Outcomes of cardiac pacing in adult patients after a Fontan operation

Alexander C. Egbe, MD, MPH,[a] Geoffery D. Huntley[b] Heidi M. Connolly, MD,[a] Naser M. Ammash, MD,[a] Abhishek J. Deshmukh, MBBS,[a] Arooj R. Khan, MBBS,[a] Sameh M. Said, MD,[c] Emmanuel Akintoye, MD, MPH,[d] Carole A. Warnes, MD,[a,e] and Suraj Kapa, MD[a] *Rochester, MN and Detroit, MI*

Background Cardiac pacing can be challenging after a Fontan operation, and limited data exist regarding pacing in adult Fontan patients. The objectives of our study were to determine risk factors for pacing and occurrence of device-related complications (DRCs) and pacemaker reinterventions.

Methods We performed a retrospective review of Fontan patients from 1994 through 2014. We defined DRCs as lead failure, lead recall, cardiac perforation, lead thrombus/vegetation, or device-related infection, and cardiovascular adverse events (CAEs) as venous thrombosis, stroke, death, or heart transplant. Pacemaker reintervention was defined as lead failure or recall.

Results Of 439 patients, 166 (38%) had pacemakers implanted (79 during childhood; 87, adulthood); 114 patients (69%) received epicardial leads initially, and 52 (31%), endocardial leads. Pacing was initially atrial in 52 patients (31%); ventricular, 30 (18%); or dual chamber, 84 (51%). There were 37 reinterventions (1.9% per year) and 48 DRCs (2.4% per year). Pacemaker implantation during childhood was a risk factor for DRCs (hazard ratio, 2.01 [CI, 1.22-5.63]; $P = .03$). There were 70 CAEs (venous thrombosis, 5; stroke, 11; transplant, 8; and death, 46), yielding a rate of 3.5% per year. DRCs, CAEs, and reintervention rates were comparable for patients with epicardial or endocardial leads.

Conclusions More than one-third of adult Fontan patients referred to Mayo Clinic had pacemaker implantation. Epicardial leads were associated with high rate of pacemaker reinterventions but similar DRC rates in comparison to endocardial leads. (Am Heart J 2017;194:92-8.)

The Fontan operation is one of the most common palliative procedures for complex congenital heart disease.[1-3] After a Fontan palliation, patients have a high prevalence of atrial arrhythmias and symptomatic bradycardia, and most patients affected by these complications require cardiac pacing.[4-8] The American College of Cardiology/American Heart Association and the European Society of Cardiology guidelines recommend cardiac pacing for patients with congenital heart disease who have symptomatic bradycardia due to sinus node dysfunction or heart block.[7,8,9,10] However, cardiac pacing can be challenging after Fontan palliation because of limited access for endocardial pacing and the need for a thoracotomy or sternotomy for epicardial pacing in some patients.[11-13]

Several investigators have reported outcomes of cardiac pacing for patients with congenital heart disease.[14-16] However, there are limited data of outcomes of cardiac pacing in adult Fontan patients.[12,13] As a result, knowledge gaps exist regarding pacing in these patients, including determination of the optimal pacing method (epicardial vs endocardial), optimal pacing mode (single-chamber vs dual-chamber pacing), reintervention rates, and the risk of device-related complications (DRCs). Therefore, the purpose of this study was to address some of these knowledge gaps in pacing for adult Fontan patients.

Methods

Patient selection and data extraction

We identified all patients with a history of a Fontan operation followed at the Mayo Clinic Adult Congenital Heart Disease program in Rochester, MN, from January 1, 1994, through December 31, 2014. The patients were identified from the electronic medical records. The Mayo Clinic Institutional Review Board approved the study and

From the [a]Division of Cardiovascular Diseases, Mayo Clinic, Rochester, MN, [b]Mayo Medical School, Mayo Clinic College of Medicine, Rochester, MN, [c]Department of Cardiovascular Surgery, Mayo Clinic, Rochester, MN, [d]Department of Internal Medicine, Wayne State University/Detroit Medical Center, Detroit, MI, and [e]Division of Pediatric Cardiology, Mayo Clinic, Rochester, MN.

Funding: none.

Conflict of interest: none.

Submitted January 27, 2017; accepted August 23, 2017.

Reprint requests: Alexander C. Egbe, MD, MPH, Division of Cardiovascular Diseases, Mayo Clinic, 200 First St SW, Rochester, MN 55905.

E-mail: egbe.alexander@mayo.edu

0002-8703

http://dx.doi.org/10.1016/j.ahj.2017.08.019

waived written informed consent for those who provided research authorization. No extramural funding was used to support this work. The authors are solely responsible for the design and conduct of this study, all study analyses, and the drafting and editing of the paper.

The following information from the electronic medical record was reviewed: clinic notes, electrocardiograms, Holter monitor records, device interrogation reports, echocardiograms, electrophysiology study reports, and surgical records. The data collected included congenital anatomic diagnosis; types of Fontan connection and other cardiac surgical procedures; age at cardiac surgical procedure(s) and at pacemaker implant(s); pacemaker type, pacing mode, and pacing indications; type of device and leads implanted/explanted; DRCs; arrhythmia data; and patient status at the time of last data entry in the electronic medical records (alive, dead, or status post–heart transplant).

Study end points and definitions

The objectives of the study were to describe (1) the outcomes of pacing (ie, freedom from pacing, indications for pacing, risk factors for pacing for all adult Fontan patients, and cardiovascular adverse events [CAEs] for patients with pacemakers) and (2) occurrence of DRCs and pacemaker reintervention procedures. DRCs were defined as lead failure, lead recall, cardiac perforation, thrombus or vegetation on a pacing lead, or device-related infection. We assessed lead functionality by evaluating data on device interrogation and included analysis of lead impedance and sensed electrograms. Lead failure was defined as the presence of any of these features: failure to capture, failure to sense, abnormal pacing impedance, and electrical noise artifact.[17] The following were considered as pacemaker-related procedures: end-of-life generator change, lead failure, lead recall, lead or generator change during cardiac surgery, and pacemaker upgrade to a defibrillator. The end point of pacemaker reintervention was defined as lead failure or recall. A CAE was defined as venous thrombosis, stroke, death (all-cause mortality), or heart transplant. Pacemaker dependence was defined as >95% pacing in any device interrogation report. For each patient, the study period began at the first clinic visit after age 18 years and ended at the last clinic visit or device interrogation before December 31, 2014.

Statistical analysis

All statistical analyses were done with JMP software from SAS (version 10.0; SAS Institute Inc, Cary, NC). Categorical variables are reported as percentages, and continuous variables are reported as mean and SD. Categorical variables were compared by using the χ^2 test or Fisher exact test, and continuous variables were compared with a 2-sided, unpaired *t* test or Wilcoxon rank sum test as appropriate. The risk for each variable was expressed as a hazard ratio (HR) with the 95% CI. The freedom from cardiac pacing, freedom from pacemaker reintervention, and freedom from DRCs were assessed with the Kaplan-Meier method and compared using the log-rank test. The beginning of adulthood (age 18 years) was considered as time 0 or the beginning of the at-risk period in analyses of freedom from cardiac pacing, whereas the date of pacemaker implantation was considered as time 0 for the freedom from DRCs and freedom from reintervention analyses. All *P* values were 2-tailed, and *P* values <.05 were considered significant.

Results

Cardiac pacing

There were 439 adult Fontan patients from January 1, 1994, through December 31, 2014. The mean (SD) age of patients at the time of their first clinic visit was 26.4 (5.4) years (median 24 years, range 20-34 years), 251 (57%) were men, and 311 (71%) had the initial Fontan operation at Mayo Clinic. The most common diagnosis of congenital heart disease was tricuspid atresia (156 patients [36%]), the most common ventricular morphology was the left ventricle (296 patients [67%]), and the most common type of Fontan palliation was an atriopulmonary connection (325 patients [74%]) (Table I).

Among the 439 patients, 79 (18%) had their first pacemaker implanted prior to age 18 years. Another 87 patients (20%) had pacemakers implanted after the age of 18 years, and the mean duration from the beginning of adulthood (age 18 years) to the time of pacemaker implantation was 9.3 (3.8) years. Table II shows baseline pacemaker-related information for all patients (n = 166, 38% of the entire cohort) who had pacemaker implantation. There was no difference in the pacing indications between the patients that underwent pacemaker implantation before age 18 years (n = 79) and after age 18 years (n = 87): sinus node dysfunction 63% vs 67%, *P* = .09, high-grade second-degree or third-degree heart block 24% vs 21%, *P* = .12, and atrial arrhythmia 19% vs 31%, *P* = .06%. Of these 166 patients, 124 patients (75%) had their pacemaker implanted initially at Mayo Clinic. These 166 patients accumulated 1992 patient-years of pacing.

Postimplantation device interrogation reports were available for 116 patients. There was no difference in the clinical characteristics of the patients with available device interrogation reports (n = 116) and those without device interrogation reports (n = 50). At the time of implantation, the mean pacing threshold for atrial leads was 1.2 (0.3) V, whereas the mean pacing threshold for ventricular leads was 1.7 (0.4) V. There was no significant difference between the pacing threshold for endocardial atrial leads and epicardial atrial leads, 1.1 (0.3) and 1.3 (0.2) V, *P* = .08. Within a year after their pacemakers were implanted, 79 of 116 patients (68%) became pacemaker dependent, and this number increased to 94