

Incidence and Predictors of Permanent Pacemaker Requirement after Transcatheter Aortic Valve Implantation with a Self-Expanding Bioprosthesis

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Background: Previous reports have suggested the occurrence of cardiac conduction disorders and permanent pacemaker (PPM) requirement after transcatheter aortic valve implantation (TAVI). Based on a single-center experience, we aim to assess the incidence of postprocedural conduction disorders, need for PPM, and its determinants after TAVI with a self-expanding bioprosthesis.

Methods: From August 2007 to October 2009, 32 consecutive patients underwent TAVI with the Medtronic CoreValve (MCV) System (Medtronic Inc., Minneapolis, MN, USA). Three patients paced at baseline and two cases of procedure-related mortality were excluded. We analyzed the 12-lead electrocardiogram at baseline, immediately after procedure and at discharge. Requirements for PPM were documented and potential clinical, electrophysiological, echocardiographic, and procedural predictors of PPM requirement were studied.

Results: After TAVI, eight patients (29.6%) required PPM implantation due to high-grade atrioventricular (AV) block. The prevalence of left bundle branch block increased from 13.8% to 57.7% directly after implantation ($P = 0.001$). Need for PPM was correlated to the depth of prosthesis implantation ($r = 0.590$; $P = 0.001$). At a cutoff point of 10.1 mm, the likelihood of pacemaker could be predicted with 87.5% sensitivity and 74% specificity and a receiver operator characteristic curve area of 0.86 ± 0.07 ($P = 0.003$). Of the seven patients with preexisting right bundle branch block (RBBB), four (57.1%) required PPM implantation after TAVI.

Conclusions: High-grade AV block requiring PPM implantation is a common complication following TAVI and could be predicted by a deeper implantation of the prosthesis. Patients with preexisting RBBB also seem to be at risk for the development of high-grade AV block and subsequent pacemaker implantation. (PACE 2010; 33:1364–1372)

aortic stenosis, transcatheter aortic valve implantation, permanent pacemaker

Introduction

Calcific aortic valve disease is commonly associated with conduction system disease leading to conduction abnormalities, including higher degrees of atrioventricular (AV) block.^{1,2} Furthermore, the anatomical proximity to the aortic valve renders the conduction system susceptible to trauma and ischemia during surgical aortic valve replacement (AVR), leading to the development

of further conduction disorders. The reported incidence of conduction abnormalities after AVR requiring a permanent pacemaker (PPM) implantation ranges from 3.2% to 8.5% of cases.^{3–7} New-onset left bundle branch block (LBBB) after AVR is even more common with an incidence reported to be as high as 16%.⁸ Development of intraventricular conduction abnormalities after AVR is associated with an increased risk of adverse events at long term, namely, complete AV block, syncope, and sudden death.^{8,9}

Transcatheter aortic valve implantation (TAVI) is a recently developed technique for patients with symptomatic aortic stenosis (AS) deemed inoperable or at too high risk for AVR.¹⁰ Since the first-in-man implantation of a percutaneous aortic valve prosthesis in 2002,¹¹ and after important improvements in technique and devices, more than 5,000 TAVI procedures were performed worldwide.¹² In contrast to AVR, TAVI involves the exclusion of the valve tissue

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by a prosthetic stent, with inevitable compression of the annulus and surrounding structures, including the fibrous skeleton of the heart and conduction system. Safety and feasibility reports have raised the concern about a nonnegligible frequency of conduction abnormalities and PPM requirements after TAVI.^{13–15}

In this retrospective study, we aim to assess the incidence of postprocedural conduction abnormalities and the need for a PPM in patients undergoing TAVI using the Medtronic CoreValve (MCV) System (Medtronic, Minneapolis, MN, USA). Additionally, we aim to identify possible predictive factors of PPM requirement in order to obtain an insight into underlying mechanisms of conduction impairment in these patients.

Methods

Patient Selection

Between August 2007 and October 2009, 32 selected patients with symptomatic severe AS were treated with the third generation 18-Fr MCV at Centro Hospitalar de Vila Nova de Gaia/Espinho, Vila Nova de Gaia, Portugal. Inclusion criteria were in accordance with the published investigational study for the third generation CoreValve device.¹⁶ Selection for the procedure required that each of the following clinical or anatomic criteria should be met: (1) native aortic valve stenosis with an aortic valve area < 1 cm² by echocardiographic measure; (2) aortic valve annulus diameter ≥ 20 mm and ≤ 27 mm; (3) sinotubular junction diameter ≤ 43 mm; (4) high-surgical risk or inoperability assessed and agreed to by both a cardiologist and cardiovascular surgeon. Patients referred to our institution for TAVI were screened for feasibility of the procedure. This morphological screening process included transthoracic (TTE) and transesophageal echocardiography (TEE), coronary angiography, aortic and iliofemoral angiography, or computed tomography (CT) scan. The logistic euroSCORE was used to estimate baseline surgical operative risk.¹⁷

Device Description and Procedure

MCV consists of a trileaflet bioprosthetic porcine pericardial tissue valve that is mounted and sutured in a self-expanding nitinol trilevel frame. MCV is currently available in sizes of 26 and 29 mm, both inserted in an 18-Fr sheath. Selection of the prosthesis size is based on measurements of the aortic valvar complex obtained by TEE, angiography, or multislice CT.

The transfemoral approach was used as the default access site. The minimum acceptable

vessel size was 6 mm. When the iliofemoral vessels were inaccessible (vessel size, calcification, tortuosity, atherosclerosis), the subclavian approach was selected using surgical cut-down. At the start of the procedure, a temporary transvenous right ventricular lead was inserted through jugular or femoral access in all cases. Balloon valvotomy was required before implantation. Prosthesis deployment and positioning was performed under fluoroscopic and angiographic guidance. Burst rapid pacing at 150–220 beat/min was used to reduce cardiac motion and transvalvular flow during balloon dilatation.

Recording of ECG and Pacemaking Data

Nonpaced 12-lead electrocardiogram (ECG) was assessed at baseline (24 hours before TAVI), immediately postprocedure (within 6 hours after TAVI), and at discharge. Data collected included heart rate, presence of atrial fibrillation (AF), PR interval, QRS duration, QRS axis (in degrees), and presence of LBBB or right bundle branch block (RBBB). Diagnostic criteria recommended by the World Health Organization and International Society and Federation for Cardiology Task Force were used to diagnose LBBB and RBBB.¹⁸ Temporal changes in electrocardiographic parameters of conduction from the baseline were analyzed.

The temporary transvenous pacemaker was maintained in place for at least 48 hours and removed in the absence of high-grade AV block or symptomatic bradycardia. Patients were monitored for further arrhythmia with telemetry until discharge. Need for PPM was reported, as well as the indication that prompted PPM implantation and the day post-TAVI when indication became apparent. In patients who required PPM, the frequency of ventricular pacing (V pacing) was registered at the first pacemaker follow-up visit.

Echocardiographic Measurements and Postimplantation Anatomy

TTE and TEE were performed as part of the screening process in order to assess anatomical criteria for feasibility of the procedure and to select prosthesis size. TTE was repeated before discharge. Variables recorded as potential predictors of pacing requirement were baseline left ventricular outflow tract (LVOT), aortic annulus and aortic root diameters from mid-esophageal aortic valve long-axis view (TEE) (Fig. 1), as well as biplane ejection fraction (EF) and end-diastolic interventricular septal dimensions (IVSd) on parasternal long-axis (TTE).

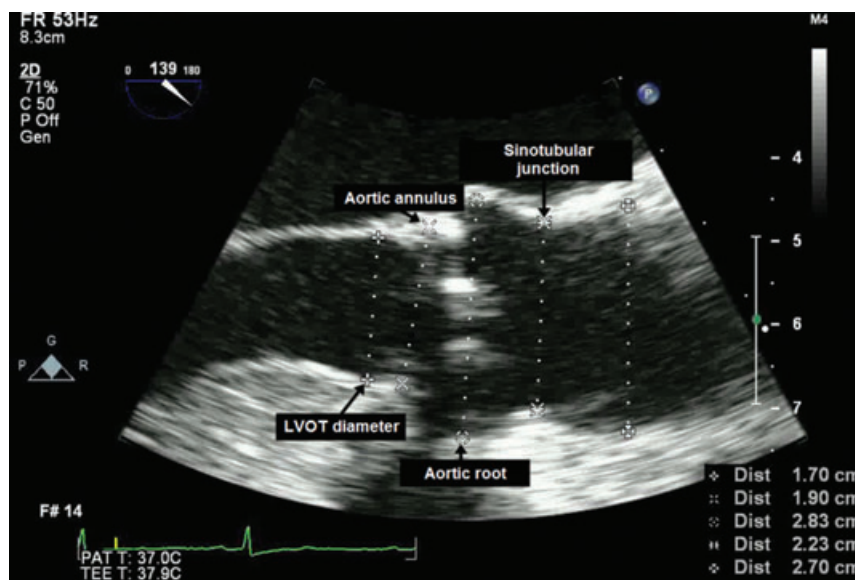


Figure 1. Echocardiographic measurements of the aortic valvar complex. Transesophageal echocardiography mid-esophageal long-axis view showing the measurements of the LVOT, aortic annulus, aortic root, and sinotubular junction.

Variables reflecting postimplantation anatomy of the aortic valve and LVOT were also studied as predictors of PPM requirement, including prosthesis size-aortic annulus ratio, post-TAVI qualitative aortic regurgitation (AR)

grade, and prosthesis depth in the LVOT, defined as the distance between the annular margin of noncoronary cusp and the proximal (or ventricular) end of the prosthesis frame. Depth of prosthesis implantation was assessed with quantitative angiography using the Axiom Artis software (Siemens Medical Systems, Erlangen, Germany) (Fig. 2). As a measure of ischemia and direct myocardial injury, postprocedural peak troponin I level was also recorded.

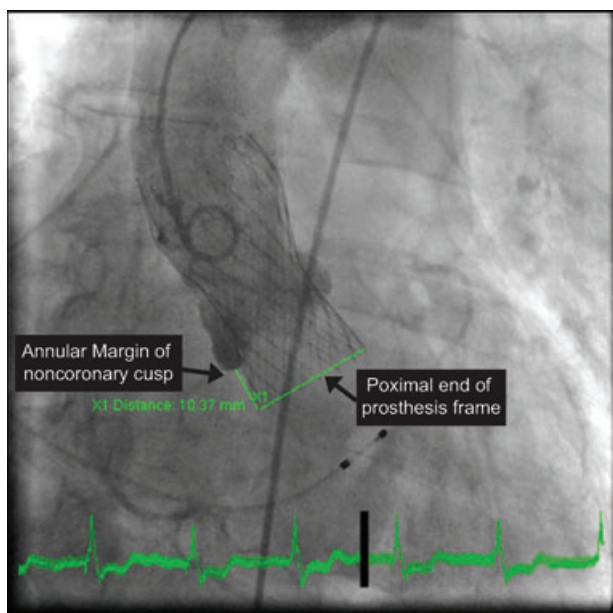


Figure 2. Quantitative angiographic measurement. This is an example of the measurement of the distance from the annular margin of the noncoronary cusp to the ventricular end of the frame of the bioprosthesis.

Statistical Analysis

Statistical analysis was performed using the Statistical Package for Social Sciences Software for Windows Version 17.0 (SPSS Inc., Chicago, IL, USA). Categorical variables are presented as frequencies and percentages. Continuous variables are presented as mean \pm standard deviation (SD) if normally distributed or as median (interquartile range [IQR]) if nonnormally distributed. Changes in ECG parameters of cardiac conduction from the baseline were assessed using a paired-sample *t*-test for normally distributed data, or Wilcoxon signed-rank 2-related-samples analysis for other distributions. Baseline clinical, ECG, and echocardiographic, as well as procedural, variables were compared between two groups, with or without PPM requirement, using Student's *t*-test or Mann-Whitney test (for continuous variables), and Fisher exact χ^2 test (for categorical variables). Variables were also studied as bivariate correlations to the endpoint of PPM requirement using Pearson

bivariate analysis. Any value of $P < 0.05$ was considered to be statistically significant.

Results

Baseline Demographic and Clinical Characteristics

Between August 2007 and October 2009, 32 patients (21 females; median age 80.5 years [IQR 75.5–84.75]) underwent TAVI with the self-expanding bioprosthesis MCV at our institution. All patients had symptomatic severe AS with a peak transvalvular aortic pressure gradient of 84.0 ± 20.9 mmHg. The preprocedural mean calculated aortic valve area was 0.55 ± 0.11 cm². The median calculated logistic EuroSCORE was 24.2% (IQR 16.9–31.0%) and 81.3% of patients were in New York Heart Association (NYHA) functional class III or IV. Other baseline patient characteristics are summarized in Table I.

Procedural and Acute Hemodynamic Results

Acute device success was achieved in all cases. We observed significant periprocedural reductions in the peak (84.0 ± 20.9 mmHg to 19.8 ± 10.3 mmHg; $P < 0.001$) and mean (50.7 ± 13.3 mmHg to 10.0 ± 5.1 mmHg; $P < 0.001$) transvalvular pressure gradients, as well as an improvement in biplane EF ($50.2 \pm 11.6\%$ to $53.8 \pm 8.8\%$; $P = 0.019$).

There were two procedure-related deaths (6.25%), one of them secondary to cardiogenic shock, and the other secondary to access-related bleeding and hemorrhagic shock. The patient dying from cardiogenic shock did not develop AV block immediately after TAVI.

In those surviving to hospital discharge, the mean postprocedural time of hospitalization was 8.3 ± 4.7 days. The postprocedural course of hospitalization was not significantly longer in those requiring PPM (7.6 ± 3.7 days in those not requiring PPM vs 10.0 ± 6.6 days in those requiring PPM; $P = 0.226$).

Evolution of Electrocardiographic Conduction Parameters

The baseline electrocardiographic conduction parameters of the 29 patients without PPM and the postprocedural changes in cardiac conduction are shown in Table II.

We did not observe significant changes in the prevalence of AF between the baseline, postprocedural, and discharge ECG. In patients in sinus rhythm, the PR interval did not statistically significantly increase after TAVI.

The QRS axis decreased from 16 ± 43 degrees at baseline to -9 ± 46 degrees immediately after TAVI ($P = 0.003$). Accordingly, the proportion of

Table I.

Baseline Characteristics of Study Population (n = 32)

Patient Characteristics	n = 32
Age, years, median (IQR)	80.5 (75.5–84.8)
Female sex, n (%)	21 (65.6)
Diabetes, n (%)	16 (50.0)
Hypertension, n (%)	31 (96.9)
Atrial fibrillation	9 (28.1)
CAD, n (%)	13 (40.6)
Prior PCI, n (%)	5 (15.6)
Prior CABG, n (%)	4 (12.5)
Permanent pacemaker, n (%)	3 (9.4%)
Renal impairment, n (%) (eGFR < 50 mL/min)	18 (56.3)
COPD, n (%)	18 (56.3)
NYHA class \geq III, n (%)	26 (81.3)
Impaired systolic LVF (Biplane EF < 35%), n, (%)	5 (15.6)
Logistic EuroScore, %, median (IQR)	24.2 (16.9–31.0)
Mean pressure gradient, mmHg, mean \pm SD	50.7 ± 13.1
Aortic valve area, cm ² , mean \pm SD	0.55 ± 0.11
LVOT diameter TEE, mm, mean \pm SD	18.7 ± 2.5
Aortic annulus diameter TEE, mm, median (IQR)	21.5 (20.2–23.7)
IVSDd, mm, median (IQR)	13.5 (12.0–16.0)
Rate-limiting medication	16 (50)
β -blocker, n (%)	8 (25)
Nondihydropyridin calcium antagonist, n (%)	1 (3.1)
Digoxin, n (%)	5 (15.6)
Amiodarone, n (%)	3 (9.4)

CABG = coronary artery bypass graft; CAD = coronary artery disease; COPD = chronic obstructive pulmonary disease; EF = ejection fraction; eGFR = estimated glomerular filtration rate; IQR = interquartile range; IVSDd = end-diastolic interventricular septal dimensions; LVOT = left ventricular outflow tract; LVF = left ventricular function; NYHA = New York Heart Association functional class; PCI = percutaneous coronary intervention; TEE = transesophageal echocardiography.

patients with left-axis deviation increased from 20.7% (6/29) to 42.3% (11/26) postimplantation ($P = 0.014$).

The prevalence of LBBB increased from 13.8% to 57.7% directly after implantation ($P = 0.001$). Of 18 patients not in BBB at baseline, 11 (61.1%) developed new LBBB. This was also expressed in the increase of mean QRS duration from 114 ± 30 to 141 ± 25 ms ($P < 0.001$) immediately after TAVI, with a mean increase of

Table II.

Temporal Changes in Electrocardiographic Parameters of Conduction

ECG Variable	Pre-TAVI	P*	Post-TAVI	P*	Predischarge (Mean 8 Days)
AF, n (%)	9/29 (31.0)	NS	5/29 (17.2)	NS	5/27 (18.5)
PR interval, ms, mean \pm SD	184 \pm 33	NS	193 \pm 30	NS	192 \pm 27
QRS duration, ms, mean \pm SD	114 \pm 30	<0.001	141 \pm 25	NS	133 \pm 31
QRS axis, degrees, mean \pm SD	16 \pm 43	0.003	-9 \pm 46	NS	-8 \pm 30
Left axis, n (%)	6/29 (20.7)	0.014	11/26† (42.3)	NS	5/21‡ (23.8)
RBBB, n (%)	7/29 (24.1)	NS	6/26† (23.1)	NS	5/21‡ (23.8)
LBBB, n (%)	4/29 (13.8)	0.001	15/26† (57.7)	NS	8/21‡ (38.1)

*Significance level of Wilcoxon signed rank sum test or paired-sample *t*-test for differences between adjacent time point.

†Three cases excluded from analysis due to paced rhythm on ECG.

‡Two cases of procedure-related mortality and six cases excluded from analysis due to paced rhythm on ECG.

27 \pm 26 ms. The prevalence of LBBB and QRS duration had decreased from postprocedure to discharge (57.7% to 38.1% and 141 \pm 25 ms to 133 \pm 31 ms, respectively), although not reaching statistical significance ($P = 0.083$ and $P = 0.295$, respectively).

Permanent Pacemaker Requirement: Incidence and Predictors

Of 32 cases who successfully underwent TAVI, five patients were excluded from analysis: three cases already paced at baseline and two cases of periprocedural mortality. Of the remaining 27 cases, eight (29.6%) underwent PPM implantation

during the procedural admission. Indications for PPM implantation were the following: prolonged high-grade AV block in two cases, intermittent high-grade AV block in two cases, and AF with complete AV block in the remaining four cases. In three patients, the indication for pacing occurred in the first 24 hours, and in the other five patients, the indication occurred from day 3 to 4 postimplantation. Four patients received VVI pacemakers, and the other four received DDD pacemakers (Table III). Of the eight patients who required PPM, five were followed at our pacemaker clinic. At 2 months of follow-up after PPM implantation (mean 67 days), two patients

Table III.

Characteristics of Patients Requiring PPM after TAVI

Case	Conduction Abnormality at Baseline	Rate Limiting Medication	Indication for PPM	Day Post-TAVI Indication for PPM	Type of PPM	% Vpacing at Follow-Up
1	First-degree AV block + RBBB	None	AF with complete AV block	3	VVI	Not available
7	None	Digoxin	AF with complete AV block	1	VVI	99
10	None	Bisoprolol	Persistent high-grade AV block	1	DDD	99
18	RBBB + left axis	None	Persistent high-grade AV block	1	DDD	Not available
23	RBBB	Digoxin	AF with complete AV block	3	VVIR	13
25	LBBB	None	Intermittent high-grade AV block	3	DDD	Not available
27	First-degree AV block + RBBB	None	Intermittent high-grade AV block	4	DDD	14
31	None	None	AF with complete AV block	3	VVIR	83

AV = atrioventricular; LBBB = left bundle branch block; RBBB = right bundle branch block; V pacing = right ventricular pacing.

required V pacing < 15% of the time, suggesting a temporal improvement in AV conduction. The other patients (n = 3) required V pacing for a mean of 93.7% of the time.

PPM requirement was unrelated to baseline demographic and clinical variables, including age, sex, NYHA class, previous syncope, logistic EuroSCORE, renal dysfunction (estimated glomerular filtration rate < 50 mL/min), prior percutaneous coronary intervention, or coronary artery bypass graft. Sixteen patients (50.0%) were on rate-limiting medication at the time of implantation; however, the presence of rate-limiting medication did not correlate with requirement for PPM (P = 0.492; r = -0.138).

Of the seven patients with baseline RBBB morphology, four (57.1%) required permanent pacing after TAVI. In the univariate analysis, baseline RBBB morphology almost correlated with need for PPM (P = 0.068; r = 0.556). None of the other baseline ECG variables significantly correlated with PPM requirement, namely, presence of AF, PR interval or QRS duration, LBBB, QRS axis.

Need for PPM was also unrelated to any of the echocardiographic variables assessed, neither to prosthesis size, prosthesis size-aortic annulus ratio, postprocedural AR grade, nor to postprocedural peak troponin I level.

Requirement for PPM was significantly correlated with prosthesis depth in the LVOT (P = 0.001; r = 0.590). Mean distance from the annular margin of the noncoronary cusp to the ventricular end of the prosthesis was significantly greater in patients with PPM requirement than patients without PPM requirement (12.9 ± 2.5 mm vs 8.6 ± 2.9, respectively). At a cutoff point of 10.1 mm, the likelihood of PPM implantation could be predicted with 87.5% sensitivity and 74% specificity and a receiver operator characteristic curve area of 0.86 ± 0.07 (P = 0.003).

Discussion

Our single-center experience shows that TAVI with a self-expanding bioprosthesis results in a high incidence of new-onset LBBB and high-grade AV block requiring PPM implantation.

Development of LBBB configuration immediately after implantation occurred in around 60% of patients not in BBB at baseline. Our results are consentaneous with previous studies assessing abnormal cardiac conduction after TAVI. In the first North American case series, four of 11 patients (36%) developed LBBB after implantation of the MCV.¹⁵ The issue of conduction disorders after TAVI has been addressed recently. The incidence of new LBBB in these reports ranged from 40 to 50%.¹⁹⁻²¹ As previously mentioned in this manuscript, development of intraventricular

conduction disorders after AVR has been associated with higher rates of adverse events at long term. The clinical and prognostic significance of new LBBB after TAVI is yet to be defined, and should be investigated in upcoming studies with prolonged periods of follow-up.

Our results show that approximately one of every four to five patients had requirements for a PPM due to high-grade AV block. These results are consistent with the initial reports from the North American series where three of 11 patients (27%) had requirements for permanent pacing after implantation of the MCV.¹⁵ The incidence of permanent pacing presented here (29.6%) is higher than that presented in the single study from Rotterdam (18%),²¹ but slightly lower than the incidence reported in the most recent study from Leicester (33%).²⁰ Owing to the small sample sizes in all the studies, the differences in the incidences of PPM implantation should not be regarded as significant.

We observed an incidence of PPM requirement of twice or more that of operative AVR. The excess of permanent pacing with TAVI relative to AVR is possibly related to a lower threshold for early pacemaker implantation. However, this is merely speculative. After AVR, temporary epicardial pacing wires allow the conduction tissue to recover when there is reversible damage, whereas in TAVI, the concerns about infection and prolonged immobilization caused by transvenous temporary pacing often prompt the physician to early PPM implantation should an indication arise.

It should be noted that the need for a PPM may only become apparent at a delayed stage as one patient developed an indication to PPM lately on day 4 post-TAVI. Furthermore, low pacing requirements at follow-up for two patients receiving PPM strongly suggest a temporal improvement in AV conduction. Our results are corroborated by the study from Leicester. In this study, 25% of the patients who ultimately underwent PPM implantation as a result of TAVI required ventricular pacing < 10% of the time at 1-month follow-up.¹⁸ Transient periprocedural inflammation and edema in the tissues surrounding the prosthesis may be responsible for the temporary nature and reversibility of AV block in these situations.

In the univariate analysis, deeper implantation of the prosthesis was the only significant predictor of PPM requirement. The close proximity between the noncoronary cusp and the branching AV node provides a strong theoretical support to the association found. The AV node is located in the right atrium, within an important structure named the triangle of Koch, which is demarcated

by the tendon of Todaro, the attachment of the septal leaflet of the tricuspid valve, and the orifice of the coronary sinus. The AV node is located just inferior to the apex of the triangle of Koch, adjacent to the membranous septum, and continues as the His bundle. In the LVOT, the triangle between the right and noncoronary leaflets adjoins the interventricular part of the membranous septum, which, together with the right fibrous trigone, forms the central fibrous body. The latter is the landmark for the site of the His bundle of the cardiac conduction system. Having penetrated the central fibrous body, the AV conduction bundle passes between the membranous septum and the crest of the muscular ventricular septum to bifurcate into right and left bundle branches (Fig. 3). When viewed from inside the left ventricle, the His bundle exits 2–3 mm below the base of the interleaflet triangle, separating the noncoronary cusp from the right coronary cusp.^{22–24} In this particular location, the conduction system is susceptible to mechanical injury and compression by the MCV stent frame. Interestingly, Piazza et al, in a retrospective study of 40 consecutive patients, demonstrated that the incidence of new-onset LBBB after TAVI was related to depth of the prosthesis in the LVOT.²¹ We therefore hypothesize that a superior “landing

zone” of the bioprosthesis within the LVOT could minimize the risk of conduction abnormalities and PPM requirement. Indeed, no patient required PPM when the ventricular end of the frame was positioned <8.5 mm from the annular margin of noncoronary cusp.

Other alternative sources of injury to the conduction system during TAVI include direct contact by catheters and guidewires, ischemia, and mechanical trauma induced by preimplantation balloon valvotomy.

In our series, four of seven patients with pre-existing RBBB required pacemaker implantation. Although this association did not reach statistical significance, it seems reasonable to hypothesize that balloon and stent trauma in the region of aortic annulus and LVOT affecting the adjacent left bundle branch would be more worrisome in the presence of preexisting compromise of the right bundle. These patients should be, therefore, closely monitored for the development of high-grade AV block after device implantation.

Incidence of Permanent Pacemaker Requirement in Self-Expanding versus Balloon-Expandable Valves

There are a number of designs for bioprosthesis that can be inserted percutaneously in

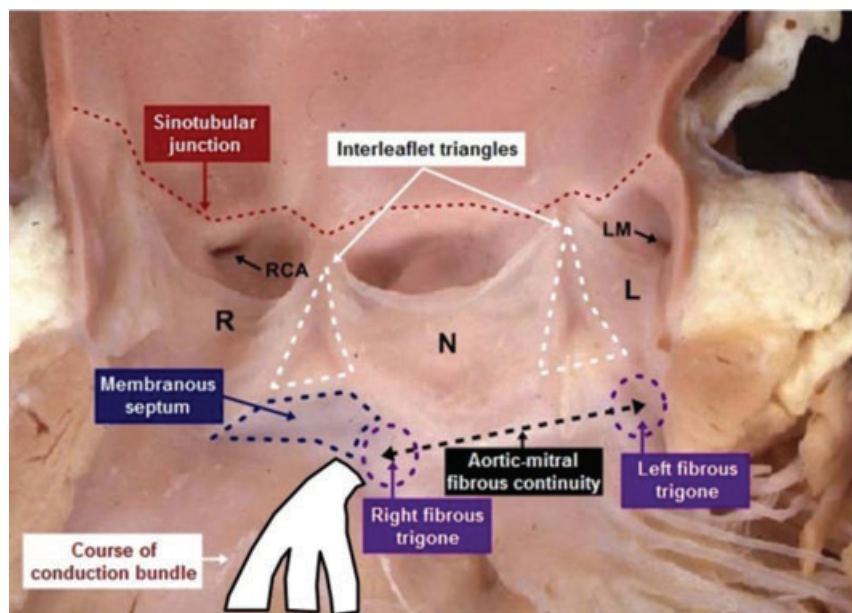


Figure 3. Anatomic relationships within the aortic root and LVOT. This image of the aortic root opened from the left ventricle shows the aortic leaflets, the interleaflet triangles, the membranous septum, and the conduction bundle exiting below the base of the interleaflet triangle separating the noncoronary and the right coronary leaflets, and fanning out along the ventricular septum. L = left coronary leaflet; LM = left main; N = noncoronary leaflet; R = right coronary leaflet; RCA = right coronary artery. Image used with permission of Dr. Andrew Cook, UCL Institute of Child Health, London, who retains copyright for the original image.

aortic position, but thus far, only two designs accumulate most of the experience and gained the CE (Conformité Européene) mark approval: the balloon-expandable Edwards-SAPIEN valve (ESV) (Edwards Lifesciences, Irvine, CA, USA) and the self-expanding MCV. The ESV consists of a balloon-expandable cylindrical stainless steel frame to which is attached a trileaflet equine pericardium heart valve.

As previously mentioned in this manuscript, previous studies using the MCV design showed an incidence of permanent pacing that varied from 18% to 33.3%.^{19–21} On the other hand, Sinhal et al. reported a lower incidence (5.7%) of PPM implantation using the balloon-expandable ESV.²⁵ More recently, Tchetché et al. performed a nonrandomized comparison of outcomes in a mixed population of patients treated with either MCV or ESV valves. They reported a higher incidence of PPM implantation in the MCV group (28.6% vs 4.2%).²⁶

Based on our results, we postulate that the lower incidence of conduction cardiac disorders seen with the ESV is probably related to the lower height of this prosthesis, extending less into the LVOT and causing less impingement of conduction bundle. Hemodynamic efficacy of the CoreValve prosthesis is critically dependent on its firm self-expansion in the aortic annulus and LVOT, which avoid recoil and paravalvular regurgitation. Overlap and compression of the structures surrounding the aortic annulus and LVOT, including the cardiac conduction system, with ensuing AV conduction impairment, is the price to pay for the greater conformability of the MCV. Indeed, indirect comparisons showed less paravalvular AR with the MCV (21% grade ≥ 2)¹⁶ relative to the ESV design (63% grade ≥ 2).¹³

Study Limitations

The limitations of the present study are evident: we present a single-center retrospective analysis of a relatively small cohort of 32 patients treated with the MCV. Unlike other studies, we did not assess PPM requirement

and ECG temporal changes after discharge. This could have been relevant to further support the reversibility of AV conduction impairment and define the prognostic and clinical significance of newly acquired intraventricular conduction abnormalities after TAVI.

There are considerable differences between various types of transcatheter prosthesis valves and our results could not be extended to other implantable devices.

Despite these limitations, our study represents an important effort to identify potential risk factors for PPM implantation after TAVI. Our results should be regarded as hypothesis generating, thus indicating the need to reassess current techniques for percutaneous implantation of aortic valve and improve device characteristics in order to lower the frequency of heart block. Larger series are needed to validate these preliminary findings.

Conclusion

TAVI is becoming an increasingly available treatment option for inoperable or high-risk patients with severe AS, and seems to be associated with a nonnegligible incidence of heart block and need for PPM. We report a 61% incidence of new-onset LBBB early after TAVI, which is comparable to previous studies. Approximately 30% of patients required PPM implantation due to high-grade AV block, which in some cases developed at a delayed stage. Deeper position of the valve prosthesis in the LVOT was the only factor shown to be predictive of PPM requirement. Our results suggest that a more superior positioning of the valve prosthesis within the LVOT may minimize the risk of heart block and subsequent need for pacing. The findings of this hypothesis-generating study should be prospectively tested.

Acknowledgments: Figure 3 from this manuscript was used and modified with permission of Dr. Andrew Cook, UCL Institute of Child Health, London, who retains copyright for the original image. We thank Dr. Jean-Claude Laborde, lead proctor for CoreValve, for training in the procedure.

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