Lifetime Cost Effectiveness of Transcatheter Aortic Valve Replacement Compared with Standard Care Among Inoperable Patients with Severe Aortic Stenosis: Results from the PARTNER Trial (Cohort B)

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Disclosures

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PARTNER Trial: Cohort B

Symptomatic Severe Aortic Stenosis

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

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

N = 699

Cohort A: High Risk

N = 358

Cohort B: Inoperable

ASSESSMENT: Transfemoral Access

1:1 Randomization

TAVR Transfemoral VS Standard Therapy (Usually BAV)

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

TA, transapical; TF, transfemoral; BAV, balloon aortic valvuloplasty.
In patients with severe, inoperable aortic stenosis, “cohort B” of the PARTNER trial has demonstrated that, compared with standard care, TAVR led to:

- Improved 12-month survival (70% vs. 50%)
- Substantial and sustained improvement in symptoms, functional status, and quality of life
- Reduced hospitalization for aortic stenosis or its treatment: 22% vs. 44% at one year
  - A full accounting of the costs and cost-effectiveness of TAVR in this population has not yet been reported

Background

Leon M et al. NEJM 2010; 363:1597-607
Cohen DJ. AHA Scientific Sessions 2010
Objectives

1. To compare the short and long-term costs of the TAVR strategy with those of standard care in patients with inoperable aortic stenosis

2. To project the long-term differences in overall and quality-adjusted life expectancy between these groups

3. To estimate the lifetime cost-effectiveness of TAVR compared with standard therapy based on the PARTNER trial results
Methods: Overview

Analytic Perspective

- US healthcare system. 2010 US dollars

Patient Population

- All intention to treat (N=358) subjects included

General approach

- In-trial (12-month) analysis based on observed survival, QOL, health care resource use, and hospital billing data
- Lifetime analysis based on projections of survival, quality-adjusted survival and costs beyond 12 months
Methods: Endpoints

Primary Endpoint

• Lifetime Incremental Cost-Effectiveness Ratio ($/LYG)

Secondary Endpoint

• Lifetime incremental costs per quality-adjusted life year gained ($/QALY)

Pre-specified Sensitivity Analyses

• Exclusion of non-cardiovascular costs
• Exclusion of all BAV procedure costs from control group
• Price of study device
• Removal of QOL improvement observed during follow-up
Methods: In-Trial Costs

• **TAVR procedure:** Measured resource utilization (procedure duration, supplies) multiplied by unit costs
  - SAPIEN Valve estimated commercial price = $30,000

• **All other costs for index admission:** Itemized charges multiplied by department-specific cost-to-charge ratios
  - Where billing data unavailable, regression model ($R^2 = 0.84$) derived from subjects with bills used to impute costs

• **Follow-up hospitalizations:** Costs from billing data or MedPAR (when bills were unavailable)

• **Resource based costs:** Also included for rehabilitation days, SNF days, outpatient visits, ER visits, outpatient cardiac testing, and medications
Methods: Lifetime Analysis

- Parametric survival models fit to trial data used to extrapolate patient-level life expectancy beyond the observed follow-up period
- EQ-5D utilities measured at baseline, 1, 6 and 12 months and used to convert life-years to QALYs
- Calculated costs from the last 6 months for surviving patients used to project future costs beyond 12 months
- All future costs, life years, and QALYs discounted at 3% consistent with current guidelines
## Baseline Characteristics

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>TAVI (N=179)</th>
<th>Control (N=179)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (yrs)</td>
<td>83 ± 9</td>
<td>83 ± 8</td>
</tr>
<tr>
<td>Female gender</td>
<td>54.2%</td>
<td>54.1%</td>
</tr>
<tr>
<td>STS Risk Score</td>
<td>11.2 ± 5.8</td>
<td>12.2 ± 6.1</td>
</tr>
<tr>
<td>STS &gt; 15%</td>
<td>21.2%</td>
<td>24.7%</td>
</tr>
<tr>
<td>Prior MI</td>
<td>18.6%</td>
<td>26.4%</td>
</tr>
<tr>
<td>Prior CABG</td>
<td>37.4%</td>
<td>45.6%</td>
</tr>
<tr>
<td>Cerebrovascular Dz</td>
<td>27.4%</td>
<td>27.5%</td>
</tr>
<tr>
<td>COPD (O2 dependent)</td>
<td>21.2%</td>
<td>25.7%</td>
</tr>
<tr>
<td>Creatinine &gt; 2.0 mg/dl</td>
<td>5.6%</td>
<td>9.6%</td>
</tr>
<tr>
<td>Frailty</td>
<td>18.1%</td>
<td>28.0%</td>
</tr>
</tbody>
</table>

P=NS for all comparisons
## TAVR Procedural Resource Use

<table>
<thead>
<tr>
<th>Resource Category</th>
<th>Mean ± SD or Count (N=175)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Procedure Duration (min)</strong></td>
<td>150 ± 84</td>
</tr>
<tr>
<td><strong>TAVR Devices</strong></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>164 (93.7%)</td>
</tr>
<tr>
<td>2</td>
<td>10 (5.7%)</td>
</tr>
<tr>
<td>3</td>
<td>1 (0.6%)</td>
</tr>
<tr>
<td><strong>Valvuloplasty Balloons</strong></td>
<td>1.3 ± 0.6</td>
</tr>
<tr>
<td><strong>Arterial Site Closure</strong></td>
<td></td>
</tr>
<tr>
<td>Surgical</td>
<td>146 (83%)</td>
</tr>
<tr>
<td>Closure Device</td>
<td>33 (19%)</td>
</tr>
<tr>
<td><strong>Concomitant Procedure</strong></td>
<td>21 (12.0%)</td>
</tr>
<tr>
<td><strong>Total Procedural Costs (excl MD fees)</strong></td>
<td>$42,806 ± 15,206 (median = $38,706)</td>
</tr>
</tbody>
</table>

*peripheral arterial surgery = 10, peripheral arterial stent/PTA = 6, CABG = 1, other = 4
TAVR Admission Costs

![Chart showing costs]

Index Admission Costs

- Procedure: $42,806
- Non-Procedure: $30,756
- MD Fees: $4,978
- Other: $0

Hospital Costs: $73,563

Mean (median) LOS (days)

- ICU: 4.0 (2.0)
- Non-ICU: 6.1 (5.0)
- Total: 10.1 (7.0)
- Post-Procedure: 8.6 (6.0)

(N=175)
12-Month Follow-up Resource Utilization

<table>
<thead>
<tr>
<th></th>
<th>TAVR Group* (N=179)</th>
<th>Control Group (N=179)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hospitalizations</td>
<td>1.02</td>
<td>2.15</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Cardiovascular</td>
<td>0.50</td>
<td>1.70</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Non-cardiovascular</td>
<td>0.51</td>
<td>0.45</td>
<td>0.43</td>
</tr>
<tr>
<td>Rehab Days</td>
<td>4.6</td>
<td>3.9</td>
<td>0.75</td>
</tr>
<tr>
<td>SNF Days</td>
<td>14.5</td>
<td>8.0</td>
<td>0.21</td>
</tr>
</tbody>
</table>

*Not including index TAVR admission
Results: 12-Month Follow-up Costs

Total F/U Costs (12 months)

- TAVR: $29,352
- Control: $52,724

\[ \Delta = \$23,372 \]

\[ p < 0.001 \]
Results: Observed Survival

Difference in In-Trial Life Expectancy = 0.49 years

Based on data available as of 28SEP2010
Results: Projected Survival

Life Expectancy (undiscounted)

- TAVR: 3.11 years
- Control: 1.23 years
- Difference: 1.88 years

The graph shows the survival probability over years for TAVR and control groups. The red line represents TAVR, and the yellow line represents control. The difference in life expectancy is marked as 1.88 years.
Cost-Effectiveness of TAVR vs. Control
Lifetime Results

- ΔCost = $79,837
- ΔLE = 1.59 years
- ICER = $50,212/LYG

$100,000 per LY

$50,000 per LY
Cost-Effectiveness of TAVR vs. Control
Lifetime Results

Diagram showing the probability of CE against the CE threshold (in $) with 95% and 47% thresholds marked respectively.
## Secondary/Sensitivity Analyses

<table>
<thead>
<tr>
<th></th>
<th>Incremental Costs (TAVR – Control)</th>
<th>Incremental Life Years (TAVR – Control)</th>
<th>ICER ($/LY)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Base Case</strong></td>
<td>$79,837</td>
<td>1.59</td>
<td>50,212</td>
</tr>
<tr>
<td><strong>QALYs</strong></td>
<td>$79,837</td>
<td>1.29</td>
<td>61,889*</td>
</tr>
<tr>
<td><strong>QALYs assuming no QOL</strong></td>
<td>$79,837</td>
<td>0.96</td>
<td>83,163*</td>
</tr>
<tr>
<td><strong>Exclude non-CV costs</strong></td>
<td>$53,837</td>
<td>1.59</td>
<td>33,860</td>
</tr>
<tr>
<td><strong>Study device = $20,000</strong></td>
<td>$69,390</td>
<td>1.59</td>
<td>43,642</td>
</tr>
<tr>
<td><strong>Study device = $40,000</strong></td>
<td>$90,284</td>
<td>1.59</td>
<td>56,782</td>
</tr>
<tr>
<td><strong>Exclude BAV costs</strong></td>
<td>$82,623</td>
<td>1.59</td>
<td>51,964</td>
</tr>
</tbody>
</table>

* $/QALY
Limitations

- Still early experience for TAVR device and procedure; care may become more efficient in future
- Care of control group patients in trial may have differed from care of similar pts in community practice
- Lifetime analysis, particularly cost projections beyond the trial period, associated with some uncertainty
- Uniquely old and high-risk patient population; results cannot be extrapolated to other groups
Summary of Findings

• TAVR was associated with index admission costs of ~$78,500 (including estimated MD fees)

• Although observed follow-up costs were ~$23,000/pt lower with TAVR vs. standard care (mainly due to reduced CV hospitalizations), overall costs remained substantially higher with TAVR at 1 year

• Based on observed data from PARTNER trial, we project that TAVR will result in an increased life expectancy of ~1.9 years and an iCER of $50,200 per life-year gained

• Results were minimally impacted by major sensitivity analyses
Conclusions

For patients with severe aortic stenosis who are unsuitable for surgical AVR, TAVR significantly increases life expectancy at an incremental cost per life year gained well within accepted values for commonly used cardiovascular technologies.
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Published Cost Effectiveness Estimates

Dollars per Life Year or QALY ($thousands)

- aspirin MI prevention
- rosuvastatin high-CRP
- ICD prim prev
- CRT-D v. medical Rx
- dabigatran AF
- PARTNER Cohort B
- AF ablation vs. AAD
- dialysis
- PCI stable CAD
- LVAD destination Rx