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

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The clinical outcomes in 1746 intermediate-risk patients with severe, symptomatic aortic stenosis were investigated in a randomized fashion comparing TAVR (performed with the use of a self-expanding prosthesis) with surgical aortic-valve replacement.

Up to 115 worldwide centers in Europe, Canada, and United States
TRIAL Timeline

- **2012:** Entry STS 4-10%
- **2013:**
- **2014:** Risk Based Entry Heart Team ≥3% to < 15%
- **2014:** Evolut R
- **2015:** Randomized Enrollment Concluded May 2016
- **2016:**

- **June 2012, 1ST EU Pt**
- **Nov 2012:** First US Pt
- **Activation of 40 Sites from US High and Extreme Risk Trials**
- **Activation of ~30 Additional Sites**
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The primary end point was a composite of death from any cause or disabling stroke at 24 months in patients undergoing attempted aortic-valve replacement.
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### Conclusion:

TAVR was a noninferior alternative to surgery in patients with severe aortic stenosis at intermediate surgical risk, with a different pattern of adverse events associated with each procedure.
CoreValve US Pivotal Trial
High Risk Study

795 patients between surgical aortic valve replacement (SAVR) and TAVI with the CoreValve System across 45 US sites.

Superior Long-Term Clinical Outcomes
Lower Rate of Mortality or Stroke with CoreValve than with SAVR.

Log-rank P=0.006

Δ9.4
Δ8.2
Δ11.1

No. at Risk
TAVR SAVR
391 359
319 257
273 208
165 128

Prof. Spencer B. King III
All-Cause Mortality at 30 Days
Edwards SAPIEN Valves (As Treated Patients)

PARTNER I and II Trials
Overall and TF Patients

- SAPIEN
- SXT
- SAPIEN 3

<table>
<thead>
<tr>
<th>Valve Type</th>
<th>Mortality Rate</th>
<th>Participants</th>
</tr>
</thead>
<tbody>
<tr>
<td>P1B (TF)</td>
<td>6.3%</td>
<td>175</td>
</tr>
<tr>
<td>P1A (All)</td>
<td>5.2%</td>
<td>344</td>
</tr>
<tr>
<td>P1A (TF)</td>
<td>3.7%</td>
<td>240</td>
</tr>
<tr>
<td>P2B (TF)</td>
<td>4.5%</td>
<td>271</td>
</tr>
<tr>
<td>P2B XT (TF)</td>
<td>3.5%</td>
<td>282</td>
</tr>
<tr>
<td>S3HR (All)</td>
<td>2.2%</td>
<td>583</td>
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<tr>
<td>S3HR (TF)</td>
<td>1.6%</td>
<td>491</td>
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<tr>
<td>S3i (All)</td>
<td>1.1%</td>
<td>1072</td>
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<tr>
<td>S3i (TF)</td>
<td>1.1%</td>
<td>947</td>
</tr>
</tbody>
</table>
Thank you