Transcatheter Valve Technologies

ARASH SALEMI, MD
ASSOCIATE PROFESSOR OF CARDIOTHORACIC SURGERY
SURGICAL DIRECTOR, ACQUAVERLA HEART VALVE CENTER
WEILL CORNELL MEDICAL CENTER
NEW YORK PRESBYTERIAN HOSPITAL
Disclosures

- Consultant and Proctor, Edwards Lifesciences (Irvine, CA)
- Case Review Board for Partner Trial, Edwards Lifesciences (Irvine, CA)
Andreas Gruentzig

Performed the first successful coronary angioplasty treatment on an awake human in 1977 in Zurich, Switzerland
A. Artery showing stent on uninflated balloon

B. Artery showing stent on inflated balloon

C. Artery showing expanded stent in place
Cardiopulmonary Bypass
Aortic Stenosis
Classic Operation

or
Surgical Aortic Valve Replacement
National Operative Mortality: Isolated Aortic Valve
TAVI Evaluation

1. Patient is diagnosed with severe symptomatic native aortic stenosis
2. Evaluation by TAVI team
3. Evaluate the aortic valvular complex using echocardiography
4. Evaluate the aortic valvular complex and peripheral vasculature using CT
5. Cardiac catheterization
6. Determine access route for transcatheter aortic valve replacement
The “Set up”

- **Cath Lab**
  - 2 Attendings
  - PTCA Specialist
  - 2 or 3 RN's
  - Research Coordinator

- **CT Surgery**
  - Attending
  - Fellow
  - 2 or 3 RN's
  - Perfusionists

- **Anesthesia**
  - Attending
  - Fellow
  - RN

- **Echo (TEE)**
  - Attending
  - Fellow

- **Clinical Specialist**
  - +

N = ~20 !!

GA / ETT
A-line
Swan Ganz
TEE
Foley
Pacemaker
Pigtail
Art Access
Positioning
Transcatheter Heart Valve Deployment
Transapical
The Society of Thoracic Surgeons (STS) risk score algorithm should be utilized to determine surgical risk.

http://209.220.160.181/STSWebRiskCalc261/
Edwards SAPIEN THV Improved Survival

**ALL-CAUSE MORTALITY**

- **P (log rank) < .0001**
- **Δ at 2 yrs = 24.7%**
- **NNT = 4.0 pts**

<table>
<thead>
<tr>
<th></th>
<th>0</th>
<th>6</th>
<th>12</th>
<th>18</th>
<th>24</th>
</tr>
</thead>
<tbody>
<tr>
<td>Edwards</td>
<td>179</td>
<td>138</td>
<td>124</td>
<td>110</td>
<td>83</td>
</tr>
<tr>
<td>SAPIEN THV</td>
<td>179</td>
<td>121</td>
<td>85</td>
<td>62</td>
<td>42</td>
</tr>
</tbody>
</table>

- **Standard Therapy**: 68.0%
- **Edwards SAPIEN THV**: 43.3%
- **30.7%**
- **50.7%**
<table>
<thead>
<tr>
<th>Outcome</th>
<th>30 Days</th>
<th></th>
<th>1 Year</th>
<th></th>
<th>2 years</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>All-cause mortality</td>
<td></td>
<td>5.00%</td>
<td>2.80%</td>
<td>30.70%</td>
<td>50.70%</td>
<td>43.30%</td>
</tr>
<tr>
<td>Death or repeat hospitalization</td>
<td></td>
<td>11.70%</td>
<td>12.30%</td>
<td>44.10%</td>
<td>71.60%</td>
<td>56.70%</td>
</tr>
<tr>
<td>Stroke</td>
<td></td>
<td>7.30%</td>
<td>1.70%</td>
<td>11.20%</td>
<td>5.50%</td>
<td>13.80%</td>
</tr>
<tr>
<td>Major vascular complications</td>
<td></td>
<td>16.80%</td>
<td>1.10%</td>
<td>17.40%</td>
<td>2.80%</td>
<td>17.40%</td>
</tr>
<tr>
<td>Bleeding events</td>
<td></td>
<td>16.20%</td>
<td>2.20%</td>
<td>17.30%</td>
<td>2.20%</td>
<td>17.30%</td>
</tr>
<tr>
<td>New pacemaker implantation</td>
<td></td>
<td>3.40%</td>
<td>5.10%</td>
<td>4.70%</td>
<td>8.60%</td>
<td>6.40%</td>
</tr>
</tbody>
</table>
**ALL-CAUSE MORTALITY AT 1 YEAR AND 2 YEARS**

**ITT Population**

HR [95% CI] = 0.88 [0.70, 1.12]

P (log rank) = 0.31

Number at Risk

<table>
<thead>
<tr>
<th>Edwards SAPIEN THV</th>
<th>348</th>
<th>312</th>
<th>298</th>
<th>269</th>
<th>260</th>
<th>247</th>
<th>224</th>
<th>222</th>
<th>172</th>
</tr>
</thead>
<tbody>
<tr>
<td>AVR</td>
<td>351</td>
<td>274</td>
<td>252</td>
<td>245</td>
<td>236</td>
<td>225</td>
<td>217</td>
<td>208</td>
<td>165</td>
</tr>
</tbody>
</table>

THE PARTNER TRIAL COHORT A
Sapien valve approved for commercial use in high risk and inoperable patients
CoreValve
Pivotal Trial Design
1 Year Mortality

- **All Cause Mortality**
- **Cardiovascular Mortality**

### Months Post-Procedure

- **0 months:**
  - All Cause Mortality: 7.9%
  - Cardiovascular Mortality: 7.9%

- **12 months:**
  - All Cause Mortality: 24.0%
  - Cardiovascular Mortality: 17.9%

Extreme Risk Study | Iliofemoral Pivotal
Major Stroke

![Graph showing major stroke percentage over months post-procedure.]{:width="400px"}

- Major Stroke
  - 2.4% at 1 month
  - 4.1% at 12 months

Extreme Risk Study | Iliofemoral Pivotal
Pivotal Trial Design

CoreValve US Pivotal Trial

- Extreme Risk
  - Iliofemoral Access > 18 Fr Sheath
    - CoreValve Iliofemoral
    - CoreValve Non-Iliofemoral

- High Risk
  - Randomization* 1:1
    - CoreValve (any route)
    - SAVR

* Randomization stratified by intended access site
Primary Endpoint: 1 Year All-cause Mortality

- Surgical: 19.1% (P = 0.04 for superiority)
- Transcatheter: 14.2%

No. at Risk
- Surgical: 357, 341, 297, 274
- Transcatheter: 390, 377, 353, 329
FDA Approval of CoreValve for high and extreme risk patients
Transaortic
Valve in Valve Aortic

"Valve In Valve" Procedure

SAPIEN Valve (Edwards)

Perimount Bovine Valve (Edwards)
Mitral Valve in Valve
Evalve Clip

Caution: Investigational Device. Limited by Federal (US) Law to Investigational Use
E-valve
Clip repair in porcine heart (6 mos post repair)
Stay Tuned...

- Sapien XT/ expandable sheath
- Valve-in-Valve
- Intermediate Risk/SURTAVI (STS 4-8%)
- S3 valve
- Mitral Transcatheter
Surgeon and Perfusionist Express
30%-50% of Patients with Severe Aortic Stenosis Are “Untreated”

Cardiology Patients Treated, %

- Bouma 1999: 41% AVR, 59% No AVR
- Iung* 2004: 32% AVR, 68% No AVR
- Pellikka 2005: 30% AVR, 70% No AVR
- Charlson 2006: 60% AVR, 40% No AVR
- Bach 2009: 48% AVR, 52% No AVR

Aortic Stenosis Patient Categories (risk is a continuum)

- **Low Risk**: 75%
- **Intermediate Risk**: 15%
- **High Risk**: 10%
- **Inoperable**: 10%
- **Too Sick**: 10%
The German Experience
Emergent cardiac surgery during transcatheter aortic valve implantation (TAVI): insights from the Edwards SAPIEN Aortic Bioprosthesis European Outcome (SOURCE) registry

Holger Egggebrecht1*, MD; Rajendra H. Mehta2, MD, MS; Philipp Kahlert3, MD; Gerhard Schymik4, MD; Thierry Lefèvre5, MD; Rüdiger Lange6, MD; Carlos Macaya7, MD; Lazar Mandinov8, MD; Olaf Wendler9, MD; Martyn Thomas10, MD

Potential Mechanism of Annulus Rupture During Transcatheter Aortic Valve Implantation

Kentaro Hayashida, MD, PhD, FESC, Erik Bouvier, MD, Thierry Lefèvre,*, MD, FSCAI, FESC, Thomas Hovasse, MD, Marie-Claude Morice, MD, FESC, FACC, Bernard Chevalier, MD, FSCAI, FESC, FACC, Mauro Romano, MD, Philippe Garot, MD, FESC, Arnaud Farge, MD, Patrick Donzeau-Gouge, MD, and Bertrand Corrier, MD

Emergent cardiac surgery during transcatheter aortic valve implantation (TAVI): a weighted meta-analysis of 9,251 patients from 46 studies

Incidence, Management, and Outcomes of Cardiac Tamponade During Transcatheter Aortic Valve Implantation

A Single-Center Study
Thirty-Day Results of the SAPIEN Aortic Bioprosthesis European Outcome (SOURCE) Registry
A European Registry of Transcatheter Aortic Valve Implantation Using the Edwards SAPIEN Valve

Martyn Thomas, MD; Gerhard Schymik, MD; Thomas Walther, MD; Dominique Himbert, MD; Thierry Lefèvre, MD; Hendrik Treede, MD; Holger Eggebrecht, MD; Paolo Rubino, MD; Iassen Michev, MD; Rüdiger Lange, MD; William N. Anderson, PhD; Olaf Wendler, MD

Background—Transcatheter aortic valve implantation was developed to mitigate the mortality and morbidity associated with high-risk traditional aortic valve replacement. The Edwards SAPIEN valve was approved for transcatheter aortic valve implantation transfemoral delivery in the European Union in November 2007 and for transapical delivery in January 2008.

Methods and Results—The SAPIEN Aortic Bioprosthesis European Outcome (SOURCE) Registry was designed to assess the initial clinical results of the Edwards SAPIEN valve in consecutive patients in Europe after commercialization. Cohort 1 consists of 1038 patients enrolled at 32 centers. Patients who were treated with the transapical approach (n=575) suffered more comorbidities than the transfemoral patients (n=463), resulting in a significantly higher logistic EuroSCORE (29.1% versus 25.7%; P<0.001). Therefore, these groups are considered different, and outcomes cannot be compared. Overall short-term procedural success was observed in 93.8%. The incidence of valve embolization was 0.3% (n=3), and coronary obstruction was reported for 0.6% (n=6 cases). Incidence of stroke was 2.5% and similar for both procedural approaches. Thirty-day mortality was 6.3% in transfemoral patients and 10.3% in transapical patients. The occurrence of vascular complications was not a predictor of <30-day mortality in the transfemoral population.

Conclusion—Technical proficiency can be learned and adapted readily as demonstrated by the short-term procedural success rate and low 30-day mortality rates reported in the SOURCE Registry. Specific complication management and refinement of patient selection are needed to further improve outcomes. (Circulation. 2010;122:62-69.)
### Table 2. Procedural Parameters and Outcomes

<table>
<thead>
<tr>
<th></th>
<th>Transfemoral (n=463), n (%)</th>
<th>Transapical (n=575), n (%)</th>
<th>Total (n=1038), n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Implanted valve size, mm</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>23</td>
<td>210/466 (45.1)</td>
<td>214/594 (36.0)</td>
<td>424/1060 (40.0)</td>
</tr>
<tr>
<td>26</td>
<td>237/466 (50.9)</td>
<td>353/594 (59.4)</td>
<td>590/1060 (55.7)</td>
</tr>
<tr>
<td>Missing</td>
<td>19/466 (4.1)</td>
<td>27/594 (4.5)</td>
<td>46/1060 (4.3)</td>
</tr>
<tr>
<td>SAPIEN-in-SAPIEN valve</td>
<td>3/463 (0.6)</td>
<td>19/575 (3.3)</td>
<td>22/1038 (2.1)</td>
</tr>
<tr>
<td>Conversion to open AVR</td>
<td>8/463 (1.7)</td>
<td>20/575 (3.5)</td>
<td>28/1038 (2.7)</td>
</tr>
<tr>
<td>Short-term procedural success*</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>AR &gt; grade 2+</td>
<td>7/462 (1.5)</td>
<td>13/574 (2.3)</td>
<td>20/1036 (1.9)</td>
</tr>
<tr>
<td>Valve embolization</td>
<td>0/463 (0)</td>
<td>3/575 (0.5)</td>
<td>3/1038 (0.3)</td>
</tr>
<tr>
<td>Coronary obstruction</td>
<td>3/463 (0.7)</td>
<td>3/575 (0.5)</td>
<td>6/1038 (0.6)</td>
</tr>
<tr>
<td>Transfusion</td>
<td>46/463 (9.9)</td>
<td>51/575 (8.9)</td>
<td>97/1038 (9.3)</td>
</tr>
</tbody>
</table>

AR indicates aortic regurgitation.

*Missing in 19 patients (1.8%): 7 transfemoral and 12 transapical patients.
10th Anniversary Edition—New With New Material

An A-Mazing Way to Deal with Change in Your Work and in Your Life

Who Moved My Cheese?
Spencer Johnson, M.D.
Foreword by Kenneth Blanchard, Ph.D.
cofounders of The One Minute Manager
The World's Most Popular Management Method

Read by
Tony Roberts
and Karen Zeno

A GEM
SMALL AND VALUABLE

Excerpts from a 10th Anniversary Interview with Spencer Johnson

THE HANDWRITING ON THE WALL

- Change Happens
- Anticipate Change
- Monitor Change
- Adapt To Change Quickly
- Change
- Enjoy Change!
- Be Ready To Change Quickly & Enjoy It Again.
Thank You

Ars9001@med.cornell.edu