All patients with aortic stenosis requiring a bioprosthetic heart valve should have a TAVR

It has Already Happened and Is Justified!

Pieter Kappetein, Erasmus MC, Rotterdam, The Netherlands
Study Devices

**Transfemoral**
- Edwards SAPIEN THV
  - 23 and 26 mm valves

**Transapical**
- RetroFlex 1
  - 22 and 24 F sheaths
- Ascendra
  - 24 and 26 F sheaths
PARTNER Study Design

Symptomatic Severe Aortic Stenosis

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

Total = 1,057 patients
2 Parallel Trials: Individually Powered

High Risk

ASSESSMENT: Transfemoral Access

Yes

Transfemoral (TF)

1:1 Randomization

N = 244

TF TAVR

No

Transapical (TA)

1:1 Randomization

N = 248

TA TAVR

VS

SAVR

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

Inoperable

ASSESSMENT: Transfemoral Access

Yes

Transfemoral Access

N = 179

TF TAVR

No

Not In Study

N = 179

SAVR

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

N = 104

TA TAVR

VS

SAVR

N = 103

SAVR

N = 699

N = 358
Study Flow

Randomized = 699 patients

Transfemoral
n = 492

TF = 492 (70%)
TA = 207 (30%)

TAVR (244)

5 Years
Alive = 81
Dead = 150
LTFU = 4
Withdrawal = 3
Censored* = 6

Follow-up Compliance
98.3%

SAVR (248)

5 Years
Alive = 69
Dead = 142
LTFU = 10
Withdrawal = 19
Censored* = 8

Follow-up Compliance
95.6%

Transapical
n = 207

TAVR (104)

5 Years
Alive = 21
Dead = 79
LTFU = 1
Withdrawal = 1
Censored* = 2

Follow-up Compliance
99.0%

SAVR (103)

5 Years
Alive = 33
Dead = 56
LTFU = 2
Withdrawal = 11
Censored* = 1

Follow-up Compliance
97.8%

* Censored = Patient alive at last contact but no information available within FU window
## Baseline Patient Characteristics

### Demographics

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>TAVR (n=348)</th>
<th>SAVR (n=351)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age – years (Mean ± SD)</td>
<td>83.6 ± 6.8</td>
<td>84.5 ± 6.4</td>
</tr>
<tr>
<td>Male</td>
<td>201 (57.8%)</td>
<td>198 (56.7%)</td>
</tr>
<tr>
<td>NYHA Class III or IV</td>
<td>328 (94.3%)</td>
<td>328 (94.0%)</td>
</tr>
<tr>
<td>Previous CABG</td>
<td>148 (42.5%)</td>
<td>152 (43.6%)</td>
</tr>
<tr>
<td>Cerebrovascular disease</td>
<td>96 (29.4%)</td>
<td>87 (26.8%)</td>
</tr>
<tr>
<td>Peripheral vascular disease</td>
<td>149 (43.2%)</td>
<td>142 (41.6%)</td>
</tr>
<tr>
<td>STS Score (Mean ± SD)</td>
<td>11.8 ± 3.3</td>
<td>11.7 ± 3.5</td>
</tr>
</tbody>
</table>
All-Cause Mortality (ITT)
*All Patients*

<table>
<thead>
<tr>
<th>No. at Risk</th>
<th>HR [95% CI]</th>
<th>p (log rank)</th>
</tr>
</thead>
<tbody>
<tr>
<td>TAVR</td>
<td>348</td>
<td>1.04 [0.86, 1.24]</td>
</tr>
<tr>
<td>SAVR</td>
<td>351</td>
<td>67.8%</td>
</tr>
</tbody>
</table>

Error Bars Represent 95% Confidence Limits
Median Survival

All Patients

SAVR
40.6 Months

p (log rank) = 0.76

TAVR
44.5 Months

Months
All-Cause Mortality (ITT)
Transfemoral Patients

HR [95% CI] = 0.91 [0.72, 1.14]
p (log rank) = 0.41

Error Bars Represent 95% Confidence Limits
### Subgroup Analysis

#### All-Cause Mortality

<table>
<thead>
<tr>
<th>Group</th>
<th>Sample Size (N)</th>
<th>Hazard Ratio for TAVR</th>
<th>95% CI [L, U]</th>
<th>Interaction p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall (N=699)</td>
<td></td>
<td>1.03</td>
<td>[0.85, 1.24]</td>
<td></td>
</tr>
<tr>
<td>Age</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt; 85 (N=358)</td>
<td></td>
<td>1.00</td>
<td>[0.76, 1.30]</td>
<td>0.71</td>
</tr>
<tr>
<td>≥ 85 (N=339)</td>
<td></td>
<td>1.07</td>
<td>[0.82, 1.39]</td>
<td></td>
</tr>
<tr>
<td>Sex</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male (N=399)</td>
<td></td>
<td>1.20</td>
<td>[0.94, 1.54]</td>
<td>0.07</td>
</tr>
<tr>
<td>Female (N=300)</td>
<td></td>
<td>0.84</td>
<td>[0.62, 1.12]</td>
<td></td>
</tr>
<tr>
<td>BMI</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>≤ 25 (N=302)</td>
<td></td>
<td>1.17</td>
<td>[0.90, 1.54]</td>
<td>0.39</td>
</tr>
<tr>
<td>&gt; 25 (N=390)</td>
<td></td>
<td>0.99</td>
<td>[0.76, 1.29]</td>
<td></td>
</tr>
<tr>
<td>STS</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>≤ 11 (N=353)</td>
<td></td>
<td>0.95</td>
<td>[0.72, 1.26]</td>
<td>0.38</td>
</tr>
<tr>
<td>&gt; 11 (N=346)</td>
<td></td>
<td>1.12</td>
<td>[0.87, 1.45]</td>
<td></td>
</tr>
</tbody>
</table>

**TAVR Better**

**SAVR Better**
### Subgroup Analysis

**All-Cause Mortality**

<table>
<thead>
<tr>
<th>Subgroup</th>
<th>Hazard Ratio for TAVR</th>
<th>95% CI</th>
<th>Interaction p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Overall (N=699)</strong></td>
<td>1.03</td>
<td>[0.85-1.24]</td>
<td></td>
</tr>
<tr>
<td><strong>Peripheral Vasc. Dis.</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No (N=395)</td>
<td>0.79</td>
<td>[0.62-1.02]</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>Yes (N=291)</td>
<td>1.49</td>
<td>[1.11-2.01]</td>
<td></td>
</tr>
<tr>
<td><strong>Pulmonary Hypertension</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No (N=360)</td>
<td>1.32</td>
<td>[1.01-1.72]</td>
<td>0.01</td>
</tr>
<tr>
<td>Yes (N=337)</td>
<td>0.76</td>
<td>[0.55-1.04]</td>
<td></td>
</tr>
<tr>
<td><strong>Mod / Sev MR</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No (N=536)</td>
<td>1.11</td>
<td>[0.89-1.38]</td>
<td>0.11</td>
</tr>
<tr>
<td>Yes (N=133)</td>
<td>0.77</td>
<td>[0.51-1.17]</td>
<td></td>
</tr>
<tr>
<td><strong>Prior CABG or PCI</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No (N=283)</td>
<td>0.85</td>
<td>[0.64-1.14]</td>
<td>0.10</td>
</tr>
<tr>
<td>Yes (N=414)</td>
<td>1.17</td>
<td>[0.91-1.50]</td>
<td></td>
</tr>
<tr>
<td><strong>Implant Approach</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Transapical (N = 207)</td>
<td>1.37</td>
<td>[0.98-1.92]</td>
<td>0.05</td>
</tr>
<tr>
<td>Transfemoral (N = 492)</td>
<td>0.91</td>
<td>[0.72-1.14]</td>
<td></td>
</tr>
</tbody>
</table>
**All Stroke (ITT)**

**All Patients**

HR [95% CI] = 1.14 [0.68, 1.93]

p (log rank) = 0.61

Error Bars Represent 95% Confidence Limits
NYHA Over Time (ITT)

Survivors

<table>
<thead>
<tr>
<th></th>
<th>TAVR (348)</th>
<th>SAVR (349)</th>
<th>TAVR (250)</th>
<th>SAVR (226)</th>
<th>TAVR (165)</th>
<th>SAVR (145)</th>
<th>TAVR (100)</th>
<th>SAVR (97)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1 Year</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3 Years</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5 Years</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- NYHA Class I: 94%, 94%, 15%, 15%
- NYHA Class II: 15%, 20%, 13%, 14%
- NYHA Class III: 14%, 15%, 14%, 19%
- NYHA Class IV: 19%

p-values:
- p = 0.64
- p = 0.91
- p = 0.35
- p = 0.93
Mortality and Post Procedural PVL TAVR Patients

M-S 24 16 13 12 7 2
Mild 137 98 84 65 52 11
N-T 158 135 120 105 88 34

p (log rank) = 0.0032

75.7%
73.0%
58.6%
Mortality and None-Trace Total AR
Transfemoral Patients

HR [95% CI] = 0.64 [0.43, 0.95]
p (log rank) = 0.03

Error Bars Represent 95% Confidence Limits

No. at Risk

<table>
<thead>
<tr>
<th></th>
<th>TAVR</th>
<th>SAVR</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>70</td>
<td>181</td>
</tr>
<tr>
<td>12</td>
<td>65</td>
<td>137</td>
</tr>
<tr>
<td>24</td>
<td>55</td>
<td>126</td>
</tr>
<tr>
<td>36</td>
<td>51</td>
<td>105</td>
</tr>
<tr>
<td>48</td>
<td>43</td>
<td>78</td>
</tr>
<tr>
<td>60</td>
<td>19</td>
<td>36</td>
</tr>
</tbody>
</table>
Edwards SAPIEN 3 Transcatheter Heart Valve

Enhanced frame geometry for ultra-low delivery profile

Bovine pericardial tissue

Outer skirt minimizes paravalvular leak
Evolution of the Edwards Balloon-Expandable Transcatheter Valves

- Cribier-Edwards
  - 2002
- SAPIEN
  - 2006
- SAPIEN XT
  - 2009
- SAPIEN 3
  - 2013

Sheath compatibility for a 23 mm valve
Edwards Commander Delivery System

- Improved coaxial alignment
- Accurate positioning
  - Distal flex
  - Fine control of valve positioning

<table>
<thead>
<tr>
<th>SAPIEN 3 Valve Size</th>
<th>23 mm</th>
<th>26 mm</th>
<th>29 mm</th>
</tr>
</thead>
<tbody>
<tr>
<td>Edwards eSheath</td>
<td>14F</td>
<td>14F</td>
<td>16F</td>
</tr>
<tr>
<td>Minimum Access Vessel Diameter</td>
<td>5.5 mm</td>
<td>5.5 mm</td>
<td>6.0 mm</td>
</tr>
</tbody>
</table>
Symptomatic Severe Aortic Stenosis

**ASSESSMENT by Heart Valve Team**

- **Intermediate Risk Operable (PII S3i)**
  - **ASSESSMENT:** Optimal Valve Delivery Access
  - Transfemoral (TF)
    - TF TAVR SAPIEN 3
  - Transapical / Transaortic (TA/TAo)
    - TAA TAVR SAPIEN 3

- **SAPIEN 3**
  - 2 Single Arm Non-Randomized Historical-Controlled Studies
  - PII A SAVR
  - PII A SAPIEN

- **High Risk Operable / Inoperable (PII S3HR)**
  - **ASSESSMENT:** Optimal Valve Delivery Access
  - Transfemoral (TF)
    - TF TAVR SAPIEN 3
  - Transapical / Transaortic (TA/TAo)
    - TAA TAVR SAPIEN 3

**n = 1076 Patients**

**n = 583 Patients**
Study Flow: S3HR & S3i
30 Day Patient Status

**S3HR**
- n = 583
- 13 Deaths
- n = 570
  - SAPIEN 3
  - 0 Withdrawal
  - 3 LTFU
  - 567 / 570 or 99.5% follow-up visits performed at 30 Days

**S3i**
- n = 1076
- 12 Deaths
- n = 1064
  - SAPIEN 3
  - 0 Withdrawal
  - 5 LTFU
  - 1059 / 1064 or 99.5% follow-up visits performed at 30 Days
Baseline Patient Characteristics
S3HR Patients

Average STS = 8.6% (Median 8.4%)
Average Age = 82.6yrs

N = 583
Mortality and Stroke: S3HR
At 30 Days (As Treated Patients)

Mortality
- All-Cause
- Cardiovascular

Stroke
- All Stroke
- Disabling

O:E = 0.26
(STS 8.6%)
Mortality: S3HR & S3i
At 30 Days (As Treated Patients)

Transfemoral

<table>
<thead>
<tr>
<th></th>
<th>All-Cause</th>
<th>Cardiovascular</th>
</tr>
</thead>
<tbody>
<tr>
<td>S3HR</td>
<td>1.6</td>
<td>1.0</td>
</tr>
<tr>
<td>S3i</td>
<td>1.1</td>
<td>0.9</td>
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</tbody>
</table>

Transapical / Transaortic

<table>
<thead>
<tr>
<th></th>
<th>All-Cause</th>
<th>Cardiovascular</th>
</tr>
</thead>
<tbody>
<tr>
<td>S3HR</td>
<td>5.4</td>
<td>3.3</td>
</tr>
<tr>
<td>S3i</td>
<td>1.6</td>
<td>0.8</td>
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</tbody>
</table>
All-Cause Mortality at 30 Days
Edwards SAPIEN Valves (As Treated Patients)

PARTNER I and II Trials
Overall and TF Patients

<table>
<thead>
<tr>
<th>SAPIEN</th>
<th>SXT</th>
<th>SAPIEN 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>P1B (TF)</td>
<td>6.3%</td>
<td>2.2%</td>
</tr>
<tr>
<td>P1A (All)</td>
<td>5.2%</td>
<td>1.6%</td>
</tr>
<tr>
<td>P1A (TF)</td>
<td>3.7%</td>
<td>1.1%</td>
</tr>
<tr>
<td>P2B (TF)</td>
<td>4.5%</td>
<td>1.1%</td>
</tr>
<tr>
<td>S3HR (All)</td>
<td>3.5%</td>
<td></td>
</tr>
<tr>
<td>S3HR (TF)</td>
<td>2.2%</td>
<td></td>
</tr>
<tr>
<td>S3i (All)</td>
<td>1.6%</td>
<td></td>
</tr>
<tr>
<td>S3i (TF)</td>
<td>1.1%</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Numbers</th>
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<tr>
<td>175</td>
</tr>
<tr>
<td>344</td>
</tr>
<tr>
<td>240</td>
</tr>
<tr>
<td>271</td>
</tr>
<tr>
<td>282</td>
</tr>
<tr>
<td>583</td>
</tr>
<tr>
<td>491</td>
</tr>
<tr>
<td>1072</td>
</tr>
<tr>
<td>947</td>
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</table>
CoreValve® Valve-in-Valve

The following presentation outlines best practices and procedural considerations for the implantation for the CoreValve® System in failed stented aortic bioprostheses.
CoreValve US Pivotal Trial
High Risk 2-Year Results
Patient Flow

As-Treated Population
N=750

Underwent Attempted TAVR
N=391

Underwent Attempted SAVR
N=359

1-Year TAVR
N=323/328
(98.5%)

1-Year SAVR
N=265/281
(94.3%)

Died-28
Exited-3
Pending follow-up-2

2-Year TAVR
N=278/295
(94.2%)

2-Year SAVR
N=221/237
(93.2%)

Died-31
Exited-13
All-Cause Mortality

<table>
<thead>
<tr>
<th>Months Post-Procedure</th>
<th>Transcatheter</th>
<th>Surgical</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>391</td>
<td>359</td>
</tr>
<tr>
<td>6</td>
<td>378</td>
<td>343</td>
</tr>
<tr>
<td>12</td>
<td>354</td>
<td>304</td>
</tr>
<tr>
<td>18</td>
<td>334</td>
<td>282</td>
</tr>
<tr>
<td>24</td>
<td>219</td>
<td>191</td>
</tr>
</tbody>
</table>

Δ = 4.8

Log-rank P = 0.04
Major Stroke

Log-rank $P=0.25$

No. at Risk

<table>
<thead>
<tr>
<th>Transcatheter</th>
<th>Surgical</th>
</tr>
</thead>
<tbody>
<tr>
<td>391</td>
<td>359</td>
</tr>
<tr>
<td>368</td>
<td>335</td>
</tr>
<tr>
<td>345</td>
<td>296</td>
</tr>
<tr>
<td>326</td>
<td>271</td>
</tr>
<tr>
<td>214</td>
<td>184</td>
</tr>
</tbody>
</table>
MACCE

- Transcatheter
- Surgical

Δ = 8.9

38.6%

Δ = 6.5

27.0%

Log-rank P=0.01

29.7%

No. at Risk

<table>
<thead>
<tr>
<th>Transcatheter</th>
<th>Surgical</th>
</tr>
</thead>
<tbody>
<tr>
<td>391</td>
<td>359</td>
</tr>
<tr>
<td>361</td>
<td>322</td>
</tr>
<tr>
<td>329</td>
<td>280</td>
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<tr>
<td>309</td>
<td>254</td>
</tr>
<tr>
<td>197</td>
<td>166</td>
</tr>
</tbody>
</table>
All-Cause Mortality STS ≤7%

- Transcatheter
- Surgical

Δ = 11.3
26.3%
15.0%
Δ = 3.6
14.0%
10.4%
Log-rank P=0.01

No. at Risk
Transcatheter
Surgical
0 202 181
6 197 174
12 191 161
18 182 151
24 128 93
Conclusions

At 2 years for patients with symptomatic severe AS at increased risk of surgery;

- The superior survival seen at 1 year for TAVR over SAVR is maintained
- All stroke was less with TAVR over SAVR but major stroke showed no difference
- MACCE was significantly less with TAVR over SAVR
- Hemodynamics were superior for TAVR over SAVR at all time points without any structural valve failure
- Post-procedural AR showed a decrease in the TAVR group between 30 days and 1 year and this low level of moderate or severe PVL was maintained at 2 years
- TAVR was favored in every subgroup analysis
European Experience
TAVR in lower risk patients
It’s already happened!
Retrospective Risk-Stratification

Lower risk patients have favorable outcomes
Improvements in Transcatheter Aortic Valve Implantation Outcomes in Lower Surgical Risk Patients

A Glimpse Into the Future

Ruediger Lange, MD, PhD, Sabine Bleiziffer, MD, Domenico Mazzitelli, MD, Yacine Elhmidi, MD, Anke Opitz, MD, Marcus Krane, MD, Marcus-André Deutsch, MD, Hendrik Ruge, MD, Gernot Brockmann, MD, Bernhard Voss, MD, Christian Schreiber, MD, Peter Tassani, MD, PhD, Nicolo Piazza, MD, PhD

Munich, Germany
### TAVR in lower risk patients
Outcomes are better

<table>
<thead>
<tr>
<th></th>
<th>Higher Risk (n=105)</th>
<th>Lower Risk (n=105)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>STS (%)</strong></td>
<td>7.13 ± 5.4</td>
<td>4.8 ± 2.6</td>
</tr>
<tr>
<td><strong>Log EuroSCORE (%)</strong></td>
<td>25.44 ± 16.0</td>
<td>17.8 ± 12.0</td>
</tr>
<tr>
<td><strong>30 Day Mortality (%)</strong></td>
<td>11.4</td>
<td>3.8</td>
</tr>
<tr>
<td><strong>Total Vascular Complications (%)</strong></td>
<td>28.6</td>
<td>14.7</td>
</tr>
<tr>
<td><strong>Stroke / TIA (%)</strong></td>
<td>6.7</td>
<td>1</td>
</tr>
</tbody>
</table>

1Lange, et al., *J Am Coll Cardiol* 2012; 59: 280-7
2Wenaweser, et al., *Eur Heart J* 2013; 34: 1894-905
CoreValve Advance Registry
STS < 7% vs. STS > 7%
## Baseline Characteristics

### CoreValve ADVANCE Registry

<table>
<thead>
<tr>
<th>Characteristic, % or mean ± SD</th>
<th>All Patients N=995</th>
<th>STS ≤7 N=697</th>
<th>STS &gt;7 N=298</th>
<th>p*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (yrs)</td>
<td>81.1 ± 6.4</td>
<td>80.0 ± 6.4</td>
<td>83.5 ± 5.8</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Female</td>
<td>50.7</td>
<td>46.1</td>
<td>61.4</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Logistic EuroSCORE</td>
<td>19.3 ± 12.3</td>
<td>16.0 ± 9.6</td>
<td>27.1 ± 14.2</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>STS</td>
<td>6.4 ± 4.4</td>
<td>4.3 ± 1.5</td>
<td>11.3 ± 5.0</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>NYHA III or IV</td>
<td>80.0</td>
<td>76.3</td>
<td>88.5</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Diabetes</td>
<td>31.2</td>
<td>29.2</td>
<td>35.8</td>
<td>0.041</td>
</tr>
<tr>
<td>CAD</td>
<td>57.8</td>
<td>56.4</td>
<td>60.9</td>
<td>0.185</td>
</tr>
<tr>
<td>PVD</td>
<td>19.9</td>
<td>17.7</td>
<td>25.1</td>
<td>0.007</td>
</tr>
<tr>
<td>Cerebrovascular Disease</td>
<td>13.3</td>
<td>11.3</td>
<td>17.9</td>
<td>0.005</td>
</tr>
<tr>
<td>Pulmonary Hypertension</td>
<td>12.9</td>
<td>11.1</td>
<td>16.9</td>
<td>0.015</td>
</tr>
<tr>
<td>COPD</td>
<td>22.8</td>
<td>17.1</td>
<td>36.1</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Creatinine Clearance &lt; 20ml/min</td>
<td>14.4</td>
<td>10.2</td>
<td>24.3</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Atrial Fibrillation</td>
<td>33.6</td>
<td>30.6</td>
<td>40.5</td>
<td>0.002</td>
</tr>
</tbody>
</table>

*p STS ≤7 vs. >7
2-Year All-Cause Mortality
CoreValve ADVANCE Registry

P-value (log rank) <0.01

CoreValve ADVANCE Study
European Experience
Durability
Studies reporting no valve failures at 1, 2 and 3 years

• Gurvitch et al. Circulation 2010;122:1319-27
• Buellesfeld et al. JACC 2011;57:1650-1657
• Ussia et al. Eur Heart J 2012;33:969-976
• Ussia et al. EuroIntervention 2012;7:1285-1292
• Kodali et al. NEJM 2012;366:1686-1695
• Nietlispach et al. JACC Cardiovasc Interv 2012;5:582-590 (autopsy 20 pts)
Global Valve in Valve Registry

Patients undergoing VIV procedures in 55 sites in Europe, North-America, Australia, New Zealand and Israel (n=593)

Isolated Mitral VIV / VIR (n=134)

Aortic VIV procedures (n=459)

Medtronic CoreValve (n=213)

Edwards Sapien (n=246)

Kornowski, EuroPCR 2013
### Baseline Demographics at Time of VIV

<table>
<thead>
<tr>
<th></th>
<th>CoreValve</th>
<th>SAPIEN</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>(n=213)</td>
<td>(n=246)</td>
</tr>
<tr>
<td>Age (yrs)</td>
<td>77.6 ± 10.0</td>
<td>77.6 ± 9.7</td>
</tr>
<tr>
<td>Gender (% male)</td>
<td>53.1%</td>
<td>59.0%</td>
</tr>
<tr>
<td>LogEuroSCORE</td>
<td>31.1 ± 16.8</td>
<td>33.0 ± 18.9</td>
</tr>
<tr>
<td>STS score (%)</td>
<td>12.8 ± 10.6</td>
<td>11.9 ± 9.2</td>
</tr>
<tr>
<td>Diabetes Mellitus</td>
<td>31.1%</td>
<td>26.5%</td>
</tr>
<tr>
<td>Peripheral Vascular Disease</td>
<td>17.9%</td>
<td>32.6%</td>
</tr>
<tr>
<td>Chronic Renal Failure</td>
<td>38.0%</td>
<td>57.3%</td>
</tr>
<tr>
<td>Previous CVA</td>
<td>12.2%</td>
<td>11.3%</td>
</tr>
<tr>
<td>NYHA III/IV</td>
<td>93.9%</td>
<td>91.5%</td>
</tr>
</tbody>
</table>

Median time from SAVR to VIV TAVI was 9 yrs (IQR 6-12)

Kornowski, EuroPCR 2013
Choice of the patient
PARTNER I A
Mortality Surgery versus TAVR

HR [95% CI] = 0.93 [0.74, 1.15]
p (log rank) = 0.483
Primary Endpoint: 1 Year All-cause Mortality

Surgical: 19.1% at 12 months
Transcatheter: 14.2% at 12 months

P = 0.04 for superiority

No. at Risk
Surgical: 357 at 0 months, 341 at 12 months
Transcatheter: 390 at 0 months, 377 at 12 months
Conclusions-1

• A systematic fall in surgical risk scores is evident (Europe > US)

• “Lower” risk patients are currently being treated (Europe > US)

• Patients with lower risk scores may have other reasons not to undergo surgery
Conclusion-2

• Clinical outcomes in patients with lower surgical risk scores are excellent

• Offering TAVR to intermediate surgical risk patients is justified if performed within the confines of a Heart Team

• Appropriate surgical and TAVR risk scores are lacking and may provide physicians better guidance in the treatment of patients