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Conduction Abnormalities and Permanent Pacemaker Implantation After Transcatheter Aortic Valve Replacement Using the Repositionable LOTUS Device

The United Kingdom Experience

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ABSTRACT

OBJECTIVES The authors report the incidence of pacemaker implantation up to hospital discharge and the factors influencing pacing rate following implantation of the LOTUS bioprosthesis (Boston Scientific, Natick, Massachusetts) in the United Kingdom.

BACKGROUND Transcatheter aortic valve replacement (TAVR) is associated with a significant need for permanent pacemaker implantation. Pacing rates vary according to the device used. The REPRISE II (Repositionable Percutaneous Replacement of Stenotic Aortic Valve Through Implantation of Lotus Valve System) trial reported a pacing rate of 29% at 30 days after implantation of the LOTUS device.

METHODS Data were collected retrospectively on 228 patients who had the LOTUS device implanted between March 2013 and February 2015 across 10 centers in the United Kingdom. Twenty-seven patients (12%) had pacemakers implanted pre-procedure and were excluded from the analysis.

RESULTS Patients were aged 81.2 ± 7.7 years; 50.7% were male. The mean pre-procedural QRS duration was 101.7 ± 20.4 ms. More than one-half of the cohort (n = 111, 55%) developed new left bundle branch block (LBBB) following the procedure. Permanent pacemakers were implanted in 64 patients (32%) with a median time to insertion of 3.0 ± 3.4 days. Chief indications for pacing were atrioventricular (AV) block (n = 46, 72%), or LBBB with 1st degree AV block (n = 11, 17%). Amongst those who received a pacemaker following TAVR the pre-procedural electrocardiogram findings included: No conduction disturbance (n = 41, 64%); 1st degree AV block (n = 10, 16%); right bundle branch block (n = 6, 9%) and LBBB (n = 5, 8%). LBBB (but not permanent pacemaker) occurred more frequently in patients who had balloon aortic valvuloplasty before TAVR (odds ratio [OR]: 1.25; p = 0.03). Pre-procedural conduction abnormality (composite of 1st degree AV block, hemiblock, right bundle branch block, LBBB) was independently associated with the need for permanent pacemaker (OR: 2.54; p = 0.048). The absence of aortic valve calcification was also associated with a higher pacing rate (OR: 0.55; p = 0.031). Multivariate regression analysis did not show an independent association between depth of implant, valve oversizing, balloon post-dilatation, and the need for pacing post-procedure.

CONCLUSIONS Following implantation of the repositionable LOTUS valve, 55% of patients developed LBBB and 32% of patients required a pacemaker during their index hospital admission. Patients with pre-procedural conduction disturbance and non-calcified aortic valves were more likely to need pacing. No other anatomic features were identified with increased pacing requirement with the LOTUS device. (J Am Coll Cardiol Intv 2017;10:1247–53) Crown Copyright © 2017 Published by Elsevier on behalf of the American College of Cardiology Foundation. All rights reserved.

ABBREVIATIONS AND ACRONYMS

AV = atrioventricular

BCIS = British Cardiovascular Interventional Society

DLZ = device landing zone

LBBB = left bundle branch block

LVOT = left ventricular outflow tract

OR = odds ratio

PPM = permanent pacemaker

RBBB = right bundle branch block

TAVR = transcatheter aortic valve replacement

Transcatheter aortic valve replacement (TAVR) is now a well-established treatment for aortic stenosis in patients deemed to be at high surgical risk. However with the growing adoption of this new technology, the complications of this procedure have become apparent. In particular, TAVR with self-expanding prostheses is associated with a significant incidence of new left bundle branch block (LBBB) as well as pacemaker implantation following the procedure. We report the incidence of conduction abnormalities and pacing rate with the second-generation LOTUS device (Boston Scientific, Natick, Massachusetts) in the United Kingdom. In addition, we analyzed factors that may influence the need for post-procedural pacemaker implantation.

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METHODS

Centers in the United Kingdom collect data on TAVR procedures in accordance to the criteria set by the British Cardiovascular Interventional Society (BCIS). A spreadsheet was designed based on the BCIS template and sent to 10 high-volume TAVR centers in the United Kingdom.

Data were collected on a total of 228 patients. The patient population underwent TAVR with the LOTUS valve between March 2013 and February 2015. Twenty-seven patients had pacemakers before the TAVR procedure and were excluded from our analysis. Of that group, 1 patient had a "prophylactic" pacemaker implantation before TAVR. Our study population thus consisted of 201 patients.

Clinical and procedural data were collated from each center and stored in a central database. Degenerative aortic stenosis was the main indication for intervention. The degree of calcification of the aortic valve was assessed on fluoroscopy and graded as mild, moderate, or severe. At the start of the LOTUS TAVR program, only the 23-mm and 27-mm valves were available. The 25-mm valve was introduced approximately halfway through most programs. A TAVR procedure was defined as urgent if it was performed during the same inpatient stay as the acute admission. Depth of implantation was defined as the distance from the noncoronary cusp to the ventricular edge of the LOTUS device on fluoroscopy. The annular size was obtained from site-reported computed tomography measurement. The difference between the diameter of the device and the annulus was calculated and expressed as a percentage compared with the annular diameter to give a measure of oversizing of the prosthesis.

Complications arising from the index procedure up to discharge were documented. The definitions were in line with VARC2 (Valve Academic Research Consortium-2) recommendations (1).

We obtained the pacing rate associated with the LOTUS device up to hospital discharge. The occurrence of new LBBB following insertion of the bioprosthesis was also documented. We analyzed factors that have previously been associated with permanent pacemaker (PPM) implantation with first-generation devices to establish whether a similar correlation was present with the second-generation LOTUS valve.

STATISTICAL ANALYSIS. Data analysis was performed using SPSS version 22.0 (IBM, Armonk, New York). We fitted a logistic regression model for PPM. The distribution of the pre-procedural QRS duration was skewed to the right, and we used the natural logarithm to better approximate a normal distribution. We allowed for random center effect in our model. Univariate logistic regression modeling was performed using an unadjusted model for each

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covariate for PPM. We then constructed a multivariate model using a backward elimination method and entry criteria of $p \leq 0.10$.

RESULTS

Table 1 shows the baseline characteristics and procedural details of the cohort of 201 patients. Approximately two-thirds of the group did not have any pre-existing conduction issues. The distribution of pre-procedural block was as follows: 1st degree atrioventricular (AV) block (13.1%), left anterior hemiblock (2.0%), right bundle branch block (RBBB) (3.5%), and LBBB (4.5%). The incidence of permanent pacemaker insertion after TAVR with the LOTUS bioprosthesis was 31.8%. 111 patients (55.2%) developed new LBBB following the procedure. Pacemaker implantation was performed predominantly for complete heart block (71.9%) followed by trifascicular block (17.2%). The indication for pacing was not specified in 10.9% of cases.

FACTORS ASSOCIATED WITH PACING. On univariate analysis, 2 variables had a p value of <0.1: pre-procedural block and lower degree of aortic valve calcification (Table 2) ($p = 0.028$ and $p = 0.038$), respectively. We fitted these 2 variables in a logistic regression model allowing for random center effects. Pre-existing rhythm disturbance and lower levels of calcification in the aortic valve maintained a statistically significant association with the need for pacing after implantation of the LOTUS device (Table 3).

FACTORS ASSOCIATED WITH NEW LBBB. The effect of different factors in the development of new LBBB are outlined in Online Table 1. Logistic regression method was used to identify a correlation between these parameters and post-procedural LBBB. Pre-procedural balloon valvuloplasty was associated with the development of LBBB post-procedure on multivariate regression analysis (odds ratio [OR]: 1.25; $p = 0.03$).

DISCUSSION

Our study presents data on conduction abnormalities following the use of the LOTUS bioprosthesis in an all-comers population in the United Kingdom. The REPRISE II (Repositionable Percutaneous Replacement of Stenotic Aortic Valve Through Implantation of Lotus Valve System) trial demonstrated the safety and efficacy of this device in treating patients with aortic stenosis at high surgical risk (2). In particular, the device is associated with a remarkably low incidence of aortic regurgitation. In brief, the LOTUS device consist of 3 bovine pericardial leaflets mounted on a mechanically expanding nitinol frame (3). It has an outer adaptive seal on its lower half to minimize paravalvular aortic regurgitation and comes in 3 sizes: 23, 25, and 27 mm.

TABLE 1 Baseline and Procedural Characteristics of Paced and Non-Paced Groups

	No Pacing	Pacing	p Value
Age, yrs	81.1 ± 8.1	81.6 ± 6.5	0.60
Female	68/130 (52.3)	30/64 (46.9)	0.54
Body mass index, kg/m^2	26.9 ± 5.1	27.2 ± 6.4	0.49
Diabetes mellitus	39/137 (28.5)	20/64 (31.3)	0.74
Chronic pulmonary disease	46/137 (33.6)	16/64 (25.0)	0.25
Significant liver disease	2/137 (1.5)	1/61 (1.6)	1.00
Dialysis	2/137 (1.5)	2/64 (3.1)	0.59
Previous cerebrovascular disease	24/137 (17.5)	7/64 (10.9)	0.30
Previous cardiac surgery	27/137 (19.7)	14/62 (22.6)	0.71
Atrial fibrillation	29/137 (21.2)	20/64 (31.3)	0.16
Pre-procedural QRS duration	99.5 ± 18.0	105.9 ± 24.1	0.086
Pre-procedural block (LBBB/RBBB/1st degree)	24/136 (17.6)	21/62 (33.9)	0.017
Peripheral vascular disease	23/137 (16.8)	6/64 (9.4)	0.20
Poor mobility	27/137 (19.7)	15/64 (23.4)	0.58
Critical pre-operative state	3/137 (2.2)	2/64 (3.1)	0.65
Pulmonary hypertension	35/104 (33.7)	12/46 (26.1)	0.45
Logistic EuroScore	17.2 ± 11.9	16.4 ± 10.7	0.66
EuroScore II	5.2 ± 4.2	5.1 ± 4.5	0.85
Left ventricular function			
≥50%	94/137 (68.6)	38/64 (59.4)	0.21
30% to 50%	32/137 (23.4)	21/64 (32.8)	0.17
<30%	11/137 (8.0)	5/64 (7.8)	1.00
Coronary artery disease			
None	80/128 (62.5)	34/61 (55.7)	0.43
1 vessel	20/128 (15.6)	11/61 (18.0)	0.68
2 vessel	18/128 (14.1)	5/61 (8.2)	0.34
3 vessel	10/128 (7.8)	11/61 (18.0)	0.048
Not investigated	9/137 (6.6)	3/64 (4.7)	0.76
Aortic valve calcification			
None	0/111 (0)	2/55 (3.6)	0.11
Mild	27/111 (24.3)	19/55 (34.5)	0.20
Moderate	46/111 (41.4)	24/55 (43.6)	0.87
Severe	38/111 (34.2)	10/55 (18.2)	0.045
Aortic valve pathology			
Stenosis	115/137 (83.9)	52/64 (81.3)	0.69
Regurgitation	4/137 (2.9)	3/64 (4.7)	0.68
Mixed	18/137 (13.1)	9/64 (14.1)	0.83
Proctored case	42/137 (30.7)	17/64 (26.6)	0.62
BAV	97/137 (70.8)	42/64 (65.6)	0.51
Valve size			
23 mm	48/137 (35.0)	16/64 (25.0)	0.19
25 mm	19/137 (13.9)	12/64 (18.8)	0.41
27 mm	70/137 (51.1)	36/64 (56.3)	0.55
Valve oversizing, %	6.7 ± 7.4	6.3 ± 6.1	0.66
Valve depth	5.5 ± 3.0	6.0 ± 3.4	0.45
Urgent case	18/137 (13.1)	13/64 (20.3)	0.21
General anesthetic	52/137 (38.0)	18/64 (28.1)	0.21

Values are mean ± SD or n/N (%).
BAV = balloon aortic valvuloplasty; LBBB = left bundle branch block; RBBB = right bundle branch block.

TABLE 2 Univariate Analysis of Factors Influencing Pacing

	OR (95% CI)	p Value
Age (yrs)	1.01 (0.97–1.05)	0.65
Female	0.80 (0.43–1.46)	0.48
Diabetes mellitus	1.16 (0.59–2.26)	0.68
Chronic pulmonary disease	0.66 (0.33–1.30)	0.26
Significant liver disease	1.03 (0.09–12.03)	0.98
Dialysis	2.38 (0.30–18.58)	0.43
Previous cerebrovascular disease	0.57 (0.23–1.43)	0.26
Previous cardiac surgery	1.26 (0.59–2.67)	0.57
Atrial fibrillation	1.60 (0.80–3.19)	0.22
Natural logarithm of pre-procedural QRS duration (in QRS)	4.62 (0.80–26.7)	0.13
Presence of pre-procedural block (LBBB/RBBB/1st degree combined)	2.79 (1.30–6.00)	0.028
Peripheral vascular disease	0.49 (0.18–1.30)	0.18
Poor mobility	1.19 (0.57–2.51)	0.66
Critical pre-operative state	1.50 (0.23–9.74)	0.68
Pulmonary hypertension	0.64 (0.26–1.59)	0.36
Logistic EuroScore	0.99 (0.96–1.02)	0.57
Left ventricular function	1.26 (0.79–2.03)	0.36
Extent of coronary artery disease	1.28 (0.93–1.74)	0.16
Aortic valve calcification	0.57 (0.37–0.88)	0.038
Proctored case	0.81 (0.39–1.70)	0.60
BAV	0.62 (0.29–1.34)	0.25
Valve size (reference level 27 mm)		
23 mm	0.61 (0.30–1.26)	0.21
25 mm	1.27 (0.54–3.00)	0.61
Valve oversizing, %	1.05 (0.94–1.18)	0.43
Valve depth	1.04 (0.94–1.16)	0.43
Urgency	1.75 (0.77–4.00)	0.21
New LBBB post-implantation	1.25 (0.65–2.38)	0.52

CI = confidence interval; OR = odds ratio; other abbreviations as in Table 1.

TABLE 3 Multivariate Logistic Regression Analysis of Factors Influencing Pacing

	OR (95% CI)	p Value
Pre-procedural block	2.54 (1.19–5.43)	0.048
AV calcification	0.55 (0.35–0.85)	0.031

Abbreviations as in Tables 1 and 2.

The conduction issues during a TAVR procedure arise due to the geographical proximity of the membranous tissue and left bundle with the final position of the bioprosthesis along the ventriculo-arterial tract (4). Indeed, a short membraneous septal length has been recently linked to higher risk of AV block (5). We have previously postulated a mechanism to explain heart block due to TAVR (6). Morphological changes associated with aortic stenosis cause the valvular attachment to shift towards the ventriculo-arterial junction. Because the TAVR device is positioned in relation to the level of the aortic leaflets, it follows that the LBBB lies closer to the implanted device than would be the case in a morphologically normal aortic valve.

Historically, the pacing rate with self-expandable valves has been higher than with balloon-expandable valves. Registry data show a pacing rate of around 18% to 49% with self-expandable valves compared with 0% to 12% with balloon expandable valves (6–9). The higher pacing rates of self-expanding valves has been attributed to the continuous radial expansion of the nitinol frame after deployment.

The pacing rate in this study (32%) is similar to the previously reported pacing rate of the LOTUS valve in the REPRISE II trial (29%) (10). Some factors that have previously been implicated in the development of conduction abnormalities post-TAVR include the depth of implant, presence of pre-procedural RBBB, and oversizing of the prosthesis.

DEPTH OF IMPLANTATION. Various studies have examined the influence of the depth of implantation of the TAVR device on the need for post-procedural PPM. Mouillet et al. (11) found that delayed high-degree AV block, and hence need for PPM, was present with deeper implants (12 ± 4 mm vs. 9 ± 5 mm). Saia et al. (12) noted that a distance of 7.7 mm between the noncoronary cusp and distal edge of the prosthesis appeared to be an independent predictor of pacing. In our study, most of the devices were positioned relatively shallower than previous studies, with a mean distance of 5.7 ± 3.2 mm in the overall cohort. This may well explain why we did not find an association between depth of implantation with the need for PPM with the LOTUS device.

PRE-PROCEDURAL HEART BLOCK. Pre-existing RBBB was associated with higher pacing rates in both first-generation TAVR bioprosthesis (13–16). The occurrence of TAVR induced LBBB in such patients results in the compromise of both conducting bundles thus leading to complete heart block. In an analysis of 120 patients from the REPRISE II trial extended cohort, Dumonteil et al. (10) found a significant association between baseline RBBB and the need for pacing at 30 days following LOTUS valve implantation. The prevalence of RBBB in the REPRISE II study was 27.8%, whereas it was 3.5% in our cohort. One possible reason for the low incidence of RBBB in our study is that the operators chose balloon-expandable devices instead of the mechanically expanding valve in the presence of pre-procedural RBBB so as minimize the risk of further damage to the conduction pathway. The resulting population bias would lead to an artificially lower rate of RBBB in the group receiving the LOTUS device. Given the low rate of RBBB in our study, we included all forms of conduction abnormalities into 1 group and evaluated the need for pacing based on the presence or absence of any form of block.

Pre-procedural conduction disturbance was associated with the need for pacing in our study. The presence of conduction abnormalities on the pre-procedural electrocardiogram indicates disease within the conduction system and thus any additional insult as a result of the TAVR is more likely to lead to significant degree of heart block requiring pacing. In some centers, pre-procedural pacemakers are routinely implanted in the presence of RBBB or bifascicular block. However, in our study, there was no report of this form of "prophylactic" pacing. Only 1 patient received a pacemaker (cardiac resynchronization therapy in this case) before his TAVR procedure, and the indication was for poor left ventricular function in the presence of LBBB. Pre-procedural heart block may help to identify patients who require a longer period of cardiac monitoring to check for the development of higher degrees of AV block.

OVERSIZING OF PROSTHESIS. In an analysis of 109 patients with the CoreValve device (Medtronic, Dublin, Republic of Ireland), Schroeter et al. (17) found a large prosthesis >26 mm to be an independent risk factor for PPM. Left ventricular outflow tract (LVOT) stretch was found to be an independent predictor of the need for pacing in the REPRISE II study (10). In our study, we calculated the degree of aortic annular overstretch rather than of the LVOT, which may explain why we did not find an association with pacing. At the outset of the LOTUS program, only 23-mm and 27-mm devices were available. The 25-mm device became available approximately halfway through the program in most centers. Even though we did not find an association between valve diameter and pacing rate, it is possible that the availability of a larger range of valve sizes will reduce the overall pacing rate using this device.

DEGREE OF AORTIC VALVE CALCIFICATION. Aortic valve calcification was not associated with an increased rate of pacing following the LOTUS device. In fact, the presence of calcification appeared to confer a protective effect with regard to pacing.

In an analysis of the German TAVR registry, Staubach et al. (18) did not find an association between the degree of aortic valve calcification and the need for pacemaker post procedure.

In a prospective study of 81 patients receiving the CoreValve device, Latsios et al. (19) quantitatively assessed the calcification load in the "device landing zone" (DLZ) using the Agatston score. The DLZ comprised, not only the native calcific aortic valve, but also the adjacent left ventricular outflow tract. His team found a positive correlation between the amount of calcification in the DLZ and need for post-TAVR pacemaker with the CoreValve (OR: 1.06; $p = 0.004$). The degree of calcification in the noncoronary cusp did not emerge as a predictor of pacemaker insertion. The highest rate of pacemaker insertion was found in the cohort with only mildly calcified aortic valves.

In line with the Latsios et al. (19) finding, calcification along the LVOT may be a more important determinant of pacing than calcification of the aortic valve apparatus itself. The distribution of calcium is not uniform across the LVOT and aortic valve annulus. In an analysis of 33 patients with severe aortic stenosis, Rivard et al. (20) found that annular calcification extended caudally into the LVOT in only about one-third of cases. In a cohort of 177 patients with severe aortic stenosis, the prevalence of annular calcification was 61%, whereas LVOT calcification was present in only 36% (21).

Larger prospective studies are needed to clarify the effect of aortic valve calcification and pacing rate with the LOTUS device.

WHAT IS THE LONG-TERM OUTCOME OF PPM IMPLANTATION POST-TAVR? The pacing rate following LOTUS device implantation is significant. However, so far, most analyses have not found a deleterious impact between pacemaker implantation post-TAVR and mortality (22,23). Urena et al. (24) did not find an increase in hard endpoints (all-cause mortality, cardiovascular mortality, and repeat hospitalization for heart failure) with PPM implantation at a mean follow-up period of 22 months. In fact, there was a lower rate of sudden death in patients with PPM. By contrast, the paced group had significantly worse left ventricular ejection fraction at follow-up compared with their non-paced counterparts. However, this did not translate into increased re-hospitalizations for heart failure or higher New York Heart Association functional class. So far, short- to medium-term outcomes do not seem to be affected by pacing, but data on longer follow up are lacking.

LEFT BUNDLE BRANCH BLOCK. New LBBB block has been reported in 29% to 65% of patients after implantation of the CoreValve and 4% to 18% of patients receiving the balloon-expandable Sapien valve (Edwards Lifesciences, Irvine, California) (25). More than one-half the patients getting a LOTUS valve developed new LBBB in our cohort. In addition to the type of device, other factors have been implicated in the development of new LBBB, including depth of implantation (13,26) and longer baseline QRS duration (27). We did not find any association

between these parameters and the development of LBBB. Balloon aortic valvuloplasty was associated with a higher incidence of post-procedural LBBB.

There is conflicting evidence on the long-term effect of new LBBB following TAVR. Pereira et al. (23) found a lower 1-year survival in patients with new LBBB. Houthuizen et al. (28) found a similar pattern at a median follow-up of 450 days. Conversely, Franzoni at al. (29) did not find a correlation between LBBB and mortality at 1 year. In a cohort consisting exclusively of patients receiving the balloon-expandable Sapien valve, Urena at al. (27) did not find an association with all cause or cardiovascular mortality. However, patients with LBBB had a lower functional status and poorer ejection fraction at 1 year.

STUDY LIMITATIONS. Although we attempted to collect as comprehensive a dataset as possible from each center, data were missing in some fields. As a result, our analysis is prone to statistical bias. One patient had a prophylactic pacemaker 1 week before TAVR and was excluded from our analysis. However, this is unlikely to have an effect on our results. We also documented the in-hospital pacing rate in our study and do not have information on any pacemaker implantation after discharge.

The measurements from pre-procedural computed tomography scans were collected from each center, and there was no independent verification using central core laboratory analysis. However, our paper describes a "real-world" study of practice using the LOTUS valve, whose strength is that TAVR centers in the United Kingdom collect procedural data on all TAVR cases, in accordance with a dedicated template set by the BCIS.

CONCLUSIONS

The LOTUS bioprosthesis has a pacing rate similar to that of first-generation self-expanding valves. Most factors that have traditionally been associated with pacing need in first-generation devices do not seem to influence pacing rate with LOTUS device. In our study, pre-procedural conduction abnormality and the presence of noncalcified aortic valve were independent risk factors for PPM. This may help identify patients who will benefit from a longer period of monitoring following their procedure.

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PERSPECTIVES

WHAT IS KNOWN? TAVR devices can be associated with significant conduction disturbance and pacing rate after implantation.

WHAT IS NEW? Following implantation of the LOTUS device in the United Kingdom, more than one-half of the patient population develop LBBB, and one-third require pacing during their index admission. The presence of pre-procedural conduction abnormalities and the absence of aortic valve calcification are independently associated with a higher pacing need.

WHAT IS NEXT? The long-term effects of LBBB and pacing need to be carefully evaluated in this patient group.

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KEY WORDS aortic stenosis, left bundle branch block, LOTUS, pacemaker, transcatheter aortic valve

APPENDIX For a supplemental table, please see the online version of this article.