Automatic Identification of Implantable Cardioverter-Defibrillator Lead Problems Using Intracardiac Electrograms

BD Gunderson, AS Patel, CA Bounds

Medtronic, Inc., Minneapolis, USA

Abstract

Implantable Cardioverter-Defibrillator (ICD) lead problems can cause inappropriate painful shocks or inappropriately withheld lifesaving shocks. ICDs contain storage for detected spontaneous episodes that can be analyzed to characterize lead performance.

The goal of this project was to develop an automatic lead problem identification algorithm using stored episode data. The algorithm combines sensed RR interval patterns and electrogram (EGM) characteristics to identify non-cardiac (NC) oversensing (OS) problems (e.g. lead failures) and cardiac (C) OS problems (e.g. T-wave OS). Stored episodes from 59 patients with OS and 147 patients with no OS were used for evaluation.

The sensitivities to identify the lead problems were 97.7% for NC-OS and 86.7% for C-OS with a specificity of 98.0%. Analysis of stored episodes with EGM may be used to identify ICD lead problems with very high sensitivity and specificity.

1. Introduction

The implantable cardioverter defibrillator (ICD) has become the treatment of choice for patients with life threatening ventricular tachyarrhythmias. ICD leads are significantly more complex than pacemaker leads (i.e. more conductors and electrodes) and may be more susceptible to oversensing problems (i.e. sensed events other than R-waves) [1-5]. Also, ICD sense amplifiers are 10 times more sensitive than pacemakers in order to sense the small VF electrogram signal. Automatically identifying these problems may provide clinicians timesaving opportunities to improve patient management.

Most lead problems resulting in an inappropriate detection due to oversensing fall into two groups:

- Non-Cardiac Oversensing
  - Lead failure (e.g. conductor fracture, insulation break, loose connectors)
  - Electromagnetic Interference (EMI) (e.g. contact with ungrounded electrical appliances)
  - Myopotential (e.g. diaphragm)
- Cardiac Oversensing
  - T-wave Oversensing (TWOS)
  - R-wave double counting (RWDC)

Each of these problems has resulted in ICD detected episodes with EGM and RR intervals that were stored in the ICD memory. The non-cardiac oversensing problems are characterized by varying degrees of noise on the EGM signal and irregular intervals (figure 1).

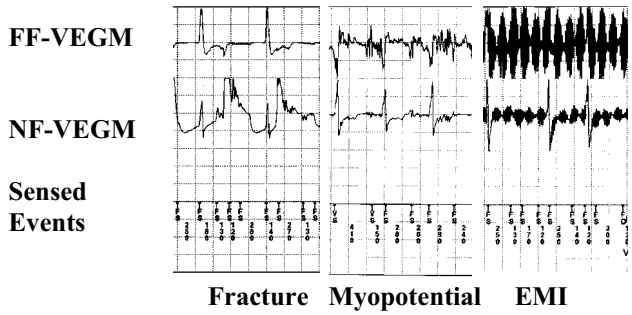

Figure 1. Non-cardiac Oversensing Lead Problems

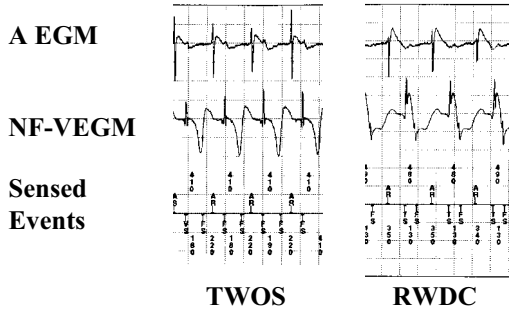

Figure 2. Cardiac Oversensing Lead Problems

Cardiac oversensing occurs when components of the R-wave and/or T-wave inappropriately exceed the sensing threshold, resulting in an oversensed event (figure 2). These include double counting a wide R-wave and oversensing the T-wave due to reduced R-wave amplitude and/or an enlarged T-wave.

The goal of this project was to develop and evaluate an algorithm that could automatically analyze the EGM from the detected episodes in the memory of an ICD to identify oversensing lead problems.

2. Methods

2.1. Algorithm design

The algorithm was designed using retrospective data from ICD detected episodes and discussions of lead problem characteristics with ICD and lead experts. Episodes were collected from patients with and without lead problems.

Each detected VF episode with ventricular EGM stored in device memory was analyzed for any of the five oversensing problems. Since nearly all the problems result in VF detection, the algorithm analyzed only VF episodes. Data used for analysis included the timing between sensed events (e.g. R-waves, noise) resulting in a series of RR intervals (10 ms resolution) and the 128 Hz, 8 bit resolution ventricular electrogram (2.5-100 Hz filter) recorded between either the near-field tip and ring/coil sensing electrodes (NF-EGM) or the far-field coil and ICD can electrodes (FF-EGM). Figure 3 displays the overall flow diagram to identify each lead problem from a VF episode. Each decision branch in the flow diagram that doesn't lead to another decision or answer indicates no problem.

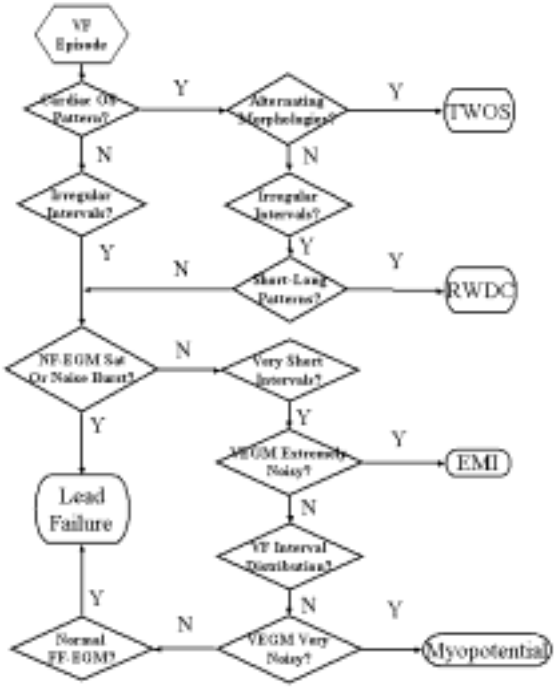

Figure 3. Lead problem identification flow diagram

First, each VF episode was checked for a cardiac oversensing (OS) pattern that would indicate at most one oversense per cardiac cycle. This was measured by the minimum difference between the current interval and each of the two previous intervals and with a combination of the two. If at least 7 of the 12 minimum interval differences were less than 12% of each current interval, then the cardiac oversensing pattern criterion was met.

Alternating morphologies of sensed R-waves and oversensed T-waves were identified using EGM segments centered at each sensed event. Similar or different morphologies were determined by using correlation waveform analysis starting with the first template (template A) of the EGM segment prior to detection. A new template was created if none of the previous templates were highly correlated with the current EGM segment. The alternating morphology criterion was satisfied when consecutive EGM segments had a common morphology alternating with any other different morphology (e.g. ABACAB, ADADAD). Episodes that met this criterion were classified as TWOS.

The other four oversensing problems had irregular intervals. Interval irregularity was defined as the sum of the absolute value of differences between consecutive intervals prior to detection. If the sum of differences was greater than a fixed threshold, then the episode was considered irregular.

Next, the intervals were checked for short-long patterns. For the intervals prior to detection, each pair of successive intervals was evaluated. If the first interval was less than the width of a wide sinus R-wave (short) and the next interval was longer, then a short-long sequence was found. If there were at least four short-long sequences, then the short-long criterion was satisfied and the episode was classified as RWDC.

Next, the algorithm checked for the non-cardiac oversensing problems. These problems have combinations of variable length, high frequency noise signals and low frequency signals. A measure of noise was used to identify each of these problems with noisy, non-cardiac like signals. A unit of noise was defined as a sign change of successive voltage differences using the sampled EGM. The maximum number of consecutive noise units was defined as a noise segment. Episodes from the development database were used to determine the noise percentage thresholds.

Successive voltages with a small difference made up a low frequency unit. Continuous low frequency units made up a low frequency segment (i.e. EGM baseline). An episode with noise bursts was defined as having irregular length low frequency segments with a maximum noise segment of at least four units and less than 20% overall noise units. If a NF-EGM segment was at maximum or minimum voltage (saturated) or there was a noise burst, then a lead failure was identified.

If the previous criterion was not met, the algorithm required very short intervals prior to detection to continue checking for non-cardiac oversensing problems. If the percentage of noise units was at least 60% (extremely noisy), then the episode was classified as EMI. Otherwise, the algorithm checked for an interval

distribution that was outside the typical VF interval range of 160 to 260 ms. If at least 6 of 16 intervals prior to detection were both below and above this range, then there was a non-VF interval distribution that was an indicator of a non-cardiac oversensing problem.

If the percentage of noise units was at least 20% but less than 60% (very noisy), then the episode was identified as myopotential oversensing. Otherwise, lead failure was checked again if the FF-EGM was available. Oversensing due to a lead failure (e.g. fracture) was caused by a noisy NF-EGM during sinus rhythm with minimal effect on the FF-EGM (figure 1). The maximum absolute instantaneous slope was calculated on FF-EGM segments centered on each sensed event. High slope variability due to segments of baseline and R-wave indicated sinus rhythm. Low slope variability occurred when only R-waves were sensed during true heart rhythms. If the coefficient of quartile variation of the last 10 sensed events was greater than 40%, then the episode was identified as a lead failure.

The algorithm was developed and tested using two separate databases, each containing episodes with confirmed lead problems and a database of episodes from ICD clinical studies without lead problems.

2.2. Lead problem data

Episodes from lead problems were collected from various sources including field engineers, clinical studies, technical services and physicians. An expert reviewed each ventricular tachycardia (VT) and VF detected episode to determine if it was due to any of the five lead problems. Lead failures and TWOS were the most common lead problems. Many of the lead failures were confirmed by x-ray, returned product analysis, lead impedances, or visual lead inspection during lead modification. The development database consisted of 98 stored ICD episodes (28 patients) from multiple centers (1 to 11 episodes / patient). The test database consisted of 385 episodes (59 patients) from multiple centers (1 to 52 episodes / patient). No additional myopotential cases were reported to the authors after the development database was created.

2.3. Normal data

These patients did not have any episodes with known oversensing problems. Only patients with VF episodes were used. The true specificity for the algorithm would be higher if patients with VT episodes or no episodes were included. The development database consisted of 996 stored ICD episodes (211 patients) from the Gem DR 7271 clinical study. The test database consisted of 640 episodes (147 patients) from the lead model 6944, ICD model 7273 and ICD model 7229 clinical studies.

2.4. Performance measures

The sensitivity and specificity were measured for the episodes and patients separately. Multiple episodes may have occurred in the same patient due to the same problem. Only one of these episodes needed to be identified by the algorithm to identify the patient with a lead problem. If a patient had at least one of the episodes identified as the correct lead problem, then that was used in the patient-based results.

3. Results

3.1. Sensitivity

The overall episode-based sensitivity to identify any of the episodes as a problem was 89.8% (88/98) on the development database. Individual problem performance was displayed in Table 1. The missed lead failures displayed oversensing due to spikes instead of noise on the EGM. Table 2 displays the performance on the test database. The number of missed failures was proportionately similar to the development database, but the missed TWOS episodes increased due to VT detection and intermittent TWOS versus consecutive TWOS. The overall episode-based sensitivity was 82.6% (318/385).

Table 1. Episode-based sensitivity (dev database)

Algo / Truth	*Failure*	*Myo*	*EMI*	*TWOS*	*RWDC*	*None*
Failure	37	1				6
Myo		13				2
EMI			4			
TWOS				22	1	
RWDC					10	2

Table 2. Episode-based sensitivity (test database)

Algo / Truth	*Failure*	*Myo*	*EMI*	*TWOS*	*RWDC*	*None*
Failure	254	18		2	2	43
Myo						
EMI		1	5			
TWOS				30	3	21
RWDC					3	3

The overall patient-based sensitivity to identify a patient with a lead problem was 100% (28/28) on the development database. The performance for each individual problem was displayed in table 3. Table 4 displays the performance on the test database. The overall patient-based sensitivity was 94.9% (56/59). The three missed problems were a TWOS detected only as VT (VTs were not analyzed), R-wave double-counting during a supraventricular tachycardia with aberrant conduction, and an insulation break without noise.

Table 3. Patient-based sensitivity (dev database)

Algo / Truth	*Failure*	*Myo*	*EMI*	*TWOS*	*RWDC*	*None*
Failure	11					
Myo		2				
EMI			2			
TWOS				7		
RWDC					6	

Table 4. Patient-based sensitivity (test database)

Algo / Truth	*Failure*	*Myo*	*EMI*	*TWOS*	*RWDC*	*None*
Failure	40	1				1
Myo						
EMI			2			
TWOS				10	1	1
RWDC					2	1

3.2. Specificity

The algorithm specificity to correctly identify episodes with no problem was 99.7% (993/996) and 99.5% (637/640) on the development and test databases, respectively. The development database false positives were one lead failure and two TWOS episodes. The test database false positives were two lead failures and one TWOS episode. They included two ventricular tachyarrhythmias with fractionated R-waves and a VT with alternating morphologies identified as TWOS. Only one false positive occurred in each of the patients. The algorithm specificity to correctly identify patients with no problem was 98.6% (208/211) and 98.0% (144/147) on the development and test databases, respectively.

4. Discussion

An algorithm was developed to automatically identify five common oversensing lead problems. This algorithm was 94.9% sensitive and 98.0% specific to identify ICD patients with one of five oversensing lead problems based on the test database.

The lead problem data was heavily weighted towards patients with the more common lead failures (71%) and TWOS (20%) problems. Individual lead problem performance may vary. These results do not include other lead problems such as lead dislodgement or fractures with a complete break in the lead conductor (i.e. open circuit).

Episodes detected as VT were excluded from the algorithm analysis because they rarely occurred in the development database due to a ventricular lead problem. During algorithm testing, multiple VT episodes due to TWOS occurred in the test database and were not identified. In addition, the algorithm missed VF episodes detected due to intermittent TWOS instead of consistent TWOS as observed in the development database and implemented in the algorithm. Future work includes improving TWOS identification from both VT and VF episodes. The missed VF episodes from lead failures contained minimal EGM noise possibly due to the lead conductors pinching together versus the conductors rubbing each other causing the noise.

Implementing this type of algorithm into remote ICD management software or an ICD programmer may provide a time saving tool to identify and supply confirming data of inappropriate detections due to lead problems. Clinicians may reduce clinical complications by acting on this information. Further algorithm improvements could provide higher performance for an on-board ICD diagnostic algorithm to potentially identify oversensing lead problems earlier and withhold inappropriate shock therapies.

5. Conclusion

Inappropriate ICD detections due to lead failures, electromagnetic interference, myopotentials, T-wave oversensing and R-wave double counting were automatically identified using stored ventricular electrograms and ventricular sensed event timing patterns with very high sensitivity and specificity.

References

[1] Stambler BS, Wood MA, Damiano RJ, et al. Sensing/pacing lead complications with a newer generation implantable cardioverter-defibrillator: a worldwide experience from the Guardian ATP 4210 clinical trial. J Am Coll Cardiol 1994;23:123-132.

[2] Lawton JS, Ellenbogen KA, Wood MA, et al. Sensing lead-related complications in patients with transvenous implantable cardioverter-defibrillators. Am J Cardiol 1996;78:647-651.

[3] Degertu FT, Khalighi K, Peters RW, et al. Sensing lead failure in implantable defibrillators: a comparison of two commonly used leads. J Cardiovasc Electrophysiol 2000;11:21-24.

[4] Mehta D, Nayak HM, Singson M, et al. Late complications in patients with pectoral defibrillator implants with transvenous defibrillator lead systems: high incidence of insulation breakdown. Pacing Clin Electrophysiol 1998;21:1893-1900.

[5] Reiter MJ, Mann DE. Sensing and Tachyarrhythmia Detection Problems in Implantable Cardioverter Defibrillators. J Cardiovasc Electrophysiol 1996;7:542-558.

Address for correspondence:

Bruce D. Gunderson,
Medtronic, Inc. B173
7000 Central Ave NE
Fridley, MN 55432
E-mail:bruce.gunderson@medtronic.com