Cost-Effectiveness of Transcatheter vs. Surgical Aortic Valve Replacement in Intermediate Risk Patients

Results From The PARTNER 2A and Sapien-3 Intermediate Risk Trials

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On behalf of the PARTNER 2 Investigators

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Disclosure

The PARTNER 2 and S3i trials (including the associated economic analyses) were funded by research grants from Edwards Lifesciences, Inc.
Background

- Previous studies have demonstrated that TAVR is cost-effective (but not cost saving) compared with medical therapy for patients with severe AS and extreme surgical risk and compared with SAVR for patients at high surgical risk.

- Recently, based on the results of both the PARTNER 2A and SURTAVI trials, TAVR has been approved for intermediate risk patients as well.

- Whether TAVR is cost-effective compared with SAVR for intermediate risk patients is currently unknown.
P2A and S3i Study Designs

**PARTNER 2A**

- Pts with severe AS and intermediate surgical risk (predicted mortality ≥4%)
  - TF Access
  - Non-TF Access
  - Stratified Randomization
    - TAVR with Sapien XT valve (N= 994)
    - SAVR (N=944)

**S3i**

- Pts with severe AS and intermediate surgical risk (predicted mortality ≥4%)
  - TAVR with SAPIEN 3 valve (n=1077)

* Patient numbers are for as-treated cohorts

To evaluate...
Economic Methods: Overview

Analytic Perspective
- US healthcare system (costs in 2016 US dollars)

Analysis Population
- P2A: As Treated population (XT-994, SAVR-944)
- S3i: Valve Implant population (S3-1068, SAVR-936)

General Approach
- In-trial (24 month) economic analysis based on observed data, followed by pt-level lifetime projections of survival, quality-adjusted life expectancy, and costs
- All future costs and benefits discounted at 3%/year
Methods: Costs

- Probabilistic matching used to link trial patients with Medicare claims data

- Index hospitalization costs calculated using a combination of resource-based accounting (for TAVR/SAVR procedures) and hospital billing data (from Medicare claims)
  - Charges converted to costs based on hospital and cost-center specific cost to charge ratios
  - Valve costs based on current acquisition costs (TAVR- $32,500; SAVR- $5000)

- All other costs (hospitalizations, MD services, outpatient testing, custodial care) based directly on Medicare payments derived from claims
Methods: Survival and QALYs

SAVR Group
- Observed mortality between 6 and 24 months compared with age/gender specific mortality from US life-tables
- Recalibrated life tables used to project patient-level survival beyond 24 months

TAVR Groups
- Hazard ratio (TAVR vs. SAVR) derived from 6-24 month landmark analysis of trial data
- Since observed HR (1.07, 95% CI 0.78 to 1.45) did not differ from unity, base case analysis assumed HR = 1.0

QALYs
- Utilities measured at baseline, 1, 6, 12, and 24 months using EQ-5D and used to calculate within-trial and lifetime QALYs
PARTNER 2A Randomized Trial
XT-TAVR vs. SAVR
### Index Hospitalization: Resource Use

<table>
<thead>
<tr>
<th></th>
<th>XT-TAVR (n = 994)</th>
<th>SAVR (n = 944)</th>
<th>P-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Proc. duration, mins</td>
<td>102 ± 46 [94]</td>
<td>236 ± 83 [219]</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>LOS, days</td>
<td>6.4 ± 5.5 [5]</td>
<td>10.9 ± 7.6 [8]</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>ICU</td>
<td>2.4 ± 3.4 [1]</td>
<td>4.6 ± 6.1 [3]</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Non-ICU</td>
<td>4.0 ± 4.0 [3]</td>
<td>6.2 ± 4.7 [5]</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>New PPM</td>
<td>7.2%</td>
<td>7.0%</td>
<td>NS</td>
</tr>
</tbody>
</table>

Values in brackets are medians.
$38,548  $19,417  $5,421
$16,465  $3,827  $5,421

$61,433*  $58,545*

$19,417  $5,421  $37,409
$38,548  $5,421  $16,465

\[ \Delta = $2888^* \ (P=0.014) \]

* Trimmed means
## Follow-up Costs by Time Interval

<table>
<thead>
<tr>
<th>Interval</th>
<th>XT-TAVR</th>
<th>SAVR</th>
<th>Δ</th>
</tr>
</thead>
<tbody>
<tr>
<td>D/C to 30 days</td>
<td>$0</td>
<td>$0</td>
<td>$0</td>
</tr>
<tr>
<td>30 days to 6 months</td>
<td>$10,000</td>
<td>$20,000</td>
<td>$10,000</td>
</tr>
<tr>
<td>6 to 12 months</td>
<td>$20,000</td>
<td>$30,000</td>
<td>$10,000</td>
</tr>
<tr>
<td>12 to 24 months</td>
<td>$30,000</td>
<td>$40,000</td>
<td>$10,000</td>
</tr>
</tbody>
</table>

**2-Year Follow-up Costs**

- **XT-TAVR**: $46,284
- **SAVR**: $55,587

Δ = -$9304

* P < 0.001

* P < 0.05
Total 2 Year Costs

\[ \Delta = - \$6,416 \quad (P=0.014) \]

- XT-TAVR: $107,716*
- SAVR: $114,132*

Follow-up

Index Hospitalization

* Trimmed means
Projected Survival

- **Projected Life Expectancy**:
  - XT-TAVR: 7.80 yrs
  - SAVR: 7.64 yrs

- **In-Trial**
  - Δ = 0.07 QALYs

*Undiscounted*
P2A Economics

XT-TAVR vs. SAVR: Cost-Effectiveness

$50,000 per QALY

$0

$10,000

$20,000

$30,000

-1

-0.75

-0.5

-0.25

0

0.25

0.5

0.75

1

△QALYs (TAVR - SAVR)

△Long-term Cost (TAVR-SAVR)

△ Cost = -$7,949
△ QALY = 0.15 years
P(dominant) = 84%
P(ICER<$50K/QALY) = 100%

* Costs and benefits discounted at 3%
**S3i Economic Methods**

*Differences vs. P2A*

**Cost data**
- Since S3i enrolled after P2A, complete Medicare claims only available through 1-year follow-up
- Year 2 costs estimated based on regression analysis

**Survival/Life Expectancy Projections**
- Identical to P2A analysis

**Statistical Approach**
- All comparisons adjusted for imbalances in baseline characteristics using propensity score stratification (for clinical outcomes) or propensity bin bootstrapping (for costs)

Turning now to the S3i trial, there were several differences in methodology for the S3i analysis…
## Index Hospitalization: Resource Use

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<td>$&lt;0.001$</td>
</tr>
<tr>
<td>ICU</td>
<td>$1.8 \pm 2.9$ [1]</td>
<td>$4.6 \pm 6.1$ [3]</td>
<td>$&lt;0.001$</td>
</tr>
<tr>
<td>Non-ICU</td>
<td>$2.7 \pm 4.8$ [2]</td>
<td>$6.2 \pm 4.7$ [5]</td>
<td>$&lt;0.001$</td>
</tr>
<tr>
<td>New PPM</td>
<td>8.4%</td>
<td>7.0%</td>
<td>NS</td>
</tr>
</tbody>
</table>

Values in brackets are medians
**Index Hospital Costs**

\[ \Delta = - \$4155^* \ (P<0.001) \]

- **S3-TAVR**:
  - MD fees: $2,998
  - Non-Procedural: $14,259
  - Procedural: $37,776
  - Total: $54,256*

- **SAVR**:
  - MD fees: $5,403
  - Non-Procedural: $37,294
  - Procedural: $16,502
  - Total: $58,410*

*Similar to the PARTNER 2A trial, procedural costs...

**Trimmed means**

**All costs propensity-adjusted**
## F/U Resource Utilization and Costs

*Count per 100 patients*

<table>
<thead>
<tr>
<th></th>
<th>S3-TAVR</th>
<th>SAVR</th>
<th>Difference</th>
<th>P-Value*</th>
</tr>
</thead>
<tbody>
<tr>
<td>CV Hosp.</td>
<td>22 ± 47</td>
<td>30 ± 55</td>
<td>↓ 27%</td>
<td>0.006</td>
</tr>
<tr>
<td>Non-CV Hosp.</td>
<td>47 ± 69</td>
<td>57 ± 75</td>
<td>↓ 18%</td>
<td>0.014</td>
</tr>
<tr>
<td>Hospital Days</td>
<td>380 ± 195</td>
<td>584 ± 241</td>
<td>↓ 35%</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Rehab Days</td>
<td>751 ± 274</td>
<td>1600 ± 400</td>
<td>↓ 53%</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>F/U Cost</td>
<td>$26,861</td>
<td>$38,238</td>
<td>-$11,377</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

* Propensity-Adjusted
**Total 1-Year Costs**

\[ \Delta = -15,511 \, (p<0.001) \]

- **S3-TAVR**
  - Index Hospitalization: $54,117
  - Follow-up: $26,861
  - Total: $80,977*

- **SAVR**
  - Index Hospitalization: $58,250
  - Follow-up: $38,238
  - Total: $96,489*

* Trimmed means
In contrast to the results of PARTNER 2A...
**S3-TAVR vs. SAVR: Cost-Effectiveness**

*S3i Economics*

- **$50,000 per QALY**
  - **Δ Cost** = -$9,692
  - **Δ QALE** = 0.27 yrs
  - **P(dominant)** = 97%
  - **P(ICER<$50K/QALY)** = 100%

* Costs and benefits discounted at 3%
S3i Economics

Are the S3 Results Real?

S3 (88% TF) vs. SAVR

$\Delta$QALYs (TAVR - SAVR)

$\Delta$Cost = -$9,692
$\Delta$QALY = 0.27 years

XT vs. SAVR (TF Subgroup)

$\Delta$QALYs (TAVR - SAVR)

$\Delta$Cost = -$11,738
$\Delta$QALY = 0.30 years
Summary

• Although procedural costs for TAVR remain substantially higher than for surgical AVR, for intermediate risk patients with severe AS, TAVR using the SAPIEN-XT valve led to substantial reductions in hospital LOS, resulting in initial treatment costs that were only slightly higher than for SAVR.

• Over the ensuing 6-12 months, follow-up costs were substantially lower with XT-TAVR (by ~$9,000/pt) such that total medical care costs were lower with TAVR than SAVR at 1 and 2-year follow-up.
• Over a lifetime horizon, XT-TAVR was projected to be an economically dominant strategy--providing both greater quality-adjusted life expectancy and lower long-term costs than SAVR with a high degree of confidence.

• Results using the SAPIEN-3 valve and more contemporary care patterns demonstrated outcomes that were even more favorable with TAVR (lifetime cost savings ~$10,000/pt, significant gain in QALYs).
Conclusions

- For patients with severe AS and intermediate surgical risk similar to those enrolled in the PARTNER 2A and S3i trials, TAVR should be the preferred strategy based on both clinical and economic considerations.
Thank You

MAHI Health Economics and Technology Assessment

- Suzanne J. Baron, MD, MSc
- Kaijun Wang, Ph.D.
- John A. House, M.S.
- Elizabeth A. Magnuson, Sc.D.

PARTNER Investigators and Publications Office

- Maria Alu, MS