



# Longitudinal Outcomes of Epicardial and Endocardial Pacemaker Leads in the Adult Fontan Patient

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Received: 22 December 2017 / Accepted: 1 June 2018 / Published online: 14 June 2018  
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## Abstract

Placement of an epicardial pacemaker system is often preferred over an endocardial system in patients who have undergone a Fontan operation, but data are limited on how these two systems perform over time in patients with Fontan palliation. We performed a retrospective review of adults with Fontan palliation who had pacemaker implantation and interrogation data at Mayo Clinic from 1994 to 2014. Lead parameters, pacing mode, and polarity were collected at the earliest device interrogation report. Clinic notes and device interrogation reports were reviewed at implantation, 6 months, and yearly after implantation to determine impedance, capture threshold (CT), and energy threshold (ET). There were 87 patients with 168 leads in the study cohort. The mean follow-up time was 7.7 years (6 months–19 years). There were 143 epicardial leads (57 atrial and 86 ventricular) and 25 endocardial leads (20 atrial and 5 ventricular). There was no difference in the baseline lead parameters between epicardial and endocardial leads for impedance ( $610 \pm 259$  versus  $583 \pm 156 \Omega$ ,  $p=0.93$ ), CT ( $2.0 \pm 1.3$  versus  $1.8 \pm 1.3$  V,  $p=0.28$ ), or ET ( $7.1 \pm 12.5$  versus  $6.8 \pm 18.1 \mu\text{J}$ ,  $p=0.29$ ). Compared to endocardial leads, ventricular epicardial leads were associated with temporal decrease in impedance and increase in ET. Regarding clinical outcomes, epicardial leads had higher rates of failure but similar generator longevity in comparison to endocardial leads. Ventricular epicardial leads were associated with temporal decrease in impedance and increase in ET. Epicardial leads had a higher rate of failure but similar generator longevity compared to endocardial leads.

**Keywords** Fontan palliation · Adult congenital heart disease · Pacemaker · Epicardial leads · Transvenous leads · Capture threshold

## Introduction

The Fontan operation is the most common palliation for complex congenital heart disease [1–3]. There has been a significant improvement in post-Fontan survival over the last 4 decades mostly due to improvement in surgical technique and perioperative care [1–4]. As more patients survive into adulthood after Fontan palliation, there is an increasing need for cardiac pacing because of a high burden of atrial arrhythmia and symptomatic bradycardia in this population [4–8].

Cardiac pacing is challenging in the Fontan circulation due to the limited access for endocardial pacing and the

need for thoracotomy or sternotomy for epicardial pacing [9, 10]. However, Fontan patients are known to have numerous suture lines with associated scarring of the epicardium, theoretically creating a substrate for increased energy thresholds (ETs) and shorter battery/generator longevity with epicardial leads [11]. Several studies have reported lead outcomes in patients with congenital heart disease [12–15]. Unfortunately, the adult Fontan patients were largely underrepresented in these studies. A few studies have evaluated lead function specifically among Fontan patients [16–19]. However, these studies focused specifically on a certain pacing method (i.e., only epicardial pacing) or certain pacing location (i.e., atrial pacing), and many of these studies were underpowered.

Knowledge gaps remain in determining the optimal pacing method in this population, and a comparative study of outcomes of epicardial versus endocardial leads in the adult Fontan population has not been performed. The purpose of this study is to compare baseline and longitudinal changes

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in pacing lead parameters and outcomes between epicardial and endocardial leads.

## Methods

### Patient Selection

This is a retrospective review of adult patients (age > 18 years) with a history of a Fontan operation and pacemaker implantation followed at the Mayo Clinic Adult Congenital Heart Disease program from January 1994 to December 2014. Based on these criteria, we identified 166 patients, of which 87 of them had serial device interrogation reports available in the medical record. These 87 patients comprised the study population. The Mayo Clinic Institutional Review Board approved this study.

### Data Collection

The following health records were reviewed: clinic notes, surgical records, electrophysiology procedure notes, electrocardiogram, Holter monitors, and device interrogation reports. The lead outcomes analyzed were lead failure and battery/generator longevity. Lead failure was defined as a sudden increase in long-term pacing and high-voltage impedance (> 50% compared with chronic values) and electrical noise artifact, or both [20]. The following pacemaker and lead parameters were collected: type of lead (epicardial versus endocardial), location of lead (atrial versus ventricle), make of lead (i.e., Medtronic), pacing mode (single [AAI or VVI], double [DDD], or switch [AAI-DDD]), pacemaker output parameters (amplitude, pulse width, sensitivity), and pacing polarity (unipolar or bipolar). Serial device interrogation reports from the time of device implantation to last follow-up were reviewed, and the following indices were collected: impedance ( $\Omega$ ), capture threshold (CT, V), and capture pulse width (ms). Lead function indices were compared at the following time points: within 30 days of lead implantation, at 6 months after implantation, and then annually until the last follow-up. For the annual interrogation report, we included all interrogations performed within 3 months of the yearly mark from the time of implantation. For instance, all device interrogations performed from 21 to 27 months were included in the censor for interrogation at 2 years. An ET was calculated to provide the most accurate reflection of long-term pacing energy demand that incorporates all three pacing parameters (amplitude, pulse width, and impedance). ET was calculated according to the following formula [21]:

$$\text{Energy threshold } (\mu\text{J}) = [\text{threshold}^2(\text{V}) \times \text{pulse width (ms)} \times 10^6] / [\text{resistance } (\Omega) \times 1000 \text{ ms/s}]$$

## Statistical Analysis

All statistical calculations were performed with the JMP version 10.0 software (SAS Institute Inc., Cary, NC, USA). Categorical variables were expressed as percentages while continuous variables were expressed as mean  $\pm$  standard deviation. Comparison of categorical variables was performed using Chi-square test or Fisher exact test, while comparison of continuous variables was performed with two-sided unpaired Student *t* test or Wilcoxon rank sum test as appropriate. Changes in values from the earliest interrogation to the latest interrogation (Table 4) were compared using matched pairs test. Changes in values over time (Table 5) were compared using a repeated measures best fit model. All *p* values were two sided, and *p* values  $\leq 0.05$  were considered significant.

## Results

A total of 87 patients met the inclusion criteria for the study. The mean age at initial Fontan operation was  $10 \pm 7$  years, mean age at the time of pacemaker implantation was  $21 \pm 11$  years, and 47 (54%) were men. The mean follow-up time was 7.7 years (6 months–19 years), although in 60 leads, data are only available at initial lead placement. This did not differ based on lead type or location. The most common congenital heart disease diagnosis was tricuspid atresia 31 (36%) followed by double inlet left ventricle 26 (30%) and pulmonary atresia 11 (14%). The most common type of Fontan connection was atriopulmonary Fontan connection 64 (74%), followed by lateral tunnel/Intraatrial conduit Fontan 15 (17%), and extracardiac Fontan 8 (9%). The indications for pacemaker implantation were sinus node dysfunction 58 (66%), heart block 25 (29%), and need for antiarrhythmic therapy during Fontan conversion operation 4 (5%).

Table 1 shows baseline information for all leads. The 87 patients enrolled in the study had 168 leads. There were 143 epicardial leads in 74 patients, and 25 endocardial leads in 19 patients. There were 6 patients who had both epicardial and endocardial leads placed throughout the study period. 95% of leads were Medtronic. Among epicardial leads, the most common atrial lead types were bipolar, suture-on 4968 (39%) and bipolar, fish-hook 4951 (37%), and the most common ventricular lead types were bipolar, screw-in 5071 (44%), and bipolar, suture-on 4968 (17%). Among endocardial leads, the most common atrial lead type was bipolar, screw-in 5076 (29%), and all ventricular leads were bipolar, suture-on 4194. There were 77 (46%) atrial leads and 96 (54%) ventricular leads. The

most common pacing mode in all leads was DDD (55%). Overall, epicardial leads were associated with higher rate of lead failure (20 versus 17%,  $p=0.04$ ) but there was no significant difference in battery longevity between epicardial and endocardial leads ( $6.1 \pm 1.9$  versus  $6.6 \pm 3.2$  years,  $p=0.07$ ).

Overall, there was no significant difference in the pacemaker parameters between epicardial and endocardial leads.

However, bipolar pacing mode (61 versus 83%,  $p=0.05$ ) were used more commonly in the epicardial position compared with endocardial. Tables 2 and 3 demonstrate pacemaker parameters for atrial and ventricular paced leads, respectively. There was no difference in output measurements of amplitude, pulse width, sensitivity, or percent of leads in bipolar pacing mode between epicardial and endocardial leads based on location of lead. Among atrial

**Table 1** Baseline characteristics of all leads

	Total ( $n=168$ )	Epicardial ( $n=143$ )	Endocardial ( $n=25$ )	$p$ Value
Number of patients	87	74	19	
Age at Fontan	$10.0 \pm 7.4$	$9.8 \pm 7.5$	$13.8 \pm 2.1$	0.07
Age at PPM placement	$21.4 \pm 11.7$	$20.4 \pm 10.8$	$43.1 \pm 7.1$	<0.001
Location of lead				
Atrial (%)	77 (46)	57 (40)	20 (80)	<0.001
Ventricle (%)	91 (54)	86 (60)	5 (20)	<0.001
Mode				
Single, AAI or VVI (%)	53 (33)	37 (27)	16 (67)	<0.001
Dual, DDD (%)	87 (55)	82 (61)	5 (21)	<0.001
Switch, AAI-DDD (%)	19 (12)	16 (12)	3 (13)	1.0
Amplitude (V)	$4.2 \pm 1.4$	$4.2 \pm 1.4$	$4.2 \pm 1.4$	0.96
Pulse width (ms)	$0.52 \pm 0.25$	$0.53 \pm 0.26$	$0.51 \pm 0.15$	0.77
Bipolar pace polarity (%)	85 (63)	70 (61)	15 (83)	0.05
Age of lead at parameter measurements (years)	$2.9 \pm 4.5$	$2.9 \pm 4.5$	$2.9 \pm 4.5$	0.96

*ms* milliseconds, *mV* millivolts, *PPM* permanent pacemaker, *V* volts

**Table 2** Pacing parameters for atrial leads

Mode	Total ( $n=77$ )	Epicardial ( $n=57$ )	Endocardial ( $n=20$ )	$p$ Value
Single, AAI (%)	24 (33)	10 (19)	14 (74)	<0.001
Dual, DDD (%)	40 (56)	36 (68)	4 (21)	<0.001
Switch, AAI-DDD (%)	8 (11)	7 (13)	1 (5)	0.67
Amplitude (V)	$3.9 \pm 1.4$	$3.8 \pm 1.4$	$4.1 \pm 1.5$	0.57
Pulse width (ms)	$0.45 \pm 0.09$	$0.44 \pm 0.78$	$0.48 \pm 0.10$	0.07
Sensitivity (mV)	$0.64 \pm 0.54$	$0.65 \pm 0.60$	$0.60 \pm 0.34$	0.90
Bipolar pace polarity (%)	41 (67)	30 (64)	11 (78)	0.35

**Table 3** Pacing parameters for ventricular leads

Mode	Total ( $n=91$ )	Epicardial ( $n=86$ )	Endocardial ( $n=5$ )	$p$ Value
Single, VVI (%)	29 (33)	27 (33)	2 (40)	1.0
Double, DDD (%)	47 (54)	46 (56)	1 (2)	0.20
Switch, AAI-DDD (%)	11 (13)	9 (11)	2 (40)	0.11
Amplitude (V)	$4.4 \pm 1.4$	$4.4 \pm 1.4$	$4.9 \pm 0.25$	0.56
Pulse width (ms)	$0.58 \pm 0.32$	$0.58 \pm 0.32$	$0.60 \pm 0.27$	0.95
Sensitivity (mV)	$2.5 \pm 1.5$	$2.5 \pm 1.5$	$2.4 \pm 1.9$	0.61
Bipolar pace polarity (%)	44 (60)	40 (58)	4 (80)	0.15

*ms* milliseconds, *mV* millivolts, *V* volts

leads, endocardial leads were more likely to have a pacing mode of AAI compared to epicardial leads (74 versus 19%,  $p < 0.001$ ).

Table 4 shows absolute change in lead measurements from earliest device interrogation and latest device interrogation, expressed as latest interrogation minus earliest interrogation. Among the epicardial ventricular leads, there was a temporal decrease in impedance ( $-120 \pm 263 \Omega$ ,  $p = 0.01$ ), and increase in ET ( $6.7 \pm 15 \mu\text{J}$ ,  $p = 0.01$ ). There were no temporal changes in impedance and ET among epicardial atrial leads and endocardial leads of any type.

Table 5 shows changes in lead measurements as a trend over time, expressed as change in value per year. Atrial epicardial leads were associated with a decrease in impedance ( $-18 \pm 3.9 \Omega$ ,  $p < 0.0001$ ) on average from year-to-year. Atrial endocardial leads were associated with an increase in impedance ( $7.2 \pm 3.7 \Omega$ ,  $p = 0.05$ ) and minor decrease in CT ( $0.05 \pm 0.02 \text{ V}$ ,  $p = 0.0175$ ) per year. Ventricular epicardial leads had a significant decrease in impedance ( $-13 \pm 4.0 \Omega$ ,  $p = 0.0009$ ) and minor decrease in CT ( $-0.04 \pm 0.02 \text{ V}$ ,  $p = 0.0399$ ) from year-to-year. The only significant

difference between epicardial and endocardial leads was in atrial impedance. Figures 1 and 2 demonstrate lead measurements based on lead location and lead type throughout the study period for the various follow-up time points.

### Discussion

This study is a retrospective review of lead characteristics and pacemaker parameters of 168 pacing leads implanted in 87 adult Fontan patients followed for 7.7 years at a tertiary Adult Congenital Heart Disease center. The main findings are as follows: (1) epicardial leads had temporal decrease in impedance and increase in ET in comparison to endocardial leads; (2) epicardial leads had higher rates of lead failure but similar battery/generator longevity in comparison to endocardial leads; and (3) among epicardial leads, ventricular leads had higher impedance, CT, and ET in comparison to atrial leads.

Lower pacing thresholds will theoretically result in longer lead longevity, as this would allow for lower output

**Table 4** Difference in lead measurements between earliest interrogation and latest interrogation

Atrial	Change, $\Delta$ , total atrial	$\Delta$ , Atrial epicardial	$\Delta$ , Atrial endocardial
Impedance ( $\Omega$ )	$-34 \pm 227$	$-39 \pm 256$	$-23 \pm 146$
Capture threshold (V)	$0.14 \pm 1.3$	$0.33 \pm 1.4$	$-0.37 \pm 1.13$
Energy threshold ( $\mu\text{J}$ )	$1.8 \pm 10$	$2.8 \pm 12.1$	$-0.50 \pm 2.2$
Years between initial and last	$5.9 \pm 4.0$	$5.5 \pm 4.0$	$6.7 \pm 4.0$
Ventricular	$\Delta$ , Total ventricular	$\Delta$ , Ventricular epicardial	$\Delta$ , Ventricular endocardial
Impedance ( $\Omega$ )	$-120 \pm 263^*$	$-119 \pm 265^*$	$-163 \pm 252$
Capture threshold (V)	$0.30 \pm 1.3$	$0.28 \pm 1.3$	$0.70 \pm 0.57$
Energy threshold ( $\mu\text{J}$ )	$6.7 \pm 15^*$	$6.8 \pm 15^*$	$4.4 \pm 5.3$
Years between initial and last	$5.3 \pm 4.3$	$5.3 \pm 4.3$	$3.5 \pm 2.1$

Expressed as “latest” value minus “earliest” value. There were no significant differences by type of lead

\*Designates  $p \leq 0.05$  significant change from earliest interrogation

**Table 5** Trends in lead measurements from year-to-year over time

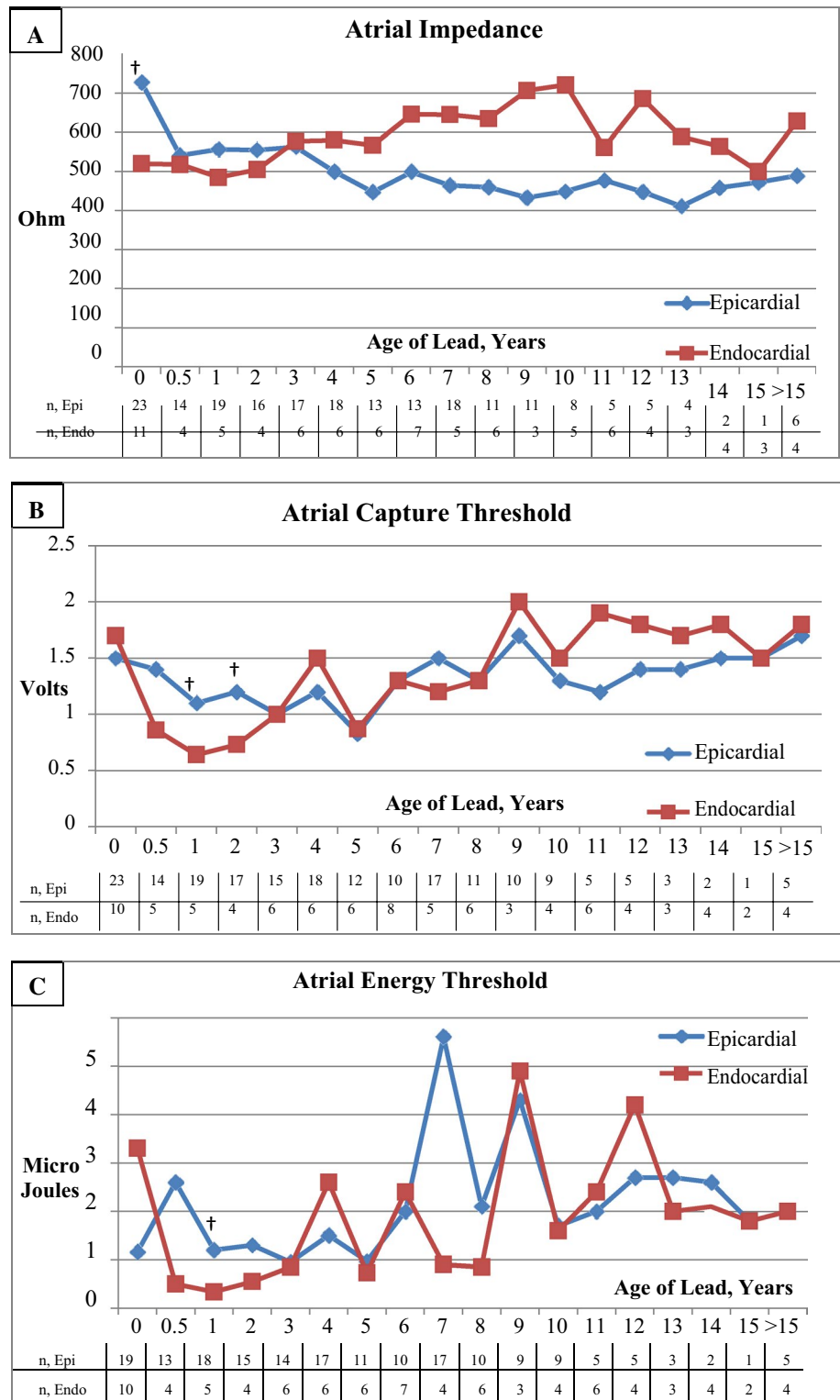
	Impedance ( $\Omega$ ) Change, $\Delta$ , per year	Capture threshold (V) $\Delta$ per year	Energy threshold ( $\mu\text{J}$ ) $\Delta$ per year
Atrial	$-7.8 \pm 2.9^{*+}$	$0.03 \pm 0.01^*$	$0.13 \pm 0.07$
A epicardial	$-18 \pm 3.9^*$	$0.01 \pm 0.02$	$0.17 \pm 0.11$
A endocardial	$7.2 \pm 3.7^*$	$0.05 \pm 0.02^*$	$0.06 \pm 0.06$
Ventricular	$-13 \pm 4.0^*$	$-0.04 \pm 0.02^*$	$-0.43 \pm 0.25$
V epicardial	$-13 \pm 4.0^*$	$-0.04 \pm 0.02^*$	$-0.40 \pm 0.25$
V endocardial	$2.8 \pm 4.4$	$-0.19 \pm 0.24$	$-3.9 \pm 4.0$

A atrial, v ventricular

\*Designates  $p \leq 0.05$  significant trend over time

+Designates significant difference between epicardial and endocardial

**Fig. 1** Atrial epicardial versus endocardial leads. Comparison by lead type of lead measurements of impedance (a), capture threshold (b), and energy threshold (c) at the various follow-up time points throughout the study period for atrial located leads. *Endo* endocardial, *epi* epicardial, *n* number. †Designates  $p \leq 0.05$ , epicardial versus endocardial

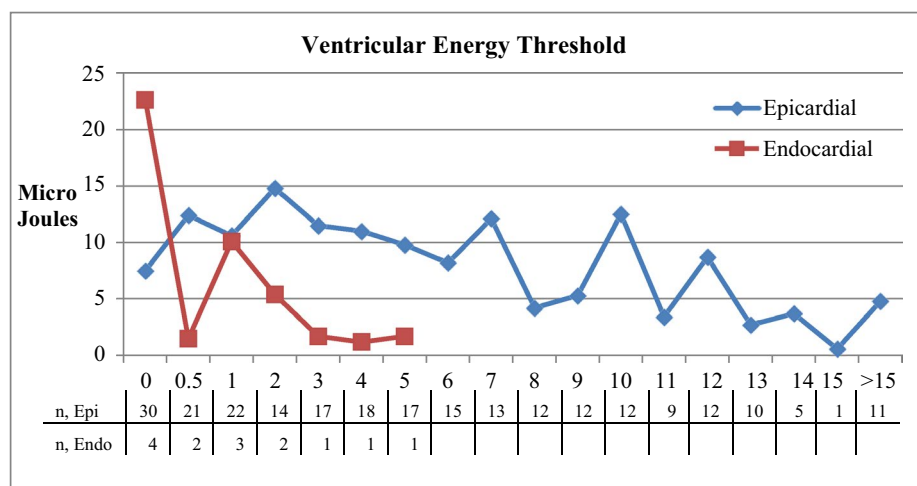
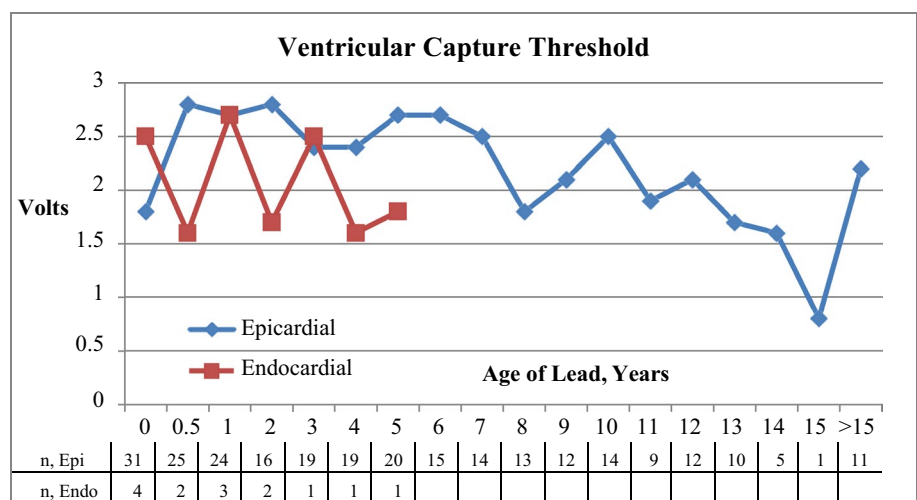
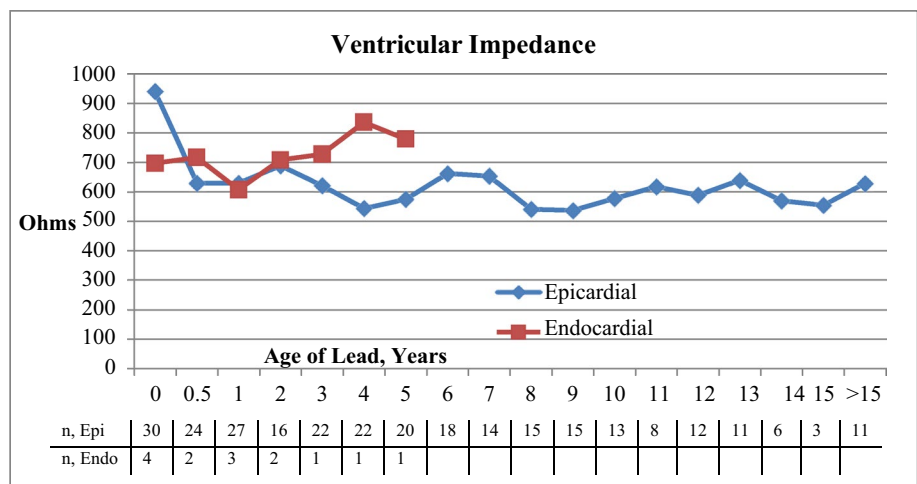


values, which prolongs the life of the generator and may decrease the frequency of interventions for battery changes [22]. Thus, use of leads that sustain lower pacing thresholds should improve battery life, although we did not see a

significant difference in battery life and need for generator change between those with epicardial versus endocardial leads.

Epicardial pacing is the most common method used in the patients with Fontan palliation, and theoretically epicardial

**Fig. 2** Ventricular epicardial versus endocardial leads. Comparison by lead type of lead measurements of impedance (a), capture threshold (b), and energy threshold (c) at the various follow-up time points throughout the study period throughout the study period throughout the study period throughout the study period. *Endo* endocardial, *epi* epicardial, *n* number. †Designates  $p \leq 0.05$ , epicardial versus endocardial



pacing should decrease the risk of thromboembolism, since there is no lead within the venous system [13, 23–25]. The limitations of epicardial pacing, however, are the need for sternotomy or thoracotomy and the inability to identify optimal pacing site due to scarring [12, 13, 25].

In the current study, ventricular epicardial leads were associated with temporal decrease in impedance and an increase in ET. The lead performance parameters for epicardial and endocardial leads in our study were comparable to data from prior studies conducted in the congenital

heart disease population, including studies of Fontan patients [12, 17–19, 26]. However, temporal changes in lead function parameters described in previous studies have been somewhat conflicting. Zhang and colleagues studied 35 patients with congenital heart disease and epicardial pacemakers and found no difference in CT or impedance during a follow-up period of 4 years [26]. Similarly, Lau and colleagues found no significant difference in the impedance and ET of epicardial ventricular leads at 5 years follow-up among patients with congenital heart disease [12]. Specific to the Fontan population, there are limited data on lead performance. Takahashi and colleagues found no difference in atrial epicardial thresholds over 3½ years of follow-up [17]. In contrast, Cohen and colleagues reported a decrease in ET among atrial epicardial leads but an increase in ET among ventricular epicardial leads during 2 years of follow-up in Fontan patients [18]. The differences in the reported lead function data from longitudinal previous studies may be due to differences in patient age, lead design type, and percentage of time the patients were paced.

In terms of clinical outcomes, our study showed that implantation of epicardial lead was associated with higher rate of lead failure. In spite of the differences in temporal changes in pacemaker output parameters, there was no significant difference in battery/generator longevity between endocardial and epicardial leads in the current study. Similar to the current study, previous studies have reported a higher risk of lead failure in patients with epicardial leads [22, 27–30]. Other studies did not find any difference in outcomes between epicardial and endocardial leads [17]. We speculate that these differences in lead performance outcomes reported in the literature may, to a large extent, be due to differences in patient age, surgical area, and percentage of time that the patients were paced. The current study was based exclusively on the cohort of adult patients with prior Fontan palliation making the data more reflective of outcome in this population.

The authors of this study recently published a manuscript in the *American Heart Journal* using the same cohort of patients [31]. The main conclusions were that epicardial leads were associated with a higher rate of lead failure compared to endocardial leads, but there was no difference in the overall device-related complication rate between the two systems. The study could only speculate on mechanisms behind those clinical outcomes. The current article extends the conclusions by investigating how the leads function in Fontan patients and the mechanism of lead failure—rather than gradually increasing over time, perhaps there is an acute increase in CT that prompts symptoms, patient presentation to clinic, and lead interrogation.

## Limitations

This is a retrospective study of an older cohort of Fontan patients followed at a single tertiary center and as a result it is subject to the bias inherent in this type of study design. The data are culled from procedures that were performed over 2 decades making it difficult to draw inferences because of improvement in lead technology or operator expertise over time. Also our study was under powered because of the under representation of certain lead types such as transvenous leads. Because transvenous leads are likely to be used in old-fashioned Fontan types (atrio-pulmonary anastomosis and lateral tunnel total cavopulmonary connection), the low number of endocardial ventricular leads limits the conclusions in patients with those types of Fontan surgeries. Interrogation reports were sporadically reported in the medical records that were reviewed, yielding a great variability in follow-up time. Finally, we are unable to correct for the impact of percentage of time paced on pacemaker and lead outcomes. All these factors limited the generalizability of our data.

## Conclusion

Based on a cohort of adult Fontan patients followed at a single center, our study showed that epicardial leads had temporal decrease in impedance and increase in ET in comparison to endocardial leads. With regard to clinical outcomes, epicardial leads had higher rates of lead failure but similar battery/generator longevity in comparison to endocardial leads.

**Author Contributions** GDH contributed to concept/design, data analysis/interpretation, drafting article, and statistics. AJD contributed to concept/design and critical revision of article. CAW contributed to concept/design and approval of article. SK contributed to concept/design and critical revision of article. ACE contributed to concept/design, data interpretation, drafting article, and critical revision of article.

## Compliance with Ethical Standards

**Conflict of interest** The authors have no conflicts of interest.

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