Posted on Authorea 18 Apr 2022 — The copyright holder is the author/funder. All rights reserved. No reuse without permission. — https://doi.org/10.22541/au.165026538.89403588/v1 — This a preprint and has not been peer reviewed. Data may be preliminary.

A survival analysis of bipolar steroid-eluting and unipolar non-steroid-eluting epicardial leads

Amir Farjam Fazelifar[1], Nina Jalily Taghavyan[1], mahdi Moeini[2], Bahador Baharestani[1], Farshad Jalili Shahandashti[1], Majid Haghjoo[1], Saeid Hosseini[1], Farzad Kamali[1], Shabnam Madadi[1], Ali Asghar Yoonesi[1], and Sogol Koolaji[1]

[1]Rajaie Cardiovascular Medical and Research Center
[2]Urmia University of Medical Sciences School of Medicine

April 18, 2022

Abstract

Background: Epicardial pacemakers are known as an alternative for endocardial pacemakers in some cases such as heart block, and complex congenital heart diseases. Considering recent advances and improvement of epicardial lead subtypes, it is essential to investigate the long-term function of them. In this study, we aimed to assess the sensing and pacing characteristics, and survival of bipolar steroid-eluting and unipolar non-steroid-eluting epicardial pacemakers. **Methods**: We conducted an entirely concentrated search on the documents of all patients who had undergone epicardial lead implantation in the Shaheed Rajaie Cardiovascular, Medical & Research Center during 2015-2018. Implant, and follow up data were extracted. Kaplan Meier analysis and Weibull regression hazards model were applied for the survival analysis. **Results**: eighty-nine leads were implanted for 77 patients. Of the total leads, 52.81%, 53.93%, and 47.19% were implanted in children (under-18-year-old), females, and patients with congenital heart diseases, respectively. Bipolar steroid-eluting leads comprised 33.71% of 89 leads. Pacing threshold of unipolar non-steroid-eluting leads that were implanted on the left ventricle and right atrium increased significantly during the follow up to greater records than bipolar steroid-eluting leads. Survival analysis also revealed that bipolar steroid-eluting leads are significantly better in 48-month survival (Weibull HR: 0.13 (95%CI, 0.02-0.99), p-value, 0.049). Age, ventricular location of the lead, and acute pacing characteristics were not associated with survival. **Conclusions**: Bipolar steroid-eluting epicardial leads have an acceptable survival compared with unipolar non-steroid-eluting, without a significant difference regarding patients age. Therefore, they could be an excellent alternative for endocardial ones.

Introduction

Epicardial pacemakers are known as an alternative for endocardial pacemakers not only for newborns with bradycardia due to sinus node disease or heart block but also in pediatrics and adults with complex congenital heart diseases. Regarding newborns and children, rapid somatic growth, small vessel size, and lack of access to the chamber requiring pacing make it hard to implement endocardial pacemakers; therefore, in these cases, permanent epicardial pacemakers are the first priority. Moreover, congenital heart disease with right-to-left shunts and intention to preserve venous access and prevent venous thrombosis (often in pediatric patients) are among other reasons to prefer epicardial pacemakers.[1,2]

Endocardial pacemakers showed better longevity than epicardial leads with higher failure over time mainly due to high thresholds, exit blocks, and fractures of epicardial leads.[3]Endocardial pacemakers are implemented in the right side of the heart and lateral wall of the left ventricle through the coronary sinus, which is not applicable in 4.3 to 7.5 % of cases due to abnormal venous anatomy.[4,5] Furthermore, studies indicated that long-term endocardial pacemakers could result in impaired LV function.[6] Otherwise, epicardial leads

Posted on Authorea 18 Apr 2022 — The copyright holder is the author/funder. All rights reserved. No reuse without permission. — https://doi.org/10.22541/au.165026538.89403588/v1 — This a preprint and has not been peer reviewed. Data may be preliminary.

are directly applicable on the left ventricle and might be a more appropriate choice for patients with RV dysfunction.[7]

Advances in epicardial pacemakers in recent decades resulted in improvement in the long-term function of these leads. Currently, these pacemakers have different characteristics, such as being unipolar or bipolar and steroid-eluting or non-steroid-eluting. Previous studies demonstrated that steroid-eluting epicardial leads have a comparative stable pacing threshold.[1,8] For instance, a 12-year follow-up of the children with bipolar steroid-eluting leads illustrated outstanding sensing characteristics and low median pacing threshold, making them an appropriate alternative for permanent endocardial pacemakers.[2]

Considering the abovementioned indication for epicardial pacemakers, recent advances, and their various characteristics, it is essential to evaluate and compare the long-term function of each subtype. In this study, we aimed to assess the sensing and pacing characteristics, and survival of different types of epicardial pacemakers and their associated factors through a 4-year follow-up of all patients who underwent epicardial pacemaker implantation in the Shaheed Rajaie Cardiovascular, Medical & Research Center.

Materials and methods

Overview of the patients and leads

We conducted an entirely concentrated search on the documents of all patients who had undergone epicardial lead implantation in the Shaheed Rajaie Cardiovascular, Medical & Research Center during 2015-2018. All documentations were retrospectively reviewed. According to a systematic search on previous studies on epicardial leads,[1,2] the following data were selected and extracted from the documentation regarding each patient; age, sex, past medical history of congenital heart disease (CHD) with exact type. The following epicardial lead characteristics were also reviewed and extracted, including indication for pacemaker implantation, symptoms before implantation, lead type (unipolar non-steroid-eluting and bipolar steroid-eluting), brand (Medtronic and St. Jude), device type (CRT, PPM-DR, and PPM-SR), pace location (atrial, and left ventricular, and right ventricular), pacing mode (DDD, DDDR, VDD, VVI, VVIR). For the 11 patients who had more than one-time epicardial lead implantation (10 patients with two and one had three), their second and third lead was also enrolled as a new lead, and its characteristics were recorded. As a result, for 77 patients in the study, 89 leads were enrolled. Furthermore, the electrocardiogram (ECG), and echocardiogram (echo) of the patients after each lead implantation were obtained, and their data was reviewed, and extracted by an expert. ECG data consisted of V1 R/S greater than 1 (yeas or no), QRS Duration (millisecond or ms.), and notch position. Echocardiographic data included left ventricular end diastolic diameter (LVEDd), left ventricular end systolic diameter (LVESd), and left ventricular ejection fraction (LVEF).

Surgical course

The implemented epicardial leads were either unipolar non-steroid-eluting or bipolar steroid-eluting. The type of epicardial lead to be applied for a patient was selected based on the preference and experience of the surgeon, discussion with electrophysiology team, and availability of the lead. Regarding availability of the leads, it should be noted that bipolar steroid-eluting leads were less available in recent years in Iran due to the sanctions and being expensive. However, since we enrolled all patients with epicardial lead implantation and considered patient and lead factors in our multivariate analysis, lead availability did not cuase a bias. Several surgeons performed the surgeries, who are well experienced regarding lead implementation. Epicardial leads were implanted through a midline sternotomy, lateral thoracotomy, or subxiphoid approach. These approaches were selected according to the patients' cardiac anatomy and position, their prior or concurrent operations.

Implant and follow-up data

For all included leads, sensing, and pacing threshold, and impedance were recorded at discharge time and their regular follow-up. Sensing and pacing thresholds were calculated for a pulse duration of 0.4 milliseconds. At follow-up time, failure of a lead and its reason also were recorded. The reason for failure was either primary or secondary. Primary reasons for failure included replacement due to unacceptable high pacing threshold and sensing abnormality, lead fracture, loss of capture, and lead displacement. Secondary ones consisted of infection of the generator pocket and accidentally lead damage during heart surgery. The lead survival time (duration of being functional) was calculated as the interval between lead implantation and the time that failure was observed in the clinical follow-up. When a failure occurred, and a lead was exchanged, the new lead enrolled in the study and the patient characteristics (demographics, electrocardiographic and echocardiographic features) at the time of lead implantation were enrolled.

Statistical analysis

All of the gathered data was entered into the Stata 14 and R version 3.5.2 for further cleaning and analysis, including managing duplicates cases and missing data, recoding variables, and handling garbage records. Missing data were managed through reviewing the documentation for a second time, searching in other sources of patient information, and calling the patients to receive missed information.

Descriptive analysis

Frequency tables describe demographic factors of the patients, history of CHD, CHD types, details of indication for pacemaker implantation, and symptoms before implantation, as well as lead characteristics. Age as a continuous variable did not have a normal distribution; thus, its median ± interquartile range of 5 to 95% was reported. Categorical variables were presented in terms of number and percentage.

Analytical analysis

Independent samples T-test used for comparing the frequency of different factors between unipolar non-steroid-eluting and bipolar steroid-eluting leads. Logistic regression was used in the case of categorical variables with more than two categories. Survival analysis was done on a subgroup of patients, that their lead failure was due to the primary failure reasons (unacceptable high pacing threshold and sensing abnormality, lead fracture, loss of capture, and lead displacement). The characteristics of these patients were also calculated and presented with the abovementioned descriptive analysis. For a 48-month follow-up time, Kaplan Meier analysis and Weibull regression hazards model was used for survival analysis of all variables.[9]Accordingly, hazard ratio was estimated for each variable with a 95% confidence interval (95%CI). Afterward, age and lead type (bipolar steroid-eluting and unipolar non-steroid eluting) adjusted hazard ratio calculated for variables using Weibull regression hazards model. The level of significance was considered as $p<0.05$ throughout the study.

Ethical statement

This study was ethically approved by the Ethical Committee of Iran University of Medical Sciences (ID; IR.IUMS.FMD.REC.1398.369).

Results

Patients characteristics

A total of 77 patients enrolled in this study whose median age at first implantation time was 20-year-old (5%-95%, 1 to 74-year-old). Under-18-year-old patients and females comprised 49.35% and 50.65% of the study population, respectively. Furthermore, 36 patients (46.75%) had at least one congenital heart defect, where moderate severity CHDs were the most prevalent (Table 1, see Supplementary Table 1).

Lead and pacing characteristics

Patients underwent 89 epicardial lead implantations, and their function was studied during 2015-2018. Indication for pacemaker implantation mostly consisted of atrioventricular block (52.81%) and CCHB (19.10%). The most prevalent symptom before pace implementation was dyspnea on exertion (59.79%), followed by syncope (8.25%), and palpitation (7.22%) (see Supplementary Table 2 and 3).

Of total implants, 59 (66.29 %) were unipolar non-steroid-eluting type, and others were bipolar steroid-eluting (33.71 %). Most of the leads were only located on the ventricles (68 leads; 88.31%), while, nine leads

Posted on Authorea 18 Apr 2022 — The copyright holder is the author/funder. All rights reserved. No reuse without permission. — https://doi.org/10.22541/au.165026538.89403588/v1 — This a preprint and has not been peer reviewed. Data may be preliminary.

Posted on Authorea 18 Apr 2022 — The copyright holder is the author/funder. All rights reserved. No reuse without permission. — https://doi.org/10.22541/au.165026538.89403588/v1 — This a preprint and has not been peer reviewed. Data may be preliminary.

were implanted on both atrium and ventricle. Left ventricular leads were more prevalent (76.62%). There was no significant difference between the unipolar non-steroid-eluting and bipolar steroid-eluting leads regarding the cavity where they were implanted on (p-value=0.35). VVR and VVIR were the most prevalent pacing modes either for unipolar non-steroid-eluting or bipolar steroid-eluting leads (68.49% of total leads). There was no significant difference between pacing modes of the unipolar non-steroid-eluting and bipolar steroid-eluting leads (Table 2). QRS duration and LVEF at lead implantation time were not significantly different between unipolar non-steroid-eluting and bipolar steroid-eluting leads (Table 2 and Table 3).

Pacemaker implantation and analysis data

The atrial impedance observed between 240 and 803 (mean 445.77) in 9 patients with atrial leads. Mean of sensing and pacing threshold of atrial leads were 2.44 and 0.86, respectively (5-95%, [0.5-5.6], and [0.25-3.5], respectively). The ventricular Impedance had mean of 557.88 (5-95%, 285-1198) in left and 490.55 (5-95%, 117-942) in right side (Table 4). The only significant difference in pacing threshold at follow up time was observed in leads locating in LV (p-value<0.001) with a mean follow up time of 14.73 months (SD, 9.18). However, the analysis for each types illustrated that rise in pacing threshold is only for the unipolar non-steroid-eluting leads.

Follow-Up and lead survival Data

Of the 77 patients who underwent epicardial pacemaker implantation, 4 patients expired in the first 30 days after implant (three with unipolar non-steroid-eluting leads, and one with bipolar steroid-eluting). Three other patients also passed away 8, 12, and 19 months after pacemaker implantation (all unipolar non-steroid-eluting leads). Their death was not related to lead malfunction. One patient was lost to follow up due to not presenting for reevaluation. None of them underwent lead replacement and just had one lead. Therefore, 81 remaining leads were followed. The epicardial lead failure occurred in 22 of 81 followed implantations (27.16%). The reason for failure included high threshold or loss of capture (16 implants), decreased EF due to RV pacing (one implant), lead fracture (one implant), and infection (four implants) (Table 5). Infected implants were not included in the survival analysis because of their failure reason that was not related to the lead characteristics. Therefore, 77 leads were enrolled in the survival analysis; 50 unipolar non-steroid-eluting and 27 bipolar steroid-eluting leads (see Supplementary Table 4 and 5).

The leads that were included in the survival analysis were followed for an average length of 25.81 months (SD, 11.70); ranged from 0.5 month (the lowest time to lead malfunction) to 48 months (one implant). The rate of lead failure was 23.37% (18 of 77 leads); 17 unipolar non-steroid-eluting and one bipolar steroid-eluting lead. The average time to lead failure was 18.20 months (from 0.5 to 44 months); 18.34 months for unipolar non-steroid-eluting (from 0.5 to 44), and 16 months for bipolar steroid-eluting leads. Bipolar steroid-eluting implants showed a significantly lower risk of failure; crude Weibull HR: 0.13 (95%CI, 0.02-0.99), and age-adjusted Weibull HR: 0.13 (95%CI, 0.02-0.96, p-value=0.045 (Figure 1).

Age, gender, and ventricular location (Figure 2) did not statistically significant affected the risk of failure. Pacing threshold over 3 μJ at hospital discharge was not correlated with higher hazards of lead failure (HR: 2.12 (95%CI, 0.48-9.28) p-value=0.32) (Table 6)

Discussion

Our findings illustrated differences in survival of different types of epicardial leads; bipolar steroid-eluting leads had considerably better survival rate than unipolar non-steroid-eluting ones, by more than 85% lower risk of failure in 48 months. However, no other lead and patient characteristics were revealed to be associated with lead failure. In this order, epicardial leads function and survival was similar between adults and children.

Epicardial lead implantation is preferable in small children, patients with congenital heart disease with right-to-left shunts, intention to preserve the venous access mainly in the ones with difficult accessibility, and prevention of venous thrombosis. However, recent advances in epicardial leads and developed bipolar steroid-eluting ones have demonstrated improved early pacing and sensing thresholds, as well as the long-term function of the lead, which is comparable with endocardial ones.[1,2,8]

Posted on Authorea 18 Apr 2022 — The copyright holder is the author/funder. All rights reserved. No reuse without permission. — https://doi.org/10.22541/au.165026538.89403588/v1 — This a preprint and has not been peer reviewed. Data may be preliminary.

We illustrated that bipolar steroid-eluting epicardial leads remained functional significantly better than unipolar non-steroid-eluting ones. Some studies investigated bipolar and unipolar leads pacing characteristics in the short-term, implying that the bipolar group had fewer sensing and pacing failure.[10,11] The probable underlying mechanism has been declared to be related to the coaxial design of Medtronic bipolar leads, which result in a lower chance of stray signal pick up and better conduction performance.[10] Furthermore, the pacing threshold illustrated to be more stable regarding bipolar steroid-eluting leads in all chambers in the long-term.[2] Our finding also demonstrated that bipolar leads have better long-term pacing characteristics because of the significant rise observed in pacing threshold of unipolar leads in the right atrium and left ventricle but not regarding bipolar group and significantly greater pacing threshold of left ventricular unipolar leads at follow up. Meanwhile, primary pacing characteristics or energy threshold (ET) which was a predictive factor of lead failure in a study did not affected the lead survival in the current study.[1] On the other hand, the observed difference between bipolar steroid-eluting and unipolar non-steroid-eluting might be related to the variation of the steroid elution. In this order, steroid-eluting leads were declared to have better long-term functions.[1,12]

A closer look at the mechanism of steroid impact reveals that addition of dexamethasone (steroid) to a lead can decrease inflammation of the electrode-tissue interface, which is the responsible factor for the rise in the acute pacing threshold. Furthermore, in the long-term, the inflammation might result in the formation of a scar or fibrous capsule in the electrode-tissue interface, which causes a higher pacing threshold.[13] Even though, it is noteworthy that steroid elution leads have been shown not to be an influential factor in a previous study in particular when comparing epicardial and endocardial leads.[14] It could be concluded that steroid elution and being bipolar could be both associated with better long-term function; however, more extensive studies that compare steroid elution within bipolar and unipolar leads are needed to evaluate this.

The paced chamber was not a significant factor in its survival, as there was no difference between pacing characteristics of leads on different chambers, whether at discharge or at follow-up time or regarding bipolar steroid-eluting and unipolar non-steroid-eluting leads, which is consistent with previous studies.[1] However, the pacing threshold significantly increased regarding unipolar non-steroid-eluting leads on the left ventricle or right atrium, but not on the right ventricle, probably due to the sample population, since there was an increase in pacing threshold in the right ventricular unipolar non-steroid-eluting leads but not statistically significant.

Our findings indicated that epicardial leads implemented in adults and children were not significantly different in long-term function. Consistent with our results, adults and children with previous CHD were compared in a study that showed no difference in epicardial and endocardial survival regarding age groups.[15] Although in that study, bipolarity and steroid elution were not investigated separately, the lead type (bipolar and unipolar) adjusted analysis of age variable in the current study similarly was not correlated with lead survival. In contrast, the longevity of a lead function was significantly better in over 12-year-old children compared with younger ones.[14] Therefore, investigating lead characteristics within children might change the results; however, we did the same analysis, which showed no association between age groups among children and better survival.

Congenital heart defect which is an indication for epicardial lead implantation observed in half of our study population but was not associated with the long-term function of a lead.[1,2]However, a study on patients with endocardial and epicardial leads in pediatrics illustrated that congenital heart defect is a significant predictive of lead failure in both type of the leads, which mostly resulted in failure due to exit block.[14]

In this study, we compared the survival of bipolar steroid-eluting leads with unipolar non-steroid-eluting ones, which is pivotal for deciding about the type of lead to be used, particularly in patients that endocardial leads are not applicable. Also, the function of epicardial leads is not different between adults and children; thus, they could be used in both groups, despite much of the previous studies that investigated their longevity in children only.

We encountered some limitations due to patients who were not presented for regular follow up, or not at

Posted on Authorea 18 Apr 2022 — The copyright holder is the author/funder. All rights reserved. No reuse without permission. — https://doi.org/10.22541/au.165026538.89403588/v1 — This a preprint and has not been peer reviewed. Data may be preliminary.

specific time. However, this centre is referral and patients who present from various regions in the country, usually prefer to get their follow up in their living area and refer to this centre in case of pacemaker problems and failures. Therefore, it could be assumed that their pacemaker was functional during the time of their absence. Furthermore, to solve this limitation, we called these patients and completed their follow up by receiving their documents as much as possible.

Conclusion

Bipolar steroid-eluting epicardial leads showed an acceptable long-term function, significantly better than unipolar non-steroid-eluting ones; therefore, they are more appropriate option in either adults or children with an indication for epicardial lead implantation. Furthermore, improved long-term function of epicardial leads, which is observed in bipolar steroid-eluting ones, indicated that they might be a better alternative for endocardial pacemakers in situations that epicardial leads are preferable.

Conflict of interests

Authors declared no conflict of interests.

Funding source

No funding source was applied in this study.

Data availability

The data that support the findings of this study are available from corresponding author upon reasonable request.

Reference

1. 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** (21): 2585-90.

2. Tomaske M, Gerritse B, Kretzers L, et al. A 12-year experience of bipolar steroid-eluting epicardial pacing leads in children. *The Annals of thoracic surgery* 2008; **85** (5): 1704-11.

3. Ten Cate FU, Breur J, Boramanand N, et al. Endocardial and epicardial steroid lead pacing in the neonatal and paediatric age group.*Heart* 2002; **88** (4): 392-6.

4. Gras D, Böcker D, Lunati M, et al. Implantation of cardiac resynchronization therapy systems in the CARE-HF trial: procedural success rate and safety. *Europace* 2007; **9** (7): 516-22.

5. Ahsan SY, Saberwal B, Lambiase PD, et al. An 8-year single-centre experience of cardiac resynchronisation therapy: procedural success, early and late complications, and left ventricular lead performance.*Europace* 2013; **15** (5): 711-7.

6. Tantengco MVT, Thomas RL, Karpawich PP. Left ventricular dysfunction after long-term right ventricular apical pacing in the young.*Journal of the American College of Cardiology* 2001;**37** (8): 2093-100.

7. Walsh EP, Cecchin F. Recent advances in pacemaker and implantable defibrillator therapy for young patients. *Current opinion in cardiology* 2004; **19** (2): 91-6.

8. Bauersfeld U, Nowak B, Molinari L, et al. Low-energy epicardial pacing in children: the benefit of auto-capture. *The Annals of thoracic surgery* 1999; **68** (4): 1380-3.

9. Goel MK, Khanna P, Kishore J. Understanding survival analysis: Kaplan-Meier estimate. *Int J Ayurveda Res* 2010; **1** (4): 274-8.

10. Mohari N, Starr JP, Gates RN, Domico MB, Batra AS. Bipolar versus unipolar temporary Epicardial ventricular pacing leads use in congenital heart disease: a prospective randomized controlled study. *Pacing and Clinical Electrophysiology* 2016; **39** (5): 471-7.

Posted on Authorea 18 Apr 2022 — The copyright holder is the author/funder. All rights reserved. No reuse without permission. — https://doi.org/10.22541/au.165026538.89403588/v1 — This a preprint and has not been peer reviewed. Data may be preliminary.

11. Yiu P, Tansley P, Pepper JR. Improved reliability of post-operative ventricular pacing by use of bipolar temporary pacing leads.*Cardiovascular Surgery* 2001; **9** (4): 391-5.

12. Radovsky AS, Van Vleet JF. Effects of dexamethasone elution on tissue reaction around stimulating electrodes of endocardial pacing leads in dogs. *American heart journal* 1989; **117** (6): 1288-98.

13. MONO HG, STOKES KB. The electrode-tissue interface: The revolutionary role of steroid elution. *Pacing and Clinical Electrophysiology* 1992; **15** (1): 95-107.

14. Fortescue EB, Berul CI, Cecchin F, Walsh EP, Triedman JK, Alexander ME. Patient, procedural, and hardware factors associated with pacemaker lead failures in pediatrics and congenital heart disease. *Heart Rhythm* 2004; **1** (2): 150-9.

15. McLeod CJ, Jost CHA, Warnes CA, et al. Epicardial versus endocardial permanent pacing in adults with congenital heart disease. *Journal of interventional cardiac electrophysiology* 2010; **28** (3): 235-43.

Figure captions

Figure 1. lead survival stratified by lead type; unipolar non-steroid-eluting and bipolar steroid-eluting epicardial leads

Figure 2. lead survival stratified by lead location; right ventricle vs. left ventricle

Tables

Table 1. characteristics of the patients.

Patient characteristics	Patient characteristics	Total patients (Num.=77) Num. (%) or median (5%-95%)
Age at implant (median)		20 (1-74)
Age at implant	[?]18-year-old	38 (49.35)
	>18-year-old	39 (50.65)
Sex	Female	39 (50.65)
	Male	38 (49.35)
Congenital heart defect	yes	36 (46.75)
	No	41 (53.25)

Table 2. Unipolar non-steroid-eluting, and bipolar steroid-eluting leads characteristics.

Lead characteristics	Lead characteristics	Num. (%) or mean (±SD)	Num. (%) or mean (±SD)
		Total leads	Unipolar non-steroid-eluting lead (Num.= 5
Age at implant	Age at implant	15 (1-75)	20 (1-74)
Age at implant	[?]18-year-old	47 (52.81)	29 (49.15)
	18-year-old<	42 (47.19)	30 (50.85)
Sex	Female	48 (53.93)	32 (54.24)
	Male	41 (46.07)	27 (45.76)
Congenital heart defect	Yes	42 (47.19)	32 (52.24)
	No	47 (52.81)	27 (45.76))
Lead location	Right ventricle	18 (23.38)	12 (24.49)
	Left ventricle	59 (76.62)	37 (75.51)
Exact location	LV	52 (67.53)	32 (65.31)
	RV	16 (32.47)	10 (20.41)
	RA & RV	2 (2.6)	2 (4.08)
	RA & LV	7 (9.09)	5 (10.20)

Posted on Authorea 18 Apr 2022 — The copyright holder is the author/funder. All rights reserved. No reuse without permission. — https://doi.org/10.22541/au.165026538.89403588/v1 — This a preprint and has not been peer reviewed. Data may be preliminary.

Lead characteristics	Lead characteristics	Num. (%) or mean (±SD)	Num. (%) or mean (±SD)
Pacing mode	DDD or VDD	23 (31.51)	16 (34.04)
	VVI or VVIR	50 (68.49)	31 (69.96)
Device	CRT	12 (14.81)	6 (11.32)
	PPM-DR or PPM-SR	69 (85.19)	47 (88.68)

Table 3. ECG and echocardiographic characteristics at the implant time.

Variables	Variables	Num. (%) or mean (±SD)	Num. (%) or mean (±SD)	Num. (%) or mea
		Total leads	Unipolar non-steroid-eluting lead (Num.= 59)	Bipolar steroid-el
QRS duration		135.95 (±25.29)	136.54 (±25.58)	134.81 (±25.17)
LVEF*	>45	32 (35.96)	19 (32.20)	13 (43.33)
	<=45	57 (64.04)	40 (67.80)	17 (56.67)
LVEDd^{+}	LVEDd^{+}	5.24 (1.02)	5.20 (0.83)	5.33 (1.36)
LVESd§	LVESd§	4.07 (1.07)	4.02 (0.88)	4.16 (1.41)

* Left ventricular ejection fraction

+ Left ventricular end diastolic diameter

§ Left ventricular end systolic diameter

Table 4. lead implementation and follow up data

		Unipolar non-steroid-eluting lead	Unipolar non-steroid-eluting lead	Unipolar
Lead location	Variables	Months mean (SD)	At dis.* Mean (5%-95%)	At f/u+ Mean (5%
RA	Obs. §		7	4
	f/u time	19.00 (11.37)		
	Impedance ()		397.0 (240.0-533.0)	384.0 (32
	Sensing threshold (mV)		2.73 (0.50-5.60)	3.05 (1.30
	Pacing threshold (µJ)		0.57 (0.25-0.75)	1.56 (0.75
LV	Obs. §		37	26
	f/u time	15.15 (10.79)		
	Impedance ()		445.4 (285.0-568.0)	431.0 (25
	Sensing threshold (mV)		10.45 (3.00-18.50)	10.86 (3.0
	Pacing threshold (µJ)		0.89 (0.25-3.00)	2.42 (0.50
RV	Obs. §		12	7
	f/u time	19.11 (13.18)		
	Impedance ()		433.4 (250.0-779.0)	393.7 (25
	Sensing threshold (mV)		7.22 (2.00-15.00)	6.03 (3.50
	Pacing threshold (µJ)		1.22 (0.50-5.00)	2.67 (0.50

* Discharge

+ Follow up

§ Observations

Table 5. Reasons for lead failure.

Posted on Authorea 18 Apr 2022 — The copyright holder is the author/funder. All rights reserved. No reuse without permission. — https://doi.org/10.22541/au.165026538.89403588/v1 — This a preprint and has not been peer reviewed. Data may be preliminary.

		Unipolar non-steroid-eluting lead (Num.)	Bipolar steroid-eluting l
Reason for failure	High threshold or loss of capture	16	0
	decreased EF due to RV pacing	0	1
	lead fracture	1	0
	infection	2	2

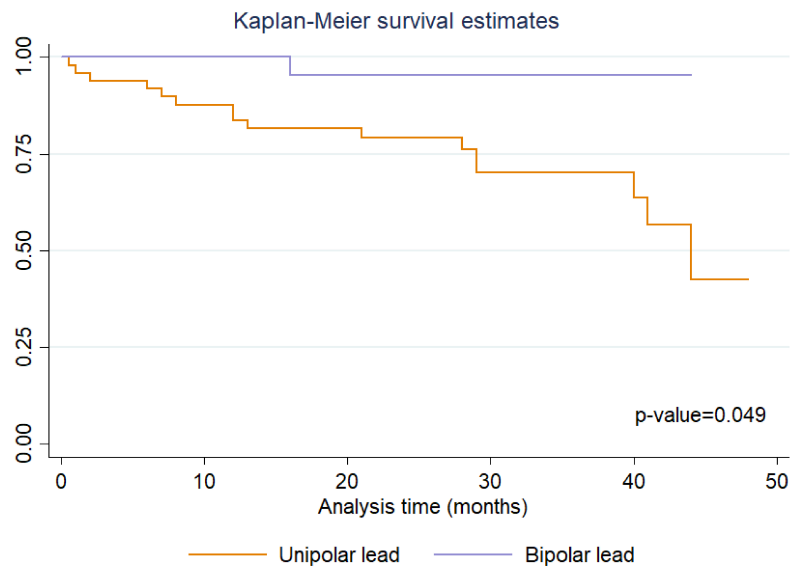
Table 6. Hazard ratio of different factors for lead failure.

Variable	Variable	Observations	Univariate	Univariate	Multivariate	Multivari
			Hazard ratio	p-value	Hazard ratio	p-value
Age at implant	[?]18-year-old	76	Reference	0.38	Reference	0.29 [a]
	18-year-old<		0.65 (0.24-1.71)		0.59 (0.22-1.56)	
Sex	Female	76	Reference	0.48	Reference	0.32 [b]
	Male		1.40 (0.54-3.63)		1.62 (0.62-4.30)	
Congenital heart defect	No	76	Reference	0.91	Reference	0.0.71 [b]
	Yes		1.06 (0.41-2.75)		0.81 (0.27-2.42)	
Ventricular location	Right ventricle	66	Reference	0.25	Reference	0.28 [b]
	Left ventricle		0.54 (0.19-1.53)		0.56 (0.20-1.59)	
LVEF	>45	77	Reference	0.49	Reference	0.18 [b]
	<=45		1.41 (0.52-3.82)		2.14 (0.70-6.54)	
Pacing threshold at discharge	<=3μJ	64	Reference	0.32	Reference	0.34 [b]
	>3μJ		2.12 (0.48-9.28)		2.09 (0.46-9.42)	

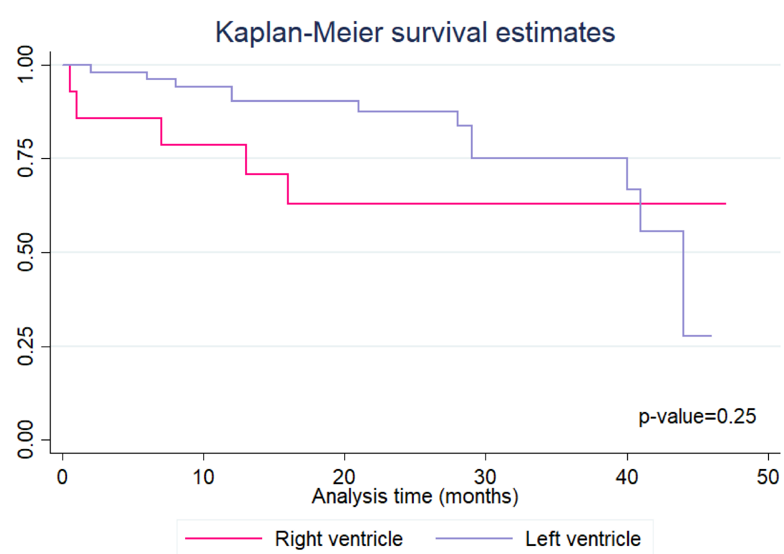
lead type (unipolar non-steroid-eluting vs. bipolar steroid-eluting) adjusted

age and lead type (unipolar non-steroid-eluting vs. bipolar steroid-eluting) adjusted

Posted on Authorea 18 Apr 2022 — The copyright holder is the author/funder. All rights reserved. No reuse without permission. — https://doi.org/10.22541/au.165026538.89403588/v1 — This a preprint and has not been peer reviewed. Data may be preliminary.



Lead type	Months	0	10	20	30	40
Unipolar non-steroid-eluting lead	Observations	50	43	35	23	11
	Survival rate % (95%CI)	100 (100-100)	87.76 (74.76-94.30)	81.63 (67.67-89.99)	70.16 (53.64-81.74)	70.16 (53.64-81.74)
Bipolar steroid-eluting lead	Observations	27	26	19	5	2
	Survival rate % (95%CI)	100 (100-100)	100 (100-100)	95.45 (71.87-99.35)	95.45 (71.87-99.35)	95.45 (71.87-99.35)



	Months	0	10	20	30	40
Right ventricle	Observations	14	10	8	6	3
	% Survival (95%CI)	100	78.57 (47.25-92.54)	62.68 (32.27-82.65)	62.68 (32.27-82.65)	62.68 (32.27-82.65)
Left ventricle	Observations	52	49	37	17	9
	% Survival (95%CI)	100	94.23 (83.17-98.10)	90.30 (78.26-95.85)	75.01 (55.41-86.94)	66.68 (41.85-82.81)