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Cardiovascular Implantable Electronic Device Lead Safety: Harnessing Real-World Remote Monitoring Data for Medical Device Evaluation

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Abstract

Background—Current methods to identify cardiac implantable electronic devices (CIED) lead failure include post-approval studies, which may be limited in scope, participant numbers, and attrition; studies relying on administrative codes, which lack specificity; and voluntary adverse event reporting, which cannot determine incidence or attribution to the lead.

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Objective—To determine whether adjudicated remote monitoring (RM) data can address these limitations and augment lead safety evaluation.

Methods—Among 48,191 actively monitored patients with CIEDs, we identified RM transmissions signifying incident lead abnormalities and, separately, identified all leads abandoned or extracted between 4/1/19–4/1/21. We queried electronic health record (EHR) and Medicare fee-for-service claims data to determine if patients had administrative codes for lead failure. We verified lead failure through manual EHR review.

Results—Of 48,191 patients, 1170 (2.4%) had incident lead abnormalities detected on RM. Of these, 409 patients had administrative codes for lead failure, and 233 (57.0%) of these patients had structural lead failure verified through chart review. Among the 761 patients without administrative codes, 167 (21.9%) had structural lead failure verified through chart review. Thus, 400 (66.7%) total patients with RM transmissions suggestive of lead abnormalities had structural lead failure. In addition, 200 patients without preceding abnormal remote transmissions had leads abandoned or extracted for structural failure. Patients with isolated right atrial or left ventricular lead failure were less likely to have lead replacement and administrative codes reflective of lead failure.

Conclusion—Remote monitoring may strengthen real-world assessment of lead failure, particularly for leads where patients do not undergo replacement.

Keywords

Cardiac implantable electronic device; Lead failure; Lead safety; Remote monitoring; Lead replacement; Veterans Affairs

Introduction

Cardiovascular implantable electronic devices (CIEDs) play a central role in the care of patients with heart rhythm disorders.[1–3] However, lead failure is an important complication that can result in inadequate pacing and/or inappropriate shocks (for high-energy leads), with clinical consequences such as sudden cardiac death and complications from reoperation.[4]

Over the past 15 years, multiple lead model recalls have been classified as Class 1 recalls by the Food and Drug Administration (FDA), which means there is "*a reasonable probability that the … product will cause serious adverse health consequences or death*."[5] Two examples are the 2007 Medtronic Sprint Fidelis and 2010 Riata/Riata ST® ICD lead recalls. Multiple publications have estimated that approximately 1 in 4 ICD leads have mechanical complications at 10-year follow-up, although these findings are influenced due to the inclusion of recalled leads.[6–8]

FDA uses multiple mechanisms to identify lead failure and ensure patient safety. First, 5-year post-approval studies have been mandated for novel or significantly modified leads for approximately the past 15 years since the Sprint Fidelis recall; however, these studies have historically been limited by scope, small participant numbers, slow enrollment, attrition, and high cost. Second, the Manufacturer and User Facility Device Experience (MAUDE)

collects reports of device malfunction, but cannot determine incidence or prevalence due to spontaneous reporting, attribution to the device, or the role of the device-associated adverse event in clinical outcomes.[9] Third, manufacturers of CIED systems are required to publicly report performance, including leads. However, these reports are derived from the post-approval studies and adverse event reports with the same aforementioned limitations as well as returned product analyses, which may be limited since not all failed leads are removed and returned.

The 21st Century Cures Act of 2016 and FDA's 2017 Guidance Document, "Use of Real-World Evidence to Support Regulatory Decision-Making for Medical Devices," in combination with advances in the availability of large, electronic datasets, has fueled interest in leveraging real-world data (RWD) for post-market device evaluations.[10,11] Electrophysiology Predictable And SuStainable Implementation Of National Cardiovascular Registries (EP PASSION) is a collaborative initiative among the FDA, CIED manufacturers, the Heart Rhythm Society, and academics to leverage existing RWD to retrospectively identify lead failure among patients with CIEDs.[12,13] EP PASSION is primarily leveraging manufacturer registration and tracking databases linked to Medicare fee-for-service (FFS) claims data to conduct safety evaluation. It is unknown if remote monitoring (RM) performed in clinical care can strengthen these approaches to lead failure detection by identifying lead failure that may not have otherwise been detected and the specific chamber affected to provide accurate ongoing post-market safety evaluation.

Since medical claims data are designed for billing purposes, they often lack granular clinical details available in electronic health records (EHRs), such as characterization of non-procedural clinical interventions for lead failure (i.e., those that may not be reflected in diagnosis or procedure codes) and distinguishing structural vs functional lead failure. Additionally, most CIEDs have multiple leads, which are indistinguishable in claims.

To address these limitations, we sought to determine if RM data could be utilized to identify lead failure and how it compared to administrative codes for lead failure via manual EHR review. We also sought to evaluate the rates of clinical actions taken for lead failure identified via RM, stratified by lead type and location. For these objectives, we leveraged the Veterans Affairs National Cardiac Device Surveillance Program (VANCDSP), which follows more than 50,000 Veterans with CIEDs from all 4 major manufacturers through RM, with more than 250,000 transmissions reviewed annually.

Methods

Data Sources

This study linked multiple data sources within the Department of Veterans Affairs (VA), the largest integrated care delivery system in the United States. The first data source was VANCDSP, which includes lead data with serial numbers for all patients with a CIED who are followed by a VA cardiologist. Veterans implanted at a VA hospital must be registered into the system and Veterans implanted outside the VA are also registered if their subsequent CIED care is at the VA. This registration is mandatory because the VANCDSP's role is to provide expertise and information in the event of FDA or manufacturer safety notification

or recalls affecting CIEDs. All currently available CIED leads are therefore tracked by VANCDSP.

The VANCDSP provides RM for all willing and able patients with transmissions sent at regular intervals (at least every 90 days for nearly all patients) and after prespecified alerts or patient initiation. RM for Veteran patients followed by VA clinics can only occur through VANCDSP. One of twenty trained staff nurses or technicians evaluates each transmission. Once an abnormality is identified, the patient's local VA cardiology care team is notified. A random subset of abnormal RM transmissions are verified by a cardiac provider.

The Veterans Health Administration Corporate Data Warehouse (VA-CDW) is a national VA database that contains patient-level data from the VA's EHR, including demographics, medical history, and data from inpatient and outpatient visits. The VA-CDW also includes information on non-VA facility care that is paid for by VA. Additionally, CMS data for veterans with Medicare FFS coverage (annual 2019 and quarterly 2020 and 2021 files through the end of the study period) were used to validate abnormalities identified by RM during the same timeframe as the analyzed VANCDSP data. These data sources do not include Veterans with Medicare Advantage.

Institutional Review Board (IRB) approval was obtained at the University of California, San Francisco, which is the IRB of record for the San Francisco VA.

Study Inclusion and Exclusion Criteria

All patients with a CIED who were actively monitored by the VANCDSP between April 1, 2019 and April 1, 2021. Patients who did not have a normal RM transmission prior to April 2019 were excluded to ensure only incident lead abnormalities were captured. Patients who had a CIED initially placed after April 1, 2019 were included.

Measurements

Baseline Characteristics—All baseline characteristics were collected from the VA-CDW (Table 1). Baseline comorbidities were documented if they appeared in the patient's EHR prior to the date of lead failure diagnosis in at least 2 ambulatory or 1 inpatient visits.

Ascertainment of Lead Failure—Structural lead failure was defined as any intrinsic lead abnormality that compromised the integrity of the lead. Lead dislodgement, perforation, exit block, and infectious complications were categorized as functional lead failure and considered distinct from structural lead failure.

This study had a multi-step process for determination of lead failure. First, for all patients who met inclusion criteria, all RM transmissions from April 2019 through April 2021 were reviewed. Patients with RM transmissions determined to have failure to capture, impedance out of range, or possible lead failure were included. "Possible lead failure" was documented beginning in 2020 for patients with RM transmissions with any of the following criteria: a) oversensing with a non-physiologic high rate which is not attributable to electromagnetic interference, myopotential, or T-wave oversensing, b) abrupt change in impedance with either impedance out of range, impedance oscillating between normal and abnormal, or

impedance with abrupt and persistent change, or c) failure to capture in conjunction with an impedance out of range.

Second, the NCDSP database was queried to identify any patients with a lead explanation or abandonment during the study period, thereby allowing more comprehensive identification of lead failure, including among patients who may not have had abnormal RM transmissions. Patients who had administrative codes suggestive of CIED-related infections[14] up to 60 days prior to lead explant, or a routine pacemaker to implantable cardioverter defibrillator (ICD) upgrade were excluded from further chart review.

We then reviewed the EHR for all of these patients with possible lead failure identified by RM transmissions or through an abandoned or explanted lead in the NCDSP database within 90-days prior to and 90-days after each RM transmission or the date of lead abandonment or explant to evaluate for a clinical diagnosis of incident lead failure documented in notes from cardiology, device clinic, emergency department, or inpatient encounters. If patients had abnormal transmissions, the gold standard for lead failure was clinician confirmation in the chart after review of the lead data to determine the importance of trends or absolute values, including the normal impedance values expected for each lead, sensing, and thresholds. Records from non-VA cardiologists and hospitals, which were faxed or electronically transmitted to VA to support ongoing care, were also reviewed. Patients with functional lead failure (infection, dislodgement, perforation, or exit block) were not included in the structural lead failure cohort, but their data are reported separately.

Outcomes—The primary outcome was identification of structural lead failure, with chart review as the gold standard. Identification of functional lead failure was a secondary outcome. Another secondary outcome was determining the rates of clinical action taken for incident lead failure, stratified by lead type and location. Leads were categorized into four types: right atrial (RA), right ventricular (RV) pacing, RV high-energy, and left ventricular (LV). Patients were considered free of lead failure if they did not have remote transmission abnormalities or explanted or abandoned leads detected by NCDSP.

Clinical Actions Taken to Address Lead Failure—For each patient who had lead failure confirmed by chart review, the EHR was also manually reviewed for the entirety of the study period and 6 months afterwards to evaluate for any procedural interventions not captured via administrative codes, as well as non-procedural interventions such as changes in lead programming, the lead being turned off, or clinical monitoring. Clinical monitoring was defined as clinician documentation of concern regarding lead integrity and/or function, with a plan to pursue clinic visits and/or remote transmissions with the lead remaining in service. A lead procedure was defined as any lead replacement with either abandonment or extraction of the failed lead. Device reprogramming was defined as any change to the device settings that altered lead function, including change from bipolar to unipolar, even if the lead was still in service because the lead was not functioning as intended.

Statistical Methods

Results were analyzed with descriptive statistics. Continuous variables were reported as mean (± standard deviation) if normally distributed or median (interquartile range, 25th–

75th percentile) if skewed. Categorical variables were reported as n (%). We compared characteristics of patients with and without lead failure using t-tests for continuous variables and Chi-square tests for categorical variables. We calculated the sensitivity, specificity, positive predictive value, and negative predictive value of remote monitoring for identification of lead abandonment or extraction with incident structural or functional lead failure as determined by chart review.

Results

Cohort Construction and Verification of Lead Failure Identified by Remote Monitoring

Of 58,027 patients actively monitored in the NCDSP during the study period, 48,191 (83.0%) sent at least one remote transmission (Figure 1). Of these, 1170 (2.4%) had an abnormal RM transmission of interest with either initial CIED placement after April 1, 2019 or a normal RM transmission prior, ensuring that any abnormal RM transmissions detected during the study period represented an incident abnormality.

Among these 1170 patients, 409 (35.0%) had at least one administrative code for lead failure and 761 (65.0%) did not (Figure 1). After review of EHRs for all 409 patients with abnormal RM transmissions and concurrent administrative codes, 233 (57.0%) had confirmed structural lead failure verified through EHR review (an additional 18 (4.4%) patients had lead failure prior to the study period and 30 (7.3%) had functional lead failure). Of the 761 patients with abnormal RM transmissions without administrative codes, 167 (21.0%) had confirmed structural lead failure on chart review. In summary, of the RM abnormalities queried, 400/1170 (34.2%) patients with abnormal RM transmissions had confirmed structural lead failure.

Leads Abandoned or Explanted

Among 583 patients with lead abandonment or extraction during the study period, excluding patients with administrative codes for infection or a routine pacemaker to ICD-upgrade, 200 (34.3%) had incident structural lead failure verified through chart review without abnormal remote monitoring transmissions. Importantly, of the 583 patients, 96 (16.5%) had lead failure diagnosed prior to the start of study period but had a delayed procedure (typically at generator elective replacement indicator [ERI]).

Among the entire cohort of 48,191 patients who sent at least one RM transmission during the study period, the sensitivity of remote monitoring for detecting lead abandonment or extraction for incident structural or functional lead failure verified by chart review, was 39.6% (237/598), specificity was 98.0% (46,660/47,593), positive predictive value was 20.3% (237/1170), and negative predictive value was 99.2% (46,660/47,021).

Patient Characteristics

At baseline, the mean age of the 600 patients with confirmed structural lead failure was 70.7 (standard deviation [SD] 10.2) years, and 579 (96.5%) were male (Table 1). Overall, 422 (73.7%) were White, 107 (17.8%) were Black, and 32 (5.1%) identified as Hispanic or Latino ethnicity. Approximately 61.0% had heart failure and 70.5% coronary artery disease.

Lead Failure Location

Overall, 31.0% of all patients with structural lead failure did not have any administrative claims codes suggesting lead failure; these patients were identified only by manual EHR review after their abnormal RM transmission (Figure 2). When stratified by lead location and type, RA lead failure (36.2%) was most likely to not have an associated administrative code, whereas only 17.7% of RV high-energy leads did not have an associated administrative code.

Clinical Actions for Lead Failure

All patients with structural lead failure with non-procedural interventions (leads turned off, leads reprogrammed or clinical monitoring) were identified via RM (Table 2). Of the 600 patients with lead failure over the 2-year study period, 407 (67.8%) had lead replacement, 104 (17.3%) had device parameters reprogrammed, 53 (8.8%) had leads turned off, and 36 (6.0%) were clinically monitored; therefore, 94% of patients needed some clinical action (Table 2).

Among patients with RA lead failure, 48.3% had lead replacement, 19.3% had their device reprogrammed, 22.8% had their lead turned off, and 9.7% had only clinical monitoring; therefore, 90% of patients needed some clinical action (Table 2). In contrast, among patients with RV high-energy lead failure, 81.4 % had lead replacement, 11.3% had their device reprogrammed, 3.5% had the lead turned off, and 3.9% had only clinical monitoring.

Among the 407 patients who underwent lead replacement, the failed lead was abandoned in 219 (53.8%) and extracted in 167 (41.0%) (Table 3). These characteristics were similar regardless of the chamber of the failed lead.

The presence of administrative codes for lead failure differed based on the clinical action taken for lead failure (Figure 3). Of the 407 patients who underwent lead replacement, 370 (90.1%) had an accompanying administrative code. By comparison, 20.2% of patients who had their device reprogrammed and 28.3% of patients who had their lead turned off had no administrative code for lead failure.

Clinical Events Other than Lead Failure and Administrative Code Details

Among the patients with an abnormal RM transmission and administrative code for lead failure who did not have confirmed structural lead failure, 30 (7.3%) had functional lead failure (dislodgement, perforation, exit block, or infection) and the remainder had other non-lead related events that included generator changes, scheduled device upgrades, ventricular tachycardia, inappropriate shocks, and death unrelated to device function.

Discussion

Identification of lead failure is important to ensuring the safety of CIEDs. There is significant interest in leveraging RWD sources for post-market safety assessment.[10,15,16] Multi-pronged approaches are needed to identify lead failure, and we show the unique potential of lead abnormalities found by RM data for this purpose, particularly among patients who do not undergo immediate procedural intervention for their lead failure.

However, a substantial proportion of lead abnormalities on RM may not indicate lead failure. In addition to identifying lead failure not captured via administrative codes, RM also identifies the chamber location, lead type, and type of electrical abnormality. These data, paired with review of linked EHR data, can determine clinical actions taken for lead failure in different chambers. Additionally, the real-time nature of RM and EHR data (since these data are available every day, as opposed to a 14-month delay with Medicare claims) can support timely analyses using VA data, in which approximately 50,000 patients are monitored across all CIED manufacturers.

Most prior studies examining lead failure include patient populations from a small number of centers, with limited numbers of patients and devices.[17–19] These data have been combined in meta-analyses to build powered conclusions,[7,8,20] but meta-analyses are limited by variation in study design, including the absence of a standardized definition of lead failure. Additionally, most studies are limited to high-energy leads[6,21] with few evaluating modern pacing leads or non-RV leads.[22]

We found that approximately 30% of patients with verified lead failure lacked administrative codes reflecting their diagnosis, which is likely due to both inclusion of patients who had lead failure without procedural interventions and poor coding. This highlights the benefit of leveraging additional datasets to identify lead failure and identify possible safety signals. Although lead procedures are more reliably identified via administrative codes, an important subset of patients will be clinically impacted and not receive a procedure. There was heterogeneity in administrative codes based on both lead location and subsequent clinical actions. Because patients with RV high-energy lead failure were more than three times as likely to have a procedure for lead failure than patients with RA or LV lead failure, they were more likely to have administrative codes reflective of their lead failure. Lower procedural rates for the RA and LV leads compared to RV leads likely reflects the risk/benefit tradeoff of lead replacement based on the indication and necessity of the lead.[4,23] Therefore, use of RM data may help to better identify safety signals associated with pacing leads.

Nearly 28% of patients with administrative codes suggestive of lead failure did not truly have lead failure on EHR review. Lead dislodgments and inappropriate shocks were among the abnormalities found; these are importantly not reflective of a structural lead malfunction, but rather clinical complications. Distinguishing structural from functional failure is important to accurately determine risk factors for structural lead failure and monitor safety across lead models. This emphasizes the importance of judicious interpretation of administrative codes and further demonstrates the benefit of having a multistep verification process, creating data-driven algorithms to accurately identify lead failure for safety surveillance.

Limitations

This study should be considered in the context of its limitations. First, data were limited to a VA population. Because the VA Health System is a single payor, there may be reduced incentives for comprehensive documentation and accurate diagnostic and procedural

coding; however, inpatient codes are very accurate and procedural relative value units are measured closely. The methods used and implications for RM determination of lead failure are generalizable to a non-VA population, although it is not known what proportion of all CIEDs in the U.S. are implanted in patients followed by the VA. Second, this study relied upon data from patients engaged in remote monitoring. Some patients do not participate in remote monitoring and, of patients who participate, we found that 17% did not send any transmissions during the study period; identification of lead abnormalities using RM would not be possible in these patients. Given that we identified all leads abandoned or explanted in the VA database during our study period, that all patients in our study must be registered with and receive remote monitoring through the NCDSP, and all patients were followed by a VA clinic and we reviewed records from non- VA cardiologists and hospitals, we expect missed lead failure diagnoses or interventions among patients who received care outside of the VA system to be rare, although this is a possibility. Third, this population is predominantly male and prior research has demonstrated that females have a higher incidence of CIED-related complications.[24] Notably, the total number of females included in this study population exceeds most other health systems, given the sheer population size. Additionally, the patient population has significant diversity by many factors including age, race, ethnicity, geography, and socioeconomic status. Fourth, because about one-third of Veterans over age 65 are enrolled in Medicare Part C, and we were only able to query claims data from Medicare Parts A and B, we may not have captured all follow-up care and interventions related to lead failure in these patients. Our study is also limited by duration of follow-up, as some procedural interventions for lead failure may not occur for several years later until a generator is at ERI.

Conclusions

This study demonstrates that remote monitoring can potentially strengthen accurate real-world safety evaluation for lead failure through validation with EHR and claims data. A significant proportion of patients with RM abnormalities and confirmed structural lead failure did not have administrative codes for lead failure and, among patients with RM abnormalities and administrative codes for lead failure, nearly one-third of patients did not ultimately have structural failure. Remote monitoring is particularly helpful for identification of failed leads when patients do not undergo replacement procedures.

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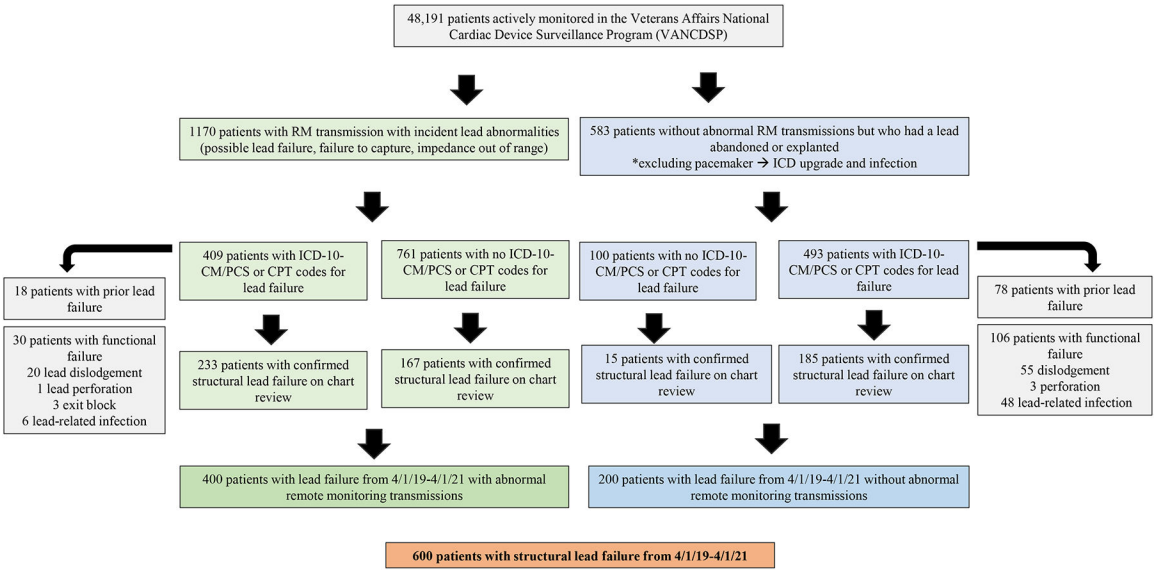

Figure 1. Flowchart for Patient Selection

Abbreviations: VANCDSP, Veterans Affairs National Cardiac Device Surveillance Program; RM, remote monitoring; ICD, international classification of diseases; CM, clinical modification; PCS, procedure coding system; CPT, current procedural terminology

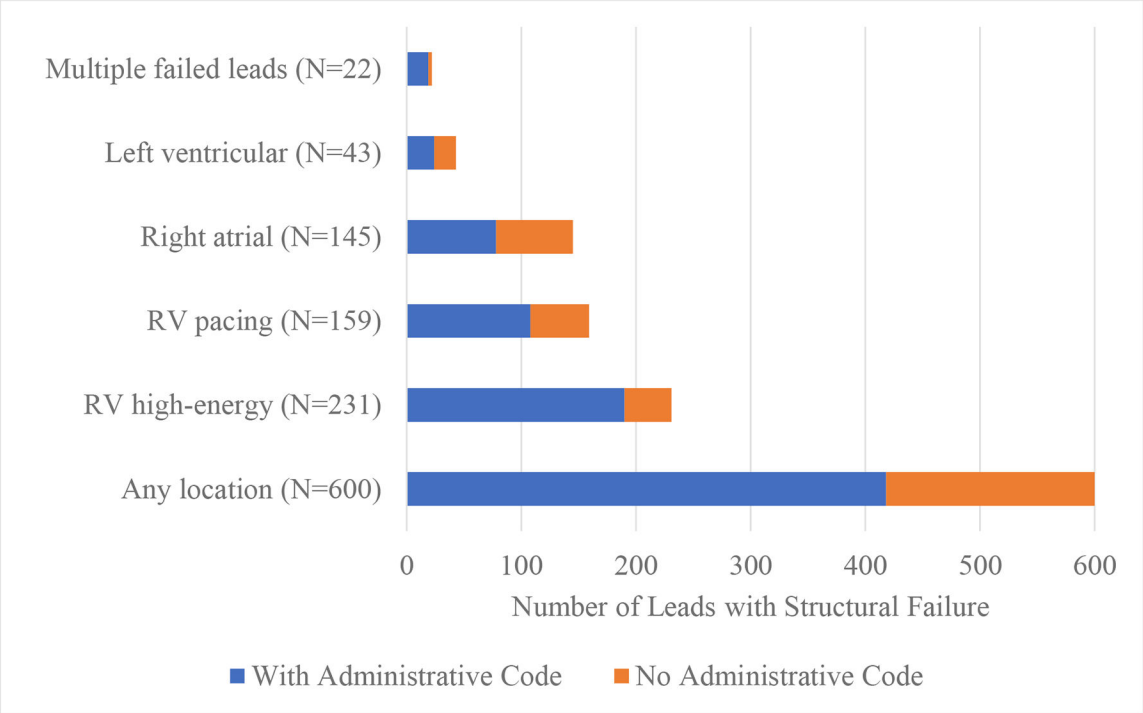

Figure 2. Location of lead failure among 600 patients with structural lead failure confirmed by electronic health record review

Abbreviations: RV, right ventricular

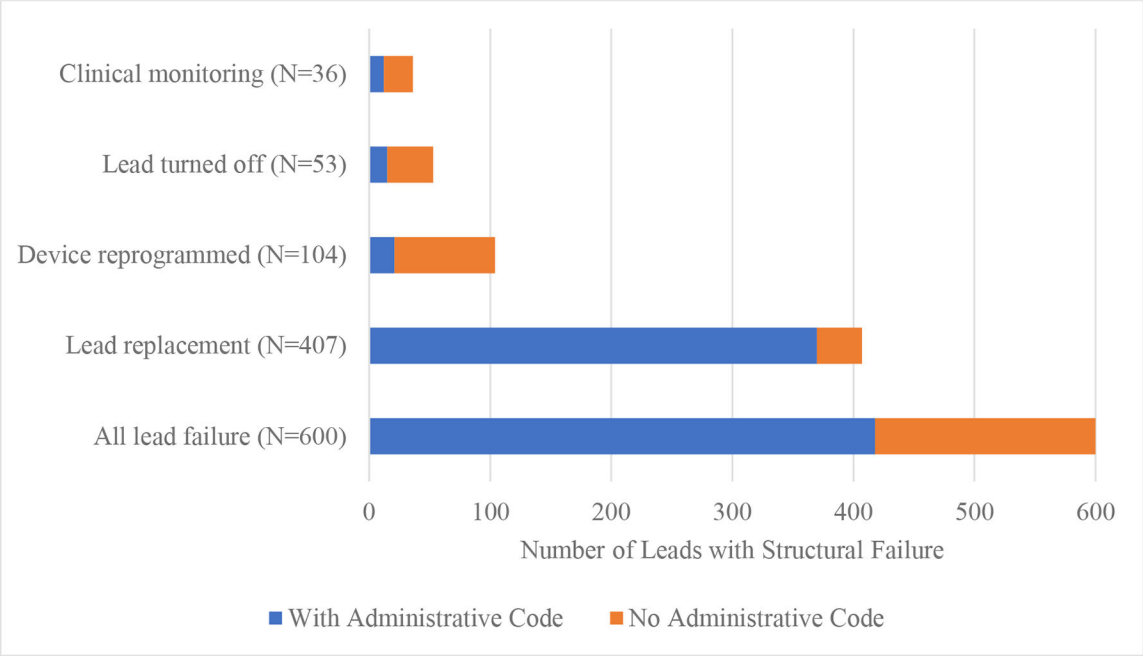

Figure 3.
Method of identification of clinical actions for structural lead failure

Table 1.

Baseline characteristics

	Total N=48,191	Patients without confirmed lead failure detected by NCDSP N=47591	Patients with confirmed structural lead failure N= 600	P value
Age	73.48±9.98	73.52±9.97	70.72±10.22	**<0.01**
Gender				
Male	46963 (97.5%)	46384 (97.5%)	579 (96.5%)	0.14
Female	1228 (2.5%)	1207 (2.5%)	21 (3.5%)	
Race				
White	37453 (77.7%)	37011(77.8%)	422(73.7%)	0.09
Black	6963 (14.4%)	6856(14.4%)	107(17.8%)	
Asian/Pacific Islander	925 (1.9%)	913(1.9%)	12(2.0%)	
Unknown	2850 (5.9%)	2811 (5.9%)	39 (6.5%)	
Ethnicity				
Non-Hispanic/ Latino	44948 (93.3%)	44403 (93.3%)	545 (90.8%)	**0.04**
Hispanic or Latino	1729 (3.6%)	1697 (3.6%)	32 (5.3%)	
Unknown	1514 (3.1%)	1491 (3.1%)	23 (3.8%)	
Liver disease	4418 (9.2%)	4354 (9.1%)	64 (10.7%)	0.25
Hypertension	44715 (92.8%)	44174 (92.8%)	541 (90.2%)	**0.01**
Diabetes mellitus	24790 (51.4%)	24516 (51.5%)	274 (45.7%)	**<0.01**
Chronic kidney disease	25250 (52.4%)	24984 (52.5%)	266 (44.3%)	**<0.01**
End-stage renal disease	1249 (2.6%)	1236 (2.6%)	13 (2.2%)	0.51
Chronic obstructive pulmonary disease	18780 (39.0%)	18539 (39.0%)	241 (40.2%)	0.55
Heart failure	29517 (61.3%)	293151 (61.3%)	366 (61.0%)	0.90
Coronary artery disease	34288 (71.2%)	33865 (71.2%)	423 (70.5%)	0.72
Prior myocardial infarction	14058 (29.2%)	13910 (29.2%)	148 (24.7%)	**0.01**
Prior percutaneous coronary intervention	4803 (10.0%)	4758 (10.0%)	45 (7.5%)	0.04
Cerebrovascular disease	6915 (14.3%)	6838 (14.4%)	77 (12.8%)	0.29

Table 2.

Clinical actions among 600 patients with verified structural lead failure

Location of failed lead	Lead replacement	Device reprogramed*	Lead turned off*	Clinical monitoring*
Total lead failure (N=600)	**407 (67.8%)**	**104 (17.3%)**	**53 (8.8%)**	**36 (6.0%)**
With administrative code	370 (90.1%)	21(20.2%)	15 (28.3%)	12 (33.3%)
No administrative code	37 (9.9%)	83 (79.8%)	38 (69.8%)	24 (66.7%)
Right atrial (N=145)	**70 (48.3%)**	**28 (19.3%)**	**33 (22.8%)**	**14 (9.7%)**
With administrative code	64 (91.4%)	3 (10.7%)	8 (14.2%)	3 (21.4%)
No administrative code	6 (8.6%)	25 (89.3%)	25 (75.8%)	11 (78.6%)
RV pacing (N=159)	**106 (66.7%)**	**39 (24.5%)**	**6 (3.8%)**	8 **(5.0%)**
With administrative code	95 (89.6%)	8 (20.5%)	2 (33.3%)	3 (37.5%)
No administrative code	11 (10.4%)	31 (79.5%)	4 (66.7%)	5 (62.5%)
RV high-energy (N=231)	**188 (81.4%)**	**26 (11.3%)**	**8 (3.5%)**	**9 (3.9%)**
With administrative code	172 (91.5%)	10 (38.5%)	5 (62.5%)	3 (33.3%)
No administrative code	16 (8.5%)	16 (61.5%)	3 (37.5%)	6 (66.7%)
Left ventricular (N=43)	**24 (55.8%)**	**9 (20.9%)**	**6 (14.0%)**	**4 (9.3%)**
With administrative code	21 (87.5%)	---	---	3 (75.0%)
No administrative code	3 (12.5%)	9 (100%)	6 (100%)	1 (25.0%)
Multiple Failed Leads (N=22)	**19 (86.4%)**	**2 (9.1%)**	---	**1 (4.5%)**
With administrative code	19 (100%)	---		---
No administrative code	---	2 (100%)	---	1 (100%)

RV, right ventricular

*All lead failure with non-procedural interventions were identified via remote monitoring

Table 3.

Details of procedures for structural lead failure among 407 patients who underwent lead replacement

Location of failed lead	Lead abandoned	Complete lead extraction	Partial lead extraction	Unable to complete procedure	Unknown
Total (N=407)	219 (53.8%)	167 (41.0%)	6 (1.5%)	1 (0.2%)	14 (3.4%)
Right atrial (N=70)	41 (58.6%)	27 (38.6%)	---	---	2 (2.9%)
RV pacing (N=106)	65 (61.3%)	37 (34.9%)	---	---	4 (3.8%)
RV high-energy (N=188)	96 (51.1%)	80 (42.6%)	3 (1.6%)	1 (0.5%)	8 (4.3%)
Left ventricular (N=24)	13 (54.2%)	11 (45.8%)	---	---	---
Multiple failed leads (N=19)	4 (21.1%)	12 (63.2%)	3 (15.8%)	---	---