## Can We Prevent Conduction Disturbances?

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## Real dimension of the problem.....

Up to 50% of TAVR patients develop conduction disturbances

✓ Complete AV block (4-11 % Edwards, 15-38% CoreValve )

✓ Left Bundle Branch Block LBBB ( about 1/3 )

 $\checkmark$  AV conduction disturbances (Variable percentage)







Permanent Pacemaker Insertion After CoreValve Transcatheter Aortic Valve Implantation : Incidence and Contributing Factors (the UK CoreValve Collaborative) M.Z. Khawaja, R. Rajani, A. Cook, A. Khavandi, A. Moynagh, S. Chowdhary, M.S. Spence, S. Brown, S.O. Khan, N. Walker, U. Trivedi, N. Hutchinson, A.J. De Belder, N. Moat, D.J. Blackman, R.D. Levy, G. Manoharan, D. Roberts, S.S. Khogali, P. Crean, S.J. Brecker, A. Baumbach, M. Mullen, J.-C. Laborde and D. Hildick-Smith



- $\checkmark$  270 patients from 10 clinical centers in UK
- ✓ 8% of patients with prior PPM
- ✓ LBBB 13% at baseline → 61% after procedure
- ✓ 33.3% new permanent pacemaker requirement
- ✓ Baseline conduction abnormalities
  - Baseline RBBB 🛛 📂 65.2% PPM
  - Baseline LBBB → 43.75% PPM
  - Normal QRS complex 
    27.6% PPM
- Multivariable predictors: AV block, balloon predilation, use of 29 mm valve, IV septum diameter, prolonged QRS







### Relation Between Prosthesis and Conduction System





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Khawaja M.Z. et al. Circulation 2011



### Left Bundle-Branch Block Induced by TAVI Increases Risk of Death





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### **Binary Logistic Regression Analysis**

|                                       | Univariate Analysis |            |         | Multivariate Analysis |            |         |
|---------------------------------------|---------------------|------------|---------|-----------------------|------------|---------|
| Variable                              | HR                  | CI         | P Value | HR                    | CI         | P Value |
| Age                                   | 0.87                | 0.98-1.03  | 0.87    |                       |            |         |
| Female sex                            | 0.84                | 0.61-1.16  | 0.30    |                       |            |         |
| Baseline creatinine                   | 0.85                | 0.68-1.05  | 0.14    | 0.83                  | 0.66-1.05  | 0.12    |
| Previous MI                           | 0.71                | 0.47-1.09  | 0.12    | 0.78                  | 0.49-1.24  | 0.29    |
| Previous CABG                         | 0.80                | 0.55-1.16  | 0.24    |                       |            |         |
| Cerebrovascular disease               | 1.18                | 0.79-1.78  | 0.42    |                       |            |         |
| Peripheral vascular disease           | 0.74                | 0.49-1.11  | 0.14    | 1.57                  | 0.97-2.55  | 0.07    |
| Diabetes mellitus                     | 1.48                | 1.03-2.13  | 0.04    | 1.52                  | 1.01-2.29  | 0.04    |
| COPD                                  | 0.96                | 0.67-1.38  | 0.84    |                       |            |         |
| LVEF $\leq$ 50%                       | 1.10                | 0.77-1.56  | 0.60    |                       |            |         |
| R(aVL) >11 mm                         | 0.87                | 0.56-1.36  | 0.55    |                       |            |         |
| $S(V_1) + R(V_{5/6}) > 35 \text{ mm}$ | 1.01                | 0.97-1.04  | 0.72    |                       |            |         |
| Absent Q in $V_6$                     | 1.05                | 0.72-1.54  | 0.79    |                       |            |         |
| MCS prosthesis*                       | 7.69                | 5.13-11.54 | < 0.001 | 8.51                  | 5.53-13.11 | < 0.001 |

TAVI indicates transcatheter aortic valve implantation; HR, hazard ratio; CI, 95% confidence interval; MI, myocardial infarction; CABG, coronary artery bypass grafting; COPD, chronic obstructive pulmonary disease; LVEF, left ventricular ejection fraction; and MCS, Medtronic CoreValve System.

\*For calculation of the HR, the MCS prosthesis was compared to the Edwards SAPIEN prosthesis.



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### Survival for the primary end point





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### Incidence of TAVI-induced LBBB according to valve type



Consecutive case number



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### Conclusion

### Left Bundle Branch Block (LBBB) Induced by TAVI Increases Risk of Death

Registry study of 679 pts receiving either CoreValve or Sapien at 8 Dutch centers.

- About one-third (n = 233) of pts experienced new LBBB within 7 days of implantation
- At 450-day follow-up, all-cause mortality higher in patients with LBBB vs. without (37.8% vs. 24.0%; P = 0.002)
- New LBBB more common in CoreValve- vs. Sapien-treated patients (51.1% vs. 12.0%; P < 0.001)</li>

Implications: LBBB is a serious complication of TAVR that may strongly attenuate the survival benefit of this procedure.



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### Predictive Factors and Long-Term Clinical Consequences of Persistent LBBB Following TAVI With a Balloon-Expandable Valve

✓ 348 consecutive patients underwent TAVI with a balloon-expandable valve (Sapien or Sapien XT, Edwards Lifesciences, Irvine LLC, California)

### ✓ 146 patients were excluded

- $\checkmark$  prior pacemaker (n = 57)
- ✓ prior intra-ventricular conduction abnormalities (complete or incomplete right or left bundle branch block, n = 83)
- death, or conversion to open heart surgery before the first ECG (4 and 2 patients, respectively)

### ✓ The final study population consisted of 202 patients



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### Baseline and Procedural Findings, According to the Occurrence of New-Onset LBBB Following TAVI

|   | No LBBB<br>(n = 141)              | Transient LBBB<br>(n = 23)        | Persistent LBBB<br>(n = 38)       | p Value* |
|---|-----------------------------------|-----------------------------------|-----------------------------------|----------|
| Baseline characteristics                    |                                   |                                   |                                   |          |
| Age (yrs)                                   | $81\pm8$                          | $79\pm 6$                         | $77 \pm 9 \dagger$                | 0.019    |
| Female                                      | 83 (58.9)                         | 17 (73.9)                         | 21 (55.3)                         | 0.328    |
| Body mass index (kg/m <sup>2</sup> )        | $26\pm5$                          | $26\pm5$                          | $28\pm6$                          | 0.125    |
| Comorbidities                               |                                   |                                   |                                   |          |
| Hypertension                                | 119 (84.4)                        | 22 (95.7)                         | 37 (97.4)                         | 0.041    |
| Diabetes mellitus                           | 44 (31.2)                         | 8 (34.8)                          | 15 (39.5)                         | 0.615    |
| COPD  | 35 (24.8)                         | 3 (13.0)                          | 12 (31.6)                         | 0.261    |
| CAD   | 79 (56.0)                         | 17 (73.9)                         | 22 (57.9)                         | 0.277    |
| eGFR (ml/min)                               | $56.6 \pm 22.5$                   | $54.6 \pm 20.4$                   | $59.1 \pm 26.3$                   | 0.742    |
| Baseline treatment                          |                                   |                                   |                                   |          |
| Beta-blockers                               | 64 (45.4)                         | 14 (60.9)                         | 16 (42.1)                         | 0.332    |
| Calcium channel blockers                    | 38 (27.0)                         | 8 (34.8)                          | 12 (31.6)                         | 0.648    |
| Amiodarone                                  | 8 (5.7)                           | 2 (8.7)                           | 3 (7.9)                           | 0.729    |
| STS-PROM score (%)                          | $7.6 \pm 3.8$                     | $6.1\pm3.7$                       | $7.4 \pm 3.4$                     | 0.476    |
| ECG (ms)                                    |                                   |                                   |                                   |          |
| PR interval                                 | $176 \pm 36$                      | $158 \pm 23$                      | $174 \pm 45$                      | 0.114    |
| QRS duration                                | $90 \pm 10$                       | $92 \pm 9$                        | $96\pm10$ †                       | 0.033    |
| Echocardiography                            |                                   |                                   |                                   |          |
| LVEF (%)                                    | $57 \pm 12$                       | $54 \pm 15$                       | $58 \pm 11$                       | 0.440    |
| Mean gradient (mm Hg)                       | $46 \pm 17$                       | $47 \pm 19$                       | $49 \pm 19$                       | 0.696    |
| Aortic valve area (cm <sup>2</sup> )        | $\textbf{0.65} \pm \textbf{0.22}$ | $\textbf{0.63} \pm \textbf{0.28}$ | $\textbf{0.61} \pm \textbf{0.17}$ | 0.547    |
| Computed tomography                         |                                   |                                   |                                   |          |
| Aortic valve calcification (Agatston units) | 2,544 (1,600-4,442)               | 2,045 (1,666-4,209)               | 3,150 (1,944-5,358)               | 0.412    |
| Procedural variables                        |                                   |                                   |                                   |          |
| Approach                                    |                                   |                                   |                                   | 0.335    |
| Transapical                                 | 79 (56.0)                         | 12 (52.2)                         | 26 (68.4)                         |          |
| Transfemoral                                | 62 (44.0)                         | 11 (47.8)                         | 12 (31.6)                         |          |
| Ratio aortic prosthesis size/aortic annulus | $\textbf{1.16} \pm \textbf{0.07}$ | $\textbf{1.18} \pm \textbf{0.09}$ | $\textbf{1.18} \pm \textbf{0.07}$ | 0.097    |
| Prosthesis ventricular depth‡ (mm)          | $\textbf{1.64} \pm \textbf{2.85}$ | $\textbf{1.22} \pm \textbf{2.23}$ | $3.04 \pm 1.72$ †§                | 0.028    |



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### Baseline and Procedural Findings, According to the Need for PPI (In-Hospital or During the Follow-Up Period)

|   | PPI (Cumulative)<br>(n = 20)        | No PPI<br>(n = 182)                 | HR (95% CI)       | p Value |
|---|-------------------------------------|-------------------------------------|-------------------|---------|
| Clinical characteristics                    |                                     |                                     |                   |         |
| Age (yrs)                                   | $81\pm6$                            | $80 \pm 8$                          | 1.02 (0.96-1.09)  | 0.454   |
| Female                                      | 12 (60.0)                           | 109 (59.9)                          | 0.90 (0.37-2.22)  | 0.803   |
| Body mass index (kg/m <sup>2</sup> )        | $27\pm6$                            | $27\pm5$                            | 1.01 (0.92-1.11)  | 0.762   |
| Comorbidities                               |                                     |                                     |                   |         |
| Hypertension                                | 17 (85.0)                           | 161 (88.5)                          | 0.59 (0.17-2.04)  | 0.406   |
| Diabetes mellitus                           | 6 (30.0)                            | 61 (33.5)                           | 0.96 (0.37-2.51)  | 0.938   |
| COPD  | 5 (25.0)                            | 45 (24.7)                           | 1.16 (0.42-3.22)  | 0.778   |
| CAD   | 11 (55.0)                           | 107 (58.8)                          | 0.95 (0.39-2.30)  | 0.903   |
| eGFR (ml/min)                               | $\textbf{51.9} \pm \textbf{20.6}$   | $\textbf{57.3} \pm \textbf{23.2}$   | 0.99 (0.97-1.01)  | 0.343   |
| Baseline treatment                          |                                     |                                     |                   |         |
| Beta-blockers                               | 8 (40.0)                            | 86 (47.3)                           | 0.70 (0.28-1.72)  | 0.434   |
| Calcium channel blockers                    | 8 (40.0)                            | 50 (27.5)                           | 1.64 (0.67-4.01)  | 0.281   |
| Amiodarone                                  | 2 (10.0)                            | 11 (6.0)                            | 1.80 (0.41-7.81)  | 0.433   |
| STS-PROM score                              | $\textbf{6.9} \pm \textbf{2.8}$     | $7.6 \pm 3.8$                       | 0.94 (0.79-1.11)  | 0.457   |
| ECG (ms)                                    |                                     |                                     |                   |         |
| PR interval                                 | $191 \pm 59$                        | $\textbf{172} \pm \textbf{35}$      | 1.01 (0.99-1.02)  | 0.354   |
| QRS duration                                | $94 \pm 10$                         | $92 \pm 10$                         | 1.02 (0.97-1.07)  | 0.500   |
| Echocardiography                            |                                     |                                     |                   |         |
| LVEF (%)                                    | $62 \pm 8$                          | $57 \pm 12$                         | 1.03 (0.99-1.08)  | 0.137   |
| Mean gradient (mm Hg)                       | $44 \pm 21$                         | $47 \pm 17$                         | 0.99 (0.97-1.02)  | 0.491   |
| Aortic valve area (cm <sup>2</sup> )        | $\textbf{0.61} \pm \textbf{0.19}$   | $\textbf{0.64} \pm \textbf{0.22}$   | 0.50 (0.40-6.26)  | 0.591   |
| Computed tomography                         |                                     |                                     |                   |         |
| Aortic valve calcification (Agatston units) | $\textbf{3,362} \pm \textbf{2,345}$ | $\textbf{3,209} \pm \textbf{2,104}$ | —                 | 0.854   |
| Procedural variables                        |                                     |                                     |                   |         |
| Approach                                    |                                     |                                     | 1.66 (0.63-4.33)  | 0.303   |
| Transapical                                 | 14 (70.0)                           | 103 (56.6)                          | —                 | _       |
| Transfemoral                                | 6 (30.0)                            | 79 (43.4)                           | —                 | —       |
| Ratio prosthesis/aortic annulus             | $\textbf{1.17} \pm \textbf{0.09}$   | $\textbf{1.16} \pm \textbf{0.07}$   | —                 | 0.407   |
| Ventricular depth of prosthesis* (mm)       | $\textbf{3.19} \pm \textbf{1.65}$   | $\textbf{1.71} \pm \textbf{2.68}$   | 1.27 (0.96-1.68)  | 0.100   |
| Residual AR ≥2                              | 1 (5.0)                             | 27 (14.8)                           | 1.02 (0.79-1.31)  | 0.977   |
| New-onset LBBB                              | 14 (70.0)                           | 47 (25.8)                           | 5.99 (2.29-15.61) | <0.001  |



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### Changes in Left Ventricular Ejection Fraction Following TAVI





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### Other Studies about LBBB and Mortality



De Carlo, et al. American Heart Journal . 2012 Urena et al. Journal of the American College of Cardiology . 2012







### CoreValve ADVANCE 30-day Outcomes

| Additional VARC Endpoints N=996       | Kaplan-Meier Estimates, % |  |  |
|---------------------------------------|---------------------------|--|--|
| Cardiovascular Mortality              | 3.4                       |  |  |
| Major Bleeding                        | 9.7                       |  |  |
| Life Threatening Bleeding             | 4.0                       |  |  |
| Major Vascular Complications          | 10.7                      |  |  |
| Acute Kidney Injury – Stages I/II/III | 5.7                       |  |  |
| Acute Kidney Injury – Stage III only  | 0.4                       |  |  |
| New Pacemaker Implantation            | 26.3                      |  |  |
| AccuTrak Delivery System              | 24.2                      |  |  |
| Pre-AccuTrak Delivery System          | 34.1                      |  |  |







# CoreValve ADVANCE Impact of LBBB

No Impact of new LBBB (v. no new LBBB) on late term mortality in those patients not receiving a PPM after CoreValve implantation





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## **Optimal MSCT Sizing**



Elliptical Shape: Max dia. 28,5 mm; Min dia. 20 mm Area 4,71 cm<sup>2</sup>, Perimeter 7,9 cm









## Sizing CoreValve Revalving System

|  |                           | 23mm   | <b>26mm</b> | <b>29mm</b> | 31mm   |
|--|---------------------------|--------|-------------|-------------|--------|
|  | Annulus<br>Diameter [mm]  | D≥18   | D≥20        | D≥23        | D≥26   |
|  |                           | D≤20   | D≤23        | D≤27        | D≤29   |
|  | Annulus Area<br>[cm2]     | A≥2,54 | A≥3,14      | A≥4,15      | A≥5,31 |
|  |                           | A≤3,14 | A≤4,15      | A≤5,72      | A≤6,60 |
|  | Annulu<br>Perimeters [cm] | P≥5,65 | P≥6,28      | P≥7,22      | P≥8,16 |
|  |                           | P≤6,28 | P≤7,22      | P≤8,48      | P≤9,11 |







## Sizing Edwards Sapien XT

### **Edwards Sapien XT Valve Sizes**



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## Area (cm<sup>2</sup>) Oversizing



 $(5,72 - 4,71) / 4,71 \times 100 = 21,5 \%$ 

# Avoid area oversizing > 20 %



 $(5,31-4,71)/4,71 \times 100 = 12,7 \%$ 







#### Early and Persistent Intraventricular Conduction Abnormalities and Requirements for Pacemaking After Percutaneous Replacement of the Aortic Valve

Nicolo Piazza, MD,\* Yoshinobu Onuma, MD,\* Emile Jesserun, MD,\* Peter Paul Kint, RN,† Anne-Marie Maugenest, RN,\* Robert H. Anderson, MD, FRCPATH,‡ Peter P. Th de Jaegere, MD, PHD,\* Patrick W. Serruys, MD, PHD\*

## Relation between deep of implantation and conduction abnormalities

### ✓ New LBBB 10,3 mm ± 2,7 mm











### Rate of PPM implantion Vs Depth of implantion











### **Optimal Depth of CoreValve Implantion**





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## LVOT Calcification and Conduction Distrurbances are Directly Related

None



Mild



Moderate



Severe









### BAV as Bridge to TAVI or BAV during TAVI

- ✓ Avoid long Balloon ( >40 mm)
- Use smallest balloon as possible (already 18 mm balloon have 2,5 cm<sup>2</sup> area during inflation)
- Always use rapid pacing during BAV (>180) in order to stabilize balloon and avoid excessive stress on membranous septum
- $\checkmark$  Avoid extended and repeated inflations









### Conclusion

- Conduction disturbances are very frequent in TAVI patients, mainly AV block and LBBB
- ✓ The anatomical relation between conduction system, implant site and depth are the explanation of the problem
- ✓ The CT scan is mandatory to perform precise measurements and avoid area oversizing > 20%
- ✓ The presence of massive LVOT calcification can play an important role in conduction system damage during TAVI and BAV
- $\checkmark$  During BAV avoid using long and large balloons
- ✓ Always perform BAV during rapid ventricular pacing
- ✓ Avoid prolonged and repeated BAV





