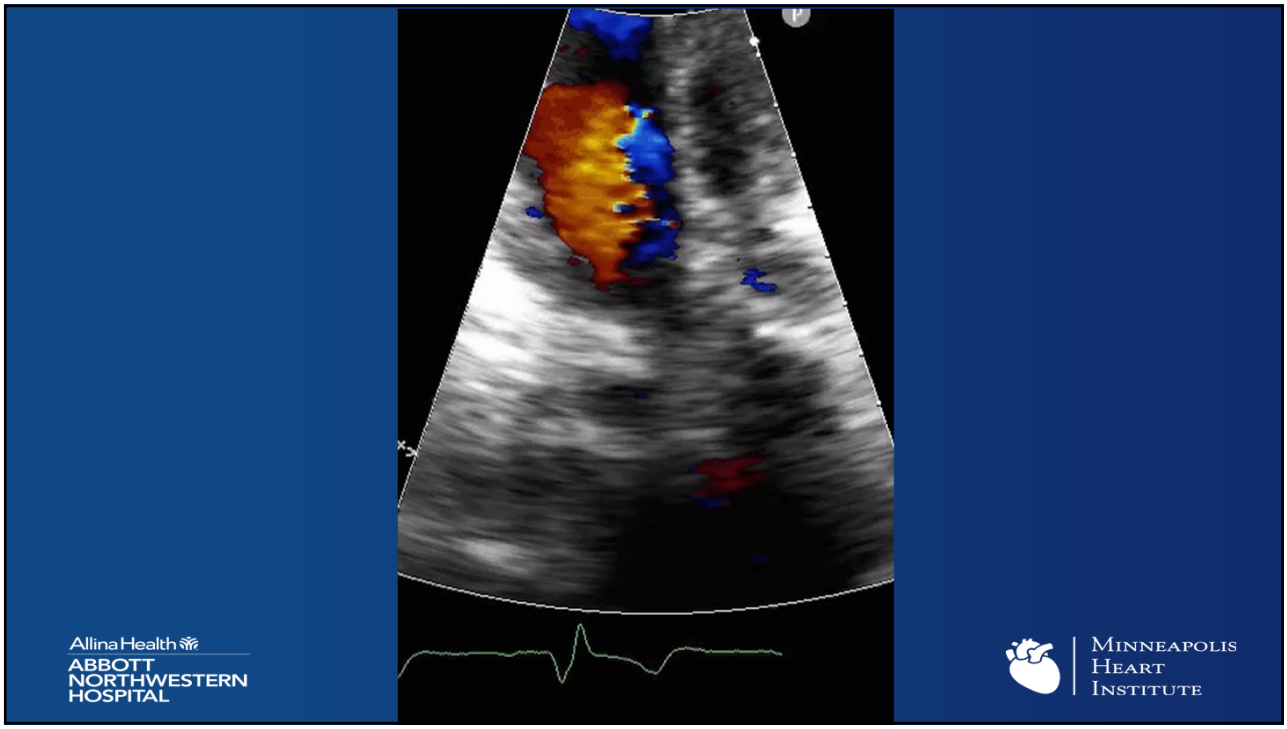
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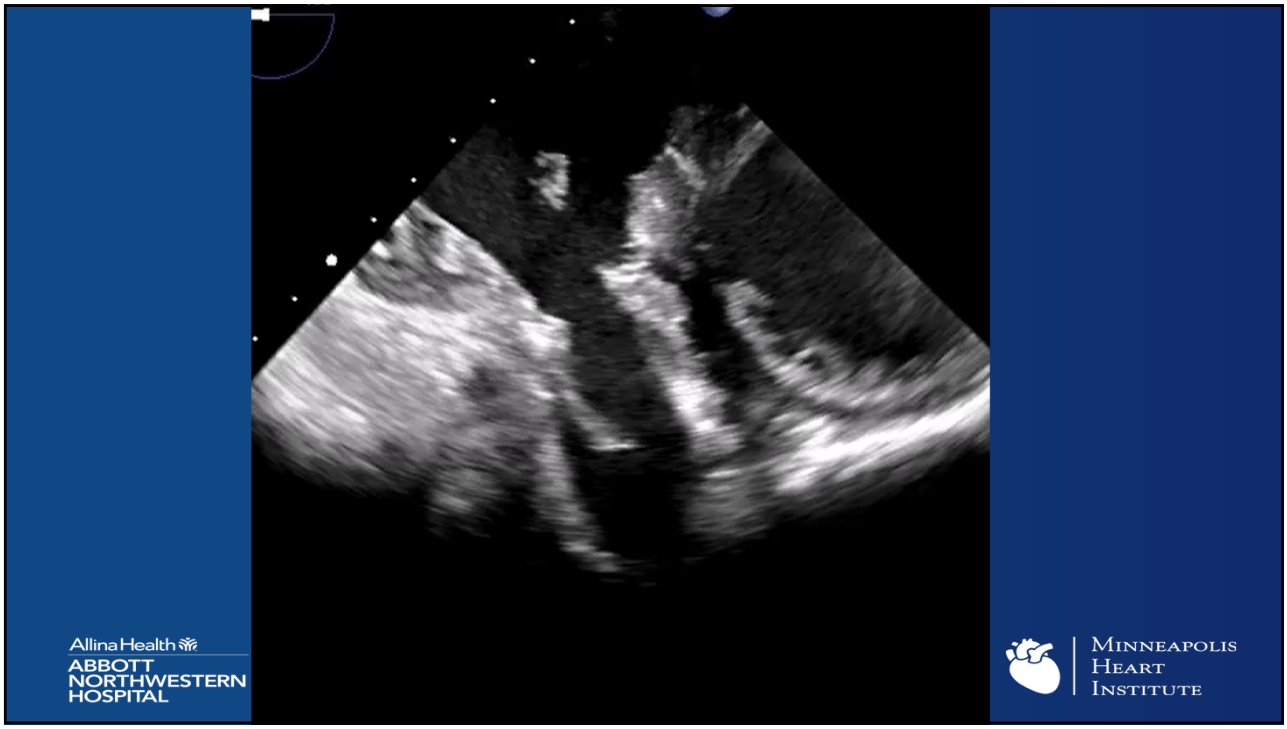
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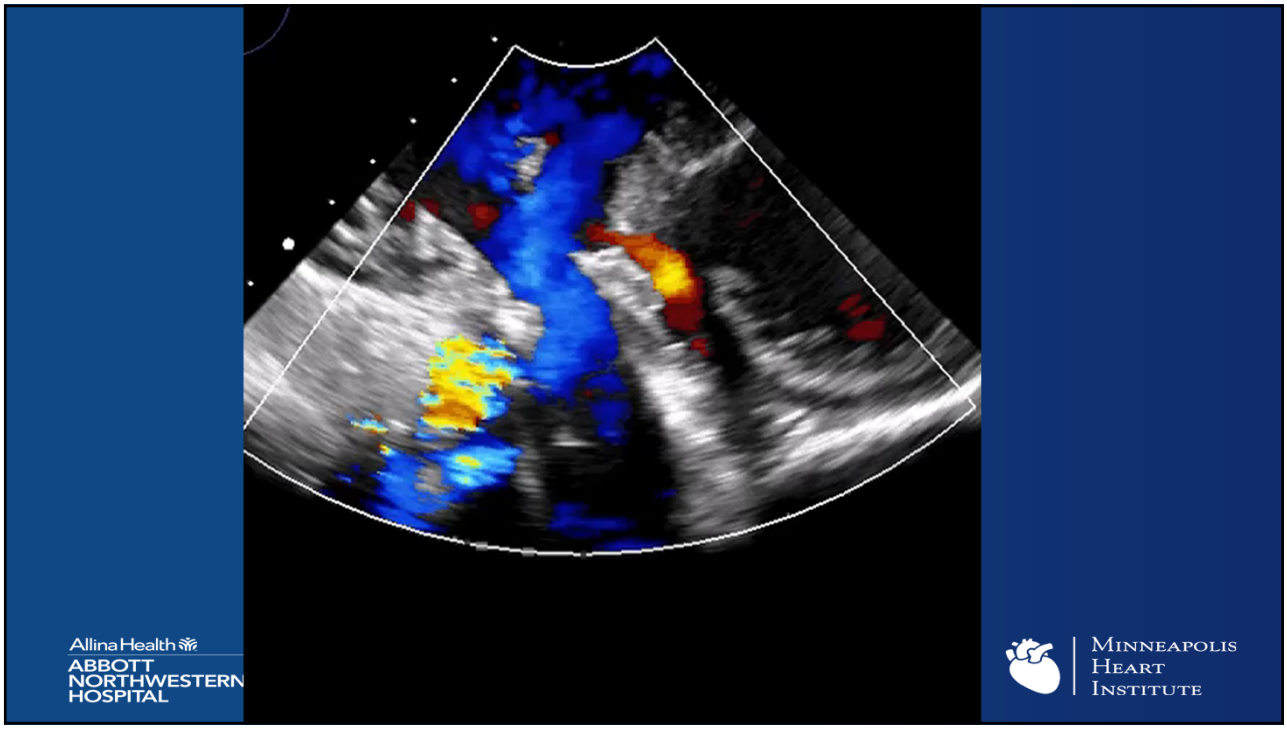
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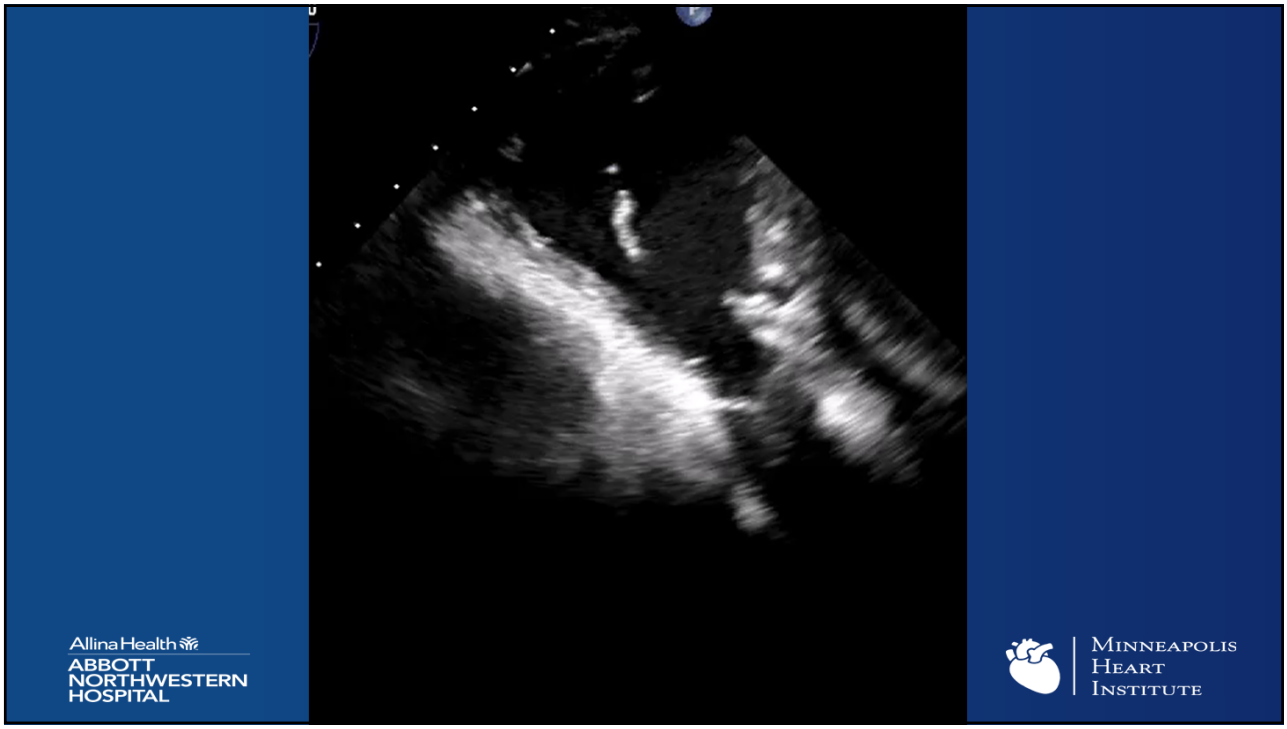
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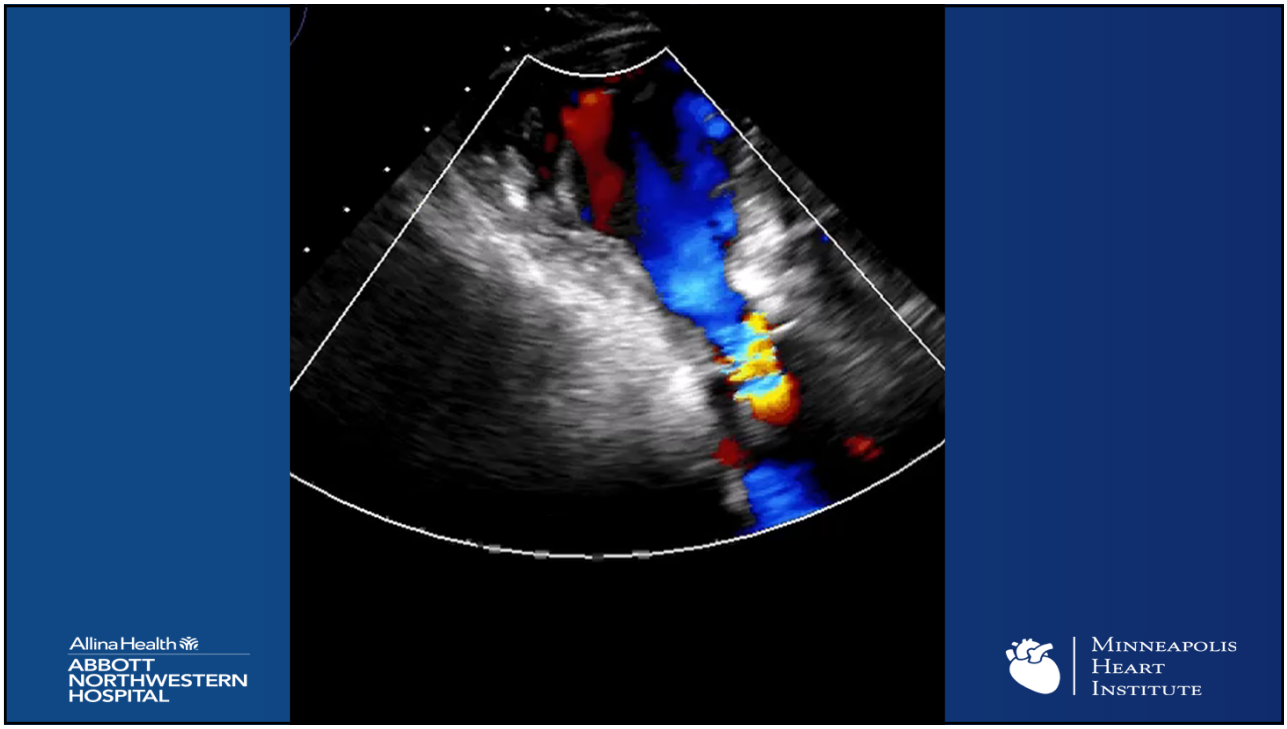

19

- ACHD meeting
- Recommendation for sub-aortic membrane resection with AV preservation and surgical pulmonary valve replacement with RVOT revision

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Operating Room

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- Redo sternotomy
- Sub-aortic membrane resection
- Pulmonary valve replacement with 25 mm bio-prosthetic Mosaic valve
- Patch augmentation of RVOT

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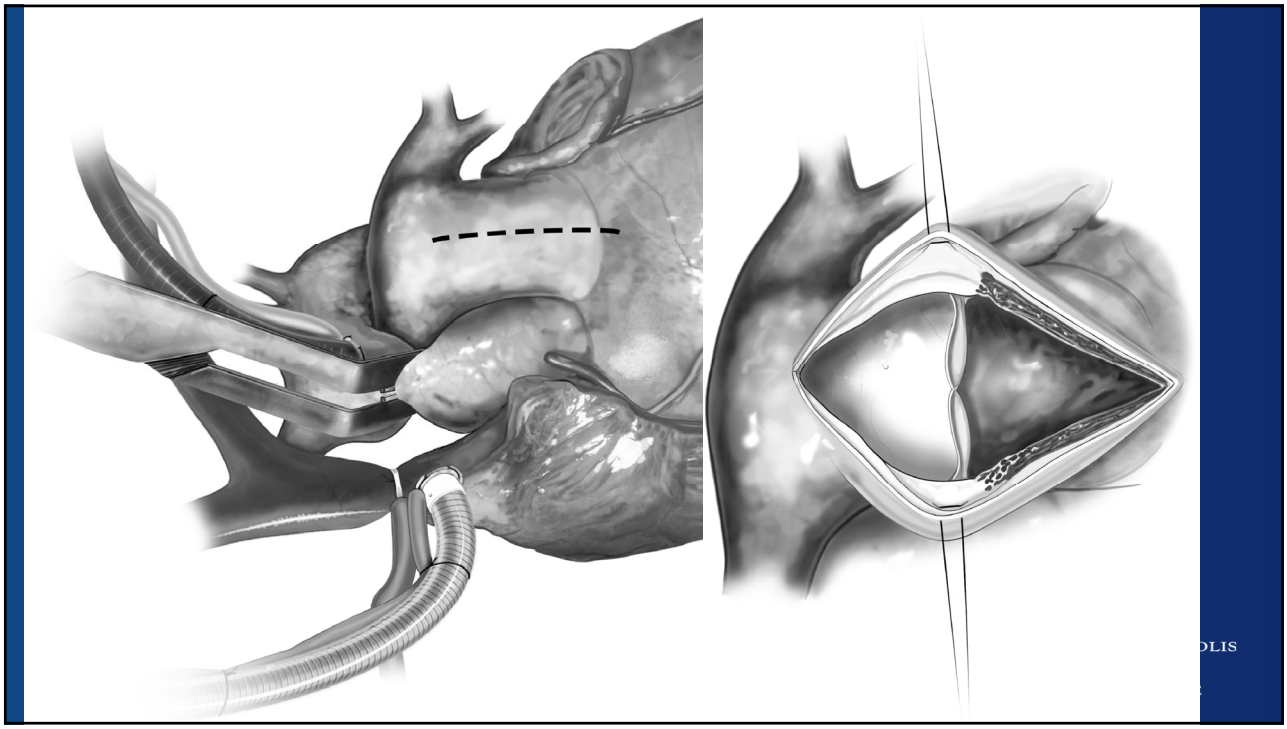

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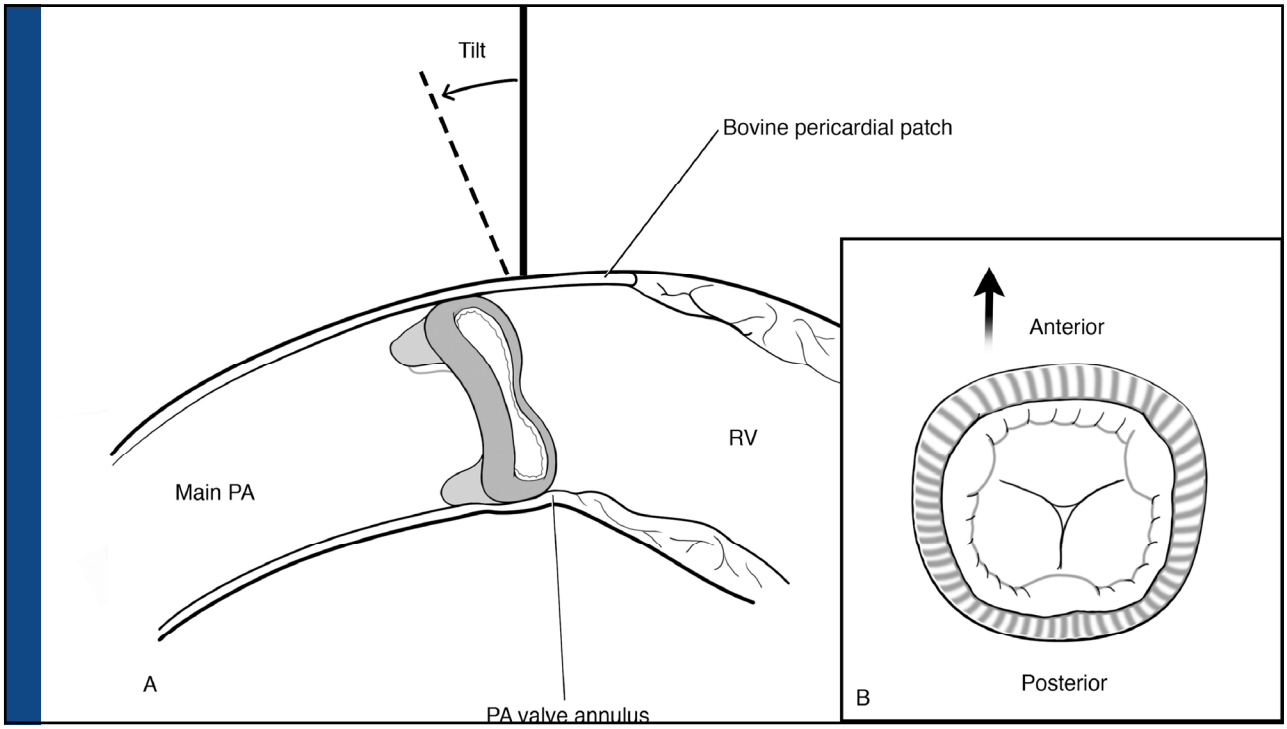
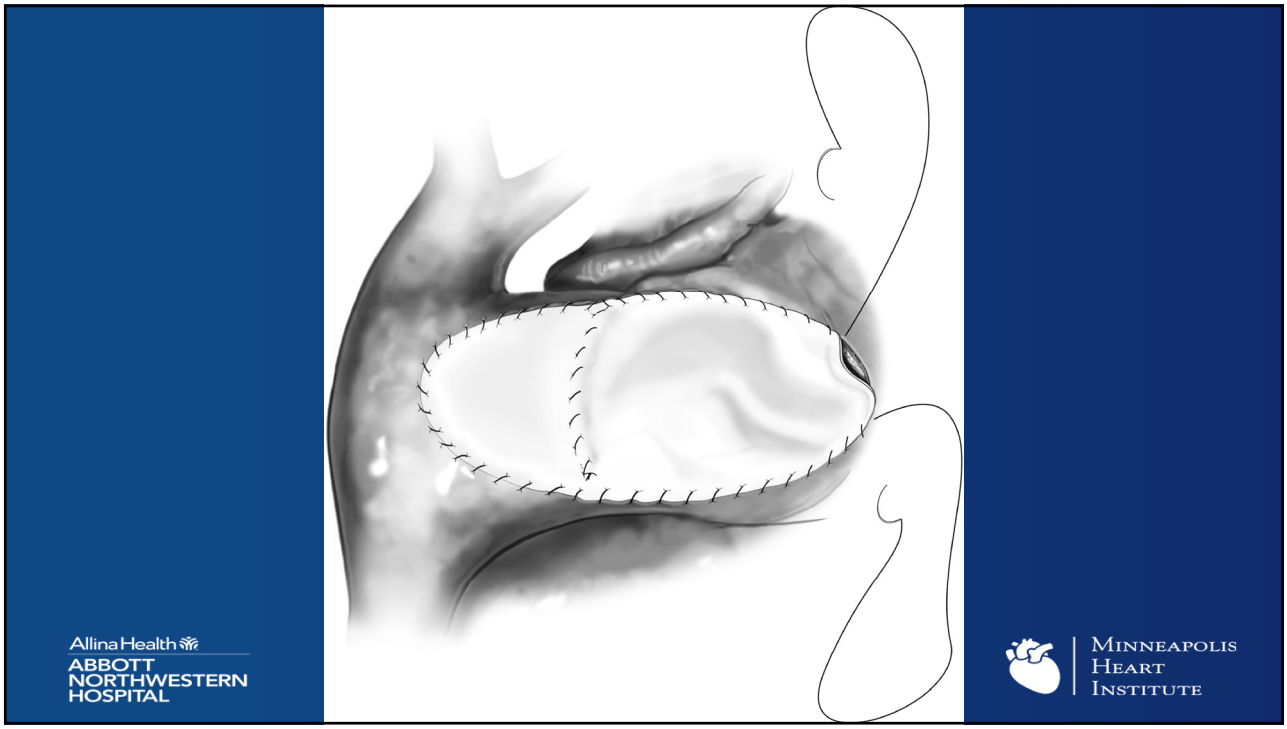

Tilt
Bovine pericardial patch
RV
Main PA
A
PA valve annulus
Anterior
Posterior
B

24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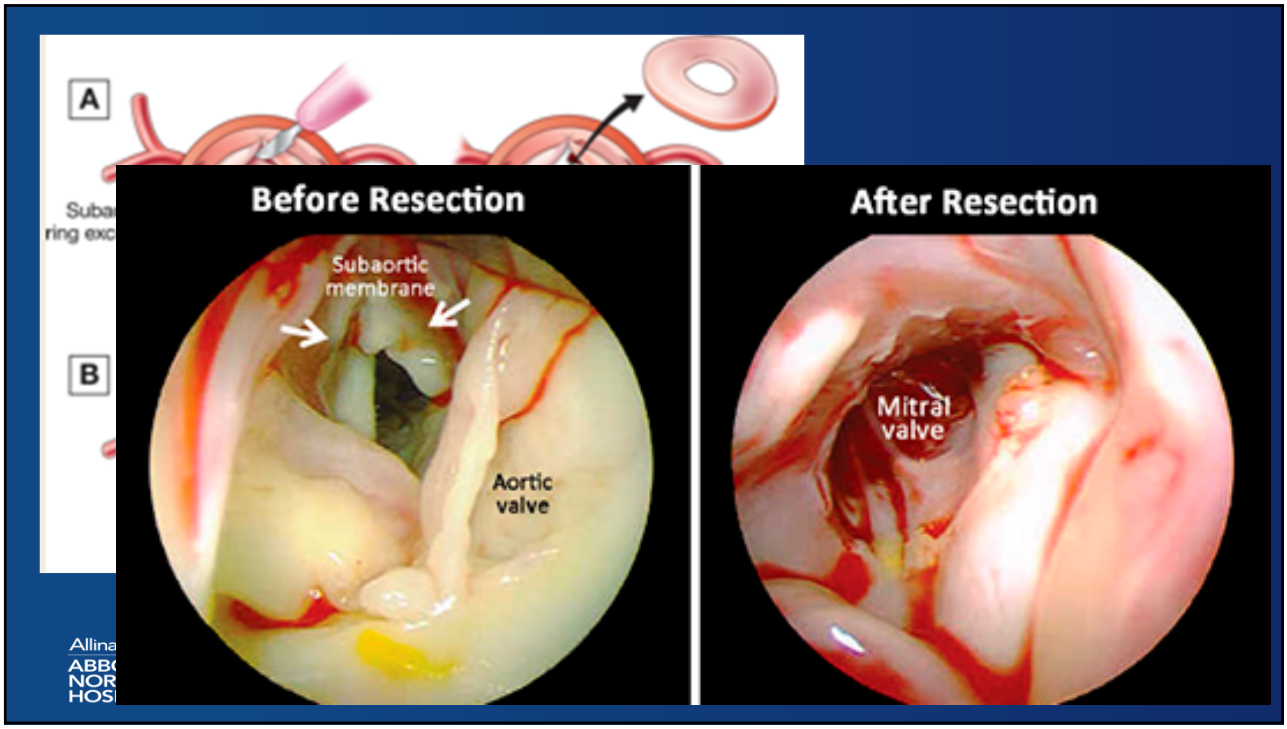
A
B
Before Resection
Subaortic membrane
Aortic valve
After Resection
Mitral valve

26

Operating Room

INTRAOPERATIVE FINDINGS:

1. **Significant displacement of the heart towards the left chest.**
2. **Subaortic membrane resected completely with good resolution of LVOT high gradient.**
3. **Significant narrowing of the RVOT by muscle bundles that were resected.**
4. **Good biventricular function at the completion of the case.**

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Operating Room

- **CARDIOPULMONARY BYPASS DATA:**
- **Crossclamp time 62 minutes.**
- **Cardiopulmonary bypass time 183 minutes.**

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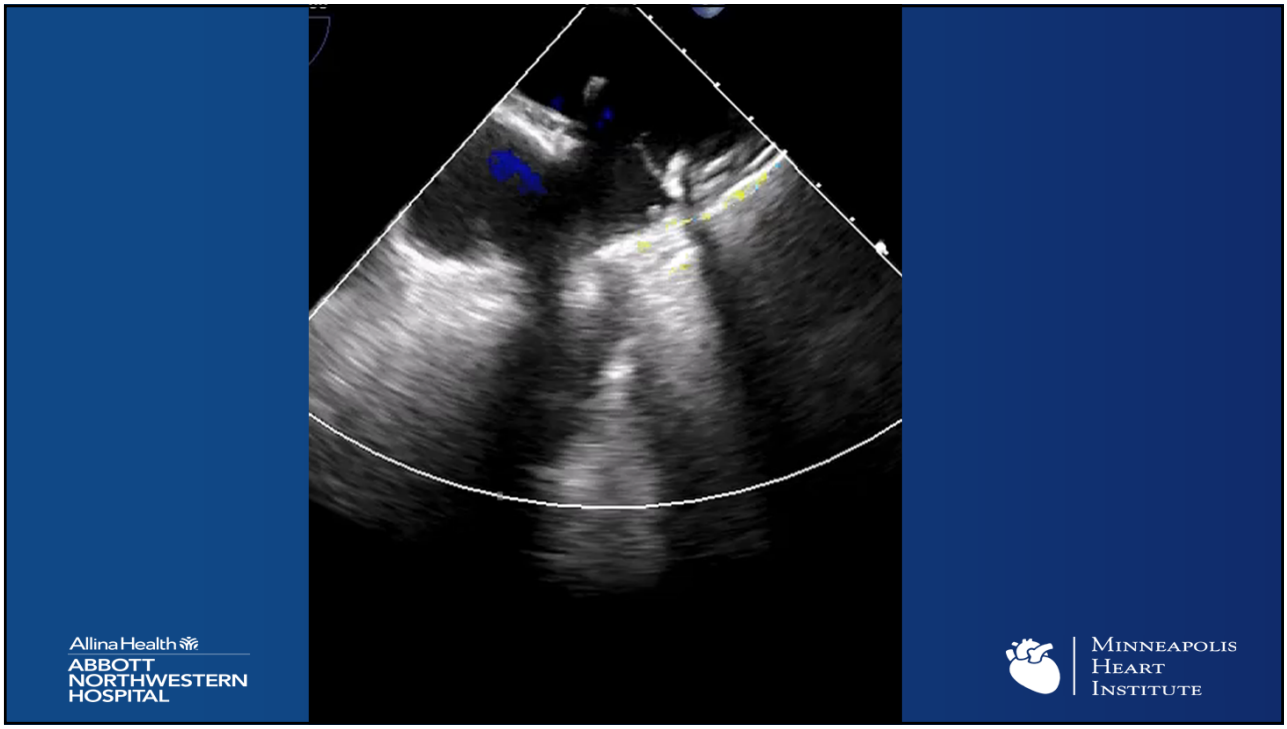
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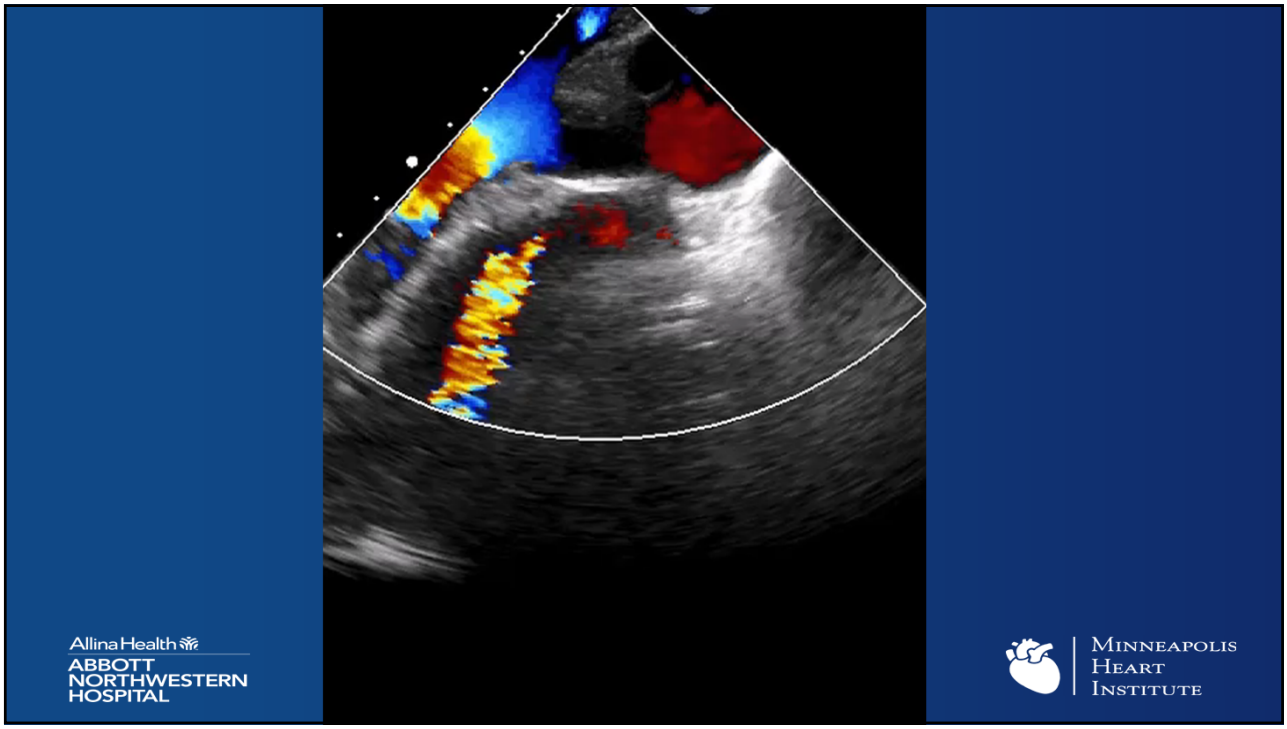
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Operating Room

- Unexpected VT storm requiring re-arresting the heart and subsequently requiring ECMO placement for stability.
- With resolution of VT, patient's LV and RV EF returned to normal.
- Right femoral ECMO→ Cath Lab

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- **POD #1** Chest washout and closure/ ECMO removal
- **POD #2** Extubated
- **POD #4** Telemetry
- **POD #7** Discharged home

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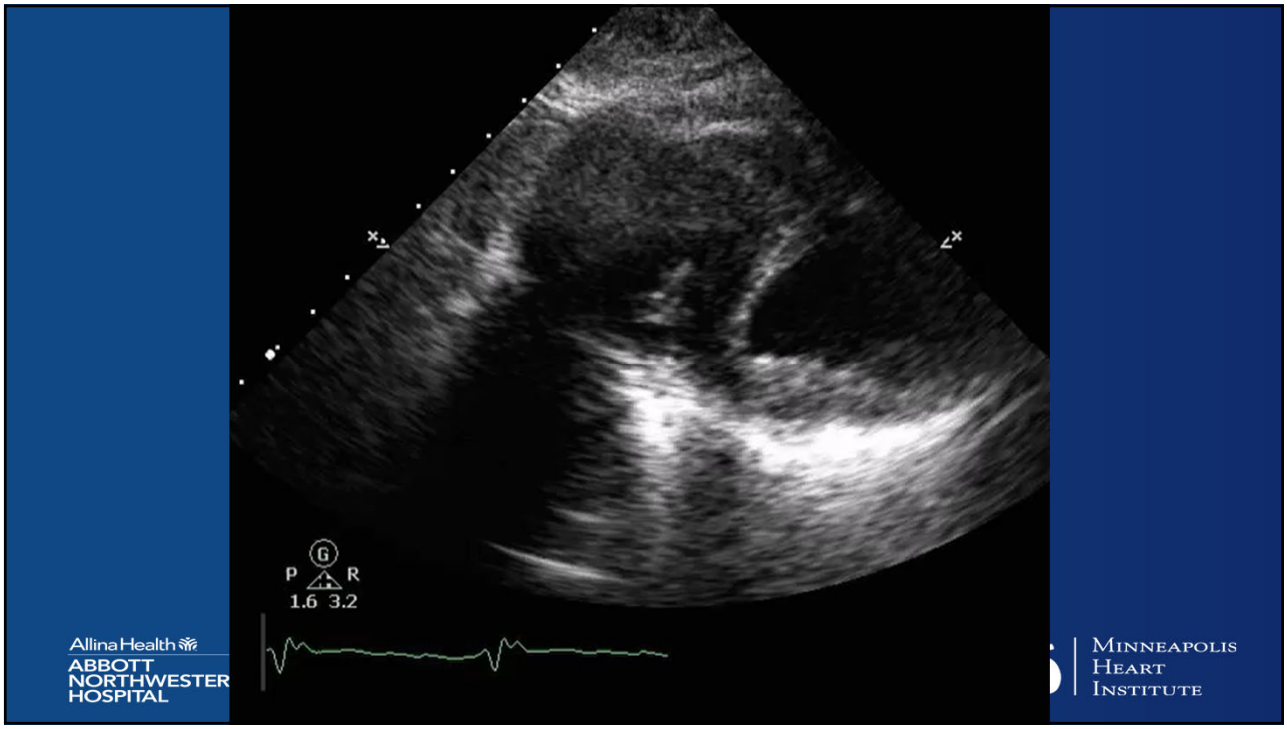
G
P
R
1.6 3.2
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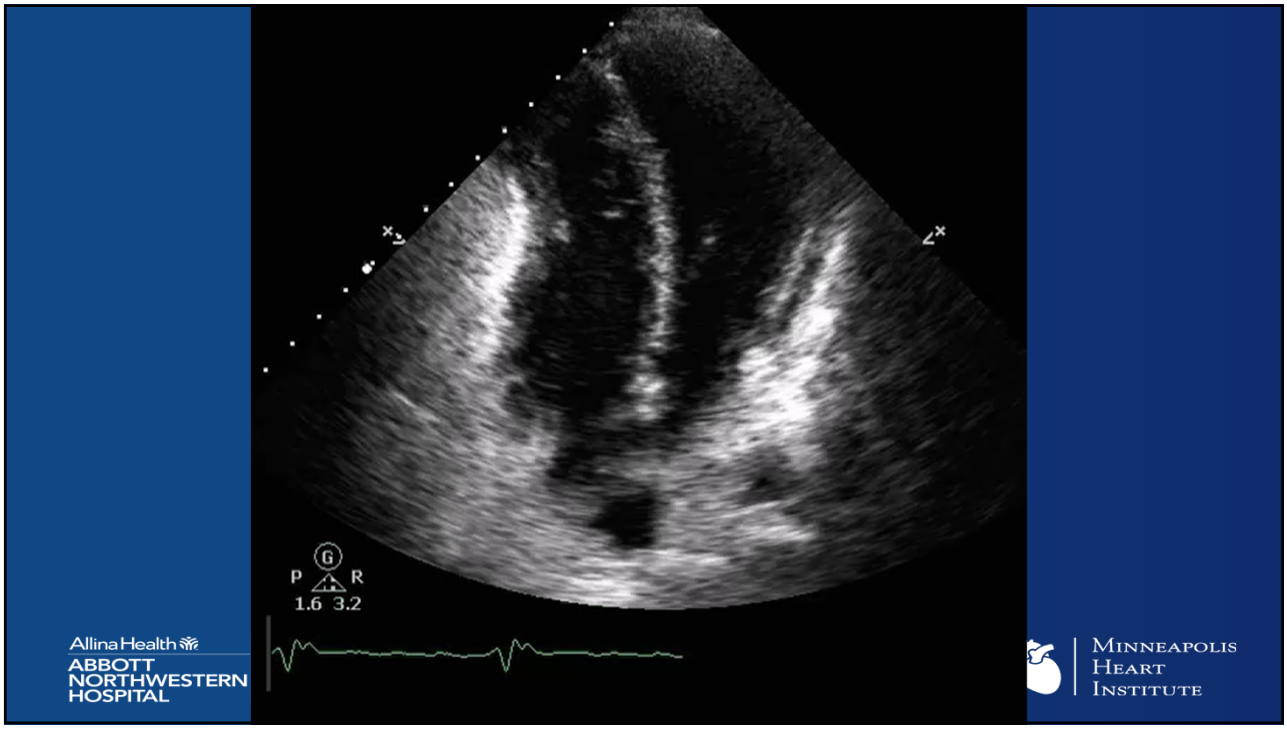
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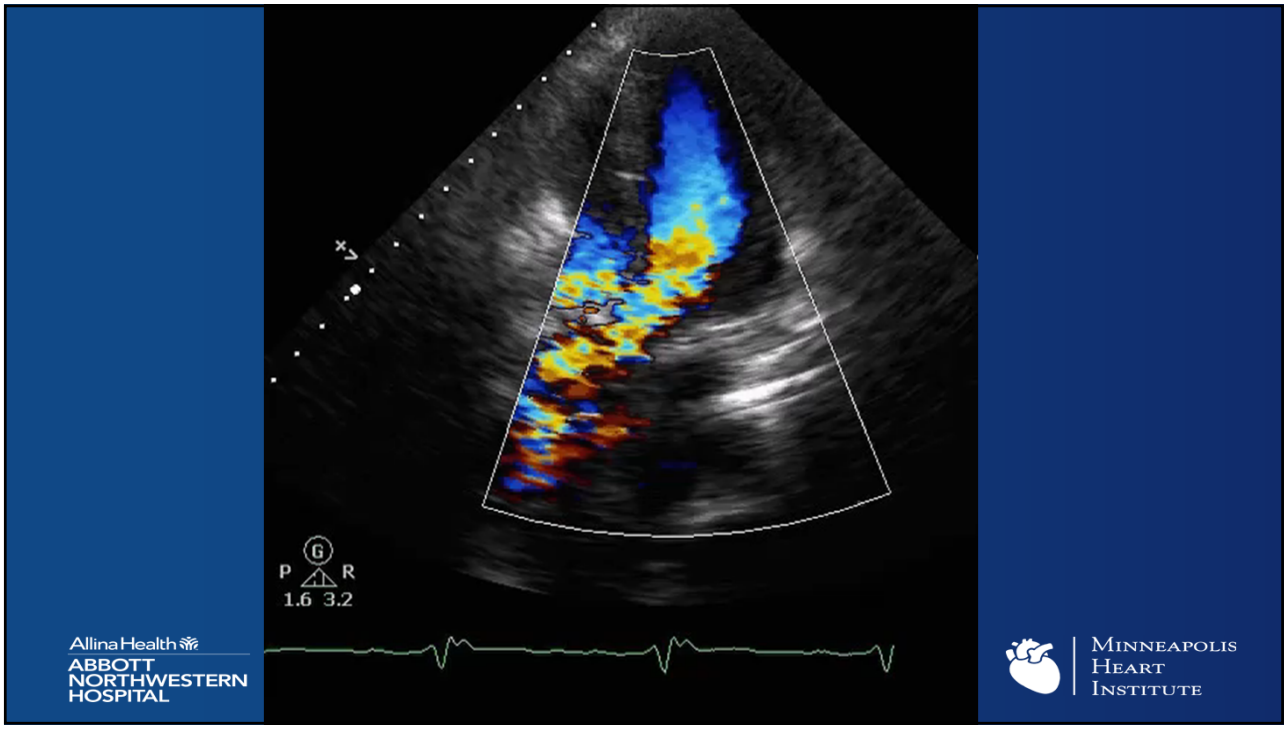
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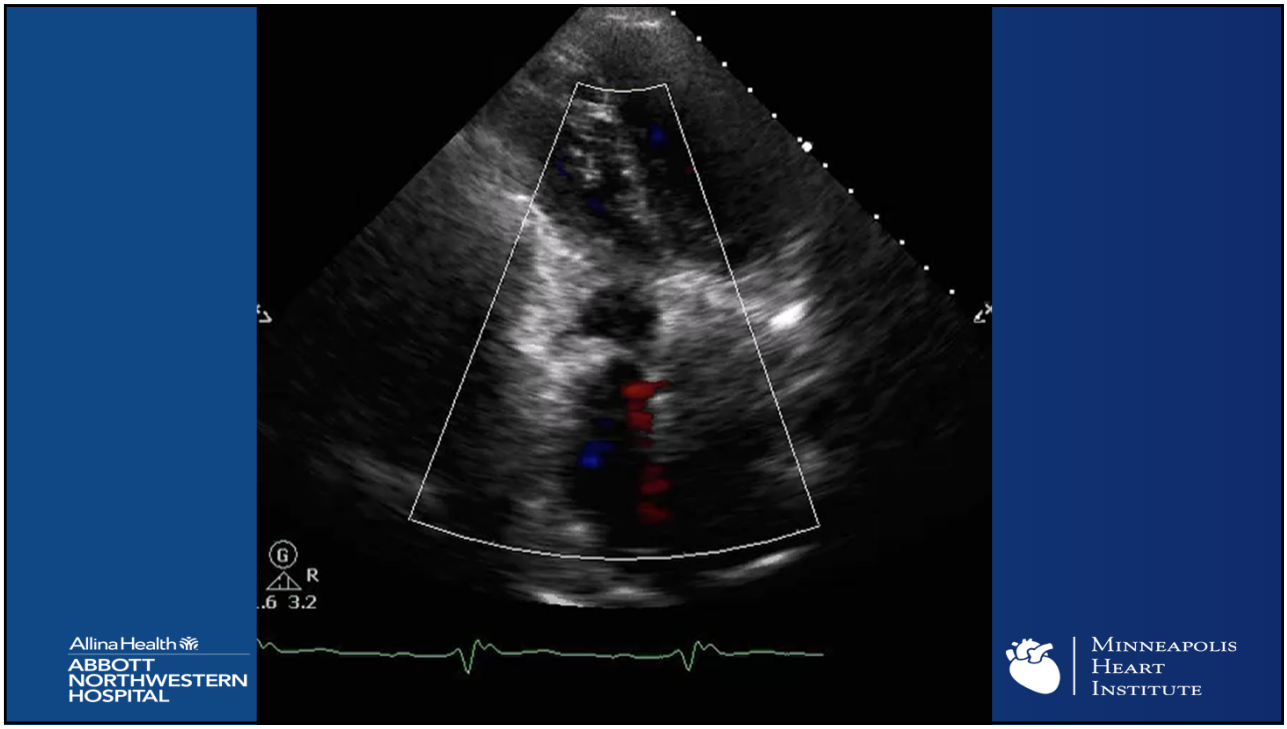
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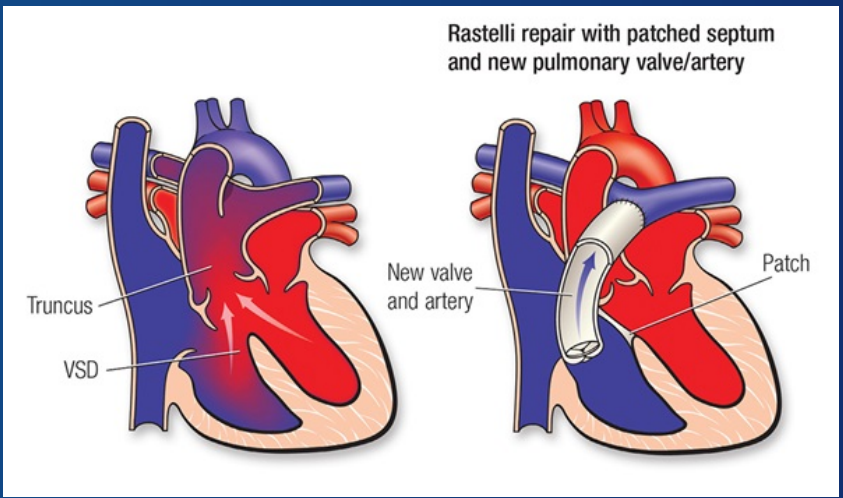
Repair of Truncus Arteriosus



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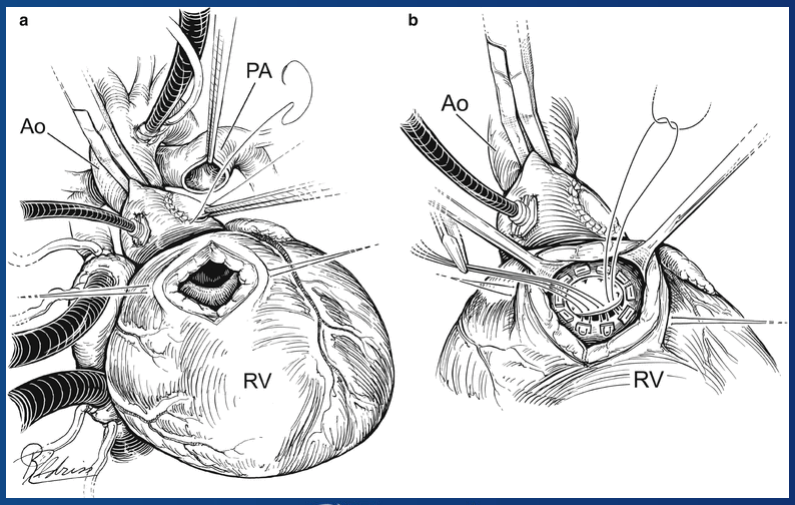
Repair of Truncus Arteriosus



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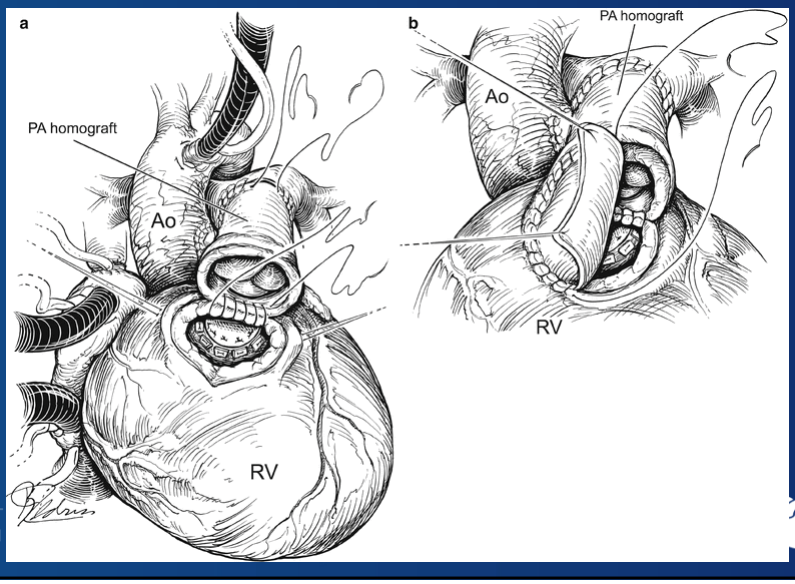
Repair of Truncus Arteriosus



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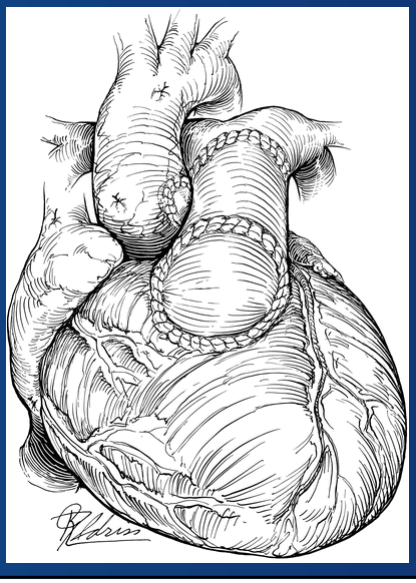
Repair of Truncus Arteriosus



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HPI- 2020

- Occasional shortness of breath
- Mild dilation of the RV and mild reduction in RV function
- Plan for intervention- percutaneous vs surgical
- Decision made for a surgical pulmonary valved conduit

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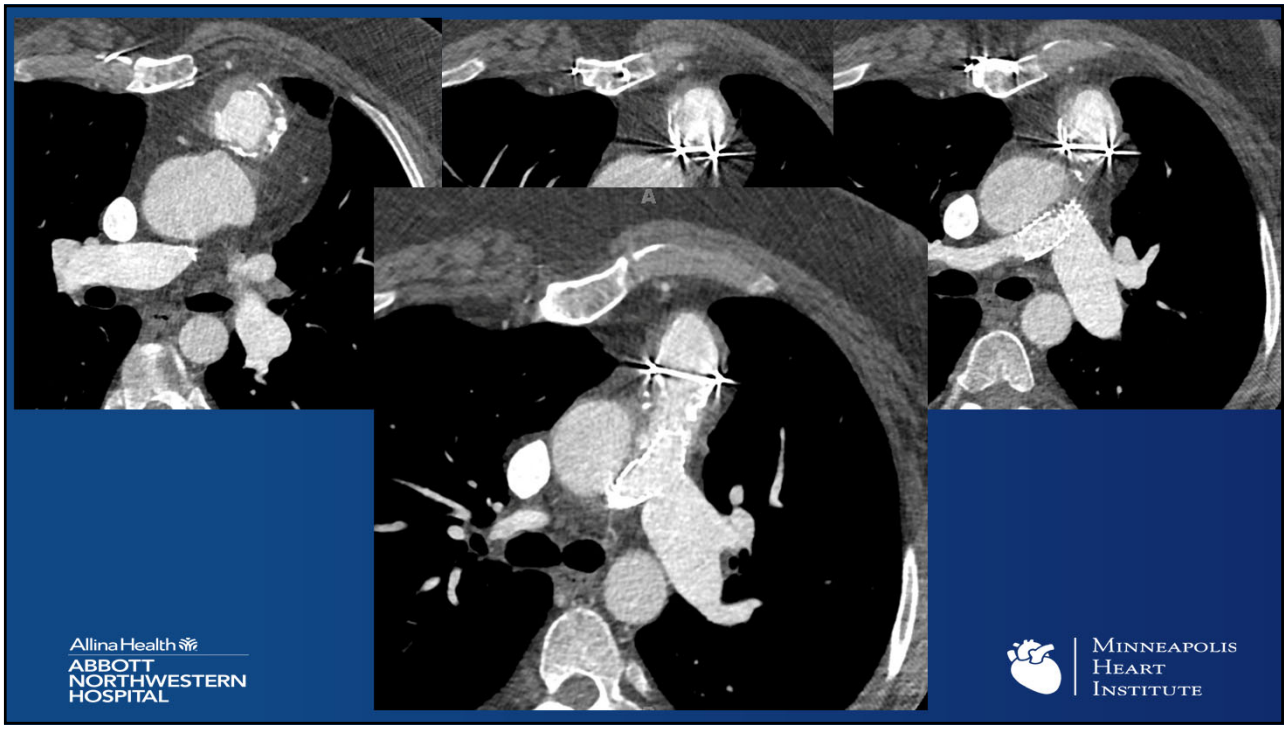
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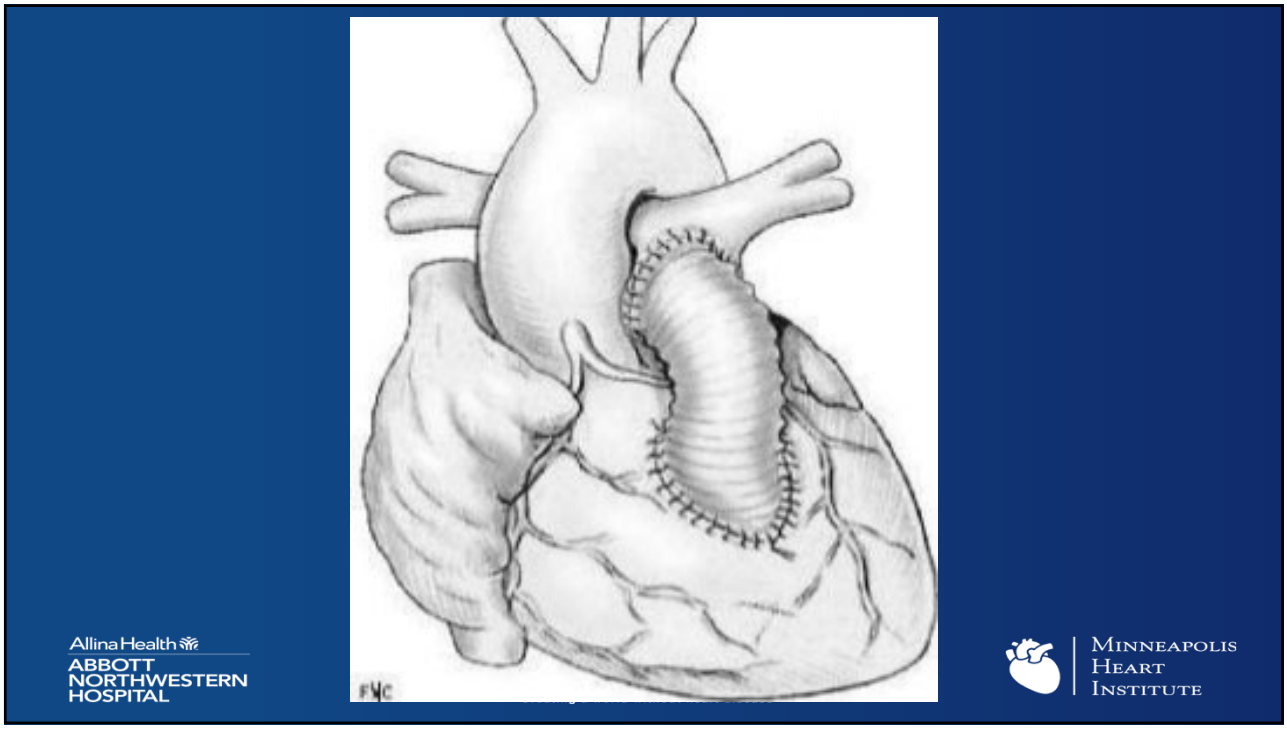
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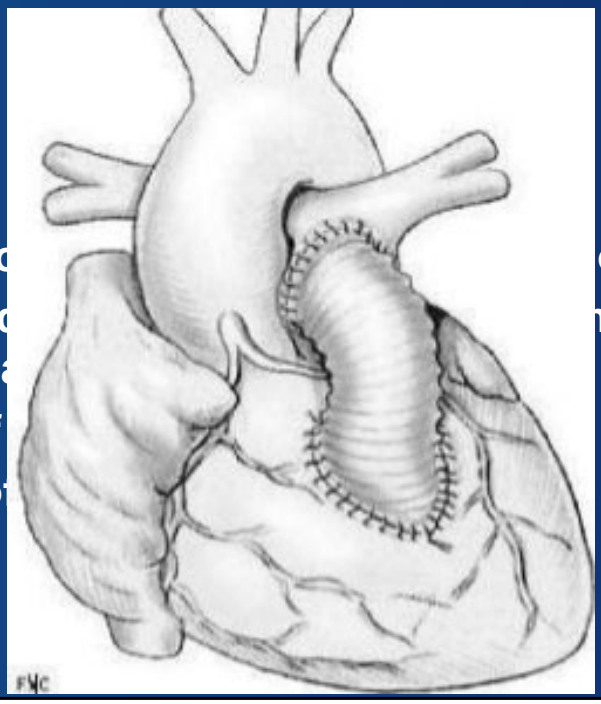
- Redo sterno on
- Redo valved he RV to main pulmonary a
- Removal of
- Trimming o



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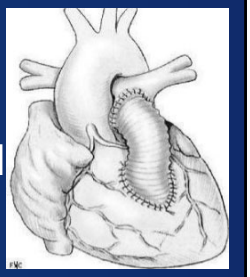
Operating Room



- Warm beating heart- truncus and PAs scarred
- 27 mm Mosaic valve + 32 mm Gelweave graft
- Main and left PA stent removal
- Coming off CPB- high RV/ PA (150 mm Hg) pressures with flow acceleration at the conduit to PA anastomosis

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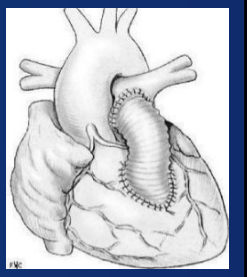
Operating Room



- Back on Cardio-Pulmonary Bypass
- Augmentation of valved-conduit anastomosis with bovine patch
- Additional graft from the main conduit (below valve) to right pulmonary artery

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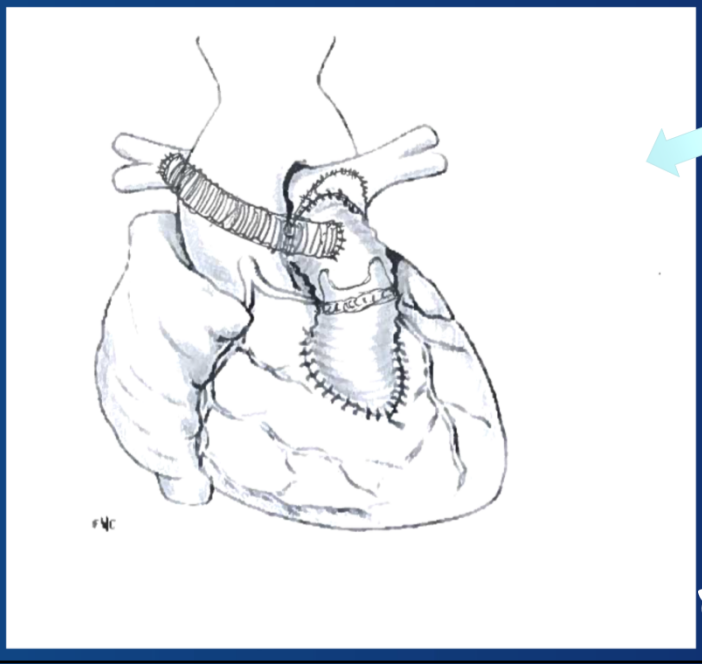

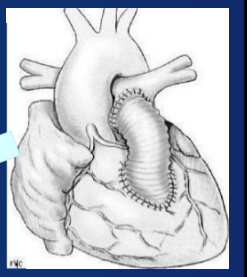

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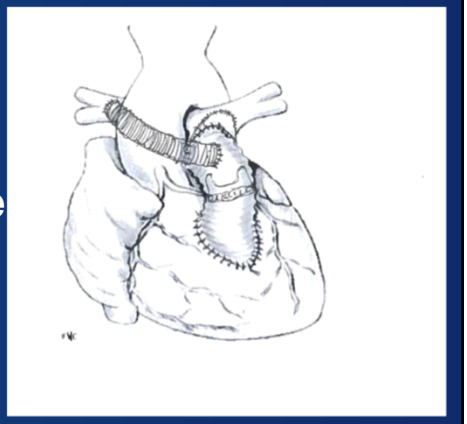
Operating Room

- RV pressures in low 60 mm Hg range



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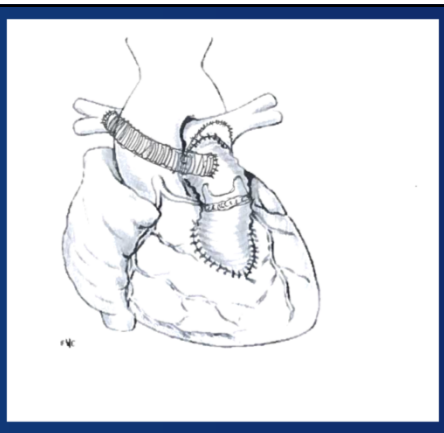
Postoperative Course

- Uneventful
- Discharged POD #7
- Returned POD # 10 with dyspnea
- Hb 5.2 g%
- EGD- duodenal ulcer- clipped, injected



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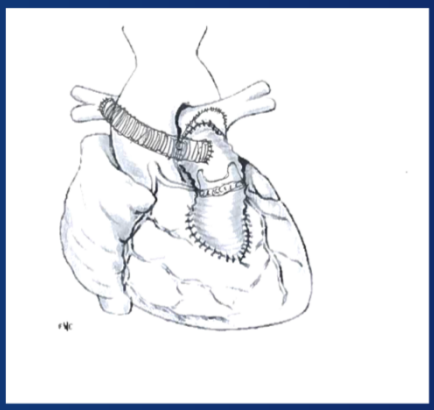
Echo

- Elevated gradient distal to the valve
- Catheter- confirmed the finding of 50 mm Hg gradient distal to the valve



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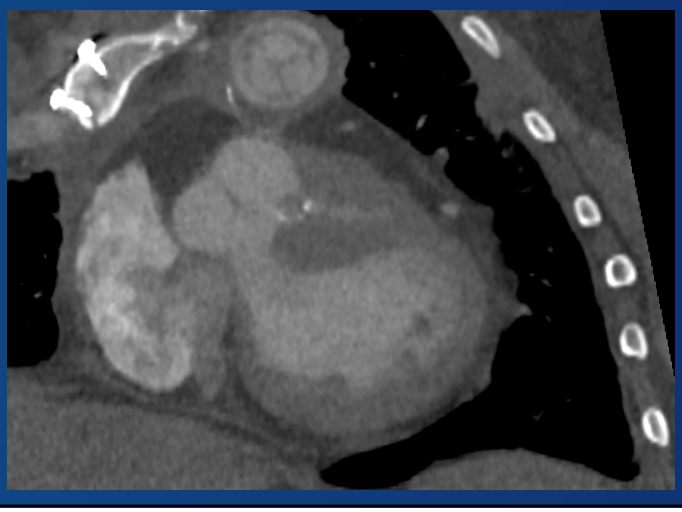
Structural CT



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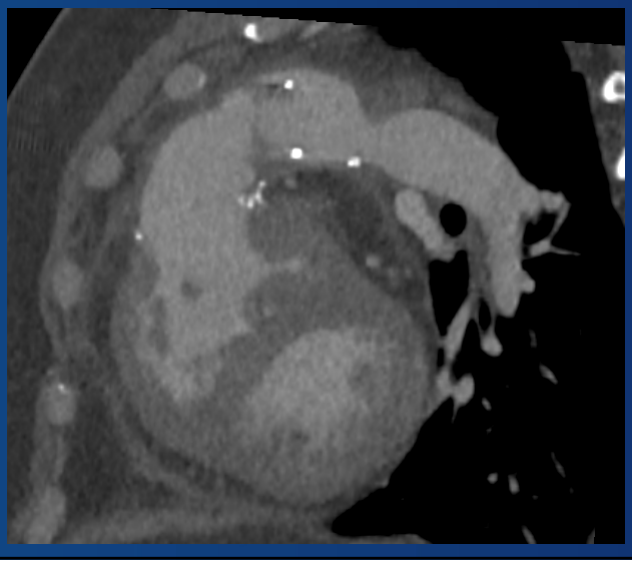
Structural CT



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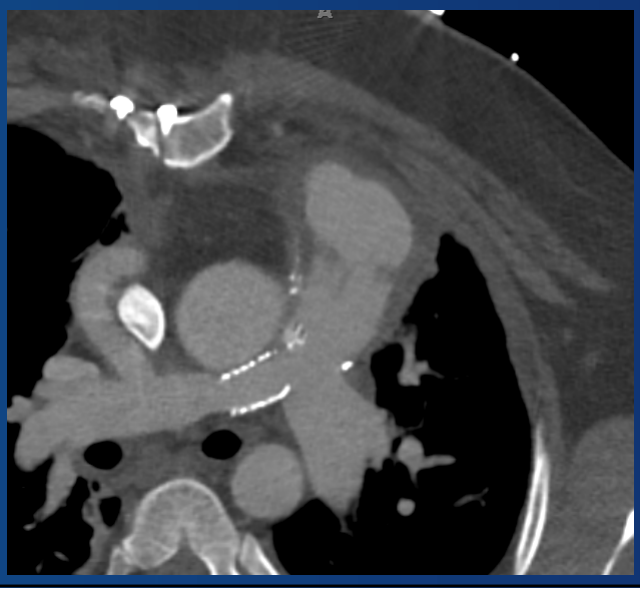
Structural CT



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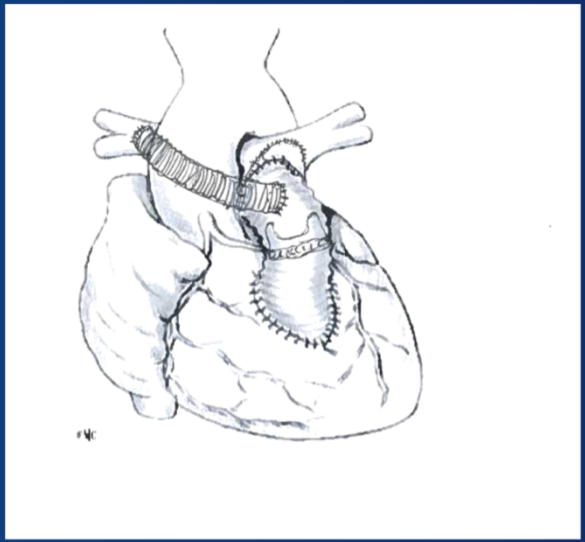
Plan

- Follow-up in 6 weeks
- Echo
- Transcatheter dilation



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THE RIGHT VENTRICULAR OUTFLOW TRACT: CONSIDERATIONS FOR TRANSCATHETER INTERVENTIONS

SANTIAGO GARCIA, MD, FACC, FSCAI
DIRECTOR, TAVR AND ADULT CONGENITAL STRUCTURAL PROGRAM
SANTIAGOGARCIA@ME.COM

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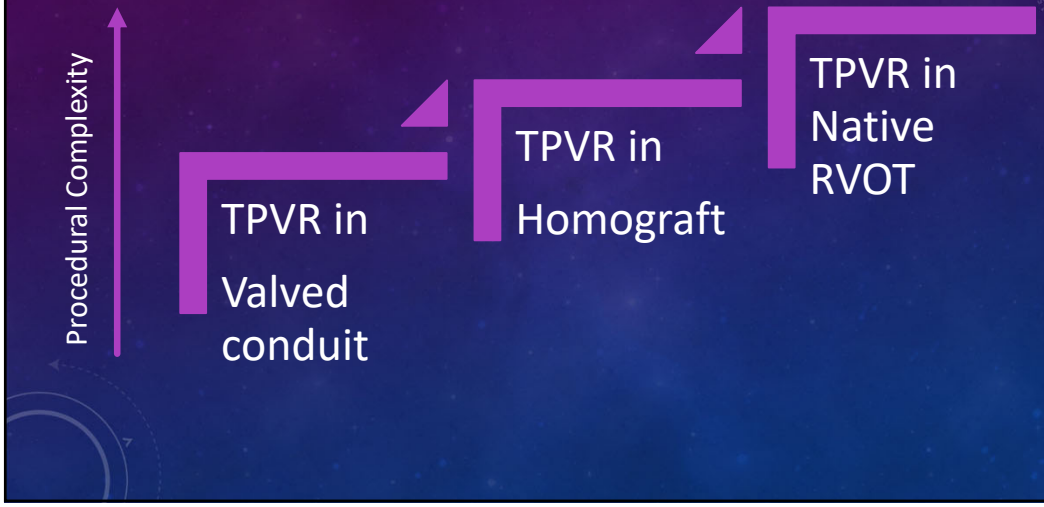
1

HIERARCHY OF PROCEDURAL COMPLEXITY



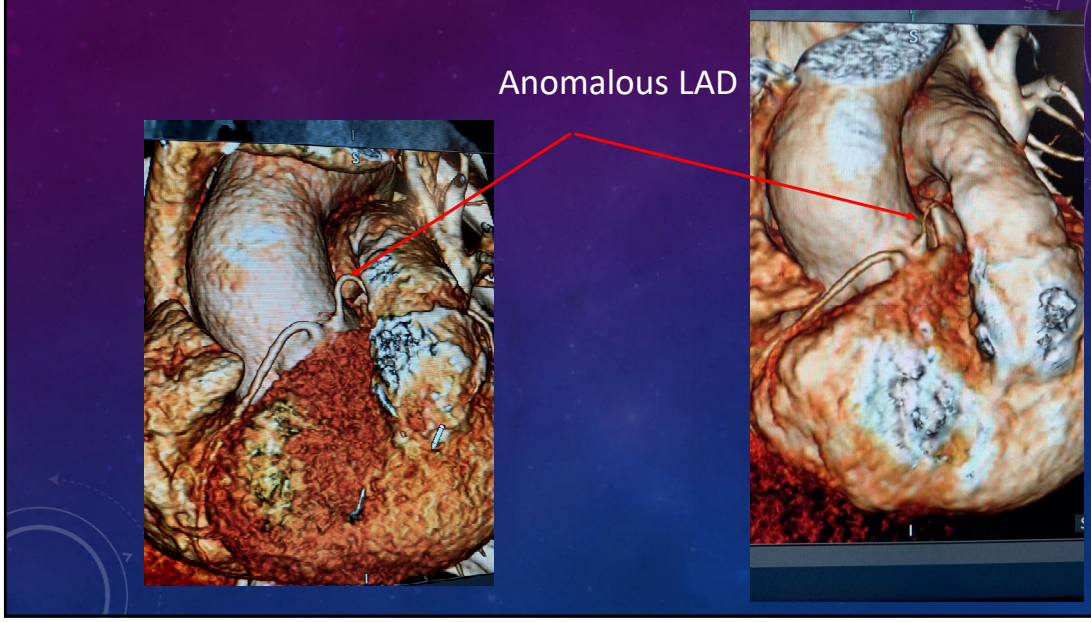
2

HIERARCHY OF PROCEDURAL COMPLEXITY

	Valved Conduit	Homograft	Native RVOT
Anatomy	Predictable (VIV app)	Partially predictable	Heterogenous
Tissue	Rigid	Semirigid	Distensible, large, pulsatile, compliant
Landing Zone	Surgical Valve	Calcified conduit	Poorly-defined
Size	Usually < 30 mm	Usually < 25 mm	Usually > 30 mm
Risk of Coronary compression	+	++	++
Suitability for commercially available devices	+++	+++	+/-

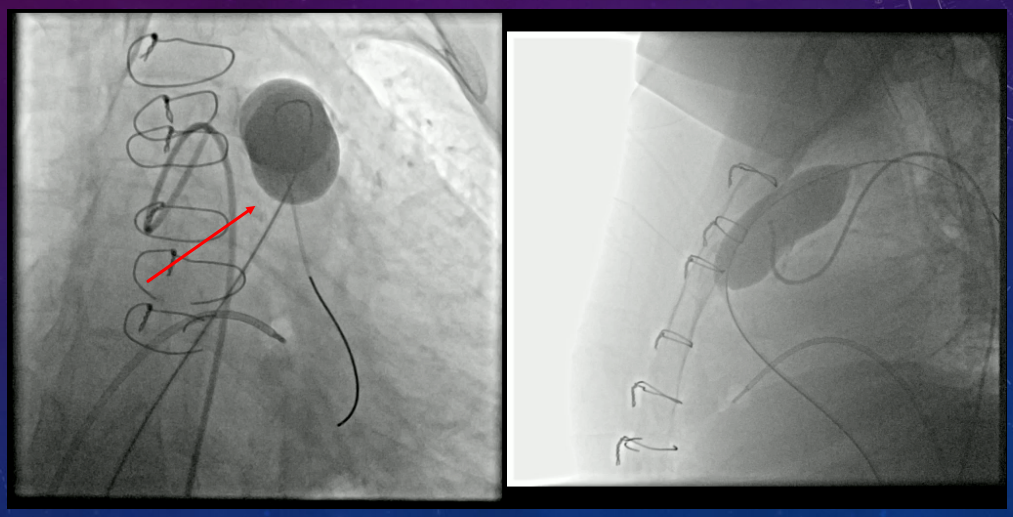
3

CORONARY COMPRESSION: CTA



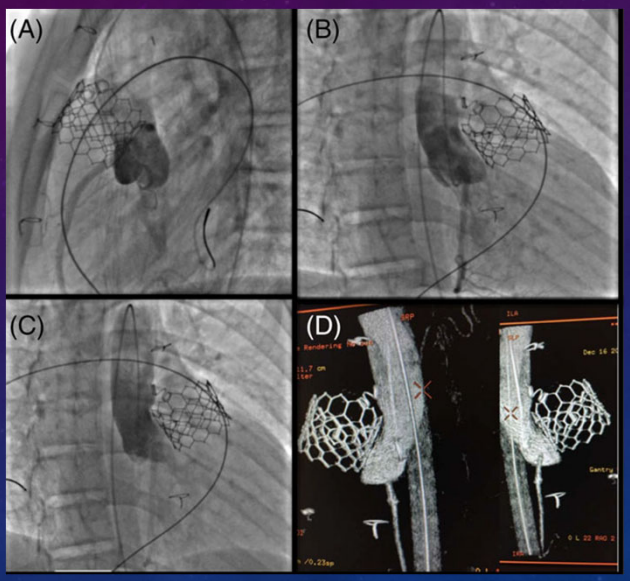
4

CORONARY COMPRESSION TESTING



5

AORTIC COMPRESSION



Sinha et al. CCI

6

CLINICAL VIGNETTE

- 22 yo man with h/o Tetralogy of Fallot s/p repair (5/23/97) with subsequent placement of a 25 mm Mosaic valved RVOT conduit with bovine pericardial RVOT patch (3/4/08)
- Previous cardiac interventions. Transannular patch repair, patch angioplasty of proximal LPA, closure of VSD and suture closure of PF0, 1997. **25 mm Mosaic valve in the right ventricular outflow tract, pericardial RVOT patching (2008).**

7

TRANSCATHETER PULMONARY VALVE REPLACEMENT WITH S3

INDICATION: BIOPROSTHETIC VALVE FAILURE (25 MM MEDTRONIC MOSAIC)

CRITERIA FOR INTERVENTION: PULMONIC STENOSIS WITH RIGHT VENTRICULAR ENLARGEMENT

PLAN: VALVE REMODELING FOLLOWED BY IMPLANTATION OF 26 MM S3

8

MRI VOLUMES

	2004	2007	2009	2011	2013	2015	2017	2019
RV EDV (mL)	13	185	141	189	216	220	231	293
RV EDVI (mL/m²)	146	176	119	142	127	126	130	162
RV ESV (mL)	76	116	94	121	149	138	157	188
RV ESVI (mL/m²)	85	110	79	92	83	79	88	104
RVEF (%)	42	37	33	36	35	36	32	36%
Pulmonary insufficiency **Right versus left flow discrepancy**	39%	42%0	-	No PI 60% right, 40% left	No PI 60% right, 40% left	No PI 65% right, 35% left	10% 65% right 35% left	20% 57% right 43% left
LVEF (%)	60	61	74	65	62	-	56	
Aortic root (cm)					3.87	3.7 x x 3.8	3.5 cusp to commissure. 4.1 commissure-commissure	
LPA							8 x 9 mm	

9

ECHO

- Tetralogy of Fallot, status post repair with most recent intervention being 25 mm Mosaic RV to PA conduit.
- **Conduit with peak velocity of 3.7 m/s for a peak gradient of 55 mm Hg and a mean gradient of 32 mmHg.**
- Mild homograft insufficiency.
- Right ventricle with mild enlargement and mildly reduced systolic function.
- Trace tricuspid insufficiency with RVSP estimate 47 mm Hg plus right atrial pressure.
- Normal left ventricular size and function.
- No residual VSD.
- Mildly dilated sinuses of Valsalva at 38 mm.

10

INDICATIONS FOR PVR

Clinical indication for intervention on a dysfunctional right ventricular outflow tract (RVOT) conduit or surgical bioprosthetic pulmonary valve that has ≥ moderate regurgitation, and/or a mean RVOT gradient ≥35 mm Hg if:

- Symptoms (Class I)
- Asymptomatic with 2 of the following (Class IIa): ≥ mild RV or LV dysfunction, severe RV dilatation (RVEDVI 160 ml/m2, RVESVI: 80 ml/m2), RV systolic pressure 2/3 of systemic, RV end-diastolic volume = 2 x LVEDV.

Minneapolis Heart Institute | Allina Health Abbott Northwestern Hospital | HOPE Discovered Here | Minneapolis Heart Institute Foundation

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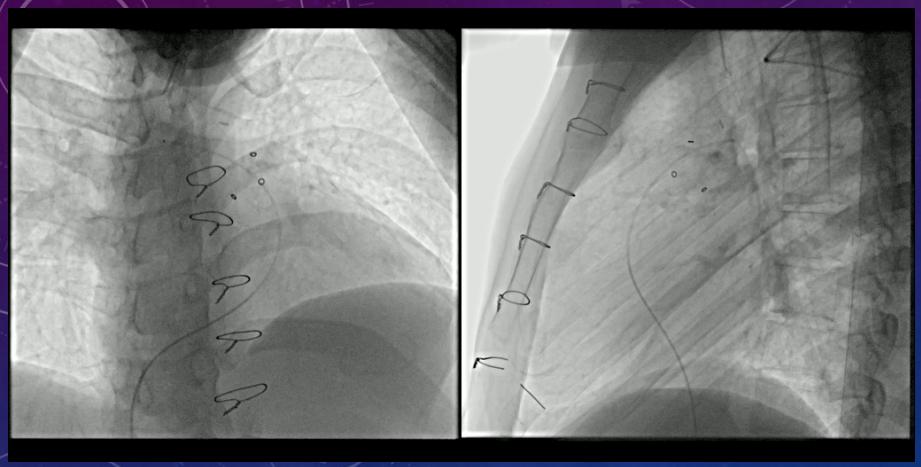
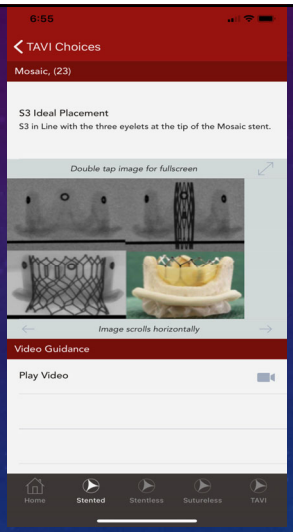
TPVR IN VALVED CONDUIT (25 MM MOSAIC)





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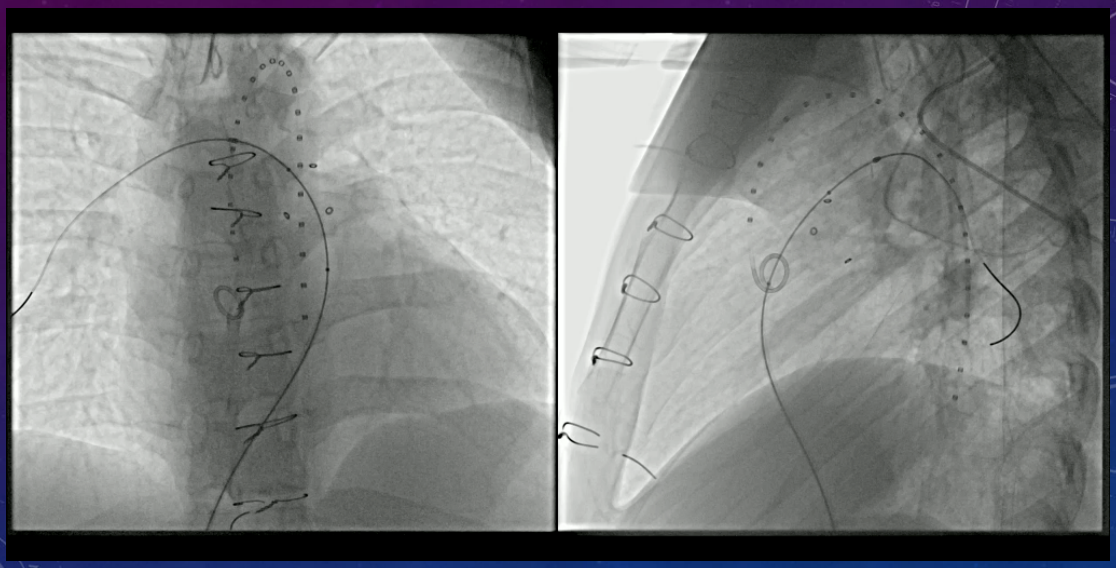
BVF: 22 mm Vida Balloon



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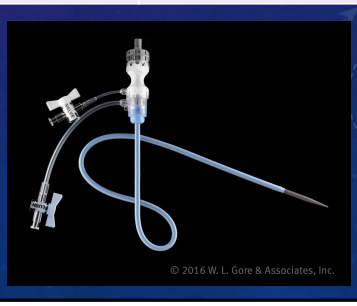
65 CM DRYSEAL FOR VALVE DEPLOYMENT

Valve	Sheath
29 mm S3	26 Dry seal
26 mm S3/Ultra	24 Dry seal
23 mm S3/Ultra	22 Fr Dry seal
20 mm S3/Ultra	20 Fr Dry seal



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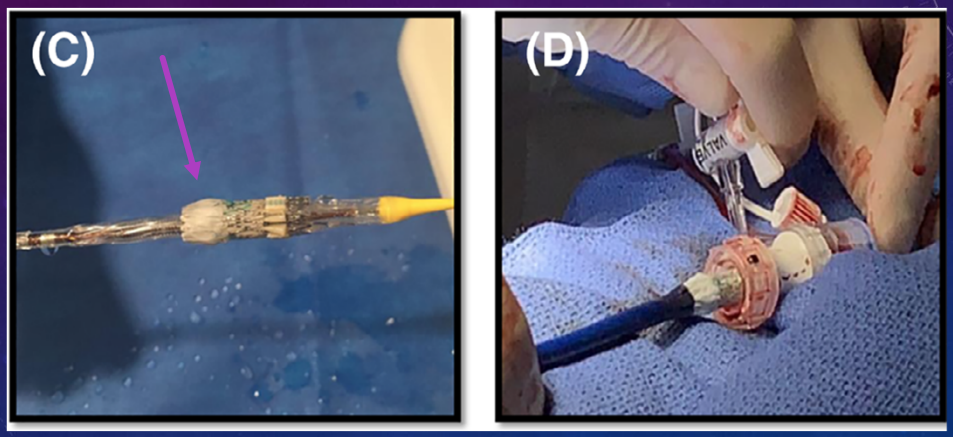
S3 VALVE DELIVERY AND DEPLOYMENT
OUTER SKIRT AWAY FROM NOSE CONE (OPPOSITE TO TAVR)



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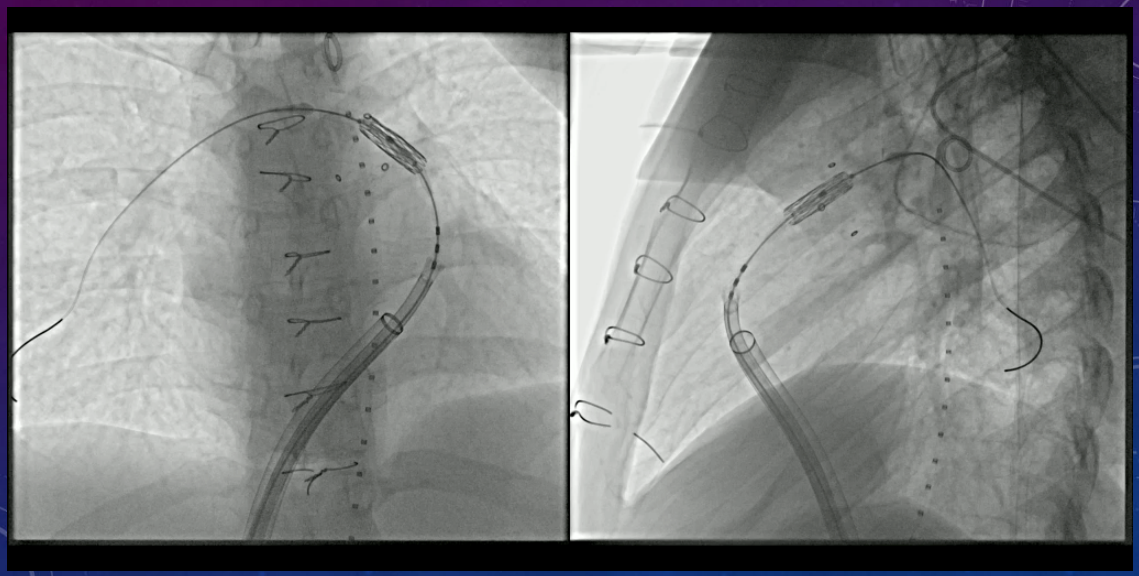
TPVR in Valved Conduit
(25 mm Mosaic) VIV 26 mm S3



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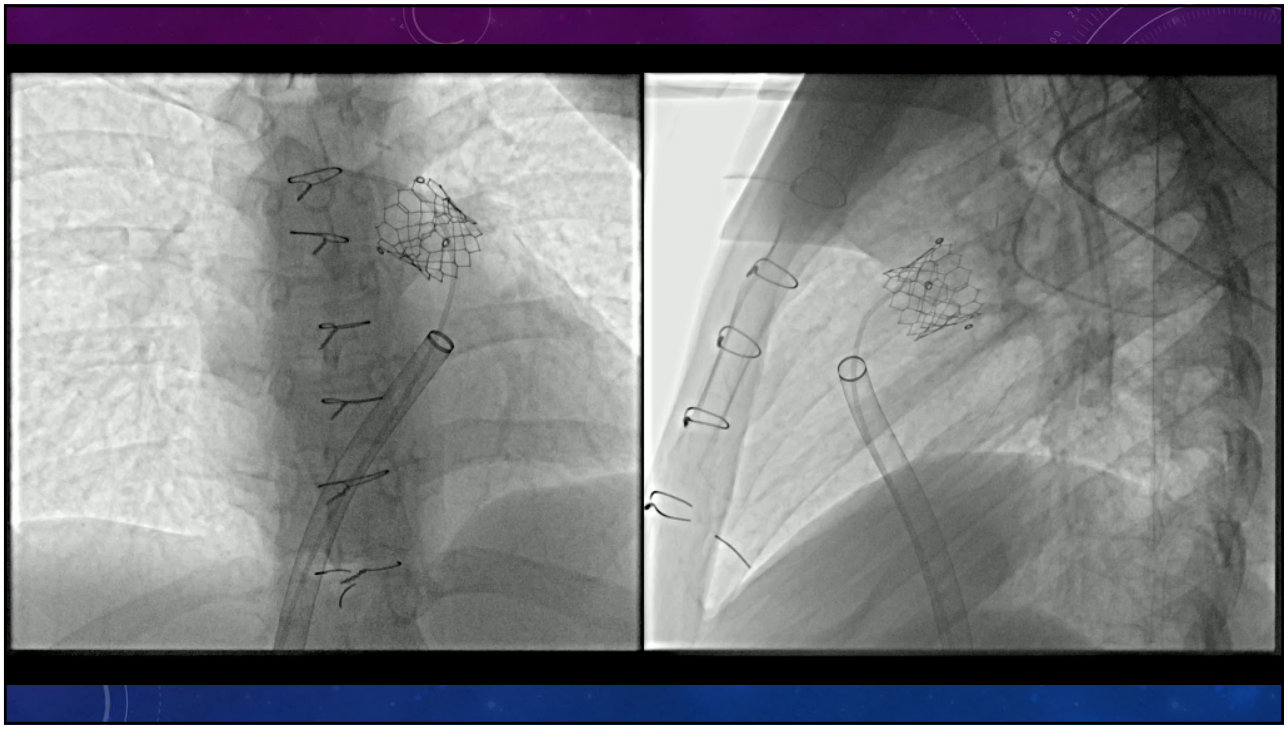

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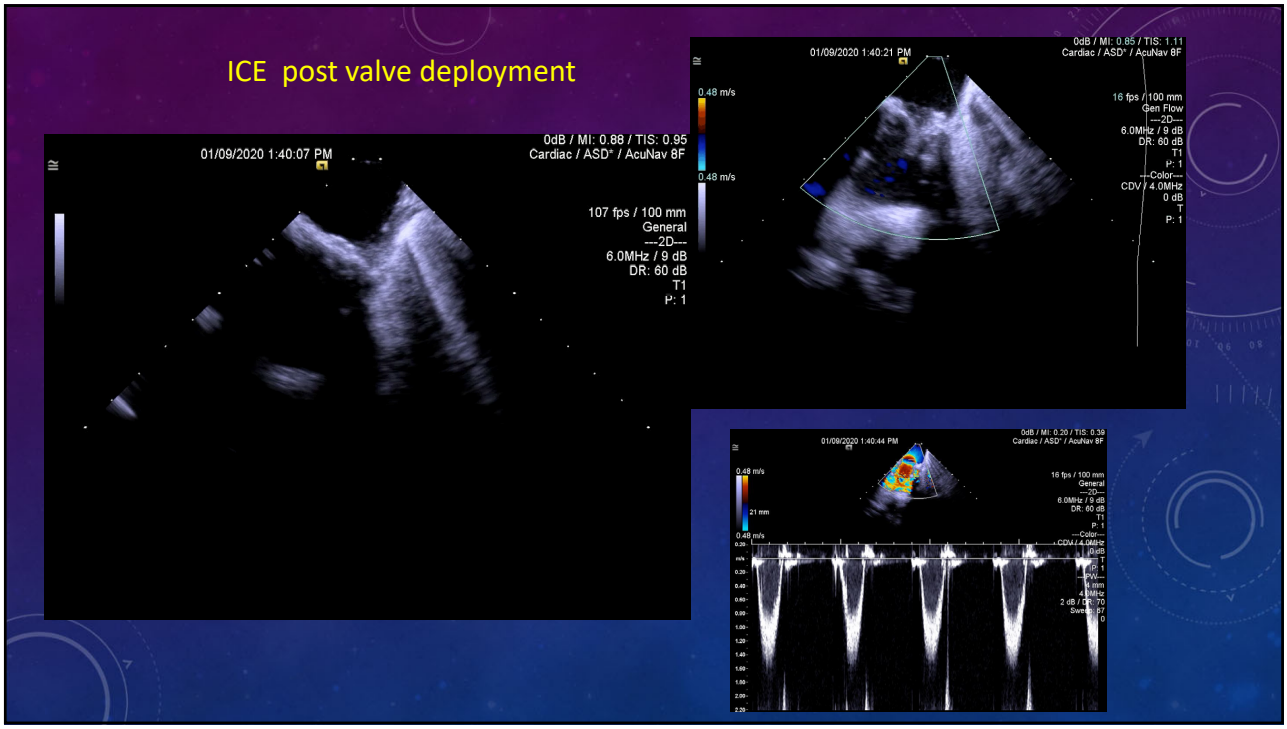
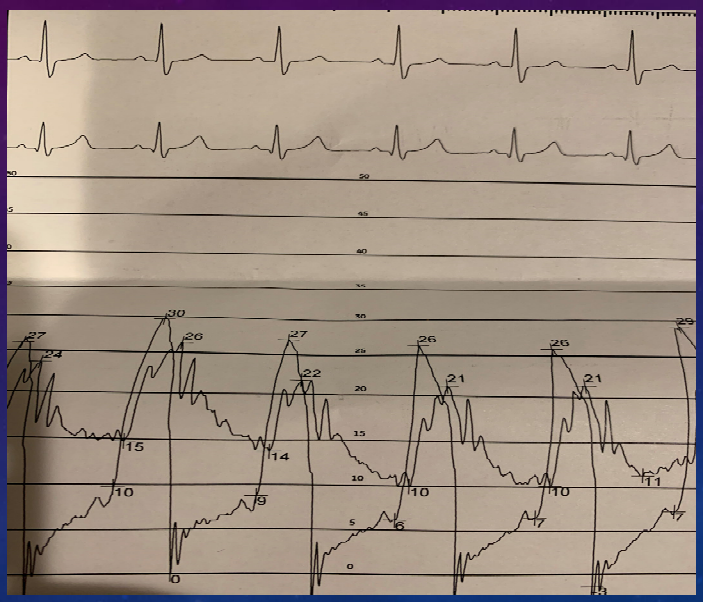

ICE post valve deployment
01/09/2020 1:40:07 PM
0dB / MI: 0.88 / TIS: 0.95
Cardiac / ASD* / AcuNav 8F
107 fps / 100 mm
General
---2D---
6.0MHz / 9 dB
DR: 60 dB
T1
P: 1
01/09/2020 1:40:21 PM
0dB / MI: 0.85 / TIS: 1.11
Cardiac / ASD* / AcuNav 8F
0.48 m/s
16 fps / 100 mm
Gen Flow
---2D---
6.0MHz / 9 dB
DR: 60 dB
T1
P: 1
---Color---
CDV / 4.0MHz
0 dB
T
P: 1
01/09/2020 1:40:44 PM
0dB / MI: 0.20 / TIS: 0.39
Cardiac / ASD* / AcuNav 8F
0.48 m/s
21 mm
16 fps / 100 mm
General
---2D---
6.0MHz / 9 dB
DR: 60 dB
T1
P: 1
---Color---
---PW---
4.0MHz

18

Residual Gradient < 10 mmHg



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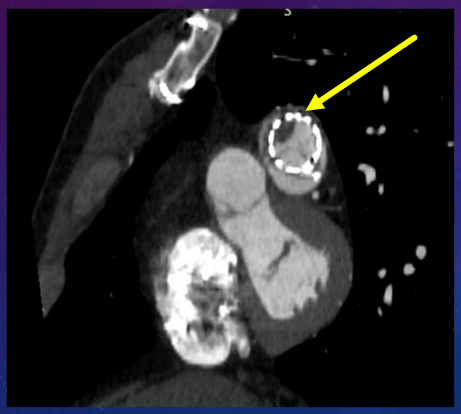
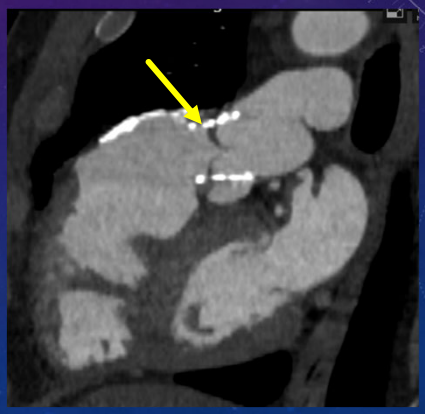
30-DAY CTA: 50% HALT INCIDENCE





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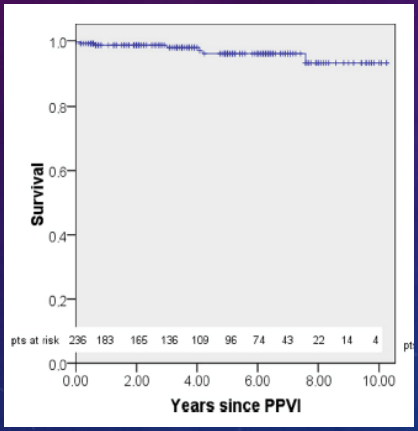
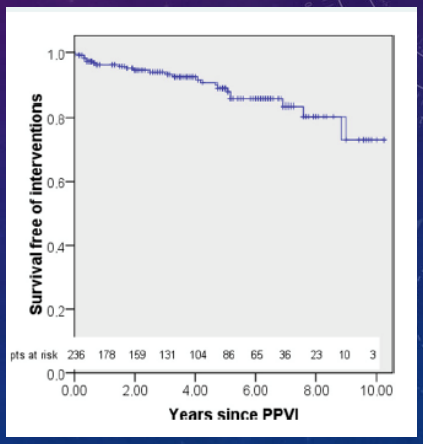
LONG-TERM RESULTS AFTER TPVR

10-year survival 93%



10-year survival free of re-intervention 72 %



Georgiev et al. JACC Int 2019

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RVOT INTERVENTIONS

- Different substrates with increased complexity
- Dedicated devices to treat Native RVOT needed
- Unmet clinical need in 2020
- Investigational devices are likely to expand the pool of patients that can benefit from TPVR

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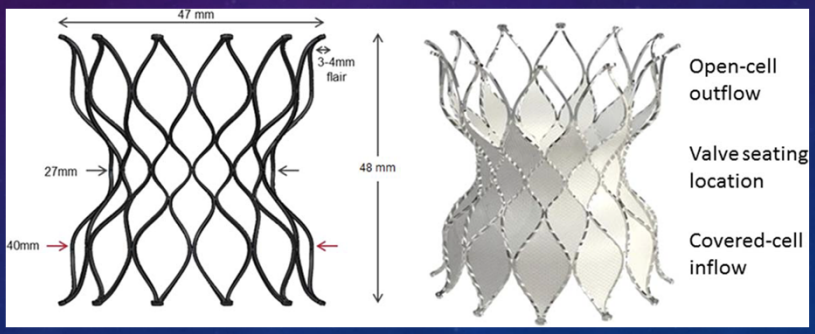
DEVICE ENHANCEMENTS: ALTERRA

First human implant of the Alterra Adaptive Prestent™: A new self-expanding device designed to remodel the right ventricular outflow tract



Zahn CCI 2018

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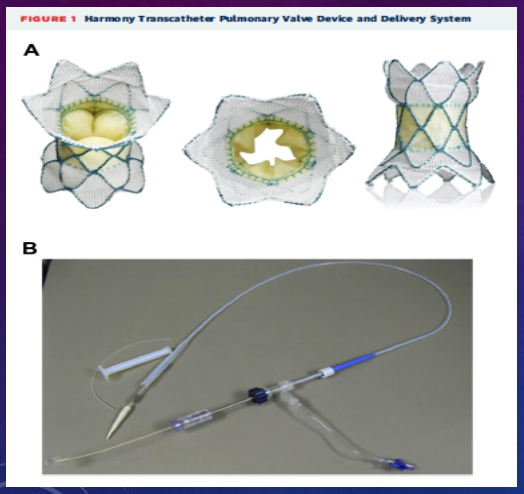
HARMONY VALVE



- Porcine pericardium
- Self-expanding nitinol frame
- 55 cm long
- 23.5 at the valved section
- Inflow 42 mm
- Outflow 34 mm
- 25 Fr delivery system

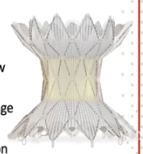
Common Design Characteristics:

- AOA-treated Porcine pericardium tissue
- Nitinol wire
- Knitted PET cloth covering
- Single delivery system for 2 valve sizes (TPV 22 and TPV 25)

TPV 22

Modified TPV 25:

- Identical tissue valve
- Shorter in length
- Wider diameters on the inflow and outflow ends of device
- Designed to treat broader range of patient population
- Modified to make implantation of the device more predictable



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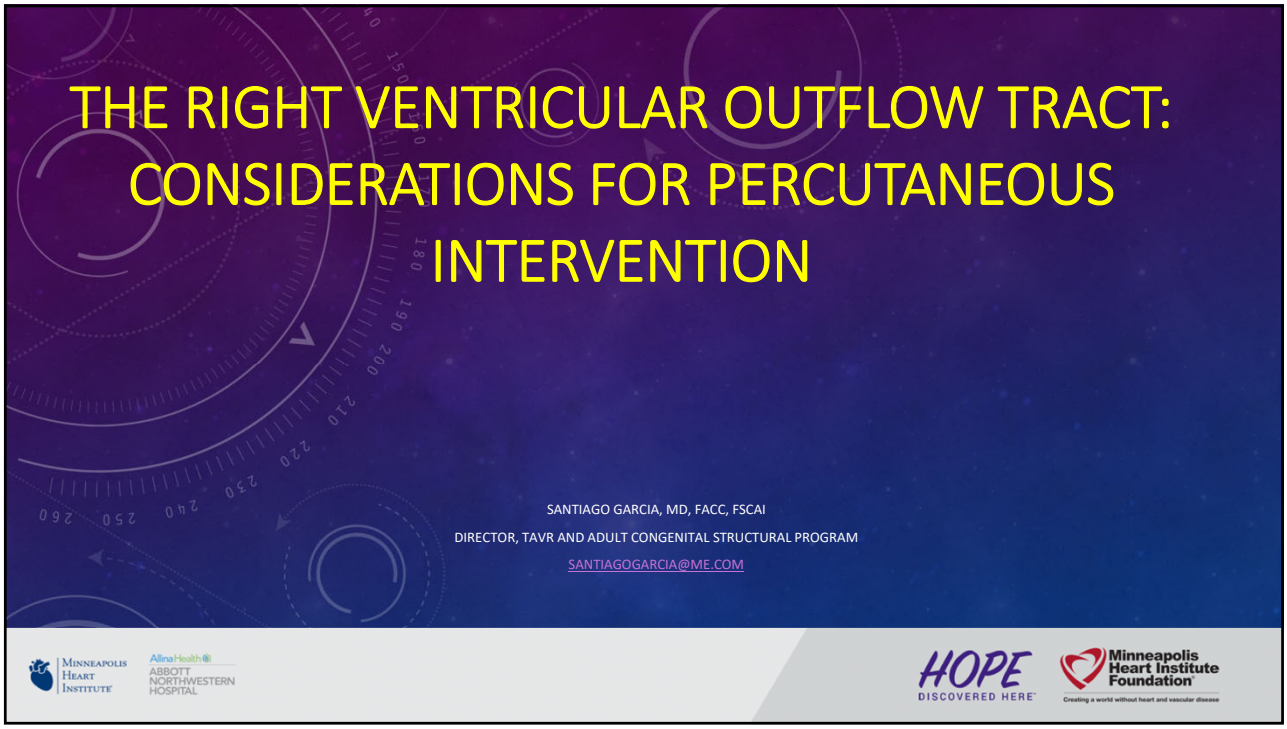
THE RIGHT VENTRICULAR OUTFLOW TRACT: CONSIDERATIONS FOR PERCUTANEOUS INTERVENTION
SANTIAGO GARCIA, MD, FACC, FSCAI
DIRECTOR, TAVR AND ADULT CONGENITAL STRUCTURAL PROGRAM
SANTIAGOGARCIA@ME.COM
Minneapolis Heart Institute
Allina Health
Abbott Northwestern Hospital
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