

Morphological Stability of Bipolar and Unipolar Endocardial Electrograms

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Abstract

Implantable Cardioverter Defibrillators (ICD) are widely used for sudden cardiac death prevention. In most ICD algorithms, decision making includes a morphological analysis of the unipolar and/or bipolar electrograms (EGM). The principle of such algorithms is to create a "normal" template by averaging normal sinus rhythm heartbeats, for comparison to each arrhythmic heartbeat.

The present study addresses the stability of unipolar and bipolar EGMs with respect to the posture of the patient, and the temporal evolution of the EGM shapes during sinus rhythm. We show that unipolar EGMs are slightly affected by position changes, while bipolar ones are unaffected. Moreover, the morphological variability of both EGMs is significant during the first post-implant month and very small after a few months.

Collectively, these findings provide important information for the design of a statistically valid template updating procedure for morphological algorithms in ICDs.

1. Introduction

In Sudden Cardiac Death (SCD), the heart abruptly and unexpectedly stops beating due to an electrical dysfunction caused by a Ventricular Fibrillation (VF). The heart is no longer able to pump blood to the rest of the body because of the very rapid and chaotic activity of the lower chamber of the heart (ventricles). The patient dies within minutes unless an appropriate electrical shock is delivered, usually by external defibrillators. People who are at high risk of SCD may be treated with an Implantable Cardioverter Defibrillator (ICD), which continuously monitors the electrical activity of the heart and decides autonomously whether a shock must be delivered.

In order to make that decision, different discrimination criteria are available in ICDs. They are based on endocardial measurements of the electrical activity of the heart, named electrograms (EGMs). Time intervals are generally extracted from EGMs and used for diagnosis. In

addition, in most ICD algorithms, an analysis of the EGM morphology can be performed [1-3]. This type of analysis implements methods based on the following physiological observations: during a non-life-threatening arrhythmia episode (Supra-Ventricular Tachycardia or SVT), the electrical pulses are conducted in the ventricles by the same conduction paths as in Normal Sinus Rhythm (NSR), so that the morphology of the ventricular contraction signal (QRS complex) is very similar to that of the signal recorded in NSR. By contrast, during a life-threatening arrhythmia episode (Ventricular Tachycardia or VT), the conduction paths are different, and so is the recorded electrical signal. Hence, those known methods discriminate arrhythmias by the measurement of the similarity of the EGM signals during the arrhythmia with the EGM signals in NSR. A template of NSR is generally used in order to filter out beat-to-beat variations. However, a template updating procedure is needed: EGM morphology may vary due to antiarrhythmic drugs, lead maturation, posture [4], disease progression [5] or ventricular cycle length [6].

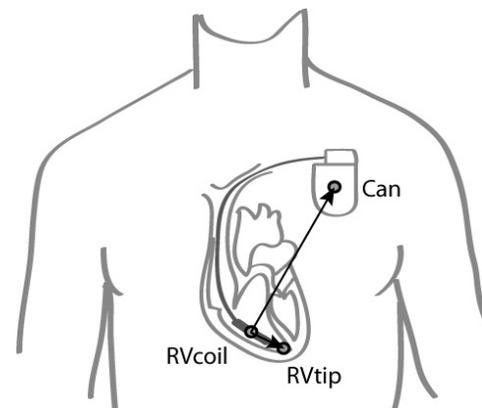


Figure 1. The simplest ICD system: a single-chamber ICD with a single-coil integrated bipolar lead. The distal electrode (tip) has a small area and is located in the apex (or the septum) of the right ventricle (RV). The proximal electrode (coil) is an elongated electrode located in the RV, close to the tip; this electrode delivers the electrical shock if necessary, together with the can.

The present work aims at studying (i) the stability of both unipolar (RVcoil-Can) and bipolar (RVcoil-RVtip) NSR EGMs (Figure 1) with respect to patient's position and (ii) their temporal evolution, in order to build a solid template updating procedure for NSR template in morphological algorithms in ICDs.

2. Stability of EGMs

2.1. Data

A total of 140 unipolar (RVcoil-Can) and 140 bipolar (RVcoil-RVtip) 10-second EGMs were recorded by Paradym ICDs (Sorin CRM) during NSR. For 23 patients (67 ± 12.5 years, 73% men), recordings were performed in different positions (supine, prone, left and right lateral, sitting, standing). EGMs were recorded 3 ± 3 days after implant and 2 ± 1 months later (early evolution) in a sub-group of 5 patients, 10 ± 6 months and 16 ± 6 months after implant (late and long-term changes) in a sub-group of 8 patients. Among the 23 patients, we retrieved arrhythmias for 10 patients. A time window of 160 ms centered on each ventricular depolarization peak measured on the bipolar signal (R wave) was chosen (Figure 2) to extract the QRS portion of each cardiac cycle.

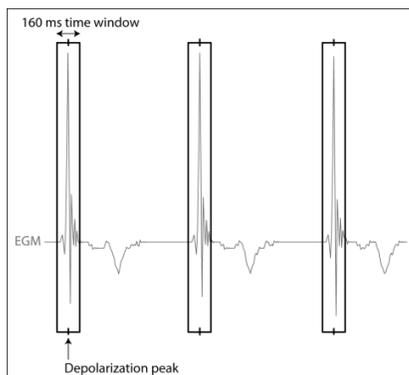


Figure 2. Extraction of QRS portion of each cardiac cycle for each EGM signal

2.2. How to compare EGMs?

In order to measure the similarity between two EGM portions E_1 and E_2 , the cross-correlation coefficient r is computed:

$$r = \frac{\sum_{t=1}^n (E_1(t) - \bar{E}_1)(E_2(t) - \bar{E}_2)}{\sqrt{\sum_{t=1}^n (E_1(t) - \bar{E}_1)^2} \sqrt{\sum_{t=1}^n (E_2(t) - \bar{E}_2)^2}}$$

where n is the number of time samples of each QRS portion, and \bar{E}_1 and \bar{E}_2 are the mean values of E_1 and E_2 respectively.

2.3. Template creation

The efficiency of morphology algorithms in ICDs depends on the quality of the NSR template created to filter out beat-to-beat variations. This template is usually obtained by averaging a predetermined number N of consecutive cardiac cycles. To determine the minimal number of beats needed for a consistent template, we built templates with an increasing value of N . Each template was then compared to any other individual beat in the same EGM sequence in order to estimate the distribution of r for each value of N ($N < 15$). For illustration purpose, for each of the 15 distributions, the mean and the standard deviation over the obtained values were computed (Figure 3).

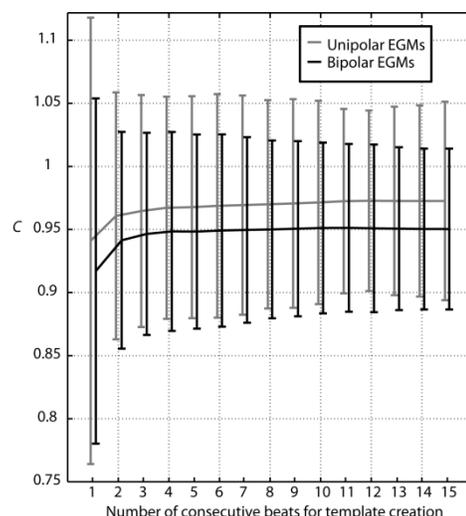


Figure 3. Intra-EGM variability with respect to different templates

From pairwise comparisons of distributions using the Wilcoxon Test, we concluded that three consecutive normal heartbeats are sufficient to create the NSR template for unipolar EGMs ($p < 0.01$). For bipolar EGMs, two consecutive beats suffice ($p < 0.01$). These results are used in the rest of this work.

2.4. Stability of EGMs with respect to posture

We started by creating three different templates for each EGM sequence corresponding to one body posture: the first one was created from the first beats of the sequence, the second one from beats in the middle of the sequence, and the last one with beats from the end of the EGM sequence. Each template was compared to the two others for each sequence, leading to the intra-position variability distribution (Figure 4).

The inter-position variability distributions were then

estimated by comparing each template of a given position to the templates in other positions for the same patient (Figure 4).

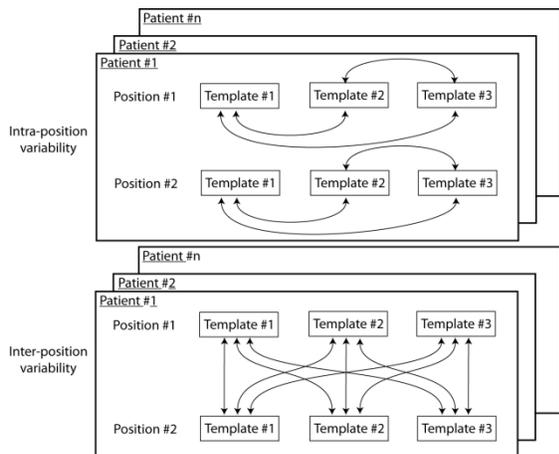


Figure 4. Schematic view of the estimation of the intra- and inter-position variability distributions: each double arrow corresponds to the correlation coefficient computation of the two templates considered.

Using the Wilcoxon Test, we concluded that the correlation between bipolar EGMs in a given position is not statistically different from the correlation between EGMs in different positions (0.96 ± 0.06 vs 0.95 ± 0.06). Conversely, unipolar EGMs are affected by position changes (0.98 ± 0.04 vs 0.97 ± 0.05). However the correlation coefficient being very high, the shape of the EGMs are very similar.

2.5. Temporal evolution of EGM shapes

In order to assess the temporal evolution of EGM shapes, we created the distribution of r , representative of the early evolution, by comparing the templates of the first follow-up to the templates of the second follow-up. In the same manner, we created the distribution of r representative of the late and long-term changes. We concluded that the time changes of unipolar and bipolar EGMs are significant during the first post-implant month (bip: 0.80 ± 0.27 , uni: 0.92 ± 0.05). These changes are probably due to lead maturation, essentially in the bipolar signal because of the tip contact with the cardiac muscle. Changes are very small after a few months (bip: 0.98 ± 0.02 , uni: 0.94 ± 0.07).

3. Normal sinus rhythm analysis for a new discrimination algorithm

The present study was primarily designed to estimate the change of the normal sinus beats to improve a new algorithm for SVT/VT discrimination recently described

[7]. It relies on an original representation of EGMs, which is described in the next section.

3.1. SPOT curve

The new arrhythmia discrimination algorithm analyzes, with a machine learning approach, the morphology of a two-dimensional representation of both a far-field unipolar and a near-field bipolar ventricular EGM. This representation of EGMs is called ‘‘Spatial Projection Of Tachycardia’’ (SPOT). The SPOT curve of a cardiac cycle is the plot of the amplitude of the unipolar EGM versus the amplitude of the bipolar EGM, with time as a parameter (Figure 5).

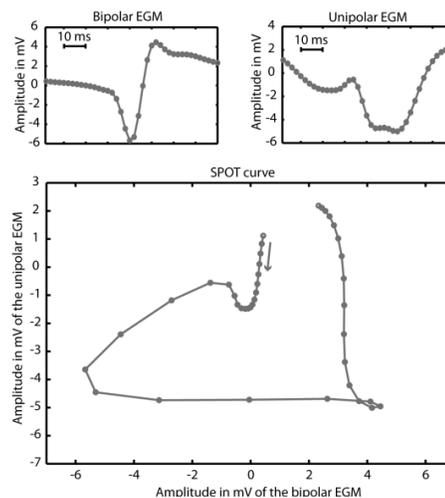


Figure 5. Example of a SPOT curve construction

3.2. Comparison between SPOT curves

Arrhythmia discrimination is performed by comparing an arrhythmia curve to a NSR template curve. Velocity vectors are extracted at each time sample for each SPOT curve. Then two comparison features are computed: the average angle of the relative velocity vectors $\langle \theta \rangle$ and the correlation coefficient C between the norms of the velocity vectors, where $0 < \langle \theta \rangle < 180^\circ$ and $-1 < C < 1$ [7]. Thus two SPOT curves are very similar when C is close to 1 and $\langle \theta \rangle$ close to 0.

We first computed the values of $\langle \theta \rangle$ and C resulting from pairwise comparisons of templates at different postures. For every EGM recording, three NSR template curves (as in subsection 2.4) were constructed by averaging separately the unipolar EGM and the bipolar EGM of three consecutive beats (*cf.* subsection 2.3). The distributions of the intra- and inter-position variability were obtained for $\langle \theta \rangle$ and C , in the same way as in Figure 4. Using the Wilcoxon Test, we concluded that the distributions are not statistically different for C (0.92 ± 0.15 vs 0.92 ± 0.14), but they are for $\langle \theta \rangle$ (11 ± 8 vs 12 ± 7) (Table 1). However, the values of $\langle \theta \rangle$ are very

small and the values of C very high as compared to mean values based on arrhythmia episodes. Table 1 also gives the mean and the standard deviation for these two features when NSR template curves are compared to arrhythmia curves. Thus, no significant differences in the intra- and inter-position variability of the SPOT features can be detected.

Table 1. Mean and standard deviation of features

Feature	Intra-position variability	Inter-position variability	NSR vs SVTs	NSR vs VTs
$\langle \theta \rangle$ (in degrees)	11±8	12±7	29±18	67±25
C	0.92±0.15	0.92±0.14	0.77±0.21	0.36±0.36

Moreover, we investigated the temporal evolution of EGM shapes based on the arrhythmia episodes of the 10 patients. For every EGM recording available for these patients, a single NSR template curve was created by averaging 3 consecutive beats. For each NSR template curve, an online version of the discrimination algorithm was applied to each arrhythmia episode. As expected, the decision for VTs is always the same: a shock must be delivered. For most SVTs, the decision of the classifier does not change with the choice of the NSR template curve. However, it does for two SVTs from two patients: when a NSR template curve is derived from EGMS recorded respectively one year and 4 months away from the arrhythmia, the classifier misclassifies them by deciding to deliver a shock. But, when the NSR template curve is created sooner before or after the arrhythmia (respectively six months and one month away from the arrhythmia), the classifier decides not to shock these two SVTs. This observation confirms the fact that the NSR EGM morphology changes with time and that a periodic update of the NSR template is necessary.

Another preliminary study conducted on two patients, shows that reestimation on a daily basis seems to be sufficient: EGMs were recorded every 2h and compared according to the above methodology.

4. Conclusion and perspectives

Based on correlation between templates as well as on the values of $\langle \theta \rangle$ and C resulting from pairwise comparisons of NSR template curves at different postures, no significant changes in EGMs nor in the SPOT features with respect to body position were observed. Moreover, as expected, a periodic update of the NSR template is necessary, especially during the first few months after implantation where NSR changes are most important. For the moment, reestimation on a daily basis seems to be sufficient.

The above results are highly relevant to the design of a statistically valid template updating procedure for morphological algorithms in ICDs.

Acknowledgements

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References

- [1] Daubert JP, Zareba X, Cannom DS, McNitt S, Rosero SZ, Wang P, Schuger C, Steinberg JS, Higgins SL, Wilber DJ, Klein H, Andrews ML, Hall WJ, Moss AJ. Inappropriate Implantable Cardioverter Defibrillator Shocks in MADIT II. *J Am Coll Cardiol* 2008;51(14):1357–1365.
- [2] Swerdlow CD, Brown ML, Lurie K, Zhang J, Wood NM, Olson WH, Gillberg JM. Discrimination of Ventricular Tachycardia from Supraventricular Tachycardia by a Downloaded Wavelet-Transform Morphology Algorithm: A Paradigm for Development of Implantable Cardioverter Defibrillator Detection Algorithms. *J Cardiovasc Electrophysiol* 2002;13:432–441.
- [3] Gold MR, Shorofsky SR, Thompson JA, Kim J, Schwartz M, Bocek J, Lovett EG, HsuW, Morris MM, Lang DJ. Advanced Rhythm Discrimination for Implantable Cardioverter Defibrillators Using Electrogram Vector Timing and Correlation. *J Cardiovasc Electrophysiol* 2002;13:1092–1097.
- [4] Wolber T, Bingeli C, Holzmeister J, Brunckhorst C, Strobel U, Boes C, Moser R, Becker D, Duru F. Wavelet-based tachycardia discrimination in ICDs: Impact of posture and electrogram configuration. *Pacing Clin Electrophysiol* 2006;29:1255–1260.
- [5] Compton SJ, Merrill JJ, Dorian P, Cao J, Zhou D, Gillberg JM. Continuous template collection and updating for electrogram morphology discrimination in implantable cardioverter defibrillators. *Pacing Clin Electrophysiol* 2006;29:244–254.
- [6] Theuns DA, Rivero-Ayerza M, Goedhart DM, Miltenburg M, Jordaens LJ. Morphology discrimination in implantable cardioverter-defibrillators: consistency of template match percentage during atrial tachyarrhythmias at different heart rates. *Europace* 2008;10:1060–1066.
- [7] Bouchet P, Dubois R, Henry C, Roussel P, Dreyfus G. Spatial Projection of Tachycardia Electrograms for Morphology Discrimination in Implantable Cardioverter Defibrillators. *IEEE Proc. Computers in Cardiology* 2009;36:9–12.

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