Update on Percutaneous Interventions in CHD and Valvular Leaks

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Disclosure Statement of Financial Interest

Within the past 12 months, I or my spouse/partner have had a financial interest/arrangement or affiliation with the organization(s) listed below.

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<tr>
<th>Affiliation/Financial Relationship</th>
<th>Company</th>
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<td>Grant/Research Support</td>
<td>Philips</td>
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<td>Consulting Fees/Honoraria</td>
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* ( >$50,000 = Significant; 10-50,000 = moderate; <10,000 = modest )
INTERVENTIONS FOR CONGENITAL HEART DISEASE
Guidelines in CHD

**Isolate Interventions – Jan 2011 – March 2013**

Moore JW et al. J Am Coll Cardiol. 2014;64(23):2439-2451

N= 4,152 isolated procedures
NCDR-IMPACT Registry: Jan 2011 – March 2013

Best Available Benchmark
Largest and most complete registry available for patients with CHD undergoing isolated (#6) transcatheter interventions

Moore JW et al. J Am Coll Cardiol. 2014;64(23):2439-2451
**Transcatheter Interventions in CHD: Transcatheter Pulmonary Valve Replacement**

- **Indications**
  - RVEDVI > 150 cc/m² + RVOT/PA > 2/3 Ao (best assessed by CMR)
  - RVESVI > 80 cc/m² + QRS > 140 ms (best assessed by CMR)
  - Sustained tachyarrhythmia + RVOT/PA 35 mmHg
  - RVOT aneurysm + LVEF < 50%

- **Melody Valve** is the only one FDA approved (HDE)
- **Ongoing trial with the Sapien Edwards valve**
  - Regurgitant or stenotic RVOT conduit ≥ 16 mm diameter at implant
    - Moderate to severe regurgitation
    - Stenosis with mean gradient ≥ 35 mmHg
  - Existence of a full (circumferential) conduit
INTERVENTIONS FOR VALVULAR LEAKS

• Native Valves
  • Aortic
  • Pulmonic
  • Mitral
  • Tricuspid

• Prosthetic Valves
  • Biological
    • Surgical
    • TAVR
  • Mechanical

• Peri-prosthetic device (valve or ring)
Leaks in Native Outflow Valves

**Native Aortic**
- Jena Valve
  - Only TAVR technology approved in EU for native aortic valve regurgitation

**Native Pulmonary**

The Venus A-Valve® System consists of the following components:
- A self-expanding Nitinol multi-level support frame with a tri-leaflet porcine pericardium tissue valve
- A 20-22 French catheter delivery system
- Disposable loading system with crimping devices

- Technically more challenging
  - Bicuspid
  - Dysplastic
Leaks in Native Inflow Valves

- Technically the most challenging cardiac structure
Native Mitral
TMVR in native valve for severe MR

FIM (compassionate use)

TIARA-I valve – FIM Clinical Trial
(FDA Conditional approval)

- Seven medical centers between Europe and North America
- **USA:**
  - Lenox Hill Hospital – NYC (USA)
  - Columbia Presbyterian – NYC (USA)
  - Cedars-Sinai – Los Angeles (USA)
- **CANADA**
  - St. Paul Hospital – Vancouver (CA)
- **BELGIUM**
  - Middelheim University
- **GERMANY**
  - Bad Nauheim
  - University of Hamburg
Peri-Prosthetic Leaks

Current Indications for Closure

Hemolysis ➤ anemia

Heart failure

[gold] standard Rx: surgical treatment

• The conventional gold standard: Surgical Closure
  – Repair (direct suturing, patch closure, full-thickness autologous tissue) or replacement
  – Technically challenging with high morbidity/mortality
  – Re-operative mortality: 6-22%
  – Mortality rates steeply increase each successive re-operation

1st re-operation  15%
2nd re-operation  22%
3rd re-operation  35%

Echevarria Eur J Cardiothorac Surg 1991
Precise quantification remains challenging

Most semi-quantitative Doppler parameters of regurgitation severity are best applied in central regurgitation jets and might not be ideal to quantify the frequently diffuse and eccentric jets in PVL
Treatment Algorithm

Symptomatic PVL

High-Risk for PVE (>1 Major/1 Minor)

(-)Ga$^{+3}$-67 SPECT/CT or PET/CT

SxVR

(-) Repeated Ga$^{+3}$-67 SPECT/CT or PET/CT

6wk-IV Abx

(+ Repeated Ga$^{+3}$-67 SPECT/CT or PET/CT

Low-Risk for PVE (<1 Major/1 Minor)

Percutaneous Closure of PVL

Failure

Success
Aortic PVL

“clockface” PVL location diagram

are more complex to define than Mitral PVL
Closure of Aortic PVL

**Surgical**

- Retrograde approach is the most common

**TAVR**

- Post-TAVI PVL requires additional precautions

- **Malposition** *(too high or too low)*
  - Valve-in-valve

- **Severe calcification**
  - Post-dilatation
  - PVL occluder (usually staged)

- **Under-sizing**
  - Post-dilatation a/o PVL occluder
  - Consider surgical AVR

Alternative approaches are sometimes needed
Access Approaches for M-PVL

- transseptal
- retro-aortic
- percutaneous transapical
Closure of PVL and TMVR-ViV/ViR

Mitral PVL + ViV

Mitral PVL + ViR
# LHH experience Jan 2007 to Nov 2014

<table>
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<tr>
<th>Total number of patients</th>
<th>221</th>
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<tr>
<td>Males</td>
<td>64.1%</td>
</tr>
<tr>
<td>Age (years)</td>
<td>69±12.6</td>
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<tr>
<td>Time since last valve replacement (months)</td>
<td>55.9 (2-324)</td>
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<tr>
<td>Patients with one prosthetic valve</td>
<td>59.2%</td>
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<tr>
<td>Patients with two prosthetic valve</td>
<td>40.8%</td>
</tr>
<tr>
<td>Mean NYHA FC</td>
<td>3.2 ± 0.7</td>
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<tr>
<td>Pulmonary hypertension</td>
<td>47.7%</td>
</tr>
<tr>
<td>CHF</td>
<td>96.1%</td>
</tr>
<tr>
<td>Systemic hypertension</td>
<td>65.4%</td>
</tr>
<tr>
<td>Atrial fibrillation</td>
<td>54.9%</td>
</tr>
<tr>
<td>Coronary artery disease</td>
<td>45.8%</td>
</tr>
<tr>
<td>Chronic renal insufficiency</td>
<td>28.8%</td>
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<tr>
<td>PPM</td>
<td>33.3%</td>
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Demographics and Outcomes

### Indications for PVL closure
- Hemolysis only: 20%
- CHF only: 19%
- Combined CHF and hemolysis: 61%
- Combined Mitral and Aortic PVL: 5%

### Transapical access
- Transapical: 57%
- Transseptal: 35%
- Transaortic: 18%

### Approach for crossing
- Transapical: 47%
- Transseptal: 35%
- Transaortic: 18%

### Type of device
- Amplatzer Ductal Occluder: 23%
- Amplatzer Muscular VSD Occluder: 7%
- Amplatzer Vascular Plug II: 67%
- Amplatzer Septal Occluder: 3%

### Technical success
- 96%

### Clinical success @ 2 years
- 78%

### Mean NYHA-FC pre: 3.2 ± 0.7%
### Mean NYHA-FC post: 1.8 ± 0.8%

### Hemolysis resolution: 76% at 30 days

Total f/u: 91%

Overall survival at 2 years: 85.7%
### Outcomes and Complications

<table>
<thead>
<tr>
<th>Event</th>
<th>Rate</th>
<th>Count</th>
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<tr>
<td>Failure to cross</td>
<td>5.8%</td>
<td>(13)</td>
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<tr>
<td>Valve interference</td>
<td>3.2%</td>
<td>(7)</td>
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<tr>
<td>Wire entrapped/conversion to surgery</td>
<td>0.5%</td>
<td>(1)</td>
</tr>
<tr>
<td>Acute embolization (&lt;1mo)</td>
<td>2.7%</td>
<td>(6)</td>
</tr>
<tr>
<td>Late embolization (&gt;1mo)</td>
<td>0.5%</td>
<td>(1)</td>
</tr>
<tr>
<td>Transseptal aortic perforation</td>
<td>0.5%</td>
<td>(1)</td>
</tr>
<tr>
<td>Cardiac perforation/Tamponade</td>
<td>0.9%</td>
<td>(2)</td>
</tr>
<tr>
<td>Hemothorax (requiring drainage)</td>
<td>2.7%</td>
<td>(6)</td>
</tr>
<tr>
<td>30-d mortality</td>
<td>1.4%</td>
<td>(3)</td>
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**Overall complication rate: 12.2%**
• Percutaneous transcatheter closure of surgical paravalvular leaks is emerging as the preferred approach
  – Low failure to cross and close the leaks (5.8%)
  – Low complication rate (12%)
  – High clinical success (85.7% at 2 years)
thank you

CRuiz@NSHS.edu
TIARA-I valve – FIM Clinical Trial
(FDA Conditional approval)

**INCLUSION**
- Severe symptomatic (NYFC III-IV) stage D (2014 AHA/ACC Guidelines)
  - Degenerative or Functional
  - Vena contracta ≥0.7 cm
  - Regurgitant volume ≥60 cc
  - ERO ≥0.4 cm²
  - MR by angio ≥3(+) 
  - Elevated Pul. Art pressures
- High surgical risk determined by the Heart Valve Team
  - STS-PROM ≥8%
- Meets the anatomical requirements
  - Annular circumference between 9-10 cm
  - A-P diameter (@A2-P2) between 23-27 mm
  - Inter-commissural distance between 31-34 mm

**EXCLUSION**
- DMR deemed reparable by Sx with acceptable surgical risk
- Prohibitive surgical risk (non-operable)
  - Too frail as ≥5 CSHA
  - Severe co-morbidities (severe COPD, CVA, dementia, malignancy with ≤1y survival etc.)
- Listed for cardiac transplantation
- Previous TAVR
- PCI with DES within 6 mo or BMS within 30 d
- Any previous valve surgery
- AMI ≤30 d
- Anatomic
  - Rheumatic MS, Severe MAC, EF≤ 25%, LVOTO, LA thrombus, sever RV dysfunction, PAP>70mmHg severe TR, CHD, etc.
Transcatheter Interventions in CHD: When to intervene in Cardiac Valves

- **Valvuloplasty**
  - *Pulmonic Stenosis:*
    - Symptomatic (*I*-B)
      - PSG>30 mmHg
      - PSG≤30 + RV dysfunction or shunt mediated cyanosis
  - Asymptomatic (*I*-B)
    - PSG>40 mmHg
  - *Aortic Stenosis:*
    - Symptomatic (*IIa*-B)
      - PSG>50 mmHg or AVA≤1 cm² with only less than moderate calcification and regurgitation
    - Asymptomatic (*IIa*-B/C)
      - PSG>60 mmHg or AVA≤0.6 cm² with less than moderate calcification and regurgitation
      - PSG>50 mmHg or AVA≤1.0 cm² with less than moderate calcification and regurgitation if patient activity demands higher C.O (pregnancy, sports, etc.)
conclusion

- Percutaneous transapical closure of M-PVL is the preferred approach for Mitral-PVL with a **Technical Success of 96%**
  - Specially useful when located between 11 and 7 o’clock)
  - Closure of the percutaneous ventricular access (6 Fr. to 12 Fr.) with off-label use of Amplatzer devices is safe and effective

- Concomitant severe AS is a major risk for procedure-related mortality
- No evidence of LV pseudoaneurys at the site of access on follow-up
  - 82% of patients alive at 6 mo. had multi-modality imaging follow-up
Transcatheter Interventions in CHD: When to intervene in CoA – PPA - Conduits

• **COA**
  – Discrete, or Post-op or Recurrent: Stenting (± covered) better than angioplasty
    • Resting PSG≥20 mmHg (>30 mmHg with exercise) and radial-femoral delay (I-B)
    • Resting PSG≥10 mmHg with LV dysfunction and radial-femoral delay (IIa-C)

• **Peripheral Pulmonary Artery Stenosis (IIa-B)**
  – Native (TOF, etc.), post-op (BTS, anterior translocation of the pulmonary artery – Le Compte's maneuver, etc.), Syndromic (William’s, Alagille’s, etc.)
  – RV>50% systemic BP or RV 25-50% systemic with either a shunt mediated cyanosis, RV dysfunction, <20% pul blood flow to 1 lung or severe PR

• **Conduits**
  – RV>50% systemic BP or RV 25-50% systemic with either a shunt mediated cyanosis, RV dysfunction
Transcatheter Interventions in CHD: When to intervene in Septal Defects

- ASD
  - Secundum type with good anatomical rims with evidence of volume overload of the RV without additional etiology (Qp:Qs≥1.5) (I-B)

- PFO
  - Recurrent cryptogenic embolizations while on therapeutic levels OAC (IIa-B)
  - Orthodeoxia-Platypnea syndrome (I-B)

- VSD (IIb-B)
  - Muscular VSD with LV volume overload without additional etiology (Qp:Qs≥1.5)
  - Post-op residual with Qp:Qs≥1.5
  - Qp:Qs<1.5 and recurrent endocarditis

- PDA
  - LV volume overload and reversible PAH (I-B)
  - Asymptomatic but audible (IIb-B)
Melody Valve Implant in Pulmonary Position

- Diagnosis
- Planning
- Preparing
- Delivering TPVR

- Landing
Peri-Prosthetic Leaks

• Uncommon yet serious complication of prosthetic valves
• Incidence:
  – Surgical valves: 2-10% in aortic, 7-17% in mitral position
  – TAVR: up to 60%
• Risk factors:
  – Intrinsic: Annular calcification, tissue friability, infection
  – Extrinsic: Suturing technique
• Early PVL (operating room): technical aspects
• Late PVL: suture dehiscence
• 1-5% of patients with PVL are symptomatic
  – Congestive heart failure (69% ≥ NYHA III)
  – Hemolytic anemia
Native Aortic

- Jena Valve

- Only TAVR technology approved in EU for native aortic valve regurgitation
Native Pulmonary

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• Disposable loading system with crimping devices
Native Tricuspid

Percutaneous Self-expanding heart valve for inferior vena cava implantation

Self-expanding percutaneous heart valve for inferior vena cava implantation. (A) The device was designed with the upper valve segment protruding into the right atrium and the lower segment for anchoring in the inferior vena cava. The middle segment constrained to facilitate fixation at the cavoatrial junction. The proximal stent segment is mounted with a tri-leaflet porcine pericardial valve and a sleeve covering the inside down to the base of the leaflets. (B) The valve was loaded into a 27 F catheter for implantation.
Native Tricuspid

Percutaneous Posterior Tricuspid Annuloplasty: Mitralign

Kay Annuloplasty
Native Tricuspid

4Tech Device
Septolateral dimension cinching

IVC Diameter 25-31mm
TriCinch Stent size: 43mm
Oversizing 40-65%
FIM by Dr. Francesco Maisano in July 2014