Clinical Outcomes Of TAVI
Edwards, CoreValve…
Which One?
Gerald Yong MBBS (Hons) FRACP FSCAI
Interventional Cardiologist
Royal Perth Hospital
Western Australia

1st TAVI Summit 3rd September 2011

Disclosure Statement of Financial Interest
Within the past 12 months, I or my spouse/partner have had a financial
Interest/arrangement or affiliation with the organization(s) listed below

Affiliation/Financial Relationship
Consulting Fees/Honoraria: Edwards Lifesciences
Major Stock Shareholder/Equity Interest:
Royalty Income:
Ownership/Founder:
Salary:
Intellectual Property Rights:
Other Financial Benefit:

TAVR vs. AVR in EU Centers
SAVR with tissue valve

> 300 centers have active TAVI programs
> 85 centers have > 50 TAVI /yr implantation experience

Current TAVI Devices
EDWARDS SAPIEN XT
- Balloon expandable
- Cobalt chromium stent
- Bovine pericardial leaflets
- Current sheath size – 16-18F
- Sizes: (20), 23, 26, 29

MEDTRONICS COREVALVE
- Self-expanding
- Nitinol frame
- Porcine pericardial leaflets
- Current sheath size – 18F
- Sizes: (23), 26, 29, 31

Current Most Widely Available TAVI Devices & Approaches
EDWARDS SAPIEN THV
- Transfemoral
- Transapical
MEDTRONICS COREVALVE
- Transfemoral
- Tran-subclavian
New TAVI Systems - *Transfemoral*
- Direct Flow
- Sadra
- AorTx
- HLT
- EndoTech
- ABPS PercValve

CONTEMPORARY CLINICAL OUTCOMES OF TAVI

**Data Source**
- Randomized controlled trial – PARTNER
- Country/Region specific registries
  - Single centre
  - Multi-centres

**PARTNER Study Design**

**PARTNER Cohort B**

**Patient Characteristics - 1**

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>TAVI n=179</th>
<th>Standard Rx n=179</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (yr)</td>
<td>83.1 ± 8.6</td>
<td>83.2 ± 8.3</td>
<td>0.95</td>
</tr>
<tr>
<td>Male sex (%)</td>
<td>45.8</td>
<td>46.9</td>
<td>0.92</td>
</tr>
<tr>
<td>STS Score</td>
<td>11.2 ± 5.8</td>
<td>12.1 ± 6.3</td>
<td>0.14</td>
</tr>
<tr>
<td>Logistic EuroSCORE</td>
<td>26.4 ± 17.2</td>
<td>30.4 ± 19.1</td>
<td>0.04</td>
</tr>
<tr>
<td>NYHA I or II (%)</td>
<td>7.8</td>
<td>6.1</td>
<td>0.68</td>
</tr>
<tr>
<td>CAD (%)</td>
<td>87.9</td>
<td>10.0</td>
<td>0.00</td>
</tr>
<tr>
<td>Prior MI (%)</td>
<td>18.6</td>
<td>26.4</td>
<td>0.10</td>
</tr>
<tr>
<td>Prior CABG (%)</td>
<td>37.4</td>
<td>45.6</td>
<td>0.17</td>
</tr>
<tr>
<td>Prior PCI (%)</td>
<td>30.5</td>
<td>24.8</td>
<td>0.31</td>
</tr>
<tr>
<td>Prior BAV (%)</td>
<td>16.3</td>
<td>24.4</td>
<td>0.00</td>
</tr>
<tr>
<td>CVD (%)</td>
<td>27.4</td>
<td>27.5</td>
<td>1.00</td>
</tr>
</tbody>
</table>
### Patient Characteristics (1)

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>TAVR (N = 348)</th>
<th>AVR (N = 351)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (yr)</td>
<td>83.6 ± 6.8</td>
<td>84.5 ± 6.4</td>
<td>0.07</td>
</tr>
<tr>
<td>Male sex - %</td>
<td>57.8</td>
<td>56.7</td>
<td>0.82</td>
</tr>
<tr>
<td>STS Score</td>
<td>11.8 ± 3.5</td>
<td>11.7 ± 3.5</td>
<td>0.61</td>
</tr>
<tr>
<td>Logistic EuroSCORE</td>
<td>29.3 ± 16.5</td>
<td>29.2 ± 15.6</td>
<td>0.93</td>
</tr>
<tr>
<td>NYHA II - %</td>
<td>94.3</td>
<td>94.0</td>
<td>0.97</td>
</tr>
<tr>
<td>NYHA III or IV - %</td>
<td>74.9</td>
<td>76.9</td>
<td>0.59</td>
</tr>
<tr>
<td>Prior MI - %</td>
<td>26.8</td>
<td>30.0</td>
<td>0.30</td>
</tr>
<tr>
<td>Prior CABG - %</td>
<td>42.6</td>
<td>44.2</td>
<td>0.70</td>
</tr>
<tr>
<td>Prior PCI - %</td>
<td>34.0</td>
<td>32.5</td>
<td>0.68</td>
</tr>
<tr>
<td>Prior BAV - %</td>
<td>13.4</td>
<td>10.2</td>
<td>0.24</td>
</tr>
<tr>
<td>Cerebrovascular disease - %</td>
<td>29.3</td>
<td>27.4</td>
<td>0.60</td>
</tr>
</tbody>
</table>

---

**PARTNER Cohort A**

**Better Haemodynamics with TAVI**

![Graph showing better haemodynamics with TAVR compared to AVR](image)

- **HR [95% CI] = 0.97 [0.71, 1.22]**
- **P (log rank) = 0.62**

**PARTNER Cohort A – All Cause Mortality**

![Graph showing all cause mortality in TAVR and AVR](image)

- **HR [95% CI] = 0.83 [0.60, 1.15]**
- **P (log rank) = 0.25**

**PARTNER Cohort A – All Cause Mortality**

- **Transfemoral Cohort**
  - **HR [95% CI] = 1.22 [0.75, 1.98]**
  - **P (log rank) = 0.41**

- **Transapical Cohort**
  - **HR [95% CI] = 0.93 [0.71, 1.22]**
  - **P (log rank) = 0.62**

---

**PARTNER Cohort A**

**Better Haemodynamics with TAVR**

- **Baseline**
  - TAVR: 80
  - AVR: 60
  - **p < 0.04**

- **30 Day**
  - TAVR: 70
  - AVR: 50
  - **p < 0.01**

- **6 Month**
  - TAVR: 60
  - AVR: 40
  - **p < 0.008**
PARTNER Cohort A – All Cause Mortality

All-Cause Mortality at 30 Days

<table>
<thead>
<tr>
<th>Outcome</th>
<th>TAVR (N = 348)</th>
<th>AVR (N = 351)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>ITT</td>
<td>12 (3.4)</td>
<td>22 (6.5)</td>
<td>0.32</td>
</tr>
<tr>
<td>AT</td>
<td>18 (5.2)</td>
<td>25 (8.1)</td>
<td>0.73</td>
</tr>
</tbody>
</table>

All-Cause Mortality at 1 Year

<table>
<thead>
<tr>
<th>Outcome</th>
<th>TAVR (N = 348)</th>
<th>AVR (N = 351)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>ITT</td>
<td>84 (24.2)</td>
<td>89 (26.8)</td>
<td>0.44</td>
</tr>
<tr>
<td>AT</td>
<td>81 (23.7)</td>
<td>78 (25.2)</td>
<td>0.85</td>
</tr>
</tbody>
</table>

Vascular complications

<table>
<thead>
<tr>
<th>All – no. (%)</th>
<th>TAVR p-value (N = 348)</th>
<th>AVR p-value (N = 351)</th>
</tr>
</thead>
<tbody>
<tr>
<td>All – no. (%)</td>
<td>50 (17.0)</td>
<td>52 (16.0)</td>
</tr>
</tbody>
</table>

Major Vascular Complication

<table>
<thead>
<tr>
<th>All – no. (%)</th>
<th>TAVR p-value (N = 348)</th>
<th>AVR p-value (N = 351)</th>
</tr>
</thead>
<tbody>
<tr>
<td>All – no. (%)</td>
<td>38 (11.0)</td>
<td>39 (11.0)</td>
</tr>
</tbody>
</table>

Major Bleed

<table>
<thead>
<tr>
<th>All – no. (%)</th>
<th>TAVR p-value (N = 348)</th>
<th>AVR p-value (N = 351)</th>
</tr>
</thead>
<tbody>
<tr>
<td>All – no. (%)</td>
<td>32 (9.3)</td>
<td>49 (14.7)</td>
</tr>
</tbody>
</table>

Vascular Complications and Bleeding Predicts Mortality

P (log rank) = 0.069

Month

Vascular Complications

Major Vascular Complication

No Major Vascular Complication

P (log rank) = 0.069

Month

Major Bleed

No Major Bleed

P (log rank) = 0.0046

Month

Stroke and TAVI

In 2006, Englehardt et al. described transient embolic phenomenon of a platinum-oxide prosthetic valve and speculated that similar events might be used in other cardiac catheterizations. Including the recent article in JACC, the embolic event is rare but cannot be disregarded.

Transcatheter Aortic-Valve Implantation — At What Price?

Editorial Response to PARTNER A

Diffusion-Weighted MRI Study

Philipp Kahlert, MD
West German Heart Center Essen

Example of an 82-year-old patient two days after successful TAVI!

Embolic phenomenon
Diffusion Weighted MRI
Silent Cerebral Insults after TAVI

Cerebral Embolic Protection Devices

Embolic Material after TAVR

Published or Presented Contemporary Multicentre Registries

Weighted Meta-Analysis of Early and Late Clinical Outcomes after CoreValve TAVI in Seven National Registries

C.Ruiz et al. Presented at EuroPCR 2011

TAVI – Contemporary Results
### TAVI – Contemporary Results

<table>
<thead>
<tr>
<th>Source</th>
<th>Edwards TF</th>
<th>Edwards 294 TF</th>
<th>Edwards 320 TF 130 TA</th>
<th>Edwards 160 TF 170 TA</th>
<th>Edwards TF</th>
<th>Edwards 130 TF 1145 TF</th>
<th>CoreValve SC 580 TF 2180 TF</th>
<th>CoreValve SC</th>
</tr>
</thead>
<tbody>
<tr>
<td>30 day mortality</td>
<td>7.8%</td>
<td>10.3%</td>
<td>11.5%</td>
<td>11.0%</td>
<td>7.8%</td>
<td>10.3%</td>
<td>11.5%</td>
<td>11.0%</td>
</tr>
<tr>
<td>6 month mortality</td>
<td>13.2%</td>
<td>16.3%</td>
<td>20.2%</td>
<td>25.9%</td>
<td>13.0%</td>
<td>16.9%</td>
<td>18.4%</td>
<td></td>
</tr>
<tr>
<td>1 year mortality</td>
<td>15.8%</td>
<td>18.5%</td>
<td>21.2%</td>
<td>25.9%</td>
<td>15.8%</td>
<td>18.5%</td>
<td>21.2%</td>
<td></td>
</tr>
<tr>
<td>2 years mortality</td>
<td>18.5%</td>
<td>21.2%</td>
<td>23.9%</td>
<td>25.9%</td>
<td>18.5%</td>
<td>21.2%</td>
<td>23.9%</td>
<td></td>
</tr>
</tbody>
</table>

### Predictors of Mortality from TAVI Registries

- **SOURCE**
  - 1 Yr mortality in TF – Smoking, Renal failure, Logistic EuroScore, Carotid endarterectomy
  - 1 Yr mortality in TA – Logistic Euroscore, Renal failure, Liver disease
- **Canadian**
  - 30-day mortality – pulmonary hypertension, severe MR, need for periprocedural support
  - Late mortality – COPD, CKD, AF, Frailty
- **FRANCE 2**
  - 30-day mortality – Logistic euroscore, NYHA class

### SOURCE - KM 1-year Survival

#### TF vs. TA

<table>
<thead>
<tr>
<th>Survival</th>
<th>TF (Edwards)</th>
<th>TA (CoreValve)</th>
</tr>
</thead>
<tbody>
<tr>
<td>30 days</td>
<td>92.5%</td>
<td>81.5%</td>
</tr>
<tr>
<td>1 year</td>
<td>85.5%</td>
<td>74.2%</td>
</tr>
<tr>
<td>2 years</td>
<td>78.5%</td>
<td>69.1%</td>
</tr>
</tbody>
</table>

### FRANCE 2 – Mortality by Access Route

<table>
<thead>
<tr>
<th>Access Site</th>
<th>TF Edwards</th>
<th>TF CoreValve</th>
<th>TA Edwards</th>
<th>SC CoreValve</th>
</tr>
</thead>
<tbody>
<tr>
<td>30 day</td>
<td>7.8%</td>
<td>10.3%</td>
<td>11.5%</td>
<td>11.0%</td>
</tr>
<tr>
<td>6 month</td>
<td>13.2%</td>
<td>16.3%</td>
<td>20.2%</td>
<td>25.9%</td>
</tr>
</tbody>
</table>

### Edwards Transfemoral Delivery System Refinement

**RetroFlex 1 System**
- Balloon-expandable transcatheter valve delivery
- Steerable catheter
- No nose-cone
- THV tends to migrate aortic on deployment
- 22-24F sheath

**RetroFlex 3 System**
- Balloon-expandable transcatheter valve delivery
- Steerable catheter
- Tapered distal end
- More accurate valve deployment (less aortic migration on deployment)
- 22-24F sheath

**NovaFlex System**
- Balloon-expandable transcatheter valve delivery
- Steerable catheter
- Tapered distal end
- More accurate valve deployment
- Valve crimped on shaft and aligned to balloon upon exit from sheath
- Combined with SAPIEN XT valve
- 18-19F sheath

### Reduction in size of sheath

24F 22F
22F 18-19F

With SAPIEN and RF 1-3
With SAPIEN XT and NovaFlex
Periprocedural and Short-term Outcomes of TAVI with Sapien XT vs. Edwards Sapien Valve

120 consecutive pts treated in Italy from November 2007 to April 2010.

<table>
<thead>
<tr>
<th>Variable</th>
<th>Sapien (n = 66)</th>
<th>Sapien XT (n = 54)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Periprocedural Life-Threatening Bleeding</td>
<td>33.3%</td>
<td>11.1%</td>
<td>0.004</td>
</tr>
<tr>
<td>Periprocedural Major Bleeding</td>
<td>40.9%</td>
<td>35.2%</td>
<td>0.52</td>
</tr>
<tr>
<td>30-Day VARC Combined Safety Endpoint</td>
<td>45.5%</td>
<td>20.4%</td>
<td>0.004</td>
</tr>
</tbody>
</table>

VARC = Valve Academic Research Consortium

**Conclusion:** The newer XT valve is comparable to the Sapien but results in fewer major vascular events and may have broader clinical application.


Transfemoral TAVI with Edwards THV

**Survival at 1 month**

<table>
<thead>
<tr>
<th>Group</th>
<th>30 Days</th>
<th>60 Days</th>
<th>90 Days</th>
</tr>
</thead>
<tbody>
<tr>
<td>REVIVE (n=22)</td>
<td>67.2%</td>
<td>56.3%</td>
<td>45.5%</td>
</tr>
<tr>
<td>RECAST (n=24)</td>
<td>71.9%</td>
<td>61.2%</td>
<td>50.8%</td>
</tr>
<tr>
<td>REVIVE (n=106)</td>
<td>86.8%</td>
<td>76.5%</td>
<td>65.2%</td>
</tr>
<tr>
<td>REVIVAL (n=59)</td>
<td>92.7%</td>
<td>82.4%</td>
<td>71.9%</td>
</tr>
<tr>
<td>PARTNER EU (n=54)</td>
<td>92.0%</td>
<td>82.1%</td>
<td>71.9%</td>
</tr>
<tr>
<td>SOURCE (n=303)</td>
<td>93.6%</td>
<td>83.4%</td>
<td>73.2%</td>
</tr>
</tbody>
</table>

EDWARDS VS COREVALVE WHICH ONE??

**TAVI – Contemporary Results**

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>N &amp; Valve Type</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Survival</td>
<td>5.0%</td>
<td>5.5%</td>
<td>2.9%</td>
<td>2.3%</td>
<td>3.8%</td>
<td>3.8%</td>
<td>2.8%</td>
<td></td>
</tr>
<tr>
<td>30 day Mortality</td>
<td>7.7%</td>
<td>8.1%</td>
<td>5.4%</td>
<td>5.4%</td>
<td>7.7%</td>
<td>7.7%</td>
<td>6.6%</td>
<td></td>
</tr>
<tr>
<td>1 year Mortality</td>
<td>10.4%</td>
<td>10.4%</td>
<td>7.7%</td>
<td>7.7%</td>
<td>10.4%</td>
<td>10.4%</td>
<td>9.9%</td>
<td></td>
</tr>
<tr>
<td>30 day Stroke</td>
<td>2.9%</td>
<td>3.3%</td>
<td>2.3%</td>
<td>2.3%</td>
<td>3.3%</td>
<td>3.3%</td>
<td>2.3%</td>
<td></td>
</tr>
<tr>
<td>Vascular Cx</td>
<td>9.5%</td>
<td>9.5%</td>
<td>6.6%</td>
<td>6.6%</td>
<td>9.5%</td>
<td>9.5%</td>
<td>6.6%</td>
<td></td>
</tr>
<tr>
<td>Bleeding</td>
<td>16.2%</td>
<td>16.2%</td>
<td>11.0%</td>
<td>11.0%</td>
<td>16.2%</td>
<td>16.2%</td>
<td>11.0%</td>
<td></td>
</tr>
<tr>
<td>PPM</td>
<td>3.8%</td>
<td>3.8%</td>
<td>3.8%</td>
<td>3.8%</td>
<td>3.8%</td>
<td>3.8%</td>
<td>3.8%</td>
<td></td>
</tr>
</tbody>
</table>

**TAVI Anatomical Criteria**

<table>
<thead>
<tr>
<th>Variable</th>
<th>Edwards SAPIEN</th>
<th>COREVALVE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bif / Femoral Vessels</td>
<td>26mm for 29mm valve, 28mm for 26mm valve</td>
<td>28mm, 27mm for 28mm valve</td>
</tr>
<tr>
<td>Acute angle</td>
<td>18-21mm for 29mm valve, 22-24mm for 28mm valve</td>
<td>19-22mm for 28mm valve</td>
</tr>
<tr>
<td>Ascending aorta size</td>
<td>No restriction</td>
<td>≤30mm for 28mm valve</td>
</tr>
<tr>
<td>Sinus height</td>
<td>≥24mm</td>
<td>≥30mm, preferably ≥25mm</td>
</tr>
<tr>
<td>Aortic valve calcification</td>
<td>NO</td>
<td>NO</td>
</tr>
<tr>
<td>LVH / Severe aortic stenosis</td>
<td>Profribly not (risk modification)</td>
<td>Lack is seen, but officially not if DF&gt;21mm</td>
</tr>
<tr>
<td>Systolic Aortic root</td>
<td>≥30mm</td>
<td>≥30mm</td>
</tr>
</tbody>
</table>

RPH Experience

N=74 cases

Edwards
- RF 1 & 3 – Feb 2009
- NF – Sept 2011

CoreValve
- Aug 2009

Not yet had access to
- 29mm Sapien XT
- 31mm CoreValve
- E-sheath
- (Direct aortic procedure)
Decision Making

- Annulus & ascending aorta
  - Annulus 18-20 or Ascending Ao >40-43 – Only Edwards
  - Annulus 25-27 – Only CoreValve

- Peripheral vessels
  - Femoral vessels <6mm – need to consider L-subclavian
  - Femoral vessels <7mm – direct aortic or transapical

- Other considerations
  - If LIMA – avoid transabdominal
  - If CAD possibly needing PCI in future – Edwards
  - If existing heart block – Edwards
  - Severe LVH / septal bulge – CoreValve

Conclusion

- Untreated severe AS has extremely poor prognosis
  - Even if treated with balloon aortic valvuloplasty

- Compared to medical treatment, TAVI significantly improved outcome in severe aortic stenosis
  - Standard of care for inoperable severe AS

- Compared to surgical AVR in high risk patients, TAVI achieves non-inferior one year outcomes
  - At the potential cost of more CVA

- Current results from TAVI
  - 30-day mortality 6.10%
  - 1 year mortality 15.30%
  - 30-day CVA 3.9%

Results should improve with
- Improving technology – smaller sheath sizes
- Lower risk patients treated – RCT undergoing (PARTNER II & SURTAVI)

No difference in clinical outcomes between Edwards valve and CoreValve
- ExCEPT PPM rate

Both valves may serve complementary purposes to allow treatment of wider proportion of patients