**MHIF FEATURED STUDY:**

**SOLVE-CRT**

**Stimulation Of the Left Ventricular Endocardium for Cardiac Resynchronization Therapy in Non-Responders, Previously Untreatable and High-risk Upgrade Patients**

<table>
<thead>
<tr>
<th>CONDITION:</th>
<th>PI:</th>
<th>RESEARCH CONTACT:</th>
<th>SPONSOR:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Heart Failure with previously untreatable CRT or High-Risk Upgrades (HRU)*</td>
<td>Jay Sengupta, MD</td>
<td>Jessie Whelan <a href="mailto:Jessica.Whelan@allina.com">Jessica.Whelan@allina.com</a></td>
<td>EBR Systems</td>
</tr>
</tbody>
</table>

**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 untreated 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.*
Overview of Pulmonary Valve Dysfunction and Indications for Intervention

AHCD

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

Disclosures

- Grant funding
  - Siemens Healthineers
  - The Jon DeHaan Foundation
**CHD is an Adult Disease**

Changing Mortality in CHD

- 85% increase in complex disease

Changing prevalence of CHD in the EU by age group.

- Median Mortality Complex Disease = 2 yo
- Median Mortality All CHD = 57 yo
- Complex Disease = 23 yo

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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
ACHD Mortality by Lesion

Referral to Specialized ACHD Centers and Mortality.
Changing ACHD Admission Demographics

% > 60 years of age 2003-2012.

- 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

National Inpatient Sample Database (195,306 admissions)

Intervention in ACHD

- 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

Kogon et al. ATS. 2013. vol 95(4). 1377-1382. Surgery in adults with CHD, risk factors for morbidity and mortality
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

Outcomes for Surgical PVR

- **137 Surgical PVR — median age 13**
  - 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

- **945 Survival PVR (Toronto) — median age 6**
  - 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

Seminars in thoracic and cardiac surgery
Outcomes of Right Ventricular to Pulmonary Artery Conduit for Biventricular Repair
Caldarone et al. JTCVS 2000;Volume 120 (6) 1022–1031.
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 outflow tract/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
TOF with Severe PS/PA – Ductal Dependent

Tetralogy of Fallot Repair

• Close the VSD
• Relieve RVOT obstruction
  • Pulmonary valvotomy/commissurotomy
  • RV muscle bundle resection
  • Valve sparing patch
  • Transannular patch
  • RV-PA conduit
• Most severe forms
  • Palliative procedure before repair
    • Unifocalization of collaterals
    • Aortopulmonary shunt
Tetralogy of Fallot: Residual Hemodynamic Lesions

<table>
<thead>
<tr>
<th>Description</th>
<th>Lesions</th>
</tr>
</thead>
<tbody>
<tr>
<td>TOF with Pulmonary stenosis</td>
<td>Pulmonary stenosis, pulmonary insufficiency, RV dilation and dysfunction, aortic root dilation</td>
</tr>
<tr>
<td>TOF with Pulmonary artery atresia</td>
<td>RV-PA conduit, branch pulmonary artery or distal pulmonary artery stenosis, conduit insufficiency, RV dilation and dysfunction, aortic root dilation</td>
</tr>
<tr>
<td>TOF with Absent pulmonary valve</td>
<td>RV-PA conduit stenosis or insufficiency, airway abnormalities, pulmonary artery dilation</td>
</tr>
</tbody>
</table>

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

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 doi:10.1038/npcardio0682
• 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%

Procedure | Residual Hemodynamic Abnormalities
---|---
Atrial switch | Systemic or pulmonary stenosis (pulmonary root); Transpulmonary root or branch narrowing or stenosis
Arterial switch | Neo-pulmonary root or branch pulmonary artery stenosis, pulmonary insufficiency
Rastelli | Neo-aortic root dilatation, stenosis or insufficiency; Compromise of re-implanted coronary arteries
Nikaidoh | Obstruction of the right ventricular outflow tract, pulmonary insufficiency; Obstruction of left ventricular outflow tract by a non-compliant patch
Simple Transposition (VA discordance)
Usually presents at birth: cyanosis

Transposition of great arteries

American Heart Association/Heart.org
CHD.gov

\[\text{Aorta (transposed)}\]
\[\text{Pulmonary artery (transposed)}\]

\[\text{d-TGA} \]
Atrial ventricular concordance
Ventricular-Arterial discordance

\[\text{Atrial Switch} \]
Atrial ventricular discordance
Ventricular-Arterial discordance

\[\text{Arterial Switch} \]
Atrial ventricular Concordance
Ventricular-Arterial concordance

Cardiology Clinics 2015 DOI: 10.1016/j.ccl.2015.07.012
Operation for d-TGA by year

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
### Indications for PVR in ACHD TOF

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

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

- **Melody®**
  - Age ≥ 3 years/weight ≥ 30 kg
  - Original conduit diameter ≥ 16 mm
  - Echocardiographic RVOT conduit dysfunction
  - Patients classified as NYHA class II, III, or IV: Doppler mean gradient ≥ 35 mmHg or ≥ moderate PR

- **SAPIEN™**
  - Weight > 35 kg
  - In situ conduit ≥ 16 mm and ≤ 24 mm
  - ≥ 3 PR (PTE) or PR > 40% (MR)
  - With or without stenosis

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**Hijazi PPVI 2015**

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

- The following situations may warrant intervention following repair [12]:
  - 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 severe RV systolic pressure >50 mmHg, TR velocity >3.5 m/s
  - PVR should be considered in asymptomatic patients with severe PR and/or PVR when at least one of the following criteria is present:
    - Decrease in objective exercise capacity
    - Progressive RV dilatation
    - Progressive RV systolic dysfunction
    - Progressive TR (at least moderate)
    - RVOT with RV systolic pressure >50 mmHg
    - Sustained atrioventricular arrhythmias

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**Percutaneous pulmonary valve implantation: the Munich experience**

Effect of PVR on the RV meta-analysis: 48 studies in 3118 pts

- RVEDV indexed
- RVESV indexed
- PI %

- Not shown to change VT or mortality
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
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

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

<table>
<thead>
<tr>
<th>Level of assessment</th>
<th>(mean±SD) in echo (ml/sec)</th>
<th>Spearman’s r²</th>
<th>Bland-Altman Bias ± 1.96 SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pulmonary veins</td>
<td>4.9±1.3 (8.9)</td>
<td>0.430</td>
<td>-0.06 to 1.26</td>
</tr>
<tr>
<td>Mitral ortricus ark</td>
<td>4.7±1.2 (10.3)</td>
<td>-0.03</td>
<td>-0.13 to 1.15</td>
</tr>
<tr>
<td>Right-left pulmonary veins</td>
<td>6.7±1.4 (18.9)</td>
<td>0.342</td>
<td>-0.03 to 1.52</td>
</tr>
<tr>
<td>Right ventricular ejection fraction</td>
<td>0.6±0.4 (8.3)</td>
<td>0.270</td>
<td>-0.15 to 0.28</td>
</tr>
</tbody>
</table>

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
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.
- Multi-detector row cardiac computed tomography accurately quantifies right and left ventricular size and function compared with cardiac magnetic resonance.
- 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.
- Assessment of right ventricular function with 320-slice volume cardiac CT: comparison with cardiac magnetic resonance imaging.

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

Previous Conduit

Coronary Origin and Height

Calcification and Branch PA
The need for 4D imaging
Dynamism of the Native RVOT

<table>
<thead>
<tr>
<th></th>
<th>n = 19</th>
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<tbody>
<tr>
<td><strong>Circumferential Pulsatility</strong></td>
<td></td>
</tr>
<tr>
<td>Maximum area (mm²)</td>
<td>636 (530, 791)</td>
</tr>
<tr>
<td>Minimal area (mm²)</td>
<td>462 (410, 622)</td>
</tr>
<tr>
<td>Max phase % difference*</td>
<td>26% (20%, 32%)</td>
</tr>
<tr>
<td><strong>Eccentricity of Annulus</strong></td>
<td></td>
</tr>
<tr>
<td>Minor axis (cm)</td>
<td>2.38 (2.05, 2.56)</td>
</tr>
<tr>
<td>Major Axis (cm)</td>
<td>2.81 (2.55, 3.58)</td>
</tr>
<tr>
<td>Major/Major Axis Ratio</td>
<td>1.23 (1.09, 1.46)</td>
</tr>
<tr>
<td><strong>Longitudinal Shortening of MPA</strong></td>
<td></td>
</tr>
<tr>
<td>Max phase MPA length (annulus to PA) (cm)</td>
<td>3.78 (3.30, 4.45)</td>
</tr>
<tr>
<td>Min phase MPA length (annulus to PA) (cm)</td>
<td>3.10 (2.20, 3.50)</td>
</tr>
<tr>
<td>MPA minimal Phase</td>
<td>45 (40, 80)</td>
</tr>
<tr>
<td>Major Axis (cm)</td>
<td>3.10 (2.44, 3.70)</td>
</tr>
<tr>
<td>Minor Axis (cm)</td>
<td>2.27 (1.80, 2.90)</td>
</tr>
<tr>
<td>MPA Variability†</td>
<td>28.1% (6.2%, 41.7%)</td>
</tr>
</tbody>
</table>
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%

HR 3.7 for gradient > 15 mmHg
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

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
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

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
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

Dynamism of the Native RVOT

![Images of Dynamism of the Native RVOT]
RVOT Open Intervention

Karol Mudy, MD
Cardiac Surgery

Conflict of Interest

• None
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
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.
8. Single coronary artery arising from the right facing aortic sinus immediately adjacent to the dilated main pulmonary artery.
• ACHD meeting
• Recommendation for sub-aortic membrane resection with AV preservation and surgical pulmonary valve replacement with RVOT revision
Operating Room

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

CARDIOPULMONARY BYPASS DATA:
• Crossclamp time 62 minutes.
• Cardiopulmonary bypass time 183 minutes.
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
• POD #1 Chest washout and closure/ ECMO removal
• POD #2 Extubated
• POD #4 Telemetry
• POD #7 Discharged home
THANK YOU

Repair of Truncus Arteriosus

Rastelli repair with patched septum and new pulmonary valve/artery

- Truncus
- VSD
- New valve and artery
- Patch
Repair of Truncus Arteriosus

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
Operating Room

- Redo sternotomy, right axillary cannulation
- Redo valved conduit replacement from the RV to main pulmonary artery
- Removal of main and left PA stent
- Trimming of right PA stent

- 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
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
Operating Room

- RV pressures in low 60 mm Hg range

Postoperative Course

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

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

Structural CT
Plan

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

THANK YOU
THE RIGHT VENTRICULAR OUTFLOW TRACT: CONSIDERATIONS FOR TRANSCATHETER INTERVENTIONS

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DIRECTOR, TAVR AND ADULT CONGENITAL STRUCTURAL PROGRAM
SANTIAGOGARCIA@ME.COM

HIERARCHY OF PROCEDURAL COMPLEXITY

TPVR in Valved conduit

TPVR in Homograft

TPVR in Native RVOT
### Hierarchy of Procedural Complexity

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

### Coronary Compression: CTA

Anomalous LAD
CORONARY COMPRESSION TESTING

AORTIC COMPRESSION

Sinha et al. CCI
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).

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
### MRI VOLUMES

<table>
<thead>
<tr>
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<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>RV EDV (mL)</td>
<td>13</td>
<td>185</td>
<td>141</td>
<td>189</td>
<td>216</td>
<td>220</td>
<td>231</td>
<td>293</td>
</tr>
<tr>
<td>RV EDVI (mL/m²)</td>
<td>146</td>
<td>176</td>
<td>119</td>
<td>142</td>
<td>127</td>
<td>128</td>
<td>130</td>
<td>162</td>
</tr>
<tr>
<td>RV ESV (mL)</td>
<td>76</td>
<td>116</td>
<td>94</td>
<td>121</td>
<td>149</td>
<td>138</td>
<td>157</td>
<td>188</td>
</tr>
<tr>
<td>RV ESVI (mL/m²)</td>
<td>85</td>
<td>110</td>
<td>79</td>
<td>92</td>
<td>83</td>
<td>79</td>
<td>88</td>
<td>104</td>
</tr>
<tr>
<td>RVEF (%)</td>
<td>42</td>
<td>37</td>
<td>33</td>
<td>36</td>
<td>35</td>
<td>36</td>
<td>32</td>
<td>36</td>
</tr>
<tr>
<td>Pulmonary insufficiency</td>
<td>39%</td>
<td>42%</td>
<td>-</td>
<td>No PI</td>
<td>No PI</td>
<td>No PI</td>
<td>10%</td>
<td>20%</td>
</tr>
<tr>
<td>Right versus left flow discrepancy</td>
<td>60% right, 40% left</td>
<td>60% right, 40% left</td>
<td>65% right, 35% left</td>
<td>65% right, 35% left</td>
<td>65% right, 35% left</td>
<td>57% right, 43% left</td>
<td></td>
<td></td>
</tr>
<tr>
<td>LVEF (%)</td>
<td>60</td>
<td>61</td>
<td>74</td>
<td>65</td>
<td>62</td>
<td>-</td>
<td>56</td>
<td></td>
</tr>
<tr>
<td>Aortic root (cm)</td>
<td>3.87</td>
<td>3.7 x 3.8</td>
<td>3.5 cusp to commissure, 4.1 commissure-commissure</td>
<td></td>
<td></td>
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<tr>
<td>LPA</td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
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<td>8 x 9 mm</td>
</tr>
</tbody>
</table>

### 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.
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.

TPVR IN VALVED CONDUIT (25 MM MOSAIC)
65 CM DRYSEAL FOR VALVE DEPLOYMENT

<table>
<thead>
<tr>
<th>Valve</th>
<th>Sheath</th>
</tr>
</thead>
<tbody>
<tr>
<td>29 mm S3</td>
<td>26 Dry seal</td>
</tr>
<tr>
<td>26 mm S3/ Ultra</td>
<td>24 Dry seal</td>
</tr>
<tr>
<td>23 mm S3/ Ultra</td>
<td>22 Fr Dry seal</td>
</tr>
<tr>
<td>20 mm S3/ Ultra</td>
<td>20 Fr Dry seal</td>
</tr>
</tbody>
</table>
S3 VALVE DELIVERY AND DEPLOYMENT
OUTER SKIRT AWAY FROM NOSE CONE (OPPOSITE TO TAVR)

TPVR in Valved Conduit
(25 mm Mosaic) VIV 26 mm S3
ICE post valve deployment
Residual Gradient $< 10 \text{ mmHg}$

30-DAY CTA: 50% HALT INCIDENCE
**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
DEVICE ENHANCEMENTS: ALTERRA

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

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

Modified TPV 25:
- Identical tissue valve
- Shorter in length
- Water 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
THE RIGHT VENTRICULAR OUTFLOW TRACT: CONSIDERATIONS FOR PERCUTANEOUS INTERVENTION

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SANTIAGOGARCIA@ME.COM