An Algorithm to Predict Implantable Cardioverter-Defibrillator Lead Failure

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OBJECTIVES The goal of this analysis was to test an algorithm that identifies implantable cardioverter-defibrillator (ICD) lead problems before clinical failure and/or inappropriate therapy.

BACKGROUND The ICD lead failures typically present as inappropriate shock therapy. Identifying lead failures before their clinical presentation may prevent patient discomfort, improve device longevity, and avoid device-induced proarrhythmia.

METHODS We tested an algorithm that uses two measures of oversensing and one measure of abnormal impedance to detect a lead failure. The oversensing measures consisted of a counter for RR intervals <140 ms and nonsustained ventricular tachycardia episodes with mean RR interval <200 ms. The impedance measure tracked lead impedances every day and each week. Abnormal impedance was defined as a decrease in impedances or an outlier value compared with baseline. Lead failures were identified when both oversensing measures were met or abnormal impedance and one oversensing measure occurred. The stored data from 696 patients with an ICD were analyzed to determine the sensitivity and specificity of the algorithm to detect lead failures.

RESULTS Twenty-nine patients demonstrated clinical lead failures with an average of 6 ± 9 inappropriate shocks per patient. The two oversensing measures used in the algorithm predicted 72% (21 of 29) of the lead failures. Fulfilling at least two of the three impedance and oversensing measures, the sensitivity of our algorithm was 83% (24 of 29) with a 100% (667 of 667) specificity.

CONCLUSION Oversensing combined with abnormal impedance trends may be used to identify ICD lead failures with high sensitivity and very high specificity. (J Am Coll Cardiol 2004;44:1898–902) © 2004 by the American College of Cardiology Foundation

The implantable cardioverter-defibrillator (ICD) has become the treatment of choice for patients with life-threatening ventricular tachyarrhythmias (1,2). Implantable cardioverter-defibrillators rely on accurate sensing of the ventricular rhythm for appropriate detection of ventricular tachycardia. Oversensing of other events (e.g., noise due to lead failure, T waves, myopotentials, electromagnetic interference) may cause inappropriate therapies. Lead failures are one of the most common causes of oversensing resulting in inappropriate shocks. A lead failure may also present with failure to sense ventricular tachycardia or ventricular fibrillation, inability to terminate ventricular tachyarrhythmias, or induction of ventricular tachyarrhythmias (“proarrhythmia”).

The ICD leads are significantly more complex in design than pacemaker leads and may be more susceptible to lead failure (3–9). The higher sensitivity used in ICD sense amplifiers makes them more susceptible to oversensing of noise signals than pacemakers.

The purpose of our study was to test an algorithm that was designed to detect abnormal ICD lead malfunction in patients with a wide variety of ICD leads before the clinical presentation of lead failure.

METHODS

Impedance measurements. The GEM (Medtronic Inc., Minneapolis, Minnesota) family of ICDs performs subthreshold lead impedance measurements to monitor multiple conductor fracture and insulation breach scenarios. For the pacing impedance measurement, a subthreshold 200 mV, 60 μs pulse is delivered from tip to ring, and voltage is measured between these conductors. The voltage and current measurements are used to calculate the impedance (voltage/current). The high voltage (HV) impedances are measured with a subthreshold 400 mV, 60 μs pulse delivered from the tip to an HV electrode (e.g., right ventricular [RV] coil). The voltage is measured between the same HV electrode (e.g., RV coil) and a different electrode (e.g., ring). For example, the ring-to-RV coil impedance is measured with a current resulting from a pulse delivered between the tip-to-RV coil, and the observed voltage difference between ring-to-RV coil. All impedance measurements are automatically made daily at 3:00 AM and stored in device memory.

Algorithm design. The algorithm was designed using a database collected retrospectively from patients with pace/sense lead failures and patients without pace/sense oversensing problems (i.e., excluding patients with myopotentials,

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external therapies, lead failures, and so on). Stored memory data used for the three components of the algorithm included the sensing integrity counter (SIC), nonsustained tachycardia (NST) episode log, and impedance trends. If at least two of the three components were satisfied, then a lead failure was said to occur.

Oversensing due to a lead failure often occurs soon after the blanking period of the sense amplifier (e.g., 120 ms). The SIC quantifies this oversensing by incrementing for RR intervals <140 ms. A date/time stamp indicates when the counter first increments since the last ICD interrogation. An average SIC per day was calculated by dividing the SIC by the fraction of days from the first count to the date/time stamp of the current ICD interrogation. If the SIC per day was ≥10 counts or the SIC total was >300, then the first component was satisfied.

Consecutive oversensed events may trigger a stored inappropriate NST episode. The ICD requires a minimum of five consecutive intervals in the tachycardia detection zones to store an NST episode. The NST log stores up to the 50 most recent episodes. Ventricular arrhythmias typically have an average cycle length ≥200 ms, and NST episodes with RR <200 ms are likely due to oversensing. Two NST episodes with RR <200 ms <1 week apart were required to satisfy the second component.

Impedance trends were stored in ICD memory for up to one year, including 14 daily measurements and 52 minimum and maximum weekly measurements. An eight-week sliding window was used to create a baseline value to be compared with the most recent impedance value. The minimum weekly baseline was the second largest value in the current eight-week window. The maximum weekly baseline was the second smallest value in the current eight-week window.

Three weekly maximum tip-ring impedances >200% of the maximum baseline were required to indicate an abnormal impedance (Fig. 1). In addition, three weekly minimum tip-ring impedances <50% of the minimum baseline were required to indicate an abnormal impedance trend. Gradual degradation of lead insulation may result in a decreasing impedance trend. The linear slope of a five-beat overlapping median window over 12 weeks was calculated. At least a 45% decrease in the minimum tip-ring impedance was considered abnormal (Fig. 2). Middle insulation degradation between the middle (i.e., ring) and outer (i.e., RV coil) coaxial conductors (10,11) was characterized by ring-RV coil impedances decreasing <15 ohms (12). An algorithm requiring four of seven minimum ring-RV coil impedances to be <15 ohms was derived from the patients that exhibited the abnormal decreasing ring-RV coil impedances (Fig. 3). The abnormal impedance criterion (i.e., third component) was satisfied when any one of these impedance algorithms was satisfied.

Individually, each of these three components may be satisfied during a lead failure. Each component may result in false positives. A high SIC may occur with R-wave double counting or electromagnetic interference. Multiple short cycle length NST episodes may occur during an electrical storm. Impedance may decrease during an increase in lung fluid. Requiring more than one component decreases the risk of false positives.

Database. The algorithm discussed earlier was designed based on our prior reported experience with ICD lead failures (12,13). Because the incidence of lead failures is small, very large and lengthy studies would be needed to collect enough patients with lead failures to develop and test the algorithm. Instead, patients with confirmed lead failures were collected from trouble-shooting consultations and multiple manufacturer clinical studies (i.e., problem group). A different group was collected from patients in ICD clinical studies without oversensing problems (i.e., normal group). The development database included 11 patients in the problem group and 211 patients in the normal group.

Abbreviations and Acronyms

- HV = high voltage
- ICD = implantable cardioverter-defibrillator
- NST = nonsustained tachycardia
- RR = consecutive QRS complexes
- RV = right ventricle/ventricular
- SIC = sensing integrity counter

Figure 1. Plot of high tip-ring impedances. The three high impedances ≥200% of the baseline are circled. The arrow indicates that the impedance criteria would have triggered four weeks before the inappropriate shock (i.e., end of impedance trend). These impedances were below the 2,000-ohm fixed threshold.

Figure 2. Plot of decreasing tip-ring impedances. The line shows the linear regression fit through the decreasing impedance values over 12 weeks. The arrow indicates the impedance criteria would have triggered three weeks before the inappropriate shock.
A different preexisting database of two patient groups was used to test the algorithm. The sensitivity of the algorithm was determined using ICD data from patients in the problem group. The specificity of the algorithm was determined using ICD data from patients in the normal group. Stored device memory was collected from single- and dual-chamber ICDs of the GEM family (models 7227, 7229, 7231, 7271, 7273; Medtronic Inc.). Each episode from the problem group contained at least one inappropriately detected ventricular fibrillation episode with electrograms. The episode electrograms, returned lead analysis (when available), clinical actions (e.g., lead replaced, lead capped) were reviewed to confirm a lead failure (e.g., insulation break or conductor fracture). The problem group consisted of 29 patients with a lead failure collected from September 1999 to January 2002. Twelve patients had a lead with a coaxial body design (model 6936; Medtronic 6944: 4; 6945: 7; Medtronic Inc.), and 17 patients had a lead with a multilumen body design (ICD lead models 6943: 1; 6944: 4; 6945: 7; Medtronic Inc.). Each episode from the problem group contained at least one inappropriately detected ventricular fibrillation episode with electrograms. The episode electrograms, returned lead analysis (when available), clinical actions (e.g., lead replaced, lead capped) were reviewed to confirm a lead failure (e.g., insulation break or conductor fracture). The problem group consisted of 29 patients with a lead failure collected from September 1999 to January 2002. Twelve patients had a lead with a multilumen body design (ICD lead models 6943: 1; 6944: 4; 6945: 7; Medtronic Inc.), and 17 patients had a lead with a coaxial body design (model 6936; Medtronic Inc.).

The normal group consisted of 667 patients with ICD lead models 6942 (n = 283), 6944 (n = 248), 6943 (n = 79), 6932 (n = 28), 6945 (n = 25), 6936 (n = 4) (Medtronic Inc.), and Guidant Corporation (St. Paul, Minnesota) model 0125 (n = 1). Patients were included in the normal group if they did not have any detected episodes classified as inappropriate due to oversensing by the clinician or did not receive external shocks resulting in oversensing observed on the detected episode. The data for this group was collected between December 1998 and December 2000 from the ICD lead model 6944 (Medtronic Inc.) and ICD pulse generator models 7229 and 7273 (Medtronic Inc.) clinical studies. They had a mean age of 64 ± 11 years, 83% were male, and the mean ejection fraction was 34 ± 14%. There was a total follow-up time of 435 patient-years.

**Data analysis.** The sensitivity and specificity were measured for each of the three algorithm components individually and as a combined algorithm. The time from prediction to an inappropriate detection was estimated using the impedance and NST components separately. Impedance trends provide continuous data over the prior 52 weeks. The NST log has limited storage and may not include the initial occurrence of satisfying the criteria.

Continuous variables were reported as mean values ± standard deviation and otherwise as percentages. McNemar’s exact test was used to compare sensitivity proportions for matched pairs. A conservative approach was taken to keep the overall error rate at 0.05 for multiple comparisons. To implement this approach, two correlated comparisons were assumed to be independent. A p value <0.025 was considered statistically significant using Bonferroni’s adjustment.

**RESULTS**

We analyzed 29 patients in the problem group averaging 11 ± 14 inappropriate detections per patient (range 1 to 56). The time to first inappropriate detection from lead implant was 44 ± 27 months (range 1 to 80 months) with a median of 55 months. On average, patients received 6 ± 9 inappropriate shocks (range 0 to 38). Shock therapy was delivered on the first inappropriate detection for 31.0% (9 of 29) of the patients. Multiple shocks were delivered to 51.7% (15 of 29) of the patients.

**Sensitivity.** The sensitivity to identify a lead failure satisfying at least two of the three criteria was 82.8% (24 of 29). Three patients had only NST episodes with no abnormal impedance trend (Fig. 4). One patient only satisfied the SIC criteria, and one patient did not satisfy any of the three criteria. Using only the two oversensing criteria, the sensitivity was 72.4% (21 of 29). Using abnormal impedance and either of the two oversensing criteria, the sensitivity was 41.4% (12 of 29). All abnormal impedance trends had at least one oversensing criteria satisfied. The sensitivity using only the fixed threshold (e.g., 2,000 ohms) was 6.9% (2 of 29). Both the two of three criteria and the two oversensing criteria were significantly better than the fixed threshold of 2,000 ohms (p ≤0.0001 for both comparisons). The NST had the highest individual sensitivity of 89.7% (Table 1).

There were 37.9% (11 of 29) patients with abnormal impedance before an inappropriately detected episode. One patient with impedance >2,000 ohms was excluded because

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**Figure 3.** Plot of decreasing ring-coil impedances. The four impedances <15 ohms were circled. The arrow indicates that the impedance criteria would have triggered 15 weeks before the inappropriate shock.

**Figure 4.** Venn diagram showing the number of patients satisfying each of the three lead failure components. Each of the 29 patients could satisfy zero, one, two, or all three components. NST = nonsustained tachycardia episode; OS = oversensing; SIC = sensing integrity counter; Z = impedance trend.
the abnormal impedance occurred after the only detected episode that did not result in a shock. Three patients had multilumen leads (Fig. 5), and eight patients had coaxial leads (Fig. 6). The mean time from abnormal impedance to inappropriate ventricular fibrillation detection was $8.1 \pm 7.2$ weeks (range 1.4 to 22.0 weeks). Decreasing impedance occurred in 82% (9 of 11) of the patients, and high impedance outliers occurred in 18% (2 of 11) of the patients.

The ICD was first interrogated $31.1 \pm 39.7$ days (median 15 days; range 0 to 158 days) after the first inappropriate detection. Of the 26 patients meeting the NST criteria, 16 patients had their entire NST logs rewritten with episodes occurring after the first inappropriate detection. Using the episodes in the 16 overwritten logs, the NST criterion was satisfied $17.1 \pm 33.3$ days (median 4 days; range 0 to 134 days) after the first inappropriate detection. The NST criterion was satisfied $19.8 \pm 56.7$ days (median 2 days; range 1 s to 181 days) before the first inappropriate detection for the 10 patients without all their NST episodes before detection. This is a less reliable estimate because the first NST episodes satisfying the criteria could have been overwritten.

Specificity. There were no false positives in the normal group during 435 patient-years resulting in a specificity of 100%. The impedance trend had the highest individual specificity of 99.7% (Table 1).
sleeping and thus not associated with body movement that may also further provoke an intermittent conductor or insulation break. Thus, single impedance measurements may have been unable to predict lead failure. Current ICDs use only fixed impedance thresholds, such as $>$2,000 ohms or $<$200 ohms as a trigger to indicate lead failures. Our algorithm incorporated these fixed impedance measurements, but also used measurements of impedance trends stored in the ICD memory for up to one year. We analyzed trends in impedance changes over time and found them helpful for predicting ICD lead failure. Our algorithm was tested on a large ICD database and identified lead failures with an 83% sensitivity and no false positives from patients followed for 435 patient-years. The algorithm detected lead failures at least an estimated three to eight weeks before clinical presentation.

From a clinical point of view, this algorithm may be helpful in a number of ways. By providing warning of an impending lead failure, it allows the clinician to intensify patient follow-up and plan a course of action for further appropriate patient management. Secondly, in a patient with a limited life expectancy, it allows the clinician to reprogram the device off and avoid the delivery of inappropriate shocks that may be stressful to a patient and their family. Finally, it allows the physician to continuously collect information on the electrical properties of leads that may help identify problem leads before clinical manifestations of failure become evident.

**Study limitations.** The exact time at which the two oversensing measures were satisfied could not be determined exactly. We could only determine if the SIC was satisfied when the data was collected at a follow-up visit. The nonsustained episodes were stored in a 50-episode buffer that may get filled up (“first in-first out”). The earliest episodes were lost if more than 50 episodes occurred. It is, therefore, possible that the measures of oversensing may have demonstrated abnormalities earlier than the three to eight weeks reported in our study. The algorithm was developed from a group of patients with lead failures, and these leads do not represent a cross-section of all ICD leads implanted in the ICD patient population. Additionally, our numbers are too small to make definitive observations on particular types of leads and modes of lead failure. Finally, we did not test how accurately the algorithm could differentiate lead failure from other noise sources (e.g., external electromagnetic interference, myopotentials).

**Conclusions.** Oversensing and abnormal impedance measurements provide an early warning before inappropriate ventricular fibrillation detection. Our algorithm demonstrated a high sensitivity and very high specificity for identifying ICD lead failures. This algorithm may be implemented in future ICD systems to identify lead failures before they result in painful unnecessary shocks, battery depletion, and potential proarrhythmia.

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**REFERENCES**


