TAVR: Transcatheter Aortic Valve Replacement – A New Option for Patients with Severe Aortic Stenosis

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Disclosures of Financial Interest

Edwards LifeSciences - Speakes Bureau
St. Jude Medical - Speakers Bureau
Astra Zeneca - Speakers Bureau
Aortic Stenosis

Gross specimen of minimally diseased aortic valve (left) and severely stenotic aortic valve (right)

Images courtesy of Renu Virmani MD at the CVPath Institute
Prevalence of Aortic Stenosis

- Aortic stenosis is estimated to be prevalent in up to 7% of the population over the age of 65\(^1\)

- It is more likely to affect men than women; 80% of adults with symptomatic aortic stenosis are male\(^3\)

What Causes Aortic Stenosis in Adults?

**Age-Related Calcific Aortic Stenosis**
- Aortic stenosis in patients over the age of 65 is usually caused by calcific (calcium) deposits associated with aging.

**Infection**
- Aortic stenosis can be caused by various infections.

**Rheumatic Fever**
- Adults who have had rheumatic fever may also be at risk for aortic stenosis.

**Congenital Abnormality**
- In some cases adults may develop aortic stenosis resulting from a congenital abnormality.
Major Risk Factors

Independent clinical factors associated with degenerative aortic valve disease include the following:\(^4\)

- Increasing age
- Male gender
- Hypertension
- Smoking
- Elevated lipoprotein A
- Elevated LDL cholesterol
Symptoms of Aortic Stenosis

What are the symptoms of aortic stenosis?

- **Angina** - A sensation of aching, burning, discomfort, fullness, pain, or squeezing in the chest. It may also be felt in the arms, back, jaw, neck, shoulders and throat.

- **Fainting** - A sudden and brief loss of consciousness.

- **Shortness of breath** - Feeling winded and tired when walking or lying down.

- **Dizziness** (after periods of inactivity).

- **Rapid or irregular heartbeat**.

- **Palpitations** – An uncomfortable awareness of the heart beating rapidly or irregularly.
Preliminary Diagnosis of Aortic Stenosis

- Detection and estimation of disease severity can often be achieved by auscultation
  - Audible systolic heart murmur
    - Longer duration with later peak is consistent with more severe stenosis
    - Loudness of the murmur does not necessarily correlate with the severity of stenosis
  - Soft or absent second heart sound
- Delayed carotid upstroke
Multiple Modalities May Be Used to Diagnose Severe Aortic Stenosis

- Auscultation
- Trans-thoracic Echo (TTE)
- Cardiac Catheterization
- Chest X-ray
- Electrocardiogram
Echocardiographic Guidelines are the Gold Standard in Assessing Severe Aortic Stenosis

**According to the 2008 ACC/AHA guidelines, severe aortic stenosis is defined as:**

- Aortic valve area (AVA) less than 1.0 cm²
- Mean gradient greater than 40 mmHg or jet velocity greater than 4.0 m/s

### Grading the Severity of Aortic Stenosis per the ACC/AHA Guidelines

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<th>Severe</th>
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<td>Jet velocity (m/s)</td>
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<td>&gt; 4.0</td>
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<tr>
<td>Mean gradient (mmHg)</td>
<td>&lt; 25</td>
<td>25 - 40</td>
<td>&gt; 40</td>
</tr>
<tr>
<td>Valve area (cm²)</td>
<td>&gt; 1.5</td>
<td>1.0 – 1.5</td>
<td>&lt; 1.0</td>
</tr>
<tr>
<td>Valve area index (cm²/m²)</td>
<td>N/A</td>
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<td>&lt; 0.6</td>
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</table>
Aortic Stenosis Is Life Threatening and Progresses Rapidly

- Survival after onset of symptoms is 50% at 2 years
- Surgical intervention for severe aortic stenosis should be performed promptly once even minor symptoms occur
Sobering Perspective

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
Addressing a Serious Unmet Need

- Studies show at least 40% of SAS patients are not treated with an AVR
Aortic Valve Replacement Greatly Improves Survival

- Study data demonstrate that early and late outcomes were similarly good in both symptomatic and asymptomatic patients.

- It is important to note that among asymptomatic patients with SAS, omission of surgical treatment was the most important risk factor for late mortality.
Standard Therapies are Inadequate Treatments for Severe Aortic Stenosis Patients

- As seen previously, survival after onset of symptoms in patients with aortic stenosis is 50% at 2 years\(^1\)
- The PARTNER Trial showed that in inoperable patients with severe aortic stenosis who did not receive a valve replacement, 50% died within 1 year
- Despite the frequent utilization of BAV, standard therapy did not do much to alter the dismal course of disease for inoperable patients with severe aortic stenosis
Options for Aortic Valve Replacement

High-risk and Inoperable Patients

- Transcatheter Aortic Valve Replacement (TAVR)

High-risk and Intermediate Risk Patients

- Surgical Aortic Valve Replacement (SAVR)
- Minimal Incision Valve Surgery (MIVS)
Edwards SAPIEN Transcatheter Heart Valve

- Bovine pericardial tissue
- Leaflets matched for thickness and elasticity
- Stainless steel frame
- PET skirt
Edwards SAPIEN Transcatheter Heart Valve Deployment
Balloon Aortic Valvuloplasty
Sheath Insertion
Tracking the Delivery System Over the Aortic Arch
An Alternative Option for Patients Without Vascular Access

- Some patients may not have adequate vascular access to accommodate the sheath used during transfemoral procedures.

- For these patients, alternative access approaches are available, such as transapical and transaortic.

During the **transapical** approach, the Edwards SAPIEN transcatheter heart valve is delivered through the apex of the heart by making a small incision between the ribs.

During the **transaortic** approach, the Edwards SAPIEN transcatheter heart valve is delivered through an incision in the front of the chest.
Current Status of Transcatheter Aortic Valve Replacement – FDA Approved Devices in US

Current Widely Available Transcatheter Valves
(A) The Edwards SAPIEN THV balloon-expandable valve (Edwards Lifesciences, Irvine, California) incorporates a stainless steel frame, bovine pericardial leaflets, and a fabric sealing cuff. (B) The SAPIEN XT THV (Edwards Lifesciences) utilizes a cobalt chromium alloy frame and is compatible with lower profile delivery catheters. (C) The Medtronic CoreValve (Medtronic, Minneapolis, Minnesota) incorporates a self-expandable frame, porcine pericardial leaflets, and a pericardial seal.
Valve Delivery Catheters
(A, top) The RetroFlex 1 delivery system for the Edwards SAPIEN THV (Edwards Lifesciences, Irvine, California) as used in the PARTNER 1 (Placement of AoRTic Transcatheter Valve 1) trials (8 mm diameter). (A, Middle) The RetroFlex 3 system (Edwards Lifesciences). (A, Bottom) The NovaFlex/SAPIEN XT system (6 mm diameter; Edwards Lifesciences).
(B) The Accutrak delivery system with the Medtronic CoreValve (6 mm diameter, also with a tapered nosecone; Medtronic, Minneapolis, Minnesota). The prosthesis is enclosed within an outer sheath.
Valves Undergoing Early Evaluation
(A) Lotus (Boston Scientific Inc., Natick, Massachusetts), (B) Direct Flow (Direct Flow Medical Inc., Santa Rosa, California), (C) HLT (Bracco Inc., Princeton, New Jersey), (D) Portico (St. Jude Medical Inc., St. Paul, Minnesota), (E) Engager (Medtronic Inc., Minneapolis Minnesota), (F) JenaClip (JenaValve Inc., Munich, Germany), (G) Acurate valve (Symetis Inc., Ecublens, Switzerland), and (H) Inovare (Braile Biomedica Inc., São José do Rio Preto, Brazil) valves.
Fluoroscopic Images of Some Newer Valves Undergoing Early Evaluation in Patients

The CENTERA valve (A) is self-expandable and utilizes an electronic motorized release and retrieval system, while the S3 valve (B) incorporates an improved sealing system and utilizes a 14-F expandable sheath (Edwards Lifesciences, Irvine, California). (C) The Portico valve (St. Jude Medical Inc., St. Paul, Minnesota) is self-expandable, retrievable, and repositionable.
Percutaneous Access and Closure

(A) The femoral artery is punctured and a guidewire placed within the artery. Percutaneous sutures are placed using a “pre-closure” device. (B) The large vascular access sheath is inserted. (C) Following sheath removal the sutures are tightened.
Definitive Results Through Rigorous Design

THE PARTNER TRIAL PROTOCOL

Severe Symptomatic Native Aortic Valve Stenosis

ASSESSMENT: OPERABILITY
(N = 3,105)

Cohort A
High-Risk
(n = 699)

2 Cohorts
Individually Powered
(n = 1,057)

Cohort B
Inoperable
(n = 358)

ASSESSMENT: TRANSFEMORAL ACCESS

TF
(n = 492)

TA
(n = 207)

TF
(n = 492)

TA
(n = 207)

TF
(n = 179)

Not in Study

AVR
(Control)
(n = 248)

AVR
(Control)
(n = 103)

Standard Therapy
(Control)
(n = 179)

1:1 Randomization

1:1 Randomization

1:1 Randomization

THE PARTNER TRIAL COHORT B
Definitive Results Through Rigorous Design

THE PARTNER TRIAL COHORT B INCLUSION CRITERIA

Severe Symptomatic Native Aortic Valve Stenosis

ASSESSMENT: OPERABILITY
(N = 3,105)

Yes

Cohort A
High-Risk
(n = 699)

2 Cohorts
Individually Powered
(n = 1,057)

No

Cohort B
Inoperable
(n = 358)

Asessment: Operability

COHORT B KEY INCLUSION CRITERIA

Predicted operative mortality or irreversible morbidity > 50%

NYHA functional class ≥ II

AVA
Mean gradient > 0.8 cm²
> 40 mmHg

Peak jet velocity > 4.0 m/s

*Patient selection required at least two cardiothoracic surgeons and a cardiologist to agree that patients were not suitable candidates for surgery.
†This mean score reflects enrolled patient group; not required for inclusion.
Definitive Results Through Rigorous Design

THE PARTNER TRIAL COHORT B ENDPOINTS

Severe Symptomatic Native Aortic Valve Stenosis

ASSESSMENT: OPERABILITY
(N = 3,105)

Cohort A High-Risk
(n = 699)

Determine Operability

Cohort B Indoperable
(n = 358)

2 Cohorts Individually Powered
(n = 1,057)

ASSESSMENT Transfemoral Access

Yes

TF
(n = 492)

1:1 Randomization

TA
(n = 207)

1:1 Randomization

TF TAVR
(Control)
(n = 244)

AVR
(n = 248)

TA TAVR
(Control)
(n = 104)

AVR
(n = 103)

COHORT B PRIMARY ENDPOINT
All-cause mortality over length of trial
(Superiority)

COHORT B CO-PRIMARY ENDPOINT
Composite of all-cause mortality or repeat hospitalization (Superiority)
Edwards SAPIEN THV Improved Survival

\[ P \text{ (log rank)} < .0001 \]
\[ \Delta \text{ at 2 yrs} = 24.7\% \]
\[ \text{NNT} = 4.0 \text{ pts} \]

Numbers at Risk

<table>
<thead>
<tr>
<th>Group</th>
<th>Numbers at Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>Edwards SAPIEN THV</td>
<td>179</td>
</tr>
<tr>
<td>Standard Therapy</td>
<td>179</td>
</tr>
</tbody>
</table>

Edwards SAPIEN THV 179

Standard Therapy 179

P (log rank) < .0001
\[ \Delta \text{ at 2 yrs} = 24.7\% \]
\[ \text{NNT} = 4.0 \text{ pts} \]
Edwards SAPIEN THV Improved Cardiac Function

The graph shows the mean gradient over time for Edwards SAPIEN THV and Standard Therapy. The mean gradient at baseline is 43.0 mm Hg, decreasing to 10.2 mm Hg at 30 days, and further decreasing to 10.9 mm Hg at 1 year. After 2 years, the mean gradient is 10.6 mm Hg. The error bars represent ±1 Std Dev.

Numbers Observed:

- Edwards SAPIEN THV: Baseline 162, 30 Days 143, 1 Year 89, 2 Years 65
- Standard Therapy: Baseline 172, 30 Days 124, 1 Year 54, 2 Years 22
Edwards SAPIEN THV Reduced Symptoms

THE PARTNER TRIAL COHORT B
## Complications

<table>
<thead>
<tr>
<th>Outcome</th>
<th>30 Days</th>
<th>1 Year</th>
<th>2 years</th>
</tr>
</thead>
<tbody>
<tr>
<td>All-cause mortality</td>
<td>5.00%</td>
<td>2.80%</td>
<td>30.70%</td>
</tr>
<tr>
<td>Death or repeat hospitalization</td>
<td>11.70%</td>
<td>12.30%</td>
<td>44.10%</td>
</tr>
<tr>
<td>Stroke</td>
<td>7.30%</td>
<td>1.70%</td>
<td>11.20%</td>
</tr>
<tr>
<td>Major vascular complications</td>
<td>16.80%</td>
<td>1.10%</td>
<td>17.40%</td>
</tr>
<tr>
<td>Bleeding events</td>
<td>16.20%</td>
<td>2.20%</td>
<td>17.30%</td>
</tr>
<tr>
<td>New pacemaker implantation</td>
<td>3.40%</td>
<td>5.10%</td>
<td>4.70%</td>
</tr>
</tbody>
</table>
Edwards SAPIEN THV Had Higher Incidence of Stroke

Stroke was defined as follows: Neurological deficit lasting ≥ 24 hours or lasting less than 24 hours with a brain imaging study showing an infarction.

THE PARTNER TRIAL COHORT B
Edwards SAPIEN THV Had Higher Incidence of Major Vascular Complications

Major vascular complications were defined as any thoracic aortic dissection, access site or access-related vascular injury (dissection, stenosis, perforation, rupture, arterio-venous fistula, pseudoaneurysm, or hematoma) leading to either death, need for significant blood transfusion (> 3 units), or percutaneous or surgical intervention, and/or distal embolization (non-cerebral) from a vascular source requiring surgery or resulting in amputation or irreversible end-organ damage.
Edwards SAPIEN THV Had Higher Incidence of Bleeding Events

<table>
<thead>
<tr>
<th></th>
<th>30 Days</th>
<th>1 Year</th>
<th>2 years</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Outcome</strong></td>
<td><strong>Outcomes</strong></td>
<td><strong>30 Days</strong></td>
<td><strong>1 Year</strong></td>
</tr>
<tr>
<td></td>
<td>Edwards SAPIEN THV</td>
<td>16.20%</td>
<td>17.30%</td>
</tr>
<tr>
<td></td>
<td>Standard Therapy</td>
<td>2.20%</td>
<td>2.20%</td>
</tr>
</tbody>
</table>

Bleeding event is defined as ≥ 2 units within the index procedure.
Critical Insights

Standard therapy is failing patients with inoperable aortic stenosis

68% mortality at 2 years

Based on the 2-year results of Cohort B, patients treated with the Edwards SAPIEN THV:

Only need to treat 4 patients to save a life

4 out of 5 patients were asymptomatic or mildly symptomatic at 2 years

First-generation Edwards SAPIEN THV was associated with important peri-procedural events at 2 years:

- Stroke
- Major vascular complications
- Bleeding Event
Study Design & Inclusion Criteria

Severe Symptomatic Native Aortic Valve Stenosis

Assessment: Operability (n=3,105)

Cohort A: High-Risk (n=699)

Yes
Assessment: Transfemoral Access

No

TF (n=492)

1:1 Randomization

TF TAVR (n=244) vs. AVR (Control) (n=248)

TA (n=207)

1:1 Randomization

TA TAVR (n=104) vs. AVR (Control) (n=103)

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

Cohort A: Key Inclusion Criteria

- Predicted operative mortality or irreversible morbidity ≥ 15%*
- Guideline: STS score ≥10, amended to ≥ 8
- NYHA functional class ≥ II
- AVA < 0.8 cm² or Mean gradient > 40 mm Hg or Peak jet velocity > 4.0 m/s

TF, transfemoral; TA, transapical.
* As determined by site surgeon and cardiologist.

THE PARTNER TRIAL COHORT A
All-Cause 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
Edwards SAPIEN THV 348 312 298 269 260 247 234 222 172
AVR 351 274 252 245 236 225 217 208 165

THE PARTNER TRIAL COHORT A
All Strokes

**AT Population**

**STROKE AT 1 YEAR AND 2 YEARS**

- HR [95% CI] = 1.23 [0.66, 2.31]
- P (log rank) = 0.51

<table>
<thead>
<tr>
<th>Months</th>
<th>Edwards SAPIEN THV</th>
<th>AVR</th>
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<tbody>
<tr>
<td>0</td>
<td>344</td>
<td>313</td>
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<td>3</td>
<td>296</td>
<td>251</td>
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<td>6</td>
<td>281</td>
<td>237</td>
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<td>9</td>
<td>257</td>
<td>231</td>
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<td>12</td>
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<td>223</td>
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<td>15</td>
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<td>18</td>
<td>223</td>
<td>206</td>
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<td>21</td>
<td>211</td>
<td>198</td>
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<td>24</td>
<td>146</td>
<td>139</td>
</tr>
</tbody>
</table>

THE PARTNER TRIAL COHORT A
Major Vascular Complications

AT Population

MAJOR VASCULAR COMPLICATIONS AT 30 DAYS, 1 YEAR, AND 2 YEARS

Event, %

0 2 4 6 8 10 12 14 16 18 20 22

Edwards SAPIEN THV  AVR

30 Days 1 Year 2 Years

11.1 3.8 11.1 3.8 11.4 3.8

p < 0.001 p < 0.001 p < 0.001

Kaplan-Meier estimates.

THE PARTNER TRIAL COHORT A
Major Bleeding

At 30 Days, 1 Year, and 2 Years

MAJOR BLEEDING COMPLICATIONS
AT 30 DAYS, 1 YEAR, AND 2 YEARS*

<table>
<thead>
<tr>
<th>Event, %</th>
<th>Edwards SAPIEN THV</th>
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<th>AVR</th>
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<tbody>
<tr>
<td>30 Days</td>
<td>10.8</td>
<td>23.0</td>
<td>15.8</td>
<td>27.5</td>
<td>19.1</td>
<td>30.1</td>
</tr>
<tr>
<td>1 Year</td>
<td>p &lt; 0.001</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2 Years</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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</table>

*Kaplan-Meier estimates. *Major bleeding is defined as any episode of major internal or external bleeding that caused death, hospitalization or permanent injury (e.g., vision loss) or necessitated transfusion of greater than 3 units PRBCs within a 24-hour period, pericardiocentesis, open and/or endovascular procedure for repair or hemostasis.

THE PARTNER TRIAL COHORT A
Key Takeaways – Inoperable Patients

At 2 years, in patients with severe symptomatic native aortic valve stenosis who were not suitable candidates for surgery:

- Treatment with the Edwards SAPIEN THV remained superior to standard therapy with incremental benefit from 1 to 2 years, reducing the rates of mortality and repeat hospitalization.
- Treatment with the Edwards SAPIEN THV improved NYHA functional status and decreased class III/IV symptoms compared to standard therapy.
- There were significantly more strokes in patients treated with the Edwards SAPIEN THV than in patients who received standard therapy.
- Patients treated with the Edwards SAPIEN THV also had a higher incidence of major vascular complications and major bleeding than standard therapy patients.
Key Takeaways – High-Risk Patients

At 2 years, in patients with symptomatic severe aortic stenosis who were high-risk candidates for surgical AVR:

- Edwards SAPIEN THV was non-inferior to surgical AVR with similar rates of all-cause and cardiovascular mortality
- Resulted in symptom improvement that was similar in both groups and maintained through two years
- Hemodynamic performance of the Edwards SAPIEN THV was maintained with similar valve gradients and effective orifice areas compared with surgical AVR
- Both TAVR and AVR had adverse procedural events which impacted subsequent mortality, such as stroke and major bleeding for both procedures, and major vascular complications for TAVR
  - There was no statistically significant difference in stroke rate between Edwards SAPIEN THV and AVR patients despite increased peri-procedural events after TAVR; there was no late (after 30 days) stroke hazard in TAVR patients
- Two-year results from the high-risk operable PARTNER cohort support the use of Edwards SAPIEN THV as an alternative to surgery with similar mortality and clinical benefits
Characteristics of a TAVR Patient

TAVR patients may present with some of the following:

- Severe, symptomatic native aortic valve stenosis
- Old age
- Frailty
- History of stroke/CVA
- History of syncope
- Reduced EF
- Heavily calcified aorta
- Prior CABG
- Prior chest radiation
- History of AFib
- History of CAD
- Prior open chest surgery
- History of COPD
- Fatigue, slow gait
- History of renal insufficiency
- Peripheral vascular disease
- Diabetes and hypertension
TAVR Case Study Example

**Echocardiographic observations:**
- Jet Velocity: 5.7 m/s
- Mean gradient: 80 mmHg
- AVA: 0.5 cm²
- Annulus measures 20 mm

**DIAGNOSIS:** Patient has severe aortic stenosis and may be a candidate for TAVR

- **John Doe**
  - 85 year old male
  - Weight: 115 kg
  - Height: 175 cm

- **History**
  - History of hypertension
  - Diabetes

- **Characteristics**
  - Delayed carotid upstroke
  - Audible systolic heart murmur
  - Soft or absent second heart sound
  - Reports marked limitation in physical activity due to symptoms such as shortness of breath present even during less than normal activity
Following Patient Referral, the TAVR Team will Perform Further Evaluation

1. Confirm the patient is diagnosed with severe symptomatic native aortic stenosis
2. Confirm the patient has been evaluated by two cardiac surgeons and meets the indication for TAVR
3. Evaluate the aortic valvular complex using echocardiography
4. Evaluate the aortic valvular complex and peripheral vasculature using CT
5. Evaluate the aortic valvular complex and peripheral vasculature using catheterization
6. Determine access route for transcatheter aortic valve replacement

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.
Echocardiographic Guidelines are the Gold Standard in Assessing Severe Aortic Stenosis

According to the 2008 ACC/AHA guidelines, severe aortic stenosis is defined as:

- Aortic valve area (AVA) less than 1.0 cm²
- Mean gradient greater than 40 mmHg or jet velocity greater than 4.0 m/s

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<td>Mean gradient (mmHg)</td>
<td>&lt; 25</td>
<td>25 - 40</td>
<td>&gt; 40</td>
</tr>
<tr>
<td>Valve area (cm²)</td>
<td>&gt; 1.5</td>
<td>1.0 - 1.5</td>
<td>&lt; 1.0</td>
</tr>
<tr>
<td>Valve area index (cm²/m²)</td>
<td>N/A</td>
<td>N/A</td>
<td>&lt; 0.6</td>
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*Doppler-Echocardiographic measurements*
Paradoxical Low Flow and/or Low Gradient Severe Aortic Stenosis

- Dobutamine stress echocardiography can be used to differentiate between true and pseudo severe aortic stenosis
  - Better define the severity of the aortic stenosis
  - Accurately assess contractile/pump reserve

- Some patients with severe aortic stenosis based on valve area have a lower than expected gradient (e.g. mean gradient < 30 mmHg) despite preserved LV ejection fraction (e.g. EF > 50%)
  - Up to 35% of patients with severe aortic stenosis present with low flow, low gradient
  - These low gradients often lead to an underestimation of the severity of the disease, so many of these patients do not undergo surgical aortic valve replacement

Dobutamine stress in low gradient, low ejection fraction AS Chambers, Heart. 2006 April; 92(4): 554–558
Ensuring the Appropriate Annular Size Range

- The Edwards SAPIEN transcatheter heart valve is offered in two sizes, 23 mm and 26 mm, and accommodates an annular size range of 18 mm to 25 mm.

- 23 mm valve requires a 22F sheath

- 26 mm valve requires a 24F sheath
Assessing Appropriate Vascular Access

Vessel diameters must be a minimum of:

- ≥ 7 mm for a 23 mm valve (requires a 22F RetroFlex 3 sheath)
- ≥ 8 mm for a 26 mm valve (requires a 24F RetroFlex 3 sheath)
An Alternative Option for Patients Without Vascular Access

- Some patients may not have adequate vascular access to accommodate the sheath used during transfemoral procedures

- For these patients, alternative access approaches are available, such as transapical and transaortic

During the **transapical** approach, the Edwards SAPIEN transcatheter heart valve is delivered through the apex of the heart by making a small incision between the ribs.

During the **transaortic** approach, the Edwards SAPIEN transcatheter heart valve is delivered through an incision in the front of the chest.
Transfemoral Case #1
TransFemoral TAVR
Transfemoral Case #1
Transfemoral Case #1
TransAortic TAVR
TransAortic Case #1
TransAortic Case #1
TransAortic Case #1
TransApical TAVR
TransApical Case #1
TransApical Case #1
TransApical Case #1
**Figure 3**  
**Freedom From All-Cause and Cardiac Mortality at the Propensity-Matched Analysis**

Freedom from all-cause (A) and cardiovascular (B) mortality in the propensity-matched population at 1 year. The green line represents MCV and the blue line the ESV. Abbreviations as in Figure 2.

**Conclusions**

No differences between the 2 commercially available TF TAVI devices were observed in the adjusted analysis in the study population in VARC outcomes at 30 days and 1 year, except for the need for a PPM with the MCV. These results need to be confirmed in a randomized trial.
Thank You

Questions?