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Complications of pacemaker therapy in adults with congenital heart disease: A multicenter study

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ABSTRACT

Background: This study aims to investigate indications and complications of permanent cardiac pacing in adults with congenital heart disease (CHD).

Methods and results: Two-hundred and seventy-four CHD patients were identified who underwent permanent pacemaker implantation between 1972 and 2009. The indication for pacing was acquired sinus node or AV node conduction disease (63%), sinus node or AV node conduction disease after cardiac surgery (28%), and drug/arrhythmia-related indications (9%). Patients with complex CHD received a pacemaker at younger age (23 versus 31 years, $p < 0.0001$) and more often received an epicardial pacing system (51% versus 23%, $p < 0.0001$) compared to those with simple or moderate CHD. Twenty-nine patients (10.6%) had a periprocedural complication during the primary pacemaker implantation (general population: 5.2%). The most common acute complications were lead dysfunction (4.0%), bleeding (2.6%), pocket infection (1.5%) and pneumothorax (1.5%). During a median follow-up of 12 years, pacemaker-related complications requiring intervention occurred in 95 patients (34.6%). The most common late pacemaker-related complications included lead failure (24.8%), pacemaker dysfunction/early battery depletion (5.1%), pacemaker migration (4.7%) and erosion (4.7%). Pacemaker implantation at younger age (<18 years) was an independent predictor of late pacemaker-related complication (adjusted hazard ratio 1.68, 95% confidence interval 1.07 to 2.63, $p = 0.023$).

Conclusions: The risk of periprocedural complications seems higher in the CHD population compared to the general population and more than one-third of CHD patients encountered a pacemaker-related complication during long-term follow-up. This risk increases for those who receive a pacemaker at younger age.

1. Introduction

The population of adult patients with congenital heart disease (CHD) is rapidly expanding due to advances in pediatric cardiology and cardiothoracic surgery over the past several decades [1,2]. However, this improved survival following congenital heart surgery is hampered by both structural and electrical late sequelae including atrioventricular (AV) block, sinus node dysfunction and atrial arrhythmias [3,4]. Many will require pacemaker therapy and are subject to lifelong need for reinterventions and follow-up [3]. Pacemaker implantation in this population may be a challenge due to the complexity of the systemic venous anatomy, venous obstructions and/or residual intra-cardiac shunting [5,6]. Furthermore, pacemaker implantation at young age and the use of epicardial leads have been associated with a high incidence of lead failures during follow-up [6–10]. Because of these issues, pacemaker therapy should be considered carefully in the patient with CHD. To improve patient management, knowledge regarding the indications and impact of pacemaker therapy is essential. Unfortunately, these data are scarce for the adult CHD population and large multi-center studies are lacking [5,6]. Furthermore, most CHD studies only focus on lead failure rate. The objective of the present multi-center study is to investigate the indications, periprocedural and late complications of permanent pacemaker therapy in adults with CHD.

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Table 1
Baseline characteristics at first pacemaker implantation.

Variable	Total (n = 274)	Simple/ moderate CHD (n = 175)	Complex CHD (n = 99)	p-value
Age at first implantation (years), median [IQR]	26 [15–39]	31 [18–44]	23 [12–28]	<0.0001
First implant <18 years	83 (30)	46 (26)	37 (37)	0.06
Male gender	152 (55)	92 (53)	60 (61)	0.20
History of atrial arrhythmias	103 (38)	63 (36)	40 (40)	0.52
Indication for pacemaker:				
Acquired SSS	91 (33)	56 (32)	35 (35)	0.57
Acquired AV block	81 (30)	47 (27)	34 (34)	0.19
Surgical AV block	70 (26)	57 (33)	13 (13)	<0.001
Drug-refractory atrial arrhythmias or drug-related bradycardia	25 (9)	14 (8)	11 (11)	0.39
Surgical SSS	7 (3)	1 (1)	6 (6)	0.01
Initial pacing mode:				
Physiologic pacing (DDD, AAI, VDD)	239 (65)	113 (65)	66 (67)	0.86
Implantation technique:				
Endocardial leads	184 (67)	135 (77)	49 (49)	<0.0001
Epicardial leads	90 (33)	40 (23)	50 (51)	

Data are presented as n (%), unless stated otherwise. AV = atrioventricular; SSS = sick sinus syndrome.

2. Methods

For the present retrospective study, all adults with CHD and a history of pacemaker implantation were identified from the participating centers using the nationwide CONgenital CORvitia (CONCOR) registry in The Netherlands and a Belgian tertiary care center adult CHD database [11]. Patients with a primary electrical disease or cardiomyopathy were excluded from analysis. We also excluded patients with an implantable cardioverter defibrillator as we previously published our experience with this specific patient group [12]. Crosscheck with the local pacemaker registries of the four participating tertiary centers revealed a total of 274 patients. The central medical Ethics Committee in The Netherlands and the local Belgian Ethics Board approved the protocol. The authors of this manuscript have certified that they comply with the Principles of Ethical Publishing in the International Journal of Cardiology.

Data were collected from medical records and pacemaker databases. Baseline data prior to pacemaker implantation were registered from the patient records including, gender, congenital anatomic diagnosis, surgical procedures, and history of atrial arrhythmias. The complexity of the CHD diagnosis was defined as simple, moderate or complex according to the classification adopted at the American Heart Association Task Force on Adults with CHD [13]. Detailed information concerning the pacemaker implantation was recorded, including age at implantation, indication for pacemaker implantation, method of implant (endocardial/epicardial), pacing mode (AAI, VVI, DDD, or VDD), and periprocedural complications. Periprocedural pacemaker complications were defined as complications occurring in the first 30 days after initial pacemaker implantation. Follow-up data included late pacemaker complications (>30 days of implantation), major clinical complications and pacemaker reinterventions. Major clinical complications included endocarditis (not pacing system-related), hospitalization for heart failure, stroke, heart transplantation, aborted sudden cardiac death, and death.

Documented pacemaker complications were: bleeding (any swelling of the pocket with clinical suspicion of hematoma requiring intervention), pacing system-related endocarditis, erosion (skin penetration of the pacemaker requiring intervention), lead failure (leads repaired, repositioned, replaced, or abandoned due to fracture, insulation break, dislodgment, or abnormalities in pacing or sensing), pacemaker dysfunction/ early battery depletion (pacemaker malfunction requiring pacemaker replacement or early battery depletion necessitating replacement <3 years post implant), pacemaker migration (requiring pacemaker repositioning), pneumothorax (absence of lung markings over the lung ipsilateral to the pacemaker pocket assessed from x-ray), pocket infection (superficial wound infection), and ventricular arrhythmias (related to lead manipulation). Normal elective replacement of a pacemaker (>3 years post-implant) or pacemaker upgrade was not considered a pacemaker complication.

2.1. Statistical methods

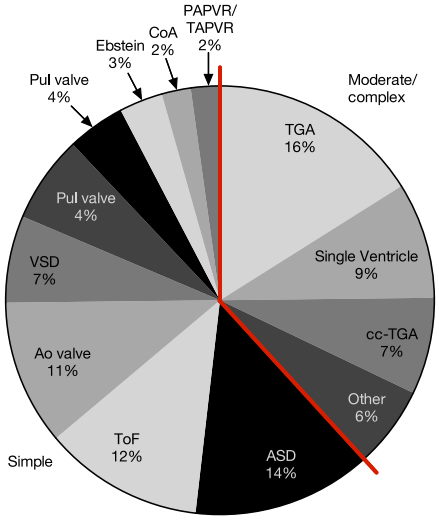
Continuous data are presented as mean ± SD. In the case of skewed data, medians and interquartile ranges (IQR) were used. Categorical variables are represented by frequencies and percentages. Comparison of continuous variables between groups was made by unpaired Student's t-tests. In the case of a skewed distribution, the Mann–Whitney U test was used. When comparing frequencies, the chi-square test or Fisher's exact test was used, where applicable.

Potential predictors of late pacemaker-related complications were identified by means of Cox regression models, and hazard ratios (HR) and 95% confidence intervals (95%CI) are reported. Variables with a $p < 0.10$ on univariable analysis were included in a multivariable model. Two-tailed probability values <0.05 were considered statistically significant. Statistical analysis was performed using the statistical package R (64 bit) for Mac, version 2.14.2.

3. Results

3.1. Patient characteristics, pacemaker indications, procedural details

The baseline characteristics of the 274 included patients with CHD are summarized in Table 1. Patients with complex CHD comprised 36% of the population, and were mainly patients with transposition of the great arteries (after atrial correction or congenitally corrected transposition) or single ventricle physiology (Fig. 1). The first implant for most patients occurred in adulthood (70%). Patients with complex CHD underwent primary pacemaker implantation at younger age compared to those with simple/moderate CHD (median age 23 versus 31 years, $p < 0.0001$). Furthermore, patients who received an epicardial pacing system were younger at implantation compared to those with an endocardial pacing system (median age 14 versus 31 years, $p < 0.0001$). The primary pacemaker devices were implanted between March 1972 and Jan 2009.



Ao valve = Aortic valve
ASD = Atrial Septal Defect
AVSD = Atrioventricular Septal Defect
cc-TGA = Congenitally corrected Transposition of the Great Arteries
CoA = Coarctation of the Aorta
Ebstein = Ebstein's anomaly
PAPVR/TAPVR = Partial Anomalous Pulmonary Venous Return / Total Anomalous Pulmonary Venous Return
Pul valve = Pulmonary valve
Single Ventricle = Single Ventricle physiology (e.g. Fontan)
TGA = Transposition of the Great Arteries
ToF = Tetralogy of Fallot
VSD = Ventricular Septal Defect

Fig. 1. Distribution of congenital anatomic diagnosis.