R-Wave Detection by Subcutaneous ECG. Possible Use for Analyzing R-R Variability

Parwis Fotuhi, M.D., William Combs, M.S.E.E.,*
Cathy Condie, B.S.E.E.,* Heinz Theres, M.D., Tino Schneider, M.D.,
Karl Stangl, M.D., and Gert Baumann, M.D.

*From the Medical Clinic I, Charité Hospital, Berlin, Germany, and *Medtronic Inc., Minneapolis, Minnesota*

Background: Atrial arrhythmia (AA) discrimination remains a technological challenge for implanted cardiac devices. We examined the feasibility of R-wave detection by a subcutaneous far field ECG (SFFECG) and analysis of these signals for R to R variability as an indicator of atrial arrhythmia (AA).

Methods: Surface ECG and SFFECG (from the pacemaker pocket) were recorded in sixteen patients (61.5 ± 11.4 years) with AA. The SFFECG was recorded with a pacemaker sized four electrode array acutely placed in the pacemaker pocket during implantation. The signals were analyzed to obtain peak-to-peak R wave amplitude and R to R interval variability (indicative of AAs).

Results: In sixteen patients R waves were visually discernible in all recordings. The percentage over and under detection for automatic R wave recognition SFFECG was 3 and 9%, respectively. R to R variability analysis using the SFFECG produced results concordant to those using the surface ECG.

Conclusion: SFFECG might be a helpful adjunct in implantable device systems for detection of R waves and may be used for measurement of R to R variability. **A.N.E. 2001;6(1):18-23**

implantable devices, atrial arrhythmia

Implantable cardiac pacemakers and defibrillators offer a therapeutic option for the treatment of certain cardiac arrhythmias.^{1,2} Detection and discrimination of ventricular and atrial arrhythmias remain a medical and technological challenge for single chamber implantable ventricular defibrillators.³⁻⁶ Inappropriate arrhythmia detection such as misclassification of atrial fibrillation as a ventricular arrhythmia may result in inappropriate shock delivery.⁶⁻⁹ The same holds true for atrial defibrillators where appropriate rhythm detection is required and defibrillation shocks have to be given synchronized to intrinsic R waves.

These devices utilize intracardiac signals recorded from implanted atrial and/or ventricular

leads for triggering and delivery of device therapy. Lead dislodgment or fracture remains a common complication^{10,11} and may result in unsynchronized shocks (e.g., T wave sensing) and possible induction of lethal ventricular arrhythmias.

A signal source which is independent of an indwelling ventricular lead may be helpful in confirming appropriate arrhythmia detection and shock synchronization in therapeutic implantable devices for treatment of atrial or ventricular arrhythmias.

Clinically, the examination of surface ECG is a standard means of diagnosing a patient's underlying cardiac rhythm. Signals similar to surface ECGs may allow an improvement in auto-

Presented in part at the American College of Cardiology, 46th Annual Scientific Session.

Supported in part by the Humbolt University research grant Charité 007/96, 004/97 and a research award by the "Stiftung Familie Klee."

Address for reprints: Parwis C. Fotuhi, M.D., Charite Hospital, Medizinische Klinik I, Schumannstr. 20-21, 10089 Berlin, Germany. Fax: 011-49-30-2802-8696; Email: parwis.fotuhi@charite.de

matic implantable device arrhythmia detection, therapy delivery and consequently, increase overall patient safety.

The aim of this study was to investigate the possibility of detecting R waves and the subsequent analysis of these signals for R to R variability as an indicator of atrial arrhythmias using a subcutaneous far field ECG (SFECG), as an additional signal source to indwelling leads.

METHODS

This study was approved by the Medical Ethics Committee of the Humboldt University conforming with Helsinki guidelines. Written informed consent was obtained from all patients prior to the study. ECGs and SFECGs were recorded in a total of 16 patients (10 male, 6 female) with mean age of 61.5 ± 11.4 years. Ten patients were undergoing initial pacemaker implantation and six pacemaker replacement.

All 16 patients were undergoing pacemaker implantation for bradyarrhythmia concomitant with atrial fibrillation ($n = 13$) or atrial flutter ($n = 3$). In 15 patients, device implantation was in a right pectoral location and in one patient on the left side. Initial pacemaker implantation or replacement was performed using standard medical technique. After surgically forming the pacemaker pocket, or explanting the pacemaker being replaced, a subcutaneous electrogram recording array (SEA) in shape

and size of a pacemaker ($3.5 \text{ cm} \times 4.6 \text{ cm} \times 0.9 \text{ cm}$) was placed in the pocket. The SEA contains three titanium electrodes (0.5 cm diameter, A, B, C) on one surface and a larger (2.5 cm diameter) indifferent electrode (D) on the opposite surface (Fig. 1). A standard 12-lead ECG was displayed on a monitor. Three channels of the 12-lead surface ECG (lead II, V_1 , V_5) and two far-field electrograms (SEA 1 = electrode A-C, Sea 2 = electrode B-D) were recorded via standard cabling using electrophysiological signal recording amplifiers and switching network (Model 2000 and Model 4000, Madaus Schwarzer, Inc., Munich, Germany).

SFECG and surface ECG signals were bandpass filtered at 0.1–500 Hz and stored on digital audio tape (TEAC RD-130TE DAT Recorder, TEAC Inc.) along with voice annotation. The sampling frequency for the SFECG and ECG were 1000 samples/seconds. The analog-to-digital converter on the digital audio tape had a 16-bit resolution for 5 volts, resulting in a resolution of 0.76 mV. The signals were gained from 500–2000 $\times$ giving an amplitude resolution of 1.52 μV to 0.38 μV .

SFECG and surface ECG signals were recorded during 3 minutes of intrinsic cardiac rhythm and during 2 minutes of VVI pacing at approximately 20 beats/min above the patient average intrinsic rate. Following SFECG and surface ECG recording, 200 μV and 1 mV calibration signals were recorded on all channels.

Figure 1. Front (a) and back (b) views of the SEA device. SEA 1 signal was recorded from electrode A-C, SEA 2 from B-D. The SEA size is similar to a standard pacemaker.

Signal Analysis

The timing of each R wave was marked with a custom automated detection tool (LabVIEW, version 3.10, National Instruments, Inc., Austin, TX, USA) using an adjustable amplitude threshold to determine intervals between recorded R waves. These results were reviewed for accuracy and manually edited if needed. This edited data was used for characterization of SFFECG and surface ECG signals. SFFECG and surface ECG channels were processed using a custom software tool which automatically analyzed signal amplitude and signal-to-noise ratios (SNRs) of all recorded channel signals within a 125-ms window triggered by the R-wave timing marks.

Intrinsic ventricular complexes for each recorded channel were analyzed for maximum peak-to-peak amplitude within the ventricular timing window and for root mean square (RMS) signal content. The noise level was measured by isolating a section of baseline signal (no R waves) and measuring the RMS content for each recorded channel. The ratio of this noise and the RMS of the signal content was used to calculate a signal-to-noise ratio for each channel.

The R wave timing intervals were also analyzed for instantaneous heart rate and for R to R variability as a rhythm discriminator. R to R variability was expressed as mean variance and standard error calculated from a 30-second time period.

Additionally, SFFECG data was processed using an automatic R-wave detection algorithm to determine the extent of over and under detection that may result from automatic signal analysis. The R-wave detection algorithm utilized a threshold and blanking scheme, similar to existing pacemakers.¹² The results from this automated tool were compared to the manually verified R-wave marks to determine the extent of over and under detection.

Statistical Analysis

The data is expressed as the mean and standard deviation for signal amplitudes and mean variance and standard error for R to R variability. Signal-to-noise ratio was expressed in decibels.

RESULTS

In these 16 patients R waves were visually discernible in all recordings. Figure 2 illustrates three recorded signals (SEA 1, SEA 2, and surface ECG

lead II) in a representative patient while in atrial fibrillation. A one-to-one QRS correlation between surface ECG and SFFECG can be seen. Interestingly, in comparing the SFFECG recorded from the right pectoral location visually with the one from the left side, no difference was seen. The same observation was seen for the automatic R-wave detection algorithm where no difference between the right sided implant and the left sided one was observed. Due to the recording setup and high gain requirement of the SFFECG, slightly more than 50 Hz noise is seen in the SEA 1 and SEA 2 recordings. Because of the presence of 50 Hz noise and the small size of the atrial signals (atrial flutter waves and atrial fibrillation), it was not possible to analyze the underlying atrial activation from recorded SFFECG.

Signal Characteristics

SEA electrogram signal R-wave peak amplitudes varied between a minimum of 64 μV to a maximum of 297 μV . Surface ECG ventricular complexes ranged from 850 μV to 1600 μV . Mean peak-to-peak measured amplitudes and signal-to-noise ratios for intrinsic R waves for the two SFFECG and surface ECG lead II are shown in Table 1.

R to R Variability

Figure 3 depicts R-R variability as ventricular rate means and standard deviations for 16 patients during rest. The R to R variability can be used as an indicator for atrial fibrillation ($n = 13$) and atrial flutter ($n = 3$) recorded from SEA 1. Atrial fibrillation had the largest R to R variability compared to atrial flutter, showing a narrow range of R-R variability.

The R to R variability expressed as mean variance and standard error during atrial fibrillation (15.6 ± 2.44 ms) and atrial flutter (4.6 ± 2.63 ms) for SEA 1 were calculated for the 3-minute recorded duration of intrinsic electrograms. Automatic software was used for comparison with manually verified R waves. The percentage of detected events not confirmed by manual inspection for automatic R-wave recognition of SFFECG was 3% (automatic "over-detection") and the percentage of manually detected events not automatically detected was 9% (automatic "under-detection").

Figure 2. SEA 1 (upper tracing), SEA 2 (middle tracing) and surface ECG lead II (lower tracing) recordings in a patient with atrial fibrillation.

DISCUSSION

In defibrillation, the adequate detection and discrimination of ventricular and atrial arrhythmias, early redetection of ventricular fibrillation and tachycardia postdefibrillation, and synchronization of therapy delivery may require electrodes in multiple cardiac chambers.^{4,7} Brandt et al. described the possibility of detecting ventricular far-field signals with the atrial lead.¹³ These intracardiac signals represent a localized view of myocardial electrical activity¹⁴⁻¹⁷ and lead failure or dislodgment remain complications that may compromise correct arrhythmia detection.^{10,11} In the case of lead failure or lead dislodgment of an implanted defi-

brillator, the use of a secondary input for sensing of intracardiac events independent of the implanted lead might allow more specific sensing and, therefore, therapy delivery. Electrograms recorded independent of leads indwelling within the heart may be one such useful secondary input.

Cardiac signals recorded within the device pocket have been demonstrated previously to hold utility for basic ECG recordings.^{18,19} Krahn et al. showed that an implantable subcutaneous electrogram monitoring device can capture electrograms during syncopal events.^{20,21}

In this study we explored the fundamentals of SFECG R wave signals in the context of atrial

Table 1. Peak-to-Peak Measured Amplitudes of Intrinsic R Waves for the Two SEA and Surface ECG Lead II Recordings During Atrial Fibrillation

	SFECG 1	SFECG 2	Surface ECG
Mean $\pm$ SD (mV)	0.1513 $\pm$ 0.1826	0.0805 $\pm$ 0.0915	1.4065 $\pm$ 0.4573
SNR $\pm$ SD (dB)	11.33 $\pm$ 5.13	9.27 $\pm$ 4.23	24.55 $\pm$ 5.64

Mean and standard deviation for signal-to-noise ratios (SNR in decibel) for SEA and surface ECG lead II are shown.

Figure 3. R to R variability in ms for all the patients with atrial fibrillation (Afib, 1-13) and atrial flutter (Aflutter, 14-16).

arrhythmia detection based upon ventricular rate. In all 16 patients, R waves from the SFECG were visually discernible, providing a similar "view" of the integrated cardiac action potentials as surface ECG. The R to R variability analysis using the SFECG produced results concordant to those using the surface ECG indicating that detection of R to R variability from SFECG signal is feasible.

The ratio of peak-to-peak amplitudes (SFECG to surface ECG) for ventricular complexes demonstrated that complexes recorded from the SEA are proportionally smaller, when compared to recorded ventricular peak-to-peak values from surface recording as expected due to the small distance between recording electrodes. Signal-to-noise ratios, an indicator of the relative signal size compared to background noise, were lower in SFECG signals compared to surface lead II ECG, but sufficient for automatic R-wave detection. A significant amount of 50 Hz noise was introduced by the experimental setup and may be diminished in a chronic implanted device. Atrial event detection in

SFECG signals using bandpass filtering and threshold detection was not attempted due to small signal amplitudes of the underlying atrial activity.

The automatic R wave detection algorithm used to determine R-R variability showed 9% automatic "under-detection." This 90% R wave sensitivity would not be sufficient to time an atrial defibrillation shock of an automatic atrial defibrillator, but should be sufficient for detection of atrial arrhythmias using one to two minutes detection time. Further algorithm development is needed prior to implementing such a diagnostic tool into implantable devices.

CONCLUSIONS

SFECG might be a helpful adjunct in implantable device systems for detection of R waves. These SFECG R waves are of sufficient amplitude for detection and measurement of R-R variability. They are also of sufficient quality to allow analysis of R to R variability as indicator of atrial rhythm status. The ability to monitor a SFECG in addition to leads indwelling in the heart might offer the opportunity for improving device system performance and safety.

REFERENCES

1. Elmquist R, Senning A. An implantable pacemaker for the heart. Proceedings of the Second International Conference of Medical-Electric Engineers, London, Riffe & Sons, 1959.
2. Mirowski M, Reid P, Mower M, et al. Termination of malignant ventricular arrhythmias with an implanted automatic defibrillator in human beings. *N Engl J Med* 1980; 303:322-324.
3. Higgins S, Lee R, Kramer R. Stability: An ICD detection criterion for discriminating atrial fibrillation from ventricular tachycardia. *J Cardiovasc Electrophysiol* 1995; 12:1081-1088.
4. Neunzer J, Pitschner H, Schlepper M. Programmable VT detection enhancements in implantable cardioverter defibrillator therapy. *PACE* 1995;18:539-547.
5. Schaumann A, Muhlen F, Gonska B, et al. Enhanced detection criteria in implantable cardioverter-defibrillators to avoid inappropriate therapy. *Am J Cardiol* 1996;78:42-50.
6. Swerdlow C, Chen P, Kass R, et al. Discrimination of ventricular tachycardia from sinus tachycardia and atrial fibrillation in a tiered-therapy cardioverter-defibrillator. *J Am Coll Cardiol* 1994;23:1342-1355.
7. Manz M, Gerkens U, Lüderitz B. Erroneous discharge from an implantable automatic defibrillator during supraventricular tachyarrhythmias induced ventricular fibrillation. *Am J Cardiol* 1986;57:343-344.
8. Grimm W, Flores B, Marchilinski F. Electrocardiographically documented unnecessary, spontaneous shocks in 241 patients with implantable cardioverter defibrillators. *PACE* 1992;15:1667-1673.
9. Fogoros R, Elson J, Bonnet C. Actuarial incidence and pattern on occurrence of shocks following implantation of the

- automatic implantable cardioverter defibrillator. *PACE* 1989;12:1465-1473.
10. Peters R, Foster A, Shorofsky S, et al. Spurious discharges due to late insulation break in endocardial sensing leads for cardioverter defibrillators. *PACE* 1995;18:478-481.
11. Lawton J, Ellenbogen K, Wood M, et al. Sensing lead-related complications in patients with transvenous implantable cardioverter-defibrillators. *Am J Cardiol* 1996;78:647-651.
12. Furman S. *A Practice of Cardiac Pacing*. Mount Kisco NY, Futura Publishing, 1993, pp. 135-194.
13. Brandt J, Fahraeus T, Schuller H. Far field QRS complex sensing via the atrial pacemaker lead. II prevalence, clinical significance and possibility of intraoperative prediction in DDD pacing. *PACE* 1988;11:1540-1544.
14. DeCaprio V, Hurzeler P, Furman S. A comparison of unipolar and bipolar electrograms for cardiac pacemaker sensing. *Circulation* 1977;56:750-755.
15. Furman S, Hurzeler P, DeCaprio V. Cardiac pacing and pacemakers. III. Sensing the cardiac electrogram. *Am Heart J* 1977;93:794-801.
16. Parsonnet V, Myers G, Kresh Y. Characteristics of intracardiac electrograms. II. Atrial endocardial electrograms. *PACE* 1980;3:406-417.
17. Platia E, Brinker J. Time course of transvenous pacemaker stimulation impedance, capture thresholds and intracardiac electrogram amplitude. *PACE* 1986;9:620-625.
18. Leitch J, Klein G, Yee R, et al. Feasibility of an implantable arrhythmia monitor. *PACE* 1992;15:2232-2235.
19. Theres H, Combs W, Fotuhi P, et al. Electrogram signals recorded from acute and chronic pacemaker implantation sites in a representative pacemaker population. *PACE* 1998; 21:11-17.
20. Krahn AD, Klein GJ, Yee R, et al. Final results from a pilot study with an implantable loop recorder to determine the etiology of syncope in patients with negative noninvasive and invasive testing. *Am J Cardiol* 1998;82:117-119.
21. Krahn A, Klein G, Norris C, et al. The etiology of syncope in patients with negative tilt table and electrophysiologic testing. *Circulation* 1995;92:1819-1824.