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ORIGINAL ARTICLE

Failure of epicardial pacing leads in congenital heart disease: not uncommon and difficult to predict

M. C. Post · W. Budts · A. Van de Bruaene · R. Willems · B. Meyns · F. Rega · M. Gewillig

Abstract
Aims We evaluate the incidence of epicardial lead failure and try to identify risk factors in patients with congenital heart disease.
Methods All patients with a congenital heart defect and an epicardial pacing system, implanted within a timeframe of 25 years, were included in this study. Patients' medical records and lead data were reviewed. Lead failure was defined as the primary endpoint.
Results In total 198 active epicardial leads (atrial 40, ventricular 158) were implanted in 93 patients (median age at implantation 4.4 years (range 0–58.6)). During a total follow-up of 1235 lead-years, 29 lead failures (14.6%, 4 atrial, 25 ventricular) were documented in 22 patients (23.7%). Lead failure occurred at a median time period of 4.8 years (range 1.2–24.1) after implantation. Five-year freedom of lead failure was 88%. The only independent predictor for lead failure was the age at implantation (HR 0.44; 95%CI 0.20–0.97, p=0.04), other characteristics failed to predict lead failure. Sudden cardiac death occurred in four patients (4.3%), in one a lead failure was documented.
Conclusion A high incidence of epicardial lead failures is found in patients with congenital heart disease. Unfortunately, it is difficult to predict this potentially life-threatening complication.

Keywords Epicardial leads · Congenital heart disease · Lead failure

M. C. Post · W. Budts · A. Van de Bruaene · M. Gewillig
Pediatric and Congenital Cardiology,
University Hospitals Leuven,
Herestraat 49,
3000 Leuven, Belgium

R. Willems
Clinical Cardiology, University Hospitals Leuven,
Herestraat 49,
3000 Leuven, Belgium

B. Meyns · F. Rega
Cardiac Surgery, University Hospitals Leuven,
Herestraat 49,
3000 Leuven, Belgium

M. C. Post (✉)
St Antonius Hospital,
Koekoekslaan 1,
3435 CM Nieuwegein, the Netherlands
e-mail: m.post@antoniusziekenhuis.nl

Introduction

Cardiac pacing is an important issue following surgery for congenital heart disease or in the presence of congenital conductance disorders. Because of the cardiac anatomy or small size of the patients, permanent pacing occurs mainly by epicardial leads. The majority of these patients require long-term pacing throughout their lives. However, epicardial leads have a shorter longevity compared with endocardial leads [1, 2]. Lead failure can lead to significant morbidity and mortality and is often sudden and unexpected, especially in the paediatric population. The aim of our study was to evaluate the incidence of epicardial lead failure and identify risk factors in congenital heart disease patients.

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Methods

Patient selection

All consecutive patients with congenital heart disease, structural or conduction disorder, who underwent implantation of an epicardial pacing system in our hospital between October 1969 and October 2004 were included in this retrospective study. Patients medical records and pacemaker databases were reviewed during follow-up. The local ethics committee approved the study.

Pacing system and follow-up

The epicardial leads were mainly implanted in a subxyphoidal subrectal position and the leads were usually tunnelled through the centreline. In two patients the pacemaker system was implanted in an intrathoracic position. During the study period different types of epicardial leads were implanted. From January 1992, exclusively steroid-eluting epicardial leads were implanted. The lead length was always adjusted to the size of the patient by the cardiac surgeon. In some patients, an additional spare lead, not connected to the pacemaker, was added to avoid re-intervention in case of lead failure. If the pacing lead was not connected to a functioning generator the lead was excluded from analysis. During follow-up visits, with an interval of 6–8 months, the pacing thresholds and impedance were measured. The primary endpoint was the occurrence of a lead failure. This was presumed if an excessively elevated pacing threshold or abnormal increase/decline in impedance occurred or fracture was confirmed by X-ray of the chest or abdomen. Lead lifetime was defined as time elapsed from lead implant to the event of lead failure. From the data of exchange, new leads were enrolled as new implants with lead measurements starting at implant.

Statistics

Descriptive statistics were used to describe patients and lead characteristics. Data are given as mean ± standard deviation if normal distribution is present or median with range if normal distribution is absent. Differences between patients with or without the occurrence of lead fracture were analysed by unpaired Student's t test for continuous variables and Chi-square test for nominal variables, and the level of significance was set at $p<0.05$. Kaplan-Meier survival analysis was done on the primary endpoint and the difference between two age groups (≤ median or >median age) was tested using the log-rank test. Cox proportional hazards were measured. Inclusion in the multivariate model was determined by the significance of the univariate analysis ($p<0.15$). Statistical analysis was performed with the SPSS software for Windows XP version 14.0.1 (Chicago, IL).

Results

Patient characteristics

Ninety-three patients received in total 198 epicardial leads, 158 ventricular and 40 atrial. The median age at implantation was 4.4 years with a range of 58.6 years. A structural congenital heart defect was present in 68 patients (73.1%)

Table 1 Baseline and lead characteristics

Total	93
Age (years)	4.4 (0–58.6)
Female	43 (46.2)
Follow up (years)	4.8 (0–30.4)
Structural Congenital heart disease	
No	25 (26.9)
Fontan	12 (12.9)
LVOTO	10 (10.8)
ASD	3 (3.2)
VSD	14 (15.1)
AVSD	6 (6.5)
TGA	19 (20.4)
TF	4 (4.3)
Reason for implantation	
Congenital complete heart block	17 (18.3)
Post-operative complete heart block	44 (47.3)
Ideopathic complete heart block	16 (17.2)
Intermittent high grade atrioventricular block	2 (2.2)
Sinus node dysfuction	11 (11.8)
Other	3 (3.2)
Leads	198
Steroid	169 (85.4)
Ventricular	158 (79.8)
Atrial	40 (20.2)
Length (cm)	27.2±9.7
Number of leads	
One	24 (25.8)
Two	45 (48.4)
Three	14 (15.1)
Four	7 (7.5)
Five	3 (3.2)
Manufacturer	
Medtronic	158 (97.8)
Cordis	3 (1.5)
Intermedics	1 (0.5)
Biotronic	2 (1.0)
Unknown	34 (17.2)

Data are presented as number (percentage) or median (range)

LVOTO left ventricle outflow tract obstruction; *ASD* atrial septal defect; *VSD* ventricular septal defect; *AVSD* atrioventricular septal defect; *TGA* transposition of the great arteries; *TF* Tetralogy of Fallot

and underwent surgical corrections. Of these patients, 12 had a single ventricular physiology. The baseline and lead characteristics are summarised in Table 1.

Follow-up

During a total follow-up of 1235 lead-years, a definite epicardial lead failures could be diagnosed in 29 leads (14.6%) within 22 patients (23.7%), resulting in an incidence of 2.3% per lead per year of follow-up. The median time to lead failure was 4.8 years, range 1.2–24.1 years. In five patients lead failure occurred in two leads (both ventricular), and in one patient lead failure was diagnosed in three leads (two ventricular and one atrial lead). At the latest follow-up prior to lead failure the median impedance of the fractured leads was 325 Ω (range 140–10.000 Ω). The age at implantation was significantly lower in patients in whom lead failure occurred, 3.7± 3.6 years versus 8.2±10.0 years (p=0.02). The number of non-steroid leads was higher in the failure subgroup compared with the non-failure group, 27.6% versus 12.4% (p=0.03). These data are summarised in Table 2. In multivariate analysis a lower age at implantation was the only independent predictor for lead failure (hazard ratio (HR) 0.44: 95% confidence interval 0.20–0.97, p=0.04). This is presented in Fig. 1.

The overall freedom of lead failure at 5, 10, and 20 years after implantation was 88%, 75%, and 64%, respectively (Fig. 2). Within the subgroup of patients with an age at implantation of less than median (4.4 years), the lead failure free survival at 5 and 10 years after implantation was 81% and 66% compared with 95% and 85% in older patients (log rank: p=0.03).

During a median follow-up of 4.6 years (range 30.4 years), 13 patients died (14.0%), four of them died suddenly (4.3%). In one out these four patients, a definite lead failure could be diagnosed.

Discussion

Children and young adults with congenital heart disease requiring pacemaker implantation might receive epicardial leads. Especially in the paediatric population, the epicardial lead durability is unpredictable because of developing body size and typical childhood behaviours [3]. However, in the presence of (relative) contraindications for the transvenous approach, such as small body size, an intra-cardiac shunt or absence of a venous access, an epicardial lead implantation is preferred despite the high rate of lead failure. The estimations of lead longevity vary widely, and seems to be difficult to predict whereas different risk factors for lead failure had been described [3–10]. In our study, we found an incidence of lead failure of 2.3% per lead per year of follow-up. The only independent predictor for lead failure was age at implantation.

Over the last decade, several studies have reported the incidence of epicardial lead failure. In one of the largest study, Fortescue et al. described 1007 leads in 497 patients [11]. Fifty-two percent (n=524) of the implanted leads were epicardial in location. Overall lead failure occurred in 15%, during a median follow-up of 6.2 years. The only independent hardware predictor for lead failure was the epicardial lead location, with an HR of 1.6 (p=0.007) [11]. In a more recent study, the same group evaluated 256 epicardial leads during a median follow-up of 3.0 years [1]. Lead failure occurred in 7.4%, with an estimated freedom from lead failure after 5 years of 58% [1]. In another study by Horenstein et al. 62 children with a median age of 5.2 years received 79 epicardial leads [10]. During a median follow-up of 6 years a lead fracture occurred in

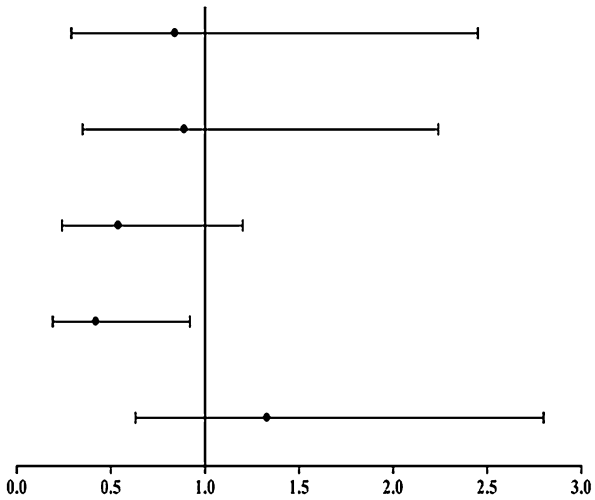
Table 2 Characteristics of patients with lead failure

	Failure	No Failure	P
Number	29 (14.6)	169 (85.4)	–
Female	12 (41.4)	72 (42.6)	0.90
Age at implantation (years)	3.7±3.6	8.2±10.0	0.02
CHD			0.18
Structural	20 (12.9)	135 (87.1)	
No structural	9 (20.9)	34 (79.1)	
Leads			
Steroid	21 (12.4)	148 (87.6)	0.03
Non-steroid	8 (27.6)	21 (72.4)	
Atrial	4 (13.8)	36 (21.3)	0.35
Ventricular	25 (86.2)	133 (78.7)	
Length (cm)	24.1±8.9	27.7±9.8	0.11
Follow up (years)	5.9±5.0	6.3±5.4	0.72

Data are presented as number (percentage) or mean ± standard deviation

CHD congenital heart disease; *cm* centimetres

Univariate	n/N	Rate	HR (95%CI)	P value
Atrial lead	40/198	20.2	0.84 (0.29-2.45)	0.75
Non-steroid lead	29/198	14.6	0.89 (0.35-2.34)	0.80
Structural CHD	155/198	78.3	0.54 (0.24-1.20)	0.14
Age > median	99/198	50.0	0.42 (0.19-0.92)	0.03
Male gender	114/198	57.6	1.33 (0.63-2.80)	0.46



Multivariate	n/N	Rate	HR (95%CI)	P value
Structural CHD	155/198	78.3	0.60 (0.27-1.34)	0.21
Age > median	99/198	50.0	0.44 (0.20-0.97)	0.04

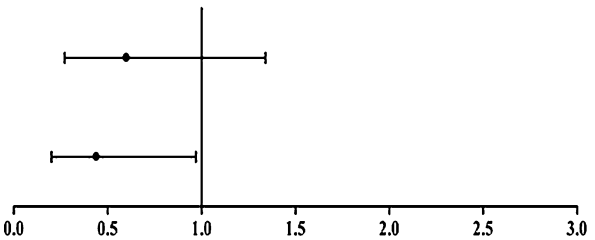


Fig. 1 Risk of failure in a univariate and multivariate Cox proportional hazard model

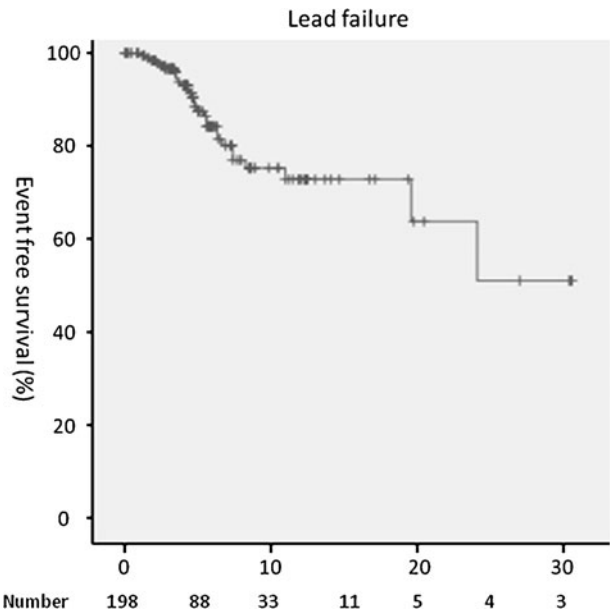


Fig. 2 Kaplan-Meier curve for lead failure free survival of the total population

7.6% of the implanted leads [10]. Murayama et al. found an incidence of lead failure of 3.4% per lead per year of follow-up. With an overall 10-years freedom of lead failure of 72.5% [6]. Recently, Tomaske et al. described their experience in the use of epicardial pacing leads in 114 children with a median age of 6.2 years [8]. They found lead failure in 7.9% of the 239 implanted leads [8]. In a retrospective study by Cohen at al., epicardial lead failure occurred in 16.4%, with a mean time to lead failure of 2.4 years. The 5-year epicardial lead survival was 74% [4]. Similar findings were reported by Silvetti et al. They described failure in 21% of the children who received in total 226 epicardial leads during a mean follow-up of 5 years [5]. In our study lead failure occurred in 15% of the implanted epicardial leads. The overall 10- and 20-year lead failure free survival was 75% and 64%, respectively.

Several predictors for lead failure are described. Fortescue et al. found that a lower age (< 12 years) at first implant and the presence of structural congenital heart disease were both independent predictors for reduced lead longevity with an HR of 2.7 ($p<0.001$) and 1.8 ($p=0.007$), respectively [11]. The presence of structural congenital

heart disease as an independent predictor for lead failure was confirmed by Murayama et al. The patient's age at implantation was not a predictor for lead failure in their study [6]. In our study we could not find an association between the presence of a structural heart disease and the occurrence of lead failure. However, we found that a lower age at implantation (≤ median age of 4.4 years) was an independent predictor for lead failure with an HR of 2.3. This might be explained by the rapid growth earlier in childhood and increased physical activity. Both factors cause an increase in mechanical stress on the epicardial leads. This might be supported by the finding that the difference in lead failure free survival between both age groups was found especially within the first decade after implantation. During this period the rate of growth is higher in younger children. Another predictor might be the atrial or ventricular position of the lead. In the study described by Tomaske et al. there tended to be a higher incidence of failure of the ventricular lead compared with the atrial lead. They found an estimated 5-year freedom from lead failure of 94% for atrial leads and 85% for ventricular leads [8]. This finding could not be confirmed by other studies described earlier or by analysing our data. In earlier studies, it is suggested that the use of steroid-eluting epicardial leads will increase lead longevity compared with the use of non-steroid eluting leads [12–14]. This was also supported by Silvetti et al. They found a significantly increased risk of lead failure using non-steroid conventional epicardial leads [5]. However, in the study by Fortescue et al. the use of steroid-eluting epicardial leads was not associated with an increased lead survival [11]. This finding was supported by Cohen et al. In this study the only predictor for epicardial lead failure was the surgical approach, with no lead failure after the subxiphoid technique [4]. Traction on epicardial leads by respiration and arm movement is minimised using this approach. In our study, we could not find a difference between steroid or non-steroid epicardial lead longevity and were not able to investigate the difference in surgical approaches because almost all leads were inserted using the subxiphoid technique.

Limitations of this study are the retrospective design and the single-centre data. Some specific details regarding lead failure were not available. We were not able to collect data about thresholds and impedance of the epicardial leads. Furthermore, data about rate of growth were not available.

In conclusion, epicardial leads provide a reliable technique for pacing in patients with congenital heart disease. However, epicardial lead failure is not uncommon and remains difficult to predict.

References

1. Fortescue EB, Berul CI, Cecchin F, et al. Comparison of modern steroid-eluting epicardial and thin transvenous pacemaker leads in pediatric and congenital heart disease patients. J Interv Card Electrophysiol. 2005;14:27–36.
2. Beaufort-Krol GC, Mulder H, Nagelkerke D, et al. Comparison of longevity, pacing, and sensing characteristics of steroid-eluting epicardial versus conventional endocardial pacing leads in children. J Thorac Cardiovasc Surg. 1999;117:523–8.
3. Ector B, Willems R, Heidbuchel H, et al. Epicardial pacing: a single-centre study on 321 leads in 138 patients. Acta Cardiol. 2006;61:343–51.
4. Cohen MI, Bush DM, Vetter VL, et al. Permanent epicardial pacing in pediatric patients: seventeen years of experience and 1200 outpatient visits. Circulation. 2001;103:2585–90.
5. Silvetti MS, Drago F, Grutter G, et al. Twenty years of paediatric cardiac pacing: 515 pacemakers and 480 leads implanted in 292 patients. Europace. 2006;8:530–6.
6. Murayama H, Maeda M, Sakurai H, et al. Predictors affecting durability of epicardial pacemaker leads in pediatric patients. J Thorac Cardiovasc Surg. 2008;135:361–6.
7. ten Udink CF, Breur J, Boramanand N, et al. Endocardial and epicardial steroid lead pacing in the neonatal and paediatric age group. Heart. 2002;88:392–6.
8. 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.
9. Sachweh JS, Vazquez-Jimenez JF, Schondube FA, et al. Twenty years experience with pediatric pacing: epicardial and transvenous stimulation. Eur J Cardiothorac Surg. 2000;17:455–61.
10. Horenstein MS, Hakimi M, Walters III H, et al. Chronic performance of steroid-eluting epicardial leads in a growing pediatric population: a 10-year comparison. Pacing Clin Electrophysiol. 2003;26:1467–71.
11. Fortescue EB, Berul CI, Cecchin F, et al. Patient, procedural, and hardware factors associated with pacemaker lead failures in pediatrics and congenital heart disease. Heart Rhythm. 2004;1:150–9.
12. Cutler NG, Karpawich PP, Cavitt D, et al. Steroid-eluting epicardial pacing electrodes: six year experience of pacing thresholds in a growing pediatric population. Pacing Clin Electrophysiol. 1997;20:2943–8.
13. Crossley GH, Brinker JA, Reynolds D, et al. Steroid elution improves the stimulation threshold in an active-fixation atrial permanent pacing lead. A randomized, controlled study. Model 4068 Investigators. Circulation. 1995;92:2935–9.
14. Johns JA, Fish FA, Burger JD, et al. Steroid-eluting epicardial pacing leads in pediatric patients: encouraging early results. J Am Coll Cardiol. 1992;20:395–401.