TAVR, Conduction Disturbances and Pacemakers
Overview and Recommendations
TAVI and Pacemakers

- Background
- Factors Affecting Pacemaker Implantation
- Implant Best Practices
- Future Advancements
- Conclusions
Background

Given the anatomical proximity of the aortic valve to the conduction system, the occurrence of conduction abnormalities and the need for permanent pacemakers in patients undergoing SAVR or TAVR is not surprising.

Modified from Tawara (Alex Hill)
Aortic Valve Replacement and Conduction Disorders

Permanent pacemaker (PM) implantation rates with aortic valve replacement:

- Surgical Aortic Valve Replacement (SAVR): 7.2%\(^1\) (Range: 3.2% - 8.5%)

- Transcatheter Aortic Valve Implantation (TAVI): 15%\(^2\) (Range: 0 – 47%)

CoreValve Pacemaker Implantation Rates Across Studies

Partner Trial New Pacemakers at 30 Days and 1 Year

- Spring Trial New Pacemakers at 30 Days and 1 Year

\[ P = 0.60 \]
\[ P = 0.27 \]

- TAVI (n=179)
- Standard Rx (n=179)
France II Registry\(^1\)
New Permanent Pacemaker

UK Registry¹
New Permanent Pacemaker

## Lower PM Rates with CoreValve are Possible

<table>
<thead>
<tr>
<th>PM Rate</th>
<th>Study Examples</th>
</tr>
</thead>
<tbody>
<tr>
<td>12%</td>
<td>Maier 2010¹</td>
</tr>
<tr>
<td></td>
<td>• 132 CoreValve patients (excluded 16 patients with PM indications at baseline)</td>
</tr>
<tr>
<td></td>
<td>• Only patients with complete AV block and/or symptomatic bradycardia received PM</td>
</tr>
<tr>
<td></td>
<td>• Aimed for more superior positioning of the CoreValve device within the left ventricular outflow tract (LVOT) to mitigate conduction problems</td>
</tr>
<tr>
<td>14%</td>
<td>Munoz-Garcia 2011²</td>
</tr>
<tr>
<td></td>
<td>• 181 CoreValve patients</td>
</tr>
<tr>
<td></td>
<td>• Traditional delivery system (n=124) and AccuTrak™ delivery system (n=57)</td>
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<tr>
<td></td>
<td>• 34.6% PM implants with Traditional Delivery System vs. AccuTrak 14% (P&lt;0.001)</td>
</tr>
<tr>
<td></td>
<td>• Depth of implant less in the LVOT for AccuTrak patients than patients receiving traditional delivery system (mean: 9.6 mm vs. 6.5 mm, P&lt;0.007)</td>
</tr>
<tr>
<td>12%</td>
<td>Grube 2011³</td>
</tr>
<tr>
<td></td>
<td>• 60 CoreValve patients</td>
</tr>
<tr>
<td></td>
<td>• No use of balloon pre-dilation</td>
</tr>
</tbody>
</table>

¹ Maier TCT 2010 Presentation.
² Munoz-Garcia 2011 EuroPCR Presentation.
TAVI and Pacemakers

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Factors Influencing Conduction Disturbances

Patient History

- Age
- Poor LVEF
- Preoperative AR
- Previous MI
- Pre-existing conduction disorders / RBBB\(^1,2,3,4\)
- Pulmonary hypertension
- Landing zone calcification\(^5\)

Patient Anatomy

- Narrow LVOT\(^6\)
- Location of the AV node
- Length and configuration of the membranous septum
- Septal wall thickness\(^7\)

## Pre-existing RBBB Conduction Disorders

Many studies have validated the presence of right bundle branch block (RBBB) before TAVI is a significant pre-procedure predictor for the development of complete atrioventricular (AV) block and subsequent PM.

<table>
<thead>
<tr>
<th>Odds Ratio and Statistical Significance</th>
<th>Study Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.358 (p=0.02) RBBB significant predictor of PM</td>
<td>Erkapic 2011¹: Meta analysis of 5,258 TAVI patients</td>
</tr>
<tr>
<td>6.132 (p=0.046) RBBB significant predictor of PM</td>
<td>Fraccaro 2011²: 70 CoreValve patients</td>
</tr>
<tr>
<td>47.6% PM rate with RBBB and 10% PM rate without RBBB (p=0.01)</td>
<td>Munoz-Garcia 2010³: 65 CoreValve patients</td>
</tr>
<tr>
<td>28.8% PM rate with RBBB and 2.7% PM rate without RBBB (p&lt;0.0001)</td>
<td>Calvi 2011⁴: 181 CoreValve patients</td>
</tr>
</tbody>
</table>

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TAVI Procedural Factors

**Pre-Deployment**

- BAV balloon type and size
- Depth of implant
- Wire stiffness and location
- Positioning of balloon catheter and valve
- Balloon: Annulus ratio
- BAV balloon over-dilation
- Valve and annulus ratio

**Deployment**

- Depth of implant
- Process and timing of repositioning

References:
<table>
<thead>
<tr>
<th>BAV Impact on Conduction Disorders Prior to TAVI</th>
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<tbody>
<tr>
<td>46% New conduction abnormalities during BAV procedure</td>
</tr>
<tr>
<td>1.5% PM rate associated with BAV²</td>
</tr>
<tr>
<td>8.5% New conduction abnormality with BAV</td>
</tr>
<tr>
<td>9% PM rate associated with BAV³</td>
</tr>
<tr>
<td>16.1% Absolute increased PM rate with BAV</td>
</tr>
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# Depth of Implant

<table>
<thead>
<tr>
<th>Odds Ratio</th>
<th>Study Examples</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.17 OR (p=0.003)</td>
<td>Giannini: 275 CoreValve patients. Depth of prosthesis implantation was an independent predictor of PM implant.</td>
</tr>
<tr>
<td>1.15 OR (p=0.001)</td>
<td>Munoz-Garcia: 181 CoreValve patients. Depth of prosthesis implantation was an independent predictor of PM implant.</td>
</tr>
<tr>
<td>1.21 OR (p=0.039)</td>
<td>Fraccaro: 70 CoreValve patients: Depth of prosthesis implantation was an independent predictor of PM implant.</td>
</tr>
<tr>
<td>1.12 OR (p=0.03)</td>
<td>Valera: 26 CoreValve patients. Depth of prosthesis implantation was the only independent predictor of PM implant.</td>
</tr>
<tr>
<td>1.37 OR</td>
<td>Saia: 73 CoreValve patients. Distance between non-coronary cusp and the distal edge of the prosthesis was independent predictor of PM implant.</td>
</tr>
</tbody>
</table>

4. Valera
Valve Procedural Differences

- CoreValve frame height 50mm. Although there is control over positioning during deployment, if the valve extends further into the LVOT, it may cause conduction disorders.¹⁻⁵

- The Edwards SAPIEN XT valve -17mm although positioning dependent on stability by pacing during balloon expansion, the frame height potentially minimises valve depth options.

4. Valera
Depth of CoreValve Implant and Proximity of Aortic Valve to Conduction System

Conduction system

15 mm past annulus  5 mm past annulus

Images from porcine heart.
TAVI and Pacemaker Clinical Practices

Potential Lower Threshold for PM Implant with TAVI

- Temporary epicardial pacing used after SAVR allows time for conductive tissue to recover
- With TAVI, concerns about infection may prompt physicians to early pacemaker implantation
- Lack of knowledge about evolution of new onset conduction bradycardia and left bundle branch block and their prognostic impact\(^1,2\)
- Variable and unknown pacing practices with TAVI patients\(^1,2,3\)

Potential Economic Factors

- May be financial advantageous to implant a pacemaker rather than hospitalizing the patient for watchful waiting (reduce length of stay)\(^4\)

4. Maier RM
ESC Pacing Guidelines for Acquired AV Block

1. Third- or second-degree (Mobitz I or II) atrioventricular block: (i) after catheter ablation of the atrioventricular junction (ii) after valve surgery when the block is not expected to resolve (Class I) C Evidence

2. Chronic symptomatic third- or second-degree (Mobitz I or II) atrioventricular block (Class I) C Evidence

3. Asymptomatic third- or second-degree (Mobitz I or II) atrioventricular block (Class IIa) C Evidence

4. Symptomatic prolonged first-degree atrioventricular block (Class IIa) C Evidence

5. Neuromuscular diseases (e.g. myotonic muscular dystrophy, Kearns–Sayre syndrome, etc.) with third- or second-degree atrioventricular block (Class I) B Evidence

6. Neuromuscular diseases (e.g. myotonic muscular dystrophy, Kearns–Sayre syndrome, etc.) with first-degree atrioventricular block (Class IIb) B Evidence

It is not known how uniformly these pacemaker guidelines are followed for TAVI patients.

Many published TAVI studies do not identify the reasons for pacemaker implants.¹

The most common published reasons for implanting pacemakers in TAVI patients are for AV block II or III.¹

TAVI and Pacemakers

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♥ Factors Affecting Pacemaker Implantation
♥ Implant Best Practices
♥ Future Advancements
♥ Conclusions
# Implant Best Practices to Reduce Conduction Disturbances

<table>
<thead>
<tr>
<th>Pre-Procedure</th>
<th>Intra-Procedure</th>
<th>Post-Procedure</th>
</tr>
</thead>
</table>
| ✨ Assess pre-existing need for pacemaker and implant prior to TAVI if needed:  
  ✨ RBBB  
  ✨ LBBB + LAD  
  ✨ Assess calcifications/annulus size (MSCT)  
  ✨ Assess septal wall thickness | ✨ RIJ or LIJ temporary pacing wire access enables early patient mobility  
  ✨ Cautiously advance guidewire to avoid septum  
  ✨ Carefully consider valvuloplasty balloon selection:  
    ✨ Undersize  
    ✨ Shorter length  
  ✨ Reduce depth of implant to < 6 mm  
  ✨ Use AccuTrak System | ✨ Continuous ECG monitoring until discharge  
  ✨ Temporary pacemaker for 48 to 72 hours  
  ✨ Use guidelines to determine need for pacemaker |
Assess Need for Pacemaker Prior to TAVI

- Clinical practices vary and strongly influence pre-TAVI PM rates
- Proactively treating patients who have pacemaker needs prior to the TAVI procedure could reduce post-TAVI PM rates

<table>
<thead>
<tr>
<th>Study</th>
<th>Pre-TAVI PM Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>PARTNER B Trial¹</td>
<td>22.9%</td>
</tr>
<tr>
<td>UK Registry²</td>
<td>8%</td>
</tr>
<tr>
<td>Italian Registry³</td>
<td>6.3%</td>
</tr>
</tbody>
</table>

Depth of Implant Recommendation

Distance of the lower edge of the non-coronary cusp to the valve inflow edge should be < 6 mm¹

Valve should be implanted in a superior location within the LVOT
Conclusion: AccuTrack System helped reduce the depth of the valve implant and lower the pacemaker implant rate.

**Depth of implantation**

<table>
<thead>
<tr>
<th></th>
<th>S. Tradicional</th>
<th>Accutrack</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-implant depth (mm)</td>
<td>10 ± 3</td>
<td>6.5 ± 3.1</td>
</tr>
</tbody>
</table>

9.6 ± 3.1 mm vs. 6.5 ± 3.1; p < 0.001

**Pacemaker (%)**

<table>
<thead>
<tr>
<th></th>
<th>34.5</th>
<th>14</th>
</tr>
</thead>
<tbody>
<tr>
<td>p</td>
<td>0.007</td>
<td></td>
</tr>
</tbody>
</table>

1. Munoz-Garcia PCR 2011
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Future Advancements in TAVI Technology

♥ Improved stability
♥ Improved control and ergonomics
♥ Refinements in valve sizing
♥ Full repositionability
TAVI and Pacemakers

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Conclusions

♥ Given the anatomical proximity of the aortic valve to the conduction system, pacemaker implants are a known complication of aortic valve replacement procedures.

♥ There are some differences between the currently available technologies with respect to the PPM requirement.

♥ Depth into the LVOT may cause conduction disorders and increase the PM rate.\(^1\)-\(^5\) CoreValve PM rate (25.8\%)\(^6\) has been reduced when the depth of implant is kept under 6 mm and the AccuTrak delivery system is used optimize the position and depth of the valve (12\% to 14\%)\(^7,8,9\).