ORIGINAL ARTICLE

Clinical and radiographic predictors of cardiovascular implantable electronic device lead failure at the time of initial implantation

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Abstract

Objective: To assess the clinical and radiographic factors associated with lead failure by comparing subjects with lead failure within 10 years of implantation with an implant-year-matched group without lead failure.

Methods: A case-control study with 49 subjects who received Cardiac Implantable Electronic Device (CIED) between January 1, 1999 and July 31, 2008 and developed lead failure within 10 years of implantation in a single center. The control group consisted of subjects (n = 54) with normally functioning leads matched one-to-one by implant year.

Results: Among the failure group, the meantime from implantation to device lead failure was 4.70 ± 2.94 years. Older age at implantation was associated with a lower likelihood of lead failure (Odds Ratio (OR) = 0.28 (75 vs 42 years old), 95% CI 0.12-0.63, *P* = .002). A larger smallest loop diameter on the chest radiograph was also associated with a lower likelihood of lead failure (OR = 0.51 (31 vs 14 mm), 95% CI 0.27-0.97, *P* = .04). CIED type (defibrillator vs pacemaker) and Ottawa scores were not significantly associated with lead failure. Among lead-specific parameters, defibrillation lead vs pace-sense lead was associated with lead failure (OR = 3.91, 95% CI 1.95-7.81, *P* < .001).

Conclusions: Younger age, defibrillation leads, and small lead loops are associated with lead failure in CIEDs. Techniques to avoid tight loops in the pocket could potentially reduce the risk of lead failure and bear important implications for the implanting physician.

KEYWORDS
artificial pacemaker, complications, implantable defibrillator

1 | INTRODUCTION

Cardiac implantable electronic devices (CIED) have been increasingly utilized in clinical practice as the population ages and indications expand. However, CIED implantation is not a perfect therapy. In addition to immediate procedure-related risks, there are ongoing risks of pocket or lead infection, battery depletion requiring generator change, and device malfunction, particularly lead failure.[1,2] Mechanical malfunction of CIED leads can occur for a variety of reasons, including outer insulation breach, inner insulation breach, and conductor fracture.[3] These malfunctions may lead to the failure of the lead to perform its basic functions. In addition, a failing lead may result in the delivery of inappropriate shocks from defibrillators.[3,4] For these reasons, in addition to this morbidity and possible mortality, lead failure may result in additional procedures such as lead revision or extraction with additional risk.[5,6]

Over the last 13 years, specific leads such as the Sprint Fidelis (Medtronic, Minneapolis, MN, USA) and Riata (St. Jude Medical, now Abbott, Sylmar, CA, USA) received significant attention due to a greater-than-expected incidence of failure. In addition to the inherent mechanical properties of particular lead designs, patient factors have also been shown to predict lead failure in advisory leads.[7-9] We hypothesized that implantation technique, which is a modifiable risk factor, may also be associated with incident lead failure.

2 | METHODS

2.1 | Study population

We conducted a case-control study evaluating adult patients followed by Vanderbilt University Medical Center (VUMC) who had a CIED implanted between January 1, 1999 and July 31, 2008. The case group was comprised of those who developed lead failure within 10 years of implantation. Controls were matched 1:1 by implant year and randomly selected among those who did not have a history of lead failure for the following 10 years for comparison. The study period for each subject was defined from the device implantation until the diagnosis of lead failure, death, last known follow-up, or July 1, 2018, whichever was the earliest. Patients with the following criteria were excluded from the study: (1) Any interim intracardiac procedure including but not limited to new lead implantation, or cardiac surgery during the study period, (2) generator change during the study period, (3) no available chest X-ray for review, (4) congenital heart disease, (5) epicardial or subcutaneous leads. Eligible subjects were extracted via query utilizing Paceart®, a curated repository of clinical data and interrogation reports from the device clinic at VUMC and information regarding specific clinical variables/predictors were obtained by chart review and review of individual chest X-ray. Following the identification of lead failure and control group, 5 additional individuals in the case group were later excluded based on the exclusion criteria (Figure 1).

2.2 | Clinical Variables

Clinical variables recorded were age at implantation, sex, body mass index (BMI), left ventricular ejection fraction (LVEF), type of device (single-chamber pacemaker, dual-chamber pacemaker, cardiac resynchronization therapy [CRT]-pacemaker, single-chamber defibrillator, dual-chamber defibrillator, CRT-defibrillator), device side (left vs right), number of leads, lead type (pacing lead vs defibrillation lead), lead location (right atrium [RA], right ventricle [RV] and left ventricle [LV]), and manufacturers.

2.3 | Radiographic Variables

Five radiographic variables were chosen for the analysis based on the prior literature and the clinical experience of lead extractors at this center. The parameters included Ottawa slack score (intracardiac slack ranging 0 with no slack to 4 with excessive slack)[10], venous entry site (cephalic vs subclavian/axillary), angle of venous entry (−30-0, 0-30, 30-60, 60-90, >90 degrees), pulse generator location (cranial vs caudal)[8], and minimum pocket loop diameter (in millimeters) (Table S1 and Figure S1). Figure 2 gives two examples of pocket loop diameter measurement. Radiographic variables were assessed by three independent reviewers who were blinded to the case. The values were scrutinized and checked for internal validity: the mean for the continuous variables, and the smallest value for the minimum pocket loop diameter was chosen for the analysis.

2.4 | Lead-specific Variables

In order to assess the lead-specific predictors of lead failure, four lead-specific variables were analyzed: defibrillation versus pace/sense lead, lead diameter (French), insulation material (silicone, polyurethane, or others), leads on advisory/recall. Since this is lead-level data, individual leads were counted for the analysis. Note, given the difference in censoring in each group (control group up to 10 years following the implant and lead failure group until the lead failure), the non-failed leads in the lead failure group were not included for the analysis.

2.5 | Outcome variables

We screened for the cases of lead failure by querying Paceart® for the key phrases "lead failure," "failed lead," "lead fracture," "fractured lead," and "noise" in clinical documentation. Thereafter, each case was individually reviewed to confirm the diagnosis. *Lead failure* was confirmed if one of the following was present: (1) sudden rise in pacing impedance (>50% rise in 1 week) or fluctuation (≥500 ohm), (2) failure to sense or capture not due to lead dislodgement, (3) ≥2 non-sustained tachycardia events with average R-R cycle length <220 ms not consistent with atrial or ventricular fibrillation (4) inappropriate
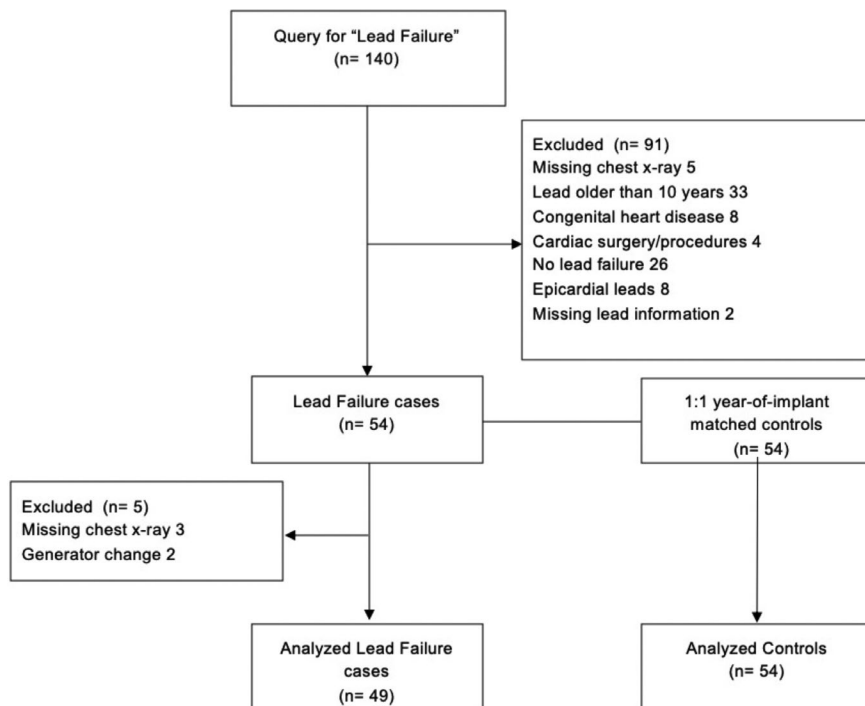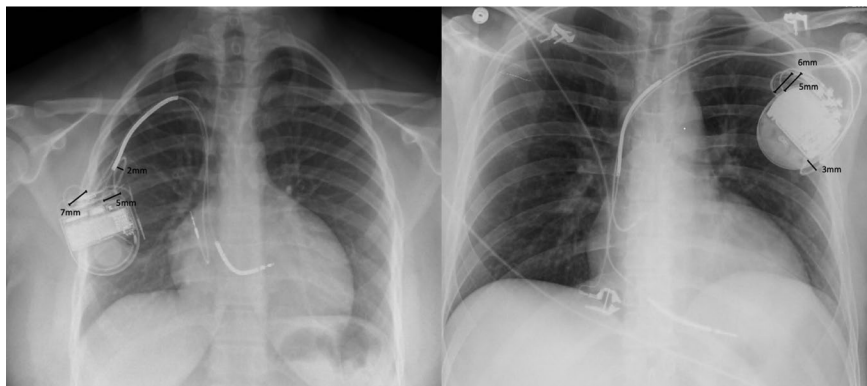
FIGURE 2 The measurement of the lead loop diameter in the pocket. Examples of minimum loop diameter measurements from the AP view of the chest X-ray

shock secondary to sensing of electric noise artifacts from make-break potentials, (5) sudden rise in defibrillation impedance (>50% rise in 1 week). Data on lead failure leading to revision or extraction, as well as inappropriate shocks (ie, unintended delivery of shocks due to sensing of electric noise artifacts from make-break potentials), was also collected.

2.6 | Statistical analysis

Demographic and clinical characteristics were described as mean with standard deviation (SD) for continuous variables and as frequencies (percentages) for categorical variables. To compare characteristics between lead failure and non-failure group, we performed analyses with the Wilcoxon test for continuous variables and Pearson's chi-squared for categorical variables. Multiple logistic regressions were performed for individual covariate for

clinical, radiographic, and lead-specific variables. Additionally, multivariable logistic regression was performed for the patient-level data (clinical and radiographic variables) in order to examine the relationship between lead failure and age at implantation, sex, LVEF, device type, smallest bend diameter, Ottawa Slack Score, and year since implant. Multivariable logistic regression was repeated for the lead-level data (lead-specific variables) separately including lead type, diameter, insulation material, and advisory/recall status. A *P*-value less than .05 was considered to indicate statistical significance; all tests were two tailed. All statistical analyses were performed with the R software program (R Foundation for Statistical Computing, Vienna, Austria, https://www.R-project.org).[11]

This study is compliant with the Declaration of Helsinki and the research protocol was approved by and conducted in accordance with the Vanderbilt University Medical Center Institutional Review Board.

3 | RESULTS

Our query resulted in 140 subjects who had a device implant prior to July 31, 2008 at Vanderbilt University Medical Center with documentation suggestive of lead failure during in-office interrogation or remote transmissions. Among those, 33 subjects with device implant prior to January 1, 1999 were excluded. Following exclusion (detail above), and chart review for confirmation of diagnosis, 49 patients with lead failure were identified (Figure 1). We then randomly selected 54 patients matched to implant-year with no history of lead failure during a minimum of 10-year follow-up. A total of 103 subjects with 154 leads were analyzed (mean age at implantation 58.2 ± 22.2, 41% female, 49 lead failure, 54 control). All had a chest X-ray within 1 week of device implant (AP and lateral). In the case group, the average time from implant to lead failure was 4.70 ± 2.94 years. Baseline medical comorbidities were not significantly different between the two groups (Table 1). However, the lead fracture group was significantly younger compared with the control group at the time of implant (50.7 ± 23.1 vs 65.1 ± 19.0, P < .001). There was a greater prevalence of defibrillator vs pacemakers in the lead failure group (26 [53%] vs 18 [33%], P = .04). Baseline LVEF was lower in the lead failure group although it did not reach statistical significance (46.0 ± 14.6%

vs 50.4 ± 14.9%, P = .08). Among the lead failure group, 40 subjects (81.6%) required lead revision or extraction and 8 subjects (30.8%) received at least one inappropriate shock.

Table 2 summarizes the characteristics of radiographic variables in each group. Minimum pocket loop diameter (mm) was smaller in the lead failure compared with the control (21.0 ± 11.4 vs 25.8 ± 14.2, P =.07) although it did not reach statistical significance. Similarly, Ottawa slack score was lower in the lead failure group, although did not reach statistical significance (2.19 ± 0.97 vs 2.51 ± 0.72, P =.07).

Table 3 demonstrates the lead characteristics among all leads (n = 106) in the control group and failed-leads (n = 54) in the lead failure group. The lead failure group had more defibrillation leads vs pace/sense leads (44% vs 17%, P <.001), leads with a larger diameter (6.89 ± 1.03 vs 6.35 ± 1.14, P <.001) and more leads on advisory/recall (26% vs 10%, P =.01).

Multiple logistic regression was performed to investigate potential predictors of lead failure (Table 4; Figure 3). Older implant age was associated with a significantly lower likelihood of lead failure (Odds Ratio [OR] = 0.28 [75 vs 42 years old], 95% CI 0.12-0.63, P = .002). Higher baseline LVEF (OR = 0.45 [60% vs 40%], 95% CI 0.20-0.98, P = .046) was also associated with significantly lower likelihood of lead failure. A larger minimum pocket loop diameter was associated with a lower

TABLE 1 Baseline characteristics

		Control N = 54	Lead fracture N = 49	P-value
Implant age		65.1 ± 19.0	50.7 ± 23.1	<.001
Female, n (%)		21 (39)	21 (43)	.68
BMI (kg/m2)		27.14 ± 5.80	29.12 ± 6.91	.26
Hypertension, n (%)		35 (65)	24 (50)	.13
Diabetes Mellitus, n (%)		17 (31)	12 (25)	.47
Chronic kidney disease, n (%)		6 (11)	6 (12)	.89
ESRD on dialysis, n (%)		3 (6)	2 (4)	.70
Coronary Artery Disease, n (%)		26 (48)	18 (38)	.28
Valvular heart disease, n (%)		6 (11)	6 (13)	.79
Congestive Heart Failure, n (%)		26 (50)	29 (60)	.30
Hx of Smoking, n (%)		8 (21)	4 (15)	.56
Hx of Cardiac Surgery, n (%)		14 (26)	11 (22)	.68
Congenital Heart Disease, n (%)		3 (6)	2 (4)	.73
LVEF, %		50.4 ± 14.9	46.0 ± 14.6	.08
Device Type, n (%)				.04
Pacemaker		36 (67)	23 (47)	
Defibrillator		18 (33)	26 (53)	
Device side, n (%)	Left	51 (94)	44 (94)	.86
Number of leads, n (%)				.19
1		9 (17)	14 (29)	
2		38 (70)	26 (53)	
3		7 (13)	9 (18)	

BMI: body mass index; CKD: chronic kidney disease (CrCl>2mg/dL but not on dialysis); ESRD: end stage renal disease on dialysis; Valvular heart disease: severe severity or requiring valve surgery or procedure; Heart failure: both systolic and diastolic; LVEF: left ventricular ejection fraction (%) on the echocardiogram or cardiac magnetic resonance image

incidence of lead failure (OR = 0.51 [31 vs 14 mm], 95% CI 0.27-0.97, P = .04). Other factors such as sex, defibrillator (vs pacemaker), time from implant, and Ottawa slack scores did not reach statistical significance. The analysis was repeated for the lead-level data evaluating potential lead characteristics to predict the incidence of lead failure. (Table S2). The presence of a defibrillation lead was significantly associated with the risk of lead failure compared with pace/sense lead (OR = 3.85, 95% CI 1.07-14.18, P = .039). Other lead characteristics such as lead diameter, insulation material, or advisory/recall status did not reveal statistical significance.

4 | DISCUSSION

We evaluated 103 patients who received a CIED implant in a single-center comparing those with a history of lead failure within 10 years of implantation with an implant-year matched cohort. On multiple regression analysis, younger age at implantation, defibrillation leads,

TABLE 2 Characteristics of radiographic variables

	Control N = 54	Lead fracture N = 49	P-value
Ottawa Score[10]	2.51 ±0.72	2.19 ±0.97	.07
Cephalic access, n (%)	3 (6)	2 (4)	.68
Angle of venous entry,[8] n (%)			.43
(-)30-0°	2 (4)	1 (2)	
0-30°	37 (73)	32 (67)	
30-60°	8 (16)	9 (19)	
60-90°	4 (8)	3 (6)	
>90°	0 (0)	3 (6)	
Pulse generator location[8]	0.47 ±0.13	0.50 ±0.13	.24
Minimum pocket loop diameter (mm)	25.8 ±14.2	21.0 ±11.4	.07

and a smaller minimum loop diameter were associated with a greater likelihood of lead failure.

Over the last several decades, the rate of CIED implants has steadily increased.[12] As more CIED leads are implanted and indwelling, the total number of leads at risk for failure increase. Most prior assessments of predictors of CIED lead failure have focused on leads with known high failure rates. We sought to understand the predictors of lead failure in a non-selected group of leads with special attention paid to modifiable factors.

There have been a few prior studies evaluating the relationship between implant technique and radiographic predictors for lead failure. Our study demonstrated that having a smaller loop in the pocket was associated with a greater risk of lead failure. It is well known that a mechanical strain on a CIED lead can result in lead conductor fracture. This was the case, for example, for the Sprint Fidelis lead in which an extremely flexible lead body likely resulted in high stress to the metal components leading to fracture and noise.[3,13] Additionally, it has been assumed that friction between the generator and leads, or between leads themselves may lead to the loss of insulation integrity causing lead failure.[14] Upon review of the chest X-rays in our series, it revealed a wide range of practice patterns regarding the number of loops and consequently how tightly the leads were wrapped in the pocket. Our finding of small loops predicting lead failure is an actionable finding for CIED implanters: an effort should be made to avoid small loops and acute angles which can result from turning the lead wraps too many times or from twisting, rather than turning, the CIED before inserting it into the pocket. This finding highlights the importance of understanding the mechanical properties of leads during the device implantation in order to minimize the risk of lead failure.

Cephalic vein access has been associated with a lower risk of lead failure compared with subclavian or axillary access.[15,16] In our study, however, the venous entry site was not significantly associated with lead failure. Most likely the small sample size in cephalic group limited the analysis in our study. Additionally, it may be that an institutional trend toward more lateral axillary access decreased crush injury compared with a traditional subclavian access undermining the differential risk as demonstrated in other studies.[10]

TABLE 3 Lead-specific characteristics

	Leads in Control group N = 106	Failed leads in Lead failure group N = 54	P
Lead type, n (%)			<.001
Pace-sense	88 (83)	30 (56)	
Defibrillation	18 (17)	24 (44)	
Lead Diameter (French)	6.35 ± 1.14	6.89 ± 1.03	<.001
Insulation material, n (%)			.065
Silicone	53 (53)	25 (47)	
Polyurethane	22 (22)	6 (11)	
Other	25 (25)	22 (42)	
Leads on advisory/ recall, n (%)	11 (10)	14 (26)	.01

Intracardiac slack was not significantly associated with the risk of lead failure in our study. The Ottawa score was initially introduced in a small case–control study evaluating predictors of lead failure, in which it did not reach a statistical significance.[15] Since then, a larger multicenter, retrospective case-control study found more intracardiac slack to be associated with increased incident lead failures among Sprint Fidelis leads.[8] Interestingly, the same study also reported that more intravascular slack and tortuosity of the lead were associated with a lower risk of fracture. Mechanistically, it is challenging to apply this finding to clinical practice: whether the slack resides in intravascular or intracardiac space is contingent upon the patient's anatomy and lead properties and may not be directly related to the implant technique. Also, it is possible that the timing of the chest X-ray may have influenced the finding. The previous studies had X-ray taken at 2 weeks from implant or earlier while our center obtained the X-ray within 24 hours following an implant.

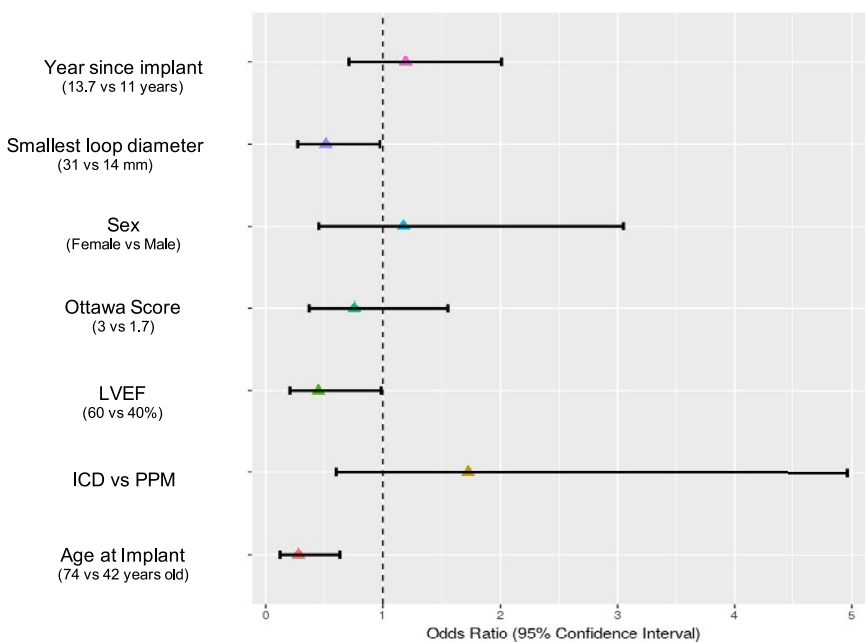**TABLE 4** Multivariate patient predictors of lead failure

	Odds Ratio	95% CI	P-value
Age at implant (75 vs 42)	0.28	0.12-0.63	.002
Sex (female vs male)	1.17	0.45-3.05	.74
LVEF (60% vs 40%)	0.45	0.20-0.98	.05
ICD vs PPM	1.73	0.60-5.00	.31
Ottawa Score (3 vs 1.7)	0.76	0.37-1.56	.45
Smallest pocket loop diameter (31 mm vs 14 mm)	0.51	0.27-0.97	.04
Time from implant (13.7 vs 11 years)	1.19	0.71-2.01	.51

Abbreviations: ICD, implantable cardioverter defibrillator; LVEF, left ventricular ejection fraction; PPM, permanent pacemaker.

In addition to mechanical flaws inherent to particular lead models, multiple studies evaluated the patient predictors for lead failure. Prior studies have found that female gender and a history of previous lead fracture were associated with a greater risk of lead failure.[15,17] We also demonstrated that younger implant age was associated with lead failure, which is consistent with the literature. A multicenter French registry of Sprint Fidelis demonstrated that younger age and a greater functional status carried a higher risk of lead failure.[9] It is plausible that younger patients who are physically more active are more prone to lead failures due to excessive friction or lead flexion. Additionally, a higher LVEF was associated with a lower risk of lead failure consistent with a prior study.[10] However, in our study, this finding was likely influenced somewhat by the fact that ICDs tend to have a shorter battery life, leading to a selection bias away from the control group in light of the 10-year follow-up without re-operation. Therefore, it is likely not possible to draw firm conclusions from this observation.

Our evaluation of the lead-specific parameters demonstrated that defibrillation leads were significantly associated with the lead failure compared with the pace-sense leads consistent with prior literature.[3,18,19] Meanwhile, the recall or advisory status of the lead such as Sprint Fidelis or Riata leads did not reveal a statistically significant relationship with lead failure. This finding may be in part due to a small sample size. However, it is also known that most defibrillation lead malfunctions are not due to recall status but rather due to random component failures. In fact, the annual failure rate for defibrillation lead has been reported from 0.58% upto 20% in 10-year-old leads.[18,19]

Our study has several limitations. First, given the retrospective nature of the study, there is a potential for selection bias, information bias, and confounding. We relied on the individual patient chart to collect the data regarding the history and clinical variables. There could be other factors associated with lead failure that was not accounted for. Second, because of the requirement for a device to reach 10 years without a generator change, the control group is likely enriched for

FIGURE 3 Patient predictors of lead failure. Odds ratio of each risk factor following multivariate analysis [Colour figure can be viewed at wileyonlinelibrary.com]

pacemakers over defibrillators due to the relative mean difference in battery life (irrespective of the likelihood of lead failure). Third, the sample size was relatively small which limits the statistical power of our study. Fourth, there could be a potential for human error in evaluating the radiographic findings. For this reason, we had three operators independently review the radiographic findings who were blinded to the case status. Fifth, given the nature of overlapping loops found on chest X-ray, it was often impossible to tell if the smallest loop belonged to the lead that failed. However, prior literature has suggested that the presence of overlapping leads may result in excessive friction which could lead to lead failure through insulation breach.

5 | CONCLUSION

Younger age at implantation, defibrillation leads, and a smaller minimum pocket lead loop diameter is associated with CIED lead failure. To our knowledge, this is the first study to reveal the effect of lead wrapping technique within the pocket on lead integrity. This finding emphasizes the importance of implant technique and suggests that caution should be taken at the time of CIED implant to minimize the risk of future lead failure.

CONFLICT OF INTEREST

Dr George Crossley has served as a consultant for Medtronic and Boston Scientific and as a speaker for Medtronic. Dr Jay Montgomery has served as a consultant for Medtronic. None of the other authors have disclosures.

ETHICS APPROVAL

The ethics approval was carried out under the terms of the Declaration of Helsinki. The study was approved by the Institutional Review Board of the Vanderbilt University Medical Center (IRB 180 039 approved on February 13, 2018).

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SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section.