PARTNER 3 Trial Outcomes
Demonstrating the superiority of SAPIEN 3 TAVI compared with sAVR in low surgical risk patients

Patient characteristics

<table>
<thead>
<tr>
<th></th>
<th>SAPIEN 3 TAVI</th>
<th>sAVR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean age, yr±SD:</td>
<td>73.3±5.8</td>
<td>73.6±6.1</td>
</tr>
<tr>
<td>STS** score, %±SD:</td>
<td>1.9±0.7</td>
<td>1.9±0.6</td>
</tr>
<tr>
<td>NYHA class III or IV, n (%):</td>
<td>155 (31.2)</td>
<td>108 (23.8)</td>
</tr>
</tbody>
</table>

Low surgical risk patients
Younger and with fewer comorbidities than in previous TAVI trials

Trial design

- 1 year
- Primary endpoint – composite of all-cause death, all stroke, or rehospitalisation (any related to the procedure, the valve, or heart failure)
- 5 Countries
- 71 Centres
- 1000 Patients
- 1:1 Randomisation to SAPIEN 3 TAVI or sAVR
- 950 Procedures carried out

Trial outcomes

<table>
<thead>
<tr>
<th></th>
<th>Risk reduction</th>
<th>SAPIEN 3 TAVI</th>
<th>sAVR</th>
</tr>
</thead>
<tbody>
<tr>
<td>All-cause death, all stroke, or rehospitalisation at 1 year:</td>
<td></td>
<td>46%</td>
<td>8.5% 15.1%</td>
</tr>
</tbody>
</table>

SAPIEN 3 TAVI superior to sAVR

Individual components of primary endpoint:

- **All-cause death:** 59% (HR 0.54, 95% CI 0.37 to 0.79, P=0.001)
- **Stroke:** 62% (HR 0.38, 95% CI 0.23 to 0.59, P=0.001)
- **Rehospitalisation:** 35% (HR 0.60, 95% CI 0.42 to 0.89, P=0.001)
Significantly higher KCCQ overall summary score

<table>
<thead>
<tr>
<th>Additional endpoints</th>
<th>Risk reduction</th>
<th>SAPIEN 3 TAVI at 1 year</th>
<th>sAVR at 1 year</th>
</tr>
</thead>
<tbody>
<tr>
<td>Death or disabling stroke</td>
<td>66%</td>
<td>1.0%</td>
<td>2.9%</td>
</tr>
<tr>
<td>Rehospitalisation due to heart failure</td>
<td>61%</td>
<td>1.4%</td>
<td>3.6%</td>
</tr>
<tr>
<td>Life-threatening or major bleeding</td>
<td>75%</td>
<td>7.7%</td>
<td>25.9%</td>
</tr>
<tr>
<td>New-onset atrial fibrillation</td>
<td>87%</td>
<td>7.0%</td>
<td>40.9%</td>
</tr>
</tbody>
</table>

**Quality of life**

TAVI compared to sAVR at:

- **30 days**
  - Δ = 16.0
  - (P < 0.001)
- **6 months**
  - Δ = 2.6
  - (P = 0.002)
- **1 year**
  - Δ = 1.8
  - (P = 0.03)

**Recovery time**

SAPIEN 3 TAVI showed better recovery time compared with sAVR:

- **3.0 days** compared with **7.0**
  - (P < 0.001)
- **95.8%** compared with **73.1%**
  - (P < 0.001)

In low-risk patients, the PARTNER 3 Trial proves SAPIEN 3 TAVI is superior to sAVR on the composite primary endpoint (all-cause death, all stroke, and rehospitalisation) and multiple pre-specified secondary endpoints at 1 year.

You can give your low-risk patients the lowest-risk procedure with Edwards SAPIEN 3 TAVI

*The PARTNER 3 Trial proved that SAPIEN 3 TAVI is superior to sAVR with regard to the primary endpoint (all-cause death, all stroke, and rehospitalisation) and multiple pre-specified secondary endpoints.**

**Society of Thoracic Surgeons Predicted Risk of Mortality (STS-PROM) scores range from 0 to 100, with higher scores indicating a greater risk of death within 30 days after the procedure. STS-PROM is based on the presence of coexisting illnesses in order to predict 30-day operative mortality. The STS-PROM score equals the predicted mortality expressed as a percentage. Less than 5% of patients in the population on which the STS-PROM algorithm is based had a predicted operative mortality score of more than 10%.”

† Valve-related, procedure-related, or heart-failure-related.

‡ Including baseline.

§ Kansas City Cardiomyopathy Questionnaire (KCCQ) overall summary scores range from 0 to 100, with higher scores indicating fewer physical limitations and a greater feeling of well-being.

Abbreviations:
- CI, confidence interval; HR, hazard ratio; KCCQ, Kansas City Cardiomyopathy Questionnaire; NYHA, New York Heart Association; QoL, quality of life; SD, standard deviation; STS-PROM, The Society of Thoracic Surgeons Predicted Risk of Mortality; TAVI, transcatheter aortic valve implantation.

References:

For professional use. For a listing of indications, contraindications, precautions, warnings, and potential adverse events, please refer to the Instructions for Use (consult eifu.edwards.com where applicable). Edwards devices placed on the European market meet the requirements for bearing the CE marking of conformity.

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