Transcatheter Aortic Valve Implantation (TAVI) - 5 important lessons learnt from HK experiences

Michael KY Lee

Queen Elizabeth Hospital, Hong Kong
President, HKSTENT

APCASH 2013
## Current Status of TAVI in Asia

**Feb 2010 to July 2013**

<table>
<thead>
<tr>
<th>Institution</th>
<th>Total 672</th>
<th>Edwards 304</th>
<th>CoreValve 368</th>
</tr>
</thead>
<tbody>
<tr>
<td>Asan Medical Center</td>
<td>87</td>
<td>36</td>
<td>51</td>
</tr>
<tr>
<td>Yonsei University</td>
<td>29</td>
<td>29</td>
<td></td>
</tr>
<tr>
<td>Seoul National University</td>
<td>23</td>
<td>3</td>
<td>20</td>
</tr>
<tr>
<td>Sam Sung Medical Center</td>
<td>10</td>
<td>10</td>
<td></td>
</tr>
<tr>
<td>Catholic Medical Center</td>
<td>7</td>
<td>7</td>
<td></td>
</tr>
<tr>
<td><strong>Korea (23%)</strong></td>
<td>156</td>
<td>56</td>
<td>100</td>
</tr>
<tr>
<td>Chiam, Tay, Singapore</td>
<td>130</td>
<td>100</td>
<td>30</td>
</tr>
<tr>
<td>Lee, Lan, Hong Kong</td>
<td>52</td>
<td>2</td>
<td>50</td>
</tr>
<tr>
<td>Paul Kao, Chang, Taiwan</td>
<td>52</td>
<td>12</td>
<td>40</td>
</tr>
<tr>
<td>Philippine</td>
<td>22</td>
<td></td>
<td>22</td>
</tr>
<tr>
<td>Thailand</td>
<td>36</td>
<td>20</td>
<td>16</td>
</tr>
<tr>
<td>Japan</td>
<td>165</td>
<td>100</td>
<td>65</td>
</tr>
<tr>
<td>China</td>
<td>35</td>
<td>10</td>
<td>25</td>
</tr>
<tr>
<td>Malaysia</td>
<td>24</td>
<td>4</td>
<td>20</td>
</tr>
</tbody>
</table>
CoreValve implants as of Aug 10\textsuperscript{th}, 2013 (excluding ANZ)

<table>
<thead>
<tr>
<th>Country</th>
<th>Total CoreValve Implants</th>
</tr>
</thead>
<tbody>
<tr>
<td>Korea</td>
<td>100</td>
</tr>
<tr>
<td>Japan</td>
<td>70</td>
</tr>
<tr>
<td>Taiwan</td>
<td>54</td>
</tr>
<tr>
<td>Hong Kong</td>
<td>53</td>
</tr>
<tr>
<td>China</td>
<td>45</td>
</tr>
<tr>
<td>Singapore</td>
<td>31</td>
</tr>
<tr>
<td>Malaysia</td>
<td>28</td>
</tr>
<tr>
<td>Philippines</td>
<td>26</td>
</tr>
<tr>
<td>Thailand</td>
<td>16</td>
</tr>
<tr>
<td>India</td>
<td>16</td>
</tr>
<tr>
<td>Vietnam</td>
<td>1</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td><strong>440</strong></td>
</tr>
</tbody>
</table>
Hong Kong Experience

Medtronic CoreValve - 53

Edwards Sapien - 2

- Queen Elizabeth Hospital: 27
- Prince of Wales Hospital: 18
- HK Adventist Hospital: 7
- Queen Mary Hospital: 2
- Union Hospital: 1

TOTAL: 55
QEH Registry

<table>
<thead>
<tr>
<th>Characteristic (N = 27)</th>
<th>Number (%) or Mean ± SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (yrs.)</td>
<td>81.6 ± 5.2 (70 – 97 years old)</td>
</tr>
<tr>
<td>Males</td>
<td>18 (66.7%)</td>
</tr>
<tr>
<td>Procedural Success</td>
<td>96.3%</td>
</tr>
<tr>
<td>In-hospital Mortality</td>
<td>3.7%</td>
</tr>
<tr>
<td>30-day Mortality</td>
<td>3.7%</td>
</tr>
</tbody>
</table>

- 1 subclavian vascular complication treated with stent graft
- 1 femoral artery dissection treated with stenting
- All femoral wounds closed with Prostar/Proglide x 2
- One patient had PCI to LAD done before TAVI, returned for NSTEMI and with redo-PCI done, died 3 months after TAVI because of acute coronary stent thrombosis
- Most patients have functionally normal CoreValve with trivial to mild AR, 3 mild to mod AR
Procedure

Subclavian
4.0%

Direct Aortic
0%

Transfemoral
96.0%

26mm
55.6%

31mm
3.7%

29mm
40.7%
Clinical Outcomes after Transcatheter Aortic Valve Implantation in Asia – Results of a Multicentre Registry

Paul TL Chiam¹, Michael KY Lee², Won-Jang Kim³, Edgar L. Tay⁴, Wacin Buddhari⁵, Mao-Shin Lin⁶, Hyo-Soo Kim⁷, Yat-Yin Lam⁸, Mann Chandavimol⁹, Cheol-Woong Yu¹⁰, Pranya Sakiyalak¹¹, Qing-Shen Lu¹², Paul HL Kao⁶, Cheuk-Man Yu⁸, Tian-Hai Koh¹, Jimmy Hon⁴, Fabio E Posas¹³, Mohd A Rosli¹⁴, Seung-Jung Park³

¹. National Heart Centre Singapore; 2. Queen Elizabeth Hospital, Hong Kong; 3. Asan Medical Centre, South Korea; 4. National University Hospital, Singapore; 5. King Chulalongkorn Hospital, Thailand; 6. National Taiwan University Hospital, Taiwan; 7. Seoul National University Hospital, South Korea; 8. Prince of Wales Hospital, Hong Kong; 9. Ramthibodi Hospital, Thailand; 10. Sejong General Hospital, South Korea; 11. Siriraj Hospital, Thailand; 12. PLA Changhai Hospital, China; 13. St. Luke’s Medical Centre, Philippines; 14. National Heart Institute, Malaysia
## Characteristics

### Comparison of QEH Registry – Asia Registry – ADVANCE

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>QEH Registry</th>
<th>Asia Registry</th>
<th>ADVANCE</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N = 27</td>
<td>N = 140</td>
<td>N = 996</td>
</tr>
<tr>
<td>Age (yrs.)</td>
<td>81.6 ± 5.2</td>
<td>79.1 ± 6.6</td>
<td>81 ± 6</td>
</tr>
<tr>
<td>Males</td>
<td>66.7%</td>
<td>51.4%</td>
<td>49.4%</td>
</tr>
<tr>
<td>Mean Log EuroSCORE</td>
<td>20.45 ± 12.1%</td>
<td>19.2 ± 15.9%</td>
<td>19.2 ± 12.4%</td>
</tr>
<tr>
<td>Weight (kg)</td>
<td>57.7 ± 8.7</td>
<td>59.1 ± 11.9</td>
<td>NR</td>
</tr>
<tr>
<td>Height (cm)</td>
<td>160.6 ± 7.3</td>
<td>158 ± 9</td>
<td>NR</td>
</tr>
<tr>
<td>Mean NYHA</td>
<td>2.6 ± 0.6</td>
<td>2.6 ± 0.7</td>
<td>NR</td>
</tr>
<tr>
<td>MPG (mmHg)</td>
<td>52.3 ± 10.6</td>
<td>46 ± 24</td>
<td>45.6</td>
</tr>
<tr>
<td>AVA (cm²)</td>
<td>0.7 ± 0.2</td>
<td>0.7 ± 0.2</td>
<td>0.7</td>
</tr>
<tr>
<td>LVEF</td>
<td>57 ± 10.6%</td>
<td>57 ± 11%</td>
<td>NR</td>
</tr>
</tbody>
</table>

NR= Not Reported
# Procedure & Hemodynamics

## Comparison of QEH Registry – Asia Registry – ADVANCE

<table>
<thead>
<tr>
<th>Variables</th>
<th>QEH Registry</th>
<th>Asia Registry</th>
<th>ADVANCE</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N = 27</td>
<td>N=140</td>
<td>N=996</td>
</tr>
<tr>
<td>Procedural success</td>
<td>96.3%</td>
<td>98.6%</td>
<td>97.8%</td>
</tr>
<tr>
<td>Serious vascular complications</td>
<td>7.4%</td>
<td>3.6%</td>
<td>NR</td>
</tr>
</tbody>
</table>

## Hemodynamics

<table>
<thead>
<tr>
<th>Variables</th>
<th>QEH Registry</th>
<th>Asia Registry</th>
<th>ADVANCE</th>
</tr>
</thead>
<tbody>
<tr>
<td>≤ Mild PVL</td>
<td>88.9%</td>
<td>84.3%</td>
<td>87%</td>
</tr>
<tr>
<td>LVEF</td>
<td>60 ± 7.9%</td>
<td>61 ± 10%</td>
<td>NR</td>
</tr>
<tr>
<td>AVA (cm²)</td>
<td>2.0 ± 0.3</td>
<td>1.7 ± 0.7</td>
<td>1.7</td>
</tr>
<tr>
<td>MPG (mmHg)</td>
<td>8.9 ± 2.7</td>
<td>9 ± 6</td>
<td>9.3</td>
</tr>
</tbody>
</table>

NR= Not Reported
### 30-day Outcomes
Comparison of QEH Registry – Asia Registry – ADVANCE

<table>
<thead>
<tr>
<th>Variables</th>
<th>QEH Registry</th>
<th>Asia Registry</th>
<th>ADVANCE</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N = 27</td>
<td>N=140</td>
<td>N=996</td>
</tr>
<tr>
<td>Mortality</td>
<td>3.7%</td>
<td>2.1%</td>
<td>4.5%</td>
</tr>
<tr>
<td>Stroke</td>
<td>0%</td>
<td>0.7%</td>
<td>2.9%</td>
</tr>
<tr>
<td>NYHA</td>
<td>1.4</td>
<td>1.5</td>
<td>NR</td>
</tr>
<tr>
<td>Pacemaker Implantation</td>
<td>14.8%</td>
<td>15.7%</td>
<td>26.3%</td>
</tr>
</tbody>
</table>

NR= Not Reported
30-Day All-Cause Mortality

2. Meredith. VARC-adjudicated Outcomes in Inoperable and High Risk AS Patients. TCT 2010, Washington, DC.
30-Day Stroke Rate

2. Meredith. VARC-adjudicated Outcomes in Inoperable and High Risk AS Patients. TCT 2010, Washington, DC.
Pacemaker Implantation Rates Across Studies

## Vascular Complications

<table>
<thead>
<tr>
<th>Study/Region</th>
<th>Complication Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>ANZ</td>
<td>9.0%</td>
</tr>
<tr>
<td>Spanish</td>
<td>5.6%</td>
</tr>
<tr>
<td>Brazilian</td>
<td>6.0%</td>
</tr>
<tr>
<td>France II</td>
<td>10.8%</td>
</tr>
<tr>
<td>Meta-analysis</td>
<td>4.2%</td>
</tr>
<tr>
<td>Asia</td>
<td>3.6%</td>
</tr>
<tr>
<td>QEH</td>
<td>7.4%</td>
</tr>
</tbody>
</table>

- **ANZ**: Meredith I.T. 12 Month Results from ANZ CoreValve TAV Study. Presented at: TCT 2011.
- **Brazilian**: Brito F.S. Brazilian Registry. Presented at TCT 2011.
- **Meta-analysis**: Ruiz C.E. Weighted meta-analysis of CoreValve® Outcomes. Presented at: EuroPCR 2011 (analysis sponsored by Medtronic, Inc.).
Mean Gradient & Valve Area

The PARTNER Trial

CoreValve ADVANCE Study
QEH | Symptom Status (NYHA Class)

NYHA Classification

- Pre-TAVI
  - Class I: 40%
  - Class II: 56%
  - Class III: 4%
  - Class IV: 4%

- Post-TAVI
  - Class I: 64%
  - Class II: 32%
  - Class III: 4%
  - Class IV: 12%

- 30-day Post-TAVI
  - Class I: 88%

- 6-month Post-TAVI
  - Class I: 16
  - Improved 1 Class: 7
  - Improved 2 Classes: 2
  - Maintained: 1

* NYHA: New York Heart Association Functional Classification for Heart Failure Stages
(Class I = Best, Class IV = Worst)
6-Minute Walk Test

Pre-TAVI: 222.2 meters
Post-TAVI: 268.5 meters

Paired-sample t-test: $p<0.05$
Measurement for Quality of Life (SF-12)

Physical Component
Paired-sample t-test: $p<0.05$

Mental Component
Paired-sample t-test: $p<0.05$
5 important lessons learnt...
TAVI Program in QEH

- Extremely high-risk procedure
- Multi-disciplinary Heart Team formed in 2009:
  - Interventional Cardiologists
  - Echo Cardiologists
  - Cardiac Surgeons
  - Cardiac Anaesthesiologists
  - Radiologists
  - Cardiac Nurses
Queen Elizabeth Hospital
Patient Flow

HA/Private Hospitals
QEH Physicians / Surgeons
Overseas

→

QEH TAVI Referral Centre

→

Initial assessment by cardiologists + Echo

TEE
Coro angio +/- PCI
CT angio

→

Heart Team final decision → workup for TAVI/SAVR

→

Pre-TAVI case review

→

TAVI Day

→

QEH TAVI Conference (debriefing)

Independent assessment by cardiac surgeons
...Patient selection is a critical success factor for transcatheter aortic valve implantation...

ESC Congress 2010
Thomas, J Am Coll Cardiol Intv 2010;3:1103–9
Potential TAVI Patients

Patients to Consider for TAVI Referral
– Patient has severe, symptomatic aortic stenosis
– Patient is high risk for surgical aortic valve replacement or is inoperable
– Patient was previously rejected for surgical aortic valve replacement

Patients NOT Recommended for TAVI Referral
– Severe ventricular dysfunction (LVEF < 20%)
– End-stage renal disease requiring chronic dialysis
– Life expectancy less than 12 months
– Mitral regurgitation greater than grade 2
Patients in whom the presence of multiple comorbidities, especially frailty, overwhelm the likelihood of functional recovery despite successful TAVR.
Proposed Indication for TAVI

- Inoperable severe symptomatic native aortic stenosis with NYHA functional class II or greater and reasonable life expectancy
  - Severe symptomatic native aortic stenosis defined as echo derived valve area of $\leq 0.8 \text{ cm}^2$ (EOA index $\leq 0.5 \text{ cm}^2$), and mean gradient $> 40 \text{ mmHg}$ or jet velocity $> 4.0 \text{ m/s}$.
  - Inoperable:
    - Risk of death or serious irreversible morbidity of SAVR as assessed by cardiologist and cardiac surgeon is $\geq 50\%$ at 30 days.
Pre-TAVI imaging assessment

- TTE +/- TEE
- Coronary angiogram +/- Aortogram & Peripheral angiogram
- MSCT
Major roles of CT in TAVI

- Iliofemoral Arterial System
  - Size, Calcification, Tortuosity, Plaques
- Annulus size measurement
- 3D annular & root morphology & dimensions
- Amounts of calcium in valve
- Relationship of annulus to both coronary ostia
- Valve positioning during implantation
- Post TAVI assessment
Known Predictors for PPM in CoreValve

81/270 pts (33%) permanent PM within 30 days; Median time = 4 days
Baseline ECG: RBBB 65.2%, LBBB 43.8%, and normal QRS 27.6%

1. Peri-AVB (OR 6.29, P<0.001),
2. Balloon pre-dilatation (OR 2.68, P<0.001),
3. Prolonged QRS duration (baseline) (OR 3.45, P=0.02)
4. Large CV prosthesis (29mm) (OR 2.50, P=0.019)
5. IV septum diameter (OR 1.18, P=0.025),
6. Depth of implantation (too low & deep),
7. Calcification several small sized of articles

J Cardiovasc Electoro 2011 (32 articles, 5258 pts analysis)
Khawaja et al. Circulation 2011;123:951-60 (270 pts analysis)
Permanent Pacemaker Predictor
Analysis from Multicenter Registry for CoreValve in Asia

- 117 patients (81.2±5.1 years) from 6 centers
- 23 patients (19.7%) required PPM, within a median time-to-insertion of 7 days (interquartile range, 5–13 days)
- QCA analysis, CT diameter, CT perimeter analysis in all Patients
Stretching Index

Device Perimeter (Calculated)

Annulus Perimeter
Stretching Index Cut-Off for Permanent Pacemaker

Device Perimeter / Annulus Perimeter > 1.13

Sensitivity 86.96%
Specificity 94.68%
PPV 80%
NPV 96.74%
Accuracy 93.2%
Implanted Depth Cut-Off for Permanent Pacemaker

Implanted Depth > 7.8 mm

Sensitivity 60.87%
Specificity 74.47%
PPV 35.14%
NPV 87.5%
Accuracy 70.94%

Cut-off = 7.8 mm
AUC=0.70
95% CI=0.593-0.806
Combined Criteria Of Depth and Stretching Index

<table>
<thead>
<tr>
<th>Implanted Depth 7.8 mm</th>
<th>PPM: 11%</th>
<th>PPM: 100%</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>PPM: 0%</td>
<td>PPM: 67%</td>
</tr>
</tbody>
</table>

1.13 Stretching Index

Logistic regression p<0.0001, AUC 0.97, 95% CI=0.94-0.99
Not too big and not too deep

Appropriate Size of Device Selection (CT perimeter Stretching Index < 1.13)
And Shallow Implantation (Depth < 7.8 mm) - Can Avoid Permanent Pacemaker Insertion after CoreValve.
Complication management & Simulator training

- CoreValve Simulator training (Symbionix)
- Scenario simulation for TAVI Heart Team on complication management
- Debriefing sessions post-TAVI
Flexible Solutions

The ANGIO Mentor™ family of products exemplifies Simbionix’s commitment to provide educators and clinicians with flexible, cost-effective solutions suitable for a wide range of settings.

Aortic Valve Replacement

Provides practice on endovascular implantation of an aortic valve bioprosthesis. The practiced steps include navigating through the aortic arch and crossing the LV using fluoroscopy and cineangiography to find the best angulation for visualizing the aortic valve annulus, pressure gradient measurements, aortic balloon valvuloplasty including rapid pacing and accurately positioning and deploying an aortic valve bioprosthesis. Complications include LV perforation. Virtual patients vary in heart orientations, annulus sizes, degrees of valve calcification and LV hypertrophy.
5 important lessons learnt

• Multi-disciplinary Heart Team
• Patient Selection
• Pre-TAVI imaging assessment
• Size of CoreValve and depth of implantation
• Complication management & Simulator training
Surgical AVR
The “Past”

TAVI
The “Future”