Transcatheter Aortic Valve Replacement with a Self-Expanding Prosthesis or Surgical Aortic Valve Replacement in Intermediate-Risk Patients: First Results from the SURTAVI Clinical Trial

Michael J. Reardon, MD
For the SURTAVI Investigators
Disclosure Statement of Financial Interest

Within the past 12 months, I or my spouse/partner have had a financial interest/arrangement or affiliation with the organization(s) listed below.

<table>
<thead>
<tr>
<th>Financial Relationship</th>
<th>Company</th>
</tr>
</thead>
<tbody>
<tr>
<td>Consultant (fees paid to institution)</td>
<td>Medtronic</td>
</tr>
</tbody>
</table>
Background

• Self-expanding transcatheter aortic valve replacement (TAVR) is preferred to medical therapy in patients with severe, symptomatic aortic stenosis deemed prohibitive for surgical aortic valve replacement (SAVR)\(^1\), and is superior in patients at high risk for operative mortality at 30 days.\(^2\)

• The comparative efficacy of TAVR and SAVR has been less well studied in aortic stenosis patients at lower surgical risk.

To assess the safety and efficacy of TAVR with the self-expanding valve vs. surgical AVR in patients with symptomatic, severe aortic stenosis at intermediate surgical risk
Trial Design

Intermediate Surgical Risk
Predicted risk of operative mortality ≥3% and <15%

Heart Team Evaluation
Assess inclusion/exclusion
Risk classification

Randomization
Stratified by need for revascularization

Screening Committee
Confirmed eligibility

Baseline neurological assessments

TAVR
TAVR + PCI
TAVR only

SAVR
SAVR only

SAVR + CABG

TAVR only

SAVR + CABG
Primary endpoint
All-cause mortality or disabling stroke at 24 months

Key secondary endpoints

Safety:
- All-cause mortality
- All stroke
- Aortic valve reintervention
- Major vascular complications
- Life-threatening or major bleeding
- Pacemaker implantation
- Major adverse cardiovascular and cerebrovascular events (MACCE)

Efficacy:
- Mean gradient
- EOA
- Moderate/severe AR

Quality of life:
- KCCQ
Study Administration

**Principal Investigators:** Patrick Serruys*, Nicolas Van Mieghem*, Michael Reardon*, Jeffrey Popma*, A. Pieter Kappetein*, David Adams, Stephan Windecker, Rüdiger Lange, Thomas Walther

**Steering Committee**
- Michael Reardon, Patrick Serruys, Nicolas Van Mieghem, Jeffrey Popma, A. Pieter Kappetein, David Adams, Blase Carabello, Eberhard Grube, Rüdiger Lange, Nicolo Piazza, Thomas Walther, Stephan Windecker, Steven Yakubov, Mathew Williams, Lars Søndergaard, Thomas Gleason, G. Michael Deeb

**Echo Core Laboratory**
- J. Oh, Mayo Clinic, Rochester, MN

**Data & Safety Monitoring Board**
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**Clinical Events Committee**

**Statistical Design and Analysis**
- Andrew Mugglin, Paradigm Biostatistics, LLC

**Sponsor**
- Medtronic

* Executive Committee members
Participating Sites – Canada and Europe

17 sites in Europe

5 sites in Canada

- Montreal Heart Institute
  - Montreal, Quebec
- St. George’s Hospital
  - London, UK
- Glenfield Hospital
  - Leicester, UK
- Leeds General Infirmary
  - Leeds, UK
- Royal Sussex County Hospital
  - Brighton, UK
- Hospital Universitario Central de Asturias
  - Oviedo, Spain
- Heart Centre - Bad Krozingen
  - Bad Krozingen, Germany
- Inselspital - Universitätsklinik Bern
  - Bern, Switzerland
- Hospital Universitario Virgen de la Victoria
  - Malaga, Spain
- Erasmus Medical Center
  - Rotterdam, Netherlands
- Medisch Centrum Leeuwarden
  - Leeuwarden, Netherlands
- Amphia Hospital
  - Breda, Netherlands
- Rigshospitalet
  - Copenhagen, Denmark
- German Heart Center
  - Munich, Germany
- Universitätsklinik Bad Krozingen
  - Bad Krozingen, Germany
- University Hospital Bonn
  - Bonn, Germany
- Karolinska University Hospital
  - Stockholm, Sweden
- Amphia Hospital
  - Breda, Netherlands
- University Hospital Bremen
  - Bremen, Germany
- University Hospital Leipzig
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- University Hospital Düsseldorf
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- University Hospital Essen
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- University Hospital Freiburg
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- University Hospital Mannheim
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- University Hospital Tübingen
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Participating Sites – United States

65 sites in the United States
Study Timeline


First patient enrolled
June 19, 2012

CoreValve: 23, 26 and 29 mm (US)
CoreValve: 23, 26 and 29 mm (CAN, EU)
CoreValve: 31 mm (US, CAN, EU)

Evolut R (US)

Enrollment completed
June 30, 2016

Primary endpoint
assessment
Dec 2016

94% TF
4% DA
2% SCA

CoreValve (n=724)

Evolut R (n=139)

CoreValve SURTAVI Trial
Key Inclusion Criteria

- Severe aortic valve stenosis defined by an initial aortic valve area of ≤1.0 cm² or aortic valve area index <0.6 cm²/m², AND a mean gradient >40 mmHg or Vmax >4 m/sec, at rest or with dobutamine provocation in patients with a LVEF <55%, or Doppler velocity index <0.25 by resting echocardiogram.

- Heart team agreement that predicted 30-day surgical mortality risk is ≥3% and <15% based on STS PROM and overall clinical status including frailty, disability and comorbidity factors.

- NYHA functional class II or greater.
Key Exclusion Criteria

- Contraindication for placement of a bioprosthetic valve
- A known hypersensitivity or contraindication to all anticoagulation/antiplatelet regimens
- Any PCI or peripheral intervention within 30 days of randomization
- Symptomatic carotid or vertebral artery disease or successful treatment of carotid stenosis within six weeks of randomization
- Recent cerebrovascular accident or transient ischemic attack
- Acute MI within 30 days
- Multivessel CAD with Syntax score >22
- Severe liver, lung or renal disease
- Unsuitable anatomy including native aortic annulus <18 mm or >29 mm
- Severe mitral or tricuspid regurgitation
- Congenital bicuspid or unicuspid valve verified by echo
Definitions

• Stroke assessment
  – All the patients were seen by a trained neurologist or stroke specialist at baseline.
  – Follow-up neurological assessments were done at discharge, 30 days, 6, 12, 18 and 24 months.
  – Neurologic events were adjudicated by a neurologist on the CEC.
  – Stroke was defined according to the VARC-2 criteria.
  – Disabling stroke was defined as a modified Rankin score of ≥2 at 90 days and an increase in at least 1 mRS category.

• Life-threatening or disabling bleeding was defined using BARC criteria.
The SURTAVI trial utilized a novel Bayesian statistical methodology.

The primary objective of the trial was to show that TAVR is noninferior to SAVR for all-cause mortality or disabling stroke at 24 months with a noninferiority margin of 0.07.

The sample size of 1600 attempted implants assumed a 17% incidence of the primary endpoint in surgery patients.

The primary and secondary endpoints were evaluated in the modified intention-to-treat (mITT) population.
Bayesian Analysis of the 24-Month Primary Endpoint

- A pre-specified interim analysis occurred when 1400 patients reached 12-month follow-up.
- Observed 24-month outcomes were used to inform modeling.
- Subjects who had not reached 24-month follow-up had their outcomes imputed using their last known event status.
- Combining imputed and observed data, the posterior distribution of the difference in 24-month event rates was calculated.
Standard of Success for Noninferiority of the Primary Endpoint

Posterior Distribution of the Difference (TAVR rate – SAVR rate)

Area > 0.971

Standard of Success:

$$\text{PP}(\pi_T - \pi_C < 0.07) > 0.971$$

(0.971 chosen to keep $\alpha \leq 0.05$)

PP = Posterior Probability; $\pi_T$ = TAVR rate; $\pi_C$ = SAVR rate
Patient Flow

1,746 patients randomized

TAVR ITT group: N=879
- 15 not attempted:
  - 4 died
  - 6 withdrew consent
  - 5 physician withdrew

TAVR implanted group: N=863
TAVR mITT* group: N=864
- 2 not implanted
  - 1 went to SAVR
  - 2 surgical patients received TAVR

TAVR implanted group: N=863

SAVR ITT group: N=867
- 71 not attempted:
  - 4 died
  - 43 withdrew consent
  - 23 physician withdrew
  - 1 lost to follow-up

SAVR implanted group: N=794
SAVR mITT* group: N=796
- 1 not implanted
  - 2 went to TAVR
  - 1 TAVR patient received SAVR

*The modified intention-to-treat (mITT) population includes all subjects with an attempted procedure
## Baseline Characteristics*

<table>
<thead>
<tr>
<th>n (%) or mean ± SD</th>
<th>TAVR (N=864)</th>
<th>SAVR (N=796)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, years</td>
<td>79.9 ± 6.2</td>
<td>79.7 ± 6.1</td>
</tr>
<tr>
<td>Male sex</td>
<td>498 (57.6)</td>
<td>438 (55.0)</td>
</tr>
<tr>
<td>Body surface area, m²</td>
<td>1.9 ± 0.2</td>
<td>1.9 ± 0.2</td>
</tr>
<tr>
<td>STS PROM, %</td>
<td>4.4 ± 1.5</td>
<td>4.5 ± 1.6</td>
</tr>
<tr>
<td>Logistic EuroSCORE, %</td>
<td>11.9 ± 7.6</td>
<td>11.6 ± 8.0</td>
</tr>
<tr>
<td>Diabetes mellitus</td>
<td>295 (34.1)</td>
<td>277 (34.8)</td>
</tr>
<tr>
<td>Serum creatinine &gt;2 mg/dl</td>
<td>14 (1.6)</td>
<td>17 (2.1)</td>
</tr>
<tr>
<td>Prior stroke</td>
<td>57 (6.6)</td>
<td>57 (7.2)</td>
</tr>
<tr>
<td>Prior TIA</td>
<td>58 (6.7)</td>
<td>46 (5.8)</td>
</tr>
<tr>
<td>Peripheral vascular disease</td>
<td>266 (30.8)</td>
<td>238 (29.9)</td>
</tr>
<tr>
<td>Permanent pacemaker</td>
<td>84 (9.7)</td>
<td>72 (9.0)</td>
</tr>
</tbody>
</table>

* mITT population; no significant difference in any baseline characteristics
## Baseline Cardiac Risk Factors*

<table>
<thead>
<tr>
<th>n (%)</th>
<th>TAVR (N=864)</th>
<th>SAVR (N=796)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Coronary artery disease</td>
<td>541 (62.6)</td>
<td>511 (64.2)</td>
</tr>
<tr>
<td>Prior CABG</td>
<td>138 (16.0)</td>
<td>137 (17.2)</td>
</tr>
<tr>
<td>Prior PCI</td>
<td>184 (21.3)</td>
<td>169 (21.2)</td>
</tr>
<tr>
<td>Prior myocardial infarction</td>
<td>125 (14.5)</td>
<td>111 (13.9)</td>
</tr>
<tr>
<td>Congestive heart failure</td>
<td>824 (95.4)</td>
<td>769 (96.6)</td>
</tr>
<tr>
<td>History of arrhythmia</td>
<td>275 (31.8)</td>
<td>250 (31.4)</td>
</tr>
<tr>
<td>Atrial fibrillation</td>
<td>243 (28.1)</td>
<td>211 (26.5)</td>
</tr>
<tr>
<td>NYHA Class III/IV</td>
<td>520 (60.2)</td>
<td>463 (58.2)</td>
</tr>
</tbody>
</table>

* mITT population; no significant difference in any baseline characteristics
Baseline Frailty, Disabilities and Comorbidities*  

<table>
<thead>
<tr>
<th></th>
<th>TAVR (N=864)</th>
<th>SAVR (N=796)</th>
</tr>
</thead>
<tbody>
<tr>
<td>n (%) or mean ± SD</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Body mass index &lt;21 kg/m²</td>
<td>20 (2.3)</td>
<td>21 (2.6)</td>
</tr>
<tr>
<td>Falls in past 6 months</td>
<td>102 (11.8)</td>
<td>101 (12.7)</td>
</tr>
<tr>
<td>5 meter gait speed &gt;6 s</td>
<td>428 (51.8)</td>
<td>403 (52.9)</td>
</tr>
<tr>
<td>6 minute walk test (meters)</td>
<td>254.1 ± 115.8</td>
<td>260.9 ± 117.9</td>
</tr>
<tr>
<td>Grip strength below threshold</td>
<td>519 (62.5)</td>
<td>490 (63.1)</td>
</tr>
<tr>
<td>Does not live independently</td>
<td>18 (2.1)</td>
<td>22 (2.8)</td>
</tr>
<tr>
<td>Chronic lung disease (mod/severe)</td>
<td>115 (13.3)</td>
<td>106 (13.3)</td>
</tr>
<tr>
<td>Home oxygen</td>
<td>18 (2.1)</td>
<td>21 (2.6)</td>
</tr>
<tr>
<td>Cirrhosis of the liver</td>
<td>4 (0.5)</td>
<td>5 (0.6)</td>
</tr>
<tr>
<td>Immunosuppressive therapy</td>
<td>64 (7.4)</td>
<td>68 (8.5)</td>
</tr>
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*niTT population; no significant difference in any baseline characteristics
RESULTS
All-Cause Mortality or Disabling Stroke

24 Months

<table>
<thead>
<tr>
<th></th>
<th>TAVR</th>
<th>SAVR</th>
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<tbody>
<tr>
<td>12.6%</td>
<td>14.0%</td>
<td></td>
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</table>

No. at Risk

<table>
<thead>
<tr>
<th></th>
<th>SAVR</th>
<th>TAVR</th>
</tr>
</thead>
<tbody>
<tr>
<td>796</td>
<td>864</td>
<td></td>
</tr>
<tr>
<td>674</td>
<td>755</td>
<td></td>
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<tr>
<td>555</td>
<td>612</td>
<td></td>
</tr>
<tr>
<td>407</td>
<td>456</td>
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<tr>
<td>241</td>
<td>272</td>
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Primary Endpoint

<table>
<thead>
<tr>
<th>TAVR (95% CI)</th>
<th>SAVR (95% CI)</th>
<th>Difference (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>12.6% (10.2%, 15.3%)</td>
<td>14.0% (11.4%, 17.0%)</td>
<td>-1.4% (-5.2%, 2.3%)</td>
</tr>
</tbody>
</table>

PP > 0.999 meets noninferiority

TAVR (95% CI) = 12.6% (10.2%, 15.3%)
SAVR (95% CI) = 14.0% (11.4%, 17.0%)
Difference (95% CI) = -1.4% (-5.2%, 2.3%)
**All-Cause Mortality**

![Graph showing all-cause mortality over time for TAVR and SAVR procedures.](image_url)

- **30 Day**
  - SAVR: 1.7% O:E 0.38
  - TAVR: 2.2% O:E 0.50

**No. at Risk**

<table>
<thead>
<tr>
<th>Procedure</th>
<th>0</th>
<th>6</th>
<th>12</th>
<th>18</th>
<th>24</th>
</tr>
</thead>
<tbody>
<tr>
<td>SAVR</td>
<td>796</td>
<td>690</td>
<td>569</td>
<td>414</td>
<td>249</td>
</tr>
<tr>
<td>TAVR</td>
<td>864</td>
<td>762</td>
<td>621</td>
<td>465</td>
<td>280</td>
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</tbody>
</table>
All-Cause Mortality

24 Months

<table>
<thead>
<tr>
<th></th>
<th>TAVR</th>
<th>SAVR</th>
<th>95% CI for Difference</th>
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</thead>
<tbody>
<tr>
<td>11.4%</td>
<td>11.6%</td>
<td>-3.8, 3.3</td>
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</table>

All-Cause Mortality

30 Day
SAVR 1.7% O:E 0.38
TAVR 2.2% O:E 0.50

No. at Risk
SAVR
TAVR

<table>
<thead>
<tr>
<th>Months Post-Procedure</th>
<th>SAVR</th>
<th>TAVR</th>
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<tbody>
<tr>
<td>0</td>
<td>796</td>
<td>864</td>
</tr>
<tr>
<td>6</td>
<td>690</td>
<td>762</td>
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<td>414</td>
<td>465</td>
</tr>
<tr>
<td>24</td>
<td>249</td>
<td>280</td>
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</table>
Instantaneous Hazard of Mortality

Disabling Stroke

<table>
<thead>
<tr>
<th>Months Post-Procedural</th>
<th>No. at Risk</th>
<th>95% CI for Difference</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>TAVR</td>
<td>SAVR</td>
</tr>
<tr>
<td>24 Months</td>
<td>2.6%</td>
<td>4.5%</td>
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</table>

<table>
<thead>
<tr>
<th>95% CI for Difference</th>
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<tbody>
<tr>
<td>-4.0, 0.1</td>
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</table>
## Procedural Characteristics

<table>
<thead>
<tr>
<th>Characteristic, mean ± SD</th>
<th>TAVR (n=864)</th>
<th>SAVR (n=796)</th>
<th>95% CI for difference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Procedure time, min</td>
<td>52.3 ± 32.7</td>
<td>203.7 ± 69.1</td>
<td>(-156.7, -146.1)</td>
</tr>
<tr>
<td>Total time in cath lab or OR, min</td>
<td>190.8 ± 61.3</td>
<td>295.5 ± 81.6</td>
<td>(-111.7, -97.6)</td>
</tr>
<tr>
<td>Aortic cross-clamp time, min</td>
<td>NA</td>
<td>74.3 ± 30.4</td>
<td>NA</td>
</tr>
<tr>
<td>CPB time, min</td>
<td>NA</td>
<td>97.8 ± 39.3</td>
<td>NA</td>
</tr>
<tr>
<td>Length of index procedure hospital stay, days</td>
<td>5.75 ± 4.85</td>
<td>9.75 ± 8.03</td>
<td>(-4.65, -3.36)</td>
</tr>
<tr>
<td>Length of ICU stay, hours</td>
<td>(n=767)</td>
<td>(n=778)</td>
<td>(-29.3, -14.3)</td>
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</table>

48.6 ± 44.0
### 30-Day Safety and Procedure-related Complications

<table>
<thead>
<tr>
<th></th>
<th>TAVR (N=864)</th>
<th>SAVR (N=796)</th>
<th>95% CI for Difference</th>
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</thead>
<tbody>
<tr>
<td>All-cause mortality or disabling stroke</td>
<td>2.8</td>
<td>3.9</td>
<td>-2.8, 0.7</td>
</tr>
<tr>
<td>All-cause mortality</td>
<td>2.2</td>
<td>1.7</td>
<td>-0.9, 1.8</td>
</tr>
<tr>
<td>Disabling stroke</td>
<td>1.2</td>
<td>2.5</td>
<td>-2.6, 0.1</td>
</tr>
<tr>
<td>All stroke</td>
<td>3.4</td>
<td>5.6</td>
<td>-4.2, -0.2</td>
</tr>
<tr>
<td>Overt life-threatening or major bleeding</td>
<td>12.2</td>
<td>9.3</td>
<td>-0.1, 5.9</td>
</tr>
</tbody>
</table>

#### Transfusion of PRBCs* - n (%)

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<thead>
<tr>
<th></th>
<th>TAVR</th>
<th>SAVR</th>
<th>95% CI for Difference</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 units</td>
<td>756 (87.5%)</td>
<td>469 (58.9%)</td>
<td>24.4, 32.5</td>
</tr>
<tr>
<td>2 – 4 units</td>
<td>48 (5.6%)</td>
<td>136 (17.1%)</td>
<td>-14.5, -8.5</td>
</tr>
<tr>
<td>≥ 4 units</td>
<td>31 (3.6%)</td>
<td>101 (12.7%)</td>
<td>-11.7, -6.5</td>
</tr>
<tr>
<td>Acute kidney injury, stage 2-3</td>
<td>1.7</td>
<td>4.4</td>
<td>-4.4, -1.0</td>
</tr>
<tr>
<td>Major vascular complication</td>
<td>6.0</td>
<td>1.1</td>
<td>3.2, 6.7</td>
</tr>
<tr>
<td>Cardiac perforation</td>
<td>1.7</td>
<td>0.9</td>
<td>-0.2, 2.0</td>
</tr>
<tr>
<td>Cardiogenic shock</td>
<td>1.1</td>
<td>3.8</td>
<td>-4.2, -1.1</td>
</tr>
<tr>
<td>Permanent pacemaker implant</td>
<td>25.9</td>
<td>6.6</td>
<td>15.9, 22.7</td>
</tr>
<tr>
<td>Atrial fibrillation</td>
<td>12.9</td>
<td>43.4</td>
<td>-34.7, -26.4</td>
</tr>
</tbody>
</table>

*Percentage rates, all others are Bayesian rates
All-Cause Mortality by Pacemaker Implantation

No. at Risk

<table>
<thead>
<tr>
<th></th>
<th>PPI Prior</th>
<th>With New PPI</th>
<th>Without New PPI</th>
</tr>
</thead>
<tbody>
<tr>
<td>PPI Prior to Procedure</td>
<td>87</td>
<td>74</td>
<td>59</td>
</tr>
<tr>
<td>With New PPI</td>
<td>217</td>
<td>198</td>
<td>164</td>
</tr>
<tr>
<td>Without New PPI</td>
<td>559</td>
<td>491</td>
<td>400</td>
</tr>
</tbody>
</table>

All-Cause Mortality by Pacemaker Implantation

P-value (log-rank) = 0.32
## Clinical Outcomes* at 12 and 24 Months

<table>
<thead>
<tr>
<th>Clinical Outcomes</th>
<th>TAVR 12 Months</th>
<th>SAVR 12 Months</th>
<th>95% CI for Difference</th>
<th>TAVR 24 Months</th>
<th>SAVR 24 Months</th>
<th>95% CI for Difference</th>
</tr>
</thead>
<tbody>
<tr>
<td>All-cause mortality or disabling stroke</td>
<td>8.1</td>
<td>8.8</td>
<td>-3.5, 2.1</td>
<td>12.6</td>
<td>14.0</td>
<td>-5.2, 2.3</td>
</tr>
<tr>
<td>All-cause mortality</td>
<td>6.7</td>
<td>6.8</td>
<td>-2.7, 2.4</td>
<td>11.4</td>
<td>11.6</td>
<td>-3.8, 3.3</td>
</tr>
<tr>
<td>All stroke</td>
<td>5.4</td>
<td>6.9</td>
<td>-3.9, 0.9</td>
<td>6.2</td>
<td>8.4</td>
<td>-5.0, 0.4</td>
</tr>
<tr>
<td>Disabling stroke</td>
<td>2.2</td>
<td>3.6</td>
<td>-3.1, 0.4</td>
<td>2.6</td>
<td>4.5</td>
<td>-4.0, 0.1</td>
</tr>
<tr>
<td>TIA</td>
<td>3.2</td>
<td>2.0</td>
<td>-0.4, 2.8</td>
<td>4.3</td>
<td>3.1</td>
<td>-0.9, 3.2</td>
</tr>
<tr>
<td>Myocardial infarction</td>
<td>2.0</td>
<td>1.6</td>
<td>-0.9, 1.8</td>
<td>2.8</td>
<td>2.2</td>
<td>-1.1, 2.4</td>
</tr>
<tr>
<td>Aortic valve re-intervention</td>
<td>2.1</td>
<td>0.5</td>
<td>0.4, 2.7</td>
<td>2.8</td>
<td>0.7</td>
<td>0.7, 3.5</td>
</tr>
<tr>
<td>Aortic valve hospitalization</td>
<td>8.5</td>
<td>7.6</td>
<td>-1.8, 3.6</td>
<td>13.2</td>
<td>9.7</td>
<td>0.1, 7.0</td>
</tr>
<tr>
<td>MACCE</td>
<td>13.2</td>
<td>12.8</td>
<td>-2.9, 3.7</td>
<td>18.6</td>
<td>18.6</td>
<td>-4.2, 4.2</td>
</tr>
</tbody>
</table>

*All are reported as Bayesian rates
Hemodynamics*

TAVR had significantly better valve performance over SAVR at all follow-up visits.

*A core lab adjudicated.
Patients recover quality of life sooner after TAVR than SAVR.

<table>
<thead>
<tr>
<th></th>
<th>Baseline</th>
<th>30 Days</th>
<th>6 Months</th>
<th>12 Months</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Change from Baseline</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>TAVR</td>
<td>18.4 ± 22.8</td>
<td>21.8 ± 22.3</td>
<td>20.9 ± 22.2</td>
<td></td>
</tr>
<tr>
<td>SAVR</td>
<td>5.9 ± 27.0</td>
<td>21.3 ± 22.3</td>
<td>20.6 ± 22.2</td>
<td></td>
</tr>
<tr>
<td>95% CI for difference</td>
<td>(10.0, 15.1)</td>
<td>(-1.9, 2.8)</td>
<td>(-2.2, 2.9)</td>
<td></td>
</tr>
</tbody>
</table>
Total Aortic Regurgitation*

* Implanted population, core lab adjudicated
## All-Cause Mortality or Disabling Stroke at 12 Months

<table>
<thead>
<tr>
<th>Subgroup</th>
<th>TAVR</th>
<th>SAVR</th>
<th>Hazard Ratios (95% CI)</th>
<th>P for Interaction</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>n/N (KM rate at 12 months)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;80</td>
<td>22/352 (6.6)</td>
<td>21/330 (6.8)</td>
<td>0.96 (0.53-1.74)</td>
<td>0.82</td>
</tr>
<tr>
<td>≥80</td>
<td>44/512 (9.2)</td>
<td>45/466 (10.0)</td>
<td>0.88 (0.58-1.33)</td>
<td></td>
</tr>
<tr>
<td>Gender</td>
<td></td>
<td></td>
<td></td>
<td>0.73</td>
</tr>
<tr>
<td>Male</td>
<td>42/498 (9.0)</td>
<td>38/438 (9.2)</td>
<td>0.94 (0.61-1.47)</td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>24/366 (6.9)</td>
<td>28/358 (8.2)</td>
<td>0.83 (0.48-1.44)</td>
<td></td>
</tr>
<tr>
<td>BMI</td>
<td></td>
<td></td>
<td></td>
<td>0.56</td>
</tr>
<tr>
<td>≤30</td>
<td>44/527 (8.8)</td>
<td>41/486 (8.8)</td>
<td>0.98 (0.64-1.49)</td>
<td></td>
</tr>
<tr>
<td>&gt;30</td>
<td>22/337 (7.1)</td>
<td>25/310 (8.6)</td>
<td>0.79 (0.45-1.40)</td>
<td></td>
</tr>
<tr>
<td>LVEF</td>
<td></td>
<td></td>
<td></td>
<td>0.73</td>
</tr>
<tr>
<td>≤50</td>
<td>10/131 (8.0)</td>
<td>12/133 (9.3)</td>
<td>0.81 (0.35-1.88)</td>
<td></td>
</tr>
<tr>
<td>&gt;50</td>
<td>56/732 (8.2)</td>
<td>52/657 (8.3)</td>
<td>0.95 (0.65-1.39)</td>
<td></td>
</tr>
<tr>
<td>PVD</td>
<td></td>
<td></td>
<td></td>
<td>0.67</td>
</tr>
<tr>
<td>No</td>
<td>42/598 (7.6)</td>
<td>45/558 (8.5)</td>
<td>0.86 (0.56-1.30)</td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>24/266 (9.4)</td>
<td>21/238 (9.3)</td>
<td>1.00 (0.56-1.80)</td>
<td></td>
</tr>
</tbody>
</table>
### All-Cause Mortality or Disabling Stroke at 12 Months

<table>
<thead>
<tr>
<th>Subgroup</th>
<th>TAVR</th>
<th>SAVR</th>
<th>Hazard Ratios (95% CI)</th>
<th>P for Interaction</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Diabetes</strong></td>
<td></td>
<td></td>
<td></td>
<td>0.45</td>
</tr>
<tr>
<td>No</td>
<td>43/569 (8.0)</td>
<td>47/519 (9.5)</td>
<td>0.83 (0.55-1.25)</td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>23/295 (8.3)</td>
<td>19/277 (7.3)</td>
<td>1.10 (0.60-2.02)</td>
<td></td>
</tr>
<tr>
<td><strong>Revascularization</strong></td>
<td></td>
<td></td>
<td></td>
<td>0.42</td>
</tr>
<tr>
<td>No</td>
<td>47/695 (7.3)</td>
<td>50/633 (8.3)</td>
<td>0.84 (0.56-1.25)</td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>19/169 (11.7)</td>
<td>16/163 (10.3)</td>
<td>1.15 (0.59-2.23)</td>
<td></td>
</tr>
<tr>
<td><strong>STS</strong></td>
<td></td>
<td></td>
<td></td>
<td>0.06</td>
</tr>
<tr>
<td>&lt;4</td>
<td>12/345 (3.8)</td>
<td>20/299 (7.2)</td>
<td>0.50 (0.25-1.03)</td>
<td></td>
</tr>
<tr>
<td>≥4</td>
<td>54/519 (10.8)</td>
<td>46/497 (9.5)</td>
<td>1.11 (0.75-1.65)</td>
<td></td>
</tr>
<tr>
<td><strong>Logistic EuroSCORE</strong></td>
<td></td>
<td></td>
<td></td>
<td>0.84</td>
</tr>
<tr>
<td>&lt;10</td>
<td>31/429 (7.8)</td>
<td>35/432 (8.7)</td>
<td>0.87 (0.54-1.41)</td>
<td></td>
</tr>
<tr>
<td>≥10</td>
<td>35/435 (8.5)</td>
<td>31/363 (8.8)</td>
<td>0.93 (0.58-1.52)</td>
<td></td>
</tr>
<tr>
<td><strong>5 m gait speed</strong></td>
<td></td>
<td></td>
<td></td>
<td>0.78</td>
</tr>
<tr>
<td>≤6 sec</td>
<td>29/399 (7.9)</td>
<td>30/359 (9.0)</td>
<td>0.86 (0.52-1.43)</td>
<td></td>
</tr>
<tr>
<td>&gt;6 sec</td>
<td>33/428 (8.2)</td>
<td>32/403 (8.1)</td>
<td>0.95 (0.58-1.54)</td>
<td></td>
</tr>
</tbody>
</table>
Summary

- SURTAVI met its primary endpoint demonstrating that TAVR with a self-expanding CoreValve or Evolut R bioprosthesis is noninferior to SAVR for all-cause mortality or disabling stroke at 24 months.
Summary

• TAVR had significantly less 30 day stroke, AKI, atrial fibrillation and transfusion use and a superior quality of life at 30 days.

• TAVR resulted in significantly improved AV hemodynamics with lower mean gradients and larger aortic valve areas than SAVR through 24 months.

• SAVR had less residual aortic regurgitation, major vascular complications and fewer new pacemakers.

• Need for a new pacemaker after TAVR was not associated with increased mortality.
Conclusion

In SURTAVI, TAVR with the self-expanding valve was safe and effective treatment for patients with symptomatic severe AS at intermediate risk for surgical mortality

IMPLICATIONS
Surgical or Transcatheter Aortic-Valve Replacement in Intermediate-Risk Patients

Thank you to all of the SURTAVI patients, site personnel and investigators who made this trial possible