Long-term atrial and ventricular epicardial pacemaker lead survival after cardiac operations in pediatric patients with congenital heart disease

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BACKGROUND Multiple cardiac operations and resultant myocardial scarring have been implicated in the overall reduced performance of epicardial pacing systems in patients with congenital heart disease (CHD).

OBJECTIVE The aim of the study is to evaluate long-term permanent epicardial pacing lead survival in patients with CHD who had epicardial lead placement in association with surgical repair or palliation.

METHODS A retrospective review of patients who had implantation of epicardial pacing systems between January 1984 and June 2010 was conducted. Inclusion criteria were as follows: (1) presence of CHD and (2) cardiac operation(s) concomitant with or before initial permanent epicardial lead implantation. Patients were divided into 2 anatomical groups: single ventricle (SV) and biventricle (Bi-V).

RESULTS Epicardial leads were implanted in 663 patients during the study period. One hundred fifty-five patients (76 SV [49%] and 79 Bi-V [51%]) were included, resulting in 259 leads and 946 lead-years of follow-up. There were 2 deaths and 8 infections attributable to pacemaker placement. Overall atrial lead survival at 1, 2, 5, and 10 years (99%, 93%, 83%, and 72%) was comparable with ventricular lead survival (97%, 90%, 74%, and 60%) ($P = .540$) and was also similar between SV and Bi-V patients. Cox regression analysis demonstrated that SV palliation and an earlier era of lead implantation (1984–1999) was significantly associated with ventricular, but not atrial, lead malfunction.

CONCLUSION Epicardial leads had acceptable longevity despite cardiac operations for complex CHD, suggesting the long-term reliability of this pacing method.

KEYWORDS Pediatrics; Pacing; Congenital heart disease; Fontan procedure

ABBREVIATIONS **Bi-V** = biventricle; **CHD** = congenital heart disease; **ET** = energy threshold; **IQR** = interquartile range; **NSE** = non–steroid eluting; **SE** = steroid eluting; **SV** = single ventricle

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Introduction

Cardiac pacing after surgery for congenital heart disease (CHD) is commonly indicated for bradycardia produced by either sinus node dysfunction or atrioventricular block.[1] Epicardial pacing systems are often used in children because of small patient size, intracardiac right to left shunts that risk potential thromboembolic events, or absence of systemic venous access to the chamber requiring pacing. Epicardial pacing has some advantages over transvenous pacing, including the avoidance of both abnormal venous anatomy related to structural heart disease and the risk of thrombus formation.[2,3] Conversely, previous studies have demonstrated that epicardial leads have a higher fracture rate and higher pacing and lower sensing thresholds.[4,5] The epicardial approach is inherently invasive, potentially requiring a full or partial sternotomy or thoracotomy along with further surgical dissection to expose the atrium and ventricle.[6,7] In patients with prior cardiac surgery including those with complex CHD who underwent staged operations culminating in the Fontan procedure, the epicardium is often covered with scar tissue and adhesions that may result in higher pacing thresholds, potentially affecting lead performance.[8–10] Although advances in epicardial lead technology have demonstrated improved lead performance, prior descriptions of the long-term survival of epicardial leads in children have included mixed cohorts of patients with and without CHD.[2,6,11–13] The significance of cardiac operations for pediatric CHD on epicardial lead survival remains uncertain.

The purpose of this study was to assess: (1) the long-term survival of epicardial pacing systems in patients who have

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undergone cardiac operations; (2) long-term epicardial lead survival in patients with single-ventricle (SV) CHD vs those with bi-ventricle (Bi-V) CHD; and (3) morbidity and mortality associated with epicardial lead implantation.

Methods

The institutional review board approved a retrospective review and granted a waiver for patient consent.

A complete search of the cardiac surgical and pacemaker databases identified all patients who underwent permanent epicardial pacemaker implantation at the Children's Hospital of Philadelphia between January 1, 1984, and June 3, 2010. Inclusion criteria were as follows: (1) presence of CHD and (2) cardiac operation(s) concomitant with or before initial permanent epicardial lead implantation. The study subjects were categorized into 2 cohorts for analysis: (1) SV and (2) Bi-V physiology groups. Subjects were excluded if (1) epicardial pacing was performed without concomitant CHD or prior/simultaneous cardiac operations or (2) leads were implanted by another institution or on a transplanted heart.

Demographic information, clinical course, epicardial lead type and performance data, epicardial lead location, and implant techniques were obtained from patient medical and surgical records. Primary epicardial leads were defined as the implantation of atrial and/or ventricular leads at the time of initial CHD surgery. Successive epicardial leads were defined as the implantation of additional atrial and/or ventricular leads at the time of reoperation for lead malfunction. Medical records including medications used and laboratory and radiological results were reviewed for epicardial pacemaker–related adverse events including superficial or deep infection, pleural and/or pericardial effusion, length of hospitalization, and mortality. Duration of pleural or pericardial drainage was defined as the total number of days from lead implantation to removal of final chest tube or drain or final thoracentesis performed during admission for pacemaker implantation. Hospital length-of-stay was defined as total days from lead implantation to hospital discharge. Infection of the pacing system was defined according to published criteria.[14]

Operative technique

Epicardial leads were implanted using standard surgical techniques. The surgical approach was chosen based on prior cardiac operations, cardiac anatomy, and any concomitant operation at the time of lead placement. The atrial lead was affixed to the right or left atrium depending on the best pacing and sensing thresholds acquired. The ventricular lead was attached to the right or left ventricle depending on the surgical approach and surgeon preference. The types of epicardial leads implanted were based on surgeon's discretion. Steroid-eluting (SE) leads (St Jude Medical Inc, (Saint Paul, MN)) 1043K; Medtronic Inc, (Minneapolis, MN) 4965, 4968 were placed starting in 1994 at our institution. Non–steroid-eluting (NSE) leads (Cardiac Pacemakers 4315 (Cardiac Pacemakers Inc, Saint Paul, MN); Medtronic 4951, 5069, 5071, 6917) were also used throughout the study period.

Pacemaker and epicardial lead analysis and follow-up

Pacemaker and lead measurements were determined using a pacing system analyzer at implantation (Medtronic 5311, 5300, or Pacesetter, Sylmar, CA). Patients were generally followed up at 7 days; 1, 3, and 6 months; and then every 6 months with interrogation using telemetry and electrocardiograms. The following recorded lead parameters were analyzed: (1) sensed P- and R-wave amplitudes (in millivolts) of underlying rhythm, when present; (2) pacing lead impedance (in ohms) conventionally measured at a paced output of 5 V and a pulse width of 0.5 ms; (3) sensing threshold, defined as minimum atrial or ventricular intracardiac signal amplitude in millivolts required to inhibit a demand pacemaker; and (4) pacing threshold, defined as the lowest programmable voltage at which there was consistent capture.[15] To facilitate the comparison of acute and chronic pacing thresholds, the energy threshold (ET), which is defined as the least amount of energy that produces a consistent capture outside the refractory period, was calculated according to the following formula[15]:

$$\mathrm{ET}(\mu\mathrm{J}) = [\mathrm{V}\ (\mathrm{V})^2 \times \text{pulse duration (ms)} \times 10^6]/\left[\text{resistance } (\Omega) \times 1000\ \mathrm{ms/s}\right]$$

Pacing and sensing thresholds, lead impedance, and ET were compared at the time of implantation and at the 1-, 2-, 5-, and 10-year time points between the SV and Bi-V groups. Similar data were extracted and calculated for subsequent pacing systems in individual patients.

Outcome variables

The primary outcome was the time to epicardial atrial and/or ventricular pacing lead malfunction from initial lead implantation in SV and Bi-V physiology patients. Lead function parameters at the time of implantation and follow-up along with factors associated with lead malfunction were compared secondarily.

Lead malfunction was defined by the need to replace or abandon a lead owing to any of the following: inappropriate elevation of pacing thresholds, loss of capture or sensing, exit block, lead displacement, conductor fracture, insulation break, or phrenic or myopotential stimulation. Data were censored for death, orthotopic heart transplantation, and lost to follow-up, including follow-up at outside institutions.

Statistical analysis

Time-independent continuous variables were expressed in medians with interquartile ranges (IQRs) and compared using the Wilcoxon rank sum test. Categorical variables were expressed as frequency counts and percentages and compared using the χ^2 test or the Fisher exact test. First, atrial and ventricular lead outcomes were compared between SV and Bi-V groups using Kaplan-Meier survival curves and the log-rank test. Then, Cox proportional hazards models were generated to compare pacing lead outcomes between SV and Bi-V groups while adjusting for possible confounding variables. These included age at implantation, race, sex,