UPDATES IN TREATMENT AND EVALUATION IN AORTIC STENOSIS

THOMAS NOEL M.D.
DISCLOSURE

No disclosures related to this lecture
OBJECTIVES

- Identify candidates for heart valve replacement
- Indications for surgical AVR and percutaneous aortic valve replacement
- Risks and benefits with percutaneous valve replacement
What college fan base is the most irritating?

A. Florida Gators
B. University of Alabama
C. Duke
D. Miami
E. Florida State University
ANSWER
Calcification of a normal trileaflet valve
- Incidence of severe aortic stenosis increases with age
- Age >75 incidence is 2.2%
- Age >85 incidence is 12%
Systolic murmur
- 2nd right intercostal space
- Crescendo-decrescendo murmur with mild to moderate aortic stenosis
- Later crescendo occurs in systole more severe is stenosis

Pulses tardus
- Delayed carotid upstroke
  - Palpate apex of the left ventricle while simultaneously palpating the carotid artery
Class I Indications

- Echo is recommended for diagnosis and assessment of Aortic stenosis
- Echo is recommended for re-evaluation of patients with known AS and changing signs and symptoms
- Echo in asymptomatic patients
  - Every year for severe aortic stenosis
  - Every 1-2 years for moderate aortic stenosis
  - Every three to five years for mild aortic stenosis
DEFINING AORTIC STENOSIS

- **Mild Aortic Stenosis**
  - Valve area of 1.5cm² - 2 cm²
  - Mean gradient of less than 25 mmHg
  - Jet velocity of less than 3.0 m/sec

- **Moderate aortic stenosis**
  - Valve area of 1.0 - 1.5 cm²
  - Mean gradient of 25 to 40 mmHg
  - Jet Velocity of 3.0 m/sec to 4.0 m/sec

- **Severe aortic stenosis**
  - Valve area of <1.0 cm²
  - Mean gradient greater than 40 mmHg (NOT ALWAYS)
GUIDE LINE MANAGEMENT

Undergoing CABG or other heart surgery? → Symptoms?

Yes: Symptoms ↓BP

No: LV ejection fraction

Symptoms? → Exercise test

Normal: LV ejection fraction

Less than 0.50: Severe valve calcification, rapid progression, and/or expected delays in surgery

Re-evaluation
GUIDELINE MANAGEMENT

Undergoing CABG or other heart surgery?

Yes

Symptoms?

Equivocal

Exercise test

Symptoms ↓BP

Less than 0.50

LV ejection fraction

Normal

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

No

Re-evaluation

Normal
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?

Equivocal

Exercise test

Normal

LV ejection fraction

Less than 0.50

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

No

Normal

Preoperative coronary angiography

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

Class I

Class IIb

Class I

Class I

Class IIb
**Severe Aortic Stenosis**

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

**Symptoms?**

- Yes
  - Exercise test
    - Symptoms ↓BP
      - Class I
      - Class I
    - Normal
      - LV ejection fraction
        - Less than 0.50
          - Yes
            - Severe valve calcification, rapid progression, and/or expected delays in surgery
          - No
            - Clinical follow-up, patient education, risk factor modification, annual echo
      - Normal
        - Class IIb

- No
  - Re-evaluation

**Undergoing CABG or other heart surgery?**

- Yes
  - Aortic Valve Replacement
  - Preoperative coronary angiography

- No
  - Re-evaluation
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
Class I
Class IIb

Equivocal
Exercise test
Symptoms ↓BP
Less than 0.50

No
LV ejection fraction
Normal
Severe valve calcification, rapid progression, and/or expected delays in surgery
Clinical follow-up, patient education, risk factor modification, annual echo

Re-evaluation

Preoperative coronary angiography
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
  - Symptoms ↓BP
  - Class I
  - Class IIb
  - Aortic Valve Replacement
  - Preoperative coronary angiography

- No
  - Equivocal
  - Exercise test
    - Normal
      - LV ejection fraction
        - Less than 0.50
          - Severe valve calcification, rapid progression, and/or expected delays in surgery
        - Normal
          - Yes
  - No

Re-evaluation
AORTIC STENOSIS CHALLENGES

- Low Gradient-Reduced Left Ventricular function
- Low Gradient –Normal Left ventricular function
LOW GRADIENT LOW FLOW AORTIC STENOSIS REDUCED LV FUNCTION

Dobutamine Stress Echo

↑ SV > 20%
LV Flow Reserve

ΔP > 40* & EOA < 1.2*
(EOA_{Proj} ≤ 1.0-1.2)
(CT Ca > 1650)
True-Severe AS
SAVR + CABG

ΔP < 40* & EOA > 1.2*
(EOA_{Proj} > 1.0-1.2)
(CT Ca < 1650)
Pseudo-Severe AS
MEDICAL Rx TRIAL

↑ SV < 20%
No LV Flow Reserve

(NO LV Flow Reserve)

(EOA_{Proj} < 1.0-1.2)^†
(CT Ca ≥ 1650)
True-Severe AS
SAVR (High Op. Risk)
TAVR?

No

Yes

Philippe Pibarot, and Jean G. Dumesnil JACC 2012;60:1845-1853

American College of Cardiology Foundation
Philippe Pibarot, and Jean G. Dumesnil JACC 2012;60:1845-1853

American College of Cardiology Foundation
LOW FLOW LOW GRADIENT NORMAL LV FUNCTION

- AVA of less than 1.0 cm²
- Mean gradient < 40 mmHg
- LV EF of > 50%
- AVA indexed < 0.6 cm²/m²
- Stroke volume index < 35 ml/m² (not always)
- Commonly seen in elderly, and women with small ventricular cavities
QUANTIFICATION OF AORTIC VALVE CALCIFICATION CORRELATES TO SEVERITY

- Severe AS >2,000 AU in men
- Severe AS >1200 in women

- Pitfalls
  - Does not correlate for bicuspid valves
  - Does not appreciate fibrosis
AORTIC STENOSIS IS LIFE-THREATENING AND PROGRESSES RAPIDLY\(^1\)

- Survival after onset of symptoms is 50% at 2 years and 20% at 5 years\(^2\)
- Surgical intervention for severe aortic stenosis should be performed promptly once even minor symptoms occur\(^2\)
NO ONE Likes Surgery (of any kind)!
Transcatheter Aortic-Valve Implantation for Aortic Stenosis in Patients Who Cannot Undergo Surgery

Martin B. Leon, M.D., Craig R. Smith, M.D., Michael Mack, M.D., D. Craig Miller, M.D., Jeffrey W. Moses, M.D., Lars G. Svensson, M.D., Ph.D., E. Murat Tuzcu, M.D., John G. Webb, M.D., Gregory P. Fontana, M.D., Raj R. Makkar, M.D., David L. Brown, M.D., Peter C. Block, M.D., Robert A. Guyton, M.D., Augusto D. Pichard, M.D., Joseph E. Bavaria, M.D., Howard C. Herrmann, M.D., Pamela C. Douglas, M.D., John L. Petersen, M.D., Jodi J. Akin, M.S., William N. Anderson, Ph.D., Duolao Wang, Ph.D., and Stuart Pocock, Ph.D., for the PARTNER Trial Investigators*
EDWARDS THV EVOLUTION

- Stainless Steel Frame
- Equine Pericardial Tissue

2004
Cribier-Edwards™ THV
23mm

2007
Edwards SAPIEN™THV
23 mm and 26 mm

2010
Edwards SAPIENXT™ THV
23 mm, 26 mm, and 29mm

- Cobalt-Chromium Frame
- Bovine Pericardial Tissue
- Semi-closed leaflets
- Reduced cramped profile
SAPIEN 3
RIGOROUS STUDY DESIGN

TWO INDIVIDUALLY STRATIFIED AND POWERED COHORTS

Severe Symptomatic Native Aortic Valve Stenosis

Assessment: Operability
(N = 3,105)

Cohort A
High-Risk
(n = 699)

Yes

Assessment: Transfemoral Access

No

2 Cohorts
Individually Powered
(n = 1,057)

Cohort B
Inoperable
(n = 358)

Yes

Assessment: Transfemoral Access

No

TF
(n = 492)

TA
(n = 207)

TF
(n = 244)

TA
(n = 104)

AVR
(Control)
(n = 249)

AVR
(Control)
(n = 133)

1:1 Randomization

1:1 Randomization

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

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

TA, transapical; TF, transfemoral
Randomized Inoperable
n = 358

Edwards SAPIEN THV
n = 179

124/124 patients
100% followed at 1 year

99/102 patients
97.1% followed at 2 years

Standard Therapy
n = 179

85/85 patients
100% followed at 1 year

56/56 patients
100% followed at 2 years
ABSOLUTE REDUCTION IN MORTALITY CONTINUES TO DIVERGE AT 2 YEARS

ALL-CAUSE MORTALITY AT 1 YEAR AND 2 YEARS

HR [95% CI] = 0.56 [0.43, 0.73]
P (log rank) < .0001

Δ at 1 yr = 20.0%
NNT = 5.0 pts

Δ at 2 yrs = 24.7%
NNT = 4.0 pts

Numbers at Risk
Edwards SAPIEN THV 179
Standard Therapy 179

Months
0 6 12 18 24

All-Cause Mortality, %
0 20 40 60 80 100

Edwards SAPIEN THV
Standard Therapy
25% of patients had an STS score ≥ 15 and 37% of patients had an STS score < 10
KCCQ SUBSCALES

**Symptom Score**
- MCID = 5 points
- $\Delta = 10.5, P < .001$
- $\Delta = 18.2, P < .001$
- $\Delta = 20.6, P < .001$

**Physical Limitations**
- MCID = 5 points
- $\Delta = 7.2, P = .006$
- $\Delta = 13.8, P < .001$
- $\Delta = 21.7, P < .001$

**Quality of Life**
- MCID = 5 points
- $\Delta = 14.8, P < .001$
- $\Delta = 24.2, P < .001$
- $\Delta = 30.5, P < .001$

**Social Limitations**
- MCID = 5 points
- $\Delta = 16.1, P < .001$
- $\Delta = 27.5, P < .001$
- $\Delta = 30.0, P < .001$
PARTNER STUDY DESIGN

Symptomatic Severe Aortic Stenosis

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

Total = 1,057 patients

High Risk

ASSESSMENT: Transfemoral Access

Yes

Transfemoral (TF)

1:1 Randomization

TF TAVR

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

No

Transapical (TA)

1:1 Randomization

TA TAVR

VS

AVR

Inoperable

ASSESSMENT: Transfemoral Access

Yes

TF TAVR

1:1 Randomization

VS

Standard Therapy

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

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

No

Not In Study
ALL-CAUSE MORTALITY (ITT)

HR [95% CI] = 0.93 [0.74, 1.15]

p (log rank) = 0.483

No. at Risk

<table>
<thead>
<tr>
<th></th>
<th>TAVR</th>
<th>AVR</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>348</td>
<td>351</td>
</tr>
<tr>
<td>6</td>
<td>298</td>
<td>252</td>
</tr>
<tr>
<td>12</td>
<td>261</td>
<td>236</td>
</tr>
<tr>
<td>18</td>
<td>239</td>
<td>223</td>
</tr>
<tr>
<td>24</td>
<td>222</td>
<td>202</td>
</tr>
<tr>
<td>30</td>
<td>187</td>
<td>174</td>
</tr>
<tr>
<td>36</td>
<td>149</td>
<td>142</td>
</tr>
</tbody>
</table>

All-Cause Mortality (ITT)
NYHA CLASS SURVIVORS (ITT)

Percent of Patients

<table>
<thead>
<tr>
<th>Period</th>
<th>Class IV</th>
<th>Class III</th>
<th>Class II</th>
<th>Class I</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline</td>
<td>348</td>
<td>349</td>
<td>94%</td>
<td>15%</td>
</tr>
<tr>
<td>30 Days</td>
<td>307</td>
<td>266</td>
<td>24%</td>
<td>35%</td>
</tr>
<tr>
<td>1 Year</td>
<td>250</td>
<td>226</td>
<td>15%</td>
<td>17%</td>
</tr>
<tr>
<td>2 Years</td>
<td>205</td>
<td>186</td>
<td>19%</td>
<td>15%</td>
</tr>
<tr>
<td>3 Years</td>
<td>151</td>
<td>133</td>
<td>14%</td>
<td></td>
</tr>
</tbody>
</table>

No. at Risk

<table>
<thead>
<tr>
<th>Period</th>
<th>Baseline</th>
<th>30 Days</th>
<th>1 Year</th>
<th>2 Years</th>
<th>3 Years</th>
</tr>
</thead>
<tbody>
<tr>
<td>307</td>
<td>349</td>
<td>266</td>
<td>226</td>
<td>186</td>
<td>133</td>
</tr>
</tbody>
</table>

p = NS

p = 0.001
Transcatheter or Surgical Aortic-Valve Replacement in Intermediate-Risk Patients

Martin B. Leon, M.D., Craig R. Smith, M.D., Michael J. Mack, M.D., Raj R. Makkar, M.D.,
Study Overview

• In a randomized trial involving more than 2000 patients, transcatheter aortic-valve replacement was noninferior to surgical replacement in the primary end point of death from any cause or disabling stroke at 2 years.
## Table 2. Clinical End Points at 30 Days, 1 Year, and 2 Years

<table>
<thead>
<tr>
<th>End Point</th>
<th>At 10 Days</th>
<th>At 1 Year</th>
<th>At 2 Years</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>TAVR (N = 1011)</td>
<td>Surgery (N = 1021)</td>
<td>P Value</td>
</tr>
<tr>
<td></td>
<td>no of patients (%)</td>
<td>no of patients (%)</td>
<td></td>
</tr>
<tr>
<td>Death</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>From any cause</td>
<td>62 (6.1)</td>
<td>95 (9.3)</td>
<td>0.11</td>
</tr>
<tr>
<td>From cardiac causes</td>
<td>33 (3.3)</td>
<td>32 (3.2)</td>
<td>0.92</td>
</tr>
<tr>
<td>Not from cardiac causes</td>
<td>5 (0.5)</td>
<td>6 (0.6)</td>
<td>0.41</td>
</tr>
<tr>
<td>Neurologic event</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Any event</td>
<td>64 (6.4)</td>
<td>63 (6.1)</td>
<td>0.94</td>
</tr>
<tr>
<td>Transient ischemic attack</td>
<td>9 (0.9)</td>
<td>4 (0.4)</td>
<td>0.17</td>
</tr>
<tr>
<td>Any stroke</td>
<td>53 (5.1)</td>
<td>61 (6.1)</td>
<td>0.57</td>
</tr>
<tr>
<td><strong>Disabling stroke</strong></td>
<td>32 (3.2)</td>
<td>41 (4.1)</td>
<td>0.20</td>
</tr>
<tr>
<td>Non disabling stroke</td>
<td>23 (2.2)</td>
<td>18 (1.8)</td>
<td>0.43</td>
</tr>
<tr>
<td>Rehospitalization</td>
<td>64 (6.1)</td>
<td>62 (6.1)</td>
<td>0.99</td>
</tr>
<tr>
<td>Death from any cause or rehospitalization</td>
<td>99 (9.1)</td>
<td>101 (10.2)</td>
<td>0.78</td>
</tr>
<tr>
<td>Death from any cause, any stroke, or rehospitalization</td>
<td>160 (15.4)</td>
<td>225 (22.1)</td>
<td>0.07</td>
</tr>
<tr>
<td>Myocardial infarction</td>
<td>12 (1.2)</td>
<td>15 (1.5)</td>
<td>0.22</td>
</tr>
<tr>
<td>Major vascular complication</td>
<td>80 (7.9)</td>
<td>51 (5.0)</td>
<td>0.006</td>
</tr>
<tr>
<td>Life-threatening or disabling bleeding</td>
<td>105 (10.4)</td>
<td>44 (4.3)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Acute kidney injury</td>
<td>13 (1.3)</td>
<td>31 (3.1)</td>
<td>0.006</td>
</tr>
<tr>
<td>New atrial fibrillation</td>
<td>91 (9.1)</td>
<td>263 (26.4)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>New permanent pacemaker</td>
<td>83 (8.1)</td>
<td>68 (6.5)</td>
<td>0.17</td>
</tr>
<tr>
<td>Endocarditis</td>
<td>0</td>
<td>0</td>
<td>—</td>
</tr>
<tr>
<td>Aortic valve reintervention</td>
<td>4 (0.4)</td>
<td>0</td>
<td>0.05</td>
</tr>
<tr>
<td>Coronary obstruction</td>
<td>4 (0.4)</td>
<td>6 (0.6)</td>
<td>0.53</td>
</tr>
</tbody>
</table>

*All percentages are Kaplan-Meier estimates at the specific time point and thus do not equal the number of patients divided by the total number of patients in the treatment group. P values are for point-in-time comparisons.*
## Table 1. Clinical End Points at 30 Days, 1 Year, and 2 Years:

<table>
<thead>
<tr>
<th>End Point</th>
<th>All 30 Days</th>
<th></th>
<th></th>
<th></th>
<th>All 1 Year</th>
<th></th>
<th></th>
<th></th>
<th>All 2 Years</th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>TAVR (N=1011)</td>
<td>Surgery (N=1021)</td>
<td>P Value</td>
<td>TAVR (N=1011)</td>
<td>Surgery (N=1021)</td>
<td>P Value</td>
<td>TAVR (N=1011)</td>
<td>Surgery (N=1021)</td>
<td>P Value</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Death</td>
<td>no. of patients (%)</td>
<td>62 (61.1)</td>
<td>80 (78.0)</td>
<td>0.11</td>
<td>145 (14.5)</td>
<td>160 (16.4)</td>
<td>0.24</td>
<td>302 (30.3)</td>
<td>202 (20.1)</td>
<td>0.33</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Death from any cause</td>
<td>39 (38.6)</td>
<td>41 (40.4)</td>
<td>0.78</td>
<td>123 (12.3)</td>
<td>124 (12.9)</td>
<td>0.66</td>
<td>166 (16.7)</td>
<td>170 (17.0)</td>
<td>0.45</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>From cardiac causes</td>
<td>33 (32.6)</td>
<td>32 (31.6)</td>
<td>0.92</td>
<td>70 (7.0)</td>
<td>71 (7.1)</td>
<td>0.40</td>
<td>97 (9.7)</td>
<td>104 (10.3)</td>
<td>0.38</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Not from cardiac causes</td>
<td>6 (5.6)</td>
<td>9 (8.9)</td>
<td>0.41</td>
<td>53 (5.2)</td>
<td>47 (4.8)</td>
<td>0.71</td>
<td>69 (6.8)</td>
<td>65 (6.7)</td>
<td>0.98</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Neurologic event</td>
<td>no. of patients (%)</td>
<td>64 (6.4)</td>
<td>65 (6.5)</td>
<td>0.04</td>
<td>69 (6.9)</td>
<td>73 (7.2)</td>
<td>0.76</td>
<td>121 (12.1)</td>
<td>103 (10.1)</td>
<td>0.25</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Any Event</td>
<td>9 (0.9)</td>
<td>4 (0.4)</td>
<td>0.17</td>
<td>36 (3.6)</td>
<td>16 (1.6)</td>
<td>0.34</td>
<td>34 (3.4)</td>
<td>20 (2.0)</td>
<td>0.09</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Transient ischemic attack</td>
<td>55 (5.5)</td>
<td>61 (6.1)</td>
<td>0.57</td>
<td>78 (7.8)</td>
<td>79 (8.1)</td>
<td>0.81</td>
<td>91 (9.1)</td>
<td>85 (8.5)</td>
<td>0.57</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Disabling stroke</td>
<td>32 (3.2)</td>
<td>42 (4.1)</td>
<td>0.20</td>
<td>49 (4.9)</td>
<td>56 (5.5)</td>
<td>0.46</td>
<td>59 (5.9)</td>
<td>61 (6.1)</td>
<td>0.33</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Non-disabling stroke</td>
<td>32 (3.2)</td>
<td>38 (3.8)</td>
<td>0.43</td>
<td>30 (3.0)</td>
<td>24 (2.5)</td>
<td>0.44</td>
<td>33 (3.3)</td>
<td>27 (2.7)</td>
<td>0.31</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rehospitalization</td>
<td>64 (6.4)</td>
<td>62 (6.5)</td>
<td>0.09</td>
<td>142 (14.1)</td>
<td>135 (14.9)</td>
<td>0.59</td>
<td>182 (18.2)</td>
<td>156 (15.9)</td>
<td>0.22</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Death from any cause or rehospitalization</td>
<td>99 (9.8)</td>
<td>102 (10.2)</td>
<td>0.78</td>
<td>214 (21.4)</td>
<td>225 (23.3)</td>
<td>0.97</td>
<td>203 (20.3)</td>
<td>241 (24.0)</td>
<td>0.57</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Death from any cause, any stroke, or rehospitalization</td>
<td>140 (13.9)</td>
<td>153 (15.3)</td>
<td>0.37</td>
<td>274 (27.4)</td>
<td>278 (28.3)</td>
<td>0.64</td>
<td>344 (34.5)</td>
<td>326 (32.9)</td>
<td>0.75</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- **Major vascular complication**
- **Life-threatening or disabling bleeding**
- **Acute kidney injury**
- **New atrial fibrillation**
- **New permanent pacemaker**
- **Endocarditis**
- **Aortic valve reintervention**
- **Coronary obstruction**

*All percentages are Kaplan-Meier estimates at the specific time point and thus do not equal the number of patients divided by the total number of patients in the treatment group. P values are for point-in-time comparisons.*
<table>
<thead>
<tr>
<th>Subgroup</th>
<th>No. of Patients</th>
<th>TAVR</th>
<th>Surgery</th>
<th>Hazard Ratio (95% CI)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall</td>
<td>2032</td>
<td>192/1011 (19.3)</td>
<td>202/1021 (21.1)</td>
<td>0.89 (0.73-1.09)</td>
<td>0.25</td>
</tr>
<tr>
<td>Age</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>0.96</td>
</tr>
<tr>
<td>&lt;85 yr</td>
<td>1245</td>
<td>111/626 (18.0)</td>
<td>114/619 (19.5)</td>
<td>0.90 (0.69-1.17)</td>
<td></td>
</tr>
<tr>
<td>≥85 yr</td>
<td>787</td>
<td>81/385 (21.5)</td>
<td>88/402 (23.6)</td>
<td>0.89 (0.65-1.20)</td>
<td></td>
</tr>
<tr>
<td>Sex</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>0.37</td>
</tr>
<tr>
<td>Female</td>
<td>924</td>
<td>77/463 (16.9)</td>
<td>88/461 (20.3)</td>
<td>0.81 (0.59-1.01)</td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>1108</td>
<td>115/548 (21.4)</td>
<td>114/560 (21.7)</td>
<td>0.96 (0.74-1.25)</td>
<td></td>
</tr>
<tr>
<td>Body-mass index</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>0.37</td>
</tr>
<tr>
<td>≤25</td>
<td>611</td>
<td>66/303 (22.1)</td>
<td>75/308 (24.8)</td>
<td>0.78 (0.56-1.09)</td>
<td></td>
</tr>
<tr>
<td>&gt;25</td>
<td>1421</td>
<td>126/708 (18.1)</td>
<td>127/713 (18.8)</td>
<td>0.95 (0.74-1.22)</td>
<td></td>
</tr>
<tr>
<td>STS score</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>0.60</td>
</tr>
<tr>
<td>≤5</td>
<td>897</td>
<td>73/469 (15.8)</td>
<td>75/425 (17.8)</td>
<td>0.84 (0.61-1.16)</td>
<td></td>
</tr>
<tr>
<td>&gt;5</td>
<td>1134</td>
<td>119/542 (22.4)</td>
<td>127/592 (23.2)</td>
<td>0.94 (0.73-1.21)</td>
<td></td>
</tr>
<tr>
<td>Left ventricular ejection fraction</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>0.27</td>
</tr>
<tr>
<td>≤55</td>
<td>496</td>
<td>44/237 (19.1)</td>
<td>53/259 (21.5)</td>
<td>0.84 (0.56-1.25)</td>
<td></td>
</tr>
<tr>
<td>&gt;55</td>
<td>841</td>
<td>85/426 (20.1)</td>
<td>71/415 (18.0)</td>
<td>1.11 (0.81-1.53)</td>
<td></td>
</tr>
<tr>
<td>Moderate or severe mitral regurgitation</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>0.53</td>
</tr>
<tr>
<td>No</td>
<td>1471</td>
<td>132/748 (17.8)</td>
<td>141/723 (20.3)</td>
<td>0.85 (0.67-1.08)</td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>322</td>
<td>38/151 (25.9)</td>
<td>39/171 (24.4)</td>
<td>1.00 (0.64-1.57)</td>
<td></td>
</tr>
<tr>
<td>Previous CABG</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>0.69</td>
</tr>
<tr>
<td>No</td>
<td>1532</td>
<td>156/772 (20.6)</td>
<td>158/760 (22.2)</td>
<td>0.91 (0.73-1.13)</td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>500</td>
<td>36/239 (15.3)</td>
<td>44/261 (18.0)</td>
<td>0.82 (0.53-1.27)</td>
<td></td>
</tr>
<tr>
<td>Peripheral vascular disease</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>0.47</td>
</tr>
<tr>
<td>No</td>
<td>1414</td>
<td>130/729 (18.2)</td>
<td>134/685 (20.7)</td>
<td>0.85 (0.67-1.09)</td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>618</td>
<td>62/282 (22.2)</td>
<td>68/336 (22.0)</td>
<td>0.99 (0.71-1.40)</td>
<td></td>
</tr>
<tr>
<td>6-Meter walk test</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>0.43</td>
</tr>
<tr>
<td>≤7 sec</td>
<td>1003</td>
<td>91/520 (17.7)</td>
<td>97/483 (20.9)</td>
<td>0.82 (0.62-1.09)</td>
<td></td>
</tr>
<tr>
<td>&gt;7 sec</td>
<td>834</td>
<td>85/416 (20.7)</td>
<td>82/418 (20.8)</td>
<td>0.97 (0.71-1.31)</td>
<td></td>
</tr>
<tr>
<td>Access route</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>0.06</td>
</tr>
<tr>
<td>Transfemoral</td>
<td>1550</td>
<td>128/775 (16.8)</td>
<td>149/775 (20.4)</td>
<td>0.79 (0.62-1.00)</td>
<td></td>
</tr>
<tr>
<td>Transthoracic</td>
<td>482</td>
<td>64/236 (27.7)</td>
<td>53/246 (23.4)</td>
<td>1.21 (0.84-1.74)</td>
<td></td>
</tr>
</tbody>
</table>
A  Intention-to-Treat Population

Hazard ratio, 0.89 (95% CI, 0.73–1.09)  
P = 0.25

Death from Any Cause or Disabling Stroke (%)

No. at Risk
TAVR  101 11 918 901 870 842 825 811 801 774
Surgery  1021 838 812 783 770 747 735 717 695

Months since Procedure

B  As-Treated Population

Hazard ratio, 0.87 (95% CI, 0.71–1.07)  
P = 0.18

Death from Any Cause or Disabling Stroke (%)

No. at Risk
TAVR  994 917 900 870 842 825 811 801 774
Surgery  944 826 807 779 766 743 731 715 694

Months since Procedure

C  Transfemoral-Access Cohort, Intention-to-Treat Analysis

Hazard ratio, 0.79 (95% CI, 0.62–1.00)  
P = 0.03

Death from Any Cause or Disabling Stroke (%)

No. at Risk
TAVR  775 718 709 685 663 652 644 634 612
Surgery  775 643 628 604 595 577 569 557 538

Months since Procedure

D  Transfemoral-Access Cohort, As-Treated Analysis

Hazard ratio, 0.78 (95% CI, 0.61–0.99)  
P = 0.04

Death from Any Cause or Disabling Stroke (%)

No. at Risk
TAVR  762 717 708 685 663 652 644 634 612
Surgery  722 636 624 600 591 573 565 555 537

Months since Procedure
Echocardiographic Findings.

A. Aortic-Valve Area
- Baseline: TAVR 899, Surgery 861
- 30 Days: TAVR 817, Surgery 727
- 1 Yr: TAVR 695, Surgery 590
- 2 Yr: TAVR 567, Surgery 488

B. Paravalvular Aortic Regurgitation
- 30 Days: TAVR 872, Surgery 757
- 1 Yr: TAVR 728, Surgery 611
- 2 Yr: TAVR 600, Surgery 514

C. Death from Any Cause, According to Severity of Paravalvular Aortic Regurgitation
- Overall P<0.001 by log-rank test
- Hazard ratio for mild vs. none or trace, 0.95 (95% CI, 0.63–1.45); P=0.82
- Hazard ratio for moderate or severe vs. none or trace, 2.85 (95% CI, 1.57–5.21); P<0.001
Compare the safety and effectiveness of TAVR with the CoreValve prosthesis to surgical valve replacement in symptomatic patients with severe aortic stenosis at increased surgical risk

STUDY DEVICE AND ACCESS ROUTES

14 Fr delivery system

Transfemoral Subclavian Direct Aortic
Primary Endpoint: 1 year All-Cause Mortality

- Surgical: 3.1% at 1 year
- Transcatheter: 3.9% at 1 year

Log-rank P = 0.59

No. at Risk:
- Surgical: 357, 333, 289, 263
- Transcatheter: 390, 367, 344, 322
Major Stroke

No. at Risk
Surgical 357 333 289 263
Transcatheter 390 367 344 322

Months Post-Procedure

Major Stroke (%)

Surgical
Transcatheter

Log-rank P = 0.59

3.9%
3.1%
7.0%
5.8%
COMPLICATIONS
VASCULAR COMPLICATIONS
Patient (ES)

RCIA 8.9mm

RCIA 10mm

REIA 8.3

RCFA 8.4x8.2mm

LCIA 8.3mm

LCIA 13mm

LEIA 8.6mm

LCFA 8.3mm
PERI-VALVULAR REGURGITATION
ANNULAR SIZING WITH CT
BIRTH OF THE STRUCTURAL HEART TEAM: A PARADIGM SHIFT IN THE TREATMENT OF CVD

- Multidisciplinary team
- Int. cardiologists & CT surgeons + Anaesth
- ++ coordination of procedures, protocols, and logistics
- Consistent flow of information between disciplines
- Administrative support
- Joint Marketing of the Structural Heart Team
The ‘Structural Heart Team’

- Surgeons
- Cardiologists
- Anesthesiologists
- Imaging specialists (Echo, CT, MRI)
- Other specialists:

Treatment of Valvular Heart disease
Tallahassee Memorial Hospital
Structural Heart Team

*Valve clinic established at SMG April 13th, 2012
TAVR is preferred in high risk and non-operative patients

TAVR is reasonable alternative with similar outcomes at 5 years for moderate risk patients (STS >4).

Randomized Trial Ongoing comparing outcomes in Low Risk Patients to Surgery
THANK YOU

Questions?