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

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Objectives In this retrospective study, we examined the incidence of post-procedural conduction abnormalities and the need for pacing in patients undergoing percutaneous implantation of the aortic valve.

Background Safety and feasibility studies have suggested anecdotally the occurrence of conduction abnormalities and requirements for pacing after percutaneous implantation of the aortic valve.

Methods We examined the standard 12-lead electrocardiograms (ECGs) of 40 consecutive patients in whom a CoreValve Revalving System (CoreValve, Paris, France) was implanted between November 2005 and March 2008. We examined the 12-lead ECG before treatment, after treatment, and at 1-month follow-up. We documented the requirements for temporary or permanent pacemaking.

Results The mean age of patients was 82 ± 7 years. Post-procedural mortality at 72 h was 0%. There was a significant increase in the frequency of left bundle branch block (LBBB) after percutaneous aortic valve replacement (15% before treatment vs. 55% after treatment, $p = 0.001$). Although the incidence of LBBB had decreased after follow-up of 1 month, it did not reach statistical significance, with the proportion decreasing from 55% to 48% ($p = 0.63$). The only 2 patients with pre-treatment right bundle branch block became dependent on temporary pacing immediately after valve implantation and subsequently needed permanent pacing. A temporary and permanent pacemaker was required in 20% and 18% of patients, respectively.

Conclusions In this study, there was a significant increase in the frequency of LBBB after percutaneous insertion of the aortic valvar prosthesis. Patients with pre-existing right bundle branch block may be at risk for the development of complete heart block and subsequent need for pacing. (J Am Coll Cardiol Intv 2008;1:310–6) © 2008 by the American College of Cardiology Foundation

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Aortic valvar stenosis is well recognized as being associated with abnormalities of cardiac conduction (1,2). In particular, electrophysiologic studies have shown prolonged PR, AH, and HV intervals in these patients (3,4). The incidence of intraventricular conduction defects after surgical replacement of the aortic valve has been reported in as many as 33% of patients, and has been associated with an increased incidence of adverse events (5,6). Furthermore, a permanent pacemaker is required in approximately 3% to 8% of these patients (7–13). The occurrence of conduction abnormalities after surgical replacement of the aortic valve is not surprising when one considers the anatomical proximity of the conduction system to the aortic valve. Surgical trauma to the ventricular conduction system, as well as myocardial ischemia, are considered to be key factors in the development of these abnormalities.

Percutaneous replacement of the aortic valve provides a new alternative for patients with severe aortic valvar stenosis considered to be at high or prohibitive surgical risk. Studies concerning the safety and feasibility of the procedures have now been published (14–16). Initial reports have suggested anecdotally the occurrence of conduction abnormalities and requirements for pacing (15–17) after percutaneous replacement of the aortic valve. In this retrospective study, we examined in more detail the incidence of early postprocedural conduction abnormalities identified on 12-lead electrocardiographic tracings and the need for a temporary or permanent pacing in patients undergoing percutaneous replacement of the aortic valve using the CoreValve ReValving System (CoreValve, Paris, France).

Methods

Patients. We reviewed the records of 40 consecutive patients with aortic stenosis in whom a CoreValve Revalving System was implanted between November 2005 and March 20, 2008. Patients were referred for percutaneous aortic valvar insertion after a cardiologist and cardiac surgeon reached consensus that surgical replacement would be associated with either high or prohibitive risk. The logistic EuroScore was used to estimate the baseline surgical operative risk (18).

The criteria for inclusion and exclusion for the implantation of the CoreValve ReValving System have been described elsewhere. In brief, patients were included if they had echocardiographic measurements demonstrating severe native valvar stenosis, with an area <1 cm^2, or <0.6 cm^2/m^2, with or without aortic regurgitation; a diameter of the basal orifice of the stenosed valve of between 20 mm and 27 mm; and a diameter at the sinutubular junction equal to or <43 mm.

Description of the device and procedure. Details of the device, and the technical aspects of the procedure, have been previously published (19). The prosthesis consists of a self-expanding nitinol tri-level frame to which is secured a trileaflet bioprosthetic porcine pericardial tissue valve. Currently, the prosthesis is available in sizes of 26 and 29 mm. Selection of the device depends on measurements of the aortic valvar complex obtained by echocardiography, angiography, or multislice computed tomography.

Balloon valvotomy was required before implantation. Positioning and deployment of the device was performed solely under fluoroscopic and angiographic guidance. On the basis of the recommendations at the time, the ventricular edge of the valve frame was implanted approximately 10 to 12 mm below the lower edge of the right noncoronary cusp (i.e., basal attachments of the aortic valvar leaflets) as identified on contrast aortography. In 29 patients (70%), we implanted the 26-mm device; later, when it became available, we used the 29-mm device in 11 patients. In 4 patients, because of inappropriate positioning of the first device, we implanted a second device of 26 mm in diameter.

Collection of ECG and pacemaking data. Electrocardiographic tracings obtained before and after treatment, along with 1-month standard recordings, were interpreted in our core laboratory, where we analyzed the recordings for rhythm, heart rate (beats/min), PR, QRS, and corrected QT intervals (all in milliseconds), and presence of second- or third-degree atrioventricular (AV) block. Diagnostic criteria recommended by the World Health Organization and International Society and Federation for Cardiology Task Force (20) was used to code for left and right fascicular hemiblock and left and right bundle branch block.

Abbreviations and Acronyms

AV = atrioventricular
ECG = electrocardiogram
LBBB = left bundle branch block

In addition, an electronic 3-lead rhythm strip was continuously recorded during the procedure and stored electronically. The timing of any increase in the width of the QRS segment during the procedure was recorded from a single-lead surface tracing obtained during fluoroscopy. We documented the requirements after the procedure for temporary or permanent pacemaking.

Distance of the aortic prosthesis within the left ventricular outflow tract. Using quantitative angiographic techniques (CAAS 5.4, Pie Medical, Maastricht, the Netherlands), we measured the distance (in millimeters) from the lower edge of the noncoronary cusp to the ventricular (i.e., proximal) end of the frame. We examined this distance to investigate the association between the depth of implantation of the aortic prosthesis within the left ventricular outflow tract and the development of conduction abnormalities.

Statistical analysis. Continuous variables are presented as means ($\pm$SD). Categorical variables are presented as frequencies and percentages. For continuous variables, paired comparisons between pre-treatment and post-treatment or 1-month follow-up and between post-treatment and

1-month follow-up were done with a Wilcoxon signed rank test. For binomial variables, paired comparisons between pre-treatment and post-treatment or 1-month follow-up and between post-treatment and 1-month follow-up were done with the McNemar test and conducted by exact methods. For the comparison of the mean distance (in millimeters) of the aortic prosthesis within the left ventricular outflow tract between those patients with and those without new-onset left bundle branch block (LBBB), the independent sample *t* test was used. Statistical significance was assumed for p values of <0.05. All statistical analyses were performed with SPSS software version 12 (SPSS Institute, Chicago, Illinois).

Results

Baseline characteristics of our 40 patients are summarized in Table 1, with 1 patient dying 6 days after implantation as a consequence of procedurally related cardiac tamponade.

Twelve-lead ECG evaluation. The flow diagram (Fig. 1) shows the number of electrocardiograms available for interpretation, and time to follow-up, with results of analysis shown in Table 2.

RHYTHM. The majority of patients (67%) were in sinus rhythm before the procedure, but this number decreased significantly after insertion, with the change being maintained at 1-month follow-up (67% vs. 51%, $p < 0.001$ and 67% vs. 55%, $p \leq 0.001$, respectively). Approximately one-third of the patients had atrial fibrillation at baseline and atrial fibrillation of new onset was noted in 2 patients.

QRS DURATION. The mean QRS duration increased after insertion of the device (111 ± 27 ms vs. 150 ± 32 ms, $p < 0.001$) and, subsequently, decreased significantly from post-treatment to 1-month follow-up (150 ± 32 ms vs. 134 ± 29 ms, $p < 0.001$) (Table 2). Despite the subsequent decrease, the difference from baseline readings at 1-months follow-up remained significant (111 ± 27 ms vs. 134 ± 29 ms, $p < 0.001$).

BUNDLE BRANCH BLOCK AND AV BLOCK. There was a significant increase in the frequency of LBBB after insertion of the device, from 15% before insertion to 55% after insertion ($p = 0.001$). Although the incidence of LBBB had decreased after follow-up of 1 month, it did not reach statistical significance, with the proportion decreasing from 55% to 48% ($p = 0.63$). Furthermore, the increase in the frequency of LBBB remained significant at 1-month follow-up (48% vs. 15%, $p = 0.02$) (Table 2). One patient with incomplete block after insertion had progressed to complete LBBB after 1 month, whereas 1 patient with new-onset LBBB after insertion had resolved during follow-up.

The distance from the lower edge of the noncoronary cusp to the proximal edge (i.e., ventricular end) of the frame of the prosthesis (Fig. 2) was measured to be a mean of 10.3 ± 2.7 mm (range 6.7 to 14.6 mm) in those who developed LBBB of new onset and distinctively after valve implanta-

Table 1. Clinical Characteristics (n = 40)

	n (%)
Age (yrs), mean ± SD	82 ± 7
Male	20 (50)
Coronary artery disease	15 (38)
1-VD	6 (15)
2-VD	1 (3)
3-VD	8 (20)
History of myocardial infarction	8 (20)
History of percutaneous coronary intervention	8 (20)
History of coronary artery bypass	12 (31)
History of heart failure	10 (26)
Left ventricular ejection fraction %, mean ± SD	41±12
Permanent pacemaker	1 (3)
Diabetes	12 (31)
Hypertension	12 (31)
Hypercholesterolemia	7 (17)
Renal failure	17 (43)
Smoker	2 (6)
Aortic valve area (cm^2), mean ± SD	0.75 ± 0.23
LVOT diameter (mm), mean ± SD	21 ± 2
Mitral annular calcification	23 (57%)
Prosthesis inflow size	
26-mm	29 (73%)
29-mm	11 (27%)

LVOT = left ventricular outflow tract; VD = vessel disease.

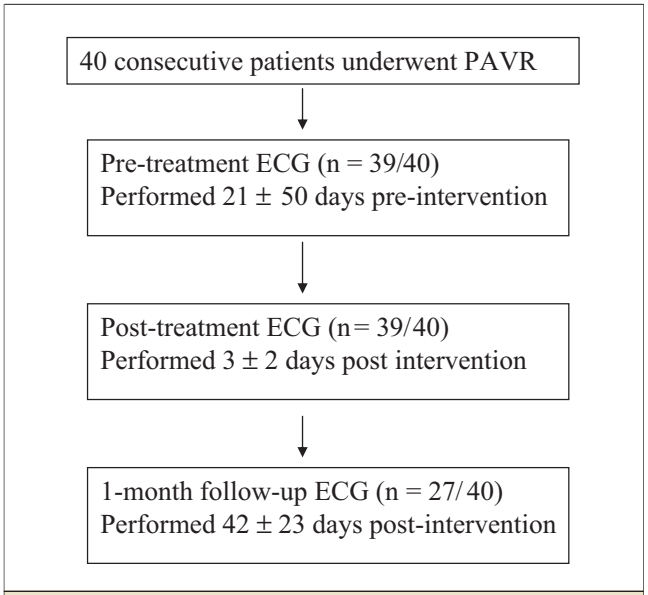

Figure 1. Flow Diagram

The diagram demonstrates the number of 12-lead electrocardiograms (ECG) available for interpretation and the mean time to follow-up expressed in days (mean ± SD). PAVR = percutaneous aortic valve replacement.

Table 2. Electrocardiogram Interpretation

	Before Treatment (n = 39)	After Treatment (n = 39)	1 Month (n = 27)	p Value Before Treatment vs. After Treatment	p Value After Treatment vs 1-Month Follow-Up	p Value Before Treatment vs. 1-Month Follow-Up
Rhythm, n (%)						
Sinus	26 (67)	20 (51)	15 (55)	<0.001	1.00	<0.001
Atrial fibrillation	11 (27)	13 (33)	7 (26)	1.00	1.00	0.50
Pacemaker	1 (3)	5 (13)	4 (15)	0.13	1.00	0.25
Other	1 (3)	1 (3)	1 (3)	1.00	1.00	1.00
Heart rate (beats/min)	77 ± 14	73 ± 18	77 ± 15	0.96	0.51	0.46
PR interval (ms)	165 ± 62	177 ± 55	186 ± 36	0.05	0.29	0.84
QRS width (ms)	111 ± 27	150 ± 32	134 ± 29	<0.001	<0.001	<0.001
QT interval (ms)	419 ± 29	458 ± 44	429 ± 33	<0.001	<0.001	0.15
Hemiblock, n (%)						
None	31 (80)	38 (95)	26 (96)	0.02	1.00	0.63
Anterior	7 (17)	1 (3)	1 (4)	0.03	1.00	1.00
Posterior	1 (3)	0 (0)	0 (0)	1.00	n/a	1.00
Bundle branch block, n (%)						
None	26 (67)	12 (31)	11 (41)	0.004	0.25	0.07
Left	6 (15)	22 (55)	13 (48)	0.001	0.63	0.02
Right	2 (5)	3 (8)	1 (4)	1.00	1.00	1.00
Incomplete left	4 (10)	1 (3)	1 (4)	1.00	1.00	0.63
Incomplete right	1 (3)	1 (3)	1 (4)	1.00	1.00	1.00

tion and 5.5 ± 3.4 mm (range 0.7 to 12.2 mm) in those without the development of LBBB (p = 0.005).

There was no clinically significant change in mean PR interval during the period of follow-up (Table 2). We found 31%, 26%, and 21% of patients with first-degree AV block before insertion, immediately after insertion, and after follow-up, respectively (p = 0.766). Second-degree AV block type I was identified in 1 patient after follow-up.

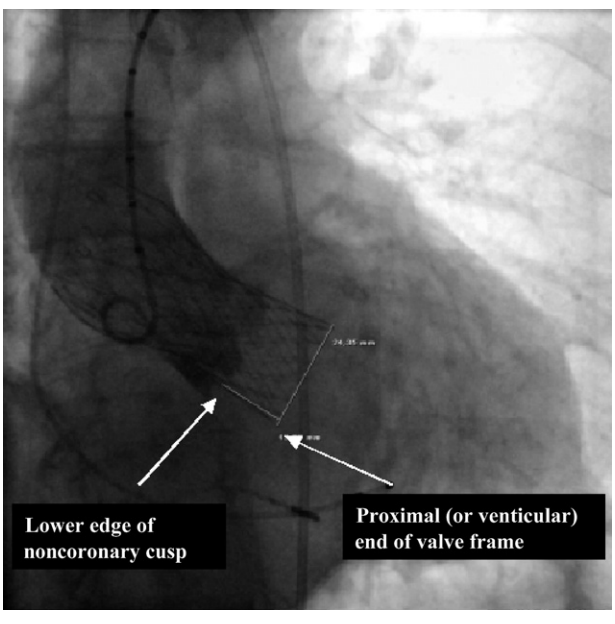

Figure 2. Quantitative Angiographic Measurement

A representative example of the measurement of the distance from the lower edge of the noncoronary cusp to the proximal (or ventricular) end of the frame of the valve prosthesis is shown.

Timing of electrocardiographic changes during the procedure. During the procedure, widening of the QRS complex of new onset was noted in 20 of 40 patients (50%). In the majority of patients (70%), the widening occurred distinctively after implantation of the device and in the remaining 30%, occurred before implantation but after percutaneous aortic balloon valvotomy or guidewire crossing of the native aortic valve.

Requirements for pacemaking. One patient had a permanent pacemaker implanted prior to the procedure. After implantation of the device, temporary pacing was required in 8 patients (20%) and permanent pacing was required in 7 patients (18%). One-half of patients with requirement for temporary pacing subsequently had implantation of a permanent pacemaker. The only 2 patients with right bundle branch block before insertion of the device both developed third-degree AV block and needed temporary pacing immediately after implantation followed by permanent pacing. Permanent pacemakers were implanted at a median of 6 days, with a range from 4 to 47 days.

Discussion

Our results show that there is an increase of 40% in the occurrence of LBBB after percutaneous insertion of the aortic valvar prosthesis, and that approximately 1 of every 5

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and 1 of every 6 of our patients had requirements for a temporary or permanent pacing, respectively.

Abnormalities in conduction. Similar to the results in our study, the first North American case series reported 4 of 11 patients (36%) in whom new-onset LBBB developed after implantation of the CoreValve Revalving System (17). To the best of our knowledge, there have been no previous studies assessing abnormal cardiac conduction after 1 month after percutaneous aortic valvar insertion. The results of this study suggest there is an improvement in intraventricular conduction (i.e., decrease in QRS duration and frequency of LBBB) from the time after implantation to 1-month follow-up. Possible explanations include transient peri-procedural inflammation, edema, ischemia, or mechanical stress with recovery of conduction.

The close anatomical relationship between the aortic valvar complex and the branching AV bundle may provide an explanation for the observed increase in LBBB after percutaneous aortic valvar implantation. Within the right atrium, the AV node is located within the triangle of Koch. The Tendon of Todaro, the attachment of the septal leaflet of the tricuspid valve, and the orifice of the coronary sinus all demarcate this important triangle. The apex of this triangle is formed by the AV component of the membranous septum, with the AV node located just inferior to the apex. The node penetrates through the membranous septum and central fibrous body as the bundle of His, emerging in the ventricles on the crest of the ventricular septum (Fig. 3), where it gives rise to the fascicles of the left bundle branch.

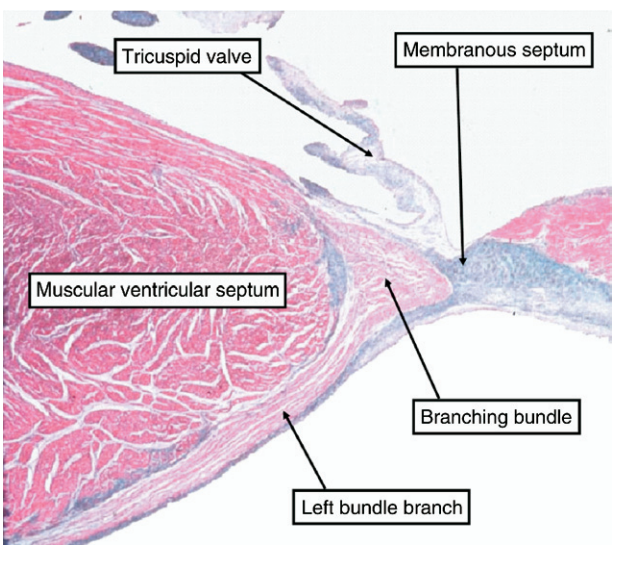

Figure 3. Histological Section

The section demonstrates the piercing of the atrioventricular bundle through the membranous septum, exiting superficially along the crest of the interventricular septum, and continuing to supply the left ventricle. Reprinted with permission from Benson R. Wilcox, Andrew C. Cook, Robert H. Anderson, *Surgical Anatomy of the Heart, 3rd Edition* (New York, NY: Cambridge University Press, 2005).

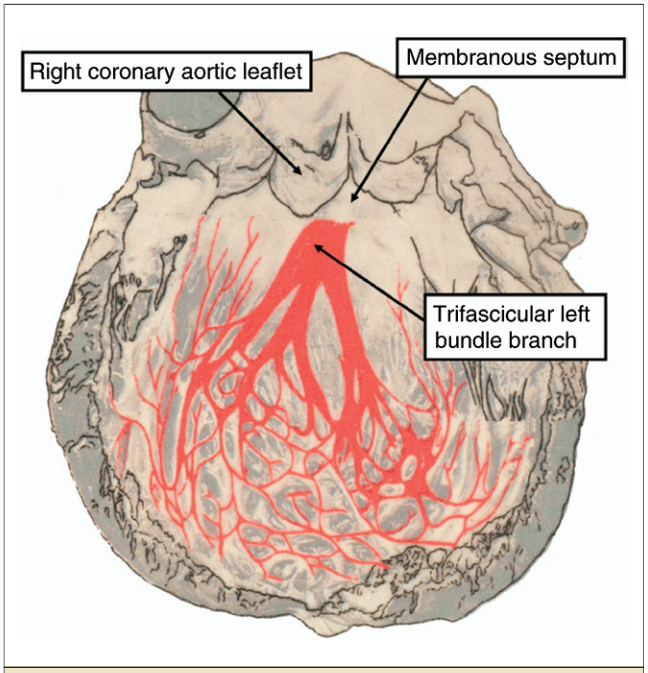

Figure 4. Monograph of Tawara

The monograph shown demonstrates how the left bundle branch exits below the base of the interleaflet triangle, separating the noncoronary and right coronary leaflets of the aortic valve and fanning along the ventricular septum to supply the left ventricle. Modified from Tawara (22).

When viewed from the left, the left bundle branch exits approximately 2 to 3 mm below the base of the interleaflet triangle separating the noncoronary and right coronary leaflets of the aortic valve, as shown exquisitely in the stellar monograph of Tawara (Fig. 4) (21–23). In the present study, the mean distance from the proximal (or ventricular) end of the frame of the valve prosthesis to the lower edge of the noncoronary cusp was significantly greater in patients with new-onset LBBB than patients without new-onset LBBB (10.3 ± 2.7 mm vs. 5.5 ± 3.4 mm, respectively). Therefore, there exists the possibility of the aortic prosthesis overlapping the left bundle branch and potentially crushing it. Although it cannot be proven at this time, our results suggest that positioning the aortic valve prosthesis in a more superior location within the left ventricular outflow tract may limit the risk of conduction abnormalities and potentially the need for pacing. Indeed, no patient in our study developed prosthesis-related LBBB when the proximal end of the valve frame was positioned <6.7 mm from the lower edge of the noncoronary cusp. Other potential sources of insult can include degeneration and calcification of the conduction system, the mechanical or ischemic effects of pre-implantation balloon valvotomy, or the direct contact and trauma by catheters and guidewires with components of the conduction system.

In our study, one-third of the patients developed intraventricular conduction abnormalities of new onset after percutaneous aortic balloon valvotomy or with passage of the guidewire across the native aortic valve. Similarly, an analysis of 207 patients who underwent mitral or aortic balloon valvotomy showed an incidence of almost one-fifth in new-onset intraventricular conduction defects after valvotomy (24). Although yet to be investigated, strategies to diminish the trauma imposed upon the conduction system by percutaneous aortic balloon valvotomy may reduce the risks of conduction abnormalities associated with these procedures. Such strategies may include limiting the size of the balloon, limiting the depth of the balloon within the left ventricular outflow tract and keeping the number of pre- and post-valve implantation balloon valvuloplasties to a minimum.

In contrast, new conduction defects can develop in as many as one-third of patients undergoing surgical replacement of the aortic valve, with LBBB being the most common abnormality (5,25–27). Although the significance of LBBB after percutaneous aortic valve insertion is not yet clear, new and persistent right or LBBB acquired after surgical replacement has been associated with a significantly increased risk of subsequent arrhythmic events, such as syncope, AV dissociation, and sudden cardiac death (5). Most of the events are thought to occur within the first year of follow-up.

Requirements for pacemaking. Approximately 1 of every 5 and 1 of every 6 of our patients required a temporary or permanent pacing, respectively. Temporary pacing was required immediately after implantation in the 2 patients with right bundle branch block before insertion, and both patients subsequently needed permanent pacing. The high occurrence of LBBB of new onset in our cohort suggests that those with pre-existing right-bundle branch block need to be closely monitored after implantation.

Previous studies have suggested that pacing may be needed after percutaneous valvar replacement. In the North American series, 3 of 11 patients (27%) had requirements for permanent pacing after implantation of the CoreValve Revalving System (17). In 27 patients undergoing implantation with the balloon-expandable Cribier-Edwards aortic prosthesis, Cribier et el. (16) reported 1 patient who developed third-degree heart block immediately after implantation, with loss of temporary pacing resulting in death. Another of their patients developed third-degree heart block 3 months after the procedure, with implantation of a permanent pacemaker complicated by pulmonary embolus and death. Webb et al. (15) described the development of transient complete heart block in only 1 of 50 patients being implanted with the Cribier-Edwards aortic prosthesis. At mean follow-up of 75 ± 55 days, they reported no further occurrences of conduction abnormalities or need for a permanent pacemaker (15).

The occurrence of complete heart block and subsequent need for permanent pacing has been reported after aortic balloon valvotomy but is rare (24). On the other hand, complete heart block can occur in approximately one-fifth of patients immediately after surgical replacement of the aortic valve (8). In approximately two-thirds of those patients suffering this complication, it is a transient phenomenon. In general, between 3% and 8% of patients need permanent pacing. Specifically in the elderly, permanent pacing has been required in approximately 6% to 6.5%. Risk factors for permanent pacing include age, additional valvar disease, history of myocardial infarction, mitral annular calcification, pre- and postoperative disease of the conduction system disease, repeat operations and multivalve surgery (13,28–30).

Study limitations. As with any retrospective analysis, our study has its inherent limitations. We report from a single-center experience. In addition, 12 patients had not reached 1-month follow-up at the time of this analysis. Although limited by the small numbers, our results are hypothesis generating and possibly indicate the need for reappraisal of the current techniques for percutaneous insertion of the aortic valve. The results of this study may be particular for the CoreValve Revalving System and may not be necessarily generalizable to other transcatheter prosthetic valves. Further studies are needed to assess predictors and the clinical consequences of conduction abnormalities following percutaneous aortic valvar insertion.

Conclusions

In 2007, the first 2 percutaneous heart valve therapy devices gained CE marking for marketing in Europe. The year 2008 will mark the first full year of commercial availability of percutaneous aortic valve replacement, with more than 1,500 implantations expected to occur. In this study, there was a significant increase in the frequency of LBBB after percutaneous insertion of the aortic valvar prosthesis. Furthermore, patients with right bundle branch block before the procedure may be at risk for the development of complete heart block and subsequent need for pacing. Proper positioning of the prosthesis within the left ventricular outflow tract may limit these risks. Physicians caring for patients undergoing percutaneous aortic valve replacement should be aware of these potential complications.

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Figure 3 from this manuscript is modified from that appearing in "Surgical Anatomy of the Heart," published by Cambridge University Press. We thank the coauthors of this book, Drs. Benson Wilcox and Andrew Cook, for permission to modify the images for the purposes of our current work.

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