Performance of bipolar steroid-eluting epicardial leads in the young—12 years single-center experience

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Background: To document a single-center experience for patients implanted with bipolar, steroid-eluting epicardial leads.

Methods: Retrospective review for patients with epicardial pacemakers implanted secondary to either postoperative or congenital complete heart block (CCHB), over a 12 years study period. All patients were identified through a surgical database.

Results: Forty-one patients met the inclusion criteria, with 26 patients following postoperative repair and 15 patients with CCHB with a total of 68 epicardial leads. The mean follow-up duration was 4.5±3 years. The mean weight and age at implantation were 6.4±5.3 kg and 1.2±2.1 years, respectively. The mean generator longevity was at 5.5±1.1 years. Twenty-nine patients (71%) received ventricular single-chamber device and another 12 patients (29%) had a dual-chamber pacemaker at initial implant. Fifteen patients (37%) required pacing system reinterventions. The median lead failure time was 51 months (range: 5 to 107 months). The incidence of lead events was 10%. The actuarial freedom from reoperation at 9.8 years was 76.5%. Two patients died from complications of cardiomyopathy.

Conclusions: Medtronic 4968 lead performance was excellent. Despite the young cohort, the incidence of lead failure was low. Indeed, bipolar steroid-eluting leads offers a reliable pacing option for the young, preserving venous route for later use.

Keywords: Epicardial leads; postoperative heart block; congenital atrioventricular block

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Introduction

The most common indications for permanent pediatric cardiac pacing include post-operative advanced second or third-degree atrioventricular block (AVB), congenital complete heart block (CCHB), and infrequently symptomatic sinus node dysfunction (SND) (1-3). Pacing system route depends upon patient's size, anatomy and/or concomitant cardiac surgery (1,3,4-10). The performance of epicardial pacing leads has been greatly refined secondary to advancements in epicardial pacing lead engineering, especially steroid-eluting leads, and the bipolar arrangement of tip electrodes (4). Given the smaller venous diameters, contraindications of transvenous pacing in many complex congenital heart diseases (CHD), and complication concerns including endocarditis, valvar damage as well as deep vein thrombosis, epicardial pacing has been frequently implanted in the young (3,5). Furthermore, since cardiac pacing is usually required throughout life, and in view of the limited lead survival throughout, pediatric patients expect lead extraction and reimplantation several times during their lifetime and as such it is of utmost importance to save the venous access for future use (3).

Certainly, epicardial pacing have been the most common form of pediatric cardiac pacing at Chest Diseases Hospital (CDH) in Kuwait, the only pediatric cardiac surgical center in the country. The purpose of this report is to present our epicardial pediatric cardiac pacing experience in Kuwait and compare these findings with other published reports. Additionally, frequency of epicardial pacing system revisions and modes of failure is examined, along with the long-term pacing complications. We present the following article in accordance with the STROBE reporting checklist (available at http://dx.doi.org/10.21037/jxym-21-20).

Methods

Study population

This is a retrospective study done at CDH from September 2008 until January 2020. Inclusion criteria included pediatric patients (<16 years old) requiring permanent pacemakers due to persistent post-operative advanced second or third-degree AVB or due to CCHB. A surgical database that includes all congenital heart surgeries performed in Kuwait, was used to identify patients that fulfill the inclusion criteria. Patients with a transvenous pacing system, SND, or pacemaker implantation (PMI) performed elsewhere were excluded. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). The research protocol was approved by the ethics committee at both Kuwait University Faculty of Medicine and the Ministry of Health (registration number 2019/1012).

Surgical technique

Subxiphoid incision and partial lower sternotomy were performed for ventricular-only system, and partial or full median sternotomy was performed for dual-chamber devices to expose the anterior surface of the right ventricle (RV) with its diaphragmatic surface and the right-sided atrium. Left thoracotomy was performed for left ventricular (LV) leads placement. A pericardial lead loop was placed to allow for patient growth. All initial generators were placed in a subrectus pocket, except for one patient with initial left subcutaneous axillary pocket. All permanent pacing leads were *Medtronic Capsure Epi model 4968* steroid-eluting leads (*Medtronic*, *Minneapolis*, *MN*, *USA*).

Variables

All patients' records were reviewed for demographics, associated cardiac anomalies, onset of AVB, age and weight at PMI. Additionally, mode of pacing, pacing complications, lead and generator longevity were noted. Electrocardiographic tracings were reanalyzed for the degree of AVB and for escape rate and rhythm. Rhythm monitoring data were examined for the average and minimum heart rates, presence of abrupt pauses in ventricular rates, escape rhythm and ventricular arrhythmia.

Definitions

Dilated cardiomyopathy (DCM) was defined as LV end diastolic diameter >97th percentile for age with impaired systolic functioning (shortening fraction <25%) (11).

Statistical analysis

Statistical analysis was performed using IBM Statistical Product and Service Solutions 26 (IBM Corporation, Armonk, NY, USA). Quantitative data were expressed as mean ± standard deviation or median ± range, as appropriate. Proportions were presented as numbers and percentages. Patients were compared using Student *t*-test or Mann–Whitney test for continuous variables and Fisher's exact test for binary variables. Freedom from lead reintervention were presented using Kaplan-Meier curve. Otherwise, descriptive statistics were used.

Results

Forty-one patients were included, with 26 patients undergone permanent PMI following intracardiac repair and another 15 patients after being born with CCHB with a total of 68 epicardial leads implantations. One patient was lost to follow-up. The mean follow-up duration was 4.5±3 years. The mean weight and age at PMI were 6.4±5.3 kg and 1.2±2.1 years, respectively. The mean generator longevity was at 5.5±1.1 years. Twenty-nine patients (71%) received ventricular single-chamber device and another 12 patients (29%) had a dual-chamber pacemaker at initial implant.

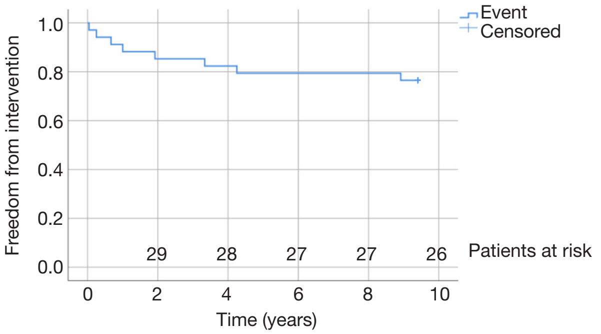

Figure 1 Kaplan-Meier curve of freedom from lead reinterventions.

Over the study period, 15 patients (37%) required pacing system reinterventions, including 4 leads with high pacing threshold or failure to capture (2 RV, 1 LV, and 1 atrial lead), 3 system upgrades to cardiac resynchronization therapy (biventricular pacing), and 3 patients with pacing system infection requiring extraction. The median lead failure time was 51 months (range: 5 to 107 months). The incidence of lead events (failure and infection) was 10% (7/68). There was one abandoned lead. Among patients with lead failure, there was no gross lead fracture noted on chest x-rays or in the operating room except for single lead with one epicardial button dislodgment. The actuarial freedom from reoperation at 9.8 years was 76.5%. The Kaplan-Meier curve of freedom from lead reinterventions for the entire cohort is illustrated in *Figure 1*.

Post-operative group

All patients developed AVB immediately in the operative room except for 2 patients with late AVB occurrence. The median time of PMI following cardiac repair was 10 days (range: 0 days to 1.5 years). The mean escape rate was at 68±9 beats per minute (bpm). Eighteen patients (69%) underwent single-chamber pacing (ventricular), and 8 patients (31%) had dual-chamber system initially implanted. All ventricular leads were placed on the anterior and diaphragmatic surface of the RV, except for 2 patients with LV apex placement. Three patients developed RV-pacing induced DCM with one patient's system upgraded to biventricular pacing. Over the study period, 5 patients (19%) required pacing system reinterventions, including 2 leads with high threshold or failure to capture (1 RV, and 1 LV), 2 patients developed pacing system infection requiring extraction, and otherwise for elective generator replacement. The median generator longevity was 4.1 years (range: 8 days to 7 years and 11 months). No deaths were reported within this sub-group (*Table 1*) (12).

CCHB Group

All patients were diagnosed at or prior to birth. Most mothers had history of clinical autoimmune disease (61%), predominantly systemic lupus erythematosus. Six mothers had documented positive anti-SSA/Ro or anti-SSB/La antibodies and 36% of the mothers with positive antibodies had subclinical disease. The mean escape rate was at 53±7 bpm. Twelve patients (80%) underwent single-chamber pacing (ventricular), and 3 patients (20%) had dual-chamber system initially implanted. All ventricular leads were placed on the anterior and diaphragmatic surface of the RV, except for 3 patients with LV apex placement. Two patients required system upgrade to biventricular pacing due to RV pacing-induced DCM. Over the study period, 10 patients (67%) required pacing system reinterventions, including 2 leads with high threshold or failure to capture (1 RV and 1 atrial lead), 1 patient developed pacing system infection, and otherwise for elective generator replacements. The median generator longevity was 5 years (range: 2 weeks to 7 years and 1 month). Two patients died from heart failure due to subsequent DCM development (*Table 1*) (11).

Discussion

In this study, we focused on evaluating the performance of steroid-eluting epicardial leads implanted subsequent to post-operative AVB and in patients born with CCHB, the 2 major indications for pediatric pacing (1-3).

Overall epicardial leads failure published rates has been variable but up to 43% in some reports (7). However, more specifically for steroid-eluting bipolar leads, the reported failure rate has been significantly reduced down to 7.5–11% (3,4,6-8). Similarly, our results showed excellent performance. Herein, the incidence for lead events was at 10%, despite the younger age at implant compared to the previously published reports, with the young age at PMI being the only recognized risk factor for lead dysfunction (9). Certainly, steroid elution reduces the inflammation at the electrode-tissue interface leading to decreased stimulation thresholds and improved lead longevity (5,6,8,10).

The major causes for reoperations in this cohort was due to lead failure, pacing system infection, and device

Table 1 Patient characteristics in both groups with pacemaker types and performance

	Post-op AVB	CCHB	P value
Patients (n)	26	15	
Weight at PMI (mean)	6.32±6.32 kg	6.4±4.5 kg	0.156**
Escape rate (mean)	68±9 bpm	53±7 bpm	<0.001*
Ventricular-only PM	18 (69%)	12 (80%)	0.356***
Dual-chamber PM	8 (31%)	3 (20%)	0.356***
Generator longevity (median)	4.1 yrs (8 d – 7 yrs & 11 m)	5 yrs (2 wks – 7 yrs & 1 m)	0.053*
RV-induced CM	3	2	0.613***
Deaths	0	2	0.128***
V-threshold (mean)	1.29±0.71 V	1.33±0.47 V	0.353**
Lead failure	4	3	0.510***

**T*-test; **Mann-Whitney U test; ***Fisher's exact test. Post-op, post-operative; CCHB, congenital complete heart block; PMI, pacemaker implantation; bpm, beats per minute; PM, pacemaker; yrs, years; d, days; wks, weeks; m, months; RV, right ventricular; CM, cardiomyopathy; V-thresholds, ventricular thresholds; V, volts.

upgrade. Lead failure is likely secondary to damage imposed on epicardial leads by torso movements, somatic growth or epicardial scaring secondary to irritation from leads placements and prior surgeries (4,6,8,9). The latter being the most likely reason for lead failure in this cohort, as most lead failures presented with gradual thresholds and impedance rise without evidence of lead fracture.

For the majority of cases, lead thresholds were acceptable throughout the study period (*Table 1*). This has been consisted with other reports examining the *Medtronic 4968* lead (3,4,6). Such lead often works well for patients with healthy or minimally scarred myocardium similar to our studied population but may not be appropriate for heavily scarred tissue, as the electrodes may not have sufficient contact with the myocardium (13). Otherwise, an active fixation lead design can be utilized for better tissue contact (13).

It has been our institutional policy to implant single chamber epicardial system for neonates with biventricular anatomy and normal function. Lately, we aim for apical lead placement to better preserve the LV function, especially when frequent ventricular pacing is expected (14-16). Otherwise, a dual-chamber pacing system is implanted for older patients and definitely for single ventricle patients aiming for systemic ventricular apical location (12). Luckily, we had not been experiencing high rate of pacing induced cardiomyopathy to deduce any specific risk factors or preventative measures (11,12).

Limitations

This study is limited due to its small sample size, single-center data, heterogenous patients and its retrospective nature with the known risk for selection bias. Causations assessment was not possible.

Conclusions

In summary, the results presented in this study confirms excellent *Medtronic 4968* lead performance. Despite the young cohort, the incidence of lead failure was rather low, over a relatively long follow-up period. Indeed, bipolar steroid-eluting leads offers a reliable pacing option for the young, preserving venous route for later use. Continual advancements of epicardial lead technology will increase the attractiveness of epicardial pacing option, particularly considering complications from the transvenous approach and the risks involved with its extraction.

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Footnote

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References

1. Singh HR, Batra AS, Balaji S. Pacing in children. Ann Pediatr Cardiol 2013:6;46-51.
2. Epstein AE, DiMarco JP, Ellenbogen KA, et al. ACC/AHA/HRS 2008 guidelines for device-based therapy of cardiac rhythm abnormalities: A report of the American College of Cardiology/American Heart Association Task Force On Practice Guidelines (Writing Committee To Revise The ACC/AHA/NASPE 2002 Guideline Update for Implantation of Cardiac Pacemakers And Antiarrhythmia Devices) Developed in Collaboration With The American Association for Thoracic Surgery and Society of Thoracic Surgeons. J Am Coll Cardiol 2008;51:e1-62.
3. Paech C, Kostelka M, Dähnert I, et al. Performance of steroid eluting bipolar epicardial leads in pediatric and congenital heart disease patients: 15 years of single center experience. J Cardiothorac Surg 2014;9:84.
4. Papadopoulos N, Rouhollapour A, Kleine P, et al. Long-term follow-up after steroid-eluting epicardial pacemaker implantation in young children: A single centre experience. Europace 2010;12:540-3.
5. Odim J, Suckow B, Saedi B, et al. Equivalent performance of epicardial versus endocardial permanent pacing in children: A single institution and manufacturer experience. Ann Thorac Surg 2008;85:1412-6.
6. Tomaske M, Gerritse B, Kretzers L, et al. A 12-year experience of bipolar steroid-eluting epicardial pacing leads in children. Ann Thorac Surg 2008;85:1704-11.
7. Lichtenstein BJ, Bichell DP, Connolly DM, et al. Surgical approaches to epicardial pacemaker placement: does pocket location affect lead survival? Pediatr Cardiol 2010;31:1016-24.
8. Silvetti MS. Twenty years of paediatric cardiac pacing: 515 pacemakers and 480 leads implanted in 292 patients. Europace 2006;8:530-6.
9. Post MC, Budts W, Bruaene A, et al. Failure of epicardial pacing leads in congenital heart disease: not uncommon and difficult to predict. Neth Heart J 2011;19:331-5.
10. Dubin A, Cannon B, Saarel E, et al. Pediatric and congenital electrophysiology society initiative on device needs in pediatric electrophysiology. Heart Rhythm 2019;16:e39-46.
11. Ebrahim MA, Alsayegh HO, Alhamdan FB, et al. Outcomes of pacemaker implantation in isolated congenital atrioventricular block. Prog Pediatr Cardiol 2020. In press.
12. Ebrahim MA, Ashkanani HK, Alramzi RS, et al. Pacemaker implantation post congenital heart disease surgical repair: tertiary center experience. Eur J Pediatr. 2020;179:1867-72.
13. Walker F, Siu SC, Woods S, et al. Long-term outcomes of cardiac pacing in adults with congenital heart disease. J Am Coll Cardiol 2004;43:1894-901.
14. Horigome H. Dilated cardiomyopathy in children with isolated congenital complete atrioventricular block. Circ J 2016;80:1110-2.
15. Jayaprasad N, Johnson F, Venugopal K. Congenital complete heart block and maternal connective tissue disease. Int J Cardiol 2006;112:153-8.

16. De Caluwé, De Bruaene A, Willems R, et al. Long term follow-up of children with heart block born from mothers with systemic lupus erythematosus: a retrospective study from the database and congenital heart disease in university hospitals Leuven. Pacing Clin Electrophysiol 2016;39:935-43.

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