Percutaneous Therapies for Aortic Stenosis

“Percutaneous aortic valve replacement: Lessons learned with the CoreValve prosthesis”

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Concepts in Contemporary Cardiovascular Medicine
George R. Brown Convention Center
Houston, TX
**Presenter Disclosure Information**

Name: R Bonan

Within the past 12 months, the presenter or their spouse/partner have had a financial interest/arrangement or affiliation with the organization listed below.

<table>
<thead>
<tr>
<th>Company Name</th>
<th>Relationship</th>
</tr>
</thead>
<tbody>
<tr>
<td>CoreValve</td>
<td>Consultant/Stock owner</td>
</tr>
</tbody>
</table>
Percutaneous Aortic Valve Replacement

**CoreValve**
- Self expandable
- Porcine pericardium
- Retrograde
- Transapical *soon*
- 18 Fr
- No more CP assistance

**Cribier-Edwards**
- Balloon expandable
- Equine pericardium
- Retrograde (ante.)
- Transapical
- 24 Fr
- Rapid pacing
Access Site Assessment  Morphological Quantification
CoreValve Self-Expanding Bioprosthesis (Generation II, 21 Fr)

- **HIGHER PART:**
  low radial force area

- **MIDDLE PART:**
  functional valve area with 3 leaflets - frame constrained to avoid coronaries (convexo-concave)

- **LOWER PART:**
  high radial frame force pushes aside the native calcified leaflets

A porcine pericardial tissue valve fixed to the frame with PTFE sutures
CoreValve Revalving™
Clinical Experience

Generation 1
25F
14 patients

2004-2005

Generation 2
21F
63 patients*

2005-2006

Generation 3
18F
75 patients#

Mid. 2006

(*: Updated Oct. 1, 2006)
(#: updated April. 2007)
CoreValve Generation 2
Self-Expanding Bioprosthesis

7 Centers
(Sept 2005 - Sept 2006)

Grube E., Gerckens U.: Siegburg, Germany
23
Schuler G., Linke A.: Leipzig, Germany
14
Bonan R.: Montreal, Canada
11
Den Heijer P.: Breda, Netherlands
7
Serruys P.W., De Jaegere P.: Rotterdam, Netherlands
5
Bosmans A.: Antwerp, Belgium
2
Benit B.: Hasselt, Belgium
1
Inclusion Criteria Gen.2
(21F Catheter)

- Native aortic valve disease
  - Severe AS: AVAI ≤ 0.6 cm²/m²
  - 23mm ≥ AV annulus ≥ 20mm
  - Sino-Tubular Junction ≤ 45mm

- Age ≥ 80 y
- Logistic EuroSCORE ≥ 20%
- Age ≥ 65 y

High-Risk patients 50
Inoperable patients 13

- Liver cirrhosis - Child class A-B
- Pulmonary insufficiency: VMS < 1L
- Previous cardiac surgery
- PHT: PAP > 60mmHg
- Recurrent P.E’s
- RV failure
- Hostile thorax (radiation, burns, etc)
- Severe connective tissue disease
- Cachexia

(Updated Oct 1, 2020)
### Patient Characteristics

<table>
<thead>
<tr>
<th>Patients</th>
<th>63</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>80.9 ± 6.5 [64-94]</td>
</tr>
<tr>
<td>Gender</td>
<td>44 females (70%)</td>
</tr>
<tr>
<td>ECHO</td>
<td>Pre-gradient Max (mmHg) 60.4 ± 16 [33-95]</td>
</tr>
<tr>
<td></td>
<td>Pre-gradient Mean 41.2 ± 15 [19-80]</td>
</tr>
<tr>
<td></td>
<td>AVA (cm²) 0.64 ± 0.2 [0.3-1.1]</td>
</tr>
<tr>
<td>Pre LVEF (%)</td>
<td>51.1 ± 17.4 [15-78]</td>
</tr>
<tr>
<td>NYHA Class II</td>
<td>7(11 %)</td>
</tr>
<tr>
<td>III</td>
<td>35(55 %)</td>
</tr>
<tr>
<td>IV</td>
<td>22(34 %)</td>
</tr>
<tr>
<td>Logistic EuroSCORE</td>
<td>25.4 ±15 [7-69]</td>
</tr>
<tr>
<td>High-risk group</td>
<td>23.4 ±14 [7-69]</td>
</tr>
<tr>
<td>Non-operable group</td>
<td>31.6 ±16 [20-63]</td>
</tr>
</tbody>
</table>

(Updated Oct 1, 2021)
# Complications

## In-hospital major complications

<table>
<thead>
<tr>
<th></th>
<th>High-Risk (50)</th>
<th>Inoperable (13)</th>
<th>Overall (63)</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>logistic EUROSCORE</em></td>
<td>23.4%</td>
<td>31.6%</td>
<td>25.4%</td>
</tr>
<tr>
<td>In-hospital mortality</td>
<td>4(8%)</td>
<td>4(31%)</td>
<td>8(13%)</td>
</tr>
<tr>
<td>Conversion to surgery</td>
<td>4(8%)*</td>
<td>-</td>
<td>4 (7%)</td>
</tr>
<tr>
<td>Discharged, alive and well</td>
<td>43(82%)</td>
<td>7(54%)**</td>
<td>50(80%)</td>
</tr>
</tbody>
</table>

*High risk group: 1 surgical conversion death

**Inoperable group: 2 patients had BAV alone

( Updated Oct. 1, 2006)
17 women
12 men

Screening

5 deaths
6 - screening on-going
3 - unsuitable
1 - withdrew
1 - surgery

Consent

13 consented

Procedure

2 unsuitable vascular access
5 women, 6 men
PAVR
<table>
<thead>
<tr>
<th>Case</th>
<th>Gender</th>
<th>Age</th>
<th>Patient comorbidity</th>
<th>Logistic Euro-Score</th>
<th>Age ≥65 + Risk Factor</th>
</tr>
</thead>
<tbody>
<tr>
<td>RC*</td>
<td>F</td>
<td>64</td>
<td><strong>Pulmonary fibrosis; FEV$_1$ = 0.4</strong></td>
<td>5</td>
<td>-</td>
</tr>
<tr>
<td>LL*</td>
<td>M</td>
<td>88</td>
<td>Arteriopath; COPD</td>
<td>11</td>
<td>✓</td>
</tr>
<tr>
<td>JV*</td>
<td>F</td>
<td>85</td>
<td>Comorbidity</td>
<td>19</td>
<td>✓</td>
</tr>
<tr>
<td>YB#</td>
<td>F</td>
<td>90</td>
<td>Severe kyphoscoliosis</td>
<td>12</td>
<td>✓</td>
</tr>
<tr>
<td>RD</td>
<td>M</td>
<td>79</td>
<td>Arteriopath; CABG</td>
<td>42</td>
<td>✓</td>
</tr>
<tr>
<td>RP</td>
<td>F</td>
<td>82</td>
<td>Connective tissue disease</td>
<td>28</td>
<td>✓</td>
</tr>
<tr>
<td>RW</td>
<td>F</td>
<td>81</td>
<td>Pulmonary cachexia</td>
<td>36</td>
<td>✓</td>
</tr>
<tr>
<td>KS</td>
<td>M</td>
<td>84</td>
<td>Heart failure</td>
<td>43</td>
<td>✓</td>
</tr>
<tr>
<td>JPS</td>
<td>M</td>
<td>85</td>
<td>Arteriopath; COPD</td>
<td>37</td>
<td>✓</td>
</tr>
<tr>
<td>JP</td>
<td>M</td>
<td>83</td>
<td>COPD</td>
<td>23</td>
<td>✓</td>
</tr>
<tr>
<td>GD</td>
<td>M</td>
<td>85</td>
<td>CABG Renal failure</td>
<td>38</td>
<td>✓</td>
</tr>
<tr>
<td>RB</td>
<td>M</td>
<td>84</td>
<td>Cardiac Surgery</td>
<td>47</td>
<td>✓</td>
</tr>
<tr>
<td>MK</td>
<td>F</td>
<td>73</td>
<td>CVD; Jehova’s witness</td>
<td>48</td>
<td>✓</td>
</tr>
</tbody>
</table>

* Refused by Surgery; # Failure/Successful Surgery 6 m later
Characteristics of consecutive consenting patients

<table>
<thead>
<tr>
<th>Aortic valve area, cm$^2$ = 0.56</th>
</tr>
</thead>
<tbody>
<tr>
<td>NYHA functional class = 3</td>
</tr>
</tbody>
</table>
### Montreal Heart Institute PAVR Outcomes

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>11 patients PAVR PTA x 2; PCI x 1 *</td>
<td>1 death died Ischemic stroke with a functional prosthesis day 5 †</td>
</tr>
<tr>
<td></td>
<td>10 discharged with hemodynamic improvements</td>
</tr>
</tbody>
</table>

#### Hospital Outcome
- 1 death died Ischemic stroke with a functional prosthesis day 5 †
- 10 discharged with hemodynamic improvements

#### 30 days Follow-up
- 1 death Cerebral bleed MV prosthesis Coumadin Day 20
- **9 Community Dwelling Survivors**

*EuroIntervention 2006;2: 257-61; †CCI in press*
CoreValve: Coronary Ostia
Relation between the Prosthesis and the Anterior Mitral leaflet

Relation between the Prosthesis and Aortic leaflets
## Procedure & hospital outcomes

<table>
<thead>
<tr>
<th>Findings</th>
</tr>
</thead>
<tbody>
<tr>
<td>Median (IQR) procedure time, min</td>
</tr>
<tr>
<td>New PPM, n (%)</td>
</tr>
<tr>
<td>New LBBB, n (%)</td>
</tr>
<tr>
<td>CKMB elevation</td>
</tr>
<tr>
<td>&gt; normal</td>
</tr>
<tr>
<td>&gt; X 5 ULN</td>
</tr>
<tr>
<td>Blood transfusion</td>
</tr>
<tr>
<td>Platelet transfusion</td>
</tr>
<tr>
<td>Median (IQR) duration of admission,</td>
</tr>
<tr>
<td>days</td>
</tr>
<tr>
<td>ICU</td>
</tr>
</tbody>
</table>
### Procedural complications

<table>
<thead>
<tr>
<th>Event</th>
<th>N</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cardiac death</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Non-cardiac death *</td>
<td>1</td>
<td>9</td>
</tr>
<tr>
<td>CKMB &gt; x 5ULN #</td>
<td>3</td>
<td>27</td>
</tr>
<tr>
<td>Bradyarrhythmia</td>
<td>4</td>
<td>36</td>
</tr>
<tr>
<td>Emergent PCI / surgery</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Stroke *</td>
<td>1</td>
<td>9</td>
</tr>
<tr>
<td>Major bleeding *</td>
<td>2</td>
<td>18</td>
</tr>
</tbody>
</table>

* Same patient
# Post PAVR thallium = no ischemic defect
Aortic valve area and function post-CoreValve PAVR

Aortic Valve Area

Baseline Post-PAVR Day 10 1 month
AV mean grad (mmHg)
P<0.001

P=0.2

Mean Aortic Valve Area

Baseline = 0.56
1 month = 1.3

Mean AV area grad. (cm²)

Baseline = 52
1 month = 9

AV area (cm²)
Aortic valve regurgitation grade post-CoreValve PAVR

![Graph showing Aortic valve regurgitation grade post-CoreValve PAVR]

<table>
<thead>
<tr>
<th>AI</th>
<th>Pts</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>11</td>
</tr>
<tr>
<td>1</td>
<td>11</td>
</tr>
<tr>
<td>1</td>
<td>10</td>
</tr>
<tr>
<td>1</td>
<td>8</td>
</tr>
</tbody>
</table>

P = 0.2
Improvement in left ventricular systolic function

LVEF (%)

Baseline Day 10 1 month

Mean LVEF (%)

49 54 56
Functional and biochemical assessments post-CoreValve PAVR

NYHA

Median NYHA
Baseline = 3
1 month = 2

NT-BNP

Mean NTBNP (pg/ml)
Baseline=10058
1 month = 5419
## Cumulative 30 day adverse events

<table>
<thead>
<tr>
<th>Event</th>
<th>N</th>
<th>%</th>
</tr>
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<td>Cardiac death</td>
<td>0</td>
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<td>1</td>
<td>9</td>
</tr>
<tr>
<td>Major bleeding</td>
<td>2</td>
<td>18</td>
</tr>
</tbody>
</table>

* 1 non-cardiac death at 20 days – cerebral hemorrhage / 1
Summary

- PAVR in high-risk patients is feasible
- Haemodynamic & functional improvements in survivors
- Periprocedural morbidity is significant & related to vascular complications
- Co-morbid burden may influence early outcomes
• First 9:
  General Anesthesia, TEE, Surgical cardio-pulmonary by pass, 21 Fr
• Next 8:
  General Anesthesia, TEE, Tandem Heart support, 1x21Fr and 7x18Fr
• Last 5:
  Light Sedation, Preclosed w/ Prostar 10Fr 18 Fr
Now! it is really a Cath-Lab procedure

- Since Nov 9\textsuperscript{th} .... 18 Fr
  At Siegburg, Lepzig & Montreal
- No Cut-down (totally percutaneous: Prostar 10Fr)
- No "support" (Cardiac assistance or pacing)
- No anesthesia (light sedation)
# Comparison 21 vs 18 Fr

<table>
<thead>
<tr>
<th></th>
<th>21 Fr</th>
<th>18 Fr</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>(50)</td>
<td>(36)</td>
</tr>
<tr>
<td><strong>Local Anesthesia</strong></td>
<td>-</td>
<td>25%</td>
</tr>
<tr>
<td><strong>No Surgical Cut-down</strong></td>
<td>12%</td>
<td>42%</td>
</tr>
<tr>
<td><strong>No Hemodynamic support</strong></td>
<td>-</td>
<td>64%</td>
</tr>
<tr>
<td><strong>Procedural Time</strong></td>
<td>188±55</td>
<td>148±50</td>
</tr>
</tbody>
</table>
Late Survival After Aortic Valve Replacement

Kvidal et al. JACC 2000; 35: 747
Operative Mortality / Comorbidity
Euro Heart Survey on Valvular Heart Disease

1231 Patients operated in 92 centers from April to July 2001

EuroScore

Mortality

% 16% of patients
Mortality MHI

22 pts- procedure (8 x 18 Fr)

Death in Hospital:
4 (3 x 18 Fr): 18%
St M.: CVA*(37)
B.: MR +++ (29)
B.: Ao. Perf.* (19)
D.: Ao. Perf.* (11)

Death after Discharge
< 1 month:
B.: Cerebral Hemor.(47)

Death after discharge
> 1 month
P.: Sepsis - CVA (23)
W.: sudden death (36)
K.: non cardiac? (48)

*: procedure related mortality: 14%, mean Logistic Euroscore > 30%
Lessons learned

• Patient selection: anatomy, co-morbidities...
• Evolution to a real percutaneous procedure:
  • Light sedation
  • “Preclosed” with Prostar 10 Fr
  • No support needed: “active” leaflets
• Learning curve: 18 Fr
• Still reserved for High Risk patient, but...
Thank you
Initial Clinical Experience

- Procedural Success
- 30-day mortality
- Discharged
- Conversion to Surgery

N=79

25 Fr (n = 14)
21 Fr (n = 63)

(Updated Oct. 1, 2006)
Percutaneous Aortic Valve Replacement

- **The 21F Revalving™ CoreValve** (Generation 2)
  - Clinical Experience in native AS
  - High-risk or inoperable patients
  - 63 patients*
- **30 day data available on 1st 54 patients**

* Updated Oct. 1, 2006
Mortality ICM

#JPS
85 y.,€ sc.: 37
Ischemic Stroke
Day 3

#RB
84 y.,€ sc.: 47
Cerebral bleed
Day 20

# JP
83 y.,€ sc.: 23
CVA ?
Day 76

# RW
81 y.,€ sc.: 36
Sudden death
Day 101

Procedural complications

Pre MVR
Elevated
INR ?
Cerebral Scan
No autopsy

ETO & TTE:N
Cerebral Scan +
Candida Albicans ?
No autopsy

Sudden death
Prosthesis : OK
autopsy