Incidence and characteristics of heart block after heart surgery in pediatric patients: A multicenter study

Leonardo Liberman, MD, a Eric S. Silver, MD, a Paul J. Chai, MD, b and Brett R. Anderson, MD, MBA a

ABSTRACT

Background: Advanced second- or third-degree heart block has been reported with variable incidence after surgery for congenital heart disease in children. We report the incidence of heart block requiring a pacemaker and describe the risk factors for this complication in a large multicenter study.

Methods: We performed a retrospective cohort study, using the Pediatric Health Information System database from 45 hospitals in the United States, for all children aged 18 years, discharged between January 1, 2004, and December 31, 2013, who underwent open surgery for congenital heart disease. Patients who had heart block and placement of a pacemaker during the same hospitalization were identified. Demographic characteristics, procedure and diagnostic codes, length of stay, and mortality were analyzed. Univariable and multivariable analyses were performed.

Results: There were 101,006 surgeries performed. The median age of patients was 0.5 years (interquartile range, 26 days to 3.2 years), and 1% of patients (n = 990) had heart block and placement of a pacemaker. Surgeries associated with the highest incidences of heart block and placement of a pacemaker included the double switch operation (15.6%), tricuspid valve (7.8%) and mitral valve (7.4%) replacement, atrial switch with ventricular septal defect repair (6.4%), and Rastelli operation (4.8%). On multivariable analysis, after controlling for surgical complexity, other comorbidities, age at surgery, admission year, and clustering by institution, patients with heart block and placement of a pacemaker had higher odds of mortality (odds ratio, 1.67; 95% confidence interval, 1.24-2.26; P < .001).

Conclusions: The incidence of postoperative heart block requiring permanent pacemaker placement immediately after congenital heart surgery is low (1%). However, these patients have higher mortality even after adjusting for heart surgery complexity. (J Thorac Cardiovasc Surg 2016;152:197-202)
recommended that children with advanced second- or third-degree atrioventricular block persisting 10 to 14 days after surgery receive a permanent pacemaker implant. In the subsequent revision of the guidelines, the recommended waiting period was shortened to 7 days. Over the last 2 decades, reports from single or few institutions have been published describing the incidence of postoperative heart block. However, the true incidence of this complication in a large cohort of patients is unknown. We report a multicenter study of tertiary care institutions to determine the incidence of surgical heart block in the current era and to identify surgical risk factors for this complication.

MATERIALS AND METHODS

Study Design
A retrospective cohort study was performed, using the Pediatric Health Information System database, to determine the incidence of complete heart block undergoing permanent pacemaker placement in pediatric patients after open surgery for congenital or acquired heart disease and to determine the effects of this outcome on mortality. This study was classified by the Columbia University Medical Center Institutional Review Board as nonhuman subjects research and was exempted from further review.

Data Source
Data for this study were obtained from the Pediatric Health Information System, an administrative database that contains inpatient observation data from 45 not-for-profit, tertiary care pediatric hospitals in the United States. These hospitals are affiliated with the Children’s Hospital Association (Overland Park, Kan). Data quality and reliability are ensured through a joint effort between the Children’s Hospital Association and participating hospitals. Participating hospitals provide discharge and encounter data, including demographics, diagnoses, and procedures. All data are de-identified at the time of data submission, and data are subjected to a number of reliability and validity checks before being included in the database.

Study Population
The database was queried for all children aged 18 years or less, discharged between January 1, 2004, and December 31, 2013, who underwent open surgery based on a Risk Adjusted Classification for Congenital Heart Surgery, version 1 (RACHS-1) score. Data collected included diagnosis of congenital heart disease based on the International Classification of Diseases, 9th Revision, Clinical Modification (ICD-9-CM) codes, age at surgery, gender, and major comorbidities (genetic abnormalities and other chronic hematologic, renal, gastroenterologic, or neurologic conditions, as previously defined by Feudtner and colleagues). Procedure codes were queried for all the surgical procedures based on the RACHS-1 classification and all the surgical procedures for placement of a pacemaker and implantable defibrillator. Death during the hospitalization, length of stay, and costs per day were recorded. Patients with multiple surgical admissions were treated as if each admission was independent.

The information was analyzed for missing data. Missing data were defined as absence of age, cardiac diagnosis, or RACHS-1 procedure. Hospitals with less than 30 patients were excluded from analysis (3 centers, n = 22 patients).

Predictors and Outcomes
The primary outcome of interest was advanced second-degree (ICD-9-CM: 426.12), third-degree (ICD-9-CM: 426.0), or unspecified heart block (ICD-9-CM: 426.10) in patients who underwent placement of a permanent ventricular or dual-chamber pacemaker or defibrillator. Patients who underwent a permanent pacemaker or defibrillator on the same date or before their RACHS-1 operation were excluded from further analysis.

The primary predictor of interest was the procedure done during the hospitalization that had the highest RACHS-1 score. Other variables considered included age at surgery, gender, RACHS-1 scoring, comorbidities (including genetic abnormalities and other chronic hematologic, renal, gastroenterologic, or neurologic conditions), year of operation, and admitting hospital.

The effects of the primary outcome on mortality, total hospital length of stay, and inpatient standardized costs per day were analyzed. Mortality was defined as in-hospital death. Standardized costs are adjusted for costs of living by hospital location, using the Centers for Medicare & Medicaid Services Wage Index (http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Wage-Index-Files.html) to allow comparison of resource use across institutions. All costs were further adjusted for inflation (to 2014 dollars), using the Medical Consumer Price Index (http://www.bls.gov/cpi/#tables).

Data Analysis
Statistical analyses were conducted in Stata software, version 13 (StataCorp LP, College Station, Tex). Standard summary statistics were used, including means with standard deviations or medians with interquartile ranges (IQRs) for continuous variables, and frequencies with proportions for categoric variables. For each of 57 operation types (defined by RACHS-1 coding), rates of heart block and pacemaker placement were calculated. These rates were compared with the overall incidence in the rest of the cohort by chi-square with Bonferroni correction. These rates were then graphically depicted for each procedure as a function of the number of cases in our cohort. Lines depicting the 5th and 95th binomial prediction limits were superimposed to create a funnel plot. Procedure types falling above or below these prediction limits were said to be associated with significantly high or low incidences, respectively.

To assess the association between predictor variables and mortality, we used chi-square, t tests, and Wilcoxon rank-sum tests. To assess the association between predictor variables and length of stay and costs per day, we used Wilcoxon rank-sum tests and Spearman correlation. Variables with P values of .10 or less in univariable analyses were evaluated together in multivariable analyses using logistic regression in the assessment of mortality and linear regression in the assessment of length of stay and costs per day. We clustered standard errors on institution to account for possible correlation between children treated within each center.

RESULTS

Patient Characteristics
A total of 102,271 hospitalizations (75,094 patients) from 42 hospitals were identified during the study period. Of
these, 1265 (1.2%) hospitalizations were excluded because the patients underwent placement of a permanent pacemaker (n = 1161 [92%]) or defibrillator (n = 104 [8%]) at the time or before the RACHS-1 operation. These patients were older (3.6 years; IQR, 1.2-8.1 years; P < .001) than patients receiving the device after the RACHS-1 operation.

The remaining 101,006 hospitalizations (74,571 patients) were included for further analysis. The median age at the time of surgery was 0.5 years (IQR, 26 days to 3.2 years) with 61,405 patients (61%) aged less than 1 year of age and 25,671 patients (25%) aged less than 1 month. There were 55,835 male patients (55%).

Pacemaker Placement
There were 1279 hospitalizations (1.3%) in which patients underwent placement of a pacemaker or defibrillator during the hospitalization and after the RACHS-1 index operation. There were 4176 hospitalizations (4.1%) in which patients were coded for advanced second- or third-degree atrioventricular block. A total of 990 patients (1%) had both heart block and a device placed, and they represent the main outcome variable analyzed. These patients underwent placement of a pacemaker (n = 947, 96%) or an implantable defibrillator (n = 43, 4%). The approach to the placement of the device was not well coded: There were 579 (59%) epicardial devices, 173 (17%) transvenous systems, and 238 (24%) unknown route of pacing. The patients who had a transvenous system were older than the patients with an epicardial system (7.9 years, IQR, 3.4-13.5 years vs 5.3 months, IQR, 35 days to 1.6 years; P < .001). The median time from the main RACHS-1 operation to the placement of the pacemaker was 9 days (IQR, 7-14 days).

Figure 1 shows the distributions of the procedures with the highest numbers of patients who underwent pacemaker placement for heart block. Figure 1 does not represent the risk of this outcome for each operation. Table 1 shows the incidence (and 95% confidence intervals [CIs]) of being coded for heart block and having a permanent pacemaker placement in the operation types with the highest incidence of this complication. The surgeries associated with the highest risk of having heart block and permanent pacemaker placement were double switch operation (15.6%), tricuspid valve (7.8%) and mitral valve (7.4%) replacement, atrial switch with ventricular septal defect (VSD) repair (6.4%), Rastelli operation (4.8%), neonatal Ebstein’s repair (4.2%), Konno operation (4.1%), arterial switch operation with VSD repair (3.4%), aortic valve replacement (2.9%), subaortic resection (2.8%), and Ross operation (2.4%).

Tricuspid valvuloplasty and non-neonatal Ebstein’s repair had a significantly high incidence of being coded for heart block (5.9% and 10.8%, respectively); however, patients with these lesions did not have a significantly high incidence of pacemaker placement (1.3% and 1.1%, respectively).

Other surgical procedures, including repair of secundum atrial septal defect, coarctation of the aorta, partial anomalous pulmonary venous return, patent ductus arteriosus repair, and Glenn and Fontan operations, had low incidences of heart block and a pacemaker placement rate that was statistically significantly lower than for the rest of the cohort (P < .001). Figure 2 shows a funnel plot indicating the surgeries with high and low incidences of heart block with pacemaker placement, accounting for the number of patients undergoing each operation.

The patient’s age, gender, and year of operation were not associated with postoperative heart block with pacemaker placement. Among the cardiac diagnoses, corrected transposition of the great arteries had the highest incidence of heart block with pacemaker placement (4.1%, P < .001). The median number of cases by center per year was 278 cases (IQR, 212-464), and the median number of cases per surgeon per year (after 2010) was 111 cases (IQR, 83-138). Center volume and surgeon volume were not associated with being coded for heart block and undergoing a pacemaker placement, even after controlling for RACHS-1 categories. The number of patients undergoing pacemaker implant for heart block after surgery varied between 0.77% and 1.1% each year without a particular trend (P = .154).

Mortality
The overall mortality rate in the entire cohort was 3% (n = 3072). The presence of heart block and having a pacemaker implanted during the same hospitalization and after the RACHS-1 procedure were significantly associated with mortality. In univariable analyses (clustering standard errors by center), the presence of heart block and having a pacemaker implanted was associated with increased odds.
of mortality (odds ratio [OR], 2.0; 95% CI, 1.51-2.74; \( P < .001 \)). In multivariable analysis, the presence of heart block and having a pacemaker implanted was still associated with increased mortality (OR, 1.67; 95% CI, 1.24-2.26; \( P < .001 \), after controlling for RACHS-1 category, other comorbidities (genetic abnormalities and other chronic hematologic, renal, gastroenterologic, or neurologic conditions), age at surgery, and admission year.

### Resource Use

The median length of stay for patients who had heart block and underwent placement of a pacemaker was longer than for the rest of the cohort (20 days, IQR, 12-41 vs 8 days, IQR, 4-17) \( (P < .001) \). In multivariable analyses, the presence of heart block and a pacemaker was associated with 2.1 times increase in length of stay (95% CI, 2.0-2.3; \( P < .001 \), after controlling for the RACHS-1 category, age at surgery, and presence of other comorbidities (genetic abnormalities and other chronic hematologic, renal, gastroenterologic, or neurologic conditions) clustering by institution, and after censoring for death.

The median inpatient total hospital cost for patients who were coded for heart block and underwent placement of a pacemaker was $120,377 (IQR, $78,900-$212,281), in 2014 dollars. The median hospital cost for the rest of the cohort was $47,841 (IQR, $30,597-$93,457) \( (P < .001) \). The median hospital cost per day was $5907 (IQR, $4532-$7793), which was not statistically different in patients with or without heart block and placement of a pacemaker on univariable or multivariable analysis.

### Table 1. Incidence of heart block with pacemaker placement by cardiac operation

<table>
<thead>
<tr>
<th>Surgery</th>
<th>Patients (n)</th>
<th>Pacemaker (n)</th>
<th>%</th>
<th>95% CI</th>
<th>( P ) value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Double switch operation</td>
<td>77</td>
<td>12</td>
<td>15.6</td>
<td>7.5-23.7</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Tricuspid valve replacement</td>
<td>230</td>
<td>18</td>
<td>7.8</td>
<td>4.3-11.3</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Mitral valve replacement</td>
<td>902</td>
<td>67</td>
<td>7.4</td>
<td>5.7-9.1</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Atrial switch with VSD</td>
<td>217</td>
<td>14</td>
<td>6.5</td>
<td>3.1-9.7</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Rastelli operation</td>
<td>313</td>
<td>15</td>
<td>4.8</td>
<td>2.4-7.1</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Ebstein’s repair &lt;30 d</td>
<td>72</td>
<td>3</td>
<td>4.2</td>
<td>0-8.8</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Konno operation</td>
<td>290</td>
<td>12</td>
<td>4.1</td>
<td>1.8-6.4</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>ASO with VSD</td>
<td>1517</td>
<td>52</td>
<td>3.4</td>
<td>2.5-4.3</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Aortic valve replacement</td>
<td>1262</td>
<td>37</td>
<td>2.9</td>
<td>2.0-3.9</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Sub-AS resection</td>
<td>1078</td>
<td>30</td>
<td>2.8</td>
<td>1.8-3.8</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Ross operation</td>
<td>918</td>
<td>22</td>
<td>2.4</td>
<td>1.4-3.4</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>CAVC repair</td>
<td>6358</td>
<td>143</td>
<td>2.2</td>
<td>1.9-2.6</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Mitral valvuloplasty</td>
<td>3802</td>
<td>66</td>
<td>1.7</td>
<td>1.3-2.2</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Coarctation with VSD</td>
<td>1107</td>
<td>19</td>
<td>1.7</td>
<td>1.0-2.5</td>
<td>.01</td>
</tr>
</tbody>
</table>

\( P \) values compare the incidence of heart block for a specific procedure with that observed in the rest of the study cohort. CI, Confidence interval; VSD, ventricular septal defect; ASO, arterial switch operation; Sub-AS, subaortic stenosis; CAVC, complete atrioventricular canal.

### Figure 2

This funnel plot displays the incidence of heart block with pacemaker placement for each of 57 operations as a function of the number of cases in the cohort. The horizontal solid line represents the average incidence across all operation subtypes. The dashed lines represent the 5th and 95th binomial prediction limits. Procedure types falling above or below these limits were said to be associated with significantly high or low incidences, respectively. TVR, Tricuspid valve replacement; MVR, mitral valve replacement; VSD, ventricular septal defect; Sub AS, subaortic stenosis; AVR, aortic valve replacement; ASO, arterial switch operation; CAVC, complete atrioventricular canal; PAPVC, partial anomalous pulmonary venous connection; TAPVC, total anomalous pulmonary venous connection; HLHS, hypoplastic left heart syndrome; PDA, patent ductus arteriosus; RV, right ventricle; PA, pulmonary artery; IAA, interrupted aortic arch; PV, pulmonary valve; BT, Blalock-Taussig shunt; ASD, atrial septal defect.
DISCUSSION

In this multicenter study, we analyzed data from more than 100,000 operations at 42 children’s hospitals over a 10-year period to provide insights into the incidence and impacts of heart block requiring permanent pacemakers for children undergoing open surgery in the current era. Previous reports have been limited to the experiences of individual centers or select lesions. In this study, we not only examined the majority of congenital heart operations but also accounted for intercenter variation and trends over time.

We were able to determine the incidence of this complication overall (1%) and to explore the risks associated with each specific procedure. We found that the risk of this complication was highest for children undergoing the double switch operation (15%), followed by tricuspid and mitral valve replacements (~7% for each). Contrary to a common belief, isolated VSD and tetralogy of Fallot surgeries did not pose a particularly high risk for developing this complication when compared with other cardiac lesions, although the absolute number of patients undergoing these operations who require pacemaker placement is high (Figure 1) because of the frequency of these operations. As expected, cardiac surgeries not involving the crux of the heart, such as coarctation of the aorta repair, Glenn or Fontan operations, pulmonary valve replacement, and secundum atrial septal defect, among others, had low incidences of heart block and pacemaker placement.

Prior reports have shown low or no incidence of postoperative heart block after repair of Ebstein’s disease or tricuspid valvuloplasty. Of note, in our cohort, patients undergoing non-neonatal Ebstein’s repair and tricuspid valvuloplasty had high incidences of heart block. However, these patients did not have a significantly high incidence of permanent pacemaker placement. This might suggest that there is a higher rate of conduction recovery in these patients. One might speculate that perhaps these patients should be observed for longer periods of time before placement of permanent pacemakers.

It has been well described that hospital mortality after repair of congenital heart disease increases with increased surgical complexity. Our study validated this finding (data not shown). Furthermore, we demonstrate that patient hospital mortality was associated with having heart block and undergoing placement of a permanent pacemaker, even after controlling for RACHS-1 category and other chronic comorbidities.

Prior studies have shown that hospital surgical volume is associated with hospital mortality, and this metric has gained increasing attention over recent years as a potential measure of experience. Our data confirmed the inverse relationship between center volume and mortality; the risk-adjusted OR for mortality was 0.77 (95% CI, 0.72-0.83) for hospitals performing more than 300 operations per year. However, the development of heart block requiring a pacemaker implant was not associated with hospital volume. Likewise, this postoperative complication was not associated with surgeon annual volume, indicating that center or surgeon experience might not be an important determinant of the development of this complication, which is probably inevitable in certain patients.

Study Limitations

This study has limitations inherent to its retrospective nature and the fact that it is based on administrative data. In addition, the conclusions rely on several assumptions. First, we assumed that patients who were coded for second- or third-degree atrioventricular block and who underwent pacemaker placement during their hospitalization, but after the reference operation, developed this complication as a result of the antecedent surgery. It is possible that some of these patients had preoperative heart block. However, one would assume that most patients with preoperative heart block should have had pacemaker placement on the same day as their reference surgery and would have been excluded from the analysis. Second, we only consider patients who underwent postoperative pacemaker placement before discharge from the hospital. There might be patients who develop late changes in conduction that result in pacemaker placement after hospital discharge. Although, in our clinical experience, these patients are few, this might increase the incidences estimated in the current study. Finally, these data include only those that are captured by administrative coding; therefore, clinical information such as electrocardiogram characteristics, ventricular function, hemodynamic parameters, and so forth are not available. Follow-up studies using clinical registries with more granularity would add increased depth.

CONCLUSIONS

In this multicenter study, examining records for more than 100,000 children from 42 institutions who underwent open surgery, we found that 1% of the patients had heart block and underwent placement of a permanent pacemaker. This complication increases hospital mortality.

Conflict of Interest Statement

Authors have nothing to disclose with regard to commercial support.

References


**Key Words:** congenital heart disease, heart block, pacemaker