PARAVALVULAR LEAK POST TAVR

- David S Rubenson MD FACC FASE
- Founding Director, Cardiac Non-Invasive Laboratory
- Scripps Clinic Medical Group

Elements of Follow-up Post TAVR

- Visual Appearance
  - Size, position
  - Leaflet mobility, thickness
  - Color Doppler

- Hemodynamics
  - Mean gradient, peak velocity
  - EOA, ESS
  - Regurgitation (incl. aortic, ventricular);
  - LV, RV, PH

- Other Structures
  - Mitral valve, aorta, coronaries

- Cardiac Function
  - LV (size, SV, cardiac index)
  - RV (size, function)
An 86 yo patient post TAVR has moderate to severe persisting dyspnea due to CHF prompting TEE evaluation to assess aortic valve function. A 2D image of the aortic valve in short axis is shown. The most appropriate and accurate method to assess the magnitude of PVR in this patient would be:

1. AI pressure half-time
2. Quantitative doppler calculation of PISA derived regurgitant volume
3. The “Senning index”
4. Percent circumference method using color doppler
5. A multi-parametric approach
PARAVALVULAR AI INCIDENCE
Marked inconsistencies in data

- MODERATE/SEVERE: 0-24%
- MILD: 7-70%
- Potential Causes
  - Baseline risk profile of the population
  - Type of THV and implant approach
  - Method of assessment
  - Criteria applied in grading

Scripps Clinic Experience
2012 – 2017 1795 patients

- None: 39%
- Trace/Mild: 49%
- Mild: 12%
- Mod/Severe: 12%
CLINICAL IMPACT OF AI (including valvular and paravalvular)

- Registry Data JACC 2013;61:1585
- Studies from 2002-2012
- 13,000 patients
  - CoreValve 5200
  - Edwards 7200

- 3X increase mortality at 30 days (mod/severe)
- 2.3X increase mortality 1 year (mod/severe)
- Outcomes less clear in mild AI (other studies)

CASE 1: 85 y/o male

- Severe symptomatic AS – progressive CHF
  - AVA 0.6cm², gradient 97/53mmHg, PAP 61mmHg
  - LV EF 47%

- Additional History
  - Moderate MR
  - Paroxysmal AF
  - Hx VT - S/P AICD
  - Diabetes
  - Non-obstructive CAD
  - History of CVA with mild cognitive impairment
Transfemoral TAVR 26mm  
Sapien  
Cusp Insertion 24.5mm  
Cover Index 5.7%

Immediate post implant mod/sev AI  
(paravalvular and valvular)  
Post dilated – improved slightly
CLINICAL COURSE

- Immediate post implant mod/sev AI (paravalvular and valvular)
  - Post dilated – improved slightly
- Readmitted 1 month with acute CHF
  - EF decline to 31%, increased AI
  - Re-do TAVR with 26mm Valve-in-valve
- Improved central AI, persisting paravalvular AI
  - Amplatzer closure of post paravalvular leak
- Discharged improved

CASE 2: 93 y/o female

- Severe AS with recurrent HF NEF
  - AVA 0.54cm², Gradients84/50mmHg, PA 42mmHg
  - LV EF 84%
- Additional History
  - Mod-severe MR
  - Paroxysmal atrial fibrillation
  - Remote breast CA
Transfemoral TAVR 23mm
Sapien
Cusp Insertion 19mm
Cover Index 17%

- Unstable immediately post deployment
  - Diffuse ST elevations
  - Increased PA pressure to 80/50mmHg
  - Severe valvular AI
Immediate deployment 23mm Sapien Valve-in-Valve

MECHANISMS OF POST IMPLANT AORTIC REGURGITATION

Sinning et al JACC 2012;59:1134
PREDICTING POST TAVR AI

• Moderate or severe AI 5-22%
• Important determinants:
  • Undersizing the prosthesis
  • Extent of calcification of the valve complex
  • Prosthesis position in relationship to the annulus

• “Cover Index” : \[ \text{Prosthesis}_{\text{diam}} - \text{Cusp Insertion}_{\text{diam}} \]
  \[ \frac{\text{Prosthesis}_{\text{diam}}}{\text{Prosthesis}_{\text{diam}}} \]

• Mod or greater AI not seen if > 8% (JACC Intv 2009;2:821)

91yo male. Severe sx AS and interstitial lung disease. TAVR valve size 26mm based on 2D echo annular dimension of 22mm
83y/o male; TAVR for extreme surg risk with severe COPD, OSA and R diaphragm paralysis

Annulus area = 380mm², perimeter 69mm

MULTIPLANAR RECONSTRUCTION
Confirming the aortic root size

3D TEE
Sagittal 2.29
Coronal 2.55
**Prediction Indices**

- TAVI echo calcification score (TAVIECS)
  - Aortic root
  - Mitral annulus
  - Aortic valve cusps
  - Aortic valve commissures
  - Aortic annulus
  - Sinotubular junction

- “Allowed prediction of the risk of postoperative paravalvular and overall aortic regurgitation”

TEE Findings before the TAVR
Bulky Calcification
Uncertain Prosthesis Sizing

Aortic Root/Annular Calcium

JACC: CV Imag 2013;6:249
Heavy MAC extending into the LVOT
Morphological Risk Factors for Post Procedural AI – modification of implant strategy

Unbehaun et al. JACC 2012;59:211

82 yo male. Severe sx AS with EF 66%
Heavy aorto-iliac Ca++
26mm Edwards Sapien THV via anterior thoracotomy
Post Implant Appearance

Immediate Intraprocedural TAVR Assessment
GRADING POST PROCEDURE AI

• Percent Circumference Criteria
  • Subjective; high inter/intra observer variability
  • High reported incidence of 3-4+ AI (not confirmed CMR etc)

• Multiparametric Approach (JACC CV Imag 2015;8:340)
  • Hemodynamic assessment (Senning index)
  • Structural parameters
  • Color doppler (multiple views) – jet width at origin
  • Beware P1/2 time (compliance effects) and PISA
  • Quantitative doppler (regurg vol from RV LV stroke vols)
  • Cardiac MRI

Data from:

JACC CV Imag 2015:8:340

Table 1: Scheme, Modalities, Parameters, and Criteria for Grading the Severity of PVR

<table>
<thead>
<tr>
<th>Scheme</th>
<th>True</th>
<th>Mild</th>
<th>Mild-to-Moderate</th>
<th>Moderate</th>
<th>Moderate-to-Severe</th>
<th>Severe</th>
</tr>
</thead>
<tbody>
<tr>
<td>Injury</td>
<td>0.25</td>
<td>&gt;25</td>
<td>&gt;25</td>
<td>&gt;25</td>
<td>&gt;10</td>
<td>&lt;10</td>
</tr>
<tr>
<td>Involuntary hemodynamics</td>
<td>Usually normal</td>
<td>Usually normal</td>
<td>Normal to abnormal</td>
<td>Normal to abnormal</td>
<td>Usually abnormal</td>
<td>Usually abnormal</td>
</tr>
<tr>
<td>Diastolic insufficiency</td>
<td>Value, usually normal</td>
<td>Usually normal</td>
<td>Normal to abnormal</td>
<td>Normal to abnormal</td>
<td>Usually abnormal</td>
<td>Usually abnormal</td>
</tr>
<tr>
<td>Doppler echocardiography</td>
<td>Usually normal</td>
<td>Usually normal</td>
<td>Normal to abnormal</td>
<td>Normal to abnormal</td>
<td>Usually abnormal</td>
<td>Usually abnormal</td>
</tr>
<tr>
<td>Dilation and characteristic</td>
<td>Usually normal</td>
<td>Usually normal</td>
<td>Normal to abnormal</td>
<td>Normal to abnormal</td>
<td>Usually abnormal</td>
<td>Usually abnormal</td>
</tr>
<tr>
<td>Jet pattern</td>
<td>Usually normal</td>
<td>Usually normal</td>
<td>Normal to abnormal</td>
<td>Normal to abnormal</td>
<td>Usually abnormal</td>
<td>Usually abnormal</td>
</tr>
<tr>
<td>Pulsatile flow reversal</td>
<td>Usually normal</td>
<td>Usually normal</td>
<td>Normal to abnormal</td>
<td>Normal to abnormal</td>
<td>Usually abnormal</td>
<td>Usually abnormal</td>
</tr>
<tr>
<td>Quantitative Doppler</td>
<td>Usually normal</td>
<td>Usually normal</td>
<td>Normal to abnormal</td>
<td>Normal to abnormal</td>
<td>Usually abnormal</td>
<td>Usually abnormal</td>
</tr>
</tbody>
</table>

JACC CV Imag 2015:8:340
Jet location - TTE views

CAREFULLY INSPECT THE VALVE
May require off-axis imaging
Rotational sweeps to locate the jets

Grading Post Implant AI

Transgastric TEE

Multiple views
Quantifying Post Procedural AI

CIRCUMFERENTIAL EXTENT

JACC Img 2012;5:441

JACC CV Imag 2015;8:340
Post TAVR Paravalvular Leak Circumference Assessment

- **TTE**
- **TEE**

**Circumferential Extent**

“Only an approximate guide”

- Multiple jets often present; cannot image in single plane
- Jets often eccentric, cross parallel to SAX and appear larger
- Calcifications may shadow the jets
- Jet width by color is dependent on gain, aliasing velocity and image quality
Eccentric Anterior PVR jet

PVR Jet Features Associated with Regurgitation Severity

- Large jet width at origin
- Visible PISA
- Abnormal THV stent shape with mal-apposition
- Large vena contracta
- Multiple jets in several views

JACC CV Imag 2015;8:340
AORTIC REGURGITATION INDEX (Sinning)

Aortic Regurgitation Index = \((\frac{DBP - LVEDP}{SBP}) \times 100\)

A. SBP 120 mm Hg
   DBP 80 mm Hg
   LVEDP 20 mm Hg

B. SBP 150 mm Hg
   DBP 90 mm Hg
   LVEDP 10 mm Hg

JACC 2013;62:11

RESOLVING DISCORDANT CLINICAL VS ECHO FINDINGS

AR index = 0.24

JACC CV Imag 2016;9:193
CMRI IMAGING

INTRAPROCEDURAL MANAGEMENT OF PVR

Cineangiography/TEE/TTE after THV Deployment

No AR

Any Degree of AR

TEE / TTE for quantification of AR severity and identification of AR location (paravalvular vs. central) and etiology

Presence of vulnerability factors to AR†

and/or

Absence of high risk features/low likelihood of success with corrective procedures‡

Yes

Corrective Procedures

Balloon post-dilation

Valve-in-valve

Closure of the leak with a plug

No

No More Procedures

Reassess
84 yo male severe AS with Class 3-4 HFrEF. Multiple medical problems. Initial BAV with improvement. Sx recurred. 26 mm Edwards Sapien THV.

Significant PVR identified
Post dilation attempted
Closure of Post TAVR Paravalvular Leak
6mm Amplatzer Vascular Occluder

Intraprocedural Guidance with RT 3-Dimensional TEE
Final Result

Pre-closure

Post-closure

Long-Term Outcomes of Percutaneous Paravalvular Regurgitation Closure After Transcatheter Aortic Valve Replacement
A Multicenter Experience

JACC Interv 2015;8:681
3-D Printed tissue-mimicking phantom of the aortic root

- CT used as source data
- TAVR simulation with in-vitro deployment
- Aortic root strain quantified
- Annular bulge calculated
- Predicted post-TAVR PVR
Scripps Experience 2012-2017

Immediate

- None: 28%
- Trace/Mild: 24%
- Mod/Severe: 18%

Thirty Day

- None: 41%
- Trace/Mild: 43%
- Mod/Severe: 6%

N = 929 patients
N = 866 patients
Self-Expanding Transcatheter Aortic Valve System for Symptomatic High-Risk Patients With Severe Aortic Stenosis
SUMMARY

• TAVR preferred option for high risk and inoperable patients
  • FDA approval 2016 for intermediate risk patients
• PVR > mild at 1 year is higher for TAVR vs SAVR
• Significantly increased mortality associated with PVR
• Accurate quantitation of PVR is difficult
• Mild PVR may have less detrimental impact
• Clinical impact variable based on patient factors
• Newer devices and procedures reduce incidence
• Management techniques to correct PVR are evolving