ECG R-WAVE AND CURRENT OF $INJURY^*$

Sally Anzelc

This work is produced by OpenStax-CNX and licensed under the Creative Commons Attribution License 2.0^{\dagger}

Abstract

Module 1: Title, Abstract, Introduction, and References

ECG R-Wave and Current of Injury Module 1: Title, Abstract, Introduction, and References Abstract

An important diagnostic tool for the electrophysiologist is Electrocardiography (ECG). ECG is utilized clinically to diagnose heart electrical problems. If a cardiac device is indicated, permanent pacing or defibrillation leads are positioned through passive tines or by active fixation with a fixed or an extendable-retractable helix. Often, the myocardial tissue undergoes some localized injury post lead implantation called the current of injury (COI). The device analyzer records a heightened, broadened R-waveform. The clinician is unable to identify if an adequate R-wave is present or if the signal is confounded with the (COI). Clinicians may think an acceptable R-wave (≥ 5 mV) is captured; however, a R-wave of 10mV during surgery can be reading 3mV one day after implantation once the COI subsides. Moreover, this R-wave over-estimation is correctable by repositioning the lead, but it will not be discovered until post implant, a situation requiring re-opening of the pocket and subjecting the sickly patient to more risks. Therefore, the goal of this project is to develop a research protocol to study the R-wave and (COI) in order to mitigate or to eliminate possible R-wave over-estimation. (J Am Coll Cardiol 2005;45:412-7)

Introduction

Three main papers were utilized to obtain background information and to develop the research protocol; these papers are Saxonhouse et al, Redfearn et al, and Laske et al. All three papers observed localized inflammation to the myocardium with active fixation cardiac leads. Moreover, the inflammation is described as a current of injury (COI) that can overestimate the R-wave, so that when the inflammation subsides, the R-wave is unacceptable. The purpose of this paper is to first reproduce the COI findings of Redfearn et al. Secondly, a research protocol will be written to either manage COI or to eliminate it through filtering of this "interference" signal. Simple filter adjustments to the sense amplifier may resolve the R-wave from the COI, reducing or eliminating the possibility of having to re-open the pocket to re-position the lead.

In a typical electrocardiogram (ECG), a P-wave describes atrial electrical activity, a R-wave (QRS complex) depicts ventricular activity, and the T-wave signifies atrial and ventricular re-polarization. It is imperative for ventricular pacemakers to reliably sense the R-wave without sensing other ECG components or any electromagnetic interference. To that end, a typical sensing circuit employs two methods for R-wave detection. These methods are time discrimination and frequency discrimination. In addition, amplitude discrimination can be used in conjunction with the other two methods. The electrocardiogram components usually happen in a specific sequence and allow for time discrimination. For example, "the T-wave always comes after the R-wave and usually does not follow the R-wave by more than 250 milliseconds, while Rwaves are usually separated from each other by more than 600 milliseconds" (Myers 90). Moreover, time

^{*}Version 1.3: Dec 17, 2007 3:16 pm +0000

[†]http://creativecommons.org/licenses/by/2.0/

discrimination can prevent sensing interference. To illustrate, "It is known that electrical pulses from the heart (P, T, and R-waves) are separated by at least 80 milliseconds." (Myers 90). Signals that are detected with greater frequency are deemed noise and are ignored.

Yet, time discrimination cannot solve all of the errors in R-wave detection. P-wave and R-wave signals are distinguished from one another by the different frequency spectra of the respective waves and interference types. Furthermore, a standard electrocardiographic waveform has a frequency spectrum ranging "from 0.5 to about 200 Hz" (Myers 91). Thus, since the electrocardiogram components and interference exhibit differing frequency spectra, electrical sensing circuits can discriminate between P, R, and T-waves and interference.

In addition to sensing electrical circuits, detecting electrical circuits must also occur. Usually, the detection circuit of a "triggered or inhibited cardiac pacemaker consists of a band-pass amplifier followed by a threshold discriminator" (Kleinert 11). The band-pass amplifier filters the signal, enhancing the P-waves, QRS complexes, and T-waves, while filtering out any interference. Signal detection occurs when the amplified, filtered signal exceeds the threshold discriminator. Additionally, the detection circuit is optimized by minimizing signal undersensing or oversensing; signal analysis makes optimization possible (Kleinert 11). Figure 1 shows a typical computational flowchart for signal analysis.



Figure 1: Simplified Computational Flowchart (Kleinert 14)

An implantable cardioverter defibrillator (ICD) monitors tachyarrhythmia with intracardiac electrograms. Clinically, a low R-wave can lead to "undersensing of ventricular tachyarrhythmia or inappropriate discharges due to oversensing of unexpected signals" by means of its specific sensing algorithm (Watanabe 363). Therefore, implanting physicians must obtain a high R-wave during device implantation.

However, what appears to be an acceptable R-wave post lead fixation may not be adequate one day post-implant. Active lead fixation causes local myocardial tissue injury (COI) that manifests as an "increase in the duration of the intracardiac electrogram and elevation of the ST-segment following the QRS signal" (Saxonhouse 412). Moreover, the COI can be confounded with the actual R-wave (Figure 2). If the implanter does not let enough time pass in order for the COI to subside, then the R-wave may be over-estimated by the analyzer.



Figure 2: R-wave read by the analyzer decreases as current of injury subsides.

Courtesy of Mr. Jim Glover, Medtronic Technical Field Engineer

In other words, the initial R-wave detected by the analyzer may read ≥ 5 mV, and the physician could proceed with closing the pocket. However, minutes to hours after implant, the R-wave may be insufficient. At that point, the only option for the patient is to re-open the pocket and re-position the lead.

Saxonhouse et al sought to utilize the COI phenomenon as a means to predict adequate lead active fixation for both pacemaker/defibrillation leads. Pacing threshold improvements were the indicator for adequate lead fixation. Moreover, "COI is recognized at the site of tissue injury as an increase in the duration of the intracardiac electrogram and elevation of the ST-segment following the QRS signal" (Saxonhouse 412). An abbreviated methodology consisted of placing the atrial lead in the right atrial appendage and the ventricular lead into the right ventricular apex. For all leads, measurements were taken before active fixation; both atrial and ventricular pacing and defibrillation leads were all "bipolar, extendable-retractable types with an electrically active helix" (Saxonhouse 412). The lead models used were Medtronic Inc., Minneapolis, MN, models 6947 (ventricular defibrillation leads) and 5076 (atrial and ventricular pacing leads) (Saxonhouse 413).

Data acquisition was obtained from sixty-five patients with a Medtronic 2090 pacing system analyzer, with the bipolar intracardiac electrogram recorded at "200 mm/sec before fixation, at the time of fixation (0 min), and then at 2, 5, and 10 minutes post-fixation" respectively (Saxonhouse 413). When the lead was fixed in place via fluoroscopy, pacing threshold, impedance, slew rate, current, and R or P-wave sensing were measured at lead fixation, and two, five, and ten minutes thereafter. Lead repositioning only took place when pacing thresholds were not acceptable (≥ 1.5 mV at 10 minutes post-fixation). The same measure-

ments as mentioned previously were recorded after repositioning (Saxonhouse 413). Tables 1 and 2 display measurement results for those leads with a COI.

	2					
(n = 50)	Before Fixation	0 min	2 min	5 min	10 min	p Value
COI: intracardiac EGM duration (ms)	150 ± 31	200 ± 25	175 ± 25	150 ± 25	138 ± 25	< 0.001
COI: ST-segment elevation (mV)	1.5 ± 0.2	10 ± 2.0	6.6 ± 1.2	3.4 ± 0.8	0.8 ± 0.2	< 0.001
Pacing threshold (V)		1.5 ± 0.4	1.3 ± 0.3	1 ± 0.2	0.8 ± 0.3	< 0.001
Impedance (ohms)		950 ± 24	910 ± 29	880 ± 26	850 ± 25	< 0.001
Current (mA)		1.9 ± 0.2	1.7 ± 0.2	1.5 ± 0.2	1.1 ± 0.1	< 0.001
R-wave sensing (mV)		18 ± 2	18 ± 2	18 ± 2	19 ± 2	NS
Slew rate (V)		2.7 ± 0.3	2.7 ± 0.3	2.8 ± 0.2	2.8 ± 0.2	NS

COI = current of injury; EGM = electrogram; NS = not significant.

Figure 3

Table 1: Acute Measurements of Ventricular Pacing or Defibrillation Leads With COI (Saxonhouse 414). P-values less than 0.01 are significant.

(n = 26)	Before Fixation	0 min	2 min	5 min	10 min	p Value
COI: intracardiac EGM duration (ms)	125 ± 25	175 ± 13	163 ± 13	150 ± 13	125 ± 25	< 0.001
COI: ST-segment elevation (mV)	0.8 ± 0.1	2 ± 0.3	1.4 ± 0.4	1.0 ± 0.3	0.5 ± 0.1	< 0.001
Pacing threshold (V)		1.5 ± 0.4	1.3 ± 0.3	1 ± 0.3	0.8 ± 0.2	< 0.001
Impedance (ohms)		900 ± 21	860 ± 25	830 ± 20	800 ± 25	< 0.001
Current (mA)		1.9 ± 0.2	1.7 ± 0.2	1.5 ± 0.2	1.1 ± 0.1	< 0.001
P-wave sensing (mV)		3.0 ± 0.3	3.0 ± 0.2	3.2 ± 0.2	3.2 ± 0.2	NS
Slew rate (V)		1.0 ± 0.3	1.0 ± 0.3	1.0 ± 0.3	0.9 ± 0.3	NS

Figure 4

Table 2: Acute Measurements of Atrial Pacing Leads With COI (Saxonhouse 416). P-

values less than 0.01 are significant.

The results support the major finding of this study: "The presence of an adequate COI at the time of an active-fixation pacing or defibrillation lead placement correlates with adequate lead fixation." (Saxonhouse 415). The authors define an adequate COI as "an increase in the duration of the atrial or ventricular intracardiac electrogram by 50 ms and an increase in ST-segment elevation of at least 5 mV for ventricular leads and 1 mV for atrial leads compared to baseline" (Saxonhouse 415). An alternate definition describes an adequate COI as "an ST-segment elevation of at least twenty-five percent of the intrinsic atrial or the ventricular electrocardiogram amplitude" (Saxonhouse 415). Interestingly, this study shows that if a COI develops after fixation, yet elevated pacing thresholds (> 1.5V) are present, the thresholds should improve ten minutes post-fixation. On the contrary, the authors support lead repositioning if there is no COI and a high pacing threshold (Saxonhouse 416).

Furthermore, Redfearn et al corroborated the work done by Saxonhouse et al as to the importance of COI in effective lead placement. Redfearn et al hypothesized that continuous COI measurements during lead fixation may be better than a single COI measurement post-fixation when predicting lead stability and acceptable pacing threshold. The authors correlated their findings with "fixation of a catheter delivered 4-Fr pacemaker lead (Medtronic 3830 Minneapolis, MN)" (Redfearn 1438). Their methodology was approved by

the "University of Western Ontario Research Ethics Board for Health Sciences Research Involving Human Subjects," with all study participants having given written informed consent (Redfearn 1438).

Moreover, the fixed screw 3830 lead was inserted into the right ventricle until it contacted the endocardial tissue; the lead body was rotated four times to achieve active fixation in the myocardium. Additionally, lead stability was determined via manual traction to the lead body. A pacing threshold measurement was taken if the lead tip remained stable. Subsequently, "lead parameters were measured at contact with endocardium and after each rotation of the lead using a Medtronic pacing system 2290 analyzer" (Redfearn 1439). At each time interval the lead bipolar ventricular electrogram was recorded on the paper strip; manual peak-to-peak R-wave amplitude and COI amplitude will be determined from the recording. Also, "maximum COI and the amplitude 80 ms after onset of the R-wave deflection (COI80)" were measured (Redfearn 1439). Figure 3 shows representative samples of electrocardiograms printed at 25 mm/sec from the Medtronic 2290 analyzer.



Figure 3: From uppermost down: surface electrocardiogram (lead II); the device marker channel; the ventricular electrogram signal delivered from the pacing lead after four turns of the helix. Panel A shows the signal obtained with good fixation and thresholds; the figure is illustrated to show where (max COI) and (COI80) were measured. Panel B is the signal from an attempt in the same patient that possessed adequate fixation but poor thresholds; a negative deflection of COI can be appreciated. Panel C shows the signal from a lead that dislodged with manual traction (Redfearn 1439).

Table 3 depicts the lead parameters at each helix turn for leads with good and bad active fixation.

	Lead Stability									
	Good Lead Fixation [26]				Poor Lead Fixation [17]					
	с	1	2	3	4	С	1	2	3	4
R (mV)	6.8 (1.2)	6.85 (1.3)	8.7 (0.7)	8.3 (0.8)	7.5 (1.1)	5.4 (1.5)	3.6 (1.7)	5.2 (1.8)	6.9 (1.4)	7.2 (1.6)
Slew (V/sec)	2.3 (0.2)	1.9 (0.4)	2.6 (0.3)	2.4 (0.2)	2.3 (0.2)	2.2 (0.3)	2.2 (0.3)	2.3 (0.3)	2.2 (0.8)	2.7 (0.3)
COI max (mV)	5.8 (1.3)	5.9 (1.3)	5.3 (1.3)	6.4 (1.2)	6.8 (1.3)	2.2 (1.9)	1.4* (1.7)	1.6 (1.7)	4.3 (1.7)	2.6* (1.4)
COI 80 (mV)	4.7 (1.1)	4.74 (1.2)	4.5 (1.2)	5.9 (1.1)	6.3 (1.2)	1.5 (1.7)	0.7* (1.4)	1.3 (1.5)	3.1 (1.5)	1.5* (1.0)
Imp (ohms)	880 (82)	807 (59)	821 (51)	841 (41)	981 (80)	1351 (292)	916 (116)	935 (99)	853 (69)	850 (79)

*: P < 0.05 for comparison between good versus poor at the same lead rotation. [] number of pacing sites

\mathbf{F}	i	oure	6
Т.	I	guie	; U

Table 3: Mean (Standard Error of the Mean) for Measured Lead Variables Demonstrating Good and Poor Fixation (Redfearn 1440).

For the results, the twenty-six leads demonstrating good fixation were subdivided into a group with good pacing thresholds and a group with poor pacing thresholds. Impedance measurements for leads with adequate fixation but unacceptable thresholds fell during helix rotations, a trend opposite those leads with good fixation and adequate threshold. Also, the leads with good fixation and good thresholds had COI values that increased with each helix rotation. In contrast, the well-fixed leads with poor thresholds had COI values that decreased with each rotation. The COI values at each rotation were statistically significant. In addition, R-wave values for leads with good fixation and adequate threshold values increased slightly with each helix turn, yet there was no statistical significance (Redfearn 1442). In summary, the authors assert that R-wave, COI, and impedance values have not been previously studied with each of four successive turns of the lead helix. To support the work of Saxonhouse et al, Redfearn et al found that the "lack of COI predicted high thresholds within the same time frame confirming the importance of COI as a predictor of subsequent threshold" (Redfearn 1443). However, the authors' data did not support their initial hypothesis that monitoring lead parameters throughout the lead fixation process would be advantageous over lead parameter measurements post-fixation.

In addition, Laske et al have visualized the device/heart tissue interface and found R-wave characteristics similar to those that Saxonhouse et al describe. In their research, Laske et al devised an isolated heart model for direct ex vivo intracardiac visualization. Their research was "reviewed and approved by the University of Minnesota Institutional Animal Care and Use Committee, and ensured humane treatment of all animals as indicated by the Guide for the Care and Use of Laboratory Animals (NIH)" (Laske 895). The in vivo experimental methodology included eight swine receiving surgical cutdowns to the right and/or left jugular veins; this is the site for lead insertion. Furthermore, the bipolar, steroid-eluting pacing/sensing leads (CapSureFix® Novus 5076, Medtronic, Inc., Minneapolis, MN) were advanced through the cutdowns to the right atria and right ventricles via fluoroscopy (Figure 4) (Laske 895).





Figure 4: Representative images of Medtronic 50076 right atrial (A) and right ventricular (B) lead implants under fluoroscopic visualization (arrows point to the site of implant). Representative images of direct ex vivo visualization of right atrial (C) and right ventricular (D) implants. (Laske 895)

In vivo unipolar measurements were recorded using a constant voltage 5311 Pacemaker Systems Analyzer (Medtronic Inc., Minneapolis, MN). "Pacing voltage thresholds (at a pulse width of 0.5ms at 120 beats per minute), P-wave or R-wave amplitudes, slew rates, and pacing impedances (at 5V/0.5 ms) were recorded" (Laske 895).

Additionally, the ex vivo methodology included excising the swine hearts with the implanted leads in place. The hearts were placed in a Krebs buffer slurry; hemodynamic monitoring probes were inserted.

Then, warm, oxygenated perfusate was introduced to the aorta and to the right atrium, a mode known as the Langendorff perfusion mode. Reaching a temperature of 36.5 + /-0.5 °C, the heart was defibrillated and consequently stabilized to normal sinus rhythm (Laske 895). Furthermore, the heart was re-animated by introduction of perfusate, filling pressures and ventricular ejection resistance were constant, and afterloads were the same as those in vivo. In addition to recording pacing and sensing measurements in the ex vivo swine hearts, IV6C6-13 and ILV-C1 Olympus endoscope cameras took pictures of the lead implant sites (Fig 4: 1c and 1d). These cameras made possible direct visualization of the heart tissue/lead interface (Laske 895).

Table 4 shows the study results. Only paired data were analyzed, with a p- value less than 0.05 being significant.

	Righ	nt Atrium (n=1)	1)	Right Ventricle (n=13)		
Measurement	In Vivo	Ex Vivo	Δ (%)	In Vivo	Ex Vivo	Δ (%)
Threshold @ 0.5 ms (V) P-Wave (mV)	3.3±2.8 4.7±0.6	4.4±3.0 2.9±1.7 ^a	33 39	0.6 ± 0.1	1.2±0.7ª	107
R-Wave (mV) Slew Rate (V/sec) Impedance (ohms)	1.1±0.8 541±117	0.42±0.3 ^a 359±73 ^b	-62 -34	10.4±5.1 1.4±0.9 525±101	6.4±3.4 ^a 0.5±0.3 ^a 365±63 ^b	-39 -62 -31

 $^{a}p < 0.05$ vs in vivo (t-test).

p < 0.005 vs in vivo (t-test).

Figure 8

Table 4: Right Atrial and Ventricular In Vivo and Ex Vivo Pacing and Sensing Parameters (Mean +/-SD) (Laske 896)

Right atrial ex vivo lead performance parameters were lowered significantly when compared to the corresponding in vivo measurements. Moreover, "ventricular R-wave amplitudes, slew rates, and pacing impedances were significantly reduced ex vivo when compared to in vivo measurements. However, pacing thresholds increased significantly." (Laske 896).

Being that the perfusate was clear, the endoscopes visualized three different lead/heart tissue interactions. The first interaction was that of a "normal" implant, with very little tissue disruption or damage. Secondly, heart tissue was seen wrapping around the lead body; this occurred when the physician over-torqued the lead at the time of implantation. Thirdly, the endoscopes recorded dramatic heart tissue distortion at the site of implant, where the lead could spin freely in the endocardial tissue. In addition, the first case occurred in seventy percent of implants and displayed elevated impedance and threshold values, the second case encompassed thirteen percent of implants that exhibited highly elevated pacing parameters, and the third case, or seventeen percent of implants, had marked decreases in both the lead impedance and threshold values (Laske 894, 896). Please see Figure 5 for endoscope pictures of the three cases.



Figure 9

Figure 5: (A) A normal right atrium lead implantation, with no endocardial tissue damage. (B) A lead that cored tissue at the site of implantation. (C) An over-torqued right atrial lead where tissue wrapped around the lead body, increasing pacing impedance and threshold values. (Laske 896)

This tissue injury or distortion has previously been termed current of injury (COI). The authors note changes in the R-wave after lead implantation, especially when the COI is present. The R-wave decrease when going from in vivo to ex vivo. Their novel endoscopic cameras allow for visualization of the lead/heart tissue interface and not only provide an explanation for variations in pacing impedance measurements at lead implantation, but also give the clinician important information such as if adequate lead placement has been achieved.

REFERENCES

1. Iaizzo, P., Laske, T., and Skadsberg, N. A Novel Ex Vivo Heart Model for the Assessment of Cardiac Pacing Systems. ASME, Vol 127, November 2005. 894-898.

2. Kleinert, M., Et Al. Spectral Properties of Atrial and Ventricular Endocardial Signals.

PACE, Vol. 2, January-February 1979. 11-19.

3. Myers, George H., Kresh, Yasha M., and Victor Parsonnet. Characteristics of Intracardiac Electrograms. PACE, Vol. 1, January-April 1978. 90-103.

4. Research Proposal Format Paper.

http://facweb.eths.k12.il.us/dhemphys/Word/Research%20Proposal.htm

5. Saxonhouse S, Conti J, Curtis A. Current of Injury Predicts Adequate Active Lead Fixation in Permanent Pacemaker/Defibrillation Leads. JACC 2005; 45: 412-417.

6. Watanabe, et al. Decreases in Amplitude of Intracardiac Ventricular Electrogram and Inappropriate Therapy in Patients With an Implantable Cardioverter Defibrillator. Int Heart J 2006; 47: 363-370.

7. Yee, Raymond, M.D. Et Al. Current of Injury Predicts Acute Performance of Catheter-

Delivered Active Fixation Pacing Leads. PACE, Vol 30, December 2007. 1438-1444.

8. Zeiger, Mimi. Essentials of Writing Biomedical Research Papers. 2nd Edition, 2000.