Aortic Stenosis: 
New Therapies, Evidence and Guidelines

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Disclosures

• Honoraria/Consultant fees:
  – Volcano Corporation
  – Medtronic Vascular
  – Boston Scientific Vascular
  – Novartis
  – Daiichi-Sankyo
  – The Medicines Company
Objectives

• Overview of Aortic Stenosis
• Diagnosis and Testing
• Evidence for use of TAVI
• Testing and work up for TAVI
• AHA/ACC Guidelines for Patient Selection, Evaluation and Referral
Overview of Aortic Stenosis
Etiology: Calcific Aortic Stenosis (AS)

Mechanism of Stenosis is Similar to Atherosclerosis

- Mainly solid calcium deposits within the valve cusps
- Similar risk factors to Coronary Artery Disease (CAD)
- High coincidence of CAD and AS in same individual
- Most prevalent 6th, 7th, and 8th decades of life
Disease Etiology
Aortic Stenosis is Predominantly a Degenerative Disease

Etiology of Single Native Left-Sided Valve Disease

- Aortic Stenosis
- Aortic Regurgitation
- Mitral Stenosis
- Mitral Regurgitation

Legend:
- Other
- Ischemic
- Congenital
- Inflammatory
- Endocarditis
- Rheumatic
- Degenerative
Aortic Stenosis Prevalence

- Aortic Stenosis (AS) is the most prevalent native valve disease
- Prevalence:
  - 2% of people over 65
  - 3% of people over 75
  - 4% of people over 85
- Over 100,000 people in the U.S. are diagnosed with severe aortic stenosis each year
- Prevalence of AS and co-morbidities that increase the risk of surgical valve replacement, increase with age
Onset of Severe Aortic Stenosis Symptoms

- Onset of dyspnea and other heart failure symptoms foretell the worst outlook for AS patients.
- Classic symptoms of AS:
  - Angina
  - Syncope
  - Dyspnea
- Without intervention, this patient population survival rate is approximately 50% at two years from the onset of symptoms.
Symptoms of Aortic Stenosis

- Shortness of breath
- Angina
- Fatigue
- Syncope or Presyncope
- Other
  - Rapid or irregular heartbeat
  - Palpitations

The symptoms of aortic disease are commonly misunderstood by patients as ‘normal’ signs of aging.\(^5\) Many patients initially appear asymptomatic, but on closer examination up to 37% exhibit symptoms.\(^6\)

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Worse Prognosis than Many Metastatic Cancers

5-year survival of breast cancer, lung cancer, prostate cancer, ovarian cancer and severe inoperable aortic stenosis

*Using constant hazard ratio. Data on file, Edwards Lifesciences LLC. Analysis courtesy of Murat Tuczu, MD, Cleveland Clinic

## Stages of Valvular Heart Disease Progression

<table>
<thead>
<tr>
<th>Stage</th>
<th>Definition</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>At Risk</td>
<td>Patients with risk factors for development of VHD</td>
</tr>
<tr>
<td>B</td>
<td>Progressive</td>
<td>Patients with progressive VHD (mild-to-moderate severity of asymptomatic)</td>
</tr>
</tbody>
</table>
| C     | Asymptomatic severe | Asymptomatic patients who have the criteria for severe VHD:  
C1: Asymptomatic patients with severe VHD in whom the left or right ventricle remains compensated  
C2: Asymptomatic patients with severe VHD, with decompensation of the left or right ventricle |
| D     | Symptomatic severe | Patients who developed symptoms as a result of VHD |
Aortic Stenosis Diagnosis
History

- Asymptomatic
- Early: Fatigue and decreased exercise tolerance
- Intermediate: Dyspnea with mild to moderate exertion
- Late: Angina, rest dyspnea, syncope
Physical Exam

• Vitals: Normal to high blood pressure; hypotension is a late finding; tachycardia
• Carotid upstroke delayed with bruit (often transmitted murmur)
• Crescendo-decrescendo systolic murmur with timing of peaking related to severity; later peaking more severe
• Diminished second heart sound also correlates with severity
• Peripheral edema and diminished pulses are late findings
Aortic Stenosis Diagnosis: Echocardiography

2D:
  Qualitative opening and degree of calcification
  LVH and chamber sizes
Doppler:
  Quantitative degree of stenosis, (>4 m/s or DI<0.25)
  Degree of aortic insufficiency
  Gold standard for quantifying AS, better than TEE
## Aortic Stenosis Severity Classification

<table>
<thead>
<tr>
<th>Indicator</th>
<th>Stage A: At Risk</th>
<th>Stage B: Progressive (Mild)</th>
<th>Stage B: Progressive (Moderate)</th>
<th>Stage C: Asymptomatic (Severe)</th>
<th>Stage D: Symptomatic (Severe)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Jet Velocity (m/s)</td>
<td>&lt;2.0</td>
<td>2.0-2.9</td>
<td>3.0-3.9</td>
<td>&gt; 4.0</td>
<td>&gt;4.0</td>
</tr>
<tr>
<td>Mean gradient (mmHg)</td>
<td>&lt;20</td>
<td>20-39</td>
<td>&gt;40</td>
<td>&gt;40</td>
<td></td>
</tr>
<tr>
<td>Valve area (cm²)</td>
<td></td>
<td></td>
<td>&lt;1.0</td>
<td>&lt;1.0</td>
<td></td>
</tr>
<tr>
<td>Valve Area Index (cm²/m²)</td>
<td></td>
<td></td>
<td>&lt;0.6</td>
<td>&lt;0.6</td>
<td></td>
</tr>
</tbody>
</table>

AHA/ACC 2014 Guidelines
Echocardiogram

A

C

B

D

CardioVascular Associates of Mesa
Cardiac Cath

- Assess pulmonary pressures
- Assess wedge and LVEDP
- Assess coronary anatomy
- Provide for coronary intervention prior to TAVR
- Assess implantation view
- Access for BAV in patients with severe CHF
Aortic root view for implantation
## TIMING OF AORTIC VALVE REPLACEMENT (AVR)

### Recommendations

<table>
<thead>
<tr>
<th>Recommendations</th>
<th>COR</th>
<th>LOE</th>
<th>References</th>
</tr>
</thead>
<tbody>
<tr>
<td>AVR is recommended with severe high-gradient AS who have symptoms by history on exercise testing (stage D1)</td>
<td>I</td>
<td>B</td>
<td>(10, 57-59)</td>
</tr>
<tr>
<td>AVR is recommended for asymptomatic patients with severe AS (stage C2) and LVEF &lt;50%</td>
<td>I</td>
<td>B</td>
<td>(61, 62)</td>
</tr>
<tr>
<td>AVR is indicated for patients with severe AS (Stage C or D) when undergoing other cardiac surgery</td>
<td>I</td>
<td>B</td>
<td>(63, 64)</td>
</tr>
<tr>
<td>AVR is reasonable for asymptomatic patients with very severe AS (Stage C1, aortic velocity ≥ 5.0 m/s) and low surgical risk</td>
<td>IIa</td>
<td>B</td>
<td>(65, 66)</td>
</tr>
<tr>
<td>AVR is reasonable in asymptomatic patients (stage C1) with severe AS and decreased exercise tolerance or an exercise fall in BP</td>
<td>IIa</td>
<td>B</td>
<td>(27, 38)</td>
</tr>
<tr>
<td>AVR is reasonable in symptomatic patients with low-flow/low-gradient severe AS with reduced LVEF (stage D2) with a low-dose dobutamine stress study that shows an aortic velocity ≥ 4.0 m/s (or mean pressure gradient ≥ 40 mm Hg) with a valve area ≤ 1.0 cm² at any dobutamine dose</td>
<td>IIa</td>
<td>B</td>
<td>(67-69)</td>
</tr>
<tr>
<td>AVR is reasonable in symptomatic patients who have low-flow/low-gradient severe AS (stage D3) who are normotensive and have an LVEF ≥ 50% if clinical, hemodynamic, and anatomic data support valve obstruction as the most likely cause of symptoms</td>
<td>IIa</td>
<td>C</td>
<td>N/A</td>
</tr>
<tr>
<td>AVR is reasonable for patients with moderate AS (stage B) (aortic velocity 3.0 – 3.9 m/s) who are undergoing other cardiac surgery</td>
<td>IIa</td>
<td>C</td>
<td>N/A</td>
</tr>
<tr>
<td>AVR may be considered for asymptomatic patients with severe AS (stage C1) and rapid disease progression and low surgical risk</td>
<td>IIb</td>
<td>C</td>
<td>N/A</td>
</tr>
</tbody>
</table>

AS=aortic stenosis; AVR=aortic valve replacement by either surgical or transcatheter approach; BP=blood pressure; COR= Class of Recommendation; LOE=Level of Evidence; LVEF=left ventricular ejection fraction; N/A=not applicable.

OPERATED VS. UNOPERATED PATIENTS

- Mortality difference for people with symptomatic AS treated with Aortic Valve Replacement (AVR) versus those not undergoing this procedure is one of the most striking in medicine
- AVR can be withheld in such patients only when compelling contraindications exist

SAVR v. TAVI

• CAD bypassed with SAVR during same procedure; PCI required before TAVI, usually with BMS

• Decision on SAVR made at time of angiography; work up for TAVI must be completed before candidacy can be determined
## Risk stratification of severe, symptomatic aortic stenosis patients

<table>
<thead>
<tr>
<th></th>
<th>Low Operative Risk (Must Meet ALL Criteria in This Column)</th>
<th>Intermediate Operative Risk (Any 1 Criterion in This Column)</th>
<th>High Operative Risk (Any 1 Criterion in This Column)</th>
<th>Prohibitive Operative Risk (Any 1 Criterion in This Column)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>STS PROM)</strong></td>
<td>&lt; 4% AND</td>
<td>4% to 8% OR</td>
<td>&gt; 8% OR</td>
<td>Prohibited risk with surgery of death or major morbidity (all-cause) &gt; 50% at 1 year OR</td>
</tr>
<tr>
<td><strong>Frailty</strong></td>
<td>None AND</td>
<td>1 Index (mild) OR</td>
<td>≥ 2 Indices (moderate to severe) OR</td>
<td></td>
</tr>
<tr>
<td><strong>Major organ system compromise not to be improved postoperatively</strong></td>
<td>None AND</td>
<td>1 Organ system OR</td>
<td>No more than 2 organ systems OR</td>
<td>≥ 3 organ systems OR</td>
</tr>
<tr>
<td><strong>Procedure specific impediment</strong></td>
<td>None</td>
<td>Possible procedure-specific impediment</td>
<td>Possible procedure-specific impediment</td>
<td>Severe procedure-specific impediment</td>
</tr>
</tbody>
</table>
Alain Cribier: First Human Transcatheter Valve Replacement (2002)
History of Edwards’ Transcatheter Heart Valve Technology

- **First successful TAVR procedure in U.S.**
- **Landmark PARTNER clinical trials begin in U.S.**
- Edwards SAPIEN valve approved in the U.S. for inoperable patients
- Edwards SAPIEN valve approved in U.S. for high-risk patients
- Edwards SAPIEN XT valve approved in U.S. for high or greater risk patients
- Edwards SAPIEN 3 valve approved in U.S. for high or greater risk patients

<table>
<thead>
<tr>
<th>Year</th>
<th>Event</th>
</tr>
</thead>
<tbody>
<tr>
<td>2005</td>
<td>First successful TAVR procedure in U.S.</td>
</tr>
<tr>
<td>2007</td>
<td>Landmark PARTNER clinical trials begin in U.S.</td>
</tr>
<tr>
<td>2011</td>
<td>Edwards SAPIEN valve approved in the U.S. for inoperable patients</td>
</tr>
<tr>
<td>2012</td>
<td>Edwards SAPIEN valve approved in U.S. for high-risk patients</td>
</tr>
<tr>
<td>2014</td>
<td>Edwards SAPIEN XT valve approved in U.S. for high or greater risk patients</td>
</tr>
<tr>
<td>2015</td>
<td>Edwards SAPIEN 3 valve approved in U.S. for high or greater risk patients</td>
</tr>
</tbody>
</table>
Clinical Outcomes Improve as Therapy Evolves

Low Mortality and Stroke Rates
Patient selection, procedural techniques, device evolution

- RetroFlex 3 Delivery System
- NovaFlex+ Delivery System
- Edwards Commander Delivery System

Improved Vascular Access
Lower profile devices expands treatment possibilities

- RetroFlex 3 Introducer Sheath
- Edwards eSheath Introducer Set
- Edwards eSheath Introducer Set*

Increased Treatment Range
Larger and smaller valves

- SAPIEN Valve 23 and 26 mm
- SAPIEN XT Valve 23, 26, 29 mm
- SAPIEN 3 Valve 20, 23, 26, 29 mm

*only used with 20, 23, 26 valve sizes
The SAPIEN 3 Valve: Transformational Design

Outer Sealing Skirt
- Designed to minimize paravalvular leak

Frame Design
- Enhanced frame geometry for low delivery profile
  - Cobalt-chromium for high radial strength

Proven Valve Tissue
- Utilizes the same bovine pericardial tissue and processes as Edwards’ surgical valves
TRANSCATHETER AORTIC VALVE REPLACEMENT GLOBAL TIMELINE

- More than 80,000 TAVR implants globally since 1st introduced commercially in 2007
- More than 60 countries

Significant body of TAVR evidence with 4 large U.S. trials

To view the complete CoreValve Instructions for Use visit: manuals.medtronic.com
The CoreValve System continues to demonstrate exceptional outcomes—and we’ve taken what we’ve learned from the design of the platform and applied it to the Evolut R System.

To view the complete CoreValve Instructions for Use visit: manuals.medtronic.com
TAVR work up

- Cath/PCI
- CTA of chest/abd/pelvis
  - Vascular access
  - Coronary artery height
  - Tortuosity and angle of deployment
- TEE at time of procedure
CTA Measurements
Coronary artery heights
Evidence for Transcatheter Aortic Valve replacement
U.S. INCIDENCE OF SEVERE AORTIC STENOSIS STRATIFIED BY RISK

Severe AS, Symptomatic ~120,000 Incidence

STS Database

Low Operative Risk¹ 32%
Intermediate Operative Risk¹ 25%
High Operative Risk¹ 31%

SAVR Indicated

TAVR Indicated

Extreme Operative Risk* 13%

* Approximately 2/3 of Extreme Operative Risk Patients are not candidates for valve replacement – Cohort C

PARTNER Study Design

Symptomatic Severe Aortic Stenosis

Inoperable
N = 358

Severe Symptomatic AS with
AVA < 0.8 cm² (EOA index
< 0.5 cm²/m²), and mean
gradient > 40 mmHg
or jet velocity > 4.0 m/s

ASSESSMENT: Transfemoral
Access

1:1 Randomization

TF TAVR n = 179
VS
Standard Therapy n = 179

Primary Endpoint: All-Cause Mortality
Over Length of Trial (Superiority)

Inoperable defined as risk of
death or serious irreversible
morbidity of AVR as assessed
by cardiologist and two
surgeons exceeding 50%.

- Primary endpoint evaluated when all patients reached one year follow-up.
- After primary endpoint analysis reached, patients were allowed to cross-over to TAVR.
All-Cause Mortality (ITT) Crossover Patients Censored at Crossover

- Standard Rx (n = 179)
- TAVR (n = 179)

HR [95% CI] = 0.50 [0.39, 0.65]

p (log rank) < 0.0001

*In an age and gender matched US population without comorbidities, the mortality at 5 years is 40.5%.
Pivotal Trial Design

CoreValve US Pivotal Trial

**Extreme Risk**
- Iliofemoral Access > 18 Fr Sheath
  - CoreValve Iliofemoral N=489
  - CoreValve Non-Iliofemoral N=150

**High Risk**
- Randomization 1:1
  - CoreValve
  - SAVR
All-Cause Mortality or Major Stroke

Performance Goal
43%

26.0%
[22.1, 29.9]

57.9%*
[33.6, 42.3]

38.0%

*Calculated rate for 117 events in 179 patients (65.4%, lower confidence bound of 57.9% by Exact method) (Makkar RR, et al, New Engl J Med, 2012)
All-Cause Mortality Has Decreased Overall

**ALL-CAUSE MORTALITY at 30 DAYS**
**PARTNER I Trial and PARTNER II Trial**

- **PARTNER I B (TF)**: 6.3% (175)
- **PARTNER I A (All)**: 5.2% (344)
- **PARTNER I A (TF)**: 3.7% (240)
- **PARTNER II B (TF)**: 4.4% (271)
- **PARTNER II B (TF)**: 3.5% (282)
- **PARTNER II HR (TF)**: 1.6% (491)

*Graph showing the mortality rates for different trials and valve types.*
### EVENTS (N=60)

<table>
<thead>
<tr>
<th>Event</th>
<th>30 Day</th>
<th>1 Year</th>
</tr>
</thead>
<tbody>
<tr>
<td>All-cause mortality</td>
<td>0</td>
<td>6.7</td>
</tr>
<tr>
<td>Disabling stroke</td>
<td>0</td>
<td>3.4</td>
</tr>
<tr>
<td>Mean gradient</td>
<td>8.1 mm HG</td>
<td>7.5 mm HG</td>
</tr>
<tr>
<td>Patients with ≤ mild PVL</td>
<td>96.6</td>
<td>95.7</td>
</tr>
<tr>
<td>Permanent pacemaker implantation</td>
<td>11.7</td>
<td>15.2</td>
</tr>
</tbody>
</table>

To view the complete CoreValve Instructions for Use visit: manuals.medtronic.com
NYHA Class in 2-Year Survivors
Paired Analysis

92% of Patients Improved at Least 1 NYHA Class by 2 Years
58% of Patients Improved at Least 2 NYHA Classes by 2 Years
At both 1 year and 5 year follow up, 85% of Patients treated with the Edwards SAPIEN valve were in NYHA Class I or II compared to only 6% at baseline.
TAVI Evidence Summary

- The 5-year results from PARTNER B demonstrate the longer-term benefits of TAVR in patients unsuitable for surgical AVR.
- The 2-year results from the CoreValve US Extreme Risk Study confirmed the improved survival benefit of this therapy. We observed:
  - low rates of mortality and major stroke
  - low rates of moderate AI, not associated with mortality
- 30 day mortality with Sapien 3 and CoreValve Evolute R comparable to SAVR
TAVI Work Up
“The management of patients with complex severe VHD is best achieved by a Heart Valve Team composed primarily of…”

- Cardiologists
- Surgeons
- Structural valve interventionalists
- Cardiovascular imaging specialists
- Cardiovascular surgeons
- Anesthesiologists
- Nurses

Testing Performed by Heart Team

- History/Consult
- Physical Exam
- STS Score
- Independent Living
- Gait Test/Grip Strength
- MMSE2
- NY Heart Failure Class
- Labs
- ECG
- Echocardiogram
- TEE
- Cardiac catheterization with FFR/IVUS
- CTA of chest/abd/pelvis
- IVUS of iliac arteries
Pre-screening Review of Records

Clinical Evaluation

Gated CTA (Chest / Abdomen / Pelvis)

RHC / LHC Coronary Angiography

Functional Status Assessment (Cognitive Function, Frailty, etc.)

STS Score Calculation

Treatment Plan

Note: The above is a suggested flow for the patient screening process, however, the order in which screening tests are conducted varies depending on the patient’s profile and should be at the discretion of the Heart Team.
Typical Patient Flow

• Consultation/Exam
• Echocardiogram
• Cardiac catheterization/PCI
• CTA of chest/abd/pelvis or IVUS of iliac
• Surgical Consultation
• Second surgical consultation
• Scheduling of procedure
BH First TAVI Patient May 2012

- 87 y.o. male
- STS  5.060 %
- NYHA  = 3
- Creatinine = 1.4
- Hb = 11.6
- PLT = 186

**Clinical History**

<table>
<thead>
<tr>
<th>Height = 173 cm</th>
<th>Hx of bilateral femur fractures</th>
</tr>
</thead>
<tbody>
<tr>
<td>Weight = 84 kg</td>
<td>Impaired mobility</td>
</tr>
<tr>
<td>BMI = 28.1</td>
<td>No significant CAD</td>
</tr>
<tr>
<td>PVD</td>
<td>HTN</td>
</tr>
<tr>
<td>AICD</td>
<td></td>
</tr>
<tr>
<td>Pulmonary HTN</td>
<td></td>
</tr>
<tr>
<td>Atrial Fibrillation</td>
<td></td>
</tr>
</tbody>
</table>
Inoperable

• Evaluated by surgeon(s)
  – Donald Polansky

• Deemed inoperable for the following reason(s):

<table>
<thead>
<tr>
<th>Reason(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>• ---- Frailty, Hx of bilateral femur fracture with subsequent infection</td>
</tr>
<tr>
<td>• ---- Get up and go test = Greater than 30 seconds = impaired mobility</td>
</tr>
<tr>
<td>• ---- Poor prognosis for recovery from open heart surgery</td>
</tr>
</tbody>
</table>
STS Score

Procedure Name: Isolated Aortic Valve Replacement

Risk of Mortality = 5.060%
Morbidity or Mortality = 29.768%
Long Length of Stay = 12.349%
Short Length of Stay = 12.436%
Permanent Stroke = 3.563%
Prolonged Ventilation = 15.685%
DSW Infection = 0.229%
Renal Failure = 8.804%
Reoperation = 12.585%
Coronary Angiography 4/4/2012

<table>
<thead>
<tr>
<th>Coronary Angiography</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Coronary Artery Disease?</td>
<td>no</td>
</tr>
<tr>
<td>Prior revascularization (CABG or PCI)?</td>
<td>none</td>
</tr>
<tr>
<td>Additional Revascularization Indicated?</td>
<td>no</td>
</tr>
</tbody>
</table>

![Coronary Angiography Images]
Echocardiography

- TTE performed on 8/15/2011

<table>
<thead>
<tr>
<th>Required Measurements</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>AVA</td>
<td>.71 cm$^2$</td>
</tr>
<tr>
<td>AVAindex</td>
<td>.35</td>
</tr>
<tr>
<td>Mean Gradient</td>
<td>40 mmHg</td>
</tr>
<tr>
<td>Peak Velocity</td>
<td>4.2 m/s</td>
</tr>
<tr>
<td>Annulus Diameter</td>
<td>19.7 mm</td>
</tr>
<tr>
<td>Ejection Fraction</td>
<td>50 %</td>
</tr>
</tbody>
</table>

Findings

- Severe aortic valve calcification
- Moderate AI
- Mild MR
- Moderate TR
Echocardiography - Annulus

LVOT = 20 mm
Echocardiography – AV V- max/PG

Mean Pressure Gradient = 40 mmHG
Vmax = 4.27 m/s
CT – Right Common Iliac Artery

Minimum Luminal Diameter = 8.6 mm (Measured on Axial view)
Minimum Luminal Diameter = 8.6 mm (Measured on axial view)
CTA – Angle of Deployment = 47.3
Example

LCOH = 15.9, RCOH = 16.5
Procedural Plan

- This patient is suitable for transfemoral TAVR

<table>
<thead>
<tr>
<th>Annulus Diameter Measurement</th>
<th>THV Valve Size Proposed</th>
<th>Femoral Access Side Proposed</th>
<th>Smallest Vessel Diameter Measurement</th>
</tr>
</thead>
<tbody>
<tr>
<td>19.7 mm</td>
<td>23 mm</td>
<td>Right</td>
<td>7.0 mm</td>
</tr>
</tbody>
</table>
TAVI Pre BAV
BAV
TAVI Deployment
Post TAVI
Post Iliac Angio
Follow up

• Patient was discharged POD #5
• Within 30 days patient was caring for his wife.
• 3.5 years later, patient only hospitalized once for pneumonia
• Wife developed severe AS and refused TAVI consideration
Case #2

- 75 y.o. with progressive dyspnea with exertion and multiple episodes of dizziness, near syncope and syncope
- PMH: AF, HTN, Rheumatic fever
- Exam: BP 138/80 HR 83 sat 98% on RA, no bruit with murmur c/w severe AS
- Echo with peak velocity 4 m/s with mild AI and EF 57%
- Cath by referring cardiologist with no CAD
ACCESS OPTIONS

Direct Aortic

Transfemoral

Subclavian

To view the complete CoreValve Evolut R Instructions for Use visit: manuals.medtronic.com
Aorta

ANNULUS
Area derived Ø: 25.0 mm
Perimeter derived Ø: 25.0 mm
Area: 489.4 mm²
Perimeter: 78.6 mm

annotated text:
Ca++
Annulus Diameter
Min. Ø: 24.5 mm
Max. Ø: 25.8 mm
30% cardiac phase
Difficult to determine annulus border due to significant annular calcification near LCC - consider aortic annulus measurements estimations

SOV DIAMETER
Ø 34.4 mm RC
NC
Comp... Dista...
Ø 34.2 mm
Ø 35.2 mm
75% cardiac phase

LVOT
LVOT Diameter
Min. Ø: 21.1 mm
Max. Ø: 23.6 mm

ASCENDING AORTA
Ascending Aorta Diameter
Min. Ø: 28.4 mm
Max. Ø: 30.0 mm

significant calcification in LVOT

CVAM
CardioVascular Associates of Mesa
<table>
<thead>
<tr>
<th>Product</th>
<th>CoreValve® Evolut™</th>
<th>CoreValve®</th>
</tr>
</thead>
<tbody>
<tr>
<td>Size</td>
<td>23 mm</td>
<td>29 mm</td>
</tr>
<tr>
<td>Annulus Diameter</td>
<td>18-20 mm</td>
<td>20-23 mm</td>
</tr>
<tr>
<td>Annulus Perimeter</td>
<td>56.5-62.8 mm</td>
<td>62.8-72.3 mm</td>
</tr>
<tr>
<td>Ascending Aorta Diameter</td>
<td>≤ 34 mm @30 mm from annulus</td>
<td>≤ 40 mm @40 mm from annulus</td>
</tr>
<tr>
<td>Sinus of Valsalva Diameter</td>
<td>≥ 25 mm</td>
<td>≥ 27 mm</td>
</tr>
<tr>
<td>Sinus of Valsalva Height</td>
<td>≥ 15 mm</td>
<td>≥ 15 mm</td>
</tr>
</tbody>
</table>
Max Ascending Aorta Diameter (mm) 30.0
Sinotubular Junction Diameter (mm) 27.6 x 29.3

Max
Min

ANNUlus

Diameter (mm) 24.5 x 25.8 25.2 mm
Min Max Mean
Perimeter (mm) 78.6 25.0

Area 489.4 mm²

LVOT Diameter (mm) 21.1 x 23.6

CIA Min Diameter (mm)
RIGHT 7.6 x 9.0
EIA Min Diameter (mm) 8.1 x 8.3
Femoral Min Diameter (mm) 6.9 x 8.2

LEFT 7.9 x 9.4
EIA Min Diameter (mm) 7.6 x 8.5
Femoral Min Diameter (mm) 6.5 x 7.9

Calcium: Mild ☑️ Moderate □ Severe □

Sinus of Valsalva Diameter (mm)
LCC 35.2 34.4 34.2
RCC 24.5 34.4 34.2
NCC 27.1 24.5 34.2

Sinus of Valsalva Height (mm)
LCC 28.6 24.5 27.1
RCC 21.2 19.8
NCC 21.2 19.8

Coronary Ostia Height (mm)
Left 21.2 19.8
Right

Subclavian Min Diameter (mm)
RIGHT
LEFT

Aortic Root Angle 53°

Please review imaged for direct aortic evaluation.
Conclusions

• Work up for aortic stenosis is standard and echo is the primary modality for deciding severity of disease
• SAVR is the standard in low risk, TAVI in high risk and evidence accumulating in intermediate risk that the two are equivalent
• Work up for TAVI is more complicated but has become standardized.
• TAVR reduces mortality and rehospitalization and improves quality of life in patients at high risk for SAVR