# Performance of Lead Integrity Alert to Assist in the Clinical Diagnosis of Implantable Cardioverter Defibrillator Lead Failures: Analysis of Different Implantable Cardioverter Defibrillator Leads

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Original Article

# Performance of Lead Integrity Alert to Assist in the Clinical Diagnosis of Implantable Cardioverter Defibrillator Lead Failures

## Analysis of Different Implantable Cardioverter Defibrillator Leads

Kenneth A. Ellenbogen, MD; Bruce D. Gunderson, MS; Kurt D. Stromberg, MS; Charles D. Swerdlow, MD

***Background***—The Lead Integrity Alert (LIA) was developed for Medtronic implantable cardioverter defibrillators to reduce inappropriate shocks for rapid oversensing caused by conductor fractures and reported for Medtronic Fidelis conductor fractures. The goal of this study was to compare the performance of LIA with conventional impedance monitoring for identifying lead system events (LSEs) and lead failures (LFs) in lead families that differ from Fidelis.

***Methods and Results***—We analyzed data from 12 793 LIA enabled implantable cardioverter-defibrillator and lead combinations including 6123 St. Jude Riata or Durata, 5114 Boston Scientific Endotak, and 1556 Fidelis combinations followed in the CareLink remote monitoring network for LSEs and LFs. Each alert was adjudicated based on implantable cardioverter-defibrillator stored electrograms/diagnostics and clinical data as an LSE or non–lead system event by 2 physicians after reviewing the electrograms and clinical data. During 13 562 patient-years of LIA follow-up, there were 179 adjudicated alerts, of which 84 were LSEs (including 65 LFs) and 95 were non–lead system events. LIA identified >66% more LSE and >67% more LF compared with conventional impedance monitoring and did not differ by lead family for LSE ($P$=0.573) or LF ($P$=0.332). Isolated spikes on electrogram were associated more often with LF in St. Jude leads (71%) compared with Endotak (9%; $P$<0.001) and Fidelis leads (11%; $P$<0.001). The non–lead system event detection rate was different among lead families ($P$<0.001) ranging from 1 in every 78.5 years (Endotak), 228.9 years (St. Jude leads), and 627.6 years (Fidelis).

***Conclusions***—LIA markedly increased the detection rate of LSE compared with conventional impedance monitoring. (***Circ Arrhythm Electrophysiol*. 2013;6:1169-1177.)**

**Key Words:** defibrillators, implantable ■ lead failure ■ shock

The reliability of an implantable cardioverter-defibrillator (ICD) system depends on the function of its components, the pulse generator and the ICD lead.[1] The lead is the weakest link in all ICD systems: multiple studies have shown failure rates ranging from 10% to 50% during long-term follow-up and smaller lead size may be a predictor of a higher failure rate.[2–6] Even with alerts based on absolute values of pacing impedance, the most common presentation of lead failure (LF) is inappropriate shocks[1–4] delivered in response to rapid oversensing of nonphysiological signals. To improve detection of LF compared with conventional impedance monitoring, the Lead Integrity Alert (LIA)[7,8] was developed, which is triggered by relative changes in impedance and evidence of transient, rapid oversensing. This algorithm was developed initially based on data from early coaxial ICD leads[2] and tested on true-bipolar Sprint Fidelis (Medtronic, Minneapolis, MN) leads, which are prone to conductor fracture.[7,8]

### Clinical Perspective on p 1177

The objectives of this retrospective study was to compare the performance of LIA with that of conventional impedance monitoring for identifying pace-sense LF in lead families that differ from Fidelis leads in either functional design or primary failure mode. To achieve the first objective, we analyzed Endotak (Boston Scientific, St. Paul, MN) leads to determine how integrated-bipolar sensing would affect the LIA's performance. To achieve the second objective, we analyzed St. Jude (St. Jude Medical, Sylmar, CA) family leads (Riata and Durata). In contrast to Fidelis leads which are prone to conductor fracture, Riata family leads are prone to insulation breaches.[9,10]

## Methods

### Patients and Leads

All patients with a Medtronic ICD pulse generator with LIA enabled and a St. Jude Medical Riata or Durata ICD lead (models 1560,

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From the Virginia Commonwealth University School of Medicine, Richmond, VA (K.A.E.); Medtronic, Inc., Minneapolis, MN (B.D.G., K.D.S.); and Cedars-Sinai Heart Institute and the David Geffen UCLA School of Medicine, Los Angeles, CA (C.D.S.).

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1561, 1570, 1571, 1572, 1580, 1581, 1582, 1590, 1591, 1592, 1940, 7000, 7001, 7002, 7010, 7020, 7021, 7022, 7040, 7041, 7042, 7052, 7070, 7071, 7120, 7121, 7122, 7130) or a Boston Scientific Endotak ICD lead (0061, 0064, 0072, 0074, 0075, 0095, 0115, 0125, 0127, 0128, 0134, 0135, 0137, 0138, 0144, 0145, 0147, 0148, 0149, 0154, 0155, 0157, 0158, 0159, 0171, 0174, 0175, 0180, 0181, 0182, 0184, 0185, 0186, 0187) with a CareLink remote monitoring transmission between August 28, 2008, and October 4, 2011, were included in the analysis. Patients with Fidelis leads (models 6930, 6931, 6948, 6949) from a separate prospectively defined cohort were included as controls. Device diagnostic data associated with LIA triggers or any pace-sense impedances that triggered conventional impedance alerts (>2000 or <200 ohms) were reviewed. Follow-up time was calculated in years from the date the LIA algorithm was programmed on to the date of the last LIA enabled transmission.

## Lead Integrity Alert

The present LIA requires 2 of 3 of components to be satisfied within 60 days: abrupt pace-sense impedance change, frequent extremely short R-R intervals, and rapid nonsustained ventricular tachycardia episodes.[7,11] The abrupt impedance change requires an increase >75% or decrease to <50% of the median of the 13 prior daily impedances. Very short R-R intervals (<140 ms) increment the sensing integrity counter and satisfy this component when 30 sensing integrity counters occur during a 3-day window. ICD-defined nonsustained tachycardia episodes are ≥5 beats, but do not reach programmed ICD detection (eg, 18/24 intervals). Two rapid nonsustained tachycardia episodes with a mean R-R <220 ms within 60 days satisfy this component (Figure 1). This analysis used only the present version of LIA. When 2 of 3 criteria are met, the number of intervals to detect ventricular tachycardia/fibrillation is extended to 30/40.

Additional device registry information, available device complaint information from the Medtronic database, and available clinical records associated with each LIA trigger were examined by the LF adjudication committee to adjudicate each trigger. Clinical data were obtained from retrospective chart review. For returned Fidelis leads, the results of returned-product analysis were considered the final adjudication. The adjudication committee consisted of 2 physicians (1 primary reviewer and 1 tie breaker reviewer) and 1 Medtronic scientist. After independent review of the device diagnostic data (electrograms [EGMs], impedance trends, etc) and all available clinical data, the LF adjudication committee classified each case as a lead system event (LSE), non–lead system event (NLE), or insufficient information event. If the independent reviews of the Medtronic reviewer and a physician reviewer agreed, the case was considered classified. If there was disagreement, then the case was independently reviewed by a second physician reviewer for tie breaking. Unresolved cases were identified, and final consensus adjudication was completed with agreement by the 2 physician adjudicators.

## Adjudication and Analysis

Each trigger was adjudicated into 2 main classifications: LSE or NLE (or insufficient information) and a specific diagnosis. LSEs included LF, connector issue, dislodgement, perforation, and lead–lead interaction. NLEs included T-wave oversensing, electromagnetic interference (EMI), myopotentials, R-wave double counting, electrode-myocardial interface issue, or ventricular arrhythmia. Definitions for each of these diagnoses have been previously published.[12–15] Triggers

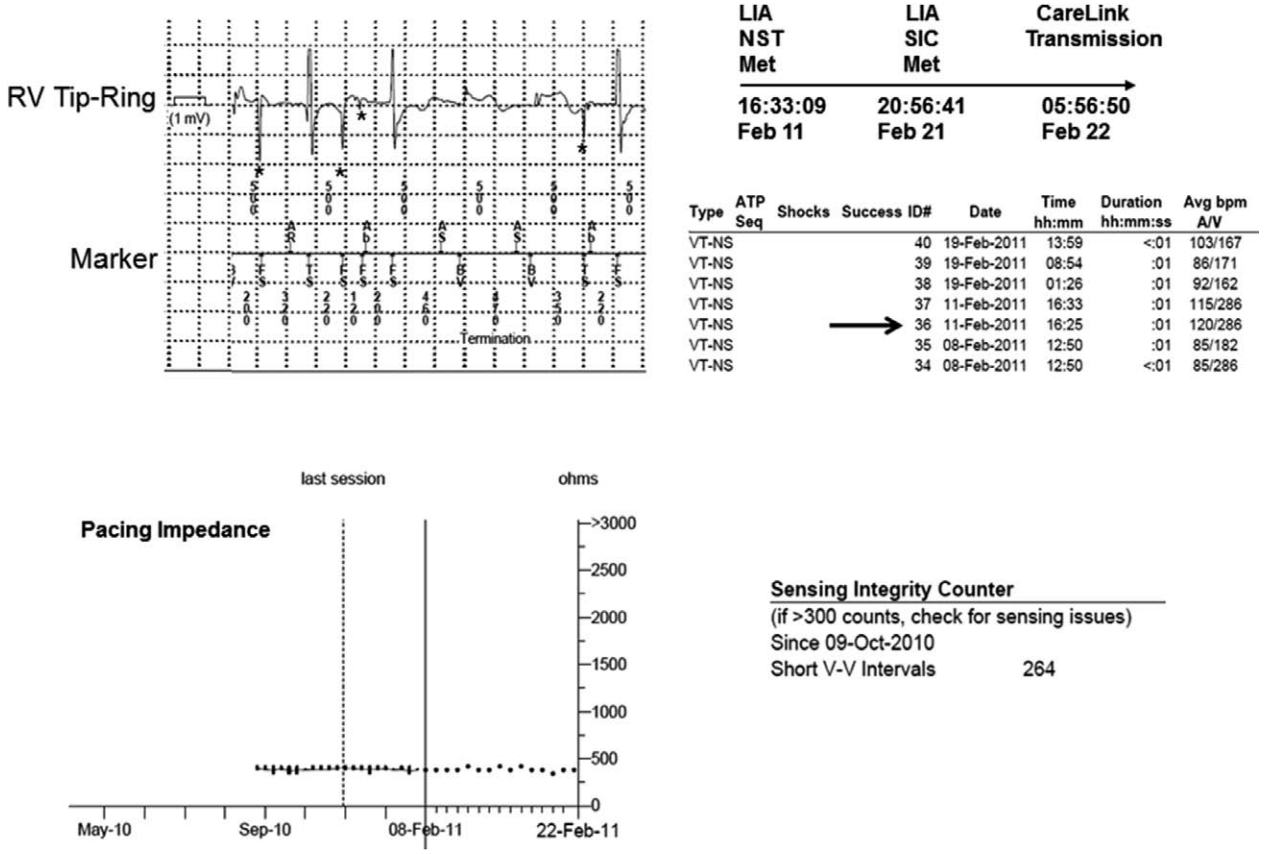


**Figure 1.** Lead Integrity Alert (LIA) oversensing trigger. A 55-year-old man with a Riata implanted on October 6, 2003, and subsequent LIA activation. The LIA trigger was February 21, 2011, at 8:57 PM after satisfying both oversensing criteria (nonsustained tachycardia [NST] first, sensing integrity counter [SIC] second). The electrogram from ventricular tachycardia-nonsustained (VT-NS) episode 36 shows oversensed noise spikes (see asterisks) on the right ventricular (RV) tip-ring electrogram. The pace-sense impedance was stable. The patient initially refused surgery. The clinic was monitoring lead impedance after the LIA trigger. The patient received an inappropriate shock 6 months after the LIA trigger. The patient then decided to have the implantable cardioverter-defibrillator lead capped and replaced.

that could not be classified as either LSE or NLE were adjudicated as insufficient information event and excluded from summary statistics. In patients with an adjudicated LF, we classified EGM characteristics of nonphysiological signals on stored and real-time CareLink near-field EGMs for 4 patterns (Figure 2): (1) previously described high-frequency, highly variable (erratic) signals often called lead noise; (2) signals that saturate the sensing amplitude[7,8]; (3) high-frequency, uniform, low-amplitude (<1 mV) signals; and (4) isolated nonphysiological spikes. The latter were defined as a nonphysiological deflections with amplitude >1 mV that leaves and returns to normal baseline within 40 ms. Spikes were identified independent of the presence or absence of other nonphysiological signals.

## Data Analysis

To calculate the incremental sensitivity (Si) of LIA compared with a conventional impedance trigger to identify LSEs, the proportion of LIA triggers associated with LSEs that were not detected by conventional impedance triggers were computed. In addition, this comparison was made for LFs only. The detection rate of false-positive NLEs was calculated by using the number of events and the total monitoring time. It was reported as the rate per LIA follow-up year and as the expected number of patient-years for 1 false-positive to occur. The percent of patients with an LSE receiving an inappropriate shock was calculated. We calculated all measures for Riata, Durata, Endotak, and Fidelis leads separately.

An LIA true-positive was defined as a LIA alert that was adjudicated as an LSE. Similarly, a conventional impedance true-positive was defined as an impedance nominal threshold crossing that was adjudicated as an LSE. A false-positive was defined as a LIA alert or conventional impedance threshold crossing in the absence of an LSE. Si was defined as the percentage of LSEs (or LFs) detected by LIA that did not cross the impedance nominal threshold. By definition, Si excludes lead events that were not detected by either the LIA algorithm or the impedance nominal threshold and was the most clinically meaningful measure of LIA performance in this analysis. The incidence of LF that occurred without a LIA alert (true sensitivity) could not be determined for St. Jude and Boston Scientific leads because returned-product analysis was not available. Si is not the same as absolute sensitivity, but it provides a measure of the benefit of the LIA algorithm over the impedance nominal threshold criterion. It is the most clinically meaningful measure of LIA performance in this analysis because impedance threshold crossings are commonly used to detect LSEs across ICD manufacturers.

Within each lead family, an exact binomial 95% confidence interval (CI) was constructed to describe the incremental benefit of LIA for detecting LSE. The Fisher exact test was used to compare the incremental benefit of LIA between lead families.

Exact Poisson tests were used to compare the frequency of EGM characteristics and false detection rates among lead families and between sensing configurations. *P* values within the same set of tests were Bonferroni adjusted for multiple comparisons. All statistical methods assumed independence of each device and lead combination. *P* values <0.05 were considered statistically significant.

## Results

LIA was enabled in 12 793 ICD and lead combinations as displayed in Figure 3. The median and interquartile duration of LIA monitoring for all leads was 0.9 years (interquartile range, 0.5–1.6). Patient and device characteristics are

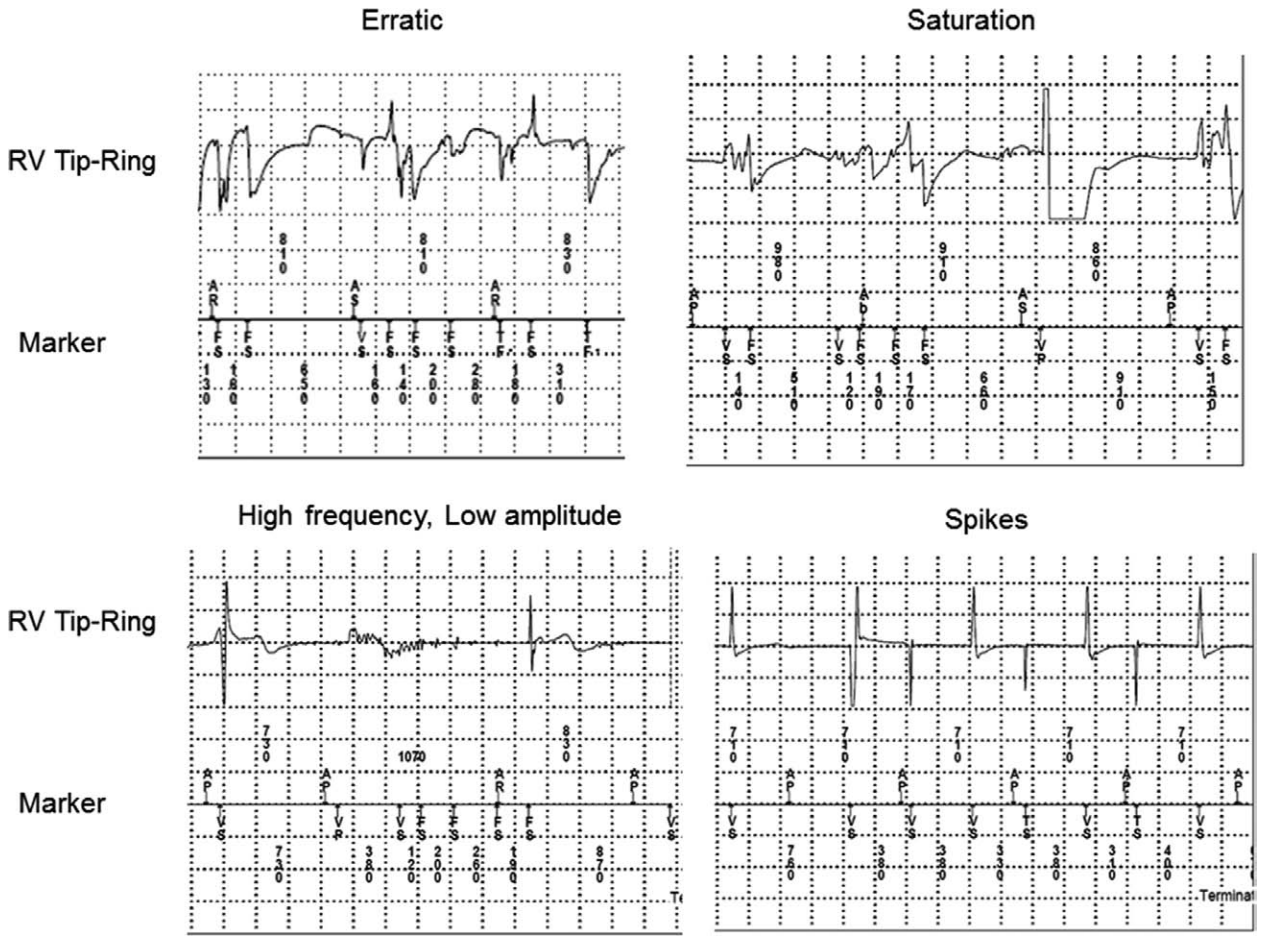


**Figure 2.** Lead noise characteristics. Four types of characteristic electrograms are shown. RV indicates right ventricular.

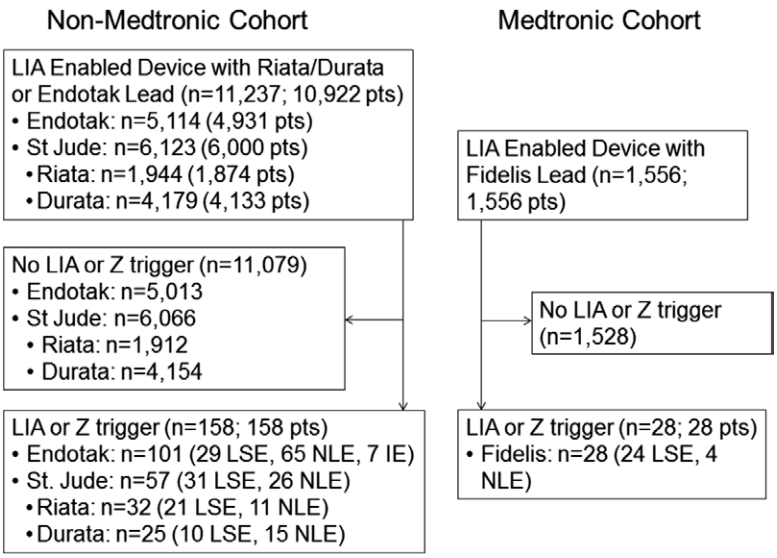


**Figure 3.** Study flowchart. The study flowchart shows the number of patients with and without a Lead Integrity Alert (LIA) trigger or an impedance (Z) trigger for each of the lead models. A patient may have had >1 generator or >1 lead which accounts for the inequality between the number of systems and patients. n represents the number of unique device and lead combinations with LIA enabled. IE indicates insufficient information event; NLE, non–lead system events; and LSE, lead system event.

summarized in Table I in the online-only Data Supplement. Overall, a LIA or conventional impedance alert was activated in 186 patients: 101 patients with Endotak leads, 57 patients with St. Jude leads (Riata: 32 and Durata: 25), and 28 patients with Fidelis leads. Seven LIA triggers from patients with an Endotak lead could not be adjudicated and were excluded from the analysis. The 179 patients used in this analysis included 84 LSEs and 95 NLEs.

## Performance of LIA Versus Conventional Impedance Monitoring

Using the total 84 LSEs (Table II in the online-only Data Supplement), LIA detected 70% (95% CI, 59%–90%) more events than conventional impedance. The Si ranged from 66% to 77% by manufacturer with no statistical differences ($P$=0.573). On a relative scale, LIA identified an additional 2.4 LSEs for every LSE identified by the conventional impedance monitoring. The relative values ranged from 1.9 to 3.4 by manufacturer.

Of the 65 adjudicated LFs, clinical data were available for 60. The 5 remaining leads for which we did not have clinical correlation presented with EGMs characteristic of LF and normal impedance >1 year postimplant. The remaining 19 LSEs that were not classified as LFs were connector issues (10), either connector issue or LF (6), lead perforations/dislodgement (2), and lead–lead interactions (1). Of the 65 LFs, LIA detected 77% (95% CI, 65%–86%) more LFs than conventional impedance. The Si ranged from 67% to 85% by manufacturer with no statistical differences ($P$=0.332). On a relative scale, LIA identified an additional 3.3 LFs for every LF identified by the conventional impedance monitoring. The relative values ranged from 2.0 to 5.5 by manufacturer. Table 1 summarizes LFs by lead family and method of diagnosis.

## Inappropriate Shocks in LSEs

Of the 84 patients with LSEs, 11 (13%) patients received inappropriate shocks: 6% (2/31) for St. Jude leads, 18% (4/29) for Endotak leads, and 21% (5/24) for Fidelis. The 11 LSEs were LF (8; 5 Fidelis, 2 Endotak, 1 St. Jude), perforation or dislodgement (2; 1 Endotak, 1 St. Jude), and connector issue (1; Endotak). Nine (82%) of the 11 patients with shocks had <1 day of LIA warning (4 Fidelis, 3 Endotak, 2 St Jude). The other 2 patients had 2 (Endotak) and 5 (Fidelis) days of LIA warning.

## Electrogram Characteristics in LFs

Table 2 shows that erratic signals were the most common nonphysiological EGM associated with LF, occurring in all

**Table 1. Lead Failures Only**

| Lead Family | Lead Failures* | LIA Only | Impedance Only | LIA and Impedance | Incremental Sensitivity† (95% CI) |
|---|---|---|---|---|---|
| All St. Jude | 26 | 22 | 2 | 2 | 85% (65%–96%) |
| Riata | 20 | 17 | 1 | 2 | 85% (62%–97%) |
| Durata | 6 | 5 | 1 | 0 | 83% (36%–99.6%) |
| Boston Scientific Endotak | 15 | 12 | 1 | 2 | 80% (52%–96%) |
| Medtronic Fidelis | 24 | 16 | 1 | 7 | 67% (45%–84%) |
| All lead families | 65 | 50 | 4 | 11 | 77% (65%–86%) |

Incremental sensitivity was not different between lead manufacturer ($P$=0.332). CI indicates confidence interval; and LIA, Lead Integrity Alert.

*Lead events classified by the lead adjudication committee as lead failures.

†Percentage of lead failures detected by LIA that were not detected by the nominal impedance criterion.

**Table 2. EGM With Spikes**

| | St. Jude | Boston Scientific | Medtronic | *P* Value* |
|---|---|---|---|---|
| Patients with near-field EGM | 24 | 11 | 19 | … |
| Erratic | 19 (79%) | 11 (100%) | 19 (100%) | … |
| Saturation | 8 (33%) | 6 (55%) | 10 (53%) | 0.339 |
| High frequency, low amplitude | 1 (4%) | 1 (9%) | 10 (53%) | <0.001 |
| Spikes total | 17 (71%) | 1 (9%) | 2 (11%) | <0.001 |
| Negative spike | 13 (54%) | 1 (9%) | 1 (5%) | … |
| Positive spike only | 4 (17%) | 0 (0%) | 2 (11%) | … |
| Spikes only | 2 (8%) | 0 (0%) | 0 (0%) | … |

EMG indicates electrogram.
**P* value from Fisher exact test testing whether any lead families are different.

Boston Scientific and Medtronic leads and 79% of St. Jude leads. The proportion of patients with isolated spikes on some EGMs was higher for St. Jude leads (71%) than Boston Scientific (9%) or Medtronic leads (11%; $P<0.001$; Figure 4). However, only 2 of 24 analyzed St. Jude patients (8%) had spikes as their only manifestation of LF. Simultaneous far-field and near-field EGMs were available for analysis in 6 patients with St. Jude leads. Of these, 4 patients (67%) showed simultaneous spikes on both near-field and far-field EGMs (Figure 4A–4C).

## Impedance Characteristics of LF

In contrast to the high prevalence of oversensing in LFs, an abrupt change in LIA impedance or out-of-range conventional impedance occurred in only 15 of 65 leads (23%; Table 1). Of these, 14 were abrupt impedance increases and 1 was an impedance decrease in a St. Jude lead (Figure 5A). An abrupt impedance change occurred in 8 of 24 (33%) of the Fidelis leads compared with 7 of 41 (17%) of the non-Medtronic leads ($P=0.222$). One patient had abnormalities of both the pace-sense and right ventricular defibrillation impedance

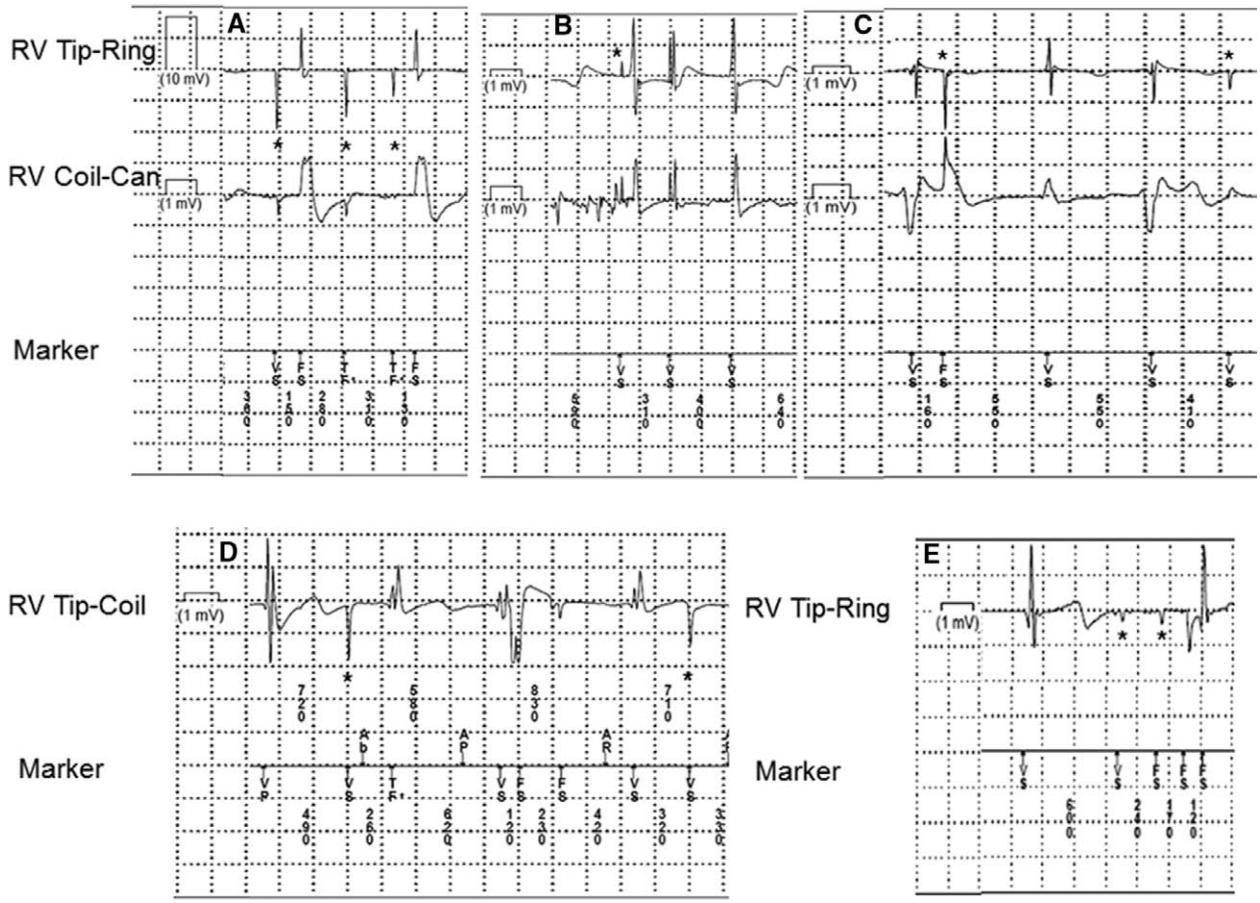


**Figure 4.** Electrogram (EGM) spikes. These examples show spikes on the near-field right ventricular (RV) tip-ring EGM that were oversensed (asterisks). **A** to **C**, Examples of spikes on both the RV tip-ring and RV coil-can EGMs from St. Jude leads. **D**, An example of a spike on the RV tip-coil EGM from an Endotak lead. **E**, An example of a spike on the RV tip-ring EGM from a Fidelis lead.

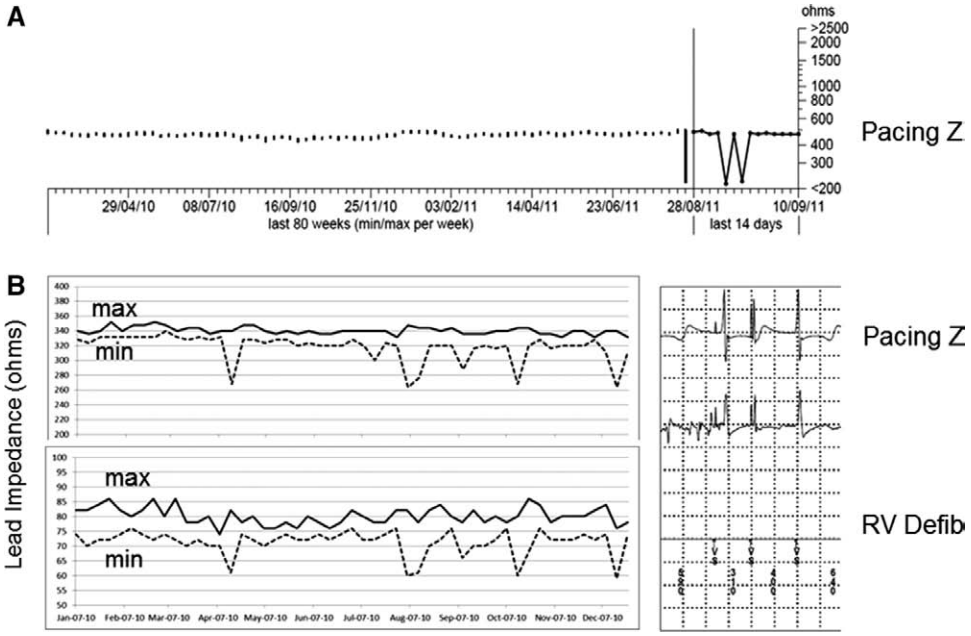


**Figure 5.** Abnormal impedance trends. **A**, Pacing impedance from a Riata ST Optim lead failure with an abrupt decrease from 480 to 216 ohms. This would satisfy the LIA impedance decrease >50%, but not the lower conventional impedance threshold of 200 ohms. **B**, Pacing impedance (Z) and shock impedance trends from a Riata ST Optim lead failure with minor and simultaneous decreases in both trends. The pacing Z ranged from 264 to 352 ohms. The right ventricular (RV) defibrillation impedance ranged from 59 to 88 ohms. In addition, both the RV tip-ring and RV coil-can electrograms were noisy.

trends along with noise on both the near-field and far-field EGMs (Figure 5B).

## Causes of False-Positive LIA Triggers

In 13 562 years of LIA enabled follow-up, there were 95 false-positive NLEs (Table III in the online-only Data Supplement). The LIA false detection (Figures I–III in the online-only Data Supplement) rate was 0.0070 (95% CI, 0.0057–0.0086) per monitoring year, or 1 for 142.8 patient-years. The LIA false detection rates were significantly higher for Boston Scientific Endotak leads compared with St. Jude Riata/Durata ($P$<0.001) and Medtronic Fidelis leads ($P$<0.001).

Among the 5101 years of LIA enabled follow-up for Boston Scientific Endotak leads, there were 65 false-positive NLEs (Table 3), 59 attributable to LIA triggers and 6 attributable to conventional impedance alerts. The primary cause of false detections was EMI (57%) triggering LIA's 2 oversensing components (Table 3). Among the 5951 years of LIA enabled follow-up for St. Jude leads, there were 26 false-positive NLEs (11 with Riata and 15 with Durata leads; Table 3), 23 attributable to LIA and 3 attributable to conventional impedance alerts. The primary cause of false detections was T-wave oversensing (accounting for 38% of NLEs) triggering the LIA's 2 oversensing components.

Table 4 shows that the influence of sensing (true bipolar versus integrated bipolar) on the distribution of 67 false-positive LIA triggers caused by oversensing. The rate of NLE attributable to oversensing was 5 times higher in integrated-bipolar Endotak and St. Jude (n=75) leads than the true-bipolar leads ($P$<0.001). The most common oversensing causes for integrated-bipolar Endotak and St. Jude leads were EMI (74%) and R-wave double counting (14%). In contrast, the most common cause for true-bipolar St. Jude and Medtronic leads was T-wave oversensing (71%). The rate of T-wave oversensing was 7 times higher in true bipolar versus integrated bipolar, but this difference was not significant.

## LIA Criteria Met

Tables IV and V in the online-only Data Supplement show the specific LIA criteria met by 84 LSEs and 95 NLEs for each lead type. A similar proportion of LSEs (11%; 9/84) and NLEs (9%; 9/95) had only a conventional impedance trigger. The

**Table 3. Non–lead Events by Lead Family and Detection Criterion**

| | Fidelis | | | Riata/Durata | | | Endotak | | | All Lead Families | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Non–Lead Event Type | LIA Only | Z Only | Total | LIA Only | Z Only | Total | LIA Only | Z Only | Total | LIA Only | Z Only | Total |
| EMI | 0 | 0 | 0 | 4 | 0 | 4 | 37 | 0 | 37 | 41 | 0 | 41 |
| VT/VF | 2 | 0 | 2 | 8 | 0 | 8 | 9 | 0 | 9 | 19 | 0 | 19 |
| T-wave oversensing | 2 | 0 | 2 | 10 | 0 | 10 | 1 | 0 | 1 | 13 | 0 | 13 |
| Electrode myocardial | 0 | 0 | 0 | 0 | 3 | 3 | 0 | 6 | 6 | 0 | 9 | 9 |
| R-wave double counting | 0 | 0 | 0 | 1 | 0 | 1 | 7 | 0 | 7 | 8 | 0 | 8 |
| Unknown | 0 | 0 | 0 | 0 | 0 | 0 | 3 | 0 | 3 | 3 | 0 | 3 |
| Myopotentials | 0 | 0 | 0 | 0 | 0 | 0 | 2 | 0 | 2 | 2 | 0 | 2 |
| Total | 4 | 0 | 4 | 23 | 3 | 26 | 59 | 6 | 65 | 86 | 9 | 95 |

There were no non–lead events detected by both LIA and impedance monitoring. EMI indicates electromagnetic interference; LIA Lead Integrity Alert; VF, ventricular fibrillation; and VT, ventricular tachycardia.

**Table 4. Oversensing Sources by Lead Type**

| | True Bipolar | | | | | | | | Integrated Bipolar | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | Fidelis | | Riata | | Durata | | Total | | Riata*/Durata†/ Endotak | | |
| Type of Oversensing | No. | No. per Year | No. | No. per Year | No. | No. per Year | No. | No. per Year | No. | No. per Year | *P* Value‡ |
| EMI | 0 | 0 | 3 | 0.0014 | 1 | 0.0003 | 4 | 0.0005 | 37 | 0.0071 | <0.001 |
| T-wave oversensing | 2 | 0.0008 | 4 | 0.0019 | 6 | 0.0016 | 12 | 0.0014 | 1 | 0.0002 | 0.091 |
| R-wave double counting | 0 | 0 | 0 | 0 | 1 | 0.0003 | 1 | 0.0001 | 7 | 0.0014 | 0.025 |
| Other | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 5 | 0.0010 | 0.032 |
| Total | 2 | 0.0008 | 7 | 0.0033 | 8 | 0.0021 | 17 | 0.0020 | 50 | 0.0097 | <0.001 |
| Total (excluding RWDC) | 2 | 0.0008 | 7 | 0.0033 | 7 | 0.0018 | 16 | 0.0019 | 43 | 0.0083 | <0.001 |

EMI indicates electromagnetic interference; and RWDC, R-wave double counting.

*Riata models 1560, 1561, 1590, 1591, 1592, 7052 have integrated-bipolar sensing. Remaining Riata models have true-bipolar sensing.

†Durata model 7130 has integrated-bipolar sensing. Remaining Durata models have true-bipolar sensing.

‡*P* value from comparison of rate of true-bipolar versus integrated-bipolar leads. *P* values for comparison for each individual type of oversensing are corrected for multiple comparisons using the Bonferroni adjustment.

remaining LIA cases were triggered by only the 2 oversensing criteria for 100% (86/86) of the NLEs and 68% (51/75) of the LSEs ($P<0.001$). The LIA impedance criterion was satisfied for 32% of the 75 LSE LIA triggers, 15% of the St. Jude leads, 28% of the Boston Scientific leads, and 57% of the Medtronic leads ($P=0.007$).

### Causes of False-Positive Conventional Impedance Triggers

All 9 (Table V in the online-only Data Supplement) false-positive conventional impedance triggers were caused by gradual impedance rises at the electrode-myocardial interface (Figure IV in the online-only Data Supplement). There were no false-positive impedance triggers for impedance decreases <200 ohms. Only 1 patient with an Endotak lead had a single impedance drop >50% in a lead which triggered LIA but did not cross the conventional impedance threshold. This patient had an abrupt impedance rise shortly after implant, followed by rare decreases to the implant value but the lead continued to function. LIA accepted the higher value as baseline and calculated a 51% impedance drop on return to the implant value.

## Discussion

Despite conventional impedance monitoring, the most common clinical presentation of ICD LFs are inappropriate shocks and other manifestations of oversensing rapid, nonphysiological signals. LIA was the first ICD diagnostic designed to monitor such oversensing. When compared with conventional impedance monitoring for Fidelis fractures, it increased warning before inappropriate shocks in a retrospective study[7] and reduced inappropriate shocks in a prospective study.[8] The primary objective of this study was to evaluate its performance with widely used leads that differ from Fidelis either in sensing dipole (Boston Scientific Endotak) or failure mode (St. Jude Riata). We found that LIA improved LF detection compared with conventional impedance monitoring independent of sensing dipole or primary LF mode. There were significant differences in types of oversensing between integrated-bipolar versus true-bipolar leads connected to the same ICD generators, and the rate of false-positive NLE was higher for integrated-bipolar leads attributable to more frequent oversensing events.

### LIA Performance

For all lead families, LIA increased Si over conventional impedance monitoring by ≥66% for LSEs by more than 67% for LFs. The overall rate of inappropriate shocks for LSE was low (13%). For Riata leads, with oversensing, the fraction of LFs that presented with inappropriate shocks was 5%, significantly lower than the ≈50% using conventional diagnostics.[10,16] The low incidence of inappropriate shocks in patients who had Fidelis leads is similar to what we and others have reported and contrasts dramatically with historical controls who have not received the LIA algorithm.[7–9] This suggests that LIA warnings resulted in clinical actions that prevented subsequent inappropriate shocks in both Medtronic and St. Jude leads. We are not aware of comparable data for Endotak LFs. When LIA was triggered for LSEs, the LIA impedance criterion was satisfied for only 15% (St. Jude) to 57% (Medtronic) of cases. Thus, an oversensing alert is an especially useful clinical tool for St. Jude leads. It is reasonable to infer that an algorithm triggered by rapid, transient oversensing is clinically useful in the general case for improving early diagnosis of pace-sense LF of right ventricular defibrillation leads and reducing related inappropriate shocks, independent of manufacturer and sensing configuration. It is not necessary to test every special case.

### Differences in False-Positives Attributable to Oversensing in Integrated-Bipolar Versus True-Bipolar Leads

The rates of false-positive triggers for NLEs were similar for true-bipolar St. Jude and Medtronic leads, but significantly higher for integrated-bipolar Endotak and St. Jude leads. This difference relates directly to the integrated bipole, which provides a wider antenna resulting in more oversensing of EMI. It also causes a longer duration of the sensed ventricular electrogram attributable to a longer conduction time from the tip electrode to the coil that may contribute to R-wave double counting. In contrast, the most common cause of NLE in true-bipolar leads was T-wave oversensing, possibly related to

higher beat-to-beat variability of R-wave amplitude with true-bipolar leads.[17] A high incidence of EMI in integrated-bipolar leads has been reported previously.[14] Similarly, T-wave oversensing has primarily been reported with true-bipolar leads.[17] However, previous studies used different ICD generators with different sensing circuits, so it is not possible to determine the relative effects of sensing bipole versus pulse generator sensing circuits. This is the first study to demonstrate differences in types of oversensing using leads connected to generators with the same sensing circuits.

### Clinical Significance of False-Positive LIA Triggers

All NLEs were caused by rapid oversensing, except for cases of true ventricular fibrillation, which require clinical evaluation. Because rapid oversensing can cause inappropriate shocks, there is clinical utility in an algorithm that identifies it and prolongs detection times in response. The most common cause in true-bipolar leads was T-wave oversensing, which requires reprogramming or lead replacement. Awareness of EMI, the most common cause in integrated-bipolar leads, is important clinically so that the patient may avoid the source. Thus, although we did not attempt to measure it, false-positive LIA triggers generally provided clinically useful information and may have prevented inappropriate shocks attributable to rapid oversensing unrelated to LF. In contrast, most false-positive conventional impedance triggers occurred in normally functioning leads.

### Electrograms in LF

Erratic EGMs, often referred to as "noise," are recognized as characteristic of LF. Previously, we correlated this EGM with Fidelis fractures and header connection problems.[8,15] The present study confirms that these EGMs are commonly seen in other leads, including St. Jude leads subject to insulation failure. Additionally, St. Jude leads showed a high proportion of spiky near-field EGMs. Near-field spikes most frequently had negative polarity and varied in amplitude. Spikes were present on both near-field and far-field EGMs in 4 of 6 patients who had both recorded. Two case reports describe simultaneous spikes on near-field and far-field EGMs in inside-out, cable-coil short circuits of St. Jude leads.[18,19] Our data indicate that such EGMs are common in failures of St. Jude leads, but we lack returned-product analysis data to confirm the failure mechanism. However, 1 case (Figure 5B, impedance trends) showed simultaneous drops in both pacing and shock impedance, coincident with simultaneous spiky EGMs on near-field and far-field EGMs (Figure 5B, impedance trends), suggesting cable-coil abrasion. Because of noise on both the near-field and far-field EGMs, algorithms that require the far-field EGM to be normal to identify an LF such as the Medtronic's Lead Noise Discrimination algorithm and St. Jude's SecureSense algorithm may not be effective.

### Impedance Trends in LF

Impedance trends were usually normal during the initial EGM noise that triggered LIA. When abnormal impedance was a leading indicator, it made an abrupt increase for Boston Scientific and Medtronic LFs. This may indicate Boston Scientific leads are prone to conductor failures similar to those in Medtronic leads. In contrast, abrupt impedance changes were rare in St. Jude leads prone to insulation failure, and they included both increases and decreases.

### Limitations

This study has several major limitations: LFs were diagnosed clinically, not confirmed by analysis of returned leads. We could not estimate LIA's absolute sensitivity because we could not identify LFs that triggered neither LIA nor a conventional impedance threshold crossing. There was no control group without LIA, so we cannot compare the fraction of patients who receive inappropriate shocks with and without LIA. Finally, because this was an observational study, it is unknown what, if any other patient or device characteristics may have influenced our findings. Specifically, few patient characteristics are available within the CareLink system.

### Conclusions

This study demonstrates that LIA markedly increases Si for diagnosis of LSE and LF over conventional impedance monitoring, not only in true-bipolar leads prone to conductor fracture, but also in integrated-bipolar leads and in true-bipolar leads prone to insulation failure. The low incidence of inappropriate shocks after LIA alerts for LF suggests that physician response reduced their incidence. Most false-positive NLEs corresponded to events that require prompt clinical attention. In addition, this study is the first to identify differences in oversensing between integrated-bipolar and true-bipolar leads connected to the same sensing circuits.

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## Disclosures

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## CLINICAL PERSPECTIVE

Implantable cardioverter-defibrillator (ICD) leads remain the weakest link in ICD systems and continue to have a significant risk of failure during long-term follow-up. The Lead Integrity Alert (LIA), which has been developed to detect ICD lead failure, measures relative changes in impedance and transient oversensing of rapid activity. The algorithm was developed from early coaxial ICD lead failures and then widely tested with the Medtronic Sprint Fidelis leads. We compared the clinical performance of the LIA to detect lead failures in 5114 ICD leads from Boston Scientific (Endotak), 6123 ICD leads from St. Jude Medical (Riata/Durata), and 1556 Fidelis ICD leads followed with remote monitoring. The LIA identified 67% more lead failures compared with conventional impedance monitoring, and detection did not differ by lead family. LIA false detections from electromagnetic interference or T-wave oversensing were more common for the Boston Scientific Endotak family of leads. The LIA algorithm markedly increased the detection rate of true lead failures for both integrated-bipolar leads and dedicated bipolar leads, was associated with a low incidence of inappropriate shocks, and was triggered despite normal impedance trends. Most false-positive LIA events are clinical events that require prompt clinical attention. Integrated-bipolar leads are associated with a higher rate of false-positive LIA alerts. LIA successfully identified ICD lead failures before inappropriate therapy delivery.

# SUPPLEMENTAL MATERIAL

**Table 1S.** Patient Demographics

| | | | Non-Medtronic Cohort | | | |
|---|---|---|---|---|---|---|
| **Variable** | **Variable Level** | **Fidelis Cohort** | **Riata** | **Durata** | **Endotak** | **All Models** |
| Device/Lead Combinations | | 1556 | 1944 | 4179 | 5114 | 12793 |
| Distinct Leads | | 1556 | 1875 | 4142 | 4933 | 12506 |
| Distinct Devices | | 1556 | 1943 | 4174 | 5114 | 12779 |
| Distinct Patients | | 1556 | 1874 | 4133 | 4931 | 12478 |
| Device Type | ICD-VR | 19.0% (296/1556) | 13.5% (263/1943) | 14.8% (617/4174) | 17.8% (912/5114) | 16.3% (2087/12779) |
| | ICD-DR | 47.6% (740/1556) | 33.2% (646/1943) | 35.3% (1473/4174) | 39.2% (2005/5114) | 38.0% (4859/12779) |
| | CRT-D | 33.4% (520/1556) | 53.2% (1034/1943) | 49.9% (2084/4174) | 43.0% (2197/5114) | 45.6% (5833/12779) |
| Device Age (years) | n reporting | 1553 | 1936 | 4170 | 5107 | 12758 |
| | Median (IQR) | 6.1 (4.4-6.2) | 1.8 (0.8-3.1) | 1.1 (0.6-1.9) | 1.3 (0.7-2.4) | 1.5 (0.8-2.9) |
| Lead Age (years) | n reporting | 1546 | 1875 | 4142 | 4922 | 12485 |
| | Median (IQR) | 6.2 (5.3-6.2) | 3.8 (2.4-5.9) | 1.1 (0.6-1.9) | 7.0 (5.1-9.3) | 4.0 (1.4-6.6) |
| LIA Follow-up time (years)* | n reporting | 1556 | 1944 | 4179 | 5114 | 12793 |
| | Median (IQR) | 1.8 (1.3-2.1) | 0.9 (0.4-1.6) | 0.8 (0.4-1.3) | 0.9 (0.4-1.4) | 0.9 (0.5-1.6) |
| Lead History† | Old Lead | 18.1% (281/1556) | 48.4% (908/1875) | 3.2% (134/4142) | 81.6% (4025/4933) | 42.8% (5348/12506) |
| | New Lead | 81.3% (1265/1556) | 51.6% (967/1875) | 96.8% (4008/4142) | 18.2% (897/4933) | 57.1% (7137/12506) |
| | Unknown | 0.6% (10/1556) | 0.0% (0/1875) | 0.0% (0/4142) | 0.2% (11/4933) | 0.2% (21/12506) |
| Patient Gender | Male | 75.9% (1181/1556) | 71.7% (1344/1874) | 70.0% (2895/4133) | 75.4% (3716/4931) | 73.1% (9125/12478) |
| | Female | 23.3% (363/1556) | 27.6% (517/1874) | 29.6% (1224/4133) | 23.9% (1178/4931) | 26.3% (3277/12478) |
| | Unknown | 0.8% (12/1556) | 0.7% (13/1874) | 0.3% (14/4133) | 0.8% (37/4931) | 0.6% (76/12478) |
| Patient Age (years)‡ | n reporting | 1549 | 1869 | 4130 | 4924 | 12456 |
| | Mean ± SD | 65.1±12.5 | 66.9±14.4 | 66.4±15.4 | 66.5±13.9 | 66.3±14.3 |
| Transmission Type | Manual | 88.2% (6832/7749) | 52.7% (5253/9973) | 56.4% (11412/20221) | 58.6% (15750/26881) | 60.5% (39247/64824) |
| | Wireless | 11.8% (917/7749) | 47.3% (4720/9973) | 43.6% (8809/20221) | 41.4% (11131/26881) | 39.5% (25577/64824) |

*LIA enabled follow-up years are the years of LIA enabled follow-up computed from the last LIA enabled transmission to the date LIA was programmed ON for each device and lead combination.

†Old lead means that lead was implanted prior to the first device a lead configured with. New lead means lead was implanted on or after the device implant date.

‡Age on date of first device implant.

A patient may have had more than one generator or more than one lead which accounts for the inequality between the number of pulse generators, ICD leads, and patients.

**Table 2S.** All Lead System Event (LSE)

| Lead Family | Lead System Events* | LIA Only | Impedance Only | LIA and Impedance | Incremental Sensitivity† (95% CI) |
|---|---|---|---|---|---|
| **All St. Jude** | **31** | **24** | **4** | **3** | **77% (59%-90%)** |
| Riata | 21 | 18 | 1 | 2 | 86% (64% - 97%) |
| Durata | 10 | 6 | 3 | 1 | 60% (26% - 88%) |
| **Endotak** | **29** | **19** | **4** | **6** | **66% (46% - 82%)** |
| **Fidelis** | **24** | **16** | **1** | **7** | **67% (45% - 84%)** |
| **All Lead Families** | **84** | **59** | **9** | **16** | **70% (59% - 80%)** |

*Lead system events as classified by the lead adjudication committee. Lead system events were those events caused by a lead connectivity issue (e.g. lead failure [insulation breach, fracture], connector issue, or lead dislodgement/perforation).
†Percentage of events detected by LIA that were not detected by the nominal impedance criterion.
Incremental sensitivity was not different between lead manufacturer (P=0.573).

**Table 3S:** Non-Lead System Event (NLE) Detection Rate

| | | | | NLEs Detected | | | | |
|---|---|---|---|---|---|---|---|---|
| **Lead Family** | **Device-Lead Combinations** | **Total LIA Follow-up Years** | **Median (IQR)* LIA Follow-up Years** | **LIA only** | **Impedance only** | **Total** | **Overall False Detection Rate per Year (95% CI)†** | **Years of Monitoring per False Detection** |
| **Integrated Bipolar Leads** | | | | | | | | |
| Boston Scientific Endotak | 5114 | 5100.9 | 0.9 (0.4 - 1.4) | 59 | 6 | 65 | 0.0127 (0.0098 - 0.0162) | 78.5 |
| St. Jude Riata/Durata | 75 | 76.4 | 0.9 (0.4 - 1.4) | 0 | 0 | 0 | 0 (0 - 0.0483) | NE |
| Riata | 74 | 75.6 | 0.9 (0.4 - 1.4) | 0 | 0 | 0 | 0 (0 - 0.0488) | NE |
| Durata | 1 | 0.7 | 0.7 (0.7 - 0.7) | 0 | 0 | 0 | 0 (0 - 4.9354) | NE |
| All Integrated Bipolar Leads | 5189 | 5177.3 | 0.9 (0.4 - 1.4) | 59 | 6 | 65 | 0.0126 (0.0097 - 0.0160) | 79.7 |
| **True Bipolar Leads** | | | | | | | | |
| St. Jude Riata/Durata | 6048 | 5874.5 | 0.8 (0.4 - 1.4) | 23 | 3 | 26 | 0.0044 (0.0029 - 0.0065) | 225.9 |
| Riata | 1870 | 2022.8 | 0.9 (0.4 - 1.6) | 9 | 2 | 11 | 0.0054 (0.0027 - 0.0097) | 183.9 |
| Durata | 4178 | 3851.7 | 0.8 (0.4 - 1.3) | 14 | 1 | 15 | 0.0039 (0.0022 - 0.0064) | 256.8 |
| Medtronic Fidelis | 1556 | 2510.5 | 1.8 (1.3 - 2.1) | 4 | 0 | 4 | 0.0016 (0.0004 - 0.0041) | 627.6 |
| All True Bipolar leads | 7604 | 8385.0 | 1.0 (0.5 - 1.7) | 27 | 3 | 30 | 0.0036 (0.0024 - 0.0051) | 279.5 |
| All lead families | 12793 | 13562.4 | 0.9 (0.5 - 1.6) | 86 | 9 | 95 | 0.0070 (0.0057 - 0.0086) | 142.8 |

*IQR = interquartile range
†Exact Poisson 95% confidence interval
NE=not estimable
P-value for comparison of Riata/Durata vs Fidelis leads: 0.208
P-value for comparison of Riata/Durata vs Endotak leads: <0.001
P-value for comparison of Fidelis vs Endotak leads: <0.001
P-values comparing false detection rate between lead families are corrected for muliple comparisons using the Bonferonni adjustment.
P-value for comparison of true bipolar leads vs integrated bipolar leads: <0.001

**Table 4S.** LIA Criteria Satisfied for LSEs

| LSE | Z+SIC | Z+NST | Z+SIC+NST | SIC+NST | conventional Z only | Total |
|---|---|---|---|---|---|---|
| Riata™ | 0 | 2 | 1 | 17 | 1 | 21 |
| Durata™ | 0 | 1 | 0 | 6 | 3 | 10 |
| Endotak™ | 3 | 3 | 1 | 18 | 4 | 29 |
| Fidelis™ | 0 | 0 | 13 | 10 | 1 | 24 |
| Total | 3 | 6 | 15 | 51 | 9 | 84 |

NST: LIA NST criterion; SIC: LIA SIC criterion; Z: LIA Z criterion

**Table 5S.** LIA Criteria Satisfied for NLEs

| NLE | Z+SIC | Z+NST | Z+SIC+NST | SIC+NST | conventional Z only | Total |
|---|---|---|---|---|---|---|
| Riata™ | 0 | 0 | 0 | 9 | 2 | 11 |
| Durata™ | 0 | 0 | 0 | 14 | 1 | 15 |
| Endotak™ | 0 | 0 | 0 | 59 | 6 | 65 |
| Fidelis™ | 0 | 0 | 0 | 4 | 0 | 4 |
| Total | 0 | 0 | 0 | 86 | 9 | 95 |

NST: LIA NST criterion; SIC: LIA SIC criterion; Z: LIA Z criterion

**Figure 1S.** False positive LIA triggers. **A.** Example of a LIA trigger due to VT/VF from a Durata™ lead. **B.** Example of a LIA trigger due to T-wave oversensing from a Durata™ lead. The asterisks (*) show where the T-wave oversensing occurred on the RV Tip-Ring EGM.

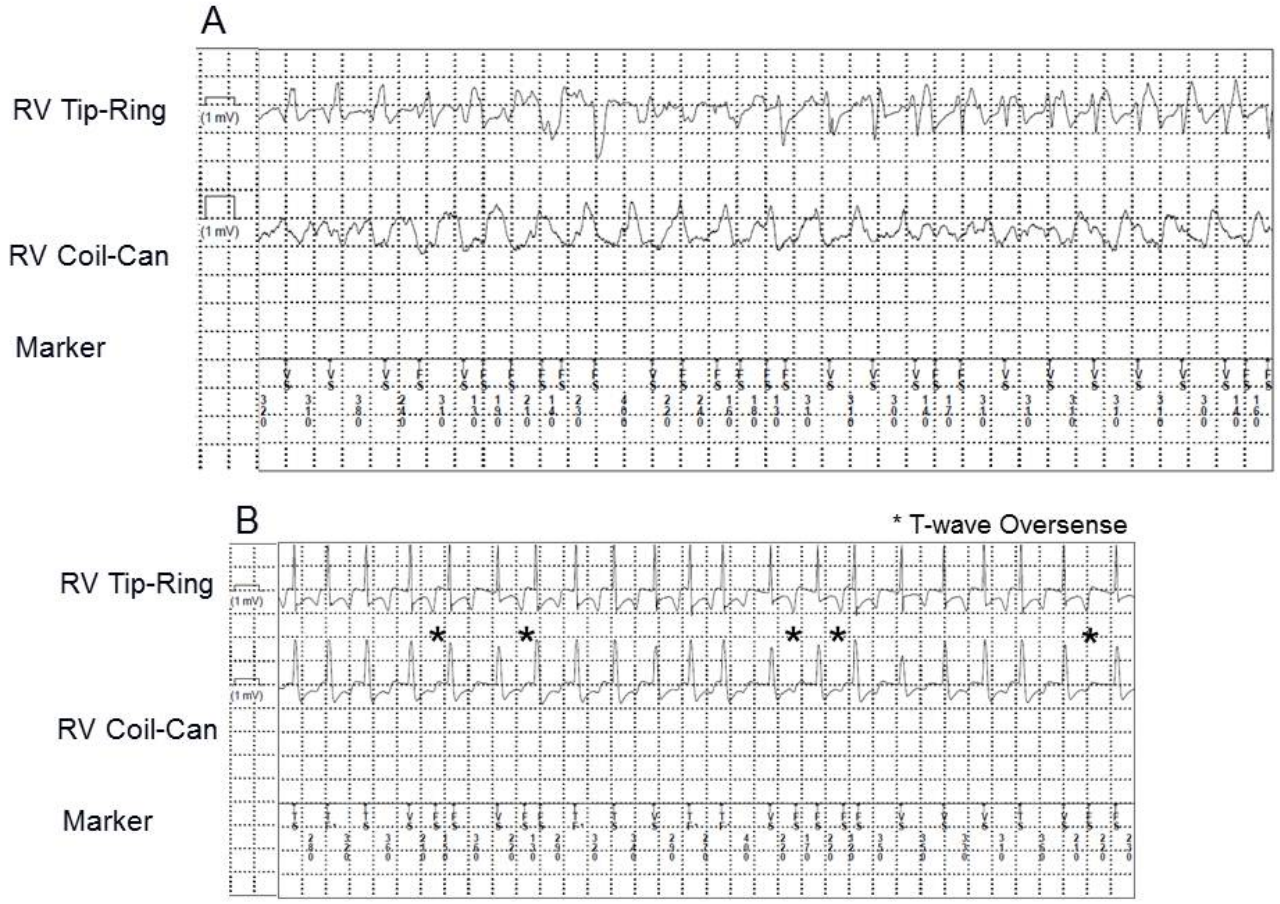

**Figure 2S.** False positive LIA triggers. **A.** Example of a LIA trigger due to R-wave double-counting (RWDC) during a non-sustained VT from an Endotak™ Reliance G lead. The oval line shows where the RWDC occurred on the RV Tip-Coil EGM. **B.** Example of a LIA trigger due to myopotential oversensing from an Endotak™ Reliance G lead. The oval line shows where the myopotentials occurred on the RV Tip-Coil EGM.

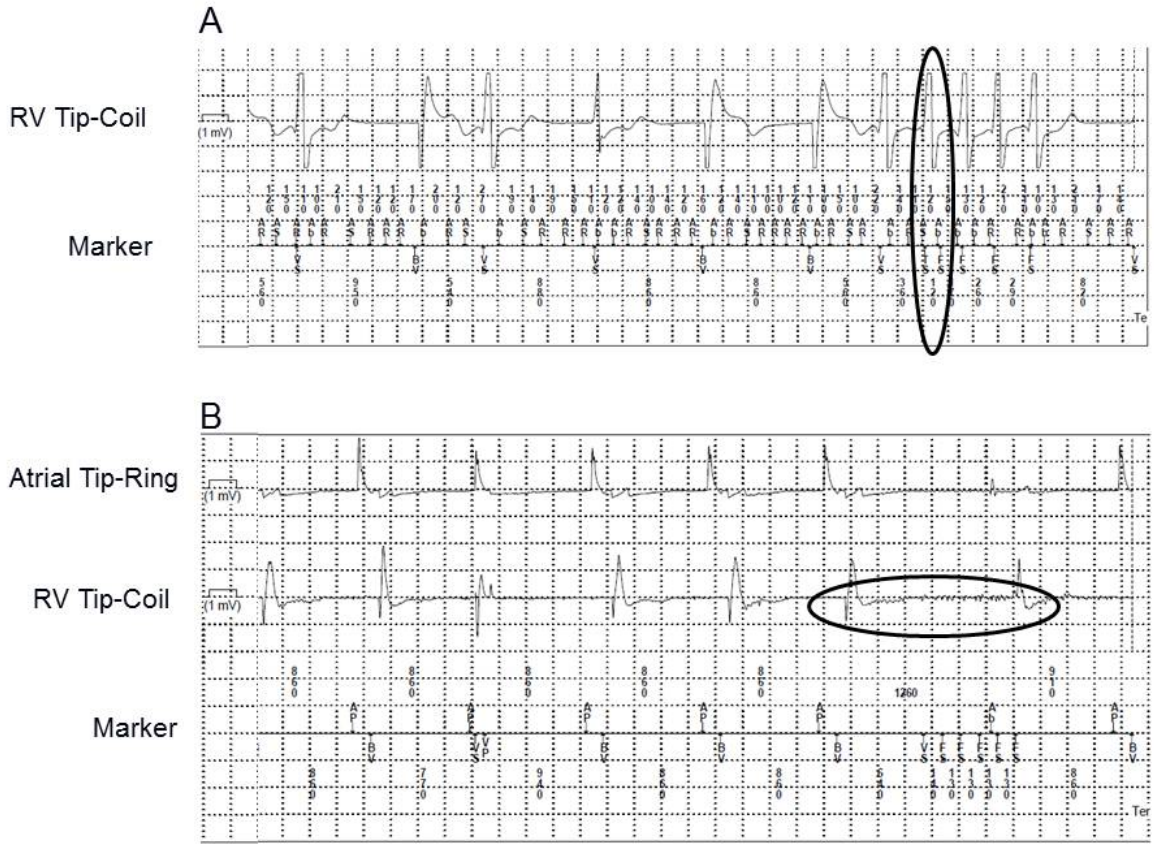

**Figure 3S.** False positive LIA trigger. Example of a LIA trigger due to electromagnetic interference (EMI) oversensing from an Endotak™ Reliance lead. The EMI is visible on both the Atrial Tip-Ring and RV Tip-Coil EGMs.

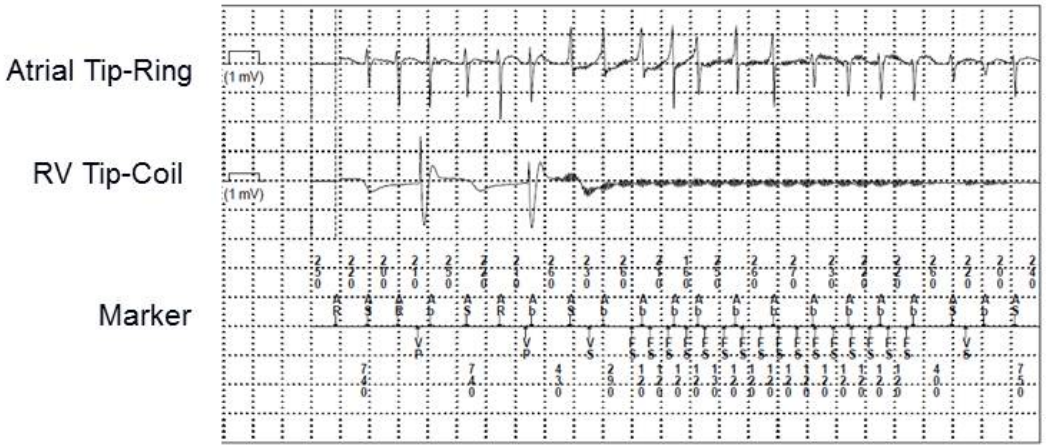

**Figure 4S.** False positive impedance trigger**.** Example of a conventional impedance trigger (pace-sense impedance > 2000 Ω) due to an electrode-myocardial interface issue from a Riata™ ST Optim lead.