Downloadable Algorithm to Reduce Inappropriate Shocks Caused by Fractures of Implantable Cardioverter-Defibrillator Leads

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Background—The primary method for monitoring implantable cardioverter-defibrillator lead integrity is periodic measurement of impedance. Sprint Fidelis leads are prone to pace-sense lead fractures, which commonly present as inappropriate shocks caused by oversensing.

Methods and Results—We developed and tested an algorithm to enhance early identification of lead fractures and to reduce inappropriate shocks. This lead-integrity algorithm, which can be downloaded into presently implanted implantable cardioverter-defibrillators, alerts the patient and/or physician when triggered by either oversensing or excessive increases in impedance. To reduce inappropriate shocks, the lead-integrity algorithm increases the number of intervals to detect (NID) ventricular fibrillation when triggered. The lead-integrity algorithm was tested on data from 15 970 patients with Fidelis leads (including 121 with clinically diagnosed fractures) and 95 other fractured leads confirmed by analysis of returned product. The effect of the NID on inappropriate shocks was tested in 92 patients with 927 shocks caused by lead fracture. Increasing the NID reduced inappropriate shocks (P<0.0001). The lead-integrity algorithm provided at least a 3-day warning of inappropriate shocks in 76% (95% CI, 66 to 84) of patients versus 55% (95% CI, 43 to 64) for optimal impedance monitoring (P=0.007). Its positive predictive value was 72% for lead fractures and 81% for lead fractures or header-connector problems requiring surgical intervention. The false-positive rate was 1 per 372 patient-years of monitoring.

Conclusions—A lead-integrity algorithm developed for download into existing implantable cardioverter-defibrillators increases short-term warning of inappropriate shocks in patients with lead fractures and reduces the likelihood of inappropriate shocks. It is the first downloadable RAMware to enhance the performance of nominally functioning implantable cardioverter-defibrillators and the first implantable cardioverter-defibrillator monitoring feature that triggers real-time changes in ventricular fibrillation detection parameters to reduce inappropriate shocks. (Circulation. 2008;118:2122-2129.)

Key Words: defibrillators ■ lead ■ lead failure ■ recall

Fractures of pace-sense conductors in implantable cardioverter-defibrillator (ICD) defibrillation leads result in high pacing impedance1,2 and oversensing of rapid, nonphysiological, make-break potentials.3-5 Despite daily, automated measurements of pacing impedance to provide advance warning, lead fractures present most commonly as inappropriate shocks. Because oversensing, rather than high impedance, causes inappropriate shocks, an algorithm that includes measures of both oversensing and impedance may enhance detection of lead fractures.

Editorial p 2117
Clinical Perspective p 2129

The risk of unnecessary shocks caused by the detection of transient, nonsustained ventricular tachycardia is reduced by increasing the number of intervals to detect (NID) ventricular fibrillation (VF).6 Because oversensing associated with lead fracture typically is transient,1,7 increasing the NID may reduce inappropriate shocks caused by lead fractures, but it also may increase the risk of syncope before appropriate shocks.8

In October 2007, Medtronic (Minneapolis, Minn) discontinued sale of Sprint Fidelis leads because of the rate of pace-sense conductor fractures.9 We evaluated the performance of a lead-integrity algorithm (LIA) that combines both impedance and oversensing components in these leads. The LIA initiates an alert10,11 and increases NID if a fracture is suspected. It was written with the constraint that it could be downloaded into implanted Medtronic ICDs.
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minimum measurements. This threshold is 1000 based on the average of the most recent weekly maximum and transmits a wireless, Internet-based alert if enabled. The LIA sounds an audible alert immediately and every 4 hours thereafter, sets the programmed NID at 30 of 40 (30/40) intervals (Figure 1A), of nonphysiological, rapid oversensing. Once the LIA is triggered, it triggered by either abnormally high impedance or sufficient evidence of insulation failures of coaxial ICD leads.12 The present LIA, which includes both substantial modifications and additions to that algorithm, is designed to work with existing diagnostics, including pacing impedance and 2 indicators of nonphysiological, rapid oversensing. It is based on an algorithm developed to identify insulation failures of coaxial ICD leads.12 The present LIA, which includes both substantial modifications and additions to that algorithm, is designed to work with existing diagnostics, including pacing impedance and 2 indicators of nonphysiological, rapid oversensing. Once the LIA is triggered, it sets the programmed NID at 30 of 40 (30/40) intervals (Figure 1A), sounds an audible alert immediately and every 4 hours thereafter, and transmits a wireless, Internet-based alert if enabled.

The impedance trigger, designed for chronic leads, uses a threshold based on the average of the most recent weekly maximum and minimum measurements. This threshold is 1000 Ω if the average is <700 Ω, 1500 Ω if the average is 700 to 1100 Ω, and 2000 Ω if the average is ≥1100 Ω.

The rapid oversensing trigger of the LIA detects nonphysiologically short R-R intervals caused by pace-sense conductor failures via a combination of 2 criteria based on existing diagnostics, the sensing integrity counter and nonsustained tachycardia log. The sensing integrity counter stores the cumulative number of nonphysiologically short R-R ≤130 ms. The sensing integrity counter criterion is satisfied by a count ≥30 within 3 days. The nonsustained tachycardia log stores ≥5 consecutive sensed events with cycle length less than or equal to the ventricular tachycardia detection interval. Most true nonsustained ventricular tachycardias have cycle lengths ≥220 ms. The nonsustained tachycardia criterion of the LIA is satisfied by 2 episodes with an average cycle length <220 ms in 60 days. The oversensing trigger of the LIA is activated if both the sensing integrity counter and nonsustained tachycardia criteria are fulfilled.

Methods

LIA Components

The LIA was designed to work with existing diagnostics, including pacing impedance and 2 indicators of nonphysiological, rapid oversensing. It is based on an algorithm developed to identify insulation failures of coaxial ICD leads.12 The present LIA, which includes both substantial modifications and additions to that algorithm, is designed to work with existing diagnostics, including pacing impedance and 2 indicators of nonphysiological, rapid oversensing. Once the LIA is triggered, it sets the programmed NID at 30 of 40 (30/40) intervals (Figure 1A), sounds an audible alert immediately and every 4 hours thereafter, and transmits a wireless, Internet-based alert if enabled.

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Patient Groups

The LIA triggers were developed and tested for positive predictive value on data sets from independent groups of patients using ICD diagnostics and electrograms stored as “save-to-disk” files from the Internet-based CareLink network.13 The development group consisted of 9411 patients in a February 2007 query of CareLink patients. The test group for positive predictive value consisted of 15 970 different patients in an April 2007 query. Together, these development and test groups included all patients with all models of the Marquis family ICDs and Fidelis leads in the database.

We estimated the advance warning of the LIA before inappropriate shocks using patients whose lead fractures were confirmed by returned-product analysis (RPA). This test group consisted of 95 patients who met 3 criteria: (1) Pace-sense lead fractures were confirmed by structural analysis and abnormally high impedance at RPA; (2) a save-to-disk file had adequate data preceding the clinical presentation of lead fracture; and (3) the patient was not included in the development group.

LIA Triggers: Development and Testing for Positive Predictive Value

CareLink files with either impedance or oversensing LIA triggers were reviewed with particular attention to electrograms showing

![Figure 1. Analysis of the relationship between NID and inappropriate shocks caused by lead failure. A, Stored electrogram shows intermittent oversensing caused by lead fracture. Pace-sense (V_Tip-V_Ring), high-voltage (RV Coil-CAN), and marker channels are shown. VS, TS, and FS are the intervals in sinus, ventricular tachycardia, and VF zones, respectively; FD indicates the detection of VF. Top and bottom panels are continuous. Pace-sense channel shows intermittent, high-frequency oversensing of nonphysiological noise characteristic of lead fracture or header-conector problem. At the programmed NID 18/24, inappropriate detection of VF occurs near left on the bottom, resulting in an inappropriate shock (not shown). Coincident with detection of VF, oversensing decreases markedly. VF would not have been detected at higher values of NID. B, Emulation of ICD detection of VF. Top, Compressed pace-sense electrogram shows true ventricular electrograms (V EGM) and high-frequency noise (oversensing), together with a marker channel from a different episode. NID is programmed to NID 12/16. The bottom panel is time aligned with the top panel. It shows time on the abscissa and the value of the VF counter on the ordinate for the programmed NID 12/16 and emulated NIDs of 18/24, 24/32, and 30/40. At each NID, VF is detected when the curve reaches the corresponding dotted horizontal line. At the programmed NID 12/16, VF was detected when the counter reached 12 just before 25 seconds (dotted black vertical line). The shock is delivered at 30 seconds. At emulated NID 18/24, the shock would have been delivered within a second of the actual shock (dotted pink vertical line). Detection was not met at emulated NIDs 24/32 and 30/40 before the shock was delivered.](http://circ.ahajournals.org/Download/10.1161/CIRCULATIONAHA.111.026581/FIG1a.png)
high-frequency “noise,” characteristic of lead fracture, and patterns characteristic of other types of oversensing.\textsuperscript{1,2,7} We cross-checked these patients against Medtronic’s device registration and RPA databases to determine the status of each lead. If we could not confirm the status of a lead, Medtronic Technical Services contacted the physician to determine whether the lead had been replaced and, if not, to provide clinical data relating to the cause of oversensing or elevated impedance.

An LIA trigger was considered a true positive indicator of lead fracture if a new defibrillation or pace-sense electrode had been inserted for the diagnosis of lead failure by April 2008. Because the impedance and oversensing characteristics of lead fracture cannot be distinguished from incomplete contact between the lead pin and pulse generator header, which often requires surgical revision, we also determined the true positive rate for the combination of lead fracture and header-connector failures requiring surgical revision. LIA triggers were considered false positive if no evidence of lead failure was detected during follow-up.

Impedance triggers were further characterized as abrupt versus gradual. An abrupt change was defined as an increase of 350 Ω relative to a baseline, defined as the minimum of the 3 preceding weekly averages of daily maximum and minimum values.

### Effect of NID on Inappropriate Shocks

We tested the hypothesis that increasing NID decreases inappropriate shocks caused by lead fracture using a validated desktop computer emulation of the ICD detection algorithm. The 92 patients analyzed included all 71 patients in the RPA group who had inappropriate shocks and all 21 patients in the CareLink test group for whom stored electrograms confirmed at least 1 inappropriate shock caused by lead fracture.

In this analysis, we used the programmed VF detection interval for each device-detected episode (312 ± 14 ms) and varied the emulated NID (12/16, 18/24, 24/32, 30/40). Each emulated episode was processed until detection occurred at the emulated NID or the actual shock was delivered (see Figure 1B). Episodes not detected at the emulated NID are subject to reset of the VF counter to 0 after 8 consecutive long RR intervals. For each NID, we computed the percentage of oversensing episodes that were detected inappropriately as VF.

### LIA: Testing for Advance Warning

We analyzed 95 RPA patients, 2 independent reviewers (including B.D.G.) reviewed each data file to determine the dates on which the impedance and oversensing LIA triggers were fulfilled. A third reviewer (C.D.S.) adjudicated uncertainties. Overall, 35 patients were programmed to NID 12/16, 55 patients to NID 18/24, and 5 patients to NID 24/32.

To estimate the incremental advance warning provided by LIA triggers, we considered 2 control conditions relating to programmed values for NID and the impedance alert in all 95 RPA patients. The first corresponded to programming before the October 15, 2007, Medtronic Physician Advisory,\textsuperscript{9} including the physician-selected NID. We applied an impedance threshold of 2500 Ω in all patients.

The second control condition corresponded to programming recommendations in the advisory. We applied the recommended impedance threshold (identical to the LIA threshold, usually 1000 Ω) to all data files. For patients who were programmed to a physician-selected NID 12/16, we simulated NID 18/24.

Using the patients in the second control condition, we estimated advance warning both for the combined impedance and oversensing triggers of the LIA alone and for the complete LIA, including trigger-initiated increase in NID to 30/40. For the last analysis, we applied the value of NID in the second control condition until the LIA was triggered and then simulated NID 30/40.

We also determined whether the specific pace-sense conductor fractured (cable to ring electrode or helix to tip electrode) influenced the advance warning of the LIA.

### Statistical Analysis

Kaplan-Meier survival analysis was used to estimate the warning time under 4 conditions: preadvisory programming, postadvisory programming, LIA triggers (impedance plus oversensing), and LIA triggers plus automatic NID increase. Survival curves were compared as follows: postadvisory versus LIA and preadvisory versus postadvisory. We used the Wilcoxon test for this comparison because it is sensitive to differences in the initial portion of the curve, which are most important clinically. Curves were adjusted for the sensitivity of each algorithm so that the initial value represents the percent of patients who had a warning before an inappropriate shock.

We further sought to compare “no warning” with “any warning,” which permits the LIA to increase NID and the patient to seek medical attention. Thus, we determined the fraction of patients with warning at 2 prospectively specified times (0 and 3 days) for each curve and present these data with 95% CIs. We used the Wilcoxon test for a point-wise comparison at 3 days to compare the postadvisory curve with the LIA and LIA-trigger curves. In the NID analysis, we used generalized estimating equations to account for multiple episodes per patient. We used logistic regression to analyze statistical significance among different values of NID and adjusted for multiplicity. The rates of false-positive triggers for impedance and oversensing were assumed to follow exponential distributions. They were compared using the normal approximation.

The authors had full access to and take full responsibility for the integrity of the data. All authors have read and agree to the manuscript as written.

### Results

#### Clinical Presentation of Lead Fractures

Of the 95 patients in the RPA group, 71 (75%) presented with at least 1 inappropriate shock. Of the patients who did not receive shocks, 9 patients (12%) were identified by abnormal impedance alone, 1 patient (1%) by oversensing alone, and 14 patients (15%) by both. The 92 patients with inappropriate shocks (71 in the RPA group, 21 in the CareLink test group) had a median of 5 shocks (range, 1 to 43; mean, 10.1).

#### LIA Triggers

Overall, 90 of the 95 RPA leads (95%) triggered the LIA before shocks, and 5 leads (5%) did not; 56 leads (59%) met the impedance trigger, 79 leads (83%) met the oversensing trigger, and 45 leads (47%) met both. Figure 2 shows individual patient LIA data. Figure 2A shows abrupt variations in impedance exceeding 1000 Ω, triggering an LIA alert 12 days before an inappropriate shock. Figure 2B shows a false-positive LIA impedance trigger gradual with an increase in impedance. Figure 2C shows a true-positive oversensing alert triggered 6 days before an inappropriate shock despite constant impedance. In Figure 2D, the LIA was not triggered before the first inappropriate shock. However, because both impedance and oversensing triggers occurred 1 hour 45 minutes after that shock, the automatic NID increase would have prevented the subsequent shocks 5 hours later.

#### LIA Positive Predictive Value and False Positives

In the CareLink test group, there were 167 LIA triggers, including 121 caused by lead fractures, 15 caused by header-connector problems that required surgical revision, and 31 that did not require surgical revision. Overall, the positive predictive value was 72% (95% CI, 65 to 79) for lead fractures alone and 81% (95% CI, 75 to 87) for lead fracture or header-connector problems requiring surgical revision.
None of the 31 false positives met both impedance and oversensing triggers.

The rate of false-positive triggers per patient-year was similar for oversensing and impedance (0.00139 versus 0.00130; \( P = 0.96 \)). Because ICDs store impedance trends longer than oversensing data (15,084 versus 7,704 patient-years), there were more false-positive impedance triggers (n=21) than oversensing triggers (n=10). From stored electrograms and clinical follow-up, the causes of 3 false-positive oversensing triggers were determined to be true VF with very short intervals, lead dislodgement, and oversensing during cardiac surgery. The causes of the remaining 28 false-positives could not be determined because patients were asymptomatic and no electrograms were stored.

None of the 56 RPA patients who met the impedance trigger had a gradual increase in impedance. Gradual increases occurred in 8 of 21 patients (38%) with false-positive impedance triggers versus only 4 of the 110 patients (4%) with clinically diagnosed fractures who met the impedance trigger (\( P = 0.00004 \)). One of these 4 patients developed oversensing and an additional abrupt increase in impedance (from 1904 to 2704 \( \Omega \)) >6 months after the LIA alert. The remaining 3 patients had no evidence of fracture other than gradual impedance rise. They underwent lead replacement 10 to 12 months after the LIA alert. Thus, no patient with a gradual increase required a lead replacement within 6 months of LIA alert.

Abnormal sensing integrity counts alone occurred in 45 additional patients. Of these, 1 patient (2%) had a header-connector problem, and 8 patients (18%) underwent lead replacement: 4 patients (9%) had clinically diagnosed lead fractures confirmed by electrogram noise, 3 patients (7%) subsequently met the LIA impedance trigger, and 1 patient (2%) had lead replacement on the basis of the sensing integrity count alone. The remaining 36 patients (80%) had intact leads. Of these, the cause of the abnormal sensing integrity counter was T-wave oversensing followed by premature beats in 6 patients, lead dislodgment in 3 patients, and unknown in 27 patients.

**Effect of Increasing NID on Inappropriate Shocks**

Figure 1A shows a stored electrogram from a patient with NID 12/16 who would not have received an inappropriate shock with NID 30/40. Figure 3 shows the effect of increasing NID on inappropriate detection of VF. Overall, we analyzed 927 inappropriate shocks in 364 device-defined, shocked episodes. The fraction of shocked episodes decreased monotonically from 100% at NID 12/16 to 16% at NID 30/40. NID 30/40 was associated with a 79% relative reduction in shocks per patient versus 18/24. The corresponding difference in shocks per patient was \( 7.9 \pm 10.5 \) (median, 3) at NID 18/24 versus \( 3.0 \pm 5.5 \) (median, 1) at NID 30/40 (\( P < 0.0001 \)).
LIA Advance Warning

Figure 4 shows the cumulative fraction of RPA patients with advance warning before the first inappropriate shock. Curves are shown for the 2 control groups (preadvisory and postadvisory programming), the 2 triggers of the LIA (impedance and oversensing), and the complete LIA, including an increase in NID after a trigger alert.

Postadvisory programming provides benefit over preadvisory programming ($P < 0.0001$) both because of the increase in NID from 12/16 to 18/24 and because of the change in impedance threshold. Addition of the LIA oversensing trigger to the postadvisory impedance trigger increases the fraction of patients with any warning from 66% (95% CI, 55 to 74) to 97% (95% CI, 90 to 99; $P = 0.02$), but it does not significantly increase the fraction of patients with 3 days of warning ($P = 0.1$). Thus, adding the oversensing trigger to postadvisory programming usually provides only brief, incremental warning. However, the complete LIA algorithm, with an automatic increase in NID to 30/40, significantly increases the fraction of patients with 3 days of warning compared with postadvisory programming from 55% (95 CI, 43 to 64) to 76% (95% CI, 66 to 84; $P = 0.007$).

Effect of Fracture Type on Performance of LIA

Of the 95 patients in the RPA group, 41 (43%) had fractures of the coil conductor to the tip electrode and 54 (57%) had fractures of the cable conductor to the ring electrode. Figure 5 shows that all coil fractures occurred at the anchor sleeve, whereas 52 of the cable fractures (96%) occurred distally or at the bifurcation/trifurcation. Figure 6 shows the expected performance of the LIA as a function of fracture type. The LIA provided greater warning for the cable fractures than coil fractures ($P = 0.0001$). However, the incremental benefit of the LIA compared with postadvisory programming was comparable for the 2 fracture types. For example, 3-day warning increased 22% (from 66% to 88%; $P = 0.04$) for cable fractures and 20% (from 41% to 61%; $P = 0.07$) for coil fractures.

Discussion

This study evaluated the performance of a downloadable LIA based only on existing diagnostics in presently implanted ICDs. Our principal findings are that this algorithm enhances the identification of lead fractures and reduces inappropriate shocks. It is both the first downloadable RAMware designed...
to enhance the performance of nominally functioning ICDs and the first ICD monitoring feature that triggers real-time changes in device programming to reduce inappropriate shocks. We validated the LIA in both the largest reported clinical cohort of patients with ICD leads and the largest reported set of leads with clinical-engineering correlation based on ICD diagnostics and findings at RPA.

Detecting Pace-Sense Conductor Failures
Inappropriate shocks are the most common clinical manifestation of ICD lead failures. Because inappropriate shocks caused by pace-sense conductor fractures usually occur in clusters, they often have severe psychological consequences. Rarely, they cause clinically significant loss of pacing, the inability to defibrillate, or fatal proarrhythmia.

Existing methods of identifying these fractures based on impedance monitoring are insufficient. Oversensing of nonphysiological signals causes inappropriate shocks in pace-sense lead failures independently of the failure mechanism. Previously, an LIA that incorporated oversensing was developed to detect insulation failure of coaxial leads.

The present study demonstrates that an LIA incorporating both oversensing and patient-specific impedance provides higher sensitivity for lead fractures than impedance monitoring alone. Because all fractured leads have abnormal impedance at RPA, the limited sensitivity of impedance monitoring probably is due to the low sampling frequency. A fracture may generate sufficient oversensing to cause inappropriate shocks before (Figure 2D) or within a few hours of the daily measurement. Over hours to a few days, oversensing is a more sensitive predictor of inappropriate shocks than impedance monitoring for 2 reasons. First, oversensing is measured continuously in real time, whereas impedance is measured daily. Second, oversensing is the proximate cause of inappropriate shocks.

A high sensing integrity count has been proposed as the single oversensing criterion, but it is nonspecific. Our data show that using it as the sole oversensing criterion markedly reduces the positive predictive value.

Preventing Inappropriate Shocks: Role of NID
Addition of the LIA oversensing trigger to impedance monitoring significantly increased the fraction of patients with any warning, but it increased the fraction of patients with 3 days of warning only insignificantly. This finding indicates that the oversensing trigger often provides only brief incremental warning over the impedance trigger at programmed values of NID. Previously, we demonstrated that increasing NID reduces inappropriate shocks caused by nonsustained ventricular tachycardia. The present study shows that increasing NID reduces inappropriate shocks caused by transient oversensing resulting from lead fracture.

Safety of Increasing NID
Because programming NID 30/40 prolongs detection of VF, it may increase the risk of syncope before appropriate shocks, especially in rare cases of significant undersensing during VF. The Primary Prevention Parameters Evaluation (PREPARE) study supports the safety of programming NID 30/40, including a low incidence of syncope. Charge-time considerations also suggest that NID 30/40 is safe in most
patients. The mean time to detect VF increased from 2.7 seconds at NID 12/16 to 6.4 seconds at NID 30/40,18 but because charge times of Medtronic ICDs have decreased 3 to 5 seconds in the last decade, the time to shock with NID 30/40 is comparable to that in the late 1990s with NID 18/24. Nevertheless, neither expert consensus nor clinical practice presently accepts routine programming of NID 30/40. For example, in our second query of the CareLink database, 99% of patients were programmed to NID <=24/32. Thus, we designed an LIA that reprograms NID to 30/40 only if an alert is triggered. It permits 97% of patients with lead fractures to receive the benefit of increasing NID for reducing inappropriate shocks. However, it does not change their NID at other times or program patients without LIA triggers to NID 30/40. Patients remain programmed to NID 30/40 only from the time of LIA trigger until they receive medical attention. Assuming a lead fracture rate of 1% per year and a mean time to medical care of 3 days after an LIA alert, the average patient will be exposed to NID 30/40 about 0.01% of the time, or 1 day per 27 years of ICD therapy. This minimal exposure to must be weighed against the benefit of increasing NID for reducing inappropriate shocks.

Coil Versus Cable Fractures

Our data show that the coil conductor to the tip electrode fractures in the anchor sleeve region, whereas the cable conductor to the ring electrode fractures either distally or at the bifurcation/trifurcation. The LIA provides greater warning for patients with fractures of the cable than those with fractures of the coil. If the distribution of fracture types is not uniform among implanters, the advance warning provided by the LIA also may not be uniform. However, both groups benefit from the LIA relative to impedance monitoring alone.

Preventing Inappropriate Shocks: Response to Alerts

Because the interval between LIA alert and inappropriate shock may be short, the value of the LIA depends on timely response to an alert. Three strategies may be used. First, patients who have wireless telemetry ICDs and are followed up by the CareLink network will have a network alert transmitted if the daily device self-check identifies an LIA alert. Second, Medtronic ICDs can be programmed to emit a warbling tone in response to an alert.10 The LIA alert sounds immediately and then every 4 hours. Third, during magnet application, Medtronic ICDs emit a constant tone in the absence of an alert. Patients or caregivers can place a magnet over the ICD for a few seconds each day to confirm the absence of an alert. Either Internet-based alerts or daily magnet application by a caregiver may be preferred for patients who cannot hear alert tones.

Clinical Approach After LIA Alert

Because inappropriate shocks may be imminent once an alert is triggered, the physician should promptly disable detection of VF and evaluate patients. All LIA alerts that included both impedance and oversensing triggers required surgical intervention. However, false positives occurred when only 1 trigger was activated. A gradual increase in impedance without oversensing never required immediate lead replacement and usually indicated a false positive: 0 of the 12 patients with gradual increases underwent lead replacement within 6 months of the alert, and only 1 patient subsequently showed confirmatory evidence of lead fracture.

Although the LIA does not analyze electrograms, electrogram evidence of intermittent, high-frequency noise generally is accepted as an indication for surgical intervention. The downloaded LIA will store electrograms for transient episodes of suspected, rapid oversensing to facilitate interpretation of alerts. Appropriate diagnostic steps1,2,7,17 including analysis of stored and real-time electrograms, should be performed before surgery to exclude a false-positive alert. At surgery, header-connector problems should be excluded before a new lead is inserted.

Downloadable Software in ICDs

Downloadable RAMware has been used to test investigational algorithms19 and to correct software anomalies. The LIA is the first downloadable RAMware developed to enhance the performance of nominally functioning ICDs. It is designed for essentially all implanted ICD models produced by the manufacturer and uses existing diagnostics and unsignaled memory. Given the increasing longevity of pulse generators, risks associated with their replacement (including infection), and the rapid rate of software innovation, this approach of enhancing the performance of nominally functioning ICDs may be used more widely. The LIA also is the first ICD monitoring feature to trigger real-time, automatic changes in VF detection parameters when the a priori probability of inappropriate shocks is high.

Relevance to Other Leads and ICDs

Oversensing of nonphysiologically short intervals and resultant inappropriate shocks are general characteristics of ICD pace-sense lead failures.1,2,12 An oversensing trigger improves identification of failures of other ICD leads,12 and increasing NID would probably reduce inappropriate shocks. Thus, the LIA probably will improve early diagnosis of pace-sense conductor fractures for all ICD leads. ICDs from other manufacturers have impedance alerts with nominal thresholds >=2000 Ω. Our data indicate that these nominal values are too high for Fidelis leads20 and raise the question of whether they are too high for other leads, most of which have pacing impedances <1000 Ω.

Study Limitations

We did not download the LIA into implanted ICDs. Prospective clinical trials are required to validate the performance of the LIA. Our method of estimating the incremental value of increasing NID has 2 sources of error: We considered only the period up to the delivered shock and only the initial detection. The first overestimates performance because only a limited number of intervals were available to satisfy higher values of NID. The second underestimates performance because the shock confirmation process at NID 30/40 would abort some shocks that were delivered at the programmed NID. In some patients, advance warning and positive predictive value may be underestimated because the earliest warnings...
may have been overwritten by subsequent events as a result of the limited memory of the nonsustained tachycardia log.

Conclusions
In a simulated retrospective analysis, an LIA that can be downloaded into implanted ICDs improved advance warning of pace-sense lead fractures compared with presently recommended impedance monitoring. Its clinical value depends on rapid response to alerts by the patient and physician. This LIA is the first downloadable RAMware developed to enhance the performance of nominally functioning ICDs and the first ICD monitoring feature that triggers real-time changes in VF detection parameters to reduce inappropriate shocks.

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