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Predicting Defibrillation Outcome based on Phase of Ventricular Activity during ICD Implantation

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Abstract—**Implantable cardioverter-defibrillaters (ICDs) are well known medical device for patients who are at a risk of sudden cardiac death caused by ventricular fibrillation (VF). The relationship between VF mechanisms and successful ICD therapy to terminate of VF is still not well understood. The purpose of this work is to evaluate the timing of ICD therapy as a predictor of successful VF termination. Clinical data sets were recorded from the patients who underwent ICD implantation in 6 Canadian centers. Timing of the defibrillation attempt (phase) was analyzed by using the ICD Marker Channel which monitors and displays cardiac events sensed by ICD. Phase, based on the VF period, was divided into 10 equally distributed bins and number of successful defibrillation episodes in each bin was compared. A total of 181 defibrillation attempts were identified from the 64 subjects. 121 of the defibrillation attempts were successful, while 60 failed. The optimal case was observed at a phase value of 1.6π with all 11 successful attempts. The lowest performance rate was found at a phase value of 0.6π with 40.6% (13 successful attempts out of 32. The probability of success seemed to be sinusoidal with these extrema. Fisher's exact test also showed a significant difference between successful defibrillation attempts and phase of ventricular activity (p-value = 0.025). From our results, timing of defibrillation shock attempt may play an important role to predict successful termination of VF for ICD implanted patients.**

I. Introduction

Sudden cardiac death (SCD) is the situation in which the heart abruptly and without warning stops working, so no blood is pumped to the rest of the body. It is responsible for half of all heart disease deaths, accounting for 300,000 to 400,000 annually in the United States, depending on the definition used [1], [2]. SCD occurs when there is a severe disturbance to the electrical system of the heart, called ventricular fibrillation (VF). An Implantable Cardioverter-Defibrillator (ICD) is a device that is implanted in patients that are identified as being at risk of SCD due to VF. The device senses VF and delivers a strong shock which terminates the episode.

In the human heart, several clinical studies have investigated VF organization on the epicardial and/or endocardial surface [3]-[5]. Previous ICD study showed there is a correlation between disorganization of VF waveforms and defibrillation outcome [6].

In ICD therapy, synchronized cardioversion (a shock delivered at the same time as the QRS complex) must be given when the device identifies the presence of a ventricular tachycardia (VT) and a fast ventricular tachycardia (FVT), but for VF, rapid administration of unsynchronized shocks is prescribed [7].

The aim of this study was to investigate whether the relative timing of ICD defibrillation attempts and ventricular activity during VF had any effect on defibrillation outcome.

II. Methods

A. Clinical Data

This was a multi center study carried out in 6 Canadian centers, including the University of Alberta Hospital (Edmonton, Alberta), Foothills Hospital (Calgary, Alberta), Royal Jubilee Hospital (Victoria, B.C.), the Montreal Heart Institute (Montreal, Quebec), Hôpital Laval, (Sainte-Foy, Quebec), and CHUM Hôpital Notre-Dame (Montreal, Quebec) with the collaboration of Medtronic Inc. (Minneapolis, MN, USA). Study data sets were recorded using the high voltage leads of an ICD during device implantation. The study protocol was approved by the local research ethics boards of the participating centers and all subjects gave written informed consent. Each data set consisted of at least 3 episodes of VF induction and corresponding defibrillation therapy. A total of 181 defibrillation episodes were identified from the 64 subjects; 121 of the defibrillation attempts were successful, while 60 failed.

B. Experimental Setup

Patient sessions were obtained and managed with either a Medtronic 2090 programmer or a Medtronic Model 9790C programmer. This device has capability to allow clinical engineers to monitor and display patient cardiac activity information, perform electrophysiological studies, and program defibrillation thresholds of implantable device. One of the key programmer functions in our study is the telemetry function which remotely communicates with implantable device and records cardiac information such as the Marker Channel, and atrial and ventricular intracardiac electrograms (EGMs) taken from the electrodes of the implantable device lead system. The study data set consist four channels of waveforms: a surface ECG, two intracardiac electrograms (EGM-1 and EGM-2), and a Marker Channel explained below:

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1) Surface ECG

ECG lead II was selected as the surface ECG channel.

2) Two intracardiac electrogram (EGM-1 and EGM-2)

Typical source of EGM-1 is the electrogram between device case to the high voltage electrode, while EGM-2 is a bipole between the tip and ring.

3) Marker Channel

Telemetered notation of what implantable device senses. It displays ongoing ventricular and device related events on a device monitor, such as sensing, pacing, detecting VT/VF, capacitor charge, buffer information and cardioversion / defibrillation pulse.

C. Data Acquisition

All four channels data were sent to a custom DAQ system. These analog signals were sampled and stored in the computer. The DAQ system consisted of a digital acquisition card (National Instruments, Austin, TX) to sample the data and Labview software (National Instruments, Austin, TX) to analyze and store the sampled data on hard disk. The sampling frequency was 2K Hz with 12 bit resolution. Figure 1 illustrates the four channels data acquired from Medtronic ICD and programmer.

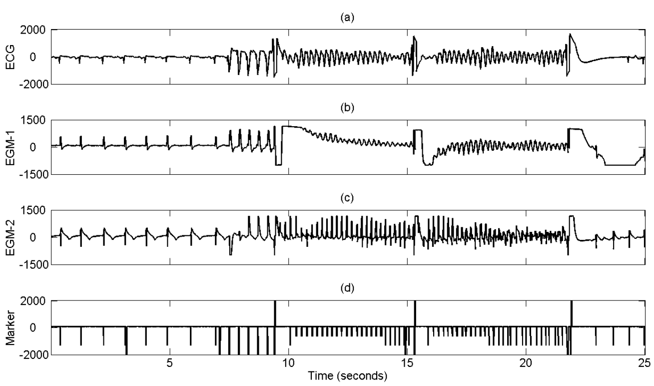

Fig. 1. Four channel Medtronic clinical data. (a) Surface ECG. (b) EGM-1is the electrogram between Can and HVX electrode (Far-Field). (c) EGM-2 (Near-Field). (d) Marker Channel. Ventricular fibrillation was induced at 9.4 seconds by 50 Hz burst pacing. Defibrillation shock was delivered at 15.3 seconds which was failed to terminate VF. Rescue shock was followed at 21.9 seconds and it successfully terminated VF and restored normal sinus rhythm.

D. Binary Search Protocol

Data were recorded during Defibrillation Threshold (DFT) testing in patients to set the strength of shock delivery to the minimum required to terminate fibrillation. There are four steps to establish the DFT using the binary search protocol (see Figure 2):

Step 1: VF was induced by giving 50 Hz burst pacing.

Step 2: A trial shock, started with 12 joules at the first VF induction, was delivered to restore normal sinus rhythm. If it failed, higher charged rescue shock was delivered to terminate VF.

Step 3: After observed proper post-shock ventricular activity, set the next appropriate energy level by using binary search protocol (Figure 2).

Step 4: Wait at least five minutes between VF inductions for most reliable defibrillation efficacy testing.

The above steps are repeated as needed. In most cases, physicians performed three induction episodes and possibly a fourth for verification only.

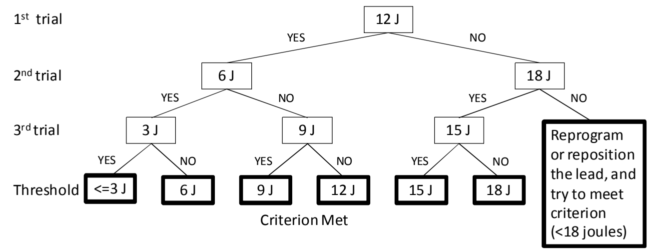

Fig.2. Binary search procedure. Binary search procedure was used to establish a defibrillation threshold, successively lower energy levels, of 18 joules or less. At least three induced VF episodes were analyzed to obtain an accurate threshold measurement [7].

E. Measure of Ventricular Activity during VF

The ICD sensed ventricular activity through a bipolar electrode implanted in the right ventricle. A threshold was set to adjust the minimum amplitude of ventricular events. Detected ventricular events were recorded in the Marker channel. The marker channel annotations were used to calculate phase of ventricular activity during VF by the following steps.

1) VS-CD interval:

The cardioversion or defibrillation pulse marker (CD) was found and then searched backwards to find the immediately preceding ventricular sense (VS). The VS-CD interval was then defined as the time between these two events.

2) Averaged V-V interval during VF:

We searched backwards to find the next three intervals of ventricular sense and averaged them to obtain an averaged V-V interval, VV_{avg}

3) Timing when CD was applied (Phase):

Finally, phase was defined by using VS-CD interval and averaged V-V interval as follows:

For VS-CD interval > averaged V-V interval,

$$\text{Phase} = (\text{Modulo}(\text{VS-CD}, VV_{avg}) / VV_{avg}) \times 2\pi$$

else

$$\text{Phase} = (\text{VS-CD} / VV_{avg}) \times 2\pi$$

F. Statistical Analysis

To quantify number of successful defibrillation attempts and phase of ventricular activities during VF, data was analyzed using Fisher's Exact Test. Statistical differences were considered significant when p-value < 0.05.

III. Results

A. Temporal distribution between defibrillation shock attempt and ventricular activity right before defibrillation shock attempt

A histogram of the VS-CD interval was constructed with 10 bins with minimum value of 0.13 seconds, maximum value of 0.42 seconds (Figure 3). Measuring the mean ±

standard deviation of interval, it is found that averaged intervals are 0.263±0.043 for successful attempts and 0.257±0.047 for failed attempts. Figure 3 clearly shows that outcome of defibrillation shock attempts and VS-CD interval are not correlated.

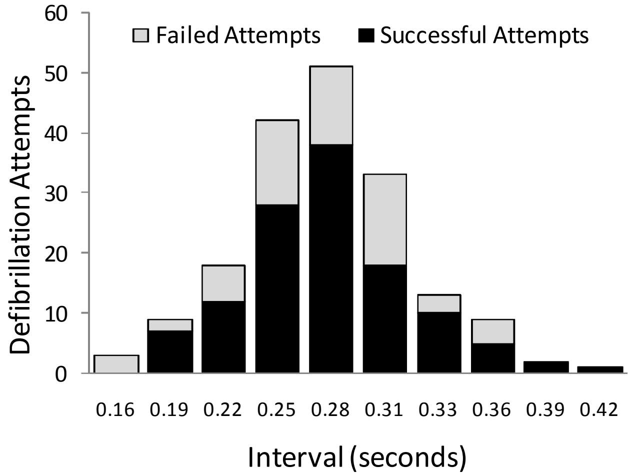

Fig.3. Temporal distribution. Time interval between defibrillation shock attempts and the ventricular activity right before electrical therapy was delivered by ICD. Bins were equally divided into 10 equal time segments which have minimum interval of 0.13 seconds and maximum of 0.42 seconds.

B. *Defibrillation attempts and phase of ventricular activity during VF*

Since we could not control the shock delivery, the number of attempts for each bin were not equal (Figure 4(a)). Looking at the probability of successful defibrillation for each bin, there was a trend in performance for successful attempts versus phase (Figure 4(b)).

We discovered that the distribution of the probability of successful against phase was almost sinusoidal with the lowest peak point at 0.6π (40.6%, 13 successful attempts out of 32) and the highest peak point at 1.6π (100%, all 11 successful attempts). In addition, phase difference between maximum and minimum successful attempts was exactly π.

Higher shock strengths were more successful (Figure 5) as expected. However, bins contained all shock strengths so the relation of success to phase was not simply related to higher strength shocks delivered at particular phases.

Fisher's exact test also shows there was a significant difference between successful defibrillation attempts and phase of ventricular activity during VF. (p-value = 0.025).

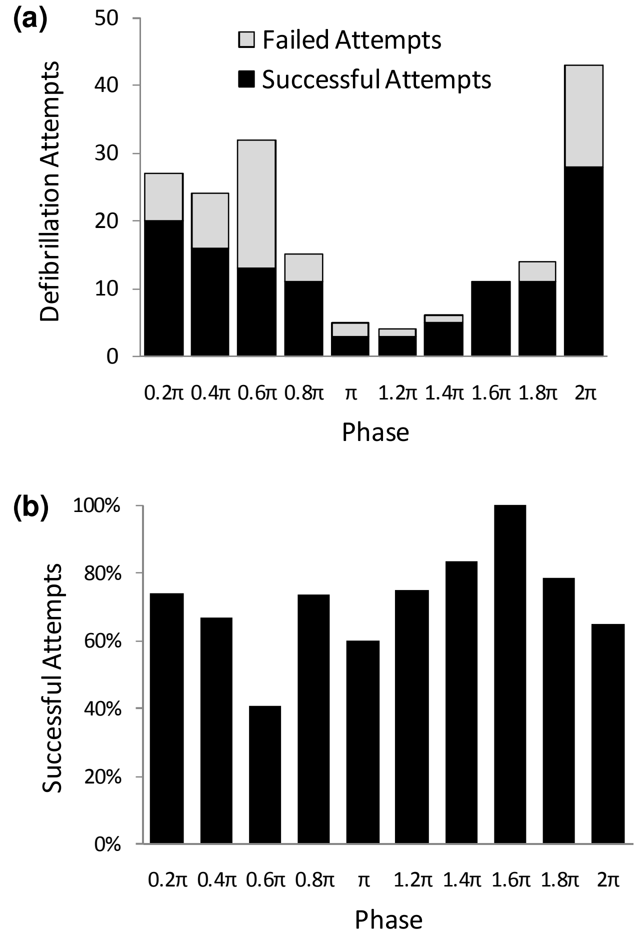

Fig.4. (a) Total number of incidents against phase. A total of 181 defibrillation attempts were identified from 64 subjects. 121 of the attempts were successful, while 60 failed. (b) Probability of successful defibrillation. Distribution was almost sinusoidal with the lowest peak point at 0.6π and the highest peak point at 1.6π. A histogram was constructed with 10 bins which were grouped by phase, so each bins contained all shock strength.

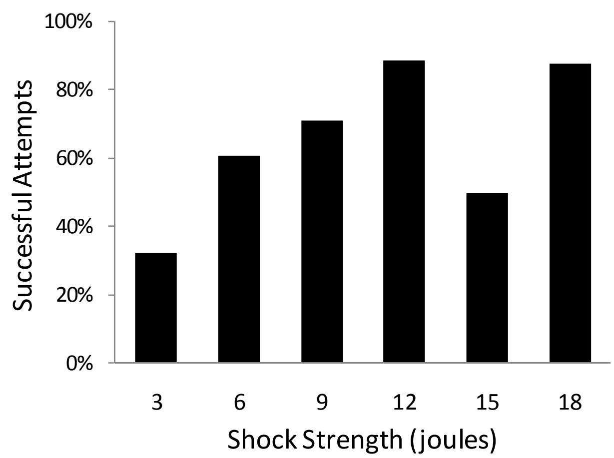

Fig. 5. Probability of successful attempts against shock strength. Higher shock strengths were more successful as expected.

IV. Discussion

The aim of this study was to investigate the relationship between successful defibrillation attempts and phase of ventricular activity during VF. The results of this study show that optimal performance rate was found at phase value of 1.6π with all 11 successful attempts followed by performance downtrend. In comparison, the lowest successful ration was found at phase value of 0.6π and it was on a strong uptrend afterwards.

Interpreting the data supports a mother rotor hypothesis where one stable rotor drives the VF. Mother rotors have been observed in VF experiments in animal hearts [8]. Long-lived stationary rotors have also been reported in isolated RV slabs of sheep [9]. Phase as sensed would be determined by the position of the spiral. Given the nonuniform spatial manner in which electrical shocks affect tissue[10], the rotor will be more affected at some times then others since the amount of refractory tissue affected will be dependent on the physical orientation of the rotor. Correct timing and location of defibrillation attempts may, therefore, play an important role to terminate VF.

Focuses of ICD research have been to reduce the defibrillation shock energy in order to prolong battery life, and to avoid failed shocks. As we showed in the binary search protocol, shocks with strength of 3 to 18 joules were applied to terminate VF for successively lower energy levels. In our study, defibrillation attempts were grouped by phase of ventricular activities during VF. Shock strength at each episode was not taken into account in this analysis. If successful termination of VF mostly relied on the relative timing of defibrillation shock delivery by the ICD, it could reduce shock strength and the number of failed shocks.

V. Limitation

We used the Marker Channel annotation for detecting ventricular events during VF, so this relied on the sensitivity of the leads and setting of the sensing threshold. Moreover, a slight sensing delay was observed on some episodes when device related event and ventricular event happened at a same time. Sensing and shock delivery were delivered through the same electrode so the VF resulting may not be the same as occurs naturally, and the phase relationship may differ.

VI. Conclusion

We investigated the relationship between defibrillation shock outcome and phase of ventricular activities during VF. From our data analysis, the timing of defibrillation shock attempts may play a key role in successful termination of VF for ICD implant patients.

Acknowledgment

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