• **CONDITION:** Coronary Artery Disease

• **PI:** Peter Alden, MD

• **CONTACT INFO:** JoAnne Goldman | joanne.goldman@allina.com | 612-863-3973

• **DESCRIPTION:** To demonstrate that the SurVeil DCB is non-inferior to the Medtronic IN.PACT DCB for treatment of subjects with symptomatic peripheral artery disease (PAD) due to stenosis of the femoral and/or popliteal arteries

• **CRITERIA LIST/QUALIFICATIONS:**
  
  **Inclusion**
  - Symptomatic PAD due to a stenotic lesion of the femoral and/or popliteal arteries
    - Target limb Rutherford classification 2, 3 or 4
    - Reference Vessel Diameter (RVD) of 4 mm to 7mm and total lesion length of < 180mm

  **Exclusion**
  - Acute limb ischemia
  - Previous therapy to target limb within 90 – 180 days

• **SPONSOR:** Surmodics, Inc.
Conduction disease and pacemaker implantation post transcatheter aortic valve replacement (TAVR) 
The MHI Experience

Jay D. Sengupta, MD, FACC, FHRS

Cardiac Electrophysiology
Director, Electrophysiology Research
Director, Genetic Arrhythmia Center
Co-director, Cardiac Device Clinic at Minneapolis Heart Institute and Abbott Northwestern Hospital

Disclosures

• No personal disclosures

• I participate in Industry-sponsored trials and studies in association with the Minneapolis Heart Institute Foundation
Objectives

• What is the scope of the problem when it comes to conduction issues after TAVR?

• What are the implications of left bundle branch block for long term outcomes and need for permanent pacemaker?

• Work towards developing a uniform and practical approach to dealing with new conduction disturbances after TAVR

• Discuss shared decision making as approach to conduction disturbances post TAVR to optimize patient care

Case presentation

• 89 year old gentleman with trileaflet aortic valve with severe aortic stenosis at moderate risk for open surgical AVR enrolled in PARTNER SAPIEN 3 Registry.
  Peak velocity 4.7 m/s, Mean gradient 52 mmHg

• History of paroxysmal atrial fibrillation on amiodarone 200 mg daily

• LVH and LVEF of 45%

• Moderate restrictive pulmonary disease

• Underwent successful left transfemoral deployment of 26 mm SAPIEN 3 pericardial bioprosthesis
  Procedure included balloon valvuloplasty with 23 mm Edwards balloon

• New LBBB ("transient", "incomplete") noted after TAVR

• Temporary pacemaker via right internal jugular vein implanted
POD#2

- Progressing well clinically, “out walking with his nurse”
- Systolic BP 130s-150s, on 2L of oxygen after ambulation due to mildly reduced oxygen saturation
  Clinically at baseline otherwise; excellent result from TAVR
- Remains on home dose of atenolol and amiodarone
- EKG description on POD#2 TAVR: QRS 116 msec (Baseline 108msec)
- Temporary pacemaker removed

Sudden complete heart block; no change in sinus rate
He reported later that he was laying in bed.

Sudden widening of QRS with LBBB vs fused PVC, then CHB and asystole
**Follow-up**

- Received approximately 1-2 minutes of chest compressions and subsequent ROSC
- Progress note mentioned that he continued to be externally paced
- Temporary pacemaker replaced in CV lab
- EP consult for permanent pacemaker

- Underwent dual chamber pacemaker implant
- One month pacemaker check: CHB, 99.6% ventricular pacing
- Six month pacemaker check: Aflutter with intact conduction 60-95 bpm, 25.1% ventricular pacing

**Case#2**

- 68 year old male with aortic dissection surgically repaired with interposition graft at an outside hospital
- Noncoronary cusp of aortic valve does not coapt with other 2 leaflets because of dissected flap; high surgical risk
- Underwent TAVR with a 31 mm Medronic CoreValve via percutaneous right transfemoral approach
POD#2

Underwent implant of a biventricular pacemaker (EF 40%)
At 8 months, complete heart block, 95% biventricular pacing

Symptoms of advanced conduction disease
(LBBB or high-degree AV block)
- Dizziness, light-headedness
- Fatigue, weakness
- Confusion, delirium
- Atrial and ventricular arrhythmias (e.g., brady-dependent torsades)
- Syncope
- Congestive heart failure
- Asystole
- Sudden death
- Often hypertensive in complete heart block with slow escape
- End organ hypoperfusion/injury
Anatomy
Valves in relation to conduction system
Variation in conduction system anatomy

- 3 major variants found in autopsy series of 115 elderly patients
  - 50% of individuals exhibit a right-sided AV bundle
  - 30% have a left-sided AV bundle
  - 20% have an AV bundle that courses under the membranous septum just below the endocardium
  - Such individuals may be at higher risk of TAVR-induced conduction disturbances


Normal EKG
Right bundle and RBBB

Right bundle branch block
- QRS > 120 msec
- rSR' pattern in V1-3
- Wide, slurred S wave in lateral leads (I, aVL, V5-6)

Left bundle and LBBB

- QRS duration of > 120 msec
- Dominant S wave in V1
  - small or non-existent r wave
- Broad monophasic R wave in lateral leads (I, aVL, V5-6)
- Absence of Q waves in lateral leads

References:
- Courtesy Lifeinthefastlane.com ecg tutorial
- Indian Pacing Electrophysiol. J. 2003;3(3):157
Valve Types

Edwards Sapien

Medtronic CoreValve

Pathophysiology
Mechanism of conduction disturbances after TAVR

• Direct mechanical insult (edema, hematoma, ischemia)
  Degree of radial forces directed at LVOT
  ♦ Valve diameter and calcification of host tissue

• Anatomical variation of AV node in apex of triangle of Koch and length of proximal part of the His bundle

• Aortic stenosis related conduction disease
  Calcium deposition on the conduction system
  LV dysfunction

Moreno R et al., Circulation; 120:e29-e30.
New LBBB

- Most conduction disturbances occur in the acute period
- A small percentage of patients develop subacute LBBB
- LBBB rates of 12% to 22% have been reported after implantation of Edwards SAPIEN 3
- PPM rates of 5 to 14% have been reported at follow-up with new-onset LBBB
  Majority of patients have AV block and sick sinus syndrome as primary indications for PPM

LBBB and mortality

- Inconsistent association between new-onset LBBB and all-cause mortality
- Meta-analysis with 4756 patients failed to show significant association between occurrence of TAVR-induced LBBB and 1-year all-cause mortality
  

- LBBB was associated with a greater risk of 1-year cardiac mortality, especially when the QRS duration > 160 msec.
  
  Urena et al. JACC 2015;65:437-438

- Higher risk of all-cause mortality and rehospitalization for CHF

  Proposed mechanisms
  - Progression to HAVB
  - Ventricular arrhythmias
  - Ventricular dyssynchrony and congestive heart failure
**LBBB and mortality**

### Supplemental Table 2: Impact of new-onset left bundle branch block on mortality among studies with a multivariable analysis

<table>
<thead>
<tr>
<th>Author, valve type (n)</th>
<th>n of patients</th>
<th>Valve type (%)</th>
<th>Mortality rate at follow-up</th>
<th>Multivariable OR/HR (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Carrabba et al., CoreValve (100)</td>
<td>p=92</td>
<td>Medtronic CoreValve (57)</td>
<td>37.8</td>
<td>24</td>
</tr>
<tr>
<td>Houhulainen et al., SAPEN XT (48)</td>
<td>s=679</td>
<td>Edwards SAPIEN/SAPIEN XT (19)</td>
<td>20.8</td>
<td>13</td>
</tr>
<tr>
<td>Schymik et al., CoreValve (19)</td>
<td>n=668</td>
<td>Edwards SAPIEN/SAPIEN XT (100)</td>
<td>27.8</td>
<td>28.4</td>
</tr>
</tbody>
</table>

CI: confidence interval; HR: hazard ratio; LBBB: left bundle branch block; OR: odds ratio.

### Figure 2. Association of new-onset left bundle-branch block (LBBB) with sudden cardiac death after transcatheter aortic valve replacement.

Kaplan-Meier curves at the 2-year follow-up for sudden cardiac death according to the occurrence of new-onset persistent (NOP) LBBB (A) and according to QRS duration >160 or >160 milliseconds (B) among patients with NOP-LBBB. Reproduced from Urena et al16 with permission from the publisher. Copyright © 2015, American College of Cardiology Foundation.
Risk factors for new onset LBBB

- Pre-existing conduction disturbances
- Female gender, prior CABG, diabetes mellitus
- Amount of calcification of aortic valve
- Use of self-expanding valves
- Prosthesis implantation depth within the left ventricular outflow tract
- Balloon pre-dilatation or implantation of large prosthesis in small LVOT

- Fadahunsi OO et al., J Am Coll Cardiol Intv 2016;9:2189-99
- Siontis GC et al., JACC 2014;64:129-40

What is the relationship of LBBB and progression to high-degree AV block (HAVB)?

- Limited data on the association of new onset of LBBB with risk of AV block
- Approximately 13% of patients with new-onset LBBB developed HAVB in a study including 45% self-expandable valve recipients vs 8% with balloon-expandable valve required pacemaker
  
  Toggweiler et al. JACC Cardiovasc Interv 2016;9:1269-1276
  Nazif et al. EurHeart J 2014;35:1599-1607

- Univariate analysis LBBB associated with higher 30-day risk of PPM
- Limitation is focus on peri-procedural development of conduction disturbances
Conduction Disease Predictors

- Previous literature has shown a variety of factors influencing eventual pacemaker implantation
  1. Pre-procedurally
     ♦ RBBB
     ♦ LAFB
     ♦ Ejection Fraction
  2. Post-procedurally
     ♦ New LBBB
     ♦ High grade AV block

Specifics of TAVR and conduction disease

- TAVR patients have historically had greater comorbidities
- Mechanism of TAVR deployment may contribute to increased incidence of conduction disturbances
- Risk factors for PPM implant:
  1. Previous RBBB, Onset of LBBB, AV Block


Rates of PPM implantation appear higher with the CoreValve (self-expandable) as compared with the SAPIEN
CoreValve 19.2-42.5% vs SAPIEN 7-22%
Heart block after discharge with latest-generation TAVR valves

- Of 158 patients with SAPIEN 3 (103/65%) and Evolut-R (55/35%), there were 9 (8.7%) and 14 (25%) who required inpatient pacemaker implant
  1. Valve sizes ranged from 26-29 mm
- 4 patients re-presented with late HB following uncomplicated TAVR
  1. SAPIEN 3: n=3 (2.9%) and Evolut-R: n=1 (1.8%)
  2. All had unchanged periprocedural ECGs with normal QRS durations on discharge
  3. Average hospital duration was 48 h and mean time to readmission was 8-10 days.
     One died from intracranial hemorrhage as a result of syncope

Sandhu et al. JACC. 2018;71:577-86.

HV interval as predictor of heart block

- 75 patients were selected who were considered to have a prohibitively high risk of open heart surgery
- EP study performed before and after TAVR
- Baseline measurements (AH, HV, QRS, QT, and RR intervals)
- Primary outcome was AV block

Typical Baseline Tracings

• 5/6 patients with prior RBBB developed complete AV block, all within 24 hours of TAVR.
  1. All patients had PPM implantation and were PPM dependent after 1-2 years of follow-up.
• 7 patients had pre-existing LBBB
  1. One patient received prophylactic PPM for prolongation of the HV interval and became pacer-dependent.

Association with complete heart block

• Univariate analysis
  Presence of RBBB, new-onset LBBB, QRS duration after TAVR, delta-QRS duration, HV interval after TAVR, and delta-HV interval.

• Multivariate analysis
  The delta-HV interval was the only factor independently associated with complete AV block (HR 1.152 per ms; 95% CI 1.063-1.248; P=0.0006). Delta-QRS duration was predictive if you excluded the EP study pre-TAVR.

Take away points

- Optimal management of conduction issues, particularly new-onset LBBB post TAVR remains a clinical conundrum
- Results regarding progression to HAVB and PPM implantation are inconsistent
- Timing of progression is inconsistent
- TAVR population is expanding and newer valves still contribute to new LBBB
- There is variable clinical practice around the country
- High grade AV block can result in serious complications
- LBBB, (particularly if > 160 msec) is associated with higher mortality after TAVR
- Current studies may be underestimating pacemaker utilization

- Pacemaker implantation ≠ HAVB

- Developed a collaborative effort to manage patients in the post-operative period
- Assisted in development of a consistent plan to implant active fixation pacemaker wires for additional stability after TAVR
- Maintained uniformity in EP consultation to question of pacemaker implantation post TAVR
- Prophylactically implanted pacemaker in new LBBB patients

  It remains unknown whether the extent to which PPMs are being implanted post-TAVR in patients with left bundle branch block is necessary.
  We determined if QRS duration of 140 msec or greater, and particularly if left axis or concomitant AV delay, we would recommend pacemaker implantation.
1. Predictors of Conduction Disturbances and timing of occurrences
2. Outcomes in patients with advanced conduction disease and prophylactic PPM implant
3. Predictors of PPM Utilization (early and long term) or lack of utilization
4. Pacemaker data that may predict outcomes
   - Type
   - Programming
   - Arrhythmia detection

**Goals**

- Characterize the patient population that is at highest risk of requiring permanent pacing within one year after aortic valve procedures of the patients in the MHI TAVR database.
- Define predictors of high pacemaker utilization in follow-up
- Retrospectively validate criteria that would outline the guidelines for early pacemaker implantation post aortic valve procedures
**Pacemaker dependency**

- What constitutes being "dependent" on a pacemaker?
  - Ambiguous and variable definition in literature
  - >40% ventricular pacing may be clinically relevant but does not always constitute “complete” dependency
    - CRT programmed with goal to pace 100% of the time
    - Often ventricular pacing percentage may be sequelae of pacemaker programming
    - In patients who have significant ventricular pacing despite presence of underlying conduction, classified as “partial” dependency
    - Two patients with atrial fibrillation with slow ventricular rates

**Preliminary results and observations**

- Our study period involves patients who underwent TAVR between 2012 and 2017
- Protocol approved by IRB
- Patients underwent pacemaker implant within one month of the procedure and commonly prior to discharge
- Patients must have had at least one pacemaker interrogation or clinical visit in follow-up after discharge to assess device utilization
- Inclusion criteria
  - >18 years of age
  - Consented to release medical records
  - Pre and post TAVR EKGs and sufficient pacemaker interrogations performed for up to one year of follow-up
**Left bundle branch block and pacemaker dependency**

Three patients of 63 did not have adequate follow up and were excluded

- Six patients were dependent on pacemaker at median follow up of 386 days (220, 570 days)
- Two patients were completely dependent and 4 partially dependent.
- Five patients had mention of intra-op pauses or heart block with recovery to LBBB only (these patients were not ultimately dependent)
## Left bundle branch block dependent patients

<table>
<thead>
<tr>
<th>Patient #</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>85</td>
<td>80</td>
<td>85</td>
<td>85</td>
<td>69</td>
<td>80</td>
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<tr>
<td>Gender (M/F)</td>
<td>M</td>
<td>F</td>
<td>M</td>
<td>M</td>
<td>M</td>
<td>M</td>
</tr>
<tr>
<td>Diabetes</td>
<td>N</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
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<tr>
<td>Hypertension</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
</tr>
<tr>
<td>Hyperlipidemia/Dyslipidemia</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
</tr>
<tr>
<td>Chronic kidney disease (GFR &lt;60%)</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
</tr>
<tr>
<td>LV ejection fraction &gt; 50%</td>
<td>Y</td>
<td>N</td>
<td>Y</td>
<td>N</td>
<td>Y</td>
<td>N</td>
</tr>
<tr>
<td>History of CAD</td>
<td>Y</td>
<td>N</td>
<td>N</td>
<td>N</td>
<td>N</td>
<td>N</td>
</tr>
<tr>
<td>Prior CABG</td>
<td>N</td>
<td>N</td>
<td>N</td>
<td>N</td>
<td>N</td>
<td>N</td>
</tr>
<tr>
<td>History of AFib</td>
<td>N</td>
<td>N</td>
<td>N</td>
<td>N</td>
<td>N</td>
<td>N</td>
</tr>
<tr>
<td>Chronic lung disease</td>
<td>Y</td>
<td>N</td>
<td>N</td>
<td>N</td>
<td>N</td>
<td>N</td>
</tr>
<tr>
<td>History of aortic aneurysm repair</td>
<td>Y</td>
<td>N</td>
<td>N</td>
<td>N</td>
<td>N</td>
<td>N</td>
</tr>
<tr>
<td>History of stroke</td>
<td>Y</td>
<td>N</td>
<td>N</td>
<td>N</td>
<td>N</td>
<td>N</td>
</tr>
<tr>
<td>Chronic endocarditis</td>
<td>N</td>
<td>N</td>
<td>Y</td>
<td>N</td>
<td>N</td>
<td>N</td>
</tr>
<tr>
<td>Bicuspid AV</td>
<td>N</td>
<td>Y</td>
<td>Y</td>
<td>N</td>
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<tr>
<td>Accession 1st degree AVB</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>N</td>
<td>Y</td>
<td>Y</td>
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<tr>
<td>PM dependency</td>
<td>Partial</td>
<td>complete</td>
<td>Partial</td>
<td>partial</td>
<td>complete</td>
<td>Partial</td>
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<tr>
<td>TAVR to PM/implantation (days)</td>
<td>7.68</td>
<td>0.82</td>
<td>1.39</td>
<td>1.52</td>
<td>1.49</td>
<td>1.44</td>
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<td>Follow up duration (days)</td>
<td>325.00</td>
<td>930.00</td>
<td>700.00</td>
<td>692.00</td>
<td>488.00</td>
<td>393.00</td>
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<td>Patient on beta-blockers</td>
<td>Y</td>
<td>Y</td>
<td>N</td>
<td>Y</td>
<td>Y</td>
<td>N</td>
</tr>
<tr>
<td>TAVR valve</td>
<td>CoreValve 31</td>
<td>CoreValve 31</td>
<td>Sapient 329</td>
<td>CoreValve 31</td>
<td>Sapient 329</td>
<td>Sapient 329</td>
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<tr>
<td>Final depth numbers (mm)</td>
<td>N/A</td>
<td>N/A</td>
<td>6.75</td>
<td>N/A</td>
<td>4.5</td>
<td>4</td>
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<tr>
<td>Porcelain aorta</td>
<td>N</td>
<td>N</td>
<td>N</td>
<td>N</td>
<td>N</td>
<td>N</td>
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<tr>
<td>Membranous IV septum length (mm)</td>
<td>7.1</td>
<td>6.1</td>
<td>6.6</td>
<td>6.5</td>
<td>7.8</td>
<td>5</td>
</tr>
<tr>
<td>Calcification in the non-coronary cusp</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
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<tr>
<td>Calcification in the basal septum</td>
<td>N</td>
<td>N</td>
<td>N</td>
<td>N</td>
<td>N</td>
<td>N</td>
</tr>
<tr>
<td>Aortic endocarditis</td>
<td>N</td>
<td>N</td>
<td>N</td>
<td>N</td>
<td>N</td>
<td>N</td>
</tr>
<tr>
<td>Value in valve or 2values in the same session</td>
<td>N</td>
<td>N</td>
<td>N</td>
<td>N</td>
<td>N</td>
<td>N</td>
</tr>
<tr>
<td>Pacing percentage</td>
<td>16% dependent</td>
<td>AF slow RVR &lt;40%</td>
<td>AF slow RVR &gt;40%</td>
<td>completely dependent</td>
<td>AF slow RVR &lt;40%</td>
<td>completely dependent</td>
</tr>
</tbody>
</table>

### Table 1. Patients characteristics

<table>
<thead>
<tr>
<th>Patients with LBBB (n=65)</th>
<th>75.3 (7.8)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hypertension (n%)</td>
<td>51 (77.6)</td>
</tr>
<tr>
<td>Diabetes Mellitus (n%)</td>
<td>32 (48.5)</td>
</tr>
<tr>
<td>Diabetes Mellitus (n%)</td>
<td>54 (81.3)</td>
</tr>
<tr>
<td>Hypertension (n%)</td>
<td>55 (83.1)</td>
</tr>
<tr>
<td>History of AFib (n%)</td>
<td>55 (85.9)</td>
</tr>
<tr>
<td>History of CABG (n%)</td>
<td>55 (85.9)</td>
</tr>
<tr>
<td>History of stroke (n%)</td>
<td>16 (24.2)</td>
</tr>
<tr>
<td>Chronic lung disease (n%)</td>
<td>16 (24.2)</td>
</tr>
<tr>
<td>Calcification in the non-coronary cusp (n%)</td>
<td>16 (24.2)</td>
</tr>
<tr>
<td>Calcification in the basal septum (n%)</td>
<td>16 (24.2)</td>
</tr>
<tr>
<td>Aortic endocarditis (n%)</td>
<td>16 (24.2)</td>
</tr>
<tr>
<td>Value in valve or 2 values in the same session (n%)</td>
<td>16 (24.2)</td>
</tr>
<tr>
<td>Pacing percentage (n%)</td>
<td>16 (24.2)</td>
</tr>
<tr>
<td>STS Score</td>
<td>5.8 (5.2)</td>
</tr>
<tr>
<td>CMS duration after TAVR (days)</td>
<td>15.3 (15.2) (83 patients)</td>
</tr>
<tr>
<td>Baseline first degree AVB (n%)</td>
<td>22 (34.9)</td>
</tr>
<tr>
<td>LV ejection fraction &gt; 50% (n%)</td>
<td>3.85 (2.3)</td>
</tr>
</tbody>
</table>
Table 2: Procedural characteristics of patients with LBBB post TAVR

<table>
<thead>
<tr>
<th>Procedure Characteristic</th>
<th>Number of Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Transfemoral access</td>
<td>58 (87.9%)</td>
</tr>
<tr>
<td>Corevalve</td>
<td>20 (30.3%)</td>
</tr>
<tr>
<td>Corevalve 24</td>
<td>13 (19.7%)</td>
</tr>
<tr>
<td>Sapien and Sapien XT</td>
<td>4 (6%)</td>
</tr>
<tr>
<td>Sapien 3</td>
<td>27 (40.9%)</td>
</tr>
<tr>
<td>St Jude Portico</td>
<td>1 (1.5%)</td>
</tr>
<tr>
<td>Final valve depth (mm) (mean±SD) (n of available data)</td>
<td>5.5±1.9 (37)</td>
</tr>
<tr>
<td>Valve in valve procedure n (%)</td>
<td>6 (4.5%)</td>
</tr>
</tbody>
</table>

Table 3: Comparison between LBBB dependent and independent groups

<table>
<thead>
<tr>
<th>Variable</th>
<th>LBBB Dependent (n=6)</th>
<th>LBBB Not Dependent (n=37)</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>82.7±8.2</td>
<td>79.3±8.5</td>
<td>0.82</td>
</tr>
<tr>
<td>Male n (%)</td>
<td>5 (83.3%)</td>
<td>31 (83.8%)</td>
<td>0.10</td>
</tr>
<tr>
<td>BMI (kg/m²)</td>
<td>4.1±0.7</td>
<td>26.8±5.9</td>
<td>0.02</td>
</tr>
<tr>
<td>CHF n (%)</td>
<td>7 (116.7%)</td>
<td>36 (97.3%)</td>
<td>0.96</td>
</tr>
<tr>
<td>Hypertension (%)</td>
<td>5 (83.3%)</td>
<td>46 (97.3%)</td>
<td>0.87</td>
</tr>
<tr>
<td>History of CAD (%)</td>
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<td>8 (22%)</td>
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<tr>
<td>Prior CABG (%)</td>
<td>2 (33.3%)</td>
<td>19 (51.4%)</td>
<td>0.91</td>
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<td>Diabetes (%)</td>
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Pacer dependent patients (excluding atrial fibrillation with slow ventricular response)

- **Patient #1 (Partial)**
  16% V pacing 1\textsuperscript{st} degree AV block and LAFB prior to TAVR, LBBB with left axis post, QRS duration 148 msec, asystolic cardiac arrest 4 days after TAVR, TAO 31 Core Valve

- **Patient #2 (Partial)**
  >40% V pacing with intact conduction at times, no pre-existing conduction disease, left axis and 1\textsuperscript{st} degree post, QRS 178 msec, transfemoral S3

- **Patient #3 (Dependent)**
  No pre-existing conduction disease, QRS duration 126 msec, normal PR, pacemaker-dependent within one month, TAO Core Valve 29

- **Patient #4 (Dependent)**
  Pre-existing 1\textsuperscript{st}-degree AV block, QRS duration 160 msec with 1\textsuperscript{st} degree AV block, intermittent heart block post pacemaker, transfemoral S3

Patients were followed up to identify recovery of LBBB. After exclusion of patients without adequate EKG follow up, 12 patients were identified to have recovery of LBBB. Median time to recovery was 5 weeks (IQR 4, 9 weeks).

- All patients who recovered their LBBB were not pacemaker-dependent at follow-up.
- Trend toward final valve depth being smaller in patients with recover
Left bundle branch block mortality

- At median follow up of 386 days (IQR: 220, 570 days), 11 patients died (17.5%).

- One patient died in the pacemaker dependent group (16.7%), and 9 patients died in the pacemaker-independent group (14.3%).

- The group who had recovery of LBBB had 8.3% mortality (n=1) compared with 15.4% (n=6) in the group who had no recovery of the LBBB.

- Very few pacemaker related complications (none at our institution).

A propensity-score 1:1 pair match was conducted to create 2 matched cohorts of the recovery and the non-recovery groups using age, gender, STS scores, and LVEF as matching variables.

Kaplan-Meier method was used to calculate cumulative mortality proportions and outcome differences were assessed with log-rank test.

No significant difference in mortality between the 2 groups (8.3% vs 16.7%), p=0.65.
**Limitations**

- Retrospective analysis with limited sample size
- Variable length of follow-up
  ECG and pacemaker interrogations are performed at different times in follow-up
- Difficult to retrospectively define clinically relevant pacing or pacer dependency
  Analyzing data to say for sure <1%, 1% or <5% ventricular pacing
  Pacemaker choice and programming can predispose to higher burden of ventricular pacing
  Difficult to ascertain whether biventricular pacemaker patients are dependent
  Most likely identified the minimal number of patients who require clinically significant pacing

**Proposed protocol**

**Shared decision making**

- Wait for symptoms
- New LBBB post TAVR QRS 120-160
- 2-4 week wearable external monitor
- Implantable cardiac monitor
- EPS Measure HV interval
- Prophylactic Pacemaker >160 msec or 1st degree AV block or left axis
- CRT-P if EF<50%
- CRT-D if EF<35%
Proposed treatment strategy

- What is the threshold for pacemaker utilization on a population level to justify prophylactic pacing?
- Assess for pre-existing conduction disease (pre-existing AV delay, RBBB, fascicular block)
- Assess for electrical and mechanical predictors of conduction disease
- Document intra-procedural conduction issues
- Assess in post-procedure period for conduction delay
- Optimal timing for monitoring in post TAVR period
- Implant for wider QRS (e.g., 160 msec) and with associated conduction abnormalities (new AV delay or left axis)

Pacemaker utilization

- Sensing
  1. Pacemakers sense and record burden of atrial and ventricular tachyarrhythmias
  2. Subclinical and asymptomatic Atrial fibrillation/Atrial flutter was often diagnosed for the first time via pacemaker interrogation
     - Different from post-operative atrial fibrillation
     - May be associated with increased stroke risk given high-risk population with valvular heart disease, advanced age, and comorbidities
Of 172 patients with pacemakers, 77 had pre-existing AF/AFl. Of the remaining 95, 24 (25.2%) had clinically documented AF/AFl.

Incidence of stroke was higher in new-onset AF/AFl compared to patients who remained in NSR (12.5% vs 1.4% p=0.019).

Thank you

• Dr. Gornick, Dr. Almquist and entire Electrophysiology Section
• Mario Gössl MD and Structural Heart/Valve Science Team
• Michael Megaly
• Ross Garberich, Larissa Stanberry
• Minneapolis Heart Institute Foundation and Summer Intern Program
  John Henstrom, Lucille Anzia, Pamela Morley