Valvular Heart Disease

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Prevalence of Valvular Heart Disease

- Prevalence in U.S.A = 2.5%
  - 0.7% age 18-44
  - 13.3% over age 75
- Epidemiology has changed significantly over past 50 years
- Decline in rheumatic heart disease
- Steady increase in life expectancy resulting in more degenerative valve disease
Relative Distribution of Native Heart Valve Disease

# Etiology of Valvular Heart Disease

<table>
<thead>
<tr>
<th>Variables</th>
<th>Aortic stenosis ( n = 1,197 )</th>
<th>Aortic regurgitation ( n = 369 )</th>
<th>Mitral stenosis ( n = 336 )</th>
<th>Mitral regurgitation ( n = 877 )</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Demographic characteristics</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean age (years)</td>
<td>69±12</td>
<td>58±16</td>
<td>58±13</td>
<td>65±14</td>
</tr>
<tr>
<td>Age &gt;70 years (%)</td>
<td>56</td>
<td>25</td>
<td>18</td>
<td>44</td>
</tr>
<tr>
<td>Male (%)</td>
<td>57</td>
<td>74</td>
<td>19</td>
<td>52</td>
</tr>
<tr>
<td><strong>Etiology</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Degenerative (%)</td>
<td>81.9</td>
<td>50.3</td>
<td>12.5</td>
<td>61.3</td>
</tr>
<tr>
<td>Rheumatic (%)</td>
<td>11.2</td>
<td>15.2</td>
<td>85.4</td>
<td>14.2</td>
</tr>
<tr>
<td>Endocarditis (%)</td>
<td>0.8</td>
<td>7.5</td>
<td>0.6</td>
<td>3.5</td>
</tr>
<tr>
<td>Inflammatory (%)</td>
<td>0.1</td>
<td>4.1</td>
<td>0</td>
<td>0.8</td>
</tr>
<tr>
<td>Congenital (%)</td>
<td>5.4</td>
<td>15.2</td>
<td>0.6</td>
<td>4.8</td>
</tr>
<tr>
<td>Ischemic (%)</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>7.3</td>
</tr>
<tr>
<td>Other (%)</td>
<td>0.6</td>
<td>7.7</td>
<td>0.9</td>
<td>8.1</td>
</tr>
</tbody>
</table>

Aortic Stenosis
Risk Factors for Development of Calcific Aortic Stenosis

- Increasing age
- Male gender
- Hypertension
- Smoking
- Elevated lipoprotein(a)
- Elevated LDL cholesterol
Aortic Stenosis-Natural History

- Survival after onset of symptoms is 50% at 2 years without intervention

5 Year Survival Rates

Management of Asymptomatic Aortic Stenosis

- Asymptomatic patients with AS have outcomes similar to age-matched normal adults.
- Treatment of concomitant hypertension and hyperlipidemia
- No specific medical therapy has been shown to slow progression of disease process
- Physical activity is not restricted in asymptomatic patients with mild AS; these patients can participate in competitive sports. Patients with moderate to severe AS should avoid competitive sports.
- Based upon ACC guidelines, echocardiography is recommended for:
  - re-evaluation of patients with known AS and changing symptoms or signs
  - re-evaluation of asymptomatic patients: every year for severe AS; every 1 to 2 years for moderate AS; and every 3 to 5 years for mild AS.
## Aortic Stenosis – Progression to Symptomatic Disease

<table>
<thead>
<tr>
<th>Study, year</th>
<th># of patients</th>
<th>Severity of AS</th>
<th>Event-free survival without symptoms</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kelly, et al. 1988</td>
<td>51</td>
<td>Vmax&gt;3.6 m/s</td>
<td>59% at 15 months</td>
</tr>
<tr>
<td>Rosenhek, et al. 2000</td>
<td>128</td>
<td>Vmax&gt;4.0 m/s</td>
<td>67% at 1 year</td>
</tr>
<tr>
<td>Das, et al. 2005</td>
<td>125</td>
<td>AVA&lt;0.8 cm²</td>
<td>46% at 1 year</td>
</tr>
<tr>
<td>Pellikka, et al. 2005</td>
<td>622</td>
<td>Vmax&gt;4.0 m/s</td>
<td>82% at 1 y, 67% at 2 y, 33% at 5 y</td>
</tr>
</tbody>
</table>
Severe Aortic Stenosis

Vmax greater than 4 m/s
AVA less than 1.0 cm²
Mean gradient > 40 mm Hg

Undergoing CABG or other heart surgery?

Symptoms?

Yes

Equivocal

Exercise test

Symptoms ↓BP

Class I

Class I

Class IIb

Class I

Class IIb

Aortic Valve Replacement

Preoperative coronary angiography

LV ejection fraction

Normal

Less than 0.50

Severe valve calcification, rapid progression, and/or expected delays in surgery

Yes

Clinical follow-up, patient education, risk factor modification, annual echo

No

Normal

Re-evaluation
Surgical Treatment for Aortic Stenosis

- In symptomatic patients with AS, AVR improves symptoms and improves survival.
- In the absence of serious comorbid conditions, AVR is indicated in virtually all symptomatic patients with severe AS.
- Average perioperative mortality in the STS database is 3.0% to 4.0% for isolated AVR and 5.5% to 6.8% for AVR plus CABG.

Types of Valve Prostheses

- Mechanical
  - Ball and cage (Starr-Edwards); single tilting disc (Medtronic-Hall); bileaflet (St. Jude, Carbomedics)
  - Durable with low rates of mechanical failure
  - Generally hemodynamically efficient except in small sizes
  - Requires long-term antithrombotic therapy (INR 2.5-3.5 x 3 months, then 2-3 thereafter)

- Stented Heterograft
  - Bovine pericardial or porcine aortic valve tissue
  - Imperfect hemodynamic efficiency
  - Low risk of thromboembolism without coumadin (<0.7%/yr)

- Stentless Heterograft
  - Stentless porcine valve tissue
  - Enhanced hemodynamic efficiency
  - Low thromboembolic risk
### Structural Deterioration of Bioprosthetic Valves

<table>
<thead>
<tr>
<th>Author, Yr</th>
<th>Valve Type</th>
<th>Time of SVD</th>
<th>Patient Age, Yr</th>
<th>Freedom from SVD, %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Jamieson, 1988</td>
<td>Porcine</td>
<td>10</td>
<td>30-59</td>
<td>81</td>
</tr>
<tr>
<td>Burr, 1992</td>
<td>Porcine</td>
<td>13-15</td>
<td>&lt;65</td>
<td>62</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>65-69</td>
<td>98</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>70-79</td>
<td>95</td>
</tr>
<tr>
<td>Pelletier, 1995</td>
<td>Pericardial</td>
<td>10</td>
<td>&lt;60</td>
<td>86</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>60-69</td>
<td>95</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>&gt;70</td>
<td>100</td>
</tr>
<tr>
<td>Banbury, 2001</td>
<td>Pericardial</td>
<td>15</td>
<td>55</td>
<td>70</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>65</td>
<td>82</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>75</td>
<td>91</td>
</tr>
</tbody>
</table>
Proportion of Patients with Severe Aortic Stenosis Treated with AVR

Only 26-57% of patients with severe AS ultimately undergo AVR
TAVR – Transcatheter Aortic Valve Replacement

• For patients who are either at high/prohibitive or intermediate risk for open-heart surgery, TAVR may be an alternative.

• This less invasive procedure allows the aortic valve to be replaced with a new valve while the heart is still beating using catheter-based techniques.
Edwards SAPIEN Transcatheter Heart Valve

- Bovine pericardial tissue
- Stainless steel frame
- PET skirt
TAVR Access Techniques

Additional: Subclavian, Innominate, Carotid, Transcaval
PARTNER RESULTS: TAVR vs. Standard Medical Treatment (Mortality)

- All-Cause Mortality:
  - Standard Therapy: 68.0%
  - Edwards SAPIEN THV: 43.3%

- Numbers at Risk:
  - Edwards SAPIEN THV: 179, 138, 124, 110, 83
  - Standard Therapy: 179, 121, 85, 62, 42

- Statistical Significance:
  - $P$ (log rank) < .0001
  - Δ at 2 yrs = 24.7%
  - NNT = 4.0 pts
PARTNER RESULTS: TAVR vs. Standard Medical Treatment (Functional Class)

NYHA CLASS OVER TIME

83% of the Edwards SAPIEN THV patients in NYHA class I or II at 2 years

Improvement observed as early as 30 days ($P < .0001$)
PARTNER RESULTS: TAVR vs. Surgical AVR (Mortality)

ALL-CAUSE MORTALITY AT 1 YEAR AND 2 YEARS

HR [95% CI] = 0.88 [0.70, 1.12]
P (log rank) = 0.31

Number at Risk

<table>
<thead>
<tr>
<th></th>
<th>Edwards SAPIEN THV</th>
<th>AVR</th>
</tr>
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<tbody>
<tr>
<td>0</td>
<td>348</td>
<td>351</td>
</tr>
<tr>
<td>3</td>
<td>312</td>
<td>274</td>
</tr>
<tr>
<td>6</td>
<td>298</td>
<td>252</td>
</tr>
<tr>
<td>9</td>
<td>269</td>
<td>245</td>
</tr>
<tr>
<td>12</td>
<td>260</td>
<td>236</td>
</tr>
<tr>
<td>15</td>
<td>247</td>
<td>225</td>
</tr>
<tr>
<td>18</td>
<td>234</td>
<td>217</td>
</tr>
<tr>
<td>21</td>
<td>222</td>
<td>208</td>
</tr>
<tr>
<td>24</td>
<td>172</td>
<td>165</td>
</tr>
</tbody>
</table>

All-Cause Mortality, %

- 0% at 0 months
- 100% at 24 months

The graph shows the all-cause mortality at 1 year and 2 years for Edwards SAPIEN THV and AVR, with the hazard ratio (HR) and 95% confidence interval (CI) provided.
TAVR in Intermediate Risk Aortic Stenosis Patients

- PARTNER 2A Trial randomized 2032 intermediate risk patients to TAVR or SAVR
- TAVR non-inferior to SAVR with regard to mortality or disabling CVA at 2 years (19.3% vs. 21.1%)
- Lower rates of AKI, Afib; larger AVA; shorter length of stay with TAVR vs SAVR

MB Leon, et al; NEJM 4/2/16
### Seton Heart Institute Valve Program

<table>
<thead>
<tr>
<th>Year</th>
<th>Volume</th>
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<tbody>
<tr>
<td>2014</td>
<td>11</td>
</tr>
<tr>
<td>2015</td>
<td>29</td>
</tr>
<tr>
<td>2016</td>
<td>47</td>
</tr>
<tr>
<td>2017</td>
<td>79</td>
</tr>
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</table>

**Rolling 4 Quarter Clinical Outcomes**

<table>
<thead>
<tr>
<th>Clinical Outcome</th>
<th>Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>In Hospital Mortality</td>
<td>1.3% (1.5%)</td>
</tr>
<tr>
<td>Major Bleeding</td>
<td>1.3% (1.7%)</td>
</tr>
<tr>
<td>LOS</td>
<td>1.9 d (1.9) (6 d in 2015)</td>
</tr>
<tr>
<td>CVA at 30 d</td>
<td>1.3% (2.0%)</td>
</tr>
<tr>
<td>&gt;mild PVL at 30 d</td>
<td>0% (1.2%)</td>
</tr>
<tr>
<td>30 d Readmission</td>
<td>11.4% (7.7%)</td>
</tr>
</tbody>
</table>
Aortic Insufficiency - Etiology

- idiopathic dilatation of the aorta
- congenital abnormalities of the aortic valve (most notably bicuspid valves)
- calcific degeneration
- rheumatic disease
- infective endocarditis
- systemic hypertension
- myxomatous degeneration
- dissection of the ascending aorta
- Marfan syndrome
- traumatic injuries to the aortic valve
- ankylosing spondylitis
- syphilitic aortitis
- rheumatoid arthritis
Acute Aortic Insufficiency

• **Diagnosis**
  
  – New diastolic murmur, tachycardia, rales
  – Pulse pressure may not be increased because systolic pressure is reduced and the aortic diastolic pressure equilibrates with the elevated LV diastolic pressure
  – LV size is usually normal on exam, CXR, echo
  – Echocardiography is indispensable in confirming the presence and severity of the valvular regurgitation and determining its cause
  – If dissection is suspected, TEE/CT/MRI is indicated
Acute Aortic Insufficiency-Treatment

- Death due to pulmonary edema, ventricular arrhythmias, electromechanical dissociation, or circulatory collapse is common in acute severe AI
- Urgent surgical intervention
- Nitroprusside for acute afterload reduction
- Dopamine, dobutamine to augment forward flow
- IABP is contraindicated
- Care should be taken if B-blockers used in the setting of dissection as this may block compensatory tachycardia
Chronic Aortic Insufficiency

- Diagnosis
  - Diastolic murmur, displace LV impulse, wide pulse pressure, S3
  - LV size is usually enlarged on exam, CXR, echo
  - Echocardiography to confirm the presence and determine the severity of the valvular regurgitation, assess aortic root size, and evaluate LV function
### Chronic Aortic Insufficiency-Natural History

<table>
<thead>
<tr>
<th>Status</th>
<th>Event Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Asymptomatic/Normal LV function</td>
<td>Progression to Sx and/or LV dysfunction = 6%/yr</td>
</tr>
<tr>
<td></td>
<td>Progression to LV dysfunction = 3.5%/yr</td>
</tr>
<tr>
<td></td>
<td>Sudden death = 0.2%/yr</td>
</tr>
<tr>
<td>Asymptomatic/LV Dysfunction</td>
<td>Progression to Sx = &gt;25%/yr</td>
</tr>
<tr>
<td>Symptomatic</td>
<td>Mortality &gt; 10%/year</td>
</tr>
</tbody>
</table>
Chronic Aortic Insufficiency-Medical Therapy

- Vasodilator therapy is indicated for chronic therapy in patients with severe AR who have symptoms or LV dysfunction when surgery is not recommended because of additional cardiac or noncardiac factors.
- Vasodilator therapy is reasonable for short-term therapy to improve the hemodynamic profile of patients with severe heart failure symptoms and severe LV dysfunction before proceeding with AVR.
- May be considered for long-term therapy in asymptomatic patients with severe AR who have LV dilatation but normal systolic function:
  - 2 small studies (Nifedipine vs. Digoxin; Nifedipine vs. Enalapril vs. placebo)
- Vasodilator therapy is not indicated for:
  - asymptomatic patients with mild to moderate AR and normal LV systolic function
  - asymptomatic patients with LV systolic dysfunction who are otherwise candidates for AVR
  - Symptomatic patients with either normal LV function or mild to moderate LV systolic dysfunction who are otherwise candidates for AVR
Mitral Stenosis

- **Etiology**
  - Predominately due to rheumatic carditis. Less commonly congenital or acquired (LA myxoma, severe annular calcification)
- **2:1 female:male**
Mitral Stenosis

• Pathophysiology
  – Reduction in valve area causes increased transmitral gradient resulting in elevated LA pressure, pulmonary edema, diminished cardiac output.
  – Valve areas >1.5 cm² usually do not cause symptoms, but decreases in diastolic filling time from tachycardia (infection, Afib, pregnancy, etc.) increases MV gradient and may provoke symptoms.
  – Progressive, indolent process with long latent period (20-40 years)

• Diagnosis
  – May present with no symptoms, fatigue, or dyspnea/pulmonary edema.
  – Accentuated S¹, opening snap, diastolic rumble
  – Echocardiography should be performed to determine the diagnosis of MS, assess hemodynamic severity (mean gradient, MV area, and pulmonary artery pressure), assess for concomitant valvular lesions, and assess valve morphology.
Mitral Stenosis-Natural History

• Annual loss of valve area 0.1-0.3 cm² per year
• Overall 10-year survival of patients with MS is 50-60% depending upon symptoms at presentation.
  – Asymptomatic: 80%
  – Significant, limiting symptoms: 0-15%
• Mortality due to progressive systemic congestion, systemic embolization, infection
Mitral Stenosis-Medical Therapy

• No medical therapy will specifically relieve obstruction to inflow at the mitral valve.
• Avoidance of unusual physical stress and tachycardia. Negative chronotropics drugs (B Blockers, Ca-Channel blockers) may be beneficial in patients with exertional symptoms.
• Salt restriction, diuretics in patients with congestive symptoms
• Treatment of atrial fibrillation (occurs in 30-40% of symptomatic MS patients)
Percutaneous Mitral Balloon Valvotomy

- Indicated for symptomatic patients (NYHA functional class II, III, or IV), with moderate or severe MS and favorable valve morphology in the absence of left atrial thrombus or moderate to severe MR.
- Results:
  - 85-95% success rate
  - 50-60% reduction in transmitral gradient
  - 80-90% event-free survival at 3-7 years in patients with favorable anatomy
  - Similar results to surgical commissurotomy
Mitral Regurgitation

• More than 2 million persons in the U.S. have moderate or severe MR

• Etiologies: degenerative (mitral valve prolapse), rheumatic heart disease, CAD, endocarditis, collagen vascular disease, annular dilatation
Degenerative vs Functional Mitral Regurgitation

- Normal
- Degenerative: Prolapse
- Degenerative: Flail
- Functional
Prevalence of Moderate or Severe Valve Disease

![Graph showing prevalence of valve disease across different age groups.](SetonHeartInstitute)
Mitral Regurgitation-Acute

- **Presentation**
  - Rapid LA, LV volume overload resulting in pulmonary congestion and decreased stroke volume/forward cardiac output
  - Almost always severely symptomatic
  - Rales, S3, normal heart size, early/holosystolic murmur
  - Confirmed by echocardiography

- **Treatment**
  - Afterload reduction (nitroprusside) to reduce afterload and improve forward cardiac output
  - Diuretics to relieve congestion and decrease preload
  - Inotopes (dobutamine)
  - IABP
  - Surgical intervention
Mitral Regurgitation-Chronic

- Patients with mild to moderate MR may remain asymptomatic with little or no hemodynamic compromise for many years
- Natural history of severe MR
  - 6-7% mortality/year
  - 90% of patients are dead or have MV surgery by 10 years
- Follow-up of Asymptomatic MR
  - Mild: Annual follow-up. Yearly echo not indicated unless change in symptoms
  - Moderate: Annual clinical follow-up with echocardiography
  - Severe: Clinical follow-up with echo every 6-12 months to assess for symptoms or asymptomatic LV dysfunction
Chronic Mitral Regurgitation-Medical Therapy

• In the asymptomatic patient with chronic MR, there is no generally accepted medical therapy

• No large, long-term studies to indicate that ACE/ARB are beneficial in improving mortality or delaying surgical intervention.

• In the absence of systemic hypertension, there is no known indication for the use of vasodilating drugs or ACE inhibitors in asymptomatic patients with MR and preserved LV function.

• ACE/ARB, B-Blockers should be used in setting of LV dysfunction or symptomatic CHF
Chronic Severe Mitral Regurgitation

- Reevaluation
  - Clinical evaluation + Echo
    - Symptoms?
      - No
        - LV function?
          - Normal LV function
            - EF > 0.60
            - ESD < 40 mm
              - New onset AF? Pulmonary HT?
                - Yes
                  - Class IIa
                - No
                  - Class IIa
          - LV dysfunction
            - EF ≤ 0.60
            - and/or
            - ESD ≥ 40 mm
              - MV repair
                - If not possible, MVR
                - Class IIa
      - Yes
        - LV function?
          - EF > 0.30
            - ESD ≤ 55 mm
              - Chordal preservation likely?
                - Yes
                  - Medical therapy
                - No
                  - Class IIa
          - EF < 0.30 and/or
            - ESD > 55 mm
              - MV repair
                - Class IIa

- Clinical eval every 6 mo
  - Echo every 6 mo
 Repair vs. Replacement?

- STS Operative Mortality: 2% MV Repair; 6% MV Replacement
- MV repair results in improved mortality and preservation of LV function vs. MV replacement

Percutaneous Mitral Valve Repair: MitraClip

- By approximating the anterior and posterior mitral leaflets and forming a double-orifice valve, the MitraClip device reduces MR.

- Currently approved for use in patients with degenerative mitral regurgitation who are high risk for conventional mitral valve surgery.
1 Year MitraClip Outcomes

**Reduction in MR Severity**

<table>
<thead>
<tr>
<th>Baseline (N = 124)</th>
<th>Discharge (N = 123)</th>
<th>1 Year (N = 84)</th>
<th>2 Years (N = 40)</th>
</tr>
</thead>
<tbody>
<tr>
<td>9.7% MR ≤ 2+</td>
<td>82% MR ≤ 2+</td>
<td>83% MR ≤ 2+</td>
<td>82.5% MR ≤ 2+</td>
</tr>
</tbody>
</table>

**Improvement in Heart Failure Symptoms**

<table>
<thead>
<tr>
<th>Baseline (N = 127)</th>
<th>30 Days (n = 113)</th>
<th>1 Year (n = 84)</th>
</tr>
</thead>
<tbody>
<tr>
<td>13.4% Class I/II</td>
<td>82% Class I/II</td>
<td>87% Class I/II</td>
</tr>
</tbody>
</table>

- From discharge to 2-year follow-up, more than 80% of surviving patients achieved and maintained reduction in MR severity to ≤ 2+.
- The proportion of patients in NYHA Class I/II increased from 13% at baseline to 87% of surviving patients at 1 year.
- 88% of surviving patients improved by at least 1 class, and 36% improved by at least 2 classes.

*Prohibitive Surgical Risk DMR Cohort (n = 127): A post-hoc analysis of data collected from the EVEREST II HRR and REALISM HR studies established the safety, effectiveness, and positive benefit-risk profile of MitraClip therapy to reduce MR in patients with degenerative MR who are at prohibitive risk for mitral valve surgery. Data from 127 patients were analyzed and subsequently formed the basis for U.S. FDA approval of MitraClip therapy.

¹In surviving patients with paired data.
**1 Year MitraClip Outcomes**

**Significant reduction in left ventricular size**

73% reduction in heart failure-related symptoms and hospitalizations:
- Between the 1-year periods before and after the procedure

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†Data as of March 2015. Procedure success was defined as post-implant MR grade ≤ 2, without cardiovascular surgery and without in-hospital mortality.
Impact of MR on Survival in Patients with CHF

COAPT: All-cause Mortality

All-cause Mortality (%)

Time After Randomization (Months)

0% 20% 40% 60% 80% 100%

MitraClip + GDMT
GDMT alone

HR [95% CI] = 0.62 [0.46-0.82]
P<0.001

NNT (24 mo) = 5.9 [95% CI 3.9, 11.7]

No. at Risk:
MitraClip + GDMT 302 286 269 253 236 191 178 161 124
GDMT alone 312 294 271 245 219 176 145 121 88

Degree of MR, functional class, QOL, need for VAD/transplant all better for MitraClip group
Future Developments: Transcatheter Mitral Valve Replacement
Conclusions

- Valvular heart disease is very prevalent in the primary care setting, particularly in the aging population (13.3% over age 75)
- Open surgical valvular repair/replacement has previously been the primary therapy for symptomatic disease.
- Medical therapy is primarily used for stabilization for acute valve dysfunction.
- Newer, less invasive percutaneous techniques may allow treatment of patients previously deemed as poor surgical candidates with less morbidity