AORTIC AND MITRAL VALVE DISEASE
HEMODYNAMICS AND CLINICAL ASPECTS

- Basics
- Mitral stenosis and PMBV
- Aortic stenosis and PABV
- TAVI
- HOCM and ASA (case presentation)

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Cath Lab Director
Memorial Regional Hospital
PRESSURE measurements: force/area

- International Units: Newton/m² (pascal or pa)
- In USA: “pounds per square inch” = psi
- At sea level: 1 ATM (760 mmHg)
- Equivalence: 1 ATM = 14.7 psi

**THEN:**

1 psi is 51.7 mmHg

Then 120/80 mmHg is 2.32/1.55 psi
Relation of different pressure measurements used in the Cath Lab

LV GRAM

- 900 psi
- 600 psi
- 300 psi
- 0 psi

10-14 ATM in pressure (147-206 psi)

120/80 mmHg = 2.32/1.55 psi
Placing the transducer 4 cm below the zero level will increase measured pressure by about 3 mmHg.
Pulmonary Artery Wedge Pressure

• Wedge pressure represent the pressure at the pulmonary capillary level / pulmonary veins (usually representing LA pressure)

• A true Wedge Pressure is measured ONLY when blood flow stops

• A Wedge pressure is confirmed if:
  - Characteristic waveform is present and mean is lower than mean PA
  - 02 Sat is greater than 95%
  - Angiographic confirmation of a wedge position with no flow
No real wedge. Still some flow around the balloon.
Real Wedge: either with balloon or catheter itself
Arterial Pressure Waveform from central to peripheral artery in a Healthy 30-year old man
CENTRAL AORTA

REFLECTED WAVEFORM

PERIPHERAL WAVEFORM

\[ P_m = P_f + P_b \]
MITRAL STENOSIS: RHEUMATIC

Normal Mitral Valve
- CARDIOPULMONARY BYPASS
- INCISION AT RA
INCISION LA AND IAS TO EXPOSE MV
MV EXPOSED FROM ABOVE
MITRAL COMMISSUROTOMY
Two latex layers, between which is polyester micromesh

PMBV: **Commissural splitting** is main mechanism of action
BEFORE

AFTER BALOONING

Mean mitral gradient 15 mmHg
Cardiac output 3.0 L/min
Mitral valve area 0.6 cm²

Mean mitral gradient 3 mmHg
Cardiac output 3.8 L/min
Mitral valve area 1.8 cm²
57 yr old female with h/o rheumatic fever at age 12 in Jamaica c/o DOE class III NYHA despite BB. Had open commissurotomy in her 30s. TTE c/w MS and AVA 1.4, mild MR and PAP 50-60 mmHg. TEE done. Wilkins score < 8.
MITRAL STENOSIS

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Valve:</td>
<td>Mitral</td>
</tr>
<tr>
<td>CO:</td>
<td>5.52 l/min</td>
</tr>
<tr>
<td>Mean gradient:</td>
<td>11.80 mmHg</td>
</tr>
<tr>
<td>Diastolic filling period:</td>
<td>28.67 sec/min</td>
</tr>
<tr>
<td>Valve Area:</td>
<td>1.49 cm²</td>
</tr>
<tr>
<td>Valve Flow:</td>
<td>192.51 ml/sec</td>
</tr>
</tbody>
</table>
RA AND LA SILHOUETTE
ICE: Transeptal Puncture
SEPTAL DILATATION (14F DILATOR)
INOUE BALLOON INFLATION
INOUE BALLOON
AFTER FIRST INFLATION 24 MM
FINAL
AFTER SECOND INFLATION 25 MM
MILD MR AFTER PROCEDURE
Mitral Balloon Valvuloplasty

**PMV Technique**

- **DOUBLE BALLOON (72%)**
- **SINGLE BALLOON (2.5%)**
- **INOUYE (25%)**
- **Mixed (0.5%)**

Mitral Balloon Valvuloplasty

COMPLICATIONS

- Procedure Mortality 0.6%
- In-Hospital Mortality 1.9%
- Severe (4 +) MR 2.7%
- Emergency MVR 1.4%
- Tamponade 0.8%
- Stroke 1.2%

PMBV Vs Open Surgical Commissurotomy (n=60 patients)
2006 AHA/ACC GUIDELINES

“In centers with skilled, experienced operators, percutaneous balloon valvotomy should be considered the **INITIAL PROCEDURE OF CHOICE** for symptomatic patients with moderate to severe mitral stenosis who have a favorable valve morphology in the absence of significant MR or LA thrombus”.
Aortic Stenosis Pathology

Normal

Degenerative Calcified

Bicuspid

Rheumatic
Aortic Stenosis
Currently

Degenerative Calcified

Normal

Bicuspid

Rheumatic
PRESSURE GRADIENT ACROSS AORTIC VALVE

Aortic pressure tracing

Left ventricular pressure tracing
Severe Aortic Stenosis Pressure Tracing

- LV Pressure
- Ao Pressure
Langston Dual Lumen Catheter
Available since 2005

Langston dual lumen catheters deliver simultaneous pressure measurements accurately and precisely through two independent lumens.

The Langston Pigtail catheter measures simultaneous pressures across the aortic valve to determine the pressure gradient and effective orifice area.
# Aortic Stenosis Severity

<table>
<thead>
<tr>
<th>Severity</th>
<th>Area (cm²)</th>
<th>Mean gradient (mmHg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>MILD</td>
<td>&gt;1.5</td>
<td>&lt; 25</td>
</tr>
<tr>
<td>MODERATE</td>
<td>1.0 - 1.5</td>
<td>25 - 40</td>
</tr>
<tr>
<td>SEVERE</td>
<td>&lt; 1.0</td>
<td>&gt; 40</td>
</tr>
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</table>

**HAKKE FORMULA:**

$$AVA = \frac{C.O.}{\text{Sq root Peak-to-peak gradient}}$$
AORTIC STENOSIS IS LIFE-THREATENING AND MAY PROGRESS RAPIDLY!
TREATMENT OPTIONS AND TIMING MATTERS

“Survival after onset of symptoms is 50% at two years and 20% at five years.”

“Surgical intervention [for severe AS] should be performed promptly once even ... minor symptoms occur.”

Sources: 1 S.J. Lester et al., “The Natural History and Rate of Progression of Aortic Stenosis,” Chest 1998
82 yr old Aortic Stenosis. Baseline aortic valve gradient: 70 mmHg.
Max Gradient: 84 mm Hg

Peak-to-Peak Gradient: 71 mmHg

Mean Gradient: 65 mmHg

Mean Gradient: 64 mmHg
Porcelain Aorta
Initiating and terminating pacing require clear communication between members of the implant team.

A clear “script” can be used:

- **Physician**: “Prepare to pace at 220 beats per minute.”
- **Nurse** ensures pulse generator rate is set at 220 beats per minute
- **Nurse**: “Ready to pace at 220 beats per minute.”
- **Physician**: “Start pacing.”
- **Nurse** initiates pacing.
- **Nurse**: “Pacing.”
- **Physician**: “Stop pacing.”
- **Nurse** terminates pacing.
- **Nurse**: “Pacing stopped.”
Post PABV: Peak gradient 18-20 mmHg
MECHANISM OF PABV DILATATION

1. Annular and leaflet stretch

2. Microfracture of valvular calcium

3. Commisural separation: not important
HEMODYNAMIC RESULTS

AVA: From mean 0.5 cm$^2$ increased to 0.8 cm$^2$
(71% had a final AVA < 1cm$^2$)
NYHA FUNCTIONAL CLASS
NHLBI PABV REGISTRY (N=672)

# Patients

<table>
<thead>
<tr>
<th>Class</th>
<th>Baseline</th>
<th>30 Day</th>
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</thead>
<tbody>
<tr>
<td>I</td>
<td>56</td>
<td>214</td>
</tr>
<tr>
<td>II</td>
<td>70</td>
<td>124</td>
</tr>
<tr>
<td>III</td>
<td>203</td>
<td>116</td>
</tr>
<tr>
<td>IV</td>
<td>155</td>
<td>30</td>
</tr>
</tbody>
</table>

78% of patients feel better

80% of patients feel better

Bashore, Davidson, Berman et al Circulation 1991: vol 84 no. 6
BALLOON AORTIC VALVULOPLASTY
LONG TERM OUTCOMES

Event Free Survival

1-yr  2-yr  3-yr

75%  62.5%  54%

50%  25%   10%

Kuntz R  NEJM 1991;325:17
Class IIb

- PABV might be reasonable as a *bridge to surgery* in hemodynamically unstable adult patients with AS who are at high risk for AVR.
- BAV might be reasonable for *palliation* in adult patients with AS in whom AVR cannot be performed because of serious comorbid conditions.

Evolving Indications

- BAV as a *bridge to transcatheter AVR*
- Diagnostic intervention on low output/low gradient AS to predict response to transcatheter AVR, (afterload mismatch vs. intrinsic contractility depression)
TAVR is the MOST EXCITING new procedure in interventional cardiovascular therapeutics!!!

THE FUTURE IS HERE!
Percutaneous Transcatheter Implantation of an Aortic Valve Prosthesis for Calcific Aortic Stenosis
First Human Case Description
Alain Cribier, MD; Helene Eltchaninoff, MD; Assaf Bash, PhD; Nicolas Borenstein, MD; Christophe Tron, MD; Fabrice Bauer, MD; Genevieve Derumeaux, MD; Frederic Anselme, MD; François Laborde, MD; Martin B. Leon, MD

AHA; Nov, 2002
EDWARDS SAPIEN XT THV

Cobalt Frame & New Leaflet Geometry

Tissue Attachment

Sapien XT
Sapien XT + NovaFlex Delivery System

18 Fr profile
Transcatheter AVR
Femoral and Trans-apical Access
AORTIC STENT VALVE IMPLANTED

Coronary ostium
Stent struts
Stent-valve leaflets
CoreValve Self-Expanding Aortic Bioprosthesis

- **HIGHER PART:** low radial force area axes the system and increases quality of anchoring

- **MIDDLE PART:** functional valve area with three leaflets and constrained to avoid coronaries (convexo-concave) – avoids need for rotational positioning

- **LOWER PART:** high radial force of the frame pushes aside the native calcified leaflets for secure anchoring and avoids recoil and para-valvular leaks

A porcine pericardial tissue valve fixed to the frame with PTFE sutures
PARTNER Study Design

Symptomatic Severe Aortic Stenosis

ASSESSMENT: High-Risk AVR Candidate
3,105 Total Patients Screened

Total = 1,057 patients
2 Parallel Trials:
Individually Powered

High Risk

ASSESSMENT: Transfemoral Access

Yes

Transfemoral (TF)

1:1 Randomization
N = 244
TF TAVR

VS

AVR

1:1 Randomization
N = 103
TA TAVR

N = 104

Primary Endpoint: All-Cause Mortality at 1 yr
(Non-inferiority)

No

Transapical (TA)

Inoperable

ASSESSMENT: Transfemoral Access

Yes

TF TAVR

1:1 Randomization
N = 179

VS

TA TAVR

N = 179

Standard Therapy

No

Not In Study

N = 358

Primary Endpoint: All-Cause Mortality Over Length of Trial (Superiority)
Co-Primary Endpoint: Composite of All-Cause Mortality
and Repeat Hospitalization (Superiority)
TAVI

Inoperable group: Outcomes
All Cause Mortality

Numbers at Risk

<table>
<thead>
<tr>
<th></th>
<th>TAVI</th>
<th>Standard Rx</th>
</tr>
</thead>
<tbody>
<tr>
<td>12 mo</td>
<td>179</td>
<td>179</td>
</tr>
<tr>
<td>18 mo</td>
<td>138</td>
<td>121</td>
</tr>
<tr>
<td>24 mo</td>
<td>122</td>
<td>83</td>
</tr>
<tr>
<td>30 mo</td>
<td>67</td>
<td>41</td>
</tr>
<tr>
<td>36 mo</td>
<td>26</td>
<td>12</td>
</tr>
</tbody>
</table>

△ at 1 yr = 20.0%
NNT = 5.0 pts
CLINICAL OUTCOMES AT 30 DAYS AND 1 YEAR

Death - All Cause

30 Days
- TAVI (n=179): 5%
- Standard Rx (n=179): 2.8%

P = 0.41

1 Year
- TAVI (n=179): 30.7%
- Standard Rx (n=179): 49.7%

P = 0.0004
TAVI not only added years to life, but also, life to years!
PARTNER PERSPECTIVES - "INOPERABLE"

• The HEART VALVE TEAM approach is preferred
• Standard therapy is associated with a prohibitive 1-year mortality.
• TAVI resulted in…
  • Low (~5%) 30-day mortality
  • Historic reduction in 1-year mortality
  • Improved symptoms in survivors
  • New complications (e.g. strokes, vascular)
• Balloon-expandable TAVR is the new standard-of-care for inoperable patients with severe AS!
High Risk Group: OUTCOMES
ALL-CAUSE MORTALITY OR STROKE
ALL PATIENTS (N=699)

No. at Risk                      Months

<table>
<thead>
<tr>
<th>TAVR</th>
<th>AVR</th>
</tr>
</thead>
<tbody>
<tr>
<td>348</td>
<td>351</td>
</tr>
<tr>
<td>289</td>
<td>247</td>
</tr>
<tr>
<td>252</td>
<td>232</td>
</tr>
<tr>
<td>143</td>
<td>138</td>
</tr>
<tr>
<td>65</td>
<td>63</td>
</tr>
</tbody>
</table>

HR [95% CI] = 0.95 [0.73, 1.23]
P (log rank) = 0.70
PARTNER PERSPECTIVES - “HIGH RISK”

- TAVI and AVR procedural mortality were similar and better than anticipated (30 days: TAVR 3.4%, AVR 6.5%, P=0.07).
- Mortality at 1-year was also similar.
- TAVI resulted in:
  - Earlier improvement in symptoms (same at 1-year).
  - Improved echo AV gradients-areas (small difference).
  - Different peri-procedural hazards – TAVI increased strokes, vascular complications and AVR increased bleeding and new onset AF.
PARTNER - “HIGH RISK”

Balloon-expandable TAVR is a new alternative therapy to surgical AVR in selected high-risk patients with severe AS!
NEW TAVI TECHNOLOGIES

- Direct Flow
- Sadra
- AorTx
- Jena Valve
- HLT
- ABPS PercValve
- EndoTech
- Ventor Embracer
- Symetis