Pacemakers for the TAVI patient: For whom? When?

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8th International Conference
Acute Cardiac Care
June 2013
Disclosures

• Research grants from device companies (MDT, Biotronik, SJM)
• Speaker / proctor for MDT, BSCI, SJM, Biotronik
TAVI

The Edwards Sapien (balloon expandable)

- Transfemoral
- Transapical
- Transaortic

Corevalve (self expanding)

- Transfemoral
- Transaxillary
- Transaortic

Piazza Circ interv 2008
## Incidence of Conduction Abnormalities Following Transfemoral TAVI

<table>
<thead>
<tr>
<th></th>
<th>New LBBB (%)</th>
<th>High degree AVB (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Core Valve</td>
<td>40 (30–65) (^{1,3,5})</td>
<td>25(12 -44) (^{1,3,5,4,8,9})</td>
</tr>
<tr>
<td>Edwards</td>
<td>12 (6-18) (^{1,7})</td>
<td>5 (0-27) (^{1,6,8,9})</td>
</tr>
</tbody>
</table>

1. Nuis Eur Heart J 2010
2. Roten AJC 2010
4. *Maier et al. TCT 2010 Lowest incidence with more superior positioning
5. Guetta Glikson AJC 2011
7. Godin Am J Cardiol 2010
8. Zahn EHJ 2011
9. Khatri Ann Int Med 2013 \(n= 16000\)
Anatomy of the Aortic Root

Figure 6. This image of the aortic root opened from the left ventricle shows the fibrous continuities between the interleaflet triangles, the fibrous trigones, and the membranous septum. A-M indicates aortic-mitral.
Location of the Conduction System

6 mm from bottom of NCC to emergence of LBB
Depth of Implantation and LBBB

New-onset LBBB:
10.3 ± 2.7 mm
(range, 6.7 to 14.6 mm)

No LBBB:
5.5 ± 3.4 mm
(range, 0.7 to 12.2 mm)

P = 0.005

Early and Persistent Intraventricular Conduction
Predictors of High Degree AVB with CoreValve - Baseline Parameters -

<table>
<thead>
<tr>
<th>Class</th>
<th>Predictors</th>
<th>OR/HR</th>
<th>Ref</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preexisting CSD</td>
<td>RBBB</td>
<td>OR &gt; 40</td>
<td>4,5</td>
</tr>
<tr>
<td></td>
<td>LBBB+long PR</td>
<td>3.45</td>
<td>5</td>
</tr>
<tr>
<td></td>
<td>Wide QRS</td>
<td>1.18</td>
<td>2</td>
</tr>
<tr>
<td>LVOT and AV anatomy</td>
<td>IVS hypertrophy</td>
<td>1.18</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>NCC thickness</td>
<td>1.5</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>AV Calcifications</td>
<td>1.5</td>
<td>2</td>
</tr>
</tbody>
</table>

### Predictors of High Degree AVB with CoreValve - Procedural Parameters -

<table>
<thead>
<tr>
<th>Class</th>
<th>Parameter</th>
<th>OR/HR</th>
<th>Ref</th>
</tr>
</thead>
<tbody>
<tr>
<td>Depth</td>
<td>Depth of Implantation &gt; 6 mm</td>
<td>OR &gt; 20</td>
<td>4,5</td>
</tr>
<tr>
<td>Size</td>
<td>Balloon : Annulus ratio &gt; 1.3</td>
<td></td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>Large prosthesis (29)</td>
<td>2.5</td>
<td>2</td>
</tr>
</tbody>
</table>

Course of AVB Over Time in CoreValve

- 40-80% occur during the procedure, 50% of which occur during balloon pre-dilatation²,³
- Later there are opposing processes of resolution of edema / inflammation vs. self expanding nature of CoreValve
  - Periprocedural AVB “resolved” (?) in 35% at discharge, 64% within ≥ 30 days ¹,²,³
  - 20-60% of HDAVB develop AFTER procedure most of them within 5 days
  - Few reports of late onset AV block after discharge ⁵, few cases of late SCD

¹- Roten Am J Cardiol 2010  
²- Nuis Eur Heart J 2010  
³- Guetta & Glikson AJC 2011  
⁴- Piazza Eurointerv 2010  
⁵- Fraccaro Am J Cardiol 2011
Time to Development of High Degree AV Block

\[ n = \frac{25}{70} \]

Predictors and Course of High-Degree Atrioventricular Block After Transcatheter Aortic Valve Implantation Using the CoreValve Revalving system

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AJC 2011
Periprocedural ECG Changes and Later Progression to HDAVB

• Periprocedural AVB is the strongest predictor of persistent AVB \(^1\) (in our series ALL had permanent pacemakers implanted)

• New LBBB is a poor predictor of later HDAVB (6/33) \(^2\)

• Of 39 cases with periprocedural worsening of conduction (other than HDAVB) only 8 progressed later to HDAVB \(^2\)

• Of 15 patients with late HDAVB only 8 had demonstrated periprocedural conduction system changes \(^2\)

• In patients with normal QRS both before and after TAVI, rate of later development of HDAVB was 0 – 13% \(^1,2\)

\(^1\) Khawaja, Circulation 2011
\(^2\) Guetta and Glikson 2011
Permanent Pacing After TAVI

• Absolute indication:
  – New high degree AV block of any duration (early or immediate implantation)
  – Alternating BBB

• Relative indication:
  – Preexisting LBBB+ 1st degree AVB with any change?
  – Preexisting RBBB with any change?
  – New LBBB + 1st degree AV block?

• Role of EPS?
  • Prophylactic pacing?
  • Early decision after procedure?
• 202 pt with no CSD implanted with Edwards Sapien TAVI
• 30% developed new LBBB which resolved later in 37% and 57% after 6 and 12 m
• New LBBB was associated with higher incidence of PPM for CAVB (20% vs 0.7%) as well as with syncope and CHF
Effect of LBBB on Permanent Pacing and Mortality

**Outcome** | **Overall (n = 176)** | **Persistent LBBB (n = 25)** | **No/Transient LBBB (n = 151)** | **p Value**
--- | --- | --- | --- | ---
Follow-up (months)* | 12 (6-24) | 12 (5-24) | 12 (5-24) | 0.164
Syncope | 5 (2.8) | 4 (16.0) | 1 (0.7) | 0.001
Heart failure requiring hospitalization | 26 (14.8) | 7 (28.0) | 19 (12.6) | 0.124
PPI | 6 (3.4) | 5 (20.0) | 1 (0.7) | <0.001
Death | Overall | 32 (18.2) | 4 (16.0) | 28 (18.5) | 0.998
Cardiac death | 14 (8.0) | 1 (4.0) | 13 (8.6) | 0.696
Sudden death | 1 (0.6) | 0 | 1 (0.7) | 0.999
Monitoring After CoreValve TAVI

• In-hospital monitoring for 5 days
• 24-48 hours with temporary pacemaker
• 3 days for “low risk” patients?
• Holter before discharge in borderline cases
• Role of pre discharge EPS?
Monitoring After Edwards Sapien TAVI

- Up to three days in hospital
- No need for temporary pacemaker if no change in conduction
Preventive Measures

• Use Edwards Sapien in RBBB
• High position of Corevalve
• Preventive permanent pacing before TAVI:
  – Absolute:
    • Preexisting indications for PPM (History of syncope, holter !)
  – Relative:
    • All patients with RBBB undergoing CoreValve implantation?
    • All patients with preexisting LBBB + 1st degree AV block undergoing CoreValve implantation??
PPM by Tertiles

I: 36%
II: 42%
III: 21%
Temporary Pacing in TAVI

• Initial experience with relatively high rate of complications, mainly perforations (ASA, Plavix)
• Prolonged temporary pacing associated with infections, perforations and dislocations
• Balance between risk of development of HDAVB and the risks of prolonged temporary pacing
• Practical approach:
  – Inserted via RIJV for stability
  – Use balloon tipped pacing catheters semi filled with saline to decrease risk of perforation *
  – Temporary pacemaker left in for 48 hours in most patients
  – Early permanent pacing when indicated

* Some use screw-in leads for stability
• 4.3% tamponade in TAVI (17/389)
• 53% of tamponades were due to temporary pacemaker wires (screw in > passive ), nearly all occurred on the table
• None of the pacemaker related tamponades was fatal
Impact of Permanent Pacemaker Implantation on Clinical Outcome Among Patients Undergoing Transcatheter Aortic Valve Implantation

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Ralf Mueller, MD,§ Peter Wernawser, MD,* Thomas Pilgrim, MD,* Steffen Gloeckler, MD,*
Ahmed A. Khattab, MD,* Christoph Huber, MD,* Thierry Carrel, MD,* Balthasar Eberle, MD,‖
Bernhard Meier, MD,* Peter Bocksteges, MD,§ Peter Jüni, MD,‡ Ulrich Gerckens, MD,‖
Eberhard Grube, MD,* Stephan Windecker, MD,*

Bern, Switzerland; and Bonn and Siegburg, Germany

Figure 3  Cumulative Incidence of All-Cause Mortality Through 1 Year According to Study Group

The blue line represents outcomes of patients with permanent pacemaker implantation before TAVI, the red line represents patients with the need for permanent pacemaker implantation after TAVI, and the green line represents patients without permanent pacemaker implantation. CI = confidence interval; HR = hazard ratio; other abbreviations as in Figure 1.

N= 98/353
Costs and complications of new PM

- Significantly prolongs the in-hospital length of stay, thus significantly increasing the TAVI related costs*

<table>
<thead>
<tr>
<th></th>
<th>No complications</th>
<th>Complications</th>
<th>New PPI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean LOS (days)</td>
<td>8</td>
<td>14</td>
<td>18</td>
</tr>
</tbody>
</table>

*Nuis RJ et Al.. Catheter Cardiovasc Interv. 2011 Sep 1;78(3):457-67*
Conclusions

• High degree AV block is a common consequence of TAVI, especially of the CoreValve type

• Its strongest predictors are preexisting RBBB and low valve position

• Temporary pacing for 48 hours and monitoring for 5 days is indicated in all patients following CoreValve TAVI

• With increased operator experience, new tools and high implant position, lower incidence of HDAVB is anticipated
Thank You!
NYHA functional class and LV function

p=0.0012, for changes over time between both groups
p=0.0014 for comparison between groups at follow-up
p=0.0014 for changes over time in No/Transient LBBB group
p=0.031 for changes over time in Persistent LBBB group
Solid line represents the group of patients with new conduction defects after TAVI; dashed line represents the group of patients without new conduction defects.

Outcome from the IQL (Icelandic Quality of Life Questionnaire): No significant differences were observed between ICD patients and pacemaker carriers on any of the 12 domains of the IQL. Comparisons with normal population values (age band 50–69 years) are shown.

Mortality in octa- and nona-genarian patients with permanent pacemaker

<table>
<thead>
<tr>
<th>Independent predictors</th>
<th>P</th>
<th>Hazard Ratio (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>CHF</td>
<td>&lt;0.001</td>
<td>2.6 (1.7 to 4.0)</td>
</tr>
<tr>
<td>COPD</td>
<td>&lt;0.001</td>
<td>4.0 (2.1 to 7.6)</td>
</tr>
<tr>
<td>Older age</td>
<td>0.002</td>
<td>1.1 (1.0 to 1.1)</td>
</tr>
<tr>
<td>Syncope</td>
<td>0.005</td>
<td>1.8 (1.2 to 2.7)</td>
</tr>
<tr>
<td>Cancer</td>
<td>0.021</td>
<td>1.9 (1.1 to 3.3)</td>
</tr>
<tr>
<td>High-degree AV block</td>
<td>0.028</td>
<td>1.5 (1.0 to 2.2)</td>
</tr>
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